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Study Data Technical Rejection Criteria, Validation, and Self-Check Worksheet

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FDA Disclaimer

The views and opinions presented here represent those of the speakers and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.

Agenda

- Purpose of eCTD and Study Data Requirements
- Study Data Technical Rejection Criteria Conformance Trend
- Revised Technical Rejection Criteria for Study Data
- Technical Rejection Criteria Validation Process and Demo of the Self-Check Worksheet
- Implementation Timeline
- Summary

Purpose of eCTD and Study Data Requirements

Purpose of eCTD and Study Data Requirements

- Reviewing study data in a timely manner is critical for FDA's review process (e.g. Reviewers have 30 days to review an IND application)
- When sponsors submit data to the FDA in a reliable and accessible format, it improves efficiency and consistency of review decisions
- CDISC Standards enable FDA to streamline the review process:
  - Reduce time for reviewers to locate and identify study data
  - Reduce the burden on sponsors and reviewers from IRs (Information Requests)
  - Reduce review time by enabling the use of COTS reviewer's tools such as JReview, JMP Clinical, etc. to automate review analyses
  - Support data driven decisions by applying data mining and data analytic techniques

"The agreement to assemble all the Quality, Safety and Efficacy information in a common format (called CTD - Common Technical Document) has revolutionized the regulatory review processes, led to harmonized electronic submission that, in turn, enabled implementation of good review practices. For industries, it has eliminated the need to reformat the information for submission to the different ICH regulatory authorities."

Source: https://www.ich.org/products/ctd.html

US FDA Study Data Requirements

- Study Data Technical Conformance Guide provides technical recommendations for submitting study data according to CDISC standards

Error	Description (Reference to FDA Study Data Technical Rejection Criteria Jan. 2019 version)	Severity Level
1734	Trial Summary (TS) dataset (ts.xpt) with information on study start date must be present for required sections*	**High**
1735	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)	**High**

- Technical Rejection Criteria for Study Data provides the conditions under which FDA will not accept submissions with study data

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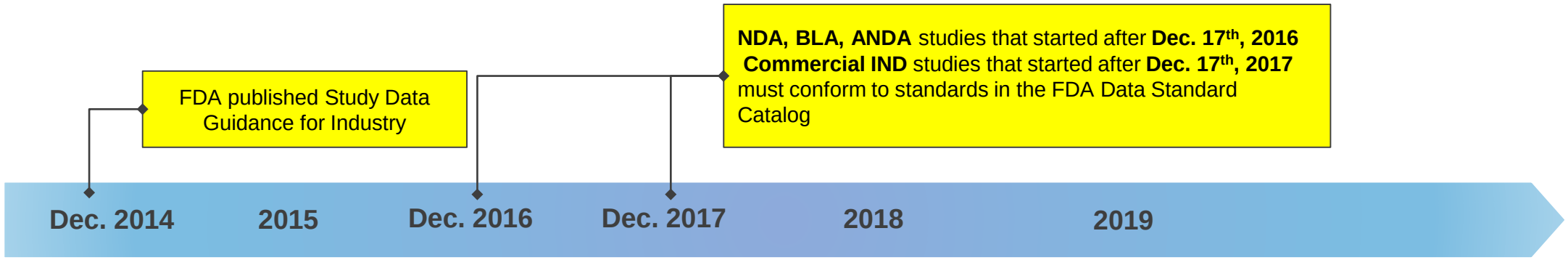
Study Data Technical Rejection Criteria Conformance Trend

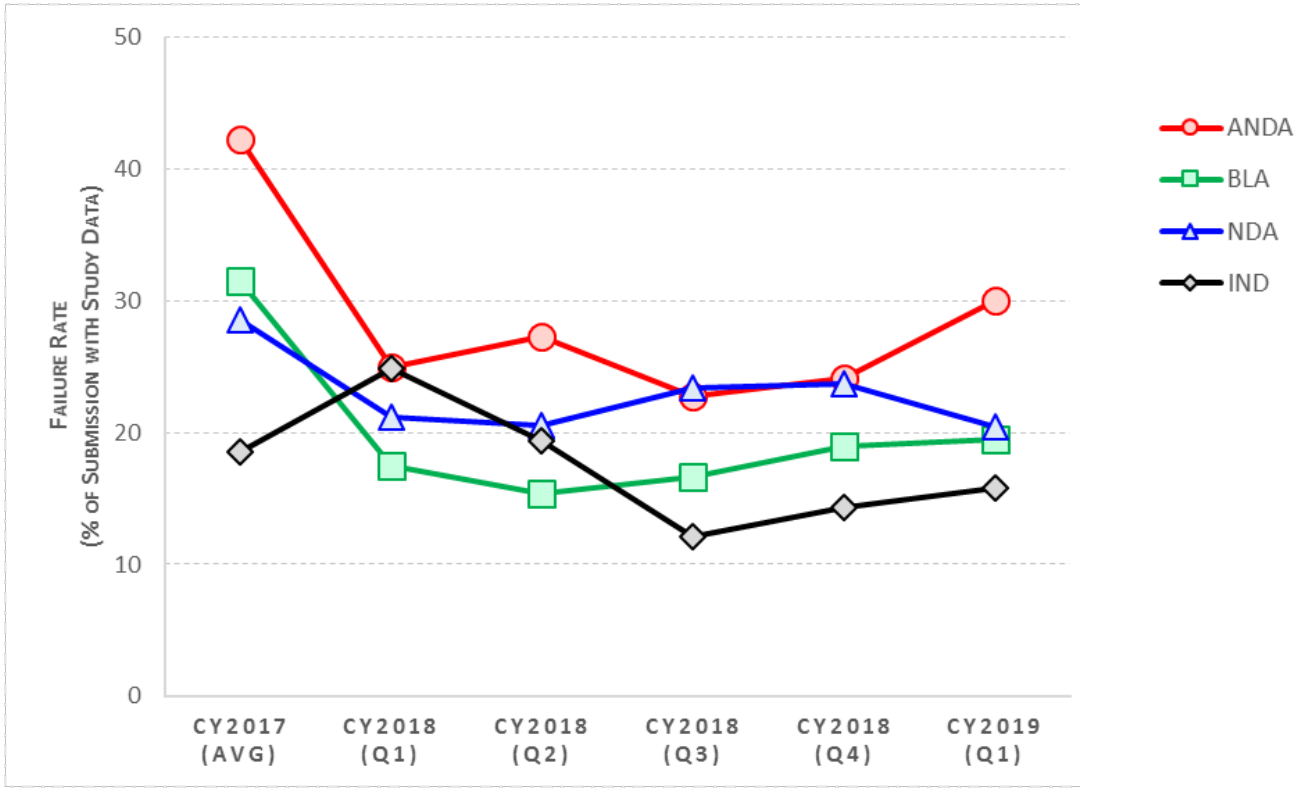
FDA Guidance and Data Standards Catalog

- Per FD&C Act Section 745A(a), drug application sponsors must use the standards defined in the FDA Data Standards Catalog starting 24 months after final guidance for a specific submission type.
- FDA issued “Providing Regulatory Submissions in Electronic Format - Standardized Study Data: Guidance for Industry” in December 2014.
- Sponsors must conform to standards in the FDA Data Standards Catalog:
  - NDA, BLA, ANDA studies that started **after December 17th, 2016**
  - Commercial IND studies started **after December 17th, 2017**



Overall Conformance Trend for Validation Errors 1734 & 1736

- Submissions with study data shows overall decreases in Validation Error 1734 and 1736 in all application types
- NDAs and INDs are showing the greatest improvements in conformance



Notes:

1) CY2017 analysis average excludes any submissions received in 2018 & 2019 and was conducted according to TRC (Revised May 2018)
2) CY2018 & CY2019 (Q1) analysis are conducted according to the TRC (Revised Jan. 2019)

Summary of Errors 1734 and 1736 Conformance Trend

- The failure rate for Errors 1734 and 1736 for all application types received in **CY2018 is 21.6%** and in **Q1 CY2019 is 22.3%**
- Overall conformance for Errors 1734 and 1736 is improving compared to the previous analysis (previous years' average of 68.0%, CY2018's average of 78.4% and Q1 CY2019 average of 77.7%)
- FDA has identified the need to provide additional clarifications on TRC to help Industry meet study data requirements and continue to improve the conformance trend over time

Technical Rejection Criteria (TRC) Revision	Self-Check Worksheet for Study Data Requirement
• Details on Errors 1734 and 1736 • Emphasis on Error 1735 • Inclusion of Error 1789 • Inclusion of Table 1 eCTD Technical Rejection Criteria for Study Data Expectation • Inclusion of Appendix 1 Examples of Validation Findings in Study Data • Inclusion of Appendix 2 Examples of ts.xpt datasets	• Details on each step of TRC validation process • Dynamically guidance through study data requirements based on study information entered • Guidance for sponsors when they prepare study data to submit to the FDA for the first time

Revised Technical Rejection Criteria for Study Data

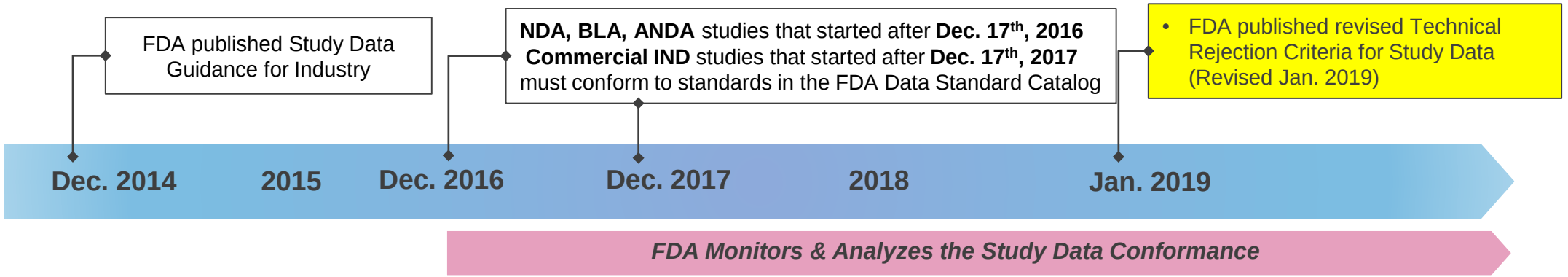
Study Data Technical Rejection Criteria (SDTRC) Revision (Jan. 2019)

