

FDA View: FDA Study Data Guidance Update

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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 (SDTRC)**
- ❖ **Study Data Conformance Statistics (CY2018 and CY2019 Q1-Q3)**
- ❖ **Revised Technical Rejection Criteria for Study Data (Oct. 2019)**
- ❖ **Study Data Conformance Analysis (CY2019 Q4)**
- ❖ **New Tools for Industry**
- ❖ **Implementation Timeline**
- ❖ **Summary**

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>

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
- ❖ **Sponsors are obligated to meet Technical Rejection Criteria for Study Data which determine whether a submission complies with FDA’s standards for study data**

FDA Study Data Technical Rejection Criteria (SDTRC)

- ❖ Study Data Technical Conformance Guide provides technical recommendations for submitting study data according to CDISC standards
- ❖ Technical Rejection Criteria for Study Data provides the conditions under which FDA will not accept submissions with study data

Error	Description (Reference to FDA Study Data Technical Rejection Criteria <u>Oct. 2019 version</u>)	Severity Level
1734	A Trial Summary (TS) dataset (ts.xpt) with information on study start date (SSD) must be present for each study in 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). STFs are not required for 4.3 Literature references, 5.2 Tabular listings, 5.4 Literature references, and 5.3.6 Postmarketing reports	High

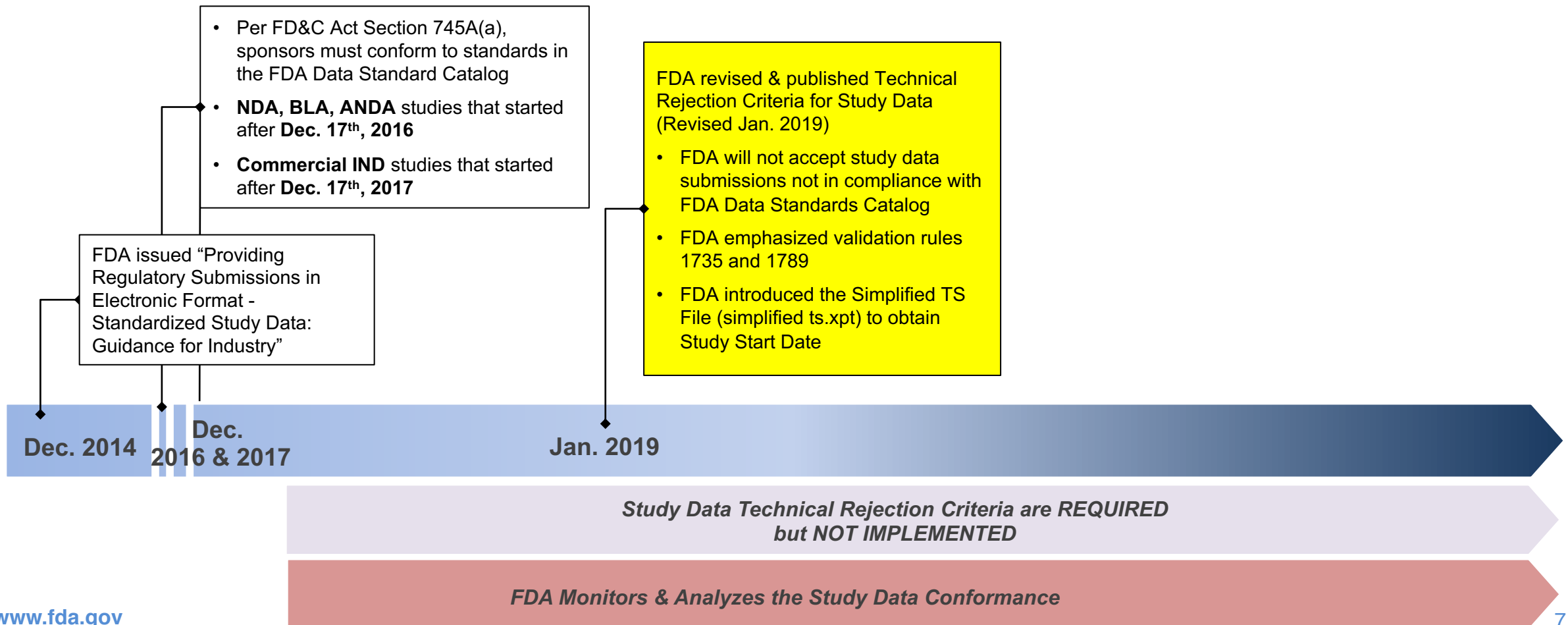
Note

1. * Refer to the latest Technical Rejection Criteria for Study Data for more details

