



Ennov InSight 7.3.1 Release Notes

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Ennov InSight 7.3.1 Release Notes

Ennov InSight 7.3.1 Release Notes

The Release Notes contain information about updated files, new functionality, resolved issues, and any open issues or workarounds in this release of Ennov InSight 7.3.1.

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

In-Process Linking Updates

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

- Publishing Settings Library
- Document Attributes

See: *Entity Fields, Columns and Options Removed: Ennov InSight 7.3.1.*

Linking plug-in (PDF)/Linking add-in (Word) Issue Resolved

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

XEVMPD Updates

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

- Entities:
 - Registration Attachment
- Wizards:
 - XEVMPD Submission wizard

XEVMPD Submission Updates

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

Entity and Tab Changes

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

- Entities:
 - Create Pending Changes

— Tabs:

- Pending Changes

Privacy Policy

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

Regulatory Updates

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

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

- *Ennov InSight 7.3 Publisher > Submissions > Create eCTD Wizard > eCTD Attributes South Africa*
- *Ennov InSight 7.3 Publisher > Extension Type and Usage > Extension Type: Regional Folders > South Africa*
- *Ennov InSight 7.3 Publisher > Administrative Activity > Import eCTD Applications > Prepare for Bulk eCTD Import > ZA 3.0 Applications*
- *Ennov InSight 7.3 Administration > eCTD Codes > eCTD Filing Types for ZA*
- *Ennov InSight 7.3 Administration > eCTD Filing Types for ZA > eCTD Sub-Filing Types for ZA*
- *Ennov InSight 7.3 Administration > Assembly XML Specification > m1-za v. 3.0*

TOC Templates Updates

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

- CNSampleTOCTemplate.docx
- JPSampleTOCTemplate.docx

Oracle Updates

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

New in Ennov InSight 7.3.1: Registrations

New features and enhancements for Registration functionality is listed below.

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

Affected Area	Update	Benefit
Create Pending Changes	The <i>Create Pending Changes</i> wizard is updated with new <i>Full Product Presentation</i> flow. See <i>Entity Fields, Columns and Options Added: Ennov InSight 7.3.1, Registrations > Pending Changes and Entity Attributes</i> .	The ability to enter pending changes values for <i>Full Product Presentation</i> on the Pending Changes tab.
Create Pending Changes	The Create Pending Changes wizard is updated with new fields for <i>Registration</i> flow. See <i>Entity Fields, Columns and Options Added: Ennov InSight 7.3.1</i> .	The ability to enter more values for <i>Registration</i> flow on the Pending Changes tab.
Create Pending Changes	The <i>Change Scope > Registration Package Set</i> flow is updated. See <i>Entity Fields, Columns and Options Removed: Ennov InSight 7.3.1</i> .	The ability to create pending changes quicker as there is no need now to populate extra field.
Create Pending Changes	The <i>Change Scope > Registration Package Set Country</i> flow is updated. See <i>Entity Fields, Columns and Options Removed: Ennov InSight 7.3.1</i> .	The ability to create pending changes quicker as there is no need now to populate extra fields.
Registration Attachment	The <i>Registration Attachment</i> page is updated with new field. See <i>Entity Fields, Columns and Options Added: Ennov InSight 7.3.1 and Registrations > Registration Attachment > Registration Attachment Attributes</i> .	The ability to create XEVMPD submissions in accordance with the latest European Medicine Agency (EMA) requirements.
Full Product Presentation	The <i>Full Product Presentation > Registrations FPP Attachments > Attached Name</i> is updated with new field. See <i>Entity Fields, Columns and Options Added: Ennov InSight 7.3.1 and Registrations > Registration Attachment > Registration Attachment Attributes</i> .	The ability to create XEVMPD submissions in accordance with the latest European Medicine Agency (EMA) requirements.
XEVMPD Submission wizard	The generated XEVMPD file is updated with new value. Also, access rules for the XEVMPD Submission wizard are changed. See <i>Entity Fields, Columns and Options Added: Ennov InSight 7.3.1 and XEVMPD > Authorised Product Attachments</i>	The ability to create XEVMPD submissions in accordance with the latest European Medicine Agency (EMA) requirements. The ability to use the <i>XEVMPD Submission</i> wizard for users without access rights configured in the <i>Security Administration</i> .