Technical Rejection Criteria for Study Data (Revised 05/01/2018)

The FDA may refuse to file (RTF) for NDAs and BLAs, or refuse to receive (RTR) for ANDAs, an electronic submission that does not have study data in conformance to the required standards specified in the FDA Data Standards Catalog

Technical Rejection Criteria for Study Data (Revised 01/22/2019)

FDA will not accept an electronic submission that does not have study data in compliance with the required standards specified in the FDA Data Standards Catalog



References:
FDA Study Data Technical Rejection Criteria (Revised May 2018); FDA Study Data Technical Rejection Criteria (Revised Jan. 2019)

Update to SDTRC List of High Errors (Revised Jan. 2019)

Error	Description (Reference to FDA Study Data Technical Rejection Criteria May 2018 version)	Severity Level
1734	Trial Summary (TS) dataset must be present for each study in eCTD section 4.2 and 5.3	High
1736	Demographic dataset (DM) and the define.xml must be submitted in Module 4 for nonclinical data; DM dataset, the subject-level analysis dataset (ADSL) and define.xml must be submitted in Module 5 for clinical data	High

Error	Description (Reference to FDA Study Data Technical Rejection Criteria Jan. 2019 version)	Severity Level
1734	Trial Summary (TS) dataset (ts.xpt) with information on study start date must be present for required sections*	**High**
1735	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)	**High**

** Refer to the latest Technical Rejection Criteria for Study Data*
*** From Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specification, Section J: Datasets must only be provided in modules 3, 4, or 5 and not in modules 1 or 2*

eCTD Technical Rejection Criteria for Study Data Expectation

Study Start Date	Application Type	Data Type	Study Sections	Expectation by Center	
				CDER	CBER
Prior to or on 17-Dec-2017	Commercial INDs	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Rejection criteria will be applied; submit a simplified TS whether or not the study contains an xpt dataset (other than the ts.xpt)	Rejection criteria will not be applied
		Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Rejection criteria will not be applied	
After 17-Dec-2017	Commercial INDs	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Rejection criteria will be applied; submit a full TS	Rejection criteria will not be applied
		Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Rejection criteria will not be applied	
Prior to or on 17-Dec-2016	NDA, BLA, ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Rejection criteria will be applied; submit a simplified TS whether or not the study contains an xpt dataset (other than the ts.xpt)	Rejection criteria will not be applied
		Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Rejection criteria will be applied; submit a simplified TS if the study contains an xpt dataset (other than the ts.xpt)	
After 17-Dec-2016	NDA, BLA, ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Rejection criteria will be applied; submit a full TS	Rejection criteria will not be applied
		Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Rejection criteria will be applied; submit a full TS	

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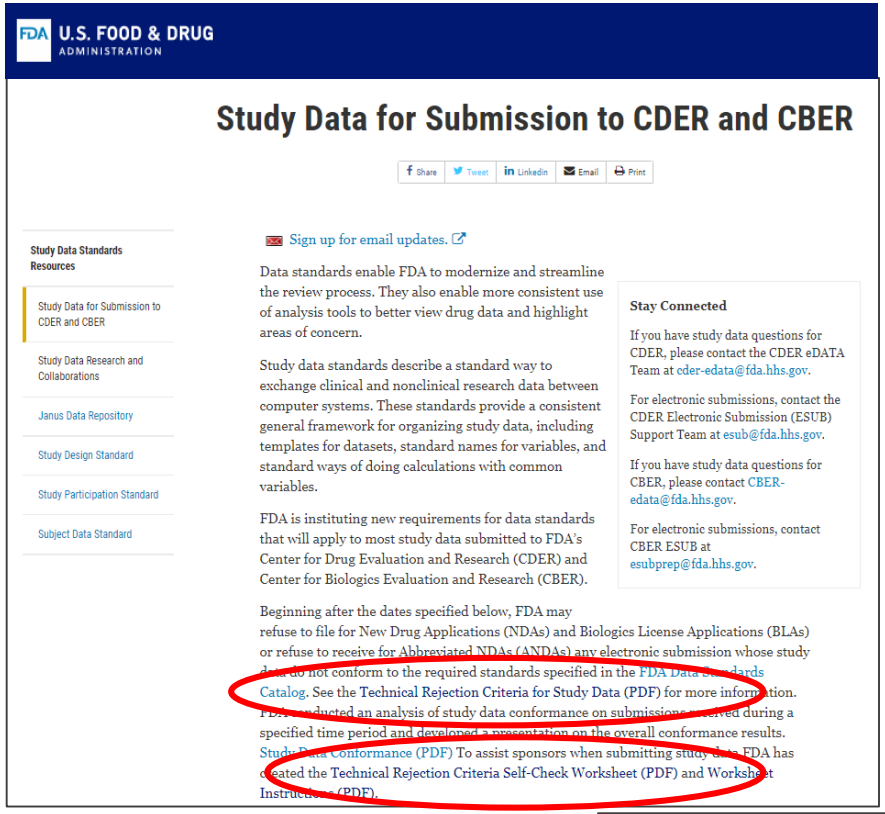
Technical Rejection Criteria Validation Process and Demo of the Self-Check Worksheet

Published SDTRC and Self-Check Worksheet



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Study Data for Submission to CDER and CBER

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Study Data Standards Resources

- Study Data for Submission to CDER and CBER
- Study Data Research and Collaborations
- Janus Data Repository
- Study Design Standard
- Study Participation Standard
- Subject Data Standard

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Data standards enable FDA to modernize and streamline the review process. They also enable more consistent use of analysis tools to better view drug data and highlight areas of concern.

Study data standards describe a standard way to exchange clinical and nonclinical research data between computer systems. These standards provide a consistent general framework for organizing study data, including templates for datasets, standard names for variables, and standard ways of doing calculations with common variables.

FDA is instituting new requirements for data standards that will apply to most study data submitted to FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER).

Stay Connected

If you have study data questions for CDER, please contact the CDER eDATA Team at cder-edata@fda.hhs.gov.

For electronic submissions, contact the CDER Electronic Submission (ESUB) Support Team at esub@fda.hhs.gov.

If you have study data questions for CBER, please contact CBER-edata@fda.hhs.gov.

For electronic submissions, contact CBER ESUB at esubprep@fda.hhs.gov.

Beginning after the dates specified below, FDA may refuse to file for New Drug Applications (NDAs) and Biologics License Applications (BLAs) or refuse to receive for Abbreviated NDAs (ANDAs) any electronic submission whose study data do not conform to the required standards specified in the FDA Data Standards Catalog. See the Technical Rejection Criteria for Study Data (PDF) for more information. FDA conducted an analysis of study data conformance on submissions received during a specified time period and developed a presentation on the overall conformance results. Study Data Conformance (PDF) To assist sponsors when submitting study data, FDA has created the Technical Rejection Criteria Self-Check Worksheet (PDF) and Worksheet Instructions (PDF).

"Technical Rejection Criteria for Study Data"
https://www.fda.gov/media/100743/download

"Technical Rejection Criteria Self-Check Worksheet"
https://www.fda.gov/media/123098/download

"Technical Rejection Criteria Self-Check Worksheet Instructions"
https://www.fda.gov/media/123099/download

FDA published Study Data Guidance for Industry

NDA, BLA, ANDA studies that started after **Dec. 17th, 2016**
Commercial IND studies that started after **Dec. 17th, 2017**
must conform to standards in the FDA Data Standard Catalog

- FDA published Study Data Self-Check Worksheet & Instruction
- FDA published revised Technical Rejection Criteria for Study Data (Revised Jan. 2019)

