



Ennov InSight Viewing User Guide

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Chapter 1. Ennov InSight Viewing 6.0

Ennov InSight Viewing 6.0 is a web-based application that supports the access and viewing of submission information.

With appropriate permissions, you can view and interact with electronic information, including eCTD and NeesS applications and associated submissions, while consistently accessing information in the same place through a secure, thin client application.

You can view the structure (TOC), contents (documents/data) and lifecycle of submissions, creating a thorough and quick review process. Using the various search features, you can search for keywords or metadata (that is stored in the XML backbone) within your submission content.

The interactive element of Ennov InSight Viewing 6.0 makes the review process a collaborative experience. Reviewers can add comments directly to submissions and Authors (Publishers and/or Submission Managers) can view, track, and respond to comments.

Note: For the most recent product updates and other product information, please refer to the product Release Notes.

Chapter 2. Controls and Navigation

Ennov InSight Viewing 6.0 provides several pages and tabs that you use to view and interact with eCTD and NeeS applications and associated submissions. Overview of the pages and tabs:

Page or Tab	Description
Administrator	<p>This menu is available for the users with administrative permissions only. Administrators can perform the following functions:</p> <ul style="list-style-type: none">– add/edit applications– add/edit user– add/edit repositories– add/edit application groups – add/edit user groups <p>Administrators can set permissions to grant user access to applications and/or submissions. Administrators can create Public or Personal comments, transfer, update, re-open other types of comments, and purge comments.</p>
Reports	Displays a list of reports for selection.
Navigator	<p>The landing or home page for all non-Administrator users, used for selecting an application or submission. <i>Navigator</i> has two panels: on the left panel you can filter and search for information, the right panel displays the search results.</p> <ul style="list-style-type: none">– <i>Submission Navigator</i> appears as part of the <i>Navigator</i> page within a panel, use various filters to find the application/submission.– <i>Search</i> displays as part of the <i>Navigator</i> page within a panel. Search for a document, submission, or application using the keyword and metadata search options.– <i>Submission Table of Contents</i> appears after you have selected a submission from the <i>Navigator Search Results</i> window or the <i>Recent Views</i> window as a result of search operation performed using the Submission Navigator or Search tabs. The <i>table of contents</i> page displays the submission table of contents on the left and the associated document on the right. This page can include items such as document properties, life cycle, comments, and submission administrative information.
Content Indexing	Opens the <i>Content Indexing</i> window.
Audit Trail	Opens the <i>Audit Trail</i> window.
Server Settings	Opens the <i>Server Settings</i> window.

Additional options within the application include the following:

Option	Description
Help	Opens the Help (this content).
About	Displays information about the application version.
Profile	Use the <i>Profile</i> page to see your account information.
Logout	Logs you out from the application.

Chapter 3. How to Change Password

You cannot change password using Ennov InSight Viewing interface.

Starting from Ennov InSight Viewing 6.0, the Change Password option is no longer available on the *Profile* window. Please contact Azure AD administrator to change password if required.

Chapter 4. Special Characters

Certain special characters in the output locations, file names, and user names might not be interpreted correctly by the system and can cause unexpected results. Therefore, it is recommended these special characters are best avoided.

Special Character	Description
*	Asterisk
\	Backslash
/	Slash or Forward Slash
"	Quotation mark
'	Apostrophe
+	Plus
	Pipe
<>	Left and right angle brackets
?	Question mark
:	Colon
#	Number
%	Percentage
{ }	Braces

Chapter 5. Role-based Security and Permissions

Ennov InSight Viewing uses role-based security, which associates feature access with a particular user role. At the feature level, the distinction primarily exists between Administrator and non-Administrator users.

Your role is assigned by your Administrator. Administrators perform administrative functions through the Administrator interface for Ennov InSight Viewing. Permissions to specific applications and/or submissions are granted by your Administrator.

Submission Manager

Users with the Submission Manager role usually perform the operations of the Publisher and may have additional privileges within the application for submission-management purposes. Starting with Ennov InSight Viewing 5.3 version, a user with Submission Manager role will be able to manually as well as auto register new applications. A Submission Manager will also have all the privileges relating to the adding, editing and deleting of applications. See the related topics for more information.

Publisher

Users with the Publisher role usually have the primary responsibility of working with submissions. Publishers typically have electronic submission proficiency and a broad range of computer skills.

Restricted Reviewer

Users with the Restricted Reviewer role usually have the primary responsibility of reviewing and verifying submissions. The basic function of these users are similar to that of the Reviewers but have certain limitations such as the inability to save and print the PDF files. The limitation related to comments are described in the *Comments feature* topic.

Reviewer

Users with the Reviewer role usually have the primary responsibility of reviewing and verifying submissions for regulatory compliance before sending to agencies. Reviewers are typically skilled in one or more medical specialties and have a broad range of computer skills.

Chapter 6. Navigator

Navigator is the landing or home page for all non-administrator users and is used as your navigational tool to locate applications, submissions and documents.

The following search options are available within the Navigator feature:

- Submission Navigator - Find applications or submissions that are registered within the system based on the set of criteria that you select.
- Search - Search for applications, submissions, or documents using either the content or metadata search methods.

Submission Navigator

When searching for an application based on a certain criteria, the values of the criteria used can be saved with a name as a single entity for future searches.

For text fields such as Agency Number and Applicant, you can also use the wild card characters _ (underscore) and * (asterisk) for searching. The _ can be used in place of a character and the * can be used in place of more than one character. For example, searching for the agency number using the string 2334_4 will display all the available applications with the agency numbers that start with 2334 and end with 4. Similarly, searching for the agency number using the string 2334* will display all the available applications that start with 2334.



Note: To quickly retrieve applications without having to individually select the search values each time, specify and save the values below to set up your own search criteria.

Search Parameter	Description
User Group	Users included under various groups.
Dossier Format	eCTD and Non-eCTD.
Region	Select a country/region in the drop-down list.
Application Name	Unique values found under registered submissions (Envelope/Administrative Information).
Agency Number	Enter an agency number (provided by the agency).
Application Type	ANDA, ASEAN CTD, Abbreviated New Drug Application (ANDA), BLA, Biologic License Application (BLA), CTA, DMF, Drug Master File (DMF), Emergency Use Authorization (EUA), IND, Investigational Device Exemption (IDE), Investigational New Drug (IND), MAA, NDA, New Drug Application (NDA), PIP, Premarket Approval Application (PMA), Premarket Notification 510K (510K), Safety Issue (FDA Use Only), User-Defined, master-file.

