



Ennov InSight 7.3 Release Notes Cumulative

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Chapter 1. Ennov InSight 7.3 Release Notes Cumulative



Ennov InSight RIM 7.3 Release

Notes Cumulative

Contents

Chapter 2. Ennov InSight 7.3 Release Notes

Ennov InSight 7.3 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 7.3.

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

Note: *Unless stated otherwise, this release provides the same functionality and regulatory updates as Ennov InSight 7.2.7.*

eCTD 4.0

Ennov InSight introduces a new functionality to maintain a new eCTD 4.0 standard that contains a new harmonized submission unit, updated document reuse capability, and context of use life cycle. For full details, see [Ennov InSight 7.3 Publishing: eCTD 4.0](#). The high level list of updates is below:

- The creation and maintenance of eCTD 4.0 submissions structure across the life cycle of the application. – The Create, Read, Update and Delete (CRUD) operation on eCTD 4.0 assembly as well as its nodes. – Electronic publishing related functionality updated.
- Changes to the following:
 - assembly, folders, leaf attributes
 - publishing settings library
 - prepare to publish
 - publish request
- Priority number management – New Modified Leaf field view
- Ability to quickly and easily incorporate regulatory agencies provided controlled vocabularies for future eCTD 4.0 specification updates.
- The XML import and export of eCTD 4.0 assemblies.
- Setting and reflecting priority for siblings under one parent.
- Context of Use definition for specified elements: Group titles, study group orders supported according to Health Authority specifications.
- New Regional Information page for eCTD 4.0 assembly root and Additional Information page for eCTD 4.0 assembly folder to set up Context of Use attributes and assembly regional attributes.
- The applicant contact type has been updated in Data Administration for eCTD 4.0.

- Applicant contact maintenance for eCTD 4.0.
- Same document reuse in several places.
- Sender-defined keywords maintenance to get better quality of the data entered.
- Tracking the long-running processes in Job Requests:
 - Add Assembly to Lifecycle
 - Remove Assembly from Lifecycle
 - Duplicate (of large folder)
 - Creating assembly
- Process of duplicating a folder. If the number of folder and child nodes exceeds the allowed limit, using the Duplicate option displays a message to see Job Requests for the status.
- Process of creating an assembly from another assembly. If the number of folder and child nodes exceeds the allowed limit, a message to see Job Requests for the status is displayed.
- Performance improvement. Duplicating folder with documents takes less time now.

Entity and Tabs Changes

To conform to the eCTD 4.0 requirements, changes have been made to the following entities: See: *Entity Fields and Columns Added: Ennov InSight 7.3, Entity Fields and Columns Updated: Ennov InSight 7.3*

- Entities:
 - Application updates (Application Attributes, Sender-defined Keywords).
 - Sequence updates (Sequence Attributes).
 - Wizards updates.
 - Product Family updates (Product Family Attributes, Application tab).
 - Data Administration updates.

IDMP Updates

For full details, see [Ennov InSight 7.3 IDMP](#). The high level list of updates is below:

Note:

— *IDMP Data Generation, IDMP Data Visualization, IDMP Validation in Job Requests and FHIR message are implemented as Proof of Concept (POC). They will be expanded with additional functionality and features in the next releases of Ennov InSight .*

— *Current IDMP Data Generation, IDMP Data Visualization, IDMP Validation in Job Request and FHIR message are for EMA authority only. This IDMP functionality will be expanded for other authorities in the next releases.*

— *The final implementation of IDMP Data Generation and Data Visualization will be available in future Ennov InSight releases.*

When available, remember to restart the IDMP Data Generation wizard for each medicinal product action entity to get the results for the IDMP Data Visualization page and validation messages in Job Requests.

To maintain a standardized and structured method of collecting, reporting, coding, and evaluating authorized medicinal product data, Ennov InSight 7.3 includes updates to the following:

— Entities:

- Medicinal Product Action (Attached Documents) updates.
- Manufactured Item (under Components) updates.
- PDS (Medical Devices, Package Set, Intended Effect/Comorbidity) updates.
- Data Administration updates.
- Security Administration updates. — IDMP Data Visualization:
- The DV (Data Visualization) icon is now available on the *Medicinal Product Actions Attributes* page.
- Data Visualization includes the color coding. — Wizards:
- IDMP Data Generation wizard
- Ennov InSight now generates data in FHIR (Fast Healthcare Interoperability Resources) standard. Ennov InSight supports FHIR version 5.0.

— Versioning:

- Updates to IDMP entities are now tracked in versions.

— Job Requests updates for IDMP Data Generation in Job Requests > Search Results.

Referentials Management Services (RMS) for IDMP

The Referentials Management Services (RMS) updates for entities and Data Administration are introduced to capture additional RMS data for IDMP. The RMS for IDMP includes description for attributes of medicinal products, such as lists of dosage forms, units of measurement and routes of administration.

XEVMPD Submission Wizard

In Ennov InSight 7.3, some XEVMPD Submission wizard sections were removed to conform to the EMA specification for XEVMPD. **Regulatory Updates**

To support the Structured Product Labeling (SPL) for Risk Evaluation and Mitigation Strategies (REMS) in the US for eCTD 3.3, the US 3.3 assembly template is updated to include additional folders and leafs.

Assembly Updates

Ennov InSight introduces the ability to track the download process of big files in Job Requests. When clicking View File and the file size exceeds the limit, the message is displayed asking to check the Job Requests for a download status.

Ennov InSight now displays the job progress in Job Requests for the following:

- Downloading of large files. If the file size exceeds the allowed limit, using the View File option displays a message to see Job Requests for download status.

Performance Improvements

The performance related to application and products query reports is improved.

Substance Search

The improved *Substance Search* selection widget included for the following entities allows you to search for a substance to associate it with an entity. You can search by EV Code and Substance name. – Product Family

- Product (Component > Reference Active Ingredient)
- Manufactured Item (Component> Manufactured Item> Substance and Reference Substance)
- Comparator
- Pharmaceutical Product (Substance and Reference Substance)
- Product Detail Set and Product Detail Set Template (Substance and Reference Strain)
- Data Administration (Manufacturer Values > Global Product Details, Other > Certificate Master File Values) – Wizards (GPP > Update Product Detail Sets)

See: *Get Started with Ennov InSight 7.3 > Substance Search*. **Functionality and Technology Not Supported**

In preparation to capture Substance Management Services (SMS) data for IDMP, the framework was implemented in earlier Ennov InSight releases. The SPOR Master List for Substance is empty as EMA has not released the Substances

(SMS) controlled vocabulary. The Term ID value for the new *Substance Search* selection widget will not be available in this release.

The following functionality is not available for eCTD 4.0 but will be included in future releases:

- Create eCTD 4.0 Assembly from: Submitted view, virtual document.
- Export to Microsoft Excel spreadsheet and Documentum virtual document (sometimes known as a compound document, depending on the repository type).
- Create eCTD wizard
- Recalculate Checksums

- Change Submittal Status wizard
- Create Study Reports wizard
- Linking activities
- Forward compatibility
- Grouped submissions
- Parallel submissions
- Applicant Contact lifecycle
- PDF Properties management
- Publishing variables defined in leafs or folders.
- Virtual Document and Veeva Binder assignment
- eCTD Import
- Submission Validation
- eCTD 4.0 Viewing – Workflows

The following functionality is deprecated in eCTD 4.0 and will not be included in future releases:

- View Baseline Differences report
- Related Documents
- Create Version
- Publishing Summary Query
- Export Published Output
- Append lifecycle operation
- Paper Publishing
- Publishing assembly view
- Standalone assemblies
- Assembly versions
- Publishing elements
- The Change Type option for folder elements

– The eCTD Lock option

Data Administration Lists - APIs CUD Operations

Ennov InSight 7.3 now includes the API Create, Update, Deactivate (CUD) operations for all Data Administration entities. See: *Ennov InSight Administration > Technical Administration and Ennov InSight API Documentation*.

DaaS Updates

Ennov InSight 7.3 includes updated DaaS database schema. See: *Ennov InSight 7.3 DaaS Database Tables Changed*.

New in Ennov InSight 7.3: Common Functionality

This table shows new features and enhancements of Ennov InSight 7.3 functionality.

eCTD 4.0

To maintain a new eCTD 4.0 standard.

Affected Area	Update	Benefit
Entities/Entity tabs	<p>Changes for eCTD 4.0 now include:</p> <ul style="list-style-type: none"> – Entity updates: <ul style="list-style-type: none"> • Application updates. See: <i>Entity Fields and Columns Added: Ennov InSight 7.3, Registrations > Application > Application Attributes and Registrations > Application > Sender-defined Keywords</i>. • Sequence updates. See: <i>Entity Fields and Columns Added: Ennov InSight 7.3, and Registrations > Sequence Attributes</i>. • The <i>Dose Form Search</i> selection widget is implemented for more entities 	The ability to separate different submission standards and use the functionality defined by the selected standard.
Affected Area	Update	Benefit

<p>Data Administration</p>	<p>To conform to eCTD 4.0 requirements, the following updates have been made to Data Administration:</p> <ul style="list-style-type: none"> – New <i>CV Profile Values</i> table in Data Administration > eCTD 4.0 Submission Maintenance. – New <i>Sender-defined Keyword Values</i> table in Data Administration > eCTD 4.0 Submission Maintenance. – Updated <i>Applicant Contact Type Values</i> table in Data Administration > Submission Maintenance – Updated <i>Applicant Contact Values</i> table in Data Administration > Submission Maintenance 	<p>To conform to eCTD 4.0 requirements, new attributes are added to Data Administration.</p>
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IDMP To maintain IDMP updates:

Affected Area	Update	Benefit
<p>Entities/Entity tabs</p>	<p>IDMP updates include:</p> <ul style="list-style-type: none"> – Attached Document updates. See <i>Entity Fields and Columns Added: Ennov InSight 7.3, Entity Fields and Columns Updated: Ennov InSight 7.3</i> – Manufactured Item updates. See: <i>Entity Fields and Columns Added: Ennov InSight 7.3</i> 	<p>To conform to the latest IDMP specification, new attributes are added to the entities and some existing attributes are updated.</p>

Affected Area	Update	Benefit
<p>Data Administration</p>	<p>IDMP updates include:</p> <ul style="list-style-type: none"> – New Data Administration Tables. See: 	<p>To conform to the latest IDMP specification, new attributes are added to the Data Administration.</p>

Data Administration Tables Added: Ennov InSight 7.3:

- *Device Classification Values* table in Medical Device Maintenance.
- *Source of Information Values* table in Other
- Regulatory Entitlement Status

Values table in Application Maintenance.

- Tables in SPOR Master Lists: ■ *Container Category*

■ *eCTD EU Context of Use*

■ *Medical Device Classification*

■ *Medical Device Legislative*

Category

■ *Medicinal Product Type*

■ *Medicine Profile*

■ *Regulating Authority Submission*

Unit Type

■ *Source of Information*

– Updated Data Administration Tables. See: *Data Administration Tables Updated: Ennov InSight 7.3:*

- Product Detail Set Maintenance > Component Type Values
- Product Detail Set Maintenance >

Device -Type of Combination Values

- Product Detail Set Maintenance > Intended Effect Values
- Registration Maintenance > Data Carrier Type Values.

	<ul style="list-style-type: none"> • Product Detail Set Maintenance > Substance Type Values • Other > Attached Document Content Type Values • Registration Maintenance > Registration Status Values <p>– Removed Data Administration Tables.</p> <p><i>See: Data Administration Tables</i></p> <p><i>Removed: Ennov InSight 7.3</i></p>	
©Ennov 2024	<ul style="list-style-type: none"> • Application Maintenance > Product Information Document7 Enno Type Values 	v InSight RIM 7.3 Release Notes Cumulative
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Affected Area	Update	Benefit
Security Administration	<p>Updated Security Administration Tables.</p> <p><i>See: Security Administration Tables Updated: Ennov InSight 7.3.</i></p>	To support user's business flow of usage xEVMPD and IDMP.

Entity Updates To conform the application updates to simplify data creation:

Affected Area	Update	Benefit
Entities/Entity tabs	<p>Entity updates include the improved <i>Substance Search</i> selection widget implemented. <i>See: Entity Fields, Columns and Options Updated: Ennov InSight 7.3</i></p> <p>– Product Family Attributes</p> <p>– Comparator Attributes</p> <p>– Product Detail Set Attributes > Substances Properties > Add Substance</p>	Improved selection widget capabilities with the updated data model enables simplified data creation.

	<ul style="list-style-type: none"> – Product Detail Set Template Attributes > Substances Properties > Add Substance – Product Detail Set Attributes > Active Ingredients > Active Ingredient Detail Attributes > Flu Strain Attributes > Add Reference Strain – Product Detail Set Template Attributes > Active Ingredients > Active Ingredient Detail Attributes > Flu Strain Attributes > Add Reference Strain – Component Attributes > Active Ingredients > Reference Active Ingredient > Create Reference Active Ingredient – Component Attributes > Manufactured Items > Substances > Create Substance – Component Attributes > Manufactured Items > Substances > Reference Substances > Create Reference Substance – Pharmaceutical Product Attributes > Substances > Create Substance – Pharmaceutical Product Attributes > Substances > Reference Substances > Create Reference Substance 	
Affected Area	Update	Benefit

Data Administration	<p>Updates include the <i>Substance Search</i> selection widget implemented. See: <i>Data Administration Tables Updated:</i></p> <p><i>Ennov InSight 7.3</i></p> <ul style="list-style-type: none"> – Manufacturer Values > Global <p>Product Details</p> <ul style="list-style-type: none"> – Other > Certificate Master File Values 	Improved selection widget capabilities with the updated data model enables simplified data creation.
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Affected Area	Update	Benefit
Create Application Wizard	<p>The <i>Create Application</i> wizard is updated with the new fields when creating a sequence. See: <i>Entity Fields and Columns Added: Ennov InSight 7.3</i></p>	To maintain a new controlled vocabularies for quick and easy eCTD 4.0 specification updates in future, the sequence and other related submission options updates are introduced.

Product Detail Set

Affected Area	Update	Benefit
Entities/Entity tabs	<p>IDMP updates include:</p> <ul style="list-style-type: none"> – Entity updates: <ul style="list-style-type: none"> • Product Details Set. See: <i>Entity Fields and Columns Added: Ennov InSight 7.3, Entity Fields and Columns Updated: Ennov InSight 7.3, Entity Fields and Columns Deleted: Ennov InSight 7.3, Ennov InSight 7.3 Registrations > PDS > Product Details in PDS > Intended Effect / Comorbidity sub-node</i> 	The ability to track intended effects/ comorbidities for the specific Indication and countries that are listed on the <i>Indication/ Intended Use Attributes</i> page.

New in Ennov InSight 7.3: Registrations

The new features and enhancements for Registration functionality are as follows.

Affected Area	Update	Benefit
Global Project Plan Wizard	The <i>Global Project Plan</i> wizard is updated with new fields when creating a sequence. See: <i>Entity Fields and Columns Added: Ennov InSight 7.3</i>	To maintain a new controlled vocabularies for quick and easy eCTD 4.0 specification updates in future, the sequence and other related submission options updates are introduced.
	The <i>Global Project Plan</i> wizard is updated with improved selection widget when creating active ingredients and substances. See: <i>Entity Fields and Columns Updated: Ennov InSight 7.3</i>	Improved selection widget capabilities with the updated data model enables simplified data creation.
Product Detail Sets (PDS)	<p>To include the changes for IDMP, additional attributes and updates are made for the following:</p> <ul style="list-style-type: none"> – Medical Devices: <ul style="list-style-type: none"> • Medical Device > Medical Device Detail Attributes – PDS Package Set: <ul style="list-style-type: none"> • Packaging > Package Detail Attributes • Pack Size > Pack Size Detail Attributes <p>See:</p> <ul style="list-style-type: none"> – <i>Entity Fields and Columns Added: Ennov InSight 7.3</i> – <i>Ennov InSight Registrations > PDS Page:</i> <ul style="list-style-type: none"> • <i>Medical Device PDS Attributes</i> • <i>Package Detail Attributes</i> • <i>Pack Size Detail Attributes</i> 	The ability to capture IDMP data in Ennov InSight in preparation for submitting IDMP data to EMA.
Affected Area	Update	Benefit

<p>Medicinal Product Actions</p>	<p>Changes to IDMP also include updates for the following:</p> <ul style="list-style-type: none"> – Medicinal Product Actions Attributes: • New DV icon is added. <p>See:</p> <ul style="list-style-type: none"> – <i>Entity Fields and Columns Added: Ennov InSight 7.3</i> – <i>Ennov InSight for IDMP > IDMP Data Visualization</i> – <i>Ennov InSight for IDMP > IDMP Data Visualization > Color Coding – Attached Document Attributes.</i> <p>See:</p> <ul style="list-style-type: none"> – <i>Entity Fields and Columns Removed: Ennov InSight 7.3</i> – <i>Entity Fields and Columns Updated: Ennov InSight 7.3</i> – <i>Ennov InSight Registrations > Attached Document > Attached Document Attributes</i> 	<p>The ability to capture IDMP data in Ennov InSight in preparation for submitting IDMP data to EMA.</p>
<p>Product Detail Sets (PDS)</p>	<p>Changes to IDMP also include the new Intended Effect/Comorbidity sub-node in the <i>Product Details in a PDS</i> window.</p> <p>See:</p> <ul style="list-style-type: none"> – <i>Entity Fields and Columns Added: Ennov InSight 7.3</i> – <i>Entity Fields and Columns Updated: Ennov InSight 7.3</i> – <i>Entity Fields and Columns Deleted: Ennov InSight 7.3</i> – <i>Ennov InSight Registrations > PDS Page:</i> 	<p>The ability to track intended effects/comorbidities for the specific Indication and countries that are listed in the <i>Indication/Intended Use Attributes</i> page.</p>

	<ul style="list-style-type: none"> • <i>Product Details in PDS</i> • <i>Associate an Intended Effect/Comorbidity</i> • <i>Intended Effect/Comorbidity Attributes</i> 	
Affected Area	Update	Benefit
IDMP Data Generation wizard	<p>To include the changes for IDMP, Ennov InSight 7.3 introduces the new IDMP Data Generation wizard. See:</p> <ul style="list-style-type: none"> – <i>Entity Fields and Columns Added: Ennov InSight 7.3</i> – <i>IDMP Data Generation</i> 	The ability to capture IDMP data in Ennov InSight in preparation for submitting IDMP data to EMA.
XEVMPD Submission wizard	<p>To include the changes based on the EMA specification for XEVMPD, the XEVMPD Submission wizard is updated. See:</p> <ul style="list-style-type: none"> – <i>Entity Fields and Columns</i> – <i>Removed: Ennov InSight 7.3</i> 	The ability to capture XEVMPD data in Ennov InSight in preparation for submitting XEVMPD data to EMA.

New in Ennov InSight 7.3: Publisher

This table shows new features and enhancements of publishing functionality.

The following are the new features and enhancements for Publishing functionality.

Affected Area	Update	Benefit
Home page: Assembly Templates	<p>To conform to the new eCTD 4.0 requirements, the columns under Assembly Templates grid view are updated. See:</p> <ul style="list-style-type: none"> – <i>Entity Fields and Columns Added: Ennov InSight 7.3</i> – <i>Ennov InSight Publishing: eCTD 4.0 >Assembly Template Attributes</i> 	The ability to see additional information for assembly templates.

Affected Area	Update	Benefit
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<p>Assembly</p>	<p>To conform to the new eCTD 4.0 requirements, the leafs, folders and other attributes of assembly like publishing settings library attributes, prepare to publish and publishing attributes are updated. See:</p> <ul style="list-style-type: none"> – <i>Ennov InSight Publishing: eCTD 4.0 >Assembly Toolbar Icons> Regional Information</i> – <i>Ennov InSight Publishing: eCTD 4.0 >Assembly Toolbar Icons> Additional Information</i> – <i>Ennov InSight Publishing: eCTD 4.0 >Assembly Attributes</i> – <i>Ennov InSight Publishing: eCTD 4.0 > Run Prepare to Publish</i> – <i>Ennov InSight Publishing: eCTD 4.0 > Submit an Electronic Publishing Request</i> – <i>Ennov InSight Publishing: eCTD 4.0 > Publishing Leaf Elements</i> – <i>Ennov InSight Publishing: eCTD 4.0 > Assemblies > Folder Elements > Folder Attributes</i> – <i>Ennov InSight Publishing eCTD 4.0 > Folder Elements > Associate Sender-defined Keywords to an Assembly Folder.</i> 	<p>To support eCTD 4.0 and to improve the user experience, the assembly view and functionality have been updated accordingly.</p>
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	<ul style="list-style-type: none"> – <i>Ennov InSight Publishing: eCTD 4.0 > Assemblies > Leaf Elements > Leaf Attributes</i> – <i>Ennov InSight Publishing: eCTD 4.0 > Assemblies > Leaf Elements > Reference Leaf Attributes</i> 	
	For eCTD 4.0, the <i>Prepare to Publish</i> and <i>Publish Request</i>	These options are unrelated to eCTD 4.0 and are therefore
©Ennov 2024 Ennov	<p>options do not support Paper₁₄ publishing.</p> <ul style="list-style-type: none"> – <i>Ennov InSight Publishing: eCTD 4.0 > Publishing</i> 	<p>removed. Ennov InSight RIM 7.3 Release Notes</p> <p>Cumulative Ennov InSight 7.3 Release Notes</p>

Ennov InSight RIM 7.3 Release Notes

Affected Area	Update	Benefit
Create Submission Wizard	<p>The <i>Create Submission</i> wizard is updated with the new fields when creating a sequence. See:</p> <ul style="list-style-type: none"> – <i>Entity Fields and Columns Added: Ennov InSight 7.3</i> – <i>Ennov InSight Publishing eCTD 4.0 > Submissions > Amendment Submission > Amendment Submission Attributes</i> – <i>Ennov InSight Publishing > Submissions > Amendment Submission > Amendment Submission Attributes</i> 	To maintain a new controlled vocabularies for quick and easy eCTD 4.0 specification updates in future, the sequence and other related submission options updates are introduced.

