U.S. FOOD & DRUG ADMINISTRATION

FDA Study Data Technical Conformance Guide v4.4

October 2019 Edition Webinar

November 22, 2019

Helena Sviglin

CDER Office of Strategic Programs, sdTCG Chair

Topics Covered in this Webinar

1. Study Data Technical Rejection Criteria (TRC)
   - *Heather Crandall, CDER Office of Bioinformatics*

The Study Data Technical Conformance Guide Working Group has worked closely with the TRC Development Group to develop a communication plan to Industry about how TRC will work

Topics Covered in this Webinar

1. Using the Simplified ts.xpt for Nonclinical Submissions
   - *Stephanie Leuenroth – Quinn, CDER Office of New Drugs*

Development of TRC has taken into account the realities of submitting study data in support of multiple nonclinical study and report types to FDA

Topics Covered in this Webinar

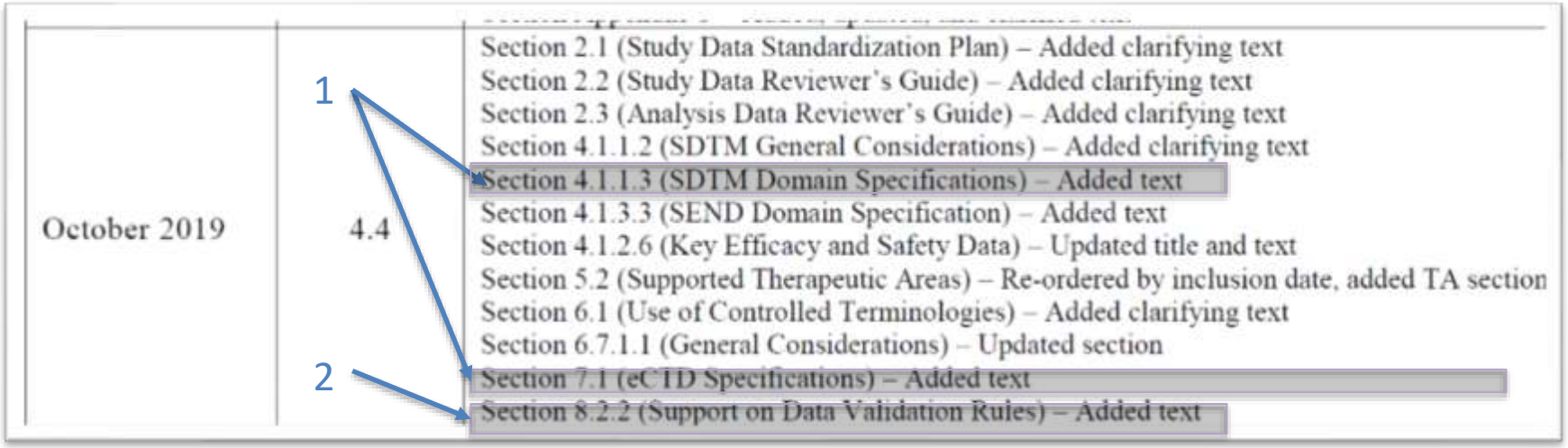
1. Demo of online TRC worksheet
   - *Heather Crandall*

The online TRC worksheet is designed to help Industry navigate the upcoming changes to the submission process with greater confidence. It is only a submission development aide and is not designed to be submitted to the FDA

Revision History

October 2019	4.4	Section 2.1 (Study Data Standardization Plan) – Added clarifying text Section 2.2 (Study Data Reviewer's Guide) – Added clarifying text Section 2.3 (Analysis Data Reviewer's Guide) – Added clarifying text Section 4.1.1.2 (SDTM General Considerations) – Added clarifying text Section 4.1.1.3 (SDTM Domain Specifications) – Added text Section 4.1.3.3 (SEND Domain Specification) – Added text Section 4.1.2.6 (Key Efficacy and Safety Data) – Updated title and text Section 5.2 (Supported Therapeutic Areas) – Re-ordered by inclusion date, added TA section Section 6.1 (Use of Controlled Terminologies) – Added clarifying text Section 6.7.1.1 (General Considerations) – Updated section Section 7.1 (eCTD Specifications) – Added text Section 8.2.2 (Support on Data Validation Rules) – Added text

Revision History



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This Document is incorporated by reference into the following Guidance Document(s):

Guidance for Industry *Providing Regulatory Submissions in Electronic Format – Standardized Study Data*

For questions regarding this technical specifications document, contact CDER at cder-edata@fda.hhs.gov or CBER at cber-edata@fda.hhs.gov