Dec. 2014 | 2015 | Dec. 2016 | Dec. 2017 | 2018 | Jan. 2019

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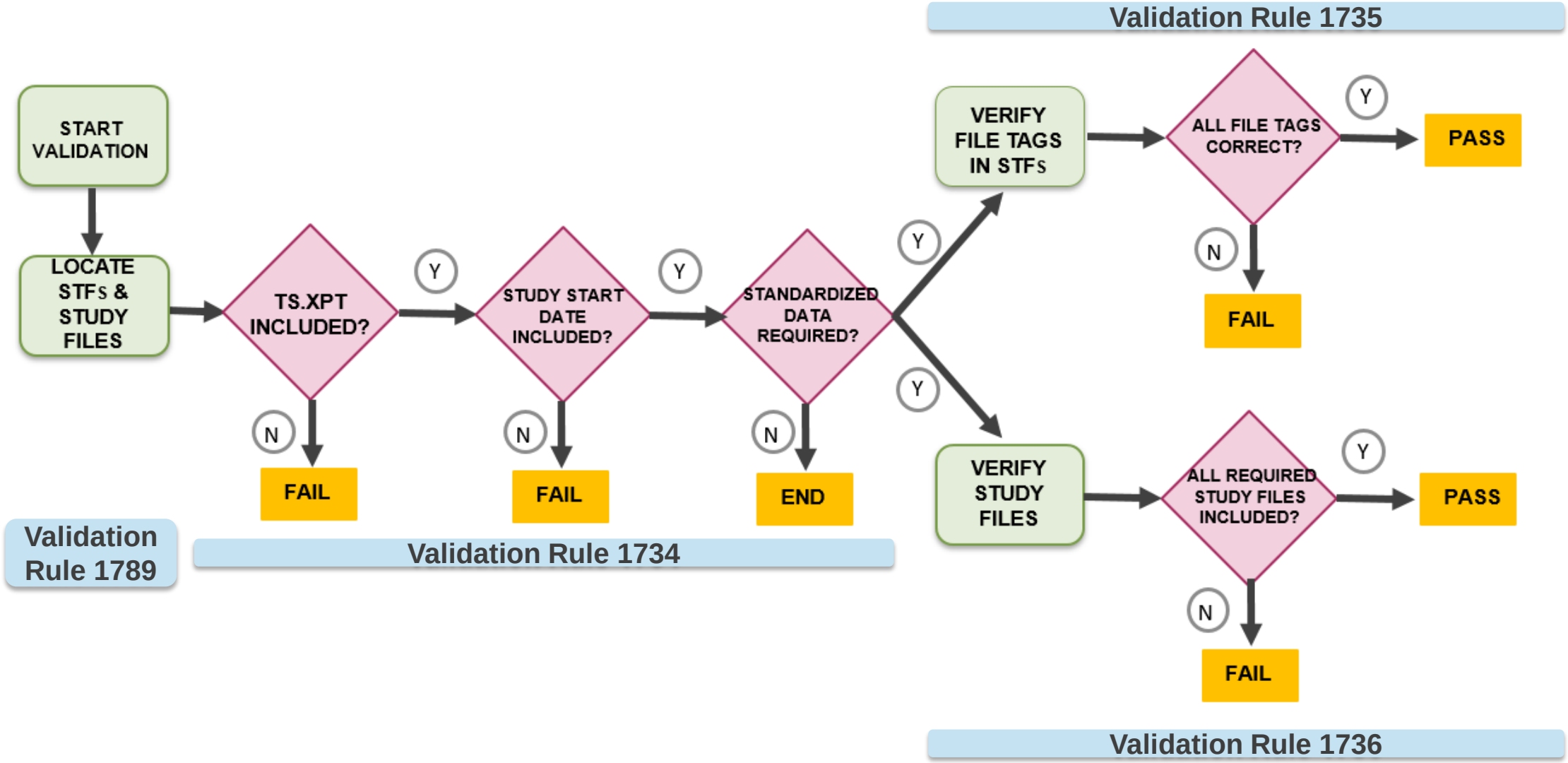
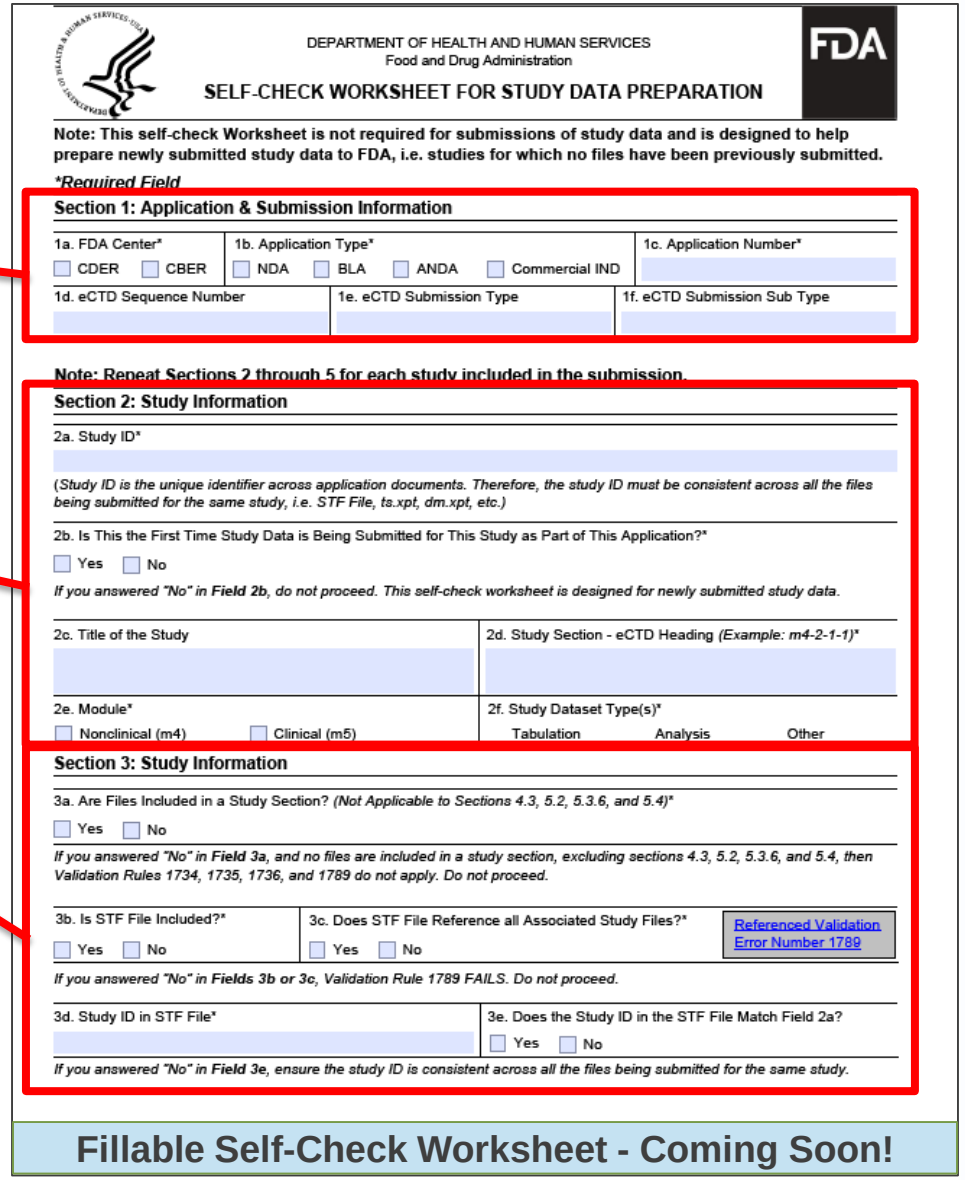
SDTRC High Level Validation Process (Revised Jan. 2019)



Self-Check Worksheet

Section	Contents
1	**Application & Submission Information** • Provides high level information about the application and submission
2	**Study Information** • Provides more detailed information about the specific study
3	**STF File Information** (1789 Validation Error) • Provide information about STF file



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SELF-CHECK WORKSHEET FOR STUDY DATA PREPARATION

Note: This self-check Worksheet is not required for submissions of study data and is designed to help prepare newly submitted study data to FDA, i.e. studies for which no files have been previously submitted.

Required Field

Section 1: Application & Submission Information

1a. FDA Center* ☐ CDER ☐ CBER | 1b. Application Type* ☐ NDA ☐ BLA ☐ ANDA ☐ Commercial IND | 1c. Application Number*

1d. eCTD Sequence Number | 1e. eCTD Submission Type | 1f. eCTD Submission Sub Type

Note: Repeat Sections 2 through 5 for each study included in the submission.

Section 2: Study Information

2a. Study ID*

(Study ID is the unique identifier across application documents. Therefore, the study ID must be consistent across all the files being submitted for the same study, i.e. STF File, ts.xpt, dm.xpt, etc.)

2b. Is This the First Time Study Data is Being Submitted for This Study as Part of This Application?* ☐ Yes ☐ No

If you answered "No" in Field 2b, do not proceed. This self-check worksheet is designed for newly submitted study data.

2c. Title of the Study | 2d. Study Section - eCTD Heading *(Example: m4-2-1-1)**

2e. Module* ☐ Nonclinical (m4) ☐ Clinical (m5) | 2f. Study Dataset Type(s)* Tabulation Analysis Other

Section 3: Study Information

3a. Are Files Included in a Study Section? *(Not Applicable to Sections 4.3, 5.2, 5.3.6, and 5.4)** ☐ Yes ☐ No

If you answered "No" in Field 3a, and no files are included in a study section, excluding sections 4.3, 5.2, 5.3.6, and 5.4, then Validation Rules 1734, 1735, 1736, and 1789 do not apply. Do not proceed.

3b. Is STF File Included?* ☐ Yes ☐ No | 3c. Does STF File Reference all Associated Study Files?* ☐ Yes ☐ No | Referenced Validation Error Number 1789

If you answered "No" in Fields 3b or 3c, Validation Rule 1789 FAILS. Do not proceed.

3d. Study ID in STF File* | 3e. Does the Study ID in the STF File Match Field 2a? ☐ Yes ☐ No

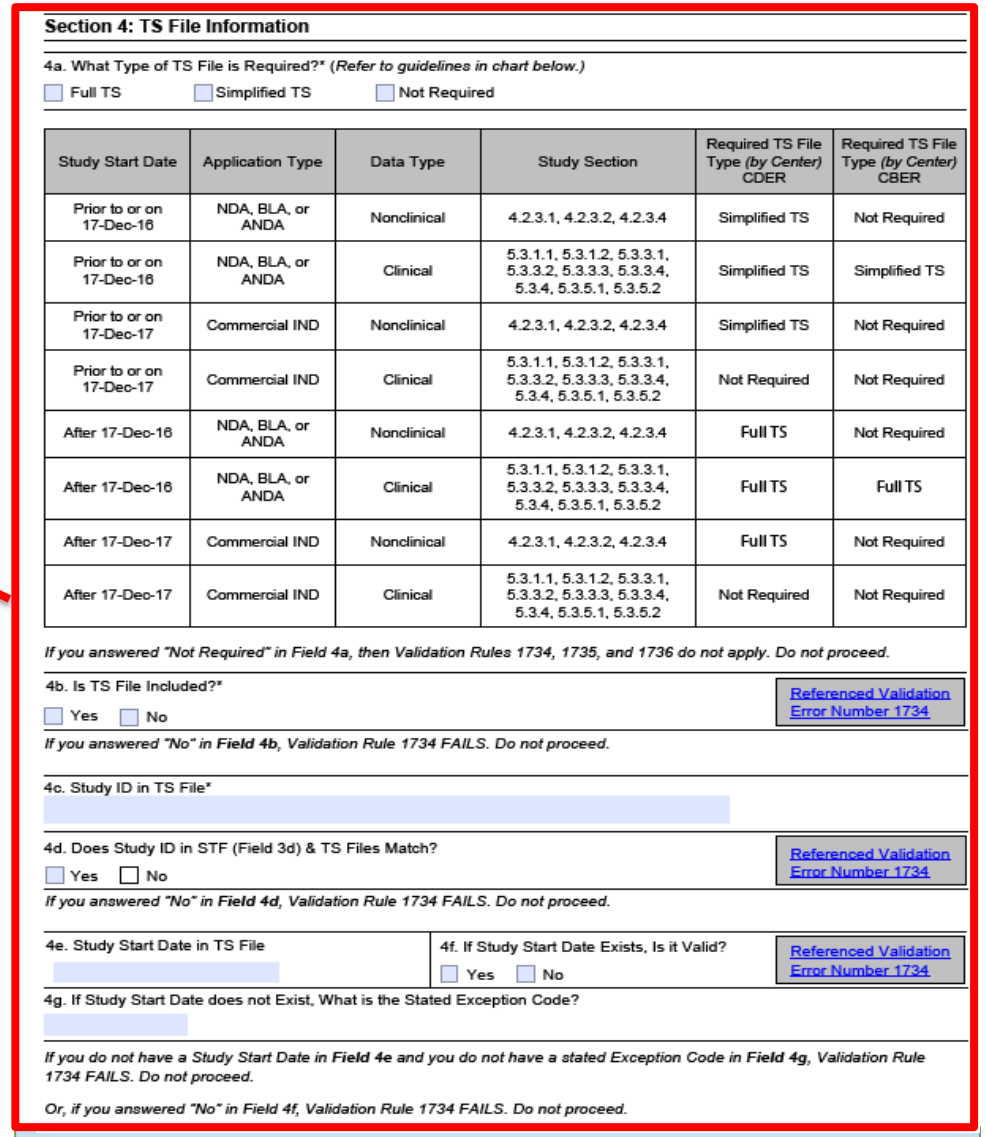
If you answered "No" in Field 3e, ensure the study ID is consistent across all the files being submitted for the same study.

