



Ennov InSight 7.4 Release Notes

RD.RN.1179.000

Application date: 29 Apr 2026

Table of contents

1	ENNNOV INSIGHT 7.4 RELEASE NOTES.....	3
1.1	Ennov InSight 7.4 Release Notes.....	3
1.1.1	Validator as a service.....	3
1.1.2	IDMP Updates.....	3
1.1.3	Common Enhancements.....	3
1.1.4	Registrations Enhancements.....	3
1.1.5	Ennov Doc integration.....	4
1.1.6	eCTD 4.0.....	4
1.1.7	eCTD import.....	4
1.2	Resolved Issues: Ennov InSight 7.4.....	4
1.2.1	Common.....	5
1.2.2	Publishing.....	5
1.3	Known Issues: Ennov InSight 7.4.....	8
1.3.1	Common.....	8
1.4	Entity Fields, Columns and Options Added: Ennov InSight 7.4.....	8
1.4.1	Navigation Tree.....	8
1.4.2	PDS -> Package Size.....	9
1.4.3	PDS -> Package Set.....	9
1.4.4	PDS -> Function.....	9
1.4.5	Home page.....	10
1.4.6	Validator -> eCTD Validator.....	10
1.4.7	Validator -> Validation Reports.....	11
1.5	Entity Fields, Columns and Options Updated: Ennov InSight 7.4.....	12
1.5.1	Navigation Tree.....	12
1.5.2	Medicinal Product.....	12
1.5.3	Document.....	12
1.5.4	Leaf.....	13

1 Ennov InSight 7.4 Release Notes

1.1 Ennov InSight 7.4 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 7.4.

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

1.1.1 Validator as a service

Ennov InSight 7.4 enables users to submit validation requests and view the results directly from the main menu. The following eCTD 3.2 regions and versions validation criteria are now supported:

- US FDA v4.4 and v4.5
- Health Canada v5.3

1.1.2 IDMP Updates

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

The Paediatric Use Indicator and Genetically Modified Organisms fields on Medicinal Product updated to be non-mandatory in user interface and the database.

The copy URL icon has been added to the entity attributes screen for the following PDS Nodes: Package Size, Package Set, and Function.

1.1.3 Common Enhancements

A new Registration Navigation Tree has been introduced with the release. It includes following nodes: Product Family, Application, Product, Medicinal Product, Registration (Package Set Type) and Full Product Presentation. Represents registrations via Medicinal Products and Full Product Presentations through the associated Products.

1.1.4 Registrations Enhancements

Both navigation trees, Product Family and Country, have been enhanced to increase performance.

Displaying all application countries except for CP applications, in which case, display only the composite country, and not many.

To improve user experience with PDS nodes management the cascade Withdrawn was introduced. Now when the parent PDS Node is Withdrawn the same status is applied to all its children regardless of the child's status.

1.1.5 Ennov Doc integration

Ennov InSight 7.4 introduces an ability to assign entire content plans from Ennov Doc. The eCTD attributes are retained upon assignment.

Now, it is possible to bind Ennov Doc document to specific version. Also, it is now possible to assign multiple documents. However, a content plan and a document cannot be assigned within one action. It also cannot be performed with two or more content plans.

1.1.6 eCTD 4.0

The behaviour of required fields across Regional Information, Additional Information, corresponding pages in Create eCTD wizard, Create Study Reports wizard has now been harmonised. Now, if a required field is empty, the user cannot proceed with changes until issue is addressed. There is an indication if a required field is hidden under collapsed group.

For Japan submissions it is now possible to specify multiple Application Reference and Application Reference Reason pairs.

Publishing output has been updated in accordance with current Japan controlled vocabularies v1.6.

Ennov InSight 7.4 user is now able to create forward compatibility assembly for EU region, even if application is associated with few countries. However, the Regional Information and Additional Information fields remain empty.

1.1.7 eCTD import

With Ennov InSight 7.4 the eCTD import gets better reporting. The list of XML definitions used upon import is now provided in the Job Requests Details. Also, the list of XML definitions is provided upon finish of the import.

1.2 Resolved Issues: Ennov InSight 7.4

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

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

1.2.1 Common

Issue	Description	Impact	Resolution
252523 [TASK-2025-10-2478]	Opening a Sequences tab under Application with more than 5000 records took extra time.	User had a suboptimal experience.	The query to receive all the Sequences has been optimized. Now, Sequences tab opens faster even if there are 5000 Sequences under the Application.
252419 [TASK-2025-10-2465]	Opening an Application page took extra time if there were more than 7000 Sequences associated with it.	User had a suboptimal experience.	The query to load an Application has been optimized. Now, Application page tab opens faster even if there are 7000 Sequences under the Application.

