

FDA Update on Technical Rejection Criteria for Study Data

Presented to: PhUSE annual Computational Science Symposium (CSS)
Silver Spring, Maryland

Ethan Chen
Director, Division of Data Management Services and Solutions
Office of Business Informatics, CDER, FDA

June 10, 2019



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.



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

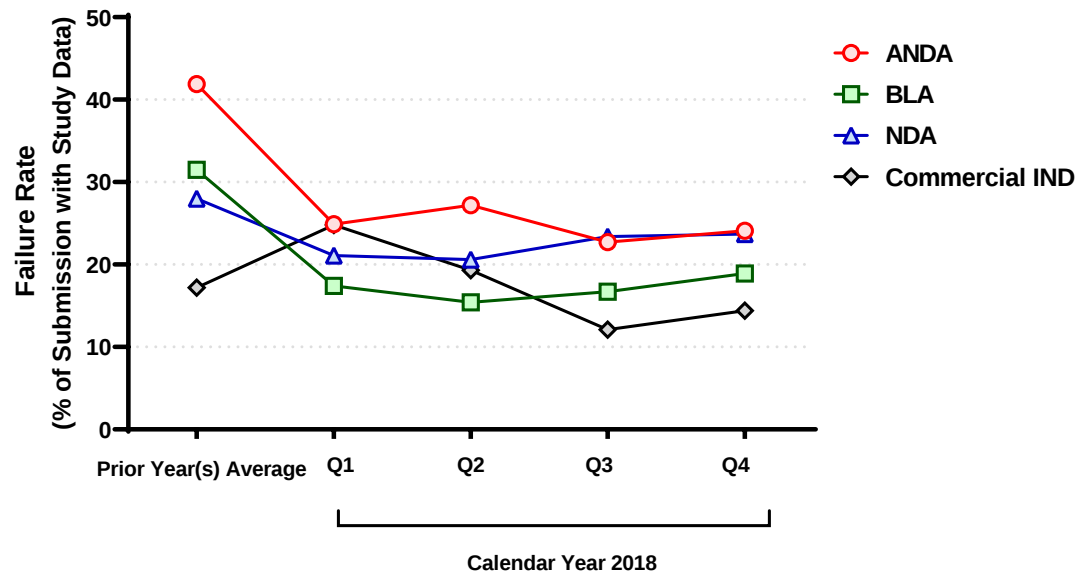
	NDA	ANDA	BLA	Comm. IND	All
Total Number of Submissions with Study Data	877	1078	291	649	2895
Total Number Submissions with Critical Errors	195	266	50	113	624
Error 1734	185	186	48	96	515
Error 1736	16	88	2	18	124
Failure Rate (% among submissions with Study Data)	22.2%	24.7%	17.2%	17.4%	21.6%

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)



❖ **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.

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 for required study 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 IND, NDS, BLA and ANDA Submission Studies: Errors 1734, 1735 & 1736



