FDA View:
Technical Rejection Criteria for Study Data

Presented to: PhUSE US Connect 2019

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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.

Topics

- Study Data Technical Rejection Criteria Conformance Statistics from Previous Analysis
- Revised Technical Rejection Criteria for Study Data
- Updated Study Data Conformance Analysis
- New Tools for Industry
- Implementation Timeline
- Summary

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

Study Data Technical Rejection Criteria Conformance Statistics from Previous Analysis

Study Data Conformance from Previous Analysis

- **Study Data was assessed for:**
  - NDA, BLA, and ANDA Submissions received from 12/18/2016 to 3/31/2018
  - Commercial IND Submissions received from 12/18/2017 to 3/31/2018
  - No duplicates
- **Conformance was checked against the existing two high-level validation rules as described in the Technical Rejection Criteria for Study Data**
  - 1734 – TS Dataset & Correct Study Start Date must be present
  - 1736 – DM Dataset, ADSL Dataset and define.xml must be present

Overall Conformance Statistics from Previous Analysis

Error	Description
1734	Trial Summary (TS) dataset must be present for each study in eCTD section 4.2 and 5.3
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

	NDA	ANDA	BLA	Comm. IND	All
Total Number of Submissions with Study Data	1,126	1,446	473	176	3,221
Total Number Submissions with Critical Errors	302	551	138	41	1,032
Error 1734	290	506	137	35	968
Error 1736	14	63	1	6	84
Failure Rate (% among submissions with Study Data)	26.8%	38.1%	29.2%	23.3%	32.0%

Notes:

(1) One drug application could contain multiple submissions throughout its review life-cycle, such as original, supplements, and amendments

(2) Analysis includes NDA, BLA, and ANDA submissions received by CDER between 12/18/2016 and 3/31/2018, and commercial IND submissions received by CDER between 12/18/2017 and 3/31/2018

(3) Validation of error 1736 of a study is not performed if a study has Error 1734

(4) A submission with multiple studies can report both Errors 1734 and 1736. In this instance, the submission is counted only once at the submission level when calculating failure rate

Reference: FDA Study Data Technical Rejection Criteria (Revised May 2018)

Revised Study Data Technical Rejection Criteria

CY2018 Conformance Analysis for Validation Errors 1734 & 1736

Error	Description
1734	Trial Summary (TS) dataset (ts.xpt) with information on study start date must be present for required sections*
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*

** Refer to the latest Technical Rejection Criteria for Study Data*

	NDA	ANDA	BLA	Comm. IND	All
Total Number of Submissions with Study Data	**877**	**1078**	**291**	**649**	**2895**
Total Number Submissions with Critical Errors	**195**	**266**	**50**	**113**	**624**
Error 1734	**185**	**186**	**48**	**96**	**515**
Error 1736	**16**	**88**	**2**	**18**	**124**
Failure Rate (% among submissions with Study Data)	**22.2%**	**24.7%**	**17.2%**	**17.4%**	**21.6%**

Notes:

(1) Analysis includes NDA, BLA, ANDA and Commercial IND submissions received by CDER between 1/1/2018 and 12/31/2018

