Ennov InSight 7.2 Data Migration Document

Contents

Chapter 1. Data Migration Documents

Document Name
Ennov InSight 7.2.12 Data Migration Document
Ennov InSight 7.2.11 Data Migration Document
Ennov InSight 7.2.10 Data Migration Document
N/A for Ennov InSight 7.2.9
N/A for Ennov InSight 7.2.8
N/A for Ennov InSight 7.2.7
Ennov InSight 7.2.6 Data Migration Document
N/A for Ennov InSight 7.2.5
N/A for Ennov InSight 7.2.4
No data migration required for 7.2.3
Ennov InSight 7.2.2 Data Migration Document
Ennov Insight 7.2 Data Migration Document
Ennov InSight 7.1.3 Data Migration Document
Ennov InSight 7.1 Data Migration Document
Ennov InSight 7.0 Data Migration Document
Data Migration Document - Previous Versions

Note: To migrate to the next version of Ennov InSight from the previous one, please contact your Business Development Representative for assistance. DB_update7_2_(7-8-9)_DE31795_0001.zip script can be run for 7.2.7, 7.2.8 and 7.2.9 after the main migration process is complete.

Chapter 2. 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 Ennov InSight database migrations. The installation and migration script package provides a convenient means for distributing the Ennov InSight database scripts and guidance 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. It should be read with the Ennov InSight Release Notes, which describe the updates that have been implemented in each release.

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

Prerequisites

Users and groups who use the Ennov InSight 7.2 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 7.2 Data Migration Requirements .

Note: *For data migration and installation assistance, 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).

— DB Upgrade 715 to 72.zip(DB_update7_2_0_0000_0096.zip) (To migrate to Ennov InSight 7.2 from Ennov InSight 7.1.5, see:*Data Migration Documents*)

— DB Upgrade 72 to 721.zip(DB_update7_2_1_0000_0002.zip)

— DB Upgrade 721 to 722.zip(DB_update7_2_2_0000_0011.zip)

— DB Upgrade 722 to 724.zip(DB_update7_2_4_0000_0003.zip)

— DB Upgrade 724 to 725.zip(DB_update7_2_5_0000_0006.zip)

— DB Upgrade 725 to 726.zip(DB_update7_2_6_0000_0012.zip)

— DB Upgrade 726 to 727.zip(DB_update7_2_7_0000_0014.zip)

— DB Upgrade 727 to 728.zip(DB_update7_2_8_0000_0002.zip)

— DB Upgrade 728 to 729.zip(DB_update7_2_9_0000_0002.zip)

— DB Upgrade 729 to 7210.zip(DB_update7_2_10_0000_0006.zip)

— DB Upgrade 7210 to 7211.zip(DB_update7_2_11_0000_0001.zip

— DB Upgrade 7211 to 7212.zip(DB_update7_2_12_0000_0001.zip

Note: *DB_update7_2_(7-8-9)_DE31795_0001.zip script can be run for 7.2.7, 7.2.8 and 7.2.9 after the main migration process is complete.*

Chapter 3. Ennov InSight 7.2.12 Updates

Data Administration Updates: Ennov InSight 7.2.12

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
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

Country Code	Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority Website
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
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/
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/

Country Code	Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority Website
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 In-	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg,

Sub Filing Type	Countries
formation	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
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
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

Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
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-reassess-ment	MAA, MAA-AH
USR Filing	eu-3-1	usr	MAA, MAA-AH
Clinical Data for Publication – Redacted Pro-posal	eu-3-1	clin-data-pub-rp	MAA, MAA-AH
Clinical Data for Publication – Final Version	eu-3-1	clin-data-pub-fv	MAA, MAA-AH
PAED Related to PIP (Article 7, 8, 30)	eu-3-1	paed-7-8-30	MAA, MAA-AH
PAED Article 29 Filing	eu-3-1	paed-29	MAA, MAA-AH
PAED Article 45	eu-3-1	paed-45	MAA, MAA-AH
PAED Article 46	eu-3-1	paed-46	MAA, MAA-AH
Article 58 Filing	eu-3-1	article-58	MAA, MAA-AH
Notification 61-3 Filing	eu-3-1	notification-61-3	MAA, MAA-AH
Transfer MA Filing	eu-3-1	transfer-ma	MAA, MAA-AH
Lifting Suspension Filing	eu-3-1	lifting-suspension	MAA, MAA-AH
Withdrawal Filing	eu-3-1	withdrawal	MAA, MAA-AH
CEP Submission	eu-3-1	cep	MAA, MAA-AH
None	eu-3-1	none	MAA, MAA-AH
Article 18 Filing	eu-3-1	article-18	MAA, MAA-AH

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.
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 Pub-

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
			lication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.
Response	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.
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

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
			Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.
Closing Information	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.
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.
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 UpdatesApplication 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)
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

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
			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	eCT-DB	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)
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)

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
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)
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-re-sponse	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 Prod-uct	WHO-1-0

Verify Migration Script Updates: Ennov InSight 7.2.12

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

Chapter 4. Ennov InSight 7.2.11 Updates

Data Administration Updates: Ennov InSight 7.2.11

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** tabThe **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
AMAP	AMA Procedure	AMA Procedure	New Drug Application	AMA Procedure	South Africa

Application Type	Name	Display Name	Entity XML Type Name	Application Category	Countries
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

