



Ennov InSight 7.2 Release Notes (Cumulative)

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Ennov InSight 7.2 Release Notes

Ennov InSight 7.2 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 7.2.

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

IDMP Entity and Tabs Changes

Changes have been made to the following entities and tabs for enhanced tracking of the medicinal product data. See: *Entity Fields and Columns Added: Ennov InSight 7.2, Entity Fields and Columns Updated: Ennov InSight 7.2.*

— Entities:

- Product Family (Product Family Attributes, CT Shared Data)
- Application (Application Attributes)
- PDS (Active Ingredient, Substance, Flu Strain, Shelf Life/Storage Condition(s), Package)
- Manufactured Item (Manufactured Item Attributes)
- Registrations (Package Set Registration, Registration Package Set, Registration Package Set Country)
- Registration Package Set Attributes (PCIDs, Package Descriptions, Data Carrier Identifiers)
- Medicinal Product (MPID, Medicinal Product Name, PMSIDs)
- IDMP
- PhPID
- Medicinal Product Action
- Active Ingredients and Reference Active Ingredients for Component, Pharmaceutical Product, Manufactured Item, PDS Details (Active Ingredients, Substance, Flu Strain)
- Substances and Reference Substances (Pharmaceutical Product, Manufactured Item)
- Queries, Wizards, Data Administration updates

— Pending Changes for Application, Registration (Registration Package Set, Registration Package Set Country) and Medicinal Product at the Event level. **Pending Changes** allows you to track pending IDMP changes that are specific to Registration attributes. **Pending Changes** are used for related IDMP data generation and defined in the scope of Event approval. See *Registrations>Events> Data Carrier Identifiers Attributes*.

— Tabs:

- My Home

Other Entity Updates

Changes have been made to the **CT Shared Data** to enhance the EU CTR application functionality.

Functionality and Technology Not Supported

Starting with Ennov InSight 7.2, the following functionality will not be supported:

- D2/LSRD
- Data Exchange

In preparation to capture Substance Management Services (SMS) data for IDMP, the framework is implemented. The SPOR Master List for Substance is empty as EMA has not released the Substances (SMS) controlled vocabulary. You cannot map RIM substance values on the tab of Substance Values.

API Updates

Ennov InSight 7.2 includes multiple API updates including the update for IDMP.

Changes between Ennov InSight 7.2 and Ennov InSight 7.1 API are documented in the *Ennov InSight Administration* guide. See: *Ennov InSight Administration > Technical Administration > Ennov InSight API Documentation*.

Data Administration Lists - APIs CRUD Operations

Ennov InSight now includes the API Create, Read, Update, Deactivate (CRUD) operations for Data Administration and new end points. See: *Ennov InSight Administration > Technical Administration > Ennov InSight API Documentation*.

Additional API Data Administration Updates

The framework for implementing Data Administration lists that are associated with RMS is completed in Ennov InSight 7.2.

The RMS Associated Data Administration Lists will be fully implemented in Ennov InSight 7.3 now that the framework is in place.

Power BI

The SQL Direct Access model now includes support for Publishing and Audit data.

New in Ennov InSight 7.2: Common Functionality

This table shows new features and enhancements of Ennov InSight 7.2 functionality.

Identification of Medicinal Products (IDMP)

To capture additional data elements for European Medicine Agency (EMA) implementation of IDMP.

Affected Area	Update	Benefit
Entities/Entity tabs	<p>Changes for IDMP now include:</p> <ul style="list-style-type: none"> — Entity updates: <ul style="list-style-type: none"> • Product Family updates. See: <i>Entity Fields and Columns Updated: Ennov InSight 7.2, Entity Fields and Columns Removed: Ennov InSight 7.2 and Registrations > Product Family Attributes .</i> • CT Shared Data updates. See: <i>Registrations > Product Family > CT Shared Data Attributes and Entity Fields and Columns Added: Ennov InSight 7.2</i> • Application updates. See: <i>Entity Fields and Columns Added: Ennov InSight 7.2, Entity Fields and Columns Removed: Ennov InSight 7.2</i> • Medicinal Product Name. See: <i>Entity Fields and Columns Added: Ennov InSight 7.2, Entity Fields and Columns Updated: Ennov InSight 7.2, Registrations > Medicinal Product Name.</i> • Manufactured Item fields and columns updates. See: <i>Entity Fields and Columns Added: Ennov InSight 7.2 and Entity Fields and Columns Updated: Ennov InSight 7.2 and Registrations > Manufactured Item.</i> • Pharmaceutical Product Updates (PhPIDs). <i>Entity Fields and Columns Added: Ennov InSight 7.2 and and Registrations > PhPID Attributes</i> • Registration-Package Sets fields updates. See: <i>Entity Fields and Columns Added: Ennov InSight 7.2, Entity Fields and Columns Updated: Ennov InSight 7.2 and Registrations > Registration Package Set Attributes.</i> • Registration-Package Set-Country fields updates. See: <i>Entity Fields and Columns Updated: Ennov InSight 7.2 and Registrations > Registration -Package Set - Country Attributes.</i> 	
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Affected Area	Update	Benefit
Data Administration	<p>To conform to latest IDMP standards, the following updates have been made to Data Administration:</p> <ul style="list-style-type: none"> – The <i>Packaging Category Values</i> table in Data Administration > Product Detail Set Maintenance is updated with new fields. See: <i>Data Administration Tables Updated: Ennov InSight 7.2.</i> – New SMS tab for SPOR SMS Substance mapping in Data Administration > Product Family Maintenance > Substance Values – New <i>Term Search</i> selection widget to associate SPOR SMS Substance to Substance Values. – New RMS tab for SPOR Regulatory Entitlement Status mapping in Data Administration > Registration Maintenance > Registration Status Values. – New RMS tab for Units of Measurement RMS list mapping in Data Administration > Product Detail Set Maintenance > Time Unit Values. – New Certificate Master File Values table in Data Administration > Other . – New File Identifier Type Values table in Data Administration > Other . – New Origin of Substance Values table in Data Administration > Product Detail Set Maintenance . – Product Detail Set Maintenance > Manufacturer Values > Global Product Details updates. See: <i>Data Administration Tables Updated: Ennov InSight 7.2</i> – Product Detail Set Maintenance > Manufacturer Values > Manufacturing Authorization Reference Number updates. See: <i>Data Administration Tables Updated: Ennov InSight 7.2</i> – OMS Term widget fields updates. See: <i>Data Administration Tables Updated: Ennov InSight 7.2.</i> – The Data Administration values are updated to include the RMS Term ID, RMS Modified On, and RMS Status columns. The Data Administration columns will display values only if the 	
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Affected Area	Update	Benefit
Security Administration	<p>To conform to the latest IDMP standards, the following updates have been made to Security Administration:</p> <ul style="list-style-type: none"> — Fields renamed: See: <i>Security Administration Tables Updated</i> — For a user to have access to Medicinal Product and Medicinal Product Actions, an administrator can now grant user access for RPT and PDM users to: Entity Security: <ul style="list-style-type: none"> • Medicinal Product • Medicinal Product Actions • Home Page Access: <ul style="list-style-type: none"> ■ Medicinal Product ■ Medicinal Product Actions 	Security Administration functionality is updated to align with the updated data model for IDMP.
Querying	<p>To conform to IDMP standards, Queries now include updated list of IDMP Presentation Strength and IDMP Concentration Strength fields for <i>Registration Planning and Tracking</i>. See: <i>Query Fields and Columns Added: Ennov InSight 7.2, Query Fields and Columns Updated: Ennov InSight 7.2.</i></p>	

New in Ennov InSight 7.2: Registrations

New features and enhancements for Registration functionality is listed below.

Affected Area	Update	Benefit
Registrations (Package Set type)	The Registration Package Set fields are updated for IDMP. See <i>Entity Fields and Columns Updated</i> .	To be updated.
Registration-Package Sets	The <i>Registration-Package Sets Attributes</i> page is updated for IDMP. See <i>Entity Fields and Columns Added, Entity Fields and Columns Removed</i> .	To be updated.
Registrations (Package Set Country)	<p>The Registration Package Set Country fields are updated for IDMP. See <i>Entity Fields and Columns Updated</i>.</p> <p>The Registrations Package Set-Country Attributes page now includes a new Data Carrier Identifiers tab.</p>	To be updated.

Affected Area	Update	Benefit
Product Detail Sets (PDS)	The following attributes and updates are included to conform to the IDMP standards: <ul style="list-style-type: none"> – PDS (Active Ingredient Detail Attributes) – PDS (Substance Detail Attributes) – PDS (Flu Strain Detail Attributes) – PDS (Shelf Life/Storage Condition(s) Attributes) – PDS (Package Detail Attributes) 	To be updated.
Events	The <i>Event Attributes</i> page now includes a new Pending Changes tab.	In the Pending Changes tab you can enter values for pending changes for Application, Registration, Registration Package Set, Registration Package Set Country and Medicinal Product.
Medicinal Product	<ul style="list-style-type: none"> – The <i>Medicinal Product Attributes</i> page is updated for IDMP . See: <i>Entity Fields and Columns Added</i> and <i>Entity Fields and Columns Removed</i>. – The Medicinal Product entity and all the associated child entities are moved from the Registration to the Application level: <ul style="list-style-type: none"> • Medicinal Product Names • Pharmaceutical Products • Product Cross-References • MPIDs • Tasks • References • Notifications 	To be updated.
Medicinal Product Action	<ul style="list-style-type: none"> – The Medicinal Product Action and Attached Document entities are removed from the Registration and added at the Application level. – The Medicinal Product Action Attributes page is updated for IDMP . See <i>Entity Fields and Columns Updated</i>. 	To be updated.

Affected Area	Update	Benefit
IDMP	The IDMP tab is removed from Registration and added at the Application level with the updated fields.	To be updated.
Active Ingredients and Reference Active Ingredients	<p>The following updates are included to conform to the IDMP standards:</p> <ul style="list-style-type: none"> — Component Active Ingredients and Reference Active Ingredients — Pharmaceutical Product Active Ingredients and Reference Active Ingredients — Manufactured Item Active Ingredients and Reference Active Ingredients — PDS: <ul style="list-style-type: none"> • PDS (Active Ingredient Detail Attributes) • PDS (Substance Detail Attributes) • PDS (Substance Detail Attributes) • PDS (Package Detail Attributes) — You can now add multiple Reference Active Ingredients to Manufactured Item Active Ingredients and Pharmaceutical Product. — You can now associate or disassociate the Active Ingredients on the Product Family Attributes page if a Product Family has associated Products with no Components, PDSs, or PDS Templates related to these Products. 	To be updated.
Substances and Reference Substances	<p>The following updates are included to conform to the IDMP standards:</p> <ul style="list-style-type: none"> — Pharmaceutical Product Substances and Reference Substances — Manufactured Item Substances and Reference Substances 	To be updated.
Create Application Wizard	When creating an Event from the Create Application Wizard for the Application with the CP Procedure Types, the Countries field displays the European Union value only in the Selected box. Other countries are displayed in the Available box.	To be updated.
Query	<p>The <i>Registration Planning and Tracking</i> query list now includes two new query:</p> <ul style="list-style-type: none"> — List of RMS Fields — List of OMS Fields 	To be updated.

Resolved Issues: Ennov InSight 7.2

The following issues 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 hotfix, that sub-minor build number is included.

Common

Issue	Build Number	Description
DE28492	N/A	The Data Administration entity could not be modified if the value in the entity field contained the carriage return. This issue is resolved. The entity can be modified even if the value contains the carriage return.
DE28390; [INC0091145]	N/A	In the Concerned Parties field as in any multiline field, on the Modify pages of any entity, the <code>
</code> tag was added when the value had many lines and the changes were saved for the first time. This prevented from making changes for the next time as the tag was recognized as unacceptable value by the application. This issue is resolved. Now, the <code>
</code> tag is not added and the changes can be made and saved.
DE28271	N/A	On the Ennov InSight migrated build, the <i>Languages</i> values were not displayed in Data Administration > Country Values > EU . This issue is resolved. Now, the <i>Languages</i> tab includes the corresponding values.
DE28251; [INC0091561, TASK0042646]	N/A	Performance issue was experienced when using the Search option on home page for assemblies, sequences and events. This issue is resolved. Search performance issue is now addressed in this release.
DE28120; [INC0094972, INC0092038]	N/A	The Ennov InSight 7.2.0 migration did not work correctly for product family broad indications. The indication category type ids were not set to Indication . This issue is resolved. Now, the product family broad indications are migrated correctly.
DE27919	N/A	Reference Active Ingredient under Pharmaceutical Product Active Ingredient was not created when using the API request. This issue is resolved. Reference Active Ingredient is created using API.

Issue	Build Number	Description
DE27916; [INC0089240]	N/A	The changes made for AAD permissions were not applied in Ennov InSight . This issue is resolved. Now, the changes for AAD permissions are applied in Ennov InSight .
DE27841; [INC0090420]	N/A	In Ennov InSight 7.2, the Event with the associated CT Shared Data could not be closed using API request. This issue is resolved. Now, using the API request, the Events with either CTA or IND Application types can be closed if they have CT Shared Data.
DE27750; [INC0086495, INC0084243]	N/A	The migration did not work correctly for the OMS organization values. The organization data replicated from SPOR duplicating the Location Id . This issue is resolved. Now, the data does not have duplicates.
DE27480; [INC0082793, INC0087569,CS0532 792]	N/A	API query operation failed for the following assembly tree elements. <ul style="list-style-type: none"> – Leaf POST /insight/api/v2/leaf/query – Folder POST /insight/api/v2/folder/query – Document POST /insight/api/v2/document/query This issue is resolved. Now, the API query returns the status "SUCCESS" with the requested data.

Publishing

Issue	Build Number	Description
DE28488; [INC0108112]	N/A	When several users simultaneously clicked the Next button on the <i>Change Submission Status</i> confirmation page of the Change Submittal Status for different sequences in different applications, the action failed. This issue is resolved. Now, the probability of such an issue is reduced.
DE28266; [INC0104113]	N/A	After the export/import of the assembly file, the DMS Synchronisation was binding the wrong document for a Veeva document when there were two documents in the same folder with the same name. This issue is resolved. Now, the DMS Synchronisation is binding the correct document.
DE28208; [INC0106878, TASK0042719]	N/A	Incremental publishing removed the <i>checksum</i> values for the files that were not published. This issue is resolved. Now, these values are displayed.

Issue	Build Number	Description
DE28204; [INC0095423, INC0108172]	N/A	The Study Report wizard did not work properly when updating the sub-folders structure for the selected indication. This issue is resolved. Now, the selected indications are updated successfully.
DE28146; [INCO 101586]	N/A	When an assembly was imported from an XML file, the TOC did not include the Range Start attribute specified before. This issue is resolved. Now, the Range Start attribute is included in the TOC of the imported assembly.
DE27966	N/A	The published output files were not exported to Documentum repository if they have Chinese characters in the file name. This issue is resolved. Now, the appropriate files are successfully exported.
DE27958	N/A	After publishing a China assembly, Chinese characters were present in the STF file name. For example, <code>stf-4.2.1.1 主要□效学.xml</code> . This issue is resolved. Now, China characters are automatically renamed as per eCTD normalization rules before exporting output.
DE27915; [INC0092041]	N/A	Editing a document assigned from DCTM and selecting the previous document version in Bind to Version failed to indicate the presence of a new version in document attributes and assembly tree. This issue is resolved. Now, the new version is indicated in both document attributes and in the assembly tree.
DE27835; [INC0087631]	N/A	If the element was locked, the color of the locked element did not change when selected. This issue is resolved. The assembly elements such as folder, leaf, and document now appear in the TOC in a different color when selected. This issue is fixed in Submitted , Working , Sequence , and Publishing views.
DE27791; [INC0089235]	N/A	Attempting to assign a document with double digits version number from DCTM resulted in a HTTP Status 404 error. This issue is resolved. Now, these documents can be assigned to an assembly without any error.
DE27739	N/A	When the <i>Publishing Setting Library</i> included overlay profile other than Default , the import of the assembly from XML failed. This issue is resolved. Now, the import is successful.

Issue	Build Number	Description
DE27515; [INC0082577]		<p>Performance issue was experienced when performing the following:</p> <ul style="list-style-type: none"> – Withdraw workflow to retrieve registrations after application entered. – Create registration from the Registration tab in the Application. – Loading of the Full Product Presentation. – The query performance when there are many users and applications in the database. <p>Performance has now been improved for the scenarios above.</p>
DE27365	N/A	<p>When the Export to Excel option was applied to Job Details, the file was saved in unknown format instead of .XLSX and with the XLSX name. This issue is resolved. Now, the following file is saved: <code>message.XLSX</code>.</p>
DE26687; [CS0205991]	N/A	<p>The PDF Exists value did not change to Yes on the Document Attributes page for the PDF documents assigned from Veeva after the Rendition Identifier was changed to Viewable Rendition. This issue is resolved. Now, the PDF Exists value is displayed as Yes.</p>
DE26679; [CS0191635]	N/A	<p>When the Apply Binding to all Children option was used to change the rendition identifier, no extraction job was launched for the document and the status PDF exists was not updated to Yes. This issue is resolved. Now, the extraction job is launched for the document and the status PDF exists is updated to Yes.</p>
26968	N/A	<p>The assembly files could not be published to Documentum if their size was 800 mb and more. The distribute job request failed. This issue is resolved. Now, these files are published to Documentum successfully.</p>
26825	6.2.0.8	<p>EAEU: If the Drug Registration Document Code field had a value in a submission, the Drug Registration Document Name was not included in the <code>index-r-022.xml</code> file after publishing. The Drug Registration Document Name was also not saved in the leaf after an eCTD import. The issue is resolved. Now, both Drug Registration Document Name and Drug Registration Document Code are included in the <code>index-r-022.xml</code> file after publishing and in the leaf after an eCTD import.</p>

Issue	Build Number	Description
26768; [INC0058320]	6.2.0.8	<p>The /all and /query endpoints did not work via API for the package set registration, product registration, full product presentation, package set - country entities and resulted in an error. This issue is resolved. The following endpoints work correctly via API:</p> <ul style="list-style-type: none"> – /insight/api/v2/license/package-set-registration/all – /insight/api/v2/license/product-registration/all – /insight/api/v2/license/full-product-presentation/all – /insight/api/v2/license/package-set/all – /insight/api/v2/license/package-set/country/all

Registrations

Issue	Build Number	Description
DE28295; [INC0102780]	N/A	It was not possible to update product family attributes if many values were present in multiple selection list. This issue is resolved. Now, product family attributes are successfully modified.
DE28182	N/A	Trying to delete PDS with Package Sets details with the status Pending Add used in Medicinal Product resulted in an error. This issue is resolved. The Delete button is now not available for selection and the "Cannot delete due to data dependencies" message is displayed.
DE28180	N/A	<p>The Product used in PDS was displayed in the Selected box while associating to Event instead of being displayed in the Assigned box. This issue is resolved.</p> <p>If the Product is already assigned to an Event and used in PDS, it is displayed in the Assigned box while associating/disassociating a new Product to Event.</p>
DE28162	N/A	The Entity History Query icon was missing on the <i>Medicinal Product Action Attributes</i> page. This issue is resolved. Now, the Entity History Query icon is present on the <i>Medicinal Product Action Attributes</i> page.

