Ennov InSight Publishing eCTD 4.0

Contents

Introduction

eCTD 4.0 focuses on easing the process and review of regulated product information. eCTD 4.0 is the new standard in pharmaceutical industry that contains new requirements and improvements based on implementation and usage of eCTD v3.2.2.

The following are the key eCTD 4.0 capabilities:

Single Submission Unit message

The Single Submission Unit message includes submissionunit.xml and submission content and contains information necessary for a sequence.

Context of Use

The Context of Use is used to add documents under a CTD heading and related keywords.

Keywords

Keywords define the submission information under an eCTD section. Keywords replace the eCTD 3.2.2 attributes and valid values.

A single keyword for each keyword type must be included in the context of use.

Context Groups and Life Cycle

A context group combines context of use and keywords and places a document under an eCTD section.

Document Reuse

The eCTD v4.0 message can include references to documents previously submitted in separate applications by referencing the unique identifier of a document.

Ennov InSight enables you to create a complete submission package.

— eCTD 4.0 includes a new structure that enables the use of a single format for ICH, Japanese, and US specifications.

— With eCTD 4.0, the maintenance is simplified and regulatory changes for compliance are addressed without delay.

— Easily manage subsequent amendments, supplements and variations to your submissions using intuitive rightclick menu options and simple drag-and-drop features, making all updates in the context of the full application.

— Create multiple submissions in multiple regions using comprehensive, built-in templates.

— Automatically transform documents in multiple file formats into enhanced PDFs with bookmarks and hyperlinks.

— Move seamlessly from product registration management to submissions management to publishing your submission to track user data.

eCTD 4.0 Template Files

Use eCTD 4.0 templates to organize tree structure to conform to the ICH and regional specifications defined in the Controlled Vocabularies (CV) and the lists of headings provided by agencies. Most of the headings have a direct mapping to Context of Use codes.

With eCTD 4.0 templates, you can organize and include granularity by deleting unnecessary folders and leaf elements or adding additional leaf elements. Typical ways to use the eCTD 4.0 templates include:

— Creating an assembly using the Create eCTD Wizard that is mapped to the regional Module 1 and eCTD 4.0 ICH Module 2-5 template.

— Creating a template based on a regional Module 1 template, importing eCTD 4.0 ICH Module 2-5 template and subsequently creating assemblies using eCTD 4.0 template.

The following topics provide information about specific eCTD 4.0 templates provided with Ennov InSight: — *eCTD 4.0 Template Files*

— *Assembly Templates and Controlled Vocabulary Dependencies*

— *Module 1 eCTD 4.0 Regional Templates*

Ennov InSight includes ICH-compliant eCTD templates with associated Context of Use codes. The provided assembly templates do not have strict dependency on Ennov InSight version, but rather proper CVs within CV profiles are required for the successful import.

Some Context of Use codes assume additional attributes defined by controlled vocabularies. The relationship between assembly templates and controlled vocabularies is defined through CV profiles in Publishing Settings Library.

Assembly Templates and Controlled Vocabulary Dependencies

Define the eCTD 4.0 submission structure with additional attributes and simplify your assembly template and CV dependency management.

Regulatory agencies provide lists of headings, controlled vocabularies with names, Context of Use codes, additional attributes and more. The structure of an eCTD 4.0 submission is defined by all of these components. Assembly template created for specific specification version includes the correct structure of headings, with specified Context of Use codes. These codes conform to the controlled vocabularies provided with the same specification. The assembly template gets value in conjunction with corresponding Context of Use codes. When different versions of controlled vocabularies and assembly templates are used, it can lead to unexpected behavior. The Context of Use codes controlled vocabulary is reliant on other CVs that define additional attributes. Controlled vocabularies are used in a special Envelope configuration to provide regional information for a given specification version. In Ennov InSight , all controlled vocabularies of some specification version are grouped as a CV profile. You can easily manage assembly templates and their CV dependencies using CV profiles.

Module 1 eCTD 4.0 Regional Templates

Each regional eCTD 4.0 template has controlled vocabulary attributes in the Module 1 folder to conform to regional regulatory guidelines and requirements.

Module 1 of the eCTD 4.0 contains regional content and metadata about a submission, as defined by the regional regulatory authorities.

When an assembly is created using the Create eCTD Wizard, the wizard filters the template to only display structure

for the countries already associated with that sequence

Publishing Settings Library Templates

Use the Publishing Settings Library Templates (PLT) for assembly consistency and optimized publishing.

Ennov InSight Publisher provides the ability to create multiple Publishing Settings Library Templates. The Ennov InSight Publishing Settings Library separates the publishing settings from the assembly structure. This enables you to control different publishing settings, link profile settings, variable settings, and overlay settings, for use within an assembly.

Publishing Settings Library Templates are stored and are accessible outside of an assembly. With Ennov InSight licenses for Electronic Lifecycle Publishing and Paper Review Publishing, PLTs can be created, or modified and saved for use when creating an assembly. Administrators with appropriate privileges can create and modify PLTs. User roles may have NONE, READ, WRITE, or DELETE permissions for access to Publishing Settings Library Templates.

Default Publishing Library Settings Template

Ennov InSight includes a default Publishing Library Settings Template (PLT) that can be used with its existing settings, or it can be modified to create additional PLTs.

The default Ennov InSight Publishing Library Settings Template includes the following publishing element settings. An asterisk (*) indicates a required field.

Template	Field Name	Value
Publishing Settings Library	Name	Default
Publishing Settings	*Printer	Generic PDF
	*Paper Size/Type	Letter
	*Tab paper Size/Type	Plain Letter 5 down Tab
	*Preview Location	blank
	XML Definitions	stf-2-2-5-0
	Default Rendition Identifier	Standard Rendition
	Missing Rendition Identifier Handling	Use Standard Rendition
	In-Process Rendition Location	blank
	TOC Destination Not Found Text	blank
	Cross-Reference Destination Not Found Text	blank
	Expand Bookmarks to Level	All
	PDF Version for Published Output	1.4, Acrobat 5
Volumes	*Volume File Naming Format	$VOLNAME
	*Begin at Volume Number	1
	*Total Sheets/Pages	300
	*Total Sheets/Pages Buffer	50
	Volumize by Size	No

	*Total Size (in MB)	100
	*Buffer Size (in MB)	10
	Volume Numbering	Assembly Relative
	Automatically Create Volume Tables of Contents	No
Link Profiles	*Link Profile Name	System Profile
	Default?	Yes
	*Electronic Hyperlink Style	Underline
	Electronic Hyperlink Color	Blue
	*Margin Cross-Reference Size	blank
	Margin Cross-Reference Text Font Style	blank
	Margin Cross-Reference Text Format	blank

Publishing Settings Library and License Modules

Publishing Settings Library Templates (PLT) are available with varying limitations according to your Ennov InSight license.

License Module	PLT
Electronic Lifecycle Publishing (ELP)	Available.
Paper Review Publishing (PRP)	Available. PLT is included.
Submission Planning and Tracking (SPT)	Includes a default PLT that cannot be modified. Only the default PLT is available when creating an assembly.
Registered Document Analysis (RDA)	Includes a default PLT that cannot be modified. Only the default Available when creating an assembly.
Registration Planning and Tracking (RPT)	Not available.
Product Detail Management (PDM)	Not available.

License Module	Available Tabs
Electronic Lifecycle Publishing (ELP)	— Publishing Settings
	— Default Values
	— Default Study Folder
	— TOCs
	— Variables
	— Link Profiles
Paper Review Publishing (PRP)	— Publishing Settings
	— Volumes
	— Cover Pages
	— Tabs
	— Slip Sheets

	— TOCs — Overlays —Variables —Link Profiles

Publishing Settings Libraries and Security Permissions

Access to PLTs and APLs is controlled by permission settings assigned to a user (or role) in the system.

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Publishing Settings Library and License Modules

Area	Permission Setting	Description
Publishing Settings Library Templates (PLT)	NONE	You have no access to, and cannot view, PLTs in the system.
	READ	You can only view PLTs in the system.
	WRITE	You can create, edit, and view PLTs, and all library elements can be created, edited, and viewed.
	DELETE	You can delete, create, edit, and view a PLT and all library elements.
Home Page Access to	Yes	The PLT tab can be accessed on the Home page.
PLT	No	The PLT tab is not available on the *Home* page. However, PLTs can be accessed via links from APLs, and can be created from the New menu.
Assembly Specific Publishing Library (APL)	NONE	You have no access to, and cannot view, APLs in the system.
	READ	You can only view APLs in the system.
	WRITE	You can create, edit, and view APLs and all library elements. WRITE or higher permissions are required to create a new Assembly and associate an APL. To use a PLT to create an APL, you must have READ or higher permissions on the PLT.
	DELETE	You can delete, create, edit, and view a APL and all library elements. To delete an Assembly, you must have DELETE permission.

Assembly Specific Publishing Settings Libraries

Assembly Specific Publishing Settings Libraries (APL) are created based on a Publishing Settings Library Templates (PLT) or on an APL from another Assembly.

Follow when you create an APL.

— An Assembly must have an associated APL.

— An APL is specific to the assembly that is being published.

— An APL can be saved as a PLT for use with other assemblies.

— A PLT cannot be modified at the assembly level.

— READ or higher system privileges are required to view, create, modify, or delete an APL.

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Assembly Specific Publishing Settings Libraries

Create a Publishing Settings Library

The Ennov InSight Publishing Settings Library separates the publishing settings from the assembly structure, enabling you to control different publishing settings, link profile settings, variable settings, overlay settings, for use within the assembly.

To create a Publishing Settings Library Template (PLT) in Ennov InSight :

1. On the New menu, click Publishing Settings Library Template.
2. On the Create Publishing Settings Library page, enter a *Publishing Library Name*.
3. Optionally, add additional details for your new Publishing Library.

   This additional information may be useful search criteria when there are many PLTs in the system.

   — Publishing Library Owner (This field is automatically populated with the creation owner, but can be updated.)

   — Created From (This field is not populated at the Template level.)

   — Publishing Library Keywords

   — Publishing Library Description — Publishing Library Add Comment
4. Save.

Your new Publishing Settings Library appears. The new Publishing Settings Library

Template is ready for the publishing settings to be established.

Create a Publishing Settings Library Template from an Existing PLT

Publishing Settings Library template (PLT) can be created from an existing PLT to use customized publishing settings for specific submission requirements.

In an Electronic Lifecycle Publishing (ERP) licensed system, only users with WRITE or greater permissions can create a new Publishing Settings Library Template (PLT) from an existing Publishing Settings Library Template.

To create a Publishing Settings Library template from an existing PLT:

1. On the Ennov InSight *Home* page, click Publishing Templates.
2. Choose an existing PLT in the Publishing Library Name list.
3. On the Publishing Settings Library toolbar, click Create Publishing Settings Library Template.
4. On the *Create Publishing Settings Library Template* page, provide a new name in place of Publishing Library Name for the new template and add additional information as needed.

   — The Publishing Library Name is required.

   — You can include Publishing Library Keywords, Description, and Comment. Existing Keywords and Descriptions are copied from the source PLT, Publishing Library Comments are removed.
5. Click Save.

The new Publishing Settings Library Template inherits the publishing settings from the PLT from which it was created. These settings may be modified.

Ennov InSight Publisher 7.3: eCTD 4.0 Create a Publishing Settings Library

Overlay Templates

Overlay templates enable you to add headers, footers, and other elements to the pages of your publication.

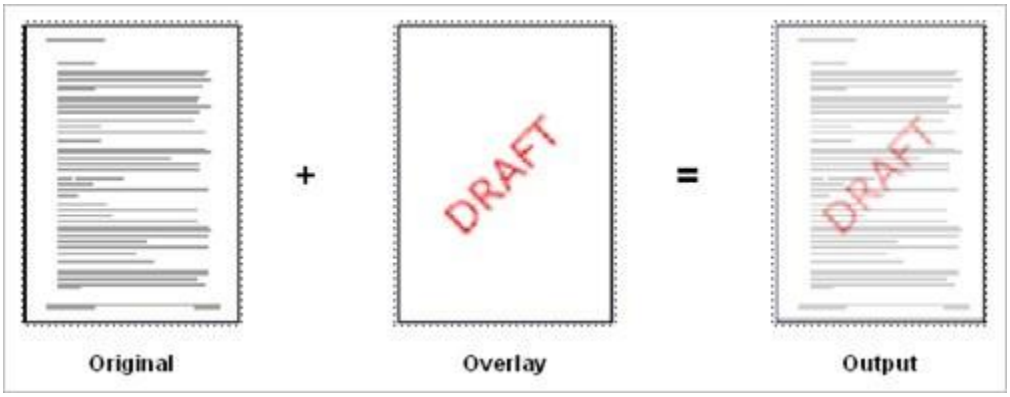
This includes page numbering and other variable data from Ennov InSight , resolved during publishing. Documents, TOCs, and cover pages may use the same or different overlay templates.

Cover page templates are similar to overlay templates, but they also allow variable placeholders in the body of the cover page.

Overlay Template File

Ennov InSight enables you to merge two PDF files so you can customize documents with headers and footers or apply a watermark.

You can apply different overlay templates to cover pages, TOCs, and documents in a submission. This effect is similar to that of a commonly used technique using transparencies and paper originals. The overlay information is printed onto a transparency, the transparency is placed onto a photocopier, and another document is placed on top of the transparency with the output being a merger of the two documents:



An overlay file is a PDF file that can contain a combination of fixed text and variables each page, including the following Assembly variables:

— Paper

— Electronic

— Variables that contain other variables

— Variables that contain formatting for other variables

— Data administration variables

— System-defined

— Ennov InSight

— Repository

— User-defined

You can create overlays in any document format that can be subsequently converted to PDF. Overlay files usually contain a single page, but you can define additional pages with an alternative page size or orientation that Ennov InSight can apply when source pages have different sizes. For examples of overlay files, refer to the samples provided for you in the installation files.

Variable Code and Delimiters

Variables are stamped on overlay files using the less-than sign or the greater-than sign, < and >, surrounding the variable's code. When a document is published, the delimiters and variable code are replaced with the resolved variable value. The space between the delimiters determines the size of the text to be placed at that position. Any

text that extends beyond these limitations is clipped. You can align the final stamp of each variable as follows: — <Left_Aligned >

— < Right_Aligned> — < Centered >

The fonts used for variables in Overlay Templates must be installed on all Ennov InSight Rendering servers used to publish output with these overlays.

In addition to size and alignment, the delimiters and variable code specify the font, point size, and formatting of the text. In order to be correctly recognized and formatted, the delimiters and variable code must all share the same font, point size, and formatting.

Less-Than Sign (<) and Greater-Than Sign (>)

In an overlay template, do not use the less-than sign or the greater-than sign, except to enclose variables. Using these characters for any other purpose can cause undesired results.

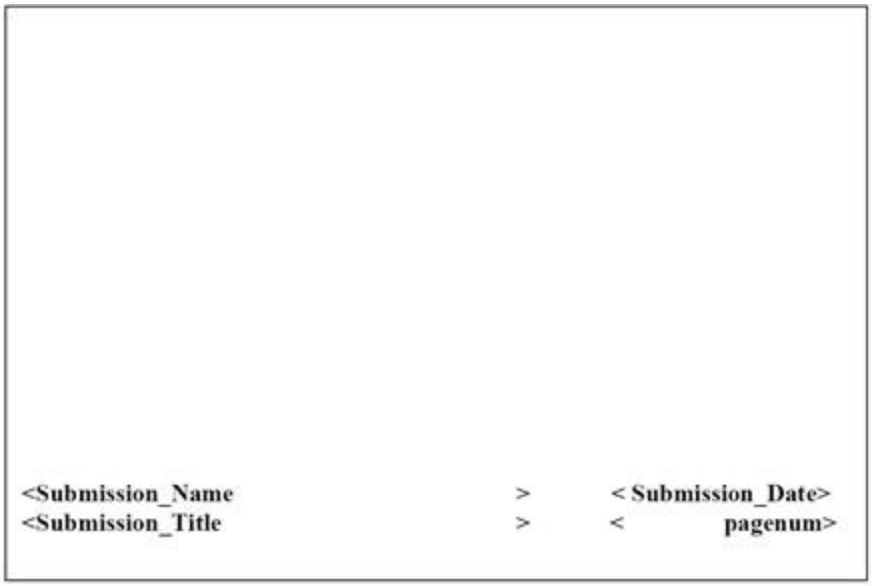
Japanese Characters

The font of the delimiters and variable code also determines which characters can be stamped. Most fonts do not contain all Unicode characters. If you intend to include Japanese characters in variable resolutions for example, make sure the font used for the delimiters and variable codes includes all of the characters that may occur in resolved variables.

Overlay Footer Example

In this sample, the variables *Submission_Name* and *Submission_Title* are left aligned, and the variables *Submission_Date* and *pagenum* are right aligned. These variables are not predefined system variables, so you must define them at the assembly level or they must be defined by an administrator in data administration userdefined variables.

Portrait Overlay Footer



Change an Overlay for a Document

Overlay templates enable you to add headers, footers, and other elements to the pages of your publication. This includes page numbering and other variable data from Ennov InSight , resolved during publishing. Documents may use the same or different overlay templates. To change an overlay for a document, cover page, or toc:

1. Select the element with an overlay you want to change.
2. Click Edit.
3. Choose an overlay from those available in the Overlay Setting list.
4. Save.

Modify an Existing Overlay

Overlay templates enable you to add headers, footers, and other elements to the pages of your publication. You can modify an existing overlay.

This includes page numbering and other variable data from Ennov InSight , resolved during publishing. Documents, TOCs, and cover pages may use the same or different overlay templates.

1. Go to the *Publishing Templates* page and choose a Publishing Library.
2. In the selected Publishing Library, open the Overlays tab to modify or add overlay settings.
3. Save.

Hide Headers and Footers with an Overlay

You can hide the headers and footers created by an assembly in Microsoft Word.

1. Open the overlay document in Word.
2. View headers and footers.
3. Insert a text box into the header and resize it to fill the width of the screen and desired depth from the top of the page.
4. Edit the text box and do the following:
   - Select White for the fill color for the text box.
   - Select either No Line or White for the line color.
5. Insert variables and/or images into the text box.

Modify Publishing Settings Library Templates

You can access a Publishing Settings Library Template (PLT) from the Ennov InSight *Home* page and can modify it. To modify publishing settings library templates

1. On the Ennov InSight *Home* page, click Publishing Templates.
2. In the Publishing Library Name list, choose a saved PLT.

   After opening the Publishing Settings Library Template, use the following procedures to modify the publishing settings.
3. On the selected *Publishing Settings Library* page, click the tabs on the *Publishing Settings Library* page to view, add, or modify the PLT settings.

Publishing Settings

- Default Values
- Default Study Folder
- PDF Properties
- Volumes
- Cover Pages
- Tabs
- Slip Sheets
- TOCs
- Overlays
- Variables
- Link Profiles

Note: *The procedures and attributes for each PLT tab are described in the corresponding topics and can be applied to both the Publishing Settings Library Templates (PLT) and the Assembly Specific Publishing Settings Library (APL).*

4. On each tab: click Create or Edit, add or modify the settings, and Save.

Create Publishing Settings

In the selected Publishing Settings Library, you can create or modify the Publishing Settings to adjust locations, rendition identifier, PDF version and CV Profiles.

For eCTD 4.0 assemblies, this procedure applies to Assembly Specific Publishing Settings Library (APL) only. See *Publishing >Create Publishing Settings*.

1. On the *Publishing Settings Library* window, select Publishing Settings .
2. Click Create:  .
3. On the *Create Publishing Settings* page, use the Preview Location
4. Click Browse to locate and select the location.
5. Complete the remaining fields as needed:

— CV Profiles

— Default Rendition Identifier

— Missing Rendition Identifier Handling

— Cross-Reference Destination Not Found Text

— Expand Bookmarks to Level

— PDF Version for Published Output

Note: *Ennov InSight includes functionality to specify the rendition identifier to allow for a non-default Documentum or*

Veeva rendition to be used for publishing jobs. This value can be set in Publishing Settings Library Templates (PLT) and

Assembly Specific Publishing Settings Libraries (APL). On the Publishing Settings tab, the option Default Rendition Identifier lists the values configured using the DMS Integration Rendition Identifier Values in Data Administration. See Maintaining a DMS Integration Value.

6. To save the new Publishing Settings, Save. To discard the changes, Cancel.

Publishing Settings Attributes

The attributes describe the details of the publishing settings used in a Publishing Settings Library Template (PLT). Required information is indicated by an asterisk (*).

Attributes	Description
Cross-Reference Destination Not Found Text	Specify the text to insert when Ennov InSight attempts to insert a margin crossreference but cannot resolve the variable. If blank, no margin cross-reference is created for links that cannot be resolved.
Attribute	Description
CV Profiles	Describes controlled vocabulary profile for eCTD 4.0. This field is not updated if the assembly is in the Sequence view and already added to life cycle.
	Note: *Changing of CV Profiles in Publishing Settings may lead to unexpected behavior affecting the Context of Use selections, additional and regional attributes.*
Default Rendition Identifier	Specify the default rendition identifier for the document. The default is Use Standard Rendition.
Expand Bookmarks To Level	Specify the number of levels to which bookmarks are expanded on the initial opening of electronic (PDF) files published from Ennov InSight . You can choose to expand bookmarks from 1 to 20 levels, or expand ALL bookmarks, when the published PDF files are opened. The expansion of bookmarks applies to all Publish to eCTD/Electronic options except XML only.
Missing Rendition Identifier Handling	Specify the rendition identifier to use when none is assigned to a document, or if the as-signed rendition identifier does not exist in the system. The default is Use Standard Rendition.
PDF Version for Published Output	Select the PDF version for your published output. The default PDF version is 1.4, Acrobat 5. Optional values are: 1.3, Acrobat 4; 1.4, Acrobat 5; 1.5, Acrobat 6; 1.6, Acrobat 7; 1.7, Acrobat 8.

CV Profiles in Publishing Settings

The CV Profiles (controlled vocabulary profiles) settings determine the set of CVs that is used for publishing your eCTD submission.

These files are generally associated with a specific assembly template, but submissions based on earlier versions of the specification may be updated to newer specifications by selecting the latest CV profile in the Publishing Settings of the active working assembly. CV Profiles are created in *Data Administration* by accumulating CVs under one profile.

For eCTD 4.0, you typically select a regional CV Profile, and the standard ICH CV profile.

For better experience, one regional CV profile should be assigned to one assembly.

CV Profiles Version Updates

Modify publishing settings to make changes to Controlled Vocabulary (CV) profile versions.

Note: *Changing the previously saved CV Profile settings will update assembly metadata and add new attributes to the existing data. Be aware that it affects the existing data and make the changes if required.*

To update the CV Profile version:

1. Apply the new controlled vocabulary profile in Edit Publishing Settings > CV Profiles field.
2. Click Save.
3. Right click on the root assembly folder and select Refresh Tree .

Applying the new controlled vocabulary profile updates the assembly according to the newly added CV profile :

— Context of Use codes

— Values in extended attributes

eCTD Publishing Settings

Specifying the general electronic eCTD publishing settings enables the entire eCTD assembly to inherit leaf element and study folder attributes. These settings contribute to default values for leaf elements in the eCTD XML files, and the default properties for study tagging or other study XML files.

The eCTD publishing settings are applicable to both the Default Values and the Default Study Folder in the Publishing Settings Library Template (PLT) and the Assembly Specific Publishing Settings Library (APL).

Generally, these settings are used to either:

— Set up a global value for an XML attribute that generally will not change, for example: the font library.

— Inherit this information from attributes that are already stored in your document repository. An administrator must have already configured repository variables (in Data Administration) so Ennov InSight can find the metadata, and placed these variables in the attributes on the settings page.

Any attributes defined on a particular leaf use the assigned values. Ennov InSight inherits only values from these settings if the value has been left blank on the element itself.

Modify Default Publishing Values

In the selected Publishing Settings Library, you can modify the default publishing values.

This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL). To modify the default publishing values:

1. On the *Publishing Settings Library* window, select the Default Values tab.
2. Click the Edit icon.
3. On the *Edit the Default Values* page, enter your changes to the default values.
4. Click Save.

Default Publishing Values Attributes for eCTD 4.0

Attributes description for default publishing values for eCTD 4.0.

The attributes differ depending on the eCTD version, for the details of eCTD 3.2 attributes, see *Publishing > Default Publishing Values Attributes*.

Attribute	Description
Folder Due Date	The default date by which the folder must be ready for submission.
Folder Owner	The owner of the folder.
Keywords	Alternative words used in searching leafs.
Leaf Due Date	The default due date by which a leaf must be ready for submission.
Leaf Owner	The owner of a leaf.
Title	Default title for new leafs.
Use Native File	Determine if new leafs should be created as Native Files. Available values: Yes, No.

About PDF Properties

Add PDF Property settings to Publishing Settings Library Template (PLT) and to the Assembly Specific Publishing Settings Library (APL) to define PDF properties for the electronic published output.

In addition to the PLT and APL PDF property settings, Ennov InSight enables you to create leaf-specific PDF property settings:

— While the APL and PLT PDF property settings are defined for the whole assembly, leaf PDF property settings are defined for an individual leaf element only.

— When importing or exporting an assembly, only APL PDF property settings are preserved. Any leaf-specific PDF property settings are automatically removed.

— Leaf PDF property settings are preserved in the duplicated leaf or folder.

— Adding or modifying leaf PDF property settings in the working assembly updates both working and publishing views.

— To use a specific property from the source document, set the PDF Property Source attribute to Use Source Document Property.

— If at least one PDF Property is defined, the submit.document.properties=true parameter in the insight.var is ignored.

Note: *Due to the additional information that is processed when using PDF Properties, the time needed to complete publishing can be increased.*

Leaf PDF properties are not available in:

— Submitted view.

— Sequence view of a locked assembly.

Add or Modify PDF Properties

PDF Properties are used to comply with the regulatory guidance for efficient review of the submissions by the authorities.

In the selected Publishing Settings Library, you can add or modify the PDF Property settings. This procedure applies to both the Publishing Settings Library Template (PLT) and the Assembly Specific Publishing Settings Library (APL).

You must have appropriate security permissions to create or modify a PDF Property setting.

To add or modify PDF properties:

1. On the *Publishing Settings Library* window, select PDF Properties.
2. Click the Create icon  .

   To edit an existing PDF Property setting, click a named PDF Property in the list on PDF Properties.
3. On the *Create PDF Property Settings* page, complete the required fields, and the optional fields as needed. Required information is indicated by an asterisk (*).

   — Output PDF Property*

   — Configuration*

   — Value*

   — Separator

   Note: *The attributes values depend on the value selected in the PDF Property Source field.*
4. To save the new PDF Property Settings, Save.

Option	Action
To create another PDF Property:	Click Create Another PDF Property. The current PDF Property will be saved automatically.
To discard the changes:	Click Cancel.
To return to the Publishing Settings Library after the updates are saved, if you are editing an exist- ing PDF Property setting:	Click the name of the Publishing Settings Library on the *View* page at the top of the page.

Delete a PDF Property

You can delete a PDF Property Setting, as necessary. Use this procedure to delete a PDF Property Setting from the

Publishing Settings Library (PLT), Assembly Specific Publishing Settings Library (APL) or a Leaf element. You must have sufficient security permissions to be able to delete a PDF Property setting.

Note: *This procedure is not applicable for deleting a PDF Property setting inherited from the APL for a specific Leaf element. In order to not apply the inherited PDF Property setting for a specific Leaf, you should set the PDF Property Source value to Do Not Populate by modifying the PDF Property setting from this Leaf element.*

1. On the PDF Property Settings tab, select the PDF Property you want to delete.
2. On the *PDF Property Settings* view page, click Delete.
3. On the warning message that appears, click OK.

PDF Property Attributes

The attribute descriptions help you to enter the appropriate attribute values while creating a PDF Property setting for the Publishing Settings Library Template (PLT) or Assembly Specific Publishing Settings Library (APL).

Required information is indicated by an asterisk (*).

Attribute	Description
Output PDF Property*	Defines the target PDF Property in the output document. The value should be unique within a Publishing Settings Library (PLT) or Assembly Specific Publishing Settings Library (APL). Values available for selection are all active values from the Data Administration > PDF Properties section, where Target Property is set to Yes. If the Output PDF Property value for both the Leaf and the APL is the same, the Leafspecific PDF Property setting will replace the inherited APL PDF Property setting.
PDF Property Source*	Defines the source for the PDF Property. The values available for selection are the following: — Define Repeatable Value - Applies a defined value as the PDF property, values are obtained from all assigned documents. The PDF Properties are distinguished by a defined separator. — Define Single Value - Applies a defined value as the PDF Properties, the value is obtained only from the first assigned document.

	— Use Source Document Property - Applies a defined PDF Property from all assigned documents. The PDF Properties are distinguished by a defined separator.
Source Document Property	Defines the PDF Property in source documents to be used as a source for the PDF Property in the output document. Values available for selection are all active values from the Data Administration > PDF Properties section, where Source Property is set to Yes. The following default values are available for selection: — Author — Keywords — Title — Subject This field appears and is required only when PDF Property Source is set to Use Source Document Property.
Attribute	Description
Separator	User defined separator to distinguish values from individual documents within a leaf. To support the use of spaces and newline breaks, the following text patterns must be used: — //space - Space character will be inserted as a separator — //newline - New line will be started. The effect of the new line break will be visible from the PDF viewer for multi-line fields only. This field does not appear when PDF Property Source is set to Define Single Value.
Value	Defines the value for the PDF Property in the output document. This field appears and is required only when PDF Property Source is set to Define Single Value or Define Repeatable Value.

Overlay Settings

With Ennov InSight, you can define headers and footers for certain elements in your assembly by creating and/or manipulating an overlay template file and specifying the overlay settings.

The overlay template is a file that you can create using Word. The overlay template can contain graphics, regular text, or variables that are resolved at publishing time. You can apply overlays to individual documents. You can easily position graphics, text, or variables such as page numbers in the headers and footers of the document, and you can also specify font styles like you would in any other Word file.

You can create as many overlay files as needed. Ennov InSight enables you to define a default overlay file separately for all the content document types of elements in your assembly:

Ennov InSight can help you manipulate how overlay files are to be applied in multiple ways, including:

— Best fit - Used when working with overlay files that contain multiple pages. The multiple pages typically contain multiple page sizes (for example, A4 and US Letter) or multiple orientations (for example, portrait and landscape). Ennov InSight selects the best overlay page size and orientation to match the output page size and orientation after normalization.

— Rotation - Applied when there is a single orientation in an overlay file. You should choose to turn on overlay rotation when you have a portrait-oriented overlay that should be rotated to landscape orientation for landscapeoriented content documents. This results in all the headers and/or footers appearing at the same position on each page.

— Scaling - Enables you to indicate whether to scale the overlay to the output page.

When defining overlay publishing settings, many of the overlay values may already be populated, especially if you created your assembly by importing another assembly or template where overlay settings were applied. If this is the case, verify that your overlay settings meet the requirements for your new assembly.

Create or Modify Overlays

In the selected Publishing Settings Library, you can modify the Overlay Settings to adjust the default formatting of the overlay. This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).

To modify the Overlay Settings:

1. On the *Publishing Settings Library* window, select Overlays.
2. Click Create  .

   To edit an existing overlay setting, click a named overlay in the list on the Overlays tab.
3. On the *Create/Edit Overlay Settings* page, complete the required fields, and the optional fields as needed. Required information is indicated by an asterisk (*).

— Name *

— Overlay Template File (click Browse to locate and select the location)

— Default Overlay For (move items from the Available box to the Selected box to apply the Overlay settings by default for those items)

— Rotate Overlay to Content

— Apply Best Fit Overlay

— Scale Overlay to Content Page Size

— Scale Content to Margins

— Measurement Unit

— Portrait Margin Left

— Portrait Margin Right

— Portrait Margin Top

— Portrait Margin Bottom

— Landscape Margin Left

— Landscape Margin Right

— Landscape Margin Top — Landscape Margin Bottom

4. Save.

Option	Action
To create another overlay setting, after saving the current settings:	Click Create Another Overlay.
To discard the changes:	Click Cancel.
To return to the Publishing Settings Library after editing an existing Overlay setting:	Click the name of the Publishing Settings Library on the *View* page at the top of the page.

Overlay Attributes

You can use the attributes to define the Overlay. Required information is indicated by an asterisk (*).

Attribute	Description
Apply Best Fit Overlay	Choose Yes to apply the best fitting overlay page from the overlay template. Default is No.
Default Overlay For	Move publishing elements to the Selected box to specify this as the default overlay for the selected publishing elements. Available options: Documents.
Landscape Margin Bottom	The bottom margin on a landscape page. Enter a numeric value from .1 to 2 inches or .03 to 5.1 centimeters.
Landscape Margin Left	The left margin on a landscape page. Enter a numeric value from .1 to 2 inches or .03 to 5.1 centimeters.

Landscape Margin Right	The right margin on a landscape page. Enter a numeric value from .1 to 2 inches or .03 to 5.1 centimeters.
Landscape Margin Top	The top margin on a landscape page. Enter a numeric value from .1 to 2 inches or .03 to 5.1 centimeters.
Measurement Unit	Measurement used to indicate margin sizes. Available options: Inches, Centimeters. Default is Inches.
Name*	Specify the name of the overlay. Must be a unique name within the Publishing Settings Library. (Limit 100 bytes.)
Overlay Template File	Browse to select the template file stored in the document repository that will be used to generate the overlay.
Portrait Margin Bottom	The bottom margin on a portrait page. Enter a numeric value from .1 to 2 inches or .03 to 5.1 centimeters.
Portrait Margin Left	The left margin on a portrait page. Enter a numeric value from .1 to 2 inches or .03 to 5.1 centimeters.
Portrait Margin Right	The right margin on a portrait page. Enter a numeric value from .1 to 2 inches or .03 to 5.1 centimeters.
Portrait Margin Top	The top margin on a portrait page. Enter a numeric value from .1 to 2 inches or .03 to 5.1 centimeters.
Rotate Overlay to Content	Choose Yes to rotate the overlay to fit the content correctly. Default is No.
Scale Content to Margins	Choose Yes to scale the content to the margins defined for the overlay. Default is No.
Scale Overlay to Content Page Size	Choose Yes to scale the overlay to fit the content correctly. Default is No.

Variables

You can set and modify variables at the different levels for overlays and assembly elements. You can create variables, which may contain existing variables defined either at the assembly level or system wide.

— Assembly level variables - These are normally user-defined variables used in the assembly. These variables are set up by an administrator in data administration and specified with the assembly or in the output templates for publishing. Publication variable settings specify which of these variables are scanned for or resolved for a particular publication.

— Data administration variables - These variables are set up by an administrator and specified with the assembly or in the output templates. Publication variable settings specify which of these variables are scanned for/resolved for a particular publication.

Once defined, these variables can be used in two places:

— Assembly attributes and metadata - Variables are specified using their name and the delimiters described below. These variables are resolved during publishing and used within the eCTD XML metadata and tabs names.

— Published output - Variables are specified using their name and the delimiters described below. These variables are resolved, for example, page stamps on overlays.

Delimiters

When creating a variable you should be aware of how Ennov InSight accepts variables and delimiters. Ennov

InSight uses the following types of delimiters:

— Dollar signs ($) and braces ({ }) are the delimiters used to describe how certain fields should be calculated in the system and/or resolved at publishing time. Always use these delimiters to describe, for example, within Drug Product additional attributes. Dollar sign and braces delimiters are used in the assembly attributes and settings.

— Angle brackets (< >) are the delimiters used in Word to describe how the publishing engine should position variables in overlays. You should always use these delimiters to insert variables that will be resolved directly as page stamps on overlays and other published output.

Create or Modify Variables

In the selected Publishing Settings Library, you can modify the variable settings. For eCTD 4.0 assemblies, this procedure applies to Assembly Specific Publishing Settings Library (APL) only. See Publishing > Create or Modify

Variables

1. On the *Publishing Settings Library* window, select Variables.
2. Click Create  .

   To edit an existing variable setting, click a named variable in the list on the Variables tab, and click Edit.
3. On the *Create Variable* page, complete the required fields, and the optional fields as needed. Required information is indicated by an asterisk (*).

   — Variable Code *

   — Variable Name *

   — Variable Value *

   — Variable Type *

   — Description

   —
4. Save.

Option	Action
To create another variable, after saving the current variable settings:	Click Create Another Variable.
To discard the changes:	Click Cancel.
If you are editing an existing Variable setting:	Click the name of the Publishing Settings Library on the *View* page at the top of the page to return to the Publishing Settings Library.

Delete a Publish Variable

You can delete a publishing variable at any level, as necessary.

To delete a publishing variable:

1. On the *Variables* page select the variable you want to delete.
2. Click Delete.
3. Click Apply.

Variable Attributes

You can use the attributes to define the publishing variables for eCTD 4.0 assemblies. Required information is indicated by an asterisk (*).

Attribute	Description
Description	Enter a description of the variable. (Limit 500 bytes)
Is Active*	Determines if the variable is active. Choose Yes or No. Default is Yes.
Variable Code*	Specify the variable code that appears in the document or tree structure. The Variable Code and Output Channel combination must be unique within the Publishing Settings Library. The Variable Code must be different from any variable code defined in Assembly Repository Variables, Assembly System-Defined Variables, Assembly User-Defined Variables, or InSight Assembly Variables. (Limit 100 bytes.)
Variable Name*	Specify the human readable name of the variable. (Limit 100 bytes.)
Variable Value*	Specify the value to which the variable will resolve. This can be free text or another variable. (Limit 4000 bytes.)
Variable Type*	Choose the type of variable configuration. Available options: Single-Line Variable, Multi-Line Vari- able

Link Profiles and the System Profile

Define how links are handled during publishing with link profiles.

The link profiles can be created in a Publishing Settings Library Template (PLT), enabling you to create publications by starting with the saved profile values. You must not respecify the settings.

Ennov InSight provides you with a default profile called the System Profile.

— The System Profile is assigned automatically to all the imported links.

— The System Profile is always used to create electronic TOC links and margin cross-references.

— Linking plug-in, in-process links and other inter-document links (links between documents) the System Profile is always applied to electronic and paper output, that is, the old links are deleted and the new links are applied.

— For intra-document links (links within a document) the assigned System Profile indicates that Ennov InSight does not alter these links during Electronic publish unless it must. Any intra-document link formatting in the original documents is preserved in its original form, including style, font, color, and target settings. If a profile other than the default is used, these settings are overwritten just like they are for inter-document links.