Resolved Issues: Ennov InSight 7.3.1

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

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

Common

Issue	Sub-Minor Build	Description
DE31646, [INC0315574]	N/A	Trying to create or update the Change External Number value using the API <code>/change/create-or-update</code> endpoint resulted in the following error message: <code>Change External Number must be unique in the system.</code> This issue is resolved. Now, External Change Number is successfully created/updated via the API <code>/change/create-or-update</code> endpoint.
DE31589	N/A	Vevea Single sign-on (SSO) authorization from DMS Browse failed to work and it was not possible to use the Vevea Vault content. This issue is resolved. Now, the Vevea Single sign-on (SSO) works correctly.
DE31469, [INC0303021]	N/A	When using the <i>Global Project Plan</i> wizard, if multiple products were associated with a product family, it took longer time than expected to download applications on the <i>Select Application</i> page. This issue is resolved. Now, it takes less time to download the applications.
DE31436	N/A	The Pending Changes tab was displayed on the <i>Events Attributes</i> page even when Product Registration was selected for the Registration Type field. This issue is resolved. Now, the Pending Changes tab is not displayed when Product Registration is selected.
DE31074, [TASK0053554]	N/A	Trying to update a specific submission with applied overrides took longer time than expected. This issue is resolved. Now, the performance is improved.
DE31030, [INC0276375]	N/A	After a sequence was created for the EU CTR application and associated with workflow, trying to navigate to the Activity page or the Workflow page resulted in the <code>Invalid reference</code> error message. This issue is resolved. Now, both pages are displayed correctly.

Issue	Sub-Minor Build	Description
DE31029, [INC0273676]	N/A	<p>If an indication associated with product family was deactivated, trying to add it to an orphan designation using the following endpoints resulted in an error:</p> <ul style="list-style-type: none"> – API /orphan-designation/update – API /orphan-designation/create – API /orphan-designation/create-or-update <p>This issue is resolved. Now, a deactivated indication associated with a product family is successfully added to an orphan designation via API.</p>
DE31016, [TASK0051801,INC0273635]	N/A	<p>It was possible to create an orphan designation using the API /orphan-designation/create endpoint even if an application did not fulfill the following criteria:</p> <ul style="list-style-type: none"> – Marketing Authorisation Application (MAA) application type is selected. – EMA country is selected. – Orphan Drug flag is set to Yes. <p>This issue is resolved. Now, it is not possible to create an orphan designation for an application that does not match the mentioned criteria using API.</p>
DE31013, [INC0276375]	N/A	<p>In 7.2.5, 7.2.7, 7.2.8 and 7.3 versions of Ennov InSight , an option used for internal testing was exposed. The Terminology System List option was displayed under Data Administration > SPOR Master Lists. This issue is resolved with the removal of the Terminology System List option.</p>
DE30866, [TASK0050835]	N/A	<p>If the Veeva session was expired when using the Veeva Single sign-on (SSO) profile with a name that matched the Ennov InSight profile name, re-authorization was required to download a file assigned from Veeva DMS using the File View option. This issue is resolved. Now, if the Veeva session is expired when using the Veeva SSO profile with a name that matches the Ennov InSight profile name, Veeva re-authorization is not required to download the file using File Menu.</p>

Issue	Sub-Minor Build	Description
DE29199	N/A	When there were 1000+ product families, trying to associate a product to an application ended in the <code>Invalid reference</code> error. This issue is resolved. Now, product is associated successfully.
DE28570	N/A	After changing the repository details in <i>Technical Administration</i> , the session of the previous user was still used and this caused issues with DMS login. As a result, performing any task in DMS required a server restart to complete. This issue is resolved. Now, performing a task in DMS does not require a server restart.
DE28565	N/A	The UCSampleTOCTemplate.docx template caused issues with fonts. This issue is resolved. Now, the two new TOC templates used for Chinese and Japanese text are created without fonts that caused the font issue.
DE26800, 26725, [INC0052690]	N/A	Ennov InSight sometimes failed to connect with the Veeva vault selected and instead established a connection with another Veeva vault if a user had more than one configured in the same domain. This issue is resolved. Now, Ennov InSight always establishes a connection with the selected vault.

Publisher

Issue	Sub-Minor Build	Description
DE31352, [TASK0361714]	N/A	For a submission with files of 1 GB size or more, performing the Recalculate Checksums operation failed and Job Requests > Job Message displayed the <code>Query stopped responding</code> message. This issue is resolved. Now, for large submissions, the Recalculate Checksums operation completes as expected.
DE31334, [TASK0444686]	N/A	When Recalculate Checksums was performed on an assembly with 1000+ leafs, the Job Requests > Job Message query displayed the <code>Error: could not execute query</code> message. This issue is resolved. Now, the Recalculate Checksums operation completes correctly and the Job Message displays relevant information.

