# Ennov InSight 7.3 Publisher Guide

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# Chapter 1. Ennov InSight Publishing

Ennov InSight Publishing enables you to create a complete submission package.

— Use submissions wizards to streamline the initiation of submissions that comply with ICH, Japanese, EU, US, STF, GCC, Swiss, AU, TH, Canadian, JO, CN, EAEU, WHO, WAHO, UA, and TW specifications.

— Quickly create all the necessary components for a paper submission, compliant NeeS, or compliant eCTD submission, including the required ICH, STF, and regional XML files, the correctly named leaf files and folder structures, and any requisite navigation aids.

— 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 your data.

— Enhance the efficiency of your organization, reduce your time to market, and be assured of compliance with the latest regulatory guidelines and specification.

# Chapter 2. Use eCTD Templates

The eCTD templates include every leaf that can be included according to the ICH and regional specifications defined in the DTDs and the ICH granularity document.

You can easily modify the assemblies that use the template by deleting the unnecessary folders and leaf elements or adding additional leaf elements if more granularity is desired. Typical ways to use the eCTD templates include:

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

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

— Creating a template based on a module 1 template, with the eCTD ICH Module 2-5 template imported and subsequently creating assemblies using this template.

— Creating an assembly using the eCTD ICH Module 2-5 template, and then importing the module 1 folder from an m1 template.

The following topics provide information about the specific eCTD templates provided with Ennov InSight .

## eCTD and NeeS Template Files

Ennov InSight includes ICH-compliant eCTD and NeeS templates with preconfigured folder types to capture the metadata for the specific headings in the eCTD that require additional information: drug substance, drug product, excipient, clinical indication, and regional administrative information.

To ensure that you have the most current version of each listed template file on your system, refer to the **New/ Updated in Version** column in the table. This column contains information about the template status for each version in the Ennov InSight 7.3 branch:

- **No** - template was not updated
- **Yes** - template was updated
- **New** - template is new with this Ennov InSight version
- Blank - template did not exist for the release

| Template | New/Updated in Version | | | | | | |
|---|---|---|---|---|---|---|---|
| | 7.3 | 7.3.1 | 7.3.2 | 7.3.3 | 7.3.4 | 7.3.4-Reg-Update | Autumn 2025 |
| templates\510k Template (Sep 2019).xml | No | No | No | No | No | | |
| \templates\510k Template.xml | No | No | No | No | No | | |
| \templates\A4SampleTOCTemplate.docx | No | No | No | No | No | | |
| \templates\ASEAN ACTD-NeeS.xml | No | No | No | No | No | | |
| \templates\AU eCTD Module 1 v0.90.xml | No | No | No | No | No | | |
| \templates\AU\AU Module 1 NeeS v2.0.xml | No | No | No | No | No | | |

| Template | New/Updated in Version | | | | | | |
|---|---|---|---|---|---|---|---|
| | 7.3 | 7.3.1 | 7.3.2 | 7.3.3 | 7.3.4 | 7.3.4-Reg-Update | Autumn 2025 |
| \templates\AU\AU eCTD Module 1 v3.0.xml | No | No | No | No | No | | |
| \templates\AU\AU Module 1 eCTD v3.1.xml | No | No | No | No | No | | |
| \templates\AU\AU Module 1 eCTD v3.2.xml | | | | | New | | |
| \templates\AUS\AUS Module 1 CTD v2.1.xml | No | No | No | No | No | | |
| \templates\AUS\AUS Module 1 CTD-NeeS v2.0 2011.xml | No | No | No | No | No | | |
| \templates\BA\BA eCTD Module 1 v3.1.xml | | | | | | New | No |
| \templates\CAN\Canadian eCTD Module 1 v1.0.xml | No | No | No | No | No | | |
| \templates\CAN\Canadian eCTD Module 1 v2.2.xml | No | No | No | No | No | | |
| \templates\CAN\Canadian electronic CTA CTA-A-29-May-2013.xml | No | No | No | No | No | | |
| \templates\CAN\Canadian electronic CTA.xml | No | No | No | No | No | | |
| \templates\CH\CH eCTD Module 1 v1.0.1.xml | No | No | No | No | No | | |
| \templates\CH\CH eCTD Module 1 v1.1.xml | No | No | No | No | No | | |
| \templates\CH\CH eCTD Module 1 v1.2.xml | No | No | No | No | No | | |
| \templates\CH\CH eCTD Module 1 v1.3.xml | No | No | No | No | No | | |
| \templates\CH\CH eCTD Module 1 v1.4.xml | No | No | No | No | No | | |
| \templates\CH\CH eCTD Module 1 v1.5.xml | No | No | No | No | No | | |
| \templates\CN\CN eCTD Module 1 v1.0.xml | No | No | No | No | No | | |
| \templates\CN\CN eCTD ICH Module 2-5 v3.2.xml | No | No | No | No | No | | |
| \templates\CN\CN Clinical Study Report (VV5-0).xml | No | No | No | No | No | | |
| \templates\CN\CN Nonclinical Study Report (SEND Dataset).xml | No | No | No | No | No | | |
| \templates\CN\CN Nonclinical Study Report.xml | No | No | No | No | No | | |
| \templates\CN\CN eSub Supplementary Application - Chinese Medicine v1.0.xml | | | | New | No | | |
| \templates\CN\CN eSub Supplementary Application - Chemical Drugs v1.0.xml | | | | New | No | | |
| \templates\CN\CN eSub Supplementary Application - the MAH change v1.0.xml | | | | New | No | | |
| \templates\CN\CN eSub CTA - MAA - Chemical-Biological-DMF v1.0.xml | | | | New | No | | |
| \templates\CN\CN eSub CTA - MAA - Chinese Medicine v1.0.xml | | | | New | No | | |
| \templates\CN\CN eSub Consistency evaluation of chemical drugs - Oral v1.0 | | | | New | No | | |

| Template | New/Updated in Version | | | | | | |
|---|---|---|---|---|---|---|---|
| | 7.3 | 7.3.1 | 7.3.2 | 7.3.3 | 7.3.4 | 7.3.4-Reg-Update | Autumn 2025 |
| \templates\CN\CN eSub Consistency evaluation of chemical drugs - Oral CTD v1.0.xml | | | | New | No | | |
| \templates\CN\CN eSub Consistency evaluation of chemical drugs - Injection v1.0.xml | | | | New | No | | |
| \templates\CN\CN eSub Consistency evaluation of chemical drugs - Injection CTD v1.0 | | | | New | No | | |
| \templates\CN\CN eSub Renewal Applications - Drug Product v1.0 | | | | New | No | | |
| \templates\CN\CN eSub Renewal Applications - Drug Substance v1.0 | | | | New | No | | |
| \templates\CN\CN eSub One time import v1.0 | | | | New | No | | |
| \templates\CN\CN eSub Dossiers review process v1.0 | | | | New | No | | |
| \templates\CN\CN eSub Excipients v1.0 | | | | New | No | | |
| \templates\CN\CN eSub Registration drug packaging v1.0 | | | | New | No | | |
| \templates\eCTD ICH Module 2-5 v3.2.xml | No | No | No | No | No | | |
| \templates\EAEU\EAEU Template v1.0.xml | No | No | No | No | No | | |
| \templates\EU\EU CTA.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v1.0 - CP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v1.0 - MRP-DCP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v1.0 - NP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v1.1 - CP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v1.1 - MRP-DCP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v1.1 - NP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v1.2.1 - CP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v1.2.1 - MRP-DCP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v1.2.1 - NP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v1.3 - CP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v1.3 - MRP-DCP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v1.3 - NP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v1.4 - CP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v1.4 - MRP-DCP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v1.4 - NP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v2.0 - CP.xml | No | No | No | No | No | | |

| Template | New/Updated in Version | | | | | | |
|---|---|---|---|---|---|---|---|
| | 7.3 | 7.3.1 | 7.3.2 | 7.3.3 | 7.3.4 | 7.3.4-Reg-Update | Autumn 2025 |
| \templates\EU\EU eCTD Module 1 v2.0 - MRP-DCP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v2.0 - NP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v3.0 - CP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v3.0 - MRP-DCP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v3.0 - NP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v3.0.1 - CP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v3.0.1 - MRP-DCP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v3.0.1 - NP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v3.0.3 - CP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v3.0.3 - MRP-DCP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v3.0.3 - NP.xml | No | No | No | No | No | | |
| \templates\EU\EU eCTD Module 1 v3.1 - CP.xml | | | | New | No | | |
| \templates\EU\EU eCTD Module 1 v3.1 - NP.xml | | | | New | No | | |
| \templates\EU\EU eCTD Module 1 v3.1 - MRP-DCP.xml | | | | New | No | | |
| \templates\EU\EU IMPD template.xml | No | No | No | No | No | | |
| \templates\EU\EU PMF Submission in eCTD.xml | No | No | No | No | No | | |
| \templates\EU\EU VNeeS - Immunological.xml | No | No | No | No | No | | |
| \templates\EU\EU VNeeS - Pharmaceutical.xml | No | No | No | No | No | | |
| \templates\EU\EU VNeeS v2.2 - Immunological.xml | No | No | No | No | No | | |
| \templates\EU\EU VNeeS v2.2 - MRL Maximum Residue Limits.xml | No | No | No | No | No | | |
| \templates\EU\EU VNeeS v2.2- Pharmaceutical.xml | No | No | No | No | No | | |
| \templates\EU\EU VNeeS v2.3 - Immunological.xml | No | No | No | No | No | | |
| \templates\EU\EU VNeeS v2.3 - MRL Maximum Residue Limits.xml | No | No | No | No | No | | |
| \templates\EU\EU VNeeS v2.3- Pharmaceutical.xml | No | No | No | No | No | | |
| \templates\GCC\GCC eCTD Module 1 v1.2 - GCC.xml | No | No | No | No | No | | |
| \templates\GCC\GCC eCTD Module 1 v1.2 - NP.xml | No | No | No | No | No | | |
| \templates\GCC\GCC eCTD Module 1 v1.5 - GCC.xml | No | No | No | No | No | | |
| \templates\GCC\GCC eCTD Module 1 v1.5 - NP.xml | No | No | No | No | No | | |

| Template | New/Updated in Version | | | | | | |
|---|---|---|---|---|---|---|---|
| | 7.3 | 7.3.1 | 7.3.2 | 7.3.3 | 7.3.4 | 7.3.4-Reg-Update | Autumn 2025 |
| \templates\HR\HR eCTD Module 1 v1.4 - NP.xml | No | No | No | No | No | | |
| \templates\study reports\ICH E3 Clinical Study Report (VV2-2).xml | No | No | No | No | No | | |
| \templates\study reports\ICH E3 Clinical Study Report (VV3-0).xml | No | No | No | No | No | | |
| \templates\study reports\ICH E3 Clinical Study Report (VV5-0).xml | No | No | No | No | No | | |
| \templates\study reports\Nonclinical Study Report (SEND Dataset).xml | No | No | No | No | No | | |
| \templates\study reports\Nonclinical Study Report.xml | No | No | No | No | No | | |
| \templates\JO\JO eCTD Module 1 v1.0.xml | No | No | No | No | No | | |
| \templates\JO\JO eCTD Module 1 v1.1.xml | No | No | No | No | No | | |
| \templates\JP\JP eCTD Module 1 v1.0.xml | No | No | No | No | No | | |
| \templates\JP\JP eCTD Module 2-5 v3.2.xml | No | No | No | No | No | | |
| \templates\MD - IMDRF (HC) IVD Template.xml | No | No | No | No | No | | |
| \templates\MD - IMDRF nIVD Template.xml | No | No | No | No | No | | |
| \templates\PMA Template (Feb 2019).xml | No | No | No | No | No | | |
| \templates\PMA Template.xml | No | No | No | No | No | | |
| \templates\ROW CTD Module 1.xml | No | No | No | No | No | | |
| \templates\SampleCoverPageTemplate.docx | No | No | No | No | No | | |
| \templates\SampleOverlayTemplate.docx | No | No | No | No | No | | |
| \templates\SampleTOCTemplate.docx | No | No | No | No | No | | |
| \templates\SA\Saudi Arabia CTD Module 1 v1.0.xml | No | No | No | No | No | | |
| \templates\SG\SG eCTD Module 1 v1.0.xml | | | | | | | New |
| \templates\TH\TH eCTD Module 1 v0.92.xml | No | No | No | No | No | | |
| \templates\TH\TH eCTD Module 1 v1.0.xml | No | No | No | No | No | | |
| \templates\TN\TN eCTD Module 1 v1.0.xml | | | | | | New | No |
| \templates\TW\TW eCTD Module 1 v1.0.xml | No | No | No | No | No | | |
| \templates\UA\UA eCTD Module 1 v1.0.xml | | | | | New | | |
| \templates\UCSampleCoverPageTemplate.docx | No | No | No | No | No | | |
| \templates\UCSampleOverlayTemplate.docx | No | No | No | No | No | | |
| \templates\CNSampleTOCTemplate.docx | | New | No | No | No | | |

| Template | New/Updated in Version | | | | | | |
|---|---|---|---|---|---|---|---|
| | 7.3 | 7.3.1 | 7.3.2 | 7.3.3 | 7.3.4 | 7.3.4-Reg-Update | Autumn 2025 |
| \templates\JPSampleTOCTemplate.docx | | New | No | No | No | | |
| \templates\US\US eCTD Module 1 v2.01.xml | No | No | No | No | No | | |
| \templates\US\US eCTD Module 1 v3.3.xml | Yes | No | No | No | No | | |
| \templates\WHO\WHO eCTD Module 1 v1.0.xml | | | | New | No | | |
| \templates\ZA\ZA eCTD Module 1 v1.0.xml | No | No | No | No | No | | |
| \templates\ZA\ZA eCTD Module 1 v2.1.xml | No | No | No | No | No | | |
| \templates\ZA\ZA eCTD Module 1 v3.0.xml | | New | No | No | No | | |
| \templates\ZA\ZA eCTD Module 1 v3.1.xm | | | New | No | No | | |

**Sample Templates**

Ennov InSight includes additional assembly templates to enable the creation of reports or other electronic submission types. The following templates are samples for the publishing finishing options for overlays, Tables of Contents (TOC), and cover pages. Unicode (UC) templates for TOC, cover pages, and overlays are available (for A4 paper size).

- A4SampleTOCTemplate.docx
- SampleCoverPageTemplate.docx
- SampleOverlayTemplate.docx
- SampleTOCTemplate.docx
- UCSampleCoverPageTemplate.docx
- UCSampleOverlayTemplate.docx
- CNSampleTOCTemplate.docx
- JPSampleTOCTemplate.docx

# Mapped eCTD Template Profiles

The standard mappings are used to configure eCTD templates and specifications with metadata entered in the wizards.**US**

| Region Ab- breviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| US | U.S. 3.3 National (default) | US eCTD Module 1 v3.3<br>eCTD ICH Module 2-5 v3.2 |
| | U.S. 2.01 National | US eCTD Module 1 v2.01<br>eCTD ICH Module 2-5 v3.2 |

**EAEU**

| Region Ab- breviation | Template Pro- file Name | Mapped Tem- plate Pair |
|---|---|---|
| EAEU | EAEU 1.0 | EAEU Template v1.0 |

**EU**

| Region Ab breviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| EU, GB, UK | E.U. 3.1 Centralised (DE- FAULT) | EU eCTD Module 1 v3.1- CP eCTD<br>ICH Module 2-5 v3.2 |
| | E.U. 3.1 National | EU eCTD Module 1 v3.1- NP eCTD<br>ICH Module 2-5 v3.2 |
| | E.U. 3.1 Mutual Recognition | EU eCTD Module 1 v3.1- MRP-DCP<br>eCTD ICH Module 2-5 v3.2 |
| EU | E.U. 3.0.3 Centralised | EU eCTD Module 1 v3.0.3 - CP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 3.0.3 Mutual Recognition | EU eCTD Module 1 v3.0.3 - MRP-DCP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 3.0.3 Decentralised | EU eCTD Module 1 v3.0.3 - MRP-DCP<br>eCTD ICH Module 2-5 v3.2 |

| Region Ab breviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| | E.U. 3.0.3 National | EU eCTD Module 1 v3.0.3 - NP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 3.0.1 Centralised | EU eCTD Module 1 v3.0.1 - CP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 3.0.3 Decentralised | EU eCTD Module 1 v3.0.3 - MRP-DCP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 3.0.3 National | EU eCTD Module 1 v3.0.3 - NP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 3.0.1 Centralised | EU eCTD Module 1 v3.0.1 - CP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 3.0.3 Decentralised | EU eCTD Module 1 v3.0.3 - MRP-DCP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 3.0.3 National | EU eCTD Module 1 v3.0.3 - NP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 3.0.1 Centralised | EU eCTD Module 1 v3.0.1 - CP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 3.0.3 Decentralised | EU eCTD Module 1 v3.0.3 - MRP-DCP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 3.0.3 National | EU eCTD Module 1 v3.0.3 - NP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 2.0 Mutual Recognition | EU eCTD Module 1 v2.0 - MRP-DCP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 2.0 Decentralised | EU eCTD Module 1 v2.0 - MRP-DCP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 2.0 National | EU eCTD Module 1 v2.0 - NP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.4 Centralised | EU eCTD Module 1 v1.4 - CP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.4 Mutual Recognition | EU eCTD Module 1 v1.4 - MRP-DCP |

| Region Ab breviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| | | eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.4 Decentralised | EU eCTD Module 1 v1.4 - MRP-DCP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.4 National | EU eCTD Module 1 v1.4 - NP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.3 Centralised | EU eCTD Module 1 v1.3 - CP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.3 Mutual Recognition | EU eCTD Module 1 v1.3 - MRP-DCP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.3 Decentralised | EU eCTD Module 1 v1.3 - MRP-DCP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.3 National | EU eCTD Module 1 v1.3 - NP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.2.1 Centralised | EU eCTD Module 1 v1.2.1 – CP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.2.1 National | EU eCTD Module 1 v1.2.1 - NP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.2.1 Mutual Recognition | EU eCTD Module 1 v1.2.1 - MRP-DCP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.2.1 Decentralised | EU eCTD Module 1 v1.2.1 - MRP-DCP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.1 Centralised | EU eCTD Module 1 v1.1 - CP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.1 Mutual Recognition | EU eCTD Module 1 v1.1 - MRP-DCP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.1 Decentralised | EU eCTD Module 1 v1.1 - MRP-DCP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.1 National | EU eCTD Module 1 v1.1 - NP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.0 Centralised | EU eCTD Module 1 v1.0 - CP |

| Region Ab breviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| | | eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.0 Mutual Recognition | EU eCTD Module 1 v1.0 - MRP-DCP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.0 Decentralised | EU eCTD Module 1 v1.0 - MRP-DCP<br>eCTD ICH Module 2-5 v3.2 |
| | E.U. 1.0 National | EU eCTD Module 1 v1.0 - NP<br>eCTD ICH Module 2-5 v3.2 |

**BA**

| Region Abbreviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| | BA 3.1 National | BA eCTD Module 1 v3.1<br>eCTD ICH Module 2-5 v3.2 |

**CAN**

| Region Abbreviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| CAN | Canada 2.2 National (default) | Canadian eCTD Module 1 v2.2<br>eCTD ICH Module 2-5 v3.2 |
| | Canada 1.0 National | Canadian eCTD Module 1 v1.0<br>eCTD ICH Module 2-5 v3.2 |

**JAP**

| Region Abbreviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| JAP | Japan 1.0 National (default) | JP eCTD Module 1 v1.0<br>JP eCTD Module 2-5 v3.2 |

**Jordan**

| Region Ab- breviation | Template Profile Name | Mapped Template Pair |
|---|---|---|

| | | |
|---|---|---|
| JO | JO 1.0 National (default) | JO eCTD Module 1 v1.0<br>eCTD ICH Module 2-5 v3.2 |
| | JO 1.1 National (default) | JO eCTD Module 1 v1.1<br>eCTD ICH Module 2-5 v3.2 |

**CH**

| Region Ab- breviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| CH | Swiss 1.5 National (default) | CH eCTD Module 1 v1.5,<br>eCTD ICH Module 2-5 v3.2 |
| | Swiss 1.4 National | CH eCTD Module 1 v1.4,<br>eCTD ICH Module 2-5 v3.2 |
| | Swiss 1.3 National | CH eCTD Module 1 v1.3,<br>eCTD ICH Module 2-5 v3.2 |
| | Swiss 1.2 National | CH eCTD Module 1 v1.2,<br>eCTD ICH Module 2-5 v3.2 |
| | Swiss 1.1 National | CH eCTD Module 1 v1.1,<br>eCTD ICH Module 2-5 v3.2 |

**CN**

| Region Abbreviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| CN | CN 1.0 National (default) | CN eCTD Module 1 v1.0<br>CN eCTD ICH Module 2-5 v3.2 |

**GCC**

| Region Abbreviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| GCC | GCC 1.5 National (default) | GCC eCTD Module 1 v1.5 - NP<br>eCTD ICH Module 2-5 v3.2 |
| | GCC 1.5 GCC | GCC eCTD Module 1 v1.5 - GCC<br>eCTD ICH Module 2-5 v3.2 |

| Region Abbreviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| | GCC 1.2 National | GCC eCTD Module 1 v1.2 - NP<br>eCTD ICH Module 2-5 v3.2 |
| | GCC 1.2 GCC | GCC eCTD Module 1 v1.2 - GCC<br>eCTD ICH Module 2-5 v3.2 |

**ROW**

| Region Abbreviation | Template Pro- file Name | Mapped Template Pair |
|---|---|---|
| ROW | Rest Of World (default) | ROW CTD Module 1.0<br>eCTD ICH Module 2-5 v3.2 |

**UNDEFINED**

| Region Ab- breviation | Template Pro- file Name | Mapped Template Pair |
|---|---|---|
| UNDEFINED | Undefined (default) | ROW CTD Module 1<br>eCTD ICH Module 2-5 v3.2 |

**HR**

| Region Abbreviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| HR | Croatia 1.4 National (de- fault) | HR eCTD Module 1 v1.4<br>eCTD ICH Module 2-5 v3.2 |

**TH**

| Region Abbreviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| TH | TH 1.0 National (default) | TH eCTD Module 1 v1.0<br>eCTD ICH Module 2-5 v3.2 |
| | TH 0.92 National | TH eCTD Module 1 v0.92<br>eCTD ICH Module 2-5 v3.2 |

**TN**

| Region Abbreviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| TN | TN 1.1 National (default) | TN eCTD Module 1 v1.1,<br>eCTD ICH Module 2-5 v3.2 |

**TW**

| Region Abbreviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| TW | TW 1.0 National (default) | TW eCTD Module 1 v1.0<br>eCTD ICH Module 2-5 v3.2 |

**AU**

| Region Abbreviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| AU | AU 3.2 National (default) | AU eCTD Module 1 v3.2<br>eCTD ICH Module 2-5 v3.2 |
| | AU 3.1 National | AU eCTD Module 1 v3.1<br>eCTD ICH Module 2-5 v3.2 |
| | AU 3.0 National | AU eCTD Module 1 v3.0<br>eCTD ICH Module 2-5 v3.2 |
| | AU 0.90 National | AU eCTD Module 1 v0.90<br>eCTD ICH Module 2-5 v3.2 |

**UA**

| Region Abbreviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| UA | UA 1.0 National | UA eCTD Module 1 v1.0<br>eCTD ICH Module 2-5 v3.2 |

**WHO**

| Region Abbreviation | Template Pro- file Name | Mapped Template Pair |
|---|---|---|
| WHO | WHO 1-0 | WHO eCTD Module 1 v1.0<br>eCTD ICH Module 2-5 v3.2 |

**ZA**

| Region Ab- breviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| ZA | ZA 3.1 National (default) | ZA eCTD Module 1 v3.1<br>eCTD ICH Module 2-5 v3.2 |
| | ZA 2.1 National (default) | ZA eCTD Module 1 v2.1<br>eCTD ICH Module 2-5 v3.2 |
| | ZA 1.0 National | ZA eCTD Module 1 v1.0<br>eCTD ICH Module 2-5 v3.2 |

**Singapore**

| Region Abbreviation | Template Profile Name | Mapped Template Pair |
|---|---|---|
| SG | SG 1.0 National | SG eCTD Module 1 v1.0<br>eCTD ICH Module 2-5 v3.2 |

## Publish Elements in eCTD Templates

The publishing elements are designed to facilitate the production of CTD paper and Non-electronic eCTD (NeeS). The folder and leaf types that you assign in an eCTD assembly are based on the current ICH and regional eCTD specification. These element types enable you to record eCTD-specified metadata attributes.

The eCTD templates also include sample publishing elements, including tables of contents, cover pages, slip sheets, tabs, overlays, and all applicable publishing settings.

In addition, the E3 Clinical Study Report template contains the elements necessary to generate a standard CSR publication.

## Module 1 Regional Templates

Module 1 of the eCTD contains regional content and metadata about a submission, as defined by the regional regulatory authorities. Each regional template has special XML fields and attributes in the Module 1 folder to capture this additional metadata.

In addition, the EU requires envelope information for each country to which you are sending the submission. For each envelope, you create a folder to capture the relevant envelope information for each country under the EU Envelope Information leaf. Envelope folders are included in the EU Module 1 templates.

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.

## Structured Product Labeling Files

Structured Product Labeling (SPL) files contain product labeling information in a structured XML format.

You can add these files to an assembly and specify whether they should be published in their native file format (.xml) or in PDF renditions. This includes the XML documents that reference style sheets, if the style sheets are located where they can be referenced by the XML.

You should place .spl files in a folder named SPL in the appropriate labeling folder according to the electronic labeling specification.

## Module Studies Folders

The Module 4 and Module 5 folders are set as Module Studies folders. These folders include extra attributes that enable you to control how studies in that module are handled in the published XML and folder structure.

When a Study Folder is included in the assembly, Ennov InSight uses the setting at the Module level to determine whether it should create a Study Tagging File (STF), node-extension, or only the leaf elements of the study. You can also choose whether Ennov InSight should create a subfolder for the study content in the output.

When Create Study Folders is set to Yes, Ennov InSight uses the Study Folder name to create an additional folder in the output and places all the content for that study in the folder.

When STFs or node-extensions are created, the Study Folder Name is also used for the value of the *<leaf>* or *<node-extension>* title. If long values are used for the Folder Names, while shorter values are needed for the output folder name, the Create Study Folder option can be set to No, and the Study Folder Output Folder attribute populated with the shorter value.

## Study Tagging Files

Study Tagging Files (STF) help identify files associated with a study and are required for U.S. submissions. Some of this information is included in the eCTD backbone, however, the STF provides more information on the content of these documents.

The eCTD templates provide two assembly element types to capture STF information:

— Study report folders capture the overall study information. This information is published as the study-information in the STF XML.

— Study report leaf elements capture the subject matter to be used as the value for the file-tag name in the studydocument portion of the STF XML.

Different folder and leaf types contain special attributes that are incorporated into the STF XML when you publish the submission. Each leaf in the templates has the Subject Matter value populated according to the STF specification. If you use DMS mapping to populate the eCTD, you can map STF-related attributes to repository attributes.

Sample study report structures are included in the ICH eCTD template for Module 4 (section 4.2.1.1) and Module 5 (section 5.3.1.1). These examples are preconfigured with the expected subject matter values. You can duplicate these folders in an assembly and remove any unnecessary components on a study-by-study basis. Alternatively, studies can be added using the *Create Study Report* Wizard. All sections in Module 4 are mapped to the Nonclinical Study Report. All sections in Module 5 are mapped to the ICH E3 Clinical Study Report template. You can configure the wizard to use different study report templates for each lowest-level section in Modules 4 and 5, if different structures are used for different study types.

Two special element types provided with Ennov InSight are set in the template for CRFs and Datasets to make them easier to use. They are Study Patient Information and Study Data.

## Study Patient Information Folder

Use the Study Patient Information folder type for case report forms and subject profiles for which the STF specification requires additional site information.

This folder type is applied to the Case Report Forms and Subject Profiles folders in the template and allows all child leaf elements to inherit the Subject Matter, preventing the need to enter the Subject Matter for each CRF or subject profile.

Adding Site folders to organize the CRFs and Subject Profiles enables Ennov InSight to automatically use the name of the Site folder to populate the site-identifier information for the child leaf elements during publishing. This completes the portion of the STF that includes those leaf elements and eliminates the need for you to enter this information for each leaf.

## Study Data Folder

Use the Study Data folder type to organize datasets, which enables you to reset the output location for the folder's child leaf elements according to the FDA Study Data specification.

Datasets are organized in the <*module*>/datasets folder in the output rather than with the other components of the study report, so that you can manage them with the study report in the assembly.

The Dataset Type attribute controls the placement of the datasets in the <*module*>/datasets folder. Each child leaf element for this type of folder inherits the Subject Matter attribute.

For files that are not datasets, but other supportive files such as the Data Definition tables, the leaf elements included are set as Study Report Leaf elements. Their Subject Matter is populated to override the inheritance from the parent folder.

Ennov InSight Publisher 7.3 Study Patient Information Folder

# Chapter 3. Publishing Settings Library Templates

## 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 |

Ennov InSight Publisher 7.3 Publishing Settings Library Templates

| Template | Field Name | Value |
|---|---|---|
| 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 |
| | 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 |

Ennov InSight Publisher 7.3

Default Publishing Library Settings Template

## 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<br>— Default Values<br>— Default Study Folder<br>— TOCs<br>— Variables<br>— Link Profiles |
| Paper Review Publishing (PRP) | — Publishing Settings<br>— Volumes<br>— Cover Pages<br>— Tabs<br>— Slip Sheets<br>— TOCs<br>— Overlays<br>— Variables<br>— 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.

Ennov InSight Publisher 7.3

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 permis- sion. |

## 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.

Ennov InSight Publisher 7.3

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 overlay settings, cover page settings, TOC types, slip sheet settings, and tab 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

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

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, change the 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. 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 Create a Publishing Settings Library

## Special Sheet Publishing Settings

When you create a publication, you can insert special sheets, such as table of contents, cover pages, tab sheets, and slip sheets to aid navigation through your submission.

Special sheets can be inserted and deleted, individually or in bulk, where they are needed in the assembly. Special sheet settings control the properties of the paper on which the sheets are printed, and the text or content that pertains to the special sheet.

Special sheets and their settings are linked to the resource file update.

The printer publishing settings you choose control which paper types are available in the special sheets settings. Additionally, the general publishing settings control the preview file location where the tab and TOC preview files are stored.

Publishing settings are specific to the following modules:

— Electronic Lifecycle Publishing (ELP)

— Registered Document Analysis (RDA)

— Submission Planning and Tracking (SPT)

— Paper Review Publishing (PRP)

Special Sheets

Special sheets consist of cover pages, tab sheets, slip sheets, and TOCs. You can insert special sheets to aid navigation through a submission. Special sheets can be inserted individually or in bulk where they are needed in the assembly. Special sheets settings control the properties of the paper on which the sheets are to be printed, and the text or content. Special sheets and their attributes are linked to the publishing settings for an assembly. The publishing settings control the printer, and therefore the paper types, that are available for printing special sheets.

You can insert special sheets for any of the following:

— Assembly

— Folders

— Leaf elements

— Documents

— Volumes

When you insert a special sheet for an element (for example, a folder), the sheet is inserted for all children of the element that meet the criteria of the chosen element type.

When adding special sheets in bulk, any leaf marked as a native file leaf or reference leaf is ignored. Special sheets cannot be added to native file leaf elements or reference leaf elements, and are ignored during publishing.

After inserting special sheets, click Volume  to refresh the *Volume Special Sheets* pane and display the inserted special sheets.

Move Special Sheets

You can promote and demote cover pages, tabs, slip sheets, and TOCs that are assigned to assembly elements. Following assembly elements are:

— Assembly

— Folder

— Leaf elements

— Documents

— Page markers

Special Sheets Commands

You can reorganize the elements in the assembly tree. You can move elements up and down, and you can promote and demote elements.

| Com- mand | Description |
|---|---|
| Move Up | Moves an element to a location above its current position in the assembly tree, one position at a time. |
| Move Down | Moves an element to a location below its current position in the assembly tree, one position at a time. |
| Promote | Moves an element one level to the left in the assembly tree hierarchy. |
| Demote | Moves an element one level to the right in the assembly tree hierarchy. |
| Delete | Removes an element from the assembly tree structure; does not delete a document from the reposito- ry. |

Promote or Demote a Special Sheet

You can promote a special sheet to earlier in the assembly, or demote a special sheet to later in the assembly.

Right-click the special sheet you want to move and choose one of the following:

| Option | Description |
|---|---|
| Move Left: | Promotes the special sheet by moving it to the left. |
| Move Right: | Demotes the special sheet by moving it to the right. |

The special sheet moves to the left or right of the adjacent element.

Overlay Templates

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

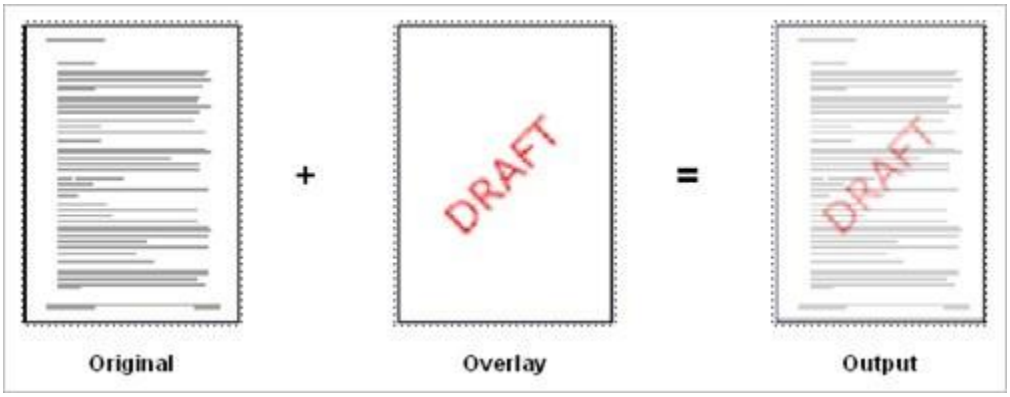
This includes page numbering and other variable data from Ennov InSight , resolved during publishing. Documents, TOCs, and cover pages may use the same or different overlay templates.

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.

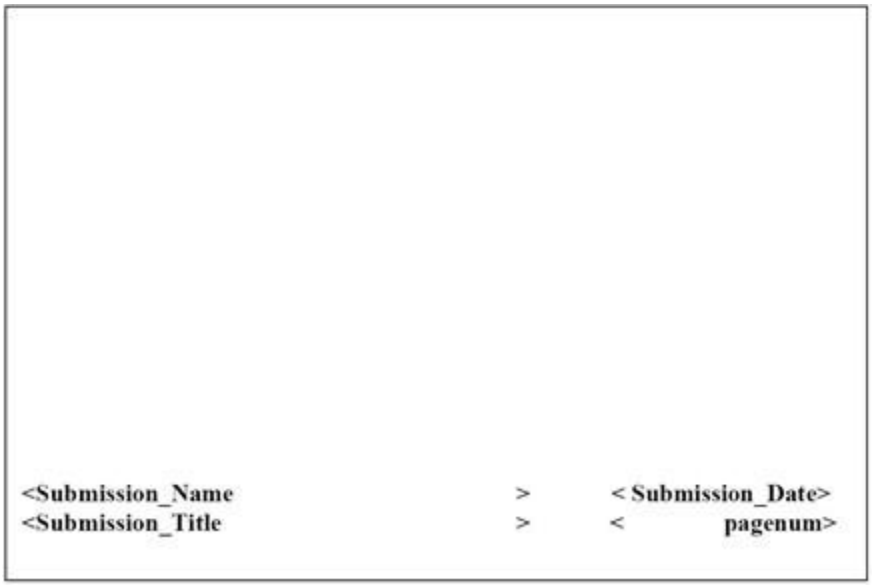
## Japanese Characters

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, you must make sure the font used for the delimiters and variable codes is MSMincho or another font containing Japanese characters. Arial Unicode MS is one of the few fonts containing almost all Unicode characters.

## 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, Cover Page, or TOC*

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. 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.

## Page Markers

A page marker is an assembly element used to mark a specific page in a document.

This is most often used to indicate where a volume break may occur, but you can also use page markers to insert other publishing elements such as TOCs, tab sheets, and other publishing effects in a document.

Insert a Page Marker

You can insert a page marker to hold the place for a special sheet.

1. Right-click the assembly element where you want to insert a page marker and select Insert Page Marker.

   The *Add or Edit Page Marker* page appears.
2. Edit the attributes.
3. Save.

For each element where a page marker has been inserted,  appears on the assembly.

Page Marker Attributes

You can use the attributes to describe the details of a page marker.

| Attribute | Description |
|---|---|
| Comments | Any additional information you want to save with the page marker. |
| Description | Describes why the Page Marker is needed. |
| Keywords | Keywords you can use to in a search for the page marker. |
| Page Marker Name | Name of the Page Marker. |

Page Markers

| Attribute | Description |
|---|---|
| Page Number | The page on which the page marker is applied. Any volume, special sheets, or TOC applied at this page marker are inserted just before this page. |

## 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 printer output settings and XML definitions.

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

1. On the *Publishing Settings Library* window, select Publishing Settings .
2. Click Create:  .
3. On the *Create Publishing Settings* page, use the drop-down lists to choose the following required settings:

    — Printer

    — Paper Size and Type

    — Tab Paper Size and Type

    — Preview Location (Click Browse to locate and select the location.)

4. Complete the remaining fields as needed:

— XML Definitions

— Default Rendition Identifier

— Missing Rendition Identifier Handling

— TOC Destination Not Found Text

— Cross-Reference Destination Not Found Text

— Expand Bookmarks to Level

— PDF Version for Published Output

— Optimize Fonts in Paper 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.*

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

*XML Definition File Version Updates*

If the XML Definitions are set to a different XML definition than was previously used for the assembly, the system will initiate a renaming process when you save the file and the new XML Definition File is applied.

1. After the new XML Definition File is applied, refresh the assembly tree.

   Applying the new XML Definition File updates the assembly according to the new specification:

   — Values in extended attributes

   — Folder names

   — Leaf names. Abbreviated Name, Title, and Output File attributes are updated for leafs within a working assembly.

2. Check the following attributes of the leaf created as a result of any life cycle operation, and update if necessary:

— Abbreviated Name

— Title

— Output File

The Create eCTD Wizard can now be used for the Sequence. After the new XML definition file is applied, the changes within the current assembly cannot be rolled back. If it is necessary to roll back the changes, the working assembly must be deleted and recreated.

*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 (*).

| Attribute | 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. |
| 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 assigned rendition identifier does not exist in the system. The default is Use Standard Rendition. |
| Optimize Fonts in Paper Output | Minimizes the font compatibility issues and provides stability to the process of printing the paper output. The default value is No. |
| Paper Size/Type* | Select the paper size to use for publishing (Letter, A4, Color A4, Drilled A4, etc.). This list is dependent on the available printers. |
| 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. |
| Preview Location* | The storage location, used for tab preview locations and Microsoft Wordgenerated TOC files.<br>— Tab preview files are not used in the final publication.<br>— Periods and decimals cannot be used in the folder name. |
| Printer* | Select the printer that will be used for the paper publish. The selected printer defines the values available for the Paper Size/Type for Tabs, Cover Pages and Slip Sheets. |
| Tab Paper Size/ Type* | The Type and Size of the paper that will be used for the Tab when printed (e.g. Blue Letter). This list is dependent on the available printers. |
| Attribute | Description |

| | |
|---|---|
| TOC Destination Not Found Text | Specify the text that appears in TOCs when a TOC Entry cannot be resolved at publishing time. Destination Not Found Text is used in TOC right-columns where the target does not exist. This attribute is blank by default, but text may be entered to assist in the QC of invalid destinations or variables. |
| XML Definitions | Select XML definitions that are applicable to the Publishing Library and to the Assembly that uses the Publishing Library. This field cannot be updated if the assembly is in the Publishing view and already added to life cycle. |

*XML Definition File Publishing Settings*

The XML Definitions settings determine the specification that is used for publishing your eCTD submission.

The XML (eXtensible Mark-up Language) DTD (document type definition) files indicate which specification your eCTD submission should use for publishing. 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 definition file in the Publishing Settings of the active working assembly. These files are placed in a repository that is accessible to Ennov InSight , and new ones may be added to this location as a result of a new agency or ICH (International Conference on Harmonisation) specification.

For eCTD, you typically select a regional DTD, the standard ICH DTD, and the STF (Study Tagging File) DTD. The STF DTD can be activated even if STFs are not being created, as this enables global reuse by allowing you to specify how Study folders should be processed in the XML at the module-level.

Only one DTD file for each output XML file can be assigned in the DTD settings. If more than one is assigned, an error may occur during publishing (fixpoint error). Multiple DTDs are assigned if multiple XML files are generated, for example: ICH index.xml, regional.xml, and possibly stf.xml.

*Update eCTD XML Definition File Selections*

When XML definition settings are updated, Ennov InSight prompts you to verify that you want to make the change. If you agree to the change, Ennov InSight automatically changes the folder and leaf types throughout the assembly to the proper versions.

In some cases, metadata is removed if it is no longer needed by the new specification XML definition. In most cases, Ennov InSight only adds new attributes or changes the labels or selections of existing attributes. If new sections are required by the new XML definition specification, it may be recommended to add these attributes separately using the Create eCTD wizard.

In every case it is a best practice to run the Create eCTD wizard immediately after updating the XML specifications. For

EU specifications, keep in mind the following:

— When you include the electronic application form in EU module 1, section 1.2, ensure the form-1-1 rules are active in the publication settings to ensure the DTD and stylesheet are copied to the appropriate location during publishing.

— If you are using v1.1 of the EU specifications, and submitting PIM information in section 1.3.1, you also need to ensure the pim-2-1 rules are active to ensure the supportive files are correctly output.

— When you are using the v1.2.1 specification or later, these rules should not be active since the PIM information is provided as a single .zip file.

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*

Attributes description for default publishing values.

The attributes differ depending on the eCTD version, for the details of eCTD 4.0 attributes, see *Publishing > Default Publishing Values Attributes eCTD 4.0* .

| Attribute | Description |
|---|---|
| Actuate | The default Actuate setting for new leafs. Available values: onLoad, onRequest, other, none. |

| | |
|---|---|
| Application Version | The default application version for new leafs. |
| Folder Due Date | The default date by which the folder must be ready for submission. |
| Folder Owner | The owner of the folder. |
| Attribute | Description |
| Font Library | The default font library for new leafs. |
| Keywords | Alternative words used in searching leafs. |
| Language | The default language for new leafs. |
| Leaf Due Date | The default due date by which a leaf must be ready for submission. |
| Leaf Owner | The owner of a leaf. |
| Role | The default role for new leafs. |
| Show | The default Show setting for new leafs. Available values: new, replace, embed, other, none |
| Title | The default title for new leafs. |
| Use Native File | Determine if new leafs should be created as Native Files. Available values: Yes, No. |
| Version | The default version for new leafs. |

Default Study Folder

In the selected Publishing Settings Library, you can modify the Default Study Folder for the Publishing Library Template (PLT). The Default Study Folder tab is available only when an STF DTD definition is selected on the

Publishing Settings tab of the PLT.

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

1. On the *Publishing Settings Library* window, select Default Study Folder.
2. Click Create  .
3. Complete the fields as needed. There are no required fields.
   - Full Report Title
   - Report Number
   - Operation
   - Species
   - Route of Administration

— Type of Control

— Duration

— Subject Matter

4. To save the new Default Study Folder, Save. To discard the changes, Cancel.

*Default Study Folder Attributes*

The Default Study Folder tab is available only when a study folder XML definition is selected on the Publishing Settings tab of the PLT. Values for Species, Route of Administration, Type of Control, Duration, and Subject Matter are controlled by the XML definition selected.

| Attribute | Description |
|---|---|
| Duration | Choose the default duration for new studies. |
| Full Report Title | Specify the default full report title for new studies. (Limit 4000 bytes) |
| Operation | Choose the default operation for new studies. Available values: append, delete, re-place, new |
| Report Number | Specify the default report number for new studies. (Limit 4000 bytes) |
| Route of Administration | Choose the default route of administration for new studies. |
| Species | Choose the default species for new studies. |
| Subject Matter | Choose the default subject matter for new studies. |
| Type of Control | Choose the default control type for new studies. |

About PDF Properties

You can add PDF Property settings to the Publishing Settings Library Template (PLT) and to the Assembly Specific Publishing Settings Library (APL) to define the PDF properties of 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:

— Approved, submitted, and sequence views.

— Publishing view of a locked assembly.

*Add or Modify PDF Properties*

PDF Properties are used to define the PDF properties of the electronic published output document.

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 Assembly Specific Publishing Settings Library (APL). You must have sufficient security permissions to be able to create or modify a PDF Property setting.

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 set of attributes varies, depending 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 existing 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.<br><br>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:<br><br>— 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.<br><br>— 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:<br>— Author<br>— Keywords<br>— Title<br>— Subject<br>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:<br>— //space - Space character will be inserted as a separator — //newline - New line will be started.<br>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. |

Volumize

Volumization is the process by which assembly content is divided into multiple volumes for the purpose of publishing paper volumes. You can define the settings for splitting the assembly into volumes using the volume settings.

Volumization settings include:

— The number of pages that make up the volume.

— The size of the page buffer, which indicates the number of pages under the specified volume pages that would still be considered as a valid volume size. — The total size of each volume.

— The buffer size of each volume, which indicates the number of MB under the specified volume total size that would still be considered as a valid volume size.

— Whether to automatically create volume TOCs for each volume.

— The name and numbering schema for each volume (specified by default as the variable $VOLNAME). — Whether volumes should be counted relative to the assembly or the major division (module).

Volume settings are included in a Publishing Settings Library by default. When creating a new Publishing Library Template (PLT), or when creating a new PLT based on an existing PLT, the Begin at Volume Number setting is set to 1.

You can start a volumization from the start of an assembly, a subset folder, or a section in the assembly. Volumization will end when either a locked volume is encountered or the end of the assembly is reached.

Volumization may take a significant amount of time to accomplish, so the recommended way to volumize is by using the Prepare to Publish process.

Positioning your cursor over a volume indicates the number of current pages, but in certain cases it may be necessary to refresh the volume page count. This can be done with either the volumes refresh option or the Prepare to Publish process.

During volumization, the assembly is not locked. You must wait for volumization to complete before attempting to select any elements.

Ennov InSight provides the ability to create volumes in an assembly based on an estimated output file size.

Because Volumize by Size can be a time-consuming process, Ennov recommends completing all assembly creation steps (including Prepare to Publish) prior to invoking this functionality. An assembly paper output location is required when using the Volumize by Size option. There is a limitation of assembly content size that can be processed at once, so it is recommended to use Volumize by Size option in a reasonable time periods. See Memory Limits for Windows and Windows Server Releases.

For Volumize by Size, using the No option causes Volumize by Page to be enforced when the right-click menu option Volumize is invoked in the assembly. Volumize by Page provides faster performance than Volumize by Size.

When the Volumize by Size option is set to Yes, all volumes will be deleted and recreated, including locked volumes.

Use the Volumes tab in the Publishing Settings Library to set or modify the following options:

— Volumize by Size

— Total Size (in MB)

— Buffer Size (in MB)

***Note:*** *1MB = 1,048,576 bytes*

Volumes also enable you to divide an assembly into logical sections that will be published to the paper output channel as separate files, one file for each volume.

If you choose to divide your assembly into paper volumes, you can create volumes in several ways: — Bulk volumization

— Insert manual volumes

— Insert and manipulate existing volumes

Volume settings must be defined in the Publishing Settings Library prior to inserting volumes.

*Define or Modify Volume Settings*

Use the Modify Publishing Settings command to modify volume attributes for your assembly.

1. In an assembly view, click Edit Publishing Settings Library to open the *Publishing Settings*.
2. Select Volumes.
3. On the Volumes tab, click Edit to specify the Volume attribute settings.
4. Save.

*Volumes*

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

To modify the Volumes settings:

1. On the *Publishing Settings Library* window, select Volumes. The default Volumes settings appear.
2. Click Edit.
3. On the *Edit Volume Settings* page complete the required fields, and the optional fields as needed. Required information is indicated by an asterisk (*).
   - Volume File Naming Format *
   - Begin at Volume Number *
   - Total Sheets/Pages *
   - Total Sheets/Pages Buffer *
   - Volumize by Size
   - Total Size (in MB) *
   - Buffer Size (in MB) *
   - Volume Numbering
   - Automatically Create Volume Tables of Contents
4. Save. To discard the changes, Cancel.

*Volume Attributes*

You can use the attributes to describe the details of a volume. Required information is indicated by an asterisk (*).

| Attribute | Description |
|---|---|
| Automatically Create Volume Tables of Contents | Controls whether TOCs are created automatically and assigned to each volume. Choose Yes or No. Default is No. |
| | ***Note:*** *When automatically creating the table of contents for volumes using Prepare to Publish or Volumize, Ennov InSight may misname the table of contents. An incorrectly generated table of contents results if the $TITLE variable is used in the header or left column entry text. If file bookmarks are used in volumes with automatically generated tables of contents, a bookmark for the table contents is named New TOC. The bookmarks do not affect the printed output. To work around this issue: set Automatically Create Volume Tables of Contents to No on the Volumes page in Publishing Settings. After volumizing, create tables of contents on the newly created volumes by right-clicking on any element in the tree and selecting Mass Insert/Update Publishing Elements, selecting Table of Contents in the drop-down, and then selecting Volumes, and set Use Default for the type. You can also create tables of contents for individual volumes by selecting This Element Only.* |
| Begin at Volume Number* | Specify the number where you want your volume to begin. Must be a number greater than 0. Default is 1. |
| Buffer Size (in MB)* | Defines the additional buffer size allowed in a volume when running volumize by size. Must be a number, 10 or greater. Default is 10. |
| Total Sheets/ Pages* | Specify the total number of sheets or pages that make up your volume when running volumize by number of pages. Must be a number greater than 0. Default is 300. |
| Total Sheets/Pages Buffer* | The number of sheets or pages, plus or minus, that Ennov InSight uses to calculate logical volume breaks during bulk volume creation when running volumize by number of pages. The Total Sheets/Pages Buffer setting should always be less than the Total Sheets/Pages setting. Must be a number. Default is 50. |
| Total Size (in MB)* | Defines the maximum size of the volume when running volumize by size. Must be a number greater than 50. Default is 100. |
| Volume File Naming Format* | The default volume naming format that applies to all the volumes in your submission. This is set by default to $VOLNAME, which is a volume-naming variable included with every Ennov InSight installation. This attribute can be set only to a specific variable name, and it cannot contain additional text or variables. If different variable attributes are needed: changes should be made to the $VOLNAME variable in data administration, or you should use a new user-defined variable instead. (Limit 150 bytes) |
| Attribute | Description |

| | |
|---|---|
| Volume Numbering | The volume number scheme. Choose Assembly Relative or Major Division. Default is Assembly Relative. |
| Volumize by Size* | Determines if the volumization will be done by the number of pages in the volume or by the estimated size of the volume. Choose Yes or No. Default is No. For Volumize by Size, using the No option causes Volumize by Page to be enforced when the right-click menu option Volumize is invoked in the assembly.<br><br>Volumize by Page provides faster performance than Volumize by Size. |

*Bulk Volumization*

Bulk volumization enables you to divide assembly content into multiple volumes automatically.

Volume publishing settings identify how the assembly is divided into volumes including the default size and other characteristics of the volumes inserted during the bulk volumization process.

Content that has been rendered or has a planned page count, and that is specified for the paper output channel, is volumized. Content that is not intended for the paper channel is not included in volumization calculations.

You can volumize from an assembly root, a folder, or a section in the assembly. Bulk volumization may take a certain amount of time to perform, so the recommended way to volumize is by using Prepare To Publish.

*Run a Bulk Volumization*

Volumes you insert have a standard naming convention based on the volume publishing settings, which may be variable-based.

## Prerequisites

Prior to running a bulk volumization, it is recommended that you verify the volume publishing settings before you insert volumes into the assembly.

To volumize an entire assembly:

1. Right-click the assembly root and select Volumize.

   A message prompts you to confirm the volumization.
2. Click OK.

   For each volume added, the book icon  appears in the assembly tree.
3. Volumization creates volumes in the assembly according to the volume publishing settings.

   — If a document is too large to fit in a volume, volumization will break up the document, creating page markers and volume breaks where appropriate.

— If you create your own page markers manually, volumization attempts to create volume breaks on those page markers if the page marker falls within the volume publishing page size, plus/minus the buffer.

4. Volumization ends when the process encounters a locked volume or the end of the assembly.

*Volume Icons*

When you create and manipulate volumes, icons in the assembly tree indicate volume statuses and features associated with the volumes. You can position the pointer over a volume in the assembly tree to see the number of pages in the volume. (It may be necessary to refresh the *Volume Attributes* page to see an accurate volume page count.)

| Icons | Description |
|---|---|
|  | Represents multiple volume breaks. Publishes all volumes where the starting range breaks fall under the collapsed multi-volume icon, including the last volume whose end break may fall past the specified range. To see all the individual volume breaks, right-click the element and choose Expand Range. |
|  | Represents a single volume break. A volume begins at one volume break and ends at either the next volume break or at the end of the assembly.<br><br>With this icon selected, when choosing Publish Request (Publish Paper > Volumes in Selected Range) only this volume will be published. |
|  | Represents a volume where the starting and end points are fixed. |

*Revolumizing*

Ennov InSight enables you to re-bulk volumize all the volumes that existed from the point where the volumization was invoked.

When you run bulk volumization again (revolumizing), the existing volumes, page markers created by previous volumizations, and any special sheets attached to those volumes and page markers, will be deleted.

If there are locked volumes, the revolumization process stops at the first locked volume it finds.

*Insert Manual Volume Breaks*

Use this procedure to insert a volume. During volumization, the assembly is not locked. You must wait for volumization to complete before attempting to select any elements.

## Prerequisites

You must specify volume publishing settings before you insert volumes into the assembly. The Volumes will have a standard naming convention based on the volume setting, these may be variable based.

To insert a volume:

1. Right-click the element where you want to insert a volume and choose Insert Volume.

   If a volume break resides on the leaf you are deleting, you should move the volume break to the closest folder.

   Volume breaks that reside on a deleted leaf will not be published.

2. Save.

   Each volume added is displayed in the assembly tree. The volume break is added and the *Edit Volume* page appears.

3. Optionally change the name of the volume and Save.

   *Modify Volumes*

   While you can change a volume's name and override the default, any changes to volume ordering (or the inclusion of new volumes) overwrites the change. Ennov InSight numbers the volumes correctly based on their order. If you overwrite a volume name, you can lock the volume to prevent additional changes.

   During volumization, the assembly is not locked. You must wait for volumization to complete before attempting to select any elements.

   To modify a volume:

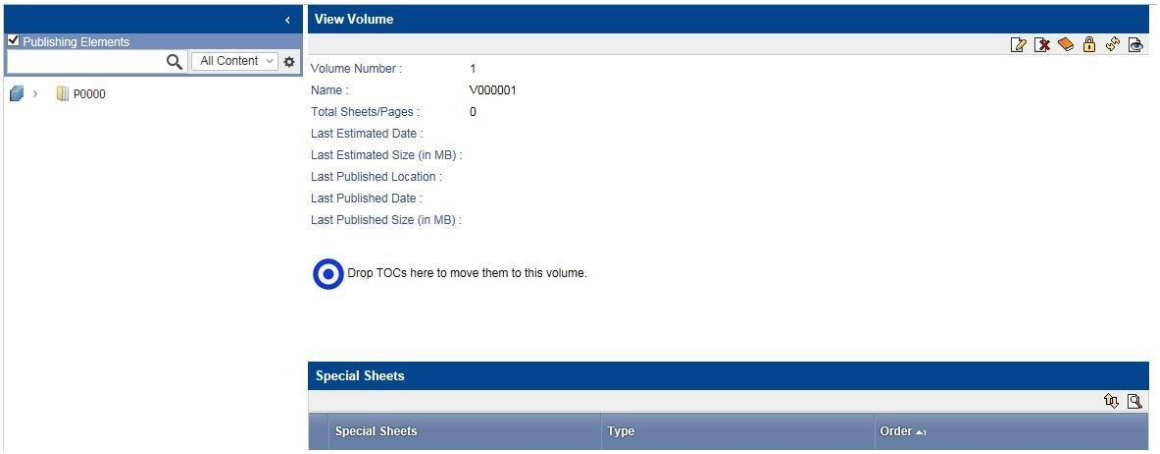
   1.

   In the assembly, click on the volume

   you want to modify.

   **Example**



The

*View Volume*

page appears.

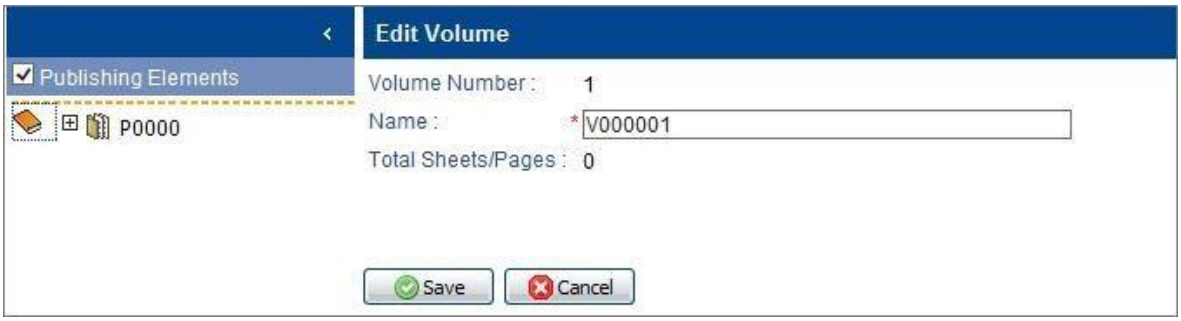
2.

Click



.

**Example**




The

*Edit Volume*

page appears.

3.

Enter a name for the volume.

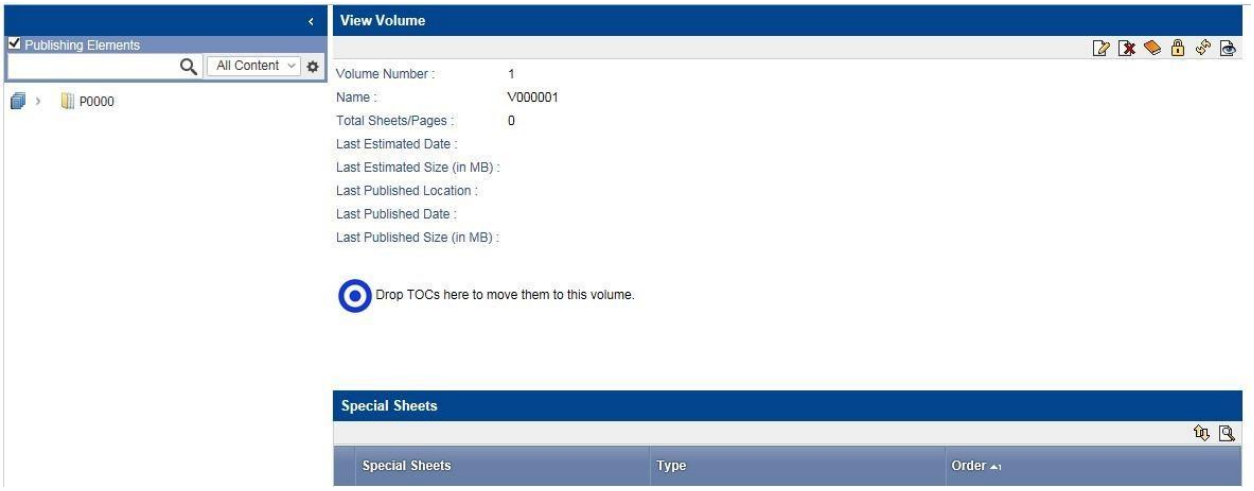
4. Save.
5. To protect the volume name from changes, click  .

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

The volume icon changes to: 

*Move TOCs to Volumes*

You can move TOCs from the assembly tree onto a volume by dragging them onto the volume icon.




*Delete Volumes*

After deleting a volume from an assembly tree, you may need to refresh the assembly tree or refresh the volume so that Ennov InSight displays the remaining volumes correctly.

After deleting a volume from an assembly tree, you may need to refresh the assembly tree or refresh the volume so that Ennov InSight displays the remaining volumes correctly.

To delete a single volume from an assembly:

1. Right-click the volume that you want to delete from the assembly.
2. Click Delete.

The volume is deleted.

*Delete All Volumes from an Assembly*

Use this procedure to delete all volumes from an assembly.

To delete all volumes from an assembly:

1. Right-click the assembly root.
2. On the pop-up menu, click Delete All Volumes.
3. To confirm that you want to delete all volumes, click Yes.

*Delete Volumes in Bulk*

With appropriate permissions, you can delete multiple volumes simultaneously. To delete volumes in bulk, the selected volumes must be unlocked.

To delete volumes in bulk:

1. Expand the assembly sections that have the volumes under them.
2. Select multiple individual volumes or a range of volumes.
3. Right-click and select Delete.
4. In the confirmation message, click OK.

The selected volumes are deleted.

*Delete Assembly Tree Elements from the Volume Range*

Assembly tree elements can be deleted from both locked and unlocked volumes. After the element is deleted from the volume range, the Volume structure will be adjusted automatically. You can remove any assembly tree element from the Volume range:

— Folder

— Leaf

— Placeholder

— Assigned Document

Before deleting an assembly tree element from a volume range, you may need to refresh the volume so that the elements inside the volume range are up-to-date. After deleting a volume from an assembly tree, you may need to refresh the assembly tree so that Ennov InSight displays the volumes correctly.

To delete an assembly tree element from a volume range:

1. Right-click the assembly tree element in a volume that you want to delete.
2. On the pop-up message click OK to continue.
3. The assembly tree element is deleted and the elements structure in the volume is adjusted.

| Option | Description |
|---|---|
| If the deleted element is the first element in the volume: | The structure is adjusted to start with the next element. |
| If the deleted element is the last element in the volume: | The structure is adjusted to finish with the previous element. |

## What to do next

Unlocked Volumes

You can delete any element inside the unlocked volume, even if the element is the first, or the last, inside the volume range.

If there is only one element in the unlocked volume, then that element and the volume are deleted.

**Important:** You cannot delete a volume that is located directly below a locked volume. When you attempt to delete the only element in an unlocked volume under a locked volume, a warning message appears and the element is not deleted.

Deleting a parent assembly tree element with child elements and volumes assigned to them causes the assembly tree and volumes structure to be adjusted. All entities are deleted, except the last volume. The last volume is automatically moved to start with the next element that is not a child element of the parent element. For example, if the parent Folder 1 element is deleted, all child elements including the first volume are deleted:

The second volume will start with the Leaf A element, that is not a child element of the Folder 1:

Locked Volumes

You can delete any element inside the locked volume, including the first and the last elements in the locked volume range. The exception is the locked volume that contains only one element.

When you attempt to delete the only element in a locked volume, a warning message appears and the element is not deleted. To delete the element, and the volume itself, the volume must be unlocked and must not be located directly under another locked volume.

When you are deleting a parent assembly tree element with child nodes that contain volumes, they are also deleted. The exception is a parent assembly tree element with child nodes that contain locked volumes. A warning message appears and the element is not deleted.

***Note:*** *The locked volume can not be deleted.*

Cover Pages

You can insert cover pages anywhere in an assembly, in both paper and electronic output, to divide volumes into sections of information or reports.

Cover pages can be a special size or color. They can have text, variable text, and graphics. You can also apply overlays, which create headers and footers.

Cover pages, and tables of contents, can be included in both paper and electronic output.

Cover page templates define the text, variable text, and graphics that are applied to the cover page. For output that contains cover pages, you should specify publishing settings for the cover pages. You can override any publishing settings for specific cover pages, as needed.

Like documents, cover pages can be one or more pages. Unlike documents, Ennov InSight cover pages cannot be lifecycled.

You must specify printer Publishing Settings before you can select or insert special sheets in your assembly.

Cover pages operate similarly to overlay templates in their ability to contain variable placeholders and other page elements.

