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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.

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.
Ennov InSight for XEVMPD	Enables you to capture, maintain, and submit data about pharmaceutical products to comply with the Extended EudraVigilance Medicinal Product Database (XEVMPD) directive.
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.
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.

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
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 *New Package Set specific Registration(s)* 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

Subfeature	Subfeature Description	License Modules
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

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 country-specific 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

Subfeature	Subfeature Description	License Modules
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

Subfeature	Subfeature Description	License Modules
Change details	Capture details of the Change as a sub-entity 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

Subfeature	Subfeature Description	License Modules
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
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
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

Subfeature	Subfeature Description	License Modules
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 leaf-specific 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
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

Subfeature	Subfeature Description	License Modules
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 cross-references	Create, retarget, and set channel, stamp, and settings on paper cross-references.	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	✓		✓		✓	
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		Publishing	
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	✓		✓	✓	✓	✓

	Registrations		Assemblies		Publishing	
Selection	RPT	PDM	SPT	RDA	ELP	PRP
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	✓	✓				
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	✓	✓				

	Registrations		Assemblies		Publishing	
Selection	RPT	PDM	SPT	RDA	ELP	PRP
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	✓	✓

	Registrations	
Selection	RPT	PDM
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	✓	✓
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	✓	✓	✓	✓	✓	✓

	Registrations		Assemblies		Publishing	
Selection	RPT	PDM	SPT	RDA	ELP	PRP
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	✓	✓
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	✓	✓

	Registrations	
Selection	RPT	PDM
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	✓		✓	
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 Maintenance

	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	✓	✓
Procedure Type RMS Values	✓	✓
Route of Administration RMS Values	✓	✓
Unit of Measure Prefix RMS 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	✓	

	Publishing	
Selection	ELP	PRP
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
Secondary Task/Sub-Task Type Values	✓		✓	
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.*

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.

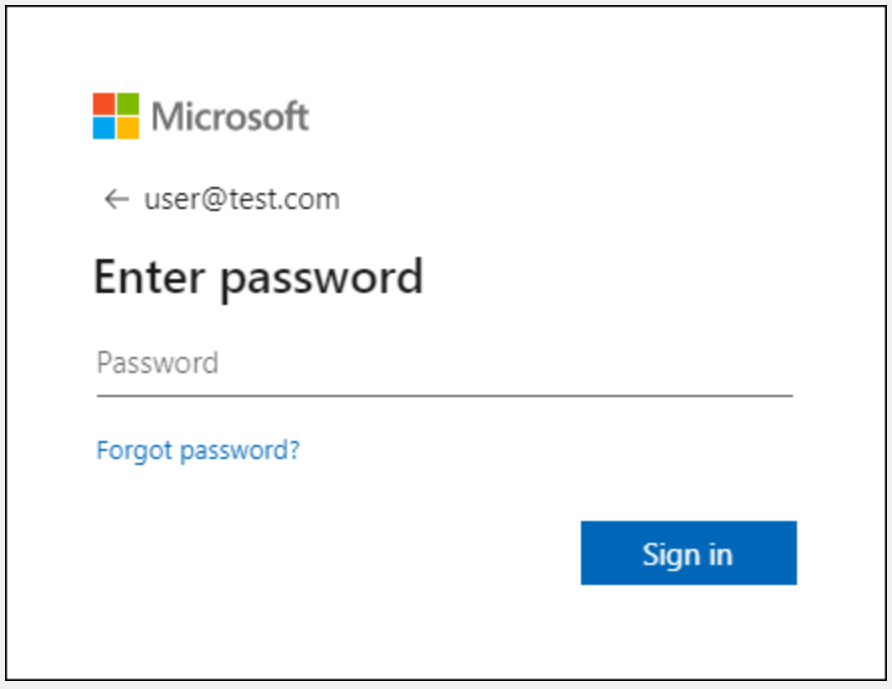
Ennov InSight supports authentication of users in the system when they are spread across multiple Identity Providers (IdP). The Ennov InSight system authenticates users if their account exists in the Azure AD individual Identity Provider (IdP) directory.

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	

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 Special Characters.*
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.

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 became 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.

Define User Access Rights Consistently

Make sure that you define user access rights consistently throughout Security Administration. Defining access rights inconsistently does not produce the results that you want.

An example of defining user access inconsistently is doing the following:

— Under Product Family/Product Rights, giving a user access to a product family.
— Under Application Country Rights, giving the user access to applications in the same product family.
— Under Product Family/Product Rights, removing user access to the product family.

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

Product Family/Product Rights

Product family/product rights provide record-level security. This prevents users from viewing applications, events, registrations, tasks, references, notifications, sequences, sequence assemblies, and product detail sets associated with the specified product family and its products. This affects all views as well as querying.

To ensure privileges are applied properly 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, etc.).

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 system. For example, if for a given user or group a product family is defined with write access, 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 results that you want.

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:*** *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.*
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.

Option	Description
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 privileges are applied properly for a user, 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 co-rapporteur country, or any one of the application countries, to see 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 Options

The *Application Country Rights* dialog box enables an administrator to grant users access to the specific countries associated with a product family. Use the options to assign the appropriate Application Country Rights to the user.

The table describes the options in the *Application Country Rights* dialog box.

Option	Description
Product Families - All	Applies the country rights you specify in the *Countries* box to all product families to which the user has access and their products. 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 assigned **All** privileges. Otherwise, a user may be able to create product families he or she cannot view.
Product Families - Select	Applies the country rights you specify in the *Countries* box to only the product families you choose in the selection box.
Countries - All	Grants the user access to all countries associated with the product families chosen in the *Product Families* 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 - prohibits access — Read - view privileges only — Write - Read privileges plus create and modify privileges — Admin - Write plus 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 *New Package Set specific Registration(s)* 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

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 country-specific 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 sub-entity 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 leaf-specific 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 cross-references	Create, retarget, and set channel, stamp, and settings on paper cross-references.	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
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
Standalone Assemblies	— Submission Planning & Tracking — Registered Document Analysis — Electronic Lifecycle Publishing — Paper Review Publishing

Permission	License Modules
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, In-Process 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 re-associate 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. ClickProduct 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.
Ennov InSight for XEVMPD	Enables you to capture, maintain, and submit data about pharmaceutical products to comply with the Extended EudraVigilance Medicinal Product Database (XEVMPD) directive.
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.

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 drop-down 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 . 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/)
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
Procedure Type Values (per Country)	XEVMPD Controlled Vocabularies - Authorisation Procedures Ennov Defined: Best Practices

Selection List Entity	Source for Values
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 . 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 . 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 . 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

Data Administration Selection Lists: Custom Lists Maintenance

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 . 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: Event Maintenance

The following table identifies the selection lists (drop-down lists and multi-select boxes) in . 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 . 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.
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

Selection List Entity	Source for Values
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 . 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
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

Selection List Entity	Source for Values
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 . 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

Selection List Entity	Source for Values
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 . 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
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

Selection List Entity	Source for Values
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 . 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 . 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 . 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 . 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 . 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) Ennov Defined: based on Regulatory Guidance
Sequence Status Values	Ennov Defined: Best Practices

Data Administration Selection Lists: SPOR Maintenance

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

Selection List Entity	Source for Values
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 . 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)

Selection List Entity	Source for Values
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)
Sequence Description Values	Regulatory Agency Defined (AU: sequence-description.xml)
Submission Product Type Values	Regulatory Agency Defined (CN:)
Sub Filing Type Values	Regulatory Agency Defined (US: submission-sub-type.xml V1.1) (CN:) http://www.nmpa.gov.cn/WS04/CL2042/
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 . 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 . 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 . 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

Administrative Functions	Entity Name
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*.

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`.`
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.

Attribute	Description
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 — Language Values — Indications/Intended Use Values — Units of Measurement — Unit of Presentation Values — Concentration Measure Type Values — Attached Document Content Type	— Application Legal Basis — Application Submission Type — Language — Medical Dictionary For Regulatory Activities — Units of Measurement — Units of Presentation — Quantity Operator
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	— Qualified Person Responsible for Pharmacovigilance (QQPV) Values — Marketing Status — Master File Type — Medicinal Product Name Part Type — Regulatory Entitlement Status — Medicinal Product Type Values — Provenance Reason	— Contact Party Role — Marketing Status — Master File Type — Medicinal Product Name Part Type — Regulatory Entitlement Status — XEVMPD Medical Product Type
Application Maintenance	— Country Values — Procedure Type Values — Legal Status Values — Regulatory Entitlement Type — Product Information Document Type	— Country — Legal Status for the Supply — Regulatory Entitlement Type — Product Information Document Type
Product Detail Set Maintenance	— Substance Role Values — Manufacturing Function Values — Material Values — Packaging Type Value — Shelf Life Type Values — Storage Condition Values — Manufacturer Values - Global Detail Sets — Component Type — Medical Device UDI — Device - Type of Combination	— Ingredient Role — Manufacturing Activity — Material — Packaging — Shelf Life Type — Special Precaution for Storage

Associate SPOR Terms with Data Administration Entities

You can map a SPOR term with the Data Administration values using the RMS tab available on the Data Administration values attributes page.
Only one SPOR term can be associated to the Data Administration value. Associating another term will replace the existing term.

To associate SPOR 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 Maintenanace > 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 SPOR Terms with Data Administration Entities

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

To disassociate SPOR Terms:

1. Navigate to the Data Administration entities and click the link for the Data Administration value. For Example: Application Maintenanace > 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.
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.

Maintain Values

As a data administrator, you can add, modify, 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.

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 *Country Attributes* 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.

Data Administration Section	Values to associate	Column	Tab	Description
Product Detail Set Maintenance	Manufacturer Values	Manufacturer Name	— Global Product Details — Manufacturing Authorization Reference Number — OMS	Associate product details with a manufacturer.
Product Family Maintenance	Substance Values	Substance Name	— Substance XEVMPD 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.

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 *GPP* 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.*

Application Value	Description
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.
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:*** *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.* ***Note:*** *If this is a Ennov InSight D2 integrated system, one the following values must be present in order for D2 to recognize the procedure type correctly:* — *Centralized or CP* — *Decentralized or DCP* — *Mutual Recognition Procedure or MRP* — *National*
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.

Application Value	Description
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: *`Regulatory Region`*. You can enter up to 200 characters for the **Region Type** value. The default value is set to **Active**. The *`Regulatory Region`* and *`IDMP`* 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 ***Region Values*** 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 ***Region Values*** section.
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:*** *By default, the section is hidden.*
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.
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 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 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.
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.

Attribute	Description
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.

Attribute	Description
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 Active Country RMS Values must be available for selection. Data will be available in the concatenation, separated by space: Term Name + Term Identifier.
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.

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.
eCTD Code	eCTD Code.
Procedure Type Code	Current codes according to the EMA Authorisatin Procedure CV. ***Note:*** *Procedure Type Abbreviation and Procedure Type Name should be unique to accept within following ligament Procedure Type Abbreviation,Procedure Type Name,Display Name, Internal Procedure Code.*
External System Procedure Type Code	External system procedure type code.
Countries	Identifies the countries for which the Procedure Type is valid.
RMS Term Name	List of Active Procedure Type RMS Values must be available for selection.

Attribute	Description
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: *EU* The value you are entering must be unique within the system.
Region Name	A full name of a region. Example: *European Union* The name you are entering must be unique within a *Region Type*.
Countries	Countries associated to a region. A country can only belong to one region within the *Region Type*.
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.

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.

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 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`.

Attribute	Description
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 clincial 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`.
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.

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.

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 (*Country Code* values are also hyperlinks to the *Modify* window).
Country Name	Country Name.
eCTD Code	*eCTD code* 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.
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.

Maintain Country Region Values

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.
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.

Maintain Country Language Values

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 Attributes

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

Attribute	Description
DTD Code	Name of the zip file supplied for the DTD. Example: `CA-1-0`.
URL	Name of the zip file supplied for the DTD. Example: `ca-1-0`.
Region	All active values of Regulatory Region type from the Region Values.
Countries	All countries for the selected regions.
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.

Attribute	Description
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:

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`.

Attribute	Description
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 Code	Document Type	Repository Attribute	Description	Active Flag
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.
   b) Populate the fields.
   c) 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 system-defined 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.
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 non-blank 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 non-blank abbreviated name.
Assembly Name	ANAME	The name of the assembly as defined by the user.	Active	

Variable Name	Variable Code	Description	Active Flag	Constraints
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 Relative Page	ARE	Page number in the electronic channel relative to the entire assembly.	Active	Publishing time variable.
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).

Variable Name	Variable Code	Description	Active Flag	Constraints
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.
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.

Variable Name	Variable Code	Description	Active Flag	Constraints
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.
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.

Variable Name	Variable Code	Description	Active Flag	Constraints
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.
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.

Variable Name	Variable Code	Description	Active Flag	Constraints
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 `cover-letter.pdf` path would be `./M1/US/` and the path and file name would be `./M1/US/cover-letter.pdf`	Active	Will work on any element assigned under a leaf.
Leaf Output Filename	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 non-blank name.
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	

Variable Name	Variable Code	Description	Active Flag	Constraints
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.
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.

Variable Name	Variable Code	Description	Active Flag	Constraints
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 non-blank name attribute.
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 non-blank 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.

Variable Name	Variable Code	Description	Active Flag	Constraints
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.
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 Application Code	RLAC	For a Reference Leaf, this is the Application Code of the Application containing the referenced leaf.	Active	

Variable Name	Variable Code	Description	Active Flag	Constraints
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 non-blank 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 non-blank name attribute.
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 non-blank 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	

Variable Name	Variable Code	Description	Active Flag	Constraints
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
Assembly Name	INA			Assembly name	Active
Assembly Status	IASS			Assembly status	Active
Assembly Subcategory	IASSC			Assembly subcategory	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

Variable Name	Variable Code	Last User Updated	Last Changed Date	Description	Active Flag
Event Sequences	IER			Event sequences	Active
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 keywords	Active
Sequence Name	ISN			Sequence name	Active
Sequence Number/ Code	ISC			Sequence number/code	Active
Sequence Status	ISS			Sequence status	Active
Sequence Status Date	ISD			Sequence status date	Active
Sequence Submission Filing Type	ISF			Sequence submission 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 Formula	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: `Company 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 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

Variable Name	Variable Code	Last User Updated	Last Changed Date	Description	Active Flag
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 Subcategory	IASSC			Assembly subcategory	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 Sequences	IER			Event sequences	Active
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

Variable Name	Variable Code	Last User Updated	Last Changed Date	Description	Active Flag
Product Name 2	IP2			Product name 2	Active
Sequence Keywords	ISK			Sequence keywords	Active
Sequence Name	ISN			Sequence name	Active
Sequence Number/ Code	ISC			Sequence number/code	Active
Sequence Status	ISS			Sequence status	Active
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.
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 event-change 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:

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
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.

Attribute	Description
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 *name*, 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: ***Note:*** *For a Veeva or Documentum repository, you cannot change the name* `Standard Rendition`.	Click Edit and Save.

Action	Description
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.*

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

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, non-standard 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.*

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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.*

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 Worksharing	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.
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.

Attribute	Description
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.
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.

Attribute	Description
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.

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.

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.
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.
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.
3. Click Next.
   The *Create Timeline/Event Plan Confirmation* page opens.
4. Click Next.
   The *Enter Lead Times Values* page opens.
5. Enter a `lead time` for each event status.
   To select a Lead Time field, double-click it.
6. Click Next.
   The *Create Timeline/Event Plan Lead Time Confirmation* page opens.
7. Click Next.
   The *Create Plan Summary* page opens.

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

8. 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.

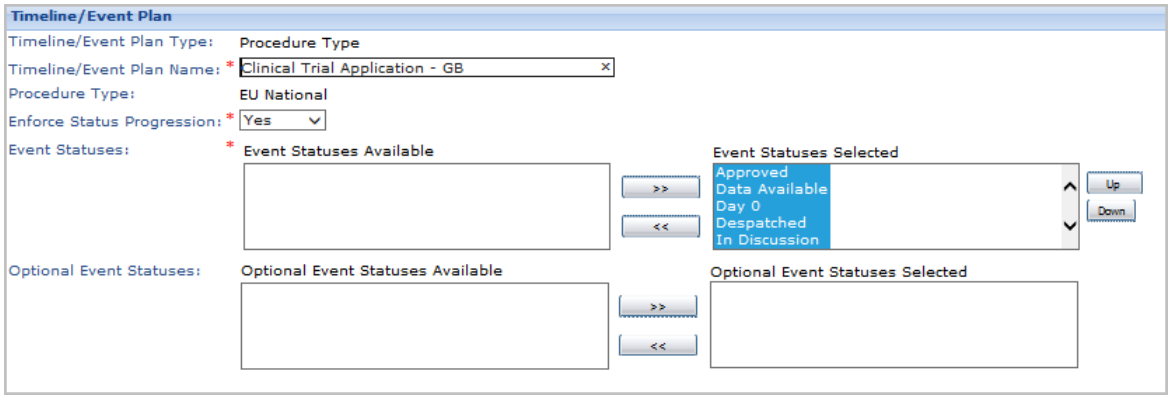
— If you move an event status from the Event Statuses Selected multi-select box to the Event Statuses Available multi-select box for Event Statuses, and then move that same status from Event Statuses Selected to Event Statuses Available for Optional Event Statuses, an error message appears after you 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.
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* *Timeline/Event Plan Countries* *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 *Create Timeline/Event Plan* 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 *Modify Timeline/Event Plan* 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.

Attribute	Description
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:*** *The first status in a timeline/event plan must not be mapped to an Ennov InSight internal status of* Approved *or* Not Approved*.*
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 *Modify Timeline/Event Plan* page, this field appears as read-only.
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 *Modify Timeline/Event Plan* 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 *Modify Timeline/Event Plan* 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

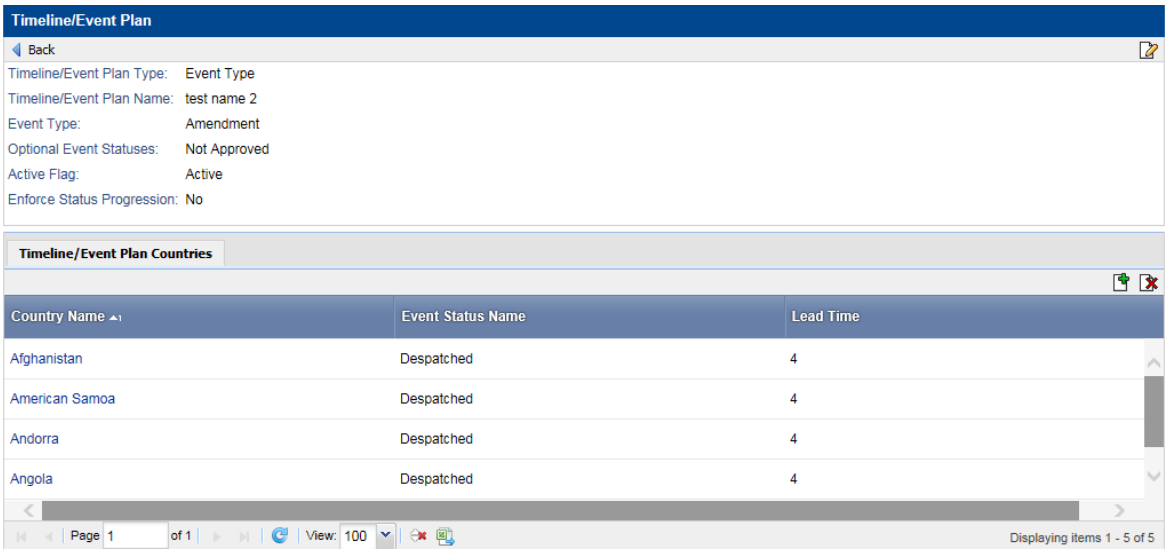
You can view a timeline/event plan, as well as perform changes to a timeline/event plan and the lead time for timeline/event plan countries, in Data Administration.

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 modified date`	The last status in the status order is the current status.

Add Timeline/Event Plan Countries

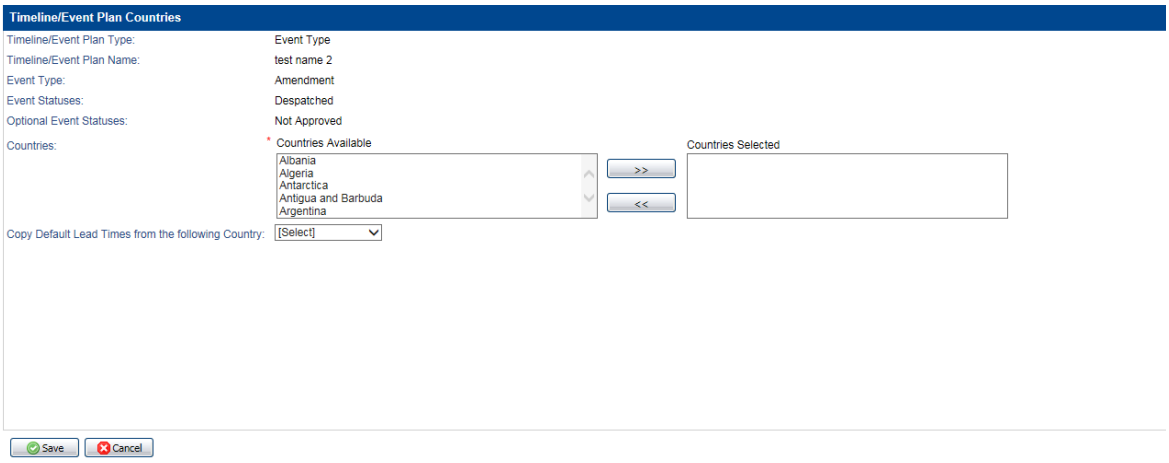
You can add countries to an existing timeline/event plan in Data Administration to associate the timeline/event plan to the added countries.

