



Ennov InSight RIM 7.1 Release Notes Cumulative

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Ennov InSight RIM 7.1 Release Notes

Ennov InSight 7.1 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 7.1.

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

Note: Unless stated otherwise, this platform release provides the same functionality and regulatory updates as Ennov InSight 6.2 CHF 7.

IDMP

To maintain a standardized and structured method of collecting, reporting, coding, and evaluating authorized medicinal product data, Ennov InSight now includes:

— New Entities/Entity tabs:

- Manufactured Items (under Components)
- Active Ingredients/Reference Active Ingredients (under Manufactured Items and Pharmaceutical Products)
- Substances/Reference Substances (under Manufactured Items and Pharmaceutical Products)
- Package Descriptions (under Registration-Package Sets)
- Orphan Designations (under Application)
- Medicinal Products, Medicinal Product Actions, and IDMP (for Package Set type Registration)
- Medicinal Product Names, Product Cross-Reference, and MPIDs (for Medicinal Products)
- Attached Document (for Medicinal Product Actions)
- PDS Pack Size node
- Tasks, References, Activities, Workflows, Notifications (under Manufactured Items, Pharmaceutical Products, and Medicinal Products)
- PhPIDs (for Pharmaceutical Products)

— Entity updates:

- Product Family
- Products
- Component Active Ingredients/Reference Active Ingredients
- Pharmaceutical Products
- Application
- PDS (Active Ingredient, Substance, Flu Strain, Medical Device, Indications/Intended Use, Shelf Life, Packaging, Manufacturing)
- Registrations (Package Set type)

- Registration-Package Set and Package Set Country
- Queries, Wizards, Data Administration updates

EU Clinical Trial Regulation Application Type

To capture EU Clinical Trial data as required by EU 536/2014 regulation, the new EU Clinical Trial Regulation type of Application is introduced and includes:

- New fields for Application Country Notifications.
- The ability to associate Member States Concerned to sequence.
- The ability to associate/disassociate multiple CT shared data to event.
- The ability to withdraw a country from application.

Note: The API functionality for EU CTR Applications has not been fully tested but you can enter the data manually. The API functionality will be available in a future release.

Term Search for Organization

The **Term Search** included for these Data Administration entities allows you to search for the Organization to associate it with the entity. You can search for the SPOR OMS Organization to associate the location id with the entity.

- MAH/Development Sponsor/Organization Values
- Manufacturer
- Health Authority

Term Search for Referentials Management Services (RMS)

The Referentials Management Services (RMS) terms includes referential master data for attributes of medicinal products. RMS allows you to map a SPOR Term with the Data Administration values.

- Lists of Dosage Forms
- Units of Measurement
- Routes of Administration

Dose Form Search

The **Dose Form Search** included for the following entities allows you to search for a dose form to associate it with the entity. You can search for a dose form by EV Code, Term ID, Type Term, and Dose Form name.

- Product
- Component
- Pharmaceutical Product
- Manufactured Item
- Full Product Presentation
- Medicinal Product

See: *Get Started with Ennov InSight 7.1 > Dose Form Search.*

API Updates

Ennov InSight 7.1 includes multiple API updates including the update for IDMP.

Changes between Ennov InSight 7.0 API and Ennov InSight 7.1 API are documented in the *Ennov InSight Administration* and *Ennov InSight Data Exchange* guide. See: *Ennov InSight Administration > Technical Administration > Ennov InSight API Documentation* and *Ennov InSight 7.1 Data Exchange > Data Exchange API > Data Exchange API Document > Ennov InSight 7.1 Data Exchange Change* .

The following Data Administration entities now support API:

- ATC
- Country
 - Region
 - Procedure Type Details
- Dosage-Pharmaceutical Form
 - Dosage/Pharmaceutical Form XEVMPD Information
- Indications/Intended Use
- Product Family
- Route of Administration
 - Route of Administration XEVMPD Information
- Substance

These components are available via the Ennov InSight 7.1 on Azure or as on-premises installations:

- Rendering 5.0.1.1
- Viewing 5.5 CHF 7 (5.5.0.6.0015)
- Validator 5.1 CHF 10 (5.1.0.124)
- Linking plug-in (PDF) 1.8 CHF 1 + (hotfix 1.8.1.4)
- Linking add-in (Word) 1.8 CHF 1 + (hotfix 1.8.1.4)
- Cumulative View Builder 2.3 (2.3.0.2)
- Authoring and QC plug-in (PDF) 4.2 CHF 1 (4.2.0.42)
- Authoring add-in (Word) 3.2 CHF 2 (3.2.022)

Functionality and Technology Not Supported

The support of D2/LSRD functionality ends with Ennov InSight 7.2 version. The ability to synchronize registration data between Ennov InSight and OpenText Documentum D2 and D2 Data Dictionaries will no longer be available.

Internet Explorer 11 Not Supported

Ennov InSight 7.1 no longer supports Internet Explorer 11 browser.

New in Ennov InSight 7.1 : Common Functionality

This table shows new features and enhancements of Ennov InSight 7.1 functionality.

Identification of Medicinal Products (IDMP)

To support capturing data elements for European Medicine Agency (EMA) Iteration 1 implementation of IDMP.

Affected Area	Update	Benefit
Entities/Entity tabs	<p>Changes for IDMP now include:</p> <ul style="list-style-type: none"> — New Entities/Entity tabs: <ul style="list-style-type: none"> • Components are updated to include Manufactured Items • Manufactured Items and Pharmaceutical Products are updated to include Active Ingredients/Reference Active Ingredients • Manufactured Items and Pharmaceutical Products)Substances/Reference Substances • Package Descriptions are updated to include Registration-Package Sets • Application is updated to include Orphan Designations • Package Set type Registration updated to include Medicinal Products, Medicinal Product Actions, and IDMP • Medicinal Products updated to include Medicinal Product Names, Product Cross-Reference, and MPIDs • Medicinal Product Actions updated to include Attached Document • PDS Pack Size node • Manufactured Items, Pharmaceutical Products, and Medicinal Products updated to include Tasks, References, Activities, Workflows, Notifications • Pharmaceutical Products updated to include PhPIDs — Entity updates: <ul style="list-style-type: none"> • Product Family • Products • Component Active Ingredients/ Reference Active Ingredients • Pharmaceutical Products • Application • PDS <ul style="list-style-type: none"> ■ Active Ingredient ■ Substance ■ Flu Strain ■ Medical Device ■ Indications/Intended Use 	<p>The ability to capture IDMP Iteration 1 data in Ennov InSight in preparation for submitting IDMP data to EMA.</p> <p>The ability to capture and provide visibility of EU CTR data for EU CTR applications in Ennov InSight.</p>
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Affected Area	Update	Benefit
Querying	<p>To conform to IDMP standards, Queries now include:</p> <ul style="list-style-type: none"> — Updated list of fields for Product Family — Updated list of fields for Application — Updated list of fields for Product and Component, and Component Active Ingredients — Updated list of fields for Manufactured Item 	IDMP data elements are reflected in out-of-the-box queries.
Data Administration	<p>Updates to Data Administration have been made to conform with IDMP standards.</p> <p>A new SPOR Master List has been included to support OMS/ RMS.</p> <p>With Ennov InSight 7.1, Data Administration now includes:</p> <ul style="list-style-type: none"> — new RMS tabs — new OMS tabs — new Term Search widget <p>The <i>Manufacturer</i> page under the Product Detail Set Maintenance > Manufacturer Values now includes a new Manufacturing Authorisation Reference Number tab.</p> <p>For details, see <i>Data Administration Tables Added, Data Administration Tables Updated</i>.</p>	Ability to capture and map SPOR ids to IDMP data elements within RIM.

Affected Area	Update	Benefit
Application	<p>To include the changes for IDMP:</p> <ul style="list-style-type: none"> – The <i>Application Attributes</i> page now includes the new <i>Orphan Designation</i> entity tab. <p>To support EU Clinical Trial data in Ennov InSight based on the EU 536/2014 regulation, the new EU Clinical Trial Regulation type of Application affects PDS, Sequences, Events and Registrations where the withdrawn countries are not available for selection.</p>	<p>The ability to capture IDMP Iteration 1 data in Ennov InSight in preparation for submitting IDMP data to EMA .</p> <p>The ability to capture and provide visibility of EU CTR data for EU CTR applications in Ennov InSight.</p>
Component	<p>To include the changes for IDMP:</p> <ul style="list-style-type: none"> – The <i>Component Attributes</i> page now includes the new <i>Manufactured Item</i> entity tab. – The <i>Manufactured Item Attributes</i> page now includes the new <i>Active Ingredients</i> tab. – The <i>Reference Active Ingredients</i> entity tab is added under Manufactured Item > Active Ingredients and includes all the respective fields. – The <i>Manufactured Item Attributes</i> now includes the new <i>Substances</i> tab. – The <i>Reference Substances</i> entity tab is added under Manufactured Item > Substances and includes all the respective fields. 	<p>The ability to capture IDMP Iteration 1 data in Ennov InSight in preparation for submitting IDMP data to EMA .</p>

Affected Area	Update	Benefit
Pharmaceutical Product	To include the changes for IDMP: <ul style="list-style-type: none"> – The <i>Pharmaceutical Product Attributes</i> page now includes the new Active Ingredients tab. – The <i>Reference Active Ingredients</i> entity tab is added under Pharmaceutical Product > Active Ingredients and includes all the respective fields. – The <i>Pharmaceutical Product Attributes</i> now includes the new Substances tab. – The <i>Reference Substances</i> entity tab is added under Pharmaceutical Product > Substances and includes all the respective fields. – The <i>Pharmaceutical Product Attributes</i> page now includes the new PhPIDs tab. 	The ability to capture IDMP Iteration 1 data in Ennov InSight in preparation for submitting IDMP data to EMA .
Full Product Presentation	The <i>Full Product Presentation Attributes</i> page now includes Pharmaceutical Products tab.	Ability to capture pharmaceutical products.

New in Ennov InSight 7.1: Registrations

New features and enhancements for Registration functionality is listed below.

Affected Area	Update	Benefit
Registration- Package Sets	<p>To include the changes for IDMP, you can now:</p> <ul style="list-style-type: none"> – define Package Descriptions entity attributes. – select PDS Package Sets with a status of Pending Add. – add new attributes for Registration Package Sets. See: <i>Entity Fields and Columns Added</i>. <p>The following new tabs are also included in Ennov InSight.</p> <ul style="list-style-type: none"> – The Medicinal Product and Medicinal Product Actions tabs are added to the <i>Registrations Attributes</i> page. – The Medicinal Product Names tab is added to the <i>Medicinal Product Attributes</i> page. – The Attached Documents tab is added to the <i>Medicinal Product Actions Attributes</i> page. 	<p>The ability to capture IDMP Iteration 1 data in Ennov InSight in preparation for submitting IDMP data to EMA.</p>
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"> – PDS Medical Device – PDS Active Ingredients – PDS Indications/Intended Use – PDS Manufacturer Detail – PDS Flu Strain – PDS Shelf Life – PDS Package Set – PDS Substance Detail – Global Project Plan <p>To support the changes for the IDMP, a new Pack Size node is introduced in the PDS tree. You can associate the Pack Size Detail for product packaging with a PDS package set. See: <i>Associate Pack Size with a PDS</i></p> <p>The Active Ingredients on the PDS are now autopopulated with the Active Ingredient details captured on the Component. See: <i>Associate an Active Ingredient with a PDS</i>.</p>	<p>The ability to capture IDMP Iteration 1 data in Ennov InSight in preparation for submitting IDMP data to EMA.</p>

Data Administration Tables

Data Administration Tables Added: Ennov InSight 7.1

The following Data Administration tables, sections, or fields were added for Ennov InSight 7.1. These include the tables added to support IDMP data capture.

Data Administration Section: Product Family Maintenance

Table 1: Domain Type Values

Entity Affected	Field Name	Value List Description
Product Family	Domain Name	To maintain a standardized and structured method of collecting, reporting, coding, and evaluating authorized medicinal product data, the <i>Domain Type Values</i> table is introduced. The value for Domain Name can be entered in the respective field.

Table 2: EURD ID Values

Entity Affected	Field Name	Value List Description
Product Family	<ul style="list-style-type: none"> – EURD Procedure Identifier – EURD ID 	To maintain a standardized and structured method of collecting, reporting, coding, and evaluating authorized medicinal product data, the <i>EURD ID Values</i> table is introduced. The values for EURD Procedure Identifier and EURD ID can be entered in their respective fields.

Data Administration Section: Product Maintenance

Table 3: Product Category Type Values

Entity Affected	Field Name	Value List Description
Product Family	Product Category Type Name	The classification of the medicinal products.

Table 4: Product Cross Reference Type Values

Entity Affected	Field Name	Value List Description
Product Family	Product Cross Reference Type Name	The type of medicinal product (MP) that is referenced. You can define it using a term ID.

Table 5: Dosage/Pharmaceutical Form Values

Entity Affected	Field Name	Value List Description
N/A	<ul style="list-style-type: none"> – FDA Code – EV Code – RMS Term ID 	The Dosage/Pharmaceutical Form Values now includes the respective new columns.

Data Administration Section: Other

Table 6: Application Submission Type Values

Entity Affected	Field Name	Value List Description
Sequences, Events	Application Submission Type Name	A marketing authorisation application. You can define it using a term ID.

Table 7: Attached Document Content Type Values

Entity Affected	Field Name	Value List Description
Attached Document	Attached Document Content Type Name	This is a new DA list that will be mapped to RMS list Product Information Document Type. Product Information Document Type is a new RMS list and will be introduced in the next upcoming release.

Table 8: Units of Measurement Values

Entity Affected	Field Name	Value List Description
Manufactured Item, PDS Packaging Detail	Units of Measurement Name	Provide the strength (quantitative composition) of the substances (including active substances, ingredients, solvents, adjuvant as applicable) in this field with a numerator and denominator value.

Data Administration Section: Application Maintenance

Table 9: Regulatory Entitlement Type Values

Entity Affected	Field Name	Value List Description
Application	Regulatory Entitlement Type	To maintain a standardized and structured method of collecting, reporting, coding, and evaluating authorized medicinal product data, the <i>Regulatory Entitlement Type Values</i> table is introduced. The values for Regulatory Entitlement Type can be entered in the respective fields.

Table 10: Orphan Status Values

Entity Affected	Field Name	Value List Description
Application	Orphan Status Name	Orphan status. For example: Expired, Pending, Valid, Withdrawn.

Table 11: Product Information Document Type Values

Entity Affected	Field Name	Value List Description
Application	Product Information Document Type Name	The document that contains the medicinal products details.

Data Administration Section: SPOR Master Lists

Table 12: Units of Measurement

Data Administration Table Name	Entity Affected	Field Name	Value List Description
Units of Measurement	N/A	N/A	The strength (quantitative composition) of the substances (including active substances, ingredients, solvents, adjuvant as applicable) must be specified in this field with a numerator and denominator.

Table 13: Units of Presentation

Entity Affected	Field Name	Value List Description
N/A	N/A	The strength (quantitative composition) of the substances (including active substances, ingredients, solvents, adjuvant as applicable) must be specified in this field with a numerator and denominator.

Table 14: XEVMPD Medical Devices

Data Administration Table Name	Entity Affected	Field Name	Value List Description
XEVMPD Medical Devices	N/A	N/A	Includes details of the XEVMPD Medical Devices.

Table 15: XEVMPD Medicinal Product Type

Entity Affected	Field Name	Value List Description
N/A	N/A	Includes details of the XEVMPD medicinal product type.

Table 16: Anatomical Therapeutic Chemical Classification System - Human

Entity Affected	Field Name	Value List Description
N/A	N/A	The Anatomical Therapeutic Chemical Classification System - Human table is introduced to provide the ATC code as indicated as Pharmacodynamic properties of the corresponding SmPC. As a term ID you must provide the regulatory documents.

Table 17: Country

Entity Affected	Field Name	Value List Description
N/A	N/A	Includes details of the medicinal product name that has been authorized as approved by the regulatory authority.

Table 18: Legal Status for the Supply

Entity Affected	Field Name	Value List Description
N/A	N/A	Provides the status of the medicinal product supply as authorized by the relevant competent authority.

Table 19: Manufacturing Activity

Entity Affected	Field Name	Value List Description
N/A	N/A	Provides details of the active substance manufacturer including active substance manufacturers.

Table 20: Marketing Status

Entity Affected	Field Name	Value List Description
N/A	N/A	Indicates the marketing status of medicinal products.

Table 21: Master File Type

Entity Affected	Field Name	Value List Description
N/A	N/A	Indicates the Master File used.