Technical Rejection Criteria Revisions Timeline

❖ FDA published Revised Study Data Technical Rejection Criteria in January 2019

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



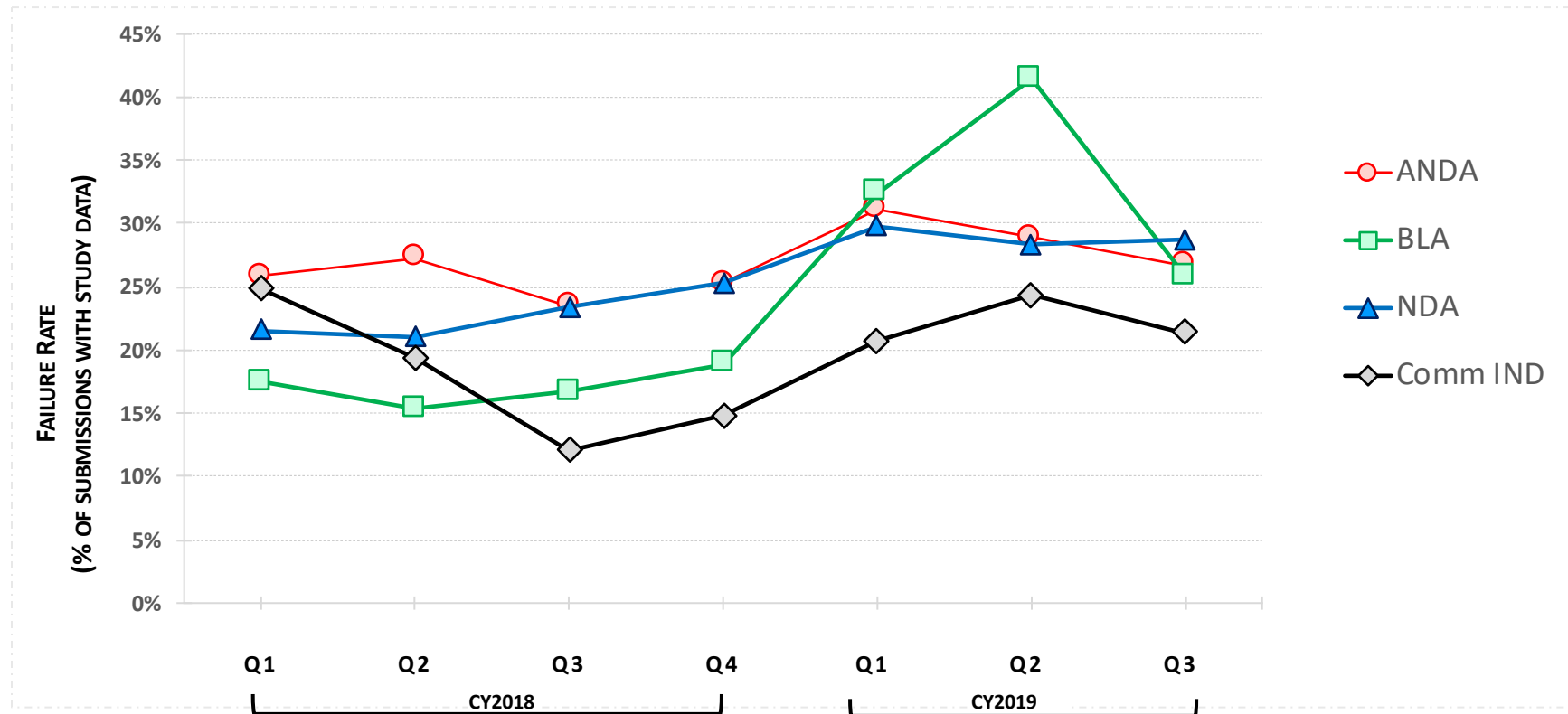
Study Data Technical Rejection Criteria Conformance Statistics and Trend

CY2018 AND CY2019 (Q1-Q3)