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:

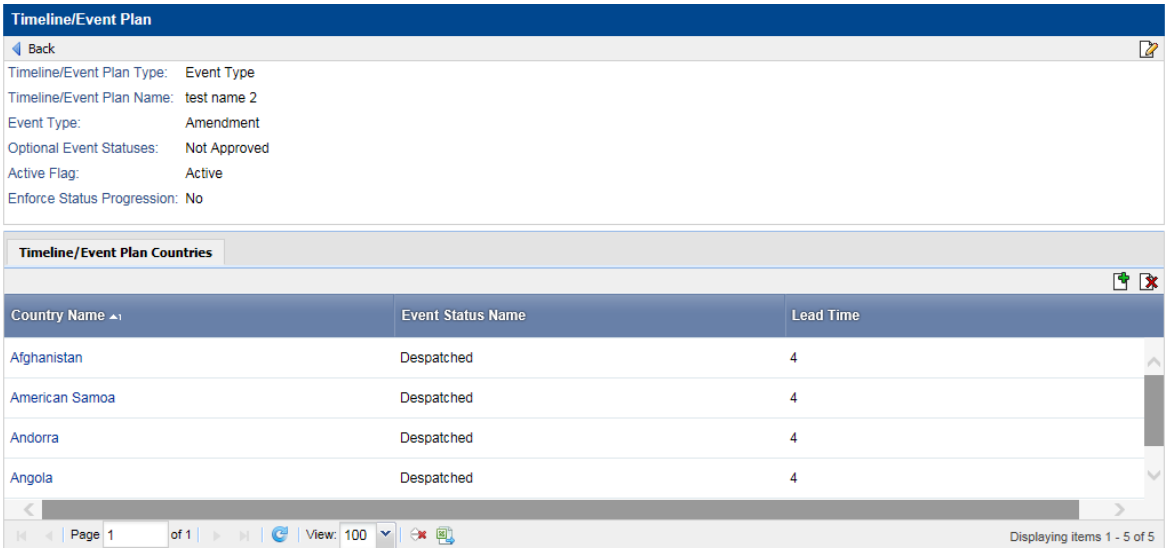
1. In Ennov InSight, click Go To > Data Administration.
   The *Data Administration* page appears.
2. On the *Data Administration* page, under Event Maintenance, click Timeline/Event Plan Values.
   The *Timeline/Event Plan* page appears.
3. On the *Timeline/Event Plan* page, click the link for the event 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.



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.

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 *multi-select field on the* Create Event *page. This is applicable only to applications of Mutual Recognition (MRP) or Decentralised Procedure (DCP) types.*
Description	Text that describes the Event.
EU Grouping/ Worksharing	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.

Attribute	Description
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:*** *The Event Add Comment field is available on the Create/Modify Event Attributes pages only.*
Event Closed As	The status to capture how the entities associated with the Event were closed.
Event Closed Date	The date the Event is closed.
Event Code	The code your organization uses to identify the Event. ***Note:*** *The Event Code and Event Name as a combination for an Event must be unique within an Application.*
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:*** *The Event Code and Event Name as a combination for an Event must be unique within an Application.*

Attribute	Description
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.
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:*** *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.*
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.

Attribute	Description
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.
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.

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 event-country 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 Notificationfunctionality 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.

Attribute	Description
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 = Admin	Created automatically from a notification specification	Entity Security, Notifications = Write or Admin

Function	Specification	Specification-triggered notification	User-created notification
Modify, Activate, Deactivate	Entity Security, Notifications = Admin	Entity Security, Notifications = Write or Admin/Ennov InSight does not validate notification creator	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 = Admin/Administrator can delete any notification

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 Content Type Values	A document format that European Medicines Agency (EMA) supports.

Value	Description
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.
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 indentify 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. *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.*
Home Page Display Properties	Used to add or remove shortcuts to wizards and to modify text labels that appear on the *Home* 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.

Value	Description
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.
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.

Value	Description
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.
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.
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.

Attribute	Description
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.
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.

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.

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 Active Denominator/Numerator Unit RMS Values must be available for selection.
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.

Attribute	Description
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.

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.
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.

Attribute	Description
ISO ALPHA-3 CODE	3-letter language code assigned to language.
RMS Term Name	List of Active Language RMS Values must be 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.

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 Active Language RMS Values must be 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.
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.

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.

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.
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

Attribute	Description
Last User Updated	Indicates the name of the user who last created/updated the MAH/ development sponsor/organisation. 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.

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.
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.

Attribute	Description
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 Active 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.

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.

Reason for E-Signature Attributes

To define a reason for E-Signature value, enter values for the following attributes:

Attribute	Description
Reason for E-Signature	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 E-Signature. 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.

Attribute	Description
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.

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 Active 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.

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.

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.

Value	Description
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.
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 Nomenclature	The nomenclature systems available to identify devices. The nomenclature system supports the description of the device.
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.

Value	Description
Global Medical Device Nomenclature (GMDN) Code Values	Global Medical Device Nomenclature (GMDN) Code is used to identify medical devices.
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.
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.
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.
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.
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 Nomenclature Attributes

To define a device allergenicity 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 nomenclature. 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.

Attribute	Description
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 soluable 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.

Attribute	Description
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.
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.

Global Medical Device Nomenclature (GMDN) Code Attributes

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

Attribute	Description
GMDN Code	The name of the code.
GMDN Term Name	Description of the GMDN Code. GMDN Code and Term Name must be unique within a system.
Last User Updated	Indicates the name of the user who last created/updated the Global Medical Device Nomenclature (GMDN) 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.

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.
RMS Term Name	List of Active 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.

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 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.
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 Active 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.
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.
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	Component color, such as red, blue, pink, and so on.
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.

Value	Description
Component Type Values	The value supports the IDMP.
Device - Type of Combination	The value is mapped to the Device – Type values in Data Administration.
Dose Frequency	Used for veterinary products, this is how often a dose is administered in a dosing schedule.
Genetically Modified Cell Origin Species	Species from which cells have been genetically modified. ***Note:*** *By default, the section is hidden.*
Human Consumption Product	Used for veterinary products, this 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.
Label Type	Example: patient insert, physician insert, carton label, package label, etc.
Manufacturer	Companies that perform manufacturing functions. `Substances`, `manufacturer functions`, `material` and `packaging` must exist in the system to be able to associate them with manufacturers.
Manufacturing Functions	Example: dosage form production, dosage form retesting, repackaging, etc.
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 value supports the IDMP.
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.

Value	Description
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.
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.*

Value	Description
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	Defines the type of the substance that you want to use in your Product Detail Set. There are 2 Substance Types available for you to choose - Adjuvant and Excipient. The default value is set to `Active`. The standard set of extra fields can be configured for this value.
Time Unit	Example: month, week, day
Type of Dossier Submitted	Example: full IMPD, simplified IMPD, and SmPC ***Note:*** *By default, the section is hidden.*
Type of Gene Therapy Transfer Product	Example: nucleic acid naked, nucleic acid, complexed, viral vector-adenovirus, 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.

Value	Description
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.
Manufacturing Function Values	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.
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 Active 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.

Attribute	Description
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.
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.

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.
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.
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.

Attribute	Description
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.
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, Pre-Dosage 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.
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.

Attribute	Description
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.
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.
Product Material	Value of Product Material from the Data Administration.
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.
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.

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.

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.
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.

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.

QC Status Attributes

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

Attribute	Description
Name	Name given for the QC Status.
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.

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.

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 Compentent Authority and none.

Attribute	Description
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.
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.

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.
4. Scroll to the bottom of the page and click next to Global Product Details.
   The *Select* page appears.
5. In the Detail Type drop-down list, select the type of global product detail to associate with the manufacturer.
6. Click Save.

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.

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.
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.

Attribute	Description
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

Use Manufacturer Authrorization 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.

You can maintain the following Manufacturer Authorization Reference Number values:

Attribute	Description
Manufacturer Name	Name of the Manufacturer.
Address Line 1	Address of the Manufacturer.
Country	The name of the country.
GMP Status	Status of the Manufacturer with respect to Good Manufacturing Practices. For example, In Good Standing, Not in Good Standing and so on.

Attribute	Description
GMP Expiration Date	Expiry date of the GMP.
Last GMP Inspection	Date of the last GMP inspection.
Contact Person	Name of the contact person.
Contact Person Title	Title of the contact person.
Phone	The phone number of the contact person.
Fax	Fax number.
e-mail	Contact person email address.
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.
Site License Number	The license number of the site.
Site Certificate Filed	Yes or No values are available.
DMV/CEP Number	The number of DMV/CEP.
US Agent	The name of the US Agent.
FEI Number	FDA Established Identifier.
Parent Company Name	Name of the parent company.
Other Firms	Other firms operating at site.
Comments	Comments for Manufacturer.
Keywords	Keywords used to search information.
Description	Description for Manufacturer.
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.
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	Current `Active`/`Inactive` setting for the Global Detail Set.

Attribute	Description
Manufacturing Authorisation Reference Number	The organisation identifier associated with SPOR OMS.
Manufacturing Authorisation Type	The location identifier associated with SPOR OMS.
Effective Date	The organisation name associated with SPOR OMS.

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	Indicate 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.

Value	Description
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	Define substances values with their affiliated attributes. The XEVMPD related substance entities such as substance alias, substance attachments, substance international codes and substance translations 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.

Attribute	Description
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 Active ATC RMS Values must be available for selection.
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 Opthalmic 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.

Attribute	Description
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.
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
EURD Procedure Identifier	Indicates the Procedure Identifier.
EURD ID	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* 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.

Attribute	Description
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 Vacine, 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.

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 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.
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: Substance, Placeholder, and Strain.
Substance Name	Name of the Substance. Combination of Substance Type + Substance Name should unique in the system.
INN	International Non-proprietary name.
CAS Number	Chemical Abstract Services number assigned to the Substance.
Molecular Formula	Chemical formula of the substance.
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.

Attribute	Description
CBD	Chemical Biological Description of the Substance.
Development Sponsor	Sponsor of the Clinical Trials if this is a Development Substance. Required by XEVMPD 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

Attribute	Description
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 Entity Values

Ennov InSight enables you to add or modify values for Substance entities such as: Substance XEVMPD Information, Substance Alias, Substance Attachments, Substance International Codes, and Substance Translations.

You can:

— Create a new Substance Value and add entity values for it.
— Add entity values for an existing Substance Value.

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 Attachments, 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.

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, Substance Attachments, Substance International Codes, and Substance Translations, 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:
   — To activate the substance and its entities, click Activate.
   — To deactivate the substance and its entities, click 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:

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.

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. Hyperlinked 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.
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.

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 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.
Medicinal Product Type	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.
Qualified Person Responsible for Pharmacovigilance (QPPV)	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:*** *The Internal System Status field includes an internal status named APPROVED. This value is used to maintain the IDMP (Identification of Medicinal Products) compliance.*
Content of Change	The content of change provided for the IDMP attachment.
Medical Product Action/ Submission Status	Submission status of the Medicinal Product.
Data Carrier Type Values	The Data Carrier Type values are used when using different packaging levels of medicinal products.
Provenance Reason Values	The reason of provenance to provide additional clarity on requirements for Postmarketing 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.
Marketing Status Reason Values	Reason for updating the marketing status of a drug.

Value	Description
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.

EMA Authorization Status Attributes

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

Attribute	Description
Authorization Status	Status of the authorisation/registration of a medicinal product.
Status Code	Authorisation status code associated with the selected Authorisation Status.
RMS Term Name	List of Active EMA Authorisation Status RMS Values must be available for selection.
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.

Medicinal Product Type 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 Active EMA Authorisation 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.

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 designnated QPPV within 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.
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.

Attribute	Description
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.

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.

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.
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.

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 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.

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.

Attribute	Description
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.

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.

Marketing Status Reason Attributes

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

Attribute	Description
Marketing Status Reason Name	Name to define the reason for the Marketing Status of the medicinal products.
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:

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.
Active	Indicates if the entity is active or inactive.

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.

   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) introduces 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 - Organisartions management service. OMS manages organization master data, comprising organization name and location address, for organizations such as marketing authorisation 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).

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

When you select a value under SPOR Maintenance, 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.

You should have Data Administration set 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.

Value	Description
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.
Country	The country where the medicinal product name has been authorized.
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.
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.

Value	Description
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 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.
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
Regulatory Entitlement Status	The status of the marketing authorization.
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.
Special Precaution for Storage	Special precautions for storage of the packaged medicinal products.
Terminology System List	

Value	Description
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.

The following table describes the OMS Value 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.
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.

Attribute	Description
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 drop-down 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.
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.

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.

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.
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.

Attribute	Description
Activate/Deactivate	Activate or deactivate to determine the availability of an organization.

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 *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.
— 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 Publisher.

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.

Note: *When creating or modifying the values listed below, regions available for selection in the Region field are limited by those of a Regulatory Region type only:*

— *Application Contact Type*
— *Applicant Contact*
— *Applicant ID*
— *Application Form Type*
— *Promotional Material Audience Type*
— *Promotional Material Doc Type*
— *Promotional Material Type*
— *Regulatory Activity Lead*
— *Sequence Description*
— *Submission Product Type*
— *Telephone Number Type*

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.
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.

Value	Description
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
Region	All active values of Regulatory Region type from the *Region Values* 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 *Region Values* are available for selection.
Applicant Contact Name	Name of the Applicant Contact.
Applicant Contact Type	All active values from the Applicant Contact Type Values.

Attribute	Description
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 *Region Values* 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 *Region Values* 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 *Drug Registration File Documents Section Values* 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 *Region Values* 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 `font name` that appears on the *Tab Sheet Attributes* 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 *Region Values* 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 *Region Values* 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 *Region Values* 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 *Region Values* 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 *Region Values* 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 *Region Values* 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 *Region Values* 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.

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:

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:

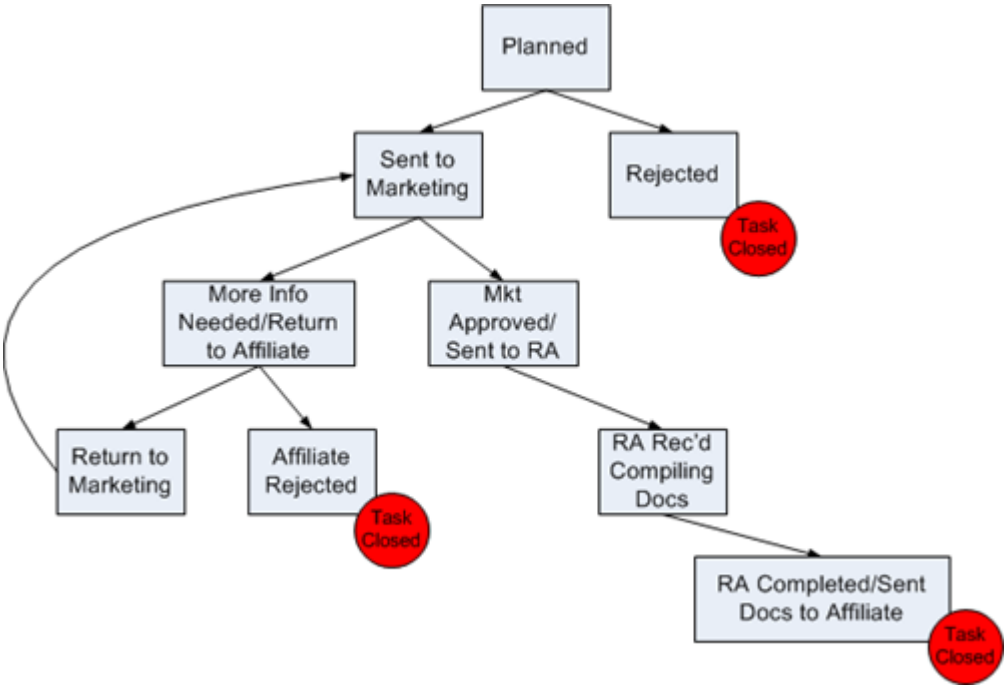
Attribute	Description
Name	Defines a value for the Task Type. Examples: Annual Report, Renewal, Other.
Last User Updated	Indicates the name of the user who last created/updated the task/ sub-task type. By default, this option is read-only. It is populated automatically when updates were made to the table.
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.

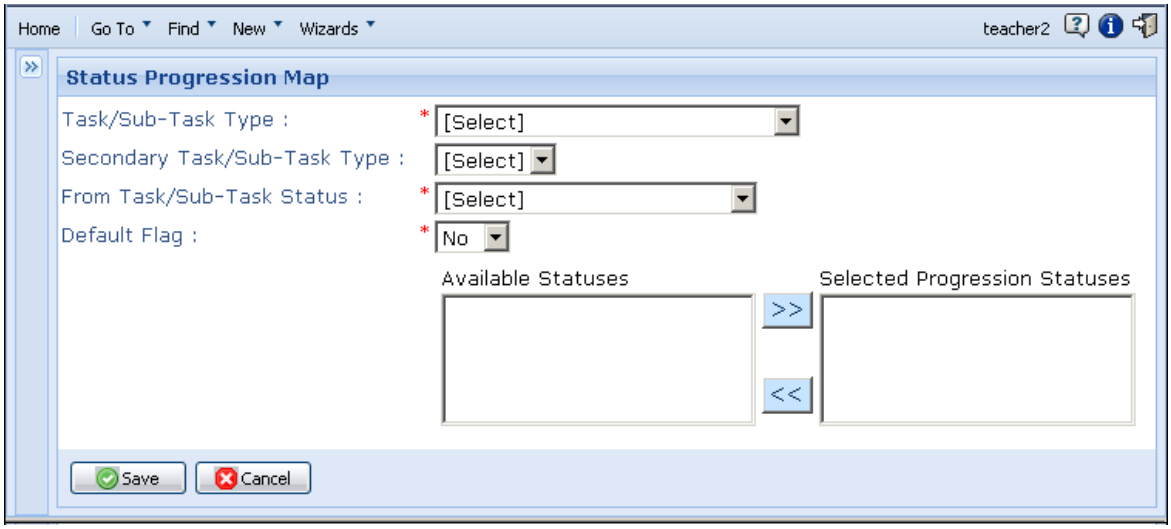
Note: *After a progression has been defined for a specific task type/secondary task type combination, associating the secondary task type with a different task type causes errors in the system. If there is a need to associate the secondary task type with a different task type, create a new Task Type/Secondary 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.

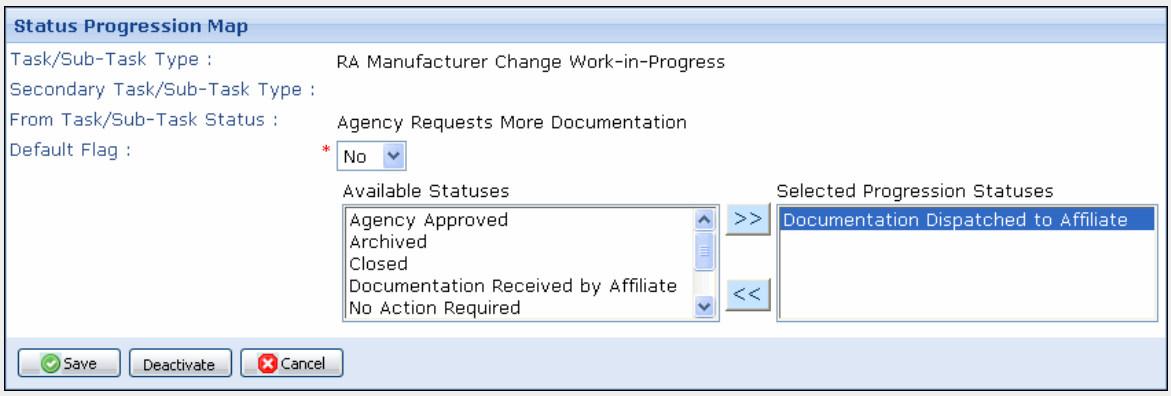
To modify a task status progression:

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



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.

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.

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, File System, 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.

During configuration, keep in mind that the names used for connecting to DMS servers and repositories, except for file systems, secure file systems, and Veeva systems, are case-sensitive, so the upper/lower case spelling of the names must be correct for the DMS to function properly. The use of special characters should be avoided. See *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 following procedures 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.

With the exception of 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
`,'	Apostrophe, single quotation mark ***Note:*** *On most keyboards, this ` character shares a key with the ~ character.*
< >	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
#	Number
&	Ampersand
$	Dollar
+	Plus
%	Percent
=	Equal

Note: *When publishing, a file name or a server name or, a file path should not exceed the Windows file system limit, which is 260 characters. It is highly recommended to take into account the limit length of the file name from DMS. Otherwise, there may be issues because of the long file names.*

Add a Documentum, File System, Secure File System, or Veeva Vault Server

Perform the following steps to add the types of servers listed below.
Use the following procedure to add any of the following types of servers to Ennov InSight:

— Documentum
— File system
— Secure file system
— Veeva Vault

The names used for connecting to DMS servers and repositories, except for file systems, 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, if necessary, 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 for the kind of the server that you want to add:
   — Documentum
   — Filesystem
   — SecureFileSystem
   — Veeva Vault
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.