Table 22: Domain

Entity Affected	Field Name	Value List Description
N/A	N/A	Helps to differentiate whether the type of medicinal product is for human or for veterinary use.

Table 23: Combination Package

Entity Affected	Field Name	Value List Description
N/A	N/A	Includes details of the pharmaceutical form that is submitted for authorization or is authorized by the regulatory authorities. These details are reflected in the regulatory documents.

Table 24: Pharmaceutical Dose Form

Entity Affected	Field Name	Value List Description
N/A	N/A	Includes details of the manufactured dose form described with the authorized pharmaceutical form(s). Pharmaceutical Form of the SmPC or other regulatory document.

Table 25: Combined Pharmaceutical Dose Form

Entity Affected	Field Name	Value List Description
N/A	N/A	Includes details of the combination of the two or more manufactured dose form described with the authorized pharmaceutical form(s). Pharmaceutical Form of the SmPC or other regulatory document.

Table 26: Combined Term

Entity Affected	Field Name	Value List Description
N/A	N/A	Defines the combined term for medicinal products.

Table 27: Medicinal Product Name Part Type

Entity Affected	Field Name	Value List Description
N/A	N/A	The medicinal product name parts are specified along with the language of the country as per the marketing authorisation applies in accordance with the referenced SmPC.

Table 28: Packaging

Entity Affected	Field Name	Value List Description
N/A	N/A	Details of the of the medicinal products packing.

Table 29: Product Category

Entity Affected	Field Name	Value List Description
N/A	N/A	Classification of the products.

Table 30: Contact Party Role

Entity Affected	Field Name	Value List Description
N/A	N/A	Type of contact in the context of the Medicinal Product that must be specified.

Table 31: Quantity Operator

Entity Affected	Field Name	Value List Description
N/A	N/A	Indicates the strength of the substance ingredient(s) contained in the medicinal product.

Table 32: Routes and Methods of Administration

Entity Affected	Field Name	Value List Description
N/A	N/A	The method and path of drug administration.

Table 33: Special Precaution for Storage

Entity Affected	Field Name	Value List Description
N/A	N/A	Indicates the precautions taken for storing and stacking drugs.

Table 34: Application Legal Basis

Entity Affected	Field Name	Value List Description
N/A	N/A	Defines the classification value of a medicinal product.

Table 35: Application Submission Type

Entity Affected	Field Name	Value List Description
N/A	N/A	Defines the type of the marketing authorization application that is described using the term id.

Table 36: Regulatory Entitlement Type

Entity Affected	Field Name	Value List Description
N/A	N/A	The type of regulatory authorization.

Table 37: Regulatory Entitlement Status

Entity Affected	Field Name	Value List Description
N/A	N/A	The status of the marketing authorization.

Table 38: Shelf Life Type

Entity Affected	Field Name	Value List Description
N/A	N/A	Shelf life types such as shelf life of the Packaged Medicinal Product itself, shelf-life after transformation, etc.

Table 39: Product Information Document Type

Entity Affected	Field Name	Value List Description
N/A	N/A	The type of contact that must be specified in the context of the Medicinal Product.

Table 40: Material

Entity Affected	Field Name	Value List Description
PDS	<ul style="list-style-type: none"> – List Id – List Name – List Owner – Term Id – Term Name – Short Name – Status – Domain – Modified On – Mapping Source – Source Term Id – xEVMPD Code – Description – Comments – Version Number – ISO Code 	Defines the material(s) of the package item. This Material RMS list is mapped to the Data Administration > Product Detail Set Maintenance > Product Materials Values .

Table 41: Medical Dictionary For Regulatory Activities

Entity Affected	Field Name	Value List Description
N/A	N/A	Comorbidity, intended effect and indication details used for the medicinal products.

Table 42: Product Cross Reference Type

Entity Affected	Field Name	Value List Description
N/A	N/A	Defines the Product Cross Reference Types.

Table 43: EU Regulatory Authorisation Procedure

Entity Affected	Field Name	Value List Description
N/A	N/A	Defines the regulatory procedure applied to grant or amend a marketing authorization for a Medicinal Product.

Table 44: Ingredient Role

Entity Affected	Field Name	Value List Description
N/A	N/A	Role of the active ingredient as part of the manufactured item/pharmaceutical product.

Table 45: Language

Entity Affected	Field Name	Value List Description
N/A	N/A	Language of the medicinal product name for the specified country, as approved by the regulatory authority.

Table 46: Organisation (OMS)

Entity Affected	Field Name	Value List Description
N/A	N/A	The Organisation SPOR Master List consists of organisations and locations from the EMA Organisation Management Services (OMS).

Table 47: Data Classification

Entity Affected	Field Name	Value List Description
N/A	N/A	The Data Classification is a RMS list and is used to populate the Confidentiality Indicator field available on the Data Administration > Manufacturer Values > Global Detail Sets Attributes page.

Data Administration Section: Product Detail Set Maintenance

Table 48: Device - Type of Combination Values

Entity Affected	Field Name	Value List Description
Product Detail Set	Device - Type of Combination Name	This value supports IDMP.

Table 49: Package Component Values

Entity Affected	Field Name	Value List Description
Product Detail Set	<ul style="list-style-type: none"> – Component Type – Product Material 	This value supports IDMP.

Table 50: Component Type Values

Entity Affected	Field Name	Value List Description
Product Detail Set	Component Type Name	This value supports IDMP.

Table 51: Intended Effect Values

Entity Affected	Field Name	Value List Description
Product Detail Set	Intended Effect	This value supports IDMP.

Table 52: Medical Device UDI Values

Entity Affected	Field Name	Value List Description
Product Detail Set	Medical Device UDI Name	This Data Administration table is used to populate the Device Type field for PDS Component - Medical Devices. This Data Administration list is mapped to the Device Type value in the SPOR RMS list section.

Table 53: Manufacturing Function Values

Entity Affected	Field Name	Value List Description
Product Detail Set	Manufacturing Function Name	This Data Administration table is used to populate the Function Name field for PDS- Function. This Data Administration list is mapped to the Manufacturing Activity value in the SPOR RMS list section.

Table 54: Data Classification Type Values

Entity Affected	Field Name	Value List Description
Product Detail Set	Data Classification Type Name	This Data Administration table is used to populate the Confidentiality Indicator field on the Data Administration Manufacturer Values - Data Administration Manufacturer Values > Global Product Details > Global Detail Sets.

Data Administration Section: Registration Maintenance

Table 55: Content of Change Values

Entity Affected	Field Name	Value List Description
Registrations	Content of Change Name	This Content of Change provided for the IDMP attachment.

Table 56: Data Carrier Type Values

Entity Affected	Field Name	Value List Description
Registrations	Data Carrier Type Name	This table is used to display the value for the Data Carrier Type field for the Registration Package Set Country.

Table 57: Provenance Reason Values

Entity Affected	Field Name	Value List Description
Registrations	Provenance Reason Name	The reason of the activity of medicinal product data submission in the Postmarketing surveillance (PMS).

Table 58: Master File Type Values

Entity Affected	Field Name	Value List Description
Registrations	Master File Type Name	The type of master file indicated for the registrations.

Table 59: Medicinal Product Name Part Type Values

Entity Affected	Field Name	Value List Description
Registrations	Medicinal Product Name Part Type Name	Specify the medicinal product name parts along with the language of the country and as the marketing authorisation applies in accordance with the referenced SmPC.

Table 60: Marketing Status Values

Entity Affected	Field Name	Value List Description
Registrations	Marketing Status Name	Marketing status for the medicinal products. This Data Administration list is mapped to the Marketing Status available in the SPOR RMS list.

Table 61: Marketing Status Reason Values

Entity Affected	Field Name	Value List Description
Registrations	Marketing Status Reason Name	Reason for updating the marketing status.

Table 62: Medical Product Action/Submission Status Values

Entity Affected	Field Name	Value List Description
Registrations	Status Name	Submission status of the Medicinal Product.

Data Administration Tables Updated: Ennov InSight 7.1

Data Administration tables, sections, or fields updated in Ennov InSight 7.1 release. These include the tables modified to support IDMP data capture.

Data Administration Section: Application Maintenance

Table 63: Country Values

Entity Affected	Column Name	Value List Description
N/A	<ul style="list-style-type: none"> – Organization ID – Location ID – Health Authority Name – Address – City – Post Code – Country – Last User Updated – Last Changed Date – Active (Flag) 	The Country Values table is updated with the OMS tab for <i>Health Authority Attributes</i> page including the respective columns to add and display the data from SPOR Master Lists > Organization .
N/A	<ul style="list-style-type: none"> – Organization ID – Location ID 	The respective columns of the Health Authority tab now retrieves values from the OMS.

Entity Affected	Column Name	Value List Description
N/A	<ul style="list-style-type: none"> – Language – Last User Updated – Last Changed Date – Default Flag 	The Country Values table is updated with the Language tab for <i>Country</i> attributes page including the respective columns to add and display the data from Other > Language Values .

Data Administration Section: Product Detail Set Maintenance

Table 64: Manufacturer Values

Entity Affected	Column/Field Name	Value List Description
N/A	<ul style="list-style-type: none"> – Organization ID – Location ID – Manufacturer Name – Address – City – Post Code – Country – Last User Updated – Last Changed Date – Active (Flag) 	The Manufacturer Values table is updated with the OMS tab including the respective columns to add and display the data from SPOR Master Lists > Organization .
N.A	<ul style="list-style-type: none"> – Organization ID – Location ID 	The respective columns of the Manufacturer Values now retrieves values from the OMS .
N/A	Confidentiality Indicator	<p>The Global Product Details > Global Detail Sets page of the Manufacturer Values table is updated with the Confidentiality Indicator field.</p> <p>The Confidentiality Indicator field is displayed only when you select the Manufacturing Functions option for the Detail Type field. This field displays values from the Product Detail Set Maintenance > Data Classification Type values.</p>

Entity Affected	Column/Field Name	Value List Description
N/A	<ul style="list-style-type: none"> – Manufacturer Name – Address Line 1 – Country – GMP Status – GMP Expiration Date – Last GMP Inspection – Contact Person – Contact Person Title – Phone – Fax – e-mail – Agent – Agent Title – Agent Address – Agent Phone – Agent Fax – Agent e-mail – Site License Number – Site Certificate Filed – DMV/CEP Number – US Agent – FEI Number – Parent Company Name – Other Firms – Comments – Keywords – Description – Last User Updated – Last Changed Date – Active Flag – Manufacturing Authorisation Reference Number 	<p>The Manufacturer Values table is updated with the Manufacturing Authorisation Reference Number tab and includes the respective fields.</p>
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Data Administration Section: Product Maintenance

Table 65: Dosage/Pharmaceutical Form Values

Entity Affected	Field Name	Value List Description
Product	<ul style="list-style-type: none"> – Term ID – Term Name – Description – Last User Updated – Last Changed Date – Active Flag 	The active values in the Dosage/Pharmaceutical Form Values table now show as values for the Combined Pharmaceutical Dose Form field.

Data Administration Section: SPOR Master Lists

Table 66: SPOR Maintenance

Entity Affected	Field Name	Value List Description
N/A	N/A	The SPOR Maintenance section is renamed to SPOR Master Lists.

Other Maintenance

Table 67: Device Type

Entity Affected	Field Name	Value List Description
N/A	N/A	The Device Type value is moved from Product Maintenance to Other Maintenance section.

Table 68: Indications/Intended Use Values

Entity Affected	Field Name	Value List Description
Product Family	N/A	<p>The information from the Indications/Intended Use Values is now available for selection on the <i>Product Family Attributes</i> page for three fields:</p> <ul style="list-style-type: none"> – Product Family Indications – Product Family Comorbidity

Table 69: MAH/Development Sponsor/Organization Values

Entity Affected	Column/Field Name	Value List Description
N/A	<ul style="list-style-type: none"> – Organization Id – Location Id – XEVMPD Code 	The MAH/Development Sponsor/Organization Values list view page is updated with the respective columns and retrieves values from the OMS.

Data Administration Tables Removed: Ennov InSight 7.1

List of Data Administration tables, sections, or fields removed in Ennov InSight 7.1 to comply to the latest requirements.

Data Administration Section: Application Maintenance

Table 70: Country Values

Entity Affected	Field/Column Name	Value List Description
Application	Organization Identifier	This field is removed from the Country Values table for the <i>Health Authority Attributes</i> page.
N/A	Type Term	This column is removed from the Country Values table.
Application	RMS Term Name	This field is removed from the Country Values table.

Table 71: Procedure Type Values

Entity Affected	Field/Column Name	Value List Description
N/A	Type Term	This column is removed from the Procedure Type Values table.
Application	RMS Term Name	This field is removed from the Procedure Type Values table.

Data Administration Section: Product Detail Set Maintenance

Table 72: Manufacturer Values

Entity Affected	Field/Column Name	Value List Description
N/A	Organization Identifier	This field is removed from the Manufacturer Values table.

Table 73: Compendial Designation/Source Values

Entity Affected	Field/Column Name	Value List Description
N/A	Type Term	This column is removed from the Compendial Designation/Source Values table.
Product Detail Set	RMS Term Name	This field is removed from the Compendial Designation/Source Values table.

Table 74: Medical Device UDI Values

Entity Affected	Field/Column Name	Value List Description
N/A	Type Term	This column is removed from the Medical Device UDI Values table.
Product Detail Set	RMS Term Name	This field is removed from the Medical Device UDI Values table.

Data Administration Section: Registration Maintenance

Table 75: EMA Authorization Status Values

Entity Affected	Field/Column Name	Value List Description
N/A	Type Term	This column is removed from the EMA Authorization Status Values table.
Registration	RMS Term Name	This field is removed from the EMA Authorization Status Values table.

Table 76: Medicinal Product Type Values

Entity Affected	Field/Column Name	Value List Description
N/A	Type Term	This column is removed from the Medicinal Product Type Values table.
Registration	RMS Term Name	This field is removed from the Medicinal Product Type Values table.

Data Administration Section: Product Maintenance

Table 77: Dosage/Pharmaceutical Form Values

Entity Affected	Field/Column Name	Value List Description
N/A	Type Term	This column is removed from the Dosage/ Pharmaceutical Form Values table.
Product	RMS Term Name	This field is removed from the Dosage/ Pharmaceutical Form Values table.

Table 78: Route of Administration Values

Entity Affected	Field/Column Name	Value List Description
N/A	Type Term	This column is removed from the Route of Administration Values table.
Product	RMS Term Name	This field is removed from the Route of Administration Values table.

Data Administration Section: Other

Table 79: MAH/Development Sponsor/Organization Values

Entity Affected	Field/Column Name	Value List Description
N/A	Organization Identifier	The respective column is removed from the MAH/Development Sponsor/Organization Values list view page.
N/A	<ul style="list-style-type: none"> – Organization Identifier – Location Identifier 	The respective fields are removed from the MAH/Development Sponsor/Organization Values (Create/View/Edit) page.

Table 80: Concentration Measure Type Values

Entity Affected	Field/Column Name	Value List Description
N/A	Type Term	This column is removed from the Concentration Measure Type Values table.
N/A	RMS Term Name	This field is removed from the Concentration Measure Type Values table.

Table 81: Denominator Unit Values

Entity Affected	Field/Column Name	Value List Description
N/A	Type Term	This column is removed from the Denominator Unit Values table.
N/A	RMS Term Name	This field is removed from the Denominator Unit Values table.

Table 82: Numerator Unit Values

Entity Affected	Field/Column Name	Value List Description
N/A	Type Term	This column is removed from the Numerator Unit Values table.
N/A	RMS Term Name	This field is removed from the Numerator Unit Values table.

Table 83: Language Values

Entity Affected	Field/Column Name	Value List Description
N/A	Type Term	This column is removed from the Language Values table.
N/A	RMS Term Name	This field is removed from the Language Values table.

Table 84: Legal Basis Values

Entity Affected	Field/Column Name	Value List Description
N/A	Type Term	This column is removed from the Legal Basis Values table.
N/A	RMS Term Name	This field is removed from the Legal Basis Values table.

Table 85: Unit of Measure Prefix Values

Entity Affected	Field/Column Name	Value List Description
N/A	Type Term	This column is removed from the Unit of Measure Prefix Values table.
N/A	RMS Term Name	This field is removed from the Unit of Measure Prefix Values table.