1.2.2 Publishing

Issue	Description	Impact	Resolution
247028 [TIC-2025-05-52988, TASK-2025-06-0972]	The Find and Replace option was not available for leafs in the initial sequence assembly.	It was not possible to make a bulk replace, as well as search of some text within a leaf. At the same time, the option was available on assemblies of other types.	The Find and Replace option has been added for a leafs in the initial sequence assembly.
250972 [TIC-2025-06-54187, TASK-2025-06-1211]	If there was a TOC with a PDF rendition and the TOC was regenerated with changes, the Preview TOC option returned outdated rendition instead of latest Word file.	Providing an outdated TOC led to confusion for the user.	The Preview button now returns the latest file, regardless of whether it is a Word file or a PDF rendition for the TOC.

<p>253742 [TASK-2026-01-0243]</p>	<p>Publishing large files (2-5GB) would time out on some DMS or Secured File Systems, if the latency is high during the copying process.</p>	<p>Submissions with large files (2-5GB size of one file) were not published on some repositories.</p>	<p>Transfer of files has been further optimized to enable seamless streaming of the data. Large files now get published successfully.</p>
<p>242038 [INC-2025-04-0166, TASK-2025-04-0390]</p>	<p>Upon migration to Secured File System some source locations failed to update, due to the encoded path</p>	<p>Long source locations for Documents, Leafs, TOCs, special sheets etc. failed to update upon migration.</p>	<p>The column size in the database has been increased for the corresponding fields. This guarantees seamless usage of the functionality related to the Secured File System.</p>
<p>253179 [TASK-2025-12-3017, INC-2025-12-0551]</p>	<p>If the user specified in Technical Administration did not have full access to the Secured File System, the distribute process (part of the Publish workflow) failed.</p>	<p>The user permissions required elevation to provide the needed functionality. This elevation is unreasonable from security perspective.</p>	<p>The Secured File System connectivity has been revised. Now, to upload files, Write permissions are sufficient.</p>
<p>253449 [TIC-2025-12-60149].</p>	<p>For specific types of Secured File System repositories, the eCTD import would fail.</p>	<p>The eCTD Import did not work. User would have to use an alternative repository.</p>	<p>The processing eCTD import request has been revised. Now, eCTD Import completes successfully even if using the specific Secured File System repositories.</p>
<p>92669 [INC0221628, PRB0044980]</p>	<p>Importing leafs and reference leafs, originating from the same leaf caused an error upon running Import Assembly wizard</p>	<p>Import Assembly wizard failed in some cases.</p>	<p>Leaf retargeting mechanism for the Import Assembly wizard has been revised. Now, such structures get imported without issues.</p>

<p>251732 [TIC-2025-05-53065, TASK-2025-09-1977]</p>	<p>There was a problem with consequent Prepare for Publishing jobs staying in Scheduled state while at least on Prepare for Publishing job was in progress.</p>	<p>Handling of only one job at a time led to unreasonable delays, especially on systems under the high load.</p>	<p>Now the limit of jobs that can be run in parallel has been increased and the system is able to start running the jobs without unreasonable delay.</p>
<p>252202 [TASK-2025-10-2406]</p>	<p>Extraction request from Documentum fails if the rendition identifier has a space in the name.</p>	<p>Using documents with such rendition identifier was not possible.</p>	<p>Processing of rendition identifier value has been optimized and now the rendition identifier name may include various symbols, including space, mdash, @ . * = ~ ? ; () ! : \$ - 0 ` _ % ^ \ [] { } " No / { } [] +. However combinations like), %20 (or any other octets of this format), # & are not supported.</p>
<p>254357 [TASK-2026-03-0519, INC-2026-03-0138]</p>	<p>After running the eCTD 4.0 Create Study Reports Wizard, Prepare to Publish would fail if option "Remove empty leaves and folders" was selected, and this would cause locks in the database preventing further assembly structure updates.</p>	<p>When reproduced the user can no longer update the assembly data until the lock is removed in the database.</p>	<p>The code causing data mismatch has been updated. Now, the probability of the database locks is reduced for the eCTD 4.0 assemblies.</p>
<p>90687 [PB-2025-02-0614, TIC- 2025-02-14669]</p>	<p>Attempt to insert a Cover Page to a leaf with long name in</p>	<p>The users could not add Cover Pages to a certain leaves.</p>	<p>The database column size has been updated to account for the names in Unicode.</p>

	Unicode failed with database related error.		
--	---	--	--

1.3 Known Issues: Ennov InSight 7.4

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.

