Ennov InSight 7.1 Data Migration Documentation

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Data Migration Documents

Document Name
Ennov_InSight_7.1.15_Data_Migration_Document
Ennov_InSight_7.1.14_Data_Migration_Document
N/A for Ennov InSight 7.1.13
N/A for Ennov InSight 7.1.12
N/A for Ennov InSight 7.1.11
N/A for Ennov InSight 7.1.10
N/A for Ennov InSight 7.1.9
N/A for Ennov InSight 7.1.8
N/A for Ennov InSight 7.1.7
N/A for Ennov InSight 7.1.6
N/A for Ennov InSight 7.1.5
N/A for Ennov InSight 7.1.4
Ennov InSight 7.1.3 Data Migration Document
N/A for Ennov InSight 7.1.2
Ennov InSight 7.1 Data Migration Document
Ennov InSight 7.0 Data Migration Document
Data Migration Document - Previous Versions

Ennov InSight Database Migration Release Notes

The Ennov InSight Database Migration Release Notes and the Ennov InSight Data Migration Documents provide information about the SQL database scripts and other procedures required to perform migrations for the Ennov InSight database. The installation and migration script package provides a convenient means for distributing the Ennov InSight database scripts and clarifies the approach for upgrading the Ennov InSight database.

Ennov InSight data migration documentation provides essential information to support new installations and upgrades, and to assist your migration planning and execution. The data migration documentation should be read in conjunction with the Ennov InSight Release Notes, which describe the updates that have been implemented in each release.

Before executing any database scripts, please verify that you have the most current version of the Ennov InSight Database Migration package. Check the FTP site or contact Technical Support to confirm that you have the latest version.

Prerequisites

The users and groups who will be using the Ennov InSight 7.1 system should have their accounts created in Azure AD and provide the User Object IDs for the User migration phase. For Data Migration requirements, see Ennov InSight 7.1 Data Migration Requirements.

Note: *For data migration and installation assistance, please contact your Business Development Representative.*

Ennov InSight Database Migration Details

The migration package includes SQL database scripts that are run on an Oracle database to establish the database instance for Ennov InSight.
You can use the database scripts as a guide for migrating your earlier version of Ennov InSight to a current release.

Note: *The migration scripts delete all saved queries.*

The scripts are supplied in ZIP files:

- `DB Upgrade 70 to 71.zip`(DB_update7_1_0_0000_0112.zip) (To migrate to Ennov InSight 7.1 from Ennov InSight 7.0, see:*Data Migration Documents*)
- `DB Upgrade 71 to 711.zip`(DB_update7_1_1_0000_0001.zip) (To migrate to Ennov InSight 7.1.1 from Ennov InSight 7.1, see: *Data Migration Documents*)
- `DB Upgrade 711 to 712.zip`(DB_update7_1_2_0000_0001.zip) (To migrate to Ennov InSight 7.1.2 from Ennov InSight 7.1.1, see:*Data Migration Documents*)

— `DB Upgrade 712 to 713.zip`(DB_update7_1_3_0000_0020.zip) (To migrate to Ennov InSight 7.1.3 from Ennov InSight 7.1.2, see:*Data Migration Documents*)
— `DB Upgrade 716 to 7111.zip`(DB_update7_1_11_0000_0004.zip) (Running the migration script does not result in any functional changes to the Data Administration data. The script provided to fix issues that occur after Oracle upgrade to the 19.17.0.0.221018 version).
— N/A for Ennov InSight 7.1.12
— N/A for Ennov InSight 7.1.13
— `DB Upgrade 7113 to 7114.zip`(DB_update7_1_13_0000_0005.zip)
— `DB Upgrade 7114 to 7115.zip`(DB_update7_1_14_0000_0004.zip)

Verify Migration Script Updates: Ennov InSight 7.1.15

After the migration script is run, changes must be verified and updated to the Data Administration data.

WHO Updates

The script includes following WHO updates:

— Creates or updates the WHO region to have the code value WHO in the database.
— Creates or updates the WHO country and associates it with the WHO region.
— Updates Health Authority Name to World Health Organization, Health Authority Abbreviation to WHO, Health Authority eCTD Code to whopqt and Health Authority Website to https://extranet.who.int/prequal/ in Application Maintenance > Country values.
— Adds the WHO-1-0 assembly DTD type in the Assembly - Assembly DTD/Schema Types section in Data Administration, if it does not already exist.
— Updates National Procedure Type in the Application Maintenance-Procedure Type values section in Data Administration values to make it activate (if inactive) and updates to include the WHO country.
— Updates Application Maintenance > Application type values with following values and assigns corresponding eCTD codes:
  - Finished Pharmaceutical Product
  - Finished Vaccine Product
  - Active Pharmaceutical Ingredient
  - Active Pharmaceutical Ingredient Master File

The Finished Pharmaceutical Product Application Type gets Default Flag set to Yes upon associating it with WHO country.

— Updates Sequence Maintenance > Filing Type values with following values and assigns corresponding eCTD codes:
  - Annual Report (FVP)
  - APIMF Procedure
  - New Emergency Use Listing (EUL) Application (FPP,FVP)
  - Post-PQ Change (API, FFP, FVP)
  - New Prequalification Application (API, FFP, FVP)
  - Reassessment (FVP)

- Requalification Application (FPP)

— Updates Submission Maintenance > Sub Filing Type values with following values and assigns corresponding eCTD codes:
  - Annual Notification (FPP)
  - Abridged
  - Immediate Notification (API)
  - Annual Notification (API)
  - Conversion
  - eCTD Baseline
  - EUL-Full (Emergency Use Listing)
  - Full
  - Immediate Notification (FPP)
  - Major
  - Minor
  - Parallel
  - Product Extension
  - Standard
  - Type A (Approval Before Implementation)(Major)(FVP)
  - Type N (Immediate Notification)(Minor) (FVP)
  - Update
  - no Application Sub Type

— Updates Submission Maintenance > Regulatory Activity Lead values with following values and assigns corresponding eCTD codes:
  - Initial
  - Validation Response
  - Response
  - Additional Info
  - Reformat

— Updates Submission Maintenance > Submission Product Type values with following values and assigns corresponding eCTD codes:
  - Biotherapeutic Product
  - Finished Pharmaceutical Product

EU 3.1 Updates

The migration script will perform multiple changes to Data Administration data related to EU 3.1. These should be verified, and where necessary, updated. The script does the following:

— Updates the eCTD Code for Northern Ireland country xi or whole country is added if does not already exist to the Application Maintenance – Country Values section in Data Administration.

— Updates EU County-Health Authority values in the Application Maintenance – Country values section in Data Administration if they do not already exist. List of new or updated values can be found below:
  - AT-BASG
  - BE-FAMHP
  - HR-HALMED
  - CY-PHS
  - CZ-SUKL
  - DK-DKMA
  - EE-SAM
  - DK-DKMA
  - EE-SAM
  - FR-ANSM
  - DE-BFARM
  - EL-EOF
  - HU-OGYI
  - IS-IMCA
  - IE-HPRA
  - IT-AIFA
  - LV-ZVA
  - LI-LLV
  - LT-SMCA
  - LU-MINSANT
  - MT-MEDAUTH
  - NL-MEB
  - NO-NOMA
  - PL-URPL
  - PT-INFARMED
  - SK-SIDC
  - SI-JAZMP
  - ES-AEMPS
  - SE-MPA
— Adds the 'EU-3-1' Assembly DTD/Schema type in the Assembly - Assembly DTD/Schema Types section in Data Administration, it will be activated (if inactive) and updated to have the code value 'EU-3-1'. Otherwise, the 'EU-3-1' Assembly DTD/Schema will be added.
— Updates Sequence Maintenance – Filing Type values with following values:
  - Article 18 Filing
— Updates Submission Maintenance – Sub Filing Type values with following values:
  - Initial
  - Validation Response
  - Response
  - Additional Information

- Closing Information
- Consolidating
- Corrigendum
- Reformat
- Re-examination

Data Administration

Data Administration Updates for Ennov InSight 7.1.15

Data Administration Updates: Ennov InSight 7.1.1.15

Running the migration script updates Data Administration with latest changes. The changes must be reviewed, and updated, as necessary.

EU v3.1 Updates

Country Code	Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority Website
AT	Austria	Austrian Federal Office for Safety in Health Care / Austrian Medicines and Medical Devices Agency	BASG	AT-BASG	www.basg.gv.at
BE	Belgium	Federal agency for medicines and health products	FAMHP	BE-FAMHP	http://www.fagg-afmps.be/
HR	Croatia	Agency for Medicinal Products and Medical Devices of Croatia	HALMED	HR-HALMED	http://www.halmed.hr/
CY	Cyprus	Pharmaceutical Services - Ministry of Health	PHS	CY-PHS	http://www.moh.gov.cy/
CZ	Czech Republic	State Institute for Drug Control	SUKL	CZ-SUKL	www.sukl.eu

Country Code	Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority Website
DK	Denmark	Danish Medicines Agency	DKMA	DK-DKMA	www.lmst.dk
EE	Estonia	State Agency of Medicines	SAM	EE-SAM	ravimiregister.ravimiamet.ee/en/default.aspx
FR	France	National Agency for the Safety of Medicines and Health Products	ANSM	FR-ANSM	http://ansm.sante.fr/
DE	Germany	BfArM - Federal Institute for Drugs and Medical Devices	BfArM	DE-BFARM	http://www.bfarm.de/
GR	Greece	Greek National Organization for Medicines	EOF	EL-EOF	http://www.eof.gr/
HU	Hungary	National Institute of Pharmacy and Nutrition	OGYI	HU-OGYI	www.ogyei.gov.hu
IS	Iceland	Icelandic Medicines Agency	IMCA	IS-IMCA	http://www.ima.is/
IE	Ireland	The Health Products Regulatory Authority	HPRA	IE-HPRA	http://www.hpra.ie
IT	Italy	Italian Medicines Agency	AIFA	IT-AIFA	www.aifa.gov.it
LV	Latvia	State Agency of Medicines	ZVA	LV-ZVA	http://www.zva.gov.lv

Country Code	Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority Website
LI	Liechtenstein	Office of Health / Medicinal Products Control Agency	LLV	LI-LLV	http://www.llv.li/
LT	Lithuania	State Medicines Control Agency	SMCA	LT-SMCA	http://www.vvkt.lt/
LU	Luxembourg	Ministry of Health	MINSANT	LU-MINSANT	www.ms.etat.lu
MT	Malta	Medicines Authority	MRU	MT-MEDAUTH	http://www.medicinesauthority.gov.mt/
NL	Netherlands	Medicines Evaluation Board	MEB	NL-MEB	http://www.cbg-meb.nl/
NO	Norway	Norwegian Medical Products Agency	NOMA	NO-NOMA	https://www.dmp.no/
PL	Poland	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products	URPL	PL-URPL	http://www.urpl.gov.pl/
PT	Portugal	National Authority of Medicines and Health Products, IP	INFARMED	PT-INFARMED	http://www.infarmed.pt/
SK	Slovakia	State Institute for Drug Control	SIDC	SK-SIDC	http://www.sukl.sk/

Country Code	Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority Website
SI	Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia	JAZMP	SI-JAZMP	http://www.jazmp.si/
ES	Spain	Spanish Agency for Medicines and Health Products	AEMPS	ES-AEMPS	http://www.aemps.gob.es/
SE	Sweden	Medical Products Agency	MPA	SE-MPA	http://www.lakemedelsverket.se/

Assembly - Assembly DTD/Schema Type

If the 'EU-3-1' Assembly DTD/Schema type already exists in the Assembly - Assembly DTD/Schema Types section in Data Administration, it will be activated (if inactive) and updated to have the code value 'EU-3-1'. Otherwise, the 'EU-3-1' Assembly DTD/Schema will be added.