Study Data Technical Rejection Criteria

Heather Crandall

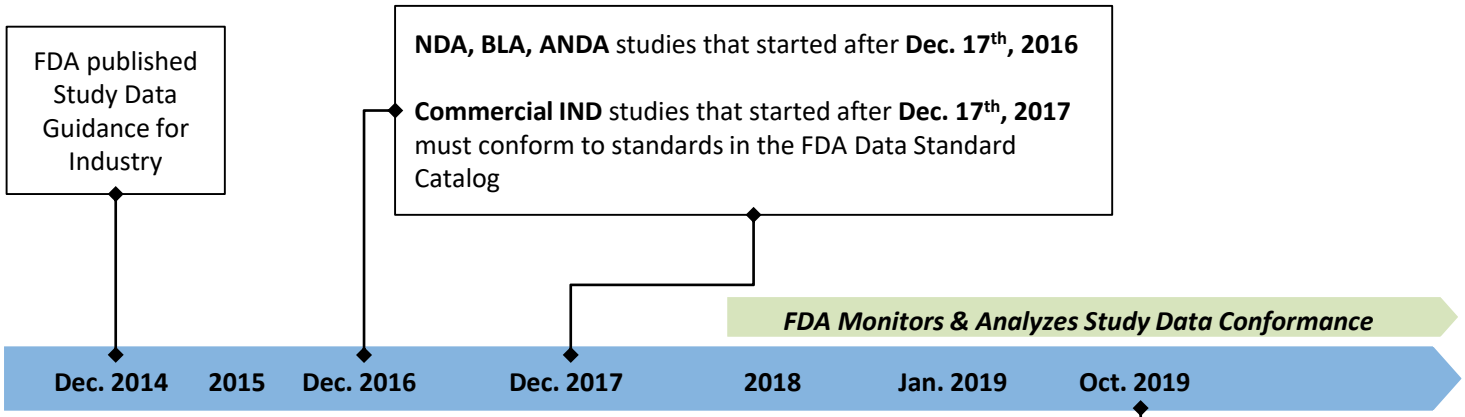
Operations Research Analyst,
DDMSS, OBI, OSP, CDER, FDA

Agenda

- Revised Technical Rejection Criteria for Study Data
- Tools for Industry and the Technical Rejection Criteria Self-Check Worksheet

Revised Technical Rejection Criteria for Study Data

Study Data Technical Rejection Criteria (SDTRC) Revisions



Significant Technical Rejection Criteria Revisions:

- FDA **will not accept** study data submissions not in compliance with FDA Data Standards Catalog
- FDA emphasized validation rules 1735 and 1789
- FDA introduced the Simplified TS File (simplified ts.xpt) to obtain Study Start Date

Technical Rejection Criteria for Study Data (Revised Jan. 2019)

Significant Technical Rejection Criteria Revisions:

- FDA included SPREFID as a valid source of Study ID in ts.xpt files
- FDA updated guidance for Simplified TS Files (simplified ts.xpt)

Technical Rejection Criteria for Study Data (Revised Oct. 2019)

Study Data Technical Rejection Criteria (SDTRC)

Error	Description	Severity
1734	A dataset named ts.xpt with information on study start date (SSD) must be present for each study in required sections	High
1735	The correct STF file-tags must be used for all standardized datasets and corresponding define.xml files in required sections	High
1736	For SEND data, a DM dataset and define xml must be submitted in required sections For SDTM data, a DM dataset and define.xml must be submitted in required sections For ADaM data, an ADSL dataset and define.xml must be submitted in required sections	High
1789	Study files must be referenced in a Study Tagging File (STF). STFs are not required for 4.3 Literature references, 5.2 Tabular listings, 5.4 Literature references, and 5.3.6 Postmarketing reports	High

References:

FDA Study Data Technical Rejection Criteria (Revised Jan. 2019); FDA Study Data Technical Rejection Criteria (Revised Oct. 2019)

Study Data Technical Rejection Criteria (SDTRC) Revisions (Oct. 2019)

Introduced the Simplified TS File (simplified ts.xpt) and TSVALNF

For a study without a valid SSD:

STUDYID	TSPARMCD	TSVAL	TSVALNF
study ID in STF	SSTDTC		Use the value 'NA'

Included SPREFID for Study ID matching

If a file is referenced within a study section in Module 4 or 5, a STF and ts.xpt must be present to identify the study ID and SSD to which the file belongs. The ts.xpt and STF need to contain matching study ID values.	If a file is referenced within a study section in Module 4 or 5, a STF and ts.xpt must be present to identify the study ID and SSD to which the file belongs. The ts.xpt needs to contain either a study ID (STUDYID) or Sponsor Reference ID (SPREFID) value that matches with the STF study ID.