CY2018 & 2019 Q1-Q3 Conformance Trend for Validation Errors 1734 & 1736



TRC validation failure rate have increased between Q1- Q3 2019 (based on TRC version Jan. 2019)



Notes:

- 1) CY2018 & CY2019 (Q1-Q3) analysis was conducted according to the TRC (Revised Jan. 2019)
- 2) Analysis includes NDA, BLA, ANDA and Commercial IND Sequence received by CDER between 1/1/2018 and 9/30/2019
- 3) Validation of error 1736 is not performed if a study has Error 1734
- 4) Definition of Study Data - .xpt files present in eCTD modules 4 or 5

2019 Q1-Q3 Conformance Analysis for Validation Errors 1734 & 1736



- ❖ ANDA, NDA, BLA, and Commercial IND Submissions received by CDER between 1/1/2019 and 09/30/2019, were assessed for conformance to the two high-level errors as revised in the Technical Rejection Criteria for Study Data (Revised Jan. 2019)

		ANDA	BLA	NDA	Comm IND	All
a	Total Number of Submissions with Study Data	623	203	679	700	2205
b	Total Number of Submissions with Study Data in TRC Applicable Sections	582	161	533	645	1921
c	Total Number Submissions with Critical Errors	181	64	197	156	598
d	Error 1734	135	59	195	135	524
e	Error 1736	46	5	2	21	74
f	Failure Rate (% among submissions with Study Data) [c/a]	29.05%	31.53%	29.01%	22.29%	27.12%
g	Failure Rate (% among submissions with Study Data in TRC Applicable section) [c/b]	31.10%	39.75%	36.96%	24.19%	31.13%

Notes:

- (1) CY2018 & CY2019 (Q1-Q3) analysis was conducted according to the TRC (Revised Jan. 2019)
- 1) Analysis includes NDA, BLA, ANDA and Commercial IND Sequence received by CDER between 1/1/2018 and 9/30/2019
- 2) Validation of error 1736 is not performed if a study has Error 1734
- 3) Definition of Study Data - .xpt files present in eCTD modules 4 or 5