Sequence Maintenance - Filing Type Values

Filing Type values will be added to the Sequence Maintenance – Filing Type values section in Data Administration, if they do not already exist. List of new values can be found in table below:

Filing Type	Display Name	Countries
Article 18 Filing	Article 18 Filing	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom

Submission Maintenance - Sub Filing Type Values

Sub Filing Type values will be added to the Submission Maintenance – Sub Filing Type values section in Data Administration, if they do not already exist. List of new values can be found in table below:

Sub Filing Type	Countries
Initial	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, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Spain, Sweden, Undefined, United Kingdom
Closing Information	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, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Spain, Sweden, Undefined, United Kingdom
Validation Response	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, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Response	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, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Additional Information	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, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Consolidating	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, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Corrigendum	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, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Reformat	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, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom

Sub Filing Type	Countries
Re-examination	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, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom

Submission Maintenance - Filing Type eCTD Codes

The Filing Type eCTD Codes values will be added to the Submission Maintenance > Filling Type Values section in Data Administration if they do not already exist. If they exist, the eCTD Code for eu-3-1 DTD/Schema is added to them. The list of new values includes the following:

Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Marketing Authorisation Application	eu-3-1	maa	MAA, MAA-AH
Variation 1A Filing	eu-3-1	var-type1a	MAA, MAA-AH
Variation 1AIN Filing	eu-3-1	var-type1ain	MAA, MAA-AH
Variation 1B Filing	eu-3-1	var-type1b	MAA, MAA-AH
Variation 2 Filing	eu-3-1	var-type2	MAA, MAA-AH
National Variation Filing	eu-3-1	var-nat	MAA, MAA-AH
Extension Filing	eu-3-1	extension	MAA, MAA-AH
Repeat Use Procedure	eu-3-1	rup	MAA, MAA-AH
Periodic Safety Update Report	eu-3-1	psur	MAA, MAA-AH
PSUR single assessment procedure	eu-3-1	psusa	MAA, MAA-AH
Risk Management Plan Filing	eu-3-1	rmp	MAA, MAA-AH
Renewal Filing	eu-3-1	renewal	MAA, MAA-AH
Specific Obligation Related to PAM	eu-3-1	pam-sob	MAA, MAA-AH
Annex II Condition Related to PAM	eu-3-1	pam-anx	MAA, MAA-AH
Additional PV Activity in the RMP Related to PAM	eu-3-1	pam-mea	MAA, MAA-AH
Legally Binding Measure Related to PAM	eu-3-1	pam-leg	MAA, MAA-AH
SDA Submission Related to PAM	eu-3-1	pam-sda	MAA, MAA-AH
Corrective/Preventive Action Related to PAM	eu-3-1	pam-capa	MAA, MAA-AH

Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Paediatric Submission Related to PAM (Article 45)	eu-3-1	pam-p45	MAA, MAA-AH
Paediatric Submission Related to PAM (Article 46)	eu-3-1	pam-p46	MAA, MAA-AH
PAES Submission Related to PAM	eu-3-1	pam-paes	MAA, MAA-AH
Recommendation Related to PAM	eu-3-1	pam-rec	MAA, MAA-AH
PASS Protocol Submission (Article 107n)	eu-3-1	pass107n	MAA, MAA-AH
PASS Report Submission (Article 107q)	eu-3-1	pass107q	MAA, MAA-AH
ASMF Filing	eu-3-1	asmf	MAA, MAA-AH
Plasma Master File	eu-3-1	pmf	MAA, MAA-AH
Article 20 Referral	eu-3-1	referral-20	MAA, MAA-AH
Article 29(4) Referral	eu-3-1	referral-294	MAA, MAA-AH
Article 29 Paediatric Referral	eu-3-1	referral-29p	MAA, MAA-AH
Article 30 Referral	eu-3-1	referral-30	MAA, MAA-AH
Article 31 Referral	eu-3-1	referral-31	MAA, MAA-AH
Article 35 Referral	eu-3-1	referral-35	MAA, MAA-AH
Article 5(3) Referral	eu-3-1	referral-5-3	MAA, MAA-AH
Article 107i Referral	eu-3-1	referral-107i	MAA, MAA-AH
Article 16c (1c)i Referral	eu-3-1	referral-16c1c	MAA, MAA-AH
Article 16c(4) Referral	eu-3-1	referral-16c4	MAA, MAA-AH
Annual Reassessment Filing	eu-3-1	annual-reassessment	MAA, MAA-AH
USR Filing	eu-3-1	usr	MAA, MAA-AH
Clinical Data for Publication – Redacted Proposal	eu-3-1	clin-data-pub-rp	MAA, MAA-AH
Clinical Data for Publication – Final Version	eu-3-1	clin-data-pub-fv	MAA, MAA-AH
PAED Related to PIP (Article 7, 8, 30)	eu-3-1	paed-7-8-30	MAA, MAA-AH
PAED Article 29 Filing	eu-3-1	paed-29	MAA, MAA-AH

Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
PAED Article 45	eu-3-1	paed-45	MAA, MAA-AH
PAED Article 46	eu-3-1	paed-46	MAA, MAA-AH
Article 58 Filing	eu-3-1	article-58	MAA, MAA-AH
Notification 61-3 Filing	eu-3-1	notification-61-3	MAA, MAA-AH
Transfer MA Filing	eu-3-1	transfer-ma	MAA, MAA-AH
Lifting Suspension Filing	eu-3-1	lifting-suspension	MAA, MAA-AH
Withdrawal Filing	eu-3-1	withdrawal	MAA, MAA-AH
CEP Submission	eu-3-1	cep	MAA, MAA-AH
None	eu-3-1	none	MAA, MAA-AH
Article 18 Filing	eu-3-1	article-18	MAA, MAA-AH

Submission Maintenance - Sub Filing Type eCTD Codes Values

Sub Filing Type eCTD codes values will be added to the Submission Maintenance – Sub Filing Type values section in Data Administration, if they do not already exist. If they already exist, the eCTD Code for ZA-3-0 DTD/Schema is added to the value. List of new values can be found in table below:

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Initial	eu-3-1	initial	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Validation Response	eu-3-1	validation-response	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Response	eu-3-1	response	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Additional Information	eu-3-1	additional-info	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Closing Information	eu-3-1	closing	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Consolidating	eu-3-1	consolidating	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Corrigendum	eu-3-1	corrigendum	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Reformat	eu-3-1	reformat	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Re-examination	eu-3-1	re-examination	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.

WHO v1.0 Updates

Application Maintenance – Region Values

If the WHO region already exists in the Application Maintenance – Region Values section in Data Administration, it will be updated to have the code value 'WHO' in the database. Otherwise, the WHO region is added with the values:

Region Abbreviation	Region Name	Active Flag
WHO	World Health Organization	Active

Application Maintenance - Country Values

New WHO country in the Application Maintenance – Country values in Data Administration, must be changed or added, if absent, with the following values:

Country Code	Country Name	eCTD Code	Region	Active Flag
WHO	World Health Organization	whopqt	World Health Organization	Active

Application Maintenance - Health Authority Name

Health Authority name for WHO country, in the Application Maintenance – Country values in Data Administration under the Health Authority tab, must be changed or added, if absent, to those listed in the following table:

Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority website
World Health Organization	World Health Organization	WHO	whopqt	https://extranet.who.int/prequal/

Assembly - Assembly DTD/Schema Type Values

If the 'WHO-1-0' Assembly DTD/Schema type already exists in the Assembly - Assembly DTD/Schema Types section in Data Administration, it will be activated (if inactive) and updated to have the code value 'WHO-1-0'. Otherwise, the 'WHO-1-0' Assembly DTD/Schema will be added.

Application Maintenance - Procedure Type Values

The 'National' Procedure Type in the Application Maintenance - Procedure Type values section in Data Administration, it will be activated (if inactive) and updated to include WHO country, in addition to already added countries.

Application Maintenance - Application Type Values

The *Application Type Values* list will be added to the Data Administration > Application Maintenance section if it does not already exist. The list includes the following values:

Application Type	Name	Display Name	Entity XML Type Name	Application Category	Countries
FPP	Finished Pharmaceutical Product	Finished Pharmaceutical Product	New Drug Application	Finished Pharmaceutical Product	World Health Organization
FVP	Finished Vaccine Product	Finished Vaccine Product	New Drug Application	Finished Vaccine Product	World Health Organization
APIPQ	Active Pharmaceutical Ingredient	Active Pharmaceutical Ingredient	New Drug Application	Active Pharmaceutical Ingredient	World Health Organization
APIMF	Active Pharmaceutical Ingredient Master File	Active Pharmaceutical Ingredient Master File	New Drug Application	Active Pharmaceutical Ingredient Master File	World Health Organization

The Finished Pharmaceutical Product Application Type gets Default Flag set to Yes upon associating it with WHO country.

Application Maintenance - Application Category Values

Application Category Values will be added to the Application Maintenance – Application Type Values section in Data Administration if they do not already exist. List of new values can be found in table below:

Application Category Name	Active Flag
Finished Pharmaceutical Product	Active
Finished Vaccine Product	Active
Active Pharmaceutical Ingredient	Active
Active Pharmaceutical Ingredient Master File	Active

Application Maintenance - Application Type eCTD Codes

The Application Type eCTD Codes values will be added to the Application Maintenance > Application Type Values list in Data Administration if they do not already exist there. If they exist, the eCTD Code for who-1-0 DTD/Schema will be added to them. The list of new values includes the following:

Application Type (Display Name)	Application DTD/ Schema	eCTD Code	Agency Abbreviation	Limit to Cross Application Only
Finished Pharmaceutical Product	who-1-0	FPP		No
Finished Vaccine Product	who-1-0	FVP		No
Active Pharmaceutical Ingredient	who-1-0	APIPQ		No
Active Pharmaceutical Ingredient Master File	who-1-0	APIMF		No

Sequence Maintenance - Filing Type eCTD Codes

The Filing Type eCTD Codes values will be added to the Sequence Maintenance > Filing Type Values list in Data Administration if they do not already exist. If they exist, the eCTD Code for who-1-0 DTD/Schema is added to them. The list of new values includes the following:

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
Annual Report (FVP)	who-1-0	AR	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File
APIMF Procedure	who-1-0	APIMF	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
New Emergency Use Listing (EUL) Application (FPP, FVP)	who-1-0	EUL	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File
Post-PQ Change (API, FFP, FVP)	who-1-0	PPQC	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File
New Prequalification Application (API, FFP, FVP)	who-1-0	PQP	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File
Reassessment (FVP)	who-1-0	REAS	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File
Requalification Application (FPP)	who-1-0	RQAP	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File