*Create or Modify Cover Pages*

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

1. On the *Publishing Settings Library* window, select Cover Pages.
2. Click the Create icon  .

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

   — Name *

   — Default?

   — Cover Page Template * (Click Browse to locate and select the location.)

   — Include in Page Numbering

   — Paper Type * — Output Channel *
4. Save.

| Option | Action |
|---|---|
| To create another cover page, after saving the current cover page settings: | Click Create Another Cover Page. |
| To discard the changes: | Cancel. |
| If you are editing an existing Cover Pages setting: | Click the name of the Publishing Settings Library on the *View* page at the top of the page to return to the<br>Publishing Settings Library. |

*Cover Page Setting Attributes*

You can use the attributes to describe the details of the cover page settings.

Required information is indicated by an asterisk (*).

| Attribute | Description |
|---|---|
| Name* | Specify a name for your Cover Page. The name must be unique within the Publishing Set- tings Library. (Limit 100 bytes.) |

| | |
|---|---|
| Default? | Determines if this is the default cover page. Choose Yes or No. Default is No. A default must exist. If a default already exists it is updated to be No, and the saved cover page setting becomes the default. |
| Attribute | Description |
| Cover Page Template* | Browse to select the cover page template you want to use for your cover pages. |
| Include In Page Numbering | Determines if the cover page is included in the page numbering and can impact the way overlay page numbers are calculated. Choose Yes or No. Default is Yes. |
| Paper Type* | Choose the paper type for your cover page. The paper type options are determined by the printer selected on the Publishing Settings tab. |
| Output Channel* | Select the output channel to publish to by default. You may default the cover page output channel to electronic, paper, or both. At least one channel must be selected. Default is paper. |

Tabs

Like cover pages, tab sheets are used to divide content in a submission and serve as a navigational aid. Tab sheets are unique to the paper output channel and cannot be included in the electronic output channel.

With tab sheets, you can insert variable text, or up to three lines of manual text, to appear on the tab. Other configurable settings include text wrap, font type, font style, font size, and vertical or horizontal positioning.

***Note:*** *You must specify printer publishing settings before you can select or insert special sheets in your assembly.*

## Generating and Previewing Individual Tabs

Tabs can be generated and previewed individually from the tab itself. A tab preview must first be generated from the Generate File option; it can then be previewed using the View Tab option.

The preview function does not display the actual tab positions. Preview is meant to test for variable resolution, and to ensure that the tab text is not running over the side of the tab printable area. Your fully published output will show the tab text in the correct position as defined by your Tab Publishing Settings for the assembly.

## Tab Review File

A Tab Review File can be generated from the Assembly root by selecting the Generate Tab Review File option. After review file has been created it can be viewed using the View Tab Review File option. Generating a tab review file creates a single file containing all of the tabs in the Assembly for review.

— Generating an individual tab will overwrite the bulk file when it creates the single file preview.

— You are not required to generate tabs prior to publishing. The publishing request executes this step automatically. Generating tabs prior to publish is only necessary for reviewing tab content.

## Unicode Characters in Tabs

You must use the MS Mincho font to properly display Unicode characters in *Tab Preview*.

*Create or Modify Tabs*

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

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

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

   — Name*

   — Text

   — Default?

   — Auto Text Wrap

   — Font Definition

   — Font Bold

   — Font Italic

   — Font Size* — Vertical Text
4. Save.

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

*Preview Tabs*

With tab preview, you can test for variable resolution and ensure that text is contained in the printable area. Preview does not show the actual tab positions. Your fully published output will show the tab text in the correct position as defined by your tab publishing settings for the assembly.

1. In the assembly tree, click the Tab icon.
2. In the Tab Sheet Attributes toolbar, click the View Tab icon to see an example of the selected Tab Sheet Attributes.

If the message No preview exists. Generate a preview appears, click the Generate File icon and then click View Tab.

*Tab Sheet Attributes*

You can use the attributes to describe the tab sheets after they have been included in an assembly. After a tab sheet has been included in an assembly, Publishing Setting is the only attribute that can be modified. Required information is indicated by an asterisk (*).

| Attribute | Description |
|---|---|
| Auto Text Wrap | Indicates whether to wrap text on the tab. The value displays as read-only and is based on the tab settings within the associated Publishing Settings Library. |
| Default? | Indicates whether to make the settings default. |
| Font Bold | Indicates whether the text is bold. The value displays as read-only and is based on the tab settings within the associated Publishing Settings Library. |
| Font Definition | The font used for the tab. The value displays as read-only and is based on the tab settings within the associated Publishing Settings Library. |
| Font Italic | Indicates whether the text is italic. The value displays as read-only and is based on the tab settings within the associated Publishing Settings Library. |
| Font Size | Indicates the text size (in points) for the tab. The value displays as read-only and is based on the tab settings within the associated Publishing Settings Library. |
| Last Generated Date | Date the tabs were last generated. You cannot change this value. |
| Name | Defines the name of the tab. |
| Overridden Tab Text | Defines the text that overrides the one taken from the Publishing Settings Library. |
| Publishing Setting * | Choose the default or a different saved publishing setting for the tab sheet. |
| Text | The text that is to appear on the tab. The value displays as read-only and is based on the tab settings within the associated Publishing Settings Library. |
| Vertical Text | Indicates whether to display text vertically on tabs. The value displays as readonly and is based on the tab settings within the associated Publishing Settings Library. |

*Tab Attributes*

You can use the attributes to describe the Tab settings within a Publishing Library.

Required information is indicated by an asterisk (*).

| Attribute | Description |
|---|---|
| Auto Text Wrap* | Determines whether or not to wrap text automatically. Default is No. |
| Default?* | Determines if the current tab is the default tab to be used when inserting tabs. Choose Yes or No. Default is No. If a default already exists it is updated to be No, and the saved tab setting become the default. |
| Font Bold* | Determines if the font appears in bold face. Default is No. |
| Font Definition* | Select a font for the tab. Available fonts: all active fonts defined in Data Administration, under Submission Maintenance. |
| Font Italic* | Determines if the font appears in italics. Default is No. |
| Font Size | Set the font size (points) for your tab. Default is 10. |
| Name* | Specify the name of the tab. Must be a unique name within the Publishing Settings Library. (Limit 200 bytes.) |
| Text | Specify the text to display on each tab. This can be text, or a variable (for example, ${NN}${LAB-BR}) can be used to create tab text. (The character count should not exceed 487 characters.) |
| | ***Note:*** *To make the first line of the tab blank, press the spacebar to enter a space, then press Enter to move to the next line.* |
| Vertical Text | Determines if the alignment of text on the tab is aligned vertically. Default is No. |

Tab paper size is controlled by the Tab Paper Size field on the Publishing Settings tab of the Publishing Settings Library Templates (PLT) and Assembly Specific Publishing Settings Libraries (APL).

Slip Sheets

You can use slip sheets to divide content in a submission and serve as a navigational aid. Slip sheets are unique to the paper output channel and are not to be included in the electronic output channel. Unlike cover pages and tab sheets, slip sheets cannot contain any text or graphics.

The only publishing setting you need to define for slip sheets is the paper type to use for the slip sheets. You must define publishing settings before you can select or insert special sheets in your assembly.

*Create or Modify Slip Sheets*

In the selected Publishing Settings Library, you can modify Slip Sheet settings. This procedure applies to both the

Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).

Like cover pages and tab sheets, you can use slip sheets to divide content in a submission and serve as a navigational aid. Slip sheets are unique to the paper output channel and can never be included in the electronic output channel.

Unlike cover pages and tab sheets, slip sheets cannot contain any text or graphics.

The only publishing setting you need to define for slip sheets is the paper type to use for the slip sheets. You must define publishing settings before you can select or insert special sheets in your assembly.

To add a slip sheet to an assembly:

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

   To edit an existing slip sheet setting, click a named slip sheet in the list on the Slip Sheets tab.
3. On the *Create Slip Sheet Settings* page, complete the required fields, and the optional fields as needed. Required information is indicated by an asterisk (*).

   — Name*

   — Default?

   — Paper Type*
4. Save.

| Option | Action |
|---|---|
| To create another slip sheet, after saving the current slip sheet settings: | Click Create Another Slip Sheet. |
| To discard the changes: | Click Cancel. |
| If you are editing an existing Slip Sheet setting: | Click the name of the Publishing Settings Library on the *View* page at the top of the page to return to the<br><br>Publishing Settings Library. |

*Modify a Slip Sheet*

You can modify the name or paper type of a slip sheet placed in an assembly.

1. Select a slip sheet in the assembly.
2. On the *Slip Sheet Attributes* page, click Edit.

3. On the *Edit Slip Sheet* page, modify the attributes.
4. Save.

*Slip Sheet Attributes*

You can use the attributes to describe the details of slip sheet settings. Attributes are editable on a slip sheet setting, and visible (read-only) on a slip sheet. A slip sheet includes an editable field for choosing the slip sheet setting. Required information is indicated by an asterisk (*).

| Attribute | Description |
|---|---|
| Default? | Determines if this is the default slip sheet. Choose Yes or No. Default is No. A default must exist. If a default already exists it is updated to be No, and the saved slip sheet becomes the default. |
| Name* | Specify a name for your slip sheet. The name must be unique within the Publishing Settings Library. (Limit 100 bytes) |
| Paper Type* | Choose the paper type for your slip sheet. The paper type options are determined by the printer option selected on the Publishing Settings tab. |

TOCs

Like special sheets, TOCs serve as navigation aids to facilitate review of the published assembly. TOC creation is a multiple step process that results in a final navigational aid.

To generate a TOC, Ennov InSight references a TOC template file. The TOC template file includes the following:

— Width of columns in the TOC

— Heading levels and styles

— General formatting

Ennov InSight includes two TOC templates, one letter and one A4. They are Microsoft Word documents you can copy and/or modify to meet your organization's needs. You can create TOCs for the paper output channel, electronic output channel, or both.

Only TOCs that are assigned to the paper output channel and that are included in a volume range are published during a paper publish request. TOCs that are assigned outside of a volume range or that are assigned only to the electronic output channel are not published during a paper publish request.

*Add or Modify TOCs*

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

Publishing Settings Library (APL). To add a TOC to an assembly:

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

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

— Name*

— TOC Definition File* (Click Browse to locate and select the location.)

— TOC Overlay

— Header

— Default TOC For (Move items from the Available box to the Selected box to apply the TOC settings by default for those items.)

— Tree Elements to Include in TOC (Move items from the Available Entry Generation Options box to the Selected Entry Generation Options box to apply them as default tree elements to include by default in the TOC.)

— Left Column Entry Text* (Leave blank to use the TOC tree values.)

— Right Column Entry Text*

— Leader

— Build TOCs to Level

— Including Bookmarks up to Level

— Include Only Bookmarks with the Text

— Exclude All Bookmarks with the Text

— Bookmark Handling

— Include in Page Numbering

— Output Channel* (move items from Output Channel Types to the Selected Output Channel Types box to apply the TOC to the selected output channel types by default)

4. Save. To discard the changes, click Cancel.

If you are editing an existing TOC 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.

*TOC Attributes*

You can use the attributes to describe TOC settings for a PLT.

Required information is indicated by an asterisk (*).

| Attribute | Description |
|---|---|
| Bookmark Handling | Indicates whether or not the entries from this TOC will be used to create the bookmarks in the Leaf, Volume, or Single File output file containing this TOC:<br>— File Bookmarks Only - Do not use the entries from this TOC to create output file bookmarks.<br>— All TOC Bookmarks - Use all of the entries from this TOC to create output file bookmarks. |
| Build TOCs to Level | Select the maximum number of levels of entries to build in the TOC, from 1 to 20. |
| Default TOC for | Select the Tree elements for which this TOC is used as the default TOC. A default must exist for every Tree element. |
| Exclude All Bookmarks with the Text | Specify text that will be used to designate the bookmarks to exclude from the TOC. |

| Attribute | Description |
|---|---|
| Header | Specify the text that will replace the word header in the TOC Definition File. (Limit 100 bytes) |
| Including Bookmarks up to Level | Select the maximum number of levels of entries in the TOC that can be created from bookmarks, from 1 to 20. |
| Include In Page Numbering | Specify whether the TOC pages are included in the page numbering: Yes or No. |
| Include Only Bookmarks with the Text | Specify text that will be used to designate the bookmarks to include in the TOC. |
| Leader | Specify the characters to use to separate TOC entry text from the corresponding page number.<br>If you select Dash, Dot, or Underline, the leader character is created for TOC entries at all levels.<br>If you select Space, no leader is created. |

| | |
|---|---|
| | If you select Use Template, the iTOC 1 to iTOC 15 styles in the Word template specify the leaders for the corresponding TOC entry levels. Select this option if you want different leader characters for all the different TOC Entry levels or if you want leaders only for some levels. If you select Use Template, do the following to set up the iTOC styles in Microsoft Word:<br><br>1. Note the width of the left column of the single row table in the Word TOC Template.<br>2. Open the Styles pane.<br>3. Click Options....<br>4. On the Style Pane Options box, for Select styles to show, click All styles.<br>5. To set up an iTOC style, right-click the iTOC Style, and click Modify....<br>6. Click Format > Tabs....<br>7. Do one of the following:<br><br>— Create a tab stop for the left column width that you noted on step 1, for the right alignment, and for a leader character.<br><br>— If you do not want leaders, clear all tab stops. |
| Attribute | Description |
| Left Column Entry Text | Specify the text that resolves in the left hand column of the TOC. If this is left blank, the values from the assembly tree (TOC Tree Values) populate the left column of the generated TOC.<br><br>— In the TOC editor and the preview file, left column entry text resolves fully.<br><br>— Volume variables, $VN and $VNAME, cannot be included in the Left Column Entry Text field for TOC Attributes. They do not resolve in published output.<br><br>— Variables resolved only at publishing time will not be resolved in the Left Column Entry Text. For more information, see: *InSight System-Defined Variables* |
| Name* | Specify the name of the TOC. Must be a unique name within the Publishing Settings Library. (Limit 100 bytes.) |
| Output Channel* | Select the output channel to which this TOC is to be published. You must choose Electronic, Paper, or both. Paper is the default. |
| Right Column Entry Text* | Text that appears in the right column. Right Column Text fully resolves only in the published output. Right Column text contains the resolved value for any variable. |
| TOC Definition File* | Browse to select the TOC template you want to use for your table of contents. This provides the link to the Word file that defines the formatting and structure of the TOC. |

| | |
|---|---|
| Tree Elements to Include in TOC* | Specify the assembly elements to display in the generated TOC by moving items from Available Entry Generation Options to Selected Generation Options.<br><br>A TOC entry for a leaf, folder, or document with a TOC or Cover Page that is included in the output channel and page numbering will stamp the page number of the TOC or Cover Page. |

*Use TOC Defaults*

When creating a TOC, you can establish a default TOC setting. This tells Ennov InSight which TOC setting to use by default when a TOC is inserted for a particular kind of element.

For example, if TOC setting ABC is mapped to leaf elements, any time you insert a TOC for a leaf it will appear as the default TOC setting ABC. A single TOC setting can be the default for multiple elements at once.

| Mapping | Sample TOC Setting |
|---|---|
| Assembly root | Table of contents |
| Volume | Volume table of contents |
| Document | Document table of contents |
| Leaf | Leaf table of contents |
| Mapping | Sample TOC Setting |
| Folder | Module table of contents |
| Extract | Table of figures |

*Table of Contents Templates*

The layout of the TOC is defined in a TOC definition file, which must be in Word format. You can define a definition file for each TOC in the document, if required. This topic describes the basic TOC definition file. You can modify a TOC template (which is a Microsoft Word document) to meet your publication submission needs. The text used for the final TOC entries is derived from two sources:

— The left column text specified for the TOC element, usually represented by a variable string containing the

$NAME element name and $N element number of the elements included from the assembly tree

— The bookmark names contained in the actual document files

Heading level styles TOC1 (TOC20) defined in the Word document correspond to the heading levels created when the TOC is generated. Each new TOC entry is generated in its own row in the table. The first row included in the template provides a place for the generator to begin.

The heading level styles may contain Word formatting (numbering, indent, character style, color, box, outline letters, font, paragraph styles, leader text, and so on). In this way, most formatting options are supported. This information

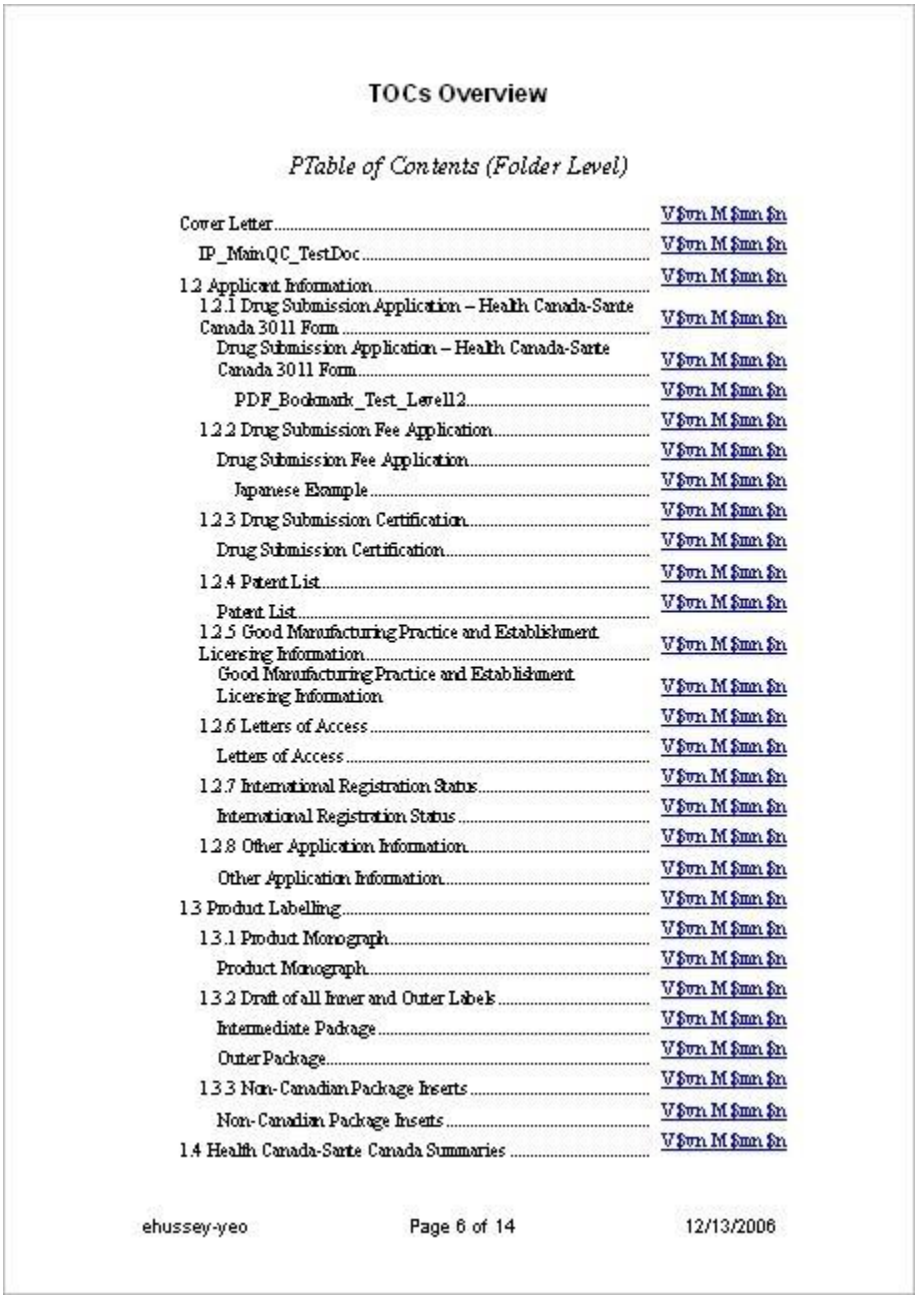
is placed in the first column of the table. The second column of the table is reserved for the right column text, and the style of this text is specified by the link text style. Again, this right column is resolved only during final publish, not during preview and editing. The left column is resolved during preview and editing.

The number of bookmark levels in the TOC element determines how many heading levels to use from all component documents in the TOC range. This should be the highest number of allowed levels in your document templates.

The number of TOC levels to include determines the total number of final heading levels that will be included in the

TOC.

The location of the header text determines where the header attribute in the TOC element will be placed, and the style of that text. This text may wrap lines. If this is insufficient, you can use Word headers on the TOC template to express the TOC subject, and you can use the TOC overlay here as well to stamp additional information.



**TOCs Overview**

*PTable of Contents (Folder Level)*


Cover Letter ..... V$vn M$mn $n
IP_MainQC_TestDoc ..... V$vn M$mn $n
1.2 Applicant Information ..... V$vn M$mn $n
1.2.1 Drug Submission Application – Health Canada-Sante Canada 3011 Form ..... V$vn M$mn $n
Drug Submission Application – Health Canada-Sante Canada 3011 Form ..... V$vn M$mn $n
PDF_Bookmark_Test_Level12 ..... V$vn M$mn $n
1.2.2 Drug Submission Fee Application ..... V$vn M$mn $n
Drug Submission Fee Application ..... V$vn M$mn $n
Japanese Example ..... V$vn M$mn $n
1.2.3 Drug Submission Certification ..... V$vn M$mn $n
Drug Submission Certification ..... V$vn M$mn $n
1.2.4 Patent List ..... V$vn M$mn $n
Patent List ..... V$vn M$mn $n
1.2.5 Good Manufacturing Practice and Establishment Licensing Information ..... V$vn M$mn $n
Good Manufacturing Practice and Establishment Licensing Information ..... V$vn M$mn $n
1.2.6 Letters of Access ..... V$vn M$mn $n
Letters of Access ..... V$vn M$mn $n
1.2.7 International Registration Status ..... V$vn M$mn $n
International Registration Status ..... V$vn M$mn $n
1.2.8 Other Application Information ..... V$vn M$mn $n
Other Application Information ..... V$vn M$mn $n
1.3 Product Labelling ..... V$vn M$mn $n
1.3.1 Product Monograph ..... V$vn M$mn $n
Product Monograph ..... V$vn M$mn $n
1.3.2 Draft of all Inner and Outer Labels ..... V$vn M$mn $n
Intermediate Package ..... V$vn M$mn $n
Outer Package ..... V$vn M$mn $n
1.3.3 Non-Canadian Package Inserts ..... V$vn M$mn $n
Non-Canadian Package Inserts ..... V$vn M$mn $n
1.4 Health Canada-Sante Canada Summaries ..... V$vn M$mn $n


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*Specify Element Level TOC Publishing Settings*

You can add special sheets at any element level, including TOCs, Tabs, Cover Pages, or Slip Sheets. Following elements are:

– Assembly

– Folder

– Leaf

— Document

— Bookmark

To specify element level TOC settings, right-click on the element and select Mass Insert/Update Publishing Elements and follow the procedure described in *Inserting a Publishing Element*.

*Resolve Entries in TOCs*

Ennov InSight calculates right column text and resolves electronic links for the entries in a TOC, based on the assembly items that are assigned to the publishing channel and the type of publish (Leaf, Volume, or Single File).

— Publishable - Publishable elements are those that can produce pages in the output (Leaf, Volume, or Single File). These are Documents, TOCs, and Cover Pages that are in-channel and in range of the type of publish. Elements attached to or descended from non-Leafs are unpublishable in electronic Leaf output.

— Placeholder - Placeholders may add to page numbering but are never resolved as TOC entry targets.

— Ready to publish - A publishable element with an extracted PDF rendition (either a PDF source or PDF rendition of the source). Entries targeting an element that is ready to publish will have resolved right column text and a working hyperlink.

The following assembly elements are resolved according to various business rules employed by Ennov InSight to calculate page numbering in TOCs.

*TOC Entries that Target Leaf, Folder, or Document Elements*

When a leaf, folder, or document that has a publishable TOC or cover page that is also assigned to be included in page numbering, the TOC entry for that leaf, folder, or document calculates the right column text for the first page of the publishable TOC or cover page. The link destination of the link under the right column TOC entry text is the first page of the publishable TOC or cover page.

When there are folders, leafs, and documents without elements attached to them (as described above), the TOC entries for those empty elements resolve to the first subsequent element in the assembly structure:

— Publishable included in page numbering TOC (see: *Sample TOC 1*.

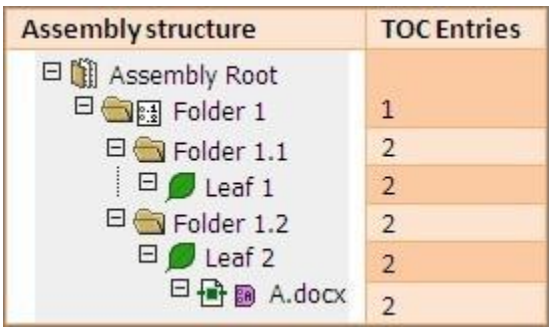
— Publishable included in page numbering cover page, or (see: *Sample TOC 2*. — Publishable document pages (see: *Sample TOC 3*.

An exception to this rule is that a paper channel cover page attached to a reference leaf is always targetable for TOC entries, even if the cover page is not included in page numbering. Electronic elements attached to a reference leaf are invalid. Tabs and Slip Sheets are never targeted because they are never included in Page Numbering.

## Sample TOC 1

— All elements are in-channel and included in page numbering

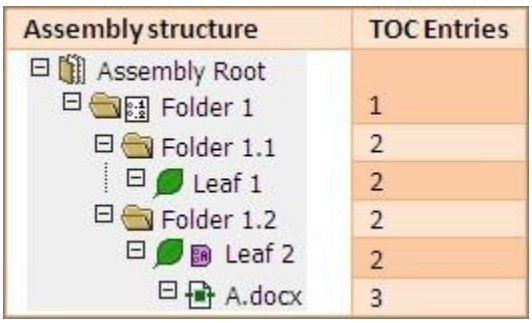
— All special sheets and documents are ready to publish




## Sample TOC 2

— All elements are in-channel and included in page numbering.

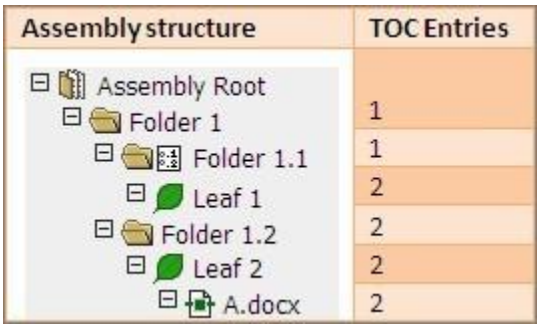
— All special sheets and documents are ready to publish.




## Sample TOC 3

— All elements are in-channel and included in page numbering.

— All special sheets and documents are ready to publish.




*TOC Entries that Target Other Tables of Contents*

For a TOC entry targeting a Table of Contents, the right-column text is calculated for the first page of the targeted

TOC.

The link destination of the link, under right-column TOC entry text, is the first page of the TOC.

*TOC Entries that Target Document Bookmarks (Extracts)*

For a TOC entry targeting an extracted document bookmark, the right-column text is calculated for the targeted page of the including document.

The link destination of the link under right-column TOC entry text, is the document page.

PageMarker attached special sheets will not be targeted by these TOC entries.

*TOC Entries that Target Planned and Not Ready to Publish Assembly Elements*

An assembly element (TOC, cover page, or document) that has not been rendered and extracted is not ready to publish.

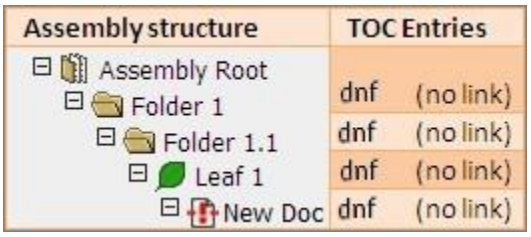
No pages are created in the leaf, volume, or single output files for these pages. When an assembly contains unpublishable elements, the right-column text for TOC entries targeting these elements (or pages in them) is the Destination Not Found Text. There is no navigable link for these TOC entries.

The Destination Not Found Text setting is defined on the *Publishing* page of the *Modify Publishing Settings* dialog box. If the Destination Not Found Text setting is not defined, a single space is used.

## Sample TOC 1

— All elements are in-channel and included in page numbering.

— Document& New Doc is planned and has not been assigned to a document in a DMS.

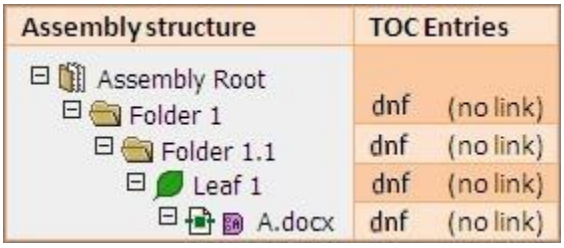



## Sample TOC 2

— All elements are in-channel and included in page numbering.

— The template for the cover page attached to A.docx has not been rendered and extracted.

— Document A.docx is ready to publish. Entries targeting extracted bookmarks in A.docx are resolved.

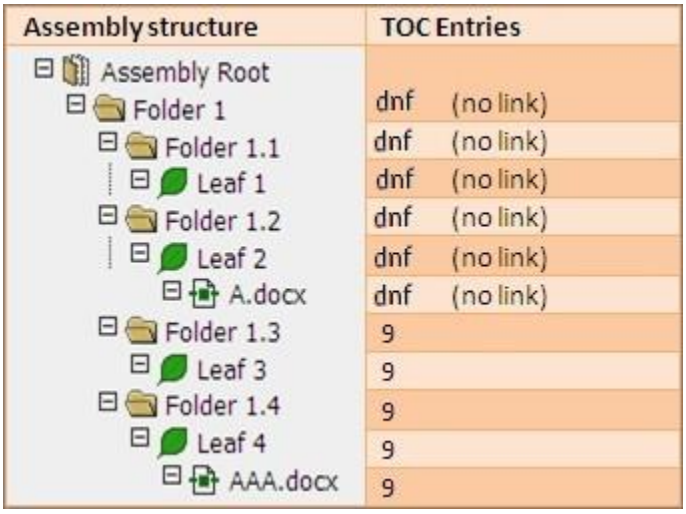



## Sample TOC 3

— All elements are in-channel and included in page numbering.

— Document A.docx is not ready to publish with a planned page count of 8.

— Document AAA.docx is ready to publish.




*TOC Entries that Target Native Leafs and Descendents*

A native leaf is a leaf with the Use Native File attribute set to YES. Because the output file of native leafs may be of any file type, Native leafs require special handling.

The following rules apply for native files:

— The page number for the first page is used for any page in a native leaf document. Page numbers and totals are always calculated using the Planned Number of Pages for native leaf documents. If you have not indicated a Planned Number of Pages for a native leaf document, one page will be used. Native leaf documents follow the usual rules of page numbering. If you do not want native leaf pages to be added to the page numbers and totals, set Include in page numbering to NO. If you do not want the native leaf document to affect the paper channel page numbers, remove it from the paper output channel.

— The PDF link for a link, TOC entry, or bookmark in published PDF output that targets a page in a native leaf appears as a Launch link. The targeted native leaf file is opened in its associated application. Because of this, individual pages

in the native leaf file cannot be targeted. If Adobe Acrobat® is the default application for PDF files, links targeting pages in native leaf output will navigate to the first page.

*Invalid Targeted Assembly Elements*

Invalid targeted assembly elements are usually created in error, and are not included in the published assembly. Invalid targeted assembly elements can be caused for several reasons.

Possible reasons for invalid target assembly elements:

— Out-of-channel TOCs and documents (and their extracted bookmarks).

— Extracted bookmarks of documents with new bindings. This situation can occur by creating a TOC tree with extracts, followed by performing a DMS synchronization on the parent document without updating/regenerating/ rendering the TOC.

— Extracted bookmarks out of page range. This situation can occur by creating a TOC tree with extracts, and then limiting the page range of the document to exclude some extracts without updating/regenerating/rendering the

TOC.

— Target elements that have been deleted from the assembly. This situation can occur by creating a TOC tree, and then deleting some of the target elements without updating/regenerating/rendering the TOC.

When a TOC contains entries targeting invalid elements, the right column text for these TOC entries is the Destination Not Found Text. There is no navigable link for these TOC entries.

Tables of Contents

Tables of Contents (TOCs) enable you to find contextual information in a published assembly. The creation of TOCs is dependent on document structure, as each submission document can contain several levels of document structure elements in a familiar hierarchy. For CTD TOCs, the hierarchical structure roughly follows the eCTD hierarchy, but for other publications such as study reports, the structure may differ.

You can treat TOCs as additional assigned documents in the repository that are not part of the life cycle or content, but are needed during electronic and paper publishing. These TOC documents can be generated into .docx format for use and modification in Microsoft Word or other word processing applications. Normal rendering processes can create final TOC documents in the publishing output file format.

When you insert a TOC into an assembly the default TOC type is used automatically, or you can choose an alternate TOC type. You specify the default TOC settings in the Publishing Settings Library Templates, and a default TOC is required. In the publishing settings, you may create an association between different TOC types and assembly elements or locations. This association is called mapping.

When publishing tables of contents that include a range to which all content has not yet been assigned, TOC entries that cannot be targeted. For example, when no content yet exists under the leaf, TOC entries are stamped with the

Destination Not Found Text from the Publishing Settings. Once the content is assigned to the leaf, the TOC entry stamp correctly resolves to the destination.

If you are defining (mapping) a TOC for volumes, when you insert a TOC on a volume the TOC type associated (mapped) with a volume may be inserted automatically. As long as the TOC types are defined correctly for the appropriate elements before bulk insertion, little editing of the assembly is necessary to generate valid TOCs.

When you generate a TOC, a Word document is created from the information about the TOC in Ennov InSight .

The TOC is combined with the style and format specified in the TOC template. The TOC is then rendered to a PDF and the right-column text and hyperlink is resolved during final publishing. There are various ways to create a TOC, for example:

— Generate the TOC from the default range directly to a PDF during final publish; this is best suited for volume

TOCs.

— Edit the TOC in the TOC editor, then generate the TOC from the TOC editor directly to a PDF during the final publishing.

— Generate the TOC from the default range to the Word document preview, edit the preview, then publish the Word document to a PDF during final publishing; this is best suited to submission TOCs.

— Edit the TOC in the TOC editor, generate the TOC from the TOC editor to a Word document preview, edit the preview, and then publish the Word document to a PDF during final publishing; this is best suited to a submission TOC.

Generated TOCs are saved to the preview location specified in the TOC publishing settings.

When you preview a generated TOC, the system makes a copy of the TOC in a temporary location (regardless of the defined preview location) and displays that copy for preview. Any changes you make to the previewed TOC are made on the temporary copy only, and are not made on the actual TOC that will be published.

***Note:*** *In some desktop configurations you may have to save the TOC to a local file and open the local file to view the TOC.*

*Insert a TOC*

You can insert a TOC in an element for the contents of the element.

When adding a TOC to a tree element, the TOC name inherits the name of the element on which it was placed. This name is used to create the file name of the generated TOC.

***Note:*** *If a TOC is placed on an element that includes a special character in its name (/ \ : * ? < > |), you must edit and update the TOC name so that it does not include special characters, otherwise it will not generate.*

To insert a TOC:

1. In the assembly, right-click the element where you want to insert the TOC and choose Mass Insert/Update Publishing Elements.
2. In the *Mass Insert/Update Elements* window, select Table of Contents.
3. Select one or more elements where you want to insert a TOC:

| Option | Description |
|---|---|
| For this Element: | Inserts a TOC for the selected assembly element. |
| Volumes: | Inserts a TOC for each volume in the assembly. |
| Folders: | Inserts a TOC for each folder in the assembly. |
| Leaf Elements: | Inserts a TOC for each leaf element in the assembly. |
| Option | Description |
| Documents: | Inserts a TOC for each assigned document and document placeholder in the assem- bly. |
| Page Markers: | Inserts a TOC for each volume break in assigned documents. |

4. In the Publishing Setting list, leave the Use Default setting, or choose an alternative TOC setting (if other TOC settings have been created in the PLT).
5. To set the Range Start option, select Entity and click Browse to specify the location in the Current Assembly to start the range of the new TOC.
6. Click Insert.

   A message prompts you to confirm the insertion.

7. Click OK.

For each element where a TOC has been inserted, the TOC icon appears in the assembly tree.

*Modify TOC Attributes*

You can modify the attributes of a TOC placed in an assembly.

To modify TOC attributes:

1. Click Edit Publishing Settings Library to open the Publishing Settings Library for the assembly.
2. In the Publishing Settings Library, click TOC.
3. On the TOC tab, click the name of the TOC you want to modify.
4. On the *TOC Types* page, click Edit TOC Type.
5. On the Edit TOC Type page, modify the TOC attributes as needed.
6. Save. To close the *Edit TOC Type* page without saving any changes, click Cancel.

*Modify a TOC*

Use the TOC editor to modify folders, leafs, or files in a TOC by: deactivating or activating them, editing their names, moving them up or down, and promoting or demoting them in the hierarchy. You cannot modify the root of the assembly in the TOC editor.

To modify a TOC:

1. In the *Publishing Elements* view of an assembly tree, click TOC. The *TOC Attributes* window appears.
2. In the TOC Attributes toolbar, click Modify TOC Content.

   The Modify TOC Content view displays the entries of the selected TOC.

   ***Note:*** *Using Modify TOC Content (the TOC entries editor) sets the TOC Content Modified flag to Yes on the TOC Attributes page. This gives you control of the TOC Content for making modifications. If you only want to view the TOC Content and do not want to make modifications, click Reset TOC Content to exit.*
3. To modify an entry in the TOC, right-click on the entry and choose an option in the list. Multiple entries can be selected to perform an action.

   The option list is contextual, depending on the location of the selected item in the TOC. Only the usable options will be available for the selected TOC entry.
4. To reset the TOC so that it includes all of your recent assembly changes, click Reset TOC Content.

   Using Reset TOC Content sets the TOC Content Modified flag to No on the *TOC Attributes* page. By clicking this button, you relinquish control of the TOC Content. Any changes you have made to the TOC Content will not be saved.
5. To save your changes, take control of the TOC Content and close the *Modify TOC Content* view, go back to the *TOC Attributes* view, and click Close.

*Select Contiguous TOC Nodes*

You can select multiple TOC entries, or nodes, either contiguously or non-contiguously.

To select contiguous TOC nodes:

1. Click the first TOC entry of the group of nodes you want to select.
2. Press and hold the Shift key on your keyboard.
3. Click the last TOC entry of the group of nodes you want to select.

All of the nodes in your selected group should appear highlighted. You can now perform the following actions on the entire selected group at once:

— Activate

— Deactivate

— Drag-and-drop

*Select Non-contiguous TOC Nodes*

You can select multiple TOC entries, or nodes, either contiguously or non-contiguously.

To select non-contiguous TOC nodes:

1. Press and hold the Ctrl key on your keyboard.
2. Click the TOC entries you want to select.

The nodes that you selected should appear highlighted, although the group is not contiguous. All of the nodes in your selected group should appear highlighted. You can now perform the following actions on the entire selected group at once:

— Activate

— Deactivate

— Drag-and-drop

*TOC Context Menu Options*

Use the TOC context menu options to manage elements in a table of contents.

| Option | Description |
|---|---|
| Expand Range | Expand the selected entry to reveal its child entries. |
| Deactivate/Activate selected | Deactivate or activate the selected entry. |
| Option | Description |
| Deactivate/Activate selected + descendants | Deactivate or activate the selected entry plus its child nodes of the same active/inactive state. |
| Edit | Change the name of the selected entry. |
| Move Up | Move the selected entry up (within its node group). |
| Move Down | Move the selected entry down (within its node group). |
| Promote | Move the selected entry (and its child entries) to the left in the TOC. |
| Demote | Move the selected entry (and its child entries) to the right in the TOC. |

*Deactivate a TOC Entry*

You can deactivate a TOC entry if is not needed in the submission.

To deactivate a TOC entry:

1. In the assembly, select a TOC and click Modify TOC Tree.
2. Right-click the TOC entry, and choose Deactivate.

   The TOC entry is not deleted, but it is made unavailable.
3. Save.
4. To activate a deactivated TOC entry, right-click it and choose Activate, then Save.

*Modify TOC Entry Text*

Use Edit TOC Entry to modify the text of an entry in the TOC tree.

To modify TOC entry text:

1. In the *Publishing Elements* view, click TOC.
2. On the *TOC Attributes* page, click Modify TOC Content.
3. Right-click a TOC level, and click Edit.

   The *Edit TOC Entry* dialog box appears.
4. Edit the text and Save.

The TOC entry content is updated.

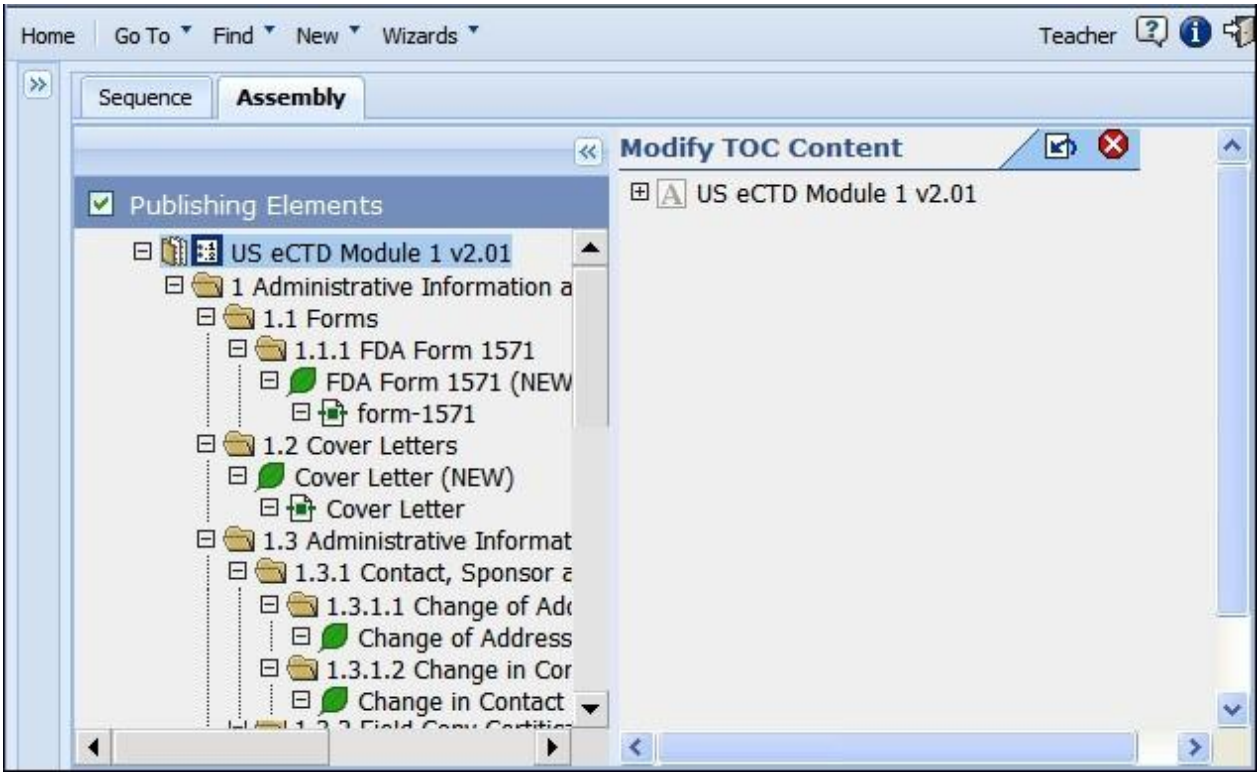
*View TOC Entry Text*

You can view the text for a TOC entry to verify it.

To view TOC entry text:

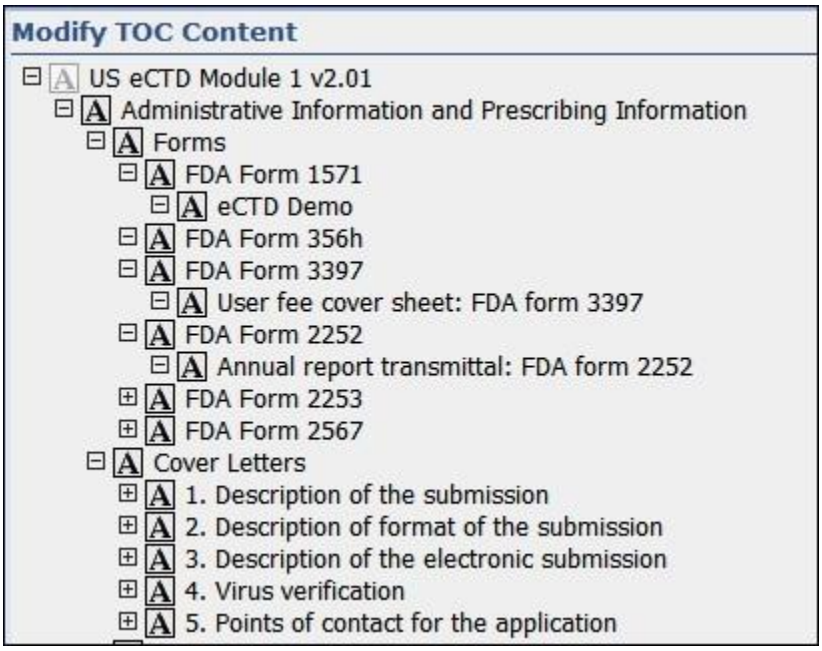
1. In the assembly, select a TOC and click Modify TOC Content to view the *Modify TOC Content* page.

## Example




2. To expand the TOC content of any node with children (other than the root TOC content node) click Expand or right-click and select Expand Range. To collapse the TOC content of a node with children, click Collapse.

**Example**



*Duplicate a TOC*

You can duplicate a TOC within an entity and add it to the assembly.

To duplicate a TOC:

1. Right-click the TOC you want to duplicate, and choose Duplicate TOC. The new TOC is added to the element and the *Edit TOC* page appears.
2. In the *Edit TOC* view, specify the values to use and Save.

The duplicated TOC is added to the assembly tree.

*Delete a TOC*

You can delete a TOC from an entity as needed.

To delete a TOC:

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

***Note:*** *If you delete the Microsoft Word TOC document created by Ennov InSight directly in the DMS repository or secure file system, the publish may fail because Ennov InSight cannot rerender the Word TOC documents into PDF output. You must delete the TOC element and create a new one.*

*Move TOCs*

You can drag a TOC to an unlocked tree element in an assembly.

If the TOC Content Modify flag is not selected, the TOC range also moves to the new location. If the TOC Content Modify flag is selected, the TOC range does not move and your edits are preserved.

You can drag items to any element in the assembly tree, or to a volume, but you cannot drag items from a volume into an assembly tree.

*Move a TOC*

You can move a TOC to another place in the assembly.

Click the TOC that you want to move and drag it to an unlocked tree element. The TOC is moved.

*Generate a TOC Manually*

Use this procedure to generate a TOC manually.

To generate a TOC manually:

1. In the assembly, click the icon for the TOC you want to generate.
2. Click Generate.

   A job request is submitted to generate the TOC.
3. Choose Go To > Job Requests to monitor the progress of the request.

When the job status is complete, you can preview the TOC.

*Generate a TOC Using Prepare to Publish*

Use this procedure to generate a TOC using Prepare to Publish.

To generate a TOC using Prepare to Publish:

1. From the assembly, select the entire assembly or the section for which you want to generate a TOC.
2. Choose Prepare to Publish from the action toolbar. The *Prepare to Publish* dialog box appears.
3. Select Generate TOCs only, and clear any other options that are selected.
4. Click OK.
   a. message prompts you to confirm the publish.
5. Click OK.
   a. job request is submitted to generate the TOCs.
6. Choose Go To > Job Requests to monitor the progress of the request.
7. When the job status is complete, click View File.

*Preview TOC*

You can preview a local, cached copy of a generated TOC in your Web browser.

A TOC must be generated before it can be previewed. Use the Generate TOCs option in the *Prepare to Publish* dialog to generate a TOC for preview.

When you preview a generated TOC, the system makes a copy of the TOC in a temporary location (regardless of the defined preview location) and displays that copy for preview. Any changes you make to the previewed TOC are made on the temporary copy only, and are not made on the actual TOC that will be published.

*Preview a TOC*

You can preview a local, cached copy of a generated TOC in your Web browser.

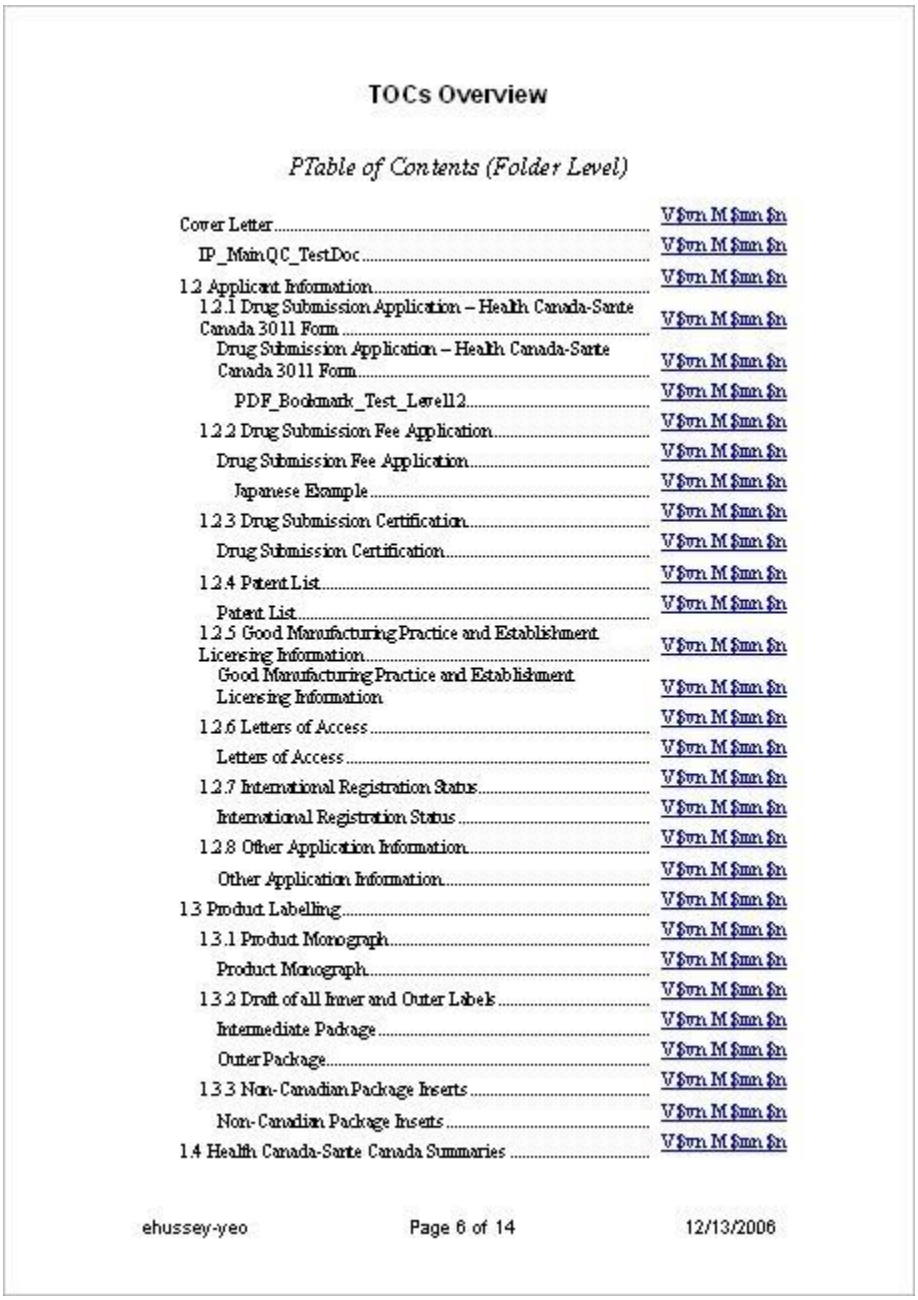
To preview a TOC:

1. When a job request to generate a TOC has completed, on the *assembly* page, click View File to preview the

   TOC.
2. When you are prompted, open the TOC.

## Example

The preview is similar to the following:



TOCs Overview

*PTable of Contents (Folder Level)*


Cover Letter ..... V$vn M $mn $n
IP_MainQC_TestDoc ..... V$vn M $mn $n
1.2 Applicant Information ..... V$vn M $mn $n
1.2.1 Drug Submission Application – Health Canada-Sante Canada 3011 Form ..... V$vn M $mn $n
Drug Submission Application – Health Canada-Sante Canada 3011 Form ..... V$vn M $mn $n
PDF_Bookmark_Test_Level12 ..... V$vn M $mn $n
1.2.2 Drug Submission Fee Application ..... V$vn M $mn $n
Drug Submission Fee Application ..... V$vn M $mn $n
Japanese Example ..... V$vn M $mn $n
1.2.3 Drug Submission Certification ..... V$vn M $mn $n
Drug Submission Certification ..... V$vn M $mn $n
1.2.4 Patent List ..... V$vn M $mn $n
Patent List ..... V$vn M $mn $n
1.2.5 Good Manufacturing Practice and Establishment Licensing Information ..... V$vn M $mn $n
Good Manufacturing Practice and Establishment Licensing Information ..... V$vn M $mn $n
1.2.6 Letters of Access ..... V$vn M $mn $n
Letters of Access ..... V$vn M $mn $n
1.2.7 International Registration Status ..... V$vn M $mn $n
International Registration Status ..... V$vn M $mn $n
1.2.8 Other Application Information ..... V$vn M $mn $n
Other Application Information ..... V$vn M $mn $n
1.3 Product Labelling ..... V$vn M $mn $n
1.3.1 Product Monograph ..... V$vn M $mn $n
Product Monograph ..... V$vn M $mn $n
1.3.2 Draft of all Inner and Outer Labels ..... V$vn M $mn $n
Intermediate Package ..... V$vn M $mn $n
Outer Package ..... V$vn M $mn $n
1.3.3 Non-Canadian Package Inserts ..... V$vn M $mn $n
Non-Canadian Package Inserts ..... V$vn M $mn $n
1.4 Health Canada-Sante Canada Summaries ..... V$vn M $mn $n


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*Modify Generated TOC*

Make the changes to the generated TOC using the TOC editor.

Generated TOCs are created as Word documents and saved to the preview location specified in the TOC publishing settings for the assembly. These TOCs are complete except for the right column, which is generated during final publishing with cross-reference stamps and hyperlinks.

You can edit the TOC, including left column. You cannot edit the table and the right column links. These must be intact during final publishing, so they are stamped and linked appropriately.

***Note:*** *In some cases the TOC editor does not resolve a left column variable immediately. This happens if the left column variable is complex and requires additional processing to define. You may need to first generate the TOC to preview it.*

*Modify a Generated TOC*

You can edit the TOC, including left column. You cannot edit the table and the right column links. These must be intact during final publishing, so they are stamped and linked appropriately.

To modify a generated TOC:

1. In the assembly, click the TOC you want to edit.
2. Verify the generated TOC *file name* and *location*.
3. Access the document repository in the normal manner and edit the TOC.

*Bookmarks*

Bookmarks are taken directly from the source files, unless they have been modified or changed in the bookmark editor. In this case, the bookmarks are used for all TOCs and file output.

When the TOC is generated, either in the TOC editor or at publish time, Ennov InSight attempts to build a valid tree structure using the edited bookmarks or bookmarks extracted from source documents. If hierarchy levels are skipped or missed, Ennov InSight will 'compress' the bookmark tree in order to ensure valid published output.

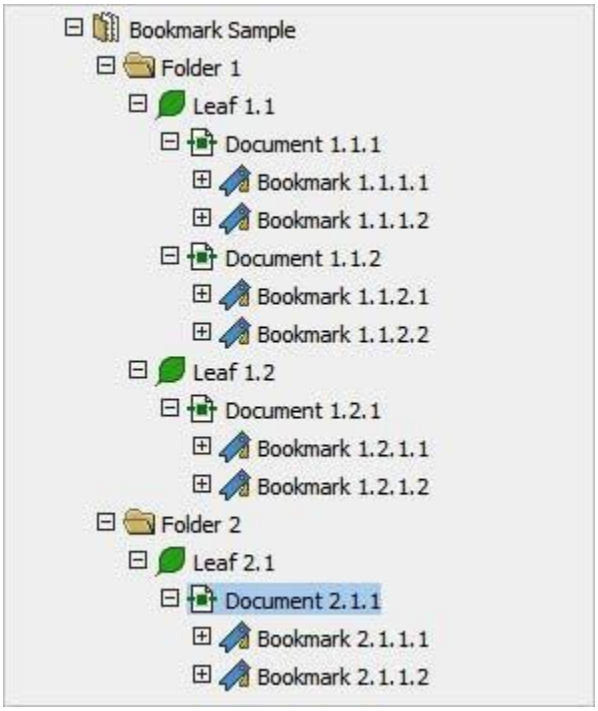
During final TOC generation, two bookmark handling options are available: File Bookmarks and TOC Bookmarks.

*File Bookmarks*

All final output files that span the range of a TOC contain their original bookmarks, and those bookmarks are used in the PDF output.

If multiple files are combined, they contain the bookmark trees of all source documents, plus a bookmark representing the document.

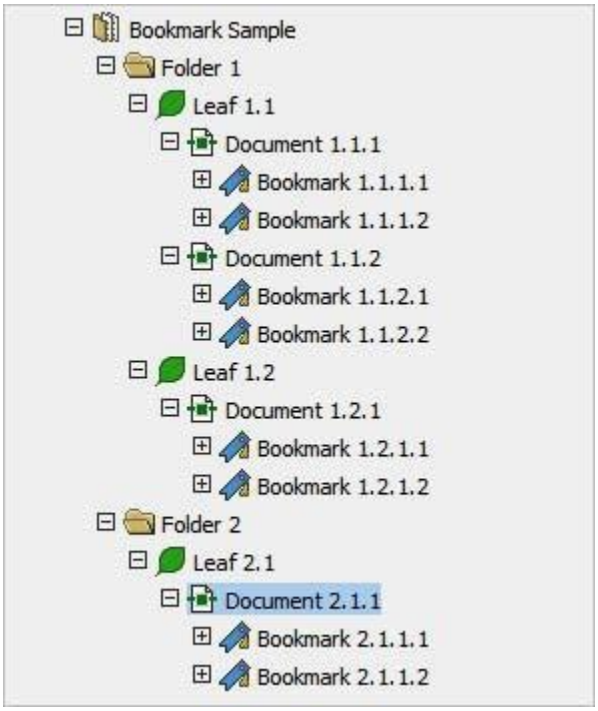
As shown in the example image, if you select File Bookmarks Only for all TOCs the final files contain the following (which is also the default for files that do not have tables of contents defined).



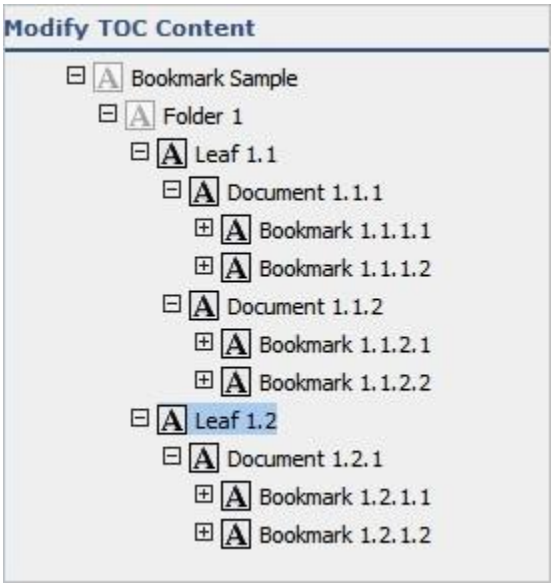

*TOC Bookmarks*

All final output files that span the range of the TOC contain the entire bookmark tree. For the output PDFs that fall within the range of that TOC, the bookmarks will match exactly what is shown in the generated TOC. Each TOC entry corresponds to a bookmark.

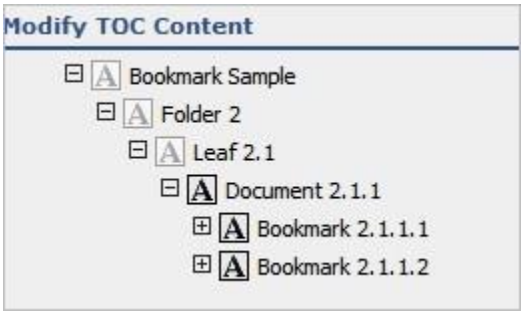
If multiple TOCs exist in this range and use this option, the TOCs are appended and the result is used as the bookmark tree. In the following example, if you select Use TOC Bookmarks for TOC #1 and TOC #2:



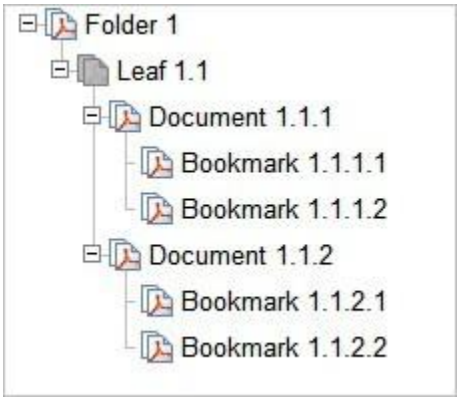

Use TOC bookmarks creates the following:



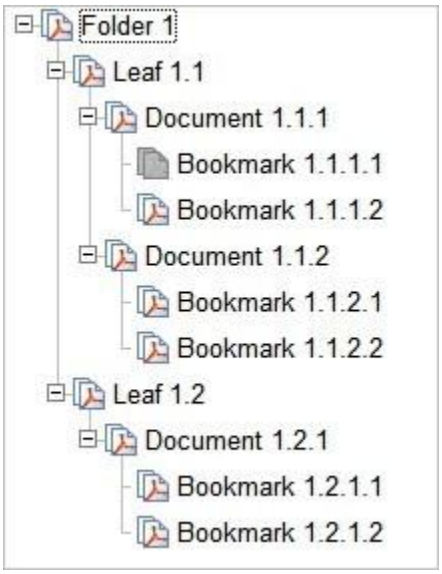

Use file bookmarks creates the following:



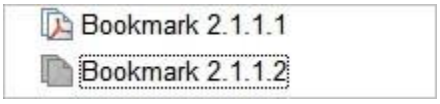

Leaf 1.1 file




Leaf 1.2 file




Leaf 2.1 file



Ennov InSight can generate bookmarks automatically for the output PDF file as part of TOC creation. The new bookmark text for each component document is determined from the left column text for the TOC element. With this function, the bookmarks for the final files can reflect exactly the content in the TOCs.

*TOC Levels and Bookmark Levels*

Bookmark levels are essentially a sub-setting of the TOC Levels setting. TOC levels defines how many levels will be displayed overall in the TOC and Bookmark levels determines how many levels of bookmarks are displayed within that number of TOC levels.

The following examples demonstrate the concept of TOC levels and Bookmark levels.

The first example shows how levels 3 and 4, although falling within the TOC level range, will not be included in the TOC because the number of levels of bookmarks to be included has been restricted to 2.