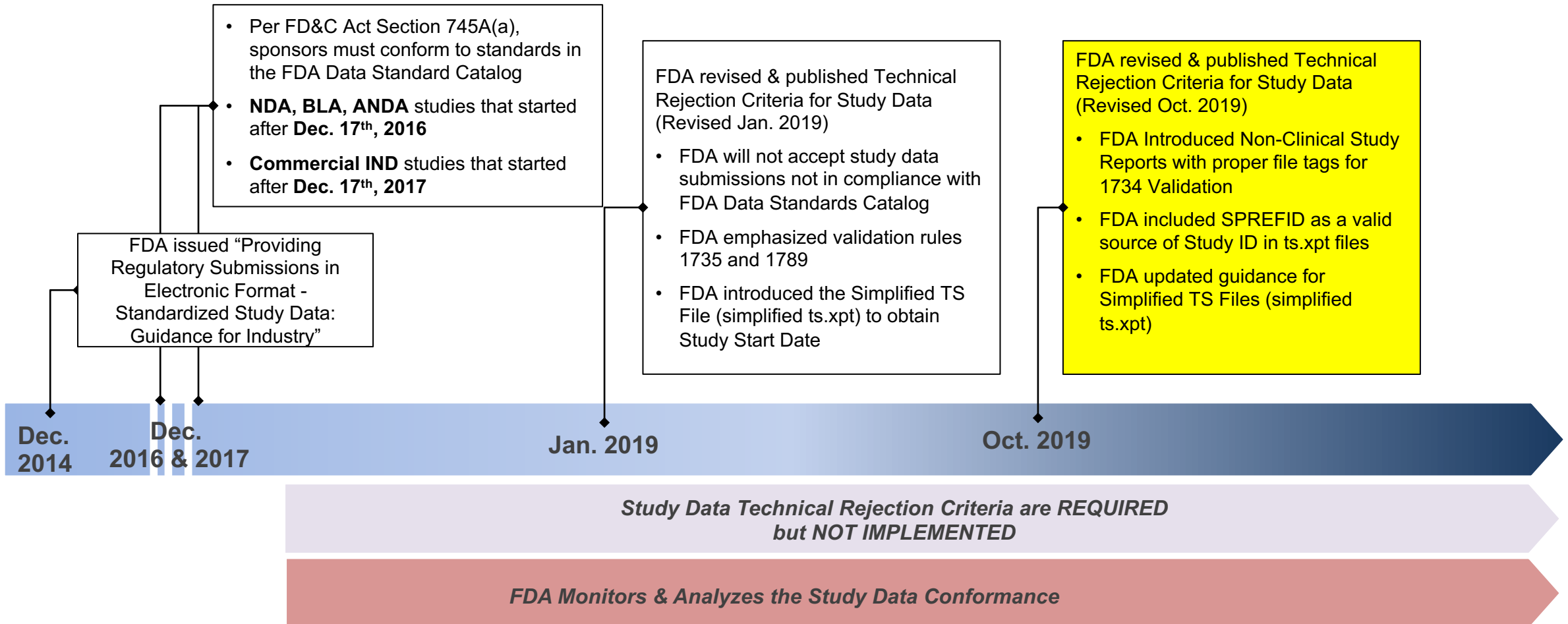
Study Data Technical Rejection Criteria

REVISIONS TO STUDY DATA TECHNICAL REJECTION CRITERIA

Technical Rejection Criteria Revisions Timeline



❖ FDA published Revised Study Data Technical Rejection Criteria October 2019



Notes:

- 1) When a submission is technically-rejected, the submission sequence is not transferred into the FDA electronic document rooms

Qualification and Exemption for Non-Clinical Studies

- ❖ Nonclinical study that are required to qualify for TRC including any study in module 4 eCTD modules 4.2.3.1, 4.2.3.2, or 4.2.3.4 that includes one of the one of the following three file tags

'pre-clinical-study-report'

'legacy-clinical-study-report'

'study-report-body'

- ❖ The qualifying non-clinical study must be submitted according to SEND specification.
- ❖ Certain Non-Clinical studies are exempted for TRC (See Study Data Technical Conformance Guide Section 8.2.2 for details <https://www.fda.gov/media/131872/download>):
 - Non-Clinical Studies does not require SEND Data
 - Non-Clinical Study Initiation Dates not relevant
- ❖ A simplified ts.xpt must submitted for exempted Non-Clinical Studies as below:

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

SDTRC Revisions: Study Reports

Introduced the Study Report File Tag Criteria

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 if a study report with the proper file tags and/or an xpt file is submitted. 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 if a study report with the proper file tags and/or an xpt file is submitted. 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	