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
Plasma Master File (PMF)	ZA-3-1	sub-type-11	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Line extension-New Strength	ZA-3-1	sub-type-12	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Line extension-New Dosage Form	ZA-3-1	sub-type-13	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Line extension-New Application	ZA-3-1	sub-type-14	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
Clone	ZA-3-1	sub-type-15	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Replica-Same	ZA-3-1	sub-type-16	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IA-Quality	ZA-3-1	sub-type-17	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IAin-Clinical	ZA-3-1	sub-type-18	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IAin-Quality	ZA-3-1	sub-type-19	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IB-Clinical	ZA-3-1	sub-type-20	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IB-Quality	ZA-3-1	sub-type-21	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type I-Inspectorate	ZA-3-1	sub-type-22	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type I-Other	ZA-3-1	sub-type-23	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Safety (Clinical)	ZA-3-1	sub-type-24	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II - Safety and Efficacy (Clinical)	ZA-3-1	sub-type-25	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Quality	ZA-3-1	sub-type-26	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Rescheduling	ZA-3-1	sub-type-27	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Proprietary Name Change	ZA-3-1	sub-type-28	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Change in Applicant- Relinquishing	ZA-3-1	sub-type-29	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Change in Applicant- Acquiring	ZA-3-1	sub-type-30	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
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 Pharma-covigilance	ZA-3-1	sub-type-34	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Application Withdrawal/Cancel-lation	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 lB-Related Clinical	ZA-3-1	sub-type-38	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type lB-Related Quality	ZA-3-1	sub-type-39	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type lB-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 ll-Related Clinical	ZA-3-1	sub-type-42	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type ll-Related Quality	ZA-3-1	sub-type-43	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type ll-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 lB-Related Clinical, Type lB-Related Quality, Type lB-Related Inspectorate, Type IA-Clinical, Type ll-Related Clinical, Type ll-Related Quality, Type ll-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 lB-Related Clinical, Type lB-Related Quality, Type lB-Related Inspectorate, Type IA-Clinical, Type ll-Related Clinical, Type ll-Related Quality, Type ll-Related Inspectorate
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 Activ-

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
			ity*, 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
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-Ac-

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
			quiring, 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
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
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 -

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
			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
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,

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

Region	Applicable DTD/Schema	eCTD Code	Regulatory Activity Lead
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

Verify Migration Script Updates

After the migration script is run, changes must be verified and updated to the Data Administration data. The script includes following updates:

— Updates ZA region to have the ZA code value in the database.

— Updates Health Authority Name to South African Health Products Regulatory Authority, Health Authority Abbreviation to SAHPRA, Health Authority eCTD Code to ZA-SAHPRA and Health Authority Website to https://ectd.sahpra.org.za/index.html in Application Maintenance > Country Values Data Administration list.

— Adds the ZA-3-1 assembly DTD type in the Assembly > Assembly DTD/Schema Types Data

Administration list, if it does not already exist.

— Activates National ZA Procedure Type in the Application Maintenance > Procedure Type Values Data Administration list and adds the National eCTD code value to it.

— Updates Application Maintenance > Application Type Values with the following values and the corresponding eCTD codes assigned to them:

- SAHPRA National Procedure
- AMA Procedure
- ZAZIBONA Joint Review
- WHO-PQ
- WHO SRA CRP

- Swissmedic MAGHP
- EU M4ALL

— Updates Sequence Maintenance > Filing Type Values with the following values and the corresponding eCTD codes assigned to them: • A - NCE New Chemical Entit

- 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

— Updates Submission Maintenance > Sub Filing Type Values with the following values and the corresponding eCTD codes assigned to them:

- Initial
- Supplementary Information
- Response-Clinical
- Response-Quality
- Response-Inspectorate
- Response-N and S
- Closing Information
- Work Grouping Partial Withdrawal
- Submission Withdrawal
- Response-Biological
- Response-Renewals
- Response-PV

— Updates Submission Maintenance > Regulatory Activity Lead Values with the following values and the corresponding eCTD codes assigned to them:

- Biologicals
- Complimentary
- Master Files
- Orthodox
- Pharmacovigilance
- Veterinary

— Updates Submission Maintenance > Evaluation Pathway Values with the following values and the corresponding eCTD codes assigned to them:

- Priority
- Full Evaluation
- Abridged Evaluation
- Rolling Review
- Section 21

— Updates Submission Maintenance > Applicant Contact Type Values with the following values for South Africa and the corresponding eCTD codes assigned to them:

- Local Applicant
- Regulatory
- Technical
- Product Information
- General

Chapter 5. Ennov InSight 7.2.10 Updates

Data Administration Updates: Ennov InSight 7.2.10

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

ZA v3.0 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** tabThe **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-3-0** 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-3-0** code value. Otherwise, the **ZA-3-0** 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
AMAP	AMA Procedure	AMA Procedure	New Drug Application	AMA Procedure	South Africa

Application Type	Name	Display Name	Entity XML Type Name	Application Category	Countries
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-3-0** 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
SAHPRA National Procedure	ZA-3-0	app-type-1		No
AMA Procedure	ZA-3-0	app-type-2		No
ZAZIBONA Joint Review	ZA-3-0	app-type-3		No
WHO-PQ	ZA-3-0	app-type-4		No
WHO SRA CRP	ZA-3-0	app-type-5		No
Swissmedic MAGHP	ZA-3-0	app-type-6		No
EU M4ALL	ZA-3-0	app-type-7		No