Add a Documentum Repository to Ennov InSight

You can configure Ennov InSight to connect with a Documentum repository so you can 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 soon 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. Provide repository credentials in the Repository User and Repository Password fields.

Note: *System Administrator credentials are encrypted in the database. The passwords are saved encrypted if a repository is added or updated.*

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 *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.

12. To save the new DMS repository settings, click Save.

Map D2 to Documentum for Ennov InSight

You can configure Ennov InSight to connect with a D2 so you can access the documents in D2.

To add a D2 to Documentum for Ennov InSight:

1. Log on as an administrator.
2. Click GoTo > Technical Administration.
3. In the Available Options list, click DMS Repository Management.
4. In the *Repositories* view, click the Create icon or select an existing repository from the list.
5. In the Server Name drop-down list, select Documentum Server (Documentum).
6. Type the name of the D2 repository in the Name (Docbase) field.
7. In the D2 URL field, type the D2 URL in the following format: `http://<host_name>:<Port>/D2/`, where `<host_name>` is the actual D2 host name and `<Port>` is the actual D2 port number.

Note: *Please follow the exact format described in this step. Remember to put slashes where indicated.*

8. In the Repository User and Repository Password fields, type the credentials for accessing the repository, if required.

9. 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. In the Ennov InSight menus, select: GoTo > Technical Administration.
3. In the Available Options list, click DMS Repository Management.
4. In the *Repositories* view, click on the Create icon.
5. Open the Server Name list and select the File System.
6. In the Name (Shared Folder Path) field, enter the full path to the `SecureFileSystem` repository in your system.

   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.
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. 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.
9. To allow repository access to defined users or groups or roles, select Yes from the Limit Access to Specific Users field.
10. 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.
11. To save the new DMS repository settings, click Save.

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 restrict access to the repository, in the Limit Access to Specific Users field, click Yes, and do any of the following:
    - Restrict access to specific users: In the Allow Selected Users section, in the Access Limited box, select users. Then click the arrows (>>) to move the users to the Access Allowed box.
    - Restrict access to specific groups: In the Allow Selected Groups section, in the Access Limited box, select groups. Then click the arrows (>>) to move the groups to the Access Allowed box.
    - Restrict access to users with specific roles: In the Allow Selected Roles section, in the Access Limited box, select roles. Then click the arrows (>>) to move the roles to the Access Allowed box.
12. 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 for a document management server, if needed.

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 for Technical Administration appear.
3. In the Available Options list, click DMS Repository Management.
4. In the *Repositories* view, click on the name of a repository in the list.
5. Modify the repository settings as needed.
   - To remove the selected repository from active use, click Deactivate.
   - To return an inactive repository to active use, 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 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 Repository Attributes

DMS Repository type	Modifiable DMS Repository attributes
Documentum	Server Name Active Flag Label Repository User Repository Password Force New Renditions and Extractions Limit Access to Specific Users
Secure File system	Server Name Active Flag Label Repository User Repository Password Force New Renditions and Extractions Limit Access to Specific Users
Veeva	Server Name Active Flag Label Vault URL Repository User Repository Password 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 (>>).
   - 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.

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 for the following:
- Assembly Structure Functions
- Registrations Entities
- Tasks and References Entities
- Product Detail Set Detail Entities
- Product Family Agnostic Entities
- Core InSight Entities
- Assembly Structure
- Lifecycle assembly creation
- Lifecycle operations and metadata
- Product related Entities
- Entering unique Events within Ennov InSight

Authenticate Users for Ennov InSight API

Authentication is required to use the API.

To pass authentication for the API, perform the following procedure.

1. Submit an HTTP 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 will include { "token": "F1AE44E28CB43CDECB2D0A104EB5DF4B" } with the current session ID. The response header contains the following values:
   — X-CSRF-HEADER → X-CSRF-TOKEN
   — X-CSRF-PARAM → _csrf
   — X-CSRF-TOKEN → 40d67d97-fb28-4a78-a111-5bae0ee706bb
2. Use that token and login information to get authenticated. Send a login POST-request to pass authentication. You should use the same session (set JSESSIONID):
   — 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 (JSON): {"username": "external_system_abc", "password": "password_abc"}
3. After successful login, the application creates a new session and a new token to use in subsequent API calls. The response header will contain the following values:
   — X-CSRF-HEADER → X-CSRF-TOKEN
   — X-CSRF-PARAM →_csrf
   — X-CSRF-TOKEN → c3cc7d40-348e-410c-bcb6-bc0accdfaff5
4. Make an API call with your new token. All subsequent REST API POST-requests (read/create/create-or-update/delete for a specific entity) should be sent through "/api/v2" URI (e.g. `http://hostname:port/insight/api/v2/event/46098/delete`) with the following attributes:
   — Request header values:
      • Content-Type: "application/json"
      • X-CSRF-TOKEN: c3cc7d40-348e-410c-bcb6-bc0accdfaff5
   — Request body: JSON object for the specific entity.
5. Instead of X-CSRF-TOKEN header, you can use the "_csrf" param.

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-or-update" api.
ApplicationCountry	ApplicationCountryRestController / application-country	— Family Id is required — Old behavior - Example: { "queryFor": { "applicationId": APPLICATION_NAME }, ... }	— Family Id is removed — New behavior - Example: { "queryFor": { "applicationId": APPLICATION_CODE + " " + APPLICATION_NAME }, ... }	The behavior of how applicationId is retrieved for use in queryFor has changed.
Event	EventRestController / event			
EventCountry	EventCountryRestController /event-country			
EventCountrySchedule	EventCountryScheduleRestController / event-country-schedule			

Entity Name	API/Controller	API 6.2	API 7.0 Updates	Description
AppEventProduct	AppEventProductRestController /event/product	Old behavior - Example: { "queryFor": { "applicationId": APPLICATION_NAME }, ... }	New behavior - Example: { "queryFor": { "applicationId": APPLICATION_CODE + " " + APPLICATION_NAME }, ... }	The behavior of how applicationId is retrieved for use in queryFor has changed.
FullProductPresentation	LicenseFppController /license/full-product-presentation	— 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 /full-product-presentation/attachment	— Family Id - required — Old behavior - Example: { "queryFor": { "applicationId": APPLICATION_NAME }, ... } — Old uniqueness rule - "name and fppId and familyId and applicationId and	— Family Id is removed — New behavior - Example: { "queryFor": { "applicationId": APPLICATION_CODE + " " + APPLICATION_NAME }, ... } — New uniqueness rule -	

Entity Name	API/Controller	API 6.2	API 7.0 Updates	Description
ProductLicense	"/license/product-registration"	Old behavior - Example: { "queryFor": { "applicationId": APPLICATION_NAME }, ... }	Please check License as it inherits all changes.	N/A
LicensePackageSet	/license/packageset	Old behavior - Example: { "queryFor": { "applicationId": APPLICATION_NAME }, ... }	New behavior - Example: { "queryFor": { "applicationId": APPLICATION_CODE + " " + APPLICATION_NAME }, ... }	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 /sequence-schedule	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 ActiveIngredientDetailRestController CharacteristicsDetailRestController CTADetailRestController DoseScheduleDetailRestController FluStrainDetailRestController FunctionDetailRestController IndicationDetailRestController LabeledIndicationDetailRestController LabelingDetailRestController ManufacturerDetailRestController ManufacturingProcessDetailRestController MaterialDetailRestController MedicalDeviceDetailRestController PackageSetDetailRestController PackagingDetailRestController RouteOfAdministrationDetailRestController ShelfLifeDetailRestController SpeciesDetailRestController StepDetailRestController SubstanceDetailRestController WithdrawalTimeDetailRestController	Old behavior - Example: { "queryFor": { "applicationId": APPLICATION_NAME }, ... }	New behavior - Example: { "queryFor": { "applicationId": APPLICATION_CODE + " " + APPLICATION_NAME }, ... }	The behavior of how applicationId is retrieved for use in queryFor has changed.

Ennov InSight 7.1 API Changes

This table describes the API changes for Ennov InSight 7.1.

Ennov InSight 7.1 includes the following API support.

Entity Name	API/Controller	Main endpoit	Description
OrphanDesignation	OrphanDesignationRestController	/orphan-designation	
EurdType	EurdTypeRestController	/data-admin/eurd-type	
DomainType	DomainTypeRestController	/data-admin/domain-type	
	ContentOfChangeTypeRestController	/content-of-change-type	
	MedicalProductActionTypeRestController	/medical-product-action-submission-status	
AttachedDocument	LicenseAttachedDocumentRestController	/license/attached-document	Hierarchy: Application->License->MedicinalProductAction->AttachedDocument
ManufacturedItem	ManufacturedItemRestController	/product-family/product/component/manufactured-item	
ManufacturedItemSubstance	ManufacturedItemSubstanceRestController	/product-family/product/component/manufactured-item/substance	
ManufacturedItemReferenceSubstance	ManufacturedItemReferenceSubstanceRestController	/product-family/product/component/manufactured-item/substance/reference	
LicensePackageSetName	LicensePackageSetNameRestController	/license/packageset/name	Hierarchy: Application->License->LicensePackageSetName
MedicinalProduct	LicenseMedicinalProductController	/license/medicinal-product	Hierarchy: Application->License->MedicinalProductAction

Entity Name	API/Controller	Main endpoit	Description
MedicinalProductAction	MedicinalProductActionRestController	/license/medicinal-product-action	
Mpname	MedicinalProductMpnameRestController	/license/medicinal-product/mpname	
MedicinalProductCrossReference	MedicinalProductCrossReferenceRestController	/license/medicinal-product/medicinalProductCrossReference	
DataCarrierType	DataCarrierTypeRestController	/data-admin/data-carrier-type	
DataClassificationType	DataClassificationTypeRestController	/data-admin/data-classification-type	
MarketingStatusReason	MarketingStatusReasonRestController	/data-admin/marketing-status-reason	
	RmsApplicationLegalBasisRestController	/data-admin/rms-app-legal-basis	
	RmsApplicationSubmissionTypeRestController	/data-admin/rms-app-submission-type	
	RmsAtcHumanRestController	/data-admin/rms-atc-human	
	RmsCombinationPackageRestController	/data-admin/rms-combination-package	
	RmsCombinedPharmaDoseFormRestController	/data-admin/rms-combined-pharma-dose-form	
	RmsCombinedTermRestController	/data-admin/rms-combined-term	
	RmsContactPartyRoleController	/data-admin/rms-contact-party-role	
	RmsCountryRestController	/data-admin/rms-country	
	RmsDomainRestController	/data-admin/rms-domain	

Entity Name	API/Controller	Main endpoit	Description
	RmsEURegulatoryAuthorisationProcedureRestController	/data-admin/rms-eu-regulatory-authority-procedure	
	RmsIngredientRoleRestController	/data-admin/rms-ingredient-role	
	RmsLanguageRestController	/data-admin/rms-language	
	RmsLegalStatusSupplyRestController	/data-admin/rms-legal-status-supply	
	RmsManufacturingActivityRestController	/data-admin/rms-manufacturing-activity	
	RmsMarketingStatusRestController	/data-admin/rms-marketing-status	
	RmsMasterFileTypeRestController	/data-admin/rms-master-file-type	
	RmsMedicalProductNamePartTypeController	/data-admin/rms-medical-product-name-part-type	
	RmsPackagingController	/data-admin/rms-packaging	
	RmsPharmaDoseFormRestController	/data-admin/rms-pharma-dose-form	
	RmsProductCategoryController	/data-admin/rms-product-category	
	RmsProductCrossReferenceTypeRestController	/data-admin/rms-product-cross-reference	
	RmsQuantityOperatorRestController	/data-admin/rms-quantity-operator	
	RmsRegulatoryEntitlementTypeController	/data-admin/rms-regulatory-entitlement-type	
	RmsRegulatoryEntitlementStatusConstoller	/data-admin/rms-regulatory-entitlement-status	

Entity Name	API/Controller	Main endpoit	Description
	RmsRoutesAndMethodsOfAdministrationRestController	/data-admin/rms-routes-methods-administration	
	RmsShelfLifeController	/data-admin/rms-shelf-life-type	
	RmsSpecialPrecautionForStorageRestController	/data-admin/rms-special-precaution-storage	
	RmsUnitsOfMeasurementRestController	/data-admin/rms-units-of-measurement	
	RmsUnitsOfPresentationRestController	/data-admin/rms-units-of-presentation	
	RmsXevmpdMedicalDevicesRestController	/data-admin/rms-xevmpd-medical-devices	
	RmsXevmpdMedicinalProductTypeRestController	/data-admin/rms-xevmpd-medicinal-product-type	
	RmsProductInformationDocumentController	/data-admin/rms-product-information-document-type	
	RmsMaterialController	/data-admin/rms-material/	
	RmsMedicalDictionaryForRegActivitiesController	/data-admin/rms-medical-dictionary-for-regulatory-activities/	
	RmsDataClassificationController	/data-admin/rms-data-classification	Data Classification Spor entity
SourceAuthorisation	SourceAuthorisationRestController	/data-admin/source-authorisation	parent is source/ manufacturer

Entity Name	API/Controller	Main endpoit	Description
OmsOrgLocation	OmsOrgLocationRestController	data-admin/oms-orglocation	This entity is a symbiosis of two EMA entities: Organisation and Location, which contains the fields of both entities: — number of records = number of Location per Organisation — entityId is ISM.TERMINOLOGY_SYSTEM_LIST_MEMBER.ID
DeviceCombinationType	DeviceCombinationTypeRestController	/data-admin/device-combination-type	This entity corresponds to the field "Device - Type of Combination" of the "Medical Device" Detail and mapped to SPOR master data set.
PhpId	PhpIdRestController	/product/xpharma-product/php-id	
	ContentOfChangeTypeRestController	/content-of-change-type	
	MedicalProductActionTypeRestController	/medical-product-action-submission-status	
PharmaProductSubstance	XPharmaProductSubstanceRestController	/product/xpharma-product/xpharma-product-substance	
PharmaProductRefSubstance	XPharmaProductRefSubstanceRestController	/product/xpharma-product/xpharma-product-substance/reference	
PharmaProductActiveIngredient	XPharmaProductActiveIngredientRestController	/product/xpharma-product/xpharma-product-active-ingredient	
PharmaProductRefActiveIngredient	XPharmaProductRefActiveIngredientRestController	/product/xpharma-product/xpharma-product-active-ingredient/reference	

Entity Name	API/Controller	Main endpoit	Description
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/ regulatory-entitlement-status	New Data Administration entity
ProvenanceReason	ProvenanceReasonRestController	/data-admin/ provenance-reason	New Data Administration entity
ProductInformationDocumentType	ProductInformationDocumentTypeRestController	/data-admin/product-information-document-type	New Data Administration entity
ProductCrossReferenceType	ProductCrossReferenceTypeRestController	/data-admin/product-cross-reference-type	New Data Administration entity
ProductCategory	ProductCategoryRestController	/data-admin/product-category	New Data Administration entity
PediatricIndicator	PediatricIndicatorRestController	/data-admin/ pediatric-indicator	New Data Administration entity
MedicinalProductNamePartType	MedicinalProductNamePartTypeRestController	/data-admin/ medicinal-product-name-part-type	New Data Administration entity
MedicalDeviceUDI	MedicalDeviceUDIRestController	/data-admin/medical-device-udi	New Data Administration entity
MasterFileType	MasterFileTypeRestController	/data-admin/master-file-type	New Data Administration entity
MarketingStatus	MarketingStatusRestController	/data-admin/ marketing-status	New Data Administration entity
DeviceTypeofCombination	DeviceTypeofCombinationRestController	/data-admin/device-type-of-combination	New Data Administration entity
AttachedDocumentContentType	AttachedDocumentContentTypeRestController	/data-admin/ attached-document-content-type	New Data Administration entity
ApplicationSubmissionType	ApplicationSubmissionTypeRestController	/application-submission-type	New Data Administration entity

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 updates		Description
			Attribute	Column	
License	PackageSetTypeRegistrationRestController	license/ packageset-registration	Added "/all", "/query" endpoints		
ProductLicense	ProductTypeRegistrationRestController	license/ product-registration	Added "/all", "/query" endpoints		
FullProductPresentation	LicenseFppController	license/full-product-presentation	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	/application-country	The following fields are added: — localStartTrial — localFirstVisit — localEndOfRecruitment — localEndOfTrial — localTemporaryHalted — localRestartTemporaryHalted — localEarlyTerminationReasonId — localEarlyTerminationReasonId	— LOCAL_START_OF_TRIAL_DATE — LOCAL_FIRST_VISIT_OF_FIRST_SUBJECT_DATE — LOCAL_END_OF_RECRUITMENT_DATE — LOCAL_END_OF_TRIAL_DATE — LOCAL_TEMP_HALT_DATE — LOCAL_RESTART_OF_TEMP_HALTED_TRIAL — LOCAL_EARLY_TERM_DATE — TERM_WITH_REASON_TYPE_ID	— DB table: .ISM.APP_COUNTRY — DB view: ISM.DV_APP_COUNTRY

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 7.1 Updates		Description
			Attribute	Column	
License	PackageSetTypeRegistrationRestController	"/license/packageset-registration"	The following field is added: — atcFlag	— column ATC_FLAG — size 1 — values "T", "F", "X"	<attr name="T">title.license.atcFlag.applied</attr> <attr name="F">title.license.atcFlag.notApplied</attr> <attr name="X">title.license.atcFlag.notApplicable</attr>

Entity Name	API/Controller	endpoint	API 7.1 Updates		Description
			Attribute	Column	
ProductLicense	ProductTypeRegistrationRestController	"/license/product-registration"	The following field is added: — atcFlag	— column ATC_FLAG — size 1 — values "T", "F", "X"	<attr name="T">title.license.atcFlag.applied</attr> <attr name="F">title.license.atcFlag.notApplied</attr> <attr name="X">title.license.atcFlag.notApplicable</attr>

Entity Name	API/Controller	endpoint	API 7.1 Updates		Description
			Attribute	Column	
LicensePackageSet	LicensePackageSetController	"/license/packageset"	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 — authorisationStatusId — authorisationStatusDate	— 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 7.1 Updates		Description
			Attribute	Column	
LicensePackageSetCountry	LicensePackageSetCountryRestController	"/license/packageset/country"	The following fields are added: — dataCarrierType — dataCarrierIdentifier — dataCarrierLanguageId — riskOfSupplyShortageFlag — riskOfSupplyShortageComment — marketingStatusReasonTypeId	— DATA_CARRIER_TYPE_ID This field is foreign key to: This field is foreign key to: 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_TYPE_ID This field is foreign key to: Class name: MarketingStatusReason; DB table: ISM.MARKETING_STATUS_REASON_TYPE	— Class name: LicensePackageSetCountry — DB table: ISM.LIC_PRODDET_COUNTRY — DB view: ISM.DV_LIC_PRODDET_COUNTR

Entity Name	API/Controller	endpoint	API 7.1 Updates		Description
			Attribute	Column	
ManufacturingFunctionGlobalDetail	ManufacturingFunctionGlobalDetailRestController	"/data-admin/manufacturing-function-global-detail"	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 now.

Entity Name	API/Controller	endpoint	API 7.1 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_TRADENAME String field.	— Class name: MedicalDeviceDetail — DB table: MGR.PDS_MED_DEVICE_CHANGE — DB view: ISM.DV_PDS_MED_DEVICE

Entity Name	API/Controller	endpoint	API 7.1 Updates		Description
			Attribute	Column	
SubstanceDetail	SubstanceDetailRestController	"/detail/substance"	The following fields are added: — presentationMeasureTypeId — presentationLowNumeratorValue — presentationLowNumeratorUnitOfMeasurement — presentationLowNumeratorUnitOfPresentation — presentationHighNumeratorValue — presentationHighNumeratorValue — presentationHighNumeratorUnitOfPresentation — concentrationLowNumeratorValue — concentrationLowNumeratorUnitOfMeasurement — concentrationLowDenominatorValue — concentrationLowDenominatorUnitOfMeasurement — concentrationHighNumeratorValue — concentrationHighNumeratorUnitOfMeasurement — concentration	— MEASURE_TYPE_ID column of MGR.CONCENTRATION_VALUE table DB table: ism.legal_basis_type. — PRESENTATION_LOW_AMT_NUMER_VALUE column of MGR.CONCENTRATION_VALUE table String field. — PRESENTATION_LOW_AMT_NUMER_UNIT_TYPE_ID column of MGR.CONCENTRATION_VALUE table — PRESENTATION_LOW_AMT_NUMER_UOP_TYPE_ID column of MGR.CONCENTRATION_VALUE table. — PRESENTATION_HI_AMT_NUMER_VALUE column of MGR.CONCENTRATION_VALUE table String field. — PRESENTATION_HI_AMT_NUMER_VALUE column of MGR.CONCENTRATION_VALUE table String field.	— Class name:SubstanceDetail — DB table:MGR.PDS_SUBSTANCE_CHANGE — DB view:ISM.DV_PDS_SUBSTANCE

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/substance-attachment

D2 Integration

About D2 Integration

This integration synchronizes the Ennov InSight entities with D2 System entities.

The following table lists Product Family and Custom Product Family types that are supported for this Integration, with their defined Ennov InSight keys for these Product Family types:

Product Family Name	Insight Key
Pharmaceutical	P
Pharmaceutical-Medical Device	PMD
Any custom type mapped to the Pharmaceutical internal type	C(P)
Any custom type mapped to the Pharmaceutical-Medical Device internal type	C(PMD)

D2 Data Integration Prerequisites

The following prerequisites should be met for a successful integration of Ennov InSight with D2 systems

— D2 dictionaries must have a format that includes both Key and Language columns.