Issue	Build Number	Description
DE28148	N/A	When a Medicinal Product Name entity was updated and then deleted, the actions performed were not recorded in the <i>Entity Audit Trail</i> search grid. The message "No data found" was displayed. This issue is resolved. Now, rows with I, U and D are displayed to indicate the actions performed for the Medicinal Product Name in the <i>Entity Audit Trail</i> search result grid.
DE28124	N/A	Rows with I and D actions were not displayed for the Medicinal Product Action in the <i>Entity Audit Trail</i> search result grid. Only the row with U action was displayed. This issue is resolved. Now, rows with I and D actions are displayed for the Medicinal Product Action in the <i>Entity Audit Trail</i> search result grid.
DE28123	N/A	After performing the search for a Medicinal Product in Querying > Administration > Entity Audit Trail, the columns were displayed without names and id values. This issue is resolved. Now, the query page results are displayed with the fields and values from the <i>Medicinal Product Attributes</i> page.
27259; [DE27259]	N/A	In the <i>Update Status</i> wizard, it was not possible to associate a Package Set with Pending Add status. The Package Set Status column was missing in the Select Package Sets grid. These issues are resolved. Now, it is possible to associate a Package Set with Pending Add status and the Package Set Status column is displayed in the grid.
26959; [DE26959]	N/A	Under Projects > Wizard > Global Project Plan > Modify Active Ingredient, it was possible to select and modify the strength fields for Active Ingredient. After wizard completion, no changes applied in PDS. This issue is resolved. Now, it is not possible to select and modify the strength fields for Active Ingredient.
DE26862; [INC0063295]	N/A	When using the <i>XEVMP Submission</i> wizard for Full Product Presentation and with the Update operation selected, the MAH/Organisation field value was not updated on the <i>Full Product Presentation Attributes</i> page. This issue is resolved. Now, the MAH/Organisation field value is successfully updated.

Issue	Build Number	Description
DE26878; [INC0073459]		In a Product Detail Set Template , when adding a package with the package type used for another package set, the following error appeared: "Packaging must be unique within the Component or Packaging". This issue is resolved. Now, the package with the same package type is added successfully in the Product Detail Set Template .

Ennov InSight 7.2 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.2 Release Notes (Cumulative)

Entity Fields

Entity Fields and Columns Added: Ennov InSight 7.2

The following tables describe fields and columns that were added in this release. These include the fields and column that were added to support IDMP data capture.

Tabs

Table 1: My Home

Field/Column/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> — Application Code — Application Name — Registration — Medicinal Product Name — Product — Authorised Pharmaceutical Form 	Hyperlink, read-only text (populated automatically)	The Medicinal Products tab is added on the <i>My Home</i> page and includes all the respective columns.	

Field/Column/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Application Code – Application Name – Sequence – Medicinal Product – Product – Medicinal Product Action – Regulatory Submission Type 	Hyperlink, read-only text (populated automatically)	The <i>Medicinal Product Actions</i> tab is added on the <i>My Home</i> page and includes all the respective columns.	

Entities

Table 2: Product Family

Field/Column/Option Name	Field Type	Description	Business Rules
EU CT Number	Text field	The <i>CT Shared Data Attributes</i> page now includes this field.	

Table 3: Application

Field/Column/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – License Root Number – PMSID – Registration Country – Related MAH(s) – Related Registration(s) – Related Sequence(Read-only text (populated automatically)	The IDMP read-only tab is removed from the Registration and added at the Application level. The <i>Application Attributes</i> page now includes this tab with the new respective columns.	

Field/Column/Option Name	Field Type	Description	Business Rules
Medicinal Product	N/A	The Medicinal Product entity and all the associated child entities are moved from the Registration to the Application level. The <i>Application Attributes</i> page now includes the Medicinal Product tab with: <ul style="list-style-type: none"> – Medicinal Product Names – Pharmaceutical Products – Product Cross-References – MPIDs – Tasks – References – Notifications 	
Medicinal Product Action	N/A	The Medicinal Product Action and Attached Document entities are removed from the Registration and added at the Application level.	
Medicinal Product Action	N/A	The <i>Medicinal Product Action Attributes</i> page now includes Tasks, References and Notifications.	

Table 4: Events

Field/Column/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Entity Name – Sub Entity Name – Attribute Name – Change Value – Approval Status – Approval Status Date 	Hyperlink, read-only text (populated automatically)	The <i>Event Attributes</i> page now includes the Pending Changes tab with respective columns.	For IDMP data generation: in the Pending Changes tab you can enter values for pending changes for Application, Medicinal Product and Registration, Registration Package Set, Registration Package Set Country.

Table 5: Component

Field/Option Name	Field Type	Description	Business Rules
Concentration Measure Type	Drop-down list	The Component > Active Ingredient Attributes and Reference Active Ingredient Attributes pages now include this field under IDMP Concentration Strength .	All the active values from Data Administration > Other > Concentration Measure Type Values are displayed for this field.

Table 6: Pharmaceutical Product

Field/Option Name	Field Type	Description	Business Rules
Concentration Measure Type	Drop-down list	This field is now available under IDMP Concentration Strength section for the following pages: <ul style="list-style-type: none"> – Pharmaceutical Product > Active Ingredient Attributes and Reference Active Ingredient Attributes. – Pharmaceutical Product > Substance Attributes and Reference Substance Attributes. 	All the active values from Data Administration > Other > Concentration Measure Type Values are displayed for this field.
– Version – Version Date	Text field, date	The PhPIDs tab and <i>PhPID Attributes</i> page now includes the respective fields and columns.	

Table 7: Manufactured Item

Field/Column/Option Name	Field Type	Description	Business Rules
Unit of Presentation	Read-only text (populated automatically)	The Manufactured Items entity tab (<i>Component</i>) includes this column.	

Field/Column/Option Name	Field Type	Description	Business Rules
Concentration Measure Type	Drop-down list	<p>The Manufactured Item > Active Ingredient Attributes and Reference Active Ingredient Attributes pages now include this field under IDMP Concentration Strength. This field is now available under IDMP Concentration Strength section for the following pages:</p> <ul style="list-style-type: none"> – Manufactured Item > Active Ingredient Attributes and Reference Active Ingredient Attributes – Manufactured Item > Substance Attributes and Reference Substance Attributes. 	All the active values from Data Administration > Other > Concentration Measure Type Values are displayed for this field.

Table 8: Medicinal Product

Field/Column/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Full Indication Text – Full Indication Language – Country – Registrations – License Root Number 	Date, multi-select, drop-down list, text field	The <i>Medicinal Product Attributes</i> page now includes these fields.	
<ul style="list-style-type: none"> – Application Code – Application Name – Medicinal Product Name – PMSID – Country – Date of First Approval – Procedure Start Date – Procedure End Date 	Hyperlink, text field, drop-down list, read-only text (populated automatically), date	The <i>Medicinal Product Attributes</i> page now includes the PMSID tab with the respective fields and columns.	

Table 9: Medicinal Product Name

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Date of First Approval – Full Indication Text 	Date	The <i>Medicinal Product Name Attributes</i> page now includes the respective fields.	

Table 10: Product Detail Sets

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Origin of Substance – Composition Grouping Description 	Drop-down list, text field	The following pages now include the respective fields: <ul style="list-style-type: none"> – <i>Active Ingredient Detail Attributes</i> – <i>Substance Detail Attributes</i> 	
Device Quantity Unit	Drop-down list	The <i>Package Detail Attributes page</i> now includes the respective field.	All the active values from Data Administration > Other > Unit of Presentation Values are displayed for this field.
Concentration Measure Type	Drop-down list	This field is now available under IDMP Concentration Strength section for the following pages: <ul style="list-style-type: none"> – Product Detail Set > Substance Detail Attributes – Product Detail Set Template > Substance Detail Attributes – Product Detail Set > Flu Strain Attributes – Product Detail Set Template > Flu Strain Attributes 	All the active values from Data Administration > Other > Concentration Measure Type Values are displayed for this field.

Table 11: Registrations

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Application Code – Application Name – License Code – Product Detail Set Name – Package Set Name – Country – PCID – Version – Version Date 	Hyperlink, drop-down list, text field, date	The <i>Registration- Package Sets Attributes</i> page now includes the PCID tab with the respective fields and columns.	
<ul style="list-style-type: none"> – Application Code – Application Name – License Code – Product Detail Set Name – Package Set Name – Country – Currently marketed in this country? – Data Carrier Type – Data Carrier ID – Data Carrier Description – Data Carrier Language – Status – Status Date 	Hyperlink, drop-down list, text field, date	The Registrations <i>Package Set-Country Attributes</i> page now includes a new Data Carrier Identifiers tab with the respective fields and columns.	N/A
MAH/Organisation	Drop-down list	The <i>Registration- Package Sets Attributes</i> page now includes the respective field.	

Table 12: Reference Active Ingredient

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Use for xEVMPD – Create Another Reference Active Ingredient 	Drop-down list, button	<p>The <i>Create Reference Active Ingredient</i> page now includes the respective fields.</p> <p>The Use for xEVMPD field is available for Reference Active Ingredient Attributes for Pharmaceutical Product only and is added to the XEVMPD Submission Wizard logic to take into consideration only that Pharmaceutical Product Reference Active Ingredient which has a field value as a Yes.</p>	

Entity Fields and Columns Updated: Ennov InSight 7.2

The following tables describe fields that were modified in this release.

Product Family

Field/Option Name	Field Type	Description	Business Rules
Product Family Indication	Multi-select, read-only text (populated automatically)	This field is renamed to Product Family Indication(s) on the <i>Product Family Attributes</i> page. For Veterinary Product Family Type, this field is still Product Family Indications/Intended Use .	
Product Family Comorbidity	Multi-select, read-only text (populated automatically)	This field is renamed to Product Family Comorbidity(s) on the <i>Product Family Attributes</i> page.	
Active Ingredients	Selection widget	<p>The selection widget for this field is modified to display XEVMPD Code and SMS Term ID columns on the <i>Product Family Attributes</i> page.</p> <p>You can now associate or disassociate the Active Ingredients on the <i>Product Family Attributes</i> page if a Product Family has associated Products with no Components, PDSs, or PDS Templates related to these Products.</p>	

Registrations

Field/Option Name	Field Type	Description	Business Rules
Status	Read-only text	This field is renamed to PDS Package Set Status on the <i>Registration-Package Sets Attributes</i> page.	
Status Date	Read-only text	This field is renamed to PDS Package Status Date on the <i>Registration-Package Sets Attributes</i> page.	
Currently Marketed in this country?	Drop-down list	This check box for this option is now changed to a drop-down list and includes the values Registration Maintenance > Marketing Status Values in <i>Data Administration</i> .	
Package Description	Text field	This field is renamed to Package Description on the <i>Package Set- Package Description Attributes</i> page.	

Component

Field/Option Name	Field Type	Description	Business Rules
IDMP Concentration Measure Type	Drop-down list	This field is moved under IDMP Presentation Strength section on the Component > Active Ingredient Attributes and Reference Active Ingredient Attributes pages and renamed to Concentration Measure Type . When <code>Equal</code> is selected for this field, <code>Equal</code> is no longer shown in XEVMPD Strength , IDMP Presentation Strength , IDMP Concentration Strength columns on the <i>Active Ingredients</i> and <i>Reference Active Ingredients</i> tabs.	

Pharmaceutical Product

Field/Option Name	Field Type	Description	Business Rules
IDMP Concentration Measure Type	Drop-down list	<p>This field is renamed to Concentration Measure Type and moved under IDMP Presentation Strength section for the following pages:</p> <ul style="list-style-type: none"> Pharmaceutical Product > Active Ingredient Attributes and Reference Active Ingredient Attributes Pharmaceutical Product > Substance Attributes and Reference Substance Attributes. <p>When <code>Equal</code> is selected for this field, <code>Equal</code> is no longer shown in XEVMPD Strength, IDMP Presentation Strength, IDMP Concentration Strength columns on the <i>Active Ingredients</i> and <i>Reference Active Ingredients</i> tabs, and also on <i>Substances</i> and <i>Reference Substances</i> tabs.</p>	

Product Detail Sets

Field/Option Name	Field Type	Description	Business Rules
Packaging MI Quantity	Text field	This field is updated to include both integer and non-integer values on the <i>Package Detail Attributes</i> page.	
IDMP Concentration Measure Type	Drop-down list	<p>This field is renamed to Concentration Measure Type and moved under IDMP Presentation Strength section for the following pages:</p> <ul style="list-style-type: none"> Product Detail Set > Substance Detail Attributes Product Detail Set Template > Substance Detail Attributes Product Detail Set > Flu Strain Attributes Product Detail Set Template > Flu Strain Attributes 	All the active values from Data Administration > Other > Concentration Measure Type Values are displayed for this field.

Manufactured Item

Field/Option Name	Field Type	Description	Business Rules
Manufactured Item Quantity	Text field	This field is updated from required to optional on the <i>Manufactured Item Attributes</i> page and may include both integer and non-integer values.	

Field/Option Name	Field Type	Description	Business Rules
Manufactured Item Quantity Unit	Drop-down list	This field is updated from required to optional on the <i>Manufactured Item Attributes</i> page.	
IDMP Concentration Measure Type	Drop-down list	This field is moved under IDMP Presentation Strength section on the Manufactured Item > Active Ingredient Attributes and Reference Active Ingredient Attributes pages and renamed to Concentration Measure Type. When <code>Equal</code> is selected for this field, <code>Equal</code> is no longer shown in XEVMPD Strength, IDMP Presentation Strength, IDMP Concentration Strength columns on the <i>Active Ingredients</i> and <i>Reference Active Ingredients</i> tabs, and also on <i>Substances</i> and <i>Reference Substances</i> tabs.	

Medicinal Product

Field/Option Name	Field Type	Description	Business Rules
Full Indication Text	Text field	This field is now available for all the EU procedure types and not restricted to just to Centralised Procedure (CP) on the <i>Medicinal Product Attributes</i> page.	
<ul style="list-style-type: none"> — Application Code — Application Name — Medicinal Product Name — MPID — Country — Version — Version Date 	Hyperlink, drop-down list, text field, date.	The <i>MPIDs</i> tab is editable now and includes the respective fields.	

Medicinal Product Name

Field/Option Name	Field Type	Description	Business Rules
Country	Multi-select, read-only text (populated automatically)	The <i>Medicinal Product Name Attributes</i> page is updated to include <code>European Union</code> for the Country field for applications with Centralized Procedure (CP). A country can be created or modified for Medicinal Product Name for applications with Centralized Procedure (CP) only.	

Medicinal Product Action

Field/Option Name	Field Type	Description	Business Rules
Sequence	Drop-down list	This field is updated to display a concatenation of the Sequence Name and Sequence Code values on the <i>Medicinal Product Actions</i> page.	

Wizards

Table 13: Create Application

Field/Option Name	Field Type	Description	Business Rules
Countries	N/A	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.	N/A

Table 14: Global Project Plan

Field/Option Name	Field Type	Description	Business Rules
EU Clinical Trial Regulation	Read-only text (populated automatically)	The Application Type field is updated with the EU Clinical Trial Regulation option in the Available box on the Global Project Plan > Select Filter Criteria page.	N/A

Entity Fields and Columns Removed: Ennov InSight 7.2

The following table describes fields and columns that are removed with Ennov InSight 7.2.

Product Family

Field/Column/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Substance Translations – Substance Aliases 	Selection widget	These columns are removed from the selection widget for the Active Ingredients field on the <i>Product Family Attributes</i> page.	

Registration

Field/Column/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Medicinal Product <ul style="list-style-type: none"> • Medicinal Product Names • Pharmaceutical Products • Product Cross-References • MPIDs • Tasks • References • Notifications – Medicinal Product Action <ul style="list-style-type: none"> • Attached Document – IDMP 	N/A	These entities are removed from the <i>Registration Attributes</i> page.	
<ul style="list-style-type: none"> – Application Code – Application Name – License Code – Product Name – Version – Version Date 	Read-only text (populated automatically)	These columns are removed from the <i>IDMP</i> read-only tab.	
PCID	Read-only	This field is removed from the <i>Registration- Package Sets Attributes</i> page.	
<ul style="list-style-type: none"> – Data Carrier Type – Data Carrier Identifier – Data Carrier Language 	Read-only	The respective fields are removed from the Registrations <i>Package Set-Country Attributes</i> and <i>Modify Package Set Country Association</i> pages.	

Medicinal Product

Field/Column/Option Name	Field Type	Description	Business Rules
PMS ID	Read-only text (populated automatically)	This field is removed from the <i>Medicinal Product Attributes</i> page.	

Database Columns Changed: Ennov InSight 7.2

The following Database Columns were added, modified, or removed in this release.

Field Name	Field Size	Database Column Name	Database Column Size	Db Table Name
N/A	N/A	N/A	N/A	DEVICE_NOMENCLATURE_TYPE is renamed to EU_DEVICE_NOMENCLATURE_TYPE.
N/A	N/A	N/A	N/A	GMDN_TYPE is renamed to FDA_DEVICE_GMDN_TYPE.
N/A	N/A	N/A	N/A	MARKETING_STATUS_REASON_TYPE is renamed to RISK_OF_SUPPLY_SHORTAGE_REASON_TYPE.
N/A	N/A	N/A	N/A	LIC_ACTION_ATTACHMENT is renamed to ACTION_ATTACHMENT.
N/A	N/A	N/A	N/A	LIC_ACTION_MP is renamed to MP_ACTION.
N/A	N/A	N/A	N/A	LIC_ACTION_EVENT is renamed to ACTION_EVENT.
N/A	N/A	N/A	N/A	LIC_ACTION is renamed to ACTION.
EU CT Number	N/A	EU_CT_NUMBER	VARCHAR2(100)	CTA_SHARED_DATA
Concentration Measure Type	N/A	CONCENTRATION_MEASURE_TYPE_ID	NUMBER	CONCENTRATION_VALUE
MAH/ Organisation	N/A	SPONSOR_MAH_ID	NUMBER	LIC_PRODDT

Field Name	Field Size	Database Column Name	Database Column Size	Db Table Name
Currently marketed in this country?	N/A	CURRENTLY_MARKETED_STATUS_ID	NUMBER	LIC_PRODDDET_COUNTRY
Country	N/A	COUNTRY_ID	NUMBER	LIC_PRODDDET_PCID
Version	N/A	VERSION	VARCHAR2(200)	LIC_PRODDDET_PCID
Version Date	N/A	VERSION_DATE	DATE	LIC_PRODDDET_PCID
Full Indication Language	N/A	FULL_INDICATION_TEXT_LANGUAGE_ID	NUMBER	MEDICINAL_PRODUCT
License Root Number	N/A	LICENSE_ROOT_NUMBER	VARCHAR2(100)	MEDICINAL_PRODUCT
Country	N/A	COUNTRY_ID	NUMBER	MP_MPID
IDMP Package Level	N/A	PACKAGE_LEVEL	VARCHAR2(200)	PACKAGING_CATEGORY_TYPE
Composition Grouping Description	N/A	COMPOSITION_GROUPING_DESCRIPTION	VARCHAR2(100)	PDS_ACTING_CHANGE
Origin of Substance	N/A	SUBSTANCE_ORIGIN_TYPE_ID	NUMBER	PDS_ACTING_CHANGE
Device Quantity Unit	N/A	PDS_MED_DEVICE_QTY_UOM_TYPE_ID	NUMBER	PDS_PACKSET_DETAIL_CHANGE
Composition Grouping Description	N/A	COMPOSITION_GROUPING_DESCRIPTION	VARCHAR2(100)	PDS_SUBSTANCE_CHANGE

Field Name	Field Size	Database Column Name	Database Column Size	Db Table Name
Origin of Substance	N/A	SUBSTANCE_ORIGIN_TYPE_ID	NUMBER	PDS_SUBSTANCE_CHANGE
Authorized Representative Name	N/A	AUTHORIZED_REPRESENTATIVE_NAME	VARCHAR2(500)	SOURCE
Labeler DUNS Number/ Legal Manufacturer Single Registration Number(SRN)	N/A	ORGANIZATION_IDENTIFIER2	VARCHAR2(50)	SOURCE
Regulatory Agency	N/A	HEALTH_AUTHORITY_ID	NUMBER	SOURCE_AUTHORISATION
Confidentiality Indicator	N/A	DATA_CLASSIFICATION_TYPE_ID	NUMBER	SRC_PACK
Confidentiality Indicator	N/A	DATA_CLASSIFICATION_TYPE_ID	NUMBER	SRC_SUBSTANCE
Category of CMR Type	N/A	DEVICE_CMR_CATEGORY_TYPE_ID	NUMBER	SUBSTANCE
EC Number	N/A	EC_NUMBER	VARCHAR2(1000)	SUBSTANCE
Index Number	N/A	INDEX_NUMBER	VARCHAR2(50)	SUBSTANCE
Type	N/A	SUBSTANCE_SUBTYPE_TYPE_ID	NUMBER	SUBSTANCE
Use for xEVMPD	N/A	XEVMPD_FLAG	VARCHAR2(1)	XPHARMA_PRODUCT_REF_AI

