BEST PRACTICE: ASSEMBLY TEMPLATE STRUCTURES

1 Contents

2 Revision History

When Ennov releases a new version of Ennov InSight, they issue Release Notes which explain the new features and updates. The Ennov Business Consulting Team reviews the Release Notes against each Best Practice to determine any impact to the document:

- Impact = Release notes-documented upgrade changes this Best Practice
- No Impact = Release notes-documented upgrade changes do not affect this Best Practice

When Release Notes impact Best Practice documentation, Ennov recommends that clients review the entire Release Notes for a full understanding of all changes associated with this Best Practice documentation.

Software Version	Release/ Revision Date	Summary of Change(s) (Refer to Release Notes for Full Description)
v7.3.1	28-Jun-2024	Update Best Practice for Ennov rebranding & for v7.3.1 – No Impact
v7.2	20-Jun-2023	Update Best Practice for v7.2 – No Impact
v7.1	13-Jan-2022	Update Best Practice for v7.1 – No Impact
v7.0	25-May-2021	Update Best Practice for v7.0 – Impact

3 Assembly Template Structures

The prepackaged assembly templates provided with Calyx RIM should be configured to meet your individual business needs. If you have a well-structured Documentum docbase, with eCTD information included in document attributes, these can be mapped at the publication level of the template so that the individual Assembly components will inherit these values upon Assembly creation and Publishing.

Leaf elements are included in the Assembly template at locations recommended by the ICH granularity document. While the DTD(s) will allow for inclusion of leaf elements at higher levels in the Assembly (and resulting XML), the granularity document provides recommendations as to where documents should and should not be included. There are sections, particularly in the Quality area, where there is flexibility in the granularity that may be used. This should be decided based on the complexity of the product, the reviewability of the content in its component parts and the impact of updates to content over the lifecycle. The templates can be adjusted to meet internal corporate standards as necessary.

The templates are designed to produce output in compliance with the granularity document as well as the DTD. The system will not prohibit the user from creating leaf elements at a higher level, however, recommends consulting with your review division prior to including a document of higher granularity than what is defined in the granularity document and the Assembly templates. If agreements have been made with reviewing decisions regarding granularity, the templates can be adjusted to address any granularity needs. Keep in mind, that the order in which components are presented within each section of the eCTD is dictated by the DTD. If any higher-level leafs are to be included in a section that also includes subsections, the leafs should be the first children of the parent folder followed by the subsection folders in their correct order. Placing these out of order will result in a warning during publishing that the structure differs from the expected output.

The Assembly templates provided include all potential sections of an eCTD. Unless the folder has a specific extended type, it is expected that that folder will appear in the assembly only once or not at all. The system will not prohibit duplication of folders, but if an 'invalid' structure is created, at publishing time, this will be recorded in the publishing log. Any sections that are not relevant to your specific submission should be removed from the Assembly prior to publishing. The eCTD Wizard and Prepare for Publishing functions can assist in this task.

You can specify assembly-level and study report meta-data in the template's Publication Settings with default DMS mappings and/or static text to eliminate the need for users to re-enter standard information each time a new Assembly is created. The templates include folders and leaf elements with specific sub-types to capture drug-specific meta-data, such as drug substance, manufacturer, clinical indication, etc. The values for these attributes may be mapped to the attributes of the documents that will be included in these sections if the assembly is created from the template.

Calyx RIM supports the concept of Major and Minor Division folders. This concept provides a means to "group" related information and leverage this grouping for common variables. In the templates, the Module 1-5 folders are set as Major Divisions. This allows those folders' attribute to be used as Major Division variables that can be resolved and stamped in Overlays, Margin Cross Reference resolution strings, TOCs, tab sheets and Cover Pages. In Modules 1 through 3, the lowest-level folders have been set as Minor Divisions. In Modules 4 and 5, the sample study report folders are set as Minor Divisions. This allows the use of Minor

Division attributes (CTD Section numbers) to be used as variables on overlays, tab sheets, cover pages, Margin Cross Reference resolution strings, and TOCs.