Fillable Self-Check Worksheet - Coming Soon!

Reference:
"Technical Rejection Criteria Self-Check Worksheet"
https://www.fda.gov/media/123098/download
"Technical Rejection Criteria Self-Check Worksheet Instructions"
https://www.fda.gov/media/123099/download

Self-Check Worksheet (1734 Validation Error)

Section	Contents
4	**TS File Information** (1734 Validation Error) • Provide information about ts.xpt file with study start date



Section 4: TS File Information

4a. What Type of TS File is Required?* (*Refer to guidelines in chart below.*)

☐ Full TS ☐ Simplified TS ☐ Not Required

Study Start Date	Application Type	Data Type	Study Section	Required TS File Type (by Center) CDER	Required TS File Type (by Center) CBER
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Simplified TS	Not Required
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Simplified TS	Simplified TS
Prior to or on 17-Dec-17	Commercial IND	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Simplified TS	Not Required
Prior to or on 17-Dec-17	Commercial IND	Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Not Required	Not Required
After 17-Dec-16	NDA, BLA, or ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Full TS	Not Required
After 17-Dec-16	NDA, BLA, or ANDA	Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Full TS	Full TS
After 17-Dec-17	Commercial IND	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Full TS	Not Required
After 17-Dec-17	Commercial IND	Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Not Required	Not Required

If you answered "Not Required" in Field 4a, then Validation Rules 1734, 1735, and 1736 do not apply. Do not proceed.

4b. Is TS File Included?* — Referenced Validation Error Number 1734

☐ Yes ☐ No

*If you answered "No" in **Field 4b**, Validation Rule 1734 FAILS. Do not proceed.*

4c. Study ID in TS File*

4d. Does Study ID in STF (Field 3d) & TS Files Match? — Referenced Validation Error Number 1734

☐ Yes ☐ No

*If you answered "No" in **Field 4d**, Validation Rule 1734 FAILS. Do not proceed.*

4e. Study Start Date in TS File

4f. If Study Start Date Exists, Is it Valid? — Referenced Validation Error Number 1734

☐ Yes ☐ No

4g. If Study Start Date does not Exist, What is the Stated Exception Code?

*If you do not have a Study Start Date in **Field 4e** and you do not have a stated Exception Code in **Field 4g**, Validation Rule 1734 FAILS. Do not proceed.*

Or, if you answered "No" in Field 4f, Validation Rule 1734 FAILS. Do not proceed.

Fillable Self-Check Worksheet - Coming Soon!

Reference:
"Technical Rejection Criteria Self-Check Worksheet"
https://www.fda.gov/media/123098/download
"Technical Rejection Criteria Self-Check Worksheet Instructions"
https://www.fda.gov/media/123099/download

Simplified vs Full ts.xpt (Section 4)

- **Full ts.xpt**

  Sponsors should submit a dataset named ‘ts.xpt’ following published CDISC Standard and FDA Study Data Technical Conformance Guide

- **Simplified ts.xpt**

  Sponsors should submit a dataset named ‘ts.xpt’ with four variables: STUDYID, TSPARMCD, TSVAL, AND TSVALNF)

Study with a valid Study Start Date

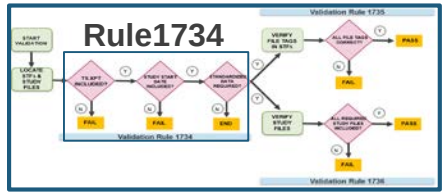
STUDYID	TSPARMCD	TSVAL	TSVALNF
Study ID in STF	STSTDTC (Nonclinical) or SSTDTC (Clinical)	yyyy-mm-dd	*Can be left blank when valid study start date is provided in TSVAL*

Study without a valid Study Start Date

STUDYID	TSPARMCD	TSVAL	TSVALNF
Study ID in STF	STSTDTC (Nonclinical) or SSTDTC (Clinical)	*Can be left blank when a study start date is not available*	Exception code as specified in the ISO 21090

References:
FDA Study Data Technical Conformance Guide (Appendices F & G; Version 4.2, October 2018)
FDA Study Data Technical Rejection Criteria (Revised Jan. 2019)

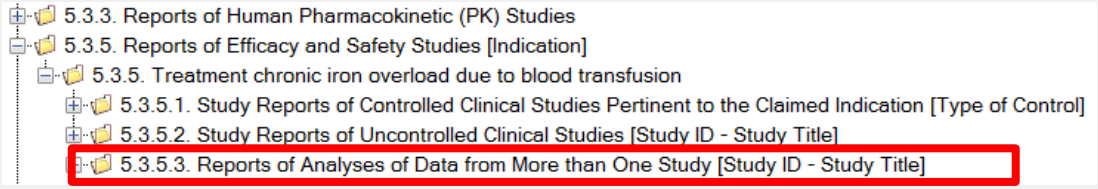
Applicable Study Sections (Section 4a)



- Technical Rejection Criteria is only applicable to Study Sections as specified in **Table 1 eCTD Technical Rejection Criteria for Study Data Expectation**

Example

1. Study Files and/or datasets submitted in **m5-3-5-3 (TRC not applicable study section)**
TRC Requirement: No ts.xpt is needed



Pass
No Further Validation Needed

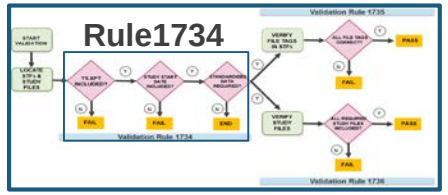
Self-Check Worksheet

Section 4: TS File Information

4a. What Type of TS File is Required?* *(Refer to guidelines in chart below.)*
☐ Full TS ☐ Simplified TS ☒ Not Required

Study Start Date	Application Type	Data Type	Study Section	Required TS File Type *(by Center)* CDER	Required TS File Type *(by Center)* CBER
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Simplified TS	Not Required
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Simplified TS	Simplified TS
Prior to or on 17-Dec-17	Commercial IND	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Simplified TS	Not Required
Prior to or on 17-Dec-17	Commercial IND	Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Not Required	Not Required
After 17-Dec-16	NDA, BLA, or ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Full TS	Not Required
After 17-Dec-16	NDA, BLA, or ANDA	Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Full TS	Full TS
After 17-Dec-17	Commercial IND	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Full TS	Not Required
After 17-Dec-17	Commercial IND	Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Not Required	Not Required

Simplified vs Full ts.xpt Examples (Section 4a)



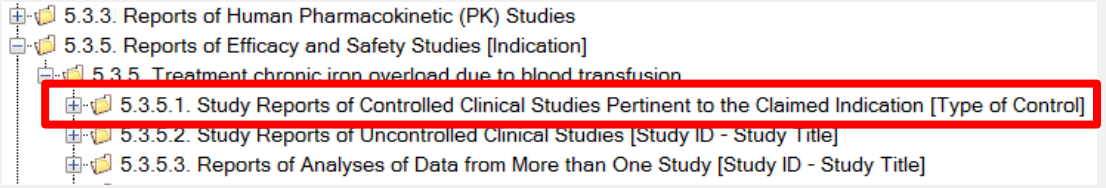
- Trial Summary (TS) dataset (ts.xpt) with information on study start date must be present for required sections

Example

2. Study Files and/or datasets submitted in **m5-3-5-1 (TRC applicable study section)**

Study Start Date: 2010-01-01

TRC Requirement: Simplified TS is needed



Self-Check Worksheet

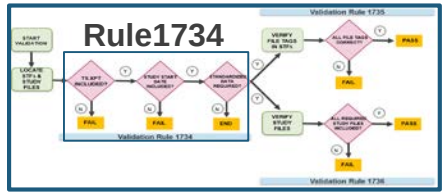
Section 4: TS File Information

4a. What Type of TS File is Required?* (*Refer to guidelines in chart below.*)

☐ Full TS ☒ Simplified TS ☐ Not Required

Study Start Date	Application Type	Data Type	Study Section	Required TS File Type *(by Center)* CDER	Required TS File Type *(by Center)* CBER
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Simplified TS	Not Required
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Simplified TS	Simplified TS
Prior to or on 17-Dec-17	Commercial IND	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Simplified TS	Not Required
Prior to or on 17-Dec-17	Commercial IND	Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Not Required	Not Required
After 17-Dec-16	NDA, BLA, or ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Full TS	Not Required
After 17-Dec-16	NDA, BLA, or ANDA	Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Full TS	Full TS
After 17-Dec-17	Commercial IND	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Full TS	Not Required
After 17-Dec-17	Commercial IND	Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Not Required	Not Required