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-3-0** 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
A - NCE New Chemical Entity	ZA-3-0	sub-type-1	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
D - New Generic Medicine	ZA-3-0	sub-type-2	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Complementary Medicine - New	ZA-3-0	sub-type-3	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
New Biological	ZA-3-0	sub-type-4	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Biosimilar (na-bs)	ZA-3-0	sub-type-5	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Clinical Trial Application	ZA-3-0	sub-type-6	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
New Vaccines	ZA-3-0	sub-type-7	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
I: Vaccine Antigen Master File	ZA-3-0	sub-type-8	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
New SMF	ZA-3-0	sub-type-9	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
New APIMF	ZA-3-0	sub-type-10	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Plasma Master File (PMF)	ZA-3-0	sub-type-11	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Line extension-New Strength	ZA-3-0	sub-type-12	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Line extension-New Dosage Form	ZA-3-0	sub-type-13	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Line extension-New Application	ZA-3-0	sub-type-14	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
Clone	ZA-3-0	sub-type-15	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Replica-Same	ZA-3-0	sub-type-16	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IA-Quality	ZA-3-0	sub-type-17	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IAin-Clinical	ZA-3-0	sub-type-18	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IAin-Quality	ZA-3-0	sub-type-19	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IB-Clinical	ZA-3-0	sub-type-20	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IB-Quality	ZA-3-0	sub-type-21	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type I-Inspectorate	ZA-3-0	sub-type-22	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type I-Other	ZA-3-0	sub-type-23	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Safety (Clinical)	ZA-3-0	sub-type-24	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II - Safety and Efficacy (Clinical)	ZA-3-0	sub-type-25	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Quality	ZA-3-0	sub-type-26	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Rescheduling	ZA-3-0	sub-type-27	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Proprietary Name Change	ZA-3-0	sub-type-28	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Change in Applicant- Relinquishing	ZA-3-0	sub-type-29	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Change in Applicant- Acquiring	ZA-3-0	sub-type-30	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
Baseline	ZA-3-0	sub-type-31	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
z-Code-Quality	ZA-3-0	sub-type-32	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Pharmacovigilance	ZA-3-0	sub-type-33	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
USRN-Clinical and Pharmacovigilance	ZA-3-0	sub-type-34	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Application Withdrawal/Cancellation	ZA-3-0	sub-type-35	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, ND
Renewal Filing	ZA-3-0	sub-type-36	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Undefined Regulatory Activity*	ZA-3-0	sub-type-37	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-3-0** 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
Initial	ZA-3-0	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 Pharmacovigi-

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
			lance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*
Supplementary Information	ZA-3-0	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*
Response-Clinical	ZA-3-0	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
Response-Quality	ZA-3-0	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 Pharmacovigi-

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
			lance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*
Response-Inspectorate	ZA-3-0	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*
Response-N and S	ZA-3-0	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*
Closing Information	ZA-3-0	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 Pharmacovigi-

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
			lance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*
Work Grouping Partial Withdrawal	ZA-3-0	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*
Submission Withdrawal	ZA-3-0	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*
Response-Biological	ZA-3-0	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 Pharmacovigi-

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
			lance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity
Response-Renewals	ZA-3-0	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*
Response-PV	ZA-3-0	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*

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-3-0	sub-lead-1	Biologicals
South Africa	ZA-3-0	sub-lead-2	Complimentary

Region	Applicable DTD/Schema	eCTD Code	Regulatory Activity Lead
South Africa	ZA-3-0	sub-lead-3	Master Files
South Africa	ZA-3-0	sub-lead-4	Orthodox
South Africa	ZA-3-0	sub-lead-5	Pharmacovigilance
South Africa	ZA-3-0	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-3-0	eval-path-1	Priority
South Africa	ZA-3-0	eval-path-2	Full Evaluation
South Africa	ZA-3-0	eval-path-3	Abridged Evaluation
South Africa	ZA-3-0	eval-path-4	Rolling Review
South Africa	ZA-3-0	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

Verify Migration Script Updates

After the migration script is run, changes must be verified and updated to the Data Administration data. The script includes following updates:

— Updates ZA region to have the ZA code value in the database.

— Updates Health Authority Name to South African Health Products Regulatory Authority, Health Authority Abbreviation to SAHPRA, to ZA-SAHPRA and Health Authority Website to https://ectd.sahpra.org.za/ index.html in Application Maintenance > Country Values Data Administration list.

— Adds the ZA-3-0 assembly DTD type in the Assembly > Assembly DTD/Schema Types Data

Administration list, if it does not already exist.

— Activates National ZA Procedure Type in the Application Maintenance > Procedure Type Values Data Administration list and adds the National eCTD code value to it.

— Updates Application Maintenance > Application Type Values with the following values and the corresponding eCTD codes assigned to them:

- SAHPRA National Procedure
- AMA Procedure
- ZAZIBONA Joint Review
- WHO-PQ
- WHO SRA CRP
- Swissmedic MAGHP
- EU M4ALL

— Updates Sequence Maintenance > Filing Type Values with the following values and the corresponding eCTD codes assigned to them: • A - NCE New Chemical Entit

- 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*

— Updates Sequence Maintenance > Sub Filing Type Values with the following values and the corresponding eCTD codes assigned to them:

- Initial
- Supplementary Information
- Response-Clinical
- Response-Quality
- Response-Inspectorate
- Response-N and S
- Closing Information
- Work Grouping Partial Withdrawal
- Submission Withdrawal
- Response-Biological
- Response-Renewals
- Response-PV

— Updates Sequence Maintenance > Regulatory Activity Lead Values with the following values and the corresponding eCTD codes assigned to them:

- Biologicals
- Complimentary
- Master Files
- Orthodox

- Pharmacovigilance
- Veterinary

— Updates Sequence Maintenance > Evaluation Pathway Values with the following values and the corresponding eCTD codes assigned to them:

- Priority
- Full Evaluation
- Abridged Evaluation
- Rolling Review
- Section 21

— Updates Sequence Maintenance > Applicant Contact Type Values with the following values for South Africa and the corresponding eCTD codes assigned to them:

- Local Applicant
- Regulatory
- Technical
- Product Information
- General

Chapter 6. Ennov InSight 7.2.6 Updates

Ennov InSight 7.2.6 Technical Administration and Configuration Updates

Updates to DMS server and repository after migration. This update will be available in Security Administration through data migration.

