



# BEST PRACTICE: RELATING A SEQUENCE TO MULTIPLE SUPPLEMENTS IN THE SAME APPLICATION

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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.

<b>Software Version</b>	<b>Release/ Revision Date</b>	<b>Summary of Change(s) (Refer to Release Notes for Full Description)</b>
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 Document Purpose

The following procedure, *Relating a Sequence to Multiple Supplements in the Same Application*, provides Best Practice guidance for creating a US 3.3 submission that updates multiple existing Supplement sequences within a single NDA or BLA application. Examples include a manufacturing change or a study report that applies across Supplements.

## 4 Relating a Sequence to Multiple Supplements in the Same Application

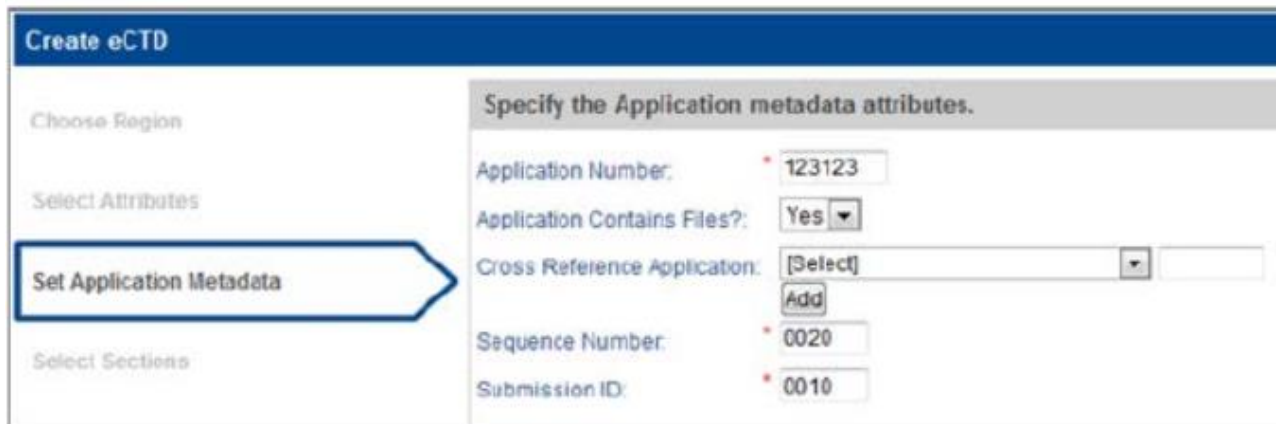
For this example, we are assuming that a manufacturing change is being submitted as an amendment. The change is in sequence 0020 and affects two different Supplements that were submitted in sequences 0010 and 0015. Specific metadata must be added to sequence 0020 that relates it to 0010 and 0015.

To create a US 3.3 submission that updates multiple, existing Supplement sequences within a single NDA or BLA application:

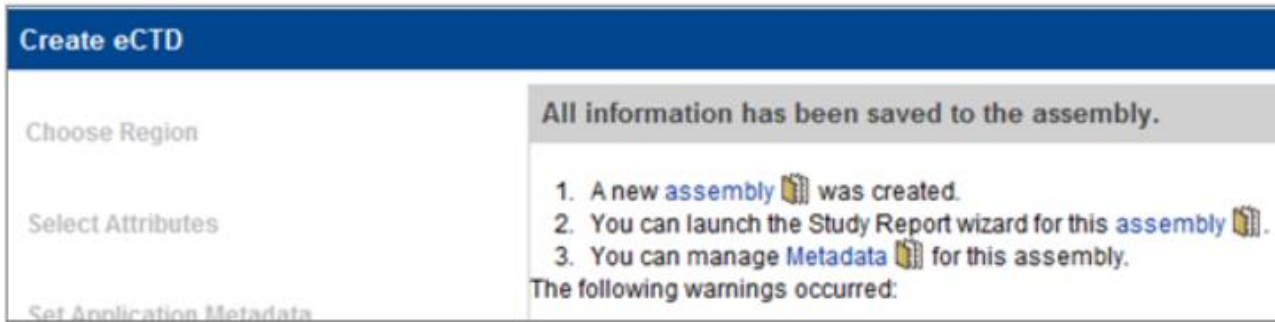
1. Browse to the Application where the new submission has to be created.
2. Create a new Sequence and Working Assembly.
3. Make sure you have the correct XML definitions in the assembly publishing library:



4. Run the **Create eCTD** wizard to create/update the structure and metadata of the assembly. Within the **Create eCTD** wizard you will be prompted to specify the metadata for the application containing files.
5. Enter the Application Number of the current application. Enter the Sequence Number (0020 in this example). Specify the Submission ID to be equal to the Sequence Number of one of the previous Supplements that this submission will update (0010 in this example).

