



Ennov InSight 7.3 Administrator Guide

Contents

Chapter 1. Ennov InSight Administration	20
Chapter 2. Ennov InSight License Components	21
Ennov InSight License Modules by Feature	7
Data Administration Functions by Module	23
Queries Available by License	33
Registration Planning and Tracking (RPT)	33
Administration	36
Electronic Lifecycle Publishing (ELP)	36
Submission Planning and Tracking (SPT) in the Assembly Tree	37
Chapter 3. Security Administration	38
Identity Providers Login	38
Log on to IdP Configured Ennov InSight	39
User Types	39
Notes About Users	39
Security Defaults for Home Page Access	60
Chapter 4. Data Administration	78
Access Data Administrator Functions	79
Data Administration Selection Lists	79
Filters for Data Administration Values	92
eCTD 4.0 CV Profiles	93
OMS Terms	95
Example	96
RMS Terms	97
Example	100
SMS Terms	101
Maintain Values	102
Status values	103
Entities to Associate	105
Application Maintenance	107
Age Span Population Attributes	110

Application Category Attributes.....	110
Application Status Attributes	111
Application Type Attributes.....	111
Chief Investigator Attributes	112
Country Attributes	112
CTA Product Role Attributes.....	113
Legal Status Attributes	113
MedDRA Term Attributes.....	113
Medical Condition Investigated Attributes	114
Medical Product Action/Submission Status Attributes	114
Medicinal Product Name Part Type Attributes	114
Medicinal Product Type Values Attributes	115
Procedure Type Attributes	115
Reason for Premature Ending Attributes	116
Region Attributes.....	117
Region Type Attributes.....	117
Regulatory Entitlement Status Attributes	118
Regulatory Entitlement Type Attributes.....	118
Sponsor Type Attributes	118
Trial Design Attributes	119
Trial Phase Attributes.....	119
Trial Scope Attributes.....	119
Trial Subject Group Attributes.....	120
Orphan Status Attributes.....	120
Chief Investigator Attributes	121
Product Information Document Type Attributes	121
Assembly Maintenance.....	126
Assembly Category Attributes.....	127
Assembly DTD/Schema Type Attributes.....	127
Assembly Status Attributes	128
Assembly Subcategory Attributes	128
Assembly Variable Maintenance.....	129
Change Maintenance.....	151

Change Type Attributes	151
Event-Change Detail Status Attributes	152
Custom Lists Maintenance	152
Custom List Name Attributes	153
Custom List Value Attributes	153
DMS Integration	154
Bind to Label Name Attributes	154
Bind to Status Attributes	155
Rendition Identifier Attributes	155
eCTD 4.0 Submission Maintenance	160
CV Profile Attributes	161
Sender-defined Keyword Attributes	162
Event Maintenance	162
Action Type Attributes	163
EU Grouping or Worksharing Attributes	164
Event Status Attributes	164
Event Type Attributes	165
PSUR Report Code Attributes	165
Secondary Event Type Attributes	166
Timeline/Event Plan Type Attributes	166
Timeline/Event Plan Attributes	167
Medical Device Maintenance	179
Device Classification Attributes	180
EU Device Nomenclature Category Attributes	180
FDA GMDN In-Vitro Term Type Attributes	180
EU Category of CMR Type Attributes	181
EU Device Nomenclature Attributes	181
Global Medical Device Nomenclature (GMDN) Code Attributes	182
Notifications Maintenance	182
Notification Specifications Attributes	184
Notification Attributes	185
Other Data Maintenance	186
Application Submission Type Attributes	190

Attached Document Content Type Attributes	190
Attached Document Status Attributes	191
Certificate Master File Attributes	191
Data Carrier Identifier Source Values	193
Device Type Attributes	193
Denominator Unit Attributes	194
Entity XML UI Mappings Attributes	194
File Identifier Type Attributes	195
Homepage Display Properties Attributes	195
Indications/Intended Use Attributes	195
Language Attributes	196
Legal Basis Attributes	197
Length Unit Of Measure Attributes	197
MAH/Development Sponsor/Organisation Attributes	198
Message Sender Attributes	199
Numerator Unit Attributes	200
Previous EV Code Attributes	201
Quantity Unit Of Measure Attributes	201
Reason for E-Signature Attributes	201
Reasons for Termination/Withdrawal Attributes	202
SME Status Attributes	202
Source of Information Attributes	202
Sub-Indication Attributes	203
System Alert Type Attributes	203
Unit of Measure Prefix Attributes	204
Unit Of Presentation Attributes	204
Weight Unit Of Measure Attributes	204
Unit of Measurement Attributes	205
Product Maintenance	205
Conformity Assessment Body Attributes	208
Conformity Assessment Path Attributes	208
Country Specific Detail Type Attributes	209
Country Specific Detail Attributes	209

Device Allergenicity Attributes.....	210
Device Sterility Indicator Attributes	210
Device Usage Attributes.....	211
Dosage/Pharmaceutical Form Attributes.....	211
EC Cert Attributes	212
Global Harmonization Task Force (GHTF) Class Attributes	212
Manufacturing Location Attributes.....	213
Medical Device Attributes	213
Product Characteristics Attributes	214
Product Status Attributes.....	214
Product Strength Unit Attributes	215
Route of Administration Attributes	215
Special Measure Attributes.....	216
Sterilization Requirement Attributes.....	216
Sterilization Attributes.....	216
Summary of Technical Documentation (STED) Attributes	217
UMDNS Code Attributes.....	217
Product Category Type Attributes	218
Product Cross Reference Type Attributes.....	218
Product Detail Set Maintenance.....	218
Compendial Designation/Source Attributes.....	223
Component Type Attributes.....	223
Device - Type of Combination Attributes	224
Dose Frequency Attributes.....	224
Genetically Modified Cell Origin Species Attributes	224
Human Consumption Products Attributes	225
Intended Effect Attributes	225
Label Type Attributes	225
Material Type Attributes.....	228
Material Attributes.....	228
Medical Device Part Code Attributes.....	229
Package Component Attributes.....	229
Packaging Category Attributes.....	230

Packaging Type Attributes	230
Product Bio Type Attributes	231
Product Detail Set Status Attributes	231
Product Material Attributes	231
Production Type Attributes	232
QC Status Attributes	232
Shape Attributes	233
Shelf Life Category Attributes	233
Shelf Life Type Attributes	233
Somatic Cell Therapy Cell Types Attributes	234
Somatic Cell Therapy Origin Species Attributes	234
Somatic Cell Therapy Origins Attributes	234
Source of Scientific Advice Attributes	235
Species Attributes	235
Storage Condition Attributes	236
Substance Role Attributes	236
Substance Type Attributes	236
Time Unit Attributes	237
Type of Dossier Submitted Attributes	237
Type of Gene Therapy Transfer Product Attributes	237
Type of Gene Therapy Attributes	238
Type of Genetically Modified Cell Origin Attributes	238
Volume Unit Of Measure Attributes	238
Medical Device UDI Attributes	239
Origin of Substance Attributes	239
Manufacturing Function Attributes	239
Data Classification Type Attributes	240
Product Family Maintenance	245
Division Attributes	247
Domain Type Attributes	248
EURD ID Attributes	248
Product Family Status Attributes	249
Product Family Attributes	249

Substance Subtype Attributes.....	250
Substance Attributes.....	251
Therapeutic Class Attributes	252
Trade Name Attributes.....	253
Substance Subtype Attributes.....	253
Project Maintenance.....	255
Project Status Attributes	255
Project Type Attributes	256
Reference Maintenance	256
Reference Content Attributes	257
Reference Participant Attributes	257
Reference Status Attributes.....	258
Reference Type Attributes	258
Registration Maintenance.....	259
Qualified Person Responsible for Pharmacovigilance (QPPV) Attributes	260
Registration Status Attributes	261
Content of Change Attributes	261
Data Carrier Type Attributes	262
Master File Type Attributes.....	262
Provenance Reason Attributes	263
Marketing Status Attributes	263
Risk of Shortage of Supply Reason Attributes	263
Sequence Maintenance.....	264
Filing Type Attributes	264
Sequence Status Attributes	265
SPOR Master Lists.....	266
Submission Maintenance	273
Applicant ID Attributes	277
Application Form Type Attributes.....	277
Drug Registration File Documents Section Attributes.....	278
Drug Registration File Document Attributes.....	278
Evaluation Pathway Attributes	279
Font Definition Attributes	279

Leaf Status Attributes	280
PDF Properties Attributes	280
Promotional Material Audience Type Attributes	281
Promotional Material Doc Type Attributes	281
Promotional Material Type Attributes	282
Regulatory Activity Lead Attributes	282
Submission Product Type Attributes	283
Sequence Description Attributes	283
Sub Filing Type Attributes	284
Supplement Effective Date Type Attributes	284
Telephone Number Type Attributes	285
Submission Plan Maintenance.....	286
Submission Plan Status Attributes	287
Task Maintenance.....	287
Secondary Task/Sub-Task Type Attributes	288
Task/Sub-Task Priority Attributes	288
Task/Sub-Task Status Progression Attributes.....	289
Task/Sub-Task Status Attributes	289
Task/Sub-Task Type Attributes	290
Example	293
Workflow Management.....	293
Chapter 5. Technical Administration	295
DMS Servers and Repositories	295
Special Characters	295
Add a Documentum, Secure File System, Ennov Doc, or Veeva Vault Server to Ennov InSight	296
Add a Documentum Repository to Ennov InSight.....	297
Add a Secure File System Repository to Ennov InSight.....	298
Add a Veeva Vault Repository to Ennov InSight	299
Add a Ennov Doc to Ennov InSight.....	300
Modify DMS Server Attributes in Ennov InSight	301
Configure DMS Access for Specific Users.....	304
Linked Systems.....	304
Ennov InSight API Documentation	305
Prerequisites	315
Prerequisites	316

Chapter 6. Administrative Activities	375
Product Family Types and Component Types.....	375
Create a Product Family	375
Delete Entities.....	376
Unlock Assemblies and Folders	378
Example	379
Limited Access	381
Limited Capabilities	382
Root.....	382
Folder	382
Other Elements with which Documents and Placeholders Can Be Associated	383
Additional Information	383
Set Assembly Baselines	383
Manage eCTD and eCTD 4.0 Templates	384
Import eCTD Applications	391
Requirements for Successful eCTD Imports	392
Import an eCTD Application	392
Bulk eCTD Import Wizard	394
Prepare for Bulk eCTD Import	394
Bulk Import Prerequisites.....	394
Applications Other Than US 3.3.....	394
GCC, MRP, DCP Applications.....	395
ZA 3.1 Applications	395
EU 3.1 Applications	395
WHO 1.0 Applications	395
UA 1.0 Applications	395
AU 3.2 Applications	395
BA 3.1 Applications	395
SG 1.0 Applications	395
TN 1.1 Applications	395
Application Code Matching Warnings	395
High Speed Printers.....	399

lpr command	400
copy command.....	400
ftp command	400
Sending Data to the XEROX FreeFlow Controller	404
Implementation Notes.....	406
Printers Running the Kodak Network Imaging System	406
Canon imageRunner with Canon imagePASS Controller	412
Kodak Network Imaging System Printer (KDKNIS)	414
KONICA MINOLTA Printers	414
Xerox Printers	414
PostScript Printing	415
Cross-site Scripting (XSS) Filtering	416
Example	417
Example	417
Example	418
Example	419

Chapter 7. eCTD Codes.....420

Maintain eCTD Code Values	420
eCTD Codes for Application Types	421
eCTD Codes for Procedure Types	423
eCTD Codes for Country Values A-C	435
eCTD Codes for Country Values D-I.....	439
eCTD Codes for Country Values J-M.....	445
eCTD Codes for Country Values N-S.....	448
eCTD Codes for Country Values T-Z	455
eCTD Codes for Filing Types	459
eCTD Filing Types for AU.....	459
AU v0.90.....	459
AU v3.0	461
AU v3.1	463
AU v3.2	465
eCTD Filing Types for BA	467

eCTD Sub-Filing Types for BA.....	469
eCTD Filing Types for CH.....	473
eCTD Filing Types for CN.....	481
eCTD Filing Types for EAEU.....	481
eCTD Filing Types for EU	482
eCTD Sub-Filing Types for EU	497
eCTD Filing Types for GCC.....	508
eCTD Filing Types for JO	510
eCTD Filing Types for SG	513
eCTD Sub-Filing Types for SG.....	514
eCTD Filing Types for TH.....	514
eCTD Filing Types for TN.....	517
eCTD Sub-Filing Types for TN.....	521
eCTD Filing Types for TW	526
eCTD Filing Types for UA.....	526
eCTD Filing Types for US	527
eCTD Sub-Filing Types for US.....	530
eCTD Filing Types for WHO	531
eCTD Sub-Filing Types for WHO	532
eCTD Filing Types for ZA	537
eCTD Sub-Filing Types for ZA.....	545
Chapter 8. Prevent Unauthorized User Access to Red Hat JBoss EJBInvokerServlet	555
Chapter 9. Assembly XML Specification.....	556
Assembly	556
Folder	557
Leaf	563
Document.....	571
Extensions.....	580
Folder Extensions	588
m1-au	588
m1-au v. 0.9	588
m1-au v. 3.0.....	591

m1-au v. 3.1	595
m1-au v. 3.2	599
m1-au-nees v. 2.0	605
m1-additional	610
m1-additional v. 1.0	610
m1-additional v. 1.2.1	610
m1-additional v. 2.0	611
m1-additional v. 3.0	611
m1-additional v. 3.1	611
m1-ca	612
m1-ca v. 1.0	612
m1-ca v. 2.2	613
m1-ch	615
m1-ch v. 1.0	615
m1-ch v. 1.1	616
m1-ch v. 1.2	618
m1-ch v. 1.3	620
m1-ch v. 1.4	621
m1-ch v. 1.5	623
m1-ch-additional	625
m1-ch-additional v. 1.0	625
m1-ch-common-form	625
m1-ch-common-form v. 1.0	625
m1-ch-galenic-form	625
m1-ch-galenic-form v. 1.0	625
m1-ch-galenic-form v. 1.1	626
m1-ch-responses m1-ch-responses v. 1.0	626
m1-ua-responses	626
m1-ua-responses v.1.0	626
clinical_indication	633
clinical_indication v.1.0, v.1.1	633
m1-cn	633

m1-cn v. 1.0	633
drug_appendix	636
drug_appendix v. 1.0, v. 1.1	636
drug_product	636
drug_product v. 1.0, v. 1.1	636
drug_substance	636
drug_substance v. 1.0	636
m1-eu	637
m1-eu v. 3.1	637
m1-eu v. 1.0	637
Envelope	637
envelope v. 1.0	637
envelope v. 1.1	640
envelope v. 1.2.1	642
envelope v. 1.3	644
envelope v. 1.4	647
envelope v. 2.0	650
envelope v. 3.0	653
envelope v. 3.0.1	657
envelope v. 3.1	661
envelope-eaeu	664
envelope-eaeu v. 1.0	664
drug_solvent	665
drug_solvent v. 1.0	665
envelope-gc	665
envelope-gc v. 1.2	665
envelope-gc v. 1.5	667
envelope-hr	669
envelope-hr v. 1.4	669
eu-envelope	672
eu-envelope v. 1.0	672
eu_module_1_country_specific_information	672
eu_module_1_country_specific_information v. 1.0	672

eu_module_1_country_specific_information v. 1.2.1	672
eu_module_1_country_specific_information v. 2.0	672
eu_module_1_country_specific_information v. 3.0	673
eu_module_1_country_specific_information v. 3.1	673
eu_xml_application_form.....	673
eu_xml_application_form v. 1.0.....	673
eu_xml_application_form v. 2.0.....	674
eu_module_1_labeling_information.....	674
eu_module_1_labeling_information v. 1.0	674
eu_module_1_labeling_information v. 1.1	675
eu_module_1_labeling_information v. 1.2.1.....	675
eu_module_1_labeling_information v.3.1.....	676
excipient	676
excipient v. 1.0, v. 1.1	676
envelope-jo	677
envelope-jo v. 1.0	677
eu_pim_additional_documents.....	678
eu_pim_additional_documents v. 1.0.....	678
m1-gc	678
m1-gc v. 1.2	679
gc_module_1_country_specific_information	679
gc_module_1_country_specific_information v. 1.2	679
gc-m1-responses.....	679
gc-m1-responses v. 1.2.....	679
gc_module_1_label.....	679
gc_module_1_label v. 1.2.....	679
gc-m1-additional	680
gc-m1-additional v. 1.2.....	680
gc-envelope	680
gc-envelope v. 1.2.....	680
envelope-ua.....	681
Envelope-ua v.1.0	683
m1-hr.....	686

m1-hr v. 1.0	686
hr-m1-additional	686
hr-m1-additional v. 1.2.1	686
hr-m1-3-1-spc-label-pl	686
hr-m1-3-1-spc-label-pl v. 1.2.1	686
hr_module_1_country_specific_information	687
hr_module_1_country_specific_information v. 1.2.1	687
hr-m1-responses	687
hr-m1-responses v. 1.2.1	687
m1-jp	687
m1-jp v. 1.1	687
m1-jo	688
m1-jo v. 1.0	688
jo_pi_doc	688
jo_pi_doc v.1.0	688
jo-additional	689
<i>jo-additional v. 1.0</i>	689
m1-th	689
m1-th v. 0.92	689
m1-th v. 1.0	690
m1-tw	693
m1-tw v. 1.0	693
m1-th-responses	697
m1-th-responses v.1.0	697
m1-th-additional	698
m1-th-additional v.1.0	698
m1-ua-additional	698
m1-ua-additional v.1.0	698
m1-ua	698
m1-ua	698
m1-us	698
m1-us v.1.0	698
m1-us v. 3.3	700
m1-us-form	702
m1-us-form v. 3.3	702

m1-us-admin-form.....	702
m1-us-admin-form v. 3.3.....	702
m1-who	703
m1-who v. 1.0.....	703
m1-za	705
m1-za v. 1.0.....	705
m1-za v.2.1	709
m1-za v.3.1	712
m1-15-2-materials	719
m1-15-2-materials v. 3.3	719
m1-15-promotional-material.....	719
m1-15-promotional-material v. 3.3.....	719
m1-15-2-1-material	719
m1-15-2-1-material v. 3.3.....	719
m1-responses.....	720
m1-responses v. 1.0.....	720
m1-responses v. 1.2.1.....	720
m1-responses v. 2.0.....	721
m1-responses v. 3.0.....	721
eu-m1-responses v. 3.1	721
m1-3-1-spc-label-pl.....	722
m1-3-1spc-label-pl v. 1.0	722
m1-3-1spc-label-pl v. 1.2.1	722
m1-3-1spc-label-pl v. 2.0	723
m1-3-1spc-label-pl v. 3.0	723
m1-3-1spc-label-pl v. 3.1	724
m1-3-1-pim	724
m1-3-1-pim v. 1.0	724
m2-3-introduction.....	724
<i>m2-3-introduction v. 1.0</i>	724
m2-3-quality-overall-summary	725
m2-3-quality-overall-summary v. 1.0	725
Stf.....	725

stf v. 1.0	725
stf v. 1.1	726
stf v. 3.0	728
stf v. 5.0	731
study_patient_information_folder.....	734
study_patient_information_folder v. 1.0	734
study_patient_information_folder v. 3.0	735
study_data_folder.....	736
study_data_folder v. 1.0.....	736
study_data_folder v. 3.0.....	737
module_studies	738
module_studies v. 1.0	738
module_studies v. 3.0	739
module_4_studies	741
module_4_studies v. 1.1	741
module_4_studies v. 1.2	741
module_5_studies	743
module_5_studies v. 1.1	743
module_5_studies v. 1.2	743
module_5_studies v. 1.3	743
node-extension	745
node-extension	745
Leaf Extensions.....	745
japanese_leaf.....	745
japanese_leaf v.1.0.....	745
study_report_leaf.....	745
study_report_leaf v. 1.0	745
study_report_leaf v. 1.1	746
study_report_leaf v. 3.0	746
study_patient_information_leaf	747
study_patient_information_leaf v. 1.0.....	747
eu-envelope	747
eu-envelope v. 1.0	747

jo-envelope	748
jo-envelope v. 1.0	748
eaeu-envelope	748
eaeu-envelope v.1.0	748
eaeu_leaf	748
eaeu_leaf v. 1.0	748
PublisherMetaData.....	751
m1-us-meta-data-application.....	752
m1-us-meta-data-application v. 3.3.....	752
Publishing Settings	753
MetaData.....	806
Assembly XML: Explanations.....	809
Index A.....	810
C.....	811
D.....	811
E.....	811
I.....	811
L.....	811
N.....	811
P.....	811
R.....	812
S.....	812
T.....	812
W.....	812
X.....	812

Chapter 1. Ennov InSight Administration

The Ennov InSight Administrator Guide provides information and procedures for system administrators, security administrators, and data administrators who work with Ennov InSight .

Chapter 2. Ennov InSight License Components

The Ennov InSight components enable different organizational roles and functions within the regulatory lifecycle of a drug product. Each component focuses on one particular area of expertise and includes the ability to control access permissions within the component for specified users and groups.

By assigning access permissions to users or roles, you can enable some users to merely observe or access queries and summaries while enabling others to perform the daily operations of project management, research, planning, and publishing.

Available Components	Description
Ennov InSight Workflow Integration	Enables you to utilize client-specific workflows that contain multiple activities, with dependencies and preset fields, that guide processes within the system.
xEVMPD	Enables you to capture, maintain, and submit data about pharmaceutical products to comply with the Extended EudraVigilance Medicinal Product Database (xEVMPD) directive.
IDMP	Enables you to capture, maintain and submit medicinal product data to comply with the extended IDMP functionality.
Registration Planning and Tracking	(RPT) enables you to plan registration activities and collect registration data without product formulation details. It improves affiliate communication, enables you to track the status of overall global product registration activities, and maintain product registration compliance.
Product Detail Management	(PDM) enables you to track product formulation and SPL exports. It also provides queries about where products are registered and other registration information.
Submission Planning and Tracking	(SPT) enables you to create, review and track submissions from planning to publishing. It also automates assembly creation and enables you to monitor the authoring process.
Registered Document Analysis	(RDA) leverages lifecycle submission information to enhance the DMS repository for better decision support based on usage information. It enables you to query for the external approval status of documents and to perform impact analysis of registered document changes.

Electronic Lifecycle Publishing	(ELP) simplifies eCTD creation and is required to publish assemblies as eCTD submissions.
Available Components	Description
Paper Review Publishing	(PRP) enables you to build assemblies for publishing to paper. PRP enables you to add paper elements such as TOCs, cover pages, overlays, and cross references to electronically published submissions suitable for generating study report submissions, hybrids, and other electronic submission formats. Using both the ELP and PRP licenses enables you to add these publishing elements to eCTD lifecycle submissions. Finally, PRP also enables you to publish an entire assembly to a single file electronically.

Ennov InSight License Modules by Feature

The following tables list Ennov InSight features and the license modules in which they are available.

Subfeature	Subfeature Description	License Modules
Product detail	Define consumable products (Example: dosage forms).	– Registration Planning and Tracking – Product Detail Management – Submission Planning & Tracking – Electronic Lifecycle Publishing – Paper Review Publishing

Product Families, Clinical Trial Shared Data

Subfeature	Subfeature Description	License Modules
Product family categorization	Define parent active substance family.	– Electronic Lifecycle Publishing – Paper Review Publishing – Product Detail Management – Registered Document Analysis – Registration Planning and Tracking – Submission Planning and Tracking

Product family extended attributes	Full support includes product family attributes.	– Registration Planning and Tracking Product Detail Management
CT Shared Data	Clinical Trial Shared Data for a product family.	– Registration Planning and Tracking – Product Detail Management

Products, Pharmaceutical Products

Subfeature	Subfeature Description	License Modules
Pharmaceutical product detail	Define a product used to treat disease (Example: medicines or drugs).	– Registration Planning and Tracking – Product Detail Management – Submission Planning & Tracking – Electronic Lifecycle Publishing – Paper Review Publishing

Registrations, Full Product Presentations, Registration FPP Attachments and FPP Previous EV Codes

Subfeature	Subfeature Description	License Modules
Registration detail	Define registration details, including those that vary by country for MRP applications.	– Registration Planning and Tracking – Product Detail Management
Copy Package Set Registration	Copy a package set registration. Requires at least Write permissions for the Registrations and Full Product Presentation (FPP) (applicable to the <i>New Package Set specific</i> <i>Registration(s)</i> flow) in the Entity Security section.	– Registration Planning and Tracking – Product Detail Management

Full product presentation detail	Define detailed information about the product (Example: Special Measures, Product Strength).	– Registration Planning and Tracking – Product Detail Management
FPP previous EV code detail	Define the previous EV code for the full product presentation.	– Registration Planning and Tracking – Product Detail Management
Registration FPP attachment detail	Presents an attachment for the detailed product information.	– Registration Planning and Tracking – Product Detail Management
Copy full product presentation	Copy a full product presentation under the same registration, or under different registrations. At least Write permissions for the Full Product Presentation (FPP) in Entity Security section.	– Registration Planning and Tracking – Product Detail Management

Registration Attachment

Subfeature	Subfeature Description	License Modules
Registration Attachment	Registration Attachment entity is a Printed Product Information (PPI) attachment type and should be created to later attach it to the Full Product Presentation.	– Registration Planning and Tracking – Product Detail Management
Copy registration attachment	Copy a registration attachment. – At least Write permissions for the Registration Attachment in Entity Security section. – At least Write permissions for the Full Product Presentation (FPP) in Entity Security section.	– Registration Planning and Tracking – Product Detail Management

Medicinal Products, Medicinal Product Actions, Data Visualization

Subfeature	Subfeature Description	License Modules
Medicinal Product detail	Medicinal product for registration. At least Write permissions for the Medicinal Product in Entity Security section.	– Registration Planning and Tracking – Product Detail Management
Medicinal Product Action detail	Medicinal product action for registration. At least Write permissions for the Medicinal Product Action in Entity Security section.	– Registration Planning and Tracking – Product Detail Management
IDMP Data Generation wizard	Access to the IDMP Data Generation wizard from the wizards menu with the Write permissions.	IDMP
IDMP Data Visualization	Access to the IDMP Data Visualization from on the Medicinal Product Action Attributes menu with Write permissions.	IDMP

xEVMPD Wizards and Queries

Subfeature	Subfeature Description	License Modules
XEVMPPD Submission wizard	Access to the XEVMPPD Submission wizard from the wizards menu and Home page with Write permissions.	xEVMPD
XEVMPPD Acknowledgement wizard	Access to XEVMPPD Acknowledgement wizard from the wizards menu and Home page with Write permissions.	xEVMPD
Queries	Access to the following Registration Planning and Tracking queries with Read and Write permissions: – XEVMPPD Submissions - QC Verification and Audit – XEVMPPD Submissions and Acknowledgements	xEVMPD

Applications

Subfeature	Subfeature Description	License Modules
Application detail	Ability to define overall marketing authorization (Example: NDA).	– Electronic Lifecycle Publishing – Paper Review Publishing – Product Detail Management – Registered Document Analysis – Registration Planning and Tracking – Submission Planning and Tracking
Application Countries tab	Support for European procedures (MRP and CP) including collection of countryspecific data (primarily dates) for the application.	– Electronic Lifecycle Publishing – Paper Review Publishing – Product Detail Management – Submission Planning and Tracking – Registration Planning and Tracking
Copy application	Copy an application.	– Registration Planning and Tracking – Product Detail Management
Subfeature	Subfeature Description	License Modules
Create Application Wizard	Access to the Create Application Wizard from the wizards menu with the Write permissions. Access to Events for the Create Application Wizard from the wizards menu with the Write permissions.	– Electronic Lifecycle Publishing – Submission Planning and Tracking

Comparators

Subfeature	Subfeature Description	License Modules
Comparators	Comparators are used in clinical trials to compare the success of a medicine under study to another medicine or placebo.	– Registration Planning and Tracking – Product Detail Management

Events

Subfeature	Subfeature Description	License Modules
Event detail	Define initial filing event and other major updates (Example: variations) to an application.	– Electronic Lifecycle Publishing – Paper Review Publishing – Product Detail Management – Registered Document Analysis – Registration Planning and Tracking – Submission Planning and Tracking
Copy Event Wizard	Copy an event to multiple applications in the product family associated with a source event.	– Electronic Lifecycle Publishing – Product Detail Management – Registration Planning and Tracking – Submission Planning and Tracking
Create Submission wizard	Automates creation of initial applications, major updates and amendments.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Registration Planning and Tracking – Submission Planning and Tracking
Event country status schedule	Define projected event status dates, track status history, and compare actual and planned dates for major milestones.	– Registration Planning and Tracking – Submission Planning and Tracking

Sequences

Subfeature	Subfeature Description	License Modules

Sequence detail	Define filings/amendments (regulatory submission correspondence to authorities in support of an application).	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Registration Planning and Tracking – Submission Planning and Tracking
Sequence status schedule	Define projected sequence status dates, track status history, and compare actual and planned dates for major milestones.	– Registration Planning and Tracking – Submission Planning and Tracking

Product Detail Sets (PDS)

Subfeature	Subfeature Description	License Modules
Product detail set detail	Capture product detail approvals, such as for substance, product, packaging manufacturers, labeling, and product indications.	– Registration Planning and Tracking – Product Detail Management
PDS templates	Save PDS information within a product family as a template.	– Registration Planning and Tracking – Product Detail Management

Assembly Types

Subfeature	Subfeature Description	License Modules
Lifecycle sequence assemblies	Build hierarchical collections of source documents associated with specific regulatory activities and sequences, and add to the current view for lifecycle.	– Electronic Lifecycle Publishing – Registered Document Analysis – Submission Planning and Tracking
Supporting sequence assemblies	Build hierarchical collections of source documents associated with specific regulatory activities and sequences.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking

Standalone assemblies	Build hierarchical collections of source documents for miscellaneous use.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
Subfeature	Subfeature Description	License Modules
Assembly templates	Build an assembly template.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking

Activity Workflow

Subfeature	Subfeature Description	License Modules
Activities	Activities are steps within the Workflow that are required to complete the assigned Workflow. Workflows can contain multiple Activities, with dependencies and pre-set values.	Ennov InSight Workflow Integrations

Projects

Subfeature	Subfeature Description	License Modules
Global Project Planning (GPP) wizard	Facilitates planning and data entry for multiple countries or applications. At least Write privileges for Projects and Events. Home page access security enabled for GPP wizard.	– Registration Planning and Tracking – Submission Planning and Tracking

Tasks, Notifications, and References

Subfeature	Subfeature Description	License Modules
Task detail	Define hierarchical to-do lists associated with other entities.	– Registration Planning and Tracking – Submission Planning and Tracking

Task status schedule	Define the sequence of statuses for a task, and for each status, the projected date when the task first has the status.	– Registration Planning and Tracking – Submission Planning and Tracking
Notification detail	Define and automatically send e-mail notifications based on data updates, approvals, and other changes in Ennov InSight .	– Registration Planning and Tracking – Submission Planning and Tracking
Subfeature	Subfeature Description	License Modules
Reference detail	Associate external documents, URLs, and internal links with entities; supports correspondence and DMS integration.	– Registration Planning and Tracking – Submission Planning and Tracking

Change, Change Details

Subfeature	Subfeature Description	License Modules
Change	Defines the actual regulatory change being planned or requested and have specific metadata associated.	Registration Planning and Tracking
Change details	Capture details of the Change as a subentity to the Change entity.	Registration Planning and Tracking

Reports

The reports listed in the table include the reports that you can generate by using Ennov InSight queries.

Subfeature	Subfeature Description	License Modules
Querying menu	Run queries and quick search; not all quick search entities may apply to the module; available queries vary by module.	The modules related to the kind of query that you run
Public/private customized queries	Create both private and public custom queries.	– Electronic Lifecycle Publishing – Paper Review Publishing – Product Detail Management – Registered Document Analysis – Registration Planning and Tracking – Submission Planning and Tracking

Ad hoc Reporting	Create and execute ad hoc reports against the Ennov InSight reporting schema.	– Product Detail Management – Registered Document Analysis – Registration Planning and Tracking – Submission Planning and Tracking
Specialized assembly queries	Execute specialized queries directly from the assembly tree.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
Subfeature	Subfeature Description	License Modules
Application, Event, Sequence report	Provides information that you select about product families, applications, events, and sequences.	– Registration Planning and Tracking – Submission Planning and Tracking

Approval Management

Subfeature	Subfeature Description	License Modules
Approved views	Create and view document collections consisting of currently approved versions for a particular country. Full support includes the ability to create new assemblies from these views.	Registered Document Analysis
Update Status wizard	Automate approval of an application or major update.	– Registered Document Analysis – Registration Planning and Tracking – Submission Planning and Tracking

Submittal Management and Lifecycle

Subfeature	Subfeature Description	License Modules
Submitted view	Create and view document collections consisting of currently submitted versions for a particular country. Create and manage eCTD	– Electronic Lifecycle Publishing – Registered Document Analysis

	lifecycles. Full support includes ability to create new assemblies from these views.	– Submission Planning and Tracking (does not enable you to create new assemblies)
Change Submittal Status wizard	Automate submittal of an application or major update and creation of lifecycle.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
Add to/remove from lifecycle	Manually create and manage lifecycle	– Electronic Lifecycle Publishing – Registered Document Analysis
Working view	Assign changes and leaf operations from a cumulative view of eCTD submission sequences.	– Electronic Lifecycle Publishing – Registered Document Analysis – Submission Planning and Tracking
Subfeature	Subfeature Description	License Modules
Sequence view	View the current cumulative sequence.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
Publishing view	Publish the current cumulative sequence and add publishing effects.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking

General Assembly

Subfeature	Subfeature Description	License Modules
General assembly features and functions	Expand/collapse all, edit hierarchical assembly structure (including lifecycle actions, if applicable), browse or search document	– Electronic Lifecycle Publishing – Paper Review Publishing

	repositories and assign documents, retrieve document properties from DMS, view DMS documents, modify assembly attributes, delete assemblies.	– Registered Document Analysis – Submission Planning and Tracking
Import/export	Create an assembly from a template, XML assembly file, or VDM. Export assemblies to XML assembly files and VDMs.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
Document placeholders	Create a planned document in the assembly.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
Mass-apply version bindings	Incrementally set bindings across the assembly, including locking the binding to the current version.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
Subfeature	Subfeature Description	License Modules
View file from document and leaf	Viewing in-place repository, submission, and published content.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
Document status awareness	Binding icons and View Document List query.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking

Support and assignment of unfinalized documents	View status of unfinished documents for assembly.	Submission Planning and Tracking

Subfeature	Subfeature Description	License Modules
Review and approval assembly features and functions	Version assemblies with assembly currency.	Submission Planning and Tracking
Incremental locking	Incrementally lock assembly by module and by section or folder hierarchy.	Submission Planning and Tracking

Planning and Tracking

Subfeature	Subfeature Description	License Modules
Planning and tracking assembly features and functions	Edit document path and binding information, view/assign related documents, export assembly to Microsoft Excel.	Submission Planning and Tracking
Assembly search and replace	Search and replace text in assembly element attributes for planning and creating templates of document locations and assignments.	Submission Planning and Tracking
Assembly Status query	Provides the current assembly status including performance metrics.	Submission Planning and Tracking

Review and Approval

Subfeature	Subfeature Description	License Modules
Assembly baselines and baseline querying	Create baselines for assembly comparison querying.	Submission Planning and Tracking
Assembly reference location	Create and set reference locations and synchronize with DMS.	Submission Planning and Tracking
Assembly status change	Change status of assembly including automatic lock down if assembly is finalized.	Submission Planning and Tracking

Unlock the folder	Unlock the locked assembly folder.	Submission Planning and Tracking

Document Analysis

Subfeature	Subfeature Description	License Modules
Document analysis features and functions	Create approved views, query and view registered documents, query and view lifecycle history.	Registered Document Analysis
Where Used query	Determine where a document is used across applications, countries, products, versions, and assemblies. The Output File hyperlink in the Where Used query is supported only for sequence assemblies, not standalone and template assemblies.	– Registered Document Analysis – Submission Planning and Tracking

General Publishing

Subfeature	Subfeature Description	License Modules
Publishing job queue and audit trail	View the status of all publishing jobs; sort, export, and cancel jobs.	– Electronic Lifecycle Publishing – Paper Review Publishing
Publishing Readiness query, Summary query, Link Inspector, and publishing log	View eCTD conformity and status before and after the publishing job is executed.	– Electronic Lifecycle Publishing – Paper Review Publishing
Repository export utility	Transfer published output from any repository source to any repository destination (DMS or File/Folder).	– Electronic Lifecycle Publishing – Paper Review Publishing
Subfeature	Subfeature Description	License Modules

Automatic extractions	Create document extractions for use in bookmarks, TOCs, and links automatically upon assignment.	– Electronic Lifecycle Publishing – Paper Review Publishing (with Ennov InSight Rendering only)
Automatic renditions	Create PDF renditions automatically and by request upon publishing or Prepare to Publish when existing renditions are missing or outdated. Requires an additional license for Ennov InSight Rendering.	– Electronic Lifecycle Publishing – Paper Review Publishing (with Ennov InSight Rendering only)

eCTD Publishing

Subfeature	Subfeature Description	License Modules
eCTD publishing assembly features and functions	Create eCTD and electronic output, specify assembly-level publishing options for eCTD, links, and variables, change element types to specify leafspecific publishing properties, request generated published output (eCTD and electronic).	Electronic Lifecycle Publishing
Electronic hyperlinks	Create, retarget, and set channel and settings on hyperlinks.	– Electronic Lifecycle Publishing – Paper Review Publishing
Reference leaf elements	Create leaf elements to reference other leaf elements with querying on referenced leaf elements for a specific submission.	– Electronic Lifecycle Publishing – Registered Document Analysis (query only)
eCTD import and merge	Import one or multiple eCTD sequences; merge eCTD sequences.	Electronic Lifecycle Publishing
Create eCTD wizard	Create or update an eCTD sequence.	Electronic Lifecycle Publishing
Bulk eCTD Wizard	Migrate multiple eCTD submissions to Ennov InSight from another system in a supported document management system (DMS).	Electronic Lifecycle Publishing
Create Study Reports wizard	Add study reports to an eCTD sequence.	Electronic Lifecycle Publishing
Subfeature	Subfeature Description	License Modules

Create Submission Plan Wizard	Create a submission plan and associate entities such as applications, events, and sequences to the submission plan.	– Electronic Lifecycle Publishing – Submission Planning and Tracking

Paper Publishing

Subfeature	Subfeature Description	License Modules
Paper publishing assembly features and functions	Create paper and electronic output, specify assembly-level publishing options for publishing effects, change folder and document attributes for publishing effects, request published output (paper and electronic).	– Electronic Lifecycle Publishing – Paper Review Publishing
Table of contents	Create, edit, generate, and modify TOCs. Access the TOC editor.	– Electronic Lifecycle Publishing – Paper Review Publishing
Special sheets	Create, edit, generate, and modify special sheets including slip sheets, tabs, and cover pages.	Paper Review Publishing
Volumes	Create and modify volumes, bulk volumize, move, lock, and manipulate volumes.	Paper Review Publishing
Overlays	Define and use overlays. Define page size, shape, scaling, and format for output.	Paper Review Publishing
Paper crossreferences	Create, retarget, and set channel, stamp, and settings on paper crossreferences.	Paper Review Publishing

Administration

Subfeature	Subfeature Description	License Modules
Administration menus (Data, Security and Technical)	Modify data picklists, connect to and define DMS and file system repositories, administer security. Not all options displayed to an administrator are available in all modules. Example: picklist options for data admin may not be displayed in an application. Notification administration does not apply to all modules. Includes all audit trail querying.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Registration Planning and Tracking – Product Detail Management – Submission Planning and Tracking

Data Administration Functions by Module

Data Administration provides the ability to manage the functions available in your system according to your Ennov InSight license modules. The following table shows the Data Administration values that should be considered based on the Ennov InSight components you use.

Application Maintenance

	Registrations		Assemblies		Publishing	
Selection	RPT	PDM	SPT	RDA	ELP	PRP
Age Span Population Values	✓		✓		✓	
Application Category Values	✓		✓			
Application Status Values	✓		✓	✓	✓	✓
Application Type Values	✓		✓	✓	✓	✓
Chief Investigator Values	✓		✓		✓	
Country Values	✓	✓	✓	✓	✓	✓
CTA Product Role Values	✓		✓		✓	
Legal Status Values	✓		✓		✓	
MedDRA Term Values	✓	✓	✓		✓	
Medical Condition Investigated Values	✓		✓		✓	
Procedure Type Values	✓		✓	✓	✓	✓
Reason for Premature Ending Values	✓		✓		✓	
	Registrations		Assemblies		Publishing	
Selection	RPT	PDM	SPT	RDA	ELP	PRP
Region Values	✓		✓	✓	✓	✓
Region Type Values	✓		✓	✓	✓	✓
Sponsor Type Values	✓		✓		✓	
Trial Design Values	✓		✓		✓	
Trial Phase Values	✓		✓		✓	
Trial Scope Values	✓		✓		✓	
Trial Subject Groups Values	✓		✓		✓	

Assembly

	Assemblies		Publishing	
Selection	SPT	RDA	ELP	PRP
Assembly Category Values	✓	✓	✓	✓
Assembly DTD/Schema Types	✓	✓	✓	
Assembly Status Values	✓	✓	✓	✓
Assembly Subcategory Values	✓	✓	✓	✓

Assembly Variables

	Publishing	
Selection	ELP	PRP
Assembly Repository Variables	✓	✓
Assembly System-Defined Variables	✓	✓
Assembly User-Defined Variables	✓	✓
Ennov InSight Assembly Variables	✓	✓

Change Maintenance

	Registrations	
Selection	RPT	
Change Type Values	✓	
Event-Change Details Status Values	✓	

Custom Lists Maintenance**DMS Integration**

Registrations

Assemblies

Selection

RPT

PDM

SPT

RDA

Custom List Names



Custom List Values



Assemblies

shing

Publi

Selection

SPT

RDA

ELP

PRP

Bind to Label Values



Bind to Status Values

**Event Maintenance**

	Registrations		Assemblies		Publishing	
Selection	RPT	PDM	SPT	RDA	ELP	PRP
Action Type Values	✓		✓	✓	✓	✓
EU Grouping or Worksharing Values	✓		✓		✓	✓
Timeline/Event Plan Values	✓		✓	✓	✓	✓
Event Status Values	✓		✓	✓	✓	✓
Event Type Values	✓		✓	✓	✓	✓
PSUR Report Code Values	✓					
Secondary Event Type Values	✓		✓	✓	✓	✓

Notifications

	Registrations		Assemblies	
Selection	RPT	PDM	SPT	RDA
Notification Specifications	✓		✓	
Notifications	✓		✓	

Other

	Registrations		Assemblies		Publishing	
Selection	RPT	PDM	SPT	RDA	ELP	PRP
Attachment Values	✓	✓				
Concentration Measure Type Values	✓	✓				

	Registrations		Assemblies		Publishing	
Selection	RPT	PDM	SPT	RDA	ELP	PRP
Denominator Unit Values	✓	✓				
Entity XML/UI Mappings	✓	✓	✓	✓	✓	✓
Home Page Display Properties	✓		✓	✓	✓	✓
Indications/Intended Use Values	✓	✓				
Language Values	✓	✓	✓	✓	✓	✓
Legal Basis Values	✓		✓			
Length Unit Of Measure Values	✓	✓				
MAH/Development Sponsor/Organization Values	✓					
Master File Location (MFL) Values	✓					
Message Sender Values	✓					
Numerator Unit Values	✓	✓				
Previous EV Code Values	✓	✓				
Quantity Unit Of Measure Values	✓	✓				
Reason for E-Signature Values	✓	✓	✓	✓	✓	✓

Note: E-signature functionality is an optional feature for Ennov InSight that requires special setup and configuration. Contact Client Enablement to enable E-signatures for your Ennov InSight version.						
Reason for Termination/Withdrawal Values	✓	✓	✓	✓	✓	✓
SME Status Values	✓	✓				
Sub-Indication Values		✓				
System Alert Type Values	✓	✓	✓	✓	✓	✓
Unit Of Measure Prefix Values	✓	✓				
Unit Of Presentation Values	✓	✓				
Weight Unit Of Measure Values	✓	✓				

Product Detail Set Maintenance

	Registrations	
Selection	RPT	PDM
Color Values	✓	✓
Compendial Designation/Source Values	✓	✓
Dose Frequency Values	✓	✓
Substance Role Values	✓	✓
Genetically Modified Cell Origin Species Values	✓	✓
Human Consumption Product Values	✓	✓
Label Type Values	✓	✓
Manufacturer Function Values	✓	✓
Manufacturer Values	✓	✓
Manufacturer Type Values	✓	✓
Material Type Values	✓	✓
Medical Device Party Code Values	✓	✓
Packaging Category Values	✓	✓
Packaging Type Values	✓	✓
Product Bio Type Values	✓	✓

Product Detail Set Status Values	✓	✓
Product Material Values	✓	✓
Production Type Values	✓	✓
QC Status Values	✓	✓
Shape Values	✓	✓
Shelf Life Category Values	✓	✓
Shelf Life Type Values	✓	✓
Somatic Cell Therapy Cell Type Values	✓	✓
Somatic Cell Therapy Origin Species Values	✓	✓
Somatic Cell Therapy Origins Values	✓	✓
Source of Scientific Advice Values	✓	✓
Species Values	✓	✓
	Registrations	
Selection	RPT	PDM
Storage Condition Values	✓	✓
Time Unit Values	✓	✓
Type of Dossier Submitted Values	✓	✓
Type of Gene Therapy Transfer Product Values	✓	✓
Type of Gene Therapy Values	✓	✓
Type of Genetically Modified Cell Origin Values	✓	✓
Volume Unit Of Measure Values	✓	✓

Product Family Maintenance

	Registrations		Assemblies		Publishing	
Selection	RPT	PDM	SPT	RDA	ELP	PRP
ATC Values	✓	✓				
Division Values	✓	✓				
Product Family Status Values	✓	✓	✓	✓	✓	✓
Product Family Values	✓	✓	✓	✓	✓	✓

Substance Class Values	✓	✓				
Substance Values	✓	✓				
Therapeutic Area Values	✓	✓				
Therapeutic Class Values	✓	✓				
Trade Name Values	✓	✓				

Product Maintenance

	Registrations	
Selection	RPT	PDM
Applicable Standards Values	✓	✓
Conformity Assessment Path Values	✓	✓
Device Allergenicity Values	✓	✓
Device Nomenclature Values	✓	✓
Device Sterility Indicator Values	✓	✓
Device Type Values	✓	✓
	Registrations	
Selection	RPT	PDM
Device Usage Values	✓	✓
Dosage/Pharmaceutical Form Values	✓	✓
EC Cert Values	✓	✓
EU Classification Rule Values	✓	✓
EU Class Values	✓	✓
FDA Device Class Values	✓	✓
FDA Regulation Number Values	✓	✓
Global Harmonization Task Force (GHTF) Class Values	✓	✓
Manufacturing Location Values	✓	✓
Medical Device Values	✓	✓
Product Characteristics Values	✓	✓
Product Status Values	✓	✓

Product Strength Unit Values	✓	✓
Route of Administration Values	✓	✓
Special Measure Values	✓	✓
Sterilization Requirement Values	✓	✓
Sterilization Values	✓	✓
Summary of Technical Documentation (STED) Values	✓	✓

Project Maintenance

	Registrations		Assemblies	
Selection	RPT	PDM	SPT	RDA
Project Status Values	✓	✓	✓	
Project Type Values	✓	✓	✓	

Reference Maintenance

	Registrations		Assemblies	
Selection	RPT	PDM	SPT	RDA
Reference Content Values	✓		✓	
Reference Participant Values	✓		✓	
	Registrations		Assemblies	
Selection	RPT	PDM	SPT	RDA
Reference Status Values	✓		✓	
Reference Type Values	✓		✓	

Registration Maintenance

	Registrations	
Selection	RPT	PDM
EMA Authorization Status Values	✓	✓
Medicinal Product Type Values	✓	✓
Qualified Person Responsible for Pharmacovigilance (QPPV) Values	✓	✓
Registration Status Values	✓	✓

Sequence Maintenance

	Registrations		Assemblies		Publishing	
Selection	RPT	PDM	SPT	RDA	ELP	PRP
Filing Type Values	✓		✓	✓	✓	✓
Sequence Status Values	✓		✓	✓	✓	✓

SPOR Master Lists

	Registrations	
Selection	RPT	PDM
ATC RMS Values	✓	✓
Compendial Designation/Source RMS Values	✓	✓
Concentration Measure Type RMS Values	✓	✓
Country RMS Values	✓	✓
Denominator/Numerator Unit RMS Values	✓	✓
Dosage/Pharmaceutical Form RMS Values	✓	✓
EMA Authorisation Status RMS Values	✓	✓
Language RMS Values	✓	✓
Legal Basis RMS Values	✓	✓
Medical Device RMS Values	✓	✓
Medicinal Product Type RMS Value	✓	✓
	Registrations	
Selection	RPT	PDM
Procedure Type RMS Values	✓	✓
Route of Administration RMS Values	✓	✓
Unit of Measure Prefix RMS Values	✓	✓

	Registrations		Assemblies	
Selection	RPT	PDM	SPT	RDA
Secondary Task/Sub-Task Type Values	✓		✓	

Submission Maintenance

	Publishing	
Selection	ELP	PRP
Applicant Contact Type Values	✓	
Applicant Contact Values	✓	
Applicant ID Values	✓	
Application Form Type Values	✓	
Font Definition Values		✓
PDF Property Values	✓	
Promotional Material Audience Type Values	✓	
Promotional Material Doc Type Values	✓	
Promotional Material Type Values	✓	
Regulatory Activity Lead Values	✓	
Sequence Description Values	✓	
Sub Filing Type Values	✓	
Supplement Effective Date Type Values	✓	
Telephone Number Type Values	✓	

Submission Plan Maintenance

	Assemblies		Publishing	
Selection	SPT	RDA	ELP	PRP
Submission Plan Status Values	✓		✓	

Task Maintenance

	Registrations		Assemblies	
Selection	RPT	PDM	SPT	RDA
Task/Sub-Task Priority Values	✓		✓	
Task/Sub-Task Status Progression Values	✓		✓	
Task/Sub-Task Status Values	✓		✓	

Task/Sub-Task Type Values	✓		✓	

Queries Available by License

Registration Planning and Tracking (RPT)

All the queries listed are available by license in . queries are available as shown in the following section.

- Applications Sent, Submitted, or Approved - Searched by INN or Active Ingredient
- Application Submitted and/or Approved and/or Terminated within a Date Range
- List of Application Countries with Registration Details
- List of Applications with Products
- List of CTA Applications
- List of Events with Application Properties
- List of IND Applications
- List of Manufacturers from Data Administration
- List of Medical Device Products
- List of Medical Device Products and Components
- List of Pharmaceutical and Medical Device Products
- List of Pharmaceutical and Medical Device Products and Components
- List of Pharmaceutical Products
- List of Pharmaceutical Products and Components
- List of Product Families
- List of Products with Event and Product Registration Details
- List of References
- List of Registrations with Application Properties
- List of Sequences with Application and Event Properties
- List of Veterinary Products
- List of Veterinary Products and Components
- List of References - Rollup by Application

- List of References - Rollup by Product Family
- List of References - Rollup by Project
- List of Registrations for a Product Family
- List of Tasks
- List of Tasks - Rollup by Application

List of Tasks - Rollup by Product Family List of Tasks - Rollup by Project

PSUR World Wide Marketing Authorization Status **Product Detail Management (PDM)**

All the queries listed are available by license in . queries are available as shown in the following section.

- Application History Query
- Application QC Status History Report
- Flu Strain with Registration and PDS Details
- Labeled Indications Query
- List of Active Ingredient Manufacturers
- List of Active Ingredient Function Manufacturers
- List of Active Ingredient Material Manufacturers
- List of Application Countries with PDS Country and Registration Details
- List of Application Countries with Registrations and Product Details
- List of Component Manufacturers
- List of CTA Applications with PDS Details
- List of Dose Schedules
- List of Substance Manufacturers
- List of IND Applications with PDS Details
- List of Package Set Manufacturers
- List of PDS Manufacturers
- List of Product Detail Sets
- List of Product Detail Set Templates

- List of Products with Registration and Flu Strain Details
- List of Registrations with Active Ingredients
- List of Registrations with Application and Product Detail Properties
- List of Registrations with Substances
- List of Registrations with Indications/Intended Use – List of Registrations with Labeling
- List of Registrations with Local Country Details
- List of Registrations with Material
- List of Registrations with Packaging
- List of Registration Package Sets Withdrawn
- List of Species and Indications
- List of Withdrawal Times
- Shelf Life Query
- Sunset Clause Marketing Status Query **Submission Planning and Tracking (SPT)**

All the queries listed are available by license in . queries are available as shown in the following section.

Assembly Comparison

Assembly Status Query

List of Applications

- List of Application Countries
- List of Assemblies/Templates
- List of Events with Application Properties
- List of Sequences with Application and Event Properties
- List of References
- List of References - Rollup by Application
- List of References - Rollup by Product Family
- List of References - Rollup by Project
- List of Tasks

- List of Tasks - Rollup by Product Family
- List of Tasks - Rollup by Application
- List of Tasks - Rollup by Project **Registered Document Analysis (RDA)**

All the queries listed are available by license in . queries are available as shown in the following section.

- Assemblies Where Document Used
- List of Applications
- List of Assemblies/Templates
- List of Events with Application Properties
- List of Sequences with Application and Event Properties
- Registered Document Query
- View Document Where Used Query

Note: *View Document Where Used Query is available only if the combination of SPT and RDA licenses is preserved.*

Administration

All the queries listed are available by license in . queries are available as shown in the following section.

- Activity Audit Trail
- Entity Audit Trail
- Job Requests

Electronic Lifecycle Publishing (ELP)

All the queries listed are available by license in . queries are available as shown in the following section.

The following queries are available from the assembly tree:

- Export Assembly to Excel
- Link Inspector

Publishing Readiness

Publishing Summary (available from the action toolbar) View Document List

Note: *The query does not include currency data unless you create lifecycle views using functionality available to ELP users only. The Output File hyperlink in the Where Used query is supported only for sequence assemblies, not standalone and template assemblies.*

Submission Planning and Tracking (SPT) in the Assembly Tree

All the queries listed are available by license in . queries are available as shown in the following section.

The following queries are available from the assembly tree:

- Submission Readiness Report
- View Document Where Used Query

Note: *One of the following rules must be met in order to use this query:*

- *SPT is set to Write and Planing and Tracking is set to Yes;*
- *SPT is set to Write and Review and Approval is set to YES; • RDA is set to Write and Document Analysis is set to Yes.*

Note: *The query does not include currency data unless you create lifecycle views using functionality available to ELP users only. The Output File hyperlink in the Where Used query is supported only for sequence assemblies, not standalone and template assemblies.*

Chapter 3. Security Administration

As a security administrator, you are responsible for assigning privileges to existing users and groups. You can view the users, user groups, and Ennov InSight roles in the *Security* pages.

Ennov InSight supports authentication of users in the system when they are spread across multiple Identity Providers (IdP). The Ennov InSight system authenticates users if their account exists in the Azure AD individual Identity Provider (IdP) directory.

The users listed are either users who have been assigned security privileges directly, or users who belong to a user group that has been added to Ennov InSight and who have logged on at least once.

The users listed have either been assigned security privileges directly, or they belong to a user group that has been added to Ennov InSight and who have logged on at least once. The Security Administration page appears with the following links depending upon the system configuration. Currently, the Ennov InSight system with a single IdP configuration displays the Users and Groups link to add or modify users and groups.

Identity Providers Login

Ennov InSight provides a login page according to your configured Identity Provider (IdP).

Identity Provider (IdP)	Login page
Azure Active Directory	 ← user@test.com Enter password Password Forgot password? Sign in

Log on to IdP Configured Ennov InSight

You log on to an Identity Provider (IdP) configured in Ennov InSight to access documents and applications associated with clinical trials. Your access to functionality and modules in the system is based on your security permissions.

To log on:

1. Navigate from the desktop to the Ennov InSight *Login* page. The login page appears.
2. In the Username field, enter your user name. Click Next.
3. In the Password field, enter your password. Click Sign in.

User Types

Use Ennov InSight Security Administration to manage Users and Groups, and to assign privileges to them appropriately. The following table describes the types of Ennov InSight users.

User	Description
Group	An IdP group that consists of one or more named users.
	Note: Avoid the use of special characters in user names as they can prevent the ability to log on to Ennov InSight . For more information, see the topic <i>Special Characters</i> .
Group user	A user who has not been assigned privileges directly; rather this user has inherited privileges from his or her group; a group user is not displayed in the list until he or she has logged in to Ennov InSight or has been added to Ennov InSight . The user's IdP groups are displayed in the list.
	Note: If a user exists in more than one IdP group that has been added to Ennov InSight and those groups have also been assigned different privileges, then the privileges executed for that user cannot be predicted.
Overridden user	A user who had previously been assigned privileges through a group, and has since been disassociated from that group (using the functionality provided by Ennov InSight to disassociate the user).
User with no groups	A user who exists in an IdP, but who is not part of an IdP group. This user is added to Ennov InSight and privileges are assigned directly.

Ennov InSight Administration 7.3 Log on to IdP Configured Ennov InSight

Notes About Users

— If the user belongs to an IdP group and the group is already in Ennov InSight , then the user inherits the established privileges of the group. If you want to assign specific privileges to the user that are different from the group's privileges, you can override the rights by disassociating the user from the group and changing the security privileges.

- To assign security privileges to users who do not belong to an IdP group, you must first override the users by clicking the Disassociate User from the Group button and then assign security privileges to each individual user.
- Alternatively, if you choose to use the field level/page-level security feature in Ennov InSight , you can associate these users with a role and assign security privileges to the role.
- Ennov InSight does not support a domain user having membership in a group of a different domain.

Security Privileges for Users or Groups

Security privileges assigned to individual users or a groups of users are used to manage the user accounts and group assignments.

The levels of security privileges that you can assign to individual users or a group of users are:

- Enabling and disabling users
- License modules
- Access rights
- Product family/product rights
- Application country rights
- Entity security
- Home page access
- Functional security
- Field-level/page-level security

You manage user accounts, passwords, and group assignments through your Identity Provider (IdP) server, rather than in Ennov InSight . However, you assign Ennov InSight privileges to an IdP users and groups by adding them to the Users/Groups page in security administration. In addition, you assign privileges to roles using security administration.

The following sections describe the procedures you should use to add users and groups and specify security privileges.

Note: When you change an IdP settings and restart the server, e-mail addresses may become unavailable in Concerned Parties attributes and Notifications; the list of available e-mail addresses will be empty. This happens because the users that existed before you change the IdP settings have not been resynchronized with an IdP. If you change an IdP, you must synchronize these changes before the e-mail list will be updated.

Enabling and Disabling User Privileges

Enabling or disabling user security privileges determines user access to the Ennov InSight system. User privileges can be enabled or disabled as follows:

User Privilege Detail	Description
Enabled	The user is able to log on to Ennov InSight .
Disabled / as of	The user cannot log on to Ennov InSight as of the date specified. Users cannot be deleted from the system after they have been assigned privileges or logged on. However, their account can be disabled. A user with an account set to be disabled as of a future date can log on until that date.

Access Rights

Your license contract for Ennov InSight determines the number of read, write, and admin licenses you may assign for each module. If you are assigning privileges to a group of users, the number of licenses you use is the same as the number of users in that group. You cannot exceed the privileges indicated by your license. Access rights cannot be assigned unless at least one module license is set to Read. The following table describes the access rights.

Access	Description
None	Users cannot view restricted entities.
Read	Users have view privileges only.
Write	Users have Read privileges plus create and modify privileges.
Admin	Users have Write privileges plus delete and override privileges. For Documentum, an admin user must have the Write privilege on repository root. The Ennov InSight Admin user also needs to have System Administrator privileges assigned in Documentum.

Manage User Access Rights

Manage user access by setting rights consistently.

Ennov InSight offers several methods for controlling user access. Using a consistent approach will ensure that the right users have access to the information they need and no more.

An example of defining user access inconsistently:

1. Under Product Family/Product Rights, the user access to a product family is provided.
2. Under Application Country Rights, the user access to applications is provided .
3. Under Product Family/Product Rights, the user access to the product family is removed.

In this case, the user cannot see the product family in the product family tree, but can still edit applications on application pages.

Product Family/Product Rights

Provide record-level security permissions with the Product Family/Product rights.

Record-level security permissions allow access to a specific product family first followed by access to an application and other elements. Enabling product family/product rights allows you to view events, registrations, tasks, references, notifications, sequences, sequence assemblies, and product detail sets associated with the specified product family and its products. This applies to all views as well as querying.

To ensure privileges are applied correctly for a user, first select and save the license module security settings, then choose the other security settings (product family/product, application country, entity security, and so on).

Important: Duplicate or conflicting product family permissions should not be defined when creating security permissions for users or groups as it may cause security conflicts for a user when they access the application. For example, if write access for a product family is enabled to a user or a group, that same product family should not be added again. The security screen as it is currently implemented does not prevent this.

Make sure that you define security for a user consistently throughout Security Administration. Defining security inconsistently does not produce the required results .

Product Family/Product Rights Options

The Product Family/Product Rights dialog box provides options for assigning user privileges for record-level access.

The following table describes the options in the Product Family/Product Rights dialog box.

Option	Description
All	Grants the user access to all product families and their products. Users who can create product families (Data Administration set to Yes) should be assigned All privileges. Otherwise, a user may be able to create product families he or she cannot view. If you do not select All, every new product family must be individually assigned for that user. The potential for an error restricting the number of security permission can occur. Note: <i>When you have a large number of individual Product Family/Product security permissions set up in the system, Ennov InSight may issue an error message or a warning that too many product families are selected when you attempt to add a new group or user. To work around this issue, create more than one Product Family/Product security entry and split the product family permissions among them. In many cases, splitting the permissions between two entries is sufficient.</i>
Selected	Grants the user access to only the product families you choose in the selection box and their products. For example, a user can be granted Read access to one set of product families and Write access to another set of product families.
Access Level	Indicates the access level for the selected product families and their products. – None - prohibits access – Read - view privileges only – Write - Read privileges plus create and modify privileges – Admin - Write privileges plus delete privilege

Product Families and the Default Administrative User

The default user in Ennov InSight is an administrative user

As an administrative user, you can: add users, groups and roles; assign and modify user security privileges; create product families. However, by default, the administrative user cannot view the product families that he or she creates. You must enable the administrative user to view the product families.

Application Country Rights

For each product family that a user can access, the Application Country Rights dialog box enables an administrator to grant the user access to the specific countries associated with those product families.

Note: To ensure user privileges are applied correctly, first select and save the license module security settings, then choose the other security settings, such as: product family/product, application country, and entity security.

– For CP (Centralized Procedure) applications, users must have access to the individual rapporteur or corapporteur country, or any one of the application countries, to view the application.

– For MRP (Mutual Recognition Procedure) type applications, users who have access to a country that is either a CMS (concerned member state) or an RMS (reference member state) can see that application, all associated sequences, and other information.

Application Country Rights Attributes

The *Application Country Rights* dialog box enables an administrator to grant users access to the specific countries. The Application Country Rights attributes provide permissions to users.

The table describes the attributes of the *Application Country Rights* option.

Option	Description
Product Families - All	Applies the country rights you specify in the <i>Countries</i> box to all product families and the products to which a user has access. If you do not select All, countries must be individually assigned to every new product family. Users who can create product families (Data Administration set to Yes) should be granted All privileges. Else, users will be able to create product families but they will not be able to view them.

Option	Description
Product Families - Select	Applies the country rights you specify in the <i>Countries</i> box to only the product families you choose in the selection box. – To create and use an application without products and product families, only NOT DEFINED must be set for Application Country Rights. In this case, product families are not selected and any option can be selected for Countries. – If the Product Families are NOT DEFINED, a product cannot be assigned to an application and the Application icon will not be available on the <i>Product Family Attributes</i> page.
Countries - All	Grants user access to all countries associated with the product families chosen in the <i>Product Families</i> box.
Countries - Select	Grants the user access to only the countries you choose in the selection box.
Access Level	Indicates the access level for the selected product families and their products. – None- denied access. – Read - view privileges only. – Write - read access with create and change privileges. – Admin - write access with delete privileges.

Entity Security Options

In the Entity Security section in System Administration, the entities that are available depend on the license modules available to the user. For example, if you give a user write privileges for the Submission Planning and Tracking (SPT) module, only the functions associated with the SPT module are available.

The Entity Security options in Security Administration enable an administrator to assign the appropriate privileges for access to entities that are required for a user. The following table describes the available entity security privilege options.

Privilege	Description
None	Prohibits access.
Read	View privileges only.
Write	Read, create, and modify privileges. Can also delete product families and applications if there are no subordinate entities.
Admin	Write plus delete privileges.

Ennov InSight License Modules by Feature

The following tables list Ennov InSight features and the license modules in which they are available.

Product Families, Clinical Trial Shared Data

Subfeature	Subfeature Description	License Modules
Product family categorization	Define parent active substance family.	– Electronic Lifecycle Publishing – Paper Review Publishing – Product Detail Management – Registered Document Analysis – Registration Planning and Tracking – Submission Planning and Tracking
Product family extended attributes	Full support includes product family attributes.	– Registration Planning and Tracking – Product Detail Management
CT Shared Data	Clinical Trial Shared Data for a product family.	– Registration Planning and Tracking – Product Detail Management

Products, Pharmaceutical Products

Subfeature	Subfeature Description	License Modules
Product detail	Define consumable products (Example: dosage forms).	– Registration Planning and Tracking – Product Detail Management – Submission Planning & Tracking – Electronic Lifecycle Publishing – Paper Review Publishing
Pharmaceutical product detail	Define a product used to treat disease (Example: medicines or drugs).	– Registration Planning and Tracking – Product Detail Management – Submission Planning & Tracking Electronic Lifecycle Publishing – Paper Review Publishing

Registrations, Full Product Presentations, Registration FPP Attachments and FPP Previous EV Codes

Subfeature	Subfeature Description	License Modules
Registration detail	Define registration details, including those that vary by country for MRP applications.	– Registration Planning and Tracking – Product Detail Management
Subfeature	Subfeature Description	License Modules
Copy Package Set Registration	Copy a package set registration. Requires at least Write permissions for the Registrations and Full Product Presentation (FPP) (applicable to the <i>New Package Set specific Registration(s)</i> flow) in the Entity Security section.	– Registration Planning and Tracking – Product Detail Management
Full product presentation detail	Define detailed information about the product (Example: Special Measures, Product Strength).	– Registration Planning and Tracking – Product Detail Management
FPP previous EV code detail	Define the previous EV code for the full product presentation.	– Registration Planning and Tracking – Product Detail Management
Registration FPP attachment detail	Presents an attachment for the detailed product information.	– Registration Planning and Tracking – Product Detail Management
Copy full product presentation	Copy a full product presentation under the same registration, or under different registrations. At least Write permissions for the Full Product Presentation (FPP) in Entity Security section.	– Registration Planning and Tracking – Product Detail Management

Registration Attachment

Subfeature	Subfeature Description	License Modules
Registration Attachment	Registration Attachment entity is a Printed Product Information (PPI) attachment type and should be created to later attach it to the Full Product Presentation.	– Registration Planning and Tracking – Product Detail Management
Copy registration attachment	Copy a registration attachment. – At least Write permissions for the Registration Attachment in Entity Security section. – At least Write permissions for the Full Product Presentation (FPP) in Entity Security section.	– Registration Planning and Tracking – Product Detail Management

Medicinal Products, Medicinal Product Actions, Data Visualization

Subfeature	Subfeature Description	License Modules
Medicinal Product detail	Medicinal product for registration. At least Write permissions for the Medicinal Product in Entity Security section.	– Registration Planning and Tracking – Product Detail Management
Medicinal Product Action detail	Medicinal product action for registration. At least Write permissions for the Medicinal Product Action in Entity Security section.	– Registration Planning and Tracking – Product Detail Management
IDMP Data Generation wizard	Access to the IDMP Data Generation wizard from the wizards menu with the Write permissions.	IDMP
IDMP Data Visualization	Access to the IDMP Data Visualization from on the Medicinal Product Action Attributes menu with Write permissions.	IDMP

xEVMPD Wizards and Queries

Subfeature	Subfeature Description	License Modules
XEVMPPD Submission wizard	Access to the XEVMPPD Submission wizard from the wizards menu and Home page with Write permissions.	xEVMPPD
XEVMPPD Acknowledgement wizard	Access to XEVMPPD Acknowledgement wizard from the wizards menu and Home page with Write permissions.	xEVMPPD
Queries	Access to the following Registration Planning and Tracking queries with Read and Write permissions: – XEVMPPD Submissions - QC Verification and Audit – XEVMPPD Submissions and Acknowledgements	xEVMPPD

Applications

Subfeature	Subfeature Description	License Modules
Application detail	Ability to define overall marketing authorization (Example: NDA).	– Electronic Lifecycle Publishing – Paper Review Publishing – Product Detail Management – Registered Document Analysis – Registration Planning and Tracking – Submission Planning and Tracking
Application Countries tab	Support for European procedures (MRP and CP) including collection of countryspecific data (primarily dates) for the application.	– Electronic Lifecycle Publishing – Paper Review Publishing – Product Detail Management – Submission Planning and Tracking – – Registration Planning and Tracking

Copy application	Copy an application.	– Registration Planning and Tracking – Product Detail Management
Create Application Wizard	Access to the Create Application Wizard from the wizards menu with the Write permissions. Access to Events for the Create Application Wizard from the wizards menu with the Write permissions.	– Electronic Lifecycle Publishing – Submission Planning and Tracking

Comparators

Subfeature	Subfeature Description	License Modules
Comparators	Comparators are used in clinical trials to compare the success of a medicine under study to another medicine or placebo.	– Registration Planning and Tracking – Product Detail Management

Events

Subfeature	Subfeature Description	License Modules
Event detail	Define initial filing event and other major updates (Example: variations) to an application.	– Electronic Lifecycle Publishing – Paper Review Publishing – Product Detail Management – Registered Document Analysis – Registration Planning and Tracking – Submission Planning and Tracking
Copy Event Wizard	Copy an event to multiple applications in the product family associated with a source event.	– Electronic Lifecycle Publishing – Product Detail Management – Registration Planning and Tracking – Submission Planning and Tracking

Create Submission wizard	Automates creation of initial applications, major updates and amendments.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Registration Planning and Tracking – Submission Planning and Tracking
Event country status schedule	Define projected event status dates, track status history, and compare actual and planned dates for major milestones.	– Registration Planning and Tracking – Submission Planning and Tracking

Sequences

Subfeature	Subfeature Description	License Modules
Sequence detail	Define filings/amendments (regulatory submission correspondence to authorities in support of an application).	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Registration Planning and Tracking – Submission Planning and Tracking
Sequence status schedule	Define projected sequence status dates, track status history, and compare actual and planned dates for major milestones.	– Registration Planning and Tracking – Submission Planning and Tracking

Product Detail Sets (PDS)

Subfeature	Subfeature Description	License Modules
Product detail set detail	Capture product detail approvals, such as for substance, product, packaging manufacturers, labeling, and product indications.	– Registration Planning and Tracking – Product Detail Management
PDS templates	Save PDS information within a product family as a template.	– Registration Planning and Tracking – Product Detail Management

Assembly Types

Subfeature	Subfeature Description	License Modules
Lifecycle sequence assemblies	Build hierarchical collections of source documents associated with specific regulatory activities and sequences, and add to the current view for lifecycle.	– Electronic Lifecycle Publishing – Registered Document Analysis – Submission Planning and Tracking
Supporting sequence assemblies	Build hierarchical collections of source documents associated with specific regulatory activities and sequences.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
Standalone assemblies	Build hierarchical collections of source documents for miscellaneous use.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
Assembly templates	Build an assembly template.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking

Activity Workflow

Subfeature	Subfeature Description	License Modules
Activities	Activities are steps within the Workflow that are required to complete the assigned Workflow. Workflows can contain multiple Activities, with dependencies and pre-set values.	Ennov InSight Workflow Integrations

Projects

Subfeature	Subfeature Description	License Modules
Global Project Planning (GPP) wizard	Facilitates planning and data entry for multiple countries or applications. At least Write privileges for Projects and Events. Home page access security enabled for GPP wizard.	– Registration Planning and Tracking – Submission Planning and Tracking

Tasks, Notifications, and References

Subfeature	Subfeature Description	License Modules
Task detail	Define hierarchical to-do lists associated with other entities.	– Registration Planning and Tracking – Submission Planning and Tracking
Task status schedule	Define the sequence of statuses for a task, and for each status, the projected date when the task first has the status.	– Registration Planning and Tracking – Submission Planning and Tracking
Notification detail	Define and automatically send e-mail notifications based on data updates, approvals, and other changes in Ennov InSight .	– Registration Planning and Tracking – Submission Planning and Tracking
Reference detail	Associate external documents, URLs, and internal links with entities; supports correspondence and DMS integration.	– Registration Planning and Tracking – Submission Planning and Tracking

Change, Change Details

Subfeature	Subfeature Description	License Modules
Change	Defines the actual regulatory change being planned or requested and have specific metadata associated.	Registration Planning and Tracking
Change details	Capture details of the Change as a subentity to the Change entity.	Registration Planning and Tracking

Reports

The reports listed in the table include the reports that you can generate by using Ennov InSight queries.

Subfeature	Subfeature Description	License Modules
Querying menu	Run queries and quick search; not all quick search entities may apply to the module; available queries vary by module.	The modules related to the kind of query that you run
Public/private customized queries	Create both private and public custom queries.	– Electronic Lifecycle Publishing – Paper Review Publishing – Product Detail Management – Registered Document Analysis – Registration Planning and Tracking – Submission Planning and Tracking
Ad hoc Reporting	Create and execute ad hoc reports against the Ennov InSight reporting schema.	– Product Detail Management – Registered Document Analysis – Registration Planning and Tracking – Submission Planning and Tracking
Specialized assembly queries	Execute specialized queries directly from the assembly tree.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
Application, Event, Sequence report	Provides information that you select about product families, applications, events, and sequences.	– Registration Planning and Tracking – Submission Planning and Tracking

Approval Management

Subfeature	Subfeature Description	License Modules
Approved views	Create and view document collections consisting of currently approved versions for a particular country. Full support includes the ability to create new assemblies from these views.	Registered Document Analysis

Update Status wizard	Automate approval of an application or major update.	– Registered Document Analysis – Registration Planning and Tracking – Submission Planning and Tracking

Submittal Management and Lifecycle

Subfeature	Subfeature Description	License Modules
Submitted view	Create and view document collections consisting of currently submitted versions for a particular country. Create and manage eCTD lifecycles. Full support includes ability to create new assemblies from these views.	– Electronic Lifecycle Publishing – Registered Document Analysis – Submission Planning and Tracking (does not enable you to create new assemblies)
Change Submittal Status wizard	Automate submittal of an application or major update and creation of lifecycle.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
Add to/remove from lifecycle	Manually create and manage lifecycle	– Electronic Lifecycle Publishing – Registered Document Analysis
Working view	Assign changes and leaf operations from a cumulative view of eCTD submission sequences.	– Electronic Lifecycle Publishing – Registered Document Analysis – Submission Planning and Tracking
Sequence view	View the current cumulative sequence.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
Publishing view	Publish the current cumulative sequence and add publishing effects.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis - Submission Planning and Tracking

General Assembly

Subfeature	Subfeature Description	License Modules
General assembly features and functions	Expand/collapse all, edit hierarchical assembly structure (including lifecycle actions, if applicable), browse or search document repositories and assign documents, retrieve document properties from DMS, view DMS documents, modify assembly attributes, delete assemblies.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
Subfeature	Subfeature Description	License Modules
Import/export	Create an assembly from a template, XML assembly file, or VDM. Export assemblies to XML assembly files and VDMs.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
Document placeholders	Create a planned document in the assembly.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
Mass apply version bindings	Incrementally set bindings across the assembly, including locking the binding to the current version.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
View file from document and leaf	Viewing in-place repository, submission, and published content.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking

Document status awareness	Binding icons and View Document List query.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Submission Planning and Tracking
Support and assignment of unfinalized documents	View status of unfinished documents for assembly.	Submission Planning and Tracking

Planning and Tracking

Subfeature	Subfeature Description	License Modules
Planning and tracking assembly features and functions	Edit document path and binding information, view/assign related documents, export assembly to Microsoft Excel.	Submission Planning and Tracking
Assembly search and replace	Search and replace text in assembly element attributes for planning and creating templates of document locations and assignments.	Submission Planning and Tracking
Subfeature	Subfeature Description	License Modules
Assembly Status query	Provides the current assembly status including performance metrics.	Submission Planning and Tracking

Review and Approval

Subfeature	Subfeature Description	License Modules
Review and approval assembly features and functions	Version assemblies with assembly currency.	Submission Planning and Tracking
Incremental locking	Incrementally lock assembly by module and by section or folder hierarchy.	Submission Planning and Tracking

Assembly baselines and baseline querying	Create baselines for assembly comparison querying.	Submission Planning and Tracking
Assembly reference location	Create and set reference locations and synchronize with DMS.	Submission Planning and Tracking
Assembly status change	Change status of assembly including automatic lock down if assembly is finalized.	Submission Planning and Tracking
Unlock the folder	Unlock the locked assembly folder.	Submission Planning and Tracking

Document Analysis

Subfeature	Subfeature Description	License Modules
Document analysis features and functions	Create approved views, query and view registered documents, query and view lifecycle history.	Registered Document Analysis
Where Used query	Determine where a document is used across applications, countries, products, versions, and assemblies. The Output File hyperlink in the Where Used query is supported only for sequence assemblies, not standalone and template assemblies.	– Registered Document Analysis – Submission Planning and Tracking

General Publishing

Subfeature	Subfeature Description	License Modules
Publishing job queue and audit trail	View the status of all publishing jobs; sort, export, and cancel jobs.	– Electronic Lifecycle Publishing – Paper Review Publishing
Publishing Readiness query, Summary query, Link Inspector, and publishing log	View eCTD conformity and status before and after the publishing job is executed.	– Electronic Lifecycle Publishing – Paper Review Publishing

Repository export utility	Transfer published output from any repository source to any repository destination (DMS or File/Folder).	– Electronic Lifecycle Publishing – Paper Review Publishing
Automatic extractions	Create document extractions for use in bookmarks, TOCs, and links automatically upon assignment.	– Electronic Lifecycle Publishing – Paper Review Publishing (with Ennov InSight Rendering only)
Automatic renditions	Create PDF renditions automatically and by request upon publishing or Prepare to Publish when existing renditions are missing or outdated. Requires an additional license for Ennov InSight Rendering.	– Electronic Lifecycle Publishing – Paper Review Publishing (with Ennov InSight Rendering only)

eCTD Publishing

Subfeature	Subfeature Description	License Modules
eCTD publishing assembly features and functions	Create eCTD and electronic output, specify assembly-level publishing options for eCTD, links, and variables, change element types to specify leafspecific publishing properties, request generated published output (eCTD and electronic).	Electronic Lifecycle Publishing
Electronic hyperlinks	Create, retarget, and set channel and settings on hyperlinks.	– Electronic Lifecycle Publishing – Paper Review Publishing
Reference leaf elements	Create leaf elements to reference other leaf elements with querying on referenced leaf elements for a specific submission.	– Electronic Lifecycle Publishing – Registered Document Analysis (query only)
Subfeature	Subfeature Description	License Modules
eCTD import and merge	Import one or multiple eCTD sequences; merge eCTD sequences.	Electronic Lifecycle Publishing
Create eCTD wizard	Create or update an eCTD sequence.	Electronic Lifecycle Publishing

Bulk eCTD Wizard	Migrate multiple eCTD submissions to Ennov InSight from another system in a supported document management system (DMS).	Electronic Lifecycle Publishing
Create Study Reports wizard	Add study reports to an eCTD sequence.	Electronic Lifecycle Publishing
Create Submission Plan Wizard	Create a submission plan and associate entities such as applications, events, and sequences to the submission plan.	– Electronic Lifecycle Publishing – Submission Planning and Tracking

Paper Publishing

Subfeature	Subfeature Description	License Modules
Paper publishing assembly features and functions	Create paper and electronic output, specify assembly-level publishing options for publishing effects, change folder and document attributes for publishing effects, request published output (paper and electronic).	– Electronic Lifecycle Publishing – Paper Review Publishing
Table of contents	Create, edit, generate, and modify TOCs. Access the TOC editor.	– Electronic Lifecycle Publishing – Paper Review Publishing
Special sheets	Create, edit, generate, and modify special sheets including slip sheets, tabs, and cover pages.	Paper Review Publishing
Volumes	Create and modify volumes, bulk volumize, move, lock, and manipulate volumes.	Paper Review Publishing
Overlays	Define and use overlays. Define page size, shape, scaling, and format for output.	Paper Review Publishing
Paper crossreferences	Create, retarget, and set channel, stamp, and settings on paper crossreferences.	Paper Review Publishing

Administration

Subfeature	Subfeature Description	License Modules
Administration menus (Data, Security and Technical)	Modify data picklists, connect to and define DMS and file system repositories, administer security. Not all options displayed to an administrator are available in all modules. Example: picklist options for data admin may not be displayed in an application. Notification administration does not apply to all modules. Includes all audit trail querying.	– Electronic Lifecycle Publishing – Paper Review Publishing – Registered Document Analysis – Registration Planning and Tracking – Product Detail Management – Submission Planning and Tracking

Home Page Access

The functions and elements that are available to users on the *Home Page* depend on the license modules selected and the Home Page Access settings in System Administration. For example, if you give a user write privileges for the Submission Planning and Tracking (SPT) module, only the elements associated with the SPT module are available.

Yes enables a user to access specific tabs and menu commands on the home page. For example, if Applications is set to Yes, the user can view the Applications tab. In addition, the Applications command appears on the New menu.

The applications that are displayed are further restricted by product family/product rights and application country rights.

Home page access options also include administration access. If you choose Yes for Security Administration, Data Administration, and Technical Administration, these commands are available on the home page and the user is able to perform administration activities.

Home Page Access Settings

In *Security Administration*, the Home Page Access settings enable an administrator to grant users access to functionality on the home page, subject to the license modules available to the user.

The availability of wizards and other options on the home page is determined by the license modules to which the user has access and whether you choose Yes or No to the wizards under Home Page Access. Wizard access is not affected by the product family/product and application country rights assigned to a user. Therefore, even though a user may have only Read privileges for product family/products and application countries, if you choose Yes for the wizard options, the wizard commands are available to the user on the home page.

If the default [Select] is set it denies permission and equals None.

Security Defaults for Home Page Access

In the following table, each permission can be changed only if any of the listed modules is installed and licensed. If the Selected Module Permission is set to Read, all elements are limited to Read.

Permission	License Modules
Create Submission Wizard	– Registration Planning & Tracking – Submission Planning & Tracking – Electronic Lifecycle Publishing – Paper Review Publishing
Create Submission Plan Wizard	– Electronic Lifecycle Publishing Submission Planning & Tracking
Create eCTD Wizard	Electronic Lifecycle Publishing
Import eCTD	Electronic Lifecycle Publishing
Bulk Import eCTD Wizard	Electronic Lifecycle Publishing
Change Wizard	Registration Planning & Tracking
Change Submittal Status Wizard	– Registration Planning & Tracking – Submission Planning & Tracking – Electronic Lifecycle Publishing – Paper Review Publishing
Event Copy Wizard	– Registration Planning & Tracking – Product Detail Management – Submission Planning & Tracking – Electronic Lifecycle Publishing
Global Project Planning Wizard	– Registration Planning & Tracking – Submission Planning & Tracking
Update Applications Wizard	– Registration Planning & Tracking – Submission Planning & Tracking
XEVMPD Wizards	– Registration Planning & Tracking – Product Detail Management

Permission	License Modules
Product Families	– Registration Planning & Tracking – Product Detail Management – Submission Planning & Tracking – Electronic Lifecycle Publishing – Paper Review Publishing
Applications	– Registration Planning & Tracking – Product Detail Management – Submission Planning & Tracking – Registered Document Analysis – Electronic Lifecycle Publishing – Paper Review Publishing
Events	– Registration Planning & Tracking – Product Detail Management – Submission Planning & Tracking – Registered Document Analysis – Electronic Lifecycle Publishing – Paper Review Publishing
Sequences	– Registration Planning & Tracking – Submission Planning & Tracking – Registered Document Analysis – Electronic Lifecycle Publishing – Paper Review Publishing
Submission Plans	– Submission Planning & Tracking – Electronic Lifecycle Publishing

Publishing Settings Library Template	– Electronic Lifecycle Publishing – Paper Review Publishing
Views	– Submission Planning & Tracking – Registered Document Analysis – Electronic Lifecycle Publishing – Paper Review Publishing
Registrations	– Registration Planning & Tracking – Product Detail Management

Permission	License Modules
Medicinal Products	– Registration Planning & Tracking – Product Detail Management
Medicinal Products Actions	– Registration Planning & Tracking – Product Detail Management
Registration Attachments	– Registration Planning & Tracking – Product Detail Management
Full Product Presentations	– Registration Planning & Tracking – Product Detail Management
Projects	– Registration Planning & Tracking – Submission Planning & Tracking
Comparators	– Registration Planning & Tracking – Submission Planning & Tracking
PDS Templates	Product Detail Management

PDS	Product Detail Management
Tasks	– Registration Planning & Tracking – Submission Planning & Tracking – Registered Document Analysis
System Alert	Any InSight Module
Alert Center	Any InSight Module
References	– Registration Planning & Tracking – Submission Planning & Tracking
Notifications	– Registration Planning & Tracking – Submission Planning & Tracking
Assembly Templates	– Submission Planning & Tracking – Registered Document Analysis – Electronic Lifecycle Publishing – Paper Review Publishing

Permission	License Modules
Standalone Assemblies	– Submission Planning & Tracking – Registered Document Analysis – Electronic Lifecycle Publishing – Paper Review Publishing
Quick Search	– Registration Planning & Tracking – Product Detail Management – Submission Planning & Tracking – Registered Document Analysis – Electronic Lifecycle Publishing – Paper Review Publishing

Querying Menu	– Registration Planning & Tracking – Product Detail Management – Submission Planning & Tracking – Registered Document Analysis – Electronic Lifecycle Publishing – Paper Review Publishing
Job Requests	– Registration Planning & Tracking – Product Detail Management – Submission Planning & Tracking – Electronic Lifecycle Publishing – Paper Review Publishing
Security Administration	– Registration Planning & Tracking – Product Detail Management – Submission Planning & Tracking – Registered Document Analysis – Electronic Lifecycle Publishing – Paper Review Publishing
Data Administration	– Registration Planning & Tracking – Product Detail Management – Submission Planning & Tracking – Registered Document Analysis – Electronic Lifecycle Publishing – Paper Review Publishing

Permission	License Modules
Technical Administration	– Registration Planning & Tracking – Product Detail Management – Submission Planning & Tracking – Registered Document Analysis – Electronic Lifecycle Publishing – Paper Review Publishing
Workflow Administration	Ennov InSight Workflow Integrations
Find Activities	Ennov InSight Workflow Integrations

Functional Security

In Security Administration, the Functional Security settings enable an administrator to grant access to users for functionality in the system, subject to their available license modules.

The following table describes the functional security on the *Privilege Detail* page.

Assembly function	Description
Planning and Tracking	Grants access to specific Submission Planning and Tracking activities (for example, grants access to creating a new assembly from a view, modifying an assembly, using the Create Submission wizard). Planning and tracking also determines the availability of the event, sequence and task status schedule activities.
Review and Approval	Grants access to specific Submission Planning and Tracking activities (for example, dragging and dropping documents from CoreDossier to an assembly, modifying an assembly, creating an assembly version).
eCTD Publishing	Grants access to specific Electronic Lifecycle Publishing activities (for example, deleting an assembly, copying an assembly URL, assigning documents), and enables publishing requests from the assembly. Allows export of publishing output to the file system or document management system (DMS).
Document Analysis	Grants access to specific Registered Document Analysis activities (for example, creating and removing an approved view, modifying an assembly, DMS synchronization, monitoring the View tab for submitted and approved sequences, and querying).

Assembly Status Change	This icon  on the Assembly Attributes page provides the ability to change the status or to lock the assembly with read access only.
Create Missing Renditions and Extractions	Enables you to create missing renditions and extractions.
Assembly function	Description
Force New Renditions and Extractions	Enables you to create new renditions and extractions and overwrite the existing ones.
Paper publishing	Enables you to generate volumes and files when submitting a publishing request, to generate table of contents (TOC) and special sheets when preparing to publish, and to specify TOCs, general/paper, overlays, special sheets, variables, and volume publishing settings from the general publication settings pages.
Volume Modification	Not currently used
Table of Contents Creation	Not currently used
Cross-reference tools	Makes available all cross-reference/linking tools (Link Inspector query, InProcess Renditions). Effects the cross-reference tools only, no other functional security selections depend on cross-reference tools or need to be added. All links are processed as normal in each file. This selection controls only access to various tools such as link inspector querying, access to edit and create preflight renditions through the interface, access or operation of selections in prepare for publishing and access to modify links in the link query.

Assembly Functions and License Modules

The assembly functions that are available depend on the license modules available to the user:

Functional Security	License Module
Planning and Tracking	Submission Planning and Tracking
Review and approval	Submission Planning and Tracking

eCTD publishing	– Registered Document Analysis – Electronic Lifecycle Publishing
Document analysis	Registered Document Analysis
Assembly status change	– Registered Document Analysis – Electronic Lifecycle Publishing – Paper Review Publishing
Create Missing Renditions and Extractions	– Registered Document Analysis – Electronic Lifecycle Publishing – Paper Review Publishing
Functional Security	License Module
Force New Renditions and Extractions	– Registered Document Analysis – Electronic Lifecycle Publishing – Paper Review Publishing
Paper publishing	Paper Review Publishing
Cross-reference tools	– Electronic Lifecycle Publishing – Paper Review Publishing

Field-Level/Page-Level Security

Field level/page level security is an optional Ennov InSight function. You can create roles in the system that enable you to assign field-level/page-level security. Each role has a set of fields that can be defined as read-only, modifiable or hidden for each page on which these fields reside.

Ennov InSight provides three XML-mapped roles: user, liquent_role1, and liquent_role2. When you create a role, you associate it with one of the XML-mapped roles available. Users and groups assigned to the role you create have access to fields as defined by the role. Field-level/page-level security applies to the following Ennov InSight entities: – Product Families

- Products
- Applications

– Registrations

Note: For each role, each field on these entity pages is defined as read-only, modifiable, or hidden.

Users associated with `liquent_role1` and `liquent_role2` have the ability to create product families. While it is best practice is to not give `liquent_role1` or `liquent_role2` users data administration access, you can add the following empty field group to `liquent_role1` and `liquent_role2` in the `meta.overrides.xml` to prevent members of these roles from creating product families:

```
<fieldGroup name="adminCreateFieldGroup"/>
```

Please note, if the overrides file is modified to use this fieldGroup, a harmless `MetaException` error will occur.

Ennov InSight ships with three roles. However, there is no limit to the number of roles you can define. Contact your Account Executive to consult with our Client Enablement team for information about defining and configuring field-level security for your system.

If you do not use field-level security, the following apply:

- Users/groups with the appropriate security privileges are able to view all attributes associated with the product family, product, application and registration entities.
- Users/groups with the appropriate security privileges are able to create and modify product family, product, application and registration entities.

View Users and Groups

To view Users and Groups for configured Identity Providers (IdP):

1. Select Go To > Security Administration.
2. On the Security Administration page, click Users and Groups.

The *Security Administration* page lists all the users and groups along with the Identity Provider Name information.

Modifying a User or Group

In Security Administration, an administrator can modify user or group privileges in the application to disable, remove, re-associate or change the privileges.

In Security Administration, an administrator can modify user or group privileges in the application to disable, remove, re-associate or change the privileges.

To modify a user or group:

1. Choose Go To > Security Administration.

The *Security Administration* page opens listing all the users and groups.

2. Click the link for the user or group you want to modify.

The *Privilege Detail* page for the user or group opens.

3. Do any of the following:

- To disable the user/group, choose Disable as of and enter the date when the user/group should no longer be able to log into Ennov InSight . If you do not specify a date, the user/group will remain enabled.
- To remove a user from a group, click Disassociate User from the Group, then change the privileges for the user. The User Type for an overridden user on the *Privilege Detail* page is STANDALONE.

Note: *If the user does not belong to an IdP group and you click Disassociate User from the Group, the field-level/page-level security assigned to the role with which the user is associated is retained unless you specifically move the user to a different role.*

- Click Re-associate User with the Group to replace the user's privileges with those defined for the IdP group.

Note: *Before you reassociate a user with a group, remove the user from any roles with which he or she has been associated.*

- Change the security privileges for the user/group.

4. Click Save when you are finished.

Assign User or Group Security Privileges

In Security Administration, an administrator can assign security privileges for users or groups on the Privilege Detail page.

To assign security privileges for users or groups:

1. Choose Go To > Security Administration.

The *Security Administration* page opens listing all the users and groups.

2. Click the link for the user or group for which you want to assign privileges. The *Privilege Detail* page for the user or group opens.
3. On the *Privilege Detail* page, specify the access rights for the license modules.

After setting the access rights for a license module, wait for the page to refresh. The entity, home page access and functional security options associated with the module become available. After the page refreshes, you may define access rights for another license module.

4. Click Save.

The license module options you chose are not saved until you click the Save.

5. Under Entity Security, click the arrow for each entity you want to grant the user/group access to and set the access level to grant.
6. Click Save.

7. Click **Product Family/Products Rights > Add.**

The *Product Family/Product Rights* dialog box opens.

8. Do one of the following in the *Product Family/Product Rights* dialog box:

Option	Description
All	Give the user/group access to all product families.
Select	Select the specific product families the user/group can access. When using Select, you must return to this page to give the user/group access to any product families that are added later.

9. Click the Access Level arrow and choose the appropriate access level.
10. Click Save.
11. On the *Privilege Detail* page, click Add under Application Country Rights.
12. In the *Application Country Rights* dialog box under Product Families, do one of the following:

Option	Description
All	Give the user/group the same application country access to all product families.
Select	Select the specific product families to which the user/group has application country access. When using Select, you must return to this page to give the user/group access to any product families that are added later.

13. In the *Application Country Rights* dialog box under Countries, do one of the following:

Option	Description
All	Give the user/group the same access to all countries for the product families specified in this step.
Select	Select the specific countries for the selected product families specified under Product Families. When using Select, you must return to this page to give the user/group access to any countries that are added later.

Note: To configure a user with Read access level to all Application Countries and with Write access to some Application

Countries, you must follow a specific order: first add the Write access for the specific Application Countries, and then

(using the Add button) add the Read access to All. If you find that you cannot modify this setting, delete the user permission and perform this procedure to configure the permission/access for the user.

14. Click the Access Level arrow and choose the appropriate access level.
15. Click Save.

Note: If you are giving the user/group different access levels to different product families, you must repeat steps 9-12 for all the product family/application country combinations.

16. Under Function Security, choose whether the user/group can access the following: — Functions on the home page

— Assembly functions

17. Click Save.

Create a Role

The system allows the creation of multiple roles with the same display name. However, this does not affect the behavior of the functionality. To avoid any confusion, it is recommended to give a unique display name to every role created in Ennov InSight .

Note: If you want to use the field-level/page-level security feature in Ennov InSight , you must create a role.

To create a role:

1. Choose Go To > Security Administration.

The *Security Administration* page opens listing all the users and groups.

2. On the *Security Administration* page, click .
3. On the *Create Role* wizard window, enter a name for the role in the *Display Name* box.
4. Click the XML-mapped Role arrow and choose the XML mapped role to associate with this role.
5. Choose users and/or groups from the *Users/Groups Available* box and move them to the *Selected* box to associate them with the role.
6. The list of available users is limited to the following: overridden users, users who do not belong to any IdP group, users who have been added to Ennov InSight , and who do not already belong to a role.
7. The list of available groups includes groups that have been added to Ennov InSight and who do not already belong to a role.
8. Click Next. The wizard confirms the creation of the role.
9. Click Finish.
10. Repeat steps 2 through 7 for each role you need to create.

Associate Users or Groups to a Role

Associating users or groups with a role provides those users or groups with the privileges assigned to the role in the system.

To associate users or groups to a role:

1. Choose Go To > Security Administration.

The *Security Administration* page opens listing all the users and groups.

2. On the *Security Administration* page, choose the role from the list.

The *Privilege Detail for role* page opens.

3. To associate users or groups to the role, select users or groups in the Available box and move them to the *Selected* box.
4. Click Save.

Disassociate Users or Groups from a Role

Users and groups can belong to only one role in Ennov InSight To

disassociate users/groups from a role:

1. Choose Go To > Security Administration.

The *Security Administration* page opens listing all the users and groups.

2. On the *Security Administration* page, choose the role from the list.

The *Privilege Detail for role* page opens.

3. To disassociate users/groups from the role, select the users/groups in the Selected box and move them to the Available box.
4. Click Save.

Security Privileges for Roles

Security privileges can be assigned to a role.

However, the security settings defined for a role are not applicable to the overridden users or groups assigned to the role. They apply to the users assigned to the role but have no defined security privileges.

Note: You may want to assign security privileges to a role when you want several users who are not part of an IdP group to have the same set of security privileges and field-level security in Ennov InSight .

Assign Security Privileges to a Role

In Security Administration, an administrator can assign security privileges to a role. Users and groups can then be assigned to the role.

To assign security privileges to a role:

1. Choose Go To > Security Administration.

The *Security Administration* page opens listing all users and groups.

2. On the *Security Administration* page, choose the role from the list.
3. On the Privilege Detail page, choose the license modules.

Note: Choose one module and wait for the page to refresh. The entity, functional and assembly level options associated with the module become available. Then choose another module. The license module options you chose are not saved until you click the Save button.

4. Save.
5. Under Product Family/Products Rights, click Add.
6. In the *Product Family/Product Rights* window, do one of the following:

Option	Description
All	Give the role access to all product families.
Select	Specific product families the role can access. When using Select, you must return to this page to give the user/group access to any product family/products that are added later.

7. In the *Application Country Rights* dialog box under Product Families, do one of the following:

Option	Description
All	Give the role access to the same application country to all product families.
Select	Select specific product families to which the role has application country access. When using Select, you must return to this page to give the role access to any product families that are added later.

8. In the *Application Country Rights* dialog box under Countries, do one of the following:

Option	Description
All	Give the role access to all countries for the product families specified in this step.
Select	Select the specific countries for the selected product families specified under Product Families. When using Select, you must return to this page to give the role access to any Countries that are added later.

9. Under Entity Security, click the arrow for each entity you want to grant the role access to and set the access level to grant, and then click Save.
10. Click the Access Level arrow and choose the appropriate access level.
11. Save.
12. Under Function Security, choose whether the role can access the following: – Functions on the home page
– Assembly functions
13. Save.

Disable Roles

An administrator can disable a role that is no longer used in the system.

Before disabling the role in the system, users and groups must be disassociated from the role. To

disable a role:

1. Disassociate users and groups from the role to be disabled.

Note: *If the users and groups are not disassociated, field level security will remain in effect for the users and groups still associated with the disabled role.*

2. Choose Go To > Security Administration.

The *Security Administration* page opens listing all IdP users and groups.

3. On the *Security Administration* page, choose the role from the list. The *Privilege Detail for role* page opens.
4. On the *Privilege Detail* page for the role, choose Disabled as of and enter the date when the role should be disabled.
5. Click Save.

Enable the Default Administrative User for Product Families

The access level for any users, including administrators, must be enabled to access or view product families.

To enable the default administrative user:

1. On the home page, choose Go To > Security Administration.
2. On the *Users/Group* page, choose the default admin user.
3. Click Disassociate User from the Group, if necessary.
4. Click OK in the dialog box that appears.

You can ignore any warnings that appear during this process.

5. Under Product Family/Product Rights, click Add.
6. Under Product Families, choose All.
7. Click the Access Level arrow and choose Admin.
8. Click Save to close the dialog box.
9. Under Application Country rights, click Add.
10. Under Product Families, choose All.
11. Under Countries, choose All.
12. Select Admin as the Access Level.
13. Click Save to close the dialog box.
14. Click Save to save the default admin user.

Ennov InSight License Components

The Ennov InSight components enable different organizational roles and functions within the regulatory lifecycle of a drug product. Each component focuses on one particular area of expertise and includes the ability to control access permissions within the component for specified users and groups.

By assigning access permissions to users or roles, you can enable some users to merely observe or access queries and summaries while enabling others to perform the daily operations of project management, research, planning, and publishing.

Available Components	Description
Ennov InSight Workflow Integration	Enables you to utilize client-specific workflows that contain multiple activities, with dependencies and preset fields, that guide processes within the system.
xEVMPD	Enables you to capture, maintain, and submit data about pharmaceutical products to comply with the Extended EudraVigilance Medicinal Product Database (xEVMPD) directive.
IDMP	Enables you to capture, maintain and submit medicinal product data to comply with the extended IDMP functionality.
Registration Planning and Tracking	(RPT) enables you to plan registration activities and collect registration data without product formulation details. It improves affiliate communication, enables you to track the status of overall global product registration activities, and maintain product registration compliance.
Product Detail Management	(PDM) enables you to track product formulation and SPL exports. It also provides queries about where products are registered and other registration information.
Submission Planning and Tracking	(SPT) enables you to create, review and track submissions from planning to publishing. It also automates assembly creation and enables you to monitor the authoring process.
Registered Document Analysis	(RDA) leverages lifecycle submission information to enhance the DMS repository for better decision support based on usage information. It enables you to query for the external approval status of documents and to perform impact analysis of registered document changes.
Electronic Lifecycle Publishing	(ELP) simplifies eCTD creation and is required to publish assemblies as eCTD submissions.

Available Components	Description
Paper Review Publishing	(PRP) enables you to build assemblies for publishing to paper. PRP enables you to add paper elements such as TOCs, cover pages, overlays, and cross references to electronically published submissions suitable for generating study report submissions, hybrids, and other electronic submission formats. Using both the ELP and PRP licenses enables you to add these publishing elements to eCTD lifecycle submissions. Finally, PRP also enables you to publish an entire assembly to a single file electronically.

Chapter 4. Data Administration

As a data administrator, you are responsible for setting up and maintaining the data available in selection lists in Ennov InSight .

To perform data administration maintenance, your security privileges for Data Administration must be set to Yes under Home Page Access on the *Privilege Detail for user* page (Go To > Data Administration).

The administrative functions enable you to create and maintain entity-specific data that appears in drop-down lists throughout Ennov InSight . Many of the values you set up are either active or inactive. An active value is available to choose from a drop-down list, and an inactive value is hidden from a drop-down list. One exception regarding the appearance of inactive values in drop-down lists is when inactive values are still available in the querying lists.

In addition, some values you create are considered default values. If you do not explicitly choose a value from a dropdown list, the default value is set for the attribute automatically.

Note: *Default values must be active.*

The administrative functions are divided into the following categories:

- Application Maintenance
- Assembly Maintenance
- Assembly Variable Maintenance
- Change Maintenance
- Custom Lists Maintenance
- DMS Integration Maintenance
- Event Maintenance
- Notifications Maintenance
- Other Data Maintenance
- Product Detail Set Maintenance
- Product Family Maintenance
- Product Maintenance
- Reference Maintenance
- Project Maintenance
- Registration Maintenance
- Task Maintenance

- Sequence Maintenance
- SPOR Master Lists
- Submission Maintenance
- Submission Plan Maintenance
- Workflow Management

Access Data Administrator Functions

The data administrator sets up and maintains the data that is available in drop-down lists in Ennov InSight . To access the Data Administration functions:

1. Go To > Data Administration.
- Hyperlinks for individual functions are listed by group.
2. Click the link for the function you want to perform.
 3. After you have completed the function, click Return to menu.

Data Administration Selection Lists

Data Administration Selection Lists: Application Maintenance

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Age Span Population Values	Clinical Trial Application Form
Application Category Values	Ennov Defined: Best Practices
Application Status Values	Ennov Defined: Best Practices
Application Type Values	Regulatory Agency Guidance (US: application-type.xml v1.1) Regulatory Agency Defined (CN: http://www.nmpa.gov.cn/WS04/CL2042/) (WHO: Product-Type.xml)
Chief Investigator Values	Client Defined

Country Values	ICH Website: 2 digit ISO Codes
CTA Product Role Values	Ennov Defined: Best Practices
Legal Status Values	FDA Website; EMA Defined
MedDRA Term Values	Client Defined
Medical Condition Investigated Values	Client Defined

Ennov InSight Administration 7.3 Access Data Administrator Functions

Selection List Entity	Source for Values
Procedure Type Values (per Country)	XEVMPD Controlled Vocabularies - Authorisation Procedures Ennov Defined: Best Practices
Reason for Premature Ending Values	Clinical Trial Application Form
Region Values	Client Defined
Region Type Values	Client Defined
Sponsor Type Values	Client Defined
Trial Design Values	Clinical Trial Application Form
Trial Phase Values	Clinical Trial Application Form
Trial Scope Values	Clinical Trial Application Form
Trial Subject Groups Values	Clinical Trial Application Form

Data Administration Selection Lists: Assembly

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Assembly Category Values	Ennov Defined: Best Practices
Assembly DTD/Schema Type Values	Ennov Defined: Based on current agency guidance
Assembly Status Values	Ennov Defined: Best Practices
Assembly Subcategory Values	Ennov Defined: Best Practices

Data Administration Selection Lists: Assembly Variables

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Assembly Repository Variables	Client Defined, examples provided
Assembly System Defined Variables	Ennov Defined: Best Practices
Assembly User Defined Variables	Client Defined
Ennov InSight Assembly Variables	Ennov Defined: Best Practices

Data Administration Selection Lists: Change Maintenance

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Change Type Values	Client Defined
Event-Change Detail Status Values	Ennov Defined: Best Practices

Data Administration Selection Lists: Custom Lists Maintenance

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Custom List Names	Client Defined
Custom List Values	Client Defined

Data Administration Selection Lists: DMS Integration

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Bind to Label Values	Client Defined

Bind to Status Values	Client Defined
Rendition Identifier Values	Client Defined

Data Administration Selection Lists: eCTD 4.0 Submission Maintenance

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
CV Profile Values	Regulatory Agency Defined
Sender-defined Keyword Values	Client Defined

Data Administration Selection Lists: Event Maintenance

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Action Type Values	Client Defined
EU Grouping or Worksharing Values	Ennov Defined: Best Practices
Event Status Values	Ennov Defined: Best Practices
Event Type Values	Ennov Defined: Best Practices
PSUR Report Code Values	EMA Defined
Secondary Event Type Values	Ennov Defined: Best Practices
Timeline/Event Plan Type Values	Ennov Defined: Best Practices
Timeline/Event Plan Values	Client Defined

Data Administration Selection Lists: Notifications

Selection List Entity	Source for Values
Notification Specifications	Client Defined
Notifications	Client Defined

Data Administration Selection Lists: Other

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Concentration Measure Type Values	XEVMPD Controlled Vocabularies - Concentration Types
Denominator Unit Values	XEVMPD Controlled Vocabularies – Units of Measurement and Units of Presentation
Entity XML/UI Mappings	Ennov Defined: Best Practices
Home Page Display Properties	Client Defined
Indications/Intended Use Values	Client Defined
Language Values	The two-letter language code ISO 639-1:2002 Alpha-2 code is assigned to the language. The default value is set to Active. The standard set of extra fields can be configured for this value.
Selection List Entity	Source for Values
Legal Basis Values	XEVMPD Controlled Vocabularies – Legal Basis
Length Unit of Measure Values	Client Defined
MAH/Development Sponsor/Organisation Values	XEVMPD Controlled Vocabularies - Organisations
Master File Location (MFL) Values	Client Defined
Message Sender Values	Client Defined
Numerator Unit Values	XEVMPD Controlled Vocabularies – Units of Measurement
Previous EV Code Values	Client Defined
Quantity Unit of Measure Values	Client Defined
Reason for E-Signature Values	Client Defined
Reason for Termination/ Withdrawal Values	Client Defined
SME Status Values	XEVMPD Controlled Vocabularies - SME Status
Sub-Indication Values	Client Defined
System Alert Type Values	Client Defined

Unit of Measure Prefix Values	XEVMPD Controlled Vocabularies – Units of Measurement
Unit of Presentation Values	Client Defined
Weight Unit of Measure Values	Client Defined

Data Administration Selection Lists: Product Detail Set Maintenance

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Color Values	Client Defined
Compendial Designation/Source Values	XEVMPD Controlled Vocabularies - Reference Sources
Dose Frequency Values	Client Defined
Substance Role Values	Client Defined
Genetically Modified Cell Origin Species Values	Client Defined
Human Consumption Product Values	Client Defined

Selection List Entity	Source for Values
Label Type Values	Client Defined
Manufacturer Values	Client Defined
Manufacturing Functions Values	Client Defined
Material Type Values	Client Defined
Material Values	Client Defined
Medical Device Part Code Values	Client Defined
Packaging Category Values	Ennov Defined: Best Practices
Packaging Type Values	Client Defined
Product Bio Type Values	Client Defined
Product Detail Set Status Values	Ennov Defined: Best Practices
Product Material Values	Client Defined

Production Type Values	Client Defined
QC Status Values	Client Defined
Shape Values	Client Defined
Shelf Life Category Values	Client Defined
Shelf Life Type Values	Client Defined
Somatic Cell Therapy Cell Types Values	Client Defined
Somatic Cell Therapy Origin Species Values	Client Defined
Somatic Cell Therapy Origins Values	Client Defined
Source of Scientific Advice Values	Clinical Trial Application form
Species Values	Client Defined
Storage Condition Values	Client Defined
Substance Type Values	Ennov Defined: Best Practices
Time Unit Values	Ennov Defined: Best Practices
Type of Dossier Submitted Values	Clinical Trial Application form
Type of Gene Therapy Transfer Product Values	Clinical Trial Application form
Type of Gene Therapy Values	Clinical Trial Application form
Type of Genetically Modified Cell Origin Values	Clinical Trial Application form
Volume Unit of Measure Values	Client Defined

Data Administration Selection Lists: Product Family Maintenance

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
ATC Values	XEVMPD Controlled Vocabularies - Anatomical Therapeutic Chemical (ATC) Code Addition
Division Values	FDA
Product Family Status Values	Ennov Defined: Best Practices
Product Family Values	Client Defined
Substance Attachment Values	Client Defined

Substance Class Values	XEVMPD Controlled Vocabularies – Substance Classes
Substance Values	XEVMPD Controlled Vocabularies – Substances
Therapeutic Area Values	CDER Website
Therapeutic Class Values	FDA Website
Trade Name Values	Client Defined

Data Administration Selection Lists: Product Maintenance

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Applicable Standards Values	Client Defined
Conformity Assessment Body Values	Client Defined
Conformity Assessment Path Values	Ennov Defined: Best Practices
Device Allergenicity Values	Client Defined
Device Classification Values	FDA; EMA
Device Nomenclature Values	Client Defined
Device Sterility Indicator Values	Client Defined
Device Type Values	Client Defined
Device Usage Values	Client Defined
Dosage/Pharmaceutical Form Values	XEVMPD Controlled Vocabularies – Pharmaceutical Dose Forms
Selection List Entity	Source for Values
EC Cert Values	Client Defined
EU Classification Rule Values	EMA
FDA Regulation Number Values	FDA
Global Harmonization Task Force (GHTF) Class Values	GHTF
Manufacturing Location Values	Client Defined
Medical Device Values	XEVMPD Controlled Vocabularies – Medical Devices

Product Characteristics Values	Client Defined
Product Status Values	Ennov Defined: Best Practices
Product Strength Unit Values	Client Defined
Route of Administration Values	XEVMPD Controlled Vocabularies - Routes of Administration
Special Measure Values	Client Defined
Sterilization Requirement Values	Client Defined
Sterilization Values	Client Defined
Summary of Technical Documentation (STED) Values	Client Defined

Data Administration Selection Lists: Project Maintenance

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Project Status Values	Client Defined
Project Type Values	Ennov Defined: Best Practices

Data Administration Selection Lists: Publishing Requirements Maintenance

This section of Data Administration is not currently used.