**Example 1**: TOC Levels = 7 Bookmark Levels = 2

| LEVEL1 | LEVEL2 | LEVEL3 | LEVEL4 | LEVEL5 | LEVEL6 | LEVEL7 | LEVEL8 | LEVEL9 | LEVEL10 |
|---|---|---|---|---|---|---|---|---|---|
| Folder 1 | | | | | | | | | |
| | Leaf 1 | | | | | | | | |
| | | Doc 1 | | | | | | | |
| | | | Bkm1 | | | | | | |
| | | | | Bkm2 | | | | | |
| | | | | | ~~Bkm3~~ | | | | |
| | | | | | | ~~Bkm 4~~ | | | |
| | | | | | | | Bkm5 | | |
| Folder 2 | | | | | | | | | |
| | Folder 3 | | | | | | | | |
| | | Folder 4 | | | | | | | |
| | | | Leaf 2 | | | | | | |
| | | | | Doc 2 | | | | | |
| | | | | | Bkm1 | | | | |
| | | | | | | Bkm2 | | | |
| | | | | | | | Bkm3 | | |
| | | | | | | | | Bkm4 | |
| | | | | | | | | | Bkm5 |
| Folder 5 | | | | | | | | | |
| | Leaf 3 | | | | | | | | |
| | | Doc 3 | | | | | | | |
| | | | Bkm1 | | | | | | |
| | | | | Bkm2 | | | | | |
| | | | | | ~~Bkm3~~ | | | | |
| | | | | | | ~~Bkm 4~~ | | | |
| | | | | | | | Bkm5 | | |

## *Table of Contents (Folder Level)*


Folder 1 ..... TOCRIGHTCOL
Leaf 1 ..... TOCRIGHTCOL
Doc 1 ..... TOCRIGHTCOL
Bkm1 ..... TOCRIGHTCOL
Bkm2 ..... TOCRIGHTCOL
Folder 2 ..... TOCRIGHTCOL
Folder 3 ..... TOCRIGHTCOL
Folder 4 ..... TOCRIGHTCOL
Leaf 2 ..... TOCRIGHTCOL
Doc 2 ..... TOCRIGHTCOL
Bkm1 ..... TOCRIGHTCOL
Bkm2 ..... TOCRIGHTCOL
Folder 5 ..... TOCRIGHTCOL
Leaf 3 ..... TOCRIGHTCOL
Doc 3 ..... TOCRIGHTCOL
Bkm1 ..... TOCRIGHTCOL
Bkm 2 ..... TOCRIGHTCOL

In the second example, Bookmarks at levels 8 and 9 in the assembly will not be included because TOC levels is restricted to 7.

**Example 2**: TOC Levels - 7 Bookmark Levels = 9

| LEVEL1 | LEVEL2 | LEVEL3 | LEVEL4 | LEVEL5 | LEVEL6 | LEVEL7 | LEVEL8 | LEVEL9 | LEVEL10 |
|---|---|---|---|---|---|---|---|---|---|
| Folder 1 | | | | | | | | | |
| | Leaf 1 | | | | | | | | |
| | | Doc 1 | | | | | | | |
| | | | Bkm1 | | | | | | |
| | | | | Bkm2 | | | | | |
| | | | | | Bkm3 | | | | |
| | | | | | | Bkm4 | | | |
| | | | | | | | Bkm5 | | |
| Folder 2 | | | | | | | | | |
| | Folder 3 | | | | | | | | |
| | | Folder 4 | | | | | | | |
| | | | Leaf 2 | | | | | | |
| | | | | Doc 2 | | | | | |
| | | | | | Bkm1 | | | | |
| | | | | | | Bkm2 | | | |
| | | | | | | | Bkm3 | | |
| | | | | | | | | Bkm4 | |
| | | | | | | | | | Bkm5 |
| Folder 5 | | | | | | | | | |
| | Leaf 3 | | | | | | | | |
| | | Doc 3 | | | | | | | |
| | | | Bkm1 | | | | | | |
| | | | | Bkm2 | | | | | |
| | | | | | Bkm3 | | | | |
| | | | | | | Bkm4 | | | |
| | | | | | | | Bkm5 | | |

*Table of Contents (Folder Level)*


Folder 1 ..... TOCRIGHTCOL
Leaf 1 ..... TOCRIGHTCOL
Doc 1 ..... TOCRIGHTCOL
Bkm 1 ..... TOCRIGHTCOL
Bkm 2 ..... TOCRIGHTCOL
Bkm 3 ..... TOCRIGHTCOL
Bkm 4 ..... TOCRIGHTCOL
Folder 2 ..... TOCRIGHTCOL
Folder 3 ..... TOCRIGHTCOL
Folder 4 ..... TOCRIGHTCOL
Leaf 2 ..... TOCRIGHTCOL
Doc 2 ..... TOCRIGHTCOL
Bkm 1 ..... TOCRIGHTCOL
Bkm 2 ..... TOCRIGHTCOL
Folder 5 ..... TOCRIGHTCOL
Leaf 3 ..... TOCRIGHTCOL
Doc 3 ..... TOCRIGHTCOL

In the third example, only one level of bookmarks will be included because the TOC level count starts from the invoked element.

**Example 3**: TOC Levels = 4 Bookmark Levels = 4

| LEVEL1 | LEVEL2 | LEVEL3 | LEVEL4 | LEVEL5 | LEVEL6 | LEVEL7 | LEVEL8 | LEVEL9 | LEVEL10 |
|---|---|---|---|---|---|---|---|---|---|
| Folder 1 | | | | | | | | | |
| | Leaf 1 | | | | | | | | |
| | | Doc 1 | | | | | | | |
| | | | Bkm1 | | | | | | |
| | | | | Bkm2 | | | | | |
| | | | | | Bkm3 | | | | |
| | | | | | | Bkm4 | | | |
| | | | | | | | Bkm5 | | |
| Folder 2 | | | | | | | | | |
| | Folder 3 | | | | | | | | |
| | | Folder 4 | | | | | | | |
| | | | Leaf 2 | | | | | | |
| | | | | Doc 2 | | | | | |
| | | | | | Bkm1 | | | | |
| | | | | | | Bkm2 | | | |
| | | | | | | | Bkm3 | | |
| | | | | | | | | Bkm4 | |
| | | | | | | | | | Bkm5 |
| Folder 5 | | | | | | | | | |
| | Leaf 3 | | | | | | | | |
| | | Doc 3 | | | | | | | |
| | | | Bkm1 | | | | | | |
| | | | | Bkm2 | | | | | |
| | | | | | Bkm3 | | | | |
| | | | | | | Bkm4 | | | |
| | | | | | | | Bkm5 | | |

*Table of Contents (Folder Level)*


Folder 4 ..... TOCRIGHTCOL
Leaf 2 ..... TOCRIGHTCOL
Doc 2 ..... TOCRIGHTCOL
Bkm1 ..... TOCRIGHTCOL
Bkm2 ..... TOCRIGHTCOL
Bkm3 ..... TOCRIGHTCOL
Bkm4 ..... TOCRIGHTCOL
Folder 2 ..... TOCRIGHTCOL
Folder 3 ..... TOCRIGHTCOL
Folder 4 ..... TOCRIGHTCOL
Leaf 2 ..... TOCRIGHTCOL
Doc 2 ..... TOCRIGHTCOL
Bkm1 ..... TOCRIGHTCOL
Bkm2 ..... TOCRIGHTCOL
Folder 5 ..... TOCRIGHTCOL
Leaf 3 ..... TOCRIGHTCOL
Doc 3 ..... TOCRIGHTCOL

*TOC Entry Links*

When a TOC entry is generated during final publishing, it is automatically hyperlinked to the page containing the TOC entry.

The destination is determined from the bookmark data that was used to create the TOC entry. The link area extends from the top left of the TOC link text column to the bottom right of the column. The link parameters are determined by the link publishing settings for the assembly.

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 publication overlays to individual documents, cover pages, and TOCs. 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 each of the following types of elements in your assembly:

— All TOCs

— All cover pages

— All content documents

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. |

| Attribute | Description |
|---|---|
| Default Overlay For | Move publishing elements to the Selected box to specify this as the default overlay for the selected publishing elements. At least one overlay must be defined as the default for Cover Pages, Documents, and TOCs. Available options: Cover Pages, Documents, TOCs |
| 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 publication level for headers, footers, tabs, cover pages, overlays, cross references, TOCs, 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 for both electronic and paper publications. These variables are set up by an administrator in data administration and specified with the assembly or in the paper or electronic 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 are used in the assembly for both electronic and paper publication. These variables are set up by an administrator and specified with the assembly or in the paper or electronic 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, tabs, TOCs, and volume names.

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

*Delimiters*

When creating a variable you should be aware of the 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, how tab text should be resolved at publishing time. 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 and cover pages. You should always use these delimiters to insert variables that will be resolved directly as page stamps on overlays, cover pages, and other published output.

*Create or Modify Variables*

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

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

   — Output Channel * (Move items from Output Channel Types to the Selected Output Channel Types box to apply the variable to the selected output channel types by default.)
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<br><br>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. 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. |
| Output Chan- nel* | Choose output channels to specify this as the default variable for the selected output channel types. Default is both, Electronic and Paper. |
| 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<br><br>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.) |
| Attribute | Description |
| 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

Link profiles enable you to define how links are handled during publishing. These profiles can be created in a Publishing Settings Library Template (PLT), enabling you to create publications by starting with the saved profile values; you do not have to respecify the settings.

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

— The System Profile is assigned automatically to all 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 publishes 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, or during a Paper publish, these settings are overwritten just like they are for interdocument links.

— When publishing to paper, the stamp generated for margin cross-reference links is created with the defined font type and font size.

***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 retargeted to another location.

The table of contents also always uses the System Profile for hyperlinks and the Table of Contents template for stamps. In all other situations, 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*

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.

For paper publications, a margin cross-reference stamp appears in the margin next to text that contains a hyperlink.

The value used to format this margin cross-reference is based on the Margin Cross Reference Text Format field in the Link Profiles. You can create the variable name for the links in this field and enter any other data you would like to appear in the final publication.

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<br>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:<br>— Default<br>— Open in the Same Window<br>— Open in a New Window<br>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. |

| Attribute | Description |
|---|---|
| Electronic Hyperlink Style* | Choose the style of the hyperlink displayed in the published output. Available options:<br>— Dashed Box<br>— None<br>— Solid Box<br>— Underline |
| Electronic Hyperlink Color | Choose the color of the hyperlink displayed in the published output. Default is Blue. Available options:<br>— Blue<br>— 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:<br>— Arial<br>— Arial Narrow<br>— Courier<br>— Times New Roman<br>— 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. |

## Mass Insert/Update Publishing Elements

Insert a Publish Element

Use the Mass Insert/Update Publishing Elements option to insert a special sheet or a table of contents in an assembly. Special sheets include cover pages, slip sheets, tab sheets, and tables of contents. This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).

To insert a special sheet or a TOC publishing element into an assembly:

1. Right-click the assembly element where you want to insert a publishing element and choose Mass Insert/ Update Publishing Elements.
2. In the *Mass Update Elements* window, choose a Publishing Element from the list:

| Publishing Element | Description |
|---|---|
| Table of Contents | Inserts a TOC for the selected assembly element or set of elements. |
| Tab Sheet | Inserts a tab sheet for the selected assembly element or set of elements. |
| Cover Page | Inserts a tab sheet for the selected assembly element or set of elements. |
| Slip Sheet | Inserts a slip sheet for the selected assembly element or set of elements. |

3. The *Mass Update Elements* window provides options to include the selected publishing element in one or more locations in the assembly:

| Publishing Element | Description |
|---|---|
| For this Element | Inserts the selected publishing element for the selected assembly element. |
| Volumes | Inserts the selected publishing element for each volume in the assembly. |
| Folders | Inserts the selected publishing element for each folder in the assembly. |
| Leaf Elements | Inserts the selected publishing element for each leaf element in the assembly. |
| Documents | Inserts the selected publishing element for each assigned document and document placeholder in the assembly. |
| Page Markers | Inserts the selected publishing element for each volume break in assigned docu- ments. |

4. The Publishing Settings field is required. Use the default, or select a different saved publishing setting in the list.
5. The Range Start field is available only when Table of Contents is the selected Publishing Element. Browse to select the location for the start of the TOC range.

Ennov InSight Publisher 7.3 Mass Insert/Update Publishing Elements

Delete a Publish Element

Use the Mass Insert/Update Publishing Elements option to delete cover pages, slip sheets, tab sheets, or tables of contents from an assembly. This procedure applies to both the Publishing Settings Library Template (PLT) and the Assembly Specific Publishing Settings Library (APL).

To delete a publishing element from an assembly:

1. Right-click the assembly element where you want to delete a publishing element and choose Mass Insert/ Update Publishing Elements.
2. In the *Mass Update Elements* window, choose a Publishing Element from the list:

| Option | Action |
|---|---|
| Table of Contents: | Deletes a TOC from the selected assembly element or set of elements. |
| Tab Sheet: | Deletes a tab sheet from the selected assembly element or set of elements. |
| Cover Page: | Deletes a cover page from the selected assembly element or set of elements. |
| Slip Sheet: | Deletes a slip sheet from the selected assembly element or set of elements. |

3. The *Mass Update Elements* window provides options to delete the selected publishing element from one or more locations in the assembly:

| Option | Action |
|---|---|
| For this Element: | Deletes the selected publishing element from the selected assembly element. |
| Volumes: | Deletes the selected publishing element from each volume in the assembly. |
| Folders: | Deletes the selected publishing element from each folder in the assembly. |
| Leaf Elements: | Deletes the selected publishing element from each leaf element in the assembly. |
| Documents: | Deletes the selected publishing element from each assigned document and document placeholder in the assembly. |
| Page Markers: | Deletes the selected publishing element from each volume break in assigned documents. |

4. The Publishing Settings field is required. Use the default, or select a different saved publishing setting in the list.
5. The Range Start field is available only when Table of Contents is the selected Publishing Element. Browse to select the location for the start of the TOC range.

# Chapter 4. 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

## Variable Values

You can define Publishing variables using text or other variables. A

variable value is made up of any combination of the following:

— Variable code delimiters

— Literal text

— Simple variable values

— Formatted variable values

Variable Code Delimiters

Variable codes must have a starting and ending tag. The starting variable code and ending variable code tags are defined within angle bracket delimiters: < and >.

### Starting Ennov InSight variable code: <my_variable_code>

— The first starting angle bracket is considered the left limit of the variable placeholder

— The top of the starting variable code is considered the upper limit of the variable placeholder

### Ending Ennov InSight variable codes are prefixed with an exclamation: <! my_variable_code>

— The last angle bracket of the ending variable code is considered the right limit of the variable placeholder. — The bottom of the ending variable code is considered the lower limit of the variable placeholder.

The variable code cannot contain spaces, however, spaces are permitted between the variable code and the delimiters. See Multi-Line variables - Alignment for more information about spaces and variable codes.

Literal Text

Any text that is not a variable value or formatted variable value is literal text.

The characters $ \ ( ) { } must be escaped with the backslash character (\) or 0x005C Unicode. For example, aaa resolves to bbb and aaa\(bbb\) resolves to aaa(bbb).

Simple Variable Values

A simple variable value is defined by a dollar sign ($) followed by the variable code of the variable whose value is to be substituted in the default format for the variable type.

For example, $ANAME resolves to the name of the current assembly; and Assembly name: $ANAME resolves to: Assembly name: My Assembly (where the name of the current assembly is My Assembly).

Formatted Variable Values

Use formatted variable values to calculate values or add the current date and time.

Formatted variable values must be resolved using either the $VARIABLE or ${VARIABLE} forms. No spaces or special (escaped) characters can exist in the formulas or variables names. Formatted variable values have the following general format: $format-name(simple-variable-value optional-param1 .. optionalparamN )

Within an overlay or cover page, all variable codes should be the same case, regardless of variable stamp type. The variable code cannot contain spaces, however, spaces are permitted between the variable code and the delimiters.

Variable Formats, Names, and Parameters

You can format variables to calculate values or add the current date and time.

| Formats | Names and parameters | Examples |
|---|---|---|
| Numeric | $Bates(simple-variable-value, width) $RomanNum(simple-variablevalue) $RomanNum(simple-variablevalue, width)<br><br>$RomanLowerNum(simple-variablevalue) $RomanLowerNum(simplevariable-value, width) simplevariable-value, "increment-step") $Reverse (simple-variable-value,<br><br>"increment-step") $Calculate<br><br>(expression) may contain numeric values and other simple variablevalues that are also numeric, characters + - * / () Where: width: numeric-param, minimum width of number. $Bates numbers are padded with 0. $Roman… numbers are padded with space. | On page 22 of a volume:<br><br>$Bates($VR, 6) resolves to<br><br>000022 $RomanNum($VR) resolves to XXII<br><br>$RomanLowerNum($VR, 6) resolves to<br><br>xxii<br><br>$Calculate - Calculates a start value by performing addition, subtraction, multiplication, or integer division. This function can accept any integer or variables that can be resolved as integers. The variables must be surrounded by curly braces ({}). Examples of variables are ARP and VT. This function can also accept the operands +, -, *, or /. $Calculate provides static value. It does the calculation |

| | | |
|---|---|---|
| | | once and no further increments happen based on a variable changing (LR in the following example). This example will create a page number defined by the LR variable plus 1:<br>$VAR = $Reverse($Calculate(${LR}<br>+1),"1")<br>$Reverse - Submits a negative integer as the increment for a dynamic attribute. This function accepts two parameters: any integer as Start Value, and a negative integer as an increment. The negative integer must be in double quotes. Using reverse numbering for a document of 100 pages, the first page number will be 100 and the last page will be 1. This function can be applied in a user-defined variable, as in this example for numbering a document to comply with Mexico submission requirements: $VOLRPGNUM =<br>$Reverse($Calculate(${ARP}+${VT}-<br>${VR}*2+1), "-1") |
| String | n/a | n/a |
| Formats | Names and parameters | Examples |
| Date/ Time | The entire date/time value is formatted in a single call.<br>$DateTime(simple-variable-value format-string)<br>Where: format-string: A date and time pattern. | $DateTime(${CT}, "EEE dd MMM yyyy<br>HH:mm:ss Z") |

Date and Time Patterns

Date and time formats are specified by date and time pattern strings. Within date and time pattern strings, unquoted letters from A to Z and from a to z are interpreted as patterns representing the components of a date or time string. Text surrounded by single quotes (') is interpreted as literal text. To include the text character for a single quote as literal text, use a double quote (''). All other characters are not interpreted; they are copied into the output string during formatting or matched against the input string during parsing.

The following pattern letters are defined (all other characters from A to Z and from a to z are reserved).

| Letter | Date or Time Component | Presentation | Examples |
|---|---|---|---|
| G | Era designator | Text | AD |
| y | Year | Year | 1996; 96 |
| M | Month in year | Month | July; Jul; 07 |
| w | Week in year | Number | 27 |
| W | Week in month | Number | 2 |
| D | Day in year | Number | 189 |
| d | Day in month | Number | 10 |
| F | Day of week in month | Number | 2 |
| E | Day in week | Text | Tuesday; Tue |
| a | AM/PM marker | Text | PM |
| H | Hour in day (0-23) | Number | 0 |
| k | Hour in day (1-24) | Number | 24 |
| K | Hour in am/pm (0-11) | Number | 0 |
| h | Hour in am/pm (1-12) | Number | 12 |
| m | Minute in hour | Number | 30 |
| s | Second in minute | Number | 55 |
| S | Millisecond | Number | 978 |
| Letter | Date or Time Component | Presentation | Examples |
| z | Time zone | General time zone | Pacific Standard Time; PST; GMT-08:00 |
| Z | Time zone | RFC 822 time zone | -0800 |

Pattern letters are usually repeated as their number determines the exact presentation:

— Text: If the number of pattern letters is four or more, the full form is used; otherwise a short or abbreviated form is used if available.

— Number: The number of pattern letters is the minimum number of digits, and shorter numbers are zero-padded to this amount.

— Year: If the number of pattern letters is two, the year is truncated to two digits; otherwise it is interpreted as a number.

— Month: If the number of pattern letters is 3 or more the month is interpreted as text; otherwise it is interpreted as a number.

— General time zone: Time zones are interpreted as text if they have names. For time zones representing a GMT offset value, the syntax GMT Sign Hours:mm is used, where Sign is + or -; Hours is H or HH and must be between 0 and 23; and $_{mm}$ must be between 00 and 59. The format is locale-independent and digits must be taken from the Basic Latin block of the Unicode standard.

— RFC 822 time zone: The four-digit time zone format of Sign Hours:mm is used, where Sign is + or -; and Hours is HH and must be between 00 and 23. Other definitions are as for general time zone.

## Examples

The following examples show how date and time patterns are interpreted in the U.S. locale. The date and time represented in these examples is 2001-07-04 12:08:56 local time in the U.S. Pacific Time time zone.

| Date and Time Pattern | Result |
|---|---|
| "yyyy.MM.dd G 'at' HH:mm:ss z" | 2001.07.04 AD at 12:08:56 PDT |
| "EEE MMM d "yy" | Wed Jul 4 '01 |
| "h:mm a" | 12:08 PM |
| "hh 'o"clock' a zzzz" | 12 o'clock PM Pacific Daylight Time |
| "K:mm a z" | 0:08 PM PDT |
| "yyyyy.MMMMM.dd GGG hh:mm aaa" | 02001.July.04 AD 12:08 PM |
| "EEE d MMM yyyy HH:mm:ss Z" | Wed 4 Jul 2001 12:08:56 -0700 |
| "yyMMddHHmmssZ" | 010704120856-0700 |

This example shows how the entire date/time value can be formatted in a single call:

$DateTime (simple-variable-value format-string)

Where: format-string: a date and time pattern

***Note:*** *$DateTime does not include the parameter lang-code for presenting date and time patterns in a language other than the designated default language.*

Example:

$DateTime (${CT}, "EEE dd MMM yyyy HH:mm:ss Z")

## Formal Grammar

The formal grammar presented below defines variable values in Extended BNF (Bakus-Naur Form):

— ' ' - literal value

— ( ) - group of values

— | - choice

— ? - multiplicity 0 or 1

— * - multiplicity 0 or more

— + - multiplicity 1 or more

— #xnnnn - 16 bit hexadecimal value

| Variable | Value | Comments |
|---|---|---|
| variable-value ::== | ( literal-string \| variable-evaluation \| function)* | |
| literal-string ::== | ( unicode-character \| character-escape )+ | /* allows $VAR or $FUNC(...) or ${VAR} */ |
| variable-evaluation :== | '$' ( variable-name \| '{' variable-name '}') | |
| variable-name :== | identifier | |
| function :== | function-name '(' parameters ') | |
| function-name :== | ( '$Bates' \| '$RomanNum' \| '$RomanLowerNum' ) | |
| parameters :== | variable-evaluation ( ',' digit+ )? | variable-evaluation must re-solve to a numeric value |
| identifier :== | letter ( letter \| digit )* | |
| character-escape ::== | '\' ( '$' \| '\' \| '(' \| ')' ) | |
| letter ::== | [ 'a' - 'z' ] \| [ 'A' - 'Z' ] \| '_' | |
| digit :== | ['0'-'9'] | |

| Variable | Value | Comments |
|---|---|---|
| unicode-character ::== | [ #x0020 - #x0023 ] \| [ #x0025 - #x0026 ] \| [ #x0029 - #x005B ] \| [ #x005D - #x007F ] \| | |

| | | |
|---|---|---|
| | [ #x00A0 - #xD7FF ] \| [#xE000 - #xFFFD ] | |

## Multi-Line Variables

You can create Multi-Line (multiline) variables within overlay or cover page templates by defining starting and ending variable codes within a Word document, which is then saved as a template.

The Multi-Line stamping functionality applies only to Assembly User-Defined Variables.

Assembly User-Defined Variables can be defined system-wide in Ennov InSight Data Administration. They can also be assembly specific, defined in Assembly Publishing Settings. For any other type of variable to be stamped as MultiLine, it must be nested inside an Assembly User-Defined Variable.

For an Assembly User-Defined Variable to be stamped as Multi-Line on a cover page or overlay, the Variable Stamp Type must be set to Multi-Line text in Ennov InSight Data Administration or in the Assembly Publishing Settings. In addition, the Variable placeholder (or attribute) on the pages of the Cover Page or Overlay template must include beginning and ending placeholders.

The area of the template defined by the starting and ending variable codes is the variable placeholder where the variable value will be inserted. Variable codes are surrounded with angle bracket delimiters.

The variable code cannot contain spaces. However, spaces are permitted between the variable code and the delimiters. — Starting variable code: <my_variable_code >

— Closing variable code: < !my_variable_code>

### Starting Ennov InSight variable code: <my_variable_code>

— The first starting angle bracket is considered the left limit of the variable placeholder

— The top of the starting variable code is considered the upper limit of the variable placeholder

### Ending Ennov InSight variable codes are prefixed with an exclamation: <! my_variable_code>

— The last angle bracket of the ending variable code is considered the right limit of the variable placeholder

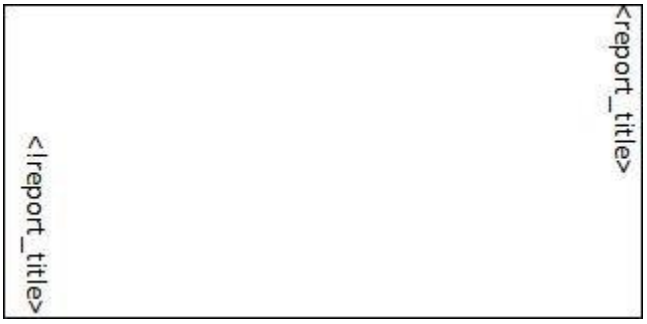
— The bottom of the ending variable code is considered the lower limit of the variable placeholder

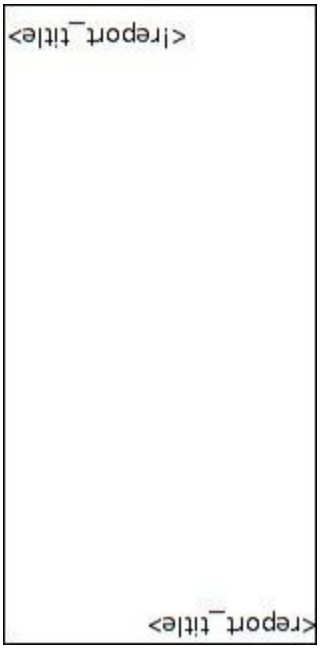


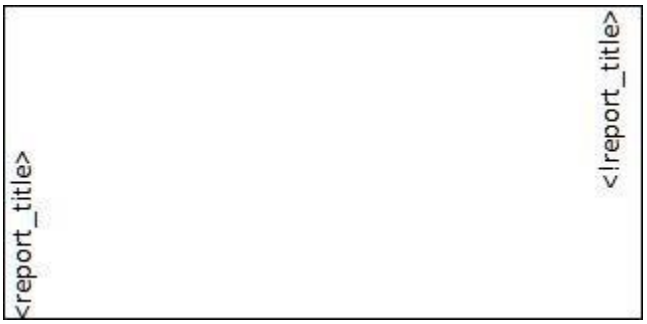

Variable Code Orientation

Variable codes can be included in the template at any 90-degree orientation: 0-, 90-, 180-, or 270-degrees. The system reads the variable codes from left to right within the orientation.

The starting variable code position and orientation determine the area - the inline and baseline - within which the system expects to find the ending variable code. The beginning of the ending variable code must be within the search area to be considered valid.




Multiple Values Within a Range

When multiple values exist within the same range, the closest ending variable code within the search area is used. In the following example the matching colors show the starting and ending variable codes found by the system:




Multi-line Variable Alignment

You can define the desired alignment for Multi-Line variables. All alignment is controlled using the starting variable code. Formatting and spacing are not applied by manipulation of the closing variable code.

To left-align the text within the variable placeholder limit:

— Enter one or more spaces between the end of the starting variable code and the closing angle bracket ( > ) of the starting variable code, with no spaces between the opening angle bracket (< ) and the starting variable code. Example: <report_title >

— No spaces between the variable code and either angle bracket. (The default variable alignment is left-align.) Example: <report_title>

To right-align the text within the variable placeholder limit:

— Enter one or more spaces between the opening angle bracket and the starting variable code, with no spaces between the closing angle bracket and the starting variable code. Example: < report_title>

To center align the text within the variable placeholder limit:

— Enter one or more spaces between the opening angle bracket and the starting variable code, AND enter one or more spaces between the end of the starting variable code and the closing angle bracket. Example: < report_title >

Font Format in Multi-Line Variables

Font style, case, color, and size can be controlled by applying effects to both the starting variable code and the ending variable code in Multi-Line variables.

When creating the Multi-Line variable in an overlay or cover page template in Word, apply the desired font style, case, color, and size to the starting and ending variable code of the variable. The starting and ending variable codes must be the same font style, case, color, and size.

If you apply bold, blue, 24pt font style to the variable code, the resulting output from the template will include that specified font formatting. The case of the variable code does not determine the case of the resulting output.

***Note:*** *Within an overlay or cover page, all variable codes should be the same case, regardless of variable stamp type.*

## 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, you must make sure the font used for the delimiters and variable codes is MSMincho or another font containing Japanese characters. Arial Unicode MS is one of the few fonts containing almost all Unicode characters.

## Font Formatting That Is Not Supported

Underlined text and highlighted text are not supported. Adobe Acrobat does not recognize these styles as part of the font.

If underlining or highlighting happens to be applied to a variable in a template: During rendering and publishing, the space used by the starting and ending variable tags will remain highlighted or underlined, but the resulting output in the remaining space will not display underlining or highlighting.

Line Breaks in Multi-Line Variables

Each line space is determined by the starting variable. Text can be wrapped at line break characters. Use the following characters:

— Hyphen

— Space

— Tab

— Carriage return (either a new line, or "/n")

If there are no line break characters in the variable, the text is truncated to fit each line - wrapped to fit the space outlined by the starting and ending variable codes. Hyphens are added at the end of each wrapped line.

## Conditions When Words Are Split for a Line Break

The word (or portion of a hyphenated or split word) is longer than the width of the text box. A word is defined as a string of non-space characters between a Space U+0020, a Tab 0x0009, a Line Feed 0x000A, or an Ideographic Space U+3000. The word will be split so the maximum amount with a trailing hyphen fits within the width of the box.

The word contains a non-leading or non-trailing hyphen U+002D. The word will be split at the hyphen. The following are also recognized as hyphens for text boxes:

— U+2010 - hyphen

— U+2012 - figure dash

— U+2013 - en dash

— U+2014 - em dash

— U+2212 - minus

## Variables Within Variables

Variables can contain other variables, or nested variables, as part of their definition. This enables you to concatenate and improve the spacing of text that is placed in published output.

— Variable text must be identical for the starting and ending tags of the variable. The variable text is case sensitive. — Within an overlay or cover page, all variable codes should be the same case, regardless of variable stamp type.

### Variables within variables: example 1

Place the following variables and text in the header or footer of a page in an overlay or cover page template:

Volume <VN >, Page < VR> of <VT >

This will be the result in the published output:

Volume 12 , Page 4 of 350

### Variables within variables: example 2

1. Place a single variable in the header or footer of the overlay or cover page template:

   <PAGE_NUM >

2. Next, add the variable PAGE_NUM to the *Variables* tab in the Assembly Publishing settings:

Volume $Bates($VN,6), Page $VR of $VT

This will be the result in the published output:

Volume 00012, Page 4 of 350.

Ennov InSight Publisher 7.3 Variables Within Variables

*Warning: Nested variables must not contain page number system variables, as they will not resolve and may cause publishing issues. Assume there is a variable placeholder on your overlays, as in this example:*

<PAGENUM >

On the Variables page in AsmPubSettings you cannot define:

PAGENUM = "Page $CHANNELPAGE"

CHANNELPAGE = "$LR of $LT" (Electronic variable)

CHANNELPAGE = "$VR of $VT" (Paper variable)

But you can define:

PAGENUM = "Page $LR of $LT" (Electronic variable)

PAGENUM = "Page $VR of $VT" (Paper variable)

### Channel Specific Variables

User-defined variables may have different values depending on the output channel being published. The

PAGE_NUM variable in example 2 (above), is suitable for paper publishing.

If the assembly is to be published in both paper and eCTD electronic channels, the PAGE_NUM variable above could be assigned to the paper output channel. Another PAGE_NUM variable should be assigned to the electronic output channel with a more appropriate value such as: ${LABBR}, Page $LR of $LT.

The *${}* notation is required so that the comma directly follows the Abbreviated Leaf name when the variable is resolved.

## User-defined Variable Values

You can define the value for specific variables.

| Variable Name | Variable Code | Variable Value | Description | Active Flag | Variable Type |
|---|---|---|---|---|---|
| Company Name | UCN | Company Name | Company name | Active | Single-line variable |
| Volume Name For-mula | VOLNAME | V$Bates($VN, 6) | | Active | Single-line variable |

Ennov InSight Publisher 7.3

User-defined Variable Values

## Ennov InSight Assembly Variable Values

You can define variables for Ennov InSight Assemblies in Data Administration.

The table lists all the variables that you can define for assemblies.

| Variable Name | Variable Code | Last User Updated | Last Changed Date | Description | Active Flag |
|---|---|---|---|---|---|
| Application Code | IAC | Username | d-m-y | Application code | Active |

| | | | | | |
|---|---|---|---|---|---|
| Application Internal Code | IIC | | | Application internal code | Active |
| Application Keywords | IAK | | | Application keywords | Active |
| Application Language | IAL | | | Application language | Active |
| Application Name | IAN | | | Application name | Active |
| Application Procedure Type | IPT | | | Application procedure type | Active |
| Application Type | IAT | | | Application type | Active |
| Assembly Category | IASC | | | Assembly category | Active |
| Assembly Keywords | IASK | | | Assembly keywords | Active |
| Assembly Name | INA | | | Assembly name | Active |
| Assembly Status | IASS | | | Assembly status | Active |
| Assembly Subcategory | IASSC | | | Assembly subcategory | Active |
| Country | ICN | | | Country name | Active |

| Name | | | | | |
|---|---|---|---|---|---|

Ennov InSight Publisher 7.3 Ennov InSight Assembly Variable Values

| Variable Name | Variable Code | Last User Updated | Last Changed Date | Description | Active Flag |
|---|---|---|---|---|---|
| Country Regulatory Authority | ICA | | | Country regulatory authority | Active |
| Event Code | IEC | | | Event code | Active |
| Event Keywords | IEK | | | Event keywords | Active |
| Event Name | IEN | | | Event name | Active |
| Event Sequences | IER | | | Event sequences | Active |
| Event Type | IET | | | Event type | Active |
| Event Variation Number | IEV | | | Event variation number | Activ |
| Product Dosage Form | IPF1 | | | Product dosage form | Active |
| Product Family Code | IPC | | | Product family code | Active |
| Product | IPN | | | Product family name | Active |

| | | | | | |
|---|---|---|---|---|---|
| Family Name | | | | | |
| Product Name 1 | IP1 | | | Product name 1 | Active |
| Product Name 2 | IP2 | | | Product name 2 | Active |
| Sequence Keywords | ISK | | | Sequence key-words | Active |
| Sequence Name | ISN | | | Sequence name | Active |
| Sequence Number/ Code | ISC | | | Sequence number/code | Active |
| Sequence Status | ISS | | | Sequence sta-tus | Active |
| Sequence Sta-tus Date | ISD | | | Sequence status date | Active |

Ennov InSight Publisher 7.3

Ennov InSight Assembly Variable Values

| Variable Name | Variable Code | Last User Updated | Last Changed Date | Description | Active Flag |
|---|---|---|---|---|---|
| Sequence Submission Filing Type | ISF | | | Sequence sub-mission filing type | Active |

# Repository Variable Values

You can define the values for Repository values.

| Variable Name | Variable Code | Document Type | Repository Attribute | Description | Active Flag |
|---|---|---|---|---|---|
| Repository Author | RSA | Null | Author | Author of the mapped document author; repeating attribute; returns a comma delimited list | Active |
| Repository Subject | RSS | Null | Subject | Subject of the mapped document | Active |

Ennov InSight Publisher 7.3

Repository Variable Values

Publishing Elements and Effects

# Chapter 5. Publishing Elements and Effects

Apply different changes on a published document using publishing elements and their effects.

To view publishing elements in the assembly tree, select Publishing Elements (located above the assembly tree). To hide publishing elements, clear the Publishing Elements option.

During volumization, the assembly is not locked. You must wait for volumization to complete before attempting to select any elements.

## Publishing Elements

— Special sheets - Special sheets enable you to organize and divide the sections of an assembly. You can insert, modify, or delete special sheets individually or in bulk wherever they are needed in the assembly.

— Tables of contents - In addition to being special sheets, tables of contents help reviewers to navigate through an assembly. You can insert, modify, or delete TOCs individually or in bulk within the assembly. Ennov InSight provides regulatory-compliant TOCs inserted in the assembly templates. Ennov InSight provides an ability to include links to TOCs. **Include Links to TOCs**

The Include Links to TOCs field defines which TOC elements will be included in the TOC in addition to the elements defined in the Tree Elements to Include in TOC field.

— If you create a new assembly from an assembly file or from an existing assembly, all selected TOCs are cleared. — When duplicating an element with a TOC, all TOCs are preserved.

— The display order of the links to TOCs will be the same as the TOCs order in the assembly.

— If a target TOC is deleted, the current TOC is automatically updated to exclude the link to the deleted TOC.

## Publishing Effects

— Overlays - Use an overlay to apply headers and footers on a published document.

— Page markers - Use a page marker to divide a document at a particular page. Special sheets, TOCs, and volume breaks can be inserted as page markers.

— Volumes - Use volume breaks to divide the assembly into logical sections. Each volume represents a unique output PDF intended for the paper output channel.

Ennov InSight Publisher 7.3

Repository Variable Values

# Chapter 6. Assemblies

## 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.

Ennov InSight supports the following types of assemblies:

— Standalone

— Sequence

— eCTD

— Supporting

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) **Creating Assemblies**

You can create an assembly by creating the folders, leaf elements and assigning documents, 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.

### Modifying Assemblies

You may want to change the attributes of an assembly, such as the name, the default binding rule, due date or description. In addition, you can set default folder and leaf attributes for the assembly and specify the referenced DTDs/schemas for assembly publishing.

### Building 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.

### Deleting Assemblies

Only an administrator can delete assemblies.

Assemblies

## 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 must have any of the following modules to perform assembly template activities:

— Electronic Lifecycle Publishing (ELP)

— Registered Document Analysis (RDA)

— Submission Planning and Tracking (SPT)

— Paper Review Publishing (PRP)

Create an Assembly Template

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

On the Ennov InSight New menu, click Assembly Template to create an assembly template from one of the following sources:

— New (Empty) - to create a new template containing no existing assembly elements

— Existing Template, Assembly or View - create a new template from an existing template or assembly, or from a current or active view

— Assembly File - create a new template from an assembly or view that has been exported as an XML file — Virtual Document - create a new template from a Documentum virtual document

Using a template, an existing assembly, or a virtual document 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. This 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.

***Note:*** *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*

You create an assembly template from an existing template, assembly, or a submitted or approved view.

The existing attribute values of the selected element is inherited to the new assembly template, minimizing the need for you to enter data.

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

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

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 Options* window, choose an assembly type from the Assembly Type to Search list, and click Next.
5. On the *Assembly Query Parameters* window, use Search to find an assembly, or you can choose an assembly from one of the other tabs: Assembly Templates, Standalone Assemblies, Sequence Assemblies, or Views.

   — Columns in the grid can be sorted in ascending or descending order using the options for each column heading.

   — Columns in the grid can be shown or hidden using the options for each column heading.

   — Move your pointer over a column heading and click the arrow next to the heading name to view the options.
6. Select an assembly and click OK.

   On the *Create Template* window, the assembly you selected appears in the Browse field.
7. 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. |

***Note:*** *If an Approved View is selected as the source assembly for creation, the Publishing Settings Library option will appear in place of the Use Source Assembly Publishing Settings Library option. Choose a Publishing Settings Library from the list.*

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

| Option |
|---|
| Retarget Copied Reference Leafs |
| Preserve Copied Reference Leafs |

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

***Note:*** *Priority numbers in eCTD 4.0 assembly correspond to the source assembly number and cannot be recalculated.*

*Use the Search Tab to Locate an Assembly*

When creating a new assembly template from an Existing Template, Assembly or View, you can 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 *Assembly Query Parameters* 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. |

***Note:*** *If an Approved View is selected as the source assembly for creation, the Publishing Settings Library option will appear in place of the Use Source Assembly Publishing Settings Library option. Choose a Publishing Settings Library from the list.*

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 Template from an Assembly File*

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

DMS.

They appear as placeholders, which prevents import failures if the referenced DMS does not exist in the current system. You must run a DMS synchronization immediately after importing to assign placeholders automatically to the DMS documents.

***Note:*** *You must have the appropriate security privileges to create an assembly template.*

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

1. On the home page, click New > Assembly Template.
2. On the *Create Template* page, click Assembly File.
3. To find the assembly file, click Browse and do either 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. For Use Source Publishing Settings Library, click Yes or No to indicate whether the new assembly template will use the publishing settings library that the source assembly uses.

| Option | Action |
|---|---|
| If you clicked Yes, then for Import Publishing Elements: | Click Yes or No to indicate whether the new assembly template will use the publishing elements that the source assembly uses. |
| If you clicked No for Use Source Publishing Settings Library, then: | Click the publishing settings library that the new assembly template will use. |

5. Save.

*Create an Assembly Template from a Virtual Document*

You can create a standalone assembly template based on an assembly exported to a Documentum virtual document.

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

To create a assembly template from a virtual document:

1. On the home page, choose New > Assembly Template.
2. On the *Create Template* page, click Virtual Document.
3. To find the virtual document, click Browse and do either of the following:

| Option | Action |
|---|---|
| On the *Documents* tab, navigate to the virtual document: | Click OK. |
| On the *Search* tab, find the virtual document: | Click OK. |

4. Click the publishing settings library to use with the assembly template.
5. Save.
6. Enter attribute values for the assembly template.
7. Click Create.

Assembly Template Attributes

You can use the assembly template attributes and descriptions to enter attribute values while creating assembly templates.

Attributes marked with an asterisk (*) are mandatory.

| Attribute | Description |
|---|---|
| Assembly Type* | Defines the output type of the Assembly. Required. The default eCTD. When set to eCTD, all folder names, file names, and paths are normalized during publishing.<br><br>When set to CN eCTD, all folder names, file names, and paths are normalized during publishing, but underscores are not replaced. |

| | |
|---|---|
| | When set to US eCTD, all folder names, file names, and paths are normalized during publishing, but capital letters and underscores are not replaced.<br><br>When set to Standard, all paths are based on the entries for the output folder and file. All output files will maintain the original context of the source:<br><br>— Source document name = Tabular_Listings-1.pdf<br><br>— eCTD name = tabular-listings-1.pdf<br><br>— CN eCTD name = tabular_listings-1.pdf<br><br>— US eCTD name = Tabular_Listings-1.pdf<br><br>— Standard name = Tabular_Listings-1.pdf |
| 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. |
| Auxiliary Output Location | Alternate location for saving a published version. |
| 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 into 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. |

| Attribute | Description |
|---|---|
| Default Binding Rule | The binding rule that will be applied to documents from the DMS assigned to assemblies created using the template.<br><br>— Bind to Label binds documents to a label you choose.<br><br>— Bind to Status binds documents to a status you choose.<br><br>— 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. |
| 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. |
| 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 available for editing. |
| 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. |
| Paper Output Location | The specified storage location for paper output. |
| Reference Location | (SPT only) The location within the DMS of a reference to the assembly. If you try to create a reference location in a repository folder to which you do not have access, a message informs you that you do not have permission to write to the folder. This field is populated automatically when Set Reference Location is selected from the More menu, after an Assembly has been created. |
| Reference Location Name | The name of the reference object. |
| 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. |

| Attribute | Description |
|---|---|
| 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 also 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.

Delete an Assembly Template

Only an administrator user can delete an assembly template.

To delete an assembly template:

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

## Create an Assembly

Create an assembly to align with regulatory compliance and data integrity.

When you create a new assembly based on a template, an existing assembly, or an assembly file, the new assembly may be generated with settings that are different from your source file. It is a best practice to review the settings of your new assembly and manually adjust the settings as necessary.

***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.*

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:

Ennov InSight Publisher 7.3 Create an Assembly

| Element | Description |
|---|---|
| Cover Page element | The planned number of pages is set to null. |
| TOC element | The comment, description, and keywords are set to null. |
| Document | — Output channel is reset to the default: both Paper and Electronic. |

| | |
|---|---|
| | — Include in page numbering is reset to YES (if it was set to NO in the existing assembly).<br>— Category is set to null, rather than the entered value from the existing assembly. |
| Volumes | Volumes may be missing from your new assembly. |

New Assembly Created from an Assembly File

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 modified:

| Element | Description |
|---|---|
| **Publishing settings** | — Cover Pages – The Cover Pages template is reset to null.<br>— TOCs – The TOC definition file is reset to null.<br>— Overlays – The Overlays template is reset to null. |
| In the new Assembly | — Custom overlays is reset to the default, and Inherit Properties from Publishing Settings is set to YES.<br>— Some volumes may be missing from your new assembly. |

***Note:*** *When an assembly is created from an assembly file, the locations included in the assembly file that do not match the repositories in Ennov InSight Technical Administrator will not be saved.*

## Standalone Assemblies

A standalone assembly is an assembly that is not associated with an application or sequence.

It has no regulatory context and is not slated for submission to a specific agency, or part of an eCTD life cycle.

Examples of standalone assemblies are reports, eCTD modules that will be submitted later, and assembly templates that are used to create assemblies submitted in different countries and regions.

After you have created a standalone assembly it becomes available in lists of standalone assemblies. The assembly is also available in various queries.

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

***Note:*** *Only authorized users can access the assemblies.*

Create an Empty Standalone Assembly

An empty standalone assembly provides the structure for a new standalone assembly without existing documents. You can use the Home page to create a standalone empty assembly. You can also use the Create eCTD wizard.

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

To create an empty standalone assembly:

1. On the home page, click New > Standalone Assembly.
2. On the *Create Assembly* page, select New (Empty) to create an empty assembly.
3. Click the publishing settings library to use with the assembly.
4. Save.
5. Enter attribute values for the assembly. See *Assembly Attributes*.

   ***Note:*** *The Created From attribute is always blank.*
6. Click Create.

Creating a Standalone Assembly from a Template, Assembly, or View

You can use the Home page to create an assembly based on a template, assembly, submitted, or approved view. You can also use the *Create eCTD* wizard.

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

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

1. On the home page, click New > Standalone Assembly.
2. On the *Create Assembly* page, click Existing Template, Assembly or View.
3. Click Browse.
4. Find and select the template, assembly, or view. Do either of the following:

| Option | Action |
|---|---|
| On the Search tab: | Use the *Search Assembly* wizard. |
| Option | Action |
| 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 can select only the assembly root. You cannot create an assembly from any other node.*
5. For Use Source Publishing Settings Library, click Yes or No to indicate whether the new assembly will use the publishing settings library that the source assembly uses.

| Option | Action |
|---|---|

| | |
|---|---|
| If you clicked Yes, then for Import Publishing Elements: | Click Yes. |
| To indicate whether the new assembly will use the publishing elements that the source assembly uses: | Click No. |
| If you clicked No for Use Source Publishing Settings Library: | Click the publishing settings library that the new assembly will use. |

6. 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.
7. Save.
8. Enter attribute values for the assembly.
9. Click Create.

Create a Standalone Assembly from an Assembly File

When you import an assembly file, the documents in the file are not automatically synchronized with the mapped DMS.

They appear as placeholders which 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.

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

You can use the Home page to create a standalone from an assembly file. You can also use the Create eCTD wizard.

To create a standalone assembly based on an assembly file:

1. On the home page, click New > Standalone Assembly.
2. On the *Create Assembly* page, click Assembly File.
3. To find the assembly file, click Browse and do either of the following:

| Option | Action |
|---|---|
| On the Documents tab, navigate to the assembly file: | Click OK. |

| Option | Action |
|---|---|
| On the Search tab, find the assembly file: | Click OK. |

4. For Use Source Publishing Settings Library, click Yes or No to indicate whether the new assembly will use the publishing settings library that the source assembly uses.

| Option | Action |
|---|---|

| | |
|---|---|
| If you clicked Yes, then for Import Publishing Elements: | Click Yes. |
| To indicate whether the new assembly will use the publishing elements that the source assembly uses: | Click No. |
| If you clicked No for Use Source Publishing Settings Library: | Click the publishing settings library that the new assembly will use. |

5. Save.

Create a Standalone Assembly from a Virtual Document

You can use the Home page to create a standalone assembly based on a virtual document. You can also use the *eCTD* wizard.

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

To create a standalone assembly based on a virtual document:

1. On the home page, choose New > Standalone Assembly.
2. On the *Create Assembly* page, click Virtual Document.
3. To find the virtual document, click Browse and do either of the following:

| Option | Action |
|---|---|
| To search for a virtual document: | On the Documents tab, navigate to the virtual document, and click OK. |
| To search for a virtual document: | On the Search tab, find the virtual document, and click OK. |

4. Click the publishing settings library to use with the assembly.
5. Save.
6. Enter attribute values for the assembly. See *Assembly Attributes*.
7. Click Create.

## 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 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

You can create an empty sequence assembly from the View Sequence page.

You can create an empty sequence assembly from the View Sequence page. You can also use the Create eCTD wizard.

***Note:*** *You must have the 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 the Assembly tab.
3. Click Create Assembly.
4. On the *Create Assembly* page, select New (Empty) to create an empty assembly.
5. Click the publishing settings library to use with the assembly.
6. Save.
7. Enter attribute values for the assembly.

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

8. Click Create.

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

You can create an empty sequence assembly from a template, assembly, or a submitted or approved view using the the

*View Sequence* page.

You can also use the *Create eCTD* wizard.

***Note:*** *You must have the 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. Find and select the template, assembly, or view. 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.*

6. For Use Source Publishing Settings Library, click Yes or No to indicate whether the new assembly will use the publishing settings library that the source assembly uses.

| Option | Action |
|---|---|
| For Import Publishing Elements: | If you clicked Yes initially, then click Yes. |
| To indicate whether the new assembly will use the publishing elements that the source assembly uses: | Click No. |
| For Use Source Publishing Settings Library: | If you clicked No, then click the publishing settings library that the new assembly will use. |

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. Click Create.

Create a Sequence Assembly from an Assembly File

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

DMS.

They will appear as placeholders which 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.

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

You can use the *View Sequence* page to create a sequence assembly from an assembly file. You can also use the *Create eCTD* wizard.

To create a sequence assembly based on 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 either 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. For Use Source Publishing Settings Library, click Yes or No to indicate whether the new assembly will use the publishing settings library that the source assembly uses.

| Option | Action |
|---|---|
| If you clicked Yes, then for Import Publishing Elements: | Click Yes. |
| To indicate whether the new assembly will use the publishing elements that the source assembly uses: | Click No. |
| If you clicked No for Use Source Publishing Settings Library: | Click the publishing settings library that the new assembly will use. |

7. Save.

Create a Sequence Assembly from a Virtual Document

You can use the View Sequence page to create a sequence assembly based on a virtual document. You can also use the *Create eCTD* wizard.

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

To create a sequence assembly based on a virtual document:

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 Virtual Document.
5. To find the virtual document, click Browse and do either of the following:

| Option | Action |
|---|---|
| On the Documents tab, navigate to the virtual document: | Click OK. |

| | |
|---|---|
| On the Search tab, find the virtual document: | Click OK. |

6. Click the publishing settings library to use with the assembly.
7. Save.
8. Enter attribute values for the assembly. See *Assembly Attributes*.
9. Click Create.

## Create Assemblies Based on Sequences

You can create an assembly template, a standalone assembly, 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.

Importing 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 or approved sequences from the existing application. Submitted sequences have been submitted to the regulatory agency. Approved sequences have been approved by the regulatory agency.

Only Registered Document Analysis (RDA) module users can create a new application using an existing application's approved sequences.

## eCTD Assemblies

Ennov InSight includes ICH-compliant eCTD templates. The assembly templates include all sections defined by the CTD/eCTD specification.

Folder types have been preconfigured to provide the metadata for specific headings in the eCTD that require additional information, for example: drug substance, drug product, excipients, clinical indication, and regional administrative information.

In Modules 4 and 5, only one sample study report is included in the first study report section. You should remove any sections that are not applicable to an individual submission. If you do not remove them, the published XML will include their corresponding elements. This XML will be valid against the DTD. However, these sections are not applicable and you should remove them prior to publishing for clarity per agency recommendations.

Typical ways to use the eCTD templates:

Ennov InSight Publisher 7.3 Create Assemblies Based on Sequences

— 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.

When performing an import of an existing eCTD, the import progress is reported in the server.log file. The Job Request Details also show messages about each sequence that is imported. The administrator can monitor the server log to follow the overall progress of the import and see more detailed messages, such as timestamps and Oracle information.

You can also create an eCTD assembly using the Create eCTD wizard.

While you are allowed to include more than one set of DTDs, you must be sure to include only one DTD of each type. For example, do not include two versions of an EU Module regional DTD. This may cause errors during publishing.

## Create Assemblies by Importing Assembly Template

Importing an assembly template enables you to create a new assembly and reuse the existing assembly values.

### Prerequisites

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

create an assembly by importing an assembly template:

1. Navigate to the Assembly tab.
2. Click Create Assembly.
3. Choose an appropriate option:

| Option | Description |
|---|---|
| Existing Template, Assembly or View | Creates a new assembly from an existing template or assembly, or from a current or active view. |
| Assembly File | Creates a new assembly from an assembly or view that has been exported as an XML file. |
| Virtual Document | Creates a new assembly from a Documentum virtual document. |

4. Choose an appropriate option from below and perform the corresponding steps under Description for publishing settings library.

Create Assemblies by Importing Assembly Template

| Option | Description |
|---|---|
| Existing Template, Assembly or View | a. Click Browse to find and select the template, assembly, or view using the Search Assembly Wizard.<br>b. On the *Search Options* window, choose an assembly type from the Assembly Type to Search list, and click Next.<br>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, Standalone AssembliesSequence Assemblies, or Views.<br>d. Select an assembly and click OK.<br>e. Choose a Use Source Assembly Publishing Settings Library option:<br>— Yes - the new assembly inherits the Publishing Settings Library used in the source assembly template that you have selected.<br>• Choose a Import Publishing Elements option:<br>■ Yes - the new assembly will use the publishing elements that the source assembly uses.<br>■ No - the new assembly will not use the publishing elements that the source assembly uses.<br>— No - select a PLT from the Publishing Settings Library field that appears when you choose No.<br>f. In the Retarget Copied Reference Leafs field, set the option for reference leafs:<br>— 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.<br>— 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. |

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Create Assemblies by Importing Assembly Template

| Option | Description |
|---|---|

| | |
|---|---|
| Assembly File | a. To find the assembly template file, click Browse and do one of the following:<br>— On the *Documents* tab, navigate to the assembly template file and click OK. — On the *Search* tab, find the assembly file and click OK.<br>b. Choose a Use Source Assembly Publishing Settings Library option:<br>— Yes - the new assembly inherits the Publishing Settings Library used in the source assembly template that you have selected.<br>• Choose a Import Publishing Elements option:<br>■ Yes - the new assembly will use the publishing elements that the source assembly uses.<br>■ No - the new assembly will not use the publishing elements that the source assembly uses.<br>— No - select a PLT from the Publishing Settings Library field that appears when you choose No. |
| Virtual Document | a. To find the virtual document, click Browse and do either of the following:<br>— On the *Documents* tab, navigate to the virtual document and click OK. — On the *Search* tab, find the virtual document and click OK.<br>b. Click the publishing settings library to use with the assembly template. |

1. Click Save.
2. On the *Create Assembly* page, specify the name of the assembly.
3. Click Create.

   The assembly template is imported into the new assembly.
4. On the *Assembly Attributes* page, select the Publishing Setting Library icon.
5. On each settings page, modify the settings, if required, and click Save.

## Supporting Assemblies

A supporting assembly is an assembly that is part of an application, but is not part of an eCTD life cycle for that application.

You can create as many supporting assemblies as you need. Circumstances when you might want to use supporting assemblies could include: making paper copies for CTD reviewers, or creating study reports.

For example, if you need to create a CTD reviewer copy in addition to the eCTD sequences, you can copy the publishing view of the eCTD sequence to a supporting assembly, and then publish to paper from the supporting assembly.

Ennov InSight Publisher 7.3 Supporting Assemblies

Create a Supporting Sequence Assembly

Use this procedure to create a supporting sequence assembly. You can import an assembly, add volumes, files, and folders.

To create a supporting sequence assembly:

1. Select the new assembly and click Assembly. Two options are available for the new assembly:

| Option | Description |
|---|---|
| Create Working Assembly | Use this option to create a life cycle sequence assembly. A working assembly contains everything previously dispatched to the authority, minus anything replaced or withdrawn. It also includes anything incremental to that sequence that is planned but not yet submitted. |
| Create Supporting Sequence Assembly | Use this option to create a supporting sequence assembly. This type of assembly may be created within an Application alongside an existing Sequence Lifecycle without having to be part of that life cycle. The supporting sequence assembly will have no relationship to the previous life cycle, and will not contain any of the previously dispatched folders or files. You may use this type of assembly for any publications that are related to the Application, for example: paper submissions, or study reports. |

2. In the Assembly tab, click Create Supporting Sequence Assembly.
3. Complete the necessary information and click Create.

   ***Note:*** *It is recommended that you name the supporting sequence assembly appropriately to identify its relationship to the eCTD.*

   The *Create Assembly* page appears.
4. The new supporting assembly is created, and you can now import an assembly, add volumes, files, and folders.

## Assembly Attributes

You can use the attribute descriptions to enter the attribute values while creating the assemblies or assembly plans.

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

Ennov InSight Publisher 7.3 Assembly Attributes

| Attribute | Description |
|---|---|
| Assembly Type | Defines the output type of the Assembly. Required. The default eCTD.<br>— When set to eCTD, all folder names, file names, and paths are normalized during publishing. |

| | |
|---|---|
| | — When set to US eCTD, all folder names, file names, and paths are normalized during publishing, but capital letters and underscores are not replaced.<br>— When set to Standard, all paths are based on the entries for the output folder and file. |
| 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. |
| Auxiliary Output Location | Alternate location for saving a published version. |
| 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 |
| Created From | The name of the Assembly that was used to create the current Assembly. — In life cycle, this will be the previous sequence.<br>— 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 that will be 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 | A description of the Assembly. |
| Due Date | The date the Assembly is due to be complete for submission. |
| Electronic Output Location | The location for the electronic published output to be stored. |
| Keywords | Keywords that apply to the specific Assembly. |

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Assembly Attributes

| Attribute | Description |
|---|---|

| | |
|---|---|
| Last Repository Data Retrieval | The date the last DMS Sync was executed. |
| Lock Indicator | Indicates whether the Assembly is locked. If the Assembly has had the Standard lock applied, set to Yes. |
| Name | The name of the Assembly; appears in the Assembly Tree. *Required* |
| Owner | The owner of the assembly. Default = current user. |
| Paper Output Location | The location for the paper published output to be stored. |
| Reference Location | SPT Only. The location within the DMS of a reference to the assembly. This field is populated when the user selects "Set Reference Location". |
| Reference Location<br><br>Name | The name of the reference object. |
| Status | The current Status of the Assembly, controlled by the Assembly Status<br><br>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 |
| Subcategory | The Assembly low level category. The available options depend on the Category selected. |
| Version Number | The version of the Assembly. SPT only. Default = 1.0, CURRENT |

## Assembly Elements Context Menu

You can 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.

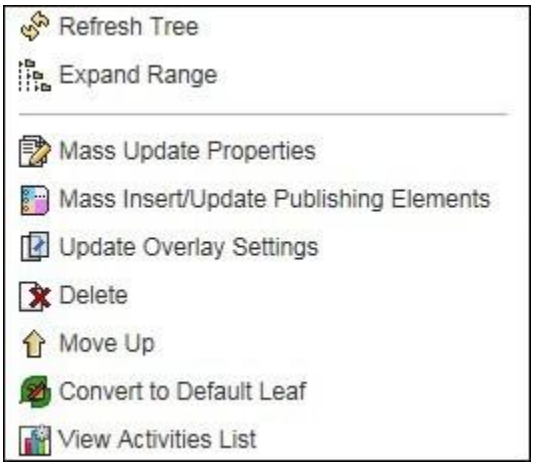


Figure 4: Context menu for a reference leaf node

## 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

## TOC Node Context Menu

The Move Left and Move Right options availability depends on the number of publishing elements assigned to the assembly tree element and the TOC position within this range. For example, if the TOC element is the first in the range, then the Move Left option will not be presented in the context menu.

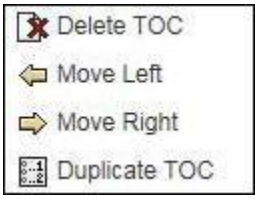



Figure 7: Context menu for a TOC node

## Page Marker Node Context Menu




Figure 8: Context menu for a page marker node

## Special Sheet Node Context Menu

Includes cover page, tab sheet, and slip sheet.

The Move Left and Move Right options availability depends on the number of publishing elements assigned to the assembly tree element and the special sheet position within this range. For example, if the special sheet element is the

first in the range, then the Move Left option will not be presented in the context menu. Includes cover page, tab sheet, and slip sheet.




Figure 9: Context menu for a special sheet node

## Auto Populate Output Folder

This option enables the automatic population of the Output Folder field when folders, virtual documents, Veeva binders, or Veeva sections are assigned to the Assembly by using the DMS Browse window (such as when adding site folders).

The value used to populate this field is the name of the DMS folder, virtual document, binder, or section. This field will also be updated automatically in any nested folders. This preserves an internal structure and naming convention in published output.

You can set the Auto Populate Output Folder attribute for an existing assembly by editing the assembly attributes page or when creating a new assembly. You can also set this attribute on a Standalone Assembly, Sequence Assembly, or Template.

The following rules apply to the Auto Populate Output Folder option:

— An Assembly created using the Create eCTD wizard will inherit the Auto Populate Output Folder attribute from the value in the Module 1 template selected in the wizard.

— An Assembly created from a Submitted view will inherit the Auto Populate Output Folder attribute from the value in the Submitted view.

— An Assembly/Template created from another Assembly/Template will inherit the Auto Populate Output Folder attribute from the source Assembly/Template

— An Assembly created from an Approved view or a virtual document will have the Auto Populate Output Folder attribute set to No.

— An Assembly created with eCTD Import will have the Auto Populate Output Folder attribute set to No.

— The value of the Auto Populate Output Folder attribute will be preserved during Export to Assembly File/ Import from Assembly File.

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 to any module in the Assembly. (These repositories include Secure File System and Documentum). You can also assign Veeva binders or Veeva sections to any module in the Assembly.

— When contents are assigned, the Output Folder attribute is populated on the folders and subfolders that are assigned to the Assembly.

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Auto Populate Output Folder

— 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 virtual document descendants is created. The Output Folder attribute is populated on the folder and all subfolders created.

## Modify Assembly Attributes

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

## Assembly Structure

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.

As you add elements to the assembly tree, consider the following rules:

— An assembly can have major and minor divisions. The major and minor settings can be found 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 secure 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.

— To make an assigned document or document placeholder the child of another document or document placeholder, you must drag it from the document browse dialog box or promote or demote it.

— 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 one 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 nonadjacent 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 document's version number.

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Modify Assembly Attributes

— When creating a new assembly, an error may occur if anything but the root is selected when previewing the assembly or template source.

Assembly Structure Table

The following guidelines may help you build an assembly.

| This element | Can be added to this element |
|---|---|
| Folder | Assembly root, other folders and leaf elements |
| Leaf element | Assembly root and folders |
| Reference Leaf element | Assembly root and 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 root, folders and leaf elements |
| Document placeholder | Assembly root, folders and leaf elements |

Automatic Leaf Creation

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

Based on the Create Leaf File attribute for an assembly, leaf creation behaves as follows when you add documents to the assembly.

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.

— Automatically, the Leaf Status for each leaf element is set to the default Leaf Status value configured in *Data Administration*.

— The Use Native File attribute of a new leaf is set to Yes if your system administrator configured the extension for the corresponding document to generate this attribute value. Your system administrator can configure the extension in the dms.nativeLeafExtension property in the insight.var file. You can extend the list by modifying the insight.var file. The following example shows the list of extensions that are set forEnnov

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. Example:

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

Ennov InSight Publisher 7.3 Assembly Structure

When the Create Leaf Element option is set to No and you drag a document to the root or a folder, you can expect the following behavior:

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

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

Regardless of whether leaf elements are created automatically: when you drag a document or documents to a leaf, they are assigned 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 extension on the leaf file name is stripped and Ennov InSight later assigns the appropriate extension during publishing.

Reference Leaf Elements

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

Reference leaf element features:

— 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 cannot point to another leaf in a standalone 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 life cycle or supporting sequence. — 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.

