

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

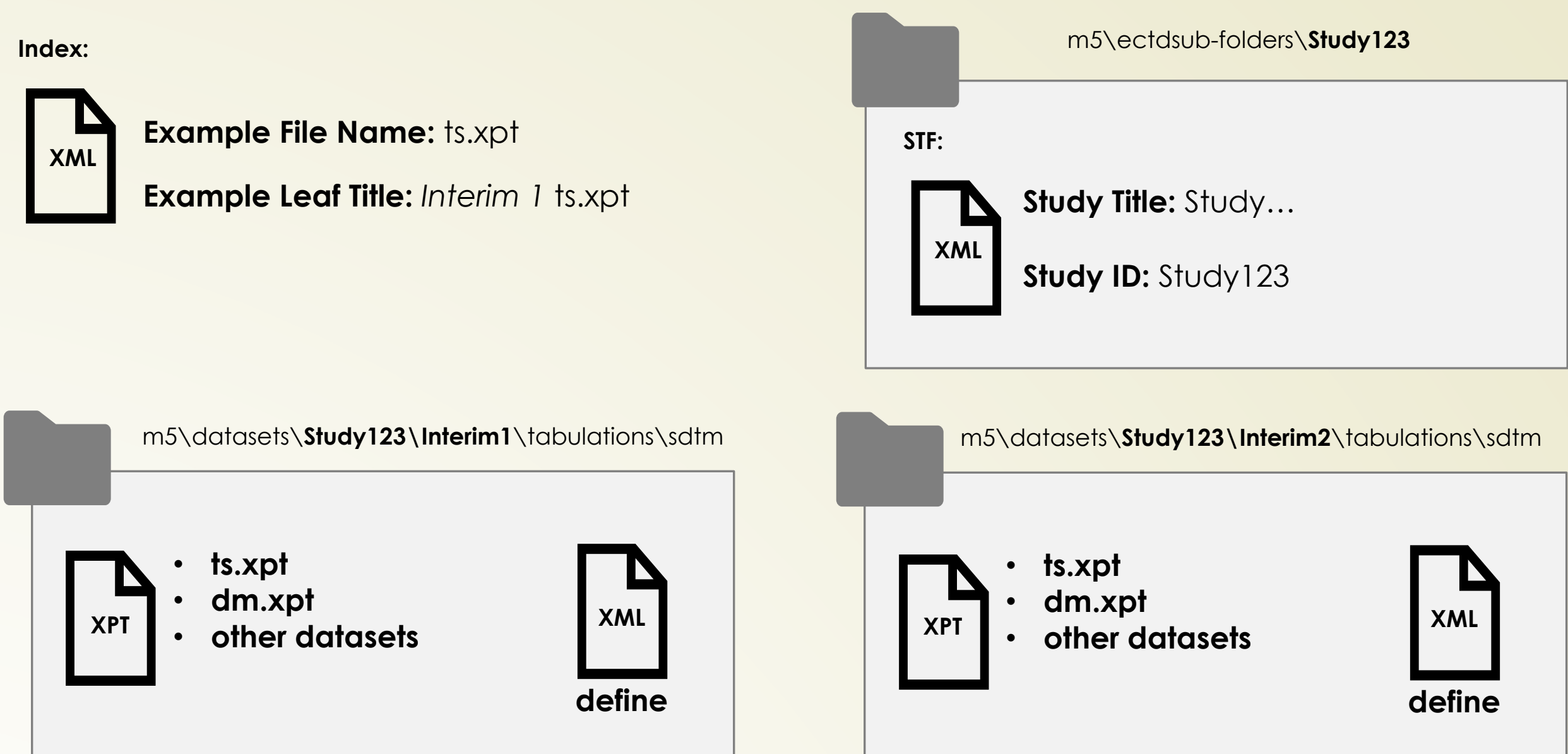
```
m5\datasets\studyid\tabulations\sdtm\parta
m5\datasets\studyid\tabulations\sdtm\partb
m5\datasets\studyid\parta\tabulations\sdtm
m5\datasets\studyid\partb\tabulations\sdtm
```

