



Ennov InSight Autumn 2025 Release Notes

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Table of Contents

1	ENNNOV INSIGHT AUTUMN 2025 RELEASE NOTES.....	4
1.1	Ennov InSight Autumn 2025 Release Notes.....	4
1.1.1	IDMP Updates.....	4
1.1.2	IDMP InSight vs Ennov IDMP Integration	5
1.1.3	Data Administration	5
1.1.4	XEVMPD	6
1.1.5	Common Enhancements.....	7
1.1.6	Registrations Enhancements	7
1.1.7	Regulatory updates	7
1.1.8	eCTD 4.0.....	9
1.1.9	API	10
1.1.10	DMS Integration.....	10
1.1.11	Integrated in-process linking.....	10
1.1.12	Technologies and software no longer supported.....	10
1.2	Resolved Issues: Ennov InSight Autumn 2025.....	11
1.2.1	Common	11
1.2.2	Registrations.....	12
1.2.3	Publishing.....	13
1.2.4	XEVMPD	15
1.2.5	IDMP.....	16
1.3	Entity Fields, Columns and Options Added: Ennov InSight Autumn 2025	17
1.3.1	Pharmaceutical Product	17
1.3.2	Event.....	17
1.3.3	Event -> Country Tab.....	17
1.3.4	Event -> Country Schedule Tab	18
1.3.5	Event -> Country Status Tab	18
1.3.6	Event -> Pending Changes Tab	18
1.3.7	PDS -> Manufacturer Detail.....	19
1.3.8	Registration (Package Set Type)	19
1.3.9	PCID	19
1.3.10	Medicinal Product	20
1.3.11	Medicinal Product Actions	20
1.3.12	Sender-defined Keywords (SDK).....	21
1.3.13	Leaf in eCTD 4.0 assembly	21
1.3.14	Publishing Settings Library	22
1.3.15	Repositories in Technical Administration.....	22
1.4	Entity Fields, Columns and Options Updated: Ennov InSight Autumn 2025	22

1.4.1	Full Product Presentation	23
1.4.2	Pharmaceutical Products Tab	23
1.4.3	Registration FPP Attachment	23
1.4.4	Pharmaceutical Product Reference Substance	23
1.4.5	Manufactured Item Reference Substance	24
1.4.6	Event->Copy Event	24
1.4.7	Associate Change Detail to Event	24
1.4.8	PDS -> Packaging Detail	25
1.4.9	Registration (Package Set Type)	26
1.4.10	IDMP Tab	26
1.4.11	PCIDs Tab	26
1.4.12	Medicinal Product	26
1.4.13	Pharmaceutical Products Tab	27
1.4.14	PMSIDs Tab.....	27
1.4.15	MPIDs Tab	27
1.4.16	Medicinal Product Name.....	28
1.4.17	Medicinal Product Actions	28
1.5	Data Administration Sections Added: Ennov InSight Autumn 2025	30
1.5.1	Secondary Event Type Values	30
1.5.2	Origin of Substance Values.....	30
1.5.3	Species Values	30
1.5.4	Target Species Values	30
1.5.5	National Classification ATC Values	31
1.5.6	MAH/Development Sponsor/Organisation Values	31
1.5.7	Substance Values.....	32
1.5.8	SPOR Master List	32
1.5.9	RMS Term Search Widget	34
1.5.10	Units of Measurement Values.....	35
1.5.11	Substance Values.....	35
1.5.12	Content Change Values	36
1.5.13	Provenance Reason Values	36
1.5.14	Certificate Master File Values.....	36
1.5.15	SPOR Master List	37
1.6	Queries Sections Updated: Ennov InSight Autumn 2025	38
1.6.1	Applications Submitted and/or Approved and/or Terminated within a Date Range	38
1.6.2	List of Manufacturers From Data Administration.....	38
1.6.3	Entity Audit	38
1.7	Wizard Sections Updated: Ennov InSight Autumn 2025	39
1.7.1	XEVMPD Submission Wizard	39

1 Ennov InSight Autumn 2025 Release Notes

1.1 Ennov InSight Autumn 2025 Release Notes

The Release Notes contain information about updated files, new functionality, resolved issues, and any open issues or workarounds in this release of Ennov InSight Autumn 2025.

The details in these Release Notes supersede all similar details that appear anywhere else in this release of the product or its other documentation.

1.1.1 IDMP Updates

To comply with the latest EMA IDMP implementation Guide (Chapter 2 version 2.4) and improve the user experience, Ennov InSight now includes various updates for IDMP data capture.

The new multi-select field Manufactured Items allows you to reference multiple Manufactured Items on the Pharmaceutical Product.

On the Medicinal Product entity, the Genetically Modified Organisms field values have been changed from Yes/No to True/False values, and the PMSID has been moved from a tab to a field on Medicinal Product as EMA have merged the EEA and EU records in PMS and only retained the EU PMSID for CP, it is also available as a read only field on MPID entity . The fields Ennov Medicinal Product and IDMP Last Submission Date have been added as Hidden OOTB to Medicinal Product. The fields Registrations, Product, and Package Sets have been updated to hyperlink fields, linking to the appropriate entities. The copy URL icon with general Copy URL functionality has been added to the entity attributes screen.

The Medicinal Product > PMSIDs tab has been deleted from the UI.

On the Medicinal Product > MPIDs tab the Country column has been deleted. The Country field has also been deleted on the MPID entity.

Entity creation rules have been changed for the Medicinal Product Actions entity. The Medicinal Products available for selection are limited to those with an Ennov Medicinal Product field value on Medicinal Product. a hyperlink to the Ennov IDMP system. The Medicinal Product Actions was updated with Sequence, Status and Regulatory Application Submission Type as no longer required fields. The FHIR Protocol Type was Hidden, Content of Change has been renamed to Content Scope, and Provenance Reason has been renamed to Message Reason.