Study Data Technical Rejection Criteria (SDTRC) Revisions - SPREFID

- Feedback from industry pointed out scenarios where ts.xpt study id (STUDYID) may not be able to be matched
  - Ex. when a study is bought by another company and the study id is already established

- Proposed solution with feedback was inclusion in TS of Sponsor Reference ID (SPREFID) parameter to match the STF study-id

- After analysis, SPREFID parameter matching with STF study-id added to October 2019 SDTRC revision
  - Allows for an alternate way for Sponsors provide a matching study id

SPREFID Analysis (CY2019 Q1-Q3) Summary

- Total number of non-clinical studies evaluated = 4631 studies
- 75.7% Studies where STUDYID in the ts.xpt file **Match** with STF study-id
- 14.7% Studies where STUDYID in the ts.xpt file **Do Not Match** with STF study-id
  - 8.6% Studies already contain SPREFID in the ts.xpt file
    - 6.1% Studies where SPREFID in the ts.xpt file **Match** STF study-id
    - 2.5% Studies where SPREFID in the ts.xpt file **Do Not** match STF study-id
- With SPREFID as a possible match to the STF study-id for Non-clinical NDA and Commercial IND studies, the **pass rate increases by 17.76%** (Revised Oct. 2019)

SPREFID Analysis (CY2019 Q1-Q3)

With SPREFID as a possible match to the STF study-id, the **pass rate increases by 6.09%** (Revised Oct. 2019)

	ANDA		BLA		NDA		Commercial IND		Total		
	m4	m5	m4	m5	m4	m5	m4	m5	m4	m5	Total
Total Number of clinical and non clinical studies in TRC Applicable sections	5	1104	61	305	313	1348	1269	226	1648	2983	**4631**
TS File do not Exist	0	147	0	48	18	133	47	50	65	378	**443**
TS File Exist	5	957	61	257	295	1215	1222	176	1583	2605	**4188**
• STF Study ID matches with TS STUDYID	5	897	60	224	215	1094	843	167	1123	2382	**3505**
• STF Study ID does not matches with TS STUDYID	0	60	1	33	80	119	379	9	460	221	**681**
• TS File contains SPREFID	0	0	0	0	78	0	320	1	398	1	**399**
• TS file SPREFID Match	0	0	0	0	39	0	242	1	281	1	**282**
• TS file SPREFID does not Match	0	0	0	0	39	0	78	0	117	0	**117**
Pass Rate without SPREFID	**100.00%**	**81.25%**	**98.36%**	**73.44%**	**68.69%**	**81.16%**	**66.43%**	**73.89%**	**68.14%**	**79.85%**	**75.69%**
Pass Rate with SPREFID	**100.00%**	**81.25%**	**98.36%**	**73.44%**	**81.15%**	**81.16%**	**85.50%**	**74.34%**	**85.19%**	**79.89%**	**81.77%**

Notes

1. Analysis includes NDA and Commercial IND non-clinical studies received by CDER between 1/1/2019 to 9/30/2019 (4631 studies)

Study Data Technical Rejection Criteria (SDTRC) Revisions (Oct. 2019) - SPREFID

Example in Revised TRC SPREFID for Study ID matching
A study in standardized format is submitted to FDA and the study files are referenced in a STF, a ts.xpt dataset is included in the study. The SPREFID in the ts.xpt dataset matches the study ID (study-id) in the STF. The Study Start Date in the ts.xpt is in SDTM or SEND format and the study begins after December 17, 2016, for NDAs, BLAs, and ANDAs (or December 17, 2017, for Commercial INDs).

- Additional parameter in the ts.xpt for matching study id with STF study-id to pass validation 1734
  - The SPREFID parameter allows for an alternate way for Sponsors provide a matching study id
  - Multiple SPREFID values are allowed in the ts.xpt

Questions

- Please submit any questions in the Q&A pod. We will review and respond to questions at the end of the webinar
- For questions about submitting study data please contact: edata@fda.hhs.gov
- For questions about eCTD, including stf.xml and file-tags, please contact: esub@fda.hhs.gov

Reference

- "Providing Regulatory Submissions In Electronic Format - Standardized Study Data: Guidance For Industry" https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM292334.pdf
- "Providing Regulatory Submissions In Electronic Format - Submissions Under Section 745a(a) Of The FD&C Act: Guidance For Industry" https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM384686.pdf
- "Technical Rejection Criteria For Study Data" https://www.fda.gov/media/100743/download
- "Study Data Technical Conformance Guide" https://www.fda.gov/media/88173/download
- "FDA Data Standards Catalog" https://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm
- "Technical Denunciation Criteria Self-Check Worksheet" https://www.fda.gov/media/123098/download
- "Technical Rejection Criteria Self-Check Worksheet Instructions" https://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM630733.pdf
- For FDA instruction of Study Data submission, see the FDA "Study Data for Submission to CDER and CBER" https://www.fda.gov/industry/study-data-standards-resources/study-data-submission-cder-and-cber
- For the full list of Study Data standards, see the FDA "Study Data Standards Resources" http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards
- PhUSE utility for Simplified TS File Creation https://geotiger.shinyapps.io/07_genTS/

Using the Simplified ts.xpt for Nonclinical Submissions

Stephanie Leuenroth-Quinn, PhD

Pharmacologist/ CDER/ OND IO

Study Data TCG Webinar

November 22, 2019

Overview

- Nonclinical perspective on the Technical Rejection Criteria (TRC) and the Standard for Exchange of Nonclinical Data (SEND) Compliance
- Nonclinical Considerations for the TRC
- Use of the Simplified ts.xpt file