Entity Fields

Entity Fields and Columns Added: Ennov InSight 7.1

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Entities

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

Table 86: Product Family

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Product Family Comorbidity – EURD ID 	Drop-down list, multi-select	The <i>Product Family Attributes</i> page now includes the respective fields.	<p>The Product Family Comorbidity field displays values from Data Administration > Other > Indications/Intended Use Values.</p> <p>The EURD ID field displays values from Data Administration > Product Family Maintenance > EURD ID Values.</p>

Table 87: Application

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Reporting Member State – Region(s) – UUID – Applicant ID – Application Code – Study Number – Legal Basis – Application Type – Procedure Type – Registration Type – Co-Rapporteur – Associated Products – IMPID – Arbitration – Application Owner – Orphan Drug – Orphan Drug Last Updated – Annual Report Date – Application Status – Application Status Date – Local PSUR Date – Local PSUR Data Lock Date – Termination/Withdraw Date – Reason for Termination/Withdrawal – Countries – Sponsor – Reason for Not Approving – Reason for Premature Ending – Application Concerned Parties – Application Keywords – Application Description – Application Comments 	Drop-down list, text field, date, multi-select	The <i>Application Attributes</i> page for the new EU Clinical Trial Regulation Application Type now includes the respective fields.	To capture EU Clinical Trial data in Ennov InSight as required by EU 536/2014 regulation, the new EU Clinical Trial Regulation type of Application is introduced.

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Application Name – Application Code – Country – Role – Sequences – Planned Submission Date – Actual Submission Date – Planned Approval Date – Actual Approval Date – Withdrawn Date – Last Role Change Date – 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 – Local Early Termination/Withdrawal/ Suspension Reason – Application Country Concerned Parties – Application Country Keywords – Application Country Description – Application Country Comments – Member States Concerned 	Drop-down list, text field, date, multi-select	The <i>Application Country Attributes</i> page for the new EU Clinical Trial Regulation Application Type now includes the respective fields.	N/A

Table 88: Event - Country Status, Sequence Status Dates, and Task Status Dates

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Add Comment – Event-Country Status Comments – Sequence Status Comments – Task Status Comments 	Text field	These pages now include the respective fields: <ul style="list-style-type: none"> – Event-Country Attributes > Status Dates > Add Event-Country Status – Event-Country Attributes > Status Dates > Modify Event-Country Status – View Sequence > Status Dates > Add Status – View Sequence > Status Dates > Modify Status – View Task > Status Dates > Add Status – View Task > Status Dates > Modify Status 	You can use this option to record comments for create/modify actions on Event - Country Status, Sequence Status Date, and Task Status Dates. <ul style="list-style-type: none"> – Event-Country Status Comments in Event- Country Attributes > Add/Modify-Country Event Status. – Sequence-Status Comments in View Sequence > Add/Modify Status. – Task Status Comments in View Task > Add/Modify Status.

Table 89: Component

Field/Option Name	Field Type	Description	Business Rules
IDMP Concentration Measure Type IDMP Presentation Strength <ul style="list-style-type: none"> – Presentation Single or Low Limit Numerator Value – Presentation Single or Low Limit Unit of Measurement – Presentation Single or Low Limit Unit of Presentation – Presentation High Limit Numerator Value – Presentation High Limit Unit of Measurement – Presentation High Limit Unit of Presentation IDMP Concentration Strength <ul style="list-style-type: none"> – Concentration Single or Low Limit Numerator Value – Concentration Single or Low Limit Unit of Measurement – Concentration Single or Low Limit Denominator Value – Concentration Single or Low Limit Unit of Measurement – Concentration High Limit Numerator Value – Concentration High Limit Unit of Measurement – Concentration High Limit Denominator Value – Concentration High Limit Unit of Measurement 	Drop-down list, text field	The Component field is included in the Active Ingredient Attributes and Reference Active Ingredient Attributes pages: <ul style="list-style-type: none"> – Component > Active Ingredient Attributes – Component > Reference Active Ingredient Attributes 	N/A

Table 90: Manufactured Item

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Family Type – Family Code – Family Name – Product Name – Component Name – Manufactured Item Name – Unit of Presentation – Manufactured Item Quantity – Manufactured Item Quantity Unit – Manufactured Dose Form – Manufactured Item Characteristics/Description – Manufactured Item Concerned Parties – Manufactured Item Keywords – Manufactured Item Description – Manufactured Item Comments – Manufactured Item Add Comment 	Display-Hyperlink, read-only text , drop-down list, multi-select , text field, widget	The <i>Manufactured Item</i> entity tab is added under <i>Component</i> and includes all the respective fields.	The values for the Manufactured Item Quantity Unit field is available from the Data Administration > SPOR Master Lists > Unit of Measurement values.

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Family Type – Family Code – Family Name – Product Name – Component Name – Manufactured Item Name – Active Ingredient Name – Strength Same as Component? <p>IDMP Concentration Measure Type</p> <p>IDMP Presentation Strength</p> <ul style="list-style-type: none"> – Presentation Single or Low Limit Numerator Value – Presentation Single or Low Limit Unit of Measurement – Presentation Single or Low Limit Unit of Presentation – Presentation High Limit Numerator Value – Presentation High Limit Unit of Measurement – Presentation High Limit Unit of Presentation <p>IDMP Concentration Strength</p> <ul style="list-style-type: none"> – Concentration Single or Low Limit Numerator Value – Concentration Single or Low Limit Unit of Measurement – Concentration Single or Low Limit Denominator Value – Concentration Single or Low Limit Unit of Measurement – Concentration High Limit Numerator Value – Concentration High Limit Unit of Measurement – Concentration High Limit Denominator Value – Concentration High Limit Unit of Measurement 	Display-Hyperlink, read-only text , drop-down list, multi-select, text field	The <i>Active Ingredients</i> entity tab is added under <i>Manufactured Item Attributes</i> and includes all the respective fields.	N/A

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Family Type – Family Code – Family Name – Product Name – Component Name – Manufactured Item Name – Active Ingredient Name – Reference Active Ingredient Name – Strength Same as Component? <p>IDMP Concentration Measure Type</p> <p>IDMP Presentation Strength</p> <ul style="list-style-type: none"> – Presentation Single or Low Limit Numerator Value – Presentation Single or Low Limit Unit of Measurement – Presentation Single or Low Limit Unit of Presentation – Presentation High Limit Numerator Value – Presentation High Limit Unit of Measurement – Presentation High Limit Unit of Presentation <p>IDMP Concentration Strength</p> <ul style="list-style-type: none"> – Concentration Single or Low Limit Numerator Value – Concentration Single or Low Limit Unit of Measurement – Concentration Single or Low Limit Denominator Value – Concentration Single or Low Limit Unit of Measurement – Concentration High Limit Numerator Value – Concentration High Limit Unit of Measurement – Concentration High Limit Denominator Value – Concentration High Limit Unit of Measurement 	<p>Display-Hyperlink, read-only text , drop-down list, multi-select editable, text field</p>	<p>The <i>Reference Active Ingredients</i> entity tab is added under Manufactured Item > Active Ingredients and includes all the respective fields.</p>	<p>N/A</p>

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Family Type – Family Code – Family Name – Product Name – Component Name – Manufactured Item Name – Substance Name – Substance Type – Strength Same as PDS Substance? <p>IDMP Concentration Measure Type</p> <p>IDMP Presentation Strength</p> <ul style="list-style-type: none"> – Presentation Single or Low Limit Numerator Value – Presentation Single or Low Limit Unit of Measurement – Presentation Single or Low Limit Unit of Presentation – Presentation High Limit Numerator Value – Presentation High Limit Unit of Measurement – Presentation High Limit Unit of Presentation <p>IDMP Concentration Strength</p> <ul style="list-style-type: none"> – Concentration Single or Low Limit Numerator Value – Concentration Single or Low Limit Unit of Measurement – Concentration Single or Low Limit Denominator Value – Concentration Single or Low Limit Unit of Measurement – Concentration High Limit Numerator Value – Concentration High Limit Unit of Measurement – Concentration High Limit Denominator Value – Concentration High Limit Unit of Measurement 	<p>Display-Hyperlink, read-only text , drop-down list, multi-select, text field</p>	<p>The <i>Substances</i> entity tab is added under <i>Manufactured Item Attributes</i> and includes all the respective fields.</p>	<p>N/A</p>

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Family Type – Family Code – Family Name – Product Name – Component Name – Manufactured Item Name – Reference Substance Name – Substance Name – Substance Type – Strength Same as PDS Substance? <p>IDMP Concentration Measure Type</p> <p>IDMP Presentation Strength</p> <ul style="list-style-type: none"> – Presentation Single or Low Limit Numerator Value – Presentation Single or Low Limit Unit of Measurement – Presentation Single or Low Limit Unit of Presentation – Presentation High Limit Numerator Value – Presentation High Limit Unit of Measurement – Presentation High Limit Unit of Presentation <p>IDMP Concentration Strength</p> <ul style="list-style-type: none"> – Concentration Single or Low Limit Numerator Value – Concentration Single or Low Limit Unit of Measurement – Concentration Single or Low Limit Denominator Value – Concentration Single or Low Limit Unit of Measurement – Concentration High Limit Numerator Value – Concentration High Limit Unit of Measurement – Concentration High Limit Denominator Value – Concentration High Limit Unit of Measurement 	<p>Display-Hyperlink, read-only text , drop-down list, multi-select, text</p>	<p>The <i>Reference Substances</i> entity tab is added under Manufactured Item > Substances and includes all the respective fields.</p>	<p>N/A</p>

Table 91: Orphan Designation

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Application Code – Application Name – Indications – Number – Orphan Status – Orphan Status Date – Community Registered Orphan Indication – Market Exclusivity Start Date – Orphan Designation Keywords – Orphan Designation Description – Orphan Designation Comments 	Display-Hyperlink, read-only text , drop-down list, multi-select, text field, date	The <i>Orphan Designation</i> entity tab is added under Application and includes all the respective fields. This tab shows if: <ul style="list-style-type: none"> – The Application type is Marketing Authorization Application (MAA). – The Application country belongs to EMA. – The Orphan Drug flag on the <i>Application Attributes</i> page is set to Yes. 	N/A

Table 92: Product Detail Sets

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Device - Type of Combination – Device Type – Device Identifier – Device Trade Name 	Drop-down list, text field	The <i>Add Medical Device</i> page now includes Device - Type of Combination field. The <i>Add Medical Device</i> page now includes all the respective fields.	The name of the device should be specified, if applicable, as recorded in the European database on medical devices (EUDAMED). The Unique Device Identifier recorded in the European database on medical devices (EUDAMED) must be specified.

Field/Option Name	Field Type	Description	Business Rules
Manufacturing Operation Start Date	Date	The <i>Add/Edit Manufacturer</i> page now includes this field.	The Manufacturing Operation Start Date is populated with the current date when the status of detail is changed from <i>Pending</i> to <i>Approved</i> . You can update this field even when the value is automatically populated .
Manufacturing Operation Stop Date	Date	The <i>Add/Edit Manufacturer</i> page now includes this field.	The Manufacturing Operation Start Date automatically populates the date on which the status of detail is changed from <i>Pending Withdrawal</i> to <i>Withdrawn</i> . You can update this field even when the value is automatically populated.

Field/Option Name	Field Type	Description	Business Rules
IDMP Concentration Measure Type IDMP Presentation Strength — Presentation Single or Low Limit Numerator Value — Presentation Single or Low Limit Unit of Measurement — Presentation Single or Low Limit Unit of Presentation — Presentation High Limit Numerator Value — Presentation High Limit Unit of Measurement — Presentation High Limit Unit of Presentation IDMP Concentration Strength — Concentration Single or Low Limit Numerator Value — Concentration Single or Low Limit Unit of Measurement — Concentration Single or Low Limit Denominator Value — Concentration Single or Low Limit Unit of Measurement — Concentration High Limit Numerator Value — Concentration High Limit Unit of Measurement — Concentration High Limit Denominator Value — Concentration High Limit Unit of Measurement	Drop-down list, text field	The following pages now includes the respective fields: — Product Detail Set > Substance Detail Attributes — Product Detail Set Template > Substance Detail Attributes — Product Detail Set > Flu Strain Attributes — Product Detail Set Template > Flu Strain Attributes	N/A
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Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Application Code – Application Name – Family Code – Family Name – Product Name – Product Detail Set Name – Pack Size Value – Unit of Presentation – QC Status – Date QC'd – QC'd by – Pack Size Status – Pack Size Status Date – Pack Size Keywords – Pack Size Description – Pack Size Comments 	Read-only text (populated automatically), Numeric, Drop-down list, Date, Text field	The Package Set > Pack Size > Add Pack Size page and Package Set > Pack Size > Edit Pack Size page includes the respective fields.	N/A
Intended Effect	Multi-select	The <i>Indication/Intended Use PDS Attributes Indication/Intended Use</i> (Add/Modify/Delete/View) pages now includes the Intended Effect field.	The Intended Effect field displays values from Data Administration > Product Detail Maintenance > Intended Effect Values .
Comorbidity	Multi-select	The <i>Indication/Intended Use PDS Attributes Indication/Intended Use</i> (Add/Modify/Delete/View) pages now includes the Comorbidity field.	The options for selection are displayed from the selected list values of the Product Family Comorbidity field on the <i>Product Family</i> page.

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Package Item Container Quantity – Package Material – Package Alternate Material – Package Components – Manufactured Item Reference – Packaging MI Quantity – Packaging MI Quantity Unit – Medical Device Reference – Device Quantity 	Numeric, Multi-select, Drop-down list	The <i>Package Detail</i> (Add/Edit) pages now includes the respective fields.	<p>The values for the Packaging MI Quantity Unit field is available from the Data Administration > Other > Units of Measurement Values.</p> <p>The Medical Device Reference field is displayed only for the Medical Device and Pharmaceutical-Medical Device product family types. This field populates Medical Device Detail. To delete Medical Device Detail, you must first delete all the references in the Packaging Detail.</p>

Table 93: Product

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Combined Pharmaceutical Dose Form – Product Category – EURD ID 	Drop-down list, multi-select, read-only text (populated automatically)	The <i>Product Attributes</i> page now includes the respective fields.	<p>The Combined Pharmaceutical Dose Form field shows on the View/Modify <i>Product Attributes</i> page when more than one component is associated. The active Dosage/Pharmaceutical Form Data Administration values with RMS values assigned mapped to values from SPOR Master Lists > Combined Pharmaceutical Dose Form appear for this field.</p>

Table 94: Pharmaceutical Product

Field/Option Name	Field Type	Description	Business Rules
Route of Administration	Multi-select	The <i>Pharmaceutical Product Attributes</i> page now includes the respective field.	N/A

Field/Option Name	Field Type	Description	Business Rules
Pharmaceutical Product Summary	Read-only text (populated automatically)	The <i>Pharmaceutical Product Attributes</i> page now includes the respective field. By default, the field is hidden.	N/A

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Family Type – Family Code – Family Name – Product Name – Pharmaceutical Product Name – Active Ingredient Name – Strength Same as Component? – Exclude from IDMP Submission – Concentration Measure Type – Low Amount Numerator Value – Low Amount Numerator Prefix – Low Amount Numerator Unit – Low Amount Denominator Value – Low Amount Denominator Prefix – Low Amount Denominator Unit – High Amount Numerator Value – High Amount Numerator Prefix – High Amount Numerator Unit – High Amount Denominator Value – High Amount Denominator Prefix – High Amount Denominator Unit – Measurement Point <p>IDMP Concentration Measure Type</p> <p>IDMP Presentation Strength</p> <ul style="list-style-type: none"> – Presentation Single or Low Limit Numerator Value – Presentation Single or Low Limit Unit of Measurement – Presentation Single or Low Limit Unit of Presentation – Presentation High Limit Numerator Value – Presentation High Limit Unit of Measurement – Presentation High Limit Unit of Presentation <p>IDMP Concentration Strength</p> <ul style="list-style-type: none"> – Concentration Single or Low Limit Numerator Value – Concentration Single or Low Limit Unit of Measurement – Concentration Single or Low Limit Denominator Value 	<p>Display-Hyperlink, read-only text , drop-down list, multi-select, text field</p>	<p>The <i>Active Ingredients</i> entity tab is added under <i>Pharmaceutical Product Attributes</i> and includes all the respective fields.</p>	<p>N/A</p>
<p>©Ennov 2024</p> <ul style="list-style-type: none"> – Concentration Single or Low Limit Unit of Measurement – Concentration High Limit Numerator 	<p>43</p>	<p>Ennov InSight RIM 7.1 RNs Cumulative</p>	<p>Entity Fields</p>