On the Medicinal Product Name entity name of the Tradename or Company Name Part field has been renamed to Company Name Part.

On the Registration (Package Set Type) entity, the new field National Classification has been added. This is a drop-down list and includes values from the new National Classification ATC value list from Data Administration. The field ATC Code flag has been renamed to ATC Request.

On the Registration-Package Set > PCIDs tab a new drop-down field Medicinal Product has been added. The PMSID and Country fields have been deleted.

It is now possible to define multiple Reference Substances on the Manufactured Item Substance and Pharmaceutical Product Substance entities.

On the PDS Packaging Detail default values have been changed for Quantity Operators to [Select]. The Package Item - MI Quantity now shows only Unit of Measurements values. The Device Quantity Operator has been renamed to Package Item Device Quantity Operator, Device Quantity has been renamed to Package Item Device Quantity, and Device Quantity Unit has been renamed to Package Item Device Quantity Unit. The Data Carrier Identifier field is now hidden OTB.

The Country column has been deleted from IDMP tab on the Application Attributes screen.

A copy URL icon with general Copy URL functionality has been added for the Manufacturer Nodes in PDS Tree for the purpose of the Ennov IDMP integration.

The new logic has been introduced for the IDMP Strength fields view on the tabs and selection widgets for the entities Component Active Ingredient/Reference Active Ingredient, Pharmaceutical Product Active Ingredient /Reference Active Ingredient, Pharmaceutical Product Substance/Reference Substance, Manufactured Item Active Ingredient /Reference Active Ingredient, Manufactured Item Substance/Reference Substance, Pharmaceutical Product tab, and Pharmaceutical Product Selection on Medicinal Product/Full Product Presentation.

1.1.2 IDMP InSight vs Ennov IDMP Integration

Following icons are available for an IDMP license only, includes IDMPD messaging functionality.

A new 'Create Ennov IDMP Medicinal Product' icon has been added to the Medicinal Product Attributes screen to trigger the API for IDMP integration.

The new 'Create Ennov IDMP Submission Plan' button is now available. When this button is pressed, the new field 'Ennov IDMP Submission Plan' will be updated through API.

1.1.3 Data Administration

Secondary Event Type Values, an existing Data Administration list, has been updated with extra fields as OOTB functionality.

Species Values, an existing Data Administration list, has been updated with extra fields as OOTB functionality.

A new list, National Classification ATC Values, has been added under Data Administration > Registration Maintenance.

A new field Include in Quantity Unit is added to the Units of Measurement Values list in Data Administration. It is now possible to include value from the Data Administration list Units of Measurement Values on PDS Packaging Detail > Device Quantity Unit by selecting Yes for the new field Include in Quantity Unit under Units of Measurement Values in Data Administration.

Origin of Substance Values, an existing Data Administration list, has been updated to add the RMS tab. Values can be mapped to the RMS list 200000027811 Substance Origin.

A new list, Target Species Values, is added under Data Administration > Product Detail Set Maintenance. This can be mapped to a new SPOR Master List, Target Species. Target Species is mapped to the RMS list 100000108853 Target Species.

Content of Change Values, an existing Data Administration list, has been renamed to Change Scope Values.

Provenance Reason Values, an existing Data Administration list, has been renamed to Message Reason Values.

There are several updates for Substance Values -> SMS tab in Data Administration. New columns for SVG Flag, EV Code, UNII Code, and Substance Type were added. The Category column has been renamed to Status. The Active Flag has been hidden from UI.

The Term Search widget for Substance Values has been updated. The columns Status, UNII Code, SVG Flag and EV Code have been added. The Domain, Category and Code columns have been deleted. The Data Classification column has been renamed to Substance Type.

The OMS in Data Administration has been updated to add the UI Label, Version Type and Version Comment fields from EMA API.

New SPOR Master Lists were added: National Classification, Origin of Substance, Species, Target Species, Record Status, Anatomical Therapeutic Chemical Classification System – Veterinary, Regulatory Regulating Authority Submission Unit Type, EU Territorial Authority and Tissue.

The RMS Term Search widgets for Data Classification Values, Ingredient Role Values, Legal Status of Supply Values, Medicinal Product Type Values, Medicine Profile Values, Regulatory Entitlement Type Values and Quantity Operator Values have been updated to include a new column Status/App.

The Substance SPOR Master List was updated with new fields SVG Flag, EV Code, Source of Information, Description and UNII Code. The Data Classification has been renamed to Substance Type, and the Name field GUI Field Size has been changed from 500 to 1800 characters.

The SPOR Master Lists Data Classification Values, Ingredient Role Values, Legal Status of Supply Values, Medicinal Product Type Values, Medicine Profile Values, Regulatory Entitlement Type Values and Quantity Operator Values have been updated to include a new column were updated with a new field Application Applicability.

1.1.4 XEVMPD

On the Full Product Presentation entity, the Full Product Name field has been updated to a text box which allows separate lines with breaks. The xEVMPD Submission Wizard now supports a format of separate lines for the Full Product Presentation Name.

The XEVMPD Submission Wizard has been updated to accommodate separate lines formatting for XML file for the Full Product Presentation Name.

1.1.5 Common Enhancements

An improved version of the Registration Attachment selection widget for advanced search and selection is included in the Create Full Product Presentation (FPP) entity..

An improved version of the Pharmaceutical Product selection widget for advanced search and selection is updated in the following locations Create Medicinal Product, Pharmaceutical Products tab on Medicinal Product Attributes screen, Create Full Product Presentation, Pharmaceutical Products tab on Full Product Presentation Attributes screen.

An improved version of the Product selection widget for advanced search and selection is included in the Copy Event wizard.

An improved version of the Substance selection widget for advanced search and selection is included in Queries Applications Submitted and/or Approved and/or Terminated within a Date Range report, List of Manufacturers From Data Administration report.

An improved version of selection widget for advanced search and selection is included in the Data Administration-> Certificate Master File Values -> Related Application field.