Field Name	Field Size	Database Column Name	Database Column Size	Db Table Name
Device Nomenclature Category	N/A	DEVICE_NOMENCLATURE_CATEGORY_TYPE_ID	NUMBER	EU_DEVICE_NOMENCLATURE_TYPE
Device Nomenclature Code	N/A	ID_CODE	VARCHAR2(300)	EU_DEVICE_NOMENCLATURE_TYPE
GMDN In-Vitro Term Type	N/A	DEVICE_INVITRO_TERM_TYPE_ID	NUMBER	FDA_DEVICE_GMDN_TYPE
Version	N/A	VERSION	VARCHAR2(100)	MP_MPID
Full Indication Text	N/A	FULL_INDICATION_TEXT	VARCHAR2(4000)	MP_NAME
Date of First Approval	N/A	FIRST_APPROVAL_DATE	DATE	MP_NAME
Device Quantity	N/A	PDS_MED_DEVICE_QTY	Integer	PDS_PACKSET_DETAIL_CHANGE
CAS Number	N/A	CAS_NUMBER	VARCHAR2(1000)	SUBSTANCE
Data Classification	N/A	DATA_CLASSIFICATION	VARCHAR2(100)	TERMINOLOGY_SYSTEM_LIST_MEMBER
Category	N/A	DATA_CATEGORY	VARCHAR2(100)	TERMINOLOGY_SYSTEM_LIST_MEMBER
Mapping Source	N/A	SOURCE_IDENTIFIER	VARCHAR2(500)	TERMINOLOGY_SYSTEM_LIST_MEMBER
xEVMPD Code	N/A	XEVMPD_CODE	VARCHAR2(500)	TERMINOLOGY_SYSTEM_LIST_MEMBER
Source Term Id	N/A	SOURCE_TERM	VARCHAR2(500)	TERMINOLOGY_SYSTEM_LIST_MEMBER

Field Name	Field Size	Database Column Name	Database Column Size	Db Table Name
Version	N/A	VERSION	VARCHAR2(200)	XPHARMA_PRODUCT_PHPID
Version Date	N/A	VERSION_DATE	DATE	XPHARMA_PRODUCT_PHPID
N/A	N/A	N/A	LICENSE_ID is deleted.	ACTION
N/A	N/A	N/A	LICENSE_ID is deleted.	ACTION_ATTACHMENT
N/A	N/A	N/A	LICENSE_ID is deleted.	ACTION_EVENT
N/A	N/A	N/A	EXTRA_FIELDS_ID is deleted.	EU_DEVICE_NOMENCLATURE_TYPE
N/A	N/A	N/A	CURRENTLY_MARKETED_FLAG is deleted.	LIC_PRODDET_COUNTRY
N/A	N/A	N/A	STATUS_DATE is deleted.	LIC_PRODDET_PCID
N/A	N/A	N/A	LICENSE_ID is deleted.	MEDICINAL_PRODUCT
N/A	N/A	N/A	LICENSE_ID is deleted.	MP_ACTION
N/A	N/A	N/A	LICENSE_ID is deleted.	MP_AUTH_PHARMA_FORM

Field Name	Field Size	Database Column Name	Database Column Size	Db Table Name
N/A	N/A	N/A	LICENSE_ID is deleted.	MP_MPID
N/A	N/A	N/A	LICENSE_ID is deleted.	MP_NAME
N/A	N/A	N/A	LICENSE_ID is deleted.	MP_NAME_COUNTRY
N/A	N/A	N/A	LICENSE_ID is deleted.	MP_PHARMA_PRODUCT
N/A	N/A	N/A	LICENSE_ID is deleted.	MP_XREF
N/A	N/A	N/A	TYPE_CODE is deleted.	SUBSTANCE
N/A	N/A	N/A	PRODUCT_MATERIAL_TYPE_ID is deleted.	PACKAGE_COMPONENT
N/A	N/A	N/A	DATA_CARRIER_LANGUAGE_TYPE_ID is deleted.	LIC_PRODDET_COUNTRY
N/A	N/A	N/A	DATA_CARRIER_IDENTIFIER is deleted.	LIC_PRODDET_COUNTRY

Field Name	Field Size	Database Column Name	Database Column Size	Db Table Name
N/A	N/A	N/A	DATA_CARRIER_TYPE_ID is deleted.	LIC_PRODDDET_COUNTRY

Data Administration Tables

Data Administration Tables Added: Ennov InSight 7.2

The following Data Administration tables, sections, or fields were added for Ennov InSight 7.2. These include the tables added to support IDMP data capture.

Data Administration Section: Other

Table 15: Certificate Master File Values

Entity Affected	Field Name	Value List Description
Application, Substance, Manufacturer	<ul style="list-style-type: none"> – Master File Name – Master File Type – Master File Version – Master Identifier – Certificate Type – Certificate Number – Submission Date – Date of Last Update – Substance Reference – Related Application – Manufacturer – Content Link – Local Identifier – Last User Updated – Last Changed Date – Status – Version 	To maintain a standardized and structured method of collecting, reporting, coding, and evaluating authorized medicinal product data, the <i>Certificate Master File Values</i> table is introduced.

Table 16: File Identifier Type Values

Entity Affected	Field Name	Value List Description
Application, Substance	<ul style="list-style-type: none"> – File Identifier Type – Last User Updated – Last Changed Date 	To maintain a standardized and structured method of collecting, reporting, coding, and evaluating authorized medicinal product data, the <i>File Identifier Type Values</i> table is introduced.

Data Administration Section: Product Family Maintenance

Table 17: Substance Subtype Type

Entity Affected	Field Name	Value List Description
Application, Substance	Name	Subtypes of substance. The following values pre-populate in the grid. You cannot activate/modify the values below. For configuration assistance, contact our support representatives. <ul style="list-style-type: none"> – Uncategorized (inactive by default) – CMR Substance – Endocrine Substance – Strain – Human Product Substance – Placeholder – Substance

Data Administration Section: Product Detail Set Maintenance

Table 18: Origin of Substance Values

Entity Affected	Column/Field Name	Value List Description
Product Detail Set	Origin of Substance	For additional medicinal product data, the <i>Origin of Substance Values</i> table is introduced. The value for Origin of Substance can be entered in the respective field.

Data Administration Section: SPOR Master Lists

Table 19: Substance

Entity Affected	Column/Field Name	Value List Description
Substance	<ul style="list-style-type: none"> – Identifier – Name – Data Classification – Category – Domain – Code 	To display the associated existing substance data to uniquely identify the ingredients and materials of a medicinal product <i>Substance</i> table is introduced.

Table 20: Reason for Marketing Unavailability Values

Entity Affected	Column/Field Name	Value List Description
N/A	<ul style="list-style-type: none"> – List ID – List Name – List Owner – Term Id – Term Name – Short Name – Status – Domain – Modified On – Source Id – Source Term Id – Default Flag – Active Flag – XEVMPD Code – Description – Comments – Version Number – ISO Code – Creation Date – Modification Date 	Indicates the reason for the drug unavailability in the market. You cannot create/modify the respective value and its attributes.

Data Administration Section: Medical Device Maintenance

Table 21: Global Medical Device Nomenclature (GMDN) Code Values

Entity Affected	Field Name	Value List Description
Product Component Device Details	<ul style="list-style-type: none"> – GMDN Code – GMDN Term Name – GMDN Term Definition – Term is IVD 	Global Medical Device Nomenclature (GMDN) Code used to identify medical devices.

Table 22: EU Device Nomenclature Values

Entity Affected	Field Name	Value List Description
Product Component Device Details	<ul style="list-style-type: none"> – Device Nomenclature Category – Device Nomenclature Code – Device Nomenclature Code Name/Description 	A set or system of names used by manufacturers when registering their medical devices in the EUDAMED database.

Table 23: EU Device Nomenclature Category Values

Entity Affected	Field Name	Value List Description
Product Component Device Details	<ul style="list-style-type: none"> – Device Nomenclature Category Name – Device Nomenclature Code Value 	They type of the nomenclature used by the manufacturers to register medical devices in EUDAMED.

Table 24: FDA GMDN In-Vitro Term Type Values

Entity Affected	Field Name	Value List Description
Product Component Device Details	GMDN In-Vitro Term Type	The GMDN type used to identify Vitro diagnostic devices for the FDA submission.

Table 25: EU Category of CMR Type Values

Entity Affected	Field Name	Value List Description
Product Component Device Details	Category of CMR Type	Different categories of the medications that are required to prepare for medical issues of a patient.

Data Administration Tables Updated: Ennov InSight 7.2

Data Administration tables, sections, or fields updated in Ennov InSight 7.2 release. These include the tables modified to support IDMP data capture.

Data Administration Section: Product Family Maintenance

Entity Affected	Column/Field Name	Value List Description
N/A	<ul style="list-style-type: none"> – RMS Term ID – RMS Modified On – RMS Status 	The following values now include the respective columns: <ul style="list-style-type: none"> – ATC Values – Domain Type Values

Table 26: Substance Values

Entity Affected	Field Name	Value List Description
Substance	<ul style="list-style-type: none"> – Term ID – Substance Name – Data Classification – Category – Domain – Last User Updated – Last Changed Date – Active Flag 	The <i>Substance Values</i> attributes page is updated with SMS tab, including the columns to associate and display the data from SPOR Master Lists > Substance.

Entity Affected	Field Name	Value List Description
Substance	<ul style="list-style-type: none"> – Type – Substance Name – INN – CAS Number – Molecular Formula – Compound Number – XEVMPD Development Substance – Substance Level Class – CBD – Development Sponsor – Compendial Designation/ Source – Keywords – Description – Comments – Last Changed Date – Alias Name – Compendial Designation/ Source: 	<p>With the implementation of the new SMS tab, the Substance Alias tab under <i>Substance Values</i> is now hidden.</p>

Entity Affected	Field Name	Value List Description
Substance	<ul style="list-style-type: none"> – Type – Substance Name – INN – CAS Number – Molecular Formula – Compound Number – XEVMPD Development Substance – Substance Level Class – CBD – Development Sponsor – Compendial Designation/ Source – Keywords – Description – Comments – Last User Updated – Last Changed Date – Language – Translation Term 	With the implementation of the new SMS tab, the Substance Translations tab under <i>Substance Values</i> is now hidden.
Substance	SMS Term ID	This column is added to Data Administration > Substance Values grid view and displays the data from SPOR Master Lists > Substance .
Substance	XEVMPD Standard Term	This column is added to Data Administration > Substance Values grid view and displays the data from Substance XEVMPD Information > EV Code .
Substance	Substance Name	This column is updated to display the data from SPOR Master Lists > Substance in the grid view.

Entity Affected	Field Name	Value List Description
N/A	Type	The Type column in the <i>Substance Values</i> page is updated to pre-populate the following values: <ul style="list-style-type: none"> – CMR Substance – Endocrine Substance – Uncategorized
N/A	Type	The Type field in the <i>Substance Values</i> (Create and Edit) page is updated to display the following values from the Data Administration > Substance Subtype Type Values grid: <ul style="list-style-type: none"> – Uncategorized (inactive by default) – CMR Substance – Endocrine Substance – Strain – Human Product Substance – Placeholder – Substance
N/A	Category of CMR Type	The <i>Substance Values</i> (Create/Edit) pages are updated with a new Category of CMR Type field. This field appears only when you select the CMR Substance value in the Type field.

Table 27: EURD ID Values

Entity Affected	Column/Field Name	Value List Description
N/A	Family Identifier/Active Substances	The EURD Procedure Identifier field and column is renamed to Family Identifier/Active Substances on the EURD ID Values.

Data Administration Section: Other

Entity Affected	Column/Field Name	Value List Description
N/A	<ul style="list-style-type: none"> – RMS Term ID – RMS Modified On – RMS Status 	The following values now include the respective columns: <ul style="list-style-type: none"> – 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

Table 28: MAH /Development Sponsor /Organisation Values

Entity Affected	Column/Field Name	Value List Description
N/A	xEVMPD	In <i>OVS Term Search</i> widget, this field is updated to pre-populate the existing XEVMPD code if it exists for Organization. If the XEVMPD Code (MAH Code EV Code) exists on the <i>MAH/Development Sponsor XEVMPD Information</i> tab for <i>MAH/Development Sponsor/Organisation Values</i> , it is pre-populated in the Code search field on the <i>OVS Term Search</i> widget.

Data Administration Section: Product Detail Set Maintenance

Entity Affected	Column/Field Name	Value List Description
N/A	<ul style="list-style-type: none"> – RMS Term ID – RMS Modified On – RMS Status 	The following values now include the respective columns: <ul style="list-style-type: none"> – 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

Table 29: Manufacturer Values

Entity Affected	Column/Field Name	Value List Description
N/A	Confidentiality Indicator	This flag is now available on the <i>Global Detail Sets</i> page (Manufacturer Values > Global Product Details) when you select <i>Packaging</i> or <i>Substance</i> option for the <i>Detail Type</i> field. The Confidentiality Indicator flag displays values from the Product Detail Set Maintenance > Data Classification Type values.
N/A	<ul style="list-style-type: none"> – Country – Regulatory Agency 	The Manufacturing Authorisation Reference Number page and tab of the Manufacturer Values table is updated to include the respective fields and columns.
N/A	<ul style="list-style-type: none"> – Labeler DUNS Number/Legal Manufacturer Single Registration Number(SRN) – Authorized Representative Name 	The <i>Manufacturer</i> (View/Create/Edit) pages are updated with the following new fields: <ul style="list-style-type: none"> – Labeler DUNS Number/Legal Manufacturer Single Registration Number(SRN) – Authorized Representative Name

Table 30: Packaging Category Values

Entity Affected	Column/Field Name	Value List Description
N/A	IDMP Package Level	The <i>Packaging Category Values</i> page now includes the respective field.

Table 31: Time Unit Values

Entity Affected	Column/Field Name	Value List Description
N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	The <i>Time Unit Values</i> table is updated with a new RMS tab to associate the SPOR Units of Measurement values. The RMS tab grid view includes the respective columns and displays the data from SPOR Master Lists > Unit of Measurement.

Table 32: Package Component Values

Entity Affected	Column/Field Name	Value List Description
N/A	Product Material	The Product Material drop-down field type is updated to an optional multi-select field type. This includes Available and Selected boxes. You can move values from the Product Material Available box to the Selected box and vice-versa.

Data Administration Section: Registration Maintenance

Entity Affected	Column/Field Name	Value List Description
N/A	<ul style="list-style-type: none"> – RMS Term ID – RMS Modified On – RMS Status 	The following values now include the respective columns: <ul style="list-style-type: none"> – 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

Table 33: Risk of Shortage of Supply Reason Values

Entity Affected	Column/Field Name	Value List Description
N/A	N/A	The <i>Marketing Status Reason Values</i> is renamed to be <i>Risk of Shortage of Supply Reason Values</i> .

Table 34: Registration Status Values

Entity Affected	Column/Field Name	Value List Description
N/A	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	The <i>Registration Status Values</i> table is updated with a new RMS tab to associate the SPOR Regulatory Entitlement Status values. The RMS tab grid view includes the respective columns and displays the data from SPOR Master Lists > Regulatory Entitlement Status.

Data Administration Section: Application Maintenance

Entity Affected	Column/Field Name	Value List Description
N/A	<ul style="list-style-type: none"> – RMS Term ID – RMS Modified On – RMS Status 	The following values now include the respective columns: <ul style="list-style-type: none"> – Country Values – Legal Status Values – Orphan Status Values – Procedure Type Values – Product Information Document Type Values – Regulatory Entitlement Type Values

Data Administration Section: Product Maintenance

Entity Affected	Column/Field Name	Value List Description
N/A	<ul style="list-style-type: none"> – RMS Term ID – RMS Modified On – RMS Status 	The following values now include the respective columns: <ul style="list-style-type: none"> – Dosage/Pharmaceutical Form Values – Medical Device Values – Product Category Values – Product Cross Reference Type Values – Routes of Administration Values

Data Administration Tables Removed: Ennov InSight 7.2

List of Data Administration tables, sections, or fields removed in Ennov InSight to comply to the latest requirements.

Data Administration Section: Product Family Maintenance

Table 35: Substance Values

Entity Affected	Field/Column Name	Value List Description
Substance	<ul style="list-style-type: none"> – CAS Number – XEVMPD Development Substance – CBD – Development Sponsor – Compendial Designation/ Source 	These columns are removed from Data Administration > Substance Values grid.

Data Administration Section: Product Maintenance

Table 36: Device Nomenclature Values

Entity Affected	Field/Column Name	Value List Description
N/A	N/A	The Device Nomenclature value is removed from the Product Maintenance section.

Table 37: Global Medical Device Nomenclature (GMDN) Code Values

Entity Affected	Field/Column Name	Value List Description
N/A	N/A	The Global Medical Device Nomenclature (GMDN) Code value is removed from the Product Maintenance section and added to the Medical Device Maintenance section.

Security Administration Tables

Security Administration Tables Updated: Ennov InSight 7.2

Security Administration tables, sections, or fields updated in Ennov InSight 7.2 release. These include the tables modified to support IDMP data capture.

Security Administration Section: License Modules

Entity Affected	Column/Field Name	Value List Description
N/A	XEVMPD (eXtended EudraVigilance Medicinal Product Dictionary)	This field is renamed to IDMP and xEVMPD to extend it to IDMP functionality in future.

Security Administration Section: Entity Security

Entity Affected	Column/Field Name	Value List Description
Medicinal Product, Medicinal Product Actions	<ul style="list-style-type: none"> – Medicinal Products – Medicinal Product Actions 	This section now includes the respective fields. See: <i>Ennov InSight License Modules by Feature</i> .

Security Administration Section: Home Page Access

Entity Affected	Column/Field Name	Value List Description
Medicinal Product, Medicinal Product Actions	<ul style="list-style-type: none"> – Medicinal Products – Medicinal Product Actions 	This section now includes the respective fields. See: <i>Home Page Access Settings</i> .

Query Fields

Query Fields and Columns Added: Ennov InSight 7.2

The following table describes fields that were updated with Ennov InSight 7.2.

Administration Queries

Table 38: Entity Audit Trail

Field/Column Name	Field/Column Type	Description
<ul style="list-style-type: none"> – Full Indication Text – Full Indication Language 	Read-only text (populated automatically)	The respective columns are now available in the <i>Search Results</i> query page of the <i>Entity Audit Trail Query</i> to display details for the Medicinal Product entity type.

Registration Planning and Tracking

Table 39: List of Veterinary Products

Field/Column Name	Field Type	Description
Concentration Measure Type	Drop-down list	This field is now available on the <i>List of Veterinary Products</i> query page under IDMP Concentration Strength .

Table 40: List of Veterinary Products and Components

Field/Column Name	Field Type	Description
Concentration Measure Type	Drop-down list	This field is now available on the <i>List of Veterinary Products and Components</i> query page under IDMP Concentration Strength.

Table 41: List of Pharmaceutical Products

Field/Column Name	Field Type	Description
Concentration Measure Type	Drop-down list	This field is now available on the <i>List of Pharmaceutical Products</i> query page under IDMP Concentration Strength.

Table 42: List of Pharmaceutical Products and Components

Field/Column Name	Field Type	Description
Concentration Measure Type	Drop-down list	This field is now available on the <i>List of Pharmaceutical Products and Components</i> query page under IDMP Concentration Strength.