Cumulative Ennov InSight 7.3 Release Notes

List of Enhancements: Ennov InSight 7.3

Affected Area	Update	Benefit
Folder and Leaf Attributes	For files with size with the size equal or larger than the value set in the configuration, using the <i>View File</i> option directs you to see the download status in Job Requests.	You can see the status of file download under Job Requests.
	If the number of folder child nodes exceeds the value set in the configuration, the process of creating a duplicate folder is displayed under Job Requests.	You can now see the status of duplicate folder creation under Job Requests.
	If the number of folder child nodes exceeds the value set in the configuration, the status of assembly creation is displayed under Job Requests.	You can now see the status of assembly creation under Job Requests.
	<p>– <i>Ennov InSight Publishing: eCTD 4.0 > Assemblies > Leaf Elements > Leaf Attributes</i></p> <p>– <i>Ennov InSight Publishing: eCTD 4.0 > Assemblies > Leaf Elements > Reference Leaf Attributes</i></p>	To maintain a new controlled vocabularies for quick and easy eCTD 4.0 specification updates in future, the assembly and other assembly related options updates are introduced.
	For eCTD 4.0, the Modified Leaf field is updated to include the sequence number next to the leaf name.	
Assembly Template	For eCTD 4.0, the Import Publishing Elements option is not available when creating the assembly template from New > Assembly Template or Existing Template, Assembly or View.	This option is unrelated to eCTD 4.0 and therefore removed to avoid any confusion.

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 RIM 7.3 Release Notes

Cumulative List of Enhancements: Ennov InSight 7.3

Issue	Sub-Minor Build	Description
DE31047	N/A	Performance issue was experienced when loading the search results for the List of Registrations with Application Properties query. This issue is resolved. The performance is improved.
DE30969	N/A	Trying to add new values to the Event Status field in the Event Maintenance > Timeline/Event Plan Values DA List resulted in the Invalid Reference error. This issue is resolved.
DE30898, [INC0256754]	N/A	After creating a PDS from the PDS template, the PDS_LOCAL_CHANGE database table showed the value D for ACTIVE_FLAG instead of Y. This issue is resolved. Now, the value Y shows for ACTIVE_FLAG.

Ennov InSight : Publishing

Issue	Sub-Minor Build	Description
CS0589800; [INC0108211]	6.2.0.4.0079	<p>The US 3.3 assembly templates now support SPL and REMS and include additional folders and leafs: – 1.16.2.1 Final REMS:</p> <ul style="list-style-type: none"> • Final REMS (New) • Final REMS - Word (New) • SPL: <p>■ SPL XML (New) ■ REMS Material (New) – 1.16.2.2 Draft REMS:</p> <ul style="list-style-type: none"> • Draft REMS • Draft REMS - Word • SPL: <p>■ SPL XML (New)</p> <p>■ REMS Material (New)</p>

Resolved Issues: Ennov InSight 7.3

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 build, that build number is included.

Common

Issue	Sub-Minor Build	Description
DE30362	N/A	When performing the API Post request, it was not possible to add more than one reference active ingredient to the active ingredient of the manufactured item. This issue is resolved. Now, more than one reference active ingredient is successfully added using API.
DE30357	N/A	It was not possible to delete a product family with child entities such as product, component, manufactured item and the warning message was displayed. This issue is resolved. Now, you can delete a product family that has child entities.
DE29488	N/A	When Family Type was selected as a search criterion for the List of Application Countries with PDS Country and Registration Details query, the Invalid Reference error was displayed for the Application Country on the Search Results page. This issue is resolved. Now, the <i>Application Country Attributes</i> page is displayed for the selected Application Country .
DE29163	N/A	The <i>About</i> page showed the wrong year for Ennov InSight copyright information. This issue is resolved. Now, '© Calyx™ 2021.' is displayed.
DE29121	N/A	In the Clinical Trial Project, on the <i>Events</i> tab with an event selected, clicking Add Event Country failed to show an option to add an event country and instead the Event must be selected. message appeared. This issue is resolved. Now, the option to add an event country appears.
DE29048	N/A	For applications, created without a product and product family, the Send to Concerned Parties option included both the Application and Product Family values on the Application Attributes > Notifications > Mail Settings page. This issue is resolved. Now, if there is no dependency on the product or product family, this option displays the Application value only.

DE27756	N/A	When searching for a value in the substance search selection widget, two icons were not visible because the Displaying items text covered them. This issue is resolved by the implementation of the improved <i>Substance Search</i> selection widget.
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Publishing

Issue	Sub-Minor Build	Description
DE30570, 26814	N/A	Using Prepare for Publishing, with the Prepare Cross Reference Leafs option selected, results in the error if there is a reference leaf to leaf published to Documentum. This issue is resolved. Now, reference list data is updated correctly after Prepare for Publishing operation and Prepare Cross Reference Leafs job displays Complete status.
DE28798	N/A	For an Assembly Plan added to the life cycle, using the <i>Publishing Settings</i> Edit option resulted in the Cannot get Sequence with given id [...] error. This issue is resolved. Now, the <i>Edit Publishing Settings</i> page is displayed.
DE28468	N/A	After a duplicate leaf was created in a supporting assembly, the attempt to delete the assembly resulted in a database error. This issue is resolved. Now, the supporting assembly is successfully deleted.
DE28449, [CS0592298, INC0115474, PRB0043774]	N/A	Opening the PDF Properties tab on a leaf from a Working assembly took longer than expected. This issue is resolved. Now, the PDF Property attributes are displayed quickly.
DE27666	N/A	Trying to modify or delete comments from Publishing Settings Library resulted in an error. This issue is resolved. Now, you can modify or delete comments from Publishing Settings Library.
26825	6.2.0.8	EAEU: If the Drug Registration Document Code field had a value in a submission, the Drug Registration Document Name was not included in the index-r-022.xml 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 in-

		dex-r-022.xml file after publishing and in the leaf after an eCTD import.
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Registrations

Issue	Sub-Minor Build	Description
DE29159	N/A	<p>In some 7.2.x versions of Ennov InSight , the Concentration Measure Type field was incorrectly displayed as IDMP Concentration Measure Type under IDMP Presentation Strength for the following pages:</p> <ul style="list-style-type: none"> – Component > Active Ingredient Attributes and Reference Active Ingredient Attributes – Pharmaceutical Product > Active Ingredient Attributes and Reference Active Ingredient Attributes – Pharmaceutical Product > Substance Attributes and Reference Substance Attributes – Manufactured Item > Active Ingredient Attributes and Reference Active Ingredient Attributes. – Manufactured Item > Substance Attributes and Reference Substance Attributes <p>This issue is resolved. Now, the Concentration Measure Type field is displayed for the pages mentioned above.</p>
DE28838	N/A	<p>The name of the Medical Product Action / Submission Status values was displayed incorrectly. This issue is resolved. Now, the name is correctly displayed as Medicinal Product Action / Submission Status.</p>
DE29818	N/A	<p>A pharmaceutical product could not be deleted if it was associated to a medicinal product. This issue is resolved. Now, a pharmaceutical product associated to a medicinal product is successfully deleted.</p>
DE29762	N/A	<p>After withdrawing an indication from a PDS, the withdrawn indication value was not available for selection in the PDS for the subsequent event. This issue is resolved. Now, this value is available in the Indication field on the <i>Add Indication/Intended Use</i> page in the PDS.</p>

Issue	Sub-Minor Build	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/packageset-registration/all – /insight/api/v2/license/product-registration/all – /insight/api/v2/license/full-product-presentation/all – /insight/api/v2/license/packageset/all – /insight/api/v2/license/packageset/country/all

Administration

Issue	Sub-Minor Build	Description
DE30821	N/A	<p>When right-clicking on the Active Ingredients node in the Product Detail Set or Product Detail Set template, the Active Ingredient > Add Active Ingredient button was displayed even if there were no values available for selection in the Active Ingredient field. This issue is resolved. Now, the Add Active Ingredient button is not available from the node.</p>
DE30115	N/A	<p>Saving details on the Data Administration > Applicant Contact Values page without any value in the Applicant Contact Name field resulted in the Invalid Reference error message. This issue is resolved. Now, the message ! Applicant Contact Name is required. appears.</p>
DE30114	N/A	<p>The email value was not displayed as a hyperlink under Applicant Contact Values > Applicant Contact Email tab. and therefore was not possible to edit the email. This issue is resolved. Now, the value is hyperlinked and can be edited.</p>
DE30062; [INC0219608,	N/A	<p>In the <i>SPOR Master Lists</i> section, all the values for the following RMS lists were not displayed:</p>

TASK0049184]		<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>
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Issue	Sub-Minor Build	Description
DE29064	N/A	On the <i>Create Division Values</i> page, the Product Family Maintenance section included extra Last User Updated and Last Changed Date fields. This issue is resolved. Now, the <i>Create Division Values</i> page does not include extra Last User Updated and Last Changed Date fields.
DE30042	N/A	Saving details on the Data Administration > Applicant Contact Type Values page without any value in the Applicant Contact Type field resulted in the Invalid Reference error message. This issue is resolved. Now, the message ! Applicant Contact Type is required. appears.

Ennov InSight 7.3 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.3 Release Notes (Cumulative)

Entity Fields

Entity Fields, Columns and Options Added: Ennov InSight 7.3

The following tables describe fields and columns that were added in this release. These include the fields and columns that were added to support IDMP data capture and eCTD 4.0 publishing standards.

Home

Table 1: I am Looking To

Field/Column/ Option Name	Field Type	Description	Business Rules
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IDMP Data Generation	Tab	The new IDMP Data Generation wizard is available from My Home > I am Looking To	The ability to capture IDMP data in Ennov InSight in preparation for submitting IDMP data to EMA.
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Ennov InSight RIM 7.3 Release Notes

Cumulative

Ennov InSight 7.3 COB and Known Issues

Table 2: Assembly Templates

Field/Column/ Option Name	Field Type	Description	Business Rules
eCTD Standard Type	Read-only field	This column is added to Home > Assembly Templates grid view.	The eCTD Standard Type column contains the eCTD 3.2, eCTD 4.0, Paper, NeeS types based on the values displayed for this field on the <i>Assembly Attributes</i> page.

Notifications

Table 3: Notifications

Field/Column/ Option Name	Field Type	Description	Business Rules
Sequence Standard Type	Option	To conform to the new eCTD 4.0 requirements, the <i>Select Rule Settings and Delivery Destinations</i> page now includes the respective option when you create or modify the notification from the: <ul style="list-style-type: none"> – Notifications tab of an appropriate entity – My Home > I am Looking To > Create new > Notifications – Data Administration > Notifications or Data Administration > Notification Specifications 	The ability to separate different submission standards and use the functionality defined by the selected standard.

Table 4: Assembly Templates

Field/Column/ Option Name	Field Type	Description	Business Rules
eCTD Standard Type	Read-only field	This column is added to Home > Assembly Templates grid view.	The eCTD Standard Type column contains the eCTD 3.2, eCTD 4.0, Paper, NeeS types based on the values displayed for this field on the <i>Assembly Attributes</i> page.

Entities

Application

Table 5: Application

Field/Column/Option Name	Field Type	Description	Business Rules
Sender-defined Keywords Codesystem	Read-only field	To conform to the new eCTD 4.0 requirements, the <i>Application Attributes</i> page now includes the respective field.	Defines code system of the sender-defined keywords for application.

Table 6: Sender-defined Keywords

Field/Column/ Option Name	Field Type	Description	Business Rules
Application Name	Read-only field	To conform to the new eCTD 4.0 requirements, the Sender-defined	The ability to manage the sender-defined
Application Codesystem ID	Read-only field	Keywords tab is introduced on the <i>Application Attributes</i> page.	keywords.
Code	Hyperlink		
Display Name	Text field		

Sequence

Table 7: Sequence

Field/ Column/ Option Name	Field Type	Description	Business Rules
Sequence Standard Type	Drop- down list	The <i>Sequence Attributes</i> page now	– The Sequence Standard Type field contains eCTD 3.2, eCTD 4.0, Paper, NeeS. If the eCTD 4.0 set for this sequence is changed to any other value, it results in Switch from
UUID	Text field	includes these fields.	eCTD 4.0 standard type is for sequence with existing assembly is disallowed. error message. – The system generates automatically the UUID value (version 4 of UUID types) on sequence creation. The UUID field is visible on the modification and view pages only. Only user with Admin permissions to the sequence can modify the field. The values should be unique (case-insensitive). The entered values should pass the validation to match the format: a hexadecimal number in the form of xxxxxxxx-xxxxxxx-xxxx-xxxxxxxxxxxx, having 32 digits and 4 hyphens. If format does not match, the The UUID must be in the form of xxxxxxxx-xxxx-Mxxx-Nxxx-xxxxxxxxxxxx, where x is a hexadecimal number, M is 1-5, and N is 8, 9, a or b. message is displayed. If uniqueness is violated, the The UUID must be unique. message appears.

Manufactured Item

Table 8: Manufactured Item

Field/Column/Option Name	Field Type	Description	Business Rules
Manufactured Item Quantity Operator	Drop-down list	The <i>Manufactured Item Attributes</i> page now includes this field.	The values for this field are available from the Data Administration > Other > Concentration Measure Type Values

Attached Document

Table 9: Attached Document

Field/Column/ Option Name	Field Type	Description	Business Rules
Attachment Document Status	Drop-down list	The <i>Attached Document Attributes</i> page now includes this field.	To conform to the latest IDMP specification released, the new attribute has been added to the entity. The values for this field are available from the Data Administration > Other > Attached Document Status Values
Attached Document URL	Browse field	The <i>Attached Document Attributes</i> page now includes this field.	To conform to the latest IDMP specification released, the new attribute has been added to the entity.

Medicinal Product Action

Table 10: Medicinal Product Action

Field/Column/ Option Name	Field Type	Description	Business Rules
DV	Option	The <i>Medicinal Product Attributes</i> page now includes this option.	To conform to the latest IDMP specification released, the new attribute has been added to the entity.

Field/Column/ Option Name	Field Type	Description	Business Rules
Family Code	Hyperlink	The Medical Devices node now	To conform to the latest IDMP
Family Name	Hyperlink	includes the Function node with the corresponding fields.	specification released, the new attribute has been added to the
Application Code	Hyperlink		entity.
Application	Hyperlink		

Name			
Product Name	Hyperlink		
Product Detail	Hyperlink		
Set Name			
Component Name	Hyperlink		
Function Name	Drop-down list		
Function Status	Drop-down list		
Function Status Date	Date		
QC Status	Read-only		
Date QC'd	Read-only		
QC'd by	Read-only		
Function Key- words	Text field		
Function Description	Text field		
Function Com- ments	Text field		
Family Code	Hyperlink	The Medical Devices node now	
Family Name	Hyperlink	includes the Manufacturer node with the corresponding fields	
Application Code	Hyperlink	associated to the new Function node .	
Application	Hyperlink		

Name			
Product Name	Hyperlink		
Product Detail ©Ennov 2024Set Name	Hyperlink	27	Ennov InSight RIM 7.3 Release Notes Cumulative
EnnovComponent Name	Hyperlink		Entity Fields

Product Detail Set Table 11: Medical Devices

Table 12: Package Set

Field/Column/Option Name	Field Type	Description	Business Rules
– Package Item Quantity Operator – Package Item - MI Quantity Operator – Device Quantity Operator	Box, text field	The Package Set > Packaging > Package Detail Attributes page now includes this field.	The values for this field are available from the Data Administration > Other > Concentration Measure Type Values.
Pack Size Quantity Operator	Box, text field	The Package Set > Pack Size > Pack Size Detail Attributes page now includes this field.	

Table 13: Indication/Intended Use

Field/Column/Option Name	Field Type	Description	Business Rules
– Intended Effect – Comorbidity	Multi-select	The Indication/Intended Use node now includes the Intended Effect/ Comor-	Multiple sub-nodes can be created for the same Indication but Country values

<p>– Countries</p>		<p>bidity sub-node with the respective fields.</p>	<p>will not be available for selection.</p> <p>Country values are available only when you create a new sub-node for another Indication.</p> <p>If all values for the Country field are selected, it will not be possible to create a new sub-node unless you modify or delete the existing one.</p>
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Assembly

Table 14: Assembly Attributes

Field/Column/ Option Name	Field Type	Description	Business Rules
eCTD Standard Type	Read-only field	The <i>Assembly Attributes</i> page now includes this field.	To identify the eCTD type for incorporating forward capability, this new option is added.

Wizards

Table 15: Create Application

Field/Option Name	Field Type	Description	Business Rules
Sequence Standard Type	Drop-down list	These fields are now available for the <i>Create Application</i> wizard	The field contains eCTD 3.2, eCTD 4.0, Paper, NeeS. If there is eCTD 4.0 set for this sequence changes to any other value, it results in Switch
UUID	Text field	when creating a sequence.	from eCTD 4.0 standard type is for sequence with existing assembly is disallowed. error message.

Table 16: Create Submission

Field/ Option Name	Field Type	Description	Business Rules
Sequence Standard Type	Drop- down list	These fields are now available in the <i>Create Submission</i> wizard	– The Sequence Standard Type field contains eCTD 3.2, eCTD 4.0, Paper, NeeS. If there is eCTD 4.0 set for this sequence changes to any other value, it results in
UUID	Text field	when creating a sequence using following options: <ul style="list-style-type: none"> – Initial Application – Major Update – Amendment 	Switch from eCTD 4.0 standard type is for sequence with existing assembly is disallowed. error message. <ul style="list-style-type: none"> – The system generates automatically the UUID value (version 4 of UUID types) on sequence creation. The UUID field is visible on the modification and view pages only. Only user with Admin permissions to the sequence can modify the field. The values should be unique (case-insensitive). The entered values should pass the validation to match the format: a hexadecimal number in the form of xxxxxxxx-xxxxxxx-xxxx-xxxxxxxxxxx, having 32 digits and 4 hyphens. If format does not match, the The UUID must be in the form of xxxxxxxx-xxxxMxxx-Nxxx-xxxxxxxxxxx, where x is a hexadecimal number, M is 1-5, and N is 8, 9, a or b. message is displayed. If uniqueness is violated, the The UUID must be unique. message appears.

Table 17: Global Project Plan

Field/ Field Option Type Name

Sequence Drop-

Standard down Type list

UUID Text field

Description

These fields are now available for the *Global Project Plan* wizard when creating a sequence using following project types:

– Create New Events

Package Set Registration

– Clinical Trial

- Create New CTA and/or IND Application(s)
- Create New CTA

Application(s) and

Create New Event for

Existing IND

Application(s)

- Create New Event for

Existing CTA and/or

IND Application(s)

– Create New Events

Product Registration

– Create New Applications

Package Set Registration Business Rules

– The Sequence Standard Type field contains eCTD 3.2, eCTD 4.0, Paper, NeeS. If there is eCTD 4.0 set for this sequence changes to any other value, it results in Switch from eCTD

4.0 standard type is for sequence with existing assembly is disallowed. error message.

– The system generates automatically the UUID value (version 4 of UUID types) on sequence creation. The UUID field is visible on the modification and view pages only. Only user with Admin permissions to the sequence can modify the field. The values should be unique (case-insensitive). The entered values should pass the validation to match the format: a hexadecimal number in the form of xxxxxxxxxxx-xxxx-xxxx-xxxxxxxxxxxx, having 32 digits and 4 hyphens. If format does not match, the

The UUID must be in the form of xxxxxxx-xxxx-Mxxx-Nxxxxxxxxxxxxxxxx, where x is a hexadecimal number, M is 1-5, and N is 8, 9, a or b. message is displayed. If uniqueness is violated, the The UUID must be unique. message appears.

Field/Option Name	Field Type	Description	Business Rules

Active Ingredients	Selection widget	This field is updated with improved <i>Substance Search</i> selection widget.	Users have an ability to search for a value using a modern Selection Widget with a wider and more advanced search capabilities and configure columns display and the number of values per page.
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Table 18: IDMP Data Generation

Field/Option Name	Field Type	Description	Business Rules
Family Type	Multiselect	Ennov InSight now introduces the new IDMP Data Generation wizard	The ability to capture IDMP data in Ennov InSight in preparation for
Family Name	Multiselect	available from Wizards > IDMP Data Generation.	submitting IDMP data to EMA.
Product Name	Multiselect		
Application Name	Multiselect		
Action Name	Text field		
Status	Multiselect		
Display Columns	Multiselect		
Sort Order	Multiselect		

Entity Fields, Columns and Options Updated: Ennov InSight 7.3

The following tables describe fields, columns and options that were modified in this release. These include the fields and column that were added to support IDMP data capture and eCTD 4.0 publishing standards.

Product Family

Field/Option Name	Field Type	Description	Business Rules
Active	Selection widget	This field is updated with improved <i>Sub-</i>	Users have an ability to search for a value using a modern Selection Widget with a wider and

Ingredients		<i>stance Search</i> selection widget.	more advanced search capabilities and configure columns display and the number of values per page.
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Comparator

Product Detail Set

Table 19: Substance

Field/Option Name	Field Type	Description	Business Rules
Substance Name	Selection widget	This field is updated with improved <i>Substance Search</i> selection widget on the Product Detail Set Attributes > Substances Properties > Add Substance and on the Product Detail Set Template Attributes > Substances Properties > Add Substance pages.	Users have an ability to search for a value using a modern Selection Widget with a wider and more advanced search capabilities and configure columns display and the number of values per page.

Table 20: Flu Strain

Field/Option Name	Field Type	Description	Business Rules
Reference Strain Name	Selection widget	This field is updated with improved <i>Substance Search</i> selection widget on the Product Detail Set Attributes > Active Ingredients > Active Ingredient Detail Attributes > Flu Strain Attributes > Add Reference Strain and on the Product Detail Set Template Attributes > Active	Users have an ability to search for a value using a modern Selection Widget with a wider and more advanced search capabilities and configure columns display and the number of values per page.

		Ingredients > Active Ingredient Detail Attributes > Flu Strain Attributes > Add Reference Strain pages.	
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Component

Table 21: Reference Active Ingredient

Field/Option Name	Field Type	Description	Business Rules
Reference Active Ingredient Name	Selection widget	This field is updated with improved <i>Substance Search</i> selection widget on the Component Attributes > Active Ingredients > Reference Active Ingredient > Create Reference Active Ingredient page.	Users have an ability to search for a value using a modern Selection Widget with a wider and more advanced search capabilities and configure columns display and the number of values per page.