An improved version of selection widget for advanced search and selection is included in the Associate Change Detail to Event ->Select Change Detail(s) field.

1.1.6 Registrations Enhancements

To enhance KPI tracking capabilities, an Original Projected Date field/column is now available on the Event-Country, Event Country-Schedule, and Event-Country Status tabs and entities.

A Product Detail Sets option has been added to the Home Page >SEARCH. A new PowerSearch capability is available for this search, which can be configured during server installation. For more information, refer to the best practices document provided with the release.

The Entity Audit Trail Query now includes Product Component, Comparator and PDS Shelf Life Detail.

1.1.7 Regulatory updates

Ennov InSight Autumn 2025 introduces support for Singapore (SG) v1.0 submissions:

- Ennov InSight Administration 7.3 > eCTD Codes > eCTD Codes for Filing Types > eCTD Filing Types for SG
- Ennov InSight Administration 7.3 > eCTD Codes > eCTD Codes for Procedure Types > Singapore (Under NATIONAL row)
- Ennov InSight Administration 7.3 > eCTD Codes > eCTD Codes for Country Values N-S
- Ennov InSight Administration 7.3 > eCTD Codes > eCTD Codes for Application Types
- Ennov InSight Administration 7.3 > eCTD Codes > Submission Sub Type for SG

- Ennov InSight Administration 7.3 > Assembly XML Specification > Extensions > Groups of Extensions by Version and Country
- Ennov InSight Administration 7.3 > Assembly XML Specification > Extensions > m1-sg > m1-sg v1.0
- Ennov InSight Administration 7.3 > Administrative Activities > Manage eCTD and eCTD 4.0 Templates > eCTD Templates.
- Ennov InSight Administration 7.3 > Administrative Activities > Import eCTD Applications > Prepare for Bulk eCTD Import.
- Ennov InSight Publishing 7.3 > Use eCTD Templates > eCTD and NeeS Template Files
- Ennov InSight Publishing 7.3 > Use eCTD Templates > Mapped eCTD Template Profiles
- Ennov InSight Publishing 7.3 > Extended Attributes Name, Type, and Version
- Ennov InSight Publishing 7.3 > Submissions > Create eCTD Wizard > Singapore-v1.0
- Ennov InSight Publishing 7.3 > Extension Type and Usage > Extension Type: Regional Folders > Singapore.

Ennov InSight Autumn 2025 now supports STF valid values v6.0.

Ennov InSight Autumn 2025 now uses au-regional.xsl updated by TGA as of 19 June 2025.

Ennov InSight Autumn 2025 now uses ZA v3.1 controlled vocabularies valid as of the 1 September 2025. It includes:

- v2.0 of application_type.xml
- v1.0 of contact_type.xml
- v1.1 of evaluation-path.xml
- v3.0 of sequence_type.xml
- v2.0 of submission_lead.xml
- v3.0 of submission_type.xml

Ennov InSight Autumn 2025 introduces support for Tunisia (TN) v1.1 submissions:

For more information about new TN values, extensions, and rules, see:

- Ennov InSight Data Migration 7.3 > Ennov InSight Autumn 2025 Updates
- Ennov InSight Administration 7.3 > eCTD Codes > eCTD Codes for Application Types
- Ennov InSight Administration 7.3 > eCTD Codes > eCTD Codes for Filing Types > eCTD Filing Types for TN v1.1
- Ennov InSight Administration 7.3 > eCTD Codes > eCTD Codes for Country Values T-Z
- Ennov InSight Administration 7.3 > Administrative Activities > Import eCTD Applications > Prepare for Bulk eCTD Import

- Ennov InSight Administration 7.3 > Assembly XML Specification > Extensions > Groups of Extensions by Version and Country
- Ennov InSight Administration 7.3 > Assembly XML Specification > Extensions > Folder Extensions > envelope->tn > Envelope-tn v1.1
- Ennov InSight Administration 7.3 > Administrative Activities > Manage eCTD and eCTD 4.0 Templates > eCTD Templates
- Ennov InSight Publishing 7.3 > Use eCTD Templates > eCTD and NeeS Template Files
- Ennov InSight Publishing 7.3 > Use eCTD Templates > Mapped eCTD Template Profiles
- Ennov InSight Publishing 7.3 > Extended Attributes Name, Type, and Version
- Ennov InSight Publishing 7.3 > Submissions > Create eCTD Wizard > Tunisia-v1.1
- Ennov InSight Publishing 7.3 > Extension Type and Usage > Extension Type: Regional Folders > Tunisia

Ennov InSight Autumn 2025 introduces support for Bosnia and Herzegovina (BA) v3.1 submissions:
For more information about new BA values, extensions, and rules, see:

- Ennov InSight Data Migration 7.3 > Ennov InSight Autumn 2025 Updates
- Ennov InSight Administration 7.3 > eCTD Codes > eCTD Codes for Filing Types > eCTD Filing Types for BA v3.1
- Ennov InSight Administration 7.3 > Assembly XML Specification > Extensions > Groups of Extensions by Version and Country
- Ennov InSight Administration 7.3 > Assembly XML Specification > Extensions > Folder Extensions > m1-ba v3.1
- Ennov InSight Administration 7.3 > Administrative Activities > Import eCTD Applications > Prepare for Bulk eCTD Import
- Ennov InSight Administration 7.3 > Administrative Activities > Manage eCTD and eCTD 4.0 Templates > eCTD Templates
- Ennov InSight Publishing 7.3 > Use eCTD Templates > eCTD and NeeS Template Files
- Ennov InSight Publishing 7.3 > Extended Attributes Name, Type, and Version
- Ennov InSight Publishing 7.3 > Use eCTD Templates > Mapped eCTD Template Profiles
- Ennov InSight Publishing 7.3 > Extension Type and Usage > Extension Type: Regional Folders > Bosnia and Herzegovina

1.1.8 eCTD 4.0

Ennov InSight Autumn 2025 introduces the following enhancements for eCTD 4.0:

When creating Sender-defined Keywords (SDKs), you can now use the new Keyword Type field to define a category for SDKs. The keyword types are mandatory and cannot be changed after SDKs are created.