— If the D2 dictionaries only have a Key column, then prior to integration with Ennov InSight a Language column should be added to these dictionaries and data in Key column should be duplicated in the Language column.
— D2 column lengths should match Ennov InSight's data column length.
— To function successfully, D2 field lengths must be at least equal to or greater than Ennov InSight field lengths.
— Existing Ennov InSight data should be migrated to the D2 system as part of initial migration.
— Fields in D2 that get data from Ennov InSight should be locked down in D2 and will be read-only fields in D2.

D2 Integration Settings

The configuration file that contains D2 error handling settings is located at: `InSightManager\server\all\deploy\hornetq\hornetq-configuration.xml`

There are two settings that can be adjusted in the `hornetq-configuration.xml` file, *redelivery-delay* and *max-delivery-attempts*.

Important: DO NOT adjust any other settings.

address-setting	Variable	Description	Type	Default Value
jms.queue.D2LifeSciencesQueue	*redelivery-delay*	The time (in milliseconds) between retries.	integer	120000
	max-delivery-attempts	The number of retries.	integer	10
jms.queue.D2LifeSciencesRetryQueue	*redelivery-delay*	The time (in milliseconds) between retries.	integer	3600000
	max-delivery-attempts	The number of retries.	integer	10

D2 Dictionary Configuration Settings

The following conditions enable the synchronization in D2.

Prerequisites

— Open Text needs to add GMP Drug Product Manufacturer and GMP Drug Substance Manufacturer dictionaries on their end in D2.

— For Application Procedure Type dictionary, additional code changes are required in Ennov InSight 7.1 apart from updating the configuration file.

Ennov InSight 7.1 allows you to enable the synchronization in D2.

Following are the D2 Data Dictionaries that are not currently integrated with Data Administration entities, can be synchronized via configuration files as needed:

— Application Procedure Type
— GMP Drug Product Manufacturer
— GMP Drug Substance Manufacturer

Modify`InSightManager\server\all\conf\insight\D2-IntegrationConfig.json` file by adding the following details for respective D2 Data Dictionaries:

— For GMP Dictionaries, add the following to the block "actions" with "triggertype": "Source".

```
{
           "externalEntity": "DrugProductmanufacturer",
           "externalEntityInfoRefs": [
           "DrugProductManufacturerData"
           ]
          },
          {
           "externalEntity": "DrugSubstanceManufacturer",
           "externalEntityInfoRefs": [
           "DrugSubstanceManufacturerData"
           ]
          }
```

— For Application Procedure Type Dictionary, add the following to the block "actions" with "triggerType": "APPPROC":

```
{
           "externalEntity": "ApplicationProcedureType",
           "externalEntityInfoRefs": [
           "ApplicationProcedureTypeData"
           ]
          },
```

D2 Data Dictionaries

D2 Data Dictionary: Application Status

When you create or update a value displayed in the following table in Data Administration, it will be created or updated as a read-only value in the Documentum D2 Data Dictionary.

InSight Data Admin Section	InSight Field Mapped to D2 Key	InSight Field Mapped to D2 Value	D2 Registration Form	D2 Entity	D2 Field
Application Status Values	Name	Name	Regulatory Application Registration Form	Regulatory Application Info	Application Status
Application Status Values	Name	Name	Submission Registration Form	Application Info (Edit Only)	Application Status

D2 Data Dictionary: Application Type

When you create or update a value displayed in the following table in Data Administration, it will be created or updated as a read-only value in the Documentum D2 Data Dictionary.

InSight Data Admin Section	InSight Field Mapped to D2 Key	InSight Field Mapped to D2 Value	D2 Registration Form	D2 Entity	D2 Field
Application Type Values	Application Type	Name	Submission Registration Form	Application Info (Edit Only)	Application Type
Application Type Values	Application Type	Name	Submission Registration Form	Submission Info (Create Only)	Application Type

D2 Data Dictionary: Dosage Forms

When you create or update a value displayed in the following table in Data Administration, it will be created or updated as a read-only value in the Documentum D2 Data Dictionary.

InSight Data Admin Section	InSight Field Mapped to D2 Key	InSight Field Mapped to D2 Value	D2 Registration Form	D2 Entity	D2 Field
Dosage/ Pharmaceutical Forms Values	Dosage Form (Long Name)	Dosage Form (Long Name)	Project Registration Form	Drug Product	Dosage Forms

D2 Data Dictionary: Dosage Levels

When you create or update a value displayed in the following table in Data Administration, it will be created or updated as a read-only value in the Documentum D2 Data Dictionary.

InSight Data Admin Section	InSight Field Mapped to D2 Key	InSight Field Mapped to D2 Value	D2 Registration Form	D2 Entity	D2 Field
Not Applicable	Product ID/ Oracle ID	— The values from the **Product Strength Measure 1**, **Product Strength Unit 1**, **Product Strength Measure 2**, and **Product Strength Unit 2** fields are concatenated (as displayed on the *View Product Attributes* page) and added to Documentum D2. — Where a slash ('/') is included, this must be translated to a hyphen.	Project Registration Form	Drug Product	Dosage Strength

D2 Data Dictionary: Geographic Regions

When you create or update a value displayed in the following table in Data Administration, it will be created or updated as a read-only value in the Documentum D2 Data Dictionary.

InSight Data Admin Section	InSight Field Mapped to D2 Key	InSight Field Mapped to D2 Value	D2 Registration Form	D2 Entity	D2 Field
Region Values	Region Abbreviation	Region Name	Regulatory Application Registration Form	Regulatory Application Info	Geographic Region
Region Values	Region Abbreviation	Region Name	Submission Registration Form	Application Info (Edit Only)	Geographic Region
Region Values	Region Abbreviation	Region Name	Submission Registration Form	Submission Info (Create Only)	Geographic Region

D2 Data Dictionary: Health Authority

When you create or update a value displayed in the following table in Data Administration, it will be created or updated as a read-only value in the Documentum D2 Data Dictionary.

InSight Data Admin Section	InSight Field Mapped to D2 Key	InSight Field Mapped to D2 Value	D2 Registration Form	D2 Entity	D2 Field
Country-Health Authority Values	Country Code - Health Authority	Health Authority Name	Regulatory Application Registration Form	Regulatory Application Info	Health Authority
Country-Health Authority Values	Country Code - Health Authority	Health Authority Name	Submission Registration Form	Application Info (Edit Only)	Health Authority
Country-Health Authority Values	Country Code - Health Authority	Health Authority Name	Submission Registration Form	Submission Info (Create Only)	Health Authority

D2 Data Dictionary: Regulatory Submission Type

When you create or update a value displayed in the following table in Data Administration, it will be created or updated as a read-only value in the Documentum D2 Data Dictionary.

InSight Data Admin Section	InSight Field Mapped to D2 Key	InSight Field Mapped to D2 Value	D2 Registration Form	D2 Entity	D2 Field
Filing Type Values	Filing Type Name	Filing Type Name	Submission Registration Form	Application Info (Edit Only)	Submission Procedure Type
Filing Type Values	Filing Type Name	Filing Type Name	Submission Registration Form	Submission Info (Create Only)	Submission Type
Filing Type Values	Filing Type Name	Filing Type Name	Submission Registration Form	Submission Info (Edit Only)	Submission Type

D2 Data Dictionary: Route of Administration List

When you create or update a value displayed in the following table in Data Administration, it will be created or updated as a read-only value in the Documentum D2 Data Dictionary.

InSight Data Admin Section	InSight Field Mapped to D2 Key	InSight Field Mapped to D2 Value	D2 Registration Form	D2 Entity	D2 Field
Route of Administration Values	Route of Administration	Route of Administration	Project Registration Form	Drug Product	Route of Admin

D2 Data Dictionary: Submission Country

When you create or update a value displayed in the following table in Data Administration, it will be created or updated as a read-only value in the Documentum D2 Data Dictionary.

InSight Data Admin Section	InSight Field Mapped to D2 Key	InSight Field Mapped to D2 Value	D2 Registration Form	D2 Entity	D2 Field
Country Values	Country Code	Country Name	Product Registration Form	Product Info	Product Trade Country
Country Values	Country Code	Country Name	Regulatory Application Registration Form	Product/Project Info	Product Trade Country
Country Values	Country Code	Country Name	Submission Registration Form	Application Info (Edit Only)	Submission Country
Country Values	Country Code	Country Name	Submission Registration Form	Product/Project Info	Product Trade Country
Country Values	Country Code	Country Name	Submission Registration Form	Submission Info (Create Only)	Submission Country
Country Values	Country Code	Country Name	Regulatory Application Registration Form	Regulatory Application Info	Submission Country

D2 Data Dictionary: Submission Status

When you create or update a value displayed in the following table in Data Administration, it will be created or updated as a read-only value in the Documentum D2 Data Dictionary.

InSight Data Admin Section	InSight Field Mapped to D2 Key	InSight Field Mapped to D2 Value	D2 Registration Form	D2 Entity	D2 Field
Sequence Status	Name	Name	Submission Registration Form	Submission Info (Create Only)	Submission Status

InSight Data Admin Section	InSight Field Mapped to D2 Key	InSight Field Mapped to D2 Value	D2 Registration Form	D2 Entity	D2 Field
Sequence Status	Name	Name	Submission Registration Form	Submission Info (Edit Only)	Submission Status

D2 Forms

Create D2 Forms

D2 integration synchronizes Ennov InSight entities with D2 System entities and provides the ability to create Forms.

You can create Forms according to the following rules:

— When a Product Family is created in Ennov InSight, both a Product Registration Form and a Project Registration Form will be created within Documentum D2.
— When an Application is created under a Product Family in Ennov InSight, a Regulatory Application Registration Form will be created within Documentum D2.
— When a Sequence is created within a Product Family in Ennov InSight, a Submission Registration Form will be created within Documentum D2.
— All forms (Product Registration Form, Project Registration Form, Regulatory Application Registration Form and Submission Registration Form) have `external_system_attribute` in the properties list.
— All forms (Product Registration Form, Project Registration Form, Regulatory Application Registration Form and Submission Registration Form) are currently created in Active status in D2 as the required fields in D2 SDK are either equal or subset of the required fields in Ennov InSight 7.1 for that entity.
— The flag for `external_system_attribute`, is always set to True.
— The value for the `external_system_attribute` cannot be empty.

However, the Product Registration Form, Project Registration Form, RARF, and SARF are created only if the Product Family type is one of the following:

— Pharmaceutical
— Pharmaceutical-Medical Device
— Any custom Product Family type that is mapped to the Pharmaceutical or Pharmaceutical-Medical Device internal type
— Any Product Family type in Data Administration that is modified and mapped to any of the Pharmaceutical or Pharmaceutical-Medical Device internal type

The following Product Family types are not integrated for the creation of D2 Forms, but can be used with Open Text Documentum:

— Medical Device
— Veterinary
— Flu Vaccine
— Any custom type that is mapped to Medical Device/Veterinary/Flu vaccine

Following are the existing Ennov InSight keys for the Product Family types:

— FV = flu vaccine

— P = pharmaceutical
— MD = medical device
— PMD = pharmaceutical-medical device
— V = veterinary

Following are the existing Ennov InSight keys for the Custom Product Family types:
— C(P) - any custom type mapped to the Pharmaceutical internal type
— C(PMD) - any custom type mapped to the Pharmaceutical-Medical Device internal type
— C(MD) - any custom type mapped to the Medical Device internal type
— C(V) - any custom type mapped to the Veterinary internal type
— C(FV) - any custom type mapped to the Flu Vaccine internal type

The following table describes the D2 Forms that are created/updated for different Product Family types and their related entities.

Product Family Type	Related Entity	Product Registration Form	Project Registration Form	Regulatory Application Registration Form	Submission Registration Form	Description
— P — PMD — C(P) — C(PMD)	Product Family	Y	Y			The Project Registration form and the Product Registration Form are created for a Product Family. — The Project Registration Form is updated when a Product is added under the specific Product Family. — The RARF Form is created when an Application is created for a specific Product Family. — The SRF Form is created when a Sequence is created for a specific Product Family. — The RARF and SRF Forms are updated when you associate/ disassociate a Product from an Application.
	Product		Y (Update)			
	Application			Y		
	Sequence				Y	
— MD — V — FV — C(MD) — C(V) — C(FV)	Product Family	N	N			No D2 Forms are created.
	Product		N (Update)			
	Application			N		
	Sequence				N	

D2 Product Registration Form

The Product Registration Form in the Documentum D2 system is created or updated when any of the business rules displayed below are fulfilled.

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
Data Administration: Substance Values	Active Ingredient INN	inn_names	If a Substance is updated in Data Administration that corresponds to an Active Ingredient associated with a Product Family, the Product Registration Form is updated. If an Active Ingredient is deleted from Ennov InSight, D2 still keeps the Active Ingredient information.

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
PDS Country	Country Trade Name	product_trade_name	The Country Trade Name and corresponding Country are added to the Product Registration Form for each PDS associated to the Product Family, through the Product/Application (regardless of Country) for nodes of all statuses. The system does not allow for the creation of duplicate values (combination of Country and Trade Name). Where the country is the same, but the trade name is different, a new row will exist. If the Trade Name is updated in Data Administration in Ennov InSight, a new row is created in D2 and Trade Name is updated. D2 keeps the old record and updates the new record in a new row. If the Trade Name is updated for the Country in the PDS, a new row is created in D2 and Trade Name is updated for that Country. D2 keeps the old record and updates the new record in a new row.
	Country (uses Country Code)	product_trade_country	The Country Trade Name and the corresponding Country are added to the Product Registration Form for each PDS associated to the Product Family, through the Product/Application (regardless of Country), for nodes of all statuses. If the Country is updated in Data Administration in Ennov InSight, a new row is created in D2 and Country is updated. D2 keeps the old record and updates the new record in a new row. If the Country is deleted from the PDS, D2 still keeps the Country value.

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
Active Ingredient	Active Ingredient Name	drug_substance_name	There can be multiple Active Ingredients per Product Family. If a Substance Name is updated in Data Administration in Ennov InSight, a new row is created in D2 and Substance Name is updated. D2 keeps the old record and updates the new record in a new row.
Product Family	Indications/ Intended Use	indication	The Product Registration Form is updated listing all Indications from the Product Family in Ennov InSight. If the Indication is updated in Data Administration in Ennov InSight, a new row is created in D2 and Indication value is updated. D2 keeps the old record and updates the new record in a new row. If the Indication is deleted from the Product Family in Ennov InSight, D2 still keeps the Indication information.
	Product Family Code	product_code	When a Product Family is created in Ennov InSight, a corresponding Product Registration Form is created within D2.
	Generic Name	product_generic_name	The value is pulled from the parent Product Family when the Active Ingredient is added to the Product Registration Form. If the Generic Name is updated in Data Administration for the Product Family in Ennov InSight, a new row is created in D2 and Generic Name is updated. D2 keeps the old record and updates the new record in a new row.

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
Data Administration: Substance Values	Compound Number	product_compound_id	If a Substance is updated in Data Administration that corresponds to an Active Ingredient used within a Product Family, the Product Registration Form is updated. If the Compound Number is updated for the Substance in Data Administration in Ennov InSight, a new row is created in D2 and Compound Number is updated. D2 keeps the old record and updates the new record in a new row.
	Molecular Formula	product_chemical_names	If a Substance is updated in Data Administration that corresponds to an Active Ingredient used within a Product Family, the Product Registration Form is updated. If the Molecular Formula is updated for the Substance in Data Administration in Ennov InSight, a new row is created in D2 and Product Chemical Name/ Molecular Formula value is updated. D2 keeps the old record and updates the new record in a new row.

Tip:

- *Information deleted in will continue to exist in D2 system.*
- *If a field on an integrated entity is updated, and it does not correspond to a column in the grid in D2, the existing Form is updated.*
- *If a field on and integrated entity is updated, and it corresponds to a column in the grid in D2, a new row is created keeping the old record in the D2 grid.*

D2 Project Registration Form

The Project Registration Form in the Documentum D2 system is created or updated when any of the following business rules are fulfilled.

Ennov InSight Entity	Ennov InSight Field	Field on D2 Form	Business Rules
Component Active Ingredient	Active Ingredient	drug_substance	Based on the Active Ingredients associated to the Product Family. For each Active Ingredient within the Product Family, a new row is created on the Drug Substance tab populating the Active Ingredient Name within D2. If a Substance Name is updated in Data Administration in Ennov InSight, a new row is created in D2 and Substance Name is updated. D2 keeps the old record and updates the new record in a new row.

Ennov InSight Entity	Ennov InSight Field	Field on D2 Form	Business Rules
PDS Active Ingredient	Active Ingredient Manufacturer	drug_substance_manufacturer	The value populates the row corresponding to the related product within the Drug Substance tab of the D2 properties (Project Registration Form). For each Component Active Ingredient within the Product Family, a new row will be created on the Drug Substance tab populating the Component Active Ingredient Manufacturer within D2. Semicolon separated list of manufacturers will be found under the Component > Active Ingredient > Manufacturer node within the Ennov InSight PDS node. This will occur for nodes of all statuses. While there is no Function under the Manufacturer node, you can configure the location within the PDS to pull the manufacturer from and define a related function if that node has functions. When multiple values exist, a new row is created for every Manufacturer in D2. If a Manufacturer Name is updated in Data Administration in Ennov InSight, a new row is created in D2 and Manufacturer Name is updated. D2 keeps the old record and updates the new record in a new row. If the Manufacturer is deleted from the PDS Active Ingredient entity in Ennov InSight, D2 still keeps the Manufacturer information.

Ennov InSight Entity	Ennov InSight Field	Field on D2 Form	Business Rules
PDS Indication/ Intended Use	Indications/ Intended Use	indication	The Project Registration Form is updated for each PDS associated to the Product through an Application (regardless of Country), for nodes of all statuses. The value populates the row corresponding to the related product on the Drug Product tab of the D2 properties (Project Registration Form). Where multiple values exist, a new row is created for every Indication/ Intended use in D2. For each Product within the Product Family, a new row will be created on the Drug Product tab populating the Indication within D2. If the Indication is updated in Data Administration in Ennov InSight, a new row is created in D2 and Indication value is updated. D2 keeps the old record and updates the new record in a new row. If the Indication is deleted from the PDS, D2 still keeps the Indication information.

Ennov InSight Entity	Ennov InSight Field	Field on D2 Form	Business Rules
PDS Manufacturer	Manufacturer (Name)	drug_product_manufacturer	From the PDS > Manufacturer node, get the Manufacturer if the associated Function is named as 'Manufacture'. The related function name is configurable. Configure the location within the PDS to pull the manufacturer from. For each Product within the Product Family, a new row is created on the Drug Product tab populating the Manufacturer (Name) within D2. The value populates the row corresponding to the related product on the Drug Product tab of the D2 properties (Project Registration Form). This occurs for nodes of all statuses. When multiple values exist, a new row is created for every Manufacturer (Name) in D2. If a Manufacturer Name is updated in Data Administration in Ennov InSight, a new row is created in D2 and Manufacturer Name is updated. D2 keeps the old record and updates the new record in a new row. If the Manufacturer is deleted from the PDS, D2 still keeps the Manufacturer information.

Ennov InSight Entity	Ennov InSight Field	Field on D2 Form	Business Rules
Product	Product Code - Full Product Name	external_product_name_dp	Row is populated per product in Ennov InSight, with: <Product Code><space><Full Product Name> Example: `123 Pharmaceutical` The field name mapping is configurable. If the Product Code or Product Name is updated in the Product Attribute page in Ennov InSight, a new row is created in D2 and Product information is updated. D2 keeps the old record and updates the new record in a new row.
	Product Dosage Form	dosage_form	For each Product within the Product Family, a new row is created on the Drug Product tab populating the Dosage Form within D2. A new row will exist for every Dosage Form of the product. If the Product Dosage Form is updated in the Product Attribute page in Ennov InSight, a new row is created for the corresponding Product in D2 and Dosage Form is updated. D2 keeps the old record and updates the new record in a new row. If the Product Dosage Form is updated in Data Administration in Ennov InSight, a new row is created in D2 and Product Dosage Form is updated. D2 keeps the old record and updates the new record in a new row.
	Product Route of Administration	route_of_admin	For each Product within the Product Family, a new row is created on the Drug Product tab populating the Route of Administration within D2. A new row will exist for every Route of Administration for the product. If the Product Route of Administration is updated in Data Administration in Ennov InSight, a new row is created in D2 and Route of Administration is updated. D2

Ennov InSight Entity	Ennov InSight Field	Field on D2 Form	Business Rules
Product Family	Family Name	project_name	One Project Registration Form is created per Product Family.
	Family Code	product_code	One Project Registration Form is created per Product Family.

Tip:

- *Information deleted in will continue to exist in D2 system.*
- *If a field on an integrated entity is updated, and it does not correspond to a column in the grid in D2, the existing Form is updated.*
- *If a field on and integrated entity is updated, and it corresponds to a column in the grid in D2, a new row is created keeping the old record in the D2 grid.*

D2 Regulatory Application Registration Form

The Regulatory Application Registration Form in the Documentum D2 system is created or updated when any of the following business rules are fulfilled.