The Value of SEND to OND Nonclinical Reviewers

- Facilitate review of nonclinical study reports (ability to focus on findings of interest, export data into review templates)
- Examine individual animal study parameters without scrolling through thousands of pages of data in pdf format
- Future data mining initiatives and cross study analyses

Study Data TCG and the TRC

- The Study Data Technical Conformance Guide (TCG) has been updated to provide additional information on the TRC and the nonclinical use of the simplified ts.xpt
- Instructions in the TCG explain when and how to use the simplified ts.xpt for nonclinical submissions
- *Study Data TCG link: https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources*

Nonclinical Purpose for the TRC: SEND Compliance

Identify the study in a machine readable format. What is the study type (based on Module and STF) and when did the study start (based on ts.xpt - simplified or full)

Does the nonclinical study report require SEND? Is a simplified ts.xpt included that would indicate SEND is not required?

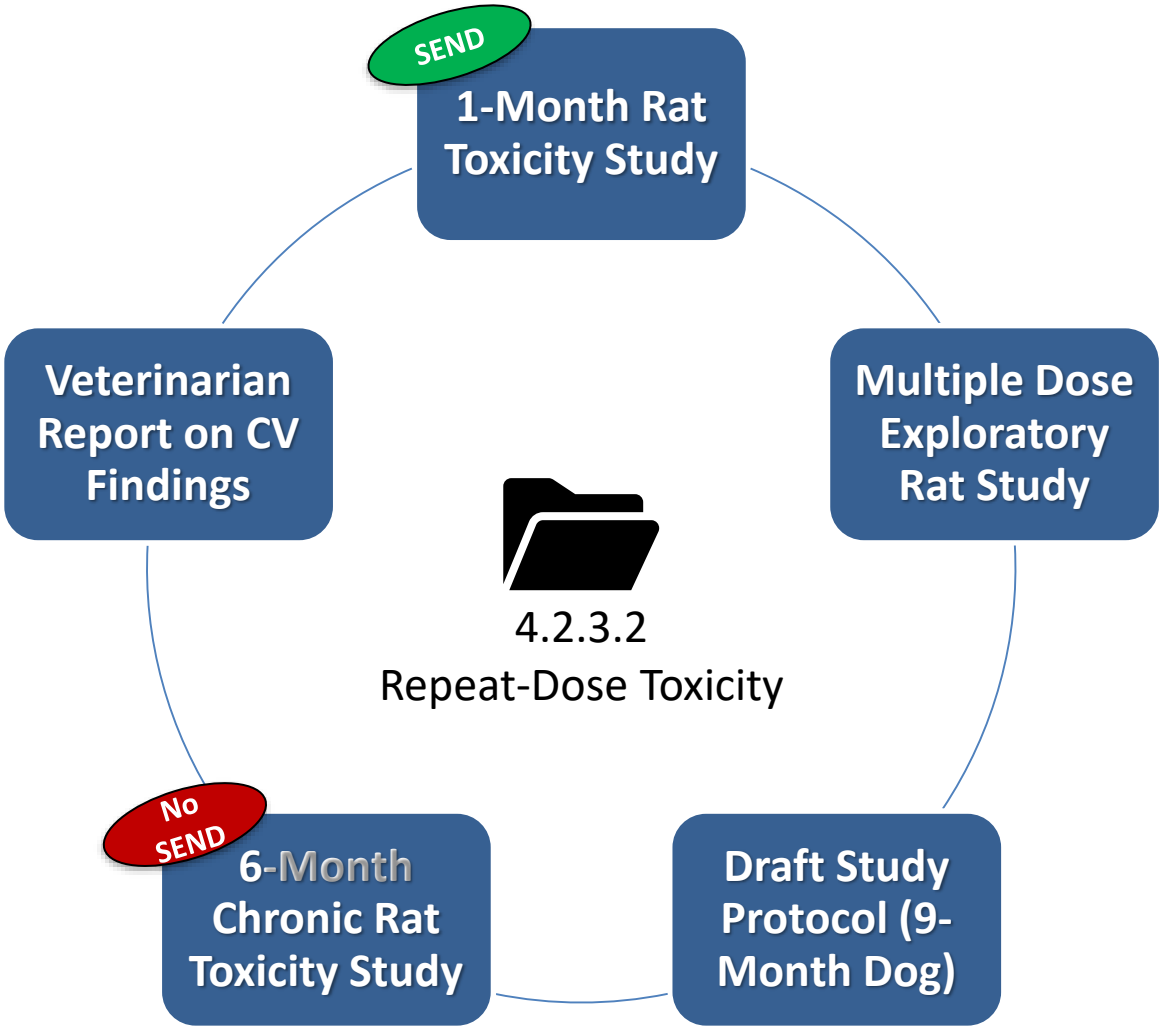
Can the submission proceed through the electronic gateway and be processed for reviewer assignment?