### Unlocked Submitted View: Assembly Plan

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

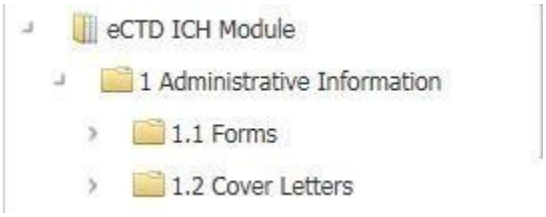
— Entity Security > Submission Plans set to at least WRITE.

— Entity Security > Sequence Assemblies set to ADMIN.

## 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

You can 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

You can 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, click the folder you want to modify. The *Edit Folder* page appears.
2. In the Edit Folder view, click  .
3. Change attributes.
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. |
| Description | The description for the folder. |
| Field | Description |
| Division | Indicates if the folder is a major or minor division. |
| Due Date | The date all content within the folder is due. |
| Extension | The type of folder within the Assembly. Additional folder types open up additional attributes on the folder. Default = Default |
| Force New Volume | Indicates if a new volume should be created at this folder during volumize. Default = No |
| Keywords | The keywords for the folder. |

| | |
|---|---|
| Last Repository Retrieval Date | The last date a DMS Sync was run against this folder. |
| Leaf Id | A unique ID for the folder, generated by the system. |
| 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. |
| Owner | The owner of the folder. Default = current user |

*Folder Element Type Attributes*

You can enter values for additional eCTD attributes in the following ICH eCTD M2-5 folders:

— 2.3.S Drug Substance - Substance, Manufacturer

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

— 2.7.3 Summary of Clinical Efficacy - Indication

— 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

Folder Element Types

You can change the element type for a folder in an eCTD assembly.

This enables you to specify additional publishing attributes for study tagging files (STFs), clinical indications, and other types of data required by the eCTD specification and by regulatory agencies. These attributes are used to create the XML backbone for eCTD submissions.

*Modify a Folder Element Type*

You can make changes to the Folder Type. The changes you make to the attributes for an extended element in a previous sequence assembly do not affect the current sequence.

You must have the appropriate security privileges to modify a folder element type.

To change the folder type:

1. On the assembly tree, select the folder you want to change.
2. In the More list, click Change Type  .
3. On the *Modify Element Type* dialog box, click the Extension arrow and choose a folder type.
4. After you choose a folder type in the Extension list and click OK, attributes specific to the folder type you chose appear on the *Folder Attributes* page.
5. To specify values for the attributes, click Edit.

Duplicate a Folder

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

***Note:*** *You must have appropriate security privileges to duplicate folders.*

To duplicate a folder:

1. Right-click the folder that you want to duplicate and select Duplicate.
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. Automatically, each leaf element within the duplicated folder is 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. Before locking the folder, keep in mind the following:

— 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, and special sheets. It will not lock Volumes or TOCs. Volumes have their own locking function, and TOCs cannot be locked.

— 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.

*Unlock a Folder*

You can unlock folders in an assembly tree from the working or publishing views, and enable users to modify the folders.

To unlock a locked folder:

1. Click a link for the assembly that has the locked folder.
2. Right-click the root and choose Expand All.
3. Click the locked folder you want to unlock.

5. Click OK when you are prompted to confirm the unlock.

4.

Click



.

***Note:*** *When you unlock a parent folder, the first child of the last child folder of the parent folder is unlocked.*

Delete a Folder

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

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

To delete a folder:

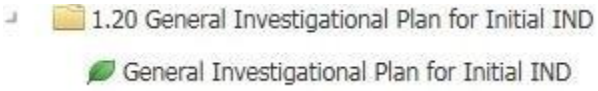
1. Right-click the folder you want to delete and choose Delete. A message prompts you to confirm the deletion.
2. Click OK.

The folder and its contents are deleted.

## Leaf Elements

A leaf element is a collection of individual, 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

You can add a leaf element to an assembly under a folder.

***Note:*** *You must have the appropriate security privileges to add leaf elements to an assembly.*

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

When a document is assigned to an assembly, Ennov InSight automatically creates a leaf under an assembly section. For a leaf to be auto-created when assigning a document from a Document Management System (DMS) repository or a secure file system, the value of the assembly attribute Create Leaf Elements must be set to Yes. 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.

*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 of the Name, Abbreviated Name, and the Output File attributes from an 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 |

*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 attribute descriptions help you to enter the appropriate attribute values while creating a leaf.

The table lists all the attributes that are available to you, while creating a leaf.

| Attribute | Description |
|---|---|
| Abbreviated Name | Short name for the leaf. |
| Actuate | Reserved eCTD attribute. |
| Application Version | The version of the PDF application (for example, PDF Ver 1.2). |
| Change Modified Leaf | Enables you to select and add attributes based on another leaf. When you select an assembly to use, you can click the Search tab to find the assembly that you want. See *Searching for an Assembly*. |
| Clear Modified Leaf | Clears leaf attributes. |
| Comments | Notes for reference. |
| Creation Date | The date the leaf was created. |
| Description | Text that describes the leaf. |
| Due Date | The completion date of a leaf. |
| Extension / Leaf Type | Defines the type of leaf in the Assembly. |
| Font Library | Commercial font or font set used to create the file. |
| Keywords | Words you can use to search for a leaf. |
| Language | The primary language that will be used for your submission. |

| Attribute | Description |
|---|---|
| Leaf ID | Unique number that identifies the leaf; read-only value. |
| Leaf Status | Leaf status for the specific leaf. The values available for selection are all active leaf statuses from Data Administration, the default status is Planned. |
| Leaf Type | Type of leaf, read-only value. |

| | |
|---|---|
| Modified File | Name of changed file. |
| Modified Leaf | Name of changed leaf. |
| Modified Leaf Sequence | Name of changed leaf sequence. |
| Name | Name of the leaf. |
| Number | A number used internally to identify a leaf. |
| Operation | An activity performed on a leaf (append, delete, replace, new). |
| Output File | Relative path and/or the file name of the published output for the leaf.<br>— The value you enter cannot exceed 500 characters.<br>— Avoid extra periods in the file name, such as output.file.doc, as this can result in an invalid file name in a DMS.<br>***Note:*** *For a reference leaf, this attribute is presented as a read-only field.* |
| Role | Indicates the regulatory role. |
| Show | Action used to show an activity performed on a leaf (embed, new, none or other). |
| Title | The title for the submission. |
| Use Native File | Determines whether to use source files or renditions for publishing.<br>— 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.<br>— 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. |
| Version | To comply with Appendix 6 of the ICH eCTD Specification, this attribute is used to indicate the internal version number or version identification for the file. However, for leaf elements pointing to STF files, this attribute is used to identify the version of the STF specification against which they are constructed, for example, STF Version 2.2 |

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

For submission 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 any children that the leaf element has and convert the leaf.
3. Click OK.
4. On the next page, find the tab that displays the assembly that has 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 leaf appears in the assembly tree as a reference leaf with a reference leaf icon.

***Note:*** *The Leaf Status attribute is not presented on the attributes page of a reference leaf.*

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.

Deleted Leafs

When you delete (withdraw) a leaf that was submitted in an earlier sequence, you are indicating that the leaf should be removed from the submitted view when the current sequence assembly is added to life cycle. — The deleted leaf is hidden in the working view.

— A new leaf with an operation of Delete is displayed in the assembly tree.

— 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 deleted leaf.

— You cannot replace, append or delete the new leaf.

— You can revert the new leaf to undo the deletion.

— If the deleted leaf had content, the new leaf has 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 deleted leaf. The modified file name is constructed as follows: Modified Leaf shows the leaf that is currently being modified by this leaf in the life cycle. Modified Sequence shows the sequence that is currently being modified by this leaf in the life cycle. 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 life cycle.

— Set Modified File is available in a working assembly to administrators, and in a standalone assembly to everyone. This allows the modified file to be manually set.

— Clear Modified File is available to administrators in a working assembly, and everyone in a standalone assembly. This allows the modified file to be manually cleared.

— You cannot change or move the new leaf, nor can you add elements to the new leaf.

— Deleted leaf elements are hidden in the submitted view after the current sequence assembly is added to life cycle.

*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.*

*— If a volume break resides on the leaf you are deleting, you should move the volume break to the closest folder. Volume breaks that reside on a deleted leaf will not be published.*

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 example, with an assembly structure for literature references and study reports. Such a structure can contain hundreds of leafs.

You can reorder leafs only if they are in an unlocked assembly and folder or in an assembly and folder locked by using the eCTD lock. You cannot reorder leafs in an assembly or folder locked by using the standard lock.

## 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:

— A standalone assembly folder

— An assembly template folder

— 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.

**Example: Reordering leafs in folders and subfolders Orginal 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

**Example: Reordering leafs in folders but not in subfolders Orginal 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 keeps each publishing element, such as a volume and or TOC, with the same leaf.

— 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.

**Example:**

**Orginal 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.

**Example: Sequence 0001 tree Orginal order:**

**New order:**

Folder 1

Leaf 4 (0000, NEW)

Leaf 2 (0001, REPLACE)

Leaf 1 (0001, NEW)

Leaf 5 (0000, NEW)

Leaf 3 (0001, APPEND)

Folder 1

Leaf 1 (0000, NEW)

Leaf 2 (0001, REPLACE)

Leaf 4 (0000, NEW)

Leaf 5 (0000, NEW)

Leaf 3 (0001, APPEND)

**Example: Sequence 0001 tree Orginal order:**

**New order:**

Folder 1

Leaf 4 (0000, NEW)

Leaf 2 (0001, REPLACE)

Leaf 1 (0001, NEW)

Leaf 5 (0000, NEW)

Leaf 3 (0001, APPEND)

Folder 1

Leaf 4 (0000, NEW)

Leaf 5 (0000, NEW)

Leaf 3 (0001, APPEND)

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 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.

Add a Leaf PDF Property

You can add or modify the PDF Property Setting for a selected Leaf from the *Leaf Attributes* view page. 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 on the value selected in the PDF Property Source field.*
4. To save the new PDF Property, Save.

To discard the changes, Cancel.

*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 active 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).<br><br>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 | Defines the source for the PDF Property. The values available for selection are the following:<br><br>— 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. |

| | |
|---|---|
| Source* | — Define Single Value - Applies a defined value as the PDF Properties, the value is obtained only from the first assigned document.<br><br>— 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:<br><br>— Author<br><br>— Keywords<br><br>— Title<br><br>— Subject<br><br>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:<br><br>— //space - Space character will be inserted as a separator — //newline - New Line will be started.<br><br>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.<br><br>This field appears and is required only when PDF Property Source is set to Define Single Value or Define Repeatable Value. |

## 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 val- ue. |

| Attribute | Description |
|---|---|
| Bound Version | Version of the document bound to the assembly. You cannot change this value.<br>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:<br>— Bind to Label binds the document to the label you choose<br>— Bind to Status binds the document to the status you choose<br>— 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. |
| 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. |
| Attribute | Description |
| 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 assembly. |
| 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.<br><br>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

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

For example, if you set your document binding to a status of approved, Ennov InSight clearly indicates when the assigned documents are in or out of compliance with that rule.

Keep in mind the following about 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 standalone assembly, a sequence assembly that is not life cycle, an unfinalized life cycle assembly, or an assembly template.

To apply or modify binding rules:

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

   The binding rule you apply or modify will apply to the selected element and all its child elements.

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 child elements.

4. Choose the Binding Rule that will apply to the selected assembly element and all child elements 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. To quit the binding action, click Cancel.

*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.

Reference Locations

You can use reference locations to open an assembly from Ennov InSight within a document management system (DMS) or repository.

The reference location is an HTML file that contains all the assembly attributes and a link that enables you to open the assembly automatically. When you click the reference location in the DMS, it opens a browse window with the attributes of the assembly, including a link to the assembly. Clicking this link takes you to the Ennov InSight login page. After you enter your login information, Ennov InSight opens the assembly.

The reference location name is the name you assign to the reference location.

Keep in mind the following:

— Ennov InSight maintains only one reference location for an assembly version. If a reference location exists in Documentum or the secure file system and it is moved or renamed, the original reference location is not deleted. Instead, another reference location is created for the same assembly version.

— You can create a reference location when the assembly is created by editing the assembly properties. Once an assembly exists, you must use the Set Reference Location action button to change it.

— When a reference location is created from the current active view, launching the reference location takes you to the first sequence assembly in the life cycle. From there, you have to switch to the current active view.

— Ennov InSight References to DMS elements can go to documents only; they cannot reference a compound document, virtual document, or link.

— For an assembly with a reference location defined in Documentum, to avoid having multiple versions of the assembly showing as Current, you must not change the reference location for any of the assembly versions to a different directory in Documentum.

Assign Documents

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

This link associates the document with the assembly.

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 |
| Location | DMSs with Accessible Document |
| 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 |
| Create Assembly or Create Assembly Template - from a virtual document | All except Veeva |
| Electronic Output Location - on the Create Assembly, Edit Assembly Attributes, and Publish Request pages | All except Veeva |
| Export Assembly - to Excel, Virtual Document, or 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 |
| 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 |
|  | 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<br>— Title<br>— Date Modified<br>— Version<br>— Keywords<br>— Path | — Subject<br>— Date Created<br>— Authors<br>— Status<br>— Document ID |
| Filesystem and Secure Filesystem | — Name<br>— Document Modified Date | — Size<br>— Absolute Path<br>— Canonical Path<br>— File Parent<br>— File Path |
| Veeva Vault | — Name<br>— Title<br>— Version<br>— Last Modified Date<br>— Created By<br>— Product — Country | — Status<br>— Created Date<br>— Last Modified By<br>— Document Number<br>— Type<br>— Subtype<br>— 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 de- fault 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 click- ing 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.<br>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. |

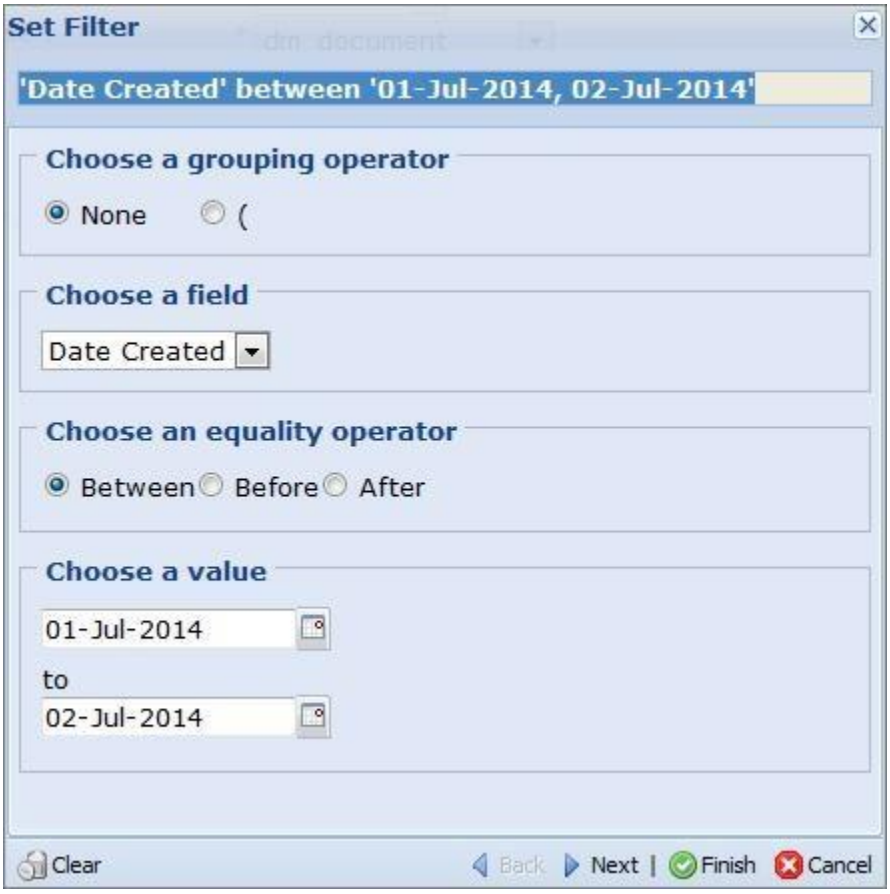
| Field | Description |
|---|---|
| Exclude Assigned Documents | Select this option to exclude assigned documents from the search. |
| Case Sensitive | Select this option to make the search case sensitive according to your filter criteria. |
| Advanced Query | Advanced Query is available only for Documentum and Veeva repositories.<br><br>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.<br><br>— Choose a grouping operator. Choose None, or choose to group multiple filter criteria within parentheses.<br><br>— 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.<br><br>— Choose an equality operator. The equality operators are dynamic and vary according to the selected field.<br><br>— Choose a value. Enter text, or choose dates, if a date field was selected, to specify the equality operator.<br><br>Example:<br><br>To find all documents created on one specific date, in this example, July 1, 2014:<br><br>1. Choose the field Date Created.<br>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'.<br>4. Click Finish, and then click Search. The *DMS Search Results* displays results for only July 1, 2014.<br><br>The system retains the last search criteria specified in Advanced Query until those criteria are re-set, 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. |
| Field | Description |
| 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.

*View an Assigned Document*

Steps to view the content of an assigned document in the assembly tree.

To view the content of an assigned document:

1. In the assembly tree, click the assigned document the content of which you want to view. The *Document Attributes* page appears.
2. Click  on the action toolbar.

   For the files with file size equal or bigger than the file size value set in assembly service configuration,The

   requested action has started processing. Please go to the Job Requests for the status message appears. You can only download the document from Go to > Job Requests. The document is downloaded to the Downloads folder.
3. Double-click on the downloaded document to view it.

*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<br>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:<br>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. |
| 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:<br>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*

You can locate documents in the browse dialog box and add them to an element you select in the assembly. You can also drag documents from a repository or secure file system to Ennov InSight .

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. |
| Option | Description |
| 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. |
| 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 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 Document 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 appropriate job request is set to Completed with the message No Documents to Render in the job details.

*Rules for a File Share or for a Documentum Document Bound to the 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 the rendition has been changed outside of Ennov InSight , only extraction request is sent.

— If there are no documents that require renditions/extractions to be created in the section where the option was 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*

The following Missing Rendition Identifier Handling rules apply only to documents assigned from a Documentum DMS.

There are specific business rules for documents assigned from a Documentum DMS when using the Rendition Identifier functionality. LIQUENT 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*

The following Missing Rendition Identifier Handling rules apply only to 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.

*Create Missing Renditions and Extractions*

Use the procedure to create missing renditions and extractions of the source documents for an assembly. You can also track the progress of the process from the *Job Request* page.

***Note:*** *You must have the appropriate security privileges to create new/missing renditions and extractions.*

To create missing renditions and extractions:

1. Right-click on a node in the assembly tree.
2. In the menu, click Create Missing Renditions and Extractions.
3. To track the progress of the process, chose Go To > Job Requests.
4. On the *Job Requests* page, set the filtering information and click Search.

*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 will cause custom bookmarks, modified TOC entries, 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*

The following Missing Rendition Identifier Handling rules apply only to documents assigned from a Documentum or Veeva DMS.

Specific 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*

You can 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, modified TOC entries, 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 the 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

   — Modified TOC entries

— 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 quit the Force New Renditions and Extractions action, click Cancel.
6. To track the progress of the action, choose Go To > Job Requests.
7. On the *Job Requests* page, enter appropriate information and click Search.
8. 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*

provides support for associating and publishing renditions using custom Rendition Identifiers (page_modifier) for documents 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 have been 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 will be 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*

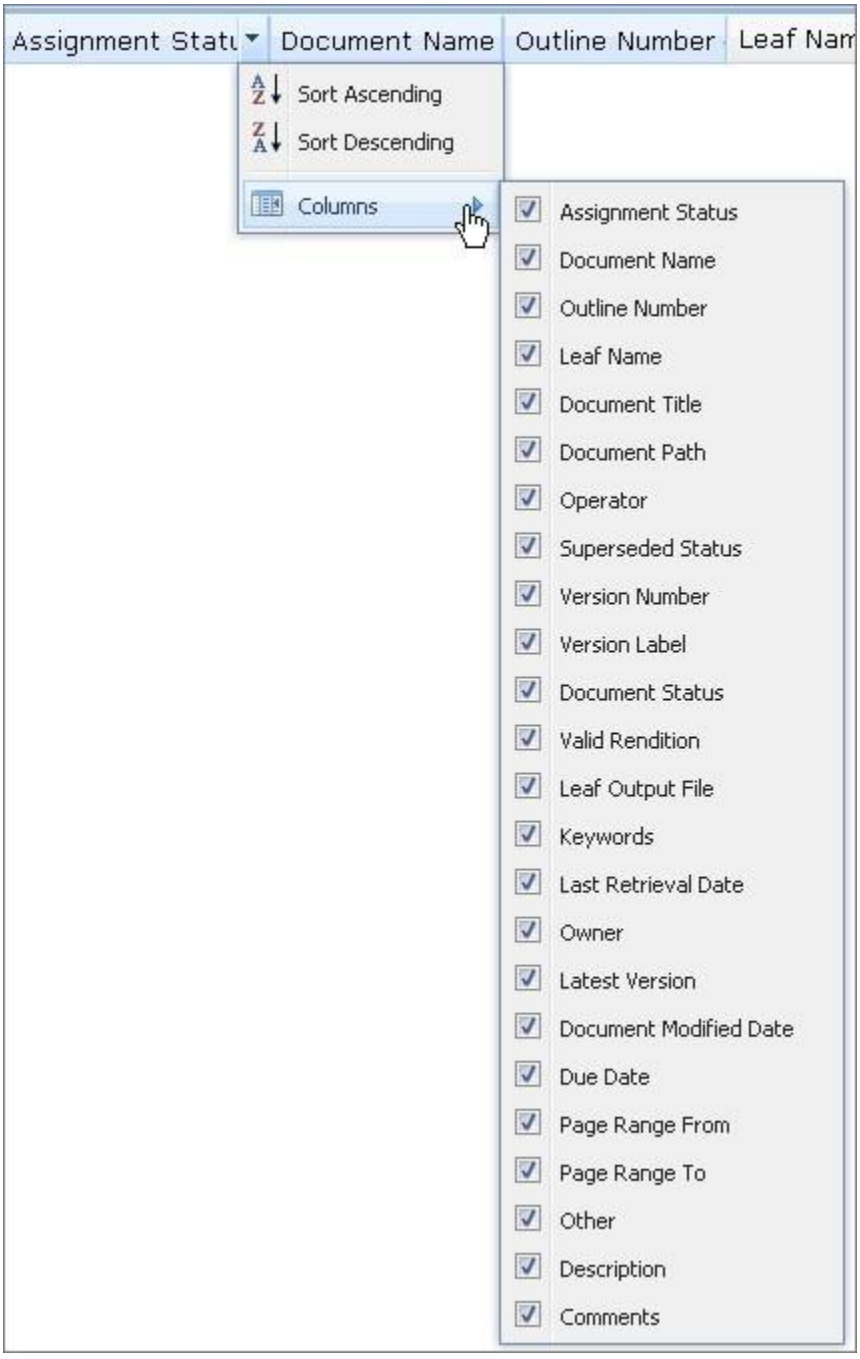
Use the Document List query to generate a table that displays assigned documents and their attributes for the assembly.

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.<br><br>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 life cycle 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. |
| Column Name | Description |
| 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. |
| 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 life cycle 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.

Submission Readiness Report

The Submission Readiness report shows, for each module in an assembly, the number and percentage of documents that fall into each of ten categories.

Each category is related to a document assignment status, approval status if assigned, due date of the parent leaf, and whether a document is in Documentum.

Your SPT license must be enabled to provide access to the Submission Readiness report.

Key questions answered by this report include:

— How many documents are assigned?

— How many documents have been approved?

— How many leafs are on time, and how many are late? — How many documents are located on a file share?

If a document is in Documentum, the document is in one of the following categories: — Assigned, Approved, Not Yet Due

— Assigned, Not Approved, Not Yet Due

— Assigned, Approved, No Due Date

— Assigned, Not Approved, No Due Date

— Not Assigned, Not Yet Due

— Assigned, Approved, Past Due

— Assigned, Not Approved, Past Due

— Not Assigned, Past Due

— Not Assigned, No Due Date

If a document is not in Documentum, the document is in the category Outside Documentum.

Synchronize the documents with the DMS before running this report.

A chart shows the categories for each module.

*Generate a Submission Readiness Report*

You can generate the Submission Readiness report to show categories of documents and the number of documents in each category.

To generate a Submission Readiness report:

1. Display the *Assembly Attributes* page for the assembly.
2. Click More in the top right corner of the page.
3. Click Submission Readiness Report.

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 |

Page 1 of 1 | View: 100 | Displaying items 1 - 6 of 6

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

Modifying documents in the assembly tree can cause unexpected results.

— 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 you assign a document to an assembly. The attribute that is stored in Documentum or the secure file system is displayed in Ennov InSight . When you synchronize Ennov InSight with a DMS repository, the DMS attributes overwrite any mapped attributes you have changed in Ennov InSight . 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.

*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.

# 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

— Standalone Assemblies — 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 functionali- ty 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. |
| 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 Update and Preserve is used.*

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. |

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<br>— Owner<br>— Language<br>— Application Version<br>— Version<br>— Font library<br>— Role<br>— Actuate<br>— Show<br>— Use Native File<br>— Due Date<br>— Link Text<br>— Keywords<br>— Description<br>— Comments |
| Document and Placeholder | — Title<br>— Category<br>— Review Status<br>— Due Date<br>— Owner<br>— Output Channel<br>— Other<br>— Keywords<br>— Description<br>— Comments |

| | |
|---|---|
| — Folder, Leaf, and Reference Leaf<br>— Folder, Document, and Placeholder | — Due Date<br>— Owner<br>— Keywords<br>— Description<br>— Comments |
| Document, Placeholder, Leaf, and Reference Leaf | — Title<br>— Due Date<br>— Owner<br>— Keywords<br>— Description<br>— 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.<br>Available values:<br>— 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.<br>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.<br>The [Select] value is set by default. |
| Show | Drop-down list.<br>Available values: |

| | |
|---|---|
| | — New<br>— Replace<br>— Embed<br>— Other — None<br>The [Select] value is set by default. |
| Leaf with Extension | Drop-down list.<br>Available values:<br>— Study Patient Information<br>— Study Report |
| Use Native File | Drop-down list.<br>Available values:<br>— Yes — No<br>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.<br>The [Select] value is set by default. |
| Show | Drop-down list.<br>Available values:<br>— New<br>— Replace<br>— Embed<br>— Other — None<br>The [Select] value is set by default. |
| Use Native File | Drop-down list.<br>Available values:<br>— Yes — No<br>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.<br>Available values:<br>— NONE<br>— MAJOR — MINOR<br>The [Select] value is set by default. |

| Property | Field Type |
|---|---|
| Folder with Extension | Drop-down list.<br>Available values:<br>— Clinical Indication<br>— Drug Product<br>— Drug Substance<br>— Excipient<br>— Promotional Material Type<br>— Promotional Material Doc Type<br>— Promotional Material Audience Type<br>— US Admin Forms |

| | |
|---|---|
| | — US Forms<br>— US Module 1 v3.3<br>— Quality Introduction<br>— Quality Overall Summary<br>— Module Studies<br>— Node-Extension<br>— Quality Appendix<br>— Study Report<br>— Study Data<br>— Study Patient Information |
| Force New Volume | Drop-down list.<br>Available values:<br>— Yes — No<br>The [No] value is set by default. |

## 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.

Ennov InSight Publisher 7.3 Move Assembly Elements

— Additional reorganization guidelines apply to assemblies in life cycle 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 |
| 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 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:

Move an Assembly Element

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.

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Move an Assembly Element

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.

## New Assembly Tree

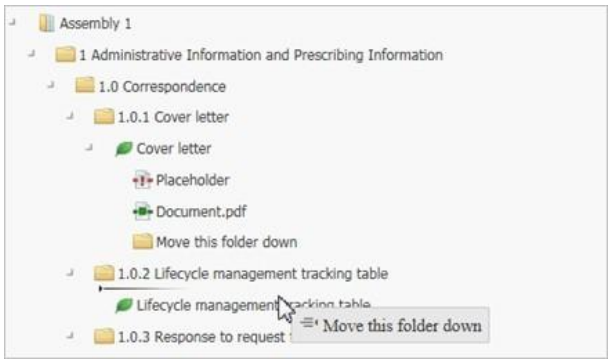
New Assembly Tree: Features

With the new version of 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.

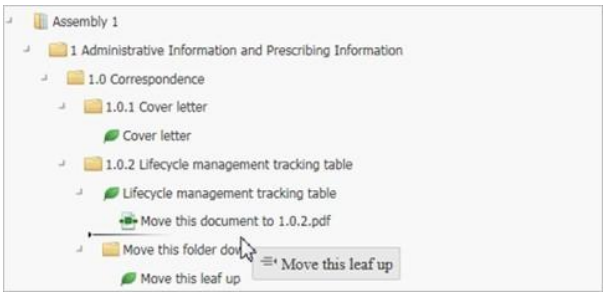
You can perform the following actions within the New Assembly Tree:

— Use the drag-and-drop feature to move the Assembly Tree elements within an Assembly Tree.

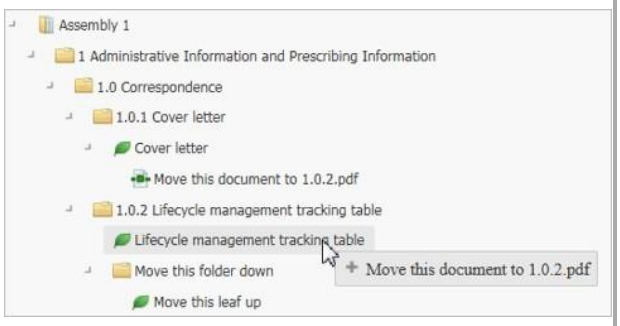
| Drag-and-Drop Folder | Drag-and-Drop Leaf |
| --- | --- |

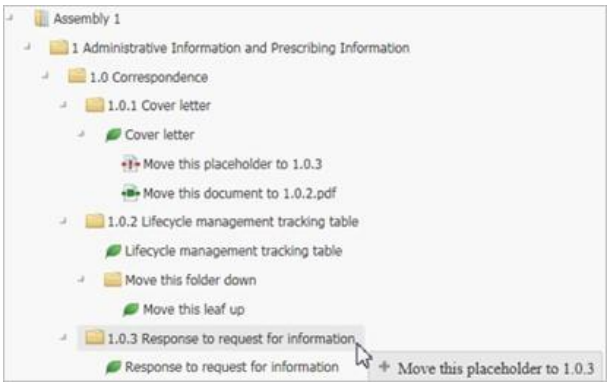



Drag-and-Drop Document




Drag-and-Drop Placeholder

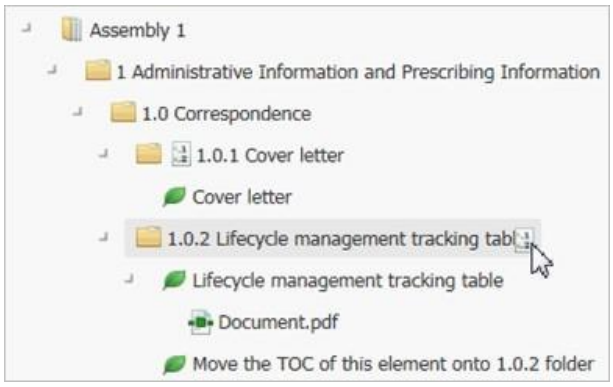



***Note:*** *Only a single node can be moved.*

— Use the drag-and-drop feature to move volumes and TOCs onto the Assembly Tree elements.

Drag-and-Drop TOC




Drag-and-Drop Volume



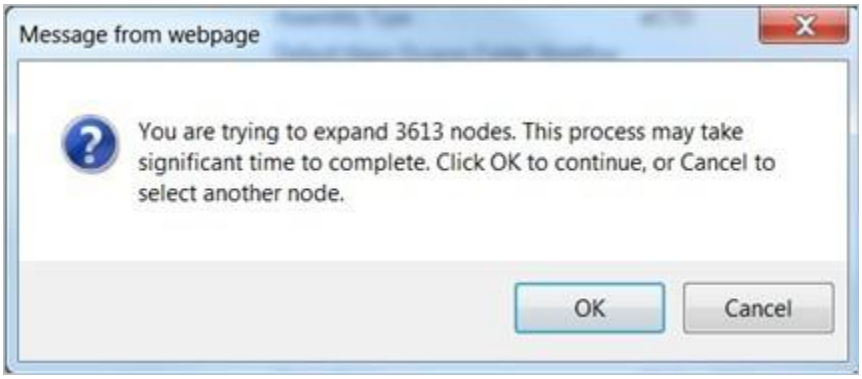

— Use the drag-and-drop feature to add folders, documents, and leafs from the *DMS Browse* and *Browse Assembly* windows to an Assembly Tree.




— Use the Search option to filter the Assembly Tree elements by the text entered in the Search field.




As an additional feature, 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.



See *Limiting Assembly Tree Expand Range*.

Assembly Tree

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. See *Limiting the Assembly Tree Search Results*.

— 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.

*Move Assembly Elements Within an Assembly Tree*

Ennov InSight enables you to perform drag-and-drop actions on assembly elements within an assembly tree. 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 standalone assembly, initial sequence assembly, assembly template, working view of the sequence assembly or assembly plan, and submitted view of the sequence assembly or assembly plan.

— Dragging elements within the publishing or sequence views of the sequence assembly or assembly plan is not allowed.

The following nodes cannot be dragged onto an assemble tree.

— Withdrawn (Delete) leaf and withdrawn elements in the range under it.

— Replaced or appended leaf.

— Folder, leaf, reference leaf, document, or a placeholder within the lock range of a standard locked root or folder. — Page Marker.

— Folder in the eCTD locked assembly, except dragging a folder under a leaf within the leaf range.

— 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.

Move Volume and TOC onto Assembly Tree Elements

Moving Volume and TOC onto Assembly Tree Elements

Ennov InSight enables you perform drag-and-drop operations to move the volume and TOC publishing elements onto assembly tree elements. The volume and TOC elements can be moved onto the following assembly tree elements.

— Root

— Folder

— Leaf

— Document

— Placeholder

— Page Marker

— Volume (only TOC can be moved onto a volume)

*Move a Volume onto Assembly Tree Elements*

The following conditions apply when moving a volume onto assembly tree elements:

— Volume cannot be moved onto a locked tree element or a range (standard lock).

— Locked volume cannot be moved.

— Volume cannot be moved to a tree node which already has a volume. — Volume cannot be moved onto the range of a locked volume.

— Volume cannot be moved onto the publishing elements and volume. — Volume cannot be moved from a locked range, except eCTD lock.

***Note:*** *Only a single volume node can be moved at a time onto assembly tree elements.*

*Move a TOC onto Assembly Tree Elements*

You can move a TOC onto Assembly Tree Elements with some conditions.

The following conditions apply when moving a TOC onto assembly tree elements:

— TOC cannot be moved onto publishing elements, except volume.

— TOC cannot be moved onto a locked tree element or a range (standard lock), except the range of a locked volume.

— TOC cannot be moved from a locked range, except eCTD lock.

***Note:*** *In the new version of the assembly tree, to move a TOC that is attached to a volume using the drag-and-drop feature, a TOC must be dragged onto the icon corresponding to a volume.*

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.

— Folders or documents cannot be moved from the DMS Browse window on to a page marker.

— A folder cannot be moved on to a document if assembly has Create Leaf Elements set to Yes.

— A folder or document cannot be moved on to an old leaf that has an appended leaf.

— A folder or leaf cannot be moved on to a withdrawn (deleted) 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.

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 insight.var file. When the results exceed the number defined in the insight.var file, 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 insight.var file is 500.

The following assembly elements can be searched using the search option:

— Assembly root

— Folder

— Leaf

— Reference leaf

— Document

— Placeholder

The search option is available for the following when the new version of the assembly tree is enabled. For procedure on enabling the new version of the assembly tree, see the topic *Enabling New Version of the Assembly Tree* in the Installation Guide.

— Standalone Assembly

— Assembly Template

— Sequence Assembly (Initial, Working View, Submitted View, Publishing View, Sequence View) — Supporting Sequence Assembly

— Assembly Plan (Initial, Working View, Publishing View, Sequence View, Submitted View) — Lifecycle Assembly/ Assembly Plan (Submitted View, Sequence View, Publishing View) — Import Assembly Wizard

— Assembly Comparison Query

— Assembly Status Query

— Change Modified Leaf on the Leaf attributes window

— Convert to Reference Leaf

— Reference Link to an Assembly

— Assembly tree in Linking plug-in (PDF) tool

— Retarget Links in Link Inspector

— Create Assembly from Existing Template, Assembly or View

You will be able to 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 | + | + | + | + | + | + |

You can also filter an assembly tree based on the search text that matches the values of the following extended attributes:

| | Extension Type | Associated Attributes |
|---|---|---|
| Folder | Drug Substance | — Drug Substance Name<br>— Drug Substance Manufacturer |
| | Drug Product | — Drug Product Name<br>— Dosage Form<br>— Drug Product Manufacturer |
| | Clinical Indication | Indication |
| | Excipient | Excipient |
| | Quality Appendix | — Manufacturer<br>— Substance<br>— Dosage Form<br>— Product Name |
| | Study Report | — Full Report Title<br>— Report Number<br>— Operation<br>— Species<br>— Route of Administration |

| | | |
|---|---|---|
| | | — Duration<br>— Type of Control<br>— Subject Matter |
| | Study Data | — Dataset Type<br>— Subject Matter |
| Leaf | Study Patient Information | — Subject Matter<br>— Site |
| | Study Report | Subject Matter |

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 drop-down list. |
| To filter an assembly tree based on the search criterion for a specific node type: | Select a node type from the search drop-down 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 with the available options. The Advanced Assembly Tree Filter feature enables you to filter an assembly tree for: — Empty folders and leafs

— Leafs with the life cycle

— Replace, Append, or Delete and that are being operated in a parallel sequence

— Leafs with leaf status

— Documents with assignment status

*Advanced Assembly Tree Filter for all Nodes*

The Advanced Search provides you with the numerous options to filter down an assembly for all the Nodes.

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.

*Advanced Assembly Tree Filter for Folders*

The Advanced Search provides you with the numerous options to filter down an assembly for Folders.

To filter an assembly for empty folders:

1. Navigate to an assembly.
2. Click the Advanced Search icon.
3. From the search drop-down list, select Folders.
4. In the Search in All Fields field, enter the search criteria.
5. To view only the empty folders that match the search criteria, select Show only empty Folders.
6. 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. |
| 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 provides you with the numerous options to filter down 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

You can only import assemblies using the Import Assemblies Wizard. Other content can be added to an assembly using different methods.

When importing an assembly file, the documents in the file are not automatically synchronized with the mapped DMS - they will appear as placeholders. This prevents import failures should the referenced DMS not exist in the current system. Run a DMS synchronization immediately after importing to assign placeholders automatically to the DMS documents.

You can import any of the following:

— An existing standalone or sequence assembly

— Part of a standalone or sequence assembly — An entire template or part of a template — An application view of the following types:

- Submitted
- Working
- Sequence
- Approved

Keep in mind the following:

— If you are importing an assembly that used versions 2.0 or earlier of the Study Tagging File specification, these are imported and the appropriate assembly is created, but any subsequent sequences must use the latest (v2.2) DTD.

— You can import an assembly root or folder into an assembly root or a folder only, as long as the target folder is not the child of a leaf.

— When you right-click a folder to import it, the whole assembly is imported, not just the selected folder. To import only part of an assembly, you must use the drag-and-drop function.

— Paper elements cannot be imported using a drag-and-drop operation from the import dialog.

— When exporting and then importing an assembly or template, TOC elements must be moved to the correct location in order to inherit any predefined values.

— You must re-target in-process links to leaf elements when using an imported assembly file that contains previously defined in-process links that target leaf elements.

— Leaf status assigned to each leaf element is automatically set to the default Leaf Status value configured in *Data Administration*.

When you import an entire assembly or part of an assembly, the following occur:

— If you import one 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 the assembly root, a folder that represents the source assembly's root is created in the target assembly, which contains the children of the imported root.

— Locks are not maintained; 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.

— Volume breaks that are imported are not maintained.

— 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.

— The Site attribute for the Study Information Leaf does not inherit a value from its parent folder, which also has a Site attribute.

Import Assembly Wizard

Use the *Import Assembly Wizard* to import an assembly into the assembly tree.

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 option How would you like to find the assembly?, use Browse to select the assembly location, or select Search to find the assembly based on the search criteria.

| Option | Action |
|---|---|
| If you choose to select the assembly by browsing: | Click the Browse button. Select the assembly type tab, select the assembly and click OK. |
| If you are using the Search option to find the assembly: | Select the assembly type under Assembly Type to Search. |

3. Choose the following options. Selecting the option = Yes, clearing the check box for the option = No.

| Option | Action |
|---|---|
| Copy Paper Publishing Elements: | Select this option to include paper publishing elements from the source assembly in the new assembly. |
| Reset Lifecycle Information: | Select this option to reset the life cycle information for the 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 will be updated to the copied target instead of the source assembly. 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. |

***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 9.

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.

9. Right-click the root or the folder and choose Expand Range to see the full assembly with the imported assembly.

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 OK.

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 a standalone assembly from a 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.*

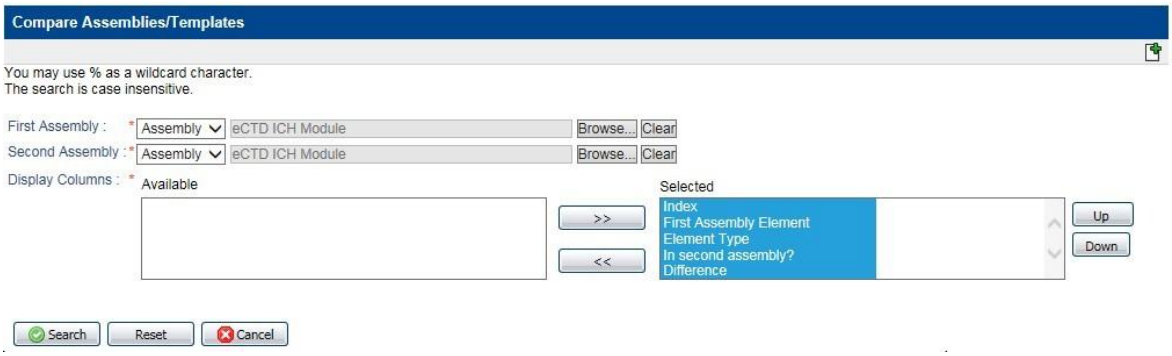
View an Assembly Baseline

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.
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.

   Ennov InSight Publisher 7.3 Assembly Baselines

   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.

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.*

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:

   Ennov InSight Publisher 7.3

   Replace Assembly Variables

| 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 |
| 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.

Ennov InSight Publisher 7.3 Lock Assemblies

eCTD and Standard Locks

In addition to locking folders, you can create eCTD and standard locks.

An eCTD lock prevents you from changing the folder structure and metadata of an assembly. You can create new leaf elements, but you must use the Create eCTD wizard to add, move, and delete folders. In addition, you must use the wizard to change folder metadata. All changes must be made by either unlocking the assembly or using the Create eCTD wizard. This prevents accidental or unauthorized changes that would cause issues with eCTD publishing, but still enables document assignment and leaf manipulation.

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.

***Note:*** *Only an administrator or the owner of the assembly can unlock an eCTD lock.*

Lock Volume Ranges

A volume lock defines the beginning and ending points of a volume.

You can think of this as bookends for a volume. The beginning and ending points of the volume are locked in place, but the contents in the middle can be altered.

When a volume is locked, bypasses it when you volumize an assembly range that includes the locked volume.

An assembly must be refreshed when locking or unlocking volumes for a "non-first" life cycle sequence assembly in order to display the assembly correctly.

Lock a Volume Range

When you lock a volume, you define the beginning point and end point of the volume. To

lock a volume range:

1. In the assembly click the volume at the beginning of the volume range you want to lock.
2. Click  .

A message prompts you to confirm the lock.

3. Click OK.

The volume icon changes to  .

Unlock a Volume Range

You can remove a lock on a volume range to change the beginning and ending points of the volume.

To unlock a volume range:

1. Select a locked volume and click  .
2. Click OK.

Ennov InSight Publisher 7.3 Lock Assemblies

## Update Assembly Status

.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.

Ennov InSight Publisher 7.3 Update Assembly Status

## 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 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. |
|  | Assign Document enables you to assign a document to the assembly tree. |
|  | DMS Synchronization enables you to synchronize the 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. |
|  | Associate Workflow enables you to associate workflows to entities. |
|  | Metadata Library enables you to view the metadata library page. |
|  | 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. |

Ennov InSight Publisher 7.3 View an Assembly

| Icon | Description |
|---|---|
|  | Unlock Sequence releases the assembly from a locked state. |
|  | Update Status enables you to change the assembly status. |
|  | Export Assembly to... enables you to export the assembly to a Microsoft Excel spreadsheet, an assembly file, or a virtual document. |
|  | Create Version enables you to create a version of the assembly. |
|  | Delete enables you to delete a document placeholder. |
|  | Set Reference Location enables you to specify a different location for the assembly reference location. |
|  | 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. |
|  | View Tab Review File enables you to open the PDF file with the generated tab review. |
|  | Generate Tab Review File generates the assembly tabs in a PDF file. |
|  | 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. |
|  | Submission Readiness Report. For each module in an assembly, the Submission Readiness report shows the number and percentage of documents that fall into each of ten categories. Each category is related to a document assignment status, approval status if assigned, due date of the parent leaf, and whether a document is in Documentum. |
|  | Recalculate Checksums enables you to recalculate checksums for content that has been changed post publishing. |
| For folders and leaf elements | |
|  | Change Type enables you choose an element type which includes additional properties specific to the ele- ment; these properties are used to create the XML backbone for eCTD submissions. |
|  | Add Metadata enables you to add metadata to an entity. |
| For documents | |
|  | Unassign Document enables you to remove the selected assigned document from the assembly tree. |

Ennov InSight Publisher 7.3 View an Assembly

| Icon | Description |
|---|---|
|  | Prepare Documents for Linking enables you to prepare documents for use in linking tools. |
|  | View File enables you to open an assigned document. |
|  | Edit Document Bookmarks enables you to edit the extracted bookmarks of the selected document. |
|  | Edit Document Links enables you to edit the hyperlinks of the selected document. |

## Export Assemblies

Exporting Assemblies provides you details in different formats.

You can export an assembly to any of three formats.

— Microsoft Excel spreadsheet (SPT users only)

— DMS repository virtual document (sometimes known as a compound document, depending on the repository type)

— XML file

Export an Assembly

You cannot view the assembly in the Approved Status View when exporting an assembly.

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 Spreadsheet: | Exports to a Excel spreadsheet. |
| Assembly File: | Exports to an XML file. |
| Virtual Document: | Exports to a virtual document. |

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.
8. Click Done.

Ennov InSight Publisher 7.3 Export Assemblies

Export an Assembly to Excel

When you export an assembly to Excel, automatically formats the resulting spreadsheet.

The spreadsheet contains the following:

— The Excel file name is the same as the assembly name.

— First-level folders (major divisions or modules) become the spreadsheet tabs. One sheet is created for each firstlevel folder. First-level folder names are truncated at 31 characters.

— One row for each folder, leaf and document element is created. The rows are in the order of the assembly. The Excel spreadsheet is not hierarchical but a Level column is provided which indicates the hierarchy.

— Folder attribute names become the column names.

— Folder attribute values become the column contents.

— Leaf attribute names that differ from the folder attribute names become additional column names. — Leaf attribute values become the column contents.

— Assigned document and placeholder attribute names that differ from the folder or leaf attribute names become column names.

— Assigned document and placeholder attribute values become the column contents.

— Leading zeros are stripped during the export process. To work around this, rename the file with a .txt extension rather than a .csv extension. Open the file in Excel. Use the Text Import wizard to make the initial cells text cells instead of general cells, and choose a comma delimiter.

***Note:*** *Occasionally Excel may prompt you to make repairs. This is an errant message; you can click Close to ignore the message.*

Export an Assembly to a Virtual Document

Exporting an assembly to a virtual document enables you to generate a virtual document you can use in a submission publishing tool.

Due to the nature of DMS repository virtual documents, you can unintentionally convert a document to a virtual document, change the structure of an existing virtual document, or check in a checked-out document by exporting an assembly as a virtual document.

— Assigning children to an assigned document in and then exporting the assembly as a virtual document forces to convert the assigned document into a virtual document.

— If the assigned document was already a virtual document, is forced to change the virtual document so it reflects the assembly hierarchy.

— If the assigned document was checked out, is forced to check the assigned document back in to convert it to a virtual document, or to change its virtual document structure.

Before you export an assembly containing assigned documents that have children, you should evaluate the effects of converting those documents to virtual documents or changing the structure of the assigned virtual document. This is generally applicable; it is not specific to InSight and applies equally when working with virtual documents through any means.

When you export an assembly to a virtual document:

— You can export only from the root level. You cannot export from the folder, leaf or document levels.

— Each time you export an assembly to a virtual document, a new virtual document is created; you cannot re-export to an existing virtual document.

— If a document in the assembly is a child of another document, the parent document is converted to a virtual document.

— The virtual document name in the DMS repository must be unique.

— The assembly name cannot contain characters that are illegal on the secure file system (slashes, asterisks, etc.).

— A new folder is created in the destination folder you choose and is assigned the following name: <User-Defined Virtual Document Name> Supporting Documents.

— A new DMS repository object is added for each assembly element that is not already in the DMS (that is, root, folders, leaf elements, document placeholders, and secure file system documents). These new objects are placed in the supporting documents folder.

— For the assembly root, folders, leaf elements and document placeholders, the object in the virtual document is a no-content object.

— Any bound document that is already checked out is checked back in during the export.

— For each document that links to content in a different repository, a link to that content object is created in the Supporting Documents folder.

— For each document in the target export repository, the existing DMS objects are linked to the virtual document.

— For documents that link to content in the secure file system, a new object is created as a no-content object. — The document type you specify is applied to all new objects created in the DMS.

The assembly version bindings are mapped to the virtual document as follows:

— If the assembly has version number binding, the virtual document bindings are set to the same number.

— If the assembly binding is version status binding, the virtual document binding defaults to the version label Current.

— If the assembly binding is version label binding, the virtual document bindings are the same.

— Currently the export will fail if there are any documents set to MISSING_VERSION (no binding).

Export to an Assembly File (XML)

When you export to an assembly file, the resulting file is an XML file. The XML file can be imported to create new assemblies.

When Export Assembly to Assembly File is performed the Rendition Identifier values set in the Assembly Specific Publishing Settings Libraries (APL), and those set on each element, are exported.

— When creating an Assembly from an Assembly file, the Rendition Identifier values are restored.

— 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.

## 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.

Ennov InSight Publisher 7.3 Delete Assemblies

When you delete an assembly or template the following occur:

— The reference location is deleted.

— 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.

— For a single-version standalone assembly, the standalone assemblies list is displayed.

— For a single-version sequence assembly, the Sequence attributes page is displayed where you can create another assembly.

— For a multiple-version standalone or sequence assembly, the current version is displayed in the assembly tree pane.

— For the system current assembly (TIP) that has no former version with an effective status, the previous version of the assembly is unlocked and assigned the TIP status.

— For the current assembly with the effective status, checks for a previous superseded version with the effective status and makes that the current version. If there is no previous superseded version with an effective status, the TIP version becomes the current version.

You cannot delete the following:

— An assembly in current active view.

— A locked assembly.

— A life cycle assembly that is finalized.

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

— Standalone Assembly

— Supporting Sequence Assembly

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:

Ennov InSight Publisher 7.3 View Activities List

| 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 users with the ability to recalculate checksums for 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 for any assembly.

Upon executing the **Recalculate Checksums** functionality, Ennov InSight verifies that the electronic output location is the same that the assembly was last published to. When all published output is correctly located, the system sends a job request to recalculate checksums. After the recalculated checksums are saved, the assembly will be republished using the XML only option, ensuring the XML contains the updated checksums, as well as recalculating the checksum for the XMLs.

***Note:*** *The Recalculate Checksums functionality for life cycle sequence assemblies and assembly plans is available from the publishing and sequence view only.*

To recalculate checksums do the following:

1. Navigate to the defined 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.
5. The checksums in the XML file are updated.

***Note:*** *If there is a cross reference leaf in the assembly, then you must execute the Prepare Cross-Reference Leafs functionality first.*

Ennov InSight Publisher 7.3 Recalculate Checksums

## 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.

## 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.

Ennov InSight Publisher 7.3 Prepare Cross-Reference Leafs

# Chapter 7. Life Cycle

Life cycle enables you to track changes you make to a submission as it progresses through the approval process. When you are ready to submit an application to a regulatory agency for approval you must lock it to prevent additional 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 the drug's life for that application. The life cycle and change tracking in the life cycle are compliant with the ICH eCTD specification.

When you lock and add the first sequence assembly to life cycle, it becomes the finalized assembly. Keep in mind the following:

— Any assembly versions are rendered non-useable after you add the first sequence assembly to life cycle.

— The application's submitted view is the accumulation of all sequence assemblies that have been added to the life cycle for the application. The submitted view, like all views, cannot be changed.

When the application life cycle contains only the first finalized life cycle assembly, the submitted view and sequence view look the same. After you add another assembly life cycle, the sequence view and the submitted view differ.

— 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, appended, withdrawn and replaced leaf elements, and deletions. 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 snapshot of the application's submitted view when the current sequence was created. If additional parallel sequences are created in the application, their changes are not included in the working view for the sequence.

— Only envelope information that is added to a life cycle will carry through to newly created life cycle assemblies. Planned life cycle assemblies created from a specific submitted view will not upgrade to the latest submitted view: they will not be placed in the context of the latest sequence until they are added to a life cycle, and they will not contain more recently added EU envelope information. However, any sequence added to a life cycle that shares leaf replaces with other sequence(s) in the same application will always have assigned the correct modified file for published output.

— The application's sequence view 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 what will be submitted as part of that sequence.

— Once there is a life cycle, you can create several supporting sequences. These can be separate assemblies that have no relation to the application life cycle, but instead support it. For example, you might create a Clinical Study Report to support an existing life cycle, or perhaps a paper reviewer's copy of the an eCTD sequence.

— You can add to life cycle only assemblies with leaf elements. Leaf elements represent the final, published documents. You can use assemblies without leaf elements for study reports or paper output, but you cannot used them for eCTD or other regulated output that requires a document life cycle.

— If you are adding documents from a DMS (such as Documentum), you must log on to the DMS before you can add a sequence assembly to a life cycle.

Ennov InSight Publisher 7.3

Working Assemblies and Assembly Specific Publishing Settings Library (APL)

***Note:*** *When using the Duplicate command on a folder that contains leafs with life cycle append operations, the duplicated structure is "flattened" and the appended documents are displayed as siblings (rather than as children) of the original source document.*

Until a submission is added to a life cycle, the workflows associated to assembly nodes are displayed under the Working, Sequence and Publishing views of the sequence assembly. When a submission is added to a lifecyle, 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 and Publishing View of the life cycled assembly.

Life cycle 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

When a sequence assembly is ready to be added to life cycle, it is locked to prevent unsolicited changes.

Once an assembly is locked, only an administrator can make changes and synchronize the assembly with the DMS. It is recommended that you lock the binding of all documents used in the assembly.

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 whose assembly 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.

   Ennov InSight Publisher 7.3

   Lock Sequence Assemblies

6. Select Standard to lock the entire assembly.

   **Example**




7. Click OK.

   — Read-Only Mode appears before *Assembly Attributes*.

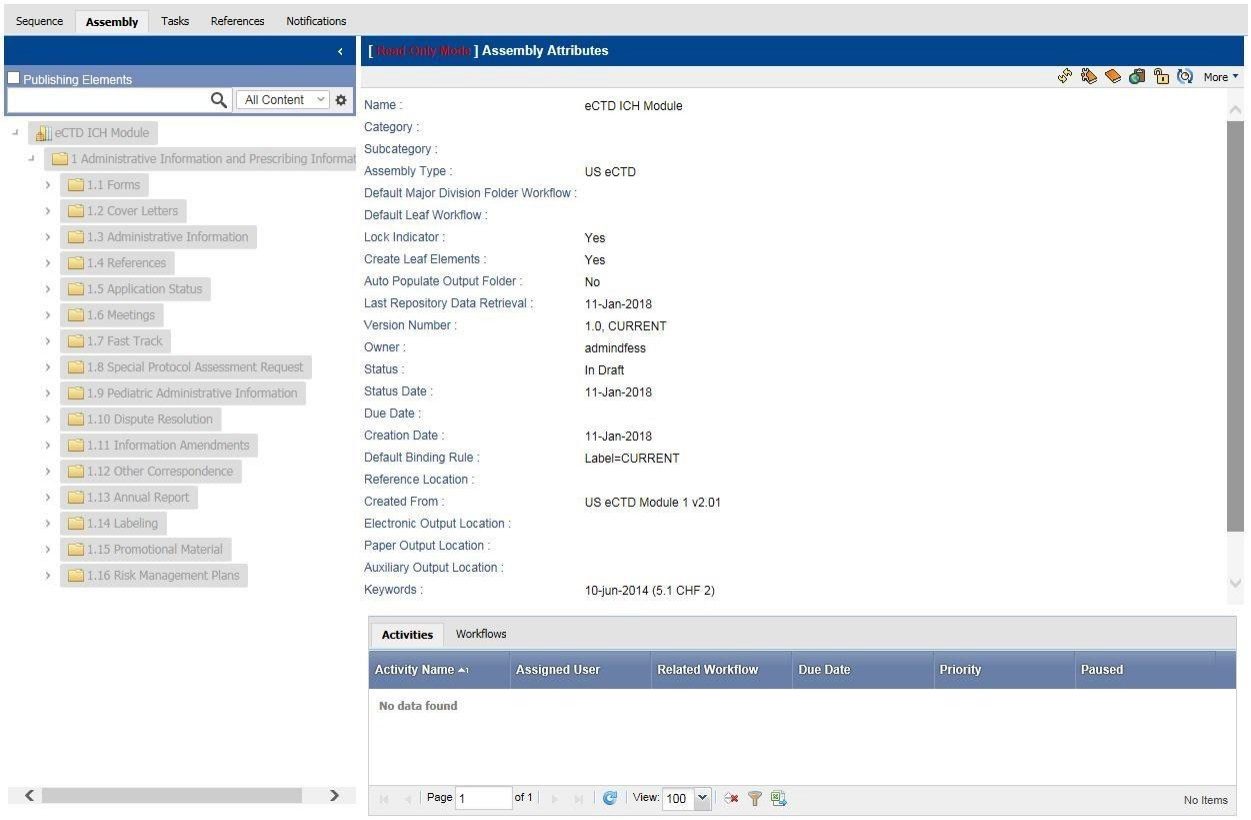
   — Lock Indicator is set to Yes.

   — 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.*

8. You can now add the locked sequence assembly to life cycle.




# Add Sequence Assemblies to Life Cycle

After adding an assembly to life cycle, any other assembly versions are deleted. Before you add the first assembly to life cycle, you can export the assembly to save the data.

When an assembly or an assembly plan is added to a life cycle, 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 life cycle. You can add subsequent sequences to a life cycle by repeating the steps used to add the first sequence. You can also use the *Create Submission* wizard to add sequences.

When a submission is added to life cycle, the leaf statuses of leaf elements are not updated.

***Note:*** *Only an administrator can remove a sequence that has been added to life cycle.*

Ennov InSight Publisher 7.3 Add Sequence Assemblies to Life Cycle

Add Sequences to Life Cycle

You can add a sequence to a life cycle to create new versions of a sequence.

### Prerequisites

Before you add the first assembly to life cycle, you can export the assembly to save the data. Other assembly versions are deleted when new assemblies are added to a life cycle.

To add the first sequence to a life cycle:

1. On the action toolbar, select Add Sequence to Lifecycle. A message prompts you to confirm the addition.
2. Click OK.

## 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.

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.*

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.

# Working Assemblies

After you have added the first sequence assembly to life cycle, you can create planned sequence assemblies to include updates and changes required by the regulatory agency. These sequence assemblies are referred to as working assemblies, the assemblies you are working on in the life cycle.

You 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 limited cases, however, it may be necessary to change these values. In this case, an administrator may use the Reset and Change Modified Leaf buttons 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.

Create A Working Assembly

After you add sequence assemblies to life cycle, 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 which 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. Above the assembly tree, choose one of the following:

| Option | Action |
|---|---|
| Submitted: | Shows the most recent sequence submitted to the regulatory agency; its folders, leaf elements and documents are shown in gray. |
| Sequence: | Shows you the folders, leaf elements and documents in this sequence only; these are also shown in gray. |
| Working: | Shows the assembly in which you make changes and updates to the submission. It is the combination of the last submitted sequence (in gray) and the current sequence you have just added (in black). |
| Publishing: | Shows you the folders, leaf elements, documents and publishing elements in this sequence only. The non-editable elements are shown in gray, but publishing elements may still be modified. |

Modify Leaf Elements in the Working Assembly

You can perform leaf operations, including add (New), replace, append, and delete from the working view. You cannot perform replace, append, or delete operations on a leaf that is part of an open Submission Plan.

## Replacing a Leaf

— You can replace a leaf only once per sequence.

— You can replace directly from the assignment page 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.

— 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. The modified file name is formatted as ../

<replaced leaf sequence number>/index.xml#<letter><numeric identifierGUID>. For example, ../0001/index.xml#a9f5078464791677a9934ae330536bffa

— You cannot replace, append, withdraw, 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 delete some or all of this content.

The only content the replacement leaf has is the content you assign.

— According to the ICH eCTD specification, when you replace a leaf, the leaf in the index.xml is created automatically for each region's regional XML. For the us-regional.xml, eu-regional.xml, and caregional.xml, the operation on the leaf element in the index.xml is always New with no value for modified file. This is done per agency recommendation. For the jp-regional-index.xml, the operation on the leaf in the index.xml is New in the first sequence and Replace in subsequent sequences. The modified file automatically refers back to the previous sequence's regional leaf.

— 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.

## Appending a Leaf

— The new leaf has an operation of Append.

— The new appendee leaf has default leaf status.

— The new appendee leaf is represented as the last child of the appended leaf.

— The new appendee leaf is created in the same folder as the appended leaf, and it appears as a child of the appended leaf.

— You can append a leaf more than once.

— The modified file for the new appendee leaf references the appended leaf. The modified file name is formatted as ../<appended leaf sequence number>/index.xml#<letter><numeric identifierGUID>. For example, ../0001/

index.xml#a9f5078464791677a9934ae330536bffa

— You cannot replace or delete the appended leaf in the current sequence. Ennov InSight does not allow a NEW leaf to be APPENDED in the same sequence. The appending document instead can be assigned below the first document under the NEW leaf, which will trigger Ennov InSight to perform a Leaf Roll-up of the two documents. This provides greater clarity to the reviewer and limits the use of Appends in the life cycle.

## 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.

## Deleting a leaf

When you delete (withdraw) a leaf that was submitted in an earlier sequence, you are indicating that the leaf should be removed from the submitted view when the current sequence assembly is added to life cycle.

— The deleted leaf is hidden in the working view.

— A new leaf with an operation of Delete 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 deleted leaf.

— You cannot replace, append or delete 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 Delete operation.

If the deleted leaf had content, the new leaf has 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 deleted leaf. The modified file name is constructed as follows: Modified Leaf shows the leaf that is currently being modified by this leaf in the life cycle. Modified Sequence shows the sequence that is currently being modified by this leaf in the life cycle. 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 life cycle.

— Set Modified File is available in a working assembly to administrators, and in a standalone assembly to everyone. This allows the modified file to be manually set.

— Clear Modified File is available to administrators in a working assembly, and everyone in a standalone assembly. This allows the modified file to be manually cleared.

— You cannot change or move the new leaf, nor can you add elements to the new leaf.

— Deleted leaf elements are hidden in the submitted view after the current sequence assembly is added to life cycle.

## Reverting a Leaf Action

If you mistakenly perform a leaf operation, you can undo it by choosing the leaf for which you want to undo the operation, and then right-clicking the leaf and choosing Revert. To revert an appended leaf, choose the appended leaf, not the appendee leaf.