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
Application	Application Code	application_num	The Application Number field is populated with the Application Code value. If the Application Code is updated in Ennov InSight, a new row is created in D2 and the Application Number value is updated. D2 keeps the old record and updates the new record in a new row.
	Application Status	application_status	N/A
	Application Type	application_type	N/A
	Countries	submission_country	Populated by the Reviewing Country for the Application.
	Countries (defined as CMS)	concerned_member_states	When the Procedure Type for the Application is linked to the External System Procedure Type Code `MRP` and `DCP`, the Concerned Member States field is populated on the Regulatory Application Registration Form. The Concerned Member States table is populated with the Health Authority and Application Code values. If the Country is updated in Data Administration in Ennov InSight, a new row is created in D2 and the Country value is updated. D2 keeps the old record and updates the new record in a new row. If the Country is deleted from the Application > Countries, D2 still keeps the Country value.
	Application Name	application_description (SDK: regulatoryForm)	The Application Name is prefixed with the Application Code and suffixed with the Product Family Code. Application Code and Application Name are separated with a hyphen. The value with this preferred combination appears for the RARF name in the `Doc List` section as

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
Data Admin: Country Values	Region	region	If a Country value is updated in Data Administration that corresponds to a Country used within an Application, the Regulatory Application Registration Form is updated. D2 Regions should be the regulatory region for the reviewing country only.
	Health Authority (Name)	health_authority	If a Country value updated in Data Administration corresponds to a Country used within an Application, the Regulatory Application Registration Form is updated. If a Country is associated with more than one Authority, a row is created for each unique combination of Country and Health Authority. If the Health Authority is updated for the Country in Data Administration in Ennov InSight, a new row is created in D2 and the Health Authority value is updated. D2 keeps the old record and updates the new record in a new row.

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
Data Admin: Substance Values	Active Ingredient INN	inn_names	If a Substance updated in Data Administration corresponds to an Active Ingredient used within a Product for the Application, the value is inherited and the Regulatory Application Registration Form is updated. If the INN is updated for the Substance in Data Administration in Ennov InSight, a new row is created in D2 and INN value is updated. D2 keeps the old record and updates the new record in a new row.
	Compound Number	product_compound_id	If a Substance is updated in Data Administration that corresponds to an Active Ingredient used within a Product for the Application, the value is inherited and the Regulatory Application Registration Form is updated. If the Compound Number is updated for the Substance in Data Administration in Ennov InSight, a new row is created in D2 and Compound Number is updated. D2 keeps the old record and updates the new record in a new row.
	Molecular formula	product_chemical_names	If a Substance is updated in Data Administration that corresponds to an Active Ingredient used within a Product for the Application, the value is inherited and the Regulatory Application Registration Form is updated. If the Molecular Formula is updated for the Substance in Data Administration in Ennov InSight, a new row is created in D2 and Product Chemical Name/Molecular Formula value is updated. D2 keeps the old record and updates the new record in a new row.

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
PDS Active Ingredient	Active Ingredient Manufacturer	drug_substance_manufacturer	Only the values from the Project Registration Form that are applicable to the Product on the Application are inherited. For each Active Ingredient within the Product Family, a new row is created on the Drug Substance tab populating the Active Ingredient Manufacturer within D2. This occurs for nodes of all statuses. If a Manufacturer Name is updated in Data Administration in Ennov InSight, a new row is created in D2 and Manufacturer Name is updated. D2 keeps the old record and updates the new record in a new row. If the Manufacturer is deleted from the PDS Active Ingredient entity in Ennov InSight, D2 still keeps the Manufacturer information.
PDS Country	Country Trade Name	product_trade_name	For each Product within the Product Family, a new row is created on the Drug Product tab populating the Trade Names within D2. This occurs for nodes of all statuses. Value is inherited in D2.
	Country Name	product_trade_country	Value is inherited in D2.

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
PDS Manufacturer	PDS Manufacturer (Name)	drug_product_manufacturer	For each Product within the Product Family, a new row is created on the Drug Product tab populating the Manufacturer (Name) within D2. This occurs for nodes of all statuses. Only the values from the Project Registration Form that are applicable to the Product on the Application are inherited. If a Manufacturer Name is updated in Data Administration in Ennov InSight, a new row is created in D2 and Manufacturer Name is updated. D2 keeps the old record and updates the new record in a new row. If the Manufacturer is deleted from the PDS, D2 still keeps the Manufacturer information.

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
Product	Product Code - Full Product Name	external_product_name_dp	Value inherited from Project Registration Form.
	Active Ingredient	drug_substance	Only the values from the Project Registration Form that are applicable to the Product on the Application are inherited. For each Active Ingredient within the Product Family, a new row is created on the Drug Substance tab populating the Active Ingredient Name within D2. If a Substance Name is updated in Data Administration in Ennov InSight, a new row is created in D2 and Substance Name is updated. D2 keeps the old record and updates the new record in a new row.
	Indications/ Intended Use	indication	The value in the Regulatory Application Registration Form is inherited for each PDS associated to the Product through an Application (regardless of Country) for nodes in all the statuses. For each Product within the Product Family, a new row is created on the Drug Product tab populating the Indication within D2. The value populates the row corresponding to the related product, on the Drug Products tab of the Product/Project Info tab on the D2 properties Regulatory Application Registration Form. Where multiple values exist, a new row is created for every Indication/ Intended Use.
	Product Dosage Form	dosage_form	For each Product within the Product Family, a new row is created on the Drug Product tab populating the Dosage Form within D2. The inherited value is populated in the row corresponding to the related product on the Drug Products tab of

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
Product Family	Family Name	project_name	The inherited value is used to create the Form hierarchy within D2.
	Family Code	product_code	The inherited value is used to create the Form hierarchy within D2.
	Generic Name	product_generic_name	Value is inherited in D2. If the Generic Name is updated for the Product Family in Ennov InSight, a new row is created in D2 and Generic Name is updated. D2 keeps the old record and updates the new record in a new row.

Tip:

- *Information deleted in will continue to exist in D2 system.*
- *If a field on an integrated entity is updated, and it does not correspond to a column in the grid in D2, the existing Form is updated.*
- *If a field on and integrated entity is updated, and it corresponds to a column in the grid in D2, a new row is created keeping the old record in the D2 grid.*

D2 Submission Registration Form

The Submission Registration Form in the Documentum D2 system is created or updated when any of the following business rules are fulfilled.

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
Application	Application Name	application_description	The Application Name is prefixed with the Application Code and suffixed with the Product Family Code. Application Code and Application Name will be separated with a hyphen. Value is inherited in D2.
	Countries (defined as CMS)	concerned_member_states	Value is inherited in D2. When the Procedure Type for the Application is linked to the **External System Procedure Type Code** `MRP` and `DCP`, the Concerned Member States field is populated on the Regulatory Application Registration Form. Concerned Member State table is populated with the Health Authority and Application Code values. If the Country is updated in Data Administration in Ennov InSight, a new row is created in D2 and the Country value is updated. D2 keeps the old record and updates the new record in a new row. If the Country is deleted from the **Application > Countries**, D2 still keeps the Country value.
	Procedure Type	submission_procedure_type	When updated, a Procedure Type value in Ennov InSight contains the following text for D2 to acknowledge the type of procedure it is: – When the **External System Procedure Type Code** is `CP`, the Procedure Type in D2 is set to Centralized. – When the **External System Procedure Type Code** is `DCP`, the Procedure Type in D2 is set to Decentralized. – When the **External System Procedure Type Code** is `MRP`, the Procedure Type in D2 is set to Mutual Recognition.

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
Data Administration: Substance Values	Active Ingredient INN	inn_names	If a Substance is updated in Data Administration that corresponds to an Active Ingredient used within a Product Family, the value is inherited and the Submission Registration Form is updated.
	Compound Number	product_compound_id	If a Substance is updated in Data Administration that corresponds to an Active Ingredient used within a Product Family, the value is inherited and the Submission Registration Form is updated. If the Compound Number is updated for the Substance in Data Administration in Ennov InSight, a new row is created in D2 and Compound Number is updated. D2 keeps the old record and updates the new record in a new row.
	Molecular Formula	product_chemical_names	If a Substance is updated in Data Administration that corresponds to an Active Ingredient used within a Product Family, the value is inherited and the Submission Registration Form is updated.
PDS Active Ingredient	Active Ingredient Manufacturer	drug_substance_manufacturer	Only the values from the Project Registration Form that are applicable to the Product on the Application are inherited. For each Active Ingredient within the Product Family, a new row is created on the Drug Substance tab populating the Active Ingredient Manufacturer within D2. This occurs for nodes of all statuses.

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
PDS Country	Country Trade Name	product_trade_name	For each Product within the Product Family, a new row will be created on the Drug Product tab populating the Trade Names within D2. This will occur for nodes in all the statuses. Value is inherited in D2. If the Trade Name is updated in Data Administration in Ennov InSight, a new row is created in D2 and Trade Name is updated. D2 keeps the old record and updates the new record in a new row. If the Trade Name is updated for the Country in the PDS, a new row is created in D2 and Trade Name is updated for that Country. D2 keeps the old record and updates the new record in a new row.
	Country Name	product_trade_country	Value is inherited in D2.

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
PDS Manufacturer	PDS Manufacturer (Name)	drug_product_manufacturer	For each Product within the Product Family, a new row is created on the Drug Product tab populating the Manufacturer (Name) within D2. This occurs for nodes of all statuses. Only the values from the Project Registration Form that are applicable to the Product on the Application are inherited. If a Manufacturer Name is updated in Data Administration in Ennov InSight, a new row is created in D2 and Manufacturer Name is updated. D2 keeps the old record and updates the new record in a new row. If the Manufacturer is deleted from the InSight PDS, D2 still keeps the Manufacturer information.

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
Product	Product Code - Full Product Name	external_product_name_dp	Value inherited from Project Registration Form.
	Active Ingredient	drug_substance	Only the values from the Project Registration Form that are applicable to the Product on the Application are inherited. For each Active Ingredient within the Product Family, a new row is created on the Drug Substance tab populating the Active Ingredient Name within D2. If a Substance Name is updated in Data Administration in Ennov InSight, a new row is created in D2 and Substance Name is updated. D2 keeps the old record and updates the new record in a new row.
	Indications/ Intended Use	indication	The value in the Regulatory Application Registration Form is inherited for each PDS associated to the Product, through an Application (regardless of Country), for nodes in all statuses. For each Product within the Product Family, a new row is created on the Drug Product tab populating the Indication within D2. The inherited value populates the row corresponding to the related product on the Drug Products tab of the Product/Project Info tab on the D2 properties Submission Registration Form. Where multiple values exist, a new row is created for every Indication/Intended Use. If the Indication Name is updated in Data Administration in Ennov InSight, a new row is created in D2 and Indication Name is updated. D2 keeps the old record and updates the new record in a new row.

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
Product Family	Product Family Code	product_code	Value is inherited in D2.
	Generic Name	product_generic_name	Value is inherited in D2.
Sequence	Filing Type	submission_type	N/A
	Sequence Code	submission_number	N/A
	Sequence Status	submission_status	N/A
	Sequence Status Date	submission_date	N/A
	Sequence Name	submission_name	Sequence Name is displayed in the Submission Name field in D2.

LIQUENT InSight Entity	LIQUENT InSight Field	Field on D2 Form	Business Rules
Event	Event Name	event_name	If the Event Name is displayed as selected Event Name in the Sequence entity, then the corresponding Event Name is displayed in the event_name field in D2. If more than one Event is associated with the Sequence in Ennov InSight, a new row is created for every Event Name in D2. When an Event Name that is associated with a Sequence in Ennov InSight is updated, the Event Name in D2 is also updated. If Event(s) are disassociated from the Sequence in Ennov InSight, Event Name information still exists in D2.
	Event Code	event_code	If the Event Name is displayed as selected Event Name in the Sequence entity, then Event Code is displayed in the event_code field in D2. When an Event Code that is associated with a Sequence in Ennov InSight is updated, the Event Code in D2 is also updated. If Event(s) are disassociated from the Sequence in Ennov InSight, Event Code information still exists in D2.
	Event Type	event_type	If the Event Name is displayed as selected Event Name in the Sequence entity in Ennov InSight, Event Type is displayed in the event_type field in D2. When an Event Type that is associated with a Sequence in Ennov InSight is updated, the Event Type in D2 is also updated. If Event(s) are disassociated from the Sequence in Ennov InSight, Event Type information still exists

Tip:

- *Information deleted in will continue to exist in D2 system.*
- *If a field on an integrated entity is updated, and it does not correspond to a column in the grid in D2, the existing Form is updated.*
- *If a field on and integrated entity is updated, and it corresponds to a column in the grid in D2, a new row is created keeping the old record in the D2 grid.*

Update D2 Forms with PDS Nodes

When the Product Detail Set details are created/updated in the Ennov InSight, D2 Forms gets updated.
The following table describes the PDS statuses based on which D2 Forms get updated:

D2 Forms	PDS Status	Status Description	D2 Forms Updates
– Project Registration Form – Product Registration Form – Regulatory Application Registration Form – Submission Registration Form	Pending Add	New PDS details are added when approval by the regulatory agency is granted.	Yes
	Approved	The detail has been approved by the regulatory agency.	Yes
	Not Approved	The detail has not been approved by the regulatory agency.	Yes
	Pending Withdrawal	The detail is to be withdrawn when approval by the regulatory agency is granted.	No
	Withdrawn	Organisation has submitted a request to withdraw a detail and the regulatory agency has approved the withdrawal.	No ***Note:*** *PDS details are not removed from the D2 Forms in a Withdrawn operation.*
	Not Approved	The detail has not been approved by the regulatory agency.	No ***Note:*** *When changing* ***Pending Withdrawal*** *node status to* ***Not Approved*** *only.*
	Pending Modify	The detail is to be changed when approval by the regulatory agency is granted.	Yes

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.

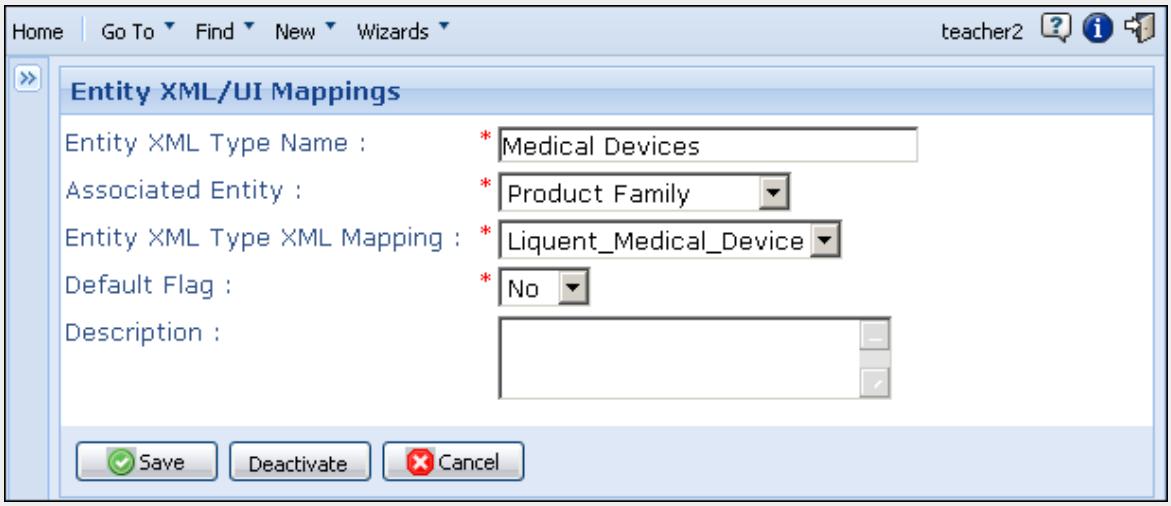
Create a Product Family Type or Component Type

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 Product Family Maintenance, click Entity XML/UI Mappings.
   The *Entity XML/UI Mappings* page appears.
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 will be 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.

Example



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.

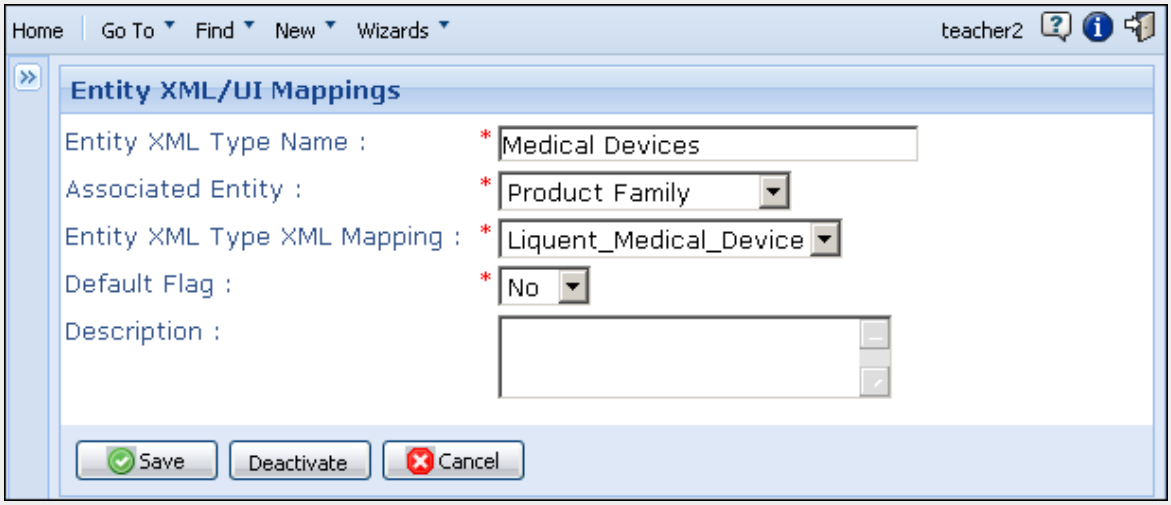
To modify a product family type or component type:

1. From the *Data Administration* page, under Product Family Maintenance, click Entity XML/UI Mappings.
   The *Entity XML/UI Mappings* page appears.
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.

Example



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.
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	a. Select a reason and enter comments for the reason. b. Select Save. c. Validate your identity by entering your user credentials in the dialog box.
When electronic signature is enabled and SSO is disabled	a. Select a reason and enter comments for the reason. b. 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.
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.

Entity	Guidelines
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 lifecycle.

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.

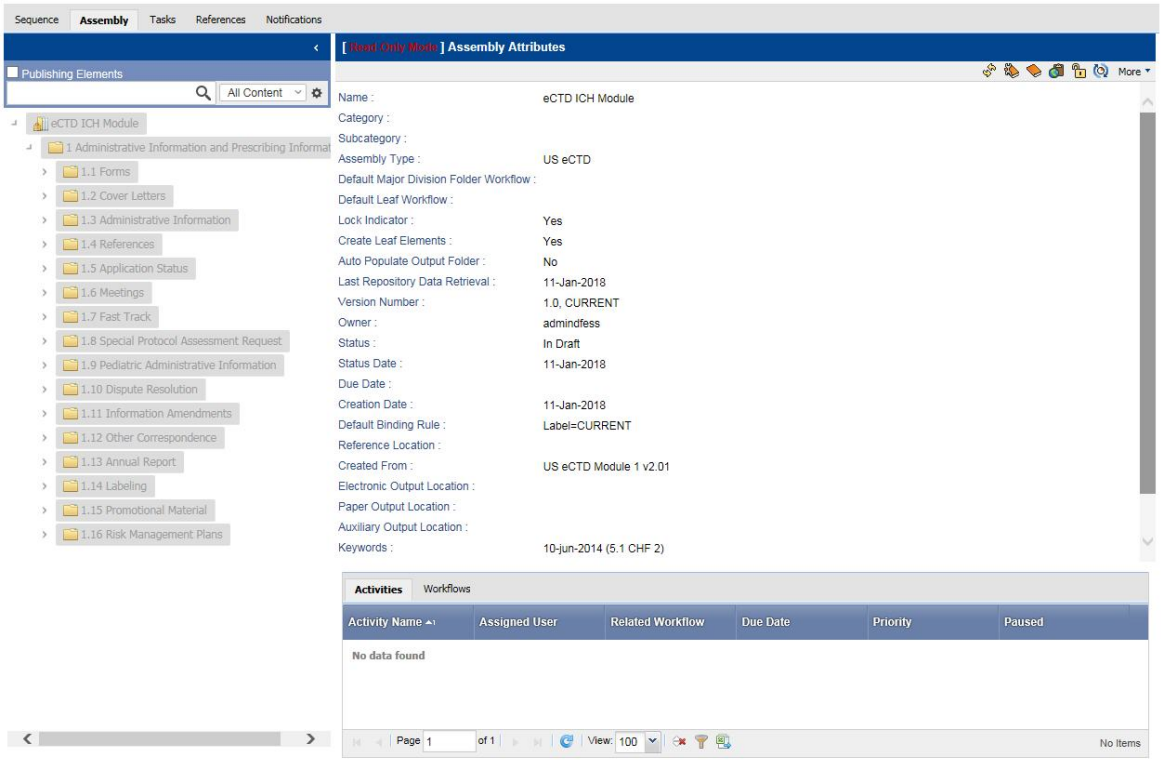
Example

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 lifecycle.



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.
4. Click .
5. Click OK when you are prompted to confirm the unlock.

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 Templates

You can use the eCTD templates provided with Ennov InSight to streamline the process of creating eCTD 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 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 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 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. 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. You must determine where you are going to maintain the definition files and configure the templates to point to that location.

