Submitting multiple sets of data to FDA for the same study within the same subsection of the CTD

Jiang Xu, Lina Cong, Office of Business Informatics/Office of Strategic Programs/CDER/FDA

Background

- There is a business need of submitting multiple sets of data package for the same study.

  Example #1: A study has multiple parts by design. Each part has their own data package. For example, a study has part A and part B etc.

  Example #2: Different time-specific analyses are needed for the same study. For example, interim analysis, final analysis etc.

- Each set of data needs to have their own lifecycle and needs to be displayed as different sets of data with eCTD viewer.
- Currently, there is no guideline from ICH or FDA for such submissions.
- Improperly submitting different sets of data for the same study can cause eCTD validation error of 1737.
- CDER eData often receive inquiries about how to submitting multiple sets of data for the same study.

Option 1: Submitting multiple sets of data under the same STF

- Creating sub-folders for each set of data.

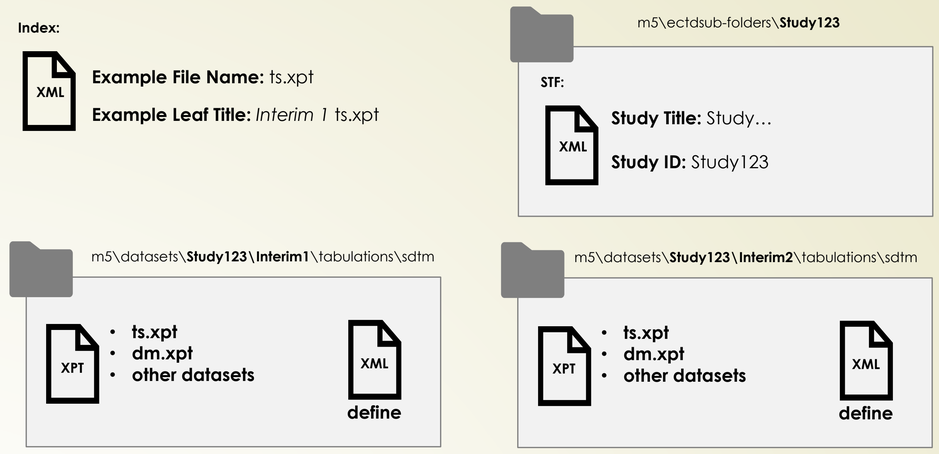
  Example of sub-folders
  m5\datasets\studyid\tabulations\sdtm**parta**
  m5\datasets\studyid\tabulations\sdtm**partb**
  m5\datasets\studyid**parta**\tabulations\sdtm
  m5\datasets\studyid**partb**\tabulations\sdtm

- Assigning different leaf titles for each set of data. This will help to avoid eCTD validation error of 1737.
- Creating sub-folders and assigning different leaf titles will help reviewers to distinguish different sets of data.
- When assigning leaf titles, it is good practice to be consistent with how the different sets of data are described in the study report.

Examples of leaf titles for datasets

interim-ae.xpt
interim-dm.xpt
interim-lb.xpt
interim-define.xml
final-ae.xpt
final-dm.xpt
final-lb.xpt
final-define.xml

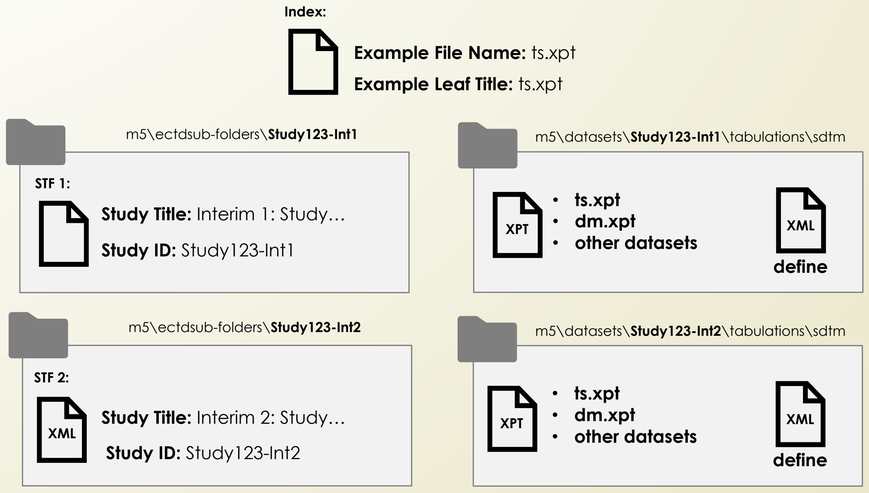
Example of Option 1



Option 2: Submitting multiple sets of data under different STFs

- Using different STFs for each set of data – treat each set of data as different studies.
- No need to create sub-folders for each set of data.
- No need to assign different leaf titles for each set of data.
- eCTD validation requires matching Study IDs between STF and TS.xpt. The ts.xpt needs to contain either a study ID (STUDYID) or Sponsor Reference ID (SPREFID) value that matches with the STF study ID

Example of Option 2



Summary

In summary, creating sub-folders and assigning different meaningful leaf titles for each set of data are important when using option 1 for submissions of multiple sets of data for the same study. When option 2 is used for submissions of multiple sets of data, it is important to make sure that study IDs match between STF and ts.xpt for each set of data.

Contact: edata@fda.hhs.gov