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Electronic Format Requirement Values	Not currently used

Data Administration Selection Lists: Reference

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Reference Content Values	Client Defined

Reference Participant Values	Client Defined
Reference Status Values	Client Defined
Reference Type Values	Client Defined

Data Administration Selection Lists: Registration Maintenance

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
EMA Authorisation Status Values	XEVMPD Controlled Vocabularies – Authorisation Status
Medicinal Product Type Values	XEVMPD Controlled Vocabularies – Medicinal Product Types
Qualified Person Responsible for Pharmacovigilance (QPPV) Values	EMA Agency
Registration Status Values	Ennov Defined: Best Practices

Data Administration Selection Lists: Sequence Maintenance

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Filing Type Values	Regulatory Agency Guidance (US: submission-type.xml V1.1) (AU: sequence-type.xml) (WHO: Application-Type.xml) Ennov Defined: based on Regulatory Guidance
Selection List Entity	Source for Values
Sequence Status Values	Ennov Defined: Best Practices

Data Administration Selection Lists: SPOR Master Lists

Selection List Entity	Source for Values
ATC RMS Values	EMA Agency - SPOR System Referentials List: Anatomical Therapeutic Chemical Classification System
Compendial Designation/Source RMS Values	EMA Agency - SPOR System Referentials List: Source of Information
Concentration Measure Type RMS Values	EMA Agency - SPOR System Referentials List: Units of Measurement Type
Country RMS Values	EMA Agency - SPOR System Referentials List: Country
Denominator/Numerator Unit RMS Values	EMA Agency - SPOR System Referentials List: Units of Measurement
Dosage/Pharmaceutical Form RMS Values	EMA Agency - SPOR System Referentials List: Combined Pharmaceutical Dose Form
EMA Authorisation Status RMS Values	EMA Agency - SPOR System Referentials List: Authorisation Status
Language RMS Values	EMA Agency - SPOR System Referentials List: Language
Legal Basis RMS Values	EMA Agency - SPOR System Referentials List: Application Legal Basis
Medical Device RMS Values	EMA Agency - SPOR System Referentials List: XEVMPD Medical Device
Medicinal Product Type RMS Value	EMA Agency - SPOR System Referentials List: XEVMPD Medicinal Product Type
Procedure Type RMS Values	EMA Agency - SPOR System Referentials List: EU Regulatory Authorisation Procedure
Route of Administration RMS Values	EMA Agency - SPOR System Referentials List: Routes and Methods of Authorisation
Unit of Measure Prefix RMS Values	EMA Agency - SPOR System Referentials List: Units of Measurement Prefix

Data Administration Selection Lists: Submission Maintenance

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Applicant Contact Type Values	Regulatory Agency Defined (US: Applicant-contact-type.xml V1.2)
Applicant Contact Values	Client Defined
Applicant ID Values	Client Defined
Application Form Type Values	Regulatory Agency Defined (US: form-type.xml V1.4)
Font Definition Values	Ennov Defined: based on Ennov InSight Rendering default configuration
Leaf Status Values	Ennov Defined: Best Practices
PDF Property Values	Client Defined
Promotional Material Audience Type Values	Regulatory Agency Defined (US: promotional-material-audience-type.xml V1.1)
Promotional Material Doc Type Values	Regulatory Agency Defined (US: promotional-material-doc-type.xml V1.1)
Promotional Material Type Values	Regulatory Agency Defined (US: promotional-material-type.xml V1.2)
Regulatory Activity Lead Values	Regulatory Agency Defined (AU: reg-activity-lead.xml) (WHO: Submission-Unit-Type.xml)
Sequence Description Values	Regulatory Agency Defined (AU: sequence-description.xml)
Submission Product Type Values	Regulatory Agency Defined (CN:) (WHO: Product-Sub-Type.xml)
Selection List Entity	Source for Values
Sub Filing Type Values	Regulatory Agency Defined (US: submission-sub-type.xml V1.1) CN: http://www.nmpa.gov.cn/WS04/CL2042/ (WHO: Application-Sub-Type.xml)

Supplement Effective Date Type Values	Regulatory Agency Defined (US: supplement-effective-date-type.xml V1.1)
Telephone Number Type Values	Regulatory Agency Defined (US: telephone-number-type.xml V1.1)

Data Administration Selection Lists: Submission Plan Maintenance

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Submission Plan Status Values	Ennov Defined: Best Practices

Data Administration Selection Lists: Task Maintenance

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Secondary Task/Sub-Task Type Values	Client Defined
Task/Sub-Task Priority Values	Ennov Defined: Best Practices
Task/Sub-Task Status Progression Values	Client Defined
Task/Sub-Task Status Values	Ennov Defined: Best Practices
Task/Sub-Task Type Values	Ennov Defined: Best Practices

Data Administration Selection Lists: Workflow Management

The following table identifies the selection lists (drop-down lists and multi-select boxes) in Ennov InSight . Some of these lists will be populated with values when shipped with the software. For those lists, the table identifies where the values were obtained.

Selection List Entity	Source for Values
Workflow Management	Client Defined

Filters for Data Administration Values

Ennov InSight enables the use of Data Administration Values to filter data and persist the query selections for Administrative entities.

The following Administrative entities support filters:

Administrative Functions	Entity Name
Application Maintenance	Country Values
Assembly	Assembly Subcategory Values
Custom Lists Maintenance	Custom List Values
Event Maintenance	Timeline/Event Plan Values
Notifications	Notifications
	Notification Specifications
Other	MAH/Development Sponsor/Organisation Values
	Indications/Intended Use Values
	Numerator Unit Values
Product Detail Set Maintenance	Manufacturer Values
	Storage Condition Values
	Packaging Type Values
Product Family Maintenance	Therapeutic Class Values
	ATC Values
	Product Family Values
	Substance Values
	Trade Name Values
Product Maintenance	Dosage/Pharmaceutical Form Values
	Route of Administration values
Sequence Maintenance	Filing Type Values

See: *Getting Started with Liquent InSight > Filters.*

eCTD 4.0 CV Profiles

Use the eCTD 4.0 CV Profiles to enable interactions with controlled vocabularies for quick and easy eCTD 4.0 specification updates in future.

Controlled vocabularies (CV) are an essential component of the eCTD v4.0. They provide communication between systems sending and receiving XML messages.

CV Profiles allow you to map a name of controlled vocabulary with the Data Administration values.

Multiple CV entries can be associated to the one CV profile value.

The following table shows the Data Administration value and the CV value it is linked to.

Data Administration Function	Data Administration Value	Affected Area
eCTD 4.0 Submission Maintenance	CV Profile Values > CV Details	Publishing Settings Library

Associate CV Details with Data Administration Entities

You can map a controlled vocabulary to a CV Profile with the Data Administration values using the CV Profile

Name tab available on the Data Administration values attributes page. You can associate multiple CV entries to one CV profile.

Note: *There are dependencies between CVs:*

— *If you associate a CV that includes dependencies, dependent CVs are associated too.*

— *If you try to associate CV that has No in Can be associated? column that action will fail. — Inactive CVs are not displayed in the eCTD 4.0 CV Profile Values widget.*

— *The previously assigned but deleted CVs are still displayed in the CV Details tab*

— *The previously assigned but deleted CVs are not displayed in the eCTD 4.0 CV Profile Values widget after disassociating from the CV Profile.*

— *The Region, Version, Category values are not removed from the columns in the eCTD 4.0 CV Profile Values page after deleting the whole CV region, or version or category in CV Service.*

To associate CV profile name:

1. On the homepage, click Go To > Data Administration > eCTD 4.0 Submission Maintenance.
2. Click CV Profile Values.
3. Click the CV profile to which you want to associate the CV profile name.

You can create a CV profile if there are none by clicking the Create icon.

4. Select the Region, Version, and Category.

Note: When you associate the CV Details, the controlled vocabularies are filtered according to these fields in the Search Results box.

5. On the selected *CV Profile Values* page, click the CV Details tab.
6. Click Associate CV
7. Select the CV in the Search Results box and click Associate CV.

You can select one or multiple CVs with Yes value in the Can be associated? column only. The selected CVs are associated with their dependencies.

Disassociate CV Details with Data Administration Entities

You can disassociate CV Details from the Data Administration values using the disassociate icon available on the CV Details tab.

To disassociate CV Details Names: 1. On the homepage, click Go To > Data Administration > eCTD 4.0 Submission Maintenance.

1. Click CV Profile Values
2. On the selected *CV Profile Values* page, click the CV Details tab.
3. Select the CV, click Dissassociate the CV 

Note: Due to dependencies between CVs, you can only disassociate CVs that have Yes in Can be disassociated?

column. You cannot disassociate CV that has No in Can be disassociated? column.

- Click OK on the confirmation message.

CV Details Attributes

The following are the CV Details attributes and their description:

Attribute	Description
Name	Name of the controlled vocabulary profile provided by CV service.
Version	Version of the controlled vocabulary profile provided by CV service.
OID	Object identifier of the controlled vocabulary profile provided by CV service.
Can be associated?	– Yes indicates that CV can be selected for association. – No indicates that CV cannot be associated due to the existing dependencies.
Can be disassociated?	– Yes indicates that CV can be selected for disassociation. – No indicates that CV cannot be disassociated due to the existing dependencies.

Ennov InSight Administration 7.3 eCTD 4.0 CV Profiles

OMS Terms

Use Organization Management Services (OMS) terms to include organization management data for attributes of manufacturer values and country values such as health authority.

OMS allows you to map a SPOR Term with the Data Administration values. The following table shows the Data Administration value and the SPOR value it is linked to.

Data Administration Function	Data Administration Value	SPOR Master List Name
Application Maintenance	Country Values => Health Authority	Organization
Product Detail Set Maintenance	Manufacturer Values	Organization
Other	MAH/Development Sponsor/Organization Values	Organization

Associate OMS Terms with Data Administration Entities

Associate an entity to an organization using OMS (Organization Management Service) values to include a single source of validated organizational data.

To associate OMS with an entity:

1. Select Go To > Data Administration.
2. Navigate to the Data Administration entities and click the link for the Data Administration value. For Example: Product Detail Set Maintenance, click Manufacturer Values.
3. Click the manufacturer to which you want to associate an organization.
4. Scroll to the bottom of the page and click the OMS tab.
5. Click Associate Term.
6. Select the organization to associate with the manufacturer. You can select only one organization.
7. Click Associate Term.

Disassociate OMS Terms with Data Administration Entities

Disassociate the term from an organization using OMS (Organization Management Service) values. To disassociate an OMS term from an entity:

1. Navigate to the Data Administration entities and click the link for the Data Administration value.

Example

Example: Under Product Detail Set Maintenance, click Manufacturer Values. OMS

Terms

2. Click the manufacturer from which you want to disassociate an organization.
3. Scroll to the bottom of the page and click the OMS tab.
4. Select the Term, and click Disassociate Term .

OMS Terms Attributes

The following are the OMS Terms attributes and their description:

Attribute	Description
Organization ID	OMS Organization Identifier.
Organization Name	The name of the OMS organization.

Address	OMS Address Line 1 + OMS Address Line 2 (if exists) + OMS Address Line 3 (if exists) + OMS Address Line 4 (if exists).
City	OMS city.
Post Code	OMS Post code of the city.
Country	The OMS county for the location.
Location ID	The OMS location identifier.
XEVMPD	The OMS XEVMPD code for the location.
Organization Category Type	Type of organization category.
Last User Updated	Indicates by whom the Data Administration value was created/updated. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates when the Data Administration value was created/updated. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

RMS Terms

Use Referentials Management Services (RMS) terms to include referential master data for attributes of medicinal products such as lists of dosage forms, units of measurement and routes of administration.

RMS allows you to map a SPOR Term with the Data Administration values. The following table shows the Data Administration value and the SPOR value it is linked to.

Data Administration Function	Data Administration Value	SPOR Master List Name
Product Family Maintenance	– ATC Values – Domain	– Anatomical Therapeutic Chemical classification system - Human – Domain – EU Regulatory Authorisation Procedure
Other	– Legal Basis Values – Application Submission Type	– Application Legal Basis – Application Submission Type – Language

	– Language Values – Indications/Intended Use Values – Units of Measurement – Unit of Presentation Values – Concentration Measure Type Values – Attached Document Content Type Values – Source of Information Values	– Medical Dictionary For Regulatory Activities – Units of Measurement – Units of Presentation – Quantity Operator – eCTD EU Context of Use, Product Information Document Type, Regulating Authority Submission Unit Type – Source of Information
Product Maintenance	– Dosage/Pharmaceutical Form – Product Category – Product Cross Reference Type – Routes of Administration Values – Medical Device Values	– Combination Package – Combined Pharmaceutical Dose Form – Combined Term – Pharmaceutical Dose Form – Product Category – Product Cross Reference Type – Routes and Methods of Administration – XEVMPD Medical Devices

Data Administration Function	Data Administration Value	SPOR Master List Name
Registration Maintenance	· Marketing Status · Master File Type · Regulatory Entitlement Status · Provenance Reason · Registration Status Values · Data Carrier Type Values · Data Carrier Identifier Source	– Marketing Status – Master File Type – Medicinal Product Name Part Type – Regulatory Entitlement Status – XEVMPD Medical Product Type – Regulatory Entitlement Status – Source of Information

Application Maintenance	– Country Values	– Country
	– Procedure Type Values	– Legal Status for the Supply
	– Legal Status Values	– Regulatory Entitlement Type
	– Regulatory Entitlement	– Product Information Document Type
	Type	– Medicinal Product Name Part Type
	– Product Information	– XEVMPD Medical Product Type
	Document Type	
	– Medicinal Product Name	
	Part Type	
	– Medicinal Product Type Values	
Product Detail Set Maintenance	– Substance Type Values	– Ingredient Role
	– Manufacturing Function	– Manufacturing Activity
	Values	– Material
	– Material Values	– Packaging
	– Packaging Type Value	– Shelf Life Type
	– Shelf Life Type Values	– Special Precaution for Storage
	– Storage Condition Values	– Units of Measurement
	– Manufacturer Values Global Detail Sets	– Medical Device Legislative Category – Container Category
	– Component Type	– Medicine Profile
	– Medical Device UDI – Device – Type of Combination – Time Unit Values Intended Effect	

Data Administration Function	Data Administration Value	SPOR Master List Name
Medical Device Maintenance	Device Classification Values	Medical Device Classification

Associate RMS Terms with Data Administration Entities

You can map a RMS term with the Data Administration values using the RMS tab available on the Data Administration values attributes page.

Only one RMS term can be associated to the Data Administration value. Associating another term will replace the existing term.

To associate RMS Terms:

1. On the homepage, click Go To > Data Administration.
2. Navigate to the Data Administration entities and click the link for the Data Administration value.

Example

Example: Application Maintenance > Country Values

3. Click the country to which you want to associate the term.
4. On the *Country* page, select RMS tab.
5. Click Associate Term 

The *Term Search* window populates the Term fields.

6. Select the Term on the Search Results box and click Associate Term.

Disassociate RMS Terms with Data Administration Entities

You can disassociate a RMS term from the Data Administration values using the disassociate icon available on the RMS tab of the Data Administration values attributes page.

To disassociate RMS Terms:

1. Navigate to the Data Administration entities and click the link for the Data Administration value. For Example:
Application Maintenance > Country Values
2. Click the country from which you want to disassociate the term.

3. On the *Country* page, select RMS tab:

4. Select the Term, Click Disassociate Term .

RMS Terms Attributes

The following are the RMS Terms attributes and their description:

Attribute	Description
Term Id	Term Identifier from the SPOR values.
Term Name	Term Name from the SPOR values.

Attribute	Description
ISO Code	The ISO code for the term, if applicable.
xEVMPD Code	The XEVMPD code for the term, if applicable.
Source Mapping Code	Source Mapping Code for the RMS list values.

SMS Terms

Substance Management Services (SMS) terms enable you to associate existing substance data to uniquely identify the ingredients and materials of a medicinal product.

SMS enables you to map a SPOR Term with the Data Administration values. The following table shows the Data Administration value and the SPOR value it is linked to. You should have at least Write privileges for RPT/PDM licenses. See the *Functionality and Technology Not Supported* section in *Ennov InSight 7.2 Release Notes*.

Data Administration Function	Data Administration Value	SPOR Master List Name
Product Family Maintenance	Substance Values	Substance

Associate SMS Terms with Data Administration Entities

Associate substance values to an SMS (Substance Management Service) to include a single source of validated substance data.

See the *Functionality and Technology Not Supported* section in *Ennov InSight 7.2 Release Notes*. To associate SMS with an entity:

1. On the homepage, click Go To.
2. Click Data Administration > Product Family Maintenance > Substance Values 3. Click the substance name to which you want to associate the SMS term.

1. Select the SMS tab.
2. Click the Associate Term icon.
3. Select the substance name to associate with the substance value. You can select only one substance.
4. Click Associate Term.

Disassociate SMS Terms with Data Administration Entities

Disassociate substance values that are not required for SMS (Substance Management Service) term.

See the *Functionality and Technology Not Supported* section in *Ennov InSight 7.2 Release Notes*. To disassociate an SMS term from an entity:

1. On the homepage, click Go To > Data Administration, then Product Family Maintenance > Substance Values.

SMS Terms

2. Click the substance name from which you want to disassociate substance values from an SMS.
3. Select the SMS tab.
4. Select the Term, and click Disassociate Term .

SMS Terms Attributes

See the *Functionality and Technology Not Supported* section in *Ennov InSight 7.2 Release Notes*. The following are the SMS Term attributes and their description:

Attribute	Description
Term ID	SMS Term Identifier. Value used to uniquely identify an SMS term.
Substance Name	Substance Name.
Data Classification	SMS Data Classification. For example: Public, Confidential.
Category	SMS Category. For example: Chemical.
Domain	SMS Domain. For example: Human use, Veterinary use.
Last User Updated	Indicates the name of the user who last created/updated the substance. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Maintain Values

As a data administrator, you can add, modify, associate, or deactivate and reactivate values in Ennov InSight .

Mapped Values

While several values for entity types and statuses are provided out-of-the-box, Ennov InSight is customizable in that you can create your own values for your environment.

Values that appear in drop-down lists and selection boxes on the Ennov InSight pages must be mapped to internal values that correlate to Ennov InSight functionality. The mapping of these values is performed by your Ennov InSight Data Administrator. Entity type values are mapped in Data Administration > Other > Entity XML/UI Mappings, and status values are mapped in Data Administration > *<InSight entity>* > *<InSight entity>* Status Values.

The following values must be mapped to internal values:

Entity type values — Application types — Registration types

- Product Component types
- Product Family types
- Project types

Status values

- Product status
- Application status
- Event status
- Product Detail Set status
- Sequence status

Unique Status Value Mappings

On the *Data Administration* pages where you create status values for the Ennov InSight entities, you are presented with internal system statuses, such as PLANNED, APPROVED, NOT APPROVED, and SUBMITTED.

When defining custom status values for the entities, there must be only one unique customer-facing status mapped to a single internal system status per entity.

Each entity should have a unique customer facing status of Approved mapped to the internal status APPROVED. You should not have an Approved1 and Approved2 both mapped to APPROVED, as this could result in erroneous system behavior.

Active Entity XML/UI Mappings for Registration Types

To provide a proper work of wizards and their procedures, some registration type values must be active.

Do not deactivate the "out-of-the-box" registration type value Package Set Registration. There are Ennov InSight functions and procedures, such as the "Create New Applications - Package Set Registration" *Global Project Planning* wizard, that rely on this value remaining active.

Add a Value

You can add values to the entity drop-downs that appear in Ennov InSight . To

add a value:

1. Select Go To > Data Administration.
2. In the list functions, click a link for the entity for which you want to add a value.
3. Click .
4. On the *values* page, enter the appropriate information in the boxes provided.
5. Save.

For video guide to add values, click [here](#).

Modify a Value

You can modify the values in entity drop-downs that appear in Ennov InSight .

To modify a value:

1. Select Go To > Data Administration. A list of value groups is displayed.
2. Click the link for the value you want to modify from the grouped list. A list of values specific to the group selected is displayed.
3. Click the link for the specific value.

Options are displayed for revising the existing settings.

4. Enter or select the appropriate information in the fields provided.
5. Click Save.

Activate/Deactivate Data Administration Values

Deactivate a value in an entity drop-down and selection boxes to hide it, and activate a value to display it. Ennov InSight does not delete a deactivated value from the database.

Note: *Product family and region values cannot be deactivated after they have been created.*

To deactivate or activate a data administration value:

1. Select Go To > Data Administration. A grouped list of values is displayed.
2. Click the link for the grouped value.

The individual values list opens.

3. Click the link for the value that you want to activate or deactivate.
4. Do one of the following:

Action	Step
To activate a value	Click Activate.
To deactivate a value	Click Deactivate.

Entities to Associate

Refer to the list of entities that can be associated or disassociated with other entities.

Data Administration Section	Values to associate	Column	Tab	Description
Application Maintenance	Country Values	Country Code	Region	Associate country with a region, disassociate a region to which your country is associated, or modify the country region association from the <i>Country Attributes</i> page.
				Note: The Region that belongs to the default region type (Regulatory Region, or IDMP) cannot be disassociated from a country.
				Note: The region values available for selection are those associated to a selected region type.
Application Maintenance	Country Values	Country Code	Languages	Associate a language that is used for a Country.

Product Detail Set Maintenance	Manufacturer Values	Manufacturer Name	– Global Product Details – Manufacturing Authorization Reference Number – OMS	Associate product details with a manufacturer.

Ennov InSight Administration 7.3 Entities to Associate

Data Administration Section	Values to associate	Column	Tab	Description
Product Family Maintenance	Substance Values	Substance Name	– Substance XEVM-PD Information – Substance International Codes – SMS	Associate substance details with a substance.

Associate an Entity

You can associate an entity to another entity or modify the association from the entity attributes page. To associate an entity:

1. Go To > Data Administration.
2. Under the appropriate maintenance section, click a link from the list of values.
3. Click the link corresponding to the entity value.
4. On the entity attributes page, click the required tab.
5. Click or  

6. Associate an entity from an existing list or create a new one.
7. Save.

Disassociate an Entity

You can disassociate an entity that is not required.

To disassociate an entity:

1. Go To > Data Administration.
2. Under the appropriate maintenance section, click a link from the list of values.
3. Click the link corresponding to the entity value.
4. On the entity attributes page, click the required tab.
5. Select the item you want to disassociate.
6. Click .

Ennov InSight Administration 7.3 Entities to Associate

Application Maintenance

Application values appear in drop-down lists on the *Application Attributes* page and are designated at the time an application is created.

Values depend on the country to which the application is being applied. Data administration enables you to add and modify drop-down list values, and set the status of a value to active or inactive. In addition, you can specify an eCTD code, which is used to translate the application type for each country to the eCTD attribute value used for publishing.

When you select a value under Application Maintenance, a page opens with a table of all values that have been defined. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

The proper data administration access privileges are required to view and modify application maintenance values.

All XEVMPD Data Administration tables provide the ability to configure extra fields. The standard set consists of twenty extra text fields, five extra date fields, and five extra number fields.

All IDMP Data Administration tables provide the ability to add information required to maintain a standardized and structured method of collecting, reporting, coding, and evaluating authorized medicinal product data.

Application Maintenance: Application Values

You can create and maintain the following application values:

Application Value	Description
Age Span Population	Ages of those being tested in a trial, such as in utero, infant, adolescent, etc.

Application Category	Groupings for similar application types used in Global Project Planning (GPP). For example: by default, Ennov InSight associates the Clinical Trial category to the application types IND (US) and CTA (EU). When you use the Clinical Trial category with the <i>GPP</i> wizard, an IND for the US and a CTA for the EU are created.
Application Status	For example: as planned, approved, withdrawn.
Application Type	For example: name and the countries associated with the type.
Chief Investigator	People who are responsible for the design, conduct, analysis, and reporting of clinical trial information. Note: By default, the section is hidden.
Country	Add new country values to the system, modify country values, associate a country with a region, set the default application type or procedure type for a country, and set the active or inactive status for a country. MRP/CP countries (other than reviewing country/ rapporteur/co-rapporteur) can have twenty extra text fields, five extra date fields, and five extra number fields configured.
CTA Product Role	The roles a product plays in a trial, such as IMP, comparator, and placebo.
Legal Status	How the product is approved to be sold. Example: pharmacy only medicine, prescription only, over the counter.
MedDRA Term	MedDRA version, level, and classification code for a trial.
Medical Condition Investigated	Condition investigated by the trial.
Medical Product Action/ Submission Status	Submission status of the Medicinal Product.
Medicinal Product Name Part Type Values	Specify the medicinal product name parts along with the language of the country and as the marketing authorisation applies in accordance with the referenced SmPC.
Medicinal Product Type Values	Defines values that are used to distinguish product type. The list contains Codes for the medicinal product type term/name from the EMA CV. The default value is set to Active. The standard set of extra fields can be configured for this value.
Procedure Type	Internally mapped to one of the following: CP, DCP, MRP, or National. The list contains the XEVMPD term ID from the Authorisation

	Procedures CV for the procedure type. The default value is set to Active. The standard set of extra fields can be configured for this value.
	Note: <i>Changing the MRP (Mutual Recognition) or CP (Centralized Procedure) procedure type values is not recommended. Specific business logic is associated with these procedure types and may result in unexpected results if you change the values.</i>
Reason for Premature Ending	The reason that the application ended prematurely. This is an attribute only for a CTA application. Example: safety, lack of efficacy, trial never commenced, etc.
Region	Regions with which the countries are associated, for example: EU, SA, AS, etc. Can have twenty extra text fields, five extra date fields, and five extra number fields configured. You must select a region type for a region you are creating. To add a region, you enter values for the attributes displayed in the Region Attributes table below.
Region Type	Type of a region. The name of a region type must be unique within the system. Example: <i>Regulatory Region</i>. You can enter up to 200 characters for the Region Type value. The default value is set to Active. The <i>Regulatory Region</i> and <i>IDMP</i> types exist in the system by default. Both values are not available for modifications and cannot be deactivated. You can: – Update the list of countries that are associated to the region of a regulatory region type, or create a new region of a regulatory region type using the <i>Region Values</i> section. – Update the list of countries that are associated to the region of an IDMP type, or Create a new region of an IDMP type using the <i>Region Values</i> section.
Regulatory Entitlement Status	The Orphan Designation status of the medicinal product (where applicable) that can be found in the individual product entry at the EC Register of medicinal product.
Regulatory Entitlement Type	Regulatory applications may be submitted to obtain different type of authorisations or regulatory entitlements such as orphan designations, Advanced therapy medicinal product (ATMP) classification, marketing authorisations and so on, accordance with the current European regulatory framework for medicinal products.
Sponsor Type	Trial sponsor, for example: commercial or noncommercial.
	Note: <i>By default, the section is hidden.</i>

Trial Design	For example: randomized, open, single blind, double blind, parallel group, cross over.
Trial Phase	For example: phase I, phase II, phase III, etc.
Trial Scope	For example: diagnosis, prophylaxis, therapy, safety, efficacy, pharmacokinetic, or pharmacodynamic.
Trial Subject Groups	For example: healthy, patients, women-child bearing potential, woman-child bearing potential on contraceptives, pregnant, nursing, emergency situation, incapable of giving consent, etc.
Application Value	Description
Orphan Status	For example: Expired, Pending, Valid, Withdrawn.
Product Information Document Type Values	The document that contains the medicinal products details.

Age Span Population Attributes

To define an age span population value, enter values for the following attributes:

Attribute	Description
Age Span Population Value	Values are: In Utero, Preterm newborn, newborn, infant and toddler, children, adolescent, adult, elderly.
Last User Updated	Indicates the name of the user who last created/updated the age span population. By default, this option is read-only. It is populated automatically when up- dates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Application Category Attributes

To define an application category value, enter values for the following attributes:

Attribute	Description
Application Category Name	Name of the application category. Examples: Clinical Trials, Marketing Application.
Last User Updated	Indicates the name of the user who last created/updated the application category. By default, this option is read-only. It is populated automatically when updates were made to the table.

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Application Status Attributes

To define an application status value, enter values for the following attributes:

Attribute	Description
Name	The name given for the Application status.
Attribute	Description
Default Flag	Flag to indicate if the product status is the default. Yes and No values are available for selection.
System Process Default Flag	Select the status to display for an Application after an Event is closed.
Internal System Status	The internal status associated to the product status. Planned, Submitted, Approved, Not Approved values and Withdrawn are available for selection.
Last User Updated	Indicates the name of the user who last created/updated the application status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Application Type Attributes

To define an application type value, enter values for the following attributes:

Attribute	Description
Application Type	Abbreviation for the Application Type. Example: NDA.
Name	Full Application Type Name. Example: New Drug Application.
Display Name	Display Name.
Entity XML Type Name	Entity XML Type Name. All the xml mappings defined for the application entity are available for selection.
Application Category	Application Category that the Application Type is mapped to. All active Application Categories defined in the system are available for selection.
Countries	Countries.

Last User Updated	Indicates the name of the user who last created/updated the application type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Chief Investigator Attributes

To define a chief investigator value, enter values for the following attributes:

Attribute	Description
Chief Investigator Values	Person responsible for the design, conduct, analysis and reporting of the clinical trial information.
Last User Updated	Indicates the name of the user who last created/updated the chief investigator. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Country Attributes

To define a country value, enter values for the following attributes:

Attribute	Description
Country Code	2-digit country code as defined by ISO. Example: UK, DE, US, etc.
Country Name	Full Country Name. Example: United Kingdom, Germany, United States, etc.
eCTD Code	eCTD Code.
RMS Term Name	List of Country RMS Values available for selection.
Last User Updated	Indicates the name of the user who last created/updated the country. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

CTA Product Role Attributes

To define a CTA product role value, enter values for the following attributes:

Attribute	Description
CTA Product Role Values	*CTA Only - values are: IMP, comparator, and placebo.
Last User Updated	Indicates the name of the user who last created/updated the CTA product role. By default, this option is read-only. It is populated automatically when updates were made to the table.
Attribute	Description
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Legal Status Attributes

To define a legal status value, enter values for the following attributes:

Attribute	Description
Legal Status Value	Abbreviation for the Legal Status Name. Example: POM, Rx, OTC.
Name	The full name of the Legal Status. Examples: Pharmacy Only Medicine, Prescription Only, Over the Counter.
Last User Updated	Indicates the name of the user who last created/updated the legal status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

MedDRA Term Attributes

To define a MedDRA Term value, enter values for the following attributes:

Attribute	Description
MedDRA Term Values	MedDRA version, level, term and classification code.

Last User Updated	Indicates the name of the user who last created/updated the MedDRA term. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Medical Condition Investigated Attributes

To define a medical condition investigated value, enter values for the following attributes:

Attribute	Description
Medical Condition Investigated Values	Medical Condition being investigated.
Last User Updated	Indicates the name of the user who last created/updated the medical condition investigated values . By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Medical Product Action/Submission Status Attributes

To define a medical product action/submission status value, enter values for the following attributes:

Attribute	Description
Status Name	Name given for the Medical Product Action/Submission Status.
Last User Updated	Indicates the name of the user who last created/updated the medicinal product action/submission status. By default, this option is read-only. It is populated automatically when updates are made to the table
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates are made to the table
Active	Indicates if the entity is active or inactive.

Medicinal Product Name Part Type Attributes

To define a medicinal product name part type value, enter values for the following attributes:

Attribute	Description
Medicinal Product Name Part Type Name	Medicinal Product Name parts type name.
Last User Updated	Indicates the name of the user who last created/updated the medicinal product name part type. By default, this option is read-only. It is populated automatically when updates are made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates are made to the table.
Active	Indicates if the entity is active or inactive.

Medicinal Product Type Values Attributes

To define a medicinal product type value, enter values for the following attributes:

Attribute	Description
Medicinal Product Type Name	Authorization – medicinal product types container name.
Medicinal Product Type Code	Authorization – medicinal product types container code.
RMS Term Name	List of EMA Authorization Status RMS Values available for selection.
Last User Updated	Indicates the name of the user who last created/updated the medicinal product type. By default, this option is read-only. It is populated automatically when updates are made to the table
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates are made to the table.
Active	Indicates if the entity is active or inactive.

Procedure Type Attributes

To define a procedure type value, enter values for the following attributes:

Attribute	Description
Procedure Type Abbreviation	Abbreviation for the Procedure Type. Example: MRP.
Procedure Type Name	Full Procedure Type Name. Example: Mutual Recognition Procedure.
Display Name	Display Name.

Internal Procedure Code	Procedure types that identify what business rules will be applied when selecting the User Facing Procedure Types on an Application. Because they are used internally, they are not configurable by a user.
Assigned Region	Identifies the region for which the procedure type is valid (For example, EU or WAHO)
eCTD Code	eCTD Code.
Procedure Type Code	Current codes according to the EMA Authorisatin Procedure CV. Note: <i>Procedure Type Abbreviation and Procedure Type Name should be unique to accept within following ligament Procedure Type</i> <i>Abbreviation, Procedure Type Name, Display Name, Internal Procedure Code.</i>
External System Procedure Type Code	External system procedure type code.
Attribute	Description
Countries	Identifies the countries for which the Procedure Type is valid.
RMS Term Name	List of Procedure Type RMS Values available for selection.
Last User Updated	Indicates the name of the user who last created/updated the procedure type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Reason for Premature Ending Attributes

To define a reason for premature ending value, enter values for the following attributes:

Attribute	Description
Reason for Premature Ending Values	Values are: Safety, Lack of efficacy, trial never commenced; other.
Last User Updated	Indicates the name of the user who last created/updated the reason for premature ending. By default, this option is read-only. It is populated automatically when updates were made to the table.

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Region Attributes

To define a region value, enter values for the following attributes:

Attribute	Description
Region Type	The type of a Region.
Region Abbreviation	An abbreviation of 1-5 characters for a region you are creating. Example: <i>EU</i> The value you are entering must be unique within the system.
Region Name	A full name of a region. Example: <i>European Union</i> The name you are entering must be unique within a <i>Region Type</i> .
Countries	Countries associated to a region. A country can only belong to one region within the <i>Region Type</i> .
Attribute	Description
Last User Updated	Indicates the name of the user who last created/updated the region. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Region Type Attributes

To define a region type value, enter values for the following attributes:

Attribute	Description
Region Type Name	The name of the Region Type to be used. The value you are entering must be unique within the system.
Last User Updated	Indicates the name of the user who last created/updated the region type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Regulatory Entitlement Status Attributes

To define a regulatory entitlement status value, enter values for the following attributes:

Attribute	Description
Regulatory Entitlement Status Name	Defines orphan designation regulatory status.
RMS Term Name	The list of Regulatory Entitlement Status values available for selection.
Last User Updated	Indicates the name of the user who last created/updated the region type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Regulatory Entitlement Type Attributes

To define a regulatory entitlement type value, enter values for the following attributes:

Attribute	Description
Regulatory Entitlement Type	Defines regulatory authorization type.
Last User Updated	Indicates the name of the user who last created/updated the regulatory entitlement type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Sponsor Type Attributes

To define a sponsor type value, enter values for the following attributes:

Attribute	Description
Sponsor Type	Sponsor Type. Values are: Commercial and Non-Commercial.
Last User Updated	Indicates the name of the user who last created/updated the sponsor type. By default, this option is read-only. It is populated automatically when updates were made to the table.

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Trial Design Attributes

To define a trial design value, enter values for the following attributes:

Attribute	Description
Trial Design Values	Trial Design. Values are: Randomized, Open, Single Blind, Double Blind, Parallel Group, Cross Over.
Last User Updated	Indicates the name of the user who last created/updated the trial design. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Trial Phase Attributes

To define a trial phase value, enter values for the following attributes:

Attribute	Description
Trial Phase Values	Phases in a clinical trial. Values are: Phase I, Phase II, Phase III, Phase IV.
Last User Updated	Indicates the name of the user who last created/updated the trial phase. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Trial Scope Attributes

To define a trial scope value, enter values for the following attributes:

Attribute	Description
Trial Scope Values	Values are: Diagnosis, Prophylaxis, Therapy, Safety, Efficacy, Pharmacokinetic, Pharmacodynamic, Bioequivalence, Bioequivalence, Pharmacogeneic, Pharmacogenomic, Pharmacoeconomic.
Last User Updated	Indicates the name of the user who last created/updated the trial scope. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Trial Subject Group Attributes

To define a trial subject group value, enter values for the following attributes:

Attribute	Description
Trial Subject Group Values	Values are: Healthy, Patients, women-child bearing potential, woman-child bearing potential on contraceptives, pregnant, nursing, emergency situation, incapable of giving consent.
Attribute	Description
Last User Updated	Indicates the name of the user who last created/updated the trial subject group. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Orphan Status Attributes

To define an orphan status value, enter values for the following attributes:

Attribute	Description
Orphan Status Name	Orphan Status Name.
Last User Updated	Indicates the name of the user who last created/updated the orphan status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Chief Investigator Attributes

To define a chief investigator value, enter values for the following attributes:

Attribute	Description
Chief Investigator Values	Person responsible for the design, conduct, analysis and reporting of the clinical trial information.
Last User Updated	Indicates the name of the user who last created/updated the chief investigator. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Product Information Document Type Attributes

To define a product information document type value, enter values for the following attributes:

Attribute	Description
Product Information Document Type Name	Unique name for the product information document type.
Last User Updated	Indicates the name of the user who last created/updated the product information document type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Application Type Conditions

When adding or modifying application types, specific conditions apply.

- Required properties must be completed with valid data.
- Both the application type (abbreviation) and name (application type full name) must be unique within the system.
- Each application type must be associated with one and only one application category. The application category is used to determine application types when creating new application projects in the *Global Project Planning* (GPP) wizard.

- An application type can be associated with zero, one, or more countries.
- A country can be associated with only one *application type* per application category. For example, a country cannot be associated with both the MAA and NDA application types for the application category Marketing Authorization.
- An existing application type can be set to active or inactive.
- An application type cannot be set to inactive if that application type is currently the default application type for a country.
- A country cannot be disassociated from an application type if that application type is the default application type for that country.

Country Value Maintenance

A country is associated with an application and is designated at the time an application is created or modified. The table on the *Country List* page displays ALL countries in the system, and enables you to create or modify the country values that are used in the system.

The proper data administration access privileges are required to view or modify country values.

Using data administration, you can:

- Add new country values to the system
- Modify country values
- Add health authority values to a country
- Associate country with a region
- Add language to the country
- Set the default application type or procedure type for a country
- Set the status of a country to active or inactive

The application created for a country by the Copy Application function will include the default application type and the default procedure type that have been defined for that country.

To set a default application type or default procedure type for a country, the country must first be associated with an application type or procedure type in data administration.

Each country must be associated with a region. The default region for a country is the Rest of World (ROW) region of Regulatory Region type.

To associate country with a region, remove or change the existing associations, the following options can be used:

- *County Values* (*Region* tab on the *Country Attributes* page)

– *Region Values (Region Attributes page)*

eCTD code and eCTD authority are necessary to add eCTD attributes in the Module 1 administrative metadata automatically. The eCTD attributes are included based on the ICH specification, and are necessary because the country code and agency names may differ between the eCTD and other specifications. This enables the *Create eCTD Wizard* to identify the correct values from the controlled value lists when there are discrepancies between specifications.

Country Value Conditions

When adding or modifying country values, specific conditions apply.

- Required properties must be populated with valid data.
- *Country code* and *country name* must each be unique within the system.
- When creating a country, the default associated region is Rest of World of Regulatory Region type.
- A country can only be associated with one region within a Region Type.
- Modifying a country value will not affect the current region association to the country. – A country value is active upon creation.
- An existing country value can be set to active or inactive.
- Up to one default application type can be set for a country. – Up to one default procedure type can be set for a country.
- Before a procedure type can be set as the default procedure type for a country, the country must be associated with the procedure type in data administration.
- Before an application type can be set as the default application type for a country, the country must be associated with the application type in data administration.
- A procedure type must be active in order to be set as the default procedure type for a country.
- An application type must be active in order to be set as the default application type for a country.

Country Value Attributes

Clicking the Country Values link in *Data Administration* displays the *Country* page, which lists all countries currently in the system. You can use the attributes to describe country values associated with an application.

Column	Description
Country Code	Country Code (<i>Country Code</i> values are also hyperlinks to the <i>Modify</i> window).
Country Name	Country Name.
eCTD Code	<i>eCTD code</i> for the Country.

Last User Updated	Indicates the name of the user who last created/updated the country value. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active Flag	Current Active/Inactive setting for the Country.

Health Authority Attributes

You can use the attributes to add Health Authority values to a Country in Data Administration.

Attribute	Description
Country Code	Code of a country for which this health authority is created.
Country Name	Name of a country for which this health authority is created.
Default Flag	Defines if this is the default health authority for a specified country.
eCTD Code	eCTD code of a country for which this health authority is created.
Health Authority Abbreviation	Abbreviation for the health authority. Example: FDA, EMA.
Health Authority Address	Health authority mailing address.
Health Authority eCTD Code	eCTD code of the health authority.
Health Authority Name	Name of a health authority for the specified country.
Health Authority Website	Website of the health authority.
Last User Updated	Name of the user who last made the change.
Last Changed Date	Date when the last change was made.
Active Flag	Indicates if the entity is active or inactive.
Organisation ID	The organisation identifier associated from SPOR Master Lists > Organisation.
Location ID	The location identifier associated from SPOR Master Lists > Organisation.
Attribute	Description
Manufacturer Name	The organisation name associated from SPOR Master Lists > Organisation.
Address	The address associated from SPOR Master Lists > Organisation.
City	The city associated from SPOR Master Lists > Organisation.
Post Code	The post code associated from SPOR Master Lists > Organisation.
Country	The country associated from SPOR Master Lists > Organisation.

Country Region Maintenance

You can associate country with a region, disassociate a region to which your country is associated, or modify the country region association from the *Country Attributes* page.

Note: The Region that belongs to the default region type (Regulatory Region, or IDMP) cannot be disassociated from a country.

To associate, disassociate, or modify a country region association:

1. Choose Go To > Data Administration.
2. Under Application Maintenance, click a link for Country Values.
3. Click a Country Code link to navigate to a needed Country.
4. On the *Country* attributes page, go to the Region tab:
 - To modify a country region association, go to step 5.
 - To associate a region, go to step 6.
 - To disassociate a region, go step 7.
5. Click the link for the value. Change the Region Type and Region values. Click Save.

The Region Type field is not available for modifications if the region is of the Regulatory Region or IDMP type.

6. Click Associate/Disassociate Region . Select the Region Type and Region values. Click Save.
7. Select the checkbox for the region you want to disassociate and click Associate/Disassociate Region. On the warning message that appears, click OK.



Note: The region values available for selection are those associated to a selected region type.

Region Attributes

You can use the attributes to associate a Region to your Country on the *view Country details* page. Required information is indicated by an asterisk (*).

Attribute	Description
Active Flag	Value from the Country to which this Region is associated.
Attribute	Description
Country Code	Country code value from the Country to which this Region is associated.
Country Name	Country name value from the Country to which this Region is associated.
eCTD Code	eCTD code value from the Country to which this Region is associated.
Region *	Region that is associated with this Country. Appears after the Region Type selection.
Region Type *	Region Type of the Region that is associated with this Country.

Country Region Maintenance

Associate a language that is used for a Country.

To associate a language to a country:

1. Go To > Data Administration.
2. Under Application Maintenance, click Country Values.
3. Click a Country Code link to navigate to a needed Country.
4. On the *Country* attributes page, click the Languages tab.
5. Click the Associate/Disassociate Language  icon.
6. Select the language.
7. Click Save.

Language Attributes

You can use the attributes to associate a language to a country on the *Country* attributes page.

Attribute	Description
Active Flag	Indicates if the country is active.
Country Code	Code of the country to which the language is associated.
Country Name	Name of the country to which the language is associated.
eCTD Code	eCTD code of an application for the country.
Language Name	The language that is associated to the country.
Last Changed Date	Date when the last change was made.
Last User Updated	Name of the user who last made the change.
Default Flag *	Indicates if the language is the default one for the country.

Assembly Maintenance

Assembly values appear in drop-down lists on the *Assembly Attributes* page and are designated when an assembly is created. Data administration enables you to add and modify drop-down list values, and set the status of a value to active or inactive.

When you select a value under Assembly, a page opens with a table of all values that have been defined. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

The proper data administration access privileges are required to view and modify assembly values.

Assembly Maintenance: Assembly Values

You can create and maintain the following assembly values:

Value	Description
Assembly Category	Clinical, non-clinical, submissions, etc.
Assembly DTD/Schema Type	us-2-01, ich-3-2, stf-2-2, etc. Note: When creating or modifying the Assembly DTD/Schema Type value, regions available for selection in the Region field are limited by those of a Regulatory Region type only.
Assembly Status	In draft, approved, suspended
Assembly Subcategory	Summary of clinical efficacy, clinical study report, drug master file, etc.

Assembly Category Attributes

To define an assembly category value, enter values for the following attributes:

Attribute	Description
Name	Category of assembly.
Last User Updated	Indicates the name of the user who last created/updated the assembly category. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Assembly DTD/Schema Type Attributes

To define an assembly DTD/Schema value, enter values for the following attributes:

Ennov InSight Administration 7.3 Assembly Maintenance

Attribute	Description
DTD Code	Name of the zip file supplied for the DTD. Example: CA-1-0.
URL	Hyperlink to the source DTD or XML Schema Definition (XSD) file, if available.
Region	All active Region values of the Regulatory Region type.
Countries	All countries for the selected regions.

eCTD 4.0 Template Mapping	Indicates the name of the eCTD 4.0 assembly template. You can select only one assembly template. The deleted eCTD 4.0 assembly template is automatically unassigned from all the <i>Assembly DTD/Schema Type</i> instances in Data Administration.
Last User Updated	Indicates the name of the user who last created/updated the assembly DTD/Schema. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Assembly Status Attributes

To define an assembly status value, enter values for the following attributes:

Attribute	Description
Name	The name given for the Assembly status.
Default Flag	Flag to indicate if the product status is the default. Yes and No values are available for selection.
Effective Status	Effective Status. Yes and No values are available for selection.
Last User Updated	Indicates the name of the user who last created/updated the assembly status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Assembly Subcategory Attributes

To define an assembly subcategory value, enter values for the following attributes:

Ennov InSight Administration 7.3 Assembly Maintenance

Attribute	Description
Category	The subcategory given for the Assembly.
Name	Subcategory name.

Last User Updated	Indicates the name of the user who last created/updated the assembly subcategory. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Assembly Variable Maintenance

Variables are numeric or string values that may change throughout an assembly in Ennov InSight . The four types of variables are:

- Assembly repository variables
- Assembly system defined variables — Assembly user defined variables
- Ennov InSight assembly variables

Additional assembly user defined variables may be defined at the assembly level in publishing settings, and these may be defined separately for each output channel.

Variable Formatting

In an assembly, the variable name is formatted with a delimiter, such as \$VARIABLE or \${VARIABLE}. The \${VARIABLE} form is required if there is no space between the variable and any literal text that follows, such as: \$ {VNAME}, pg \$VR.

Because only documents are mapped from a repository, the variable is resolved by using the current assembly as the starting point for its definition and searching down through the tree until it finds a bound document of the correct doctype, or by searching up to the first parent.

Variables are resolved in a leaf element to the first assigned document, and the publishing elements search for their parent and resolve from there. If the publishing element is not assigned to a document, it should follow the rules for searching the tree (as described above).

In a publishing template file (overlay, cover page), the variable name is formatted with an angle bracket delimiter, for example: <VARIABLE>. This can be used in overlay or cover page templates. The variable is resolved by using the current assembly as the starting point for its definition. These variables are not resolved in the body matter or content of the output, but only on the cover page and on the overlay.

Note: The variable code cannot contain spaces. However, spaces are permitted between the variable code and the delimiters.

Assembly Repository Variables

Assembly repository variables are used to pull document attributes from the repository for use in a submission.

For example, the repository author variable returns the value for the mapped *author name* of the source documents bound to the assembly. Assembly repository variables are set up and maintained in data administration.

When you create an assembly repository variable, keep in mind the following:

- If you enter a value for Repository Attribute Name but not for Document Type, the variable resolves to the closest assigned repository document in the assembly. The variable resolves to the value of the repository attribute name that matches the name you enter.
- If you enter values for both Repository Attribute Name and Document Type, the variable resolves to the closest assigned repository document in the assembly that matches the document type you enter. Once that document is found, the variable resolves to the value of the *repository attribute name* defined in that document type that matches the name you enter.

Assembly Repository Variable Attributes

You can use the attributes to describe the assembly repository variables.

Attribute	Description
Description	Free form text that helps describe the value.
Document Type	Identifies the type of object for which this variable should be used. For example: dm_object.
Variable Code	Ennov InSight code for the variable. When used in Ennov InSight for XML or paper publishing resolution, this code, prefaced by a \$, is used. When included in an overlay or cover page document, this code is surrounded by angle brackets (<, >). Cannot include spaces. Examples: Duration, Route, and Species.
Variable Name	A descriptive name to identify the variable in Ennov InSight . Examples: LL_Duration, LL_Route, LL_Species, DM_Duration, DM_Route and DM_Species.
Variable Value	Name of the attribute as it is displayed in the DMS repository interface. It should not include category information for OpenText repository variables. Examples: eCTD_Duration, eCTD_Route_of_Administration, and eCTD_Species.

Assembly Repository Variable Values

You can use the variables to automatically insert assembly repository data into your document.

Variable Name	Variable	Document Type	Repository Attribute	Description	Active Flag

	Code				
Repository Author	RSA	null	Author	The author of the mapped document; repeating attribute; returns a comma delimited list	Active
Repository Subject	RSS	null	Subject	The subject of the mapped document	Active

Configure Ennov InSight Repository Variables

Use this procedure to create repository variables in Ennov InSight . To

create repository variables:

1. In Ennov InSight , go to *Data Administration*.
2. Click Assembly Repository Variables.
3. For each repository server attribute that you would like to use, create a new repository variable. a) Click the Create icon. 
 - a. Populate the fields.
 - b. Click Save.

The new variable appears on the *Assembly Repository Variables* page.

4. Update the propertyMappings.xml file on the Ennov InSight application server.

Assembly System-Defined Variables

Assembly system-defined variables are preconfigured in Ennov InSight . While you can change the name of a systemdefined variable, the value to which the variable resolves cannot be changed. System-defined variables resolve to values calculated during publishing or prepare for publishing.

InSight System-Defined Variables

Ennov InSight uses system-defined variables to automatically insert data into documents.

The following descriptions are relevant to a number of the variables in this table:

Word/Phrase	Description
Division	Divisions, like Volumes, function independently from the assembly folder hierarchy.
Major Division	A Major Division starts at a folder marked as a Major Division and ends at the next folder marked as a Major Division, regardless of its position in the folder structure.
Minor Division	A Minor Division starts at a folder marked as a Minor Division and ends at the next folder marked as a Minor Division or Major Division, regardless of its position in the folder structure.

Word/Phrase		Description		
Publishing time variables		Publishing time variables can be stamped only on: cover pages and overlays, published tabs (not preview), TOC right column text, paper cross-reference link text. They cannot be used within other variables.		
Paper Publishing time variables		Publishing time variables that are available during a paper channel publish only.		
Variable Name	Variable Code	Description	Active Flag	Constraints
Abbreviated Major Division Name	MABBR	The Abbreviated Name attribute defined on the folder element in the assembly that has been selected to be a major division. For eCTD, this is an abbreviated form of the eCTD module name (Qual.). For other submission types, this is the Item.	Active	There must be major division folder assigned somewhere above the ancestor tree, with a nonblank abbreviated name.
Abbreviated Minor Division Name	NABBR	The Abbreviated Name attribute defined on the folder element in the assembly that has been selected to be a minor division. For eCTD, this is an abbreviated form of the eCTD section name (Drug Prod). For other submission types, this is the section.	Active	There must be minor division folder assigned somewhere above the ancestor tree, with a nonblank abbreviated name.
Assembly Name	ANAME	The name of the assembly as defined by the user.	Active	
Assembly Relative Major Division Number	ARM	Major divisions number relative to the assembly.	Active	Publishing time variable. There must be major division folder assigned somewhere above the ancestor tree, with a non-blank number.
Assembly Relative Page	ARP	Page number in the paper channel relative to the entire assembly.	Active	Publishing time variable.
Assembly	ARE	Page number in the electronic channel relative to the entire assembly.	Active	Publishing time variable.

Relative Page				
Variable Name	Variable Code	Description	Active Flag	Constraints
Assembly Relative Volume Number	ARV	The volume count relative to the current assembly.	Active	Paper Publishing time variable. Must be within a defined volume.
Assembly Total Major Divisions	ATM	Total major divisions in assembly.	Active	Publishing time variable.
Assembly Total Pages	ATP	The total number of paper channel pages in the assembly.	Active	Publishing time variable.
Assembly Total Pages	ATE	The total number of electronic channel pages in the assembly.	Active	Publishing time variable.
Blank	BL	A blank character, used to resolve a variable to a blank.	Active	
Current Date	CD	Current date and time.	Active	Current date {CD} will not work for \$DATETIME patterns. Use Current time {CT} to produce equivalent results.
Current Document Version	DV	Current document version.	Active	Must be used on a document assigned from a DMS repository (no filesystem).

Current Time	CT	Current date and time.	Active	Must be used within the date format function \$DATETIME.
Document Name	DNAME	The Name attribute defined on the document element in the assembly.	Active	Must be used somewhere under a document that has a defined name.
Document Number	DN	The Number attribute defined on the document element in the assembly.	Active	Must be used somewhere under a document that has a defined number.

Variable Name	Variable Code	Description	Active Flag	Constraints
Document Relative Page	DRP	Page number in the paper channel relative to the current document (including TOC and cover pages that are included in page numbering).	Active	Publishing time variable.
Document Relative Page Number	DRE	Page number in the electronic channel relative to the current document (including TOCs and cover pages that are included in page numbering.	Active	Publishing time variable.
Document Total Pages	DTE	The total number of electronic channel pages in the current document.	Active	Publishing time variable.
Document Total Pages	DTP	The total number of paper channel pages in the current document.	Active	Publishing time variable.
Element Abbreviated Name	ABBR	The current element abbreviated name. For Volume and Page Marker entities, ABBR resolves to the NAME of the entity.	Active	There must be a defined, abbreviated name on the current element. For a TOC or Tab, this resolves to the Abbreviated Name (or NAME) of the entity where the special sheet is attached.

Element Name	NAME	The current element name.	Active	There must be a defined name on the current element. For a TOCs or Tab, this resolves to the NAME of the entity where the special sheet is physically located. Cover Pages resolve to the NAME field attribute on the Cover Page entity. If no value is entered in the NAME field attribute of the Cover Page, this variable is not resolved.

Variable Name	Variable Code	Description	Active Flag	Constraints
Element Number	N	The current element number. Page Markers do not have a Number Attribute.	Active	There must be a defined number on the current element. For a TOC or Tab, this resolves to the NUMBER of the entity where the special sheet is attached. N does not resolve on Cover Pages.
Element Title	TITLE	The current element title. For Volume, Folder, and Page Marker entities, TITLE resolves to the NAME of the entity.	Active	There must be a defined TITLE on the current element. For a Tab, this resolves to the TITLE (or NAME) of the entity where the Tab is attached.

				For a TOC, this resolves to the TITLE field on the TOC entity (from the TOC attributes). The TITLE variable does not resolve for Cover Pages.
File Relative Page Number	FR	Page number relative to the current assigned file (TOC or cover page); or portion of a document between any special sheet or volume. Does not include any publication elements such as TOC or cover page.	Active	Publishing time variable.
File Total Pages	FT	Total number of pages in the current assigned file (TOC or cover page); or portion of a document between any special sheet or volume.	Active	Publishing time variable.

Variable Name	Variable Code	Description	Active Flag	Constraints
Leaf Abbreviated Name	LABBR	The abbreviated name on the current leaf.	Active	Will work on any element assigned under a leaf.
Leaf Name	LNAME	The Name attribute defined on the leaf element in the assembly.	Active	Will work on any element assigned under a leaf.
Leaf Number	LN	The Number attribute defined on the leaf element in the assembly.	Active	Will work on any element assigned under a leaf.
Leaf Output File Path	LOP	Actual output path of the leaf parts may be overridden by user but in general this is calculated; path should be the relative path starting at the publish destination (minus the application and sequence number), for example coverletter.pdf path would be ./M1/US/ and the	Active	Will work on any element assigned under a leaf.

		path and file name would be ./M1/US/cover-letter.pdf		
Leaf Output File-name	LOF	Actual output file of leaf determined by user but also may be calculated at publishing time	Active	Will work on any element assigned under a leaf.
Leaf Relative Page	LR	Page number in the electronic channel relative to the current leaf. This variable numbers electronic channel pages only.	Active	Publishing time variable. Will work on any element assigned under a leaf.
Leaf Total Pages	LT	Total number of pages contained in the leaf. This variable totals electronic channel pages only.	Active	Publishing time variable. Will work on any element assigned under a leaf.
Major Division Name	MNAME	The Name attribute defined on the folder element in the assembly that has been selected to be a major division. For eCTD, this is the eCTD module name (Quality). For other submission types, this is the Item.	Active	There must be major division folder assigned somewhere above the ancestor tree, with a nonblank name.

Variable Name	Variable Code	Description	Active Flag	Constraints
Major Division Number	MN	The Number attribute defined on the folder element in the assembly that has been selected to be a major division. For eCTD, this is the eCTD module number (3). For other submission types, this is the item.	Active	
Major Division Relative Minor Division	MRN	The count of the current minor division relative to the current major division.	Active	Publishing time variable. There must be both a major division folder and a minor division folder assigned somewhere above the ancestor tree.
Major Division Relative Page	MRP	Page number in paper channel relative to the current major division.	Active	Publishing time variable. There must be major division folder assigned somewhere

				above the ancestor tree.
Major Division Relative Page	MRE	Page number in the electronic channel relative to the current major division.	Active	Publishing time variable. There must be major division folder assigned somewhere above the ancestor tree.
Major Division Relative Volume Number	MRV	The current volume number relative to the current major division.	Active	Paper Publishing time variable. There must be a volume defined, and there must be major division folder assigned somewhere above the ancestor tree.

Variable Name	Variable Code	Description	Active Flag	Constraints
Major Division Total Minor Divisions	MTN	The total minor divisions in the current major division.	Active	Publishing time variable. There must be both a major division folder and a minor division folder assigned somewhere above the ancestor tree.
Major Division Total Pages	MTP	Total number of paper channel pages contained in the major division.	Active	Publishing time variable. There must be major division folder assigned somewhere above the ancestor tree.
Major Division Total Pages	MTE	Total number of electronic pages contained in the major division.	Active	Publishing time variable. There must be major division folder assigned somewhere

				above the ancestor tree.
Major Division Total Volumes	MTV	The total volumes in the current major division.	Active	Paper Publishing time variable. There must be a volume defined, and there must be major division folder assigned somewhere above the ancestor tree.
Minor Division Name	NNAME	The Name attribute defined on the folder element in the assembly that has been selected to be a minor division. For eCTD, this is the eCTD section name (Drug Product). For other submission types, this is the section.	Active	There must be minor division folder assigned somewhere above the ancestor tree, with a nonblank name attribute.

Variable Name	Variable Code	Description	Active Flag	Constraints
Minor Division Number	NN	The Number attribute defined on the folder element in the assembly that has been selected to be a minor division. For eCTD, this is the eCTD section (3.2.P). For other submission types, this is the section.	Active	There must be a major division folder assigned somewhere above the ancestor tree, with a nonblank number attribute.
Minor Division Relative Page	NRE	Page number in the electronic channel relative to the current minor division.	Active	Publishing time variable. There must be major division folder assigned somewhere above the ancestor tree.
Minor Division Relative Page	NRP	Page number in the paper channel relative to the current minor division.	Active	Publishing time variable. There must be major division folder assigned somewhere

				above the ancestor tree.
Minor Division Relative Volume Number	NRV	The current volume number relative to the current minor division.	Active	Paper Publishing time variable. There must be a volume defined, and there must be minor division folder assigned somewhere above the ancestor tree.
Minor Division Total Pages	NTE	Total number of electronic channel pages contained in the minor division.	Active	Publishing time variable. There must be major division folder assigned somewhere above the ancestor tree.
Minor Division Total Pages	NTP	Total number of paper channel pages contained in the minor division.	Active	Publishing time variable. There must be major division folder assigned somewhere above the ancestor tree.

Variable Name	Variable Code	Description	Active Flag	Constraints
Minor Division Total Volumes	NTV	The total volumes in the current minor division.	Active	Paper Publishing time variable. There must be a volume defined, and there must be minor division folder assigned somewhere above the ancestor tree.
Referenced Leaf	RLAC	For a Reference Leaf, this is the Application Code of the Application containing the referenced leaf.	Active	

Application Code				
Referenced Leaf Leaf Name	RLLNAME	For a Reference Leaf, this is the Name attribute defined on the Leaf element of the referenced leaf.	Active	Will work on any element assigned under a leaf.
Referenced Leaf Major Division Name	RLMNAME	For a Reference Leaf, this is the Name attribute defined on the Folder element containing the referenced leaf that has been selected to be a major division. For eCTD, this is the eCTD module name (Quality), for other submission types, this is the Item.	Active	There must be major division folder assigned somewhere above the ancestor tree, with a nonblank name.
Referenced Leaf Major Division Number	RLMN	For a Reference Leaf, this is the Number attribute defined on the Folder element containing the referenced leaf that has been selected to be a major division. For eCTD, this is the eCTD module number (3), for other submission types, this is the Item.	Active	
Referenced Leaf Minor Division Name	RLNNAME	For a Reference Leaf, this is the Name attribute defined on the Folder element containing the referenced leaf that has been selected to be a minor division. For eCTD, this is the eCTD section name (Drug Product), for other submission types, this is the section.	Active	There must be minor division folder assigned somewhere above the ancestor tree, with a nonblank name attribute.

Variable Name	Variable Code	Description	Active Flag	Constraints
Referenced Leaf Minor Division Number	RLNN	For a Reference Leaf, this is the Number attribute defined on the Folder element containing the referenced leaf that has been selected to be a minor division. For eCTD, this is the eCTD section (3.2.P), for other submission types, this is the section.	Active	There must be major division folder assigned somewhere above the ancestor tree, with a nonblank number attribute.

Referenced Leaf Sequence Number/Code	RLSC	For a Reference Leaf, this is the Sequence Number/Code of the Sequence containing the referenced leaf.	Active	
Referenced Leaf Volume Number	RLVN	For a Reference Leaf, this is the Volume Number found on the Volume element containing the referenced leaf which is set by volumization.	Active	
Source Filename	DFNAME	The source file name according to the assigned document.	Active	Must be under an assigned document.
Space	SP	A single-space character, used to buffer other values or to resolve a variable to a blank. Inserts a Space into a variable string, which are normally removed from the beginning and end of evaluated variables.	Active	
Total Volumes	ATV	The total number of volumes in the assembly.	Active	Paper Publishing time variable
Volume Name	VNAME	The name of the current volume.	Active	Must be in a defined volume.
Volume Number	VN	Volume number found on volume element which is set by volumization.	Active	Must be in a defined volume.
Volume Relative Page	VR	Page number relative to the current volume. This variable numbers paper channel pages only.	Active	Paper Publishing time variable.
Volume Total Pages	VT	Total number of pages contained in the volume. This variable totals paper channel pages only.	Active	Paper Publishing time variable.

Assembly System-defined Variables Attributes

You can use these attributes to describe the assembly system defined variables.

Attribute	Description
Variable Name	Name of System Variable used. Examples: Abbreviated Major Division Name, Assembly Relative Page.

Last User Updated	Defines by whom the Data Administration value was created. By default, this option is read-only.
Last Changed Date	Defines when the Data Administration value was created. By default, this option is read-only.
Active	Indicates if the entity is active or inactive.

Ennov InSight Assembly Variable Values

You can define variables for Ennov InSight Assemblies in Data Administration.

The table lists all the variables that you can define for assemblies.

Variable Name	Variable Code	Last User Updated	Last Changed Date	Description	Active Flag
Application Code	IAC	Username	d-m-y	Application code	Active
Application Internal Code	IIC			Application internal code	Active
Application Keywords	IAK			Application keywords	Active
Application Language	IAL			Application language	Active
Application Name	IAN			Application name	Active
Application Procedure Type	IPT			Application procedure type	Active

Application Type	IAT			Application type	Active
Assembly Category	IASC			Assembly category	Active
Assembly Keywords	IASK			Assembly keywords	Active

Variable Name	Variable Code	Last User Updated	Last Changed Date	Description	Active Flag
Assembly Name	INA			Assembly name	Active
Assembly Status	IASS			Assembly status	Active
Assembly Sub-category	IASSC			Assembly sub-category	Active
Country Name	ICN			Country name	Active
Country Regulatory Authority	ICA			Country regulatory authority	Active
Event Code	IEC			Event code	Active
Event Keywords	IEK			Event keywords	Active
Event Name	IEN			Event name	Active
Event	IER			Event sequences	Active

Sequences					
Event Type	IET			Event type	Active
Event Variation Number	IEV			Event variation number	Activ
Product Dosage Form	IPF1			Product dosage form	Active
Product Family Code	IPC			Product family code	Active
Product Family Name	IPN			Product family name	Active
Product Name 1	IP1			Product name 1	Active
Product Name 2	IP2			Product name 2	Active
Sequence Keywords	ISK			Sequence key-words	Active
Sequence Name	ISN			Sequence name	Active
Variable Name	Variable Code	Last User Updated	Last Changed Date	Description	Active Flag
Sequence Number/	ISC			Sequence number/code	Active

Code					
Sequence Status	ISS			Sequence sta- tus	Active
Sequence Sta- tus Date	ISD			Sequence status date	Active
Sequence Submission Filing Type	ISF			Sequence sub- mission filing type	Active

Assembly User-Defined Variables

User-defined variables may be added and modified in your project:

- By a publisher at the assembly level using Publishing Settings > Variables
- By a data administrator using Go To > Data Administration

At the assembly level, you can specify that a user-defined variable is used for the paper channel or the electronic output channel. If you want to use the same variable for both channels, you can define the same variable for each channel.

A user-defined variable you create at the assembly level must be unique so it does not conflict with a variable that is established in Data Administration. You can redefine a Data Administration-level user-defined variable to create an assembly-level user-defined variable. Assembly-level variables override Data Administration-level variables during publishing.

User-defined Variable Values

You can define the value for specific variables.

Variable Name	Variable Code	Variable Value	Description	Active Flag	Variable Type
Company Name	UCN	Company Name	Company name	Active	Single-line variable
Volume Name For- mula	VOLNAME	V\$Bates(\$VN, 6)		Active	Single-line variable

Assembly User-defined Variables Attributes

You can use these attributes to describe the assembly user defined variables.

Attribute	Description
Variable Name	A variable name. Example: <i>Company Name</i> .
Attribute	Description
Variable Code	The code for the variable. This is what will be used in a TOC, overlay, and elsewhere to refer to this variable.
Variable Value	Value which will replace the variable code in the output.
Variable Type	Defines the type of the variable. Possible values: Single-Line Variable, Multi-Line Variable.
Description	Description of the variable.
Last User Updated	Defines by whom the Data Administration value was created. By default, this option is read-only.
Last Changed Date	Defines when the Data Administration value was created. By default, this option is read-only.
Active	Indicates if the entity is active or inactive.

Ennov InSight Assembly Variables

Ennov InSight assembly variables resolve to attribute values stored in Ennov InSight , such as application name and assembly status. They are calculated during publishing or prepare for publishing.

Ennov assembly variables are preconfigured in Ennov InSight and cannot be modified in Data Administration. However, they can be reconfigured by the Ennov consulting organization.

Ennov InSight Assembly Variables Attributes

You can use these attributes to describe the Ennov InSight assembly variables.

Attribute	Description
Variable Name	A variable name.
Variable Code	The code for the variable. This is what will be used in a TOC, overlay, and elsewhere to refer to this variable.
Variable Value	Value which will replace the variable code in the output.
Variable Type	Defines the type of the variable. Possible values: Single-Line Variable, Multi-Line Variable.
Description	Description of the variable.

Last User Updated	Defines by whom the Data Administration value was created. By default, this option is read-only.
Last Changed Date	Defines when the Data Administration value was created. By default, this option is read-only.
Active	Indicates if the entity is active or inactive.

Ennov InSight Assembly Variable Values

You can define variables for Ennov InSight Assemblies in Data Administration.

The table lists all the variables that you can define for assemblies.

Variable Name	Variable Code	Last User Updated	Last Changed Date	Description	Active Flag
Application Code	IAC	Username	d-m-y	Application code	Active
Application Internal Code	IIC			Application internal code	Active
Application Keywords	IAK			Application keywords	Active
Application Language	IAL			Application language	Active
Application Name	IAN			Application name	Active
Application Procedure Type	IPT			Application procedure type	Active

Application Type	IAT			Application type	Active
Assembly Category	IASC			Assembly category	Active
Assembly Keywords	IASK			Assembly keywords	Active
Assembly Name	INA			Assembly name	Active
Assembly Status	IASS			Assembly status	Active
Assembly Sub-category	IASSC			Assembly sub-category	Active
Country Name	ICN			Country name	Active
Country Regulatory Authority	ICA			Country regulatory authority	Active

Variable Name	Variable Code	Last User Updated	Last Changed Date	Description	Active Flag
Event Code	IEC			Event code	Active
Event Keywords	IEK			Event keywords	Active
Event Name	IEN			Event name	Active
Event	IER			Event sequences	Active

Sequences					
Event Type	IET			Event type	Active
Event Variation Number	IEV			Event variation number	Activ
Product Dosage Form	IPF1			Product dosage form	Active
Product Family Code	IPC			Product family code	Active
Product Family Name	IPN			Product family name	Active
Product Name 1	IP1			Product name 1	Active
Product Name 2	IP2			Product name 2	Active
Sequence Keywords	ISK			Sequence key-words	Active
Sequence Name	ISN			Sequence name	Active
Sequence Number/Code	ISC			Sequence number/code	Active
Sequence	ISS			Sequence status	Active

Status					
Sequence Status Date	ISD			Sequence status date	Active
Sequence Submission Filing Type	ISF			Sequence submission filing type	Active

Change Maintenance

Change Maintenance values appear in drop-down lists on the *Change Attributes* page and are designated when you assign a document to an assembly. Data Administration enables you to add and modify drop-down list values, and to set the status of a value to active or inactive.

When you select a value under Change Maintenance, a page opens with a table of all values that have been defined. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

Note: The proper data administration access privileges are required to view and modify Change Maintenance values.

Change Maintenance: Application Values

You can create and maintain the following application values:

Value	Description
Change Type	Values - the type of the change. For example, Manufacturing Change, Labeling Change, etc.
Event-Change Detail Status	Values - the status of the change detail within an event.

Change Type Attributes

To define a change type value, enter values for the following attributes:

Attribute	Description
Change Type Name	User defined name of the Change Type.
Last User Updated	Indicates the name of the user who last created/updated the change type value. By default, this option is read-only. It is populated automatically when updates were made to the table.

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Event-Change Detail Status Attributes

To define an event - change detail status value, enter values for the following attributes:

Attribute	Description
Name	User defined name of the Change Type.

Ennov InSight Administration 7.3 Change Maintenance

Attribute	Description
Default Flag	Flag to indicate if the Event-Change Detail Status is the default. Yes and No values are available for selection.
System Process Default Flag	Select which of the added statuses will show for an Event-Change Detail status after the Event is closed.
Internal System Status	The internal status associated to the Event-Change Status. The list of internal statuses are : PLANNED, SUBMITTED, APPROVED, NOT APPROVED, and WITHDRAWN.
Last User Updated	Indicates the name of the user who last created/updated the eventchange detail status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Custom Lists Maintenance

Ennov InSight enables you to maintain the lists of custom values to configure additional entity attributes. You can add and modify lists, and set the status of a value to active or inactive from Data Administration.

Note: You must have appropriate Data Administration access privileges to create and maintain custom list maintenance values.

You can create and maintain the following values:

- Custom List Names - The name of the list that contains custom values.
- Custom List Values - The values in the custom lists.

Custom Lists Maintenance: Custom Lists Values

You can create and maintain the following custom lists values:

Custom List Value	Description
Custom List Names	The name of the list the value belongs to.
Custom List Values	The name of the list value.

Custom List Name Attributes

To define a custom list name value, enter values for the following attributes:

Ennov InSight Administration 7.3 Custom Lists Maintenance

Attribute	Description
List Name	The name of the list the value belongs to.
Force Default Flag	Defines if the default of value will be enforced in the custom list. Yes and No values are available for selection.
Last User Updated	Indicates the name of the user who last created/updated the custom list name. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Custom List Value Attributes

To define a custom list value, enter values for the following attributes:

Attribute	Description
List Name	The name of the list the value belongs to. Values available for selection are all active values from the Data Administration Custom List Names.
List Value	The name of the list value.
Default Flag	Flag to indicate if the value is the default one in the list. Yes and No values are available for selection.
Last User Updated	Indicates the name of the user who last created/updated the custom

	list value. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

DMS Integration

Document management system (DMS) integration values appear in drop-down lists on the *Document Attributes* page and are designated when you assign a document to an assembly. Data Administration enables you to add and modify drop-down list values, and to set the status of a value to active or inactive.

When you select a value under DMS Integration, a page shows a table of all values that have been defined. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

Note: *The proper data administration access privileges are required to view and modify DMS integration values.*

For documents assigned to SharePoint in Ennov InSight, you cannot change the Label or Status attributes and can only bind to the file version. SharePoint supports minor and major file versions, but does not support labels and statuses.

For Veeva documents, binding to a label is supported only when the label is set to CURRENT. Veeva does not use labels. When the label is set to CURRENT, the latest version of the document is used.

DMS Integration Values

Data Administration lets you to add and modify DMS values and attributes for: bind to label name, bind to status, and rendition identifier.

You can create and maintain the following DMS values:

Value	Description
Bind to Label	DMS documents assigned to an assembly are bound to their label
Bind to Status	DMS documents assigned to an assembly are bound to their status
Rendition Identifier Values	Rendition identifier values for Veeva and Documentum

Bind to Label Name Attributes

To define a bind to label name value, enter values for the following attributes:

Attribute	Description
Bind to Label Name	Name of the label used.

Last User Updated	Indicates the name of the user who last created/updated the bind label name. By default, this option is read-only. It is populated automatically when updates are made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates are made to the table.
Active	Indicates if the entity is active or inactive.

Bind to Status Attributes

To define a bind to status value, enter values for the following attributes:

Attribute	Description
Bind to Status Name	The name given for the Bind to Status. Examples: Approved, In Approval, In Draft, In Review, NONE
Attribute	Description
Last User Updated	Indicates the name of the user who last created/updated the bind status. By default, this option is read-only. It is populated automatically when updates are made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates are made to the table.
Active	Indicates if the entity is active or inactive.

Rendition Identifier Attributes

To define a rendition identifier value, enter values for the following attributes:

Attribute	Description
Rendition Identifier Name	The display name for the PDF Rendition Identifier.
Last User Updated	Indicates the name of the user who last created/updated the rendition identifier. By default, this option is read-only. It is populated automatically when updates are made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates are made to the table.
Active	Indicates if the entity is active or inactive.

Maintaining DMS Integration Values

Add a DMS Integration Value

You can add and modify DMS integration values, and set the status of a value to active or inactive, in Data Administration.

1. Choose Go To > Data Administration.
2. Under DMS Integration, click the link for which you want to add a value: — Bind to Label Values
— Bind to Status Values — Rendition Identifier Values
3. Click the Create icon.
4. Type the bind to label *name*, bind to status *name*, or rendition identifier *name*.
5. Save.

If you are adding a bind to label value or a bind to status value, do not perform the remaining steps in this procedure.

If you are adding a rendition identifier value, perform the remaining steps.

6. Click the rendition identifier *name* of the rendition identifier that you are creating.
7. Under Rendition Identifier Values, click the Create icon.
8. For Rendition Identifier Value, type the *value*.

Note: For Veeva, the value must match exactly an internal rendition name that Veeva generated from a rendition type that a Veeva administrator entered.

Note: For Documentum, the value must match the *page_modifier* attribute.

9. Click the server *type*.

Note: For each rendition name, for each server type only one rendition identifier value can be active at a time.

10. Save.

Modify a Bind to Label or Bind to Status Value

1. Choose Go To > Data Administration.
2. Under DMS Integration, click the link for the kind of value that you want to modify:

Option	Action
Bind to Label Values	Modifies the label values.
Bind to Status Values	Modifies the status values.

3. Click the bind to label *name* or bind to status *name*.
4. Do either of the following:

Action	Description

Change the <i>name</i> , and click Save.	The name value will be changed and saved.
Click Activate or Deactivate.	The value will be activated or deactivate.

Modify a Rendition Identifier Value

Data Administration lets you to add and modify DMS values and attributes for: bind to label name, bind to status, and rendition identifier.

To modify a rendition identifier value:

1. Choose Go To > Data Administration.
2. Under DMS Integration, click Rendition Identifier Values.
3. Click the rendition identifier *name*.
4. Do one of the following:

Action	Description
To change the rendition identifier name:	Click Edit and Save.
Note: For a Veeva or Documentum repository, you cannot change the name Standard Rendition.	
To activate or deactivate Rendition Identifier Value:	Under Rendition Identifier Values, click the value that you want to modify. Click Activate or Deactivate. Note: For each rendition name, for each server type only one rendition identifier value can be active at a time. For a Veeva or Documentum repository, you cannot deactivate rendition identifier values for the rendition named Standard Rendition. Additional PDF rendition formats can be defined in Ennov InSight configuration to trust them as PDFs. The additional renditions must comply to the PDF standard.

How Rendition Identifier Values Are Used

You can specify the rendition identifier value for a non-default rendition to be used for publishing jobs. You can set this value in Publishing Settings Library Templates (PLT) and Assembly Specific Publishing Settings Libraries (APL). On the Publishing Settings tab, the Default Rendition Identifier option lists the rendition identifier values configured in Data Administration. See *Publishing Settings* in Liquent InSight Publisher.

Rendition Identifiers are also used for Registration Attachment entities. When the value is set on the *Registration Attachment Attributes* page, it enables the use of the existed rendition file in DMS, instead of the source file, during the submission creation via the *XEVMPD Submission wizard*.

Note: *It is recommended that you do not use the same rendition identifier for two different document formats for Documentum rendition.*

Create Publishing Settings

In the selected Publishing Settings Library, you can create or modify the Publishing Settings to adjust printer output settings and XML definitions.

This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).

1. On the *Publishing Settings Library* window, select Publishing Settings .
2. Click Create: .
3. On the *Create Publishing Settings* page, use the drop-down lists to choose the following required settings:

- Printer
- Paper Size and Type
- Tab Paper Size and Type
- Preview Location (Click Browse to locate and select the location.)

4. Complete the remaining fields as needed:

- XML Definitions
- Default Rendition Identifier
- Missing Rendition Identifier Handling
- In-Process Rendition Location (Click Browse to locate and select the location.)
- TOC Destination Not Found Text
- Cross-Reference Destination Not Found Text
- Expand Bookmarks to Level
- PDF Version for Published Output
- Optimize Fonts in Paper Output

Note: *Ennov InSight includes functionality to specify the rendition identifier to allow for a non-default Documentum or*

Veeva rendition to be used for publishing jobs. This value can be set in Publishing Settings Library Templates (PLT) and

Assembly Specific Publishing Settings Libraries (APL). On the Publishing Settings tab, the option Default Rendition Identifier lists the values configured using the DMS Integration Rendition Identifier Values in Data Administration. See Maintaining a DMS Integration Value.

5. To save the new Publishing Settings, Save. To discard the changes, Cancel.

Rendition Identifier Values Attributes

You can use the attributes to associate a Region to your Country on the *view Country details* page. Required information is indicated by an asterisk (*).

Attribute	Description
Rendition Identifier Value	Rendition identifier values for Veeva and Documentum.
Rendition Identifier Name	The display name for the PDF Rendition Identifier.
Server Type	Indicates the Server Type.
Attribute	Description
Last User Updated	Indicates the name of the user who last created/updated the bind status. By default, this option is read-only. It is populated automatically when updates are made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates are made to the table.
Active Flag	Value from the Country to which this Region is associated.

Create Veeva Rendition Types and Obtain Veeva Rendition Names

In Veeva, an administrator creates rendition types for document renditions. If the rendition type is for a custom, nonstandard rendition, the administrator can add the rendition type to a document. The administrator can also add a standard rendition type to a document type, if the standard rendition type is not by default added to all standard document types.

To create a rendition type and obtain the rendition name that will use:

1. In the Veeva vault, if the rightmost item on the bar is Admin, click Admin.
2. On the bar, click Configuration.
3. On menu on the left, under DOCUMENT SETUP, click Rendition Types.
4. In the top-right area of the *Rendition Types* page, click Create.

5. On the *Create Rendition Type* page, for Rendition Type type parexel.

Note: *Rendering requires the rendition type parexel in the Veeva Vault repository that Rendering connects to.*

Rendering uses this rendition type to reference the standard rendition.

6. Click Save.
7. To obtain the rendition name that Veeva generates from the rendition type, call Veeva Support.

Note: *Veeva generates a unique rendition name from each rendition type. The rendition identifier values that you create in Rendering Administration must match the rendition names that Veeva generates.*

Note the following:

- Editing a rendition type does not change the generated rendition name.
- Deleting a rendition type does not delete the generated rendition name.
- Recreating a deleted rendition type creates a new rendition name, not the name generated from the rendition type before the rendition type was deleted. If you recreate a deleted rendition type, call Veeva Support to get the new rendition name.

Add the Rendition Type to All Documents

To enable Ennov InSight Rendering users to access Veeva Vault documents that were in their Vault before your Veeva administrator created the Ennov InSight . Service user, assign the Ennov InSight rendition type to every document type in the vault.

1. If the rightmost item on the bar is Admin, click Admin.
2. On the bar, click Configuration.
3. On menu on the left, under DOCUMENT SETUP, click Document Types.
4. Assign the Ennov rendition type and give the Ennov InSight Service account Create Document Permission to every document type in the vault. For each document:
 - a. On the *Document Types* page, navigate to and point to the document type.
 - b. Click the arrow to the right of the document type, and click Edit Details.
 - c. On the *Edit Details* page, for Rendition Types click Ennov.
 - d. Click the Security link.
 - e. For Create Document Permission , click the arrow and add Ennov InSight Service. f) Click Save.

Note: *If you add a document type after performing the preceding procedure, remember to add the Ennov rendition type to the new document type.*

eCTD 4.0 Submission Maintenance

Use *eCTD 4.0 Submission Maintenance* to specify values for eCTD 4.0 Modules. Use the *eCTD 4.0 Submission Maintenance* pages to define: — CV Profile values

– Sender-defined Keyword values

When you click a type of value under eCTD 4.0 Submission Maintenance, a page shows a table of all defined values for that type. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

On the eCTD 4.0 Submission Maintenance values pages, you can set the status of a value to active or inactive.

eCTD 4.0 Submission Maintenance: eCTD 4.0 Submission Values

The following submission values can be created and maintained under eCTD 4.0 Submission Maintenance:

Value	Description
CV Profile	The values that eCTD 4.0 defines to describe controlled vocabulary profile.

Ennov InSight Administration 7.3 eCTD 4.0 Submission Maintenance

Value	Description
Sender-defined Keyword	The values that eCTD 4.0 users define to get better quality of the data entered.

CV Profile Attributes

To define an eCTD 4.0 controlled vocabulary profile, enter values for the following attributes:

Attribute	Description
CV Profile Name	Name of the controlled vocabulary profile.
Regions	Regions provided by controlled vocabulary service.
Version	Versions for the selected region.
Category	Category for selected version.
Specification Name	Name of the specification that defines the requirements by the agencies.
Specification OID	The object identifier of a specification is a sequence of numbers that uniquely identify the specification in the system.
Last User Updated	Indicates the name of the user who last created/updated the eCTD 4.0 controlled vocabulary profile. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

To define an eCTD 4.0 controlled vocabulary profile details, associate the CVs with the following attributes:

Table 1: CV Details Attributes

Attribute	Description
Name	Name of the controlled vocabulary provided by CV service.
Version	Version of the controlled vocabulary provided by CV service.
OID	Object identifier provided by CV service.
Can be associated?	Yes indicates that CV can be selected for association/disassociation.
Can be disassociated?	No indicates that CV cannot be associated/disassociated due to existing dependencies.

Sender-defined Keyword Attributes

To define an sender-defined keyword attributes, enter values for the following attributes:

Ennov InSight Administration 7.3 eCTD 4.0 Submission Maintenance

Attribute	Description
Code	Code of the keyword defined and referenced in eCTD 4.0 published output.
Display Name	Name of the sender-defined keyword mapped to the code in eCTD 4.0 published output.
Last User Updated	Indicates the name of the user who last created/updated the PDF properties. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Event Maintenance

Event values appear in selection lists on the *Event Attributes* page and are designated when an event is created. You can use Data Administration to add and modify event attribute values, and to set the status of a value to active or inactive.

When you select a value under Event Maintenance, a page opens with a table of all values that have been defined. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

Note: The proper data administration access privileges are required to view and modify event maintenance values.

Event Maintenance: Event Values

Ennov InSight lets you use Data Administration to add and modify Event values and attributes, and to set statuses on those attributes.

You can create and maintain the following Event values:

Value	Description
Action Type	Approval required before request is considered active, for example, implement without notification, notification after implementation, etc.
EU Grouping or Work-sharing	Identifies whether an event is part of a sharing or work group activity.
Event Status	For example, planned, in effect, in discussion, approved, refused, etc. Create event statuses before you create timeline/event plans.
Event Type	Regulatory action for example, original filing, variation type I, variation type II, supplement, etc. Create event types before you create secondary event types. Secondary event types can be associated only with existing event types.

Value	Description
PSUR Report Code	Abbreviation associated with the PSUR being reported on, for example: A = Authorized, AQ = Authorized with Qualifications, LA = Lack of Approval, V = Voluntary Marketing Application Withdrawn by Company, AR = Authorization Renewal
Secondary Event Type	Type of event based on the primary event type, for example, Change to Content of Manufacturing Authorization, Change in Name of Medicinal Product, Change in Name and/or Address of MAH for a primary event of Variation Type I.
Timeline/Event Plan Type	The type of timeline/event plan used to create or update an event. The timeline/ event plan type can be procedure type, event type, or none. An event created or updated by using the procedure type of timeline/plan has a sequence of statuses that are relevant to the procedure type selected for the event. An event created or updated by using the event type of timeline/event plan has a sequence of statuses that are relevant to the event type selected for the event. An event created or updated by specifying none for timeline/event plan type can have any sequence of active statuses.
Timeline/Event Plan	An ordered set of milestones that represent the progression of event statuses you expect to occur for an event.

Action Type Attributes

To define an action type value, enter values for the following attributes:

Attribute	Description
Name	The name of the action type. Examples: Notification before Implementation, Implement w/o Notification, Notification after Implementation.
Last User Updated	Indicates the name of the user who last created/updated the action type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

EU Grouping or Worksharing Attributes

To define a EU grouping or worksharing activity value, enter values for the following attributes:

Attribute	Description
EU Grouping or Worksharing	Values available for selectin to indicate Grouping or Worksharing activities on the Event entity.
Attribute	Description
Default Flag	Flag to indicate if the value is the default. Yes and No values are available for selection.
Last User Updated	Indicates the name of the user who last created/updated the EU grouping or worksharing value. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Event Status Attributes

To define an event status value, enter values for the following attributes:

Attribute	Description
Name	The name given for the Event Status. Examples: Approved, In Discussion, If Effect, In Review, Planned, Not Approved, Refused, Submitted, Despatched, Data Available, Day 0, Withdrawn.
Last User Updated	Indicates the name of the user who last created/updated the event

	status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Default Flag	Flag to indicate if the value is the default. Yes and No values are available for selection.
Internal System Status	The internal status associated to the PDS status. Examples: Submitted, Approved, Not Approved, Day 0, Data Available, Despatched and Withdrawn.
Active	Indicates if the entity is active or inactive.

Event Type Attributes

To define an event type value, enter values for the following attributes:

Attribute	Description
Name	The name of the event type. Examples: Original, Supplement, Amendment, Variation I, Variation II, Withdrawal, Annual Report, Resubmission, Pre-submission, Establishment Description Supplement, Efficacy Supplement, Labeling Supplement, CMC Supplement.
Last User Updated	Indicates the name of the user who last created/updated the event type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

PSUR Report Code Attributes

To define a PSUR report code value, enter values for the following attributes:

Attribute	Description
PSUR Report Code	Code/Abbreviation associated with the PSUR being reported on. Examples: A=Authorized, AQ=Authorized with Qualifications, LA = Lack of Approval, V= Voluntary marketing application withdrawn by company, AR=Authorization Renewal.

PSUR Report Code Name	Full Description of the Report Code.
Last User Updated	Indicates the name of the user who last created/updated the PSUR report code values. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Secondary Event Type Attributes

To define a secondary event type value, enter values for the following attributes:

Attribute	Description
Name	Secondary Level Events that are based on the Primary Event Type.
Primary Event	Primary Event Types.
Attribute	Description
Last User Updated	Indicates the name of the user who last created/updated the secondary event type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Timeline/Event Plan Type Attributes

To define a timeline/event plan type value, enter values for the following attributes:

Attribute	Description
Timeline/Event Plan Type	The type (event type, procedure type or none) that the Timeline/Event Plan is created from. Hyperlinked from the view screen.
Default Flag	Flag to indicate if the value is the default. Yes and No values are available for selection.
Last User Updated	Indicates the name of the user who last created/updated the timeline/event plan type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.

Active	Indicates if the entity is active or inactive.

Timeline/Event Plan Attributes

To define a timeline/event plan value, enter values for the following attributes:

Attribute	Description
Timeline/Event Plan Type	The type (event type or procedure type) that the Event Plan is created from.
Timeline/Event Plan Name	Name for the Event Plan.
Procedure Type	Procedure Types for which the milestones apply. All active external Procedure Types are available for selection.
Enforce Status Progression	Yes/No drop-down menu that determines if the status for the Event Plan should have progression enforced.
Event Statuses	The milestones/statuses that are applicable.
Attribute	Description
Optional Event Statuses	These are the optional statuses that the event might progress to that are not planned/expected for the event. Examples: Not Approved, Rejected etc.
Last User Updated	Indicates the name of the user who last created/updated the timeline/event plan. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Timeline/Event Plans and Country Lead Times

In Ennov InSight , a timeline/event plan is an ordered set of milestones that you define for an event. The ordered milestones in a timeline/event plan represent the progression of event statuses you expect to occur for an event. You have the option to apply a timeline/event plan when creating an event.

Note: The set of event statuses can vary depending on the regulatory action taking place or on the procedure type.

Country lead times is a feature that enables you to predefine a default interval of days on a per country basis for each event status in a timeline/event plan. The lead times are tracked in a table on the *Timeline/Event Plan* page that displays all of the event statuses per country in the order defined for the timeline/event plan.

You can create a timeline/event plan by using the *Timeline/Event Plan Wizard*.

Use the Create Timeline/Event Plan Wizard

You can create a timeline/event plan using the *Create Timeline/Event Plan* wizard.

Note: Access to the *Create Timeline/Event Plan* wizard is established in *Ennov InSight Security Administration*. In the *Home Page Access* section, the *Data Administration* option must be set to *Yes* for the user.

To create a timeline/event plan:

1. Start the *Create Timeline/Event Plan* wizard using one of the options:
 - Wizards > Create Timeline/Event Plan .
 - On the upper navigation pane, choose GO TO > Data Administration. Under Event Maintenance, click Timeline/Event Plan Values. Click the Create icon.
2. On the *Enter Timeline/Event Plan Details* page:
 - Select a timeline/event plan type.
 - Enter a timeline/event plan *name*.
 - Select the event type or procedure type.
 - Select the region type of the region, containing the countries for which you will use the timeline/event plan. — Select the region that belongs to the selected region type.
 - Select the countries for which you will use the timeline/event plan.
 - In the Enforce Status Progression field, select Yes or No. Enforcing a status progression limits the statuses an event country schedule can transition to. It is based on the progression setup in the timeline/event plan when the event was created.
 - Select the required event statuses for which you want to specify lead times in the timeline/event plan.
 - Optionally, select the optional event statuses for which you want to specify lead times in the timeline/event plan.
 1. Click Next.

The *Create Timeline/Event Plan Confirmation* page opens.
 2. Click Next.

The *Enter Lead Times Values* page opens.
 3. Enter a *lead time* for each event status.

To select a Lead Time field, double-click it.
 4. Click Next.

The *Create Timeline/Event Plan Lead Time Confirmation* page opens.
 5. Click Next.

The *Create Plan Summary* page opens.

Note: The timeline/event plan is a hyperlink to the created Timeline/Event Plan Attributes page.

6. Click Finish.

Prepare to Modify a Timeline/Event Plan

You can modify a timeline/event plan to change the progression of event statuses you expect to occur for an event. However, certain configurations must be performed before you modify a timeline/event plan. The configurations to be performed are:

- To use the *Change Approval* wizards with events created from a timeline/event plan, the Approved and Not Approved statuses must be included in the timeline/event plan.
- To use the *Change Submittal* wizards with events created from a timeline/event plan, the Submitted status must be included in the timeline/event plan.
- If you move an event status from the Event Statuses Selected multi-select box to the Event Statuses Available multi-select box for Event Statuses, and then move that same status from Event Statuses Selected to Event Statuses Available for Optional Event Statuses, an error message appears after you click Save. Instead, click Save immediately after moving the event status from Event Statuses Selected to Event Statuses Available for Event Statuses, and then resume modifying the timeline/event plan to move the event status from Event Statuses Selected to Event Statuses Available for Optional Event Statuses. Click Save again when you have completed your additional modifications.

Modify a Timeline/Event Plan

You can modify a timeline/event plan from the *Data Administration* page.

To modify an existing timeline/event plan:

1. In Ennov InSight, click Go To > Data Administration.
2. On the *Data Administration* page, under Event Maintenance, click Timeline/Event Plan Values.
3. On the *Timeline/Event Plan* main page, click the link for the timeline/event plan that you want to modify.
4. Click the Edit icon to modify the timeline/event plan.

The initial fields for modifying a timeline/event plan are displayed.

5. On the *Timeline/Event Plan* page, do one of the following:

Action	Procedure
Enter your changes to the timeline/event plan attributes	Click Save.
To add this timeline/event plan to these drop-down lists and selection boxes	Click Activate.
To hide this timeline/event plan from the drop-down lists and selection boxes where you would be selecting an timeline/event plan value	Click Deactivate.

6. You are returned to the *Timeline/Event Plan* Attributes page.

Timeline/Event Plan Attributes

Use the timeline/event plan attribute information to select and enter the appropriate values while you define and modify timeline/event plans. The table describes the timeline/event plan attributes that are available when you define a timeline/event plan.

Attribute	Description
Active Flag	Displayed only on the view page, this indicates whether the timeline/event plan is hidden from or shown in the drop-down lists or selection boxes where you select a timeline/event plan value.

Attribute	Description
Countries	The countries for which lead times can be defined for the different statuses defined in a timeline/event plan. When creating a timeline/event plan for the CP procedure type, select European Union as the country. Note: For existing timeline/event plans, all associated countries are displayed under the <i>Timeline/Event Plan Countries</i> tab.
Lead Time	This specifies the interval of days to occur between a selected event status and the previous status in the timeline/event plan for the selected country. – The recommended best practice is for the first status in the timeline/event plan to have a lead time of zero since this is the starting point for the timeline/event plan. – The Default Lead Time attribute appears only on the <i>Create Timeline/Event Plan</i> page.
Timeline/Event Plan Name	Name for the timeline/event plan.

Timeline/Event Plan Type	The type of timeline/event plan. Can be event type or procedure type. This attribute is required, and is editable only when creating the Timeline/Event Plan. On the <i>Modify Timeline/Event Plan</i> page, this field appears as read-only.
Enforce Status Progression	Enforcing a status progression limits the statuses an event country schedule can transition to based on the progression defined in the timeline/event plan. Yes or No.
Event Statuses	The milestones that are applicable to the timeline/event plan. The order that you select these statuses dictates the status order for the plan. Note: <i>The first status in a timeline/event plan must not be mapped to an Ennov InSight internal status of Approved or Not Approved.</i>
Event Type	The Event Type field appears only if the Timeline/Event Plan Type is set to Event Type. The event type to which the milestones for this timeline/event plan apply. This field is required and editable only when creating the Timeline/Event Plan. On the <i>Modify Timeline/Event Plan</i> page, this field appears as read-only.
Attribute	Description
Optional Event Statuses	These are optional statuses that the event might progress to, but that are not planned or expected for the event, such as Not Approved or Rejected. You must define event statuses before you can define optional event statuses. Country lead times are not defined for optional event statuses.
Procedure Type	The Procedure Type field appears only if the Timeline/Event plan Type is set to Procedure Type. The procedure type to which the milestones for this timeline/ event plan apply. This field is required and editable only when creating the Timeline/Event Plan. On the <i>Modify Timeline/Event Plan</i> page, this field appears as read-only.
Region	Region applicable to the Timeline/Event Plan. Only regions under the selected region type are available for selection. This field is required and editable only when creating the Timeline/Event Plan. On the <i>Modify Timeline/Event Plan</i> page, this field appears as read-only.
Region Type	The regions available for selection in the Region field depend on the region type selection. The field is required and editable only when creating the Timeline Event Plan. The field is not available on the view and modify pages.

If there are multiple Event-Country Statuses with the same actual date, then the following business logic determines the displayed current status:

- If the statuses have different last modified dates, the status with the most recent modified date is the current status
- If the statuses have the same last modified date, the last status in the status order is the current status

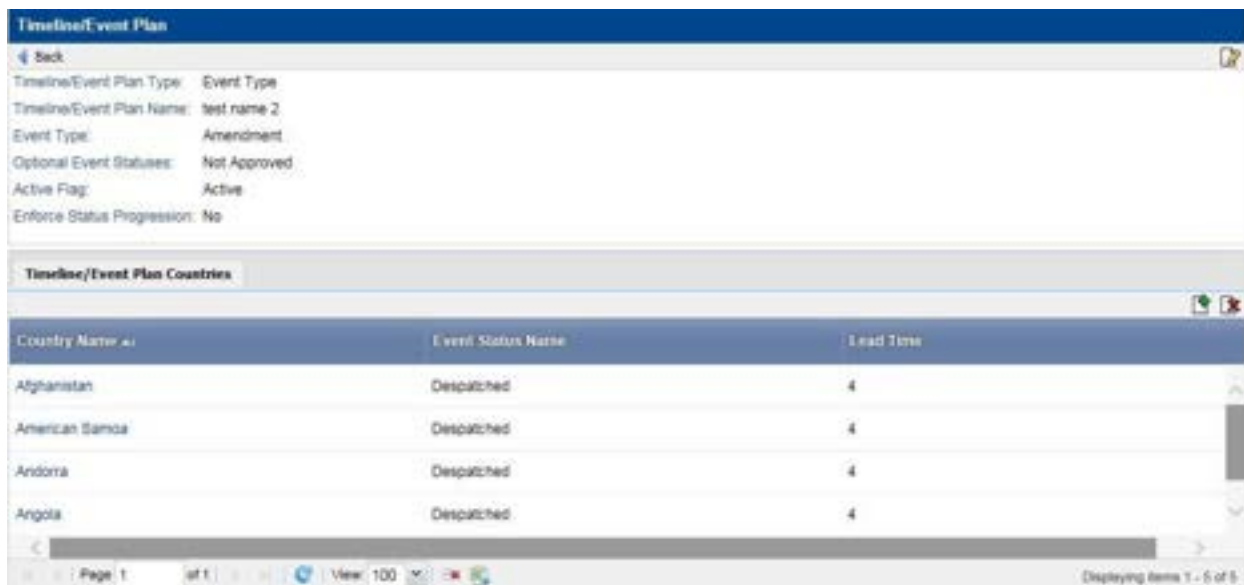
View Timeline/Event Plans

You can view a timeline/event plan, as well as perform changes to a timeline/event plan and the lead time for timeline/event plan countries, in Data Administration.

To view a timeline/event plan:

1. In Ennov InSight, click Go To > Data Administration. The *Data Administration* page appears.
2. On the *Data Administration* page, under Event Maintenance, click Timeline/Event Plan Values. The *Timeline/Event Plan* page appears.
3. On the *Timeline/Event Plan* page, click the link for the timeline/event plan to view.
4. On the *Timeline/Event Plan* view page, do any of the following:

Action	Procedure
To modify the timeline/event plan attributes	Click the Edit icon.
To modify the lead time for a country event status	Click the appropriate country link.



If there are multiple Event-Country Statuses with the same actual date, then the following business logic determines the displayed current status:

Condition	Result
If the statuses have different last modified dates	The status with the most recent modified date is the current status.
If the statuses have the same last	The last status in the status order is the current status.

modified date	

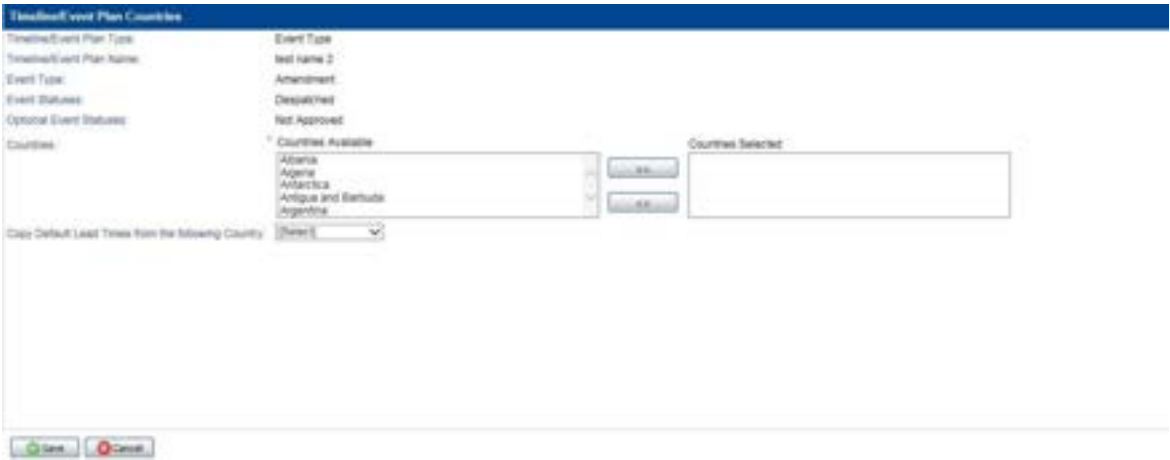
Add Timeline/Event Plan Countries

You can add countries to an existing timeline/event plan in Data Administration to associate the timeline/event plan to the added countries.

To add countries to an event plan:

1. In Ennov InSight , click Go To > Data Administration. The *Data Administration* page appears.
2. On the *Data Administration* page, under Event Maintenance, click Timeline/Event Plan Values. The *Timeline/Event Plan* page appears.
3. On the *Timeline/Event Plan* page, click the link for the timeline/event plan to which you want to add countries.
4. On the Timeline/Event Plan Countries tab, click the Add Countries icon.

The *Timeline/Event Plan Countries* page appears.



5. To add countries to the timeline/event plan, select countries in the Countries Available box and move them to the Countries Selected box.

The default lead times for the countries that you add are 0.

6. As an option, you can apply the default lead times for another country to the country that you are adding. In the Copy Default Lead Times from the following Country list, select the country that has the default lead times that you want to apply.

If you do not select a country lead time to apply, the default lead times for the country that you add are 0.

7. Click Save.

Remove Timeline/Event Plan Countries

To disassociate countries from an event plan, you can remove countries from an event plan in Data Administration. To remove countries from an event plan:

1. In Ennov InSight, click Go To > Data Administration. The *Data Administration* page appears.
2. On the *Data Administration* page, under Event Maintenance, click Timeline/Event Plan Values. The *Timeline/Event Plan* page appears.
3. On the *Timeline/Event Plan* page, click the link for the event plan from which you want to remove countries.
4. On the Timeline/Event Plan Countries tab, click the Delete Countries icon. The *Timeline/Event Plan Countries* page appears.
5. To remove one or more countries from the timeline/event plan, select countries in the *Associated with Plan* box and move them to the *Disassociated from Plan* box.
6. Click Save.

Modify Lead Times for Timeline/Event Plan Countries

You can modify the number of days that represent the lead time for an event status for a country. Country lead times are not defined for optional event statuses.

To modify lead times for countries in a timeline/event plan:

1. In Ennov InSight, click Go To > Data Administration.
2. On the *Data Administration* page, under Event Maintenance, click Timeline/Event Plan Values.
3. On the *Timeline/Event Plan* page, click the link for the timeline/event plan whose country event status you wish to modify.

Country Name	Event Status Name	Lead Time
Afghanistan	Dispatched	4
American Samoa	Dispatched	4
Andorra	Dispatched	4
Angola	Dispatched	4

4. In the Timeline/Event Plan Countries table, click the appropriate country link for the event status that you want to modify for that country.

Timeline/Event Plan Countries	
Timeline/Event Plan Type:	Event Type
Timeline/Event Plan Name:	test name 2
Event Type:	Amendment
Optional Event Statuses:	Not Approved
Active Flag:	Active
Enforce Status Progression:	No
Country Name:	American Samoa
Event Status Name:	Despatched
Lead Time:	4

5. In the Lead Time box, enter the number of days lead time for the country and event status.
6. Click Save.

The modified lead time value for the country and event status appears on the Timeline/Event Plan Countries tab. Event Attributes

Events represent key business objectives or regulatory actions for an Application. The attributes describe the type of Event and the Event details.

Attribute	Description
Action Type	The type of approval required to consider the Event active.
Application Code	The agency-identified Application number (or identifier), which may not be known until submittal time. It may be the same as the internal code.
Application Internal Code	The internal code for the Application. This is by default hidden for CTA and IND Applications.
Application Name	The name of the Application that is associated with the Event.
Closed	Indicates whether the Event is closed.
Copy Default Lead Times from the following Country	When adding an Event-Country, select this option to specify the country whose default lead times you want to apply to the country you are adding.
Countries	Countries of the Event.
	Note: Withdrawn application countries with the Withdraw Date value equal to today's date or earlier are not available for selection in the Countries multiselect field on the Create

	<i>Event page. This is applicable only to applications of Mutual Recognition (MRP) or Decentralised Procedure (DCP) types.</i>
CT Shared Data	Clinical Trial shared data associated with an event based on the type of application. This field is available on the <i>Create Event</i> page if the application type is CTA, CTR or IND.
Description	Text that describes the Event.
EU Grouping/ Work-sharing	Used to identify if the Event is part of a Grouping or Worksharing activity for a European variation. Worksharing is used when there is one change to multiple Applications in multiple Procedures. Grouping is used when there are many of the same changes for one Application.
EU Grouping/ Worksharing Number	Used to identify the high-level submission number, either a 'Worksharing' number or the high-level submission number to be used when grouping Type 1A variations for multiple Marketing Authorizations.
Event Add Comment	Comments you want to share with others in a discussion thread. Will be displayed in the Event Comments box, stamped with the date and time you enter the information and your user ID. Note: <i>The Event Add Comment field is available on the Create/Modify Event Attributes pages only.</i>
Event Closed As	The status to capture how the entities associated with the Event were closed.

Attribute	Description
Event Closed Date	The date the Event is closed.
Event Code	The code your organization uses to identify the Event. Note: <i>The Event Code and Event Name as a combination for an Event must be unique within an Application.</i>
Event Comments	The discussion thread that includes all comments entered by users; includes the date and time the comments were entered and the user ID of the person who entered them.
Event Concerned Parties	Concerned Parties are anyone who may be copied on notifications about this entity; use semi-colons (;) to separate e-mail addresses.
Event-Country Status	The current status for the country associated with the Event.

	When the Event-Country schedule enforces a status progression, only the next status in the progression and optional statuses are available for selection.
Event Name	The name of the Event.
	Note: <i>The Event Code and Event Name as a combination for an Event must be unique within an Application.</i>
Timeline/Event Plan Type	The type of Timeline/Event Plan. The Timeline/Event Plan Type can be Procedure Type, Event Type, or None. When the Timeline/Event Plan Type is Procedure Type, the Timeline/Event Plans available for selection are those associated with the Application Procedure Type. When the Timeline/Event Plan type is Event Type the Timeline/Event Plans available for selection are those associated with the selected Event Type. When the Timeline/Event Plan Type is None, no Timeline/Event Plans will be available for selection. – The Timeline/Event Plan Type is only displayed when an Event is created.
Timeline/Event Plan Used	The Timeline/Event Plan used to create the Event.
Event Type	The type of the Event.
Keywords	Words you can use to search for the Event.
Attribute	Description
Procedure Closure Date	The date of the first approval when the RMS approves an Application.
Products	The Products associated with the Event.
Project Name	The name of the Global Project Planning (GPP) project with which this Event is associated.
PSUR Flag	Indicates whether or not there is information associated with the Event to drive the PSUR worldwide report.
PSUR Reason/ Comment	Identifies the reason for the PSUR filing. Note: <i>If you enter more than 4,000 characters in this field, none of the text is saved when you save changes to the event attributes.</i>

PSUR Report Code	The Code identified in the World Wide PSUR Report. When PSUR flag is set to 'Y', this field is used for the PSUR Report Code.
Reason	Reason for creating, modifying or deleting an event.
Reason for Comments	Comments related to reason entered by users.
Reason for Termination/ Withdrawal	The reason that event was terminated or withdrawn. Appears and is required only when the Event Closed As is set to WITHDRAWN.
Reportable in PSUR	Indicates whether an Event needs to be included in the PSUR.
Secondary Event Type	Used to further define the Event Type.
Status Date	The effective date for the current event-country status.

