



CALYX™

Pre- Submission Activities

CALYX.AI

Revision History

When Calyx releases a new version of InSight, they issue Release Notes which explain the new features and updates. Calyx 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, Calyx 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)
v6.2 CHF6	24-Mar-2021	Update Best Practice for Calyx Rebranding – No Impact
v6.2 CHF6	21-Oct-2020	Update Best Practice for v6.2 CHF6 – No Impact
v6.2 CHF5	11-Sep-2020	Update Best Practice for v6.2 CHF5 – No Impact
v6.2 CHF4	28-Feb-2020	Update Best Practice for v6.2 CHF4 – No Impact
v6.2 CHF3	27-Jun-2019	Update Best Practice for v6.2 CHF3 – No Impact
v6.2 CHF2	15-Feb-2019	Update Best Practice for v6.2 CHF2 – No Impact

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2 Document Purpose

The purpose of this document is to provide a Best Practice guide for the management of pre-submission activities, such as briefing documents and meeting requests, in preparation for a major filing for an initial application within an Application in Calyx RIM.

2.1 Scope

This document covers the management of activities prior to submitting the initial Application.

3 Data Administration Activities

3.1 Event Type

A new Event Type should be created (example: Pre-Submission) as required by your organization. This Event Type will be used to capture Pre-Submission activities.

3.2 Secondary Event Type

Secondary Event Types should be created to further classify the type of Pre-Submission (example: Briefing Package, Scientific Advice) as required by your organization. This should be mapped to the parent Event Type.

3.3 Sequence Filing Type

Review Data Admin to see if the appropriate Filing Type exists. Where one is not available, a new value should be created (example: Pre-Submission).

4 General Considerations

Pre-Submission activity (e.g. Scientific Advice, Briefing Package, Communication with the Health Authority) will be tracked as a standalone Event under the Application.

If an Application does not exist within Calyx RIM, an initial Application will be created.

Pre-Submission sequence numbering is dependent on the region the Application is created for.

Note:**• eCTD:**

For example: If utilizing DTD v3.3, Sequence should be coded as “original application” for submission-type, and “presubmission” for submission-subtype. The original application will use the next available Sequence number depending on the number of submitted “presubmissions”.

Submission Entities must take the default Submission ID (Check the Lifecycle box when using Change Submittal Status Wizard for the Initial Application).

• Non-eCTD:

For example: Paper and/or NeeS Submission, the Submission Entities can take the default Submission ID. Do Not Check the Lifecycle box when using Change Submittal Status Wizard. The first eCTD Submission (Initial Marketing Application) will take the next available submission ID.

5 Best Practice for creating Pre-Submissions

The Pre-Submission activity is covered under an existing Application in the appropriate Product Family.

1. Create an Event with the following attributes:
 - **Event Name:** follow organisation naming convention (e.g. Briefing Book/Scientific Advice)
 - **Event Type:** e.g. Pre-Submission
 - **Secondary Event Type:** e.g. Scientific Advice, Briefing Package
 - Complete other fields as required by your organization.
2. Create a **Sequence** as required by your organization.
 - Complete fields as required by your organization.
3. Create **Assembly** as required by your organization.
4. On Submission, run the Submittal Status Wizard.
5. Once approval is received:
 - a. Close and Approve the Initial Event.
 - b. Create Reference as required by your organization.

Planning and Tracking activities will follow standard Calyx RIM processes.