Submission Maintenance - Sub Filing Type eCTD Codes

The Sub Filing Type eCTD Codes values will be added to the Submission Maintenance > Sub Filling Type Values section in Data Administration if they do not already exist. If they exist, the eCTD Code for who-1-0 DTD/Schema is added to them. The list of new values includes the following:

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Annual Notification (FPP)	WHO-1-0	AN	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Abridged	WHO-1-0	PQA	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Immediate Notification (API)	WHO-1-0	AIN	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Annual Notification (API)	WHO-1-0	AAN	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Conversion	WHO-1-0	CONV	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
eCTD Baseline	WHO-1-0	eCTDB	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
EUL-Full (Emergency Use Listing)	WHO-1-0	EULF	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Full	WHO-1-0	Full	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Immediate Notification (FPP)	WHO-1-0	IN	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Major	WHO-1-0	Major	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Minor	WHO-1-0	Minor	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Parallel	WHO-1-0	Parallel	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Product Extension	WHO-1-0	PEX	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Standard	WHO-1-0	STD	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Type A (Approval Before Implementation) (Major)(FVP)	WHO-1-0	AMAJ	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Type N (Immediate Notification) (Minor) (FVP)	WHO-1-0	NMI	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Update	WHO-1-0	UPD	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
no Application Sub Type	WHO-1-0	none	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)

Submission Maintenance - Regulatory Activity Lead Values

The Regulatory Activity Lead Values will be added to the Submission Maintenance > Regulatory Activity Lead Values list in Data Administration if they do not already exist. The list of new values includes the following:

Region	Applicable DTD/Schema	eCTD Code	Regulatory Activity Lead
WHO	who-1-0	initial	Initial
WHO	who-1-0	validation-response	Validation Response
WHO	who-1-0	response	Response
WHO	who-1-0	additional-info	Additional Info
WHO	who-1-0	reformat	Reformat

Submission Maintenance Submission Product Type Values

Submission Product Type values will be added to the Submission Maintenance > Submission Product Type Values section in Data Administration if they do not already exist. List of new values can be found in table below:

Region	eCTD Code	Product Type	Applicable DTD/Schema
WHO	BTP	Biotherapeutic Product	WHO-1-0
WHO	FPP	Finished Pharmaceutical Product	WHO-1-0

Data Administration Updates for Ennov InSight 7.1.14

Data Administration Updates: Ennov InSight 7.1. 14

Running the migration script updates Data Administration with latest changes. The changes must be reviewed, and updated, as necessary.

ZA v3.1 Updates

If ZA region already exists in the Application Maintenance > Region Values section in Data Administration, it will be updated to have the ZA code value in the database. If ZA region does not exist, an error message will be generated, and the script will skip South Africa updates.

The Health Authority name for South Africa country must be changed to the following:

Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority website
South Africa	South African Health Products Regulatory Authority	SAHPRA	ZA-SAHPRA	https://ectd.sahpra.org.za/index.html

The Health Authority name can be found in Application Maintenance > Country Values in Data Administration under the Health Authority tab

The South Africa country will be updated to belong to South Africa region if it does not belong to it already.
The South Africa country will receive ZA as eCTD code.

If the ZA-3-1 Assembly DTD/Schema type already exists in the Assembly > Assembly DTD/Schema Types list in Data Administration, it will be activated (if inactive) and updated to have the ZA-3-1 code value. Otherwise, the ZA-3-1 Assembly DTD/Schema will be added.

If the National ZA Procedure Type already exists in the Application Maintenance > Procedure Type Values list in Data Administration, it will be activated (if inactive) and updated to have the National eCTD code value. Otherwise, the National ZA Procedure Type will be added.

Application Type Values

The *Application Type Values* list will be added to the Data Administration > Application Maintenance section if it does not already exist. The list includes the following values:

Application Type	Name	Display Name	Entity XML Type Name	Application Category	Countries
ZA-NP	SAHPRA National Procedure	SAHPRA National Procedure	New Drug Application	SAHPRA National Procedure	South Africa

Application Type	Name	Display Name	Entity XML Type Name	Application Category	Countries
AMAP	AMA Procedure	AMA Procedure	New Drug Application	AMA Procedure	South Africa
JR	ZAZIBONA Joint Review	ZAZIBONA Joint Review	New Drug Application	ZAZIBONA Joint Review	South Africa
WHO-PQ	WHO-PQ	WHO-PQ	New Drug Application	WHO-PQ	South Africa
WHO-CRP	WHO SRA CRP	WHO SRA CRP	New Drug Application	WHO SRA CRP	South Africa
CH-GHP	Swissmedic MAGHP	Swissmedic MAGHP	New Drug Application	Swissmedic MAGHP	South Africa
EU-M4ALL	EU M4ALL	EU M4ALL	New Drug Application	EU M4ALL	South Africa

Application Type eCTD Codes

The Application Type eCTD Codes values will be added to the Application Maintenance > Application Type Values list in Data Administration if they do not already exist there. If they exist, the eCTD Code for ZA-3-1 DTD/Schema will be added to them. The list of new values includes the following:

Application Type (Display Name)	Application DTD/ Schema	eCTD Code	Agency Abbreviation	Limit to Cross Application Only
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

Application Category Values

The Application Categories values will be added to the Application Maintenance > Application Category list in Data Administration if they do not already exist there. The list of new values can be found in the table below:

Application Category Name
SAHPRA National Procedure

Application Category Name
AMA Procedure
ZAZIBONA Joint Review
WHO-PQ
WHO SRA CRP
Swissmedic MAGHP
EU M4ALL

Filing Type eCTD Codes

The Filing Type eCTD Codes values will be added to the Sequence Maintenance > Filing Type Values list in Data Administration if they do not already exist. If they exist, the eCTD Code for ZA-3-1 DTD/Schema is added to them. The list of new values includes the following:

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

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
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
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
Type II-Rescheduling	ZA-3-1	sub-type-27	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-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
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

Sub Filing Type eCTD Codes

The Sub Filing Type eCTD Codes values will be added to the Submission Maintenance > Sub Filling Type Values section in Data Administration if they do not already exist. If they exist, the eCTD Code for ZA-3-1 DTD/ Schema is added to them. The list of new values includes the following:

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

Regulatory Activity Lead Values

The Regulatory Activity Lead Values will be added to the Submission Maintenance > Regulatory Activity Lead Values list in Data Administration if they do not already exist. The list of new values includes the following:

Region	Applicable DTD/Schema	eCTD Code	Regulatory Activity Lead
South Africa	ZA-3-1	sub-lead-1	Biologicals
South Africa	ZA-3-1	sub-lead-2	Complimentary
South Africa	ZA-3-1	sub-lead-3	Master Files
South Africa	ZA-3-1	sub-lead-4	Orthodox
South Africa	ZA-3-1	sub-lead-5	Pharmacovigilance
South Africa	ZA-3-1	sub-lead-6	Veterinary

Evaluation Pathway Values

The Evaluation Pathway Values will be added to the Submission Maintenance > Evaluation Pathway Values list in Data Administration if they do not already exist. The list of new values includes the following:

Region	Applicable DTD/Schema	eCTD Code	Regulatory Activity Lead
South Africa	ZA-3-1	eval-path-1	Priority
South Africa	ZA-3-1	eval-path-2	Full Evaluation
South Africa	ZA-3-1	eval-path-3	Abridged Evaluation
South Africa	ZA-3-1	eval-path-4	Rolling Review
South Africa	ZA-3-1	eval-path-5	Section 21

Applicant Contact Type Values

The Applicant Contact Type Values will be added to the Submission Maintenance > Applicant Contact Type Values section in Data Administration if they do not already exist. The list of new values includes the following:

eCTD Standard Type	Region	Regulatory Code	Applicant Contact Type
eCTD 3.2	South Africa	contact-type-1	Local Applicant
eCTD 3.2	South Africa	contact-type-2	Regulatory
eCTD 3.2	South Africa	contact-type-3	Technical
eCTD 3.2	South Africa	contact-type-4	Product Information
eCTD 3.2	South Africa	contact-type-5	General

Data Administration Updates for Ennov Insight 7.1.3

Data Administration Updates for Ennov InSight 7.1.3

Running the migration script results in multiple changes to the Data Administration data. The changes must be reviewed, and updated, if necessary.

Changes related to CN-1-0 implementation:

— Associates China with China region in the Application Maintenance - Region Values, if it is not associated already.

— Health Authority name for China country, that already exists in the Application Maintenance - Country Values in *Data Administration* under the Health Authority tab, must be changed to:

Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority Website
China	National Medical Products Administration	NMPA	https://www.nmpa.gov.cn/

— The country value China will be updated to the China region if it does not belong to it already.

— The eCTD code cn will be assigned to the country value China..

— If the CN-1-0 Assembly DTD/Schema type already exists in the inactive state under Assembly > Assembly DTD/Schema Types section in *Data Administration*, it will be activated and updated to have the code value CN-1-0. Else, the CN-1-0 Assembly DTD/Schema will be added.

— New Procedure Type value will be added to Application Maintenance > Procedure Type Values the attributes below, if it does not exist already:

Field Name	Field Value
Procedure Type Abbreviation	CN - National
Procedure Type Name	CN - National
Display Name	National
Countries	China
Internal Procedure Code	NATIONAL
eCTD Code	national
Procedure Type Code	5
Active Flag	Active

— No changes for Application Types.

— The filing type values will be added to the Sequence Maintenance > Filing Type Values section in *Data Administration* if they do not exist already. If they exist, they will be updated with an eCTD Code for CN-1-0 DTD/Schema based on the following approach:

- For all eCTD Codes from the following table, the Filing Type Value that has the same name will be found and updated with the new eCTD Code for the CN-1-0 DTD/Schema. If the found Filing Type does not have China as an associated county, the value of China will be added to the list of Countries.
- If more than one Filing Type is found with a matching eCTD Code, the one with the matching Filing Type Name will be updated with the new eCTD Code for the CN-1-0 DTD/Schema. If the Filing Type name does not match any Filing Type with a matching eCTD Code, no Filing Type will be updated and the following message will be added to the log: `The Filing Type <name> with eCTD Code <code> could not be created/updated within Data Admin, please verify the configuration post-installation.`
- If the Filing Type is not found based on the eCTD Code, a new Filing Type will be created and assigned to China. The list of Filing Types:

Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Type
Original Application	CN-1-0	cnrat1	IND, NDA, ANDA
Supplement Filing	CN-1-0	cnrat2	IND, NDA, ANDA
Record	CN-1-0	cnrat3	IND, NDA, ANDA
Annual Report Filing	CN-1-0	cnrat4	IND, NDA, ANDA
New Indication and Drug Combination	CN-1-0	cnrat5	IND
New Indication	CN-1-0	cnrat6	IND, NDA, ANDA
Development Safety Report	CN-1-0	cnrat7	IND, NDA, ANDA
Renewal Filing	CN-1-0	cnrat8	NDA, ANDA
Baseline	CN-1-0	cnrat9	IND, NDA, ANDA

Note: *The actual Application Type list may differ from database to database. This is caused by user changes. During the migration, application types are added to fulfill the NMPA requirements, but not removed to prevent the user data corruption.*

Differences in Filing Types and eCTD codes of China drafts 2019 and 2021

Differences in China Filing Types and Sub Filing Types and their eCTD codes between the draft of 2019 and the final draft of 2021.