Attribute	Description
Timeline/Event Plan	A Timeline/Event Plan provides the ability to create an Event-Country Schedule with statuses in the order they are expected to be achieved for a country(s). – The option to apply a Timeline/Event Plan is only available during initial creation of the Event. – The Timeline/Event Plans that are available for selection depend on the Timeline/Event Plan type selected. – If the Event was created with a plan, only the statuses associated with the plan will be available for selection when updating the Event-Country Status. – If the Event was not created with a plan, all active statuses available in the system will be available for selection when updating the Event-Country Status. – If the Event-Country schedule enforces a status progression, only the next status in the progression and optional statuses are available for selection when updating the Event-Country Status. – After the Event is created, changes in the Timeline/Event Plan in Data Administration are not applied to existing Event-Country Schedules.
User ID	The user name to validate user identity.
Password	The user password to validate user identity.

Variation Number	The regulatory agency-assigned number that identifies the Event as a variation of a submission.

Medical Device Maintenance

Values for Medical Device are managed in the Data Administration for use on the *Product Component Device*

Details Attributes page.

The Medical Device Data Administration section provides capability to capture Component UDI attributes for a Product at the Application level based on country. It helps to distinguish a Medical Device RIM Component that is co-packaged with a RIM Pharmaceutical Product.

When you select a value under Medical Device Maintenance, a page opens with a table of all values that have been defined. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

Appropriate data administration privileges are required to view and modify Medical Device Maintenance values.

Medical Device Maintenance: Medical Device Values

Ennov InSight lets you use Data Administration to add and modify Medical Device values and attributes, and to set statuses on those attributes.

You can create and maintain the following Medical Device values:

Value	Description
Device Classification Values	Categorization of medical devices based on their potential risks and intended use. The RMS value is mapped to the Medical Device Classification SPOR RMS List.
EU Category of CMR Type Values	Different categories of the medications that are required to prepare for medical issues of a patient.
Device Classification Values	Different classes the medical devices are assigned to based on the level of control.
EU Device Nomenclature Category Values	The type of the nomenclature used by the manufacturers to register medical devices in EUDAMED.
EU Device Nomenclature Values	A set or system of names used by manufacturers when registering their medical devices in the EUDAMED database.
FDA GMDN In-Vitro Term Type Values	The GMDN type used to identify Vitro diagnostic devices for the FDA submission.
Global Medical Device	Global Medical Device Nomenclature (GMDN) Code used to identify medical devices.

Nomenclature (GMDN) Code	
Values	

Device Classification Attributes

To define a device classification value, enter values for the following attributes:

Attribute	Description
Device Classification Name	The name of the device classification. Example: Class II.
Countries	The list of countries where the device classification is applicable.
RMS Term Name	List of Medical Device Classification RMS Values available for selection.
Last User Updated	Indicates the name of the user who last created/updated the action type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

EU Device Nomenclature Category Attributes

To define an EU device nomenclature category value, enter values for the following attributes:

Attribute	Description
Device Nomenclature Category Name	The name of the nomenclature category for the European medical devices.
Device Nomenclature Code Value	The actual unique value for the Device code.
Last User Updated	Indicates the name of the user who last created/updated the action type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

FDA GMDN In-Vitro Term Type Attributes

To define FDA GMDN in-vitro term type value, enter values for the following attributes:

Attribute	Description
GMDN In-Vitro Term Type	The GMDN type used to determine the In-Vitro type.
Last User Updated	Indicates the name of the user who last created/updated the action type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

EU Category of CMR Type Attributes

To define an EU category of CMR type value, enter values for the following attributes:

Attribute	Description
Category of CMR Type	CMR substances are substances that are carcinogenic, mutagenic or toxic to reproduction (CMR). They are classified into 3 categories depending on the severity they can cause.
Last User Updated	Indicates the name of the user who last created/updated the action type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Attribute	Description
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

EU Device Nomenclature Attributes

To define an EU device nomenclature value, enter values for the following attributes:

Attribute	Description
Device Nomenclature Category	The Device Nomenclature Category associated with the UDI-DI.
Device Nomenclature Code	The Device Nomenclature Code associated with the UDI-DI.
Device Nomenclature Code Name/Description	The Device Nomenclature Code(s) description associated with the UDI-DI.
Last User Updated	Indicates the name of the user who last created/updated the action type. By default, this option is read-only. It is populated automatically when updates were made to the table.

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Global Medical Device Nomenclature (GMDN) Code Attributes

To define a global medical device nomenclature (GMDN) code value, enter values for the following attributes:

Attribute	Description
GMDN Code	A unique code provided by Global Medical Device Nomenclature to identify medical devices.
GMDN Term Name	The international naming and grouping convention used to identify and consistently describe medical devices.
GMDN Term Definition	Description of the GMDN code and Term Definition..
Term is IVD	Indicates whether the Term is IVD (In-Vitro Diagnostic) or Non-IVD (Non-In-Vitro Diagnostic).
Last User Updated	Indicates the name of the user who last created/updated the action type. By default, this option is read-only. It is populated automatically when updates were made to the table.

Attribute	Description
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Notifications Maintenance

Notifications trigger e-mails or alerts in the Alert center, based on changes that occur in Ennov InSight entities.

You can create global notifications for all instances of the entity matching the criteria, or notifications for specific instances of entities, or you can create Notification Specifications that trigger automatically for all entities when the criteria in the specification are met.

Notifications can be associated with the following entities:

- Product Family
- Product
- Product Component
- Pharmaceutical Product

- Application
- Event
- Event-Country
- Sequence
- Registration
- Full Product Presentation
- Registration FPP Attachment
- Reference
- Task
- Project

Note: When creating a notification for an event country, you can create notifications for the event country or the eventcountry status schedule.

When you select a value under Notifications in Data Administration, a page opens with a table of all values that have been defined. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

You can also create a notification for the XEVMPD Acknowledgement Import. This notification can be created using Home Page > Wizards > Create Notification functionality only. See *Creating a Notification*.

The proper Data Administration access privileges are required to view and modify Notifications and Notification Specifications.

Notifications:

- Activate, deactivate, modify, or delete existing notifications.
- All notifications created for a specific instance of an entity (whether created using the wizard or created automatically based on a specification) appear on the Notifications tab for the particular entity and on the Notifications tab in Data Administration.

Notification Specifications:

- Send all date-based notifications; activate, deactivate, modify, or delete existing notification specifications.
- All Global specifications created using the *Notifications* wizard appear on the Notifications Specifications tab in Data Administration.
- New Record notifications are displayed on the Notification Specifications Data Administration tab.

For information about creating notifications, see *Creating a Notification*.

Warning: The notification framework leverages SMTP. To ensure notifications can be sent, customers must provide all the domains to be whitelisted by security policy. Please, be sure to discuss it with your Project manager prior to setup to ensure the appropriate domains are added. In the event of an acquisition, merger, separation or other activities resulting in domain changes you will need to raise a ServiceNow ticket using the following link: https://calyx.service-now.com/csm?id=calyx_login detailing the domains for inclusion or removal.

Create a Notification

You can create notifications using either the *Create Notification* wizard or the Notification option in the I Am Looking To > Create A New section on the *home page*.

You must have the appropriate security privileges to create, modify, and view notifications. Only users with administrator privileges for notifications can create a global notification.

- If you launch the *Create Notification* wizard from the *home page*, you can select a Ennov InSight entity and create a notification. See *Use the Create Notification Wizard* in the Getting Started online help.
- If you launch the wizard while viewing an entity, you can create an instance notification or a global notification for the entity you are viewing.

Notifications: Notifications Values

You can create and maintain the following Notification values:

Value	Description
Notification Specifications	Trigger automatically for all entities when the criteria in the specification are met.
Notifications	Trigger e-mail alerts based on changes that occur in Ennov InSight entities. You can create Notifications for specific instances of entities.

Notification Specifications Attributes

To define a notification specifications value, enter values for the following attributes:

Attribute	Description
Notification Name	The name of the notification.
Notification Type	The type of the notification.
Notification Subject	The subject of notification.
Notification Comment	The comment to notification.
Last User Updated	Indicates the name of the user who last created/updated the notification specification. By default, this option is read-only. It is populated automatically when updates were made to the table.

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Created by	Username of the notification author.
Active	Indicates if the entity is active or inactive.

Notification Attributes

To define a notification value, enter values for the following attributes:

Attribute	Description
Notification Name	The name of the notification.
Notification Type	The type of the notification.
Notification Subject	The subject of notification.
Notification Comment	The comment to notification.
Last User Updated	Indicates the name of the user who last created/updated the notification values. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Created by	Username of the notification author.
Derived from Notification Specification	The name of the notification specification the current notification derives from.
Last Sent Date	Last date the notification was sent.
Active	Indicates if the entity is active or inactive.

Notification Security Privileges

Users with administrator privileges to notifications should also have data administration privileges to create, modify, deactivate, and delete notification specifications.

The following table outlines the security privileges required to work with notifications:

Function	Specification	Specification-triggered notification	User-created notification
Create	Entity Security, Notifications =	Created automatically from a notification specification	Entity Security, Notifications = Write or Admin

	Admin		
Modify, Activate, Deactivate	Entity Security, Notifications = Admin	Entity Security, Notifications = Write or Admin/Ennov InSight does not validate notification cre- ator	Entity Security, Notifications = Write or Admin/Ennov InSight does not validate notification creator
Delete	Entity Security, Notifications = Admin	Entity Security, Notifications = Admin	Entity Security, Notifications = Write, user should also be the notification creator Entity Security, Notifications = Ad- min/Administrator can delete any noti- fication

Other Data Maintenance

In Data Administration, data values in the Other section appear in lists on the *Entity Attributes* pages and are designated when an entity is created or changed.

When you select a value under Other, a page opens with a table of values that have been defined. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

Note: *The proper Data Administration access privileges are required to view and modify the values in Other Data Maintenance section.*

All XEVMPD Data Administration tables provide the ability to configure extra fields. The standard set consists of twenty extra text fields, five extra date fields, and five extra number fields.

Other Data Maintenance Values

You can create and maintain the following values:

Value	Description
Application Submission Type Values	A marketing authorisation application. You can define it using a term ID.
Attached Document	A document format that European Medicines Agency (EMA) supports.

Content Type Values	
Attached Document Status Values	Used to define the status of the document attached. For example: Current, Planned.
Certificate Master File Values	Used to include certificates referring to the composition of the medicinal product.
Concentration Measure Type Values	Name and code for a relational operator used with a concentration unit to define the concentration of an active ingredient in a pharmaceutical product. For example, if a tablet has 200 milligrams of the active ingredient, the concentration measure type is equal and the concentration unit is milligrams. The list contains the concentration type term names and concentration type codes from the EMA Concentration Types CV. The default value is set to Active. The standard set of extra fields can be configured for this value.
Data Carrier Identifier Source Values	Defines the source of data carrier identifiers for medicinal product packaging.
Denominator Unit Values	Name and code that identify a unit of measure, such as milligram, in denominators used to define the strengths of ingredients in medicinal products. The list contains the CV for Denominator Unit. The standard set of extra fields can be configured for this value.
Device Type Values	Name and code that identify a type of the device, such as administration device, integrated device, medical device, other device.
Entity XML/UI Mappings	Defines XML mappings for Ennov InSight entity elements. <i>Warning: Do not deactivate the Entity XML Type Name Package Set Registration. There are Ennov InSight functions and procedures, such as the "Create New Applications - Package Set Registration" Global Project Planning wizard, that rely on this value remaining active.</i>
File Identifier Type Values	The list of file identifier types.

Value	Description
Home Page Display Properties	Used to add or remove shortcuts to wizards and to modify text labels that appear on the <i>Home</i> page. You can enter a maximum of 50 characters for Home Page Title Bars, Menu Bar Display, and I Am Looking To entity labels. You can enter a maximum of 250 characters for Tooltip text.

Indications/ Intended Use Values	An indication is a disease or condition for which a drug is approved and for which it is intended to be used. Sub-indication values must exist in the system to be able to associate them with indication/intended use values. The default value is set to Active. The standard set of extra fields can be configured for this value.
Language Values	The two-letter language code ISO 639-1:2002 Alpha-2 is assigned to the language. The default value is set to Active. The standard set of extra fields can be configured for this value.
Legal Basis Values	Assigned name and code for the legal basis of the product. The list contains values for legal basis and codes for the legal basis term/name from the EMA CV. The default value is set to Inactive. The standard set of extra fields can be configured for this value.
Length Unit of Measure Values	The length can be specified using a numerical value and its unit of measurement.
MAH/Development Sponsor/ Organisation Values	Name, address, and other information, including the Organisation Identifier, Location Identifier and Location Status attributes, for marketing holder authorization/development sponsor and organization. The default value is set to Inactive. The standard set of extra fields can be configured for this value. Note: The following attributes are used to maintain the integration with Organisations management service (OMS) introduced by European Medicines Agency (EMA): — MAH/Development Sponsor/Organisation Name — Organisation Identifier — Address — City — Post Code — Country — Location Identifier — Location Status
Master File Location (MFL) Values	Name and address information for the master file location company, with EudraVigilance code and comments. The standard set of extra fields can be configured for this value.
Value	Description
Message Sender Values	The unique identifier of an organization that can send information to EudraVigilance. This identifier is assigned when the organization registers with EudraVigilance. The standard set of extra fields can be configured for this value.

Numerator Unit Values	Name and code that identify a unit of measure in numerators used to define the strengths of ingredients in medicinal products. The default value is set to Inactive. The standard set of extra fields can be configured for this value.
Previous EV Code Values	Define previous EV code values to map with new EV codes. The Previous EV Code is assigned to Approved Substance, Pharmaceutical Form, and Route of Administration. The standard set of extra fields can be configured for this value.
Quantity Unit of Measure Values	Describes the quantity of the pharmaceutical product. It is specified as a value and a unit.
Reason for E-Signature Values	Reasons for changing entities; available when an e-signature is required.
Reason for Termination/Withdrawal Values	Reasons for entity termination or withdrawal. Available for: Application, Product, Event, Sequence, Registration.
SME Status Values	Define values to determine N/A (for non-SMEs), micro, small, and medium companies in correspondence with the quantity of employees, along with their codes. The SME status is required for all updates and inserts of organisations that are Marketing Authorisation Holders. SME Status Name and SME Status Code must be unique in the system. The default value is set to Active. The standard set of extra fields can be configured for this value.
Source of Information Values	Defines the sources of information. The RMS value is mapped to the Source of Information SPOR RMS List.
Sub-Indication Values	Used for veterinary products, sub-indication values represent parasites to be associated with an indication. Multiple sub-indications can be associate with an indication, and a sub-indication can be associated with multiple indications.
System Alert Type Values	The System Alert Type allows the user to further define or categorize the System Alert. The System Alert entity provides the ability to create and distribute important messages to Ennov InSight users and groups. System Alerts appear in the Alert Center on the Effective Date set for the Alert. They are displayed for the recipients of the Alert and are removed automatically from the Alert Center on the Expiration Date set for the Alert.

Value	Description
Units of Measurement Values	Strength (quantitative composition) of the substances (including active substances, ingredients, solvents, adjuvant as applicable) as a numerator and denominator value. This table provides values for the following reports: – Entity History Query – Querying > Product Detail Management > Application History Query – Querying > Product Detail Management > Application QC Status History Query
Unit of Measure Prefix Values	Name and code that identify a unit of measure, such as milligram, used to define the strengths of ingredients in medicinal products. The list contains unit of measure prefix values and prefix codes for the unit of measure prefix term/name from the EMA Units of Measure CV. The default value is set to Inactive. The standard set of extra fields can be configured for this value.
Unit of Presentation Values	The unit of presentation is a qualitative term describing the discrete unit in which a pharmaceutical product is presented to describe strength or quantity in cases where a quantitative unit of measurement is not appropriate.
Weight Unit of Measure Values	The weight can be specified using a numerical value and its unit of measurement.

Application Submission Type Attributes

To define an application submission type value, enter values for the following attributes:

Attribute	Description
Application Submission Type Name	Application Submission Type name.
Last User Updated	Indicates the name of the user who last created/updated the application submission type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Attached Document Content Type Attributes

To define a attached document content value, enter values for the following attributes:

Attribute	Description
Attached Document Content Type Name	Attached Document Content Type name.
Attribute	Description
Last User Updated	Indicates the name of the user who last created/updated the attached document content. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Attached Document Status Attributes

To define a attached document status value, enter values for the following attributes:

Attribute	Description
Attached Document Status Name	The name of the status of the document attached.
Last User Updated	Indicates the name of the user who last created/updated the attached document status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Certificate Master File Attributes

To define a certificate master file value, enter values for the following attributes:

Attribute	Description
Master File Name	The name of master file.
Master File Type	Displays a list of the file types.
Master File Version	Displays the version of the master file.
Master Identifier	Unique identifier from Practice Management System (PMS) system.
Certificate Type	A file Identifier type.
Certificate Number	A file identifier code.

Submission Date	The date when the certificate is submitted.
Date of Last Update	The date of last update.
Substance Reference	Displays substances to select as a substance reference.
Related Application	Displays related applications.
Attribute	Description
Manufacturer	Displays manufacturers.
Content Link	A link to DMS content.
Local Identifier	Unique identifier generated on creation.
	Note: By default, the field is hidden.
Status	Status from Practice Management System (PMS) , for example, Active, Draft, Current, Superseded, Entered-in-error.
Version	This field is used for IDMP submission logic functionality.
	Note: By default, the field is hidden.
Last User Updated	Indicates the name of the user who last created/updated the certificate master file values. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Concentration Measure Type Attributes To define a concentration measure type value, enter values for the following attributes:

Attribute	Description
Concentration Measure Type Name	Concentration Measure Type term name. Examples: Equal, Range, Less Than.
Concentration Code	Concentration Measure Type Code associated with the Concentration Measure Type Name.
RMS Term Name	List of Active Concentration Measure Type RMS Values must be available for selection.

Last User Updated	Indicates the name of the user who last created/updated the concentration measure type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Attribute	Description
Active	Indicates if the entity is active or inactive.

Data Carrier Identifier Source Values

To define a data carrier identifier source value, enter values for the following attributes:

Attribute	Description
Data Carrier Identifier Source	Indicates the source of data carrier identifier for medicinal product packaging.
RMS Term Name	List of Source of Information RMS Values available for selection.
Last User Updated	Indicates the name of the user who last created/updated the concentration measure type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Device Type Attributes

To define a device type value, enter values for the following attributes:

Attribute	Description
Code Value	The actual value for the code.
Code Name	The full name and/or description for the code.
Last User Updated	Indicates the name of the user who last created/updated the device type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.

Active	Indicates if the entity is active or inactive.

Denominator Unit Attributes

To define a denominator unit value, enter values for the following attributes:

Attribute	Description
Denominator Unit Name	Denominator Unit Name assigned by EMA.
Denominator Code	Denominator Unit Code assigned by EMA.
RMS Term Name	List of Denominator/Numerator Unit RMS Values available for selection.
Attribute	Description
Last User Updated	Indicates the name of the user who last created/updated the denominator unit. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Entity XML UI Mappings Attributes

To define an entity XML UI mappings value, enter values for the following attributes:

Attribute	Description
Entity XML Type Name	Name of the Product Family Type in InSight.
Associated Entity	The entity for which the type is being defined.
Entity XML Type XML Mapping	The list of entity types defined in XML.
Default Flag	Flag to indicate if the value is the default. Yes and No values are available for selection.
Description	Free format text box for entering descriptive information.
Last User Updated	Indicates the name of the user who last created/updated the entity XML UI mappings. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

File Identifier Type Attributes

To define an application submission type value, enter values for the following attributes:

Attribute	Description
File Identifier Type	File Identifier Type name.
Last User Updated	Indicates the name of the user who last created/updated the file identifier type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Homepage Display Properties Attributes

To define a homepage display properties value, enter values for the following attributes:

Attribute	Description
Entity Type	Displays a list of entity types in Ennov InSight . The user will have the ability to modify the display properties for the entity type selected.
Name	Displays a list of entities for the Entity Type selected.
Display	The display value for the entity name selected.
Comments	Displays a blank text box to enter comments.
Last User Updated	Indicates the name of the user who last created/updated the homepage display properties. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Indications/Intended Use Attributes

To define an indications/intended use value, enter values for the following attributes:

Attribute	Description
Indications/ Intended Use	Name of the Indication or Indication Group - When populated with MedDRA terms, this will be the Preferred Term (PT) from the MedDRA dictionary.

Sub-Indications	Sub-indications that belong to a specific indication group. Examples would be parasites such as Fasciola Hepatica, Fasciola Gigantica etc that belong to the Fasciola Hepatica Indication group.
MedDRA Level	MedDRA Level: Higher Level Group Term (HLGT), Higher Level Term (HLT), Lower Level Class (LLT), Preferred Term (PT), System Organ Class (SOC).
MeDRA Code	This field should have correct value depending on MeDRA Level value selected.
	Note: one of three following fields Indications/Intended Use, MedDRA Level, MedDRA Code should be unique in the system.
MedDRA Term Version	When populated with MedDRA terms this is the version where the term can be found.
MedDRA Term Last Updated	Last time the Medra Term was updated auto populated by system.
Description	Free format text box for entering descriptive information.
Comments	Free format text box where users can enter information.
Attribute	Description
Keywords	Free format text box where users can enter text for searching purposes.
Last User Updated	Indicates the name of the user who last created/updated the indications. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Language Attributes

To define a language value, enter values for the following attributes

Attribute	Description
Language Name	Name of the Language.
Language Code	2-letter language code assigned to language ISO.
ISO ALPHA-3 CODE	3-letter language code assigned to language.
RMS Term Name	List of Language RMS Values available for selection.

Last User Updated	Indicates the name of the user who last created/updated the language. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

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Legal Basis Attributes

To define a legal basis value, enter values for the following attributes:

Attribute	Description
Legal Basis Name	Legal Basis term.
Legal Basis Code	Code assigned to the Legal Basis value.
RMS Term Name	List of Language RMS Values available for selection.
Last User Updated	Indicates the name of the user who last created/updated legal basis. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Attribute	Description
Active	Indicates if the entity is active or inactive.

Length Unit Of Measure Attributes

To define a length unit of measure value, enter values for the following attributes:

Attribute	Description
Code Value	The actual value for the code.
Code Name	The full name and/or description for the code.
Last User Updated	Indicates the name of the user who last created/updated the length unit of measure. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

MAH/Development Sponsor/Organisation Attributes

To define a MAH/Development Sponsor/Organisation value, enter values for the following attributes:

Attribute	Description
MAH/Development Sponsor/ Organisation Name	Name of the Marketing Authorization Holder or Sponsor.
Address	MAH/Sponsor address line.
City	MAH/Sponsor city.
Region	MAH/Sponsor state.
Post Code	MAH/Sponsor post code.
Country	MAH/Sponsor country name.
Telephone Number	MAH/Sponsor telephone number.
Telephone Extension	MAH/Sponsor telephone extension.
Telephone Country Code	MAH/Sponsor telephone country code.
Fax Number	MAH/Sponsor fax number.
Fax Extension	MAH/Sponsor fax extension.
Fax Country Code	MAH/Sponsor fax country code.
E-Mail Address	MAH/Sponsor E-Mail address
Is Company Responsible for XEVMPD	Is used in the XEVMPD Wizard to help in selecting only records that the company is responsible for sending.
Attribute	Description
Organisation Sender ID	Organization Sender ID
Location Status	Location Status. Predefined values: [Select], Active, Inactive.
SME Status	SME Status.
SME Number	SME number of the organisation where applicable.
Comments	Comments
Last User Updated	Indicates the name of the user who last created/updated the MAH/ development sponsor/organisation. By default, this option is readonly. It is populated automatically when updates were made to the table.

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Master File Location (MFL) Attributes To define a master file location value, enter values for the following attributes:

Attribute	Description
MFL Company	Name of the company that holds the Pharmacovigilance System Master File (PSMF). MFL is currently optional by EMA, but if the MFL used, schema will require associated fields.
Department	Name of the department that holds the PSMF.
Building	Building part of the address.
Street	Street part of the address.
City	City part of the address must be specified.
State	State part of the address
Post Code	Post Code (ZIP) part of the address must be specified.
Country	All active Country codes from the Country Values pick list are available for selection. Note: one of following listed fields: MFL Company, Street, City, Post Code, Country, Department, Building should be unique in the system.
Date Submitted to EMA	Date Submitted to EMA. It will be populated automatically when Acknowledgement Wizard is passed.
Attribute	Description
EV Code	Official EV Code assigned by the EMA.
XEVMPD Comments	Comments field. Comments are required for nullification.
Last User Updated	Indicates the name of the user who last created/updated the master file location. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Updated Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Message Sender Attributes

To define a message sender value, enter values for the following attributes:

Attribute	Description
Message Sender Name	Name of the Sender associated with the XML file created. Should be unique in the system.
Message Sender ID	Unique identifier of the sender organisation as assigned during the EudraVigilance registration process. This ID is used in the XML. This ID is used in the XML and is constrained for use on Marketing Auth (License) instead of the Organisation Sender ID, although they are likely the same. Should be unique in the system.
Last User Updated	Indicates the name of the user who last created/updated the message sender. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Numerator Unit Attributes

To define a numerator unit value, enter values for the following attributes:

Attribute	Description
Numerator Unit Name	Name of the Sender associated with the XML file created. Should be unique in the system. Long Version of the Unit Measure name of the AI, Excipients, Adjuvants. Examples of short names to long names: %w/v=%wt/volume, etc Value taken from the OOTB pick list Substance Numerator Unit Values published by EMA. Should be unique in the system.
Numerator Code	Short Version of the Unit Measure name of the AI, Excipients, Adjuvants. Examples: % w/v, etc. Value taken from the OOTB pick list Substance Numerator Unit Values published by EMA. Should be unique in the system.
Attribute	Description
RMS Term Name	List of Denominator/Numerator Unit RMS Values available for selection.
Last User Updated	Indicates the name of the user who last created/updated the numerator unit. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.

Active	Indicates if the entity is active or inactive.

Previous EV Code Attributes

To define a previous EV Code value, enter values for the following attributes:

Attribute	Description
Previous EV Code	Value of previous EV Code.
Code Type	Code Type. Examples: Select, Approved Substance, Pharmaceutical Form, Route of Administration.
Comments	Comments to the value.
Last User Updated	Indicates the name of the user who last created/updated the previous EV Code. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Quantity Unit Of Measure Attributes

To define a quantity unit of measure value, enter values for the following attributes:

Attribute	Description
Code Value	The actual value for the code.
Code Name	The full name and/or description for the code.
Last User Updated	Indicates the name of the user who last created/updated the quantity unit of measure. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Reason for E-Signature Attributes

To define a reason for E-Signature value, enter values for the following attributes:

Attribute	Description
Reason for ESignature	Reason for making a modification on an entity. Examples: Status Update, Error correction, Date Correction.

Last User Updated	Indicates the name of the user who last created/updated reason for ESignature. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Reasons for Termination/Withdrawal Attributes

To define a reason for termination/withdrawal value, enter values for the following attributes:

Attribute	Description
Reasons for Termination/Withdrawal	Reason for termination or withdrawal an entity. Applicable for: Application, Product, Event, Sequence, Registration (both types).
Last User Updated	Indicates the name of the user who last created/updated the reasons of termination/withdrawal. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

SME Status Attributes

To define a SME status value, enter values for the following attributes:

Attribute	Description
SME Status Name	SME Status Name.
SME Status Code	SME Status Code.
Last User Updated	Indicates the name of the user who last created/updated the SME status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Source of Information Attributes

To define a source of information value, enter values for the following attributes:

Attribute	Description
Source of Information Name	The name of source of information.
RMS Term Name	List of Source of Information RMS Values available for selection.
Last User Updated	Indicates the name of the user who last created/updated the source of information. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Sub-Indication Attributes

To define a sub-indication value, enter values for the following attributes:

Attribute	Description
Sub-Indication	Sub-Indication.
Last User Updated	Indicates the name of the user who last created/updated a sub-indication. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

System Alert Type Attributes

To define a system alert type value, enter values for the following attributes:

Attribute	Description
Alert Type	The Alert Type allows the user to further define or categorize the System Alert entity.
Last User Updated	Indicates the name of the user who last created/updated the system alert type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.

Active	Indicates if the entity is active or inactive.

Unit of Measure Prefix Attributes

To define a unit of measure prefix value, enter values for the following attributes:

Attribute	Description
Unit of Measure Prefix Name	The System Alert Type allows the user to further define or categorize the System Alert entity.
Prefix Code	Code assigned to the Unit of Measure prefix. Should be unique in the system.
RMS Term Name	List of Unit of Measure Prefix RMS available for selection.
Last User Updated	Indicates the name of the user who last created/updated the unit of measure prefix. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Unit Of Presentation Attributes

To define a unit of presentation value, enter values for the following attributes:

Attribute	Description
Code Value	The actual value for the code.
Code Name	The full name and/or description for the code.
Last User Updated	Indicates the name of the user who last created/updated the unit of presentation. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Weight Unit Of Measure Attributes

To define a weight unit of measure value, enter values for the following attributes:

Attribute	Description
Code Value	The actual value for the code.

Code Name	The full name and/or description for the code.
Last User Updated	Indicates the name of the user who last created/updated the weight unit of measure. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Unit of Measurement Attributes

To define a weight unit of measure value, enter values for the following attributes:

Attribute	Description
Unit of Measurement Name	Name that defines the unit of measurement.
Last User Updated	Indicates the name of the user who last created/updated the unit of measure. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Product Maintenance

Product maintenance values appear in lists on the Product Attributes page and are designated when a product is created. Data Administration enables you to add and modify list values, and set the status of a value to active or inactive.

When you select a value under Product Maintenance, a table of all values that have been defined appears. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

Note: The proper Data Administration access privileges are required to view and modify application maintenance values.

All XEVMPD Data Administration tables provide the ability to configure extra fields. The standard set consists of twenty extra text fields, five extra date fields, and five extra number fields.

Product Maintenance: Product Values

You can create and maintain the following product values:

Value	Description
Applicable Standards	Standards to which a medical device must adhere (values are codes). Typically referenced in the essential requirements checklist of the technical file and are printed on the Declaration of Conformity. EU-specific.
Conformity Assessment Body	An agency, organization, or company, which may include a third party or a supplier's testing laboratory, or a certification body, that performs conformity assessment or testing to an importing Party's Technical Regulations.

Value	Description
Conformity Assessment Path	Paths taken for conformity assessment as identified in the EU MDD (Medical Device Directive) - Annex II, III, IV, V, VI, VII and in combination. The EU rules and regulations to which a medical device must adhere. EU only.
Country Specific Detail Type	The type of details specific to a country.
Country Specific Detail Value	The detail value specific to a country.
Device Allergenicity	The Device Allergenicity is used to specify whether the device contains allergens and/or materials of concern.
Device Sterility Indicator	Is used to specify whether the device is supplied as sterile using an appropriate controlled terminology.
Device Usage	Specifies the number of times that the device may be used as described in the regulated product information.
Dosage/Pharmaceutical Form	Pharmaceutical product in the form in which it is marketed for use, typically involving a mixture of active drug components and non-drug components (excipients), along with other non-reusable material that may not be considered either ingredient or packaging. Can be defined at the product level, at the individual component level, or at both levels. The list contains the pharmaceutical dose form values from the EMA Pharmaceutical Forms CV. The default value is set to Active. The standard set of extra fields can be configured for this value.
EC Cert	Design certification for Class III products.
EU Classification Rule	Rules 1 through 18, Rule 99.

EU Class	Classes of increasing risk to a patient according to the device properties, function and intended purpose as defined by the MDD for medical devices.
FDA Device Class	FDA classification based on risk.
Global Harmonization Task Force (GHTF) Class	Class as defined by the GHTF with values 1, 2, or 3.
Manufacturing Location	Where a device component can be manufactured. Defined at the product level, the individual component level, or both.
Medical Device	Defines a category of devices based on the level of control necessary to assure the safety and effectiveness of the device. The list contains medical device values and medical device code from the EMA Medical Device CV. The standard set of extra fields can be configured for this value.
Value	Description
Product Characteristics	Can be used to describe various characteristics of the pharmaceutical product. It can be defined to complete the definition of a product using variants. Product Characteristics are attributes that can be added to the product definition to extend the description of each product.
Product Status	Current status of a product. Product statuses can be mapped to internal system statuses for the purpose of event-product associations.
Product Strength Unit	Abbreviated measurement name of the product strength, such as: mg/g, ml, g, or % w/v
Route of Administration	Defines how a product is introduced into the system, such as oral or intravenous. Dependent on dosage form. Can be defined at the product level, the individual component level, or both. The default value is set to Active. The standard set of extra fields can be configured for this value.
Special Measure	If the medicinal product is subject to specific special measures, these can be specified using an appropriate controlled vocabulary.
Sterilization	For example: none, ETO, radiation, or steam. For devices made of many components, each can be separately sterilized.
Sterilization Requirement	Where applicable, this can be used to specify whether the device shall be sterilized before use based on an appropriate controlled terminology.

Summary of Technical Documentation (STED)	Client-specific Summary of Technical Documentation IDs.
UMDNS Code Values	The nomenclature and coding system used for identifying, processing, retrieving, transferring, and communicating data about medical devices.
Product Category Type	The classification of the medicinal products.
Product Cross Reference Type	The type of medicinal product (MP) that is referenced. You can define it using a term ID.

Applicable Standards Attributes To define an applicable standard value, enter values for the following attributes:

Attribute	Description
Applicable Standards	Standards to which the device adheres (values are codes).
Version of Standard	Version of the applicable standard.
Last User Updated	Indicates the name of the user who last created/updated the applicable standards. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Attribute	Description
Active	Indicates if the entity is active or inactive.

Conformity Assessment Body Attributes

To define a conformity assessment body value, enter values for the following attributes:

Attribute	Description
Conformity Assessment Body Name	The name of the conformity assessment body (also know as Notified Body in EU).
Last User Updated	Indicates the name of the user who last created/updated the conformity assessment body. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Conformity Assessment Path Attributes

To define a conformity assessment body path value, enter values for the following attributes:

Attribute	Description
Conformity Assessment Path Name	Path taken for conformity assessment - Annex II, III, IV, V, VI, VII and in combination.
Last User Updated	Indicates the name of the user who last created/updated the country specific detail conformity assessment path. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Country Specific Detail Type Attributes

To define a country specific detail type value, enter values for the following attributes:

Attribute	Description
Country Specific Detail Type Name	The name of the country specific detail type.
Attribute	Description
Field Value Control	Field Value Control. Allowed HARDCODED values for Selection: Controlled-Single Value (default selection), Controlled-Multiple Values, User Entered. Note: The controlled field value for a Country Specific Detail type is locked post creation of Country Specific Detail values/Link up with Product.
Last User Updated	Indicates the name of the user who last created/updated the country specific detail. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Country Specific Detail Attributes

To define a country specific detail value, enter values for the following attributes:

Attribute	Description
Country Specific Detail Type	All active values of Country Specific Detail Types.
Countries	All active Countries values.
Country Specific Value	Value defined for the detail type when Field Value Control is "Controlled" in Country Specific detail Type. Field is hidden when Field Value Control is "User Entered". Country Specific Detail Value must be unique within Country Specific Detail Type.
Last User Updated	Indicates the name of the user who last created/updated the country specific detail. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Device Allergenicity Attributes

To define a device allergenicity value, enter values for the following attributes:

Attribute	Description
Code Value	The actual value for the code.
Attribute	Description
Code Name	The full name and/or description for the code.
Last User Updated	Indicates the name of the user who last created/updated the device allergenicity. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Device Sterility Indicator Attributes

To define a device sterility indicator value, enter values for the following attributes:

Attribute	Description
Code Value	The actual value for the code.

Code Name	The full name and/or description for the code.
Last User Updated	Indicates the name of the user who last created/updated the device sterility indicator. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Device Usage Attributes

To define a device usage value, enter values for the following attributes:

Attribute	Description
Code Value	The actual value for the code.
Code Name	The full name and/or description for the code.
Last User Updated	Indicates the name of the user who last created/updated the device usage. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Dosage/Pharmaceutical Form Attributes

To define a dosage/pharmaceutical form value, enter values for the following attributes:

Attribute	Description
Dosage Form (Long Name)	Full Dosage Form Name. Example: Capsule.
Dosage Form (Short Name)	Abbreviation for Dosage Form. Example: CAP.
FDA Code	FDA Code.
Type Term	Type of Dosage Form Term. Values available for selection are: – Development Term – Proposed Term

	– Standard Term
Version Date	The date of the last update of the administration route.
Description	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container or shell made from a suitable form of gelatin.
Route of Administration	Routes of Administration associated with the dosage form.
Term ID	Term identifier of the Combined Pharmaceutical Dose Form.
Term Name	Name of the term to which the Combined Pharmaceutical Dose Form belongs.
Description	Description of the Combined Pharmaceutical Dose Form.
Last User Updated	Indicates the name of the user who last created/updated the dosage/ pharmaceutical form. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active Flag	Indicates if the entity is active or inactive.
Active	Indicates if the entity is active or inactive.

EC Cert Attributes

To define a EC Cert value, enter values for the following attributes:

Attribute	Description
EC Cert	Design certs for class III products. Hyperlinked from the view screen.
Last User Updated	Indicates the name of the user who last created/updated the EC Cert value. By default, this option is read-only. It is populated automatically when updates were made to the table.
Attribute	Description
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Global Harmonization Task Force (GHTF) Class Attributes

To define a GHTF class value, enter values for the following attributes:

Attribute	Description
GHTF Class	Class as defined by the GHTF.
Last User Updated	Indicates the name of the user who last created/updated the Global Harmonization Task Force (GHTF) class. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Manufacturing Location Attributes

To define a manufacturing location value, enter values for the following attributes:

Attribute	Description
Manufacturing Location	Locations of the Device Manufacturers (assuming no PDS).
Last User Updated	Indicates the name of the user who last created/updated the manufacturing location. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Medical Device Attributes

To define a medical device value, enter values for the following attributes:

Attribute	Description
Medical Device Name	Medical Device Name value.
Medical Device Code	Medical Device Code for the Medical Device name. When a medical device is part of a product the Medical Device Code is required for XEVMPD.
Attribute	Description
RMS Term Name	List of Medical Device RMS Values available for selection.
Last User Updated	Indicates the name of the user who last created/updated the medical

	device. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Product Characteristics Attributes

To define a product characteristics value, enter values for the following attributes:

Attribute	Description
Code Value	Medical Device Name value.
Code Name	The full name and/or description for the code.
Last User Updated	Indicates the name of the user who last created/updated the product characteristics. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Product Status Attributes

To define a product status value, enter values for the following attributes:

Attribute	Description
Name	The name given for the Product Status.
Default Flag	Flag to indicate if the product status is the default. Yes and No values are available for selection.
System Process Default Flag	Select which of the added statuses will show for a Product status after the Event is closed.
Internal System Status	The internal status associated to the product status.
Last User Updated	Indicates the name of the user who last created/updated the product status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Attribute	Description

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Product Strength Unit Attributes

To define a product strength unit value, enter values for the following attributes:

Attribute	Description
Product Strength Unit	Short Version of the Unit Measure name of the Product Strength.
Product Strength Unit Name	Long Version of the Unit Measure name of the Product Strength.
Last User Updated	Indicates the name of the user who last created/updated the product strength unit. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Route of Administration Attributes

To define a route of administration value, enter values for the following attributes:

Attribute	Description
Route of Administration (Long Name)	Full Route of Administration Name. Example: Oral.
Route of Administration (Short Name)	Abbreviation Route of Administration. Example: OR.
FDA Code	The list of FDA codes available for selection.
Type Term	Type of Route of Administration Term. Examples: 1 -Development Term, 2 - Proposed Term, 3 - Standard Term.
Version Date	The date of the last update of the administration route should be specified.
RMS Term Name	List of Route of Administration RMS Values available for selection.
Description	Description field.
Last User Updated	Indicates the name of the user who last created/updated the route of administration. By default, this option is read-only. It is populated automatically when updates were made to the table.

Attribute	Description
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Special Measure Attributes

To define a special measure value, enter values for the following attributes:

Attribute	Description
Code Value	The actual value for the code.
Code Name	The full name and/or description for the code.
Last User Updated	Indicates the name of the user who last created/updated the special measure. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Sterilization Requirement Attributes

To define a sterilization requirement value, enter values for the following attributes:

Attribute	Description
Code Value	The actual value for the code.
Code Name	The full name and/or description for the code.
Last User Updated	Indicates the name of the user who last created/updated the sterilization requirement. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Sterilization Attributes

To define a sterilization value, enter values for the following attributes:

Attribute	Description

Sterilization	Sterilization value. Examples: Values of none, ETO, Radiation, Steam.
Attribute	Description
Last User Updated	Indicates the name of the user who last created/updated the sterilization. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Summary of Technical Documentation (STED) Attributes

To define a summary of technical documentation value, enter values for the following attributes:

Attribute	Description
Summary of Technical Documentation	(STED) Client specific Summary of Technical Documentation Id's.
Last User Updated	Indicates the name of the user who last created/updated the summary of technical documentation (STED). By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

UMDNS Code Attributes

To define a UMDNS code value, enter values for the following attributes:

Attribute	Description
UMDNS Code	The name of the code.
UMDNS Description	Description of the UMDNS Code.
Last User Updated	Indicates the name of the user who last created/updated the UMDNS code. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.

Active	Indicates if the entity is active or inactive.

Product Category Type Attributes

To define a product category value, enter values for the following attributes:

Attribute	Description
Product Category Type Name	The name of the product category.
Last User Updated	Indicates the name of the user who last created/updated the product category. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Product Cross Reference Type Attributes

To define a product cross reference type value, enter values for the following attributes:

Attribute	Description
Product Cross Reference Type Name	The name of the product that is referenced.
Last User Updated	Indicates the name of the user who last created/updated the product cross reference type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Product Detail Set Maintenance

Product detail set (PDS) values appear in lists on the *Product Detail Set*, *Product Detail Set Details*, *Product*

Detail Set Template, and *Product Detail Set Template Details Attributes* pages and are designated when a PDS, PDS detail, PDS template, or PDS template detail is created.

Data administration enables you to add and modify list values, and to set the status of a value to active or inactive. When you select a value under Product Detail Set Maintenance, a page appears with a table of all values that have been defined. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

The proper data administration access privileges are required to view and modify application maintenance values.

Note: Twenty extra text fields, five extra date fields, and five extra number fields can be configured for all PDS values.

Product Detail Set Maintenance: PDS Values

You can create and maintain the following PDS values:

Value	Description
Color	The color of the component color
Compendial Designation/Source	Contains information for each reference source that will be stored directly in the XEVMPD. Must contain all values for which approval is requested or given. A value can be, for example, USP, PhEUR, or JP. The list contains reference sources (compendial designations) from the EMA reference sources CV. The default value is set to Active. The standard set of extra fields can be configured for this value.
Component Type	The type of component. The RMS value is mapped to the Container Category SPOR RMS List.
Device - Type of Combination	The type of the device. The RMS value is mapped to the Medical Device Legislative Category SPOR RMS List.
Dose Frequency	The frequency of the dose administered. Used for veterinary products.
Genetically Modified Cell Origin Species	Species from which cells have been genetically modified. Note: By default, the section is hidden.
Human Consumption Product	Indicates whether a product produced from an animal is not to be used by humans while a drug is administered, or is considered safe for humans to use after a withdrawal period.
Intended Effect	Expected result of the drug. The RMS value is mapped to the Medicine Profile SPOR RMS List.
Label Type	The type of label. For example, patient insert, physician insert, carton label, package label, etc.
Manufacturer	The name of the manufacturer. Substances, manufacturer functions, material and packaging The following Detail Types must exist under Global Detail Sets to associate Global Product Details with a manufacturer:

	– Substance – Manufacturer Functions – Material – Packaging
Manufacturing Functions	The functions associated with the manufacturing Example: dosage form production, dosage form retesting, repackaging, etc.

Value	Description
Material Type	Used to add material types to the system, such as by-product, raw material, or intermediate. Can also deactivate active material types.
Material	The substance or substances out of which a thing is or can be made.
Medical Device Part Code	Identification codes assigned to parts of medical devices.
Package Component	The type pf packaging component values.
Packaging Category	Example: primary, secondary
Packaging Type	Example: blister, glass bottle, plastic bottle
Product Bio Type	Type of biologic or technobiologic product, such as extractive, recombinant, vaccine, GMO, plasma derived, etc.
Product Detail Set Status	Example: approved, in-progress, withdrawn, and not approved
Product Material	The material out of which the product is made.
Production Type	Used for veterinary products, production types are the varieties of a species for which a drug is targeted. Multiple production types can be associated with a species, and a production type can be associated with multiple species. If a production type is used in the dosing schedule detail for a species in a PDS or PDS template, do not disassociate the production type from the species. Note: By default, the section is hidden.
QC Status	The QC (quality control) status that you can assign to a pending PDS detail to indicate whether it has been checked to verify that it is correct. The default QC Status values are: Not Applicable (QC statuses are not used), QC Passed, QC Failed, and Not QC'd (not checked).
Shape	Component shape, such as oval, round, etc.

Shelf Life Category	The kind of shelf life for a product. For example, a category can be registered, for an actual product shelf life that is registered with the registration authority, or labeled, for a shelf life that is on the product package label.
Shelf Life Type	This describes the shelf life, taking into account various scenarios such as shelf life of the packaged medicinal product itself, shelf life after transformation where necessary and shelf life after the first opening of a product, etc.

Value	Description
Somatic Cell Therapy Cell Type	Types of somatic cells used in a trial.
	Note: By default, the section is hidden.
Somatic Cell Therapy Origin Species	Species from which somatic cells are derived.
	Note: By default, the section is hidden.
Somatic Cell Therapy Origins	Origination of somatic cells in a trial.
	Note: By default, the section is hidden.
Source of Scientific Advice	Used in a trial.
	Note: By default, the section is hidden.
Species	Used for veterinary products, species types are the animals for which a drug is targeted. Production types must exist in the system to be able to associate them with a species.
Storage Condition	Conditions approved for packaging.
Substance Role	Name of a role that can be associated to an Substance Detail in a Product Detail Set. For example, colorant, filler, etc. The default value is set to Active. The standard set of extra fields can be configured for this value.
Substance Type	Indicates the substance type in the Product Detail Set. The different Substance Types available are - Adjuvant and Excipient. The default value is set to Active. The standard set of extra fields can be configured for this value. The RMS value is mapped to the Ingredient Role SPOR RMS List.
Time Unit	Example: month, week, day
Type of Dossier Submitted	Example: full IMPD, simplified IMPD, and SmPC

	Note: By default, the section is hidden.
Value	Description
Type of Gene Therapy Transfer Product	Example: nucleic acid naked, nucleic acid, complexed, viral vectoradenovirus, viral vector-retrovirus, viral vector-AAV
	Note: By default, the section is hidden.
Type of Gene Therapy	Example: in-vivo, ex-vivo
	Note: By default, the section is hidden.
Type of Genetically Modified Cell Origin	Origination of genetically modified cells.
	Note: By default, the section is hidden.
Volume Unit of Measure	The volume can be specified using a numerical value and its unit of measurement.
Medical Device UDI Values	A Unique Device Identification (UDI) system identifies the medical devices with it's usage. This table displays the values for the Device Type field for PDS Component - Medical Devices. This Data Administration list is mapped to the Device Type value in the SPOR RMS list section.
Origin of Substance	The list of substance sources required for IDMP.
Manufacturing Function	This Data Administration table is used to populate the Function Name field for PDS- Function. This Data Administration list is mapped to the Manufacturing Activity value in the SPOR RMS list section.
Data Classification Type	This Data Administration table is used to populate the Confidentiality Indicator field on the Data Administration Manufacturer Values - Data Administration Manufacturer Values > Global Product Details > Global Detail Sets.

Color Attributes To define a color value, enter values for the following attributes:

Attribute	Description
Color	Color value.
Last User Updated	Indicates the name of the user who last created/updated the color. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.

Attribute	Description
Active	Indicates if the entity is active or inactive.

Compendial Designation/Source Attributes

To define a compendial designation/source value, enter values for the following attributes:

Attribute	Description
Compendial Designation/Source Name	Contains reference sources (compendial designations) from the EMA reference sources CV.
Date Submitted to EMA	Date Submitted to EMA populated automatically when Acknowledgement Wizard passed.
EV Code	Code assigned by the EMA to this Compendial Designation.
RMS Term Name	List of Compendial Designation/Source RMS Values available for selection.
XEVMPD Comments	Comments field. For EMA submissions, comments must be limited to 500 characters. Comments are mandatory for the Nullify operation type.
Last User Updated	Indicates the name of the user who last created/updated the compendial designation/source value. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Component Type Attributes

To define a color value, enter values for the following attributes:

Attribute	Description
Component Type Name	The Type of the component.
RMS Term Name	List of Container Category RMS Values available for selection.
Last User Updated	Indicates the name of the user who last created/updated the component type. By default, this option is read-only. It is populated automatically when updates were made to the table.

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Device - Type of Combination Attributes

To define a type of the device values, enter values for the following attributes:

Attribute	Description
Device - Type of Combination Name	The name of the device type.
RMS Term Name	List of Medical Device Legislative Category RMS Values available for selection.
Last User Updated	Indicates the name of the user who last created/updated the device type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Dose Frequency Attributes

To define a dose frequency value, enter values for the following attributes:

Attribute	Description
Dose Frequency	Dose Frequency. Example: Single Administration.
Last User Updated	Indicates the name of the user who last created/updated the dose frequency. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Genetically Modified Cell Origin Species Attributes

To define a genetically modified cell origin species value, enter values for the following attributes:

Attribute	Description

Genetically Modified Cell Origin Species	Genetically Modified Cell Origin Species.
Last User Updated	Indicates the name of the user who last created/updated the genetically modified cell origin species values. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Human Consumption Products Attributes

To define a human consumption products value, enter values for the following attributes:

Attribute	Description
Human Consumption Products	Human Consumption Products. Examples: Milk, Meat.
Last User Updated	Indicates the name of the user who last created/updated the genetically modified human consumption products value. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Intended Effect Attributes

To define an intended effect value, enter values for the following attributes:

Attribute	Description
Intended Effect	Expected result of the treatment.
RMS Term Name	List of Medicine Profile RMS Values available for selection.
Last User Updated	Indicates the name of the user who last created/updated the intended effect value. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Label Type Attributes

To define a label type value, enter values for the following attributes:

Attribute	Description
Label Type	Name of the type of label. Example: Package Insert, Carton Label.
Last User Updated	Indicates the name of the user who last created/updated the label type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Manufacturer Attributes To define a manufacturer value, enter values for the following attributes:

Attribute	Description
Manufacturer Name	Name of the Manufacturer. Uniqueness by concatenation: Manufacturer Name + Address Line 1 + Country.
Labeler DUNS Number/Legal Manufacturer Single Registration Number(SRN)	Indicates the Labeler DUNS Number for US and the Manufacturer Single Registration Number (SRN) for EU.
Authorized Representative Name	Name of the authorised representative of the Manufacturer.
Address Line 1	Full address of the Manufacturer.
Country	Country Code based on site address. Data from Data Administration >Country Values.
GMP Status	Status of the Manufacturer respectively to Good Manufacturing Practices. Example: In Good Standing, Not in Good Standing
GMP Expiration Date	Date on which the GMP status is expected to expire before the Manufacturer needs to renew.
Last GMP Inspection	Date on which the last GMP inspection took place.
Contact Person	Contact at the Manufacturer.
Contact Person Title	Contact person's title.
Phone	Full phone number.

Fax	Full fax number.
e-mail	Email address of contact.
Agent	Name of the agent.
Agent Title	Title of the agent.
Agent Address	The address of the agent.
Agent Phone	Agent phone number.
Agent Fax	Agent fax number.
Agent e-mail	Email address of contact.
Site License Number	
Site Certificate Filed	check = yes
DMV/CEP Number	
US Agent	Name of the US Agent.
Attribute	Description
FEI Number	FDA Established Identifier.
Parent Company Name	Name of the parent company.
Other Firms	Other firms operating at site.
Comments	Free format text box where users can enter information.
Keywords	Free format text box where users can enter text for searching purposes.
Description	Free format text box for entering descriptive information.
Organization ID	The organization identifier associated from SPOR Master Lists > Organization.
Location ID	The location identifier associated from SPOR Master Lists > Organization.
Manufacturer Name	The organization name associated from SPOR Master Lists > Organization.
Address	The address associated from SPOR Master Lists > Organization.
City	The city associated from SPOR Master Lists > Organization.
Post Code	The post code associated from SPOR Master Lists > Organization.
Country	The country associated from SPOR Master Lists > Organization.
Last User Updated	Indicates the name of the user who last created/updated the manufacturer. By default, this option is read-only. It is populated automatically when updates were made to the table.

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active Flag	Indicates if the entity is active or inactive.
Active	Indicates if the entity is active or inactive.

Manufacturing Functions Attributes To define a manufacturing functions value, enter values for the following attributes:

Attribute	Description
Manufacturing Function Name	Full Manufacturing Function Name. For example, Stability Testing, PreDosage Processing.
Last User Updated	Indicates the name of the user who last created/updated the manufacturing functions. By default, this option is read-only. It is populated automatically when updates were made to the table.
Attribute	Description
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Material Type Attributes

To define a material type value, enter values for the following attributes:

Attribute	Description
Material Type	Material Type. Example: Raw Material, Intermediate, By-Product.
Last User Updated	Indicates the name of the user who last created/updated the material type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Material Attributes

To define a material value, enter values for the following attributes:

Attribute	Description

Material Name	Material Name.
Description	Description of the Material.
Comments	Internal comments including exceptions and clarifications.
Keywords	Free format text box where users can enter text for searching purposes.
Last User Updated	Indicates the name of the user who last created/updated the material. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Medical Device Part Code Attributes

To define a medical device part code value, enter values for the following attributes:

Attribute	Description
Medical Device Part Code	Material Type. Example: Raw Material, Intermediate, By-Product.
Attribute	Description
Last User Updated	Indicates the name of the user who last created/updated the medical device part code. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Package Component Attributes

To define a package component, enter values for the following attributes:

Attribute	Description
Component Type	Value of the Component type from the Data Administration > Component Type Values .
Product Material	Value of Product Material from the Data Administration > Product Material Values .
Package Component Name	Name of the Package Component. Package Components name is displayed as a concatenation of Component Type and Component Material. Example:

	CompType1-Material1
Last User Updated	Indicates the name of the user who last created/updated the package component value. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.

Packaging Category Attributes

To define a packaging category value, enter values for the following attributes:

Attribute	Description
Name	Name of the Packaging Category. Example: primary, secondary.
IDMP Package Level	IDMP Package Level defined in numbers and characters. For example: 123/456/78Z.
Last User Updated	Indicates the name of the user who last created/updated the packaging category. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Packaging Type Attributes

To define a packaging type value, enter values for the following attributes:

Attribute	Description
Category	Selected Packaging Category associated to the packaging type.
Name	Name of the Packaging Type associated to a selected Category.
Description	Free format text box for entering descriptive information.
Comments	Free format text box where users can enter information
Keywords	Free format text box where users can enter text for searching purposes
Last User Updated	Indicates the name of the user who last created/updated the packaging type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Product Bio Type Attributes

To define a product bio type value, enter values for the following attributes:

Attribute	Description
Product Bio Type	Is selected only when the product is considered to be biological or biotechnological. Values: Extractive, Recombinant, Vaccine, GMO, Plasma Derived.
Last User Updated	Indicates the name of the user who last created/updated the product bio type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Product Detail Set Status Attributes

To define a product detail set status value, enter values for the following attributes:

Attribute	Description
Name	The name given for the Product Detail Set Status.
Default Flag	Flag to indicate if the status value is the default. Yes and No values are available for selection.
System Process Default Flag	Select which of the added statuses will show for a Product Detail Set status after the Event is closed.
Attribute	Description
Internal System Status	The internal status associated to the PDS status.
Last User Updated	Indicates the name of the user who last created/updated the product detail set status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Product Material Attributes

To define a product material value, enter values for the following attributes:

Attribute	Description

Code Value	The actual value for the code.
Code Name	The full name and/or description for the code.
Last User Updated	Indicates the name of the user who last created/updated the product material. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Production Type Attributes

To define a production type value, enter values for the following attributes:

Attribute	Description
Production Type	Production Type. Examples: Breeders, Fatteners.
Last User Updated	Indicates the name of the user who last created/updated the product type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

QC Status Attributes

To define a QC status value, enter values for the following attributes:

Attribute	Description
Name	Name given for the QC Status.
Attribute	Description
Default Flag	Flag to indicate if the status value is the default. Yes and No values are available for selection.
Internal System Status	The internal status associated to the QC Status.
Last User Updated	Indicates the name of the user who last created/updated the QC status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Shape Attributes

To define a shape value, enter values for the following attributes:

Attribute	Description
Shape	Defines a shape. Examples: Round, Oval.
Last User Updated	Indicates the name of the user who last created/updated the shape value. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Shelf Life Category Attributes

To define a shelf life category value, enter values for the following attributes:

Attribute	Description
Shelf Life Category	The Shelf Life Category identifies whether the Shelf Life being tracked in the PDS is the registered Shelf Life (approved by the Reg Authority) or the Shelf Life that appears on the product label.
Default Flag	Flag to indicate if the value is the default. Yes and No values are available for selection.
Last User Updated	Indicates the name of the user who last created/updated the shelf life category. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Shelf Life Type Attributes

To define a shelf life type value, enter values for the following attributes:

Attribute	Description
Code Value	The actual value for the code.
Code Name	The full name and/or description for the code.
Last User Updated	Indicates the name of the user who last created/updated the shelf life type. By default, this option is read-only. It is populated automatically when updates were made to the table.

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Somatic Cell Therapy Cell Types Attributes

To define a somatic cell therapy cell types value, enter values for the following attributes:

Attribute	Description
Somatic Cell Therapy Cell Types	Is selected only when Somatic Cell Therapy Origin is populated. Values are: Stem Cells, Differentiated Cells, Keratinocytes, Fibroblasts, Chondrocytes.
Last User Updated	Indicates the name of the user who last created/updated the somatic cell therapy cell types. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Somatic Cell Therapy Origin Species Attributes

To define a somatic cell therapy origin species value, enter values for the following attributes:

Attribute	Description
Somatic Cell Therapy Origin Species	Is selected only when Somatic Cell Therapy Origin is populated.
Last User Updated	Indicates the name of the user who last created/updated the somatic cell therapy origin species value. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Somatic Cell Therapy Origins Attributes

To define a somatic cell therapy origins value, enter values for the following attributes:

Attribute	Description
Somatic Cell Therapy Origins	Is selected only when there is no genetic modification. Values are: Autologous, Allogenic, Xenogeneic.
Last User Updated	Indicates the name of the user who last created/updated the somatic cell therapy origin value. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Source of Scientific Advice Attributes

To define a source of scientific advice value, enter values for the following attributes:

Attribute	Description
Source of Scientific Advice	Source of Scientific Advice. Values are CHMP, MS Competent Authority, CHMP and MS Competent Authority and none.
Last User Updated	Indicates the name of the user who last created/updated the source of scientific advice. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Species Attributes

To define a species value, enter values for the following attributes:

Attribute	Description
Species	Species. Examples: Cattle, Sheep.
Production Types	All active Production Types defined in Data Administration available for selection.
Last User Updated	Indicates the name of the user who last created/updated the species. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.

Active	Indicates if the entity is active or inactive.

Storage Condition Attributes

To define a storage condition value, enter values for the following attributes:

Attribute	Description
Storage Condition	Name of the Storage Condition.
Last User Updated	Indicates the name of the user who last created/updated the storage condition. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Substance Role Attributes

To define a substance role value, enter values for the following attributes:

Attribute	Description
Name	Name of Substance Role. Examples: Not Applicable.
Last User Updated	Indicates the name of the user who last created/updated the substance role. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Substance Type Attributes

To define a substance type value, enter values for the following attributes:

Attribute	Description
Substance Type	Name of Substance Type. Examples: Adjuvant, Excipient.
RMS Term Name	Name of the RMS term used to describe attributes of products.
Last User Updated	Indicates the name of the user who last created/updated the substance type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Time Unit Attributes

To define a time unit value, enter values for the following attributes:

Attribute	Description
Time Unit	Name of Time Unit. Examples: Second(s), Minute(s), Hour(s), Day(s), Month(s), Year(s).
Last User Updated	Indicates the name of the user who last created/updated the time unit. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Type of Dossier Submitted Attributes

To define a type of dossier submitted value, enter values for the following attributes:

Attribute	Description
Type of Dossier Submitted	Name of Type of Dossier Submitted. Examples: Full IMPD, Simplified IMPD, and SmPC.
Last User Updated	Indicates the name of the user who last created/updated the type of dossier submitted. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Type of Gene Therapy Transfer Product Attributes

To define a type of gene therapy transfer product value, enter values for the following attributes:

Attribute	Description
Type of Gene Therapy Transfer Product	Name of Gene Therapy Transfer Product. Examples: Full IMPD, Simplified IMPD, and SmPC.
Last User Updated	Indicates the name of the user who last created/updated the type of gene therapy transfer product. By default, this option is read-only. It is populated automatically when updates were made to the table.

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Type of Gene Therapy Attributes

To define a type of gene therapy value, enter values for the following attributes:

Attribute	Description
Type of Gene Therapy	Name of Gene Therapy. Examples: in-vivo, ex-vivo.
Last User Updated	Indicates the name of the user who last created/updated the type of gene therapy. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Type of Genetically Modified Cell Origin Attributes

To define a type of genetically modified cell origin value, enter values for the following attributes:

Attribute	Description
Type of Genetically Modified Cell Origin	Name of Type of Genetically Modified Cell Origin. Examples: Autologous, Allogeneic, Xenogeneic.
Last User Updated	Indicates the name of the user who last created/updated the type of gene therapy modified cell origin. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Volume Unit Of Measure Attributes

To define a volume unit of measure value, enter values for the following attributes:

Attribute	Description
Code Value	The actual value for the code.

Code Name	The full name and/or description for the code.
Last User Updated	Indicates the name of the user who last created/updated the volume unit of measure. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Medical Device UDI Attributes

To define a medical device UDI value, enter values for the following attributes:

Attribute	Description
Medical Device UDI Name	Unique name for the Medical Device UDI.
Last User Updated	Indicates the name of the user who last created/updated the medical device UDI. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Origin of Substance Attributes

To define an origin of substance value, enter values for the following attributes:

Attribute	Description
Origin of Substance	Unique name for the substance source.
Last User Updated	Indicates the name of the user who last created/updated the substance source. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Manufacturing Function Attributes

To define a manufacturing function value, enter values for the following attributes:

Attribute	Description
Manufacturing Function Name	Unique name for the Manufacturing Function.
Last User Updated	Indicates the name of the user who last created/updated the manufacturing function. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Data Classification Type Attributes

To define a data classification type value, enter values for the following attributes:

Attribute	Description
Data Classification Type Name	Name for the Data Classification Type.
Last User Updated	Indicates the name of the user who last created/updated the data classification type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Associate Product Details with a Manufacturer

You can associate product details with a manufacturer in Data Administration.

To associate product details with a manufacturer:

1. Choose Go To > Data Administration.
2. Under Product Detail Set Maintenance, click Manufacturer Values.
3. Click the manufacturer for which you want to make an association.

Option	Action

To associate a type of global product detail with the manufacturer:	Click  next to Global Product Details. Select the type in De- tail Type drop-down list.
To associate a manufacturing authorization reference number with the manufacturer:	Click  next to Manufacturing Authorization Reference Number.
To save the changes:	Click Save for each page.

Manufacturer Entities

Global Product Details Attributes

Use the global product details option to create global detail sets to display general information about manufacturer, good manufacturing practices statuses and expiration dates ,drug master file number detail type and so on.

You can define the following Global Detail Sets values:

Attribute	Description
Manufacturer Name	Name of the manufacturer.
Address Line 1	Address of the Manufacturer.
Country	Country of the Manufacturer.

Attribute	Description
Country Code	Country Code based on site address.
GMP Status	Status of the Manufacturer with respect to Good Manufacturing Practices. For example, In Good Standing, Not in Good Standing, and so on.
GMP Expiration Date	Date on which the GMP status is expected to expire before the Manufacturer needs to renew.
Last GMP Inspection	Date of the last GMP inspection.
Comments	Comments for Global Detail Sets.
Keywords	Keywords used to search Global Detail Sets .
Description	Description for Global Detail Sets.
Detail Type	Type of Manufacturer PDS Detail: Substance, Material, Manufacturing Functions, Packaging.
Substance Name	Name of the Substance. Available when the Detail Type is a Substance. You can select only one substance.
DMF Number	The number for the Drug Master File that is used to submit data to regulatory authorities for review and approval of a drug. Available when the Detail Type is a Substance.

Raw Material	The name of Material. Available when the Detail Type is a Material.
Function	The name of Manufacturing Functions. Available when the Detail Type is Manufacturing Functions.
Confidentiality Indicator	The Confidentiality Indicator is populated by the Data Classification SPOR RMS list. Available when the Detail Type is Manufacturing Functions, Substance and Packaging.
Category	The Category of Packaging. Available when Detail Type is a Packaging.
Packaging	The type of Packaging. Available when Detail Type is a Packaging.
Last User Updated	Indicates the name of the user who last created/updated the global detail set value. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active Flag	Current Active/Inactive setting for the Global Detail Set.

Manufacturer Authorization Reference Number Attributes

Use Manufacturer Authorization Reference Number option to display general information about manufacturer, good manufacturing practices statuses and expiration dates, information when the last GMP inspection took place, contact details and so on.

Note: You can create multiple Manufacturing Authorization Reference Number entities with the same name, type, and effective date, but the Function Types or Substances fields should contain different values.

You can maintain the following Manufacturer Authorization Reference Number values:

Attribute	Description
Active Flag	Current Active/Inactive setting for the Global Detail Set.
Address Line 1	Address of the Manufacturer.
Agent	Name of the agent.
Agent Title	Title of the agent.
Agent Address	The address of the agent.
Agent Phone	The phone number of the agent.
Agent Fax	The fax number of the agent.
Agent e-mail	Agent email address.
Authorised Representative	The name of Authorised Representative.

Name	
Comments	Comments for Manufacturer.
Contact Person	Name of the contact person.
Contact Person Title	Title of the contact person.
Country	Country Code based on site address.
Country	The country that approved the manufacturing site. When country is selected, choose the related Regulatory Agency associated to the country, otherwise the country value is not saved.
Description	Description for Manufacturer.
DMF/CEP Number	The number of Drug Master File (DMF)/Certificate of Suitability (CEP). Issued by the authorities when the manufacturer of a drug provides relevant proof for the drug quality.
e-mail	Contact person email address.
Effective Date	The organisation name associated with SPOR OMS.
Fax	Fax number.

Attribute	Description
FEI Number	FDA Established Identifier.
GMP Status	Status of the Manufacturer with respect to Good Manufacturing Practices. For example, In Good Standing, Not in Good Standing and so on.
GMP Expiration Date	Expiry date of the GMP.
Keywords	Keywords used to search information.
Labeler DUNS Number/ Legal Manufacturer Single Registration Number (SRN)	Indicates the Labeler DUNS Number for US and the Manufacturer Single Registration Number (SRN) for EU.
Last GMP Inspection	Date of the last GMP inspection.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates are made to the table.
Last User Updated	Indicates the name of the user who last created/updated the manufacturing authorization reference number value. By default, this option is read-only. It is populated automatically when updates are made to the table.

Function Types	The list of function types taken from Manufacturing Authorisation Reference Number > Global Product Details.
Substances	The list of substances taken from Manufacturing Authorisation Reference Number > Global Product Details.
Manufacturer Name	Name of the Manufacturer.
Manufacturing Authorisation Reference Number	The organisation identifier associated with SPOR OMS.
Manufacturing Authorisation Type	The location identifier associated with SPOR OMS.
Other Firms	Other firms operating at site.
Parent Company Name	Name of the parent company.
Phone	The phone number of the contact person.
Regulatory Agency	<i>Data Administration</i> values assigned in Application Maintenance > Country Values > Health Authority. The regulatory agency must be selected for the country..
Site License Number	The license number of the site.
Site Certificate Filed	Indicates if site certificate is available or not.
Status Type	The type of status: Active or Inactive.

Attribute	Description
Status Date	The effective date for the current status.
US Agent	The name of the US Agent.

Modify an Association with a Manufacturer

You can modify the manufacturer associated with a product detail in Data Administration.

To modify a product detail association with a manufacturer:

1. Choose Go To > Data Administration.
2. Under Product Detail Set Maintenance, click Manufacturer Values.
3. Click the manufacturer you want to modify.
4. Scroll to the bottom of the page and click the global product detail you want to modify, and proceed as follows:

Action	Procedure
To deactivate an association with a manufacturer	Click the Active Flag arrow and choose Inactive.

To reactivate a deactivated association with a manufacturer

Click the Active Flag arrow and choose Inactive.

5. Click Save.
6. Click Back to return to the *Manufacturers* page.

Product Family Maintenance

Product family values appear in lists on the *Product Family Attributes* page and are designated at the time a product family is created or modified.

Data Administration enables you to add or modify list values, and set the status of a value to active or inactive. When you select a value under Product Family Maintenance, a table of all values that have been defined appears. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

Note: *The proper data administration access privileges are required to view and modify product family maintenance values.*

All XEVMPD Data Administration tables provide the ability to configure extra fields. The standard set consists of twenty extra text fields, five extra date fields, and five extra number fields.

Product Family Maintenance: Product Family Values

You can create and maintain the following product family values:

Value	Description
ATC	EU-specific Pharma Anatomical Therapeutic Chemical class code. The list contains ATC codes from the EMA ATC Code Additions CV. The default value is set to Active. The standard set of extra fields can be configured for this value.
Division Values	Related to the Office of Device Evaluation (ODE) Review Divisions, for example, Division of Cardiovascular, Respiratory and Neurological Devices, Division of Clinical Laboratory Devices, etc.
Domain Type Values	Indicates whether the type of medicinal product is for human or for veterinary use.
EURD ID Values	When the medicinal product is part of a PSUR single assessment procedure in accordance with the European Union reference date dates and frequency of submission of periodic safety reports list (EURD list), the EURD ID shall be provided. The EURD ID shall be derived from the procedure number of the PSUR single assessment, which is published in the EURD list Excel file available on the 'Periodic safety update reports' webpage.
Product Family Status	The status of the product family, such as investigational, planned, approved, active, withdrawn.

Product Family	The highest level of a product defined by the company-based user-defined product family code and/or name.
Substance Class	Classification given to substances. Examples are mixture, and specified substance classes. The list contains substance classes and substance class code from the EMA Substance Class CV. The default value is set to Active. The standard set of extra fields can be configured for this value.
Substance Subtype Type Values	Subtypes of substance. The following values pre-populate in the grid. You cannot activate/modify the values below. For configuration assistance, contact our support representatives. – Uncategorized (inactive by default) – CMR Substance – Endocrine Substance – Strain – Human Product Substance – Placeholder – Substance
Value	Description
Substance	Defines substance values with their affiliated attributes. The XEVMPD related substance entities such as substance alias (the tab is hidden), substance attachments, substance international codes and substance translations (the tab is hidden), substance management services can be added using the Substance option. Several types, such as Substance, Placeholder, and Strain, can be selected from the list. The default type value is Substance. The list contains the substances from the EMA Substances CV. The default value is set to Inactive. The standard set of extra fields can be configured for this value.
Therapeutic Area	Therapeutic use, such as oncology, cardio-renal, pulmonary. The standard set of extra fields can be configured for this value.
Therapeutic Class	Groups of similar drugs used to treat a specific condition. The standard set of extra fields can be configured for this value.
Trade Name	The name under which a company markets a drug.

ATC Attributes To define an ATC value, enter values for the following attributes:

Attribute	Description
ATC Code	Standard Code defined by the EMEA used to identify Anatomical Therapeutic Chemicals (ATC). ATC is a classification system for drug substances which is maintained by the WHO Division of Drug Management and Policies (DMP).
ATC Description	Name of the Anatomic Therapeutic Class assigned by the EMEA.
Term Type	Type of ATC term. Examples: Development Term, Proposed Term, Standard Term
ATC Level	Level of the ATC Code. The field can be used to track the level of the ATC.
Version Date	Only needed for dev and proposed terms for XEVMPD.
Development Type Acknowledged	This field is needed for the application. It is not specified by the EMA. Values available for selection: Yes/No. Default is No
Proposed Type Acknowledged	This field is needed for the application. It is not specified by the EMA. Values available for selection: Yes/No. Default is No
Date Submitted to EMA	Date Submitted to EMA populated automatically when Acknowledgment Wizard passed.
Last Updated Date	Last Updated Date populated automatically when updates were made to the table.
RMS Term Name	List of ATC RMS Values available for selection.
Attribute	Description
Comments	Comments associated with the ATC.
XEVMPD Comments	Comment field.
Last User Updated	Indicates the name of the user who last created/updated the ATC values. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Division Attributes

To define a division value, enter values for the following attributes:

Attribute	Description

Division	Relates to the Office of Device Evaluation (ODE) Review Divisions. Examples: Division of Cardiovascular, Respiratory and Neurological Devices; Division of Clinical Laboratory Devices; Division of Dental, Infection Control and General Hospital Devices; Division of General and Restorative Devices; Division of Ophthalmic Devices; Division of Reproductive, Abdominal, Ear, Nose and Throat Radiological Devices
Default Flag	Flag to indicate if the product status is the default. Yes and No values are available for selection.
Last User Updated	Indicates the name of the user who last created/updated the division value. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Domain Type Attributes

To define a domain value, enter values for the following attributes:

Attribute	Description
Domain Name	Indicates whether the type of medicinal product is for human or for veterinary use.
Last User Updated	Indicates the name of the user who last created/updated the domain type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Attribute	Description
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

EURD ID Attributes

To define an EURD ID value, enter values for the following attributes:

Attribute	Description
Family Identifier/ Active Substances	Indicates the Family Identifier.

EURD ID	The EURD ID is derived from the procedure number of the PSUR single assessment which is published in the EURD list Excel file available on the <i>Periodic safety update reports</i> web page.
Last User Updated	Indicates the name of the user who last created/updated the EURD ID value. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Product Family Status Attributes

To define a product family status value, enter values for the following attributes:

Attribute	Description
Name	The name given for the Product Family Status.
Default Flag	Flag to indicate if the product status is the default. Yes and No values are available for selection.
Last User Updated	Indicates the name of the user who last created/updated the product family status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Product Family Attributes

To define a product family value, enter values for the following attributes:

Attribute	Description
Product Family Type	Type of Product Family. Examples: Pharmaceutical, Flu Vaccine, Veterinary, Medical Devices, Pharma-Med Device
Family Code	Code of Product Family.
Family Name	Name of Product Family.
Product Family Status	Status of Product Family. Example: Active, Planned.
	Note: By default, the field is hidden.
Product Family Status Date	Status Date of Product Family.

	Note: By default, the field is hidden.
Development Sponsor	Development Sponsor value in following concatenation MAH/Development Sponsor/Organisation Name + Address + City + Country Code. Note: By default, the field is hidden.
Last User Updated	Indicates the name of the user who last created/updated the product family. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Substance Class Attributes To define a substance class value, enter values for the following attributes:

Attribute	Description
Substance Class Name	Classification given to a substance. Examples: Mixture, Single, Specified Substance (must be specified for an Insert or Update operation)
Substance Class Code	Code assigned to the substance class.
Last User Updated	Indicates the name of the user who last created/updated the substance class. By default, this option is read-only. It is populated automatically when updates were made to the table.
Attribute	Description
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Substance Subtype Attributes

To define a substance value, enter values for the following attributes:

Attribute	Description
Name	A unique name for the substance subtype value.
Last User Updated	Indicates the name of the user who last created/updated the substance. By default, this option is read-only. It is populated automatically when updates were made to the table.

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Substance Attributes

To define a substance value, enter values for the following attributes:

Attribute	Description
Type	Defines the type of each Substance value. The values available are: – Uncategorized (inactive by default) – CMR Substance – Endocrine Substance – Strain – Human Product Substance – Placeholder – Substance
Substance Name	Name of the Substance. Combination of Substance Type + Substance Name should be unique in the system.
Category of CMR Type	Indicates the CMR Substance categories. This field appears only when you select the CMR Substance value in the Type field.
INN	International Non-proprietary name.
CAS Number	Chemical Abstract Services number assigned to the Substance.
Molecular Formula	Chemical formula of the substance.
Attribute	Description
Compound Number	The compound number of substance, if exists.
XEVMPD Development Substance	Identifies the substance as a Development Substance.
Substance Level Class	All active Substance Level Class Values from Data Administration.
CBD	Chemical Biological Description of the Substance.

Development Sponsor	Sponsor of the Clinical Trials if this is a Development Substance. Required by XEVM- PD if this is a Development Substance in following concatenation MAH/Development Sponsor/Organisation Name + Address + City + Country Code.
Compendial Designation/ Source	Compendial Designation/ Source. Substance Source in XEVMPD.
Keywords	Free format text box where users can enter text for searching purposes.
Description	Free format text box for entering descriptive information.
Comments	Free format text box where users can enter information.
Last User Updated	Indicates the name of the user who last created/updated the substance. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Therapeutic Area Attributes To define a therapeutic area value, enter values for the following attributes:

Attribute	Description
Therapeutic Area Name	Full Therapeutic Area Name. Example: Oncology, Anti-Inflammatory.
Last User Updated	Indicates the name of the user who last created/updated the therapeutic area. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Therapeutic Class Attributes

To define a therapeutic class value, enter values for the following attributes:

Attribute	Description
Therapeutic Class	Full Therapeutic Class Name. Example: Oncology, Anti-Inflammatory

Therapeutic Class Code	Code used to define Therapeutic Class.
Last User Updated	Indicates the name of the user who last created/updated the therapeutic class values. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Trade Name Attributes

To define a trade name value, enter values for the following attributes:

Attribute	Description
Trade Name	The trade name given.
Last User Updated	Indicates the name of the user who last created/updated the trade name. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Substance Subtype Attributes

To define a substance subtype value, enter values for the following attributes:

Attribute	Description
Name	Indicates a unique substance subtype name.
Last User Updated	Indicates the name of the user who last created/updated the division value. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Substance Entity Values

Use different tabs on the *Substance Values* page to add or modify additional substance data.

Ennov InSight enables you to add or modify values for Substance entities such as: Substance XEVMPD Information, Substance Alias, Substance Attachments, Substance International Codes, Substance Translations and SMS (Substance Management Services).

You can:

— Create a new Substance Value and add entity values for it. — Add entity values for an existing Substance Value.

Note: *The Substance Aliases and Substance Translations tabs can be hidden or made visible via overrides on the Substance Values page.*

Add Substance Entity Values

To add substance entity values:

1. Choose Go To > Data Administration.
2. Under Product Family Maintenance, click Substance Values.
3. Click the link corresponding to the substance value.
4. Select the tab corresponding to the substance entity to which you want to enter the values.
5. Click the Create icon .
6. Enter the values and click Save.
7. Repeat steps 4 through 6 to add values for different substance entities.

Modify Substance Entity Values via Entity Name

Ennov InSight enables you to modify values for Substance entities such as: Substance XEVMPD Information, Substance Alias, Substance International Codes, and Substance Translations via entity name.

You also can modify substance entity values by clicking on the entity name:

1. Choose Go To > Data Administration.
2. Under Product Family Maintenance, click Substance Values.
3. Click the link for the substance you want to modify.
4. Select the tab corresponding to the substance entity for which you want to modify the values.
5. Click on the name of the entity.

The entity attributes page opens.

6. Enter the information and click Save.
7. Repeat steps 4 through 6 to modify values for different substance entities.

Note: *The Substance Aliases and Substance Translations tabs can be hidden or made visible via overrides on the Substance Values page.*

Mass Activating or Deactivating Substance Entities

Ennov InSight enables you to activate or deactivate all the entities of a substance value using a single operation.

The entities of a substance such as the Substance Alias (the tab is hidden), Substance Attachments, Substance International Codes, and Substance Translations(the tab is hidden), can be activated or deactivated by activating or deactivating the substance.

To activate or deactivate substance entities:

1. Choose Go To > Data Administration.
2. Under Substance Values, click the link for the value you want to activate/deactivate.
3. Click the Edit icon.
4. Do one of the following:

Option	Action
To activate the substance and its entities	Select Activate.
To deactivate the substance and its entities	Select Deactivate.

The activation process can be performed for the whole Substance entity only, and all its sub tabs will be activated automatically. You can deactivate either the whole Substance entity, or deactivate separately all Substance sub tabs, such as the Substance Alias, Substance Attachments, Substance International Codes, and Substance Translations.

Project Maintenance

Project values appear in drop-down lists on the *Project Attributes* page and are designated when a project is created or modified. Data Administration enables you to add and modify drop-down list values, and set the status of a value to active or inactive.

When you select a value under Project Maintenance, a page shows a table of all values that have been defined. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

Note: *The proper data administration access privileges are required to view and modify project maintenance values.*

Project Maintenance: Project Values

You can create and maintain the following project values:

Ennov InSight Administration 7.3 Project Maintenance

Value	Description
Project Status Name	Can be, for example, completed, in progress, or planned. Default Flag indicates whether the project status name is the default status in Global Project Planning (GPP) project status fields, and can be Yes or No.
Project Type	Describes the scope of the project, for example create new events, and so on.

Project Status Attributes

To define a project status value, enter values for the following attributes:

Attribute	Description
Project Status Name	Project Status Name.
Default Flag	Flag to indicate if the project status is the default. Yes and No values are available for selection.
Last User Updated	Indicates the name of the user who last created/updated the project status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Project Type Attributes

To define a project type value, enter values for the following attributes:

Attribute	Description
Project Type	The type of project taking place. Examples: New Application, Manufacturing Change.
Internal Project Type	The Internal Project Type which is mapped to the Client defined Project Type.
Last User Updated	Indicates the name of the user who last created/updated the project type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Ennov InSight Administration 7.3 Project Maintenance

Reference Maintenance

Reference values appear in drop-down lists on the *Reference Attributes* page and are designated when a reference is created. Data administration enables you to add and modify drop-down list values, and set the status of a value to active or inactive.

When you select a value under Reference Maintenance, a page opens with a table of all values that have been defined. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

Note: The proper data administration access privileges are required to view and modify application maintenance values.

Reference Maintenance: Reference Values

You can create and maintain the following reference values:

Value	Description
Reference Content	Content of the reference, such as meeting agenda or approval letter
Reference Participant	Who the reference was to or from, for example: agency/agency name, internal departments, affiliates, etc.
Reference Status	For example: planned, active, open, completed, etc.
Reference Type	For example: announcement, internal note or content received

Note: Create reference types in the system before you create statuses, participants, and content. Statuses, participants, and content can only be associated with existing reference types.

Reference Content Attributes

To define a reference content value, enter values for the following attributes:

Attribute	Description
Reference Content	Content of the Reference like meeting agenda or approval letter. Different content values show in the drop down for different reference types selected. Hyper-linked from the view screen.
Reference Type	The type of reference. Examples: Announcement, Note or Content Received.
Last User Updated	Indicates the name of the user who last created/updated the reference content. By default, this option is read-only. It is populated automatically when updates were made to the table.

Ennov InSight Administration 7.3 Reference Maintenance

Attribute	Description
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Reference Participant Attributes

To define a reference participant value, enter values for the following attributes:

Attribute	Description
Reference Participant	Participant of the Reference such as who provided the content or who it was sent to. Different Participants show in the drop down for different reference types selected.
Reference Type	The type of reference. Examples: Announcement, Note or Content Received.
Last User Updated	Indicates the name of the user who last created/updated the reference participant. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Reference Status Attributes

To define a reference status value, enter values for the following attributes:

Attribute	Description
Reference Status	Status of the Reference like open/close or approved/unapproved. Different Statuses show in the drop down for different reference types selected.
Reference Type	The type of reference. Examples: Announcement, Note or Content Received.
Last User Updated	Indicates the name of the user who last created/updated the reference status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Ennov InSight Administration 7.3 Reference Maintenance

Reference Type Attributes

To define a reference status value, enter values for the following attributes:

Attribute	Description
Reference Type	The type of reference. Examples: Announcement, Note or Content Received.
Last User Updated	Defines by whom the Data Administration value was created/updated. By default, this option is read-only. It is populated automatically when updates were made to the table.

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Registration Maintenance

Registration values appear in lists on the *Registration Attributes* page and are designated when a registration is created or modified. Data Administration enables you to add and modify list values, and set the status of a value to active or inactive.

When you select a value under Registration Maintenance, a table of all values that have been defined appears. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

Note: *The proper data administration access privileges are required to view and modify registration maintenance values.*

All XEVMPD Data Administration tables provide the ability to configure extra fields. The standard set consists of twenty extra text fields, five extra date fields, and five extra number fields.

Registration Maintenance: Registration Status Values

You can create and maintain the following registration values:

Value	Description
EMA Authorization Status	The status of a medicinal product registration that uses the EMA controlled vocabulary. The default value is set to Active. The standard set of extra fields can be configured for this value.
Value	Description
Qualified Person Responsible for Pharmacovigilance (QPPV)	Individual residing within the European Economic Area (EEA) and is responsible by law for the safety of a human pharmaceutical product within the EEA. The QPPV must register with EudraVigilance. The EV registration system assigns the QPPV code to the QPPV responsible for the authorized medicinal product. The code is defined in the pharmacovigilance system master file. The standard set of extra fields can be configured for this value.
Registration Status	The status of a registration can be Planned, Active, Pending, Expired, or Withdrawn.
	Note: <i>The Internal System Status field includes an internal status named APPROVED. This value is used to maintain the IDMP (Identification of Medicinal Products) compliance.</i>
	The RMS value is mapped to the Registration Entitlement Status RMS List

Content of Change	The content of change provided for the IDMP attachment.
Data Carrier Type Values	The Data Carrier Type values are used when using different packaging levels of medicinal products. The RMS value is mapped to the Source of Information SPOR RMS List.
Provenance Reason Values	The reason of provenance to provide additional clarity on requirements for Post-marketing surveillance (PMS) submissions.
Master File Type Values	The type of master file indicated for the registrations.
Marketing Status	Marketing status for the medicinal products. This Data Administration list is mapped to the Marketing Status available in the SPOR RMS list.
Risk of Shortage of Supply Reason Values	Reason for updating the shortage of drug supply to the market.

EMA Authorization Status Attributes To define an EMA authorization status value, enter values for the following attributes:

Attribute	Description
Authorization Status	Status of the authorization/registration of a medicinal product.
Status Code	Authorization status code associated with the selected Authorisation Status.
RMS Term Name	List of EMA Authorization Status RMS Values must be available for selection.
Attribute	Description
Last User Updated	Indicates the name of the user who last created/updated the EMA authorization status. By default, this option is read-only. It is populated automatically when updates were made to the table
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates are made to the table.
Active	Indicates if the entity is active or inactive.

Qualified Person Responsible for Pharmacovigilance (QPPV) Attributes

To define a qualified person responsible for pharmacovigilance (QPPV) value, enter values for the following attributes:

Attribute	Description
QPPV Name	Internal Company QPPV Name.
QPPV Code	QPPV Code for the Qualified person responsible for

	Pharmacovigilance. Should be unique in the system. The EV Registration System QPPV code assigned to the QPPV detailed in the Pharmacovigilance System Master File in place for the product. Format of this code is USRnnnn. The value must match a current user who is designated QPPV with- in the EV registration system and who is a member of the same EV Group as the Sender organisation. Should be unique in the system.
Last User Updated	Indicates the name of the user who last created/updated the qualified person responsible for pharmacovigilance (QPPV). By default, this option is read-only. It is populated automatically when updates were made to the table
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates are made to the table.
Active	Indicates if the entity is active or inactive.

Registration Status Attributes

To define a registration status value, enter values for the following attributes:

Attribute	Description
Name	Name given for the Registration Status.
RMS Term Name	List of Regulatory Entitlement Status RMS Values available for selection.
Attribute	Description
Default Flag	Flag to indicate if the product status is the default. Yes and No values are available for selection.
System Process Default Flag	Enables you to select which status will show for a Registration after the Event is closed.
Internal System Status	Internal status associated to the Registration status.
Last User Updated	Indicates the name of the user who last created/updated the registration status. By default, this option is read-only. It is populated automatically when updates are made to the table
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates are made to the table.
Active	Indicates if the entity is active or inactive.

Content of Change Attributes

To define a content of change value, enter values for the following attributes:

Attribute	Description
Content of Change Name	Name given to the Content of Change.
Last User Updated	Indicates the name of the user who last created/updated the content of change. By default, this option is read-only. It is populated automatically when updates are made to the table
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates are made to the table.
Activate/Deactivate	Indicates if the entity is active or inactive.

Data Carrier Type Attributes

To define a data carrier type value, enter values for the following attributes:

Attribute	Description
Data Carrier Type Name	Name of the Data Carrier Type.
Data Carrier Identifier Source	Indicates the source of data carrier identifier for medicinal product packaging. Values are taken from the Data Carrier Identifier Source Values Data Administration List.
RMS Term Name	List of Source of Information RMS Values available for selection.
Attribute	Description
Last User Updated	Indicates the name of the user who last created/updated the data carrier type. By default, this option is read-only. It is populated automatically when updates are made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates are made to the table.
Active	Indicates if the entity is active or inactive.

Master File Type Attributes

To define a master file type value, enter values for the following attributes:

Attribute	Description
Master File Type Name	Name of the Master File Type.
Last User Updated	Indicates the name of the user who last created/updated the master

	file type. By default, this option is read-only. It is populated automatically when updates are made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates are made to the table.
Active	Indicates if the entity is active or inactive.

Provenance Reason Attributes

To define a provenance reason value, enter values for the following attributes:

Attribute	Description
Provenance Reason Name	Name for the provenance reason.
Last User Updated	Indicates the name of the user who last created/updated the provenance reason. By default, this option is read-only. It is populated automatically when updates are made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates are made to the table.
Active	Indicates if the entity is active or inactive.

Marketing Status Attributes

To define a marketing status value, enter values for the following attributes:

Attribute	Description
Marketing Status Name	Name to define the Marketing Status for the medicinal products.
Last User Updated	Indicates the name of the user who last created/updated the marketing status. By default, this option is read-only. It is populated automatically when updates are made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates are made to the table.
Active	Indicates if the entity is active or inactive.

Risk of Shortage of Supply Reason Attributes

To define a risk of shortage of supply reason value, enter values for the following attributes:

Attribute	Description
Marketing Status Reason	Name to define the reason for the Marketing Status of the medicinal products.

Name	
Last User Updated	Indicates the name of the user who last created/updated the marketing status reason. By default, this option is read-only. It is populated automatically when updates are made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates are made to the table.
Active	Indicates if the entity is active or inactive.

Sequence Maintenance

Sequence values created in Data Administration appear in drop-down lists on the *Sequence Attributes* page and are designated when a sequence is created. Data administration enables you to add and modify drop-down list values, and set the status of a value to active or inactive.

When you select a value under Sequence Maintenance, a page opens with a table of all values that have been defined. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

Note: *The proper data administration access privileges are required to view and modify sequence maintenance values.*

Sequence Maintenance: Sequence Values

You can create and maintain the following sequence values:

Ennov InSight Administration 7.3 Sequence Maintenance

Value	Description
Filing Type	For example: Amendment, Annual Reassessment, Efficacy Supplement
Status	For example: Approvable, In Discussion, Submitted

Filing Type Attributes

To define a filing type value, enter values for the following attributes:

Attribute	Description
Filing Type	Identifies the type of Filing. Examples: Original, Supplement, Withdrawal
Display Name	Display Name.
Countries	Identifies the countries for which the Filing Type is valid. Examples: US, JP, CA

Last User Updated	Indicates the name of the user who last created/updated the filing type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Sequence Status Attributes

To define a sequence status value, enter values for the following attributes:

Attribute	Description
Name	The name given for the Sequence Status.
Default Flag	Flag to indicate if the product status is the default. Yes and No values are available for selection.
System Process Default Flag	Select which of the added statuses will show for a Sequence status after the Event is closed.
Internal System Status	The internal status associated to the Sequence status.
Last User Updated	Indicates the name of the user who last created/updated the sequence status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.

Ennov InSight Administration 7.3 Sequence Maintenance

Define Application Types Under Filing Type eCTD Code for Grouped Submissions

You can define the US FDA eCTD Module 1 Specification v2.3 / DTD v3.3 Grouped Submission application types using Filing Type Values in the Sequence Maintenance section in Data Administration.

Note: Please refer to the US Module 1 Specifications for the valid values to complete this procedure.

To define the application types for grouped submissions:

1. On the Ennov InSight *home* page, click Go To > Data Administration.
2. Under Sequence Maintenance, click Filing Type Values.
3. Click the *Filing Type* that you wish to update.
4. Under Applicable DTD/Schema, click us-3-3.
5. In the Types Valid for Grouped Submissions box, select the applicable *Application Type(s)*.

6. Click >> to move the Application Type(s) to the Selected box.
7. Save.

Attribute	Description
Active	Indicates if the entity is active or inactive.

The defined application types will be available for selection while creating submission plans for grouped submissions.

SPOR Master Lists

The *SPOR Master Lists* section in Ennov InSight Data Administration is designed to maintain the European Medicines Agency (EMA) Substance, Product, Organization, and Referential (SPOR) service.

To facilitate the reliable exchange of Medicinal Product information the European Medicines Agency (EMA) introduced Substance, Product, Organization, and Referential (SPOR) program.

According to the roadmap designed by EMA the SPOR support starts with an introduction of OMS and RMS components:

- OMS - Organizations management service. OMS manages organization master data, including organization name and location address, for organizations such as marketing authorization holders (MAH), sponsors, regulatory authorities, and manufacturers.
- RMS - Referentials management service. RMS manages the referential master data. In Ennov InSight it is included to the Data Administration > SPOR Master Lists section as lists of values used to describe the attributes of a medicinal product. For example: dosage forms, units of measure, and routes of administration (ROA).

When you select a value under SPOR Master List, a page opens with a table of all values that have been defined. You can sort these values by column, define the number of values to be displayed on the page, or export the table data to Excel.

Set Data Administration to Yes in the Security Administration > Home Page Access section to be able to access the *SPOR Master Lists* values.

SPOR Master Lists Values

You can add and modify RMS Value lists and set the status of a value to active or inactive from Data Administration > SPOR Master Lists.

The following RMS Values are included to the SPOR Master Lists section in Data Administration. The table view display name is a combination of the value name and the appropriate SPOR System Referentials List from which the value is derived.

Value	Description

Anatomical Therapeutic Chemical Classification System - Human	The Anatomical Therapeutic Chemical Classification System Human table is introduced to provide the ATC code as indicated as Pharmacodynamic properties of the corresponding SmPC regulatory authority.
Application Legal Basis	A classification value of a medicinal product.
Application Submission Type	The type of marketing authorization application that is described using the term id.
Combination Package	The pharmaceutical form that is submitted for authorizations or is authorized by the regulatory authorities. These details are reflected in the regulatory documents. Combination package of the combined pharmaceutical form, when two or more manufactured dose forms are intended to be combined to create a single administrable dose form.
Combined Pharmaceutical Dose Form	The pharmaceutical form is submitted for authorizations or as authorised by regulatory authorities. These details are reflected in the regulatory documents. A combined pharmaceutical form is used when two or more manufactured dose forms are intended to be combined to create a single administrable dose form.
Combined Term	The combined term for the medicinal products.
Contact Party Role	The type of contact in the context of the Medicinal Product must be specified.
Container Category	The names of specific containers or categories to manage and classify various referential data such as ingredient names, dosage forms, and route of administration to provide their proper use and consistency.
Country	The country where the medicinal product name has been authorized.

Value	Description
Data Classification	The Data Classification is a RMS list and is used to populate the Confidentiality Indicator field available on the Data Administration > Manufacturer Values > Global Detail Sets Attributes page.
Domain	The Domain describes whether the type of medicinal product is for human or for veterinary use.
ECTD EU Context of Use	The ECTD EU Context of Use is used to place documents under a CTD heading and associated keywords in accordance with EU requirements.
EU Regulatory Authorisation Procedure	The regulatory procedure applied to grant or amend a marketing authorization for a Medicinal Product.

Ingredient Role	The role of the active ingredient as part of the manufactured item/ pharmaceutical product.
Language	The language of the medicinal product name for the specified country, as approved by the regulatory authority.
Legal Status for the Supply	The legal status of supply of the medicinal product as authorized by the relevant competent authority.
Manufacturing Activity	The manufacturer of the active substance (including active substance manufacturers). You must specify the solvent/adjuvant for combined pharmaceutical forms from the list of manufacturers based on the resource Marketing Status.
Marketing Status	The marketing status of the medicinal products.
Master File Type	Indicates the type of master file.
Material	The material(s) within a package. This Material RMS list is mapped to the Data Administration > Product Detail Set Maintenance > Product Materials Values .
Medical Device Classification	The classification for medical devices that has an impact on the conformity assessment procedures to place the device on European market.
Medical Device Legislative Category	Category to determine the intended purpose of the devices and their inherent risks.
Medical Dictionary For Regulatory Activities	Standardized medical terminology to facilitate sharing of regulatory information.
Medicinal Product Name Part Type	The medicinal product name parts must be specified along with the language of the country and as per the marketing authorization that is applied in accordance with the referenced SmPC.

Value	Description
Medicinal Product Type	The categorization of medicinal products based on their characteristics and intended use.
Medicine Profile	The detailed information about the medicine or drug. Medicine profile provides the healthcare specialists with essential information to ensure the effective use of a medicine.
Organization (OMS)	The organizations and locations from the EMA Organization Management Services (OMS).
Packaging	The packaging of the medicinal products.

Pharmaceutical Dose Form	The manufactured dose form is described with the authorized pharmaceutical form(s). Pharmaceutical Form of the SmPC or other regulatory document.
Product Category	The product classification.
Product Cross Reference Type	The cross-reference types used to reduce submission size and lessen redundancies.
Product Information Document Type	The type of the contact must be specified in the context of the Medicinal Product.
Quantity Operator	To provide the strength of the substance ingredient(s) contained in the medicinal product, the corresponding quantity operator is selected. The quantity operator applies to each of the below data elements: – Strength Presentation – Strength Concentration
Reason for Marketing Unavailability	The factors that influence the product availability in the market.
Regulatory Entitlement Status	The status of the marketing authorization.
Regulating Authority Submission Unit Type	A type of a document to submit for regulatory assessment.
Regulatory Entitlement Type	The type of regulatory authorization.
Routes and Methods of Administration	Routes and Methods of Authorization.
Shelf Life Type	Shelf life types such as the shelf life of the Packaged Medicinal Product itself, shelf-life after transformation, etc.
Source of Information	Different types of information categorized based on its format and purpose.
Value	Description
Special Precaution for Storage	Special precautions for storage of the packaged medicinal products.
Substance	Substance Management Services (SMS) terms to associate existing substance data to uniquely identify the ingredients and materials of a medicinal product. See the <i>Functionality and Technology Not Supported</i> section in <i>Ennov InSight 7.2 Release Notes</i> .
Terminology System List	A compilation of inventory of various terminology systems to organize and standardize the language, concepts and information relevant to particular discipline.

Units of Measurement	The strength (quantitative composition) of the substances (including active substances, ingredients, solvents, adjuvant as applicable) must be specified in this field with a numerator and denominator.
Units of Presentation	The strength (quantitative composition) of the substances (including active substances, ingredients, solvents, adjuvant as applicable) must be specified in this field with a numerator and denominator.
XEVMPD Medical Devices	Details of the XEVMPD Medical Devices.
XEVMPD Medicinal Product Type	Details of the XEVMPD medicinal product type.
Reason for Marketing Unavailability	Indicates the reason for the drug unavailability in the market. You cannot create/modify the respective value and its attributes.

Attribute	Description
Active Flag	The active flag for the term in the RMS list from the RMS Details.
Comments	The comments of the term in the RMS list from the RMS Details.
Creation Date	Defines when the values are added, either via automated updates from the EMA or manually by Data Administration users. By default, this option is read-only. It is populated automatically when updates are made to the table.
Default Flag	The default flag for the term in the RMS list from the RMS Details.
Description	The description of the term in the RMS list from the RMS Details.
Domain	The Domain of the term in the RMS list from the RMS Details. Human use or Veterinary use.
List Id	The list identifier for the RMS list from the RMS Summary.
List Name	The List Name for the RMS list from the RMS Summary.

The following table describes the OMS Value attributes.

Attribute	Description
List Owner	The List Owner for the RMS list from the RMS Summary. Examples are EMA, EDQM, WHO CC, MSSO.
Mapping Source	The Source Identifier for the term in the RMS list from the RMS Details.
Modification Date	The modification date and time for when the term was updated. Used to compare to the Modified on date in the Ennov InSight database to determine if the row has changed since it was last retrieved by Ennov InSight .

Modified On	The modified on date from operational attributes for the term in the RMS list from the RMS Details.
ISO Code	The ISO Code for the term in the RMS list from the RMS Details.
Short Name	The shortened name of a specific RMS Value, for example its abbreviation. Short Name is a text field. The Short Name from the SPOR System.
Source Term Id	The Source Term Identifier for the term in the RMS list from the RMS Details.
Status	The status assigned to a specific RMS Value. Status Type is a dropdown field with the following values available for selection: – Active (the specific RMS Value has been created and is in Active state) – Current (the specific RMS Value has been approved for the further use) – Inactive (the specific RMS Value is in Inactive state) – Non Current (the specific RMS Value has not been approved for the further use) – Nullified (the specific RMS Value has been published in error and needs to be removed) – Provisional (this specific RMS Value is created after validation by EMA, but prior to the approval)
Term Id	The term identifier from the SPOR System. The concatenation of the Term Name and Term Identifier values must be unique within the specific RMS List.
Term Name	The name of a term to which this specific RMS Value belongs. Term Name is a required field. The concatenation of the Term Name and Term Identifier values must be unique within the specific RMS List. The Term Name from the SPOR System.
Attribute	Description
XEVMPD Code	The XEVMPD code for the term in the RMS list from the RMS Details.
Version Number	The version number of the term in the RMS list from the RMS Details.
Created By	Defines by whom the values are added, either via automated updates from the EMA or manually by Data Administration users. By default, this option is read-only. It is populated automatically when updates are made to the table.

Last User Updated	Indicates the name of the user who last created/updated the value. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

The following is the list of attributes used for defining an organization.

Attribute	Description
Location ID	The location identifier.
Organization ID	The organization identifier.
Name	The name of the organization.
Status	The status of organization. Example: Active or Inactive.
Created On	The date on which the organization entity is created
Modified On	The date on which the organization entity is modified
Is Headquarters	Indicates if the location is a headquarter.
XEVMPD Code	The XEVMPD code for the location.
Address 1	Address 1 of the organization
Address 2	Address 2 of the organization
Address 3	Address 3 of the organization
Address 4	Address 4 of the organization
City	The city of the organization
County	The county of the organization
Region	The region of the organization.
Attribute	Description
Postal Code	The postal code for the location of the organization.
GPS Location	The GPS location information of the organization.
Default Flag	The default flag for the location. Example: "Yes" or "No". By default, "No" is selected.
Active Flag	Indicates if the organization is active.

Creation Date	The creation date when the location was added to the Ennov InSight database.
Modification Date	The modification date and time for when the term was updated. Used to compare to the Modified on date in the Ennov InSight database to determine if the row has changed since it was last retrieved by Ennov InSight .
Activate/Deactivate	Activate or deactivate to determine the availability of an organization.

The following table describes RMS Value attributes.

Attribute	Description
List ID	The list identifier for the RMS list from the RMS summary.
List Name	The list name for the RMS list from the RMS summary.
List Owner	The list owner for the RMS list from the RMS summary. Examples: EMA, EDQM, WHO CC, and MSSO.
Term Id	The term identifier for term in the RMS list from the RMS details.
Term Name	The term name for the term in the RMS list from the RMS details.
Short Name	The short name for the term in the RMS list from the RMS Details.
Status	The status of the term in the RMS list from the RMS details.
Domain	The domain of the term in the RMS list from the RMS details. Human use or veterinary use.
Modified On	The date when the data was modified for the term in the RMS list from the RMS details.
Mapping Source	The mapping source identifier for the term in the RMS list from the RMS details.
Source Term Id	The source term identifier for the term in the RMS list from the RMS details.
XEVMPD Code	The XEVMPD code for the term in the RMS list from the RMS Details.
Description	The description of the term in the RMS list from the RMS details.
Comments	The comments of the term in the RMS list from the RMS details.

Submission Maintenance

Use *Submission Maintenance* to specify values for eCTD Modules. Use the *Submission Maintenance* pages to define:

– Values for supporting the US eCTD Module 1 v2.3 specification (DTD 3.3). You can select these values for extended attributes of an assembly. In the *Create eCTD* wizard, you can do this after selecting the necessary template.

– Values for supporting the CN eCTD Module 1 v1.0 specification. You can select these values for extended attributes of an assembly. In the *eCTD* wizard, you can do this after selecting the necessary template.

Attribute	Description
Version Number	The version number of the term in the RMS list from the RMS details.
ISO Code	The ISO Code for the term in the RMS list from the RMS details.

– Values for supporting the ZA eCTD Module 1 v3.1 specification. You can select these values for extended attributes of an assembly. In the *eCTD* wizard, you can do this after selecting the necessary template. – Fonts that you can use in tab sheets created in Ennov InSight .

Note: *Viewing and modifying Submission Maintenance values requires specific Data Administration access privileges.*

When you click a type of value under *Submission Maintenance*, a page shows a table of all defined values for that type. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

On the *Submission Maintenance* pages, you can set the status of a value to Active or Inactive.

Submission Maintenance: Submission Values

The following submission values can be created and maintained under Submission Maintenance:

Value	Description
Applicant Contact Type	The applicant contact types that match the codes that the regulatory agency provides.
Applicant Contact	All active applicant contact values.
Applicant ID	The applicant ID.
Application Form Type	The application form types that match the codes that the regulatory agency provides.
Drug Registration File Documents Section	The values that EAEU defines to describe a drug registration file documents section.
Drug Registration File Documents	The values that EAEU defines to describe a drug registration file documents.
Value	Description
Evaluation Pathway	The Evaluation Pathway applicable to the ZA submissions.
Font Definition	The fonts that you can use in tab sheets created in Ennov InSight Publisher. For further information, refer to the Font Definition Attribute table below.

Leaf Status	The status that can be assigned to a leaf. When assigned, helps to identify the leafs in an assembly that need to be published or have already been published. Three "out-of-the-box" statuses are provided: – Planned – Ready for Publish – Published Default value is Planned. For further information, refer to the Leaf Status Attributes table below.
PDF Properties	The PDF properties that you can use in Leaf Elements and Publishing Settings Library. For further information, refer to the PDF Properties Attributes table below.
Promotional Material Audience Type	The promotional material audience types that match the code that the regulatory agency provides.
Promotional Material Doc Type	The promotional material doc types that match the codes that the regulatory agency provides.
Promotional Material Type	The promotional material types that match the codes that the regulatory agency provides.
Regulatory Activity Lead	Health Canada groups that can take the lead in reviewing the regulatory activity that a regulatory transaction supports.
Sequence Description	The values that Health Canada defines to describe a sequence (regulatory transaction).
Submission Product Type	The values that describe a submission product type as defined by the China region.
Sub Filing Type	The sub filing types that match the codes that the regulatory agency provides.
Supplement Effective Date Type	The supplement effective date types that match the codes that the regulatory agency provides.
Telephone Number Type	The telephone number types that match the codes that the regulatory agency provides.

Applicant Contact Type Attributes To define an applicant contact type, enter values for the following attributes:

Attribute	Description
eCTD Standard Type	Can be either eCTD 3.2 or eCTD 4.0 defining the version where the value is applicable. By default, the eCTD 3.2 is displayed. It is always eCTD 4.0 if associated from eCTD 4.0 controlled vocabulary. See <i>Associate eCTD 4.0 Applicant Contact Type</i> and <i>eCTD 4.0 Applicant Contact Type Attributes</i> .

Region	All active values of Regulatory Region type from the <i>Region Values</i> are available for selection.
Regulatory Code	Regulatory Code provided by the Regulatory Agency.
Applicant Contact Type	Applicant Contact Type name matching the code provided by the agency.
Last User Updated	Indicates the name of the user who last created/updated the applicant contact type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Applicant Contact Attributes To define an applicant contact, enter values for the following attributes:

Attribute	Description
Region	All active values of Regulatory Region type from the <i>Region Values</i> are available for selection.
Applicant Contact Name	Name of the applicant contact.
Applicant Contact Type	All active values from the Applicant Contact Type Values.
UUID	Universal Unique Identifier of the applicant contact.
Prefix	A title placed before the applicant contact name. Example: Mr.(Mister), Mrs. (Missis), Dr. (Doctor), Prof. (Professor).
First Name	First name of the applicant contact.
Middle Name	Middle name of the applicant contact.
Last Name	Last name of the applicant contact.
Suffix	A title placed after the applicant contact name. Example: Jr.(Junior), Sr. (Senior), Ph.D (Doctor of Philosophy).
Initials	Capitalized letters representing each word of in an applicant contact name. Example: M.J.S (Mary Jane Smith).
Delimiter	Character used to separate different parts of texts.
Attribute	Description
Represented Company Name	Name of the company or organization.

Last User Updated	Indicates the name of the user who last created/updated the applicant contact. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Applicant ID Attributes

To define an applicant ID, enter values for the following attributes:

Attribute	Description
Region	All active values of Regulatory Region type from the <i>Region Values</i> are available for selection.
Applicant ID Format	The format for the Applicant ID. Allowed values: DUNS.
Applicant Name	Applicant Name matching the Applicant ID.
Applicant ID	Applicant ID must be unique within the region.
Default for Region	Yes and No values are available for selection to indicate if the region is the default or not. Note: Only one region can have the default flag set to Yes within the system. When you change the region to the default, the previously defaulted entity is automatically updated to have the default flag set to No.
Last User Updated	Indicates the name of the user who last created/updated the applicant ID values. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Application Form Type Attributes

To define an application form type, enter values for the following attributes:

Attribute	Description
Region	All active values of Regulatory Region type from the <i>Region Values</i> are available for selection.

Regulatory Code	Regulatory Code provided by the Regulatory Agency.
Application Form Type	Application Form Type name matching the code provided by the agency.
Last User Updated	Indicates the name of the user who last created/updated the application form type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Drug Registration File Documents Section Attributes

To define a drug registration file documents section, enter values for the following attributes:

Attribute	Description
Section Code	Section code provided by agency.
Name	Name provided by agency.
Last User Updated	Indicates the name of the user who last created/updated the drug registration file documents section. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Drug Registration File Document Attributes

To define a drug registration file document, enter values for the following attributes:

Attribute	Description
Section	Section code provided by agency. All active values of Section Code from the <i>Drug Registration File Documents Section Values</i> are available for selection.
Document Code	Document code provided by agency.
Name	Name provided by agency.
Attribute	Description
Last User Updated	Indicates the name of the user who last created/updated the drug registration file document. By default, this option is read-only. It is populated automatically when updates were made to the table.