Table 43: List of Pharmaceutical and Medical Device Products

Field/Column Name	Field Type	Description
Concentration Measure Type	Drop-down list	This field is now available on the <i>List of Pharmaceutical and Medical Device Products</i> query page under IDMP Concentration Strength.

Table 44: List of Pharmaceutical and Medical Device Products and Components

Field/Column Name	Field Type	Description
Concentration Measure Type	Drop-down list	This field is now available on the <i>List of Pharmaceutical and Medical Device Products and Components</i> query page under IDMP Concentration Strength.

Table 45: List of RMS Fields

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> – RMS List Name – RMS Term Name – RMS Term ID – RMS Status – Associated DA List Name – Display Columns – Sort Order 	Text, Multi-select box,	The new <i>List of RMS Fields</i> query includes the respective fields.

Table 46: List of OMS Fields

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> – 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 	Text, Multi-select box,	The new <i>List of OMS Fields</i> query includes the respective fields.

Table 47: Entity History Query

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> – Full Indication Text – Full Indication Language 	Read-only text (populated automatically)	The respective fields and columns are now available for Medicinal Product Attributes > Entity History Query to display details for the Medicinal Product entity type: <ul style="list-style-type: none"> – Display Columns, multi-select field options – <i>Search Results</i> page
<ul style="list-style-type: none"> – Version – Version - ASC – Version - DESC 	Read-only text (populated automatically)	The respective field values and columns are available in the Entity History Query : <ul style="list-style-type: none"> – Display Columns, multi-select field options – Sort Order, multi-select field options – <i>Search Results</i> page
MAH/Organisation	Read-only text (populated automatically)	The respective field values and column are now available for Registration-Package Set Attributes > Entity History Query to display details for the Registration-Package Set entity type: <ul style="list-style-type: none"> – Display Columns, multi-select field options – Sort Order, multi-select field options – <i>Search Results</i> page

Product Detail Management

Table 48: List of Application Countries with PDS Country and Registration Details Query

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> – Data Carrier Type – Data Carrier ID – Data Carrier Description – Data Carrier Language – Data Carrier Status – Data Carrier Status Date 	Read-only text (populated automatically)	The respective field values and columns are available in the List of Application Countries with PDS Country and Registration Details Query : <ul style="list-style-type: none"> – Display Columns, multi-select field options – Sort Order, multi-select field options – <i>Search Results</i> page

Table 49: Sunset Clause Marketing Status Query

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> – Data Carrier Type – Data Carrier ID – Data Carrier Description – Data Carrier Language – Data Carrier Status – Data Carrier Status Date 	Read-only text (populated automatically)	The respective field values and columns are available in the Sunset Clause Marketing Status Query : <ul style="list-style-type: none"> – Display Columns, multi-select field options – Sort Order, multi-select field options – <i>Search Results</i> page

Query Fields and Columns Updated: Ennov InSight 7.2

The following table describes fields that were updated with Ennov InSight 7.2

Registration Planning and Tracking Queries

Table 50: List of References

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> – Associated with (select parent entity) – Association Type – Association Name 	Drop-down list, Read-only text	The field is updated to include a Medicinal Product Action entity on the <i>List of References Query</i> page. The columns Association Type and Association Name are updated to include the Medicinal Product Action on the <i>Search Results</i> page.

Table 51: List of References - Rollup by Application

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> – Association Type – Association Name 	Read-only text	The columns Association Type and Association Name are updated to include the Medicinal Product Action on the <i>Search Results</i> page.

Table 52: List of Tasks

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> – Associated with (select parent entity) – Association Type – Association Name 	Drop-down list, Read-only text	The field is updated to include a Medicinal Product Action entity on the <i>List of Tasks Query</i> page. The columns Association Type and Association Name are updated to include the Medicinal Product Action on the <i>Search Results</i> page. .

Table 53: List of Tasks - Rollup by Application

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> – Task Name – Task Association Type – Task Association 	Hyperlink, Read-only text	These columns display the corresponding values for Medicinal Product Action on the <i>Search Results</i> page. .

Table 54: List of Veterinary Products

Field Name	Field Type	Description
IDMP Concentration Measure Type	Drop-down list	This field is renamed to Concentration Measure Type on the <i>List of Veterinary Products</i> query page and placed under the IDMP Presentation Strength section.

Table 55: List of Pharmaceutical Products

Field Name	Field Type	Description
IDMP Concentration Measure Type	Drop-down list	This field is renamed to Concentration Measure Type on the <i>List of Pharmaceutical Products</i> query page and placed under the IDMP Presentation Strength section.

Table 56: List of Pharmaceutical Products and Components

Field Name	Field Type	Description
IDMP Concentration Measure Type	Drop-down list	This field is renamed to Concentration Measure Type on the <i>List of Pharmaceutical Products and Components</i> query page and placed under the IDMP Presentation Strength section.

Table 57: List of Pharmaceutical and Medical Device Products

Field Name	Field Type	Description
IDMP Concentration Measure Type	Drop-down list	This field is renamed to Concentration Measure Type on the <i>List of Pharmaceutical and Medical Device Products</i> query page and placed under the IDMP Presentation Strength section.

Table 58: List of Pharmaceutical and Medical Device Products and Components

Field Name	Field Type	Description
IDMP Concentration Measure Type	Drop-down list	This field is renamed to Concentration Measure Type on the <i>List of Pharmaceutical and Medical Device Products and Components</i> query page and placed under the IDMP Presentation Strength section.

Table 59: Applications Sent, Submitted, or Approved - Searched by INN or Active Ingredient

Field/Column Name	Field Type	Description
Currently Marketed in this Country?	Drop-down list	This field is updated on the <i>Applications Sent, Submitted, or Approved - Searched by INN or Active Ingredient</i> page with the values assigned from Registration Maintenance > Marketing Status Values in <i>Data Administration</i> .
Marketed?	Read-only text (populated automatically)	This column is updated on the <i>Search Results</i> page with the values assigned from Registration Maintenance > Marketing Status Values in <i>Data Administration</i> .

Product Detail Management

Table 60: List of Registration Package Set Withdrawn

Field/Column Name	Field Type	Description
Currently Marketed in this Country?	Read-only text (populated automatically)	This column is updated on the <i>Search Results</i> page with the values assigned from Registration Maintenance > Marketing Status Values in <i>Data Administration</i> .

Table 61: Labeled Indications Query

Field/Column Name	Field Type	Description
Currently Marketed in this Country?	Read-only text (populated automatically)	This column is updated on the <i>Search Results</i> page with the values assigned from Registration Maintenance > Marketing Status Values in <i>Data Administration</i> .

Table 62: Shelf Life Query

Field/Column Name	Field Type	Description
Currently Marketed?	Read-only text (populated automatically)	This column is updated on the <i>Search Results</i> page with the values assigned from Registration Maintenance > Marketing Status Values in <i>Data Administration</i> .

Table 63: List of Products with Registration and Flu Strain Details

Field/Column Name	Field Type	Description
Currently Marketed in this Country?	Read-only text (populated automatically)	This column is updated on the <i>Search Results</i> page with the values assigned from Registration Maintenance > Marketing Status Values in <i>Data Administration</i> .

Table 64: Flu Strain with Registration and PDS Details

Field/Column Name	Field Type	Description
Currently Marketed in this Country?	Read-only text (populated automatically)	This column is updated on the <i>Search Results</i> page with the values assigned from Registration Maintenance > Marketing Status Values in <i>Data Administration</i> .

Table 65: Entity History Query

Field/Column Name	Field Type	Description
Package Description	Text field	This field is renamed to Package Description on the Package Set- Package Description Attributes > Entity History Query page to display details for the Registration-Package Set-Package Description entity type: <ul style="list-style-type: none"> – Display Columns, multi-select field options – Sort Order, multi-select field options – <i>Search Results</i> page

Query Fields and Columns Removed: Ennov InSight 7.2

The following table describes fields that were updated with Ennov InSight 7.2.

Table 66: Entity History Query

Field/Column Name	Field Type	Description
PMS ID	Read-only text (populated automatically)	The respective fields and columns are removed for Medicinal Product Attributes > Entity History Query: <ul style="list-style-type: none"> – Display Columns, multi-select field options – Sort Order, multi-select field options – <i>Search Results</i> page

Ennov InSight 7.2.1 Release Notes

Ennov InSight 7.2.1 Release Notes

Release Notes contain information about updated files, new functionality, resolved issues, and any open issues or work-arounds in this release of Ennov InSight 7.2.1.

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

Resolved Issues: Ennov InSight 7.2.1

The following issues 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 previous sub-minor release, that sub-minor build number is included.

Power BI

Issue	Build Number	Description
DE28616	N/A	Refreshing a Power BI Dataset in Azure Data Factory resulted in the ADF pipelines fail: Cannot insert duplicate key in object 'S_reporting.EXTRA_FIELDS' error. This issue is resolved. Now, the Power BI Dataset is successfully refreshed in the Azure Data Factory.

Ennov InSight 7.2 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.2 Release Notes (Cumulative)

Ennov InSight 7.2.2 Release Notes

Ennov InSight 7.2.2 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 7.2.

The details in these Release Notes supersede all similar details that appear anywhere else in this release.

Application Updates

Ennov InSight 7.2.2 release introduces the following application updates:

- The ability to create an application from the *Product Family Attributes* page.
- The ability to create an application without the need to associate a product.

— Entities:

- Product Family (Application tab)
- Application (Create Application, Product tab)
- Events (Create Event, CT Shared Data)
- Search, Wizards, Security Administration

— Tabs:

- Applications (Applications grid, Set Filter)

— Home page:

- Countries and Product Family tree

New in Ennov InSight 7.2.2: Common Functionality

This table shows new features and enhancements of Ennov InSight 7.2.2 functionality.

Affected Area	Update	Benefit
Home page: — Search menu results Navigation: — Product Family tree — Countries tree	To enable the new ability to create an application without the need to associate a product, changes have been made to the following sections: — Search menu updates: <ul style="list-style-type: none"> • Applications. See: <i>Entity Fields and Columns Added: Ennov InSight 7.2.2.</i> — Navigation updates: <ul style="list-style-type: none"> • Applications. See: <i>Entity Fields and Columns Added: Ennov InSight 7.2.2.</i> 	The ability to view and navigate to the applications that are not associated to products or product families.
Entities/Entity tabs	Changes for Application now include: — Entity updates: <ul style="list-style-type: none"> • Product Family Attributes updates. See: <i>Entity Fields and Columns Added: Ennov InSight 7.2.2 and Registrations > Create Application from the Product Family Attributes.</i> • Applications. See: <i>Entity Fields and Columns Updated: Ennov InSight 7.2.2.</i> • Events. See: <i>Entity Fields and Columns Added: Ennov InSight 7.2.2 and Registrations > Entity Attributes.</i> — Tab updates: <ul style="list-style-type: none"> • Applications. See: <i>Entity Fields and Columns Added: Ennov InSight 7.2.2</i> 	The ability to create application and search for products from the specific product family.

Affected Area	Update	Benefit
Wizards	<p>The following wizards are updated to enable an application to be created without a product and then associate it later:</p> <ul style="list-style-type: none"> – Create Application wizard – Create Submission wizard <p><i>See: Entity Fields and Columns Updated: Ennov InSight 7.2.2.</i></p>	The ability to create applications via the wizard without products associations.
Security Administration	<p>As an application can be created without a product, the Application Country Rights security permissions related to associating a product are updated.<i>See: Entity Fields and Columns Updated: Ennov InSight 7.2.2.</i></p>	The ability to create applications without products associations.

New in Ennov InSight 7.2.2: Registrations

New features and enhancements for Registration functionality are listed below.

Affected Area	Update	Benefit
Application	<p>On the <i>Create Application</i> page, associating a product is now optional. <i>See: Entity Fields and Columns Updated: Ennov InSight 7.2.2</i></p>	The ability to create applications without products association.
Event	<p>The CT Shared Data can now be associated to an event when there is no product assigned and application is created under the product family. <i>See:Entity Fields and Columns Added: Ennov InSight 7.2.2</i></p>	The ability to assign the CT Shared Data without adding the product to an event.
Create Application Wizard	<p>The fields are updated in the <i>Create Application</i> wizard when associating a product. <i>See: Entity Fields and Columns Updated: Ennov InSight 7.2.2</i></p>	The ability to create applications via the wizard without products associations.
Create Submission Wizard	<p>The <i>Create Submission</i> wizard fields are updated to enable associating a product. <i>See: Entity Fields and Columns Updated: Ennov InSight 7.2.2</i></p>	
Product Family	<p>The <i>Product Family Attributes</i> page now includes the Create Application option. <i>See: Entity Fields and Columns Added</i></p>	The ability to create applications under product families with the ability to select products under this current product family create page.

Resolved Issues: Ennov InSight 7.2.2

The following issues 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 certified hotfix (CHF), that CHF build number is included.

Registrations

Issue	CHF/Hotfix Build	Description
DE29178; [INC0092523]	N/A	During the migration process, placeholder (pseudo) products were not associated to the events of CTA applications. This issue is resolved. Now, placeholder products are associated with the events with CT Shared Data of CTA or IND Applications.
DE28959	N/A	When creating a role in <i>Security Administration</i> , the values required for the XML Mapped Role field were missing. This issue is resolved. Now, the XML Mapped Role field includes a box with the values to select.
DE28990	N/A	Assigning different Registrations to the same Medicinal Product resulted in duplicate MAH value in the the IDMP tab Related MAH column. The issue is resolved. Now, no duplicate MAH values are created.
DE28575	N/A	When there were 200K or more products to select, the performance of <i>Product Select</i> widget was affected. The issue is resolved. Now the performance of the <i>Product Select</i> widget is increased.

Addendum 2

Issue	CHF/Hotfix Build	Description
DE29984 [INC0220440]	N/A	Using custom DCTM attributes in the folder name resulted in the errors after publishing as DCTM output location in the Document Attributes window was not recognized as a folder. This issue is resolved. The microservice dctm.connector 1.0.4 is updated to allow using custom attributes in the folder name for publishing.

Addendum 3

Issue	CHF/Hotfix Build	Description
DE29753 [INC0203009]	N/A	Power BI scheduled refreshing failed due to a table schema column error: The given ColumnMapping does not match up with any column in the source or destination., Source=System.Data. This issue is resolved. Now, Power BI scheduled refreshing completes successfully.

Ennov InSight 7.2 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.2 Release Notes (Cumulative)


Entity Fields

Entity Fields and Columns Added: Ennov InSight 7.2.2

Describes fields and columns that were added in this release including those that support the application updates.

Home

Table 67: Navigation Tree

Field/Column/Option Name	Field Type	Description	Business Rules
NOT DEFINED	Node	When you expand the Select Entity Trees for Product Families or Countries , the corresponding node is displayed under product families for the applications without associated products.	The correct security rights should be selected.  <i>Warning: This feature is not available by default. For any requests to expose it, please contact your Business Development Representative for assistance.</i>

Search

Table 68: Applications

Field/ Column/ Option Name	Field Type	Description	Business Rules
Products	Read-only text (populated automatically)	The <i>Search Results</i> page opened from Search > Applications now includes the corresponding column.	<ul style="list-style-type: none"> – If no product is associated with the application, the Products column is displayed with No value. – If any product is associated with the application, the Products column is displayed with Yes value.

Tabs

Table 69: Applications

Field/ Column/ Option Name	Field Type	Description	Business Rules
Products	Read-only text (populated automatically)	When you select Select Entity List > Applications on the left navigation pane, the corresponding field now appears as a column in the table view.	<ul style="list-style-type: none"> – If no product is associated with the application, the Products column is displayed with No value. – If any product is associated with the application, the Products column is displayed with Yes value.
Products	Option	When you select Select Entity List > Applications > Set Filter the corresponding field now appears as an option in the Choose a Field box.	When the Set Filter is used, only the applications with or without associated products are displayed in the <i>Applications</i> grid.

Entities

Table 70: Events

Field/Column/Option Name	Field Type	Description	Business Rules
CT Shared Data	Box, multi-select	The <i>Create Event</i> page now includes the corresponding field when you create an event for the CTA, CTR or IND applications.	The CT Shared Data can now be associated to the event for the application without a product.

Product Family

Field/Column/Option Name	Field Type	Description	Business Rules
Create Application	N/A	The <i>Create Application</i> option is added to the top right corner of the <i>Application</i> tab on the <i>Product Family Attributes</i> page.	The ability to create applications under product families with the ability to select products under this current product family create screen.

Entity Fields and Columns Updated: Ennov InSight 7.2.2

Describes entity fields that were changed in this release.

Entities

Table 71: Applications

Field/Column/Option Name	Field Type	Description	Business Rules
Associated Products	Multi-select, read-only text	This field has changed from mandatory to optional on the <i>Create Application</i> page when adding an application from <i>Product Family Attributes > Applications</i> tab.	With the ability to create an application without a product associated or associate/disassociate a product from the <i>Products</i> tab of the <i>Application Attributes</i> page, this change provides the continued implementation of the uniqueness rules to identify entities within the new data model.

Wizards

Table 72: Create Application

Field/Option Name	Field Type	Description	Business Rules
Associated Products	Multi-select, read-only text	This field is changed from mandatory to optional on the <i>Create Application</i> page after selecting the Reviewing Country .	With the ability to create an application without a product associated or associate/disassociate a product from the Products tab of the <i>Application Attributes</i> page, this change provides the continued implementation of the uniqueness rules to identify entities within the new data model.

Table 73: Create Submission


Field/Option Name	Field Type	Description	Business Rules
Associated Products	Multi-select, read-only text	This field is changed from mandatory to optional when selecting Create Submission > Intitial Application > Reviewing Country .	With the ability to create an application without the a product associated and to associate/disassociate a product from the Products tab of the <i>Application Attributes</i> page, this change provides the continued implementation of the uniqueness rules to identify entities within the new data model.

Security Administration Tables

Security Administration Tables Updated: Ennov InSight 7.2.2

Security Administration tables, sections, or fields updated in Ennov InSight 7.2.2 release. These include the tables modified to support IDMP data capture.

Security Administration Section: Application Country Rights

Entity Affected	Column/Field Name	Value List Description
<ul style="list-style-type: none"> – Product Family – Application – Product 	<ul style="list-style-type: none"> – Product Families – Countries – Access Level 	<p>The <i>Application Country Rights</i> page is updated to have more security permissions using the Add button:</p> <ul style="list-style-type: none"> – To use an orphan application, the NOT DEFINED must be set up for <i>Application Country Rights</i>. In this case no Product Families are selected and any option can be selected for Countries. – If the Product Families are NOT DEFINED, a product cannot be assigned to an application and the Application icon will not be available on the <i>Product Family Attributes</i> page. <hr/> <p> <i>Warning: This feature is not available by default. For any requests to expose it, please contact your Business Development Representative for assistance.</i></p> <hr/>

Ennov InSight 7.2.3 Release Notes

Ennov InSight 7.2.3 Release Notes

The Release Notes contain information about resolved issues and any open issues or workarounds in this release of Ennov InSight 7.2.3.

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

Resolved Issues: Ennov InSight 7.2.3

The following issues 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 hotfix, that sub-minor build number is included.

Common Issues

Issue	Build Number	Description
DE26858 [INC0068801]	N/A	API users experienced permissions problems. This issue is resolved. Now, API users get proper permissions upon login.
DE26747 [INC0042673]	N/A	Incorrect username was recorded in the API Debug log. This issue is resolved. Now, the API Debug log shows the name of the currently logged-on API user.
DE26733, DE26714 [INC0037879]	N/A	When logging on to API, authentication data was not recorded in the Log on Audit Trail query. This issue is resolved. Now, authentication data is recorded correctly.
DE26732, [INC0042515]	N/A	Passwords were exposed in the API server.log file. This issue is resolved. Now, Hashes (#) are displayed instead of passwords in the server.log file.
DE29199	N/A	When there were 1000+ product families, trying to associate a product from them to an application ended in the "Invalid reference" error. This issue is resolved. Now, product is associated successfully.