Submission Navigator

Search Parameter	Description
Submission Type	Select the submission type from its corresponding drop-down list.
Applicant	Name of the applicant, entered by the user.
Product Name	Name of the product, entered by the user.
Internal Name	Unique values found under registered Application. Value entered by the user during the registration.
Remarks	Unique values found under registered Application. Value entered by the user during the registration.
Submission Status	Select the submission status from its corresponding drop-down list.
Date of Submission	Enter the date in <i>MM/DD/YYYY</i> format or select the date using the date picker. When you enter one date, the application will search for the exact date; when both date values are present it will find the matching submissions within the date range, including the start and end dates.
Region Specific Filter	Enter the values for the parameters of the region selected.
Any Term	When selected, the search option will be based on any matching options, as the OR condition is used to find the matching applications/submissions.
All Terms	When selected, the search option will be based on all matching options, as the AND condition is used to find the matching applications/submissions.
	Note: <i>If more than one search criteria is selected, the option All Terms will be defaulted instead of Any Terms</i>
Application Name	To collapse or expand the list in the search results table, click the - and + buttons.
Display	<p>When clicked, the matching Applications/Submissions is displayed in the <i>results</i> panel on the right. You can access only the permitted Applications according to your assigned Role.</p> <p>By default, only the submission of the highest sequence is displayed. To view all the sequences, click on the Expand All icon. To display all the sequences of the applications in the <i>Navigation Search Results</i> window by default, the value of the corresponding property must be changed in the config.xml file. For more information, refer to the topic <i>Display all sequences in Navigation Search Results window</i>.</p>

Submission Navigator

Search Parameter	Description
Save	Use this option to save the currently selected search criteria so you can reuse it later.
Reset	When clicked, the selected options and the results on the right panel are cleared.
Load	Use this option to load the criteria from a saved search. To display the Navigator Search Results, you must click the Display button.
Hide/Expand Left Panel	<p>In the middle of the left panel is an arrow icon for collapsing or expanding the left panel. Click the icon to collapse the left panel and increase the width of the right panel. Click the icon again to restore the left panel view.</p> <p> Click to collapse the left panel.</p> <p> Click to expand the left panel.</p>

Submission Navigator: EU Region Specific Values

The EU (European Union) region values section provides you the ability to search for applications based on the criteria specific to European Union.

Search Parameter	Description
Procedure Type	Searches based on Centralised, Decentralised, Mutual Recognition, National procedure types.
Submission Type	Searches for matching submissions types and lists those submissions.
Submission Unit Type	Searches for matching submission unit types and lists those submissions.
Country (EU)	Searches for countries. EU countries can be selected using this drop-down.
Submission Description	Searches for any matching words or letters in the submission description of submissions and list those submissions.

Submission Navigator: CH Region Specific Values

The CH (Confoederatio Helvetica) section provides the ability to search for applications based on the criteria specific to Swissmedic.

Search Parameter	Description
Submission Description	Searches for any matching text in the submission description of submissions and lists those submissions.

Galenic Form	Searches for matching galenic forms of submissions and lists those submissions.
Galenic Name	Searches for matching galenic names of submissions and lists those submissions.
DMF Holder	Searches for matching DMF holders of submissions and lists those submissions.
PMF Holder	Searches for matching PMF holders of submissions and lists those submissions.
Paragraph/Article 13 LTP/TPA	Yes, No. Searches the submissions based on the value selected from this list.

Submission Navigator: CN Region Specific Values

The CN (China) section provides the ability to search for applications based on the criteria specific to China NMPA. All the submission navigator filter options are in Chinese, English translation is in brackets.

Search Parameter	Description
Application type	Searches for matching application types and lists those submissions.
Product type	Searches based on Chemical Product and Biological Product.
Regulatory activity type	Searches for matching regulatory activity types and lists those submissions.
Sequence type	Searches for matching sequence types and lists those submissions.
Sequence description	Searches for matching sequence description and list those submissions.
Sequence number	Searches for matching sequence numbers and lists those submissions.
Sequence contact Name	Searches for matching related sequence contact names and lists those submissions.
Related sequence	Searches for matching related sequences and lists those submissions.

Submission Navigator: JO Region Specific Values

The JO (Jordan) section provides the ability to search for applications based on the criteria specific to Jordan FDA.

Search Parameter	Description
Procedure Type	Searches based on JO and National procedure types.
Submission Type	Searches for matching submissions types and lists those submissions.
Submission Unit	Searches for matching submission units and lists those submissions.
Submission Description	Searches for any matching text in the submission description of submissions and lists those submissions.

Submission Navigator: GCC Region Specific Values

The GCC (The Gulf Cooperation Council) section provides you the ability to search the applications based on the criteria specific to the GCC countries which include: Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and United Arab Emirates.

Search Parameter	Description
Procedure Type	Searches based on GCC and National procedure type.
Submission Type	Searches for matching submissions types and lists those submissions.
Country (GCC)	Searches for GCC countries based on drop-down selection.
Submission Unit	Searches for matching submission units and lists those submissions.
Submission Description	Searches for any matching text in the submission description of submissions and lists those submissions.

Submission Navigator: ZA Region Specific Values

The ZA (Zuid-Afrika) section provides you the ability to search the applications based on the criteria specific to South Africa.

Search Parameter	Description
Submission Efficacy	Searches for matching efficacy of submissions and lists those submissions.
Multiple Applications	Searches for matching applications.
Dosage Form	Searches for matching dosage form of submissions and lists those submissions.

Submission Navigator: US Region Specific Values

The US (United States) section provides you the ability to search the applications based on the criteria specific to U.S. Food and Drug Administration.

Search Parameter	Description
Applicant ID	Searches for the matching application IDs and lists those submissions.
Submission Description	Searches for description of the submissions and lists those submissions.
Submission Sub Type	Searches for matching submissions sub types and lists those submissions.
Contact Type	Searches for matching contact types of submissions and lists those submissions.
Contact Name	Searches for matching contact names of submissions and lists those submissions.
Grouped Submissions	Searches for submissions that are part of a grouped submission.

Submission Navigator: AU Region Specific Values

The AU (Australia) region values section provides you the ability to search for applications based on the criteria specific to the Australia regulatory authority Therapeutic Goods Administration (TGA).

Search Parameter	Description
Sequence Type	Searches for matching sequence types and list those submissions.
Sequence Description	Searches for matching sequence description and list those submissions.

Submission Navigator: TW Region Specific Values

The Taiwan section provides you the ability to search the applications based on the criteria specific to Taiwan Food and Drug Administration.

Search Parameter	Description
Submission Type	Searches for matching submissions types and lists those submissions.
Submission Unit	Searches for matching submission units and lists those submissions.
Submission Objective	Searches for matching submission objectives and lists those submissions.
Submission Description	Searches for any matching words or letters in the submission description of submissions and list those submissions.

Submission Navigator: TH Region Specific Values

The Thailand FDA section provides you the ability to search the applications based on the criteria specific to Thailand Food and Drug Administration.

Search Parameter	Description
Sequence Type	Search for matching sequence types and list those submissions.
Sequence Description	Search for matching sequence description and list those submissions.

Submission Navigator: UA Region Specific Values

Search Parameter	Description
Submission Mode	Searches for matching submissions based on Single or Grouping submission modes.
Submission Type	Searches for matching submissions types and lists those submissions.
Submission Unit	Searches for matching submission units and lists those submissions.

Submission Description	Searches for any matching words or letters in the submission description of submissions and list those submissions.
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Submission Navigator Search Results

When search results are displayed, you have the option to open the desired application or submission by selecting the internal name, application name, agency number or submission number. These values appear as blue text to indicate a hyperlink.

For an eCTD Application:

Ennov InSight Viewing User Guide 6.0 Submission Navigator: Australia Region

- When the internal name, application name or the agency number is selected, the current view of the selected application is displayed.
- When the submission number is selected, the sequence view of the selected submission is displayed.

For a non-eCTD Application:

- When the internal name, application name or the submission number is selected, the submission view of selected application is displayed.

Collapse & Expand Search Results View

To collapse or expand the list of applications based on their names in the search results table, click the - and + buttons on the Submission Navigator tab.