Issue	Sub-Minor Build	Description
DE31322	N/A	Rendering of selected files sometimes failed if a folder contained many files (approximately 80,000 or more). This issue is resolved. Now, for a file in the folder with many files, rendering completes successfully.
DE31296, [TASK0373863]	N/A	When working with large assemblies, performing the Recalculate Checksums operation even on a single element timed out and failed. This issue is resolved. Now, the performance is improved, and the Recalculate Checksums operation is performed only on the files selected by the user.
DE31146	N/A	When searching a document using the values of DMS Repository, Repository, Document Type, and Search Folders as search criteria, the DMS Search Results failed to show the keywords and other repeated or custom attributes. This issue existed only for Documentum. This issue is resolved. Now, the DMS Search Results are displayed with values if they are added to the document searched
DE31122	N/A	If file downloading was interrupted due to any technical issues, trying to download the same file later resulted in the <code>Invalid reference</code> error. This issue is resolved. Now, the file is downloaded successfully.
DE31057	N/A	The DMS search on a folder that contained around 1000 or more documents took longer than expected. This issue is resolved. The performance is improved.
DE30878	N/A	Performance issue was experienced when creating a working assembly in an application with 1000 sequences added to the life cycle and multiple nodes in the Submitted view. This issue is resolved. Now, performance is improved
DE30601	N/A	When creating a TOC in an assembly using the <code>UCSampleTOCTemplate.docx</code> template, the Generate TOC jobs failed. This issue is resolved. Now, the template is updated and Generate TOC jobs complete successfully.

Issue	Sub-Minor Build	Description
DE30593	N/A	Trying to create an assembly from an XML file with specific metadata populated for US Module1 v3.3 resulted in the following error message: <code>You do not have the appropriate privileges to access the requested resource error message</code> . This issue is resolved. Now, an assembly is successfully created from an XML when using the US Module v3.3 specification.
DE30518	N/A	The Application Number value in the US Admin Forms folder was missing when the US 3.3 assembly had been created using the <i>Create eCTD</i> wizard causing the publish operation to fail. This issue is resolved. Now, the wizard populates the Application Number field automatically by selecting a single value from the Application Contain Files? entry, if it is set to Yes . As a result, publishing completes successfully even if the Application Number has not been populated directly by a user.
DE30391	N/A	Authoring links created using Linking plug-in (PDF) or Linking add-in (Word) did not work with the enhanced Secured File System of Ennov InSight when a document was assigned and Run Link Inspector was performed. This issue is resolved. Now, the links work with the enhanced Secured File System of Ennov InSight .
DE29594	N/A	When a sequence with sequence code starting with the upper case P was created and the assembly was published, using Recalculating Checksum generates extra files in the output location. This issue is resolved. Now, Recalculating Checksum operation completes correctly and does not generate extra files.

Registrations

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

Ennov InSight 7.3 COB and Known Issues

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

Entity Fields

Entity Fields, Columns and Options Added: Ennov InSight 7.3.1

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

Events

Table 1: Pending Changes

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

Table 2: Create Pending Changes

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

Table 3: Create Pending Changes

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

Registration Attachment

Table 4: Create Registration Attachment

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

Full Product Presentations

Table 5: Registration FPP Attachment

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

Wizards

Table 6: XEVMPD Submission

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

Entity Fields, Columns and Options Removed: Ennov InSight 7.3.1

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

Assembly, Assembly Templates

Table 7: Publishing Settings Library

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

Table 8: Document

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

Events

Field/Column/Option Name	Field Type	Description	Business Rules
Medicinal Products	Multi-select	This field is removed from the Create Pending Changes > Change Scope > Registration Package Set .	The Registration Package Sets field is still available to populate. It appears after values for the fields Application Reviewing Country and Registrations are selected.
Medicinal Products	Multi-select	This field is removed from the Create Pending Changes > Change Scope > Registration Package Set Countries .	The fields Country and Registration Package Sets are still available to populate. They appear after values for the fields Application Reviewing Country and Registrations are selected.

Data Administration

Data Administration Sections Added: Ennov InSight 7.3.1

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

Data Administration Section: Submission Maintenance

Table 9: Evaluation Pathway Values

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

Database Columns

Database Columns Added: Ennov InSight 7.3.1

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

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

Database Columns Removed: Ennov InSight 7.3.1

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

UI Field Name	Database Table Name	Database Column Name	Database Column Type	Description
In-Process Rendition Location	ODS.PUB_SETTINGS	IN_PROCESS_RENDITION_LOC_ID	NUMBER	To support the default in-process linking for Linking plugin (PDF) without the need to access the DMS, the IN_PROCESS_RENDITION_LOC_ID column is deleted from the ODS.PUB_SETTINGS table.

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