Update a Working Assembly

You can perform actions to update a working assembly such as replacing a leaf, updating a leaf, or deleting a leaf.

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 life cycle (adding the new leaf elements, their operations and their modified file references) lock the assembly in the working view and add it to life cycle.

Reorganize a Life Cycle Assembly

You can reorganize a life cycle assembly under specific limitations.

Following limitations are:

— 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, appended or modified leaf elements should not be placed under new leaf elements.

— When an assembly is removed from the current active view, slip sheets that were added to the leaf and folder no longer appear in the assembly.

# Add Subsequent Sequences to Life Cycle

Add subsequent sequences to a life cycle like you add the first sequence.

You can add subsequent sequences that are already submitted to the authorities or are no longer required to life cycle.

To add subsequent sequences to a life cycle:

1. Click a link for the sequence that you want to add to the life cycle.

   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.

   — The Read-Only Mode appears next to the Assembly Attributes.

   — The Lock Indicator value is set to Yes.

   — A lock is displayed on the root in the assembly tree.

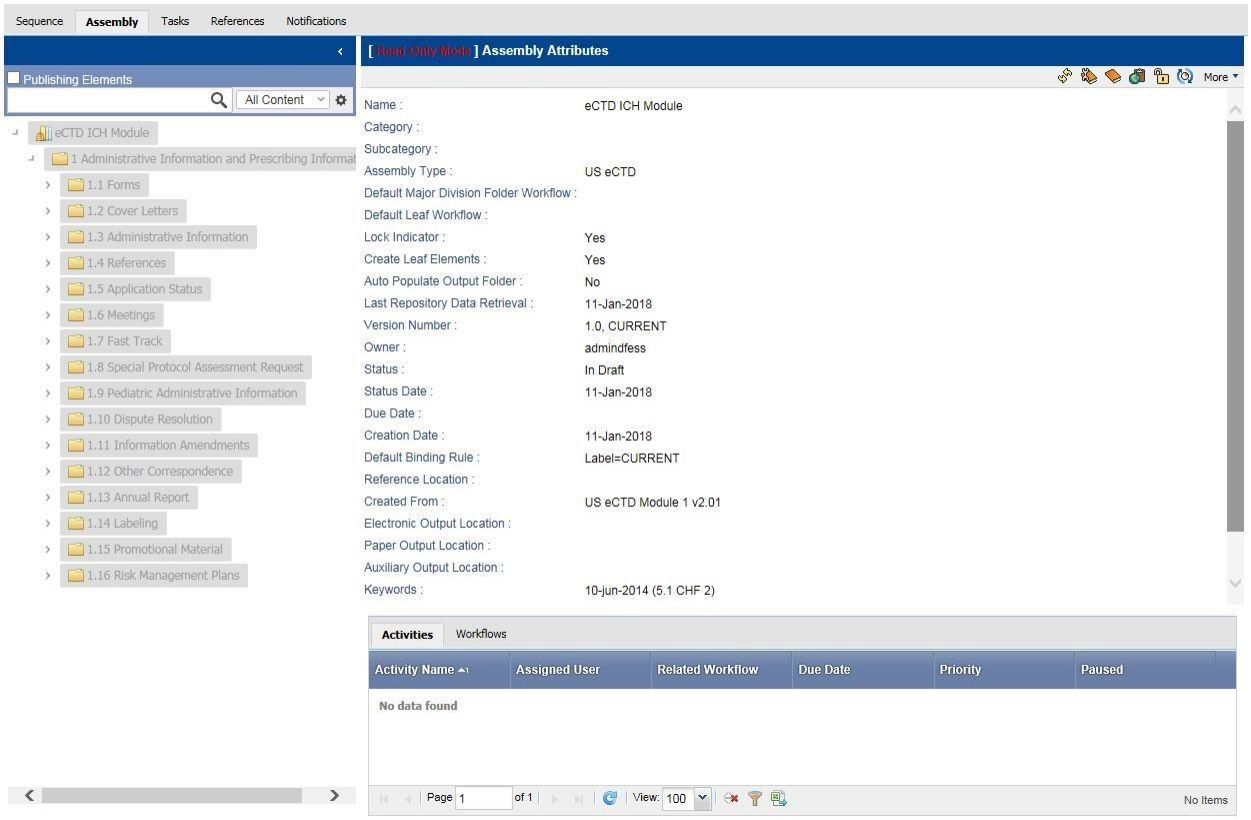
   — When you expand the assembly tree, the elements are grayed out to show they cannot be changed.

   ***Note:*** *The sequence assembly is locked but you can still change attributes for the assembly root.*
6. To add the assembly to life cycle, click 

   .
7. When you are prompted to confirm the addition, click OK.

Ennov InSight Publisher 7.3 Add Subsequent Sequences to Life Cycle

## Example




Modify Submission Statuses

When you have submitted a life cycle 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 life cycle 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 life cycle sequence:

1. Click the link of the sequence you want to modify.
2. On the Sequence View page, click Edit .
3. On the Modify Sequence page, click the Status arrow and choose Submitted.
4. For the Status Date, do one of the following to choose when the sequence was submitted:

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Modify Submission Statuses

— 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:

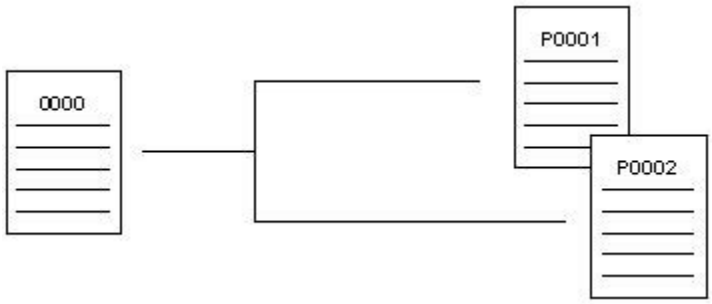
1. On the home page, click the Submitted Views tab.
2. Do one of the following:

| Option | Action |
|---|---|
| To view the *Assembly Attributes* page: | Click a link in the Status View column. |
| 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 P0001 and P0002 are based on 0000, which is the only submitted sequence.



You may submit P0002 to the regulatory agency before you submit P0001. The approved view is based on what has already been submitted, and enables you to make and view your changes. Both of these sequences may modify the same eCTD sections, and in fact they may modify the same eCTD leaf elements.

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View Submitted Sequences

In the example above, when P0001 is submitted, it does not show the changes in the P0002 Submitted and working views. However, sequences P0001 and P0002 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.

For a more specific example, suppose that in P0001 a leaf containing drug product information is updated in section

3.2.P.1. This information is also updated in P0002 with different data. The change in P0001 is an APPEND to the

3.2.P.1 leaf, and the change in P0002 is a replace to the 3.2.P.1 leaf. If P0002 is submitted before P0001, the REPLACE leaf in 3.2.P.1 updates the NEW 3.2.P.1 leaf in sequence 0000. If sequence P0001 were published before running the submittal wizard, its APPEND to the 3.2.P.1 leaf would point to the leaf in sequence 0000. If this is incorrect, P0001 would have to be submitted first and synchronized with the life cycle. Once this was done, the APPEND leaf in 3.2.P.1 would point to the REPLACE 3.2.P.1 leaf in P0002.

In a similar example suppose that in P0001 a leaf containing drug product information is updated in section 3.2.P.1. This information is also updated in P0002 with different data. The change in P0001 is a REPLACE to the 3.2.P.1 leaf, and the change in P0002 is also a REPLACE to the 3.2.P.1 leaf. If P0002 is submitted before P0001, 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 P0001. If sequence P0001 were published before running the submittal wizard, its REPLACE to the 3.2.P.1 leaf would point to the leaf in sequence P0001.

In this way, the eCTD XML is verified to be 100% correct with a valid life cycle. Of course, in the act of submitting P0002 forces the sequence code to change to 0001, and when P0001 is submitted, the wizard again forces the sequence code to change to 0002. This is how Ennov InSight enforces consistency of the life cycle to help prevent compliance issues later.

If many changes have been made to P0001 that you must compare with what is showing in P0002, you can use the *Assembly Comparison* query to view the differences between the planned sequences. This can help you determine the changes you need to make in the unsubmitted planned sequence.

As implied in the second 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. The only situation that cannot be handled is if sequence P0002 has a DELETE operation on a leaf, and sequence P0001 attempts to REPLACE or APPEND on that same leaf. This will trigger an error when sequence P0001 is added to life cycle, because it is an illegal eCTD operation. You can use the *Assembly*

*Comparison* query to view the differences between the planned sequences. This can help you determine the changes you need to make in the unsubmitted planned sequence.

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.

   Ennov InSight Publisher 7.3

   Manage Concurrently Planned Sequences
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 to import parts of the unsubmitted planned sequence.
6. When you finish creating the working assembly, delete the unsubmitted planned working assembly.

## Parallel Submissions

Synchronize Current Working View or Initial Assembly with Latest Submitted View

Ennov InSight enables you to synchronize the current Working view or an initial assembly with the updates made in a Submitted view. To use the option to synchronize, you must have WRITE permissions to an ELP or SPT License, at least READ permissions for parent entities (for Sequence Assembly: Sequences, for Assembly Plan: Submission Plans), and WRITE permissions to Sequence Assemblies.

## Prerequisites

Prerequisites for synchronizing the Working view or an Initial Assembly with the Submitted view:

— Changes must have been made in a Submitted view. Changes made in the Submitted view are indicated by the status Yes for the Updated Submitted Available attribute on the Assembly Attributes page. — The Working Assembly as well as the folders in an assembly must be unlocked.

To synchronize a current Working view or an initial assembly with updates of the Submitted view:

1. In the Working View or an initial assembly, choose the root to synchronize the entire assembly.
2. On the More menu, click Synchronize with the Submitted View.
3. On the confirmation message, click OK.

   The synchronization process starts. While the synchronization process is in progress, some assembly actions are unavailable.
4. To view the status of the synchronization process, use the Job Requests feature.

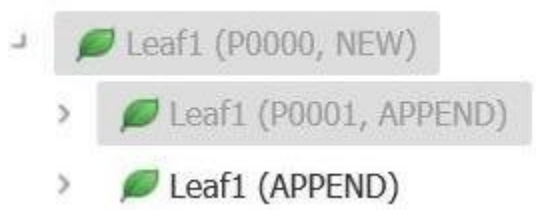
When the synchronization process is complete, the status of the Updated Submitted Available attribute is set to No.

***Note:*** *Synchronization does not make any changes to APL. APL remains, irrespective of the changes made in parallel sequences.*

*Conflicting Operations Rules - Synchronization with Submitted View*

The following rules are applied during synchronization with Submitted view to conflicting operations.

— If a leaf has Append status in the Planned Submission and Append status in the latest Submitted view then after synchronization the current Working View will have the following structure.



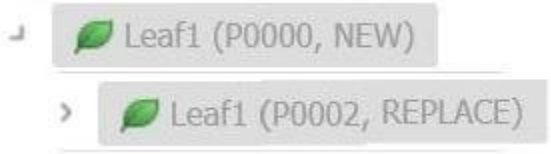

— If a leaf has Append status in the Planned Submission and Replace status in the latest Submitted View then after synchronization the current Working View will have the following structure.



— If a leaf has Append status in the Planned Submission and the Delete/Withdrawn status in the latest Submitted view then after synchronization the current Working view will have the following structure.




— If a leaf has Replace status in the Planned Submission and Append status in the latest Submitted view then after synchronization the current Working view will have the following structure.



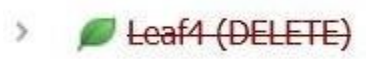

— If a leaf has Replace status in the Planned Submission and Replace status in the latest Submitted view then after synchronization the current Working view will have the following structure.




— If a leaf has Replace status in the Planned Submission and Delete/Withdrawn status in the latest Submitted view then after synchronization the current Working view will have the following structure.




— If a leaf has Delete/Withdrawn status in the Planned Submission and Append status in the latest Submitted view then after synchronization the current Working view will have the following structure.

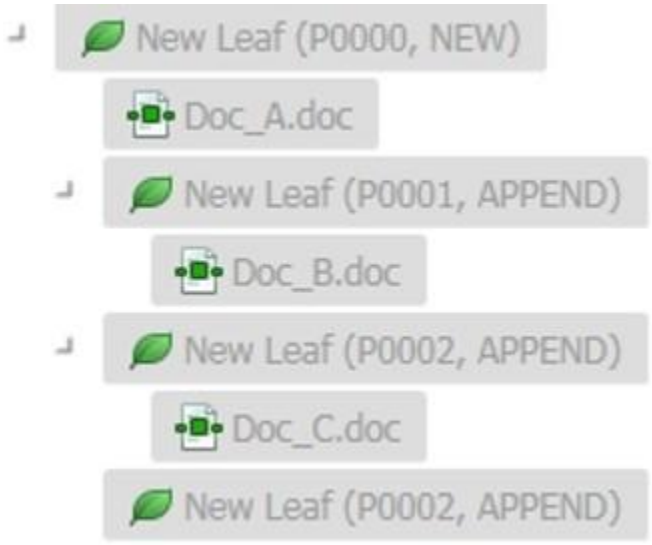



— If a leaf has Delete/Withdrawn status in the Planned Submission and Replace status in the latest Submitted view then after synchronization the current Working view will have the following structure.

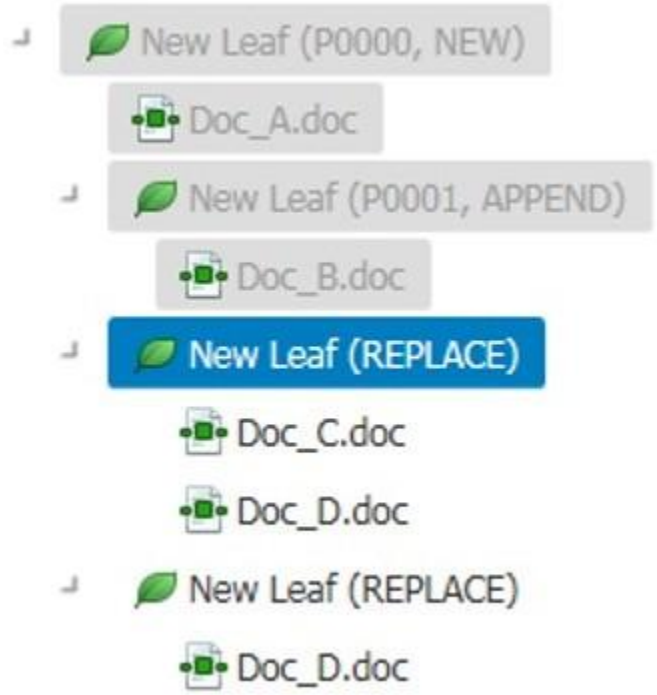



— If a leaf has Delete/Withdrawn status in the Planned Submission and Delete/Withdrawn status in the latest Submitted view then after synchronization the leaf in current Working view will not be displayed (the leaf is deleted from the structure).

— Consider a submission with multiple Appends to a leaf. The tree structure will be as below.




If we now apply Replace or Withdrawn operation to the initial leaf (P0000), the Replace or Withdrawn operation is applied to all the appended leaf from the last lifecycled sequence.




After synchronization, the documents are retained in different views as per the rules noted below:

— If final operation is Append, the documents from Planned submission are retained.

— If final operation is Replace, the documents from both the Planned Submission and the Submitted View are retained.

– If final operation is Withdrawn, the documents from the Submitted view are retained.

All Workflows added to nodes in the Working view are retained. If a leaf with assigned Workflow is re-targeted to several leaves from Submitted view, a Workflow is retained for the first resulting leaf only.

***Note:***

*— If the operation is an Append/Withdraw, all the documents from all of the sequences appear under the resulting leaf.*

*— It is recommended that you avoid synchronization with Submitted view for submissions that have too many changes between Working and Submitted views, as it could result in unpredictable results. For example, if we have P0001 created from P0000 and it is in Working view, and if 10 assemblies are added to life cycle, P0001 will have to be synchronized with P0011.*

*— Synchronization with the Submitted View is not supported when the selected XML definitions are changed.*

*— Publishing Settings Library and US M1 Metadata Submitted View updates are not synchronized with the current Working View.*

*— Some conflicting operations, such as life cycle operations resulting in different leaf locations in cross-specification applications, cannot be resolved by the Synchronize with the Submitted View feature. The synchronization process skips the conflicting leafs and logs the details of the leaf name and ID in the Job Requests.*

Parallel Life Cycle

You can use the View Parallel Lifecycle option to view a report of the concurrent changes of a leaf across planned sequences.

This report is available in the working view of a sequence assembly and an assembly plan.

*View Parallel Life Cycle*

Using the Advanced Assembly Filter feature, an assembly can be filtered to get a list of lifecycled leafs in parallel sequences. You can use the View Parallel Lifecycle feature to view a report of the concurrent changes of the lifecycled leafs across a planned submission.

To view the parallel life cycle of a leaf:

1. In the Working View of a sequence assembly or an assembly plan, choose a leaf to view its parallel life cycle.
2. Right-click on the leaf and select View Parallel Lifecycle.

   The report is displayed in the *Parallel Lifecycle Operations* pane.
3. To view the attributes of a leaf in the report, click the leaf name hyperlink. The leaf attributes are displayed on the *Leaf Attributes* page.

# Chapter 8. Submissions

## Submissions

The Ennov InSight submission wizards help you to create and modify submissions.

— Create eCTD provides an alternate way for you to create and organize standalone and sequence assemblies.

— Create Study Reports enables you to add study report structures (for example, folders, leaf elements) to existing assemblies.

— Create Submission enables you to create an application, its associated event, and sequence.

— Change Submittal Status 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) — Paper Review Publishing (PRP)

— Registered Document Analysis (RDA)

— Submission Planning and Tracking (SPT)

## Submission Wizard Administrative Prerequisites

Before you can use the submission wizards, certain fields and information types must already be set up and configured in data administration.

Includes the following :

— Product family type values

— Product family name

— Product family code

— Country values

— Default application status

— Default event status

— Default sequence status

— Default application type

— Default procedure type

— Event type

— Sequence filing type

— Products

Submissions

## 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 MRP and DCP 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.

For European submissions, the wizard displays only the countries that have been selected as part of the sequence. For certain submission procedures such as Centralized, only one country (EMEA) will be available. The common country is treated in a special way by the Create eCTD wizard. It is not included in normal country selections when creating submissions. However, if the common country is found in a section of the regional templates, it is always included as a possible selection in the Create eCTD wizard.

**Note:** Only the MRP/DCP templates include any folders where the country is common. These appear in the following sections: 1.0, 1.2, 1.3.2, 1.3.3, 1.3.4, 1.3.5, Responses to Questions, and Additional Data. The common option does not apply to CP or NP submissions, which is why separate templates are required for the different procedure types.

## 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 EU-CP internal procedure type applications, automatically associate the EU Country with the event
- For WAHO-CP internal procedure type applications, automatically associate the WAHO 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 cre- ate 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 time- line/event plan to cre- ate 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 de- fault. |
| To cre- ate a se- quence: | 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 se- quence 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 and SSO are enabled | a. In the confirmation page, select a reason and enter comments for the reason.<br>b. Click **Next**.<br>c. Validate your identity by entering your user credentials in the dialog box. |
| When electronic signature is enabled and SSO is disabled | a. Select a reason and enter comments for the reason.<br>b. Enter user ID and password and click Next. |

9. 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.** |

10. 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. |

| Option | Action |
|---|---|
| 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:<br>• For US applications, the application code is always a 6-digit number.<br>• For Canadian applications, the application is generally an *e* followed by a 6-digit number (for example, e123456).<br>• For Japan the application code is generally ectd- followed by a 6-digit number (for example, ectd-123456).<br>• 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. |
| 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 included in the Product Family that are available to include in the application. |

| Attribute | Description |
|---|---|
| Products | |
| Co-Rapporteur | Used when the Reviewing Country is a member of the European Union (EU) or Western African Health Organization (WAHO) 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. When a WAHO country is selected, Western African Health Organization 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. |

| Attribute | Description |
|---|---|
| Keywords | Words used to enable a search for entities associated with the submission. |
| 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 Nation- al 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:<br>• **NeeS**<br>• **Paper**<br>• **eCTD 3.2**<br>• **eCTD 4.0** |
| UUID | UUID (version 4 of UUID types) is a universal unique identifier that is automatically generated by the sys- tem on sequence creation. This field is visible and available for modification and view pages only. |

| Attribute | Description |
|---|---|
| | • The value can be modified only by users with Administrator permissions to the sequence.<br>• 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.<br><br>**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-xxxx-Mxxx-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. |

## 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 EU-CP internal procedure type applications, automatically associate the EU Country with the event.
- For WAHO-CP internal procedure type applications, automatically associate the WAHO 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 deviation 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 and SSO are enabled | a. In the confirmation page, select a reason and enter comments for the reason.<br>b. Click **Next**.<br>c. Validate your identity by entering your user credentials in the dialog box. |

| Scenario | Steps |
|---|---|
| When electronic signature is enabled and SSO is disabled | a. Select a reason and enter comments for the reason.<br>b. Enter user ID and password and click Next. |

7. 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**. |

8. 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 avail- able for 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. |
| 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 cre- nated 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 npt rocedure 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. |

| Attribute | Description |
|---|---|
| Filing Type | The filing type for the application. |
| Keywords | Words used to search for when creating a submission. |
| 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 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 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:<br>• **NeeS**<br>• **Paper**<br>• **eCTD 3.2**<br>• **eCTD 4.0** |
| UUID | UUID (version 4 of UUID types) is a universal unique identifier that is automatically generated by the sys- tem on sequence creation. This field is visible and available for modification and view pages only. |

| Attribute | Description |
|---|---|
| | • The value can be modified only by users with Administrator permissions to the sequence.<br>• 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.<br><br>**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-xxxx-Mxxx-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 and SSO are enabled | a. In the confirmation page, select a reason and enter comments for the reason.<br>b. Click **Next**.<br>c. Validate your identity by entering your user credentials in the dialog box. |
| When electronic signature is enabled and SSO is disabled | a. Select a reason and enter comments for the reason.<br>b. Enter user ID and password and click Next. |

5. 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.
6. Click **Next**.The *Create Submission Confirmation* page appears.
7. 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. Additional 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.**. |

8. 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 *Searching 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) or WAHO, 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 WAHO. |
| 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. |

| 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) or WAHO, the Concerned Member States attribute appears and enables you to select multiple countries for the submission. |
| 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 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 Description | Text that describes an entity within the submission. |
| Sequence Keywords | Words used to search for when creating a submission. |
| Sequence Stan- | The following sequence standard types are available for selection:<br>• NeeS<br>• Paper |

| Attribute | Description |
|---|---|
| dard Type | • eCTD 3.2<br>• 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 or a standalone assembly.

— 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 standalone assemblies

— 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.

Based on eCTD 3.2 or eCTD 4.0 values selected for the Sequence Standard Type, the corresponding templates are displayed under Template Selection on the *Create eCTD* wizard page. 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 (US, Canada, Europe. Switzerland, Japan, Rest of World), some of the properties are different. For example, United States does not require a country.

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.

When running the *Create eCTD* wizard for a new standalone assembly, the regions available for selection in the Region drop-down list are all active regions of the Regulatory Region type. The list is alphabetically sorted.

When running the *Create eCTD* wizard, or editing the M1 or envelope folders:

— The current sequence code for the sequence entity is always updated in the eCTD metadata in the folder extension.

— The sequence code is always used when publishing.

Null Value and Swiss eCTD Assemblies

When using the *Create eCTD* wizard to create a Swiss eCTD assembly, you are prompted for the number of Galenic Forms included in the sequence, the name of the form, and Swissmedic Number. A separate folder is created for each Galenic Form indicated in the resulting assembly and includes the value 'null' in the Name attribute.

You MUST edit the extended attributes of each folder to provide the Galenic Form's translation languages and values (the Galenic Language Name attribute pair).

You may also update the folder name to remove the 'null' value, but this has no effect on the published output. At least one Galenic Language Name pair must be provided in order to produce valid XML.

Create eCTD 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, standalone assembly, or assembly plan from which you want to create an eCTD 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. For assembly plans, the name of the submission plan associated with the assembly plan is populated automatically as the name for the assembly. |
| To import the TOC and special sheet values from the publication settings | Select Copy TOCs and Special Sheets. |

| | |
|---|---|
| of the template on which you are basing the eCTD: | |
| 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. |
| Next to Template Selection: | Select the template on which to base the eCTD. |
| | ***Note:*** *Based on eCTD 3.2 or eCTD 4.0 values selected for the Sequence Standard Type, the corresponding templates are displayed under Template Selection on the Create eCTD wizard page.* |

***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 standalone, 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. 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.

    ***Note:*** *To pre-populate the values, it is recommended that the Sender-defined Keywords are created before using the Create eCTD wizard.*

12. Enter the submission metadata. For metadata description, see *Submission Metadata*.
13. Click Next.

    The *Confirmation* page appears.

14. Click Next.

    The *Summary* page displays a message indicating that the eCTD information has been saved to the assembly.

15. 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. |

Add Metadata to Assembly

Ennov InSight enables you to add metadata such as application number, cross-reference application details, sequence number, and submission ID to US DTD v3.3 submissions.

To add metadata to an assembly:

1. Navigate to the assembly to which you want to add metadata.
2. Expand the assembly tree and select the module level folder to which you want to add the metadata.
3. Click More > Add Metadata.
4. Select the metadata type from the drop-down list.
5. Enter relevant details in their corresponding fields.

   For an assembly plan with multiple applications associated to it, only one application containing files can be configured.

6. Save.

The metadata is added to the assembly. eCTD Attributes Australia

You can use the following attributes to describe eCTD submissions for Australia.

## Australia-v0.90

| Attribute | Description |
|---|---|
| Applicant | The applicant name as listed in the eBS client database. |
| ARTG Number | The Australian Register of Therapeutic Goods number. The ARTG can be a four, five or six digit number. Multiple comma-separated values can be provided. |
| Australian Approved Name(s) | The name of the active ingredients that are accepted for inclusion in the Australian Approved Name list. Multiple comma-separated values can be provided. |
| eSubmission Identifier | The Application Number as provided by the agency. |
| Product Name | The name or proposed product (trade) name to be used on the Certificate of Registration. Multiple comma-separated values can be provided. |
| Regulatory Activity Lead | Identifies the group within the TGA which is expected to take the lead in the review process. |
| Related Sequence Number | Four digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity. |
| Sequence Description | Content description for the submitted sequence. |
| Sequence Number | Four digit sequence number matching the sequence folder being submitted. |

## Australia-v3.0

| Attribute | Description |
|---|---|
| Applicant | The applicant name as listed in the eBS client database. |
| ARTG Number | The Australian Register of Therapeutic Goods number. The ARTG can be a four, five or six digit number. Multiple comma-separated values can be provided. |
| Australian Approved Name(s) | The name of the active ingredients that are accepted for inclusion in the Australian Approved Name list. Multiple comma-separated values can be provided. |
| eSubmission Identifier | The Application Number as provided by the agency. |

| | |
|---|---|
| Product Name | The name or proposed product (trade) name to be used on the Certificate of Registration. Multiple comma-separated values can be provided. |
| Regulatory Activity Lead | Identifies the group within the TGA which is expected to take the lead in the review process. |
| Related Sequence Number | Four digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity. |
| Sequence Description | Content description for the submitted sequence. |
| Sequence Number | Four digit sequence number matching the sequence folder being submitted. |
| Sequence Type | Identifies the type of activity that is being submitted with the sequence, either the regulatory activity type if it is the first sequence of the regulatory activity or supplementary information if it is a follow-up to information already submitted for the regulatory activity. |

## Australia-v3.1

| Attribute | Description |
|---|---|
| Approved Name(s) | The name of the active ingredients that are accepted for inclusion in the Australian Approved Name list. You can enter up to 500 characters. Multiple comma-separated values can be provided. |
| ARTG Number(s) | The Australian Register of Therapeutic Goods number. The ARTG can be a four, five, or six digit number. Multiple comma-separated values can be provided. |
| Contact Email | Results of the sequence validation are sent to the email addresses provided. You can enter up to 500 characters. Multiple comma-separated values can be provided. |
| e-Identifier | The Application Number as provided by the agency. The value must be a lowercase letter followed by six digits.<br>Example: a123456 |
| Attribute | Description |
| eBS Client ID | The client ID as listed in the eBS client database. You can enter up to 200 characters. |
| Regulatory Activity Lead | Identifies the group within the TGA that is expected to take the lead in the review process. |

| | |
|---|---|
| Related Sequence Number | Four-digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity. |
| Sequence Description | Content description for the submitted sequence. |
| Sequence Number | Four-digit sequence number matching the sequence folder being submitted. |
| Sequence Type | Identifies the type of activity that is being submitted with the sequence, either the regulatory activity type if it is the first sequence of the regulatory activity or supplementary information if it is a follow-up to information already submitted for the regulatory activity. |
| Submission or Application Number(s) | The submission number(s) or application number(s) applicable to the sequence being submitted. You can enter up to 500 characters. Multiple commaseparated values can be provided. |
| Submission Mode | The value can be set to Single, Work-grouping, or Work-sharing. Until the work grouping and work sharing functions are sufficiently developed, the only valid mode is Single which denotes a single regulatory activity. |
| Trade Name(s) | The name or proposed product (trade) name to be used on the Certificate of Registration. You can enter up to 500 characters. Multiple comma-separated values can be provided. |

The following table describes are recommendation for providing the Submission Number values:

| Submission Number Value | Description | Allowable Combinations |
|---|---|---|
| PM-2017-12345-1-5 Prescription medicines submission numbers | Prefix PM followed by the submission number and stream.<br>— If the submission number is not yet known it is appropriate to only include the prefix and the stream. Example: PM-1<br>***Note:*** *This will apply whether the activity refers to a biological medicine or other molecular type ('chemical' medicine).* | — PM with PV or MF<br>— BA with PV or MF<br>— OM with PV<br>— PV with PM, BA, or OM<br>— MF with PM or BA |
| BA-2017-12345-1 Biologicals submission numbers | Prefix BA followed by the submission number. | |

| | | |
|---|---|---|
| | — If the submission number is not yet known it is appropriate to only include the prefix.<br><br>Example: BA. | |
| OM-2017-12345-1 OTC medicines submission numbers | Prefix OM followed by the submission number.<br><br>— If the submission number is not yet known it is appropriate to only include the prefix.<br><br>Example: OM. | |
| Complementary Medicines | For registered complementary medicines the same protocol applies as for OTC medicines as detailed above. For listed complementary medicines no validation is planned at this time. | |
| PV Pharmacovigilance | No submission number is assigned.<br>PV should be entered for all sequences where pharmacovigilance information is submitted. | |
| MF Master Files | No submission number is assigned.<br>MF should be entered for all sequences where master file information is submitted. | |
| MD Medical Devices | Depending on whether the eCTD application is a device application | |
| | or a conformity assessment, the | |
| ©Ennov 2024 Ennov | prefix should be DA or DC.278<br><br>Example: DA-2017-12345-1. | Ennov InSight Publisher 7.3 Create eCTD Wizard |

eCTD Attributes Canada

You can use the following attributes to describe eCTD submissions for Canada.

## Australia-v3.2

The metadata is added to the assembly. eCTD Attributes Australia

You can use the following attributes to describe eCTD submissions for Australia.

| Attribute | Description |
|---|---|
| Approved Name(s) | The name of the active ingredients that are accepted for inclusion in the Australian Approved Name list. You can enter up to 500 characters. Multiple comma-separated values can be provided. |
| ARTG Number(s) | The Australian Register of Therapeutic Goods number. The ARTG can be a four, five, or six digit number. Multiple comma-separated values can be provided. |
| Contact Email | Results of the sequence validation are sent to the email addresses provided. You can enter up to 500 characters. Multiple comma-separated values can be provided. |
| e-Identifier | The Application Number as provided by the agency. The value must be a lowercase letter followed by six digits.<br>Example: a123456 |
| eBS Client ID | The client ID as listed in the eBS client database. You can enter up to 200 characters. |
| Regulatory Activity Lead | Identifies the group within the TGA that is expected to take the lead in the review process. |
| Related Sequence Number | Four-digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity. |
| Sequence Description | Content description for the submitted sequence. |
| Sequence Number | Four-digit sequence number matching the sequence folder being submitted. |
| Sequence Type | Identifies the type of activity that is being submitted with the sequence, either the regulatory activity type if it is the first sequence of the regulatory activity or supplementary information if it is a follow-up to information already submitted for the regulatory activity. |
| Sequence Type / Sequence Description | Identifies the type of activity that is being submitted with the sequence, either the regulatory activity type if it is the first sequence of the regulatory activity or supplementary information if it is a follow-up to information already submitted for the regulatory activity. |
| Submission or Application Number(s) | The submission number(s) or application number(s) applicable to the sequence being submitted. You can enter up to 500 characters. Multiple commaseparated values can be provided. |

| | |
|---|---|
| Submission Mode | The value can be set to Single, Work-grouping, or Work-sharing. Until the work grouping and work sharing functions are sufficiently developed, the only valid mode is Single which denotes a single regulatory activity. |
| Trade Name(s) | The name or proposed product (trade) name to be used on the Certificate of Registration. You can enter up to 500 characters. Multiple comma-separated values can be provided. |

## Bosnia and Herzegovina – v3.1

| Attribute | Description |
|---|---|
| Country | Defines which country the envelope information is related to |
| UUID | A UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 \| ISO/IEC 9834-8:2005. The same UUID must be used for all sequences of an eCTD application |
| Submission Type | The Filing type of the submission |
| Submission Mode | The mode of the submission, either single, grouping, or worksharing |
| Submission Unit Type | Submission unit type describes the content at a lower level (a “sub-activity”) which is submitted in relation to a defined regulatory activity. |
| High Level/Worksharing Submission Number | The high level submission number for the specific submission, used when the submission mode is grouping or worksharing |
| Application Tracking Number | The Application Number as provided by the agency |
| Applicant | The name of the company submitting the Application |
| Agency Name | The name of the agency that the submission is being sent to |
| Procedure Type | The procedure type being used to submit |
| Invented Name | The invented name of the product being submitted for approval |
| INN | The INN of the product being submitted for approval |
| Sequence | The Sequence Number for this submission |
| Related Sequence | This is the sequence number of previous submission(s) to which this submission relates e.g. the responses to questions to a particular variation. In the case of |

| | |
|---|---|
| | submission unit types ‘initial’ and ‘reformat’ related sequence is identical to the sequence number. |
| Submission Description | The description of the Submission to be included in the XML |

## Canada-v2.2

| Attribute | Description |
|---|---|
| Applicant | The company that is submitting the regulatory transaction. |
| Dossier Identifier | The unique identifier assigned to the dossier by Health Canada. The Dossier Identifier is 7 characters: a lower case letter followed by 6 digits. |
| Dossier Type | The dossier type: Biologic Dossier, Drug Master File Dossier, or Pharmaceutical Dossier. |
| Product Name | The product or products that are being addressed in the application |
| Regulatory Activity Lead | Defines which group within Health Canada is expected to take the lead in reviewing the regulatory activity supported by the regulatory transaction. |
| Regulatory Activity Type | The type of regulatory activity: i.e. what regulatory purpose the filing is addressing. |
| Related Sequence Number | The four digit sequence number of the first sequence in the regulatory activity. |
| Sequence Number | The four digit number that is the unique identifier for the sequence (regulatory transaction) inside the overall dossier. |
| Sequence Description | The description of the sequence (regulatory transaction) based upon a series of possibilities defined by Health Canada. |

eCTD Attributes China

You can use the following attributes to describe eCTD submissions for China.

## China-v1.0

| Attribute | Description |
|---|---|

| | |
|---|---|
| Application Number | Unique identification number for an application in its full life cycle, assigned by the regulato- ry agency.<br><br>The applicant obtains the application number from the regulatory agency when it submits eCTD applications for IND, NDA, ANDA for the first time.<br><br>The application number format:<br><br>Letter (x = NDA; y = ANDA; I = IND) + year (4 digits) + 5 digit serial number.<br><br>Example: x201912345. |
| Application Type | Describes the application purpose. Example: IND, NDA, ANDA |
| Attribute | Description |
| Product Type | Describes the product classification information. Example: Chemical Product, Biological Product. |
| Original Number | The basic and permanent number given to a drug entering the registration approval process. The original number is assigned by the regulatory agency and is used as the unique code to identify the applicant, active ingredient (API), and dosage form.<br><br>The original number format: year (4 digits) + 6-digit serial number. Example: *2019123456*. |
| Related Sequence | Used to group the sequences in one application according to the regulatory activity. The first sequence in one regulatory activity is the related sequence for all other sequences sub- mitted in the regulatory activity. |
| Regulatory Activity Type | Describes the purpose of the regulatory activity. |
| Sequence Number | A unique 4-digit character string in the application, a unique identifier that distinguishes dif- ferent submitted sequences.<br><br>The applicant shall submit the application from 0000 and the sequence number shall be incremented by 1 for each submission. The application shall be submitted based on se- quence. |
| Sequence Type | Describes the purpose of the sequence. |
| Sequence Descrip- tion | Brief description of the sequence purpose, used to distinguish the sequence of similar type. The sequence description length shall be controlled within 120 Chinese characters. The se- quence description shall not substitute the reply and cover letter to the request raised by the regulatory agency, and shall not be used to raise questions to the regulatory agency. |

| | |
|---|---|
| Sequence Contact Name | Name of the contact person responsible for the sequence. |
| Sequence Contact Telephone | Telephone number of the contact person responsible for the sequence. |
| Sequence Contact Email | Email address of the contact person responsible for the sequence. |

eCTD Attributes EAEU

You can use the following attributes to describe eCTD submissions for the EAEU.

## EAEU-v.1.0

| Attribute | Description |
|---|---|
| Country | List of country codes associated to the EAEU region. |
| EDoc Id | Electronic Document ID. UUID format. |
| EDoc Reference Id | Electronic Document ID of the document the current document is referred to. UUID format. |
| EDoc Date Time | Creation timestamp. Date of the assembly creation. Date format - Unix Timestamp. |
| Registration Number Id | Registration Number. Six digits. |
| Application Id | Application Id. |
| Registration Kind Code | Defines a procedure:<br>— 01 – mutual recognition: MRP.<br>— 02 - decentralized: DCP. |
| Submission Sequence | Defines a current sequence code for all the leafs in the assembly. Four digits. |

eCTD Attributes European Union

## European Union-v3.1

| Attribute | Description |
|---|---|
| Country | Defines which country the envelope information is related to. |
| UUID | A UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 \| ISO/IEC 9834-8:2005. The same UUID must be used for all sequences of an eCTD application. |

| | |
|---|---|
| Submission Type | The Filing type of the submission. |
| Submission Mode | The mode of the submission, either single, grouping, or worksharing. |
| Submission Unit Type | Submission unit type describes the content at a lower level (a "subactivity") which is submitted in relation to a defined regulatory activity. |
| High Level/ Worksharing Submission Number | The high level submission number for the specific submission, used when the submission mode is grouping or worksharing. |
| Application Tracking Number | The Application Number as provided by the agency. |
| Applicant | The name of the company submitting the application. |
| Agency Name | The name of the agency that the submission is being sent to. |
| Procedure Type | The procedure type being used to submit. |
| Attribute | Description |
| Invented Name | The invented name of the product being submitted for approval. |
| INN | The INN of the product being submitted for approval. |
| Sequence | The Sequence Number for this submission. |
| Related Sequence | This is the sequence number of previous submission(s) to which this submission relates. For example, the responses to questions to a particular variation. In the case of submission unit types 'initial' and 'reformat' related sequence is identical to the sequence number. |
| Submission Description | The description of the Submission to be included in the XML. |

## European Union-v3.0.1

| Attribute | Description |
|---|---|
| Agency Name | The name of the receiving agency for the submission. The default is based on the country for the application. |
| Applicant | The name of the company submitting the eCTD. |
| Application | The number used by an agency or applicant to track the submission, in any procedure, in relation to a particular product. There must be at least one tracking number identified from the regulators. The applicant can choose to include an internal tracking number. |

| | |
|---|---|
| Tracking Number | |
| Country | The country to which the envelope applies. The default is the country of the application. |
| High Level/ Worksharing Submission Number | The high-level submission number, either a 'worksharing' number or the highlevel submission number to be used when grouping Type IA variations for multiple marketing authorisations. It is used when the submission mode is either Grouping or Worksharing. |
| INN | International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. |
| Invented Name | The invented name of the medicinal product which is submitting for an approval. |
| Procedure Type | The type of procedure for the submission. The default is based on the application Country. |
| Related Sequence | The sequence number(s) of previous submission(s) to which this submission relates. |
| Sequence | The sequence number of the submission. |
| Submission Description | The description of the submission to be included in the XML. |
| Attribute | Description |
| Submission Mode | The mode of the submission, either Single, Grouping, or Worksharing. The submission mode should only be used in variation or line extension regulatory activities and must be included in every sequence of that activity. |
| Submission Type | The type of submission material sent to the regulatory agency. |
| Submission Unit Type | Submission unit type describes the content at a lower level (a “sub-activity”) which is submitted in relation to a defined regulatory activity. |
| UUID | A UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 \| ISO/IEC 9834-8:2005. The same UUID is used for all sequences of an eCTD applications. UUID is a universal unique identifier.<br>Through the eCTD wizard, users with appropriate permissions are able to modify the UUID to support Sequences that may require a different UUID than the remainder of the Applica- tion. In most cases, the UUID value should not change. |

## European Union-v3.0

| Attribute | Description |
|---|---|

| | |
|---|---|
| Agency Name | The name of the receiving agency for the submission. The default is based on the country for the application. |
| Applicant | The name of the company submitting the eCTD. |
| Application Tracking Number | The number used by an agency or applicant to track the submission, in any procedure, in relation to a particular product. There must be at least one tracking number identified from the regulators. The applicant can choose to include an internal tracking number. |
| Country | The country to which the envelope applies (or 'ema'). The default is the country of the application. |
| High Level/ Worksharing Submission Number | The high-level submission number, either a 'worksharing' number or the highlevel submission number to be used when grouping Type IA variations for multiple marketing authorisations. It is used when the submission mode is either Grouping or Worksharing. |
| INN | International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. |
| Invented Name | The name of the medicinal product. |
| Procedure Type | The type of procedure for the submission. The default is based on the application Country. |
| Related Sequence | The sequence number(s) of previous submission(s) to which this submission relates. |
| Attribute | Description |
| Sequence | The sequence number of the submission. |
| Submission Description | The description of the submission to be included in the XML. |
| Submission Mode | The mode of the submission, either Single, Grouping, or Worksharing. The submission mode should only be used in variation or line extension regulatory activities and must be included in every sequence of that activity. |
| Submission Type | The type of submission material sent to the regulatory agency. |
| Submission Unit Type | Submission unit type describes the content at a lower level (a “sub-activity”) which is submitted in relation to a defined regulatory activity. |
| UUID | A UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 \| ISO/IEC 9834-8:2005. The same UUID is used for all sequences of an eCTD applications. UUID is a universal unique identifier. |

| | |
|---|---|
| | Through the eCTD wizard, users with appropriate permissions are able to modify the UUID to support Sequences that may require a different UUID than the remainder of the Applica- tion. In most cases, the UUID value should not change. |

## European Union-v2.0

| Attribute | Description |
|---|---|
| Agency Name | The name of the receiving agency for the submission. The default is based on the country for the application. |
| Applicant | The name of the company submitting the eCTD. |
| Application Tracking Number | The number used by an agency or applicant to track the submission, in any procedure, in relation to a particular product. There must be at least one tracking number identified from the regulators. The applicant can choose to include an internal tracking number. Multiple comma-separated values can be provided |
| Country | The country to which the envelope applies (or 'ema'). The default is the country of the application. |
| High Level/ Worksharing Submission Number | The high-level submission number, either a 'worksharing' number or the highlevel submission number to be used when grouping Type IA variations for multiple marketing authorisations. It is used when the submission mode is either Grouping or Worksharing. |
| INN | International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Multiple comma-separated values can be provided. |
| Attribute | Description |
| Invented Name | The name of the medicinal product. Multiple comma-separated values can be provided. |
| Procedure Type | The type of procedure for the submission. The default is based on the application Country. |
| Related Sequence | The sequence number(s) of previous submission(s) to which this submission relates. Multiple comma-separated values can be provided. |
| Sequence | The sequence number of the submission. |
| Submission Description | The description of the submission to be included in the XML. |
| Submission Mode | The mode of the submission, either Single, Grouping, or Worksharing. The submission mode should only be used in variation or line extension regulatory activities and must be included in every sequence of that activity. |
| Submission Type | The type of submission material sent to the regulatory agency. |

eCTD Attributes Gulf Cooperation Council

You can use the following attributes to describe eCTD submissions for Gulf Cooperation Council (GCC).

## Gulf Cooperation Council-v1.2

| Attribute | Description |
|---|---|
| Agency Name | The name of the receiving agency for the submission. |
| Applicant | The name of the company submitting the eCTD. |
| Application Number | The number issued for the sponsor and the product by the GCC (Gulf Cooperation Council). The Application Number remains from the first data submission for the full life cycle of the product. Multiple comma-separated values can be provided. |
| ATC | The ATC (Anatomical Therapeutic Chemical) code. Multiple comma-separated values can be provided. |
| Country | The GCC country for which the envelope information is related. |
| INN | The International Nonproprietary Name, used to identify pharmaceutical substances or ac- tive pharmaceutical ingredients. Multiple comma-separated values can be provided. |
| Invented Name | The name of the medicinal product. Multiple comma-separated values can be provided. |
| Procedure Type | The procedure type for the product. Available values: gcc, national |
| Attribute | Description |
| Related Sequence | The sequence number of a previous submission to which this submission relates. Multiple comma-separated values can be provided. |
| Sequence | The sequence number of the submission. The default is from the Sequence Code, but can be overridden. |
| Submission Descrip- tion | The description of the Submission to be included in the XML. |
| Submission Type | The filing type of the submission. |

## Gulf Cooperation Council-v1.5

| Attribute | Description |
|---|---|
| Agency Name | The name of the receiving agency for the submission. |
| Applicant | The name of the company submitting the eCTD. |

| | |
|---|---|
| Application Number | The number issued for the sponsor and the product by the GCC. The Application Number remains from the first data submission for the full life cycle of the product. Multiple comma-separated values can be provided. |
| ATC | The ATC (Anatomical Therapeutic Chemical) code. Multiple comma-separated values can be provided. |
| Country | The GCC country for which the envelope information is related. |
| INN | The International Nonproprietary Name, used to identify pharmaceutical substances or ac- tive pharmaceutical ingredients. Multiple comma-separated values can be provided. |
| Invented Name | The name of the medicinal product. Multiple comma-separated values can be provided. |
| Procedure Type | The procedure type for the product. Available values: gcc, national |
| Related Sequence | The sequence number of a previous submission to which this submission relates. Multiple comma-separated values can be provided. |
| Sequence | The sequence number of the submission. The default is from the Sequence Code, but can be overridden. |
| Submission Description | The description of the Submission to be included in the XML. |
| Submission Type | The filing type of the submission. |
| Submission Unit Type | The actions within the regulatory activity (initial submission, update, responses to questions, any additional information or consolidation submission respectively when closing a regulatory activity). |

eCTD 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. |
| Brand Name | The marketing name for the product. |
| Generic Name | The generic name for the product. |
| 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. |

eCTD Attributes Jordan

You can use the following attributes to describe eCTD submissions for Jordan.

**Jordan-v1.0.2.**

| Attribute | Description |
|---|---|
| Country | Country Code |
| Application Reference Number | Element for the reference number of the product as taken from eJDWS. Multiple comma-separated values can be provided. |
| Number | Reference number of the product allocated by the regulatory authority. If the number is not yet allocated at the time point of submission, 'to be advised' should be added instead and replaced by the number in follow-up submissions when registered. |
| UUID | UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 \| ISO/IEC 9834-8:2005. The same UUID is used for all sequences of an eCTD Application. UUID is a universal unique identifier.<br>Using the eCTD wizard, users with appropriate permissions are able to modify the UUID to support Sequences that may require a different UUID than the remainder of the Application. In most cases, the UUID value should not change. |
| Applicant | Name of the company submitting the eCTD. |
| Agency | Name of the receiving agency for the submission. |
| Attribute | Description |
| MAH | Marketing Authorisation Holder. |
| ATC | ATC (Anatomical Therapeutic Chemical) code. Multiple comma-separated values can be provided. |
| Submission Type | Filing type of the submission. |

| | |
|---|---|
| Submission Unit | Actions within the regulatory activity: initial submission, update, responses to questions, any additional information or consolidation submission respectively when closing a regulatory activity. |
| Procedure | Procedure type for the product. Available values: jo, national. |
| Invented Name | Name of the medicinal product. Multiple comma-separated values can be provided. |
| INN | International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Multiple comma-separated values can be provided. |
| Sequence | Sequence number of the submission. The default is from the Sequence Code, but can be overridden. |
| Related Sequence | Sequence number of a previous submission to which this submission relates. Multiple comma-separated values can be provided. |
| Submission Description | Description of the Submission to be included in the XML. |

**Jordan-v1.1.**

| Attribute | Description |
|---|---|
| Country | Country Code |
| Application Reference Number | Element for the reference number of the product as taken from eJDWS. Multiple comma-separated values can be provided. |
| Number | Reference number of the product allocated by the regulatory authority. If the number is not yet allocated at the time point of submission, 'to be advised' should be added instead and replaced by the number in follow-up submissions when registered. |
| UUID | UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 \| ISO/IEC 9834-8:2005. The same UUID is used for all sequences of an eCTD Application. UUID is a universal unique identifier.<br><br>Using the eCTD wizard, users with appropriate permissions are able to modify the UUID to support Sequences that may require a different UUID than the remainder of the Application. In most cases, the UUID value should not change. |
| Attribute | Description |
| Applicant | Name of the company submitting the eCTD. |

| | |
|---|---|
| Agency | Name of the receiving agency for the submission. |
| MAH | Marketing Authorisation Holder. |
| ATC | ATC (Anatomical Therapeutic Chemical) code. Multiple comma-separated values can be provided. |
| Submission Type | Filing type of the submission. |
| Submission Unit | Actions within the regulatory activity: initial submission, update, responses to questions, any additional information or consolidation submission respectively when closing a regulatory activity. |
| Procedure | Procedure type for the product. Available values: jo, national. |
| Invented Name | Name of the medicinal product. Multiple comma-separated values can be provided. |
| INN | International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Multiple comma-separated values can be provided. |
| Sequence | Sequence number of the submission. The default is from the Sequence Code, but can be overridden. |
| Related Sequence | Sequence number of a previous submission to which this submission relates. Multiple comma-separated values can be provided. |
| Submission Description | Description of the Submission to be included in the XML. |

eCTD Attributes Singapore

You can use the following attributes to describe eCTD submissions for Singapore.

## Singapore-v1.0

| Attribute | Description |
|---|---|
| Application Type | The type value for the Application. |
| SG eCTD ID | A unique identifier issued by HSA via the HSA eCTD Portal, will be used for all Sequences of an eCTD Application and cannot ever be changed. |
| Application Number | Each product in an Application should have a unique Application Number. prefix of “e” should be added to the Application Number for all eCTD applications. The prefix is followed by the application number issued for the NDA or GDA in PRISM (case-sensitive) or the Drug Master File (DMF) number to form the eCTD Application Number.<br>If multiple strengths are combined in a single eCTD Application, then the Application Number of each strength should be listed in the eCTD Application. |
| INN | The recognised International Non-proprietary Name(s) should be given. It should only be written in lower-case letters and provided exactly as listed as INN without abbreviations. |
| Product Type | The type of product being submitted |
| DMF Number | The Drug Master File (DMF) Number for all manufacturers referenced in the eCTD |

| | |
|---|---|
| | application should be added as issued. |
| PMF Number | If a Plasma Master File (PMF) is reference in the eCTD application, the PMF Number as issued should be added. |
| Proprietary Name | The name as proposed or registered. For API Master Files, insert drug substance name and APIMF holder name. |
| Singapore Registration Number | SRN is provided for all sequence types of registered products.written in upper-case letters |
| Submission (Submission Type / Submission Number) | Contains information relating to the Submission (regulatory activity) that is being submitted |
| Sequence Type | The Sequence Element section contains all the Sequence-related information. It identifies what is happening to the Submission with the Sequence being submitted. Only one Sequence Element section can be specified per Sequence however multiple types of Responses can be specified as types. Responses can only be combined with other responses. |
| Sequence Description | The Sequence Description element gives the Applicant the opportunity to better describe what is being done in the Sequence. |
| Sequence Date | The Sequence Date is a date field indicating the date the Sequence is submitted. This date should correlate as closely as possible with the date on the Letter of Application and in the Application Form but does not need to be identical. The Sequence Date is mainly used to ensure the validity of the codes used from the Defined Lists. |
| Sequence Number | Four-digit number matching the Sequence folder being submitted. |
| Related Sequence | The Related Sequence Number is used to group Sequences belonging to the same Submission. This enables agency to easily evaluate Sequences associated with a particular Submission together. |
| Contact | Multiple contacts may be provided in the Envelope. The Contact Name, Contact Phone and Contact Email must be provided for each contact, along with the Type of contact. At least one Local Applicant contact must be provided. |

eCTD Attributes Switzerland

You can use the following attributes to describe eCTD submissions for Switzerland.

## Switzerland-v1.2

| Attribute | Description |
|---|---|
| Agency | The name of the receiving agency for the submission: Swissmedic |
| Applicant | The name of the company submitting the eCTD. Entered as "n/a" (case sensitive) if the submission is a DMF (Drug Master File) or PMF (Plasma Master File). |
| Application Number | The application number as provided by the agency. Multiple comma-separated values can be provided. |
| DMF Holder | The name of the company submitting the DMF. Entered as "n/a" (case sensitive) if the submission is not a DMF. |
| Attribute | Description |

| | |
|---|---|
| DMF Number | The number assigned to the DMF. Entered as "pending" (case sensitive) if the assigned DMF number is not known. Entered as "n/a" (case sensitive) if the submission is not a DMF. |
| INN | International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Multiple comma-separated values can be provided. |
| Invented Name | The name of the medicinal product. Enter an invented name even if it is not yet definitive. Entered as "pending" (case sensitive) only as a last choice. Multiple comma-separated val- ues can be provided. |
| Paragraph 13 TPA | Identifies the submission as Paragraph 13 TPA. |
| PMF Holder | The name of the company submitting the PMF. Entered as "n/a" (case sensitive) if the sub- mission is not a PMF. |
| PMF Number | The number assigned to the PMF. Entered as "pending" (case sensitive) if the assigned PMF number is not known. Entered as "n/a" (case sensitive) if the submission is not a PMF. |
| Related Sequence | The sequence number of a previous submission to which the submission is related. Enter the numeric value (must have 4 digits) or, if there is no related sequence, enter "none" (case sensitive). Multiple comma-separated values can be provided. |
| Sequence Number | The sequence number of the submission. The default is from the sequence code, but can be overridden. |
| Submission Descrip- tion | The description of the submission to be included in the XML. |
| Submission Type | The type of procedure for the submission. |

## Switzerland-v1.3

| Attribute | Description |
|---|---|
| Agency | The name of the receiving agency for the submission: Swissmedic |
| Applicant | The name of the company submitting the eCTD. Entered as "n/a" (case sensitive) if the sub- mission is a DMF (Drug Master File) or PMF (Plasma Master File). |
| Application Number | The application number as provided by the agency. Multiple comma-separated values can be provided. |
| DMF Holder | The name of the company submitting the DMF. Entered as "n/a" (case sensitive) if the sub- mission is not a DMF. |
| Attribute | Description |

| | |
|---|---|
| DMF Number | The number assigned to the DMF. Entered as "pending" (case sensitive) if the assigned DMF number is not known. Entered as "n/a" (case sensitive) if the submission is not a DMF. |
| INN | International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Multiple comma-separated values can be provided. |
| Invented Name | The name of the medicinal product. Enter an invented name even if it is not yet definitive. Entered as "pending" (case sensitive) only as a last choice. Multiple comma-separated val- ues can be provided. |
| Paragraph 13 TPA | Identifies the submission as Paragraph 13 TPA. |
| PMF Holder | The name of the company submitting the PMF. Entered as "n/a" (case sensitive) if the sub- mission is not a PMF. |
| PMF Number | The number assigned to the PMF. Entered as "pending" (case sensitive) if the assigned PMF number is not known. Entered as "n/a" (case sensitive) if the submission is not a PMF. |
| Related Sequence | The sequence number of a previous submission to which the submission is related. Enter the numeric value (must have 4 digits) or, if there is no related sequence, enter "none" (case sensitive). Multiple comma-separated values can be provided. |
| Sequence Number | The sequence number of the submission. The default is from the sequence code, but can be overridden. |
| Submission Descrip- tion | The description of the submission to be included in the XML. |
| Submission Type | The type of procedure for the submission. |

## Switzerland-v1.4

| Attribute | Description |
|---|---|
| Agency | The name of the receiving agency for the submission: Swissmedic |
| Applicant | The name of the company submitting the eCTD. Entered as "n/a" (case sensitive) if the sub- mission is a DMF (Drug Master File) or PMF (Plasma Master File). |
| Application Number | The application number as provided by the agency. Multiple comma-separated values can be provided. |
| DMF Holder | The name of the company submitting the DMF. Entered as "n/a" (case sensitive) if the sub- mission is not a DMF. |
| Attribute | Description |

| | |
|---|---|
| DMF Number | The number assigned to the DMF. Entered as "pending" (case sensitive) if the assigned DMF number is not known. Entered as "n/a" (case sensitive) if the submission is not a DMF. |
| INN | International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Multiple comma-separated values can be provided. |
| Invented Name | The name of the medicinal product. Enter an invented name even if it is not yet definitive. Entered as "pending" (case sensitive) only as a last choice. Multiple comma-separated val- ues can be provided. |
| Paragraph 13 TPA | Identifies the submission as Article 13 TPA. |
| PMF Holder | The name of the company submitting the PMF. Entered as "n/a" (case sensitive) if the sub- mission is not a PMF. |
| PMF Number | The number assigned to the PMF. Entered as "pending" (case sensitive) if the assigned PMF number is not known. Entered as "n/a" (case sensitive) if the submission is not a PMF. |
| Related Sequence | The sequence number of a previous submission to which the submission is related. Enter the numeric value (must have 4 digits) or, if there is no related sequence, enter "none" (case sensitive). Multiple comma-separated values can be provided. |
| Sequence Number | The sequence number of the submission. The default is from the sequence code, but can be overridden. |
| Submission Descrip- tion | The description of the submission to be included in the XML. |
| Submission Type | The type of procedure for the submission. |

## Switzerland-v1.5

| Attribute | Description |
|---|---|
| Agency | The name of the receiving agency for the submission: Swissmedic |
| Applicant | The name of the company submitting the eCTD. Entered as "n/a" (case sensitive) if the sub- mission is a DMF (Drug Master File) or PMF (Plasma Master File). |
| Application Number | The application number as provided by the agency. Multiple comma-separated values can be provided. |
| DMF Holder | The name of the company submitting the DMF. Entered as "n/a" (case sensitive) if the sub- mission is not a DMF. |
| DMF Number | The number assigned to the DMF. Entered as "pending" (case sensitive) if the assigned DMF number is not known. Entered as "n/a" (case sensitive) if the submission is not a DMF. |

| Attribute | Description |
|---|---|
| INN | International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Multiple comma-separated values can be provided. |
| Invented Name | The name of the medicinal product. Enter an invented name even if it is not yet definitive. Entered as "pending" (case sensitive) only as a last choice. Multiple comma-separated val- ues can be provided. |
| Article 13 TPA | Identifies the submission as Article 13 TPA. |
| PMF Holder | The name of the company submitting the PMF. Entered as "n/a" (case sensitive) if the sub- mission is not a PMF. |
| PMF Number | The number assigned to the PMF. Entered as "pending" (case sensitive) if the assigned PMF number is not known. Entered as "n/a" (case sensitive) if the submission is not a PMF. |
| Related Sequence | The sequence number of a previous submission to which the submission is related. Enter the numeric value (must have 4 digits) or, if there is no related sequence, enter "none" (case sensitive). Multiple comma-separated values can be provided. |
| Sequence Number | The sequence number of the submission. The default is from the sequence code, but can be overridden. |
| Submission Descrip- tion | The description of the submission to be included in the XML. |
| Submission Type | The type of procedure for the submission. |

eCTD Attributes South Africa

You can use the following attributes to describe eCTD submissions for South Africa.

## South Africa-v1.0

| Attribute | Description |
|---|---|
| Applicant | The name of the applicant/HCR (Holder of Certificate of Registration) submitting the eCTD. |
| Application Number | The number issued for the product by the MCC (Medicines Control Council). The Applica- tion Number remains from the first data submission for the full life cycle of the product. Multiple comma-separated values can be provided. |
| Dosage Form | The dosage form of the medicinal product. Multiple comma-separated values can be provid- ed. |
| Attribute | Description |

| | |
|---|---|
| Duplicated Applications (Proprietary Names/ Dates of Application) | The name of the multiple/duplicate applications of the medicinal product (include, even if the name is not yet approved) plus the application date of the duplicate applications. Multi- ple paired values can be provided. |
| eCTD Sequence | The sequence number of the data submission. The default is from the Sequence Code, but can be overridden. |
| INN | The INN of the API(s) accompanied by its salt or hydrate form (if relevant) or chemical de- scription of the API(s). Multiple comma-separated values can be provided. |
| Proof of Efficacy | The data type submitted as proof of efficacy, and a description of the data type if "other" is selected as data type. Multiple paired values can be provided. |
| Proprietary Name | The name of the medicinal product. Include even if not yet approved. Multiple comma-sepa- rated values can be provided. |
| Related Sequence | The sequence number of a previous submission to which the submission relates. Multiple comma-separated values can be provided. |
| Submission Type | The type of regulatory submission to which the data submission relates. |

## South Africa-v2.1

| Attribute | Description |
|---|---|
| Applicant | The name of the applicant/HCR (Holder of Certificate of Registration) submitting the eCTD. |
| Application Number | The number issued for the product by the MCC (Medicines Control Council). The Applica- tion Number remains from the first data submission for the full life cycle of the product. Multiple comma-separated values can be provided. |
| Dosage Form | The dosage form of the medicinal product. Multiple comma-separated values can be provid- ed. |
| Duplicated Applications (Proprietary Names/Application | The name of the multiple/duplicate applications of the medicinal product (include, even if the name is not yet approved) plus the application number(s) of the duplicate applications. Multiple paired values can be provided. |

| | |
|---|---|
| Numbers) | |
| eCTD Sequence | The sequence number of the data submission. The default is from the Sequence Code, but can be overridden. |
| INN | The INN of the API(s) accompanied by its salt or hydrate form (if relevant) or chemical description of the API(s). Multiple comma-separated values can be provided. |
| Attribute | Description |
| Proprietary Name | The name of the medicinal product. Include even if not yet approved. Multiple comma-separated values can be provided. |
| Related Sequence | The sequence number of a previous submission to which the submission relates. Multiple comma-separated values can be provided. |
| Submission Type / Proof of Efficacy | The type of regulatory submission to which the data submission relates followed. The type of regulatory submission is followed by data type submitted as proof of efficacy, and a description of the data type if "other" is selected as data type. Multiple paired values can be provided for the Proof of Efficacy, each bound to the specific submission type. |

## South Africa-v3.1

| Attribute | Description |
|---|---|
| Application ID | A unique 14-character identifier number automatically issued by SAHRA for an application once it is created on SAHPRA application portal. Application ID is used for all sequences of an eCTD application and cannot be changed. |
| Application Number | A unique number automatically issued by SAHPRA for each product, strength, replica/clone/duplicate once an application is created or a new replica/clone is added to the existing application on SAHPRA application portal. Multiple commaseparated values can be provided. |
| Application Type | The type value for the Application. |
| APIMF Number | A unique identifier number of certified Active Pharmaceutical Ingredient Master File (APIMF). Populated, if APIMF is referenced in the eCTD application. Multiple comma-separated values can be provided. |
| Contact | Applicant contact data. Multiple contacts can be provided in the envelope if needed, but adding at least one local applicant contact is required. The following values must be provided for each contact: Contact Name, Contact Email, Contact Type. |
| Dosage Form | The dosage form of the medicinal product. |
| INN | The recognized International Non-proprietary Name should be given for the active ingredients and pharmaceutical drug if available. It should be written in all lower-case letters and provided exactly as officially listed in international lists like WHO INN, British Approved |

| | |
|---|---|
| | Names (BAN), United States Pharmacopoeia (USP) and without abbreviations. Multiple comma-separated values can be provided. |

| Attribute | Description |
|---|---|
| Multiple Applications (Application Number/ Proprietary Name) | Multiple Application Indicator of any replicas/clones/duplicates with proprietary name and application number for each additional application. Multiple paired values can be provided (both Application Number and Proprietary Name must be either populated or empty). |
| PMF Number | A unique identifier number of certified Plasma Master File (PMF). Populated, if PMF is referenced in the eCTD application. Multiple comma-separated values can be provided. |
| Proprietary Name | The name as proposed or registered. For API Master Files, insert drug substance name and APIMF holder name. Multiple comma-separated values can be provided. |
| Related Sequence | The attribute is used to group sequences associated with the same submission. This helps the agency quicklier evaluate sequences associated with a particular submission. Multiple comma-separated values can be provided.<br>If the submission type does not set to Response to a pre-registration recommendation or post-registration, then the Related Sequence attribute must set to NONE. |
| Sequence Date | Indicating the date of a sequence was being submitted. The date should correlate but should not necessarily be identical to the date shown in the Letter of Application and the Application Form. The Sequence Date is mainly used to ensure the validity of the codes tak- en from the Defined Lists. |
| Sequence Number | Four-digit sequence number matching the sequence folder being submitted. |
| Sequence Description | The Sequence Description attribute gives the Applicant the opportunity to better describe what is being done in the Sequence. |
| Sequence Type | Contains all the Sequence-related information. It identifies what is happening to the Submission with the Sequence being submitted. Only one Sequence attribute can be specified per Sequence, however, multiple types of Responses can be specified as types. Responses can only be combined with other responses. Multiple values can be provided Values for Sequence Type are taken from |

| | |
|---|---|
| | Sequence Maintenance > Sub Filling Type Values Data Administration List. |
| Attribute | Description |
| Submission (Submission Type/Evaluation Pathway/ Submission Lead/Submission Number) | Contains all the submission-related information for the regulatory activity that is not related to a specific sequence. Multiple Submission sets can be provided if the combination is allowed in the Submission Type Matrix.<br>For Submission Type, values are taken from Display Name attribute in the Sequence Maintenance > Filling Type Values Data Administration List.<br>For Evaluation Pathway, values are taken from Display Name attribute in the Submission Maintenance > Evaluation Pathway Values Data Administration List.<br>For Submission Lead, values are taken from Display Name attribute in the Submission Maintenance > Regulatory Activity Lead Values Data Administration<br>List. |
| SMF Number | The Site Master File (SMF) Number for all manufacturers referenced in the eCTD application. Multiple comma-separated values can be provided. |
| VAMF Number | A unique identifier number of certified Vaccine Master File (VAMF). Populated, if VAMF is referenced in the eCTD application. Multiple comma-separated values can be provided. |

eCTD Attributes Taiwan

You can use the following attributes to describe eCTD submissions for Taiwan.