- The collapsed view displays most recent submission for each application, enabling you to reduce the list of applications based on your search criteria.
- To sort the results based on the applications or view type (in ascending or descending order), click on the respective column heading.
- The expanded view displays all submissions for each application.

Recent Views

On returning to the *Submission Navigator* after viewing submissions, the recently viewed submissions are displayed in the *Recent views* window. This feature enables you to return quickly to submissions you have viewed or worked on recently.

Chapter 7. PDF Navigation

You can browse through a PDF document using the navigation buttons.

When navigating within a PDF document, to view the previous and next pages, use the navigation buttons:



The Ennov InSight Viewing Back and Forward buttons function only at document level and keep track of all the documents viewed using the table of contents.

Chapter 8. Search

The search tab provides two options:

- Content Search- Search keywords in submission documents.
- Metadata Search - Search metadata present in the submission backbone.

Content Search

The Content Search option enables you to search for documents based on its text content. The scope of the search can be defined based on the submissions and applications that are registered and indexed.

1. Click Navigator and select the Search tab.
2. In the Content Search section, select the application from the Application Name list.

The values under this option will be ALL and the unique application names of all the registered and indexed applications.

3. From the Submissions list, select the submission.

The values under this option will be ALL and the unique submission names of all the submissions of the selected application.

4. To search for documents based on its text content, enter the word in the Keyword text field.

To save this search criteria so as to use it the next time, move to the next step. Else, move to step 8.

5. Save.
6. Provide a name for the search criteria that you selected.

By naming and saving the search criteria, you can select the name that you provide for future searches and load the same search criteria.

7. Click OK.

The search criteria is saved.

8. To search for the documents, click Display.

The results appear in the *Content Search Results* window.

9. To export the search result to a spreadsheet, click Export.

You are provided with the choice to view or save the spreadsheet.

Work with Content Search Results

When a search is performed, the results are shown in the *Content Search Results* panel on the right.

To sort the results based on the dossier format, application name, submission number, file name or the file path (in ascending or descending order), click on the respective column heading.

Content Search

Hyperlinks are also provided to the application names, submission numbers and file names. Clicking the *application name* or *submission number* will display their respective details. Clicking the *file name* will display its document in the external window.

Metadata Search

The Metadata Search option enables you to search for applications based on the application metadata. The scope of the search can be narrowed by defining the search criteria based on the application, submission, region, and the metadata.

For the text fields such as the Agency Number and Product Name, you can also use the wild card characters _ (underscore) and * (asterisk) for searching. The _ can be used in place of a character and the * can be used for more than one character. For example, searching for the agency number using the string 2334_4 will display all the available applications with the agency numbers that start with 2334 and end with 4. Similarly, searching for the agency number using the string 2334* will display all the available applications that start with 2334.

1. Click Navigator and select the Search tab.
2. In the Metadata Search section, select the application from the Application Name list.

The values under this option will be ALL and the unique application names of all the registered and indexed applications.

3. From the Submissions list, select the submission.

The values under this option will be ALL and the unique submission names of all the submissions of the selected application.

4. Select the values for the Region and Submission Type options from their respective lists.
5. Enter values for the following attributes in their respective fields:

- Agency Number - Agency number (provided by the agency).
- Product-Name - Name of the product.
- Dosage Form - Product in the form in which it is marketed for use.
- Product Manufacturer - Name of the product manufacturer.
- Excipient - Name of the excipient.
- Substance Name - Name of the substance.
- Substance Manufacturer - Name of the substance manufacturer.

- Indication - Medical situation for which the product is used. – Related Sequence - Associated sequence in an application.
6. Using the date picker, select the date from its respective field.
 7. Select one of the following options:
 - Any Term - When Any Term is selected, the search option is based on any matching options, as the OR condition is used to find the matching applications/submissions.
 - All Terms - When All Terms is selected, the search option is based on all matching options, as the AND condition is used to find the matching applications/submissions.

Note: *If more than one search criteria is selected, the option All Terms will be defaulted instead of Any Terms.*
 8. Click Display.

The applications matching the search criteria is displayed in the window on the right.

Metadata Search Results

Search results are always displayed in the window on the right side of the Ennov InSight Viewing application. When search results are displayed, you have the option to open an application or submission by selecting the *application name* or the *submission number*. These values appear as blue text to indicate a hyperlink.

- When an *application Name* is selected, the current view of the selected application is displayed.
- When a *submission Number* is selected, the sequence view of the selected submission is displayed.

Save and Load Search Criteria

When searching for an application based on a certain criteria, the values of the criteria used can be saved with a name as a single entity for future searches.

This helps to quickly retrieve applications without having to individually select the search values.

Save Search Criteria

When searching for an application based on a certain criteria, the values of the criteria used can be saved with a name as a single entity for future searches.

1. Select the options that you want to use to perform a search.
2. Click Save.
3. Provide a name for the search criteria you have selected.
4. Click OK.

Load Search Criteria

When searching for an application based on a certain criteria, the values of the criteria used can be saved with a name as a single entity for future searches.

1. In the applicable search option that you are using (Submission Navigator, Content or Metadata Search), click Load.
2. In the drop-down list, select the name for the search criteria that you want to load.
3. Click Load.
4. To display the search results, click Display.

Modify Search Criteria

When searching for an application based on a certain criteria, the values of the criteria used can be saved with a name as a single entity for future searches.

1. Load the saved search criteria.
2. Modify the search criteria.
3. Click Save.
4. Select the name of the search criteria that you want to update from the dropdown list of saved searches.
5. Click OK
6. Do one of the following:
 - Click Yes to confirm that you want to overwrite the existing saved search.
 - Click No to cancel the Save request.

Work with Search Results

After you select a search method and enter search criteria, the search results appear in the pane on the right side of the window.

The resulting applications or submissions listed are hyperlinked to their corresponding table of contents.

Note: *Selecting a leaf in the table of contents displays the document in the pane on the right side of the window. The documents with formats not supported by Ennov InSight Viewing are displayed outside of the application.*

Submission Table of Contents

When an application or submission is selected from the *results* window, the table of contents appears along with the following options:

Option	Description
Table of Contents	Displays eCTD or NeeS submission table of contents.

Lifecycle	Displays eCTD submission lifecycle information of the selected document.
Properties	Displays eCTD or NeeS submission leaf properties of the selected document.
Comments	Displays comments for the selected document.
Reference Leaf Details	Displays the details of the cross referenced documents. If a cross referenced document is present under a study or node extension, the study or node extension column will display the title of the study or node extension.

Chapter 9. Comments

The commenting feature is the interactive element of Ennov InSight Viewing that enables Reviewers and Authors to collaborate in the submission review process.

You can view, track, and respond to comments using various methods within the interface. Your ability to view comments or receive e-mail notification of modifications (additions/updates) to comments is based on the comment type. Reviewers can add comments directly to submissions. Authors can view, track, and respond to comments.

You can be notified via e-mail when comments are modified, according to your assigned role (as determined by the Administrator) for that particular application. Permissions to specific applications and/or submissions that are granted by your Administrator determine whether you can view particular comments or receive e-mail notifications.

Comments can be added to various levels in the submission, including: documents, sections, or modules. Comments are assigned levels of security based on the visibility and e-mail notification requirements of the comment. These security and notification requirements create different types of comments: Public, Private, and Personal.