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Evaluation Pathway Attributes

To define an evaluation pathway, enter values for the following attributes:

Attribute	Description
Region	All active values of Regulatory Region type from the <i>Region Values</i> are available for selection.
Applicable DTD/Schema	All active DTD/Schemas from the Assembly DTD/Schema Types limited by the selected Region.
eCTD Code	The regulatory code from the controlled vocabulary provided by the agency.
Evaluation Pathway	The Evaluation Pathway applicable to the submission.
Last User Updated	Indicates the name of the user who last created/updated the evaluation pathway. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Font Definition Attributes

To define a font, enter values for the following attributes:

Attribute	Description
Font Display Name	The <i>font name</i> that appears on the <i>Tab Sheet Attributes</i> page.
Font Name	Must match the font name on the Ennov InSight Rendering server.
Font Code	Used when an assembly with tab settings is exported from or imported into Ennov InSight .
Attribute	Description
Last User Updated	Indicates the name of the user who last created/updated the font definition. By default, this option is read-only. It is populated automatically when updates were made to the table.

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Leaf Status Attributes

To define a leaf status, enter values for the following attributes:

Attribute	Description
Leaf Status Name	The leaf status name that appears in Leaf Elements. The name must be unique within the system.
Default Flag	Yes and No values are available for selection to indicate if the leaf status is the default or not. Note: Only one leaf status can have the default flag set to Yes within the system. When you change leaf status to the default, the previously defaulted entity is automatically updated to have the default flag set to No.
Internal System Status	The internal system status to associate to the leaf status. The values available for selection are PLANNED, NOT APPROVED, and PUBLISHED. Or, you can leave the field blank.
Last User Updated	Indicates the name of the user who last created/updated the leaf status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

PDF Properties Attributes

To define a PDF property, enter values for the following attributes:

Attribute	Description
PDF Property Name	The PDF property name that appears in Leaf Elements and Publishing Settings Library.
Attribute	Description
Source Property	Yes and No values are available for selection to indicate if the property is a source or not.

Target Property	Yes and No values are available for selection to indicate if the property is a target or not.
Last User Updated	Indicates the name of the user who last created/updated the PDF properties. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Promotional Material Audience Type Attributes

To define a promotional material audience type, enter values for the following attributes:

Attribute	Description
Region	All active values of Regulatory Region type from the <i>Region Values</i> are available for selection.
Regulatory Code	Regulatory Code provided by agency.
Promotional Material Audience Type	Promotional Material Audience Type name matching the code provided by the agency.
Last User Updated	Indicates the name of the user who last created/updated the promotional material audience type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Promotional Material Doc Type Attributes

To define a promotional material doc type, enter values for the following attributes:

Attribute	Description
Region	All active values of Regulatory Region type from the <i>Region Values</i> are available for selection.
Regulatory Code	Regulatory Code provided by agency.
Attribute	Description
Promotional Material Doc Type	Promotional Material Doc Type name matching the code provided by the agency.

Last User Updated	Indicates the name of the user who last created/updated the promotional material doc type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Promotional Material Type Attributes

To define a promotional material type, enter values for the following attributes:

Attribute	Description
Region	All active values of Regulatory Region type from the <i>Region Values</i> are available for selection.
Regulatory Code	Regulatory Code provided by agency.
Promotional Material Type	Promotional Material Type matching the code provided by the agency.
Last User Updated	Indicates the name of the user who last created/updated the promotional material type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Regulatory Activity Lead Attributes

To define a regulatory activity lead, enter values for the following attributes:

Attribute	Description
Region	All active values of Regulatory Region type from the <i>Region Values</i> are available for selection.
eCTD Code	The regulatory code from the controlled vocabulary provided by the agency.
Regulatory Activity Lead	The regulatory activity lead which corresponds to the eCTD code.
Attribute	Description
Applicable DTD/Schema	All active DTD/Schemas from the Assembly DTD/Schema Types limited by the selected Region.

Last User Updated	Indicates the name of the user who last created/updated the regulatory activity lead. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Submission Product Type Attributes

To define a submission product type, enter values for the following attributes:

Attribute	Description
Region	Region value for Submission Product Type. All active values of Regulatory Region type from the <i>Region Values</i> are available for selection.
eCTD Code	eCTD Code provided by agency.
Product Type	Description of Product Type. Allowed values: Chemical Product or Biological Product .
Applicable DTD/Schema	List of DTD names filtered out by selected region.
Last User Updated	Indicates the name of the user who last created/updated the submission product type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Sequence Description Attributes

To define a sequence description, enter values for the following attributes:

Attribute	Description
Region	All active values of Regulatory Region type from the <i>Region Values</i> are available for selection.
eCTD Code	The regulatory code from the controlled vocabulary provided by the agency. Combination of DTD/Schema and eCTD Code must be unique.
Sequence Description	The submission description which corresponds to the regulatory code.

Attribute	Description
Sequence Description Additional Data Type	The type of additional data (variables) that can be used in the description. Values available for selection are: Text, Date Range, Date, Number and Date.
Applicable DTD/Schema	All active DTD/Schemas from the Assembly DTD/Schema Types limited by the selected Region.
Last User Updated	Indicates the name of the user who last created/updated the sequence description. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Sub Filing Type Attributes

To define a sub filing type, enter values for the following attributes:

Attribute	Description
Sub Filing Type	Sub Filing Type matching the code provided by the agency. Sub Filing Type must be unique.
Countries	Countries that are applicable to this sub type.
Last User Updated	Indicates the name of the user who last created/updated the sub filing type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Supplement Effective Date Type Attributes

To define a supplement effective date type, enter values for the following attributes:

Attribute	Description
Supplement Effective Date Type Name	Supplement Date Effective Type name matching the code provided by the agency.
Countries	A list of all countries that this effective date type applies to.

Attribute	Description
Last User Updated	Indicates the name of the user who last created/updated the supplement effective date type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Telephone Number Type Attributes

To define a telephone number type, enter values for the following attributes:

Attribute	Description
Region	All active values of Regulatory Region type from the <i>Region Values</i> are available for selection.
Regulatory Code	Regulatory Code provided by the Regulatory Agency.
Telephone Number Type	Telephone Number Type name matching the code provided by the agency.
Last User Updated	Indicates the name of the user who last created/updated the telephone number type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Associate eCTD 4.0 Applicant Contact Type

Associate applicant contact type to conform to the eCTD 4.0 submission requirements.

To associate eCTD 4.0 applicant contact type:

1. On the homepage, click Go To > Data Administration > Submission Maintenance.
2. Click Applicant Contact Type Values.
3. Click the Associate eCTD 4.0 Applicant Contact Type .

The list of all active values from Submission Contact Type CV is displayed, excluding those already added.

4. Filter the values with by Region, CV OID, Code or Value.
5. Select the required information from the list.
6. Click Associate .

Update Applicant Contact Type Values

Make changes to existing applicant contact type values to include appropriate information in submission.

To update applicant contact type values:

1. On the homepage, click Go To > Data Administration > Submission Maintenance.
2. Click Applicant Contact Type Values.
3. Click Regulatory Code for the selected applicant contact type.
4. Modify the attributes.
5. Click Save.

eCTD 4.0 Applicant Contact Type Attributes

Use the following attributes to filter eCTD 4.0 applicant contact type values.

Attribute	Description
Region	The region name taken from Data Administration > Region Values.
CV OID	Object identifier of the controlled vocabulary profile provided by CV service.
Code	Regulatory code provided by the regulatory agency.
Value	The contact type of the controlled vocabulary profile provided by CV service.

Submission Plan Maintenance

You can define the status of a submission plan depending on its progress using the Submission Plan Status Values. On the *Submission Plan Maintenance* page in Data Administration, you can set the status of a value to active or inactive.

The Submission Plan Status Values define the position of the submission plan. The following submission plan status values are provided with Ennov InSight :

- In Progress
- In Review
- Planned
- Withdrawn
- Ready for Submission

Administrators and other permitted users can create and modify additional, custom Submission Plan Status Values.

Submission Plan Maintenance Values

You can create and maintain the following submission plan maintenance values:

Ennov InSight Administration 7.3 Submission Plan Maintenance

Value	Description
Submission Plan Status Values	For example: In Review, In Progress, Planned, Ready for Submission, Withdrawn

Submission Plan Status Attributes

To define a submission plan status value, enter values for the following attributes:

Attribute	Description
Submission Plan Status Name	Identifies the status name. Examples: In Review, In Progress, Planned, Ready for Submission, Withdrawn
Default Flag	Flag to indicate if the status is the default. Yes and No values are available for selection.
Last User Updated	Indicates the name of the user who last created/updated the submission plan status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Task Maintenance

Task maintenance values appear in drop-down lists on *task* and *sub-task attribute* pages and are designated when a task or sub-task is created. Data administration enables you to add and modify drop-down list values, and set the status of a value to active or inactive.

When you select a value under Task/Sub-Task Maintenance, a page shows a table of all values that have been defined. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

Note: The proper data administration access privileges are required to view and modify application maintenance values.

Task Maintenance Values

You can create and maintain the following values:

Value	Description

Secondary Task/Sub-Task Type	Additional information to further identify the type of task, for example: assemble documentation, marketing approval, etc.
	Note: Create task types in the system before you create secondary task types. Secondary task types must be associated with existing task types.
Task/Sub-Task Priority	For example: low, medium, high
Task/Sub-Task Status Progression	You can set up task statuses in such a way that they help users understand the progression specific types of tasks may take.
Task/Sub-Task Status	For example: open, archive, closed
Task/Sub-Task Type	For example: annual report, renewal, PSUR, etc.

Secondary Task/Sub-Task Type Attributes

To define a secondary task/sub-task type value, enter values for the following attributes:

Attribute	Description
Name	Identifier for Secondary Task Type.
Task/Sub-Task Type	Active Primary Task Types.
Last User Updated	Indicates the name of the user who last created/updated the secondary task/sub-task type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Task/Sub-Task Priority Attributes

To define a task/sub-task priority value, enter values for the following attributes:

Attribute	Description
Name	Priority given to Task or Sub-Task. Example: Low, Medium, High
Last User Updated	Indicates the name of the user who last created/updated the task/ sub-task priority. By default, this option is read-only. It is populated automatically when updates were made to the table.
Attribute	Description

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Task/Sub-Task Status Progression Attributes

To define a task/sub-task status progression value, enter values for the following attributes:

Attribute	Description
Task/Sub-Task Type	Active Task Types.
Secondary Task/Sub-Task Type	Active Secondary Task Types.
From Task/Sub-Task Status	Active Task Status Values.
Default Flag	Flag to indicate if the value is the default. Yes and No values are available for selection.
Task/Sub-Task Status Progression	Offers Available Statuses and Selected Progression Status fields for multi-select.
Last User Updated	Indicates the name of the user who last created/updated the task/ sub-task progression. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Task/Sub-Task Status Attributes

To define a task/sub-task status value, enter values for the following attributes:

Attribute	Description
Name	The name given for the Task/Sub-Task Status.
Default Flag	Flag to indicate if the value is the default. Yes and No values are available for selection.
Last User Updated	Indicates the name of the user who last created/updated the task/ sub-task status. By default, this option is read-only. It is populated automatically when updates were made to the table.
Attribute	Description

Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Task/Sub-Task Type Attributes

To define a task/sub-task type value, enter values for the following attributes:

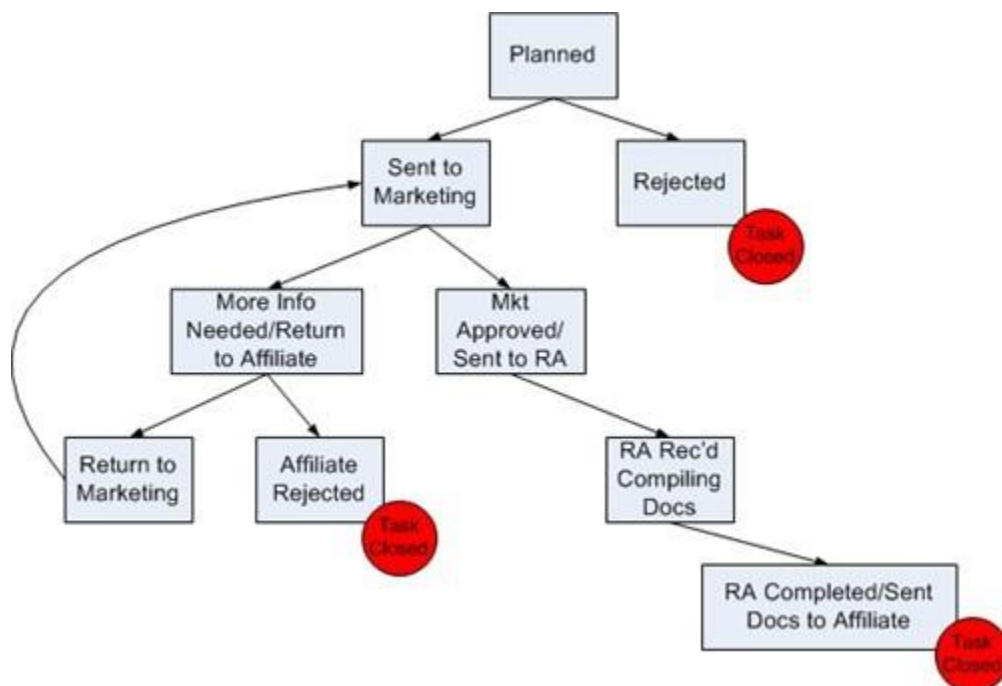
Attribute	Description
Name	Defines a value for the Task Type. Examples: Annual Report, Renewal, Other.
Last User Updated	Indicates the name of the user who last created/updated the task/ sub-task type. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Task Status Progressions

You can set up task statuses in such a way that they help users understand the progression specific types of tasks may take. We refer to this as task status progression.

When you set up a task status progression, Ennov InSight enables users to choose from the statuses that you have defined as appropriate when moving from the current status.

The following illustrates an example of a task status progression named Marketing Approval Required.



As this example illustrates, Ennov InSight displays only the statuses a user can progress to - a task with a Planned status can progress only to the Send to Marketing status or to the Rejected status. These are the only statuses available when a user modifies the task status.

If you do not set up a task status progression, users can choose from any of the available statuses when they modify the task.

Note: After a progression has been defined for a specific task type/secondary task type combination, associating the secondary task type with a different task type causes errors in the system. If there is a need to associate the secondary task type with a different task type, create a new Task Type/Secondary Task Type combination using Data Admin > Task Maintenance > Secondary Task/Sub-Task Type Values.

Create a Task Status Progression

You can create a task status progression in Data Administration.

To create a task status progression:

1. On the *home* page, choose Go To > Data Administration.
2. Scroll to Task Maintenance.
3. Choose Task/Sub-Task Status Progression.
4. Click .

The *Status Progression Map* page opens.

5. Click the Task/Sub-Task Type arrow and choose the *Task Type* to which this progression will apply.
6. Click the Secondary Task/Sub-Task Type arrow and choose the secondary task type.

The available drop-down list values depend on the *Task Type* you choose in step 5. These values must be configured first in Data Admin > Task Maintenance > Secondary Task/Sub-Task Type Values.

7. Click the From Task/Sub-Task Status arrow and choose a status from which the task will progress.
8. Click the Default Flag arrow to indicate whether this task status should be the default status value displayed when the user creates a task of the type/secondary type combination chosen in steps 5 and step 6 above.
9. From the Available Statuses box, choose statuses that should be the next set of statuses available and move them to the Selected Progression Statuses box.

If the current status of the task is the same as the From Task Status you chose in step 7 above, when you modify a type/secondary type task the list of available statuses that the task can progress to are those listed in the Selected Progression Statuses in step 9.

10. Click Save.

Modify a Task Status Progression

You can add, modify, activate, or deactivate a task status progression in Data Administration. To modify a task status progression:

1. On the home page, choose Go To > Data Administration.
2. Scroll to Task Maintenance.
3. Choose Task/Sub-Task Status Progression Values.
4. From the list provided, click the progression you want to modify in the From Task/Sub-Task Status column.

The Status Progression Map for the selected progression is displayed.

5. Make the necessary updates.

Action	Procedure
To deactivate the progression	Click Deactivate.
Action	Procedure
To reactivate a deactivated status progression	Click Activate. When you modify a task, a deactivated progression is no longer available.

Example

Status Progression Map

Task/Sub-Task Type : RA Manufacturer Change Work-in-Progress

Secondary Task/Sub-Task Type :

From Task/Sub-Task Status : Agency Requests More Documentation

Default Flag : * No

Available Statuses:

- Agency Approved
- Archived
- Closed
- Documentation Received by Affiliate
- No Action Required

Selected Progression Statuses:

- Documentation Dispatched to Affiliate

Buttons: Save, Deactivate, Cancel

6.

Click

Save

.

Workflow Management

The *Workflow Management* page displays the workflow attributes derived from the workflows deployed on the Ennov InSight server. Use the *Workflow Management* page to manage workflows.

To modify the Workflow Management values:

1. Choose Go To > Data Administration.
2. Under Workflow Management, click the link for which you want to modify the values.
3. Do the following:
 - a. Modify the workflow display *name*.
 - b. Define associated entities using the >> buttons.
 - c. Disassociate the entities using the << buttons.

- d. To deactivate the workflow, click Deactivate.
 - e. To activate a previously deactivated workflow, click Activate.
4. Save.

The changes are updated in the system.

Workflow Management: Workflow Management Values

To define a workflow management value, enter values for the following attributes:

Attribute	Description
Workflow Display Name	User defined display name for the workflow.

Ennov InSight Administration 7.3 Workflow Management

Attribute	Description
Workflow XML Name	Name of the XML file used.
Available Entities	Entities that can be associated with the workflow.
Last User Updated	Indicates the name of the user who last created/updated the available entity. By default, this option is read-only. It is populated automatically when updates were made to the table.
Last Changed Date	Indicates the date when the last change was made. By default, this option is read-only. It is populated automatically when updates were made to the table.
Active	Indicates if the entity is active or inactive.

Ennov InSight Administration 7.3 Workflow Management

Chapter 5. Technical Administration

System Administrators can access the Ennov InSight *Technical Administration* page, which provides links for creating and maintaining DMS repositories and DMS servers and also create connection to external systems.

In the Go To menu, choose Technical Administration. The available options are: – DMS Repository Management
– DMS Server Management – Linked Systems

DMS Servers and Repositories

Document Management Systems (DMS) are configured for Ennov InSight as a combination of a server and repository. These can be set up and maintained by Ennov InSight system administrators.

Ennov InSight can be connected to one or more types of DMS repositories, including: Documentum, Secure File System, and Veeva Vault.

By default, the Ennov InSight installation automatically adds a server for a Documentum system, a Secure File System, or a Veeva Vault. Other types of DMS servers must be added manually.

You can add multiple DMS repositories to each of these servers. However, Ennov InSight does not support hidden repositories or file shares.

The names used to connect to DMS servers and repositories, except Secure File systems and Veeva systems, are case sensitive. When connecting to a DMS server, the name must be exact. It is recommended to avoid special characters.

To add a DMS to Ennov InSight you must first install and configure a DMS server. One or more DMS servers must be configured for Ennov InSight before DMS repositories can be added. After the server is established, you can then add and configure the repository for the server. Graphical user interfaces for adding and modifying DMS servers and DMS repositories are located in the Technical Administration area of the Ennov InSight Administration control panel.

The DMS can be configured to be accessible by specified users, groups, or roles. A DMS tree will display only the repositories that the assigned user, group, or role has been granted permission to access.

Use the procedures from the *Add a Documentum, Secure File System, or Veeva Vault Server to Ennov InSight section*. to add Document Management System (DMS) or Secure File System repositories to Ennov InSight .

Special Characters

Output locations, file names, and user names that include certain special characters might not be interpreted correctly by the system and can cause unexpected results.

Except for document names, overlay and cover page template names, and variables, avoid the use of these characters in Ennov InSight:

Special character	Description
\	backslash
/	slash, or forward slash
"	quotation mark
< >	left and right angle brackets
	Note: Due to the thin-client Web interface of Ennov InSight , avoid using angle brackets (< >) in attributes. While these characters will be saved correctly, they will not display correctly when you view the page or entity.
:	colon

Add a Documentum, Secure File System, Ennov Doc, or Veeva Vault Server to Ennov InSight

Perform the following steps to add the servers types listed below.

Use the following procedure to add the following servers types to Ennov InSight :

- Documentum Server
- Secure File System
- Veeva Vault
- Ennov Server

The names used for connecting to DMS servers and repositories, except for secure file systems, and Veeva systems, are case-sensitive. When you add a server, make sure that you type the name in the correct case to enable Ennov InSight to connect to the DMS.

To add a DMS server:

1. Log on to Ennov InSight as an administrator.
2. In the Ennov InSight menus, click GoTo > Technical Administration.
3. In the Available Options list, click DMS Server Management.
4. In the Servers view, click Create.
5. For Server Type, click the option of the following:
 - Documentum
 - Secure File System
 - Veeva Vault
 - Ennov Server
6. For Server Name, type the name of the server that you are adding.

The Active Flag default setting is Y, for active, so the server is active as soon as it is added to Ennov InSight.

DMS servers can be deactivated or activated again at any time after configuration.

7. Click Save.

Add a Documentum Repository to Ennov InSight

You can configure Ennov InSight to connect with a Documentum repository to access the documents in the repository.

During configuration, keep in mind that the names used for connecting to Documentum servers and repositories, are case-sensitive. When the name is case-sensitive, the uppercase or lowercase spelling of the name must be correct for the Documentum DMS to function correctly.

To add a Documentum repository to Ennov InSight :

1. Log on as an administrator.
2. In the menus, select: GoTo > Technical Administration.
3. In the Available Options list, click DMS Repository Management.
4. In the *Repositories* view, click the Create icon.
5. Open the Server Name list and select the Documentum server.
6. In the repository Name (Docbase) field, enter the name of the Documentum repository.

The Active Flag default setting is Y, for active, so the repository is active as it is added. DMS repositories can be deactivated or activated again at any time after configuration.

7. To change the display name for the repository when it appears in the DMS browser window, enter a name in the optional Label field.
8. Select the Authentication Type:

Option	Description
Basic	For this type of authentication, provide repository credentials in the Repository User and Repository Password fields.
oAuth	For this type of authentication, log on using SSO: a. Click Authentication. b. Select the account. c. Enter the credentials and click OK. d. Click Save. Note: If the token had been revoked, you will not be able to access registration attachments or repositories by clicking the Browse Documents window. In this case, you must re-authenticate. On the Repositories page, you will see the appropriate message.

Note: System administrator credentials are not encrypted in the database. The passwords are saved encrypted if a repository is added or updated in the secured vault through the technical administration service.

9. If you want to enable the Ennov InSight users who can access the repository to force new renditions and extractions, in the Force New Renditions and Extractions field, click Yes.

Forcing new renditions and extractions means creating missing document renditions and extractions and overwriting document renditions and extractions in the repository.

10. To allow repository access to defined users or groups or roles, select Yes from the Limit Access to Specific Users field.
11. Do the following:

Option	Action
To permit access to specific users:	In the Allow Selected Users section, select users in the <i>Access Limited</i> box and click the arrows (>>) to move them to the <i>Access Allowed</i> box.
To permit access to specific groups:	In the Allow Selected Groups section, select groups in the <i>Access Limited</i> box and click the arrows (>>) to move them to the <i>Access Allowed</i> box.
To permit access to users with specific roles:	In the Allow Selected Roles section, select roles in the <i>Access Limited</i> box and click the arrows (>>) to move them to the <i>Access Allowed</i> box.

12. To save the new DMS repository settings, click Save.

Add a Secure File System Repository to Ennov InSight

You can configure a Secure File System to work with Ennov InSight so you can retrieve documents from the repository.

To add a Secure File System repository to Ennov InSight :

1. Log on to Ennov InSight as an administrator.
2. From the menus, select GoTo > Technical Administration.
3. In the Available Options list, click DMS Repository Management.
4. In the *Repositories* view, click Create .
5. Open the Server Name list and select Secure File System.
6. Enter the repository name in the Repository Name field.
7. To change the display name for the repository when it appears in the DMS browser window, enter a name in the optional Label field.
8. Enter the repository domain name in the Repository Domain field.
9. Enter repository credentials in the Repository User and Repository Password fields.

Note: System administrator credentials are not saved in the database. If a repository is added or updated in the secured vault through the technical administration service, the passwords saved will be encrypted.

10. To enable repository access to use force new renditions and extractions in the Force New Renditions and Extractions field, click Yes.

See: *Ennov InSight Publishing > Force New Renditions and Extractions*Ennov InSight .

11. To allow repository access to defined users or groups or roles, select Yes from the Limit Access to Specific Users field.
12. Do the following:

Option	Action
To permit access to specific users:	In the Allow Selected Users section, select users in the <i>Access Limited</i> box and click the arrows (>>) to move them to the <i>Access Allowed</i> box.
To permit access to specific groups:	In the Allow Selected Groups section, select groups in the <i>Access Limited</i> box and click the arrows (>>) to move them to the <i>Access Allowed</i> box.
To permit access to users with specific roles:	In the Allow Selected Roles section, select roles in the <i>Access Limited</i> box and click the arrows (>>) to move them to the <i>Access Allowed</i> box.

13. To save the new secure file system repository settings, click Save.

The Active Flag default setting is Y, for active, so the repository is active as soon as it is added to Ennov InSight . DMS repositories can be deactivated or activated again at any time after configuration. See:*Activate/Deactivate Data Administration Values*.

Add a Veeva Vault Repository to Ennov InSight

You can configure Ennov InSight to connect with a Veeva Vault repository so you can access the documents in the repository.

To add a Veeva Vault repository to Ennov InSight :

1. Log on as an administrator.
2. In the menus, click GoTo > Technical Administration.
3. In the Available Options list, click DMS Repository Management.
4. In the *Repositories* view, click the Create icon.
5. Open the Server Name list, and click the Veeva Vault server.
6. In the repository Name (Docbase) field, type the name of the Veeva Vault repository.

Note that the Active Flag field is set to Y, for Yes, so the repository is active as soon as it is added. After you add the repository, you can deactivate it and reactivate it.

7. If you want a different repository name to be displayed in the *DMS Browse* window, in the Label field enter the name.
8. In the Vault URL field, type the Veeva Vault URL in the format https://

<vault_name>.veevavault.com, where <vault_name> is the actual Veeva Vault name.

9. In the Repository User and Repository Password fields, type the credentials for accessing the repository.
10. If you want to enable the Ennov InSight users who can access the repository to force new renditions and extractions, in the Force New Renditions and Extractions field, click Yes.

Forcing new renditions and extractions means creating missing document renditions and extractions and overwriting document renditions and extractions in the repository.

11. To allow repository access to defined users or groups or roles, select Yes from the Limit Access to Specific Users field.
12. Do the following:

Option	Action
To permit access to specific users:	In the Allow Selected Users section, select users in the <i>Access Limited</i> box and click the arrows (>>) to move them to the <i>Access Allowed</i> box.
To permit access to specific groups:	In the Allow Selected Groups section, select groups in the Access Limited box and click the arrows (>>) to move them to the Access Allowed box.
To permit access to users with specific roles:	In the Allow Selected Roles section, select roles in the <i>Access Limited</i> box and click the arrows (>>) to move them to the <i>Access Allowed</i> box.

13. To save the new DMS repository, click Save.

Add a Ennov Doc to Ennov InSight

You can configure Ennov InSight to connect with a Ennov Doc repository so you can access the documents in the repository.

To add an Ennov Doc repository to Ennov InSight :

1. Log in as an administrator.
2. In the menus, click GoTo > Technical Administration.
3. In the Available Options list, click DMS Repository Management.
4. In the *Repositories* view, click the Create icon.
5. Open the Server Name list, and select the Ennov Server.
6. In the repository Name (Docbase) field, type the name of the Ennov Doc repository.

Note that the Active Flag field is set to Y, for Yes, so the repository is active as soon as it is added. After you add the repository, you can deactivate it and reactivate it.

7. If you want a different repository name to be displayed in the *DMS Browse* window, in the Label field enter the name.
8. In the Ennov Repository URL field, type the full Ennov doc URL in the format `https://<domain>[/path]` where domain - will be name of repository and used across the system, path - optional if applicable.
9. In the Repository User and Repository Password fields, type the credentials for accessing the repository.
10. If you want to enable the Ennov InSight users who can access the repository to force new renditions and extractions, in the Force New Renditions and Extractions field, click Yes. Forcing new renditions and extractions means creating missing document renditions and extractions and overwriting document renditions and extractions in the repository.
11. To allow repository access to defined users or groups or roles, select Yes from the Limit Access to Specific Users field.
12. To allow repository access to defined users or groups or roles, select Yes from the Limit Access to Specific

Users field.

13. Do the following:

Option	Action
To permit access to specific users:	In the Allow Selected Users section, select users in the <i>Access Limited</i> box and click the arrows (>>) to move them to the <i>Access Allowed</i> box.
To permit access to specific groups:	In the Allow Selected Groups section, select groups in the <i>Access Limited</i> box and click the arrows (>>) to move them to the <i>Access Allowed</i> box.
To permit access to users with specific roles:	In the Allow Selected Roles section, select roles in the <i>Access Limited</i> box and click the arrows (>>) to move them to the <i>Access Allowed</i> box.

14. To save the new DMS repository, click Save.

Modify DMS Server Attributes in Ennov InSight

You can modify the server settings for a document management system, if necessary.

To modify DMS server settings in Ennov InSight :

1. Log on to Ennov InSight as an administrator.
2. In the Ennov InSight menus, select: GoTo > Technical Administration. The Available Options for Technical Administration appear.
3. In the Available Options list, click DMS Server Management.
4. In the *Servers* view, click on the name of the server in the list.
5. Modify the server settings, as needed:

– To remove the server from active use, click Deactivate.

– To change other server settings, modify the content of the available text boxes for the selected server. The available text boxes will vary according to the selected server or file system.

The names used for connecting DMS servers and repositories, except for file systems, secure file systems, and Veeva systems, are case-sensitive. When the name is case-sensitive, the uppercase or lowercase spelling of the name must be correct for the DMS to function correctly.

Modifiable DMS Server Attributes

DMS Server type	Modifiable DMS Server attributes
Documentum	Server Type Server Name Active Flag
Secure File System	Server Type Server Name Active Flag
Veeva Vault	Server Type Server Name Active Flag

Modify DMS Repository Attributes

You can modify repository attributes to include appropriate values for a document management server..

To modify DMS repository settings in Ennov InSight :

1. Log on to Ennov InSight as an administrator.
2. In the Ennov InSight menus, select: GoTo > Technical Administration. The Available Options list for Technical Administration appears.
3. In the Available Options list, click DMS Repository Management.
4. In the *Repositories* view, click the name of a repository.
5. Modify the repository settings as needed. — To deactivate a repository, click Deactivate.

— To activate a repository, click Activate.

— To change the repository settings, modify the content of the available text box(es) for the selected repository. The available attributes will vary according to the selected repository type.

The names used for connecting to DMS servers and repositories, except for secure file systems, and Veeva systems, are case-sensitive. Use the exact letter case for the names for the DMS to function correctly.

Modifiable DMS Repository Attributes

DMS Repository type	Modifiable DMS Repository attributes
Documentum Server	Server Name

	Name(Docbase) Active Flag Label Authentication Type: Basic or oAuth Repository User Repository Password Force New Renditions and Extractions Limit Access to Specific Users
Secure File System	Server Name Label Repository Name Active Flag Repository Domain Repository User Repository Password Force New Renditions and Extractions Limit Access to Specific Users
DMS Repository type	Modifiable DMS Repository attributes
Veeva System Server	Server Name Name(Docbase) Active Flag Label Vault URL Repository User Repository Password Authorization Server Client ID

	Authorization Server Client Secret
	Force New Renditions and Extractions
	Limit Access to Specific Users

Configure DMS Access for Specific Users

Users with administrator privilege can configure a DMS within Ennov InSight so that it is only accessible by defined users, groups, or roles.

This limits the DMS repositories that are displayed within the DMS Browse field. The restrictions imposed impact the areas where the DMS tree is used. For example: Reference Links, Export Assembly, PDS Labeling Link, and so on.

To configure access to specific users:

1. Log on to Ennov InSight as an administrator.
2. In the Ennov InSight menus, select: GoTo > Technical Administration.
3. In the Available Options list, click DMS Repository Management.
4. To set user access to the existing repositories, in the *Repositories* view, click on the name of a repository in the list.
5. From Limit Access to Specific Users drop-down list, click Yes.
6. Do the following:
 - To permit access to specific users, select the user under Access Limited for Allow Selected Users and click on the arrows pointing towards right (>).
 - To permit access to specific groups, select the group under Access Limited for Allow Selected Groups and click on the arrows pointing towards right (>).

Ennov InSight Administration 7.3 Configure DMS Access for Specific Users

 - To permit access to users with specific roles, select the role under Access Limited for Allow Selected Roles and click on the arrows pointing towards right (>).
7. Click Save.

Linked Systems

The External Systems section in Ennov InSight can be used to provide access to external systems from Ennov InSight .

As a System Administrator, you are able to create and update URLs to external Systems. The Linked Systems can be configured to be accessible by specified users, groups, or roles.

After the external system URL is added it will appear in the menu bar on the Ennov InSight *Home* Page.

Add a Linked System

Use the following procedure to add a URL for an external system to the Ennov InSight .

To add a Linked System URL:

1. Log on to Ennov InSight as an administrator.
2. In the Ennov InSight menus, click GoTo > Technical Administration.
3. In the Available Options list, click Linked Systems.
4. In the *Linked Systems* view, click Create.
5. For Display Name, type the name of the URL you are adding.

This name should be unique within the system. You can type up to 30 characters.

6. For URL, type the valid link to the external system.

You can enter up to 4000 characters. The Active Flag default setting is Y for active, so the linked system is active as soon as it is added to Ennov InSight . Linked systems can be deactivated or activated again at any time after configuration.

7. For Limit Access to Specific Users, select No if the access to this linked system should not be limited and go to step 10.
8. To allow repository access to defined users or groups or roles, select Yes from the Limit Access to Specific Users and proceed to the next step.
9. Do the following:
 - To permit access to specific users: In the Allow Selected Users section, select users in the Access Limited box and click the arrows (>>) to move them to the Access Allowed box.
 - To permit access to specific groups: In the Allow Selected Groups section, select groups in the Access Limited box and click the arrows (>>) to move them to the Access Allowed box.
 - To permit access to users with specific roles: In the Allow Selected Roles section, select roles in the Access Limited box and click the arrows (>>) to move them to the Access Allowed box.
10. To save the new *Linked System* settings, click Save.

Linked Systems

Ennov InSight API Documentation

You can import/extract data, perform create/update queries, or delete entities to enhance the functionality of the Ennov InSight user interface.

The Ennov InSight API (application programming interface) enables you to integrate external systems with Ennov InSight .

The Ennov InSight API can be used to manage:

- Assembly Structure Functions – Registrations Entities
- Tasks and References Entities
- Product Detail Set Detail Entities
- Product Family Agnostic Entities
- Core Ennov InSight Entities
- Assembly Structure
- Life cycle assembly creation
- Life cycle operations and metadata
- Product related Entities
- Entering unique Events within Ennov InSight For Data Admin API, [click here](#).

Ennov InSight API Authentication OAuth 2.0

OAuth 2.0 protocol is used to authorize access to protected resources.

Authorized client application access to protected resources like web APIs is obtained by [Microsoft supported OAUTHv2 flow](#).

Depending on the Azure Portal configuration, some of the values below may not be required.

Ennov InSight includes the following grant access types:

Grant Type	Description
Resource Owner Password Credentials (ROPC)	Used where specified user credentials are supplied in the authentication request.
Client Credentials	Used by the built-in "Data Exchange" user.
Authorization Code	The code generated after a user logs on with the credentials. This code is supplied to the API.
Device Code	Used to allow access to a device from a remote site in a multi-factor authentication. User authentication is still required via the browser to gain access.
Grant Type	Description

Refresh Token	Authorizes servers to use temporary access tokens without the need for a user to authenticate with the token expires. Refresh Token is also known as Offline Access.

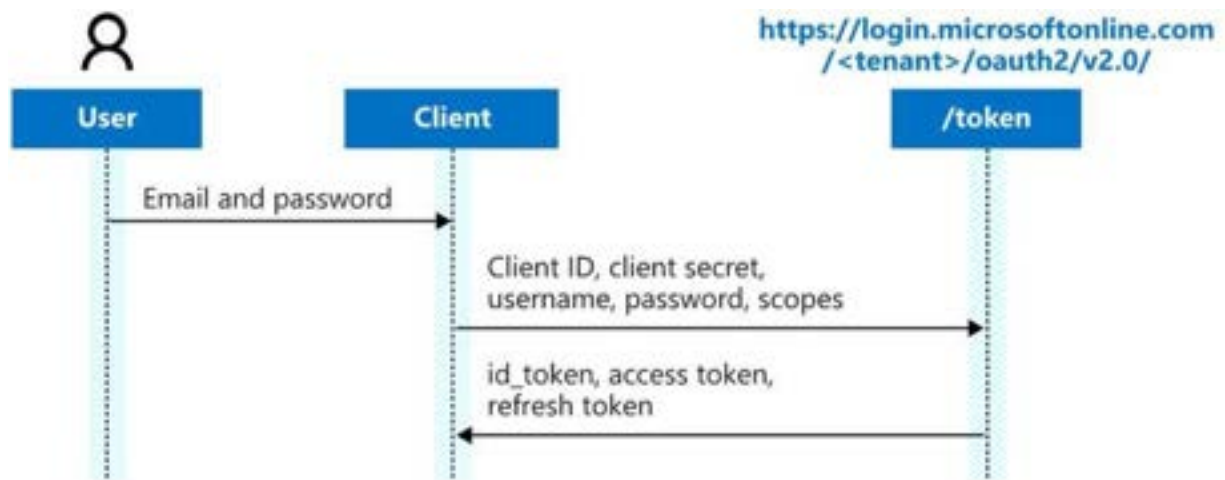
Resource Owner Password Credentials (ROPC)

Resource Owner Password Credentials (ROPC) allows an application to sign in by directly handling the user password.

To enable an API to perform operations based on the defined permissions, you should provide tenant, client_id, user name, password and client_secret values of an active user account configured in Ennov InSight Security Administration. The client_secret value is optional and depends on Azure configuration.

The Audit Trail defines all the operations in logs as specified user.

Resource Owner Password Credentials (ROPC) grant type is a legacy authentication method and is only supported for Azure Accounts, not Federated Accounts.

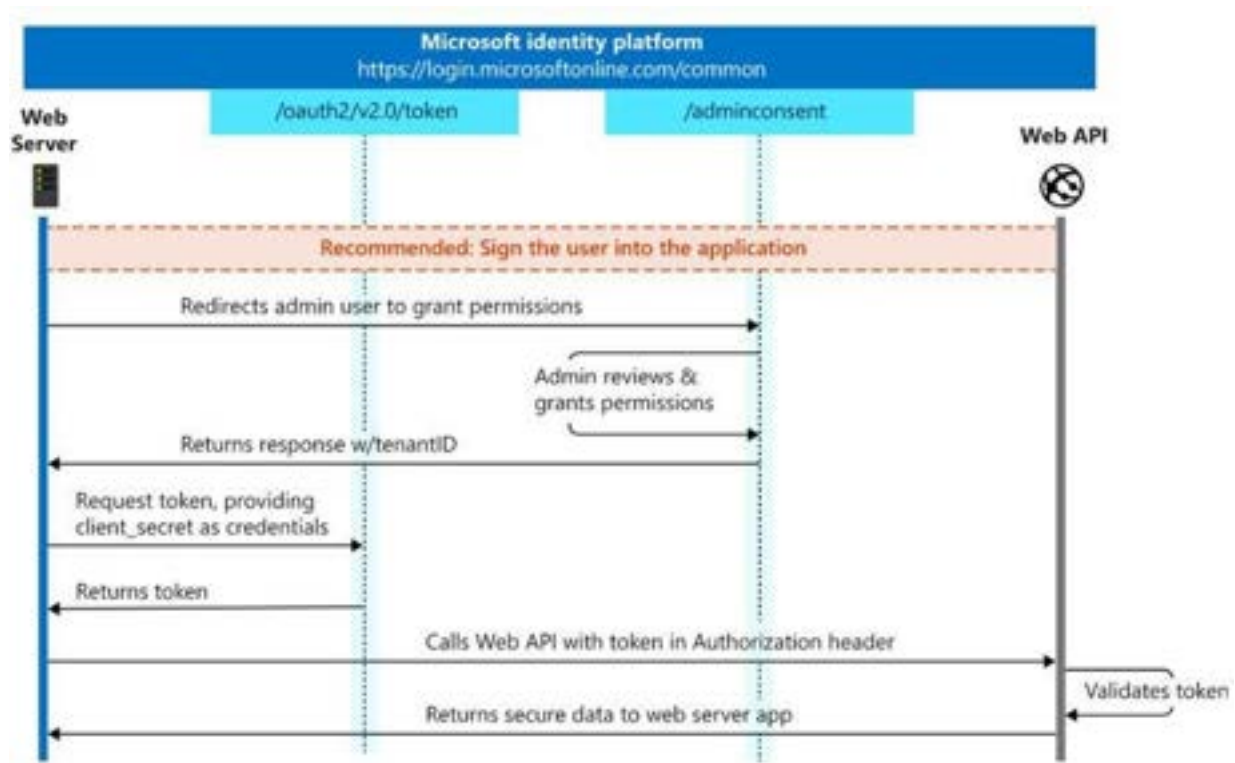


Client Credentials

Use this grant type if you are the built-in "Data Exchange" user.

To enable the API to use the built-in "Data_Exchange" user account, you should provide the tenant, client_id, client_secret in the Azure Portal - App Registration associated with Ennov InSight .

The Audit Trail defines all the operations in logs as Data_Exchange user.



Authorization Code

Use this grant type for configurations that use Federated accounts without Azure Active Directory as the underlying Identity Provider.

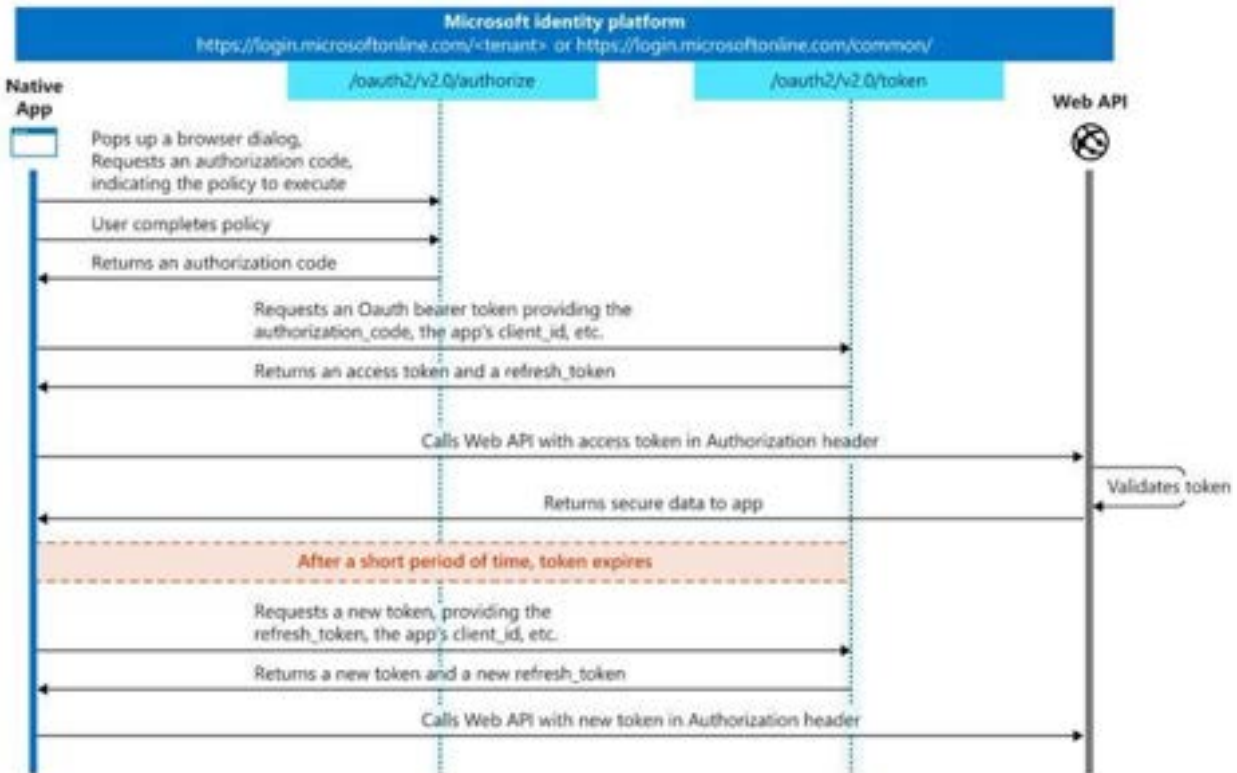
For this process, the auth code flow requires the OAuth flow to redirect the API to access Ennov InSight . You will be able to generate a time expiring code that grants access to the API.

To generate this code, you should have an account configured in Security Administration with appropriate permissions.

The Audit Trail defines all the operations in logs as the specific user that generated the access token.

If an appropriate redirect_uri is not configured in the Azure Portal - App Registration, this process becomes a manual operation to provide the code to the API.

As the Bearer Token Generated expires quickly, it is recommended that the Authorization Code grant is generated with the "offline_access" scope. This way the refresh_token grant can be utilized on subsequent API authentication requests.



Device Code

Use this grant type for configurations that use Federated accounts without Azure Active Directory as the underlying Identity Provider.

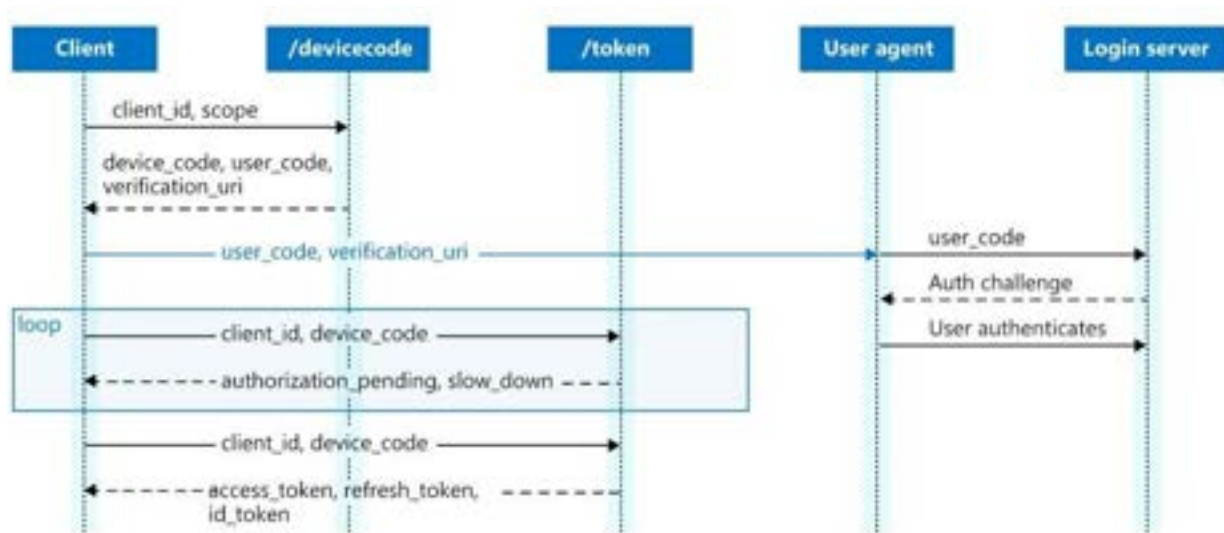
For this process, the device code flow requires the user to authenticate in a two-stage process to generate the bearer token. Authorizing access via the `device_code` grant should not be performed in a browser on the same client or server that performs the API calls.

The account used to generate the approval should be the account configured in Security Administration with appropriate permissions.

The Audit Trail defines all the operations in logs as the specific user that generated the access token.

This grant type requires "Allow public client flow" to be configured in the Azure Portal - App Registration.

As the Bearer Token Generated expires quickly, it is recommended that the Device Code grant is generated with the "offline_access" scope. This way the refresh_token grant can be utilized on subsequent API authentication requests.



Refresh Token

Use this grant type in conjunction with the access token to extend the frequency required for authentication requests. This grant type is also known as "Offline Access".

All the grant types can be configured to use the Refresh Token, but the OAuth v2 Microsoft endpoints are required to define a scope parameter on initial authentication.

As the Bearer Token is generated with refresh_token parameter, the grant type can be utilized for subsequent authentication requests without additional verification steps. For example: generate an authentication code, completing a device code approval, or sending username or password in the API request.

Worked Examples OAuth 2.0

Client Credentials Defined Example OAuth 2.0

Use OAuth 2.0 client credentials grant flow to enable a web service to use its own credentials to authenticate another call web service.

To define client credentials:

1. Submit a HTTPS POST request to: https://login.microsoftonline.com/<tenant_id>/oauth2/v2.0/token
tenant_id format: xxxxxxxx-xxxx-xxxx-xxxxxxxxxxxx

Note: In the URL above common is no longer supported with the v2 oauth2 endpoints so tenant_id must be used. The following parameters are updated.

The body of the request should include the form-data:

Parameter Name	Value

grant_type	client_credentials
Parameter Name	Value
client_id	xxxxxxxx-xxxx-xxxx-xxxxxxxxxxxx
scope	<registered client_id>/default openid
client_secret	<registered client_secret>

The Response generates an AzureBearerBody Token used in conjunction with the API X-CSRF-TOKEN access token generated in step 3.

2. Submit an HTTPS GET request to get a token.

Send an HTTP request (GET-request) to: <http://hostname:port/insight/api/v2/token>

The body of the JSON response includes

```
{ "token": "xAuthToken": "44B1E9C995C654E38DDD82BF708784D1" }
```

with the current session ID. The response header contains the following values:

Parameter Name	Value
X-CSRF-HEADER	X-CSRF-TOKEN
X-CSRF-PARAM	_csrf
X-CSRF-TOKEN	40d67d97-fb28-4a78-a111-5bae0ee706bb

3. Use that token and login information to authenticate.
4. Send a login POST-request to pass authentication using the same session (set JSESSIONID):

Parameter Name	Value
URI:	http://hostname:port/insight/api/v2/login
Request header values:	
Content-Type:	"application/json"
X-CSRF-TOKEN:	40d67d97-fb28-4a78-a111-5bae0ee706bb. This value is retrieved as a result of the previous request. (http://hostname:port/insight/api/v2/token)
Cookie:	JSESSIONID=44B1E9C995C654E38DDD82BF708784D1

	The value is taken from XAuthToken form described in the step 2.
Request body (raw):	{{AzureBearerBody}}
	This is the Azure Generated Authorization Token gathered in steps 1 and 2.

After successful logon, the application creates a new session and a new token to use in subsequent API calls. The response header contains the following values:

Parameter Name	Values
X-CSRF-HEADER	X-CSRF-TOKEN
X-CSRF-PARAM	_csrf
X-CSRF-TOKEN	40d67d97-fb28-4a78-a111-5bae0ee706bb

5. Make an API call with your new token.

All subsequent REST API POST-requests (read/create/create-or-update/delete for a specific entity) are sent through "/api/v2" URI (example: <http://hostname:port/insight/api/v2/event/46098/delete>) with the following attributes:

Parameter Name	Value
Request header values:	
Content-Type:	"application/json"
X-CSRF-TOKEN:	40d67d97-fb28-4a78-a111-5bae0ee706bb
Cookie:	JSESSIONID=44B1E9C995C654E38DDD82BF708784D1 The value is taken from XAuthToken form described in the step 2.
Request body:	JSON object for the specific entity.

Instead of X-CSRF-TOKEN header, you can use the "_csrf" param.

ROPC Defined Example OAuth 2.0

Specify user credentials in the authentication request to perform API operations based on Ennov InSight security permissions.

To define client credentials:

1. Submit a HTTPS POST request to: https://login.microsoftonline.com/<tenant_id>/oauth2/v2.0/token The tenant_id format: xxxxxxxx-xxxx-xxxx-xxxxxxxxxxxx.

Note: In the URL above common is no longer supported with the v2 oauth2 endpoints so tenant_id must be used. The following parameters are updated.

The body of the request should include the form-data:

Parameter Name	Value
grant_type	password
client_id	xxxxxxxx-xxxx-xxxx-xxxxxxxxxxxx
scope	<registered client_id>/.default openid
user name	<user account with security permissions>
password	<password_for user_account>
Parameter Name	Value
client_secret	<registered client_secret>

The Response generates an AzureBearerBody Token used in conjunction with the API X-CSRF-TOKEN access token generated in step 3.

2. Submit an HTTPS GET request to get a token.

Send an HTTP request (GET-request) to: <http://hostname:port/insight/api/v2/token> The body of the JSON response includes

```
{ "xAuthToken": "44B1E9C995C654E38DDD82BF708784D1" }
```

with the current session ID. The response header contains the following values:

Parameter Name	Value
X-CSRF-HEADER	X-CSRF-TOKEN
X-CSRF-PARAM	_csrf
X-CSRF-TOKEN	40d67d97-fb28-4a78-a111-5bae0ee706bb

3. Use that token and login information to authenticate.
4. Send a login POST-request to pass authentication using the same session (set JSESSIONID):

Parameter Name	Value
URI:	http://hostname:port/insight/api/v2/login

Request header values:	
Content-Type:	"application/json"
X-CSRF-TOKEN:	40d67d97-fb28-4a78-a111-5bae0ee706bb. This value is retrieved as a result of the previous request. (http://hostname:port/insight/api/v2/token)
Request body (raw):	<pre>{"access_token":"<obtained_access_token>", "token_type":"Bearer"}</pre> This is the Azure Generated Authorization Token gathered in steps 1 and 2.

After successful login, the application creates a new session and a new token to use in subsequent API calls. The response header contains the following values:

Parameter Name	Values
X-CSRF-HEADER	X-CSRF-TOKEN
X-CSRF-PARAM	_csrf
X-CSRF-TOKEN	40d67d97-fb28-4a78-a111-5bae0ee706bb
Cookie	JSESSIONID=44B1E9C995C654E38DDD82BF708784D1 The value is taken from XAuthToken form described in the step 2.

5. Make an API call with your new token.

All subsequent REST API POST-requests (read/create/create-or-update/delete for a specific entity) are sent through "/api/v2" URI (example: http://hostname:port/insight/api/v2/event/46098/delete) with the following attributes:

Parameter Name	Value
Request header values:	
Content-Type:	"application/json"
X-CSRF-TOKEN:	40d67d97-fb28-4a78-a111-5bae0ee706bb
Cookie:	JSESSIONID=44B1E9C995C654E38DDD82BF708784D1 The value is taken from XAuthToken form described in the step 2.
Request body:	JSON object for the specific entity.

Instead of X-CSRF-TOKEN header, you can use the "_csrf" param.

Authorization Code Defined Example OAuth 2.0

Use OAuth 2.0 client credentials grant flow to enable a web service to use its own credentials to authenticate another call web service.

Prerequisites

Use the offline_access scope parameter when connecting through this method. Logging into the RIM API should follow the refresh_token grant after initial bearer token has been generated.

If there is no redirection configured to verify the user login details, and the callback URI is not registered in the Azure Portal - App Registration, this process will require a manual step The parameters for URL to the OAuth end- point:

Parameter Name	Value
client_id	xxxxxxxx-xxxx-xxxx-xxxxxxxxxxxx
response_type	code
redirect_uri	https://some-void-uri-configured-in-azure-portal
response_mode	query
scope	<registered client_id>/.default openid offline_access
state	<A random string>

Example: https://login.microsoftonline.com/<tenant_id>/oauth2/v2.0/authorize? client_id=<client_id>&response_type=code&redirect_uri=<login_url_registered_in_app-portal>&response_mode=query&scope=<client_id>%2F.default%20openid%20offline_access&state=<a_state_string>

The tenant_id format: xxxxxxxx-xxxx-xxxx-xxxxxxxxxxxx.

Once the URL is updated, paste the string into a web browser. This will direct you to Ennov InSight login page. If there is no redirection configured, you will logon Ennov InSight . In this case, close the browser window and re-copy the original URL.

A successful code generation displays an Http 400 error page without a valid redirection_uri defined. Example:

<login_url_registered_in_app-portal>?
code=<very_long_hash_string>&state=<a_state_value>&session_state=<a_auto_generated_string>

Copy the whole of the URL to a text editor and extract the very long hash string between code= and &state.

To define client credentials:

1. Submit a HTTPS POST request to: https://login.microsoftonline.com/<tenant_id>/oauth2/v2.0/token The body of the request should include the form-data:

Parameter Name	Value
grant_type	authorization_code
client_id	xxxxxxxx-xxxx-xxxx-xxxxxxxxxxxx
scope	<registered client_id>/.default openid
redirect_uri	<login url defined in code request>
code	<hash string extracted earlier>
offline_access	Optional. Add this parameter if you want to use the refresh_token flow.

The Response generates an AzureBearerBody Token.

2. Use this bearer token in the refresh_token grant flow if the offline_access parameter is defined. If not, follow the usual steps to generate the X-CSRF-TOKEN, JSESSION & RIM API login.

Device Code Example OAuth 2.0

Use this grant type for configurations that use Federated accounts without Azure Active Directory as the underlying Identity Provider.

Prerequisites

Use the offline_access scope parameter when connecting through this method. Logging into the RIM API should follow the refresh_token grant after initial bearer token has been generated.

To define client credentials:

1. Submit a HTTPS POST request to: https://login.microsoftonline.com/<tenant_id>/oauth2/v2.0/token

The tenant_id format: xxxxxxxx-xxxx-xxxx-xxxxxxxxxxxx.

The body of the request should include the form-data:

Parameter Name	Value
client_id	xxxxxxxx-xxxx-xxxx-xxxxxxxxxxxx
scope	<registered client_id>/.default openid offline_access

A "user_code" is generated on successful POST operation.

2. In a browser, navigate to: <https://microsoft.com/devicelogin>.
3. Enter the user_code string generated into the browser field.
4. Follow the prompts to complete the authentication request.

- Record or capture the device_code generated as part of the POST request
- Submit a HTTPS POST request to: https://login.microsoftonline.com/<tenant_id>/oauth2/v2.0/token

Parameter Name	Value
grant_type	urn:ietf:params:oauth:grant-type:device_code
client_id	<registered client_id>
device_code	<device_code_from_previous_step>

The Response generates an AzureBearerBody Token with the offline_access parameter set.

- Use this bearer token in the refresh_token grant flow.

If the offline_access parameter is not defined, follow the usual steps to generate the X-CSRF-TOKEN, JSESSION & RIM API login.

Refresh Token Code Example OAuth 2.0

Use Refresh Token to get new access token when your current access token expires..

To use Refresh Token:

- Submit a HTTPS POST request to: https://login.microsoftonline.com/<tenant_id>/oauth2/v2.0/token The tenant_id format: xxxxxxxx-xxxx-xxxx-xxxxxxxxxxxx.

Parameter Name	Value
grant_type	refresh_token
client_id	<registered client_id>
refresh_token	To obtain it, see: <i>Authorization Code Defined Example OAuth 2.0</i>
scope	<registered client_id>/.default openid offline_access The offline_access parameter must be added to the scope on the initial authorization request to be valid on the refresh_token grant.

The Response generates an AzureBearerBody Token used in conjunction with the API X-CSRF-TOKEN access token.

- Submit an HTTPS GET request to get a token.

Send an HTTP request (GET-request) to: <http://hostname:port/insight/api/v2/token> The body of the JSON response includes the following with the current session ID.

```
{ "xAuthToken": "F6A8C5D3B1C2EC9A37DF380C7EB5A9C5" }
```

The response header contains the following values:

Parameter Name	Value
X-CSRF-HEADER	X-CSRF-TOKEN
X-CSRF-PARAM	_csrf
X-CSRF-TOKEN	40d67d97-fb28-4a78-a111-5bae0ee706bb

3. Use that xAuthToken as JSESSIONID for cookies and X-CSRF-TOKEN to start user session.
4. Send a login POST-request to pass authentication using the same session (set JSESSIONID):

Parameter Name	Value
URI:	http://hostname:port/insight/api/v2/login
Request header values:	
Content-Type:	"application/json"
X-CSRF-TOKEN:	40d67d97-fb28-4a78-a111-5bae0ee706bb. This value is retrieved as a result of the previous request. (http:// hostname:port/insight/api/v2/token)
Cookie:	JSESSIONID=F6A8C5D3B1C2EC9A37DF380C7EB5A9C5. This value is retrieved from XAuthToken form as a result of the step 2.
Request body (raw):	{ "access_token": "<obtained_access_token>", "refresh_token": "<obtained_refresh_token>", "token_type": "Bearer" } This is the Azure Generated Authorization Token gathered in steps 1 and 2.

After successful logon, the application creates a new session and a new token to use in subsequent API calls. The response header contains the following values:

Parameter Name	Values
X-CSRF-HEADER	X-CSRF-TOKEN
X-CSRF-PARAM	_csrf

X-CSRF-TOKEN	40d67d97-fb28-4a78-a111-5bae0ee706bb

5. Make an API call with your new token.

All subsequent REST API POST-requests (read/create/create-or-update/delete for a specific entity) are sent through "/api/v2" URI (example: <http://hostname:port/insight/api/v2/event/46098/delete>) with the following attributes:

Parameter Name	Value
Request header values:	
Content-Type:	"application/json"
X-CSRF-TOKEN:	40d67d97-fb28-4a78-a111-5bae0ee706bb
Cookie:	JSESSIONID=F6A8C5D3B1C2EC9A37DF380C7EB5A9C5. This value is retrieved from XAuthToken form as a result of the step 2.
Request body:	JSON object for the specific entity.

Instead of X-CSRF-TOKEN header, you can use the "_csrf" param.

Ennov InSight RIM 7.3 API Changes

Ennov InSight 7.3 Data Administration Lists - CUD Operations

Ennov InSight 7.3 includes the following List of Data Administration entities supported by API Create, Update, Delete (CUD) operations:

Table 2: Data Administration Lists

Data Administration Section	Data Administration Section List Name
Application Maintenance	Age Span Population Values
	Application Category Values
	Application Status Values
	Application Type Values
	CTA Product Role Values
	Country Values
	Country Values - Health Authority
	Legal Status Values
	MEDRA Term Values

	Medical Condition Investigated Values
	Orphan Status Values
	Procedure Type Values
	Product Information Document Type Values
	Reason for Premature Ending Values
	Region Type Values
	Regulatory Entitlement Type Values
Assembly	Assembly Category Values
	Assembly DTD/Schema Types
	Assembly Status Values
	Assembly Subcategory Values
Assembly Variables	Assembly Repository Variables
	Assembly System Defined Variables
	Assembly User Defined Variables
	Calyx RIM Assembly Variables
Change Maintenance	Change Type Values
Custom List Maintenance	Custom List Names
	Custom List Values

Data Administration Section	Data Administration Section List Name
DMS Integration	Bind to Label Values
	Bind to Status Values
	Rendition Identifier Values
Event Maintenance	Action Type Values
	EU Grouping or Worksharing Values
	Event Status Values
	Event Type Values
	Secondary Event Type Values
	Timeline/Event Plan Type Values

	Timeline/Event Plan Values
	Timeline/Event Plan Values - Timeline/Event Plan Countries
Other	Application Submission Type Values
	Attached Document Content Type Values
	Concentration Measure Type Values
	Denominator Unit Values
	Entity XML/UI Mappings
	Indications/Intended Use Values
	Legal Basis Values
	MAH/Development Sponsor/Organization Values
	Previous EV Code Values
	Quantity Unit of Measure Values
	SME Status Values
	Units of Measurement Values
	Unit of Measure Prefix Values
	Unit of Presentation Values
	Weight Unit of Measure Values

Data Administration Section	Data Administration Section List Name
Product Detail Set Maintenance	Color Values
	Compendial Designation/Source Values
	Component Type Values
	Data Classification Type Values
	Device – Type of Combination Values
	Dose Frequency Values
	Human Consumption Product Values
	Intended Effect Values
	Label Type Values
	Manufacturer Values

	Manufacturer Values – Global Detail Sets
	Manufacturing Functions Values
	Material Types Values
	Medical Device UDI Values
	Medical Device Part Code Values
	Origin of Substance Values
	Packaging Type Values
	Product Material Values
	Production Type Values
	QC Status Values
	Shape Values
	Shelf Life Category Values
	Shelf Life Type Values
	Species Values
	Storage Condition Values
	Substance Role Values
	Substance Values > Substance International Codes
	Time Unit Values
	Volume Unit of Measure Values

Data Administration Section	Data Administration Section List Name
Product Family Maintenance	ATC Values
	Division Values
	Domain Type Values
	EURD ID Values
	Product Family Status Values
	Substance Class Values
	Therapeutic Class Values
Product Maintenance	Applicable Standards Values

	Conformity Assessment Body Values
	Conformity Assessment Path Values
	Country Specific Detail Type Values
	Country Specific Detail Values
	Device Allergenicity Values
	Device Sterility Indicator Values
	Dosage/Pharmaceutical Form Values
	EC Cert Values
	Global Harmonization Task Force (GHTF) Class Values
	Manufacturing Location Values
	Medical Device Values
	Product Category Type Values
	Product Cross Reference Type Values
	Product Status Values
	Route of Administration Values
	Special Measure Values
	Sterilization Requirement Values
	Sterilization Values
	UMDNS Code Values
Project Maintenance	Project Status Values
	Project Type Values

Data Administration Section	Data Administration Section List Name
Publishing Requirements Maintenance	Electronic Format Requirement Values
Reference Maintenance	Reference Content Values
	Reference Participant Values
	Reference Status Values
	Reference Type Values
Registration Maintenance	Content of Change Values

	EMA Authorisation Status Values
	Marketing Status Values
	Master File Type Values
	Medical Product Actions/Submission Status Values
	Medicinal Product Name Part Type
	Medicinal Product Name Part Type Values
	Medicinal Product Type Values
	Provenance Reason Values
	Qualified Person Responsible for Pharmacovigilance (QPPV) Values
	Registration Status Values
	Risk of Supply of Shortage Reason Values
Sequence Maintenance	Filing Type Values – Filing Type eCTD Code
	Sequence Status Values
Data Administration Section	Data Administration Section List Name
Submission Maintenance	Applicant Contact Type Values
	Applicant Contact Values
	Applicant ID Values
	Application Form Type Values
	Font Definition Values
	Leaf Status Values
	PDF Properties Values
	Promotional Material Audience Type Values
	Promotional Material Type Values
	Regulatory Activity Lead Values
	Sequence Description Values
	Sub Filing Type Values
	Sub Filing Type Values – Sub Filing Type eCTD Code
	Supplement Effective Date Type Values

	Supplement Effect Date Type - Supplement Effective Date Type eCTD
	Telephone Number Type Values
Submission Plan Maintenance	Submission Plan Status Values
Task Maintenance	Secondary Task/Sub-Task Values
	Task/Sub-Task Status Progression Values
	Task/Sub-Task Status Values

Ennov InSight 7.2 API Changes

This table describes the API changes for Ennov InSight 7.2.

Ennov InSight 7.2 includes the following API support.

Entity Name	API/Controller	Main endpoint	Description
EUCategoryOfCMRType e	EUCategoryOfCMRType e- RestController	/data-admin/eucatego- ry-of-cmr-type	EU Category of CMR Type Values
EuDeviceNomenclatur e- Category	EuDeviceNomenclatur eCategoryRestController	/data-admin/eude- vice-no menclature-cate- gory	EU Device Nomenclature Catego- ry Values

Entity Name	API/Controller	Main endpoint	Description
EuDeviceNomenclatur e	EuDeviceNomenclatur e- RestController	/data-admin/eude- vice-nomenclature	EU Device Nomenclature Values
FdaDeviceInvitroTerm	FdaDeviceInvitroTerm RestController	/data-admin/fdade- vice-inviro-term	FDA GMDN In-Vitro Term Type Values
FdaDeviceGMDN	FdaDeviceGMDNRest Controller	/data-admin/gmdn	Global Medical Device Nomenclature (GMDN) Code Values
SubstanceSubtypeTy pe	SubstanceSubtypeRe st- Controller	/data-admin/ sub- stance-subtypetype	Substance Subtype Type
OriginOfSubstance	OriginOfSubstanceRe st- Controller	/data-admin/origi- nof-substance	Origin Of Substance Values
CertificateMasterFile	CertificateMasterFileR estController	data-admin/ certifi- cate-master-file	Certificate Master File Values

CertificateType	CertificateTypeRestController	/data-admin/ certificate-type	Certificate Type Values
DataCarrierIdentifier	LicenseDataCarrierIdentifierRestController	/data-admin//license/ data-carrier-identifier	Data Carrier Identifier

Comparison Table API changes between Ennov InSight 7.2 and Ennov InSight 7.1

This table describes the API changes between Ennov InSight 7.2 and Ennov InSight 7.1.

Entity Name	API/Controller	endpoint	API 7.2 Updates		Class/Table	Description
			Attribute	Column		
Substance	SubstanceRestController	/data-admin/ substance	The following fields are added: – deviceCmrCategoryId – indexNumber – ecNumber	– DEVICE_CMR_CATEGORY_TYPE_ID – INDEX_NUMBER – EC_NUMBER	Classname: Substance – DB table: ISM.SUBSTANCE – DB view: ISM.DV_SUBSTANCE	– This field is foreign key to: Class name: EUCategoryOf CMRTYPE; DB table: ism.eu_device_cmr_category_typeRequired for Substances of type 'CMR Substance', non mandatory for other types. – Optional – Optional

Entity	API/Controller	endpoint	API 7.2 Updates		Class/Table	Description
			Attribute	Column		

Name						
Manufacturer	SourceRestController(read only)	/data-admin/source	The following fields are added: – dunsSrN umber – authorize dReprese nt ativeNam e	– ORGANIZAT ION_IDENT IFIER2 – AUTHORIZED_REPRESENTATIVE_NAME	Classname:Source – DB table: ISM.SOURCE – DB view: ISM.DV_SOURCE	– Optional – Optional
Manufactured Item	ManufacturedItemRestController	/manufactured-item	The following fields are changed: – quantityValue – quantityUnit		Classname:ManufacturedItem – ISM.MANUFACTURED_ITEM – ISM.DV_MANUFACTURED_ITEM	– The field is changed from required to optional and to accept float values (up to 5 digits then '.'). – The field is changed to optional

						I.

Entity Name	API/Controller	endpoint	API 7.2 Updates		Class/Table	Description
			Attribute	Column		
PDS Substance Detail	SubstanceDetailRestController	/detail/ substance	The following fields are added: – originOfSubstanceId – compositionGroupingDescription – concentrationMeasureTypeId	– SUBSTANCE_ORIGIN_TYPE_ID – COMPOSITION_GROUPING_DESCRIPTION – ISM.CONCENTRATION_MEASURE_TYPE_ID	Classname ActiveIngredientDetail – DB table: ISM.PDS_SUBSTANCE_CHANGE – DB view: ISM.DV_PDS_SUBSTANCE	– Optional I. This field is foreign key to: Class name: OriginOfSubstance / ISM.SUBSTANCE BSTAN CE_ORIGIN_TYPE compositionGroupingDescription / COMPOSITION_GROUPING_DESCRIPTION. – Optional

Entity	API/Controller	endpoint	API 7.2 Updates		Class/Table	Description
			Attribute	Column		

Name						
PDS ActiveIngr redientDet ail	ActiveIngre dientDetailRestCo ntroller	/detail/ai	The follow- ing fields are added: – originOfSu bstanceld – compositi onGroupin gDescripti on	– SUBSTANCE _ORIGIN_T YPE_ID – COMPOSITI ON_GROUPI NG_DESCRI PTION	Class Name: Ac- tiveIngre die nt- Detail – DB table: ISM.PDS_A CTING_CHA NGE – DB view: ISM.DV_PD S_ACTING	– This field is for- eign key to: Class name: Orig inO fSub- sta nce / ISM.SU BSTAN CE_ORIGIN _TYPE. Op- tiona l. – Optiona l.
FluStrainD etail	FluStrainDetail RestController	/detail/flustrain	The following field is added: concentratio nMeasureTy peld	ISM.CONCENT RATION_VALU E.CONCENTRA TION_MEASUR E_TYPE_ID		
Manufact uredItem Substance	ManufacturedI temSubstance RestController	/productfamily/ product/ com- ponent/ manu- factured -item/ substance	The following field is added: c oncentration MeasureTyp eld	ISM.CONCENT RATION_VALU E.CONCENTRA TION_MEASUR E_TYPE_ID		

Entity	API/Controller	endpoint	API 7.2 Updates		Class/Table	Descriptio n
			Attribute	Column		

Name						
ManufacturedItemReferenceSubstance	ManufacturedItemReferenceSubstanceRestController	/productfamily/ product/ component/ manufactured -item/ substance/ reference	The following field is added: concentrationMeasureTyped	ISM.CONCENTRATION_VALUE.CONCENTRATION_MEASURE_TYPE_ID		
ManufacturedItemActiveIngredient	ManufacturedItemActiveIngredientRestController	/productfamily/ product/ component/ manufactured -item/ activeingredient	The following field is added: concentrationMeasureTyped	ISM.CONCENTRATION_VALUE.CONCENTRATION_MEASURE_TYPE_ID		
ManufacturedItemRefActiveIngredient	ManufacturedItemRefActiveIngredientRestController	/productfamily/ product/ component/ manufactured -item/ activeingredient/ reference	The following field is added: concentrationMeasureTyped	ISM.CONCENTRATION_VALUE.CONCENTRATION_MEASURE_TYPE_ID		
Strength	StrengthRestController	/strength	The following field is added: concentrationMeasureTyped	ISM.CONCENTRATION_VALUE.CONCENTRATION_MEASURE_TYPE_ID		
ReferenceStrength	ReferenceStrength	/referencestrength	The following field is added:	ISM.CONCENTRATION_VALUE		

	ngthRestContr oller		concentratio nMeasureTy peld	E.CONCENTRA TION_MEASUR E_TYPE_ID		

Entity Name	API/Con- troller	endpoint	API 7.2 Updates		Class/Ta- ble	Descrip- tio n
			Attribute	Column		
XPharmaP roductSub- stance	XPharma- Produ ctSub- stanceRe st- Controller	– /product/ xpharmaproduct – /xpharmaproductsubstance	The follow- ing field is added: concentratio nMeasureTy peld	ISM.CON- CENT RATION_- VALU E.CONCEN- TRA TION_- MEASUR E_TYPE_ID		
XPharmaP roduct- Ref Sub- stance	XPharma- Produ ctRef- Substanc eRestCon- trolle r	– /product/ xpharmaproduct – /xpharmaproductsubstance/ reference	The follow- ing field is added: concentratio nMeasureTy peld	ISM.CON- CENT RATION_- VALU E.CONCEN- TRA TION_- MEASUR E_TYPE_ID		
XPharmaP roductAc- tiveIngre- di ent	XPharma- Produ ctAc- tiveIngre di entRestCon- tro	– /product/ xpharmaproduct – /xpharmaproductactiveingredi- ent	The follow- ing fields are added: – concentra tionMeasu reTypeld	– ISM.CONCE NTRATION_ VALUE.CON		

	ller		– substance Id	CENTRATIO N_MEASUR E_TYPE_ID – ISM.SUBST ANCE.ID		
XPharmaP roductRef ActiveIn- gr edient	XPharma- Produ ctRef- ActiveIng re- dientRestCo ntroller	– /product/ xpharmaproduct – /xpharmaproductactiveingredi- ent	The follow- ing field is added: concentratio nMeasureTy peld	ISM.CON- CENT RATION_- VALU E.CONCEN- TRA TION_- MEASUR E_TYPE_ID		

Ennov InSight 7.2 Data Administration Lists - APIs CUD Operations

List of Data Administration entities supported by API Create, Update, Delete (CUD) operations.

Table 3: Data Administration Lists

Data Administration Section	Data Administration Section List Name
Application Maintenance	Age Span Population Values
	Application Category Values
	CTA Product Role Values
	MedDRA Term Values
	Medical Condition Investigated Values
	Product Information Document Type Values
	Reason for Premature Ending Values
	Region Type Values
Assembly	Assembly Category Values
Change Maintenance	Change Type Values

Custom List Maintenance	Custom List Names
	Custom List Values
DMS Integration	Bind to Label Values
	Bind to Status Values
	Rendition Identifier Values
Event Maintenance	ActionType Values
	Event Type Values
Other	Application Submission Type Values
	Attached Document Content Type Values
	Denominator Unit Values

Data Administration Section	Data Administration Section List Name
Product Detail Set Maintenance	Color Values
	Compendial Designation/Source Values
	Data Classification Type Values
	Device – Type of Combination Values
	Dose Frequency Values
	Human Consumption Product Values
	Intended Effect Values
	Label Type Values
	Manufacturing Functions Values
	Medical Device UDI Values
	Medical Device Part Code Values
	Origin of Substance Values
	Product Material Values
	Production Type Values
	Shape Values
	Shelf Life Category Values
	Species Values

	Storage Condition Values
	Substance Values > Substance International Codes
Product Family Maintenance	Domain Type Values

Data Administration Section	Data Administration Section List Name
Product Maintenance	Applicable Standards Values
	Conformity Assessment Body Values
	Conformity Assessment Path Values
	Device Allergenicity Values
	Device Sterility Indicator Values
	EC Cert Values
	Global Harmonization Task Force (GHTF) Class Values
	Manufacturing Location Values
	Product Category Type Values
	Product Cross Reference Type Values
	Cross Reference Type Values
	Sterilization Values
Publishing Requirements Maintenance	Electronic Format Requirement Values
Registration Maintenance	Medicinal Product Name Part Type Values
	Provenance Reason Values
	Marketing Status Values
	Master File Type Values
	Component Type Values
	Content of Change Values
	Risk of Supply of Shortage Reason Values
	Medical Product Actions/Submission Status Values
	Applicant Contact Values
	Qualified Person Responsible for Pharmacovigilance (QPPV) Values
Submission Maintenance	Applicant Contact Type Values

	Promotional Material Audience Type Values
	Promotional Material Type Values

Ennov InSight 7.2 API End Points Entities Added

The API End Points for Data Administration entities added to the Ennov InSight 7.2.

Endpoints

```

put("meddra-term-type", DataAdminEntityConfig.builder()

.metaClassName(MeddraTermType.CLASSNAME)

.build());

put("medical-condition-type", DataAdminEntityConfig.builder()

.metaClassName(MedicalConditionType.CLASSNAME)

.build());

put("medical-device-udi", DataAdminEntityConfig.builder()

.metaClassName(MedicalDeviceUDI.CLASSNAME)

.build());

put("medicinal-product-name-part-type", DataAdminEntityConfig.builder()

.metaClassName(MedicinalProductNamePartType.CLASSNAME)

.build());

put("part-code", DataAdminEntityConfig.builder()

.metaClassName(PartCode.CLASSNAME)

.build());

put("premature-ending-type", DataAdminEntityConfig.builder()

.metaClassName(PrematureEndingType.CLASSNAME)

.build());

put("product-category", DataAdminEntityConfig.builder()

.metaClassName(ProductCategory.CLASSNAME)

.build());

```

```
put("product-cross-reference-type", DataAdminEntityConfig.builder()

.metaClassName(ProductCrossReferenceType.CLASSNAME)

.build());

put("product-information-document-type", DataAdminEntityConfig.builder()

.metaClassName(ProductInformationDocumentType.CLASSNAME)

.build());

put("provenance-reason", DataAdminEntityConfig.builder()

.metaClassName(ProvenanceReason.CLASSNAME)

.build());

put("reference-type", DataAdminEntityConfig.builder()

.metaClassName(ReferenceType.CLASSNAME)

.build());

put("region-type", DataAdminEntityConfig.builder()

.metaClassName(RegionType.CLASSNAME)

.build());

put("rendition-identifier", DataAdminEntityConfig.builder()

.metaClassName(RenditionIdentifier.CLASSNAME)

.build());

put("sterilization-type", DataAdminEntityConfig.builder()

.metaClassName(SterilizationType.CLASSNAME)

.build());

put("storage-conditions", DataAdminEntityConfig.builder()

.metaClassName(StorageConditions.CLASSNAME)

.build());

put("application-submission-type", DataAdminEntityConfig.builder()

.metaClassName(ApplicationSubmissionType.CLASSNAME)
```



```
.build());

put("attached-document-content-type", DataAdminEntityConfig.builder()

.metaClassName(AttachedDocumentContentType.CLASSNAME)

.build());

put("bind-label", DataAdminEntityConfig.builder()

.metaClassName(BindLabel.CLASSNAME)

.build());

put("bind-status", DataAdminEntityConfig.builder()

.metaClassName(BindStatus.CLASSNAME)

.build());

put("material-type", DataAdminEntityConfig.builder()

.metaClassName(MaterialType.CLASSNAME)

.build());

put("ec-cert-type", DataAdminEntityConfig.builder()

.metaClassName(ECCertType.CLASSNAME)

.build());

put("electronic-format-requirement-type", DataAdminEntityConfig.builder()

.metaClassName(ElectronicFormatRequirementType.CLASSNAME)

.build());

put("event-type", DataAdminEntityConfig.builder()

.metaClassName(EventType.CLASSNAME)

.build());

put("ghtf-type", DataAdminEntityConfig.builder()

.metaClassName(GHTFType.CLASSNAME)

.build());

put("human-consumption-products", DataAdminEntityConfig.builder()
```

```
.metaClassName(HumanConsumptionProducts.CLASSNAME)

.build());

put("intended-effect-type", DataAdminEntityConfig.builder()

.metaClassName(IntendedEffectType.CLASSNAME)

.build());

put("label-type", DataAdminEntityConfig.builder()

.metaClassName(LabelType.CLASSNAME)

.build());

put("manufacturing-location-type", DataAdminEntityConfig.builder()

.metaClassName(ManufacturingLocationType.CLASSNAME)

.build());

put("marketing-status", DataAdminEntityConfig.builder()

.metaClassName(MarketingStatus.CLASSNAME)

.build());

put("master-file-type", DataAdminEntityConfig.builder()

.metaClassName(MasterFileType.CLASSNAME)

.build());

put("component-type", DataAdminEntityConfig.builder()

.metaClassName(ComponentType.CLASSNAME)

.build());

put("conformity-assessment-body-type", DataAdminEntityConfig.builder()

.metaClassName(ConformityAssessmentBodyType.CLASSNAME)

.build());

put("source-authorisation", DataAdminEntityConfig.builder()

.metaClassName(SourceAuthorisation.CLASSNAME)

.createFieldGroup("dataExchangeADD")
```

```

.updateFieldGroup("dataExchangeUPDATE")

.build());

put("content-of-change-type", DataAdminEntityConfig.builder()

.metaClassName(ContentOfChangeType.CLASSNAME)

.build());

put("risk-supply-shortage-reason", DataAdminEntityConfig.builder()

.metaClassName(RiskOfSupplyShortageReason.CLASSNAME)

.build());

put("promotional-material-audience-type", DataAdminEntityConfig.builder()

.metaClassName(PromotionalMaterialAudienceType.CLASSNAME)

.build());

put("promotional-material-doc-type", DataAdminEntityConfig.builder()

.metaClassName(PromotionalMaterialDocType.CLASSNAME)

.build());

put("custom-list-value", DataAdminEntityConfig.builder()

.metaClassName(CustomListValue.CLASSNAME)

.createFieldGroup("dataExchangeADD")

.updateFieldGroup("dataExchangeUPDATE")

.build());

put("application-category", DataAdminEntityConfig.builder()

.metaClassName(ApplicationCategory.CLASSNAME)

.build());

put("applicant-contact-type", DataAdminEntityConfig.builder()

.metaClassName(ApplicantContactType.CLASSNAME)

.build());

put("age-span-type", DataAdminEntityConfig.builder()

```

```
.metaClassName(AgeSpanType.CLASSNAME)

.build());

put("color", DataAdminEntityConfig.builder()

.metaClassName(Color.CLASSNAME)

.build());

put("shape", DataAdminEntityConfig.builder()

.metaClassName(Shape.CLASSNAME)

.build());

put("production-type", DataAdminEntityConfig.builder()

.metaClassName(ProductionType.CLASSNAME)

.build());

put("origin-of-substance", DataAdminEntityConfig.builder()

.metaClassName(OriginOfSubstance.CLASSNAME)

.build());

put("dose-frequency", DataAdminEntityConfig.builder()

.metaClassName(DoseFrequency.CLASSNAME)

.build());

put("gm-cell-origin-species-type", DataAdminEntityConfig.builder()

.metaClassName(GMCellOriginSpeciesType.CLASSNAME)

.build());

put("somatic-cell-therapy-type", DataAdminEntityConfig.builder()

.metaClassName(SomaticCellTherapyType.CLASSNAME)

.build());

put("cell-origin-species-type", DataAdminEntityConfig.builder()

.metaClassName(CellOriginSpeciesType.CLASSNAME)

.build());
```

```
put("somatic-cell-therapy-origin-type", DataAdminEntityConfig.builder()

.metaClassName(SomaticCellTherapyOriginType.CLASSNAME)

.build());

put("scientific-source-type", DataAdminEntityConfig.builder()

.metaClassName(ScientificSourceType.CLASSNAME)

.build());

put("shelf-life-category", DataAdminEntityConfig.builder()

.metaClassName(ShelfLifeCategory.CLASSNAME)

.build());

put("species-type", DataAdminEntityConfig.builder()

.metaClassName(SpeciesType.CLASSNAME)

.build());

put("compendial-designation", DataAdminEntityConfig.builder()

.metaClassName(CompendialDesignation.CLASSNAME)

.build());

put("product-material", DataAdminEntityConfig.builder()

.metaClassName(ProductMaterial.CLASSNAME)

.build());

put("manufacturer-function", DataAdminEntityConfig.builder()

.metaClassName(ManufacturerFunction.CLASSNAME)

.build());

put("substance-international-codes", DataAdminEntityConfig.builder()

.metaClassName(SubstanceInternationalCodes.CLASSNAME)

.build());

put("custom-list", DataAdminEntityConfig.builder()

.metaClassName(CustomListName.CLASSNAME)
```

```
.build());

put("applicable-standards", DataAdminEntityConfig.builder()

.metaClassName(ApplicableStdType.CLASSNAME)

.build());

put("medical-product-action-submission- status",

DataAdminEntityConfig.builder()

.metaClassName(MedicalProductActionType.CLASSNAME)

.build());

put("applicant-contact-email", DataAdminEntityConfig.builder()

.metaClassName(ApplicantContactEmail.CLASSNAME)

.build());

put("applicant-contact", DataAdminEntityConfig.builder()

.metaClassName(ApplicantContact.CLASSNAME)

.build());

put("applicant-contact-phone", DataAdminEntityConfig.builder()

.metaClassName(ApplicantContactPhone.CLASSNAME)

.build());

put("qppv", DataAdminEntityConfig.builder()

.metaClassName(Qppv.CLASSNAME)

.build());

put("manufacturing-function-globaldetail", DataAdminEntityConfig.builder()

.metaClassName(ManufacturingFunctionGlobalDetail.CLASSNAME)

.createFieldGroup("apiCreateFieldGroup")

.updateFieldGroup("dataExchangeUPDATE")

.parentFieldName(ManufacturingFunctionGlobalDetail.SOURCEID)

.build());
```

```
put("raw-material-global-detail", DataAdminEntityConfig.builder()

.metaClassName(RawMaterialGlobalDetail.CLASSNAME)

.createFieldGroup("apiCreateFieldGroup")

.updateFieldGroup("dataExchangeUPDATE")

.parentFieldName(RawMaterialGlobalDetail.SOURCEID)

.build());

put("packaging-global-detail", DataAdminEntityConfig.builder()

.metaClassName(PackagingGlobalDetail.CLASSNAME)

.createFieldGroup("apiCreateFieldGroup")

.updateFieldGroup("dataExchangeUPDATE")

.parentFieldName(PackagingGlobalDetail.SOURCEID)

.build());

put("substance-global-detail", DataAdminEntityConfig.builder()

.metaClassName(SubstanceGlobalDetail.CLASSNAME)

.createFieldGroup("apiCreateFieldGroup")

.updateFieldGroup("dataExchangeUPDATE")

.parentFieldName(SubstanceGlobalDetail.SOURCEID)

.build());

put("change-type", DataAdminEntityConfig.builder()

.metaClassName(ChangeType.CLASSNAME)

.build());

put("change-reason", DataAdminEntityConfig.builder()

.metaClassName(ChangeReason.CLASSNAME)

.build());

put("action-type", DataAdminEntityConfig.builder()

.metaClassName(ActionType.CLASSNAME)
```

```
.build());

put("assembly-category", DataAdminEntityConfig.builder()

.metaClassName(AssemblyCategory.CLASSNAME)

.build());

put("conform-assess-path-type", DataAdminEntityConfig.builder()

.metaClassName(ConformAssessPathType.CLASSNAME)

.build());

put("cta-product-role-type", DataAdminEntityConfig.builder()

.metaClassName(CTAProductRoleType.CLASSNAME)

.build());

put("denominator-unit-type", DataAdminEntityConfig.builder()

.metaClassName(DenominatorUnitType.CLASSNAME)

.build());

put("device-allergenicity", DataAdminEntityConfig.builder()

.metaClassName(DeviceAllergenicity.CLASSNAME)

.build());

put("device-combination-type", DataAdminEntityConfig.builder()

.metaClassName(DeviceCombinationType.CLASSNAME)

.build());

put("device-sterility-indicator", DataAdminEntityConfig.builder()

.metaClassName(DeviceSterilityIndicator.CLASSNAME)

.build());

put("domain-type", DataAdminEntityConfig.builder()

.metaClassName(DomainType.CLASSNAME)

.build());

put("data-classification-type", DataAdminEntityConfig.builder()
```



```
.metaClassName(DataClassificationType.CLASSNAME)
```

```
.build());
```

Ennov InSight 7.2 Read-Only API Entities

The list of read-only API entities.

Table 4: Read-Only API Entities

These entities do not support the following endpoints: /create, /update, /create-or-update, / delete/{id}.

API Entity Name
ApplicantID
ApplicationFormType
ApplicationStatus
ApplicationType
AssemblyStatus
AssemblySubcategory
BioType
ConcentrationMeasureType

API Entity Name
CountryHealthAuthority
CountryLeadTime
CountryRegion
CountrySpecificDetailType
CountrySpecificDetailValue
DataClassificationType
DeviceType
DeviceUsage
DivisionType
DossierType
DtdAppTypeEctd
DtdEffDateTypeEctd

DtdSeqTypeEctd
DtdSubTypeEctd
EmaAuthStatus
EntityXMLType
EUClassificationRuleType
EuGroupingType
EurdType
EventChangeDetailStatus
EventMilestones
EventPlanType
EventStatus
EvmpdCodeMappingReadOnly
FilingType
GeneTherapyTransProdType
GeneTherapyType
GMCellOriginType
InternalTypeView
InvestigatorType

API Entity Name
Language
LeafStatus
LegalBasisType
LegalStatus
LengthUnitOfMeasure
MahSponsor
MahSponsorEvmpdCodeMapping
ManufacturerFunction
MasterFileLocationType

MedicalDeviceType
MedicinalProductType
MessageSender
NumeratorUnitType
OmsOrgLocation
PdfProperty
PreviousEvCode
ProductCharacteristics
ProductDetailSetStatus
ProductFamilyStatus
ProductStatus
ProductStrengthUnit
ProjectStatus
ProjectType
PromotionalMaterialType
Property
PsurReportCode
QCStatus
QuantityUnitOfMeasure
RawMaterial
ReferenceContent

API Entity Name
ReferencedDTDType
ReferenceParticipant
ReferenceStatus
RegistrationStatus
RegulatoryActingLeadType
RegulatoryEntitlementStatus

RegulatoryEntitlementType
RenditionIdentifierValues
RmsApplicationLegalBasis
RmsApplicationSubmissionType
RmsAtcHuman
RmsCombinationPackage
RmsCombinedPharmaDoseForm
RmsCombinedTerm
RmsContactPartyRoleController
RmsCountry
RmsDataClassificationController
RmsDomain
RmsEURegulatoryAuthorisationProcedure
RmsIngredientRole
RmsLanguage
RmsLegalStatusSupply
RmsManufacturingActivity
RmsMarketingStatus
RmsMasterFileType
RmsMaterialController
RmsMedicalDictionaryForRegActivitiesController
RmsMedicalProductNamePartTypeController
RmsPackagingController
RmsPharmaDoseForm

API Entity Name
RmsProductCategoryController
RmsProductCrossReferenceType
RmsProductInformationDocumentTypeController

RmsQuantityOperator
RmsReasonForMarketingUnavailability
RmsRegulatoryEntitlementStatusController
RmsRegulatoryEntitlementTypeController
RmsRoutesAndMethodsOfAdministration
RmsShelfLifeTypeController
RmsSpecialPrecautionForStorage
RmsUnitsOfMeasurement
RmsUnitsOfPresentation
RmsXevmpdMedicalDevices
RmsXevmpdMedicinalProductType
SecondaryEvent
SequenceDescriptionType
SequenceStatus
ShelfLifeType
SmeStatus
SmsSubstance
Source
SpecialMeasure
SterilizationRequirement
StudySponsorType
SubFilingType
SubIndication
SubmissionPlanStatus
SubstanceLevelClass
SubstanceRoleType
SubstanceType
API Entity Name

SummaryOfTechdocType
SupplementEffectiveDateType
SystemAlertSubjectType
TabFontType
TaskPriority
TaskStatus
TaskSubtype
TaskType
TelephoneNumberType
TermWithdrawalReason
TherapeuticArea
TherapyClass
TrialDesignType
TrialPhaseType
TrialScopeType
TrialSubjectGroupType
UMDNSType
UnitOfMeasurement
UnitOfMeasurePrefix
UnitOfPresentation
ValidStatusProgressions
VariableRepository
VariableSystem
VariableUser
VolumeUnitOfMeasure
WeightUnitOfMeasure

Ennov InSight 7.1.3 API Changes

This table describes the API changes for Ennov InSight 7.1.3.

Ennov InSight 7.1.3 includes the following API support.

Entity Name	API/ Controller	endpoint	API Ennov InSight 7.1.3 up- dates		Description
			Attribute	Column	
License	PackageSetTypeRegistrationRestController	license/ packagesetregistration	Added "/all", "/query" endpoints		
ProductLicense	ProductTypeRegistrationRestController	license/ productregistration	Added "/all", "/query" endpoints		
FullProductPresentation	LicenseFppController	license/fullproductpresentation	Added "/all", "/query" endpoints		
LicensePackageSet	LicensePackageSetController	license/ packageset	Added "/all", "/query" endpoints		
LicensePackageSetCountry	LicensePackageSetCountryRestController	license/ packageset/ country	Added "/all", "/query" endpoints		

Entity Name	API/ Controller	endpoint	API Ennov InSight 7.1.3 updates		Description
			Attribute	Column	
AppCountry	ApplicationCountryRestController	/applicationcountry	The following fields are added: – localStartTrial – localFirstVisit – localEndOfRecruitment – localEndOfTrial	– LOCAL_START_OF_TRIAL_DATE – LOCAL_FIRST_VISIT_OF_FIRST_SUBJECT_D	– DB table: .ISM.AP_P_COUNTRY – DB view: ISM.DV_APP_C

			– localTemporaryHalted – localRestartTemporaryHalted – localEarlyTerminationReasonId – localEarlyTerminationReasonId	ATE – LOCAL_END_OF_RECRUITMENT_DATE – LOCAL_END_OF_TRIAL_DATE – LOCAL_TEMPORARY_HALT_DATE – LOCAL_RESTART_OF_TEMPORARY_HALTED_TRIAL – LOCAL_EARLY_TERM_DATE – TERM_WITH_REASON_TYPE_ID	COUNTRY

Comparison Table API changes between Ennov InSight 7.1.3 and Ennov InSight 7.1

This table describes the API changes between Ennov InSight 7.1.3 and Ennov InSight 7.1.

Entity Name	API/Controller	endpoint	API 7.1.3 Updates		Description
			Attribute	Column	
License	PackageSetTypeRegistrationRestController	license/ packagesetregistration	Added "/all", "/ query" endpoints		
Product-License	ProductTypeRegistrationRestController	license/productregistration	Added "/all", "/ query" endpoints		
FullProduct Presentation	LicenseFppController	license/fullproductpresentation	Added "/all", "/ query" endpoints		

Entity Name	API/Controller	endpoint	API 7.1.3 Updates		Description
			Attribute	Column	
LicensePackageSet	LicensePackageSetController	license/ packageset	Added "/all", "/ query" end-points		
LicensePackageSetCountry	LicensePackageSetCountryRestController	license/ packageset/ country	Added "/all", "/ query" end-points		
AppCountry	ApplicationCountryRestController	/applicationcountry	The following fields are added: – localStartTrial – localFirstVisit – localEndOfRecruitment – localEndOfTrial – localTemporarilyHalted – localRestartTemporaryHalted – localEarlyTerminationReasonId	– LOCAL_START_OF_TRIAL_DATE – LOCAL_FIRST_VISIT_OF_FIRST_SUBJECT_DATE – LOCAL_END_OF_RECRUITMENT_DATE – LOCAL_END_OF_TRIAL_DATE – LOCAL_END_OF_TEMPORARILY_HALTED_TRIAL_DATE – LOCAL_TEMPORARILY_HALTED_DATE – LOCAL_RESTART_OF_TEMPORARILY_HALTED_TRIAL	– DB table: .ISM.APP_COUNTRY – DB view: ISM.DV_APP_COUNTRY

			– localEarlyTerminationReasonId	– LOCAL_EARLY_TERM_DATE – TERM_WITH_REASON_TYPE_ID	

Ennov InSight 7.1 API Changes

This table describes the API changes for Ennov InSight 7.3.

Ennov InSight 7.1 includes the following API support.

Entity Name	API/Controller	Main endpoint	Description
OrphanDesignation	OrphanDesignationRestController	/orphan-designation	

Entity Name	API/Controller	Main endpoint	Description
EurdType	EurdTypeRestController	/data-admin/eurdtype	
DomainType	DomainTypeRestController	/data-admin/domaintype	
	ContentOfChangeTypeRestController	/content-of-changetype	
	MedicalProductActionTypeRestController	/medical-productaction-submissionstatus	
AttachedDocument	LicenseAttachedDocumentRestController	/license/attacheddocument	Hierarchy: Application->License->MedicinalProductAction>AttachedDocument
ManufacturedItem	ManufacturedItemRestController	/product-family/ product/component/ manufactured-item	

ManufacturedItem-Substance	ManufacturedItem-SubstanceRestController	/product-family/ product/component/ manufactured-item/ substance	
ManufacturedItem-ReferenceSubstance	ManufacturedItem-ReferenceSubstanceRestController	/product-family/ product/component/ manufactured-item/ substance/reference	
LicensePackage-SetName	LicensePackage-SetNameRestController	/license/packageset/ name	Hierarchy: Application- >License- >LicensePackageName
MedicinalProduct	LicenseMedicinal-ProductController	/license/medicinalproduct	Hierarchy: Application- >License- >MedicinalProductAction
MedicinalProduct-Action	MedicinalProduct-ActionRestController	/license/medicinalproduct-action	
Mpname	MedicinalProduct-MpnameRestController	/license/medicinalproduct/mp-name	
MedicinalProduct-CrossReference	MedicinalProduct-CrossReferenceRestController	/license/medicinalproduct/medicinalProductCrossReference	

Entity Name	API/Controller	Main endpoint	Description
DataCarrierType	DataCarrierTypeRestController	/data-admin/datacarrier-type	

DataClassificationType	DataClassificationTypeRestController	/data-admin/dataclassification-type	
MarketingStatusReason	MarketingStatusReasonRestController	/data-admin/marketing-statusreason	
	RmsApplicationLegalBasisRestController	/data-admin/rmsapp-legal-basis	
	RmsApplicationSubmissionTypeRestController	/data-admin/rmsapp-submission-type	
	RmsAtcHumanRestController	/data-admin/rms-atc-human	
	RmsCombinationPackageRestController	/data-admin/rmscombination-package	
	RmsCombinedPharmaceuticalDoseFormRestController	/data-admin/rmscombined-pharmadose-form	
	RmsCombinedTermRestController	/data-admin/rmscombined-term	
	RmsContactPartyRoleController	/data-admin/rmscontact-party-role	
	RmsCountryRestController	/data-admin/rmscountry	
	RmsDomainRestController	/data-admin/rmsdomain	
	RmsEURegulatoryAuthorisationProcedureRestController	/data-admin/rms-euregulatory-authorityprocedure	

	RmsIngredientRoleRestController	/data-admin/rmsingredient-role	
	RmsLanguageRestController	/data-admin/rmslanguage	
	RmsLegalStatusSupplyRestController	/data-admin/rmslegal-status-supply	

Entity Name	API/Controller	Main endpoint	Description
	RmsManufacturingActivityRestController	/data-admin/rmsmanufacturingactivity	
	RmsMarketingStatusRestController	/data-admin/rmsmarketing-status	
	RmsMasterFileTypeRestController	/data-admin/rmsmaster-file-type	
	RmsMedicalProductNamePartTypeController	/data-admin/rmsmedical-productname-part-type	
	RmsPackagingController	/data-admin/rmspackaging	
	RmsPharmaDoseFormRestController	/data-admin/rmspharma-dose-form	
	RmsProductCategoryController	/data-admin/rmsproduct-category	
	RmsProductCrossReferenceTypeRestController	/data-admin/rmsproduct-cross-reference	
	RmsQuantityOperatorRestController	/data-admin/rmsquantity-operator	
	RmsRegulatoryEntitlementTypeController	/data-admin/rmsregulatoryentitlement-type	

	RmsRegulatoryEntitlementStatusController	/data-admin/rmsregulatoryentitlement-status	
	RmsRoutesAndMethodsOfAdministrationRestController	/data-admin/rmsroutes-method-administration	
	RmsShelfLifeController	/data-admin/rmsshelf-life-type	
	RmsSpecialPrecautionForStorageRestController	/data-admin/rmsspecial-precautionstorage	

Entity Name	API/Controller	Main endpoint	Description
	RmsUnitsOfMeasurementRestController	/data-admin/rmsunits-of-measurement	
	RmsUnitsOfPresentationRestController	/data-admin/rmsunits-of-presentation	
	RmsXevmPdMedicalDevicesRestController	/data-admin/rmsxevm-pd-medicaldevices	
	RmsXevmPdMedicinalProductTypeRestController	/data-admin/rmsxevm-pd-medicinalproduct-type	
	RmsProductInformationDocumentController	/data-admin/rmsproduct-informationdocument-type	
	RmsMaterialController	/data-admin/rmsmaterial/	
	RmsMedicalDictionaryForRegActivitiesController	/data-admin/rmsmedical-dictionaryfor-regulatoryactivities/	
	RmsDataClassificationController	/data-admin/rmsdata-classification	Data Classification Spor entity

SourceAuthorisation	SourceAuthorisationRestController	/data-admin/sourceauthorisation	parent is source/ manufacturer
OmsOrgLocation	OmsOrgLocationRestController	data-admin/omsorglocation	This entity is a combination of two EMA entities: Organization and Location, which contains the fields of both entities: – number of records = number of Locations per Organisation – entityId is ISM.TERMINOLOGY_SYST EM_LIST_MEMBER.ID

Entity Name	API/Controller	Main endpoint	Description
DeviceCombinationType	DeviceCombinationTypeRestController	/data-admin/devicecombination-type	This entity corresponds to the field "Device - Type of Combination" of the "Medical Device" Detail and mapped to SPOR master data set.
Phpld	PhpldRestController	/product/xpharmaproduct/php-id	
	ContentOfChangeTypeRestController	/content-of-changetype	
	MedicalProductAction TypeRestController	/medical-productaction-submissionstatus	
PharmaProductSubstance	XPharmaProductSubstanceRestController	/product/xpharmaproduct/xpharmaproduct-substance	
PharmaProductRefSubstance	XPharmaProductRefSubstanceRestController	/product/xpharmaproduct/xpharmaproduct-substance/ reference	

PharmaProductActiveIngredient	XPharmaProductActiveIngredientRestController	/product/xpharmaproduct/xpharmaproduct-activeingredient	
PharmaProductReferenceActiveIngredient	XPharmaProductReferenceActiveIngredientRestController	/product/xpharmaproduct/xpharmaproduct-activeingredient/reference	
PackSizeDetail	PackSizeDetailRestController	/pack-size	New detail under PDS -> Package Set
PackageComponent	PackageComponentRestController	/data-admin/ package-component	New Data Administration entity
ComponentType	ComponentTypeRestController	/data-admin/ component-type	New Data Administration entity
RegulatoryEntitlementStatus	RegulatoryEntitlementStatusRestController	/data-admin/ regulatoryentitlement-status	New Data Administration entity
ProvenanceReason	ProvenanceReasonRestController	/data-admin/ provenance-reason	New Data Administration entity

Entity Name	API/Controller	Main endpoint	Description
ProductInformationDocumentType	ProductInformationDocumentTypeRestController	/data-admin/productinformationdocument-type	New Data Administration entity
ProductCrossReferenceType	ProductCrossReferenceTypeRestController	/data-admin/productcross-reference-type	New Data Administration entity
ProductCategory	ProductCategoryRestController	/data-admin/productcategory	New Data Administration entity
PediatricIndicator	PediatricIndicatorRestController	/data-admin/ pediatric-indicator	New Data Administration entity
MedicinalProductNamePartType	MedicinalProductNamePartType	/data-admin/ medicinal-product-name-part-type	New Data Administration entity

	ePartTypeRestController		
MedicalDeviceUDI	MedicalDeviceUDIRestController	/data-admin/medicaldevice-udi	New Data Administration entity
MasterFileType	MasterFileTypeRestController	/data-admin/masterfile-type	New Data Administration entity
MarketingStatus	MarketingStatusRestController	/data-admin/ marketing-status	New Data Administration entity
DeviceTypeofCombination	DeviceTypeofCombinationRestController	/data-admin/devicetype-of-combination	New Data Administration entity
AttachedDocumentContentType	AttachedDocumentContentTypeRestController	/data-admin/ attached-documentcontent-type	New Data Administration entity
ApplicationSubmissionType	ApplicationSubmissionTypeRestController	/applicationsubmission-type	New Data Administration entity

Comparison Table API Changes between Ennov InSight 7.1 and Ennov InSight 7.0

This table describes the API changes between Ennov InSight 7.1 and Ennov InSight 7.0.

Entity Name	API/Controller	Endpoint	API 7.3 Updates		Description
			Attribute	Column	
License	PackageSetTypeRegistrationRestController	/license/ packageseregistration"	The following field is added: atcFlag	- column ATC_FLAG - size 1 - values "T", "F", "X"	<pre><attr name="T">title .license.atcFlag.applied</attr> <attr name="F">title .license.atcFlag.notApplied</attr> <attr name="X">title .license.atcFlag.notApplicable</attr></pre>

Entity Name	API/Controller	Endpoint	API 7.3 Updates		Description
			Attribute	Column	
ProductLicense	ProductTypeRegistrationRestController	"/license/ product-registration"	The following field is added: – atcFlag	– column ATC_FLAG – size 1 – values "T", "F", "X"	<pre><attr name="T">title .license.atcFlag.applied</attr> <attr name="F">title .license.atcFlag.no-tA pplied< /attr> <attr name="X">title .license.atcFlag.no-tA plicable</attr></pre>

Entity Name	API/Controller	Endpoint	API 7.3 Updates		Description
			Attribute	Column	
LicensePackageSet	LicensePackageSetController	"/license/ package-set"	The EU Presentation Number is renamed to Package Set License Code.	euPresentationNumber/ EU_PRESENTATION_NUMBER size 100 changed to packageSetLicenseCode/ LICENSE_CODE size 100 licenseCode/ PACKSET_LICENSE_CODE mapping changed to licenseCode/	

				REGISTRATION_	
				CODE	
			The following fields are added: – legalBasisId – authorisation StatusId – authorisation StatusDate	– LEGAL_BASIS_ TYPE_ID This field is foreign key to: Class name: LegalBasisType DB table: ism.legal_basis_type. – AUTHORISATION_STATUS_TYPE_ID This field is foreign key to: Class name: RegistrationStatus DB table: ism.lic_status_type. – AUTHORISATION_STATUS_DATE	

Entity Name	API/Controller	Endpoint	API 7.3 Updates		Description
			Attribute	Column	
LicensePackageSetCountry	LicensePackageSetCountryRestController	"/license/ package-set/ country"	The following fields are added: – dataCarrierType – dataCarrierId entifier	– DATA_CARRIER_TYPE_ID This field is foreign key to:	– Class name: LicensePackageSetCountry

				– dataCarrierLanguageId – riskOfSupplyShortageFlag – riskOfSupplyShortageComment – marketingStatusReasonType	Class name: DataCarrierType; DB table: ism.data_carrier_type. – DATA_CARRIER_IDENTIFIER size 100 – DATA_CARRIER_LANGUAGE _TYPE_ID This field is foreign key to: Class name: Language; DB table: ism.language_type. – RISK_OF_SUPPLY_SHORTAGE_FLAG Y/N – RISK_OF_SUPPLY_SHORTAGE_COMMENT size 4000 – MARKETING_STATUS_REASON N_TYPE_ID This field is foreign key to: Class name: MarketingStatusReason; DB table: ISM.MARKETING_STATUS_REASON	– DB table: ISM.LIC_PRODDET_COUNTRY – DB view: ISM.DV_LIC_PROD_DET_COUNTRY

				EASON_TYPE	

Entity Name	API/Controller	Endpoint	API 7.3 Updates		Description
			Attribute	Column	
ManufacturingFunctionGlobalDetail	ManufacturingFunctionGlobalDetailRestController	"/data-admin/ manufacturingfunction-globaldetail"	The following field is added: — confidentialityIndicator	DATA_CLASSIFICATION_TYPE_ID This field is foreign key to: Class name: DataClassificationType; DB table: ism.data_classification_type.	
ActiveIngredientDetail	ActiveIngredientDetailRestController	"/detail/ai"	Removed fields: — measureTypeId — lowNumeratorValue — lowNumeratorPrefixId — lowNumeratorUnitId — lowDenominatorValue — lowDenominatorPrefixId — lowDenominatorUnitId — highNumeratorValue — highNumeratorPrefixId — highNumeratorUnitId — highDenominatorValue — highDenominatorPrefixId — highDenominatorUnitId — measurementPoint		Those fields are taken from Active Ingredient under component.