Note: *The XML definition files path is configured in the* `insight.var` *file using the configuration utility. It is important to note that this is case sensitive if you store them in Documentum or in a case-sensitive file system.*

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 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 Module 1 CTD v2.1.xml
— AU Module 1 CTD-NeeS v2.0 2011.xml
— AU Module 1 NeeS v2.0.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 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
- JP eCTD Module 1 v1.0.xml
- JP eCTD Module 2-5 v3.2.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

— TH eCTD Module 1 v.0.92.xml
— TH eCTD Module 1 v.1.0.xml
— US eCTD Module 1 v2.01.xml
— US eCTD Module 1 v3.3.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
— UCSampleTOCTemplate.docx

Import eCTD Applications

When you import an eCTD application you can import the entire eCTD, a series of eCTD sequences. The eCTD sequences are imported into an existing application with the required views.
The following files, at a minimum, 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 only have 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 not be referenced in the assembly: only leafs will be created. To ignore 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. The location of these folders must be in a mapped file system repository. 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 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 ensure successful importing of eCTD assemblies, confirm that specific conditions are met in your system.

- In Data Administration > Other > 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 LIQUENT InSight.
- The `index`, `regional`, and `content` files must follow the naming convention `filename.extension`. This is not an issue on 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.
   For performance reasons, the status of the import is logged to the `server.log` file on the Application server (rather than to the job requests).

Bulk eCTD Import Wizard

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 the Application Code value.

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) "<coma separated list of application codes from xml>" cannot be matched in the system, please create the Application and try again."`

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.*

---

10. 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.`"
11. 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 dæmon.
- `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 dæmon (`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.prnlpr -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 fromEnnov 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 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
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

Name	Size	Weight (gsm*)	Hole Count	Seq. Count.	Color	Type
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
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.

[1] *gsm = grams per square meter

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 pre-pended 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.

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

Name	Size	Weight (gsm*)	Color	Type
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]

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.

[2] * gsm = grams per square meter

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
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

Name	Size	Hole Count	Color	Type
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
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.

Create a PingOne Application

A PingOne application is required to create applications with PingOne.

To create a PingOne Application:

1. Create an account at PingOne using the following link: https://www.pingidentity.com/en/account/register.html
2. Sign in to PingOne with your username and password using the following link: https://www.pingidentity.com/en/account/sign-on.html
3. Register for a developer account using the following link: https://www.pingidentity.com/en/account/register.html?type=developer
4. After obtaining a developer account, request a product license and trial using the following links:
   — https://www.pingidentity.com/en/products/request-license-key.html?type=developer
   — https://www.pingidentity.com/content/developer/en/pingone.html
5. Sign in with your PingOne developer account using the following link: https://admin.pingone.com/web-portal/login
6. In the main menu bar on the top of the page, select Applications.
7. On the *My Applications* page, click the Add Application button, and select New SAML Application.
8. In the *Application Details* pane, enter the following information and click Continue to Next Step.

Field Name	Value
Application Name	Enter a unique name.
Application Description	Enter a short description of the application.
Category	Select a category that most closely aligns with your organization.

9. In the *Application Configuration* pane, enter the following information and click Continue to Next Step.

Field Name	Value
Protocol Version	SAML v 2.0
Assertion Consumer Service (ACS)	http://<IP_Address or hostname of server with Ennov InSight>:8080/insight/saml/SSO
Entity ID	Enter a unique ID. ***Note:*** *Record this ID, as it will be used later in the* `insight.var` *file.*
Application URL	http://<IP_Address or hostname of server with Ennov InSight>:8080/insight/saml/SSO

10. In the *SSO Attribute Mapping* pane, click Save & Publish.
11. In the *Review Setup* pane, verify that the information displayed is correct, and then click Finish.
12. In the *My Applications* pane, click on the name of the application that was just created.
13. Click the links next to Signing Certificate and SAML Metadata to download these files, and save them to a secure location.

Enable PingOne E-signature

E-signature functionality is available for a PingOne Identity Provider (IdP) in Ennov InSight.

Prerequisites

Administrator role permissions are required to perform this task.

E-signatures via PingOne IdP work in the same way as e-signatures for Azure SSO, so the "username" and "password" field references should not be included in the Field Group that you are about to activate.

To enable e-signatures for PingOne IdP:

1. Open the meta.overrides.xml file, located at :\InSightManager\server\all\conf\insight.
2. In the meta.overrides.xml file, remove the comment tags from all lines except the eSignature fields, as shown in the following image.

```
<class package="com::liquent::insight::manager::registration::domain" name="Family">
    <attr name="useEsig">true</attr>
    <roles>
        <role name="user">
            <fieldGroup name="commonCreateFieldGroup">
                <fieldRef name="concernedParties" view="email" mode="edit" required="false" refresh="false" formName=""/>
                <fieldRef name="keywords" view="html" mode="edit" required="false" refresh="false" formName=""/>
                <fieldRef name="description" view="html" mode="edit" required="false" refresh="false" formName=""/>
                <fieldRef name="comments" view="html" mode="edit" required="false" refresh="false" formName=""/>
                <fieldRef name="reasonForChange" view="eSignature" mode="edit" required="true" refresh="false" formName="" />
                <fieldRef name="reasonForChangeComment" view="eSignature" mode="edit" required="false" refresh="false" formName="" />
                <fieldRef name="esignatureTransactionUuid" view="hidden" mode="read" required="true" refresh="false" formName="" />
                <!--<fieldRef name="username" view="eSignature" mode="edit" required="true" refresh="false" formName="" />-->
                <!--<fieldRef name="password" view="eSignature" mode="edit" required="true" refresh="false" formName="" />-->
            </fieldGroup>
```

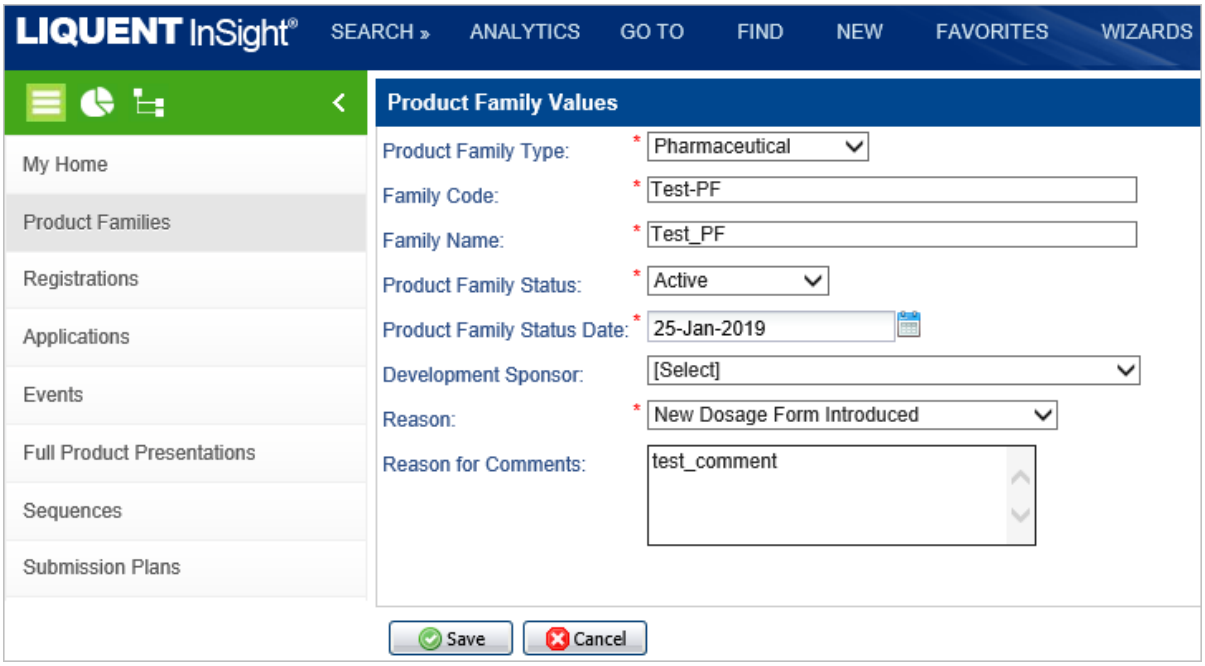
3. Save the meta.overrides.xml file.
4. Restart the InSightManager service.

After the meta.overrides.xml file has been configured to enable e-signatures, and InSightManager has been restarted, a user will have the ability to apply an e-signature to an entity.

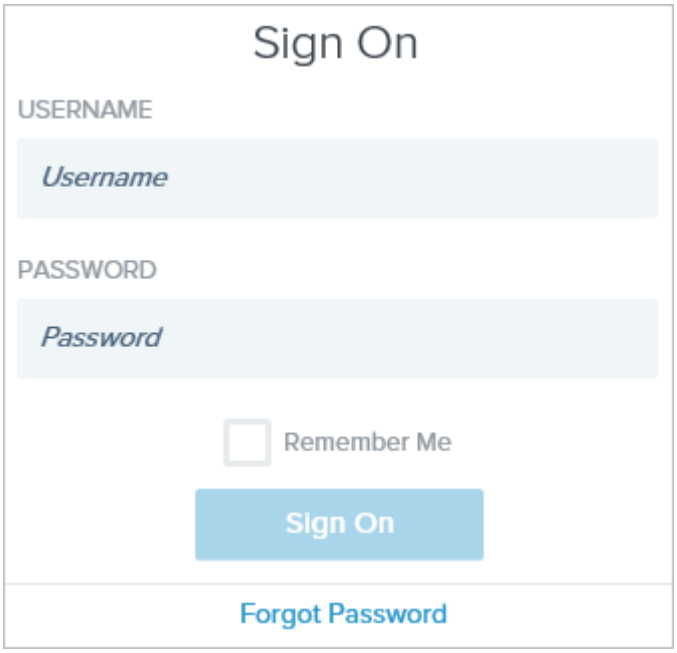
5. After the meta.overrides.xml file has been configured to enable e-signatures, a user will have the ability to apply an e-signature to an entity. You will be prompted with a PingOne login when the Reason field was selected and then Save button pressed as well for the entities which user has activated in meta.overides.xml

E-signature example

Completing the required fields and selecting a `Reason` enables you to apply your e-signature.



After completing the form with a `Reason` selected, clicking Save opens the PingOne login to apply your e-signature.


Sign On
USERNAME
Username
PASSWORD
Password
Remember Me
Sign On
Forgot Password

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.

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 the 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-reference-application-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	ABSNDS		No
Supplemental Abbreviated Biologic New Drug Submission	ca-2-2	ABSNDS		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
SAHPRA National Procedure	za-3-1	app-type-1		No
AMA Procedure	za-3-1	app-type-2		No
ZAZIBONA Joint Review	za-3-1	app-type-3		No
WHO-PQ	za-3-1	app-type-4		No
WHO SRA CRP	za-3-1	app-type-5		No
Swissmedic MAGHP	za-3-1	app-type-6		No
EU M4ALL	za-3-1	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	mutual-recognition	Active
EAEU DCP	EAEU - Decentralised Procedure	EAEU - Decentralised Procedure	Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russian Federation	DCP	decentralised	Active

Procedure Type Abbreviation	Procedure Type Name	Display Name	Countries	Internal Procedure Code	eCTD Code	Active Flag
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 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	NATIONAL	national	Active

Procedure Type Abbreviation	Procedure Type Name	Display Name	Countries	Internal Procedure Code	eCTD Code	Active Flag
EU CP Bio	EU CP - Biotechnological Process	EU CP - Biotechnological Process	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

Procedure Type Abbreviation	Procedure Type Name	Display Name	Countries	Internal Procedure Code	eCTD Code	Active Flag
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, Spain, Sweden, Undefined, United Kingdom	CP	centralised	Active

Procedure Type Abbreviation	Procedure Type Name	Display Name	Countries	Internal Procedure Code	eCTD Code	Active Flag
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

Procedure Type Abbreviation	Procedure Type Name	Display Name	Countries	Internal Procedure Code	eCTD Code	Active Flag
EU CTR	EU CTR - EU Clinical Trial Regulation	EU CTR - EU Clinical Trial Regulation	Austria, Belgium, Bulgaria, Croatia, Republic of Cyrus, 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	MRP	initial-maa	Active

Procedure Type Abbreviation	Procedure Type Name	Display Name	Countries	Internal Procedure Code	eCTD Code	Active Flag
EU DCP	EU Decentralised Procedure	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, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom	MRP	decentralised	Active

Procedure Type Abbreviation	Procedure Type Name	Display Name	Countries	Internal Procedure Code	eCTD Code	Active Flag
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	mutual-recognition	Active
GCC	GCC Procedure	GCC Procedure	Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen	MRP	GCC	Active

Procedure Type Abbreviation	Procedure Type Name	Display Name	Countries	Internal Procedure Code	eCTD Code	Active Flag
GCC - National	GCC National	National	Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen	NATIONAL	national	Active

Procedure Type Abbreviation	Procedure Type Name	Display Name	Countries	Internal Procedure Code	eCTD Code	Active Flag
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,	NATIONAL	NATIONAL	Active

Procedure Type Abbreviation	Procedure Type Name	Display Name	Countries	Internal Procedure Code	eCTD Code	Active Flag
National CDN	National CDN	National	Canada	NATIONAL		Active
JO National	JO National	National	Jordan	NATIONAL	national	Active
CN National	CN National	National	China	NATIONAL	national	Active
National JP	National JP	National	Japan	NATIONAL		Active
National US	National US	National	United States	NATIONAL		Active
National ZA	National ZA	National	South Africa	NATIONAL	national	Active
EU Herbal	EU Herbal	EU -Traditional use registration for herbal medicinal products	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European 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	MRP		Active

Procedure Type Abbreviation	Procedure Type Name	Display Name	Countries	Internal Procedure Code	eCTD Code	Active Flag
EU Homeopathic	EU Homeopathic	EU - Simplified registration procedure for homeopathic medicinalproducts	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European 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	MRP		Active
National TH	National TH	National	Thailand	NATIONAL		Active
National AU	National AU	National	Australia	NATIONAL		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		Ministry of Health and Welfare			Rest Of World	Active
AE	United Arab Emirates	ae	UAE Ministry of Health	MOH	AE-MOH	Gulf Cooperation Council	Active
AF	Afghanistan		Ministry of Health			Rest Of World	Active
AG	Antigua and Barbuda		Ministry of Health			Rest Of World	Active
AI	Anguilla		Health Authority of Anguilla			Rest Of World	Active
AL	Albania					Rest Of World	Active
AM	Armenia	am	Ministry of Health of the Republic of Armenia			EAEU	Active
AN	Netherlands Antilles		Department of Public Health and Environmental Protection			Rest Of World	Active
AO	Angola		Ministry of Health			Rest Of World	Active
AQ	Antarctica					Rest Of World	Active
AR	Argentina		Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica (ANMAT)	ANMAT		Rest Of World	Active
AS	American Samoa					Rest Of World	Active
AT	Austria	at	Bundesministerium für Gesundheit und Frauen	AGES	AT-AGES	European Union	Active
AU	Australia		Therapeutic Goods Administration	TGA		Australia	Active
AW	Aruba					Rest Of World	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
AZ	Azerbaijan		Ministry of Health			Rest Of World	Active
BA	Bosnia and Herzegovina		Federal Ministry of Health			Rest Of World	Active
BB	Barbados		Ministry of Health			Rest Of World	Active
BD	Bangladesh		Ministry of Food			Rest Of World	Active
BE	Belgium	be	Direction Générale Médicaments	FAMHP	BE-FAMHP	European Union	Active
BF	Burkina Faso		Ministry of Health			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		Ministry of Health			Rest Of World	Active
BJ	Benin		Ministry of Health			Rest Of World	Active
BM	Bermuda		Ministry of Health and Family Services			Rest Of World	Active
BN	Brunei Darussalam		Ministry of Health			Rest Of World	Active
BO	Bolivia		Ministry of Health and Social Welfare			Rest Of World	Active
BR	Brazil		Agencia Nacional de Vigilancia Sanitaria	ANVISA		Rest Of World	Active
BS	Bahamas		Ministry of Health Bahamas National Drug Agency			Rest Of World	Active
BT	Bhutan		Ministry of Health			Rest Of World	Active
BV	Bouvet Island					Rest Of World	Active
BW	Botswana		Ministry of Health			Rest Of World	Active
BY	Belarus	by	Ministry of Health of the Republic of Belarus			EAEU	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
BZ	Belize		Ministry of Health			Rest Of World	Active
CA	Canada		Health Protection Branch	HPB	HPB	Canada	Active
CC	Cocos (Keeling) Islands					Rest Of World	Active
CD	Congo, The Democratic Republic Of The					Rest Of World	Active
CF	Central African Republic		Ministry of Health			Rest Of World	Active
CG	Congo					Rest Of World	Active
CH	Switzerland		Swissmedic (Schweizerisches Heilmittelinstitut)			Switzerland	Active
CI	Cote D'Ivoire					Rest Of World	Active
CK	Cook Islands					Rest Of World	Active
CL	Chile		Institute of Public Health			Rest Of World	Active
CM	Cameroon		Ministry of Health			Rest Of World	Active
CN	China		National Medical Products Administration	NMPA		China	Active
CO	Colombia		Ministry of Health			Rest Of World	Active
CR	Costa Rica		Ministry of Health			Rest Of World	Active
CS	Serbia and Montenegro					Rest Of World	Active
CU	Cuba					Rest Of World	Active
CV	Cape Verde		Ministry of Health			Rest Of World	Active
CX	Christmas Island					Rest Of World	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
CY	Cyprus	cy	Ministry of Health	VS	CY-VS	European Union	Active
CZ	Czech Republic	cz	State Institut 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	Bundesinstitut für Arzneimittel und Medizinprodukte	BfArM	DE-BFARM	European Union	Active
DJ	Djibouti					Rest Of World	Active
DK	Denmark	DK	Lægemiddelstyrelsen	DKMA	DK-DKMA	European Union	Active
DM	Dominica					Rest Of World	Active
DO	Dominican Republic		Ministry of Agriculture			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	Agencia Española del Medicamento	AGEMED	ES-AGEMED	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 States Of					Rest Of World	Active
FO	Faroe Islands					Rest Of World	Active
FR	France	FR	Agence national de sécurité du médicament et des produits de Santé	ANSM	FR-ANSM	European Union	Active
GA	Gabon					Rest Of World	Active
GB	United Kingdom	UK	Medicines and Healthcare products Regulatory Agency	MHRA	UK-MHRA	European Union	Active
GD	Grenada					Rest Of World	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
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	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	Guinea-Bissau					Rest Of World	Active
GY	Guyana		Ministry of Health National Bureau of Standards			Rest Of World	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
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	HALMED	HR-HALMED	Croatia	Active
HT	Haiti					Rest Of World	Active
HU	Hungary	HU	National Institute of Pharmacy	IVMP	HU-OGYI	European Union	Active
ID	Indonesia		Ministry of Health			Rest Of World	Active
IE	Ireland	IE	Irish Medicines Board	IMB	IE-IMB	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
IQ	Iraq					Rest Of World	Active
IR	Iran, Islamic Republic Of					Rest Of World	Active
IS	Iceland	IS	Medicines Control Agency (Lyfjastofnun)	IMCA	IS-IMCA	European Union	Active
IT	Italy	IT	Ministero della Salute	AIFA	IT-AIFA	European Union	Active

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
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

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
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	Liechtensteinische Landesverwaltung Amt für Lebensmittelkontrolle und Veterinärwesen Kontrollstelle für Arzneimittel	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	Ministère de la Santé	MINSANT	LU-MINSANT	European Union	Active
LV	Latvia	lv	Food and Veterinary Service	ZVA	LV-ZVA	European Union	Active
LY	Libyan Arab Jamahiriya					Rest Of World	Active
MA	Morocco		Ministry of Public Health			Rest Of World	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
MC	Monaco					Rest Of World	Active
MD	Moldova, Republic Of					Rest Of World	Active
ME	Montenegro					Rest Of World	Active
MG	Madagascar					Rest Of World	Active
MH	Marshall Islands					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

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
MV	Maldives		Ministry of Health			Rest Of World	Active
MW	Malawi					Rest Of World	Active
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	Staatstoezicht op de volksgezondheid Inspectie voor de Gezondheidszorg College ter Beoordeling van Geneesmiddelen	CBG	NL-MEB	European Union	Active
NO	Norway	no	Norwegian Medicines Agency (Statens Legemiddelverk)	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 Devices Safety Authority			Rest Of World	Active
OM	Oman	om	Oman Ministry of Health	MOH	OM-MOH	Gulf Cooperation Council	Active
PA	Panama		Ministry of Health Ministry of Agricultural Development, Office of Plant Health			Rest Of World	Active
PE	Peru		Ministry of Health General Directorate of Pharmaceuticals, Devices and Drugs			Rest Of World	Active
PF	French Polynesia					Rest Of World	Active
PG	Papua New Guinea		Department of Health			Rest Of World	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
PH	Philippines		Ministry of Health			Rest Of World	Active
PK	Pakistan					Rest Of World	Active
PL	Poland	pl	Office for Medicinal 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	Instituto Nacional da Farmácia e do Medicamento	INFARMED	PT-INFARMED	European Union	Active
PW	Palau					Rest Of World	Active
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

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
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 (Läkemedelsverket)	MPA	SE-MPA	European Union	Active
SG	Singapore		Health Sciences Authority			Rest Of World	Active
SH	Saint Helena					Rest Of World	Active
SI	Slovenia	si	Agency of the Republic of Slovenia for Medicinal Products and Medical Devices	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

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
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

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
TL	Timor-Leste					Rest Of World	Active
TM	Turkmenistan					Rest Of World	Active
TN	Tunisia		Office of Pharmacy and Medicines			Rest Of World	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		Ministry of Health			Rest Of World	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
VA	Holy See (Vatican City State)					Rest Of World	Active

Country Code	Country Name	eCTD Code	Regulatory Authority	Authority Abbreviation	Agency eCTD Code	Region	Active Flag
VC	Saint Vincent and The Grenadines					Rest Of World	Active
VE	Venezuela		Ministry of Health and Social Development			Rest Of World	Active
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
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
ZA	South Africa	za	South African Health Products Regulatory Authority	SAHPRA		South Africa	Active
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).