Note: *Not all formatting for old links can be deleted. For example, some underlines cannot be removed and text color cannot be changed. Also, intra-document links cannot be suppressed from published output. As a workaround, you can mask intra-document links by changing the link profile from the System profile to black text.*

System Profile and Hyperlinks

If you use the System Profile, there are specific rules that Ennov InSight follows when publishing links. Ennov InSight writes out hyperlink settings and cross-reference stamp styles unless the link matches all of the following conditions:

— The link is an intra-document link (it points to another place in the document).

— The link is not published as part of a split document.

— The link has not been manually re-targeted to another location.

Links that are set to the System Profile will always be written out exactly like the profile settings indicate. Also, when copying parts or an entire assembly to a new assembly, all link profiles are reverted to the System Profile.

When importing or copying assemblies from an assembly, all links are assigned automatically to the System Profile.

PLT Link Options

Use PLT link options to set up the predefined settings for your publication.

Link settings in a Publishing Settings Library Template (PLT) enable you to create hyperlink and margin crossreference styles at the publication level. These predefined settings are applied to your publication and establish how Ennov InSight formats links that were created during Publish time.

— The electronic hyperlink settings control the formatting of the hyperlinks that are published to the electronic output channel.

— The margin cross-reference settings control the formatting of the margin cross-references that will appear for output published to the paper output channel.

You can create, modify and view link settings (including color, size, and style) by clicking Links in the *Publishing Settings* dialog box.

Select a previously created profile and links will use the settings defined in the profile. You can create a new profile by clicking Create Link Profile on the Link Profiles tab.

Ennov InSight cannot remove underline styles from text when suppressing an existing hyperlink or cross-reference. Default Microsoft Word templates normally dictate that the link style is blue text, otherwise you will need to cleanup PDFs if they suppress, disable, or delete any hyperlinks or cross-references.

Links do not resolve correctly if they target a document page and the page in that document exists twice in the same assembly. Links work properly if the same document is assigned twice with two different page ranges for splitting up a document.

Create or Modify Link Profiles

This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).

To modify the Link Profile settings:

1. On the *Publishing Settings Library* window, select Link Profiles. The default Link Profiles appear.
2. Click Create  .

   To edit an existing link profile setting, click a named link profile in the list on the Link Profiles tab.
3. On the *Create Link Profile* page, complete the required fields, and the optional fields as needed. Required information is indicated by an asterisk (*).

   — Link Profile Name* — Default?

   — Electronic Hyperlink Style *

   — Electronic Hyperlink Color

   — Electronic Hyperlink Line Thickness (available when the selected Electronic Hyperlink Style is other than None)

— Margin Cross-Reference Size*

— Margin Cross-Reference Text Font Style

— Margin Cross-Reference Text Format

— Cross-Document Link Handling

4. Save.

Option	Action
To create another Link Profile, after saving the current Link Profile settings:	Click Create Another Link Profile.
To discard the changes:	Click Cancel.
If you are editing an existing Link Profile setting:	Click the name of the Publishing Settings Library on the *View* page at the top of the page to return to the Publishing Settings Library.

When you change the Default field for the link profile, it is important to remember:

— For a Link Profile with the Default value set to Yes: if you set the Default field to No and try to save the changes, an error message appears.

— If the Default value is set to Yes for a link profile, but you want to assign another link profile to be the default, set the Default field to Yes for the preferred link profile. The profile that was previously marked as default will be updated automatically.

Link Profiles Attributes

You can use the attributes to define the Link Profiles. Required information is indicated by an asterisk (*).

Attribute	Description
Cross-Document Link Handling	Determines if cross-document links are opened in the same window or in a new window. Available options:
	— Default
	— Open in the Same Window
	— Open in a New Window

	The Default option opens the cross-document link according to the Open Settings applied in Adobe Acrobat or Reader (Edit > Preferences > Documents).
Default?	Determines if this is the default link profile. The system automatically generates the default Link Profile (named System Profile). The default profile cannot be deleted.
Electronic Hyperlink Style*	Choose the style of the hyperlink displayed in the published output. Available options: — Dashed Box — None — Solid Box — Underline

Attribute	Description
Electronic Hyperlink Color	Choose the color of the hyperlink displayed in the published output. Default is Blue. Available options: — Blue — Black
Electronic Hyperlink Line Thickness	Defines the thickness of hyperlink line. This option is available when the selected Electronic Hyperlink Style is other than None
Link Profile Name*	Specify a name for the link profile. The name must be unique within the Publishing Settings Library. (Limit 100 bytes.)
Margin Cross- Reference Size*	Specify the font size to use for Margin Cross-References. Default is 10.
Margin CrossReference Text Font Style	Specify the font style to use for Margin Cross-References. Default is Arial. Available options: — Arial — Arial Narrow — Courier — Times New Roman

	— MS Mincho
Margin CrossReference Text Format	Specify the format to use for all Margin Cross-Reference links. Use variables.
Publishing Settings Library	The link to the Publishing Settings Library.

Types of Publish Variables

Types of Publish Variables

Publishing variables are placeholders publishers use to reserve space in documents for variable text. When the document is published, the value of the variable is resolved and entered into the published document.

Variables can be used in cover pages, overlays, and in the body of the submission.

There are several types of variables:

— Assembly user-defined variables

— Assembly system-defined variables

— Ennov InSight assembly variables

— Assembly repository variables

Assemblies

An assembly is the logical bill of materials (BOM) or dossier as represented in a publishing product interface that represents one sequence.

When you create an assembly, you specify attributes like due date, owner, and output location. Some of these attributes are required, others are optional, and still others default to preconfigured values.

You must have the following modules to perform assembly activities:

— Electronic Lifecycle Publishing (ELP)

— Submission Planning and Tracking (SPT)

— Registered Document Analysis (RDA)

— Paper Review Publishing (PRP)

Create Assemblies

You can create a new empty assembly and then add the folders, leaf elements and assigning documents to them, or you can create an assembly from another entity. When you create an assembly from a template, an existing assembly, an application view or an assembly file many of that entity's attributes are inherited by the new assembly.

For details, see the following sections:

— Assembly Templates

- Create an Empty Assembly Template
- Create an Assembly Template from a Template, Assembly, or View
- Use the Search Tab to Locate an Assembly
- Create an Assembly from an Assembly File

— Sequence Assemblies

- Create an Empty Sequence Assembly
- Create a Sequence Assembly from a Template, Assembly, or View
- Use the Search Tab to Locate a Sequence Assembly
- Create a Sequence Assembly from an Assembly File

Build Assemblies

When you build an assembly you create its structure. You can add the folders, leaf elements, documents and document placeholders that make up the hierarchical content of the assembly. Throughout the life of the assembly, it may go through numerous changes and updates.

Delete Assemblies

Only an administrator can delete assemblies.

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Assembly Elements Context Menu

Use the Assembly Elements Context Menu to add, modify, or perform actions on publishing elements.

The Assembly Elements Context Menu is dynamic, providing options relevant to the selected root, folder, leaf, or document element node.

The options in the context menu depend on the Locked/Unlocked status of the assembly and on the particular node, user license, security settings, and view of the assembly where it is invoked.

In the Assembly Elements tree of an assembly, right-click on a node in the tree to view the Assembly Elements Context Menu for that node. The following images show some (but not all) of the different Assembly Elements Context Menu options available for the different types of nodes. See *Icons* for descriptions.

Root Node Context Menu

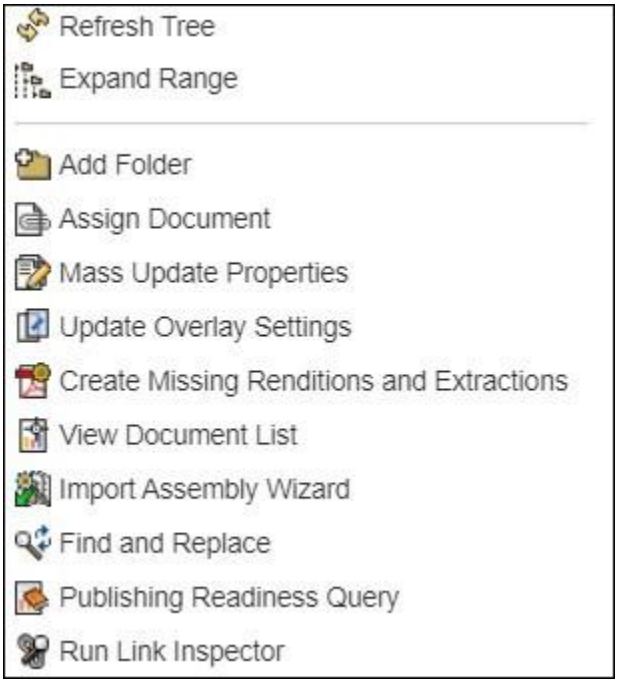

Figure 1: Context menu for a root node

Folder Node Context Menu

The Promote, Demote, Move Up, and Move Down options availability depends on the position of the selected Folder element in the Assembly Tree. For example, if the folder element is the first in the range, then the Move Up option will not be presented in the context menu for such an element.

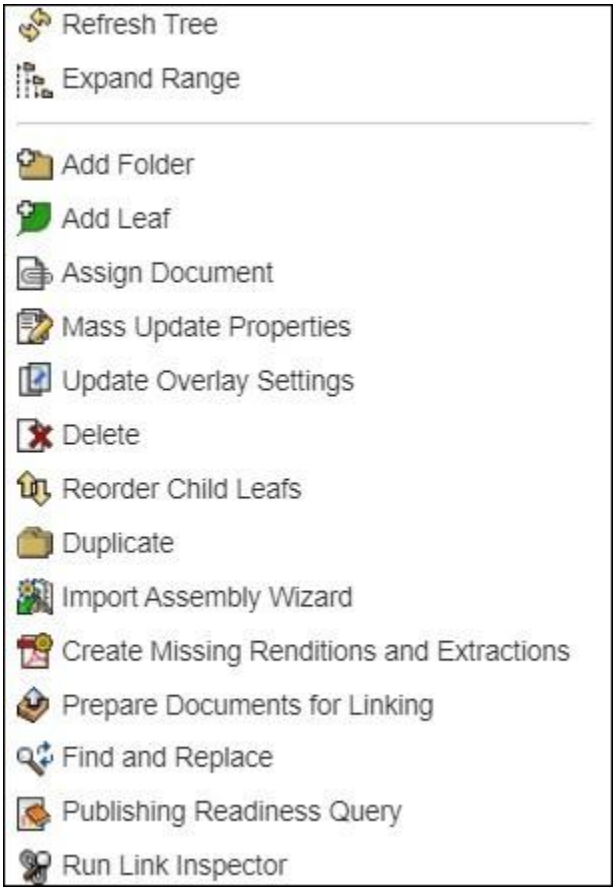

Figure 2: Context menu for a folder node

Leaf Node Context Menu

The Promote, Demote, Move Up, and Move Down options availability depends on the position of the selected Leaf element in the Assembly Tree. For example, if the leaf element is the first in the range, then the Move Up option will not be presented in the context menu for such an element.

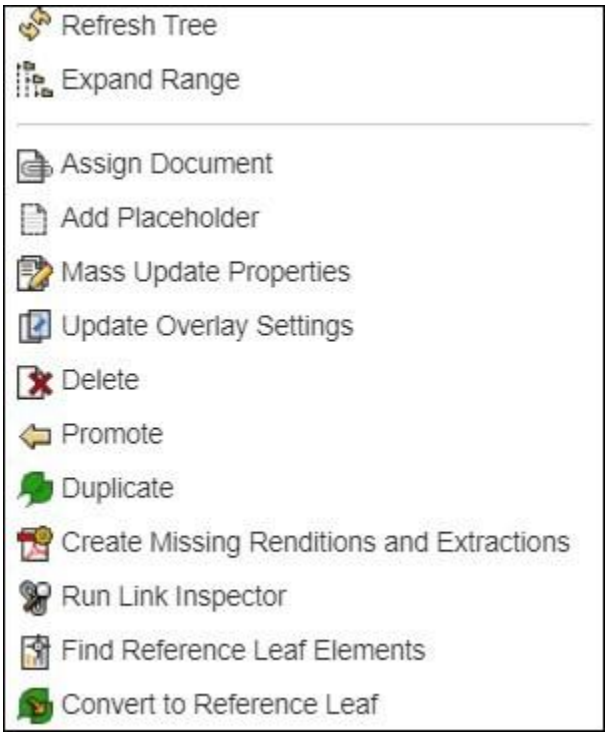

Figure 3: Context menu for a leaf node **Reference Leaf Node Context Menu**

The Promote, Demote, Move Up, and Move Down options availability depends on the position of the selected Reference Leaf element in the Assembly Tree. For example, if the reference leaf element is the first in the range, then the Move Up option will not be presented in the context menu for such an element.

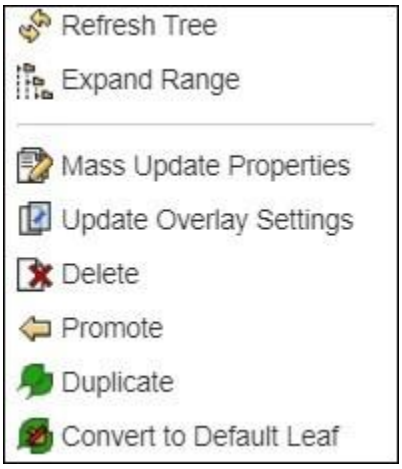

Figure 4: Context menu for a reference leaf node

Document Node Context Menu

The Promote, Demote, Move Up, and Move Down options availability depends on the position of the selected Document element in the Assembly Tree. For example, if the document element is the first in the range, then the Move Up option will not be presented in the context menu for such an element.

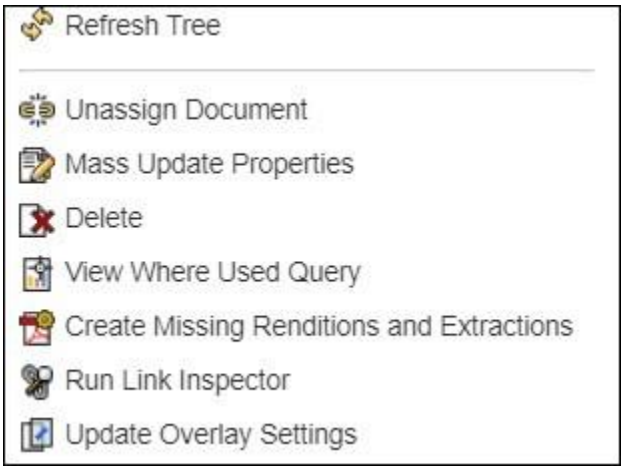

Figure 5: Context menu for a document node

Placeholder Node Context Menu

The Promote, Demote, Move Up, and Move Down options availability depends on the position of the selected Placeholder element in the Assembly Tree. For example, if the placeholder element is the first in the range, then the Move Up option will not be presented in the context menu for such an element.

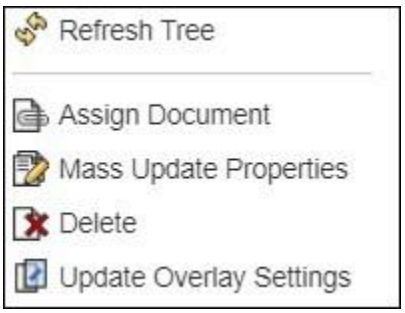

Figure 6: Context menu for a placeholder node

Automatic Leaf Creation

You can create leaf elements automatically by dragging documents from the DMS browse window into an assembly folder or root node.

When the Create Leaf Elements option is set to Yes and you drag documents to the root or a folder:

— A leaf element is added for each document.

— Each leaf element is created as the last child of the target element. — Each leaf has the same name as the corresponding document.

— The Leaf Status for each leaf element is automatically set to default Leaf Status value configured in *Data Administration*.

— The Use Native File attribute of a new leaf is set to Yes if the extension for the corresponding document is configured by your system administrator to generate this attribute value. Your system administrator can configure the extension in the dms.nativeLeafExtension property in the insight.var file. You can include additional extensions in the insight.var file. The following example shows the list of extensions that are set for Ennov InSight by default. If additional extensions are needed, you must include the complete list of default extensions (shown below) along with the additional file types you are adding when using the dms.nativeLeafExtension property in the Insight.var configuration file. For example:

dms.nativeLeafExtension=sas,xpt,xml,sc2,sct,sdq,sd2,ssd,ssp,stc,stx,sxs,s xx,sx,aml,dmn,imx,jmp,ecg

The following applies when the Create Leaf Element option is set to No and you drag a document to the root or a folder:

— The document you drag to an assigned document is added as the last child of that document.

— The document placeholder to which you drag a document becomes an assigned document. — The document you drag to a folder becomes the last child of that element.

Even if leaf elements are created automatically, dragging a document or documents to a leaf assigns them to that leaf and no additional leaf elements are created.

When a leaf element is created automatically during document assignment, the leaf is named with the document file name. The file extension is removed and Ennov InSight later assigns the appropriate extension during publishing.

Assembly Structure

Reference Leaf Elements

A reference leaf element is used to lifecycle and reuse content.

A reference leaf element has the same lifecycle requirements as a standard leaf element in the assembly. Both require a unique ID and lifecycle management to track modified file information.

Reference leaf element features are as follows:

— A reference leaf element allows multiple leaf elements to point to a single piece of content or another leaf in either a current or submitted assembly.

— A reference leaf must include the application number, prefix, and the sequence number.

— To reference an entity across assemblies, the target leaf must be included in a lifecycle.

— A reference leaf element does not have the Leaf Status attribute.

Unlocked Submitted View: Assembly

To modify a Reference Leaf element in the unlocked submitted assembly view, you must have the following set of access permissions in Security Administration:

— Application Country Rights set to at least WRITE.

— Entity Security > Sequence Assemblies set to ADMIN.

— .

Assembly Templates

An assembly template enables you to set up an assembly structure that you can use to create similar assemblies. The template can include the elements and metadata that are common to the assemblies you create.

You can create an assembly template by using the New menu or by using existing assembly elements.

On the Ennov InSight New > Assembly Template menu, you can create an assembly template from one of the following sources:

Option	Description
New (Empty)	Creates a new template containing no existing assembly elements.
Existing Template, Assembly or View	Creates a new template from an existing template or assembly, or from a current or active view.
Assembly File	Creates a new template from an assembly or view that has been exported as an XML file.

Using a template or an existing assembly to create a new assembly template streamlines the process because existing attribute values are inherited by any new assembly you create. A template or an existing assembly can contain publishing settings, the assembly structure, the hierarchical order of folders and leaf elements, documents, document placeholders, publishing elements, and default mappings to DMS attributes for leaf and study report attributes. It minimizes the need for you to enter data already captured in the DMS.

Note: *When creating a new assembly template, from an assembly file, if the repository path in Technical Administration does not relate to any location within assembly file, the location path will not be populated.*

Create an Empty Assembly Template

You can create an empty assembly template from the home page. An empty assembly template provides the structure for a new assembly without existing documents.

To create an assembly template, you must have the appropriate security privileges.

To create an empty assembly template:

1. On the home page, click New > Assembly Template.
2. On the *Create Template* page, select New (Empty) to create an empty assembly template.
3. Click and select the Publishing Settings Library to use with the assembly template.
4. Save.

The *Create Assembly* window appears.

5. Enter attribute values for the assembly template.

   Note: *The Created From attribute is always blank.*

6. Click Create.

Create an Assembly Template from a Template, Assembly, or View

Reusing assembly values improves efficiency when an assembly template is created from an existing template, assembly, or a submitted or approved view.

Prerequisites

You must have an existing assembly template to create a new assembly.

When you create a new assembly template, the existing attribute values of the selected element is inherited.

To create an assembly template based on a template, assembly, or a submitted or approved view:

1. On the home page, click Create a New > Assembly Template.
2. On the *Create Template* page, use the Existing Template, Assembly, or View option.

Option	Description
Existing Template, Assembly or View	a. Click Browse to find and select the template, assembly, or view using the Search Assembly Wizard. b. On the *Search Options* window, choose an assembly type from the Assembly Type to Search list, and click Next. c. On the *Choose Assembly* window, use Search to find an assembly, or you can choose an assembly from one of the other tabs: Assembly Templates, Sequence Assemblies, or Views. d. Select an assembly and click OK. e. Choose a Use Source Assembly Publishing Settings Library option: — Yes - the new assembly inherits the Publishing Settings Library used in the source assembly template that you have selected. — No - select a PLT from the Publishing Settings Library field that appears when you choose No. f. In the Retarget Copied Reference Leafs field, set the option for reference leafs: — Retarget Copied Reference Leafs - select this option to retarget the reference links copied from the source assembly template to link to their targets in the new assembly. If the Reference Leaf points to a leaf that is also part of the import, the Reference Leaf will

	be updated to the copied target instead of the source assembly template. If the Reference Leaf points to a leaf that was not included in the import, but a leaf in the target assembly matches the source assembly and was created from the same template, then the leaf will be retargeted. — Preserve Copied Reference Leafs - select this option preserve the destinations of links in the reference leafs that are copied to the assembly that you create.

3. Click Save.
4. On the *Create Assembly* window, type a name for your new assembly and enter attribute values for the assembly.
5. Click Create.

   If the number of folder child nodes exceeds the value set in the configuration, The Create Assembly action has started processing. Please go to the Job Requests for the status. message appears.

   Note: *As Priority numbers are copied from the source assembly, they may be outdated. It is recommended that you recalculate the Priority numbers using Reorder Child Leafs option.*
6. Click Go to > Job Requests to see the status.

Changes to New Assembly Created from a Template or an Assembly

After creating a new assembly from an existing assembly, the following settings in your new assembly can be different from your source assembly, and may need to be modified:

Element	Description
Document	— Output channel is reset to the default:Electronic. — Include in page numbering is reset to YES (if it was set to NO in the existing assembly). — Category is set to null, rather than the entered value from the existing assembly.

Note: *As Priority numbers are copied from the source assembly, they may be outdated. It is recommended that you recalculate the Priority numbers using Reorder Child Leafs option.*

Use the Search Tab to Locate an Assembly

When creating a new assembly template from an Existing Template, Assembly or View, use the Search tab options to locate an assembly.

1. On the home page, click New > Assembly Template.
2. On the *Create Template* page, click Existing Template, Assembly or View .
3. Click Browse to find and select the template, assembly, or view using the Search Assembly Wizard.

4. On the Search tab, choose an assembly type from the Assembly Type to Search list, and click Next.
5. On the *Choose Assembly* window, set your search parameters and click Next.
6. On the *Matching Assemblies* window, select an assembly.
7. After selecting an assembly, click Next.
8. On the *Selected Assembly* window, click OK.

   On the *Create Template* window, the assembly you selected appears in the Browse field.

9. Choose a Use Source Assembly Publishing Settings Library option:

Option	Description
Yes :	The new assembly template inherits the Publishing Settings Library used in the source assembly you have selected. Selecting Yes also provides the option to Import Publishing Elements (choose Yes or No).
No :	You must select a PLT from the Publishing Settings Library field that appears when you choose No.

10. In the Retarget Copied Reference Leafs field, set the option for reference leafs in your new assembly template:

    — Retarget Copied Reference Leafs — Preserve Copied Reference Leafs

11. Save.
12. On the *Create Assembly* window, enter a name for your new assembly and enter attribute values for the assembly.

Create an Assembly from an Assembly File

An assembly created from an assembly file is used to restore the assemblies from the backup or transfer them between different systems.

When importing an assembly file, the documents in the file are not synchronized automatically with the mapped

Document Management System (DMS). They appear as placeholders that prevents import failures if the referenced DMS does not exist in the current system. Run a DMS synchronization immediately after importing to assign placeholders automatically to the DMS documents.

You must have appropriate security privileges to create an assembly.

Note: *When creating a new assembly, or a new assembly template, from an assembly file, if the repository path in*

Technical Administration does not relate to any location within assembly file, the location path will not be populated.

To create an assembly based on an assembly exported as XML to an assembly file:

1. On the home page, click Create a New > Assembly Template.
2. On the *Create Assembly Template* page, click Assembly File.

3. To find the assembly file, click Browse and do one of the following:

Option	Action
On the *Documents* tab, navigate to the assembly file:	Click OK
On the *Search* tab, find the assembly file:	Click OK

4. Click Save.

After creating a new assembly from an assembly file, the following settings in your new assembly can be different from your source assembly, and may need to be changed:

Element	Description
Publishing Settings Library	Overlays – The Overlays Template File is reset to null.
In the new Assembly	— The extra fields with values assigned to the folder based on the set Context of Use Code are imported successfully. — After the import, the extended fields with assigned values are displayed in the appropriate folder in the same order as they were assigned. — The assembly file is imported successfully if there is an inactive CV Profile with required CVs. — If an xml file is imported without the source Publishing Settings Library and the extra fields with values assigned to the folder based on the set Context of Use Code are not found in the system, an appropriate message will be displayed on the *Create Assembly* page. — If CV Profiles with appropriate CVs exist in Data Administration > CV Profile Values, CV Profiles selected in Publishing Settings are imported successfully. Any CV Profile containing all the CVs indicated in the .xml file is taken. — When creating a new assembly template from assembly file, the Senderdefined Keyword values of folders are always imported empty. — If Applicant Contact ID values match in Ennov InSight database and in xml file, the Applicant Contact field is populated with the values. — If the initial Code value contains zeros after a character or symbol and ends with the number, the Code is generated based on the largest value that contains the same number of zeros after the character or symbol. Example:

	• SDK value in XML file: Keyword-030 / Keyword-030 • Existing SDK values in the application: Keyword-030 / Keyword-030a | Keyword-0101 / Keyword-0101a | Keyword-00888 / Keyword-00888a • Imported SDK value: Keyword-0102 / Keyword-030 — The Sender-defined Keywords are not imported and an assembly is not created from an assembly file when: • a new generated Code value exceeds 50 characters. • An application has an empty Sender-defined Keywords Codesystem field

Assembly Template Attributes

Use assembly template attributes and descriptions to enter attribute values while creating assembly templates.

The table lists all the attributes that are available to you while creating an assembly template.

Ennov InSight Publisher 7.3: eCTD 4.0 Assembly Template Attributes

Attribute	Description
Assembly Type	Defines the output type of the Assembly. Required. The default eCTD is set up and can be changed for the assembly created from this template. These types are available: eCTD, CN eCTD, US eCTD, Standard. See *Normalization Rules*.
Auto Populate Output Folder	Determines if the Output Folder attribute of a folder is populated with the name of the object used to create the folder when a vdoc structure, folder structure, Veeva binder, or Veeva section is assigned to an assembly.
Category	High level category associated with the assembly. The available Subcategory options are dependent on the selected category.
Comments	Comments about the assembly.
Create Leaf Elements	Determines if leaf elements are created automatically when you assign documents to assemblies you create from the template, as when using a dragand-drop action to add files in-to folders. Default is Yes.
Created From	The name of the Assembly that was used to create the current Assembly. This field is blank if no Assembly was used to create the current Assembly.
Creation Date	The date the assembly was created.

Default Binding Rule	The binding rule that is applied to documents from the DMS assigned to assemblies created using the template. — Bind to Label binds documents to a label you choose. — Bind to Status binds documents to a status you choose. — Bind to Version binds documents to the version number you enter. When you create a template from a virtual document or you assign a virtual document to a template, no warning is displayed if the virtual document contains binding rules that are not defined in Ennov InSight by the administrator.
Default Leaf Workflow	Defines the workflow that is associated with the leaf automatically when the leaf is created within the assembly.
Default Major Division Folder Workflow	Defines the workflow that will be associated with the major division folder automatically when major division folder is created within the assembly.
Description	Text that describes the assembly.
Due Date	The date the assembly is due to be complete for submission.
Electronic Output Location	The specified storage location for electronic output.

Ennov InSight Publisher 7.3: eCTD 4.0 Assembly Template Attributes

Attribute	Description
eCTD Standard Type	Categorize the assembly type using these options : — NeeS — Paper — eCTD 3.2 — eCTD 4.0 After the import, the field is populated with data from XML. If empty, it is recognized as eCTD 3.2.
Keywords	Words you can use to search for the assembly.

Last Repository Data Retrieval	The date the last DMS Sync was executed. View only, not editable.
Lock Indicator	Indicates if the assembly has been locked. If the standard lock has been applied to the assembly, set to Yes.
Name	Name of the assembly, which appears in the assembly tree.
Owner	Person responsible for the assembly.
Status	The current status of the assembly. Default is In Draft (unless modified in Data Administration - Assembly Status Values). Can be updated using Update Assembly Status.
Status Date	The current status date of the assembly. Default is Date of Assembly Creation.
Subcategory	The subcategory to further classify the assembly.
Version Number	(SPT only) Indicates the version of the assembly. Default is 1.0, CURRENT.

Modify an Assembly Template

You can modify the assembly template attributes to create additional, reusable assembly templates.

You can set default folder and leaf attributes for the assembly and specify the referenced DTDs/schemas for assembly publishing.

Note: *The assembly attributes that you can modify depend on your security privileges.*

To modify an assembly:

1. Click a link for the assembly template you want to modify.
2. Click Edit.
3. On the *Edit Assembly* page, enter your changes.
4. Save.

Ennov InSight Publisher 7.3: eCTD 4.0 Modify an Assembly Template

Delete an Assembly Template

Delete the assembly templates that are not required.

To delete an assembly template:

Note: *You should have the administrative permissions to delete an assembly template.*

1. Click the link to the assembly template you want to delete.
2. Delete.
3. When you are prompted to confirm the deletion, click OK.

Sequence Assemblies

Sequence assemblies represent a submission.

They are associated with a particular product, country, application, event, and sequence.

When you create a sequence assembly, you must specify its attributes. Some of these attributes are required, others are optional, and others are provided by Ennov InSight automatically.

If you create an assembly from a template, existing assembly, or application view, many attributes are maintained and saved in the new assembly. You can use these default values for the new assembly or you can overwrite them with different attribute values.

In the sequence assembly created from an Assembly File, or Existing Template, Assembly or View, each imported Leaf Element is assigned automatically with the default Leaf Status value from Data Administration.

When you copy an assembly to another assembly, Ennov InSight does not clear the assembly, folder and leaf due dates. This is because these due dates may be templated before assembly creation for project planning purposes.

Once you have created a sequence assembly, it becomes available in lists of sequence assemblies and in the sequence it is associated with. Users who are authorized to work with assemblies can access the assembly from its sequence.

Create an Empty Sequence Assembly

Create an empty sequence assembly from the *View Sequence* page.

Note: *You must have appropriate security privileges to create a sequence assembly.*

To create an empty sequence assembly:

1. Click a link for the sequence for which you are creating a sequence assembly.

   Ennov InSight Publisher 7.3: eCTD 4.0 Delete an Assembly Template

2. On the *View Sequence* page, click the Assembly tab.
3. Create Assembly.
4. On the *Create Assembly* page, select New (Empty) to create an empty assembly.
5. Select the Publishing Settings Library to use with the assembly.
6. Save.
7. Enter the attribute values for the assembly.

   Note: *The Created From attribute is always blank.*

8. Create.

Create a Sequence Assembly from a Template, Assembly, or View

Create an empty sequence assembly from a template, assembly, or a submitted view for optimal reuse of sequence and assembly properties.

Note: *You must have appropriate security privileges to create a sequence assembly.*

To create an empty sequence assembly:

1. Click a link for the sequence for which you are creating a sequence assembly.
2. On the *View Sequence* page, click Assembly.
3. Click Create Assembly.
4. On the *Create Assembly* page, click Existing Template, Assembly or View.
5. Click Browse next to Existing Assembly.
6. Do either of the following:

Option	Action
On the Search tab:	Use the *Search Assembly* wizard.
On any other tab:	Click the versions or view types from which you want to select an assembly. Select an assembly.

   Note: *If you click Show, you must select the Assembly root. You cannot create an assembly from any other node.*

7. For Retarget Copied Reference Leafs, click a value to retarget (change) or preserve the destinations of links in the reference leafs that are copied to the assembly that you create.
8. Save.
9. Enter attribute values for the assembly.
10. Create.

Note: *As Priority numbers are copied from the source assembly, they may be outdated. It is recommended that you recalculate the Priority numbers using Reorder Child Leafs option.*

Changes to New Assembly Created from a Template or an Assembly

After creating a new assembly from an existing assembly, the following settings in your new assembly can be different from your source assembly, and may need to be modified:

Element	Description
Docu-ment	— Output channel is reset to the default:Electronic. — Include in page numbering is reset to YES (if it was set to NO in the existing assembly).

	— Category is set to null, rather than the entered value from the existing assembly.

Note: *As Priority numbers are copied from the source assembly, they may be outdated. It is recommended that you recalculate the Priority numbers using Reorder Child Leafs option.*

Use the Search Tab to Locate a Sequence Assembly

When creating a sequence assembly from a template, assembly, or view, use the Search tab options to locate an assembly.

1. Click a link for the sequence for which you are creating a sequence assembly.
2. On the *View Sequence* page, click Assembly.
3. Click Create Assembly.
4. On the *Create Assembly* page, click Existing Template, Assembly or View.
5. Click Browse to find and select an assembly.
6. On the Search tab, choose an assembly type from the Assembly Type to Search list, and click Next.
7. On the *Choose Assembly* window, set your search parameters and click Next.
8. On the *Matching Assemblies* window, select an assembly.
9. After selecting an assembly, click Next.
10. On the *Selected Assembly* window, click OK.

    On the *Create Assembly* window, the assembly you selected appears in the Browse field.

11. Choose a Use Source Assembly Publishing Settings Library option:

Option	Description
Yes :	The new assembly inherits the Publishing Settings Library used in the source assembly you have selected. Selecting Yes also provides the option to Import Publishing Elements (choose Yes or No).

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Option	Description
No :	You must select a PLT from the Publishing Settings Library field that appears when you choose No.

12. In the Retarget Copied Reference Leafs field, set the option for reference leafs in your new assembly:

    — Retarget Copied Reference Leafs — Preserve Copied Reference Leafs

13. Save.
14. On the *Create Assembly* window, enter a name for your new assembly and enter attribute values for the assembly.

Create a Sequence Assembly from an Assembly File

A sequence assembly created from an assembly file is used to restore the assemblies from the backup or transfer them between different systems.

When importing an assembly file, the documents in the file are not synchronized automatically with the mapped

Document Management System (DMS). They appear as placeholders that prevents import failures if the referenced DMS does not exist in the current system. Run a DMS synchronization immediately after importing to assign placeholders automatically to the DMS documents.

You must have appropriate security privileges to create an assembly.

Note: *When creating a new assembly, or a new assembly template, from an assembly file, if the repository path in*

Technical Administration does not relate to any location within assembly file, the location path will not be populated.

To create a sequence assembly based on an assembly exported as XML to an assembly file:

1. Click a link for the sequence for which you are creating a sequence assembly.
2. On the *View Sequence* page, click Assembly.
3. Click Create Assembly.
4. On the *Create Assembly* page, click Assembly File.
5. To find the assembly file, click Browse and do one of the following:

Option	Action
On the *Documents* tab, navigate to the assembly file:	Click OK.
On the *Search* tab, find the assembly file:	Click OK.

6. Click Save.

After creating a new sequence assembly from an assembly file, the following settings in your new assembly can be different from your source assembly, and may need to be changed:

Element	Description
Publishing Settings Library	Overlays – The Overlays Template File is reset to null.
In the new Assembly	— The extra fields with values assigned to the folder based on the set Context of Use Code are imported successfully.

	— After the import, the extended fields with assigned values are displayed in the appropriate folder in the same order as they were assigned. — The assembly file is imported successfully if there is an inactive CV Profile with required CVs. — If an xml file is imported without the source Publishing Settings Library and the extra fields with values assigned to the folder based on the set Context of Use Code are not found in the system, an appropriate message will be displayed on the *Create Assembly* page. — After an assembly import, the Sender-defined keywords from .xml assembly file are displayed under the Sender-defined Keywords tab. — If the initial Code value contains zeros after a character or symbol and ends with the number, the Code is generated based on the largest value that contains the same number of zeros after the character or symbol. Example: • SDK value in XML file: Keyword-030 / Keyword-030 • Existing SDK values in the application: Keyword-030 / Keyword-030a | Keyword-0101 / Keyword-0101a | Keyword-00888 / Keyword-00888a • Imported SDK value: Keyword-0102 / Keyword-030 — The Sender-defined Keywords are not imported and an assembly is not created from an assembly file when: • a new generated Code value exceeds 50 characters. • An application has an empty Sender-defined Keywords Code system field

Create Assemblies Based on Sequences

Create an assembly template or a sequence assembly based on sequences from another application.

For example, you might want to create an application for one country using an existing application for another country, and all the information available in its first three sequences.

The import of any one assembly from the first three sequences for the existing application does not produce a culmination of the three submissions. For example, if the third sequence of the application is a working assembly, it includes the changes made to the previous sequences but not the content of those sequences. However, creating an application from the application view captures all content and all changes to date.

You can create the new application using submitted sequences from the existing application. Submitted sequences are submitted to the regulatory agency.

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eCTD Assemblies

Ennov InSight includes eCTD 4.0-compliant assembly templates. The eCTD 4.0 assembly templates include all sections that conform to the requlatory requirements eCTD assemblies include predefined Context of Use codes with metadata for specific headings.

You can create eCTD templates using one of the following ways:

— Create an assembly using a module 1 template, then import additional modules from the eCTD ICH Module 2-5 template.

— Create a new template based on a module 1 template, with the eCTD ICH Module 2-5 template imported. You can subsequently create new assemblies using this template.

— Create an assembly using the eCTD ICH Module 2-5 template, then import the module 1 folder from a module 1 template.

While you are allowed to include more than one set of CV Profiles, make sure to include only one regional and one ICH profile. For example, do not include two versions of an EU Module regional CV Profile. This may cause errors during publishing.

Assembly Attributes

Use assembly template attributes and descriptions to enter attribute values while creating assembly templates.

The table lists all the attributes that are available to you while creating an assembly or an assembly plan.