Filing Type and eCTD code

It is recommended to verify you have the correct data after the migration is completed.

Draft 2019 Filing Type	Draft 2019 eCTD Code	Final 2021 Filing Type	Final 2021 eCTD Code
Original Application	cnrat1	Original Application	cnrat1
Supplement Filing	cnrat2	Supplement Filing	cnrat2
New Indication	cnrat3	New Indication	cnrat6
Annual Report Filing	cnrat4	Annual Report Filing	cnrat4
Periodic Safety Update Report	cnrat5	N/A	CN eCTD code is deactivated
Renewal Filing	cnrat6	Renewal Filing	cnrat8
Baseline	cnrat7	Baseline	cnrat9

Draft 2019 Filing Type	Draft 2019 eCTD Code	Final 2021 Filing Type	Final 2021 eCTD Code
N/A	N/A	New Indication and Drug Combination	cnrat5
N/A	N/A	Record	cnrat3
N/A	N/A	Development Safety Report	cnrat7

Sub Filing Types eCTD Codes

Sub Filing Type	Draft 2019 Filing Types	Final 2021 Filing Types	Difference
Original	Original Application, Supplement Filing, New Indication, Annual Report Filing, Periodic Safety Update Report, Renewal Filing.	Original Application, Supplement Filing, New Indication and Drug Combination, Development Safety Report, Record, Annual Report Filing, New Indication, Renewal Filing.	Added: New Indication and Drug Combination, Development Safety Report. Removed: Periodic Safety Update Report.
Response	Original Application, Supplement Filing, New Indication, Annual Report Filing, Periodic Safety Update Report, Renewal Filing, Baseline.	Original Application, Supplement Filing, New Indication and Drug Combination, Development Safety Report, Record, Annual Report Filing, New Indication, Renewal Filing, Baseline.	Added: New Indication and Drug Combination, Development Safety Report. Removed: Periodic Safety Update Report.
Withdrawal	Original Application, Supplement Filing, New Indication, Annual Report Filing, Periodic Safety Update Report, Renewal Filing, Baseline	Original Application, Supplement Filing, New Indication and Drug Combination, Development Safety Report, Record, Annual Report Filing, New Indication, Renewal Filing, Baseline	Added: New Indication and Drug Combination, Development Safety Report. Removed: Periodic Safety Update Report.
Reformat	Baseline	Baseline	No changes.

Data Administration Updates for Ennov InSight 7.1

Data Administration Updates: Country Values

Ennov InSight 7.1 includes the changes and updates related to Counry Values.

Country Values

Ennov InSight 7.1 introduces a new Languages sub-tab for Application Maintenance > Country Values. This enables you to map language values to a specific country value and define the default one.

After migrating to Ennov InSight 7.1, OOTB mapping for Country - Language values must be as follows:

Country	Language
Angola	Portuguese
Antigua and Barbuda	English
Australia	English
Austria	English; German
Bahamas	English
Belgium	Dutch; Flemish; English; French; German
Belize	English
Benin	French
Bosnia and Herzegovina	Croatian
Botswana	English
Brazil	Portuguese
Brunei Darussalam	English
Bulgaria	Bulgarian; English
Burkina Faso	French
Burundi	English; French
Cameroon	English; French
Canada	English; French
Cape Verde	Portuguese
Central African Republic	French
Chad	French
Christmas Island	English
Cocos (Keeling) Islands	English
Comoros	French
Cook Islands	English
Croatia	Croatian; English
Cyprus	English; Greek
Czech Republic	Czech; English; Slovak
Denmark	Danish; English
Djibouti	French

Country	Language
Dominica	English
Equatorial Guinea	French; Portuguese
Estonia	English; Estonian
Ethiopia	English
Fiji	English
Finland	English; Finnish; Swedish
France	English; French
Gabon	French
Gambia	English
Germany	English; German
Ghana	English
Greece	English; Greek
Grenada	English
Guinea	French
Guinea-Bissau	Portuguese
Guyana	English
Haiti	French
Hungary	English; Hungarian
Iceland	English; Icelandic
India	English
Ireland	English; Irish
Italy	English; Italian
Jamaica	English
Kenya	English
Kiribati	English
Latvia	English; Latvian
Lesotho	English
Liberia	English
Liechtenstein	English; German
Lithuania	English; Lithuanian

Country	Language
Luxembourg	English; French; German
Madagascar	French
Malawi	English
Malaysia	English
Mali	French
Malta	English; Maltese
Marshall Islands	English
Mauritius	English
Micronesia, Federated States Of	English
Moldova, Republic Of	Romanian; Moldavian; Moldovan
Monaco	French
Montenegro	Croatian
Mozambique	Portuguese
Namibia	English
Nauru	English
Netherlands	Dutch; Flemish; English
New Zealand	English
Niger	French
Nigeria	English
Niue	English
Norfolk Island	English
Norway	English; Norwegian Nynorsk; Nynorsk, Norwegian
Pakistan	English
Palau	English
Papua New Guinea	English
Philippines	English
Poland	English; Polish
Portugal	English; Portuguese
Romania	English; Romanian; Moldavian; Moldovan
Rwanda	English; French

Country	Language
Saint Kitts and Nevis	English
Saint Lucia	English
Saint Vincent and The Grenadines	English
Samoa	English
San Marino	Italian
Senegal	French
Seychelles	English; French
Sierra Leone	English
Singapore	English
Slovakia	English; Slovak
Slovenia	English
Solomon Islands	English
South Africa	English
Spain	English
Sudan	English
Suriname	Dutch; Flemish
Sweden	English; Swedish
Switzerland	French; German; Italian
Togo	French
Tokelau	English
Tonga	English
Trinidad and Tobago	English
Tunisia	French
Tuvalu	English
Uganda	English
United Kingdom	English
United Republic Of Tanzania	English
United States	English
Vanuatu	English; French
Zambia	English

Country	Language
Zimbabwe	English

You can manage the migrated Language values under Country manually.

Data Administration Updates: SPOR Master Lists

Ennov InSight 7.1 includes changes related to SPOR Master Lists Data Administration Updates.

Data Administration Updates

The Data Administration section has been updated to include the changes for SPOR Master Lists.

SPOR Master Lists

SPOR is the European Medicines Agency's (EMA) Master Data Management service that complies with ISO Identification of Medicinal Products (IDMP). There are two sub sections of SPOR that have controlled vocabularies supported in Ennov InSight 7.1:

— OMS (Organisation Management Services
— RMS (Referentials Management Services)

Ennov InSight 7.1 will maintain local master copies of the SPOR source lists for OMS and RMS. The following SPOR data value lists are supported:

— Anatomical Therapeutic Chemical Classification System – Human
— Application Legal Basis
— Application Submission Type
— Combination Package
— Combined Pharmaceutical Dose Form
— Combined Term
— Contact Party Role
— Country
— Data Classification
— Domain
— EU Regulatory Authorisation Procedure
— Ingredient Role
— Language
— Legal Status for the Supply
— Manufacturing Activity
— Marketing Status
— Master File Type
— Material
— Medical Dictionary For Regulatory Activities
— Medicinal Product Name Party Type
— Organization
— Packaging

— Pharmaceutical Dose Form
— Product Category
— Product Cross Reference Type
— Product Information Document Type
— Quantity Operator
— Regulatory Entitlement Status
— Regulatory Entitlement Type
— Routes and Methods of Administration
— Shelf Life Type
— Special Precaution for Storage
— Units of Measurement
— Units of Presentation
— XEVMPD Medical Devices
— XEVMPD Medicinal Product Type

SPOR Mapping to Ennov InSight 7.1 Data Administration Lists

To support mapping EMA SPOR terms to Ennov InSight value lists, new RMS and OMS tabs are added to applicable value lists.

Name of the SPOR Master List in Ennov InSight	Existing Ennov InSight Value List Mapping	NewEnnov InSight Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
Anatomical Therapeutic Chemical Classification System – Human	Product Family > ATC Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	N/A
Application Legal Basis	Other > Legal Basis Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	N/A

Name of the SPOR Master List in Ennov InSight	Existing Ennov InSight Value List Mapping	NewEnnov InSight Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
Application Submission Type	N/A	Other > Application Submission Type Values	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	
Combination Package	Product Maintenance > Dosage/ Pharmaceutical Form Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	
Combined Pharmaceutical Dose Form	Product Maintenance > Dosage/ Pharmaceutical Form Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	
Combined Term	Product Maintenance > Dosage/ Pharmaceutical Form Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	
Contact Party Role	Registration Maintenance > Qualified Person Responsible for Pharmacovigilance (QPPV) Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	

Name of the SPOR Master List in Ennov InSight	Existing Ennov InSight Value List Mapping	NewEnnov InSight Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
Country	Application Maintenance > Country Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	
Data Classification	Product Detail Set Maintenance > Manufacturer Values – Global Detail Sets	N/A	Confidentiality Indicator on the *Global Detail Sets* attribute page.	
Domain	N/A	Product Family Maintenance > Domain Type Values	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	
EU Regulatory Authorisation Procedure	Application Maintenance > Procedure Type Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	
Ingredient Role	Product Detail Set Maintenance > Substance Role Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	

Name of the SPOR Master List in Ennov InSight	Existing Ennov InSight Value List Mapping	NewEnnov InSight Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
Language	Other > Language Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	
Legal Status for the Supply	Application Maintenance > Legal Status Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	
Manufacturing Activity	Product Detail Set Maintenance > Manufacturing Function Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	
Marketing Status	Registration Maintenance > Marketing Status Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	
Master File Type	N/A	Registration Maintenance > Master File Type Values	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	

Name of the SPOR Master List in Ennov InSight	Existing Ennov InSight Value List Mapping	NewEnnov InSight Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
Material	Product Detail Set Maintenance > Product Material Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	
Medical Dictionary For Regulatory Activities	Other > Indications/ Intended Use Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	
Medicinal Product Name Part Type	N/A	Registration Maintenance > Medicinal Product Name Part Type Values	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	
Organization	Other > MAH/ Development Sponsor/Organisation Values	N/A	N/A	— Organization ID — Location ID — Organization — Name — Address — City — Post Code — Country — Last User Updated — Last Changed Date — Active Flag

Name of the SPOR Master List in Ennov InSight	Existing Ennov InSight Value List Mapping	NewEnnov InSight Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
Organization	Product Detail Set Maintenance > Manufacturer Values	N/A	N/A	— Organization ID — Location ID — Manufacturer — Name — Address — City — Post Code — Country — Last User Updated — Last Changed Date — Active Flag
Organization	Application Maintenance > Country Values - Health Authority	N/A	N/A	— Organization ID — Location ID — Health Authority — Name — Address — City — Post Code — Country — Last User Updated — Last Changed Date — Active Flag
Packaging	Product Detail Set Maintenance > Packaging Type Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	N/A

Name of the SPOR Master List in Ennov InSight	Existing Ennov InSight Value List Mapping	NewEnnov InSight Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
Pharmaceutical Dose Form	Product Maintenance > Dosage/ Pharmaceutical Form Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	N/A
Product Category	N/A	Product Maintenance > Product Category Values	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	N/A
Product Cross Reference Type	N/A	Product Maintenance > Product Cross Reference Type Values	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	N/A
Product Information Document Type	N/A	Application > Product Information Document Type	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	N/A
Quantity Operator	Other > Concentration Measure Type Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	

Name of the SPOR Master List in Ennov InSight	Existing Ennov InSight Value List Mapping	NewEnnov InSight Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
Regulatory Entitlement Status	N/A	Application Maintenance > Orphan Status Values	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	N/A
Regulatory Entitlement Type	N/A	Application Maintenance > Regulatory Entitlement Type Values	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	N/A
Routes and Methods of Administration	Product Maintenance > Routes of Administration Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	N/A
Shelf Life Type	Product Detail Set Maintenance > Shelf Life Type Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	N/A
Special Precaution for Storage	Product Detail Set Maintenance > Storage Condition Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	N/A

Name of the SPOR Master List in Ennov InSight	Existing Ennov InSight Value List Mapping	NewEnnov InSight Value List Mapping	New RMS Tab with Fields	New OMS Tab with Fields
Units of Measurement	N/A	Other > Units of Measurement Values	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	N/A
Units of Presentation	Other > Unit of Presentation Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	N/A
XEVMPD Medical Devices	Product Maintenance > Medical Device Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	N/A
XEVMPD Medical Product Type	Registration Maintenance > Medicinal Product Type Values	N/A	— Term ID — Term Name — Description — Last User Updated — Last Changed Date — Active Flag	N/A

Mapping of RMS and OMS is facilitated by a new selection widget.