Included Additional Reference for Study ID Match

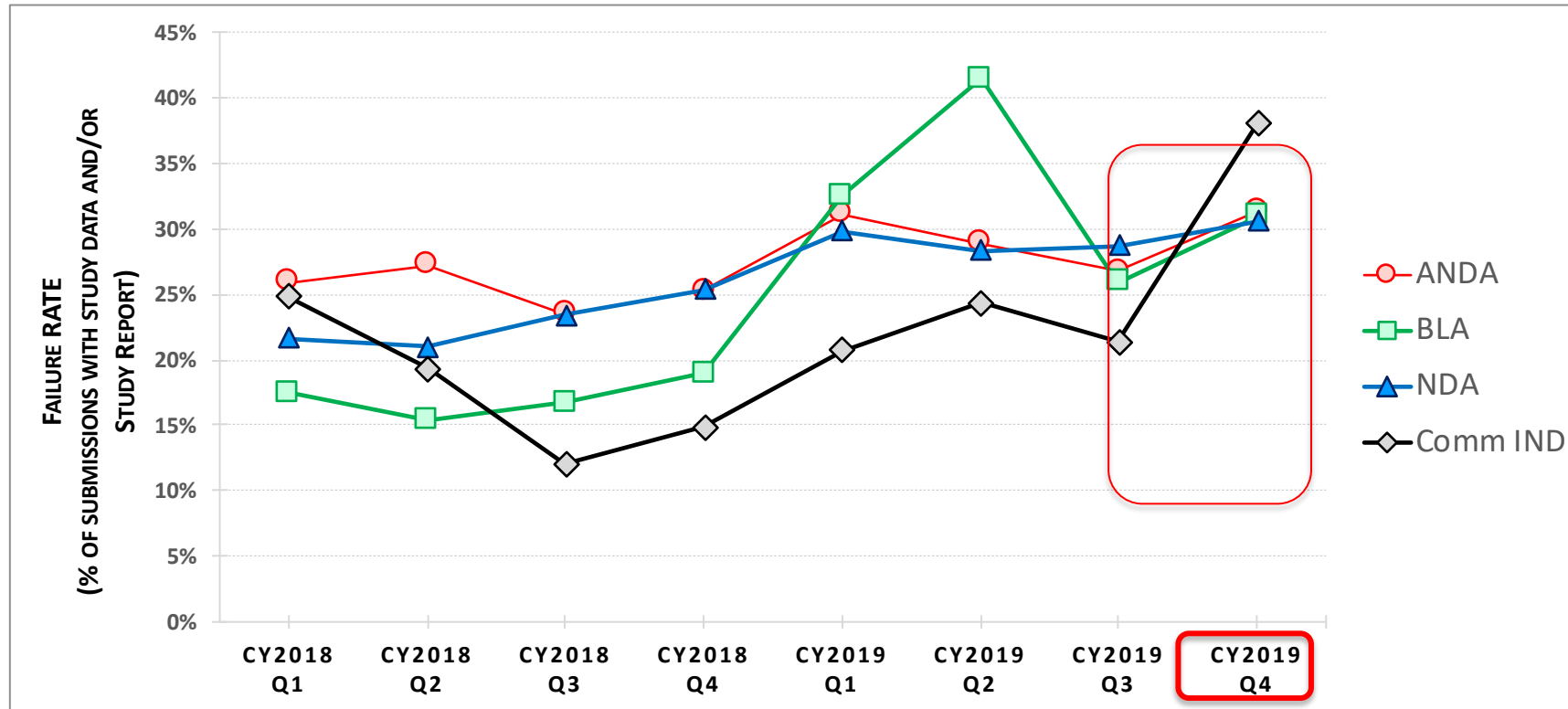
- ❖ Feedback from industry pointed scenarios where ts.xpt study-id may not be able to matched (Ex. when a study is bought by another company and the study id is already established)
- ❖ Proposed solution with feedback was inclusion of Sponsor Reference ID (SPREFID) parameter to match the STF study-id
- ❖ After analysis, SPREFID parameter matching with STF study-id added to October 2019 SDTRC revision

Included SPREFID for Study ID matching	
TRC January 2019	TRC October 2019
If a file is referenced within a study section in Module 4 or 5, a STF and ts.xpt must be present to identify the study ID and SSD to which the file belongs. The ts.xpt and STF need to contain matching study ID values.	If a file is referenced within a study section in Module 4 or 5, a STF and ts.xpt must be present to identify the study ID and SSD to which the file belongs. The ts.xpt needs to contain either a study ID (STUDYID) or Sponsor Reference ID (SPREFID) value that matches with the STF study ID.

Study Data Technical Rejection Criteria Conformance Statistics and Trend

CY2019 (Q4)

CY2018 & CY2019 Conformance Trend for Validation Errors 1734 & 1736



Notes:

- (1) CY2018 & CY2019 (Q1-Q3) analysis was conducted according to the TRC (Revised Jan. 2019)
- (2) CY2019 (Q4) analysis was conducted according to the TRC (Revised Oct. 2019)
- (3) Analysis includes NDA, BLA, ANDA and Commercial IND Sequence received by CDER between 1/1/2018 and 12/31/2019
- 1) Validation of error 1736 is not performed if a study has Error 1734
- 2) M4 Definition of Study Data - .xpt files and/or a Study Report tagged as pre-clinical-study-report, legacy-clinical-study-report, or study-report-body present in the submission
- 3) M5 Definition of Study Data - .xpt files present in the submission

2019 Q4 Conformance Analysis for Validation Errors 1734 & 1736



	ANDA	BLA	NDA	Comm IND	All
a Total Number of Submissions with Study Data and/or Study Report	230	110	262	827	1429
b Total Number of Submissions with Study Data and/or Study Report in TRC Applicable section	213	80	192	480	965
c Total Number Submissions with Critical Errors	72	34	80	314	500
d Error 1734	55	27	73	293	448
e Error 1736	17	7	7	21	52
f Failure Rate (% among submissions with Study Data and/or study Report) [c/a]	31.30%	30.91%	30.53%	37.97%	34.99%
g Failure Rate (% among submissions with Study Data and/or study Report in TRC Applicable sections) [c/b]	33.80%	42.50%	41.67%	65.42%	51.81%