1.3.1 Common

Issue	Description	Impact	Workaround
254772 [TIC-2026-04-3202, TASK-2026-04-0833]	Creating a Registration for the EU National Procedure Application Type is not possible when the European Union country is selected.	Users are unable to create a Registration for the European Union country when using the EU National Procedure Application Type.	Use an alternative, appropriate Procedure Type to create the Registration until the issue is resolved.
250453 [TIC-2026-03-3027, TASK-2026-04-0833]	An Application created for the European Union country using the EU National Procedure Application Type is not visible in the Home Navigation Trees.	Users cannot locate or navigate to Applications created for the European Union with the EU National Procedure Application Type using the Home Navigation Trees.	Access the affected Applications using alternative navigation options, such as SEARCH, FIND, the Applications tab, or other available navigation methods.

1.4 Entity Fields, Columns and Options Added: Ennov InSight 7.4

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

1.4.1 Navigation Tree

Field/Column/Option Name	Field Type	Description	Business Rules
Navigation Tree	Registration	Navigation Tree is now having an option to show Registrations,	To improve client journey and data visibility in Ennov

		Medicinal Product, and Full Product Presentations entities via tree hierarchy.	InSight new navigation tree option has been introduced.
--	--	--	---

1.4.2 PDS -> Package Size

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

1.4.3 PDS -> Package Set

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

1.4.4 PDS -> Function

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

1.4.5 Home page

Field/Column/Option Name	Field Type	Description	Business Rules
Validator	New menu on the top of the Home Page	Provides a functionality to submit a submission to validate through the eCTD Validator option. The validation results can be reviewed on the Validation Results page.	The option is present if both eCTD Validator option in the Security Administration is at least Read and the background service is configured.

1.4.6 Validator -> eCTD Validator

Field/Column/Option Name	Field Type	Description	Business Rules
Submission Folder	DMS Browse	To enable users to select a submission folder.	The selected folder must contain an eCTD submission.
Validator Region	Text	The Validator Region field shows an eCTD region identified for the selected submission.	
Validator Criteria Version	Drop down	The Validator Criteria Version field shows the list of supported criteria versions for the detected region. The user may select a version from the list.	The current version is selected by default.
Select Regulatory Center	Radio button group	If an eCTD region has Regulatory Centers, the user is opted to select one.	For US region the CDER option is selected by default
Criteria groups	Expandable groups with ability select or deselect	Provides a list of criteria groups with short description of checks to be performed.	All groups are selected by default.

1.4.7 Validator -> Validation Reports

Field/Column/Option Name	Field Type	Description	Business Rules
User Name	Text	Shows the user submitted the validation.	
Submission Location	Text	The Validator Region field shows an eCTD region identified for the selected submission.	
Validation Status	Text	The Validator Criteria Version field shows the list of supported criteria versions for the detected region. The user may select a version from the list.	
Start Time	Text	If an eCTD region has Regulatory Centers, the user is opted to select one.	By default, the results are sorted by this field, in descending order.
End Time	Text	Provides a list of criteria groups with short description of checks to be performed.	
Validation Details	Hyperlink		By clicking on hyperlink the report opens, with status, failures and options to download PDF report.

1.5 Entity Fields, Columns and Options Updated: Ennov InSight 7.4

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

1.5.1 Navigation Tree

Field/Column/Option Name	Field Type	Description	Business Rules
Navigation Tree	Product Family Country	Updated for CP Applications to show only the composite country.	The change is made to user journey based on regulatory rules and EMA requirements.

1.5.2 Medicinal Product

Field/Column/Option Name	Field Type	Description	Business Rules
Genetically Modified Organisms	Drop-down	Updated to be non-mandatory, with [Select] set as the default value.	The change is made to based on EMA requirements for IDMP.
Paediatric Use Indicator	Drop-down	Updated to be non-mandatory, with [Select] set as the default value.	The change is made to based on EMA requirements for IDMP.

1.5.3 Document

Field/Column/Option Name	Field Type	Description	Business Rules
Source Location	DMS Browse	The DB length is changed to 1000	

1.5.4 Leaf

Field/Column/Option Name	Field Type	Description	Business Rules
Genetically Modified Organisms	Drop-down	Updated to be non-mandatory, with [Select] set as the default value.	The change is made to based on EMA requirements for IDMP.