Simplified vs Full ts.xpt Examples (Section 4a)



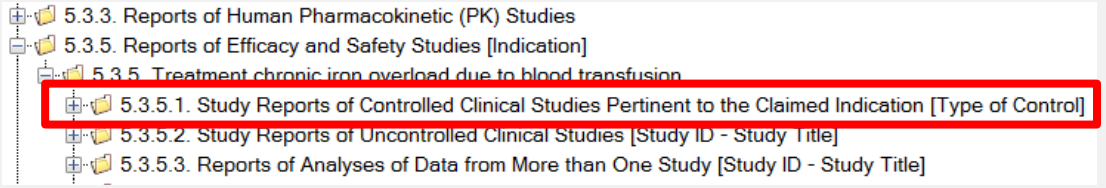
- Trial Summary (TS) dataset (ts.xpt) with information on study start date must be present for required sections

Example

3. Study Files and/or datasets submitted in **m5-3-5-1 (TRC applicable study section)**

Study Start Date: 2018-01-01

TRC Requirement: Full TS is needed



Self-Check Worksheet

Section 4: TS File Information

4a. What Type of TS File is Required?* (*Refer to guidelines in chart below.*)

☒ Full TS ☐ Simplified TS ☐ Not Required

Study Start Date	Application Type	Data Type	Study Section	Required TS File Type *(by Center)* CDER	Required TS File Type *(by Center)* CBER
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Simplified TS	Not Required
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Simplified TS	Simplified TS
Prior to or on 17-Dec-17	Commercial IND	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Simplified TS	Not Required
Prior to or on 17-Dec-17	Commercial IND	Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Not Required	Not Required
After 17-Dec-16	NDA, BLA, or ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Full TS	Not Required
After 17-Dec-16	NDA, BLA, or ANDA	Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Full TS	Full TS
After 17-Dec-17	Commercial IND	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Full TS	Not Required
After 17-Dec-17	Commercial IND	Clinical	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	Not Required	Not Required

Study ID Match Requirements

- STUDYID in STF.xml and ts.xpt should match
  - Based on the FDA Study Data TCG and the ICH STF Specification the Study ID **uniquely and unambiguously** identifies a particular study

ICH M2 EWG: The eCTD Backbone File Specification for Study Tagging Files (June 2008)

II. STUDY-IDENTIFIER ELEMENT

Information describing the study is contained in the *study-identifier* element of the STF. There are three elements contained in the *study-identifier* element: *title*, *study-id*, and *category*.

A. Title Element

The *title* element provides the full title of the study, not the title of each individual document.

B. study-id Element

The *study-id* is the internal alphanumeric code used by the sponsor to unambiguously identify this study.

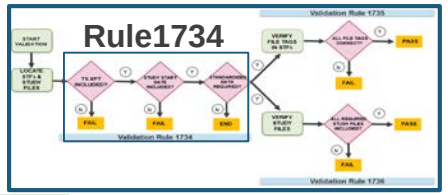
CDISC Submission Metadata Model

The following variables are considered core selection variables for use in all CDISC domain models. These variable roles may also be defined with other roles (such as Key), and roles may differ from dataset to dataset.

Variable Name	Variable Label	Comments	Included in:
STUDYID	Study ID	Uniquely identifies a study within a particular submission.	All files
SITEID	Site ID	Some sponsors may use INVID instead of or in addition to a SITEID.	At least one of these variables must be included in all files
INVID	Investigator ID		
USUBJID	Unique Subject ID	Must be unique subject identifier within a submission (previously defined as PID; should be consistent with PID references used elsewhere in the submission)	All files

References:
ICH M2 EWG: The eCTD Backbone File Specification for Study Tagging Files (June 2008)
(http://estri.ich.org/STF/STFV2-6-1.pdf)
CDISC Submission Metadata Model
(https://www.cdisc.org/system/files/all/reference_material_category/application/pdf/submissionmetadatamodelv2.pdf)

TRC Validation Rule 1734 (Section 4b)



- Trial Summary (TS) dataset (ts.xpt) with information on study start date must be present for required sections

Example	Self-Check Worksheet

Study Files and/or datasets submitted in **m5-3-5-1 (clinical)**
Study Start Date: 2018-01-01
TRC Requirement: Full TS is needed

- 5.3.3. Reports of Human Pharmacokinetic (PK) Studies
- 5.3.5. Reports of Efficacy and Safety Studies [Indication]
  - 5.3.5. Treatment chronic iron overload due to blood transfusion
    - 5.3.5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication [Type of Control]
    - 5.3.5.2. Study Reports of Uncontrolled Clinical Studies [Study ID - Study Title]
    - 5.3.5.3. Reports of Analyses of Data from More than One Study [Study ID - Study Title]

*If you answered "No" in **Field 4b**, Validation Rule 1734 FAILS. Do not proceed.*

Section 4: TS File Information

4a. What Type of TS File is Required?* (*Refer to guidelines in chart below.*)
☒ Full TS ☐ Simplified TS ☐ Not Required

4b. Is TS File Included?*
☒ Yes ☐ No
Referenced Validation Error Number 1734

*If you answered "No" in **Field 4b**, Validation Rule 1734 FAILS. Do not proceed.*

4c. Study ID in TS File*

4d. Does Study ID in STF (Field 3d) & TS Files Match?
☐ Yes ☐ No
Referenced Validation Error Number 1734

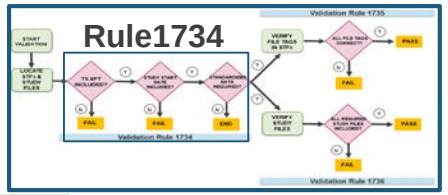
*If you answered "No" in **Field 4d**, Validation Rule 1734 FAILS. Do not proceed.*

4e. Study Start Date in TS File

4f. If Study Start Date Exists, Is it Valid?
☐ Yes ☐ No
Referenced Validation Error Number 1734

4g. If Study Start Date does not Exist, What is the Stated Exception Code?

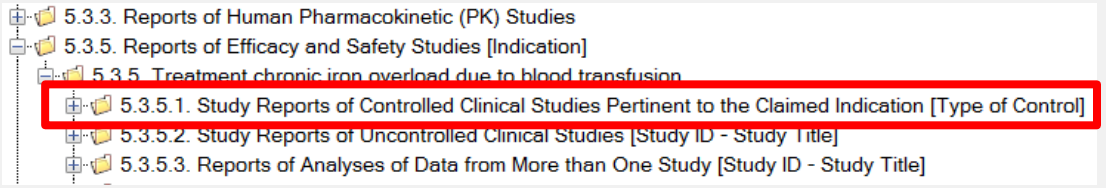
TRC Validation Rule 1734 (Section 4c)



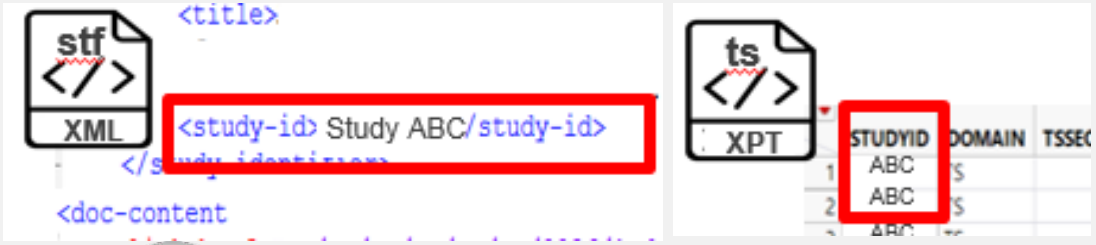
- Trial Summary (TS) dataset (ts.xpt) with information on study start date must be present for required sections

Example	Self-Check Worksheet

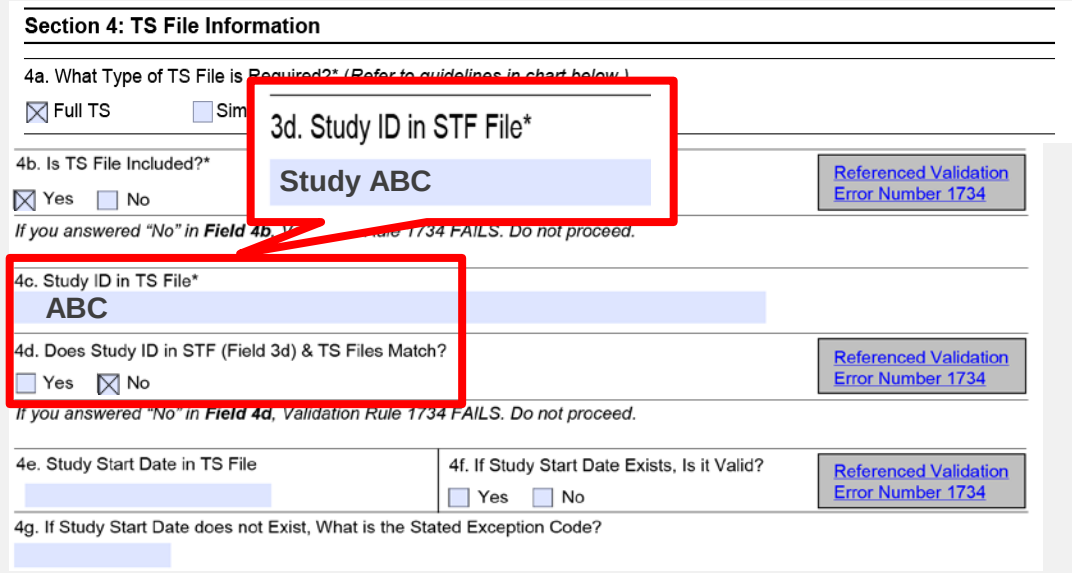
Study Files and/or datasets submitted in **m5-3-5-1 (clinical)**
Study Start Date: 2018-01-01
TRC Requirement: Full TS is needed



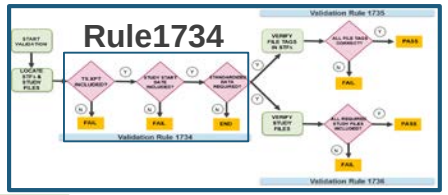
[Study IDs Match Requirement]