Table 22: Manufactured Item

Field/Option Name	Field Type	Description	Business Rules
Substance Name	Selection widget	This field is updated with improved <i>Substance Search</i> selection widget on the Manufactured Item Attributes > Substances > Create Substance page.	Users have an ability to search for a value using a modern Selection Widget with a wider and more advanced search capabilities and configure columns display and the number of values per page.

Table 23: Reference Substances

Field/Option Name	Field Type	Description	Business Rules
Reference Substance	Selection widget	This field is updated with improved <i>Substance Search</i> selection widget on the	Users have an ability to search for a value using a modern Selection Widget with a wider and more advanced search

Name		Manufactured Item Attributes > Substances > Reference Substances > Create Reference Substance page.	capabilities and configure columns display and the number of values per page.
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Pharmaceutical Product

Table 24: Substances

Field/Option Name	Field Type	Description	Business Rules
Substance Name	Selection widget	This field is updated with improved w <i>Substance Search</i> selection widget on the Pharmaceutical Product Attributes > Substances > Create Substance page.	Users have an ability to search for a value using a modern Selection Widget with a wider and more advanced search capabilities and configure columns display and the number of values per page.

Table 25: Reference Substances

Field/Option Name	Field Type	Description	Business Rules
Reference Substance Name	Selection widget	This field is updated with improved <i>Substance Search</i> selection widget on the Pharmaceutical Product Attributes > Substances > Reference Substances > Create Reference Substance page.	Users have an ability to search for a value using a modern Selection Widget with a wider and more advanced search capabilities and configure columns display and the number of values per page.

Attached Document

Table 26: Attached Document

Field/Column/ Option Name	Field Type	Description	Business Rules
N/A	N/A	The <i>Attached Document</i> entity is now available for all the	To conform to the latest IDMP specification, the entity has been updated.

	Application Procedure Types.	
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Table 27: Attached Document Attributes

Field/ Column/ Option Name	Field Type	Description	Business Rules
Content Type	Drop-down list	On the <i>Attached Document Attributes</i> page, these fields are renamed to:	To conform to the latest IDMP specification released, the
Effective Date	Date	<ul style="list-style-type: none"> – Attached Document Type – Attached Document Effective Date 	existing attributes have been updated for the entity.
Language	Drop-down list	– Attached Document Language	

Assembly: eCTD 4.0

Table 28: Assembly Attributes

Field/Column/ Option Name	Field Type	Description	Business Rules
Create an Assembly > Existing Template, Assembly or View	Option	The Create an Assembly > Existing Template, Assembly or View option is updated on the <i>Create Assembly</i> page to track the creation process of an assembly from another assembly in Job Requests if the number of folder child nodes exceeds the value set in the configuration.	Users can track the creation process of an assembly from another assembly in Job Requests. When creating an assembly from another assembly if the number of folder child nodes exceeds the value set in a configuration, the message is displayed asking to check the Job Requests for a status.

Table 29: Folder Attributes

Field/ Column/	Field Type	Description	Business Rules

Option Name			
Duplicate	Option	The Duplicate option is updated on the <i>Folder Attributes</i> page to track the duplicate folder process in Job Requests if the number of folder child nodes exceeds the value set in the configuration.	Users can track the duplicate folder process in Job Requests. After clicking the Duplicate on the folder, if the number of folder child nodes exceeds the limit, the message is displayed asking to check the Job Requests for a status.

Assembly

Table 30: Document Attributes

Field/ Column/ Option Name	Field Type	Description	Business Rules
View File	Option	The View File option is updated on the <i>Document Attributes</i> page to track the download process in Job Requests for the files that are equal or bigger than the file size value set in the configuration.	Users can track the download process in Job Requests. After clicking the View File if the file size exceeds the limit, the message is displayed asking to check the Job Requests for a status.

Product Detail Set

Table 31: Package Set

Field/Column/ Option Name	Field Type	Description	Business Rules
Package Type	Dropdown list	On the Package Set > Packaging > Package Detail Attributes page, these fields are renamed to:	To conform to the latest IDMP specification released, the existing
Package Item Container Quantity	Text field	<ul style="list-style-type: none"> – Package Item Type – Package Item Quantity – Package Item Material 	attributes have been updated for the entity.

Package Material	Multiselect	– Package Item Alternate Material – Package Item Component(s)	
Package Alternate Material	Multiselect	– Package Item - MI Quantity – Package Item - MI Quantity Unit	
Package Components	Select		
Packaging MI Quantity	Text field		
Packaging MI Quantity Unit	Dropdown list		

Table 32: Indication/ Intended Use

Field/ Column/ Option Name	Field Type	Description	Business Rules
Countries	Multiselect	This field is updated to optional from required on the <i>Add Indication/Intended Use</i> window.	<p>Multiple sub-nodes can be created for the same Indication but Country values will not be available for selection.</p> <p>Country values are available only when you create a new sub-node for another Indication.</p> <p>If all values for the Country field are selected, it will not be possible to create a new sub-node unless you modify or delete the existing one.</p>

Wizards

Table 33: Global Project Plan

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Active Ingredient – Substance 	Selection widget	<p>These fields are updated with improved <i>Substance Search</i> selection widget for the following pages:</p> <ul style="list-style-type: none"> – Global Project Plan > Update Product Detail Sets > Active Ingredient > Input Query Filter Criteria – Global Project Plan > Update Product Detail Sets > Substance > Input Query Filter Criteria 	Users have an ability to search for a value using a modern Selection Widget with a wider and more advanced search capabilities and configure columns display and the number of values per page.

Entity Fields, Columns and Options Removed: Ennov InSight 7.3

The following table describes fields and columns that are removed with Ennov InSight 7.3.

Wizards

Table 34: XEVMPD Submission

Field/Column/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Organization – Source – Master File Location – ATC – Pharmaceutical Form – Route of Administration – Authorised Product 	Check box	<p>The <i>Select XEVPRM Sections</i> page along with its corresponding fields is removed from the <i>XEVMPD Submission</i> wizard. Now, after the sender and receiver information selection, the <i>Authorized Product Selection</i> page is available.</p>	The ability to capture XEVMPD data in Ennov InSight in preparation for submitting XEVMPD data to EMA.

Product Detail Sets

Table 35: Indication/Intended Use

Field/Column/ Option Name	Field Type	Description	Business Rules
Intended Effect	Multiselect	These fields are removed from the	Multiple sub-nodes can be created for the same Indication but Country values will not be available for
Comorbidity	Multiselect	<i>Add Indications/ Intended Use</i> window.	selection. Country values are available only when you create a new sub-node for another Indication. If all values for the Country field are selected, it will not be possible to create a new sub-node unless you modify or delete the existing one.

UI Field Name	Database Table Name	Database Column Name	Database Column Type and Size	Description
N/A	N/A	APP_ORPHAN_DESIG_STATUS ID	N/A	ORPHAN_STATUS_TYPE is added to display data from Application Maintenance > Orphan Statues Values DA list.

Attached Document

Table 36: Attached Document Attributes

Field/Column/ Option Name	Field Type	Description	Business Rules
Attached Document Type	Drop-down list	This field is removed from the <i>Attached Document Attributes</i> page.	The ability to capture and maintain correct SPOR controlled vocabulary lists in Ennov InSight in preparation for submitting data to EMA.

Database Columns and Tables

Database Columns Added: Ennov InSight 7.3

The following Database columns were added in this release.

UI Field Name	Database Table Name	Database Column Name	Database Column Type and Size	Description
N/A	N/A	N/A	N/A	REGULATORY_ENTITLEMENT_STATUS _TYPE is updated to display data from Data Administration > Regulatory Entitlement Status DA list
Device Description	MGR.PDS_MED_DEVICE_CHANGE	DEVICE_DESCRIPTION	VARCHAR2(4000)	To conform to the latest IDMP specification released, the new DEVICE_DESCRIPTION column is added to the MGR.PDS_MED_DEVICE_CHANGE table.
Device Description of Intended Purpose	MGR.PDS_MED_DEVICE_CHANGE	DEVICE_INTENDED_USE	VARCHAR2(4000)	To conform to the latest IDMP specification released, the new DEVICE_INTENDED_USE column is added to the MGR.PDS_MED_DEVICE_CHANGE table.
Device Description Language	MGR.PDS_MED_DEVICE_CHANGE	DEVICE_LANGUAGE_TYPE_ID	NUMBER	To conform to the latest IDMP specification released, the new DEVICE_LANGUAGE_TYPE_ID column is added to the MGR.PDS_MED_DEVICE_CHANGE table.

Device Classification	MGR.PDS_MED_DEVICE_CHANGE	DEVICE_CLASS_TYPE_ID	NUMBER	To conform to the latest IDMP specification released, the new DEVICE_CLASS_TYPE_ID column is added to the MGR.PDS_MED_DEVICE_CHANGE table.
N/A	N/A	CODE	VARCHAR2(100)	MGR.EVENT_PLAN_COUNTRY

UI Field Name	Database Table Name	Database Column Name	Database Column Type and Size	Description
Manufactured Item Quantity Operator	MGR.MANUFACTURED_ITEM	QUANTITY_MEASURE_TYPE_ID	NUMBER	To maintain a standardized and structured method of collecting, reporting, coding, and evaluating authorized medicinal product data, the new QUANTITY_MEASURE_TYPE_ID is added to the MGR.MANUFACTURED_ITEM table.
Package Item Container Quantity	MGR.PDS_PACKSET_DETAILED_CHANGE	PI_CONTAINER_QUANTITY_MEASURE_TYPE_ID	NUMBER	To conform to the latest IDMP specification released, the new PI_CONTAINER_QUANTITY_MEASURE_TYPE_ID column is added to the MGR.PDS_MED_DEVICE_CHANGE table.MGR.
Package Item - MI	MGR.PDS_PACKSET_DETAILED_CHANGE	MI_QUANTITY_MEASURE_TYPE_ID	NUMBER	To conform to the latest IDMP specification released, the new MI_QUANTITY_MEASURE_TYPE_ID

Quantity Operator		E_ID		D column is added to the MGR.PDS_PACKSET_DETAIL_CHANGE table.
Device Quantity Operator	MGR.PDS_PACKSET_DETAIL_CHANGE	PDS_MED_DEVICE_QTY_MEASURE_TYPE_ID	NUMBER	To conform to the latest IDMP specification released, the new PDS_MED_DEVICE_QTY_MEASURE_TYPE_ID column is added to the MGR.PDS_PACKSET_DETAIL_CHANGE table.
Pack Size Quantity Operator	MGR.PDS_PACKSIZE	QUANTITY_MEASURE_TYPE_ID	NUMBER	To conform to the latest IDMP specification released, the new QUANTITY_MEASURE_TYPE_ID column is added to the MGR.PDS_PACKSIZE table.

UI Field Name	Database Table Name	Database Column Name	Database Column Type and Size	Description
Pack Size Quantity Operator	MGR.PDS_PACKSIZE_CHANGE	QUANTITY_MEASURE_TYPE_ID	NUMBER	To conform to the latest IDMP specification released, the new QUANTITY_MEASURE_TYPE_ID column is added to the MGR.PDS_PACKSIZE_CHANGE table.
Attachment Document Status	MGR.ACTION_ATTACHMENT	ATTACHED_DOCUMENT_STATUS_TYPE_ID	NUMBER	To conform to the latest IDMP specification released, the new ATTACHED_DOCUMENT_STATUS_TYPE_ID column is added to the

				MGR.ACTION_ATTACHMENT table.
Attached Document URL	MGR.ACTION_ATTACHMENT	URL	VARCHAR2(4000)	To conform to the latest IDMP specification released, the new URL column is added to the MGR.ACTION_ATTACHMENT table.
Sequence Standard Type	MGR.SEQUENCE	CTD_TYPE_ID	NUMBER	To conform to the new eCTD 4.0 requirements, the new CTD_TYPE_ID column is added to the MGR.SEQUENCE table.
UUID	MGR.SEQUENCE	UUID	VARCHAR2(50)	To conform to the new eCTD 4.0 requirements, the new UUID column is added to the MGR.SEQUENCE table.
Senderdefined Keywords Codesystem	MGR.APPLICATION	CODESYSTEM_FOR_SDKEYWORDS	VARCHAR2(200)	To conform to the new eCTD 4.0 requirements, the new CODESYSTEM column is added to the MGR.APPLICATION table.
UUID	MGR.APPLICANT_CONTACT	UUID	VARCHAR2(100)	To conform to the new eCTD 4.0 requirements, the new CODESYSTEM column is added to the MGR.APPLICANT_CONTACT table.

UI Field Name	Database Table Name	Database Column Name	Database Column Type and Size	Description
Prefix	MGR.APPLICANT_CONTACT	PREFIX	VARCHAR2(20)	To conform to the new eCTD 4.0 requirements, the new PREFIX column is added to the

				MGR.APPLICANT_CONTACT table.
First Name	MGR.APPLICANT_CONTACT	FIRST_NAME	VARCHAR2(200)	To conform to the new eCTD 4.0 requirements, the new PREFIX column is added to the MGR.APPLICANT_CONTACT table.
Middle Name	MGR.APPLICANT_CONTACT	MIDDLE_NAME	VARCHAR2(200)	To conform to the new eCTD 4.0 requirements, the new PREFIX column is added to the MGR.APPLICANT_CONTACT table.
Last Name	MGR.APPLICANT_CONTACT	LAST_NAME	VARCHAR2(200)	To conform to the new eCTD 4.0 requirements, the new LAST_NAME column is added to the MGR.APPLICANT_CONTACT table.
Suffix	MGR.APPLICANT_CONTACT	SUFFIX	Varchar2(20)	To conform to the new eCTD 4.0 requirements, the new SUFFIX column is added to the MGR.APPLICANT_CONTACT table.
Initials	MGR.APPLICANT_CONTACT	INITIALS	Varchar2(20)	To conform to the new eCTD 4.0 requirements, the new INITIALS column is added to the MGR.APPLICANT_CONTACT table.
Delimiter	MGR.APPLICANT_CONTACT	DELIMITER	Varchar2(10)	To conform to the new eCTD 4.0 requirements, the new DELIMITER column is added to the MGR.APPLICANT_CONTACT table.
Represented Company	MGR.APPLICANT_CONTACT	COMPANY_NAME	VARCHAR2(200)	To conform to the new eCTD 4.0 requirements, the new

Name				COMPANY_NAME column is added to the MGR.APPLICANT_CONTACT table.
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UI Field Name	Database Table Name	Database Column Name	Database Column Type and Size	Description
eCTD Standard Type	MGR.APPLICANT_CONTACT_TYPE	CTD_TYPE_ID	NUMBER	To conform to the new eCTD 4.0 requirements, the new CTD_TYPE_ID column is added to the MGR.APPLICANT_CONTACT_TYPE table.
Associated Entity ID	ODS.EXTRA_FIELDS_IP	ASSOCIATED_ENTITY_ID	NUMBER	To conform to the new eCTD 4.0 requirements, the new ASSOCIATED_ENTITY_ID column is added to the ODS.EXTRA_FIELDS_IP table.
eCTD Standard Type	ODS.ASSEMBLY	CTD_TYPE_ID	NUMBER	To conform to the new eCTD 4.0 requirements, the new CTD_TYPE_ID column is added to the ODS.ASSEMBLY table.
N/A	ODS.FOLDER	CV_NODE_ID	NUMBER	To conform to the new eCTD 4.0 requirements, the new CV_NODE_ID column is added to the ODS.FOLDER table.
Priority Number	ODS.LEAF	LEAF_PRIORITY_NO	NUMBER	To conform to the new eCTD 4.0 requirements, the new LEAF_PRIORITY_NO column is added to the ODS.LEAF table.

Document ID	ODS.LEAF	LEAF_PUB_DOC_UUID	VARCHAR2(100)	To conform to the new eCTD 4.0 requirements, the new LEAF_PUB_DOC_UUID column is added to the ODS.LEAF table.
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Database Columns Changed: Ennov InSight 7.3

The following Database columns were modified in this release.

UI Field Name	Database Table Name	Database Column Name	Database Column Type and Size	Description
N/A	ODS.ECTD_IMPORT	ASSEMBLY_PREFIX	VARCHAR2(30) has been changed to VARCHAR2(100)	To conform to the new eCTD 4.0 requirements, the ASSEMBLY_PREFIX column size is changed in the ODS.ECTD_IMPORT table.
N/A	ODS.ECTD_IMPORT	JOB_STATUS	VARCHAR2(30) has been changed to VARCHAR2(100)	To conform to the new eCTD 4.0 requirements, the JOB_STATUS column size is changed in the ODS.ECTD_IMPORT table.

N/A	ODS.LEAF_PDF_PROPERT Y	FIELD_NAME	VARCHA R2(30) has been changed to VARCHA R2(100)	To conform to the new eCTD 4.0 re- quirements, the FIELD_NAME column size is changed in the ODS.LEAF_PDF_PROPERTY table.
N/A	ODS.PSL_PDF_PROPER TY	FIELD_NAME	VARCHA R2(30) has been changed to VARCHA R2(100)	To conform to the new eCTD 4.0 re- quirements, the FIELD_NAME column size is changed in the ODS.PSL_PDF_PROPERTY table.
N/A	ODS.LEAF_STATUS_TY PE	CODE	VARCHA R2(30) has been changed to VARCHA R2(100)	To conform to the new eCTD 4.0 re- quirements, the CODE column size is changed in the ODS.LEAF_STATUS_TYPE table.

Database Columns Removed: Ennov InSight 7.3

The following Database columns and tables were removed in this release.

UI Field Name	Database Table Name	Database Column Name	Database Column Type and	Database Table Name
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			Size	
Attached Document Type	MGR.MEDICAL_DEVICE_UDI_TYPE	ATTACHED_DOCUMENT_TYPE_ID	N/A	The ATTACHED_DOCUMENT_TYPE_ID column is deleted from the MGR.MEDICAL_DEVICE_UDI_TYPE table.
Attached Document Type	ACTION_ATTACHMENT	ATTACHED_DOCUMENT_TYPE_ID	N/A	The ATTACHED_DOCUMENT_TYPE_ID column is deleted from the ACTION_ATTACHMENT table.
N/A	BROAD_INDC_CATEGORY	N/A	N/A	The BROAD_INDC_CATEGORY table is deleted. The data has been migrated to the PDS_BROAD_INDC_COUNTRY_INTENDED_EFFECT_COMORBIDITY table.
N/A	BROAD_INDC_INTENDED_EFFECT	N/A	N/A	The BROAD_INDC_INTENDED_EFFECT table is deleted. The data has been migrated to the PDS_BROAD_INDC_COUNTRY_INTENDED_EFFECT_COMORBIDITY table.
N/A	PRODUCT_INFORMATION_DOC_TYPE	N/A	N/A	The PRODUCT_INFORMATION_DO

				C_TYPE table is deleted.
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DaaS Database Tables Changed: Ennov InSight 7.3

The following DaaS Database fields, columns or/and tables 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.
N/A	N/A	N/A	N/A	The ATTACHED_DOCUMENT_STATUS_TYPE table is added.
N/A	N/A	N/A	N/A	The CTD_TYPE table is added.
N/A	N/A	N/A	N/A	The PDS_BROAD_INDC_COUNTRY_INTENDED_EFFECT_COMORBIDITY table is added.
N/A	N/A	N/A	N/A	The SOURCE_OF_INFORMATION_TYPE table is added.
N/A	N/A	ATTACHED_DOCUMENT_TYPE_ID	N/A	The respective column is removed from ACTION_ATTACHMENT table.
N/A	N/A	ATTACHED_DOCUMENT_STATUS_TYPE_ID	N/A	The respective columns are added to the ACTION_ATTACHMENT table.

		URL		
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Field Name	Field Size	Database Column Name	Database Column Size	Database Table Name
N/A	N/A	COMPANY_NAME DELIMITER FIRST_NAME INITIALS LAST_NAME MIDDLE_NAME PREFIX SUFFIX UUID	N/A	The respective columns are added to the APPLICANT_CONTACT table.
N/A	N/A	CTD_TYPE_ID	N/A	The respective columns are added to the APPLICANT_CONTACT_TYPE table.
N/A	N/A	CODESYSTEM_FOR_SDKEYWORDS	N/A	The respective columns are added APPLICATION table.
N/A	N/A	CODE	N/A	The respective column is added to the EVENT_PLAN_COUNTRY table.
N/A	N/A	QUANTITY_MEASURE_TYPE_ID	N/A	The respective column is added to the MANUFACTURED_ITEM table.
N/A	N/A	DEVICE_CLASS_TYPE_ID DEVICE- DESCRIPTION DEVICE_INTENDED_USE DEVICE_LANGUAGE_TYPE_ID	N/A	The respective columns are added to the PDS_MED_DEVICE_CHANGE table.

Field Name	Field	Database Column Name	Database Column	Database Table Name
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	Size		Size	
N/A	N/A	MI_QUANTITY_MEASURE_TYPE_ID D PDS_MED_DEVICE_QTY_MEASURE_TYPE_ID PI_CONTAINER_QUANTITY_MEASURE_TYPE_ID	N/A	The respective columns are added to the PDS_PACKSET_DETAIL_CHANGE table.
N/A	N/A	QUANTITY_MEASURE_TYPE_ID	N/A	The respective column is added to the PDS_PACKSIZE table.
N/A	N/A	QUANTITY_MEASURE_TYPE_ID	N/A	The respective column is added to the PDS_PACKSIZE_CHANGE table.
N/A	N/A	CTD_TYPE_ID UUID	N/A	The respective columns are added to the SEQUENCE table.

Data Administration

Data Administration Sections Added: Ennov InSight 7.3

The following Data Administration tables, sections, options, widgets, filters or fields were added for Ennov InSight 7.3.