(2) Validation of error 1736 is not performed if a study has Error 1734

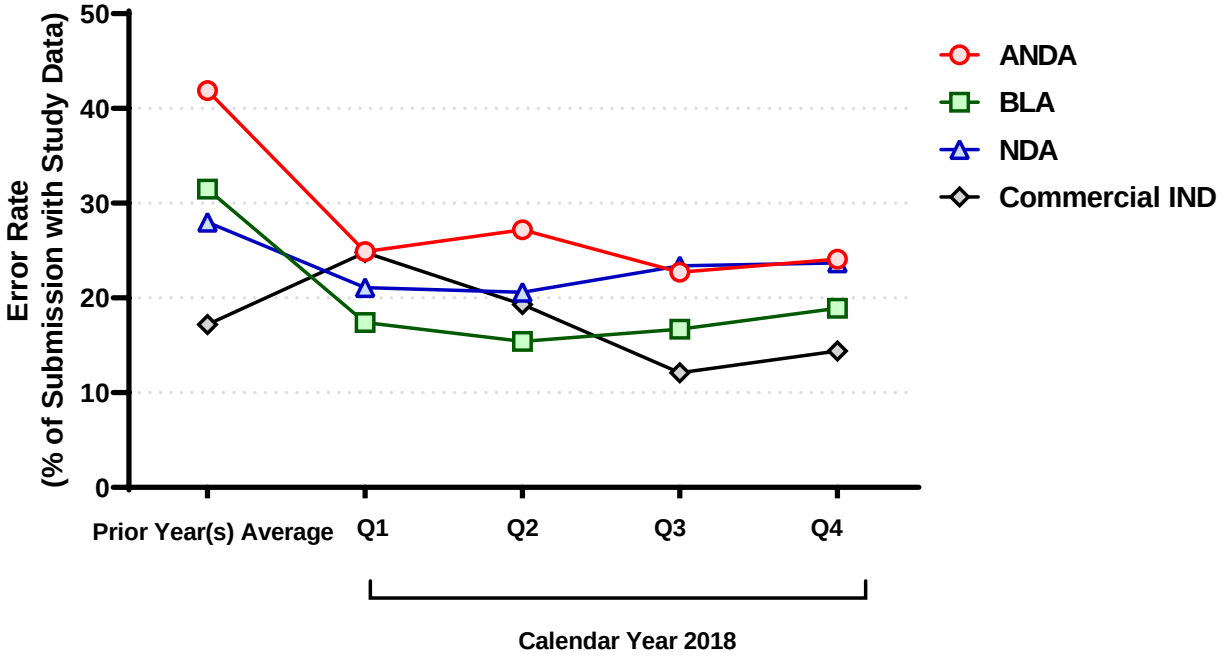
(3) A submission with multiple studies can report both Errors 1734 and 1736. In this instance, the submission is counted only once at the submission level when calculating failure rate

(4) Analysis is conducted according to the revised TRC (Revised Jan. 2019)

Reference: FDA Study Data Technical Rejection Criteria (Revised Jan. 2019)

Overall Conformance Trend for Validation Errors 1734 & 1736

- Submissions with study data received during CY2018 showed overall decreases in Validation Errors 1734 and 1736 compared to prior years' average error rate



Notes:

(1) Prior year(s) average uses data from the previous analysis, but excludes any submissions received in 2018

(2) CY2018 analysis is conducted according to the revised TRC (Revised Jan. 2019)

Summary of 1734 and 1736 Conformance Trend

- The failure rate for Errors 1734 and 1736 for all application types received in CY2018 is 21.6%
- Overall conformance for Errors 1734 and 1736 improved compared to the previous analysis (previous years' average of 68.0% vs. CY2018's average of 78.4%)
- 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
  - Revision to TRC
    - Details on 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
  - **Additional Tools**: Self-Check Worksheet and Instructions for Study Data

Summary of Latest Revisions to the Technical Rejection Criteria for Study Data (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**	STF Files must be submitted in a study section. STF s are not required for required sections*	**High**