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Family Type – Family Code – Family Name – Product Name – Pharmaceutical Product Name – Active Ingredient Name – Reference Active Ingredient Name – Strength Same as Component? – Exclude from IDMP Submission – Concentration Measure Type – Low Amount Numerator Value – Low Amount Numerator Prefix – Low Amount Numerator Unit – Low Amount Denominator Value – Low Amount Denominator Prefix – Low Amount Denominator Unit – High Amount Numerator Value – High Amount Numerator Prefix – High Amount Numerator Unit – High Amount Denominator Value – High Amount Denominator Prefix – High Amount Denominator Unit – Measurement Point <p>IDMP Concentration Measure Type</p> <p>IDMP Presentation Strength</p> <ul style="list-style-type: none"> – Presentation Single or Low Limit Numerator Value – Presentation Single or Low Limit Unit of Measurement – Presentation Single or Low Limit Unit of Presentation – Presentation High Limit Numerator Value – Presentation High Limit Unit of Measurement – Presentation High Limit Unit of Presentation <p>IDMP Concentration Strength</p> <ul style="list-style-type: none"> – Concentration Single or Low Limit Numerator Value – Concentration Single or Low Limit Unit of Measurement 	<p>Display-Hyperlink, read-only text , drop-down list, multi-select, text field, widget</p>	<p>The <i>Reference Active Ingredients</i> entity tab is added under Pharmaceutical Product > Active Ingredients and includes all the respective fields.</p>	<p>N/A</p>
<ul style="list-style-type: none"> – Concentration Single or Low Limit Denominator Value – Concentration Single or Low Limit Unit of Measurement 	<p>44</p>	<p>Ennov InSight RIM 7.1 RNs Cumulative</p>	<p>Entity Fields</p>

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Family Type – Family Code – Family Name – Product Name – Pharmaceutical Product Name – Component Name – Substance Name – Substance Type – Strength Same as PDS Substance? <p>IDMP Concentration Measure Type</p> <p>IDMP Presentation Strength</p> <ul style="list-style-type: none"> – Presentation Single or Low Limit Numerator Value – Presentation Single or Low Limit Unit of Measurement – Presentation Single or Low Limit Unit of Presentation – Presentation High Limit Numerator Value – Presentation High Limit Unit of Measurement – Presentation High Limit Unit of Presentation <p>IDMP Concentration Strength</p> <ul style="list-style-type: none"> – Concentration Single or Low Limit Numerator Value – Concentration Single or Low Limit Unit of Measurement – Concentration Single or Low Limit Denominator Value – Concentration Single or Low Limit Unit of Measurement – Concentration High Limit Numerator Value – Concentration High Limit Unit of Measurement – Concentration High Limit Denominator Value – Concentration High Limit Unit of Measurement 	<p>Display-Hyperlink, read-only text , drop-down list, multi-select, text field</p>	<p>The <i>Substances</i> entity tab is added under <i>Pharmaceutical Product Attributes</i> and includes all the respective fields.</p>	<p>N/A</p>

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Family Type – Family Code – Family Name – Product Name – Pharmaceutical Product Name – Component Name – Substance Name – Reference Substance Name – Substance Type <p>IDMP Concentration Measure Type</p> <p>IDMP Presentation Strength</p> <ul style="list-style-type: none"> – Presentation Single or Low Limit Numerator Value – Presentation Single or Low Limit Unit of Measurement – Presentation Single or Low Limit Unit of Presentation – Presentation High Limit Numerator Value – Presentation High Limit Unit of Measurement – Presentation High Limit Unit of Presentation <p>IDMP Concentration Strength</p> <ul style="list-style-type: none"> – Concentration Single or Low Limit Numerator Value – Concentration Single or Low Limit Unit of Measurement – Concentration Single or Low Limit Denominator Value – Concentration Single or Low Limit Unit of Measurement – Concentration High Limit Numerator Value – Concentration High Limit Unit of Measurement – Concentration High Limit Denominator Value – Concentration High Limit Unit of Measurement 	<p>Display-Hyperlink, read-only text , drop-down list, multi-select, text field, widget</p>	<p>The <i>Reference Substances</i> entity tab is added under Pharmaceutical Product > Substances and includes all the respective fields.</p>	<p>N/A</p>

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Family Type – Family Code – Family Name – Product Name – Pharmaceutical Product Name – PhPID 	Display-Hyperlink, read-only text, text field	The <i>PhPIDs</i> entity tab is added under <i>Pharmaceutical Product</i> and includes all the respective fields.	N/A

Table 95: Registrations

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Application Code – Application Name – License Code – MAH/Organisation – Medicinal Product Name – Product – Package Sets – Authorised Pharmaceutical Form – Pediatric Use Indicator – Genetically Modified Organisms – PMS ID – Full Indication Text – Pharmaceutical Products – Medicinal Product Keywords – Medicinal Product Description – Medicinal Product Comments 	Display-Hyperlink, read-only text, drop-down list, multi-select editable, text field, widget	The <i>Medicinal Product</i> (Create/View/Modify) page includes the respective fields.	N/A

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Application Code – Application Name – Container or Pack Part – Country – Delimiter Part – Device Part – Flavour Part – Formulation Part – Full Name – Intended Use Part – Invented Name Part – Language – License Code – Medicinal Product Name – Medicinal Product Name Comments – Medicinal Product Name Description – Medicinal Product Name Keywords – Pharmaceutical Dosage Form Part – Scientific Name Part – Strength Part – Target Population Use Part – Trademark or Company Name Part – Time/Period Part 	Display-Hyperlink, read-only text , drop-down list, multi-select, text field	The Medicinal Product Name (Create/View/Modify) page includes the respective fields.	N/A
<ul style="list-style-type: none"> – MPID – Version – Version Date 	Read-only text, date	The MPID tab page includes the following columns. The information on the MPID tab is read-only. The MPID tab appears under Medicinal Product Attributes.	N/A

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Pharmaceutical Product Name – Pharmaceutical Product Summary 	Display-Hyperlink, read-only text	The <i>Pharmaceutical Product</i> tab page includes these columns. The <i>Pharmaceutical Product</i> tab appears under Medicinal Product Attributes with the ability to associate/disassociate the pharmaceutical products.	N/A

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Application Code – Application Name – License Code – MAH/Organisation – Sequence – Events – Medicinal Product – Regulatory Application Submission Type – Event Variation Number – Event EU Grouping/ Worksharing – Regulatory application Identifier/Number – FHIR Protocol Type – Action Name – Content of Change – Provenance Reason – Status – Status Date – Medicinal Product Action Keywords – Medicinal Product Action Description – Medicinal Product Action Comments 	Display-Hyperlink, read-only text , drop-down list, multi-select , text field, date	The <i>Medicinal Product Action</i> (Create/View/Modify) page includes the following fields.	The values for the Regulatory Application Submission Type fields are available from the Data Administration > Other > Application Submission Type values. The Event field is displayed only with the following conditions: <ul style="list-style-type: none"> – CP Applications: <ul style="list-style-type: none"> • Event is Open +Event is Closed with APPROVED status (status should be only APPROVED). • Event Closed Date should not be greater than 31 days. • Event Country = Registration Country. – Non-CP Applications: <ul style="list-style-type: none"> • Event is Closed with APPROVED status(status should be only APPROVED)(Open Events should not be displayed). • Event Closed Date should not be greater than 31 days. • Event Country = Registration Country.

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Application Code – Application Name – License Code – Sequence – Medicinal Product List – Attached Document Identifier (Master) – Attached Document Name – Attached Document Type – Alternate Identifier (EV Code) – Title – Content Type – Content Link – Effective Date – Language – Full Indication Text 	Display-Hyperlink, read-only text , drop-down list, multi-select, text field, date	The <i>Attached Documents</i> (Create/View/Modify) page includes the respective fields.	The Attached Documents tab appears for Applications of MRP, DCP, EU National Type only.
<ul style="list-style-type: none"> – Application Code – Application Name – License Code – Product Name – Medicinal Product Name – MPID – Version – Version Date 	Display-Hyperlink, read-only text	The <i>IDMP</i> page includes the following columns. The information on the IDMP tab is read-only. The IDMP tab appears under Registration Attributes when the Medicinal Product is created.	N/A
<ul style="list-style-type: none"> – Application Code – Application Name – License Code – Product Detail Set Name – Package Set Name – Short Package Description – Package Description – Language – Package Description – Package Description Description – Package Description Comments 	Hyperlink, drop-down list, text field	The <i>Package Descriptions</i> entity is added under <i>Registration-Package Set Attributes</i> and includes all the respective fields.	N/A

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Legal Basis – Authorisation Status – Authorisation Status Date – Status – Status Date – PCID – Package Set License Code – Withdrawn – Withdrawn Date 	Drop-down list, text field, date	The Registration- Package Sets Attributes page now includes the respective fields.	N/A
<ul style="list-style-type: none"> – Package Set Name – Package Set License Code – Product Detail Set Name – Product Detail Set Code – Status – Status Date – Authorisation Status – Authorisation Status Date – PCID – MPID 	Hypelink, text field, date	The Package Sets tab grid view on the Registration Attributes page for Package Set Registration type now includes the respective columns.	N/A
<ul style="list-style-type: none"> – ATC Code Flag 	Drop-down list	The Registration Attributes page for Package Set Registration type now includes the respective fields.	N/A

Table 96: Full Product Presentation

Field/Option Name	Field Type	Description	Business Rules
Pharmaceutical Products	Multi-select, read-only text (populated automatically)	<p>The <i>Create Full Product Presentation</i> page now includes the Pharmaceutical Products field:</p> <ul style="list-style-type: none"> – <i>Create Full Product Presentation</i> – <i>Copy Full Product Presentation</i>(under Same Registrations) 	<p>Only Pharmaceutical Products from Products that are associated to FPP via Pack Sets are displayed in the Pharmaceutical Products field.</p> <p>Pharmaceutical Product value is displayed as a concatenation of Pharmaceutical Product Name and Pharmaceutical Product Summary.</p>

Wizards

Table 97: Create Notification Wizard

Field Name	Field Type	Description	Business Rules
Available Options	Drop-down list	<p>The Available Options field under the Select Rule Settings and Delivery Destinations step now includes the following options for selection:</p> <ul style="list-style-type: none"> – Community Registered Orphan Designation Indication – Indications – Market Exclusivity Start Date – Number – Orphan Status – Orphan Status Date 	<p>These options are available for selection when you:</p> <ul style="list-style-type: none"> – set Orphan Drug flag to Yes. – select When a Value Changes option under the Choose Notification Type step.
Application Status	Drop-down list	<p>The Application Status field under the Select Rule Settings and Delivery Destinations step now includes the Orphan Status option for selection.</p>	<p>This option is available for selection when you:</p> <ul style="list-style-type: none"> – set Orphan Drug flag to Yes. – select When Status Changes to a Specific Value option under the Choose Notification Type step.

Field Name	Field Type	Description	Business Rules
Available Options	Drop-down list	The Available Options field under the Select Rule Settings and Delivery Destinations step now includes the Orphan Status Date option for selection.	These options are available for selection when you: <ul style="list-style-type: none"> – set Orphan Drug flag to Yes. – select When a Date Approaches or Passes option under the Choose Notification Type step.
Available Options	Drop-down list	The Available Options field under the Select Rule Settings and Delivery Destinations step now includes the following options for selection for the <i>Product Family</i> Attributes when creating notifications: <ul style="list-style-type: none"> – EURD ID – Product Family Indications – Product Family Comorbidity – Product Family Indications/Intended Use 	These options are available for selection, when you select When a Value Changes option under the Choose Notification Type step.
Available Options	Drop-down list	The Available Options field under the Select Rule Settings and Delivery Destinations step now includes the following option for selection for the <i>Application Country</i> Attributes when creating notifications for EU CTR applications only: Local Early Termination/Withdrawal/Suspension Reason.	This option is available for selection when you select the When a Value Changes option in the Choose Notification Type step.

Field Name	Field Type	Description	Business Rules
Available Options	Drop-down list	<p>The Available Options field under Select Rule Settings and Delivery Destinations now includes the following options for the <i>Application Country</i> attributes when creating notifications for EU CTR applications only:</p> <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 option is available for selection when you select the When a Date Approaches or Passes option in the Choose Notification Type step.

Entity Fields and Columns Updated: Ennov InSight 7.1

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

Product Family

Field/Option Name	Field Type	Description	Business Rules
Product Family Indications/Intended Use	Multi-select, read-only text (populated automatically)	This field is renamed to Product Family Indication on the <i>Product Family Attributes</i> page. For Veterinary Product Family Type, this field is still Product Family Indications/Intended Use.	The Assigned Indications box of the Product Family Indication field display values from the Indications field on the <i>Indications/Intended Use PDS Attributes</i> page.

Product

Field/Option Name	Field Type	Description	Business Rules
Product Dosage Form	Selection widget	This field is renamed to Product Dose Form and updated with <i>Dose Form Search</i> selection widget.	N/A

Pharmaceutical Product

Field/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Product Quantity Value – Product Quantity Unit – Product Characteristics 	Read-only text (populated automatically)	These fields are hidden by default on the <i>Pharmaceutical Product Attributes</i> page.	N/A
Administrable Dosage Form	Selection widget	This field is renamed to Administrable Dose Form and updated with <i>Dose Form Search</i> selection widget on the <i>Pharmaceutical Product Attributes</i> page.	N/A
<ul style="list-style-type: none"> – Pharmaceutical Product Name – Administrable Dose Form – Unit of Presentation – Pharmaceutical Product Description – Route of Administration 	Read-only text (populated automatically)	The <i>Pharmaceutical Products</i> tab now includes these columns.	N/A

Component

Field/Option Name	Field Type	Description	Business Rules
Active Ingredients and Reference Active Ingredients	N/A	The <i>Active Ingredients</i> and <i>Reference Active Ingredients</i> work logic is changed. These attributes are added one by one, not in bulk now. More than one Reference Active Ingredient can be added to Active Ingredient now.	N/A
Component Form	Selection widget	This field is updated with <i>Dose Form Search</i> selection widget.	N/A

Application

Field/Option Name	Field Type	Description	Business Rules
Legal Status	Drop-down list	This field is renamed to Legal Status of Supply on the <i>Application Attributes</i> page.	N/A

Registration

Field/Option Name	Field Type	Description	Business Rules
EU Presentation Number	Text field	This field is renamed to Package Set License Code on the Registration- Package Sets > Associate Package Set page.	N/A
Package Set Name	Drop-down list	This field is updated to select a PDS Package Set with a status of Pending Add and associate it to Registration Package Set entity while updating existing Registration.	N/A

Active Ingredients and Reference Active Ingredients

Field/Option Name	Field Type	Description	Business Rules
Active Ingredients/ Reference Active Ingredients	Read-only text (populated automatically)	<p>The <i>Active Ingredients</i> and <i>Reference Active Ingredients</i> tabs now include these columns for:</p> <ul style="list-style-type: none"> – Component Attributes – Pharmaceutical Product Attributes – Pharmaceutical Product Substance – Pharmaceutical Product Reference Substance – Manufactured Item – Manufactured Item Substance – Manufactured Item Reference Substance 	N/A

Product Detail Sets

Field/Option Name	Field Type	Description	Business Rules
Indications/ Intended Use	Multi-select	This field is renamed to Indications on the <i>Indication/Intended Use</i> (Add/Modify/Delete/View) pages.	N/A
Indications/ Intended Use	Read-only text (populated automatically)	This field is renamed to Indication on the <i>Indication/Intended Use Detail Attributes</i> (Add/Modify/Delete/View) pages.	N/A

Field/Option Name	Field Type	Description	Business Rules
Shelf Life Type	Drop-down list	The field value is modified to display details for the Shelf life(s)/storage condition(s) grouping node only.	The options for this field are displayed from the Shelf Life Type Data Administration table. This field does not indicate the details for Shelf life(s)/storage condition(s) After Opening and Shelf life(s)/storage condition(s) After Reconstitution grouping nodes.
Shelf Life Grouping	Drop-down list	This field is renamed to Shelf Life Type on the <i>Shelf Life/Storage Condition(s)</i> (Add/Edit/View) pages.	N/A
Concentration Measure Type	Drop-down list	This field type is updated to Read-only text (populated automatically) on the Product Detail Set > Add/Edit Active Ingredient pages.	You can modify only the PDS attributes. You cannot modify the values populating from the Product Component Active Ingredient.
Low Amount Numerator Value	Text field	This field type is updated to Read-only text (populated automatically) on the Product Detail Set > Add/Edit Active Ingredient pages.	You can modify only the PDS attributes. You cannot modify the values populating from the Product Component Active Ingredient.
Low Amount Numerator Prefix	Drop-down list	This field type is updated to Read-only text (populated automatically) on the Product Detail Set > Add/Edit Active Ingredient pages.	You can modify only the PDS attributes. You cannot modify the values populating from the Product Component Active Ingredient.
Low Amount Numerator Unit	Drop-down list	This field type is updated to Read-only text (populated automatically) on the Product Detail Set > Add/Edit Active Ingredient pages.	You can modify only the PDS attributes. You cannot modify the values populating from the Product Component Active Ingredient.