DMS Server Management

After migration, the servers with the Filesystem Server Type are deactivated.

DMS Repository Management

For existing Documentum repositories, set Basic Authentication Type as the authentication type unless specified otherwise.

After migration, the repositories with Filesystem Server Type or Secure Filesystem Server Type are deactivated.

As part of migration, after running the migration script and after updating the Secured File System configuration, create Secured Filesystem repository manually. *See: Administration > Add a Secure File System Repository to Ennov*

InSight **Configuration Update**

Updates

As part of migration procedure DTD location, Workflows location, and import XEVMPD location should be updated to conform new format of data location.

Ennov InSight 7.2.6 Locations Updated by Entities

Entity updates included in Ennov InSight 7.2.6 to work with remote file shares.

All Locations to Filesystem

Ennov InSight 7.2.6 includes the following changes:

— The locations are updated to use the Server Message Block (SMB) protocol. The server path is replaced by repository name. For example, before migration some share points were defined as //server_name/ server_folder. After migration the same part of location is changed to smb://repository_name. Also, the previously existing File System repository needs to added as the repository with Server Type set to Secured File System and Active Flag set to Yes.

List of Locations Updated by Entity

Entity Name	Locations

Assembly	— Reference Location — Electronic Output Location — Paper Output Location — Auxiliary Output Location
Leaf	Published Output Location
Document	Source Location
Link	Target
Volume	Last Published Location
Cover Page\CP Settings	Cover Page Template
Tab	Location
TOC\TOC Settings	— TOC Definition File — TOC Generation location
Publishing Settings	— Preview Location — In-Process Rendition Location
Overlays\Overlay Settings	Overlay Template File
Attached Document	Content Link
Registration Attachment	Attachment Link
Reference	— Reference Link — Origination Link — Action Link
PDS Label	Label Reference
XEVMPD message	ZIP Message Link
Certificate Master File Values	Content Link

Chapter 7. Ennov InSight 7.2.2 Updates

Ennov InSight 7.2.2 Security Administration Updates

This update will be available in Security Administration through data migration.

Application Country Rights

If no value is selected for the Product Family box and the Select option is chosen, the NOT DEFINED value is displayed. It means that the application is not connected to any of the products or product families. To set up a connection, a proper product family name must selected.

Ennov InSight 7.2.2 Home Page Updates

Updates to the Home Page through data migration.

Product Family Tree

The applications in the system with no association to the product or product family are displayed in the NOT DEFINED folder in the Product Family tree.

Countries Tree

The applications in the system with no association to the product or product family are displayed in the NOT DEFINED folder under a country the application is created for in the Countries tree.

Entities

Ennov InSight 7.2.2 Application Updates

The following updates are available for the Application through data migration.

Application

When there is an application entity change in the database, a column is added to the app_prod_fam table. The following values appear after migration:

— If the application was created under a product family, the record will have DEFAULT_FLAG = "Y"

— If the application has products from the multiple product families, the record for a parent product family will be created with the DEFAULT_FLAG = "Y" , the other product families will have the DEFAULT_FLAG = "N" .

Note: *If there is a request to change how this new column is populated by the out-of-the-box migration process described in the current document, please contact your Business Development Representative for assistance.*

Ennov InSight 7.2.2 Event Updates

Updates to Events through data migration.

Event

There is a change to the *Create Event* page, when creating it manually, the CT Shared Data field is now available for Clinical Trial Authorization (CTA), Investigational New Drug (IND) or European Union Clinical Trials Regulations (EU CTR) applications. Rules for the field are the same as on the *Create Application* wizard.

— For the CTA application type, the CT Shared Data field is not a required box.

— For the IND application type, the CT Shared Data field is not a required multi-select.

— For the EU CTR application type, the CT Shared Data field is not a required multi-select.

Data availability for CT Shared Data:

— If an application is created under the product family with no product association, the values for CT Shared Data are taken from this product family.

— If an application is created under the product family with a product association from another product family, the values for CT Shared Data are taken from the both product families.

— If an application is created via the *Create Application* wizard with no product association, the CT Shared Data field is empty.

— If an application is created via the *Create Application* wizard and there is at least one associated product, the values for CT Shared Data are taken from that product/product family association.

Optional Post Migration Scripts

Optional Post Migration Scripts

The post migration scripts identify the pseudo (placeholder) products and delete them if required.

It was not possible to migrate Ennov InSight 7.0 applications without products. Therefore, pseudo (placeholder) products were created.

You can use the optional post migration scripts below to identify the pseudo (placeholder) products and delete them if necessary:

— post_mig_all_rpt_placeholder_appl_products.sql script

— post_mig_rpt_placeholder_appl_products.sql

— post_mig_delete_placeholder_appl_products.sql

In Ennov InSight 7.2.2 it is possible to create an application without a product.
post_mig_all_rpt_placeholder_appl_products.sql script

The migration script identifies the pseudo (placeholder) products created via Ennov InSight 7.0 migration process. The final output is in TXT format.