- 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
```

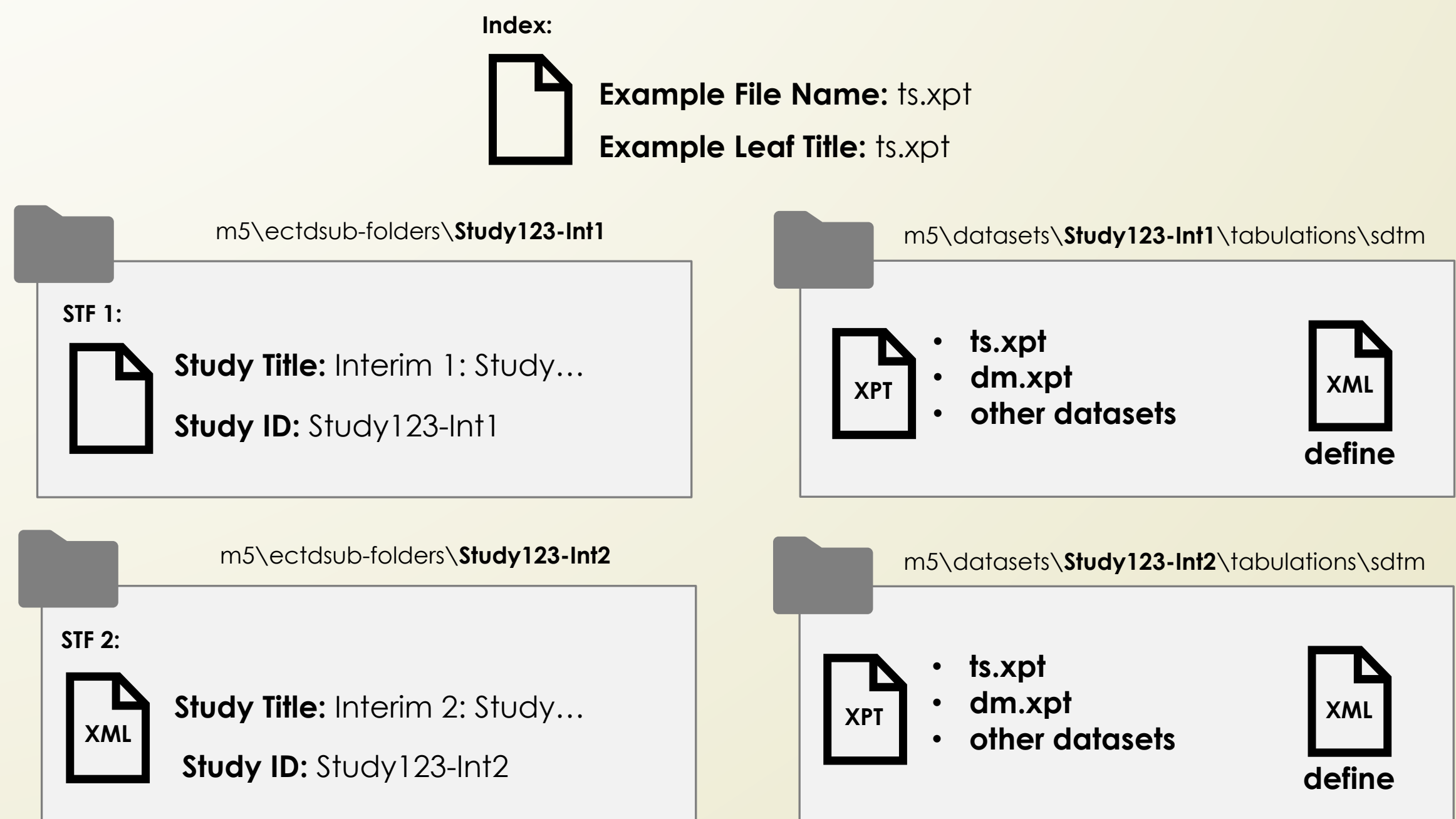
Example of Option 1



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