** Refer to the latest Technical Rejection Criteria for Study Data*

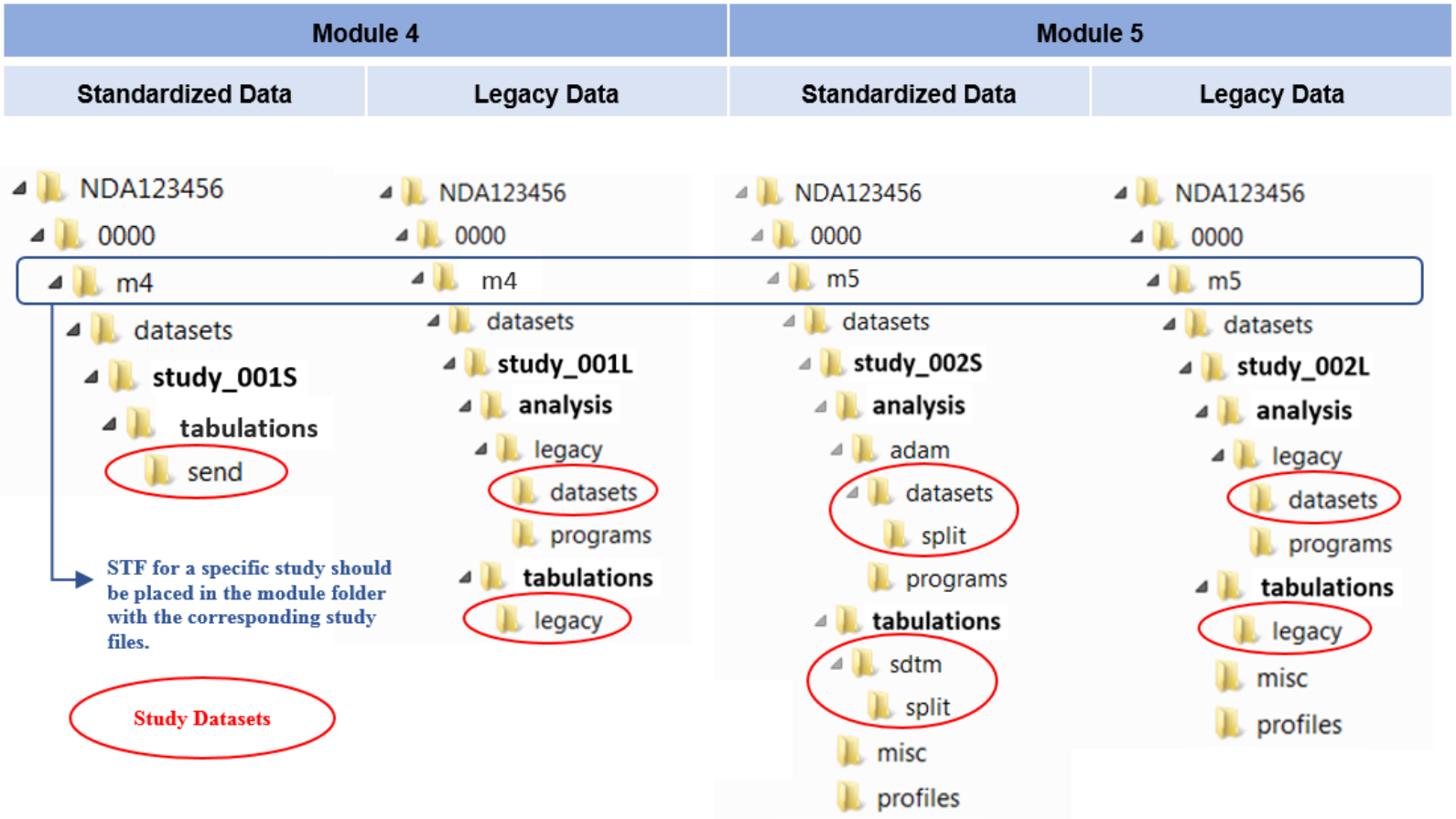
*** From Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specification, Section J: Datasets must only be provided in modules 3, 4, or 5 and not in modules 1 or 2*

Reference:

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

Folder Structure for Module 4 and Module 5

- STF files and their associated datasets should be organized into a specific file directory structure and a specific headings and hierarchy structure



References:
FDA Study Data Technical Conformance Guide (Appendix E; Version 4.2, October 2018)
ICH M2 EWG: The eCTD Backbone File Specification for Study Tagging Files

Additional Details for Error 1734

❖ **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)

Example of ts.xpt Datasets

STUDYID	TSPARMCD	TSVAL	TSVALNF
•Study ID in STF File	•SSTDTC for a clinical study •STSTDTC for a nonclinical study	•Format: yyyy-mm-dd •Left blank when study start date is not available	• Left blank when study start date is provided in TSVAL • Exception code as specified in the ISO 21090 Standard when study start date is not available

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

Study Data Requirements for Submissions

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, 5.3.3.1z, 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	

Reference: FDA Study Data Technical Rejection Criteria (Revised Jan. 2019)