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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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Type
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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Type
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

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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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Type
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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Type
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

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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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Type
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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Type
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

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 Protection	ch-1-0-1	eas	CTA, MAA, MAA-AH
Co-Marketing Medicinal Product	ch-1-0-1	co-marketing	CTA, MAA, MAA-AH

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
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
Variation Requiring Product Information Authorisation	ch-1-0-1	var-pi	CTA, MAA, MAA-AH
Variation Requiring Scientific Review	ch-1-0-1	var-authorisation-scientific	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-authorisation-admin	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

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
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
Variation Requiring Product Information Authorisation	ch-1-1	var-pi	CTA, MAA, MAA-AH
Variation Requiring Scientific Review	ch-1-1	var-authorisation-scientific	CTA, MAA, MAA-AH
Variation with Notification	ch-1-1	notification	CTA, MAA, MAA-AH
Variation without Scientific Review	ch-1-1	var-authorisation-admin	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

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
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
Variation Requiring Product Information Authorisation	ch-1-2	var-pi	CTA, MAA, MAA-AH
Variation Requiring Scientific Review	ch-1-2	var-authorisation-scientific	CTA, MAA, MAA-AH
Variation with Notification	ch-1-2	notification	CTA, MAA, MAA-AH
Variation without Scientific Review	ch-1-2	var-authorisation-admin	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

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
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
Variation Requiring Product Information Authorisation	ch-1-3	var-pi	CTA, MAA, MAA-AH
Variation Requiring Scientific Review	ch-1-3	var-authorisation-scientific	CTA, MAA, MAA-AH
Variation with Notification	ch-1-3	notification	CTA, MAA, MAA-AH
Variation without Scientific Review	ch-1-3	var-authorisation-admin	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

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
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 - Co-Marketing	ch-1-4	na-co-marketing	CTA, MAA, MAA-AH
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

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
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 Obligation 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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
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
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 Obligation 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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
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
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 Obligation 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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
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
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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
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
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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
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
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 Obligation 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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
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
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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
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 Related to PAM	eu-3-0	pam-leg	MAA, MAA-AH
Lifting Suspension Filing	eu-3-0	lifting-suspension	MAA, MAA-AH
Marketing Authorisation Application	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 Related to PAM (Article 45)	eu-3-0	pam-p45	MAA, MAA-AH

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
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
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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
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
Clinical Data for Publication – Final Version	eu-3-0-1	clin-data-pub-fv	MAA, MAA-AH
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 Related 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 Application	eu-3-0-1	maa	MAA, MAA-AH
National Variation Filing	eu-3-0-1	var-nat	MAA, MAA-AH

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
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
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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
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

eCTD Filing Types for GCC

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
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

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
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 Filling	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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
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	rnr	CTA, NDA
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	vrt	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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
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
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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
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 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: Pharmaceutics - New Chemical Entity	th-0-92	a-ph-newce	CTA, NDA
A: Pharmaceutics - New Salt or Ester of Existing Active Ingredient	th-0-92	a-ph-newse	CTA, NDA
A: Pharmaceutics - New Dosage Form	th-0-92	a-ph-newdosage	CTA, NDA
A: Pharmaceutics - New Route of Administration	th-0-92	a-ph-newroute	CTA, NDA
A: Pharmaceutics - New Combination	th-0-92	a-ph-newcomb	CTA, NDA
A: Pharmaceutics - New Medicinal Product (Others)	th-0-92	a-ph-newothers	CTA, NDA
A: Pharmaceutics - New Generic	th-0-92	a-ph-newgen	CTA, NDA
A: Pharmaceutics - 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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
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: Pharmaceutics - New Chemical Entity	th-1-0	a-ph-newce	CTA, NDA
A: Pharmaceutics - New Salt or Ester of Existing Active Ingredient	th-1-0	a-ph-newse	CTA, NDA
A: Pharmaceutics - New Dosage Form	th-1-0	a-ph-newdosage	CTA, NDA

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
A: Pharmaceutics - New Route of Administration	th-1-0	a-ph-newroute	CTA, NDA
A: Pharmaceutics - New Combination	th-1-0	a-ph-newcomb	CTA, NDA
A: Pharmaceutics – Abridge application	th-1-0	a-ph-abridge	CTA, NDA
A: Pharmaceutics - New Medicinal Product (Others)	th-1-0	a-ph-newothers	CTA, NDA
A: Pharmaceutics - New Generic	th-1-0	a-ph-newgen	CTA, NDA
A: Pharmaceutics - 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

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
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 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 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, CNADA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
Annual Report Filing	us-2-01	annual-report	ANADA, ANDA, BLA, CNADA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA
CMC Supplement	us-2-01	chemistry-manufacturing-controls-supplement	ANADA, ANDA, BLA, CNADA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA
Efficacy Supplement	us-2-01	efficacy-supplement	ANADA, ANDA, BLA, CNADA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA
Labeling Supplement	us-2-01	labeling-supplement	ANADA, ANDA, BLA, CNADA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA
Original Filing	us-2-01	original-application	ANADA, ANDA, BLA, CNADA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA
Other Filing	us-2-01	other	ANADA, ANDA, BLA, CNADA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA
Presubmission Filing	us-2-01	presubmission	ANADA, ANDA, BLA, CNADA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA
Re-submission Filing	us-2-01	resubmission	ANADA, ANDA, BLA, CNADA, DAPM, DMF, MASTER, EUA, IDE, INAD, IND, NADA, NDA, PMA
Supplement Filing	us-2-01	establishment-description-supplement	ANADA, ANDA, BLA, CNADA, 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

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
Periodic Safety Update 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
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

Country	Specification	Filing Type	Sub-Filing Type	eCTD Code
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 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

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
Complementary Medicines (na-cm)	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-pa-insp)	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 (post-reg-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 (na-cm)	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

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
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 (post-reg-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-pn-update	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, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
D - New Generic Medicine	za-3-1	sub-type-2	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
Complementary Medicine - New	za-3-1	sub-type-3	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
New Biological	za-3-1	sub-type-4	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Biosimilar (na-bs)	za-3-1	sub-type-5	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Clinical Trial Application	za-3-1	sub-type-6	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
New Vaccines	za-3-1	sub-type-7	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
I: Vaccine Antigen Master File	za-3-1	sub-type-8	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
New SMF	za-3-1	sub-type-9	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
New APIMF	za-3-1	sub-type-10	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Plasma Master File (PMF)	za-3-1	sub-type-11	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Line extension-New Strength	za-3-1	sub-type-12	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Line extension-New Dosage Form	za-3-1	sub-type-13	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Line extension-New Application	za-3-1	sub-type-14	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
Clone	za-3-1	sub-type-15	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Replica-Same	za-3-1	sub-type-16	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IA-Quality	za-3-1	sub-type-17	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IAin-Clinical	za-3-1	sub-type-18	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IAin-Quality	za-3-1	sub-type-19	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IB-Clinical	za-3-1	sub-type-20	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IB-Quality	za-3-1	sub-type-21	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type I-Inspectorate	za-3-1	sub-type-22	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type I-Other	za-3-1	sub-type-23	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Safety (Clinical)	za-3-1	sub-type-24	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II - Safety and Efficacy (Clinical)	za-3-1	sub-type-25	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Quality	za-3-1	sub-type-26	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
Type II-Rescheduling	za-3-1	sub-type-27	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Proprietary Name Change	za-3-1	sub-type-28	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Change in Applicant-Relinquishing	za-3-1	sub-type-29	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Change in Applicant-Acquiring	za-3-1	sub-type-30	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Baseline	za-3-1	sub-type-31	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
z-Code-Quality	za-3-1	sub-type-32	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Pharmacovigilance	za-3-1	sub-type-33	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
USRN-Clinical and Pharmacovigilance	za-3-1	sub-type-34	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Application Withdrawal/ Cancellation	za-3-1	sub-type-35	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, ND
Renewal Filing	za-3-1	sub-type-36	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Undefined Regulatory Activity*	za-3-1	sub-type-37	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IB-Related Clinical	za-3-1	sub-type-38	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
Type IB-Related Quality	za-3-1	sub-type-39	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IB-Related Inspectorate	za-3-1	sub-type-40	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IA-Clinical	za-3-1	sub-type-41	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Related Clinical	za-3-1	sub-type-42	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Related Quality	za-3-1	sub-type-43	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Related Inspectorate	za-3-1	sub-type-44	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA

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[3] *If there is no such filing type in the database, South Africa will be associated with the existing Withdrawal Filing filing type.

eCTD Sub-Filling Types for ZA

The following table lists the eCTD code and the applicable Sub-Filing Type for each Filing Type. The Sub-Filling 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, Replica-Same, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type I-Other, 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 I-Other, 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, Replica-Same, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type I-Other, 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
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, Replica-Same, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type I-Other, 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-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, Replica-Same, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type I-Other, 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
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, Replica-Same, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type I-Other, 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
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, Replica-Same, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type I-Other, 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
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, Replica-Same, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type I-Other, 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
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, Replica-Same, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type I-Other, 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
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, Replica-Same, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type I-Other, 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

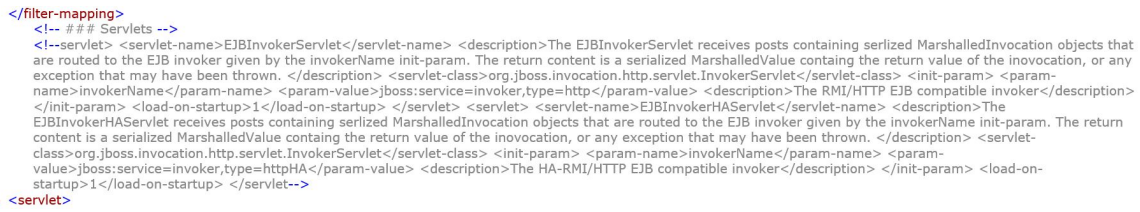
Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Response-Renewals	za-3-1	seq-type-11	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine 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, Replica-Same, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type I-Other, 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
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, Replica-Same, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type I-Other, 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

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\httpha-invoker.sar\invoker.war\WEB-INF`
2. In the `web.xml` file, comment the `JBoss EJBInvokerServlet` code block as shown in the image below.



3. Save the `web.xml` file.
4. Restart the InSightManager service.

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>
</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	Req (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 Name	Req (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` topi
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 Definitio`
com::liquent::insight::manager::publisher::data::publishsettings::PublishingSettings	Y	See `Publishin Settings`

Class Name	Req (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 Publishin Settings Library
com::liquent::insight::manager::publisher::data::publishsettings::DefaultPublishingValues	N	See Defaul Values
com::liquent::insight::manager::publisher::data::specialsheets::Tab	N	See Tab
com::liquent::insight::manager::publisher::data::specialsheets::Slip	N	SeeSlip
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

Class Name	Req (Y/N)	Description
com::liquent::insight::manager::publisher::data::outputchannels::TOCTypeOutputChannel	N	See Output Channel fo TOC Settings
com::liquent::insight::manager::publisher::data::outputchannels::ContentOutputChannel	N	See Output 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 Overla Settings

Assembly

Class Name: `com::liquent::insight::manager::content::dto::Assembly`

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	
assemblyTypeId	long	Assembly Type	Y	Internal codes that correspond to the assemblySubmissionType field: — eCTD = ECTD — US eCTD = US — CN eCTD = CN — Standard = STANDARD	— ECTD — US — CN — STANDARD	
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 (Y/N)	Description	Acceptable Values	Default Value
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 assignmen t 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.ASSEMBLY_CATEGORY_TYPE.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`	
extensionDisplayName	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 Assembly XML. This value will be used to populate correspondin g fields in child classes. This ID will be replaced by the database ID in the imported assembly.	Example: `5513035`	
internalCopyC hronId	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.		
latestVersion Flag	string		N	This field is not used for import.		
leafAutoStart WorkflowIds	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.		
numLifecycledChildren	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.
statusTypeId	long	Status	N	The field is not used for import.		IN_DRAFT

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
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.ASSEMBLY_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.		
transAsmType	string		N	The numeric Assembly type code.	— 1 – Template — 2 – Standalone Assembly — 6 – Sequence Assembly — 11 – Assembly Plan Sequence	2
transOperatedSeqId	long		N	This field is not used for import.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	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 value is `CURRENT`.
versionNumber	string		N	This field is not used for import.		Automatically populated value 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 Values	Default Value
abbreviatedName	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 693.	
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 node (can be any node).	See example in Explanation for childSeqNo and absoluteChildSeqNo Fields on page 693.	

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, m1-ca, 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 volumize.	— Y — N	N
guid	string	Leaf ID	N	Identifier, format is "a" + md5 string.	Example: `ad41d8cd98f00b204e9800998ecf8427e`	

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
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 correspondin g 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.
numLifecycledChildren	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 694.	

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 childSeqNo and absoluteChildSeqNo 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 checksum.	Example: `d1322e3afb89ed6fd93794f96bebf941`	

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 childSeqNo and absoluteChildSeqNo 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 (Y/N)	Description	Acceptable Values	Default Value
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 correspondin g 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.		
numLifecycledChildren	long		N	This field is not used for import.		
operationTypeId	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.		
transApplicationId	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
useApplicationPrefixFlag	string	Use Application Prefix	N	Defines if the Application Prefix should be applied to the link, for use when the reference leaf exists in another Application/ Assembly.	— Y — N	N
useNativeFileFlag	string	Use Native File	N	Defines if the documents within the leaf should be passed through to the output without being touched by Ennov InSight Publisher. If set to T (stands for True), only one document should be associated to the leaf.	— T - stands for True (Yes) — F - stands for False (No)	

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 693.	
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=(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 (Y/N)	Description	Acceptable Values	Default Value
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 693.	
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	Desciption	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 correspondin g fields in child classes. This ID will be replaced by the database ID in the imported Document.	Example: `5516639`	
inclInPageNu mbersFlag	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.
numLifecycledChildren	long		N	This field is not used for import.		
operatedInSequenceId	long		N	This field is not used for import.		
other	string	Other	N	Other information about the document.		
overlaySettingsId	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 Values	Default Value
pageRangeFrom	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 element.	See example in Explanation for parentId Field on page 694.	
plannedPageCount	int	Planned Number of Pages	N	For placeholders, enables the user to plan for 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.
renditionModifierTypeId	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.		
srcDisplayAssignmentStatus	string		N	This field is not used for import.		
srcDisplayBoundVersion	string		N	This field is not used for import.		
srcHasRenditionslFlag	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.pdf`	
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.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
statusTypeId	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"

ContentOutputChannel

Class Name: `com::liquent::insight::manager::publisher::data::outputchannels::ContentOutputC`

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.		
changeReasonTypeId	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
AU	3.0	m1-au	3.0	Folder
		node-extension	1.0	Folder
AU	3.1	au-3-1	3.1	Folder
AU	AU 2.0 NeeS	au-2-0-nees	2.0	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
CH	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
CH	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

Group Name	Group Version	Extension Name	Extension Version	Class Reference
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
CH	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
CH	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
CH	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
CDN	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

Group Name	Group Version	Extension Name	Extension Version	Class Reference
EU	1.0	envelope	1.0	Folder
		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
EU	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
EU	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

Group Name	Group Version	Extension Name	Extension Version	Class Reference
EU	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-envelope	1.0	Leaf
EU	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
EU	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

Group Name	Group Version	Extension Name	Extension Version	Class Reference
EU	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
EU	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

Group Name	Group Version	Extension Name	Extension Version	Class Reference
GC	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

Group Name	Group Version	Extension Name	Extension Version	Class Reference
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

Group Name	Group Version	Extension Name	Extension Version	Class Reference
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
TH	1.0	m1-th	1.0	Folder
		m1-th-responses	1.0	Folder
		node-extension	1.0	Folder
TW	1.0	m1-tw	1.0	Folder
		node-extension	1.0	Folder
US	2.01	m1-us	1.0	Folder
		node-extension	1.0	Folder
US	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
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
ZA	3.1	m1-za	3.1	Folder
		node-extension	1.0	Folder

Folder Extensions

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.		

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/sequence-description.xml>. Multiple comma-separated 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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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/reg-activity-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	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

xValue1	date		Belongs to the sequenceDescription field. In the UI, the sequenceDescription field is a list with values, some values have or do not have additional parameters.
			
			If customer selects a value with no additional parameter, then the system yields the following XML (see example):
			
			`<extensions> <extension type="m1-au" version="0.9"> <field name="sequenceDescription" type="string" >seq-desc-0000</ field> </extension> </extensions>`
			
			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):
			
			`<extensions> <extension type="m1-au" version="0.9"> <field name="sequenceDescription" type="string" >seq-desc-22</ field> <field name="xValue1" type="date" >1487887200000</ field> </extension> </extensions>`
			
			If a customer selects the 2nd type of additional parameter, the system yields the sequenceDescription field and date range (see example):
			
			`<extensions>`		

xValue2From	date				
xValue2To	date				
xValue3	map				
xValue3_text	string				
xValue3_date	date				
xValue4	string				

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 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.		

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/sequence-description.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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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/reg-activity-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**	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value

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):
			
			`<extensions> <extension type="m1-au" version="3.0"> <field name="sequenceDescription" type="string" >seq-desc-0000</ field> </extension> </extensions>`
			
			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):
			
			`<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>`
			
			If a customer selects the 2nd type of additional parameter, the system yields the sequenceDescription field and date range (see example):
			
			`<extensions>`		

xValue2From	date				
xValue2To	date				
xValue3	map				
xValue3_text	string				
xValue3_date	date				
xValue4	string				

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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 comma-separated values can be provided.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
artgNumber	string	ARTG Number(s)	The Australian Register of Therapeutic Goods number should be provided if available. Multiple comma-separated values can be provided.	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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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/reg-activity-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"	

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/sequence-type.xml>.	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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/sequence-description.xml>.	eCTD Code value from Data Administration > Sequence Description Values	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
xValue1	date		Belongs to the sequenceDescription field. In the UI, the sequenceDescription field is a list with values, some values have or do not have additional parameters. If customer selects a value with no additional parameter, then the system yields the following XML (see example): `<extensions> <extension type="m1-au" version="3.1"> <field name="sequenceDescription" type="string" >seq-desc-0000</field> </extension> </extensions>` 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): `<extensions> <extension type="m1-au" version="3.1"> <field name="sequenceDescription" type="string" >seq-desc-22</field> <field name="xValue1" type="date" >1487887200000</field> </extension> </extensions>` If a customer selects the 2nd type of additional parameter, the system yields the sequenceDescription field		
xValue2From	date				
xValue2To	date				
xValue3	map				
xValue3_text	string				
xValue3_date	date				
xValue4	string				

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
email	string	Contact Email	The email is used to notify the applicant in case of change in application status. Must be valid email format. Multiple comma-separated values can be provided.	The value must represent a valid e-mail, the validation mask is ^([\sa-zA-Z0-9._%-]+@[a-zA-Z0-9.-]+\.[a-zA-Z]{2,4})$	

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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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 comma-separated 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")	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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/reg-activity-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"	

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/sequence-type.xml>.	eCTD Code value from Data Administration > Filing Type Values > Filing Type eCTD Code	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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/sequence-description.xml>.	eCTD Code value from Data Administration > Sequence Description Values	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
xValue1	date		Belongs to the sequenceDescription field. In the UI, the sequenceDescription field is a list with values, some values have or do not have additional parameters. If customer selects a value with no additional parameter, then the system yields the following XML (see example): `<extensions> <extension type="m1-au-nees" version="2.0"> <field name="sequenceDescription" type="string" >seq-desc-0000</field> </extension> </extensions>` 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): `<extensions> <extension type="m1-au-nees" version="2.0"> <field name="sequenceDescription" type="string" >seq-desc-22</field> <field name="xValue1" type="date" >1487887200000</field> </extension> </extensions>` If a customer selects the 2nd type of additional parameter, the system		
xValue2From	date				
xValue2To	date				
xValue3	map				
xValue3_text	string				
xValue3_date	date				
xValue4	string				

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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._%-]+@[a-zA-Z0-9.-]+\.[a-zA-Z]{2,4})$	

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-ca

m1-ca v. 1.0

Field Name	Field Type	Matching UI Ffield	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.		

Field Name	Field Type	Matching UI Ffield	Description	Acceptable Values	Default Value
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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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, PSUR-PV, UD-PV, 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	
sequenceNumber	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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.		

Field Name	Field Type	Matching UI Field	Description	Available Values	Default Value
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 comma-separated 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, na-nde, na-ndo, notification, var-authorisation-scientific, var-authorisation-admin, renewal, psur, pi, eas, co-marketing, withdrawal, var-pi, transfer, dmf, pmf, reformat, supplemental-info-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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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 comma-separated 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.		