Note: Only an Administrator can purge comments from the system. For more information, see the topics about purging comments in the Ennov InSight Viewing Administrator Guide.

Comment Types

Security Level/Comment Type	Visibility	E-mail Notification
Public	Visible to all Administrator and non-Administrator users who have access to the application and/or submission.	All roles that are assigned e-mail notification privileges and those users with permissions to the application or submission. Regardless of settings, e-mail notification is sent to the comment owner. A comment owner is the individual who creates the comment.
Private	Visible to Administrators, Submission Managers, Publishers and the Reviewer (owner) of the comment.	Submission Manager, Publisher, or Administrator roles that are assigned e-mail notification privileges. Additionally, those users must have permissions to the application or submission. Regardless of settings, e-mail notification

		is sent to the comment owner when the comment is either updated or closed.
Personal	Visible only to the owner of the comment.	None

Comments Functions and User Roles

Public Comments - Open, In Review, In Progress

The following table shows the functional operations that you can perform with comments, according to the comment type and your assigned role.

Comment created by the user role	Ability of the user role				
	Administrator	Submission Manager	Publisher	Reviewer	Restricted Reviewer
Administrator	N, V, U, C, T	V, U, C	V, U, C	V, U	V, U
Submission Manager	V, U, C, T	N, V, U, C	V, U, C	V, U	V, U
Publisher	V, U, C, T	V, U, C	N, V, U, C	V, U	V, U
Reviewer	V, U, C, T	V, U, C	V, U, C	N, V, U	V, U
Restricted Reviewer	V, U, C, T	V, U, C	V, U, C	V, U	N, V, U

- N - Create new
- V - View
- U - Update
- O - Open
- C - Close
- T - Transfer

Examples of user roles and their ability to perform functional operations:

- If a comment is created by Administrator and is in the Open, In Review, or In Progress state, it can be viewed, updated, or closed by a Submission Manager.
- If a comment is created by Submission Manager and is in the Open, In Review, or In Progress state, it can be viewed, updated, closed, or transferred by the Administrator.

Public Comments - Closed

The following table shows the functional operations that you can perform with comments, based on the comment type and your assigned role.

Comment created by the user role	Ability of the user role				
	Administrator	Submission Manager	Publisher	Reviewer	Restricted Reviewer
Administrator	V, O	V	V	V	V
Submission Manager	V, O	V	V	V	V
Publisher	V, O	V	V	V	V
Reviewer	V, O	V	V	V	V
Restricted Reviewer	V, O	V	V	V	V

– N - Create new

– V - View

– U - Update

– O - Open

– C - Close

Private Comments - Open, In Review, In Progress

The following table shows the functional operations that you can perform with comments, based on the comment type and your assigned role.

Comment created by the user role	Ability of the user role				
	Administrator	Submission Manager	Publisher	Reviewer	Restricted Reviewer
Administrator	-	-	-	-	-
Submission Manager	-	-	-	-	-
Publisher	-	-	-	-	-
Reviewer	V, U, C, T	V, U, C	V, U, C	N, V*, U*	-
Restricted Reviewer	V, U, C, T	V, U, C	V, U, C	-	N, V*, U*

* Applicable only to the creator of the comment.

- N - Create new
- V - View
- U - Update
- O - Open
- C - Close
- T - Transfer

Private Comments - Closed

The following table shows the functional operations that you can perform with comments, based on the comment type and your assigned role.

Comment created by the user role	Ability of the user role				
	Administrator	Submission Manager	Publisher	Reviewer	Restricted Reviewer
Administrator	-	-	-	-	-
Submission Manager	-	-	-	-	-
Publisher	-	-	-	-	-
Reviewer	V, O	V	V	V*	-
Restricted Reviewer	V, O	V	V	-	V*

* Applicable only to the creator of the comment.

- N - Create new
- V - View
- U - Update
- O - Open
- C - Close

Personal Comments - Open, In Review, In Progress

The following table shows the functional operations that you can perform with comments, based on the comment type and your assigned role.

Comment created by the user role	Ability of the user role				
	Administrator	Submission Manager	Publisher	Reviewer	Restricted Reviewer
Administrator	N, V*, U*, C*, T, V**, U**, C**		-	-	-
Comment created by the user role	Ability of the user role				
Submission Manager	V, C, T	N, V*, U*, C*	-	-	-
Publisher	V, C, T	-	N, V*, U*, C*	-	-
Reviewer	V, C, T	-	-	N, V*, U*, C*	-
Restricted Reviewer	V, C, T	-	-	-	N, V*, U*, C*

* Applicable only to the creator of the comment.

** An administrator can view, update, and close the comments of other administrators. This is applicable only when the attribute value of enhanceRoleBasedSecurityForComments is set to true in the config.xml file. See: *Enhance Role-Based Security for Comments*.

- N - Create new
- V - View
- U - Update
- O - Open
- C - Close
- T - Transfer

Personal Comments - Closed

The following table shows the functional operations that you can perform with comments, based on the comment type and your assigned role.

Comment created by the user role	Ability of the user role				
	Administrator	Submission Manager	Publisher	Reviewer	Restricted Reviewer

Administrator	V, O*	-	-	-	-
Submission Manager	V	V*	-	-	-
Publisher	V	V	V*	-	-
Reviewer	V	V	-	V*	-
Restricted Reviewer	V	V	-	-	V*

* Applicable only to the creator of the comment.

- N - Create new
- V - View
- U - Update
- O - Open
- C - Close

Add Comments

Comments can be added at the module, section, or document level in the sequence view. In the current and cumulative view, you can add comments only at the document level.

When a new comment is added, its status is set automatically to Open. Before a comment status can be set to Closed, a comment or response must be added to the comment.

1. Right-click on a module, section, or a document in the table of contents and select Add Comment.
2. In the *Add Comment* window, select values for the following options to classify your comments:
 - Scope
 - Focus (The availability of this field depends on the Focus field settings in the config.xml file)
 - Priority
 - Type
 - Category
3. In the Comment Text box, enter your comments.
4. To add an attachment to your comment, click Select files and locate the attachment file on your system.

Files of any format can be attached to the comment.
5. Save.

The comments are added. Your role-based security and permissions to the application or submission, established by your Administrator, determines whether you will receive e-mail notifications.

View Comments and Modify the Comments Status

Selecting a module, section, or document in the TOC displays the comments attached to it under the *Comments* section on the left side of the Ennov InSight Viewing application.

Clicking an item in the Comments list opens the *Comment History* window. The *Comment History* window can also be opened by clicking the comment item in the Comments Report.

You can enter your comment/and or response to a comment in this window, and set the comment Status (Open, Closed, In Review, In Progress).

To respond to or add to a comment, enter your comments under the Enter your comment/response here field and click Add.