Emphasis on Errors 1735 and Inclusion of 1789

- Each submission typically contains many studies, an STF file is necessary to process study files into their corresponding studies; Accepting a submission where CDER cannot process the study tagging file will result in the reviewer seeing a list of files for which they do no not know the study they belong to

- If a study data file (e.g. define.xml) is not properly tagged in the STF file, it cannot be identified and located, resulting in Error 1736 being reported

Error	Description	Severity Level
1789	STF Files must be submitted in a study section. STF s are not required 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**

** Refer to the latest Technical Rejection Criteria for Study Data*

Reference: FDA Study Data Technical Rejection Criteria (Revised Jan. 2019)

Updated Study Data Conformance Analysis

Study Data Conformance Analysis

- One drug application could contain multiple submissions throughout its review life-cycle, such as original, supplements, and amendments
- Each submission may contain more than one study
- Analysis includes submissions received by CDER between 1/1/2018 and 12/31/2018
- Validation of errors 1735 and 1736 is not performed if a study has Error 1734
- Analysis is conducted according to the revised TRC (Revised Jan. 2019)

CY2018 Conformance Analysis of Submissions: Error 1789

Error	Description	Severity Level
1789	STF Files must be submitted in a study section. STF s are not required for required sections*	**High**

** Refer to the latest Technical Rejection Criteria for Study Data*

	IND	NDA	BLA	ANDA
Total Number of Submission	**79473**	**41077**	**11042**	**62695**
Error 1789	**193**	**43**	**1**	**225**
Failure Rate (% among Total Number of Submission)	**0.24%**	**0.10%**	**<0.01%**	**0.36%**

CY2018 Conformance Analysis of IND, NDA, BLA and ANDA Submission Studies: Errors 1734, 1735 & 1736

Error	Description
1734	Trial Summary (TS) dataset (ts.xpt) with information on study start date must be present for required sections*
1735	Correct STF file-tags must be used for all standardized datasets and corresponding define.xml files in required sections*
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*

** Refer to the latest Technical Rejection Criteria for Study Data*

	IND		NDA		BLA		ANDA	
	Nonclin (m4)	Clin (m5)	Nonclin (m4)	Clin (m5)	Nonclin (m4)	Clin (m5)	Nonclin (m4)	Clin (m5)
Total Number of Studies	883	288	403	1810	12	206	N/A	1004
Total Number Studies with Critical Errors	105	98	38	390	3	51	N/A	673
Error 1734	65	85	33	321	2	46	N/A	186
Error 1735	36	2	6	53	0	5	N/A	497
Error 1736	11	13	1	35	1	1	N/A	88
Error Rate (% among Total Number of Studies)	11.9%	34.0%	9.7%	21.6%	25.0%	24.8%	N/A	67.0%

New Tools for Industry

Tools for Industry

FDA has developed tools to help sponsors meet updated study data standard requirements and provide more transparency on the validation process

www.fda.gov

Gateway

Sponsor reviews Study Data Standard Resources: • **Revised Study Data Technical Rejection Criteria with eCTD Validation Table** • **Study Data Self-Check Worksheet & Instruction**	**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**

1. **Revised Study Data Technical Rejection Criteria** (Revised Jan. 2019)

Purpose: To clarify the requirements for eCTD Validation of submissions with study data and to provided examples (**Appendix 1 and 2**) to illustrate the requirements