Technical Rejection Criteria

- *Automated Validation Process*
- Added to the existing eCTD validation criteria to enforce compliance with the SEND requirements for study types modeled in an FDA-supported SEND Implementation Guide (SENDIG) version.

Currently, for nonclinical studies, the Technical Rejection Criteria (TRC) will only apply to eCTD Modules 4.2.3.1 (single-dose toxicity), 4.2.3.2 (repeat-dose toxicity), and 4.2.3.4 (carcinogenicity)

Nonclinical Considerations for the Technical Rejection Criteria (TRC)



Nonclinical Submissions to the EDR eCTD Structure

eCTD Structure
Module 4: Nonclinical Study Reports

4.2.1
Pharmacology

4.2.2
Pharmacokinetics

4.2.3
Toxicology

Nonclinical Submissions, SEND, and the TRC

eCTD Structure
Module 4: Nonclinical Study Reports

4.2.1
Pharmacology

4.2.2
Pharmacokinetics

4.2.3
Toxicology

4.2.3.1 Single-Dose Toxicity
4.2.3.2 Repeat-Dose Toxicity
4.2.3.3 Genotoxicity
4.2.3.4 Carcinogenicity
4.2.3.5 Reproductive and Developmental Toxicity
4.2.3.6 Local Tolerance
4.2.3.7 Other Toxicity Studies

Nonclinical Submissions, SEND, and the TRC

eCTD Structure
Module 4: Nonclinical Study Reports

4.2.3
Toxicology

4.2.3.1 Single-Dose Toxicity
4.2.3.2 Repeat-Dose Toxicity
4.2.3.3 Genotoxicity
4.2.3.4 Carcinogenicity
4.2.3.5 Reproductive and Developmental Toxicity
4.2.3.6 Local Tolerance
4.2.3.7 Other Toxicity Studies

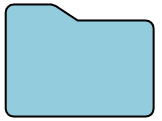
Examples of Nonclinical Reports

Single Dose Rat Toxicity Study
Initiated 12-7-2018 ✓
However - No endpoint modeled in SEND
(Specialized Endpoint)

4.2.3.1
Single-Dose
Toxicity

28-Day Draft Rat Toxicity Study
Initiated 5-30-2018 ✓

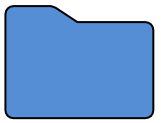
14-Day Rat Toxicity Study
Initiated 10-7-2016 *(no machine readable format)*



4.2.3.2
Repeat-Dose
Toxicity

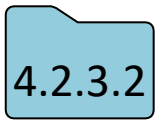
Expert Pathologist Report (for 3-Month Dog)
(Text Based Document)

Rodent Carcinogenicity Risk Assessment
(Text Based Document)



4.2.3.4
Carcinogenicity

Examples of Nonclinical Reports



Module triggers TRC

Repeat-Dose Toxicity

STF
(Study Tagging File)

28-Day Rat Toxicity Study
Initiated 5-30-2018 ✓

study-report-body

14-Day Rat Toxicity Study
Initiated 10-7-2016

study-report-body

Expert Pathologist Report
(Text Based Document)