Entity Name	API/Controller	Endpoint	API 7.3 Updates	Description

			Attribute	Column	
MedicalDeviceDetail	MedicalDeviceDetailRestController	"/detail/ medical-device"	The following fields are added: – deviceCombinationTypeid – deviceTypeid – deviceIdentifier – deviceTradeName	– DEVICE_COMBINATION_TYPE_ID This field is foreign key to: Class name: DeviceCombinationType DB table: MGR.DEVICE_COMBINATION_TYPE. – DEVICE_TYPE_ID This field is foreign key to: Class name: DeviceType; DB table: MGR.DEVICE_TYPE – DEVICE_IDENTIFIER String field. – DEVICE_TRADE_NAME String field.	– Class name: MedicalDeviceDetail – DB table: MGR.PDS_MED_DEVICE_CHANCE – DB view: ISM.DV_PDS_MED_DEVICE

Entity Name	API/Controller	Endpoint	API 7.3 Updates		Description
			Attribute	Column	

SubstanceDetailR etail	SubstanceDetailR estController	"/detail/ sub- stance"	The following fields are added: – presentation MeasureType - Id – presentationLowNumerator Value – presentationLowNumerator Unit-OfMeasur ement – presentationLowNumerator Unit-OfPresen tation – presentation HighNumerator or-Value – presentation HighNumerator or-Value – presentation HighNumerator or-UnitOfPres entation – concentration LowNumerator orVal-ue – concentra- tion LowNumerator orUnitOfMeas ure-ment – concentration LowDenomin ator-Value	– MEASURE_TYP E_ID column of MGR.CONCEN TRATION_VAL UE table DB table: ism.legal_basi s_- type. – PRESENTATIO N_- LOW_AMT_ NUMER_VALU E column of MGR.CONCEN TRATION_VAL UE table String field. – PRESENTATIO N_- LOW_AMT_ NUMER_UNIT _- TYPE_ID column of MGR.CONCEN TRATION_VAL UE table – PRESENTATIO N_- LOW_AMT_ NUMER_UOP_ TYPE_ID column of	– Class name:Su bstanceD etail – DB table:MG R.PDS_S UBSTANC E_CHANG E – DB view:ISM. DV_PDS_ SUBSTAN CE

			– concentration LowDenomin atorUnitOfMe asurement – concentration HighNumerator or- Value – concentration	MGR.CONCEN TRATION_VAL UE table. – PRESENTATIO N_ HI_AMT_N UMER_ VALUE column of MGR.CONCEN TRATION_VAL UE table String field. – PRESENTATIO N_ HI_AMT_N UMER_ VALUE column of	
©Ennov 2024 Ennov		3	HighNumerator ⁴¹ orUnitOfMeas urement – concentration	MGR.CONCENEnnov InSight A TRATION_ VALEnnov InSight A UE table	dministration 7.3 PI Docu- mentation

String field.

HighDenomin

Ennov InSight 7.0 API Changes

This table describes the API changes related to Product Family decoupling between Ennov InSight 7.0 and InSight 6.2.

Ennov InSight 7.0 includes the following API changes:

- Application has moved to the top entity in its own hierarchy.
- Application has a one-to-many relationship with the Product Family via the selectedProducts field.
- FamilyId field is removed.
- The uniqueness criteria for the Application has changed (Uniqueness for the API is used in "/create-or-update" controller operations).

Entity Name	API/Controller	API 6.2	API 7.0 Updates	Description
Application	ApplicationRestController CTAApplicationRestController INDApplicationRestController /application / application/cta / application/ind	– Family Id required – selectedProducts field - is not required – Application uniqueness rule (appCode and familyId) or uuid"	– Family Id is removed – selectedProducts field - required – Application uniqueness rule changed (appCode and appName) or uuid"	If application is not found it executes an uniqueness expression. Unique expression is used in " / create-orupdate" api.
ApplicationCountry	ApplicationCountryRestController / application-country	– Family Id is required – Old behavior -	– Family Id is removed – New behavior -	The behavior of how applicationId is
Event	EventRestController / event	Example: <pre>{ "queryFor": { "applicationId":</pre>	Example: <pre>{ "queryFor": { "applicationId":</pre>	retrieved for use in queryFor has changed.
EventCountry	EventCountryRestController /event-country	APPLICATION_NAME }, ... }	APPLICATION_CODE + " " +	
EventCountrySchedule	EventCountryScheduleRestController / event-countryschedule		APPLICATION_NAME }, ... }	

Entity Name	API/Controller	API 6.2	API 7.0 Updates	Description
AppEventProduct	AppEventProductRestController /event/ product	Old behavior Example: <pre>{ "queryFor": { "applicationId": APPLICATION_NAME }, ... }</pre>	New behavior Example: <pre>{ "queryFor": { "applicationId": APPLICATION_CODE }, ... }</pre>	The behavior of how applicationId is retrieved for use in queryFor has changed.

			APPLICATION_NAME }, ... }	
FullProductPresentation	LicenseFppController /license/full-productpresentation	– Family Id is required – Old behavior Example: { "queryFor": { "applicationId": APPLICATION_NAME }, ... }	– Family Id is removed – New behavior Example: { "queryFor": { "applicationId": APPLICATION_CODE + " " + APPLICATION_NAME }, ... }	
License	This entity is inherited by ProductLicense Doesn't have direct controller	– Family Id is required – registeredAtc is required – Old behavior Example: { "queryFor": { "applicationId": APPLICATION_NAME }, ... } – Old uniqueness rule - "Code and AuthorityId and FamilyID and ApplicationId"	– Family Id is removed – registeredAtc is not required – New behavior Example: { "queryFor": { "applicationId": APPLICATION_CODE + " " + APPLICATION_NAME }, ... } – New uniqueness rule - "Code and AuthorityId and ApplicationId"	
MaAttachment	MaAttachmentRestController	– Family Id required	– Family Id is removed	

	ntroller /full-productpre- sentation/ attachment	– Old behavior Exam- ple: { "queryFor": { "applicationId": APPLICATION_N AME }, ... }	– New behavior Exam- ple: { "queryFor": { "applicationId": APPLICATION_C ODE + " " + APPLICATION_N	
©Ennov 2024 Ennov		– Old uniqueness rule - "name and343 fp- pId and familyId and	AME }, ... }Ennov InSig – New uniquenessEn- nov InSigh rule -	ht Administra- tion 7.3 t API Documentation

applicationId and

Entity Name	API/Controller	API 6.2	API 7.0 Updates	Description
ProductLicense	"/license/productregistration"	Old behavior Exam- ple: { "queryFor": { "applicationId": APPLICATION_NAM E }, ... }	Please check License as it inherits all changes.	N/A
LicensePackag eSet	/license/packageset	Old behavior Exam- ple: { "queryFor": { "applicationId": APPLICATION_NAM E }, ... }	New behavior Exam- ple: { "queryFor": { "applicationId": APPLICATION_COD E + " " + APPLICATION_NAM E }, ... }	The behavior of how applicationId is retrieved for use in queryFor has changed.

LicensePackageSetCountry	/license/packageset/ country	– Family Id required – registeredAtc is required – Old behavior Example: { "queryFor": { "applicationId": APPLICATION_NAME }, ... }	– Family Id is removed – registeredAtc is not required – New behavior Example: { "queryFor": { "applicationId": APPLICATION_CODE + " " + APPLICATION_NAME }, ... }	
Subset (PDS)	PDSRestController /pds	Old behavior Example: { "queryFor": { "applicationId": APPLICATION_NAME }, ... }	New behavior Example: { "queryFor": { "applicationId": APPLICATION_CODE + " " + APPLICATION_NAME }, ... }	
Schedule (seq status schedule)	Schedule /sequenceschedule	Family Id is required	Family Id is removed	N/A

Entity Name	API/Controller	API 6.2	API 7.0 Updates	Description
PDS Details	/detail/* CountryDetailRestController ActiveIngredientDetail	Old behavior Example: { "queryFor": { "applicationId": APPLICATION_NAME	New behavior Example: { "queryFor": { "applicationId": APPLICATION_CODE	The behavior of how applicationId is retrieved for use

RestController	E }, ... }	E + " " +	in queryFor has
CharacteristicsDetailR estController		APPLICATION_NAM	changed.
CTADetailRestControll er		E }, ... }	
DoseScheduleDetailR est- Controller			
FluStrainDetailRestCo ntroller			
FunctionDetailRestCo ntroller			
IndicationDetailRestC on- troller			
LabeledIndicationDet ail- RestController Labeling- DetailRestCo ntroller			
ManufacturerDetailRe st- Controller			
ManufacturingProcess			
DetailRestController Ma- terialDetailRestCon troller			
MedicalDeviceDetailR est- Controller			
PackageSetDetailRest			
Controller			
PackagingDetailRestC on- troller			
RouteOfAdministratio nDetailRestController			
ShelfLifeDetailRestCo ntroller			
SpeciesDetailRestCon troller			

	StepDetailRestController			
	SubstanceDetailRestController			
	WithdrawalTimeDetail			
	RestController			

Ennov InSight 7.0 API End Points Entities Removed

This table describes the API End Points entities deleted from the Ennov InSight 7.0.

Entity Name	Controller Name	Controller URL
Component Source Type	Component Source Type Rest Controller	/data-admin/component-source-type/
Contact Address Type	Contact Address Type Rest Controller	/data-admin/contact-address-type
Contact Role	Contact Role Rest Controller	/data-admin/contact-role
Contact Type	Contact Type Rest Controller	/data-admin/contact-type/
Discipline Res	Discipline Rest Controller	/data-admin/discipline/
Dossier Metadata Type	Dossier Metadata Type Rest Controller	/data-admin/dossier-metadata-type
PSI Attachment	PSI Attachment Rest Controller	/data-admin/p-s-i-attachment/
Recipient For Type	Recipient For Type Rest Controller	/data-admin/recipient-for-type/
RI Product Type	RI Product Type Rest Controller	/data-admin/ri-product-type/
Substance Attachment	Substance Attachment Rest Controller	/data-admin/substanceattachment

Chapter 6. Administrative Activities

Administrators have security privileges to actions that control the set up and completion of applications and assemblies.

Only an administrator can perform the following activities:

- Creating product family types
- Creating product families
- Deleting entities
- Locking and unlocking assemblies and folders
- Locking volume ranges
- Setting assembly baselines

As an administrator, you may also be responsible for maintaining eCTD assembly templates and their respective XML definition files (DTDs and schemas).

Note: *Read-only attribute values that are provided by Ennov InSight automatically are not described in the online help.*

Product Family Types and Component Types

You can create product family type names or product component names and map them to existing entity types that are defined in XML.

Ennov InSight ships with the following entity type XMLs:

- Pharmaceutical
- Medical devices
- A pharmaceutical-medical devices combination
- Veterinary
- Flu Vaccine

These entity XMLs determine which attributes are presented on the screen when creating product families and product components. There is no limit to the number of types you can create.

Note: *Active ingredients for products are initially defined at the product family level. To track active ingredients, the product family must be associated with the pharmaceutical, pharmaceutical-medical devices combination, or veterinary entity type. You cannot define active ingredients for products belonging to a medical device-only product family.*

Contact Consulting for information about defining and configuring entity types for your system.

Ennov InSight Administration 7.3

Product Family Types and Component Types

Create a Product Family Type or Component Type

You can create product family type names or product component names and map them to existing entity types that are defined in XML.

To create a product family type or component type:

1. From the *Data Administration* page, under Other , click Entity XML/UI Mappings.
2. Click  to open the *Entity XML/UI Mappings data entry* page.
3. In the Entity XML Type Name field, enter a name for the product family type or product component type.
4. In the *Associated Entity* field, select either Product Family or Product Component.
5. In the *Entity XML Type XML Mapping* field, select the XML file to which this type should be mapped.
6. In the *Default Flag* field, select Yes or No to indicate if this is the default type for the product families or components you create in Ennov InSight .

You can choose only one product family type or product component type as the default.

7. In the Description field, enter a description for the product family type or product component type.
8. Save.

Modify a Product Family Type or Component Type

You can modify a product family type or component type that is mapped to an XML entity.

To modify a product family type or component type:

1. From the *Data Administration* page, under Other, click Entity XML/UI Mappings.
2. Click the link for the product family type or product component type you want to modify. The *Entity XML/UI Mappings data entry* page appears.
3. Make the necessary updates.
4. Do one of the following:
 - To deactivate a type, click Deactivate. Deactivating a type make it no longer available for selection. — To reactivate a deactivated type, click Activate.
5. Save.

Create a Product Family

You can create product families to track your applications.

Product families appear on the Product Families tab only when you have the appropriate viewing security privileges.

Note: Only an administrator can create a product family. Product families are created in Liquent Data Administration.

To create a product family:

1. On the home page, choose Go To > Data Administration.

Ennov InSight Administration 7.3 Create a Product Family

2. Under Product Family Maintenance, click Product Family Values.
3. On the *Product Family Values* page, click .
4. Click the Product Family Type drop-down arrow and choose the product family type.

The values available in the Product Family Type list are those you have created in Data Administration > Other > Entity XML/UI Mappings.

5. In the Family Code box, enter a code for the product family.
6. In the Family Name box, enter a name for the product family.
7. Choose the Product Family Status.
8. For Product Family Status Date, enter the date when the product family status is effective.
9. Choose the Development Sponsor.

The values available in the drop-down list are those you have created in Data Administration and identified as development sponsors.

10. Save.
11. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature and SSO are enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.
When electronic signature is enabled and SSO is disabled	1. Select a reason and enter comments for the reason. 2. Enter user ID and password and click Save.

Delete Entities

Administrative privileges are required to delete some entities. In some instances, users with the appropriate permissions can also delete entities. The following table defines deletion guidelines.

Entity	Guidelines

Application	An administrator can delete an application regardless of whether other entities (events, sequences, registrations, tasks, references or notifications) are associated with it. If any of these entities are associated with an application, they are also deleted. A user can delete only an application that has no entities associated with it.
Event	Only an administrator can delete an event that has no associated entities (product detail sets, sequences, tasks, references or notifications). If an event is associated with a PDS or a sequence, or tasks, references, or notifications are associated with the event, you must first delete those entities. Then you can delete the event.

Delete Entities

Entity	Guidelines
Notification	An administrator can delete a global notification and any notification created by a user. A user may delete only notifications he or she created.
Product	Only an administrator can delete a product that has no entities associated with it (PDSs, tasks, references or notifications). If a product is associated with a PDS, or tasks, references or notifications are associated with the product, you must first delete those entities. Then you can delete the product.
Product family	An administrator can delete a product family regardless of whether other entities (products, applications, tasks, references or notifications) are associated with it. If any of these entities are associated with a product family, they are also deleted. A user can delete a product family only if it has no entities associated with it.
Projected status date	Only an administrator can delete a projected status date for an event, sequence or task.
Reference	An administrator can delete a reference created by any user. A user may delete only references he or she created.
Registration	An administrator or a user can delete a registration that has no entities associated with it (tasks, references, notifications). If a registration has tasks, references or notifications associated with it, you must first delete those entities. Then you can delete the registration.
Sequence	An administrator or a user can delete a sequence that has no entities (assemblies, tasks, references or notifications) associated with it. If a sequence is associated with an assembly, or tasks, references, or notifications are associated with the sequence, you must first delete those entities. Then you can delete the sequence.
Tasks and sub-tasks	Only an administrator can delete a task or sub-task created by any user. A user may delete only tasks or sub-tasks he or she created.

Delete an Entity

Administrators with the appropriate privileges can delete entities, if needed. To delete an entity:

1. Click a link for the entity.
2. On the *entity attributes* page, click .
3. When you are prompted to confirm the deletion, click OK.

Unlock Assemblies and Folders

Users cannot change the content of a locked assembly or folder. Administrators or the owner of the assembly can unlock it and enable users to change the assembly structure.

You can only unlock assemblies, templates, lifecycle assemblies, and folders from the working or publishing views. You cannot unlock an assembly from the sequence view.

An unlock can occur at two levels:

— At the root level, the you can unlock the entity and unlock all locked folders in the entity. — At the folder level, you must select the child folders to unlock.

Unlock an Assembly

Perform the following steps if you want to modify an assembly.

Administrators or the owner of an assembly can unlock an assembly and enable users to modify the assembly. To unlock a locked assembly:

1. Click a link for the locked assembly.
The *Assembly Attributes* page opens.
2. Click .
3. Click OK when you are prompted to confirm the unlock.

Lock Sequence Assemblies

When you are ready to add a sequence assembly to lifecycle, you must lock it to prevent additional changes. Then you can add the sequence to lifecycle. This creates the lifecycle and makes the sequence assembly you used to create it the first finalized lifecycle assembly.

Once an assembly is locked, only an administrator can make changes and synchronize the assembly with the DMS. It is recommended, however, that you lock the binding of all documents used in the assembly, thus preventing binding changes should the assembly be unlocked and synchronized.

You can manually lock an assembly or you can use the *Change Submittal Status* wizard to mark the assembly as submitted. This locks the assembly automatically. The *Change Submittal Status* wizard enables you to update a submission status after a sequence assembly has been received by the regulatory agency. When you change the

status, the submission is finalized and you can use it in subsequent submission lifecycle updates by adding it to the submitted view. In addition, the statuses of related entities (application, event, sequence, assembly) and key status attributes such as first submittal date are updated automatically.

Note: Only an administrator can unlock a locked assembly.

Manually Lock an Assembly

You can manually lock a sequence assembly to add it to a life cycle.

To manually lock a sequence assembly:

1. Click a link for the sequence whose assembly you want to lock.
2. Click the Assembly tab to open the *Assembly Attributes* page.
3. Optionally, review the assembly tree and any of its attributes.
4. Click the assembly root.
5. Click  on the action button toolbar.

A message prompts you to select the lock type.

6.

Select

Standard

to lock the entire assembly.

Example



7.

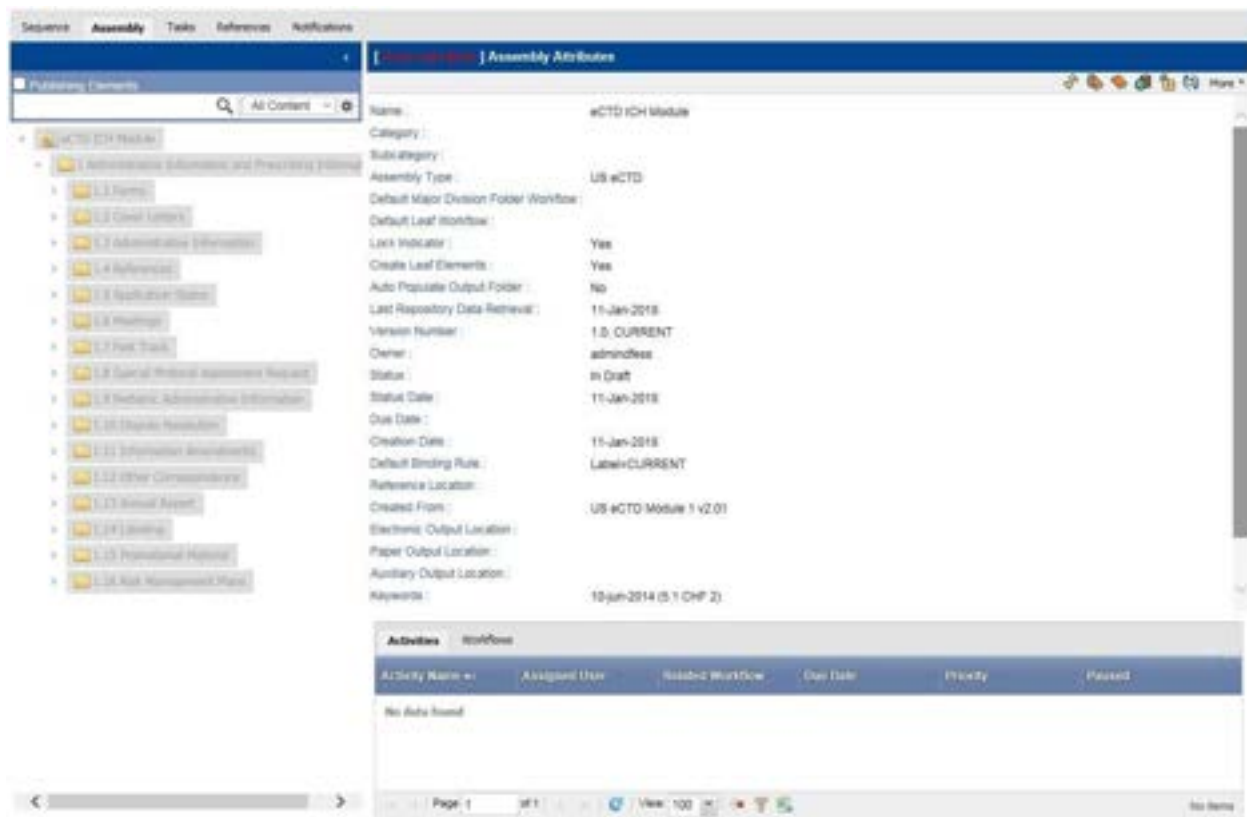
Click

OK

- Read-Only Mode appears before *Assembly Attributes*.
- Lock Indicator is set to Yes.
- A lock appears on the root in the assembly tree.
- When you expand the assembly tree, the elements are grayed out to show they cannot be changed.

Note: Although the sequence assembly is locked, you can still change attributes for the assembly root.

8. You can now add the locked sequence assembly to life cycle.



Unlock a Folder

You can unlock folders in an assembly tree from the working or publishing views, and enable users to modify the folders.

To unlock a locked folder:

1. Click a link for the assembly that has the locked folder.
2. Right-click the root and choose Expand All.
3. Click the locked folder you want to unlock.

5. Click OK when you are prompted to confirm the unlock.

4.

Click



Note: When you unlock a parent folder, the first child of the last child folder of the parent folder is unlocked.

Lock a Folder

You can lock the folder to prevent any changes from being made to its content.

To lock a folder:

1. On the assembly tree, choose the folder you want to lock.
2. On the action toolbar, click .

A message prompts you to confirm the lock.

3. Click OK.

Modify Submitted Views for Imported eCTDs

After importing an eCTD into Ennov InSight, an administrator can unlock the submitted view for a lifecycle application to perform basic structural changes.

Such changes may be necessary due to the sorting performed by Ennov InSight's eCTD importer. Also, you may want to re-order leaf elements in a given section to make subsequent working assemblies easier to manage. The changes you make will persist in subsequent working assemblies.

For modifying lifecycle applications, the conditions describe below exist.

Limited Access

- Only lifecycle administrators (individuals with administrator access to sequence assemblies and with lifecycle views rights) may unlock the submitted view.
- To unlock the submitted view, there cannot be any planned working sequence assemblies in the current application.
- The administrator must re-lock the submitted view when modifications are complete.
- When the submitted view is unlocked, a user (non-administrator) cannot create a working assembly or add to lifecycle.

- When the submitted view is locked, a user (non-administrator) receives a warning when attempting to create a working assembly or add to lifecycle.

Limited Capabilities

The functions described below are available in an unlocked submitted view (the locked submitted view continues to follow existing requirements and available functions, with the addition of a Lock/Unlock option on the root element of the assembly)

Root

- Refresh
- Expand
- View document list
- Export (More menu)
- Copy URL (More menu)
- Lock (More menu)

Folder

- Refresh
 - Expand
 - Add folder
 - Move up
 - Move down
 - Promote
 - Demote
 - Delete (More menu, only empty folders may be deleted in an unlocked submitted view)
 - Edit (More menu)
 - Change type (More menu)
 - Drag-and-drop is allowed
- #### Leaf Elements
- Refresh
 - Expand

- View lifecycle history
- Promote
- Demote
- Move up
- Move down
- Edit (More menu; also available for reference leafs)
- Change type (More menu)
- View file (More menu)
- Drag-and-drop is allowed

Reference Leaf elements can be edited in the Unlocked Submitted View of a Sequence Assembly:

- To modify a Reference Leaf element in the unlocked submitted assembly plan view, in Security Administration you must have Entity Security > Submission Plans set to at least WRITE and Entity Security > Sequence Assemblies set to ADMIN.
- To modify a Reference Leaf element in the unlocked submitted assembly view, in Security Administration you must have Application Country Rights set to at least WRITE and Entity Security > Sequence Assemblies set to ADMIN.

Other Elements with which Documents and Placeholders Can Be Associated

- No other right-click or More menu functions are available.
- No publishing elements may be viewed in the submitted view.
- Drag-and-drop functionality is disabled.

Additional Information

For administrators, multi-select drag-and-drop is permitted on leaf elements. However, as a user (non-administrator):

- You can only create and delete folders. Leaf elements and documents may not be created or deleted.
- You cannot assign documents. Drag-and-drop functionality is disabled and auto leaf creation is not permitted.
- You can only use drag-and-drop to re-order existing elements in an assembly.

Set Assembly Baselines

You can set a baseline for an assembly and begin to track changes made by user groups.

Once an assembly is in a semi-completed state, multiple groups of users can begin to track changes to the assembly structure and content by comparing it to a baseline. It also enables an assembly group and publishing group to synchronize changes to the assembly with an external publishing application.

When you set the baseline, you are taking a picture of the assembly as it exists at that point in time and using it as the basis for tracking changes. All changes made to the assembly from that point onward can be compared to the baseline. When the current assembly outline becomes the new baseline, the existing baseline for that version is erased.

Set the Baseline for an Assembly

You can set a baseline for an assembly and begin to track changes made by user groups. To

set the baseline for an assembly:

1. Click a link for the assembly.
2. Click the root and choose Save Baseline.
3. Click OK when you are prompted to confirm the action.

Manage eCTD and eCTD 4.0 Templates

You can use the eCTD and eCTD 4.0 templates provided with Ennov InSight to streamline the process of creating eCTD and eCTD 4.0 assemblies.

Separate templates are provided for each region's module 1. In addition, a common template for modules 2-5 is also provided. These templates are current with the latest ICH eCTD and eCTD 4.0 specification.

All the templates include elements and settings for both electronic and paper submissions. The folder types in the templates have been preconfigured to provide the metadata for the specific headings in the eCTD that require additional information: drug substance, drug product, excipients, clinical indication and regional administrative information. For example, the US, Canada and Japan regional module 1 templates include the entire administrative information and prescribing information folder/leaf /document structure required by regulatory authorities in those countries. A user can simply create an assembly from a template, remove the unnecessary folders/leafs and provide specific documents for the submission.

If a reference leaf in M1 is used to point outside of Module 1 to another module in the same sequence, the href-xlink path must be modified using Ennov InSight Validator in the published output. `..\..\` must be added to the beginning of this path in the reference leaf, and the checksums must be recalculated.

In addition, you can modify the templates to contain default values for DMS attributes. If you have a well-organized Documentum Docbase with eCTD and eCTD 4.0 information included in document attributes, you can map these attributes at the publication level in the template. These attributes will be inherited in the assembly elements.

After a user creates an assembly from a template, he or she can easily modify specific folder and leaf attributes that are different from the default values. For attributes that are based on the ICH eCTD and ICH eCTD 4.0 specification and for which default values are not configured in a template, users can choose values from preconfigured lists you set up in Data Administration.

Leaf elements are included in the templates at the lowest level, as defined by the ICH granularity document. While the DTDs allow for inclusion of leafs at higher levels in the assembly, the granularity document recommends where in the assembly to include documents. The templates conform with the granularity document. However, users are free to include leafs at higher levels in the assembly as required by your review division.

Maintain XML Definition Files

Manage all XML definition files (DTDs and schemas) in one central location in the repository to process XML instance documents stored.

Ennov provides you with specification updates as they are released and an analysis of how the changes impact your organization.

This information can include any of the following:

- Whether compliance to the new specification requires simply pointing to the latest XML definition file – Structural changes to assemblies based on the template
- Additional software changes

New XML definition files are provided when they are available. You can import these files into the repository and add them to the list of available definition files using the Assembly DTD/Schema Types function in Data Administration. You can then update assembly templates to use the latest XML definition files. The updated definition files are available for users who create assemblies using the updated templates.

The assembly templates provided do not point to their corresponding XML definition files.

Note: *The XML definition files path can be changed in configuration. For any updates, please contact Ennov support.*

Configure eCTD Templates

You can configure the eCTD templates provided with Ennov InSight for your product family and applications.

To configure eCTD templates for use, do the following for each template:

1. Choose a standard repository location for all eCTD, TOC, overlay, and cover page templates.
2. Choose a temporary repository location for publishing files.
3. Open the publishing settings for every template and do the following:
 - a. Specify the temporary publishing location.
 - b. Specify the template locations for all TOC types, cover pages, and all overlays (TOC, document, cover page) .
 - c. Click Apply on each settings page after confirming that all the default settings are completed.

Note: If you click away from the publishing settings without applying the settings you choose, the values you enter are not saved.

Module 2-5 Template - Recommended Configurations

It is best practice to configure the templates for Modules 2-5 to prevent errors.

Add relevant XML definition files in the publishing settings for the template. If your organization always creates STFs (Study Tagging Files) regardless of region, include the ICH (ich3-2) and the STF (stf2-2) files. If you create STFs for US submissions only, you can add the STF files to the full Module 2-5 template later.

Set default leaf and study report DMS mappings and values in the publication settings for the template. Setting study report values in the Module 2-5 template while also using the STF XML definition file triggers the creation of STFs during publishing. If you create STFs only for US submissions, setting default values in the Module 2-5 template does not create STFs automatically for other regions as long you do not specify the STF XML definition file for those regions.

Set the assembly output location with the appropriate DMS location and cabinet in the template. When a user creates an assembly using the template, the user does not have to navigate through the entire repository to get to the specific product.

For product-specific information that maps to DMS attributes, set default values in the template. These include the following:

- 2.3.S Drug Substance (substance and manufacturer)
- 2.3.P Drug Product (product name, manufacturer, dosage form)
- 2.7.3 Summary of Clinical Efficacy (indication)
- 3.2.S Drug Substance (substance and manufacturer)
- 3.2.P Drug Product (product name, manufacturer, dosage form) – 3.2.P.4 Excipients (excipient name)
- 3.2.A.1 Facilities and Equipment (manufacturer, substance, dosage form, and product name)
- 3.2.A.2 Adventitious Agents (manufacturer, substance, dosage form, and product name)
- 5.3.5 Reports of Efficacy and Safety Studies (indication)

For detailed information about creating and modifying templates, see the topics *Assembly templates* and *Assemblies*.

eCTD Templates

Ennov InSight includes ICH-compliant eCTD and eCTD 4.0 templates with preconfigured folder types to capture the metadata for the specific headings in the eCTD that require additional information: drug substance, drug product, excipient, clinical indication, and regional administrative information.

Ennov InSight also includes a number of other assembly templates to enable the creation of reports or other electronic submission types.

These templates are current with the latest specifications and include the following:

- 510k Template (Sep 2019).xml
- 510k Template.xml
- ASEAN ACTD-NeeS.xml
- AU eCTD Module 1 v0.90.xml
- AU eCTD Module 1 v3.0.xml
- AU eCTD Module 1 v3.1.xml
- AU eCTD Module 1 v3.2.xml
- AU Module 1 CTD v2.1.xml
- AU Module 1 CTD-NeeS v2.0 2011.xml
- AU Module 1 NeeS v2.0.xml
- BA eCTD Module 1 v3.1.xml
- Canadian eCTD Module 1 v1.0.xml
- Canadian eCTD Module 1 v2.2.xml
- Canadian electronic CTA CTA-A 29-May-2013.xml – Canadian electronic CTA.xml
- CH eCTD Module 1 v1.0.1.xml
- CH eCTD Module 1 v1.1.xml
- CH eCTD Module 1 v1.2.xml
- CH eCTD Module 1 v1.3.xml
- CH eCTD Module 1 v1.4.xml
- eCTD ICH Module 2-5 v3.2.xml
- CN eCTD Module 1 v1.0.xml
- CN Nonclinical Study Report (SEND Dataset).xml
- CN Nonclinical Study Report.xml
- CN Clinical Study Report (VV5-0).xml
- CN eCTD ICH Module 2-5 v3.2.xml

- EAEU Template v1.0.xml
- EU CTA.xml
- EU eCTD Module 1 v1.0 - CP.xml
- EU eCTD Module 1 v1.0 - MRP-DCP.xml
- EU eCTD Module 1 v1.0 - NP.xml
- EU eCTD Module 1 v1.1 - CP.xml
- EU eCTD Module 1 v1.1 - MRP-DCP.xml
- EU eCTD Module 1 v1.1 - NP.xml
- EU eCTD Module 1 v1.2.1 - CP.xml
- EU eCTD Module 1 v1.2.1 - MRP-DCP.xml
- EU eCTD Module 1 v1.2.1 - NP.xml
- EU eCTD Module 1 v1.3 - CP.xml
- EU eCTD Module 1 v1.3 - MRP-DCP.xml
- EU eCTD Module 1 v1.3 - NP.xml
- EU eCTD Module 1 v1.4 - CP.xml
- EU eCTD Module 1 v1.4 - MRP-DCP.xml
- EU eCTD Module 1 v1.4 - NP.xml
- EU eCTD Module 1 v2.0 - CP.xml
- EU eCTD Module 1 v2.0 - MRP-DCP.xml
- EU eCTD Module 1 v2.0 - NP.xml
- EU eCTD Module 1 v3.0 - CP.xml
- EU eCTD Module 1 v3.0 - MRP-DCP.xml
- EU eCTD Module 1 v3.0 - NP.xml
- EU eCTD Module 1 v3.0.1 - CP.xml
- EU eCTD Module 1 v3.0.1 - MRP-DCP.xml
- EU eCTD Module 1 v3.0.1 - NP.xml

- EU eCTD Module 1 v3.0.3 - CP.xml
- EU eCTD Module 1 v3.0.3 - MRP-DCP.xml
- EU eCTD Module 1 v3.0.3 - NP.xml
- EU eCTD Module 1 v3.1 - CP.xml.
- EU eCTD Module 1 v3.1 - NP.xml.
- EU eCTD Module 1 v3.1 - MRP-DCP.xml.
- EU IMPD template.xml
- EU PMF Submission in eCTD.xml
- EU VNees - Immunological.xml
- EU VNees - Pharmaceutical.xml
- EU VNeeS v2.2 - Immunological.xml
- EU VNeeS v2.2 - MRL Maximum Residue Limits.xml
- EU VNeeS v2.2 - Pharmaceutical.xml
- EU VNeeS v2.3 - Immunological.xml
- EU VNeeS v2.3 - MRL Maximum Residue Limits.xml
- EU VNeeS v2.3 - Pharmaceutical.xml
- GCC eCTD Module 1 v1.2 - GCC.xml
- GCC eCTD Module 1 v1.2 - NP.xml
- GCC eCTD Module 1 v1.5 - GCC.xml
- GCC eCTD Module 1 v1.5 - NP.xml
- HR eCTD Module 1 v1.4 - NP.xml
- ICH E3 Clinical Study Report (VV2-2).xml
- ICH E3 Clinical Study Report (VV3-0).xml
- ICH E3 Clinical Study Report (VV5-0).xml
- ICH eCTD 4.0 Module 2-5 v1.5.xml
- JP eCTD Module 1 v1.0.xml
- JP eCTD Module 2-5 v3.2.xml
- JAP eCTD 4.0 Module 1 v1.5.xml
- JO eCTD Module 1 v1.0.xml

- MD - IMDRF (HC) IVD Template.xml
- MD - IMDRF nIVD Template.xml
- Nonclinical Study Report (SEND Dataset).xml
- Nonclinical Study Report.xml
- PMA Template (Feb 2019).xml
- PMA Template.xml
- ROW CTD Module 1.xml
- Saudi Arabia CTD Module 1 v1.0.xml
- SG eCTD Module v1.0.xml
- TH eCTD Module 1 v.0.92.xml
- TH eCTD Module 1 v.1.0.xml
- TH eCTD Module 1 v.1.1.xml
- TN eCTD Module 1 v1.1.xml
- UA eCTD Module 1 v1.0.xml
- US eCTD Module 1 v2.01.xml
- US eCTD Module 1 v3.3.xml
- US eCTD 4.0 Module 1 v1.5.1.xml
- WHO eCTD Module 1 v1.0.xml
- ZA eCTD Module 1 v1.0.xml
- ZA eCTD Module 1 v2.1.xml
- ZA eCTD Module 1 v3.1.xml

The following files are included with the templates as samples for the publishing finishing options for overlays, Tables of Contents (TOC), and cover pages. Unicode (UC) templates for TOC, cover pages, and overlays are available (for A4 paper size).

- A4SampleTOCTemplate.docx
- SampleCoverPageTemplate.docx
- SampleOverlayTemplate.docx
- SampleTOCTemplate.docx
- UCSampleCoverPageTemplate.docx
- UCSampleOverlayTemplate.docx

– CNSampleTOCTemplate.docx

– JPSampleTOCTemplate.docx

Import eCTD Applications

When you import an eCTD application you can import an entire eCTD with sequences. The eCTD sequences are imported into an existing application with the required views. The following files are required to import an eCTD:

– The index.xml in a folder named based on the sequence number. – The regional XML in the M1 folder. – All of the necessary DTD files.

Example:

0000

index.xml m1 us-regional.xml

util dtd

<DTD files>

stylesheet

<Stylesheet files>

Content files are not required for eCTD import. If you have only an index.xml file, you can substitute placeholder files (with Leafs removed) for the regional.xml and util folders from another sequence. During the import, if content files are found to be missing, they will not be referenced in the assembly: only leafs will be created. To prevent import of existing content files during an eCTD import, use the Import Leaf Files Only option.

The eCTD importer sets the assembly status for the first sequence in an application to In Draft instead of Approved.

Once you import the eCTD application, you can create new sequences that are based on the existing lifecycles either to continue these lifecycles or for archival purposes. Any imported sequences must be in the correct file/folder format.

Each sequence folder is imported as a separate sequence. All files that are referenced by the eCTD XML leaf elements become assigned files underneath each leaf, pointing to this repository for content. The entire eCTD XML is imported as assembly metadata, including: leaf IDs, modified files, and envelope information.

You can import and add to the same application lifecycle more than once. In this way you can import sequences

0000 and 0001, and then when you have added sequences 0002 through 0005 to the folder you can import again. The subsequent eCTD Import will process only the newly added sequences.

When performing an import of an existing eCTD, the import progress is reported in the server.log file. The Job Request Details also show messages about each sequence that is imported. The administrator can monitor the server log to follow the overall progress of the import and see more detailed messages, such as timestamps and Oracle information.

Although other repositories may be available in the eCTD XML import utility, only secure file systems, OpenText Content Server, and Documentum repositories are currently supported.

Note: To import China assemblies, verify that the following assembly templates exist in the system:

- CN eCTD Module 1 v.1.0.xml
- CN eCTD ICH Module 2.5 v.3.2.xml
- CN Clinical Study Report (VV5-0).xml
- CN Nonclinical Study Report (SEND Dataset).xml
- CN Nonclinical Study Report.xml

To import EAEU assemblies, verify that the following assembly template exists in the system: — EAEU Template v1.0.xml

To import GCC assemblies, verify that the following assembly templates exist in the system:

- GCC eCTD Module 1 v1.5 - GCC.xml
- GCC eCTD Module 1 v1.5 - NP.xml

Requirements for Successful eCTD Imports

To import eCTD assemblies successfully, the following conditions apply.

- In Data Administration > Assembly > Assembly Subcategories Values, do not disable the subcategory values for eCTD submissions.
- When importing US-3-3 eCTDs, the application code in the XML must match the application code in Ennov InSight
- The index, regional, and content files must follow the naming convention filename.extension.

This is not an issue on secure file systems. However, it is critical in a DMS where the file name may not have the extension appended, but rather, is identified as a format type. As an example, a file named index with a format type of xml will not import, but index.xml will import. The same is true for content files. For example, cover-letter.pdf will import but cover-letter with a format type of pdf will not.

For a bulk eCTD import, the Product Family and Application entities must exist in Ennov InSight .

Import an eCTD Application

You can import an existing/new eCTD into an application and give it a new sequence or assembly prefix.

Note: If the import is to an existing Application (i.e. there are existing Sequence Assemblies) then the eCTD Import will not prompt you for the Publishing Settings Library Template to use, but will instead use the Submitted View from the previous existing Sequence as the basis for the APL for the imported Sequences.

When performing an import of an existing eCTD, the import progress is reported in the server.log file. The Job Request Details also show messages about each sequence that is imported. The administrator can monitor the server log to follow the overall progress of the import and see more detailed messages, such as timestamps and Oracle information.

To import an eCTD application:

1. Click a link for the application into which you want to import an eCTD application. The *Application Attributes* page opens.

2. Click to open the *Import eCTD to Application* window. 

Note: If you are importing eCTD submissions, select eCTD as Import Type. For EAEU submissions, select EAEU XML with embedded PDFs in Import Type drop down. See: *Ennov InSight Best Practice: EAEU Submissions* for details.

3. Click Browse, locate and select the eCTD application folder to import, then click OK.

For EAEU XML with embedded PDFs Import type, EAEU XML Location, Output Document type, DMS Versioning Scheme fields will appear. Refer: Import section of *Ennov InSight Best Practice: EAEU Submissions* for details.

4. Select the Publishing Settings Library template.

Note: Publishing Settings Library field is enabled only under the following conditions:

— *New Application:* If the import is to a new Application (No existing Sequence Assemblies) then the eCTD Import will prompt you for the Publishing Settings Library Template to use as the APL for the imported Sequences.

— *If the Publishing Settings Library Template does not contain a Publishing Settings entry, the system displays an error message: The Publishing Settings Library Template must contain an entry for Publishing Settings, please select another Template to use.*

5. In the *Sequence Name Prefix* box, enter a prefix to use for sequences.
6. In the *Assembly Name Prefix* box, enter a prefix to use for the assembly name.

Automatically, each imported leaf element is assigned with the Published leaf status, or any other leaf status that has the Internal System Status set to "PUBLISHED".

Option	Action
To import only XML leafs found in the eCTD XML, without importing references to the content files:	Select Import Leaf Elements Only. This prevents Ennov InSight from creating and assigning content document elements below each leaf during the import. It can also improve import speed significantly, as the content files are not necessary for subsequent sequence publishing. This option captures all lifecycle operations correctly, and it prevents republishing of submissions already published. If extracts and renditions are needed for the imported documents, you can run create renditions and extractions from each assembly.
To include orphan leaf elements in the import:	Select the Import Orphan Leaf Elements option. This informs the Ennov InSight system that some of the eCTD XML could be incorrect in that it might contain references to leaf IDs or files that do not exist in the current view of the application. This can occur, for example, if an identical leaf is replaced twice, or if a deleted leaf is replaced. During a normal import, Ennov InSight fails when it finds these instances. However, if the Import Orphan Leaf Elements checkbox is selected, Ennov InSight ignores orphan leaf instances and creates new leaf elements instead.

7. Click Next.

The *Summary* page indicates the import has been scheduled.

8. Click Finish.

The status of the import is logged to the Job Requests.

Use the *Bulk eCTD Import Wizard* to migrate multiple eCTD submissions to Ennov InSight from another system in a supported document management system (DMS).

The *Bulk eCTD Wizard* is available on the Ennov InSight Wizards menu when you have a license for the Electronic Lifecycle Publishing (ELP) module and the following permissions are set in Security Administration:

- For the ELP module, Security permissions must be WRITE or ADMIN
- In the Home Page Access section, Import eCTD and Bulk Import eCTD options must be set to Yes
- In the Entity Security section, permission for Events must be WRITE or ADMIN to make the Create

Grouping Events option available on the *Bulk eCTD Import* window

The Bulk eCTD Import process matches the Application Code within the XML being imported.

Bulk eCTD Import is not supported for EAEU submissions.

Prepare for Bulk eCTD Import

The Bulk eCTD Import process matches the Application Code within the XML being imported. This process is executed by a job named Preparing for Bulk eCTD Import. This job finds all valid applications in the source folder and parses regional.xml files to find an application number to match with an application code in Ennov InSight .

When you click on the details of the Preparing for Bulk eCTD Import job, you will see messages that show the matching application code found in the system. This is the application where the imported sequences are located.

Bulk Import Prerequisites

The appropriate Application must exist in Ennov InSight prior to performing a bulk eCTD import, you will need to create the applications before performing the bulk import.

If the system encounters a sequence folder without a valid 'util' folder, sequence XML, or valid regional XML file during the bulk import process, the following message appears: "WARNING: The Application

located here: "<path to application>" failed to import: Required files were not found, ensure all Sequence folders contain a valid 'util' folder, and/or XML file."

Applications Other Than US 3.3

For Applications other than US 3.3 Applications, the Preparing for Bulk eCTD Import job will look in the

Sequence folder with the highest sequence number first. This is to account for Europe's "UNKNOWN" Submission

Number in early sequences. To ensure a successful import, set the Application Code within Ennov InSight to the Application Code/Application Number/Application Tracking Number in the last XML in the Application folder.

When there is no regional.xml in the folder with the highest sequence number, or when there is a regional.xml without an Application Code/Application Number/Application Tracking Number, the system checks the folder(s) with the previous sequence number - continuing until the Application Code/Application Number/Application Tracking Number is found. If no Application Code/Application Number/Application Tracking Number is found, the application is skipped and the following message appears in the log: "WARNING: The

Application located here: "<path to application>" failed to import: The Application Code was not found in the regional.xml, please ensure that folder contains a valid application."

GCC, MRP, DCP Applications

For GCC, MRP, and DCP, multiple Application Codes can exist for the same Country, or for different Countries within the XML. The list of all application codes within the XML is matched against an Application Code within Ennov InSight .

US 3.3 Applications

For US 3.3 applications, the Preparing for Bulk eCTD Import job will look in the Sequence folder with the lowest sequence number first. To ensure a successful import, set the Application Code to the Application Number in the us-regional.xml with the lowest number.

ZA 3.1 Applications

The Application ID from regional.xml file will be used to identify Application Code value.

EU 3.1 Applications

An Application Tracking Number is used to identify an application. When there are multiple Application Tracking Numbers, even a single instance of an Application Tracking Number matching an application initiates the process of bulk import. If there are multiple matches, the bulk import process stops.

WHO 1.0 Applications

Import of WHO applications is possible only using eCTD import and not via bulk eCTD import. For information on eCTD import, see *Administrative Activities > Import eCTD Applications* in the *Ennov InSight Administration* help module.

UA 1.0 Applications

A Submission Number is used to identify an application. When there are multiple Submission Numbers, even a single instance of a Submission Number matching an application initiates the process of bulk import. If there are multiple matches, the bulk import process stops.

AU 3.2 Applications

Import of AU applications is possible using eCTD import and via bulk eCTD import. The e-identifier identifies the applications for bulk import. For information on eCTD import, see *Administrative Activities > Import eCTD Applications* in the *Ennov InSight Administration* help module.

BA 3.1 Applications

An Application Tracking Number is used to identify an application.

SG 1.0 Applications

An SG eCTD ID is used to identify an application.

TN 1.1 Applications

An Application Tracking Number is used to identify an application

Application Code Matching Warnings

If no matching Application Code is found, the application is skipped and the following message appears in the log:

"WARNING: The Application located here: "<path to application>" failed to import: The Application Code(s) "<comma separated list of application codes from xml>" cannot be matched in the system, please create the Application and try

When there are multiple matching Application Codes, the system includes the Application Code and Folder path to the Application within the Job Messages for that Job with the following message: "WARNING: The Application located here: "<path to application>" failed to import: The Application Code(s) "<coma separated list of application codes from xml that matched multiple applications>" matched multiple Applications in the system."

Note: *Canceling a Preparing for Bulk eCTD Import job will not cancel individual eCTD import jobs that have already been prepared and are in the queue.*

Define Default Values for eCTD Bulk Import

Ennov InSight provides the ability to perform batch imports of eCTD applications using the *Bulk eCTD Import* wizard.

The bulk import functionality requires specific default values for the number of concurrently running import jobs (default is 3), and for the frequency that the system checks for a free place in the queue (in seconds, default is 300).

To define the eCTD Bulk Import values for your system:

1. Go to the directory C:\InSightManager\server\all\conf\insight and open the insight.var file in a text editor.
2. At the bottom of the insight.var file, add the following records:
 - bulk.ectd.import.limit = 3 (the number of concurrently running import jobs)
 - bulk.ectd.import.update.interval = 300 (frequency of checking if there is a free place in the queue, in seconds)
3. Save the insight.var file.

Use the Bulk eCTD Import Wizard

You can use the *Bulk eCTD* wizard to import multiple submissions to a supported document management system. Prior to running the Bulk eCTD Import, all applications should be configured correctly, as described in *Prepare for Bulk eCTD Import*.

To perform Bulk eCTD Import:

1. In Ennov InSight , open the Wizards menu and select Bulk eCTD Import.
2. In the Publishing Settings Library field, select the Publishing Settings Library Template (PLT) to create Assembly Specific Publishing Settings Libraries (APL) for the imported eCTDs.

This field is applied according to the following rules for new or existing applications:

- New Application – If the import is to a new Application (there are no existing Sequence Assemblies) then the Publishing Settings Library Template selected in this field is the APL for the imported Sequences.
 - Existing Application – If the import is to an existing Application (there are existing Sequence Assemblies) then the eCTD Import uses the Submitted View from the previous existing Sequence as the basis for the APL for the imported Sequences.
3. On the Import Location field, click Browse to locate source of the eCTDs to import.
 4. Select the folder containing all Applications with their nested eCTD sequences. It is prerequisite to have collected all eCTD imports into one folder.
 5. In the Import Orphan Leaf Elements field:
 - Select Yes to include orphan leaf elements in the import.
 - Select No and Ennov InSight ignores orphan leaf instances and instead creates new leaf elements.
 6. In the Import Leaf Elements Only field:
 - Select Yes to import only the XML leafs in the eCTD XML, without importing references to the content files.
 - Select No if extracts and renditions are needed for the imported documents. You can run Create Renditions and Extractions from each assembly.

Note: Each imported leaf element is automatically assigned with the Published leaf status, or any other leaf status that has the Internal System Status set to "PUBLISHED".

7. In the Use Application Code for Prefixes field:

- Select Yes to use the existing application codes as prefixes.
- Select No to enter a new Sequence Prefix and Assembly Prefix.

8. In the Create Grouping Event field:

- Select No (the default), and no grouping event is created.
- Select Yes and use the default (Legacy Submissions) or enter a different *Event Name*.

9. If Create Grouping Event is Yes, the Close Event as Approved field appears. In the Close Event Approved field:

- Select No to keep the Event open, it will not be closed.
- Select Yes to close the Event with the status Approved. If Yes is selected, the Event Name field is created and required (limit 200 characters). The Event Name default is Legacy Submissions. If any submissions failed to import, the Event is not closed.

On import, all Sequences are associated with the defined Event and the Application. If any of the imported sequences already exist in the Application, they are not added to the defined event. If set to No, all Sequences will only be associated with the Application

When imported:

- If an Event with the same name already exists and is not closed, the sequences are added to that Event. The Status Date of the Event is not updated.
- If more than one Event with the same name already exists and is not closed, the sequences are added to the most recent open Event, according to the creation date.
- If an Event with the same name already exists and is closed, a new Event is created with the same name and a sequential number added as a suffix. New sequences are added to this Event

For each country on the Application, an Event-Country is created. The Status is set to the default Event status. The Status Date is set to the date of import.

Note: Because many regions do not contain a submission date, and in some regions the submission date is dropped between specifications, it is not possible to obtain a valid date for all eCTD regions.

1. Click Next, and the system parses the XMLs to determine the Application Codes.

The Application Codes are matched to the Application Codes within Ennov InSight , and the system imports the eCTD structures. The *Summary* window displays this message: "The bulk eCTD import has been scheduled successfully. Choose Go To > Job Requests for the status."

2. Click Finish.

High Speed Printers

Ennov InSight supports the use of a high-speed printer, which can be used to print your final output.

Your printer may require specific configuration and certain printer attributes to accept certain paper weights, sizes, tabs, colors and other print settings.

For a complete list of the printers supported by Ennov InSight , as well as information on PostScript support, see the *Ennov InSight System Support Documentation (SSD)*.

Print Commands

You can use a high speed printer to print your assembly.

Ennov InSight creates the data in the .prn file in a format specific for your printer. Your high-speed printer is able to read and process the file to print the information as you configured it in Ennov InSight .

You may send the generated .prn files to the printer using the *Command Prompt* window to type command lines. The commands instruct your machine which files to send to a specified printer.

Note: *The following instructions may be used to send .prn files from the File system only.*

To open the *Command Prompt* window on your computer:

1. Click Start.
2. In the Start menu, click Run.
3. In the *Run* dialog, type cmd and then click OK.
4. At the prompt, use one of the following print commands:

– Lpr

– Copy

– ftp

Print Command Types

You can send print jobs from Ennov InSight with the help of different commands.

There are three types of commands that you can use to send print jobs from Ennov InSight to the printer:

- `lpr` - Copy a volume .prn file to a network printer that uses a line printer daemon.
- `copy` - Copy a volume .prn file to a Windows Printer Port which has been set up using the Windows printer driver, on shared Windows printers.
- `ftp` - Use an ftp (file transfer protocol) service to transfer .prn files to a printer.

lpr command

Use the `lpr` (line printer requester) command to copy a volume .prn file to a network printer, which is running a line printer daemon (`lpd`) process.

In the following examples, the `-o l` argument (lowercase O, space, lowercase L) designates a binary file. Use this argument to send all Ennov InSight output to any network printer.

This is the format for the `lpr` command line: `lpr -o l -S <printer name or IP Address> -P print <Printable output file name>`

```
lpr -o l -S 10.224.140.8 -P print C:\MyOutout\v0000001.prn
lpr -o l -S Ecopy2.us.liquent.com -P print v0000001.prn
```

copy command

Use the `copy` command to copy a volume .prn file to a shared Windows printer port that has been set up using the Windows printer driver for the target printer.

This is the format for the `copy` command line: `copy /B <Printable output file name> <Windows`

Printer Port>

```
copy /B C:\MyOutout\v0000001.prn \\LIQUENTPRINT\Ecopy2
```

Note: The `/B` argument designates binary file. This argument should be used for sending all Ennov InSight output to any network printer.

ftp command

Use ftp (File Transfer Protocol) to exchange files over your network between your computer and your printer. You can use ftp with the Windows Command Prompt or with an ftp client program that offers a graphical user interface to transfer files from Ennov InSight to an ftp-capable printer.

To use ftp to transfer files to the printer, an ftp service must be running on the printer controller. Before transferring files using `put`, `mput` or `send`, set the transfer type to binary by sending the `binary` command.

For additional information about high-speed printing, refer to the instruction manual for your printer.

Canon imageRUNNER Printers

Ennov InSight is compatible with Canon ImageRUNNER printers for paper output. These printers must be used with a Canon ImagePASS printer controller. Ennov InSight does not support the standard imageRUNNER printer controller.

The paper output from these printers is limited to white and one other paper color supported for slip sheets and color cover pages. Because Ennov InSight selects paper by media attributes (size, weight, media type, and color) your Canon ImageRUNNER printer must be configured for the paper stocks you use in it. This setup is done on the printer operator panel and touch screen.

- Only white and color paper color are supported. The imageRUNNER cannot be configured to distinguish paper by color.
- Drilled (pre-punched) color and tab papers are not supported.

Tabs are inserted in the volume PDF and PostScript output file as normal letter or A4 pages. Special ImagePASS commands select the correct media and shift the page image to the correct position. Tab pages will appear as normal letter or A4 when the PostScript output file is distilled to PDF.

- Extra pages for any unused tabs in the last set of tabs are added to the printable output.
- All supported imageRUNNER printers have an unprintable area 13 points (13/72 in. or approx. 4.5mm) wide around the page. This includes Tab pages. Tab text is set inside the printable area of the page in the Volume PDF. Any PDF content which falls outside of the printable area of the physical page will be clipped by the printer

The following paper types are supported for imageRUNNER printers:

- A4
- Color A4
- Drilled A4
- Letter
- Color Letter
- Drilled Letter
- Plain Flush-Cut A4 5 down Tab
- Plain Gutter-Cut A4 5 down Tab
- Plain Letter 5 down Tab
- Plain A4 10 down Tab

Note: When using Canon imagePASS S-1 or Canon imagePASS M3 printers, Tabs in Volumes that do not begin with a tab page are printed with the text in the original position - the text is not shifted. This is a Canon printer problem and users must contact the Canon corporation for a resolution.

Set up a Canon imageRUNNER Printer

To have a proper output processing from Ennov InSight, configure Canon ImageRUNNER printer for the paper stocks you use in it.

Ennov InSight selects paper by media type, so the Canon imageRUNNER printer must be configured to recognize which paper stocks are loaded. Use the operator panel and touch screen to setup the Canon imageRUNNER printer to process output from Ennov InSight.

Note: *If the touch screen on your printer is blank, the printer is in power save mode. Press the Off/On button on the operator panel.*

Select a Drawer for Color Cover Pages and Slip Sheets

The procedure described in this topic is specific to Canon imageRUNNER printers. Your printer's operator panel may be different.

To select a drawer for cover pages and slip sheets:

1. Press Additional Functions on the operator panel to display the touch screen controls.
2. Press Common Settings.
3. At the bottom of the operator panel touch screen, press the arrow to scroll to the next page.
4. Press the arrow to the right of Store Paper Type (labeled Register Paper Type on some models).
5. On the *Store Paper Type* screen, touch the drawer where the color paper for cover pages and slip sheets is located.

(Drawer 1, 2, 3 or 4 may be selected.)

6. Next, press the Color button.
7. Press OK.
8. Touch Done and OK until the main menu is displayed.
9. When the main menu appears, the Additional Functions button on the operator panel will stop blinking.

Select a Drawer for 5 down Tab Stock

The procedure described in this topic is specific to Canon imageRUNNER printers. Your printer's operator panel may be different.

To select a drawer for tab stock:

1. Press Additional Functions on the operator panel to display the touch screen controls.
2. Press Common Settings.
3. At the bottom of the operator panel touch screen, press the arrow to scroll to the next page.
4. Press the arrow to the right of Store Paper Type (labeled Register Paper Type on some models).
5. On the *Store Paper Type* screen, touch the drawer where the 5 down tab stock is located. (Drawer 3 or 4 may be selected.)
6. Next, press Tab Paper.
7. Set the number of tabs to 5 using the + and - buttons.

8. Press Done, and then press OK until the main menu is displayed.
9. When the main menu appears, the Additional Functions button on the operator panel will stop blinking.

Select a Drawer for 10 down Tab Stock

The procedure described in this topic is specific to Canon imageRUNNER printers. The printer's operator panel may be different.

To select a drawer for tab stock:

1. Press Additional Functions on the operator panel to display the touch screen controls.
2. Press Common Settings.
3. At the bottom of the operator panel touch screen, press the arrow to scroll to the next page.
4. Press the arrow to the right of Store Paper Type (labeled Register Paper Type on some models).
5. On the *Store Paper Type* screen, touch the drawer where the 10 down tab stock is located. (Drawer 3 or 4 may be selected.)
6. Next, press Tab Paper.
7. Set the number of tabs to 10 using the + and - buttons.
8. Press Done, and then press OK until the main menu screen is displayed.
9. When the main menu appears, the Additional Functions button on the operator panel will stop blinking.

Load Tab Stock into Drawer 3 or 4

The procedure described in this topic is specific to Canon imageRUNNER printers.

To load tab stock:

1. Confirm that the mylar drawer liner is in the bottom of the tab stock drawer.

It is shipped with the printer in drawer 3.
2. Load tab stock with the straight edge against the right side of the drawer and the tab at position 1 to the left rear of the drawer.

The imageRUNNER printers use reverse collated tab stock.
3. Place the tab paperweight bar over the tab ends of the stock.

The tab paperweight bar is stored on a magnet inside drawer 3.
4. Slide the adjustable paper stop to contact the tab paperweight bar.

Xerox FreeFlow Printers

Your printer must be configured to process Ennov InSight output. Ennov InSight selects paper according to the media attributes of size, weight, hole count, sequence count, media type, and color.

The printer must be set up to recognize the paper stocks supplied in its drawers, using the FreeFlow printer controller supplied with the printer. Ennov InSight does not support paper loaded in any post-fuser paper drawer. Page images are generated for all pages, including slip sheets.

Sending Data to the XEROX FreeFlow Controller

Use the print commands for sending printable output on a secure file system to a Xerox FreeFlow based printer

Media Parameters for Xerox Printers

Ennov InSight requests media parameters for Xerox ASCII job ticket printers, except: DocuPrint 75, 90 (XPIF) and DocuPrint 75, 90 Postscript (XPIF).

Name	Size	Weight (gsm*)	Hole Count	Seq. Count.	Color	Type
Letter	8.5x11in.	75	0	0	white	Plain
A4	210x297mm	80	0	0	white	Plain

Name	Size	Weight (gsm*)	Hole Count	Seq. Count.	Color	Type
Drilled Letter	8.5x11in.	75	3	0	white	Drilled
Drilled A4	210x297mm	80	4	0	white	Drilled
Blue Letter	8.5x11in.	75	0	0	blue	Plain
Blue A4	210x297mm	80	0	0	blue	Plain
Blue Drilled Letter	8.5x11in.	75	3	0	blue	Drilled
Blue Drilled A4	210x297mm	80	4	0	blue	Drilled
Green Letter	8.5x11in.	75	0	0	green	Plain
Green A4	210x297mm	80	0	0	green	Plain
Green Drilled Letter	8.5x11in.	75	3	0	green	Drilled
Green Drilled A4	210x297mm	80	4	0	green	Drilled
Pink Letter	8.5x11in.	75	0	0	pink	Plain
Pink A4	210x297mm	80	0	0	pink	Plain
Pink Drilled Letter	8.5x11in.	75	3	0	pink	Drilled
Pink Drilled A4	210x297mm	80	4	0	pink	Drilled
Yellow Letter	8.5x11in.	75	0	0	yellow	Plain
Yellow A4	210x297mm	80	0	0	yellow	Plain
Yellow Drilled Letter	8.5x11in.	75	3	0	yellow	Drilled

Yellow Drilled A4	210x297mm	80	4	0	yellow	Drilled
Plain Letter 5 down Tab	11x9in.	163	0	5	white	PlainPreCutTab
Drilled Letter 5 down Tab	11x9in.	163	3	5	white	DrilledPreCutTab
Plain Flush-Cut A4 5 down Tab	297x223mm	160	0	5	white	PlainPreCutTab
Drilled Flush-Cut A4 5 down Tab	297x223mm	160	4	5	white	DrilledPreCutTab
Plain Gutter-Cut A4 5 down Tab	297x223mm	160	0	5	white	PlainPreCutTab
Drilled Gutter-Cut A4 5 down Tab	297x223mm	160	4	5	white	DrilledPreCutTab
Plain A4 10 Down Tab	297x223mm	160	0	10	white	PlainPreCutTab
Name	Size	Weight (gsm*)	Hole Count	Seq. Count.	Color	Type
Drilled A4 10 Down Tab	297x223mm	160	4	10	white	DrilledPreCutTab

1

– 75gsm = 20 lb. bond

– 163gsm = 90 lb. index

Name	Weight (gsm*)	Hole Count	Seq. Count.	Color	Type
All Paper Types	75	see above	see above	see above	see above
All Tab Types	150	see above	see above	see above	see above

Print Tabs on a Xerox Printer

You must disable the Edge Erase feature to print Tabs correctly on Xerox printers.

Some Xerox DocuTech and Nuvera printers are shipped with the Edge Erase feature enabled. You must disable this feature to print Tabs correctly.

To correctly print tabs on a Xerox printer using a FreeFlow Controller, you must configure the controller appropriately.

To turn off the Edge Erase feature:

1. At the Xerox FreeFlow Controller, click Printer:Switches.
2. Select the Edge Treatment Off option.

— The Edge Treatment option must be set to Off before sending a print job containing tabs. — Ask your System Administrator to verify that the system is configured in this way.

For more information about edge-to-edge printing, see the Xerox Web site.

Kodak Network Imaging System Printers

Ennov InSight Publisher supports NexPress Network Imaging System based printers via a KDK+DSC job ticket prepended to PDF or Postscript page descriptions.

The KDK+DSC job ticket is a Kodak/NexPress proprietary technology supported by the Kodak Network Imaging System controller (also referred to in this documentation as KDKNIS). The Kodak Network Imaging System controller is used by several manufacturers (Canon, IBM, Heidelberg AG) for differently branded products. InSight produces identical Job Tickets for all supported printers.

Because Ennov InSight selects paper by media attributes (size, weight, media type, and color) your printer must be configured for the paper stocks you use in it. You can set up the printer using the Network Imaging System application running the Sun workstation connected to the printer.

1 *gsm = grams per square meter

You must configure the printer before any Ennov InSight output can be processed. The printer controller must be rebooted after you set up the paper catalog so it is recommended that you add all US and/or international paper stock to the paper catalog at the same time.

Implementation Notes

- In the last set of tabs, extra pages for any unused tabs are added to the printable output. The job ticket is created so that these tabs are output from the top output bin of the Printer.
- Drilled Color Media is not supported.

Printers Running the Kodak Network Imaging System

These printers are:

- Canon imageRUNNER 110/125/150
- Heidelberg Digimaster 9110/9150
- IBM Infoprint 2000
- Kodak DIGIMASTER EX

– Network Imaging System Job Ticket with PostScript

Add Paper Types to the Paper Catalog

Perform the following steps to add paper types to the Paper Catalog. You must add defined paper types to the Paper Catalog.

Note: *The exact sequence may be different on your version of the Network Imaging System.*

To add paper type to the Paper Catalog:

1. On the *Kodak Network Imaging System* main screen, click the Manage button.
2. To open the *Paper Catalog* view choose Manage > System Administration > Paper Catalog.
3. To configure the paper color settings for the printer, click Catalog Attributes.
4. In the *Color Attributes* dialog box, click Color and confirm that all the following options are available:
 - Any
 - White
 - Pink
 - Yellow – Blue
 - Green
5. For each unavailable option, click **Add**, enter the missing option, then click Apply.
6. Click Exit.
7. To configure media types for your printer, click Catalog Attributes.
8. Click Type or Media type and confirm that the following media types are available:
 - Plain
 - Color
 - 3hole
 - 4hole
 - Tab
9. For each unavailable media type, click Add, enter the missing type, then click Apply.
10. Click Exit.
11. In the *Paper Catalog* view, for each North American and/or international paper stock, click Add and enter parameters from the table below. Click Apply after adding each one.

Media Parameters for Kodak Network Imaging System

Name	Size	Weight (gsm*)	Color	Type

Letter	8.5 x 11 in.	75	white	plain
DrilledLetter	8.5 x 11 in.	75	white	3hole
LetterTab5	9 x 11 in.	163	white	tab
ColorLetter	8.5 x 11 in.	75	any	color
BlueLetter	8.5 x 11 in.	75	blue	color
GreenLetter	8.5 x 11 in.	75	green	color
PinkLetter	8.5 x 11 in.	75	pink	color
YellowLetter	8.5 x 11 in.	75	yellow	color
A4	210 x 297 mm	80	white	plain
DrilledA4	210 x 297 mm	80	white	4hole
FlushA4Tab5	223 x 297 mm	160	white	tab
GutterA4Tab5	223 x 297 mm	160	white	tab
PlainA4Tab10	223 x 297 mm	160	white	tab
ColorA4	210 x 297 mm	80	any	color
BlueA4	210 x 297 mm	80	blue	color
GreenA4	210 x 297 mm	80	green	color
PinkA4	210 x 297 mm	80	pink	color
YellowA5	210 x 297 mm	80	yellow	color

2

2 * gsm = grams per square meter

Note: Ennov InSight does not support paper types marked as post-fuser only. Page images are generated for all pages including slip sheets.

Change a Drawer to Accept Tab Sheet Stock

Kodak printers display only paper stocks that can physically fit in a paper drawer.

To set up a drawer to accept tab sheet stock:

1. Unlock the drawer by pressing the button on the outside of the drawer.
2. Pull the drawer open.
3. Lift the latch on the front left paper guide and slide the guide to the left to accommodate the tab sheet stock.

Assign InSight Paper Stock to Drawers

You can assign paper stock to specific drawers of the Kodak printers.

To assign Ennov InSight paper stock to drawers:

1. On the Kodak Network imaging system main screen, click Manage.
2. Choose Manage Menu > Printer Monitor.
3. For each paper source, assign a stock from the paper catalog, then click Apply.
4. When all are paper stocks have been selected, click Exit.

All stock attributes must match exactly or an exception will be reported.

Konica Minolta Printers

Your printer must be configured to process Ennov InSight output.

Ennov InSight selects paper according to the media attributes of size, weight, hole count, sequence count, media type, and color.

Because Ennov InSight selects paper by media attributes (size, weight, media type, and color) your printer must be configured for the paper stocks you use in it.

Media Parameters for Konica Minolta Printers

Ennov InSight requests media parameters for Konica Minolta printers.

Name	Size	Hole Count	Color	Type
Letter	8.5x11in.	0	white	Plain
A4	210x297mm	0	white	Plain
Drilled Letter	8.5x11in.	3	white	Plain
Drilled A4	210x297mm	4	white	Plain
Blue Letter	8.5x11in.	0	blue	Plain
Name	Size	Hole Count	Color	Type
Blue A4	210x297mm	0	blue	Plain
Blue Drilled Letter	8.5x11in.	3	blue	Plain
Blue Drilled A4	210x297mm	4	blue	Plain
Green Letter	8.5x11in.	0	green	Plain
Green A4	210x297mm	0	green	Plain
Green Drilled Letter	8.5x11in.	3	green	Plain

Green Drilled A4	210x297mm	4	green	Plain
Pink Letter	8.5x11in.	0	pink	Plain
Pink A4	210x297mm	0	pink	Plain
Pink Drilled Letter	8.5x11in.	3	pink	Plain
Pink Drilled A4	210x297mm	4	pink	Plain
Yellow Letter	8.5x11in.	0	yellow	Plain
Yellow A4	210x297mm	0	yellow	Plain
Yellow Drilled Letter	8.5x11in.	3	yellow	Plain
Yellow Drilled A4	210x297mm	4	yellow	Plain
Plain Letter 5 down Tab	11x9in.	0	white	Plain, TAB5
Drilled Letter 5 down Tab	11x9in.	3	white	Plain, TAB5
Plain Flush-Cut A4 5 down Tab	297x223mm	0	white	Plain, TAB5
Drilled Flush-Cut A4 5 down Tab	297x223mm	4	white	Plain, TAB5
Plain Gutter-Cut A4 5 down Tab	297x223mm	0	white	Plain, TAB5
Drilled Gutter-Cut A4 5 down Tab	297x223mm	4	white	Plain, TAB5

Ricoh Printers

Your printer must be configured to process Ennov InSight output. Ennov InSight selects paper according to the media attributes of size, weight, hole count, sequence count, media type, and color.

Because Ennov InSight selects paper by media attributes, your printer must be configured for the paper stocks you use in it.

The following paper types are supported for Ricoh Pro C5200s/C5210s printers:

- Letter
- A4
- Blue Letter
- Blue A4
- Green Letter
- Green A4
- Pink Letter

- Pink A4
- Yellow Letter
- Yellow A4
- Plain Letter 5 down Tab
- Plain Gutter-Cut A4 5 down Tab
- Plain Flush-Cut A4 5 down Tab
- Plain A4 10 down Tab

The following paper types are supported for Ricoh Pro C5200s/C5210s, US Punch printers:

- Letter
- Blue Letter
- Green Letter – Pink Letter
- Yellow Letter
- Plain Letter 5 down Tab

The following paper types are supported for Ricoh Pro C5200s/C5210s, ISO printers:

- A4
- Blue A4
- Green A4 – Pink A4
- Yellow A4
- Plain Gutter-Cut A4 5 down Tab
- Plain Flush-Cut A4 5 down Tab
- Plain A4 10 down Tab

Media Parameters for Ricoh Printers

Insight Paper Name	Paper Size	Paper Type	Paper Weight	Tab Position Shift
Letter	8½ x 11 	Plain Paper	3 81-100.9g/m2	N/A
A4	A4 	Plain Paper	3 81-100.9g/m2	N/A

Blue Letter	8½ x 11 	Blue	3 81-100.9g/m2	N/A
Blue A4	210 x 297	Blue	3 81-100.9g/m2	N/A
Green Letter	8½ x 11 	Green	3 81-100.9g/m2	N/A
Green A4	210 x 297 	Green	3 81-100.9g/m2	N/A
Insight Paper Name	Paper Size	Paper Type	Paper Weight	Tab Position Shift
Pink Letter	8½ x 11 	Pink	3 81-100.9g/m2	N/A
Pink A4	210 x 297 	Pink	3 81-100.9g/m2	N/A
Yellow Letter	8½ x 11 	Yellow	3 81-100.9g/m2	N/A
Yellow A4	210 x 297 	Yellow	3 81-100.9g/m2	N/A
Plain Letter 5 down Tab	8½ x 11 	Tab Stock	3 81-100.9g/m2	0.5 inch
Plain Gutter-Cut A4 5 down Tab	A4 	Tab Stock	3 81-100.9g/m2	13 mm
Plain Flush-Cut A4 5 down Tab	A4 	Tab Stock	3 81-100.9g/m2	13 mm
Plain A4 10 down Tab	A4 	Tab Stock	3 81-100.9g/m2	13 mm

*(Portrait) is denoted by 

** Tabs do not use the actual page dimension

High Speed Printer Support

These optional components are supported by your Rendering publishing environment for printing final published output.

Canon imageRunner with Canon imagePASS Controller

Rendering supports a variety of Canon imageRUNNER printers using the Canon imagePASS controller. The Rendering Printer Type selections are listed below with the specific devices supported.

Canon imageRUNNER with imagePASS-M1/M2 v1.0

— imageRUNNER 7200

- imageRUNNER 8500

- imageRUNNER 85

- imageRUNNER 105

Canon imageRUNNER with imagePASS-M2 v2.x

- imageRUNNER 7200

- imageRUNNER 8500

- imageRUNNER 85

- imageRUNNER 105

Rendering does not support the iR5020/iR6020 printers because they do not handle index tabs.

Canon imageRUNNER with imagePASS-M3

- imageRUNNER 85PLUS

- imageRUNNER 105PLUS

- imageRUNNER 8070

- imageRUNNER 9070

- imageRUNNER 5570

- imageRUNNER 6570

Canon imageRUNNER with imagePASS-S1

- imageRUNNER 7086

- imageRUNNER 7095

- imageRUNNER 7105

- imageRUNNER 8070

The imagePASS S2 controller supports the imageRUNNER 7086/7095/7105, and the imageRUNNER

5055/5065/5075 Series. According to published specifications, Rendering should be able to support these printer/controller combinations by using the Canon imageRUNNER with imagePASS S1 selection.

Canon imageRUNNER ADVANCE with imagePASS-U2

Rendering provides support for the Canon imageRUNNER ADVANCE with imagePASS-U2 controller:

- imageRUNNER ADVANCE 8205

- imageRUNNER ADVANCE 8295
- imageRUNNER ADVANCE 8285
- imageRUNNER ADVANCE 6275
- imageRUNNER ADVANCE 6265
- imageRUNNER ADVANCE 6255

Kodak Network Imaging System Printer (KDKNIS)

Rendering supports printers using the Kodak/NexPress Network Imaging System Controller. Printer Type selections:

- Canon imageRUNNER 110/125/150
- Heidelberg Digimaster 9110/9150
- IBM Infoprint 2000
- Kodak DIGIMASTER EX
- Network Imaging System Job Ticket with Postscript

Rendering supports other Network Imaging System based printers that support the DCS+KDK Protocol.

KONICA MINOLTA Printers

Rendering provides support for the following KONICA MINOLTA printers:

- bizhub PRO 1200P/bizhub PRO 1051
- bizhub PRO 1050/bizhub PRO 1050P

Xerox Printers

Ricoh Pro Printers

- Ricoh Pro C5200s/C5210s
- Ricoh Pro C5200s/C5210s, US Punch*
- Ricoh Pro C5200s/C5210s, ISO Punch*

*Requires optional hardware

Rendering supports Xerox Printers using the FreeFlow Print Server. The FreeFlow Print Server is supported via Xerox ASCII and XPIF JobTickets.

No special processing is performed by Rendering for color printers.

The Rendering Printer Type selections producing ASCII Job Ticket output are:

- Xerox DocuTech 135 (Network Server Plus)
- Xerox DocuTech 6100
- Xerox DocuTech 6135 (ASCII Job Ticket)
- Xerox DocuTech 6180 (ASCII Job Ticket)
- Xerox ASCII Job Ticket with PDF
- Xerox ASCII Job Ticket with Postscript

Rendering supports all Xerox FreeFlow controlled printers that support the XPIF Job Ticket Protocol. The Rendering Printer Type selections producing XPIF Job Ticket output are:

- Xerox DocuTech (XPIF)
- DocuPrint 75, 90 (XPIF)
- DocuPrint 75, 90 Postscript (XPIF)
- Xerox DocuPrint 100, 115, 135, 155, 180 EPS (XPIF)
- Xerox DocuPrint 4110, 4590 (XPIF)
- Xerox Nuvera 100, 120, 144 DPS
- Xerox Nuvera EA DPS PS
- Xerox DocuColor 250 - The optional Creo Spire Controller supports XPIF Job Tickets, although this has not been tested with Rendering. The EFI Fiery controller is not supported.
- Xerox XPIF Job Ticket with Postscript
- Xerox Color 550/560/570 (XPIF)
- Xerox Color 550/560/570 Postscript (XPIF)
- Xerox Color C60/C70 (XPIF)
- Xerox Color C60/C70 Postscript (XPIF)

Rendering supports all Xerox and FreeFlow controlled printers that support the XPIF Job Ticket Protocol. Creo Spire controlled Xerox printers have not been tested with InSight.

PostScript Printing

The ability to drive all printers in the DocuTechJT, XeroxXPIF, and KDKNIS families via PostScript rather than PDF is available. Using PostScript may solve some PDF problems, such as non-embedded font issues.

In use, the difference is minimal for these printers: a job ticket and output generated as PostScript rather than a job ticket and output generated as PDF. The PostScript output for these printers, like all other printers, is in a file with a PRN extension (.prn = printer-ready output). Rendering creates the data in the .prn file in a format specific to your printer.

Cross-site Scripting (XSS) Filtering

Ennov InSight includes Cross-site Scripting (XSS) filtering that prevents users from adding malicious script codes in the form of user input in an attempt to access data.

Any data that includes HTML tags and text patterns not included in the exception list (whitelist) will not be saved by the system.

By default, the following text patterns will be prevented from being saved unless they are included in the whitelist:

- onmouseover
- document.cookie
- window.open
- onload
- onerror
- onreset
- onclick
- ondblclick
- ondrag
- onfocus
- onblur
- onchange
- onselect
- onkey
- oncut
- oncopy
- onpaste
- onmouse

- onscroll
- onwheel
- oninput
- oninvalid

Enabling Cross-site Scripting Filtering

The Cross-site Scripting (XSS) filter can be enabled by setting its property value to true in the securityConfiguration.xml file.

To enable Cross-site Scripting Filter:

1. On the Application Server, locate: <Installation drive>\InSightManager\server\all
 \conf\insight\securityConfiguration.xml
2. Open this file in a text editor and locate the section:

Example

```
<property name="enableXssFilter" value="false"/>
```

3. Change the value of enableXssFilter to true.
4. Save and close the securityConfiguration.xml.
5. Restart the Application Server.

Whitelist Tags, Tag Attributes, and Text Patterns

Ennov InSight enables you to add tags, tag attributes, and text patterns to the whitelist. To specify the tag attributes and text patterns in the whitelist:

1. On the Application Server, find the securityConfiguration.xml file in the following location:
 <Installation drive>\InSightManager\server\all\conf\insight
 \securityConfiguration.xml
2. Open this file in a text editor.
3. To add tags, locate the section <property name="allowedTags">
4. Add <value></value> to the list of tags and replace *new tag* with the value of the tag you want to add. Repeat this step to add more tags.

Example

```

<property name="allowedTags">

<list>

<value>b</value>

<value>new tag</value>

</list>

</property>

```

5. To add tag attributes, locate the section <property name="allowedTagAttributes">
6. Locate the list that corresponds to the tag to which you want to add the tag attributes.
7. Add <value>*new tag attribute*</value> to the list of tag attributes and replace *new tag attribute* with the value of the tag attribute you want to add. Repeat this step to add more tag attributes.

Example

```

<property name="allowedTagAttributes">

<map>

<entry>

<key>

<value>div</value>

</key>

<list>

<value>title</value>

<value>style</value>

<value>new tag attribute</value>

</list>

</entry>

</map>

</property>

```

8. To add text patterns, locate the section `<property name="allowedTextPatterns">`
9. Add `<value>new text pattern</value>` to the list of text patterns and replace *new text pattern* with the value of the text pattern you want to add. Repeat this step to add more text patterns.

Example

```
<property name="allowedTextPatterns">
<list>
<value>onclick</value>
<value>onmouseover</value>
<value>document.cookie</value>
<value>window.open</value>
<value>new text pattern</value>
</list>
</property>
```

10. Save and close the securityConfiguration.xml file.
11. Restart the Application Server.

Chapter 7. eCTD Codes

eCTD codes and their values can be maintained by your system administrator using the Ennov InSight Data Administration interface.

For new Ennov InSight installations, the current eCTD codes are installed automatically on your system. For subsequent Ennov InSight database upgrade installations, your existing eCTD code values are not affected. However, if there are new eCTD code values since your previous Ennov InSight installation, those new eCTD code values are added to your system during the database upgrade.

To accommodate changes or additions to the eCTD codes, we recommend that you review and update your eCTD codes periodically, and particularly after performing an Ennov InSight upgrade from a previous version.

- Application Type Values (Application Maintenance section)
- Country Values (Application Maintenance section)
- Procedure Type Values (Application Maintenance section)
- Filing Type Values (Sequence Maintenance section)

Please refer to the information provided in help.liquent.com for eCTD Application Types, eCTD Filing types, eCTD Procedure Types, and eCTD Country Values.

Warning: eCTD codes are part of your company's data in Ennov InSight , and eCTD code maintenance in Ennov InSight is the responsibility of your company.

Maintain eCTD Code Values

Ennov InSight administrators can modify or update eCTD codes and values in the Ennov InSight Data Administration interface.

To open the Data Administration interface for eCTD code maintenance, select Go To > Data Administration.

All of the categories of values that can be maintained and modified in Ennov InSight are listed in groups alphabetically. In the list, click the link for the type of values that you want to modify (for example, Application Type Values).

Add an eCTD Value

To add an eCTD value:

1. Select Go To > Data Administration.
2. In the list, click the name of the entity to which you want to add a value.
3. Click .
4. On the *values* page, enter the required and additional information.

Ennov InSight Administration 7.3 Maintain eCTD Code Values

5. Save.

Modify an eCTD Value

To modify an eCTD code value:

1. In the selected list of values, click the name of the value you want to modify.

For some categories, you may also need to click  to modify value data.

2. Enter the required and additional information.
3. Save.

- To deactivate a code or value, click Deactivate.
- To activate the code of value again, click Activate.

eCTD Codes for Application Types

An eCTD code is assigned for each application type.

- Application Type - The related Application Type Name.
- Applicable DTD/Schema - The active DTD or Schema from the Assembly DTD/Schema Types.
- eCTD Code - The eCTD Code for DTD or Schema.
- Agency Abbreviation - The abbreviation used as an application prefix for cross-application references.
- Limit to Cross Application Only - Determines if the eCTD Code should be used only in the cross-referenceapplication-number element on the envelope. Only values set to No appear in the Application Type drop-down list on the Envelope.

Application Type (Display)	Applicable DTD/ Schema	eCTD Code	Agency Abbreviation	Limit to Cross Application Only
Abbreviated Biologic New Drug Submission	ca-1-0	ABNDS		No
Abbreviated Biologic New Drug Submission	ca-2-2	ABNDS		No
Abbreviated New Drug Application	us-3-3	fdaat2	anda	No
Abbreviated New Drug Application	us-2-01	anda		No
Abbreviated New Drug Submission	ca-1-0	ANDS		No
Abbreviated New Drug Submission	ca-2-2	ANDS		No
Administrative Submission	ca-1-0	ADMIN		No

Application Type (Display)	Applicable DTD/ Schema	eCTD Code	Agency Abbreviation	Limit to Cross Application Only
Administrative Submission	ca-2-2	ADMIN		No
Biologic License Application	us-3-3	fdaat3	bla	No
Biologic License Application	us-2-01	bla		No
Clinical Trial Application	ca-1-0	CTA		No
Clinical Trial Application	ca-2-2	CTA		No
Drug Identification Number Submission - all types	ca-1-0	DIN		No
Drug Identification Number Submission - all types	ca-2-2	DIN		No
Drug Master File	us-3-3	fdaat5	mf	No
Drug Master File	us-2-01	dmf		No
Drug Master File (master)	us-2-01	master-file		No
Emergency Use Authorization	us-3-3	fdaat6		No
Investigational Device Exemption	us-3-3	fdaat7		Yes
Investigational New Drug	us-3-3	fdaat4	ind	No
Investigational New Drug	us-2-01	ind		No
New Drug Application	us-3-3	fdaat1	nda	No
New Drug Application	us-2-01	nda		No
New Drug Submission	ca-1-0	NDS		No
New Drug Submission	ca-2-2	NDS		No
Notifiable Change	ca-1-0	NC		No
Notifiable Change	ca-2-2	NC		No
Premarket Approval Application	us-3-3	fdaat9		Yes
Premarket Notification 510k	us-3-3	fdaat10		Yes
Safety Issue (FDA Use Only)	us-3-3	fdaat8		No
Supplemental Abbreviated Biologic New Drug Submission	ca-1-0	ABSND		No
Supplemental Abbreviated Biologic New Drug Submission	ca-2-2	ABSND		No
Supplemental Abbreviated New Drug Submission	ca-1-0	SANDS		No

Application Type (Display)	Applicable DTD/ Schema	eCTD Code	Agency Abbreviation	Limit to Cross Application Only
Supplemental Abbreviated New Drug Submission	ca-2-2	SANDS		No
Supplemental New Drug Submission	ca-1-0	SNDS		No
Supplemental New Drug Submission	ca-2-2	SNDS		No
Finished Pharmaceutical Product	who-1-0	FPP		No
Finished Vaccine Product	who-1-0	FVP		No
Active Pharmaceutical Ingredient	who-1-0	APIPQ		No
Active Pharmaceutical Ingredient Master File	who-1-0	APIMF		No
SAHPRA National Procedure	za-3-1	app-type-1		No
REA - AMA Procedure	za-3-1	app-type-2		No
RIA - ZAZIBONA Joint Review	za-3-1	app-type-3		No
RIA - WHO-PQ	za-3-1	app-type-4		No
RIA - WHO-SRA CRP	za-3-1	app-type-5		No
RIA - Swissmedic MAGHP	za-3-1	app-type-6		No
RIA - EU M4ALL	za-3-1	app-type-7		No
Emergency Use Listing	za-3-1	app-type-8		No
REA - Work Sharing - Country	za-3-1	app-type-9		No
Therapeutic Products	sg-1-0	app-type-1		No
ANMPS National Procedure	tn-1-1	app-type-1		No
AMA Procedure	tn-1-1	app-type-2		No
North African Joint Review	tn-1-1	app-type-3		No
WHO PQ CRP	tn-1-1	app-type-4		No
WHO SRA CRP	tn-1-1	app-type-5		No
Reliance	tn-1-1	app-type-6		No
Emergency Use Licensing	tn-1-1	app-type-7		No

eCTD Codes for Procedure Types

Ennov InSight assigned the eCTD code for each procedure type, its associated countries, and internal code.

Procedure Type Abbreviation	Procedure Type Name	Display Name	Countries	Internal Procedure Code	eCTD Code	Active Flag
EAEU MRP	EAEU - Mutual Recognition Procedure	EAEU - Mutual Recognition Procedure	Belarus, Kazakhstan, Russian Federation, Armenia, Kyrgyzstan	MRP	mutualrecognition	Active
EAEU DCP	EAEU Decentralised Procedure	EAEU - Decentralised Procedure	Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russian Federation	DCP	decentralised	Active
EAEU National	EAEU - National	EAEU - National	Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russian Federation	NATIONAL	national	Active
EU - National	EU National	EU National	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European	NATIONAL	national	Active

			Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom, EDQM			
EU CP Bio	EU CP Biotech- nological Process	EU CP Biotech- nological Process	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein,	CP	centralised	Active

			Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom			
EU CP New API	EU CP - New Active Substance	EU CP - New Active Substance	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia,	CP	centralised	Active

			Spain, Sweden, Undefined, United Kingdom			
EU CP Orphan	EU CP - Orphan Medicinal Products	EU CP - Orphan Medicinal Products	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom	CP	centralised	Active
EU CTR	EU CTR - EU Clinical Trial Regulation	EU CTR - EU Clinical Trial Regulation	Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus,	MRP	initial-maa	Active

			Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden			
EU DCP	EU Decen- tralised Pro- cedure	EU Decentralised Procedure	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands,	MRP	decentralised	Active

			Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom			
EU MRP	EU - Mutual Recognition Procedure	EU - Mutual Recognition Procedure	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom	MRP	mutualrecognition	Active
GCC	GCC Procedure	GCC Procedure	Bahrain, Kuwait, Oman, Qatar, Saudi	MRP	GCC	Active

			Arabia, United Arab Emirates, Yemen			
GCC - National	GCC National	National	Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen	NATION AL	national	Active
National	National	National	Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, Brazil, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African Republic, Chad, Chile, China, Christmas Island, Cocos (Keeling) Islands, Colombia, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Cuba, Djibouti, Dominica, Dominican	national	national	Active

Republic, Ecuador, Egypt, El Salvador, Equatorial Guinea, Er- itrea, Ethiopia, Falk- land Islands (Malv- inas), Faroe Islands, Fiji, French Guiana, French Polynesia, French Southern Ter- ritories, Gabon, Gam- bia, Georgia, Ghana, Gibraltar, Greenland, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Heard Is- land and Mcdonald Is- lands, Holy See (Vat- ican City State), Hon- duras, Hong Kong, In- dia, Indonesia, Iran, Is- lamic Republic Of, Iraq, Israel, Jamaica, Jersey, Jordan, Kazakhstan, Kenya, Kiribati, Ko- rea, Democratic Peo- ple's Republic Of, Ko- rea, Republic Of, Kyr- gyzstan, Lao People's Democratic Repub- lic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Macao, North Macedonia, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Maurita- nia, Mauritius, May- otte, Mexico, Microne- sia, Federated States Of, Moldova, Repub-

			lic Of, Monaco, Mon- golia, Montenegro, Montserrat, Morocco, Mozambique, Myan- mar, Namibia, Nauru, Nepal, Netherlands Antilles, New Cale- donia, New Zealand, Nicaragua, Niger, Nige- ria, Niue, Norfolk Is- land, Northern Mari- ana Islands, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Paraguay, Pe- ru, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Sene- gal, Serbia, Serbia and Montenegro, Sey- chelles, Sierra Leone, Singapore, Singapore, Solomon Is- lands, Somalia, South Africa, South Georgia and The South Sandwich Islands, Sri Lanka, Sudan, Suriname, Svalbard and Jan Mayen, Swaziland, Switzerland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Timor-Leste,		

			Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, Undefined, United Republic Of Tanzania, United States Minor Outlying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe			
National CDN	National CDN	National	Canada	NATION AL		Active
JO National	JO National	National	Jordan	NATION AL	national	Active
CN National	CN National	National	China	NATION AL	national	Active
National JP	National JP	National	Japan	NATION AL		Active
National US	National US	National	United States	NATION AL		Active
National ZA	National ZA	National	South Africa	NATION AL	national	Active
EU Herbal	EU Herbal	EU -Traditional use registration for herbal medi- cinal products	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European	MRP		Active

			Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom			
EU Homeo- pathic	EU Homeo- pathic	EU - Simplified registration procedure for homeopathic medicinal prod- ucts	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta,	MRP		Active

			Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom			
National TH	National TH	National	Thailand	NATION AL		Active
National AU	National AU	National	Australia	NATION AL		Active
WAHO CP	WAHO Cen- tralized Pro- cedure	WAHO CP	Benin, Burkina Fa- so, Cabo Verde, Côte d'Ivoire, The Gambia, Ghana, Guinea, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Sene- gal, Sierra Leone, Togo, West African Health Organization	CP	wa	Active

eCTD Codes for Country Values A-C

Ennov InSight assigns the eCTD codes for country values, and their associated authorities and regions.

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
AD	Andorra	N/A	Ministry of Health and Welfare	N/A	N/A	Rest Of World	Active
AE	United Arab Emirates	ae	UAE Ministry of Health	MOH	AE-MOH	Gulf Cooperation Council	Active

AF	Afghanistan	N/A	Ministry of Health	N/A	N/A	Rest Of World	Active
AG	Antigua and Barbuda	N/A	Ministry of Health	N/A	N/A	Rest Of World	Active
AI	Anguilla	N/A	Health Authority of Anguilla	N/A	N/A	Rest Of World	Active
AL	Albania	N/A	N/A	N/A	N/A	Rest Of World	Active
AM	Armenia	am	Ministry of Health of the Republic of Armenia	N/A	N/A	EAEU	Active
AN	Netherlands Antilles	N/A	Department of Public Health and Environmental Protection	N/A	N/A	Rest Of World	Active
AO	Angola	N/A	Ministry of Health	N/A	N/A	Rest Of World	Active
AQ	Antarctica	N/A	N/A	N/A	N/A	Rest Of World	Active
AR	Argentina	N/A	Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica (ANMAT)	ANMAT	N/A	Rest Of World	Active
AS	American Samoa	N/A	N/A	N/A	N/A	Rest Of World	Active
AT	Austria	at	Austrian Federal Office for Safety in Health Care / Austrian Medicines and Medical Devices Agency	BASG	AT-BASG	European Union	Active
AU	Australia	N/A	Therapeutic Goods Administration	TGA	N/A	Australia	Active

AW	Aruba	N/A	N/A	N/A	N/A	Rest Of World	Active
AZ	Azerbaijan	N/A	Ministry of Health	N/A	N/A	Rest Of World	Active
BA	Bosnia and Herzegovina	ba	Agency for medicinal products and medical devices of Bosnia and Herzegovina	ALMBIH	BA-ALMBIH	Bosnia and Herzegovina	Active
BB	Barbados	N/A	Ministry of Health	N/A	N/A	Rest Of World	Active
Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
BD	Bangladesh	N/A	Ministry of Food	N/A	N/A	Rest Of World	Active
BE	Belgium	be	Federal agency for medicines and health products	FAMHP	BE-FAMHP	European Union	Active
BF	Burkina Faso	N/A	Ministry of Health	N/A	N/A	Rest Of World	Active
BG	Bulgaria	bg	Bulgarian Drug Agency	BDA	BG-BDA	European Union	Active
BH	Bahrain	bh	Ministry of Health	MOH	BH-MOH	Gulf Cooperation Council	Active
BI	Burundi	N/A	Ministry of Health	N/A	N/A	Rest Of World	Active
BJ	Benin	N/A	Ministry of Health	N/A	N/A	Rest Of World	Active
BM	Bermuda	N/A	Ministry of Health and Family Services	N/A	N/A	Rest Of World	Active
BN	Brunei Darussalam	N/A	Ministry of Health	N/A	N/A	Rest Of World	Active
BO	Bolivia	N/A	Ministry of Health and Social Welfare	N/A	N/A	Rest Of World	Active
BR	Brazil	N/A	Agencia Nacional de Vigilancia Sanitaria	ANVISA	N/A	Rest Of World	Active

BS	Bahamas	N/A	Ministry of Health Bahamas National Drug Agency	N/A	N/A	Rest Of World	Active
BT	Bhutan	N/A	Ministry of Health	N/A	N/A	Rest Of World	Active
BV	Bouvet Island	N/A	N/A	N/A	N/A	Rest Of World	Active
BW	Botswana	N/A	Ministry of Health	N/A	N/A	Rest Of World	Active
BY	Belarus	by	Ministry of Health of the Republic of Be- larus	N/A	N/A	EAEU	Active
BZ	Belize	N/A	Ministry of Health	N/A	N/A	Rest Of World	Active
CA	Canada	N/A	Health Protection Branch	HPB	HPB	Canada	Active
Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
CC	Cocos (Keeling) Islands	N/A	N/A	N/A	N/A	Rest Of World	Active
CD	Congo, The Democratic Republic Of The	N/A	N/A	N/A	N/A	Rest Of World	Active
CF	Central African Republic	N/A	Ministry of Health	N/A	N/A	Rest Of World	Active
CG	Congo	N/A	N/A	N/A	N/A	Rest Of World	Active
CH	Switzerland	N/A	Swissmedic (Schweizerisches Heilmittelinstitut)	N/A	N/A	Switzerland	Active
CI	Cote D'Ivoire	N/A	N/A	N/A	N/A	Rest Of World	Active

CK	Cook Islands	N/A	N/A	N/A	N/A	Rest Of World	Active
CL	Chile	N/A	Institute of Public Health	N/A	N/A	Rest Of World	Active
CM	Cameroon	N/A	Ministry of Health	N/A	N/A	Rest Of World	Active
CN	China	N/A	National Medical Products Administration	NMPA	N/A	China	Active
CO	Colombia	N/A	Ministry of Health	N/A	N/A	Rest Of World	Active
CR	Costa Rica	N/A	Ministry of Health	N/A	N/A	Rest Of World	Active
CS	Serbia and Montenegro	N/A	N/A	N/A	N/A	Rest Of World	Active
CU	Cuba	N/A	N/A	N/A	N/A	Rest Of World	Active
CV	Cape Verde	N/A	Ministry of Health	N/A	N/A	Rest Of World	Active
CX	Christmas Island	N/A	N/A	N/A	N/A	Rest Of World	Active
CY	Cyprus	cy	Pharmaceutical Services - Ministry of Health	PHS	CY-PHS	European Union	Active
CZ	Czech Republic	cz	State Institute for Drug Control	SUKL	CZ-SUKL	European Union	Active

eCTD Codes for Country Values D-I

Ennov InSight assigns the eCTD codes for country values, and their associated authorities and regions.

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
DE	Germany	DE	BfArM - Federal Institute for Drugs and Medical Devices	BfArM	DE-BFARM	European Union	Active
DJ	Djibouti					Rest Of World	Active
DK	Denmark	DK	Danish Medicines Agency	DKMA	DK-DKMA	European Union	Active
DM	Dominica					Rest Of World	Active

DO	Dominican Re- public		Ministry of Agricul- ture			Rest Of World	Active
DZ	Algeria		Ministère de la Santé			Rest Of World	Active
EC	Ecuador		Ministry of Public Health			Rest Of World	Active
EDQM	EDQM	Edqm	European Directorate for the Quality of Medicines & HealthCare	EDQM	EU-EDQM	European Union	Active

EE	Estonia	EE	State Agency of Medicines	SAM	EE-SAM	European Union	Active
EG	Egypt		Ministry of Agriculture and Land Reclamation			Rest Of World	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
Eh	Western Sahara					Rest Of World	Active
ER	Eritrea					Rest Of World	Active
ES	Spain	ES	Spanish Agency for Medicines and Health Products	AEMPS	ES-AEMPS	European Union	Active
ET	Ethiopia					Rest Of World	Active
EU	European Union	Ema	European Medicines Evaluation Agency	EMA	EU-EMA	European Union	Active
FI	Finland	FI	National Agency for Medicines	NAM	FI-FIMEA	European Union	Active
FJ	Fiji		Ministry of Health			Rest Of World	Active
FK	Falkland Islands (Malvinas)					Rest Of World	Active
FM	Micronesia, Federated					Rest Of World	Active

	States Of						
FO	Faroe Islands					Rest Of World	Active
FR	France	FR	National Agency for the Safety of Medicines and Health Products	ANSM	FR-ANSM	European Union	Active
GA	Gabon					Rest Of World	Active
GB	United King- dom	UK	Medicines and Healthcare products Regulatory Agency	MHRA	UK- MHRA	United King- dom	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
GD	Grenada					Rest Of World	Active
GE	Georgia		Ministry of Labor, Health and Social Protection			Rest Of World	Active
GF	French Guiana					Rest Of World	Active
GH	Ghana		Ministry of Health			Rest Of World	Active
GI	Gibraltar					Rest Of World	Active
GL	Greenland					Rest Of World	Active
GM	Gambia					Rest Of World	Active
GN	Guinea					Rest Of World	Active
GP	Guadeloupe					Rest Of World	Active
GQ	Equatorial Guinea					Rest Of World	Active

GR	Greece	EL	Greek National Organization for Medicines	EOF	EL-EOF	European Union	Active
GS	South Georgia and The South Sandwich Islands					Rest Of World	Active
GT	Guatemala		Ministry of Health			Rest Of World	Active
GU	Guam					Rest Of World	Active
GW	GuineaBissau					Rest Of World	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
GY	Guyana		Ministry of Health National Bureau of Standards			Rest Of World	Active
HK	Hong Kong		Department of Health			Rest Of World	Active
HM	Heard Island and Mcdonald Islands					Rest Of World	Active
HN	Honduras					Rest Of World	Active
HR	Croatia	HR	Agency for Medicinal Products and Medical Devices of	HALMED	HR- HALMED	Croatia	Active

			Croatia				
HT	Haiti					Rest Of World	Active
HU	Hungary	HU	National Institute of Pharmacy and Nutrition	OGYI	HU-OGYI	European Union	Active
ID	Indonesia		Ministry of Health			Rest Of World	Active
IE	Ireland	IE	The Health Products Regulatory Authority	HPRA	IE-HPRA	European Union	Active
IL	Israel		Ministry of Health			Rest Of World	Active
IN	India		Central Drugs Standard Control Organization			Rest Of World	Active
IO	British Indian Ocean Territory					Rest Of World	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
IQ	Iraq					Rest Of World	Active
IR	Iran, Islamic Republic Of					Rest Of World	Active
IS	Iceland	IS	Icelandic Medicines Agency	IMCA	IS-IMCA	European Union	Active
IT	Italy	IT	Italian Medicines	AIFA	IT-AIFA	European Union	Active

			Agency				

eCTD Codes for Country Values J-M

Ennov InSight assigns the eCTD codes for country values, and their associated authorities and regions.

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
JE	Jersey					Rest Of World	Active
JM	Jamaica		Ministry of Health			Rest Of World	Active
JO	Jordan		Ministry of Health			Rest Of World	Active
JP	Japan		Ministry of Health, Labour and Welfare	MHLW	MHLW	Japan	Active
KE	Kenya		Ministry of Health			Rest Of World	Active
KG	Kyrgyzstan	kg	Ministry of Health of the Kyrgyz Republic			EAEU	Active
KH	Cambodia		Ministry of Health			Rest Of World	Active
KI	Kiribati					Rest Of World	Active
KM	Comoros					Rest Of World	Active
KN	Saint Kitts and Nevis					Rest Of World	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
KP	Korea, Democratic People's Republic Of					Rest Of World	Active

KR	Korea, Republic Of		Ministry of Health and Welfare			Rest Of World	Active
KW	Kuwait	kw	Kuwait Ministry of Health	MOH	KW-MOH	Gulf Cooperation Council	Active
KY	Cayman Islands		Ministry of Health			Rest Of World	Active
KZ	Kazakhstan	kz	Ministry of Health of Kazakhstan			EAEU	Active
LA	Lao People's Democratic Republic					Rest Of World	Active
LB	Lebanon		Ministry of Health			Rest Of World	Active
LC	Saint Lucia					Rest Of World	Active
LI	Liechtenstein	li	Office of Health / Department of Pharmaceuticals	LLV	LI-LLV	European Union	Active
LK	Sri Lanka		Ministry of Health, Highways and Social Services			Rest Of World	Active
LR	Liberia					Rest Of World	Active
LS	Lesotho					Rest Of World	Active
LT	Lithuania	lt	State Medicines Control Agency	SMCA	LT-SMCA	European Union	Active

LU	Luxembourg	lu	Ministry of Health	MINSANT	LU- MINSANT	European Union	Active
LV	Latvia	lv	State Agency of Medicines	ZVA	LV-ZVA	European Union	Active
LY	Libyan Arab Jamahiriya					Rest Of World	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
MA	Morocco		Ministry of Public Health			Rest Of World	Active
MC	Monaco					Rest Of World	Active
MD	Moldova, Re- public Of					Rest Of World	Active
ME	Montenegro					Rest Of World	Active
MG	Madagascar					Rest Of World	Active
MH	Marshall Is- lands					Rest Of World	Active
MK	North Macedonia					Rest Of World	Active
ML	Mali		Ministry of Health			Rest Of World	Active
MM	Myanmar					Rest Of World	Active
MN	Mongolia		Ministry of Health and Social Welfare			Rest Of World	Active
MO	Macao					Rest Of World	Active
MP	Northern Mariana Islands					Rest Of World	Active

MQ	Martinique					Rest Of World	Active
MR	Mauritania					Rest Of World	Active
MS	Montserrat					Rest Of World	Active
MT	Malta	mt	Medicines Authority	MRU	MT- MEDAUTH	European Union	Active
MU	Mauritius		Ministry of Health and Quality of Life			Rest Of World	Active
MV	Maldives		Ministry of Health			Rest Of World	Active
MW	Malawi					Rest Of World	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
MX	Mexico		General Directorate for Medicinal Products and Technologies Related to Health			Rest Of World	Active
MY	Malaysia		National Pharmaceutical Control Bureau			Rest Of World	Active
MZ	Mozambique					Rest Of World	Active

eCTD Codes for Country Values N-S

Ennov InSight assigns the eCTD codes for country values, and their associated authorities and regions.

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
NA	Namibia		Ministry of Health and Social Services			Rest Of World	Active
NC	New Caledonia					Rest Of World	Active
NE	Niger					Rest Of World	Active
NF	Norfolk Island					Rest Of World	Active
NG	Nigeria		National Agency for Food and Drug Administration and Control			Rest Of World	Active
NI	Nicaragua		Ministry of Health			Rest Of World	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
NL	Netherlands	nl	Medicines Evaluation Board	MEB	NL-MEB	European Union	Active

NO	Norway	no	Norwegian Medical Products Agency	NOMA	NO-NOMA	European Union	Active
NP	Nepal					Rest Of World	Active
NR	Nauru					Rest Of World	Active
NU	Niue					Rest Of World	Active
NZ	New Zealand		Medicines and Medical De- vices Safety Authority			Rest Of World	Active
OM	Oman	om	Oman Ministry of Health	MOH	OM-MOH	Gulf Cooper- atio n Coun- cil	Active
PA	Panama		Ministry of Health Ministr y of Agricultural Development, Office of Plant Health			Rest Of World	Active
PE	Peru		Ministry of Health Genera l Directorate of			Rest Of World	Active

			Pharmaceu- tic als, Devices and Drugs				

Country Code	Country Name	eCTD Code	Regulatory Au- thority	Authorit y Abbrevia tion	Agency eCTD Code	Region	Active Flag
PF	French Polynesia					Rest Of World	Active
PG	Papua New Guinea		Department of Health			Rest Of World	Active
PH	Philippines		Ministry of Health			Rest Of World	Active
PK	Pakistan					Rest Of World	Active
PL	Poland	pl	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products	URPL	PL-URPL	European Union	Active
PM	Saint Pierre and Miquelon					Rest Of World	Active
PN	Pitcairn					Rest Of World	Active
PR	Puerto Rico					Rest Of World	Active

PS	Palestinian Territory, Occupied		Ministry of Health			Rest Of World	Active
PT	Portugal	pt	National Authority of Medicines and Health Products, IP	INFARMED	PT-INFARMED	European Union	Active
PW	Palau					Rest Of World	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
PY	Paraguay		Ministry of Public Health and Social Welfare			Rest Of World	Active
QA	Qatar	qa	Qatar National Health Authority	NHA	QA-NHA	Gulf Cooperation Council	Active
RE	Reunion					Rest Of World	Active
RO	Romania	ro	National Agency for Medicines and Medical Devices	ANMMD	RO-ANMMD	European Union	Active

RS	Serbia					Rest Of World	Active
RU	Russian Federation	ru	Ministry of Health of the Russian Federation			EAEU	Active
RW	Rwanda					Rest Of World	Active
SA	Saudi Arabia	sa	Saudi Arabia Saudi Food and Drug Authority	SFDA	SA-SFDA	Gulf Cooperation Council	Active
SB	Solomon Islands					Rest Of World	Active
SC	Seychelles					Rest Of World	Active
SD	Sudan					Rest Of World	Active
SE	Sweden	se	Medical Products Agency	MPA	SE-MPA	European Union	Active
SG	Singapore		Health Sciences Authority	HSA	SG-HSA	Singapore	Active

SH	Saint Helena					Rest Of World	Active
SI	Slovenia	si	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia	JAZMP	SI-JAZMP	European Union	Active
SJ	Svalbard and Jan Mayen					Rest Of World	Active
SK	Slovakia	sk	State Institute for Drug Control	SIDC	SK-SIDC	European Union	Active
SL	Sierra Leone					Rest Of World	Active
SM	San Marino		Ministry of Health and Social Security			Rest Of World	Active
SN	Senegal		Ministry of Health, Hygiene and Prevention			Rest Of World	Active
SO	Somalia					Rest Of World	Active

SR	Suriname					Rest Of World	Active
ST	Sao Tome and Principe					Rest Of World	Active
SV	El Salvador		Ministry of Public Health and Social Assistance			Rest Of World	Active
SY	Syrian Arab Republic					Rest Of World	Active
SZ	Swaziland		Ministry of Health and Social Welfare			Rest Of World	Active

eCTD Codes for Country Values T-Z

Ennov InSight assigns the eCTD codes for country values, and their associated authorities and regions.

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
TC	Turks and Caicos Islands					Rest Of World	Active
TD	Chad		Ministry of Health			Rest Of World	Active
TF	French Southern Territories					Rest Of World	Active
TG	Togo					Rest Of World	Active
TH	Thailand	th	Food and Drug Administration			Thailand	Active
TJ	Tajikistan					Rest Of World	Active
TK	Tokelau					Rest Of World	Active

TL	Timor-Leste					Rest Of World	Active
TM	Turkmenistan					Rest Of World	Active
TN	Tunisia		National Agency for Medicines and Health Products	ANMPS	TN-ANMPS	Tunisia	Active
TO	Tonga					Rest Of World	Active
TR	Turkey		Ministry of Health			Rest Of World	Active
TT	Trinidad and Tobago					Rest Of World	Active
TV	Tuvalu					Rest Of World	Active
TW	Taiwan, Province Of China	tw	Taiwan Food and Drug Administration	TFDA		Taiwan	Active
TZ	United Republic Of Tanzania		Ministry of Health			Rest Of World	Active
UA	Ukraine		The State Expert Center of MOH of Ukraine	SECMOH	UA-SECMOH	Ukraine	Active
UG	Uganda		Ministry of Health			Rest Of World	Active
UM	United States Minor Outlying Islands					Rest Of World	Active
UNDEFINED	Undefined					Undefined	Active
US	United States	us	Food and Drug Administration	FDA	FDA	United States	Active
UY	Uruguay		Ministry of Public Health			Rest Of World	Active

UZ	Uzbekistan					Rest Of World	Active
Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
VA	Holy See (Vatican City State)					Rest Of World	Active
VC	Saint Vincent and The Grenadines					Rest Of World	Active
VE	Venezuela		Ministry of Health and Social			Rest Of World	Active

			Development				
VG	British Virgin Islands					Rest Of World	Active
VI	U.S. Virgin Islands					Rest Of World	Active
VN	Vietnam		Ministry of Agriculture and Rural Development			Rest Of World	Active
VU	Vanuatu					Rest Of World	Active
WHO	World Health Organization	whopqt	World Health Organization	WHO	whopqt	World Health Organization	Active
WF	Wallis and Futuna					Rest Of World	Active
WS	Samoa					Rest Of World	Active
YE	Yemen	ye	Republic of Yemen Ministry of Public Health and Population	MOPHP	YE- MOPHP	Gulf Cooperation Council	Active
YT	Mayotte					Rest Of World	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
ZA	South Africa	za	South African Health Products Regulatory	SAHPRA	ZA- SAHPRA	South Africa	Active

			Authority				
ZM	Zambia					Rest Of World	Active
ZW	Zimbabwe		Ministry of Health and Child Welfare			Rest Of World	Active

eCTD Codes for Filing Types

Filing Type Values are maintained in the Sequence Maintenance section in Ennov InSight Data Administration.

eCTD codes and their values can be maintained by your system administrator using the Ennov InSight Data Administration interface. To accommodate changes or additions to the eCTD codes, we recommend that you review and update your eCTD codes periodically, and particularly after performing an upgrade from a previous Ennov InSight version.