Table 1: Report Column Definition

post_mig_all_rpt_placeholder_appl_products.sql script	
Report Column	Value
FamilyName	Displays the Product Family Name.
FamilyType	Displays the Product Family Type.
ApplicationName/Study	Displays the Application Name with a Study Number for CTA Application Type.
ApplicationCode	Displays Internal System Status for Application Status value.
ApplicationType	Displays the Application Type.
ProcedureType	Displays the Application Procedure Type.
ReviewingCountry	Displays the Application Reviewing Country.
ProductName	Displays the Product Name created by the migration.
CreationDate	Displays the date that the product was created.
Creator	Displays the user who created the product.

post_mig_rpt_placeholder_appl_products.sql

The migration script identifies the pseudo (placeholder) products created via Ennov InSight 7.0 migration process which can be deleted by the next optional script.

This script generates a list of the pseudo (placeholder) products which can be deleted by the next script. Those products meet the following requirements:

— The absence of the PDS templates, or events as association for the non-CTA/IND application types. — The absence of the event and the CT Shared Data selected for CTA/IND applications.

Script columns are the same as for post_mig_all_rpt_placeholder_appl_products.sql script. See *post_mig_all_rpt_placeholder_appl_products.sql script*.

For any requests of product deletion rules changes for out-of-the-box migration process, please contact your Business Development Representative for assistance.

post_mig_delete_placeholder_appl_products.sql

The migration script deletes the pseudo (placeholder) products created via Ennov InSight 7.0 migration process.

This script deletes all the products based on the name of the template (the same that was used for Ennov InSight 6.2 > 7.0 migration). You can specify the PREFIX or use the default one.

The script will not affect any products that you have used or those which have PDS templates or events as association.

For the CTA/IND applications, when there is an event with the CT Shared Data association, and no PDS, the product will be deleted from both the application and the event.

Chapter 8. Ennov InSight 7.2 Updates

Security Administration

Ennov InSight 7.2 Security Administration Updates

The following updates will be available in Security Administration through data migration.

XEVMPD License Module

To support IDMP, the XEVMPD (eXtended EudraVigilance Medicinal Product Dictionary)) field in Ennov InSight 7.2 is renamed to IDMP and xEVMPD.

Entity Security and Home Page Access

Two new entities: Medicinal Products and Medicinal Product Actions are added to the Entity Security and Home Page Access sections.

Home Page

Ennov InSight 7.2 Home Page Updates

The following updates will be available on the Home Page through data migration.

My Home

For better navigation to the IDMP entities, the Medicinal Products and the Medicinal Product Actions tabs are added to the *My Home* page.

Data Administration Updates

Data Administration Updates for Ennov InSight 7.2

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

Application Maintenance

For the Country Values, Legal Status Values, Orphan Status Values, Procedure Type Values, Product

Information Document Type Values, Regulatory Entitlement Type Values, the Data Administration lists that are associated with SPOR RMS now display the following columns in the grid/list view if there is an associated RMS Term for the value(s):

— RMS Term ID - the term ID from the SPOR Master List.

— RMS Modified On - the modified data from the operational attributes of the SPOR Master List.

— RMS Status - the status of the term from the SPOR Master List.

Medical Device Maintenance

To capture the data of Class III High Risk Medical Device products for UDI FDA and UDI MDR submissions, the new Medical Device Maintenance section is added to the *Data Administration* and includes the following sub sections:

— EU Device Nomenclature Category Values .

— EU Device Nomenclature Values .

— FDA GMDN In-Vitro Term Type Values

— Global Medical Device Nomenclature (GMDN) Code Values is moved from the Product Maintenance section.

Other

To support IDMP specification, the Certificate Master File Values and File Identifier Type Values sections are added to the Other section.

For the Application Submission Type Values, Concentration Measure Type Values, Indications/ Intended Use Values, Language Values, Legal Basis Values, Units of Measurement Values,Unit of

Presentation Values, the Data Administration lists that are associated with SPOR RMS now display the following columns in the grid/list view if there is an associated RMS Term for the value(s):

— RMS Term ID - the term ID from the SPOR Master List.

— RMS Modified On - the modified data from the operational attributes of the SPOR Master List. — RMS Status - the status of the term from the SPOR Master List.

Product Detail Set Maintenance

To support IDMP specification, the Origin of Substance Values list is added to the Product Detail Set Maintenance section.

The Packaging Category Values list now includes the IDMP Package Level field.

To define more than one material for a package component, the following changes are implemented for Package Component Values:

— the Product Material field type is changed to multiple selection. — the Product Material field is not required.

The following changes are implemented for Manufacturer Values:

— The Confidentiality Indicator is available on the Manufacturer Values > Global Product Details when you select the Packaging or Substance option for the Detail Type field.

— The Manufacturing Authorization Reference Number tab now includes the Country that approved the manufacturing site and the Regulatory Agency in the country that approved the manufacturer.

— The Regulatory Agency is populated from the Country Values > Health Authority tab.

— The Labeler DUNS Number/Legal Manufacturer Single Registration Number(SRN) and Authorised Representative Name are added to the *Manufacturer* page

For the Data Classification Type Values, Manufacturing Functions Values, Medical Device Values, Packaging Type Values, Product Material Values , Shelf Life Type Values, Storage Condition

Values,Substance Role Values , Time Unit Values, the Data Administration lists that are associated with SPOR RMS now display the following columns in the grid/list view if there is an associated RMS Term for the value(s):

— RMS Term ID - the term ID from the SPOR Master List.

— RMS Modified On - the modified data from the operational attributes of the SPOR Master List.

— RMS Status - the status of the term from the SPOR Master List.