Fail Rule 1734



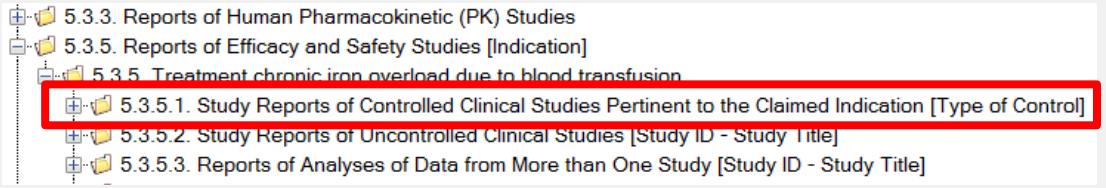
TRC Validation Rule 1734 (Section 4c)



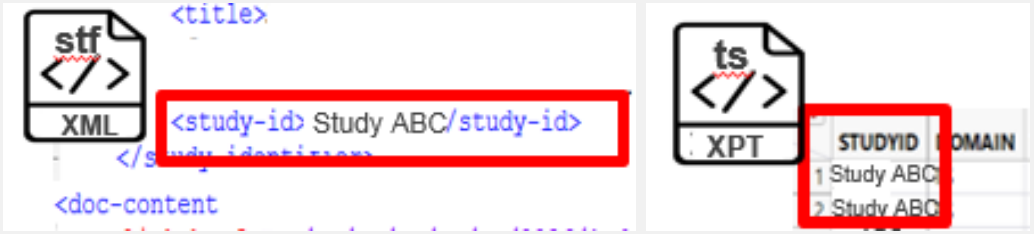
- Trial Summary (TS) dataset (ts.xpt) with information on study start date must be present for required sections

Example	Self-Check Worksheet

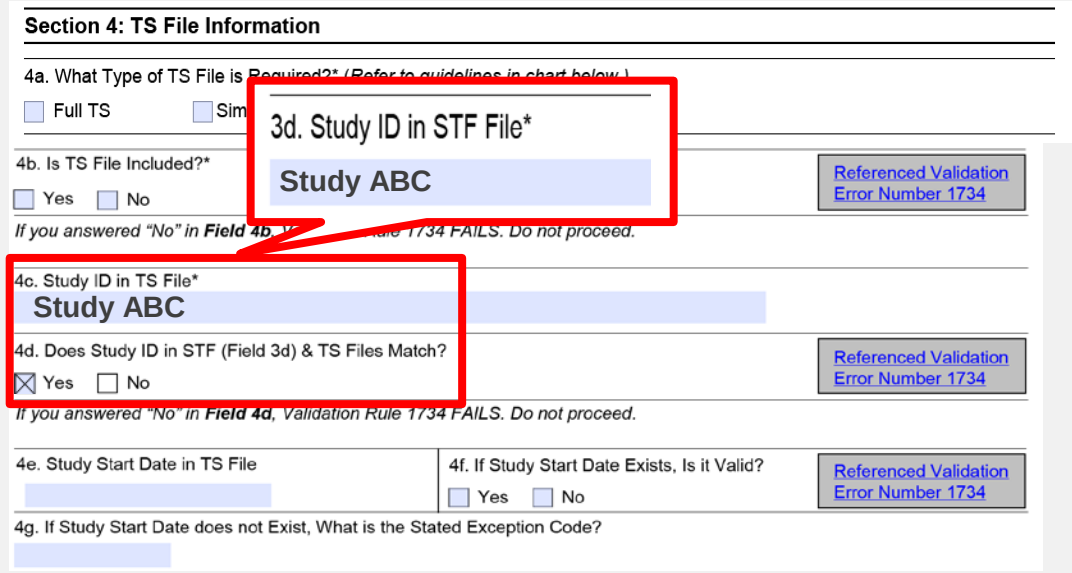
Study Files and/or datasets submitted in **m5-3-5-1 (clinical)**
Study Start Date: 2018-01-01
TRC Requirement: Full TS is needed



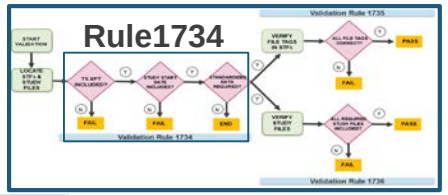
[Study IDs Match Requirement]



Pass Rule 1734



TRC Validation Rule 1734 (Section 4c)



- Trial Summary (TS) dataset (ts.xpt) with information on study start date must be present for required sections

Example	Self-Check Worksheet

Study Files and/or datasets submitted in **m5-3-5-1 (clinical)**
Study Start Date: 2018-01-01
TRC Requirement: Full TS is needed

[Study Date Format Requirement]

- yyyy-mm-dd

TS.XPT

SSTDTC	Study Start Date	42622

Study Start Date in SAS Date Format

Fail Rule 1734

Section 4: TS File Information

4a. What Type of TS File is Required?* (*Refer to guidelines in chart below.*)
☒ Full TS ☐ Simplified TS ☐ Not Required

4b. Is TS File Included?*
☒ Yes ☐ No
Referenced Validation Error Number 1734
*If you answered "No" in **Field 4b**, Validation Rule 1734 FAILS. Do not proceed.*

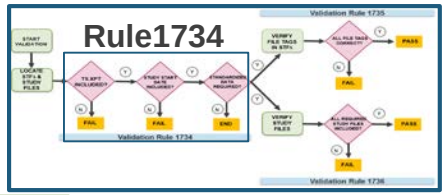
4c. Study ID in TS File*
☒ Study ABC

4d. Does Study ID in STF (Field 3d) & TS Files Match?
☐ Yes ☐ No
Referenced Validation Error Number 1734
*If you answered "No" in **Field 4d**, Validation Rule 1734 FAILS. Do not proceed.*

4e. Study Start Date in TS File	4f. If Study Start Date Exists, Is it Valid?	
42622	☒ Yes ☐ No	Referenced Validation Error Number 1734

4g. If Study Start Date does not Exist, What is the Stated Exception Code?

TRC Validation Rule 1734 (Section 4c)



- Trial Summary (TS) dataset (ts.xpt) with information on study start date must be present for required sections

Example	Self-Check Worksheet

Study Files and/or datasets submitted in **m5-3-5-1 (clinical)**
Study Start Date: 2018-01-01
TRC Requirement: Full TS is needed

[Study Date Format Requirement]
- yyyy-mm-dd

TS.XPT

SSTDTC	Study Start Date	2018-01-01

Section 4: TS File Information

4a. What Type of TS File is Required?* (*Refer to guidelines in chart below.*)
☒ Full TS ☐ Simplified TS ☐ Not Required

4b. Is TS File Included?*
☒ Yes ☐ No
Referenced Validation Error Number 1734
*If you answered "No" in **Field 4b**, Validation Rule 1734 FAILS. Do not proceed.*

4c. Study ID in TS File*
Study ABC

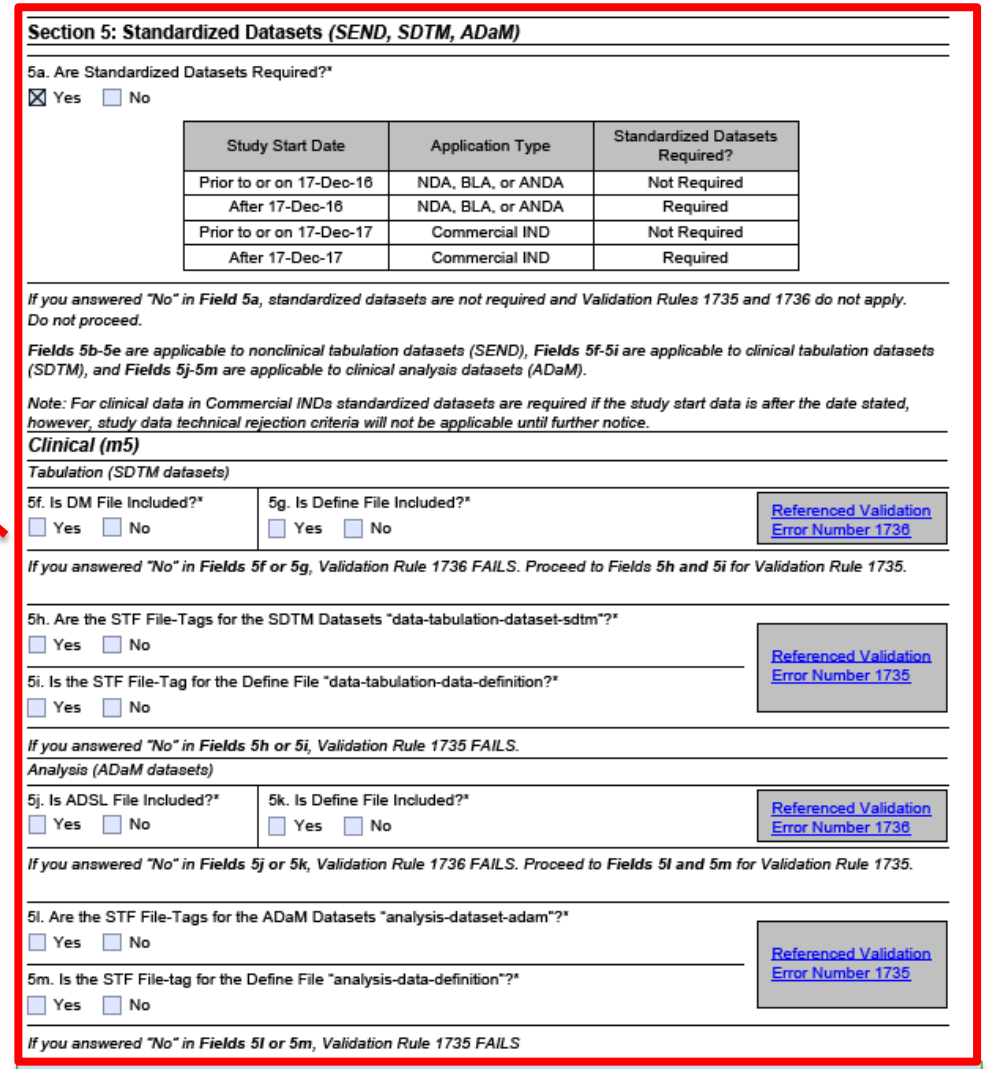
4d. Does Study ID in STF (Field 3d) & TS Files Match?
☒ Yes ☐ No
Referenced Validation Error Number 1734
*If you answered "No" in **Field 4d**, Validation Rule 1734 FAILS. Do not proceed.*

4e. Study Start Date in TS File: 2018-01-01
4f. If Study Start Date Exists, Is it Valid? ☒ Yes ☐ No
Referenced Validation Error Number 1734
4g. If Study Start Date does not Exist, What is the Stated Exception Code?