Field/Option Name	Field Type	Description	Business Rules
Low Amount Denominator Value	Text field	This field type is updated to Read-only text (populated automatically) on the Product Detail Set > Add/Edit Active Ingredient pages.	You can modify only the PDS attributes. You cannot modify the values populating from the Product Component Active Ingredient.
Low Amount Denominator Prefix	Drop-down list	This field type is updated to Read-only text (populated automatically) on the Product Detail Set > Add/Edit Active Ingredient pages.	You can modify only the PDS attributes. You cannot modify the values populating from the Product Component Active Ingredient.
Low Amount Denominator Unit	Drop-down list	This field type is updated to Read-only text (populated automatically) on the Product Detail Set > Add/Edit Active Ingredient pages.	You can modify only the PDS attributes. You cannot modify the values populating from the Product Component Active Ingredient.
High Amount Numerator Value	Text field	This field type is updated to Read-only text (populated automatically) on the Product Detail Set > Add/Edit Active Ingredient pages.	You can modify only the PDS attributes. You cannot modify the values populating from the Product Component Active Ingredient.
High Amount Numerator Prefix	Drop-down list	This field type is updated to Read-only text (populated automatically) on the Product Detail Set > Add/Edit Active Ingredient pages.	You can modify only the PDS attributes. You cannot modify the values populating from the Product Component Active Ingredient.
High Amount Numerator Unit	Drop-down list	This field type is updated to Read-only text (populated automatically) on the Product Detail Set > Add/Edit Active Ingredient pages.	You can modify only the PDS attributes. You cannot modify the values populating from the Product Component Active Ingredient.

Field/Option Name	Field Type	Description	Business Rules
High Amount Denominator Value	Text field	This field type is updated to Read-only text (populated automatically) on the Product Detail Set > Add/Edit Active Ingredient pages.	You can modify only the PDS attributes. You cannot modify the values populating from the Product Component Active Ingredient.
High Amount Denominator Prefix	Drop-down list	This field type is updated to Read-only text (populated automatically) on the Product Detail Set > Add/Edit Active Ingredient pages.	You can modify only the PDS attributes. You cannot modify the values populating from the Product Component Active Ingredient.
High Amount Denominator Unit	Drop-down list	This field type is updated to Read-only text (populated automatically) on the Product Detail Set > Add/Edit Active Ingredient pages.	You can modify only the PDS attributes. You cannot modify the values populating from the Product Component Active Ingredient.
Measurement Point	Text field	This field type is updated to Read-only text (populated automatically) on the Product Detail Set > Add/Edit Active Ingredient pages.	You can modify only the PDS attributes. You cannot modify the values populating from the Product Component Active Ingredient.
Container Material	Multi-select editable	This field is renamed to Package Material on the <i>Package Detail</i> (Add/Edit) pages.	N/A
Container Alternate Material	Multi-select editable	This field is renamed to Package Alternate Material on the <i>Package Detail</i> (Add/Edit) pages.	N/A

Full Product Presentations

Field/Option Name	Field Type	Description	Business Rules
Authorized Pharmaceutical Form	Selection widget	This field is updated with <i>Dose Form Search</i> selection widget.	N/A

Wizards

Table 98: Create Application Wizard

Field Name	Field Type	Description	Business Rules
Legal Status	Drop-down list	This field is renamed to Legal Status of Supply on the Enter values for a new application > Create Application page.	N/A

Table 99: Update Applications Wizard

Field Name	Field Type	Description	Business Rules
Legal Status	Multi-select	This field is renamed to Legal Status of Supply on the Enter Applications Search Criteria > Select values to refine search page.	N/A

Table 100: Create Notification Wizard

Field Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Product Characteristics – Product Quantity Unit – Product Quantity Value 	Drop-down list	These fields are hidden by default on the Available Options drop-down list in Create Notification > Select Rule Settings and Delivery Destination invoked from the Notifications tab on <i>Pharmaceutical Product Attributes</i> page.	N/A
Administrable Dosage Form	Drop-down list	This field is renamed to Administrable Dose Form in the Available Options drop-down list in Create Notification > Select Rule Settings and Delivery Destination invoked from the Notifications tab on <i>Pharmaceutical Product Attributes</i> page.	N/A

Table 101: Global Project Plan Wizard

Field Name	Field Type	Description	Business Rules
Indications/Intended Use	Multi-select	This field is renamed to Indications in the Select Indications/Intended Use > Select the indication/intended use tab of the Update Product Detail Set Project Type option.	N/A

Entity Fields and Columns Removed: Ennov InSight 7.1

The following table describes fields and columns that are removed with Ennov InSight 7.1.

Registrations - Package Sets

Field/Column/Option Name	Field Type	Description	Business Rules
<ul style="list-style-type: none"> – Withdrawn – Withdrawn Date 	Text field, date	These columns are removed from the: Registrations - Package Sets grid view	N/A

Full Product Presentation

Field/Option Name	Field Type	Description	Business Rules
Use Reference Ingredient for XEVMPD	Drop-down list	This field is removed from the following pages: <ul style="list-style-type: none"> – <i>Full Product Presentation</i>(Create, Modify, and View) – <i>Copy Full Product Presentation</i> – <i>XEVMPD Submissions - QC Verification and Audit</i> 	N/A

Query Fields

Query Fields and Columns Added: Ennov InSight 7.1

The following table describes fields that were updated with Ennov InSight 7.1.

Administration Queries

Table 102: Entity Audit Trail

Field/Column Name	Field/Column Type	Description
Entity Type	Read-only text (populated automatically)	The Manufactured Item value is added to the Entity Type field of the <i>Entity Audit Trail Query</i> to display details for the Manufactured Item entity type.

Field/Column Name	Field/Column Type	Description
<ul style="list-style-type: none"> – Manufactured Item ID – Manufactured Item ID – Manufactured Item Name – Manufactured Dose Form – Unit of Presentation – Manufactured Item Quantity – Manufactured Item Keywords – Manufactured Item Description 	Read-only text (populated automatically)	These columns are added to the <i>Search Results</i> page of the <i>Entity Audit Trail Query</i> to display details for the Manufactured Item entity type.
<ul style="list-style-type: none"> – Manufacturer Operation Start Date – Manufacturer Operation Stop Date 	Read-only text (populated automatically)	The respective columns are displayed in the <i>Search Results</i> page of the <i>Entity Audit Trail Query</i> . These columns are displayed in the report from the Manufacturer Operation Start Date and Manufacturer Operation Stop Date fields of the Manufacturer page.
<ul style="list-style-type: none"> – Package Set Pack Size Details Changed? – Package Set Pack Size Details QC Passed? 	Read-only text (populated automatically)	The respective fields are added to the <i>Search Results</i> page of the <i>Entity Audit Trail Query</i> to support the changes for PDS Pack Size Detail.
<ul style="list-style-type: none"> – Package Item Container Quantity – Manufactured Item Reference – Packaging MI Quantity – Packaging MI Quantity Unit (Measurement) – Device Quantity – Medical Device Reference 	Read-only text (populated automatically)	<p>The respective columns are added to the <i>Search Results</i> page of the <i>Entity Audit Trail Query</i> to display details for the Product Detail- Packaging entity type.</p> <p>The values in the Manufactured Item Reference column are displayed as a concatenation of (Manufactured Item Name + Unit of Presentation + Manufactured Item Quantity + Manufactured Item Quantity Unit + Manufactured Item Dose Form + Manufactured Item Characteristics) All the values are separated with space.</p> <p>The Medical Device Reference column is available for the Medical Device and PharmaMed Components only.</p>
Combined Pharmaceutical Dose Form	Read-only text (populated automatically)	The Combined Pharmaceutical Dose Form column is added to <i>Search Results</i> page of the Product > Entity History Query .

Product Detail Management Queries

Table 103: Shelf Life Query

Field/Column Name	Field Type	Description
Component Name	Read-only text (populated automatically)	This column is now available in the <i>Search Results</i> page of the <i>Shelf Life Query</i> .

Table 104: Application QC Status History Report

Field/Column Name	Field/Column Type	Description
<ul style="list-style-type: none"> – Packaging MI Quantity – Packaging MI Quantity Unit – Medical Device Reference – Device Quantity – Package Item Container Quantity – Package Material – Package Alternate Material – Package Components – Manufactured Item Reference – Intended effect – Comorbidity – Component Name 	Read-only text (populated automatically)	<p>The respective columns are available on the <i>Search Results</i> page of the <i>Application QC Status History Report</i>.</p> <p>The manufactured Item Reference column is available after you select the value under Package Component. There should be at least one Component with a MedDev or Pharma MedDev Type.</p> <p>The values in the Manufactured Item Reference column are displayed as a concatenation of (Manufactured Item Name + Unit of Presentation + Manufactured Item Quantity + Manufactured Item Quantity Unit + Manufactured Item Dose Form + Manufactured Item Characteristics) All the values are separated with space.</p> <p>The Intended Effect and Comorbidity columns are available after you select the value under Species Indications Details Changed? column for the Veterinary Product Family.</p> <p>The Component Name column is available after you select the value under "Shelf Life(s)/Storage Condition(s) Changed column.</p>
<ul style="list-style-type: none"> – Package Set Pack Size Details Changed? (ASC, DESC) – Package Set Pack Size Details QC Passed? 	Multi-select editable, Read-only text (populated automatically)	<p>The respective fields are now available in the <i>Application QC Status History Report</i> :</p> <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Table 105: Application History Query

Field/Column Name	Field/Column Type	Description
<ul style="list-style-type: none"> – Packaging MI Quantity – Packaging MI Quantity Unit – Medical Device Reference – Device Quantity – Package Item Container Quantity – Package Material – Package Alternate Material – Package Components – Comorbidity – Intended Effect – Component Name – Manufactured Item Reference 	Read-only text (populated automatically)	<p>The respective columns are available on the <i>Search Results</i> page of the <i>Application History Query</i> .</p> <p>The Component Name column is available after you select the value under Shelf Life(s)/Storage Condition(s) Changed column.</p> <p>The Manufactured Item Reference column is available after you select the value under Package Component. There should be at least one Component with a MedDev or Pharma MedDev Type.</p> <p>The values in the Manufactured Item Reference column are displayed as a concatenation of (Manufactured Item Name + Unit of Presentation + Manufactured Item Quantity + Manufactured Item Quantity Unit + Manufactured Item Dose Form + Manufactured Item Characteristics) All the values are separated with space.</p>
<ul style="list-style-type: none"> – Package Set Pack Size Details Changed? (ASC, DESC) – Package Set Pack Size Details QC Passed? 	Multi-select editable, Read-only text (populated automatically)	<p>The respective fields are now available in the <i>Application History Query</i> :</p> <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Table 106: List of Package Set Manufacturers

Field/Column Name	Field/Column Type	Description
<ul style="list-style-type: none"> – Manufacturer Operation Start Date – Manufacturer Operation Stop Date 	Multi-select editable, Read-only text (populated automatically)	<p>The respective fields are now available in the <i>List of Package Set Manufacturers</i> query:</p> <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Table 107: List of Component Manufacturers

Field/Column Name	Field/Column Type	Description
<ul style="list-style-type: none"> – Manufacturer Operation Start Date – Manufacturer Operation Stop Date 	Multi-select editable, Read-only text (populated automatically)	The respective fields are now available in the <i>List of Component Manufacturers</i> query: <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Table 108: List of PDS Manufacturers

Field/Column Name	Field/Column Type	Description
<ul style="list-style-type: none"> – Manufacturer Operation Start Date – Manufacturer Operation Stop Date 	Multi-select editable, Read-only text (populated automatically)	This respective fields are now available in the <i>List of PDS Manufacturers</i> query: <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Table 109: List of Excipient Manufacturers

Field/Column Name	Field/Column Type	Description
<ul style="list-style-type: none"> – Manufacturer Operation Start Date – Manufacturer Operation Stop Date 	Multi-select editable, Read-only text (populated automatically)	The respective fields are now available in the <i>List of Excipient Manufacturers</i> query: <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Table 110: List of Active Ingredient Material Manufacturers

Field/Column Name	Field/Column Type	Description
<ul style="list-style-type: none"> – Manufacturer Operation Start Date – Manufacturer Operation Stop Date 	Multi-select editable, Read-only text (populated automatically)	The respective fields are now available in the <i>List of Active Ingredient Material Manufacturers</i> query: <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Table 111: List of Active Ingredient Function Manufacturers

Field/Column Name	Field/Column Type	Description
<ul style="list-style-type: none"> – Manufacturer Operation Start Date – Manufacturer Operation Stop Date 	Multi-select editable, Read-only text (populated automatically)	The respective fields are now available in the <i>List of Active Ingredient Function Manufacturers</i> query: <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Table 112: List of Active Ingredient Manufacturers

Field/Column Name	Field/Column Type	Description
<ul style="list-style-type: none"> – Manufacturer Operation Start Date – Manufacturer Operation Stop Date 	Multi-select editable, Read-only text (populated automatically)	The respective fields are now available in the <i>List of Active Ingredient Manufacturers</i> query: <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page

Registration Planning and Tracking

Table 113: List of Pharmaceutical Products

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> – Combined Pharmaceutical Dose Form – Product Category – EURD ID – IDMP Concentration Measure Type 	Drop-down list, Multi-select editable, Text field, editable	The respective fields/ columns are now available in the <i>List of Pharmaceutical Products</i> query: <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
IDMP Presentation Strength <ul style="list-style-type: none"> – Presentation Single or Low Limit Numerator Value – Presentation Single or Low Limit Unit of Measurement – Presentation Single or Low Limit Unit of Presentation – Presentation High Limit Numerator Value – Presentation High Limit Unit of Measurement – Presentation High Limit Unit of Presentation 		
IDMP Concentration Strength <ul style="list-style-type: none"> – Concentration Single or Low Limit Numerator Value – Concentration Single or Low Limit Unit of Measurement – Concentration Single or Low Limit Denominator Value – Concentration Single or Low Limit Unit of Measurement – Concentration High Limit Numerator Value – Concentration High Limit Unit of Measurement – Concentration High Limit Denominator Value – Concentration High Limit Unit of Measurement 		

Table 114: List of Veterinary Products

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> – IDMP Concentration Measure Type 	Drop-down list, Text field, editable	The respective fields/columns are now available in the <i>List of Veterinary Products</i> query: <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
IDMP Presentation Strength <ul style="list-style-type: none"> – Presentation Single or Low Limit Numerator Value – Presentation Single or Low Limit Unit of Measurement – Presentation Single or Low Limit Unit of Presentation – Presentation High Limit Numerator Value – Presentation High Limit Unit of Measurement – Presentation High Limit Unit of Presentation 		
IDMP Concentration Strength <ul style="list-style-type: none"> – Concentration Single or Low Limit Numerator Value – Concentration Single or Low Limit Unit of Measurement – Concentration Single or Low Limit Denominator Value – Concentration Single or Low Limit Unit of Measurement – Concentration High Limit Numerator Value – Concentration High Limit Unit of Measurement – Concentration High Limit Denominator Value – Concentration High Limit Unit of Measurement 		

Table 115: List of Pharmaceutical and Medical Device Products

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> – Combined Pharmaceutical Dose Form – Product Category – EURD ID – IDMP Concentration Measure Type 	Drop-down list, Multi-select editable, Text field, editable	The respective fields/columns are now available in the <i>List of Pharmaceutical and Medical Device Products</i> query: <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
IDMP Presentation Strength <ul style="list-style-type: none"> – Presentation Single or Low Limit Numerator Value – Presentation Single or Low Limit Unit of Measurement – Presentation Single or Low Limit Unit of Presentation – Presentation High Limit Numerator Value – Presentation High Limit Unit of Measurement – Presentation High Limit Unit of Presentation 		
IDMP Concentration Strength <ul style="list-style-type: none"> – Concentration Single or Low Limit Numerator Value – Concentration Single or Low Limit Unit of Measurement – Concentration Single or Low Limit Denominator Value – Concentration Single or Low Limit Unit of Measurement – Concentration High Limit Numerator Value – Concentration High Limit Unit of Measurement – Concentration High Limit Denominator Value – Concentration High Limit Unit of Measurement 		