Ennov InSight 7.2 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.2 Release Notes (Cumulative)

Ennov InSight 7.2.4 Release Notes

Ennov InSight 7.2.4 Release Notes

Information about updated files, new functionality, resolved issues, and any open issues or workarounds in Ennov InSight 7.2.4.

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

Application Updates

Ennov InSight 7.2.4 release introduces the following Application updates:

- The ability to create **Global Project Plan > Clinical Trial** project without a product as mandatory selection with the ability to associate CT Shared Data.
- The ability to create **Global Project Plan > Create Application Registration Package Set** project without a product as mandatory selection.
- The ability to create and manage applications created through wizards without a product and product family association with the specific **NOT DEFINED Application Rights** settings set up in the **Security Administration**.
- Entities: Queries, Wizards, Security Administration

Oracle Updates

Oracle is updated to version 19.18 for Ennov InSight 7.2.4.

New in Ennov InSight 7.2.4: Common Functionality

This table shows new features and enhancements of Ennov InSight 7.2.4 functionality.

Affected Area	Update	Benefit
Wizards	As an application can be created without a product associated, the following wizards are updated: <ul style="list-style-type: none"> — Global Project Plan wizard <i>See: Entity Fields and Columns Updated</i> Ennov InSight 7.2.4.	The ability to create an application through the wizards to simplify the work of data creation.

Affected Area	Update	Benefit
Querying	To support the ability to create an application without a product and associate CT Shared Data, Queries now include the updated Product field from required to optional.	Aligned Querying capabilities with the updated data model.
Security Administration	To manage applications without products and product families separately, the access rights for Application Country Rights option are updated. <i>See: Security Administration Tables Updated: Ennov InSight 7.2.4.</i>	The ability to manage not assigned applications with a separate security settings to provide more flexibility.

New in Ennov InSight 7.2.4: Registrations

New features and enhancements for Registration functionality are listed below.

Affected Area	Update	Benefit
Global Project Plan Wizard	<p>The <i>Global Project Plan</i> wizard fields are updated or added when:</p> <ul style="list-style-type: none"> — Creating an application of CTA or IND application type without a product with the ability to associate CT Shared Data. — Creating an application of package set registration type without a product. <p><i>See Entity Fields and Columns Updated: Ennov InSight 7.2.4</i></p>	The ability to create an application through the wizards to simplify the work of data creation.

Resolved Issues: Ennov InSight 7.2.4

The following issues 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 hotfix before the release, the hotfix build number is included in the table.

Registrations

Issue	Build Number	Description
DE29688	N/A	An error was displayed when trying to delete a product family that had an application without a product. This issue is resolved. Now, the Delete icon is disabled on the <i>Product Family Attributes</i> page.
DE29563	N/A	It was not possible to delete an application without child entities when the Write access was set for Application Country Rights as the Delete icon was disabled. This issue is resolved. Now, the Delete icon is enabled and the application can be deleted successfully.
DE29266	N/A	When performing the API Post request, if Security Administration > Application Country Rights were set for a particular product family, the application values were not created. This issue is resolved. Now, the application values are successfully created.
DE29264	N/A	When creating an application using the Create Application icon on the <i>Product Family Attributes</i> page, if CTA, IND or CTR was selected as the application type, the fields displayed were different from those displayed while creating an application using the <i>Create Application</i> wizard. This issue is resolved. Now, the correct fields appear as a result.
DE29263	N/A	When performing the API Post request, if NOT DEFINED was selected in Security Administration > Application Country Rights section, the child entities were not created for an application without a product and a product family. This issue is resolved. Now, the child entities are successfully created.
DE29212	N/A	When performing the API Post request, an application that did not have a product was not created under a product family. This issue is resolved. Now, the application without a product is successfully created.
DE29139	N/A	When performing the API Post request to create an event with associated CT Shared Data for EU CTR application, the request failed with an error message. This issue is resolved. Now, the event is created successfully.

Migration

Issue	Build Number	Description
DE28913; [INC0136665]	N/A	After updating Oracle from 19.16.0.0.220719 to 19.17.0.0.221018 version, a column ambiguity error occurred when using the <i>XEVMPD Submission</i> wizard. This issue is resolved. Now, you can use the XEVMPD Submission wizard without errors.
DE29651	N/A	<p>After the Oracle database update to 19.18 version, the following pages were not opened from Ennov InSight left panel and some entities could not be created:</p> <ul style="list-style-type: none"> – Product Families – Registrations – Applications – Events <p>This issue is resolved. Now, these pages are successfully opened and the entities can be created or modified.</p>

Ennov InSight 7.2 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.2 Release Notes (Cumulative)

Entity Fields

Entity Fields and Columns Updated: Ennov InSight 7.2.4

The following tables describe fields that were modified in this release.

Global Project Plan

Field/ Option Name	Field Type	Description	Business Rules
Products	Multi-select	This field is now optional when selecting Global Project Plan > Clinical Trial: <ul style="list-style-type: none"> – Create New CTA and/or IND Application(s) > Select Products and Countries – Create New CTA Application(s) and Create New Event for Existing IND Application(s) > Select Products, Countries and IND Application Statuses 	The ability to create an application through the wizards to simplify the work of data creation.
		This field is now optional when selecting Global Project Plan > Create New Application Package Set Registration > Select Application Category, Product Family, Products and Countries	

Security Administration Tables

Security Administration Tables Updated: Ennov InSight 7.2.4

Security Administration tables, sections, or fields updated in Ennov InSight 7.2.4 release.

Security Administration Section: Application Country Rights

Entity Affected	Column/Field Name	Value List Description
Product Families	Access	This field is updated with the condition that if the access level to Product Families is NOT DEFINED in Application Country Rights, the applications without products and product families can be created from the Create Application, Create Submission > Initial Application wizards if only the NOT DEFINED option is set in Application Country Rights.

Queries

Query Fields and Columns Updated: Ennov InSight 7.2.4

The following table describes fields that were updated with Ennov InSight 7.2.4

Registration Planning and Tracking Queries

Table 74: List of CTA Applications

Field/Column Name	Field Type	Description
Product	Multi-select	This field is now changed to optional on the <i>List of CTA Applications</i> query page.

Table 75: List of IND Applications

Field/Column Name	Field Type	Description
Product	Multi-select	This field is now changed to optional on the <i>List of IND Applications</i> query page.

Ennov InSight 7.2.5 Release Notes

Ennov InSight 7.2.5 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 7.2.5.

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

Application Updates

Ennov InSight 7.2.5 release introduces the following Application updates:

- The ability to navigate from an application page to the specific product families with a new **Family Name** field.
- The ability to use the **Update Applications** wizard to update an application that does not have a product associated to it.
- Entities: Queries, Wizards.

Regulatory Updates

EAEU v1.0:

- The index-r-022.xml file now includes new checksum attributes to conform to EAEU v1.0 eCTD requirements.
- Publishing functionality is updated with the checksum information in index-r-022.xml for each document. The checksum attributes are removed for EAEU XML with embedded PDFs during the export and import of EAEU submissions.
- The Export Publish Output page is updated to get the copy of submission without checksums with the help of the XML without checksum option.

New in Ennov InSight 7.2.5: Common Functionality

This table shows new features and enhancements of Ennov InSight 7.2.5 functionality.

Affected Area	Update	Benefit
Wizards	The Update Applications wizard is updated to enable an application to be created without the need to associate a product. <i>See: Entity Fields and Columns Updated: Ennov InSight 7.2.5.</i>	The ability to create an application through the wizards to simplify the work of data creation.
Querying	To support the creation of an application without a product, Queries now include the applications with and without products. <i>See: Query Fields and Columns Updated: Ennov InSight 7.2.5</i>	Improved Querying capabilities with the updated data model enables simplified data creation.

New in Ennov InSight 7.2.5: Registrations

New features and enhancements for Registration functionality are listed below.

Affected Area	Update	Benefit
Entities/Entity tabs	Changes for Application now include: <ul style="list-style-type: none"> Entity updates: <ul style="list-style-type: none"> Application Attributes updates. See: <i>Entity Fields, Columns and Options Added: Ennov InSight 7.2.5</i> 	The ability to navigate to the specific product families from an application page.
Update Applications wizard	The Update Applications wizard fields are updated to enable an application without product to be updated. See: <i>Entity Fields, Columns and Options Updated: Ennov InSight 7.2.5</i>	The ability to create an application through the wizards to simplify data creation.

Resolved Issues: Ennov InSight 7.2.5

The following issues 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 hotfix before the release, the hotfix build number is included in the table.

Registrations

Issue	Build Number	Description
DE30204; [INC0229723]	N/A	Trying to associate 1000+ products to the Registration resulted in the "Invalid reference" error. This issue is resolved. Now, the products are associated successfully.
DE30162; [INC0226907]	N/A	Trying to view a Product Family with 25000+ products in the UI took longer than expected. This issue is resolved.
DE29739	N/A	Using Major Update or Amendment under Wizards > Create Submission for the applications without products resulted in an error. This issue is resolved. Now, these options work correctly for applications without products.
DE29738	N/A	When performing the API Post request, if Write access was set for Product Family/Product Rights , it was not possible to delete a product family without child entities. This issue is resolved. Now, product families can be successfully deleted.
DE29653; [INC0168860]	N/A	In a Registration, when the Full Product Presentation wizard was used to copy its attributes, the package description was duplicated. This issue is resolved.

Issue	Build Number	Description
DE29642	N/A	After entering the search criteria in the Update Applications wizard and clicking Next , the Select Applications page contained two rows for one application with discrepancy in the Region Type and Region values. This issue is resolved. Now, this page contains one row for one application.

Administration

Issue	Build Number	Description
DE28576	N/A	To retrieve results from the queries List of RMS Fields and List of OMS Fields , a DA List Name was required to be selected from the required field Associated DA List Name . This issue is resolved as the Associated DA List Name is no longer required. It is now possible to retrieve RMS and OMS values regardless of Data Administration list association.
DE28186; [TASK0042598]	N/A	After mapping SPOR Terms to Ennov InSight , RMS terms that had NULLIFIED or NON_CURRENT status were replicated. This issue is resolved. Now, RMS terms are not replicated if they have NULLIFIED or NON_CURRENT status.

Publisher

Issue	Build Number	Description
DE30161	N/A	After publishing the EAEU assembly and recalculating checksums, the <code>index-r-022.xml</code> file was generated in the <code>//filesystem/Folder1</code> location instead of <code>//filesystem/Folder1/Folder2</code> . The checksums were also not updated for the documents added to the assembly. This issue is resolved.
DE29791; [INC0088918]	N/A	When an EAEU submission was published after a leaf was deleted, the attributes CHECKSUMM and CHECK_ALG were included in the <code><hccd:RegistrationDossierDocDetails></code> element. This issue is resolved. Now, the CHECKSUMM and CHECK_ALG attributes are not included in the <code><hccd:RegistrationDossierDocDetails></code> element. Also, now in the <code>index-r-022.xml</code> file, the CHECKALG attribute is generated as CHECK_ALG .

Issue	Build Number	Description
DE29710; [INC0200183]	N/A	After publishing an assembly, the generated <code>stf.xml</code> files included incorrect links. This issue is resolved.
DE29656; [INC0184736]	N/A	Details of failed jobs were not displayed in the Job Requests query leading to extra effort in troubleshooting. This issue is resolved. Now, detailed information about failed jobs, along with the cause of the failure and document name where applicable, is displayed in the Job Requests .
DE29613; [INC0184045]	N/A	After publishing, xml output included incorrect Applicant ID phone number type. This issue is resolved.
DE29565; [INC0184222]	N/A	When a Japanese submission that included comma-separated values in the assembly was published, the fields Brand Name , Submission Type , Applicant , and Generic Name included in the xml output were incorrect. This issue is resolved. Now, all the fields mentioned above are included in the xml file correctly.
DE29387; [INC0163084, INC0206337]	N/A	After reusing and publishing US study reports content in EU dossier, the order of the tags in the <code>index.xml</code> output location was incorrect. This issue is resolved. Now, tags in the <code>index.xml</code> are generated correctly.
DE29359; [INC0160614]	N/A	After launching Job Requests operation, Job Status data did not correspond to the Job Requests Details , displaying incorrect or outdated information. This issue is resolved. Now, the statuses correspond to the Job Requests Details data, displaying a short summary of errors/warnings detected.
DE29280; [INC0145064]	N/A	<p>Adding the "/" (forward slash) character in assembly metadata resulted in the following issues after publishing.</p> <ul style="list-style-type: none"> — Empty attributes in published output XML for 2.3.P Leaf. — Missing galenic-name XML elements in the <code>ch-regional.xml</code> file. <p>Both issues are now resolved. Now, assembly metadata is published correctly even with the "/" (forward slash) character added.</p>

Issue	Build Number	Description
DE29276; [INC0124015]	N/A	Trying to modify the manufacturer with multiline value in the Address attribute resulted in an error. This issue is resolved.
DE29254	N/A	In an assembly with empty leafs, running the Recalculate checksum operation failed. This issue is resolved. Now, the Recalculate checksum operation completes.
DE29174; [INC0143854]	N/A	When importing an assembly with assigned source document from assembly file, the source location path in the Document Attributes window was not populated. This issue is resolved. Now, the source location displays the location path to the assigned source document.
DE28921; [INC0139947, INC0136904]	N/A	After replacing a PDF file in the output location and the recalculating checksum, the wrong checksum was displayed in the XML. This issue is resolved. Now, the correct checksum is displayed in the XML after recalculating the checksum.
DE28912; [INC0139930]	N/A	In two parallel submissions, a replaced leaf was not copied to a working assembly after synchronizing with the submitted view. This resulted in incorrect assembly structure. This issue is resolved. Now, the submitted view synchronization process works correctly and the assembly shows the correct structure.
DE28851; [INC0123232]	N/A	Group Submissions: In an Assembly Plan with multiple applications, when two folders containing leafs and a form were added for each application, the xml file displayed leaf elements under one application entry after publishing. This issue is resolved. Now, the xml file displays leaf elements under each application entry.

Issue	Build Number	Description
DE28846; [INC0127050]	N/A	<p>When publishing STF, the output STF XML file name was being normalized differently than the reference to the STF XML file name in the <code>index.xml</code> file. As a result, the link in the <code>index.xml</code> file to the output STF XML file was broken. Additionally, the normalization method used to create the STF XML file name was determined by the XML definition files assigned to the assembly in Publishing Settings and not the Assembly Type value that is used to determine how to normalize non-STF file names. This sub-minor release now uses the Assembly Type value to determine which normalization method to use for all output file names (including the STF XML file name) as it was in Ennov InSight 6.2. See Assembly Template Attributes.</p>
DE28730	N/A	<p>If assembly contains both target and reference leafs, output location was not populated for a reference leaf if the target leaf was replaced. This issue is resolved. Now, the output location path contains the correct value.</p>
DE28535; [INC0122230]	N/A	<p>Checksums were missing in the XML files in the following cases:</p> <ul style="list-style-type: none"> – JP regional XML: Checksums were missing after the first publish. A subsequent publish displayed the checksum values of the previous publish, not the current one. – EU regional XML: Checksums were missing for leafs with a relative output path (For example., <code>.././ctd-toc.pdf</code>). – Reference leafs: Checksum value was that of the target document when it was chosen as the reference leaf target and did not get updated with subsequent publishes. <p>These issues are resolved.</p>
DE28514, DE26746, DE26596; [INC0120502, CS0266424, INC0014091]	N/A	<p>In two parallel submissions, when a leaf was replaced along with the document under it, performing the synchronization process resulted in both the old and current documents displaying under the replaced leaf in the working view. This issue is resolved. Now, only the current document remains after synchronization.</p>

Issue	Build Number	Description
DE28427; [INC0102271]	N/A	API: It was not possible to update a PDS that was already assigned to a new <i>Event</i> . This issue is resolved. Now, a PDS can be updated even if it is already assigned to a new <i>Event</i> .
DE28390; [CS0562479; INC0091145]	N/A	Using the Enter key to separate values in the Concerned Parties field resulted in an extra tag generation that could be deleted only manually. This issue is resolved.

Ennov InSight 7.2 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.2 Release Notes (Cumulative)

Entity Fields

Entity Fields, Columns and Options Added: Ennov InSight 7.2.5

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

Entities

Application

Table 76: Application

Field/Column/Option Name	Field Type	Description	Business Rules
Family Name	Hyperlink	To navigate to specific product families from an application page, the <i>Application Attributes</i> page now includes the respective field.	Improves efficiency of data creation.

Entity Fields, Columns and Options Updated: Ennov InSight 7.2.5

The following tables describe fields that were modified in this release.

Update Applications

Field/Option Name	Field Type	Description	Business Rules
Products	Multi-select	This field is now optional when selecting Update Applications > Enter Applications Search Criteria .	The ability to create an application through the wizards to simplify data creation.

EAEU Submissions

Field/Option Name	Field Type	Entity Name	Description	Business Rules
Embed PDFs into EAEU XML?	Box	EAEU Output	This field is renamed to EAEU Output and updated to the list with the Embed PDFs and XML without checksum options on the <i>Export Published Output</i> page.	You can use EAEU Output to export EAEU submissions. See: <i>Ennov InSight Best Practice: EAEU Submissions</i> .

Queries

Query Fields and Columns Updated: Ennov InSight 7.2.5

The following table describes fields that were updated with Ennov InSight 7.2.5

Registration Planning and Tracking Queries

Table 77: List of Events with Application Properties

Field/Column Name	Field Type	Description
Application Name	Hyperlink	When you select the Family Name and Family Type on the query page, the <i>Search Results</i> page displays applications with or without products associated.

Table 78: List of Events with Change Details

Field/Column Name	Field Type	Description
Application Name	Hyperlink	When you select the Family Name and Family Type on the query page, the <i>Search Results</i> page displays applications with or without products associated.

Table 79: List of Sequences with Application and Event Properties

Field/Column Name	Field Type	Description
Application Name/Study Number	Hyperlink	When you select the Family Name and Family Type on the query page, the <i>Search Results</i> page displays applications with or without products associated.

Table 80: List of Application Countries with Registration Details

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> — Application Name — Application Code — Products 	Hyperlink	When you select the Family Name and Family Type on the query page, the <i>Search Results</i> page displays applications with or without products associated.

Table 81: List of Registrations with Application Properties

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> – Application Name – Application Products 	Hyperlink	When you select the Family Name and Family Type on the query page, the <i>Search Results</i> page displays registrations of applications with or without products associated.

Table 82: List of References - Rollup by Application

Field/Column Name	Field Type	Description
Reference Name	Hyperlink	When you select the Family Name , Family Type and Country on the query page, you can then select the applications with or without products associated. The <i>Search Results</i> page displays the appropriate reference.

Table 83: List of Tasks - Rollup by Application

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> – Task Name – Task Association 	Hyperlink	When you select the Family Name , Family Type and Country on the query page, you can then select the applications with or without products associated. The <i>Search Results</i> page displays the appropriate task.

Table 84: List of Registrations for a Product Family

Field/Column Name	Field Type	Description
Licence Code	Hyperlink	When you select the Family Name and Family Type on the query page, the <i>Search Results</i> page displays the registrations of applications with or without products associated.

Table 85: List of RMS Fields

Field/Column Name	Field Type	Description
Associated DA List Name	Multiselect, display	This field is updated to optional from required.

Table 86: List of OMS Fields

Field/Column Name	Field Type	Description
Associated DA List Name	Multiselect, display	This field is updated to optional from required.

Product Detail Management

Table 87: Application History Query

Field/Column Name	Field Type	Description
Event Name	Hyperlink	When you select the Family Name , Family Type and Country on the query page, you can then select the applications with or without products associated. The <i>Search Results</i> page displays the appropriate information.

Ennov InSight 7.2.6 Release Notes

Ennov InSight 7.2.6 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 7.2.6.

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

Secure File System Integration

Secure File System integration got enhanced security in response to the current client needs. It introduces:

- New auditing capabilities.
- All the components aligned in regards to configuration with a unified approach.