## Taiwan-v1.0

| Attribute | Description |
|---|---|
| Identifier | A UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 \| ISO/IEC 9834-8:2005.<br>The same UUID must be used for all sequences of an eCTD application. |
| Submission Type Tier 1 | Examples: Domestic, Import, Export Only. |
| Submission Type Tier 2 | Examples: New Drugs Application, Biological Drugs Application, Generic Drug Application, Active Pharmaceutical Ingredient. |
| Submission Type | Examples: Prescription, Over The Counter, Controlled Drugs, Nuclear |

| | |
|---|---|
| Tier 3 | Medicine, Biological Drugs, Biosimilar Drugs, Regenerative Medicine, Others. |
| Submission Type<br>Tier 4 | Examples: New Chemical Entity, New Indication, New Combination, New<br>Dosage Form, New Administration, New Dosage, New Strength, Genetic<br>Engineering, Vaccine, Plasma Derivative, Cell Therapy, Gene Therapy, Tissue Engineering, Allergen, Safety Monitoring, Non-Safety Monitoring, Others. |

| Attribute | Description |
|---|---|
| Submission Type<br>Tier 5 | Examples: New Chemical Entity, New Indication, New Combination, New Dosage Form, New Administration, New Dosage, New Strength, Comply With OTC Criteria, Not Comply With OTC Criteria, Others. |
| Submission Objective | Explains the main purpose of this submission. The high-level handling of the information submitted as part of variation(s) and extension applications. |
| Submission Unit | Submission unit type describes the content at a lower level (a “sub-activity”) which is submitted in relation to a defined regulatory activity. |
| Applicant Name | Name of the company submitting the application. |
| Applicant Corporate<br>Certification<br>Authority | Corporate Certification Authority IC Card for submission. |
| Applicant Phone<br>Number | Phone number of the company. |
| Applicant Email Address | Email address of the company. |
| Invented Name<br>(Name, Drug Permit<br>License, PreAssigned<br>Application Number,<br>Code ) | Fields group that allows multiple sets of Invented Name of the medicinal product including:<br>— the name of the medicinal product.<br>— the drug permit license defined by unique invented name, dose and ingredient. Drug Permit License can have multiple comma-separated values.<br>— the pre-assigned application number as the number as the evidence of permission to submit. (For example, YYYYMMDD##). |

| | |
|---|---|
| | — the code to link drug permit license. (For example, YYYYMMDD ##DOSE).<br><br>Multiple items can be provided. |
| INN | International Non-proprietary Name used to identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A non-proprietary. |
| Sequence | Sequence number of the submission – this should start at 0000 for the initial submission, and then increase incrementally with each subsequent submission related to the same product. For example, 0000, 0001, 0002,<br><br>0003, and so on. |
| Related Sequence | Sequence number of previous submission(s) to which this submission relates. For example, the responses to questions to a particular variation. In the case of submission unit types 'initial' and 'reformat', related sequence is identical to the sequence number. |
| Attribute | Description |
| Submission Description | Description for the submission. |

eCTD Attributes Tunisia

You can use the following attributes to describe eCTD submissions for Tunisia

## Tunisia-v1.1

| Attribute | Description |
|---|---|
| Application Type | The type value for the Application. |
| Application ID | An identifier provided by the ANMPS Application Portal when a new Application is created. The same ID will be used for all Sequences of an eCTD application and cannot ever be changed. |
| Application Number | An Application Number will be automatically issued for each product, strength, replica / clone / duplicate by the ANMPS Application Portal when a new Application is created or a new replica / clone is added to an existing Application. Multiple Application Numbers can be included in an eCTD Application |
| Submission Type | The Submission Type must be indicated for the Submission Element indicating the type of 991 regulatory activities being undertaken with the Submission |
| Sequence Type | The Sequence Element section contains all the Sequence-related information.<br>It identifies what is happening to the Submission with the Sequence being submitted. Only one Sequence Element section can be specified per Sequence however multiple types of Responses can be specified as types. Responses can only be combined with other responses. |
| Sequence Date | The Sequence Date is a date field indicating the date the Sequence is submitted. This date should correlate as closely as possible with the date on the Letter of Application and in the Application Form but does not need to be identical. The Sequence Date is mainly used to ensure the validity of the codes used from the Defined Lists. |
| Sequence Number | Four-digit number matching the Sequence folder being submitted. |

| | |
|---|---|
| Related Sequence Number | The Related Sequence Number is used to group Sequences belonging to the same Submission. This enables agency to easily evaluate Sequences associated with a particular Submission together. |
| Contact | Multiple contacts may be provided in the Envelope. The Contact Name and Contact Email must be provided for each contact, along with the Type of contact. At least one Local Applicant contact must be provided. |

eCTD Attributes Thailand

You can use the following attributes to describe eCTD submissions for Thailand.

## Thailand-v0.92

| Attribute | Description |
|---|---|
| eSubmission Identifier | The Application Number as provided by the agency. |
| INN/Generic Name | The INN or Generic Name of the active ingredients used in the product. Multiple comma-separated values can be provided. |
| Licensee | The licensee name that is legally responsible for the application in Thailand. |
| Product Name | The name or proposed product (trade) name to be used on the Certificate of Registration. Multiple comma-separated values can be provided. |
| Regulatory Activity Lead | Identifies the group within the THAI FDA which is expected to take the lead in the review process. |

| | |
|---|---|
| Related Sequence Number | Four digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity. |
| Sequence Description | Free text description of the submission. The description provided here should also be used in the node title for 1.0 Cover Letter and 1.R Response to Questions. |
| Sequence Number | Four digit sequence number matching the sequence folder being submitted. |
| Sequence Type | Identifies the type of activity that is being submitted with the sequence, either the regulatory activity type if it is the first sequence of the regulatory activity or supplementary information if it is a follow-up to information already submitted for the regulatory activity. |

## Thailand-v1.0

| Attribute | Description |
|---|---|
| Contact Email | The email address used to notify the applicant of a change in application status. |
| eSubmission Identifier | The Application Number as provided by the agency. |
| INN/Generic Name | The INN or Generic Name of the active ingredients used in the product. Multiple comma-separated values can be provided. |
| Attribute | Description |
| Licensee Name | The licensee name that is legally responsible for the application in Thailand. |
| Licensee Number | The licensee number of the company that is legally responsible for the application in Thailand. |
| Licensee Type | The licensee type of Licensee Number for the application in Thailand. |
| Product Name | The name or proposed product (trade) name to be used on the Certificate of Registration. Multiple comma-separated values can be provided. |
| Regulatory Activity Lead | Identifies the group within the THAI FDA which is expected to take the lead in the review process. |
| Related Sequence Number | Four digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity. |

| | |
|---|---|
| Sequence Description | Free text description of the submission. The description provided here should also be used in the node title for 1.0 Cover Letter and 1.R Response to Questions. |
| Sequence Number | Four digit sequence number matching the sequence folder being submitted. |
| Sequence Type | Identifies the type of activity that is being submitted with the sequence, either the regulatory activity type if it is the first sequence of the regulatory activity or supplementary information if it is a follow-up to information already submitted for the regulatory activity. |

eCTD Attributes Ukraine

List of eCTD attributes and their description used for a submission.

Ukraine-v1.0

| Attribute | Description |
|---|---|
| Country | Unique country code for Ukraine (ua) |
| UUID | A UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 \| ISO/IEC 9834-8:2005. The same UUID must be used for all sequences of an eCTD application. |
| Submission Type | The type of regulatory activity to which the content will be submitted. |
| Submission Mode | The high-level handling of the information submitted as part of variation(s) and extension applications. The mode should only be used in variation or line extension regulatory activities and must be included in every sequence of that activity. |
| Submission Unit Type | Submission unit type describes the content at a lower level (a "sub activity") which is submitted in relation to a defined regulatory activity. |
| Attribute | Description |
| Submission Number | This number is used by regulatory authority to track the submission, in any procedure, in relation to a particular medicinal product. This is the number of the registration form or package of registration forms. |
| Applicant | The name of the company submitting the Application. |
| Agency Name | Regulatory authority which is The State Expert Center of MOH of Ukraine. |
| Procedure Type | The type of procedure for the submission. |
| Invented Name | The name of the medicinal product. |
| INN | International Non-proprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. A non-proprietary name is also known as a generic name. |

| | |
|---|---|
| Sequence | This is the sequence number of the submission - this should start at 0000 for the initial submission, and then increase incrementally with each subsequent submission related to the same medicinal product. |
| Related Sequence | This is the sequence number of previous submission to which this submission relates e.g. the responses to questions to a particular variation. |
| Submission Description | This element is used to provide a short text description of the submission. |

eCTD Attributes United States

You can use the following attributes to describe eCTD submissions for the United States.

## Ukraine-v1.0

You can use the following attributes to describe eCTD submissions for Ukraine.

| Attribute | Description |
|---|---|
| Country | Unique country code for Ukraine (ua) |
| UUID | A UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 \|ISO/IEC 9834-8:2005. The same UUID must be used for all sequences of an eCTD application. |
| Submission Type | The type of regulatory activity to which the content will be submitted. |
| Submission Mode | The high-level handling of the information submitted as part of variation(s) and extension applications. The mode should only be used in variation or line extension regulatory activities and must be included in every sequence of that activity. |
| Submission Unit Type | Submission unit type describes the content at a lower level (a "sub activity") which is submitted in rela- tion to a de³ned regulatory activity. |
| Submission Number | This number is used by regulatory authority to track the submission, in any procedure, in relation to a particular medicinal product. This is the number of the registration form or package of registration forms. |
| Applicant | The name of the company submitting the Application. |
| Agency Name | Regulatory authority which is The State Expert Center of MOH of Ukraine. |
| Procedure Type | The type of procedure for the submission. |

| Attribute | Description |
|---|---|
| Invented Name | The name of the medicinal product. |
| INN | International Non-proprietary Name, used to identify pharmaceutical substances or active pharmaceuti- cal ingredients. A non-proprietary name is also known as a generic name. |
| Se- quence | This is the sequence number of the submission - this should start at 0000 for the initial submission, and then increase incrementally with each subsequent submission related to the same medicinal product. |
| Relat- ed Se- quence | This is the sequence number of previous submission to which this submission relates e.g. the respons- es to questions to a particular variation. |
| Submis- sion De- scription | This element is used to provide a short text description of the submission. |

## United States-v2.01

| 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. |

## United States-v3.3

| Attribute | Description |
|---|---|
| Applicant Contact | The Applicant Contact for the submission. |
| Applicant ID | The D-U-N-S® number identifier for the business entity that is the sponsor, applicant, or holder of the submission.The same D-U-N-S number should be used for all submissions to |

| | |
|---|---|
| | an application, unless there is a change in ownership of the application. The default value is taken from the Application<br><br>level value. If not defined at the Application level, the default for United States region in Data Administration is used. |
| Application Contains Files? | Indicates if the application contains the files in a grouped submission. |
| Application Number | The application number provided by the agency. |
| Application Type | The type of application. |
| Company Name | The sponsor or applicant name. |
| Cross-Reference Application | The application number and type of cross-reference applications. Should only be provided when an application makes reference to other application.<br><br>Multiple paired values can be provided. |
| Sequence Number | The sequence number of the submission. It should start at 0001, and should not exceed 9999. |
| Submission Description | The description of the submission to be included in the XML. |
| Submission ID | The sequence number of the first submission that refers to the same regulatory activity as the sequence that is being submitted. |
| Submission SubType | The filing/submission sub-type for the submission. Dependent on the value selected for Submission Type. |
| Submission Type | The filing/submission type for the submission. Dependent on the selected Application Type. |
| Supplement<br><br>Effective Date Type | The supplement effective date type for the submission. Dependent on the selected Submission Type. |

## World Health Organization-v1.0

List of eCTD attributes and their description used for a submission.

| Attribute | Description |
|---|---|
| Identifier | The Universally Unique identifier (UUID) identifies the instances submitted by eCTD |
| Product Type | Product code for product type |
| Attribute | Description |

| | |
|---|---|
| Product Subtype | Description of the product type. Mandatory for FPP only. |
| Product Name | The name or proposed product (trade) name used on the Certificate of Registration. |
| Application Type | Administrative information associated with a submission. The type of regulatory activity to which the content is submitted. |
| Application Subtype | Provides further information about a submission. Mandatory for FPP. |
| Submission Unit Type | Submission unit type describes the content at a lower level (a "sub-activity") that is submitted in relation to a defined regulatory activity. |
| Applicant | The name of the company submitting the eCTD. |
| Contact Email | Email address of the contact or an applicant. |
| Product ID | Unique product record identifier, following the format WHO Product ID: Issued by Salesforce. |
| SF Case ID | A Salesforce generated number, unique to the application submitted. It follows a simple 8 digit number format. |
| Sequence | Sequence number for a submission. |
| Related Sequence | This is the sequence number of previous submission(s) to which this submission relates. For example., the responses to questions to a particular variation. In the case of submission unit types 'initial' and 'reformat' related sequence is identical to the sequence number. |
| Submission Description | Description of a Submission included in the XML. |

## Repeatable Assembly Sections

The eCTD assembly contains repeatable sections and captures section-specific metadata for their associated extended type.

| Assembly section number | Assembly section name | Associated extended type |
|---|---|---|
| 1.15.2.1 | Material | Promotional Material Type |
| N/A | Galenic Form | CH Galenic Form |
| 2.3.S | Drug Substance | Drug Substance |
| 2.3.P | Drug Product | Drug Product |
| 2.7.3 | Clinical Indication | Clinical Indication |
| 3.2.S | Drug Substance | Drug Substance |
| 3.2.P | Drug Product | Drug Product |

| | | |
|---|---|---|
| 3.2.P.4 | Excipient | Excipient |
| Assembly section number | Assembly section name | Associated extended type |
| 3.2.A.1 | Quality Appendix | Quality Appendix |
| 3.2.A.2 | Quality Appendix | Quality Appendix |
| 3.2.A.3 | Excipient | Excipient |
| 5.3.5 | Clinical Indication | Clinical Indication |

## Submission Metadata

You can use the attributes to enter submission metadata on the *Set Submission Metadata* page in the *Create eCTD* wizard.

| Metadata | Description |
|---|---|
| Dosage Form | The dosage form (e.g.: liquid, capsules). |
| Drug Product Manufacturer | Enter the name of the manufacturer for the marketing name product. |
| Drug Product Name | The Marketing Name for the product. |
| Drug Substance Manufacturer | The name of the manufacturer for the active ingredient of the product. |
| Drug Substance Name | The active ingredient for the product. |
| Excipient | The nonactive substance for the product. |
| Galenic Form Name | The name of the galenic form. |
| Galenic Language Name | The language of the galenic form. |
| Galenic Language Text | The galenic language text. |
| Indication | The disease or medical problem for which the drug is used. |
| Manufacturer | The name for the marketing manufacturer. |
| Product Name | The marketing name for the product. |
| Promotional Material ID | The applicant identification code or other designation of the specific promotional material. |
| Promotional Material Type | Defines the promotional material document type. |
| Substance | The active ingredients for the product. |
| SwissMedic Number | The number for the galenic form from the SwissMedic agency. 5digits, or 'pending'. |

| | |
|---|---|
| Update the sub-folder structure for | If selected, set submission structure for selected nodes is updated with missing folders and their children. If no folders are missing but leaf elements are missing in the assembly, the update has no effect.<br><br>The wizard checks for folders only. |

## Create Study Reports

The Create Study Reports wizard enables you to add study report structures (folders and leaf elements) to an existing eCTD or CTD. You can run the wizard one or more times as you obtain information about the study reports to include in the assembly.

***Note:*** *The Create Study Reports wizard does not support EAEU submissions.*

The wizard is designed to be run after using the Create eCTD wizard, but you can use it any time after an eCTD is created. It enables you to do the following:

— Insert the appropriate study reports into an existing sequence or standalone assembly based on specification, template configuration, and user selections

— Insert a study report into an assembly structure with selected or confirmed metadata

Before creating a study report:

— An assembly must already exist and cannot be locked.

— The XML definitions must be applied for the assembly in the publishing settings.

Use the Create Study Report Wizard

The *Create Study Reports* wizard enables you to add study report structures (folders and leaf elements) to an existing eCTD or CTD. You can run the wizard one or more times as you obtain information about the study reports to include in the assembly.

***Note:*** *The Create Study Reports wizard does not support EAEU submissions.*

To create a study report:

1. In the selected eCTD 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 use the default values specified in the template, select Default Study Report Values from Template.

— To copy the TOCs and special sheets from the template, select Copy TOCs and Special Sheets. — Select the individual folders and subfolders for the eCTD.

— To remove a section, select it.

— For existing standalone, 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.

Ennov InSight Publisher 7.3 Create Study Reports

***Note:*** *In the Create Study Reports wizard, if you click Back to return to the Select Sub-Sections page your checkbox selections are not retained.*

1. Click Next.

   The *Enter Quantities* page appears.

2. Enter the study report quantities per subsection.
3. Click Next.

   The *Enter Properties* page appears.

4. To add study reports to Indication folders, select the Update the sub-folder structure for 5.3.5 Reports of

   Efficacy and Safety Studies option specific to the indication folder.

   The study reports are added to the selected Indication folders. If no Indication folders are selected, an error is shown.

5. Enter the property values for the study report. These values are normally populated automatically based on the template.

   — A Study Name value is initially populated with the name of the section that it is in. You must change the name value to avoid having folders in the section with the same name as the section.

   — If you selected Default Values from Template, any changes you make to the metadata that would reflect a deviation from the metadata values in the template are ignored when you complete the wizard.

6. Click Next.

   The *Confirmation* page appears, confirming the information has been saved permanently to the assembly.

7. Click Next.

   The Summary page appears.

8. Click Finish.

# Publish Submissions

Ennov InSight offers several publishing options for assemblies.

You can publish an assembly, in whole or in part, to the electronic output channel, to the paper output channel, or to both.

EAEU Submissions Publish

EAEU submission has specific publishing rules that differ from other eCTD submissions. The specific things you must be aware of:

1. Ennov InSight 7.3 enables you to publish XML with PDF files placed nearby. For using the PDFs built into XML, use the export functionality. See *Export a Published Submission*.
2. You must populate Document Creation Date for every leaf in the assembly.

   ***Note:*** *To define the same date for the set of leafs, use the Mass Update Properties functionality.*
3. EAEU output has no util folder.
4. As there is no stylesheet provided, raw XML is displayed if it is opened in a web browser.
5. To keep the submission format required by a regulatory agency for EAEU submissions, XML validation is disabled at the process of publishing.

Electronic Publish

There are a number of ways you can create electronic output. You will need to determine which options to select based on your publishing needs. These needs are likely to change throughout your submission process. You can create different kinds of electronic output, including:

— Leaf elements

— eCTD XML

## — A single file Leaf Elements

When you publish leaf elements, you create a PDF file for each standard leaf. Ennov InSight creates a file in the native format (for example, Microsoft Word) for any published leaf elements that were flagged in the assembly to use the native file. You can choose to publish a full set or a subset of leaf elements in the assembly. You can use the Leaf Status values to identify the leaf elements in an assembly that need to be published.

## eCTD XML

Ennov InSight is designed to publish eCTD XML. You have the ability to publish an eCTD XML backbone independently, or in conjunction with publishing leaf elements.

## Single File Output

Publishing to single file output is by its nature an electronic publish, not paper. When publishing to a single file, all electronic output including sheets (TOCs, cover pages, etc.) and documents outside of the leaf are published, with the exception of native files. If a document belongs to a native leaf, it is not be included in the single file output.

Single file report publishing to paper or electronic ignores the location from where it was run; the entire assembly is always published in these cases. A single output PDF file is created by the publishing engine. Unlike electronic or paper publishing, this option is not sensitive to the section from which the publish was executed.

***Note:*** *For single file electronic output, elements both within and without leafs are included in the published output. Only native files are excluded from the published output. The leaf statuses selected in the Publish Request page do not affect the Publish to a Single File option, all leafs are included in the published output.*

Paper Publish

You can publish a CTD-compliant paper and paper reports. You can manipulate your assembly and publishing elements and effects to meet the requirements for your paper output.

For example you can separate content into paper volumes, create module and document levels, create tables of contents, use tab sheets, slip sheets, and cover pages, and create cross-reference stamps.

## High-Speed Printer Support

Ennov InSight supports the use of a high-speed printer for printing the final output. Setting up the printer may require a specific configuration and this configuration may require certain printer attributes to accept the use of certain paper weights, sizes, tabs, colors and so on. For additional information and a complete list of compatible printers, see your system administrator.

***Note:*** *If your printer supports the printing of special characters (UNICODE), Ennov InSight should be able to produce those characters specified in the publication.*

Publish Guidelines

## Folders

You can avoid errors in your publishing jobs by following these guidelines.

— Some publishing attributes in folders may accept or require multiple values. Delimit multiple values for publishing attributes with commas.

## Documents

— Some publishing attributes in documents may accept or require multiple values. Delimit multiple values for publishing attributes with commas.

— Encrypted PDFs can cause errors during publishing. An encrypted PDF cannot be concatenated with other files and may cause an error for that volume or leaf. For the paper output channel, you will need to remove the encryption prior to successfully publishing the document. For the electronic output channel, you can either remove the encryption, or simply change the Use Native File leaf attribute to Yes on the parent leaf.

— When output contains a PDF document which is under a leaf set with Use Native File, and then it is Published to a Single File, the TOC generates as expected in that the native leaf and PDF TOC are unchanged in a single file output.

— Documents in your assembly must be uniquely named in the document repository, relative to other documents in your assembly. If they cannot be uniquely named, they must be stored in uniquely named folders in the repository.

*Warning: You should not attempt to manipulate or delete an assigned document or publishing element while it is being published.*

## Document Placeholders

— When publishing, document placeholders are flagged as errors, but the publish completes successfully. This is expected behavior. **Leaf Elements**

— Some publishing attributes in leaf elements may accept or require multiple values. Delimit multiple values for publishing attributes with commas.

— Leaf elements that are to be created in the same output folder cannot have the same output file name. If two leaf elements have the same output file name and are in different folders that have the same output folder locations, the publish log reports duplicate folder/file paths.

— The Output File attribute must have a value. The file name must include the appropriate extension (for example, outputfile.pdf). The submission cannot be published without a file name.

— The Output File attribute must include the correct extension. For example, when you choose Yes for the Use Native File attribute to publish a Word document and you enter outputfile.pdf for the Output Filename attribute, you cannot open the file with Acrobat. You can change the file name extension to .docx to open it in Word.

— If you choose Yes for the Use Native File attribute for a leaf element containing two or more non-PDF documents, a message warns you that Ennov InSight cannot concatenate non-PDF documents.

— If a leaf element contains multiple documents and one but not all the documents are encrypted or password protected, the output for the leaf comprises only the non-encrypted documents. The encrypted documents are overwritten by the non-encrypted documents.

— When a leaf element contains multiple encrypted documents, the final output comprises the last encrypted document in the leaf definition.

— The output file on a leaf must contain content. Otherwise, the following error will occur: unable to calculate attribute checksum for leaf...exception detected...access denied.

— If a volume break resides on the leaf you are deleting, you should move the volume break to the closest folder. Volume breaks that reside on a deleted leaf will not be published.

General Publish Considerations

Publishing helps you with your details in a formatted document. However, you must have file format for your document to be published.

When publishing from Ennov InSight , you should consider the following: — PDF File format

— Document Structure

— Major and Minor Divisions

— Page Scaling and Overlays

*PDF File Format*

Ennov InSight publishes to PDF version 1.4 by default, which is compatible with Acrobat version 5 and later. This can be changed on an assembly-by-assembly basis within the Publishing Settings.

It is useful to understand Acrobat, the way PDF files are created and used, and the Adobe Acrobat products. You can find information about Acrobat at the Adobe Web site.

***Note:*** *In certain cases, links created with Acrobat 8 or 9 will not resolve to the correct file if viewed with an earlier version of Acrobat (7 or previous). This is due to changes to the Adobe Acrobat PDF version that are not backwards compatible.*

*Document Structure*

A composite document, or document roll-up is an ordered list of files comprised of multiple subdocuments, each maintained in their own right. Ennov InSight is specifically designed to compile and publish these documents as single, seamless entities that are a complete package ready for printing, distributing or saving as separate documents. You can publish electronically, retaining the original structure of the document list. You can also define a complete folder hierarchy for this, which is independent of the original document locations.

The composite document can be thought of as having three key parts:

— The cover page comprises previously prepared sheets that are usually placed at the front of the document, for example, title and copyright information. Cover pages can be added anywhere in an assembly.

— The table of contents (TOC) is prepared from a TOC definition template that defines the layout of the TOC pages, and is compiled from a combination of assembly elements and document extracts or bookmarks held in the constituent documents. The TOC may have up to 20 levels and has no limit on the number of entries. All TOC entries can be automatically numbered. Ennov InSight can also automatically enter the page numbers and a series of roughly fifty page-counting variables associated with TOC entries. Several TOCs can appear in a single publication, each with its own scope of pages. Tables of equations, figures and tables can also be defined separately.

— The document, sometimes called body matter, comprises constituent documents or specified page ranges from within constituent documents. Documents may be in any format supported by rendering, but must be in a repository Ennov InSight can access. The resulting output is a new document, eCTD XML structure, set of volumes for printing, or set of electronic files in a folder hierarchy defined as part of the publish process. Page ranges are useful for dividing a single document into multiple pieces, and for omitting or replacing pages in a source document that do not apply. In the case of dividing a single document into multiple parts, all links between pages are maintained during publishing. When copying placeholders between assemblies, these page ranges are maintained. A complex document may consist of several volumes, each with its own TOC and with an overall master TOC. Any page in the output document can be overlaid by a previously designed overlay template. This provides for the addition to the document of custom headers and footers, watermarks and other information. Different templates can be applied to the cover page, TOC and individual major divisions, minor divisions, volumes, folders, leafs elements, documents, and pages.

Keep in mind that any document that has security or requires a password will fail to render, and may cause a long delay as rendering attempts to complete.

*Warning: While you can create documents that are children of other documents within the assembly, this is for viewing only and may cause issues during publish. To roll up documents under a leaf, simply include all documents in the proper order as children of the leaf.*

*Major and Minor Divisions*

Any folder in the assembly can be set as a major or minor division. These divisions can represent modules, sections, items, parts, chapters, and other standard subdivisions of a publication, depending on the type that is published.

These divisions are used for page counting and to support variables such as major division name and minor division number.

There are three major and minor division variables available to access the Name, Abbreviated Name, and Number of the previous folder of each division type:

| Division name | Major division variable | Minor division variable |
|---|---|---|
| Name | *$MNAME* | *$NNAME* |
| Abbreviated Name | *$MABBR* | *$NABBR* |
| Number | *$MN* | *$NN* |

— Name = *$MNAME*

— Abbreviated Name = *$MABBR*

— Number - *$MN*

These major division variables (*$MNAME*, *$MABBR*, *$MN*) resolve the corresponding attribute of the previous folder in the tree marked as a major division. The minor division variables, *$NNAME $NABBR*, *$NN*, resolve the

corresponding attribute of the previous folder in the tree marked as a minor division. Major and minor divisions do not follow parent/child hierarchy, the previous major or minor division is the next one encountered in bottom-to-top order in the navigation tree. A major division also ends the current minor division. You can control the major and minor divisions on the folder attributes.

Any folder may be set with a major or minor division, but for standard publications the first level folder should be set as a major division, and the second level folder as the minor division, for example items and sections in a legacy electronic submission.

***Note:*** *When using Major Division Relative Volume breaking and the default volume file naming format ($VOLNAME), the system will overwrite the volume named V000001.pdf for each major relative division it encounters. When using this scheme, you should either substitute or add an additional variable to the volume name format to prevent overwriting.*

For eCTD submissions, the first level folder is set to major division to represent the current module name and number, and each folder containing leaf elements is set to the minor division. In this way, any leaf may refer to the minor division to reference the current eCTD section.

In the following example, for a leaf in the 3 Quality folder, the minor division number $NN will be set to 3.2.P.4.1 and the major division name will always be set to Quality, as shown in this example:



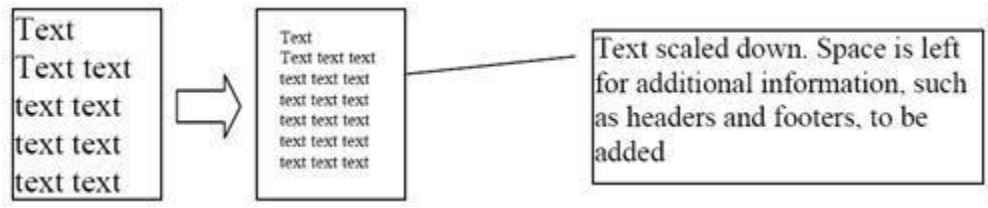

The minor division (*$NN*) resolves as expected, after the folder is set as minor division, and that number is then used for that element.

*Page Size and Overlays*

You can customize your electronic output by adding paper effects and setting a common page size.

With appropriate licensing, you can include some paper effects in electronic assemblies. Paper effects that might be appropriate for the electronic output channel include the following: TOCs, overlays and cover pages.

When publishing PDF content, Ennov InSight supports the normalization of final page sizes. The page size is automatically determined based on the output paper type. For example, if the constituent documents comprise both A4 and US sized paper, and the target output is A4, the US pages are scaled to fit. Ennov InSight enables you to scale down a page to a set of standard margins to leave space for additional information you might add, for example, headers and footers.




This enables you to use a single overlay for all page sizes in the publication. The overlay file can only be made smaller, so if you use this option, you must ensure that the overlay is at least as large as the largest page of your publication. For example, a US letter sized overlay applied to an A4 page will not be scaled to account for the longer dimension of the A4 page. **Overlay Handling**

Selecting the best fit overlay option searches for the closest match in the overlay file on a page-by-page basis. If an exact match is not found, or you do not choose best fit, Ennov InSight rotates an overlay to get an exact or close match for the page. If an exact match is not found with best-fit or rotation or neither has been set, then the closest match is scaled to fit.

— Selecting Best Fit overlays will increase the time to publish due to the extra processing required for matching each page. If the page size is known, this option should be avoided.

— Before publishing to different page sizes with overlays, you must define the appropriate page sizes in your overlays and have best fit enabled. If this is not properly set up in your overlay files, you may get improper stamps; Ennov InSight requires these settings in order to choose the correct overlay to fit the output page.

Publish Links

Intra-document links (links within documents) are treated differently by Ennov InSight than inter-document links (links between documents). These links are read into the Ennov InSight database during extraction but in many cases they should not be rewritten during publish time.

These links are often verified during document finalization and any manipulation of these in the final rendition would require additional quality control of the published output.

For this reason, any internal link set to the System Profile is not rewritten to documents during publishing unless absolutely necessary. The System Profile only writes inter-document links (because the relative paths have all changed) and writes intra-document links in cases where documents are split during publishing.

If you want the intra-document links to be rewritten, you must set all links to publish with a different link profile, one that you have defined in the assembly link settings. For paper cross-references, all links are rewritten during the process of stamping the final cross-reference text on the page.

*Cross-References*

Cross-references are the paper-publication equivalent of hyperlinks. Since output to paper does not contain hyperlinks, Ennov InSight stamps text in the right margin of the published documents. The text of these page stamps is defined for the link's profile in the link publishing settings.

***Note:*** *By default, only inter-documents links are set to the paper output channel for the creation of a cross-reference.*

If there are too many cross-references to fit on one page, the stamps extend past the end of the page. You must reduce the number of cross-references so that they can all fit.

To use the cross-reference variables, you must first set up the variable publishing settings. After setting up the variable publishing settings, you can enter the variables enclosed in brackets on the applicable location. See the topic Ennov InSight variables more information about system, Ennov InSight , repository, and user-defined variables.

For cross-references, margin stamps appear in the right margin (regardless of page orientation) starting at the top and are listed sequentially down the page. The link box still exists but does not show in the paper copy output. The link box still works but it does not work outside the current volume. Each cross-reference is tagged with a number at the link box next to the referenced text and next to the margin page stamp.

*Margin Stamp*

Use the document overlay attributes to adjust the area used by the margin stamp. The document overlay settings control the allowable space used by margin stamps. Setting the Scale contents to margins option to Yes will scale the document to fit the parameters defined by the document overlay settings.

***Note:*** *You are not required to set an overlay template file when setting document overlay margins.*

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. Following are the publishing ways as follows:

— 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.

— It refreshes your volume and page count information to ensure that your page number variables resolve correctly.

***Note:*** *When using variables for tab text, certain variables cannot be used as they will not resolve: element number, element name, element title. Instead, it is recommended that you use the leaf number, leaf name, minor division number, and minor division name variables to represent the current tab location. If you use minor division variables, be sure to verify that minor divisions have been appropriately assigned to folders in the current assembly, or they will not resolve correctly and may cause previews to fail.*

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.

— eCTD Definition Files are defined in the Publication Settings.

— For paper output, at least one volume was created.

— For paper or 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: | Choose Electronic or Paper output. |
| Generate Missing Renditions and Extractions: | You must have a license for Ennov InSight rendering and publishing services to generate missing renditions. |
| Remove Empty Assembly Folders: | This removes any empty folder elements from the assembly. |
| Option | Description |
| 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. |
| Render Generated TOCs and Special Sheet Templates: | If TOCs or special sheets are missing, they are created. |
| Generate TOCs: | If you have not generated TOCs or if the TOC is outdated, this generates the TOCs. After generation is complete, the TOC is available as a Word document and can be previewed in Ennov InSight . (The text in the right column of a TOC will not resolve for a leaf element that has no document assigned.) |

| | |
|---|---|
| Generate Volumes: | If you have not inserted or locked volumes, this function recalculates all volumes in the assembly. If there are locked volumes in the assembly, this refresh- es the page counts and volume names prior to publishing. |
| Update Volume Page Counts: | When selected, this function updates the page count for each volume within an assembly. The number is shown on the *Volume View* page as a Total Sheets/ Pages attribute. It is also shown in brackets on the tooltip that appears on the Volume icon in the assembly. |
| 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 view the log file to check for any errors.

*Cancel Prepare to Publish*

You can cancel a Prepare to Publish action after the process is started. When canceled, the Prepare to Publish will complete the current phase and then stop, and no other selected Prepare to Publish phases will be run.

Use the following procedure to cancel a Prepare to Publish before it is completed.

To cancel a Prepare to Publish:

1. After Prepare to Publish has started, open GO TO > Job Requests.
2. On the *Job Requests* Search page, click Search.
3. On the *Search Results* page, find the row for your Prepare to Publish job in the list and click Cancel Job.
4. In the *Cancel Job* dialog box, click OK to cancel the Prepare to Publish.

## Example

| |
|---|
| Phase 0: Prepare for Publish: constructs context<br><br>Phase 1: Validate and Remove Empty Content<br><br>Phase 2: Traverse and build context Phase 3A: Perform extractions |

| |
|---|
| (concurrent with 3B)<br>Phase 3B: Perform renditions (concurrent with 3A)<br>Phase 4: Generate TOCs<br>Phase 5: Render and Extract Generated TOCs<br>Phase 6: Recalculate Checksums<br>Phase 7: Bulk Volumize and Refresh Volumes<br>Phase 8: Generate Auto TOCs on Volumes<br>Phase 9: Render and Extract generated auto TOCs on Volumes<br>Phase 10A: Generate Publish Readiness Report (concurrent with 10B)<br>Phase 10B: Generate Link Inspector Report (concurrent with 10A)<br>Phase 11: Finish Prepare for Publish: update statuses, determine overall<br>success |

The Prepare to Publish phases (options) run in the order shown in the list (which can be seen in the Job Request page - phases that can run at the same time are labeled a/b of the same number). When the Prepare to Publish is canceled, the currently running phase will finish and then the Prepare to Publish will stop and any subsequent selected phases will not be executed. The exceptions to this are the pairs of phases, which must both be completed before the Prepare to Publish will be canceled.

*Maximum Job Message Length*

Be aware that some information in job messages is cut due to limit in characters. All job messages are truncated at 2000 characters. Because of this limit, you may not see the entire set of information that is generated by a job message.

For example, if you run Remove Empty Assembly Leaf Elements a job message listing all of the empty leafs and folders that were deleted is generated. Ennov InSight can only display the first 2000 characters in the job message, so you may not see the entire list of deleted empty leafs and folders.

*Publishing Summary Query*

The *Publishing Summary Query* displays the assembly elements in a tree hierarchy that you can export to a comma-separated file (CSV). You can import the CSV file into Microsoft Excel spreadsheet for further analysis. The *Publishing Summary Query* displays each component in the assembly, its types and sub-types, and indicates leaf options:

— Whether a leaf has at least one child document

— Whether the leaf has any overridden attributes with renditions

*Generate a Publishing Summary Query*

The *Publishing Summary* Query displays the assembly elements in a tree hierarchy that you can export to a comma-separated file (CSV). You can import the CSV file into Microsoft Excel spreadsheet for further analysis.

To generate a Publishing Summary query:

1. Click a link for the assembly you want to publish.
2. From the action toolbar, choose Publishing Summary Query. The *Publishing Summary* query opens.
3. When you are finished reviewing the summary query, click Back.

*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. |

| Column | Description |
|---|---|
| Query Type | The following types are available for selection:<br>— Electronic — Paper<br>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:<br>— append<br>— delete<br>— new<br>— replace<br>You can select multiple operations. |
| Object Type | All types are selected by default:<br>— Cover Page<br>— Document Folder<br>— Leaf<br>— Slip Sheet<br>— Table of Contents — Volume<br>You can deselect any type, if needed. |
| Filter on<br>Elements that have Errors | The Yes and No 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:<br>— The list of all columns with an ascending or descending options. For example: Element Type - DESC.<br>— Order - ASC<br>— Order - DESC<br>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. |
| 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.<br>— If a default type leaf contains a planned or placeholder document, it is considered not empty.<br>— If a default type leaf has aligned TOCs or Special Sheets, it is still considered empty.<br>— 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).<br>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.<br>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. |

| Column Name | Description |
|---|---|
| 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. |
| Extracts Exist | The “Extracts Exist” value pertains to the system’s captured data about the document’s PDF Rendition bookmarks. This value is assigned by the system as a default value and can be overridden in document element attributes.<br>— If the Extracts Exist value is set to Y (Yes), the system pulls the extracts from the PDF Rendition and populates those values for use in TOC generation.<br>— If the Extracts Exist value is set to N (No), the system 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 the presence of 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. |

| Column Name | Description |
|---|---|
| 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 value. 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. |
| 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<br><br>"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  . |

*Browse for an Assembly*

Use the tabs and buttons in the dialog box to locate and select the assembly for which you want to generate the Publishing Readiness query.

To select an assembly:

1. Click the tab for the entity type you want to choose.
2. Select the entity, and then do one of the following:

| Option | Action |
|---|---|
| To choose one of the following:<br>— All shows all entities.<br>— Current includes all entities with a status of current.<br>— Submitted includes all entities that have been submitted to the regulatory agency.<br>— Approved includes all entities that have been approved by the regulatory agency. | Click the Show Versions arrow. |
| To see the content of the entity you choose: | Click the Show button. |

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.

— TOCs may be regenerated.

— Overlay preferences are calculated and applied.

— Special sheets are inserted as appropriate.

— 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 .pdf document that has a rendition, source .pdf document, not the rendition is used for publishing.

## Electronic/eCTD Publishing

— XML files are created and validated against their specified XML definition files.

— 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.

— Cross-references are converted to hyperlinks. See the chart in the *Linking Tools* section.

## Paper Publishing

— Volumes are refreshed.

— Files are concatenated as per defined volume ranges.

— Cross-references are converted to margin cross-references. See the chart in the *Linking Tools* section.

*Submit an Electronic Publishing Request*

Before submitting an electronic publishing request, you should be aware of the limitations.

— All electronic publish requests must be made from assemblies that have leaf elements. Leaf elements represent output documents to Ennov InSight . Electronic publishes without leaf elements in the assembly will not generate output.

— For single file electronic output, all content and sheets (such as TOCs and cover pages), with the exception of native files, are included in the published output.

To submit an electronic publishing request:

1. On the *Assembly Attributes* page, do the following:

| Option | Action |
|---|---|
| For a sequence assembly: | Choose Publishing above the assembly tree. |
| To publish the entire assembly or choose a folder to publish: | Click the assembly root. |

2. Click  .
3. On the *Publish Request* page, choose Electronic from the Publishing Output Channel list.
4. To choose the repository location to publish the electronic submission, click Browse.

When choosing a folder for a published output location, the name of the folder cannot contain both Unicode characters and a space character, as this will cause an invalid path error. If you are using Documentum as the repository location, move to the next step. Else, go to step 6.

5. Under Output Document Type, choose the document type.
6. Check Append Application and Sequence Number to create subfolders in the output location. The subfolder names comprise the application followed by the sequence number.

   — You must check this box to avoid having an invalid relative path in the STF.xml file.

   — 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: \ / : * ? " < > |

   *Warning: For Assembly Plans, the values are taken from the Application Number and Sequence Number values of the Metadata Library (US Module 1 Application metadata type).*

7. If you need to generate renditions for assigned documents, special sheets, TOCs, overlays, select Prepare to Publish .
8. Choose one of the following to indicate what should be published:

| Option | Description |
|---|---|
| Publish to a Single File: | Publishes to one PDF file all elements in the entire assembly that are flagged for the electronic output channel. All content and sheets (TOCs, cover pages, etc) are included in the published output, except native files. Native files are omitted. |
| 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 XML definition 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 XML definition file. |
| XML Only: | Publishes the eCTD backbone XML based on the appropriate XML definition file. None of the leaf elements are published. |

***Note:*** *Reference leaf elements publish their xlink:href path as the minimum necessary relative path required to take the reviewer to the correct document. References to other sequences do not contain the application number; references outside the application contain the application number.*

9. If Publish to a Single File is selected, in the *Single File Output Filename* box, enter the output file name for the assembly.
10. In the Include Leafs with Status multi-select box, select the leaf statuses of leafs you want to be published.

    By default, all active Leaf Statuses from Data Administration|Submission Maintenance section are listed in the Selected box. Deselect, if needed. 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.
11. Next to DMS Versioning Scheme, choose one of the following for the published output files:

| Option | Description |
|---|---|
| Same: | Indicates the published output files should have the same version number as previous output. (Choose this when you are publishing to a file system.) |
| Minor Version: | Indicates the published output files should be increments to a minor version. |
| Major Version: | Indicates the published output files should be increments to a major version. |

12. Click OK to submit a publish request.
13. Chose Go To > Job Requests to view the status of your publication request.
14. Once the job is complete, navigate to the publish output location and confirm publication.

*Submit a Paper Publishing Request*

You can submit a paper publishing request and customize its details such as page counts and versions. To

submit a paper publishing request:

1. On the Assembly tree, do the following:

| Action |
|---|
| For a lifecycled sequence assembly, choose Publishing view above the assembly tree. |
| Click the assembly root, a volume, a folder, a leaf, or a document. |

2. From the action bar on the right, click  . The *Publish Request* window opens.
3. Under Publishing Output Channel, choose Paper.
4. To choose the repository location to publish the paper publication, click Browse. If you are using Documentum as the repository location, move to the next step. Else, go to step 6.

   ***Note:*** *If this is a Standalone assembly, do not check Append Application and Sequence Number.*
5. Under Output Document Type, choose the document type.
6. Check Prepare to Publish to create PDF renditions if you are using the Ennov InSight rendering and publishing services.

7. Use the Update Volume Page Count option to update the volume page counts from the publish request screen.
8. Next to Publish Paper, select which volumes to publish:

| Option | Description |
|---|---|
| All Volumes: | Publishes all volumes in the submission. |
| Volumes in Selected Range: | Publishes only those volumes that start in the node you have selected to publish. |

9. Next to DMS Versioning Scheme, choose one of the following for the published output files:

| Option | Description |
|---|---|
| Same: | Indicates the published output files should have the same version number as previous output. (Choose this when you are publishing to a secure file system.) |
| Minor Version: | Indicates the published output files should be increments to a minor version. |
| Major Version: | Indicates the published output files should be increments to a major version. |

10. Click OK to submit a publish request.
11. Choose Go To > Job Requests to view the status of your publication request.
12. When the job is complete, navigate to the publish output location and confirm publication.

When publishing paper volumes, regardless of where invoked, the Publish All Volumes option will output all publishable volumes in your assembly.

*Publish Commands and Volumes*

For publishing volumes in the selected range, the output produced is dependent on where the publishing command was invoked.

| Selected range | Description |
|---|---|
| Assembly root |  Publishes all volumes. |
| Volume |  (Single volume icon) Publishes this volume only. With this icon selected, when choosing Publish Request (Publish Paper > Volumes in Selected Range) only this volume will be published.<br><br>  (Multi-volume icon) Publishes all volumes where the starting range break falls under the collapsed multi-volume icon, including the last volume whose start break falls under the icon, up to the next volume break following the collapsed multivolume icon. |

| | |
|---|---|
| Folder | Publishes all volumes where the volume begins (is attached to) or is under (is attached to a descendant of) the selected folder. If no volumes fit this criteria, no volumes will be produced. |
| Leaf | Publishes all volumes where the volume begins (is attached to) or is under (is attached to a descendant of) the selected leaf. If no volumes fit this criteria, no volumes will be produced. |
| Document | Publishes all volumes where the volume begins (is attached to) or is under (is attached to a descendant of) the selected document. If no volumes fit this criteria, no volumes will be produced. |

*Publishing Leaf Elements*

During publishing, if a leaf has no content, it will be published with a checksum of null (empty checksum attribute) in the XML.

A final run of the Ennov InSight Validator tool will correctly set all checksums and confirm XML validity.

After publishing, when you choose View File for an empty SPL XML leaf element, an error message appears in the assembly. This is expected behavior.

You cannot preview cover pages. You can preview only source document renditions, TOCs, and tabs.

## 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 Publish to a Single File option, all leafs are published to a single file, independent from the selected statuses.

— 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.

— For the Paper Publish only, all leafs under volumes are published, independent from the selected statuses.

The publishing job fails, if:

— All leafs have no publishable elements.

— There are no leafs in the assembly with the selected leaf statuses.

*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 as follows:

— 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 date 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

— Failed

— Canceled

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.

*Export Submissions*

From Ennov InSight , you can export published output from one repository location to another repository location.

When you publish a submission, Ennov InSight creates eCTD files at the submission output location you specified in the publish request. This enables you to copy completed publications to their final storage, archival, or dispatch location in the repository.

*Export a Published Submission*

You can export a published submission from the repository you specified in the publish request to another repository.

To export a published submission:

1. Click a link for the assembly you want to export.
2. Right-click the root and choose Export Published Output. The *Export Published Output* dialog box opens.
3. In the *Source Location* box, specify the output location for the assembly. You can click Browse under the

*Source Location* box to choose the published output from a DMS repository or a secure file system.

4. In the *Destination Location* box, specify the DMS repository or secure file system to which you want to copy the published output. You can click Browse under the *Destination Location* box to choose a location in a DMS repository or a secure file system.

   ***Note:*** *When exporting published output, you can only export to an existing location within the DMS repository or secure file system. If the path that is entered in the output location attribute does not exist, the export will fail.*

   ***Note:*** *For EAEU submissions, provide the valid values for the Source Location and Destination Location fields. For Source Location, a folder containing the index-r-022.xml file must be specified. See: EAEU Submissions Best Practices document for details.*

5. If you are exporting to a DMS repository, do the following:

| Option | Action |
|---|---|
| In the Output Document Type drop-down list: | Select the object type to be created for the exported documents. Use dm_-document for Documentum. |
| For DMS Versioning Scheme: | Select either Minor to version existing documents as a minor version, for example 1.1, or Major to version existing documents as a major version, for example 2.0. |

6. Click OK.

***Note:*** *For EAEU submissions, select Embed PDFs into EAEU XML? and proceed further. See: EAEU Submissions Best Practices document for details.*

Ennov InSight processes the export as a batch job and the following occur:

— A new document/file is created for each repository document that is a descendant of the source folder.

— A new folder is created for each repository folder that is a descendant of the selected folder.

— Only the CURRENT version of a particular source repository's document or folder is exported.

— The document or folder name attribute is set to the repository object name for the document file.

— The documents are placed as children of the matching folders to mirror the hierarchy in the repository.

— Virtual documents (with and without content) and objects with no content are ignored.

— Destination Not Found text will be used to stamp TOC entries or cross-references where the destination is undefined. By default it is set to blank, but in some processes it may be helpful to set it to some text indicating an issue with a TOC entry or cross-reference.

*About Distribute Published Output as Rendition*

The Export Published Output functionality includes the ability to distribute published output as a rendition of a virtual document or a secure file system document.

To distribute published output as a rendition, the source must be a single PDF file, such as the resulting PDF from performing a Publish to Single File publish, and the destination file cannot be a PDF (since that would be a rendition of itself).

If the destination file is a virtual document, it cannot be an object with no content. If you are exporting to a secure file system, there must be an existing pub folder in the same directory as the destination file.

Ennov InSight will distribute the PDF to the pub folder. Existing PDF renditions are overwritten when performing subsequent distributions.

*Distributing Published Output as a Rendition*

You can distribute the published output as a rendition of a virtual document or a secure file system document using the Export Published Output.

To distribute published output as a rendition:

1. Right-click on the root node of an assembly and select Export Published Output.
2. In the *Source Location* box, browse to select a PDF file.
3. In the *Destination Location* box, browse to select a virtual document or secure file system file.
4. Click OK.

***Note:*** *The options for Output Document Type, Status of Documents, and DMS Versioning Scheme are only applicable when exporting folders. They do not apply to exported files.*

*Export a Source File to a Destination File as a Rendition*

Using the Export Published Output function you can specify and export a source file to a destination file (publish a rendition), with certain limitations. The source must be a PDF file, and the destination file cannot be a PDF (since that would be a rendition of itself). If the destination file is a virtual document, the root must already have content.

To export a source file to a destination file as a rendition:

1. On the root node of the assembly, right-click and select Export Published Output.
2. In the Export Published Output window, browse to select a PDF file for the Source Location.
3. For the Destination Location, browse to select either a non-PDF file or a Virtual Document (VDM).

   The options for Output Document Type, Status of Documents, and DMS Versioning Scheme are applicable only when exporting folders. They do not apply to exported files.
4. To export the selected file to the specified destination, click OK.

If the source file and the destination file have the same name, the source file will overwrite the destination file without notice.

*Review an eCTD*

You can review an eCTD for XML files and folder/file structure using Ennov InSight Validator.

See *View Index and Regional XML Files in a Web Browser* in the Ennov InSight Validator User Guide.

You should still perform a typical electronic submission PDF validation by opening files in Acrobat and checking bookmarks and links.

***Note:*** *PDF files launched from a supported browser view of the index.xml or xx-regional.xml might not open to bookmarks and page because of the Acrobat embedding specifics. Use the XML links only to verify that the file can be opened. Do not rely on this to verify the PDF files.*

*View Study Tagging Files (STFs)*

To view STF XML files in Google Chrome:

1. Open files in Google Chrome by right-clicking them in Windows Explorer and choosing Open With > Google Chrome.

   Alternatively, you can open STFs by clicking their links while viewing the index.xml in Google Chrome.
2. For each STF, verify that the Study Title and Study ID are populated and correct.

   If the study is in a section that requires extra STF category metadata, verify that as well.

   ***Note:*** *Only studies contained in 4.2.3.1, 4.2.3.2, 4.2.3.4.1, and 5.3.5.1 require various combinations of the four category elements (species, route of administration, duration, type of control). Studies in other sections can omit the category metadata.*

   Each leaf referenced in the STF needs to correctly point to the leaf ID in the index.xml file. When the leaf ID is correctly referenced, both the Document Title and Relative Filename are populated on the STF. If the ID is not referenced properly to the index.xml, these fields are blank.
3. Click the blue Relative Filename links to ensure that leaf files can be launched.

Each leaf in the STF must have a valid file-tag as described in the STF implementation guide. Tags are displayed in the STF as [us] nonclinical-data or [ich] study-report-body. The text in square brackets is the info-type tag and the rest of the text is the file-tag. Any tags that are misspelled or use the wrong info-type are highlighted in red.

# Chapter 9. Grouped Submissions

A grouped submission is a submission type that is created and managed using submission plans. It is an eCTD submission where all files referenced in it are applicable to multiple applications identified as parts of the group.

Content of the grouped submission physically resides in one application. This is considered the Application Containing Files, or primary application, and remains constant in future sequences. Consider the following constraints while grouping a submission:

— Grouped submissions are supported using US DTD 3.3 or higher versions only.

— All submissions within a group must have the same application and submission type.

***Note:*** *The application type and submission type of the submission are limited by the agency. Please check the latest version of the specification for the list of types applicable for grouped submissions.*

— The initial submission within a grouped submission can only contain new leafs.

— Subsequent submissions within a grouped submission can only contain new leafs or life cycle operations against previous submissions within that group.

In Ennov InSight , all data related to the grouped submission is maintained in the submission plan entity with the Grouped Submission type. This includes:

— Applications, events, and sequences included in the grouped submission.

— Tasks and references related to the grouped submission.

— Assembly Plans that keep the structure, life cycle, content, and metadata of the eCTD submission.

## Submission Plans

Submission Plans facilitate the creation of submissions for multiple similar applications.

In Ennov InSight , the submission plan is a single source scheme used to eliminate redundant tasks of creating similar submissions while working with identical applications.

At this time, Submission Plans are for use with Grouped Submissions only.

To use the *Submission Plan* wizard, you must meet the following security requirements:

— An Electronic Lifecycle Publishing (ELP) and Submission Planning and Tracking (SPT) license modules with at least WRITE privileges.

— At least WRITE privileges on Submission Plan to be able to create a Submission Plan entity from the New menu.

— At least WRITE privileges on Submission Plan to be able to modify a Submission Plan entity.

— At least ADMIN privileges on Submission Plan to be able to delete a Submission Plan entity.

— At least READ privileges on Submission Plan to be able to view a Submission Plan entity.

— At least WRITE privileges to Submission Plans to be able to disassociate an Application.

— At least WRITE privileges to Submission Plans to be able to disassociate an Event.

— At least WRITE privileges to Submission Plans to be able to disassociate a Sequence.

— Home Page Access for Submission Plan set to YES to access the Submission Plan from the Home Page tab. An Assembly Plan can be created with at least WRITE privileges on Submission Plan.

Submissions Plans are available with the Electronic Lifecycle Publishing (ELP) and Submission Planning and Tracking (SPT) license modules.

With a submission plan, you can:

— Scheme the submission structure and the content.

— Automatically transfer the structure and documents to the applications.

To create a submission plan, you must have appropriate privileges from your application security administrator.

Create Submission Plan Wizard

The Create Submission Plan wizard guides you through the process to create a submission plan and associate entities such as applications, events, and sequences to the submission plan.

To use the Create Submission Plan wizard, you must have appropriate privileges from your application security administrator.

Using the Create Submission Plan wizard, you can:

— Create submission plan

— Associate existing applications to the submission plan

— Create new events and associate them with the submission plans, or associate existing events to the submission plan

— Create new sequences and associate them with the submission plans, or associate existing sequences to the submission plan

To create submission plan using the wizard:

1. On the home page, click Wizard > Create Submission Plan.
2. On the *Submission Plan Creation* page, enter the attribute values for the submission plan and click Next. The application page appears.

   — For description of the submission plan attributes, see the topic *Submission Plan Attributes*.

3. Do one of the following:

| Option | Action |
|---|---|
| To search for the application to associate: | Enter the relevant details in the respective fields (for description of the attributes in the *Search for Applications to Associate* page, see the topic *Associating Applications to Submission Plans*. Click Next. |
| To view the list of existing US applications that have the application type selected for the submission plan: | Click Next. |

4. Select the application and click Next.
5. On the confirmation page, click Next.

   The *Confirmation* pages appear during the execution of the wizard that indicate entities are being created, even though the wizard is still in progress. If the wizard prematurely terminates after a confirmation screen is displayed, the entities created continue to exist in Ennov InSight .

6. On the *Summary* page, to create or associate events and sequences, click Next and move to next step. Otherwise, click Finish to create the submission plan.
7. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

| Scenario | Steps |
|---|---|
| When electronic signature and SSO are enabled | a. In the confirmation page, select a reason and enter comments for the reason.<br>b. Click Next.<br>c. Validate your identity by entering your user credentials in the dialog box. |
| When electronic signature is enabled and SSO is disabled | a. Select a reason and enter comments for the reason.<br>b. Enter user ID and password and click Next. |

1. On the *Create/Associate Events* page, select an appropriate option and follow the wizard to associate new or existing events to the submission plan.

   For the description of the event attributes, see the topic *Event Attributes*.

2. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

| Scenario | Steps |
|---|---|

| | |
|---|---|
| When electronic signature and SSO are enabled | a. In the confirmation page, select a reason and enter comments for the reason.<br>b. Click Next.<br>c. Validate your identity by entering your user credentials in the dialog box. |
| When electronic signature is enabled and SSO is disabled | a. Select a reason and enter comments for the reason.<br>b. Enter user ID and password and click Next. |

1. On the *Create/Associate Sequences* page, select an appropriate option and follow the wizard to associate new or existing sequences to the submission plan.

   For the description of the sequence attributes, see the topic *Sequence Attributes*.

2. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

| Scenario | Steps |
|---|---|
| When electronic signature and SSO are enabled | a. In the confirmation page, select a reason and enter comments for the reason.<br>b. Click Next.<br>c. Validate your identity by entering your user credentials in the dialog box. |
| When electronic signature is enabled and SSO is disabled | a. Select a reason and enter comments for the reason.<br>b. Enter user ID and password and click Next. |

1. Click Finish.

The submission plan is created.

Create Submission Plans

Ennov InSight enables you to create submission plans and associate entities such as applications and sequences to the submission plans.

To create a submission plan, you must have appropriate privileges from your application security administrator.

To create a submission plan:

1. On the home page, click New > Submission Plan.
2. On the *Create Submission Plan* page, enter the attribute values for the submission plan.
3. Save.
4. Choose the applicable procedure to enter an electronic signature for entities:

| Scenario | Steps |
|---|---|

| | |
|---|---|
| When electronic signature and SSO are enabled | 1. Select a reason and enter comments for the reason.<br>2. Select Save.<br>3. Validate your identity by entering your user credentials in the dialog box. |
| When electronic signature is enabled and SSO is disabled | 1. Select a reason and enter comments for the reason.<br>2. Enter user ID and password and click Save. |

Modify Submission Plans

You can modify a submission plan to make edits to the attributes that were entered when the submission plan was created.

***Note:*** *When modifying the values for the submission plan it is not possible to modify the following fields: Submission Plan Type, DTD/Schema, Filing Type, and Submission Plan Countries.*

To modify a submission plan:

1. On the home page left panel, click Submission Plans.
2. Click a link for the submission plan you want to modify.
3. On the View Submission Plan page, click the Edit icon.
4. On the Edit Submission Plan page, enter your changes to the submission plan attributes.
5. Click Save.
6. Choose the applicable procedure to enter an electronic signature for entities:

| Scenario | Steps |
|---|---|
| When electronic signature and SSO are enabled | 1. Select a reason and enter comments for the reason.<br>2. Select Save.<br>3. Validate your identity by entering your user credentials in the dialog box. |
| When electronic signature is enabled and SSO is disabled | 1. Select a reason and enter comments for the reason.<br>2. Enter user ID and password and click Save. |

Delete Submission Plans

Users with administrator privileges can delete a submission plan from Ennov InSight . When a submission plan is deleted, its associated tasks and references will be deleted.

A submission plan with an associated assembly plan cannot be deleted. To delete a submission plan, the assembly plan associated to it must be deleted first.

To delete a submission plan:

1. Navigate to the submission plan you want to delete.
2. Click the link for the submission plan.
3. On the *View Submission Plan* page, click the Delete icon.
4. Select a reason and enter comments for the reason.
5. Click Next.
6. Choose the applicable procedure to enter an electronic signature for entities:

| Scenario | Steps |
|---|---|
| When electronic signature and SSO are enabled | 1. Select a reason and enter comments for the reason.<br>2. Select Save.<br>3. Validate your identity by entering your user credentials in the dialog box. |
| When electronic signature is enabled and SSO is disabled | 1. Select a reason and enter comments for the reason.<br>2. Enter user ID and password and click Save. |

Submission Plan Attributes

You can use the attribute descriptions to enter the attribute values while creating the submission plans.

| Attribute | Description |
|---|---|
| Submission Plan Name | The name of the submission plan. |
| Submission Plan Code | The code of the submission plan. |
| Submission Plan Owner | The person responsible for managing the submission plan. |
| Submission Plan Type | The type of submission plan you are creating.<br>***Note:*** *At this time, only Grouped Submission is available.* |
| DTD/Schema | The DTD/Schema version for the submission. |
| Application Type | The type of the application which will be associated with the submission plan. |
| Filing Type | The submission filing type. |
| Submission Plan Countries | The countries for which the submission is planned. |

| | |
|---|---|
| Submission Plan Status | The status of the submission plan. |
| Submission Plan Status Date | The date the current submission plan status is effective. |
| Submission Plan Keywords | Keywords that apply to the specific submission plan. |
| Submission Plan Description | A description of the submission plan. |
| Submission Plan Add Comment | Comments regarding the submission plan. |
| Reason | Reason for creating, modifying or deleting a submission plan. |
| Reason for Comments | Comments related to reason entered by users. |
| User ID | The user name to validate user identity. |
| Password | The user password to validate user identity. |

## Assembly Plans

An assembly plan enables you to create an assembly that can be used for multiple applications. An assembly plan helps in eliminating the redundant effort required in creating identical assemblies for similar applications.