Table 116: List of Pharmaceutical Products and Components

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> – Combined Pharmaceutical Dose Form – Product Category – EURD ID – IDMP Concentration Measure Type 	Drop-down list, Text field, editable	The respective fields/ columns are now available in the <i>List of Pharmaceutical Products and Components</i> query: <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
IDMP Presentation Strength <ul style="list-style-type: none"> – Presentation Single or Low Limit Numerator Value – Presentation Single or Low Limit Unit of Measurement – Presentation Single or Low Limit Unit of Presentation – Presentation High Limit Numerator Value – Presentation High Limit Unit of Measurement – Presentation High Limit Unit of Presentation 		
IDMP Concentration Strength <ul style="list-style-type: none"> – Concentration Single or Low Limit Numerator Value – Concentration Single or Low Limit Unit of Measurement – Concentration Single or Low Limit Denominator Value – Concentration Single or Low Limit Unit of Measurement – Concentration High Limit Numerator Value – Concentration High Limit Unit of Measurement – Concentration High Limit Denominator Value – Concentration High Limit Unit of Measurement 		

Table 117: List of Veterinary Products and Components

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> – IDMP Concentration Measure Type 	Drop-down list, Text field, editable	The respective fields/ columns are now available in the <i>List of Veterinary Products and Components</i> query: <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
IDMP Presentation Strength <ul style="list-style-type: none"> – Presentation Single or Low Limit Numerator Value – Presentation Single or Low Limit Unit of Measurement – Presentation Single or Low Limit Unit of Presentation – Presentation High Limit Numerator Value – Presentation High Limit Unit of Measurement – Presentation High Limit Unit of Presentation 		
IDMP Concentration Strength <ul style="list-style-type: none"> – Concentration Single or Low Limit Numerator Value – Concentration Single or Low Limit Unit of Measurement – Concentration Single or Low Limit Denominator Value – Concentration Single or Low Limit Unit of Measurement – Concentration High Limit Numerator Value – Concentration High Limit Unit of Measurement – Concentration High Limit Denominator Value – Concentration High Limit Unit of Measurement 		

Table 118: List of Pharmaceutical and Medical Device Products and Components

Field/Column Name	Field Type	Description
<ul style="list-style-type: none"> – Combined Pharmaceutical Dose Form – Product Category – EURD ID – IDMP Concentration Measure Type 	Drop-down list, Multi-select editable, Text field, editable	The respective fields/columns are now available in the <i>List of Pharmaceutical and Medical Device Products and Components</i> query: <ul style="list-style-type: none"> – Display Columns multi-select field options – Sort Order multi-select field options – <i>Search Results</i> page
IDMP Presentation Strength <ul style="list-style-type: none"> – Presentation Single or Low Limit Numerator Value – Presentation Single or Low Limit Unit of Measurement – Presentation Single or Low Limit Unit of Presentation – Presentation High Limit Numerator Value – Presentation High Limit Unit of Measurement – Presentation High Limit Unit of Presentation 		
IDMP Concentration Strength <ul style="list-style-type: none"> – Concentration Single or Low Limit Numerator Value – Concentration Single or Low Limit Unit of Measurement – Concentration Single or Low Limit Denominator Value – Concentration Single or Low Limit Unit of Measurement – Concentration High Limit Numerator Value – Concentration High Limit Unit of Measurement – Concentration High Limit Denominator Value – Concentration High Limit Unit of Measurement 		

Query Fields and Columns Updated: Ennov InSight 7.1

The following table describes fields that were updated with Ennov InSight 7.1

Administration Queries

Table 119: Entity Audit Trail

Field Name	Field Type	Description
Administrable Dosage Form	Read-only text (populated automatically)	The Administrable Dosage Form column is renamed with Administrable Dose Form in the <i>Search Results</i> page of the <i>Entity Audit Trail Query</i> for Pharmaceutical Product entity type.

Field Name	Field Type	Description
Product Characteristics	Read-only text (populated automatically)	These columns are hidden by default in the <i>Search Results</i> page of the <i>Entity Audit Trail Query</i> for Product Entity type.
Product Quantity Unit	Read-only text (populated automatically)	
Product Quantity Value	Read-only text (populated automatically)	
Indications/ Intended Use	Read-only text (populated automatically)	The <i>Indications/ Intended Use</i> column is renamed to <i>Indication</i> on the <i>Search Results</i> page of the <i>Entity Audit Trail Query</i> for the Product - Detail Indications/ Intended Use entity type.

Product Detail Management Queries

Table 120: Application History Query

Field Name	Field Type	Description
Indications/Intended Use	Read-only text (populated automatically)	This column is renamed to <i>Indications</i> in the <i>Application History Query > Search Results</i> page.

Table 121: Application QC Status History Report

Field Name	Field Type	Description
Indications/Intended Use	Read-only text (populated automatically)	This column is renamed to <i>Indications</i> in the <i>Application QC Status History Report > Search Results</i> page.

Table 122: List of Package Set Registrations with Application and Product Detail Properties

Field Name	Field Type	Description
Legal Status Type	Multi-select editable, Read-only text (populated automatically)	This field/column is renamed to <i>Legal Status of Supply</i> in the: <ul style="list-style-type: none"> – <i>List of Package Set Registrations with Application and Product Detail Properties Query</i> page. – <i>Search Results</i> page.

Table 123: List of Product Registrations with Application and Product Detail Properties

Field Name	Field Type	Description
Legal Status Type	Multi-select editable, Read-only text (populated automatically)	This field/column is renamed to Legal Status of Supply in the: <ul style="list-style-type: none"> – <i>List of Product Registrations with Application and Product Detail Properties Query</i> page. – <i>Search Results</i> page.

Submission Planning and Tracking Queries

Table 124: List of Application Countries

Field Name	Field Type	Description
Application Legal Status Type	Multi-select editable, Read-only text (populated automatically)	This field/column is renamed to Legal Status of Supply in the: <ul style="list-style-type: none"> – <i>List of Application Countries Query</i> page. – <i>Search Results</i> page.

Table 125: List of Applications

Field Name	Field Type	Description
Legal Status Type	Multi-select editable, Read-only text (populated automatically)	This field/column is renamed to Legal Status of Supply in the: <ul style="list-style-type: none"> – <i>List of Application Query</i> page. – <i>Search Results</i> page.

Registration Planning and Tracking Queries

Table 126: List of Applications with Products

Field Name	Field Type	Description
Legal Status Type	Multi-select editable, Read-only text (populated automatically)	This field/column is renamed to Legal Status of Supply in the: <ul style="list-style-type: none"> – <i>List of Applications with Products Query</i> page. – <i>Search Results</i> page.

Table 127: List of Events with Application Properties

Field Name	Field Type	Description
Legal Status Type	Multi-select editable, Read-only text (populated automatically)	This field/column is renamed to Legal Status of Supply in the: <ul style="list-style-type: none"> – <i>List of Events with Application Properties Query</i> page. – <i>Search Results</i> page.

Table 128: List of Registrations with Application Properties

Field Name	Field Type	Description
Legal Status Type	Multi-select editable, Read-only text (populated automatically)	This field/column is renamed to Legal Status of Supply in the: <ul style="list-style-type: none"> – <i>List of Registrations with Application Properties Query</i> page. – <i>Search Results</i> page.

Table 129: List of Sequences with Application and Event Properties

Field Name	Field Type	Description
Legal Status Type	Multi-select editable, Read-only text (populated automatically)	This field/column is renamed to Legal Status of Supply in the: <ul style="list-style-type: none"> – <i>List of Sequences with Application and Event Properties Query</i> page. – <i>Search Results</i> page.

Table 130: List of Application Countries with Registration Details

Field Name	Field Type	Description
Application Legal Status Type	Multi-select editable, Read-only text (populated automatically)	This field/column is renamed to Legal Status of Supply in the: <ul style="list-style-type: none"> – <i>List of Application Countries with Registration Details Query</i> page. – <i>Search Results</i> page.

Table 131: List of References

Field Name	Field Type	Description
Associated with (select parent entity)	Drop-down list	The Associated with (select parent entity) field is updated to include the following new values to support the IDMP entities: <ul style="list-style-type: none"> – Medicinal Product – Pharmaceutical Product – Manufactured Item

Table 132: List of References - Rollup by Application

Field Name	Field Type	Description
Association Type	Read-only text (populated automatically)	The Association Type column is updated to include the Medicinal Product value.

Table 133: List of References -Rollup by Product Family

Field Name	Field Type	Description
Association Type	Read-only text (populated automatically)	The Association Type column is updated to include the new following values: <ul style="list-style-type: none"> – Pharmaceutical Product – Manufactured Item

Table 134: List of Tasks

Field Name	Field Type	Description
Associated with (select parent entity)	Drop-down list	The Associated with (select parent entity) field is updated to include the following new values to support the IDMP entities: <ul style="list-style-type: none"> – Medicinal Product – Pharmaceutical Product – Manufactured Item

Table 135: List of Tasks - Rollup by Application

Field Name	Field Type	Description
Association Type	Read-only text (populated automatically)	The Association Type column is updated to include the Medicinal Product value.

Table 136: List of Tasks -Rollup by Product Family

Field Name	Field Type	Description
Association Type	Read-only text (populated automatically)	The Association Type column is updated to include the new following values: <ul style="list-style-type: none"> – Pharmaceutical Product – Manufactured Item

List of Enhancements: Ennov InSight 7.1

Common

Issue	Affected Area	CHF/Hotfix build	Description
26686	Application	6.2.0.7.0006	You can record comments for create/modify actions on Event Country, Sequence Status Date, and Task Status Dates. <ul style="list-style-type: none"> – Event Country Status Comments in Event Country Attributes > Add/Modify-Country Event Status. – Sequence-Status Comments in View Sequence > Add/Modify Status. – Task Status Comments in View Task > Add/Modify Status. Comments on status level are modified/deleted by Admin in the discussion thread field.
26581	Application	N/A	To capture EU Clinical Trial data in Ennov InSight based on the EU 536/2014 regulation, the new EU Clinical Trial Regulation type of application is introduced and includes the ability: <ul style="list-style-type: none"> – To select new fields for Application Country Notifications. – To associate Member States Concerned to sequence. – To associate/disassociate multiple CT shared data to event. – To withdraw a country from application.

Publishing

Issue	Affected Area	CHF/Hotfix build	Description
26747	Assembly	6.2.0.7.0006	Ennov InSight 7.1 now supports Taiwan eCTD Module 1 Version 1.1.
26700	Assembly	6.2.0.7.0006	US 3.3 assembly templates now support eCTD specification v.2.5 and include: <ul style="list-style-type: none"> – the updated xml generation to use <code>https</code> instead of <code>http</code> in dtd reference and stylesheet. – two additional folders with US Forms extension: <ul style="list-style-type: none"> • 1.1.10 Form FDA 3988: Transmittal of PMR/PMC Submissions for Drugs and Biologics • 1.1.11 Form FDA 3938: Drug Master File – fdaft10 and fdaft11 Application Form Type Values – REMS Supplement Filing Type with NDA, BLA and ANDA application types for Grouped Submissions.

Resolved Issues: Ennov InSight 7.1

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

Common

Issue	CHF/Hotfix Build	Description
26808; [INC0069223]	N/A	When a user is trying to assign a D2 document, an invalid reference error is displayed. This issue is resolved. You can assign a D2 document successfully without any error.
26790; [CS0401640, INC0058360]	6.2.0.6.0032	When a Veeva document with overlay was assigned to an assembly and the <i>Prepare to Publish</i> query was run with the Generate Missing Renditions and Extractions option selected, the extract document data request failed to process correctly. This issue is resolved. Now, the extraction request is sent only if document with overlay is updated since last data retrieval.

Issue	CHF/Hotfix Build	Description
26789; [INC0061160]	6.2.0.6.0032	<p>In some cases, in FPP for Package Set Registrations with Yes value for XEVMPD Submission Required? , after processing the XEVMPD Acknowledgement, the XEVMPD Submission Required? field did not change its value to No. This issue is resolved.</p> <p>After processing the XEVMPD Acknowledgement, the XEVMPD Submission Required? field shows as No in some cases. After the update of XEVMPD related fields in FPP, XEVMPD Submission Required? field value previously set up to No shows as Yes.</p>
26778; [INC0057113]	6.2.0.6.0032	<p>When creating a new Veeva document and assigning it to Assembly, Veeva Vault Connector failed to receive the latest document version. Veeva Vault received the latest version only when the DMS cache was refreshed every time. This issue is resolved.</p> <p>If Properties of the Veeva document were changed, DMS synchronization of this document, happened within cache timeout, resulted out of date properties. The issue is resolved</p> <p>The DMS cache refreshes automatically and Veeva Vault receives the latest version of the document.</p>
26774	N/A	<p>Some users experienced ORA-06512 error and users were unable to use the system. This issue is resolved.</p> <p>Database configuration is updated to prevent this issue in future.</p>

Publishing

Issue	CHF/Hotfix Build	Description
26784; [INC0061598]	6.2.0.6.0032	<p>When nodes were updated in a Working view through Mass Update Properties, the changes were not applied to the Sequence and Publishing views. This issue is resolved.</p> <p>After updating nodes in a Working view through Mass Update Properties, changes appear in the Sequence and Publishing views.</p>

Issue	CHF/Hotfix Build	Description
26705; [INC0046004]	6.2.0.7.0006	Performance issue related to the Synchronize with the Submitted View job resulted in a timeout. Changes have been made to the synchronization mechanism and now the job request passes with efficiency.
26692	6.2.0.7.0006	A mismatch between a Publishing Settings database sequence used by the code and the database sequence used in the corresponding database function caused the following error: <code>ORA-00001 : unique constraint (ODS.PKSLIP_SETTING) violated</code> . This issue is resolved. The database function is updated to use the same database sequence the code uses and ensuring that the sequence values are unique going forward.
26687; [INC0033088, INC0030024]	6.2.0.6.0009	The variables specified in the Default Values section of the <i>Publishing Settings Library</i> failed to resolve in the submission output if an assembly root was not selected during publishing. However, the variables set in places such as leaf properties resolved successfully. This issue is resolved. Now, the variables specified in the <i>Default Values</i> section of the <i>Publishing Settings Library</i> are resolved.

Rendering

Issue	CHF/Hotfix Build	Description
VCS-5014	5.0.1.1	The format of the Ennov InSight Rendering log files was changed to comply with Azure Log Analytics requirements. This change has no impact on end user experience or system functionality.
VCS-5013	5.0.1.1	SmartLinks in documents rendered by Documentum Content Transformation Services (CTS) were not present in the published output. This issue is resolved for Microsoft Office documents rendered by the CTS Doc6 plugin.

Ennov InSight RIM 7.1.1 Release Notes

Ennov InSight 7.1.1 Release Notes

This release is not a general release of Ennov InSight 7.1.1.

This release includes the following database scripts.

Component	Customizable	Build Number
Migration	No	DB_update7_1_0_0000_0114
Post-Migration	No	DB_update7_1_1_0000_0001

Note: The DB_update7_1_0_0000_0114 migration script resolves all the errors listed in the Ennov InSight 7.1.1 Resolved Issues topic. This migration script must be used when migrating. The Post-Migration script resolves only the 26961 defect listed in the Ennov InSight 7.1.1 Resolved Issues topic and must be used if you have already migrated to 7.1.

Ennov InSight 7.1.1 Resolved Issues

The following 7.1 migration issues have been reported and have been resolved.

Issue	Description
27305	ORA-54033 errors occurred when using the DB_update7_1_0_0000_0112 database migration script to migrate to 7.1 if some of the CREATION_DATE/BEG_DATE fields were defined to use the DATE data type instead of the TIMESTAMP data type. This issue is resolved when migrating to 7.1 using the DB_update7_1_0_0000_0114 database migration script included in this release.
27304	Having a product with a very large number of applications and full product presentations resulted in an ORA-01489 error when using the DB_update7_1_0_0000_0112 database migration script to migrate to 7.1. This issue is resolved when migrating to 7.1 using the DB_update7_1_0_0000_0114 database migration script included in this release.
26961	Substances in the PDS tree were not displayed when using the DB_update7_1_0_0000_0112 database migration script to migrate to 7.1. This issue is resolved when migrating to 7.1 using the DB_update7_1_0_0000_0114 database migration script included in this release. For customers that have already migrated successfully to 7.1, this issue can be resolved by using the DB_update7_1_1_0000_0001 post-migration script included in this release.

Ennov InSight 7.1 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.1 Release Notes (Cumulative).

Ennov InSight RIM 7.1.2 Release Notes

Ennov InSight 7.1.2 Release Notes

This document describes a sub-minor release provided to fix the defects found with Ennov InSight version 7.1.

The Quality Control team performed first product install and regression testing on this sub-minor release.

Ennov InSight 7.1.2 Resolved Issues

Ennov InSight 7.1.2 resolves the following issues.

