



Update on Technical Rejection Criteria for Study Data

Presented to: Regulatory Education for Industry (REI)
Generic Drug Forum

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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 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

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

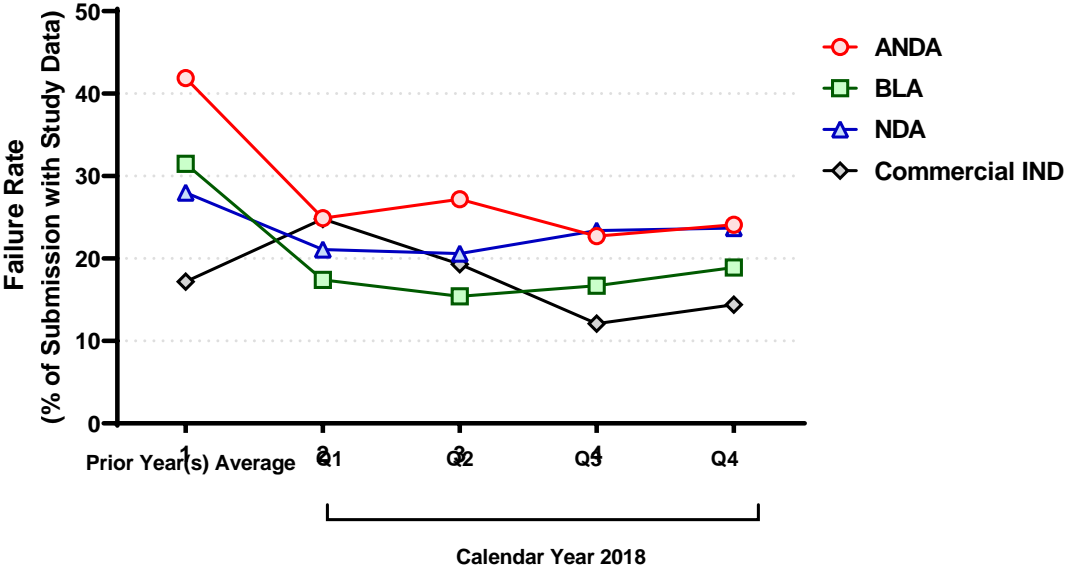
	NDA	ANDA	BLA	Comm. IND	All
Total Number of Submissions with Study Data	877	1078	291	649	2895
Total Number Submissions with Critical Errors	195	266	50	113	624
Error 1734	185	186	48	96	515
Error 1736	16	88	2	18	124
Failure Rate (% among submissions with Study Data)	22.2%	24.7%	17.2%	17.4%	21.6%

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)

Overall Conformance Trend for Validation Errors 1734 & 1736

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

CY2018 Conformance Analysis of ANDA Submission Studies: Errors 1734, 1735 & 1736

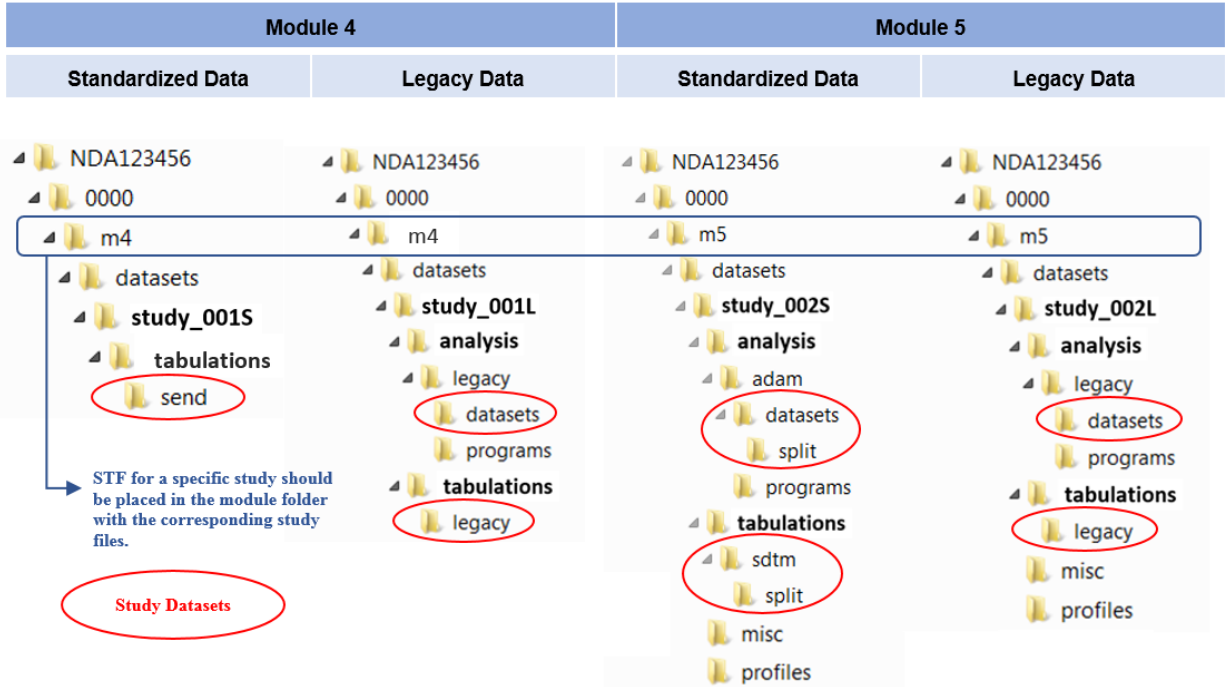
Error	Description
1734	Trial Summary (TS) dataset (ts.xpt) with information on study start date must be present for required sections*
1735	Correct STF file-tags must be used for all standardized datasets and corresponding define.xml files in required sections*
1736	For SEND data, a DM dataset and define 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