Product Family Maintenance

The EURD Procedure Identifier) field and column are renamed to Family Identifier / Active Substances on the *EURD ID Values* page.

For the ATC Values and Domain Type Values, the Data Administration lists that are associated with SPOR RMS now display the following columns in the grid/list view if there is an associated RMS Term for the value(s):

— RMS Term ID - the term ID from the SPOR Master List.

— RMS Modified On - the modified data from the operational attributes of the SPOR Master List. — RMS Status - the status of the term from the SPOR Master List.

Product Maintenance

For the Dosage/Pharmaceutical Form Values, Medical Device Values, Product Category Values,

Product Cross Reference Type Values, Routes of Administration Values, the Data Administration lists that are associated with SPOR RMS now display the following columns in the grid/list view if there is an associated RMS Term for the value(s):

— RMS Term ID - the term ID from the SPOR Master List.

— RMS Modified On - the modified data from the operational attributes of the SPOR Master List.

— RMS Status - the status of the term from the SPOR Master List.

Registration Maintenance

The Registration Status Values list is now mapped to the Regulatory Entitlement Status from the SPOR Master Lists section. The RMS tab is added and mapping is done using the RMS search widget to associate RMS term to RIM value.

The Marketing Status Reason Values is renamed to Risk of Shortage of Supply Reason Values

For the Marketing Status Values, Master File Type Values, Medicinal Product Name Part Type Values,

Medicinal Product Type Values, Provenance Reason Values, Qualified Person Responsible for Pharmacovigilance (QPPV) Values, Registration Status Values, Risk of Shortage of Supply Reason Values, the Data Administration lists that are associated with SPOR RMS now display the following columns in the grid/list view if there is an associated RMS Term for the value(s):

— RMS Term ID - the term ID from the SPOR Master List.

— RMS Modified On - the modified data from the operational attributes of the SPOR Master List.

— RMS Status - the status of the term from the SPOR Master List.

SPOR Master Lists

The Reason of Marketing Unavailability list is added to the the SPOR Master Lists section and mapped to the Risk of Shortage of Supply Reason Values list from the Registration Maintenance section.

For the Data Classification Type Values, Manufacturing Functions Values, Medical Device UID Values,

Packaging Type Values, Product Material Values , Shelf Life Type Values, Storage Condition

Values,Substance Role Values , Time Unit Values, the Data Administration lists that are associated with SPOR RMS now display the following columns in the grid/list view if there is an associated RMS Term for the value(s):

— RMS Term ID - the term ID from the SPOR Master List.

— RMS Modified On - the modified data from the operational attributes of the SPOR Master List. — RMS Status - the status of the term from the SPOR Master List.

Entities

Entities Updates: Ennov InSight 7.2

Ennov InSight 7.2 Product Family Updates

New changes and implementations are included in Ennov InSight 7.2 to conform to the regulatory requirements.

Product Family

Ennov InSight 7.2 includes the following changes:

— The Product Family Indication is renamed to Product Family Indication(s) for all the Product Family Types, except for Veterinary.

— The Product Family Comorbidity is renamed to Product Family Comorbidity(s) for all the Product Family Types, except for Veterinary.

— It is now possible to modify active Ingredient(s) association with product Family, when there is a product created with no components.

— The EU CT Number is added to *CT Shared Data Attributes* page.

Ennov InSight 7.2 Active Ingredient and Reference Active Ingredient Updates

Active Ingredients and Reference Active Ingredients are updated through data migration.

Active Ingredient Updates

To support IDMP, Ennov InSight 7.2 includes:

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.
Concentration Measure Type	This field field is added to the IDMP Concentration Strength set of fields for Component Active Ingredient, Manufactured Item Active Ingredient, Pharmaceutical Product Active Ingredient, Substance and Reference Substance.

Reference Active Ingredient Updates

To support IDMP, Ennov InSight 7.2 includes:

Field Name	Description
Concentration Measure Type	This field is added to the IDMP Concentration Strength set of fields for

	Component Reference Active Ingredient, Manufactured Item Reference Active Ingredient, Pharmaceutical Product Reference Active Ingredient, Substance and Reference Substance.
Use for xEVMPD	This field is added for Reference Active Ingredient Attributes for Pharmaceutical Product.

Manufactured Item Reference Active Ingredient can now be a multiple value for Manufactured Item Active Ingredient, Pharmaceutical Product, Component Active Ingredients.

Ennov InSight 7.2 Application Updates

New features and fields are included in Ennov InSight 7.2 to conform to the regulatory requirements.

Application

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

Ennov InSight 7.2 includes the ability to track Pending Changes for the entities at the Event level and select attributes for Pending Changes in a wizard. The new Pending Changes tab on the Event Attributes page displays the Pending Changes attributes. The Legal Status of Supply and Procedure Type fields are tracked for application.

Ennov InSight 7.2 PhPIDs Updates

New changes and implementations are included in Ennov InSight 7.2 to conform to the regulatory requirements.

PhPIDs

To support IDMP, the following new fields and columns are added to the PhPID entity:

— Version

— Version Date

Ennov InSight 7.2 PDS and PDS Template Updates

PDS and PDS Templates are updated through data migration.

To support IDMP, Ennov InSight 7.2 includes these changes for PDS and PDS Templates:

— The Origin of Substance field is added to the *Active Ingredient Detail Attributes* and *Substance Detail Attributes* pages.

— The Composition Grouping Description field is added to the *Active Ingredient Detail Attributes* and *Substance Detail Attributes* pages.