Data Administration: Application Maintenance

Table 37: Regulatory Entitlement Status Values

Entity Affected	Field Name	Value List Description
N/A	<ul style="list-style-type: none"> – Regulatory Entitlement Status Name – Term ID – Term Name – Description – Last User 	To conform to IDMP requirements, the Regulatory Entitlement Status Values table with the corresponding fields and RMS tab is introduced in Data Administration. This list is mapped to the SPOR Master Lists > Regulatory Entitlement Status.

	Updated – Last Changed Date – Active Flag – RMS Term ID – RMS Modified On – RMS Status	
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Data Administration Section: Medical Device Maintenance

Table 38: Device Classification Values

Entity Affected	Field Name	Value List Description
N/A	– Device Classification Name – Countries – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag	To conform to IDMP requirements, the Device Classification Values table with the corresponding fields is introduced in Data Administration.

Data Administration Section: eCTD 4.0 Submission Maintenance

Table 39: CV Profile Values

Entity Affected	Field Name	Value List Description
Publishing Settings Library	<ul style="list-style-type: none"> – CV Profile Name – Region – Version – Category – Specification Name – Specification OID – Last User Updated – Last Changed Date – Active Flag 	To enable new controlled vocabularies to easily work with future eCTD 4.0 specification updates, the <i>CV Profile Values</i> table is introduced.

Table 40: CV Details

Entity Affected	Field Name	Value List Description
Publishing Settings Library	<ul style="list-style-type: none"> – Name – Version – OID – Can be associated? – Can be disassociated? 	To show the set of controlled vocabularies currently associated with selected eCTD 4.0 CV profile, the CV Details table is introduced.

Table 41: Sender-defined Keyword Values

Entity Affected	Field Name	Value List Description
Publishing Settings Library	<ul style="list-style-type: none"> – Code – Display Name – Last User Updated <ul style="list-style-type: none"> – Last Changed Date <ul style="list-style-type: none"> – Active Flag 	To maintain a new controlled vocabularies improvement for quick and easy eCTD 4.0 specification updates in future, the <i>Senderdefined Keyword Values</i> table is introduced.

Data Administration Section: Other

Table 42: Attached Document Status Values

Entity Affected	Field Name	Value List Description
Attached Document	<ul style="list-style-type: none"> – Attached Document Status Name <ul style="list-style-type: none"> – Last User Updated <ul style="list-style-type: none"> – Last Changed Date <ul style="list-style-type: none"> – Active Flag 	To conform to IDMP requirements, the Attached Document Status Values table with the corresponding fields is introduced in Data Administration.

Table 43: Source of Information Values

Entity Affected	Field Name	Value List Description
N/A	<ul style="list-style-type: none"> – Source of Information Name <ul style="list-style-type: none"> – Term ID 	To conform to IDMP requirements, the Source of Information Values table with the corresponding fields and RMS tab is introduced in Data

	<ul style="list-style-type: none"> – Term Name – Description – Last User <p>Updated</p> <ul style="list-style-type: none"> – Last Changed <p>Date</p> <ul style="list-style-type: none"> – Active – RMS Term ID – RMS Modified <p>On</p> <ul style="list-style-type: none"> – RMS Status 	<p>Administration. This list is mapped to the SPOR Master Lists > Source of Information.</p>
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Data Administration Section: SPOR Master Lists

Entity Affected	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 – Mapping <p>Source</p> <ul style="list-style-type: none"> – Source Term <p>Id</p>	<p>To conform to IDMP requirements to capture additional RMS data, the following tables are introduced:</p> <ul style="list-style-type: none"> – <i>Container Category</i> – <i>eCTD EU Context of Use</i> – <i>Medical Device Classification</i> – <i>Medical Device Legislative Category</i> – <i>Medicinal Product Type</i> – <i>Medicine Profile</i> – <i>Regulating Authority Submission Unit Type</i> – <i>Source of Information</i>

	<ul style="list-style-type: none"> – XEVMPD Code – Description – Comments – Version 	
	<p>Number</p> <ul style="list-style-type: none"> – ISO Code 	

Data Administration Section: Submission Maintenance Table 44: Applicant Contact Type Values

Entity Affected	Field/Column Name	Value List Description
Applicant Contact Type	eCTD Standard Type	To conform to the new eCTD 4.0 requirements, the <i>Applicant Contact Type Values</i> table now includes the this column.
Applicant Contact Type	<ul style="list-style-type: none"> – Region – CV OID – Code – Value 	To make the applicant contact type updates compatible with eCTD 4.0, the applicant contact type values now can be added using the Associate eCTD 4.0 Applicant Contact Type option taking values directly from the corresponding controlled vocabulary.

Data Administration Sections Updated: Ennov InSight 7.3

Data Administration tables, sections, options, widgets, filters or fields updated in Ennov InSight 7.3 release.

Data Administration Section: Other

Table 45: Attached Document Content Type Values

Entity Affected	Column/Field Name	Value List Description
Attached Document Content Type Values	<ul style="list-style-type: none"> – Term ID – Term Name – Short Name – Mapping Source 	<p>To capture and maintain correct SPOR controlled vocabulary lists for submitting data to EMA, the <i>Attached Document Content Type Values</i> is updated to allow RMS data association only from following SPOR Master Lists:</p> <ul style="list-style-type: none"> – <i>Product Information Document Type</i>

– Source Term ID	– <i>eCTD EU Context of Use</i>
– xEVMPD Code	– <i>Regulating Authority Submission Unit Type</i>
– ISO Code	

Table 46: Certificate Master File Values

Entity Affected	Column/Field Name	Value List Description
Substance	Substance Reference	This field is updated with improved <i>Substance Search</i> selection widget.

Data Administration Section: Product Detail Set Maintenance

Table 47: Component Type Values

Entity Affected	Column/Field Name	Value List Description
N/A	<ul style="list-style-type: none"> – RMS Term ID – RMS Modified On – RMS Status 	To conform to IDMP requirements to capture additional RMS data, the Component Type Values grid now includes the respective columns. The RMS tab is updated to allow data association from SPOR Master Lists > Container Category .

Entity Affected	Column/Field Name	Value List Description
Substance	Substance Name	This field is updated with improved <i>Substance Search</i> selection widget on the Manufacturer > Global Product Details > Global Detail Sets page (Detail Type > Substance).

Table 48: Device -Type of Combination Values

Entity Affected	Column/Field Name	Value List Description
N/A	<ul style="list-style-type: none"> – RMS Term ID – RMS Modified On – RMS Status 	<p>To conform to IDMP requirements to capture additional RMS data, the Device -Type of</p> <p>Combination Values grid now includes the respective columns. The <i>RMS</i> tab on the <i>Device -Type of Combination Values</i> page is enabled and updated to allow data association from SPOR Master Lists > Medical Device Legislative Category.</p>

Table 49: Intended Effect 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 – RMS Term ID – RMS Modified On – RMS Status 	The Intended Effect Values attributes page is updated with RMS tab, including the columns to associate and display the data from SPOR Master Lists > Medicine Profile .

Table 50: Manufacturer Values

Table 51: Substance Type Values

Entity Affected	Column/Field Name	Value List Description
Substance	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active – RMS Term ID 	The Substance Type Values page is updated with RMS tab, including the columns to associate and display the data from SPOR Master Lists > Ingredient Role.

	<ul style="list-style-type: none"> – RMS Modified On – RMS Status 	
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Data Administration Section: Registration Maintenance

Table 52: Data Carrier Type 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 – RMS Term ID – RMS Modified On – RMS Status 	To conform to IDMP requirements to capture additional RMS data, the <i>Data Carrier Type Values</i> attributes page is updated with RMS tab, including the columns to associate and display the data from SPOR Master Lists > Source of Information.

Table 53: Registration Status Values

Entity Affected	Column/Field Name	Value List Description
Registration Status Values	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag – RMS Term ID 	To conform to IDMP requirements to capture additional RMS data, the <i>Registration Status Values</i> attributes page is updated to associate and display the data from SPOR Master List > Regulatory Entitlement Status.

	<ul style="list-style-type: none"> – RMS Modified On – RMS Status 	
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Data Administration Section: Submission Maintenance

Table 54: Applicant Contact Values

Entity Affected	Field/Column Name	Value List Description
Applicant Contact	<ul style="list-style-type: none"> – UUID – Prefix – First Name – Middle Name – Last Name – Suffix – Initials – Delimiter – Represented Company Name 	To support 4.0 and 3.2 specification updates, you can now create an applicant contact with specific attributes. The <i>Applicant Contact Values</i> table is now updated with these fields.

Data Administration Sections Removed:Ennov InSight 7.3

The following Data Administration tables, sections, options, widgets, filters or fields were removed in Ennov InSight 7.3.

Data Administration Section: Application Maintenance

Table 55: Product Information Document Type Values

Entity Affected	Column/Field Name	Description

N/A	<ul style="list-style-type: none"> – RMS Term ID – RMS Modified On – RMS Status – Last User Updated – Last Changed Date – Active Flag – Product Information Document Type Name 	<p>The <i>Product Information Document Type Values</i> entity along with its fields and columns are removed from the <i>Application Maintenance</i> section.</p>
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Data Administration Section: Product Detail Set Maintenance

Table 56: Substance Roles Values

Entity Affected	Column/Field Name	Description
Substance	<ul style="list-style-type: none"> – RMS Term ID – RMS Modified On – RMS Status 	<p>The <i>RMS</i> tab along with its fields and columns are removed from this table.</p>

Data Administration Section: Registration Maintenance

Table 57: Qualified Person Responsible for Pharmacovigilance (QPPV) Values

Entity Affected	Column/Field Name	Description
N/A	<ul style="list-style-type: none"> – RMS Term ID – RMS Modified On – RMS Status 	<p>The <i>RMS</i> tab along with its fields and columns are removed from this table.</p>

Security Administration

Security Administration Tables Updated: Ennov InSight 7.3

Security Administration tables, sections, or fields updated in Ennov InSight 7.3 release.

Security Administration Section: License Modules

Entity Affected	Column/Field Name	Description
N/A	IDMP and xEVMPD	To support user's business flow of usage xEVMPD and IDMP, this field is now split into two fields: IDMP and xEVMPD.

Query Fields

Query Fields and Columns Updated: Ennov InSight 7.3

The following table describes fields that were updated with Ennov InSight 7.3

Registration Planning and Tracking Queries

Field/Column Name	Field Type	Description
Active Ingredient	Selection widget	This field is updated with improved <i>Substance Search</i> selection widget on the following pages: <ul style="list-style-type: none"> – <i>List of Product Families</i> – <i>Applications Sent, Submitted, or Approved - Searched by INN or Active Ingredient</i> when Use Active Ingredient Name Filter is selected for INN or Active Ingredient

Product Detail Management Queries

Field/Column Name	Field Type	Description
Active Ingredient Name	Selection widget	This field is updated with improved <i>Substance Search</i> selection widget on the following pages: <ul style="list-style-type: none"> – <i>List of Active Ingredient Manufacturers</i> – <i>List of Active Ingredient Function Manufacturers</i> – <i>List of Active Ingredient Material Manufacturers</i> – <i>List of Registrations with Active Ingredients</i>

Cumulative Security Administration

Field/Column Name	Field Type	Description
Substance Name	Selection widget	This field is updated with improved <i>Substance Search</i> selection widget on the following pages: – <i>List of Excipient Manufacturers</i> – <i>List of Registrations with Excipients</i>
Field/Column Name	Field Type	Description
Substance Name	Selection widget	This field is updated with improved <i>Substance Search</i> selection widget on the <i>List of Products with Registration and Flu Strain Details</i> page.

Job Requests

Job Requests Updated: Ennov InSight 7.3

The following table describes the columns that were updated with Ennov InSight 7.3.

Job Requests

Column Name	Column Type	Description
Job Name	Text	To support eCTD 4.0, the column in Job Requests > Search Results now includes the following values when an assembly is added, removed individually or, removed in bulk from life cycle: – Add Assembly to Lifecycle – Remove Assembly from Lifecycle – Duplicate Folder – Creating assembly
Job Name	Text	eCTD 4.0: When a leaf is auto-created on assigning a document, the status of the Priority number recalculation is shown under Job Requests > Search Results.
Job Name	Text	To notify users when the long running process is complete for the assembly files and folders with the size equal or bigger than the file or folder child nodes value set in the configuration, the column in Job

		Requests > Search Results now includes the Download document value.
Job Name	Text	With the IDMP Data Generation wizard implementation, the IDMP Data Generation Initial Flow value is added to Job Requests > Search Results.

Cumulative Job Requests

Chapter 3. Ennov InSight 7.3.1 Release Notes

Ennov InSight 7.3.1 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 7.3.1.

The details in these Release Notes supersede all similar details that appear anywhere else in this release of the product or its other documentation. **In-Process Linking Updates**

To support in-process linking for Linking plug-in (PDF) without accessing the Document Management System (DMS) of users, the following sections are updated:

- Publishing Settings Library
- Document Attributes

See: *Entity Fields, Columns and Options Removed: Ennov InSight 7.3.1. Linking plug-in (PDF)/Linking add-in (Word)*
Issue Resolved

In Ennov InSight 7.3.1, the authoring links created using Linking plug-in (PDF)/ Linking add-in (Word) with target documents in all supported file shares work correctly. See: *Defect DE30391 in Ennov InSight 7.3.1, Resolved Issues*

XEVMPD Updates

To support the latest European Medicine Agency (EMA) XEVMPD requirements, the following entities and wizards have been updated. See: *Entity Fields and Columns Added: Ennov InSight 7.3.1, Database Columns Changed Ennov InSight 7.3.1 – Entities:*

- Registration Attachment

– Wizards:

- XEVMPD Submission wizard

XEVMPD Submission Updates

In Ennov InSight 7.3.1, access rules for the XEVMPD Submission wizard are changed. Now, users with Data Administration rights set to NO can also create the XEVPRM .zip file for submission to the EMA.

Entity and Tab Changes

To improve application usability, changes have been made to the following entities and tabs. See: *Entity Fields and Columns Added: Ennov InSight 7.3.1.*

– Entities:

- Create Pending Changes

– Tabs:

- Pending Changes

Privacy Policy

To ensure compliance with data protection requirements, a link to the [Privacy Policy](#) is added to the Ennov InSight application, available from the Username menu on the top-right corner.

Regulatory Updates

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

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

- *Ennov InSight 7.3 Publisher > Submissions > Create eCTD Wizard > eCTD Attributes South Africa*
- *Ennov InSight 7.3 Publisher > Extension Type and Usage > Extension Type: Regional Folders > South Africa*

Affected Area	Update	Benefit
Pending Changes	The Pending Changes tab is updated with new option. See <i>Entity Fields, Columns and Options Added: Ennov InSight 7.3.1</i> and <i>Registrations > Apply Pending Changes</i> .	The ability to apply all/selected pending changes without closing an event.
Pending Changes	The Pending Changes tab is updated with new column. See <i>Entity Fields, Columns and Options Added: Ennov InSight 7.3.1</i> and <i>Registrations > Pending Changes and Entity Attributes</i> .	The ability to view countries associated with Change Scope > Registration on the Pending Changes tab.

- *Ennov InSight 7.3 Publisher > Administrative Activity > Import eCTD Applications > Prepare for Bulk eCTD Import > ZA 3.0 Applications*
- *Ennov InSight 7.3 Administration > eCTD Codes > eCTD Filing Types for ZA*
- *Ennov InSight 7.3 Administration > eCTD Filing Types for ZA > eCTD Sub-Filing Types for ZA*
- *Ennov InSight 7.3 Administration > Assembly XML Specification > m1-za v. 3.0*

TOC Templates Updates

The following TOC templates have been added for Chinese and Japanese languages: –

CNSampleTOCTemplate.docx

– JPSampleTOCTemplate.docx

Oracle Updates

To reduce the risk of the cursor leaks issue that was found to be an Oracle issue, Oracle jdbc driver is updated.

New in Ennov InSight 7.3.1: Registrations

New features and enhancements for Registration functionality is listed below.

Affected Area	Update	Benefit
Create Pending Changes	The <i>Create Pending Changes</i> wizard is updated with new <i>Full Product Presentation</i> flow. See <i>Entity Fields, Columns and Options Added: Ennov InSight 7.3.1, Registrations > Pending Changes and Entity Attributes</i> .	The ability to enter pending changes values for <i>Full Product Presentation</i> on the Pending Changes tab.
Create Pending Changes	The Create Pending Changes wizard is updated with new fields for <i>Registration</i> flow. See <i>Entity Fields, Columns and Options Added: Ennov InSight 7.3.1</i> .	The ability to enter more values for <i>Registration</i> flow on the Pending Changes tab.
Create Pending Changes	The Change Scope > Registration Package Set flow is updated. See <i>Entity Fields, Columns and Options Removed: Ennov InSight 7.3.1</i> .	The ability to create pending changes quicker as there is no need now to populate extra field.
Create Pending Changes	The Change Scope > Registration Package Set Country flow is updated. See <i>Entity Fields, Columns and Options Removed: Ennov InSight 7.3.1</i> .	The ability to create pending changes quicker as there is no need now to populate extra fields.
Registration Attachment	The <i>Registration Attachment</i> page is updated with new field. See <i>Entity Fields, Columns and Options Added: Ennov InSight 7.3.1 and Registrations > Registration Attachment > Registration Attachment Attributes</i> .	The ability to create XEVMPD submissions in accordance with the latest European Medicine Agency (EMA) requirements.
Full Product Presentation	The Full Product Presentation > Registrations FPP Attachments > Attached Name is updated with new field. See <i>Entity Fields, Columns and Options Added: Ennov InSight</i>	The ability to create XEVMPD submissions in accordance with the latest European Medicine Agency (EMA) requirements.

	<i>7.3.1 and Registrations > Registration Attachment > Registration Attachment Attributes.</i>	
XEVMPD Submission wizard	The generated XEVMPD file is updated with new value. Also, access rules for the XEVMPD Submission wizard are changed. See <i>Entity Fields, Columns and Options Added: Ennov InSight 7.3.1 and XEVMPD > Authorised Product Attachments</i>	The ability to create XEVMPD submissions in accordance with the latest European Medicine Agency (EMA) requirements. The ability to use the <i>XEVMPD Submission</i> wizard for users without access rights configured in the <i>Security Administration</i> .

Resolved Issues: Ennov InSight 7.3.1

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 previously released sub-minor build, that build number is included.

Common

Issue	SubMinor Build	Description
DE31646, [INC0315574]	N/A	Trying to create or update the Change External Number value using the API /change/create-or-update endpoint resulted in the following error message: Change External Number must be unique in the system. This issue is resolved. Now, External Change Number is successfully created/updated via the API /change/ create-or-update endpoint.
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 signon (SSO) works correctly.
DE31469, [INC0303021]	N/A	When using the <i>Global Project Plan</i> wizard, if multiple 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 less time to download the applications.

DE31436	N/A	The Pending Changes tab was displayed on the <i>Events Attributes</i> page even when Product Registration was selected for the Registration Type field. This issue is resolved. Now, the Pending Changes tab is not displayed when Product Registration is selected.
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	After a sequence was created for the EU CTR application and associated with workflow, trying to navigate to the Activity page or the Workflow page resulted in the Invalid reference error message. This issue is resolved. Now, both pages are displayed correctly.

Issue	SubMinor Build	Description
DE31029, [INC0273676]	N/A	<p>If an indication associated with product family was deactivated, trying to add it to an orphan designation using the following endpoints resulted in an error:</p> <ul style="list-style-type: none"> – API /orphan-designation/update – API /orphan-designation/create – API /orphan-designation/create-or-update <p>This issue is resolved. Now, a deactivated indication associated with a product family is successfully added to an orphan designation via API.</p>
DE31016, [TASK0051801,INC0273635]	N/A	<p>It was possible to create an orphan designation using the API /orphan-designation/create endpoint even if an application did not fulfill the following criteria:</p> <ul style="list-style-type: none"> – Marketing Authorisation Application (MAA) application type is selected. – EMA country is selected. – Orphan Drug flag is set to Yes.

		This issue is resolved. Now, it is not possible to create an orphan designation for an application that does not match the mentioned criteria using API.
DE31013, [INC0276375]	N/A	In 7.2.5, 7.2.7, 7.2.8 and 7.3 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.
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 reauthorization is not required to download the file using File Menu.
Issue	SubMinor Build	Description
DE29199	N/A	When there were 1000+ product families, trying to associate a product to an application ended in the Invalid reference error. This issue is resolved. Now, product is associated successfully.
DE28570	N/A	After changing the repository details in <i>Technical Administration</i> , the session of the previous user was still used and this caused issues with DMS login. As a result, performing any task in DMS required a server restart to complete. This issue is resolved. Now, performing a task in DMS does not require a server restart.
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 text are created without fonts that caused the font issue.
DE26800, 26725,	N/A	Ennov InSight sometimes failed to connect with the Veeva vault selected and instead established a connection with another Veeva

[INC0052690]		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.
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Publisher

Issue	Sub-Minor Build	Description
DE31352, [TASK0361714]	N/A	For a submission with files of 1 GB size or more, performing the Recalculate Checksums operation failed and Job Requests > Job Message displayed the Query stopped responding 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 Error: could not execute query message. This issue is resolved. Now, the Recalculate Checksums operation completes correctly and the Job Message displays relevant information.

Issue	Sub-Minor Build	Description
DE31322	N/A	Rendering of selected files sometimes failed 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	N/A	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 repeated 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

DE31122	N/A	<p>If file downloading was interrupted due to any technical issues, trying to download the same file later resulted in the Invalid reference error. This issue is resolved.</p> <p>Now, the file is downloaded successfully.</p>
DE31057	N/A	<p>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.</p>
DE30878	N/A	<p>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</p>
DE30601	N/A	<p>When creating a TOC in an assembly using the UCSampleTOCTemplate.docx template, the Generate TOC jobs failed. This issue is resolved. Now, the template is updated and Generate TOC jobs complete successfully.</p>

Issue	Sub-Minor Build	Description
DE30593	N/A	<p>Trying to create an assembly from an XML file with specific metadata populated for US Module1 v3.3 resulted in the following error message: You do not have the appropriate privileges to access the requested resource error message. This issue is resolved. Now, an assembly is successfully created from an XML when using the US Module v3.3 specification.</p>
DE30518	N/A	<p>The Application Number value in the US Admin Forms folder was missing when the US 3.3 assembly had been created using the <i>Create eCTD</i> wizard causing the publish operation to fail. This issue is resolved. Now, the wizard populates the Application Number field automatically by selecting a single value from the Application Contain Files? entry, if it is set to Yes. As a result, publishing completes successfully even if the Application Number has not been populated directly by a user.</p>
DE30391	N/A	<p>Authoring links created using Linking plug-in (PDF) or</p>

		Linking add-in (Word) did not work with the enhanced Secured File System of Ennov InSight when a document was assigned and Run Link Inspector was performed. This issue is resolved. Now, the links work with the enhanced Secured File System of Ennov InSight .
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.