Attribute	Description
Assembly Type	Defines the output type of the Assembly. Required. The default eCTD. is set up. These types are available: eCTD, CN eCTD, US eCTD, Standard. See *Normalization Rules*.
Assign Workflow	Defines the workflow that will be associated with the root of the assembly automatically when the assembly is created.
Auto Populate Output Folder	Determines whether the Output Folder attribute of a folder is populated with the name of the object used to create the folder when a vdoc structure, folder structure, Veeva binder, or Veeva section is assigned to an assembly.
Category	The Assembly high-level category.
Comments	Comments regarding the Assembly.
Create Leaf Elements	Determines if Leaf elements are created when dragging files onto folders. Default =Yes

eCTD Assemblies

Attribute	Description
Created From	The name of the Assembly that was used to create the current Assembly. — In life cycle, this will be the previous sequence. — When versioning, this will be the name of the previous version.
Creation Date	The date the Assembly was created.
Default Binding Rule	The default rule used to bind documents from the DMS.
Default Leaf Workflow	Defines the workflow to associate with the leaf automatically when the leaf is created in the assembly.
Default Major Division Folder Workflow	Defines the workflow that to associate with the major division folder automatically when major division folder is created in the assembly.
Description	A description of the Assembly.
Due Date	The date the Assembly is due to be complete for submission.
eCTD Standard Type	Categorize the assembly type using these options:

	— NeeS — Paper — eCTD 3.2 — eCTD 4.0 After the import, the field is populated with data from XML. If unspecified, it is recognized as eCTD 3.2.
Electronic Output Location	The location for the electronic published output to be stored.
Keywords	Keywords that apply to the specific Assembly.
Last Repository Data Retrieval	The date the last DMS Sync was executed.
Lock Indicator	Indicates whether the Assembly is locked.Set to Yes if the Standard lock is applied to the Assembly.
Name	The name of the Assembly. Appears in the Assembly Tree. Required.
Owner	The owner of the assembly. Default = current user.
Publishing Settings Library	Name of the Assembly-specific Publishing Settings Library (APL).
Status	The current Status of the Assembly, controlled by the Assembly Status Values Data Administration default. Updated using the "Update Assembly Status". Default = In Draft
Status Date	The current status date of the assembly. Default = Date of Assembly Creation

eCTD 4.0 Normalization Rules

Normalization is the process of revising folder and file names to ensure it complies with the eCTD and regional requirements.

Attribute	Description
Subcategory	The Assembly low-level category. The available options depend on the Category selected.
Updated Submitted Available	Indicates if the submitted view has been updated since the current working assembly was created.

Normalization rules for different assembly types.

Note: *As a general recommendation, the following symbols must be avoided in file names and path to prevent undefined system issues: for \ / " ` < > : # & $ +.*

eCTD 4.0 Assembly Type	Rule	Examples
eCTD	When the assembly type is set to eCTD all paths are normalized during publishing.	N/A
	eCTD allows a-z, 0-9, and -.. Other symbols are removed or changed with exceptions listed below.	
	Spaces, periods and underscores are converted to hyphens during publishing.	
CN eCTD	CN eCTD allows a-z, 0-9, _, and - . Other symbols are removed or changed with exceptions listed below.	N/A
US eCTD	When set to US eCTD, all folder names, file names, and paths are normalized during publishing. However, capital letters and underscores are not replaced.	N/A
	US eCTD allows a-z, A-Z, 0-9, _, and - . Other symbols are removed or changed with exceptions listed below.	
	Spaces and periods are converted to hyphens during publishing.	

eCTD 4.0 Assembly Type	Rule	Examples
Standard	When set to Standard, all paths are based on the entries for the output folder and file.	N/A
	Standard allows a-z, A-Z, 0-9, _, -, ., and spaces . Other symbols are removed or changed with exceptions listed below.	
	Periods are removed from the end of the value during publishing for (applies only for Folders). See example.	folder1../folder2./file.pdf --> folder1/folder2/file.pdf.
	Spaces are removed from the beginning and the end of the value during publishing	/ folder1 / folder2 / file.pdf -->folder1/folder2/ file.pdf

	(should be applies only for Folders). See example.	
eCTD, CN eCTD	— Uppercase letters are converted to lowercase during publishing. — Spaces and periods are converted to hyphens during publishing.	N/A
CN eCTD, US eCTD	Multiple underscores in the value are replaced with one underscore during publishing. See examples.	Multiple underscores examples: — CN eCTD : Out_put_File__Name.pdf--> out_put_file_name.pdf. — US eCTD : Out_put__File__Name.pdf -- > Out_put_File_Name.pdf
eCTD 4.0 Assembly Type	Rule	Examples
eCTD, CN eCTD, US eCTD	Multiple hyphens in the value are replaced with one hyphen during publishing. See examples.	Multiple hyphens examples: — eCTD: Out-put--File--Name.pdf --> out-put-filename.pdf . — CN eCTD : Out-put--File--Name.pdf --> out-put-filename.pdf . — US eCTD :Out-put--File--Name.pdf --> Out- put-FileName.pdf.
	— Spaces, underscores and periods are removed from the beginning and the end of the value during publishing. — The file extensions are kept if extension is present after publishing. — Two periods and more in line are not present in the resulting value after publishing. Periods are converted to hyphens. See examples.	Periods rule examples: — eCTD:..Out.put.File...Name.....pdf --> out-put-filename.pdf. — CN eCTD: ..Out.put.File...Name .....pdf --> out-put-filename.pdf. — US

		eCTD: ..Out.put.File...Name . ..... pdf --> Out-putFile-Name.pdf
eCTD, CN eCTD, US eCTD, Standard.	The following symbols are removed from resulting value after publishing: [^<|:\">*?] `~!@#%^&*()+=<> .	N/A

Add Assembly Elements from DMS Browse and Browse Assembly windows

Ennov InSight enables you to perform drag-and-drop actions to add folders, documents and leafs from the DMS Browse and Browse Assembly windows to an assembly tree.

To add folders, documents, and leafs you must have the WRITE permission for those assemblies.

The following rules apply when using the drag-and-drop function:

— Folders or documents cannot be moved on to a locked assembly node or range. — A folder cannot be moved on to a document.

— A folder or leaf cannot be moved on to a suspended leaf.

— A folder or document cannot be moved on to reference leaf.

You must click the text of the name, not the icon preceding the text, to successfully drag a folder, document, or leaf to a new location.

Auto Populate Output Folder

Assigning folders, virtual documents, Veeva binders, or Veeva sections to an assembly using DMS Browse, autopopulates the value for the Output Folder field.

To auto-populate the Output Folder, the Auto Populate Output Folder option must be set to Yes. The name of the DMS folder, virtual document, binder, or section is auto populated as the value for the Output Folder The Output Folder is also updated automatically for nested folders. This retains the folder structure and naming convention in the published output.

The Auto Populate Output Folder attribute for an existing assembly is set on the *Edit Assembly* page or *Create Assembly* page. You can also set this attribute on a sequence assembly, or template.

The following rules apply when using the Auto Populate Output Folder option:

— An assembly created using the Create eCTD wizard will inherit the Auto Populate Output Folder attribute from the templates selected in wizard.

— An assembly created from the Submitted view inherits the Auto Populate Output Folder attribute from the value in the Submitted view.

— An assembly/template created from another assembly/template inherits the Auto Populate Output Folder attribute from the source Assembly/Template.

— The value of the Auto Populate Output Folder attribute is retained during Export to Assembly File/Import from Assembly File activities.

When Auto Populate Output Folder is set to Yes:

— From the DMS Browse field, you can assign a folder or nested folders from any configured DMS repository that has folders in any module in an assembly (These repositories include Secure File System and Documentum). You can also assign Veeva binders or Veeva sections to any module in assembly.

— When content is assigned, the Output Folder attribute is populated on the folders and sub-folders that are assigned to an assembly.

— When assigning a virtual document without content from Documentum by choosing it in the DMS Browse tree or in the DMS Search window, a folder with all the underlying virtual documents is created. The Output Folder attribute is populated on the folder and all subfolders created.

Modify Assembly Attributes

Modify the assembly attributes to change the attribute values for an assembly.

Note: *The attributes you can modify depend on your security privileges.*

To modify an assembly:

1. Click a link for the assembly you want to modify.

   Ennov InSight Publisher 7.3: eCTD 4.0 Auto Populate Output Folder

2. Click  .
3. Choose and change attributes.
4. Save

Rules that apply when adding elements to an assembly tree.

When you build an assembly you create its structure. You can add the folders, leaf elements, documents, and document placeholders that make up the hierarchical content of the assembly.

The following rules apply when adding elements to an assembly tree.:

— An assembly can have major and minor divisions. The major and minor settings are available on the *Folder Elements* in an assembly.

— You cannot add an element at the same level as the root.

— Documents you add to the assembly are saved as links to the document location in a repository or file system. No content is stored in Ennov InSight .

— An element you add is inserted as the last child of the selected element.

— You cannot add a leaf as a child of a leaf or as a child of another document.

— You cannot add a folder or a leaf as a child of a document or a document placeholder.

— You cannot make an assigned document or document placeholder the child of another document or document placeholder.

— You cannot directly add an assigned document or document placeholder as a child of an assigned document or a document placeholder.

— When specifying the source location for a placeholder, do not end the source location with a backslash (/).

— You can only assign documents from one DMS at a time.

— To add multiple documents at the same time from the DMS browse window in Ennov InSight , do the following: - Shift+click adjacent documents to choose them. - Ctrl+click non-adjacent documents to choose them.

— When you add a specific version of a document to the assembly, the document binding rule for that document defaults to Bind to Version and the version number of a document.

— When creating a new assembly, select only a root to preview an assembly or template source.

Assembly Structure Table

The table below lists the elements that can be added under other elements in an assembly.

This element	Can be added to this element
Folder	Assembly root, other folders elements.
Leaf element	Assembly folders.

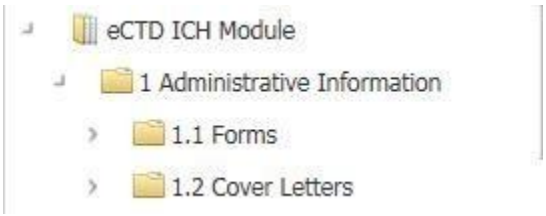
Assembly Structure

This element	Can be added to this element
Reference Leaf element	Assembly folders
	Note: *There is no option to add a reference leaf itself. The Reference Leaf element is a standard Leaf element that was previously converted to be a reference to a specific Leaf element.*
Assigned document	Assembly leaf elements.
Document placeholder	Assembly leaf elements.

Folder Elements

A folder element is the node beneath the root or another folder, and can contain other folders and leaf elements.

The root folder is represented by the icon  and the folder element is represented by the icon  in the tree view.



Add a Folder

Add folders to the assembly structure under an assembly root.

To add a folder to an assembly:

1. Right-click the assembly root or the element on the assembly tree where you want to add a folder, and choose Add Folder.

   The folder is added to the assembly tree with the name New Folder and the *Edit Folder* page appears.
2. Enter values for the attributes.
3. Save.

Modify a Folder

Modify the folder attributes in an assembly tree.

Before you modify the folder attributes, make sure that the DMS browse window is closed. Content for one pop-up window sometimes appears in another pop-up window. If this occurs, close the pop-up windows and try the operation again.

To modify a folder:

1. On the assembly tree, select the folder you want to modify.
2. Edit.
3. Change attributes on the *Edit Folder* page.
4. Save.

Folder Attributes

You can use the field descriptions to enter attribute values while adding a folder. The table lists all the fields that appear while adding a folder.

Field	Description
Abbreviated Name	The short name for the folder.
Comments	The comments for the folder.
Creation Date	The date the folder was created.
Context of Use Code	The Context of Use defines the place in the submission structure where documents should be included in the eCTD heading/section list. The context of use elements are not available for the selection if: — Appropriate CV was disassociated from CV Profile. — Appropriate CV was deleted from CV Service. — Appropriate CV Profile was deselected from *Publishing Settings Library*. When the assembly contains folders with the set of the Context of Use Code values and contains no CV profiles in *Publishing Settings Library*, it can be exported.
Description	The description for the folder.
Division	Indicates if the folder is a major or minor division.
Field	Description
Due Date	The date all content within the folder is due.
Keywords	The keywords for the folder.
Last Repository Data Retrieval	The last date a DMS Sync was run against this folder.
Lock Indicator	Indicates if the folder is locked.
Name	The name of the folder. Required
Number	The outline number for the folder. For eCTD submissions this is necessary for XML generation.
Output Folder	The folder name to be created in the output. This is used to override any automatically created eCTD folders, or where there is no folder to be created. Example: For a Study, a folder will be created. If the Assembly Type is set to eCTD, US eCTD or CN eCTD, this will be normalized during publishing. Default = blank.
	Note: *The eCTD 4.0 output structure depends on the selected Context of Use Codes and/ or the populated Output Folder field. The Output Folder field values override the Context of Use Code values when creating the publised output.*

Owner	The owner of the folder. Default = current user.

Folder Element Type Attributes

The values for additional eCTD 4.0 attributes defined in controlled vocabularies can be entered in assembly folders. For example:

— 2.3.S Drug Substance - Substance, Manufacturer

— 2.3.P Drug Product - Product Name, Manufacturer, Dosage Form

— 2.3.A.1 Appendencies

— 2.3.A.2 Appendencies

— 2.7.3 Summary of Clinical Efficacy - Indication

— 3.2.A.3

— 3.2.S Drug Substance - Substance, Manufacturer

— 3.2.P Drug Product - Product Name, Manufacturer, Dosage Form — 3.2.P.4 Excipients - Excipient Name

— 3.2.A.1 Facilities and Equipment - Manufacturer, Substance, Dosage Form, Product Name

— 3.2.A.2 Adventitious Agents - Manufacturer, Substance, Dosage Form, Product Name — 5.3.5 Reports of Efficacy and Safety Studies - Indication

Associate Sender-defined Keywords to an Assembly Folder

Associate Sender-defined Keyword entity to an assembly folder with specific Context of Use code (CoU) to improve the data quality and follow the eCTD 4.0 specification requirements.

You can associate or disassociate the Sender-defined Keywords (SDKs) to sequence assembly folders if they are one of the following: 2.3.S, 2.3.P, 2.3.A.1, 2.3.A.2, 2.7.3, 3.2.A.1, 3.2.A.2, 3.2.A.3, 3.2.S, us_1.15.2.1.1. Depending on the controlled vocabularies provided by the regulatory agency, this list can change.

You can edit the SDK values based on the application level.

To associate SDKs:

1. Select the folder with specific Context of Use Code.
2. Click More > Additional Information.
3. Find the required keyword using the widget.
   All the SDK values available for the application are displayed.
4. If required, enter some symbols to search values by some criteria. If SDK is not found, new SDK can be created right here. For that, just enter needed value, and click on Add new … The Type and Code will be generated automatically basing on a field and entered value.
5. Select the keyword.
6. Save.

Duplicate a Folder

Duplicate an existing folder and change its attributes to create a new folder type.

To duplicate a folder:

1. Right-click the folder that you want to duplicate and select Duplicate.

   If the number of folder child nodes exceeds the value set in the configuration, The requested action has started processing. Please go to the Job Requests for the status message appears.
2. Verify the new folder is positioned as a sibling below the folder you duplicated.
3. Select the duplicated folder in the assembly and click Edit to edit attributes for the duplicated folder. Each leaf element within the duplicated folder is automatically assigned the default Leaf Status value from *Data Administration*. You can change the status, if needed.

Lock Folders

Locking a folder prevents any changes from being made to the content of the folder.

Keep in mind the following points before locking a folder:

— To unlock a locked folder, you must have License Modules > SPT (Submission Planning and Tracking) set to at least Write, and Functional Security > Review and Approval set to Yes in Security Administration. All child folders are also unlocked.

— The location of the locked folder in the assembly tree cannot be changed; that is, you cannot move the folder up or down, and you cannot promote or demote the folder.

— If you move the locked folder parent element, the folder moves with its parent. — You cannot change elements in a locked folder.

— You cannot add elements to a locked folder.

— The locked folder and its contents cannot be duplicated directly or deleted.

— The locked folder parent element cannot be deleted.

— Structure locking an assembly will lock in place Folders, Leaf elements, documents.

— In the sequence view, when a folder and its contained elements are locked, the locked folder icon is not displayed, but the folder is shown as read-only.

Lock a Folder

You can lock the folder to prevent any changes from being made to its content. To

lock a folder:

1. On the assembly tree, choose the folder you want to lock.
2. On the action toolbar, click .

   A message prompts you to confirm the lock.
3. Click OK.

Delete a Folder

A folder and all of its contents can be deleted from an assembly tree if required.

To delete a folder:

1. Right-click the folder you want to delete and choose Delete. A message prompts you to confirm the deletion.
2. Click OK.

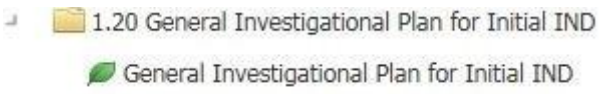
The folder and its contents are deleted.

Leaf Elements

Leaf elements are a collection of individual and published files submitted to a regulatory agency per the eCTD guidance.

A leaf node is included under a folder in an assembly tree. A folder can contain other folders and leaf elements.

A leaf node appears in an assembly tree as a green leaf icon.



The following tabs are present on the *Leaf Attributes* page:

— PDF Properties

— Activities (displayed for the user with permissions on activities within the Entity Security section of Security Administration)

— Workflows (displayed for the user with permissions on activities within the Entity Security section of Security

Administration)

Add a Leaf

Add a leaf element to an assembly under a folder.

To add a leaf element to an assembly:

1. Right-click the assembly root or the element in the assembly where you want to add a leaf, and click Add Leaf. The leaf is added to the assembly tree with the name New Leaf.
2. On the *Edit Leaf* page, rename and enter attributes for the new leaf.
3. Save.
4. To undo modifications to the attributes, click Cancel. (The added leaf will remain, with the default attributes.)

Leaf Auto-Creation

A leaf is automatically created under an assembly when a document is assigned.

When Create Leaf Elements in an assembly is set to Yes, assigning a document from a Document Management System (DMS) repository or a secure file system automatically creates a leaf. By default, the value of Create Leaf Elements is set to Yes. Some attributes of the auto-created leaf are populated with the source document attributes.

For more information, see *Attribute Values for Auto-Created Leafs*, *Leaf Auto Creation: Job Requests Results*.

Attribute Values for Auto-Created Leafs

When a leaf is auto-created, the value of the leaf attributes such as the Name, Abbreviated Name, and Output File are taken from the attributes of a source document that is assigned.

A leaf gets the values for Name, Abbreviated Name, and the Output File from a source assembly document.

Note: *For a Veeva document, it is possible to use a file name with and without an extension using the nameWithExtension and name__v attributes respectively. The attribute owner_v cannot be used for customization. This is disabled to avoid extra API calls to Veeva Vault.*

The following table lists the names of the attributes of a source document and their corresponding default names in different Document Management Systems (DMS) and the secure file system.

Document	DCTM Attribute by Default	Secure File System Attribute by Default	Veeva Attribute by Default
Name	object_name	name	nameWithExtension
Abbreviated Name	object_name	name	nameWithExtension
Title	title	n/a	title__v
Source Document	object_name	name	nameWithExtension
Review Status	a_status	n/a	status__v
Owner	owner_name	n/a	n/a
Content Type	a_content_type	n/a	format__v
Keywords	keywords	n/a	n/a
Description	subject	n/a	n/a
Comments	log_entry	n/a	n/a

Leaf Auto Creation: Job Requests Results

The Job Request results show the status details of priority number recalculation when a leaf is auto-created. Priority numbers in leafs can be recalculated when a document is assigned to an assembly using the Assign Document option.

For example, when you assign a document to a folder above a leaf with the priority number value set to $_1$, the

following message appears: The Priority number recalculation has started processing.

Please go to Job Requests for the status. It is recommended to avoid adding, moving, duplicating, and deleting nodes within the folder, folder parent, closest parent with Context of Use code defined, and folder child nodes until the request is completed.

The table below shows Job Request results for the Priority number recalculation job .

Job Status	Job Message Details
Completed	— Info: Started priority number recalculation for {Node_name}. — Completed priority number recalculation for {Node_name}
Failed	— Info: Started priority number recalculation for {Node_name}. — Error: An error occurred during priority number recalculation... Check the affected node.
Job Status	Job Message Details
For Failed Jobs when the priority number limit is exceeded:	— Info: Started priority number recalculation for {Node_name}. — Error: The maximum allowable value for the leaf priority number has been exceeded, max value: {priority number limit}.

Define Document Attributes in the propertyMappings.xml File

Ennov InSight provides the ability to define auto-created leaf attributes as well as assembly document attributes that are taken from a source document in the propertyMappings.xml file.

By defining the Output File value, irrespective of whether a file with or without an extension is assigned, the extension for the native file remains unchanged. The extension of an Output File can be removed if the value of the attribute Use Native File is set to No. The same applies when a file is dragged within an assembly or imported from another assembly that results in leaf creation. Configuration can be made in the propertyMappings.xml file to enable removing of an extension from any leaf field. If such a configuration is applied and a leaf is updated, it is necessary to ensure the intended attribute value is taken. If the leaf attributes defined in the

propertyMappings.xml file fail to retrieve due to configuration discrepancies, the corresponding auto-created leaf attributes fields show blank values.

To define leaf attributes for an auto-created leaf:

1. Go to the <installation drive>:\InsightManager\server\all\conf\insight folder and open the propertyMappings.xml file in Notepad.
2. Locate the code section for the Document Management System or the secure file system that you use as repository for documents. Example of the code section for the secure file system:

Example

<!--These mappings indicate what attributes will be populated in an Assembly Document when a File System document is assigned.WARNING:

This is the default property mapping. It must not be removed.Working bean!

-->

<bean id="file.file_object-assembly.leaf" parent="propertyMapper">

<property name="retriever" ref="dmsContentRetriever" />

<property name="populator" ref="metaObjectPopulator" />

<property name="mappings">

1. To exclude the file extension for non-native files for auto-created leafs, locate the following section:

   <bean parent="simpleMapping">

   <property name="source" value="name" />

   <property name="target" value="outputFileName" />

   </property>

   </bean>

2. Add the following code lines after the code line <property name="target" value="outputFileName" />:

<property name="converter">

<bean parent="removeExtensionConverter"/>

Example

After adding the code lines, the code block will look like the following:

<bean parent="simpleMapping"/>

<property name="source" value="name" />

<property name="target" value="outputFileName" />

<property name="converter">

<bean parent="removeExtensionConverter"/>

</property>

</bean>

1. Save and close the propertyMappings.xml file.
2. Restart the Ennov InSight service.

Document Attributes taken from Veeva DMS

Below is the list of Veeva DMS attributes that can be used to configure in the propertyMappings.xml file and to populate the same in Ennov InSight documents or auto-created leafs.

— id

— name__v

— title__v

— major_version_number_v

— minor_version_number_v

— type__v

— subtype__v

— classification_v

— binder__v

— document_number__v

— version_creation_date_v

— document_creation_date_v

— format__v

— filename__v

— status__v

— version_modified_date_v

— size__v

— product__v

— country__v

— description__v

— lifecycle__v

— locked__v

— locked_date__v

— export_filename__v — md5checksum__v

Modify Leaf Elements

When you modify a leaf element, you need to know the type of leaf element and follow the procedure to modify according to the leaf element type.

There are two distinct types of leaf elements in Ennov InSight Publisher:

— A Standard leaf element is one that, upon eCTD publish or a publish of the electronic files, publishes to a unique PDF file. The published file has unique checksums and metadata.

— A Reference leaf element serves a different purpose. Often, when creating an eCTD, you may wish to submit to the agency an output leaf that is simply a reference or a pointer to either previously-submitted information or information that is present elsewhere in your assembly.

Changes you make to the attributes for an extended element in a previous sequence assembly do not affect the current sequence.

Before you modify leaf attributes, be sure the DMS browse window is closed. Content for one popup window sometimes appears in another popup window. If this occurs, close the pop-up windows and try the operation again.

Modify a Leaf Element

If you need to modify a reference leaf target location, first convert the leaf to a standard leaf, make the required edits, and then change it back to a reference leaf.

Note: *You must have the appropriate security privileges to modify a leaf element.*

To modify reference leaf attributes:

1. On the assembly tree, select a leaf.
2. Click Edit .
3. On the *Edit Leaf* page, modify the attributes.
4. Save

Leaf Attributes

The table lists the attributes of a leaf.

Attribute	Description
Abbreviated Name	Short name for a leaf.

Attribute	Description
Comments	Notes for reference.
Creation Date	The date a leaf was created.
Description	Text that describes a leaf.
Document ID	Universally Unique Identifier (UUID) of the published document.
Due Date	The completion date of a leaf.
Keywords	Text to search for a leaf.
Last Repository Data Retrieval	The last date a DMS sync was run against this leaf.
Leaf ID	Unique number that identifies a leaf; read-only value.
Leaf Status	Leaf status for a specific leaf. The values available for selection are all active leaf statuses from Data Administration, the default status is Planned.
Link Text	Link information entered when a link destination is not found.
Modified File Over-ride	Name of the modified file that replaces the original file.
Modified Leaf	The leaf modified when performing the lifecycle operation. Includes the leaf name and the sequence number. For example, Cover Letter (P0004).
Name	Name of a leaf.
Number	A number used internally to identify a leaf.
Operation	Leaf operation such as suspend, replace, mreplace, new .
Output File	Relative path and/or the file name of the published output for a leaf. — The file name limit is 500 characters. — Avoid extra periods in the file name, such as output.file.doc, as this can result in an invalid file name in a DMS. ***Note:*** *For a reference leaf, this attribute is a read-only field.*
Owner	The owner of the leaf. Default = current user.
Priority Number	The display order of Context of Use. See *Unchanged Priority Number*, *Priority Number Calculation Rules*, *Leaf Auto Creation: Priority Number*.
Published Output Lo-cation	The location of a published leaf.

Title	The title of a leaf.
Attribute	Description
Use Native File	Defines source files or renditions for publishing. — To include a PDF rendition, create a leaf, assign the document and choose No for Use Native File. — when Use Native File is set to Yes, do not assign a publishing effect (special sheet, TOC) or multiple documents to a leaf. During publication, the publishing effect or document is not added to the leaf, and no error message is generated to indicate this.

Priority Number Calculation Rules

The priority number is calculated according to specific rules.

The priority number defines the display order of Context of Use in a specific section for viewers. The priority number scope is limited to the first parent folder with eCTD 4.0 context of use code and it is then changed for the next folder. Using the following options can result in the priority number recalculation for a selected folder or leaf: — Leaf auto-creation with Assign Document — Reorder Child Leafs

See: *Folder Attributes and Leaf Attributes*, *Leaf Auto Creation: Job Requests Results*, *Reorder Child Leafs: Priority Number*.

Leaf auto-creation with Assign Document

The priority number calculations are limited to the first parent folder with eCTD 4.0 Context of Use Code and are restarted for next folder with eCTD 4.0 Context of Use Code.

The priority number calculations are limited to whole assembly root for folders that have no parent folder in hierarchy with assigned Context of Use Code.

The priority number calculation is performed for all leafs under the folder with assigned Context of Use Code, including all leafs in all nested folders that have no Context of Use Code values.

The priority number calculation is performed for all leafs within the assembly root for all folders that have no parent folder in hierarchy with assigned Context of Use Code.

Reorder Child Leafs

The priority number calculation is performed for all the leafs under the folder with assigned Context of Use Code and all the nested folders that have no Context of Use Code values.

The priority number calculation is performed for all the leafs under an assembly root and on all the folders that have no parent folder in the hierarchy with assigned Context of use code.

The priority number of the moved/promoted/demoted leaf/reference leaf is changed within the folder or from another folder.

The priority number of duplicated leaf/reference leaf changes based on the following conditions:

— The priority number of the leafs under duplicated folder without assigned Context of use code and for all the folders without a parent folder in a hierarchy with assigned Context of use code, is calculated within and limited to the assembly root (not including the folders with Context of use code).

— The priority number of the leafs under duplicated folder without assigned context of use code is calculated within the first parent folder with assigned Context of use code (and limited to the same first parent folder with the assigned Context of use code).

— The priority number of the leafs under duplicated folder with assigned Context of use code is copied.

The priority number value does not change after the Convert to Reference Leaf action is performed.

If the folder hierarchy is changed or removed from the Context of use code, the reorder leafs action must be performed.

When performing some folder operations such as import, duplicate and so on, the priority number limit may exceed the default 999999 number. When this happens, the operations are not processed. The warning message is displayed when priority number limit is exceeded.

The priority number of new leafs created after using the one-to-many Replace operation is recalculated for each new replaced leaf.

Using the Revert operation after the following actions are performed with leafs or folders can create incorrect or duplicated priority numbers of reverted leafs:

— Move

— Promote or Demote

— Add Leaf

— Duplicate

— Leaf auto-creation during assigning Document on Folder

Reorder Child Leafs eCTD 4.0 Working Assembly Created from eCTD 3.2 Assembly

The valid leaf priority number value is set after creating eCTD 4.0 working assembly from eCTD 3.2 assembly.
See:*Leaf Ordering Rules* .

Unchanged Priority Number

Conditions when the priority number of a leaf is not changed.

The priority number recalculation is not performed after moving a leaf to the same place. The scenarios below explain the context when the priority number of the moved leaf remains the same. **Scenario 1:**

The initial assembly is created for eCTD 4.0 sequence with the following structure and Leaf 1 is moved to the Folder 1 section.

Root

Folder 1

Leaf 1

Scenario 2:

The initial assembly is created for eCTD 4.0 sequence with the following structure and Leaf 2 is moved between Leaf 1 and Leaf 3.

Root

Folder 1

Leaf 1

Leaf 2

Leaf 3

Scenario 3:

The initial assembly is created for eCTD 4.0 sequence with the following structure and Leaf 2 is moved between Leaf 2 and Leaf 3.

Root

Folder 1

Leaf 1

Leaf 2

Leaf 3

Scenario 4:

The initial assembly is created for eCTD 4.0 sequence with the following structure and Leaf 1 is moved above Folder 1_1, Leaf_2 is moved between Folder 1_2 and Folder 1_3, Leaf_3 is moved under Folder 1_4.

Root 1

Folder 1

Folder 1_1

Leaf 1

Leaf 2

Folder 1_2

Folder 1_3

Leaf 3

Folder 1_4

Scenario 5:

The priority number is not updated:

— When a submission is added to a life cycle.

— When the Replace operation is performed.

— When the Suspend operation is performed.

Duplicate a Leaf

You can create a new leaf by duplicating an existing leaf.

Note: *You must have the appropriate security privileges to duplicate a leaf.*

To duplicate a leaf:

1. Right-click the leaf you want to duplicate and choose Duplicate.

   A new leaf appears below the duplicated leaf and the *Edit Leaf* page appears.
2. Enter attributes for the leaf.
3. Save

The leaf status of the duplicated leaf is set to the default Leaf Status value configured in *Data Administration*. You can change the Leaf Status on the duplicated leaf, as needed.

Convert a Leaf to a Reference Leaf

Before submitting an application to an agency, output leafs that are references or pointers to previously submitted information or to information that is present elsewhere in your assembly must be converted to reference leafs.

To convert a leaf to a reference leaf:

1. On the assembly tree, navigate to a leaf.
2. Right-click on the leaf and click Convert to Reference Leaf.

   A message prompts you to confirm that you want to delete a leaf that has leaf element and convert it.
3. Click OK.
4. On the next page, find the tab that displays the assembly with the leaf that you want to reference and select that assembly.

   If you want to search for an assembly, click Search.
5. Expand the assembly, and select a leaf.
6. Click OK.

Note: *A reference leaf that points to an empty leaf will cause Prepare to Publish to fail.*

The target of a reference and modified leafs cannot be a leaf from another assembly type. The leaf from NeeS, Paper and eCTD 3.2 cannot be referenced to eCTD 4.0 leaf and vice versa.

The leaf appears in the assembly tree as a reference leaf with a reference leaf icon. The Leaf Status attribute is not presented on the attributes page of a reference leaf.

Reference Leaf Attributes

The table lists the attributes of a leaf.

Attribute	Description
Abbreviated Name	Short name for a leaf.

Attribute	Description
Comments	Notes for reference.
Creation Date	The date a leaf was created.
Description	Text that describes a leaf.
Document ID	Universal Unique Identifier (UUID) of the published document.
Due Date	The completion date of a leaf.
Keywords	Text to search for a leaf.
Last Repository Data Retrieval	The last date a DMS Sync was run against this leaf.
Leaf ID	Unique number that identifies a leaf; read-only value.
Link Text	Link information entered when a link destination is not found.

Modified File Override	Name of the modified file that replaces the original file.
Modified Leaf	The leaf modified when performing the lifecycle operation. Includes the leaf name and the sequence number. For example., Cover Letter (P0004).
Name	Name of the leaf.
Number	A number used internally to identify a leaf.
Operation	Leaf operation such as append, delete, replace, new.
Output File	Relative path and/or the file name of the published output for the leaf. — The value you enter cannot exceed 500 characters. — Avoid extra periods in the file name, such as output.file.doc, as this can result in an invalid file name in a DMS. ***Note:*** *For a reference leaf, this attribute is presented as a read-only field.*
Owner	The owner of the leaf. Default = current user.
Priority Number	The display order of Context of Use. See *Unchanged Priority Number*, *Priority Number Calculation Rules*.
Reference Leaf Application	The link to the application.
Reference Leaf Assembly	The link to the assembly.
Reference Leaf Hierarchy	The path to the leaf the reference leaf links to.
Attribute	Description
Reference Leaf ID	The ID of the leaf the reference leaf links to.
Title	The title of the leaf.
Use Application Prefix	Indicates if an application prefix is necessary when the reference leaf exists in another application or assembly.
Use Native File	Use to choose source files or renditions for publishing. — To include both the native SPL XML and a PDF rendition, create a second leaf, assign the same document and choose No for Use Native File. — Do not assign a publishing effect (special sheet, TOC) or more than one document to a leaf when Use Native File is set to Yes. During publication, the publishing effect or document will not be added to the leaf, and no error message will be generated to indicate this.

Convert a Reference Leaf to a Standard Leaf

To modify the target location of a reference leaf, you must convert a reference leaf to standard (default) leaf. After the target location has been changed, you can then convert it back to a reference leaf.

To convert a reference leaf to a standard leaf:

1. On the assembly tree, right-click the reference leaf you want to convert.
2. Select Convert to Default Leaf.

   The reference leaf changes to a default leaf. The leaf status of the converted leaf is set to the default Leaf Status value configured in *Data Administration*.
3. Change the Leaf Status on the converted leaf, as needed.

Delete a Leaf

You can delete a leaf from an assembly tree if it is not required to be published and submitted to the regulatory agency.

Note: *You must have the appropriate security privileges to delete leaf elements.*

To delete a leaf:

1. Right-click the leaf you want to delete and choose Delete. A message prompts you to confirm the deletion.
2. Click OK.

The leaf and its contents are deleted.

Reorder Leafs

You can create leafs and assign documents to them as the documents become available and later you can reorder leafs in folders alphanumerically.

Reordering leafs can be useful for the folder that contains large number of leafs.

You can reorder leafs only if they are in an unlocked assembly and folder. You cannot reorder leafs in an assembly or folder locked by using the standard lock. You can reorder leafs based on their name, title and output fie.

What You Can Reorder

You can reorder:

— All leafs in one folder

— All leafs and reference leafs in a folder and in each subfolder

Where You Can Reorder

You can reorder leafs from:

— An initial working assembly folder

— A folder on the sequence view page of a lifecycled assembly

— A folder in the unlocked submitted view

Leaf Ordering Rules

In-order to reorder Leafs, you must follow specific rules.

— Reordering is case-insensitive.

— Values starting with numerals are placed before values starting with letters.

— If two leafs have the same value for the field on which the leafs are reordered, the leaf created earlier is placed first.

— Reordering leafs in folders and subfolders keeps each leaf in the same folder or subfolder.

— Reordering leafs in a folder containing subfolders places leafs that are on the same level as subfolders after those subfolders. This happens whether or not you reorder leafs in the subfolders.

Table 1: Example: Reordering leafs in folders and subfolders

Original order

New order

Folder 1

Folder 2

Leaf 3

Leaf 1

Leaf 2

Leaf b

Leaf d

Leaf c

Leaf a

Folder 1

Folder 2

Leaf 1

Leaf 2

Leaf 3

Leaf a

Leaf b

Leaf c

Leaf d

Table 2: Example: Reordering leafs in folders but not in subfolders

Original order

New order

Folder 1

Leaf d

Folder 2

Folder 1

Leaf c

Leaf a

Leaf b

Folder 1

Folder 2

Folder 1

Leaf a

Leaf b

Leaf c

Leaf d

Reordering does not change the positions of non-leaf nodes that are in the folder containing the leafs. Reordering places the leafs after non-leaf nodes.

Table 3: Example

Original order

New order

Folder 1

Doc 4

Leaf c

Placeholder i

Doc 1

Folder 1.1

Leaf a

Folder 1

Doc 4

Placeholder i

Doc 1

Folder 1.1

Leaf a

Leaf c

If Include Lifecycle Items is set to Yes, reordering leafs in a folder containing lifecycled leafs reorders all leafs in the folder.

Table 4: Example: Sequence 0001 tree

Original order

New order

Folder 1

Leaf 4 (0000, NEW)

Leaf 2 (0001, REPLACE)

Leaf 1 (0001, NEW)

Folder 1

Leaf 1 (0000, NEW)

Leaf 2 (0001, REPLACE)

Leaf 4 (0000, NEW)

Table 5: Example: Sequence 0001 tree

Original order

New order

Folder 1

Leaf 4 (0000, NEW)

Leaf 2 (0001, REPLACE)

Leaf 1 (0001, NEW)

Folder 1

Leaf 4 (0000, NEW)

Leaf 1 (0001, NEW)

Leaf 2 (0001, REPLACE)

Reordering a folder containing leafs and documents directly under the folder places the reordered leafs before the reordered documents.

Reorder Child Leafs: Priority Number

The priority number is changed when the reordering the child leafs.

Priority numbers in a folder can be reset using the Reorder Child Leafs option. The table below shows the different settings for a folder with Context of Use (CoU) and the results when the Reorder Child Leafs option is used.

Option	Action
Include Subfolders set to No. For Folder with CoU Code.	The priority number for leafs in folder is recalculated after reordering.
Include Subfolders set to Yes. For Folder with CoU Code.	The priority number for leafs in folder is recalculated after reordering.The priority number for leafs in nested folders with CoU Code is recalculated after reordering.
Include Subfolders set to No. For Folder without CoU Code.	The priority number is recalculated only for the leafs under that folder including all the leafs in all the nested folders that have no CoU Code values.

Include Subfolders set to Yes. For Folder without CoU Code.	The priority number is recalculated for all Leafs under that Folder including all Leafs in all nested Folders that have no CoU Code values. The priority number for leafs in nested folders with CoU Code is recalculated after reordering. Priority numbers are recalculated for leafs in folder but do not change their order after reordering due to the Reorder Child Leafs options.

Reorder Leafs

You can change the existing order of leafs in folders and subfolders. You can also reorder lifecycled leafs with other leafs.

Important: After you reorder leafs, you cannot change the order again. Before you perform this procedure, be sure of the result you want.