With these capabilities, you will now have the flexibility to work with remote file shares. The need to other tools for synchronizing the files share for distributed solutions is minimized.

OpenText Documentum Integration

To increase the efficiency and improve the collaboration between Documentum and Ennov InSight application, the following changes are introduced:

- DCTM Connector authentication mechanism is updated to use Single Sign On (SSO). With SSO you can access the requested resource using a single set of credentials.
- Ennov InSight is updated to save the credentials in secured vault. Credentials are no longer saved in the database.

New in Ennov InSight 7.2.6: Common Functionality

This table shows new features and enhancements of Ennov InSight 7.2 functionality.

Technical Administration

Affected Area	Update	Benefit
Technical Administration	<p>The authentication types Basic and oAuth are introduced in this release and can be used when creating or updating the repository in DMS Repository Management. These authentication types are used for the content from DMS repository for all the active Documentum Server types using SSO as well as existing authentication method. See:</p> <ul style="list-style-type: none"> — <i>Technical Administration Tables Added: Ennov InSight 7.2.6.</i> — <i>Ennov InSight Administration > Technical Administration > Add a Documentum Repository to Ennov InSight</i> — <i>Ennov InSight Administration > Technical Administration > Modifiable DMS Repository Attributes</i> 	To increase the efficiency and improve the collaboration between Documentum and Ennov InSight , the new options are added to the DMS Repository Management .
	<p>File System Server is now Secure File System. Secure File System Integration updates are introduced in this release.</p>	To align all the technology solutions related to DMS connectivity and comply security standards, Ennov InSight now supports the file system connectors.

New in Ennov InSight 7.2.6: Publishing

This table shows new features and enhancements of publishing functionality.

New features and enhancements for Publishing functionality are listed below.

Affected Area	Update	Benefit
Rendering 5.1	Rendering 5.1 will now work with docx TOC templates only. The doc TOC templates will not be supported starting with this release.	<ul style="list-style-type: none"> – Stability improvement. – Ability to run multiple Generate TOC requests concurrently on a Rendering single server without conflicts with rendering any Microsoft Word documents.

List of Enhancements: Ennov InSight 7.2.6

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

Ennov InSight

Issue	CHF/Hotfix Build	Description
DE26164; [PRB0041149, PTASK0010527]	N/A	When an Excel document failed to render, Ennov InSight did not stop the Excel process that sometimes led to performance issues. The system now automatically stops these stray processes.
2605	N/A	It is now possible to set up the path for temporary files on Ennov InSight servers to Azure. For the details contact your Business Development Representative.

Resolved Issues: Ennov InSight 7.2.6

The following issues 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 certified hotfix (CHF), that CHF build number is included.

Common

Issue	CHF/Hotfix Build	Description
DE29923; [INC0215705]	N/A	Trying to view list of products in <i>Application</i> window launched under <i>Product Family</i> took longer than expected. This issue is resolved.

Issue	CHF/Hotfix Build	Description
DE29756; [TASK0048010]	N/A	The cache storage for user role access (rolesAccessLevelCache) was restricted to 30 minutes. It is now possible to configure this parameter. It can be used to decrease server load in cases of large amount of users with complex security settings.

Administration

Issue	CHF/Hotfix Build	Description
DE30062; [INC0219608, TASK0049184]	N/A	<p>In the <i>SPOR Master Lists</i> section, all the values for the following RMS lists were not displayed:</p> <ul style="list-style-type: none"> – Anatomical Therapeutic Chemical Classification System - Human. – Medical Dictionary for Regulatory Activities. <p>This issue is resolved. Now, mentioned above RMS lists display values correctly.</p>

Rendering

Issue	CHF/Hotfix Build	Description
DE26170	5.0.1.1	SmartLinks in documents rendered by Documentum Content Transformation Services (CTS) were not present in the published output. This issue is resolved for Microsoft Office documents rendered by the CTS Doc6 plugin.
DE26166	N/A	<p>The links were not placed correctly when rendering the .xls spreadsheets:</p> <ul style="list-style-type: none"> – changing paper size from Letter to A4 and orientation from Portrait to Landscape – using Fit to 1 page and wide by with null tall. <p>The issue with changing paper size and orientation is resolved. For the Fit to pages and wide by tall, we recommend to use any positive value except null.</p>
DE26161; [INC0041743]	4.4.1.11	When publishing multiple documents with different signatures, the signatures from one document were incorrectly applied to another document. This issue is resolved.

Issue	CHF/Hotfix Build	Description
4998; [INC0037216]	4.4.1.11	Publishing a Veeva document larger than 2GB failed. This issue is resolved.
4997; [INC0038898]	4.4.1.11	The first character of a link was placed in a different link box in the PDF rendition when the Preserve Word Font Formatting option was not selected. This issue is resolved.
4980; [INC0023819]	4.4.1.11	Adobe Acrobat displayed a warning message saying that the page may not be displayed correctly when viewing a published document containing links created using Linking plug-in (PDF). This issue is resolved.

Ennov InSight 7.2 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.2 Release Notes (Cumulative)

Database Columns Changed: Ennov InSight 7.2.6

The following Database Columns were added, modified, or removed in this release.

Field Name	Field Size	Database Column Name	Database Column Size	Db Table Name
Repository User	N/A	USER_CODE	USER_CODE is deleted.	ODS.DMS_REPOSITORY
Repository Password	N/A	USER_PASSWORD	USER_PASSWORD is deleted.	ODS.DMS_REPOSITORY
D2 URL	N/A	DOMAIN	DOMAIN is deleted.	ODS.DMS_REPOSITORY

Technical Administration

Technical Administration Tables Added: Ennov InSight 7.2.6

Technical Administration tables, sections, or fields added in Ennov InSight 7.2 .6 release. These include the tables modified to support new types of authentication.

Technical Administration Section: DMS Repository Management

Entity Affected	Field/Column/Option Name	Value List Description
Repository	Authentication Type	The Basic and oAuth authentication types are introduced to enable access to Documentum repositories. These authentication types are available on the <i>Repositories</i> page for Documentum Server . You can access Ennov InSight using SSO or the existing authentication method.

Technical Administration Tables Updated: Ennov InSight 7.2.6

List of Technical Administration tables, sections, or fields updated in Ennov InSight 7.2.6 to comply to the latest requirements.

Technical Administration Section: DMS Server Management

Entity Affected	Field/Column/Option Name	Value List Description
DMS Server	File System Server	This option is deactivated in Technical Administration > DMS Server Management > Servers > Server Type field. FileSystem is Secure File System now.

Technical Administration Tables Removed: Ennov InSight 7.2.6

List of Technical Administration tables, sections, or fields removed in Ennov InSight 7.2.6 to comply to the latest requirements.

Technical Administration Section: DMS Repository Management

Entity Affected	Field/Column/Option Name	Value List Description
Repository	D2 URL	This field is removed from Technical Administration > DMS Repository Management > Repositories.

Ennov InSight 7.2.7 Release Notes

Ennov InSight 7.2.7 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 7.2.7.

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

Entity and Tabs Changes

Changes have been made to the following entities and tabs. See: *Entity Fields and Columns Updated : Ennov InSight 7.2.7*, *Data Administration Tables Updated: Ennov InSight 7.2.7*.

— Entities:

- Product Family (Substance Selection widget on the Modify Product Family page)
- Component Reference Active Ingredients (Substance Selection widget on the Create Component Reference Active Ingredients page)
- Registrations (Package Set Registration Attributes, Product Registration Attributes)
- Data Administration (Product Family Maintenance > Substance Values, Other > Certificate Master File Values)
- Wizards (Create Application Wizard)

Performance Improvements

In Ennov InSight 7.2.7, the performance is improved:

- For DMS synchronization and DMS search operations for the source documents stored in Documentum repository.
- For queries that include an association with application, application country, product and product family.

New in Ennov InSight 7.2.7: Registrations

This table shows new features and enhancements of Ennov InSight 7.2.7 functionality.

Affected Area	Update	Benefit
Create Application Wizard	The <i>Create Application Wizard</i> is updated to allow the creation of an application associated to the selected product family even if a product is not selected. See: <i>Entity Fields and Columns Added: Ennov InSight 7.2.7</i> .	The ability to create applications already associated to the product family.

Affected Area	Update	Benefit
Package Set Registrations	The <i>Package Set Registration Attributes</i> page is updated to retain ATC values even after Product deletion in Application unless a user manually deselects the ATC value from Registration. <i>See: Entity Fields and Columns Updated: Ennov InSight 7.2.7.</i>	The ability to select ATC values without association of a package set with a registration.
Product Registrations	The <i>Product Registration Attributes</i> page is updated to retain ATC values even after Product deletion in Application unless a user manually deselects the ATC value from Registration. <i>See: Entity Fields and Columns Updated: Ennov InSight 7.2.7.</i>	The ability to select ATC values without association of an event with a registration.

Resolved Issues: Ennov InSight 7.2.7

The following issues 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.

Common

Issue	Sub-Minor Build	Description
DE30966, [TASK0051648,INC0269896]	N/A	Trying to use API GET/orphan-designation/query and GET/orphan-designation/all endpoints to locate the orphan designation records resulted in an error. This issue is resolved. Now, both endpoints work correctly, and show the results based on your access rights.
DE30865; [INC0258628,TASK0051345]	N/A	When using a single API Post request to modify the event name and also close it, the request failed with an error message. This issue is resolved. Now, this request successfully updates and closes the event.
DE30677	N/A	Performance issue was experienced when loading the search results for the List of Events with Application Properties query. This issue is resolved. Now, the performance is improved.

Issue	Sub-Minor Build	Description
DE30616	N/A	Performance issue was experienced when saving changes to any product family. This issue is resolved. Now, the performance is improved.
DE30565; [INC0237879]	N/A	Ennov InSight failed to update the Location status in the SPOR Master Lists > Organization . This issue is resolved. Now, the Location status is correctly synchronized with EMA SPOR OMS.
DE30461; [TASK0049689,INC0230795]	N/A	To protect SPOR API from peaks in usage, EMA introduced an API request Rate Limiting Mechanism on July 12, 2023. As a result, the system failed to handle the following responses showing 403 error in the <code>server.log</code> file instead: <ul style="list-style-type: none"> — HTTP Status 429 (Too many requests) — HTTP Header Retry-After This issue is resolved. Now, the system successfully handles both responses showing <code>Get Rate Limit</code> from EMA API message in the <code>server.log</code> file.
DE30213	N/A	API: Trying to create a manufacturer using API resulted in the <code>Action is not supported</code> error. This issue is resolved. Now, the <code>Create</code> , <code>Deactivate</code> , <code>Update</code> , <code>Create-or-update</code> and <code>Read</code> operations are successfully executed for Manufacturer Values in <i>Data Administration</i> .
DE30083	N/A	Performance issue experienced when selecting some values in the Product Family Indication(s) or Product Family Comorbidity(s) fields on the <i>Modify Product Family</i> page is resolved. Now, you can successfully select the values without any lag.
DE30136; [INC0225022, INC0226510]	N/A	Performance issue was experienced when loading Registrations from the entities list on the Ennov InSight left pane. This issue is resolved. Now, performance is improved.

Publisher

Issue	Sub-Minor Build	Description
DE30983	N/A	In the Documentum repository, searching for a document without using search criteria in a folder that had more than 5000 documents resulted in Ennov InSight becoming unresponsive. This issue is resolved. Now, if you search without search criteria by mistake, the system responds accordingly.
DE30931	N/A	When trying to create an assembly, using an XML file that contained a path to a non-existent repository resulted in an error. This issue is resolved. Now, an assembly is created successfully and the path is removed.
DE30844	N/A	Performing DMS synchronization for a deleted document in working, publishing, or sequence assembly on the <i>Document Attributes</i> page showed UNASSIGNED value for Assignment Status . This issue is resolved. Now, the MISSING value appears for Assignment Status .
DE30733	N/A	During long-running operations such as DMS Synchronization, the 'UNAUTHORIZED' error appeared. This issue is resolved. Now, DMS Synchronization is completed without errors.
DE30662	N/A	When multiple users simultaneously searched for documents in the <i>DMS Browse</i> window to assign them from Documentum, the Invalid Reference error appeared occasionally. This issue is resolved. Now, the documents that match the search criteria appear.
DE30647	N/A	Using remote file share to publish resulted in the publish job request taking longer time to complete than expected. This issue is resolved. Now, publish job operation completes without delay.
DE30627	N/A	Using remote file share with a slow connection resulted in the delay in displaying fields for <i>Publish Request</i> . This issue is resolved. Now, the fields are displayed instantly.
DE30732	N/A	When creating an assembly template from an assembly file from Secure File System, selecting a file in the right pane and clicking OK in the <i>DMS Search Results</i> window results in the 'HTTP Status 404' error. This issue is resolved. Now, the window is closed without errors and the Assembly File field is populated with the correct path.

Issue	Sub-Minor Build	Description
DE30325; [TASK0049487, PRB0045018,CS0705806]	N/A	When an assembly in an application that does not have a product assigned is published, the variables in the assembly are not resolved in the output. This issue is resolved. Now, the IPT, IPN, IAN, IER, IEC, IEN, IAC, IAT, IET, ISC, ISD, ISF, ISN, ISS, IP1, ICN, IPC variables are resolved correctly.
DE29823; [INC0208226, PRB0045201]	N/A	<p>After performing the Recalculate Checksums operation, existing values in the following fields were not retained in the <i>Publish Request</i> window:</p> <ul style="list-style-type: none"> – Prepare to Publish – Single File Output Filename – Publish eCTD/Electronic – Include Leafs with Status <p>This issue is resolved. Now, all options are retained in the <i>Publish Request</i> window even after the checksums are recalculated.</p>

Registrations

Issue	Sub-Minor Build	Description
DE30858 [TASK0051282,INC0257893]	N/A	Trying to update a product family with an assigned ATC using API resulted in an error. This issue is resolved. Now, the endpoint successfully updates a product family with an assigned ATC.
DE30826	N/A	When a Product Registration is created via an API, the values for the MAH/Organization Last Updated and Registered ATC Last Updated fields are not displayed on the <i>Registration Attributes</i> page. This issue is resolved. Now, these values are successfully displayed on the <i>Registration Attributes</i> page after creating registration via API.
DE30685	N/A	When a package set was already associated to a registration, the Package Set Name field still showed the empty drop-down list on the <i>Associate Package Set</i> page. This issue is resolved. Now, the empty drop-down list do not appear for Package Set Name.

Issue	Sub-Minor Build	Description
DE30679	N/A	After an event with a PDS associated to it is closed with the Approved status, trying to reopen it using the <code>/event/update</code> API endpoint failed. This issue is resolved. This issue is resolved. Now, updating the event to Open status completes successfully.
DE30356; [INC0237172, TASK0050023]	N/A	After reassigning an Activity to a user, the API <code>POST/activity/assign/{activity_id}/{user_id}</code> endpoint failed both to update and to show user ID value. This issue is resolved. Now, the endpoint successfully updates and shows the user ID value.
DE30173; [INC0230687]	N/A	After a registration is created using the Application > Create Registration option and a package set is selected, running the <code>packageset-registration/update/packageset-registration/update</code> endpoint via an API fails. This issue is resolved. Now, the endpoint works correctly and shows all the Package Set updates for the Registration .
DE30069; [INC0221329, TASK0049242]	N/A	After creating a product family with at least one active ingredient, product and component, the <code>/product-family/update</code> endpoint failed to work via API. This issue is resolved. Now, the endpoint works correctly showing all the product family updates.
DE30065; [INC0221329]	N/A	For the Component ID field in the PDS entity, the <code>/product-family/product/component/query</code> endpoint failed to work via API and resulted in an error. This issue is resolved. Now, this endpoint works correctly and is available for users with appropriate access rights.
DE30027; [INC0221329]	N/A	The <code>detail/package-set/query</code> endpoint did not work via API for the Package Set PDS entity and resulted in an error. This issue is resolved. Now, the <code>detail/package-set/query</code> endpoint works correctly and is available for users with appropriate access rights.

Addendum 2. Certified on Ennov InSight 7.2.8

Issue	Sub-Minor Build	Description
DE31795	N/A	Missing indexes in the database caused performance issue when trying to save entities after editing. This issue is resolved. Run DB_update7_2_(7-8-9)_DE31795_0001.zip script in addition to the main scripts during the migration procedure. The additional script must be run after the main script. See <i>Ennov InSight Database Migration Details</i> .

Ennov InSight 7.2 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.2 Release Notes (Cumulative)

Entity Fields

Entity Fields, Columns and Options Added: Ennov InSight 7.2.7

Describes fields and columns that were added in this release including those that support the application updates.

Wizards

Table 88: Create Application Wizard

Field/Column/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Family Type – Family Name 	Drop-down list	The Create Application Wizard > Enter values for a new application page now includes the respective fields.	<p>The Family Name field displays the product families according to the type previously selected in the Family Type field.</p> <p>When the both fields are selected, the product selection widget lists the products from the product families selected in the Family Name field.</p>

Entity Fields and Columns Updated: Ennov InSight 7.2.7

The following describes fields and columns that are updated in Ennov InSight 7.2.7.

Product Family

Field/Column/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Substance Aliases – Substance Translations 	Selection widget	These columns are now visible in the selection widget for Active Ingredients on the <i>Modify Product Family</i> page. Both can be hidden via overrides.	Improves the usability of the application.

Component

Field/Column/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Substance Aliases – Substance Translations 	Selection widget	These columns are now visible in the selection widget for Reference Active Ingredient Name on the <i>Create Component Reference Active Ingredient</i> page. Both can be hidden via overrides.	Improves the usability of the application.

Registrations

Field/Column/Option Name	Field Type	Description	Business Rules
Registered ATC	Multi-select	For the <i>Package Set Registration Attributes</i> page, this field is updated to display the values available for selection without the mandatory Package Set association.	If application is associated to the product family, the Registered ATC values are now taken from the product family and not from the application product.
Registered ATC	Multi-select	For the <i>Product Registration Attributes</i> page, this field is updated to display the values available for selection without the mandatory Event association.	If application is associated to the product family, the Registered ATC values are now taken from the product family and not from the application product.

Data Administration Tables

Data Administration Tables Updated: Ennov InSight 7.2.7

Data Administration tables, sections, or fields updated in Ennov InSight 7.2.7. release.

Data Administration Section: Product Family Maintenance

Table 89: Substance Values

Entity Affected	Field Name	Description
Substance Values	<ul style="list-style-type: none"> – Substance Name – Alias Name – Compendial Designation/Source 	The Substance Aliases tab is now visible under <i>Substance Values</i> and can be hidden via overrides.
Substance Values	<ul style="list-style-type: none"> – Language – Translation Term – Last User Updated – Last Changed Date – Active Flag 	The Substance Translations tab is now visible under <i>Substance Values</i> and can be hidden via overrides.

Data Administration Section: Other

Table 90: Certificate Master Files

Field/Column/Option Name	Field Type	Description
<ul style="list-style-type: none"> – Substance Aliases – Substance Translations 	Selection widget	These columns are now visible for the Substance Reference field on the <i>Certificate Master File</i> and can be hidden via overrides.

Ennov InSight 7.2.8 Release Notes

Ennov InSight 7.2.8 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 7.2.8.

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

DaaS Updates

Ennov InSight 7.2.8 includes updated database schema. See: *Ennov InSight 7.2.8 Release Notes: DaaS Database Field and Columns Changed*.

Note: Links created in authoring mode via Linking plug-in (PDF)/Linking add-in(Word) and targeting documents in all supported file shares currently are not resolved in the published output. The same links created for documents in the Documentum as well as in-process and comment links are resolved as expected. This issue has already been documented before as DE30391. See: Ennov InSight 7.2.6 Release Notes, Known Issues

Resolved Issues: Ennov InSight 7.2.8

The following issues 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.