Registrations

Issue	Sub-Minor Build	Description
DE30067, [INC0221620 PRB0044941]	N/A	Even after an event was closed as Approved, the Medical Device value with Withdrawn status was displayed in the Medical Device Reference field on the PDS Detail > Package Set > Add Package page. When a new event was assigned to the same PDS, the Medical Device value with Withdrawn status was also displayed in the Medical Device Reference field. Both issues are resolved. Now, if an event is closed as Approved or a new event is assigned to the same PDS Detail, the withdrawn Medical Device value is not displayed in the Medical Device Reference field.

Ennov InSight 7.3 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.3 Release Notes (Cumulative)

Entity Fields

Entity Fields, Columns and Options Added: Ennov InSight 7.3.1

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

Events

Ennov InSight RIM 7.3 Release Notes

Cumulative

Ennov InSight 7.3 COB and Known Issues

Table 58: Pending Changes

Field/ Column/ Option Name	Field Type	Description	Business Rules
Apply Pending Changes	N/A	The Apply Pending Changes icon is added to the Pending Changes tab on the <i>Events Attributes</i> page.	<p>If no pending changes are selected, using the Apply Pending Changes option results in the following alert message displayed: At least one value must be selected.</p> <p>If one or more pending changes are selected, using the Apply Pending Changes option results in the following message displayed: You are about to apply pending changes. Click OK to continue.</p> <p>Applied pending changes are not displayed on the Pending Changes tab.</p> <p>If two pending changes are created for the same entity, the Pending Changes tab shows only one, the newest, value.</p>
Country	N/A	The Pending Changes tab now includes the respective column.	Improves the usability of the application

Table 59: Create Pending Changes

Field/Column/ Option Name	Field Type	Description	Business Rules
Application Reviewing Countries	Multiselect	The <i>Full Product Presentation</i> flow is added to the Create	After <i>Full Product Presentation</i> flow is selected, the Application Reviewing Countries field is displayed. Once it populated, the Registrations
Registrations	Multiselect	Pending Changes > Select Pending Changes Entities >	field appears. The Full Product Presentation appears after registrations values are selected.

Full Product Presentation	Multiselect	Change Scope and includes all the	All other fields are displayed on the <i>Enter values for Pending Changes</i> page available after
Full Product Name	Text field	respective fields.	clicking on the Next button on the Select Pending Changes Entities page. If no values are selected for the fields Application Reviewing
Full Product Short Name	Text field		Countries, Registrations or Full Product Presentation, it is impossible to create pending
Product INN/ Common Name	Text field		changes. It is impossible to apply changes to FPP using
Product Company Name	Text field		the Pending Changes tab if the following fields are populated with the same values as the other
Product Strength	Text field		FPPs applied to the same registration: Concatenation of Full Product Name, EEA Country, Language, Package Description,
Product Form	Text field		Authorisation Status, Authorisation/Renewal
Authorisation Status	Select		Date, EVCode.
Authorized Pharmaceutical Form	Selection widget		
Authorisation/ Renewal Date	Date		
Withdrawn/ Invalidated Date	Date		
Information Date	Date		

XEVMPD Comments	Text field		
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Table 60: Create Pending Changes

Field/Column/ Option Name	Field Type	Description	Business Rules
License Issue Date	Date	The <i>Registration</i> flow on the Create Pending Changes > Select	New fields are displayed on the <i>Enter values for Pending Changes</i> page
Expiration Date/ Registration Valid Until	Date	Pending Changes Entities page now includes the respective fields.	available after clicking on the Next button on the <i>Select Pending Changes Entities</i> page.
Registered ATC	Multiselect		

Registration Attachment

Table 61: Create Registration Attachment

Field/Column/Option Name	Field Type	Description	Business Rules
2nd Attachment Language	Drop-down	The <i>Create Registration Attachment</i> page now includes the respective field.	The new 2nd Attachment Language field is displayed under the Attachment Language field. Values for the field are taken from the Other > Language Values DA List. The 2nd Attachment Language field can be updated on the pages <i>Modify Registration</i>

			<p><i>Attachment and Copy</i></p> <p><i>Registration</i></p> <p><i>Attachment.</i></p>
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Full Product Presentations

Table 62: Registration FPP Attachment

Field/Column/ Option Name	Field Type	Description	Business Rules
2nd Attachment Language	Select	<p>On the <i>Create Registration FPP Attachment</i> page, the concatenation of fields that displays in the Attached Name field now includes the respective field. The concatenation of fields displays in the following order: Internal Name - Attachment Language - 2nd Attachment Language - Attachment Name Attachment Version.</p>	<p>Values for the 2nd Attachment Language field are taken from the Other > Language Values Data Administration List.</p> <p>The 2nd Attachment Language field can be populated only on the <i>Create Registration FPP Attachment</i> page. For the following pages, this field is readonly:</p> <ul style="list-style-type: none"> – <i>Registration FPP Attachment</i> <p><i>Attributes</i></p> <ul style="list-style-type: none"> – <i>Copy Registration FPP Attachment</i> – <i>Modify Registration FPP Attachment</i>

Wizards

Table 63: XEVMPD Submission

Field/Column/ Option Name	Field Type	Description	Business Rules
2nd Attachment Language	N/A	<p>XEVMPD XML file generated after using <i>XEVMPD Submission</i> wizard now displays the respective value.</p>	<p>The 2nd Attachment Language value is displayed in the <attachment> section of the XEVMPD XML file under <languagecode2> tag.</p> <p>If 2nd Attachment Language field is not populated for the <i>Registration Attachment</i> entity, <languagecode2> tag also remains blank.</p>

Entity Fields, Columns and Options Removed: Ennov InSight 7.3.1

The following table describes fields, columns and options that were removed in this release.

Assembly, Assembly Templates

Table 64: Publishing Settings Library

Field/Column/ Option Name	Field Type	Description	Business Rules
In-Process Rendition Location	Browse field	This field is removed from Publishing Settings Library > Edit Publishing Settings for Assembly Specific Publishing Settings Library (APL) and Publishing Settings Library Template (PLT).	To support the default in-process linking for Linking plug-in (PDF) without the need to access the DMS, the configuration privilege for the user is removed.

Table 65: Document

Field/Column/ Option Name	Field Type	Description	Business Rules
Prepare Documents for Linking Location	Read-only field	This field will no longer be available on the <i>Document Attributes</i> page for the Prepare Document for Linking option applied.	To support the default in-process linking for Linking plug-in (PDF) without the need to access the DMS, the Prepare Documents for Linking Location field is removed.

Events

Field/ Column/ Option Name	Field Type	Description	Business Rules
Medicinal Products	Multiselect	This field is removed from the	The Registration Package Sets field is still available to populate. It appears after values for the fields Application Reviewing Country and Registrations are selected.

		Create Pending Changes > Change Scope > Registration Package Set.	
Medicinal Products	Multiselect	This field is removed from the Create Pending Changes > Change Scope > Registration Package Set Countries.	The fields Country and Registration Package Sets are still available to populate. They appear after values for the fields Application Reviewing Country and Registrations are selected.

Data Administration

Data Administration Sections Added: Ennov InSight 7.3.1

The following Data Administration tables, sections, options, widgets, filters or fields were added for Ennov InSight 7.3.1.

Data Administration Section: Submission Maintenance

Table 66: 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.

Database Columns

Database Columns Added: Ennov InSight 7.3.1

The following Database fields, columns and tables were added in this release.

UI Field Name	Database Table Name	Database Column Name	Database Column Type and Size	Description
2nd Attachment Language	MGR.ATTACHMENT_TYPE	LANGUAGE_TYPE_2_ID	NUMBER	To support XEVMPD requirements, new LANGUAGE_TYPE_2_ID column is added to provide additional language for Attached Documents. Populated from MGR.LANGUAGE_TYPE.

Cumulative Data Administration

Database Columns Removed: Ennov InSight 7.3.1

The following Database fields, columns and tables were removed in this release.

UI Field Name	Database Table Name	Database Column Name	Database Column Type	Description
In-Process Rendition Location	ODS. PUB_SETTINGS	IN_PROCESS _RENDITION _LOC_ID	NUMBER	To support the default inprocess linking for Linking plugin (PDF) without the need to access the DMS, the IN_PROCESS_RENDITION_LOC

Chapter 4. Ennov InSight 7.3.2 Release Notes

Ennov InSight 7.3.2 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 7.3.2.

The details in these Release Notes supersede all similar details that appear anywhere else in this release of the product or its other documentation. **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 Data Migration 7.3 > Ennov InSight 7.3.2 Updates*
- *Ennov InSight Publisher 7.3 > Submissions > Create eCTD Wizard > eCTD Attributes South Africa*
- *Ennov InSight Publisher 7.3 > Extension Type and Usage > Extension Type: Regional Folders > South Africa*
- *Ennov InSight Administration 7.3 > Administrative Activity > Import eCTD Applications > Prepare for Bulk eCTD Import > ZA 3.1 Applications*
- *Ennov InSight Administration 7.3 > eCTD Codes > eCTD Filing Types for ZA*
- *Ennov InSight Administration 7.3 > eCTD Filing Types for ZA > eCTD Sub-Filing Types for ZA*
- *Ennov InSight Administration 7.3 > 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. The Data Administration changes to support version 3.0 have been removed and replaced with support for version 3.1.*

Ennov InSight 7.3 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.3 Release Notes (Cumulative)

Chapter 5. Ennov InSight 7.3.3 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 7.3.3.

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

eCTD 4.0

Ennov InSight 7.3.3 introduces the following enhancements for eCTD 4.0:

- Ability to create an eCTD 4.0 working assembly from the locked eCTD 3.2 assembly submitted view. At this moment, envelope, additional attributes, and SDK creation are not copied over.
- Tracking the long-running process in Job Requests to monitor the creation of large eCTD 4.0 assemblies.
- Ability to map eCTD 4.0 template to Assembly DTD/Schema Types in Data Administration (Assembly > Assembly DTD/Schema Types).
- Recalculate Checksums
- Change Submittal Status wizard
- Create eCTD wizard - Initial assembly creation. For existing assembly, additional attributes are not populated. For more information, see *Create an eCTD Submission* under *Ennov InSight 7.3.3 eCTD 4.0 Publishing* help module.
- Please note, when performing incremental publishing, follow existing best practice and generate the XML only when doing the final publishing. This mechanism significantly improves the performance of XML generation.

Regulatory Updates

Ennov InSight 7.3.3 now supports World Health Organization (WHO) v1.0.

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

- Ennov InSight Data Migration 7.3 > Ennov InSight 7.3.3 Updates
- Ennov InSight Publishing 7.3 > Use eCTD Templates > eCTD Template Files
- Ennov InSight Publishing 7.3 > Submissions > eCTD Attributes World Health Organization
- Ennov InSight Publishing 7.3 > Extension Type and Usage > Extension Type: Regional Folders > WHO
- Ennov InSight Publishing 7.3 > Use eCTD Templates > Mapped eCTD Template Profiles
- Ennov InSight Publishing 7.3 > Extended Attributes Name, Type, and Version
- Ennov InSight Publishing 7.3 > Extension Types and Usage

– Ennov InSight Administration 7.3 > Data Administration > Data Administration Selection Lists: Submission Maintenance

– Ennov InSight Administration 7.3 > eCTD Codes > eCTD Codes for Filing Types > eCTD Filing Types for

WHO

– Ennov InSight Administration 7.3 > eCTD Codes > eCTD Codes for Filing Types > eCTD Filing Types for WHO > eCTD Sub-Filing Types for WHO

– Ennov InSight Administration 7.3 > Assembly XML Specification > Extensions > Groups of Extensions by Version and Country

– Ennov InSight Administration 7.3 > Assembly XML Specification > Extensions > Folder Extensions > m1-who v.

1.0

Ennov InSight 7.3.3 now supports European Union (EU) v3.1 submissions.

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

– Ennov InSight Publishing 7.3 > Use eCTD Templates > eCTD Template Files

– Ennov InSight Publishing 7.3 > Extended Attributes Name, Type, and Version

– Ennov InSight Administration 7.3 > Administrative Activities> Import eCTD Applications > Prepare for Bulk eCTD Import

– Ennov InSight Administration 7.3 > eCTD Codes > eCTD Codes for Country Values

– Ennov InSight Administration 7.3 > eCTD Codes > eCTD Codes for Filing Types > eCTD Filing Types for EU

– Ennov InSight Administration 7.3 > eCTD Codes > eCTD Codes for Filing Types > eCTD Filing Types for EU > eCTD Sub-Filing Types for EU

– Ennov InSight Administration 7.3 > Assembly XML Specification > Groups of Extensions by Version and Country

– Ennov InSight Administration 7.3 > Assembly XML Specification > Folder Extensions > m1-additional > m1additional v. 3.1

– Ennov InSight Administration 7.3 > Assembly XML Specification > Folder Extensions > envelope > envelope v.

3.1

– Ennov InSight Administration 7.3 > eu_module_1_country_specific_information > eu_module_1_country_specific_information v.3.1

– Ennov InSight Administration 7.3 > Folder Extensions > m1-responses > m1-responses v. 3.1

– Ennov InSight Administration 7.3 > Folder Extensions > m1-3-1-spc-label-pl > m1-3-1-spc-label-pl v. 3.1

– Ennov InSight Administration 7.3 > Administrative Activities > Manage eCTD and eCTD 4.0 Templates > eCTD Templates

Ennov InSight 7.3.3 now includes assembly templates for China eSubmissions.

IDMP Updates

Note: *The IDMP Data Generation, IDMP Data Visualization, IDMP Validation in Job Requests and FHIR message functionalities that were implemented as Proof of Concept (POC) in Ennov InSight 7.3 are updated in Ennov InSight 7.3.3. This release includes enhancements to the Proof of Concept (POC). To see and use the enhancements, rerun the IDMP Data Generation wizard..*

To conform to the latest standards set by International Organization for Standardization (ISO) and also improve the user experience, Ennov InSight now includes the following updates:

- New attributes in Data Administration (Other > Data Carrier Identifier Source Values, Registration Maintenance > Data Carrier Type, Product Detail Set Maintenance > Manufacturer Values > Manufacturing Authorization Reference Number).
- Multiple Data Administration tables moved from *Registration Maintenance* to *Application Maintenance*.

Ennov InSight RIM 7.3 Release Notes Cumulative

- New Alternate IDMP Reference Active Ingredient attribute on *Manufactured Item Reference Active Ingredient* and *Pharmaceutical Product Reference Active Ingredient*. For both pharmaceutical products and manufactured items, the same substance values can be selected multiple times for the Active Ingredient Name field if the Alternate IDMP Active Ingredient Name field is configured via overrides and contains a unique value.
- New Attached Document Country attribute on the *Attached Documents* page.
- New Device Quantity Unit of Measurement attribute on the *PDS Packaging Detail* page.
- The Device Quantity Unit attribute renamed to Device Quantity Unit of Presentation on the *PDS Packaging Detail* page.
- The length of the Manufactured Item Characteristics/Description value on the Manufactured Item and Manufactured Items tab on the Component is increased.
- Multiple fields renamed for *Registrations* entity.

IDMP POC Support

- Additional and updated entities and data points with the improved search and filter functionality and the ability to view validation messages from Job Requests on the IDMP Data Visualization page. When data does not meet the validation criteria, entity fields are marked with a symbol denoting errors or warnings.
- Job Requests updates for IDMP Data Generation in Job Requests > Search Results and Excel reports.

Product Search

The improved *Product Search* selection widget enables to filter products using specific search criteria in the following entities and wizards: – Entities:

- Applications (Create Application > Associated Products, Application Attributes > Associate/ Dissociate Products > Products)
- Events (Create Event > Products, Event Attributes > Associate/Dissociate Products > Associated Products)
- Product Registration (Application Attributes > Create Registration > Products, Registration Attributes > Associate/Dissociate Products > Products)

– Wizards:

- Create Application (Enter values for new application > Associated Products on *Create Application* and *Create Event* pages of the wizard)

Support of Special Characters

Ennov InSight 7.3.3 supports the use of more special characters in Documentum and File system. See: Ennov InSight 7.3 > Special Characters

Privacy Policy

To ensure compliance with data protection requirements, a link to the [Privacy Policy](#) is added to the Ennov InSight application, available from the Username menu on the top-right corner.

New in Ennov InSight 7.3.3: Common Functionality

This table shows new features and enhancements of Ennov InSight 7.3 functionality.

eCTD 4.0

To support eCTD 4.0, the following features are added:

Affected Area	Update	Benefit
Data Administration	<p>The following updates have been made to Data Administration:</p> <ul style="list-style-type: none"> – eCTD 4.0 Template Mapping in Assembly DTD/Schema Types. <i>See Data Administration Tables Updated: Ennov InSight 7.3.3</i> 	<p>To provide flexible configuration while updating submissions from eCTD 3.2 to eCTD 4.0, new attributes are added to Data Administration.</p>

IDMP

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

Affected Area	Update	Benefit
Entities/Entity tabs	<p>To conform to the latest IDMP specification, the following tab has been updated:</p> <ul style="list-style-type: none"> – Attached Documents. See <i>Entity Fields, Columns and Options Added: Ennov InSight 7.3.3</i> 	<p>The ability to view/add countries associated with the selected medicinal product on the <i>Attached Documents</i> page. The ability to create attached documents in accordance with the latest European Medicine Agency (EMA) IDMP requirements.</p>

Ennov InSight RIM 7.3 Release Notes

Cumulative

New in Ennov InSight 7.3.3: Common Functionality

Affected Area	Update	Benefit
Data Administration	<p>To conform to the latest IDMP specification, the following changes have been made to Data Administration:</p> <ul style="list-style-type: none"> – New fields added to Product Detail Set Maintenance > Manufacturer Values > Manufacturing Authorization Reference Number – New <i>Data Carrier Identifier Source Values</i> table added to Data Administration > Other – New Data Carrier Identifier Source value added to Registration Maintenance > Data Carrier Type – <i>Medicinal Product Action/Submission Statuses Values</i> table moved from <i>Registration Maintenance</i> to <i>Application Maintenance</i> – <i>Medicinal Product Name Part Type Values</i> table moved from <i>Registration Maintenance</i> to <i>Application Maintenance</i> – <i>Medicinal Product Type Values</i> table moved from <i>Registration Maintenance</i> to <i>Application Maintenance</i> 	<p>The ability to populate Data Administration values in accordance with the latest European Medicine Agency (EMA) IDMP requirements.</p>

	<p>See <i>Data Administration Tables Added: Ennov InSight 7.3.3</i>, <i>Data Administration Table Updated: Ennov InSight 7.3.3</i>, <i>Data Administration Table</i></p> <p>Removed: <i>Ennov InSight 7.3.3</i></p>	
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New in Ennov InSight 7.3.3: Registrations

The new features and enhancements for Registration functionality are as follows.

Affected Area	Update	Benefit
Applications	These entities are updated to include the	The widget enables effective
Events	improved <i>Product Search</i> selection widget.	and faster product search in these entities.
Product Registration	See: <i>Entity Fields, Columns and Options Updated: Ennov InSight 7.3.3</i>	
Create Application wizard		
Affected Area	Update	Benefit
Medicinal Product Actions	<p>Changes to IDMP include updates for the following:</p> <ul style="list-style-type: none"> – New and updated nodes on the <i>IDMP Data Visualization</i> page. See <i>Ennov InSight IDMP > IDMP Data Visualization Attributes</i>. – New field on the <i>Attached Documents</i> page. <p>See:</p> <ul style="list-style-type: none"> – <i>Entity Fields and Columns Added: Ennov InSight 7.3.3</i> – <i>Entity Fields and Columns Updated: Ennov InSight 7.3.3</i> – Job Requests updates. <p>See: <i>Job Requests Updated: Ennov InSight 7.3.3</i></p>	<p>To conform to the latest standards set by International Organization for Standardization (ISO) and also improve the user experience to capture IDMP data in Ennov InSight in preparation for submitting IDMP data to EMA.</p>

<p>Registrations</p>	<p>To support the latest IDMP requirements, changes are made to the following <i>Registrations</i> tabs:</p> <ul style="list-style-type: none"> – Package Sets – Package Descriptions – PDS-Manufacturer Details – Alternate IDMP Reference Active Ingredient field added <p>See: <i>Entity Fields, Columns and Options Updated: Ennov InSight 7.3.3</i></p>	<p>To conform to the latest standards set by International Organization for Standardization (ISO) and also improve the user experience to capture IDMP data in Ennov InSight in preparation for submitting IDMP data to EMA.</p>
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Ennov InSight RIM 7.3 Release Notes Cumulative

Affected Area	Update	Benefit
<p>Manufactured Items</p>	<p>To support the latest IDMP requirements, the <i>Manufactured Items</i> page now includes the following updates:</p> <ul style="list-style-type: none"> – Manufactured Item Characteristics/Description field length increased – If Alternate IDMP Reference Active Ingredient is configured via overrides and populated with a unique value, the Active Ingredient field on the <i>Create Active Ingredient</i> page allows users to select same substance values multiple times. <p>See: <i>Entity Fields, Columns and Options Added: Ennov InSight 7.3.3</i></p> <p><i>Entity Fields, Columns and Options Updated: Ennov InSight 7.3.3</i></p>	<p>To conform to the latest standards set by International Organization for Standardization (ISO). The update also improves user experience of capturing IDMP data in Ennov InSight in preparation for submitting IDMP data to EMA.</p>
<p>Pharmaceutical Products</p>	<p>To support the latest IDMP requirements, changes are made to the following:</p> <ul style="list-style-type: none"> – New Alternate IDMP Reference Active Ingredient field added on the <i>Reference Active Ingredient</i> page 	<p>To conform to the latest standards set by International Organization for Standardization (ISO). The update also improves user experience of capturing IDMP data in Ennov InSight in preparation for submitting IDMP data to EMA.</p>

	<p>– If Alternate IDMP Reference Active Ingredient is configured via overrides and populated with a unique value, the Active Ingredient field on the <i>Create Active Ingredient</i> page allows users to select same substance values multiple times.</p> <p>See: <i>Entity Fields, Columns and Options Added: Ennov InSight 7.3.3</i></p>	<p>turing IDMP data in Ennov InSight in preparation for submitting IDMP data to EMA.</p>
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Affected Area	Update	Benefit
PDS Details	<p>To support the latest IDMP requirements, the <i>PDS Packaging Detail</i> page now includes the following updates:</p> <ul style="list-style-type: none"> – New field added Device Quantity Unit of Measurement – The Device Quantity Unit field is renamed to Device Quantity Unit of Presentation <p>See: <i>Entity Fields, Columns and Options Added: Ennov InSight 7.3.3</i> and <i>Entity Fields, Columns and Options Updated: Ennov InSight 7.3.3</i></p>	<p>To conform to the latest standards set by International Organization for Standardization (ISO). The update also improves user experience of capturing IDMP data in Ennov InSight in preparation for submitting IDMP data to EMA.</p>

New in Ennov InSight 7.3.3: Publisher

New features and enhancements for Publishing functionality are listed below.