— The Concentration Measure Type field is added the IDMP Concentration Strength set of fields to the

Substance Detail Attributes, *Flu Strain Attributes*

— The Packaging MI Quantity field is updated to include both integer and non-integer values on the *Package Detail Attributes* page.

— The Device Quantity Unit is added to the *Package Detail Attributes* pages and mapped to the Data Administration > Other > Unit of Presentation Values

Ennov InSight 7.2 Registration Updates

New features and fields are included in Ennov InSight 7.2 to conform to the regulatory requirements.

Registration

Ennov InSight 7.2 includes the ability to track Pending Changes for the entities at the Event level and select attributes for Pending Changes in a wizard. The new Pending Changes tab on the Event Attributes page displays the Pending Changes attributes. The following fields are tracked for registration:

— Subject to Additional Monitoring

— MAH

— QPPV

— MFL

— Enquiry Email

— Enquiry Phone Number

— Next Renewal Date

— Last Renewal Date

— License Status — License Date

.

Ennov InSight 7.2 Registration Package Set Updates

New features and fields **Registration Package Set**

To support IDMP, Ennov InSight 7.2 includes the following changes for registration package set:

— The Status field is renamed to PDS Package Set Status.

— The Status Date field is renamed to PDS Package Status Date.

— The PCID field is removed from the *Registration- Package Sets Attributes* page.

— The PCID tab is added to the *Registration- Package Sets Attributes* page.

— The MAH field is added to the *Registration- Package Sets Attributes* page.

— The Package Description Description field is renamed to Package Description on the RegistrationPackage Set Attributes > Package Set- Package Description Attributes page.

Ennov InSight 7.2 includes the ability to track Pending Changes for the entities at the Event level and select attributes for Pending Changes in a wizard. The new Pending Changes tab on the Event Attributes page displays the Pending Changes attributes. The following fields are tracked for registration package set:

— MAH

— License Status

— License Date

— Withdrawn Date

Ennov InSight 7.2 Registration Package Set Country Updates

New features and fields are included in Ennov InSight 7.2 to conform to the regulatory requirements.

Registration Package Set Country

To support IDMP, Ennov InSight 7.2 includes the following changes for registration package set country:

— The Currently Marketed in this country? field is updated from a check box to a drop-down list and mapped to the Data Administration > Registration Maintenance > Marketing Status Values. — Migration for existing data for this field is as follows:

- If the check box value is Y, then Marketed value is displayed.
- If the check box value is N, then Not Marketed value is displayed.

Changes related to Data Carrier Identifier:

— The Data Carrier Type, Data Carrier Identifier, Data Carrier Language fields are removed from the *Registrations Package Set-Country Attributes* and *Modify Package Set Country Association* pages.

— The Data Carrier Identifiers tab is added to the *Registrations Package Set-Country Attributes* page

Ennov InSight 7.2 includes the ability to track Pending Changes for the entities at the Event level and select attributes for Pending Changes in a wizard. The new Pending Changes tab on the Event Attributes page displays the Pending Changes attributes. The Legal Status of Supply field is tracked for registration package set country.

Ennov InSight 7.2 Medicinal Product Updates

New features and fields **Medicinal Product**

To support IDMP, Ennov InSight 7.2 includes the following changes for the medicinal product:

— The Medicinal Product entity and all the associated child entities are moved from the Registration to the Application level.

— The Medicinal Product tab is added to the *Application Attributes* page.

— The PMSID field is removed from the *Medicinal Product Attributes* page.

— The PMSIDs tab is added to the *Medicinal Product Attributes* page.

— The following fields are added to the *Medicinal Product Attributes* page:

- Full Indication Text
- Full Indication Language
- Country
- Registrations
- License Root Number

— The following columns are now displayed for the *Medicinal Product* tab:

- Registration Country
- Product
- PMSID
- MPID
- License Root Number
- Related Registration(s)

Ennov InSight 7.2 includes the ability to track Pending Changes for the entities at the Event level and select attributes for Pending Changes in a wizard. The new Pending Changes tab on the *Event Attributes*page displays the Pending Changes attributes. The following fields are tracked for medicinal product:

— Pediatric Use Indicator — Full Indication Text

The Full Indication Language attribute was added to medicinal product to correspond with Full Indication Text. However, this new attribute will not be tracked with the Pending Changes functionality.

MPIDs

To support IDMP, Ennov InSight 7.2 includes the following changes for the MPIDs:

— The MPIDs tab is editable now.

— The Country field is added to the *MPID Attributes*. This field is available if the application procedure type is CP and includes the values: European Union , Iceland , Liechtenstein , Norway .

— The MPIDs tab now includes the Country column.

Ennov InSight 7.2 Medicinal Product Name Updates

New features and fields

Medicinal Product Name

To support IDMP, Ennov InSight 7.2 includes the following changes for the medicinal product name:

— The Country field is now hidden on the *Medicinal Product Name Attributes* page for applications with noncentralized procedure.

— The Country field is updated to include European Union for applications with Centralized Procedure (CP).

— The following fields are added to the *Medicinal Product Name Attributes* page:

- Date of First Approval. This field is available only for the applications with Centralized Procedure (CP), and for Iceland, Liechtenstein, and Norway countries.
- Full Indication Text

Ennov InSight 7.2 Medicinal Product Action Updates

New features and fields are included in Ennov InSight 7.2 to conform to the regulatory requirements.

Medicinal Product Action

To support IDMP, Ennov InSight 7.2 includes the following changes for the medicinal product actions:

— The Medicinal Product Action entity and all the associated child entities are moved from the Registration to the Application level.