SPOR RMS Lists not Released by EMA

There are new data value lists created to map to SPOR RMS lists that have not yet been released by EMA.

SPOR RMS List not yet released by EMA	Existing Ennov InSight Value List Mapping	New Ennov InSight Value List Mapping
Attached Document Content Type	N/A	Other > Attached Document Content Type Values

SPOR RMS List not yet released by EMA	Existing Ennov InSight Value List Mapping	New Ennov InSight Value List Mapping
Component Type	N/A	Product Detail Set Maintenance > Component Type Values
Device Type	N/A	Product Detail Set Maintenance > Medical Device UDI Values
Device - Type of Combination	N/A	Product Detail Set Maintenance > Device - Type of Combination Values
Provenance Reason	N/A	Registration Maintenance > Provenance Reason Values

Entities

Entity Updates: Ennov InSight 7.1.3

Ennov InSight 7.1. 3 Active Ingredients

Manufactured Item Active Ingredients and Pharmaceutical Product Active Ingredients are added through data migration.

Active Ingredients

To support IDMP, Ennov InSight 7.1.3 now includes the new field for Manufactured Item Active Ingredients and Pharmaceutical Product Active Ingredients:

Field Name	Description
Alternate IDMP Active Ingredient	— For Manufactured Item Active Ingredient: this field can be configured as a drop-down list with the values from the Component Reference Active Ingredients. — For Pharmaceutical Product Active Ingredient: this field can be configured as a drop-down list with the values from the Component Reference Active Ingredients of Components associated with a Pharmaceutical Product. To search for a Component Active Ingredient, you need to assign Components to Pharmaceutical Product For both: this field can also be configured as the substance selection widget with all the active values from Data Administration > Substance Values.

Entity Updates: Ennov InSight 7.1

Ennov InSight 7.1 Product Family Updates

New changes and implementations are included in Ennov InSight 7.1 to conform to the regulatory requirements.

Product Family

In Ennov InSight 7.1 the Product Family Indications/Intended Use field is renamed to Product Family Indication for all the Product Family Types, except Veterinary.

IDMP

Ennov InSight 7.1 now includes the following IDMP attributes:

- Product Family Comorbidity - a new multi-select field under Product Family Indication.
- EURD ID - a new multi-select field, available for all the Product Family Types, except Medical Devices.

Ennov InSight 7.1 Application Updates

New features and fields are included in Ennov InSight 7.1 to conform to the regulatory requirements.

Application

The Legal Status attribute is renamed to Legal Status of Supply.

Ennov InSight 7.1 includes a new sub-entity for Application - Orphan Designation. To show Orphan Designation on the Application Attributes page, an application must be created for the Orphan Drug and Yes must be selected on the *Create Application* window.

Ennov InSight 7.1 Product Updates

New features and fields are included in Ennov InSight 7.1 to conform to the regulatory requirements.

Product Updates

To support IDMP , the following new fields are added to the Product entity and are available for Pharmaceutical, Pharma-Med Device, and Flu Vaccine Product Family Types:

- Combined Pharmaceutical Dose Form - This is a drop-down list field and available when there is more than one Component created for a Product and isplaced under Product Route of Administration.
- Product Category - This is a multi-select field and is available under Combined Pharmaceutical Dose Form, if available. If not, this field is displayed under Product Route of Administration.
- EURD ID - a new multi-select field.

These new fields will show after migration requirements are met.

Ennov InSight 7.1 Component Active Ingredients Updates

New features and fields are included in Ennov InSight 7.1 to conform to the regulatory requirements.

Component Active Ingredient

In Ennov InSight 7.1, the Component Active Ingredient is created one-by-one and not in bulk. This is because of the change in cardinality between the Component Active Ingredient and the Reference Active Ingredient.

The following strength fields to indicate IDMP strength values are added to the Component Active Ingredient, placed under the XEVMPD strength fields divided by the UI separator:

— IDMP Concentration Measure Type

IDMP Presentation Strength

— Presentation Single or Low Limit Numerator Value
— Presentation Single or Low Limit Unit of Measurement
— Presentation Single or Low Limit Unit of Presentation
— Presentation High Limit Numerator Value
— Presentation High Limit Unit of Measurement
— Presentation High Limit Unit of Presentation

IDMP Concentration Strength

— Concentration Single or Low Limit Numerator Value
— Concentration Single or Low Limit Unit of Measurement
— Concentration Single or Low Limit Denominator Value
— Concentration Single or Low Limit Unit of Measurement
— Concentration High Limit Numerator Value
— Concentration High Limit Unit of Measurement
— Concentration High Limit Denominator Value
— Concentration High Limit Unit of Measurement

In Ennov InSight 7.1 , the grid view for this entity is updated.

Component Reference Active Ingredient

In Ennov InSight 7.1, multiple Reference Active Ingredients can be created for one Component Active Ingredient as required. The Reference Active Ingredients tab is available on the *Active Ingredient Attributes* window.

The following strength fields are added to the Component Active Ingredient to indicate IDMP strength values. The strength fields are placed under the XEVMPD and divided by the UI separator:

— IDMP Concentration Measure Type

IDMP Presentation Strength

— Presentation Single or Low Limit Numerator Value
— Presentation Single or Low Limit Unit of Measurement
— Presentation Single or Low Limit Unit of Presentation
— Presentation High Limit Numerator Value
— Presentation High Limit Unit of Measurement
— Presentation High Limit Unit of Presentation

IDMP Concentration Strength

- Concentration Single or Low Limit Numerator Value
- Concentration Single or Low Limit Unit of Measurement
- Concentration Single or Low Limit Denominator Value
- Concentration Single or Low Limit Unit of Measurement
- Concentration High Limit Numerator Value
- Concentration High Limit Unit of Measurement
- Concentration High Limit Denominator Value
- Concentration High Limit Unit of Measurement

Ennov InSight 7.1Manufactured Item

New features and fields are included in Ennov InSight 7.1 to conform to the regulatory requirements.

Manufactured Item

To support IDMP, Ennov InSight 7.1 now includes the following new entities:

- Manufactured Item This is added as a child entity of Product Component.
- Active Ingredient - This is added as achild entity of Manufactured Item.
- Reference Active Ingredient - Thisis added as a child entity of Active Ingredient under Manufactured Item.
- Substance - This is added as a child entity of Manufactured Item.
- Reference Substance This is added as a child entity of Substance and is under Manufactured Item.

Ennov InSight 7.1 Pharmaceutical Product Updates

New features and fields are included in Ennov InSight 7.1 to conform to the regulatory requirements.

Pharmaceutical Product

In Ennov InSight 7.1, same Components can now be assigned to different Pharmaceutical Products under the same Product.

The unicity rule is updated to make Pharmaceutical Product Name unique under a Product.

To support IDMP, the following changes apply for the fields on the Pharmaceutical Product entity:

- Pharmaceutical Product Summary This is a display-only field and is available when a Pharmaceutical Product is created. By default, this field is hidden. This is available on the Pharmaceutical Product tab for other entities.
- Administrable Dosage Form - This is renamed to Administrable Dose Form and updated with a selection widget.
- Route of Administration - This isa new multi-select field.
- Product Quantity Value - This field is now hidden by default.
- Product Quantity Unit - This field is now hidden by default.
- Product Characteristics - This field is now hidden by default.

In Ennov InSight 7.1 , the grid view for this entity is updated.

To support IDMP, Ennov InSight 7.1 now includes new PhPIDs child entity under Pharmaceutical Products.

Ennov InSight 7.1 Pharmaceutical Product Active Ingredient

New features and fields are included in Ennov InSight 7.1 to conform to the regulatory requirements.

Pharmaceutical Product Active Ingredient

Ennov InSight 7.1 now includes the following new entities for IDMP and XEVMPD support:

- Active Ingredient - This is added as a child entity of Pharmaceutical Products.
- Reference Active Ingredient - This is added as a child entity of Active Ingredient under Pharmaceutical Products.

Reference Substance is added as a child entity of Substance under Pharmaceutical Products (for IDMP support only).

Ennov InSight 7.1 Event-Country Status Updates

New features and fields are included in Ennov InSight 7.1 to conform to the regulatory requirements.

Event-Country Status

The Add Comment field is added on the Event- Country Attributes > Add/Modify-Country Event Status page.

The Event-Country Status Comments field is added on Event- Country Attributes > Add/Modify-Country Event Status page to display comments added. The comments can be deleted or modified.

Ennov InSight 7.1 Status Dates Updates

New features and fields are included in Ennov InSight 7.1 to conform to the regulatory requirements.

Status Dates under Sequence

The Add Comment field is added on the View Sequence > Add/Modify Status pages.

The Sequence Status Comments field is added on View Sequence > Add/Modify Status pages to display comments added., The comments can be deleted or modified.

Status Dates under Task/Sub-Task

The Add Comment field is added on the View Task > Add/Modify Status pages.

The Task Status Comments field is added on View Task > Add/Modify Status pages to display comments added. The comments can be , deleted or modified.

Product Detail Set/Product Detail Set Template

Ennov InSight 7.1 PDS and PDS Template Updates

New features and fields are included in Ennov InSight 7.1 to conform to the regulatory requirements.

PDS Component Node

In Ennov InSight 7.1, the Pharmaceutical Product field is no longer available on the *Component Attributes* page on the PDS.

PDS Active Ingredient Detail

In Ennov InSight 7.1, the XEVMPD strength fields are view-only with the data taken from the *Component Active Ingredient* under the Product.

The Active Ingredient node is now created automatically within the PDS.

See *Pre-Migration Scripts* section for details on how to prepare your data for migration to v7.1.