Upon upgrade to Ennov InSight Autumn 2025 each SDK gets keyword type assigned. Usage of the keyword types now accounted for forward compatibility and import assembly scenarios.

It is now possible to create SDK directly from the corresponding field in one click without switching to SDK tab under the Application.

Applicant Contact lifecycle is now supported.

eCTD 4.0 Regional Information now supports regions with more than one country.

Create Study Reports wizard is now available for eCTD 4.0 assemblies.

Appearance of suspended Context of Use in the XML has been corrected to pass the validation.

1.1.9 API

Using an API, it is now possible to create a list of applications associated with a Product Family.

It is now possible to search for applications by productFamilyId and countryId.

1.1.10 DMS Integration

Vevea connectivity has been aligned with Documentum and Secured Filesystem perspective improving flexibility. Publish request pre-processing and document properties retrieval has been optimized and now completes faster. The burst API limit handling has also been updated: now, when reaching the limit, the processing works slower instead of failing as it did before. The user experience remains the same.

It is now possible to leverage source documents from Ennov Doc. The user can drag and drop documents directly out of the native Ennov Doc window.

1.1.11 Integrated in-process linking

Ennov InSight users can now create in-process links within the browser, without requiring Adobe Acrobat and Smartlink for PDF to be installed on the client machine.

1.1.12 Technologies and software no longer supported

From version Autumn 2025 and onward, Microsoft Office and SmartLink for Word (Linking Add-in (Word)) products will no longer be part of the RDS deployment. Please see the user documentation regarding the new linking functionality in Autumn 2025.

1.2 Resolved Issues: Ennov InSight Autumn 2025

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

If an issue was resolved in a previously released sub-minor build, that build number is included.

1.2.1 Common

Issue	Description	Impact	Resolution
243884	During an API call, using the POST /application-country/query method resulted in an error. This issue is resolved.	API users for Application Country.	API for /application-country/query method has been fixed.
239674	For an Event name with 400 characters, when a notification is created and sent, an error occurred. This issue is resolved. Now, a notification is successfully sent even if an Event name is more than 400 characters.	Notifications were not sent for Events with long names.	Notifications were fixed to accommodate large entity names.
91949, DE31843 [PTASK0015442]	It was not possible to open tasks from Alert Center if the user did not have the Activity Read permissions. This issue is resolved. Now, it is possible to open tasks from Alert Center even if the Tasks permission is Read and the Activity permission is None.	Users could not open Tasks when they did not have Activity Read permissions.	Tasks security has been fixed so that users are able to open Tasks from the Alert Center.
90686, DE31868 [PRB0046033, CS0956975]	BEG_DATE field did not populate as part of DaaS solution.	Users using DaaS did not receive all the information needed.	Depending on configuration such information is either stored in the database or skipped as before.

1.2.2 Registrations

Issue	Description	Impact	Resolution
243302	It was not possible to get the PDS -> Package Set -> Shelf Life(s)/Storage Conditions option when using the API /all and /query calls. This issue is resolved. Now, the PDS -> Package Set -> Shelf Life(s)/Storage Conditions option is displayed on using the API /all and /query calls.	API users for PDS Nodes, Package Sets -> Shelf Life(s)/Storage Conditions.	API for PDS->Shelf Life(s)/ Storage Conditions has been fixed, an array storageReqList was added.
250839	It was not possible to delete a Package Set with Packaging Detail with selected Package Component. This issue is resolved.	User could not delete the Package Set if a Packaging Detail had been created under PDS.	Deleting process for PDS-> Packaging Detail was fixed.
250350	Package Set name appeared twice after renaming under being assigned to the different Events under registration. This issue is resolved.	When creating the registration renamed package sets from different events were present for selection.	Create registration was updated to show up to date values.
246919	The event with many associated Projects shows performance degradation. The issue is fixed.	The work with the Event was affected.	The general performance for Event with assigned Projects has been improved.
249632	The Country Tree expansion has shown a performance degradation, took more time to expand the structure. The issue is resolved.	The work with navigation withing Country Tree.	The Country Tree work was optimized with performance improvements.
250832	When copying the Product with the PDS with at least one Shelf Details attached the Product is not copied and SQL error appears. This issue is resolved. Now the Product can be copied without errors.	Copy Product functionality.	Copy Product with PDS Nodes has been fixed for the Shelf Details.

1.2.3 Publishing

Defect ID	Description	Impact	Resolution
247029	Under some conditions several parallel Recalculate Checksums requests, containing more than 1000 leaves failed.	Multiple users working on heavy submissions had to resubmit requests multiple times.	Processing of many leaves is now optimized and number of files to be processed at a time, can be configured.
241758 [TIC-2025-03-51787, TASK-2025-04-0378]	Some Veeva documents with Unicode characters in name did not download using View File or Edit Document Links option	The user could not download Veeva documents via View File or Edit Document Links if they contained Unicode characters in the name.	Additional handling of Unicode has been added to download Veeva file processing.
240952 [TIC-2025-03-51199, TASK-2025-03-0269]	Assemblies where document query did not work if the parent folder for the document contained plus ('+') in the name.	The user is unable to see documents which contain (+) in the parent folder when using the Assemblies where Document Query.	The user is able to run the Assemblies where document query even if the parent folder for the document contained plus ('+') in the name.
240629 [TIC-2025-03-48415, TASK-2025-03-0240]	If an eCTD 4.0 assembly containing documents from DMS no longer supported had published, the publish failed	Forward compatibility assemblies made from eCTD 3.2 submissions with a long history were unable to publish.	The eCTD 4.0 publish process has been revisited, now processing only actual documents and ignoring old documents from the Submitted View.
92738	It was possible to select Replace on a leaf that had already been replaced for eCTD 3.2.	Data Corruption on duplicated replace leaf requiring deletion of entire assembly.	User is unable to select replace on replaced leaf.