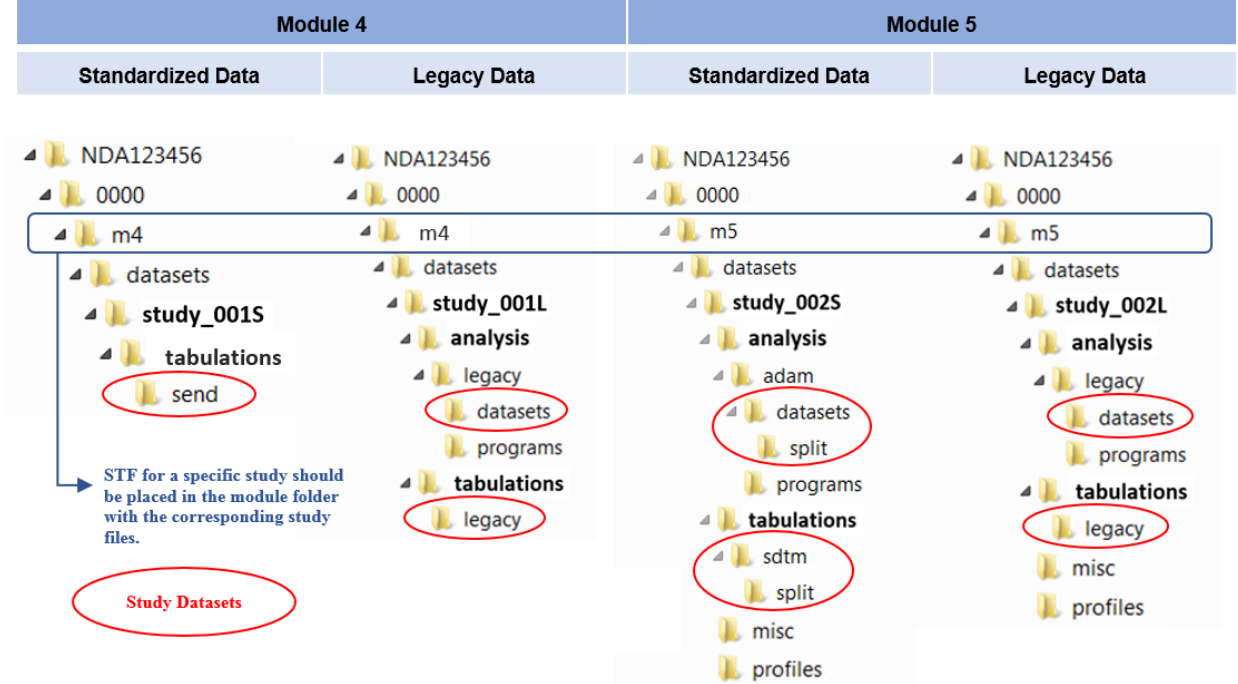
Error	Description
1734	Trial Summary (TS) dataset (ts.xpt) with information on study start date must be present for required sections*
1735	Correct STF file-tags must be used for all standardized datasets and corresponding define.xml files in required sections*
1736	For SEND data, a DM dataset and define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

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



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 •SSTDTC 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

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

Additional Details for Error 1734

❖ 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:

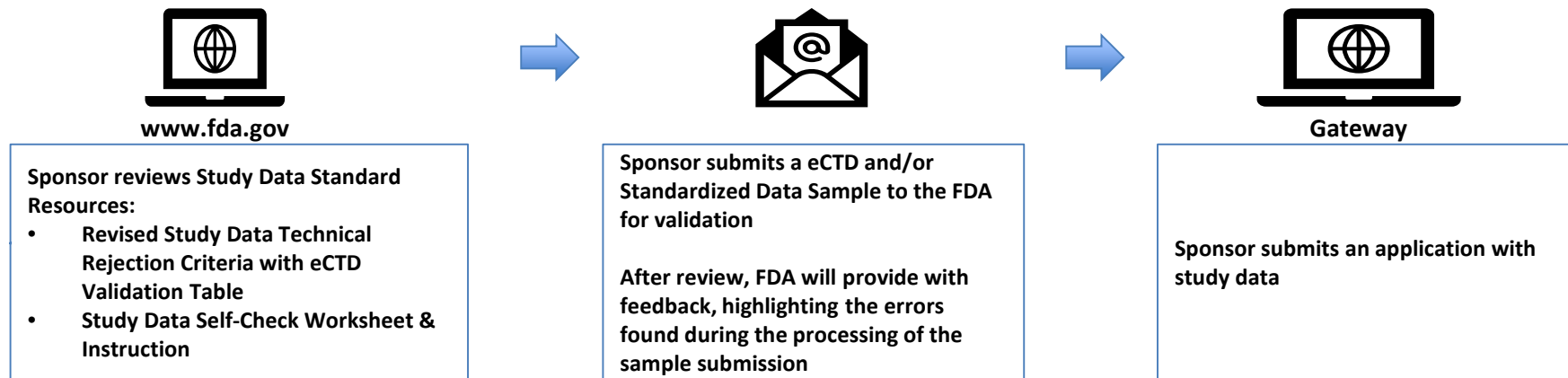
- ICH M2 EWG: The eCTD Backbone File Specification for Study Tagging Files (June 2008) (<http://estri.ich.org/STF/STFV2-6-1.pdf>)
- CDISC Submission Metadata Model (https://www.cdisc.org/system/files/all/reference_material_category/application/pdf/submissionmetadatamodelv2.pdf)

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	

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 provide examples (**Appendix 1 and 2**) to illustrate the requirements