PDS Substance Detail

The following strength fields to indicate IDMP strength values are added to the Component Active Ingredient under the XEVMPD strength fields divided by the UI separator:

— IDMP Concentration Measure Type

IDMP Presentation Strength

— Presentation Single or Low Limit Numerator Value
— Presentation Single or Low Limit Unit of Measurement
— Presentation Single or Low Limit Unit of Presentation
— Presentation High Limit Numerator Value
— Presentation High Limit Unit of Measurement
— Presentation High Limit Unit of Presentation

IDMP Concentration Strength

— Concentration Single or Low Limit Numerator Value
— Concentration Single or Low Limit Unit of Measurement
— Concentration Single or Low Limit Denominator Value
— Concentration Single or Low Limit Unit of Measurement
— Concentration High Limit Numerator Value
— Concentration High Limit Unit of Measurement
— Concentration High Limit Denominator Value
— Concentration High Limit Unit of Measurement

PDS Indications/Intended Use Detail

In Ennov InSight 7.1, Indications/Intended Use details are created one at a time and not in bulk.

To support IDMP, Ennov InSight 7.1 now includes the following updates:

— Indications/Intended Use - This field is renamed to Indications.
— Product Family Comorbidity - This is a new multi-select field added to the Product Family.
— Intended Effect - This is a new multi-select field added with the values from Data Administration.

PDS Manufacturer Detail

To support IDMP, Ennov InSight 7.1 now includes the new fields:

— Manufacturing Operation Start Date, This is a new date field under Manufacturer Status Date and has a NULL value after migration.
— Manufacturing Operation Stop Date This is a new date field under Manufacturing Operation Start Date and has a NULL value after migration.

PDS Packaging Detail

To support IDMP, Ennov InSight 7.1 now includes the following updates:

— Package Item Container Quantity This is a new numeric field under the Packaging Type field.
— The Container Package Material - This field is renamed to Package Material.
— The Container Package Alternate Material - This field is renamed to Package Alternate Material.
— Package Components - This is a new multi-select field and added under the Unit of Presentation field
— Manufactured Item Reference This is a new multi-select field and added under the Package Components field.
— Packaging MI Quantity - This is a new numeric field and added under the Manufactured Item Reference.
— Packaging MI Quantity Unit - This is, a new drop-down list added under the Packaging MI Quantity.
— Medical Device Reference - This is a new drop-down list added under the Packaging MI Quantity Unit field. This field is, available for Medical Devices and Pharma-Med Device components.

PDS Shelf Life Detail

In Ennov InSight 7.1, one common Shelf Life Node is available - Shelf Life(s)/Storage Condition(s). If there is more than one Component for the PDS, the Shelf Life(s)/Storage Condition(s) node will be shown under each Component.

Unicity is updated to include concatenation of the following fields:

— Shelf Life Type
— Shelf Life
— Shelf Life Unit
— Shelf Life Category

Shelf Life Type is now a required field. This is available under the Product Detail Set Name field and available in the PDS Tree before the PDS Details Status.

The following migration rules apply:

— If the Shelf Life(s)/Storage Condition(s) Node is present before migration, it will migrate to the Shelf Life(s)/Storage Condition(s) with the Shelf Life Type with Code Name in original pack.
— If there is a Shelf Life(s)/Storage Condition(s) After Opening Node before migration, it will migrate with the Shelf Life Type with Code Name ‘After first opening’

— If there is a Shelf Life(s)/Storage Condition(s) After Reconstitution Node before migration, it will migrate with the Shelf Life Type with Code Name 'After transformation'.
— If any of the nodes have a value in the Shelf Life Type before migration it will be added to the Comments field on the entity.
— It is now possible to update the fields on the Shelf Life while the node is still in Pending Add status.

Note: *Verify the* Shelf Life Type *field appears on the user interface. Else, contact your Business Development Representative for assistance.*

PDS Flu Strain Detail

The following strength fields to indicate IDMP strength values are added to the Flu Strain detail and placed under the XEVMPD strength fields divided by the UI separator:

— IDMP Concentration Measure Type

IDMP Presentation Strength

— Presentation Single or Low Limit Numerator Value
— Presentation Single or Low Limit Unit of Measurement
— Presentation Single or Low Limit Unit of Presentation
— Presentation High Limit Numerator Value
— Presentation High Limit Unit of Measurement
— Presentation High Limit Unit of Presentation

IDMP Concentration Strength

— Concentration Single or Low Limit Numerator Value
— Concentration Single or Low Limit Unit of Measurement
— Concentration Single or Low Limit Denominator Value
— Concentration Single or Low Limit Unit of Measurement
— Concentration High Limit Numerator Value
— Concentration High Limit Unit of Measurement
— Concentration High Limit Denominator Value
— Concentration High Limit Unit of Measurement

PDS Pack Size Detail

To support IDMP, Ennov InSight 7.1 now includes a new PDS Node Pack Size as a child of Package Set Node.

Registrations

Ennov InSight 7.1 Registrations (Package Set Type)

New features and fields are included in Ennov InSight 7.1 to conform to the regulatory requirements.

Registrations (Package Set Type)

In Ennov InSight 7.1, the Registrations with the Package Sets with Pending Add status can now be created.

To support IDMP, Ennov InSight 7.1 now includes:

— ATC Code Flag - This new drop-down list is under the Registered ATC field.
— Package Sets - This field displays for both the Package Set Name and the Package Set Status for the PDS Detail.

Ennov InSight 7.1 Registrations (Package Set Type)

New features and fields are included in Ennov InSight 7.1 to conform to the regulatory requirements.

Registration-Package Sets

To support IDMP, Ennov InSight 7.1 now includes:

— Legal Basis, a new drop-down list under Package Set Name
— Authorisation Status, a new drop-down list under Legal Basis
— Authorisation Status Date, a new date field under Authorisation Status
— Status, a new display-only field with data driven from PDS Package Set Detail
— Status Date, a new display only field with data driven from PDS Package Set Detail
— EU Presentation Number renamed to Package Set License Code

The grid view for this entity is updated for Ennov InSight 7.1 release.

Package Set-Country

To support IDMP, Ennov InSight 7.1 now includes:

— Data Carrier Type, a new drop-down list under Legal Status of Supply
— Data Carrier Identifier, a new text field under Data Carrier Type
— Data Carrier Language, a new drop-down list under Data Carrier Identifier
— Risk of Supply Shortage, a new field with Yes or No selection.
— Risk of Supply Shortage Comment, a new text field.
— Marketing Status Reason, a new drop-down list with values from Data Administration > Marketing Status Reasons Values.

Package Set-Package Description

To support IDMP, Ennov InSight 7.1 now includes a new Reference Substance enity, a child entity of Registration Package Sets.

Ennov InSight 7.1 Medicinal Product

New features and fields are included in Ennov InSight 7.1 to conform to the regulatory requirements.

Medicinal Product

To support IDMP, Ennov InSight 7.1 now includes:

— Medicinal Product - This is included as a child entity for Registration Package Set Type.
— Medicinal Product Names - This is included asa child entity for Medicinal Product.
— Product Cross-Reference - This is included asa child entity for Medicinal Product.
— MPIDs - This is included as a child entity for Medicinal Product.

— Medicinal Product Actions -This is included as a child entity for Medicinal Product under the Registrations (Package Set Type).
— Attached Documents - This is included asa child entity for Medicinal Product Actions.

Ennov InSight 7.1 Full Product Presentation

New features and fields are included in Ennov InSight 7.1 to conform to the regulatory requirements.

Full Product Presentation

Ennov InSight 7.1 now includes the following changes for Full Product Presentation:

— The Use Reference Ingredient for XEVMPD option is removed from Full Product Presentation. This option will not be available after migration.
— The working logic of the XEVMPD Submission wizard is also changed to comply to the latest requirement. For more details, see Ennov InSight 7.1 XEVMPD
— Pharmaceutical Product - This is a new multi-select field that is available in Ennov InSight 7.1 .

If there is an existing Full Product Presentation that is associated to a Product through the Package Set and this Product has a Pharmaceutical Product, after migration it will be shown as selected in the new *Pharmaceutical Products* tab on the *Full Product Presentation Attributes* page.

IDMP Tab

Ennov InSight 7.1 now includes a new IDMP tab to support IDMP information visibility on the *Registration Attributes* page.

Ennov InSight 7.1 XEVMPD

New features and fields are included in Ennov InSight 7.1 to conform to the regulatory requirements.

XEVMPD

Starting with Ennov InSight 7.1, the XEVMPD Submission wizard includes the following updates:

— Instead of Component Active Ingredient/Component Reference Active Ingredient, the values of Active Ingredient will be taken from Pharmaceutical Product Reference Active Ingredient, if present. Else, it will be taken from Pharmaceutical Product Active Ingredient.
— The Pharmaceutical Product information, as well as the entities data associated with it and with a Product, will be taken for XEVMPD submission. This is based on the Pharmaceutical Product association with Full Product Presentation and not from the PDS as it was before the new updates. For details of the Full Product Presentation association with Pharmaceutical Product after migration, see the *Full Product Presentation* section of this document.

The following rules apply when migrating XEVMPD strength data for Component Active Ingredient/Component Reference Active Ingredient and affects Full Product Presentation when the Use Reference Active Ingredient field is deleted.:

— When there is a Component Active Ingredient with values for XEVMPD strength fields and there is a Full Product Presentation with the Use Reference Active Ingredient for XEVMPD with No or NULL for the EU Country package set registration for the Product where component with active ingredient is assigned to, a Pharmaceutical Product Active Ingredient with XEVMPD data will be created after the migration.

— When there is a Component Active Ingredient with Reference Active Ingredient with values for XEVMPD strength fields and there is a Full Product Presentation with the Use Reference Active Ingredient for XEVMPD with Yes for the EU Country package set registration for the Product where component with active ingredient is assigned to, a Pharmaceutical Product Active Ingredient with Reference Active Ingredient with XEVMPD data will be created after migration.

Wizards

Ennov InSight 7.1 Wizards

New features and fields are included in Ennov InSight 7.1 to conform to the regulatory requirements.

The following table lists the new and renamed fields in Ennov InSight 7.1

Change	Field Name	Wizard Name
Field renamed	Legal Status Type to Legal Status of Supply	— Create Application — Update Application ,
	Indications/Intended Use to Indications	Global Project Plan > Update Product Detail Sets
New field added	Comorbidity	Global Project Plan > Update Product Detail Sets
	Intended Effect	

Queries

Ennov InSight 7.1 Queries

New features and fields are included in Ennov InSight 7.1 to conform to the regulatory requirements.

The following table lists the new and renamed fields in Ennov InSight 7.1 .