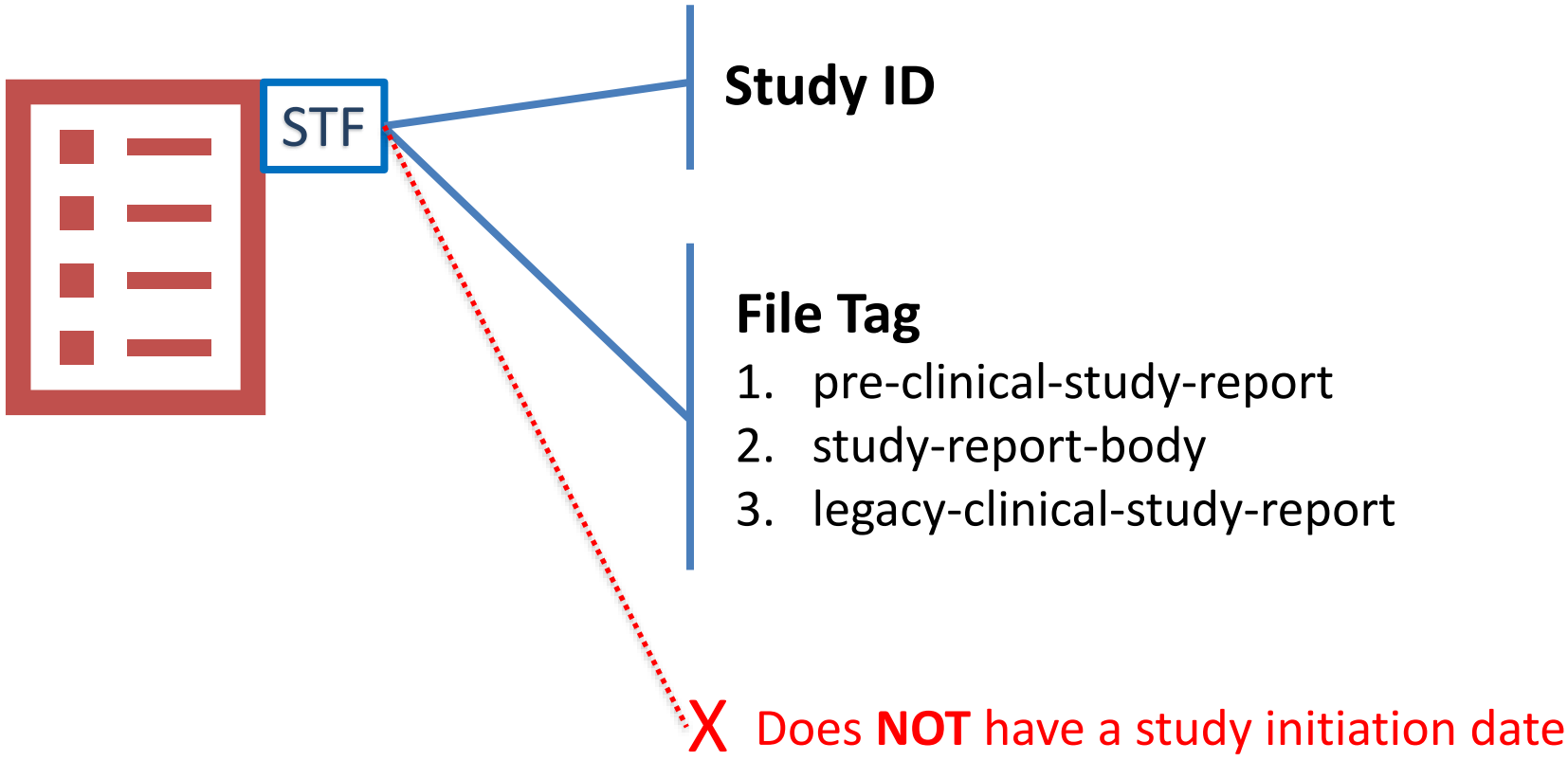
study-report-body

* There are a limited number of ICH-specified file tags

pre-clinical-study-report
legacy-clinical-study-report
study-report-body

STFs trigger TRC

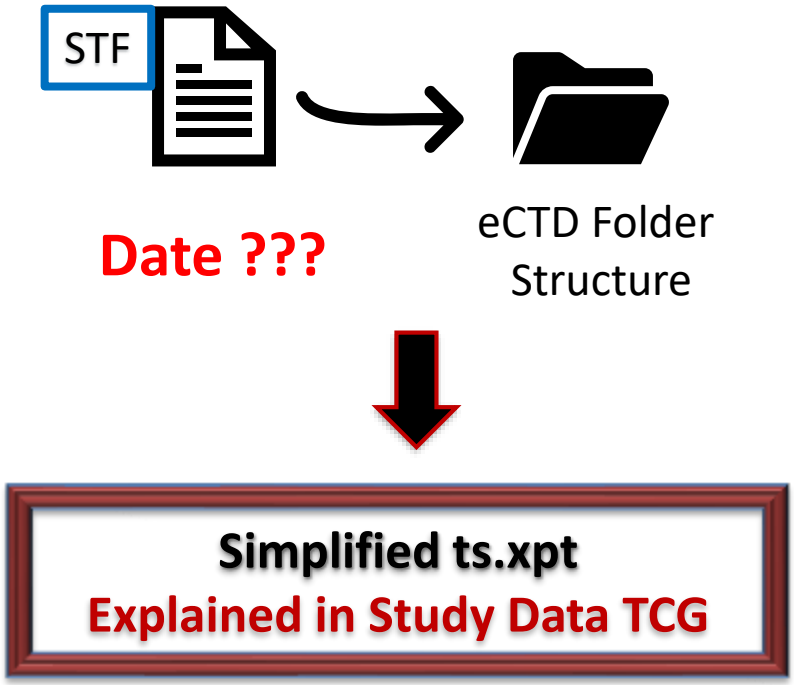
Study Tagging File (STF)



Simplified ts.xpt

Goal: SEND compliance (based on study type and study initiation date)

- How can study start date be identified in an automated way when SEND is not required?
- What if the study report doesn't have a start date (e.g., text based document)?