To reorder leafs, do the following:

1. Right-click the folder containing the leafs that you want to reorder, and click Reorder Child Leafs.
2. Click the field on which to reorder the leafs: Leaf Name, Leaf Title, or Leaf Output File.
3. If you want to reorder leafs in subfolders under the selected folder, for Include Subfolders?, click Yes. If not, for this field, click No.
4. If you want to reorder lifecyled leafs with other leafs, for Include Lifecyled Leafs?, click Yes. If not, for this field, click No.
5. Click OK.
6. To confirm reordering, click Yes.

The order of all direct child leafs is changed and the priority numbers are reassigned. This action cannot be reverted.

Add or Modify a Leaf PDF Property

You can add or modify the PDF Property Setting for a selected Leaf from the *Leaf Attributes* view page.

Prerequisites

You must have sufficient security permissions to be able to create a PDF Property.

To add or modify the PDF property:

1. On the view *Leaf Attributes* page, select PDF Properties.
2. Click Create  .

   — To edit an existing PDF property setting, click the named PDF property in the list on the *PDF Properties* tab.

3. On the *Create PDF Property Settings* page, complete the required fields, and the optional fields as needed. Required information is indicated by an asterisk (*).

   — Output PDF Property*

   — PDF Property Source*

   — Source Document Property*

   — Value*

   — Separator

   Note: *The set of attributes varies based on the value selected in the PDF Property Source field.*

4. To save the new PDF Property, click Save.

Leaf PDF Property Attributes

The attribute descriptions help you to enter the appropriate attribute values while creating a PDF Property setting for a Leaf element. Required information is indicated by an asterisk (*).

Attribute	Description
Output PDF Property*	Defines the target PDF Property in the output document. Values available for selection are all ac- tive values from the Data Administration|PDF Properties section, where Target Property is set to Yes. The value should be unique within settings defined explicitly for the leaf. The value can be the same as the value inherited from the Assembly Specific Publishing Settings Library (APL). The Leaf-specific PDF Property setting will replace the inherited APL PDF Property setting, if the Output PDF Property value for both the Leaf and the APL is the same.
PDF Property Source*	Defines the source for the PDF Property. The values available for selection are the following: — Define Repeatable Value - Applies a defined value as the PDF property, values are obtained from all assigned documents. The PDF Properties are distinguished by a defined separator. — Define Single Value - Applies a defined value as the PDF Properties, the value is obtained only from the first assigned document. — Use Source Document Property - Applies a defined PDF Property from all assigned documents. The PDF Properties are distinguished by a defined separator.
Source Document Property	Defines the PDF Property in source documents to be used as a source for the PDF Property in the output document. Values available for selection are all active values from the Data Administra-

	tion|PDF Properties section, where Source Property is set to Yes. The following default values are available for selection: — Author — Keywords — Title — Subject This field appears and is required only when PDF Property Source is set to Use Source Document Property.
Attribute	Description
Separator	User defined separator to distinguish values from individual documents within a leaf. To support the use of spaces and newline breaks, the following text patterns must be used: — //space - Space character will be inserted as a separator — //newline - New Line will be started. The effect of the new line break will be visible from the PDF viewer for multi-line fields only. This field does not appear when PDF Property Source is set to Define Single Value.
Value	Defines the value for the PDF Property in the output document. This field appears and is required only when PDF Property Source is set to Define Single Value or Define Repeatable Value.

Mass Update Properties

About Mass Update Properties

The Mass Update Properties functionality is designed to simplify the process of updating properties of a defined list of Assembly tree elements. Instead of updating properties for one element type at a time, the properties can be updated in bulk for all elements of the same type.

Using the Mass Update Properties feature, you can also:

— update common properties for a combination of elements with different types

— set extensions or extension attributes for folders and leafs within a section of an assembly in bulk

Before using the Mass Update Properties feature, make sure you have read the following information on security restrictions, invocation points, and the assembly types for which this functionality can be invoked.

Security Information

To be able to apply the Mass Update Properties functionality you should have the SPT (Submission Planning and Tracking) license in Security Administration > License Modules section set to at least Write.

Assembly Types

The Mass Update Properties functionality is supported for the following assembly types: — Sequence Assemblies: Initial Sequence Assemblies, Working View, Publishing View — Assembly Templates **Assembly Tree Elements**

There is a defined list of Assembly Tree Elements that the Mass Update Properties functionality can be invoked from:

— Assembly Root - Right-click and select Mass Update Properties from the root of the specific assembly to select an element type to be updated within this assembly. You can also select a combination of element types, or all element types to be updated.

— Folder - Right-click and select Mass Update Properties from the specific assembly folder to select an element type to be updated within this folder range. You can also select a combination of element types, or all element types to be updated within the folder range.

— Leaf - Right-click and select Mass Update Properties from the specific leaf to select an element type to be updated within this leaf range. You can also select a combination of element types, or all element types to be updated within the leaf range.

— Reference Leaf - Right-click and select Mass Update Properties from the specific reference leaf to select an element type to be updated within this reference leaf range. You can also select a combination of element types, or all element types to be updated within the reference leaf range.

— Document - Right-click and select Mass Update Properties from the specific document to select an element type to be updated within this document range. You can also select a combination of element types, or all element types to be updated within the document range.

— Placeholder - Right-click and select Mass Update Properties from the specific placeholder to select an element type to be updated within this placeholder range. You can also select a combination of element types, or all element types to be updated within this placeholder range.

Element Types

There is a defined list of Element Types that can be updated using the Mass Update Properties functionality:

— Document

— Placeholder

— Leaf

— Reference Leaf

— Folder

Available Options

The following options are available on the *Select an Assembly Tree Element to Update* page:

— Update and Overwrite - When you select an element type to update you also select the properties you would like to update. If you select this option, the specified properties are overwritten by the system with the values you have entered, even if those properties for some elements are already populated with values.

— Update and Preserve - Unlike the Update and Overwrite option, the Update and Preserve option enables you to update only those properties without any existing values. If the property you have selected to update is already populated with value, that value is preserved and the system only adds the values where the selected property is either blank or set to [Select]. This is applicable to all field types.

Apply Mass Update Properties

You can apply the Mass Update Properties functionality to bulk update properties of the defined list of elements with the same type across the Assembly, or across the defined Assembly Tree Element. It also can be applied to bulk update the common properties either for a combination, or for all element types.

Prerequisites

If you need to update properties of a defined element type, or a combination of element types, for the whole assembly at once you should invoke the Mass Update Properties functionality from the Assembly Root. If you already know a specific assembly tree element range to update, you should invoke the Mass Update Properties functionality from that specific assembly tree element.
Note: *When using the Mass Update Properties, updating fields with inappropriate value or creating a number of envelope elements in an assembly, may corrupt data.*

To mass update properties:

1. Navigate to an assembly you need to update.
2. Depending on the update action you would like to perform, select one of the following invocation points:

    — Assembly Root

    — Folder

    — Leaf

    — Reference Leaf

    — Document

    — Placeholder

3. Right-click the selected assembly tree element. The menu appears.
4. Select Mass Update Properties from the menu.

   The *Select an Assembly Tree Element to Update* window appears.

5. On the *Select an Assembly Tree Element to Update* page, select the check box next to the element you need to update. The list of properties to update appears on the same page.

   You can select one or multiple elements to update. The list of properties that appears after you select the check box depends on the selected element or combination of selected elements.

6. Select the check box next to each property you need to update and enter the values.
7. When all the needed updates are performed, do one of the following:

Option	Action
To cancel the changes:	Click Cancel.
To save the changes and overwrite the values of the element properties that existed before your updates:	Click Save and Overwrite.
Option	Action
To save the changes and preserve the values for the element properties that existed before your updates:	Click Save and Preserve.

Apply Mass Update Properties - Extension

You can apply the Mass Update Properties functionality to bulk update extension.

Prerequisites

To update extensions of an entire assembly at once, invoke the Mass Update Properties functionality from an assembly root. To update extension of an assembly tree element range at once, invoke the Mass Update Properties functionality from that specific assembly tree element.

To mass update extension:

1. Navigate to an assembly you need to update.
2. Depending on the update action you would like to perform, select one of the following innovation points:

   — Assembly Root

   — Folder

   — Leaf

   — Reference Leaf

   — Document

— Placeholder

3. Right-click the selected assembly tree element. The menu appears.
4. Select Mass Update Properties from the menu.

   The *Select an Assembly Tree Element to Update* window appears.

5. Do one of the following:

Option	Action
To update a leaf extension:	Select Leaf.
To update a folder extension:	Select Folder.

6. Select Extension and select an extension value from the drop-down list.

Note: *No elements will be updated if the option Default is selected and then the option used.*	*Update and Preserve is*
Do one of the following:	
Option	Action
To cancel the changes:	Click Cancel.

7.

Option	Action
To save the changes and overwrite the values of the element properties that existed before your updates:	Click Update and Overwrite.
To save the changes and preserve the values for the element properties that existed before your updates:	Click Update and Preserve.

Apply Mass Update Properties - Extension Attributes

You can apply the Mass Update Properties functionality to bulk update extension attributes.

Prerequisites

To update extension attributes of an entire assembly at once, invoke the Mass Update Properties functionality from an assembly root. To update extension attributes of an assembly tree element range at once, invoke the Mass Update Properties functionality from that specific assembly tree element.
Note: *Exercise caution when using the Mass Update Properties feature, as updating fields with inappropriate values or creating a number of envelope elements in an assembly can corrupt data.*

To mass update extension attributes:

1. Navigate to the assembly to which you want to update extension attributes.
2. Depending on the update action you would like to perform, select one of the following innovation points:
   - Assembly Root
   - Folder
   - Leaf
   - Reference Leaf
   - Document
   - Placeholder
3. Right-click the selected assembly tree element. The menu appears.
4. Select Mass Update Properties from the menu.

   The *Select an Assembly Tree Element to Update* window appears.
5. Do one of the following:

Option	Action
To update folders with extensions:	Select Folder with Extension.
To update leafs with extensions:	Select Leaf with Extension.

   The list of properties to update appears on the same page.
6. Select an element to update. The list of properties that appears after you select the check box depends on the selected element or combination of selected elements. Enter values in the text box where necessary.
7. Do one of the following:

Option	Action
To cancel the changes:	Click Cancel.
To save the changes and overwrite the values of the element properties that existed before your updates:	Click Update and Overwrite.
To save the changes and preserve the values for the element properties that existed before your updates:	Click Update and Preserve.

Mass Update Properties: Common Attributes

When you apply the Mass Update Properties functionality for all element types, or for a combination of different element types, the system filters properties of the selected element types and returns only those properties common

for all of them. This topic describes the attributes being displayed when all element types, or some combinations of them have been selected.

The following list describes the properties displayed when all element types are selected on the *Select an Assembly Tree Element to Update* page:

— Due Date — Owner

— Keywords

— Description

— Comments

The following table describes the attributes displayed on the *Select an Assembly Tree Element to Update* if a combination of element types has been selected.

Element Types Combination	Properties Displayed
Leaf and Reference Leaf	— Title — Owner — Language — Application Version — Version — Font library — Role — Actuate — Show — Use Native File — Due Date — Link Text — Keywords — Description — Comments
Document and Placeholder	— Title

	— Category — Review Status — Due Date — Owner — Output Channel — Other — Keywords — Description — Comments
— Folder, Leaf, and Reference Leaf — Folder, Document, and Placeholder	— Due Date — Owner — Keywords — Description — Comments
Document, Placeholder, Leaf, and Reference Leaf	— Title — Due Date — Owner — Keywords — Description — Comments

Mass Update Properties: Document/Placeholder Attributes

The list of attributes displayed for Document and Placeholder element types on the *Select an Assembly Tree Element to Update* page does not depend on the selected invocation point.

The following table describes the properties displayed on the *Select an Assembly Tree Element to Update* page when a Document or Placeholder element type has been selected:

Property	Field Type
Title	Text field
Category	Text field
Review Status	Text field
Due Date	Date field
Owner	Text field
Output Channel	Multiselect field. Available values: — Electronic — Paper
Other	Text field
Keywords	Text field
Description	Text field
Comments	Text field

Mass Update Properties: Leaf Attributes

The list of attributes displayed for a Leaf element type on the *Select an Assembly Tree Element to Update* page does not depend on the selected invocation point.

The following table describes the properties displayed on the *Select an Assembly Tree Element to Update* page when a Leaf element type has been selected:

Property	Field Type
Title	Text field
Owner	Text field
Leaf Status	Drop-down list. Values available for selection are all active leaf statuses from Data Administration. The Planned status is set by default.
Language	Text field

Property	Field Type
Application Version	Text field
Version	Text field
Font Library	Text field
Role	Text field
Actuate	Drop-down list. The [Select] value is set by default.
Show	Drop-down list. Available values: — New — Replace — Embed — Other — None The [Select] value is set by default.
Leaf with Extension	Drop-down list. Available values: — Study Patient Information — Study Report
Use Native File	Drop-down list. Available values: — Yes — No The [No] value is set by default.
Due Date	Date field
Link Text	Text field
Keywords	Text field
Description	Text field
Comments	Text field

Mass Update Properties: Reference Leaf Attributes

The list of attributes displayed for a Reference Leaf element type on the *Select an Assembly Tree Element to Update* page does not depend on the selected invocation point.

The following table describes the properties displayed on the *Select an Assembly Tree Element to Update* page when a Reference Leaf element type has been selected:

Property	Field Type
Title	Text field
Owner	Text field
Language	Text field
Application Version	Text field
Version	Text field
Font Library	Text field
Role	Text field
Actuate	Drop-down list. The [Select] value is set by default.
Show	Drop-down list. Available values: — New — Replace — Embed — Other — None The [Select] value is set by default.
Use Native File	Drop-down list. Available values: — Yes — No

	The [No] value is set by default.
Due Date	Date field
Link Text	Text field
Keywords	Text field

Property	Field Type
Description	Text field
Comments	Text field

Mass Update Properties: Folder Attributes

The list of attributes displayed for a Folder element type on the *Select an Assembly Tree Element to Update* page does not depend on the selected invocation point.

The following table describes the properties displayed on the *Select an Assembly Tree Element to Update* page when a Folder element type has been selected:

Property	Field Type
Owner	Text field
Due Date	Date field
Keywords	Text field
Description	Text field
Comments	Text field
Division	Drop-down list. Available values: — NONE — MAJOR — MINOR The [Select] value is set by default.

Document Elements

Documents are placed under leaf elements in an assembly tree.

The features related to document elements include automatic leaf creation, document place holders, document binding, and reference locations.

You can perform the following actions:

— Automatic leaf creation - You can determine if leaf elements are created automatically when you drag documents from the DMS browse window into an Ennov InSight folder or root.

— Document placeholders - You can create document placeholders in an assembly where you expect to later assign documents.

— Document binding - When you create an assembly, you choose a default document binding. The documents you assign to the assembly assume the specified document binding.

— Reference locations - A reference location enables you to open an assembly from within a document management system (DMS) or repository.

Document Attributes

The attributes and descriptions help you to enter the appropriate attribute values when you create documents.

The table list all the attribute values that are available to you when you create a document.

Attribute	Description
Abbreviated Name	Short name for the document.
Assignment Status	Indicates whether the document is available in the DMS. You cannot change this value.
Bound Version	Version of the document bound to the assembly. You cannot change this value. If a version of the document in the DMS supersedes the bound version, Newer Version Available is displayed.
Category	Descriptive information about the document.
Comments	Exceptions or clarifications about the document.
Content Type	Type of content in the document.
Copied From	If applicable, indicates the origin location of the copied document.
Default Binding Rule	Set Default Document Binding:

	— Bind to Label binds the document to the label you choose — Bind to Status binds the document to the status you choose — Bind to Version binds the document to the version number you enter
	Note: *For Veeva documents, binding to a label is supported only when the label is set to CURRENT. Veeva does not use labels. When the label is set to CURRENT, Veeva displays the latest version in the tree.*
Description	Text that describes the document.
Document Modified Date	When the document was last modified.
Document Type	DMS document type. You cannot change this value.
Due Date	Date document is due.
Extraction Exists	Indicates whether or not extractions exist for the document.
Has Relations	Indicates whether or not the document has any relations.

Attribute	Description
Include in Page Numbering	Include page numbering on document.
Keywords	Words you can use to search for the document.
Last Rendered	Displays the last known rendition date.
Last Repository Data Retrieval	Indicates the last time the document was synchronized with the DMS. You cannot change this value.
Latest Version	Current version of the document. You cannot change this value.
Name	Name of the document.
Number	Number to use with publishing tools that require section numbering.
Number of Pages	Displays the number of pages in the document.
Other	Information you want to save about the document.
Output Channel	Available publication output (electronic, paper).
Overlay Setting	Choose the overlay to apply to the document.
Owner	Person responsible for the document.

Page Range From	Define the start of the range of pages within the document to be used in the assem-bly.
Page Range To	Define the end of the range of pages within the document to be used in the assembly.
PDF Exists	Indicates whether a PDF rendition exists for the document. You cannot change this value.
Planned Number of Pages	This enables you to indicate the number of pages you are planning to include in the document; may be useful if you do not yet have a finalized document. For documents in native file leafs: Planned number of pages is always used, even if the document has been extracted at some point and Extraction Exists = YES, and Number of Pages has been extracted. If Planned Number of Pages is not set, one page is assumed.
Rendition Identifier	Choose the Rendition Identifier to use for the document.
Review Status	Text about the status of the document review process.
Source Document	Name of the source document. You cannot change this value.
Source Location	Indicates where the source document is located in the DMS or file system. You cannot change this value.
Title	Title that helps you identify the document.

Document Placeholders

You can create document placeholders in an assembly where you expect to assign documents at a later time.

A document placeholder has an assignment status of Unassigned. This status changes when you assign a document to the placeholder.

Document Binding

Document Binding enables to select the required document version.

When you create an assembly, the default document binding type is selected. The documents you assign to an assembly assume the specified document binding. For example, if you set your document binding to a status of approved, Ennov InSight indicates when the assigned documents are in or out of compliance.

The following applies when using document binding:

— When you apply a document binding to all children, it is not applied to child documents that reference a branched version and that are set to 'Bind to Version'. In this case, after you navigate through any messages, the selected binding is applied to documents up to, but not including, the document that references the branched version. You can

apply the version binding to documents individually, or you can select a more granular range that does not include the branched document versions.

— When you create an assembly from a virtual document or when you assign a virtual document to an assembly, no warning is displayed if the virtual document contains binding rules that are not defined in Ennov InSight by the administrator.

— Including the same document in an assembly twice when one of the documents is bound to a non-existent status (such as Approved) produces the inclusion of this document as a bound document in an exported virtual document.

— Binding cannot be removed after it is applied. However, it can be modified by using the *Apply Binding to All Children* option.

— Binding can be applied to DMS documents only, and does not apply to secure file system documents.

— Your options for applying binding rules are controlled by the configuration of Ennov InSight Data Administration, your DMS, and your permissions in the system.

Modify Document Binding Rules for a Document Range

You can change the binding rule for all documents in the root, a folder, or a leaf.

When you change the binding rule for a folder or a leaf, the binding rule for elements outside the folder or leaf remain unchanged. The new rule affects only the contents of the folder or leaf.

When you add any elements to the assembly tree, after you change the binding rule for the root, a folder, or a leaf use the default document binding rules set for the assembly.

You can also lock the binding rule to the current content so that the same document is referenced regardless of later versions that may become available. For example, if the binding rule for a document is set to Current and the current document version is 3.0, locking the binding will make the reference to version 3.0 permanent. Even if later versions of the document become available, the assembly will reference version 3.0.

Apply Binding to All Children

Use the Apply Binding to All Children option to apply or modify binding rules for assembly elements in a sequence assembly that is not lifecycle, an unfinalized lifecycle assembly, or an assembly template.

To apply or modify binding rules:

1. On the assembly tree, select the assembly root, a folder, or leaf.

   The binding rule you apply or modify will apply to the selected element and all children assigned to that element.

2. On the More menu, choose Apply Binding to All Children  .
3. On the *Apply Binding to All Children* window, select a Rendition Identifier.

The selected Rendition Identifier will apply to the selected assembly element and all of the children of that element.

4. Choose the Binding Rule that will apply to the selected assembly element and all of the children of that element, and click OK.

Option	Action
Bind to Label	Select the option to provide a dynamic list of options for the binding rule after choosing the appropriate Label.
Bind to Status	Select the option to provide a dynamic list of options for the binding rule after choosing the appropriate Status.
Bind to Version	Select the option to provide a dynamic list of options for the binding rule after choosing the appropriate Version.
Lock Binding	Select the option to provide a dynamic list of options for the binding rule.

5. A message appears, warning that you are about to change the binding for all documents under the selected element and that the binding action cannot be undone. To complete the binding action, click OK.

Lock Binding

Lock Binding is an option of the Apply Binding to All Children function.

When you select Lock Binding from the Binding Rule options, a repository property retrieval is performed for each Placeholder or Assigned Document within the range and their mapped or calculated properties (including Assignment Status) are updated.

Bindings are changed on all Placeholders and Assigned Documents that:

— Are within the selected element or Root, except for Placeholders and Assigned Documents descended from a Standard locked Folder or Root.

— Have a binding option of Bind to Label or Bind to Status. Those set to Bind to Version are already locked and are not affected.

— Have an object that exists within a DMS (Documentum or Veeva) that fulfills the binding option and its value. If no object meets the current binding criteria, a version number cannot be determined and binding on these elements cannot be locked.

For Documentum, branched versions are not supported so bindings are not changed on any branched Assigned Document version.

Assign Documents

When you add an assigned document to an assembly tree, a link is created from the assembly tree to the document in the repository or secure file system.

You can add document assignments in the following ways:

— Assign a document to a placeholder

— Assign a document as a child of an element

— Add a virtual document to the assembly tree

— Replace an assigned document with a related document

— Add an entire file/folder structure to the assembly tree

— Adding a Veeva binder, classification folder, or section to the assembly tree

You can perform the drag-and-drop function with documents from the repository browse window only. You cannot drag-and-drop documents from Windows Explorer. To access a specific secure file system from Ennov InSight , it must be mapped by an administrator and accessed from the DMS Browse window as a file/folder repository.

DMS Browse

The DMS Browse function displays a tree structure used to access documents in the selected document management system (DMS).

You can use the tree from the following places in :

Location	DMSs with Accessible Document
Assigning documents	All
Attachment Values in Data Administration	All except Veeva
Auxilary Output Location	All except Veeva
Bulk eCTD Import	All except Veeva
Create Assembly or Create Assembly Template - from an assembly file	All
Electronic Output Location - on the Create Assembly, Edit Assembly Attributes, and Publish Request pages	All except Veeva
Export Assembly - to Assembly File	All except Veeva
Export Published Output	All except Veeva
Import eCTD	All except Veeva

Paper Output Location - on the Create Assembly, Edit Assembly Attributes, and Publish Request pages	All except Veeva
PDS Label	All
Location	DMSs with Accessible Document
Publishing Settings Browse - Preview Location and Process Rendition Location	All except Veeva
Reference Location - on the Create Assembly page	All except Veeva
Set Reference Location	All except Veeva
XEVMPD Acknowledgement wizard	All except Veeva
XEVMPD Submission wizard	All except Veeva

Where the DMS Browse function is available, clicking the Browse button opens the DMS Browse window. The DMS Browse window displays the tree structure used to access documents in the DMS that you select.

Choosing any of the following in the tree view displays additional information about the selected item in the grid view to the right of the tree:

— Folder

— Document

— Virtual document

— Veeva binder

— Veeva section

For a description of the grid view, see *DMS Search Results – Grid View.*

The tree view displays all of the configured repositories that the logged on user has permission to access. User access to repositories is configured in Technical Administration.

DMS Browse Icons - Tree View

The DMS tree is used to access documents in document management systems (DMSs).

In the DMS Browse tree view, different icons are used for different types of nodes:

Icon	Node Type
	Documentum repository
	Documentum

	Standard document
	Documentum virtual document
	File system
	File system folder
Icon	Node Type
	Server
	Secure file system
	Veeva Vault
	Veeva binder
	Veeva type, subtype, or classification
	Veeva section

Use The Tree

Expand the tree to view available documents.

Clicking the arrow icon next to a node will:

— Expand the node by one level if the selected node was collapsed

— Collapse the selected and all nodes under it if the selected node was expanded

A document displayed in the tree view is the:

— CURRENT document, for Documentum

— Latest version of the document, for any DMS except Documentum

Expanding the document node displays all available versions of the document.

A virtual document displayed in the tree view is the CURRENT version and not the latest version. Expanding the virtual document or binder node displays the content of the virtual document or binder, not all available versions.

DMS Browse - Select Multiple Rows In Tree View: Contiguous Nodes

You can select the multiple nodes in the DMS Browse tree view, contiguously, using the SHIFT keys. Following are the multiple nodes in the DMS Browse tree view:

— Folders

— Documents

— Virtual documents

— Veeva placeholders, binders, classifications, and sections

To select contiguous nodes:

1. Click the first entry of the group of nodes that you want to select.

   Select the name of the node, not the icon.

2. Press and hold the Shift key on your keyboard.
3. Click the last entry that you want to select.

All of the nodes in your selected group appear highlighted.

DMS Browse - Select Multiple Rows In Tree View: Non-Contiguous Nodes

You can select the multiple nodes in the DMS Browse tree view, non-contiguous, using the CTRL keys. Following are the multiple nodes in the DMS Browse tree view:

— Folders

— Documents

— Virtual documents

— Veeva placeholders, binders, classifications, and sections

To select non-contiguous nodes:

1. Press and hold the Ctrl key on your keyboard.
2. Click each node that you want to select.

   The nodes that you selected appear highlighted, although the group is not contiguous.

3. You can now drag-and-drop the nodes, or click OK to assign them.

DMS Browse - Tree View of a Veeva Repository

In DMS Browse, the tree for a Veeva repository has the following structure. Each node in this structure can contain one or more nodes of each type shown. Note the following:

— The tree shows documents, placeholders, and binders that you have permission to see. — The tree does not show deactivated types, subtypes, and classifications.

— A binder can contain other binders.

— A section can contain other sections.

— A document, placeholder, or binder for which no classification is specified is at the same level as a subtype.

— A document, placeholder, or binder for which no subtype is specified is at the same level as a type.

— You can assign the following to assemblies: documents, placeholders, binders, classifications, and sections.

> Veeva Vault [server level} > Vault [repository label defined in Technical Administration] > type > subtype > classification > document > placeholder > binder > document > placeholder > binder ... > section > document > placeholder > binder ... > section
... > section ... > subtype > document

> placeholder

> binder ...

> type

> document

> placeholder

> binder ...

The following is an example of part of a DMS Browse tree for a Veeva repository:

> Veeva Vault [server level]

> Vault 1 [vault]

> Clinical [type]

> Trial Management [subtype]

> Data Monitoring Committee classification]

> US binder [binder]

> Administrative Information [section]

> Forms [section]

> Initial Request.doc [document]

> ...

DMS Browse - Grid View

The DMS Browse grid view displays different columns by default, depending on which repository type is accessed.

The following attributes are configured to display, or are available to display, as columns within the grid view for the specified DMS. Additional attributes can be configured using the XML overrides.

DMS	Default Column Attributes	Optional Column Attributes
Documentum	— Name — Title — Date Modified	— Subject — Date Created — Authors

	— Version — Keywords — Path	— Status — Document ID
Filesystem and Secure Filesystem	— Name — Document Modified Date	— Size — Absolute Path — Canonical Path — File Parent — File Path
Veeva Vault	— Name — Title — Version — Last Modified Date — Created By — Product — Country	— Status — Created Date — Last Modified By — Document Number — Type — Subtype — Classification

DMS Browse - Modify Grid View Columns

You can add or remove columns in the grid view using the Columns list.

To modify the columns in the grid view:

1. Open the Columns list by clicking the arrow on any column heading.
2. Point to Columns and then select or clear the available column options.
3. The selected columns appear in your DMS Search Results grid view.

Option	Action
You can sort any column in ascending or descending order:	Click the sort arrow on the column heading. You can restore the grid view to the default sort by clicking Reset Sort at the bottom of the grid view.
DMS Search Results:	The DMS Search Results can display multiple pages of data in the grid view, but you cannot select items across multiple pages.

DMS Search Results:	You can export the DMS Search Results from the grid view as a spreadsheet by clicking Export to Excel at the bottom of the grid view.

DMS Browse - Documents Tab

DMS Browse - Documents Tab comes with two different options to complete your selection process.

The DMS Browse Documents tab consists of two panes: Browse Documents and Browse Recently Selected. Each pane can be expanded to show their respective lists and perform certain actions.

Preview Documents

You can preview a document selected in either the tree view or the grid view by clicking Preview (located below the tree view).

The DMS Browse Documents tab consists of two panes: *Browse Documents* and *Browse Recently Selected*.

If you select multiple documents in the grid view and click Preview, the document selected first will be previewed. If multiple documents are selected in the tree view, the last document selected will be previewed.

To preview a virtual document, the selected virtual document must have content.

Browse Selected Documents

This view helps you to keep track of the documents, virtual documents, Veeva placeholders, and Veeva binders that you have selected as you browse a DMS and choose entries to add to an assembly.

When you are assigning documents in an assembly, the Browse Recently Selected pane is available on the Documents tab of the Browse window.

The Browse Recently Selected pane automatically lists all documents, virtual documents, Veeva placeholders, and Veeva binders that you select in the grid view, with the most recently selected added to the bottom of the list. To remove an entry from the Browse Recently Selected pane, select the root folder, and then clear the check box of the entry in the grid view.

The Browse Recently Selected list is expandable and collapsible at the root folder and at nodes for virtual documents and Veeva binders. The expanded view enables you to see all versions of a selected entry:

— To view an entry in the Browse Recently Selected pane, select the entry in the list and click Preview. The entry opens in the appropriate application for viewing.

— To add entries from the list of recently selected entries to an assembly, select the check box next to each entry that you want to add and click OK.

— To quit the DMS Search without assigning any of the recently selected entries to the assembly, click Close.

DMS Search

Use the Search tab on the *DMS Browse* window to search any of the following repositories for which you have access permission:

— Documentum — Veeva

Warning: When searching against a Veeva repository using DMS Search in Ennov InSight , an error may appear about exceeding the API calls limit. By default, Veeva Vault has an API burst limit of 2,000 API calls within a 5-minute period, and 100,000 API calls daily. These limits help to prevent runaway script scenarios (e.g. where the logic creates an infinite loop that continuously calls the Vault APIs). To request an increase to this limit, please contact Veeva Support .

The available DMS Search options depend on the type of DMS repository you are searching. Different options are available for different DMS repositories. For example, the Advanced Query functionality is available only for Documentum and Veeva repositories.

By default, a DMS search returns only the first 50 objects found. If your company wishes to modify the default setting, please contact Technical Support.

Field	Description
DMS Repository	Select the DMS repository to search. Required.
Repository	This field appears on the search tab after you select a DMS Repository. Select the name of the repository to search. Required.
Document Type	This field appears on the search tab after you select a Repository. Select the document type to search for in the repository. Required.
	Note: *The Document Type field in the Ennov InSight DMS Search function is not equal to the Document Type term in Veeva. Ennov InSight DMS Search treats the Veeva Document Type as a top level folder in the DMS folders/files tree.*
Search Folder	Click the Browse option to choose a folder in the repository to search. In addition to the required fields, you must choose a Search Folder or Advanced Query to complete a search.
Exclude Assigned	Select this option to exclude assigned documents from the search.

Documents	
Case Sensitive	Select this option to make the search case sensitive according to your filter criteria.

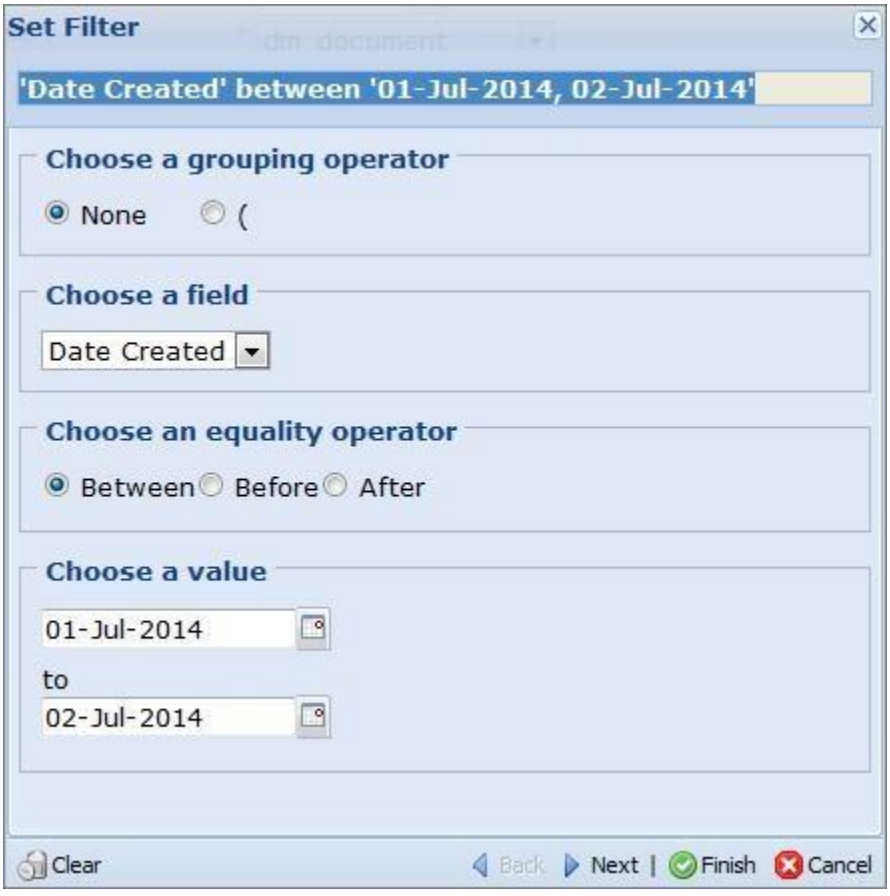
Field	Description
Advanced Query	Advanced Query is available only for Documentum and Veeva repositories. Click Build Query to open the *Set Filter* window and add operators to refine your search criteria. In addition to the required fields, you must choose a Search Folder or Advanced Query to complete a search. — Choose a grouping operator. Choose None, or choose to group multiple filter criteria within parentheses. — Choose a field. Select a field from the keywords list. This list, except for Path, corresponds to the columns in the grid view. If your company configures custom fields for the grid view, those fields also are available. — Choose an equality operator. The equality operators are dynamic and vary according to the selected field. — Choose a value. Enter text, or choose dates, if a date field was selected, to specify the equality operator. Example: To find all documents created on one specific date, in this example, July 1, 2014: 1. Choose the field Date Created. 2. Choose the operator Between. 3. Set the first date to 01-Jul-2014, and set the second date to 02-Jul-2014. The search filter looks like this: 'Date Created' between '01-Jul-2014, 02-Jul-2014'. 4. Click Finish, and then click Search. The *DMS Search Results* displays results for only July 1, 2014. The system retains the last search criteria specified in Advanced Query until those criteria are reset, regardless of whether the DMS Browse/Search window is closed/ reopened, the user logs off from , or the browser window is closed.
Clear	Clears and closes the *Set Filter* window.
Back	To return to the previous criteria in your search filter, click Back.

Next	To add another item to your search filter, click Next.
Finish	When your search filter is completed, click Finish.
Cancel	To cancel your last selection while creating the search filter, click Cancel.
Reset	To remove all search criteria and start over, click Reset.
Search	To initiate the search using your selected criteria, click Search. The results appear in the *DMS Search Results* grid view.

DMS Search Examples

The following images show two different Advanced Query filter examples. The first image shows the filter for searching the repository for documents modified on a single, specific date. The second image shows the filter for searching the repository for documents modified by either of two authors within a date range.

Advanced Query – Set Filter – single date



Advanced Query – Set Filter – either of two authors within a date range

DMS Search Results - Grid View

The DMS Search Results grid view displays the documents for the node selected in the tree view.

When a selected node or folder consists of child folders and documents, then only the documents assigned to selected folder appear in the grid view.

The grid view displays additional attributes for the node selected in the tree view. Folders do not appear in the grid view.

If a repository or folder is selected:

— All documents in that repository or folder appear in the grid view.

— All versions of each document are displayed.

— All versions of each virtual documents are displayed.

If a document or virtual document is selected, all versions of the documents are displayed.

If a version of a document or virtual document is selected, all versions of that document are displayed. The selected version appears first in the grid view.

If multiple nodes are selected in the tree view, the grid view displays only the last node selected.

Assign a Document

You can assign documents to a folder from the assembly tree, or from the repository, using the DMS browse window. You can perform the drag-and-drop function for documents from the DMS browse window only. You cannot perform drag-and-drop with documents from Windows Explorer.

To access a file system from Ennov InSight , it must be mapped by an administrator and accessed from the DMS browse window as a file/folder repository.

To assign a document:

1. In the assembly tree do one of the following:

Option	Action
To select the element that you want to assign a document to	Right-click the element and choose Assign Docu- ment.
To select from a document placeholder	Right-click a document placeholder and choose Assign Document.
To select from different document placeholders	Choose a document placeholder and click Assign Document .

2. In the repository browse window, do one of the following:

Option	Action
To successfully drag the document to the assembly	Locate the document and click on the document name and drag it to the element or document placeholder. (You must click the text of the document name, not the icon preceding the text.)
Locate and choose the document	Click OK.

3. Continue to assign documents or click Close to close the repository browse dialog box.

   The *DMS browse* window is specific to the assembly from which it is launched and must be closed before assigning documents to another assembly. If you attempt to use the same *DMS browse* window for a different assembly, this message appears: The open *DMS Browse* window was not opened for this

   Assembly, it will now be closed.

4. When creating an assembly, if you click Cancel in the DMS browse window, you are not returned to the assembly tree.

When importing a VDM, the *DMS Import* dialog box appears behind the browser window. You must minimize the browser window to continue.

Drag-and-Drop Documents from a Veeva Window

You can drag-and-drop documents from another browser instance with opened Veeva Vault page.

Prerequisites

Before you can use the feature, review the following procedures and make sure that the needed configurations are appropriately applied:	
Configuring the Veeva Cache Timeout Setting	The procedure in this topic describes the changes that need to be performed in insight.var file to change the default Veeva cache timeout that is set to 3 minutes to be any other integer value.

The file can be dragged from another browser window with Veeva Vault opened. You can drag a file or binder from the Veeva Vault Library to the:

— Assembly

— Template

— Working View

To drag-and-drop from Veeva Window:

1. From a separate browser window, navigate to the Veeva Vault window.
2. Select any file.
3. Drag-and-drop the selected file to the target assembly element.