92615	Assigning a document to an eCTD 4.0 folder caused leaf creation with an incorrect ID.	The incorrect ID leads to an invalid output, causing validation errors.	The leaf ID is generated in the format of UUID, which is the expected format for the eCTD 4.0.
92161	Recalculating checksum for a leaf downloaded all the files of the output folder rather than downloading just the leaf output file.	Performance implication for the folders containing many files.	If Recalculate Checksums is called for the leaf, only the leaf output file is downloaded.
91166	When the end of a folder name included a space character, publishing failed.	The publish fail was really confusing as it is hard for a user to notice a space at the end of a folder name.	Publishing completes successfully even if the end of a folder name has a space character. This fix works for Paper Output Location, Electronic Output Location, and Preview Location.
91574	Generated TOCs had the incorrect extension in TOC Generation Location.	Possible incompatibility between *.doc and *.docx formats. Also, a cosmetic issue.	The TOCs are generated with *.docx extension.
91145, DE31470	The Publish Request window did not close after clicking OK while publishing eCTD 4.0 assembly.	The user had to explicitly close the window. The job in Job Requests did not appear until switch to Waiting status.	The Publish Request window closes after clicking OK button without additional user action. The publish job is listed in Job Requests immediately after submission.
90938, DE31336	While importing assembly or folder into another assembly, as well as duplicating a Folder, the action took more time than expected.	Users experienced performance issues upon doing assembly structure updates in bulk.	The performance level has been improved comparing to the previous release.

1.2.4 XEVMPD

Defect ID	Description	Impact	Resolution
251373 [TASK-2025- 09-1905]	When using the Copy Registration FPP Attachment Wizard for any wizarding flow, once the Wizard is completed only one attachment is copied and not all of them. Now the issue is resolved, and the Wizard copies all attachments for the selected FPP.	Copy Registration FPP Wizard failed to copy all Attachments.	The Copy Registration FPP Wizard functionality related to the Attachments was updated.
251426 [TASK-2025- 09-1951]	When modifying an FPP through the UI, in certain cases a database error occurs when the user attempts to Save the record saying there are Countries assigned to it. This issue is resolved. Now when updating an FPP, there are no DB errors and changes are saved properly.	Modifying an FPP entity didn't work if there was previously a Country assigned to the FPP entity.	Migration script was created to correctly update DB FPP entity table.
251778	When modifying an FPP through the UI, Package Description was automatically changed to match the Package Sets field value. This issue is resolved.	Modifying an FPP entity automatically changed the value for the field even if it was previously updated and in use.	Modify an FPP entity field auto populate was fixed for Package Description field.
90632	When Package Set was associated with FPP entity and then it was Withdrawn there were no ability to disassociate that Package Set from FPP. This issue is resolved.	Modifying an FPP entity Package Sets with Withdrawn statuses weren't visible through UI.	Modify an FPP entity mechanism was fixed to show Package Sets with Withdrawn statuses.
250367	When running the XEVMPD Submission Wizard for Authorisation Status with 'Not Valid - Superseded by Marketing Authorisation Transfer' the correct value for MAH appeared in UI only, XML file contained incorrect value. This issue is resolved.	Running the XEVMPD Submission Wizard didn't pull the correct MAH value.	XEVMPD Submission Wizard XML creation logic was fixed.

1.2.5 IDMP

Defect ID	Description	Impact	Resolution
245280	RIM SPOR service failed to synchronise data for OMS List after cleaning. This issue is resolved.	Creating a data setup for the IDMP OMS fails.	RIM SPOR service has been fixed.
250781	RIM SPOR service failed to synchronise OMS with the timestamp nano seconds. That issue is resolved/	Creating a data setup for the IDMP OMS fails.	The root cause was in Linis system usage, RIM SPOR service was fixed.

1.3 Entity Fields, Columns and Options Added: Ennov InSight Autumn 2025

The following tables describe fields and columns that were added in this release.

1.3.1 Pharmaceutical Product

Field/Column/Option Name	Field Type	Description	Business Rules
Manufactured Items	New multi-select	Manufactured Items is now included on Pharmaceutical Product.	To conform to the latest IDMP specification, this field is added under Product Detail Set Maintenance.

1.3.2 Event

Field/Column/Option Name	Field Type	Description	Business Rules
Pending Changes	New Drop-down	When Event is closing as Approved to select should Pending Changes apply or not.	The change is made to support registration functionality.

1.3.3 Event -> Country Tab

Field/Column/Option Name	Field Type	Description	Business Rules
Original Projected Date	New date field	To save the projected date of the Event.	The change is made to support registration functionality.
Save Projected Date(s)	New icon	To apply the projected date of the event.	The change is made to support registration functionality.

1.3.4 Event -> Country Schedule Tab

Field/Column/Option Name	Field Type	Description	Business Rules
Original Projected Date	New column	To show the original projected date of the Event.	The change is made to support registration functionality.

1.3.5 Event -> Country Status Tab

Field/Column/Option Name	Field Type	Description	Business Rules
Original Projected Date	New read only field	To show original projected date of the Event auto populated with data from 'Projected Date' when 'Save Projected Date(s)' icon is selected.	The change is made to support registration functionality.

1.3.6 Event -> Pending Changes Tab

Field/Column/Option Name	Field Type	Description	Business Rules
Set Filter	New icon	To enable filter capability for the Pending Changes tab.	The change is made to support registration functionality.

1.3.7 PDS -> Manufacturer Detail

Field/Column/Option Name	Field Type	Description	Business Rules
Copy URL	New icon	To enable Copy URL capability for the manufacturers in the PDS Tree.	The change is made to support IDMP functionality.