	Submission Type		Study Type			Total
	Original	Other	Nonclinical (m4)	Clinical (m5)	Other	
Total Number of Studies	591	497	N/A	1004	74	1078
Total Number Studies with Critical Errors	392	281	N/A	673	0	673
Error 1734	77	109	N/A	186	0	186
Error 1735	327	170	N/A	497	0	497
Error 1736	55	33	N/A	88	0	88
Error Rate (% among Total Number of Studies)	67.5%	56.5%	N/A	67.0%	0	62.4%

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
<ul style="list-style-type: none"> • Study ID in STF File 	<ul style="list-style-type: none"> • SSTDTC for a clinical study • STSTDTC for a nonclinical study 	<ul style="list-style-type: none"> • Format: yyyy-mm-dd • Left blank when study start date is not available 	<ul style="list-style-type: none"> • 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:



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	

Emphasis on Errors 1735 and Inclusion of 1789

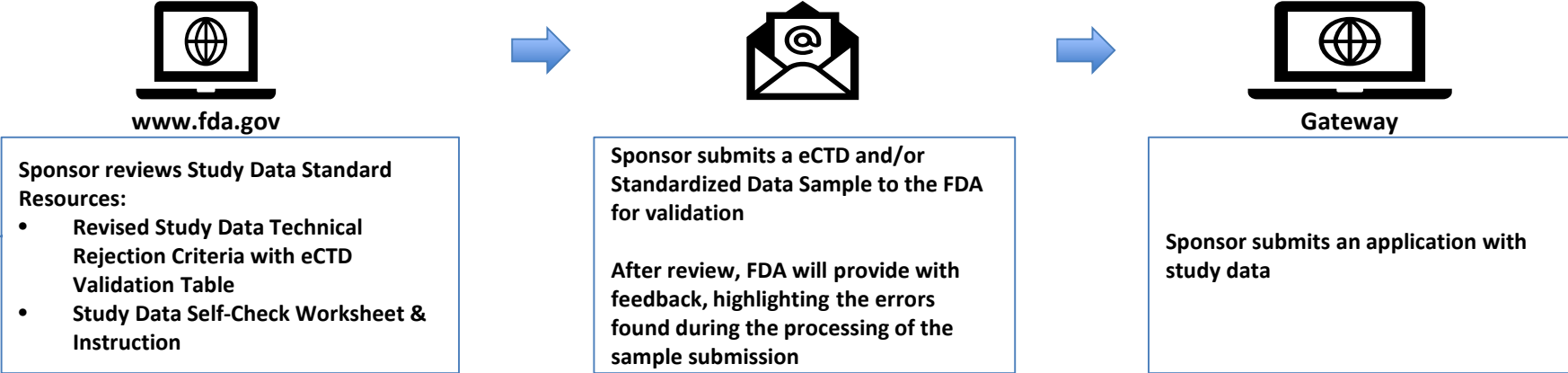
- ❖ Each submission typically contains many studies, an STF file is necessary to process study files into their corresponding studies; Accepting a submission where CDER cannot process the study tagging file will result in the reviewer seeing a list of files for which they do not know the study they belong 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