Condition	Result
If the file dropped onto an assembly element belongs to Veeva Vault, configured and active in Technical Administration:	The file is assigned.
If the file dropped onto an assembly element belongs to Veeva Vault, deactivated or absent in Technical Administration:	The following warning message is displayed: Repository is either invalid or deactivated.
If the file or object dropped onto an assembly element does not belong to Veeva Vault:	The action is ignored.

4. Select any binder.
5. Drag-and-drop the selected binder to the target assembly element.

Condition	Result
If the binder dropped onto an assembly element belongs to Veeva Vault, configured and active in Technical Administration:	The file is assigned.
Condition	Result
If the file is dropped onto an assembly element belongs to Veeva Vault, deactivated or absent in Technical Administration:	The following warning message is displayed: Repository is either invalid or deactivated.
If the file or object dropped onto assembly element does not belong to Veeva Vault:	The action is ignored.

Assign a Virtual Document

You can assign a virtual document from a DMS repository to an assembly tree.

You can assign either the root as an assigned document or assign the root with all the child folders and documents with the same hierarchy to the assembly tree.

To assign a virtual document:

1. In the assembly tree, right-click the root, folder or leaf where you want to assign the virtual document.
2. Choose Assign Document.
3. In the *Browse* dialog box that opens, locate and choose the virtual document.
4. Choose one of the following:

Option	Action
To add the root as an assigned document to the assembly tree without its children	Click Only the root node.
To add the assembly root and its children, maintaining the same hierarchy as the virtual document	Click All child nodes.

Note: *Assigning a virtual document with all child nodes converts no-content objects in the virtual document to documents with a MISSING CONTENT assignment status in Ennov InSight .*

5. Click OK.

The virtual document is added to the assembly tree.

Add a Document Placeholder

You can add a document placeholder to an assembly tree to indicate where a document will be added when it becomes available.

To add placeholder elements to an assembly:

1. Right-click the assembly root, or the target element on the assembly tree, and choose Add Placeholder.

   Note: *When leaf elements are created automatically for the assembly, a new leaf (named New Leaf) is created.*

   A document placeholder, named New Document, is added to the assembly tree and the *Edit Document* page appears.
2. Enter attributes.
3. Save.

Locate Documents

Locate documents in the browse window to add them to an assembly element.

You can also drag documents from a repository or secure file system to an assembly element.

If no repositories have been configured by the Ennov InSight system administrator, an HTTP 500 error will occur when you try to open the DMS browser.

Note: *It may be necessary to turn off the pop-up blocker in Google Chrome (Settings > Security and Privacy > Site Settings > Pop-ups and redirects) to enable the drag-and-drop function for moving documents to the assembly from the document browse window.*

Search for Documents

To find the DMS location of a document you want to add to the assembly, you can perform a search using the Search tab in the DMS Browse window.

Keep in mind the following as you enter search criteria:

— Ennov InSight searches for a date exactly as you enter it.

— Ennov InSight searches for text exactly as you enter it. You can use wildcard characters (* or %) to search for documents that contain the text you enter.

Search Criteria Options

When performing a search using the Search tab in *DMS Browse* window, the search option descriptions will help you to enter appropriate search criteria.

The table list all the options that are available to you while performing search in the *DMS Browse* window.

Option	Description
Authors	Authors whose documents you are searching for.
Created Date	The creation date of the document you are searching for.
Repository	The repository you want to search.
Document Type	The repository document type you are searching for.
Keywords	Text to search for.
Modified Date	Date the document you are searching for was last modified.
Name	Name of the document you are searching for.
Status	Status of the document you are searching for.
Subject	Subject of the document you are searching for.
Option	Description
Title	Title of the document you are searching for.
Version	Version of the document you are searching for.

Search for a Document in a Repository

Ennov InSight search functionality enables you to locate a document in a DMS repository and then assign it to an assembly tree.

To find documents to assign to an assembly:

1. In the *browse repository* dialog box, click Search.
2. Enter the criteria with which you want to perform the search. You must enter some selection criteria in addition

   to the required DMS Repository, Repository, and Document Type search criteria fields to receive search results.
3. Do either of the following:

Option	Action
To clear your entries and re-enter search criteria:	Click Reset.
To find documents that meet the search criteria.	Click Search.

4. Choose one or more documents from the search results on the right side of the browse dialog box and do one of the following:

Action
Click Assign.
Drag them to the target location in the assembly and drop them.

Create Missing Renditions and Extractions

Ennov InSight enables you to create new and missing renditions and extractions of the source documents for an assembly.

Rendering process retains the content and layout of the source document while transforming it into a PDF file. The extracts, such as bookmarks and headings, of the source documents are copied to the PDF file.

For rules that apply to documents with the Use Native File option set to No and that are in the section where missing renditions and extractions are created, see:

— *Rules for a Veeva DMS Document Bound to the Standard Rendition Identifier*

— *Rules for File Share and Documentum Documents Bound to Standard Rendition Identifier*

— *Missing Rendition Identifier Handling for a Documentum Document*

— *Missing Rendition Identifier Handling for a Veeva Document*

Rules for a Veeva DMS Document Bound to the Standard Rendition Identifier You must follow specific rules for a Veeva DMS Document.

— If the PDF document does not exist, the job request for creating renditions and extractions is sent.

— If the PDF document exists but an extraction does not exist, the job request for the extraction is sent, and the current rendition is not changed.

— If no documents require renditions or extractions to be created in the section where you try to create missing renditions and extractions, the corresponding job request is set to Completed with the message No Documents to Render in the job details.

Rules for File Share and Documentum Documents Bound to Standard Rendition Identifier

Rules are applied for all documents with Use Native File set to No within the section where the option was invoked from, if the document is from Documentum and is bound to Standard Rendition, or if a document is from File Share.

The following rules are:

— If PDF Exists is set to Yes, but Extraction Exists is set to No, the request for extraction is sent, and the currently existing rendition is not changed.

— If both PDF Exists and Extraction Exists are set to Yes, Ennov InSight compares the .pdf file size of a rendition with the one that is stored internally. If they are different, for example, if the rendition is changed outside of Ennov InSight , only extraction request is sent.

— If there are no documents that require renditions/extractions to create in the section where the option is invoked from, the appropriate job request is set to Completed with No Documents to Render message in job details.

Missing Rendition Identifier Handling for a Documentum Document

Rules for missing Rendition Identifier for documents assigned from Documentum DMS.

There are specific business rules for documents assigned from a Documentum DMS when using the Rendition Identifier functionality. Ennov InSight will only create renditions for the Standard Rendition Identifier.

Renditions and extractions are created when the Missing Rendition Identifier Handling setting is Use Standard Rendition, and no rendition exists.

Renditions are not created:

— When the Missing Rendition Identifier Handling setting is Use Standard Rendition, and a rendition exists for the non-standard Rendition Identifier value.

— When the Missing Rendition Identifier Handling setting is Do Nothing and no rendition exists for the nonstandard Rendition Identifier value.

Only extractions are created when the following conditions are met:

— When the Missing Rendition Identifier Handling setting is Use Standard Rendition and a rendition exists for the non-standard Rendition Identifier value, but no extractions currently exist.

— When the Missing Rendition Identifier Handling setting is Use Standard Rendition and a rendition exists for the non-standard Rendition Identifier value, and the rendition file size has changed.

— When the Missing Rendition Identifier Handling setting is Do Nothing and a rendition exists for the nonstandard Rendition Identifier value, but no extractions currently exist.

— When the Missing Rendition Identifier Handling setting is Do Nothing and a rendition exists for the nonstandard Rendition Identifier value, and the rendition file size has changed.

Missing Rendition Identifier Handling for a Veeva Document

Rules for handling Missing Rendition Identifier for documents assigned from a Veeva DMS.

Renditions and extractions are created when the Missing Rendition Identifier Handling setting is Use Standard Rendition, no PDF rendition exists, and no rendition with the rendition identifier value Ennov exists.

No renditions or extractions are created when the Missing Rendition Identifier Handling setting is Do Nothing and no PDF rendition exists.

Only extractions are created:

— When the Missing Rendition Identifier Handling setting is Use Standard Rendition, no PDF rendition exists, and a rendition with the rendition identifier value parexel exists, but no extractions for the latter rendition exists.

— When a PDF rendition exists, but no extractions for that rendition exists.

Force New Renditions and Extractions

Force New Renditions and Extractions overwrites all existing renditions and extractions, and creates missing renditions and extractions for the selected node and all of its child nodes.

Forcing new renditions and extractions causes custom bookmarks, in-process links, and (depending on your DMS configuration) signature pages to be lost.

Note: *Access to this functionality is dependent on your user role and permissions in the system, and on your permissions within the repository.*

Force Renditions and Extractions with Rendition Identifiers

Rules for handling missing Rendition Identifier for documents assigned from a Documentum or Veeva DMS.

The following are the business rules for documents assigned from a Documentum or Veeva DMS apply when using the rendition identifier functionality. Ennov InSight creates renditions only for the Standard Rendition Identifier.

Note: *In a Documentum DMS, the Standard Rendition identifier (NULL) identifies renditions with PAGE_MODIFIER set to NULL. In a Veeva repository, the Standard Rendition identifier (parexel) identifies the same kind of renditions.*

Renditions and extractions are created/overwritten when the Missing Rendition Identifier Handling setting is Use Standard Rendition.

Renditions are not created when the following conditions exist:

— When the Missing Rendition Identifier Handling setting is Use Standard Rendition and a rendition exists for the non-standard Rendition Identifier value.

— When the Missing Rendition Identifier Handling setting is Do Nothing.

Only Extractions are created when the following conditions are met:

— When the Missing Rendition Identifier Handling setting is Use Standard Rendition and a rendition exists for the non-standard Rendition Identifier value.

— When the Missing Rendition Identifier Handling setting is Do Nothing and a rendition exists for the nonstandard Rendition Identifier value.

Force New Renditions and Extractions

Use the Force New Renditions and Extractions option to overwrite existing renditions and extractions, creating missing renditions and extractions for the selected node and all of its child nodes.

Forcing new renditions and extractions causes custom bookmarks, in-process links, and (depending on your DMS configuration) signature pages to be lost.

To force new renditions and extractions:

1. On the assembly tree, select an assembly root, a folder, or leaf.

   The Force New Renditions and Extractions function applies to the selected element and all children assigned to that element.

2. On the *More*menu, choose Force New Renditions and Extractions  .
3. Read the CAUTION message, and make sure that you want to proceed.

   Force New Renditions and Extractions creates missing renditions and extractions, overwrites all existing renditions and extractions for the selected node and all of its child nodes, and will result in the loss of:

   — Custom bookmarks

   — In-process links

   — Signature pages (depending on your DMS configuration)

4. To complete the Force New Renditions and Extractions action, click OK.

   Existing renditions and extractions will be overwritten. Missing renditions and extractions will be created.

5. To track the progress of the action, choose Go To > Job Requests.
6. On the *Job Requests* page, enter appropriate information and click Search.
7. After the Force New Renditions and Extractions action is completed, refresh the assembly (or reselect the document elements) to see that the following options are set to Yes:

— PDF Exists

— Extraction Exists

Multiple Renditions Support

Use custom Rendition Identifiers (page_modifier) in documets to associate and publish renditions in a Documentum

DMS.

All documents assigned within an assembly are bound to the default Rendition Identifier that is set in the Publishing Settings for the assembly. After documents are assigned to an assembly, the Rendition Identifier can be updated for a single document or for a group of documents (the selected assembly element and all of its children) using Apply Binding to All Children.

If the rendition with the defined Rendition Identifier does not exist, you can set the Missing Rendition Identifier Handling option to control how the document is included during publishing. This option is available in the Publishing Settings Library, on the Publishing Settings tab. The Missing Rendition Identifier Handling option on the Publishing Settings tab provides two options: Use Standard Rendition (this is the default option), or Do Nothing.

If Use Standard Rendition is selected, Ennov InSight searches for a rendition with page_modifier set to NULL and uses it for publishing. If Do Nothing is selected, a missing rendition message will be logged.

Document List Query

The Document List query provides a view of the placeholders and assigned documents associated with an assembly structure.

This view is a non-hierarchical view of the placeholders and assigned documents in the submission. You can use the query to perform ad-hoc querying, tracking, and planning of placeholders and assigned documents.

Note: *The Document List query is specific to the current assembly, not the current active view.*

Generate a Document List Query

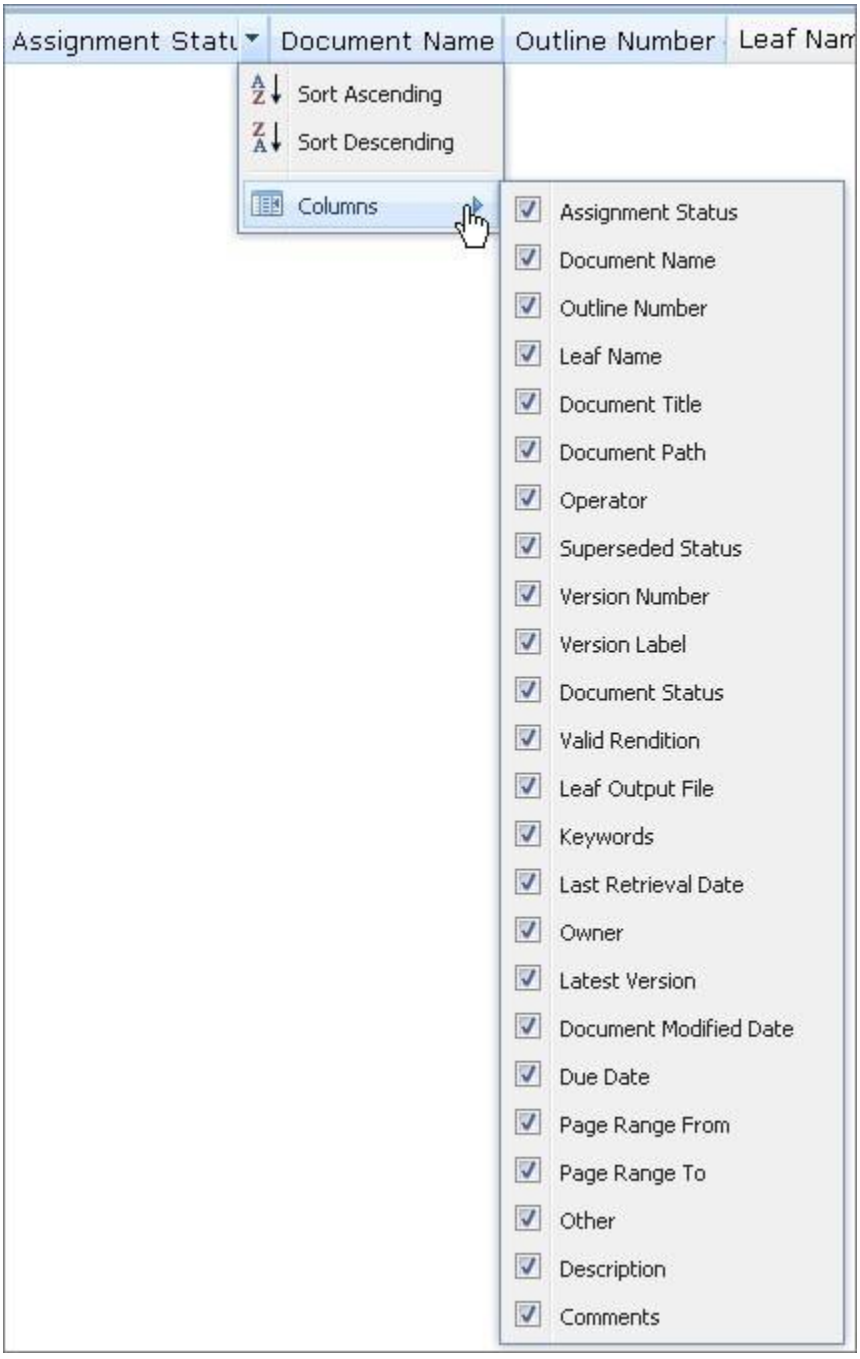
Use the Document List query to generate a table that displays assigned documents and their attributes for the assembly.

On the assembly root, right-click and select View Document List.

The resulting table lists all of the documents that are assigned to the assembly.

Select Document List Columns for Display

By default, all of the available columns are displayed in the generated Document List. You can choose to view fewer columns by opening the Columns list and clearing the check boxes next to the column names. To add an omitted column back to the Document List view, select the check box for that column.



Document List Query Results

The descriptions of column names helps you to understand the information displayed in the Document List query results.

This table contains all of the columns and describes the information displayed in the Document List query results.

Column Name	Description
Assignment Status	Lists documents that meet binding or missing binding or no longer exist in the data repository. Leaf elements that have no documents are not displayed.
Comments	Exceptions or clarifications about the document
Description	A brief description of the document
Document Family ID	The reference code for the document family
Document ID	The reference code for a document
Document Modified Date	When the document was last modified
Document Name	The name of the document.
Document Path	The location of the document in your system
Document Status	The status of the document
Document Title	The title given to the document
Due Date	The date that the document is due
Has Open Activities	Indicates whether there are active activities associated with the document
Keywords	Words that help to identify or describe the content of the document
Last Retrieval Date	Last time the document was synchronized with the DMS
Latest Version	Most current version of the document
Leaf Name	The name of the leaf where the document is located
Leaf Name	The name of the leaf where the document is located
Leaf Output File	Relative path and / or the file name of the published output for the leaf
Leaf Status	The value of the Leaf Status attribute from the leaf element
Operator	The eCTD lifecycle status for the leaf
Other	Additional information about the document that was saved
Outline Number	The eCTD outline number for the leaf
Owner	Person responsible for the document
Page Range From	Start of the range of pages in the source document that are used in the assembly
Page Range To	End of the range of pages in the source document that are used in the assembly
Superseded Status	Indicates if a more recent version of the specified file is available in the repository

Column Name	Description
Valid Rendition	Indicates that a valid rendition of the document exists
Version Label	The status of the version (Current, Superseded)
Version Number	Version of the document

Document Status Indicators

You can view the assignment status of an assigned document or a document placeholder, and the superseded status of an assigned document. A document with a superseded status is identified by the red label: Newer Version Available. The assignment status is determined by the binding options and the values and availability of documents in the repository, as follows:

— The assignment status indicates whether the file you want to bind to the assembly is available in the repository.

— The superseded status, indicated by a red label that says Newer Version Available, indicates whether a document available in the repository is more recent than the document assigned in the assembly.

When you assign a document to an assembly, it is added to the assembly tree and its icon indicates its status. The following table identifies the document status icons.

Icon	Meaning	Description
	Bound	The document exists, it has content and the binding rule has been satisfied.
	Unassigned	This is a document placeholder; it indicates that no document has been assigned.
	Superseded	The document exists, it has content and the binding rule has been satisfied, however a newer version of the document exists.
	Missing version	A version of the document exists that is different from the one specified by the binding rule.
	Missing	No version of the assigned document exists.
	Missing content	The document exists and the binding rule has been satisfied, however the document has no content associated with it. This can occur if a virtual document has been as- signed from the repository.

Synchronize Document Attributes

As the documents change in the DMS, synchronizing document attributes enables you to see the current DMS attributes in Ennov InSight .

Attributes that map to DMS values are indicated by  on the *Document Attributes* page.

When a DMS synchronization occurs, the following happen:

— The value for Last Repository Data Retrieval (on the *Document Attributes* page) is updated for the root, all folders, leaf elements, documents, and document placeholders.

— All calculated and mapped attributes (for example, assignment status and version numbers) are updated.

— Any other attributes for which you changed the values in Ennov InSight revert to their DMS attribute values.

Keep in mind the following:

— HTML text strings enclosed in angle brackets (< >) that map to Ennov InSight attributes do not appear in document attributes. HTML numeric strings map correctly.

— Running a DMS Synchronization on the root of a lifecycle working view performs a synchronization on documents from the previous sequence. Updates to documents from previous sequences do not become part of the current active view. Be aware, however, that if you synchronize the root and thereafter find unexpected attribute values on documents from previous sequences, you should check the same document in the current active view to determine the values of the document in the previous sequence.

— Running a DMS Synchronization from the Working View sends all previous sequences for Rendition & Extraction. Only documents for which there are no renditions and extractions are sent.

— Synchronizing large assemblies can slow the repository's performance and prevent other users from accessing it temporarily.

— Synchronization may be slower than expected if the DMS has limited space.

— Ennov InSight binds directly to specific versions of documents in a DMS repository. Because of this, Ennov InSight does not support the automatic or manual deletion of previous versions in a DMS. If you delete versions in your repository, Ennov InSight may generate an error when you attempt to synchronize to a version that no longer exists. You can avoid this by reassigning the document through the binding rule to a version that still exists.

Synchronize Documents with the DMS

You can run a DMS Synchronization from the Working View to send all previous sequences for Rendition & Extraction. Only documents for which there are no renditions and extractions are sent for Rendition & Extraction.

To synchronize document attributes with the DMS:

1. In the assembly tree, do one of the following to open the attributes page for the element:

Action
Choose the root to synchronize the entire assembly.
Choose an individual element to synchronize.

2. Click  . A message prompts you to confirm the synchronization. Click Yes for one of the following:

Option	Action
Update the InSight document properties from the attributes:	Replaces the assembly attributes with those values in the DMS.
Update the Reference Location attributes from InSight:	Updates the existing reference location in the DMS with the latest version, label, and status information from the assembly, as well as additional configured attributes.

Note: *The Ennov InSight hourglass does not appear as the DMS synchronization occurs, however, synchronization can sometimes take several minutes to complete, depending on the speed of the associated DMS.*

Attributes preceded with

are updated with the current values in the DMS.

View a Document Content

Steps to view the content of the document being assigned from the Browse Documents.

To view the content of the document being assigned:

1. In the assembly tree, right-click on the leaf.
2. Select Assign Document.
3. In the Documents tab, find and select a document from Documentum, Veeva, or Secured File System.
4. Click Preview under the Browse Resently Selected section. The document is downloaded to the Downloads folder.
5. Find the document and check its content.

View Document Versions

You can view the version of a document from the assembly tree.

To view document versions:

1. Click a link for the assembly whose document versions you want to view.
2. On the assembly tree, click the document whose versions you want to view.

The document versions appear in the lower-right corner under the document attributes.

Related Documents

You can replace an assigned document in an assembly tree with one of its related documents. Ennov

InSight provides a list of related documents, if they exist, for each assigned document.

Related documents are defined by document relations, a concept defined and supported by Documentum. When you replace a document with a related document, the link from the assembly tree to the original document is deleted and a link is created between the assembly tree and the related document.

Note: *Replacing a document with a virtual document is not currently supported.*

Assign a Related Document

Use the procedure to replace an assigned document with one of its related documents in an assembly tree. To

replace a document with a related document:

1. In the assembly tree, right-click the document you want to replace and choose Assign Related Documents. The list of related documents appears.
2. Choose a related document from the list and click Assign Document.

Unassign Documents

You can remove the link to a document from the assembly tree by unassigning the document. When you unassign a document, the following happen:

— Selected attributes (as specified by your administrator) are cleared from the *Document Attributes* page.

— The assignment status on the *Document Attributes* page changes.

— The icon next to the document in the assembly tree changes to 

Unassign a Document

Use the procedure to remove the link to a document from the assembly tree by unassigning a document. To

unassign a document:

1. Do one of the following:

Action
Choose the document in the assembly tree and click  .
Right-click the document in the assembly tree and choose Unassign Document. A message prompts you to confirm the change.

2. Click OK.
3. If  does not replace the document icon in the assembly tree, right-click the assembly root and choose Refresh Tree.

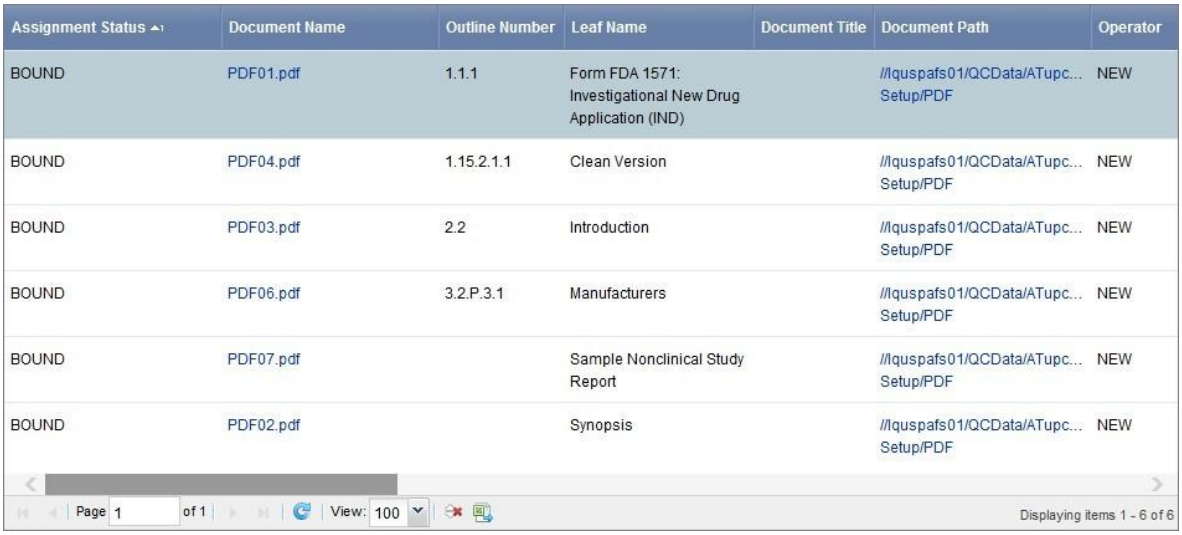
View the Assembly Document List

You can view the list of documents in the assembly tree.

To view a document list:

1. Right-click the assembly root and choose View Document List.

Example



Assignment Status	Document Name	Outline Number	Leaf Name	Document Title	Document Path	Operator
BOUND	PDF01.pdf	1.1.1	Form FDA 1571: Investigational New Drug Application (IND)		//lquspafs01/QCData/ATupc... Setup/PDF	NEW
BOUND	PDF04.pdf	1.15.2.1.1	Clean Version		//lquspafs01/QCData/ATupc... Setup/PDF	NEW
BOUND	PDF03.pdf	2.2	Introduction		//lquspafs01/QCData/ATupc... Setup/PDF	NEW
BOUND	PDF06.pdf	3.2.P.3.1	Manufacturers		//lquspafs01/QCData/ATupc... Setup/PDF	NEW
BOUND	PDF07.pdf		Sample Nonclinical Study Report		//lquspafs01/QCData/ATupc... Setup/PDF	NEW
BOUND	PDF02.pdf		Synopsis		//lquspafs01/QCData/ATupc... Setup/PDF	NEW

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Attributes for each document assigned to the assembly appear.

2. Click Back to Outline View to return to the assembly tree.

Modify Document and Placeholder Attributes

You can modify a document to include necessary changes.

— You can change the pathname or file name of an assigned document with a status of missing content, missing version, or bound.

— Many attributes are mapped to their DMS repository or secure file system attributes when a document is assigned to an assembly. The attribute that is stored in Documentum or the secure file system is displayed in . When you synchronize with a DMS repository, the DMS attributes overwrite any mapped attributes you have changed in . appears next to attributes that are mapped to their DMS repository or secure file system attributes.

When you assign a document to a placeholder, the placeholder is not bound to the assigned document until you perform a DMS synchronization.

Note: *When modifying documents, unwarranted change in the placement of assembly elements can cause unexpected results.*

Modify Document Attributes

You can modify attributes for a document in the assembly tree.

To modify the attributes for a document:

1. On the assembly tree, select the document you want to modify.
2. On the *Document Attributes* page, click Edit  .
3. Change attributes, then Save.

Move Assembly Elements

Moving the location of an element can cause unexpected results.

As you move elements around in the assembly tree, keep in mind the following:

— A leaf cannot be moved, promoted, or demoted to a level where it becomes a parent or child of another leaf.

— A document or document placeholder cannot be the parent of a leaf.

— You cannot move or demote elements into a locked folder.

— When you promote an element, it becomes a sibling of its previous parent.

— When you demote an element, it becomes the last child of its next higher sibling.

— Additional reorganization guidelines apply to assemblies in lifecycle applications.

Move Assembly Elements Table

You can move elements up and down and you can promote and demote elements in the following ways:

Choose this	To do this
Move Up	Move an element to a location above its current position in the assembly tree, one position at a time

Choose this	To do this
Move Down	Move an element to a location below its current position in the assembly tree, one position at a time
Promote	Move an element one level to the left in the assembly tree hierarchy
Demote	Move an element one level to the right in the assembly tree hierarchy
Delete	Remove an element from the assembly tree structure; does not delete a document from the repository

Move Assembly Elements Within an Assembly Tree

Perform drag-and-drop actions on assembly elements within an assembly tree to change the assembly structure. To perform drag-and-drop operations in an assembly tree, you must have the WRITE permission for those assemblies.

A single node of the following elements can be dragged onto an assembly tree.

— Folder

— Leaf

— Document

— Placeholder

— Reference Leaf

The following rules apply when using the drag-and-drop feature.

— You can drag single elements within the initial sequence assembly, assembly template, working view of the sequence assembly, and submitted view of the sequence assembly.

— Dragging elements within the sequence view of the sequence assembly is not allowed.

The following nodes cannot be dragged onto an assembly tree.

— Suspended leaf and suspended elements in the range under it. — Replaced leaf.

— Folder, leaf, reference leaf, document, or a placeholder within the lock range of a standard locked root or folder.

— Root of the assembly.

— Old folder, leaf, document. or a placeholder onto the new assembly tree elements.

— Leaf to another Leaf or document including missing document, document with missing content, document with the missing version, or superseded document.

— Leaf to placeholder.

— Folder to placeholder.

— Folder to document, document including missing document, document with missing content, document with the missing version, or superseded document. — Parent node to its child node.

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Move an Assembly Element

You can move the location of a single element or multiple elements in the assembly tree. To

move an element in the assembly tree:

1. On the assembly tree, right-click the element you want to move and choose one of the following:

Option	Action
Move up :	Moves the element one position up.
Move down:	move the element one position down.
Promote :	move the element one position to the left.
Demote:	move the element one position to the right.

2. To move multiple elements in the assembly tree:

Option	Action
Shift +click:	To select contiguous elements, then drag the elements to a new location in the assembly.
Ctrl+click:	To select non-contiguous elements, then drag the elements to a new location in the assembly.

Move Leafs That Are Siblings in a Folder

Use this procedure to move leafs that are siblings within a folder.

To move leafs that are siblings within a folder:

1. To select a range of leafs:

Action
Click the first leaf in the range.
Hold down the Shift key and click the last leaf in the range.
Drag one of the selected leafs onto a folder.

When you let go of the mouse the dragged leafs will become children of the folder. 2. To select specific leafs:

Action
Click the first leaf to be selected.
Hold down the Ctrl key, and select the rest of the leafs.
Drag one of the selected leafs onto a folder.

When you let go of the mouse the dragged leafs will become children of the folder.

Move Leafs That Are in Different Folders

Use this procedure to move leafs that are in different folders.

To move leafs that are in different folders:

1. Hold the Shift key down and click on leafs one at a time. While still holding down Shift, click one of the selected leafs and drag it onto a folder.

   When you let go of the mouse and Shift key the dragged leafs will become children of the folder.
2. Hold the Shift key down and click on leafs one at a time. While still holding down Shift, click one of the selected leafs and drag it onto another leaf.

When you let go of the mouse and Shift key the dragged leafs will become siblings to the leaf.

Move Folders That Are Siblings in a Folder

Use this procedure to move folders that are siblings in another folder.

To move folders that are siblings in another folder:

1. Hold the Shift key down and click the first and last folder.
2. While still holding down Shift, click one of the selected folders and drag it onto a folder.

When you let go of the mouse and Shift key the dragged folders will become children of the folder.

Move Folders That Are in Different Folders

Use this procedure to move folders from a different folder.

To move a folder from a different folder:

1. Hold the Shift key down and click on folders one at a time.
2. While still holding down Shift, click one of the selected folders and drag it onto a folder.

When you let go of the mouse and Shift key the dragged folders will become children of the folder.

Move Different Element Types in Different Folders

Use this procedure to move different element types in different folders.

To move different element types in different folders:

1. Hold the Ctrl key down and click on different non-contiguous elements one at a time.
2. While still holding down Ctrl, click one of the selected elements and drag it onto a folder.

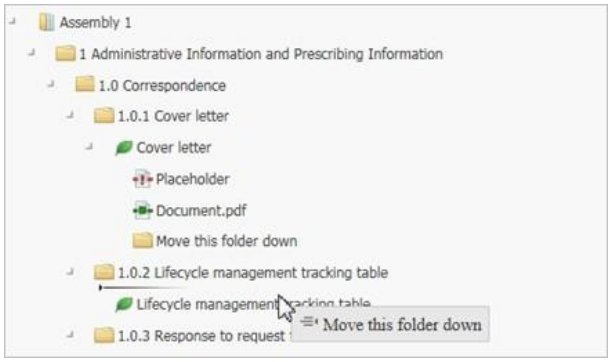
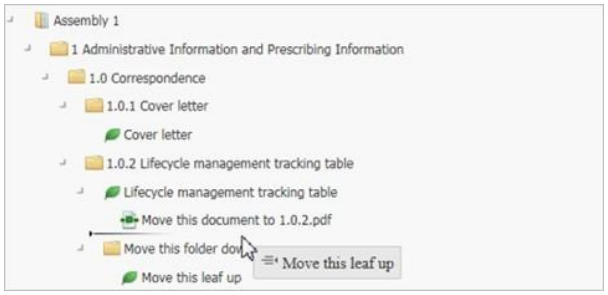
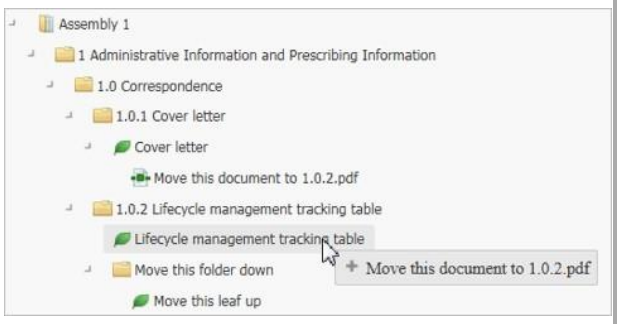
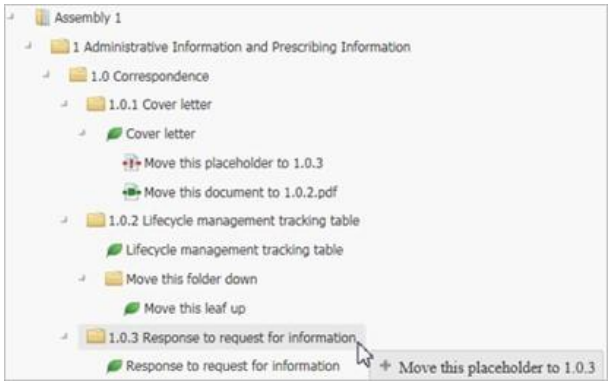
When you let go of the mouse and Ctrl key the dragged elements will become children of the folder.

Assembly Tree

With the Assembly Tree, you can drag assembly elements to place them between Assembly Tree nodes and also filter the Assembly Tree elements using the new Assembly Tree search option.

Use the following methods to add elements to an assembly:

— Use the drag-and-drop feature to move the assembly tree elements within an assembly tree.

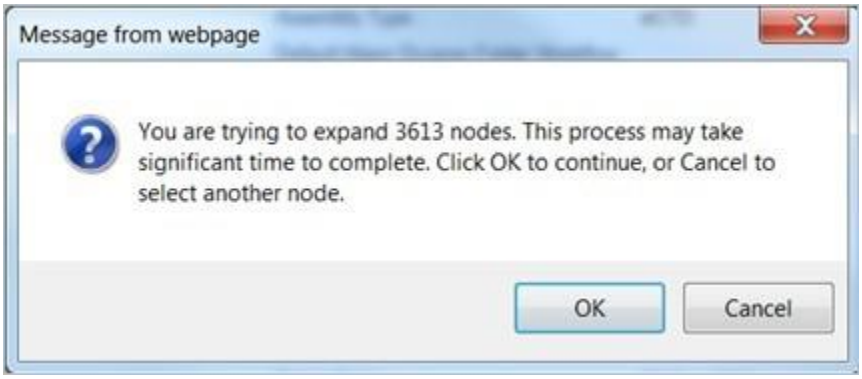
Drag-and-Drop Folder	Drag-and-Drop Leaf
	
Drag-and-Drop Document	Drag-and-Drop Placeholder
	

Note: *Only a single node can be moved.*

— Use the drag-and-drop feature to add folders, documents, and leafs from the *DMS Browse* and *Browse Assembly* windows to an Assembly Tree.

— Use the Search option to filter the assembly tree elements by the text entered in the Search field.

You can select Right-click > Expand Range for an Assembly that has a complicated structure and contains an extensive amount of elements. A confirmation prompt appears and you can confirm that you want to proceed.



Assembly Tree Notes

For better system performance, please consider the following when your Assembly has a complicated structure and contains an extensive amount of elements:

— Assembly Tree Search functionality can be used to help in navigation through complex and large assemblies.

— The number of displayed assembly tree elements that match the search criteria can be restricted by defining an upper limit in the insight.var file.

— If the requested range exceeds the value defined in the insight.var, a confirmation prompt appears and you can confirm that you want to proceed.

— If the desired node is placed under a folder with a large number of nodes located at the same level, it is recommended to create a copy of that node and make a custom template including the node.

Assembly Tree Filter

Filter the assembly tree elements using the search option on the assembly tree.

Using the search drop-down list, you can also select a node type as a criterion to narrow your search results. The results appear in the same order as they are in the assembly. The maximum number of matching elements displayed depends on the limit set in the configuration file. When the results exceed the defined number, a message is displayed with the number of matching elements and the number of elements that will be displayed in the assembly tree. By default, the maximum number for displaying the matching elements defined in the file is 500.

The following assembly elements can be searched using the search option:

— Assembly root

— Folder

— Leaf

— Reference leaf

— Document

— Placeholder

You can filter an assembly tree based on the search text that matches the values in the following fields:

	Name	Abbreviated Name	Title	Number	Owner	Keywords
Assembly Root	+				+	+
Folder	+	+		+	+	+
Leaf	+	+	+	+	+	+

Document/Placeholder	+	+	+	+	+	+

Use the following wildcard characters to filter the assembly tree elements:

Wildcard Character	Description
%	Use % to specify that characters can occur in multiple positions.
_ (Underscore)	Use _ to specify a single position in which a character can occur.