Change	Field Name/Entity Name	Query Name
Field Renamed	Dosage Form to Administrable Dosage Form	Entity Audit Query for Pharmaceutical Product
	Indications/Intended Use to Indications	— Application History Query — Application QC Status History Report
	Legal Status Type or Application Legal Status Type to Legal Status of Supply	— List of Package Set Registrations with Application and Product Detail Properties — List of Product Registrations with Application and Product Detail Properties — List of Applications — List of Applications with Products — List of Events with Application Properties — List of Application Countries — List of Registrations with Application Properties — List of Sequences with Application and Event Properties — List of Application Countries with Registration Details
Field Deleted	— Product Characteristics — Product Quantity Unit — Product Quantity Value	Entity Audit Query for Product
	Use Reference Ingredient for XEVMPD	XEVMPD Submissions - QC Verification and Audit

Change	Field Name/Entity Name	Query Name
New Added	— Attached Document entity — Manufactured Item entity — Medicinal Product entity — Medicinal Product Action entity — Medicinal Product Name entity — Product Cross Reference entity — Product Detail-Pack Size PDS detail	Entity Audit Query
	— Manufacturing Operation Start Date — Manufacturing Operation Stop Date	— Entity Audit Query for Product Detail-Manufacturer — List of Component Manufacturers — List of Package Set Manufacturers — List of PDS Manufacturers — List of Excipient Manufacturers — List of Active Ingredient Material Manufacturers — List of Active Ingredient Function Manufacturers — List of Active Ingredient Manufacturers — Application History Query — Application QC Status History Report
	— Packaging MI Quantity — Packaging MI Quantity Unit — Medical Device Reference — Device Quantity — Package Item Container Quantity — Package Material — Package Alternate Material — Package Components — Manufactured Item Reference	— Application History Query — Application QC Status History Report
	— Pharmaceutical Product — Manufactured Item — Medicinal Product	— List of References — List of Tasks
	— Pharmaceutical Product — Manufactured Item	— List of References -Rollup by Product Family — List of Tasks -Rollup by Product Family
	Medicinal Product	— List of References - Rollup by Applicationt — List of Tasks - Rollup by Application
	Combined Pharmaceutical Dose Form	— Entity Audit Query for Product — List of Pharmaceutical Products — List of Pharmaceutical and Medical Device Products

Pre-Migration Manual Tasks for Ennov InSight 7.1

Taiwan: Pre-Migration Manual Tasks for Ennov InSight 7.1

Add Taiwan region values to include the new Taiwan updates in Ennov InSight 7.1

To add the TW region to Ennov InSight:

1. On the Ennov InSight application *Home* page, click Go To > Data Administration.
2. Under Application Maintenance, click Region Values.
3. Click Create.
4. Enter the following:

Field Name	Value
Region Type	Regulatory Region
Region Abbreviation	TW
Region Name	Taiwan
Countries	Taiwan, Province of China

5. Click Save.
6. Click Return to menu.

Pre-migration Scripts

Component Active Ingredient vs PDS Active Ingredient Data Migration

Ennov InSight 7.1 changes the way how PDS Active Ingredients are created.

When there are Component Active Ingredients under Product, a PDS is created from this Product with Active Ingredient PDS Details added automatically with the strength information from Component Active ingredient.

After migration to Ennov InSight 7.1 strength data in the existing PDS Active Ingredients will become equal to Component Active Ingredients.

To avoid missing data there is a pre-migration script which helps to identify if values for existing PDS Active Ingredient strength fields are different from Component Active Ingredients.

You can make any correction to the Component Active Ingredient data before the migration. The data correction for Component Active Ingredient is done in in user interface.

Migration script that identifies Active Ingredients from entity level Component that are different from PDS Active Ingredients for Ennov InSight 7.1 (output is txt):

Table 1: Report Column Definition

pre_mig_rpt_ai_diff.sql	
Report Column	Value
PRODUCT FAMILY NAME	Displays the Product Family Name.
APPLICATION NAME	Displays the Application Name.
PRODUCT NAME	Displays the Product Name.
COMPONENT NAME	Displays the Component Name.
ACTIVE INGREDIENT NAME	Displays the Active Ingredient Name.
CONCENTRATION MEASURE TYPE	Displays the Concentration Measure Type.
LOW AMOUNT NUMERATOR VALUE	Displays the Low Amount Numerator Value.
LOW AMOUNT NUMERATOR PREFIX	Displays the Low Amount Numerator Prefix.
LOW AMOUNT NUMERATOR UNIT	Displays the Low Amount Numerator Unit.
LOW AMOUNT DENOMINATOR VALUE	Displays the Low Amount Denominator Value.
LOW AMOUNT DENOMINATOR PREFIX	Displays the Low Amount Denominator Prefix.
LOW AMOUNT DENOMINATOR UNIT	Displays the Low Amount Denominator Unit.

pre_mig_rpt_ai_diff.sql	
Report Column	Value
HIGH AMOUNT NUMERATOR VALUE	Displays the High Amount Numerator Value.
HIGH AMOUNT NUMERATOR PREFIX	Displays the High Amount Numerator Prefix.
HIGH AMOUNT NUMERATOR UNIT	Displays the High Amount Numerator Unit.
HIGH AMOUNT DENOMINATOR VALUE	Displays the High Amount Denominator Value.
HIGH AMOUNT DENOMINATOR PREFIX	Displays the High Amount Denominator Prefix.
HIGH AMOUNT DENOMINATOR UNIT	Displays the High Amount Denominator Unit.
MEASUREMENT POINT	Displays the Measurement Point.

Note: *The output will be in the following format* `[COMPONENT AI VALUE] --->[PDS AI VALUE].`

Post Migration Script Updates for Ennov InSight 7.1

Post-Migration Script Updates for Ennov InSight 7.1.3

Changes affected by the migration script.

Migration affects the following changes:

— Updates CN code value to the CN region in the database.

— Updates the China eCTD Code to 'cn'.

— Updates Health Authority Abbreviation to NMPA and Health Authority Website to https://www.nmpa.gov.cn/ in Application Maintenance > Country Values

— Adds CN-1-0 assembly DTD type to Assembly > Assembly DTD/Schema Types in *Data Administration*, if it does not exist already.

— Does not do any updates to Application Maintenance > Application Type Values.

— Adds the following values to Sequence Maintenance > Filing Type Values in *Data Administration* if they do not exist already:

- New Indication and Drug Combination
- Record
- Development Safety Report

— Updates the following Filing Type eCTD Codes to Filing Type Values:

- New Indication - cnrat6
- Renewal Filing - cnrat8
- Baseline - cnrat9
- New Indication and Drug Combination - cnrat5
- Record - cnrat3
- Development Safety Report - cnrat7

— Deactivates the following Filing Type eCTD Codes from Filing Type Values:

- Periodic Safety Update Report - cnrat5

— Assigns the New Indication and Drug Combination, Development Safety Report Filing Type values to the Original, Response, Withdrawal Sub Filing Type eCTD Code values.

— Unassigns the Periodic Safety Update Report Filing Type value from the Original, Response, Withdrawal Sub Filing Type eCTD code values.

— Assigns the Application Type values to the Filing Type eCTD Code values:

- Abbreviated New Drug Application to cnrat3
- New Drug Application, Abbreviated New Drug Application to cnrat4
- New Drug Application, Abbreviated New Drug Application to cnrat8
- Investigational New Drug, New Drug Application, Abbreviated New Drug Application to cnrat9.

Post-Migration Script Updates for Ennov InSight 7.1

Running the migration script results in multiple changes to the Data Administration data. The changes must be reviewed, and updated if necessary.

Changes related to TW-1-0 implementation:

— Associates Taiwan with Taiwan region in the Application Maintenance - Region Values, if it is not associated already.

— Health Authority name for Taiwan country, that already exists in the Application Maintenance - Country Values in *Data Administration* under the Health Authority tab, must be changed to `Taiwan Food and Drug Administration`.

— Adds the TW-1-0 assembly DTD type in the Assembly - Assembly DTD/Schema Types section in *Data Administration*, if it does not already exist.

— The Filing Type values will be added to the Sequence Maintenance > Filing Type Values section in *Data Administration*, if they do not already exist. If they already exist, they will be updated with an eCTD Code for the TW-1-0 DTD/Schema based on the following approach:

- For all the eCTD Codes from the table below, the Filing Type value that has the same eCTD Code will be found and updated with the new eCTD Code for the TW-1-0 DTD/Schema. If the found Filing Type does not have Taiwan as an associated county, Taiwan will be added to the list of Countries.
- If there are any other Filing Type values found, that are not listed in the table, they are not updated.
- If more than one Filing Type is found with a matching eCTD Code, the one with the matching Filing Type name will be updated with the new eCTD Code for the TW-1-0 DTD/Schema. If the Filing Type name does not match for any Filing Type with a matching eCTD Code, no Filing Type will be updated and the following message will be added to the log: `The Filing Type <name> with eCTD Code <code> could not be created/updated within Data Admin, please verify the configuration post-installation.`
- If the Filing Type is not found based on the eCTD Code, one will be created and assigned to Taiwan.

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

Changes related to US-3-3 implementation:

— If `Form FDA 3988: Transmittal of PMR/PMC Submissions for Drugs and Biologics` already exists in *Application Form Type Values*, it will be updated with fdaft10 code and set to Active. Otherwise, this record will be created.

— If `Form FDA 3938: Drug Master File already exist in Application Form Type Values` already exists in *Application Form Type Values*, it will be updated with fdaft11 code and set to Active. Otherwise, this record will be created.

- If `REMS Supplement` already exists in the Filing Type Values, it will be updated with fdaft11 Filing Type eCTD code for us-3-3 DTD, and New Drug Application, Biologic License Application, Abbreviated New Drug Application will be added to Types Valid for Grouped Submissions. Otherwise, this record will be created.
- For the United States in the Country Values, the Health Authority Website will be updated to `https://www.fda.gov/`.

Database Script Error Messages

The list of database script errors that you may encounter when running the scripts.

Upgrade path	Error	Description/Resolution
5.0 or 5.0 CHF 6 to 5.1	`ORA-01920: user name 'MIGRATION' conflicts with another user or role name`	The migration user already exists.
5.0 or 5.0 CHF 6 to 5.1	`ora-01543: tablespace 'IDX_MIG' already exists`	The migration tablespace already exists.
5.0 or 5.0 CHF 6 to 5.1	`ora-01543: tablespace 'DAT_MIG' already exists`	The migration tablespace already exists.
5.0 or 5.0 CHF 6 to 5.1	`ORA-02296: cannot enable (ODS.) - null values found`	The data will be updated later in the migration, and the constraint on SETTINGS_PROFILE.LINK_STYLE_TYPE_ID will be added at that point.
5.0 or 5.0 CHF 6 to 5.1	`ORA-02273: this unique/primary key is referenced by some foreign keys`	Ignore any index and constraint errors on asm_pub_settings/ asm_pub_settings_profile tables.
5.0 or 5.0 CHF 6 to 5.1	`ORA-02429: cannot drop index used for enforcement of unique/primary key`	Ignore any drop index errors on “enforcement of unique/primary key”.
5.0 or 5.0 CHF 6 to 5.1	`ORA-00936: missing expression`	Ignore
5.0 or 5.0 CHF 6 to 5.1	`ORA-04098: trigger 'ODS.UCNTNT' is invalid and failed re-validation`	Ignore
5.0 or 5.0 CHF 6 to 5.1	Any errors for the `PACKAGE BODY ISM.PRODUCT_FAMILY_COPY:`	Ignore