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, ANDA and Commercial IND submissions received by CDER between 1/1/2019 and 12/31/2019
- (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) M4 Definition of Study Data - .xpt files and/or a Study Report tagged as pre-clinical-study-report, legacy-clinical-study-report, or study-report-body present in submission
- (5) M5 Definition of Study Data - .xpt files present in the submission
- (6) Analysis is conducted according to the revised TRC (Revised Oct. 2019)

2019 (Q1-Q3) vs 2019 Q4 Study Level Comparison

- ❖ A large number of non-clinical studies fail 1734 in Q4 because of expectation of a ts.xpt for Non-Clinical studies when a study report is submitted as per revised TRC (Oct. 2019)

		CY2019 (Q1-Q3)		CY2019 (Q4)	
		Nonclinical (m4)	Clinical (m5)	Nonclinical (m4)	Clinical (m5)
a	Total Number of Studies	1778	3959	10,128	1513
b	Total Number of Studies in TRC Applicable Sections	1648	2983	1623	1135
c	Total Number Studies with Critical Errors	283	782	940	290
d	Error 1734	253	655	903	239
e	Error 1736	30	127	37	51
f	Error Rate [c/a] (% among Total Number of Studies)	15.92%	19.75%	9.28%	19.17%
g	Error Rate (% among failed studies with Study Data* Data in TRC Applicable Sections) [c/b]	17.17%	26.22%	57.92%	25.55%

Notes:

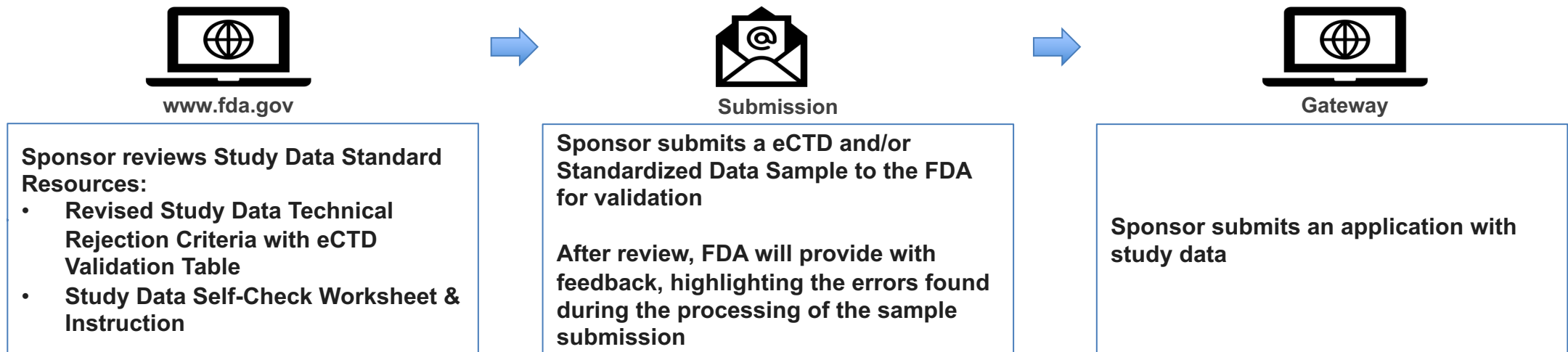
- (1) Analysis includes NDA submissions received by CDER between 1/1/2019 and 12/31/2019
- (2) Validation of errors 1735 and 1736 is not performed if a study has Error 1734
- (3) A submission with multiple studies can report Errors 1734, 1735 and/or 1736. In this instance, the submission is counted only once at the submission level when calculating failure rate
- (4) Analysis is conducted according to the revised TRC (Revised Oct. 2019)
- (5) M4 Definition of Study Data - .xpt files and/or a Study Report tagged as pre-clinical-study-report, legacy-clinical-study-report, or study-report-body present in submission
- (6) M5 Definition of Study Data - .xpt files present in the submission