Pass Rule 1734

Self-Check Worksheet (1735 & 1736 Validation Error)

Section	Contents
5	**Standardized Dataset Information** (1735 & 1736 Validation Error) • Provide information about SEND or STDM and/or ADaM dataset and define.xml • Provide information about STF File-tags



Section 5: Standardized Datasets *(SEND, SDTM, ADaM)*

5a. Are Standardized Datasets Required?*
☒ Yes ☐ No

Study Start Date	Application Type	Standardized Datasets Required?
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Not Required
After 17-Dec-16	NDA, BLA, or ANDA	Required
Prior to or on 17-Dec-17	Commercial IND	Not Required
After 17-Dec-17	Commercial IND	Required

*If you answered "No" in **Field 5a**, standardized datasets are not required and Validation Rules 1735 and 1736 do not apply. Do not proceed.*

***Fields 5b-5e** are applicable to nonclinical tabulation datasets (SEND), **Fields 5f-5i** are applicable to clinical tabulation datasets (SDTM), and **Fields 5j-5m** are applicable to clinical analysis datasets (ADaM).*

Note: For clinical data in Commercial INDs standardized datasets are required if the study start data is after the date stated, however, study data technical rejection criteria will not be applicable until further notice.

Clinical (m5)

Tabulation (SDTM datasets)

5f. Is DM File Included?* ☐ Yes ☐ No
5g. Is Define File Included?* ☐ Yes ☐ No
Referenced Validation Error Number 1736

*If you answered "No" in **Fields 5f or 5g**, Validation Rule 1736 FAILS. Proceed to **Fields 5h and 5i** for Validation Rule 1735.*

5h. Are the STF File-Tags for the SDTM Datasets "data-tabulation-dataset-sdtm"?* ☐ Yes ☐ No
5i. Is the STF File-Tag for the Define File "data-tabulation-data-definition?* ☐ Yes ☐ No
Referenced Validation Error Number 1735

*If you answered "No" in **Fields 5h or 5i**, Validation Rule 1735 FAILS.*

Analysis (ADaM datasets)

5j. Is ADSL File Included?* ☐ Yes ☐ No
5k. Is Define File Included?* ☐ Yes ☐ No
Referenced Validation Error Number 1736

*If you answered "No" in **Fields 5j or 5k**, Validation Rule 1736 FAILS. Proceed to **Fields 5l and 5m** for Validation Rule 1735.*

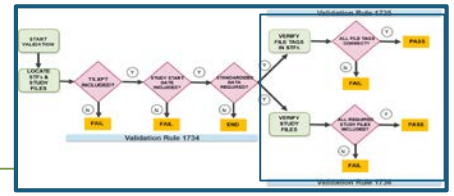
5l. Are the STF File-Tags for the ADaM Datasets "analysis-dataset-adam"?* ☐ Yes ☐ No
5m. Is the STF File-tag for the Define File "analysis-data-definition"?* ☐ Yes ☐ No
Referenced Validation Error Number 1735

*If you answered "No" in **Fields 5l or 5m**, Validation Rule 1735 FAILS*

Fillable Self-Check Worksheet - Coming Soon!

Reference:
"Technical Rejection Criteria Self-Check Worksheet"
https://www.fda.gov/media/123098/download
"Technical Rejection Criteria Self-Check Worksheet Instructions"
https://www.fda.gov/media/123099/download

TRC Validation Rule 1735 and 1736 (Section 5a)



- **Rule 1735:** Correct STF file-tags must be used for all standardized datasets and corresponding define.xml files in required sections
- **Rule 1736:** For SEND data, a DM dataset and define xml must be submitted in required sections

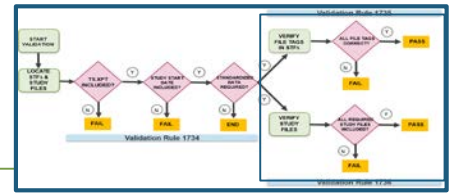
  For SDTM data, a DM dataset and define.xml must be submitted in required sections

  For ADaM data, an ADSL dataset and define.xml must be submitted in required sections

Example	Self-Check Worksheet
Study Files and/or datasets submitted in **m5-3-5-1 (clinical)** **Study Start Date:** 2018-01-01 **Dataset Type:** Tabulation (SDTM)	**Section 5: Standardized Datasets *(SEND, SDTM, ADaM)*** 5a. Are Standardized Datasets Required?* ☒ Yes ☐ No

Study Start Date	Application Type	Standardized Datasets Required?
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Not Required
After 17-Dec-16	NDA, BLA, or ANDA	Required
Prior to or on 17-Dec-17	Commercial IND	Not Required
After 17-Dec-17	Commercial IND	Required

TRC Validation Rule 1735 and 1736 (Section 5f-5g)



- **Rule 1735:** Correct STF file-tags must be used for all standardized datasets and corresponding define.xml files in required sections
- **Rule 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

Example

Study Files and/or datasets submitted in **m5-3-5-1 (clinical)**
Study Start Date: 2018-01-01
Dataset Type: Tabulation (SDTM)

Files Referenced in stf.xml

acrf.pdf	ds.xpt	mh.xpt	suppda.xpt	suppmh.xpt	tv.xpt
ae.xpt	dv.xpt	pe.xpt	suppdm.xpt	sv.xpt	vs.xpt
cm.xpt	eg.xpt	sc.xpt	suppds.xpt	ta.xpt	
co.xpt	ex.xpt	se.xpt	suppeg.xpt	te.xpt	
csdrg.pdf	ie.xpt	suppae.xpt	suppex.xpt	ti.xpt	

dm.xpt and define.xml are missing

Fail Rule 1736

Self-Check Worksheet

Section 5: Standardized Datasets *(SEND, SDTM, ADaM)*

5a. Are Standardized Datasets Required?*
☒ Yes ☐ No

Study Start Date	Application Type	Standardized Datasets Required?
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Not Required
After 17-Dec-16	NDA, BLA, or ANDA	Required
Prior to or on 17-Dec-17	Commercial IND	Not Required
After 17-Dec-17	Commercial IND	Required

Clinical (m5)

Tabulation (SDTM datasets)

5f. Is DM File Included?* ☐ Yes ☒ No

5g. Is Define File Included?* ☐ Yes ☒ No

Referenced Validation Error Number 1736

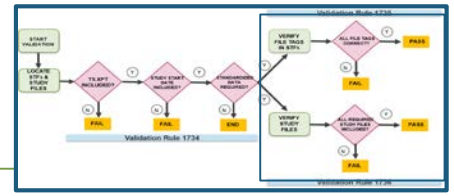
*If you answered "No" in **Fields 5f or 5g**, Validation Rule 1736 FAILS. Proceed to Fields **5h and 5i** for Validation Rule 1735.*

5h. Are the STF File-Tags for the SDTM Datasets "data-tabulation-dataset-sdtm"?*
☐ Yes ☐ No

5i. Is the STF File-Tag for the Define File "data-tabulation-data-definition?*
☐ Yes ☐ No

Referenced Validation Error Number 1735

*If you answered "No" in **Fields 5h or 5i**, Validation Rule 1735 FAILS.*



TRC Validation Rule 1735 and 1736 (Section 5f-5g)

- **Rule 1735:** Correct STF file-tags must be used for all standardized datasets and corresponding define.xml files in required sections
- **Rule 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

Example

Study Files and/or datasets submitted in **m5-3-5-1 (clinical)**
Study Start Date: 2018-01-01
Dataset Type: Tabulation (SDTM)

Files Referenced in stf.xml

acrf.pdf	define.xml	ex.xpt	se.xpt	suppeg.xpt	te.xpt
ae.xpt	define2-0-0.xsl	ie.xpt	suppae.xpt	suppex.xpt	ti.xpt
cm.xpt	dm.xpt	lb.xpt	suppcm.xpt	supplb.xpt	ts.xpt
co.xpt	ds.xpt	mh.xpt	suppda.xpt	suppmh.xpt	tv.xpt
csdrg.pdf	dv.xpt	pe.xpt	suppdm.xpt	sv.xpt	vs.xpt

Pass Rule 1736

Self-Check Worksheet

Section 5: Standardized Datasets *(SEND, SDTM, ADaM)*

5a. Are Standardized Datasets Required?*
☒ Yes ☐ No

Study Start Date	Application Type	Standardized Datasets Required?
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Not Required
After 17-Dec-16	NDA, BLA, or ANDA	Required
Prior to or on 17-Dec-17	Commercial IND	Not Required
After 17-Dec-17	Commercial IND	Required

Clinical (m5)

Tabulation (SDTM datasets)

5f. Is DM File Included?* ☒ Yes ☐ No

5g. Is Define File Included?* ☒ Yes ☐ No

Referenced Validation Error Number 1736

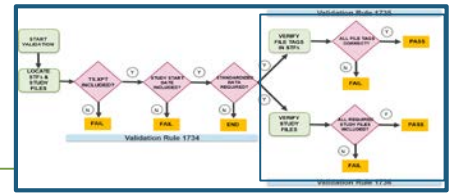
*If you answered "No" in **Fields 5f or 5g**, Validation Rule 1736 FAILS. Proceed to Fields **5h and 5i** for Validation Rule 1735.*