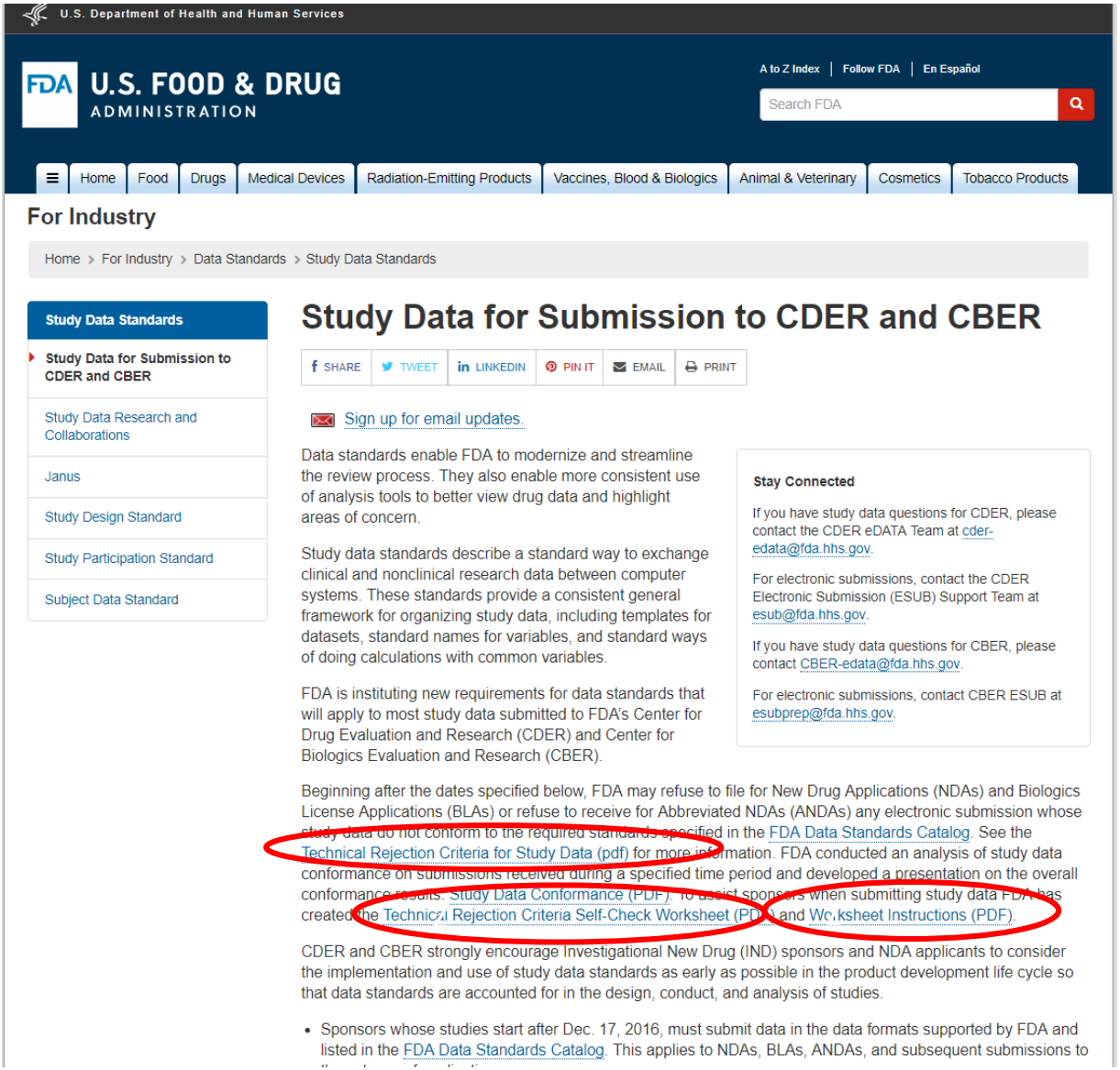
2. TRC Self-Check Worksheet & Instruction

Purpose: To help sponsors understand criteria for submissions with study data to pass the updated TRC

3. eCTD and/or Standardized Data Sample Validation

Purpose: To help sponsors validate their sample submissions and receive feedback with identified errors

Published Technical Rejection Criteria for Study Data & Self-Check Worksheet



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Study Data Standards

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Study Data for Submission to CDER and CBER

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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).

CDER and CBER strongly encourage Investigational New Drug (IND) sponsors and NDA applicants to consider the implementation and use of study data standards as early as possible in the product development life cycle so that data standards are accounted for in the design, conduct, and analysis of studies.