1.3.8 Registration (Package Set Type)

Field/Column/Option Name	Field Type	Description	Business Rules
National Classification	New Drop-down	Values from DA->National Classification ATC Values	The change is made to support IDMP data capture.

1.3.9 PCID

Field/Column/Option Name	Field Type	Description	Business Rules
Medicinal Product	New Drop-down	Shows in a format Medicinal Product Name + PMSID	The change is made to support IDMP data capture.
MPID	New Drop-down	Dependent on Medicinal Product selection	The change is made to support IDMP data capture.

1.3.10 Medicinal Product

Field/Column/Option Name	Field Type	Description	Business Rules
PMSID	New Text	Not required field	The change is made to support IDMP Integration.
Ennov Medicinal Product	New read-only	Can be configured through API	The change is made to support IDMP Integration.
IDMP Last Submission Date	New Date	Not required field	The change is made to support IDMP Integration.
Copy URL	New icon	To enable Copy URL capability for the manufactures in the PDS Tree.	The change is made to support IDMP Integration.
Create Ennov IDMP Medicinal Product	New icon	To enable IDMP Integration.	The change is made to support IDMP Integration.

1.3.11 Medicinal Product Actions

Field/Column/Option Name	Field Type	Description	Business Rules
Ennov IDMP Submission Plan	Read only, hyperlinked	Can be configured via API	The change is made to support IDMP functionality.
Create Ennov IDMP Submission Plan	Icon	When selected an Integration between InSight IDMP and Ennov IDMP will be initiated for to generate the IDMP message.	The change is made to support IDMP functionality.

1.3.12 Sender-defined Keywords (SDK)

Field/Column/Option Name	Field Type	Description	Business Rules
Keyword Type	Drop-down	When creating/editing Sender-defined Keywords, the option Keyword Type is now available on the SDK tab on the Application page. The Keyword Type is mandatory and cannot be changed once an SDK is created.	This new field enables assigning of SDKs only to applicable fields.

1.3.13 Leaf in eCTD 4.0 assembly

Field/Column/Option Name	Field Type	Description	Business Rules
Document Type	Drop-down	This new field allows to define Document Type at Leaf level for eCTD 4.0 assemblies, removing the need in additional folders for study reports to cover each unique combination of Study ID, Document Type and Context of Use code	Optional field. The values are sourced by Document Type CV from the ICH profile, currently associated with the assembly.

1.3.14 Publishing Settings Library

Field/Column/Option Name	Field Type	Description	Business Rules
Use integrated in-process linking	Drop-down	Used to switch between integrated way of creating in-process links and standalone, using Adobe Acrobat and SmartLink for PDF	By default, is set to No.

1.3.15 Repositories in Technical Administration

Field/Column/Option Name	Field Type	Description	Business Rules
Ennov Repository URL	Text	Used to be provided as hyperlink in the DMS Browse window for the user to navigate exactly to the configured repository.	Should be complete URL to navigate to specified repository
Repository User	Text	User for service account	
Repository Password	Text	Password for the service account	Encrypted

1.4 Entity Fields, Columns and Options Updated: Ennov InSight Autumn 2025

The following tables describe fields, columns, and options that were modified in this release.

1.4.1 Full Product Presentation

Field/Column/Option Name	Field Type	Description	Business Rules
Full Product Presentation Name	Text Area	Updated to a text to support separate line format for UI	The change is made to support XEVMPD functionality.
Pharmaceutical Products	Selection widget	Selection widget has been updated with new modern version.	This improved search and selection capabilities enhances efficiency.

1.4.2 Pharmaceutical Products Tab

Field/Column/Option Name	Field Type	Description	Business Rules
Associate/Dissociate Pharmaceutical Products	Selection widget	Selection widget has been updated with new modern version.	This improved search and selection capabilities enhances efficiency.

1.4.3 Registration FPP Attachment

Field/Column/Option Name	Field Type	Description	Business Rules
Attachment Name	Selection widget	Selection widget has been updated with new modern version.	This improved search and selection capabilities enhances efficiency.

1.4.4 Pharmaceutical Product Reference Substance

Field/Column/Option Name	Field Type	Description	Business Rules
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Reference Substance Name	Drop-down	Cardinality for the entities has been updated. It is now possible to have more than one Reference Substance.	The change is made to support IDMP data capture.
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1.4.5 Manufactured Item Reference Substance

Field/Column/Option Name	Field Type	Description	Business Rules
Reference Substance Name	Drop-down	Cardinality for the entities has been updated. It is now possible to have more than one Reference Substance.	The change is made to support IDMP data capture.

1.4.6 Event->Copy Event

Field/Column/Option Name	Field Type	Description	Business Rules
Products	Selection widget	Selection widget has been updated with new modern version.	This improved search and selection capabilities enhances efficiency.

1.4.7 Associate Change Detail to Event

Field/Column/Option Name	Field Type	Description	Business Rules
Select Change Detail(s)	Selection widget	Selection widget has been updated with new modern version.	This improved search and selection capabilities enhances efficiency.

1.4.8 PDS -> Packaging Detail

Field/Column/Option Name	Field Type	Description	Business Rules
Data Carrier Identifier	Text	Hidden OOTB	The change is made to support IDMP functionality.
Device Quantity Operator	Drop-down	Renamed to Package Item Device Quantity Operator	The change is made to support IDMP functionality.
Device Quantity	Drop-down	Renamed to Package Item Device Quantity	The change is made to support IDMP functionality.
Device Quantity Unit	Drop-down	Renamed to Package Item Device Quantity Unit	The change is made to support IDMP functionality.
Package Item Quantity Operator,	Drop-down	Default value to update from Equal to Select	The change is made to support IDMP functionality.
Package Item - MI Quantity Operator,	Drop-down	Default value to update from Equal to Select. Shows only 'Unit of Measurements' values	The change is made to support IDMP functionality.
Package Item Device Quantity Operator	Drop-down	Default value to update from Equal to Select. Includes only values from the Data Administration list 'Units of Measurement' with Yes for the field 'Include in Quantity Unit'	The change is made to support IDMP functionality.

