Creating Assemblies

CALYX.AI

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2 Creating Assemblies

The Create Submission Wizard is provided to assist you with the process of creating submissions. The wizard creates many of the supportive entities and relationships within Calyx RIM that enable the overall lifecycle management of the entire Application. It is highly recommended that Create Submission Wizard is used when setting up new Assemblies.

When creating a completely new application, at the final confirmation screen, you can click on the link to create the new assembly using the eCTD Wizard or create the assembly using an existing template. At any point after the assembly has been created, you may re-execute the Wizard or import sections from the templates to adjust the structure of the assembly.

If a new Sequence is being created for an existing Application, and the submission has spanned multiple specification versions, please follow the best practices for that specific region.

- Updating Existing CH Submissions Migrated to M1 v1.4
- Updating Existing Canada Submissions Migrated to the 2.2 Schema
- Transitioning to Valid Values v5.0 & Study Data Specification v2.0
- Updating Existing EU Submissions Migrated to v3.0
- Updating Existing US Submissions Migrated to v2.3 (DTD v3.3)
- Updating an AU Submission to Migrate to v3.0
- Updating Existing TH Submissions Migrated to v1.0
- Updating Existing ZA Submissions Migrated to v2.1

When adding an amendment or major update to an existing application, the submitted view of the application as it currently exists is used to create a working view, so you can perform lifecycle operations on previously submitted content directly. The wizard may be re-executed at this point to add any sections that were not included in the previous sequence(s), or you may import sections from the template as desired. Please review the regional best practice guides for additional important information.

The eCTD Wizard uses the region indicated during the submission creation step to provide relevant prompts for information.

Note: The administrator may configure which templates are applicable for which regions and/or sections within regions.

The wizard prompts you to confirm or enter the administrative information for the sequence. Some values may be derived from the supporting RIM entities (Application, Event, Sequence) or the submitted view for existing submissions. These are displayed, and you can accept or override them.

The wizard then displays the expanded Module 1 through 5 folder structure with check boxes so you may indicate which sections are applicable for the current submission. Checking a lower level folder will automatically check the necessary higher-level folders to maintain the required hierarchy. Selecting a folder with descendent elements will automatically check all descendent folders.

If your selection includes repeatable sections (those with extended attributes: 2.3.S, 2.3.P, 2.7.3, 3.2.S, 3.2.P, 3.2.P.4, 3.2.A.1-3, 5.3.5), the next two windows will prompt you to indicate:

- The number of sets of each type of information that are included in the sequence, and
- The extended attribute values

At the completion of the eCTD Wizard, you can review the Assembly, or immediately run the Study Report Wizard. The Study Report Wizard enables you to indicate which sections of Module 4 and 5

include study reports, how many reports are in each section, and to populate the information for each study report.

After the Assembly is created with the Wizard, confirm that all of the preset information from the template is relevant to the current assembly, such as: binding rules, output location, and publishing settings. If attributes are not captured in the DMS and therefore could not be mapped in the template, and were not completed with the wizard, complete the additional eCTD attributes at this time for the following elements:

- 1 Administrative Information and Prescribing Information (different attributes associated with each
  region to provide overall submission meta-data, further discussed for each region below)
- 1.1 Forms (all subfolders in this section have extended attributes to define the form type and application number, where applicable) (US M1 3.3 Template Only)
- 1.15 Promotional Material (Promotional Material Audience Type) (US M1 3.3 Template Only)
- 1.15.2 Materials (Promotional Material Doc Type) (US M1 3.3 Template Only)
- 1.15.2.1 Material (Promotional Material Type, Promotional Material ID, Issue Date) (US M1 3.3 Template Only)
- 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 product name)
- 3.2.A.2 Adventitious Agents (manufacturer, substance, dosage form, and product name)
- 5.3.5 Reports of Efficacy and Safety Studies (indication)
- Regardless of whether DMS mappings or static values are used for these components, when multiple sets of information are provided in this sequence a folder for each set of information is included in the Assembly. If changes to the number of sets of information or attribute values are necessary after completing the wizard, it can be re-executed at any time. Or, you can duplicate the folder within the Assembly and edit the values as necessary, such as when an additional drug substance manufacturer is added. See the following Module-specific topics for additional information on managing the repeating sections.