Full and Simplified ts.xpt

Full ts.xpt

- Accompanies SEND datasets
- Follows published CDISC Standard

Simplified ts.xpt

- Used when SEND datasets are not required for submissions in Modules 4.2.3.1, 4.2.3.2 or 4.2.3.4
- Needed when using a STF file tag of:
    - pre-clinical-study-report
    - legacy-clinical-study-report
    - study-report-body

Full and Simplified ts.xpt

Study Initiation Date After Dec. 17, 2017 (INDs)	Module 4.2.3.1 (Single-Dose Tox) Module 4.2.3.2 (Repeat-Dose Tox) Module 4.2.3.4 (Carcinogenicity)	**SEND Required (full TS.xpt)**
Study Initiation Date Before or On Dec. 17, 2017 (INDs)	Module 4.2.3.1 (Single-Dose Tox) Module 4.2.3.2 (Repeat-Dose Tox) Module 4.2.3.4 (Carcinogenicity)	**Simplified ts.xpt**
Study Initiation Date Not Applicable	Module 4.2.3.1 (Single-Dose Tox) Module 4.2.3.2 (Repeat-Dose Tox) Module 4.2.3.4 (Carcinogenicity)	**Simplified ts.xpt**

Note: This slide represents dates for INDs, but SEND requirements also apply to NDAs/BLAs (Study Initiation Date after December 17, 2016).

Use of Simplified ts.xpt: When Study Initiation Date is Not Applicable

Study Data TCG v. 4.4 (Section 8.2.2: Support on Data Validation Rules)
https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources

- Expert pathologist's report (Working Group Report) or Veterinarian report (e.g., Veterinary Cardiologist)
- Nonclinical safety report
- Carcinogenicity protocol amendments or Carcinogenicity risk assessments
- Exploratory or tolerability toxicology study summaries (e.g., text based, limited animals used with few endpoints tested). Does not include those studies that would be submitted to the Agency to support the adequacy of dose selection for subsequent nonclinical studies (e.g., dose range finding studies to support dosing for rodent carcinogenicity studies).

Use of Simplified ts.xpt: When Study Initiation Date is Not Applicable (con't)

Study Data TCG v. 4.4 (Section 8.2.2: Support on Data Validation Rules)
https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources

- Literature study reports specifically used as nonclinical support for safety
- Nonclinical study protocols
- Study types not currently modeled in an applicable SENDIG
- Specialized toxicity studies conducted where there are no study parameters modeled in an applicable SENDIG (e.g., a single-dose toxicity study conducted to only assess otic endpoints)
- The Agency, at its discretion, could allow for use of a simplified ts.xpt file with submission of a study report (e.g., for reasons of safety or significant clinical concern)

Simplified ts.xpt

I. Valid Study Initiation Date

Studies modelled in an FDA-supported SENDIG version

> *Study Data TCG (Section 8.2.2): "A simplified ts.xpt file would be expected when the study type could be modeled in an applicable SEND Implementation Guide (SENDIG) version (e.g., repeat dose toxicity) but the study initiation date is prior to the implementation of the requirement (e.g., before or on Dec. 17, 2016 for NDAs)."*

14-Day Rat Toxicity Study
Initiated 10-7-2016

pre-clinical-study-report

STUDYID	TSPARMCD	TSVAL	TSVALNF
Study ID in STF	STSTDTC	yyyy-mm-dd	*(Leave blank)*

STUDYID	TSPARMCD	TSVAL	TSVALNF
123456-a	STSTDTC	2016-10-07	

Simplified ts.xpt

II. Study Initiation Date Not Applicable

Primarily text-based documents with no tabulated data or line listings

Study Data TCG (Section 8.2.2): *"There may also be cases where a study initiation date is not relevant. When nonclinical submissions are primarily text based, do not have tabulated data or line listings, are specifically sent to or requested by the Agency due to emergent safety concerns (with prior agreement), or only contain data that are not modeled in an applicable SENDIG, a simplified ts.xpt file should be used."*

Expert Pathologist Report
(Text Based Document)

study-report-body

STUDYID	TSPARMCD	TSVAL	TSVALNF
Study ID in STF	STSTDTC	*(Leave blank)*	NA

STUDYID	TSPARMCD	TSVAL	TSVALNF
123-abc	STSTDTC		NA

TRC: Nonclinical Submission Scenarios

SEND Required!

Submission	Module	STF	ts.xpt	Pass TRC?
Draft Report: 30-Day Rat Toxicity Study (SSD = 6/22/2018)	4.2.3.2	pre-clinical-study-report	Full TS.xpt and SEND	✓YES

SEND Required!

Submission	Module	STF	ts.xpt	Pass TRC?
Draft Report: 30-Day Rat Toxicity Study (SSD = 6/22/2018)	4.2.3.2	pre-clinical-study-report	None	X NO

Submission	Module	STF	ts.xpt	Pass TRC?
3-Month Mouse Toxicity Study (SSD = 3/18/2016)	4.2.3.2	pre-clinical-study-report	Simplified ts.xpt with SSD = 3/18/2016	✓YES

Submission	Module	STF	ts.xpt	Pass TRC?
Draft Protocol: 9-Month Dog Toxicity	4.2.3.2	**protocol-or-amendment**	None	✓YES

What do Sponsors Need to Consider for the TRC (Nonclinical Considerations)?

What is in the Submission?

- Is the study type modeled in an FDA supported SEND Implementation Guide (SENDIG) and supported in the current FDA data standards catalog?
- Does the study have endpoints modeled in SEND?
- What is the Study Initiation Date?
- What is the submission? (e.g., text based document)

What is the best STF to use?