ADDITIONAL 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



1. Revised Study Data Technical Rejection Criteria (Revised Oct. 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

Tools Available to create a Simplified TS File

FDA Guide for creating a Simplified TS File

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

Publicly available Tool

- ❖ PHUSE utility to generate Simplified TS file

https://geotiger.shinyapps.io/07_genTS/

Study Data TCG (Oct 2019) references this Guide

Contains Nonbinding Recommendations 

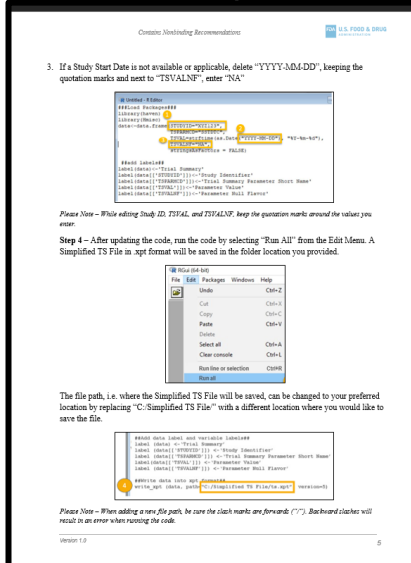
submission. Use of the SDSP will allow for identification of potential data standardization issues and timely discussion with the review division, if needed.

Information on the Technical Rejection Criteria and the FDA Data Standards Catalog may be found at <https://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM630740.pdf>.

The CDER resource 'Creating Simplified ts.xpt Files', using free and open-source software may be found at <https://www.fda.gov/industry/study-data-standards-resources/study-data-submission-cder-and-cber>

If there are any questions as to the appropriate use of the simplified ts.xpt file, contact the CDER eDATA Team at cder-edata@fda.hhs.gov.

Simplified TS File Creation Guide



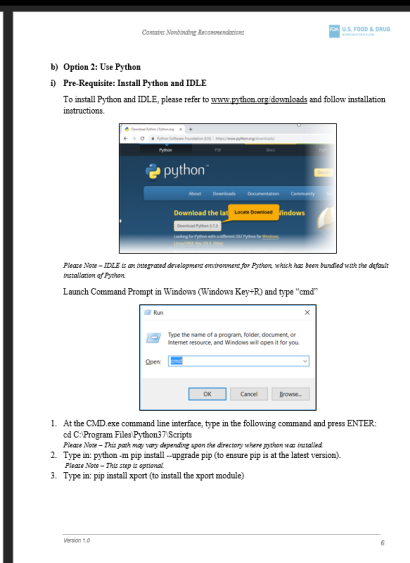
3. If a Study Start Date is not available or applicable, delete "YYYY-MM-DD", keeping the question marks and enter "TSVALNP".

Please Note - While editing Study ID, TSVAL, and TSVALNP, keep the question marks around the values you enter.

Step 4 - After updating the code, run the code by selecting "Run All" from the Edit Menu. A Simplified TS File in .xpt format will be saved in the folder location you provided.

The file path, i.e. where the Simplified TS File will be saved, can be changed to your preferred location by replacing "C:\Simplified TS File" with a different location where you would like to save the file.

Please Note - When adding a new file path, be sure the slash marks are forward (""). Backward slashes will result in an error when running the code.



b) Option 2: Use Python

i) Pre-Requisite: Install Python and IDLE

To install Python and IDLE, please refer to www.python.org/downloads and follow installation instructions.

Please Note - IDLE is an integrated development environment for Python, which has been bundled with the default installation of Python.

Launch Command Prompt in Windows (Windows Key+R) and type "cmd"

At the CMD.exe command line interface, type in the following command and press ENTER: cd C:\Program Files\Python77\Scripts

Please Note - The path may vary depending upon the directory where python was installed.

Type in: python -m pip install --upgrade pip (to ensure pip is at the latest version).

Please Note - This step is optional.

Type in: pip install report (to install the report module)

FDA Tools - Study Data Self-Check Worksheet & Instructions (Revised Nov. 2019)



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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).