Tools for Industry

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



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

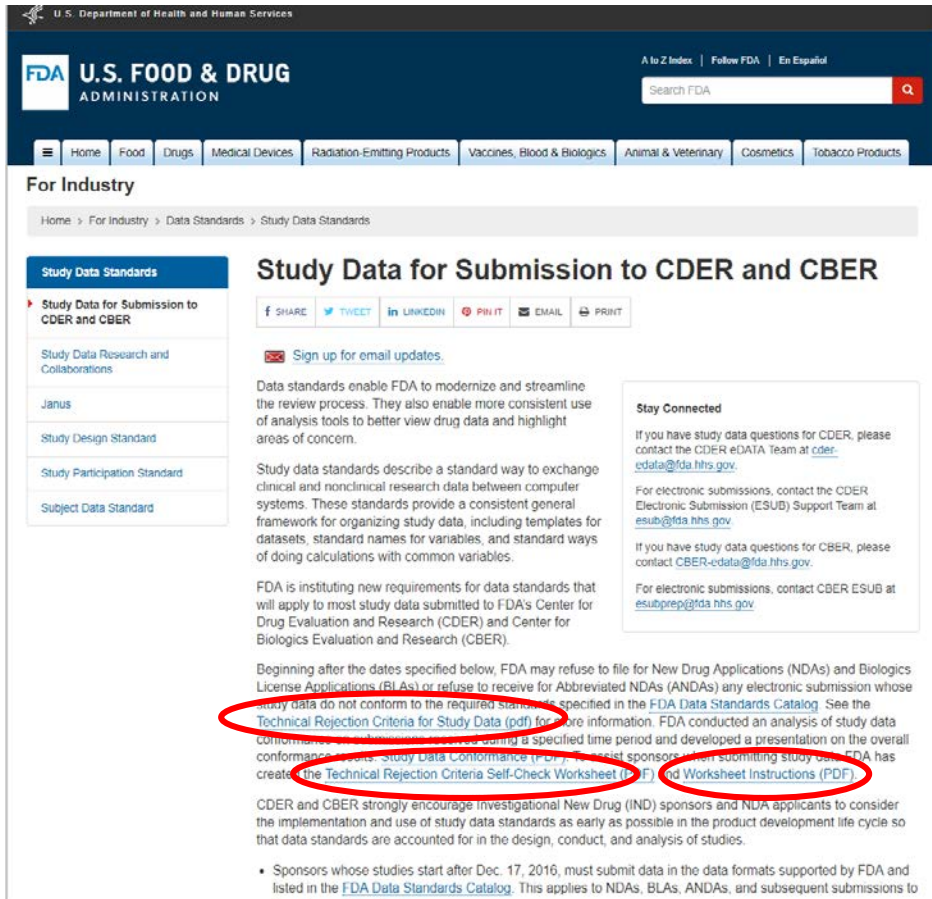
2. TRC Self-Check Worksheet & Instruction

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



The screenshot shows the FDA website page for 'Study Data for Submission to CDER and CBER'. The page includes a navigation menu with categories like Home, Food, Drugs, Medical Devices, etc. The main content area is titled 'Study Data Standards' and 'Study Data for Submission to CDER and CBER'. It features a sidebar with a list of standards, a main text area with a 'Sign up for email updates' button, and a 'Stay Connected' section with contact information for CDER and CBER. At the bottom, there is a list of links, including 'Technical Rejection Criteria for Study Data (pdf)' and 'Technical Rejection Criteria Self-Check Worksheet (PDF) and Worksheet Instructions (PDF)', which are circled in red in the original image.

Study Data Standards

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

Study Data for Submission to CDER and CBER

Sign up for email updates.

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).

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 results. Study Data Conformance (PDF). For 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>

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

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>

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 <input type="checkbox"/>	CBER <input type="checkbox"/>	
	1b. Application Type*:	NDA <input type="checkbox"/>	BLA <input type="checkbox"/>	ANDA <input type="checkbox"/> Commercial IND <input type="checkbox"/>
	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*:	_____		
	<i>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.</i>			
	2b. Is This the First Time Study Data is Being Submitted for This Study as Part of This Application?*	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
	<i>If you answered "No" in Field 2b, do not proceed. This self-check worksheet is designed for newly submitted study data.</i>			
	2c. Name of the Study:	_____		
	2d. Study Section - eCTD Heading (Example: m4-2-1-1):	_____		
2e. Module*:	Nonclinical (m4) <input type="checkbox"/>	Clinical (m5) <input type="checkbox"/>		
2f. Study Dataset Type(s)*:	Tabulation <input type="checkbox"/>	Analysis <input type="checkbox"/>		

***Required field**

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 <input type="checkbox"/>	No <input type="checkbox"/>	
	<i>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.</i>			
	3b. Is STF File Included?*	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Referenced Validation Error Number 1789
	3c. Does STF File Reference all Associated Study Files?*	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
<i>If you answered "No" in Fields 3b or 3c, Validation Rule 1789 FAILS. Do not proceed.</i>				
3d. Study ID in STF File*:	_____			