- Sponsors whose studies start after Dec. 17, 2016, must submit data in the data formats supported by FDA and listed in the FDA Data Standards Catalog. This applies to NDAs, BLAs, ANDAs, and subsequent submissions to

"Technical Rejection Criteria for Study Data"
https://www.fda.gov/downloads/forindustry/datastandards/studydatastandards/ucm630740.pdf"

"Technical Rejection Criteria Self-Check Worksheet"
https://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM630732.pdf

"Technical Rejection Criteria Self-Check Worksheet Instructions"
https://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM630733.pdf

Selected Examples of Validation Findings in Study Data

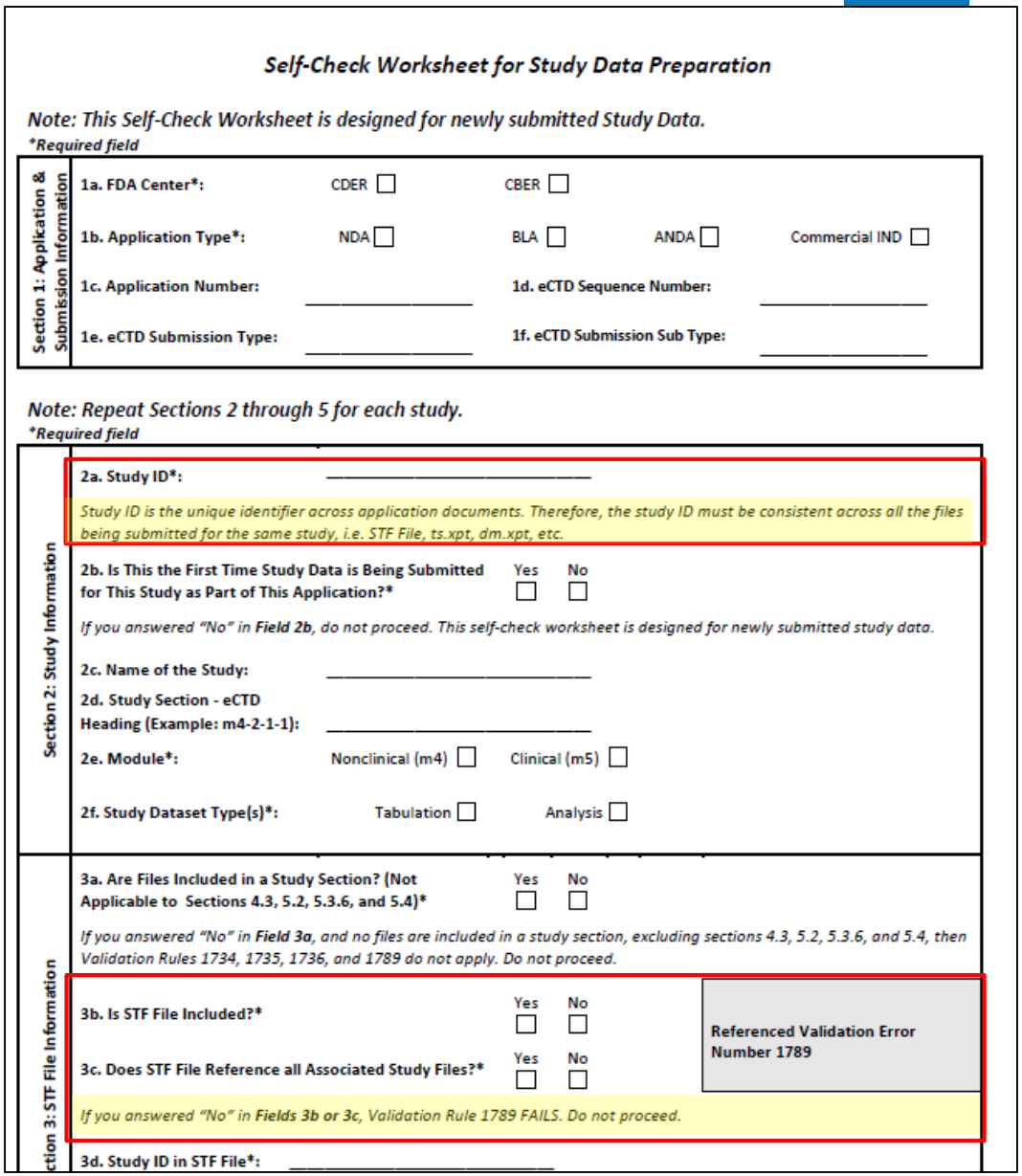
1. A study prior to December 17, 2016 for NDAs, BLAs, and ANDAs (or December 17, 2017 for Commercial INDs), is submitted to FDA and the study files are referenced in a Study Tagging File (STF), a ts.xpt dataset is not included in the study. The Study Data Start Date cannot be determined, the study fails validation 1734.