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.	na-nas, na-ngf, na-nko, na-bws, na-gen, na-ie, na-nde, na-ndo, notification, var-authorisation-scientific, var-authorisation-admin, renewal, psur, pi, eas, co-marketing, withdrawal, var-pi, transfer, dmf, pmf, reformat, supplemental-info, 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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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 comma-separated 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	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.	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, var-pi, var-authorisation-scientific, notification, var-authorisation-admin, withdrawal	

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.		
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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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 comma-separated 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

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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 comma-separated 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

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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.

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 v. 1.0

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	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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.

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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: `样&#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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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. 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.		

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	
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="relatedSequence" type="map"><value key="emea" value="1234" /></field>`	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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. 1.1

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 Application's Country.		
applicant	string	Applicant	The name of the company submitting the Application.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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="relatedSequence" 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. 1.2.1

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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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="relatedSequence" 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	

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 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, DE-BFARM, DE-BVL, DE-PEI, DK-DKMA, EE-SAM, EL-EOF, ES-AGEMED, FI-NAM, FR-AFSSAPS, FR-ANMV, HU-IVMP, HU-OGYI, IE-IMB, IE-DAFF, IS-IMCA, IT-AIFA, IT-LMV, IT-SPV, LI-LLV, LT-SMCA, LT-VVPI, LT-VMVT, LU-MINSANT, LV-ZVA, MT-MRU, MT-MEDAUTH, NL-MEB, NO-NOMA, PL-URPL, PT-DGV, PT-INFARMED, RO-ANM, SE-MPA, SI-JAZMP, SK-SIDC, SK-USKVBL, UK-MHRA, UK-VMD, 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.		

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, 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")	

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.	— 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, DE-BFARM, DE-BVL, DE-PEI, DK-DKMA, EE-SAM, EL-EOF, ES-AGEMED, FI-NAM, FR-AFSSAPS, FR-ANMV, HU-IVMP, HU-OGYI, IE-IMB, IE-DAFF, IS-IMCA, IT-AIFA, IT-LMV, IT-SPV, LI-LLV, LT-SMCA, LT-VVPI, LT-VMVT, LU-MINSANT, LV-ZVA, MT-MRU, MT-MEDAUTH, NL-MEB, NO-NOMA, PL-URPL, PT-DGV, PT-INFARMED, RO-ANM, SE-MPA, SI-JAZMP, SK-SIDC, SK-USKVBL, UK-MHRA, UK-VMD, 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.		

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, 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")	

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.	— 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, SK-SIDC, 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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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")	

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.	— 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.		

envelope 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 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-xxxx-Mxxx-Nxxx-xxxxxxxxxxxx*, 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 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 comma-separated values can be provided.		
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.	— initial — validation-response — response — additional-info — closing — consolidating — corrigendum — reformat	
applicant	string	Applicant	The name of the company submitting the Application.		

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. Based on the Application's Country.	AT-BASG, 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-HPRA, 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, SK-SIDC, UK-MHRA, EU-EMA, EU-EDQM	
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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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, 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 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 — *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 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 comma-separated values can be provided.		
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.	— initial — validation-response — response — additional-info — closing — consolidating — corrigendum — reformat	
applicant	string	Applicant	The name of the company submitting the Application.		

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. Based on Application's Country.	AT-BASG, 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-HPRA, 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, SK-SIDC, UK-MHRA, EU-EMA, EU-EDQM	
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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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-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 Number Id	Registration Number.	Six digits.	
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 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, KW-MOH, OM-MOH, QA-NHA, YE-MOPHP, SA-SFDA, AE-MOH	
atc	string	ATC	ATC code. Multiple comma-separated values can be provided.		

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.	— 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 comma-separated 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, KW-MOH, OM-MOH, QA-NHA, YE-MOPHP, 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**	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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 comma-separated 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	

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.	— 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	
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 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		

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.		

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_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	

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	

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	
labelingType	string	Labeling Type	Defines the type of label reference in the submission.	— spc — annex2 — outer — interpack — impack — 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	

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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
applicationNumber	string	Application Reference Number	Application Number as provided by the agency. Multiple comma-separated 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 "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.	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 comma-separated 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.

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 lLanguage used for submission in the defined country.	— de — en — hr	

m1-jp

m1-jp v. 1.0

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. Multiple comma-separated values can be provided		
sequenceNumber	string	Sequence Number	The Sequence Number for this submission.	Sequence Code (without prefix "P")	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
genericName	string	Generic Name	The generic name of the product being submitted to the agency. Multiple comma-separated values can be provided		
applicant	string	Applicant	The company filing the application. Multiple comma-separated values can be provided		
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. Multiple comma-separated values can be provided		
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	

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 — 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
esubId	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	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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 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 (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
esubId	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	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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	

m1-tw

m1-tw v. 1.0

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
identifier	string	Identifier	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.	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 the parent applicati
submissionTypeTier1	string	Submission Type Tier 1		Domestic, Import, Export Only.	
submissionTypeTier2	string	Submission Type Tier 2		New Drugs Application, Biological Drugs Application, Generic Drug Application, Active Pharmaceutical Ingredient.	
submissionTypeTier3	string	Submission Type Tier 3		Prescription, Over The Counter, Controlled Drugs, Nuclear Medicine, Biological Drugs, Biosimilar Drugs, Regenerative Medicine, Others.	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
submissionTypeTier4	string	Submission 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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
applicantCertAuth	string	Application Corporate Certification Authority	Applicants should use Corporate Certification Authority IC Card for submission.		
applicantPhoneNum	string	Applicant Phone Number	Phone number of the company. Multiple comma-separated values can be provided		
applicantEmailAddr	string	Applicant Email Address	Multiple comma-separated values can be provided	If entered value does not met xx@yy.zz criterion `Invalid e-mail address` message appears.	
procedure	string	Procedure	Defines the procedure in use with the submission National is the default and the only option to be chosen.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
inventedName	map	Invented Names (Name/ Drug Permit License/ Pre-Assigned Application Number/ Code)	The group of fields that allows multiple sets of Invented Name. Multiple comma-separated values can be provided.	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 non-proprietary. Multiple comma-separated values can be provided.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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.	

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 ‘initial’ and ‘reformat’, related sequence is identical to the sequence number. Multiple comma-separated values can be provided.	'Related Sequence must be numeric' error message appears if the value is not numeric.	
submissionDescription	string	Submission Description	This element is used to provide a free text description of the submission.		

m1-th-responses

m1-th-responses v. 1.0

No additional fields for folder.

m1-th-additional

m1-th-additional v. 1.0

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	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
submissionType	string	Submission Type	The Filing type of the submission. Will default from the Sequence's Filing Type.	— amendment — annual-report — chemistry-manufacturing-controls-supplement — efficacy-supplement — establishment-description-supplement — labeling-supplement — original-application — 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	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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-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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
applicant	string	Applicant	The name of the applicant/HCR 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, pre-reg-biol, pre-reg-cams, pre-reg-cr, post-reg-insp, post-reg-pa, post-reg-pa-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__uniqueSuffix__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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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/HCR submitting the eCTD.		
submissionType	string	Submission Type / Proof of Efficacy	This field is not used for import.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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="post-reg-hcr__uniqueSuffix__1" value="other" /> <value key="post-reg-hcr__uniqueSuffix__1" value="comments text" />` `<value key="post-reg-hcr__uniqueSuffix__0" value="other" /> <value key="post-reg-hcr__uniqueSuffix__0" value="comments text" /></field>` 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.	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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")	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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	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

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
inn	string	INN	The recognised International Non-proprietary 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 comma-separated values can be provided.	N/A	N/A

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
vamfNumber	string	VAMF Number	A number for certified Vaccine Master File (VAMF). Populated, if VAMF is referenced in the eCTD application. Multiple comma-separated values can be provided.	N/A	N/A
applicationIdentifier	string	Application ID	A unique 14-character 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.	1717459200000	N/A

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
proprietaryName	string	Proprietary Name	The name as proposed or registered. For API Master Files, insert drug substance name and APIMF holder name. Multiple comma-separated values can be provided.	N/A	N/A
submissionInfoCombination	map	Submission (Submission Type / Evaluation Pathway / Submission Lead / Submission Number)	Contains all the submission-related information 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 Submission Type Matrix.	<field name="submissionInfoCombination" type="map"> <value key="sub-type-31__uniqueSuffix__0" value="eval-path-1"/> <value key="sub-type-31__uniqueSuffix__0" value="sub-lead-2"/> <value key="sub-type-31__uniqueSuffix__0" value="num1,num1b"/> </field>	N/A

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
pmfNumber	string	PMF Number	A number for the certified Active Plasma Master File (PMF). Populates, if PMF is referenced in the eCTD application. Multiple comma-separated 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.	<field name="multipleApplications" type="map" > <value key="appnum01__uniqueSuffix__0" value="propname01"/> </field>	N/A

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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	

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	

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. 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	

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	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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	

m1-3-1-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-human-primate — other-non-rodent-mammal — non-mammals	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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	
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-rodent-mammal — 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-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, 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,	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
docId	string		This field is not used for import.		

stf v. 3.0

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-rodent-mammal — non-mammals	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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-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, available-on-request, complete-patient-list, serious-adverse-event-patient-list, adverse-event-patient-list, abnormal-lab-values-patient-list, data-tabulation-dataset-legacy, 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,	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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-rodent-mammal — non-mammals	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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-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, available-on-request, complete-patient-list, serious-adverse-event-patient-list, adverse-event-patient-list, abnormal-lab-values-patient-list, data-tabulation-dataset-legacy, 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,	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
docId	string		This field is not used for import.		

study_patient_information_folder

study_patient_information_folder 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.	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, 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, nonclinical-data, case-report-forms	

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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-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-legacy, 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	
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-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	

study_data_folder v. 3.0

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-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-legacy, 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	

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 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. 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, nonclinical-data	

module_studies v. 3.0

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 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. 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-legacy, 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,	

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 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. 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, 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, 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, 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-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, available-on-request, complete-patient-list, serious-adverse-event-patient-list, adverse-event-patient-list, abnormal-lab-values-patientlist, data-tabulation-dataset, data-tabulation-data-definition, data-listing-dataset, data-listing-data-definition, analysis-dataset, analysis-program, analysis-data-definition, annotated-crf, image, safety-report, antibacterial, special-pathogen, antiviral, iss, ise, pm-description, nonclinical-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-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, 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	

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 the specific study.	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, available-on-request, complete-patient-list, serious-adverse-event-patient-list, adverse-event-patient-list, abnormal-lab-values-patient-list, data-tabulation-dataset-legacy, 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	

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-report-forms — subject-profiles	
site	string	Site	The name of the site where the study was conducted.		

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
registrationFileIndicator	string	Registration File Indicator	Defines if element belongs to a registration dossier or a drug master file.	true/false	true

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 specified or there is no appropriate code in the classifier.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
docCreationDate	date	Document Creation Date	Date of document creation.	Date format - Unix Timestamp. If empty, this message appears: `"Document Creation Date is required"` message is displayed. If the entered data cannot be recognized as a date, `"Invalid date specified"`.	
docValidityDate	date	Document Validity Date	Date when document expires.	Date format - Unix Timestamp. If entered data cannot be recognized as a date, this message appears: `"Invalid date specified"`.	
businessEntityName	string	Business Entity Name	Organization name issued registration dossier.		

Field Name	Field Type	Matching UI Field	Description	Acceptable Values	Default Value
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.		

PublisherMetaData

m1-us-meta-data-application

m1-us-meta-data-application v. 3.3

Field Name	Field Type	Matching UI Field	Description	Acceptable Values
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 Application Type (eCTD code) to be entered, and then for additional Application Numbers and Types to be entered. The values must be paired.	`<field name="crossReferenceApplication" type="map"><value key="1195__uniqueSuffix__0" value="123456" /></field>`
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")

Field Name	Field Type	Matching UI Field	Description	Acceptable Values
submissionId	string	Submission ID	Identifies each individual regulatory activity (original application, supplement, annual report, etc.) in an application.	Example: `0001`

Publishing Settings

PublishingSettingsLibrary

Class Name: `com::liquent::insight::manager::publisher::data::publishsettings::PublishingSet`

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 will be replaced by database ID in the imported assembly.	Example: `370515`	

Field Name	Field Type	Req (Y/N)	Matching UI Field	Description	Acceptable Values	Default Value
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.	Exampe: `713424`	
defaultSettingsProfileId	long	N		Value of the ID field of the SettingsProfile class.	Example: `370520`	

PublishingSettings

Class Name: `com::liquent::insight::manager::publisher::data::publishsettings::PublishingSet`

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 PublishingSettings ID represented by numerical value. Field is used to link classes within Assembly XML.	Example: `370516`	

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
printerTypeId	long	Printer	Y	The Printer that will be used for a Paper Publish.	Values from the database: — CODE column from ODS.PRINTER_TYPE table	By default `STANDARDPDF`

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
mediaParameterTypeId	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: `SELECT mpt.code FROM ods.printer_type pt, ods.valid_printer_media_type valid, ods.media_parameter_type mpt WHERE valid.printer_type_id = pt.id AND mpt.id = valid.media_parameter_type_id AND mpt.tabs_per_set IS NULL AND pt.code = <CODE>;` Where *<CODE>* is value of `ODS.PRINTER_TYPE.CODE` (field value of `printerTypeId`). Example: — L-1 — A4-1	

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
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: `SELECT mpt.code FROM ods.printer_type pt, ods.valid_printer_media_type valid, ods.media_parameter_type mpt WHERE valid.printer_type_id = pt.id AND mpt.id = valid.media_parameter_type_id AND mpt.tabs_per_set IS NOT NULL AND pt.code = <CODE>;` Where *<CODE>* is value of `ODS.PRINTER_TYPE.CODE` (field value of `printerTypeId`).	

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
previewLocationPath	string	Preview Location	N	The location used to store any generated previews (Volumes, Tabs).	Example: `//root/folder`	
inProcessRenditionLocationPath	string	In-Process Rendition Location	N	The location used to store the in-process rendition used when creating in-process links in Ennov InSight.	Example: `//root/folder`	

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
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 `tocDestinationNotFoundText` 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.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
marginXrefDestinationNotFoundText	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 cross-reference 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.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
expandBookmarksToLevel	long	Expand Bookmarks to Level	N	This field enables users to specify the number of levels to which bookmarks are expanded 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.	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20	0 - it means ALL bookmarks

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
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 — 1.4, Acrobat 5 — 1.5, Acrobat 6 — 1.6, Acrobat 7 — 1.7, Acrobat 8	— 1.3 — 1.4 — 1.5 — 1.6 — 1.7	1.4
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 Name: `com::liquent::insight::manager::publisher::data::publishsettings::PubSettingsRe`

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 Name: `com::liquent::insight::manager::publisher::data::publishsettings::PubSettingPdf`

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	

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default 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.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
sourceValue	string		Y/N	— If the value of the propertySource field is D then the value of this field duplicates the value of the sourcePdfPropertyTypeId field. — If the value of the propertySource field is S or R then the value of this field duplicates the value of the value field.		

Tab

Class Name: `com::liquent::insight::manager::publisher::data::specialsheets::Tab`

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.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
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.		
ssIcon	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.		

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 Tab. It can be any class in the following list: — Assembly — Folder — Leaf — Document		
parentVolumeId	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 691.	0, 1, 2, etc.	
changeReasonTypeId	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 Name: `com::liquent::insight::manager::publisher::data::publishsettings::TabSetting`

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 Name: `com::liquent::insight::manager::publisher::data::outputchannels::SpecialSheetOu`

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 Name: `com::liquent::insight::manager::publisher::data::specialsheets::TOC`

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.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
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 691.	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.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
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.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
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		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
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.		
ssIcon	string		Y	See fixed value.		Fixed value is TOC

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
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 Name: `com::liquent::insight::manager::publisher::data::specialsheets::TocType`

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.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
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

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
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 Name: `com::liquent::insight::manager::publisher::data::outputchannels::TOCTypeOutputC`

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 Name: `com::liquent::insight::manager::publisher::data::specialsheets::TOCEntryGenOpti`

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.		

Volume

Class Name: `com::liquent::insight::manager::publisher::data::Volume`

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Defau Value
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

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Defau 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.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Defau Value
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	The additional sheets/ pages buffer allowed in a volume, used when running volumize by number of pages.		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 Naming Format	N	The format that should be applied to the Volume File Name, typically this is a variable.		$VOL
relativeType	string	Volume Numbering	N	Defines if the Volume numbering should be reset at every major division, or relative to the Assembly.	— divRelative — asmRelative	asmR
isDuplexFlag	string		N	This field is not used for import.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Defau Value
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.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
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 within 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	Req (Y/N)	Description	Acceptable Values	Default Value
typeId	long		Y	See fixed value.		Fixed value is USER
variableStampType	string	Variable Type	N	The type of variable being configured.	— S - Single-Line Variable — M - Multiple-Line Variable	S
variableValue	string	Variable Value	Y	The value to which the variable will resolve. This could be free text or another variable.		

VariableOutputChannel

Class Name: `com::liquent::insight::manager::publisher::data::outputchannels::VariableOutput`

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.		
outputChannelTypeId	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.		
changeReasonTypeId	long		N	This field is not used for import.		

Slip

Class Name: `com::liquent::insight::manager::publisher::data::specialsheets::Slip`

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.		
changeReasonTypeId	long		N	This field is not used for import.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
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 691.		
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
parentVolumeId	long		N	This field is not used for import.		
printSlipMediaTypeId	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.		
ssIcon	string		Y	See fixed value.		Fixed value is SLIP

SlipSetting

Class Name: `com::liquent::insight::manager::publisher::data::publishsettings::SlipSetting`

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 Settings Library	Y	The value of the ID field of the PublishingSettingsLibrary class.	Example: `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 Name: `com::liquent::insight::manager::publisher::data::publishsettings::CoverSettingC`

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.		
outputChannelTypeId	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 Name: `com::liquent::insight::manager::publisher::data::publishsettings::CoverPageSett`

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.		
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 Name: `com::liquent::insight::manager::publisher::data::specialsheets::Cover`

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.		
changeReasonTypeId	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 691.		

Field Name	Field Type	Matching UI Field	Req (Y/N)	Description	Acceptable Values	Default Value
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.		
ssIcon	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.		
linkStyleTypeId	long	Electronic Hyperlink Style	Y	Defines the style of the hyperlink.	— DASHEDBOX — SOLIDBOX — UNDERLINE — NONE	
linkColorTypeId	long	Electronic Hyperlink Color	N	The color of the hyperlink in the published output.	— BLUE — BLACK	BLUE
linkLineThicknessTypeId	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 cross-document 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 Name: `com::liquent::insight::manager::publisher::data::publishsettings::DefaultPublis`

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 Name: `com::liquent::insight::manager::publisher::data::paper::ValidPrinterMedia`

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 `ValidaPrinterMedia` 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

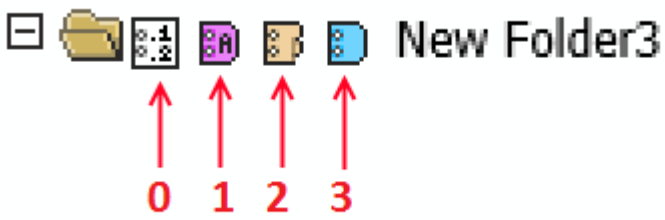
Field Name	Field Type	Matching UI Field	Req(Y/N)	Description	Acceptable Values	Default Value
bestfitFlag	string	Apply Best Fit Overlay	N	Used to find the best fitting overlay page from the overlay template.	— Y — N	N
changeReasonComment	string		N	This field is not used for import.		
changeReasonTypeId	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.		

Field Name	Field Type	Matching UI Field	Req(Y/N)	Description	Acceptable Values	Default Value
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 Overlay to Content 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 defined, 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 measurementTypeId field.
— If the value of the measurementTypeId 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 measurementTypeId 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 Name: `com::liquent::insight::manager::publisher::data::metadata::MetaDataLibrary`

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`

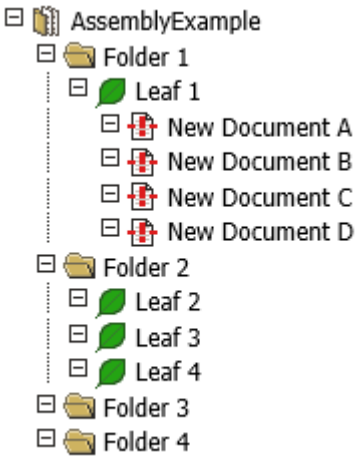
Field Name	Field Type	Matching UI field	Req (Y/N)	Description	Acceptable values	Default value
id	long		Y	Unique PublisherMetaData ID represented by numerical value. Field is used to link classes within Assembly XML. This value will be used to populate corresponding fields in child classes. This ID will 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`

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 PublisherMetaData. 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 PublisherMetaData, then additional extension fields appear.		Fixed value is `m1-us-meta-data-application|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:

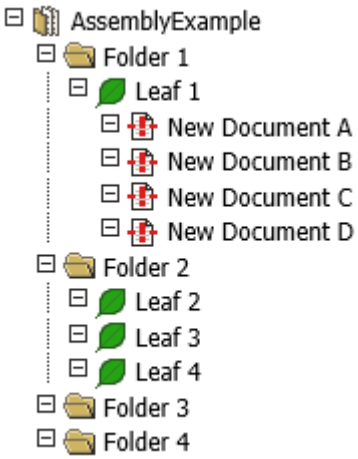


The following Field values are applicable:

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
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