Common

Issue	Sub-Minor Build	Description
DE31074, [TASK0053554]	N/A	Trying to update a specific submission with applied overrides took longer time than expected. This issue is resolved. Now, the performance is improved.
DE31030, [INC0276375]	N/A	Trying to create a submission for an EU CTR application resulted in an error. This issue is resolved. Now, the submission is created successfully.

Issue	Sub-Minor Build	Description
DE31013, [INC0276375]	N/A	In some 7.2.x versions of Ennov InSight , an option used for internal testing was exposed. The Terminology System List option was displayed under Data Administration > SPOR Master Lists . This issue is resolved with the removal of the Terminology System List option.

Publisher

Issue	Sub-Minor Build	Description
DE31122	N/A	If file downloading was interrupted due to any technical issues, trying to download the same file later resulted in the <code>Invalid reference</code> error. This issue is resolved. Now, the file is downloaded successfully.
DE31057	N/A	The DMS search on a folder that contained around 1000 or more documents took longer than expected. This issue is resolved. The performance is improved.
DE30973	N/A	Publishing multiple assemblies at the same time resulted in the Job Status getting updated with a delay. This issue is resolved. Now, the delay is minimized.
DE30878	N/A	Performance issue was experienced when creating a working assembly in an application with 1000 sequences added to the life cycle and multiple nodes in the Submitted view. This issue is resolved. Now, performance is improved
DE29594	N/A	When a sequence with sequence code starting with the upper case P was created and the assembly was published, using Recalculating Checksum generates extra files in the output location. This issue is resolved. Now, Recalculating Checksum operation completes correctly and does not generate extra files.

Addendum 2. Certified on Ennov InSight 7.2.8

Issue	Sub-Minor Build	Description
DE31795	N/A	Missing indexes in the database caused performance issue when trying to save entities after editing. This issue is resolved. Run <code>DB_update7_2_(7-8-9)_DE31795_0001.zip</code> script in addition to the main scripts during the migration procedure. The additional script must be run after the main script. See <i>Ennov InSight Database Migration Details</i> .

Ennov InSight 7.2 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.2 Release Notes (Cumulative)

DaaS Database Fields and Columns Changed: Ennov InSight 7.2.8

The following DaaS Database fields or/and columns were added, modified, or removed in this release.

Field Name	Field Size	Database Column Name	Database Column Size	Database Table Name
Default Flag	N/A	N/A	N/A	The APP_PRODFAM table is updated to display the new Default Flag field. If a product family is assigned to an application this field shows YES value. Otherwise, the value NO is shown.

Ennov InSight 7.2.9 Release Notes

Ennov InSight 7.2.9 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 7.2.9.

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

Performance Improvements

In Global Project Plan wizard, performance is improved for the following flows:

- Create New Events Product Registration
- Create New Events Package Set Registration

Resolved Issues: Ennov InSight 7.2.9

The following issues 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.

Common

Issue	Sub-Minor Build	Description
DE31469, [INC0303021]	N/A	When using the <i>Global Project Plan</i> wizard, if more products were associated with a product family, it took longer time than expected to download applications on the <i>Select Application</i> page. This issue is resolved. Now, it takes lesser time to download the applications.
DE28565	N/A	The UCSampleTOCTemplate.docx template caused issues with fonts. This issue is resolved. Now, the two new TOC templates used for Chinese and Japanese writings are created without fonts that caused the font issue.

Publisher

Issue	Sub-Minor Build	Description
DE31352, [TASK0361714]	N/A	For submission with files of 1GB size or more, performing the Recalculate Checksums operation failed and Job Requests > Job Message displayed the <code>Query stopped responding</code> message. This issue is resolved. Now, for large submissions, the Recalculate Checksums operation completes as expected.
DE31334, [TASK0444686]	N/A	When Recalculate Checksums was performed on an assembly with 1000+ leafs, the Job Requests > Job Message query displayed the <code>Error: could not execute query</code> message. This issue is resolved. Now, the Recalculate Checksums operation completes correctly and the Job Message displays relevant information.
DE31322	N/A	Rendering of selected files could fail if a folder contained many files (approximately 80,000 or more). This issue is resolved. Now, for a file in the folder with many files rendering completes successfully.
DE31296, [TASK0373863]	N/A	When working with large assemblies, performing the Recalculate Checksums operation even on a single element timed out and failed. This issue is resolved. Now, the performance is improved, and the Recalculate Checksums operation is performed only on the files selected by the user.
DE31146	Assembly	When searching a document using the values of DMS Repository, Repository, Document Type, and Search Folders as search criteria, the DMS Search Results failed to show the keywords and other repeatable or custom attributes. This issue existed only for Documentum. This issue is resolved. Now, the DMS Search Results are displayed with values if they are added to the document searched.
DE30601	Assembly	When creating a TOC in an assembly using the <code>UCSampleTOCTemplate.docx</code> template, the Generate TOC jobs failed. This issue is resolved. Now, the template is updated and Generate TOC jobs complete successfully.

Addendum 2. Certified on Ennov InSight 7.2.8

Issue	Sub-Minor Build	Description
DE31795	N/A	Missing indexes in the database caused performance issue when trying to save entities after editing. This issue is resolved. Run <code>DB_update7_2_(7-8-9)_DE31795_0001.zip</code> script in addition to the main scripts during the migration procedure. The additional script must be run after the main script. See <i>Ennov InSight Database Migration Details</i> .

Ennov InSight 7.2 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.2 Release Notes (Cumulative)

Ennov InSight 7.2.10 Release Notes

Ennov InSight 7.2.10 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 7.2.10.

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

Regulatory Updates

Support for South Africa (ZA) eCTD Module 1 version 3.0.

Note: This functionality is for presentation purpose only. ZA 3.0 is not supported by the agency and therefore cannot be used for a submission as it won't be accepted.

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

- [Ennov InSight 7.2 Publisher > Submissions > Create eCTD Wizard > eCTD Attributes South Africa](#)
- [Ennov InSight 7.2 Publisher > Extension Type and Usage > Extension Type: Regional Folders > South Africa](#)
- [Ennov InSight 7.2 Publisher > Administrative Activity > Import eCTD Applications > Prepare for Bulk eCTD Import > ZA 3.0 Applications](#)
- [Ennov InSight 7.2 Administration > eCTD Codes > eCTD Filing Types for ZA](#)
- [Ennov InSight 7.2 Administration > eCTD Filing Types for ZA > eCTD Sub-Filing Types for ZA](#)
- [Ennov InSight 7.2 Administration > Assembly XML Specification > m1-za v. 3.0](#)

Resolved Issues: Ennov InSight 7.2.10

The following issues 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.

Common

Issue	Sub-Minor Build	Description
DE31815, [TASK0925392]	N/A	If Documentum Virtual Document (VD) with child elements was assigned to an assembly, the display order of assembly elements was not in the same order as in Documentum. This issue is resolved. Now, the assigned VD retains the original order defined in Documentum.
DE31799, [INC0321912, TASK0869957]	N/A	Trying to assign a virtual document using DMS Search resulted in a placeholder being displayed instead of the expected content. This issue is resolved. Now, a virtual document assigned using DMS Search is displayed correctly.

Addendum 1. Certified on Ennov InSight 7.2.8

Issue	Sub-Minor Build	Description
DE31757; [INC0321912, TASK0869957]	N/A	If the Documentum file names included invalid characters: <code>\\ : * ? \ " < > </code> , performing some actions in assembly resulted in an error. This issue is resolved. Invalid symbols in file names are now automatically deleted, and there are no errors when working with assembly.

Addendum 2. Certified on Ennov InSight 7.2.8

Issue	Sub-Minor Build	Description
DE31795	N/A	Missing indexes in the database caused performance issue when trying to save entities after editing. This issue is resolved. Run <code>DB_update7_2_(7-8-9)_DE31795_0001.zip</code> script in addition to the main scripts during the migration procedure. The additional script must be run after the main script. See <i>Ennov InSight Database Migration Details</i> .

Ennov InSight 7.2 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.2 Release Notes (Cumulative)

Data Administration Tables

Data Administration Sections Added: Ennov InSight 7.2 .10

The following Data Administration tables and/or sections were added for Ennov InSight 7.2.10.

Data Administration Section: Submission Maintenance

Table 91: Evaluation Pathway Values

Entity Affected	Field Name	Value List Description
Assembly	<ul style="list-style-type: none"> – Region – Applicable DTD/Schema – eCTD Code – Evaluation Pathway – Last User Updated – Last Changed Date – Active Flag 	To conform to the latest standards set by South African Health Products Regulatory Authority (SAHPRA), the <i>Evaluation Pathway Values</i> table is introduced.

Ennov InSight 7.2.11 Release Notes

Ennov InSight 7.2.11 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 7.2.11.

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

Support of Special Characters

Ennov InSight 7.2.11 supports the use of more special characters in Documentum and File system. *See: Ennov InSight Administration 7.2 > Special Characters.*

Regulatory Updates

Support for South Africa (ZA) eCTD Module 1 version 3.1.

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

- *Ennov InSight 7.2 Data Migration > Ennov InSight 7.2.11 Updates*
- *Ennov InSight 7.2 Publisher > Submissions > Create eCTD Wizard > eCTD Attributes South Africa*
- *Ennov InSight 7.2 Publisher > Extension Type and Usage > Extension Type: Regional Folders > South Africa*
- *Ennov InSight 7.2 Publisher > Administrative Activity > Import eCTD Applications > Prepare for Bulk eCTD Import > ZA 3.1 Applications*
- *Ennov InSight 7.2 Administration > eCTD Codes > eCTD Filing Types for ZA*
- *Ennov InSight 7.2 Administration > eCTD Filing Types for ZA > eCTD Sub-Filing Types for ZA*
- *Ennov InSight 7.2 Administration > Assembly XML Specification > m1-za v. 3.1*

Note: *As the South Africa (ZA) eCTD Module 1 version 3.0 is not accepted by SAHPRA, it is no longer supported in Ennov InSight .*

Resolved Issues: Ennov InSight 7.2.11

The following issues 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.

Common

Issue	Sub-Minor Build	Description
DE31877	N/A	For a Documentum Virtual Document (VD) assigned to an assembly, changes made to its structure (for example, adding a new child document) were not displayed after a VD was reassigned. This issue is resolved. Now, a VD structure correctly displays the changes after a VD is reassigned.

Ennov InSight 7.2 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.2 Release Notes (Cumulative)

Ennov InSight 7.2.12 Release Notes

Ennov InSight 7.2.12 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 7.2.12.

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

Regulatory Updates

Ennov InSight 7.2.12 now supports World Health Organization (WHO) v1.0.

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

- [Ennov InSight Data Migration 7.2 > Ennov InSight 7.2.12 Updates](#)
- [Ennov InSight Publisher 7.2 > Use eCTD Templates > eCTD Template Files](#)
- [Ennov InSight Publisher 7.2 > Submissions > eCTD Attributes World Health Organization](#)
- [Ennov InSight Publisher 7.2 > Extension Type and Usage > Extension Type: Regional Folders > WHO](#)
- [Ennov InSight Publisher 7.2 > Use eCTD Templates > Mapped eCTD Template Profiles](#)
- [Ennov InSight Publisher 7.2 > Extended Attributes Name, Type, and Version](#)
- [Ennov InSight Publisher 7.2 > Extension Types and Usage](#)
- [Ennov InSight Administration 7.2 > Data Administration > Data Administration Selection Lists: Submission Maintenance](#)
- [Ennov InSight Administration 7.2 > eCTD Codes > eCTD Codes for Filing Types > eCTD Filing Types for WHO](#)
- [Ennov InSight Administration 7.2 > eCTD Codes > eCTD Codes for Filing Types > eCTD Filing Types for WHO > eCTD Sub-Filing Types for WHO](#)
- [Ennov InSight Administration 7.2 > Assembly XML Specification > Groups of Extensions by Version and Country](#)
- [Ennov InSight Administration 7.2 > Assembly XML Specification > Folder Extensions > m1-who v.1.0](#)

Ennov InSight 7.2.12 now supports European Union (EU) v3.1 submissions.

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

- [Ennov InSight Publishing 7.2 > Use eCTD Templates > eCTD Template Files](#)
- [Ennov InSight Publishing 7.2 > Extended Attributes Name, Type, and Version](#)
- [Ennov InSight Administration 7.2 > Data Administration > Data Administration Selection Lists: Submission Maintenance](#)

- Ennov InSight Administration 7.2 > Administrative Activities > Import eCTD Applications > Prepare for Bulk eCTD Import
- Ennov InSight Administration 7.2 > eCTD Codes > eCTD Codes for Country Values
- Ennov InSight Administration 7.2 > eCTD Codes > eCTD Codes for Filing Types > eCTD Filing Types for EU
- Ennov InSight Administration 7.2 > eCTD Codes > eCTD Codes for Filing Types > eCTD Filing Types for EU > eCTD Sub-Filing Types for EU
- Ennov InSight Administration 7.2 > Assembly XML Specification > Groups of Extensions by Version and Country
- Ennov InSight Administration 7.2 > Assembly XML Specification > Folder Extensions > m1-additional > m1-additional v. 3.1
- Ennov InSight Administration 7.2 > Assembly XML Specification > Folder Extensions > envelope > envelope v. 3.1
- Ennov InSight Administration 7.2 > eu_module_1_country_specific_information > eu_module_1_country_specific_information v.3.1
- Ennov InSight Administration 7.2 > Folder Extensions > m1-responses > m1-responses v. 3.1
- Ennov InSight Administration 7.2 > Folder Extensions > m1-3-1-spc-label-pl > m1-3-1-spc-label-pl v. 3.1
- Ennov InSight Administration 7.2 > Administrative Activities > Manage eCTD and eCTD 4.0 Templates > eCTD Templates

Ennov InSight 7.2 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.2 Release Notes (Cumulative)

Ennov InSight 7.2.13 Release Notes

Ennov InSight 7.2.13 Release Notes

The Release Notes contain resolved issues, and any open issues or workarounds in this release of Ennov InSight 7.2.13.

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

Resolved Issues: Ennov InSight 7.2.13

The following issues 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.

Common

Issue	Sub-Minor Build	Description
DE31589	N/A	Veeva Single sign-on (SSO) authorization from DMS Browse failed to work and it was not possible to use the Veeva Vault content. This issue is resolved. Now, the Veeva Single sign-on (SSO) works correctly.
DE30866, [TASK0050835]	N/A	If the Veeva session was expired when using the Veeva Single sign-on (SSO) profile with a name that matched the Ennov InSight profile name, re-authorization was required to download a file assigned from Veeva DMS using the File View option. This issue is resolved. Now, if the Veeva session is expired when using the Veeva SSO profile with a name that matches the Ennov InSight profile name, Veeva re-authorization is not required to download the file using File Menu .

Issue	Sub-Minor Build	Description
DE26800, 26725, [INC0052690]	N/A	Ennov InSight sometimes failed to connect with the Veeva vault selected and instead established a connection with another Veeva vault if a user had more than one configured in the same domain. This issue is resolved. Now, Ennov InSight always establishes a connection with the selected vault.

Ennov InSight 7.2 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.2 Release Notes (Cumulative)

Clarification of Behavior: Ennov InSight 7.2

This section provides an explanation of functionality that may be interpreted as an issue, but is in fact working as designed.

Ennov InSight : Common

Issue	Affected Area	Description
N/A	N/A	After migrating to Ennov InSight 7.2, the following user settings are reset to default for the migrated users. <ul style="list-style-type: none"> – Assembly tree width – Product Details Set tree width – Home page side panels width and show/hide condition – Home page widgets show/hide condition – Columns width – Columns order – Columns sort order – Columns show/hide condition – DMS Browse window size
N/A	N/A	After migrating to Ennov InSight 7.2, Public or Private queries saved in the Ennov InSight 6.2 query list will not be available in the Ennov InSight 7.2 query list for the migrated and newly added users.
N/A	Assembly	Performing any actions from Ennov InSight 6.2 CHF 1 against a Veeva repository on limited release version 18R2.2 will result in an exception caused by an unexpected error response from Veeva Vault. If you experience this issue, please contact Veeva Support .
N/A	N/A	If you are using network security products to scan your local intranet hosts for vulnerabilities, be aware that these products have a specific scan used against a JBoss server at TCP/IP port AJP/8009. Scanning the Ennov InSight server with a network security product will cause an outage, requiring a restart. To avoid issues caused by network security scanning products, see <i>Firewall Rule for TCP_IP Port AJP_8009</i> in the Ennov InSight Installation Guide.

Issue	Affected Area	Description
26746	Application	In D2, the application_description attribute value is a concatenation of Application Code, and Application Name and separated by a hyphen. The application_description attribute value does not contain the Family Code. This is because of the decoupling of Product Family and Product from Application.
26740	N/A	With the value for user.device.limit set to 1 in the insight.var file, when a user is logged on to InSight on device one, logging on to a second device terminates the InSight session on device one. However, refreshing the page on device one displays the InSight Home page. This is because of the Azure SSO functionality.
26727	N/A	When a user is not included in the mapping list during the migration process, attempting to reassociate the user with a group can cause an “Invalid Reference” error. The error indicates the user profile is corrupted and Azure AD does not recognize it for synchronization.
26518; [INC0028282, CS0199557]	N/A	When using the Google Chrome or Microsoft Edge web browsers, selecting documents in the <i>Browse Documents > Assign Document</i> window sends the <i>Browse Documents</i> window to the background (behind the Assembly window), making a user activate the window for subsequent document assignment.
26418	N/A	Duplicating Browser Tabs: Prior to Ennov InSight 6.2 CHF 3, duplicating a browser tab of an active Ennov InSight session DID NOT require login for the duplicated session created on the new tab. From Ennov InSight 6.2 CHF 3 onward, duplicating a browser tab of an active Ennov InSight session WILL require login for the duplicated session created on the new tab.
24513	Assembly	When searching against a Veeva repository using DMS Search in Ennov InSight , an error may appear about exceeding the API calls limit. By default, Veeva Vault has an API burst limit of 2,000 API calls within a 5-minute period, and 100,000 API calls daily. These limits help to prevent runaway script scenarios (e.g. where the logic creates an infinite loop that continuously calls the Vault APIs). To request an increase to this limit, please contact Veeva Support .

Ennov InSight Publisher

Issue	Affected Area	Description
N/A	Assembly, Technical Administration	When an assembly is created from an assembly file, the locations included in the assembly file that do not match the repositories in Ennov InSight Technical Administration will not be saved.
DE32135	Assembly	After creating an EU 3.0.3 working assembly using Create eCTD wizard, when the eu-3-0-1 XML Definition is replaced with eu-3-1, the Submission Unit Type field cleared on the envelope\s attributes.
DE31682	Assembly	<p>When publishing, a file name or a server name or, a file path should not exceed the Windows file system limit, which is 260 characters.</p> <hr/> <p><i>Note: It is highly recommended to take into account the limit length of the file name from DMS. Otherwise, there may be issues because of the long file names. See Special Characters.</i></p> <hr/>
DE31596; [TASK0670199, INC0312539]	Assembly	<p>When the TOC is generated, the job fails with the following status: Error 400. The request is badly formed.</p> <p>Reason: the file name with a Unicode character is not allowed and therefore cannot be converted.</p> <p>Solution: Ennov InSight 7.2.9 has updated components to support these characters.</p>
DE30044	Assembly	Using a forward slash ("/") in the Report Number on the Folder Attributes page results in invalid published output in accordance to validation criteria 1884 and 1204.
DE28529	Data Administration (SPOR Master List)	For Ennov InSight 7.2, after the migrated build is installed, the values for the new SPOR Master Lists tables may not appear. This was determined to be a data setup error. This issue can be resolved by starting the synchronization process from the beginning. The architecture requires that the database and blob data are in sync and replacing a database or blob from another environment will cause issues.

Issue	Affected Area	Description
DE27968	Assembly	When the length of the output path exceeds the limit allowed by the operating system, publishing fails. This issue can be resolved by shortening the folder or leaf output names in assembly.
26732	Publishing Settings library	In Internet Explorer only, the <i>Link Inspector</i> report page is not refreshed when Edit Link Output Channel is performed. The change is reflected after clicking the Refresh button in the report. The <i>Link Inspector</i> report page refreshes as expected in Microsoft Edge or Google Chrome.