Filter Assembly Tree Elements

Use the filtering function to search for assembly tree elements.

To filter the assembly tree elements:

1. Navigate to an assembly.
2. In the search text field, enter the criterion and do the following:

Option	Action
To filter an assembly tree based on the search criterion across all node types	Select All Content from the Search dropdown list.
To filter an assembly tree based on the search criterion for a specific node type	Select a node type from the Search dropdown list.

3. Click the search icon.

The assembly tree is refreshed and shows the branches with the nodes that match the search criteria. Each branch can be expanded up to the matching node.

Advanced Assembly Tree Filter

The Advanced Assembly Tree Filter feature enables you to filter an assembly tree for specific assembly elements.

The Advanced Assembly Tree Filter feature enables you to filter an assembly tree for:

— Empty folders and leafs.

— Leafs with the life cycle Replace or Suspend and that are being operated in a parallel sequence.

— Leafs with a specified leaf status.

— Documents with assignment status.

Advanced Assembly Tree Filter for all Nodes

The Advanced Search enables you to filter an assembly for elements based on node types.

To filter an assembly for all node types:

1. Navigate to an assembly.
2. Click the Advanced Search icon.
3. To filter an assembly tree across all node types, select All Content from the search drop-down list.
4. In the Search in All Fields field, enter the search criteria.
5. Click Search.

All the node types are displayed according to the search criteria.

Advanced Assembly Tree Filter for Folders

The Advanced Search enables you to filter an assembly for folders.

To filter an assembly for empty folders: 1. Navigate to an assembly.

1. Click the Advanced Search icon.
2. From the search drop-down list, select Folders.
3. In the Search in All Fields field, enter the search criteria.
4. To view only the empty folders that match the search criteria, select Show only empty Folders.
5. Click Search.

Advanced Assembly Tree Filter for Leafs

The Advanced Search enables you to filter an assembly for specific leafs based on multiple search criteria. To

filter an assembly for leafs:

1. Navigate to an assembly.
2. Click the Advanced Search icon.
3. From the search drop-down list, select Leafs.
4. In the Search in All Fields field, enter the search criteria.

Option	Action
To filter leafs based on the status:	Select a status from the Leaf Status dropdown list.
To view only the empty leafs that match the search criteria:	Select Show only empty Leafs.

Option	Action
To view leafs that are being operated in one or more parallel sequences:	Select Show leafs operated in parallel sequences.

The option Show leafs operated in parallel sequences is available only in the Working view of a sequence assembly.

5. Click Search.

Advanced Assembly Tree Filter for Documents

The Advanced Search enables you to filter an assembly for documents.

To filter an assembly for documents:

1. Navigate to an assembly.
2. Click the Advanced Search icon.
3. From the search drop-down list, select Documents.
4. In the Search in All Fields field, enter the search criteria.
5. To filter documents based on the document assignment status, select a status from the Assignment Status drop-down list.

   For information about the document statuses, refer to the topic *Document Status Indicators*.

6. Click Search.

Import Assemblies

Conditions under which an assembly can be imported.

You can only import assemblies using the Import Assemblies Wizard. Content can be added to an assembly using different methods. For example, by selecting a root folder or any other folder or by dragging an assembly on to another assembly.

You can import the following:

— A sequence assembly

— Part of a sequence assembly

— An entire template or part of a template — An application view of the following types:

- Submitted
- Working
- Sequence

The following conditions apply when importing an assembly:

— To import only a part of an assembly, you must use the drag-and-drop function or select a folder.

— When using an imported assembly file that contains previously defined in-process links that target leaf elements, you must re-target in-process links to leaf elements.

— Leaf status assigned to each leaf element is automatically set to the default Leaf Status value configured in Data Administration.

The following are the results of importing a full or partial assembly:

— If you import an assembly into a new assembly, the settings in the imported assembly are copied into the new assembly.

— The source assembly or assembly folder you import becomes a child of the target element in the target assembly.

— Element attributes of the imported assembly or folder are referenced.

— If you import an assembly root, the folder that represents the root of a source assembly is created in the target assembly and contains the children of the imported root.

— Elements that are locked in the imported assembly are not locked in the target assembly.

— All leaf elements contained in the imported assembly root or folder are added to the target assembly with the NEW operator and a blank modified file value.

— Documents in the imported assembly do not have a value for the Created From attribute.

— You cannot import individual leaf elements, documents, or document placeholders.

— A document will not change to a placeholder when importing a source assembly where it is assigned.

— Even if the quantity limit for eCTD 4.0 assembly nodes is exceeded, the import will still be completed, and a job will be created in Job Requests.

— If the quantity limit for eCTD 4.0 assembly nodes is not exceeded, the import will be completed. — CV nodes on folders and CV values are copied after the import.

— If Reset Lifecycle Information? is selected, the unique identifiers of the leafs are recreated.

Import Assembly Wizard

Use the *Import Assembly Wizard* to import an assembly into the assembly tree.

Prerequisites

Only the assemblies of the eCTD 4.0 type are visible if wizard is invoked from eCTD 4.0 assembly.

Publishing settings must be specified for the assembly into which you are importing an assembly.

To use the *Import Assembly Wizard*:

1. On the assembly tree, right-click the root or folder where you want to import the assembly and choose Import Assembly Wizard.
2. For the How would you like to find the assembly? option, select one of the following to find an assembly.

Option	Action
Browse	a. Click Browse. b. Select the required assembly type tab. c. Select an assembly and click OK. d. If you want to select an assembly element to import, click Show, make a selection and then click OK.
Option	Action
Search	Select the assembly type in the Assembly Type to Search.

3. Choose the following options as necessary.

Option	Action
Reset Lifecycle Information:	Select this option to reset the life cycle information for a new assembly. If this option is not selected, the life cycle from the source assembly will be included in the new assembly.

Retarget copied Reference Leafs:	Select this option to retarget the reference links copied from the source assembly to link to their targets in the new assembly. If the Reference Leaf points to a leaf that is also part of the import, the Reference Leaf is updated to the copied target instead of the source assembly. If the Reference Leaf points to a leaf is not included in the import, but a leaf in the target assembly matches the source assembly and is created from the same template, the leaf is retargeted.

Note: *You must retarget in-process links to leaf elements when using an imported assembly file that contains previously defined in-process links that target leaf elements.*

4. Click Next.

   If you have selected the assembly by using the Browse option, move to step 7.

5. Enter the search criteria and click Next.
6. Select the assembly from the matching assemblies and click Next.
7. Expand the assembly, then click the root or part of the assembly to import, and click Next.

   The *Import Completed* window appears, listing the actions taken.

8. Click Finish.

The updated Assembly is displayed. Right-click the root or the folder and choose Expand Range to see the full assembly with the imported assembly. See *The Import of the Sender-defined Keywords* for specific rules.

The Import of the Sender-defined Keywords

The Sender-defined Keywords (SDKs) are imported according to specific rules.

The SDKs are defined at the application level and are referenced from the assemblies that belong to that application.

While copying an assembly folder elements that reference the SDK of an application, there is a mechanism responsible for adding the required SDKs to the target application and assigning them to the imported folder instance. Examples of possible scenarios are provided in the table below.

When importing from sequence assembly or submitted view to initial or working assemblies, the SDK is copied to an application and assigned to the imported folders. See the details in the table below.

If the folders are imported to the assembly template, the SDKs are not copied.

The Sender-defined Keywords of the imported folder is not changed after updating the Display Name of the Sender-defined Keywords in a source application.

Note: *Changing of CV Profiles in Publishing Settings may lead to unexpected behavior affecting the Context of Use selections, additional and regional attributes.*

Action	Result
Importing of folders from the source Assembly1 to the target Assembly2, where the existing SDK has the same Code and Display Name as an SDK referenced in the imported assembly.	After the import, the SDK is not copied from the source Application1 to the target Application2. Additional Information for the imported folder contains the SDK from the Application2.
Importing of folders from the source Assembly1 to the target Assembly2, where the existing SDK has Code and Display Name different from Display Name and Code of an SDK referenced in the imported assembly.	After the import, the SDK is copied from the source Application1 to the target Application2. Additional Information for the imported folder contains the copied SDK.
Importing of folders from the Assembly1 to the target Assembly2, where the existing SDK has the same Display Name as an SDK referenced in the imported assembly, but different Code.	After the import, the SDK is not copied from the source Application1 to the target Application2. Additional Information for the imported folder contains the SDK from the Application2.
Importing of folders from the source Assembly1 to the target Assembly2, where the existing SDK has the same Code as an SDK referenced in the imported assembly, but different Display Name.	After the import, the SDK is copied from the source Application1 to the target Application2. The Code of the copied SDK is generated in the following way: — If the Code value ends with a number, then the number is increased by 1. Example: SDK-001 --> SDK-002. — If the Code value ends with a letter/symbol, then '1' should be added to the end of the value. Example: 001-SDK ---> 001-SDK1. Additional Information for the imported folder contains the copied SDK.

Search for an Assembly

The wizard launches when you click whichever is available on the page that you are viewing: the Search tab or the Browse button.

To search for an assembly:

1. Select the type of assembly you are searching for and click Next.
2. Enter the assembly query parameters. Only the display columns are required, and they have default values.
3. Click Next.

4. On the *Matching Assemblies* page, select the assembly that you want to use.
5. On the *Selected Assembly* page, select the assembly element that you want to use, and click Next.

Notes on Search for an Assembly

You can use the *Search Assembly* wizard to search for an assembly when you take specific actions. — Change a modified leaf

— Convert a leaf to a reference leaf

— Create an assembly template from an existing template, assembly, or view

— Create an assembly after you create an initial application submission, an amendment submission, or a major update submission

— Retarget links while running the Link Inspector query

The wizard launches when you click either the Search tab or the Browse button.

Assembly Baselines

You can track the changes of an assembly by multiple user groups to establish a baseline.

Once an assembly is in a semi-completed state, you can begin to track changes to its structure and content. This enables multiple groups of users to track changes before the assembly is approved. It also enables an assembly group and publishing group to synchronize changes to the assembly with an external publishing application.

The current assembly outline becomes the baseline when the baseline is set; any existing baseline for that version is erased. After you begin to make changes to the assembly, you can view differences between the updated assembly and the baseline.

Note: *Only an administrator can set the baseline for an assembly.*

View an Assembly Baseline

You can track the changes of an assembly by multiple user groups to establish a baseline. To

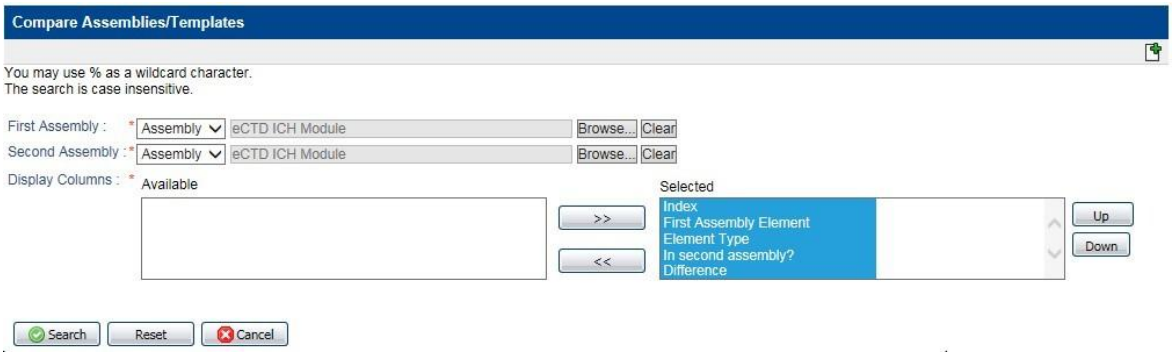
view baseline differences:

1. Click a link for the assembly whose baseline differences you want to view.

Assembly Baselines

2. Right-click the assembly root and choose View Baseline Differences.

Example



The *Compare Assemblies/Templates* page opens with the baseline assembly in the *First Assembly* box and the current assembly in the *Second Assembly* box.

3. In the *Available Columns* box, select the columns to include in the query and move them to the *Selected Columns* box.

   To remove columns from the *Selected Columns* box, select them and move them to the *Available Columns* box.

4. To change the order of the columns as they appear from left to right in the query results, select a column in the *Selected Columns* box and click up or down.

5. Click Search.

   The comparison query results are displayed.

6. To return to the *Assembly Attributes* page, click Back.

Replace Assembly Variables

You can use Find and Replace to update delimited variables to text values for a specific assembly.

Find and Replace is available for the assembly root and folder-level elements. All folders, leaf elements, and documents that are children of the root or a folder on which you perform a find and replace are searched and instances of the search criteria are replaced.

When you create an assembly from a template that contains delimited variables, you can use Find and Replace to replace those variables with unique values for the assembly. For example, if a template contains [docbase]/regulatory/[product]/substance for the document path, you could search for [docbase] and replace it with the name of your repository.

When you perform a find and replace:

— The find and replace values are limited to 500 characters.

— Values must be text values.

— No validation is performed on the values you enter.

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For find and replace in a working view:

— Attributes of folders from previous sequences are searched.

— Attributes of read-only leaf elements from previous sequences are not searched.

Note: *Although some attributes in folders from previous sequences appear to be read-only, they are modified by the find and replace because some of the attributes affect publication of XML for the current sequence.*

Find and Replace an Assembly Variable

You can use Find and Replace to update delimited variables to text values for a specific assembly.

You cannot undo a find-and-replace action. To restore changed values, you must perform another find-and-replace action.

It is strongly recommended that you create an assembly version before using Find and Replace, so you can revert to the original version if something is replaced in error. It is also recommended that you carefully choose the text to replace.

To find and replace a variable in an assembly:

1. Click a link for the assembly you want to search.
2. Right-click the element you want to search.
3. Choose Find and Replace.

4. In the *Find and Replace* dialog box, choose one of the following:

Option	Description
Text Search:	Searches all text attributes.
Date Search :	Searches date attributes.

5. In the *Find what* box enter the text value or date to find.
6. In the *Replace with* box, enter the replacement value or date.
7. Click OK.
8. To view the replaced values, click  .

Replaceable Assembly Variables

You can use Find and Replace to update delimited variables to text values for assembly root and folder-level elements.

Element	Attribute
Folder	Name
	Output folder
	Keywords
	Extended publishing attributes

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Element	Attribute
Leaf	Name
	Output file
	Keywords
	Extended publishing attributes
Document	Name
	Title
	Category
	Source Location
	Source Document
	Due Date
	Owner
	Keywords

Lock Assemblies

With the proper permissions, you can lock assemblies at various levels.

Locks

In addition to locking folders, you can create standard locks.

A standard lock prevents most changes to the assembly, including changes to folders, leaf elements, documents, and publishing elements. However, you may still change document binding; binding must be locked separately.

eCTD 4.0: Unlock Assemblies

You can remove a lock on an assembly to change the beginning and ending points.

To unlock an assembly:

1. Select an assembly and click  .
2. Click OK.

Lock Assemblies

.When you update an assembly status to the effective status as defined by your system administrator, the assembly is locked and its version label is set to Current, which may already be assigned to another assembly version in the version tree.

Updating as assembly status to the effective status has limitations and consequences. Once the assembly version has an effective status, only an administrator can change the assembly status and status date. If the administrator changes an effective status to a non-effective status, the assembly remains locked until the administrator unlocks it. To work around this, you can create a new assembly version and make changes to the new version.

If after the administrator unlocks a non-effective status assembly you change the assembly to an effective status again the assembly is not relocked. You must lock the assembly.

If you change a noneffective status to an effective status on an assembly version, the version label of the assembly version is set to CURRENT.

If the assembly version being set to the effective status is not the latest version for the assembly, the version label for the latest version of the assembly with the CURRENT version is set to blank, or if a previous version of the assembly has the effective status, its version label is set to SUPERSEDED.

If the administrator changes an assembly version's effective status to a noneffective status:

— The assembly version label changes to blank unless the assembly is the latest version and no other version has an effective status.

— The CURRENT version label is assigned to an effective assembly with the most recent version number in the version tree.

— The label is set to blank if the assembly version had a label of SUPERSEDED.

If a reference location exists in the DMS repository for the version of the assembly, the reference location that corresponds to the CURRENT assembly version is made current in the DMS repository. In some instances, this may require the creation of a new version of the reference location.

Update an Assembly Status

You must have the appropriate security privileges to update the status of an assembly. You should be aware of the limitations and consequences before updating the assembly status.

To update an assembly status:

1. Click a link for the assembly version whose status you want to update.
2. On the *Assembly Attributes* page, click  .
3. Click the New Status arrow and choose the updated status.

4. For Status Date, choose the effective date for the new status.
5. Save.

View an Assembly

You must have the appropriate security privileges to view and take action on an assembly and its attributes. To view attributes for an assembly:

1. Click a link for the assembly you want to view.

   The *Assembly Attributes* page opens.

2. Do any of the following:

   — Click an action button to perform an action on the entire assembly.

   — Right-click the root, then choose Expand Range to expand the assembly so you can choose an element on which to perform an action.

3. Click the toolbar icons to perform an action. Do any of the following:

— To view the sequence with which the assembly is associated, click the Sequence tab and click a sequence link.

— To view tasks and sub-tasks associated with the sequence, click the Tasks tab and click a task link.

— To view references associated with the sequence, click the References tab and click a reference link.

— To view notifications associated with the sequence, click the Notifications tab and click a notification link.

— To view a version of an assembly document, click the document in the assembly tree, then click the version at the bottom of the page.

Assembly Root Toolbar Icons

You can take action on assemblies using the icons in the toolbar.

Icon	Description
	Edit enables you to change the assembly or element attributes.
	DMS Synchronization enables you to synchronize the Ennov InSight attributes with the DMS repository mappings for documents in the assembly.
	Publishing Settings Library enables you to specify leaf and default study file attributes for publishing. This button is for ELP users only.

	Publish Request enables you to: choose a submission output location and document type, specify whether to create renditions automatically, and what to publish. This button is available for ELP users only.
	Copy URL enables you to copy the URL for the assembly or an element to the Clipboard.
	Lock Sequence locks the assembly from further changes.

	Unlock Sequence releases the assembly from a locked state.
	Regional Information enables you to assign regional attributes that include additional properties specific to the assembly root. This option is available in the eCTD 4.0 assembly root if the CV Profile with envelope CV is assigned to Publishing Settings Library.

Icon	Description
	Update Status enables you to change the assembly status.
	Add Submission to Lifecycle enables you to add an assembly to a life cycle.
	Export Assembly to... enables you to export the assembly to an assembly file.
	Delete enables you to delete an assembly.
	Apply Binding to all Children enables you to apply the binding rule for documents that are currently assigned to the assembly. If you first choose an element, the binding changes only for the children in the selected element.
	Force New Renditions and Extractions creates renditions and extractions, overwriting all existing renditions and extractions.
	Prepare to Publish opens the dialog box to prepare the assembly element for publishing.
	Publishing Summary Query displays each component in the assembly, its types and sub-types, and indicates whether a leaf has at least one child document and whether the leaf has any overridden attributes with renditions.
	Recalculate Checksums enables you to recalculate checksums for the content that has been changed post publishing.

Regional Information

Regional information is specific to each region and included into a submission provided to regulatory authority.

Using Regional Information, you can assign regional attributes that include additional properties specific to the assembly. This option is available in the More menu of the eCTD 4.0 assembly root if the CV Profile with envelope CV is assigned to Publishing Settings Library.

Regional Information is available the following eCTD 4.0 assemblies:

— Locked or unlocked Initial Sequence Assembly.

— Locked or unlocked Working Assembly

— Locked or unlocked Sequence View not added to a life cycle.

— Sequence View added to a life cycle.

— Locked or unlocked Submitted View.

— Locked or unlocked Assembly Template.

Modify Regional Information

Configure regional attributes to the assembly root to easily incorporate regulatory changes.

Prerequisites

To make the Regional Information option available in the More menu of the eCTD 4.0 assembly root, you must have the CV Profile with envelope CV assigned to Publishing Settings Library.

To view or modify the regional information:

1. On the assembly tree, select to the eCTD 4.0 assembly root folder.
2. In the More list, click Regional Information.
3. On the *Regional Information* page, click Edit.

   This option is not available if Regional Information is invoked from a locked Submitted view and sequence assembly added to a life cycle.

   Note: *The regional information attributes are displayed according to the CV service configuration. If the Applicant Contact values were previously set for Regional Information and then deactivated in Data Administration, they will still be available on the attributes page and included in the published output.*
4. Modify the attributes.
5. Click Save.

Assembly Folder Icons

You can take action on assembly folder elements using the icons in the toolbar.

Icon	Description
	Edit enables you to change the folder attributes.
	DMS Synchronization enables you to synchronize the Ennov InSight attributes with the DMS repository mappings for documents in the assembly.
	Publishing Settings Library enables you to specify leaf and default study file attributes for publishing. This button is for ELP users only.
	Publish Request enables you to: choose a submission output location and document type, specify whether to create renditions automatically, and what to publish. This button is available for ELP users only.

	Lock locks the folder from further changes.
	Unlock releases the folder from a locked state.
	Additional Information enables you to assign additional properties specific to the assembly root or any other folder. This option is available in the eCTD 4.0 assembly folder if the CV Profile with envelope CV is assigned to Publishing Settings Library.
	Apply Binding to all Children enables you to apply the binding rule for documents that are currently assigned to the assembly. If you first choose an element, the binding changes only for the children in the selected ele- ment.
	Force New Renditions and Extractions creates renditions and extractions, overwriting all existing renditions and extractions.
	Prepare to Publish opens the dialog box to prepare the assembly element for publishing.

Additional Information

Additional information that is used to define eCTD 4.0 folders metadata, as required by the regional and ICH regulatory authorities.

Using Additional Information, you can assign additional properties specific to the assembly folder. This option is available if the Context of Use Code field is populated for selected folder.

Additional Information is available the following eCTD 4.0 assemblies:

— Locked or unlocked Initial Sequence Assembly.

— Locked or unlocked Working Assembly

— Locked or unlocked Sequence View not added to a life cycle.

— Sequence View added to a life cycle.

— Locked or unlocked Submitted View.

— Locked or unlocked Assembly Template.

Modify Additional Information

Configure additional attributes specific to the folder to easily incorporate regulatory changes.

Prerequisites

To make the Additional Information option available under More menu of the eCTD 4.0 assembly folder, you must have the Context of Use Code field populated for selected folder.

To view or modify the additional information:

1. On the assembly tree, select the folder you want to change.
2. In the More list, click Additional Information.

   This icon is displayed if the Context of Use Code field is populated for selected folder.
3. On the *Additional Information* page, click Edit.

   This option is not available if Additional Information is invoked from a locked Submitted view and sequence assembly added to a life cycle.

   Note: *The regional information attributes are displayed according to the CV service configuration.*
4. Modify the attributes.
5. Click Save.

Assembly Leaf Toolbar Icons

You can take action on assembly leafs using the icons in the toolbar.

Icon	Description
	Edit enables you to change the leaf attributes.

Icon	Description
	DMS Synchronization enables you to synchronize the Ennov InSight attributes with the DMS repository mappings for documents in the assembly.
	Publishing Settings Library enables you to specify leaf and default study file attributes for publishing. This button is for ELP users only.
	Publish Request enables you to: choose a submission output location and document type, specify whether to create renditions automatically, and what to publish. This button is available for ELP users only.
	View Leaf Output enables you to open an assigned document.
	Apply Binding to all Children enables you to apply the binding rule for documents that are currently assigned to the assembly. If you first choose an element, the binding changes only for the children in the selected element.
	Force New Renditions and Extractions creates renditions and extractions, overwriting all existing renditions and extractions.
	Prepare to Publish opens the dialog box to prepare the assembly element for publishing.

Assembly Document Toolbar Icons

You can take action on assembly documents using the icons in the toolbar.

Icon	Description
	Edit enables you to change the document attributes.
	Assign Document enables you to assign a document to the assembly tree.
	Unassign Document enables you to remove the selected assigned document from the assembly tree.
	DMS Synchronization enables you to synchronize the Ennov InSight attributes with the DMS repository mappings for documents in the assembly.
	View File enables you to open an assigned document.
	Edit Document Bookmarks enables you to edit the extracted bookmarks of the selected document.
	Force New Renditions and Extractions creates renditions and extractions, overwriting all existing renditions and extractions.

Export Assemblies

Format and conditions for assembly export. You can export an assembly to XML file.

Export Assemblies

When you export an entire assembly or part of an assembly, the following occur:

— Only an assembly that has CV Profile/s (Active or Inactive) with CV details assigned (Active or Inactive) and selected in Publishing Settings is exported successfully.

— If you try to export an assembly that has CV Profiles but without CV details assigned to them, the message to assign the CV details to CV Profile is displayed.

— The information about CV Profiles is included in .xml file after an assembly is exported.

— An assembly containing additional fields with values assigned to a folder based on the set Context of Use Code is exported successfully from the Initial Sequence Assembly, Submitted View, Working Assembly view, Sequence view, and the Sequence view that is already in life cycle.

— When exporting from the Sequence view or Sequence view that is already in life cycle, the only tree elements shown in Sequence view are exported. There will be no old tree elements from the Working view in the exported file.

— The New, Replace, MReplace, Suspend leafs with a document or placeholder are exported successfully for Sequence view only.

— When CVs are different to the Context of Use Code assigned to the folders, an assembly with the assigned CV Profile is exported successfully. Folders with additional fields with values based on the set Context of Use Code are exported too.

— Additional fields with values assigned to the folder based on the set Context of Use Code are displayed in the exported .xml file.

— If an assembly contains folders extended by additional fields with values based on the set Context of Use Code and there are no CV Profiles in Publishing Settings Library, an assembly is exported successfully.

Export an Assembly

Export an assembly to create an xml file which can be imported to Ennov InSight system for backup, migration or troubleshooting purposes.

To export an assembly:

1. Click a link for the assembly you want to export.
2. In the More menu, click the Export Assembly to...  .
3. On the *Export Assembly* page, enter a name for the export file.
4. In the Export Type field, choose one of the following:

Option	Description
Excel :	Exports to a Excel spreadsheet.
Assembly File:	Exports to an XML file.

5. In the Output Location field, click the Browse button to choose where to save the exported document.
6. In the Please select a document type list (optional), you may choose the document type in which to save the exported document, and click Next.
    a. message prompts you to confirm the export.
7. Click OK.
    a. message confirms the export was successful.

    Export Assemblies

8. Click Done.

Export to an Assembly File (XML)

A XML file created when exporting to an assembly file is used to create new assemblies.

When an assembly is exported to an assembly file, the Rendition Identifier values set in the Assembly Specific Publishing Settings Libraries (APL), and those set on each element, are exported.

— If a Rendition Identifier value does not exist in the database, the Standard Rendition is used.

— If the Rendition Identifier information does not exist in the XML, the Standard Rendition is used.

When you export an entire assembly or part of an assembly, the following occur:

— Assembly with the CV Profile/s selected in Publishing Settings is exported successfully if there is a CV Profile (Active or Inactive) with CV details assigned (Active or Inactive).

— If an assembly is exported with assigned CV Profiles but without the CV details assigned to them, the message is displayed prompting to assign the CV details to CV Profile.

— The information about CV Profiles is included in .xml file.

— Assembly with additional fields with values assigned to the folder based on the set Context of Use Code is exported successfully from the Initial Sequence Assembly, Submitted View, Working Assembly views.

— When CVs are different to that of the Context of Use Code assigned to the folders, the assembly with the assigned CV Profile is exported successfully. Folders with additional fields with values based on the set Context of Use Code are exported too.

— The additional fields with values assigned to the folder based on the set Context of Use Code are displayed in the exported .xml file.

— If the assembly contains folders extended by additional fields with values based on the set Context of Use Code and there are no CV Profiles in Publishing Settings Library, the assembly is exported successfully.

— An assembly is exported successfully when the assembly contains the Sender-defined keywords with assigned CV Profile and CVs are different to that of the Context of Use Code assigned to the folders.

Delete Assemblies

The information provides you detailed unintended consequences when deleting an assembly.

When administrators delete an assembly or assembly template, there can be unintended consequences.

When you delete an assembly or template the following occur:

— The assembly or template is no longer available in lists of assemblies and templates.

— For a working assembly, the Sequence attributes page is displayed where you can create another assembly.

You cannot delete the following:

— An assembly in submitted view

— A locked assembly

— A lifecycle assembly that is finalized

Delete Assemblies

Deleted Assemblies and Assembly Specific Publishing Settings Library (APL)

With some exceptions, deleting an assembly from deletes the associated APL. The APL is deleted if the deleted assembly type is assembly template.

If the deleted assembly is a Sequence Assembly or a Working Assembly, the APL is deleted only if the APL is not referenced by a Submitted View.

View Activities List

You can view the list of activities across the assembly entities, or a for a selection of the assembly entities. For the sequence assembly, the list displays the activities associated to a selected section and all sub-sections in the Working view.

You must have at least READ permission for Activities within the entity security to be able to view the activities list. To view an activities list:

1. Right-click on an assembly root, a folder, or a leaf and select View Activities List.

   A list of activities with activity attributes is displayed.

2. Do any of the following:

Option	Action
To find specific activities:	You can use the Set Filter option. For information on using Set Filter, see *Set Filter*.
To view the details of an activity:	Click on the activity name.
To view the details of an associated entity:	Click on the entity under Related Entity.

Recalculate Checksums

Ennov InSight provides you the ability to recalculate checksums on content that has been changed post publishing. Using the Recalculate Checksums functionality will ensure that Ennov InSight contains the correct checksums which are submitted to the agency. You can use recalculate checksums on any assembly.

The **Recalculate Checksums** functionality verifies if the electronic output location is the same as the assembly was last published to. Once confirmed, a job request is sent to recalculate checksums. After job is completed, the XML should contain the updated checksums.

Note: *The Recalculate Checksums functionality for life cycle sequence assemblies and assembly plans is available from the initial sequence assembly, working assembly, and Sequence view.*

To recalculate checksums:

View Activities List

1. Navigate to the assembly root, folder, or leaf level.
2. Select More > Recalculate Checksums.
3. Click OK.

   The request is sent.
4. Select Go To > Job Requests. Confirm that the job is completed.

The checksums in the XML file are updated.

Prepare Cross-Reference Leafs

The Prepare Cross-Reference Leafs functionality enables you to ensure that the checksum is correct, and is available when publishing any cross-reference leafs that point to content outside of the current sequence.

Note: *Prepare Cross-Reference Leafs can only be executed from the Prepare to Publish window.*

To prepare cross-reference leafs:

1. On the assembly root, click More > Prepare to Publish.
2. In the prepare to publish window click the Prepare Cross-Reference Leafs checkbox, and click OK. The prepare to publish request is sent.
3. Navigate to the Job Requests window.
4. Confirm that the jobs are completed.
5. Click Close.
6. To submit the publishing request, click More > Publishing Request.
7. Select Publishing Output Channel: Electronic and Publish eCTD/Electronic: All leaf elements and XML, and click OK.

The Prepare Cross-Reference Leafs functionality pulls the database value for the target of the cross reference leaf, ensuring that the correct checksum value is used at publish time.

Move Assembly Elements for eCTD 4.0

Moving the location of an element can cause unexpected results.

As you move elements around in the assembly tree, keep in mind the following:

— A leaf cannot be moved, promoted, or demoted to a level where it becomes a parent or child of another leaf.

— A document or document placeholder cannot be the parent of a leaf.

— You cannot move or demote elements into a locked folder.

— When you promote an element, it becomes a sibling of its previous parent.

— When you demote an element, it becomes the last child of its next higher sibling.

— Additional reorganization guidelines apply to assemblies in lifecycle applications.

Ennov InSight Publisher 7.3: eCTD 4.0 Prepare Cross-Reference Leafs

Move an Assembly Element

You can move the location of a single element or multiple elements in the assembly tree. To

move an element in the assembly tree:

1. On the assembly tree, right-click on the element you want to move and choose one of the following:

Option	Action
Move up	Moves the element one position up.
Move down:	move the element one position down.
Promote	move the element one position to the left.
Demote	move the element one position to the right.

2. To move multiple elements in the assembly tree:

Option	Action
Shift +click:	To select contiguous elements, then drag the elements to a new location in the assembly.
Ctrl+click:	To select non-contiguous elements, then drag the elements to a new location in the assembly.

Life Cycle

Life cycle enables you to track changes you make to a submission as it progresses through the approval process.

When an application is ready to be submitted to a regulatory agency for approval, you must lock it to prevent further unsolicited changes. In addition, because the regulatory agency may require changes throughout the approval process, Ennov InSight enables you to track changes as they occur. You do this by creating a life cycle. A life cycle begins with the first sequence you submit for approval and continues through each additional sequence until the end of life of a drug for that application.

When you lock and add the first sequence assembly to a life cycle, it becomes the finalized assembly.

Note: *the submitted view of an application is the accumulation of all sequence assemblies that have been added to the life cycle for an application. The submitted view, like all views, cannot be changed.*

When an application life cycle contains only the first finalized life cycle assembly, the submitted view and sequence view look the same. The distinction between the sequence view and the submitted view is noticeable after another assembly life cycle is added.

— The working view is the submitted view plus any changes you have made. These changes can include new folders, leaf elements, documents and document placeholders, replaced (as one to one, one to many and many to one) and suspended elements. Sections of the working view that were added to life cycle in previous sequences (that is, the submitted view) cannot be changed. The working view initially represents a submitted view snapshot of an application when the current sequence is created. If additional parallel sequences are created in the application, the changes are not included in the working view for the sequence.

— The sequence view of an application contains only the changes that comprise the current sequence. As changes are made to the working view, these changes are reflected in the sequence view that represents exactly that which will be submitted as part of that sequence.

— You can add only assemblies with leaf elements to a life cycle. Leaf elements represent the final, published documents. You can use assemblies without leaf elements for study reports or paper output, but you cannot use them for eCTD that requires a document life cycle.

Until a submission is added to a life cycle, the workflows associated to assembly nodes are displayed under the Working and Sequence views of the sequence assembly. When a submission is added to a life cycle, the incomplete workflows associated with the assembly nodes are canceled. All current activities of the canceled workflows are deleted. All canceled and completed workflows for the sequence assembly will be available from the Sequence View of the lifecycled assembly.

Lifecycle procedures are applicable to the following Ennov InSight modules:

— Electronic Lifecycle Publishing (ELP)

— Registered Document Analysis (RDA)

— Submission Planning and Tracking (SPT)

Lock Sequence Assemblies

A sequence assembly is locked to prevent changes being made once an application is ready to be submitted to a regulatory agency.

When a sequence assembly is locked, you can create life cycless to include changes to assemblies. Once an assembly is locked, only an administrator can make changes and synchronize an assembly with the DMS. It is recommended, however, that you lock the binding of all documents used in the assembly, thus preventing binding changes, should an assembly be unlocked and synchronized.

You can manually lock an assembly or you can use the *Change Submittal Status* wizard to mark the assembly as submitted. This locks the assembly automatically. The *Change Submittal Status* wizard enables you to update a submission status after a sequence assembly has been received by the regulatory agency. When you change the status, the submission is finalized and you can use it in subsequent submission life cycle updates by adding it to the submitted view. In addition, the statuses of related entities (application, event, sequence, assembly) and key status attributes such as first submittal date are updated automatically.

Note: *Only an administrator can unlock a locked assembly.*

Manually Lock an Assembly

You can manually lock a sequence assembly to add it to a life cycle.

To manually lock a sequence assembly:

1. Click a link for the sequence the assembly of which you want to lock.
2. Click the Assembly tab to open the *Assembly Attributes* page.
3. Optionally, review the assembly tree and any of its attributes.
4. Click the assembly root.
5. Click  on the action button toolbar.

   A message prompts you to select the lock type.
6. Select Standard to lock the entire assembly.
7. Click OK.

You can now add the locked sequence assembly to life cycle.

— Read-Only Mode appears before *Assembly Attributes*.

— Lock Indicator is set to Yes.

— A lock appears on the root in the assembly tree.

— When you expand the assembly tree, the elements are grayed out to show they cannot be changed.

Note: *Although the sequence assembly is locked, you can still change attributes for the assembly root.*

Ennov InSight Publisher 7.3: eCTD 4.0 Lock Sequence Assemblies

Add Sequence Assemblies to Life Cycle

Sequence assemblies are added to a life cycle when a document set is considered complete.

Before you add an assembly to a life cycle, you can export an assembly to reuse the assembly content. When an assembly or an assembly plan is added to a life cycle all the incomplete workflows of an assembly or an assembly plan are canceled. See *Life Cycle*.

The Sequence view and the Submitted view are the same when you add the first locked sequence to a life cycle. You can add subsequent sequences to a life cycle just as you add the first sequence. You can also use the *Create Submission* wizard to add sequences.

When a submission is added to a life cycle, the priority numbers, the leaf statuses of leaf elements are not updated.

Note: *Only an administrator can remove a sequence that has been added to a life cycle.*

Add Sequences to Life Cycles

Add sequences to life cycles to create new versions of a sequence.

Prerequisites

Before you add the first assembly to a life cycle, you can export the assembly to reuse the assembly content. Earlier versions are deleted when new assemblies are added.

To add the locked sequence to life cycle:

1. On the action toolbar, select Add Sequence to Lifecycle. A message prompts you to confirm the addition.
2. Click OK.
3. Choose Go To > Job Requests to see the progress of the request.

Remove the Last Sequence from Life Cycle

Administrators can remove the last sequence added to life cycle.

The options Remove Submission from Lifecycle and Remove Submissions from Lifecycle to this

Sequence are used to remove the last sequence added to a lifecycle and multiple sequences respectively. To remove multiple sequences, see *Remove Multiple Sequences from a Life Cycle*.

Note: *Same icon is used for both Remove Submission from Lifecycle and Remove Submissions from Lifecycle to this Sequence options. The system determines which to use based on the sequence order.*

Ennov InSight Publisher 7.3: eCTD 4.0

Add Sequence Assemblies to Life Cycle

To the last sequence from a life cycle:

1. Navigate to the sequence in the life cycle.
2. On the entity view page, click the toolbar option Remove Submission from Lifecycle.
3. Click OK.
4. Click Go To > Job Requests to see the progress of the request.

Remove Multiple Sequences from a Life Cycle

Administrators can remove multiple sequences to revert to a specific point in the life cycle.

The options Remove Submission from Lifecycle and Remove Submissions from Lifecycle to this

Sequence are used to remove the last sequence added to a life cycle and multiple sequences respectively. To remove the last sequence added to life cycle, see *Remove the Last Sequence from Life Cycle*.