2. A study in standardized format is submitted to FDA and the study files are referenced in a Study Tagging File (STF). The ADaM study in Module 5 contains a define.xml file and a adsl.xpt file and they are appropriately file tagged. The study passes validation 1736.

Reference: FDA Study Data Technical Rejection Criteria (Revised Jan. 2019)

Overview of the Self-Check Worksheet

- **Designed to walk sponsors through each step of TRC validation process**
- **Dynamically guides sponsors through study data requirements based on study information entered**
- **Designed to help the sponsors when they prepare study data to submit to the FDA for the first time**



Self-Check Worksheet for Study Data Preparation

Note: This Self-Check Worksheet is designed for newly submitted Study Data.

**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.

**Required field*

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. Name 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 ☐

Section 3: STF File 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*: _____

Reference: "Technical Rejection Criteria Self-Check Worksheet"
https://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM630732.pdf
"Technical Rejection Criteria Self-Check Worksheet Instructions"
https://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM630733.pdf

Sections of the Study Data Self-Check Worksheet

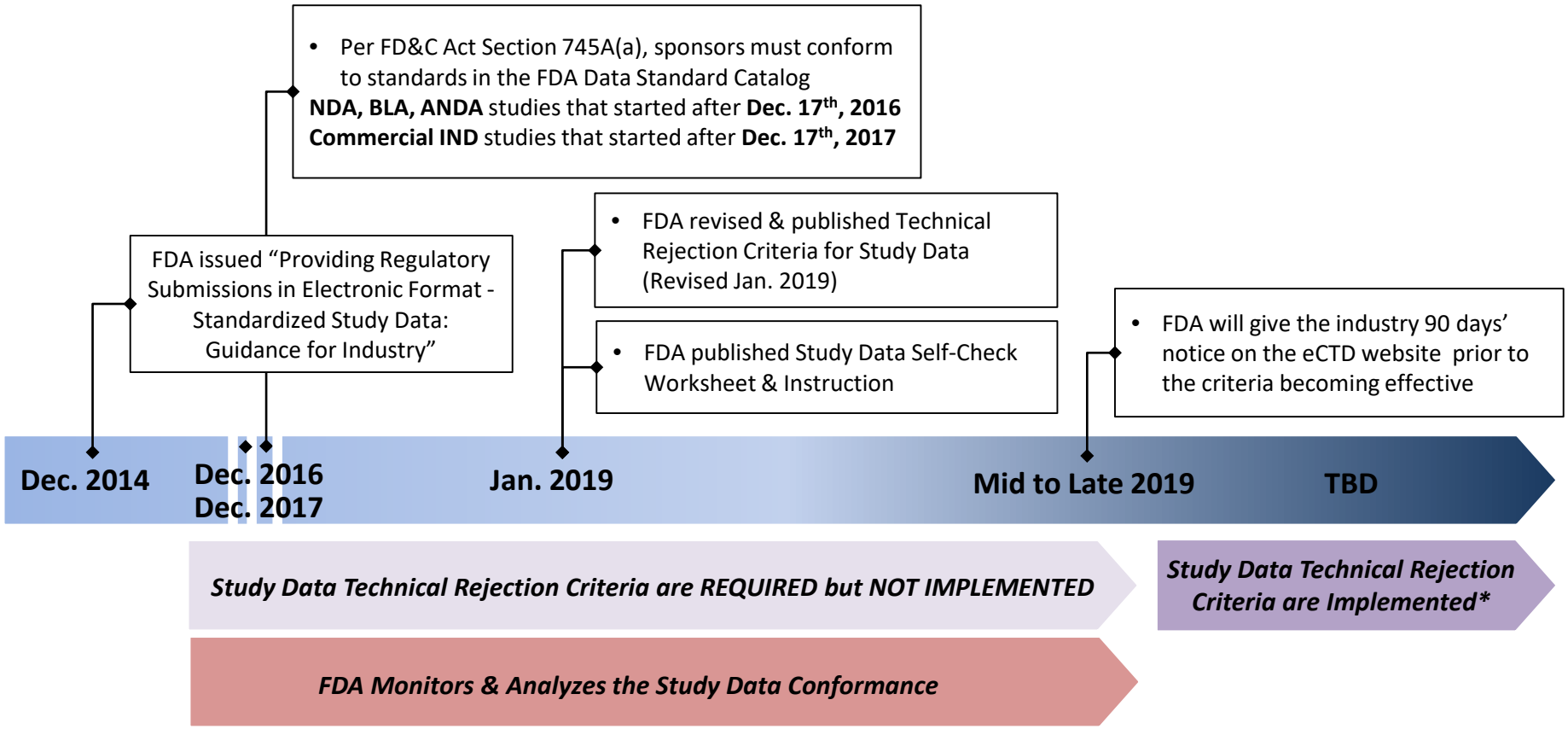
Section	Contents	Example(s)
1	**Application & Submission Information** • Provides high level information about the application and submission	1a. FDA Center*: CDER ☐ CBER ☐
2	**Study Information** • Provides more detailed information about the specific study	2a. Study ID*: 2f. Study Dataset Type(s)*: Tabulation ☐ Analysis ☐
3	**STF File Information** (1789 Validation Error) • Provide information about STF file	3b. Is STF File Included?* Yes ☐ No ☐ 3c. Does STF File Reference all Associated Study Files?* Yes ☐ No ☐
4	**TS File Information** (1734 Validation Error) • Provide information about ts.xpt file with study start date	4c. Study ID in TS File*: _____ 4d. Does Study ID in STF & TS Files Match?* Yes ☐ No ☐
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	5f. Is DM File Included?* Yes ☐ No ☐ 5g. Is Define File Included?* Yes ☐ No ☐

