



BEST PRACTICE: UPDATE THE UUID FOR AN EU ECTD ASSEMBLY

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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	11-May-2023	Update Best Practice for 7.2 - Impact
v7.0	30-Apr-2021	Update Best Practice for 7.0 - No Impact
N/A	24-Mar-2021	Update Best Practice for Calyx Rebranding – No Impact
v6.2 CHF6	21-Oct-2020	Update Best Practice for v6.2 CHF5 – No Impact
v6.2 CHF5	09-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

3 Document Purpose

The purpose of this document is to provide Best Practice guidance on updating the UUID field in the eCTD metadata of EU eCTD submissions following the 3.0.1 or 3.0.3 EMA specification. This could be due to copying an existing Assembly, for imported eCTD Applications, or creating UUID values outside of Calyx RIM.

3.1 Scope

This document covers EU eCTD Assemblies, copied or imported, compliant with either 3.0.1 or 3.0.3 EU specification. The document also covers EU Assemblies where Calyx RIM is not used to create the UUID value. If this process is not followed the UUID value presented in the M1 envelope may not be unique (in the case of a copied Assembly) or match the eCTD itself (imported Assembly).

4 UUID Update Process

4.1 Copied Assembly

The following steps should be taken:

1. Navigate to the copied Assembly.
2. Navigate to the Envelope Information Folder.
3. Delete the Envelope Information folder.
4. Select the eCTD Wizard.
5. Select the Appropriate values in the Select Region screen.
6. Select Next.
7. Select the Appropriate values in the Select Attributes screen*.
8. Select Next.
9. Complete the Create eCTD wizard and update as required.

On completing the steps within the eCTD wizard, the UUID captured in the M1 envelope will match that of the parent Application.

**At this point the UUID field now matches the UUID of the parent Application.*

4.2 An Imported eCTD

When an eCTD is imported against an existing Application, the import process will include a warning to indicate that the UUID of the imported eCTD does not match that of the Application. To ensure that the UUID matches, the following steps should be taken prior to the creation of a new Sequence Assembly:

1. Navigate to the parent Application.
2. Select the modify button.
3. Update the UUID value to match that of the imported eCTD*.

**The user must have Administrator rights on the Application to perform this change.*

4.3 UUID Values Generated Outside of Calyx RIM

Prior to the creation of the first Sequence Assembly the following steps should be taken:

1. Navigate to the parent Application.
2. Select the modify button.
3. Update the UUID value to match that of the generated UUID*.

**The user must have Administrator rights on the Application to perform this change.*