The referenced eCTD Filing Types tables list the eCTD values, the applicable DTD or Schema, and the available Application Types for the Filing Types available for each region.

eCTD Filing Types for AU

Ennov InSight provides the following filing types for all application types associated with Australia (AU).

AU v0.90

This table list the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Type
A - NCE New Chemical Entity	au-0-90	seq-type-1	CTA, NDA
A - NCE New Salt or Ester of Existing Active Ingredient	au-0-90	seq-type-2	CTA, NDA
A - NCE Similar Biological Medicinal Product	au-0-90	seq-type-3	CTA, NDA
B - New Combination	au-0-90	seq-type-4	CTA, NDA
C - Extension of Indication	au-0-90	seq-type-5	CTA, NDA
D - New Generic Medicine	au-0-90	seq-type-6	CTA, NDA
E - Additional Tradename	au-0-90	seq-type-7	CTA, NDA
F - Major Variation - New Strength	au-0-90	seq-type-8	CTA, NDA
F - Major Variation - New Dosage Form	au-0-90	seq-type-9	CTA, NDA
F - Major Variation - New Route of Administration	au-0-90	seq-type-10	CTA, NDA

F - Major Variation - Change in Patient Group	au-0-90	seq-type-11	CTA, NDA
F - Major Variation - Change of Dosage	au-0-90	seq-type-12	CTA, NDA
G - Minor Variation, New Register Entry Change of Formulation	au-0-90	seq-type-13	CTA, NDA
G - Minor Variation, New Register Entry New Container Type	au-0-90	seq-type-14	CTA, NDA
Change of Tradename	au-0-90	seq-type-15	CTA, NDA
H - Minor Variation, Not Resulting in a New Register Entry	au-0-90	seq-type-16	CTA, NDA
J - PI Change requiring evaluation	au-0-90	seq-type-17	CTA, NDA
K - PI Change without Data	au-0-90	seq-type-18	CTA, NDA
Rolling Review	au-0-90	seq-type-19	CTA, NDA
OTC - N1	au-0-90	seq-type-20	CTA, NDA
OTC - N2	au-0-90	seq-type-21	CTA, NDA
OTC - N3	au-0-90	seq-type-22	CTA, NDA
OTC - N4	au-0-90	seq-type-23	CTA, NDA
OTC - N5	au-0-90	seq-type-24	CTA, NDA
OTC - C1	au-0-90	seq-type-25	CTA, NDA
OTC - C2	au-0-90	seq-type-26	CTA, NDA
OTC - C3	au-0-90	seq-type-27	CTA, NDA
OTC - C4	au-0-90	seq-type-28	CTA, NDA
OTC - New Active Ingredient	au-0-90	seq-type-29	CTA, NDA
Ingredient - New	au-0-90	seq-type-30	CTA, NDA
Ingredient - Variation	au-0-90	seq-type-31	CTA, NDA
Complementary Medicine - New	au-0-90	seq-type-32	CTA, NDA
Complementary Medicine - Variation	au-0-90	seq-type-33	CTA, NDA
Biologicals - Class 1	au-0-90	seq-type-34	CTA, NDA
Biologicals - Class 2	au-0-90	seq-type-35	CTA, NDA
Biologicals - Class 3	au-0-90	seq-type-36	CTA, NDA
Biologicals - Class 4	au-0-90	seq-type-37	CTA, NDA
Biologicals - Variation	au-0-90	seq-type-38	CTA, NDA
Medical Devices	au-0-90	seq-type-39	CTA, NDA

ASMF / DMF	au-0-90	seq-type-40	CTA, NDA
Plasma Master File (PMF)	au-0-90	seq-type-41	CTA, NDA
Tissue Master File (TMF)	au-0-90	seq-type-42	CTA, NDA
Biological Master File (BMF)	au-0-90	seq-type-43	CTA, NDA
Pharmacovigilance	au-0-90	seq-type-44	CTA, NDA
Supplementary information	au-0-90	seq-type-45	CTA, NDA
Baseline	au-0-90	seq-type-46	CTA, NDA
Periodic Safety Update Report	au-0-90	seq-type-47	CTA, NDA
Risk Management Plan	au-0-90	seq-type-48	CTA, NDA
Clinical Trial Application	au-0-90	seq-type-49	CTA, NDA
Pre-Submission Meeting Documentation	au-0-90	seq-type-50	CTA, NDA
Pre-Submission Planning Form	au-0-90	seq-type-51	CTA, NDA
Undefined Regulatory Activity*	au-0-90	seq-type-52	CTA, NDA

AU v3.0

This table list the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Type
A - NCE New Chemical Entity	au-3-0	seq-type-1	CTA, NDA
A - NCE New Salt or Ester of Existing Active Ingredient	au-3-0	seq-type-2	CTA, NDA
A - NCE Similar Biological Medicinal Product	au-3-0	seq-type-3	CTA, NDA
B - New Combination	au-3-0	seq-type-4	CTA, NDA
C - Extension of Indication	au-3-0	seq-type-5	CTA, NDA
D - New Generic Medicine	au-3-0	seq-type-6	CTA, NDA
E - Additional Tradename	au-3-0	seq-type-7	CTA, NDA
F - Major Variation - New Strength	au-3-0	seq-type-8	CTA, NDA
F - Major Variation - New Dosage Form	au-3-0	seq-type-9	CTA, NDA
F - Major Variation - New Route of Administration	au-3-0	seq-type-10	CTA, NDA
F - Major Variation - Change in Patient Group	au-3-0	seq-type-11	CTA, NDA
F - Major Variation - Change of Dosage	au-3-0	seq-type-12	CTA, NDA

G - Minor Variation, New Register Entry Change of Formulation	au-3-0	seq-type-13	CTA, NDA
G - Minor Variation, New Register Entry New Container Type	au-3-0	seq-type-14	CTA, NDA
Change of Tradename	au-3-0	seq-type-15	CTA, NDA
H - Minor Variation, Not Resulting in a New Register Entry	au-3-0	seq-type-16	CTA, NDA
J - PI Change requiring evaluation	au-3-0	seq-type-17	CTA, NDA
OTC - N1	au-3-0	seq-type-20	CTA, NDA
OTC - N2	au-3-0	seq-type-21	CTA, NDA
OTC - N3	au-3-0	seq-type-22	CTA, NDA
OTC - N4	au-3-0	seq-type-23	CTA, NDA
OTC - N5	au-3-0	seq-type-24	CTA, NDA
OTC - C1	au-3-0	seq-type-25	CTA, NDA
OTC - C2	au-3-0	seq-type-26	CTA, NDA
OTC - C3	au-3-0	seq-type-27	CTA, NDA
OTC - C4	au-3-0	seq-type-28	CTA, NDA
Ingredient - New	au-3-0	seq-type-30	CTA, NDA
Ingredient - Variation	au-3-0	seq-type-31	CTA, NDA
Complementary Medicine - New	au-3-0	seq-type-32	CTA, NDA
Complementary Medicine - Variation	au-3-0	seq-type-33	CTA, NDA
Biologicals - Class 1	au-3-0	seq-type-34	CTA, NDA
Biologicals - Class 2	au-3-0	seq-type-35	CTA, NDA
Biologicals - Class 3	au-3-0	seq-type-36	CTA, NDA
Biologicals - Class 4	au-3-0	seq-type-37	CTA, NDA
Biologicals - Variation	au-3-0	seq-type-38	CTA, NDA
ASMF / DMF	au-3-0	seq-type-40	CTA, NDA
Plasma Master File (PMF)	au-3-0	seq-type-41	CTA, NDA
Tissue Master File (TMF)	au-3-0	seq-type-42	CTA, NDA
Biological Master File (BMF)	au-3-0	seq-type-43	CTA, NDA
Pharmacovigilance	au-3-0	seq-type-44	CTA, NDA
Supplementary information	au-3-0	seq-type-45	CTA, NDA
Baseline	au-3-0	seq-type-46	CTA, NDA
Periodic Safety Update Report	au-3-0	seq-type-47	CTA, NDA

Risk Management Plan	au-3-0	seq-type-48	CTA, NDA
Clinical Trial Application	au-3-0	seq-type-49	CTA, NDA
Undefined Regulatory Activity*	au-3-0	seq-type-52	CTA, NDA
9D(1) - Correction of Register Entry	au-3-0	seq-type-53	CTA, NDA
9D(2) - Safety Related Request	au-3-0	seq-type-54	CTA, NDA
9D(3) - Change to PI (not J)	au-3-0	seq-type-55	CTA, NDA
Change of Sponsor	au-3-0	seq-type-56	CTA, NDA
Withdrawal	au-3-0	seq-type-57	CTA, NDA

AU v3.1

This table list the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Type
A - NCE New Chemical Entity	au-3-1	seq-type-1	CTA, NDA
A - NCE New Salt or Ester of Existing Active Ingredient	au-3-1	seq-type-2	CTA, NDA
A - NCE Similar Biological Medicinal Product	au-3-1	seq-type-3	CTA, NDA
B - New Combination	au-3-1	seq-type-4	CTA, NDA
C - Extension of Indication	au-3-1	seq-type-5	CTA, NDA
D - New Generic Medicine	au-3-1	seq-type-6	CTA, NDA
E - Additional Tradename	au-3-1	seq-type-7	CTA, NDA
F - Major Variation - New Strength	au-3-1	seq-type-8	CTA, NDA
F - Major Variation - New Dosage Form	au-3-1	seq-type-9	CTA, NDA
F - Major Variation - New Route of Administration	au-3-1	seq-type-10	CTA, NDA
F - Major Variation - Change in Patient Group	au-3-1	seq-type-11	CTA, NDA
F - Major Variation - Change of Dosage	au-3-1	seq-type-12	CTA, NDA
G - Minor Variation, New Register Entry Change of Formulation	au-3-1	seq-type-13	CTA, NDA
G - Minor Variation, New Register Entry New Container Type	au-3-1	seq-type-14	CTA, NDA
Change of Tradename	au-3-1	seq-type-15	CTA, NDA
H - Minor Variation, Not Resulting in a New Register Entry	au-3-1	seq-type-16	CTA, NDA

J - PI Change requiring evaluation	au-3-1	seq-type-17	CTA, NDA
OTC - N1	au-3-1	seq-type-20	CTA, NDA
OTC - N2	au-3-1	seq-type-21	CTA, NDA
OTC - N3	au-3-1	seq-type-22	CTA, NDA
OTC - N4	au-3-1	seq-type-23	CTA, NDA
OTC - N5	au-3-1	seq-type-24	CTA, NDA
OTC - C1	au-3-1	seq-type-25	CTA, NDA
OTC - C2	au-3-1	seq-type-26	CTA, NDA
OTC - C3	au-3-1	seq-type-27	CTA, NDA
OTC - C4	au-3-1	seq-type-28	CTA, NDA
Ingredient - New	au-3-1	seq-type-30	CTA, NDA
Ingredient - Variation	au-3-1	seq-type-31	CTA, NDA
Complementary Medicine - New	au-3-1	seq-type-32	CTA, NDA
Complementary Medicine - Variation	au-3-1	seq-type-33	CTA, NDA
Biologicals - Class 1	au-3-1	seq-type-34	CTA, NDA
Biologicals - Class 2	au-3-1	seq-type-35	CTA, NDA
Biologicals - Class 3	au-3-1	seq-type-36	CTA, NDA
Biologicals - Class 4	au-3-1	seq-type-37	CTA, NDA
Biologicals - Variation	au-3-1	seq-type-38	CTA, NDA
ASMF / DMF	au-3-1	seq-type-40	CTA, NDA
Plasma Master File (PMF)	au-3-1	seq-type-41	CTA, NDA
Tissue Master File (TMF)	au-3-1	seq-type-42	CTA, NDA
Biological Master File (BMF)	au-3-1	seq-type-43	CTA, NDA
Pharmacovigilance	au-3-1	seq-type-44	CTA, NDA
Supplementary information	au-3-1	seq-type-45	CTA, NDA
Baseline	au-3-1	seq-type-46	CTA, NDA
Periodic Safety Update Report	au-3-1	seq-type-47	CTA, NDA
Risk Management Plan	au-3-1	seq-type-48	CTA, NDA
Clinical Trial Application	au-3-1	seq-type-49	CTA, NDA
Undefined Regulatory Activity*	au-3-1	seq-type-52	CTA, NDA
9D(1) - Correction of Register Entry	au-3-1	seq-type-53	CTA, NDA
9D(2) - Safety Related Request	au-3-1	seq-type-54	CTA, NDA

9D(3) - Change to PI (not J)	au-3-1	seq-type-55	CTA, NDA
Change of Sponsor	au-3-1	seq-type-56	CTA, NDA
Product Withdrawal	au-3-1	seq-type-57	CTA, NDA
Provisional registration - TGA initiated variation	au-3-1	seq-type-58	CTA, NDA
Notification	au-3-1	seq-type-59	CTA, NDA
CN	au-3-1	seq-type-60	CTA, NDA
Extension of provisional registration	au-3-1	seq-type-61	CTA, NDA
Duplicate	au-3-1	seq-type-62	CTA, NDA

AU v3.2

This table lists the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Type
New Entity	au-3-2	seq-type-1	CTA, NDA
Similar Biological Medicinal Product	au-3-2	seq-type-3	CTA, NDA
New Combination	au-3-2	seq-type-4	CTA, NDA
Extension of Indication	au-3-2	seq-type-5	CTA, NDA
New Generic Medicine	au-3-2	seq-type-6	CTA, NDA
Major Variation	au-3-2	seq-type-8	CTA, NDA
PI Change requiring evaluation	au-3-2	seq-type-17	CTA, NDA
Minor Variation (Cat 1)	au-3-2	seq-type-13	CTA, NDA
Additional Tradename	au-3-2	seq-type-7	CTA, NDA
Change of Tradename	au-3-2	seq-type-15	CTA, NDA
Correction of Register Entry	au-3-2	seq-type-53	CTA, NDA
Safety Related Request/Variation	au-3-2	seq-type-54	CTA, NDA
Self Assessable Request/Variation	au-3-2	seq-type-55	CTA, NDA
Notification	au-3-2	seq-type-59	CTA, NDA
OTC - New - 1	au-3-2	seq-type-20	CTA, NDA
OTC - New - 2	au-3-2	seq-type-21	CTA, NDA

OTC - New - 3	au-3-2	seq-type-22	CTA, NDA
OTC - New - 4	au-3-2	seq-type-23	CTA, NDA
OTC - New - 5	au-3-2	seq-type-24	CTA, NDA
OTC - Change - 1	au-3-2	seq-type-25	CTA, NDA
OTC - Change - 2	au-3-2	seq-type-26	CTA, NDA
OTC - Change - 3	au-3-2	seq-type-27	CTA, NDA
OTC - Change - 4	au-3-2	seq-type-28	CTA, NDA
Ingredient - New	au-3-2	seq-type-30	CTA, NDA
Ingredient - Variation	au-3-2	seq-type-31	CTA, NDA
Complementary Medicine - New	au-3-2	seq-type-32	CTA, NDA
Complementary Medicine - Variation	au-3-2	seq-type-33	CTA, NDA
Biologicals - Class 1	au-3-2	seq-type-34	CTA, NDA
Biologicals - Class 2	au-3-2	seq-type-35	CTA, NDA
Biologicals - Class 3	au-3-2	seq-type-36	CTA, NDA
Biologicals - Class 4	au-3-2	seq-type-37	CTA, NDA
Biologicals - Variation	au-3-2	seq-type-38	CTA, NDA
ASMF / DMF	au-3-2	seq-type-40	CTA, NDA
Plasma Master File (PMF)	au-3-2	seq-type-41	CTA, NDA
Tissue Master File (TMF)	au-3-2	seq-type-42	CTA, NDA
Biological Master File (BMF)	au-3-2	seq-type-43	CTA, NDA
Vigilance	au-3-2	seq-type-44	CTA, NDA
Extension of provisional registration	au-3-2	seq-type-61	CTA, NDA
Supplementary information	au-3-2	seq-type-45	CTA, NDA
Baseline	au-3-2	seq-type-46	CTA, NDA
Clinical Trial Application	au-3-2	seq-type-49	CTA, NDA
Product Withdrawal	au-3-2	seq-type-57	CTA, NDA
Undefined Regulatory Activity*	au-3-2	seq-type-52	CTA, NDA
Minor Variation (Cat 3)	au-3-2	seq-type-63	CTA, NDA

Minor Editorial Change (MEC)	au-3-2	seq-type-64	CTA, NDA
Generic extension of indications	au-3-2	seq-type-65	CTA, NDA
Pre-Advice	au-3-2	seq-type-66	CTA, NDA
Designation / Determination	au-3-2	seq-type-67	CTA, NDA
S14/14A	au-3-2	seq-type-68	CTA, NDA
Post-requirement or Administrative	au-3-2	seq-type-69	CTA, NDA
RCM - New - 1	au-3-2	seq-type-70	CTA, NDA
RCM - New - 2	au-3-2	seq-type-71	CTA, NDA
RCM - New - 3	au-3-2	seq-type-72	CTA, NDA
RCM - New - 4	au-3-2	seq-type-73	CTA, NDA
RCM - New - 5	au-3-2	seq-type-74	CTA, NDA
RCM - Change - 1	au-3-2	seq-type-75	CTA, NDA
RCM - Change - 2	au-3-2	seq-type-76	CTA, NDA
RCM - Change - 3	au-3-2	seq-type-77	CTA, NDA
RCM - Change - 4	au-3-2	seq-type-78	CTA, NDA
Transition to full registration	au-3-2	seq-type-79	CTA, NDA

eCTD Filing Types for BA

Ennov InSight provides the following filing types for all application types associated with Bosnia and Herzegovina. This table lists the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Type
Marketing Authorisation Application	ba-3-1	maa	CTA, NDA
Variation 1A Filing	ba-3-1	var-type1a	CTA, NDA
Variation 1AIN Filing	ba-3-1	var-type1ain	CTA, NDA
Variation 1B Filing	ba-3-1	var-type1b	CTA, NDA
Variation 2 Filing	ba-3-1	var-type2	CTA, NDA
National Variation Filing	ba-3-1	var-nat	CTA, NDA
Extension Filing	ba-3-1	extension	CTA, NDA
Repeat Use Procedure	ba-3-1	rup	CTA, NDA
Periodic Safety Update Report	ba-3-1	psur	CTA, NDA

PSUR single assessment procedure	ba-3-1	psusa	CTA, NDA
Risk Management Plan Filing	ba-3-1	rmp	CTA, NDA
Renewal Filing	ba-3-1	renewal	CTA, NDA
Specific Obligation Related to PAM	ba-3-1	pam-sob	CTA, NDA
Annex II Condition Related to PAM	ba-3-1	pam-anx	CTA, NDA
Additional PV Activity in the RMP Related to PAM	ba-3-1	pam-mea	CTA, NDA
Legally Binding Measure Related to PAM	ba-3-1	pam-leg	CTA, NDA
SDA Submission Related to PAM	ba-3-1	pam-sda	CTA, NDA
Corrective/Preventive Action Related to PAM	ba-3-1	pam-capa	CTA, NDA
Paediatric Submission Related to PAM (Article 45)	ba-3-1	pam-p45	CTA, NDA
Paediatric Submission Related to PAM (Article 46)	ba-3-1	pam-p46	CTA, NDA
PAES Submission Related to PAM	ba-3-1	pam-paes	CTA, NDA
Recommendation Related to PAM	ba-3-1	pam-rec	CTA, NDA
PASS Protocol Submission (Article 107n)	ba-3-1	pass107n	CTA, NDA
PASS Report Submission (Article 107q)	ba-3-1	pass107q	CTA, NDA
ASMF Filing	ba-3-1	asmf	CTA, NDA
Plasma Master File	ba-3-1	pmf	CTA, NDA
Article 20 Referral	ba-3-1	referral-20	CTA, NDA
Article 29(4) Referral	ba-3-1	referral-294	CTA, NDA
Article 29 Paediatric Referral	ba-3-1	referral-29p	CTA, NDA
Article 30 Referral	ba-3-1	referral-30	CTA, NDA
Article 31 Referral	ba-3-1	referral-31	CTA, NDA
Article 35 Referral	ba-3-1	referral-35	CTA, NDA
Article 5(3) Referral	ba-3-1	referral-5-3	CTA, NDA
Article 107i Referral	ba-3-1	referral-107i	CTA, NDA
Article 16c (1c)i Referral	ba-3-1	referral-16c1c	CTA, NDA
Article 16c(4) Referral	ba-3-1	referral-16c4	CTA, NDA
Annual Reassessment Filing	ba-3-1	annual-reassessme nt	CTA, NDA
USR Filing	ba-3-1	usr	CTA, NDA
Clinical Data for Publication – Redacted Proposal	ba-3-1	clin-data- pub-rp	CTA, NDA
Clinical Data for Publication – Final Version	ba-3-1	clin-data- pub-fv	CTA, NDA

PAED Related to PIP (Article 7, 8, 30)	ba-3-1	paed-7-8-30	CTA, NDA
PAED Article 29 Filing	ba-3-1	paed-29	CTA, NDA
PAED Article 45	ba-3-1	paed-45	CTA, NDA
PAED Article 46	ba-3-1	paed-46	CTA, NDA
Article 58 Filing	ba-3-1	article-58	CTA, NDA
Notification 61-3 Filing	ba-3-1	notification-61-3	CTA, NDA
Transfer MA Filing	ba-3-1	transfer-ma	CTA, NDA
Lifting Suspension Filing	ba-3-1	lifting-suspension	CTA, NDA
Withdrawal Filing	ba-3-1	withdrawal	CTA, NDA
CEP Submission	ba-3-1	cep	CTA, NDA
None	ba-3-1	none	CTA, NDA
Article 18 Filing	ba-3-1	article-18	CTA, NDA

eCTD Sub-Filing Types for BA

The list of eCTD code and the applicable Sub-Filing Type for each Filing Type.

The Sub-Filing Type values are available to select in the *Sub Filing Type Values* section of *Submission Maintenance* Data Administration List.

Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Initial	ba-3-1	initial	Marketing Authorisation Application, Variation 1A Filing, Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED

			Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Validation Response	ba-3-1	validation-response	Marketing Authorisation Application, Variation 1A Filing, Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Response	ba-3-1	response	Marketing Authorisation Application, Variation 1A Filing, Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting

			Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Additional Information	ba-3-1	additional-info	Marketing Authorisation Application, Variation 1A Filing, Variation 1A IN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Closing Information	ba-3-1	closing	Marketing Authorisation Application, Variation 1A Filing, Variation 1A IN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing

Consolidating	ba-3-1	consolidating	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Corrigendum	ba-3-1	corrigendum	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Reformat	ba-3-1	reformat	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing,

			Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Re-examination	ba-3-1	re-examination	Marketing Authorisation Application, Variation 1A Filing, Variation 1A IN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing

eCTD Filing Types for CH

Ennov InSight provides the following filing types for all application types associated with Switzerland (CH). This table lists the eCTD code and the applicable DTD or Schema for each Filing Type

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Application for 5 years Data Protec- tion	ch-1-0-1	eas	CTA, MAA, MAA-AH
Co-Marketing Medicinal Product	ch-1-0-1	co-marketing	CTA, MAA, MAA-AH
Corrigendum Filing	ch-1-0-1	corrigendum	CTA, MAA, MAA-AH
DMF Filing	ch-1-0-1	dmf	CTA, MAA, MAA-AH
Generics	ch-1-0-1	na-gen	CTA, MAA, MAA-AH
Known Active Substance	ch-1-0-1	na-bws	CTA, MAA, MAA-AH

New Active Substance	ch-1-0-1	na-nas	CTA, MAA, MAA-AH
New Combination	ch-1-0-1	na-nko	CTA, MAA, MAA-AH
New Dosage Recommendation	ch-1-0-1	na-nde	CTA, MAA, MAA-AH
New Dosage Strength	ch-1-0-1	na-ndo	CTA, MAA, MAA-AH
New Galenic Form	ch-1-0-1	na-gen	CTA, MAA, MAA-AH
New Indication	ch-1-0-1	na-ie	CTA, MAA, MAA-AH
Parallel Import	ch-1-0-1	pi	CTA, MAA, MAA-AH
Periodic Safety Update Report	ch-1-0-1	psur	CTA, MAA, MAA-AH
Plasma Master File	ch-1-0-1	pmf	CTA, MAA, MAA-AH
Reformat Filing	ch-1-0-1	reformat	CTA, MAA, MAA-AH
Renewal Filing	ch-1-0-1	renewal	CTA, MAA, MAA-AH
Supplement Filing	ch-1-0-1	supplemental-info	CTA, MAA, MAA-AH
Transfer MA Filing	ch-1-0-1	transfer	CTA, MAA, MAA-AH

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Variation Requiring Product Information Authorisation	ch-1-0-1	var-pi	CTA, MAA, MAA-AH
Variation Requiring Scientific Review	ch-1-0-1	var-authorisationscientific	CTA, MAA, MAA-AH
Variation with Notification	ch-1-0-1	notification	CTA, MAA, MAA-AH
Variation without Scientific Review	ch-1-0-1	var-authorisationadmin	CTA, MAA, MAA-AH
Withdrawal Filing	ch-1-0-1	withdrawal	CTA, MAA, MAA-AH
Application for 5 years Data Protection	ch-1-1	eas	CTA, MAA, MAA-AH

Co-Marketing Medicinal Product	ch-1-1	co-marketing	CTA, MAA, MAA-AH
Corrigendum Filing	ch-1-1	corrigendum	CTA, MAA, MAA-AH
DMF Filing	ch-1-1	dmf	CTA, MAA, MAA-AH
Generics	ch-1-1	na-gen	CTA, MAA, MAA-AH
Known Active Substance	ch-1-1	na-bws	CTA, MAA, MAA-AH
New Active Substance	ch-1-1	na-nas	CTA, MAA, MAA-AH
New Combination	ch-1-1	na-nko	CTA, MAA, MAA-AH
New Dosage Recommendation	ch-1-1	na-nde	CTA, MAA, MAA-AH
New Dosage Strength	ch-1-1	na-ndo	CTA, MAA, MAA-AH
New Galenic Form	ch-1-1	na-gen	CTA, MAA, MAA-AH
New Indication	ch-1-1	na-ie	CTA, MAA, MAA-AH
Parallel Import	ch-1-1	pi	CTA, MAA, MAA-AH
Periodic Safety Update Report	ch-1-1	psur	CTA, MAA, MAA-AH
Plasma Master File	ch-1-1	pmf	CTA, MAA, MAA-AH
Reformat Filing	ch-1-1	reformat	CTA, MAA, MAA-AH
Renewal Filing	ch-1-1	renewal	CTA, MAA, MAA-AH
Supplement Filing	ch-1-1	supplemental-info	CTA, MAA, MAA-AH
Transfer MA Filing	ch-1-1	transfer	CTA, MAA, MAA-AH

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Variation Requiring Product Information Authorisation	ch-1-1	var-pi	CTA, MAA, MAA-AH
Variation Requiring Scientific Review	ch-1-1	var-authorisationscientific	CTA, MAA, MAA-AH
Variation with Notification	ch-1-1	notification	CTA, MAA, MAA-AH

Variation without Scientific Review	ch-1-1	var-authorisationadmin	CTA, MAA, MAA-AH
Withdrawal Filing	ch-1-1	withdrawal	CTA, MAA, MAA-AH
Application for 5 years Data Protection	ch-1-2	eas	CTA, MAA, MAA-AH
Co-Marketing Medicinal Product	ch-1-2	co-marketing	CTA, MAA, MAA-AH
Corrigendum Filing	ch-1-2	corrigendum	CTA, MAA, MAA-AH
DMF Filing	ch-1-2	dmf	CTA, MAA, MAA-AH
Generics	ch-1-2	na-gen	CTA, MAA, MAA-AH
Known Active Substance	ch-1-2	na-bws	CTA, MAA, MAA-AH
New Active Substance	ch-1-2	na-nas	CTA, MAA, MAA-AH
New Combination	ch-1-2	na-nko	CTA, MAA, MAA-AH
New Dosage Recommendation	ch-1-2	na-nde	CTA, MAA, MAA-AH
New Dosage Strength	ch-1-2	na-ndo	CTA, MAA, MAA-AH
New Galenic Form	ch-1-2	na-gen	CTA, MAA, MAA-AH
New Indication	ch-1-2	na-ie	CTA, MAA, MAA-AH
Orphan Fast Track Filing	ch-1-2	orphan-fasttrack	CTA, MAA, MAA-AH
Parallel Import	ch-1-2	pi	CTA, MAA, MAA-AH
Periodic Safety Update Report	ch-1-2	psur	CTA, MAA, MAA-AH
Plasma Master File	ch-1-2	pmf	CTA, MAA, MAA-AH
Reformat Filing	ch-1-2	reformat	CTA, MAA, MAA-AH
Renewal Filing	ch-1-2	renewal	CTA, MAA, MAA-AH
Supplement Filing	ch-1-2	supplemental-info	CTA, MAA, MAA-AH
Transfer MA Filing	ch-1-2	transfer	CTA, MAA, MAA-AH
Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application

			Types
Variation Requiring Product Information Authorisation	ch-1-2	var-pi	CTA, MAA, MAA-AH
Variation Requiring Scientific Review	ch-1-2	var-authorisationscientific	CTA, MAA, MAA-AH
Variation with Notification	ch-1-2	notification	CTA, MAA, MAA-AH
Variation without Scientific Review	ch-1-2	var-authorisationadmin	CTA, MAA, MAA-AH
Withdrawal Filing	ch-1-2	withdrawal	CTA, MAA, MAA-AH
Application for 5 years Data Protection	ch-1-3	eas	CTA, MAA, MAA-AH
Co-Marketing Medicinal Product	ch-1-3	co-marketing	CTA, MAA, MAA-AH
Corrigendum Filing	ch-1-3	corrigendum	CTA, MAA, MAA-AH
DMF Filing	ch-1-3	dmf	CTA, MAA, MAA-AH
Follow-up Measures	ch-1-3	fum	CTA, MAA, MAA-AH
Known Active Substance	ch-1-3	na-bws	CTA, MAA, MAA-AH
New Active Substance	ch-1-3	na-nas	CTA, MAA, MAA-AH
New Combination	ch-1-3	na-nko	CTA, MAA, MAA-AH
New Dosage Recommendation	ch-1-3	na-nde	CTA, MAA, MAA-AH
New Dosage Strength	ch-1-3	na-ndo	CTA, MAA, MAA-AH
New Galenic Form	ch-1-3	na-ngf	CTA, MAA, MAA-AH
New Indication	ch-1-3	na-ie	CTA, MAA, MAA-AH
Orphan Fast Track Filing	ch-1-3	orphan-fasttrack	CTA, MAA, MAA-AH
Parallel Import	ch-1-3	pi	CTA, MAA, MAA-AH
Periodic Safety Update Report	ch-1-3	psur	CTA, MAA, MAA-AH
Plasma Master File	ch-1-3	pmf	CTA, MAA, MAA-AH

Reformat Filing	ch-1-3	reformat	CTA, MAA, MAA-AH
Renewal Filing	ch-1-3	renewal	CTA, MAA, MAA-AH
Supplement Filing	ch-1-3	supplemental-info	CTA, MAA, MAA-AH
Transfer MA Filing	ch-1-3	transfer	CTA, MAA, MAA-AH

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Variation Requiring Product Information Authorisation	ch-1-3	var-pi	CTA, MAA, MAA-AH
Variation Requiring Scientific Review	ch-1-3	var-authorisationscientific	CTA, MAA, MAA-AH
Variation with Notification	ch-1-3	notification	CTA, MAA, MAA-AH
Variation without Scientific Review	ch-1-3	var-authorisationadmin	CTA, MAA, MAA-AH
Withdrawal Filing	ch-1-3	withdrawal	CTA, MAA, MAA-AH
Application for 5 years Data Protection	ch-1-4	eas	CTA, MAA, MAA-AH
Co-Marketing Medicinal Product	ch-1-4	co-marketing	CTA, MAA, MAA-AH
Corrigendum Filing	ch-1-4	corrigendum	CTA, MAA, MAA-AH
DMF Filing	ch-1-4	dmf	CTA, MAA, MAA-AH
Follow-up Measures	ch-1-4	fum	CTA, MAA, MAA-AH
Known Active Substance	ch-1-4	na-bws	CTA, MAA, MAA-AH
New Active Substance	ch-1-4	na-nas	CTA, MAA, MAA-AH
Orphan Fast Track Filing	ch-1-4	orphan-fasttrack	CTA, MAA, MAA-AH
Parallel Import	ch-1-4	pi	CTA, MAA, MAA-AH
Periodic Safety Update Report	ch-1-4	psur	CTA, MAA, MAA-AH
Plasma Master File	ch-1-4	pmf	CTA, MAA, MAA-AH
Reformat Filing	ch-1-4	reformat	CTA, MAA, MAA-AH

Renewal Filing	ch-1-4	renewal	CTA, MAA, MAA-AH
Supplement Filing	ch-1-4	supplemental-info	CTA, MAA, MAA-AH
Transfer MA Filing	ch-1-4	transfer	CTA, MAA, MAA-AH
Variation Requiring Product Information Authorisation	ch-1-4	var-pi	CTA, MAA, MAA-AH
Withdrawal Filing	ch-1-4	withdrawal	CTA, MAA, MAA-AH
Used for Meeting	ch-1-4	advice	CTA, MAA, MAA-AH
New Application - CoMarketing	ch-1-4	na-co-marketing	CTA, MAA, MAA-AH

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
New Application - Parallel Import	ch-1-4	na-pi	CTA, MAA, MAA-AH
Variation 1A Filing	ch-1-4	var-type1a	CTA, MAA, MAA-AH
Variation 1AIN Filing	ch-1-4	var-type1ain	CTA, MAA, MAA-AH
Variation 1B Filing	ch-1-4	var-type1b	CTA, MAA, MAA-AH
Variation 2 Filing	ch-1-4	var-type2	CTA, MAA, MAA-AH
Extension Filing	ch-1-4	extension	CTA, MAA, MAA-AH
Corrigendum Filing	ch-1-5	corrigendum	CTA, MAA, MAA-AH
DMF Filing	ch-1-5	dmf	CTA, MAA, MAA-AH
Follow-up Measures	ch-1-5	fum	CTA, MAA, MAA-AH
Known Active Substance	ch-1-5	na-bws	CTA, MAA, MAA-AH
New Active Substance	ch-1-5	na-nas	CTA, MAA, MAA-AH
Orphan Fast Track Filing	ch-1-5	orphan-fasttrack	CTA, MAA, MAA-AH
Periodic Safety Update Report	ch-1-5	psur	CTA, MAA, MAA-AH
Plasma Master File	ch-1-5	pmf	CTA, MAA, MAA-AH
Reformat Filing	ch-1-5	reformat	CTA, MAA, MAA-AH
Renewal Filing	ch-1-5	renewal	CTA, MAA, MAA-AH
Supplement Filing	ch-1-5	supplemental-info	CTA, MAA, MAA-AH
Transfer MA Filing	ch-1-5	transfer	CTA, MAA, MAA-AH

Withdrawal Filing	ch-1-5	withdrawal	CTA, MAA, MAA-AH
Used for Meeting	ch-1-5	advice	CTA, MAA, MAA-AH
Co-Marketing Medicinal Product	ch-1-5	na-co-marketing	CTA, MAA, MAA-AH
Parallel Import	ch-1-5	na-pi	CTA, MAA, MAA-AH
Variation 1A Filing	ch-1-5	var-type1a	CTA, MAA, MAA-AH
Variation 1AIN Filing	ch-1-5	var-type1ain	CTA, MAA, MAA-AH
Variation 1B Filing	ch-1-5	var-type1b	CTA, MAA, MAA-AH
Variation 2 Filing	ch-1-5	var-type2	CTA, MAA, MAA-AH
Extension Filing	ch-1-5	extension	CTA, MAA, MAA-AH

eCTD Filing Types for CN

Ennov InSight provides the following filing types for all application types associated with China. This table lists the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Original Application	cn-1-0	cnrat1	IND, NDA, ANDA
Supplement Filing	cn-1-0	cnrat2	IND, NDA, ANDA
Record	cn-1-0	cnrat3	NDA, ANDA
Annual Report Filing	cn-1-0	cnrat4	NDA, ANDA
New Indication and Drug Combination	cn-1-0	cnrat5	IND
New Indication	cn-1-0	cnrat6	IND, NDA
Development Safety Report	cn-1-0	cnrat7	IND
Renewal Filing	cn-1-0	cnrat8	NDA, ANDA
Baseline	cn-1-0	cnrat9	NDA, ANDA

eCTD Filing Types for EAEU

Ennov InSight provides the following filing types for all application types associated with EAEU. This table lists the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/Schema	eCTD Code

Amendment Filing	eaeu-1-0	am, by, kg, kz, ru
Line Extension	eaeu-1-0	am, by, kg, kz, ru
Original Filing	eaeu-1-0	am, by, kg, kz, ru
Other Filing	eaeu-1-0	am, by, kg, kz, ru
Renewal Filing	eaeu-1-0	am, by, kg, kz, ru
Technical Variation	eaeu-1-0	am, by, kg, kz, ru
Variation	eaeu-1-0	am, by, kg, kz, ru

eCTD Filing Types for EU

Ennov InSight provides the following filing types for all application types associated with the European Union (EU). This table lists the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Annual Reassessment Filing	eu-1-0	annual-reassessment	CTA, MAA, MAA-AH
Arbitration Filing	eu-1-0	arbitration	CTA, MAA, MAA-AH
Article 58 Filing	eu-1-0	article-58	CTA, MAA, MAA-AH
ASMF Filing	eu-1-0	asmf	CTA, MAA, MAA-AH
Conditional Specific Obliga- tion Filing	eu-1-0	cond-specific-obligation	CTA, MAA, MAA-AH
Corrigendum Filing	eu-1-0	corrigendum	CTA, MAA, MAA-AH
DMF Filing	eu-1-0	dmf	CTA, MAA, MAA-AH
Extension Filing	eu-1-0	extension	CTA, MAA, MAA-AH
Follow-Up Filing	eu-1-0	follow-up	CTA, MAA, MAA-AH
Follow-Up Measures	eu-1-0	fum	CTA, MAA, MAA-AH
Lifting Suspension Filing	eu-1-0	lifting-suspension	CTA, MAA, MAA-AH
National Variation Filing	eu-1-0	var-nat	CTA, MAA, MAA-AH
Notification 61-3 Filing	eu-1-0	notification-61-3	CTA, MAA, MAA-AH

Original Filing	eu-1-0	initial-maa	CTA, MAA, MAA-AH
PAED Article 29 Filing	eu-1-0	paed-article-29	CTA, MAA, MAA-AH
Periodic Safety Update Report	eu-1-0	psur	CTA, MAA, MAA-AH
Referral Filing	eu-1-0	referral	CTA, MAA, MAA-AH
Reformat Filing	eu-1-0	reformat	CTA, MAA, MAA-AH
Renewal Filing	eu-1-0	renewal	CTA, MAA, MAA-AH
Safety Filing	eu-1-0	safety	CTA, MAA, MAA-AH
Specific Obligation Filing	eu-1-0	specific-obligation	CTA, MAA, MAA-AH
Supplement Filing	eu-1-0	supplemental-info	CTA, MAA, MAA-AH
Transfer MA Filing	eu-1-0	transfer-ma	CTA, MAA, MAA-AH
USR Filing	eu-1-0	usr	CTA, MAA, MAA-AH
Variation 1A Filing	eu-1-0	var-type1a	CTA, MAA, MAA-AH
Variation 1B Filing	eu-1-0	var-type1b	CTA, MAA, MAA-AH
Variation 2 Filing	eu-1-0	var-type2	CTA, MAA, MAA-AH

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Annual Reassessment Filing	eu-1-1	annual-reassessment	CTA, MAA, MAA-AH
Arbitration Filing	eu-1-1	arbitration	CTA, MAA, MAA-AH
Article 58 Filing	eu-1-1	article-58	CTA, MAA, MAA-AH
ASMF Filing	eu-1-1	asmf	CTA, MAA, MAA-AH
Conditional Specific Obliga- tion Filing	eu-1-1	cond-specific-obligation	CTA, MAA, MAA-AH
Corrigendum Filing	eu-1-1	corrigendum	CTA, MAA, MAA-AH
DMF Filing	eu-1-1	dmf	CTA, MAA, MAA-AH
Extension Filing	eu-1-1	extension	CTA, MAA, MAA-AH
Follow-Up Filing	eu-1-1	follow-up	CTA, MAA, MAA-AH

Follow-Up Measures	eu-1-1	fum	CTA, MAA, MAA-AH
Lifting Suspension Filing	eu-1-1	lifting-suspension	CTA, MAA, MAA-AH
National Variation Filing	eu-1-1	var-nat	CTA, MAA, MAA-AH
Notification 61-3 Filing	eu-1-1	notification-61-3	CTA, MAA, MAA-AH
Original Filing	eu-1-1	initial-maa	CTA, MAA, MAA-AH
PAED Article 29 Filing	eu-1-1	paed-article-29	CTA, MAA, MAA-AH
Periodic Safety Update Report	eu-1-1	psur	CTA, MAA, MAA-AH
Referral Filing	eu-1-1	referral	CTA, MAA, MAA-AH
Reformat Filing	eu-1-1	reformat	CTA, MAA, MAA-AH
Renewal Filing	eu-1-1	renewal	CTA, MAA, MAA-AH
Safety Filing	eu-1-1	safety	CTA, MAA, MAA-AH
Specific Obligation Filing	eu-1-1	specific-obligation	CTA, MAA, MAA-AH
Supplement Filing	eu-1-1	supplemental-info	CTA, MAA, MAA-AH
Transfer MA Filing	eu-1-1	transfer-ma	CTA, MAA, MAA-AH
USR Filing	eu-1-1	usr	CTA, MAA, MAA-AH
Variation 1A Filing	eu-1-1	var-type1a	CTA, MAA, MAA-AH
Variation 1B Filing	eu-1-1	var-type1b	CTA, MAA, MAA-AH
Variation 2 Filing	eu-1-1	var-type2	CTA, MAA, MAA-AH

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Annual Reassessment Filing	eu-1-2-1	annual-reassessment	CTA, MAA, MAA-AH
Arbitration Filing	eu-1-2-1	arbitration	CTA, MAA, MAA-AH
Article 58 Filing	eu-1-2-1	article-58	CTA, MAA, MAA-AH
ASMF Filing	eu-1-2-1	asmf	CTA, MAA, MAA-AH
Conditional Specific Obliga- tion Filing	eu-1-2-1	cond-specific-obligation	CTA, MAA, MAA-AH

Corrigendum Filing	eu-1-2-1	corrigendum	CTA, MAA, MAA-AH
DMF Filing	eu-1-2-1	dmf	CTA, MAA, MAA-AH
Extension Filing	eu-1-2-1	extension	CTA, MAA, MAA-AH
Follow-Up Filing	eu-1-2-1	follow-up	CTA, MAA, MAA-AH
Follow-Up Measures	eu-1-2-1	fum	CTA, MAA, MAA-AH
Lifting Suspension Filing	eu-1-2-1	lifting-suspension	CTA, MAA, MAA-AH
National Variation Filing	eu-1-2-1	var-nat	CTA, MAA, MAA-AH
Notification 61-3 Filing	eu-1-2-1	notification-61-3	CTA, MAA, MAA-AH
Original Filing	eu-1-2-1	initial-maa	CTA, MAA, MAA-AH
PAED Article 29 Filing	eu-1-2-1	paed-article-29	CTA, MAA, MAA-AH
Periodic Safety Update Report	eu-1-2-1	psur	CTA, MAA, MAA-AH
Referral Filing	eu-1-2-1	referral	CTA, MAA, MAA-AH
Reformat Filing	eu-1-2-1	reformat	CTA, MAA, MAA-AH
Renewal Filing	eu-1-2-1	renewal	CTA, MAA, MAA-AH
Safety Filing	eu-1-2-1	safety	CTA, MAA, MAA-AH
Specific Obligation Filing	eu-1-2-1	specific-obligation	CTA, MAA, MAA-AH
Supplement Filing	eu-1-2-1	supplemental-info	CTA, MAA, MAA-AH
Transfer MA Filing	eu-1-2-1	transfer-ma	CTA, MAA, MAA-AH
USR Filing	eu-1-2-1	usr	CTA, MAA, MAA-AH
Variation 1A Filing	eu-1-2-1	var-type1a	CTA, MAA, MAA-AH
Variation 1B Filing	eu-1-2-1	var-type1b	CTA, MAA, MAA-AH
Variation 2 Filing	eu-1-2-1	var-type2	CTA, MAA, MAA-AH

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Annual Reassessment Filing	eu-1-3	annual-reassessment	CTA, MAA, MAA-AH
Arbitration Filing	eu-1-3	arbitration	CTA, MAA, MAA-AH

Article 58 Filing	eu-1-3	article-58	CTA, MAA, MAA-AH
ASMF Filing	eu-1-3	asmf	CTA, MAA, MAA-AH
Conditional Specific Obligation Filing	eu-1-3	cond-specific-obligation	CTA, MAA, MAA-AH
Corrigendum Filing	eu-1-3	corrigendum	CTA, MAA, MAA-AH
DMF Filing	eu-1-3	dmf	CTA, MAA, MAA-AH
Extension Filing	eu-1-3	extension	CTA, MAA, MAA-AH
Follow-Up Filing	eu-1-3	follow-up	CTA, MAA, MAA-AH
Follow-Up Measures	eu-1-3	fum	CTA, MAA, MAA-AH
Lifting Suspension Filing	eu-1-3	lifting-suspension	CTA, MAA, MAA-AH
National Variation Filing	eu-1-3	var-nat	CTA, MAA, MAA-AH
Notification 61-3 Filing	eu-1-3	notification-61-3	CTA, MAA, MAA-AH
Original Filing	eu-1-3	initial-maa	CTA, MAA, MAA-AH
PAED Article 29 Filing	eu-1-3	paed-article-29	CTA, MAA, MAA-AH
Periodic Safety Update Report	eu-1-3	psur	CTA, MAA, MAA-AH
Referral Filing	eu-1-3	referral	CTA, MAA, MAA-AH
Reformat Filing	eu-1-3	reformat	CTA, MAA, MAA-AH
Renewal Filing	eu-1-3	renewal	CTA, MAA, MAA-AH
Safety Filing	eu-1-3	safety	CTA, MAA, MAA-AH
Specific Obligation Filing	eu-1-3	specific-obligation	CTA, MAA, MAA-AH
Supplement Filing	eu-1-3	supplemental-info	CTA, MAA, MAA-AH
Transfer MA Filing	eu-1-3	transfer-ma	CTA, MAA, MAA-AH
USR Filing	eu-1-3	usr	CTA, MAA, MAA-AH
Variation 1A Filing	eu-1-3	var-type1a	CTA, MAA, MAA-AH
Variation 1B Filing	eu-1-3	var-type1b	CTA, MAA, MAA-AH
Variation 2 Filing	eu-1-3	var-type2	CTA, MAA, MAA-AH

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types

Annual Reassessment Filing	eu-1-4	annual-reassessment	CTA, MAA, MAA-AH
Arbitration Filing	eu-1-4	arbitration	CTA, MAA, MAA-AH
Article 58 Filing	eu-1-4	article-58	CTA, MAA, MAA-AH
ASMF Filing	eu-1-4	asmf	CTA, MAA, MAA-AH
Conditional Specific Obligation Filing	eu-1-4	cond-specific-obligation	CTA, MAA, MAA-AH
Corrigendum Filing	eu-1-4	corrigendum	CTA, MAA, MAA-AH
DMF Filing	eu-1-4	dmf	CTA, MAA, MAA-AH
Extension Filing	eu-1-4	extension	CTA, MAA, MAA-AH
Follow-Up Filing	eu-1-4	follow-up	CTA, MAA, MAA-AH
Follow-Up Measures	eu-1-4	fum	CTA, MAA, MAA-AH
Lifting Suspension Filing	eu-1-4	lifting-suspension	CTA, MAA, MAA-AH
National Variation Filing	eu-1-4	var-nat	CTA, MAA, MAA-AH
Notification 61-3 Filing	eu-1-4	notification-61-3	CTA, MAA, MAA-AH
Original Filing	eu-1-4	initial-maa	CTA, MAA, MAA-AH
PAED Article 29 Filing	eu-1-4	paed-article-29	CTA, MAA, MAA-AH
Periodic Safety Update Report	eu-1-4	psur	CTA, MAA, MAA-AH
Referral Filing	eu-1-4	referral	CTA, MAA, MAA-AH
Reformat Filing	eu-1-4	reformat	CTA, MAA, MAA-AH
Renewal Filing	eu-1-4	renewal	CTA, MAA, MAA-AH
Safety Filing	eu-1-4	safety	CTA, MAA, MAA-AH
Specific Obligation Filing	eu-1-4	specific-obligation	CTA, MAA, MAA-AH
Supplement Filing	eu-1-4	supplemental-info	CTA, MAA, MAA-AH
Transfer MA Filing	eu-1-4	transfer-ma	CTA, MAA, MAA-AH
USR Filing	eu-1-4	usr	CTA, MAA, MAA-AH
Variation 1A Filing	eu-1-4	var-type1a	CTA, MAA, MAA-AH
Variation 1B Filing	eu-1-4	var-type1b	CTA, MAA, MAA-AH

Variation 2 Filing	eu-1-4	var-type2	CTA, MAA, MAA-AH

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Annual Reassessment Filing	eu-2-0	annual-reassessment	CTA, MAA, MAA-AH
Arbitration Filing	eu-2-0	arbitration	CTA, MAA, MAA-AH
Article 58 Filing	eu-2-0	article-58	CTA, MAA, MAA-AH
ASMF Filing	eu-2-0	asmf	CTA, MAA, MAA-AH
Conditional Specific Obliga- tion Filing	eu-2-0	cond-specific-obligation	CTA, MAA, MAA-AH
Corrigendum Filing	eu-2-0	corrigendum	CTA, MAA, MAA-AH
DMF Filing	eu-2-0	dmf	CTA, MAA, MAA-AH
Extension Filing	eu-2-0	extension	CTA, MAA, MAA-AH
Follow-Up Filing	eu-2-0	follow-up	CTA, MAA, MAA-AH
Follow-Up Measures	eu-2-0	fum	CTA, MAA, MAA-AH
Lifting Suspension Filing	eu-2-0	lifting-suspension	CTA, MAA, MAA-AH
National Variation Filing	eu-2-0	var-nat	CTA, MAA, MAA-AH
Notification 61-3 Filing	eu-2-0	notification-61-3	CTA, MAA, MAA-AH
Original Filing	eu-2-0	initial-maa	CTA, MAA, MAA-AH
PAED Article 29 Filing	eu-2-0	paed-article-29	CTA, MAA, MAA-AH
Periodic Safety Update Report	eu-2-0	psur	CTA, MAA, MAA-AH
Referral Filing	eu-2-0	referral	CTA, MAA, MAA-AH
Reformat Filing	eu-2-0	reformat	CTA, MAA, MAA-AH
Renewal Filing	eu-2-0	renewal	CTA, MAA, MAA-AH
Risk Management Plan Filing	eu-2-0	rmp	CTA, MAA, MAA-AH

Safety Filing	eu-2-0	safety	CTA, MAA, MAA-AH
Specific Obligation Filing	eu-2-0	specific-obligation	CTA, MAA, MAA-AH
Supplement Filing	eu-2-0	supplemental-info	CTA, MAA, MAA-AH
Transfer MA Filing	eu-2-0	transfer-ma	CTA, MAA, MAA-AH
USR Filing	eu-2-0	usr	CTA, MAA, MAA-AH
Variation 1A Filing	eu-2-0	var-type1a	CTA, MAA, MAA-AH

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Variation 1B Filing	eu-2-0	var-type1b	CTA, MAA, MAA-AH
Variation 2 Filing	eu-2-0	var-type2	CTA, MAA, MAA-AH
Additional PV Activity in the RMP Related to PAM	eu-3-0	pam-mea	MAA, MAA-AH
Annex II Condition Related to PAM	eu-3-0	pam-anx	MAA, MAA-AH
Annual Reassessment Filing	eu-3-0	annual-reassessment	MAA, MAA-AH
Article 107i Referral	eu-3-0	referral-107i	MAA, MAA-AH
Article 16c (1c)i Referral	eu-3-0	referral-16c1c	MAA, MAA-AH
Article 16c(4) Referral	eu-3-0	referral-16c4	MAA, MAA-AH
Article 20 Referral	eu-3-0	referral-20	MAA, MAA-AH
Article 29 Paediatric Referral	eu-3-0	referral-29p	MAA, MAA-AH
Article 29(4) Referral	eu-3-0	referral-294	MAA, MAA-AH
Article 30 Referral	eu-3-0	referral-30	MAA, MAA-AH
Article 31 Referral	eu-3-0	referral-31	MAA, MAA-AH
Article 35 Referral	eu-3-0	referral-35	MAA, MAA-AH
Article 5(3) Referral	eu-3-0	referral-53	MAA, MAA-AH
Article 58 Filing	eu-3-0	article-58	MAA, MAA-AH

ASMF Filing	eu-3-0	asmf	MAA, MAA-AH
CEP Submission	eu-3-0	cep	MAA, MAA-AH
Clinical Data for Publication – Final Version	eu-3-0	clin-data-pub-fv	MAA, MAA-AH
Clinical Data for Publication – Redacted Proposal	eu-3-0	clin-data-pub-rp	MAA, MAA-AH
Corrective/Preventive Action Related to PAM	eu-3-0	pam-capa	MAA, MAA-AH
Extension Filing	eu-3-0	extension	MAA, MAA-AH
Legally Binding Measure Re- lated to PAM	eu-3-0	pam-leg	MAA, MAA-AH

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Lifting Suspension Filing	eu-3-0	lifting-suspension	MAA, MAA-AH
Marketing Authorisation Appli- cation	eu-3-0	maa	MAA, MAA-AH
National Variation Filing	eu-3-0	var-nat	MAA, MAA-AH
None	eu-3-0	none	MAA, MAA-AH
Notification 61-3 Filing	eu-3-0	notification-61-3	MAA, MAA-AH
PAED Article 29 Filing	eu-3-0	paed-29	MAA, MAA-AH
PAED Article 45	eu-3-0	paed-45	MAA, MAA-AH
PAED Article 46	eu-3-0	paed-46	MAA, MAA-AH
PAED Related to PIP (Article 7, 8, 30)	eu-3-0	paed-7-8-30	MAA, MAA-AH
Paediatric Submission	eu-3-0	pam-p45	MAA, MAA-AH

Related to PAM (Article 45)			
Paediatric Submission Related to PAM (Article 46)	eu-3-0	pam-p46	MAA, MAA-AH
PAES Submission Related to PAM	eu-3-0	pam-paes	MAA, MAA-AH
PASS Protocol Submission (Article 107n)	eu-3-0	pass107n	MAA, MAA-AH
PASS Report Submission (Article 107q)	eu-3-0	pass107q	MAA, MAA-AH
Periodic Safety Update Report	eu-3-0	psur	MAA, MAA-AH
Plasma Master File	eu-3-0	pmf	MAA, MAA-AH
PSUR single assessment procedure	eu-3-0	psusa	MAA, MAA-AH
Recommendation Related to PAM	eu-3-0	pam-rec	MAA, MAA-AH
Renewal Filing	eu-3-0	renewal	MAA, MAA-AH
Repeat Use Procedure	eu-3-0	rup	MAA, MAA-AH
Risk Management Plan Filing	eu-3-0	rmp	MAA, MAA-AH

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
SDA Submission Related to PAM	eu-3-0	pam-sda	MAA, MAA-AH
Specific Obligation Related to PAM	eu-3-0	pam-sob	MAA, MAA-AH
Transfer MA Filing	eu-3-0	transfer-ma	MAA, MAA-AH
USR Filing	eu-3-0	usr	MAA, MAA-AH

Variation 1A Filing	eu-3-0	var-type1a	MAA, MAA-AH
Variation 1AIN Filing	eu-3-0	var-type1ain	MAA, MAA-AH
Variation 1B Filing	eu-3-0	var-type1b	MAA, MAA-AH
Variation 2 Filing	eu-3-0	var-type2	MAA, MAA-AH
Withdrawal Filing	eu-3-0	withdrawal	MAA, MAA-AH
Additional PV Activity in the RMP Related to PAM	eu-3-0-1	pam-mea	MAA, MAA-AH
Annex II Condition Related to PAM	eu-3-0-1	pam-anx	MAA, MAA-AH
Annual Reassessment Filing	eu-3-0-1	annual-reassessment	MAA, MAA-AH
Article 107i Referral	eu-3-0-1	referral-107i	MAA, MAA-AH
Article 16c (1c)i Referral	eu-3-0-1	referral-16c1c	MAA, MAA-AH
Article 16c(4) Referral	eu-3-0-1	referral-16c4	MAA, MAA-AH
Article 20 Referral	eu-3-0-1	referral-20	MAA, MAA-AH
Article 29 Paediatric Referral	eu-3-0-1	referral-29p	MAA, MAA-AH
Article 29(4) Referral	eu-3-0-1	referral-294	MAA, MAA-AH
Article 30 Referral	eu-3-0-1	referral-30	MAA, MAA-AH
Article 31 Referral	eu-3-0-1	referral-31	MAA, MAA-AH
Article 35 Referral	eu-3-0-1	referral-35	MAA, MAA-AH
Article 5(3) Referral	eu-3-0-1	referral-5-3	MAA, MAA-AH
Article 58 Filing	eu-3-0-1	article-58	MAA, MAA-AH
ASMF Filing	eu-3-0-1	asmf	MAA, MAA-AH
CEP Submission	eu-3-0-1	cep	MAA, MAA-AH

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Clinical Data for	eu-3-0-1	clin-data-pub-fv	MAA, MAA-AH

Publication – Final Version			
Clinical Data for Publication – Redacted Proposal	eu-3-0-1	clin-data-pub-rp	MAA, MAA-AH
Corrective/Preventive Action Related to PAM	eu-3-0-1	pam-capa	MAA, MAA-AH
Extension Filing	eu-3-0-1	extension	MAA, MAA-AH
Legally Binding Measure Re- lated to PAM	eu-3-0-1	pam-leg	MAA, MAA-AH
Lifting Suspension Filing	eu-3-0-1	lifting-suspension	MAA, MAA-AH
Marketing Authorisation Appli- cation	eu-3-0-1	maa	MAA, MAA-AH
National Variation Filing	eu-3-0-1	var-nat	MAA, MAA-AH
None	eu-3-0-1	none	MAA, MAA-AH
Notification 61-3 Filing	eu-3-0-1	notification-61-3	MAA, MAA-AH
PAED Article 29 Filing	eu-3-0-1	paed-29	MAA, MAA-AH
PAED Article 45	eu-3-0-1	paed-45	MAA, MAA-AH
PAED Article 46	eu-3-0-1	paed-46	MAA, MAA-AH
PAED Related to PIP (Article 7, 8, 30)	eu-3-0-1	paed-7-8-30	MAA, MAA-AH
Paediatric Submission Related to PAM (Article 45)	eu-3-0-1	pam-p45	MAA, MAA-AH
Paediatric Submission Related to PAM (Article 46)	eu-3-0-1	pam-p46	MAA, MAA-AH
PAES Submission Related to PAM	eu-3-0-1	pam-paes	MAA, MAA-AH
PASS Protocol Submission (Article 107n)	eu-3-0-1	pass107n	MAA, MAA-AH

PASS Report Submission (Article 107q)	eu-3-0-1	pass107q	MAA, MAA-AH
Periodic Safety Update Report	eu-3-0-1	psur	MAA, MAA-AH

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Plasma Master File	eu-3-0-1	pmf	MAA, MAA-AH
PSUR single assessment procedure	eu-3-0-1	psusa	MAA, MAA-AH
Recommendation Related to PAM	eu-3-0-1	pam-rec	MAA, MAA-AH
Renewal Filing	eu-3-0-1	renewal	MAA, MAA-AH
Repeat Use Procedure	eu-3-0-1	rup	MAA, MAA-AH
Risk Management Plan Filing	eu-3-0-1	rmp	MAA, MAA-AH
SDA Submission Related to PAM	eu-3-0-1	pam-sda	MAA, MAA-AH
Specific Obligation Related to PAM	eu-3-0-1	pam-sob	MAA, MAA-AH
Transfer MA Filing	eu-3-0-1	transfer-ma	MAA, MAA-AH
USR Filing	eu-3-0-1	usr	MAA, MAA-AH
Variation 1A Filing	eu-3-0-1	var-type1a	MAA, MAA-AH
Variation 1AIN Filing	eu-3-0-1	var-type1ain	MAA, MAA-AH
Variation 1B Filing	eu-3-0-1	var-type1b	MAA, MAA-AH
Variation 2 Filing	eu-3-0-1	var-type2	MAA, MAA-AH
Withdrawal Filing	eu-3-0-1	withdrawal	MAA, MAA-AH
Marketing Authorisation Application	eu-3-1	maa	MAA, MAA-AH
Variation 1A Filing	eu-3-1	var-type1a	MAA, MAA-AH

Variation 1AIN Filing	eu-3-1	var-type1ain	MAA, MAA-AH
Variation 1B Filing	eu-3-1	var-type1b	MAA, MAA-AH
Variation 2 Filing	eu-3-1	var-type2	MAA, MAA-AH
National Variation Filing	eu-3-1	var-nat	MAA, MAA-AH
Extension Filing	eu-3-1	extension	MAA, MAA-AH
Repeat Use Procedure	eu-3-1	rup	MAA, MAA-AH
Periodic Safety Update Report	eu-3-1	psur	MAA, MAA-AH

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
PSUR single assessment procedure	eu-3-1	psusa	MAA, MAA-AH
Risk Management Plan Filing	eu-3-1	rmp	MAA, MAA-AH
Renewal Filing	eu-3-1	renewal	MAA, MAA-AH
Specific Obligation Related to PAM	eu-3-1	pam-sob	MAA, MAA-AH
Annex II Condition Related to PAM	eu-3-1	pam-anx	MAA, MAA-AH
Additional PV Activity in the RMP Related to PAM	eu-3-1	pam-mea	MAA, MAA-AH
Legally Binding Measure Related to PAM	eu-3-1	pam-leg	MAA, MAA-AH
SDA Submission Related to PAM	eu-3-1	pam-sda	MAA, MAA-AH
Corrective/Preventive Action Related to PAM	eu-3-1	pam-capa	MAA, MAA-AH
Paediatric Submission	eu-3-1	pam-p45	MAA, MAA-AH

Related to PAM (Article 45)			
Paediatric Submission Related to PAM (Article 46)	eu-3-1	pam-p46	MAA, MAA-AH
PAES Submission Related to PAM	eu-3-1	pam-paes	MAA, MAA-AH
Recommendation Related to PAM	eu-3-1	pam-rec	MAA, MAA-AH
PASS Protocol Submission (Article 107n)	eu-3-1	pass107n	MAA, MAA-AH
PASS Report Submission (Article 107q)	eu-3-1	pass107q	MAA, MAA-AH
ASMF Filing	eu-3-1	asmf	MAA, MAA-AH
Plasma Master File	eu-3-1	pmf	MAA, MAA-AH
Article 20 Referral	eu-3-1	referral-20	MAA, MAA-AH
Article 29(4) Referral	eu-3-1	referral-294	MAA, MAA-AH

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Article 29 Paediatric Referral	eu-3-1	referral-29p	MAA, MAA-AH
Article 30 Referral	eu-3-1	referral-30	MAA, MAA-AH
Article 31 Referral	eu-3-1	referral-31	MAA, MAA-AH
Article 35 Referral	eu-3-1	referral-35	MAA, MAA-AH
Article 5(3) Referral	eu-3-1	referral-5-3	MAA, MAA-AH
Article 107i Referral	eu-3-1	referral-107i	MAA, MAA-AH
Article 16c (1c)i Referral	eu-3-1	referral-16c1c	MAA, MAA-AH
Article 16c(4) Referral	eu-3-1	referral-16c4	MAA, MAA-AH
Annual Reassessment Filing	eu-3-1	annual-reassessment	MAA, MAA-AH

USR Filing	eu-3-1	usr	MAA, MAA-AH
Clinical Data for Publication – Redacted Proposal	eu-3-1	clin-data-pub-rp	MAA, MAA-AH
Clinical Data for Publication – Final Version	eu-3-1	clin-data-pub-fv	MAA, MAA-AH
PAED Related to PIP (Article 7, 8, 30)	eu-3-1	paed-7-8-30	MAA, MAA-AH
PAED Article 29 Filing	eu-3-1	paed-29	MAA, MAA-AH
PAED Article 45	eu-3-1	paed-45	MAA, MAA-AH
PAED Article 46	eu-3-1	paed-46	MAA, MAA-AH
Article 58 Filing	eu-3-1	article-58	MAA, MAA-AH
Notification 61-3 Filing	eu-3-1	notification-61-3	MAA, MAA-AH
Transfer MA Filing	eu-3-1	transfer-ma	MAA, MAA-AH
Lifting Suspension Filing	eu-3-1	lifting-suspension	MAA, MAA-AH
Withdrawal Filing	eu-3-1	withdrawal	MAA, MAA-AH
CEP Submission	eu-3-1	cep	MAA, MAA-AH
None	eu-3-1	none	MAA, MAA-AH
Article 18 Filing	eu-3-1	article-18	MAA, MAA-AH

eCTD Sub-Filing Types for EU

The list of eCTD code and the applicable Sub-Filing Type for each Filing Type.

The Sub-Filing Type values are available to select in the *Sub Filing Type Values* section of *Submission Maintenance* Data Administration List.

Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Initial	eu-3-1	initial	Marketing Authorisation Application, Variation 1A

		Filing, Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/ Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing,

			Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing

Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Validation Response	eu-3-1	validation response	Marketing Authorisation Application, Variation 1A Filing, Variation 1A IN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/ Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual

			Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing

Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Response	eu-3-1	response	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/ Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report

		Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing

Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Additional Information	eu-3-1	additiona l-info	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/

			Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Closing Information	eu-3-1	closing	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing,

Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to

PAM, Annex II Condition Related to PAM,

Additional PV Activity in the RMP Related to PAM,

Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/

Preventive Action Related to PAM, Paediatric

Submission Related to PAM (Article 45),

Paediatric Submission Related to PAM (Article

46), PAES Submission Related to PAM,

Recommendation Related to PAM, PASS Protocol

Submission (Article 107n), PASS Report

Submission (Article 107q), ASMF Filing, Plasma

Master File, Article 20 Referral, Article 29(4)

Referral, Article 29 Paediatric Referral, Article 30

Referral, Article 31 Referral, Article 35 Referral,

Article 5(3) Referral, Article 107i Referral, Article

16c (1c)i Referral, Article 16c(4) Referral, Annual

Reassessment Filing, USR Filing, Clinical Data for

Publication - Redacted Proposal, Clinical Data for

Publication - Final Version, PAED Related to PIP

(Article 7, 8, 30), PAED Article 29 Filing, PAED

Article 45, PAED Article 46, Article 58 Filing,

Notification 61-3 Filing, Transfer MA Filing,

Lifting Suspension Filing, Withdrawal Filing, CEP

			Submission, None, Article 18 Filing
Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Consolidating	eu-3-1	consolidating	Marketing Authorisation Application, Variation 1A Filing, Variation 1A IN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/ Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for

			Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Corrigendum	eu-3-1	corrigendum	Marketing Authorisation Application, Variation 1A Filing, Variation 1A IN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obliga- tion, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submis- sion Related to PAM, Corrective/ Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma

		Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Reformat	eu-3-1	reformat	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/ Preventive Action Related to PAM, Paediatric

			Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Re-examination	eu-3-1	reexamination	Marketing Authorisation Application, Variation 1A Filing, Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk

		Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/ Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing

Ennov InSight provides the following filing types for all application types associated with Gulf Cooperation Council (GCC). This table lists the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
GCC Responses	gc-1-2	responses	MAA
GCC Variation Type 1	gc-1-2	var-type1	MAA
GCC Variation Type 2	gc-1-2	var-type2	MAA

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
MAA - Biological	gc-1-2	new-bio	MAA
MAA - Generic (Multisource)	gc-1-2	new-gen	MAA
MAA - Health	gc-1-2	new-hea	MAA
MAA - Herbal	gc-1-2	new-her	MAA
MAA - New Chemical Entity	gc-1-2	new-nce	MAA
MAA - Radiopharmaceuticals	gc-1-2	new-rad	MAA
MAA - Veterinary	gc-1-2	new-vet	MAA
Periodic Safety Update Report	gc-1-2	psur	MAA
Renewal Filing	gc-1-2	renewal	MAA
Transfer MA Filing	gc-1-2	transfer-ma	MAA
Withdrawal Filing	gc-1-2	withdrawal	MAA
ASMF Filing	gc-1-5	asmf	MAA
Extension Filing	gc-1-5	extension	MAA
GCC Variation Type 1	gc-1-5	var-type1	MAA
GCC Variation Type 2	gc-1-5	var-type2	MAA
MAA - Biological	gc-1-5	new-bio	MAA
MAA - Generic (Multisource)	gc-1-5	new-gen	MAA
MAA - New Chemical Entity	gc-1-5	new-nce	MAA

MAA - Radiopharmaceuticals	gc-1-5	new-rad	MAA
None	gc-1-5	none	MAA
Periodic Safety Update Report	gc-1-5	psur	MAA
Plasma Master File	gc-1-5	pmf	MAA
PSUR single assessment procedure	gc-1-5	psusa	MAA
Renewal Filing	gc-1-5	renewal	MAA
Risk Management Plan Filing	gc-1-5	rmp	MAA
Transfer MA Filing	gc-1-5	transfer-ma	MAA
USR Filing	gc-1-5	usr	MAA
Withdrawal Filing	gc-1-5	withdrawal	MAA

eCTD Filing Types for JO

Ennov InSight provides the following filing types for all application types associated with Jordan. This table lists the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
ASMF Filing	jo-1-0	asmf	CTA, NDA
Biological Allergen	jo-1-0	bla	CTA, NDA
Biological Bio-similar	jo-1-0	bls	CTA, NDA
Biological Blood Product	jo-1-0	blb	CTA, NDA
Biological Drug	jo-1-0	bld	CTA, NDA
Biological Vaccine	jo-1-0	blv	CTA, NDA
CEP Submission	jo-1-0	cep	CTA, NDA
Extension Filing	jo-1-0	extension	CTA, NDA
Generics	jo-1-0	bgd	CTA, NDA
Generic Narcotics	jo-1-0	bgn	CTA, NDA
Generic Vitamin Drug	jo-1-0	bgv	CTA, NDA
Herbal Drug	jo-1-0	hrd	CTA, NDA

MAA - Originator Drug	jo-1-0	ord	CTA, NDA
MAA - Originator Vitamin Drug	jo-1-0	orv	CTA, NDA
New Drug	jo-1-0	mnd	CTA, NDA
New Narcotics	jo-1-0	nnd	CTA, NDA
New Vitamin Drug	jo-1-0	nvd	CTA, NDA
None	jo-1-0	none	CTA, NDA
Notification with pricing	jo-1-0	var-n2	CTA, NDA
Notification without pricing	jo-1-0	var-n1	CTA, NDA
Originator Narcotics	jo-1-0	orn	CTA, NDA
Periodic Safety Update Report	jo-1-0	psur	CTA, NDA
Plasma Master File	jo-1-0	pmf	CTA, NDA
PSUR single assessment procedure	jo-1-0	psusa	CTA, NDA
Radiopharmaceutical Non-Radioactive Components (kits)	jo-1-0	rrr	CTA, NDA

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Radiopharmaceutical Ready-for-use Radioactive Product	jo-1-0	rrp	CTA, NDA
Registration Department approval	jo-1-0	var-ra	CTA, NDA
Renewal Filing	jo-1-0	renevar	CTA, NDA
Risk Management Plan Filing	jo-1-0	risk	CTA, NDA
Technical committee approval	jo-1-0	var-tca	CTA, NDA
Transfer MA Filing	jo-1-0	transfer-ma	CTA, NDA
USR Filing	jo-1-0	usr	CTA, NDA
Value added medicine	jo-1-0	vam	CTA, NDA
Veterinary drug	jo-1-0	vt	CTA, NDA
Withdrawal Filing	jo-1-0	withdrawal	CTA, NDA
ASMF Filing	jo-1-1	asmf	CTA, NDA

Biological Allergen	jo-1-1	bla	CTA, NDA
Biological Bio-similar	jo-1-1	bls	CTA, NDA
Biological Blood Product	jo-1-1	blb	CTA, NDA
Biological Drug	jo-1-1	bld	CTA, NDA
Biological Vaccine	jo-1-1	blv	CTA, NDA
CEP Submission	jo-1-1	cep	CTA, NDA
Extension Filing	jo-1-1	extension	CTA, NDA
Generics	jo-1-1	bgd	CTA, NDA
Generic Narcotics	jo-1-1	bgn	CTA, NDA
Generic Vitamin Drug	jo-1-1	bgv	CTA, NDA
Herbal Drug	jo-1-1	hrd	CTA, NDA
MAA - Originator Drug	jo-1-1	ord	CTA, NDA
MAA - Originator Vitamin Drug	jo-1-1	orv	CTA, NDA
New Drug	jo-1-1	mnd	CTA, NDA
New Narcotics	jo-1-1	nnd	CTA, NDA
New Vitamin Drug	jo-1-1	nvd	CTA, NDA
None	jo-1-1	none	CTA, NDA
Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Notification with pricing	jo-1-1	var-n2	CTA, NDA
Notification without pricing	jo-1-1	var-n1	CTA, NDA
Originator Narcotics	jo-1-1	orn	CTA, NDA
Periodic Safety Update Report	jo-1-1	psur	CTA, NDA
Plasma Master File	jo-1-1	pmf	CTA, NDA
PSUR single assessment procedure	jo-1-1	psusa	CTA, NDA
Radiopharmaceutical Non-Radioactive Components (kits)	jo-1-1	rnr	CTA, NDA

Radiopharmaceutical Ready-for-use Radioactive Product	jo-1-1	rrp	CTA, NDA
Registration Department approval	jo-1-1	var-ra	CTA, NDA
Renewal Filing	jo-1-1	renevar	CTA, NDA
Risk Management Plan Filing	jo-1-1	risk	CTA, NDA
Technical committee approval	jo-1-1	var-tca	CTA, NDA
Transfer MA Filing	jo-1-1	transfer-ma	CTA, NDA
USR Filing	jo-1-1	usr	CTA, NDA
Value added medicine	jo-1-1	vam	CTA, NDA
Veterinary drug	jo-1-1	vrt	CTA, NDA
Withdrawal Filing	jo-1-1	withdrawal	CTA, NDA
Periodic Benefit-Risk Evaluation Report	jo-1-1	pbrer	CTA, NDA

eCTD Filing Types for SG

Ennov InSight provides the following filing types for all application types associated with Singapore (SG). This table lists the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
NDA	sg-1-0	sub-type-1	Therapeutic Products
NDA-V	sg-1-0	sub-type-2	Therapeutic Products
GDA	sg-1-0	sub-type-3	Therapeutic Products
GDA-V/CECA	sg-1-0	sub-type-4	Therapeutic Products
MAV1	sg-1-0	sub-type-5	Therapeutic Products
MAV1-V	sg-1-0	sub-type-6	Therapeutic Products
MAV2	sg-1-0	sub-type-7	Therapeutic Products
MIV1-PI	sg-1-0	sub-type-8	Therapeutic Products
MIV1-PI-V	sg-1-0	sub-type-9	Therapeutic Products
MIV1-CMC	sg-1-0	sub-type-10	Therapeutic Products
MIV1-CMC-V	sg-1-0	sub-type-11	Therapeutic Products
MIV2-N	sg-1-0	sub-type-12	Therapeutic Products
MIV2-DnT	sg-1-0	sub-type-13	Therapeutic Products

PV-EDU/RMP Materials	sg-1-0	sub-type-14	Therapeutic Products
PV-PBRER/RMP Reports	sg-1-0	sub-type-15	Therapeutic Products
Reg Cond (non-PV)	sg-1-0	sub-type-16	Therapeutic Products
DMF Filing	sg-1-0	sub-type-17	Therapeutic Products
Baseline	sg-1-0	sub-type-18	Therapeutic Products
Transfer MA Filing	sg-1-0	sub-type-20	Therapeutic Products
Other Regulatory Activity	sg-1-0	sub-type-21	Therapeutic Products

eCTD Sub-Filing Types for SG

The list of eCTD code and the applicable Sub-Filing Type for each Filing Type.

The Sub-Filing Type values are available to select in the *Sub Filing Type Values* section of *Submission Maintenance* Data Administration List.

Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Initial	sg-1-0	seq-type-1	NDA, NDA-v, GDA, GDA-V/CECA, MAV1, MAV1-V, MAV2, MIV1-P1, MIV1-P1-V, MIV1-CMC, MIV1-CMC-V, , M1V2-N, M1V2-DnT, PV-EDU/RMP Materials, PV-PBRER/RMP Reports, Reg Cond (non-PV), DMF Filing, Baseline, Transfer MA Filing, Other Regulatory Activity
Supplementary Information	sg-1-0	seq-type-2	NDA, NDA-v, GDA, GDA-V/CECA, MAV1, MAV1-V, MAV2, MIV1-P1, MIV1-P1-V, MIV1-CMC, MIV1-CMC-V, , M1V2-N, M1V2-DnT, PV-EDU/RMP Materials, PV-PBRER/RMP Reports, Reg Cond (non-PV), DMF Filing, Baseline, Transfer MA Filing, Other Regulatory Activity
Response	sg-1-0	seq-type-3	NDA, NDA-v, GDA, GDA-V/CECA, MAV1, MAV1-V, MAV2, MIV1-P1, MIV1-P1-V, MIV1-CMC, MIV1-CMC-V, , M1V2-N, M1V2-DnT, PV-EDU/RMP Materials, PV-PBRER/RMP Reports, Reg Cond (non-PV), DMF Filing, Baseline, Transfer MA Filing, Other Regulatory Activity
Closing Information	sg-1-0	seq-type-4	NDA, NDA-v, GDA, GDA-V/CECA, MAV1, MAV1-V, MAV2, MIV1-P1, MIV1-P1-V, MIV1-CMC, MIV1-CMC-V, , M1V2-N, M1V2-DnT, PV-EDU/RMP Materials, PV-PBRER/RMP Reports, Reg Cond (non-PV), DMF Filing, Baseline, Transfer MA Filing, Other Regulatory Activity
Submission Withdrawal	sg-1-0	seq-type-5	NDA, NDA-v, GDA, GDA-V/CECA, MAV1, MAV1-V, MAV2, MIV1-P1, MIV1-P1-V, MIV1-CMC, MIV1-CMC-V, , M1V2-N, M1V2-DnT, PV-EDU/RMP Materials, PV-PBRER/RMP Reports, Reg Cond (non-PV), DMF Filing, Baseline, Transfer MA Filing, Other Regulatory Activity

eCTD Filing Types for TH

Ennov InSight provides the following filing types for all application types associated with Thailand (TH). This table lists the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
A: Pharmaceuticals - New Chemical Entity	th-0-92	a-ph-newce	CTA, NDA
A: Pharmaceuticals - New Salt or Ester of Existing Active Ingredient	th-0-92	a-ph-newse	CTA, NDA
A: Pharmaceuticals - New Dosage Form	th-0-92	a-ph-newdosage	CTA, NDA
A: Pharmaceuticals - New Route of Administration	th-0-92	a-ph-newroute	CTA, NDA
A: Pharmaceuticals - New Combination	th-0-92	a-ph-newcomb	CTA, NDA
A: Pharmaceuticals - New Medicinal Product (Others)	th-0-92	a-ph-newothers	CTA, NDA
A: Pharmaceuticals - New Generic	th-0-92	a-ph-newgen	CTA, NDA
A: Pharmaceuticals - Generic	th-0-92	a-ph-generic	CTA, NDA
A: House Hold Remedies	th-0-92	a-ph-house	CTA, NDA
B: Biologics - Vaccine	th-0-92	b-bio-vaccine	CTA, NDA
B: Biologics - Blood and Plasma Derived Product	th-0-92	b-bio-blood	CTA, NDA
B: Biologics - Cell- and Tissue- Based Therapy Product	th-0-92	b-bio-cell	CTA, NDA
B: Biologics - Biotechnology Product	th-0-92	b-bio-biotech	CTA, NDA
B: Biologics - Biosimilar Product	th-0-92	b-bio-biosimilar	CTA, NDA
B: Biologics - Others	th-0-92	b-bio-others	CTA, NDA
C: Veterinary - New Medicinal Product	th-0-92	c-vet-newprod	CTA, NDA
C: Veterinary - New Generic Medicinal Product	th-0-92	c-vet-newgeneric	CTA, NDA
C: Veterinary - Generic Medicinal Product	th-0-92	c-vet-generic	CTA, NDA
C: Veterinary - Medicated Premixed	th-0-92	c-vet-premixed	CTA, NDA
C: Veterinary - Biologics	th-0-92	c-vet-bio	CTA, NDA
D: Traditional Medicinal Product	th-0-92	d-traditional	CTA, NDA
F: Variation - Major Variation (MaV)	th-0-92	f-var-major	CTA, NDA
F: Variation - Minor Variation (MiV-PA)	th-0-92	f-var-minor-pa	CTA, NDA
F: Variation - Minor Variation (MiV-N)	th-0-92	f-var-minor-n	CTA, NDA
F: Variation - Others	th-0-92	f-var-others	CTA, NDA
G: Clinical Trial Authorization Application	th-0-92	g-clin-authapp	CTA, NDA

G: Clinical Trial Authorization Amendments	th-0-92	g-clin-authamend	CTA, NDA
H: Review of SMP Application	th-0-92	h-review-smph	CTA, NDA
H: Risk Management Plan	th-0-92	h-riskmgtplan	CTA, NDA
H: Pharmacovigilance	th-0-92	h-pv	CTA, NDA
H: Periodic Safety Update Report	th-0-92	h-psur	CTA, NDA
I: Drug Master Files	th-0-92	i-dmf	CTA, NDA
I: Plasma Master Files	th-0-92	i-pmf	CTA, NDA
I: Vaccine Antigen Master File	th-0-92	i-vamf	CTA, NDA
I: Tissue Master File	th-0-92	i-tmf	CTA, NDA
J: Supplementary Information	th-0-92	j-suppl	CTA, NDA
K: Orphan Drug Application	th-0-92	k-orphan	CTA, NDA
K: Emergency Used Application	th-0-92	k-emergency	CTA, NDA
Z: Undefined Regulatory Activity	th-0-92	z-undefined-regact	CTA, NDA
A: Pharmaceuticals - New Chemical Entity	th-1-0	a-ph-newce	CTA, NDA
A: Pharmaceuticals - New Salt or Ester of Existing Active Ingredient	th-1-0	a-ph-newse	CTA, NDA
A: Pharmaceuticals - New Dosage Form	th-1-0	a-ph-newdosage	CTA, NDA
A: Pharmaceuticals - New Route of Administration	th-1-0	a-ph-newroute	CTA, NDA
A: Pharmaceuticals - New Combination	th-1-0	a-ph-newcomb	CTA, NDA
A: Pharmaceuticals – Abridge application	th-1-0	a-ph-abridge	CTA, NDA
A: Pharmaceuticals - New Medicinal Product (Others)	th-1-0	a-ph-newothers	CTA, NDA
A: Pharmaceuticals - New Generic	th-1-0	a-ph-newgen	CTA, NDA
A: Pharmaceuticals - Generic	th-1-0	a-ph-generic	CTA, NDA
A: House Hold Remedies	th-1-0	a-ph-house	CTA, NDA
B: Biologics - Vaccine	th-1-0	b-bio-vaccine	CTA, NDA
B: Biologics - Blood and Plasma Derived Product	th-1-0	b-bio-blood	CTA,NDA
B: Biologics - Cell- and Tissue- Based Therapy Product	th-1-0	b-bio-cell	CTA, NDA
B: Biologics - Biotechnology Product	th-1-0	b-bio-biotech	CTA, NDA
B: Biologics - Biosimilar Product	th-1-0	b-bio-biosimilar	CTA, NDA

B: Biologics – Abridge application	th-1-0	b-bio-abridge	CTA, NDA
B: Biologics - Others	th-1-0	b-bio-others	CTA, NDA
C: Veterinary - New Medicinal Product	th-1-0	c-vet-newprod	CTA, NDA
C: Veterinary - New Generic Medicinal Product	th-1-0	c-vet-newgeneric	CTA, NDA
C: Veterinary - Generic Medicinal Product	th-1-0	c-vet-generic	CTA, NDA
C: Veterinary - Medicated Premixed	th-1-0	c-vet-premixed	CTA, NDA
C: Veterinary - Biologics	th-1-0	c-vet-bio	CTA, NDA
D: Traditional Medicinal Product	th-1-0	d-traditional	CTA, NDA
F: Variation - Major Variation (MaV)	th-1-0	f-var-major	CTA, NDA
F: Variation - Minor Variation (MiV-PA)	th-1-0	f-var-minor-pa	CTA, NDA
F: Variation - Minor Variation (MiV-N)	th-1-0	f-var-minor-n	CTA, NDA
F: Variation - Others	th-1-0	f-var-others	CTA, NDA
G: Clinical Trial Authorization Application	th-1-0	g-clin-authapp	CTA, NDA
G: Clinical Trial Authorization Amendments	th-1-0	g-clin-authamend	CTA, NDA
H: Review of SMP Application	th-1-0	h-review-smph	CTA, NDA
H: Risk Management Plan	th-1-0	h-riskmgtplan	CTA, NDA
H: Pharmacovigilance	th-1-0	h-pv	CTA, NDA
H: Periodic Safety Update Report	th-1-0	h-psur	CTA, NDA
I: Drug Master Files	th-1-0	i-dmf	CTA, NDA
I: Plasma Master Files	th-1-0	i-pmf	CTA, NDA
I: Vaccine Antigen Master File	th-1-0	i-vamf	CTA, NDA
I: Tissue Master File	th-1-0	i-tmf	CTA, NDA
J: Supplementary Information	th-1-0	j-suppl	CTA, NDA
K: Orphan Drug Application	th-1-0	k-orphan	CTA, NDA
K: Emergency Used Application	th-1-0	k-emergency	CTA, NDA
L: Consultative Application	th-1-0	l-consult	CTA, NDA
Z: Undefined Regulatory Activity	th-1-0	z-undefined-regact	CTA, NDA

eCTD Filing Types for TN

Ennov InSight provides the following filing types for all application types associated with Tunisia (TN). This table lists the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
New Chemical Entity	tn-1-1	sub-type-1	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Combination	tn-1-1	sub-type-2	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Generic (Multi-source)	tn-1-1	sub-type-3	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New OTC	tn-1-1	sub-type-4	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Vaccines	tn-1-1	sub-type-6	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Radiopharmaceutical	tn-1-1	sub-type-7	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Gene and Cell Therapy	tn-1-1	sub-type-8	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Blood Product	tn-1-1	sub-type-9	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Biotherapeutic	tn-1-1	sub-type-10	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Biosimilar	tn-1-1	sub-type-11	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Traditional	tn-1-1	sub-type-12	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Clinical Trial Application	tn-1-1	sub-type-13	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Excipient	tn-1-1	sub-type-14	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN

ASMF / DMF	tn-1-1	sub-type-15	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Plasma Master File (PMF)	tn-1-1	sub-type-16	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Vaccine Antigen Master File (VAMF)	tn-1-1	sub-type-17	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Tissue Master File (TMF)	tn-1-1	sub-type-18	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Biological Master File (BMF)	tn-1-1	sub-type-19	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Line extension-New Dosage Form	tn-1-1	sub-type-20	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Line extension-New Strength	tn-1-1	sub-type-21	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Line Extension - New Route of Administration	tn-1-1	sub-type-22	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Line extension-New Application	tn-1-1	sub-type-23	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Clone	tn-1-1	sub-type-24	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Replica-Same	tn-1-1	sub-type-25	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Post Approval Commitment	tn-1-1	sub-type-26	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Immediate Notification - Administrative	tn-1-1	sub-type-27	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Annual Notification - Administrative	tn-1-1	sub-type-28	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Annual Notification - Quality	tn-1-1	sub-type-29	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN,

			WHO-SRA CRP - TN, Reliance, EUL-TN
VT Immediate Notification - Quality	tn-1-1	sub-type-30	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Immediate Notification - Clinical	tn-1-1	sub-type-31	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Minor - Quality	tn-1-1	sub-type-32	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Minor - Clinical	tn-1-1	sub-type-33	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Minor - Other	tn-1-1	sub-type-34	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Moderate - Quality	tn-1-1	sub-type-35	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Major - Safety (Clinical)	tn-1-1	sub-type-36	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Major - Safety and Efficacy (Clinical)	tn-1-1	sub-type-37	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Major - Quality	tn-1-1	sub-type-38	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Major - Change in Applicant - Relinquishing	tn-1-1	sub-type-39	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Major - Change in Applicant - Acquiring	tn-1-1	sub-type-40	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Baseline	tn-1-1	sub-type-41	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Renewal Filing	tn-1-1	sub-type-42	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Application Withdrawal/Cancellation	tn-1-1	sub-type-43	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN

Pharmacovigilance	tn-1-1	sub-type-44	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Undefined Regulatory Activity*	tn-1-1	sub-type-45	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Appeal	tn-1-1	sub-type-46	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN

eCTD Sub-Filing Types for TN

The list of eCTD code and the applicable Sub-Filing Type for each Filing Type.

The Sub-Filing Type values are available to select in the *Sub Filing Type Values* section of *Submission Maintenance* Data Administration List.

Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Initial	tn-1-1	seq-type-1	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Supplementary Information	tn-1-1	seq-type-2	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-

			New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Response - Screening Content	tn-1-1	seq-type-3	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Response - Screening Payment	tn-1-1	seq-type-4	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline,

			Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Response - Evaluation Quality	tn-1-1	seq-type-5	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Response - Evaluation Clinical	tn-1-1	seq-type-6	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Response - Evaluation Admin	tn-1-1	seq-type-7	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-

			New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Response - Pharmacovigilance	tn-1-1	seq-type-8	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Closing Information	tn-1-1	seq-type-9	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline,

			Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Work Grouping Partial Withdrawal	tn-1-1	seq-type-10	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Submission Withdrawal	tn-1-1	seq-type-11	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Priority Response	tn-1-1	seq-type-12	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-

			New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal

eCTD Filing Types for TW

Ennov InSight provides the following filing types for all application types associated with Taiwan (TW). This table lists the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
New	TW-1-0	new	NDA, CTA
Change	TW-1-0	change	NDA, CTA
Extension Filing	TW-1-0	extension	NDA, CTA
Expiration	TW-1-0	expiration	NDA, CTA

eCTD Filing Types for UA

Ennov InSight provides the following filing types for all application types associated with Ukraine Authority (UA). This table lists the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
Marketing Authorisation Application	ua-1-0	maa	Clinical Trial Authorisation, New Drug Application
Renewal Filing	ua-1-0	renewal	Clinical Trial Authorisation, New Drug Application
Variation 1A Filing	ua-1-0	var-type1a	Clinical Trial Authorisation, New Drug Application
Variation 1AIN Filing	ua-1-0	var-type1ain	Clinical Trial Authorisation, New Drug Application
Variation 1B Filing	ua-1-0	var-type1b	Clinical Trial Authorisation, New Drug Application
Variation 2 Filing	ua-1-0	var-type2	Clinical Trial Authorisation, New Drug Application

Variation 1 and 2 Filing	ua-1-0	var-type1-2	Clinical Trial Authorisation, New Drug Application
Technical Mistake	ua-1-0	var-tm	Clinical Trial Authorisation, New Drug Application
Extension Filing	ua-1-0	extension	Clinical Trial Authorisation, New Drug Application
Transfer MA Filing	ua-1-0	transfer-ma	Clinical Trial Authorisation, New Drug Application
Withdrawal Filing	ua-1-0	withdrawal	Clinical Trial Authorisation, New Drug Application
Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
None	ua-1-0	none	Clinical Trial Authorisation, New Drug Application

eCTD Filing Types for US

Ennov InSight provides the following filing types for all application types associated with the United States (US).

This table lists the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
Amendment Filing	us-2-01	amendment	ANADA, ANDA, BLA, CNA-DA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA
Annual Report Filing	us-2-01	annual-report	ANADA, ANDA, BLA, CNA-DA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA

CMC Supplement	us-2-01	chemistrymanufacturingcontrolssupplement	ANADA, ANDA, BLA, CNA-DA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA
Efficacy Supplement	us-2-01	efficacy-supplement	ANADA, ANDA, BLA, CNA-DA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA
Labeling Supplement	us-2-01	labeling-supplement	ANADA, ANDA, BLA, CNA-DA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA
Original Filing	us-2-01	original-application	ANADA, ANDA, BLA, CNA-DA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA
Other Filing	us-2-01	other	ANADA, ANDA, BLA, CNA-DA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA
Presubmission Filing	us-2-01	presubmission	ANADA, ANDA, BLA, CNA-DA, DAPM,

			DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA
Re-submission Filing	us-2-01	resubmission	ANADA, ANDA, BLA, CNA- DA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA
Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
Supplement Filing	us-2-01	establishmentdescriptionsupplement	ANADA, ANDA, BLA, CNA- DA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA
Annual Report Filing	us-3-3	fdast5	NDA, ANDA, BLA, IND, DMF
CMC Supplement	us-3-3	fdast3	NDA, ANDA, BLA
Efficacy Supplement	us-3-3	fdast2	NDA, BLA
IND Safety Reports	us-3-3	fdast9	IND
Labeling Supplement	us-3-3	fdast4	NDA, ANDA, BLA
Original Filing	us-3-3	fdast1	IND, NDA, ANDA, BLA, DMF, EUA
Periodic Safety Up- date Report	us-3-3	fdast10	NDA, ANDA, BLA
Postmarketing Requirements or Postmarketing Commitments	us-3-3	fdast7	NDA, BLA

Product Correspondence	us-3-3	fdast6	NDA, ANDA, BLA, IND, DMF
Promotional Labeling Advertising	us-3-3	fdast8	NDA, ANDA, BLA
REMS Supplement	us-3-3	fdast11	ANDA, BLA, NDA

eCTD Sub-Filing Types for US

Ennov InSight provides the following sub-filing types for all application types associated with the United States (US).

This table lists the eCTD code and the applicable Sub-Filing Type for each Filing Type.

Country	Specification	Filing Type	Sub-Filing Type	eCTD Code
United States	us-3-3	Annual Report Filing	Amendment	fdasst4
United States	us-3-3	Annual Report Filing	Report	fdasst6
United States	us-3-3	CMC Supplement	Amendment	fdasst4
United States	us-3-3	CMC Supplement	Application	fdasst3
United States	us-3-3	CMC Supplement	Presubmission	fdasst2
United States	us-3-3	CMC Supplement	Resubmission	fdasst5
United States	us-3-3	Efficacy Supplement	Amendment	fdasst4
United States	us-3-3	Efficacy Supplement	Application	fdasst3
Country	Specification	Filing Type	Sub-Filing Type	eCTD Code
United States	us-3-3	Efficacy Supplement	Presubmission	fdasst2
United States	us-3-3	Efficacy Supplement	Resubmission	fdasst5
United States	us-3-3	IND Safety Reports	Amendment	fdasst4
United States	us-3-3	IND Safety Reports	Report	fdasst6
United States	us-3-3	Labeling Supplement	Application	fdasst3
United States	us-3-3	Labeling Supplement	Presubmission	fdasst2
United States	us-3-3	Labeling Supplement	Resubmission	fdasst5
United States	us-3-3	Original Filing	Amendment	fdasst4
United States	us-3-3	Original Filing	Application	fdasst3
United States	us-3-3	Original Filing	Presubmission	fdasst2

United States	us-3-3	Original Filing	Resubmission	fdasst5
United States	us-3-3	Periodic Safety Update Report	Amendment	fdasst4
United States	us-3-3	Periodic Safety Update Report	Report	fdasst6
United States	us-3-3	Postmarketing Requirements or Postmarketing Commitments	Amendment	fdasst4
United States	us-3-3	Postmarketing Requirements or Postmarketing Commitments	Original	fdasst1
United States	us-3-3	Product Correspondence	Amendment	fdasst4
United States	us-3-3	Product Correspondence	Correspondence	fdasst7
United States	us-3-3	Promotional Labeling Advertising	Amendment	fdasst4
United States	us-3-3	Promotional Labeling Advertising	Original	fdasst1
United States	us-3-3	Promotional Labeling Advertising	Resubmission	fdasst5

eCTD Filing Types for WHO

Ennov InSight provides the following filing types for all application types associated with World Health Organization (WHO). This table lists the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
Annual Report (FVP)	who-1-0	AR	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File
Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
APIMF Procedure	who-1-0	APIMF	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File
New Emergency Use	who-1-0	EUL	Finished Pharmaceutical Product, Finished

Listing (EUL) Application (FPP,FVP)			Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File
Post-PQ Change (API, FFP, FVP)	who-1-0	PPQC	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File
New Prequalification Application (API, FFP, FVP)	who-1-0	PQP	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File
Reassessment (FVP)	who-1-0	REAS	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File
Requalification Application (FPP)	who-1-0	RQAP	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File

eCTD Sub-Filing Types for WHO

The list of eCTD code and the applicable Sub-Filing Type for each Filing Type.

The Sub-Filing Type values are available to select in the *Sub Filing Type Values* section of *Submission Maintenance* Data Administration List.

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type

Annual Notification (FPP)	who-1-0	AN	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Abridged	who-1-0	PQA	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Immediate Notification (API)	who-1-0	AIN	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Annual Notification (API)	who-1-0	AAN	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)

Conversion	who-1-0	CONV	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Applica- tion (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
eCTD Baseline	who-1-0	eCTDB	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
EUL-Full (Emergency Use Listing)	who-1-0	EULF	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Full	who-1-0	Full	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type

Immediate Notification (FPP)	who-1-0	IN	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Major	who-1-0	Major	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Applica- tion (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Minor	who-1-0	Minor	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Parallel	who-1-0	Parallel	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Product Extension	who-1-0	PEX	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment

			(FVP),Requalification Application (FPP)
Standard	who-1-0	STD	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Type A (Approval Before Implementation) (Major)(FVP)	who-1-0	AMAJ	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Type N (Immediate Notification)(Minor) (FVP)	who-1-0	NMI	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Update	who-1-0	UPD	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Applica- tion (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)

no Application Sub Type	who-1-0	none	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
EUL-Abridged (Emergency Use Listing)	who-1-0	EULA	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)

eCTD Filing Types for ZA

Ennov InSight provides the following filing types for all application types associated with South Africa (ZA). This table lists the eCTD code and the applicable DTD or Schema for each Filing Type.

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
Applicant transfer, name and address change of applicant (post-reg-hcr)	za-1-0	post-reg-hcr	CTA, NDA
Biological committee response (pre-reg-biol)	za-1-0	pre-reg-biol	CTA, NDA
Biologicals and biosimilars (post-reg-biol)	za-1-0	post-reg-biol	CTA, NDA
Biosimilar (na-bs)	za-1-0	na-bs	CTA, NDA
Call-up (na-cu)	za-1-0	na-cu	CTA, NDA
Cancellation of a registered product (cancellation)	za-1-0	cancellation	CTA, NDA
Clinical (post-reg-cl)	za-1-0	post-reg-cl	CTA, NDA
Clinical (pre-reg-cl)	za-1-0	pre-reg-cl	CTA, NDA
Complementary Medicines (nacm)	za-1-0	na-cams	CTA, NDA

Complementary Medicines (post-reg-cm)	za-1-0	post-reg-cams	CTA, NDA
Complementary Medicines (pre-reg-cm)	za-1-0	pre-reg-cams	CTA, NDA
Inspectorate (post-reg-insp)	za-1-0	post-reg-insp	CTA, NDA
Inspectorate (pre-reg-insp)	za-1-0	pre-reg-insp	CTA, NDA
Line extension (na-le)	za-1-0	na-le	CTA, NDA
Multisource (na-ms)	za-1-0	na-ms	CTA, NDA
New Chemical Entity – Biological (na-nce-b)	za-1-0	na-nce-b	CTA, NDA
New Chemical Entity – Pharmaceutical (na-nce-ph)	za-1-0	na-nce-ph	CTA, NDA
Pharmaceutical and Analytical (post-reg-pa)	za-1-0	post-reg-pa	CTA, NDA
Pharmaceutical and Analytical (pre-reg-pa)	za-1-0	pre-reg-pa	CTA, NDA
Pharmaceutical and Analytical and Inspectorate (post-reg-painsp)	za-1-0	post-reg-pa-insp	CTA, NDA
Pharmaceutical & Analytical and Inspectorate (pre-reg-pa-insp)	za-1-0	pre-reg-pa-insp	CTA, NDA
Proprietary name (pre-reg-pn)	za-1-0	pre-reg-pn	CTA, NDA
Proprietary name change application (post-reg-pn)	za-1-0	post-reg-pn	CTA, NDA
Response to Council resolutions (pre-reg-cr)	za-1-0	pre-reg-cr	CTA, NDA
Scheduling (pre-reg-sch)	za-1-0	pre-reg-sch	CTA, NDA
Updates following a proprietary name change approval (postreg-pn-update)	za-1-0	post-reg-pn-update	CTA, NDA
Withdrawal of a submission* (withdrawal)	za-1-0	withdrawal	CTA, NDA

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
Applicant transfer, name and address change of applicant (post-reg-hcr)	za-2-1	post-reg-hcr	CTA, NDA
Biological committee response (pre-reg-biol)	za-2-1	pre-reg-biol	CTA, NDA
Biologicals and biosimilars (post-reg-biol)	za-2-1	post-reg-biol	CTA, NDA
Biosimilar (na-bs)	za-2-1	na-bs	CTA, NDA
Call-up (na-cu)	za-2-1	na-cu	CTA, NDA
Cancellation of a registered product (cancellation)	za-2-1	cancellation	CTA, NDA
Clinical (post-reg-cl)	za-2-1	post-reg-cl	CTA, NDA
Clinical (pre-reg-cl)	za-2-1	pre-reg-cl	CTA, NDA
Complementary Medicines (nacm)	za-2-1	na-cm	CTA, NDA
Complementary Medicines (post-reg-cm)	za-2-1	post-reg-cm	CTA, NDA
Complementary Medicines (pre-reg-cm)	za-2-1	pre-reg-cm	CTA, NDA
Inspectorate (post-reg-insp)	za-2-1	post-reg-insp	CTA, NDA
Inspectorate (pre-reg-insp)	za-2-1	pre-reg-insp	CTA, NDA
Line extension (na-le)	za-2-1	na-le	CTA, NDA
Multisource (na-ms)	za-2-1	na-ms	CTA, NDA
New Chemical Entity – Biological (na-nce-b)	za-2-1	na-nce-b	CTA, NDA
New Chemical Entity – Pharmaceutical (na-nce-ph)	za-2-1	na-nce-ph	CTA, NDA
Pharmaceutical and Analytical (post-reg-pa)	za-2-1	post-reg-pa	CTA, NDA

Pharmaceutical and Analytical (pre-reg-pa)	za-2-1	pre-reg-pa	CTA, NDA
Proprietary name (pre-reg-pn)	za-2-1	pre-reg-pn	CTA, NDA
Proprietary name change application (post-reg-pn)	za-2-1	post-reg-pn	CTA, NDA
Reformat Filing	za-2-1	baseline	CTA, NDA
Response to Council resolutions (pre-reg-cr)	za-2-1	pre-reg-cr	CTA, NDA
Scheduling (pre-reg-sch)	za-2-1	pre-reg-sch	CTA, NDA
Updates following a proprietary name change approval (postreg-pn-update)	za-2-1	post-reg-pn-update	CTA, NDA
Withdrawal Filing	za-2-1	withdrawal	CTA, NDA
Inspectorate (resp-post-reg-insp)	za-2-1	resp-post-reg-insp	CTA, NDA
Pharmaceutical and Analytical (resp-post-reg-pa)	za-2-1	resp-post-reg-pa	CTA, NDA
Clinical (resp-post-reg-cl)	za-2-1	resp-post-reg-cl	CTA, NDA
Proprietary name change application (resp-post-reg-pn)	za-2-1	resp-post-reg-pn	CTA, NDA
Updates following a proprietary name change approval (resp-post-reg-pn-update)	za-2-1	resp-post-reg-pnup- date	CTA, NDA
Applicant transfer, name and address change of applicant (resp-post-reg-hcr)	za-2-1	resp-post-reg-hcr	CTA, NDA
Biologicals and biosimilars (resp-post-reg-biol)	za-2-1	resp-post-reg-biol	CTA, NDA
Complementary Medicines (resp-post-reg-cm)	za-2-1	resp-post-reg-cm	CTA, NDA
A - NCE New Chemical Entity	za-3-1	sub-type-1	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS

D - New Generic Medicine	za-3-1	sub-type-2	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Complementary Medicine - New	za-3-1	sub-type-3	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
New Biological	za-3-1	sub-type-4	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Biosimilar (na-bs)	za-3-1	sub-type-5	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Clinical Trial Application	za-3-1	sub-type-6	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
New Vaccines	za-3-1	sub-type-7	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
I: Vaccine Antigen Master File	za-3-1	sub-type-8	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
New SMF	za-3-1	sub-type-9	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
New APIMF	za-3-1	sub-type-10	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Plasma Master File (PMF)	za-3-1	sub-type-11	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS

Line extension-New Strength	za-3-1	sub-type-12	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Line extension-New Dosage Form	za-3-1	sub-type-13	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Line extension - New Application (De-Linking of Application)	za-3-1	sub-type-14	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Clone	za-3-1	sub-type-15	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Replica-Same	za-3-1	sub-type-16	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type IA-Quality	za-3-1	sub-type-17	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type IAin-Clinical	za-3-1	sub-type-18	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type IAin-Quality	za-3-1	sub-type-19	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type IB-Clinical	za-3-1	sub-type-20	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type IB-Quality	za-3-1	sub-type-21	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS

Type IA - Inspectorate	za-3-1	sub-type-22	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type IAin - Inspectorate	za-3-1	sub-type-23	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type II-Safety (Clinical)	za-3-1	sub-type-24	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type II - Safety and Efficacy (Clinical)	za-3-1	sub-type-25	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type II-Quality	za-3-1	sub-type-26	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type II-Rescheduling	za-3-1	sub-type-27	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type II-Proprietary Name Change	za-3-1	sub-type-28	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type II-Change in ApplicantRelinquishing	za-3-1	sub-type-29	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type II-Change in ApplicantAcquiring	za-3-1	sub-type-30	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Baseline	za-3-1	sub-type-31	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS

z-Code - Type II	za-3-1	sub-type-32	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Pharmacovigilance	za-3-1	sub-type-33	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
USRN-Clinical and Pharmacovigilance	za-3-1	sub-type-34	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Application Withdrawal/ Cancellation	za-3-1	sub-type-35	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Renewal Filing	za-3-1	sub-type-36	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Undefined Regulatory Activity*	za-3-1	sub-type-37	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Grouped Variation Clinical	za-3-1	sub-type-38	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Grouped Variation Quality	za-3-1	sub-type-39	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Grouped Variation Inspectorate	za-3-1	sub-type-40	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type IA-Clinical	za-3-1	sub-type-41	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS

Type II-Related Clinical	za-3-1	sub-type-42	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type II-Related Quality	za-3-1	sub-type-43	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type II - Inspectorate	za-3-1	sub-type-44	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type IB - Inspectorate	ZA-3-1	sub-type-45	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
z-Code - Type IAin	ZA-3-1	sub-type-47	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
z-Code - Type IB	ZA-3-1	sub-type-48	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type II - Grouped Variation N and S	ZA-3-1	sub-type-49	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
z-Code - Type IA	ZA-3-1	sub-type-50	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS

*If there is no such filing type in the database, South Africa will be associated with the existing Withdrawal Filing filing type.

eCTD Sub-Filing Types for ZA

The following table lists the eCTD code and the applicable Sub-Filing Type for each Filing Type. The Sub-Filing

Type values are available to select in the *Sub Filing Type Values* section of *Submission Maintenance Data Administration List*.

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Initial	za-3-1	seq- type-1	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II- Safety (Clinical), Type II - Safety and Efficacy

			(Clinical), Type II-Quality, Type II-Rescheduling, Type II-Proprietary Name Change, Type II-Change in Applicant-Relinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB-Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate
Supplementary Information	za-3-1	seq-type-2	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, Replica Same, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type II-Proprietary Name Change, Type II-Change in Applicant-Relinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB-Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate
Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type

Response- Clinical	za-3-1	seq- type-3	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type IIProprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate
Response- Quality	za-3-1	seq- type-4	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type II- Proprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application

			Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Response- Inspectorate	za-3-1	seq- type-5	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type IIProprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate
Response-N and S	za-3-1	seq- type-6	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine

			Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type II- Proprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Closing Information	za-3-1	seq- type-7	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type IIProprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharma-

			covigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate
Work Grouping Partial Withdrawal	za-3-1	seq-type-8	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type II- Proprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate
Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Submission Withdrawal	za-3-1	seq-type-9	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar

			(na-bs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type IIProprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate
Response-Biological	za-3-1	seq-type-10	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type II- Proprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related

			Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate
Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
ResponseRe- newals	za-3-1	seq- type-11	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type IIProprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate
Response-PV	za-3-1	seq- type-12	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New

			Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type II-Proprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB-Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate

Chapter 8. Prevent Unauthorized User Access to Red Hat JBoss EJBInvokerServlet

Ennov InSight enables you to prevent unauthorized users from accessing Red Hat JBoss EJBInvokerServlet.