***Note:*** *Assembly Plans are for use within a Submission Plan only. See Grouped Submissions for usage constraints.*

For grouped submissions, the initial assembly plan that is created has no relationship to the already submitted assembly. Any subsequent assembly plans are built on top of the existing assembly plans.

Assembly Plans

With the assembly plan having no relation to the other assemblies, the life cycle operations are contained within the submission plan until the sequence assembly is created.

See the following topics for information and procedures related to assemblies and assembly plans.

Create Assembly Plans

Ennov InSight enables you to create assembly plans within submission plans. Assembly Plans can only be created if the Submission Plan has associated Applications.

To create an assembly plan:

1. On the Home page, click Submission Plan.
2. In the Submission Plans list, click the submission plan under which you want to create an assembly plan.
3. On the *View Submission Plan* window, select Assembly Plans tab.
4. Click the Create icon.
5. In the *Create Assembly* page, select an appropriate option to create an assembly.

   — New (Empty) - to create a new assembly containing no existing assembly elements.

— Existing Template, Assembly or View - create a new assembly from an existing template or assembly, or from a current or active view.

— Assembly File - create a new assembly from an assembly or view that has been exported as an XML file. — Virtual Document - create a new assembly from a Documentum virtual document.

6. For the selected mode, follow the wizard and enter details where necessary.
7. Click Save.
8. Enter details as necessary.

— If the method chosen to create an assembly plan is other than the one using the assembly file, the Applicable Applications field automatically shows the applications associated to the submission plan under the Selected box on the *Create Assembly* page.

— The list of the applications applicable for the assembly plan can be changed after an assembly plan is created.

9. Click Create.

The assembly plan is created.

Modify Assembly Plan Attributes

You can make edits to the attributes of an assembly plan.

To modify an assembly plan:

1. On the home page left panel, click Submission Plans.
2. Click the link for the submission plan which includes the assembly plan you want to modify.
3. On the View Submission Plan page, select the Assembly Plans tab.
4. Click the link for the assembly plan that you want to modify.
5. Click the Edit icon.
6. On the *Edit Assembly* page, enter your changes to the assembly plan attributes.

   Assembly Plans

7. Click Save.

The new attributes of assembly plan are saved.

Delete Assembly Plans

Deleting an assembly plan removes its sub-entities, such as folders and leafs. You can delete an unlocked assembly plan from Ennov InSight .

To delete an assembly plan:

1. Go to the submission plan that contains the assembly plan you want to delete.
2. On the *View Submission Plan* page, go to the Assembly Plans tab and select the assembly plan that you want to delete.
3. On the *Assembly Attributes* page, click More.
4. Click Delete.
5. When you are prompted to confirm the deletion, click OK.

The assembly plan is deleted.

## Life Cycle Operations in Assembly Plan

Life Cycle operations are performed similarly in sequence assemblies and assembly plans. However, in an assembly plan, the target leaf of the operation will be set to the leaf on the sequence assembly of the Application Containing Files, as defined within the Assembly Plan metadata of the previously lifecycled Assembly Plan.

Life Cycle operations on leafs (replace, append, and delete) can be performed from the assembly plan working view.

— To perform any operation, the operated leaf should reside in the assembly plan that is already merged to the sequence assemblies.

— Though the operation is performed on the leaf from the previous assembly plan, the modified leaf and modified sequence attributes will be populated with the links targeting this leaf in the sequence assembly of the application containing files.

— The modified file path references the application number, sequence number, and leaf id for the application where the leaf was submitted with the application-containing-files element value indicating “true.”. The modified file attribute is formatted as ../../<application prefix><operated leaf application code>/<operated leaf sequence code>/ index.xml#<leafid>. For example, ../../ nda678901/0004/index.xml#a08f474cfe3cad534c64843a54c534382

## Associate Applications to Submission Plans

Ennov InSight enables applications to be associated to submission plans. Applications available for association are those which:

— are not assigned to the submission plan

— have the same application type and country as the submission plan

— have at least the Read permission enabled

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***Note:*** *When an application associated with a submission plan is deleted, the association of the application with that submission plan ends automatically.*

To associate applications to submission plans:

1. On the Home page, click Submission Plan.
2. In the submission plans list, click the submission plan to which you want to associate applications.
3. On the *View Submission Plan* window, select Associated Applications tab.
4. Click the Associate/Disassociate Application(s)  icon. The *Associate Applications* window opens.
5. Enter relevant details of the application you want to associate in their respective fields and click Next.

   The applications matching the details entered are displayed in the *Select Application* window.
6. Select the applications and click Next.
7. Click Finish.

The applications are associated with the submission plan.

Attributes used while associating application

Use the following attribute descriptions to enter the attribute values while associating applications to submission plans.

| Attribute | Description |
|---|---|
| Application Name | The name of the application. |
| Application Owner | The person responsible for managing the application. |
| Application Status | The status of the application. |
| Display Columns | The application related columns you want displayed in the grid. |
| Sort Order | The display of applications based on the order of the application attributes set in the *Associate Applications* window. |

Disassociate Applications from Submission Plans

Applications affiliated to submission plans can be disassociated. Events and sequences that are associated with the application will also be disassociated when the application is disassociated from the submission plan. Applications that have existing association with assembly plans cannot be disassociated.

To disassociate applications from submission plan:

1. On the Home page, click Submission Plan.
2. In the submission plans list, click the submission plan from which you want to disassociate the application.
3. On the *View Submission Plan* window, select Associated Applications tab.
4. Select the checkbox for the application you want to disassociate from the submission plan.
5. Click the Associate/Disassociate Application(s)  icon.

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Associate Applications to Submission Plans

6. Click OK on the confirmation message.

The association of the application with the submission plan is removed.

## Associate Sequences to Submission Plans

Ennov InSight enables sequences to be associated to submission plans. To associate a sequence to a submission plan, an application must already be associated to the submission plan. Existing sequences will be available for association when:

— the sequence filing type matches the filing type of the submission plan to which it is being associated — it is not already associated to any submission plan

— it does not have an assembly

— its application does not have a sequence without an assembly already associated to the submission plan to which it is being associated

— its application has Read permission based on the Application/Country rights

To associate sequences to submission plans:

1. On the Home page, click Submission Plan.
2. In the Submission Plans list, click the submission plan to which you want to associate sequences.
3. On the *View Submission Plan* window, select Associated Sequences tab.
4. Click the Associate/Disassociate Sequence(s)  icon. The *Create/Associate Sequences* window opens.
5. Proceed as follows:

   — If a sequence you want to associate already exists, select Associate. — If no sequence exists, select Create.

6. Click Next.
7. Proceed as follows:

| Option | Action |
|---|---|
| If Create was selected: | Skip to step 9. |
| If Associate was selected: | Enter the search criteria to find the sequences. Click Next. |

   Only sequences matching the entered criteria, and with the same filing type listed on the Submission Plan, are returned.

8. Select the Sequence you wish to associate and click Next. Skip to step 11.
9. If Create was selected, select the Events to associate the sequence to, and click Next.
10. Complete the *Sequence Details* screen, and click Next.

The Sequence Filing Type is automatically set to the same filing type as listed on the Submission Plan.

11. On the *Confirmation* screen click Next to save the associated Sequences.

    The *Summary* page confirms the association of the sequences.

12. Click Finish.

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Associate Sequences to Submission Plans

The sequences are associated to the submission plan. The Included in Grouped Submission field in the *View Sequence* window displays the submission plan to which the sequence is associated.

***Note:*** *Creating assemblies manually in sequences associated to submission plans is not allowed.*

Disassociate Sequences from Submission Plans

Sequences without assemblies can be disassociated from submission plans.

To disassociate sequences from submission plans:

1. On the Home page, click Submission Plan.
2. In the submission plans list, click the submission plan from which you want to disassociate a sequence.
3. On the *View Submission Plan* window, click the Associated Sequences tab.
4. Select the check box next to the sequence you want to disassociate from the submission plan.
5. Click the Associate/Disassociate Sequence(s)  icon.
6. Click OK on the confirmation message.

The association of the sequence with the submission plan is removed. Assemblies can be manually created for sequences that are no longer associated with the submission plans.

## Associate Events to Submission Plans

Ennov InSight enables you to associate events to submission plans.

To associate an event to a submission plan, an application must already be associated to the submission plan. An existing event cannot be associated if it is:

— already associated to the submission plan

— related to the application which has other event(s) associated to the submission plan

— associated to other submission plans

— related to the applications for which the user does not have at least the Read permissions based on the Application/Country rights.

To associate sequences to submission plans:

1. On the Home page, click Submission Plan.
2. In the *Submission Plans* list, click the submission plan to which you want to associate events.
3. On the *View Submission Plan* window, select Associated Events tab.
4. Click the Associate/Disassociate Event(s) icon. The *Associate Events* window opens.
5. Proceed as follows:

   — If an event you want to associate already exists, select Associate.

   — If no event exists, select Create.

6. Click Next.

   Ennov InSight Publisher 7.3 Associate Events to Submission Plans

7. Proceed as follows:

| Option | Action |
|---|---|
| If Create was selected: | Skip to step 9. |
| If Associate was selected: | Enter the search criteria for the events to find, and click Next. |

8. Select the event you wish to associate and click Next. Skip to step 12.
9. If Create was selected, select the applications to associate the event to. Click Next.
10. Complete the *Events Details* screen, and click Next.
11. Select the timeline/event plan from the drop-down list.
12. On the *Confirmation* screen click Next to save the associated events. The *Summary* page confirms the association of the events.
13. Click Finish.

The events are associated to the submission plan.

Disassociate Events from Submission Plans

You can disassociate events associated with submission plans.

To disassociate events from submission plans:

1. On the Home page, click Submission Plan.
2. In the submission plans list, click the submission plan from which you want to disassociate an event.
3. On the *View Submission Plan* window, select Associated Events tab.
4. Select the event you want to disassociate from the submission plan.
5. Click the Associate/Disassociate Event(s) icon.
6. Click OK on the confirmation message.

The association of the event with the submission plan is removed.

***Note:*** *Even after an event is disassociated, the sequence belonging to the event will continue to be associated with the submission plan.*

## Use the Ready for Submission Wizard

The *Ready for Submission* wizard enables an assembly plan to be merged into the life cycle of the existing applications applicable to the assembly plan. Merging the assembly plan copies all of its files into the life cycle. Using this wizard, you can also copy paper publishing elements and create events and sequences if they are not already associated with the submission plan.

***Note:*** *You must have the appropriate security privileges of sequences and sequence assemblies to use the Ready for Submission wizard*

To prepare an assembly plan for submission:

1. On the homepage, click Submission Plans.
2. Click the link of the submission plan which includes the assembly plan that you want to prepare for submission.
3. Select the assembly plans tab and click the link of the assembly plan.
4. Click Wizards from the menu.
5. Click Ready for Submission.

   The *Ready for Submission* wizard opens.
6. Do the following:

| Option | Action |
|---|---|
| To add submissions to life cycle: | Select the option Add Submissions to Lifecycle?. |
| To copy paper publishing elements: | Select the option Copy Paper Publishing Elements?. Selecting this option copies all the publishing elements in the assembly plan to the corresponding nodes of the created sequence assembly. The source Assembly Specific Publishing Settings Libraries (APL) settings for the publishing elements that are copied, will be merged into the target APL(s). |

7. Click Next.
8. Do one of the following:

| Option | Action |
|---|---|
| If the events are already associated with the submission plan, in the *Event creation* page: | Click Next. Move to step 13. |

| | |
|---|---|
| If the events are not already associated with the submission plan, in the *Enter Event Details* page: | Enter details for the event and click Next. |

9. In the select *Event Plan* page, select an appropriate plan from the Timeline/Event Plan option and click Next.
10. Select a reason and enter comments for the reason.
11. Click Next.
12. If eSignature is enabled, validate your identify by entering your user credentials and click Sign in.
13. If the sequences from the applicable applications on the assembly plan are already associated, in the *Sequence Verification* and *Sequence creation* pages, click Next. Move to step 20. Else, move to next step.
14. If the sequences from the applicable applications on the assembly plan are not associated, in the *Enter Sequence Details* page, enter details for the sequence. Click Next.
15. Select a reason and enter comments for the reason.
16. Click Next.
17. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

| Scenario | Steps |
|---|---|
| When electronic signature and SSO are enabled | a. In the confirmation page, select a reason and enter comments for the reason.<br>b. Click Next.<br>c. Validate your identity by entering your user credentials in the dialog box. |
| When electronic signature is enabled and SSO is disabled | a. Select a reason and enter comments for the reason.<br>b. Enter user ID and password and click Next. |

1. In the *Confirmation* page, click Next.

   — A sequence will be created for every application listed as an associated application on the assembly plan, that does not have a currently associated sequence.

   — The created sequence will be associated to the event listed as the associated event for that application.

   — If no events are associated, the sequence will only be associated to the applications on the assembly plan.

   — If an existing sequence is associated and already has an assembly associated, the system will create a new sequence using the next available sequence code.

   — The sequence code for created sequences will be automatically set to the next available number, within the associated application, with a prefix of ‘P’.
2. In the next *Confirmation* page, click Next.
3. In the *summary* page, click Finish.

To know the status of the submitted job, click GO TO from the menu and click Job Requests. Upon the completion of the job request, the files are merged into the life cycle.

***Note:***

*— If merging any application from the list of applicable applications into the life cycle fails, all changes to all applications will be automatically reverted.*

*— If the changes are successfully merged and you then want to make changes to the submission that was merged, all the created sequence assemblies must be deleted and the changes must be made in the assembly plan. Sequence assemblies must be created again using the Ready for Submission Wizard to reflect the changes made to the submission.*

*— When an assembly plan is merged to sequence assemblies, there will be no synchronization between that assembly plan and the sequence assemblies.*

*— The leaf statuses of leaf elements in the assembly plan are not updated during the Ready for Submission wizard execution and after the wizard is finished.*

Order of the copied elements in the target Assembly

The order of the copied elements in the target Assembly will be based on the number attribute.

If there are several nodes with the same number, the newly copied ones will be added to the end under the appropriate parent. The nodes with the number attribute which ends with a letter (Example: 2.3.S, 2.3.P, 2.3.A, 2.3.R) will be placed in the following order:

1. x.x.S
2. x.x.P
3. x.x.A 4. x.x.R

# Chapter 10. Publishing Messages (Troubleshooting)

During publishing, messages related to the publishing process are noted in either the publishing log or the

*Publishing Readiness* query.

An error message that starts with ERROR or WARNING is an error reported in the publishing log. Many of the other errors and warnings are strictly reported in the Publishing Readiness query.

These publishing messages do not include messages from the rendering and publishing servers, including the fusion business service, internal error messages caused by build or installation failures, or messages related to an incorrect engineering configuration.

## Repository Messages

You can view repository error messages in either the publishing log or the *Publishing Readiness* query.

| Message | Description |
|---|---|
| Document Repository {name} does not appear to be available. | A DMS is not working or the Ennov InSight login credentials are wrong. |
| Credentials not available for repository {name}. | The system has not received the user name and password for logging in to the DMS specified in a document crossreference in the assembly. The cross-reference cannot be resolved. |
| LoginInfo and Principal for<br>{name} docbase are not defined or wrong. | The specified Docbase is shut down. |

## Assembly Messages

You can view assembly error messages in either the publishing log or the *Publishing Readiness* query.

| Message | Description |
|---|---|
| Missing Rendition/Rendition does not exist | A rendition does not exist and must be created to successfully publish the assembly as you expect. Documents that are missing renditions will not publish. When this warning appears at the assembly level, an overlay file rendition is missing. |

Ennov InSight Publisher 7.3 Repository Messages

| Message | Description |
|---|---|

| | |
|---|---|
| Assembly doesn't have any volumes associated with. | The assembly has been prepared for the paper output channel, however, there are no volumes in the assembly. There must be at least one volume to publish to paper. |
| Missing DTD Settings | The assembly is missing assigned DTDs. These should be assigned in the publishing settings before performing an eCTD publish. |
| No Document associated with the assembly | There are no documents in the assembly. No content documents will be included in the publish job. |
| ERROR: Not all publish options set for prepare for publish | One or more options in the publishing settings have not been set. Access Publishing Settings and verify that all settings have been applied. This is noted in the publishing log. |
| At least one XML definition is required.<br>Please use Publication Settings to select<br>XML Definition | At least one DTD XML mapping has not been set in the publishing settings. Access Publishing Settings and verify that at least one DTD has been applied. |
| ERROR: com.liquent.ip.ectd.EctdException: ectd_1004 Error detected in trying to parse the ectd rules file >path to rules file (The system cannot find the file specified) | The DTD XML mapping files cannot be found. Verify with your system administrator that they have been correctly installed and configured. This is noted in the publishing log. |
| Has no major division. | The assembly contains no folders flagged for major division. This is important if you are using any variables that resolve to major division. In this case, you would see unresolvable variables in your output. |
| Has no minor division. | The assembly contains no folders flagged for minor division. This is important if you are using any variables that resolve to minor division. In this case, you would see unresolvable variables in your output. |
| Minor division is defined before the first major division folder. | The assembly contains a minor division folder that appears higher in the assembly tree than a folder flagged for major division. In this instance, the minor division variable may not resolve properly. |

| Message | Description |
|---|---|
| ERROR: Unable to calculate the attribute xlink:href for folder on object null. Exception detected String index out of range: 1. | When the DTD does not have a mapping for folders added to an assembly, this error appears in the job requests job message log during publishing. |

## Folder Messages

You can view folder error messages in either the publishing log or the *Publishing Readiness* query.

| Message | Description |
|---|---|
| Supplied publish folder of name {name} is not found | Internal error; contact Technical Support. |
| The folder output path includes invalid characters. | Invalid characters are specified for the output path. Valid characters include only lowercase letters (a-z), numbers (0-9) and hyphens. If these are not adjusted prior to publishing time, the publishing engine will make the correction according to normalization rules. |
| Required metadata on a folder has a missing value: | The folder has a required attribute value that is currently blank. This should be corrected before attempting an eCTD publish. |
| The extended attributes, output folder, or leaf output file name contain non-substitutable characters that contribute to eCTD the output path. | You can override this manually by changing the output folder or leaf output file name to use only valid eCTD characters. |
| The max length exceeded. | The output file path exceeds maximum regulation file length. This should be corrected before a final publish. |
| Missing output file location. | The folder is missing an output file location. The eCTD will not publish fully without the file location defined. |

## Leaf Messages

You can view leaf error messages in either the publishing log or the *Publishing Readiness* query.

| Message | Description |
|---|---|
| There is no policy called<br>'{name}' in the DMS {name} | You have chosen a Documentum business policy to attach published documents to, but the policy does not exist. |

| Message | Description |
|---|---|
| Cannot find attribute '{name}' on element '(name)' when importing into DMS | You have specified attributes that should be copied from leaf elements to published results, but the attributes specified in this message cannot be found. |
| Could not find an ICH definition. | No DTD/schema has been specified; one is required to publish an eCTD. |
| Leafs {name 1} and {name 2} produce documents at the same location {location}. | Change one of the leaf output paths to resolve this issue. |
| Native file leaf {name} contains multiple documents that cannot be concatenated. Excluding the documents from the publication. | You chose Yes for the Use Native File attribute but the parent leaf contains more than one source document. Change Use Native File to No or remove the necessary documents from the leaf. |
| No Documents detected in<br><br>Assembly, Executing ECTD XML Backbone only publish. | The assembly contains no documents to publish. Only the XML backbone will be published. |
| Cannot find attribute {name} on element {name} when importing into DMS | You have specified attributes that should be copied from leaf elements to published results, but an attribute of this name cannot be found. |
| Invalid input error: {error description} | The specified XML file or one of its dependencies (for example, a DTD or stylesheet) does not exist or cannot be read. |
| Cannot find the Insight configuration file {name} | An installation fault has occurred. |
| The leaf with assembly path<br><br>{name} has no output file defined. | You did not enter a path for the leaf. Each leaf requires a resulting file name. A temporary name is generated and publishing continues. |
| You have not defined any agency definitions for your assembly. | You have not chosen the XML definition files in the publishing options. |
| ERROR: Error with Component 4 | Occurs when Ennov InSight is unable to put multiple files together, often because one is encrypted or contains invalid data. This is not- ed in the publishing log. |

Ennov InSight Publisher 7.3 Leaf Messages

| Message | Description |
|---|---|

| | |
|---|---|
| ERROR: XML structure error: line 155, column 25: The content of element type m1-5specific"" must match ((m1-5-1bibliographic\|m1-5-2abridged)?, (leaf\|nodeextension)*)" | Elements m1-5-1-bibliographic and m1-5-2-abridged are both present in your assembly structure. Remove one to create a valid xml. This is noted in the publishing log. |
| ERROR: NVPair has no attribute name | NONE is not a valid selection for country. Please assign all related sequences to a specific country. This is noted in the publishing log. |
| WARNING: Page number is missing | Indicates that a native file leaf is included in publishing and will not be counted in page numbering. This is noted in the publishing log. |
| WARNING: FileNameRule: leaf output path ../../../../JCS 24-17 AppC1/0000/m1/eu/16environ-risk/162-gmo/1-6-2nodeext-01.pdf contains invalid characters: `J', `C', `S', ` `,<br><br>`A'. [XPath: /eu:eubackbone/m1-eu/m1-9-clinical-trials/leaf/@xlink:href] | Indicates that an output folder, output file name, or eCTD metadata used for XML paths contains illegal characters. Most illegal characters are normalized for valid output, but these must be confirmed in the output. This is noted in the publishing log. |
| Missing Content, no children. | The leaf has no content documents assigned to it. This warning is only valid on standard leaf elements, and not applicable to reference leaf elements. |
| The extended attributes, output folder, or leaf output file name contain non-substitutable characters that contribute to the eCTD output path. | Override manually by changing the output folder or leaf output file name to use only valid eCTD characters. |
| File name is blank | A file name is not specified. At publishing time, if this is not corrected, the publishing engine will use the leaf name as the file name. |
| File extension on the leaf file name doesn't match the type of document. | The leaf output file name extension does not agree with the file type for the first document under the leaf. This should be corrected prior to performing an eCTD publish. |
| Only one document will be published | This warning appears when a native file leaf has more than one child beneath it. In this instance, only the first child document will be included. |

Ennov InSight Publisher 7.3 Leaf Messages

| Message | Description |
|---|---|

| | |
|---|---|
| Two leafs cannot have same output file | If two leaf elements in your assembly have the same output file, there is a risk the file will be overwritten. This should be corrected prior to publishing. |
| File extensions are missing. | Special required leaf attributes are missing. Values should be entered prior to performing an eCTD publish. |
| This native formatted document will be published without page numbers. | It is possible to mark a leaf as native or to have a reference leaf that has an associated overlay. However, in these special cases of leaf elements, no overlay will be applied, and the element will not be included in the page count. |
| The max length exceeded. | The output file path exceeds maximum regulation file length. This should be corrected before a final publish. |
| The maximum leaf file size has been exceeded. | The leaf file size exceeds regulatory guidance. |
| Inconsistent Lifecycle;<br>Modified leaf must indicate its modified file. | A leaf operation is something other than NEW, but its modified file value is missing. This is a discrepancy that may need to be resolved by your administrator in order to successfully publish your eCTD. |
| Inconsistent lifecycle; a new leaf cannot have a modified file value. | A leaf operation is NEW, but the leaf contains a value for modified file. This is a discrepancy that may need to be resolved by your administrator in order to successfully publish your eCTD. |
| Excluded from Volume Range. | You have volumes defined, but this element is not included in a volume. Therefore, it will not be published. |
| ERROR: Unable to distribute | Generally caused by failure to remove a file that already exists, failure to classify/register published output in a DMS repository, or failure to save the published output or version on a DMS or file system repository. This is noted in the publishing log. |

## Document Messages

You can view document error messages in either the publishing log or the *Publishing Readiness* query.

| Message | Description |
|---|---|
| There is no policy called {name} in the DMS {name} | You have chosen a Documentum business policy to attach published documents to, but the policy does not exist. |

Ennov InSight Publisher 7.3 Document Messages

| Message | Description |
|---|---|

| | |
|---|---|
| Failed to create the checksum file {name} for backbone file<br><br>{name} | You may not have access to the file or folder. Save the log file information and see your system administrator. |
| Native file leaf {name} contains multiple documents that cannot be concatenated. Excluding the documents from the publication. | You chose Yes for the Use Native File attribute but the parent leaf contains more than one source document. Change Use Native File to No or remove the necessary documents from the leaf. |
| No Documents detected in<br><br>Assembly, Executing ECTD XML Backbone only publish. | The assembly contains no documents to publish. Only the XML backbone will be published. |
| Cannot find the file system extension of document {name}: {error description}. | Ennov InSight Publisher failed to find the file extension of a document in a DMS repository. The extension is required to save the results in the DMS repository. |
| Cannot find attribute {name} on element {name} when importing into DMS | You have specified attributes that should be copied from leafs to published results, but an attribute of this name cannot be found. |
| There is no policy called<br><br>{name}" in the DMS {name} | You have specified a Documentum business policy to attach published documents to, but the policy does not exist. |
| An exception has been detected in resolving attribute {name},<br><br>Exception: {description} | Internal error; contact Technical Support. |
| {validation rule class}: {target<br><br>Xpath}: missing leaf content file {file name} | The specified leaf document does not exist or cannot be read. The document may not exist (for example, because of an incremental publish). |
| There is no attribute named<br><br>{name} defined on an element of type {name} | The attribute may be incorrectly named. Check attribute mappings and see if the attribute exists. |
| Failed to read content file {PDF file name} : {error description} | The PDF document has not been published or does not exist. Please verify the PDF document exists. |

| | |
|---|---|
| Input error: missing or invalid input file {file name}" | The document specified does not exist or cannot be accessed. Please verify that the document exists and is readable. |
| Input error: unable to parse XML file {file name}": {error type}:<br><br>{error description} | The file specified cannot be accessed or its content is invalid. Please verify that the file specified is readable and that its content is valid. |

Ennov InSight Publisher 7.3 Document Messages

| Message | Description |
|---|---|
| Assembly document {name} does not have an attached DMS document | Warning to users that they have forgotten to attach a repository document to an IMA document. |
| Failed to read content file<br><br>{name}": {error description} | The PDF document has not been published or does not exist. |
| Input error: missing or invalid input file {name}" | This is an installation fault. |
| No output channel has been specified | This element does not have an output channel associated with it. Therefore, it will not be published. |
| Missing Rendition/Rendition does not exist | A rendition does not exist and must be created to successfully publish the assembly as you expect.<br><br>Documents that are missing renditions will not publish. |
| This is a placeholder and it is not going to be published. | The element is a placeholder. Placeholders cannot be published, and will therefore not be included in the published output. |
| Unable to set properties for documents in folder {file path}:<br><br>Unable to find document | The distribute sub-job on the Ennov InSight Rendering server attempts to set properties on placeholders. When there is no document to accept the properties, the sub-job reports an error. This error can safely be ignored for placeholders. |
| Document are not assigned and a<br><br>DMS synch is required | The document is not assigned. A DMS Sync is required for these documents to publish successfully. |
| ERROR: ESPSLoadContainer | This message is informational and may be safely ignored. This is noted in the Publishing Log. |

| | |
|---|---|
| ERROR: Odd Page Overlay | This message is informational and may be safely ignored. This is noted in the Publishing Log. |
| Excluded from Volume Range | You have volumes defined, but this element is not included in a volume. Therefore, it will not be published. |

## Page Marker Messages

You can view page marker error messages in either the publishing log or the *Publishing Readiness* query.

| Message | Description |
|---|---|
| Page Marker out of range. | The page marker does not fall within the page range of the document that it is associated with. The system will assume that the page marker is intended for the final page of the content document. |

Ennov InSight Publisher 7.3 Page Marker Messages

## TOC Messages

You can view TOC error messages in either the publishing log or the *Publishing Readiness* query.

| Message | Description |
|---|---|
| No output channel has been specified | This element does not have an output channel associated with it. Therefore, it will not be published. |
| Excluded from Volume Range. | You have defined volumes but this element is not included in a volume. Therefore, it will not be published. |
| Missing Rendition/ Rendition does not exist | A rendition does not exist and must be created to successfully publish the assembly as you expect. Documents that are missing renditions will not publish. |
| This TOC will not publish to paper if it is assigned to an element that is set only to the electronic output channel | There is a discrepancy between the TOC output channel designation (paper) and the output channel associated with the element the TOC is assigned to. The TOC will not publish to the paper output channel. |
| ERROR: Unable to<br>Distribute | Generally caused by failure to remove a file that already exists, failure to classify/register published output in a DMS repository, or failure to save the published output or version in a DMS or file system repository. This is noted in the Publishing Log |

## Cover Page Messages

You can view cover page error messages in either the publishing log or the *Publishing Readiness* query.

| Message | Description |
|---|---|
| No output channel has been specified. | This element does not have an output channel associated with it. Therefore, it will not be published. |
| Missing Rendition/ Rendition does not exist | A rendition does not exist and must be created in order to successfully publish the assembly as you expect. Documents that are missing renditions will not publish. |

## Special Sheet Messages

You can view special sheet error messages in either the publishing log or the *Publishing Readiness* query.

TOC Messages

| Message | Description |
|---|---|
| Excluded from Volume Range | You have defined volumes but this element is not included in a volume. Therefore, it will not be published. |
| No paper type defined | The element does not have a paper type defined. This is necessary before proceeding with a paper publish. |

## Volume Messages

You can view volume error messages in either the publishing log or the *Publishing Readiness* query.

| Message | Description |
|---|---|
| Volumes have no documents. | The volume is in the assembly, but it contains no content documents. It may contain placeholders, TOCs and special sheets. The volume will publish with any associated TOCs and special sheets. |
| Volume page counts are over the maximum volume count plus buffer. | The volume exceeds the maximum size as indicated in your settings. It can still publish successfully, however. |
| Volume page counts are under the minimum volume count minus the buffer. | The volume is too small to meet the minimum size as indicated in your settings. It can still publish successfully, however. |
| Some documents in this volume has UNASSIGNED status and will not publish. | There is at least one document in the volume that has a status of unassigned. If you want to publish all your documents that appear in this volume, you perform a DMS sync. |

## Checksum Messages

You can view checksum error messages in either the publishing log or the *Publishing Readiness* query.

| Message | Description |
|---|---|
| Failed to create the checksum file<br><br>{name} for backbone file {name} | You may not have access to the file or folder. Save your error log and see your system administrator. |
| Cannot export the checksum values to the job definition: {name}:<br><br>{error description} | Internal error. Contact Technical Support. |
| Failed to create the checksum file<br><br>{name} for backbone file {name} | There may be a file system permission issue. Save the log information and contact your system administrator. |

Ennov InSight Publisher 7.3 Volume Messages

| Message | Description |
|---|---|
| Error in creating checksum file:<br><br>{name} for backbone {name} | You may not have access to the file or folder. See your system administrator. |

## Other Messages

You can view other error messages in either the publishing log or the *Publishing Readiness* query.

| Message | Description |
|---|---|
| There was a problem while submitting the publish request, please refer to the server log for more details. | This is an incorrect error message when publishing the M2-M5 template without changes. If the sample study reports found in sections 5.3.5.1 and other locations in 4.2 and 5.3 are removed, everything publishes fine. |
| Problem storing job results to database: {error description} | Most likely the Ennov InSight database is not available. |
| Problem determining the id of the job {name}, unable to store the job results. | Ennov InSight service has probably stopped working. |

| | |
|---|---|
| No schemas have been defined in the assembly. | You must choose XML definition files for the assembly. |
| Failed to find validation.properties file.<br><br>Exception {error description} | This is an installation fault. |
| Error finding jobs for assembly with ID {name}:<br><br>{error description} | The database may be inaccessible. Check the database connection and password. |
| ERROR:<br><br>org.hibernate.LazyInitializationException | Generally caused by a server timing issue due to heavy workload or network latency. Try the operation again. This is noted in the publishing log. |
| There was a problem while submitting the publish request, please refer to the server log for more details | Generally caused by a server timing issue due to heavy workload or network latency. Try the operation again. |

Other Messages

| Message | Description |
|---|---|
| Cannot use a task file reference before it has been evaluated | This can happen when:<br><br>— Publishing an empty structure<br><br>— There are no publishable documents<br><br>— Volumes have not been setup<br><br>Do a DMS synch to make sure the extraction requests are up to date and that each document has renditions and extractions.<br><br>To troubleshoot the assembly:<br><br>— For a paper publish, check that you have a volume.<br><br>— Check that you have publishable documents. |

| | |
|---|---|
| | — Check that you have output channels.<br>— Check that you have a file under a native leaf.<br>— Check that you do not have more than one file under a native leaf.<br>— Check that each volume has at least one publishable document, output channel, renditions, extractions. |

Other Messages

# Chapter 11. Linking

Linking activities are available depending on the license modules available to the user. You

must have the following Ennov InSight modules to perform linking activities:

— Electronic Lifecycle Publishing (ELP)

— Paper Review Publishing (PRP)

Four kinds of links are supported by Ennov InSight .

— Authoring

— Lifecycle

— Post-publishing

— In-process

## Authoring Links

Authoring links are hyperlinks created by authors in source documents. These links may point to documents in the DMS or secure file system. These links may also go to versions, pages, and bookmarks, or may be comments that indicate to the publisher how the link should be created.

Authoring links may be reused freely, and will automatically persist in new versions of modified documents within a source DMS repository or secure file system.

You can create authoring links in most content-editing software (such as Microsoft Word or Adobe Acrobat) as long as they are relative paths to target documents. While creating authoring links:

— You can use tools such as Microsoft Word and Linking add-in (Word) to generate both in-document links and cross-document links.

— Ennov InSight can interpret and understand links embedded in a document that point to other areas of the same document as well as links that point to other documents.

— Links may be targeted across servers and file shares, and DMS repositories of the same or different types.

— Links may target documents, specific page numbers within documents, and in the case of and Linking add-in (Word), they may target bookmarks or headings within documents.

— Links may target specific versions of documents, or by default the current (latest) version.

— Links may also consist of just a comment that indicates where the link should eventually be targeted.

# Life Cycle Links

Life cycle links are links that target documents across sequences in the same application.

Life cycle links are automatically updated in the Ennov InSight link database to always point to the most current or specific version of a document in the application for published output. All life cycle linking in Ennov InSight is done through the Link Inspector.

Authoring Links

Life cycle links have three basic types: broken, stale, and historical.

— Broken links point to content that does not exist or has moved due to life cycle operations. They occur when a leaf is replaced in a new sequence with a new document, but that document's links are still targeting the old content and must be updated with new path information.

— Stale links are links where the source document and target document reside in different sequences, and Ennov InSight has not needed to update the link to insure a valid target during publishing. These links start in the old sequence targeting the current sequence. Any link marked as stale should be evaluated by the publisher for the correct target, because the target document may need to be operated on in the current sequence to resolve the link correctly, or you may need to verify that the historical target of the link is still valid for the reviewer.

— Historical links point from updated documents in newer sequences back to documents in old sequences.

Create In-Process Life Cycle Links

You can create life cycle links by targeting a link to a document that exists in an assembly outside the current assembly. This includes an assembly in any other sequence and is not restricted to the current application.

For historical in-process links pointing to a submitted sequence, you can target a leaf, a document or bookmark. To create historical links from a working assembly to previously submitted content, the target assembly must have been published prior to adding to life cycle. This sets the published output location on those leaf elements so that the appropriate relative path to the target may be determined.

Unless links are set to a document or a bookmark and any links targeting the old document get moved automatically to target the new document you assign under that leaf. The link is modified to point to the new location. In-process links created to a document or a bookmark will target to the location in previous sequence like it was selected when the link was created.

While links going to documents cannot target outside the current assembly/sequence, links going to leaf elements may target both old sequences and targets outside the current application. These links will have a status of Targeted even if the source document is not in the same assembly as the target document. They will be published as crossapplication links according to the same rules that govern reference leaf elements.

Reference Leafs and Hyperlinks Between Applications

You can link to content between different application lifecycles using reference leafs or hyperlinks. Links or references pointing to separate applications must navigate back to the root of the output, below the application number. For example, you might want to make reference to content in your IND application from your new NDA application by either reference links or hyperlinks, as shown in the following scenarios.

*Reference Leafs*

Any reference leaf can point to any other leaf in a separate application. The reference will navigate back to the root of the output under the application number. This example shows a target (Leaf 1) in a IND application that is referenced from Leaf 2 in the NDA application.

| Leaf | Application number | Prefix* | Sequence | HREF |
|---|---|---|---|---|
| 1 | 123456 | ind | 0000 | m1\mydoc.pdf |
| 2 | 234567 | nda | 0001 | m1\mydoc2.pdf |

Life Cycle Links

*For the US, a 3-letter Application Prefix attribute is added to the application number.

In this example, the target document in the reference leaf is two levels removed from the root of the application.

— The navigation path of the href from Leaf 2 to Leaf 1 is: ..\..\ind123456\0000\m1\mydoc.pdf

— The navigation path of the href from Leaf 1 to Leaf 2 is: ..\..\nda234567\0001\m1\mydoc2.pdf

*Hyperlinks*

Any hyperlink can point to content in any other leaf in a separate application. The hyperlink will navigate back to the root of the output under the application number. This example shows a hyperlink target (in Leaf 1) in a IND application that is referenced from Leaf 2 in the NDA application.

| Leaf | Application number | Prefix* | Sequence | HREF |
|---|---|---|---|---|
| 1 | 123456 | ind | 0000 | m1\test\mydoc.pdf |
| 2 | 234567 | nda | 0001 | m1\mydoc2.pdf |

*For the US, a 3-letter Application Prefix attribute is added to the application number.

In this example, the target document in the reference leaf is three levels removed from the root of the application. — The navigation path of the href from Leaf 2 to Leaf 1 is: ..\..\..\ind123456\0000\m1\test

\mydoc.pdf

— The navigation path of the href from Leaf 1 to Leaf 2 is: ..\..\nda234567\0001\m1\mydoc2.pdf

# Post-Publishing Links

Post-publishing links are hyperlinks created by publishers after the publishing has completed. Most links cannot be reused in their current state, but can be edited for reuse.

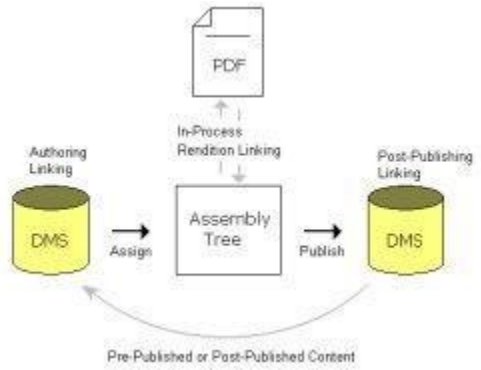
These links cannot be reused automatically across documents or assemblies, but they may be exported, imported, repaired or updated. Post-publishing links may be reused if output documents are used as new source documents, as in the case of published reports that are used within a submission.

After publishing the documents in an assembly, if they are on different file shares or DMS repositories, Linking plugin (PDF) creates a link that can be read only by Ennov InSight . Starting with Linking plug-in (PDF) 1.8, the create and update support for post-publishing links is discontinued.

***Note:*** *Be sure you are always linking documents on the same file share when creating post-publishing links.*

Published documents can be used again by Ennov InSight as though they were original source documents. Once PDFs have been published from the assembly, Ennov InSight can reuse these published documents in an entirely new assembly just like it would original source documents. You can use Linking plug-in (PDF) again to create in-process renditions of the documents and create, update, and delete links in Ennov InSight .

Ennov InSight Publisher 7.3 Post-Publishing Links




As shown above, the source documents from the DMS repository are assigned to Ennov InSight 's assembly tree. During assignment, all the links contained in the source documents are extracted and stored in Ennov InSight . Once there, you can adjust the links through Linking plug-in (PDF) using a PDF rendition of the documents. The links may also be viewed and edited using the Link Inspector. Afterwards, you can publish the documents back to the DMS repository, and modify the links after publishing. The published content can be used again as the original if you need to reuse content in another publication. In this way, Ennov InSight can support your own best-practice linking processes, as links may be updated at each phase as needed.

# In-Process Links

In-process links are content that is approved and finalized; they cannot be directly modified in the DMS. In-process links can be reused between documents and submissions/regions as well as automatically reconciled between document versions.

These links can be:

— Created in a final, non-editable PDF

— Retargeted in a final or draft document

Ennov InSight enables you to insert, modify, and delete in-process links and bookmarks in documents that are assigned to assembly leafs from Ennov InSight . Ennov InSight uses a database-centric approach to manage both life cycle links and links found in documents assigned to an assembly.

Ennov InSight also enables you to link to a leaf, document, or a bookmark of a document from the previous sequence.

Link to a document in a previous sequence is not updated if there is a newer copy of target document in current assembly. If target is not valid, links become broken and do not appear in the output. It reflects in Link Inspector, thereby allowing to select an appropriate target.

When creating an in-process link via SmartLink for PDF it is possible to restrict the presence of the in-process link to an application. Not imposing any restriction makes the in-process links appear for all copies of source document in the system.

After a document is assigned to a leaf in an assembly, the linking information is extracted, stored, and manipulated in a secure database. Ennov InSight publishes a temporary rendition (called an in-process rendition) of each document in PDF format. You can use this viewable copy of the rendition prior to publication to create new links or modify links created during the authoring stage and target them to other locations in the current submission.

When editing links in an in-process document rendition, only changes to links are stored in Ennov InSight . While Acrobat enables you to change other items (text, bookmarks, etc.), they are not saved.

***Note:*** *In-process linking with Linking plug-in (PDF) in Ennov InSight is enabled by using the supported versions of Acrobat. Be sure to select the system viewer option (Acrobat) when opening a document for in-process linking, not the Web browser's viewing option. See the Linking plug-in (PDF) 1.8 System Support Document (SSD) for details.*

## Create In-Process Links

To use in-process linking, your assembly must be a standalone assembly, a sequence assembly, or a working assembly that has not been locked and lifecyled.

To create an in-process link, a PDF rendition must exist, and the document must be prepared for linking.

— You can request that a particular document in the assembly tree be rendered and then be prepared for linking.
— You can select a folder or the assembly root and indicate that all documents be prepared for linking. — You can specify the link applicability for new links to Global or Application.

A temporary PDF rendition is created when a document is prepared, and you can use Linking plug-in (PDF) to create links. The rendition is only available in the assembly for creating and modifying links prior to publishing. Also, you can only create links in in-process renditions. Any text modifications made in an in-process rendition will not be saved.

The standard Ennov InSight tool for creating and modifying links in PDF documents is Linking plug-in (PDF). When creating or modifying in-process links using Linking plug-in (PDF), if you want to create an internal link to a different page of the current document, you must choose the current document in the assembly tree as your destination with a different page number. Linking plug-in (PDF) defaults to the current document to make this easier.

Comment Links

A comment link is a placeholder for a link to a document that does not yet exist in an assembly.

The comment reminds publishers that a link must be created once the document exists. You can create comment links using Linking plug-in (PDF).

## Linking Tools

Ennov InSight supports a number of tools that can be used to create links from source to target content on authored documents.

— Internal native Adobe links

— External native Adobe links

— Word cross-references

— Linking plug-in (PDF)

— Linking add-in (Word)

These links are treated distinctly in the following ways:

| Linking Type | Electronic Output Channel | Paper Output Channel |
|---|---|---|
| Internal native Adobe | Links published to retain the behavior and format of the authored document. | Links stripped from the output; no margin cross-reference is created for these links |
| External native Adobe | Native external links created within the PDF source document by any product other than Linking plug-in (PDF) will not display in the electronic output channel. | Links stripped from the output, no margin cross-reference is created for these links. |

| | | |
|---|---|---|
| Native Word cross-references | Links converted to Adobe hyperlinks; the Ennov InSight Rendering server controls the formatting of these links. See the Ennov InSight Rendering server documentation to configure this to meet your requirement for formatting links. | These links are converted to margin crossreferences. If the variable for the margin cross-reference text cannot be resolved, it will display the "Cross-Reference Text" from the link profile. ***Note:*** *These types of links are recommended only for users who have a license for Ennov InSight Rendering.* |
| Linking plug-in<br>(PDF) (in-process) | Links are published, and are formatted based on the characteristics established in the Publishing Settings. | These links are converted to margin crossreferences. If the variable for the margin cross-reference text cannot be resolved, it will display the "Cross-Reference Text" from the link profile. |
| (Linking add-in (Word) is not pro- vided with Ennov InSight , it must be purchased separate- ly.) | Links converted to Adobe hyperlinks; the Ennov InSight Rendering server controls the formatting of these links; see the Ennov InSight Rendering server documentation to configure this to meet your requirement for formatting the links. | These links are converted to margin crossreferences. If the variable for the margin cross-reference text cannot be resolved, it will display the "Cross-Reference Text" from the link profile.<br>***Note:*** *Due to LinkText limitations in PDF,*<br>*Ennov InSight does not support nonEnglish characters when extracting linked text.* |

Ennov InSight Link Types

Three types of links can be created in Ennov InSight : authoring, in-process, and post-publish. Three

types of links can be created in Ennov InSight : authoring, in-process, and post-publish.

— Authoring Links – Links created by the authors in the source document

— In-Process Links – Links created by publishers (without modifying approved documents – because the data used to reconcile links is extracted and persisted and you can add/modify links without actually modifying the original rendition)

— Post-publish Links – Links created by publishers after the publish has been completed

## Copy Links Between Assemblies

Ennov InSight enables you to copy links from assembly to assembly, view to assembly, or just by reusing the same file again in a different assembly. The following applies to this feature:

— The link applicability setting determines ultimately whether an in-process link is copied from one assembly to the other. Application only links remain in the source application. Global links show up in new applications.

— Link profiles are not copied to new assemblies. They are always reset to the System Profile.

— Link output channels are copied in certain cases only. If the link has been created using in-process linking and the applicability is set to Global, the output channel is always copied to the new assembly.

When copying an assembly from another assembly, the following rules impact how links are copied:

— Link applicability determines exactly whether links are copied across assemblies. Any links with Global Applicability are copied, and any links with Application Applicability are not copied.

— While life cycle links are updated to point to the correct replaced leaf during publishing, the original targets are retained for an assembly copy. This is also to ensure the links are valid if sequences are removed from life cycle.

# Get Started with Linking add-in (Word)

Linking plug-in (PDF) and Linking add-in (Word) enable you to create hyperlinks in documents that target pages or bookmarks in the same document, in external documents, or in Ennov InSight assemblies.

When creating a hyperlink, you can specify attributes for the link, such as the text color and the line width and color of the bounding box. You can also open the target document for an external link to determine the destination page in the target document. **Linking plug-in (PDF)**

Linking plug-in (PDF) enables you to create and modify hyperlinks during each stage of the publication process: authoring, in-process, and post-publishing. Each stage uses Linking plug-in (PDF) in its own way:

— In the authoring stage, the Linking plug-in (PDF) Acrobat plug-in enables you to create links in or between documents on secure file systems or DMS repositories. The Linking plug-in (PDF) Acrobat plug-in also supports comments, link quality control, keyword linking, and bookmark linking.

— In in-process linking, the Linking plug-in (PDF) Acrobat plug-in enables you to create or update links in a document in Ennov InSight by editing a temporary PDF rendition. Links are targeted directly to the assembly tree. The Linking plug-in (PDF) Acrobat plug-in also supports comments, keyword linking, and bookmark linking.

— In post-publishing linking, the Linking plug-in (PDF) Acrobat plug-in enables you to create or update bookmarks on a final published PDF. Import/export to Microsoft Excel and bookmark linking are supported. Starting with Linking plug- in (PDF) 1.8, the create and update support for post-publishing links is discontinued.

Ennov InSight Publisher 7.3 Copy Links Between Assemblies

## Linking add-in (Word)

Linking add-in (Word) is a plug-in for Microsoft Word that enables you to create links in or between Word documents on secure file systems or DMS repositories. It also supports comments, keyword linking, version linking, and bookmark linking.

***Note:*** *Linking plug-in (PDF) or Linking add-in (Word) must be installed on your local machine. A successful installation creates new toolbar icons in either Acrobat or Word.*

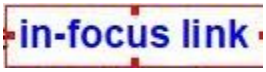
# Modify In-Process Links

You can modify in-process links and retarget the links to new locations.

***Note:*** *You cannot update the link Applicability for new links from Global to Application using Linking plug-in (PDF). To set up the necessary link Applicability, delete the link in Ennov InSight and create it again. See Link Applicability.*

When a link is in focus, meaning you have clicked the link and it is selected, you can change the destination and retarget the link by clicking the link icon. This is true for both normal and fast link modes. However, when you are in fast link mode you can draw a new link on top of the original link and the new link overwrites the original link. When you do this, only the new link remains.

The following is an example of an in-focus link:




When linking in-process, all links in a document will display with a red border. This is to indicate that only links may be modified from this interface. Any other changes made to the PDF will not be retained by Ennov InSight.

## Link to Assembly Elements

After you log on, the Linking plug-in tool appears with the in-process mode turned on by default. Ennov InSight is selected and a window displaying the working view tree is open.

When the in-process mode is displayed, you can create links two ways: in fast link mode or normal link mode.

### Targeting Assembly Elements in Fast Link Mode

With the fast link check box selected (the default), every time you draw a box in the rendition you create a link, so prior to creating a link you must select the destination. You can create a destination by highlighting a location in the assembly. You may also select a page number to target if you are highlighting a non-bookmark leaf (selecting a bookmark nullifies the page number field). Once you select a destination, you can draw one or multiple links to the destination without ever clicking another button.

Ennov InSight Publisher 7.3 Modify In-Process Links

### Targeting Assembly Elements in Normal Link Mode

When the fast link check box is not selected, you must click the link icon to execute creation of the link. When you are in the normal link mode, you can either draw the box or select the destination first. Once both are set you create the link by clicking the link icon. You can create a destination by highlighting a location in the assembly tree. You may also select a page number to target if you are highlighting a non-bookmark leaf (selecting a bookmark will nullify the page number field).

## Create a Comment Link

You can link comments to specific text in an Ennov InSight in-process rendition.

To create a comment link in an in-process rendition:

1. Open *Link Stamper*.
2. Click and drag the pointer to create a bounding box around the text you want to be the hyperlink.

   The Linking plug-in (PDF) dialog box opens.
3. Select Comment.
4. In the Link To drop-down box, enter an appropriate comment to remind publishers of the link that needs to be created once the target document exists.

5. Under Appearance, specify the attributes for the magnification, text color and bounding box.
6. Click Link.

   A comment hyperlink has been created with the attributes you defined.

7. Repeat these steps for comment link you need to create.

   The *Link Stamper* dialog box retains the previously defined settings so you can create multiple links with minimal or no changes.

8. To save your hyperlinks to the in-process rendition, click File > Save in Acrobat.

Ennov InSight in-process rendition changes must be checked in to Ennov InSight .

## Save Links to Ennov InSight

After you have finished creating links in the rendition, you can upload the links to Ennov InSight so they show in the published output.

To upload the links:

1. Select Linking plug-in > Save to Ennov InSight in the PDF editor.
2. Ennov InSight prompts you to upload the links when closing the Linking plug-in (PDF) dialog box and/or PDF editor.
3. In Acrobat, click Save.

## Integrated in-process linking

If the Use integrated in-process linking option in Publishing Settings Library is set to Yes, user can select Edit Document Link without calling Prepare Document for Linking and invoking Adobe Acrobat using seamless integration.
The applicability of such links is always set to Global. The user can update created links later in Link Inspector, if any update is needed. The source documents are not changed upon links creation.

### Create a link:

1. Make sure Use integrated in-process linking option in Publishing Settings Library is set to Yes.
2. Select Edit Document Links.
3. Scroll, select or set a page, zoom in and zoom out to navigate to the text for future link.
4. Draw a rectangle to define a link box.
5. By clicking on … icon select a link target. As a target leaf, document or a bookmark can be selected. It is possible to select leafs and documents from previous sequences. Click Select.
6. Set a target page. Click on Save Link icon.
7. Click OK on confirmation.

### Update a link

1. Select a link from links list or from document content
2. By clicking on … icon select a link target. As a target leaf, document or a bookmark can be selected. It is possible to select leafs and documents from previous sequences. Click Select.
3. Click OK on confirmation.

### Delete a link:

1. Select a link from links list or from document content
2. Click on Delete icon.
3. Click OK on confirmation.

## Modify Bookmarks

The bookmark editor enables you to modify the existing bookmark structure of a document. Bookmarks modified in the editor impact all occurrences of the source document in Ennov InSight including TOCs, link targets, and final published bookmark structure.

Bookmarks are not affected by the output channel. When a document is assigned, its document structure is extracted according to rendering settings and bookmarks are created in the Ennov InSight database. These bookmarks are published for each file as-is unless you update them in the bookmark editor or they are overridden by a TOC. Bookmarks are applied only at publish time. They do not appear in in-process renditions.

If a link targets a bookmark and the document is updated with a new version, all bookmarks from the previous version are deleted and new bookmarks are created. Bookmark changes in the editor are not merged with a new version of the document. If a new version is checked-in and accepted by the publisher, its source bookmarks automatically overwrite any changes made with the bookmark editor.

Ennov InSight does not capture any actual bookmark information when extracting internal link information. Instead, it captures the page number for the document's bookmark. If the links are to external documents, information is captured because you are targeting to a bookmark of a PDF rendition.

After you have saved bookmark changes in the bookmark editor:

— Each item in the list is comprised of a page number and the bookmark name. You can edit both values.

— You can select individual or multiple bookmarks in the list and run any of the operations on all of them at once using the action buttons.

— You can move each bookmark up or down by dragging it to a different location and dropping it. Moving a bookmark changes its location in the source document association.

— You can move individual or multiple bookmarks up or down, promote or demote them, and increment or decrement their page numbers using action buttons on the toolbar.

## Modify a Bookmark

You can modify bookmarks in a specific document in an assembly, including updating the location or deleting the bookmark.

To view and modify bookmarks:

1. Right-click a document in the assembly and select Edit Bookmarks.

   A comment hyperlink has been created with the attributes you defined.

2. Do one of the following:

| Action | Procedure |
|---|---|
| To add a bookmark tied to the current source document | Click the Add Bookmark button. |
| To add the bookmark as a sibling of the bookmark you clicked | Click an existing bookmark then click Add Bookmark . |

   Ennov InSight Publisher 7.3 Modify Bookmarks

   ***Note:*** *During the extraction of documents, blank levels are filled in if they are missing. If levels are missing in the bookmark editor, Ennov InSight compresses the tree and promotes the higher levels to fill in the missing gaps at publishing time.*

3. Select one bookmark in the list and click the Edit action button to edit fields not found on this page.
4. Select one or more bookmarks in the list and click to delete the specified bookmarks.

   ***Note:*** *Deleting bookmarks that are targeted by links may not always invalidate the link. Ennov InSight still attempts to resolve these links at publishing time using a combination of page number, bookmark hierarchies, and bookmark neighbors. In most cases a warning results on the target document indicating the link was retargeted; in some cases however the bookmark represents a target page and no warning results.*

5. Click Save.

Changes you make to bookmark values are saved once you click the Save button. Changes you make using the action buttons are saved immediately.

***Note:*** *Changes you make in the bookmark editor are not merged with a new version of the document. If a new version is checked-in and accepted by the publisher, its source bookmarks automatically overwrite any changes you make using the bookmark editor.*

## Link Inspector Query

The Link Inspector query enables you to view the status of all hyperlinks and cross references, and make any necessary changes prior to publishing.

The query shows the link status for links created with Linking plug-in (PDF) , Linking add-in (Word), native Word cross references, and internal (intra-document) native Adobe links.

You can run the Link Inspector query at the assembly, folder, leaf, volume, or document level. However, Link Inspector shows only the links within the selected element.

When a document has been modified, it must be saved as a different version in order for the changes to appear in the Link Inspector query.

Hyperlinks or cross references targeted to documents that do not exist in the current assembly, or that are targeted to versions of documents that do not exist in the current assembly, show as invalid links in the Link Inspector. They may be easily corrected by bulk retargeting them to the same destination document. This resets the target document to the current version assigned in the assembly.

To minimize confusion, unresolved links where the link source exists outside the current assembly do not appear in the Link Inspector query. The current assembly is based on how you last refreshed the query from Prepare for Publish:

— If you refreshed the current sequence view only, the query shows only links in the current sequence.

— If you refreshed the entire working assembly, stale links that target documents in the current assembly are also displayed.

In some cases, the link text does not come through from the PDF. This can occur when:

— The text under the link is an image that cannot be interpreted by the OCR. — The text is not completely under the link.

— The text is Japanese or Eastern characters.

Refresh the Link Inspector Query

You can use the Link Inspector query to view updated links in the current sequence or the entire assembly.

When refreshing the Link Inspector query from Prepare for Publish, there are two options:

— Current Sequence View Only is recommended for life cycle sequence assemblies. This refreshes only links in the current sequence/publishing view and not the entire working view. For standalone or non-life cycle assemblies, this option does not refresh anything.

— Entire Working Assembly is recommended for standalone and non-life cycle sequence assemblies. This refreshes the entire assembly for link changes. For life cycle sequence assemblies, this is useful to allow an impact analysis to be made against older documents that link to current documents for possible inclusion of these documents in the latest sequence. However, this should be used sparingly within life cycle sequence assemblies because it may take much longer to refresh this linking information during the Prepare for Publish process.

***Note:*** *You must refresh link information using Prepare for Publish at least once before running the Link Inspector on an assembly.*

Run the Link Inspector Query

You can use the filters in the Link Inspector to view specific links, or specific types of links.

*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 run a Link Inspector query:

1. Right-click a folder, leaf or document and select Run Link Inspector.
2. Select the filtering options.
3. Click Search. All the links that meet the search criteria are displayed.

Link Inspector Action Buttons

You can use the Link Inspector to edit or delete links in your assembly.

| But-ton | Name | Description |
|---|---|---|
|  | Retarget Links | You may change the location of the target document to a leaf or bookmark. To find an assembly, click the Search tab and use the *Search Assembly* wizard. See Searching for an Assembly. |
|  | Edit Link Applicability | You may change where the link is applicable (for example, globally to each occurrence of the link pair in any assembly or for this application only). |
|  | Edit Link Profile | You may modify the link properties to change the profile to change settings for each link either individually or through the multi-select checkbox. |

| | | |
|---|---|---|
|  | Edit Link Output Channel | You may modify the link properties to activate or deactivate output channels for each link either individually, or through the multi-select checkbox. |
|  | Delete Link | Existing information about this link will be deleted. |

Link Statuses

Ennov InSight uses flags in the results of the Link Inspector query to show the status of links.

| Status Flag | Description | Details | Examples |
|---|---|---|---|
| OK | Link Targeted and Current | Link is targeted to resolvable location in the current or working assembly. Link is current with latest document rendition and the target document has not been updated since the link was established. | — Both documents exist in DMS.<br>— Link points to valid page, leaf or bookmark in the target.<br>— Source and target are both assigned in the same sequence. |
| OK | Link Suppressed | Link has output channel set to None. | Same as Link Targeted and Current but output channel set to none. |

| Status Flag | Description | Details | Examples |
|---|---|---|---|
| Warning | Link Life cycle AutoUpdate<br>(Historical Link<br>Scenario) | The link targets a document in an Ennov InSight assembly in the current Application, but not in the current sequence.<br>In this scenario the target is linked to by a source that's been included in a prior sequence in the same Application. Ennov InSight life cycle auto-updates this link to resolve correctly to the already-submitted document. | — Both documents exists in DMS.<br>— Source document assigned in original sequence.<br>— Target document not assigned in original sequence.<br>— Target document assigned in current sequence.<br>— Source document not included in current sequence.<br>— Prepare for publish is run on the working or sequence view of the current sequence. |
| Warning | Link Life cycle Auto-<br>Update | The source link (bound to current) targets a document in an Ennov InSight assembly, and the | — Both documents exists in DMS.<br>— Source and target document assigned in original sequence. |

| | | | |
|---|---|---|---|
| | (Stale Link Scenario) | target document is bound to current and replaced in the second sequence with a new version of the target which is now bound to current.<br><br>Ennov InSight will life cycle auto-update this stale link because it considers this link to be following the latest replaced version of the document. | — In current sequence an updated version of the target document is replaced with the "current" (label) document.<br><br>— Source document not assigned in current sequence.<br><br>— Prepare for publish is run on the working view of the current sequence. |

| Status Flag | Description | Details | Examples |
|---|---|---|---|
| ***Note:*** *When two or more sequences exist in a working assembly, and an authoring link in two different source documents point to the same target document, adding a new leaf with an updated version of the target document will cause the Lifecycle Auto Update status to display "auto updated" in the inspector report when Prepare to Publish is run. This is expected behavior, because: * Both documents exist in the DMS. - The target document was assigned in the original sequence. * In the current sequence, an updated version of the target document is replaced with the "current" (label) document. * The source document is assigned in the current sequence. (Even though this document has just been added to the sequence, it will still be auto-updated because the target has*<br><br>*been replaced. It is updated to link to the new version that is in the sequence.) * Prepare to publish is run on the working view of the current sequence* | | | |
| Warning | Stale Link | The source link targets a document in an Ennov InSight assembly, but the target document is bound to a specific version in the first sequence and replaced in the second sequence with a new version of the target which is now bound to current.<br><br>InSight cannot life cycle auto-update this link because it considers this link to be bound to the old version. | — Both documents exists in DMS.<br><br>— Source and target document assigned in original sequence.<br><br>— In current sequence an updated version of the target document is replaced with the "current" (label) document.<br><br>— Source document not assigned in current sequence.<br><br>— Prepare for Publish is run on the working view of the current sequence. |

| | | | |
|---|---|---|---|
| Error | Incomplete Link | The link is of comment type, not a document. | Comment link type |
| Error | Incomplete Link | Target document cannot be found in the DMS. | Target document does not exist in DMS. |
| Error | Incomplete Link | The link targets a document that is not resolvable when published (not contained in any known assembly). | Target document does not exist in the application. |
| Status Flag | Description | Details | Examples |
| Error | Target Missing | The link must be retargeted because either (1) the targeted bookmark was deleted from the document or (2) the targeted page (last page in the document) was removed from the revised document. | Specific destination in document does not exist. |
| Unknown | Link Modified | The link has been modified in the Link Inspector since<br>Prepare for Publish was run. | — Change of link from the Link Inspector query screen without prior to running a prepare for publish.<br>— Link Modified status will be updated once prepare for publish is run. |
| Unknown | Undetermined Link | Gives a status to links we cannot determine. | Scenario where none of the other descriptions applies. |

View the Link Inspector Query

When viewing the *Link Inspector* query, you can modify one or multiple links using the action buttons.