Affected Area	Update	Benefit
Assembly	<p>To expand the eCTD 4.0 functionality, Ennov InSight provides the ability to create an eCTD 4.0 working assembly from the locked eCTD 3.2.2 assembly submitted view. See:</p> <ul style="list-style-type: none"> – <i>Ennov InSight Publisher 7.3: eCTD 4.0 > Submissions > Create Working Assembly from Locked eCTD 3.2.2 Assembly</i> 	<p>To ensure forward compatibility with upcoming implementations and maintain the functionality of the existing submission elements, the assembly view and features are updated accordingly.</p>

	<p>– <i>Ennov InSight Administration > Data Administration > Assembly Maintenance: Assembly Values</i></p>	
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Ennov InSight RIM 7.3 Release Notes

Cumulative New in Ennov InSight 7.3.3: Publisher

Affected Area	Update	Benefit
<p>Assembly</p>	<p>To expand the eCTD 4.0 functionality, the following options are now available:</p> <ul style="list-style-type: none"> – Recalculate Checksums – Change Submittal Status wizard – Create eCTD wizard <p>See:</p> <ul style="list-style-type: none"> – <i>Ennov InSight Publisher 7.3: eCTD 4.0 >Assemblies> Recalculate Checksums</i> – <i>Ennov InSight Publisher 7.3: eCTD 4.0 >Submissions: <ul style="list-style-type: none"> • <i>Ennov InSight Publisher 7.3: eCTD 4.0 >Lifecycle> Modify Submission</i> <i>Statuses</i> <ul style="list-style-type: none"> • <i>Ennov InSight Publisher 7.3: eCTD 4.0 > Life Cycle> Lock Sequence</i> </i> <p><i>Assemblies</i></p> <ul style="list-style-type: none"> – <i>Entity Fields, Columns and Options Updated: Ennov</i> 	<p>To expand the eCTD 4.0 functionality and maintain the functionality of the existing submission elements, the wizards and features are updated accordingly.</p>

<p><i>InSight 7.3.3</i></p> <p>– <i>Ennov InSight Publisher 7.3:</i> <i>eCTD 4.0 > Submissions > Create</i> <i>eCTD Wizard:</i></p> <ul style="list-style-type: none"> • <i>Ennov InSight Publisher</i> <p><i>7.3: eCTD 4.0 > Submissions> Cre-</i> <i>ate eCTD Wizard> Create eCTD 4.0</i> <i>Submission</i></p>

Resolved Issues: Ennov InSight 7.3.3

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 build, that build number is included.

Common

Issue	Sub-Minor Build	Description
DE32097	N/A	Trying to edit or deactivate a Regulatory Entitlement Type value resulted in an error. This issue is resolved. Now, you can edit or deactivate a Regulatory Entitlement Type value successfully.
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.
DE31815, [TASK0925392]		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.

DE31795	N/A	Missing indexes in the database caused performance issue when trying to save entities after editing. This issue is resolved. Run the 7_3_3_0066_0058.zip script in addition to the main scripts during the migration procedure. The additional script must be run after the main script.
DE31757; [INC0321912, TASK0869957]	N/A	If the Documentum file names included invalid characters: \:*?\"<> , 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.
Issue	Sub-Minor Build	Description
DE31437	N/A	The API queryFor method failed to substitute the entityXMLMappingId, the applicationCategoryId and the associatedCountries fields values with their IDs for Application Type Values, Applicant ID Values and Secondary Event Type Values. These entities were not created and an error was displayed. This issue is resolved. Now, the Create or Update operations are successfully performed specifying the fields with IDs.
DE30586	N/A	For the applications with EU Clinical Trial Regulation application type and EU CTR procedure type, the values for the following fields were not saved if populated on the <i>Add Application Countries</i> page: <ul style="list-style-type: none"> – Local Start of Trial Date – Local First Visit of First Subject Date – Local End of Recruitment Date – Local End of Trial Date – Local Temporary Halt Date – Local Restart of Temporarily Halted Trial Date – Local Early Termination/Withdrawal/Suspension Date This issue is resolved. Now, the populated values are saved.
DE27309	N/A	When you select Global Project Plan > Modify Substance or Add Substance from <i>Project Attributes</i> page for the Update Product Details Sets project type, not all the fields are displayed in comparison to the Substance page in PDS.

		This issue is resolved. Now, all the fields are displayed.
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Publishing

Issue	Sub-Minor Build	Description
DE32081	N/A	For a document assigned to an assembly and its file type extension (such as .pdf) removed, running Prepare documents for linking and then running the Edit document links failed to download the document. This issue is resolved. Now, the document is downloaded successfully.
DE31792	N/A	In a study report datasets folder, if leafs have same names, using Recalculate Checksums from an assembly root results in same checksums for the leafs with same names. This issue is resolved. Now, even if the leafs have same names, the checksums will be different.

Issue	Sub-Minor Build	Description
DE31551	N/A	Using the Recalculate Checksums option on a published eCTD assembly that contained a period in the Application Code value generated extra files in the output location instead of updating the existing ones. This issue is resolved. Now, the existing files are updated.
DE31473	N/A	eCTD 4.0: Performance issue experienced when using Electronic Publish > All Leaf Elements and XML is resolved. The performance is improved.
DE31468	N/A	Trying to perform the Recalculate Checksums operation for an updated output document more than once in a short span of time failed and resulted in an error on the <i>Assembly Attributes</i> page. The same issue existed for DMS Synchronization. In this case the Bound Version field failed to be updated. These issues are resolved. The Recalculate Checksums and DMS Synchronization operations are successfully performed.
DE31457	N/A	When trying to simultaneously generate and render TOC within Prepare for Publishing job or separately within a short period of time, the job failed with the following error messages: <ul style="list-style-type: none"> – Resource not found – Unable to get rendition

		This issue is resolved. Now, you can simultaneously generate and render TOC more than once within a short period of time.
DE31448	N/A	Trying to search for entities using criteria in the API /query endpoint resulted in an error for many entities from the Application Maintenance section. This issue is resolved. Now, the entities are returned with parameters that match the specified criteria.
DE31130	N/A	Creating an in-process link in an assembly for the second time resulted in the document not opening in Adobe Acrobat or in Linking plug-in (PDF). This issue is resolved. Now, you can create an in-process link in an assembly for the second time and open the document in Adobe Acrobat or in Linking plug-in (PDF).
Issue	Sub-Minor Build	Description
DE30901	N/A	After a document is assigned to an assembly from the SMB file share, if that document in the SMB file share is deleted, the document icon and the Assignment status are only updated after a delay. This issue is resolved. Now, the document icon and the Assignment status are updated when the DMS synchronization window closes.

Registrations

Issue	Sub-Minor Build	Description
DE32280 [TASK1600548]	N/A	When Oracle is updated, previously working actions with some duplicating values may not work correctly. For example, trying to close an Event, having a PDS Substance with the same Substance Name and same Substance Role but with a different Substance Type, as approved resulted in an error. The issue is resolved. This issue is resolved.
DE32162	N/A	The XEVMPD acknowledgment file failed to auto upload when put on SMB fileshare. This issue is resolved. Now, the XEVMPD acknowledgment file auto uploads.
DE31861	N/A	The SPOR value was displayed in the IDMP Data Visualization Tree for Manufactured Item and Pharmaceutical Product - Substance. This issue is resolved. Now, the SPOR value is not displayed in the Tree.
DE31582	N/A	Trying to view Action values (U, I, or D) for the <i>Product</i>

		<i>Detail-Manufacturer</i> entity type in the Entity Audit Trail > Search Results table resulted in an error. This issue is resolved. Now, all Action values are successfully displayed in the Search Results table.
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Issue	Sub-Minor Build	Description
DE28575	N/A	<p>The performance of the Product Selection widget in the following areas has been improved by introducing the new Product Search widget:</p> <ul style="list-style-type: none"> – Create Application from <i>Applications</i> tab under PF Attributes. – <i>Create Application Wizard</i> (both Application and Event creation). – Associate/Disassociate Product under <i>Products</i> tab on <i>Application Attributes</i> page. – Create Event on <i>Application Attributes</i> page. – Associate/Disassociate Product under <i>Products</i> tab on <i>Event Attributes</i> page. – Create Registration on <i>Application Attributes</i> page. – Associate/Disassociate Product under <i>Products</i> tab on <i>Registration Attributes</i> page.

Entity Fields

Entity Fields, Columns and Options Added: Ennov InSight 7.3.3

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 and eCTD 4.0 publishing standards.

Medicinal Product Action

Table 67: IDMP Data Visualization

Field/Column/Option Name	Field Type	Description	Business Rules
N/A	N/A	The <i>IDMP Data</i>	To conform to the latest IDMP specification released and to improve the user experience, the validation messages from Job Requests are also available from the <i>IDMP Data Visualization</i> page.

		<i>Visualization</i> page now includes the validation messages from Job Requests.	
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Table 68: Attached Documents

Field/Column/ Option Name	Field Type	Description	Business Rules
Attached Document Country	Drop-down	The <i>Attached Documents</i> page now includes the respective field.	<p>New Attached Document Field is displayed under the Attached Document Effective Date. Values for the new field are taken from the Application Maintenance > Countries Values DA List.</p> <p>The new field can be populated on the <i>Create Attached Document</i> page and modified on the <i>Edit Attached Document</i> page.</p>

Manufactured Item

Table 69: Reference Active Ingredient

Field/Column/ Option Name	Field Type	Description	Business Rules
Alternate IDMP Reference Active Ingredient	Selection widget, drop-down	<p>The following pages are updated to include this field:</p> <ul style="list-style-type: none"> – <i>Create Reference Active Ingredient</i> – <i>Reference Active Ingredient Attributes</i> – <i>Modify Reference Active Ingredient Attributes</i> 	<p>The Alternate IDMP Reference Active Ingredient field is hidden OTB and only available if unhidden using overrides.</p> <p>This field can be configured as a substance selection widget with all active values from Data Administration > Substance Values, or as drop-down list with the values from the Component > Reference Active Ingredient.</p> <p>Only one value can be selected for the Alternate IDMP Reference Active Ingredient field and it can not be updated.</p>

Pharmaceutical Product

Table 70: Reference Active Ingredient

Field/Column/ Option Name	Field Type	Description	Business Rules
Alternate IDMP Reference Active Ingredient	Selection widget, drop-down	<p>The following pages are updated to include this field:</p> <ul style="list-style-type: none"> – <i>Create Reference Active Ingredient</i> – <i>Reference Active Ingredient Attributes</i> – <i>Modify Reference Active Ingredient Attributes</i> 	<p>The Alternate IDMP Reference Active Ingredient field is hidden OTB and only available if unhidden using overrides.</p> <p>This field can be configured as a substance selection widget with all active values from Data Administration > Substance Values, or as drop-down list with the values from the Component > Reference Active Ingredient.</p> <p>Only one value can be selected for the Alternate IDMP Reference Active Ingredient field and it can not be updated.</p>

PDS Details

Table 71: Packaging Details

Field/Column/ Option Name	Field Type	Description	Business Rules
Device Quantity Unit of Measurement	Drop-down	<p>The following pages now include the respective field:</p> <ul style="list-style-type: none"> – PDS Packaging > Add Packaging – PDS Packaging > Edit Packaging – PDS Packaging > Package Detail Attributes 	<p>Values for the Device Quantity Unit of Measurement field are taken from the Other > Units of Measurement Values Data Administration list.</p> <p>The Device Quantity Unit of Measurement field can not be populated if the Device Quantity Unit of Presentation field is already populated. Trying to populate the field in this case results in the You can set only one Device Quantity Unit type warning message.</p>

Entity Fields, Columns and Options Updated: Ennov InSight 7.3.3

The following tables describe fields, columns and options that were modified in this release. These include the fields and column that were added to support IDMP data capture, eCTD 4.0 publishing standards.

Applications

Field/ Column/ Option Name	Field Type	Description	Business Rules
Associated Products	Selection widget	<p>For the following pages, this field is updated with improved <i>Product Search</i> selection widget:</p> <ul style="list-style-type: none"> – Applications > Create Application – Application Attributes > Associate/Dissociate Products 	<p>The improved <i>Product Search</i> selection widget allows to filter search results using the following criteria: – All Products Family</p> <ul style="list-style-type: none"> – Family Code – Family Name – Family Type – Product Code – Product Name – Product Status <p>The Family Name filter remains blank if an application is associated with multiple product families.</p> <p>By default, only 20 products are displayed per page. However, this number can be increased via overrides. To configure overrides, please contact your Business Support Representative.</p>

Events

Field/ Column/ Option Name	Field Type	Description	Business Rules

Products	Selection widget	<p>The improved <i>Product Search</i> selection widget is added to the following pages:</p> <ul style="list-style-type: none"> – Events > Create Application – Event Attributes > Associate/Dissociate Products 	<p>With the improved <i>Product Search</i> selection widget, you can filter search results using the following criteria:</p> <ul style="list-style-type: none"> – All Products Family – Family Code – Family Name – Family Type – Product Code – Product Name – Product Status <p>The Family Name filter remains blank if an application is associated with multiple product families.</p> <p>By default, only 20 products are displayed per page. However, this number can be increased via overrides. To configure overrides, please contact your Business Support Representative.</p>
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Field/ Column/ Option Name	Field Type	Description	Business Rules
PDS Package Status Date	Read-only text	<p>The respective field is renamed to PDS Package Set Status Date on the following pages:</p> <ul style="list-style-type: none"> – <i>Modify Registration Package Set Association</i> – <i>Registration-Package Set Attributes</i> – <i>Entity Audit Trail</i> 	<p>To conform to the latest standards set by International Organization for Standardization (ISO) and also improve the user experience, the field name is also renamed on the Registration-Package Set tab.</p>

Product Registration

Field/ Column/ Option Name	Field Type	Description	Business Rules
Products	Selection widget	<p>The improved <i>Product Search</i> selection widget is added to the following pages:</p> <ul style="list-style-type: none"> – Application Attributes > Create Registration – Registration Attributes > Associate/Dissociate <p>Products</p>	<p>With the improved <i>Product Search</i> selection widget, you can filter search results using the following criteria: – All Products Family</p> <ul style="list-style-type: none"> – Family Code – Family Name – Family Type – Product Code – Product Name – Product Status <p>The Family Name filter remains blank if an application is associated with multiple product families.</p> <p>By default, only 20 products are displayed per page. However, this number can be increased via overrides. To configure overrides, please contact your Business Support Representative.</p>

Registrations

Table 72: Registration-Package Set Table 73: Package Descriptions

Field/ Column/ Option Name	Field Type	Description	Business Rules
Package Description	Box	<p>The respective field is renamed to PMP Package Description on the following pages:</p> <ul style="list-style-type: none"> – <i>Create Package Description page</i> 	<p>To conform to the latest standards set by International Organization for Standardization (ISO) and also improve the user experience, the exist-</p>

		<ul style="list-style-type: none"> – <i>Modify Package Description</i> – <i>Package Set-Package Description</i> <p><i>Attributes</i></p> <ul style="list-style-type: none"> – <i>Entity Audit Trail</i> <p>Also, the renamed field is now displayed in the Search Results table when using the Registration Package Set > Entity History Query option.</p>	<p>ing fields have also been renamed on the Package Descriptions tab.</p>
Language	Select	<p>The respective field is renamed to PMP Package Description Language on the following pages:</p> <ul style="list-style-type: none"> – Create Package Description – Modify Package Description – Package Set-Package Description <p><i>Attributes</i></p> <ul style="list-style-type: none"> – Entity Audit Trail <p>Also, the renamed field is now displayed in the Search Results table when using the Registration Package Set > Entity History Query option.</p>	<p>To conform to the latest standards set by International Organization for Standardization (ISO) and also improve the user experience, the existing fields have also been renamed on the Package Descriptions tab.</p>

Table 74: PDS-Manufacturer Details

Field/Column/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Manufacturer Operation Start Date – Manufacturer Operation Stop Date 	Date	<p>The fields are renamed to the Manufacturing Operation Start Date and Manufacturing Operation End Date respectively on the following pages:</p> <ul style="list-style-type: none"> – <i>Add Manufacturer</i> – <i>Edit Manufacturer</i> 	<p>To conform to the latest standards set by International Organization for Standardization (ISO) and also improve the user experience, the existing fields have been updated on the <i>PDSManufacturer Details</i> page.</p>

		<ul style="list-style-type: none"> – <i>Manufacturer Detail Attributes</i> – <i>Entity Audit Trail</i> 	
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Pharmaceutical Product

Table 75: Active Ingredient

Field/Column/ Option Name	Field Type	Description	Business Rules
Active Ingredient Name	Drop-down	On the <i>Create Active Ingredient</i> page, the field allows users to select the same substance value multiple times even if it was previously used to create Active Ingredient.	This functionality is only available if the Alternate IDMP Active Ingredient Name field is configured via overrides and contains a unique value.

Manufactured Items

Field/Column/Option Name	Filed Type	Description	Business Rules
Manufactured Item Characteristics/Description	Text	<p>On the following pages, the field length is increased to allow entering/displaying of up to 4000 characters when using single-byte character sets (one byte per character):</p> <ul style="list-style-type: none"> – <i>Create Manufactured Item</i> – <i>Modify Manufactured Item</i> – <i>Manufactured Item Attributes</i> – <i>Entity Audit Trail</i> 	<p>To conform to the latest standards set by International Organization for Standardization (ISO) and also improve the user experience, the maximum field length is increased. New rule is only applicable for single-byte character sets.</p>

Active Ingredient Name	Drop-down	On the <i>Create Active Ingredient</i> page, the field allows to select the same substance value multiple times even if it was previously used to create Active Ingredient.	This functionality is only available if the Alternate IDMP Active Ingredient Name field is configured via overrides and contains a unique value.
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PDS Details

Table 76: PDS Packaging Detail

Field/ Option/ Column Name	Field Type	Description	Business Rules
Device Quantity Unit	Drop-down	The respective field is now renamed to the Device Quantity Unit of Presentation.	To conform to the latest standards set by International Organization for Standardization (ISO) and also improve the user experience, the Device Quantity Unit field is renamed. Also, the values for the Device Quantity Unit field will not be populated if the Device Quantity Unit of Measurement field is already populated. Trying to populate the field in this case results in the You can set only one Device Quantity Unit type warning message displayed.

Wizards

Table 77: Create Application

Field/ Column/ Option Name	Field Type	Description	Business Rules
Associated Products	Selection widget	For the following pages, this field is updated with improved	New <i>Product Search</i> selection widget allows to filter search results using the following criteria: – All Products Family

		<p><i>Product Search</i> selection widget:</p> <ul style="list-style-type: none"> – Events > Create Event – Event Attributes > Associate/Dissociate <p>Products</p>	<ul style="list-style-type: none"> – Family Code – Family Name – Family Type – Product Code – Product Name – Product Status <p>The Family Name filter remains blank if an application is associated with several product families.</p> <p>By default, only 20 products are displayed per page. However, this number can be increased via overrides.</p>
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Table 78: Create eCTD

Field/Column/Option Name	Field Type	Description	Business Rules
Copy TOCs and Special Sheets	Check box	This field is not available in the <i>Create eCTD</i> wizard, when the submissions are created from the sequence which has the eCTD 4.0 value selected in the Sequence Standard Type.	To expand the eCTD 4.0 functionality and maintain the functionality of the existing submission elements, the wizards and features are
Template Selection	Drop-down list	This field is updated to load the corresponding eCTD 3.2 or eCTD 4.0 templates based on the region, values selected in the Sequence Standard Type and defined configuration.	updated accordingly.

Data Administration Tables

Data Administration Tables Added: Ennov InSight 7.3.3

The following Data Administration tables were added for Ennov InSight 7.3.3 release.

Data Administration: Other

Table 79: Data Carrier Identifier Source Values

Entity	Field Name	Value List Description
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Affected		
N/A	<ul style="list-style-type: none"> – Data Carrier Identifier Source – RMS Term ID – RMS Modified On – RMS Status – Last User Updated – Last Changed Date – Active Flag – Term ID – Term Name – Description 	<p>To conform to IDMP requirements, the Data Carrier Identifier Source Values table with the respective fields and RMS tab is introduced in <i>Data Administration</i>. The list is mapped to the SPOR Master Lists > Source of Information.</p> <p>The Data Carrier Identifier Source value can be modified using Edit option.</p>

Data Administration: Registration Maintenance

Table 80: Data Carrier Type Values

Entity Affected	Field Name	Value List Description
Data Carrier Type Values	Data Carrier Identifier Source	To conform to IDMP requirements, the Data Carrier Type Values table now includes the respective field. Values for it are taken from Other > Source of Information Values.