Upgrade path	Error	Description/Resolution
5.1 to 6.0	Any indexing or constraint errors regarding the following tables can be ignored: — Excipient — Active_ingredient — Prod_acting — Prodfam_acting — Pds_excip — Pds_excip_change — Concentration_unit_type — Fda_device_class_type — Eu_class_type Also ignore the following error messages: — `Warning: Package Body created with compilation errors. Errors for PACKAGE BODY ISM.PRODUCT_FAMILY_COPY: 285/26 PL/SQL: ORA-00942: table or view does not exist` — `Revoke inherit privileges on system from dbo ERROR at line 1: ORA-00990: missing or invalid privilege revoke select any table privilege from aud ERROR at line 1: ORA-00990: missing or invalid privilege`	Ignore Example: Error dropping constraint ACTIVE_INGREDIENT:PKACTIVE_INGREDIENT ORA-02273: this unique/primary key is referenced by some foreign keys Dropping index: ACTIVE_INGREDIENT:PKACTIVE_INGREDIENT Columns: ID-->> Error dropping index ACTIVE_INGREDIENT:PKACTIVE_INGREDIENT ORA-02429: cannot drop index used for enforcement of unique/primary key
5.1 to 6.0	`ORA-01543: tablespace 'IDX_IDMP' already exists`	Ignore
5.1 to 6.0	`ORA-01543: tablespace 'DAT_IDMP' already exists`	Ignore

Upgrade path	Error	Description/Resolution
5.1 to 6.0	ORA-01543: tablespace 'IDX_DM' already exists	Ignore
5.1 to 6.0	ORA-01543: tablespace 'DAT_DM' already exists	Ignore
5.1 to 6.0	ORA-01918: all ORA-01918 messages	Ignore
5.1 to 6.0	ORA-01919: all ORA-01919 messages	Ignore
5.1 CHF 3 to 6.0 to 6.0 CHF 1	ORA-00955: name is already used by an existing object CREATE TABLE MGR.REGULATORY_ACT_LEAD(ERROR at line 1: ORA-00955: name is already used by an existing object CREATE TABLE MGR.SEQ_DESCR_TYPE(* ORA-00001: unique constraint (MGR.UX1REGULATORY_ACT_LEAD) violated ORA-00001: unique constraint (MGR.UX1SEQ_DESCR_TYPE) violated	Ignore
6.0 to 6.0 CHF 1	ORA-01952: system privileges not granted.	Ignore. This error can appear when running the master-pre.sql script. It means that the system privileges are not granted to MGR, ODS, or SEC.

Upgrade path	Error	Description/Resolution
6.0 CHF 1 to 6.0 CHF 2 to 6.0 CHF 3	drop table view_column_metadata * ERROR at line 1: ORA-00942: table or view does not exist comment on column vd_conten.logical_parent_id is 'Reserved for Internal Use; Do not Use' * ERROR at line 1: ORA-00942: table or view does not exist	Ignore

Upgrade path	Error	Description/Resolution
6.0 CHF 2 to 6.0 CHF 3	********** ******** build dimension views ********** ******** ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS_LAB_HIST6 ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS_LAB_HIST1 ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS_LAB_HIST3 ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS_LAB_HIST2 ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS_LAB_HIST4 ORA-24344: success with compilation error VD_PDS_LAB_HIST.R_VD_PDS_LAB_HIST5 PL/SQL procedure successfully completed.	Ignore
6.0 CHF 2 to 6.0 CHF 3 to 6.0 CHF 4 to 6.0 CHF 5	from dba_views v * ERROR at line 36:	Ignore

Upgrade path	Error	Description/Resolution
6.0 CHF 3 to 6.1	`drop table tmp_ind_expressions * ERROR at line 1: ORA-00942: table or view does not exist`	Ignore
6.0 CHF 3 to 6.1	When executing the data migration from 6.0 CHF 3 to Ennov InSight 6.1 (script DB Upgrade 60 CHF3 to 61), the following error messages appeared: — `Line 146: Error creating indexes on table aud.GENERICLOAD ORA-00904: "DATASET_NAME":` — `Line 363: ORA-00942: table or view does not exist` — `Line 4344: ORA-02437: cannot validate (AUD.PKAPPLICANT_CONTACT) - primary key violated` — `Line 4345: ORA-06512: at line 58` — `Line 9644: ORA-00942: table or view does not exist` — `Line 15517: Error creating indexes on table aud.GENERICLOAD ORA-00904: "DATASET_NAME":`	Resolved with the Ennov InSight 6.1 CHF 1 database migration script.
6.0 CHF 7 to 6.1	— `ORA-24344: success with compilation error` — `ORA-06512: at line 115`	Ignore

Upgrade path	Error	Description/Resolution
6.1 to 6.1 CHF 1	— `********** fix EU-3-0 EMA-eAF ********** declare * ERROR at line 1: ORA-01403: no data found ORA-06512: at line 9` — `drop table tmp_ind_expressions * ERROR at line 1: ORA-00942: table or view does not exist`	Ignore
6.1 to 6.1 CHF 1	— `ORA-00955: name is already used by an existing object` — `ORA-02260: table can have only one primary key` — `ORA-24344: success with compilation error` — `ORA-06512: at line 115`	Ignore. These errors can be ignored if the migration path contained Ennov InSight 6.0 CHF 6 or Ennov InSight 6.0 CHF 7.
6.1 to 6.1 CHF 1 to 6.1 CHF 2	`ERROR at line 1: ORA-04043: object WRITE_STORAGE_REQUIREMENTS does not exist`	Ignore
6.1 CHF 1 to 6.1 CHF 2	— `ORA-24344: success with compilation error` — `ORA-06512: at line 115`	Ignore. These errors can be ignored if the migration path contained Ennov InSight 6.0 CHF 6 or Ennov InSight 6.0 CHF 7.

Upgrade path	Error	Description/Resolution
6.1 CHF 2 to 6.1 CHF 3	— ORA-01918: user 'DBCOMMON' does not exist — ORA-04043: object GET_DIRLIST does not exist — ORA-00904: "SUB_TO_ADD_MONITOR_CODE": invalid identifier — ORA-00904: "ORPHAN_DRUG_FLAG": invalid identifier	Ignore
6.1 CHF 2 to 6.1 CHF 3	ORA-02298: cannot validate (MGR.T_1671) - parent keys not found	Ignore
6.1 CHF 2 to 6.1 CHF 3 to 6.1 CHF 4	ORA-02298: cannot validate (MGR.T_1671) - parent keys not found	Ignore
6.1 CHF 2 to 6.1 CHF 3	— ORA-00001: unique constraint (MGR.AK0BROAD_INDC_COUNTRY) violated — ORA-00955: name is already used by an existing object	Ignore. These errors can be ignored if the migration path contained Ennov InSight 6.0 CHF 6 or Ennov InSight 6.0 CHF 7.
6.1 CHF 3 to 6.1 CHF 4	— ORA-00001: unique constraint (MGR.UX1REGULATORY_ACT_LEAD) violated — ORA-00001: unique constraint (MGR.UX1SEQ_DESCR_TYPE) violated	Ignore. These errors can be ignored if the migration path contained Ennov InSight 6.0 CHF 6 or Ennov InSight 6.0 CHF 7.
6.1 to 6.2	ORA-01418: specified index does not exist	Ignore

Upgrade path	Error	Description/Resolution
6.1 CHF 4 to 6.2 CHF 1	— `ORA-24344: success with compilation error` — Any errors for the `PACKAGE BODY ISM.PRODUCT_FAMILY_COPY:` — `ORA-02298: cannot validate (MGR.T_1671) - parent keys not found`	Ignore
6.2 (new installation only)	`drop table d_date * ERROR at line 1: ORA-00942: table or view does not exist`	Ignore This error does not appear during the migration from the previous Ennov InSight versions to Ennov InSight 6.2. It may be seen only if you install a new Ennov InSight 6.2 database. If you see this error, you can ignore it.
6.2 CHF 1 to 6.2 CHF 2	— `drop table dbcommon.role *ERROR at line 1:ORA-00942: table or view does not exist` — `drop table dbcommon.entity_type *ERROR at line 1:ORA-00942: table or view does not exist`	Ignore.

Upgrade path	Error	Description/Resolution
6.2 CHF 2 to 6.2 CHF 3	— drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist — drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist	Ignore
6.2 CHF 3 to 6.2 CHF 4	— drop table assembly_totals * ORA-00942: table or view does not exist — drop index XAK1CONTENT * ERROR at line 1: ORA-01418: specified index does not exist — drop view vw_assembly_totals * ERROR at line 1: ORA-00942: table or view does not exist — drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist — drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist — drop table view_column_name_overrides * ERROR at line 1: ORA-00942: table or view does not exist	Ignore

Upgrade path	Error	Description/Resolution
6.2 CHF 4 to 6.2 CHF 5	— `drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist` — `drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist`	Ignore
6.2 CHF 5 to 6.2 CHF 6	— `drop table dbcommon.role * ERROR at line 1: ORA-00942: table or view does not exist` — `drop table dbcommon.entity_type * ERROR at line 1: ORA-00942: table or view does not exist`	Ignore
6.2 CHF 6 to 7.0	— `ORA-02443: Cannot drop constraint - nonexistent constraint` — `ORA-01418: specified index does not exist`	Ignore

Upgrade path	Error	Description/Resolution
7.1.2 to 7.1.3	– ORA-30674: identity column cannot have a default value – ORA-20000: extension does not exist/ ORA-20007: extension already exists in the table – Error changing data type for column AUD.SOURCE_SYSTEM_TYPE BEG_DATE: ORA-00942: table or view does not exist – Error changing data type for column AUD.SOURCE_SYSTEM_MEMBER_TYPE BEG_DATE: ORA-00942: table or view does not exist – Error changing data type for column AUD.SOURCE_SYSTEM_TYPE CREATION_DATE: ORA-00942: table or view does not exist – Error changing data type for column AUD.SOURCE_SYSTEM_MEMBER_TYPE CREATION_DATE: ORA-00942: table or view does not exist	Ignore
7.1.6 to 7.1.11	– ORA-30674: identity column cannot have a default value	Ignore

The following are the common errors you may encounter when migrating to a subsequent version.

Table 2: Common Errors

Error	Description
SP2-0310: unable to open file "define.passwords"	Ignore
SP2-0310: unable to open file "define.application"	Ignore
ORA-02264: name already used by an existing constraint	DO NOT IGNORE. Call Technical Support

Errors Message - Example

```
Errors for PACKAGE BODY ISM.PRODUCT_FAMILY_COPY

LINE/COL ERROR

--------------------------------------------------------------

971/11 PL/SQL: SQL Statement ignored

973/21 PL/SQL: ORA-00942: table or view does not exist

977/9 PLS-00364: loop index variable 'IREC' use is invalid

977/9 PL/SQL: Statement ignored

978/9 PLS-00364: loop index variable 'IREC' use is invalid

978/9 PL/SQL: Statement ignored

979/9 PLS-00364: loop index variable 'IREC' use is invalid

979/9 PL/SQL: Statement ignored

980/9 PLS-00364: loop index variable 'IREC' use is invalid

980/9 PL/SQL: Statement ignored

982/9 PL/SQL: SQL Statement ignored

LINE/COL ERROR

--------------------------------------------------------------

991/35 PL/SQL: ORA-00904: "IREC"."PRODUCT_ID": invalid identifier
```

```
993/9 PL/SQL: SQL Statement ignored

993/25 PL/SQL: ORA-00942: table or view does not exist

1004/11 PL/SQL: SQL Statement ignored

1006/21 PL/SQL: ORA-00942: table or view does not exist

1010/9 PLS-00364: loop index variable 'IREC' use is invalid

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