To prevent unauthorized users from accessing JBoss EJBInvokerServlet:

1. Open the web.xml file in a text editor. The web.xml file is located at: \InSightManager\server

\all\deploy\httpa-invoker.sar\invoker.war\WEB-INF

2. In the web.xml file, comment the JBoss EJBInvokerServlet code block as shown in the image below.

```
</filter-mapping>
<!-- EJB Servlets -->
<!--servlet> <servlet-name>EJBInvokerServlet</servlet-name> <description>The EJBInvokerServlet receives posts containing serialized MarshalledInvocation objects that
are routed to the EJB invoker given by the invokerName init-param. The return content is a serialized MarshalledValue containing the return value of the invocation, or any
exception that may have been thrown. </description> <servlet-class>org.jboss.invocation.http.servlet.InvokerServlet</servlet-class> <init-param> <param-
name>invokerName</param-name> <param-value>{jboss.service=invoker,type=http}</param-value> <description>The RMI/HTTP EJB compatible invoker</description>
</init-param> <load-on-startup>1</load-on-startup> </servlet> <servlet> <servlet-name>EJBInvokerHAServlet</servlet-name> <description>The
EJBInvokerHAServlet receives posts containing serialized MarshalledInvocation objects that are routed to the EJB invoker given by the invokerName init-param. The return
content is a serialized MarshalledValue containing the return value of the invocation, or any exception that may have been thrown. </description> <servlet-
class>org.jboss.invocation.http.servlet.InvokerServlet</servlet-class> <init-param> <param-name>invokerName</param-name> <param-
value>{jboss.service=invoker,type=httpHA}</param-value> <description>The HA-RMI/HTTP EJB compatible invoker</description> </init-param> <load-on-
startup>1</load-on-startup> </servlet>
--> <servlet>
```

3. Save the web.xml file.
4. Restart the InSightManager service.

Chapter 9. Assembly XML Specification

Assembly

Assembly XML Structure

The Assembly XML has the following structure:

```
<?xml version="1.0"?>
```

```
<insightExport version="5.1" product="Insight Manager" name="root tag name">
```

```
<class name="class name">
```

```
<field name="field name" type="field type">field value</field>
```

Class Name	Relevance (Y/N)	Description
com::liquent::insight::manager::content::dto::Assembly	Y	See Assembly topic
com::liquent::insight::manager::content::dto::Folder	N	See Folder topic
com::liquent::insight::manager::content::dto::Leaf	N	See Leaf topic

```
</class>
```

```
</insightExport>
```

Where the XML attributes represent the following:

- *root tag name* – Arbitrary text. This does not take part in assembly import, and can be left blank.
- *class name* – The name of the class corresponding to the node of Assembly hierarchy.
- *field name* – The name of the field being imported.
- *field type* – The type of field being imported.

– *field value* – The value of the field being imported.

For convenience, the AssemblyImport.xsd file is provided to enable you to validate Assembly XML created manually or programmatically using third-party tools. Validation should be done according to the instructions or guidelines of the third-party tool being used.

Assembly XML Classes

Class Name	Re (Y/ N)	Description
com::liquent::insight::manager::content::dto::Document	N	See Document topic
com::liquent::insight::manager::content::dto::PublisherMetaData	N	See Metadata topic
com::liquent::insight::manager::content::documents::DocRef	N	This class is not used for import.
com::liquent::insight::manager::publisher::data::Volume	Y	See Volume Settings topic
com::liquent::insight::manager::publisher::data::Variable	N	See Variable topic
com::liquent::insight::manager::publisher::data::Extract	N	This class is not used for import.

com::liquent::insight::manager::publisher::data::SettingsProfile	Y	See Link Profiles topic
com::liquent::insight::manager::publisher::data::PageMarker	N	See Page Marker topic
com::liquent::insight::manager::publisher::data::paper::ValidPrinterMedia	N	This class is not used for import.
com::liquent::insight::manager::publisher::data::publishsettings::SlipSetting	N	See Slip Sheet Settings
com::liquent::insight::manager::publisher::data::publishsettings::TabSetting	N	See Tab Settings
com::liquent::insight::manager::publisher::data::publishsettings::PubSettingsRefDtd	Y	See XML Definition
com::liquent::insight::manager::publisher::data::publishsettings::PublishingSettings	Y	See Publishing Settings

Class Name	Re (Y/ N)	Description
com::liquent::insight::manager::publisher::data::publishsettings::CoverPageSetting	N	See Cover Page

		Settings
com::liquent::insight::manager::publisher::data::publishsettings::PubSettingPdfProperty	N	See PDF Property Settings
com::liquent::insight::manager::publisher::data::publishsettings::CoverSettingOutputChannel	N	See Output Channel fo Cover Page Settings
com::liquent::insight::manager::publisher::data::publishsettings::PublishingSettingsLibrary	Y	See Publishing Settings Library
com::liquent::insight::manager::publisher::data::publishsettings::DefaultPublishingValues	N	See Default Values
com::liquent::insight::manager::publisher::data::specialsheets::Tab	N	See Tab
com::liquent::insight::manager::publisher::data::specialsheets::Slip	N	See Slip
com::liquent::insight::manager::publisher::data::specialsheets::TOC	N	See Table Of Content (TOC)
com::liquent::insight::manager::publisher::data::specialsheets::Cover	N	See Cover
com::liquent::insight::manager::publisher::data::specialsheets::TOCEntryGenOption	N	See Tree Elements t Include in

		TOC
com::liquent::insight::manager::publisher::data::specialsheets::TocType	N	See TOC Settings
com::liquent::insight::manager::publisher::data::outputchannels::VariableOutputChannel	N	See Output Channel fo Variable
com::liquent::insight::manager::publisher::data::outputchannels::SpecialSheetOutputChannel	N	See Output Channel fo Tab

Assembly

Class Name: com::liquent::insight::manager::content::dto::Assembly

Class Name	Re (Y/ N)	Descrip- tion
com::liquent::insight::manager::publisher::data::outputchannels::TOCTypeOutputChannel	N	See Out- put Channel fo TOC Settings
com::liquent::insight::manager::publisher::data::outputchannels::ContentOutputChannel	N	See Out- put Channel fo

		Document
com::liquent::insight::manager::publisher::data::metadata::MetaDataLibrary	N	See Metadata Library
com::liquent::insight::manager::publisher::data::overlays::Overlay	N	See Over- lay Settings

If a field name contains an automatically populated value, that value will be used in the Assembly. It will overwrite any value that may be defined in the Assembly XML.

If a field name is not required, but does contain a default value, the default value will be set automatically in the imported Assembly unless otherwise specified in the Assembly XML.

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
abbreviatedName	string		N	This field is not used for import.		Automatically populated value is the Name of Assembly.
absoluteChildSeqNo	long		N	This field is not used for import.		Automatically populated value is "1"
activeFlag	string		N	This field is not used for import.		Automatically populated value is "Y".
assemblyId	long		N	This field is not used for import.		Default value is equal to id field.

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
assemblySubmissionType	string		Y	Defines the output type of the Assembly.	– eCTD – US eCTD – CN eCTD – Standard	
assemblyType	long	Assembly Type	Y	Internal codes that correspond to the assemblySubmissionType field: – eCTD = ECTD – US eCTD = US – CN eCTD = CN – Standard = STANDAR D	– ECTD – US – CN – STANDAR D	
autoCreateLeafFlag	string	Create Leaf Elements	N	Determines if Leaf elements are created when dragging files onto folders.	– Y – N	Y

Field Name	Field Type	Matching UI Field	Req	Description	Acceptable Values	Default Value

			(Y/N)			
autoPopulate OutputFlag	string	Auto Populate Output Folder	N	If “Auto Populate Output Folder” is set to Yes and a folder is created during assignment from DMS: – A folder that is created has Output Folder attribute set to the name of VDoc/ Folder that was used to create it. – All subfolders that were created as a result of the parent VDoc/ Fodleer assignment have Output Folder attribute set to the name of VDoc/ Folder that was used to create them.	– Y – N	N

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
auxiliaryOutputLocation	string	Auxiliary Output Location	N	Path to the location for the publishing elements to be stored.	Example: // root/ folder	
baselineFlag	string		N	This field is not used for import.		
bindingRule	string	Default Binding Rule	N	The default rule used to bind documents from the DMS to one of the following document properties: – version_label=CURRENT; – status=(In Draft In Review Approved In Approval); – version_number=[string that represent version number]	Example: version_label=CURRENT; status=Approved; version_number=1.0;	version_label=CURRENT

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value

category	long	Category	N	The Assembly high level category. The field value is CODE value of Data Administration: Assembly Category.	Values from the database: ISM.ASEMBLY_CATEGORY.CODE	
changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeId	long		N	This field is not used for import.		
childSeqNo	long		N	This field is not used for import.		Automatically populated value is "-1"
comments	string	Comments	N	Comments to be added to the Assembly.		
currencyFlag	string		N	This field is not used for import.		
dctmRefObjectId	string		N	This field is not used for import.		
depth	long		N	This field is not used for import.		
description	string	Description	N	Description of the Assembly.		
discriminator	string		N	Discriminator.		The fixed value for Assembly is "A".
Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value

displayBindingRule	string		N	This field is not used for import.		
displayCopiedFromName	string	Created From	N	This field is not used for import.		
displayStatusName	string		N	This field is not used for import.		
dueDate	date	Due Date	N	The date the Assembly is due to be complete for submission.	Date is in Unix Timestamp date format.	
electronicOutputLocation	string	Electronic Output Location	N	Path to the location for the electronic published output to be stored.	Example: // root/ folder	
extensionDisplayLayoutName	string		N	This field is not used for import.		Fixed value is "Default".
extensionType	string		N	This field is not used for import.		Fixed value is "Default".
guid	string		N	This field is not used for import.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
id	long		Y	Unique Assembly ID represented by a numerical value. This field is used to link classes within the	Example: 5513035	

				Assembly XML. This value will be used to populate corresponding fields in child classes. This ID will be replaced by the database ID in the imported assembly.		
internalCopyChronId	long		N	This field is not used for import.		
keywords	string	Keywords	N	Keywords that apply to the specific Assembly.		
lastTemplate	string		N	This field is not used for import.		
latestVersionFlag	string		N	This field is not used for import.		
leafAutoStartWorkflowIds	object	Default Leaf Workflow	N	This field is not used for import.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
lockFlag	string	Lock Indicator	N	Indicates if the Assembly has been locked or not.	– U – Unlocked – L – Locked – E - Locked with an eCTD lock	U

majorFolderAutoStartWorkflowIds	object	Default Major Division Folder Workflow	N	This field is not used for import.		
modifiedFile	string		N	This field is not used for import.		
name	string	Name	Y	Assembly Name.		
nodeNumber	string		N	This field is not used for import.		
numLifecycleChildren	long		N	This field is not used for import.		
operatedInSequenceId	long		N	This field is not used for import.		
other	string		N	This field is not used for import.		
owner	string	Owner	N	The owner of the Assembly. The User name of existing User in the system.		Default value is User name of User who performs import.

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
paperOutputLocation	string	Paper Output Location	N	Path to the location for the paper published output to be stored.	Example: // root/ folder	
parentId	long		N	This field is not used for import.		
publishingSettingsLibraryId	long		Y	Value of the		

				ID field of the Publishing Settings Library class.		
referenceLocationName	string	Reference Location Name	N	This field is not used for import.		
refreshDate	date	Last Repository Data Retrieval	N	The date when content was created. Date format - Unix Timestamp.	Unix Timestamp date format. Example: 1169580727000	Default is today's date.
refreshFlag	string		N	This field is not used for import.		
revision	string		N	This field is not used for import.		
statusDate	date	Status Date	N	This field is not used for import.	Unix Timestamp date format. Example: 1169580727000	Default is today's date.
statusTypeIdd	long	Status	N	The field is not used for import.		IN_DRAFT

Field Name	Field Type	Matching UI Field	Req	Description	Acceptable Values	Default Value

			(Y/N)			
subCategory	long	Subcategory	N	The Assembly low-level category. Available options depend on the Category selected. The field value is CODE value of Data Administration: Assembly Subcategory Values.	Values from the database: ISM.ASEMBLY_SUBCATEGORY_TYPE. CODE	
supersededFlag	string		N	This field is not used for import.		
titleRef	string		N	This field is not used for import.		
transApplicationId	long		N	This field is not used for import.		
transAssemblyType	string		N	The numeric Assembly type code.	– 1 – Template – 2 – Standalone Assembly – 6 – Sequence Assembly – 11 – Assembly	2

					Plan Sequence	
transOperate dSeqId	long		N	This field is not used for import.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Val- ues	Default Value
type	string		N	This field is not used for import.		
uiVersion	string	Version Number	N	This field is not used for import.		
versionLabel	string		N	This field is not used for import.		Automatically populated val- ue is CURRENT.
versionNumb er	string		N	This field is not used for import.		Automatically populated val- ue is 1.0

Folder

Folder

Class Name: com::liquent::insight::manager::content::dto::Folder

Note: If a field name is not required, but does contain a default value, the default value will be set automatically in the imported Assembly unless otherwise specified in the Assembly XML.

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Val- ues	Default Value
abbreviatedN ame	string	Abbreviated Name	N	The short name for the folder.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
absoluteChildSeqNo	long		Y	All nodes from the top to bottom in assembly (including) have number (absolutechildseqno) depending of top node (assembly).	See example in Explanation for childSeqNo and absoluteChildSeqNo Fields on page 747.	
activeFlag	string		N	This field is not used for import.		Y
assemblyId	long		Y	Value of the ID field of the Assembly class.	Example: 5513035	
bindingRule	string		N	This field is not used for import.		
changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeId	long		N	This field is not used for import.		
childSeqNo	long		Y	All nodes from the top to bottom in assembly (including) have number (childSeqNo) depending of parent	See example in Explanation for childSeqNo and absoluteChildSeqNo Fields on page 747.	

				node (can be any node).		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
comments	string	Comments	N	Comments regarding the Folder.		
copiedFromId	long		N	This field is not used for import.		
depth	long		N	This field is not used for import.		
description	string	Description	N	Description of the Folder.		
discriminator	string		N	Discriminator.		The fixed value for Folder is "F".
divisionTypeId	long	Division	N	Folder division.	– MAJOR – MINOR – NONE	Empty
dueDate	date	Due Date	N	The date all content within the folder is due. Date is in Unix Timestamp date format.		

extensionDisplayName	string	Extension	N	This field is not used for import.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
extensionType	string		N	Name of extension that user can set on folder. Format is "type version" where type is m1-us, m1ca, m1-jp, etc. and version is 1.0, 2.2, 3.3, etc. If extension is set on folder then additional folder types appear.		Default
forceNewVolumeFlag	string	Force New Volume	N	Indicates if a new volume should be created at this folder during volume.	– Y – N	N
guid	string	Leaf ID	N	Identifier, format is "a" + md5 string.	Example: ad41d8cd98 f00b204e98 00998ecf84 27e	

Field Name	Field Type	Matching UI Field	Req	Description	Acceptable Values	Default Value

			(Y/N)			
id	long		Y	Unique Folder ID represented by a numerical value. This field is used to link classes within the Assembly XML. This value will be used to populate corresponding fields in child classes. This ID will be replaced by the database ID in the imported Folder.	Example: 5516639	
isLifecycled	string		N	This field is not used for import.		
keywords	string	Keywords	N	Keywords that apply to the specific Folder.		
lockFlag	string	Lock Indicator	N	Indicates if the folder is locked or not.	– U - Unlocked – L - Locked	U
modifiedFile	string		N	This field is not used for import.		
name	string	Name	Y	Folder Name.		
Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value

nodeNumber	string	Number	N	Number of folder, can contain numbers and letters.	Example: 1, 2, 3, 4, 5, 1.0, 1.A, etc.	Default value is empty.
numLifecycle dChildren	long		N	This field is not used for import.		
other	string		N	This field is not used for import.		
outputFolder	string	Output Folder	N	The folder name to be created in the output, this is used to override any automatically create eCTD folders, or where there is no folder to be create (example: A Study), a folder will be created.		
owner	string	Owner	N	The owner of the Folder. This is the User name of existing User in the system.		Default value is the User name of User who performs import.
parentId	long		Y	id of parent element.	See example in Explanation for parentId Field on page 748.	

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
publishingSettingsLibraryId	long		N	This field is not used for import.		
refreshDate	date	Last Repository Data Retrieval	N	The date when content was created. Date format - Unix Timestamp.	Example: 1169580727000	Default is today's date.
statusTypeId	long		N	This field is not used for import.		
supersededFlag	string		N	This field is not used for import.		
titleRef	string		N	This field is not used for import.		
transApplicationId	long		N	This field is not used for import.		

Leaf

Leaf

Class Name: com::liquent::insight::manager::content::dto::Leaf

Note: If a field name is not required, but does contain a default value, the default value will be set automatically in the imported Assembly unless otherwise specified in the Assembly XML.

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
abbreviatedName	string	Abbreviated Name	N	The abbreviated name of the leaf.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
absoluteChildSeqNo	long		Y	The value of this field is an index that increases from top to bottom in the assembly tree.	See example in Explanation for child-SeqNo and absolute-ChildSeqNo Fields	
activeFlag	string		N	This field is not used for import.	– Y – N	
actuate	string	Actuate	N	Leaf actuate.	– onLoad – onRequest – other – none	
applicationVersion	string	Application Version	N	This field represents the Application Version field.		
assemblyId	long		Y	Value of the ID field of the Assembly class.	Example: 5513035	
bindingRule	string		N	This field is not used for import.		
changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeId	long		N	This field is not used for import.		

checksum	string		N	A leaf check-sum.	Example: d1322e3afb89ed 6fd93794f96beb f941	

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
childSeqNo	long		Y	The value of this field is an index that increases from top to bottom within the current parent node of the assembly tree.	See example in Explanation for child-SeqNo and absolute-ChildS eqNo Fields	
comments	string	Comments	N	Comments about the leaf.		
copiedFromId	long		N	This field is not used for import.		
depth	long		N	This field is not used for import.		
description	string	Description	N	A description of the leaf.		
discriminator	string		N	This field is not used for import.		Fixed value for Leaf is L
displayOperation	string		N	This field is not used for import.		
dueDate	date	Due Date	N	The date the leaf is due to be completed.		

ectdHref	string		N	This field is not used for import.		
extensionDisplayName	string	Extension	N	This field is not used for import.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
extensionType	string		N	Name of extension that user can set on Leaf. Format is "type version" where type is study_report_leaf , japanese_leaf , etc. and version is 1.0, 2.2, 3.3, etc. If extension is set on Leaf then additional extension fields appear.		Default
fontLibrary	string	Font Library	N	The font library used in this leaf.		
guid	string	Leaf ID	N	Unique identifier, format is "a" + md5 string.	Example: ad41d8cd98f00b204e9800998ecf8427e	

Field Name	Field Type	Matching UI Field	Req	Description	Acceptable Values	Default Value

			(Y/N)			
id	long		Y	Unique Leaf ID represented by a numerical value. This field is used to link classes within the Assembly XML. This value will be used to populate corresponding fields in child classes. This ID will be replaced by the database ID in the imported Leaf.	Example: 5516639	
keywords	string	Keywords	N	The keywords specific to the leaf.		
language	string	Language	N	The language of the document.		
leafVersion	string	Version	N	The version of the file.		
linkText	string	Link Text	N	This field is a text attribute and represents the Link Text field.		
Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value

lockFlag	string		N	Indicates of the Leaf has been locked or not.	– U - Unlocked – L - Locked	U
modifiedFile	string		N	This field is a text attribute and represents the Modified File field.		
name	string	Name	Y	The name of the leaf as it appears in the tree.		
nodeNumber	string	Number	N	The eCTD Number for that leaf.		
numLifecycleChildren	long		N	This field is not used for import.		
operationType	long	Operation	N	The operation of the leaf.	– NEW – APPEND – REPLACE – DELETE	
other	string		N	This field is not used for import.		
outputFileName	string	Output File	N	The output file name to be created in the published output		
outputLocation	string	Published Output Location	N	The location of the published leaf.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
owner	string	Owner	N	The Responsible person for that leaf.		
parentId	long		Y	Id of parent element.	See example in Explanation for parentId Field	
refreshDate	date	Last Repository Data Retrieval	N	The date when content was created.	Date format - Unix Timestamp.	Default is today's date.
role	string	Role	N	A leaf role.		
show	string	Show	N	A leaf show.	– new – replace – embed – other – none	
statusTypeid	long		N	This field is not used for import.		
supersededFlag	string		N	This field is not used for import.		
title	string	Title	N	The Title of the leaf.		
titleRef	string		N	This field is not used for import.		

transApplicati onId	long		N	This field is not used for import.		
typeCode	string		N	This field is not used for import.		Default value is LEAF

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
useApplicatio nPrefixFlag	string	Use Application Prefix	N	Defines if the Application Pre- fix should be ap- plied to the link, for use when the reference leaf exists in another Application/ As- sembly.	– Y – N	N
useNativeFile Flag	string	Use Native File	N	Defines if the documents within the leaf should be passed through to the output without being touched by En- nov InSight Pub- lisher. If set to T (stands for True), only one document should be as-	– T - stands for True (Yes) – F - stands for False (No)	

				sociated to the leaf.		

Document

Document

Class Name: com::liquent::insight::manager::content::dto::Document

Note: If a field name is not required, but does contain a default value, the default value will be set automatically in the imported Assembly unless otherwise specified in the Assembly XML.

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
abbreviatedName	string	Abbreviated Name	N	The abbreviated name of the Document/ Placeholder.		
absoluteChildSeqNo	long		Y	The value of this field is an index that increases from top to bottom in the assembly tree.	See example in Explanation for childSeqNo and absoluteChildSeqNo Fields on page 747.	
activeFlag	string		N	This field is not used for import.		
assemblyId	long		N	This field is not used for import.		
assignmentStatus	string		N	This field is not used for import.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value

bindingRule	string	Bound Version	N	The default rule used to bind documents from the DMS to one of the following document properties: – version_label=CURRENT – status=Approved – version_number=1 .0 – version_label=CURRENT – status=(In Draft In Review Approved In Approval) – version_number=[string that represent version number]	Example: – version_label=CURRENT – status=Approved – version_number=1 .0	version_label=CURRENT
category	string	Category	N	The category of the document/placeholder.		
changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeId	long		N	This field is not used for import.		
checkOutDate	date		N	This field is not used for import.		
Field Name	Field Type	Matching UI Field	Req	Description	Acceptable Values	Default Value

			(Y/N)			
checkOutLocationId	long		N	This field is not used for import.		
childSeqNo	long		Y	The value of this field is an index that increases from top to bottom within the current parent node of the assembly tree.	See example in Explanation for childSeqNo and absoluteChildSeqNo Fields on page 747.	
comments	string	Comments	N	Comments regarding the Document.		
copiedFromId	long	Copied From	N	This field is not used for import.		
depth	long		N	This field is not used for import.		
description	string	Description	N	Description of the document.		
discriminator	string		N	This field is not used for import.		The fixed value for Document is "D"
displayCopiedFromName	string		N	This field is not used for import.		
displayNewerVersionAvailable	string		N	This field is not used for import.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
displayReviewStatus	string		N	This field is not used for import.		
displayTypeName	string		N	This field is not used for import.		
dueDate	date	Due Date	N	Displays the date the document is due to be completed.	Date is in Unix Timestamp date format.	
extensionDisplayname	string		N	This field is not used for import.		
extensionType	string		N	This field is not used for import.		
guid	string		N	This field is not used for import.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
id	long		Y	Unique Document ID represented by a numerical value. This field is used to link classes within the Assembly XML. This value will be used to populate corresponding	Example: 5516639	

				g fields in child classes. This ID will be replaced by the database ID in the imported Document.		
inclInPageNumbersFlag	string	Include in Page Numbering	N	Enables the document to be exempt from page numbering (when using variables).	– Y – N	Y
keywords	string	Keywords	N	Keywords about the document.		
lockFlag	string		N	Indicates if the Leaf has been locked or not.	– U - Unlocked – L - Locked	U

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
modifiedFile	string		N	The name of the leaf that is modified, used when lifecycling.		
name	string	Name	Y	The name of the Document/ Placeholder.		
nodeNumber	string	Number	N	Number of the document, can contain numbers and letters.	1, 2, 3, 4, 5, 1.0, 1.A, etc.	Default value is empty.

numLifecycle dChildren	long		N	This field is not used for import.		
operatedInSe quenceld	long		N	This field is not used for import.		
other	string	Other	N	Other informa- tion about the document.		
overlaySettin gsld	long	Overlay Settings	N	This field is not used for import.		
owner	string	Owner	N	Displays the owner of the document. User who assigned the document.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Val- ues	Default Value
pageRangeFr om	int	Page Range From	N	Enables the user to define the range of pages within the document to be used.		
pageRangeTo	int	Page Range To	N	Enables the user to define the range of pages within the document to be used.		
parentId	long		Y	id of parent ele- ment.	See example in Explanation for parentId Field on page 748.	
plannedPage Count	int	Planned Number of	N	For placeholder- ers, enables the user to plan for		

		Pages		a specific number of pages.		
refreshDate	date	Last Repository Retrieval Date	N	The date of the last DMS sync execution.	Date is in Unix Timestamp date format.	Default value is Creation date.
renditionModifierType	long	Rendition Identifier	N	The rendition identifier to use for this document.	Rendition Identifier Name value from Data Administration > Rendition Identifier Values	Default value is "Standard Rendition"
reviewStatus	string		N	This field is not used for import.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
srcContentType	string	Content Type	N	Displays the content type of the assigned document.		
srcDisplayAssignments	string		N	This field is not used for import.		
srcDisplayBoundVersion	string		N	This field is not used for import.		
srcHasRenditionsFlag	string		N	This field is not used for import.		

srcLocation	string	Source Location	N	The location of the physical file within DMS.	Example: //root/ folder	
srcName	string	Source Document	N	The name of the physical file including extension within DMS.	Example: SomeFile.p df	
srcPageCount	int		N	This field is not used for import.		
srcReviewStatus	string	Review Status	N	The review status of the document.		
srcTitle	string	Title	N	The title of the document/ placeholder.		

ContentOutputChannel

Class com::liquent::insight::manager::publisher::data::outputchannels::ContentOutputC **Name:**

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
statusTypeeld	long	Assignment Status	N	Status of assigned document.	– BOUND – MISSING – MISSING_CONTENT – MISSING_VERSION – SUPERCEDED – UNASSIGNED	UNASSIGNED

supersededFlag	string		N	This field is not used for import.		
titleRef	string		N	This field is not used for import.		
transApplicationId	long		N	This field is not used for import.		
typeCode	string		N	This field is not used for import.		The fixed value for Document is "DOCUMENT"

Note: The *ContentOutputChannel* is a specific class that is related to the "Output Channel" UI multiselect field of the Document UI element. Therefore, you need to declare as many *ContentOutputChannel* classes in Assembly XML for each Document class as you need to select the "OutputChannel" values for the corresponding Document class.

For example, if you want to select ELEC and PAPER for the current Document class, then you need to create two *ContentOutputChannel* classes. One for ELEC (the *outputChannelTypeId* field value is ELEC), one for PAPER (the *outputChannelTypeId* field value is PAPER), and associate both to the current Document class (value of the *documentId* field is value of *id* field of this Document class).

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
id	long		Y	Unique ContentOutputChannel ID represented by numerical value. This value will be used to populate corresponding fields in child classes. This ID will be replaced by the database ID in the imported assembly.		
outputChannelTypeId	long	Output Channel	Y	Defines if the document should be included in the paper or electronic (or both) output channels.	– ELEC	

					– PAPER	
documentId	long		Y	Value of the ID field of a Document class that the ContentOutputChannel belong to.		
changeReasonComment	string		N	This field is not used for import.		
changeReasonType	long		N	This field is not used for import.		

Extensions

Extensions Structure

The Integration of Extensions has the following structure.

```
<class name="class name" >
```

```
<field name="field name" type="field type">field value</field>
```

```
...
```

```
<extensions>
```

```
<extension type="extension type" version="extension version"> <field name="field name" type="field type">field value</ field>
```

```
...
```

```
</extension>
```

```
</extensions>
```

```
</class>
```

Where the XML attributes represent the following:

- *class name* - The name of the class corresponding to the node of Assembly hierarchy.
- *field name* - The name of the field being imported.
- *field type* - The type of field being imported.
- *field value* - The value of the field being imported.
- *extension type* - The name of the Extension being imported, (example: m1-us).
- *extension version* - The version of the Extension being imported, (example: 3.3).

Groups of Extensions by Version and Country

Group Name	Group Version	Extension Name	Extension Version	Class Reference
AU	0.9	m1-au	0.9	Folder
		node-extension	1.0	Folder
	3.0	m1-au	3.0	Folder
		node-extension	1.0	Folder
	3.1	m1-au	3.1	Folder
		node-extension	1.0	Folder
	3.2	m1-au	3.2	Folder
		node-extension	1.0	Folder
	AU 2.0 NeeS	au-2-0-nees	2.0	Folder
BA	3.1	m1-ba	1.0	Folder
		ba-m1-additional	3.1	Folder
		ba-m1-responses	3.1	Folder
		ba_module_1_country_specific_information	3.1	Folder
		ba-m1-splabelinfo	3.1	Folder
		envelope-ba	3.1	Folder
		eu-envelope	1.0	Leaf
		node-extension	1.0	Folder
CH	1.0	m1-ch	1.0	Folder
		m1-ch-galenic-form	1.0	Folder
		m1-ch-responses	1.0	Folder
		m1-ch-additional	1.0	Folder
		m1-ch-common-form	1.0	Folder
	1.0.1	m1-ch	1.0	Folder
		m1-ch-galenic-form	1.0	Folder
		m1-ch-responses	1.0	Folder
		m1-ch-additional	1.0	Folder
		m1-ch-common-form	1.0	Folder
	1.1	m1-ch	1.1	Folder

		m1-ch-galenic-form	1.1	Folder
		m1-ch-responses	1.0	Folder
		m1-ch-additional	1.0	Folder
		m1-ch-common-form	1.0	Folder
CH	1.2	m1-ch	1.2	Folder
		m1-ch-galenic-form	1.1	Folder
		m1-ch-responses	1.0	Folder
		m1-ch-additional	1.0	Folder
		m1-ch-common-form	1.0	Folder
	1.3	m1-ch	1.3	Folder
		m1-ch-galenic-form	1.1	Folder
		m1-ch-responses	1.0	Folder
		m1-ch-additional	1.0	Folder
		m1-ch-common-form	1.0	Folder
	1.4	m1-ch	1.4	Folder
		m1-ch-galenic-form	1.1	Folder
		m1-ch-responses	1.0	Folder
		m1-ch-additional	1.0	Folder
		m1-ch-common-form	1.0	Folder
	1.5	m1-ch	1.5	Folder
		m1-ch-galenic-form	1.1	Folder
		m1-ch-responses	1.0	Folder
		m1-ch-additional	1.0	Folder
		m1-ch-common-form	1.0	Folder
CA	1.0	m1-ca	1.0	Folder
		node-extension	1.0	Folder
CDN	2.2	m1-ca	2.2	Folder
		node-extension	1.0	Folder
CN	1.0	m1-cn	1.0	Folder
EAEU	1.0	eaeu_leaf	1.0	Leaf
		envelope-eaeu	1.0	Folder
		eaeu-envelope	1.0	Leaf
EU	1.0	envelope	1.0	Folder

EU		eu_module_1_country_specific_information	1.0	Folder
		eu-envelope	1.0	Leaf
		m1-3-1-pim	1.0	Folder
		m1-3-1-spc-label-pl	1.0	Folder
		m1-additional	1.0	Folder
		m1-eu	1.0	Folder
		node-extension	1.0	Folder
	1.1	envelope	1.1	Folder
		eu_module_1_country_specific_information	1.0	Folder
		eu-envelope	1.0	Leaf
		m1-3-1-pim	1.0	Folder
		eu_pim_additional_documents	1.0	Folder
		m1-3-1-spc-label-pl	1.1	Folder
		m1-additional	1.0	Folder
		m1-eu	1.0	Folder
		node-extension	1.0	Folder
	1.2.1	envelope	1.2.1	Folder
		eu_module_1_country_specific_information	1.2.1	Folder
		m1-3-1-spc-label-pl	1.2.1	Folder
		m1-3-1-pim	1.0	Folder
		m1-additional	1.2.1	Folder
		m1-responses	1.2.1	Folder
		m1-eu	1.0	Folder
		node-extension	1.0	Folder
		eu-envelope	1.0	Leaf
	1.3	envelope	1.3	Folder
		eu_module_1_country_specific_information	1.2.1	Folder
		m1-3-1-spc-label-pl	1.2.1	Folder
		m1-3-1-pim	1.0	Folder
		m1-additional	1.2.1	Folder
		m1-responses	1.2.1	Folder
		m1-eu	1.0	Folder
		node-extension	1.0	Folder

EU		eu-envelope	1.0	Leaf
	1.4	envelope	1.4	Folder
		eu_module_1_country_specific_information	1.2.1	Folder
		m1-3-1-spc-label-pl	1.2.1	Folder
		m1-3-1-pim	1.0	Folder
		m1-additional	1.2.1	Folder
		m1-responses	1.2.1	Folder
		m1-eu	1.0	Folder
		node-extension	1.0	Folder
		eu-envelope	1.0	Leaf
	2.0	envelope	2.0	Folder
		eu_module_1_country_specific_information	2.0	Folder
		m1-3-1-spc-label-pl	2.0	Folder
		m1-additional	2.0	Folder
		m1-responses	2.0	Folder
		m1-eu	1.0	Folder
		node-extension	1.0	Folder
		eu-envelope	1.0	Leaf
	3.0	envelope	3.0	Folder
		eu_module_1_country_specific_information	3.0	Folder
		m1-3-1-spc-label-pl	3.0	Folder
		m1-additional	3.0	Folder
		m1-responses	3.0	Folder
		m1-eu	1.0	Folder
		node-extension	1.0	Folder
		eu-envelope	1.0	Leaf
	3.0.1	envelope	3.0.1	Folder
		eu_module_1_country_specific_information	3.0	Folder
		m1-3-1-spc-label-pl	3.0	Folder
		m1-additional	3.0	Folder
		m1-responses	3.0	Folder
		m1-eu	1.0	Folder
		node-extension	1.0	Folder

		eu-envelope	1.0	Leaf
FORM	1.1	eu_xml_application_form	1.0	Folder
		m1-eu	1.0	Folder
GC	1.2	envelope-gc	1.2	Folder
		m1-gc	1.2	Folder
		gc-envelope	1.2	Leaf
		gc-m1-responses	1.2	Folder
		gc-m1-additional	1.2	Folder
		gc_module_1_label	1.2	Folder
		gc_module_1_country_specific_information	1.2	Folder
	1.5	envelope-gc	1.5	Folder
		m1-gc	1.2	Folder
		gc-envelope	1.2	Leaf
		gc-m1-responses	1.2	Folder
		gc-m1-additional	1.2	Folder
		gc_module_1_label	1.2	Folder
		gc_module_1_country_specific_information	1.2	Folder
HR	1.4	envelope-hr	1.4	Folder
		hr_module_1_country_specific_information	1.2.1	Folder
		hr-m1-3-1-spc-label-pl	1.2.1	Folder
		m1-3-1-pim	1.0	Folder
		hr-m1-additional	1.2.1	Folder
		hr-m1-responses	1.2.1	Folder
		m1-hr	1.0	Folder
		node-extension	1.0	Folder
		eu-envelope	1.0	Leaf
ICH	3.2	study_patient_information_leaf	1.0	Folder
		drug_product	1.0	Folder
		quality_appendix	1.1	Folder
		excipient	1.1	Folder
		clinical_indication	1.0	Folder
		module_studies	1.0	Folder
		m2-3-quality-overall-summary	1.0	Folder

		m2-3-introduction	1.0	Folder
		node-extension	1.0	Folder
JO	1.0	m1-jo	1.0	Folder
		jo-envelope	1.0	Leaf
		envelope-jo	1.0	Folder
		jo_pic_doc	1.0	Folder
		jo-additional	1.0	Folder
JP	1.0	m1-jp	1.1	Folder
		japanese_leaf	1.0	Leaf
PIM	2.1	m1-3-1-pim	1.0	Folder
		eu_pim_additional_documents	1.0	Folder
		m1-eu	1.0	Folder
STF	2.2	stf	1.1	Folder
		study_data_folder	1.0	Folder
		study_report_leaf	1.1	Leaf
		study_patient_information_leaf	1.0	Leaf
STF	2.2.3.0	stf	3.0	Folder
		study_data_folder	3.0	Folder
		study_patient_information_folder	3.0	Folder
		module_studies	3.0	Folder
		study_report_leaf	3.0	Leaf
		study_patient_information_leaf	1.0	Leaf
STF	2.2.5.0	stf	5.0	Folder
		study_data_folder	5.0	Folder
		study_patient_information_folder	5.0	Folder
		module_studies	5.0	Folder
		study_report_leaf	5.0	Leaf
		study_report_folder	5.0	Folder
SG	1.0	m1-sg	1.0	Folder
TH	0.92	m1-th	0.92	Folder
		m1-th-responses	1.0	Folder
		m1-th-additional	1.0	Folder
		node-extension	1.0	Folder

	1.0	m1-th	1.0	Folder
		m1-th-responses	1.0	Folder
		node-extension	1.0	Folder
TN	1.1	m1-tn	1.1	Folder
TW	1.0	m1-tw	1.0	Folder
		node-extension	1.0	Folder
UA	1.0	envelope-ua	1.0	Folder
		m1-ua-additional	1.0	Folder
		m1-ua-responses	1.0	Folder
		m1-ua	1.0	Folder
		node-extension	1.0	Folder
		ua-envelope	1.0	Leaf
US	2.01	m1-us	1.0	Folder
		node-extension	1.0	Folder
	3.3	m1-us	3.3	Folder
		m1-us-meta-data-application	3.3	PublisherMeta Data
		m1-us-admin-form	3.3	Folder
		m1-us-form	3.3	Folder
		m1-15-promotional-material	3.3	Folder
		m1-15-2-materials	3.3	Folder
		m1-15-2-1-material	3.3	Folder
		node-extension	1.0	Folder
WHO	1.0	m1-who	1.0	Folder
ZA	1.0	m1-za	1.0	Folder
		node-extension	1.0	Folder
ZA	2.1	m1-za	2.1	Folder
		node-extension	1.0	Folder
	3.1	m1-za	3.1	Folder
		node-extension	1.0	Folder

m1-au

m1-au v. 0.9

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
esubmissionIdentifier	string	eSubmission Identifier	The Application Number as provided by the agency. Default value is Application Code.	The value should consist of the small EN letter and 6 digits ([a-z][0-9]{6})	
applicant	string	Applicant	Identifies the type of activity that is being submitted with the sequence, either the regulatory activity type if it is the first sequence of the regulatory activity, or supplementary information if it is a follow-up to information already submitted for the regulatory activity.		
australianApprovedNames	string	Australian Approved Name(s)	The name of the active ingredients that are accepted for inclusion in the Australian Approved Name list. Multiple comma-separated values can be provided.		
productName	string	Product Name	The name or proposed product (trade) name to be used on the Certificate of Registration. Multiple comma-separated values can be provided.		

artgNumber	string	ARTG Number	The Australian Register of Therapeutic Goods number should be provided if available.	The ARTG can be a four, five, or six digit number	
sequenceDescription	string	Sequence Description	Content description for the submitted sequence should be one of the values from the defined list. Codes have been implemented to help provide consistency of input and reduce validation issues based on semantics of values. The sequence description defined list of codes and values is available from < http:// apps.tga.gov.au/ downloads/sequencedescription.xml >. Multiple commaseparated values can be provided. The value used in the XML should be taken from that matching eCTD Code.	eCTD Code value from Data Administration > Sequence Description Values	
sequenceNumber	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
relatedSequenceNumber	string	Related Sequence Number	Four-digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity.		
regulatoryActivityLead	string	Regulatory Activity Lead	Identifies the group within the TGA which is expected to take the lead in the review process. The regulatory activity lead defined list of codes and values is managed at < http:// apps.tga.gov- .au/ downloads/regactiv- ity-lead.xml >. Applicants should refer to this list for current list values.	eCTD Code value from Data Adminis- tration > Regulatory Activity Lead Values	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
sequenceType	string	Sequence Type	Identifies the type of activity that is being submitted with the sequence: either the regulatory activity type if it is the first sequence of the regulatory activity, or supplementary information if it is a follow-up to information already submitted for the regulatory activity. The sequence type defined list of codes and values is available from http:// apps.tga.gov.au/ downloads/sequencetype.xml.	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	
xValue1	date		Belongs to the sequenceDescription field.		
xValue2From	date		In the UI, the sequenceDescription field is a		
xValue2To	date		list with values, some values have or do not have additional parameters.		
xValue3	map		If customer selects a value with no		
xValue3_text	string		additional parameter, then the system		
xValue3_date	date		yields the following XML (see example):		
xValue4	string		<pre> <extensions> <extension type="m1-au" version="0.9"> <field name="sequenceDescription" type="string" >seq- desc-0000</ field> </extension> </extensions> </pre>		
			There are four types of additional parameters:		

			1. date 2. date range (i.e. two dates, "from date" and "to date") 3. number and date 4. description If a customer selects the 1st type of additional parameter, the system yields the sequence-Description field and date (see example): <extensions> <extension type="m1-au" version="0.9"> <field name="sequenceDescription" type="string" >seq- desc-22</ field> <field name="xValue1" type="date" <div>1487887200000< <="" div=""> field> </extension> </extensions> If a customer selects the 2nd type of additional parameter, the system yields the </div>1487887200000<>	
			sequenceDescription 531 fieldEnnov InSight Ad- minis and date range (see example):	tration 7.3 Ex- ten- sions

m1-au v. 3.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

esubmissionIdentifier	string	eSubmission Identifier	The Application Number provided by the agency. Default value is Application Code. The entered values should be validated before saving.	The value should consist of the small EN letter and 6 digits ([a-z]([0-9]{6})).	
applicant	string	Applicant	Identifies the type of activity that is being submitted with the sequence: either the regulatory activity type if it is the first sequence of the regulatory activity, or supplementary information if it is a follow-up to information already submitted for the regulatory activity.		
australianApprovedNames	string	Australian Approved Name(s)	The name of the active ingredients that are accepted for inclusion in the Australian Approved Name list. Multiple commaseparated values can be provided.		
productName	string	Product Name	The name or proposed product (trade) name to be used on the Certificate of Registration.		
Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
artgNumber	string	ARTG Number	The Australian Register of Therapeutic Goods number should be provided if available.	The ARTG can be a four, five, or six digit number.	
sequenceDescription	string	Sequence Description	Content description for the submitted sequence should be one of the values from the defined list. Codes have been implemented to help provide consistency of input and reduce validation issues based on semantics of values. The sequence description defined list of codes and values is available from http:// apps.tga.gov.au/ downloads/sequencedescription.xml .	eCTD Code value from Data Administration > Sequence Description Values	

sequenceNumber	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
relatedSequenceNumber	string	Related Sequence Number	Four-digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity.		
regulatoryActivityLead	string	Regulatory Activity Lead	Identifies the group within the TGA which is expected to take the lead in the review process. The regulatory activity lead defined list of codes and values is managed at < http:// apps.tga.gov.au/ downloads/regactivity-lead.xml >. Applicants should refer to this list for current list values.	eCTD Code value from Data Administration > Regulatory Activity Lead Values	
sequenceType	string	Sequence Type	Identifies the type of activity that is being submitted with the sequence: either the regulatory activity type if it is the first sequence of the regulatory activity, or supplementary information if it is a follow-up to information already submitted for the regulatory activity. The sequence type defined list of codes and values is available from http:// apps.tga.gov- .au/ downloads/sequence-type.xml .	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	
xValue1	date		Belongs to sequenceDescription field.		
xValue2From	date		In UI sequenceDescription field is a list		
xValue2To	date		with values, some values have or do not have additional parameters.		
xValue3	map		If a customer selects a value with no		

xValue3_text	string		additional parameter, then the system	
xValue3_date	date		yields the following XML (see example):	
xValue4	string		<pre> <extensions> <extension type="m1-au" version="3.0"> <field name="sequenceDescription" type="string" >seq- desc-0000</ field> </extension> </extensions> </pre>	
			There are four types of additional parameter: 1. date 2. date range (i.e. two dates, "from date to date") 3. number and date 4. description If a customer selects the 1st type of additional parameter, the system yields the sequence-Description field and date (see example):	
			<pre> <extensions> <extension type="m1-au" version="3.0"> <field name="sequenceDescription" type="string" >seq- desc-22</ field> <field name="xValue1" type="date" >1487887200000</ field> </extension> </extensions> </pre>	

If a customer selects the 2nd type of additional parameter, the system yields the

m1-au v. 3.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
esubmissionIdentifier	string	eSubmission Identifier	The Application Number as provided by the agency. Default value is Application Code.	The value should consist of the small EN letter and 6 digits ([a-z]([0-9]){6})	
applicant	string	eBS Client ID	Identifies the type of activity that is being submitted with the sequence, either the regulatory activity type if it is the first sequence of the regulatory activity, or supplementary information if it is a follow-up to information already submitted for the regulatory activity.		
australianApprovedNames	string	Approved Name(s)	The name of the active ingredients that are accepted for inclusion in the Australian Approved Name list. Multiple comma-separated values can be provided.		

productName	string	Trade Name(s)	The name or proposed product (trade) name to be used on the Certificate of Registration. Multiple commaseparated values can be provided.		
artgNumber	string	ARTG Number(s)	The Australian Register of Therapeutic Goods number should be provided if available.	The ARTG can be a four, five, or six digit number	
submissionOrApplicationNumber	string	Submission of Application Number(s)	The submission number(s) or application number(s) applicable to the sequence being submitted. Multiple comma-separated values can be provided.		
sequenceNumber	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
relatedSequenceNumber	string	Related Sequence Number	Four-digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity.		
regulatoryActivityLead	string	Regulatory Activity Lead	Identifies the group within the TGA which is expected to take the lead in the review process. The regulatory activity	eCTD Code value from Data Administration > Regulatory Activity Lead	

			lead defined list of codes and values is managed at <http://apps.tga.gov.au/downloads/regactivity-lead.xml>. Applicants should refer to this list for current list values.	Values	
submissionMode	string	Submission Mode	Until the work grouping and work sharing functions are sufficiently developed for specific guidance to be published, the only valid mode is 'single' which denotes a single regulatory activity.	One of "single", "work-sharing", "work-grouping"	
sequenceType	string	Sequence Type	Identifies the type of activity that is being submitted with the sequence: either the regulatory activity type if it is the first sequence of the regulatory activity, or supplementary information if it is a follow-up to information already submitted for the regulatory activity. The sequence type defined list of codes and values is available from <http://apps.tga.gov.au/downloads/sequencetype.xml>.	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	

sequenceDescription	string	Sequence Description	Content description for the submitted sequence should be one of the values from the defined list. Codes have been implemented to help provide consistency of input and reduce validation issues based on semantics of values. The sequence description defined list of codes and values is available from http:// apps.tga.gov.au/ downloads/ sequencedescription.xml.	eCTD Code value from Data Administration > Sequence Description Values	
xValue1	date		If a customer selects the 3rd type of additional parameter, the system yields the sequenceDescription field and number/date pair (see example): <pre><extensions> <extension type="m1-au" version="3.1"> <field name="sequenceDescription" type="string" >seq-desc-19</field> <field name="xValue3" type="map"> <!-- it is predefined value --> <value key="999_uniqueSuffix_0" value="24-Feb-2017" /> <!-- number/date pair --> </field></pre>		
xValue2From	date				
xValue2To	date				
xValue3	map				
xValue3_text	string				
xValue3_date	date				
xValue4	string				

			</extension> </extensions> Where: 999__uniqueSuffix__0 - it is xValue3_text, "999" is number and "__uniqueSuffix__0" is predefined suffix 24-Feb-2017 - it is xValue3_date If a customer selects the 4th type of additional parameter, the system yields the sequenceDescription field and description (see example): <extensions> <extension type="m1-au" version="3.1"> <field name="sequenceDescription" type="string" >seq-desc-0004</field> <field name="xValue4" type="string">description for sequenceDescription</field> <!-- description --> </extension> </extensions>		
email	string	Contact Email	The email is used to notify the applicant in case of change in application status. Must be valid email format.	The value must represent a valid e-mail, the validation mask is ^([\sa-zA-Z0-9._%~]+@[azA-Z0-9.-]+\.[azA-Z]{2,4})\$	

m1-au v. 3.2

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
esub-id	string	e-Identifier	The Application Number provided by the agency. Default value is Application Code. The entered values should be validated before saving.	The value should consist of the small EN letter and 6 digits ([a-z]([0-9]){6})	

client-id	string	eBS Client ID	Identifies the type of activity that is being submitted with the sequence: either the regulatory activity type if it is the first sequence of the regulatory activity, or supplementary information if it is a follow-up to information already submitted for the regulatory activity.		
aan	string	Approved Name(s)	The name of the active ingredients that are accepted for inclusion in the Australian Approved Name list. Multiple comma-separated values can be provided.		
product-name	string	Trade Name(s)	The name or proposed product (trade) name to be used on the Certificate of Registration. Multiple commaseparated values can be provided.		
artg-number	string	ARTG Number(s)	The Australian Register of Therapeutic Goods number should be provided if available.	The ARTG can be a four, five, or six digit number	

submission-number	string	Submission or Application Number(s)	The submission number(s) or application number(s) applicable to the sequence being submitted. Multiple comma-separated values can be provided.		
sequence-number	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
related-sequence-number	string	Related Sequence Number	Four-digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity.		
reg-activity-lead	string	Regulatory Activity Lead	Identifies the group within the TGA which is expected to take the lead in the review process. The regulatory activity lead defined list of codes and values is managed at http://apps.tga.gov.au/downloads/regactivity-lead.xml . Applicants should refer to this list for current list values.	eCTD Code value from Data Administration > Regulatory Activity Lead Values	
submission-mode	string	Submission Mode	Until the work grouping and work sharing functions are sufficiently developed for specific guidance to be published, the only valid mode is 'single' which denotes a single regulatory activity.	One of "single", "work-sharing", "work-grouping"	

sequence-type	string	Sequence Type	"Identifies the type of activity that is being submitted with the sequence, either the regulatory activity type if it is the first sequence of the regulatory activity or supplementary information if it is a follow-up to information already submitted for the regulatory activity. Content description for the submitted sequence should be one of the values from sequence-description. Refer to the sequence description for the current list of values. Please be aware that additional attributes for sequence description cannot be specified in workgrouping submission mode. The examples listed below are a subset of the overall list and show how to handle the different approaches. Multiple Sequence Type/Sequence description pairs are used if Submission Mode is set to workgrouping"	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	

sequence-description	string		Content description for the submitted sequence should be one of the values from the defined list. Codes have been implemented to help provide consistency of input and reduce validation issues based on semantics of values. The sequence description defined list of codes and values is available from < http://apps.tga.gov.au/downloads/sequence-description.xml >.	eCTD Code value from Data Administration > Sequence Description Values	
xValue1	date		Belongs to sequenceDescription field. In UI sequenceDescription field is a list with values, some values have or do not have additional parameters.		
xValue2From	date				
xValue2To	date				
xValue3	map				
xValue3_text	string		If a customer selects a value with no additional parameter, then the system yields the following XML (see example):		
xValue3_date	date				
xValue4	string		seq-desc-0000 There are four types of additional parameter: 1. date 2. date range (i.e. two dates, "from date to date") 3. number and date 4. description If a customer selects the 1st type of additional parameter, the system yields the sequenceDescription field and date (see example): seq-desc-221487887200000 If a customer selects the 2nd type of additional parameter, the system yields the		

sequenceDescription field and date range (see example):

seq-desc-20 xValue1 date Belongs to sequenceDescription field. In UI sequenceDescription field is a list with values, some values have or do not have additional parameters. If a customer selects a value with no additional parameter, then the system yields the following XML (see example):seq-desc-0000 There are four types of additional parameter:

1. date
2. date range (i.e. two dates, "from date to date")
3. number and date
4. description

			If a customer selects the 1st type of additional parameter, the system yields the sequenceDescription field and date (see example): seq-desc-221487887200000 If a customer selects the 2nd type of additional parameter, the system yields the sequenceDescription field and date range (see example): seq-desc-2014878872000001487973600000 If a customer selects the 3rd type of additional parameter, the system yields the sequenceDescription field and number/date pair (see example): seq-desc-19 Where: 999__uniqueSuffix__0 - it is xValue3_text, "999" is number and "__uniqueSuffix__0" is predefined suffix 24-Feb-2017 - it is xValue3_date If a customer selects the 4th type of additional parameter, the system yields the sequenceDescription field and description (see example): seq-desc-0004description for sequence-Description		
email	string	Contact Email	The email is used to notify the applicant in case of change in application status. Must be valid email format.	The value must represent a valid e-mail, the validation mask is <code>^([\\sa-zA-Z0-9._%~]+@[azA-Z0-9.-]+\\. [azA-Z]{2,4})\$</code>	

m1-au-nees v. 2.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

esubmissionIdentifier	string	eSubmission Identifier	The Application Number as provided by the agency. Default value is Application Code.	The value should consist of the small EN letter and 6 digits ([a-z]([0-9]){6})	
applicant	string	eBS Client ID	Identifies the type of activity that is being submitted with the sequence, either the regulatory activity type if it is the first sequence of the regulatory activity, or supplementary information if it is a follow-up to information already submitted for the regulatory activity.		
australianApprovedNames	string	Approved Name(s)	The name of the active ingredients that are accepted for inclusion in the Australian Approved Name list. Multiple comma-separated values can be provided.		
productName	string	Trade Name(s)	The name or proposed product (trade) name to be used on the Certificate of Registration. Multiple commaseparated values can be provided.		

artgNumber	string	ARTG Number(s)	The Australian Register of Therapeutic Goods number should be provided if available.	The ARTG can be a four, five, or six digit number	
submissionOrApplicationNumber	string	Submission of Application Number(s)	The submission number(s) or application number(s) applicable to the sequence being submitted. Multiple comma-separated values can be provided.		
sequenceNumber	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
relatedSequenceNumber	string	Related Sequence Number	Four-digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity.		
regulatoryActivityLead	string	Regulatory Activity Lead	Identifies the group within the TGA which is expected to take the lead in the review process. The regulatory activity lead defined list of codes and values is managed at < http:// apps.tga.gov- .au/ downloads/regac- tivity-lead.xml >. Applicants should refer to this list for current list values.	eCTD Code value from Data Administration > Regulatory Activity Lead Values	

submissionMode	string	Submission Mode	Until the work grouping and work sharing functions are sufficiently developed for specific guidance to be published, the only valid mode is 'single' which denotes a single regulatory activity.	One of "single", "work-sharing", "work-grouping"	
sequenceType	string	Sequence Type	Identifies the type of activity that is being submitted with the sequence: either the regulatory activity type if it is the first sequence of the regulatory activity, or supplementary information if it is a follow-up to information already submitted for the regulatory activity. The sequence type defined list of codes and values is available from <http://apps.tga.gov.au/downloads/sequenceType.xml>.	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	
sequenceDescription	string	Sequence Description	Content description for the submitted sequence should be one of the values from the defined list. Codes have been implemented to help provide consistency of input and reduce validation issues based on semantics of values.	eCTD Code value from Data Administration > Sequence Description Values	

			The sequence description defined list of codes and values is available from http:// apps.tga.gov.au/ downloads/ sequencedescription.xml.	
xValue1	date		Belongs to the sequenceDescription	
xValue2From	date		field.	
xValue2To	date		In the UI, the sequenceDescription field is a list with values, some values	
xValue3	map		have or do not have additional	
xValue3_text	string		parameters.	
xValue3_date	date		If customer selects a value with no additional parameter, then the system	
xValue4	string		yields the following XML (see example): <pre><extensions> <extension type="m1-aunees" version="2.0"> <field name="sequenceDescription" type="string" >seqdesc-0000</field> </extension> </extensions></pre> There are four types of additional parameters: 1. date 2. date range (i.e. two dates, "from date" and "to date") 3. number and date 4. description If a customer selects the 1st type of additional parameter, the system yields the sequenceDescription field and date (see example): <pre><extensions></pre>	

			<pre> <extension type="m1-aunees" ver- sion="2.0"> <field name="sequenceDescription" type="string" >seqdesc-22</field> <field name="xValue1" type="date" >1487887200000</field> </extension> </extensions> If a customer selects the 2nd type of addi- tional parameter, the system yields the se- quence </pre>		
email	string	Contact Email	The email is used to notify the applicant in case of change in application status. Must be valid email format.	The value must represent a valid e-mail, the validation mask is <code>^([\\sa-zA-Z0-9._%~]+@[azA-Z0-9.-]+\\. [azA-Z]{2,4}))\$</code>	

m1-additional

m1-additional v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	at, be, bg, common, cy, cz, de, dk, ee, el, emea, es, fi, fr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	

m1-additional v. 1.2.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	at, be, bg, common, cy, cz, de, dk, ee, el, emea, es, fi, fr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	

m1-additional v. 2.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	at, be, bg, common, cy, cz, de, dk, ee, el, ema, es, fi, fr, hr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	

m1-additional v. 3.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	at, be, bg, common, cy, cz, de, dk, edqm, ee, el, ema, es, fi, fr, hr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	

m1-additional v. 3.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

country	string	Country	Defines which country the envelope information is related to.	Show all EU countries, plus EMEA and Common. List of countries: at, be, bg, common, cy, cz, de, dk, edqm, ee, el, es, ema, fi, fr, hr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk, xi.	Defaults based on application country.
language	string	Language	The Language that is being used for submission in the defined country.	List of languages: bg, cs, da, de, el, en, es, et, fi, fr, ga, hr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv.	

m1-ca

m1-ca v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
applicant	string	Applicant	The name of the company that is submitted the approval.		
productName	string	Product name	The Product name that is being submitted for approval.		
relatedSequenceNumber	string	Related Sequence Number	The related sequence number for this submission.		
sequenceNumber	string	Sequence Number	The Sequence Number for this submission. Will default from the Sequence Code, but can be overridden.	Sequence Code (without prefix "P")	
submissionDate	date	Submission Date	The date the submission is to be submitted.	Date format - Unix Timestamp.	
submissionIdentifier	string	Submission Identifier	The Application Number as provided by the agency.	Application Code	

submissionType	string	Submission Type	The Filing type of the submission. Based on the Sequence's Filing Type eCTD Code in Ennov InSight , otherwise blank.	– CTA – CTA-A – IND – NDS – SNDS – ANDS – ABNDS – SANDS – ABSNDS – NC – DIN – ADMIN	

m1-ca v. 2.2

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
applicant	string	Applicant	The name of the company that is submitted the approval.		
productName	string	Product name	The Product name that is being submitted for approval.		
dossierIdentifier	string	Dossier Identifier	The Application Number as provided by the agency.	Application Code	
dossierType	string	Dossier Type	The high-level type of the Application.	– Biologic Dossier – Drug Master File Dossier – Pharmaceutical Dossier	

regulatoryActivityType	string	Regulatory Activity Type	The Filing type of the submission. Based on the Sequence's Filing Type eCTD Code in Ennov InSight , otherwise blank.	NDS, SNDS, SNDS-C, ANDS, SANDS, NC, CTA, CTA-A, DINA, DINB, PDC, PDC-B, PSUR-C, PSURPV, UDPV, RMP-PV, Level III, YBPR, MPNDS, MPSNDS, MPNC, MPDIN, PRECTA, PRNDS, PRSNDS, PAND, DMF type I, DMF type II, DMF type III, DMF type IV, EU NDS, EU SNDS, UDRA, DSUR	
regulatoryActivityLead	string	Regulatory Activity Lead	Defines the group in Health Canada that will perform the review.	– Pharmaceutical – Biological – Post-Marketed Pharmacovigilance – Drug Master File	
Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
sequenceNumber	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
sequenceDescription	string	Submission Description	The description of the Submission to be included in the XML. Note: The numeric values are not supported.		

relatedSequenceNumber	string	Related Sequence Number	The related sequence number for this submission.		

m1-ch

m1-ch v. 1.0

Field Name	Field Type	Matching UI Field	Description	Available Values	Default Value
agencyName	string	Agency	The name of the agency that the submission is being sent to.		
applicant	string	Applicant	The name of the applicant filing the submission.		
applicationNumber	string	Application Number	The Application Number as provided by the agency. Multiple comma-separated values can be provided.	Application Code	
dmfHolder	string	DMF Holder	The Drug Master File Holder for the Product the submission is for.		
dmfNumber	string	DMF Number	The Drug Master File Number for the Product the submission is for.		
inn	string	INN	The INN of the product being submitted for approval. Multiple comma-separated values can be provided.		
inventedName	string	Invented Name	The invented name of the Product being submitted. Multiple comma-separated values can be provided.		
paragraph13LTP	string	Paragraph 13 LTP	Identifies the submission as Paragraph 13 TPA.	– yes – no	

pmfHolder	string	PMF Holder	The Plasma Master File Holder for the Product the submission is for.		
pmfNumber	string	PMF Number	The Plasma Master File Number for the Product the submission is for.		
relatedSequence	string	Related Sequence	This is the Sequence number of a previous submission to which this submission relates. Multiple related sequence numbers may be entered as commaseparated values.		
sequenceNumber	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
submissionDescription	string	Submission Description	The description of the Submission to be included in the XML.		
Field Name	Field Type	Matching UI Field	Description	Available Values	Default Value
submissionType	string	Submission Type	The Filing type of the submission. Based on the Sequence's Filing Type eCTD Code in Ennov InSight , otherwise blank.	na-nas, na-ngf, na-nko, na-bws, na-gen, na-ie, nande, na-ndo, notification, varauthorisationscientific, varauthorisation-admin, renewal, psur, pi, eas, comarketing, withdrawal, varpi, transfer, dmf, pmf, reformat, supplementalinfo-to, corrigendum	

m1-ch v. 1.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

agencyName	string	Agency	The name of the agency that the submission is being sent to.		
applicant	string	Applicant	The name of the applicant filing the submission.		
applicationNumber	string	Application Number	The Application Number as provided by the agency. Multiple comma-separated values can be provided	Application Code	
dmfHolder	string	DMF Holder	The Drug Master File Holder for the Product the submission is for.		
dmfNumber	string	DMF Number	The Drug Master File Number for the Product the submission is for.		
inn	string	INN	The INN of the product being submitted for approval. Multiple comma-separated values can be provided.		
inventedName	string	Invented Name	The invented name of the Product being submitted. Multiple comma-separated values can be provided.		
paragraph13LTP	string	Paragraph 13 TPA	Identifies the submission as Paragraph 13 TPA.	– yes – no	
pmfHolder	string	PMF Holder	The Plasma Master File Holder for the Product the submission is for.		
pmfNumber	string	PMF Number	The Plasma Master File Number for the Product the submission is for.		
relatedSequence	string	Related Sequence	This is the Sequence number of a previous submission to which this submission relates. Multiple commaseparated values can be provided.		

sequenceNumber	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
submissionDescription	string	Submission Description	The description of the Submission to be included in the XML.		
submissionType	string	Submission Type	The Filing type of the submission. Based on the Sequence's Filing Type eCTD Code in Ennov InSight , otherwise blank.	na-nas, na-ngf, na-nko, na-bws, na-gen, na-ie, nande, na-ndo, notification, varauthorisationscientific, varauthorisation-admin, renewal, psur, pi, eas, comarketing, withdrawal, varpi, transfer, dmf, pmf, reformat, supplementalinfo, corrigendum	

m1-ch v. 1.2

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
agencyName	string	Agency	The name of the agency that the submission is being sent to.		
applicant	string	Applicant	The name of the applicant filing the submission.		
applicationNumber	string	Application Number	The Application Number as provided by the agency. Multiple comma-separated values can be provided.	Application Code	
dmfHolder	string	DMF Holder	The Drug Master File Holder for the Product the submission is for.		
dmfNumber	string	DMF Number	The Drug Master File Number for the Product the submission is for.		

inn	string	INN	The INN of the product being submitted for approval. Multiple comma-separated values can be provided		
inventedName	string	Invented Name	The invented name of the Product being submitted. Multiple comma-separated values can be provided		
paragraph13LTP	string	Paragraph 13 TPA	Identifies the submission as Paragraph 13 TPA.	– yes – no	
pmfHolder	string	PMF Holder	The Plasma Master File Holder for the Product the submission is for.		
pmfNumber	string	PMF Number	The Plasma Master File Number for the Product the submission is for.		
relatedSequence	string	Related Sequence	This is the Sequence number of a previous submission to which this submission relates. Multiple related sequence numbers may be entered as commaseparated values.		
sequenceNumber	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
submissionDescription	string	Submission Description	The description of the Submission to be included in the XML.		

submissionType	string	Submission Type	The Filing type of the submission. Based on the Sequence's Filing Type eCTD Code in Ennov InSight , otherwise blank.	eas, co-marketing, corrigendum, dmf, na-gen, na-bws, na-nas, na-nko, na-nde, na-ndo, na-ngf, na-ie, orphan-fasttrack, pi, psur, pmf, reformat, renewal, supplemental- info, transfer, varpi, varauthorisationscientific, notification, varauthorisationadmin, withdrawal	

m1-ch v. 1.3

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
agencyName	string	Agency	The name of the agency that the submission is being sent to.		
applicant	string	Applicant	The name of the applicant filing the submission.		
applicationNumber	string	Application Number	The Application Number as provided by the agency. Multiple commaseparated values can be provided.	Application Code	
dmfHolder	string	DMF Holder	The Drug Master File Holder for the Product the submission is for.		
dmfNumber	string	DMF Number	The Drug Master File Number for the Product the submission is for.		
inn	string	INN	The INN of the product being submitted for approval. Multiple comma-separated values can be provided		
inventedName	string	Invented Name	The invented name of the Product being submitted. Multiple commaseparated values can be provided.		
paragraph13LTP	string	Paragraph 13 TPA	Identifies the submission as Paragraph 13 TPA.	– yes – no	

pmfHolder	string	PMF Holder	The Plasma Master File Holder for the Product the submission is for.		
pmfNumber	string	PMF Number	The Plasma Master File Number for the Product the submission is for.		
relatedSequence	string	Related Sequence	This is the Sequence Number of a previous submission to which this submission relates. Multiple related sequence numbers may be entered as commaseparated values		
sequenceNumber	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
submissionDescription	string	Submission Description	The description of the Submission to be included in the XML.		
submissionType	string	Submission Type	The Filing Type of the submission. Based on the Sequence's Filing Type eCTD Code in Ennov InSight , otherwise blank.	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	

m1-ch v. 1.4

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
agencyName	string	Agency	The name of the agency that the submission is being sent to.	N/A	N/A
applicant	string	Applicant	The name of the applicant filing the submission.	N/A	N/A

applicationNumber	string	Application Number	The Application Number as provided by the agency. Multiple comma-separated values can be provided.	Application Code	Application Code
dmfHolder	string	DMF Holder	The Drug Master File Holder for the Product the submission is for.	N/A	N/A
dmfNumber	string	DMF Number	The Drug Master File Number for the Product the submission is for.	N/A	N/A
inn	string	INN	The INN of the product being submitted for approval. Multiple comma-separated values can be provided	N/A	N/A
inventedName	string	Invented Name	The invented name of the Product being submitted. Multiple comma-separated values can be provided.	N/A	N/A
paragraph13LTP	string	Paragraph 13 TPA	Identifies the submission as Paragraph 13 TPA.	– yes – no	N/A
pmfHolder	string	PMF Holder	The Plasma Master File Holder for the Product the submission is for.	N/A	N/A
pmfNumber	string	PMF Number	The Plasma Master File Number for the Product the submission is for.	N/A	N/A

relatedSequence	string	Related Sequence	This is the Sequence Number of a previous submission to which this submission relates. Multiple related sequence numbers may be entered as commaseparated values	N/A	N/A
sequenceNumber	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	N/A
submissionDescription	string	Submission Description	The description of the Submission to be included in the XML.	N/A	N/A
submissionType	string	Submission Type	The Filing Type of the submission. Based on the Filing Type eCTD Code of the Sequence in Ennov InSight, otherwise blank.	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	N/A

m1-ch v. 1.5

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
agencyName	string	Agency	Name of the agency that the submission is being sent to.	N/A	N/A
applicant	string	Applicant	Name of the company filing the submission.	N/A	N/A
applicationNumber	string	Application Number	Application Number provided by the agency. Multiple comma-separated values can be provided.	Application Code	Application Code
dmfHolder	string	DMF Holder	Drug Master File Holder for the Product the submission is for.	N/A	N/A

dmfNumber	string	DMF Number	Drug Master File Number for the Product the submission is for (alphanumeric).	N/A	N/A
inn	string	INN	INN of the product being submitted for approval. Each INN is a unique name that is globally recognized and is public property. Multiple comma-separated values can be provided	N/A	N/A
inventedName	string	Invented Name	Invented name of the Product being submitted. Multiple comma-separated values can be provided.	N/A	N/A
paragraph13LTP	string	Article 13 TPA	Identifies the submission as Article 13 TPA.	– yes – no	N/A
pmfHolder	string	PMF Holder	Plasma Master File Holder for the Product the submission is for.	N/A	N/A
pmfNumber	string	PMF Number	Plasma Master File Number for the Product the submission is for.	N/A	N/A
relatedSequence	string	Related Sequence	Sequence Number of a previous submission to which this submission relates. Multiple related sequence numbers may be entered as comma-separated values	N/A	N/A
sequenceNumber	string	Sequence Number	Sequence Number for this submission.	Sequence Code (without prefix "P")	N/A
submissionDescription	string	Submission Description	Description of the Submission to be included in the XML.	N/A	N/A

submissionType	string	Submission Type	Filing Type of the submission. Based on the Filing Type eCTD Code of the Sequence in Ennov InSight , otherwise blank.	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	N/A

m1-ch-additional

m1-ch-additional v. 1.0

No additional fields for folder.

m1-ch-common-form

m1-ch-common-form v. 1.0

No additional fields for folder.

m1-ch-galenic-form

m1-ch-galenic-form v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
galenicFormName	string	Galenic Form Name	The name of the galenic form.		
swissMedicNumber	string	SwissMedic Number	The number for the galenic form from the SwissMedic agency.	Example: "12345", or "pending"	

galenicNameLanguage	map	Galenic Language Name	The language of the galenic form.	– de – fr – it – en Example: <field name="galenicNameLanguage" type="map"><value key="en" value="english" /></field>	

m1-ch-galenic-form v. 1.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
galenicFormName	string	Galenic Form Name	The name of the galenic form.		
swissMedicNumber	string	SwissMedic Number	The number for the galenic form from the SwissMedic agency.	Example: "12345", or "pending"	
galenicNameLanguageSelect	string	Galenic Language Name	The language of the galenic form.	– de – fr – it	
Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
galenicNameLanguageText	string	Galenic Language Text	The Galenic Language Text.		

m1-ch-responses m1-ch-responses v. 1.0

No additional fields for folder.

m1-ua-responses

m1-ua-responses v.1.0

No additional fields for folder.

ba-m1-responses

ba-m1-responses v3.1

Field Name	Field Type	Matching UI field	Description	Acceptable values	Default value

country	string	Country	Defines which country the envelope information is related to.	Show all EU countries, plus EMEA and Common. List of countries: at,ba,be,bg,common,cy,cz,de,dk,edqm,ee,el,es,ema,fi,fr,hr,hu,ie, is,it,li,lt,lu,lv,mt,nl,no,pl,pt,ro,se,si,sk,uk,xi	
language	string	Language	The Language that is being used for submission in the defined country.	List of languages: bg,bs,cs,da,de,el,en,es,et,fi,fr,ga,hr,hu,is,it,lt,lv,mt,nl,no, pl,pt,ro,sk,sl,sr,sv	

ba-m1-splabelinfo

ba-m1-splabelinfo v3.1

Field Name	Field Type	Matching UI field	Description	Acceptable values	Default value
country	string	Country	Defines which country the envelope information is related to.	List of countries: at,ba,be,bg,common,cy,cz,de,dk,edqm,ee,el,es,ema,fi,fr,hr, hu,ie,is,it,li,lt,lu,lv,mt,nl,no,pl,pt,ro,se,si,sk,uk,xi	
language	string	Language	The Language that is being used for submission in the defined country.	List of languages: bg,bs,cs,da,de,el,en,es,et,fi,fr,ga,hr,hu,is,it,lt,lv,mt,nl,n o,pl, pt,ro,sk,sl,sr,sv	
labelingType	string	Labeling Type	Defines the type of label reference in the submission.	spc, annex2, outer, interpack, impack, other, pl, combined	

m1-sg

m1-sg v. 1.0

Field Name	Field Type	Matching UI field	Description	Acceptable values	Default value
applicationTypeSg	string	Application Type	The type value for the Application.		
applicationIdentifier	string	SG eCTD ID	A unique identifier issued by HSA via the HSA eCTD Portal, will be used for all Sequences of an eCTD Application and cannot ever be changed.		
applicationNumber	string	Application Number	Each product in an Application should		

Field Name	Field Type	Matching UI field	Description	Acceptable values	Default value
			have a unique Application Number. prefix of "e" should be added to the Application Number for all eCTD applications. The prefix is followed by the application number issued for the NDA or GDA in PRISM (case-sensitive) or the Drug Master File (DMF) number to form the eCTD Application Number. If multiple strengths are combined in a single eCTD Application, then the Application Number of each strength should be listed in the eCTD Application.		
inn	string	INN	The recognised International Non-proprietary Name(s) should be given. It should only be written in lower-case letters and provided exactly as listed as INN without abbreviations.		
productTypeSg	string	Product Type	The type of product being submitted		
dmfNumber	string	DMF Number	The Drug Master File (DMF) Number for all manufacturers referenced in the eCTD application should be added as issued.		
pmfNumber	string	PMF Number	If a Plasma Master File (PMF) is reference in the eCTD application, the PMF Number as issued should be added.		
proprietaryName	string	Proprietary Name	The name as proposed or registered. For API Master Files, insert		

Field Name	Field Type	Matching UI field	Description	Acceptable values	Default value
			drug substance name and APIMF holder name.		
registrationNumberSg	string	Singapore Registration Number	SRN is provided for all sequence types of registered products. written in upper-case letters		
submissionInfoCombinationSg	map	Submission (Submission Type / Submission Number)	Contains information relating to the Submission (regulatory activity) that is being submitted	<value key="sub-type-13__uniqueSuffix_0" value="Submission Number" />	
sequenceTypeSg	string	Sequence Type	The Sequence Element section contains all the Sequence-related information. It identifies what is happening to the Submission with the Sequence being submitted. Only one Sequence Element section can be specified per Sequence however multiple types of Responses can be specified as types. Responses can only be combined with other responses.		
sequenceDescriptionSg	string	Sequence Description	The Sequence Description element gives the Applicant the opportunity to better describe what is being done in the Sequence.		
sequenceDate	string	Sequence Date	The Sequence Date is a date field indicating the date the Sequence is submitted. This date should correlate as closely as possible with the date on the Letter of Application and in the Application Form but does not need to be identical. The Sequence Date is mainly used to ensure the validity of the codes used		

Field Name	Field Type	Matching UI field	Description	Acceptable values	Default value
			from the Defined Lists.		
sequenceNumber	string	Sequence Number	Four-digit number matching the Sequence folder being submitted.		
relatedSequences	string	Related Sequence	The Related Sequence Number is used to group Sequences belonging to the same Submission. This enables agency to easily evaluate Sequences associated with a particular Submission together.		
submissionContactSg	string	Contact	Multiple contacts may be provided in the Envelope. The Contact Name, Contact Phone and Contact Email must be provided for each contact, along with the Type of contact. At least one Local Applicant contact must be provided.		

m1-tn

m1-tn v. 1.1

Field Name	Field Type	Matching UI field	Description	Acceptable values	Default value
applicationTypeTn	string	Application Type	The type value for the Application.		
applicationIdentifier	string	Application ID	An identifier provided by the ANMPS Application Portal when a new Application is created. The same ID will be used for all Sequences of an eCTD application and cannot ever be changed.		
applicationNumber	string	Application Number	An Application Number will be automatically		

			issued for each product, strength, replica / clone / duplicate by the ANMPS Application Portal when a new Application is created or a new replica / clone is added to an existing Application. Multiple Application Numbers can be included in an eCTD Application		
submissionTypeTn	string	Submission Type	The Submission Type must be indicated for the Submission Element indicating the type of 991 regulatory activities being undertaken with the Submission	Multiple coma separated values are allowed. Example: sub-type-46,sub-type-43	
sequenceTypeTn	string	Sequence Type	The Sequence Element section contains all the Sequence-related information. It identifies what is happening to the Submission with the Sequence being submitted. Only one Sequence Element section can be specified per Sequence however multiple types of Responses can be specified as types. Responses can only be combined		

			with other responses.		
sequenceDate	string	Sequence Date	The Sequence Date is a date field indicating the date the Sequence is submitted. This date should correlate as closely as possible with the date on the Letter of Application and in the Application Form but does not need to be identical. The Sequence Date is mainly used to ensure the validity of the codes used from the Defined Lists.		
sequenceNumber	string	Sequence Number	Four-digit number matching the Sequence folder being submitted.		
relatedSequences	string	Related Sequence Number	The Related Sequence Number is used to group Sequences belonging to the same Submission. This enables agency to easily evaluate Sequences associated with a particular Submission together.		
submissionContactTn	string	Contact	Multiple contacts may be provided in the Envelope. The Contact Name and Contact Email must be provided for each contact, along with the Type of	Example: TN_StandContact_With_1Email_1Tel_Type_1, TN_StandContact_With_1Email_1Tel_Type_2	

			contact. At least one Local Applicant contact must be provided.		

clinical_indication

clinical_indication v.1.0, v.1.1

Field Name	Matching UI Field	Matching UI Field	Description	Acceptable Values	Default Value
indication	string	Indication	The indication for the product being submitted.		

m1-cn

m1-cn v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
applicationId	string	Application Number	The unique identification number for an application in its full lifecycle assigned by the regulatory agency.	A lowercase letter or a digit followed by nine digits.	
applicationType	string	Application Type	Describes the application purpose.	– cnapt1 – cnapt2 – cnapt3	Defaults based on Application Type from the parent Application.
productType	string	Product Type	Describes the product classification information	– cnprt1 – cnprt2	

productNumber	string	Original Number	The basic and permanent number given to a drug entering the registration approval process. The original number is assigned by the regulatory agency and is used as the unique identification code to identify the applicant, active ingredient (API) and dosage form.	10 digits	
relatedSequence	string	Related Sequence	The sequence first submitted in a regulatory activity is called the related sequence of all sequences submitted in the regulatory activity.	One value, 0000-9999	
regulatoryActivityType	string	Regulatory Activity Type	The type of regulatory activity: i.e. the regulatory purpose the filing is addressing.	– cnrat1 – cnrat2 – cnrat3 – cnrat4 – cnrat5 – cnrat6 – cnrat7	Defaults based on Filing Type from the parent Sequence, for initial Sequence Assembly.

sequenceNumber	string	Sequence Number	The applicant should submit the application from 0000 and the sequence number should be increased by 1 for each time of submission. The application will be submitted based on sequence.	One value, 0000-9999	
sequenceTypeCn	string	Sequence Type	Describes the purpose of the sequence.	– cnsqt1 – cnsqt2 – cnsqt3 – cnsqt4	
sequenceDescriptionCn	string	Sequence Description	A brief description of the sequence purpose, which is used to distinguish the sequence of similar type.	Unicode symbols for all text values must be encoded using numeric character reference, for example: &#26679;&#26412.	
sequenceContactName	string	Sequence Contact Name	The name of the contact person responsible for the sequence.		
sequenceContactPhone	string	Sequence Contact Telephone Number	The phone number of the contact person responsible for the sequence.		
sequenceContactEmail	string	Sequence Contact Email	The email address of the contact person responsible for the sequence.	Should be in the format: xx@yy.zz	

[drug_appendix](#)[drug_appendix v. 1.0, v. 1.1](#)

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
manufacturer	string	Manufacturer	The manufacturer of the drug product.		
substance	string	Substance	The Active Ingredient of the product being submitted.		
dosageForm	string	Dosage Form	The dosage form of the product being submitted.		
productName	string	Product Name	The Product Name that is being submitted.		

[drug_product](#)[drug_product v. 1.0, v. 1.1](#)

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
drugProductName	string	Drug Product Name	The Product Name that is being submitted.		
dosageForm	string	Dosage Form	The dosage form of the product being submitted.		
drugProductManufacturer	string	Drug Product Manufacturer	The manufacturer of the drug product.		

[drug_substance](#)[drug_substance v. 1.0](#)

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
dosageForm	string	Dosage Form	This field is not used for import.		
drugProductManufacturer	string	Drug Product Manufacturer	This field is not used for import.		
drugProductName	string	Drug Product Name	This field is not used for import.		

drugSubstanceManufacturer	string	Drug Substance Manufacturer	The manufacturer of the Active Ingredient.		
drugSubstanceName	string	Drug Substance Name	The Active Ingredient Name of the Product being submitted.		

m1-eu

m1-eu v. 3.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines the country the envelope information is related to. Defaults based on the application country. Show all EU countries, plus EMEA and Common.	at, be, bg, common, cy, cz, de, dk, edqm, ee, el, ema, es, fi, fr, hr, hu, ie, is, it, li, lt,lu, lv, mt, nl, no, pl, pt, ro, se,si, sk, uk	
language	string	Language	The language that is used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, ga, hr, hu, is, it, lt, lv, mt,nl, no, pl, pt, ro, sk, sl, sv	

m1-eu v. 1.0

No additional fields for folder.

Envelope

envelope v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
agencyName	string	Agency Name	The name of the agency that the submission is being sent to. Defaults based on the Application's Country.		

applicant	string	Applicant	The name of the company submitting the Application.		
applicationNumber	string	Application Number	The Application Number as provided by the agency.		
atc	string	ATC	The ATC of the Product being submitted.		
country	string	Country	Defines which country the envelope information is related to. Defaults based on the Application's Country. Show all EU countries, plus EMEA and common.	at, be, bg, common, cy, cz, de, dk, ee, el, emea, es, fi, fr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
inn	string	INN	The INN of the product being submitted for approval.		
inventedName	string	Invented Name	The invented name of the product being submitted for approval.		
procedureType	string	Procedure Type	The procedure type being used to submit. Based on the Application's Procedure Type.	– centralised – national – mutual-recognition	

relatedSequence	map	Related Sequence	The related sequence number as well as the country for the specific relation. Country values include all of Europe, Common, and EMEA.	Example: <field name="related-Sequence" type="map"><value key="emea" value="1234" /></field>	
sequence	string	Sequence	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
submissionType	string	Submission Type	The Filing type of the submission. Based on the Sequence's Filing Type eCTD Code in Ennov InSight, otherwise blank.	– arbitration – cond-specific-obligation – dmf – follow-up – initial-maa – psur – renewal – safety – sepcific-obligation – supplemental-info – var-type1a – var-type1b – var-type2	
submissionDescription	string	Submission Description	The description of the Submission to be included in the XML.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
agencyName	string	Agency Name	The name of the agency that the submission is being sent to. Defaults based on Application's Country.		
applicant	string	Applicant	The name of the company submitting the Application.		
applicationNumber	string	Application Number	The Application Number provided by the agency.		
atc	string	ATC	The ATC of the Product being submitted.		
country	string	Country	Defines which country the envelope information is related to. Defaults based on the Application's Country. Show all EU countries, plus EMEA and Common.	at, be, bg, common, cy, cz, de, dk, ee, el, emea, es, fi, fr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
inn	string	INN	The INN of the product being submitted for approval.		
inventedName	string	Invented Name	The invented name of the product being submitted for approval.		

procedureType	string	Procedure Type	The procedure type being used to submit. Based on the Application's Procedure Type.	– centralised – national – mutual-recognition	
relatedSequence	map	Related Sequence	The related sequence number as well as the country for the specific relation. Country values include all of Europe, Common, and EMEA.	Example: <field name="related-Sequence" type="map"><value key="emea" value="1234" /></field>	
sequence	string	Sequence	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
submissionType	string	Submission Type	The Filing type of the submission. Based on the Sequence's Filing Type eCTD Code in Ennov InSight, otherwise blank.	– arbitration – cond-specific-obligation – dmf – follow-up – initial-maa – psur – renewal – safety – sepcific-obligation – supplemental-info – var-type1a – var-type1b – var-type2	

submissionDescription	string	Submission Description	The description of the Submission to be included in the XML.		

envelope v. 1.2.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
agencyName	string	Agency Name	The name of the agency that the submission is being sent to. Defaults based on the Application's Country.		
applicant	string	Applicant	The name of the company submitting the Application.		
applicationNumber	string	Application Number	The Application Number as provided by the agency.		
atc	string	ATC	The ATC of the Product being submitted.		
country	string	Country	Defines which country the envelope information is related to. Defaults based on the Application's Country. Show all EU countries, plus EMEA and common.	at, be, bg, common, cy, cz, de, dk, ee, el, emea, es, fi, fr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	

inn	string	INN	The INN of the product being submitted for approval.		
inventedName	string	Invented Name	The invented name of the product being submitted for approval.		
procedureType	string	Procedure Type	The procedure type being used to submit. Based on the Application's Procedure Type	– centralised – national – mutual-recognition	
relatedSequence	map	Related Sequence	The related sequence number as well as the country for the specific relation. Country values include all of Europe, Common, and EMEA	Example: <field name="related-Sequence" type="map"><value key="emea" value="1234" /></field>	
sequence	string	Sequence	The Sequence Number for this submission.	Sequence Code (without prefix "P")	

submissionType	string	Submission Type	The Filing type of the submission. Based on the Sequence's Filing Type eCTD Code in Ennov InSight , otherwise blank. – arbitration – cond-specific-obligation – dmf – follow-up – initial-maa – psur – renewal – safety – sepcific-obligation – supplemental-info – var-type1a – var-type1b – var-type2	
submissionDescription	string	Submission Description	The description of the Submission to be included in the XML.	

envelope v. 1.3

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

agencyName	string	Agency Name	The name of the agency that the submission is being sent to. Defaults based on the Application's Country.	AT-AGES, BE-FAMHP, BG-BDA, BG-NVS, CY-VS, CZ-SUKL, CZ-USKVBL, DEBFARM, DE-BVL, DE-PEI, DK-DKMA, EE-SAM, ELEOF, ES-AGEMED, FINAM, FR-AFSSAPS, FR-ANMV, HU-IVMP, HUOGYI, IE-IMB, IE-DAFF, IS-IMCA, IT-AIFA, IT-LMV, IT-SPV, LI-LLV, LT-SMCA, LT-VVPI, LT-VMVT, LUMINSANT, LV-ZVA, MTM-RU, MT-MEDAUTH, NLMEB, NO-NOMA, PL-URPL, PT-DGV, PT-INFARMED, RO-ANM, SE-MPA, SI-JAZMP, SK-SIDC, SKUSKVBL, UK-MHRA, UKVMD, EU-EMEA	
applicant	string	Applicant	The name of the company submitting the Application.		
applicationNumber	string	Application Number	The Application Number as provided by the agency.		
atc	string	ATC	The ATC of the Product being submitted.		

country	string	Country	Defines which country the envelope information is related to. Defaults based on the Application's Country. Show all EU countries, plus EMEA and Common.	at, be, bg, cy, cz, de, dk, ee, el, emea, es, fi, fr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
inn	string	INN	The INN of the product being submitted for approval.		
inventedName	string	Invented Name	The invented name of the product being submitted for approval.		
procedureType	string	Procedure Type	The procedure type being used to submit. Based on the Application's Procedure Type.	– centralised – national – mutual-recognition	
relatedSequence	string	Related Sequence	The related sequence number as well as the country for the specific relation. Country values include all of Europe, Common, and EMEA.		
sequence	string	Sequence	The Sequence Number for this submission.	Sequence Code (without prefix "P")	

submissionType	string	Submission Type	The Filing type of the submission. Based on the Sequence's Filing Type eCTD Code in Ennov InSight , otherwise blank.	– initial-maa – supplemental-info – fum – specific-obligation – var-type1a – var-type1b – var-type2 – extension – psur – renewal – asmf – referral – annual-reassessment – usr – article-58 – notification-61-3 – transfer-ma, – corrigendum – lifting-suspension – withdrawal – paed-article-29 – var-nat – reformat	
submissionDescription	string	Submission Description	The description of the Submission to be included in the XML.		

envelope v. 1.4

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

agencyName	string	Agency Name	The name of the agency that the submission is being sent to. Defaults based on the Application's Country.	AT-AGES, BE-FAMHP, BG-BDA, BG-NVS, CY-VS, CZ-SUKL, CZ-USKVBL, DEBFARM, DE-BVL, DE-PEI, DK-DKMA, EE-SAM, ELEOF, ES-AGEMED, FINAM, FR-AFSSAPS, FR-ANMV, HU-IVMP, HUOGYI, IE-IMB, IE-DAFF, IS-IMCA, IT-AIFA, IT-LMV, IT-SPV, LI-LLV, LT-SMCA, LT-VVPI, LT-VMVT, LUMINSANT, LV-ZVA, MTMRU, MT-MEDAUTH, NLMEB, NO-NOMA, PL-URPL, PT-DGV, PT-INFARMED, RO-ANM, SE-MPA, SI-JAZMP, SK-SIDC, SKUSKVBL, UK-MHRA, UKVMD, EU-EMEA	
applicant	string	Applicant	The name of the company submitting the Application.		
applicationNumber	string	Application Number	The Application Number as provided by the agency.		
atc	string	ATC	The ATC of the Product being submitted.		

country	string	Country	Defines which country the envelope information is related to. Defaults based on the Application's Country. Show all EU countries, plus EMEA and common	at, be, bg, cy, cz, de, dk, ee, el, emea, es, fi, fr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
inn	string	INN	The INN of the product being submitted for approval.		
inventedName	string	Invented Name	The invented name of the product being submitted for approval.		
procedureType	string	Procedure Type	The procedure type being used to submit. Based on the Application's Procedure Type	– centralised – national – mutual-recognition	
relatedSequence	string	Related Sequence	The related sequence number as well as the country for the specific relation. Country values include all of Europe, Common, and EMEA.		
sequence	string	Sequence	The Sequence Number for this submission.	Sequence Code (without prefix "P")	

submissionType	string	Submission Type	The Filing type of the submission. Based on the Sequence's Filing Type eCTD Code in Ennov InSight , otherwise blank.	– initial-maa – supplemental-info – fum – specific-obligation – var-type1a – var-type1b – var-type2 – extension – psur – renewal – asmf – pmf – referral – annual-reassessment – usr – article-58 – notification-61-3 – transfer-ma, – corrigendum – lifting-suspension – withdrawal – paed-article-29 – paed-article-46 – var-nat – reformat	
submissionDescription	string	Submission Description	The description of the Submission to be included in the XML.		

envelope v. 2.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

agencyName	string	Agency Name	The name of the agency that the submission is being sent to. Defaults based on the Application's Country.	AT-AGES, BE-FAMHP, BG-BDA, CY-PHS, CZ-SUKL, DE-BFARM, DE-PEI, DK-DKMA, EE-SAM, EL-EOF, ES-AEMPS, FI-FIMEA, FR-ANSM, HR-HALMED, HU-OGYI, IE-IMB, IS-IMCA, IT-AIFA, LI-LLV, LT-SMCA, LU-MINSANT, LV-ZVA, MT-MEDAUTH, NL-MEB, NO-NOMA, PL-URPL, PT-INFARMED, RO-ANMMD, SE-MPA, SI-JAZMP, SKSIDC, UK-MHRA, EU-EMA	
applicant	string	Applicant	The name of the company submitting the Application.		
applicationNumber	string	Application Number	The Application Number provided by the agency.		
atc	string	ATC	The ATC of the Product being submitted.		
country	string	Country	Defines which country the envelope information is related to. Defaults based on the Application's Country. Show all EU countries, plus EMEA and Common.	at, be, bg, cy, cz, de, dk, ee, el, ema, es, fi, fr, hu, hr, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
inn	string	INN	The INN of the product being submitted for approval.		

inventedName	string	Invented Name	The invented name of the product being submitted for approval.		
procedureType	string	Procedure Type	The procedure type being used to submit. Based on the Application's Procedure Type.	– centralised – national – mutual-recognition	
relatedSequence	string	Related Sequence	The related sequence number as well as the country for the specific relation. Country values include all of Europe, Common, and EMEA.		
sequence	string	Sequence	The Sequence Number for this submission.	Sequence Code (without prefix "P")	

submissionType	string	Submission Type	The Filing type of the submission. Based on the Sequence's Filing Type eCTD Code in Ennov InSight , otherwise blank.	– initial-maa – supplemental-info – fum – specific-obligation – var-type1a – var-type1b – var-type2 – extension – psur – renewal – asmf – pmf – referral – annual-reassessment – usr – article-58 – notification-61-3 – transfer-ma, – corrigendum – lifting-suspension – withdrawal – paed-article-29 – paed-article-46 – var-nat – reformat – rmp	
submissionDescription	string	Submission Description	The description of the Submission to be included in the XML.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to. Defaults based on Application's Country.	at, be, bg, cy, cz, de, dk, ee, edqm, el, ema, es, fi, fr, hu, hr, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
uuid	string	UUID	A UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 ISO/IEC 9834-8:2005. The same UUID must be used for all sequences of an eCTD application. Defaults based on the UUID from the parent Application.	The UUID must be in the form of xxxxxxxx-xxxxMxxx-Nxxxxxxxxxxxxxx, where: – x is a hexadecimal number – M is 1-5 – N is 8, 9, a or b	
submissionType	string	Submission Type	The Filing type of the submission. Based on the Sequence's Filing Type eCTD Code in Ennov InSight , otherwise blank.	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	
submissionMode	string	Submission Mode	The mode of the submission, either Single, Grouping, or Worksharing.	– single – grouping – worksharing	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

highLevelSubmissionNumber	string	High Level/ Worksharing Submission Number	The high level sub- mission number for the specific submis- sion, used when the submission mode is Grouping or Worksharing.		
applicationNumber	string	Application Tracking Number	The Application Number as provided by the agency. Multi- ple commaseparated values can be provid- ed.		
submissionUnit	string	Submission Unit Type	Submission unit type describes the con- tent at a lower lev- el (a “subactivity”) which is submitted in relation to a defined regulatory activity.	– initial – validationresponse – response – additional-info – closing – consolidating – corrigendum – reformat	
applicant	string	Applicant	The name of the company submitting the Application.		
agencyName	string	Agency Name	The name of the agency that the sub- mission is being sent to. Based on the Appli- cation's Country.	AT-BASG, BEFAMHP, BG-BDA, CY-PHS, CZ-SUKL, DE-BFARM, DE- PEI, DK-DKMA, EE-SAM, EL-EOF, ES-AEMPS, FIFIMEA, FR-ANSM, HR-HALMED, HU- OGYI, IE-HPRA,	

				IS-IMCA, IT-AIFA, LHLLV, LT-SMCA, LU-MINSANT, LV- ZVA, MT- MEDAUTH, NLMEB, NO-NOMA, PL-URPL, PTIN- FARMED, ROANM- MD, SE-MPA, SI-JAZMP, SKSIDC, UK-MHRA, EU-EMA, EUEDQM	
procedureType	string	Procedure Type	The procedure type being used to submit. Based on the Applica- tion's Procedure Type.	— centralised — national — mutual- recognition — decentralised	
inventedName	string	Invented Name	The invented name of the product being sub- mitted for approval. Multiple comma-sep- arated values can be provided.		
inn	string	INN	The INN of the product being submitted for ap- proval. Multiple com- ma-separated values can be provided.		
sequence	string	Sequence	The Sequence Number for this submission.	Sequence Code (without prefix "P")	

relatedSequence	string	Related Sequence	This is the sequence number of previous submission(s) to which this submission relates, for example the responses to questions to a particular variation. If value of submissionUnit field is 'initial' and 'reformat' then value of relatedSequence field is identical to the value of sequence field. Multiple comma-separated values can be provided.		
submissionDescription	string	Submission Description	The description of the Submission to be included in the XML.		

envelope v. 3.0.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to. Defaults based on the Application's Country. Show all EU countries, plus EMA and EDQM.	at, be, bg, cy, cz, de, dk, ee, edqm, el, ema, es, fi, fr, hu, hr, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
uuid	string	UUID	A UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 ISO/IEC 9834-8:2005. The same UUID must be	The UUID must be in the form of xxxxxxxx-xxxxMxxx-Nxxxxxxxxxxxxx, where: – x is a hexadecimal number – M is 1-5	

			used for all sequences of an eCTD application. Defaults based on the UUID from the parent Application.	– <i>N</i> is 8, 9, a or b	
submissionType	string	Submission Type	The Filing type of the submission. Based on the Sequence's Filing Type eCTD Code in Ennov InSight , otherwise blank.	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	
submissionMode	string	Submission Mode	The mode of the submission, either Single, Grouping, or Worksharing.	– single – grouping – worksharing	
highLevelSubmissionNumber	string	High Level/ Worksharing Submission Number	The high level submission number for the specific submission, used when the submission mode is Grouping or Worksharing.		
applicationNumber	string	Application Tracking Number	The Application Number as provided by the agency. Multiple commaseparated values can be provided.		
submissionUnit	string	Submission Unit Type	Submission unit type describes the content at a lower level (a “subactivity”) which is submitted in	– initial – validationresponse – response	

			relation to a defined regulatory activity.	– additional-info – closing – consolidating – corrigendum – reformat	
applicant	string	Applicant	The name of the company submitting the Application.		
agencyName	string	Agency Name	The name of the agency that the submission is being sent to. Based on Application's Country.	AT-BASG, BEFAMHP, BG-BDA, CY-PHS, CZ-SUKL, DE-BFARM, DE-PEI, DK-DKMA, EE-SAM, EL-EOF, ES-AEMPS, FIFIMEA, FR-ANSM, HR-HALMED, HU-OGYI, IE-HPRA, IS-IMCA, IT-AIFA, LI-LLV, LT-SMCA, LU-MINSANT, LV-ZVA, MT-MEDAUTH, NLMEB, NO-NOMA, PL-URPL, PTIN-FARMED, ROANM-MD, SE-MPA, SI-JAZMP, SKSIDC, UK-MHRA, EU-EMA, EUEDQM	

procedureType	string	Procedure Type	The procedure type being used to submit. Based on the Application's Procedure Type.	– centralised – national – mutual-recognition – decentralised	
inventedName	string	Invented Name	The invented name of the product being submitted for approval. Multiple comma-separated values can be provided.		
inn	string	INN	The INN of the product being submitted for approval. Multiple comma-separated values can be provided.		
sequence	string	Sequence	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
relatedSequence	string	Related Sequence	This is the sequence number of previous submission(s) to which this submission relates, e.g. the responses to questions to a particular variation. If value of submissionUnit field is 'initial' and 'reformat' then value of relatedSequence field is identical to the value of sequence field. Multiple comma-separated values can be provided.		

submissionDescription	string	Submission Description	The description of the Submission to be included in the XML.		

envelope v. 3.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to. Defaults based on the Application's Country. Show all EU countries, plus EMA and EDQM.	Show all EU countries, plus EMA and EDQM. The list is: at, be, bg, cy, cz, de, dk, edqm, ee, el, es, ema, fi, fr, hr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk, xi.	
uuid	string	UUID	A UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 ISO/IEC 9834-8:2005. The same UUID must be used for all sequences of an eCTD application. Defaults based on the UUID from the parent Application.	The UUID must be in the form of xxxxxxxx-xxxxMxxx-Nxxxxxxxxxxxxxx, where: — x is a hexadecimal number — M is 1-5 — N is 8, 9, a or b	
submissionType	string	Submission Type	The Filing type of the submission. Based on the Sequence's Filing Type eCTD Code in Ennov InSight , otherwise blank.	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	

submissionMode	string	Submission Mode	The mode of the submission, either Single, Grouping, or Worksharing.	– single – grouping – worksharing	
highLevelSubmissionNumber	string	High Level/ Worksharing Submission Number	The high level submission number for the specific submission, used when the submission mode is Grouping or Worksharing.		
applicationNumber	string	Application Tracking Number	The Application Number as provided by the agency. Multiple commaseparated values can be provided.		
submissionUnit	string	Submission Unit Type	Submission unit type describes the content at a lower level (a “subactivity”) which is submitted in relation to a defined regulatory activity.	– initial – validationresponse – response – additional-info – closing – consolidating – corrigendum – reformat	
applicant	string	Applicant	The name of the company submitting the Application.		
agencyName	string	Agency Name	The name of the agency that the submission is being sent to. Based on Application's Country.	AT-BASG, BEFAMHP, BG-BDA, CY-PHS, CZ-SUKL, DE-BFARM, DE- PEI, DK-DKMA, EE-SAM, EL-EOF,	

				ES-AEMPS, FIFIMEA, FR-ANSM, HR-HALMED, HU- OGYI, IE-HPRA, IS-IMCA, IT-AIFA, LHLLV, LT-SMCA, LU-MINSANT, LV- ZVA, MT- MEDAUTH, NLMEB, NO-NOMA, PL-URPL, PTIN- FARMED, ROANM- MD, SE-MPA, SI-JAZMP, SKSIDC, UK-MHRA, EU-EMA, EUEDQM	
procedureType	string	Procedure Type	The procedure type being used to submit. Based on the Application's Procedure Type.	– centralised – national – mutual-recognition – decentralised	
inventedName	string	Invented Name	The invented name of the product being submitted for approval. Multiple comma-separated values can be provided.		
inn	string	INN	The INN of the product being submitted for approval. Multiple comma-separated values can be provided.		
sequence	string	Sequence	The Sequence Number for this submission.	Sequence Code (without prefix "P")	

relatedSequence	string	Related Sequence	This is the sequence number of previous submission(s) to which this submission relates, e.g. the responses to questions to a particular variation. If value of submission-Unit field is 'initial' and 'reformat' then value of relatedSequence field is identical to the value of sequence field. Multiple comma-separated values can be provided.		
submissionDescription	string	Submission Description	The description of the Submission to be included in the XML.		

envelope-eaeu

envelope-eaeu v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	List of country codes associated to EAEU region.	Two letters country code, upper case.	
eDocId	string	EDoc Id	Electronic Document ID.	UUID format.	
eDocRefId	string	EDoc Reference Id	Electronic Document ID of the document the current document is referred to.	UUID format.	
eDocDateTime	string	EDoc Date Time	Creation timestamp. Date of the assembly creation.	Date format - Unix Timestamp.	
registrationNumberId	string	Registration	Registration Number.	Six digits.	

		Number Id			
applicationId	string	Application Id	Application Id.		
registrationKindCode	string	Registration Kind Code	Defines a procedure.	– 01 – mutual recognition: MRP. – 02 - decentralized: DCP.	
submissionSequence	string	Submission Sequence	Defines a current sequence code for all the leafs in the assembly.	Four digits.	

[drug_solvent](#)[drug_solvent v. 1.0](#)

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
drugSolventName	string	Solvent Name	Defines a current solvent name.	N/A	N/A
Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
drugSolventManufacturer	string	Solvent Manufacturer	Defines a current manufacturer name.	N/A	N/A

[envelope-gc](#)[envelope-gc v. 1.2](#)

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	ae, common, bh, kw, om, qa, sa, ye	
applicationNumber	string	Application Number	The Application Number as provided by the agency. Default value is Application Code. Multiple commaseparated values can be provided.		

applicant	string	Applicant	The name of the applicant filing the submission		
agencyName	string	Agency Name	The name of the agency that the submission is being sent to.	BH-MOH, KWMOH, OM-MOH, QA-NHA, YEMOPHP, SA-SFDA, AE-MOH	
atc	string	ATC	ATC code. Multiple comma-separated values can be provided.		
submissionType	string	Submission Type	The Filing type of the submission. Based on the Sequence's Filing Type eCTD Code in Ennov InSight , otherwise blank.	– new-gen – new-nce – new-bio – new-rad – new-her – new-hea – new-vet – renewal – var-type1 – var-type2 – transfer-ma – withdrawal – responses – psur	
procedureType	string	Procedure Type	Procedure type of the submission.	– gcc – national	
inventedName	string	Invented Name	The invented name of the Product being submitted. Multiple comma-separated values can be provided.		

inn	string	INN	The INN of the product being submitted for approval. Multiple comma-separated values can be provided.		
sequence	string	Sequence	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
relatedSequence	string	Related Sequence	This is the Sequence number of a previous submission to which this submission relates. Multiple related sequence numbers may be entered as commaseparated values.		
Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
submissionDescription	string	Submission Description	The description of the Submission to be included in the XML.		

envelope-gc v. 1.5

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	ae, common, bh, kw, om, qa, sa, ye	
applicationNumber	string	Application Number	The Application Number as provided by the agency. Multiple comma-separated values can be provided.		
applicant	string	Applicant	The name of the applicant filing the submission.		
agencyName	string	Agency Name	The name of the agency that the submission is being sent to.	BH-MOH, KWMOH, OM-MOH, QA-NHA, YEMOPHP, SA-SFDA, AE-MOH	

atc	string	ATC	ATC code. Multiple comma-separated values can be provided.		
submissionType	string	Submission Type	The Filing type of the submission.	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	
submissionUnitType	string	Submission Unit Type	The submission unit element of the envelope metadata set describes the content at a lower level (a "sub-activity") which is submitted in relation to a defined regulatory activity such as the applicant response to validation issues or list of questions or any other additional information.		
procedureType	string	Procedure Type	Procedure type of the submission.	– gcc – national	
inventedName	string	Invented Name	The invented name of the Product being submitted.		
inn	string	INN	The INN of the product being submitted for approval. Multiple comma-separated values can be provided.		
sequence	string	Sequence	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
relatedSequence	string	Related Sequence	This is the Sequence number of a previous submission to which this submission relates.		

submissionDescription	string	Submission Description	The description of the Submission to be included in the XML. Multiple related sequence numbers may be entered as commaseparated values.		

envelope-hr

envelope-hr v. 1.4

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	hr	
applicationNumber	string	Application Tracking Number	The Application Number as provided by the agency.		
applicant	string	Applicant	The name of the company submitting the Application.		
agencyName	string	Agency Name	The name of the agency that the submission is being sent to.	– HR-AZLMP – HR-VET	

submissionType	string	Submission Type	The Filing type of the submission. Based on the Sequence's Filing Type eCTD Code in Ennov InSight , otherwise blank.	– initial-maa – supplemental-info – fum – specific-obligation – var-type1a – var-type1b – var-type2 – extension – psur – renewal – asmf – pmf – referral – annualreassessment – usr – article-58 – notification-61-3 – transfer-ma – corrigendum – lifting-suspension – withdrawal – paed-article-29 – paed-article-46 – var-nat – reformat	
submissionMode	string	Submission Mode	The mode of the submission, either Single, Grouping, or Worksharing.	– single – grouping – worksharing	

highLevelSubmissionNumber	string	High Level Submission Number	The high level submission number for the specific submission, used when the submission mode is grouping or worksharing.		
procedureType	string	Procedure Type	The procedure type being used to submit. Based on the Application's Procedure Type.	– centralised – national – mutual-recognition – decentralised	national
inventedName	string	Invented Name	The invented name of the product being submitted for approval.		
inn	string	INN	The INN of the product being submitted for approval.		
sequence	string	Sequence	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
relatedSequence	string	Related Sequence	The related sequence number as well as the country for the specific relation. Country values include all of Europe, Common and EMEA		
submissionDescription	string	Submission Description	The description of the Submission to be included in the XML.		

[eu-envelope](#)[eu-envelope v. 1.0](#)

No additional fields for folder.