Note: *Same icon is used for both Remove Submission from Lifecycle and Remove Submissions from Lifecycle to this Sequence options. The system determines which to use based on the sequence order.*

If an assembly with the updated submitted available set to Yes before adding to life cycle is removed from a life cycle, the Updated Submitted Available flag value changes from No to Yes.

To remove multiple sequences from a life cycle:

1. Navigate to the sequence that you want to remove from the life cycle.
2. On the entity view page, click the toolbar option Remove Submissions from Lifecycle to this Sequence.
3. Click OK.

   The system verifies that each sequence assembly that you want to remove has a corresponding associated *Submitted* View.

   — If the removed sequence was the first in the life cycle, then the assembly is unlocked and the Submitted view, the Working view, and the Sequence view are no longer available.

   — If the removed sequence is not the first in the life cycle, the assembly will be visible in the Sequence view. The changes that you made are seen in the Working view, and it is locked. The Submitted View is not changed. The removed assembly is added to a life cycle. The system returns you to the Application window related to the sequence.
4. Click Go To > Job Requests to see the progress of the request.

Ennov InSight Publisher 7.3: eCTD 4.0

Remove Multiple Sequences from a Life Cycle

Working Assemblies

From Submitted view you can create working assemblies to incorporate updates and changes for the next regulatory activity. These sequence assemblies are referred to as working assemblies, the assemblies you are working on in the lifecycle.

You can update a working assembly in the working view. In the working view, normally the modified file and operation attributes cannot be changed; changes are managed by the lifecycle change control process. In some cases, it may be necessary to change these values. In such a case, an administrator may use the Reset and Change Modified Leaf options on individual leaf elements to make changes. Ennov InSight calculates the correct modified file values based on the specified leaf element.

Working Assemblies and Assembly Specific Publishing Settings Library (APL)

When a working assembly is created, it copies the APL of the submitted view and it updates the submitted view to use the new copy of the APL. The previous sequence view still uses the previous APL. When you create multiple working assemblies, the submitted view is updated to the last created working assembly.

Working Assemblies Created from the eCTD 3.2 Assemblies

You can create the eCTD 4.0 working assembly from the locked eCTD 3.2 assembly submitted view. See: *Submissions >Create Working Assembly from Locked eCTD 3.2 Assembly* section.

Create a Working Assembly

After you add sequence assemblies to lifecycle, you can create working assemblies that include updates and changes required by the regulatory agency.

To create a working assembly:

1. Click the link for the application for that you want to create the working assembly.
2. Click the Sequences tab, and then click  .
3. Enter the required information for the sequence and Save.
4. Click the Assembly tab.
5. Click Create Working Assembly.
6. Provide the information for the working assembly and click Create.

   The working assembly is created and displayed on the Assembly tab.
7. Choose an option that is above the assembly tree:

Option	Action
Submit-ted:	Shows the most recent and actual content of all the assemblies sent to the regulatory agency; its fold- ers, leaf elements, and documents are shown in gray.
Option	Action

Sequence:	Shows you the folders, leaf elements, and documents in this sequence only; these are also shown in gray. This option appears when there are changes to the leaf nodes such as additions or replacements in the current sequence.
Working:	Shows the assembly in which you make changes and updates to the submission. It is the combination of the submitted content of all the assemblies (in gray) and the current sequence you have just added (in black).

Modify Leaf Elements in the Working Assembly

You can perform leaf operations, including add (New), replace, and suspend from the working view.

Replacing a Leaf

— You can replace a leaf only once in a sequence.

— You can replace directly from the DMS Browse window by dragging one or more documents to an old leaf. This will automatically assign these documents to the leaf and change the leaf to an active Replace leaf.

— You can perform the one-to-many Replace action by selecting already replaced leaf by replacing it multiple times. In this case, the Modified Leaf value will be the same for all replacements.

— You can perform the many-to-one Replace (MReplace) action by selecting multiple leafs under the folder using the Ctrl or Shift key on your keyboard. That results in one leaf with all selected leafs listed in the Modified Leaf field.

— When you replace a leaf, the replaced leaf is hidden and the replacement leaf is displayed.

— The replacement leaf appears at the same location in the assembly tree as the leaf you replaced and you cannot move it.

— The replacement leaf has an operation of Replace.

— The replacement leaf has the default leaf status.

— When a reference leaf is replaced, it is converted back to a normal leaf. It must be manually converted again into a reference leaf, and it will need to be re-targeted to the new, replaced, version of the referenced document.

— The modified file for the replacement leaf references the replaced leaf with the specification of original leaf sequence number

— You cannot replace, suspend, or delete the replacement leaf in the current sequence.

— You can revert the replacement leaf to undo the replacement. The leaf status is automatically reverted to the status that was set before the Replace operation.

— The replacement leaf assumes the content that was assigned to the replaced leaf. You can add, reorganize, or suspend some or all of this content.

— The only content the replacement leaf has is the content you assign.

— If there are links that target the document assigned under the replaced leaf, they are re-targeted to point to the document assigned under the replacing leaf in the new sequence.

— The target old leaf is replaced after multi-assign documents on it and the first selected document will be assigned to this leaf.

Duplicating a Folder

When you duplicate a leaf element, an identical leaf is created in the new sequence. The attributes are the same, except for the leaf ID, modified file, and any assigned documents.

Suspending a Leaf

When you suspend a leaf that was submitted in an earlier sequence, you are indicating that the leaf is no longer actual in the submitted view when the current sequence assembly is added to lifecycle.

— The suspended leaf is hidden in the working view.

— A new leaf with an operation of Suspend is displayed in the assembly tree.

— The new leaf has the default leaf status.

— The new leaf is positioned in the same location as the deleted leaf.

— The leaf and all its components are displayed with a line through them.

— Except for the leaf ID and operation, the new leaf has the same attributes as the suspended leaf.

— You cannot replace, append or suspend the new leaf.

— You can revert the new leaf to undo the deletion. The leaf status is automatically reverted to the status that was set before the Suspend operation.

— If a suspended leaf had content, the new leaf will have the same content in the working view. In the sequence view however, the leaf is displayed with no content.

— The modified file for the new leaf references the suspended leaf. The modified file name is constructed as follows: Modified Leaf shows the leaf that is currently being modified by this leaf in the lifecycle. Modified Sequence shows the sequence that is currently being modified by this leaf in the lifecycle. Modified File Override is available to administrators only to allow an override of the modified leaf/sequence. This should only be used in certain situations because the change is not tracked in the lifecycle.

— Change Modified Leaf is available in a working assembly to administrators. This allows the modified file to be manually set.

— Cleaf Modified Leaf is available to administrators in a working assembly. This allows the modified file to be manually cleared.

— You cannot change or move a new leaf, nor can you add elements to a new leaf.

— Suspended leaf elements are copied over to the submitted view after the current sequence assembly is added to lifecycle to provide ability to reuse content in the reference leaf later.

Reverting a Leaf Action

You can undo an operation performed on a leaf by right-clicking the leaf and selecting Revert.

Update a Working Assembly

Leaf operations such as replace, update, delete can be performed in a working assembly.

To change and update the working assembly:

1. At the top of the assembly tree, choose Working from the drop-down menu.
2. Expand the folder or leaf you want to change and update.

   Note: *You cannot change the submitted view elements; you can update only the working assembly with new information.*

3. Update the working assembly with new elements as needed.

   To undo an action, right-click the appropriate leaf, choose Revert, and confirm the action when you are prompted.

4. When you are ready to add the working assembly to lifecycle (adding the new leaf elements, their operations and their modified file references) lock the assembly in the working view and add it to lifecycle.

Reorganize a Lifecycle Assembly

You can reorganize a lifecycle assembly under specific limitations.

Following limitations are:

— A document cannot be promoted or demoted.

— A document or leaf cannot be moved under the root.

— In Working/Sequence view an operated leaf cannot be moved in a way that changes parent of the leaf.

— In unlocked Submitted view a leaf cannot be moved in a way that changes parent of the leaf.

— New documents should not be added directly under the assembly root. They should always be added to leaf elements, which are children of folders.

— Folders in the current sequence can be moved up or down.

— An element cannot be demoted when the leaf directly above it is in a previous sequence.

— When you drag an element to another element, it becomes the last child in the target element with the following exception: A leaf dragged to another leaf becomes the next sibling of the target leaf.

— An element you promote becomes the next sibling of its previous parent.

— An element you demote becomes the last child of its previous sibling.

— To satisfy eCTD compliance, or modified leaf elements should not be placed under new leaf elements.

Add Subsequent Sequences to Lifecycle

You can add subsequent sequences to lifecycle just as you add the first sequence. You can also use the Create Submission wizard to add sequences. For details, see Creating submissions.

To add subsequent sequences to lifecycle:

1. Click a link for the sequence you want to add to lifecycle.

   The *Sequence View* page opens.
2. Click the Assembly tab.

   The *Assembly Attributes* page opens.
3. Click  on the action button toolbar.

   A message prompts you to select the lock type.
4. Select Standard to lock the entire assembly.
5. Click OK.

   — Read-Only Mode appears above Assembly Attributes.

   — Lock Indicator is set to Yes.

   — A lock appears on the root in the assembly tree.

   — When you expand the assembly tree, the elements are grayed out to show they cannot be changed.

   Note: *Although the sequence assembly is locked, you can still change attributes for the assembly root.*
6. To add the assembly to lifecycle, click 

   .
7. When you are prompted to confirm the addition, click OK.

Modify Submission Statuses

When you have submitted a lifecycle sequence to the regulatory agency for approval, you can change its submission status to help track its progress through the approval process.

You can change the submission status in either of two ways:

— By modifying the sequence attributes manually

— Using the *Change Submittal Status* wizard

Modify a Submission Status

When you have submitted a lifecycle sequence to the regulatory agency for approval, you can change its submission status to help track its progress through the approval process.

To manually change the status for a lifecycle sequence:

1. Click the link of the sequence you want to modify.
2. On the *View Sequence* page, click Edit  .
3. On the *Modify Sequence* page, click the Sequence Status arrow and choose Submitted.
4. For the Sequence Status Date, do one of the following to choose when the sequence was submitted:

   — Enter the date in the format appropriate for the language preferences of your Web browser. — Click the calendar icon and choose a date.
5. Save.

The new status appears under Status Dates at the bottom of the *Sequence View* page.

View Submitted Sequences

You can view all sequences that have a submitted status.

To view submitted sequences:

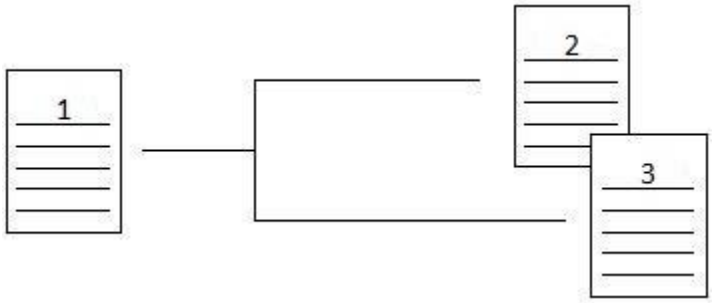
1. On the home page, click the Submitted Views tab.
2. Do one of the following:

Option	Action
To view the *Assembly Attributes* page:	Click a link in the Status View column.
Option	Action
To view the *Event Attributes* page for the event associated with the sequence:	Click a link in the Event Name column.

Manage Concurrently Planned Sequences

As you work on multiple planned sequences, it is important to understand how the submitted view is created. When you create the working assembly, the submitted view is a cumulative snapshot of all the sequences you have submitted. Once a submitted view is created for a planned assembly, it does not change.

If you are working on two planned sequences at the same time, they are both based on the same submitted sequence. In the example below, the submitted view of both 2 and 3 are based on 1, which is the only submitted sequence.



You may submit 3 to the regulatory agency before you submit 2. Both of these sequences may modify the same eCTD sections, and in fact they may modify the same eCTD leaf elements.

In the example above, when 2 is submitted, it does not show the changes in the 3 Submitted and working views. However, sequences 2 and 3 may still be submitted in any order. As each sequence is submitted, it looks for other planned sequences that have leafs in common with it. If these other planned sequence's leafs all have REPLACE leaf operations, they are automatically updated to point to the common leafs in the current sequence. It is extremely important to confirm leafs that are in common between the sequences after submittal, to make sure the correct document versions have been included in each case.

In an example suppose that in 2 a leaf containing drug product information is updated in section 3.2.P.1. This information is also updated in 3 with different data. The change in 2 is a REPLACE to the 3.2.P.1 leaf, and the change in 3 is also a REPLACE to the 3.2.P.1 leaf. If 3 is submitted before 2, the REPLACE leaf in 3.2.P.1 updates the NEW 3.2.P.1 leaf in sequence 0000, and then updates the REPLACE leaf in sequence 2. If sequence 2 were published before adding to lifecycle, its REPLACE to the 3.2.P.1 leaf would point to the leaf in sequence 2.

As implied in the example above, more than one planned sequence may be created and added in any order. The same leaf files may even be REPLACED, and as long as both are added to the submitted view and the XML is republished, both are valid sequences. This will trigger an error when sequence 2 is added to lifecycle, because it is an invalid eCTD operation.

Generate an Assembly Comparison Query

The Assembly Comparison query is available to Submission Planning and Tracking (SPT) users only.

To generate an assembly comparison query:

1. Choose Go To > Querying.
2. Click the Submission Planning and Tracking tab.
3. Choose Assembly Comparison.
4. Choose the assemblies to compare and the columns to include in the query results.
5. Click Search.

The comparison query results are returned.

Update an Unsubmitted Planned Sequence

You can update an unsubmitted planned sequence manually by creating a working assembly and importing parts of the unsubmitted planned sequence.

To update an unsubmitted planned sequence manually:

1. Create a sequence for the application.
2. On the *Sequence View* page, click the Assembly tab.
3. Click Create Working Assembly.
4. Enter the appropriate information to create the assembly and click Create.
5. Right-click the root in the assembly tree and choose Import Assembly Wizard to import parts of the unsubmitted planned sequence.
6. When you finish creating the working assembly, delete the unsubmitted planned working assembly.

Submissions

A submission includes applications, supplements, and reports in a standard format as per regulatory requirements. The Ennov InSight submission wizards help you to create and modify submissions.

Wizards are used to create submissions and associated components. Wizards are also used for specific function.

— The Change Submittal Status wizard enables you to mark a submission as submitted and protect it from further changes.

You must have the following modules to perform submission activities:

— Electronic Lifecycle Publishing (ELP)

— Registered Document Analysis (RDA)

— Submission Planning and Tracking (SPT)

Change Submittal Status Wizard

Use Change Submittal Status wizard to update all entities simultaneously to reflect in Ennov InSight once a submission is submitted.

The following are the activities and functions of the Change Submittal Status wizard:

— Confirmed Sequence Code is adjusted to eCTD 4.0 standard type.

— The value starts with '1' and each subsequent sequence number is increased by 1. The Confirmed Sequence Code field is pre-populated based on the type of a sequence in application when using the wizard from an application or an event. If both eCTD 3.2 and eCTD 4.0 sequences are present in an application, the field is prepopulated with the eCTD 4.0 Code value.

— After the Change Submittal Status wizard is used for Initial Sequence Assembly with the Lifecycle checkbox selected/ for Working Assembly, summary of the Change Submittal Status for an assembly is displayed under Job Requests.

— Sequence Code is updated to the Confirmed Sequence Code value.

— Sequence Status is updated to Submitted.

— Sequence Status Date is updated to the entered Submittal Date.

— For initial assembly if Lifecycle checkbox is checked the assembly is getting locked and added to lifecycle.

— For Working Assemblies assembly is locked and added to Lifecycle.

— Assembly Status is updated to Effective status (by default it is Approved).

— Assembly Status Date is updated to the entered Submittal Date.

— For Initial Sequence Assembly without the Lifecycle option selected:

Submissions

- when no assembly exists: the 'Change submittal status for Assembly Name' Job is not created. Sequence Code, Sequence Status and Sequence Status Date are updated.

- If assembly exists: assembly is locked, but not added to Lifecycle, assembly status and Status Date are updated.

The Change Submittal Status wizard can be used when:

— There is no Event associated with a Sequence.

— Several Events are associated with a Sequence (the date and status are updated for all events).

— Sequence Code and Sequence Status Date can be updated when re-running the Change Submittal Status wizard.

Create Submission Wizard

The Create Submission wizard enables you to create an assembly within the context of its appropriate Ennov InSight relationship. The submission wizards facilitate the creation and/or confirmation of the application event (or activity) and sequence that correspond to the assembly you are creating.

To create an assembly, you must first determine its relationship in Ennov InSight . Except for template assemblies, every assembly in Ennov InSight has a relationship to other entities. Specifically, every assembly has an associated application, event, and sequence number.

The Create Submission wizard enables you to create an application and its associated event and sequence. You can create any of three types of submissions using the wizard:

— An initial application is the original filing event (request for marketing) in the history of a submission application. After a product family and its associated products have been created, you can create a submission.

— A major update is a variation or supplement to an original application. A new request for approval against the application is being made, for example, a new indication or a manufacturing change. Alternatively, a major update can be used for renewals or PSUR reporting. The major update is used for all event types other than the original application.

— An amendment is a change to filing content that supports an existing approval objective for which the application and event already exist. For example, you may be asked to clarify a statement in a previously-submitted document.

The Create Submission wizard controls which countries can be assigned to a sequence based on the submission type for different procedures. For major updates, all countries for the procedure are listed. For an amendment, only

countries associated with the application are listed. If a new country is needed in an amendment, it must be added by modifying the application.

You cannot complete the Create Submission wizard without associating a Product.

Initial Application Submission

You must have at least Write security permissions for one of the following Ennov InSight modules to create an initial application submission using the *Create Submission* wizard:

— Submission Planning and Tracking (SPT)

— Registration Planning and Tracking (RPT)

— Electronic Lifecycle Publishing (ELP)

— Paper Review Publishing (PRP)

When you create a submission using the wizard, you choose a product family with which to associate the submission, and assign several other required properties. The *Create Submission* wizard automatically creates:

— An application

— An event

— A sequence (optional)

If you are a product detail management (PDM) user, you can also associate products with the application. For PDM users, a link is created so you can create a product detail set (PDS). For submission planning and tracking (SPT) users, a link is created that takes you to the *Create Assembly* page, so you can create the assembly associated with the sequence. Application countries are set to:

— For MRP, RMS country plus selected CMS countries

— For CP, all countries selected. Role=Other

The Countries attribute on the event is set as follows:

— For National internal procedure type applications, automatically associate the user selected reviewing country with the event

— For CP internal procedure type applications, automatically associate the EU Country with the event

— For MRP internal procedure type applications, countries is set to the RMS and the CMS countries selected in the wizard

Create an Initial Application Submission

Use the Create Submission wizard to create an initial application submission for a specific country, set of countries, or region. When an initial application is created, the event-country status schedules are created for each country included in the application.

Note: *The wizard for creating a submission for an initial application does not use the default Application Type and Procedure Type values for the selected Reviewing Country. These defaults are for Copying Applications and the Global Project Planning (GPP) wizard.*

To create an initial application submission:

1. Select Wizards > Create Submission.

   The *Create Submission* wizard opens to the *Choose Submission Type* page.

2. Click Initial Application.
3. Click Next.

   The *Complete Submission Properties* (application) page appears.

4. Enter the application properties for the submission.
5. Click Next. The *Complete Submission Properties (event/sequence)* page appears.
6. On the *Complete Submission Properties (event/sequence)* page, do any of the following:

Option	Action
To create an event:	Enter an Event Code, Keywords and Description. If no entry is made to the event-related fields, the event is created with default values.
To use a timeline/ event plan to create the event:	Select a Timeline/Event Plan from the drop-down list.
To change the event type:	Select the value from Event Type drop-down list. The New Application value is selected by default.
To create a sequence:	Select the Create sequence? check box.
	Note: *If you choose to create a sequence, you can change the default sequence numbering of a P followed by four digits. This numbering scheme is the format recommended for an eCTD submission. If you change, the format, Ennov InSight will issue a message requesting confirmation that you accept the deviation from the default sequence numbering format.*
	Select the Filing Type and Sequence Standard Type.

7. Click Next.

The *Create Submission Confirmation* page opens, confirming the actions that are performed based on your selections.

8. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click Next. c. Validate your identity by entering your user credentials in the dialog box.

1. On the *Create Submission Confirmation* page, do any of the following:

Option	Action
To confirm your selections:	Click Next. The *Create Submission Summary* page opens, listing the created items. Additional items you can add to the submission may be listed.
To return to the previous pages to change your selections:	Click Back.
To cancel the submission entirely and return to the view form which you invoked the wizard:	Click Cancel.

2. On the *Create Submission Summary* page, do any of the following:

Option	Action
To view the created event:	Click the event link.
If you created a sequence and want to view it:	Click the sequence link.
To update a PDS associated with the event:	Click the PDS link. This option is available for PDM users.
To create an assembly:	Click the first assembly link. This options is available for SPT users. If you create an assembly from an existing template, assembly, or view, to find an assembly, click Browse and use the *Search Assembly Wizard*. See *Search for an Assembly*.
To create an eCTD:	Click the second assembly link to start the Create eCTD wizard.
To return to the location from which you invoked the Create Submission wizard:	Click Finish.

Initial Application Submission Attributes

You can use the attributes to describe the details of the initial application submission.

Attribute	Description
Applicant ID	Identifies the entity that submits the application to regulatory authorities.
Application	The Application field now shows the value as a concatenation of [Application Code + Application Name].
Application Code	The agency-identified application number (or identifier). This number may not be known until the time of submission, so it may be the same as the internal code. Keep in mind the following when you enter an application code or number: — For US applications, the application code is always a 6-digit number. — For Canadian applications, the application is generally an *e* followed by a 6-digit number (for example, e123456). — For Japan the application code is generally ectd- followed by a 6-digit number (for example, ectd-123456). — For the EU, applications numbers are generally not available until you have filed and numbers may vary by country. It is best to enter an application number that is unique and meaningful according to the specification. Samples may include a country abbreviation or an internal drug code abbreviation or number, for example, uk-h-323-001.

Attribute	Description
Application Name	The name of the application that will be associated with the submission event.
Application Type	The type of application for which you are creating the submission. The list of available options depends on the Reviewing Country selected.
Associated Products	Products included in the Product Family that are available to include in the application.
Co-Rapporteur	Used when the Reviewing Country is a member of the European Union (EU) and the submission involves a Centralised Procedure (CP).
Countries	Used when the submission involves a member of the European Union (EU) and the

	Procedure Type is Mutual Recognition Procedure (EU MRP) or a Decentralised Procedure (EU DCP), the Countries attribute appears and enables you to select multiple countries for the submission. When an EU country is selected, European Union is automatically included in the countries selected for the submission for CP applications.
Create Sequence	Determines whether the wizard will create a sequence for the application.
Description	Text that describes an entity within a submission.
Event Code	The code used to identify the event.
Event Type	The drop-down list displays all Active values from Data Administration > Event Maintenance > Event Type Values. The New Application value is selected by default in the Event Type field.
Timeline/Event Plan	A preset plan that determines the ordered progression of primary event statuses that will apply for events created from the plan.
Timeline/Event Plan Type	The type of timeline/event plan used to create or update the event. The timeline/ event plan type can be procedure type, event type, or none. An event created or updated by using the procedure type of timeline/event plan has a sequence of statuses that are relevant to the procedure type selected for the event. An event created or updated by using the event type of timeline/event plan has a sequence of statuses that are relevant to the event type selected for the event. An event created or updated by specifying none for the timeline/event plan type can have any sequence of active statuses. The sequence of statuses for a timeline/event plan type is defined in Data Administration.
Filing type	The filing type (for example, original filing, extension filing, reformatting filing) for the application, which is required only if sequences will be created with the submission.
Keywords	Words used to enable a search for entities associated with the submission.

Attribute	Description
Procedure Type	The procedure type for the application, such as National, CP, DCP, or MRP. The list of available options depends on the reviewing country for the submission.
Registration Type	This attribute specifies whether the registrations you associate with the application will be of a registration type that is mapped to an internal value of either package set or product. This attribute can be configured to default to one registration type and be non-editable.
Reviewing Country	The country responsible for performing the submission review. When the submission involves a member of the European Union (EU) and the Procedure Type is Mutual Recognition Procedure (EU MRP) or a Decentralised Procedure (EU DCP), the Countries attribute appears and enables you to

	select multiple member countries from the EU for the submission. The Reviewing Country is automatically assigned for National procedure types.
Sequence Code	The identifier for the sequence associated with the application, which is required only if a sequence will be created. The sequence code defaults to the next available four-digit sequence number, prepended with the letter P to indicate that this is the planned sequence number. This enables working on multiple planned sequences concurrently. When you mark the sequence as submitted, Ennov InSight Manager reconfirms the next available sequence number and removes the P. If you enter a value that deviates from the default format, the wizard displays a message requiring you to confirm that you want to deviate from the default numbering format. For the first sequence in an application, the start sequence code from the application is always used. For subsequent sequences, all the sequences in the application are considered. When the highest existing sequence number has been determined, the default sequence number for the new sequence is the highest plus one. For example, if there are four sequences with the codes P0000, 0001, 0005, and R0006-512, the next sequence number by default is P0006.
Sequence Standard Type	The following standard types are available for selection: — NeeS — Paper — eCTD 3.2 — eCTD 4.0
Attribute	Description
UUID	UUID (version 4 of UUID types) is a universal unique identifier that is automatically generated by the system on sequence creation. This field is visible and available for modification and view pages only. — The value can be modified only by users with Administrator permissions to the sequence. — Through the eCTD wizard, users with appropriate permissions are able to modify the UUID to support sequences that may require a different UUID. In most cases, the UUID value should not change. The UUID field is not available in case of sequences bulk update.
	Note: *The values should be unique (case-insensitive). The entered values should pass the validation to match the format: a hexadecimal number in the form of xxxxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx, having 32 digits and 4 hyphens. If format does not match, the The UUID must be in the form of xxxxxxxx-xxxxMxxx-Nxxx-xxxxxxxxxxxx, where x is a hexadecimal number, M is 1-5, and N is 8, 9, a or b. message is displayed. If uniqueness is violated, The UUID must be unique. message appears.*

Major Update Submission

When you create a major update submission, you create an event and, optionally, a sequence. Links to create assemblies and edit PDSs (for all but ELP-only users) are provided as well. To create a major update submission, an application must exist for the product family and country. Application countries:

— If additional CMS countries have been added that are not already part of the application, they are added to the application.

— If CMS countries that are part of the application are removed from the CMS list, they are not removed from the application.

The Countries attribute on the event is set as follows:

— For national internal procedure type applications, automatically associate the reviewing country on the selected application with the event.

— For CP internal procedure type applications, automatically associate the EU Country with the event.

— For MRP internal procedure type applications, the Reviewing Country/RMS on the selected application and the CMSs selected in the wizard are associated with the event.

Create a Major Update Submission

You can update an existing application for a new business objective or regulatory activity. When creating a major update submission, an event is created and you can create a sequence, if needed.

Note: *To create a major update submission, an application must exist for the product family and associated country, and you must have the appropriate security permissions.*

To create a major update submission:

1. Click Wizards > Create Submission.

   The *Create Submission* wizard opens to the *Choose Submission Type* page.
2. Click Major Update.
3. Click Next.

   The *Complete Submission Properties* page appears.
4. On the *Complete Submission Properties (event/sequence)* page, do any of the following:

Option	Action
To create an event:	Enter an Event Code, Keywords and Description.
To use a timeline/event plan to create the event:	Select a Timeline/Event Plan from the drop-down list.
To change the event type:	Select the value from Event Type drop-down list.
To create a sequence:	Select the Create sequence? check box. Creating a sequence is optional.
	Note: *If you choose to create a sequence, you can change the default sequence numbering of a P followed by four digits. This numbering scheme is the format recommended for an eCTD submission. If you change, the format, Ennov InSight will issue a message requesting confirmation that you accept the devia- tion from the default sequence numbering format.*
	Select the Filing Type and Sequence Standard Type.

5. Click Next to confirm your selections.

   The *Create Submission Confirmation* page appears.

6. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click Next. c. Validate your identity by entering your user credentials in the dialog box.

1. Do one of the following:

Option	Action
To confirm your selections.:	Click Next. The *Create Submission Summary* page opens, listing the created items. Additional items you can add to the submission may also be listed. Proceed to step 8.
To return to previous pages to change your selections:	Click Back.
To cancel the submission entirely and return to the view from which you invoked the wizard:	Click Cancel.

2. On the *Create Submission Summary* page, do any of the following:

Option	Action
To view the created event:	Click the event link.
If you created a sequence and want to view it:	Click the sequence link.
To update a PDS associated with the event. This option is available for PDM users:	Click the PDS link.
To create an assembly:	Click the first assembly link. This link is available for SPT, ELP, and RDA users.
If you create an assembly from an existing template, assem- bly, or view, to find an assembly:	Click Browse and use the Search Assembly wizard.
To create an eCTD:	Click the second assembly link to start the eCTD wizard.
To return to the location where you invoked the Create Submission Wizard:	Click Finish.

Major Update Submission Attributes

You can use the attributes to modify submission attributes.

Attribute	Description
Application Code	The agency-identified application number (or identifier), which may not be known until the time of submission, so it may be the same as the internal code.
Application Name	The name of the application that is associated with the submission event. The value is a concatenation of [Application Code + Application Name].
Countries	When the Reviewing Country is a member of the European Union (EU), the Concerned Member States attribute appears and enables you to select multiple countries for the submission. This section does not appear if the Reviewing Country is not a member of the EU or for applications of national procedure type.
Create Sequence	Determines whether the wizard will create a sequence for the application.
Description	Text that describes the submission

Event Code	The code your organization uses to identify the event.
	Note: *The event code and event name as a combination for an event must be unique within an application.*
Event Name	The name of the event.
	Note: *The event code and event name as a combination for an event must be unique within an application.*
Timeline/Event Plan	A timeline/event plan determines the ordered progression of event statuses that will apply for events created from the plan.
Timeline/Event Plan Type	The type of timeline/event plan used to create or update the event. The timeline/ event plan type can be procedure type, event type, or none. An event created or updated by using the procedure type of timeline/event plan has a sequence of statuses that are relevant to the procedure type selected for the event. An event created or updated by using the event type of timeline/event plan has a sequence of statuses that are relevant to the event type selected for the event. An event created or updated by specifying none for the timeline/event plan type can have any sequence of active statuses. The sequence of statuses for a timeline/event plan type is defined in Data Administration.
Event Type	The type of event.
Family Name/ Code	The product family with which to associate application you are updating.
Filing Type	The filing type for the application.
Keywords	Words used to search for when creating a submission.

Attribute	Description
Reason	Reason for creating, modifying or deleting a submission.
Reason for Comments	Comments related to reason entered by users.
Reviewing Country	The country performing the submission review. Only the countries associated with the application will be listed. When the Reviewing Country is a member of the European Union (EU), the Concerned Member States attribute appears and enables you to select multiple countries for the submission except for EU national procedure type applications. The wizard automatically sets the Reviewing Country for national applications.
Sequence Code	The identifier for the sequence associated with the application, which is required only if a sequence will be created. The sequence code defaults to the next available four-digit sequence number, prepended with the letter P to indicate that this is the planned sequence number. This en-

	ables working on multiple planned sequences concurrently. When you mark the sequence as submitted, Ennov InSight Manager reconfirms the next available sequence number and removes the P. If you enter a value that deviates from the default format, the wizard displays a message requiring you to confirm that you want to deviate from the default numbering format. For the very first sequence in an application, the start sequence code from the application is always used. For subsequent sequences, all the sequences in the application are considered. When the highest existing sequence number has been determined, the default sequence number for the new sequence is the highest plus one. For example, if there are four sequences with the codes P0000, 0001, 0005, and R0006-512, the next sequence number by default is P0006.
Sequence Standard Type	The following standard types are available for selection: — NeeS — Paper — eCTD 3.2 — eCTD 4.0
Attribute	Description
UUID	UUID (version 4 of UUID types) is a universal unique identifier that is automatically generated by the system on sequence creation. This field is visible and available for modification and view pages only. — The value can be modified only by users with Administrator permissions to the sequence. — Through the eCTD wizard, users with appropriate permissions are able to modify the UUID to support sequences that may require a different UUID. In most cases, the UUID value should not change. The UUID field is not available in case of sequences bulk update.
	Note: *The values should be unique (case-insensitive). The entered values should pass the validation to match the format: a hexadecimal number in the form of xxxxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx, having 32 digits and 4 hyphens. If format does not match, the The UUID must be in the form of xxxxxxxx-xxxxMxxx-Nxxx-xxxxxxxxxxxx, where x is a hexadecimal number, M is 1-5, and N is 8, 9, a or b. message is displayed. If uniqueness is violated, the The UUID must be unique. message appears.*
User ID	The user name to validate user identity.
Password	The user password to validate user identity.

Amendment Submission

You can create an amendment submission to change the filing content of an existing approval objective. When you create an amendment submission, you change the filing content of an existing approval objective. For example, you may be asked to clarify a statement in a previously submitted document. A sequence is created to support the amendment.

Create an Amendment Submission

You can create a new sequence for an existing application and event. You must have the appropriate security permissions to create an amendment using the *Create Submission* wizard.

To create an amendment submission:

1. Click Wizards > Create Submission.

   The *Create Submission* wizard opens to the *Choose Submission Type* page.

2. Click Amendment.
3. Click Next.

   The *Complete Submission Properties* page appears.

4. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click Next. c. Validate your identity by entering your user credentials in the dialog box.

1. Enter the properties for the submission.

   Concerned Member States will display only if the procedure type is MRP.

   Note: *If you choose to create a sequence, you can change the default sequence numbering of a P followed by four digits. This numbering scheme is the format recommended for an eCTD submission. The sequence code must be unique within the application. If you change default numbering format, the wizard will issue a message requesting confirmation that you accept the deviation from the default sequence numbering format.*

2. Click Next.

   The *Create Submission Confirmation* page appears.

3. On the *Create Submission Confirmation* page, do one of the following:

Option	Action
To confirm your selections:	Click Next . The *Create Submission Summary* page appears, indicating that a sequence has been created. Addi- tional items that you can add to the submission may also be listed. Proceed to step 8.
To return to previous pages to change your selections:	Click Back.
To cancel the submission and return to the view form which you invoked the wizard:	Click Cancel..

4. On the *Create Submission Summary* page, do any of the following:

Option	Action
To view the newly created sequence attributes:	Click the sequence link.
To create an assembly:	click the first assembly link. This link is available for or SPT, ELP, and RDA users. If you create an assembly from an existing template, assembly, or view, to find an assembly, click Browse and use the *Search Assembly* wizard. See *Search for an Assembly*
To create an eCTD:	Click the second assembly link to start the eCTD wizard.
Option	Action
To return to the location from which you invoked the *Create Submission* wizard:	Click Finish.

Amendment Submission Attributes

You can use the attributes to modify an existing submission.

Attribute	Description
Application Code	The agency identified application number (or identifier), which may not be known until the time of submission, so it may be the same as the internal code.
Application Name	The name of the application that is associated with the submission event. The value is a concatenation of [Application Code + Application Name].
Application Type	The type of application associated with the submission event
Concerned Member States	When the Reviewing Country is a member of the European Union (EU), the Concerned Member States attribute appears and enables you to select multiple countries for the submission. This section does not appear if the Reviewing Country is not a member of the EU.

Event Code	The code your organization uses to identify the event.
Event Name	The name of the event.
Event Type	The type of event.
Family Name/Code	The product family with which to associate the application you are updating.
Filing Type	The filing type for the application.
Reason	Reason for creating, modifying or deleting a submission.
Reason for Comments	Comments related to reason entered by users.
Reviewing Country	The country performing the submission review. Only the countries associated with the application will be listed. When the Reviewing Country is a member of the European Union (EU), the Concerned Member States attribute appears and enables you to select multiple coun- tries for the submission.

Attribute	Description
Sequence Code	The identifier for the sequence associated with the application, which is required only if a sequence will be created. The sequence code defaults to the next available four-digit sequence number, prepended with the letter P to indicate that this is the planned sequence number. This enables working on multiple planned sequences concurrently. When you mark the sequence as submitted, InSight Manager reconfirms the next available sequence number and removes the P. If you enter a value that deviates from the default format, the wizard displays a message requiring you to confirm that you want to deviate from the default numbering format. For the first sequence in an application, the start sequence code from the application is always used. For subsequent sequences, all the sequences in the application are considered. When the highest existing sequence number has been determined, the default se- quence number for the new sequence is the highest plus one. For example, if there are four sequences with the codes P0000, 0001, 0005, and R0006-512, the next sequence number by default is P0006.
Sequence Description	Text that describes an entity within the submission.
Sequence Keywords	Words used to search for when creating a submission.

Sequence Standard Type	The following sequence standard types are available for selection: — NeeS — Paper — eCTD 3.2 — eCTD 4.0
User ID	The user name to validate user identity.
Password	The user password to validate user identity.

Create eCTD Wizard

The *Create eCTD* wizard enables you to create and organize structured and compliant eCTD assemblies. Using standard templates, you can create folder structure, leaf elements, and metadata in an assembly.

You can run the wizard multiple times to ensure the metadata is up to date, to add new sections, or to refresh structures. The *eCTD wizard* shows all eCTD components that are available for inclusion in the submission.

The *eCTD wizard* enables you to perform the following tasks:

— Create the assembly for the first sequence.

— Build the assembly with the correct eCTD components based upon region, specifications, template, configuration, and user selections.

— Create the assembly structure with selected or confirmed metadata.

You can use the *Create eCTD* wizard with:

— Existing sequence assemblies (both life cycle and non-life cycle)

— Existing sequences with no assembly created

— Applications or events

Using the *Create eCTD* Wizard, you can select a template other than the default template to use with the assembly, and that selected template will persist as the default whenever you run the *Create eCTD* Wizard for that assembly.

The eCTD 3.2 templates and the eCTD 4.0 templates are loaded separately in the wizard based on the Sequence Standard Type.

When you create an eCTD using the wizard, all attributes display the default values from the assembly template you are using. The assembly templates provide all available sections for an eCTD.

Automatically, each leaf element created using the *Create eCTD* wizard is assigned the default Leaf Status value configured in *Data Administration*.

Based on the module you select, some of the properties are different. This is defined by configuration inherited from regulatory agency Controlled Vocabularies.

When creating an eCTD from an existing sequence and application, the region, application number, sequence number, and countries attributes are pre-populated based on the information stored in those entities.