1.4.9 Registration (Package Set Type)

Field/Column/Option Name	Field Type	Description	Business Rules
ATC Code Flag	Drop-down	Renamed to ATC Request	The change is made to support IDMP data capture.

1.4.10 IDMP Tab

Field/Column/Option Name	Field Type	Description	Business Rules
Country	Column	Deleted	The change is made to support IDMP data capture.

1.4.11 PCIDs Tab

Field/Column/Option Name	Field Type	Description	Business Rules
Country	Drop-down	Deleted	The change is made to support IDMP data capture.

1.4.12 Medicinal Product

Field/Column/Option Name	Field Type	Description	Business Rules
Genetically Modified Organisms	Drop-down	Updated to show True/False values	The change is made to support IDMP Integration.

Registrations	Read only	Now a hyperlink to Registrations Attributes screen	The change is made to support IDMP Integration.
Product	Read only	Now a hyperlink to Product Attributes screen	The change is made to support IDMP Integration.
Package Sets	Read only	Now a hyperlink to Registration-Package Sets Attributes screen	The change is made to support IDMP Integration.
Pharmaceutical Products	Selection widget	Selection widget has been updated with new modern version.	This improved search and selection capabilities enhances efficiency.

1.4.13 Pharmaceutical Products Tab

Field/Column/Option Name	Field Type	Description	Business Rules
Associate/Dissociate Pharmaceutical Products	Selection widget	Selection widget has been updated with new modern version.	This improved search and selection capabilities enhances efficiency.

1.4.14 PMSIDs Tab

Field/Column/Option Name	Field Type	Description	Business Rules
PMSID	Tab	Deleted	The change is made to support IDMP data capture.

1.4.15 MPIDs Tab

Field/Column/Option Name	Field Type	Description	Business Rules
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PMSID	Read only	Changed from drop down	The change is made to support IDMP data capture.
Country	Drop-down	Deleted	The change is made to support IDMP data capture.

1.4.16 Medicinal Product Name

Field/Column/Option Name	Field Type	Description	Business Rules
Trademark or Company Name Part	Text	Renamed to Company Name Part	The change is made to support IDMP data capture.

1.4.17 Medicinal Product Actions

Field/Column/Option Name	Field Type	Description	Business Rules
Sequence	Drop-down	not required field	The change is made to support IDMP functionality.
Regulatory Application Submission Type	Drop-down	not required field	The change is made to support IDMP functionality.
FHIR Protocol Type	Drop-down	Hidden OOTB	The change is made to support IDMP functionality.
Content of Change	Multi-select	renamed to Content Scope	The change is made to support IDMP functionality.

Provenance Reason	Drop-down	renamed to Message Reason	The change is made to support IDMP functionality.
Status	Drop-down	not required field	The change is made to support IDMP functionality.
Medicinal Product	Multi-select	Shows only those Medicinal Products (for the parent Registration) which have value in the Ennov Medicinal Product field	The change is made to support IDMP functionality.

1.5 Data Administration Sections Added: Ennov InSight Autumn 2025

The following Data Administration tables, sections, options, widgets, filters or fields were added for Ennov InSight Autumn 2025.

1.5.1 Secondary Event Type Values

Entity Affected	Field Type	Field Name	Description
Secondary Event Type Values	New Tex, Drop-down, Date	Extra Fields	To gave flexibility for the users to comply with IDMP specification Data Administration > Event Maintenance > Secondary Event Type Values.

1.5.2 Origin of Substance Values

Entity Affected	Field Type	Field Name	Description
Origin of Substance Value	New Associate Term Widget	RMS tab	To comply with the latest IDMP IG 2.3 specification, the RMS tab is now available under Data Administration > Other > Origin of Substance Values.

1.5.3 Species Values

Entity Affected	Field Type	Field Name	Description
Species	Extra Fields	Extra Fields	To Support IDMP with Veterinary Products.

1.5.4 Target Species Values

Entity Affected	Field Type	Field Name	Description
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Target Species Values	New value list	Target Species Values	To comply with the latest IDMP IG 2.4 specification, the new Target Species Values with RMS tab is now available under Data Administration > Product Detail Set Maintenance > Target Species Values.

1.5.5 National Classification ATC Values

Entity Affected	Field Type	Field Name	Description
National Classification ATC Values	New table	National Classification ATC Values	The change is made to support IDMP data capture for Homeopathic and/or Herbal Products the change is included under Data Administration > Registration Maintenance.

1.5.6 MAH/Development Sponsor/Organisation Values

Entity Affected	Field Type	Field Name	Description
MAH/Development Sponsor/Organisation Values -> OMS	API fields	UI Label, Version Type, Version Comment	The change is made to support IDMP data capture for OMS the change is included under Data Administration > Other Maintenance -> MAH/Development

			Sponsor/Organisation Values.
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1.5.7 Substance Values

Entity Affected	Field Type	Field Name	Description
Substance Values -> SMS tab	New columns	SVG Flag, EV Code, UNII Code, Substance Type	The change is made to support IDMP data capture for SMS the change is included under Data Administration > Product Family -> Substance Values.
Substance Values -> SMS tab -> Term Search widget	New columns	EV Code, SVG Flag	The change is made to support IDMP data capture for SMS the change is included under Data Administration > Product Family -> Substance Values.