Add Comments

Note: *Closed comments may or may not be visible to you, according to the settings established for your role by your Administrator. An e-mail notification is sent to the users of all roles with assigned e-mail notification privileges and to users with permissions to the application or submission.*

Transfer Comments

A Ennov InSight Viewing administrator can transfer the comments from one user to another. Comments can be transferred only to a user with:

- the same role as that of the original comment owner
 - an Active status in the system
 - the same permissions as that of the original comment owner
- To transfer comments:

1. In the Ennov InSight Viewing Reports menu, select Comments Report.
2. In the *Comments Report Filter* window, set the criteria based on the available options to view the submissions with comments.
3. Click Display to view the Comments for the selected criteria.
4. Select the check boxes next to the individual comments or select the check box next to the Comment Text column header to select all the comments.
5. Click Transfer Comments.
6. Select a user for the comments transfer.
7. Click Transfer Comments and click Yes on the *confirmation* window. An e-mail notification is sent to:

- new owner

- person who transferred the comments – previous owner of the comments
- all roles with assigned email privileges
- persons with permissions for the application or submission

Close Comments

Any public, private, or personal comment(s) can be closed at the application, submission, module, element, or document level, and from different locations in the Ennov InSight Viewing interface.

Comments of Open, In Review, and In Progress status can be closed. See: *Comments Functions and User Roles* section.

Bulk closing of comments is restricted to Administrative users and is only available if enhanced security is configured in the config.xml file.

Transfer Comments

Administrators have two options available for closing comments from a submission:

- Navigator: TOC
- Comments Report :
 - change status to Close.
 - Close Comments button.

Close Comments from TOC

Ennov InSight Viewing enables users with appropriate permissions to close comments from the TOC.

Prerequisites

See *Comments Functions and User Roles* section.

To close comments:

1. Select the module, section, or document in the TOC to which comments are attached. The *Comments* section is on the left side of the application.
2. Click on the comments you want to close from the list.
3. Enter the reason for closing the comment in the Enter your comment/response here text field.
4. Change the status to Close.
5. Click Yes on the confirmation message. The comment is closed.

Close Comments from Comments Report

Ennov InSight Viewing enables an Administrator to close comments from the *Comments Report*, either by changing status or using the Close Comments option.

Prerequisites

Verify that Enhanced Role based security is enabled by setting the

enhanceRoleBasedSecurityForComments parameter in the config.xml file to true before closing comments with Close Comments option.

To close comments from Comments Report:

1. From the Reports menu, select Comments Report.
2. In the *Comments Report Filter* window, set the criteria to generate the report.
3. To view the comments for the specified criteria, click Display.
4. In *Comments Report Results*, select the desired comment.
5. Click Close Comments.
6. Enter the reason for closing the comment in the Enter your comment/response here text field.
7. Click OK.
8. Click Yes in the confirmation message window.

The closed comment is deleted from the *Comments Report Results*.

Chapter 10. Table of Contents - eCTD

The eCTD *Table of Contents* page has two panels: the *Table of Contents* on the left and the *Administrative Information/Document viewer* panel on the right.

Warning: Do not use the Back and Forward buttons on your Web browser to navigate within the application. Instead, use the navigation options provided within the Ennov InSight Viewing application.

Panels & Windows

You can adjust the width of panels using the vertical resize bars located between the panels. Click on the resize bar and drag it to make the panel wider or narrower.

Panel/Window	Description
<i>Table of Contents</i>	Displays eCTD or NeeS submission table of contents. To view the documents in the TOC, click on the documents. This will open the document in the Document Viewer. To see the document in an external browser, right-click on the document and click Open Document in External Browser.
<i>Module Buttons</i>	To view or hide the modules in the TOC.
<i>Lifecycle</i>	Displays the leaf lifecycle information.
<i>Properties</i>	Displays the XML properties information.
<i>Comments</i>	Displays the comments associated with the section or leaf.
<i>Reference Leaf Details</i>	Displays the details of the cross referenced documents. If the referenced document is present under a study or node extension, the study or node extension column will display the title of the study or node extension.
<i>Administrative Information</i>	Displays the submission administrative/envelope information.
<i>Document Viewer</i>	Displays the selected document (PDF, XML, images and other browser supported documents).

Buttons & Lists

Most buttons are active/inactive based on the current selection.

Panels & Windows

Button/List	Description
Submission	Select a sequence number, approved, cumulative, or current view. Sequence Number View - The sequence number view displays a sequence with all its leaf elements.

	<p>Cumulative View - The cumulative view provides a consolidated view of the eCTD sequences that includes all of their leaf elements.</p> <p>Current View - The current view is similar to the cumulative view but it does not include the deleted or replaced leaf elements of the sequences.</p> <p>Approved View - The approved view is similar to the cumulative view but displays only the submissions with status Approved.</p>
Activity	The Activity drop-down lists the sequence number and submission type of any sequence that does not have a related sequence number. This option enables you to filter the TOC based on the regulatory activity.
Disciplines	Filter the table of contents based on the discipline, such as the summary, quality, safety, efficacy, or DSI.
Country	Filter the table of contents based on the EU regions available for that application (available only for EU submissions).
Refresh	<p>Use the application Refresh button to refresh the TOC.</p> <p><i>Warning: Do not use the browser Refresh/Reload button to refresh the TOC.</i></p>
Back to Search	Return to the navigator search results. This button is available in the Document Viewer for the documents searched through the Submission Navigator and Search tabs. This button is not available for documents viewed through Recent Views.
URL	Copy the URL of a file, sequence, or application to the clipboard for access, sharing (via e-mail), and favorites.
Admin	View the submission administrative/envelope information.
Navigation Buttons	<p>Navigate backward and forward to previously viewed documents.</p> <p><i>Warning: Do not use the Back and Forward buttons on your Web browser to navigate to the previously viewed documents. Instead, use the navigation options provided within the Ennov InSight Viewing application.</i></p>
Reports	Lists the reports available to run.
Navigator	Return to the <i>Navigator</i> page.
Profile	Opens the <i>Profile</i> window.
About	Displays information about Ennov InSight Viewing.
Help	Opens help (this document).
Logout	Log off from the application.







Identify Invalid eCTD Links




Ennov InSight Viewing includes the capability to identify links that are no longer valid within a document. This typically occurs when the destination file for a particular link within a document has been either replaced or deleted in a subsequent submission.

Depending upon the settings established by your Administrator, you will be notified that the original destination file has been modified in subsequent submissions when a link is selected. You can then choose to open the original destination file or the modified destination file.

TOC Hierarchy


The table of contents (TOC) is always displayed in a hierarchical, or tree view. The Module appears at the very top of the hierarchy; and Sections, Sub-sections, Node Extensions, and STF are displayed following the DTD structure.

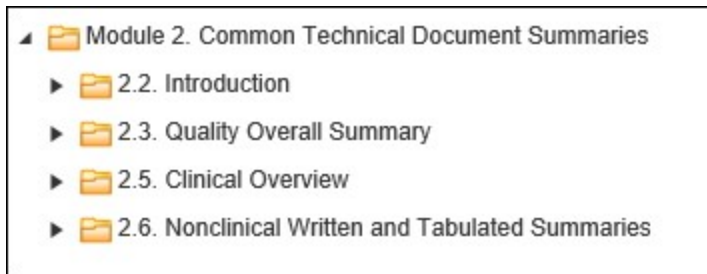
Item	Icon
Module	▶  Module 5. Clinical Study Reports
Section/Sub-Sections	▶  5.3.1. Reports of Biopharmaceutic Studies
Study Tagging File (STF)	▲  4211-new-4211-new
Node Extension (NE)	▲  Study 123
STF: File Tag	▲  Data tabulation dataset (FDA)
STF: Site	▲  site1


Item	Icon
Document	 Introduction.doc Document-specific icon based on user settings (when available).  Thumbs.db Unknown or not defined.
Document Cross Reference	 Introduction [new-0000]

Operation: New	  LEGACY [new-0000]
Operation: Append	  LEGACY [append-0001]
Operation: Replace	  LEGACY [replace-0001]
Operation: Delete	  Information for Professionals [delete-0001]

The TOC items (Modules, Sections, Node Extensions, STF and Sites) can be expanded or collapsed in several different ways:

– Clicking  in the TOC will expand the item.