Issue	Build	Description
DE27634; [INC0084824]	7.1.2.0.0013	When running the <i>Global Project Plan</i> wizard with the Create CTA/IND Applications and Events project type selected and clicking Next on <i>Select the protocol</i> , the <i>Enter Application properties</i> page timed out. The wizard could not load the Applications. This performance issue is resolved. The <i>Global Project Plan</i> wizard loads Applications successfully.
DE27552; [INC0084364]	7.1.2.0.0013	Publishing a Documentum document with a null keyword attribute value resulted in the publish job failing with the error <code>Unable to get DMS attribute 'keywords[]' for document XXX</code> . This issue is resolved.
DE27527; [INC0082927, INC0085354]	7.1.2.0.0013	When publishing STFs using an Output Folder setting along with Create Study Folders = No , the published output contained 2 STF Folders, one at the root containing the STF.xml and another in the correct location containing the associated PDF. This issue is resolved.
DE27515; [INC0082577]	7.1.2.0.0013	Performance issues were experienced in the following cases: <ul style="list-style-type: none"> — After the Withdrawal Workflow to retrieve Registrations after Application entered. — When Registration was created from the Registrations tab on the Application page. — During FPP loading. These issues are resolved. The performance of the queries is now improved.

Ennov InSight 7.1 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.1 Release Notes (Cumulative).

Ennov InSight RIM 7.1.3 Release Notes

Ennov InSight 7.1.3 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 7.1.3.

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

Regulatory Updates

Support for China (CN) eCTD Module 1 version 1.0.

API Updates

Ennov InSight 7.1.3 includes multiple API updates including updates for IDMP.

API support for Application Country EU CTR Applications. Any entity created or updated as a result of the EU CTR support is API enabled.

Changes between Ennov InSight 7.1 API and Ennov InSight 7.1.3 API are documented in the *Ennov InSight Administration*. See: *Ennov InSight Administration > Technical Administration > Ennov InSight API Documentation*.

IDMP

Additional IDMP data points for capturing alternate active ingredients for Pharmaceutical Products and Manufactured Items.

Power BI

Support for the SQL Direct Access model that includes the SQL reporting database with support for the Registration, Security Data and tables that support out of the box Power BI reports.

Entity Fields

Fields and Columns Added: Ennov InSight 7.1.3

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Entities

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

Table 137: Active Ingredients

Field/Option Name	Field Type	Description	Business Rules
Alternate IDMP Active Ingredient	Drop-down list, selection widget.	The <i>Pharmaceutical Product Active Ingredient Attributes</i> and <i>Manufactured Item Active Ingredient Attributes</i> pages now include the respective field. See: <i>Registrations > Active Ingredient Attributes</i> .	<ul style="list-style-type: none"> For Manufactured Item Active Ingredient: this field can be configured as a drop-down list with the values from the Component Reference Active Ingredients. For Pharmaceutical Product Active Ingredient: this field can be configured as a drop-down list with the values from the Component Reference Active Ingredients of Components associated with a Pharmaceutical Product. To search for a Component Active Ingredient, you need to assign Components to Pharmaceutical Product. <p>This field can also be configured as the substance selection widget with all the active values from Data Administration > Substance Values.</p> <hr/> <p><i>Note: For configuration assistance, please contact your Business Development Representative.</i></p> <hr/>

Database Columns Changed: Ennov InSight 7.1.3

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

Field Name	Field Size	Database Column Name	Db Column Size	Db Table Name
Alternate IDMP Active Ingredient	N/A	ALTERNATE_SUBSTANCE_ID	NUMBER	XPHARMA_PRODUCT_AI
	N/A	ALTERNATE_SUBSTANCE_ID	NUMBER	MI_AI

Resolved Issues: Ennov InSight 7.1.3

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

Publishing

Issue	Build	Hotfix Build	Description
DE27672 [INC0085185]	7.1.3.0.0006	N/A	When searching for a document based on EDMS Number in <i>DMS Browse</i> window to assign it to the assembly, it was not displayed and no custom attributes were populated. This issue is resolved. The document with the custom attributes is displayed.
DE27588; [INC0084413]	7.1.3.0.0006	N/A	When an assembly contained docrefs that were in a repository that was not specified in <i>Technical Administration</i> , the import of an assembly failed. This issue is resolved. The assembly imports with the documents unassigned.
DE26892	7.1.3.0.0006	N/A	China: After importing an eCTD folder, the 2.3.1 section was missing in the structure of the imported assembly. This was caused by incorrect published output. This issue is resolved. Now, the structure of the imported assembly will be the same as the source. The CN eCTD ICH Module2-5 v3.2.xml file template is updated for China region with this fix.
26825	7.1.3.0.0006	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 index-r-022.xml file after publishing and in the leaf after an eCTD import.

Registrations

Issue	Build	Hotfix Build	Description
26768; [INC0058320]	7.1.3.0.0006	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

Ennov InSight 7.1 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.1 Release Notes (Cumulative).

Ennov InSight RIM 7.1.4 Release Notes

Ennov InSight 7.1.4 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 7.1.4.

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

This release resolves issues with the Documentum connector and also includes fixes for RIM Assembly Management, Publishing, and API defects.

Resolved Issues: Ennov InSight 7.1.4

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

Common

Issue	Build	Description
DE27869; [INC0088814]	7.1.4.0.0007	In Ennov InSight 7.1, the CT Shared Data could not be associated to the Event of the custom CTA or IND Application Type using the API request and the existing Event with CT Shared Data could not be updated. These issues are resolved. Now, using the API request the CT Shared Data can be associated to the Event of the custom CTA or IND Application Type and the existing Event with CT Shared Data can be updated.
DE27841; [INC0090420]	7.1.4.0.0007	In Ennov InSight 7.1, the Event with the associated CT Shared Data could not be closed using API request. This issue is resolved. Now, using the API request, the Events with either CTA or IND Application types can be closed if they have CT Shared Data.

Publishing

Issue	Build	Description
DE28062; [INC0095410]	7.1.4.0.0007	A "Class cast exception" error appeared while searching for Documentum documents when custom document types were used. This issue is resolved. Now, you can search successfully for a document when using custom document types in DCTM.

Issue	Build	Description
DE28013; [INC0094233]	7.1.4.0.0007	PDF files in Documentum could not be viewed from within the assembly. This issue is resolved. Now, PDF files can be opened.
DE27966	7.1.4.0.0007	The published output files were not exported to Documentum repository if they have Chinese characters in the file name. This issue is resolved. Now, the appropriate files are successfully exported.
DE27791; [INC0089235]	7.1.4.0.0007	Attempting to assign a document with double digits version number from DCTM resulted in a HTTP Status 404 error. This issue is resolved. Now, these documents can be assigned to an assembly without any error.
DE27676; [INC0085509]	7.1.4.0.0007	When using a custom StudyReportResources.properties file, executing the Study Report Wizard to add section 5.3.5.1 resulted in no folders and leafs added to the assembly. This issue is resolved. Now, the assembly contains all the folders and leafs specified by the user.
DE27528; [INC0082955]	7.1.4.0.0007	In Ennov InSight 7.1, assigning a document to a leaf which was created before took more time than just dragging and dropping it to a folder. This issue is resolved. The performance is improved when the document is assigned to an existing leaf.
DE27372	7.1.4.0.0007	DCTM Connector failed to make a successful connection using the HTTPS protocol. This resulted in a Publishing Job failure due to session timeout. The following error was displayed in the DCTM Connector log file "Please input whether authenticate the rest server: [default false]". This issue is resolved. Now, Publish job is completed successfully.

Ennov InSight 7.1 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.1 Release Notes (Cumulative).

Ennov InSight RIM 7.1.5 Release Notes

Ennov InSight 7.1.5 Release Notes

The Release Notes contain information about updated files, new functionality, resolved issues, and any open issues or workarounds in this release of Ennov InSight 7.1.5.

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

Rendering

Rendering service is updated to address corrupted content problem while publishing to some PostScript printers.

Ennov InSight 7.1.5 Resolved Issues

Ennov InSight 7.1.5 resolves the following issues.

Common

Issue	Build Number	Description
DE28251; [INC0091561, TASK0042646]	7.1.5.0.0004	Performance issue was experienced when using the Search option on home page for assemblies, sequences and events. This issue is resolved. Search performance issue is now addressed in this release.
DE28120; [INC0094972, INC0092038]	7.1.5.0.0004	The Ennov InSight 7.1.0 migration did not work correctly for product family broad indications. The indication category type ids were not set to Indication . This issue is resolved. Now, the product family broad indications are migrated correctly.
DE27919	7.1.5.0.0004	Reference Active Ingredient under Pharmaceutical Product Active Ingredient was not created when using the API request. This issue is resolved. Reference Active Ingredient is created using API.
DE27750; [INC0086495, INC0084243]	7.1.5.0.0004	The migration did not work correctly for the OMS organization values. The organization data replicated from SPOR duplicating the Location Id . This issue is resolved. Now, the data does not have duplicates.

Issue	Build Number	Description
DE27480; [INC0082793, INC0087569,CS0532 792]	7.1.5.0.0004	<p>API query operation failed for the following assembly tree elements.</p> <ul style="list-style-type: none"> – Leaf POST /insight/api/v2/leaf/query – Folder POST /insight/api/v2/folder/query – Document POST /insight/api/v2/document/query <p>This issue is resolved. Now, the API query returns the status "SUCCESS" with the requested data.</p>

Publishing

Issue	Build Number	Description
DE28266; [INC0104113]	7.1.5.0.0004	<p>After the export/import of the assembly file, the DMS Synchronisation was binding the wrong document for a Veeva document when there were two documents in the same folder with the same name. This issue is resolved. Now, the DMS Synchronisation is binding the correct document.</p>
DE28208; [INC0106878, TASK0042719]	7.1.5.0.0004	<p>Incremental publishing removed the <i>checksum</i> values for the files that were not published. This issue is resolved. Now, these values are displayed.</p>
DE28204; [INC0095423, INC0108172]	7.1.5.0.0004	<p>The Study Report wizard did not work properly when updating the sub-folders structure for the selected indication. This issue is resolved. Now, the selected indications are updated successfully.</p>
DE28171	7.1.5.0.0004	<p>When the document was assigned from DCTM to a leaf or folder, the time to assign took longer than expected. It happened only for the first time when the document was assigned after the login. This issue is resolved. The performance is improved. Now, the document assignment takes less time.</p>
DE28146; [INC0101586]	7.1.5.0.0004	<p>When an assembly was imported from an XML file, the TOC did not include the Range Start attribute specified before. This issue is resolved. Now, the Range Start attribute is included in the TOC of the imported assembly.</p>

Issue	Build Number	Description
DE27958	7.1.5.0.0004	After publishing a China assembly, Chinese characters were present in the STF file name. For example, stf-4.2.1.1 主要□效学.xml. This issue is resolved. Now, China characters are automatically renamed as per eCTD normalization rules before exporting output.
DE27915; [INC0092041]	7.1.5.0.0004	Editing a document assigned from DCTM and selecting the previous document version in Bind to Version failed to indicate the presence of a new version in document attributes and assembly tree. This issue is resolved. Now, the new version is indicated in both document attributes and in the assembly tree.
DE27835; [INC0087631]	7.1.5.0.0004	If the element was locked, the color of the locked element did not change when selected. This issue is resolved. The assembly elements such as folder, leaf, and document now appear in the TOC in a different color when selected. This issue is fixed in Submitted, Working, Sequence, and Publishing views.
DE26687; [CS0205991]	7.1.5.0.0004	The PDF Exists value did not change to Yes on the <i>Document Attributes</i> page for the PDF documents assigned from Veeva after the Rendition Identifier was changed to Viewable Rendition . This issue is resolved. Now, the PDF Exists value is displayed as Yes .
DE26679; [CS0191635]	7.1.5.0.0004	When the Apply Binding to all Children option was used to change the rendition identifier, no extraction job was launched for the document and the status PDF exists was not updated to Yes . This issue is resolved. Now, the extraction job is launched for the document and the status PDF exists is updated to Yes .

Registrations

Issue	Build Number	Description
DE28295; [INC0102780]	7.1.5.0.0004	It was not possible to update product family attributes if many values were present in multiple selection list. This issue is resolved. Now, product family attributes are successfully modified.

Rendering

Issue	Build Number	Description
DE27949; [INC0087977]	5.0.3.1.	Paper publishing to the Postscript (PS) file format resulted in the generation of distorted content that was unreadable. This issue is resolved. Now, the paper publishing has the correct file output with comprehensible content.

Ennov InSight 7.1 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.1 Release Notes (Cumulative).

Ennov InSight RIM 7.1.6 Release Notes

Ennov InSight 7.1.6 Release Notes

The Release Notes contain information about updated files, new functionality, resolved issues, and any open issues or workarounds in this release of Ennov InSight 7.1.6.

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

This release resolves issues with missing database indexes.

Note: Ennov InSight 7.1.6 is a database-only release and includes the DB_update7_1_6_0000_0001.zip file only.

Ennov InSight 7.1.6 Resolved Issues

Ennov InSight 7.1.6 resolves the following issue.

Publishing

Issue	Build Number	Description
DE28488; [INC010811 2]	7.1.5.0.0004 + DB_update7_1_6_0000_0001	Multiple users creating/updating different entities simultaneously resulted in Ennov InSight being unusable for a period of time. This issue is resolved.

Ennov InSight 7.1 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.1 Release Notes (Cumulative).

Ennov InSight RIM 7.1.7 Release Notes

Ennov InSight 7.1.7 Release Notes

The Release Notes contain information about updated files, new functionality, resolved issues, and any open issues or workarounds in this release of Ennov InSight 7.1.7.

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

This release resolves issues with checksum values and parallel submissions synchronization.

Ennov InSight 7.1.7 Resolved Issues

Ennov InSight 7.1.7 resolves the following issues.

Publishing

Issue	Description
DE28535; [INC0122230]	Checksums were missing in the XML files in the following cases: <ul style="list-style-type: none"> – JP regional XML: Checksums were missing after the first publish. A subsequent publish displayed the checksum values of the previous publish, not the current one. – EU regional XML: Checksums were missing for leafs with a relative output path (For example., ../../ctd-toc.pdf). – Reference leafs: Checksum value was that of the target document when it was chosen as the reference leaf target and did not get updated with subsequent publishes. These issues are resolved.
DE28514, DE26746, DE26596; [INC0120502, CS0266424, INC0014091]	In two parallel submissions, when a leaf was replaced along with the document under it, performing the synchronization process resulted in both the old and current documents displaying under the replaced leaf in the working view. This issue is resolved. Now, only the current document remains after synchronization.

Ennov InSight 7.1 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.1 Release Notes (Cumulative).

Ennov InSight RIM 7.1.8 Release Notes

Ennov InSight 7.1.8 Release Notes

The Release Notes contain information about updated files, resolved issues, and any open issues or workarounds in this release of Ennov InSight 7.1.8.

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

Ennov InSight 7.1.8 Resolved Issues

Ennov InSight 7.1.8 resolves the following issues.

Publishing

Issue	Description
DE28921 [INC0139947, TASK0045320, INC0136904, TASK0045184]	After replacing a PDF file in the output location and the recalculating checksum, the wrong checksum was displayed in the XML. This issue is resolved. Now, the correct checksum is displayed in the XML after recalculating the checksum.
DE28912 [INC0139930, TASK0045319]	In two parallel submissions, a replaced leaf was not copied to a working assembly after synchronizing with the submitted view. This resulted in incorrect assembly structure. This issue is resolved. Now, the submitted view synchronization process works correctly and the assembly shows the correct structure.
DE28846 [INC0127050,TASK 0044604]	When publishing STF, the output STF XML file name was being normalized differently than the reference to the STF XML file name in the index.xml file. As a result, the link in the index.xml file to the output STF XML file was broken. Additionally, the normalization method used to create the STF XML file name was determined by the XML definition files assigned to the assembly in Publishing Settings and not the Assembly Type value that is used to determine how to normalize non-STF file names. This sub-minor release now uses the Assembly Type value to determine which normalization method to use for all output file names (including the STF XML file name) as it was in Ennov InSight 6.2. See Assembly Template Attribute .
DE28730	If assembly contains both target and reference leaves, output location was not populated for a reference leaf if the target leaf was replaced. This issue is resolved. Now, the output location path contains the correct value.

Ennov InSight 7.1 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.1 Release Notes (Cumulative).

Ennov InSight RIM 7.1.9 Release Notes

Ennov InSight 7.1.9 Release Notes

The Release Notes contain information about updated files, resolved issues, and any open issues or workarounds in this release of Ennov InSight 7.1.9.

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

Regulatory Updates

EAEU v1.0:

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

Entity Fields Updated: Ennov InSight 7.1.9

Entities fields updated in Ennov InSight 7.1.9.

The following entity field is updated in Ennov InSight 7.1.9.