Sections of the Study Data Self-Check Worksheet

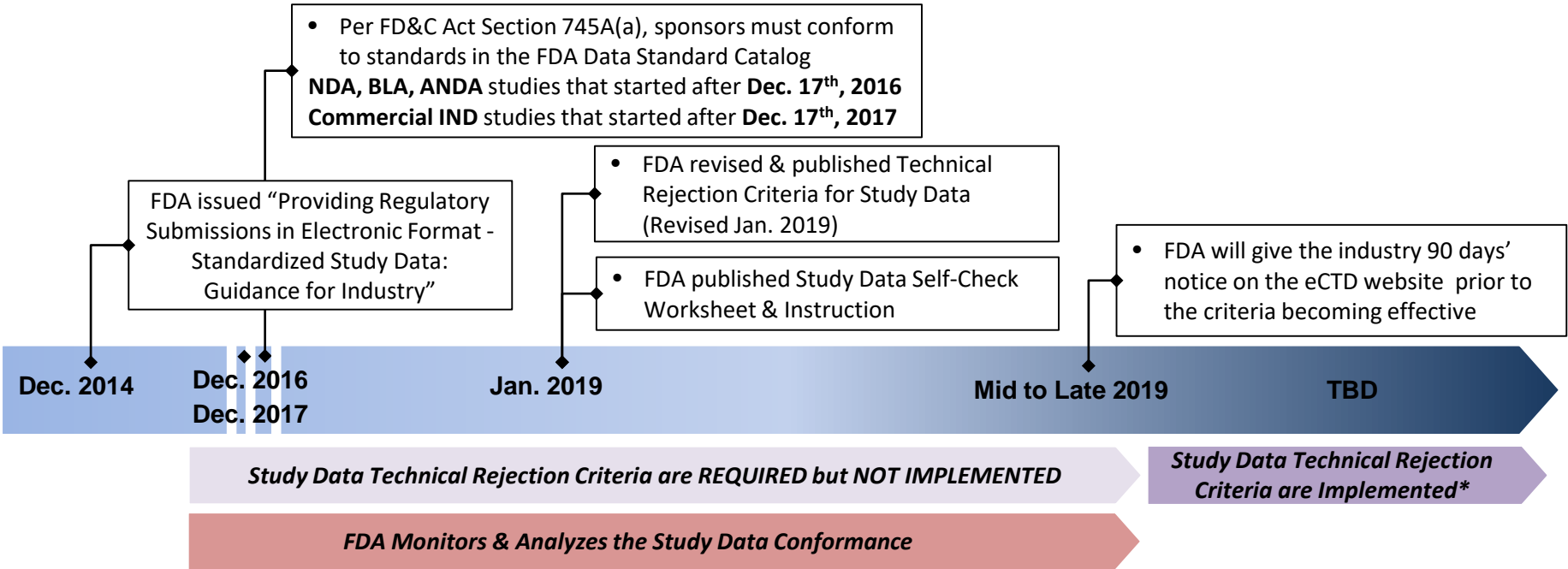
Section	Contents	Example(s)
1	Application & Submission Information <ul style="list-style-type: none"> Provides high level information about the application and submission 	1a. FDA Center*: CDER <input type="checkbox"/> CBER <input type="checkbox"/>
2	Study Information <ul style="list-style-type: none"> Provides more detailed information about the specific study 	2a. Study ID*: 2f. Study Dataset Type(s)*: Tabulation <input type="checkbox"/> Analysis <input type="checkbox"/>
3	STF File Information (1789 Validation Error) <ul style="list-style-type: none"> Provide information about STF file 	3b. Is STF File Included?*: Yes <input type="checkbox"/> No <input type="checkbox"/> 3c. Does STF File Reference all Associated Study Files?*: Yes <input type="checkbox"/> No <input type="checkbox"/>
4	TS File Information (1734 Validation Error) <ul style="list-style-type: none"> 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 <input type="checkbox"/> No <input type="checkbox"/>
5	Standardized Dataset Information (1735 & 1736 Validation Error) <ul style="list-style-type: none"> 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 <input type="checkbox"/> No <input type="checkbox"/> 5g. Is Define File Included?*: Yes <input type="checkbox"/> No <input type="checkbox"/> 5h. Are the STF File-Tags for the SDTM Datasets "data-tabulation-dataset-sdtm"?* Yes <input type="checkbox"/> No <input type="checkbox"/> 5i. Is the STF File-Tag for the Define File "data-tabulation-data-definition"?* Yes <input type="checkbox"/> No <input type="checkbox"/>

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](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](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](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](https://www.fda.gov/downloads/forindustry/datastandards/studydatastandards/ucm624939.pdf)
- ❖ **“FDA Data Standards Catalog”**
[HTTPS://WWW.FDA.GOV/FORINDUSTRY/DATASTANDARDS/STUDYDATASTANDARDS/DEFAULT.HTM](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](https://www.fda.gov/downloads/forindustry/datastandards/studydatastandards/ucm630732.pdf)
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- ❖ **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](https://www.fda.gov/drugs/developmentapprovalprocess/formssubmissionrequirements/electronic submissions/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](http://www.fda.gov/forindustry/datastandards/studydatastandards)

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*Thank
You*



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