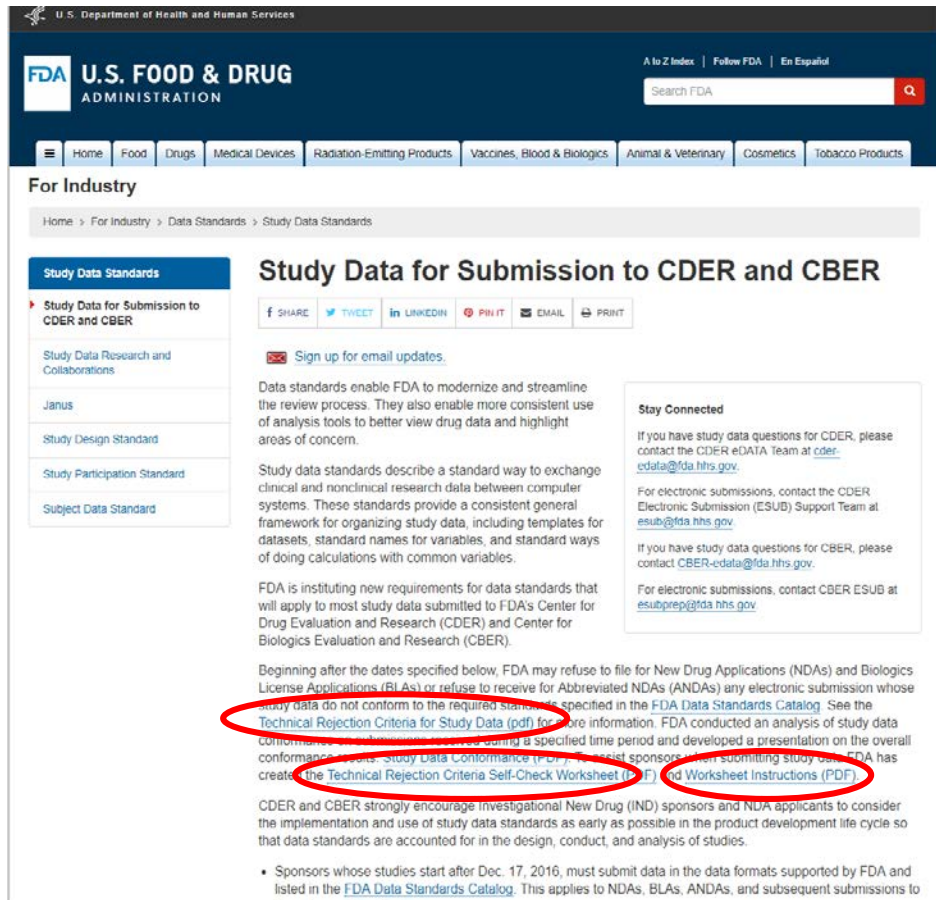
2. TRC Self-Check Worksheet & Instruction

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



U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En Español

Search FDA

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

For Industry

Home > For Industry > Data Standards > Study Data Standards

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

SHARE | TWEET | LINKEDIN | PINTEREST | EMAIL | PRINT

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 with standards received during a specified time period and developed a presentation on the overall conformance results: [Study Data Conformance \(PPT\)](#). 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>

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			
<i>Note: This Self-Check Worksheet is designed for newly submitted Study Data.</i> <i>*Required field</i>			
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:	
<i>Note: Repeat Sections 2 through 5 for each study.</i> <i>*Required field</i>			
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 ☐	No ☐
	<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):	_____	
Section 2: Study Information	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 ☐
	<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 ☐	No ☐
	3c. Does STF File Reference all Associated Study Files?*	Yes ☐	No ☐
<i>If you answered "No" in Fields 3b or 3c, Validation Rule 1789 FAILS. Do not proceed.</i>			Referenced Validation Error Number 1789
3d. Study ID in STF File*:	_____		