You can sort columns using standard Ennov InSight query functions. Please note that all columns do not appear by default.

| Column Name | Description |
|---|---|
| Character Encoding Status | Indicates the status for each source or target link component:<br>— Green - Character encoding appears to be correct.<br>— Red - Character encoding update may be required. |

| | |
|---|---|
| | — White - Character encoding is not applicable. Either, the link is not an external link or the document contains no links. |
| Internal | Indicates if link source and destination documents are the same (intradocument link) or different (inter-document link). |
| Link Applicability | Displays whether the link pair and any modifications made through the Link Inspector are applicable globally to each occurrence of the link pair in any assembly or for this assembly only. |
| Link Code | A system-generated sequential number or alphanumeric equivalent unique to the link. |

| Column Name | Description |
|---|---|
| Output Channel | The output channels (paper/electronic) for each link. The user may modify the link properties to activate or deactivate output channels for each link either individually, or through the multi-select check box. |
| Source Assembly Name(s) | A system-interpreted, read-only field that displays the assembly names for the link source's assembly. |
| Source Description | A text message describing the link results based on the source flag and status. |
| Source File Path, Name and Version | The path, name and version of the bound document. |
| | ***Note:*** *If the source file name is too long to fit properly in the source column in the link inspector, go to the filter page and include Source Path and File name and Version as one of the selected columns for the query results.* |
| Source Filename | The name of the original document. |
| Source Flag | Displays a color indicating the link status of each link source:<br>— Green = OK<br>— Yellow = Warning<br>— Red = Error |
| Source Link Status | System-generated text based on the source flag. |
| Source Link Text | The underlying text of the link in the document. |
| Source Page Number | A system-generated, read only numeric field that displays the source page number of the link. |
| Source Sequence Number(s) | A system-interpreted, read-only field that displays the sequence number(s) for the link source's assembly. |

| | |
|---|---|
| Target Assembly Name(s) | A system-interpreted, read-only field that displays the assembly name(s) for the link target's assembly. |
| Target Bookmark | The target bookmark, if applicable. |
| Target Comment | This is available if a planned destination or comment exists. |
| Target Description | A text message describing the link results based on the target flag and time stamp when the query was generated. |
| Target File Path, Name and Version | If the target is a document element, this column contains the path, name and version of the bound document. If the target is a leaf element, this column contains the file name attribute on the leaf (if defined). |
| Target Filename | Name of the file that contains the link target. |

| Column Name | Description |
|---|---|
| Target Flag | Displays a color indicating the link status of each link target:<br>— Green = OK<br>— Yellow = Warning<br>— Red = Error |
| Target Link Status | System-generated text based on the target flag. |
| Target Page Number | The target page number (whether explicit or through a bookmark). |
| Target Sequence Number(s) | A system-interpreted, read-only field that displays the sequence numbers for the link target's assembly. |
| Time Stamp | The creation date of the record. This is displayed only once in the header of the query results. |

*Character Encoding Status*

You need to verify and update external links in documents created with earlier versions of Acrobat 8.

For external links in PDF renditions that were created with Acrobat prior to Acrobat version 8, non-Unicode encoding of the links may not be correct in Ennov InSight . When assigning a document to an Ennov InSight assembly, Ennov InSight extracts linking information from the PDF. During the extraction, Ennov InSight applies the default character encoding of the Windows operating system that is used on the Ennov InSight Rendering server that processes the job. As a result, the character encoding that was used when creating the links in the existing PDF rendition of the document may be different than the character encoding applied by Ennov InSight when performing extractions.

The purpose of the *Character Encoding Status* column of the *Link Inspector* query is to identify external links affected by this scenario. When the encoding of the external links is flagged by this column, the following actions can be taken:

— You can re-render the source document.

— You can re-target the links using the re-targeting functionality built into the Link inspector query.

— For source PDF files, you can update the character encoding using Linking plug-in (PDF), and then perform a DMS Synchronization to re-extract the links.

# Set Up Link Applicability

Set the default link Applicability to Global or Application.

## Prerequisites

Before performing the steps below, verify that you have Adobe Acrobat and Linking plug-in (PDF) installed on your computer.

To set the default link Applicability to Global or Application:

1. In Ennov InSight , highlight any document with rendition assigned to the Assembly.
2. In Document Attributes, select More > Prepare Documents for Linking.

   If the document is already prepared for linking, click OK to overwrite it. Verify that other users are not working with the link before overwriting.

   ***Note:*** *You cannot update the link Applicability for new links from Global to Application using Linking plug-in (PDF). To set up the necessary link Applicability, delete the link in Ennov InSight and create it again.*
3. Agree with the message about opening the file. The file will be opened in Adobe Acrobat.
4. Highlight the text in the document.
5. Select the target in the Assembly (example: leaf) where the link should be connected.
6. Select the Application or Global in the Applicability options list.

   The changes made to the links of the Application type are restricted by the Application. The changes made to the links of the Global type affect all the copies of the link.
7. Select Linking plug-in > Save to Ennov InSight .
8. Click OK to close the current in-process rendition.
9. Go back to the Ennov InSight Assembly
10. Highlight the document (example: leaf).
11. Select Prepare to Publish to refresh the link inspector data.
12. Highlight any node (example: leaf).
13. Click Run Link Inspector.
14. Select Link Inspector Query > Display Columns.

15. In the filtering options, select Applicability.
16. Click Search.
17. Verify that the Applicability type corresponds to the one you set up.

    To edit the link Applicability in the previously existing way, select the necessary link from the list in the Search Results.

18. Click Edit Link Applicability .
19. In the Applicability drop-down menu, change Global to Application.
20. Click Save.

    The link modified flag changes its color to red and the Link Modified description appears.

21. To save the changes, go back to the Ennov InSight Assembly.
22. Highlight the document (example: leaf).
23. Select Prepare to Publish to refresh the link inspector data.
24. Verify that the Applicability value is saved.

# Chapter 12. Extension Types and Usage

You should provide attribute values in each assembly for the following elements that result in the creation of additional attributes for their corresponding XML elements.

— 1 Administrative Information and Prescribing Information in US (DTD 2.01), CH, JP, ZA, AU, WHO, or TH template

— 1 Administrative and Product Information in CA template

— 1 Administrative Information folder in US (DTD 3.3) template

— EMA Envelope Information in EU template (The path to this is: 1 Administrative Information and Prescribing Information\Envelope Information folder\EU Envelope Information leaf\EMA Envelope Information.) EMA is used as an example. You can name any value you choose from the country list.

— GCC Envelope Information in GCC templates

— Galenic Form in CH template

— Elements under 1.1 Forms in US (DTD 3.3) template

— 1.15 Promotional Material Audience Type in US (DTD 3.3) template

— 1.15.2 Materials in US (DTD 3.3) template

— 1.15.2.1 Material in US (DTD 3.3) template

— 2.3.S Drug Substance (substance and manufacturer)

— 2.3.P Drug Product (product name, manufacturer, dosage form)

— 2.7.3 Summary of Clinical Efficacy (indication)

— 3.2.S Drug Substance (substance and 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, and/or product name)

— 3.2.A.2 Adventitious Agents (manufacturer, substance, dosage form, and/or product name)

— 5.3.5 Reports of Efficacy and Safety Studies (indication)

— Study Report Folders (when creating STFs: Full Report Title, Report Number, Category information as applicable)

There are more extension types available, but the extension types listed here are needed for the XML headings that have additional attributes. The others are used to differentiate unnumbered sections and create other components in the XML that do not require additional information.

## Extension Type: General Folders

| Extension Type | Associated Attributes | Applied to Assembly Element | Result |
|---|---|---|---|
| Drug Substance folder | — Substance<br>— Manufacturer | — 2.3.S Drug Substance folder<br>— 3.2.S Drug Substance folder | Creates the appropriate <m2-3-s-drugsubstance> and <m3-2-s-drugsubstance> elements in the XML with applicable attributes. Also builds the directory structure for 32s to include substance and manufacturer information. If the combination of substance and manufacturer information result in a folder or overall path length that is too long, the automatic creation of these folders can be overridden by populating the Output Folder attribute on the 3.2.S folder with an abbreviated value. The Output folder should be populated as follows: 32s-drug-sub/ sub-mfg, where the italicized information is the abbreviated value for the folder. |
| Drug Product folder | — Product name<br>— Manufacturer<br>— Dosage form | — 2.3.P Drug Product folder<br>— 3.2.P Drug Product folder | Creates the appropriate <m2-3-p-drugproduct> and <m3-2-p-drug-<br>product> elements in the XML with applicable attributes. Also builds the directory structure for 32p to include product and dosage form information. If the combination of product and dosage form information result in a folder or overall path length that is too long, the automatic creation of these folders can be overridden by populating the Output Folder attribute on the 3.2.P folder with an abbreviated value. The Output folder should be populated as<br>follows: 32p-drug-prod/prod-form, where the italicized information is the abbreviated value for the folder. |

| Extension Type | Associated Attributes | Applied to Assembly Element | Result |
|---|---|---|---|
| Clinical Indication folder | Indication | — 2.7.3 Summary of Clinical Efficacy folder | Creates the appropriate <m2-7-3summary-of-clinical-efficacy> and <5-3-5-reports-of-efficacy-and- |

| | | | |
|---|---|---|---|
| | | — 5.3.5 Reports of Efficacy and<br>Safety Studies | safety-studies> in the XML with applicable attributes. Also builds the directory structure for m535 to include indication information. If the indication value results in a folder or overall path length that is too long, the automatic creation of this folders can be overridden by populating the Output Folder attribute on the 5.3.5 folder with an abbreviated value. The Output folder should be populated as follows: 535-rep-effic-safety-stud/ indication, where the italicized information is the abbreviated value for the folder. |
| Excipient folder | Excipient name | 3.2.P.4 Excipients | Creates the appropriate <m3-2-p-4control-of-excipients> in the XML<br>with applicable attributes. Also builds the directory structure for m32p4 to include excipient information. If the excipient value results in a folder or overall path length that is too long, the automatic creation of these folders can be overridden by populating the Output Folder attribute on the 3.2.P.4 folder with an abbreviated value. The Output folder should be populated as follows:<br>32p4-contr-excip/excipient-1,<br>where the italicized information is the abbreviated value for the folder. |
| Quality Appendix folder | — Manufacturer<br>— Substance<br>— Dosage form<br>— Product name | — 3.2.A.1 Facilities and Equipment<br>— 3.2.A.2 Adventitious Agents | Creates the appropriate <m3-2-a-1facilities-and-equipment> and <m3-2-a-2-adventitious-agentssafety-evaluation> with applicable<br>attributes, and builds the directory structure to include manufacturer information. |

| Extension Type | Associated Attributes | Applied to Assembly Element | Result |
|---|---|---|---|
| Quality Overall Summary | No additional attributes | 2.3. Quality Overall Summary folder | Used during XML creation to differentiate between the two eCTD elements that are both numbered 2.3 (2.3 Quality Overall Summary result- ing in XML element <m2-3quality-overall-summa- |

| | | | |
|---|---|---|---|
| folder | | | ry>, and 2.3 Introduction resulting in XML element <m2-3-introduction>). |
| Quality Introduction folder | No additional attributes | 2.3 Introduction folder | Used during XML creation to differentiate between the two eCTD elements that are both numbered 2.3 (2.3 Quality Overall Summary result- ing in XML element <m2-3quality-overall-summary>, and 2.3 Introduction resulting in XML element <m2-3-introduction>). |
| Study Report folder | — Full Report Title<br>— Report Number<br>— Operation<br>— Species<br>— Route of Administration<br>— Duration<br>— Type of Control | In Assembly template for modules 2-5, applied to sample study report folders in sections 5.3.1.1 and 4.2.1.1. Should be applied to all study report folders as studies are added to the assembly. | When applied to study folders in an assembly that is using the stf-2-2 XML definition file, triggers the creation of STF XML files for each study. The values provided as folder attributes are used to<br>populate the <study-information><br>portion of the STF. All child leaf elements in the study report folder should have the leaf type of Study Report to capture their subject matter which is used to populate the<br><study-document> portion of the STF. The FDA has provided guidelines for which study types sponsors should provide information for species, route of administration, duration, and type of control. Studies under section 4.2.3.1 should include species and route of administration. Studies under section 4.2.3.2 should includes species, route of administration, and duration. Studies under section 4.2.3.4.1 should include species. Studies under 5.3.5.1 should include type of control. For all other study types, inclusion of this additional information in the study tagging files is optional. |

| Extension Type | Associated Attributes | Applied to Assembly Element | Result |
|---|---|---|---|
| Study Data folder | — Dataset type<br>— Subject Matter | Individual Patient Data Listings folder included in the sample study report under section | Places the datasets in the location as specified by the FDA Study Data |

| | | | |
|---|---|---|---|
| | | 5.3.1.1. This folder type should be used as the parent folder for all datasets, and the value for Dataset type is datasets-andassociated-files. The subfolders of the Individual Patient Data Listings folder also have this type applied with different values for the Dataset type attribute. | Specification (m5\datasets\study xx). This allows datasets to still be located in the assembly with the other study files, and referenced by the STF, but have them located in a different output location from the other study files. The value of the dataset type attribute dictates which subfolder the datasets should be placed in (analysis, tabulations, etc). |
| Study Patient Information folder | — Subject Matter<br>— Site | Case Report Forms and Subject Profiles folders included in the sample study report under section 5.2.1.1. This folder type should be used as the parent folder for Case Report Form and Subject<br>Profiles leaf elements to group them by site. | Creates the additional <property> element in the STF with the attribute name="site-identifier" and uses the value for the Site attribute to populate the value of the <property> element. |

| Extension Type | Associated Attributes | Applied to Assembly Element | Result |
|---|---|---|---|
| Node<br>Extension folder | No additional attributes | This folder type is not applied to any<br>folders in the assembly templates, but may be applied to folders if needed to create additional subheadings in the XML using the nodeextension concept. | Creates a <node-extension> element in the XML using the name of the folder as the value for the <node-extension><title> element. This should be used only after consulting with the review- ing agency as some have indicated they do not want nodeextensions to be used. This folder type should only be applied to folders at the lowest level of the assembly as only the lowest level elements may be extended. |

# Extension Type: Regional Folders

## Eurasian Economic Union

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| EAEU Module 1<br>Envelope<br>Information | — EDoc Id<br>— EDoc Reference Id<br>— EDoc Date Time<br>— Country<br>— Registration<br>Number Id<br>— Application Id<br>— Registration Kind Code<br>— Submission Sequence | EAEU Module 1<br>Envelope<br>Information folder in EAEU Template v1.0 assembly template | Attribute values provided for each folder with this type complete the envelope information within the index-r-022.xml file. |
| Quality Overall<br>Summary | No additional attributes | Quality Overall<br>Summary folder in EAEU Template v1.0 assembly template. | Creates the appropriate <m2-3quality-overall-summary> element in the index-r-022.xml file. |
| Drug Substance | — Drug Product<br>Name<br>— Drug Substance Manufacturer | Drug Substance folder in EAEU Template v1.0 assembly template. | Creates the appropriate<br><drug_substance> element in the index-r-022.xml file. |
| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |

| | | | |
|---|---|---|---|
| Solvent | — Solvent Name<br>— Solvent Manufacturer | Solvent folder in EAEU Template v1.0 assembly template. | Attribute values provided for each folder of this type contain information about every solvent set within indexr-022.xml file and included under each leaf entry as additional attributes. |

## European Union

| Extension Type | Associated Attributes | Applied to Assembly Element | Result |
|---|---|---|---|
| EU Module 1 folder | No additional attributes | 1 Administrative Information and Prescribing Information folder in EU Module 1 assembly template | When applied to an Assembly folder that is using the eu-2-0 XML Definition file, triggers the creation of the euregional.xml file during publishing. The child folders of this folder complete the content included in the eu-regional.xml file. |

| Extension Type | Associated Attributes | Applied to Assembly Element | Result |
|---|---|---|---|
| EU Module 1 Envelope Information folder (v3.0 and v3.0.1) | — Country<br>— UUID<br>— Submission Type<br>— Submission Mode<br>— High-Level/ Worksharing Submission Number<br>— Application Tracking Number | Depending on the procedure type/ template selected, there will be appropriate CC Envelope Information folder(s) that is a child of the EU Envelope Information leaf in EU Module 1 assembly template. A folder for each country | Attribute values provided for each folder with this type complete the envelope information for the country specified within the euregional.xml file. You must create a separate folder for each country for which envelope information is provided. These folders should reside beneath the EU Envelope Information Leaf to ensure proper behavior during life cycle updates. Multiple commaseparated values can be provided for:<br>— Application Tracking number<br>— Invented Name<br>— INN |

| | | | |
|---|---|---|---|
| | — Submission Unit Type<br>— Applicant<br>— Agency Name<br>— Procedure Type<br>— Invented Name<br>— INN<br>— Sequence<br>— Related Sequence<br>— Submission Description | applicable in the sequence should be included to provide the appropriate envelope information. | — Related Sequence |

| Extension Type | Associated Attributes | Applied to Assembly Element | Result |
|---|---|---|---|
| EU Module 1 Envelope Information folder (v2.0) | — Country<br>— Submission Type<br>— Submission Mode<br>— High-Level/ Worksharing Submission Number<br>— Application Tracking Number<br>— Applicant<br>— Agency Name | Depending on the procedure type/ template selected, there will be appropriate CC Envelope Information folder(s) that is a child of the EU Envelope Information leaf in EU Module 1 assembly template. A folder for each country applicable in the se- | Attribute values provided for each folder with this type complete the envelope information for the country specified within the euregional.xml file. You must create a separate folder for each country for which envelope information is provided. These folders should reside beneath the EU Envelope Information Leaf to ensure proper behavior during life cycle updates. Multiple commaseparated values can be provided for:<br>— Application Tracking number<br>— Invented Name<br>— INN<br>— Related Sequence |

| | | | |
|---|---|---|---|
| | — Procedure Type<br>— Invented Name<br>— INN<br>— Sequence<br>— Related Sequence<br>— Submission Description | quence should be included to provide the appropriate envelope information. | |

| Extension Type | Associated Attributes | Applied to Assembly Element | Result |
|---|---|---|---|
| EU Module 1 Country-specific Information folder | — Country<br>— Language | — In EU Module 1 Assembly template, applied to the following folders:<br>— 1.0 Cover Letter<br>— 1.2 Application Forms<br>— 1.3.2 Mock-up<br>— 1.3.3 Specimen<br>— 1.3.4 Readability Testing<br>— 1.3.5 SPCs already approved in Member States | Creates the appropriate <m1-0cover>, <m1-2-form>, <m1-3-2mockup>, <m1-3-4-readability>, and <m1-3-5-approved> elements in eu-regional.xml with country values for the <specific> child element. Also includes the appropriate country values in the output directory structure. Each folder with this type can be duplicated for different countries and/or languages for which information is being provided. |
| EU Module 1 Labeling | — Country<br>— Language | — 1.3.1 SPC, Labeling and Package Leaflet | Creates the appropriate <m1-3-1-spc-label-pl> element with the <pi-doc> child element using attribute values to populate the |

| | | | |
|---|---|---|---|
| Information folder | — Labeling type | folder in EU<br>Module 1 Assembly template | attributes of the <pi-doc> element. Also includes appropriate country and language information in the output directory structure. Each folder with this type can be duplicated for different countries, languages, and/or labeling types for which information is being provided. The *Create eCTD* Wizard allows the user to indicate which sections should be included for all countries. |
| EU Responses folder | — Country<br>— Language | Responses to<br>Questions folder in the EU Module 1 Assembly template | Creates the appropriate <m1responses> element in euregional.xml with country values for the <specific> child element. Also includes appropriate country information values in the output directory structure. |
| EU Additional Information folder | — Country<br>— Language | Additional Data folder in the EU<br>Module 1 Assembly template | Creates the appropriate <m1additional> element in euregional.xml with country values for the <specific> child element. Also includes appropriate country information values in the output directory structure. |

## Bosnia and Herzegovina

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| BA Module 1 Envelope Information (v3.1) | - Country<br>- UUID<br>- Submission Type<br>- Submission Mode<br>- Submission Unit Type<br>- High Level/Worksharing Submission Number<br>- Application Tracking Number<br>- Applicant<br>- Agency Name<br>- Procedure Type<br>- Invented Name<br>- INN<br>- Sequence<br>- Related Sequence<br>- Submission Description | Bosnia and Herzegovina Envelope Information folder that is a child of the EU Envelope Information leaf in BA Module 1 assembly template. | Attribute values provided for each folder with this type complete the envelope information for the country specified within the ba-regional.xml file. This folder should reside beneath the EU Envelope Information Leaf to ensure proper behavior during life cycle updates. Multiple comma separated values can be provided for:<br>— Application Tracking number<br>— Invented Name<br>— INN<br>— Related Sequence |

| | | | |
|---|---|---|---|
| BA Module 1 Country-Specific Information (v3.1) | - Country<br>- Language | In BA Module 1 Assembly template, applied to the following folders:<br>— 1.0 Cover Letter<br>— 1.2 Application Forms<br>— 1.3.2 Mock-up<br>— 1.3.3 Specimen<br>— 1.3.4 Consultation with Target Patient Groups<br>— 1.3.5 Product Information Already Approved in the Member States | Creates the appropriate <m1-0cover>, <m1-2-form>, <m1-3-2mockup>, <m1-3-4-readability>, and <m1-3-5-approved> elements in ba-regional.xml with country values for the <specific> child element. Also includes the appropriate country values in the output directory structure. Each folder with this type can be duplicated for different countries and/or languages for which information is being provided. |
| BA Module 1 Labelling Information | - Country<br>- Language<br>- Labeling Type | 1.3.1 SPC, Labelling and Package Leaflet | Creates the appropriate <m1-3-1-spc-la- bel-pl> element with the <pi-doc> child element using attribute values to populate the attributes of the <pi-doc> element. Also includes appropriate country and language information in the output directory structure. Each folder with this type can be duplicated for different countries, languages, and/or labeling types for which information is being provided. The *Create eCTD* Wizard allows the user to indicate which sections should be included for all countries |
| BA Responses folder | — Country<br>— Language | Responses to Questions folder in the BA Module 1 Assembly template | Creates the appropriate <m1responses> element in euregional.xml with country values for the <specific> child element. Also includes appropriate country information values in the output directory structure. |
| BA Additional Information folder | — Country<br>— Language | Additional Data folder in the BA Module 1 Assembly template | Creates the appropriate <m1additional> element in ba-regional.xml with country values for the <specific> child element. Also includes appropriate country information values in the output directory structure. |

## Canada

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Canadian Module 1 folder (v2.2) | — Applicant<br>— Product Name<br>— Dossier Identifier<br>— Dossier Type<br>— Regulatory Activity Type<br>— Regulatory Activity Lead<br>— Sequence Number<br>— Submission Description<br>— Related Sequence Number | 1 Administrative and Product Information folder in Canadian Module 1 assembly template | When applied to a folder in an Assembly that is using the ca-2-2 XML Definition file, triggers the creation of the ca-regional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <ectd-regulatory-transactioninformation> element of the caregional.xml file. The child folders of this folder complete the remainder of the ca-regional.xml file. |

## China

| Extension Type | Associated Attributes | Applied to Assembly Element | Result |
|---|---|---|---|
| CN Module 1 v1.0 folder | — Application Number<br>— Application Type<br>— Product Type<br>— Original Number<br>— Related Sequence<br>— Regulatory | CN Module 1 Administration Information folder in CN Module 1 assembly template | When applied to an Assembly folder that is using the cn-1-0 XML Definition file, triggers the creation of the cnregional.xml file during publishing. The child folders of this folder complete the content included in the cn-regional.xml file. |

| | | | |
|---|---|---|---|
| | Activity Type – Sequence Number | | |

| | | | |
|---|---|---|---|
| | — Sequence Type<br>— Sequence Description<br>— Sequence Contact Name<br>— Sequence Contact Telephone<br>— Sequence Contact Email | | |

## United States

| Extension Type | Associated Attributes | Applied to Assembly Element | Result |
|---|---|---|---|
| US Module 1 folder (v2.01) | — Company Name<br>— Submission Date<br>— Application Number<br>— Product name and type<br>— Application Type<br>— Submission Type<br>— Sequence Number<br>— Related Sequence | 1 Administrative Information and Prescribing Information folder in US Module 1 assembly template (v2.01) | When applied to folder in an Assembly that is using the us-2-0-1 XML Definition file, triggers the creation of the us-regional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <admin> element of the us-regional.xml file. Multiple related sequence number values may be added by separating them with commas. The child folder and leaf elements in this folder complete the remainder of the us-regional.xml file. |

| | | | |
|---|---|---|---|
| | Number | | |

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| US Module 1 folder (DTD v3.3) | — Applicant ID<br>— Company Name<br>— Submission<br>Description<br>— Applicant<br>Contact<br>— Application Number<br>— Application Contains Files?<br>— Application<br>Type<br>— Cross-<br>Reference<br>Application<br>— Sequence<br>Number<br>— Submission ID<br>— Submission Type<br>— Submission Sub-Type<br>— Supplement<br>Effective Date | 1 Administrative Information folder in US Module 1 assembly template<br>(v3.3) | When applied to a folder in an<br>Assembly that is using the us-3-3 XML Definition file, triggers the creation of the us-regional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <admin> element of the us-regional.xml file. The<br>child folders of this folder complete the remainder of the us-regional.xml file. |

| | | | |
|---|---|---|---|
| | Type | | |

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| US Admin Forms folder | Application Form Type | The following folders in US Module 1 assembly template (v3.3):<br>— 1.1.1 Form FDA 1571:<br>Investigational<br>New Drug<br>Application<br>(IND)<br>— 1.1.2 Form FDA 356h:<br>Application to<br>Market a New Drug, Biologic, or an Antibiotic Drug for Human<br>Use folders in | Creates the appropriate <form formtype=""> element within the<br><submission-information> element in us-regional.xml. |

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| US Forms folder | Application Form Type | The following folders in US Module 1 assembly template (v3.3): | Creates the appropriate <form formtype=""> element within the <m1-1forms> element in usregional.xml. |

| | | | | |
|---|---|---|---|---|
| | | — 1.1.3 Form FDA 3397: User Fee Cover Sheet<br>— 1.1.4 Form FDA 2252:<br>Transmittal of Annual Reports for Drugs and Biologics for Human Use<br>— 1.1.5 Form FDA 2253:<br>Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use<br>— 1.1.6 Form FDA 2567:<br>Transmittal of Labels and Circulars<br>— 1.1.7 Form FDA 3674:<br>Certification of Compliance<br>— 1.1.8 Form FDA 3792:<br>Biosimilar User | | |

| | | | |
|---|---|---|---|
| | | Fee Cover Sheet<br>(BsUFA)<br>— 1.1.9 Form FDA 3794: Generic<br>Drug User Fee<br>Cover Sheet<br>(GDUFA) | |

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| Promotional<br>Material Audience<br>Type folder | Promotional<br>Material Audience<br>Type | 1.15 Promotional<br>Material Audience<br>Type folder in US Module 1<br>assembly template<br>(v3.3) | Creates the appropriate <m1-15promotional-material> element in us-regional.xml. The value of the attribute populated on this folder is used to complete the promotionalmaterial-audience-type attribute of<br><m1-15-promotional-material> element. |
| Promotional Material Doc Type folder | Promotional<br>Material Doc Type | 1.15.2 Materials<br>folder in US Module 1<br>assembly template<br>(v3.3) | Creates the appropriate <m1-15-2materials> element in usregional.xml. The value of the attribute populated on this folder is used to complete the promotionalmaterial-doc-type attribute of<br><m1-15-2-materials> element. |
| Promotional Material Type<br>folder | — Promotional Material Type<br>— Promotional<br>Material ID<br>— Issue Date | 1.15.2.1 Material<br>folder in US Module 1<br>assembly template<br>(v3.3) | Creates the appropriate <m1-15-2-1material> element in usregional.xml. The values of the attributes populated on this folder are used to complete the attributes<br><m1-15-2-1-material> element. |

## Japan

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| JP Module 1 folder | — Submission<br>Number<br>— Brand Name<br>— Sequence<br>Number<br>— Generic Name<br>— Applicant<br>— Submission Date<br>— Submission<br>Type<br>— Operation | 1 Administrative<br>Information and<br>Prescribing Information folder in JP Module 1 assembly template | When applied to a folder in an<br>Assembly that is using the jp-1-0 XML Definition file, triggers the creation of the jp-regional-index.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the<br><content-block param="admin"> element of the jp-regionalindex.xml file.<br>Multiple values for fields Brand Name,<br>Generic Name, Applicant and Submission Type may be added by separating them with commas. The child folder and leaf elements of this folder complete the remainder of the jp-regional-index.xml file. |

## Jordan

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| JO Module 1 folder (v1.0, v1.1) | No additional attributes | JO Module 1 folder in JO Module 1 assembly template | When applied to an Assembly folder that is using the jo-1-0 or the jo-1.1 XML Definition file, triggers the creation of the jo-regional.xml file during publishing. |

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|

| | | | |
|---|---|---|---|
| JO Module 1<br>Envelope<br>Information folder<br>(v1.0, v1.1) | — Application Reference<br>Number<br>— UUID<br>— Applicant<br>— MAH<br>— Agency<br>— ATC<br>— Submission<br>Type<br>— Submission Unit<br>— Procedure<br>— Invented Name<br>— INN<br>— Sequence<br>— Related<br>Sequence<br>— Submission<br>Description<br>— Number | JO Envelope Information folder<br>is a child of the JO<br>Envelope<br>Information leaf in JO Module 1 assembly template. | Attribute values provided for each folder with this type complete the envelope information within the joregional.xml file. Multiple commaseparated values can be provided for:<br>— Application Reference Number<br>— ATC<br>— Invented Name<br>— INN<br>— Related Sequence |

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| JO Product<br>Information folder | — Language<br>— Product Information | In JO Module 1 assembly template, applied to the product information subfold- | Populates the labeling and language attribute of the <pi-doc> element within appropriate elements in the joregional.xml file. Also includes appropriate language values in the output directory structure. |

| | | | |
|---|---|---|---|
| | Type | ers of the following folders:<br>— 1.3.1 Arabic<br>SPC<br>— 1.3.1 English<br>SPC<br>— 1.3.1 Arabic<br>SPC-comp<br>— 1.3.1 English<br>SPC-comp<br>— 1.3.2 Arabic<br>— 1.3.2 English<br>— 1.3.3 Arabic Patient<br>Information<br>Leaflet (PIL)<br>— 1.3.3 Arabic Patient<br>Information<br>Leaflet (COMP)<br>— 1.3.3 English Patient<br>Information<br>Leaflet (PIL)<br>— 1.3.3 English Patient<br>Information<br>Leaflet (COMP) | |

| | | | |
|---|---|---|---|
| JO Additional<br>Information folder | No additional attributes | Additional Data<br>folder in JO Module 1 assembly template | Creates the appropriate <m1additional-data> element in the jo-regional.xml file. |

## Switzerland

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| CH Module 1 folder (v1.2 , v.1.3, and v1.4) | — Application Number<br>— Submission<br>Description<br>— Invented Name<br>— DMF Number<br>— PMF Number<br>— INN<br>— Applicant<br>— DMF Holder<br>— PMF Holder<br>— Agency<br>— Submission<br>Type<br>— Paragraph 13<br>TPA<br>— Sequence Number<br>— Related<br>Sequence | 1 Administrative<br>Information and<br>Prescribing Information folder in CH Module 1 assembly template | When applied to a folder in an Assembly that is using the ch-1-2, ch-1-3, or ch-1-4 XML Definition file, triggers the creation of the chregional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <ch-envelope> element of the ch-regional.xml file. Multiple comma-separated values can be provided for:<br>— Application Number<br>— Invented Name<br>— INN<br>— Related Sequence<br>The child folders of this folder complete the remainder of the chregional.xml file. |

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| CH Module 1 folder (v1.5) | — Application Number<br>— Submission Description<br>— Invented Name<br>— DMF Number<br>— PMF Number<br>— INN<br>— Applicant<br>— DMF Holder<br>— PMF Holder<br>— Agency<br>— Submission Type<br>— Article 13 TPA<br>— Sequence Number<br>— Related Sequence | 1 Administrative Information and Prescribing Information folder in CH Module 1 assembly template | When applied to a folder in an Assembly that is using the ch-1-5 XML Definition file, triggers the creation of the ch-regional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <ch-envelope> element of the ch-regional.xml file. Multiple comma-separated values can be provided for: — Application Number<br>— Invented Name<br>— INN<br>— Related Sequence<br>The child folders of this folder complete the remainder of the chregional.xml file. |
| CH Galenic Form folder | — Galenic Form Name<br>— SwissMedic Number<br>— Galenic Language Name | Galenic Form folder in CH Module 1 assembly template | Creates the <galenic-form> element within the <envelope country="ch"> element in the chregional.xml. If there are leafs submitted under the subfolders of the folder with this extension applied, creates the <m1-galenic-form> element in the ch-regional.xml file. The values of the attributes populated on this folder are used to complete the attribut- |

| | | | |
|---|---|---|---|
| | — Galenic<br>Language Text | | es of <galenic-form> and <m1-galenic form> elements. |
| CH Common Form<br>folder | No additional attributes | Common folder in CH Module 1 assembly template | Creates the <m1-galenic-form> element in the ch-regional.xml file with the name="common" attribute populated. |
| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
| CH Swiss<br>Responses folder | No additional attributes | Responses to Swissmedic LoQ<br>folder in CH Module 1 assembly template | Creates the appropriate <m1-swissresponses> element in the chregional.xml file. |
| CH Additional Data folder | No additional attributes | Additional<br>Information in CH Module 1 assembly template | Creates the appropriate <m1additional-data> element in the ch-regional.xml file. |

## Gulf Cooperation Council

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| GCC Module 1 folder (v1.5) | No additional attributes | GCC Module 1 folder in GCC Module 1 assembly template | When applied to an Assembly folder that is using the gc-1-5 XML Definition file, triggers the creation of the gcregional.xml file during publishing. The child folders of this folder complete the content included in the gcregional.xml file. Multiple comma-separated values can be provided for:<br>— Application Number<br>— ATC<br>— Invented Name |

| | | | |
|---|---|---|---|
| | | | — INN<br>— Related Sequence |
| GCC Module 1 folder (v1.2) | No additional attributes | GCC Module 1 folder in GCC Module 1 assembly template | When applied to an Assembly folder that is using the gc-1-2 XML Definition file, triggers the creation of the gcregional.xml file during publishing. The child folders of this folder complete the content included in the gc-regional.xml file. |

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| GCC Module 1<br>Envelope<br>Information folder<br>(v1.5) | — Country<br>— Application<br>Number<br>— Applicant<br>— Agency Name<br>— ATC<br>— Submission<br>Type<br>— Submission Unit Type<br>— Procedure Type<br>— Invented Name<br>— INN<br>— Sequence<br>— Related<br>Sequence<br>— Submission | Depending on the procedure type/ template selected, there will be appropriate CC Envelope<br>Information<br>folder(s) that is a<br>child of the CC<br>Envelope<br>Information leaf in GCC Module 1 assembly template. A folder for each country applicable in the sequence should be included to provide the appropriate envelope information. | Attribute values provided for each folder with this type complete the envelope information for the country specified within the gcregional.xml file. You must create a separate folder for each country for which envelope information is being provided. These folders should reside beneath the GCC Envelope Information leaf. This is to ensure proper behavior<br>during life cycle updates. Multiple comma-separated values can be provided for:<br>— Application Number<br>— ATC<br>— Invented Name<br>— INN<br>— Related Sequence |

| | | | |
|---|---|---|---|
| | Description | | |

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| GCC Module 1<br>Envelope<br>Information folder<br>(v1.2) | — Country<br>— Application<br>Number<br>— Applicant<br>— Agency Name<br>— ATC<br>— Submission<br>Type<br>— Procedure Type<br>— Invented Name<br>— INN<br>— Sequence<br>— Related<br>Sequence<br>— Submission<br>Description | Depending on the procedure type/ template selected, there will be appropriate CC Envelope<br>Information<br>folder(s) that is a child of the GCC Envelope<br>Information leaf in GCC Module 1 assembly template. A folder for each country applicable in the sequence should be included to provide the appropriate envelope information. | Attribute values provided for each folder with this type complete the envelope information for the country specified within the gcregional.xml file. You must create a separate folder for each country for which envelope information is being provided. These folders should reside beneath the GCC Envelope Information leaf. This is to ensure proper behavior<br>during life cycle updates. Multiple comma-separated values can be provided for:<br>— Application Number<br>— ATC<br>— Invented Name<br>— INN<br>— Related Sequence |

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| GCC CountrySpecific<br>Information folder | — Country<br>— Language | In GCC Module 1 assembly template, applied to the countryspecific subfold- | Populates the country attribute of the<br><specific> element within appropriate elements in the gcregional.xml file. Also in- |

| | | | |
|---|---|---|---|
| | | ers of the following folders:<br>— 1.0 Cover Letter Application<br>Form Summary of Product Characteristics<br>(SPC)<br>— 1.3.2 Labeling<br>— 1.3.3 Patient information<br>leaflet<br>— 1.3.4 Artwork<br>(mock-ups)<br>— 1.3.5 Samples<br>— 1.7.4 Certificate of analysis Excipients<br>— 1.7.5 Alcoholcontent declaration<br>— 1.7.6 Porkcontent declaration<br>— 1.7.7 Certificate of suitability for<br>TSE<br>— 1.7.8 The diluents and coloring agents in product formula<br>— 1.7.9 Patent<br>Information | cludes appropriate country information values in the output directory structure. |

| | | | |
|---|---|---|---|
| | | — 1.7.10 Letter of access or acknowledgeme nts to DMF<br>— 1.8.1 Price list | |
| GCC Label folder | — Country<br>— Language<br>— Labeling Type | In GCC Module 1 assembly template, applied to the language specific subfolders of the following folders:<br>— 1.3.1 Summary of Product Characteristics<br>(SPC)<br>— 1.3.2 Labeling<br>— 1.3.3 Patient information leaflet | Populates attributes for the <pi-doc> element within appropriate elements in the gc-regional.xml file. Also includes appropriate language values in the output directory structure. |
| GCC Responses folder | Country | 1.9 Responses to Questions folder in GCC Module 1 assembly template | Creates the appropriate <m1-9responses> element in the gcregional.xml file with country values for the <specific> child element. Also includes appropriate country information values in the output directory structure. |
| GCC Additional Data folder | Country | Additional Data folder in GCC Module 1 assembly template | Creates the appropriate <m1additional-data> element in the gc-regional.xml file with country values for the <specific> child element. Also includes appropriate country information values in the output directory structure. |

## Singapore

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| SG Module 1 folder v1.0 | — Application | 1 Administrative | When applied to a folder in an |

| Extension Type | Associated Attributes | Applied to<br><br>Assembly Element | Result |
|---|---|---|---|
| | Type<br>— SG eCTD ID<br>— Application Number<br>— INN<br>— Product Type<br>— DMF Number<br>— PMF Number<br>— Proprietary Name<br>— Singapore Registration Number<br>— Submission (Submission Type / Submission Number)<br>— Sequence Type<br>— Sequence Description<br>— Sequence Date<br>— Sequence Number<br>— Related Sequence<br>— Contact | Information and Prescribing Information folder in SG Module 1 assembly template | Assembly that is using the sg-1-0 Definition file creates the sg-regional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <sg-envelope> element of the sg-regional.xml file. Multiple comma-separated values can be provided for:<br>— Application Number<br>— INN<br>— DMF Number<br>— PMF Number<br>— Proprietary Name<br>— Singapore Registration Number<br>— Submission Number |

## South Africa

| Extension Type | Associated Attributes | Applied to<br><br>Assembly Element | Result |
|---|---|---|---|
| ZA Module 1 folder v3.1 | — Application | 1 Administrative | When applied to a folder in an |

| Extension Type | Associated Attributes | Applied to<br><br>Assembly Element | Result |
|---|---|---|---|
| | Type<br>— Application ID<br>— Application Number<br>— Proprietary Name<br>— Dosage Form<br>— INN<br>— APIMF Number<br>— PMF Number<br>— VAMF Number<br>— SMF Number<br>— Submission (Submission Type/Evaluation Pathway/ Submission Lead/ Submission Number<br>— Sequence Type<br>— Sequence | Information and<br><br>Prescribing Information folder in ZA Module 1 assembly template | Assembly that is using the za-3-1 Definition file creates the zaregional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <za-envelope> element of the za-regional.xml file. Multiple comma-separated values can be provided for:<br>— SMF Number<br>— Application Number<br>— Dosage Form<br>— INN<br>— APIMF Number<br>— VAMF Number<br>— Proprietary Name<br>— PMF Number<br>— Related Sequence |
| | | | ***Note:*** *Multiple paired values can be provided for the Multiple Applications attribute. While Multiple Applications is not required (both Application Number and Proprietary Name can be empty) it is required to have both values either populated or empty. If only one field is populated, a validation message is displayed.* |
| | | | The child folders of this folder complete the remainder of the zaregional.xml file. |

| | | | |
|---|---|---|---|
| | Description<br>— Sequence Date<br>— Sequence Number<br>— Related Sequence<br>— Multiple Applications (Application Number/ Proprietary Name)<br>— Contact | | |

| Extension Type | Associated Attributes | Applied to Assembly Element | Result |
|---|---|---|---|
| ZA Module 1 folder v2.1 | — Application Number<br>— Applicant<br>— Submission Type/Proof of Efficacy<br>— Proprietary Name<br>— Dosage Form<br>— INN<br>— eCTD Sequence | 1 Administrative Information and Prescribing Information folder in ZA Module 1 assembly template | When applied to a folder in an Assembly that is using the za-2-1 Definition file, triggers the creation of the za-regional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <za-envelope> element of the za-regional.xml file. Multiple comma-separated values can be provided for:<br>— Application Number<br>— Proprietary Name<br>— Dosage Form<br>— INN<br>— Related Sequence |

| | | | |
|---|---|---|---|
| | — Related<br>Sequence<br>— Duplicated Applications<br>(Proprietary<br>Names/<br>Application<br>Numbers) | | The child folders of this folder complete the remainder of the za-regional.xml file. |

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| ZA Module 1 folder v1.0 | — Application<br>Number<br>— Applicant<br>— Submission<br>Type<br>— Proof of Efficacy<br>— Proprietary<br>Name<br>— Dosage Form<br>— INN<br>— eCTD Sequence<br>— Related<br>Sequence<br>— Duplicated Applications<br>(Proprietary | 1 Administrative<br>Information and<br>Prescribing Information folder in ZA Module 1 assembly template | When applied to folder in an Assembly that is using the za-1-0 Definition file, triggers the creation of the zaregional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <za-envelope> element of the za-regional.xml file. Multiple comma-separated values can be provided for:<br>— Application Number<br>— Proprietary Name<br>— Dosage Form<br>— INN<br>— Related Sequence<br>The child folders of this folder complete the remainder of the za-regional.xml file. |

| | | | |
|---|---|---|---|
| | Names/Dates of Application | | |

## Australia

| Extension Type | Associated Attributes | Applied to Assembly Element | Result |
|---|---|---|---|
| AU Module 1 folder (v3.2) | — e-Identifier<br>— eBS Client ID<br>— Approved Name(s)<br>— Trade Name(s)<br>— ARTG Number(s)<br>— Submission or Application Number(s)<br>— Sequence Number<br>— Related Sequence Number<br>— Regulatory Activity Lead<br>— Submission Mode<br>— Sequence Type / Sequence Description | 1 Administrative Information and Prescribing Information folder of the AU eCTD template | When applied to a folder in an Assembly that is using the au-3-2 Definition file, triggers the creation of the au-regional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <au-envelope> element of the au-regional.xml file. Multiple, comma-separated values can be provided for:<br>— Approved Name<br>— Trade Name<br>— ARTG Number<br>— Submission or Application Number<br>— Contact Email<br>The child folders of this folder complete the remainder of the au-regional.xml file. |

| | | | |
|---|---|---|---|
| | — Contact Email | | |

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| AU Module 1 folder (v3.1) | — e-Identifier<br>— eBS Client ID<br>— Approved Name (s)<br>— Trade Name(s)<br>— ARTG Number (s)<br>— Submission or Application Numbers (s)<br>— Sequence Number<br>— Related Sequence Number<br>— Regulatory Activity Lead<br>— Submission Mode<br>— Sequence Type<br>— Sequence Description<br>— Contact Email | 1 Administrative Information and Prescribing Information folder of the AU eCTD template | When applied to a folder in an Assembly that is using the au-3-1 Definition file, triggers the creation of the au-regional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <au-envelope> element of the au-regional.xml file. Multiple, comma-separated values can be provided for:<br>— Approved Name<br>— Trade Name<br>— ARTG Number<br>— Submission or Application Number — Contact Email<br>The child folders of this folder complete the remainder of the au-regional.xml file. |

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| AU Module 1 folder (v0.90 and v3.0) | — eSubmission Identifier | 1 Administrative Information and | When applied to a folder in an Assembly that is using the au-0-90 or au-3-0 Definition file, triggers the creation of the au- |

| | | | |
|---|---|---|---|
| | — Applicant<br>— Australian Approved<br>Name(s)<br>— Product Name — ARTG Number<br>— Sequence<br>Description<br>— Sequence Number<br>— Related<br>Sequence<br>Number<br>— Regulatory<br>Activity Lead<br>— Sequence Type | Prescribing Information folder of the AU eCTD template | regional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <auenvelope> element of the auregional.xml file. Multiple, comma separated values can be provided for:<br>— Australian Approved Name(s)<br>— Product Name — ARTG Number<br>The child folders of this folder complete the remainder of the au-regional.xml file. |

## Thailand

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| TH Module 1 folder (v1.0) | — eSubmission<br>Identifier<br>— Sequence Type<br>— Regulatory<br>Activity Lead<br>— Licensee<br>Number<br>— Licensee Type | 1 Administrative<br>Information and<br>Prescribing Information folder of the TH eCTD template | When applied to a folder in an<br>Assembly that is using the th-1-0 Definition file, triggers the creation of the th-regional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <envelope> element of the th-regional.xml file. Multiple, comma-separated values can be provided for: — INN/ Generic Name — Product Name |

| | | | |
|---|---|---|---|
| | — Licensee Name<br>— INN/Generic Name<br>— Product Name<br>— Sequence Number<br>— Related Sequence Number<br>— Sequence Description<br>— Contact Email | | The child folders of this folder complete the remainder of the th-regional.xml file. |
| TH Module 1 folder (v0.92) | — eSubmission Identifier<br>— Sequence Type<br>— Regulatory Activity Lead<br>— Licensee<br>— INN/Generic Name<br>— Product Name<br>— Sequence Number<br>— Related Sequence Number<br>— Sequence Description | 1 Administrative Information and Prescribing Information folder of the TH eCTD template | When applied to a folder in an Assembly that is using the th-0-92 Defini- tion file, triggers the creation of the th-regional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <envelope> element of the th-regional.xml file. Multiple, comma-separated values can be provided for: — INN/Generic Name — Product Name<br>The child folders of this folder complete the remainder of the th-regional.xml file. |

## Taiwan

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| TW Module 1 folder (v1.0) | — Identifier<br>— Submission Type Tier 1<br>— Submission Type Tier 2<br>— Submission Type Tier 3<br>— Submission Type Tier 4<br>— Submission Type Tier 5<br>— Submission Objective<br>— Submission Unit<br>— Applicant Name<br>— Applicant Corporate Certification Authority<br>— Applicant Phone Number<br>— Applicant Email Address | 1 Administrative Information and Prescribing Information folder of the TW eCTD template | When applied to a folder in an Assembly that is using the tw-1-0 Definition file, triggers the creation of the tw-regional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <envelope> element of the tw-regional.xml file. The child folders of this folder complete the remainder of the tw-regional.xml file.<br>Multiple comma-separated values can be provided for:<br>— Applicant Phone Number<br>— Applicant Email Address<br>— Invented Names<br>— Drug Permit License<br>— INN<br>— Related Sequence |

| | | | |
|---|---|---|---|
| | — Invented Names (Name/ Drug Permit License/ Pre-Assigned Application Number) — Code<br>— INN<br>— Sequence<br>— Related Sequence<br>— Submission Description | | |

## Tunisia

| Extension Type | Associated Attributes | Applied to<br><br>Assembly Element | Result |
|---|---|---|---|
| TN Module 1 folder (v1.1) | - Application Type<br>- Application ID<br>- Application Number<br>- Submission Type<br>- Sequence Type<br>- Sequence Date<br>- Sequence Number<br>- Related Sequence Number<br>- Contact | 1 Administrative Information and Prescribing Information | When applied to a folder in an assembly that is using the tn-1-1 definition file, triggers the creation of the tn-regional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <envelope> element of the tn-regional.xml file. The child folders of this folder complete the remainder of the tn-regional.xml file. |

## Ukraine

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| Ukraine Module 1 folder (v1.0) | — Country<br>— UUID<br>— Submission Type<br>— Submission Mode<br>— Submission Unit Type<br>— Submission Number<br>— Applicant<br>— Agency Name<br>— Procedure Type<br>— Invented Name<br>— INN<br>— Sequence<br>— Related Sequence<br>— Submission Description | Envelope<br>Information folder that is a child of the UA Envelope Information leaf in UA eCTD Module 1 assembly template. | When applied to a folder in an<br>Assembly that is using the ua-1-0<br>Definition file, triggers the creation of the ua-regional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements<br>and attributes in the <envelope> element of the ua-regional.xml file.<br>The child folders of this folder complete the remainder of the ua-regional.xml file.<br>Multiple comma-separated values can be provided for:<br>— Submission Number<br>— INN<br>— Related Sequence<br>— Invented Name |

## World Health Organization (WHO)

| Extension Type | Associated Attributes | Applied to<br>Assembly Element | Result |
|---|---|---|---|
| WHO Module 1 | — Identifier | 1 Administrative | When applied to a folder in an |

| | | | |
|---|---|---|---|
| folder (v1.0) | — Product Type<br>— Product Subtype<br>— Product Name<br>— Application Type<br>— Application Subtype<br>— Submission Unit Type<br>— Applicant<br>— Contact Email<br>— Product ID<br>— SF Case ID<br>— Sequence<br>— Related Sequence<br>— Submission Description | Information and Prescribing Information folder of the WHO eCTD template | Assembly that is using the who-1-0 Definition file, triggers the creation of the whopqt-regional.xml file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <envelope> element of the whopqtregional.xml file.<br>The child folders of this folder complete the remainder of the whopqt-regional.xml file.<br>Multiple comma-separated values can be provided for:<br>— Contact Email Address<br>— Related Sequence |

## Extension Type:Leaf Types

| Extension Type | Associated Attributes | Applied to Assembly Element | Result |
|---|---|---|---|
| Study Patient Information | — Subject Matter<br>— Site | Can be applied directly to CRF and/or Subject Matter leaf elements in lieu of using the inheritance structure using the same folder type. | See *Study Patient Information Folder*. |

| Extension Type | Associated Attributes | Applied to Assembly Element | Result |
|---|---|---|---|

| | | | |
|---|---|---|---|
| EAEU Module 1 Envelope | No additional Attributes | Applied to a placeholder leaf element that holds envelope information. | Is automatically duplicated for each new working assembly to ensure that the appropriate envelope information is available and managed by the sequence. |
| EAEU Leaf | — Registration File Indicator<br>— Drug Registration Document Code<br>— Drug Registration Document Name<br>— Drug Registration File Section | Applied to each leaf in an EAEU submission. | Is applied to each leaf of EAEU submission to enable users to indicate additional attributes, if necessary. |

| | | | |
|---|---|---|---|
| | — Drug Registration File Code<br>— Drug Registration File Name<br>— Document Creation Date<br>— Document Validity Date<br>— Business Entity Name<br>• Request Response Date<br>• Reason Document Number<br>• Requested Drug Registration File Section<br>• Requested Drug Registration File Code<br>• Requested Drug Registration Document Code<br>• Other Information<br>• General Information | | |

| Extension Type | Associated Attributes | Applied to | Result |
|---|---|---|---|

| | | | |
|---|---|---|---|
| | | Assembly Element | |
| EU Module 1 Envelope | No additional Attributes | Applied to a placeholder leaf element that holds<br>envelope information. | Is automatically duplicated for each new working assembly to ensure that the appropriate envelope information is available and managed by the sequence. |
| GCC Module 1 Envelope | No additional Attributes | Applied to a placeholder leaf element that holds<br>envelope information. | Is automatically duplicated for each new working assembly to ensure that the appropriate envelope information is available and managed by the sequence. |
| Japanese Module 1 | Leaf Sequence | Applied to each leaf in the JP Module 1 assembly template. | Creates the appropriate <property> element with the attribute name="sequencenumber" using the value of the attribute to populate the value of the <property> element in the jp-regional-index.xml file. |
| JO Module 1 Envelope | No additional Attributes | Applied to a placeholder leaf element that holds<br>envelope information. | Is automatically duplicated for each new working assembly to ensure that the appropriate envelope information is available and managed by the sequence. |
| Study Report | Subject Matter | Leafs in a Study Report. | See *Study Report folder*. |

# Chapter 13. Extended Attributes Name, Type, and Version

The following table includes the list of extended attributes with name, type, and version.

| Extended Attributes Name | Type | Version |
|---|---|---|
| AU Module 1 | m1-au | 0.9 |
| AU Module 1 | m1-au | 3.0 |
| AU Module 1 | m1-au-2.0-nees | 2.0 |
| AU Module 1 | m1-au | 3.1 |
| AU Module 1 | m1-au | 3.2 |
| Canadian Module 1 | m1-ca | 1.0 |
| Canadian Module 1 v2.2 | m1-ca | 2.2 |
| CH Module 1 | m1-ch | 1.0. |
| CH Module 1 | m1-ch | 1.0.1 |
| CH Module 1 | m1-ch | 1.1 |
| CH Module 1 | m1-ch | 1.2 |
| CH Module 1 | m1-ch | 1.3 |
| CH Module 1 | m1-ch | 1.4 |
| CH Module 1 | m1-ch | 1.5 |
| CH Galenic Form | m1-ch-galenic-form | 1.0 |
| CH Galenic Form | m1-ch-galenic-form | 1.0.1 |
| CH Galenic Form | m1-ch-galenic-form | 1.1 |
| CH Galenic Form | m1-ch-galenic-form | 1.3 |
| CH Swiss Responses | m1-ch-responses | 1.0 |
| CH Additional Data | m1-ch-additional | 1.0 |
| CH Common Form | m1-ch-common-form | 1.0 |
| CN Module 1 v1.0 | m1-cn | 1.0 |
| EAEU Module 1 Envelope Information | envelope-eaeu | 1.0 |
| EAEU Module 1 Envelope | eaeu-envelope | 1.0 |
| EAEU Leaf | eaeu_leaf | 1.0 |

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| Quality Overall Summary | m2-3-quality-overall-summary | 1.0 |
| Drug Substance | drug_substance | 1.0 |
| Solvent | drug_solvent | 1.0 |
| EU Module 1 | m1-eu | 1.0 |
| EU Module 1 v.1.1 | m1-eu | 1.1 |
| EU Module 1 v.1.2.1 | m1-eu | 1.2.1 |
| EU Module 1 v.1.3 | m1-eu | 1.3 |
| EU Module 1 v.1.4 | m1-eu | 1.4 |
| EU Module 1 v.2.0 | m1-eu | 2.0 |
| EU Module 1 v.3.0 | m1-eu | 3.0 |
| EU Module 1 v.3.0.1 | m1-eu | 3.0.1 |
| EU Module 1 v.3.1 | m1-eu | 3.1 |
| EU Module 1 Envelope Information | envelope | 1.0 |
| EU Module 1 Envelope | eu-envelope | 1.0 |
| EU Module 1 Envelope Information | envelope | 1.2.1 |
| EU Module 1 Envelope Information | envelope | 1.3 |
| EU Module 1 Envelope Information | envelope | 1.4 |
| EU Module 1 Envelope Information | envelope | 2.0 |
| EU Module 1 Envelope Information | envelope | 3.0 |
| EU Module 1 Envelope Information | envelope | 3.0.1 |
| EU Module 1 Envelope Information | envelope | 3.1 |
| EU Module 1 Country-Specific Information | eu_module_1_country_specific_information | 1.0 |
| EU Module 1 Country-Specific Information | eu_module_1_country_specific_information | 1.2.1 |
| EU Module 1 Country-Specific Information | eu_module_1_country_specific_information | 2.0 |
| EU Module 1 Country-Specific Information | eu_module_1_country_specific_information | 3.1 |
| EU Responses to Questions | m1-responses | 1.0 |
| EU XML Application Form | eu_xml_application_form | 1.0 |
| EU XML Application Form | eu_xml_application_form | 2.0 |
| EU Additional Information | m1-additional | 1.0 |
| EU Additional Information | m1-additional | 1.2.1 |
| EU Additional Information | m1-additional | 2.0 |

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| EU Additional Information | m1-additional | 3.0 |
| EU Additional Information | m1-additional | 3.1 |
| EU Responses | m1-responses | 1.2.1 |
| EU Responses | m1-responses | 2.0 |
| EU Responses | m1-responses | 3.0 |
| EU Responses | m1-responses | 3.1 |
| EU Module 1 Labelling Information | m1-3-1-spc-label-pl | 1.0 |
| EU Module 1 Labelling Information | eu_module_1_labeling_information | 1.0 |
| EU Module 1 Labelling Information | m1-3-1-spc-label-pl | 1.1 |
| EU Module 1 Labelling Information | eu_module_1_labeling_information | 1.1 |
| EU Module 1 Labelling Information | m1-3-1-spc-label-pl | 1.2.1 |
| EU Module 1 Labelling Information | m1-3-1-spc-label-pl | 2.0 |
| EU Module 1 Labelling Information | m1-3-1-spc-label-pl | 3.0 |
| EU Module 1 Labelling Information | m1-3-1-spc-label-pl | 3.1 |
| EU Module 1 Labelling Information | eu_module_1_labeling_information | 1.2.1 |
| EU Module 1 Labelling Information | combined | 3.1 |
| EU PIM Labelling | m1-3-1-pim | 1.0 |
| EU PIM Labelling | eu_pim_labeling | 1.0 |
| EU PIM Additional Documents | eu_pim_additional_documents | 1.0 |
| EU Responses to Questions | eu_responses_to_questions | 1.0 |
| GCC Module 1 | m1-gc | 1.2 |
| GCC Module 1 | m1-gc | 1.5 |
| GCC Module 1 Envelope | gc-envelope | 1.2 |
| GCC Module 1 Envelope Information | envelope-gc | 1.2 |
| GCC Module 1 Envelope Information | envelope-gc | 1.5 |
| GCC Responses | gc-m1-responses | 1.2 |
| GCC Additional Data | gc-m1-additional | 1.2 |
| GCC Country-Specific Information | gc_module_1_country_specific_information | 1.2 |
| GCC Label | gc_module_1_label | 1.2 |
| BA Module 1 Envelope Information | m1-ba | 1.0 |
| BA Additional Information | ba-m1-additional | 3.1 |
| BA Responses | ba-m1-responses | 3.1 |
| BA Module 1 Country-Specific Information | ba_module_1_country_specific_information | 3.1 |

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| BA Module 1 Labelling Information | ba-m1-spclabelinfo | 3.1 |
| BA Module 1 | envelope-ba | 3.1 |
| HR Module 1 v.1.4 | m1-hr | 1.4 |
| HR Module 1 EU Country-Specific Information | hr-m1-eu-country-specific_information | 1.0 |
| HR Responses | m1-hr-responses | 1.0 |
| HR Module 1 Labelling Information | hr-m1-3-1-spc-label-pl | 3.1 |
| HR Additional Data | hr-m1-additional | 1.0 |
| JO Module 1 | m1-jo | 1.0 |
| JO Module 1 | m1-jo | 1.1 |
| JO Module 1 JO Envelope Leaf | jo-envelope | 1.0 |
| JO Module 1 Envelope Information | envelope-jo | 1.0 |
| JO Product Information | jo_pi_doc | 1.0 |
| JO Specification Documents | jo-spc-doc | 1.0 |
| JO Label Documents | jo-label-doc | 1.0 |
| JO Patient Information Leaf | jo-pil-doc | 1.0 |
| JO Additional Information | jo-additional | 1.0 |
| JP Module 1 | m1-jp | 1.1 |
| Japanese Leaf | japanese_leaf | 1.0 |
| SG Module 1 | m1-sg | 1.0 |
| TH Module 1 | m1-th | 0.92 |
| TH Module 1 | m1-th | 1.0 |
| TH Responses | m1-th-responses | 1.0 |
| TH Additional Data | m1-th-additional | 1.0 |
| TN Module 1 | m1-tn | 1.1 |
| TW Module 1 | m1-tw | 1.0 |
| UA Module 1 | m1-ua | 1.0 |
| UA Responses | m1-ua-responses | 1.0 |
| UA Module 1 Envelope Information | envelope-ua | 1.0 |
| UA Module 1 Envelope | ua-envelope | 1.0 |
| UA Module 1 Additional Data | m1-ua-additional | 1.0 |
| US Module 1 v2.01 | m1-us | 1.0 |
| US Module 1 v3.3 | m1-us | 3.3 |
| US Module 1 Application | m1-us-meta-data-application | 3.3 |

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| US Admin Forms | m1-us-admin-form | 3.3 |
| US Forms | m1-us-form | 3.3 |
| Promotional Material Audience Type | m1-15-promotional-material | 3.3 |
| Promotional Material Doc Type | m1-15-2-materials | 3.3 |
| Promotional Material Type | m1-15-2-1-material | 3.3 |
| WHO Module 1 | m1-who | 1.0 |
| ZA Module 1 | m1-za | 1.0 |
| ZA Module 1 | m1-za | 2.1 |
| ZA Module 1 | m1-za | 3.1 |
| Clinical Indication | clinical_indication | 1.0 |
| Clinical Indication | clinical_indication | 1.1 |
| Drug Substance | drug_substance | 1.0 |
| Drug Product | drug_product | 1.0 |
| Drug Product | drug_product | 1.1 |
| Excipient | excipient | 1.0 |
| Excipient | excipient | 1.1 |
| ICH Study Report | study_report_leaf | 1.0 |
| Study Report | study_report_leaf | 1.1 |
| Study Report | study_report_leaf | 3.0 |
| Module 4 Studies | module_4_studies | 1.1 |
| Module 4 Studies | module_4_studies | 1.2 |
| Module 5 Studies | module_5_studies | 1.1 |
| Module 5 Studies | module_5_studies | 1.2 |
| Module 5 Studies | module_5_studies | 1.3 |
| Module Studies | module_studies | 1.0 |
| Module Studies | module_studies | 3.0 |
| Node Extension | node-extension | 1.0 |
| Quality Appendix | quality_appendix | 1.0 |
| Quality Appendix | quality_appendix | 1.1 |
| Quality Introduction | m2-3-introduction | 1.0 |
| Quality Overall Summary | m2-3-quality-overall-summary | 1.0 |
| Study Data | study_data_folder | 1.0 |
| Study Data | study_data_folder | 3.0 |

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| Study Patient Information | study_patient_information_folder | 1.0 |
| Study Patient Information | study_patient_information_folder | 3.0 |
| Study Patient Information | study_patient_information_leaf | 1.0 |
| Study Report | stf | 1.0 |
| Study Report | stf | 1.1 |
| Study Report | stf | 3.0 |
| Study Report | stf | 5.0 |

# Chapter 14. Assembly Node Creation by API Request

Use API request to populate the default values of the assembly node automatically.

When an assembly node is created by an API request but with a value missing for a field, the default value of the field

(if it exists) is automatically populated by the system for that field. For example, the Abbreviated Name is automatically taken as a value from the Name Field.

***Note:*** *When a field does not have a default value, no value is assigned to a field.*

# Chapter 15. Ennov InSight Publishing Best Practices

The publishing best practice topics provide recommendations to enable you to take advantage of built-in efficiencies in Ennov InSight.

The following topics are intended to be used in conjunction with the Ennov InSight user documentation. They provide best practices and process recommendations for using the Ennov InSight suite to create and manage eCTD submissions to regulatory authorities. It provides general best practice usage guidelines as well as module-by-module tips and tricks to best leverage the lifecycle management aspects and assembly features of the Ennov InSight suite. It is not intended to replace the user documentation. Specific details on how to perform individual functions are included in the online help, not in these Best Practice guides. For Registration Best Practice guides, see Registration Best Practices.

| Name |
| --- |
| Assembly Template Structures |
| Complying with the Study Data Technical Conformance Guide v4.5 |
| Configuring Templates |
| Creating Assemblies |
| Creating IMDRF Assembly Templates for Health Canada |
| Creating US Grouped Submissions |
| CTD Based Assembly |
| Data Management |
| FDA eCTD Submission Standards v3.9 |
| Guide to Managing BREXIT Related Regulatory Activities |
| Hyperlinking Best Practice |
| Importing Existing eCTDs |
| Maintaining Currency with Specifications |
| Pre-Submission Activities |
| Publishing Best Practice |
| Publishing Guidelines |
| Relate Sequence to Multiple Supplements Same Application |
| Table of Contents and Bookmark Handling |
| Taiwan eCTD-R2 - DTD update for Taiwan 2.0 Specifications Compli- ance |

| Name |
| --- |
| Troubleshooting Publishing |
| UUID for an EU eCTD Assembly |
| WHO eCTD - Adding Application Sub Type |
| Working in the Assembly |
| ZA v3.1 June 2025 XML Updates |