— The Sequence field is updated to display a concatenation of the Sequence Name and Sequence Code values on the *Medicinal Product Actions Attributes* page.

— The Tasks, References and Notifications tabs are added to the *Medicinal Product Actions Attributes* page.

Ennov InSight 7.2 IDMP Updates

New features and fields are included in Ennov InSight 7.2 to conform to the regulatory requirements.

IDMP

To support IDMP, Ennov InSight 7.2 includes the following changes for the IDMP tab:

— The IDMP entity tab is moved from the Registration to the Application level.

— The IDMP tab is added to the *Application Attributes* page. — The following columns are now displayed for the IDMP tab:

- Medicinal Product Name
- PMSID
- Registration Country
- Product
- MPID
- License Root Number

- Related Registration(s)
- Related MAH(s)
- Medicinal Product Action(s)
- Related Sequence

Queries

Ennov InSight 7.2 Queries

New features and fields are included in Ennov InSight 7.2 to conform to the regulatory requirements.

The following table lists the changes for Ennov InSight 7.2 Queries.

Change	Field or Column Name/Entity Name	Query Name
New Added Fields and Columns	Concentration Measure Type	— List of Pharmaceutical Products — List of Veterinary Products — List of Pharmaceutical and Medical Device Products — List of Pharmaceutical Products and Components — List of Veterinary Products and Components — List of Pharmaceutical and Medical Device Products and Components
	Version	— Entity History Query — Entity Audit Trail

Queries

Change	Field or Column Name/Entity Name	Query Name
New Added Queries	— RMS List Name — RMS Term Name — RMS Term ID	List of RMS Fields

	— RMS Status — Associated DA List Name — Display Columns — Sort Order	
	— OMS Organisation Name — OMS Organisation ID — OMS Location ID — OMS Address — OMS City — OMS Country — OMS Status — Associated DA List Name — Display Columns — Sort Order	List of OMS Fields
New Added Entities	Medicinal Product Action entity	— List of References — List of References - Rollup by Application — List of Tasks — List of Tasks - Rollup by Application
	Data Carrier Identifier entity	— List of Application Countries with PDS Country and Registration Details Query — Sunset Clause Marketing Status Query

Wizards

Ennov InSight 7.2 Wizards

New features and fields are included in Ennov InSight 7.2 to conform to the regulatory requirements.

The following table lists the new and renamed fields in Ennov InSight 7.2

Change	Field Name	Wizard Name
The wizard is updated to select only European Union when an Event is created for EU CP application. European Union is selected in the Selected. All other countries are in the Available box.	Countries	Create Application
The Application Type field is updated with the EU Clinical Trial Regulation in the Available box on the Global Project Plan > Select Filter Criteria page.	Application Type	Global Project Plan
The Use for xEVMPD field is now added to the wizard logic to take into consideration only that Pharmaceutical Product Reference Active Ingredient which has a field value as a Yes.	Use for xEVMPD	XEVMPD Submission Wizard

Chapter 9. Database Script Error messages

Description 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
5.1 to 6.0	Any indexing or constraint errors regarding the following tables can be ignored:	Ignore Example:

Upgrade path	Error	Description/Resolution
	• 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`	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
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`
		Ignore

Upgrade path	Error	Description/Resolution
	CREATE TABLE MGR.SEQ_DESCR_TYPE(* ORA-00001: unique constraint (MGR.UX1REGULATORY_AC-T_LEAD) violated ORA-00001: unique constraint (MGR.UX1SEQ_DESCR_TYPE) violated	
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.
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
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	from dba_views v * ERROR at line 36:	Ignore

Upgrade path	Error	Description/Resolution
6.0 CHF 4 to 6.0 CHF 5		
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
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

Upgrade path	Error	Description/Resolution
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.
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.

Upgrade path	Error	Description/Resolution
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
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	IgnoreThis 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.
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	Ignore

Upgrade path	Error	Description/Resolution
	• 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	
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	• c • 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
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	Ignore

Upgrade path	Error	Description/Resolution
	• 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	
7.1.3 to 7.2	ORA-30674: identity column cannot have a default value	Ignore
7.2 to 7.2.2	ORA-30674: identity column cannot have a default value	Ignore
7.2.4 to 7.2.5	• CREATE TABLE LEAF_MODIFIED(* ERROR at line 1:ORA-00955: name is already used by an existing object • ALTER TABLE LEAF_MODIFIED ADD CONSTRAINT PKLEAF_MODIFIED PRIMARY KEY (ID)* ERROR at line 1: ORA-02260: table can have only one primary key • ORA-30674: identity column cannot have a default value	Ignore
7.2.5 to 7.2.6	• ORA-30674: identity column cannot have a default value	Ignore
7.2.6 to 7.2.7	• ORA-30674: identity column cannot have a default value • ORA-02264: name already used by an existing constraint	Ignore

Upgrade path	Error	Description/Resolution
	• SP2-0310: unable to open file "define.passwords" • SP2-0310: unable to open file "define.application"	
7.2.7 to 7.2.8	• ORA-30674: identity column cannot have a default value	Ignore
7.2.8 to 7.2.9	• ORA-30674: identity column cannot have a default value	Ignore
7.2.9 to 7.2.10	• ORA-30674: identity column cannot have a default value	Ignore
7.2.10 to 7.2.11	• 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 1. Table 1. 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. Contact 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
1010/9 PL/SQL: Statement ignored
1011/9 PLS-00364: loop index variable 'IREC' use is invalid
991/35 PLS-00364: loop index variable 'IREC' use is invalid
```

Chapter 10. Index

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