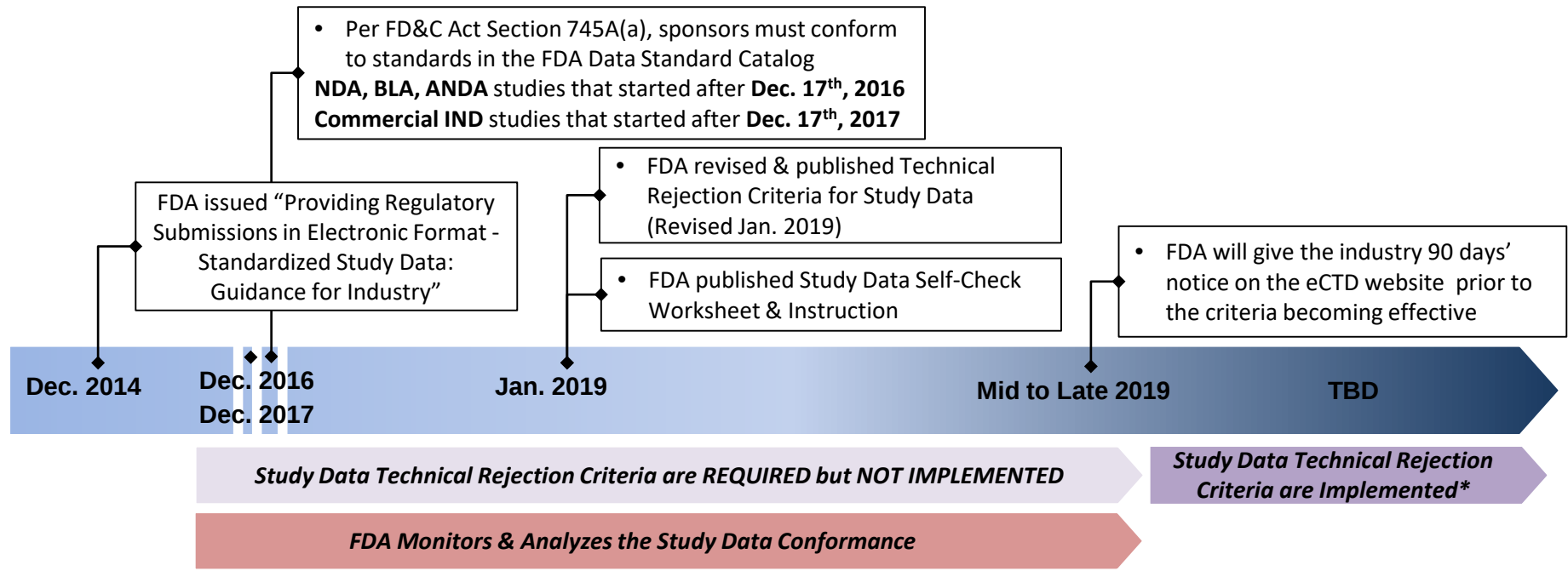
Sections of the Study Data Self-Check Worksheet

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 ☐ 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 ☐

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

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/GUIDANCECOMPLIANCEREGLATORYINFORMATION/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/GUIDANCECOMPLIANCEREGLATORYINFORMATION/GUIDANCES/UCM384686.PDF](https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm384686.pdf)
- ❖ **“Technical Rejection Criteria For Study Data”**
[HTTPS://WWW.FDA.GOV/MEDIA/100743/DOWNLOAD](https://www.fda.gov/media/100743/download)
- ❖ **“Study Data Technical Conformance Guide”**
[HTTPS://WWW.FDA.GOV/MEDIA/122913/DOWNLOAD](https://www.fda.gov/media/122913/download)
- ❖ **“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/MEDIA/123098/DOWNLOAD](https://www.fda.gov/media/123098/download)
- ❖ **“Technical Rejection Criteria Self-Check Worksheet Instructions”**
[HTTPS://WWW.FDA.GOV/MEDIA/123099/DOWNLOAD](https://www.fda.gov/media/123099/download)
- ❖ **For FDA instruction of Study Data submission, see the FDA “Study Data for Submission to CDER and CBER” page at:**
[HTTPS://WWW.FDA.GOV/INDUSTRY/STUDY-DATA-STANDARDS-RESOURCES/STUDY-DATA-SUBMISSION-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” page at:**
[HTTP://WWW.FDA.GOV/FORINDUSTRY/DATASTANDARDS/STUDYDATASTANDARDS](http://www.fda.gov/forindustry/datastandards/studydatastandards)

Acknowledgments

The author would like to thank In Young Choi, Lina Cong, Jiang Xu, Jonathan Resnick, Heather Crandall, Jeffery Florian, Lisa Lin, Gang Wang, and other FDA staff for their time and effort in helping collect and analyze data and information as presented in this paper.

*Thank
You*



U.S. FOOD & DRUG
ADMINISTRATION