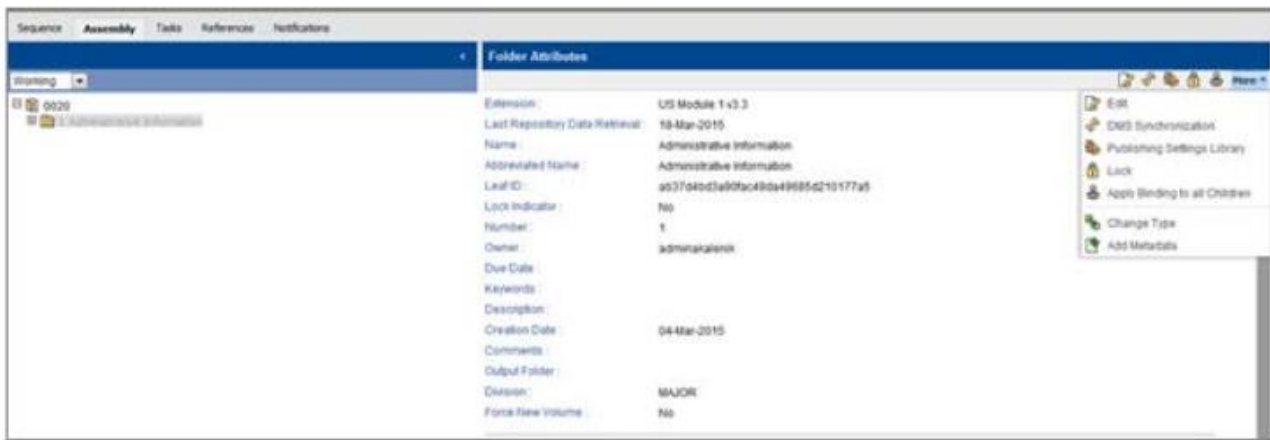


6. On the **Summary** page of the **Create eCTD** wizard, click the link to manage the Metadata.

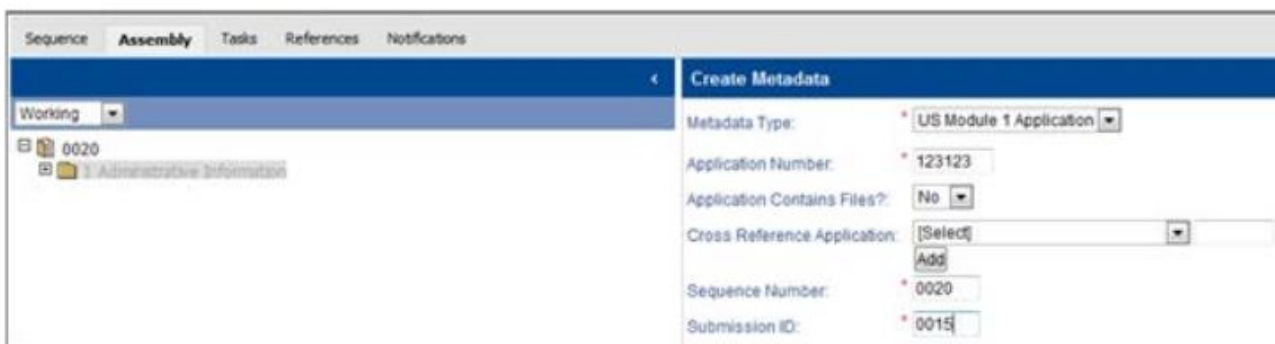


When you click on this link, you will be taken to the assembly folder with the US Module 1 v3.3 extension.

7. Choose the **Add Metadata** menu option to add metadata for other Supplement sequence that will be affected by this submission:



8. Specify the metadata for the other Supplement (0015 in this example). The sequence number is the same as the one entered in Step 5 above (0020).



You will be able to see all the metadata added in the Regional Information tab from the folder with the US Module 1 v3.3 extension.

9. Any corrections to it may be made by clicking the Application Number hyperlink on the tab:

Regional Information				
Application Number	Metadata Type	Application Contains File...	Sequence Number	Submission ID
123123	US Module 1 Application	Yes	0020	0010
123123	US Module 1 Application	No	0020	0015

There is no need to duplicate the 356h form. The leaf for the form will be published to the output XML under the section related to the application-containing-files = "true".

10. It is recommended to specify the Application Number extended attribute on the folder for the 356h form:

*Note: When this Working Assembly is added to lifecycle, the metadata related to it will be the one associated with the Submitted View. When the next working assembly is created, the metadata is automatically copied from the metadata of the Submitted View. Be sure to remove unnecessary records from the metadata associated with the assembly.*