Ennov InSight RIM 7.3 Release Notes

Cumulative Data Administration Tables Added:

Data Administration Tables Updated: Ennov InSight 7.3.3

Data Administration tables were updated for Ennov InSight 7.3.3 release.

Data Administration Section: Application Maintenance

Table 81: Medicinal Product Action/Submission Status Values

Entity Affected	Column/Field Name	Value List Description
Medicinal Product	– Status Name	To conform to the latest IDMP requirements, the

Action / Submission Status Values	<ul style="list-style-type: none"> – Last User Updated – Last Changed Date – Active Flag 	<p><i>Application Maintenance</i> DA List is updated to include the <i>Medicinal Product Action/Submission Status Values</i> table with respective fields/columns. Values for the Status Name field can now only be populated via <i>Application Maintenance</i> and not <i>Registration Maintenance</i>.</p>
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Table 82: Medicinal Product Name Part Type Values

Entity Affected	Column/Field Name	Value List Description
Medicinal Product Name Part Type Values	<ul style="list-style-type: none"> – Medicinal Product Name Part Type Name – RMS Term ID – RMS Modified On – RMS Status – Last User Updated – Last Changed Date 	<p>To conform to the latest IDMP requirements, the <i>Application Maintenance</i> DA List is updated to include the <i>Medicinal Product Name Part Type Values</i> table with respective fields/columns. Values for the Medicinal Product Name Part Type Name field can now only be populated via <i>Application Maintenance</i> and not <i>Registration Maintenance</i>.</p>

Table 83: Medicinal Product Type Values

Entity Affected	Column/Field Name	Value List Description
Medicinal Product Type Values	<ul style="list-style-type: none"> – Medicinal Product Type Name – Medicinal Product Type Code – RMS Term ID – RMS Modified On – RMS Status – Last User Updated – Last Changed Date – Active Flag 	<p>To conform to the latest IDMP requirements, the <i>Application Maintenance</i> Data Administration List is updated to include the <i>Medicinal Product Type Values</i> table with respective fields/columns. Values for the fields Medicinal Product Type Name and Medicinal Product Type Code can now only be populated only via <i>Application Maintenance</i> and not <i>Registration Maintenance</i>.</p>

Ennov InSight RIM 7.3 Release Notes

Cumulative Data Administration Tables Updated:

Data Administration: Assembly

Table 84: Assembly DTD/Schema Types

Entity Affected	Field Name	Value List Description
Assembly	eCTD 4.0 Template Mapping	To determine fields and settings transition while migrating to eCTD 4.0, the <i>Assembly DTD/Schema Types</i> table now includes this field.

Data Administration Section: Product Detail Set Maintenance

Table 85: Manufacturer Values

Entity Affected	Field/Column Name	Value List Description
Manufacturer	<ul style="list-style-type: none"> – Function Types – Substances – Status Type – Status Date 	To conform to IDMP requirements, the <i>Manufacturing Authorization Reference Number</i> table now includes these these fields.

Data Administration Tables Removed: Ennov InSight 7.3.3

Data Administration tables were removed for Ennov InSight 7.3.3 release.

Data Administration Section: Application Maintenance

Table 86: Medicinal Product Action/Submission Status Values

Entity Affected	Column/Field Name	Value List Description
Medicinal Product Action / Submission	<ul style="list-style-type: none"> – Status Name – Last User Updated 	To conform to the latest IDMP requirements, the <i>Medicinal Product Action / Submission Status Values</i> table is now removed from Data Administration > Registration Maintenance.

Status Values	<ul style="list-style-type: none"> – Last Changed Date – Active Flag
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Ennov InSight RIM 7.3 Release Notes

Cumulative Data Administration Tables Removed:

Table 87: Medicinal Product Name Part Type Values

Entity Affected	Column/Field Name	Value List Description
Medicinal Product Name Part Type Values	<ul style="list-style-type: none"> – Medicinal Product Name Part Type Name – RMS Term ID – RMS Modified On – RMS Status – Last User Updated – Last Changed Date 	To conform to the latest IDMP requirements, the <i>Medicinal Product Name Part Type Values</i> table is now removed from Data Administration > Registration Maintenance.

Table 88: Medicinal Product Type Values

Entity Affected	Column/Field Name	Value List Description
Medicinal Product Type Values	<ul style="list-style-type: none"> – Medicinal Product Type Name – Medicinal Product Type Code – RMS Term ID – RMS Modified On – RMS Status – Last User Updated – Last Changed Date – Active Flag 	To conform to the latest IDMP requirements, the <i>Medicinal Product Type Values</i> table is now removed from Data Administration > Registration Maintenance.

Ennov InSight RIM 7.3 Release Notes

Cumulative Data Administration Tables Removed:

Query Fields

Query Fields

Query Fields and Columns Updated: Ennov InSight 7.3.3

The following table describes columns that were added with Ennov InSight 7.3.3

Entity Audit Trail Query

Field/Column Name	Field Type	Description
Attached Document Country	N/A	The respective column is displayed in the Entity Audit > Search Results > Query table available after Action column value on Search Results is selected.

Ennov InSight RIM 7.3 Release Notes

Cumulative Query Fields and Columns Updated:

Job Requests

Job Requests

Job Requests Updated: Ennov InSight 7.3.3

The following table describes the job requests and their options added and updated with the release of Ennov InSight 7.3.3.

Job Requests

Field/ Column/ Option Name	Field Type	Description
Export to Excel	Option	To improve user experience and report readability, all the tags are excluded in the Excel report from the Job Requests for IDMP Data Generation wizard.
Job Name	Text	The following Job status messages under IDMP Data Generation Initial Flow value in Job Requests > Search Results are now included to provide clarity of the Job results:

		<ul style="list-style-type: none"> – Completed with Warnings Job Status. – Error messages that indicate multiple values are assigned to an entity. – Error messages that indicate missing SPOR values for Data Administration entity. – Error messages that indicate inconsistent or empty values for repeatable entities. – Error message that indicates inconsistencies in values combinations. – Error and warning messages that indicate missing substance, and active ingredients values. – Warning messages that indicate some missing values for CP applications, registrations, and medicinal products.
Job Name	Text	To ensure forward compatibility with future implementations for eCTD 4.0, the column in Job Requests > Search Results now includes the Create Forward Compatibility assembly value when an eCTD 4.0 assembly is created from the locked eCTD 3.2 assembly submitted view.
Job Name	Text	To expand the eCTD 4.0 functionality, the column in Job Requests > Search Results now includes the Recalculate Checksums for: <node name> value for eCTD 4.0 that recalculates checksums for content that has been changed post publishing.

Ennov InSight RIM 7.3 Release Notes

Cumulative

Job Requests Updated: Ennov InSight

7.3.3

Database Columns

Database Columns Added: Ennov InSight 7.3.3

The following Database fields, columns and tables were added in this release.

UI Field Name	Database Table Name	Database Column Name	Database Column Type and Size	Description
Attached	MGR.ATTACHMENT_TYPE	COUNTRY_ID	NUMBER	The COUNTRY_ID

Document Country				column is added to the MGR.ATTACHMENT_TYP E table.
Attached Document Country	MGR.ACTION_ATTACHMENT	COUNTRY_ID	NUMBER	The COUNTRY_ID column is added to the MGR.ACTION_ATTACHMENT table.
Alternate IDMP Active Ingredient	MGR.XPHARMA_PRODUCT_REF_AI	ALTERNATE_REF_SUBSTANCE_ID	NUMBER	The ALTERNATE_REF_SUBSTANCE_ID column is added to the MGR.XPHARMA_PRODUCT_REF_AI table
Alternate IDMP Active Ingredient	MGR.MI_REF_AI	ALTERNATE_REF_SUBSTANCE_ID	NUMBER	The ALTERNATE_REF_SUBSTANCE_ID column is added to the MGR.MI_REF_AI table.
N/A	ODS.MIGRATION_ASSEMBLY_TEMPLATE_ID	REFERENCED_DT D_TYPE	NUMBER	The new REFERENCED_DTD_TYP E column is added to the ODS.MIGRATION_ASSEMBLY_TEMPLATE_ID table.
N/A	RAWSTAGE.ENTITY_INSTANCE_FIELD_VALUE	RAW_VALUE	CLOB	The new RAW_VALUE column is added to the RAWSTAGE.ENTITY_INSTANCE_INSTANCE table.

				STANCE_FIELD_VALUE table.
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Ennov InSight RIM 7.3 Release Notes

Cumulative

Database Columns Added: Ennov InSight

7.3.3

Database Columns Changed: Ennov InSight 7.3.3

The following Database fields, columns and tables were modified in this release.

UI Field Name	Database Table Name	Database Column Name	Database Column Size Old	Database Column Size New	Description
Manufactured Item Characteristics /Description	MGR.MANUFACTURED_ITEM	MANUFACTURED_ITEM	VARCHAR 2(500)	VARCHAR 2(4000)	The column size is changed to VARCHAR 2(4000).

Database Columns Removed: Ennov InSight 7.3.3

UI Field Name	Database Table Name	Database Column Name	Database Column Type and Size	Description
N/A	RAWSTAGE.ENTITY_INSTANCE_FIELD_VALUE	CONVERTED_VALUE	CLOB	The new CONVERTED_VALUE column is added to the RAWSTAGE.ENTITY_INSTANCE_FIELD_VALUE table.

The following Database fields, columns and tables were removed in this release.

UI Field Name	Database Table Name	Database Column Name	Database Column Type and Size	Description
N/A	RAWSTAGE.ENTITY_INS TANCE_FIELD_VALUE	TEXT_VALUE	CLOB	The TEXT_VALUE column is deleted from the RAWSTAGE.ENTITY_INS TANCE_FIELD_VALUE table.
N/A	RAWSTAGE.ENTITY_INS TANCE_FIELD_VALUE	DATE_VALUE	CLOB	The DATE_VALUE column is deleted from the RAWSTAGE.ENTITY_INS TANCE_FIELD_VALUE table.

Ennov InSight RIM 7.3 Release Notes

Cumulative Database Columns Changed: Ennov

UI Field Name	Database Table Name	Database Column Name	Database Column Type and Size	Description
N/A	RAWSTAGE.ENTITY_INS TANCE_FIELD_VALUE	LONG_VALUE	CLOB	The LONG_VALUE column is deleted from the RAWSTAGE.ENTITY_INS TANCE_FIELD_VALUE table.
N/A	RAWSTAGE.FIELD_DEFINITION	FIELD_TYPE_ID	CLOB	The FIELD_TYPE_ID column is deleted from the

				RAWSTAGE.ENTITY_FIEL D_DEFINITION table.
N/A	RAWSTAGE.FIELD_TYPE	N/A	CLOB	The RAWSTAGE.FIELD_TYPE ta- ble is deleted.
N/A	MGR.PDS_PACKSET_DE TAIL_CHANGE	COMP_QUANTITY_UOM _TYPE_ID	NUMBER	The unused COMP_QUANTITY_UOM_ TYPE_ID column is deleted from the MGR.PDS_PACKSET_DET AIL_CHANGE table to re- move the deprecated PDS Packaging Details entity fields
N/A	MGR.PDS_PACKSET_DE TAIL_CHANGE	COMP_QUANTITY_UOP_ TYPE_ID	NUMBER	The unused COMP_QUANTITY_UOP_T YPE_ID column is deleted from the MGR.PDS_PACKSET_DET AIL_CHANGE table to re- move the deprecated PDS Packaging Details entity fields
UI Field Name	Database Table Name	Database Column Name	Database Column Type and Size	Description

N/A	MGR.PDS_PACKSET_DE TAIL_CHANGE	COMP_QUANTITY_VALU E	NUMBER (24,12)	The unused COMP_QUANTITY_VALUE column is deleted from the MGR.PDS_PACKSET_DET AIL_CHANGE table to re- move the deprecated PDS Packaging Details entity fields
N/A	MGR.PDS_PACKSET_DE TAIL_CHANGE	CONTAINS_DI_PACKA GE_FLAG	VARCHAR 2 (1)	The unused CONTAINS_DI_PACKA _FLAG column is deleted from the MGR.PDS_PACKSET_DET AIL_CHANGE table to re- move the deprecated PDS Packaging Details entity fields
N/A	MGR.PDS_PACKSET_DE TAIL_CHANGE	PACKAGE_DISCONTIN UE_DATE	DATE	The unused PACKAGE_DISCONTINUE _DATE column is deleted from the MGR.PDS_PACKSET_DET AIL_CHANGE table to re- move the deprecated PDS Packaging Details entity fields

Ennov InSight 7.3 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.3 Release Notes (Cumulative)

Chapter 6. Ennov InSight 7.3.4 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 7.3.4.

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

eCTD 4.0

Ennov InSight 7.3.4 introduces the following enhancements for eCTD 4.0:

- In the forward compatibility assembly, the functions on leafs will be the same as in eCTD 3.2.
- Leafs migrated with forward compatibility are published with a different leaf reference format.
- For forward compatibility, eCTD 4.0 leaf now includes the reference to the eCTD 3.2 leaf.
- Envelope field values and sender-defined keywords are automatically migrated from the submitted 3.2 assembly to the working 4.0 assembly.
- The sender-defined keywords are created from the text values in metadata.
- The envelope fields are populated automatically in some cases.
- After making any changes to the Sender-defined Keywords, the Sender-defined Keywords tab now remains available on the Application Attributes page. This enhancement eliminates the need to navigate to the Sender-defined Keywords tab.
- Publishing of JP eCTD 4.0 submissions is improved in this release.
- When a whole module node is added and the Create eCTD Wizard is used, the repeatable folders are no longer sorted. The sub-nodes of repeatable folders, however, are sorted.

Regulatory Updates

Ennov InSight 7.3.4 now introduces Ukraine (UA) v1.0 submissions:

For more information about new UA values, extensions, and rules, see

- Ennov InSight Data Migration 7.3 > Ennov InSight 7.3.4 Updates
- Ennov InSight Administration 7.3 > eCTD Codes > eCTD Codes for Filing Types > eCTD Filing Types for UA v1.0
- Ennov InSight Administration 7.3 > eCTD Codes > eCTD Codes for Procedure Types
- Ennov InSight Administration 7.3 > eCTD Codes > eCTD Codes for Country Values T-Z
- Ennov InSight Administration 7.3 > Assembly XML Specification > Extensions > Groups of Extensions by Version and Country
- Ennov InSight Administration 7.3 > Assembly XML Specification > Extensions > Folder Extensions > envelope-ua > Envelope-ua v1.0
- Ennov InSight Administration 7.3 > Administrative Activities > Manage eCTD and eCTD 4.0 Templates > eCTD Templates
- Ennov InSight Publishing 7.3 > Use eCTD Templates > eCTD and NeeS Template Files
- Ennov InSight Publishing 7.3 > Use eCTD Templates > Mapped eCTD Template Profiles

- Ennov InSight Publishing 7.3 > Extended Attributes Name, Type, and Version
- Ennov InSight Publishing 7.3 > Submissions > Create eCTD Wizard > Ukraine-v1.0
- Ennov InSight Publishing 7.3 > Extension Type and Usage > Extension Type: Regional Folders > Ukraine

Ennov InSight 7.3.4 now introduces Australia (AU) v3.2 submissions:

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

- Ennov InSight Data Migration 7.3 > Ennov InSight 7.3.4 Updates
- Ennov InSight Administration 7.3 > Assembly XML Specification > Extensions > Groups of Extensions by Version and Country
- Ennov InSight Administration 7.3 > Assembly XML Specification > Extensions > Folder Extensions > m1-au v3.2
- Ennov InSight Administration 7.3 > Administrative Activities > Import eCTD Applications > Prepare for Bulk eCTD Import
- Ennov InSight Administration 7.3 > Administrative Activities > Manage eCTD and eCTD 4.0 Templates > eCTD Templates
- Ennov InSight Administration 7.3 > eCTD Codes > eCTD Codes for Filing Types > AU v3.2
- Ennov InSight Publishing 7.3 > Use eCTD Templates > eCTD and NeeS Template Files
- Ennov InSight Publishing 7.3 > Extended Attributes Name, Type, and Version
- Ennov InSight Publishing 7.3 > Use eCTD Templates > Mapped eCTD Template Profiles
- Ennov InSight Publishing 7.3 > Extension Type and Usage > Extension Type: Regional Folders > Australia

Ennov InSight 7.3.4 now supports Centralised Procedure for West African Health Organization (WAHO) v1.0 submissions:

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

- Ennov InSight Data Migration 7.3 > Ennov InSight 7.3.4 Updates
- Ennov InSight 7.3 Administration > eCTD Codes > eCTD Codes for Procedure Types > WAHO
- Ennov InSight 7.3 Administration > Application Maintenance > Application Maintenance: Application Values > Procedure Type Values
- Ennov InSight 7.3 Registration > Applications
- Ennov InSight 7.3 Registration > Applications > Create Application Wizard > CTA, CTR and IND Application
- Ennov InSight 7.3 Registration > Applications > Create Application Wizard > CTA, CTR and IND Application > Create a CTA, CTR or an IND Application
- Ennov InSight 7.3 Registration > Global Project Planning > Create a Project > New Applications Package Set Registration Project > Create a New Applications Package Set Registration Project
- Ennov InSight 7.3 Registration > Global Project Planning > Create Product Registrations for Project Events
- Ennov InSight 7.3 Registration > Applications > Copy Applications
- Ennov InSight 7.3 Registration > Applications > Application Countries > Remove Application Countries
- Ennov InSight 7.3 Registration > Events > Event-Country Statuses, Actual Dates, Projected Dates, and Lead Times

- Ennov InSight 7.3 Publisher > Ennov InSight Publishing
- Ennov InSight 7.3 Publisher > Create Submission Wizard > Major Update Submission
- Ennov InSight 7.3 Publisher > Create Submission Wizard > Initial Application Submission
- Ennov InSight 7.3 Publisher > Create Submission Wizard > Initial Application Submission > Initial Application Submission Attributes
- Ennov InSight 7.3 Publisher > Create Submission Wizard > Major Update Submission
- Ennov InSight 7.3 Publisher > Create Submission Wizard > Amendment Submission > Amendment Submission Attributes

Common Enhancements

For better search and selection capability, an improved version of Product Selection widget is included in the Create Submission and GPP wizards.

IDMP Updates

To comply with the latest EMA IDMP implementation Guide (Chapter 2 version 2.2) and also improve the user experience, Ennov InSight now includes various updates for IDMP data capture:

- The following fields have been added to the Pharmaceutical Product Substance and Active Ingredient entities:
 - Origin of Substance
 - Composition Grouping Description
- Ability to create same Substance value with the Same Substance Name and Type and different Composition Grouping Description field.
- By default, the Origin of Substance and Composition Grouping Description fields are hidden on the *PDS > Active Ingredient Detail* and *PDS > Substance Detail* pages.
- The Manufacturing Authorisation Reference Number under Data Administration > Manufacturer is enabled for extra fields functionality. Also, new Function Types, Substances and Status Types fields have been added on the Manufacturing Authorisation Reference Number.
- It is now possible to use RMS mapping for Data Administration > File Identifier Type Values to RMS Master File Identifier Type list.
- It is now possible to edit the Confidentiality Indicator under Data Administration > Manufacturer Values > Global Product Details.
- The new field **Required for IDMP?** is now included for all PDS > Manufacturer Details.
- The field type for **Medicinal Product Names > Full Name** is changed from Text field to Text area. This allows more than 4000 characters to be entered for the **Medicinal Product Names > Full Name** entity.

- The Manufacturer value now displays as a concatenation of **Manufacturer Name + Address Line + Country Code + (Location ID**, when associated to OMS).
- For a Registration Package Set entity, the field **Legal Status of Supply** is moved from **Registration Package Set Country** to **Registration Package Set**.
- For the following entities, new fields have been added for Presentation Strength and existing fields have been modified to comply with EMA's implementation guide for IDMP for the following entities:
 - Component Active Ingredient
 - Reference Active Ingredient
 - Manufactured Item Active Ingredient
 - Reference Active Ingredient
 - Pharmaceutical Product Active Ingredient
 - Reference Active Ingredient
 - Product Details Set Active Ingredient
 - Manufactured Item Substance
 - Reference Substance
 - Pharmaceutical Product Substance
 - Reference Substance
 - Product Detail Set Substance
 - Product Details Flu Strain

For more information about about the new fields added, see the *Presentation Strength* section under *Entity Fields, Columns and Options Added: Ennov InSight 7.3.4*

For more information on the changes made to the existing fields, see the *Presentation Strength* section under *Entity Fields, Columns and Options Updated: Ennov InSight 7.3.4*

- For the MI Quantity Unit and Device Quantity Unit fields under PDS Packaging Details, values are shown from both the **Unit of Presentation** and **Unit of Measurement** Data Administration lists.
- The heirarchy for PMSID is updated based on IDMP specification changes. In addition, the IDMP tab on the Application Attributes page is updated..
- For all Application Procedure Types, the new field **Package PMSID** is included for Registration Package Set.
- To prepare for IDMP, the Associate Term icon is available on Data Administration > Substance Values and allows SMS values to be associated.
- For Packaging PDS Detail, the new field Parent Package is included with a logic. For more information, see Entity Fields, Columns and Options Added: Ennov InSight 7.3.4.

Publishing

When using the Remove Submissions from Lifecycle to this Sequence option to remove multiple sequences from lifecycle, the confirmation message now specifies the number of sequences that will be removed.

Registration

- It is now possible to disassociate multiple Change Details from an Event simultaneously.

XEVMPD

- The new option **Full Product Presentation under the same Registration per each Package Set is used** is now available to create a copy of the original Full Product Presentation for each Package Set selected under the same Registration. Using this option does not update the **Package Description** field.
- Full Product Presentation entity
 - Country field on Full Product Presentation is hidden OOTB now, same as in the Copy FPP wizards.
 - The new field **MAH/Organisation Transferred To** is available when Authorisation Status **Not Valid - Superseded by Marketing Authorisation Transfer** is selected for FPP entity.
 - XEVMPD Submission Wizard is updated to reflect those changes to include new tag to the XML structure.
- The Copy FPP wizard is enhanced to copy fields that were empty.

API

It is now possible to search by substanceReference and manufacturers fields using the API query endpoint.