[eu_module_1_country_specific_information](#)[eu_module_1_country_specific_information v. 1.0](#)

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to. Defaults based on the Application's Country. Show all EU countries, plus EMEA and Common.	at, be, bg, common, cy, cz, de, dk, ee, el, emea, es, fi, fr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	

[eu_module_1_country_specific_information v. 1.2.1](#)

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to. Defaults based on the Application's Country. Show all EU countries, plus EMEA and Common.	at, be, bg, common, cy, cz, de, dk, ee, el, emea, es, fi, fr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	

[eu_module_1_country_specific_information v. 2.0](#)

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

country	string	Country	Defines which country the envelope information is related to. Defaults based on the Application's Country. Show all EU countries, plus EMEA and Common.	at, be, bg, common, cy, cz, de, dk, ee, el, ema, es, fi, fr, hr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	

eu_module_1_country_specific_information v. 3.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to. Defaults based on the Application's Country. Show all EU countries, plus EMEA and Common.	at, be, bg, common, cy, cz, de, dk, edqm, ee, el, ema, es, fi, fr, hr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	

eu_module_1_country_specific_information v. 3.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	Show all EU countries, plus EMEA and Common. List of countries: at, be, bg, common, cy, cz, de, dk, edqm, ee, el, es, ema, fi, fr, hr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk, xi.	
language	string	Language	The language used for submission in the defined country.	List of languages: bg, cs, da, de, el, en, es, et, fi, fr, ga, hr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv.	

eu_xml_application_form

eu_xml_application_form v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	at, be, bg, common, cy, cz, de, dk, ee, el, emea, es, fi, fr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	

eu_xml_application_form v. 2.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	at, be, bg, common, cy, cz, de, dk, ee, el, ema, es, fi, fr, hr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	

eu_module_1_labeling_information

eu_module_1_labeling_information v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	at, be, bg, common, cy, cz, de, dk, ee, el, emea, es, fi, fr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	
labelingType	string	Labeling Type	Defines the type of label reference in the submission.	– spc – annex2 – outer – interpack	

				– impact – other – pl – combined	

eu_module_1_labeling_information v. 1.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	at, be, bg, common, cy, cz, de, dk, ee, el, emea, es, fi, fr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	
Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
labelingType	string	Labeling Type	Defines the type of label reference in the submission.	– spc – annex2 – outer – interpack – impact – other – pl – combined	

eu_module_1_labeling_information v. 1.2.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	at, be, bg, common, cy, cz, de, dk, ee, el, emea, es, fi, fr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	

labelingType	string	Labeling Type	Defines the type of label reference in the submission.	– spc – annex2 – outer – interpack – impack – other – pl – combined	
country	string	Country	Defines which country the envelope information is related to.	Show all EU countries, plus EMEA and Common. List of countries: at,be,bg,common,cy,cz,de,dk,edqm,ee,el,es,ema,fi,fr,hr,hu,ie,is,it,li,l	
language	string	Language	The language used for submission in the defined country.	List of languages: bg,cs,da,de,el,en,es,et,fi,fr,ga,hr,hu,is,it,lt,lv,mt,nl,	
labeling-Type	string	Labeling Type	Defines the type of label reference in the submission.		

eu_module_1_labeling_information v.3.1

excipient

excipient v. 1.0, v. 1.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
excipient	string	Excipient	The excipient of the product being submitted.		

envelope-jo

envelope-jo v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.		
applicationNumber	string	Application Reference Number	Application Number as provided by the agency. Multiple commaseparated values can be provided.		
applicant	string	Applicant	Name of the applicant filing the submission.		
mah	string	MAH	Name of Marketing Authorization Holder.		
agencyName	string	Agency	Name of the agency that the submission is being sent to.	JO-JFDA	
atc	string	ATC	ATC code. Multiple comma-separated values can be provided.		
submissionType	string	Submission Type	Filing type of the submission.	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	
submissionUnitType	string	Submission Unit	Submission unit element of the envelope metadata set describes the content at a lower level (a "subactivity") which is submitted in relation to a defined regulatory activity such as the applicant response to validation issues or list of questions or any other additional information.	initial, response, additional-info, closing, correction, reformat	

procedureType	string	Procedure	Procedure type of the submission.	– jo – national	
inventedName	string	Invented Name	Invented name of the Product being submitted.		
Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
inn	string	INN	INN of the product being submitted for approval. Multiple commaseparated values can be provided.		
sequence	string	Sequence	Sequence Number for this submission.	Sequence Code (without prefix "P")	
relatedSequence	string	Related Sequence	Sequence number of a previous submission to which this submission relates.		
submissionDescription	string	Submission Description	Description of the Submission to be included in the XML. Multiple related sequence numbers may be entered as comma-separated values.		
number	string	Number	Reference number of the product allocated by the regulatory authority. If the number is not yet allocated at the time point of submission, 'to be advised' should be added instead and replaced by the number in follow-up submissions when registered.		

eu_pim_additional_documents

eu_pim_additional_documents v. 1.0

No additional fields for folder.

m1-gc

m1-gc v. 1.2

No additional fields for folder.

gc_module_1_country_specific_information**gc_module_1_country_specific_information v. 1.2**

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	– ae – common – bh – kw – om – qa – sa – ye	
language	string	Language	The Language that is being used for submission in the defined country.	– ar – en	

gc-m1-responses**gc-m1-responses v. 1.2**

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	– ae – common – bh – kw – om – qa – sa – ye	

gc_module_1_label**gc_module_1_label v. 1.2**

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to. Defaults based on the Application's Country. Shows all GCC countries.	– ae – common – bh – kw – om – qa – sa – ye	
language	string	Language	The Language that is being used for submission in the defined country.	– ar – en	
labelingType	string	Labeling Type	Defines the type of label reference in the submission.	– spc – label – pil	

gc-m1-additional
gc-m1-additional v. 1.2

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	– ae – common – bh – kw – om – qa – sa – ye	

gc-envelope
gc-envelope v. 1.2

No additional fields for folder.

envelope-ba

envelope-ba v3.1

Field Name	Field Type	Matching UI field	Description	Acceptable values	Default value
country	string	Country	Defines which country the envelope information is related to	ba	ba
uuid	string	UUID	A UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 ISO/IEC 9834-8:2005. The same UUID must be used for all sequences of an eCTD application	national	national
submissionType	string	Submission Type	The Filing type of the submission		
submissionMode	string	Submission Mode	The mode of the submission, either single, grouping, or worksharing		
submissionUnit	string	Submission Unit Type	Submission unit type describes the content at a lower level (a "sub-activity") which is submitted in relation to a defined regulatory activity.	Can be one of the following values: - initial - validation-response - response - additional-info - consolidating - reformat	
highLevelSubmissionNumber	string	High Level/Worksharing Submission Number	The high level submission number for the specific submission, used when the submission mode is grouping or worksharing		
applicationNumber	string	Application Tracking Number	The Application Number as provided by the agency		
applicant	string	Applicant	A UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 ISO/IEC 9834-8:2005. The same UUID must be used for all sequences of an eCTD application. Defaults based on the UUID from the parent Application.	The UUID must be in the form of xxxxxxxx-xxxx-Mxxx-Nxxx-xxxxxxxxxxxx, where x is a hexadecimal number, M is 1-5, and N is 8, 9, a or b.	
agencyName	string	Agency Name	The name of the agency that the submission is being sent to	BA-ALMBIH	
procedureType	string	Procedure Type	The procedure type being used to submit	national	
inventedName	string	Invented Name	The invented name of the product being	eCTD Code value from Data	

Field Name	Field Type	Matching UI field	Description	Acceptable values	Default value
			submitted for approval	Administration > Filing Type Values > Filing Type eCTD Code	
inn	string	INN	The INN of the product being submitted for approval	Sequence Code (without prefix "P")	
sequence	string	Sequence	The Sequence Number for this submission		
relatedSequence	string	Related Sequence	This is the sequence number of previous submission(s) to which this submission relates e.g. the responses to questions to a particular variation. In the case of submission unit types 'initial' and 'reformat' related sequence is identical to the sequence number.	Can be one of two values: - single - grouping	
submissionDescription	string	Submission Description	The description of the Submission to be included in the XML		

m1-ba

m1-ba v1.0

No additional fields for this extension.

ba_module_1_country_specific_information

ba_module_1_country_specific_information v. 3.1

Field Name	Field Type	Matching UI field	Description	Acceptable values	Default value
country	string	Country	Defines which country the envelope information is related to.	Show all EU countries, plus EMEA and Common. List of countries: at,ba,be,bg,common,cy,cz,de,dk,edqm,ee,el,es,ema,fi,fr,hr,hu,ie,is, it,li,lt,lu,lv,mt,nl,no,pl,pt,ro,se,si,sk,uk,xi	
language	string	Language	The Language that is being used for submission in the defined country.	List of languages: bg,bs,cs,da,de,el,en,es,et,fi,fr,ga,hr,hu,is,it,lt,lv, mt,nl,no,pl,pt,ro,sk,sl,sr,sv	

envelope-ua

Envelope-ua v.1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	ua	ua
procedureType	string	Procedure Type	The type of procedure for the submission.	national	national
relatedSequence	string	Related Sequence	This is the sequence number of previous submission to which this submission relates. Example, the responses to questions to a particular variation.		
submissionUnit	string	Submission Unit Type	Submission unit type describes the content at a lower level (a "sub activity") which is submitted in relation to a defined regulatory activity.	Can be one of the following values: – initial – validationresponse – response – additionalinfo – consolidating – reformat	
inn	string	INN	International Non- proprietary Name, used to identify pharmaceutical substances or active pharmaceu-		

			tical ingredients. A non-proprietary name is also known as a generic name.		
submissionNumbers	string	Submission Number	This number is used by regulatory authority to track the submission, in any procedure, in relation to a particular medicinal product. This is the number of the registration form or package of registration forms.		
inventedName	string	Invented Name	The name of the medicinal product.		
uuid	string	UUID	A UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 ISO/IEC 9834-8:2005. The same UUID must be used for all sequences of an eCTD application. Defaults based on the UUID from the parent Application.	The UUID must be in the form ofxxxxxxxxxx-MxxxNxxxxxxxxxxxxx, where x is a hexadecimal number, M is 1-5, and N is 8, 9, a or b.	

agencyName	string	Agency Name	Regulatory authority which is The State Expert Center of MOH of Ukraine.	UA-SECMOH	
applicant	string	Applicant	The name of the company submitting the Application.		
submissionType	string	Submission Type	The type of regulatory activity to which the content will be submitted.	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	
sequence	string	Sequence	This is the sequence number of the submission this should start at 0000 for the initial submission, and then increase incrementally with each subsequent submission related to the same medicinal product.	Sequence Code (without prefix "P")	
submissionDescription	string	Submission Description	This element is used to provide a short text description of the submission.		

submissionMode	string	Submission Mode	The high-level handling of the information submitted as part of variation(s) and extension applications. The mode should only be used in variation or line extension regulatory activities and must be included in every sequence of that activity.	Can be one of two values: – single – grouping	

[m1-hr](#)[m1-hr v. 1.0](#)

No additional fields for folder.

[hr-m1-additional](#)[hr-m1-additional v. 1.2.1](#)

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to. Defaults based on the Application's Country.	hr	
language	string	Language	The language used for submission in the defined country.	– de – en – hr	

[hr-m1-3-1-spc-label-pl](#)[hr-m1-3-1-spc-label-pl v. 1.2.1](#)

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	hr	

language	string	Language	The language used for submission in the defined country.	– de – en – hr	
labelingType	string	Labeling Type	Defines the type of label reference in the submission.	– spc – annex2 – outer – interpack – impack – other – pl – combined	

hr_module_1_country_specific_information

hr_module_1_country_specific_information v. 1.2.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	hr	
language	string	Language	The language used for submission in the defined country.	– de – en – hr	

hr-m1-responses

hr-m1-responses v. 1.2.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	hr	
language	string	Language	The language used for submission in the defined country.	– de – en – hr	

m1-jp

m1-jp v. 1.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

submissionNumber	string	Submission Number	The Application Number as provided by the agency.	Application Code	
brandName	string	Brand Name	The brand name of the product being submitted to the agency.		
sequenceNumber	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
genericName	string	Generic Name	The generic name of the product being submitted to the agency.		
applicant	string	Applicant	The company filing the application.		
submissionDate	date	Submission Date	The date the submission is to be submitted.	Date format - Unix Timestamp.	
submissionType	string	Submission Type	The Filing type of the submission.		
jpOperation	string	Operation	The operation of the element pointing to JP regional XML.	– new – append – replace – delete	new

m1-jo

m1-jo v. 1.0

No additional fields for folder.

jo_pi_doc

jo_pi_doc v.1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
language	string	Language	The language used for submission in the defined country.	– ar – en	

labelingType	string	Labeling Type	Defines the type of label reference in the submission.	– spc – label – pil – spccomp – pilcomp	

[jo-additional](#)[jo-additional v. 1.0](#)

No additional fields for folder.

[m1-th](#)[m1-th v. 0.92](#)

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
esubld	string	eSubmission Identifier	The Application Number as provided by the agency. Default value is Application Code. The entered values should be validated before saving.		
sequenceType	string	Sequence Type	Identifies the type of activity that is being submitted with the sequence. If it is the first sequence then submit the regulatory activity type. If it is the second, third, etc. sequences then submit supplementary information. The value used in the XML should be taken from that matching eCTD Code.	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	
regActivityLead	string	Regulatory Activity Lead	Identifies the group within the THAI FDA, which is expected to take the lead in the review process.	– Biologicals – Pharmaceuticals – Pharmacovigilance	

licensee	string	Licensee	The licensee name that is legally responsible for the application in Thailand. The official registered name of the company should be provided.		
inn	string	INN/Generic Name	The INN or Generic Name of the active ingredients used in the product. Multiple commaseparated values can be provided.		
productName	string	Product Name	The name or proposed product (trade) name(s) to be used on the Certificate of Registration. If duplicate products are being submitted within one application, all products should be listed. Multiple commaseparated values can be provided.		
sequence	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
relatedSequence	string	Related Sequence Number	Four digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity (without prefix "P").		
seqDescription	string	Sequence Description	Free text description of the submission. The description provided here should also be used in the node title for 1.0 Cover Letter and 1.R Response to Questions.		

m1-th v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
esubld	string	eSubmission Identifier	The Application Number as provided by the agency.	Application Code. The value should consist of the small EN letter and 7 digits ([a-z]([0-9]{7}))	

sequenceType	string	Sequence Type	Identifies the type of activity that is being submitted with the sequence. If it is the first sequence then submit the regulatory activity type. If it is the second, third, etc. sequences then submit supplementary information. The value used in the XML should be taken from that matching eCTD Code.	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	
regActivityLead	string	Regulatory Activity Lead	Identifies the group within the THAI FDA, which is expected to take the lead in the review process.	– Biologicals – Pharmaceuticals – Pharmacovigilance – Cosmetic – Medical-Devices	
licenseeNumber	string	Licensee Number	The licensee number of the company that is legally responsible for the application in Thailand.		
licenseeType	string	Licensee Type	The licensee type of Licensee Number for the application in Thailand. The licensee type of the company should be provided.	– Importer – Manufacturer	
licensee	string	Licensee Name	The licensee name that is legally responsible for the application in Thailand. The licensee name of the company should be provided in all capital letters.		
inn	string	INN/Generic Name	The INN or Generic Name of the active ingredients used in the product. Multiple comma-separated values can be provided.		

productName	string	Product Name	The name or proposed product (trade) name(s) to be used on the Certificate of Registration. If duplicate products are being submitted within one application, all products should be listed. Multiple comma-separated values can be provided.			
sequence	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")		
relatedSequence	string	Related Sequence Number	Four digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity.			
seqDescription	string	Sequence Description	Free text description of the submission. The description provided here should also be used in the node title for 1.0 Cover Letter and 1.R Response to Questions.			
email	string	Contact Email	The email is used to notify the applicant in case of change in application status. Must be valid email format.	Example: xxx@xxx.com		
identifier	string	Identifier	A UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec	The entered values should pass the validation to match the format: a hexadecimal number in the form of xxxxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx, having 32 digits and 4 hyphens.		Defaults based on the UUID from

			X.667 ISO/IEC 9834-8:2005. The same UUID must be used for all se- quences of an eCTD applica- tion.		the par- ent ap- plicati
submissionTypeTier1	string	Submis- sion Type Tier 1		Domestic, Import, Export Only.	
submissionTypeTier2	string	Submis- sion Type Tier 2		New Drugs Application, Biological Drugs Application, Generic Drug Application, Ac- tive Pharmaceutical Ingredient.	
submissionTypeTier3	string	Submis- sion Type Tier 3		Prescription, Over The Counter, Controlled Drugs, Nuclear Medicine, Biological Drugs, Biosimilar Drugs, Regenerative Medicine, Others.	

m1-tw

m1-tw v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
submissionTypeTier4	string	Submis- sion Type Tier 4		New Chemical Entity, New Indication, New Combination, New Dosage Form, New Administration, New Dosage, New Strength, Genetic Engineering, Vaccine, Plasma Derivative, Cell Therapy, Gene Therapy, Tissue Engineering, Allergen, Safety Monitoring, Non-Safety Monitoring, Others.	

submissionTypeTier5	string	Submission Type Tier 5		New Chemical Entity, New Indication, New Combination, New Dosage Form, New Administration, New Dosage, New Strength, Comply With OTC Criteria, Not Comply With OTC Criteria, Others.	
submissionObjective	string	Submission Objective	Explains the main purpose of this submission. The high-level handling of the information submitted as part of variation(s) and extension applications.	Change, Expiration, Extension, New.	
submissionUnitType	string	Submission Unit	Submission unit type describes the content at a lower level (a "sub-activity") which is submitted in relation to a defined regulatory activity.	Initial, Validation Response, Response, Additional Info, Corrigendum, Reformat.	
applicantName	string	Applicant Name	The name of the company submitting the eCTD.		

applicantCertAuth	string	Application Corporate Certifica- tion Authority	Applicants should use Corporate Certification Authority IC Card for sub- mission.		
applicantPhoneNum	string	Applicant Phone Number	Phone number of the compa- ny.	Multiple comma-separated values can be provided.	
applicantEmailAddr	string	Applicant Email Address		If entered value does not met xx@yy.zz criterion Invalid e-mail address message appears. Multiple comma-separated values can be provided.	
procedure	string	Procedure	Defines the procedure in use with the submission National is the default and the only option to be chosen.		

inventedName	map	Invented Names (Name/ Drug Permit License/ PreAssigned Application Number/ Code)	The group of fields that allows multiple sets of Invented Name.	Example: field name="inventedName" type="map"><value key="2uniqueSuffix_1" value="22,3333" /><value key="2_uniqueSuffix_1" value="222" /><value key="2_uniqueSuffix_1" value="2222" /><value key="Invented NamesNameValue_uniqueSuffix_0" value="Drug Permit License" /><value key="Invented NamesNameValue_uniqueSuffix_0" value="Pre-Assigned Application Number" /><value key="Invented NamesNameValue_uniqueSuffix0" value="Code" />	
inn	string	INN	International Non-proprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary.	Multiple comma-separated values can be provided	

sequence	string	Sequence	This is the sequence number of the submission – this should start at 0000 for the initial submission, and then increase incrementally with each subsequent submission related to the same product For example, 0000, 0001, 0002, 0003, etc.	Only digits, if not, the error appears.	

m1-th-responses

m1-th-responses v.1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
relatedSequence	string	Related Sequence	This is the sequence number of previous submission(s) to which this submission relates. For example, the responses to questions to a particular variation. In the case of submission unit types 'ini-	Multiple comma-separated values can be provided. 'Related Sequence must be numeric' error message appears if the value is not numeric.	

			tial' and 'reformat', related sequence is identical to the sequence number.		
submissionDescription	string	Submission Description	This element is used to provide a free text description of the submission.		

No additional fields for folder.

m1-th-additional

m1-th-additional v.1.0

No additional fields for folder.

m1-ua-additional

m1-ua-additional v.1.0

No additional fields for folder.

m1-ua

m1-ua

No additional fields for folder.

m1-us

m1-us v.1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
companyName	string	Company Name	The name of the company sending the submission.		
submissionDate	date	Submission Date	The date the submission is to be submitted.	Date format - Unix Timestamp	
applicationNumber	string	Application Number	The Application Number provided by the agency.		

productName	string	Product Name	The name or proposed product (trade) name(s) to be used in the Certificate of Registration. If duplicate products are being submitted within one application, all products should be listed. Multiple comma-separated values can be provided.	
applicationType	string	Application Type	The Application Type for this Application. Based on a mapping of the eCTD code to the Application Type selected on the related Application. – nda – anda – bla – dmf – ind – master-file	
submissionType	string	Submission Type	The Filing type of the submission. Will default from the Sequence's Filing Type. – amendment – annual-report – chemistrymanufacturingcontrolssupplement – efficacysupplement – establishmentdescriptionsupplement – labelingsupplement – originalapplication – other – presubmission – resubmission	

sequenceNumber	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
relatedSequenceNumber	string	Related Sequence Number	The related sequence number for this submission.		

m1-us v. 3.3

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
applicantContact	string	Applicant Contact	The Applicant Contact for this submission.	Applicant Contact Name value from Data Administration > Applicant Contact Values	
applicantId	string	Applicant ID	The Applicant's ID. Values from Data Administration. Default displays the Application Level value, if defined.	Applicant ID value from Data Administration > Applicant ID Values	
applicationNumber	string	Application Number	The Application Number as provided by the agency.		
applicationType	string	Application Type	The Application Type for this Application. Based on a mapping of the eCTD code to the Application Type selected on the related Application.	eCTD Code value from Data Administration > Applicant Contact Values > Application Type eCTD Code	

companyName	string	Company Name	Applicant Name from Data Admin, or editable field if no default Applicant ID. Refreshes based on Applicant ID Selected.		
sequenceNumber	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
submissionDescription	string	Submission Description	The description of the Submission.		
submissionSubType	string	Submission Sub-Type	The Filing/Submission Sub Type for this Submission. Dependent on the value selected for Submission Type (eCTD code).	eCTD Code value from Data Administration > Sub Filing Type Values > Sub Filing Type eCTD Code	
submissionType	string	Submission Type	The Filing/Submission Type for this Submission. Values from Data Administration - All active US Regulatory Region values in the Filing Type table. Dependent on Application Type selected (eCTD code).	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	

supplementEffectiveDate	string	Supplement Effective Date Type	Supplement Effective Date Type for this Submission. Dependent on the Submission Type selected (eCTD code).	eCTD Code value from Data Administration > Supplement Effective Date Type Values > Supplement Effective Date Type eCTD Code	

[m1-us-form](#)[m1-us-form v. 3.3](#)

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
formType	string	Application Form Type	Defines the form type of the form included into the submission (eCTD code).	Regulatory Code value from Data Administration > Application Form Type Values	

[m1-us-admin-form](#)[m1-us-admin-form v. 3.3](#)

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
adminFormType	string	Application Form Type	Defines the form type of the form included into the submission (eCTD code).	Regulatory Code value from Data Administration > Application Form Type Values	
applicationNumber	string	Application Number	Defines the application number of the application that the form refers to. All Application Number values defined in the metadata library for the US 3.3 admin section.		

m1-who

m1-who v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
identifierWho	string	Identifier	The Universally Unique identifier (UUID) used for all sequences of an eCTD application.	UUID format	
productTypeWho	string	Product Type	Product code for product type.		
productSubType	string	Product Subtype	Description of the product type. Mandatory for FPP only.		
productId	string	Product Name	The name or proposed product (trade) name used on the Certificate of Registration. FPPs equates to the SF field Generic Name. FVPs equates to the SF field WHO vaccine name (full). APIMFs and APIPQs equates to the SF field Active Pharmaceutical Ingredient.		

applicationTypeWho	string	Application Type	Provides administrative information associated with the submission. The type of regulatory activity to which the content is submitted.		
applicationSubType	string	Application Sub-type	Provides further information about the submission. Mandatory for FPP.		
submissionUnitTypeWho	string	Submission Unit Type	Submission unit type describes the content at a lower level (a "sub-activity") which is submitted in relation to a defined regulatory activity.		
applicantWho	string	Applicant	The name of the company submitting the eCTD.		
contactEmail	string	Contact E-mail	Email Address of the Contact from Applicant.		
productId	string	Product ID	Unique product record identifier, following the format WHO Product ID: Issued by Salesforce.		

sfCaseId	string	SF Case ID	A Salesforce generated number, unique to the application submitted. It follows a simple 8 digit number format.		
sequenceWho	string	Sequence	The Sequence Number for this submission.		
relatedSequence Who	string	Related Sequence	This is the sequence number of previous submission(s) to which this submission relates. For example, the responses to questions to a particular variation. In the case of submission unit types 'initial' and 'reformat' related sequence is identical to the sequence number.		
submissionDescriptionWho	string	Submission Description	The description of the Submission to be included in the XML.		

m1-za

m1-za v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

applicationNumber	string	Application Number	This is the number issued for the product by the MCC and remains for the full lifecycle of the product from the first data submission. Multiple comma-separated values can be provided.		
applicant	string	Applicant	The name of the applicant/HC R submitting the eCTD.		
submissionType	string	Submission Type	The type of regulatory submission that this data submission relates to.	na-nce-ph, na-nce-b, na-ms, na-bs, na-le, na-cu, na-cams, pre-reg-pa, pre-reg-cl, pre-reg-pn, pre-reg-sch, pre-reg-insp, pre-reg-pa-insp, prereg-biol, pre-reg-cams, pre-reg-cr, post-reg-insp, post-reg-pa, post-regpa-insp, post-reg-cl, post-reg-pn, post-reg-pn-update, post-reg-hcr, post-reg-biol, post-reg-cams, withdrawal, cancellation	
proofEfficacy	map	Proof of Efficacy	The data type submitted as proof of efficacy and a description of the data type if "other" is selected as data type.	– non-cl – cl – be – other – na Example: <field name="proofEfficacy" type="map"><value key="other_unique-Suffix_0" value="123456" /></field>	

proprietaryName	string	Proprietary Name	The name of the medicinal product. Include even if not yet approved. Multiple comma-separated values can be provided.		
dosageForms	string	Dosage Form	The dosage form of the medicinal product. Multiple comma-separated values can be provided.		
inn	string	INN	The INN of the API(s) accompanied by its salt or hydrate form (if relevant) or chemical description of the API(s). Multiple comma-separated values can be provided.		
sequence	string	eCTD Sequence	The Sequence Number for this submission.	Sequence Code (without prefix "P")	

relatedSequences	string	Related Sequence	This is the sequence number of a previous submission to which this submission relates. Multiple comma-separated values can be provided.		
duplicateApplications	map	Duplicated Applications (Proprietary Names / Application Numbers	The name of the multiple / duplicate applications of the medicinal product (include even if the name is not yet approved) plus the date of application of the duplicate applications. Multiple paired values can be provided.	Example: <field name="duplicateApplications" type="map"><value key="value1_uniqueSuffix_0" value="1" /></field>	
supportProofDD	string		This field is not used for import.		
supportProofText	string		This field is not used for import.		
supportTestDD_text	string		This field is not used for import.		
supportTestDD_text2	string		This field is not used for import.		

m1-za v.2.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
applicationNumber	string	Application Number	This is the number issued for the product by the MCC and remains for the full lifecycle of the product from the first data submission. Multiple comma-separated values can be provided.		
applicant	string	Applicant	The name of the applicant/HC R submitting the eCTD.		
submissionType	string	Submission Type / Proof of Efficacy	This field is not used for import.		
proofEfficacy	map	Submission Type / Proof of Efficacy	The data type submitted as proof of efficacy and a description of the data type if "other" is selected as data type.	– non-cl – cl – be – other – na Example: <field name="proofEfficacy" type="map"> <value key="postreg-hcr_uniqueSuffix_1" value="other" /> <value key="post-reghcr_uniqueSuffix_1" value="comments text" />	

				<pre><value key="post-reghcr_uniqueSuffix_0" value="other" /> <value key="post-reghcr_uniqueSuffix_0" value="comments text" /></ field></pre> Where: – post-reg-hcr is an eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code – other is a Proof of Efficacy value. – comments text is a free text value, can be empty.	
proprietaryName	string	Proprietary Name	The name of the medicinal product. Include even if not yet approved. Multiple comma-separated values can be provided.		
dosageForms	string	Dosage Form	The dosage form of the medicinal product. Multiple comma-separated values can be provided.		

inn	string	INN	The INN of the API(s) accompanied by its salt or hydrate form (if relevant) or chemical description of the API(s). Multiple comma-separated values can be provided.		
sequence	string	eCTD Sequence	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
relatedSequences	string	Related Sequence	This is the sequence number of a previous submission to which this submission relates. Multiple comma-separated values can be provided.		

duplicateApplications	map	Duplicated Applications (Proprietary Names / Application Numbers	The name of the multiple / duplicate applications of the medicinal product (include even if the name is not yet approved) plus the date of application of the duplicate applications. Multiple paired values can be provided.	Example: <field name="duplicateApplications" type="map"><value key="value1_uniqueSuffix_0" value="1" /></field>	
supportProofDD	string		This field is not used for import.		
supportProofText	string		This field is not used for import.		
Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
supportTestDD_text	string		This field is not used for import.		
supportTestDD_text3	string		This field is not used for import.		

m1-za v.3.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
sequenceNumber	string	Sequence Number	Four-digit number matching the Sequence folder being submitted	N/A	N/A

applicationType e	string	Application Type	Defines an application type.	– app-type-1 – app-type-2 – app-type-3 – app-type-4 – app-type-5 – app-type-6 – app-type-7	N/A
smfNumber	string	SMF Number	The Site Master File (SMF) Number for all manufacturers referenced in the eCTD application should be added as issued. Multiple comma-separated values can be provided.	N/A	N/A
sequenceDescriptionZa	string	Sequence Description	The Sequence Description attribute gives the Applicant an opportunity to better describe what is being done in the Sequence.	N/A	N/A

applicationNumber	string	Application Number	A unique number automatically issued by SAHPRA for each product, strength, replica/ clone/duplicate once an application is created or a new replica/clone is added to the existing application on SAHPRA application portal. Multiple comma-separated values can be provided.	N/A	N/A
dosageForm	string	Dosage Form	The dosage form of the medicinal product. Multiple comma-separated values can be provided.	N/A	N/A
inn	string	INN	The recognised International Nonproprietary Name should be given for the active ingredients and pharmaceutical drug if available. It should be written in all lower-case letters and provided exactly as officially listed in international lists like WHO INN, British Approved Names (BAN), United States Pharmacopoeia (USP) and so on without abbreviations. Multiple comma-separated values can be provided.	N/A	N/A

apimfNumber	string	APIMF Number	A number for certified Active Pharmaceutical Ingredient Master File (APIMF). Populated, if APIMF is referenced in the eCTD application. Multiple commaseparated values can be provided.	N/A	N/A
vamfNumber	string	VAMF Number	A number for certified Vaccine Master File (VAMF). Populated, if VAMF is referenced in the eCTD application. Multiple commaseparated values can be provided.	N/A	N/A
applicationIdentifier	string	Application ID	A unique 14character identifier number automatically issued by SAHPRA for an application once it is created on SAHPRA application portal. Application ID is used for all sequences of an eCTD application and cannot be changed	N/A	Current Application Code

sequenceDate	string	Sequence Date	The date when the sequence was submitted. The date should correlate but should not necessarily be identical to the date shown in the Letter of Application and the Application Form. Sequence Date is mainly used to ensure the validity of the codes taken from the Defined Lists.	171745920 0000	N/A
proprietaryName	string	Proprietary Name	The name as proposed or registered. For API Master Files, insert drug substance name and APIMF holder name. Multiple commaseparated values can be provided.	N/A	N/A

submissionInfo Combination	map	Submission (Submission Type / Evaluation Pathway / Submission Lead / Submission Number)	Contains all the sub- mission-related in- formation for the regulatory activity that is not related to a specific sequence. Multiple Submission sets can be provided if the combination is allowed in the Sub- mission Type Matrix.	<field name="sub mis- sionInfo Combi- nation " type="map" > <value key="sub- type-31_u nique- Suffix_ _0" value="eval- path-1"/> <val- ue key="sub- type-31_u nique- Suffix_ _0" value="sub- lead-2"/> <val- ue key="sub- type-31_u nique- Suffix_ _0" value="num 1,num1b"/> </field>	N/A
pmfNumber	string	PMF Number	A number for the cer- tified Active Plasma Master File (PMF). Populates, if PMF is referenced in the eCTD application. Multiple commasep- arated values can be provided.	N/A	N/A

multipleApplications	map	Multiple Applications (Application Number / Proprietary Name)	The data type submitted as proof of efficacy and a description of the data type if other is selected as data type. Multiple paired values can be provided. The value is not required to populate but it is required to have both Application Number and Proprietary Name either populated or empty. If only one field is populated, a validation message is displayed.	<pre><field name="multipleApplications" type="map" > <value key="appnum01_uniqueSuffix_0" value="propname01"/> </field></pre>	N/A
submissionSubType	string	Sequence Type	The Sequence Element section contains all the Sequence-related information. It identifies what is happening to the Submission with the Sequence being submitted. Only one Sequence Element section can be specified per Sequence, however multiple types of Responses can be specified as types. Responses can only be combined with other responses. Multiple values can be provided	N/A	N/A

submissionContact	string	Contact	Multiple contacts may be provided in the Envelope. The Contact Name and Contact Email must be provided for each contact, along with the Type of Contact. At least one Local Applicant contact must be provided.	N/A	N/A

m1-15-2-materials

m1-15-2-materials v. 3.3

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
promotionalMaterialDocType	string	Promotional Material Doc Type	Defines the promotional material document type of US region.	Regulatory Code value from Data Administration > Promotional Material Doc Type Values	

m1-15-promotional-material

m1-15-promotional-material v. 3.3

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
promotionalMaterialAudienceType	string	Promotional Material Audience Type	Defines the promotional material audience type of US region.	Regulatory Code value from Data Administration > Promotional Material Audience Type Values	

m1-15-2-1-material

m1-15-2-1-material v. 3.3

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

issueDate	date	Issue Date	The date of the initial dissemination of the promotional labeling or the date of initial publication for an advertisement.	Date format - Unix Timestamp.	
promotionalMaterialId	string	Promotional Material ID	The applicant identification code or other designation of the specific promotional material.		
promotionalMaterialType	string	Promotional Material Type	Defines the promotional material document type of US region.	Regulatory Code value from Data Administration > Promotional Material Type Values	

m1-responses

m1-responses v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	at, be, bg, common, cy, cz, de, dk, ee, el, emea, es, fi, fr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The language for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	

m1-responses v. 1.2.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	at, be, bg, common, cy, cz, de, dk, ee, el, emea, es, fi, fr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	

language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	

m1-responses v. 2.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	at, be, bg, common, cy, cz, de, dk, ee, el, ema, es, fi, fr, hr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	

m1-responses v. 3.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	at, be, bg, common, cy, cz, de, dk, edqm, ee, el, ema, es, fi, fr, hr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	

eu-m1-responses v. 3.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	Show all EU countries, plus EMEA and Common. List of countries: at, be, bg, common, cy, cz, de, dk, edqm, ee, el, es, ema, fi, fr, hr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk, xi.	Defaults based on application country.

language	string	Language	The Language that is being used for submission in the defined country.	List of languages: bg, cs, da, de, el, en, es, et, fi, fr, ga, hr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv.	

m1-3-1-spc-label-pl

m1-3-1spc-label-pl v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	at, be, bg, common, cy, cz, de, dk, ee, el, emea, es, fi, fr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	
labelingType	string	Labeling Type	Defines the type of label reference in the submission.	– spc – annex2 – outer – interpack – impack – other – pl – combined	

m1-3-1spc-label-pl v. 1.2.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	at, be, bg, common, cy, cz, de, dk, ee, el, emea, es, fi, fr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	
Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

labelingType	string	Labeling Type	Defines the type of label reference in the submission.	– spc – annex2 – outer – interpack – impack – other – pl – combined	

m1-3-1spc-label-pl v. 2.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	at, be, bg, common, cy, cz, de, dk, ee, el, ema, es, fi, fr, hr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	
language	string	Language	The Language that is being used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	
labelingType	string	Labeling Type	Defines the type of label reference in the submission.	– spc – annex2 – outer – interpack – impack – other – pl – combined	

m1-3-1spc-label-pl v. 3.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

country	string	Country	Defines which country the envelope information is related to.	at, be, bg, common, cy, cz, de, dk, edqm, ee, el, ema, es, fi, fr, hr, hu, ie, is, it, li, lt, lu, lv, mt, nl, no, pl, pt, ro, se, si, sk, uk	

language	string	Language	The language used for submission in the defined country.	bg, cs, da, de, el, en, es, et, fi, fr, hr, hu, is, it, lt, lv, mt, nl, no, pl, pt, ro, sk, sl, sv	
labelingType	string	Labeling Type	Defines the type of label reference in the submission.	– spc – annex2 – outer – interpack – impack – other – pl – combined	

m1-3-1spc-label-pl v. 3.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
country	string	Country	Defines which country the envelope information is related to.	All EU countries.	Defaults based on application country.
language	string	Language	The language used for submission in the defined country.		
labelingType	string	Labeling Type	Defines the type of label reference in the submission.		

m1-3-1-pim

m1-3-1-pim v. 1.0

No additional fields for folder.

m2-3-introduction

m2-3-introduction v. 1.0

No additional fields for folder.

m2-3-quality-overall-summary

m2-3-quality-overall-summary v. 1.0

No additional fields for folder.

Stf

stf v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
stfOperation	string	Operation	Defines the lifecycle operation of the Study Report (New, Replace, Append, Delete).	– new – replace – append – delete	new
fullReportTitle	string	Full Report Title	The Full name of the Report being submitted.		
reportNumber	string	Report Number	The Report number of the report being submitted.		
species	string	Species	The species that was used in the study.	– mouse – rat – hamster – other-rodent – rabbit – dog – non-humanprimate – other-non-rodentmammal – non-mammals	

routeOfAdministration	string	Route of Administration	The route of administration that was used in the study.	– oral – intravenous – intramuscular – intraperitoneal – subcutaneous – inhalation – topical – other	
duration	string	Duration	The duration of the study.	– medium – long – short	
typeOfControl	string	Type of Control	The type of control used during the study.	– placebo – no-treatment – dose-responsewith-out-placebo – active-controlwithout-placebo – external	
docId	string		This field is not used for import.		

stf v. 1.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
stfOperation	string	Operation	Defines the lifecycle operation of the Study Report (New, Replace, Append, Delete).	– new – replace – append – delete	new
fullReportTitle	string	Full Report Title	The Full name of the Report being submitted.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
reportNumber	string	Report Number	The Report number of the report being submitted.		
species	string	Species	The species that was used in the study.	– mouse – rat – hamster – other-rodent – rabbit – dog – non-human-primate – other-non-rodentmammal – non-mammals	
routeOfAdministration	string	Route of Administration	The route of administration that was used in the study.	– oral – intravenous – intramuscular – intraperitoneal – subcutaneous – inhalation – topical – other	
duration	string	Duration	The duration of the study.	– medium – long – short	
typeOfControl	string	Type of Control	The type of control used during the study.	– placebo – no-treatment – dose-responsewith-out-placebo	

				– active-control-without-placebo – external	
subjectMatter	string	Subject Matter	The subject matter for the specific study.	pre-clinical-study-report, legacy-clinical-studyreport, synopsis, studyreport-body, protocol-oramendment, samplecase-report-form, iec-irbconsent-form-list, listdescription-investigator-site, signaturesinvestigators, list-patients-with-batches, randomisation-scheme, audit-certificates-report, statistical-methodsinterim-analysis-plan, inter-laboratorystandardisationmethods-qualityassurance, publicationsbased-on-study, publications-referencedin-report, discontinuedpatients, protocoldeviations, patientsexcluded-from-efficacyanalysis, demographicdata, compliance-and-drug-concentration-data, individual-efficacyresponse-data, adverseevent-listings, listingindividual-laboratorymeasurements-by-patient, available-onrequest, completepatient-list, seriousadverse-event-patientlist, adverse-eventpatient-list, abnormal-lab-values-patient-list, data-tabulation-dataset, data-tabulation-datadefinition, data-listing-dataset, data-listingdata-definition, analysisdataset, analysis-program, analysis-data-definition, annotated-crf, ecg, image, subjectprofiles, safety-report, antibacterial, special-pathogen, antiviral, iss, ise, pm-description	
docId	string		This field is not used for import.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
stfOperation	string	Operation	Defines the lifecycle operation of the Study Report (New, Replace, Append, Delete).	– new – replace – append – delete	new
fullReportTitle	string	Full Report Title	The Full name of the Report being submitted.		
reportNumber	string	Report Number	The Report number of the report being submitted.		
species	string	Species	The species that was used in the study.	– mouse – rat – hamster – other-rodent – rabbit – dog – non-human-primate – other-non-rodentmammal – non-mammals	
routeOfAdministration	string	Route of Administration	The route of administration that was used in the study.	– oral – intravenous – intramuscular – intraperitoneal – subcutaneous – inhalation – topical – other	

duration	string	Duration	The duration of the study.	– medium – long – short	
typeOfControl	string	Type of Control	The type of control used during the study.	– placebo – no-treatment – dose-responsewith-out-placebo – active-control-without-placebo – external	
subjectMatter	string	Subject Matter	The subject matter for the specific study.	pre-clinical-study-report, legacy-clinical-studyreport, synopsis, studyreport-body, protocol-oramendment, samplecase-report-form, iec-irbconsent-form-list, listdescription-investigator-	

				site, signaturesinvestigators, list-patients-with-batches, randomisation-scheme, audit-certificates-report, statistical-methodsinterim-analysis-plan, inter-laboratorystandardisationmethods-qualityassurance, publicationsbased-on-study, publications-referencedin-report, discontinuedpatients, protocoldeviations, patientsexcluded-from-efficacyanalysis, demographicdata, compliance-and-drug-concentration-data, individual-efficacyresponse-data, adverseevent-listings, listingindividual-laboratorymeasurements-by-patient, available-onrequest, completepatient-list, seriousadverse-event-patientlist, adverse-eventpatient-list, abnormal-lab-values-patient-list, data-tabulation-datasetlegacy, data-tabulationdataset-sdtm, datatabulation-dataset-send, me="data-tabulationdataset, data-tabulation-dataset-sdtm, data-tabulation-dataset-send, me="data-tabulation-dataset, data-tabulation-data-definition, data-listing-dataset, data-listing-data-definition, analysis-dataset-adam, analysis-dataset-legacy, e="analysis-dataset, analysis-program, analysis-data-definition, annotated-crf, ecg, image, subject-profiles, safety-report, antibacterial, special-pathogen, antiviral, iss, ise, pm-description	
docId	string		This field is not used for import.		

stf v. 5.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

stfOperation	string	Operation	Defines the lifecycle operation of the Study Report (New, Replace, Append, Delete).	– new – replace – append – delete	new
fullReportTitle	string	Full Report Title	The Full name of the Report being submitted.		
reportNumber	string	Report Number	The Report number of the report being submitted.		
species	string	Species	The species that was used in the study.	– mouse – rat – hamster – other-rodent – rabbit – dog – non-human-primate – other-non-rodentmammal – non-mammals	
routeOfAdministration	string	Route of Administration	The route of administration that was used in the study.	– oral – intravenous – intramuscular – intraperitoneal – subcutaneous – inhalation – topical – other	
duration	string	Duration	The duration of the study.	– medium – long – short	

typeOfControl	string	Type of Control	The type of control used during the study.	– placebo – no-treatment – dose-response-without-placebo – active-control-without-placebo – external	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
subjectMatter	string	Subject Matter	The subject matter for the specific study.	pre-clinical-study-report, legacy-clinical-studyreport, synopsis, studyreport-body, protocol-oramendment, samplecase-report-form, iec-ir-bconsent-form-list, listdescription-investigatorsite, signaturesinvestigators, listpatients-with-batches, randomisation-scheme, audit-certifi-	

				cates-report, statistical-methodsinterim-analysis-plan, inter-laboratorystandardisationmethods-qualityassurance, publicationsbased-on-study, publications-referencedin-report, discontinued-patients, protocoldeviations, patientsexcluded-from-efficacyanalysis, demographicdata, compliance-and-drug-concentration-data, individual-efficacyresponse-data, adverseevent-listings, listingindividual-laboratorymeasurements-by-patient, available-onrequest, completepatient-list, seriousadverse-event-patientlist, adverse-eventpatient-list, abnormallab-values-patient-list, data-tabulation-datasetlegacy, data-tabulation-dataset-sdtm, datatabulation-dataset-send, me="data-tabulationdataset, data-tabulationdataset-sdtm, data-tabulationdataset-send, me="data-tabulationdataset, data-tabulation-data-definition, data-listing-dataset, data-listing-data-definition, analysis-dataset-adam, analysis-dataset-legacy, e="analysis-dataset, analysis-program, analysis-data-definition, annotated-crf, ecg, image, subject-profiles, safety-report, antibacterial, special-pathogen, antiviral, iss, ise, pm-description	
docId	string		This field is not used for import.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
subjectMatter	string	Subject Matter	The subject matter for the specific study.	pre-clinical-study-report, legacy-clinicalstudy-report, synopsis, study-reportbody, protocol-or-amendment, samplecase-report-form, iec-irb-consent-formlist, list-description-investigator-site, signatures-investigators, list-patientswith-batches, randomisation-scheme, audit-certificates-report, statisticalmethods-interim-analysis-plan, interlaboratory-standardisation-methodsquality-assurance, publications-basedon-study, publications-referenced-in-report, discontinued-patients, protocoldeviations, patients-excluded-fromefficacy-analysis, demographic-data, compliance-and-drug-concentrationdata, individual-efficacy-response-data, adverse-event-listings, listing-individual-laboratory-measurements-by-patient, available-on-request, complete-patientlist, serious-adverse-event-patient-list, adverse-event-patient-list, abnormal-labvalues-patient-list, data-tabulationdataset, data-tabulation-data-definition, data-listing-dataset, data-listing-datadefinition, analysis-dataset, analysisprogram, analysis-data-definition, annotated-crf, ecg, image, subjectprofiles, safety-report, antibacterial, special-pathogen, antiviral, iss, ise, pmdescription, nonclinical-data, casereport-forms	
site	string	Site	The name of the site where the study was conducted.		

study_patient_information_folder v. 3.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

subjectMatter	string	Subject Matter	The subject matter for the specific study.	pre-clinical-study-report, legacy-clinicalstudy-report, synopsis, study-reportbody, protocol-or-amendment, samplecase-report-form, iec-irb-consent-formlist, list-description-investigator-site, signatures-investigators, list-patientswith-batches, randomisation-scheme, audit-certificates-report, statisticalmethods-interim-analysis-plan, interlaboratory-standardisation-methodsquality-assurance, publications-based-onstudy, publications-referenced-in-report, discontinued-patients, protocoldeviations, patients-excluded-fromefficacy-analysis, demographic-data, compliance-and-drug-concentration-data, individual-efficacy-response-data, adverse-event-listings, listing-individuallaboratory-measurements-by-patient, case-report-forms, available-on-request, complete-patient-list, serious-adverseevent-patient-list, adverse-event-patientlist, abnormal-lab-values-patient-list, data-tabulation-dataset-legacy, datatabulation-dataset-sdtm, data-tabulationdataset-send, me="data-tabulationdataset, data-tabulation-data-definition, data-listing-dataset, data-listing-datadefinition, analysis-dataset-adam, analysis-dataset-legacy, e="analysisdataset, analysis-program, analysis-datadefinition, annotated-crf, ecg, image, subject-profiles, safety-report, antibacterial, special-pathogen, antiviral, iss, ise, pm-description	
site	string	Site	The name of the site where the study was conducted.		

study_data_folder

study_data_folder v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
dataset	string	Dataset	The type of dataset contained in the folder.		

subjectMatter	string	Subject Matter	The subject matter for the specific study.	pre-clinical-study-report, legacy-clinicalstudy-report, synopsis, study-reportbody, protocol-or-amendment, samplecase-report-form, iec-irb-consent-formlist, list-description-investigator-site, signatures-investigators, list-patientswith-batches, randomisation-scheme, audit-certificates-report, statisticalmethods-interim-analysis-plan, interlaboratory-standardisation-methodsquality-assurance, publications-basedon-study, publications-referenced-in-report, discontinued-patients, protocoldeviations, patients-excluded-fromefficacy-analysis, demographic-data, compliance-and-drug-concentrationdata, individual-efficacy-response-data, adverse-event-listings, listing-individuallaboratory-measurements-by-patient, case-report-forms, available-on-request, complete-patient-list, serious-adverseevent-patient-list, adverse-event-patientlist, abnormal-lab-values-patient-list, data-tabulation-dataset, data-tabulationdata-definition, data-listing-dataset, datalistings-data-definition, analysis-dataset, analysis-program, analysis-datadefinition, annotated-crf, ecg, image, subject-profiles, safety-report, antibacterial, special-pathogen, antiviral, iss, ise, pm-description	

study_data_folder v. 3.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
daaset	string	Dataset	The type of dataset contained in the folder.		

subjectMatter	string	Subject Matter	The subject matter for the specific study.	pre-clinical-study-report, legacy-clinicalstudy-re- port, synopsis, study-report-body, protocol-or-amendment, sample-casereport-form, iec-irb-consent-form-list, list-description-investigator-site, signatures-investigators, list-patientswith-batches, randomisation-scheme, audit-certificates-report, statisticalmethods-interim-analysis-plan, interlaboratory-standardisation-methodsquality-assurance, publications-based-onstudy, publications-referenced-in-report, discontinued-patients, protocoldeviations, patients-excluded-fromefficacy-analysis, demographic-data, compliance-and-drug-concentration-data, individual-efficacy-response-data, adverse-event-listings, listing-individuallaboratory-measurements-by-patient, case-report-forms, available-on-request, complete-patient-list, serious-adverseevent-patient-list, adverse-event-patientlist, abnormal-lab-values-patient-list, data-tabulation-dataset-legacy, datatabulation-dataset-sdtm, data-tabulationdataset-send, me="data-tabulationdataset, data-tabulation-da- ta-definition, data-listing-dataset, data-listing-datadefinition, analysis-dataset-adam, analysis-dataset-legacy, e="analysisdataset, analysis-program, analysis-datadefinition, annotated-crf, ecg, image, subject-profiles, safety-report, antibacterial, special-pathogen, antiviral, iss, ise, pm-description	

module_studies

module_studies v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
createStudyFolders	string	Create Study Folders	Choose if Study Report Folders are created automatically when publishing.	– Y – N	Y

studyOrganizationInXml	string	Study Organization in XML	Defines how studies should be organised within the published XML.	– stfs – study_elem_in_index – node_ext_in_index – leaf_elem_only	
subjectMatter	string	Subject Matter	Defines the subject matter of the study reports within that section. Can be overridden at the lower levels.	pre-clinical-study-report, legacy-clinical-study-report, synopsis, study-report-body, protocol-or-amendment, sample-case-report-form, iec-irb-consent-form-list, list-description-investigator-site, signatures-investigators, list-patients-with-batches, randomisation-scheme, audit-certificates-report, statistical-methods-interim-analysis-plan, inter-laboratory-standardisation-methods-quality-assurance, publications-based-on-study, publications-referenced-in-report, discontinued-patients, protocol-deviations, patients-excluded-from-efficacy-analysis, demographic-data, compliance-and-drug-concentration-data, individual-efficacy-response-data, adverse-event-listings, listing-individual-laboratory-measurements-by-patient, case-report-forms, available-on-request, complete-patient-list, serious-adverse-event-patient-list, adverse-event-patient-list, abnormal-lab-values-patient-list, data-tabulation-dataset, data-tabulation-data-definition, data-listing-dataset, data-listing-data-definition, analysis-dataset, analysis-program, analysis-data-definition, annotated-crf, ecg, image, subject-profiles, safety-report, antibacterial, special-pathogen, antiviral, iss, ise, pm-description, non-clinical-data	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
createStudyFolders	string	Create Study Folders	Choose if Study Report Folders are created automatically when publishing.	– Y – N	Y
studyOrganizationInXml	string	Study Organization in XML	Defines how studies should be organised within the published XML.	– stfs – study_elem_in_index – node_ext_in_index – leaf_elem_only	
subjectMatter	string	Subject Matter	Defines the subject matter of the study reports within that section. Can be overridden at the lower levels.	pre-clinical-study-report, legacy-clinical-study-report, synopsis, study-report-body, protocol-or-amendment, sample-case-report-form, iec-irb-consent-form-list, listdescription-investigator-site, signatures-investigators, listpatients-with-batches, randomisation-scheme, audit-certificates-report, statistical-methods-interimanalysis-plan, inter-laboratory-standardisationmethods-quality-assurance, publications-based-on-study, publications-referenced-inreport, discontinued-patients, protocol-deviations, patientsexcluded-from-efficacyanalysis, demographic-data, compliance-and-drugconcentration-data, individual-efficacy-responsedata, adverse-event-listings, listing-individual-laboratorymeasurements-by-patient, case-report-forms, availableon-request, completepatient-list, serious-adverseevent-patient-list, adverseevent-patient-list, abnormal-lab-values-patient-list, datatabulation-dataset-legacy, data-tabulation-datasetsdtm, data-tabula-	

				tiondataset-send, me="datatabulation-dataset, datatabulation-data-definition, data-listing-dataset, datalisting-data-definition, analysis-dataset-adam, analysis-dataset-legacy, e="analysis-dataset, analysis-program, analysis-data-definition, annotated-crf, ecg, image, subject-profiles, safety-report, antibacterial, special-pathogen, antiviral, iss, ise, pm-description	

module_4_studies

module_4_studies v. 1.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
createStudyFolders	string	Create Study Folders	Choose to automatically create Study Report Folders when publishing.	– Y – N	N
studyOrganizationInXml	string	Study Organisation in XML	Defines how studies should be organized within the published XML.	– stfs – study_elem_in_index – node_ext_in_index – leaf_elem_only	

module_4_studies v. 1.2

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
createStudyFolders	string	Create Study Folders	Choose if Study Report Folders are created automatically when publishing.	– Y – N	N

studyOrganizationInXml	string	Study Organization in XML	Defines how studies should be organised within the published XML.	– stfs – study_elem_in_index – node_ext_in_index – leaf_elem_only	
subjectMatter	string	Subject Matter	Defines the subject matter of the study reports within that section. Can be overridden at the lower levels.	pre-clinical-study-report, legacy-clinical-study-report, synopsis, study-report-body, protocol-or-amendment, sample-case-report-form, iec-irb-consent-form-list, list-description-investigator-site, signatures-investigators, list-patients-with-batches, randomisation-scheme, audit-certificates-report, statistical-methods-interimanalysis-plan, inter-laboratory-standardisationmethods-quality-assurance, publications-based-on-study, publications-referenced-inreport, discontinuedpatients, protocol-deviations, patients-excluded-from-efficacy-analysis, demographic-data, compliance-and-drugconcentration-data, individual-efficacy-responsedata, adverse-event-listings, listing-individual-laboratorymeasurements-by-patient, case-report-forms, availableon-request, completepatient-list, serious-adverseevent-patient-list, adverseevent-patient-list, abnormal-lab-values-patient-list, datatabulation-dataset, datatabulation-data-definition, data-listing-dataset, datalistig-data-definition, analysis-dataset, analysisprogram, analysis-datadefinition, annotated-crf, ecg, image, subject-profiles, safety-report, antibacterial, special-pathogen, antiviral, iss, ise, pm-description, nonclinical-data	

[module_5_studies](#)[module_5_studies v. 1.1](#)

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
createStudyFolders	string	Create Study Folders	Choose if Study Report Folders are created automatically when publishing.	– Y – N	Y
studyOrganizationInXml	string	Study Organisation in XML	Defines how studies should be organised within the published XML.	– STFs – Node extension in index.xml – Leaf elements only - no differentiation between studies	STFs

[module_5_studies v. 1.2](#)

No additional fields for folder.

[module_5_studies v. 1.3](#)

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
createStudyFolders	string	Create Study Folders	Choose if Study Report Folders are created automatically when publishing.	– Y – N	Y
studyOrganizationInXml	string	Study Organisation in XML	Defines how studies should be organised within the published XML.	– stfs – study_elem_in_index – node_ext_in_index – leaf_elem_only	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
subjectMatter	string	Subject Matter	Defines the subject matter of the study reports within that section.	pre-clinical-study-report, legacy-clinical-study-report, synopsis, study-report-body, protocol-or-amendment, sample-case-report-form, iec-irb-consent-form-list, listdescription-investigator-site, signatures-investigators, listpatients-with-batches, randomisation-scheme, audit-certificates-report, statistical-methods-interimanalysis-plan, inter-laboratory-standardisationmethods-quality-assurance, publications-based-on-study, publications-referenced-inreport, discontinued-patients, protocol-deviations, patientsexcluded-from-efficacyanalysis, demographic-data, compliance-and-drugconcentration-data, individual-efficacy-responsedata, adverse-event-listings, listing-individual-laboratorymeasurements-by-patient, case-report-forms, availableon-request, completepatient-list, serious-adverseevent-patient-list, adverseevent-patient-list, abnormal-lab-values-patient-list, datatabulation-dataset, datatabulation-data-definition, data-listing-dataset, datalistig-data-definition, analysis-dataset, analysisprogram, analysis-datadefinition, annotated-crf, ecg, image, subject-profiles, safety-report, antibacterial, special-pathogen, antiviral, iss, ise, pm-description, nonclinical-data	

[node-extension](#)[node-extension](#)

No additional fields for folder.

Leaf Extensions[japanese_leaf](#)[japanese_leaf v.1.0](#)

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
leafSequenceNumber	string	Leaf Sequence	The Sequence Number for the specific leaf (JP Only).	Example: 01	

[study_report_leaf](#)[study_report_leaf v. 1.0](#)

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
subjectMatter	string	Selection	The subject matter for the specific study.	pre-clinical-study-report, legacy-clinicalstudy-report, synopsis, study-report-body, protocol-amendment, sample-casereport-form, iec-irb-consent-form-list, listdescription-investigator-site, signaturesinvestigators, list-patients-with-batches, randomisation-scheme, audit-certificatesreport, statistical-methods-interimanalysis-plan, inter-laboratorystandardisation-methods-qualityassurance, publications-based-on-study, publications-referenced-in-report, discontinued-patients, protocol-deviations, patients-excluded-from-efficacy-analysis, demographic-data, compliance-and-drugconcentration-data, individual-efficacyresponse-data, adverse-event-listings, listing-individual-laboratorymeasurements-by-patient, available-onrequest, complete-patient-list, seriousadverse-event-patient-list, adverse-eventpatient-list, abnormal-lab-valuespatientlist, data-tabulation-dataset, datatabulation-data-definition, data-listingdataset, data-listing-data-definition, analysis-dataset, analysis-program, analysis-data-definition, annotated-crf, image, safety-report, antibacterial, special-pathogen, antiviral, iss, ise, pm-description, non-clinical-data	

study_report_leaf v. 1.1

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
subjectMatter	string	Selection	The subject matter for the specific study.	pre-clinical-study-report, legacy-clinicalstudy-report, synopsis, study-report-body, protocol-or-amendment, sample-casereport-form-, iec-irb-consent-form-list, listdescription-investigator-site, signaturesinvestigators, list-patients-with-batches, randomisation-scheme, audit-certificatesreport, statistical-methods-interimanalysis-plan, inter-laboratorystandardisation-methods-qualityassurance, publications-based-on-study, publications-referenced-in-report, discontinued-patients, protocol-deviations, patients-excluded-from-efficacy-analysis, demographic-data, compliance-and-drugconcentration-data, individual-efficacyresponse-data, adverse-event-listings, listing-individual-laboratorymeasurements-by-patient, available-onrequest, complete-patient-list, seriousadverse-event-patient-list, adverse-eventpatient-list, abnormal-lab-values-patientlist, data-tabulation-dataset, datatabulation-data-definition, data-listingdataset, data-listing-data-definition, analysis-dataset, analysis-program, analysis-data-definition, annotated-crf, ecg, image, subject-profiles, safety-report, antibacterial, special-pathogen, antiviral, iss, ise, pm-description	

study_report_leaf v. 3.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
subjectMatter	string	Selection	The subject matter for	pre-clinical-study-report, legacy-clinicalstudy-report, synopsis, study-report-body, protocol-or-	

			the specific study.	amendment, sample-casereport-form, iec-irb-consent-form-list, listdescription-investigator-site, signaturesinvestigators, list-patients-with-batches, randomisation-scheme, audit-certificatesreport, statistical-methods-interimanalysis-plan, inter-laboratorystandardisation-methods-qualityassurance, publications-based-on-study, publications-referenced-in-report, discontinued-patients, protocol-deviations, patients-excluded-from-efficacy-analysis, demographic-data, compliance-and-drugconcentration-data, individual-efficacyresponse-data, adverse-event-listings, listing-individual-laboratorymeasurements-by-patient, available-onrequest, complete-patient-list, seriousadverse-event-patient-list, adverse-eventpatient-list, abnormal-lab-values-patientlist, data-tabulation-dataset-legacy, datatabulation-dataset-sdtm, data-tabulation-dataset-send, me="data-tabulation-dataset, data-tabulation-data-definition, datalistings-dataset, data-listing-data-definition, analysis-dataset-adam, analysis-datasetlegacy, e="analysis-dataset, analysisprogram, analysis-data-definition, annotated-crf, ecg, image, subject-profiles, safety-report, antibacterial, specialpathogen, antiviral, iss, ise, pm-description	

study_patient_information_leaf

study_patient_information_leaf v. 1.0

Field Name	Field Type	Matching UI Field	Description		Acceptable Values	Default Value
subjectMatter	string	Subject Matter	The subject matter for the specific study.		– case-reportforms – subject-profiles	
site	string	Site	The name of the site where the study was conducted.			
registrationFileIndicator		string	Registration File Indicator	Defines if element belongs to a registration dossier or a drug master file.	true/false	true

eu-envelope

eu-envelope v. 1.0

No additional fields for folder.

jo-envelope**jo-envelope v. 1.0**

No additional fields for leaf.

eaeu-envelope**eaeu-envelope v.1.0**

No additional fields for leaf.

eaeu_leaf**eaeu_leaf v. 1.0**

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
drugRegistrationDocCode	string	Drug Registration Document Code	Defines a purpose of the leaf in the output, according to the assembly template.	Five digits, according to classifier.	
drugRegistrationDocumentName	string	Drug Registration Document Name	Name is specified if Drug Registration Document Code is not specified or there is no appropriate code in the classifier.		
drugRegistrationFileCodeSection	string	Drug Registration File Section	Helps to sort out value from Drug Registration File Code list.	Two digits	
drugRegistrationFileCode	string	Drug Registration File Code	Defines the Drug Registration File Code value.	Four digits	

drugRegistrationFileName	string	Drug Registration File Name	Name is specified if Drug Registration File Code is not speci- fied or there is no appropriate code in the classifier.		
docCreationDate	date	Document Creation Date	Date of document creation.	Date format - Unix Timestamp. If empty, this mes- sage appears: "Document Creation Date is required" message is dis- played. If the en- tered data cannot be recognized as a date, "Invalid date specified".	
docValidityDate	date	Document Validity Date	Date when docu- ment expires.	Date format - Unix Timestamp. If entered data can- not be recognized as a date, this message appears: "Invalid date speci- fied".	
businessEntityName	string	Business Entity Name	Organization name issued registration dossier.		

drugAttributeText01	date	Request Response Date	Response to request must be provided before specified date.	Date format - Unix Timestamp. If entered data cannot be recognized as a date, this message appears: "Invalid date specified".	
drugAttributeText02	string	Reason Document Number	Reason Document Number.		
drugAttributeText03Section	string	Requested Drug Registration File Section	Helps to sort out value from Drug Registration File Code list .	Two digits	
drugAttributeText03Code	string	Requested Drug Registration File Code	Defines Drug Registration File Code value.	Four digits	
drugAttributeText04	string	Requested Drug Registration Document Code	Code that defines purpose of the leaf in the output, according to assembly template.	Five digits, according to classifier	
drugAttributeTexts99	string	Other Information	User may add several text boxes using the Add button.		
drugAttributeTextName	string	General Information	Defines general information.		

applicationContainsFiles	string	Application Contains Files?	Will this submission contain files or not.	– Y – N
applicationNumber	string	Application Contains Files?	The Application Number provided by the agency.	Example: 123456
crossReferenceApplication	map	Cross Reference Application	These fields must allow for the Application Number and	<code><field name="crossReferenceApplication" type="map"><value key="1195_unique-Suffix_0" value="123456" /></field></code>
crossReferenceApplicationNumber	string	Cross Reference Application	Application Type (eCTD code) to be entered,	Example: 1234
crossReferenceApplicationType	string	Cross Reference Application	and then for additional Application Numbers and Types to be entered. The values must be paired.	eCTD Code value from Data Administration > Application Type Values > Application type eCTD Code
sequenceNumber	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")

m1-us-meta-data-application

m1-us-meta-data-application v. 3.3

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
applicationContainsFiles	string	Application Contains Files?	Will this submission contain files or not.	• Y • N	Y
applicationNumber	string	Application Contains Files?	The Application Number provided by the agency.	Example: 123456	
crossReferenceApplication	map	Cross Reference Application	These fields must allow for the Application Number and Application Type (eCTD code) to be entered, and then for additional Application Numbers and Types to be entered. The values must be paired.	<pre><field name="crossReferenceApplication" type="map"><value key="1195__uniqueSuffix__0" value="123456" / ></field></pre>	
crossReferenceApplicationNumber	string	Cross Reference Application		Example: 1234	
crossReferenceApplicationType	string	Cross Reference Application		eCTD Code value from Data Administration > Application Type Values > Application type eCTD Code	
sequenceNumber	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	
submission	string	Sub-	Identifies each individual regulatory activity (original	Example: 0001	

sionId		mis- sion ID	application, supplement, annual report, etc.) in an ap- plication.		

Publishing Settings

PublishingSettingsLibrary

Field Name	Field Type	Matching UI Field	Description	Acceptable Values
submissionId	string	Submission ID	Identifies each individual regulato- ry activity (original ap- plication, supplement, annual report, etc.) in an appli- cation.	Example: 0001

Class com::liquent::insight::manager::publisher::data::publishsettings::PublishingSet **Name:**

Note: If a field name is not required, but does contain a default value, the default value will be set automatically in the imported Assembly unless otherwise specified in the Assembly XML.

Field Name	Field Type	Req (Y/ N)	Matching UI Field	Description	Acceptable Values	Default Value
id	long	Y		Unique PublishingSettingsLibrary ID represented by numerical value. This field is used to link classes within Assembly XML. This value will be used to populate corresponding fields in child classes. This ID	Example: 370515	

				will be replaced by database ID in the imported assembly.		
name	string	Y	Publishing Library Name	A unique name for the Publishing Library.		
templateFlag	string	N		Indicates if the Publishing Setting Library is a template or not.	– Y - creates Publishing Library Template; – N - creates Assembly Publishing Setting Library.	Y
owner	string	N	Publishing Library Owner	The named owner for the Publishing Library.		
keywords	string	N	Publishing Library Keywords	Keywords for the Publishing Library.		
changeReasonTypeId	long	N		This field is not used for import.		
changeReasonComment	string	N		This field is not used for import.		
defaultCoverPageId	long	N		Value of the ID field of the CoverPageSetting class.	Example: 713432	

defaultTabSheetId	long	N		Value of the ID field of the TabSetting class.	Example: 713435	
defaultSlipSheetId	long	N		Value of the ID field of the SlipSetting class.	Example: 713436	
defaultDocumentOverlayId	long	N		Value of the ID field of the Overlay class.	Example: 355046	
defaultCoverPageOverlayId	long	N		Value of the ID field of the Overlay class.	Example: 355046	
defaultTocOverlayId	long	N		Value of the ID field of the Overlay class.	Example: 355046	
Field Name	Field Type	Req (Y/N)	Matching UI Field	Description	Acceptable Values	Default Value
defaultAssemblyTocId	long	N		Value of the ID field of the TocType class.	Example: 713424	
defaultFolderTocId	long	N		Value of the ID field of the TocType class.	Example: 713424	
defaultLeafTocId	long	N		Value of the ID field of the TocType class.	Example: 713424	
defaultDocumentTocId	long	N		Value of the ID field of the TocType class.	Example: 713424	
defaultExtractTocId	long	N		Value of the ID field of the TocType class.	Example: 713424	

defaultVolumeTocId	long	N		Value of the ID field of the TocType class.	Example: 713424	
defaultSettingsProfileId	long	N		Value of the ID field of the SettingsProfile class.	Example: 370520	

PublishingSettings

Class com::liquent::insight::manager::publisher::data::publishsettings::PublishingSet **Name:**

Note: If a field name is not required, but does contain a default value, the default value will be set automatically in the imported Assembly unless otherwise specified in the Assembly XML.

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
id	long		Y	Unique PublishingSet tings ID represented by numerical value. Field is used to link classes within Assembly XML.	Example: 370516	
printerTypeId	long	Printer	Y	The Printer that will be used for a Paper Publish.	Values from the database: — CODE column from ODS.PRIN TER_ TYPE table	By default STANDARDPD F

mediaParameterTypeeld	long	Paper Size/ Type	Y	The Type and Size of the paper that will be printed on (Example: Blue Letter), available options controlled by which printer is selected.	Values from the database: <pre>SELECT mp- t.code FROM ods.printe r_type pt, ods.valid_ print- er_me dia_type valid, ods.me- dia_ parameter_ type mpt WHERE valid.prin ter_- type_i d = pt.id AND mpt.id = valid.medi a_- paramete r_- type_id AND mpt.tabs_p er_set IS NULL AND pt.code = <CODE>; Where <CODE> is value of ODS.PRINTE R_TYPE.COD E (field value of printerTyp eld). Example: – L-1 – A4-1</pre>	

tabPaperSizeId	long	Tab Paper Size/Type	Y	The Type and Size of the paper that will be used for the Tab when printed (Example: Blue Letter). Available options are controlled by the printer that is selected.	Values from the database: <pre> SELECT mp- t.code FROM ods.printe r_type pt, ods.valid_ printer_me dia_type valid, ods.me- dia_ parameter_ type mpt WHERE valid.prin ter_- type_id = pt.id AND mpt.id = valid.medi a_- paramete r_- type_id AND mpt.tabs_ p er_set IS NOT NULL AND pt.code = <CODE>; Where <CODE> is value of ODS.PRINTE R_TYPE.COD E (field value of printerType eld). </pre>	
previewLocationPath	string	Preview Location	N	The location used to store any generated previews (Volumes, Tabs).	Example: <pre> //root/ folder </pre>	

inProcessRenditionLocationPath	string	In-Process Rendition Location	N	The location used to store the inprocess rendition used when creating in-process links in Ennov InSight .	Example: //root/ folder	
tocDestinationNotFoundText	string	TOC Destination Not Found Text	N	The text that appears in TOCs when a TOC Entry cannot be resolved at publishing time. Destination Not Found Text is used in the following places: – If the target does not exist then value of tocDestination-NotFoundText field is used in the right columns of a TOC – This attribute is left blank by default, but text may be entered to assist in the QC of invalid destinations or variables.		

marginXrefDestinationNotFound	string	Cross Reference Destination Not Found Text	N	The text to insert when Ennov InSight attempts to insert a margin cross-reference but cannot resolve the variable. If blank, no margin crossreference is created for links that cannot be resolved.		
publishingSettingsLibraryId	long	Publishing Settings Library	Y	Value of the ID field of the PublishingSettingsLibrary class.	Example: 370515	
printerAndPaperSizeId	long		Y	Value of the ID field of the ValidPrinterMedia class.		
expandBookmarksToLevel	long	Expand Bookmarks to Level	N	This field enables users to specify the number of levels to which bookmarks are expanded	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18,	0 - it means ALL book- marks

				on the initial opening of electronic (PDF) files published from Ennov InSight . Users can choose to expand bookmarks from 1 to 20 levels, or expand ALL bookmarks, when the published PDF files are opened. The expansion of bookmarks applies to all Publish to eCTD / Electronic options, except XML only.	19, 20	
pdfVersion	string	PDF Version for Published Output	N	The field enables users to select the PDF version for the published output. Select one of the following items: – 1.3, - Acrobat 4	– 1.3 – 1.4 – 1.5 – 1.6 – 1.7	1.4

				– 1.4, Acrobat 5 – 1.5, Acrobat 6 – 1.6, Acrobat 7 – 1.7, Acrobat 8		
defaultRenditionIdentifier	long		N	The default Rendition Identifier.	Rendition Identifier value from Data Administration > Rendition Identifier Values Example: Standard Rendition	Standard Rendition
Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
useStandardRenditionFlag	string	Missing Rendition Identifier Handling	N	Defines how to handle situations when the PDF with the defined Rendition Identifier is not available.	– Y – N	Y

allTabsPreviewLocationPath	string		N	This field is not used for import.		

PubSettingsRefDtd

Class com::liquent::insight::manager::publisher::data::publishsettings::PubSettingsRe **Name:**

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
id	long		Y	Unique PubSettingsRefDtd ID represented by numerical value. This value will be used to populate corresponding fields in child classes. This ID will be replaced by the database ID in the imported assembly.	Example: 370518	
referencedDTDTypeid	long	XML Definitions	Y	The XML definitions that are applicable to this Publishing Library (and ultimately the Assembly that uses the Publishing Library).	DTD Code value from Data Administration > Assembly DTD/Schema Types	
pubSettingsId	long		Y	The value of the ID field of the PublishingSettings class.	Example: 370516	

PubSettingPdfProperty

Class com::liquent::insight::manager::publisher::data::publishsettings::PubSettingPdf **Name:**

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
id	long		Y	Unique PubSettingPdfProperty ID represented by numerical value. This field is used to link classes within Assembly XML. This value will be used to populate corresponding fields in child classes. This ID will be replaced by the database ID in the imported assembly.	Example: 370522	
name	string		N	This field is not used for import.		
outputPdfPropertyTypeid	long	Output PDF Property	Y	Defines the PDF property in the output document.	PDF Property Name value from Data Administration > PDF Properties Values	
propertySource	string	PDF Property Source	Y	Defines the source for the PDF property.	– R - Define Repeatable Value – D - Use Source Document Property – S - Define	

					Single Value	
sourcePdfPropertyTypeid	long	Source Document Property	Y/N	Defines the PDF property in source documents to be used as a source for the PDF property in the output document. This field is required if the value of propertySource field is D, otherwise it is not required.	PDF Property Name value from Data Administration > PDF Properties Values	
value	string	Value	Y/N	Defines the value for the PDF Property in the output document. This field is required if the value of propertySource field is R or S, otherwise it is not required.		
separator	string	Separator	N	Defines the separator to separate values from individual documents within a leaf.		
publishingSettingsLibraryId	long	Publishing Settings Library	Y	Value of the ID field of the PublishingSettingsLibrary class.	Example: 370515	
changeReasonTypeid	long		N	This field is not used for import.		
changeReasonComment	string		N	This field is not used for import.		
sourceValue	string		Y/N	– If the value of the property-Source field is D then the value of this field duplicates the value of the sourcePdfPropertyTypeid field. – If the value of the property-Source field is S or R then the value of this field duplicates the value of the value field.		

Class com::liquent::insight::manager::publisher::data::specialsheets::Tab **Name:**

Note: If the Tab class is declared in Assembly XML, then the TabSetting class must also be declared.

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
name	string		N	This field is not used for import.		
lastGenerationDate	date	Last Generated Date	N	This field is not used for import.		
autoTextWrap	string	Auto Text Wrap	N	This field is not used for import.		
fontBold	string	Font Bold	N	This field is not used for import.		

fontItalic	string	Font Italic	N	This field is not used for import.		
verticalText	string	Vertical Text	N	This field is not used for import.		
previewFileName	string		N	This field is not used for import.		
tabSettingId	long	Publishing Setting	Y	The value of the ID field of the TabSettings class.		
generationLocationId	long		N	This field is not used for import.		
tabText	string	Overridden Tab Text	N	Text that will overwrite the default tab text.		
tabTextFromLibrary	string	Tab Text from Publishing Settings Library	N	This field is not used for import.		
fontTypeId	long	Font Definition	N	This field is not used for import.		
fontSize	int	Font Size	N	This field is not used for import.		
printTabMediaTypeId	long		N	This field is not used for import.		
sslcon	string		Y	See fixed value.		Fixed value is TAB
specialSheetType	string		N	This field is not used for import.		
assemblyId	long		Y	The value of the ID field of the Assembly class.		

id	long		Y	Unique Tab ID represented by numerical value. This value is used to populate corresponding fields in child classes. This ID is replaced by the database ID in the imported assembly.		
parentExtractId	long		N	This field is not used for import.		
parentContentId	long		Y	The value of the ID field of the class that contains this Tab. It can be any class in the following list: – Assembly – Folder – Leaf – Document		
parentVolumId	long		N	This field is not used for import.		
documentSourceId	long		N	This field is not used for import.		
childSeqNo	long		Y	Sequential number of the Tab in the list of Publishing Elements that defines the place in the sequence among the elements that are attached to the current Assembly node. The index starts from zero. See the example in Explanation for childSeqNo Field on page 745.	0, 1, 2, etc.	
changeReasonType	long		N	This field is not used for import.		
changeReasonComment	string		N	This field is not used for import.		
begDate	date		N	This field is not used for import.		

begUserId	long		N	This field is not used for import.		
creatorId	long		N	This field is not used for import.		
Field Name	Field Type	Matching UI Field	Req (Y/ N)	Description	Acceptable Values	Default Value
creationDate	date		N	This field is not used for import.		

TabSetting

Class com::liquent::insight::manager::publisher::data::publishsettings::TabSetting **Name:**

Field Name	Field Type	Matching UI Field	Req (Y/ N)	Description	Acceptable Values	Default Value
id	long		Y	The unique TabSetting ID represented by a numerical value. This value is used to populate corresponding fields in child classes. This ID is replaced by the database ID in the imported assembly.	Example: 713435	
name	string	Name	Y	Defines the Name of the Tab. Must be unique within the Publishing Settings Library.		
autoTextWrap	string	Auto Text Wrap	N	Defines if the text will wrap to multiple lines or not.	– Y – N	N
publishingSettingsLibraryId	long	Publishing Settings Library	Y	The value of the ID field of the PublishingSettingsLibrary class.	Example: 370515	
tabText	string	Text	Y	Defines the text to appear on tabs. Variables can be used to create the tab text.		

fontBold	string	Font Bold	N	Defines if the font on the tab is bold or not.	– Y – N	N
fontItalic	string	Font Italic	N	Defines if the font on the tab is italic or not.	– Y – N	N
Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
fontSize	int	Font Size	Y	Defines the size of the font on the tab.		10
verticalText	string	Vertical Text	N	Defines if the text will appear horizontally or vertically.	– Y – N	N
fontTypeId	long	Font Definition	Y	Defines the font style to use on the tabs.		ARIAL
changeReasonTypeId	long		N	The field is not used for import.		
changeReasonComment	string		N	The field is not used for import.		

SpecialSheetOutputChannel

Class com::liquent::insight::manager::publisher::data::outputchannels::SpecialSheetOu **Name:**

Note: If you create Tab class then SpecialSheetOutputChannel class should be created as well. Relationship is "one Tab class to one SpecialSheetOutputChannel class", for example each specialSheetId field from SpecialSheetOutputChannel class should reference ID field of a Tab class.

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value

id	long		Y	Unique SpecialSheetOutputChannel ID represented by numerical value. This value will be used to populate corresponding fields in child classes. This ID will be replaced by the database ID in the imported assembly.		
outputChannelTypeid	long		Y	See fixed value.		Fixed value is PAPER
specialSheetId	long		Y	Value of ID field of a Tab class.		
Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeid	long		N	This field is not used for import.		

TOC

Class com::liquent::insight::manager::publisher::data::specialsheets::TOC **Name:**

Note: If the TOC class is declared in the Assembly XML, then the TocType class must also be declared.

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
assemblyId	long		Y	The value of the ID field of the Assembly class.		
begDate	date		N	This field is not used for import.		
begUserId	long		N	This field is not used for import.		
bookmark	long	Bookmark Handling	N	This field is not used for import.		

changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeId	long		N	This field is not used for import.		
childSeqNo	long		Y	The sequential number of the TOC in the list of Publishing Elements that defines the place in the sequence among the elements that are attached to the current Assembly node. The index starts from zero. See the example in Explanation for childSeqNo Field on page 745.	0, 1, 2, etc.	
comments	string	Comments	N	Comments specific to the TOC in the Assembly Outline.		
creationDate	date		N	This field is not used for import.		
creatorId	long		N	This field is not used for import.		
definitionFileReferenceName	string	TOC Definition File	N	This field is not used for import.		
desc	string	Description	N	A description of the TOC in the Assembly Outline.		
destinationEntryText	string	Right Column Entry Text	N	This field is not used for import.		

destinationHyperlinkStyle	string		N	This field is not used for import.		
documentSourceId	long		N	This field is not used for import.		
extractionExcludeText	string	Exclude All Bookmarks with the Text	N	This field is not used for import.		
extractionIncludeText	string	Include Only Bookmarks with the Text	N	This field is not used for import.		
extractLevels	long	Include Bookmarks up to Level	N	This field is not used for import.		
generationDate	date	TOC Last Generated	N	Displays the date the TOC was last generated.	Date format - Unix Timestamp.	
generationLocationDisplay	string	TOC Generation location	N	This field is not used for import.		
generationLocationId	long		N	This field is not used for import.		
id	long		Y	Unique TOC ID represented by numerical value.		

				This field is used to link classes within Assembly XML. This value will be used to populate corresponding fields in child classes. This ID will be replaced by database ID in the imported assembly.		
includeInPageCountFlag	string	Include in Page Numbering	N	This field is not used for import.		
keywords	string	Keywords	N	Keywords specific to the TOC in the Assembly Outline.		
leaderText	string	Leader	N	This field is not used for import.		
linksToInclude	object	Include Links to TOCs	N	This field is not used for import.		
overlaySettingsId	long	Overlay Settings	N	The overlay to apply on the published output. If set to Use Default, the default overlay at the time of publish will be used. If the overlay settings are set to anything else, these settings will be used at the time of publish. The value of the ID field of the Overlay class.		

overwriteDocFlag	string	Do Not Overwrite Document	Y	Do not overwrite document.	– Y - Yes – N - No	
parentContentId	long		Y	The value of the ID field of the class that contains this TOC. It can be any class from the following list: – Assembly – Folder – Leaf – Document		
parentExtractId	long		N	This field is not used for import.		
parentVolumeId	long		N	This field is not used for import.		
plannedPageCount	int	Planned Number of Pages	N	The planned number of pages.		
previewDate	date		N	This field is not used for import.		
previewFileName	string		N	This field is not used for import.		
previewGenerationLocation	string		N	This field is not used for import.		
previewGenerationLocationId	long		N	This field is not used for import.		

rangeContentId	long	Range Start	N	Define a starting location for the content to be included in the TOC other than the node the TOC is inserted onto. It can be any class from the following list: – Assembly – Folder – Leaf – Document		
sourceEntryText	string	Left Column Entry Text**	N	This field is not used for import.		
specialSheetType	string		N	This field is not used for import.		
sslcon	string		Y	See fixed value.		Fixed value is TOC
title	string	Title	Y	A title for the Table of Contents.		
tocLevels	long	Build TOCs to Level	N	This field is not used for import.		
tocTypeId	long	Publishing Setting	Y	Value of the ID field of TocType class.		
typeCaption	string	Header	N	This field is not used for import.		

TocType

Class com::liquent::insight::manager::publisher::data::specialsheets::TocType **Name:**

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value

bookmark	long	Bookmark Handling	N	Indicates whether or not the entries from this TOC will be used to create the bookmarks in the Leaf, Volume, or SingleFile output file containing this TOC: – File Bookmarks Only Do not use the entries from this TOC to create output file bookmarks. – All TOC Bookmarks - Use all of the entries from this TOC to create output file bookmarks.	– FILE – ALL	ALL
changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeId	long		N	This field is not used for import.		
definitionFileReferenceName	string	TOC Definition File	Y	A link to the document to use to define the Table of Contents.	Example: // root/ folder/ file	
destinationEntryText	string	Right Column Entry Text	Y	Defines the text to appear on the right side of the output TOC, typically a variable.		
destinationHyperlinkStyle	string		N	This field is not used for import.		
elementType	long		N	This field is not used for import.		
extractionExcludeText	string	Exclude All Bookmarks with the Text	N	Defines the bookmarks to exclude based on name, and allows for tables and figures to be excluded. Words separated by ; are treated as separate entries.		

extractionIncludeText	string	Include Only Bookmarks with the Text	N	Defines the bookmarks to include based on name, and allows tables and figures to be included. Words separated by ; are treated as separate entries.		
extractLevels	long	Including Bookmarks up to Level	N	Defines how many levels of Bookmarks from the starting point of the TOC to include in the output TOC. Must be within the Build TOCs to level range.	Number from 1 to 20.	1
id	long		Y	The unique TocType ID represented by a numerical value. This field is used to link classes within Assembly XML. This value is used to populate corresponding fields in child classes. This ID is replaced by the database ID in the imported assembly.		
includeInPageCountFlag	string	Include in Page Numbering	Y	Defines if the TOC pages should be included in the overall page count.	– Y – N	
leaderText	string	Leader	Y	Defines the leader to use between the text and the right column entry text.	– USETEMPLATE - Use Template; – SPACE - Space " "; – DASH - Dash "___"; – DOT - Dot "..."; – UNDERLINE - Underline "___".	

name	string	Name	Y	A unique name for the Table of Contents.	Must be unique within Assembly XML.	
publishingSettingsLibraryId	long		Y	The value of the ID field of the PublishingSettingsLibrary class.	Example: 370515	
sourceEntryText	string	Left Column Entry Text**	N	Defines the text to appear on the left side of the output TOC, typically either blank or a variable.		
Field Name	Field Type	Matching UI Field	Req (Y/ N)	Description	Acceptable Values	Default Value
tocLevels	long	Build TOCs to Level	N	Defines how many levels from the starting point of the TOC to include in the output TOC.	Number from 1 to 20.	3
typeCaption	string	Header	N	The header that replaces the word header within the TOC Definition File.		

TOCTypeOutputChannel

Class com::liquent::insight::manager::publisher::data::outputchannels::TOCTypeOutputC **Name:**

The TOCTypeOutputChannel is a specific class that is related to the "Output Channel" UI multiselect field of the TOC Type UI element. Therefore, you need to declare as many TOCTypeOutputChannel classes in Assembly XML for each TocType class as you need to select the "OutputChannel" values for the corresponding TocType class. For example, if you want to select ELEC and PAPER for the current TocType class, then you must create two TOCTypeOutputChannel classes. One for ELEC (the outputChannelTypeId field value is ELEC), one for PAPER (the outputChannelTypeId field value is PAPER) and associate both to the current TocType class (value of the tocTypeId field is value of id field of this TocType class).

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
id	long		Y	Unique TOCTypeOutputChannel ID represented by numerical value. This field is used to link classes within Assembly XML. This value is used to populate corresponding fields in child classes. This ID is replaced by the database ID in the imported assembly.		
outputChannelTypeid	long	Output Channel	Y	Defines what Output channel to use within the published output.	– ELEC – PAPER	
tocTypeid	long		Y	Value of the ID field of TocType class.		
Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeid	long		N	This field is not used for import.		

TOCEntryGenOption

Class com::liquent::insight::manager::publisher::data::specialsheets::TOCEntryGenOpti **Name:**

The TOCEntryGenOption is a specific class that is related to the "Tree Elements to Include in TOC" UI multiselect field of the TOC Type UI element. Therefore, you need to declare as many TOCEntryGenOption classes in Assembly XML for each TocType class as you need to select the "Tree Elements to Include in TOC" values for the corresponding TocType class. For example, if you want to select FOLDER, DOCUMENT, etc., for the current TocType class, then you must create a TOCEntryGenOption class for each value. One for FOLDER (the entityTypeid field value is FOLDER), one for DOCUMENT (the entityTypeid field value is

DOCUMENT), etc., and associate all classes to the current TocType class (value of the tocTypeid field is the value of the id field of this TocType class).

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
id	long		Y	The unique TOCEntryGenOption ID represented by a numerical value. This field is used to link classes within Assembly XML. This value is used to populate corresponding fields in child classes. This ID is replaced by the database ID in the imported assembly.		
entityTypeid	long	Tree Elements to Include in TOC	Y	Defines which Tree elements will be included in this TOC.	– TOC – EXTRACT – LEAF – FOLDER – DOCUMENT	
Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
tocId	long		N	This field is not used for import.		
tocTypeid	long		Y	The value of the ID field of the TocType class.		

changeReasonTypeId	long		N	This field is not used for import.		
changeReasonComment	string		N	This field is not used for import.		
lastPublishedOutputLocationDisplay	string	Last Published Location	N	This field is not used for import.		
lastEstimatedSize	long	Last Estimated Size (in MB)	N	This field is not used for import.		
lastEstimatedDate	date	Last Estimated Date	N	This field is not used for import.		
lastPublishedSize	long	Last Published Size (in MB)	N	This field is not used for import.		
lastPublishedDate	date	Last Published Date	N	This field is not used for import.		
volumizeBySizeFlag	string	Volumize by Size	N	Defines if the volumization should be done by number of pages or by estimated size of the volume.	– Y – N	N

Volume

Class Name: com::liquent::insight::manager::publisher::data::Volume

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
maxVolumeSize	long	Total Size (in MB)	N	Defines the maximum size of the volume, used when running volumize by size.	Numeric and greater than 50	100
volumeBufferSize	long	Buffer Size (in MB)	N	The additional buffer allowed in a volume, used when running volumize by size.	Numeric and greater than 10	10
id	long		Y	The unique Volume ID represented by a numerical value. This field is used to link classes within Assembly XML. This value will be used to populate corresponding fields in child classes. This ID will be replaced by the database ID in the imported assembly.		
firstContentId	long		N	This field is not used for import.		
lastContentId	long		N	This field is not used for import.		
firstContentSeqNum	long		N	This field is not used for import.		

lastContentSeqNum	long		N	This field is not used for import.		
firstExtractSeqNum	long		N	This field is not used for import.		
lastExtractSeqNum	long		N	This field is not used for import.		
assemblyId	long		N	This field is not used for import.		
firstExtractId	long		N	This field is not used for import.		
lastExtractId	long		N	This field is not used for import.		
name	string	Name	N	This field is not used for import.		
nodeNumber	int	Begin at Volume Number	N	The number that should be used to start the volumes.	Numeric and greater than zero.	1
actualSheetCount	int	Total Sheets/Pages	N	The total number of sheets/pages to include in a volume, used when running volumize by number of pages.		300
maxSheetCount	int		N	This field is not used for import.		
sheetBufferCount	int	Total Sheets/Pages Buffer	N	When volumize by number of pages, the additional sheets/pages buffer allowed in the file.		50
lockType	string		N	This field is not used for import.		
autoCreateTocsFlag	string	Automatically Create Volume Tables of Contents	N	Defines if a TOC should be created for each Volume inserted.	– Y – N	N
numberingSchema	string	Volume File	N	The format that should be applied to the Volume		\$VOLIN

lastPublishedOutputLocationId	string		N	This field is not used for import.		
changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeId	string		N	This field is not used for import.		
publishingSettingsLibraryId	long		Y	Value of ID field of PublishingSettingsLibrary class.	Example: 370515	

Variable

Class Name: com::liquent::insight::manager::publisher::data::Variable

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
activeFlag	string	Is Active?	N	Defines if the variable is active or not.	– Y – N	Y
changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeId	long		N	This field is not used for import.		
code	string	Variable Code	Y	The variable code that is used in the document or tree structure. The Variable Code - Output Channel combination must be unique with- in the Publishing Settings Library. The Variable Code must not be the one defined in Assembly Repository Variables, Assembly System Defined		

				Variables, Assembly User Defined Variables, and Ennov InSight Assembly Variables.		
description	string	Description	N	A description of the variable.		
documentType	string		N	This field is not used for import.		
id	long		Y	The unique Variable ID represented by a numerical value. This value is used to populate corresponding fields in child classes. This ID is replaced by the database ID in the imported assembly.		
name	string	Variable Name	Y	The human readable name of the variable code.		
outputChannelTypeid	long		N	This field is not used for import.		
publishingSettingsLibraryId	long	Publishing Settings Library	Y	The value of the ID field of the PublishingSettingsLibrary class.	Example: 370515	
Field Name	Field Type	Matching UI Field	Required (Y/N)	Description	Acceptable Values	Default Value
typeid	long		Y	See fixed value.		Fixed value is USER
variableStampType	string	Variable	N	The type of variable being configured.	– S -	S

		Type			Single-Line Variable – M - Multiple-Line Variable	
variableValue	string	Variable Value	Y	The value to which the variable will resolve. This could be free text or another variable.		

VariableOutputChannel

Class com::liquent::insight::manager::publisher::data::outputchannels::VariableOutput **Name:**

Note: The *VariableOutputChannel* is a specific class that is related to the "Output Channel" UI multiselect field of the Variable UI element. Therefore, you need to declare as many *VariableOutputChannel* classes in Assembly XML for each Variable class as you need to select the "OutputChannel" values for the corresponding Variable class.

For example, if you want to select ELEC and PAPER for the current Variable class, then you must create two

VariableOutputChannel classes: one for ELEC (the *outputChannelTypeid* field value is ELEC), one for PAPER (the *outputChannelTypeid* field value is PAPER), and associate both to the current Variable class (value of the *variableid* field is the value of the *id* field of this Variable class).

Field Name	Field Type	Matching UI field	Req (Y/N)	Description	Acceptable values	Default value
id	long		Y	The unique VariableOutputChannel ID represented by a numerical value. This value is used to populate corresponding fields in child classes. This ID is replaced by the database		

				ID in the imported assembly.		
outputChannelTypeld	long	Output Channel	Y	Defines the output channel for the variable to resolve in.	– ELEC – PAPER	
variableId	long		Y	The value of the ID field of the Variable class.		
changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeld	long		N	This field is not used for import.		

Slip

Class com::liquent::insight::manager::publisher::data::specialsheets::Slip **Name:**

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
assemblyId	long		Y	The value of the ID field of the Assembly class.		
begDate	date		N	This field is not used for import.		
begUserId	long		N	This field is not used for import.		
changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeld	long		N	This field is not used for import.		
childSeqNo	long		Y	Sequential number of Slip in list of Publishing		

				Elements that defines the place in the sequence among the elements that are attached to the current Assembly node. Index starts from zero. See the example in Explanation for childSeqNo Field on page 745.		
creationDate	date		N	This field is not used for import.		
creatorId	long		N	This field is not used for import.		
documentSourceId	long		N	This field is not used for import.		
id	long		Y	The unique Slip ID represented by a numerical value. This value will be used to populate corresponding fields in child classes. This ID will be replaced by the database ID in the imported assembly.		
parentContentId	long		Y	The value of the ID field of the class that contains this Slip. It can be any class from the following list: – Assembly – Folder – Leaf – Document		
parentExtractId	long		N	This field is not used for import.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
parentVolumeld	long		N	This field is not used for import.		
printSlipMediaTypeld	long	Paper Type	N	This field is not used for import.		
slipSettingId	long	Publishing Setting	Y	The value of the ID field of the SlipSetting class.		
specialSheetType	string		N	This field is not used for import.		
sslcon	string		Y	See fixed value.		Fixed value is SLIP

SlipSetting

Class com::liquent::insight::manager::publisher::data::publishsettings::SlipSetting **Name:**

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
id	long		Y	The unique SlipSetting ID represented by a numerical value. This value will be used to populate corresponding fields in child classes. This ID will be replaced by the database ID in the imported assembly.		
name	string	Name	Y	A unique name for the Slip Sheet settings.		
publishingSettingsLibraryId	long	Publishing	Y	The value of the ID field of the	Example:	

		Settings Library		PublishingSettingsLibrary class.	370515	
printMediaTypeId	long		Y	The value of the ID field of the ValidPrinterMedia class.		
Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
paperTypeId	long	Paper Type	N	This field is not used for import.		
changeReasonTypeId	long		N	This field is not used for import.		
changeReasonComment	string		N	This field is not used for import.		

CoverSettingOutputChannel

Class com::liquent::insight::manager::publisher::data::publishsettings::CoverSettingO **Name:**

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeId	long		N	This field is not used for import.		
coverSettingId	long		Y	The value of the ID field of the CoverPageSetting class.		
id	long		Y	The unique CoverSettingOutputChannel ID represented by a numerical value. This value will be used to populate corresponding fields in child classes. This ID will be replaced		

				by the database ID in the imported assembly.		
outputChannelTypeld	long	Output Channel	Y	Defines if the Cover Page is published for a specific output channel or for all output channels.	– ELEC – PAPER	

CoverPageSetting

Class com::liquent::insight::manager::publisher::data::publishsettings::CoverPageSett **Name:**

Field Name	Field Type	Matching UI field	Req (Y/N)	Description	Acceptable values	Default value
changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeld	long		N	This field is not used for import.		
id	long		Y	The unique CoverPageSetting ID represented by a numerical value. This value is used to populate corresponding fields in child classes. This ID is replaced by the database ID in the imported assembly.		
inclInPageCountFlag	string	Include in Page Numbering	Y	Defines if the Cover Page is counted in the page numbering, affects variables.	– Y – N	
name	string	Name	Y	The name used to identify the Cover Page, and is also resolved as the <NAME> variable. The Cover Page Name		

				must be unique within the Publishing Settings Library.		
paperTypeId	long	Paper Type	N	This field is not used for import.		
plannedPageCount	int	Planned Number of Pages	N	The planned number of pages this cover page will use in the published output.	Must be numeric, max number: 2^31 -1	
printMediaTypeId	long		Y	The value of the ID field of the ValidPrinterMedia class.		
Field Name	Field Type	Matching UI field	Req (Y/N)	Description	Acceptable values	Default value
publishingSettingsLibraryId	long		Y	The value of ID field of the PublishingSettingsLibrary class.	Example: 370515	
srcName	string	Cover Page Template	Y	The location of the document to be used as the template for the Cover Page.	Example: // root/ folder/ file	
templateId	long		N	This field is not used for import.		

Cover

Class com::liquent::insight::manager::publisher::data::specialsheets::Cover **Name:**

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
assemblyId	long		Y	The value of the ID field of the Assembly class.		

changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeld	long		N	This field is not used for import.		
childSeqNo	long		Y	The sequential number of the Cover in the list of Publishing Elements that defines the place in the sequence among the elements that are attached to the current Assembly node. The index starts from zero. See example in Explanation for childSeqNo Field on page 745.		
coverPageSettingId	long	Publishing Setting	Y	The value of the Name field of the CoverPageSetting class.		
coverSettingId	long		Y	The value of the ID field of the CoverPageSetting class.		
creatorId	long		N	This field is not used for import.		
documentSourceId	long		N	This field is not used for import.		
generationLocationId	long		N	This field is not used for import.		
id	long		Y	The unique Cover ID represented by a numerical value. This value is used to populate corresponding fields in child classes. This ID is replaced by database ID in the imported assembly.		

inclInPageNumbersFlag	string	Include in Page Numbering	N	This field is not used for import.		
lastGenerationDate	date		N	This field is not used for import.		
name	string	Name	Y	The name used to identify the Cover Page, and is also resolved as the <NAME> variable. The Cover Page Name must be unique within the Publishing Settings Library.		
overlaySettingsId	long	Overlay Setting	N	The value of the ID field of the Overlay class.		
Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
parentContentId	long		Y	The value of the ID field of the class that contains this Cover. It can be any class from the following list: – Assembly – Folder – Leaf – Document		
parentExtractId	long		N	This field is not used for import.		
parentVolumeId	long		N	This field is not used for import.		
plannedPageCount	int	Planned Number of Pages	N	This field is not used for import.		

printCoverMediaTypeId	long	Paper Type	N	This field is not used for import.		
publishingSettingsLibraryId	long		N	This field is not used for import.		
specialSheetType	string		N	This field is not used for import.		
srcName	string	Cover Page Template	N	This field is not used for import.		
sslcon	string		Y	See fixed value.		Fixed value is COVER
templateId	long		N	This field is not used for import.		
title	string	Title	N	The title of the Cover Page.		

SettingsProfile

Class Name: com::liquent::insight::manager::publisher::data::SettingsProfile

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
id	long		Y	The unique SettingsProfile ID represented by a numerical value. This value is used to populate corresponding fields in child classes. This ID is replaced by the database ID in the imported assembly.		
profileName	string	Link Profile Name	Y	The unique name for the Link Profile.		

linkStyleTypeld	long	Electronic Hyperlink Style	Y	Defines the style of the hyperlink.	– DASHEDBOX – SOLIDBOX – UNDERLINE – NONE	
linkColorTypeld	long	Electronic Hyperlink Color	N	The color of the hyperlink in the published output.	– BLUE – BLACK	BLUE
linkLineThicknessTypeld	long	Electronic Hyperlink Line Thickness	Y	Defines the thickness of the line in the published output.	– MEDIUM – THIN – THICK	
marginXrefSize	long	Margin Cross Reference Size	Y	The font size to use when creating Margin Cross References.	Example: 10	
Field Name	Field Type	Matching UI Field	Req (Y/ N)	Description	Acceptable Values	Default Value
marginXrefFontStyleId	long	Margin Cross Reference Text Font Style	Y	The font to use when creating Margin Cross References.	– Arial - ARIAL – Arial Narrow - ARIALN – Courier - COURIERN – MS Mincho MSMINCHO – Times New Roman TIMESNR	

marginXrefTextFormat	string	Margin Cross Reference Text Format	N	The format for all margin cross reference links to follow. Variables will be used here.		
changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeId	long		N	This field is not used for import.		
publishingSettingsLibraryId	long	Publishing Settings Library	Y	Value of ID field of PublishingSettingsLibrary class.	Example: 370515	
isLibraryDefault	string	Default?	N	Defines if the Profile is the System Default Profile.	– Y – N	
crossDocumentLinkHandling	string	Cross- Document Link Handling	N	Defines whether crossdocument links are opened in the same window.	S, N, or D: – Open in a the Same Window - S – Open in a New Window - N – Default - D	D

PageMarker

Class Name: com::liquent::insight::manager::publisher::data::PageMarker

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
begDate	date		N	This field is not used for import.		

begUserId	long		N	This field is not used for import.		
changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeid	long		N	This field is not used for import.		
comments	string	Comments	N	Any additional information you want to save with the page marker.		
createdByVolumizeFlag	string	Created by Volumization	N	This field is not used for import.		
creationDate	date		N	This field is not used for import.		
creatorId	long		N	This field is not used for import.		
depth	int		N	This field is not used for import.		
description	string	Description	N	The description of the Page Marker.		
documentSourceId	long		N	This field is not used for import.		
id	long		Y	The unique PageMarker ID represented by a numerical value. This value will be used to populate corresponding fields in child classes. This ID will be replaced by the database ID in the imported assembly.		
keywords	string	Keywords	N	The keywords you can use in a search for the page marker.		
Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value

name	string	Page Marker Name	N	The name of the Page Marker. Name is not unique.		By default name is "Page Marker"
orderNo	long		Y	The index is the size of the pageNumber field. The index starts from zero. For example: – pageNumber=3, orderNo=0 – pageNumber=11, orderNo=1 – pageNumber=22, orderNo=2 – pageNumber=99, orderNo=3	Example: 0, 1, 2, etc.	
pageMarkerFlag	string		N	This field is not used for import.		
pageNumber	int	Page Number	Y	The page on which the page marker is applied.		
parentContentId	long		Y	The value of the ID field of the Document class. Every PageMarker belongs to Document.		

DefaultPublishingValues

Class com::liquent::insight::manager::publisher::data::publishsettings::DefaultPublis **Name:**

Field Name	Field Type	Matching UI Field	Req (Y/ N)	Description	Acceptable Values	Default Value

actuate	string	Actuate	N	The default Actuate setting of any new leafs.	– onLoad – none – other – onRequest	
applicationVersion	string	Application Version	N	The default Application Version of any new leafs.		
folderDueDate	date	Folder Due Date	N	The default due date of any new folders.	Date is in Unix Timestamp date format.	
folderOwner	string	Folder Owner	N	The default owner of any new folders.		
fontLibrary	string	Font Library	N	The default Font Library of any new leafs.		
Id	long		Y	The unique DefaultPublishingValues ID represented by numerical value. This value is used to populate corresponding fields in child classes. This ID is replaced by the database ID in the imported assembly.		
keywords	string	Keywords	N	The default Keywords of any new leafs.		
language	string	Language	N	The default language of any new leafs.		
leafDueDate	date	Leaf Due Date	N	The default due date of any new leafs.	Date is in Unix Timestamp date format.	
leafOwner	string	Leaf Owner	N	The default owner of any new leafs.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
publishingSettingsLibraryId	long	Publishing Settings Library	Y	The value of the ID field of the PublishingSettingsLibrary class.	Example: 370515	
role	string	Role	N	The default Role of any new leafs.		
show	string	Show	N	The default Show setting of any new leafs.	– embed – none – other – new – replace	
title	string	Title	N	The default title of any new leafs.		
useNativeFileFlag	string	Use Native File	N	Defines if new leafs should be created as Native Files.	– T - Yes – F - No	
version	string	Version	N	The default Version of any new leafs.		

ValidPrinterMedia

Class com::liquent::insight::manager::publisher::data::paper::ValidPrinterMedia **Name:**

You can skip the creation of the XML for ValidPrinterMedia class, because this is a shared class. The import does not create it, the import finds it and attaches it to the Ennov InSight system. When a valid XML is created for the PublishingSettings class, the corresponding ValidPrinterMedia class will be created automatically, so there is no need to define that class in the Assembly XML.

Overlay

Class Name: com::liquent::insight::manager::publisher::data::overlays::Overlay

Field Name	Field Type	Matching UI Field	Req(Y/N)	Description	Acceptable Values	Default Value
autofitFlag	string	Scale Content to Margins	N	Scales the content to the margins defined for the overlay.	– Y – N	N
bestfitFlag	string	Apply Best Fit Overlay	N	Used to find the best fitting overlay page from the overlay template.	– Y – N	N
changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeId	long		N	This field is not used for import.		
id	long		Y	The unique Overlay ID represented by a numerical value. This value is used to populate corresponding fields in child classes. This ID is replaced by the database ID in the imported assembly.		
landscapeMarginBottom	long	Landscape Margin Bottom	N	Defines the size of the bottom margin on landscape pages.	See Explanation for Overlay Class Fields	
landscapeMarginLeft	long	Landscape Margin Left	N	Defines the size of the left margin on landscape pages.	See Explanation for Overlay Class Fields	
landscapeMarginRight	long	Landscape Margin Right	N	Defines the size of the right margin on landscape pages.	See Explanation for Overlay Class Fields	

landscapeMarginTop	long	Landscape Margin Top	N	Defines the size of the top margin on landscape pages.	See Explanation for Overlay Class Fields	
measurementTypeId	long	Measurement Unit	N	Defines the measurement unit to be used for the margins.	– INCHES – CENTIMETERS	INCHES
name	string	Name	Y	A unique name for the Overlay.		
portraitMarginBottom	long	Portrait Margin Bottom	N	Defines the size of the bottom margin on portrait pages.	See Explanation for Overlay Class Fields	
portraitMarginLeft	long	Portrait Margin Left	N	Defines the size of the left margin on portrait pages.	See Explanation for Overlay Class Fields	
portraitMarginRight	long	Portrait Margin Right	N	Defines the size of the right margin on portrait pages.	See Explanation for Overlay Class Fields	
portraitMarginTop	long	Portrait Margin Top	N	Defines the size of the top margin on portrait pages.	See Explanation for Overlay Class Fields	
publishingSettingsLibraryId	long	Publishing Settings Library	Y	Value of ID field of PublishingSettingsLibrary class.	Example: 370515	
refNotFoundText	string		N	This field is not used for import.		

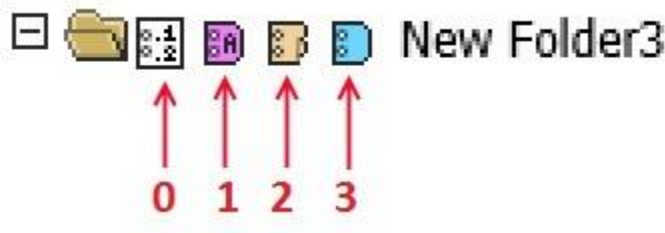
rotateOverlayFlag	string	Rotate Overlay to Content	N	Rotates the overlay to fit the content correctly.	– Y – N	N
scaleOverlayFlag	string	Scale Over- lay to Con- tent Page Size	N	Scales the overlay to fit the content correctly.	– Y – N	N
srcNameOverlay	string	Overlay Template File	N	A link to the document to use to define the Overlay. No template has to be de- fined, this will effectively be a blank overlay if there is nothing defined.	Example: //root/ folder/file	

Assembly XML Publishing Settings: Explanations

Explanation for childSeqNo Field

The value of the childSeqNo field contains the position number of the element in the element's sequence of the node (from left to right starting at 0). The elements can be in any order.

This example shows values for childSeqNo fields of several elements:



Where:

- 0 - TOC
- 1 - Cover
- 2 - Tab
- 3 - Slip

Explanation for Overlay Class Fields

This field has a validator that checks the input value. If a specified value is not valid, then the following message appears:

Margin Value is invalid. Not valid range (inches 0.1 - 2.0, centimeters 0.26 - 5.1).

The input value should be a number with fractional part, but if the field type is long, the field does not accept the number with fractional part. Converter solves this.

There are two cases, depending on value of measurementTypeld field.

- If the value of the measurementTypeld field is INCHES and you want to put 0.1 into a field, then you should multiply 0.1 by 2540. The result is the value of field.
- If the value of the measurementTypeld field is CENTIMETERS and you want to put 0.26 into a field, then you should multiply 0.26 by 1000. The 260 result is the value of field.

MetaData

MetaDataLibrary

Class com::liquent::insight::manager::publisher::data::metadata::MetaDataLibrary **Name:**

MetaData

Field Name	Field Type	Matching UI field	Req (Y/N)	Description	Acceptable values	Default value

id	long		Y	Unique MetaDataLibrary ID represented by numerical value. Field is used to link classes within Assembly XML. This value will be used to populate corresponding fields in child classes. This ID will be replaced by database ID in the imported assembly.		
name	string	Related Assembly Name	N	Name of MetaDataLibrary.		
assemblyId	long		Y	Value of the ID field of Assembly class.		

PublisherMetaData

Class Name: com::liquent::insight::manager::content::dto::PublisherMetaData

Field Name	Field Type	Matching UI field	Req (Y/N)	Description	Acceptable values	Default value
id	long		Y	Unique PublisherMetaData ID represented by numerical value. Field is used to link classes within Assembly XML. This value will be used to populate corresponding fields in child classes. This ID will be replaced by database ID in the imported assembly.		
metaDataLibraryId	long		Y	Value of the ID field of MetaDataLibrary class.		

internalType	string		Y	This is the internal type of the Publisher Meta Data.		Fixed value is ENVELOPE

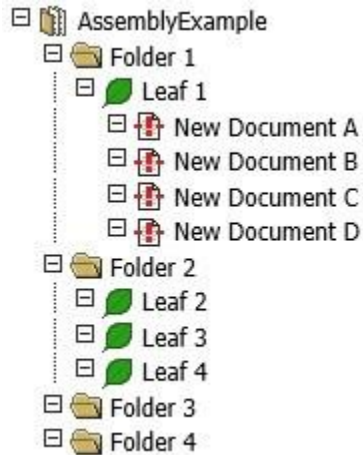
MetaData

Field Name	Field Type	Matching UI field	Req (Y/N)	Description	Acceptable values	Default value
extensionType	string		Y	Name of extension that a user can set on PublisherMeta-Data. The format is "type version", where type is m1-us-meta-data-application, etc., and version is 1.0, 2.2, 3.3, etc. If an extension is set on Publisher-MetaData, then additional extension fields appear.		Fixed value is m1-us-metadataapplication 3.3
targetNode	long		Y	Value of the ID field of Folder class where PublisherMetaData class is assigned.		
associatedEntityId	long		N	This field is not used for import.		

changeReasonComment	string		N	This field is not used for import.		

Assembly XML: Explanations

Explanation for childSeqNo and absoluteChildSeqNo Fields Use the following assembly tree as an example:

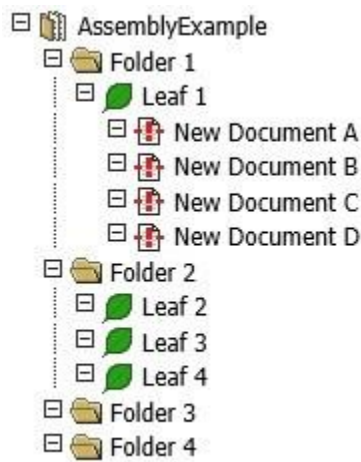


The following Field values are applicable:

Class name	Field Value for childSeqNo	Field Value for absoluteChildSeqNo
AssemblyExample	-1	1
Folder 1	0	1000001
Leaf 1	0	2000001
New Document A	0	3000001
New Document B	1	4000001
New Document C	2	5000001
New Document D	3	6000001
Folder 2	1	7000001
Leaf 2	0	8000001
Leaf 3	1	9000001
Leaf 4	2	10000001
Folder 3	2	11000001
Folder 4	3	12000001

Explanation for parentId Field

Use the following assembly tree as an example:



The following Field values are applicable:

Class name	Field value for id	Field value for parentId
AssemblyExample	13	NULL
Folder 1	14	13
Leaf 1	15	14
New Document A	16	15
New Document B	17	15
New Document C	18	15
New Document D	19	15
Folder 2	20	13
Leaf 2	21	20
Leaf 3	22	20
Leaf 4	23	20
Folder 3	24	13
Folder 4	25	13

Index

A

Administration 481

API 282–286, 288, 290–292, 294, 300, 302, 308, 311, 320, 325,

327, 328, 335, 342, 346

Applications 361, 363

Assemblies 350, 351, 353, 354, 356, 363

C

Common 1–3, 17, 26, 37, 64 Configuration 243

D

Data Admin 66–71, 73–76, 78–83, 86–93, 107–112, 114–116, 127,

129–131, 1ddd33–140, 142, 144, 149–151, 153–155, 160, 161, 164, 165, 167, 185, 197, 198, 218, 220, 222, 231, 232, 234, 236, 241, 243, 244, 251, 262–264, 267–270, 347, 348, 350, 367, 387, 388, 390, 398, 402, 406, 409, 414, 417, 424, 430, 444, 452, 454, 456, 460–464, 467, 475

E

Events 156

I

Installation 141, 142

L

Lifecycle 351

N

Navigation 273

Notifications 165

P

Prerequisites 381

Printing 373, 378

Product Families 232, 347, 348

Publishing 139, 369–373, 375–377, 379, 380

Publishing Elements 129

R

Registrations 149

Repository 272–275, 277–279

S

Security 30, 32, 33, 50, 280, 384, 385

Security Admin 30, 31, 33–36, 50, 55–63

T

Technical Admin 272, 276, 281, 349

Templates 356–358

W

Wizards 365, 367

X

XML Assembly 482, 485, 495, 501, 508, 517–519, 527, 532, 536,

542, 548–552, 554, 556, 558, 560, 561, 563–565, 568–570, 572, 574, 577, 580, 583, 586, 590, 594, 598, 599, 601, 603,
606–611, 613–616, 620–623, 625, 627, 632, 633, 635–637, 641, 645, 649,

656–663, 666, 669, 672, 674–677, 679, 681, 683, 685–689, 693, 694, 696, 705, 706, 708, 711–713, 718, 721–723, 726,
728, 729,

731, 732, 734, 736, 738, 740, 742, 745–748