- **STFs**: Preclinical-study-report, study-report-body and legacy-clinical-study-report will trigger TRC.
- Use other STFs appropriately (e.g., nonclinical safety reports, nonclinical protocol submissions) -or- use simplified ts.xpt

What Module?

- When activated, the TRC will check nonclinical studies submitted to **Modules** 4.2.3.1, 4.2.3.2, and 4.2.3.4

Use of the SDSP

- It is recommended that the Study Data Standardization Plan (SDSP) should be used during development to communicate the intent to submit SEND datasets.
- The SDSP can be updated so that all historical, current, and planned use of study data standards is included. When appropriate, the SDSP may also be used to further explain the intended use of simplified ts.xpt files.
- Use of the SDSP will allow for identification of potential data standardization issues and timely discussion with the review division, if needed.

Summary

- SEND datasets facilitate the review of nonclinical study reports.
- The TRC will ensure SEND compliance using an automated validation process.
- The simplified ts.xpt file will provide additional machine readable information when SEND is not required (e.g., study start date).

Further Information

Study Data Technical Conformance Guide (October 2019):
https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources

Technical Rejection Criteria:
https://www.fda.gov/industry/study-data-standards-resources/study-data-submission-cder-and-cber

Electronic Common Technical Document (eCTD):
https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd

Standardized Study Data Guidance:
Guidance for Industry, Providing Regulatory Submissions in Electronic Format — Standardized Study Data (PDF - 131 KB)

Questions

- Please submit any questions in the Q&A pod. We will review and respond to questions at the end of the webinar
- For questions about submitting study data please contact: edata@fda.hhs.gov
- For questions about eCTD, including stf.xml and file-tags, please contact: esub@fda.hhs.gov

Tools for Industry and the Technical Rejection Criteria Self-Check Worksheet

Tools for Industry

FDA is developing tools and resources to help sponsors meet study data standard requirements and provide more transparency on the validation process

Online Resources

Gateway

Sponsor reviews Study Data Standard Resources and Tools for Industry:

- Study Data Technical Rejection Criteria with *eCTD Validation Table and Example Submission Scenarios*
- Simplified TS File Generator Utility (PhUSE)

  OR

  Simplified TS File Creation Guide
- Study Data Self-Check Worksheet & Instructions

Sponsor submits a eCTD and/or Standardized Data Sample to the FDA for validation:

After review, FDA will provide with feedback, highlighting the errors found during the processing of the sample submission

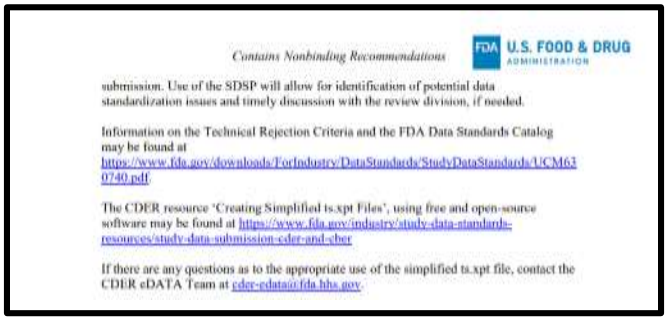
Sponsor submits an application with study data

FDA Tool - Simplified TS File Creation Guide

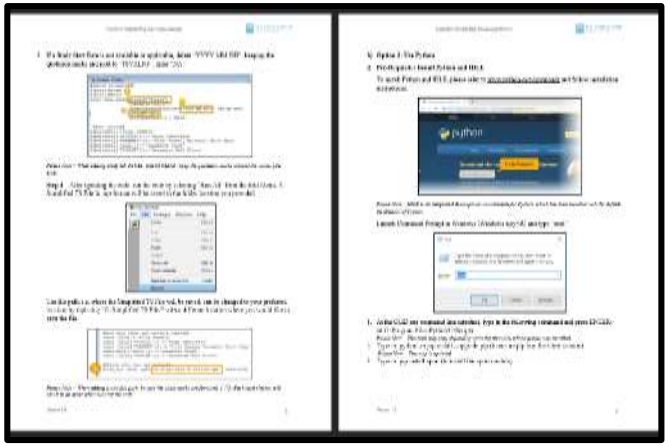
- **Purpose** – The *Simplified ts.xpt Creation Guide* is a resource that FDA is providing industry to help create a simplified TS file using free and open-source software
  - R
  - Python
- This Guide provides step by step instructions to install the necessary software to create and view the simplified ts.xpt file
- Users can simply copy paste the code from the guide to generate the simplified ts.xpt
- This guide is intended for users with non programming background to create the simplified ts.xpt with ease
- This link to this Guide will be available on the FDA's Web Page

  Study Data for Submission to CDER and CBER

Study Data TCG (Oct 2019) references the Guide



Simplified TS File Creation Guide

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