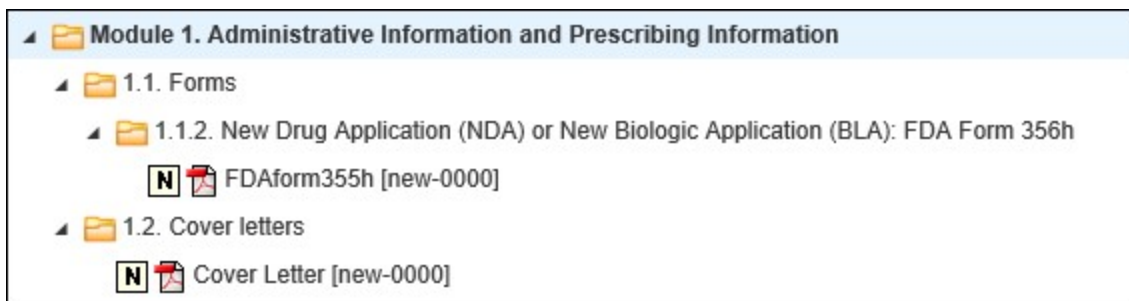


– Clicking  in TOC will collapse the item.



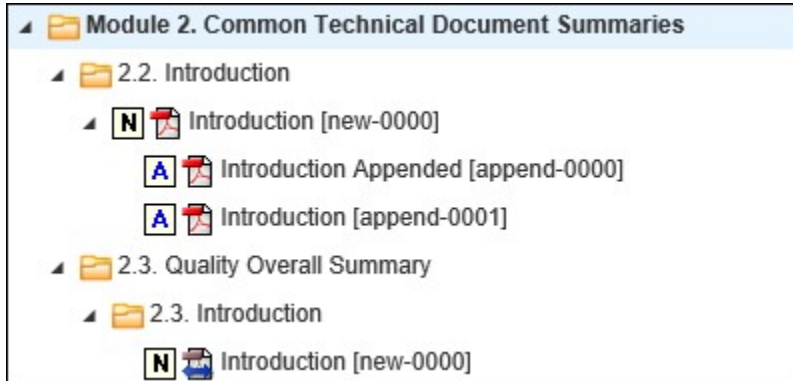
– Double-clicking on the item (on text only) will expand all submission items to the document level.

TOC Hierarchy



– Double-clicking on the expanded item (on text only) will collapse the clicked item.

– Selecting a document in the TOC will display that document in the document viewer. The Lifecycle and Properties information for that document will be populated in their respective windows.



Note: For FDA 3.3 submissions, the Form FDA 356h and Form FDA 1571 section/document will not be displayed under the TOC. The document link will be displayed under Administrative Information.

For China NMPA submissions (starting from Ennov InSight Viewing 5.5 CHF 5) a new feature that translates the names of TOC folders is included. Moving a mouse pointer over Module 1 shows the Chinese text in English and moving a mouse pointer over Modules 2-5 shows the English text in Chinese.

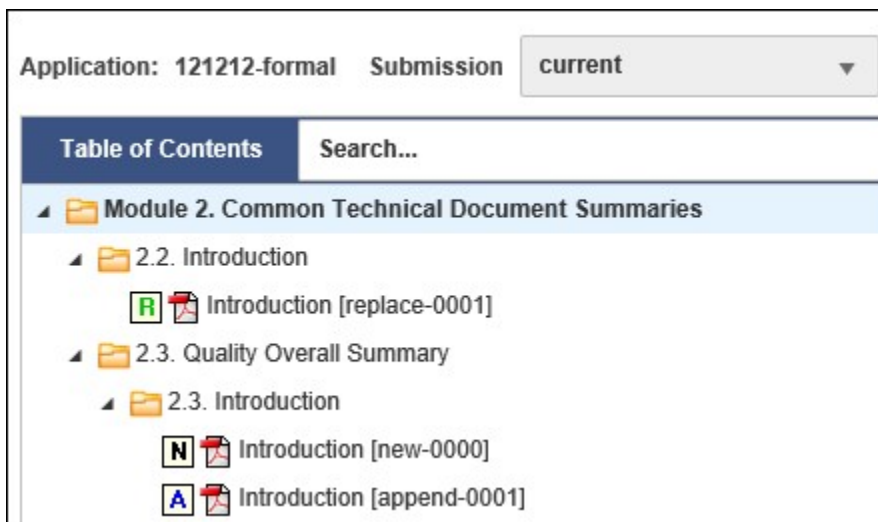
TOC Flat and Parent-Child Structures

Ennov InSight Viewing can display documents in the TOC at the same level as a flat structure, or as a Parent-Child structure where a modified leaf appears indented below the parent document.

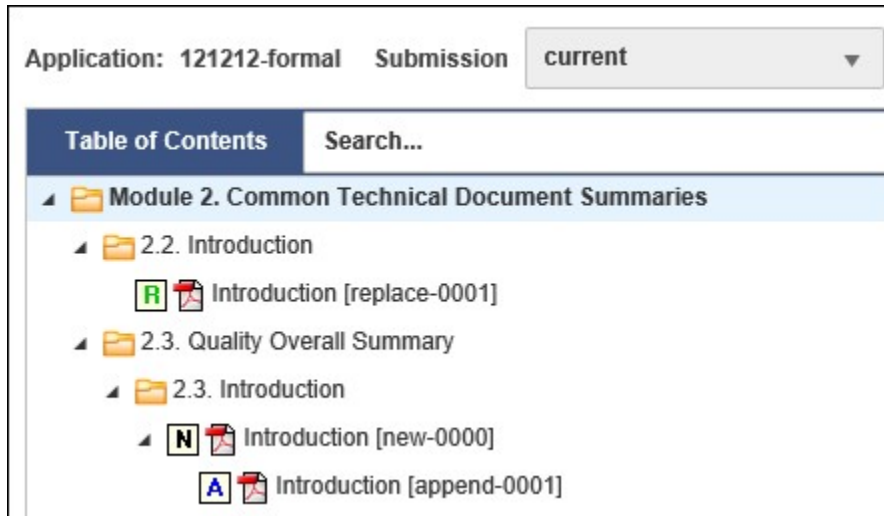
To display the TOC as a flat structure or as a Parent-Child, the appropriate value must be set for the attribute enableFlatTOCStructure in the config.xml file.

The TOC structure can be changed to display either Flat or Parent-Child structure by using the Cache Migration tool.

Flat Structure



Parent-Child Structure



Module Buttons

The module buttons are displayed based on the modules present in the Table of Contents and may include 1 to 5 buttons. Each button represents a specific module: M1, M2, M3, M4 and M5. Clicking on the module button will hide the corresponding module in the TOC. Clicking the module button again will show the module.

Lifecycle View

The *Lifecycle* window displays the document lifecycle information for the selected document.

The *Lifecycle* window includes links to all listed documents within this window. You can click on the links provided in Blue color to open the corresponding document in an external window. To sort the submissions based on the sequence number, operation, title, file path or the modified file, click on the respective column heading.