Note: Sections 2 through 5 are repeated for each study.

Reference: "Technical Rejection Criteria Self-Check Worksheet"
https://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM630732.pdf
"Technical Rejection Criteria Self-Check Worksheet Instructions"
https://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM630733.pdf

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 TRC, about 21.6% 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 TRC
- 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.

References

- **"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/DOWNLOADS/FORINDUSTRY/DATASTANDARDS/STUDYDATASTANDARDS/UCM630740.PDF
- **"Study Data Technical Conformance Guide"**
  HTTPS://WWW.FDA.GOV/DOWNLOADS/FORINDUSTRY/DATASTANDARDS/STUDYDATASTANDARDS/UCM624939.PDF
- **"FDA Data Standards Catalog"**
  HTTPS://WWW.FDA.GOV/FORINDUSTRY/DATASTANDARDS/STUDYDATASTANDARDS/DEFAULT.HTM
- **"Technical Rejection Criteria Self-Check Worksheet"**
  HTTPS://WWW.FDA.GOV/DOWNLOADS/FORINDUSTRY/DATASTANDARDS/STUDYDATASTANDARDS/UCM630732.PDF

  "Technical Rejection Criteria Self-Check Worksheet Instructions"
  HTTPS://WWW.FDA.GOV/DOWNLOADS/FORINDUSTRY/DATASTANDARDS/STUDYDATASTANDARDS/UCM630733.PDF

Recommended Readings:

- **For FDA instruction of Study Data submission, see the FDA "Study Data for Submission to CDER and CBER" page at:**
  HTTPS://WWW.FDA.GOV/DRUGS/DEVELOPMENTAPPROVALPROCESS/FORMSSUBMISSIONREQUIREMENTS/ELECTRONICSUBMISSIONS/UCM248635.HTM

- **For the full list of Study Data standards, see the FDA "Study Data Standards Resources" page at:**
  HTTP://WWW.FDA.GOV/FORINDUSTRY/DATASTANDARDS/STUDYDATASTANDARDS

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