Known Issues

The following general issues and module-specific issues were known at the time this document was published, but (due to time limitations) could not be included in the module-specific user documentation packaged with the software product.

Ennov InSight : Common

Issue	Affected Area	Description
DE32075 (Added on the 29th of September, 2024)	Application	Without the NOT DEFINED Country rights, trying to delete an application that has a submission in the lifecycle results in an error message.
DE31898 (Added on the 28th of August, 2024)	Reference Links	If a Documentum folder has two documents with the same name and one of these documents have more than one version, creating a reference to this document results in the reference created to the document with only one version.
DE31882 (Added on the 29th of August, 2024)	Assembly	Trying to rename a document previously assigned to an assembly results in a new name not being displayed in the leaf after a document is reassigned.
DE31854 (Added on the 25th of July, 2024)	Queries	<p>When using <i>Application History Query</i> or <i>Application QC Status History Report</i> to track changes for a pharmaceutical product family, the following columns display blank spaces if selected:</p> <ul style="list-style-type: none"> — Label Details Changed? (for <i>Application History Query</i>) — Label Details QC Passed? (for <i>Application QC Status History Report</i>) <p>Expected: Both columns display relevant information.</p>

Issue	Affected Area	Description
DE31817 (Added on the 11th of July, 2024)	Technical Administration	<p>Trying to edit the <i>Repository</i> page without user authentication resulted in the following error message: Resource key not found in default bundle.</p> <p>Expected: The <i>Repository</i> page displays the Please authenticate user in Technical Administration warning message.</p>
DE31589 (Added on the 28th of May, 2024)	DMS Browse, Technical Administration	Veeva Single sign-on (SSO) authorization from DMS Browse fails to work and therefore it is not possible to use the Veeva Vault content.
DE31047 (Added on the 22th of January, 2024)	Queries	Performance issue is experienced when loading the search results for the List of Registrations with Application Properties query.
DE31029 (Added on the 10th of January, 2024)	Orphan Designation	Trying to update orphan designation containing at least one active indication via API <code>/orphan-designation/update</code> endpoint results in an error.
DE31016 (Added on the 8th of January, 2024)	Orphan Designation	If an application did not have the MAA type selected and was not assigned to EMA countries, using the <code>/orphan-designation/create</code> endpoint via an API results in an orphan designation created rather than an error being displayed.
DE31013 (Added on the 5th of December, 2023)	Administration	In some 7.2.x versions of Ennov InSight the <i>Terminology System List</i> option is displayed under Data Administration > SPOR Master Lists . Expected: This option should not be present.
DE30929 (Added on the 7th of November, 2022)	Administration	When creating a new repository with the Basic Authentication Type , entering an incorrect repository name results in an invalid reference error instead of the user-friendly error message.

Issue	Affected Area	Description
DE30467 (Added on the 15th of August, 2022)	Administration	The following operations do not work correctly for the Authentication Type column under Technical Administration > DMS Repository Management > Repositories : <ul style="list-style-type: none"> — Sorting — Export to Excel — Changing column order
DE29048 (Added on the 23rd of December, 2022)	Notifications wizard	The Send to Concerned Parties option includes the Application and Product Family values on the Application Attributes > Notifications > Mail Settings page. This option should display Application only as there is no dependency on Product Family.
DE28641 (Added on the 20th of October, 2022)	Application, Products	When all the products are disassociated on the Application Attributes page, the system allows disassociation. No warning messages informing that at least one product should be associated to the application is displayed.
DE27749 (Added on the 19th of April, 2022)	Application, Country	For individual users, when the Application Country Rights for Product Families is set to All and Countries is set to any rights, navigating to a county from the Application Attributes > Countries tab results in an error. Workaround: Set the Application Country Rights for Product Families and Countries to All .
DE27309 (Added on the 12th of January, 2022)	Update Product Details Sets, PDS, Substance	When you select Global Project Plan > Modify Substance or Add Substance from Project Attributes page for the Update Product Details Sets project type, not all the fields are displayed in comparison to the Substance page in PDS .
26814	Publishing	Using Prepare for Publishing with the Prepare Cross Reference Leafs option selected results in the <code>Unable to extract checksum</code> error if there is a reference leaf to leaf published to Documentum.

Issue	Affected Area	Description
26807 (Added on the 20th Aug 2021)	Assembly	When updating a leaf in an assembly, selecting OnLoad for the Actuate option results in an error message. This is because of the default security settings. Workaround: Update the leaf using API.
26799	eCTD Import	After you use the Bulk eCTD Import for TW submission, the Job Status is set to Scheduled instead of Completed . This is because the <code>tw-regional.xml</code> file does not contain the application code. Workaround: Use Import eCTD to Application instead of Bulk eCTD Import . See: <i>Import eCTD to Application</i> .
26728	Global Project Plan wizard, PDS	In the <i>Global Project Plan</i> wizard, when modifying an active ingredient for a PDS the Withdraw Material that is already selected is not shown in the drop-down list.
26699	Assembly	Ennov InSight can incorrectly send a Native .PDF file to for extraction. Also, while a large file can fail extraction, it might not prevent successful publishing.
26637; [INC0045216]	Administration	In Data Administration, the Check for Date-based Notifications menu is not available on the Notification Specifications grid.

Ennov InSight Publisher

Issue	Affected Area	Description
DE32241 [INC0362790] (Added on 21st of November, 2024)	Publishing	To conform to the regulatory requirements, Ennov InSight removes non-latin characters from a folder name. Such folder name can result from the metadata value. For example, Excipient. If the folder name is empty, the published output path contains double slashes.
DE32034 (Added on 17th of September, 2024)	Assembly	Publishing a ZA v3.1 assembly with study reports by default has outdated version of valid values. To use the correct version, replace STF-2-2 with STF-2-2-5-0 in Publishing Settings Library for the assembly you want to publish.

Issue	Affected Area	Description
DE31961 (Added on the 21st of August, 2024)	Assembly	When a document is assigned from the Secure File System and then the Extract Document Data job is performed, editing the document from the Secure File System and performing the DMS Synchronization results in the creation of two Extract Document Data jobs.
DE31940 (Added on the 16th of August, 2024)	Assembly	Searching for a document to assign using Build Query results in an error. Workaround: Form a search request without Build Query option.
DE31934 (Added on the 14th of August, 2024)	Assembly	After the subsequent volume is inserted into the assembly folder or deleted, the previous volume name changes to the default one. Workaround: Update volume names manually.
DE31925 (Added on the 28th of August, 2024)	Create eCTD wizard	On some systems it takes longer than expected to create new folders using the Create eCTD wizard. Workaround: Create a folder manually or wait for a wizard to complete the folder creation.
DE31893 (Added on the 29th of August, 2024)	Assembly	When publishing assembly that contains folders with Node-Extension selected using the All Leaf and XML option, node extensions are generated in incorrect order causing validation errors.
DE31551 (Added on the 2nd of May, 2024)	Publishing	Using the Recalculate Checksums option on a published eCTD assembly that contains a period in the Application Code value generates extra files in the output location instead of updating the existing ones.

Issue	Affected Area	Description
DE31468 (Added on the 10th of April, 2024)	Assembly	<p>In a sequence assembly, if you try to perform the Recalculate Checksums operation for an updated output document more than once in a short span of time, the operation fails and results in an error on the <i>Assembly Attributes</i> page. The same issue exists for DMS Synchronization. If you run DMS Synchronization for a selected output document more than once in a short span of time, the Bound Version field fails to be updated.</p> <p>Workaround for both issues: wait for 3 minutes and try again.</p>
DE31357 (Added on the 14th of May, 2024)	Publishing	<p>Performing a task that includes downloading multiple files using the same source file may result in an error.</p> <p>Workaround: Try performing the task again.</p>
DE31130 (Added on the 16th of January, 2024)	Assembly	<p>Creating an in-process link in an assembly for the second time results in the document not opening in Adobe Acrobat or in Linking plug-in (PDF).</p> <p>Workaround: Log on to the Ennov InSight again and create an in-process link in the assembly.</p>
DE31040 (Added on the 11th of December, 2023)	Assembly	<p>If a document in Documentum repository has the <code>keywords</code> attributes populated and you search for it using Build Query, the additional redundant entries appear in DMS Search Results.</p> <p>Expected: If Build Query is used, the redundant entries should not appear in DMS Search Results.</p>

Issue	Affected Area	Description
DE30948	Assembly	When an assembly has a reference location to a folder in the Documentum repository, the Remove Submissions from Lifecycle to this Sequence option does not work. The Remove Sequences from Lifecycle job displays the Started status but submissions are not removed from the lifecycle.
DE30885 (Added on the 24th of October, 2023)	Assembly	When a custom attribute selected in Build Query does not belong to the selected Document Type value, searching for a document using Build Query results shows complicated error messages in DMS Search Results instead of the user-friendly error message.
DE30649 (Added on the 7th of September, 2023)	Assembly	Using a folder, that includes unicode symbols in the name, for the In-Process Rendition Location on the <i>Edit Publishing Settings</i> results in the 400 BAD_REQUEST Unable to set an invalid name for DocRefId error.
DE30647 (Added on the 12th of September, 2023)	Assembly	Using external SMB fileshare to publish eCTD XML and leaf elements results in the distribute job request taking longer time to complete than expected.
DE30630 (Added on the 4th of September, 2023)	Assembly	Trying to export published elements from source to destination for an assembly containing over 2000 items results in an error message. This issue exists for Documentum only.
DE30628 (Added on the 4th of September, 2023)	Assembly	After assigning a PDF document to the assembly folder, a new leaf is created automatically and the PDF Exists field on the <i>Document Attributes</i> page shows the value No . This issue does not occur when you assign a PDF document to an existing leaf.
DE30625 (Added on the 4th of September, 2023)	Assembly	When assigning a folder with 2000+ documents to the Working Assembly and then sending Publish Request using Prepare to Publish with Generate Missing Extractions and Renditions option selected, the publish assembly job fails after a long time.

Issue	Affected Area	Description
DE30593 (Added on the 31th of August, 2023)	Assembly	The attempt to create an assembly from the XML file with the specific metadata populated for Module1 in US Module1 v3.3 fails showing the <code>You do not have the appropriate privileges to access the requested resource</code> error message.
DE30589 (Added on the 31th of August, 2023)	Assembly	After performing Publish Request for an assembly with a native leaf containing a Veeva document, the retrieve job fails. It happens for both viewable and standard rendition types selected as Default Rendition Identifier .
DE30585 (Added on the 29th of August, 2023)	Assembly	After performing Publish Request > Publish to a Single File with Prepare to Publish , the TOC render job fails for an assembly with an assigned root TOC.
DE30581 (Added on the 29th of August, 2023)	Assembly	Sending two publishing jobs for the same assembly or modifying the assembly tree during the incomplete publishing process could result in the <code>Unable to obtain lock in 60 seconds</code> database error message.
DE30571 (Added on the 28th of August, 2023)	Assembly	After performing Publish Request with Append Application and Sequence Number , and then renaming the folder which name corresponds to the Application Code , the next published output goes to that renamed folder. Expected: A new folder must be created, and published output must be located there.
DE30569 (Added on the 28th of August, 2023)	Assembly	Assigning a folder with 2000+ documents to the Working Assembly takes longer than expected.
DE30547 (Added on the 24th of August, 2023)	Assembly	When creating a standalone assembly, if you have limited permissions to the Documentum location, selecting a value for Reference Location and clicking Create results in the invalid reference error instead of an insufficient permissions message. Workaround: Use cabinet or folder that you have required permissions to.

Issue	Affected Area	Description
DE30536 (Added on the 23rd of August, 2023)	Assembly	In DMS Browse , if you expand and collapse and then try to expand again a file system folder containing about 5000-10,000 items, the loading icon will not appear for some time. Workaround: Wait a little after the attempt to expand the folder with many items.
DE30521 (Added on the 22th of August, 2023)	Assembly	The Documentum folder path, selected before the token is revoked from the Technical Administration , is retained in the cache and allows the creation of new links for Electronic Output Location, Paper Output Location, Auxiliary Output Location, and Reference Location . Expected: A message to authenticate the user must be displayed. You can observe this activity until performing an action that requires cache refresh. For example, if you expand a folder that was not expanded before.
DE30519 (Added on the 1st of September, 2023)	Assembly	Trying to assign a folder containing 2000 items from Documentum to a folder in the Working Assembly fails and results in the 504 timeout error message.
DE30515 (Added on the 18th of August, 2023)	Assembly	In an assembly, if a user selects a folder with limited access in the Electronic Output Location field, the attempt to save changes results in the 404 error instead of the user-friendly error message.
DE30514 (Added on the 18th of August, 2023)	Assembly	When exporting an assembly, trying to overwrite the existing read-only assembly file results in a non-informative message instead of an insufficient permissions message.

Issue	Affected Area	Description
DE30489 (Added on the 17th of August, 2023); DE28570 (Added on 22nd of April, 2022)	Administration, Assembly	<p>After changing the repository user details in Technical Administration, the session of the previous user is still used. For example, a document can be assigned to an assembly successfully until the user selects a new location or session expires.</p> <p>Workaround: After changing the repository user details in Technical Administration, restart the server.</p>
DE30391 (Added on the 7th of August, 2023)	Administration, Assembly, Rendering	<p>Links created with Linking plug-in (PDF) or Linking add-in (Word) do not work with the enhanced Secured File System of Ennov InSight when the document is assigned and Run Link Inspector is performed.</p>
DE27966 (Added on the 1st of June, 2022)	Assembly	<p>The published output files are not exported to Documentum repository if they have Chinese characters in the file name.</p> <p>Workaround: rename files as per eCTD normalization rules before exporting output.</p>
DE27958 (Added on the 1st of June, 2022)	Assembly	<p>After publishing the China assembly, China symbols are present in the name of the STF file. For example: stf- 4.2.1.1 □效学.xml</p> <p>Workaround: rename files as per eCTD normalization rules before exporting output.</p>
DE26695, [INC0034585] (Added on the 29th of January, 2024)	Assembly	<p>When performing DMS synchronization, the throbber icon (used to represent a process in progress) and a pop-up window appear on the screen. The throbber icon disappears after sometime while the pop-up window continues to stay on the screen and does not close automatically.</p> <p>Workaround: log on to DMS and perform the operation again. Wait for the icon to disappear and close the pop-up window manually.</p>

Issue	Affected Area	Description
25259; [00052856]	Create eCTD wizard	When modifying Applicant Contact Values for M1 in a US 3-3 assembly, if you Deselect a value it does not re-appear in the selection box. As a workaround, you must save an entry with other contact values and then edit M1 again and select the Applicant Contact Value .
25084; [00051037, 00052759, 00056925, 00058862]	Assembly	Deleting large applications or removing multiple sequences from a lifecycle can take much longer than expected to produce results.
20270; [136797FW]	Assembly	Links for External Bookmarks are incorrect for split documents in paper published output.

Ennov InSight Registrations

Issue	Affected Area	Description
DE32198 (Added on 28th October 2024)	Application	For a WHO country application, the UUID is absent on the Application Attributes page.
DE30517 (Added on the 18th of August, 2023)	Registration Attachment	When you do not have appropriate access to a file, clicking the Attachment Link value on the Registration Attachment Attributes page results in the invalid reference error instead of the insufficient permissions error message.
DE30516 (Added on the 18th of August, 2023)	Registration Attachment	When you add a file you do not have access to as a registration attachment, the 404 error message for insufficient permissions is displayed.
DE30157	Registration Attachment	DCTM SSO: If a user is authenticated to a Documentum repository and if the token is revoked, trying to open a registration attachment from Registration Attachment > Attachment Name results in an Invalid reference error.

Issue	Affected Area	Description
26821	Update Application wizard	Trying to update the UUID field in the <i>Update Application</i> wizard resulted in the <code>MetaField [submittorId] does not exist in MetaClass</code> error message. This issue exists for the for the Applications of MAA type with the EU CTR Procedure type and will be resolved in Ennov InSight 7.2. Workaround: Update the UUID field using <i>Edit on Application Attributes</i> page.
26818	Global Project Plan wizard	When you run the <i>Global Project Plan</i> wizard for the Clinical Trial Project Type with the Create New Event for Existing CTA and/or IND Application(s) option and get to <i>Select CT Shared Data</i> , select a value and click Next , it takes a long time to proceed further. This performance issue will be resolved in Ennov InSight 7.2. Workaround: Wait for the wizard to proceed.

Ennov InSight Outlook add-in

Issue	Affected Area	Description
DE26820	Outlook add-in form	You cannot attach the following items from an e-mail in the add-in forms: <ul style="list-style-type: none"> — Contact - .vcf — Calendar (Event) - .ics — Outlook e-mails - e-mails without an extension (e-mail chain, single e-mail, and composed e-mail)
DE26804	Outlook add-in form	When using the API GET request for retrieving the recipients from Microsoft Graph, if the search criteria contains a space, the following error is shown: <code>500 Internal Server Error</code>
DE26803	Outlook add-in form	In the Add Notification Recipients field, it is not possible to delete any spaces.
DE26782	Outlook add-in form	If more than 50 users try to submit a form, the system fails and an error is displayed.

Issue	Affected Area	Description
DE26781	Outlook add-in form	When an API request with invalid product id is sent for CreateSubmissionAndReference, an incorrect error message is displayed.
DE26738	Outlook add-in form	If Ennov InSight Outlook add-in fails to submit the forms, an incorrect error message is displayed.
DE26731	Outlook add-in form	An auto-populate functionality does not work for the Product field in the Ennov InSight Outlook add-in forms if the product name starts with an article. Example: "The Product 01", "A Product 123" In the Ennov InSight Outlook add-in forms, the auto populate does not work for product unless more than 3 characters are typed.
DE26715	Tool Box and Activity History	When using the Ennov InSight Outlook add-in desktop version on Windows 10, version 2004 and Outlook version 1908, it is not possible to click the Export button on the <i>Activity History Analysis</i> page.
DE26711	Add-in meta overrides	Trying to change the Ennov InSight Outlook add-in icon takes longer time than expected.
DE26704	Outlook add-in form	Empty text files cannot be attached using the Browse File button.
DE26703	Add-in meta overrides	In the Ennov InSight Outlook add-in desktop version, even after restarting the Microsoft 365 Outlook, the system fails to override the "Liquent InSight" launch icon.
DE26702	Outlook add-in form	When trying to attach the files for the Ennov InSight Outlook add-in forms, ToolTips are not displayed for the following: <ul style="list-style-type: none"> — Attach from email button — Browse files button — "No available items to attach" Tooltip when all the attachments are already attached

Ennov InSight Rendering

Issue	Affected Area	Description
DE31457 (Added on the 14th of May, 2024)	Assembly	<p>The following error messages may be displayed in the Prepare to publish job when trying to simultaneously generate and render TOC more than once within a short period of time:</p> <ul style="list-style-type: none"> — Resource not found — Unable to get rendition. <p>Workaround: Generate TOC separately or via the Prepare to Publish option and wait for at least 3 minutes before rendering TOC again.</p>
DE31028 (Added on the 7th of December, 2023)	Assembly	<p>Publishing the submission containing the same large file in several places results in an internal server error (status 500) message and the job fails.</p> <p>Workaround: Use incremental publishing with fewer number of large files for each publish request.</p>
DE26968 (Added on the 23rd of December, 2021)	Assembly	<p>The assembly files cannot be published to Documentum if their size is 800 mb and more. The distribute job request fails.</p> <p>Workaround: Ensure that the size of the assembly files is less than 800 mb.</p>
DE28324; [TASK0043134, INC0109855] (Added on the 12th of August, 2022)	Assembly	<p>Publishing to some printers may result in tab text misplacement.</p>
DE26794	Assembly	<p>When eCTD assembly is published, the validation messages from the backbone generator are not displayed in Job Requests Details.</p>

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