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

Ennov InSight 7.1.9 Resolved Issues

Ennov InSight 7.1.9 resolves the following issues.

Publishing

Issue	Description
DE29280 [INC0145064]	<p>Adding the "/" (forward slash) character in assembly metadata resulted in the following issues after publishing.</p> <ul style="list-style-type: none"> - Empty attributes in published output XML for 2.3.P Leaf. - Missing galenic-name XML elements in the ch-regional.xml file. <p>Both issues are now resolved. Now, assembly metadata is published correctly even with the "/" (forward slash) character added.</p>
DE29254	<p>In an assembly with empty leafs, running the Recalculate checksum operation failed. This issue is resolved. Now, the Recalculate checksum operation completes.</p>
DE29174 [INC0143854]	<p>When importing an assembly with assigned source document from assembly file, the source location path in the Document Attributes window was not populated. This issue is resolved. Now, the source location displays the location path to the assigned source document.</p>
DE28851 [INC0123232]	<p>Group Submissions: In an Assembly Plan with multiple applications, when two folders containing leafs and a form were added for each application, the xml file displayed leaf elements under one application entry after publishing. This issue is resolved. Now, the xml file displays leaf elements under each application entry.</p>

Ennov InSight 7.1 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.1 Release Notes (Cumulative).

Ennov InSight RIM 7.1.10 Release Notes

Ennov InSight 7.1.10 Release Notes

The Release Notes contain information about updated files, resolved issues, and any open issues or workarounds in this release of Ennov InSight 7.1.10.

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

Ennov InSight 7.1.10 Resolved Issue

Ennov InSight 7.1.10 resolves the following issues.

Publishing

Issue	Description
DE29565 [INC0184222]	When a Japanese submission that included comma-separated values in the assembly was published, the fields Brand Name , Submission Type , Applicant , and Generic Name included in the xml output were incorrect. This issue is resolved. Now, all the fields mentioned above are included in the xml file correctly.
DE29710 [INC0200183]	After publishing an assembly, the generated stf.xml files included incorrect links. This issue is resolved.

Ennov InSight 7.1 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.1 Release Notes (Cumulative).

Ennov InSight RIM 7.1.11 Release Notes

Ennov InSight 7.1.11 Release Notes

The Release Notes contain information about updated files, resolved issues, and any open issues or workarounds in this release of Ennov InSight 7.1.11.

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

Ennov InSight 7.1.11 Resolved Issues

Ennov InSight 7.1.11 resolves the following issues.

Publishing

Issue	Description
DE29656 [INC0184736]	Details of failed jobs were not displayed in the Job Requests query leading to extra effort in troubleshooting. This issue is resolved. Now, detailed information about failed jobs, along with the cause of the failure and document name where applicable, is displayed in the Job Requests .
DE29613 [INC0184045]	After publishing, xml output included incorrect Applicant ID phone number type. This issue is resolved.
DE29387 [INC0163084, INC0206337]	After reusing and publishing US study reports content in EU dossier, tags in the <code>index.xml</code> output location were generated in the incorrect order. This issue is resolved. Now, tags in the <code>index.xml</code> are generated correctly.
DE29359 [INC0160614]	After launching Job Requests operation, Job Status data did not correspond to the Job Requests Details , displaying incorrect or outdated information. This issue is resolved. Now, the statuses correspond to the Job Requests Details data, displaying a short summary of errors/warnings detected.
DE29276 [INC0124015]	Trying to modify the manufacturer with multiline value in the Address attribute resulted in an error. This issue is resolved.
DE28913 [INC0136665]	After updating Oracle from 19.16.0.0.220719 to 19.17.0.0.221018 version, a column ambiguity error occurred when using the <i>XEVMPD Submission</i> wizard. This issue is resolved. Now, you can use the <i>XEVMPD Submission</i> wizard without errors.

Issue	Description
DE28390 [CS0562479; INC0091145]	Using the Enter key to separate values in the Concerned Parties field resulted in an extra tag generation that could be deleted only manually. This issue is resolved.
DE27365 [INC0186417/ TASK0047873]	When the Export to Excel option was used for Job Message Details , the file was saved in an unknown format instead of .XLSX and with the XLSX name. This issue is resolved.

Ennov InSight 7.1 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.1 Release Notes (Cumulative).

Ennov InSight RIM 7.1.12 Release Notes

Ennov InSight 7.1.12 Release Notes

The Release Notes contain information about updated files, resolved issues, and any open issues or workarounds in this release of Ennov InSight 7.1.12.

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

Ennov InSight 7.1.12 Resolved Issues

Ennov InSight 7.1.12 resolves the following issues.

Publishing

Issue	Description
DE29823; [INC0208226, PRB0045201]	<p>After performing the Recalculate Checksums operation, existing values in the following fields were not retained in the <i>Publish Request</i> window:</p> <ul style="list-style-type: none"> – Prepare to Publish – Single File Output Filename – Publish eCTD/Electronic – Include Leafs with Status <p>This issue is resolved. Now, the user selection is persisted from the previous Publish Request action.</p>

Registrations

Issue	Description
DE30539; [TASK0050412, INC0236916]	<p>When an event without a product associated with application containing registrations was updated, the Registered ATC values were missing in all the associated registrations. This issue is resolved. Now, all the Registered ATC values are successfully displayed.</p>
DE30471; [INC0228355, INC0236916]	<p>After a package set was dissociated from a registration, incorrect username was displayed for the operation on the Entity History Query > Registered ATC > Search Results field. This issue is resolved. Now, after a package set is dissociated, correct username is displayed.</p>

Ennov InSight 7.1 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.1 Release Notes (Cumulative).

Ennov InSight 7.1.13 Release Notes

The Release Notes contain information about updated files, resolved issues, and any open issues or workarounds in this release of Ennov InSight 7.1.13.

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

Ennov InSight 7.1.13 Resolved Issues

Ennov InSight 7.1.13 resolves the following issues.

Publishing

Issue	Description
DE31334, [TASK0444686]	When Recalculate Checksum was performed on an assembly with 1000+ leaves, the Job Requests > Job Message query displayed the <code>Error: could not execute query</code> message. This issue is resolved. Now, the Recalculate Checksum operation completes correctly and the Job Message displays relevant information.
DE31296, [TASK0373863]	When working with large assemblies, performing the Recalculate Checksum operation even on a single element timed out and failed. This issue is resolved. Now, the performance is improved, and the Recalculate Checksum operation is performed only on the files selected by the user.

Ennov InSight 7.1 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.1 Release Notes (Cumulative).

Ennov InSight RIM 7.1.14 Release Notes

Ennov InSight 7.1.14 Release Notes

The Release Notes contain information about updated files, resolved issues, and any open issues or workarounds in this release of Ennov InSight 7.1.14.

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 7.1 > Ennov InSight 7.1 Data Migration Details > Data Administration Updates for Ennov InSight 7.1.14*
- *Ennov InSight Publisher 7.1 > Submissions > Create eCTD Wizard > eCTD Attributes South Africa*
- *Ennov InSight Publisher 7.1 > Extension Type and Usage > Extension Type: Regional Folders > South Africa*
- *Ennov InSight Administration 7.1 > Administrative Activity > Import eCTD Applications > Prepare for Bulk eCTD Import > ZA 3.1 Applications*
- *Ennov InSight Administration 7.1 > eCTD Codes > eCTD Filing Types for ZA*
- *Ennov InSight Administration 7.1 > eCTD Filing Types for ZA > eCTD Sub-Filing Types for ZA*
- *Ennov InSight Administration 7.1 > Assembly XML Specification > m1-za v. 3.1*

Ennov InSight 7.1 COB and Known Issues

For Clarification of Behavior (COB) and Known Issues, see: [COB](#) and [Known Issues](#) topics under Ennov InSight 7.1 Release Notes (Cumulative).

Data Administration Tables

Data Administration Tables Added: Ennov InSight 7.1.14

The following Data Administration tables and/or sections were added for Ennov InSight 7.1.14.

Data Administration Table: Submission Maintenance

Table 138: 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.

Clarification of Behavior: Ennov InSight 7.1

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

Ennov InSight: Common

Issue	Affected Area	Description
N/A	N/A	<p>After migrating to Ennov InSight 7.1, 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 7.1, Public or Private queries saved in the Ennov InSight 6.2 query list will not be available in the Ennov InSight 7.1 query list for the migrated and newly added users.</p>
N/A	Assembly	<p>Performing any actions from Ennov InSight 6.2 CHF 1 against a Veeva repository on limited release version 18R2.2 will result in an exception caused by an unexpected error response from Veeva Vault. If you experience this issue, please contact Veeva Support.</p>
N/A	N/A	<p>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.</p>

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

Ennov InSight Publisher

Issue	Affected Area	Description
DE32135	Assembly	After creating an EU 3.0.3 working assembly using Create eCTD wizard, when the eu-3-0-1 XML Definition is replaced with eu-3-1, the Submission Unit Type field cleared on the envelope\s attributes.
DE31682	Assembly	<p>When publishing, a file name or a server name or, a file path should not exceed the Windows file system limit, which is 260 characters.</p> <hr/> <p><i>Note: It is highly recommended to take into account the limit length of the file name from DMS. Otherwise, there may be issues because of the long file names. See Special Characters.</i></p> <hr/>
DE30044	Assembly	Using a forward slash ("/") in the Report Number on the Folder Attributes page results in invalid published output in accordance to validation criteria 1884 and 1204.
DE27968	Assembly	When the length of the output path exceeds the limit allowed by the operating system, publishing fails. This issue can be resolved by shortening the folder or leaf output names in assembly.
26732	Publishing Settings library	In Internet Explorer only, the Link Inspector report page is not refreshed when Edit Link Output Channel is performed. The change is reflected after clicking the Refresh button in the report. The Link Inspector report page refreshes as expected in Microsoft Edge or Google Chrome.

Known Issues

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

Ennov InSight: Common

Issue	Affected Area	Description
DE31854 (Added on the 25th of July, 2024)	Queries	<p>When using <i>Application History Query</i> or <i>Application QC Status History Report</i> to track changes for a pharmaceutical product family, the following columns display blank spaces if selected:</p> <ul style="list-style-type: none"> — Label Details Changed? (for <i>Application History Query</i>) — Label Details QC Passed? (for <i>Application QC Status History Report</i>) <p>Expected: Both columns display relevant information.</p>
DE27749 (Added on 19th of April 2022)	Application, Country	<p>For individual users, when the <i>Application Country Rights for Product Families</i> 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 for Product Families and Countries</i> to All.</p>
DE27309 (Added on 12th Jan 2022)	Update Product Details Sets, PDS, Substance	<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>
DE27259 (Added on 3rd Jan 2022)	Update Status wizard, PDS	<p>In the <i>Update Status</i> wizard, you cannot associate a Package Set with Pending Add status. The Package Set Status column is missing in the Select Package Sets grid.</p>

Issue	Affected Area	Description
DE26959 (Added on 23rd Dec 2021)	Global Project Plan wizard, PDS	Under Projects > Wizard > Global Project Plan > Modify Active Ingredient , you can select and modify the strength fields for Active Ingredient. After wizard completion, no changes apply in PDS.
26814	Publishing	Using Prepare for Publishing with the Prepare Cross Reference Leafs option selected results in the <code>Unable to extract checksum</code> error if there is a reference leaf to leaf published to Documentum.
26807 (Added on 20th Aug 2021)	Assembly	When updating a leaf in an assembly, selecting OnLoad for the Actuate option results in an error message. This is because of the default security settings. Workaround: Update the leaf using API.
26799	eCTD Import	After you use the Bulk eCTD Import for TW submission, the Job Status is set to Scheduled instead of Completed . This is because the <code>tw-regional.xml</code> file does not contain the application code. Workaround: Use Import eCTD to Application instead of Bulk eCTD Import . See: <i>Import eCTD to Application</i> .
26728	Global Project Plan wizard, PDS	In the <i>Global Project Plan</i> wizard, when modifying an active ingredient for a PDS the Withdraw Material that is already selected is not shown in the drop-down list.
26699	Assembly	Ennov InSight can incorrectly send a Native .PDF file to Ennov InSight Rendering for extraction. Also, while a large file can fail extraction, it might not prevent successful publishing.
26642	Assembly	Assembly files created by exporting an assembly to the Assembly File (XML) on versions of Ennov InSight starting with 6.2 CHF 4 cannot be imported to Ennov InSight versions 6.2 CHF 3 and earlier.

Issue	Affected Area	Description
26637	Administration	In Data Administration, the Check for Date-based Notifications menu is not available on the Notification Specifications grid.

Ennov InSight Publisher

Issue	Affected Area	Description
DE32034 (Added on 17th of September, 2024)	Assembly	Publishing a ZA v3.1 assembly with study reports by default has outdated version of valid values. To use the correct version, replace STF-2-2 with STF-2-2-5-0 in Publishing Settings Library for the assembly you want to publish.
DE3155 (Added on the 2nd of May, 2024)	Publishing	Using the Recalculate Checksums option on a published eCTD assembly that contains a period in the Application Code value generates extra files in the output location instead of updating the existing ones.
DE30849 (Added on 12th October 2023)	Assembly	When searching for a document to assign when the DMS Manager or Technical Administration services are not available, the DMS Search Results window does not show any appropriate error message.
DE30844 (Added on 12th October 2023)	Assembly	Performing DMS synchronization for a deleted document in working, publishing, or sequence assembly on the Document Attributes page shows the value UNASSIGNED for Assignment Status . Expected: the MISSING value for Assignment Status .
DE30733	Assembly	When the dctm session expiry process is in progress and at the same time the DMS Synchronization is initiated, the error 'UNAUTHORIZED Token has expired.' is displayed randomly.

Issue	Affected Area	Description
DE29387; [INC0163084, PRB0044404, INC0206337] (Added on 23rd Feb 2023)	Assembly	When trying to reuse and publish US M4 or M5 in an EU dossier, the <code>index.xml</code> shows the output elements in incorrect order.
DE29594	eCTD Publishing	When a sequence with sequence code starting with upper case P is created and the assembly is published, running Recalculating Checksum generates extra files in the output location. Workaround: enter sequence code in 4-digit format. Example: 0001.
DE29256	Electronic Publishing	When the Append Application and Sequence Number options are not selected in the Publish Request, publishing using electronic Output Channel results in adding unnecessary Sequence Code in link to <code>index.xml</code> from <code>stf-.xml</code> .
DE29255	Electronic Publishing	An extra folder is created after publishing if the: <ul style="list-style-type: none"> — Assembly Type attribute is set to Standard and the Output folder field contains a period — Assembly Type attribute is set to eCTD eCTD\US eCTD\CN eCTD and the Output folder field contain two or more periods.
DE29254	eCTD Publishing	After creating a sequence with sequence code starting from P0000 and publishing assembly, running Recalculating Checksums creates a new XML in a separate location if the published document in a publishing assembly was previously changed. The issue is reproduced only for the assembly sequence containing the P0000 sequence code.
DE29253	eCTD Publishing	If more than one period is included in the Output Folder value, selecting the Standard Assembly Type attribute fails publishing.

Issue	Affected Area	Description
DE29252	eCTD Templates	Adding forward slash in the Report Number field results in invalid path from <code>stf-.xml</code> to <code>index.xml</code> .
DE29239	eCTD Publishing	The output location path is not updated for reference leafs that are targeted to leafs in another assembly neither after publish, nor prepare to publish with Prepare Cross-Reference Leafs selected.
DE26968 (Added on 23 December 2021)	Assembly	The assembly files cannot be published to Documentum if their size is 800 mb and more. The distribute job request fails. Workaround: Ensure that the size of the assembly files is less than 800 mb.
25259; [00052856]	Create eCTD wizard	When modifying Applicant Contact Values for M1 in a US 3-3 assembly, if you Deselect a value it does not re-appear in the selection box. As a workaround, you must save an entry with other contact values and then edit M1 again and select the Applicant Contact Value .
25084; [00051037, 00052759, 00056925, 00058862]	Assembly	Deleting large applications or removing multiple sequences from a lifecycle can take much longer than expected to produce results.
20270; [136797FW]	Assembly	Links for External Bookmarks are incorrect for split documents in paper published output.

Ennov InSight Registrations

Issue	Affected Area	Description
DE32198 (Added on 28th October 2024)	Application	For a WHO country application, the UUID is absent on the Application Attributes page.

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

Ennov InSight Outlook add-in

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

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

Ennov InSight Rendering

Issue	Affected Area	Description
DE28324; [TASK0043134 INC0109855] (Added on 12 Aug 2022)	Assembly	Publishing to some printers may result in tab text misplacement.
DE26794	Assembly	When eCTD assembly is published, the validation messages from the backbone generator are not displayed in Job Requests Details.

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