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” (Oct 2019)
<https://www.fda.gov/downloads/forindustry/datastandards/studydatastandards/ucm630740.pdf>

“Technical Rejection Criteria Self-Check Worksheet” (Nov 2019)
<https://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM630732.pdf>

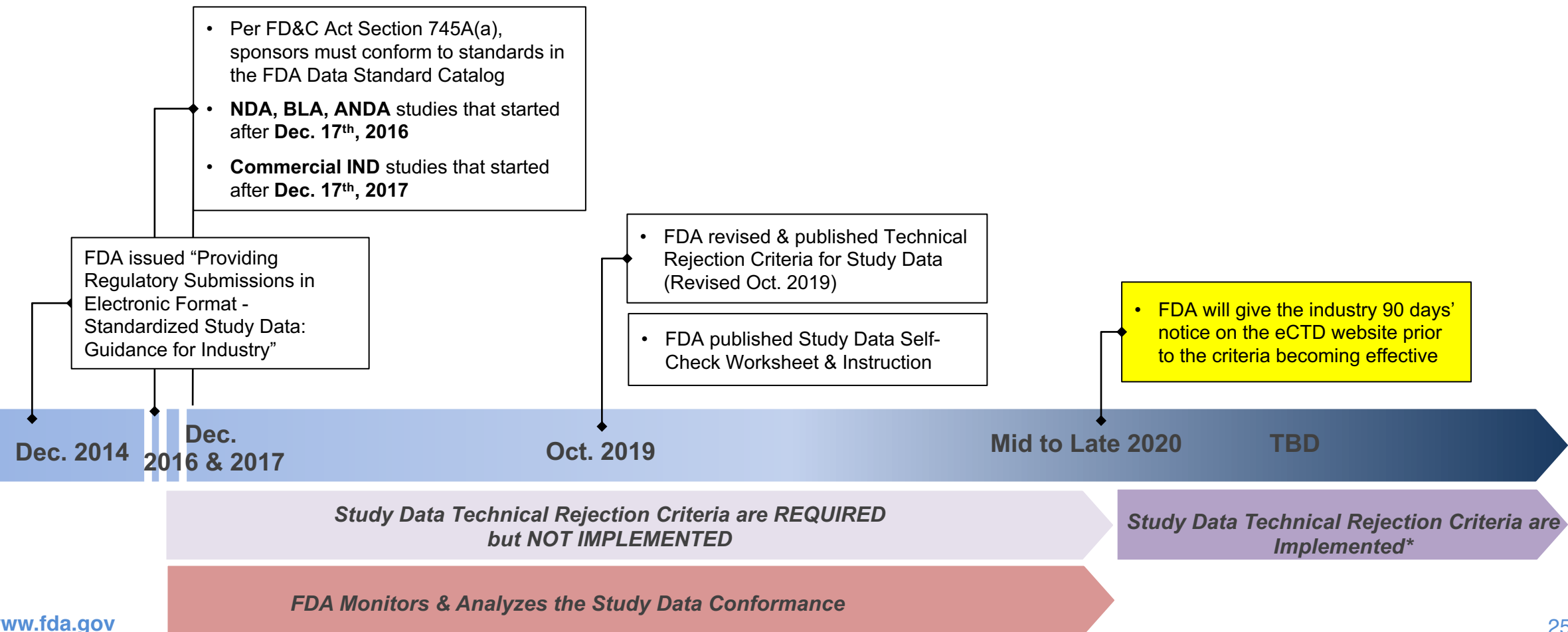
“Technical Rejection Criteria Self-Check Worksheet Instructions” (Nov 2019)
<https://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM630733.pdf>

TRC IMPLEMENTATION TIMELINE

Implementation Timeline

FDA published Revised Study Data Technical Rejection Criteria (Revised Oct. 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

- ❖ Overall conformance for Errors 1734 and 1736 has increased
- ❖ 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
- ❖ FDA published Study Data Self-Check Worksheet to help sponsors to follow the revised TRC
- ❖ FDA published Simplified TS file creation guide and utility to Generate Simplified TS file



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/GUIDANCECOMPLIANCEREGLATORYINFORMATIO
N/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/GUIDANCECOMPLIANCEREGLATORYINFORMATIO
N/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/131872/DOWNLOAD](https://www.fda.gov/media/131872/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)

Recommended Readings

- ❖ For FDA instruction of Study Data submission, Self-Check Worksheet and Simplified TS file creation guide 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:
[HTTPS://WWW.FDA.GOV/INDUSTRY/FDA-RESOURCES-DATA-STANDARDS/STUDY-DATA-STANDARDS-RESOURCES](https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources)

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*Thank
You*