5h. Are the STF File-Tags for the SDTM Datasets "data-tabulation-dataset-sdtm"?*
☐ Yes ☐ No

5i. Is the STF File-Tag for the Define File "data-tabulation-data-definition?*
☐ Yes ☐ No

Referenced Validation Error Number 1735

*If you answered "No" in **Fields 5h or 5i**, Validation Rule 1735 FAILS.*



TRC Validation Rule 1735 and 1736 (Section 5h-5i)

- **Rule 1735:** Correct STF file-tags must be used for all standardized datasets and corresponding define.xml files in required sections
- **Rule 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

Example

Study Files and/or datasets submitted in **m5-3-5-1 (clinical)**
Study Start Date: 2018-01-01
Dataset Type: Tabulation (SDTM)

Files Referenced in stf.xml

acrf.pdf	ae.xpt	cm.xpt
co.xpt	csdrg.pdf	define.pdf
define.xml	define2-0-0.xsl	dm.xpt
ds.xpt	dv.xpt	eg.xpt
ex.xpt	ie.xpt	lb.xpt

stf.xml

```
<doc-content xlink:href="../../../../../../0001/index.xml#0003"><file-tag name=
"data-tabulation-dataset-sdtm" info-type="us" />
<doc-content xlink:href="../../../../../../0001/index.xml#0004"><file-tag name=
"data-tabulation-dataset-sdtm" info-type="us" /></doc-content>
```

define.xml is tagged as "data-tabulation-dataset-sdtm"

Fail Rule 1735

Self-Check Worksheet

Section 5: Standardized Datasets *(SEND, SDTM, ADaM)*

5a. Are Standardized Datasets Required?*
☒ Yes ☐ No

Study Start Date	Application Type	Standardized Datasets Required?
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Not Required
After 17-Dec-16	NDA, BLA, or ANDA	Required
Prior to or on 17-Dec-17	Commercial IND	Not Required
After 17-Dec-17	Commercial IND	Required

Clinical (m5)

Tabulation (SDTM datasets)

5f. Is DM File Included?* ☒ Yes ☐ No

5g. Is Define File Included?* ☒ Yes ☐ No

Referenced Validation Error Number 1736

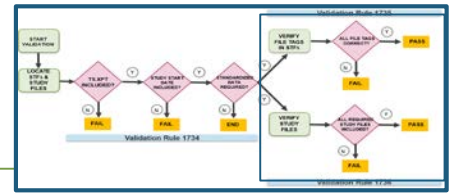
*If you answered "No" in **Fields 5f or 5g**, Validation Rule 1736 FAILS. Proceed to Fields **5h and 5i** for Validation Rule 1735.*

5h. Are the STF File-Tags for the SDTM Datasets "data-tabulation-dataset-sdtm"?*
☒ Yes ☐ No

5i. Is the STF File-Tag for the Define File "data-tabulation-data-definition?*
☐ Yes ☒ No

Referenced Validation Error Number 1735

*If you answered "No" in **Fields 5h or 5i**, Validation Rule 1735 FAILS.*



TRC Validation Rule 1735 and 1736 (Section 5h-5i)

- **Rule 1735:** Correct STF file-tags must be used for all standardized datasets and corresponding define.xml files in required sections
- **Rule 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

Example

Study Files and/or datasets submitted in **m5-3-5-1 (clinical)**
Study Start Date: 2018-01-01
Dataset Type: Tabulation (SDTM)

Files Referenced in stf.xml

acrf.pdf	ae.xpt	cm.xpt
co.xpt	csdrg.pdf	define.pdf
define.xml	define2-0-0.xsl	dm.xpt

stf.xml

```
<doc-content xlink:href="../../../../../../../0001/index.xml#0003"><file-tag name=
"data-tabulation-dataset-sdtm" info-type="us" />
<doc-content xlink:href="../../../../../../../0001/index.xml#0004"><file-tag name=
"data-tabulation-data-definition" info-type="us" /></doc-content>
```

define.xml is tagged as "data-tabulation-data-definition"

Pass Rule 1736

Self-Check Worksheet

Section 5: Standardized Datasets *(SEND, SDTM, ADaM)*

5a. Are Standardized Datasets Required?*
☒ Yes ☐ No

Study Start Date	Application Type	Standardized Datasets Required?
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Not Required
After 17-Dec-16	NDA, BLA, or ANDA	Required
Prior to or on 17-Dec-17	Commercial IND	Not Required
After 17-Dec-17	Commercial IND	Required

Clinical (m5)

Tabulation (SDTM datasets)

5f. Is DM File Included?* ☒ Yes ☐ No

5g. Is Define File Included?* ☒ Yes ☐ No

Referenced Validation Error Number 1736

*If you answered "No" in **Fields 5f or 5g**, Validation Rule 1736 FAILS. Proceed to Fields **5h and 5i** for Validation Rule 1735.*

5h. Are the STF File-Tags for the SDTM Datasets "data-tabulation-dataset-sdtm"?*
☒ Yes ☐ No

5i. Is the STF File-Tag for the Define File "data-tabulation-data-definition?*
☒ Yes ☐ No

Referenced Validation Error Number 1735

*If you answered "No" in **Fields 5h or 5i**, Validation Rule 1735 FAILS.*

Polling Question 3

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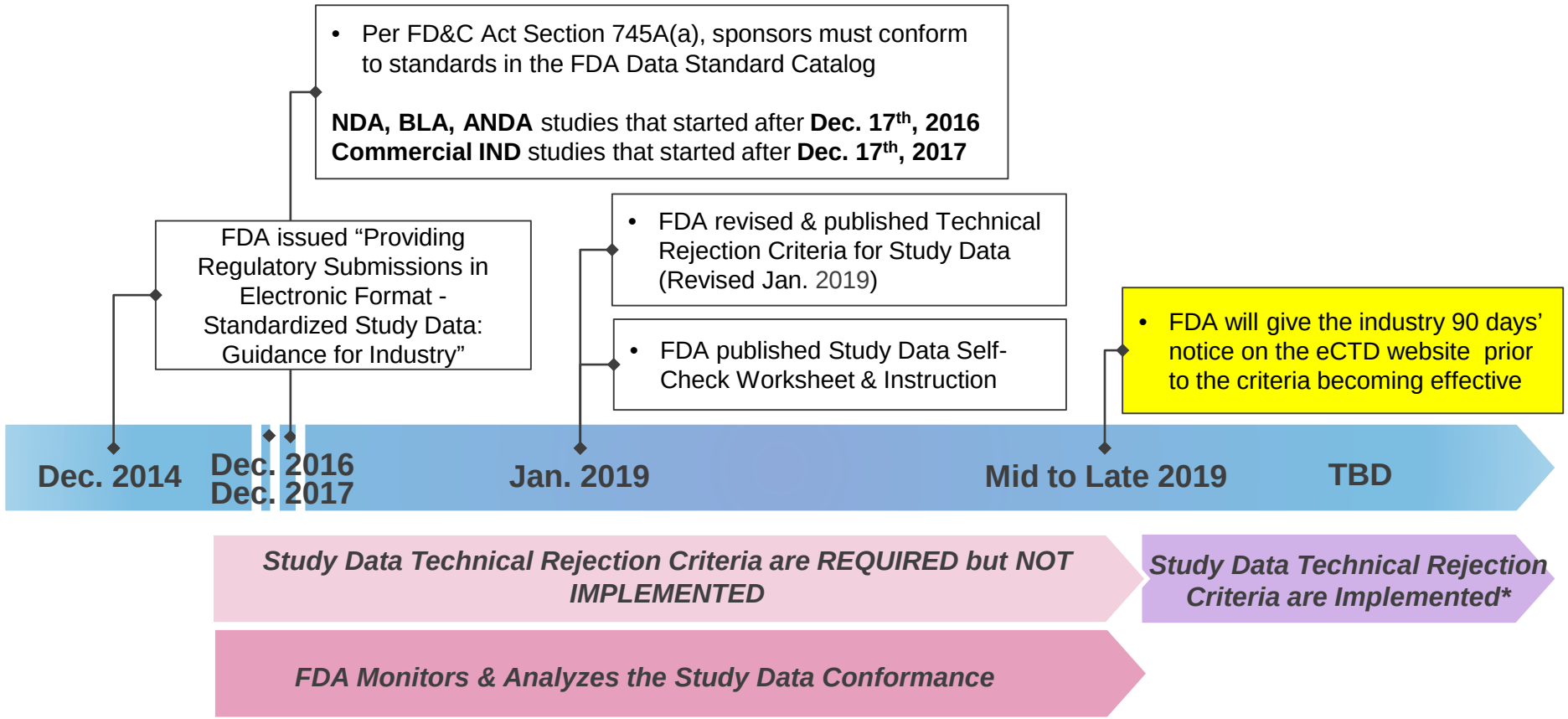
Implementation Timeline

Implementation Timeline

- FDA published Revised Study Data Technical Rejection Criteria (Revised Jan. 2019) and Study Data Self-Check Worksheet to assist sponsors with the TRC Conformance



** Note: When a submission is technically-rejected, the submission sequence is not transferred into the FDA electronic document rooms*

Summary

- Based on the revised SDTRC, about 22% all submissions were received with non-critical errors for 1734 and 1736
- FDA published Study Data Self-Check Worksheet to help sponsors to follow the revised SDTRC
- FDA requires the submission of standardized Study Data as defined in the FDA Data Standard Catalog
- FDA has not rejected any submission that contains errors as reflected in this analysis
- FDA plans to use technical rejection criteria to identify applications that are not fulfilling this requirement

TIP

To avoid validation errors, it is important for sponsors and applicants to understand the requirements specified in guidance and recommendations for submitting study data in the Study Data Technical Conformance Guide.

Questions

- For questions about submitting study data please contact:
  - CDER – edata@fda.hhs.gov
  - CBER – cber.cdisc@fda.hhs.gov

- For questions about eCTD, including stf.xml and file-tags, please contact:
  - CDER - esub@fda.hhs.gov
  - CBER – esubprep@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

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Thank You

Ethan Chen
Office of Business Informatics
Center for Drug Evaluation and Research

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