Create eCTD 4.0 Submission

The *Create eCTD* wizard enables you to create, update, and organize structured and compliant eCTD assemblies.

Using standard templates, you can create folder structure, leaf elements, and metadata in an assembly.

To create an eCTD assembly:

1. Click a link for the sequence, assembly or assembly plan from which you want to create an eCTD 4.0 assembly.
2. Choose Wizards > Create eCTD. The *Create eCTD* wizard appears.
3. Do the following:

Option	Action
In the *Assembly Name* box:	Enter a name for the assembly.
From the *Available* countries box:	Select the appropriate countries and move them to the *Selected* box.
To remove countries from the *Selected* box:	Select them and move them back to the *Available* box.
Option	Action
Next to Template Selection:	Select the template on which to base the eCTD 4.0.
	Note: *The eCTD 3.2 templates and the eCTD 4.0 templates are loaded separately in the wizard based on the Sequence Standard Type.*

Note: *Using the Create eCTD Wizard, you can select a template other than the default template to use with the assembly, and that selected template will persist as the default whenever you run the Create eCTD Wizard for that assembly.*

4. Click Next .

   The *Select Attributes* page appears. The region for which you are creating the eCTD determines the attributes that appear in the wizard. Enter details as necessary.

5. Click Next.

   The *Set Application Metadata* page appears. The type of assembly for which you are creating the eCTD determines the attributes that appear in the wizard. Enter details as necessary.

6. Click Next.

   The *Select Sections* page displays all of the available CTD sections you can add to the assembly.

7. Select the individual folders and subfolders for the eCTD.

   — For existing, life cycle or non-life cycle sequence assemblies, any section folders that already exist in the assembly are not available.

   — Selecting a top-level section automatically includes all the subsections for that folder.

— To update the metadata values in sections that already exist, or to add the subsections to existing sections, select the checkbox next to the existing sections that need to be updated.

Tip: Folders or leaves that are copied from the template appear in the same order as in template. New sections, folders or leaves that do not belong to any template are placed at the top of the list.

8. Click Next.

   The Select *Sets of Submission Metadata* page appears. If you have included any of the repeatable assembly sections, they are displayed.

9. Enter the number of sets of information for each repeatable section. In some instances, the metadata may be dependent on a section being created or on one that already exists. A list of the repeating sections can be customized based on the regulatory specification updates. To customize the repeatable sections as per your requirements, contact your business support representative.
10. Click Next.

    The *Set Submission Metadata* page appears.

11. Select values for the attributes. Use + or - to expand or collapse the field groups. If there is no needed Sender defined keyword available in the list, it can be create using Add new… line.

    A list of the fields can be customized based on the regulatory specification updates. To customize the fields as per your requirements, contact your business support representative.

12. Click Next.

    The *Confirmation* page appears. Depending on the system configuration the process of creation can be tracked in the Job Requests, if the number of newly created nodes exceeds predefined limit.

13. Click Next.

    The *Summary* page displays a message indicating that the eCTD information has been saved to the assembly.

14. Do one of the following:

Option	Action
To view the assembly that was created:	Click the first assembly link.
To start the Create Study Reports wizard for the assembly:	Click the second assembly link.
To close the wizard:	Click Finish.

eCTD 4.0 Attributes Japan

You can use the following attributes to describe eCTD submissions for Japan.

Japan-v1.0

Attribute	Description
Applicant	The name of the entity presenting the submission. Multiple comma-separated values can be provided.
Brand Name	The marketing name for the product. Multiple comma-separated values can be provided.
Generic Name	The generic name for the product. Multiple comma-separated values can be provided.
Operation	The operation used for the submission (for example, new, append, replace).

Sequence Number	The number for the initial sequence for filing.
Submission Date	The effective date for the submission.
Submission Number	The number used to identify the submission, must be numeric. See Application Code Guidelines.
Submission Type	The filing type of the submission. Multiple comma-separated values can be provided.

eCTD 4.0 Attributes United States

You can use the following attributes to describe eCTD submissions for the United States.

United States-v1.5

Attribute	Description
Application Number	The number assigned to the application.
Application Type	The type of the application.
Company Name	The company presenting the submission.
Product Name	The product or products that are being addressed in the application.
Related Sequence Number	Any sequence related to the registered product name. Click Add to create additional rows for adding more related sequences.

Sequence Number	The number for the initial sequence for filing.
Submission Date	The effective date for the submission.
Submission Type	The type of the submission.

Create Study Reports Wizard

The Create Study Reports wizard enables you to add study report structures to an existing assembly. You can run the wizard one or more times as you obtain information about the study reports to include in the assembly. The wizard is designed to be run after using the Create eCTD wizard.

Before creating a study report:

— An assembly must already exist and cannot be locked.

— A regional and ICH CV profile must be applied for the assembly in the publishing settings.

Use the Create Study Report Wizard

To create a study report:

1. In the selected eCTD 4.0 assembly, choose Wizards > Create Study Reports.

   The *Create Study Reports* wizard appears and the *Select Subsections* page lists the available report subsections.
2. Select the sub-section options to include in your study report.

— To remove a section, select it.

— For existing life cycle or non-life cycle sequence assemblies, any section folders that already exist in the assembly are not available.

— Selecting a top-level section automatically includes all the subsections for that folder.

3. Click Next.

   The *Enter Quantities* page appears.
4. Enter the study report quantities per subsection.
5. Click Next.

   The *Enter Properties* page appears.
6. Enter the property values for the study report. The study report attributes are grouped into sets according to the previous user's selection.
7. Click Next.

   The *Confirmation* page appears, confirming the information has been saved permanently to the assembly. Depending on the system configuration the process of creation can be tracked in the Job Requests, if the number of newly created nodes exceeds predefined limit.
8. Click Next.

The Summary page appears.

9. Click Finish.

Prepare to Publish

Preparing to publish is an optional but recommended step in the publishing process. It is a flexible function that enables you to prepare your assembly for publishing.

The purposes are the following:

— It ensures that you have all the files, renditions, and extractions that will be necessary for a successful publish. — It updates data used in queries so you can see predicted issues.

Before you publish a submission, be sure that:

— All required fields are completed.

— All output filenames on leafs are completed.

— Leaf names are unique within an output folder.

— Reference leaf elements point to leaf elements that are not empty.

— CV Profiles are defined in the Publishing Settings.

— For electronic output, at least one document is assigned.

Failure to verify any of these items may result in a failed publish.

Run Prepare to Publish

Use the Prepare to Publish option to prepare your assembly for publishing. To

prepare to publish:

1. On the action toolbar, choose Prepare to Publish.
2. On the Prepare to Publish dialog box, select the options you want to perform for the publication.

Option	Description
Publishing Output Channel:	The Electronic output only is available for eCTD 4.0 assemblies.
Generate Missing Renditions and Extractions:	You must have a license for Ennov InSight rendering and publishing services to generate missing renditions.

Option	Description
Remove Empty Assembly Folders:	This removes any empty folder elements from the assembly.
Remove Empty Assembly Leafs:	This removes any leaf elements that have no content from the assembly. It skips reference leaf elements and elements with metadata.
Prepare Cross-Reference Leafs:	This ensures that the checksum is correct and is available when you are publishing any cross-reference leafs that point to content outside of the current sequence.
Refresh Publishing Readiness Data:	This refreshes the information in the Publishing Readiness Report based on the selected output channel. To see the report, this must be run at least once.
Refresh Link Inspector Data:	This is required if you want to run the Link Inspector report. This is necessary to create in-process links or perform in-process link retargeting.
Refresh Link Inspector View:	Choose Current Sequence View Only (refreshes only the current sequence), or Entire Working Assembly (refreshes the current sequence and all previous sequences).

3. Click OK.

   A message indicates that some of the processes may take awhile.

4. Click OK.
5. Choose Go To > Job Requests to check for any errors.

Publishing Readiness Query

The Publishing Readiness Query enables you to view your assembly metadata at a glance and find predicted errors and warnings that may occur during publishing if an issue is not remedied.

The following information is included in the query results:

— The assembly name

— Element types and subtypes

— Default attributes that have been overridden

— Whether each leaf element includes at least one assigned document

— Whether documents are set to Use Native File

— Whether PDF renditions are available for each assigned document

— Output location information

— Number of bound documents and total documents

When you generate the query, you choose the columns that appear in the query results. You can export the query results to a Microsoft Excel spreadsheet for further analysis. The table in Publishing Readiness Query Attributes describes the information you can include in the query.

Warning: Always run a DMS Synchronization before refreshing the Publishing Readiness query, Link Inspector query, and other queries. Ennov InSight uses the data available in the Ennov InSight database, and relies on DMS Synchronization to ensure this information matches what is in the DMS for each document.

Publishing Readiness Query Filters

You use the filters in the Publishing Readiness query to return details about the assembly. The required filters are indicated by an asterisk (*).

Column	Description
Assembly *	The current assembly is selected by default. You can select the other assembly, if needed.
Query Type	The following types are available for selection: — Electronic — Paper The Electronic type is selected by default. Deselect, or add the other type, if needed.
Leaf Operation	The following operation types are available for selection: — append — delete — mreplace — new — replace — suspend You can select multiple operations.
Object Type	All types are selected by default: — Cover Page — Document

	— Folder — Leaf — Slip Sheet — Tab Sheet — Table of Contents — Volume You can deselect any type, if needed.
Column	Description
Filter on Elements that have Errors	The Yes and All values are available for selection, Yes is selected by default. You can change the value, if needed.
Display Columns *	You can select the columns you want to be displayed in the *Publishing Readiness Query* results. You also can change the columns order.
Sort Order	You can select how to sort the columns in the query results table. The values available for selection are: — The list of all columns with an ascending or descending options. For example: Element Type - DESC. — Order - ASC — Order - DESC The ascending order (Order - ASC) is selected by default. You can deselect or add the other types, is needed.

Publishing Readiness Query Attributes

You can use the attributes to describe the Publishing Readiness of an assembly. The attributes are valid for all elements of an assembly, unless otherwise noted.

Column Name	Description
Actual Page Count	The actual number of pages in the element.
All Pages Included	Indicates whether all pages in documents are to be published.
Application Version	An eCTD attribute.

Assembly Level	The relative level in the assembly where the element has been assigned. For example: the assembly root is 0, folders under the root are 1, the first element in folders is 2, and so on. Aligned TOCs and special sheets are assigned numerically, immediately after the element to which they are assigned in the order they appear, from left to right. Volumes are level 1 for a Paper Report Type, and folders are level 1 for an eCTD Report Type.

Column Name	Description
Element Empty	Indicates whether the folder or leaf element contains children. If a leaf or folder is empty, it is a candidate for deletion during Prepare To Publish. Leaf files are considered by the system to be empty when they are “default” type, as opposed to “reference” type. Default leafs are considered by the system to be empty when the leaf contains no child documents. — If a default type leaf contains a planned or placeholder document, it is considered not empty. — If a default type leaf has aligned TOCs or Special Sheets, it is still considered empty. — A Leaf Operation with a value of DELETE will be marked as empty, but will not be deleted as part of Prepare for Publishing (both eCTD and Paper). Valid for Folders and Leafs and Volumes.
Element Name	Inherited from the Element Name provided in the element attributes. If there is no “Element Name” the system provides a value of NA.
Element Number	Elements may contain an element number in addition to the element name, and sometimes instead of an element name. In these instances, an element number is provided. Element Number is valid for volumes, folders and leaf elements only. For leaf elements, the value should also contain the parent folder number.
Element Path	The location of the element in the assembly, including ancestry. (Element Path is similar in concept to "breadcrumbs".) Generations (levels in the assembly) are separated by back-slashes (or some other character) in the Element Path. Valid for all elements except vol-umes.
Element Type	Describes the element. For example: Assembly Root, Folder, Leaf, Reference Leaf, Volume, Document, TOC, Cover Page, Tab, Slip Sheet, Placeholder.
Error and Warning Count	Indicates the number of errors detected.
Error and Warning Details	Detailed information about errors and warnings.
Extended Attributes	Lists extended attributes for the element.

Extended Subtype	Describes the subtype for the element.

Column Name	Description
Extracts Exist	This is the captured data of a PDF document Rendition bookmarks. This is default value but can be overridden in document element attributes. — If the Extracts Exist value is set to Y (Yes), Ennov InSight pulls the extracts from the PDF Rendition and populates those values for use in TOC generation. — If the Extracts Exist value is set to N (No), Ennov InSight does not pull the extracts from the PDF Rendition; any previously pulled extracts are used in the creation of TOCs.
Font Library	The repository data file for the fonts.
Has Errors	Indicates errors.
Has Open Activities	Indicates whether there are active activities associated with the node.
Included in Page Numbering	Indicates the application of page numbers to the documents, cover pages, TOCs, and the system's inclusion of those elements in page number calculations for other elements.
Inherited Attributes	Lists the inherited attributes for an element.
Language	The language used in the assembly.
Leaf ID	An eCTD attribute, valid for leaf elements only. The leaf ID number.
Leaf Status	The value of the Leaf Status attribute from the leaf element. Valid for a leaf element only.
Modified File	An eCTD attribute, valid for leaf elements only. Indicates that a file has been modified.
Operation	An eCTD attribute, valid for leaf elements only. New, Replace, Append, and Delete are leaf operations. If the operation on a leaf is New and the leaf has a value for modified file, an error is reported indicating Inconsistent Lifecycle; a new leaf cannot have a modified file val- ue. If the operation on a leaf is Replace, Append, or Delete, and the modified file attribute does not have a value, an error is reported indicating Inconsistent Lifecycle; a modified leaf must indicate its modified file.
Order	A system generated value depicting the order from top to bottom for the element.
Column Name	Description
Output Filename	The name the output file receives at publishing time. Inherited from the Element Name provided in the element attributes. If there is no "Output Filename" associated with the element, the system will provide a value of NA. Valid for Volumes and Leaf Files.

	Note: *Underscores are stripped out of file names instead of being converted into dashes in the output file name.*
Output Path	Lists the repository path to where the element is published. Inherited from the Element Name provided in the element attributes. If there is no "Output Path" associated with the element, the system provides a value of NA. Output Path is valid for Volumes and Leaf Files.
Output Channel	Indicates the output channel: Paper Output Channel, Electronic Output Channel, eCTD Output Channel.
Overwritten Attributes	Indicates the values for Folder and Leaf attributes that would otherwise be inherited from a parent or root defined attributes, but have been overwritten by the user.
Planned Page Count	Indicates the total number of planned pages represented by this element.
Rendition Exists	Indicates whether a PDF rendition is associated with the element. The "Rendition Exists" value pertains to the presence of a current PDF Rendition for the bound document. This value is assigned by the system in document element attributes. The value of "Rendition Exists" is set by the system for PDF renditions created. Valid for documents.
Rendition File Size	Indicates the file size of the leaf file or volume.
Section	The folder or leaf in the assembly that is being queried.
Tab Text	Provides the resolved Tab Text (if known by the system).
Use Native File	Indicates whether to use native file format or to create a PDF for output.

Generate a Publishing Readiness Query

The *Publishing Readiness* Query enables you to view your assembly metadata at a glance and find predicted errors and warnings that may occur during publishing if an issue is not remedied.

Warning: Always run a DMS synchronization before refreshing the Publishing Readiness query, Link Inspector query, and other queries. Ennov InSight uses the data available in the Ennov InSight database, and relies on DMS synchronization to ensure this information matches what is in the DMS for each document.

To generate a Publishing Readiness query:

1. Click a link for the assembly you want to publish.

   The *Assembly Attributes* page opens.
2. Right-click the assembly root and choose Publishing Readiness Query. The *Publishing Readiness Query* dialog box opens.
3. Under Selected Columns, choose any data you do not want to include in the query and move it to the *Available Columns* box.

4. Optionally choose selected columns and click up or down to change the order in which columns appear in the query.
5. Do one of the following:

Option	Action
To generate the query results:	Click Search.
To clear your choices and start again:	Click Reset.
To save your choices as a query that you can use again:	Click .

6. Do one of the following:

Option	Action
To return to the *Publishing Readiness Query* page:	Click Back.
To export the query results to a comma-separated file:	Click .

Publishing Requests

This feature enables you to query tasks that are directly or indirectly associated with publishing. You can use Job requests to view the status of the operations such as publishing jobs and print or view an output log from a completed job list.

For all publishing jobs:

— Documents are rendered (for customers who have licenses for rendering and publishing services).

— Links are resolved.

— Rendered documents are concatenated.

— Variables are resolved.

— Output files are created in the document repository with the appropriate names, locations, and metadata. — Any errors and warnings are noted in the job requests.

— Ennov InSight Publisher will not re-render or re-extract documents that have been checked in as the same version in a DMS . However, you can manually re-render and re-extract documents by right-clicking on any document and creating renditions and extractions or using Force New Renditions and Extractions functionality. This will refresh all links, bookmarks, and page count data as well as rendering the document.

— When you publish a .pdf document that has a rendition, the source .pdf document, not the rendition is used for publishing.

Electronic/eCTD Publishing

— XML files are created and validated against their specified CV Profiles.

— Checksums for all published files are calculated and are included in the values in their respective leaf elements. — Files are concatenated for each standard leaf element.

Submit eCTD 4.0 Publishing Request

An application with specific assembly components can be submitted for publishing.

You must be aware of the following limitations before submitting an electronic publishing request:

— All the eCTD 4.0 publish requests must be made from assemblies that have leaf elements. — Output is not generated for an eCTD 4.0 application published without leaf elements.

To submit eCTD 4.0 publishing request:

1. On the *Assembly Attributes* page, click  .
2. On the *Publish Request* page, click Browse to choose the repository location to publish the submission.

   The folder for the published output should not contain both Unicode characters and spaces as this results in an invalid path error. If you are using Documentum as the repository location, move to the next step. Else, go to step 4.
3. Under Output Document Type, choose the document type.
4. Select Append Application and Sequence Number to create subfolders in the output location.

   Because Ennov InSight automatically appends the application number and sequence code to the folder path during publishing, you should always use legal file system characters in these attributes. The following characters are not legal on a file system: \ / : * ? " < > |.

   a. subfolder is created with the application name followed by the sequence number.
5. If you need to generate renditions for the assigned documents and overlays select Prepare to Publish.
6. Choose one of the following to indicate what should be published:

Option	Description
All Leaf Elements:	Publishes all the leaf elements in the assembly to individual output files.
Selected Leaf Elements:	Publishes only those leaf elements that are included in the selected folder.
All Leaf Elements and XML:	Publishes all the leaf elements in the assembly to individual output files. The eCTD XML backbone is published according to the appropriate CV Profile file.

Selected Leaf Elements and XML:	Publishes only those leaf elements that are included in the selected folder. The eCTD XML backbone is published according to the appropriate CV Profile file.
XML Only:	Publishes the eCTD backbone XML based on the appropriate CV Profile file. None of the leaf elements are published.

7. Under Include Leafs with Status, select the leaf statuses of the leafs you want to publish.

   By default, all active leaf statuses from Data Administration > Submission Maintenance section under Selected are selected. Clear the selection as appropriate The leafs with selected statuses are included in the electronic publish to generate output leaf files. This option does not affect the XML generation. For XML, all leafs are included, independent from the status assigned.

8. Under DMS Versioning Scheme, choose one of the following for the published output files:

Option	Description
Same:	Includes the same version number as previous output for the published output files. (Choose this when you are publishing to a file system.)
Minor Version:	Includes increments to a minor version for the published output files.
Major Version:	Includes increments to a major version for the published output files.

9. Click OK to submit a publish request.
   a. message confirms the publish request has been successfully sent.
10. Select Go To > Job Requests to view the status of your publication request.

Once the job is complete, navigate to the publish output location and confirm publication. The submission including submissionunit.xml is generated.

Publishing Leaf Elements

Submit a publishing request for leafs properly to get output you expect.

Leaf Statuses

You can select the leaf elements to be published. When the *Publish Request* page is initiated, in the Include Leafs with Status box select the leaf statuses of leafs you want to be published. The leafs with selected statuses are included in the electronic publish to generate output leaf files.

— This option does not affect the XML generation. For XML, all leafs are included, independent from the status assigned.

— After publishing is completed, the leaf statuses of leafs that have publishable elements are changed automatically to Published.

— For the All Leaf Elements or Selected Leaf Elements options, only leafs with the selected leaf statuses are published.

— For the All Leaf Elements and XML and Selected Leaf Elements and XML, the backbone files and only leafs with the selected leaf statuses are published. When you do not specify the leaf statuses in the *Publish Request*, then only the backbone files are published.

The publishing job fails, if:

— No leafs have publishable elements.

— There are no leafs with the selected leaf statuses in the assembly.

Publishing of Sender-defined Keywords

Submit a publishing request for Sender-defined properly to get output you expect.

When publishing the sender-defined keywords (SDKs) for the first time, the both declaration and usage of it is included. Declaration part contains the value, the code and the code system from the UI. Only code and codessytem are present in the usage section. They are potentially present many times across the submission, unlike the declaration.

For a sender-defined keywords added to a folder, the child leafs are published with the following entries:

<component>

<priorityNumber value="...."></priorityNumber>

<componextofUse>

<id root="...."></id>

<referencedBy typeCode="REFR">

<keyword>

<code code="AAA" codeSystem="BBB"></code>

</keyword>

</referencedBy>

Value	Description
REFR	Hard coded value.
AAA, BBB	Sender-defined values.
<component0f1> ...	

<document> ... <referencedBy> <keywordDefinition> <code code="CCC" codeSystem ="DDD"</code> <statusCode code="active"></statusCode> <value> <item code="EEE" codeSystem ="FFF"> <displayName value ="GGG"></displayName> </item> </value> </keywordDefinition> </referencedBy>
Value Description
Correspond to the keyword definition and related data. In particular: CCC and DDD are the code and code system CCC, for agency defined vocabulary. For example, Keyword Type vocabulary from ICH package. EEE is the code from SDDDD, CV under the Application. FFF is the Codesystem from the Application. GGG is the name from SDCV under the Application. EEE, FFF, GGG

Leaf Statuses

You can select the leaf elements to be published. When the *Publish Request* page is initiated, in the Include Leafs with Status box select the leaf statuses of leafs you want to be published. The leafs with selected statuses are included in the electronic publish to generate output leaf files.

— This option does not affect the XML generation. For XML, all leafs are included, independent from the status assigned.

— After publishing is completed, the leaf statuses of leafs that have publishable elements are changed automatically to Published.

— For the All Leaf Elements or Selected Leaf Elements options, only leafs with the selected leaf statuses are published.

— For the All Leaf Elements and XML and Selected Leaf Elements and XML, the backbone files and only leafs with the selected leaf statuses are published. When you do not specify the leaf statuses in the *Publish Request*, then only the backbone files are published.

The publishing job fails, if:

— No leafs have publishable elements.

— There are no leafs with the selected leaf statuses in the assembly.

After Submitting a Publishing Request

When you create a publish request, a confirmation message indicates whether the request was successful and an audit trail is created.

The publish request is sent to, and processed by, the server based on the following conditions:

— If you chose to prepare for publishing automatically, Ennov InSight checks the rendition status of each source document before trying to publish the submission.

— Any renditions that are missing or out-dated are queued for processing.

— Ennov InSight holds the publishing request until all renditions are created for source files in the submission.

— If a rendition fails, a message is saved in the publish log and the leaf including that document is not published

— If a rendition fails for one or more source files, a message is saved in the publish log and the submission is not processed.

— If all renditions are created successfully, they are written to the DMS as renditions of their respective documents and the system continues to process the submission.

— You are notified when the job is completed and whether it was successful.

Note: *When a job has left the queue to be processed, it cannot be cancelled from the InSight job requests window. Jobs must be cancelled immediately if they are to be stopped, in the web interface.*

Viewing a Publishing Request

You can generate a Publishing Request query to view all or specific publishing requests.

To view a publishing requests:

1. Choose Go To > Job Requests.

   The *Job Requests* page opens.

2. Do any of the following:

Option	Action
To view the job request:	Click the User Name arrow and choose the user who submitted the job requests.
To choose the date range during which the requests were submitted:	Click the Time arrows.
To view the specific publishing request: Enter the name of the specific publishing request you want to view:	In the Job Name box, enter the name of the specific publishing request.
To view the publishing request:	In the Job Status box, choose the statuses of the publishing request.
If you do not want to include in the query:	Under Selected Columns, choose any data and click <-- to move it to the *Available Columns* box.
To change the order in which columns appear in the query results:	Choose Selected Columns and click Up or Down.
To sort the job requests:	Under Available Sort Orders, choose the columns and click <-- to move it to the *Available Columns* box.
To change the order in which columns appear in the query results:	Choose selected sort orders and click Up or Down.

3. Do one of the following:

Option	Action
To generate the query:	Click Search.
To clear your choices and start again:	Click Reset.
To save your choices as a query you can use again:	Click  .

4. Do any of the following:

Option	Action
To return to the Job Requests page:	Click Back.
To export the query results to a comma-separated file:	Click  .

Publishing Request Results

Each publishing request that fits the criteria you specify on the *Job Requests* page appears on a row in the resulting report. If an error has occurred during publishing, an error message is returned. The message that appears in the Job Message column is a link you can click to view the details of the message.

When publishing, if Prepare To Publish has been selected, the process is initiated before the publish function. The *Job Requests* page shows the prepare to publish running prior to showing the publish execution.

Suspended Ennov InSight Rendering processes (either purposefully or through an error) may cause Ennov InSight to incorrectly report jobs as completed in the job requests report. For all jobs that require Ennov InSight Rendering to be involved, the following Job Statuses exist to identify the job progress:

— Scheduled

— Started

— Waiting for Ennov InSight

— Waiting for Ennov InSight Rendering

— Processing Ennov InSight Rendering Results

— Completed

— Completed with Errors

— Completed with Warnings

— Failed

The following table describes the different statuses of the publishing job results.

Status Description	Result
Publishing job is complete but with at least one error in job details.	Completed with Errors
Publishing job is complete but with at least one warning is present in job details.	Completed with Warnings
Publishing job is complete but with at least a warning and an error present in job details.	Completed with Errors
Publishing job is complete but without any warning and error in job details.	Completed
Publishing job is complete but at least a critical error present in job details.	Failed

View a Job Message

You can track the progress of your publishing job on the *Job Message* page.

To view a job message:

1. Click a link in the Job Message column in the *Job Requests* query results.
2. On the *Job Message* page, do any of the following:

Option	Action
To save the content of the message to the Windows Clipboard:	Click Copy to Clipboard.
To print the message:	Click Print.

Option	Action
To close the *Job Message* page and return to the *Job Requests* query results:	Click Close.

Note: *Suspended processes may cause Ennov InSight to incorrectly show jobs as completed in the Job Request query results.*

Cancel Publishing Requests

Only an administrator can delete a publishing request submitted by another user.

You can cancel your own publishing requests under certain conditions.

— You have the appropriate security privileges. — The job has not already been completed.

You can only cancel in-progress jobs that have reached the Ennov InSight Rendering server, which is indicated by the Job Details. When doing so, the currently processing sub-task is completed and then the parent job is canceled.

Warning: If you attempt to cancel while the job is still being processed by Ennov InSight (before you see any Job Details), then resubmit the same job, you could cause the database to lock.

Cancel a Publishing Request

You can cancel a publishing job before processing if you have the appropriate security permissions.

To cancel a publishing request:

1. Click Go To > Job Requests.
2. On the Job Requests page, enter the information for the publishing request you want to cancel.
3. Click Search.
4. In the query results, click Cancel Job in the Cancel Job column for the publishing request.
5. Click OK when you are prompted to confirm the cancellation.

Create Working Assembly from Locked eCTD 3.2 Assembly

eCTD 4.0: Create Working Assembly from Locked eCTD 3.2 Assembly

Create an eCTD 4.0 working assembly from a locked eCTD 3.2 assembly submitted view to upgrade the existing assembly and its elements to submit the new version to the agency.

Ennov InSight provides the ability to create the eCTD 4.0 working assembly from the locked eCTD 3.2 assembly submitted view in the application under the sequence with the eCTD 4.0 value in Sequence Standard Type. The official term for this kind of assembly is forward compatibility assembly.

For the Create Working Assembly option to be available on the Assembly tab of the eCTD 4.0 sequence, any sequence under the application should not contain previously created working assembly.

The attributes of the following elements are transferred from the eCTD 3.2 assembly to the eCTD 4.0 working assembly: — Root folder

— Folder

— Leaf. Leafs with the lifecycle operations are transferred with as follows:

- eCTD 3.2 > eCTD 4.0. All the eCTD 3.2 values are transferred to the appropriate or equivalent attributes of the created eCTD 4.0 working assembly.
- New > New. The leaf with NEW operation is transferred as a leaf with NEW operation.
- Replace > Replace. The leaf with REPLACE operation is transferred as a leaf with REPLACE operation. — Placeholder

— Document

— Reference Leaf

The eCTD 3.2 assembly structure is retained in the eCTD 4.0 working assembly, excluding Page Markers, Volumes, TOCs, Cover Pages, Slip Sheets, and Tabs.

Submissions in bulk cannot be removed from lifecycle if this process affects both eCTD 4.0 and eCTD 3.2 Sequences.

See: eCTD 4.0: Transferring PSL Attributes from eCTD 3.2 Submitted View.

Create the eCTD 4.0 Working Assembly from the eCTD 3.2 Assembly

Create an eCTD 4.0 working assembly from the locked eCTD 3.2 assembly submitted view to retain the existing assembly elements.

Prerequisites

You must have Write permissions for Electronic Lifecycle Publishing to create eCTD 4.0 working assembly. You can create an eCTD 4.0 working assembly from a locked eCTD 3.2 assembly submitted view in the application under the sequence with the eCTD 4.0 value in Sequence Standard Type.

1. Go to the application with the locked eCTD 3.2 assembly submitted view that does not have any working assemblies.
2. Go to Application Attributes > Sequences tab and click  .
3. On the *Create Sequence* page, select the eCTD 4.0 from the Sequence Standard Type.
4. Click Save.
5. Click the link for the sequence for that you want to create the working assembly.
6. On the *Assembly* tab, click Create Working Assembly.

   If any sequence with a working assembly exists in the application, the Create Working Assembly button will not be available and the following message will be displayed: An eCTD 4.0 working assembly cannot be created until an unlifecycled eCTD 3.2 working Assembly exists!.
7. Enter the required information for the working assembly and click Create.

   If amount of nodes exceeds the configured parameter, you will get this message: 'The Create Forward Compatibility action has started processing. Please go to Job Requests for the status.' . Click OK. The working assembly is created. You will be redirected to the *View Sequence* page.
8. Click Go to > Job Requests to see the status.
9. From *View Sequence* page, click the Assembly tab.

   The eCTD 4.0 working assembly has been created from the locked eCTD 3.2 assembly submitted view.
10. Click  , select the Publishing Settings tab and click  .
11. Check the CV Profile field values to make sure the migration is successful.

eCTD 4.0: Transferring PSL Attributes from eCTD 3.2 Submitted View

Creating an eCTD 4.0 working assembly from a locked eCTD 3.2 assembly submitted view allows you to retain the existing Publishing Settings Library elements for future use.

The Publishing Settings Library (PSL) attributes are taken from the eCTD 3.2 assembly submitted view and transfers to the eCTD 4.0 Template Mapping defined in the assembly template.

Note: *To ensure the DTD Code of the file selected corresponds to the required eCTD 4.0 Template Mapping that has a CV profile, check the following:*

— Assembly > Assembly DTD/Schema Types in Data Administration.

— Assembly Templates > <name of the template> from the eCTD 4.0 Template Mapping > Publishing Settings Library > Publishing Settings > CV Profiles.

The following PSL elements are transferred:

Elements Transferred	What Is Not Transferred
The Overlays tab.	Overlays with the following values in the Default Overlay For field are not transferred: Cover Pages and TOCs.
The Variables tab.	Variables with Paper value in the Output Channel field are not transferred. If both Electronic and Paper values are in the Output Channel field, only Electronic value is displayed after transfer.

The CV Profiles field replaces the XML Definitions field after the transfer.

In the following cases, the forward compatibility assembly is not created:

— No values are selected in the XML Definitions field in the source eCTD 3.2 PSL.

— Values are selected in the XML Definitions field of the source eCTD 3.2 PSL, but all of them do not have eCTD

4.0 Template Mapping indicated in *Data Administration*.

— If more than one regional DTD is selected in Edit Publishing Settings > XML Definitions values.

The forward compatibility assembly is created, and appropriate values are transferred to the CV Profiles field if at least one value in the XML Definitions field of the source eCTD 3.2 Publishing Settings Library has mapped to eCTD 4.0 assembly template in *Data Administration*.

The following PSL elements are not transferred:

Element Type Not Transferred	Element Name
Tabs	— Default Study Folder — Volumes — Cover Pages — Tabs — Slip Sheets — TOCs
Fields and Values	The fields and values of the source eCTD 3.2 PSL are not transferred to eCTD 4.0 PSL of forward compatibility eCTD 4.0 assembly.

eCTD 4.0: CoU Codes Transferring from eCTD 3.2 Submitted View

An eCTD 4.0 working assembly created from a locked eCTD 3.2 assembly submitted view gets assigned CoU Codes.

For eCTD 4.0 assemblies, the Context of use (CoU) codes work the same way as the eCTD 3.2 extensions. *See Ennov InSight 7.3 > Extension Types and Usage.*

CoU codes define how the leaf is published both in folders and XML file.

CoU codes are assigned according to the mapping from *Data Administration* that indicate the attribute node and name.

CoU codes are defined with the corresponding value in the Number field for a folder in the eCTD 3.2 assembly. If there is a value in the Number field for a folder in the eCTD 3.2 assembly, there will be a corresponding value in the Context of Use Code field for such folders in eCTD 4.0 assembly.

Published Output

Sender-defined Keywords (SDKs) in submissionunit.xml

The eCTD 4.0 submissionunit.xml is a part of the eCTD submission package for health authority regulatory submissions.

The eCTD 4.0 submissionunit.xml contains submission unit information being submitted like application type, crossreferenced documents and submission metadata.

SDKs are included as submission metada in the eCTD 4.0 submissionunit.xml file. They allow the sender to provide the additional information about the submission for tracking, organization and searching.

The updateMode element indicates a name change in SDK .Ennov InSight records these changes providing a user with updated information. It is necessary for managing and tracking the updates for eCTD submissions.

The updateMode is supported for sender-defined keyword values, priority numbers and, leaf titles. When adding the SDKs to an updated sequence assembly, the new values appear in published output.

If a given SDKs value is same as the lifecycled published assembly within an application, the definition and the updateMode sections are not generated in the published output.

For published assemblies with newer sequences, SDKs is updated after the current assembly is published. The next publishing will have an updated value without the definition and the updateMode sections. In this case, the system uses the latest SDK value even if there is a difference between the current value and the last published value within the sequence. The last change of SDK is published within the application.

Published Output Specific Conditions

A submissionunit.xml file contains ICH and Regional sequence content that includes study data.

The submissionunit.xml file is created according to the ICH eCTD v4.0 XML schema. See:*Submit eCTD 4.0 Publishing Request*.

Depending on the controlled vocabularies selected in publishing settings, the object identifiers (OIDs) of applied versions are specified in the <receiver> section.

Each assembly leaf is published as onecontextOfUseelement along with the priorityNumber. The priorityNumber is populated in the Priority Number field of a leaf. If there is a change of the priority number value, the updateMode is applied.

Each contextOfUse has a code attribute populated. It is taken from the corresponding attribute of the parent folder for each particular leaf.

Each contextOfUse has statusCode populated. It is active for all the leafs and suspended for leafs with the Suspend operation.

A contextOfUse may have controlActProcess>> subject>>

submissionUnit>>component>>priorityNumber> contextOfUse>> replacementOf>>

relatedContextOfUse populated. It takes a value only if the corresponding leaf has Replace or Mreplace operation. The value is UUID value or values of the old replaced leaf(s). It is Modified Leaf field.

Each contextOfUse has derivedFrom>> documentReference. It is populated with UUID value of the

published document, not the documents under the leaf. It is not provided for the leafs with the Suspend operation.

Each contextOfUse has referencedBy>> keyword populated. It is taken from the parent folder of the corresponding leaf. In the cases where the SDKs are included, the keyword code and codesystem are

provided in the referencedBy>> keyword>> code section. If the keyword code is not present in controlActProcess >> subject >> submissionUnit>> componentOf1>> submission>> componentOf>> application>> referencedBy>> keywordDefinition>> value>> item, its

definition is provided here. There should be only one definition for each code within codesystem value. The keyword definition includes code, codesystem and value (the name of the keyword). If the value is changed, the updateMode is applied. controlActProcess >> subject >> submissionUnit >> componentOf1 >> sequenceNumber is populated with the sequence code value.

controlActProcess>> subject>> submissionUnit>>componentOf1>>submission>> componentOf>>application>> component >> document provides: — id - UUID of published document

— Title - title of the leaf. If the title is changed, the updateMode is applied.

— Text attributes - different values related to the text.

— Reference - the path to the output file.

— integrityCheck - checksum value for output document.

— All the SDKs are defined in controlActProcess >> subject >> submissionUnit>> componentOf1 >> submission >> componentOf >> application>> referencedBy >>

keywordDefinition section. The value from the agency-defined vocabulary is introduced as code@code and as codesystem for it is put as code@code. The SDK name is introduced as

value>>displayName@Value. The sender-defined code is introduced as value>>item@code. The application code system is introduced as value>>item@codesystem.

The folder structure is created according to assembly structure.

The values mapped to the DMS attributes use the attributes of the first document under a folder or a leaf to resolve the mappings.

A reference leaf element is published as a regular contextOfUse. The output document UUID of target reference leaf is used.

Depending on assembly type and the path entered, the file names are normalized to include only allowable characters. See: *eCTD 4.0 Normalization Rules* for more information. The other options can be as following: — If the filename is left blank for any leaf in the assembly, the system should use the leaf name, normalized per the rules above, adding the appropriate extension (.pdf, if Use Native File=No, extension of the assigned file if Use Native File = Yes) and include a message in the publishing log that no file name was provided so the leaf name was used.

— The checksum for the full submissionunit.xml file is calculated and included in a single-line text file named sha256.txt.txt and placed in the same location as the submissionunit.xml.

— If the assembly contains an empty folder, the system logs an error that the assembly is incomplete, including the section where the empty folder is. That portion of the XML includes an error code to indicate it is incomplete.

— If the assembly contains an element that does not have the expected parent information, so that the appropriate XML structure cannot be created, the system logs an error that the assembly is incomplete, including the section where the missing information is. That portion of the XML includes an error code to indicate it is incomplete.

— If the user cancels the publishing job while in progress, no xml file is generated. Any temporary files created during processing are removed.