Properties Window

The *Properties* window displays the properties present in the XML backbone for a selected leaf.

At any time, you can focus in on only this window or a different window by clicking on the desired title bar below the Module buttons. To sort the properties based on the properties name or its value, click on the respective column heading.

Administrative Information

When an application or a submission is selected, the Administrative/Envelope information of it is displayed on the right.

The Administrative information is present in the regional XML backbone files in all submissions and contains region specific information about the submission.

When a single submission is selected to view, the administrative information will be displayed only for that selected submission.

When a document is displayed in the panel on the right, the administrative information is not visible. To view administrative information at any time, click the ADMIN button.

Document Viewer

You can read and navigate within the document using the tools in the Document Viewer window.

When a document is selected from the table of contents, the selected document is displayed in the window on the right side of the application. To view multiple documents at the same time, right-click on the document and click Open Document in External Browser.

The navigation within the displayed document is dependent on the type of document displayed. Ennov InSight Viewing displays .pdf, .htm, .xml, .jpg, .gif and other known format files in the *Document viewer* window on the right. Other format files such as .sas, .xpt, .zip, .doc, .rtf, .xls, etc., are downloaded to your computer.

Lifecycle View

To view documents of different file types in Ennov InSight Viewing, the software that supports the respective file type must be installed on the your system. Web browser-supported file types, such as XML, JPG, GIF, HTML, and Text files require only a web browser. **History Navigation**

When more than one document from the table of contents is viewed, the Back and Forward buttons of the document viewer are enabled. **PDF Navigation**

Navigation within a PDF document is performed according to the pdf.js library. Bookmarks and links are active and function as expected when they are valid.

When navigating within a PDF document, use the navigation buttons to view the previous and next pages:

The Ennov InSight Viewing Back and Forward buttons function only at document level and keep track of all the documents viewed using the table of contents. With the Back and Forward buttons or Alt+Left Arrow/Alt+Right Arrow keyboard shortcuts, you can navigate to the documents in the order they were viewed. You can switch back and forward through bookmarks and the links inside the document.

To turn on/off some layers, use PDF Layers.

Reference Leaf Details

Users with the proper role permissions can view details of a referenced leaf including: submission number, module, section, study/node extension title, leaf title, operation, and location/file name.

In the TOC, select a leaf identified with the cross-reference icon.

In the area below the TOC, the *Reference Leaf Details* section displays the source leaf and details of the associated cross-reference leaves, including:





- Submission
- Module
- Section
- Study/NE Title
- Leaf Title
- Operation
- Location and File Name

Chapter 11. Table of Contents - NeeS

The Documents and Folder are based on the folder structure present in the submission. Folder contents are sorted in alphabetical order.

Non-eCTD Electronic Submissions (NeeS)

The following icons are used:

Item	Icon
Submission Root	 Submission2
Folder/Sub-Folders	 OTHER
Document	 Summary.pdf Document-specific icon based on the user settings (when available)  Thumbs.db Unknown or not defined

Non-eCTD submissions do not include the lifecycle, and the document properties includes only limited information.

Usage

A document selected in the table of contents is displayed in the *Document Viewer* window.

Chapter 12. Filter Table of Contents

Ennov InSight Viewing enables you to filter the table of contents to view submissions, modules, and documents. The contents are filtered based on the submission, activity, disciplines, and country (only for EU and GCC applications) criteria that you select, and also by the text value you enter to extract documents with titles matching the text value.

When a particular regulatory activity is selected using the Activity filter, only sequences related to that activity will be displayed in the current and cumulative views. To view the table of contents with module outline numbering, select the option Display Outline Numbers.

Chapter 13. Columns

Sort Column Values

You can sort search results by column values for specific pages.

The ability to sort the column values is available on the following pages. The access to these pages depends on the security privileges for your role.

- Edit User
- Edit Application

Clicking on a column header sorts the values in an ascending or descending order. The Up and Down arrows indicate the values are sorted in ascending or descending order respectively. The third click on the column header removes the sorting. When you perform a sort, the order is automatically saved and remains until it is changed again. The sorting order is applied when you export an Excel or when you print a document.

Reposition Columns

You can change the order of the columns on the *Edit User* and *Edit Application* pages.

When you reposition columns, the order is automatically saved and remains until it is changed again. The same order is applied to the Excel you export or the document you print.

To change the position of a column:

1. Press and hold your left mouse button on the column header.
2. Drag the column to the desired position and release the mouse button.

Column Width

You can change the column width on the *Edit User* and *Edit Application* pages

The column width you set is automatically saved and remains until it is changed again. The same width is used for the Excel you export or the document you print.

1. To adjust the width of a column, hover your mouse pointer over the border between two column headers. Your pointer will become a double-sided arrow.
2. Press and hold your left mouse button, then move the pointer left or right to adjust the column width.

Column Filters

The column filters enable you to filter the content based on the required criteria.

The column filters are available on the following pages. The access to these pages depends on the security privileges for your role.

- Edit User
- Edit Application
- Administrative Information

For filtering instructions and operators, see *Filter Grid Content* , *Filter Operators*.

Filter Grid Content

Use the column filters to search for specific data in a grid.

To filter content:

1. Click the Filter icon next to the column header.
2. Use the filter operators to set the required criteria. See: *Filter Operators*.
3. Click Filter.

Filter Operators

Filter operators enable you to set the required criteria for filtering content.

This table lists the filter operators and their descriptions.

Operator	Description
Is equal to	Use to display records that have the operator value.
Is not equal to	Use to display records that do not have the operator value.
Starts With	Display records that contain values that begin with the operator value.
Ends With	Display records that contain values that end with the operator value.
Contains	Display records that contain operator value.
Does Not Contain	Display records that does not contain the operator value.
Has value	Display only those records that have a specific value.
Has no value	Display only those records that have no value.

Chapter 14. Interceptor

When a document is hyperlinked to a target document that has been replaced or deleted, Ennov InSight Viewing shows an interceptor message notifying a user of the activity.

If a target document has been replaced during lifecycle, a notification message presents the option to view the original document or an updated document. If the document was deleted during lifecycle, you can view the original document.

Note: For Ennov InSight Viewing to display an interceptor message, the attribute `<property name="interceptorEnable">` in the `config.xml` file must be set to `True`. See: [Intercept Invalid eCTD Links](#)

If the content of an updated document is different from the original document, clicking Go to Updated Document sends you to the first page of the document. However, if the content of the updated document is the same as the original document, clicking Go to Updated Document sends you to the updated section.

Chapter 15. Print TOC

Use the Print TOC feature to generate sections of the table of contents (TOC) in a rich text format (RTF) file. This file can be printed to produce the paper format of the TOC.

The TOC file can be generated from the current, cumulative, or sequence views

1. Select the section in the TOC, right-click, and choose Print TOC.
2. Choose the options Include File Name and Indent TOC Entries, as necessary.
3. Click OK.

A rich text format TOC file is created.

Chapter 16. Reporting

Ennov InSight Viewing includes a variety of reports to aid you with the submission review process.

– Comments Report - The Comments Report displays information about comments created in the system such as the comment text, status, scope, focus, created by, and created time with the application, submission, module, type, priority, and category.

– Review Matrix By User Report - The Review Matrix By User Report displays the overall activity of accessed documents and the user details in the selected application/submission.