New in Ennov InSight 7.3.4: Common Functionality

This table shows new features and enhancements of Ennov InSight 7.3.4 functionality.

IDMP

Affected Area	Update	Benefit
Entities	<p>The following new fields are added for Manufactured Item and Pharmaceutical Product Active Ingredient and Substance:</p> <ul style="list-style-type: none"> • Origin of Substance • Composition Grouping Description 	To support IDMP data capture.
Entities	<p>On the pages listed below, the manufacturer value now displays as a concatenation of Manufacturer Name + Address Line + Country Code + (Location ID (when associated to</p>	This enhancement enables a user to select the correct manufacturer when preparing for IDMP submission.

Affected Area	Update	Benefit
	<p>OMS)). The OMS Status is added if not 'Active'.</p> <ul style="list-style-type: none"> • GPP: Update PDS • Application History Query • Application QC Status History Report • List of Active Ingredient Manufacturers • List of Active Ingredient Function Manufacturers • List of Active Ingredient Material Manufacturers • List of Excipient Manufacturers • List of PDS Manufacturers • List of Component Manufacturers • List of Package Set Manufacturers 	

New in Ennov InSight 7.3.4: XEVMPD

This table shows new features and enhancements of Ennov InSight 7.3.4 functionality.

Affected Area	Update	Benefit
Entity	<p>The new wizard flow Full Product Presentation under the same Registration per each Package Set is used is now available for each Package Set.</p>	<p>This new option allows you to create a copy of the original Full Product Presentation for each Package Set selected under the same Registration..</p>

Resolved Issues: Ennov InSight 7.3.4

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

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

Common

Issue	Sub-Minor Build	Description
DE32075		Without the NOT DEFINED Country rights, trying to delete an application that had a submission in the lifecycle resulted in an error message. This issue is resolved. Now, you can delete an application with a submission in the lifecycle even without the NOT DEFINED Country rights.
DE32055; [TASK1344819]		The override to hide or rename failed for the Create Application label in the Wizards menu. This issue is resolved. Now, the Create Application label can be hidden or renamed using the override option.
DE31886		If the Manufacturing Authorisation Reference Number, under Data Administration > Product Detail Set Maintenance > Manufacturer Values > Manufacturer, was updated through API, the Effective Date field was empty. This issue is resolved. Now, the Effective Date field contains the correct date.
DE31480		API request failed to update the following fields under Data Administration > Product Detail Set Maintenance > Manufacturer > Manufacturing Authorisation Reference Number: – Effective Date – Country – Regulatory Agency This issue is resolved. Now, all the fields are updated when using the API.

Resolved Issues: Ennov InSight 7.3.4

IDMP

Issue	Sub-Minor Build	Description
DE32277		When making a POST request to delete the Origin of Substance data administration value, the following error was displayed in the response. This issue is resolved. Now, no error is displayed When

		making a POST request to delete the Origin of Substance data administration value.
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New in Ennov InSight 7.3.4: Common Functionality

Entity Fields

Entity Fields, Columns and Options Added: Ennov InSight 7.3.4

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

PDS Manufacturer

Field/Column/Option Name	Field Type	Description	Business Rules
Required for IDMP?	Dropdown	The Required for IDMP? field is now included for PDS Manufacturer Details.	To conform to the latest IDMP specification, the Required for IDMP? field is now included for PDS Manufacturer.

Manufactured Item and Pharmaceutical Product

Field/Column/Option Name	Field Type	Description	Business Rules
Origin of Substance Composition Grouping Description	Dropdown	<p>These fields are included for the following entities:</p> <ul style="list-style-type: none"> • Manufactured Item Active Ingredient • Manufactured Item Substance • Pharmaceutical Product Active Ingredient • Pharmaceutical Product Substance 	To conform to the latest IDMP specification, these fields are now included.

Presentation Strength

Field/Column/Option Name	Field Type	Description	Business Rules
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Presentation Single/Low Limit Denominator Value	Number	These Presentation Strength fields are newly added for the following entities: <ul style="list-style-type: none"> • Component Active Ingredient • Reference Active Ingredient • Manufactured Item Active Ingredient • Reference Active Ingredient • Pharmaceutical Product Active Ingredient • Reference Active Ingredient • Product Details Set > Active Ingredient Detail • Manufactured Item Substance • Reference Substance • Pharmaceutical Product Substance • Reference Substance • Product Detail Set > Substance Details 	These new fields are added to comply with EMA's ISO standards for IDMP
Presentation Single/Low Limit Denominator - Unit of Presentation/Measurement	Drop-down		
Presentation High Limit Denominator Value	Number		
Presentation High Limit Denominator - Unit of Presentation/Measurement	Drop-down		

Medicinal Product Identifier (MPID)

Field/Column/Option Name	Field Type	Description	Business Rules
PMSID	Drop-down	For CP Application Procedure Type, the new field PMSID is included for Medicinal Product and shows a concatenated value of PMS and EU or EEA Country.	This new field is added to comply with EMA's ISO standards for IDMP.

Packaged Medicinal Product Identifier (PCID)

Field/Column/Option Name	Field Type	Description	Business Rules
PMSID	Drop-down	For CP Application Procedure Type, the new field PMSID is included for PMSID and shows a concatenated value of PMS and EU or EEA Country.	This new field is added to comply with EMA's ISO standards for IDMP.
MPID	Drop-down	Shows the MPID assigned to PMSID.	This new field is added to comply with EMA's ISO standards for IDMP.

Product Management Service Identifier (PMSID)

Field/Column/Option Name	Field Type	Description	Business Rules
PMSID Country	Drop-down	For CP Application Procedure Type, selecting PMSID shows the EEA Country value under PMSID Country.	This new field is added to support IDMP data capture.

Registration Package Set

Field/Column/Option Name	Field Type	Description	Business Rules
Legal Status of Supply	Drop-down	This option is available in the Registration Package Set Country for a Registration Package Set entity.	This option is introduced to conform to the requirements of the health authorities.
Package PMSID	Text	For all Application Procedure Type, the text field Package PMSID is added to the Registration Package Set.	This new field is added to comply with EMA's Implementation Guide for IDMP.

Packaging PDS Detail

Field/Column/Option Name	Field Type	Description	Business Rules
Parent Package	Text	<p>This field is included for Packaging PDS Detail with the following logic:</p> <ol style="list-style-type: none"> 1. List in Component Packaging - From same component: <Component name> + <PDS packaging Category> + <PDS Packaging Type> defined (but not self). 2. List in Packset Packaging - On the packset level: all "Packset " + <PDS packaging Category> + <PDS Packaging Type> defined (but not self) 	This new field is added to comply with EMA's ISO standards for IDMP.

Change Details

Field/Column/Option Name	Field Type	Description	Business Rules
Change Details	Check box	This option is available on the Change Details tab for an Event.	This feature allows you to simultaneously disassociate multiple Change Details and thereby enhances efficiency when working with Events and Change Details.

Full Product Presentation

Field/Column/Option Name	Field Type	Description	Business Rules
MAH/Organisation Transferred To	Drop-down	The option is available for Authorisation Status when Not Valid - Superseded by Marketing Authorisation Transfer is selected for FPP entity.	This new option is introduced to reflect changes to include new tag to the XML structure.
Full Product Presentation under the same Registration per each Package Set	Check box	This option is available in the Copy Full Product Presentation wizard.	This new option allows you to create a copy of the original Full Product Presentation for each Package Set selected under the same Registration.

Entity Fields, Columns and Options Updated: Ennov InSight 7.3.4

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

Medicinal Product Name

Field/Option Name	Field Type	Description	Business Rules
Full Name	Text	The field type is changed from Text to Text area for Medicinal Product.	The change allows more than 4000 characters to be entered for the Medicinal Product name.

PDS Component

Field/Option Name	Field Type	Description	Business Rules
Origin of Substance Composition Grouping Description	Text	By default, these fields are hidden on the <i>PDS Component > Active Ingredient Details</i> and <i>PDS Compo-</i>	These fields are hidden as they are available now on Pharmaceutical Product and Manufactured Item.

Field/Option Name	Field Type	Description	Business Rules
		<i>ment > Substance Details</i> pages.	

Presentation Strength

The table below provides details of the changes made to the Presentation Strength fields to conform to EMA's requirements. For a list of entities with changes to Presentation Strength fields, see IDMP Updates section in the Ennov InSight 7.3.4 Release Notes topic.

Existing Field Name	Existing Field Type	Change	New Field Name	New Field Type
Concentration Measure Type	Drop-down	Field name changed	Strength (Presentation) Quantity Operator	Drop-down (no change)
Presentation Single or Low Limit Numerator Value	Text	Field name and type changed	Presentation Single/Low Limit - Numerator Value	String
Presentation Single or Low Limit Unit of Measurement	Drop-down	Field name changed	Presentation Single/Low Limit Numerator - Unit of Measurement	Drop-down (No change)
Presentation Single or Low Limit Unit of Presentation	Drop-down	Field name changed This field is hidden by default.	DP Presentation Single or Low Limit Unit of Presentation	Drop-down (No change)
Presentation High Limit Numerator Value	Text	Field name and type changed	Presentation High Limit Numerator Value	String
Presentation High Limit Unit of Measurement	Drop-down	Field name changed	Presentation High Limit Numerator - Unit of Measurement	Drop-down (no change)

Existing Field Name	Existing Field Type	Change	New Field Name	New Field Type
Presentation High Limit Unit of Presentation	Drop-down	Field name changed. This field is hidden by default.	DP Presentation High Limit Unit of Presentation	Drop-down (no change)

Packaging PDS Detail

Field/Option Name	Field Type	Description	Business Rules
MI Quantity Unit and Device Quantity Unit	Text	Values from both Unit of Presentation and Unit of Measurement Data Administration are displayed for MI Quantity Unit.	The change is made to support IDMP data capture.

Substance Values

Field/Option Name	Field Type	Description	Business Rules
Associate Term	Text	SMS values may be assigned under Data Administration > Substance Values > SMS tab.	The change is made to support IDMP data capture.

Device Quantity Unit

Field/Option	Field Type	Description	Business Rules
Device Quantity Unit	Text	The field Device Quantity Unit of Presentation is now renamed to Device Quantity Unit and shows values from Unit of Presentation Values and Units of Measurement.	The change is made to comply with EMA's implementation of the ISO standards for IDMP.

Confidentiality Indicator

Field/Option	Field Type	Description	Business Rules
Confidentiality Indicator	Text	The Confidentiality Indicator value under Data Administration > Manufacturer Values > Global Product Details can now be modified.	The change is made to comply with EMA's implementation of the ISO standards for IDMP.

XEVMPD

Field/Option Name	Field Type	Description	Business Rules
Country	Drop-down	This option is hidden by default.	This change is introduced to comply with EMA's requirement and enhance user experience.

Entity Fields, Columns and Options Removed: Ennov InSight 7.3.4

The following table describes fields, columns and options that were removed in this release.

Medicinal Product Identification (MPID)

Field/Column/Option Name	Field Type	Description	Business Rules
Device Quantity Unit of Measurement	Text	This field is removed by default.	This change is made to comply with EMA's implementation of the ISO standards for IDMP
Country	Drop-down	The Country field is hidden by default.	This change is made to comply with EMA's implementation of the ISO standards for IDMP.

Registration Package Set Country

Field/Column/Option Name	Field Type	Description	Business Rules
Legal Status of Supply	Drop-down	This field under Registration Package Set Country is removed by default.	This change is made to support IDMP data capture.

Chapter 7. Clarification of Behavior: Ennov InSight 7.3

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
DE32324	N/A	<p>Veeva SSO does not work some times if the Ennov InSight user credentials does not match the Federated User for Veeva SSO.</p> <p>Workaround: Make multiple Microsoft accounts on the browser. You will be prompted to select the appropriate account to log on.</p>
N/A	N/A	<p>After migrating to Ennov InSight 7.3, the following user settings are reset to default for the migrated users.</p> <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	<p>After migrating to Ennov InSight 7.3, Public or Private queries saved in the Ennov InSight 6.2 query list will not be available in the Ennov InSight 7.3 query list for the migrated and newly added users.</p>
N/A	Assembly	<p>Performing any action 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.</p>
Issue	Affected Area	Description

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.
DE30854	Entity History Query	If selected ATC is removed, the Entity History Query > Registered ATC Audit Details query shows new row with D (Delete) action instead of both D and I (Insert). If multiple ATCs are removed, rows with D action as many as the number of ATCs removed are shown in the query.
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	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.

Ennov InSight Publisher

Issue	Affected Area	Description
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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	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. <i>Note: It is highly recommended to consider the file name length from DMS as long file names can cause issues. See Special Characters.</i>
DE26775	Assembly,DMS Browse, Technical Administration	The attempt to log in to Veeva from DMS Browse using SSO profile results in an error message.
DE30272	Assembly	It is not possible to download output file for published reference leaf using the View File option.
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
DE28147	Global Project Plan wizard	Using the <i>Global Project Plan</i> wizard, if multiple applications are created with the Create New Event for Existing CTA and/or IND Application(s) option and then a sequence is created, the same Sequence Standard Type value will be applied to all the created sequences.

		If there is at least one eCTD 4.0 sequence, under affected applications, the eCTD 4.0 will be the only available option.
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.

Chapter 8. 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
240123 (Added on 9th April, 2024)	Assembly	When using the Prepare Cross Reference Leafs option, if there are multiple reference leafs pointing to the same target leaf, the checksum value is generated for one leaf only.
DE32002 (Added on the 29th of August, 2024)	Assembly	After assigning a document on folder from SMB, the PDF Exists value of the document is not set to Yes.
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.
DE30194	Entity History Trail	After deleting an entity, the Entity Audit Trail query displays only a row with D (Delete) action instead of both U (Update) and D (Delete) rows. Details about performed action are now displayed in D (Delete) row.
DE29212 (Added on the 23rd of January, 2023)	Application, Product, Product Family	When performing the API Post request, an application that does not have a product is not created under a product family. Workaround: use override updates to fix this issue.
DE28641 (Added on the 20th of October, 2022)	Application, Products	When all the products are disassociated on the <i>Application Attributes</i> page, the system allows disassociation. No warning messages informing that at

		<p>least one product should be associated to the application is displayed.</p>
<p>DE27749 (Added on the 19th of April, 2022)</p>	<p>Application, Country</p>	<p>For individual users, when the <i>Application Country Rights</i> 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.</p> <p>Workaround: Set the <i>Application Country Rights</i> for Product Families and Countries to All .</p>
<p>DE29739</p>	<p>Application, Product Family, Create Submission wizard</p>	<p>The Create Submission wizard does not work for applications without products when selecting Major Update or Amendment options. When it is opened from:</p> <ul style="list-style-type: none"> – the <i>Application Attributes</i> page, the error message is displayed. – any other pages, for example: Home > Wizards > Create Submission, the applications with products can be only selected.
<p>DE27309 (Added on the 12th of January, 2022)</p>	<p>Update Product Details Sets, PDS, Substance</p>	<p>When you select Global Project Plan > Modify Substance or Add Substance from <i>Project Attributes</i> page for the Update Product Details Sets project type, not all the fields are displayed in comparison to the Substance page in PDS.</p>
<p>26814</p>	<p>Publishing</p>	<p>Using Prepare for Publishing with the Prepare Cross Reference Leafs option selected results in the Unable to extract checksum error if there is a reference leaf to leaf published to Documentum.</p>

26807 (Added on 20th Aug 2021)	Assembly	When updating a leaf in an assembly, selecting On-Load 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 twregional.xml 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 Ennov InSight Rendering 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 Databased Notifications menu is not available on the Notification Specifications grid.

Ennov InSight Publisher

Issue	Affected Area	Description
DE32388 (Added on the 21st of January, 2025)	Publishing	eCTD 4.0: Working assemblies are not displayed in the Quick Search results.
DE32365 (Added on 7th of December, 2024)	Publishing	After creating an assembly from an EU 3.1 assembly that is exported, the Submission Type and Submission Unit Type envelope values are not displayed.

<p>DE32346 (Added on 19th of December, 2024)</p>	<p>Publishing</p>	<p>When importing an eCTD application having leafs with Replace, Append, and Withdraw lifecycle operation performed on them, the values for the following may be missing: Language, Application Version, Version, Font Library, Role, Actuate, and Show.</p>
<p>DE32056 (Added on 20th of September, 2024)</p>	<p>Assembly</p>	<p>Performance issue is experienced when using the Insert Volume functionality.</p>
<p>DE31961 (Added on the 21st of August, 2024)</p>	<p>Assembly</p>	<p>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.</p>
<p>DE31940 (Added on the 16th of August, 2024)</p>	<p>Assembly</p>	<p>Searching for a document to assign using Build Query results in an error.</p> <p>Workaround: Form a search request without Build Query option.</p>
<p>DE31934 (Added on the 14th of August, 2024)</p>	<p>Assembly</p>	<p>After the subsequent volume is inserted into the assembly folder or deleted, the previous volume name changes to the default one.</p> <p>Workaround: Update volume names manually.</p>
<p>DE31925 (Added on the 28th of August, 2024)</p>	<p>Create eCTD wizard</p>	<p>It takes longer than expected to create a 1.1.5 folder using the <i>Create eCTD</i> wizard.</p> <p>Workaround: Create a folder manually or wait for a wizard to complete the folder creation.</p>
<p>DE31470</p>	<p>Publishing</p>	<p>eCTD 4.0: After submitting the publish request with All Leaf Elements and XML options selected, the Publish Request window fails to close.</p>

DE30999 (Added on the 27th of November, 2023)	Assembly	<p>eCTD 4.0: After a CV Profile is removed from the Edit Publishing Settings > CV Profiles > Selected section, some of the Sender-defined</p> <p>Keyword values are not displayed on the <i>Additional Information</i> page in the assembly folder.</p> <p>Expected: All fields are displayed on the <i>Additional Information</i> page.</p> <p>The change of CV Profiles for the existing assembly is not supported.</p>
DE30247	Assembly	<p>After exporting an assembly to XML file,</p> <p>Default Overlay For field does not contain Documents value. Adding the same value to a new assembly created from XML file results in Invalid Reference error.</p>
DE29906	Assembly	<p>In the Working eCTD 4.0 assembly, when a duplicate folder or a reference leaf is created, the Document ID field fails to inherit the value in the duplicate reference leaf.</p> <p>Workaround: After a duplicate reference leaf is created, recreate it by using the option Convert to Default Leaf first and then Convert to Reference Leaf.</p>
DE29855 (Added on the 22th of May, 2023)	Assembly	<p>After re-running the Refresh Tree operation, sequence assembly structure does not update.</p> <p>Workaround: Log out from your user account and log on again.</p>
DE29521 (Added on the 23th of March, 2023)	Assembly	<p>In an assembly, the username format displayed when changing the user in the Owner field is incorrect. Instead of</p> <p>firstname.lastname@calyx.ai, firstname.lastname is displayed.</p>

DE28539 (Added on the 28th of September, 2022)	Assembly	<p>Operations with eCTD 4.0 assembly can fail if their processing time exceeds four minutes.</p> <p>Workaround: In the assembly created, reduce the number of operated nodes to make the processing time faster.</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 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 药效学.xml</p> <p>Workaround: rename files as per eCTD normalization rules before exporting output.</p>
DE27442 (Added on the 9th of February, 2022)	Assembly	<p>eCTD 4.0: After clicking Lock or Unlock on an assembly folder or an assembly root, the Throbber icon used to indicate an action in progress does not appear and all the folder or assembly elements remain enabled.</p>
20270; [136797FW]	Assembly	<p>Links for External Bookmarks are incorrect for split documents in paper published output.</p>
DE32383 (Added on the 16th of January, 2024)	Data Administrator	<p>If the Display Name exceeds 1000 characters, it is not possible to create and update Senderdefined Keyword Value.</p>

Ennov InSight Registrations

Issue	Affected Area	Description
DE31108 (Added on the 10th of January, 2024)	Substance, Pharmaceutical Product	<p>On the Medicinal Product Attributes > Pharmaceutical Products tab, the</p>

		<p>Pharmaceutical Product Summary column displays the Range value from Concentration Measure Type and does not show all the reference active ingredients.</p> <p>The column should display all the reference active ingredients while hiding the Range value.</p>
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Ennov InSight Outlook add-in

Issue	Affected Area	Description
DE26820	Outlook add-in form	<p>You cannot attach the following items from an e-mail in the add-in forms: – Contact - .vcf</p> <p>– Calendar (Event) - .ics</p> <p>– Outlook e-mails - e-mails without an extension (e-mail chain, single e-mail, and composed e-mail)</p>
DE26804	Outlook add-in form	<p>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: 500 Internal Server</p> <p>Error</p>
DE26803	Outlook add-in form	<p>In the Add Notification Recipients field, it is not possible to delete any spaces.</p>
DE26782	Outlook add-in form	<p>If more than 50 users try to submit a form, the system fails and an error is displayed.</p>
DE26781	Outlook add-in form	<p>When an API request with invalid product id is sent for CreateSubmissionAndReference, an incorrect error message is displayed.</p>
DE26738	Outlook add-in form	<p>If Ennov InSight Outlook add-in fails to submit the forms, an incorrect error message is displayed.</p>
DE26731	Outlook add-in form	<p>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</p>

		<p>01", "A Product 123"</p> <p>In the Ennov InSight Outlook add-in forms, the auto populate does not work for product unless more than 3 characters are typed.</p>
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	<p>When trying to attach the files for the Ennov InSight Outlook add-in forms, ToolTips are not displayed for the following:</p> <ul style="list-style-type: none"> – Attach from email button – Browse files button – "No available items to attach" <p>ToolTip when all the attachments are already attached</p>

Ennov InSight Rendering

Issue	Affected Area	Description
<p>DE26968</p> <p>(Added on the 23rd of December, 2021)</p>	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>

<p>DE28324; [TASK0043134, INC0109855] (Added on the 12th of August, 2022)</p>	<p>Assembly</p>	<p>Publishing to some printers may result in tab text misplacement.</p>
<p>DE26794</p>	<p>Assembly</p>	<p>When eCTD assembly is published, the validation messages from the backbone generator are not displayed in Job Requests Details.</p>