1.5.8 SPOR Master List

Entity Affected	Field Type	Field Name	Description
Substance	New fields	SVG Flag, EV Code, Source of Information, Description, UNII Code	To comply with the latest IDMP IG 2.4 specification, the RMS tab is now available under Data Administration > SPOR Master List.
National Classification	New SPOR Master List	SPOR List #200000016508	To comply with the latest IDMP IG 2.4 specification, the RMS

			tab is now available under Data Administration > SPOR Master List.
Origin of Substance	New SPOR Master List	SPOR List #200000027811	To comply with the latest IDMP IG 2.4 specification, the RMS tab is now available under Data Administration > SPOR Master List.
Species	New SPOR Master List	SPOR List #200000000019	To comply with the latest IDMP IG 2.4 specification, the RMS tab is now available under Data Administration > SPOR Master List.
Target Species	New SPOR Master List	SPOR List #100000108853	To comply with the latest IDMP IG 2.4 specification, the RMS tab is now available under Data Administration > SPOR Master List.
Record Status	New SPOR Master List	SPOR List #200000005003	To comply with the latest IDMP IG 2.4 specification, the RMS tab is now available under Data Administration > SPOR Master List.
Anatomical Therapeutic Chemical Classification System – Veterinary	New SPOR Master List	SPOR List #100000116677	To comply with the latest IDMP IG 2.4 specification, the RMS tab is now available under Data Administration > SPOR Master List.
Regulatory Regulating Authority Submission Unit Type	New SPOR Master List	SPOR List #100000155552	To comply with the latest IDMP IG 2.4 specification, the RMS tab is now available under Data Administration > SPOR Master List.

EU Territorial Authority	New SPOR Master List	SPOR List #100000160680	To comply with the latest IDMP IG 2.4 specification, the RMS tab is now available under Data Administration > SPOR Master List.
Tissue	New SPOR Master List	SPOR List #100000072054	To comply with the latest IDMP IG 2.4 specification, the RMS tab is now available under Data Administration > SPOR Master List.
Data Classification Values, Ingredient Role Values, Legal Status of Supply Values, Medicinal Product Type Values, Medicine Profile Values, Regulatory Entitlement Type Values, Quantity Operator Values	New field	The field to extract from RMS Application Applicability= term-applicability / applicable-to @name Update value with applicable-to @status="CURRENT.	To comply with the latest IDMP IG 2.4 specification, the RMS tab is now available under Data Administration > SPOR Master List.

1.5.9 RMS Term Search Widget

Entity Affected	Field Type	Field Name	Description
Data Classification Values, Ingredient Role Values, Legal Status of Supply Values, Medicinal Product Type Values, Medicine Profile Values, Regulatory Entitlement Type Values, Quantity Operator Values	New column	Status/App	To comply with the latest IDMP IG 2.4 specification, the RMS tab is now available under Data Administration > Data Classification Values, Ingredient Role Values, Legal Status of Supply Values, Medicinal Product Type Values, Medicine Profile Values, Regulatory Entitlement Type Values, Quantity Operator Values.

Data Administration Sections Updated: Ennov InSight Autumn 2025

The following Data Administration tables, sections, options, widgets, filters or fields were updated for Ennov InSight Autumn 2025.

1.5.10 Units of Measurement Values

Entity Affected	Field Type	Field Name	Description
Include in Quantity Unit	Drop-down	Include in Quantity	The change is made to support IDMP data capture Unit is included under Data Administration > Other Maintenance -> Units of Measurement Values.

1.5.11 Substance Values

Entity Affected	Field Type	Field Name	Description
Substance Values -> SMS tab	columns	Category replaced with Status Active Flag has been hidden	The change is made to support IDMP data capture for SMS the change is included under Data Administration > Product Family -> Substance Values.
Substance Values -> SMS tab -> Term Search widget	columns	Domain replaced with UNII Code Category replaced with Status	The change is made to support IDMP data capture for SMS the change is included under Data Administration > Product Family -> Substance Values.

		Data Classification renamed to Substance Type Code deleted	
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1.5.12 Content Change Values

Entity Affected	Field Type	Field Name	Description
Content of Change Values	Value list	Content of Change Values renamed to Change of Scope Values	To comply with the latest IDMP IG 2.4 specification, the RMS tab is now available under Data Administration > Registration Maintenance ->Content Change Values.

1.5.13 Provenance Reason Values

Entity Affected	Field Type	Field Name	Description
Provenance Reason Values	Value list	Provenance Reason renamed to Message Reason Values	To comply with the latest IDMP IG 2.4 specification, the RMS tab is now available under Data Administration > Other > Origin of Substance Values.

1.5.14 Certificate Master File Values

Entity Affected	Field Type	Field Name	Description
Related Application	selection widget	Selection widget has been updated with new modern version.	This improved search and selection capabilities enhances efficiency.

1.5.15 SPOR Master List

Entity Affected	Field Type	Field Name	Description
Substance	Read only	Data Classification renamed to Substance Type Name GUI Field Size has been changed 1800 char	To comply with the latest IDMP IG 2.4 specification, the RMS tab is now available under Data Administration > SPOR Master List -> Substance.

1.6 Queries Sections Updated: Ennov InSight Autumn 2025

The following tables describe fields, columns and options that were modified in this release.

1.6.1 Applications Submitted and/or Approved and/or Terminated within a Date Range

Entity Affected	Field Type	Field Name	Description
Active Ingredient	selection widget	Selection widget has been updated with new modern version.	This improved search and selection capabilities enhances efficiency.

1.6.2 List of Manufacturers From Data Administration

Entity Affected	Field Type	Field Name	Description
Detail Name - >Substance	selection widget	Selection widget has been updated with new modern version.	This improved search and selection capabilities enhances efficiency.

1.6.3 Entity Audit

Entity Affected	Field Type	Field Name	Description
Entity Audit	Drop-down	Added: Product Component Comparator PDS Shelf Life Detail	This improved search and selection capabilities enhances efficiency.

1.7 Wizard Sections Updated: Ennov InSight Autumn 2025

The following tables describe fields, columns and options that were modified in this release.

1.7.1 XEVMPD Submission Wizard

Functional Area	Wizard Name	Description	Business Rules
XEVMPD	XEVMPD Submission	When running the XEVMPD Submission Wizard XML includes multi line brakes for Full Product Presentation Name	If multi lines added in UI, they will be shown with special characters in XEVMPD XML.