– Auto Registration Report - The Auto registration report displays the new and updated auto registered submissions for an application.

– User Group Report - The User Group Report gives you the details of a user group such as the permitted applications, users, and disciplines. For EU regions, you can get details about the permitted EU countries.

Option	Description
User Group	Permitted user groups available for filtering.
Application Group	Permitted application groups available for filtering.
Application	Option for registered and indexed applications.
Submission	Submission for the selected application.
Module	Options are All and each available module number for the selected submission. When All is selected, the comments entered in the modules are displayed.
Current Owner	Options are All and all the permitted users.

Comments Report

Use the *Comments Report* to view comments added to submissions by authors and reviewers.

1. In the Ennov InSight Viewing Reports menu, select Comments Report.
2. In the *Comments Report Filter* window, set the criteria using the options available to generate the report.
3. Click Display to view the comments for the specified criteria.

Comments Report Filtering Options

You can use specific criteria to filter the results of the Comments Report.

Use the following options to filter the Comments Report.

Option	Description
--------	-------------

<p>Priority</p>	<p>Options:</p> <ul style="list-style-type: none"> – All – High – Medium – Low <p>When All is selected, each priority is displayed.</p>
<p>Scope</p>	<p>Options:</p> <ul style="list-style-type: none"> – All – Private – Public – Personal <p>When All is selected, each scope is displayed.</p>
<p>Type</p>	<p>Options: – All</p> <ul style="list-style-type: none"> – Issue – Comment – Content – Formatting – Linking <p>When All is selected, each comment type is displayed.</p>
<p>Status</p>	<p>Options:</p> <ul style="list-style-type: none"> – Open – Closed – In Review – In Progress <p>Your administrator determines whether closed comments are displayed or hidden in the interface.</p>

Focus	<p>Options:</p> <ul style="list-style-type: none"> – Both – Regulatory Affairs – Publishing <p>The availability of this field depends on the Focus field settings in the config.xml file.</p>
Category	<p>Options:</p> <ul style="list-style-type: none"> – All – Regulatory – Clinical – CMC <p>When All is selected, each category is displayed.</p>
Title	You can enter one or more titles separated by spaces.
From	User Entered value(s). When you enter one date, the application will search for the specified date. When you enter both date values, the application displays the matching submissions within the specified date range, including the start date.
To	User Entered value(s). When you enter the From date, the application searches for all comments entered from that day to the current date. When you enter both the From and To dates, the application searches for all the comments entered within the specified date range. You have the option to enter the date in MM/DD/YYYY format or to select the date using the date selection tool.
Any Term	When selected, search results are based on any criteria that matches. The search uses the OR condition to find the matching application/ submission/module/scope/ user and status.
All Terms	When selected, search results are based on all criteria that matches. The search uses the AND condition to find

	the matching application/ submission/module/scope/ user, status, type, priority, and category.
Grouped Submissions	Searches submissions that are part of a grouped submission.
Purge Comments	Administrators can purge all comments from the selected submission. This button is activate when query results are displayed.
Transfer Comments	Transfers comments to another user.

Review Matrix By User Report

Use the Review Matrix Report to view the overall activity of the documents accessed and the user details for the selected application or Submission.

1. On the Ennov InSight Viewing Reports menu, select Review Matrix By User Report.
2. On the *Review Matrix By User Filter* page, set the criteria to generate the report.
3. To view the Review Matrix report for the specified criteria, click Display.

The review matrix report by user shows on the right.

Review Matrix Report for Section/Document

In the table of contents, right-click on a module, section, or document and select Review Matrix for Section/ Document. The Review Matrix report is displayed.

Option	Description
Display	Displays the matching Comments Title, Status, Created By, and Created Time with the Application, Submission, and Modules.
Print	Prints the report.
Reset	Clears the selected options and the results displayed from previous search.
Refresh	Use this option to view the latest results.
Close	Closes the window. When comments are closed, an e-mail notification is sent to the owner of the comments.
Export to Excel	Administrators can export Comment Report results to an Excel file.

- To print the report, click the Print icon.
- To save the report in .xlsx format, click the Excel icon.
- To close the report, click Cancel.

Review Matrix By User Report Filtering Options

You can refine and organize a Review Matrix by User report using the filter options.

Option	Description
Application	Lists the registered and indexed applications.

Auto Registration Report

Use the Auto Registration Report to search for new and updated auto registered submissions for an application. If no submissions are registered automatically, no results will be displayed. Only the applications that you have permission to access are displayed.

Note: If Auto Registration is not activated for a particular application, the report will not generate any results. Your administrator can modify the auto registration options specified in the Administrator interface.

1. On the Ennov InSight Viewing Reports menu, select Auto Registration Report.
2. On the *Auto Registration Report* window, set the criteria using the options available to generate the report.
3. Click Display.

The new and updated auto registered submissions show.

Option	Description
User	Lists the options All and each available user name of the users who have entered comments under the selected submission. When All is selected, the comments entered by all the users are displayed.
Submission	Select a submission listed for the selected application.
Module	Lists the options All and each available Module Number for the selected Submission. When All is selected, all the comments entered in the modules are displayed.
Display	Display the review matrix report based on the options selected.
Print	Print the report.
Reset	Clear the options selected as well as the results displayed from previous search operation.
Export to Excel	Export the report to an Excel file.

Auto Registration Report Filtering Options

You can refine and organize an Auto Registration report using the filter options.

Option	Description
Application	Lists the applications that are enabled via the Administrator interface options: Automatically Register Updated Submissions and/or Automatically Register New Submissions.
Type	The options are New and Update.

User Group Report

Use the User Group Report to view the details such as the permitted applications, users, and disciplines of a user group. For EU regions, you can also view details about the permitted EU countries.

1. In the Ennov InSight Viewing Reports menu, select User Group Report.
2. On the User Group Report Filter page, set the criteria to generate the report.
3. To view the User Group report for the specified criteria, click Display.

The user group report shows on the right.

User Group Report Filtering Options

Option	Description
Date of Registration	User entered value(s). When you enter only one date in the calendar (From), the application will search for the specified date. If you enter both date values (From / To), the application displays matching submissions within the specified date range, including the start date and end date. You have the option to enter the date in <i>MM/DD/YYYY</i> format or to select the date using the date selection tool that is provided.
Display	View auto registered applications.
Print	Print the report.
Reset	Clear the options selected as well as the results displayed from previous search operation.
Export to Excel	Export the report to an Excel file.

You can refine and organize a User Group report using the filter options.

Option	Description
Repository	Filter user groups associated with a specific repository.

User Groups	View details pertaining to a specific user group.
Application Groups	The options All and each available application group for the selected User Group are listed. When All is selected, all the application groups associated with the selected user group are included in the report.
Permitted Disciplines	The options All and each permitted discipline for the selected Application Group are listed. When All is selected, all the permitted disciplines associated with the selected application group are included in the report.
Permitted Users	The options All and each permitted user for the selected User Group is listed. When All is selected, all the permitted users of the selected user group are included in the report.
Permitted EU Countries	The options All and each permitted EU country for the selected User Group are listed. When All is selected, all the permitted EU countries of the selected user group are included in the report.
Display	Display the user group report.
Print	Print the report.
Reset	Clear the options selected as well as the results displayed from previous search operation.
Export to Excel	Export the report to an Excel file.