U.S. FOOD & DRUG ADMINISTRATION

# Update on Technical Rejection Criteria for Study Data

Presented to: CDISC-SEND Spring F2F

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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



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

# 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;<br>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)

# 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*<br>For SDTM data, a DM dataset and define.xml must be submitted in required sections*<br>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

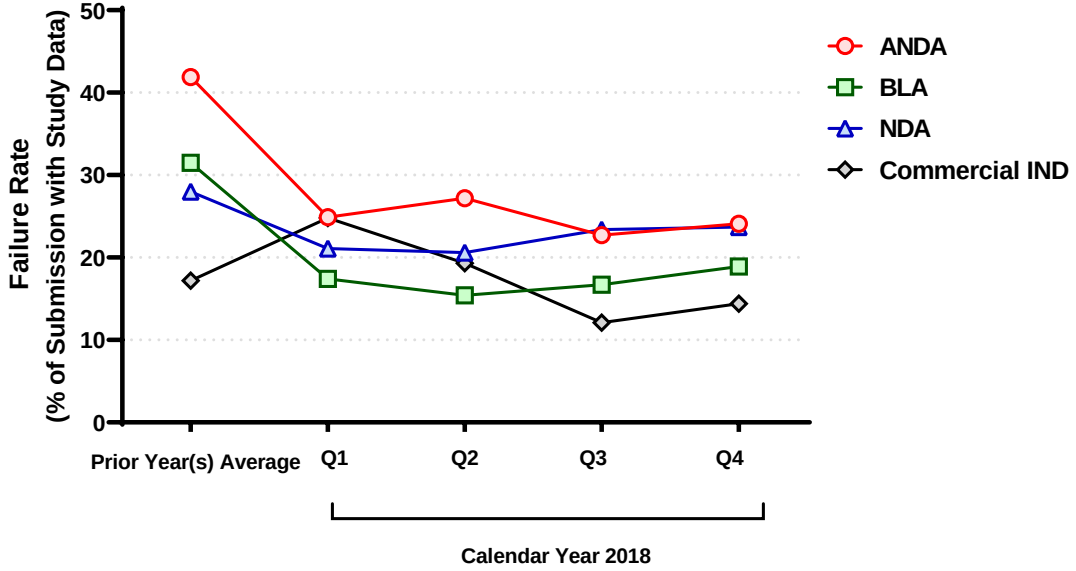
(4) Analysis is conducted according to the revised TRC (Revised Jan. 2019)



**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 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;<br>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*<br>For SDTM data, a DM dataset and define.xml must be submitted in required sections*<br>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)

# 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** |

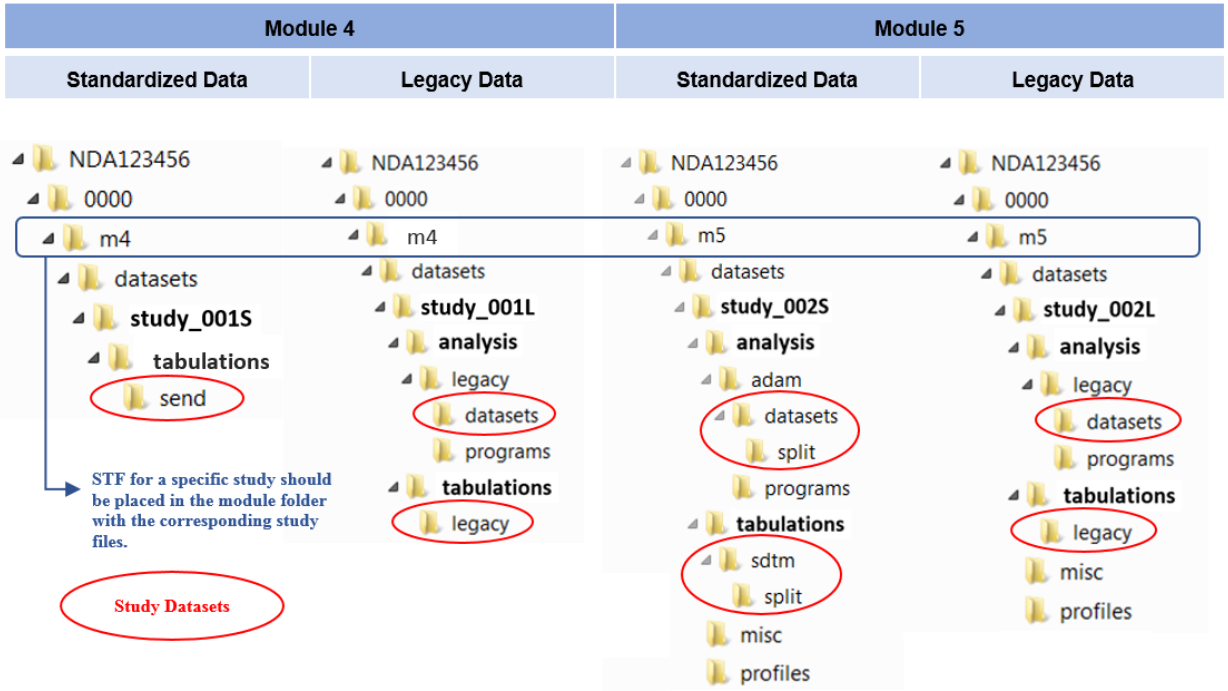
** Refer to the latest Technical Rejection Criteria for Study Data*



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

# 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<br>•STSTDTC for a nonclinical study | •Format: yyyy-mm-dd<br><br>•Left blank when study start date is not available | • Left blank when study start date is provided in TSVAL<br><br>• 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)

# 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

**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**:
FDA Study Data Technical Conformance Guide (Version 4.2, October 2018)
FDA Study Data Technical Rejection Criteria (Revised Jan. 2019)
ICH M2 EWG: The eCTD Backbone File Specification for Study Tagging Files (June 2008)
CDISC Submission Metadata Model (Version 2.0, 26 November 2001)

# 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)

# CY2018 Conformance Analysis of NDA 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*<br>For SDTM data, a DM dataset and define.xml must be submitted in required sections*<br>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 | Efficacy | Rolling | Other | Nonclinical (m4) | Clinical (m5) | Other | |
| Total Number of Studies | 1201 | 194 | 128 | 904 | 403 | 1810 | 214 | 2427 |
| Total Number Studies with Critical Errors | 172 | 42 | 14 | 201 | 38 | 390 | 0 | 354 |
| Error 1734 | 122 | 37 | 10 | 185 | 33 | 321 | 0 | 354 |
| Error 1735 | 42 | 5 | 1 | 11 | 6 | 53 | 0 | 59 |
| Error 1736 | 23 | 0 | 4 | 9 | 1 | 35 | 0 | 36 |
| Error Rate (% among Total Number of Studies) | 14.3% | 21.7% | 10.9% | 22.2% | 9.7% | 21.6% | 0 | 17.7% |

# CY2018 Conformance Analysis of IND 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*<br>For SDTM data, a DM dataset and define.xml must be submitted in required sections*<br>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 | 718 | 631 | 883 | 288 | 178 | 1,349 |
| Total Number Studies with Critical Errors | 77 | 126 | 105 | 98 | 0 | 203 |
| Error 1734 | 44 | 106 | 65 | 85 | 0 | 150 |
| Error 1735 | 27 | 11 | 36 | 2 | 0 | 38 |
| Error 1736 | 9 | 15 | 11 | 13 | 0 | 24 |
| Error Rate (% among Total Number of Studies) | 10.7% | 20.0% | 11.9% | 34.0% | 0% | 15.0% |

# 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**

**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**

**Gateway**

**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

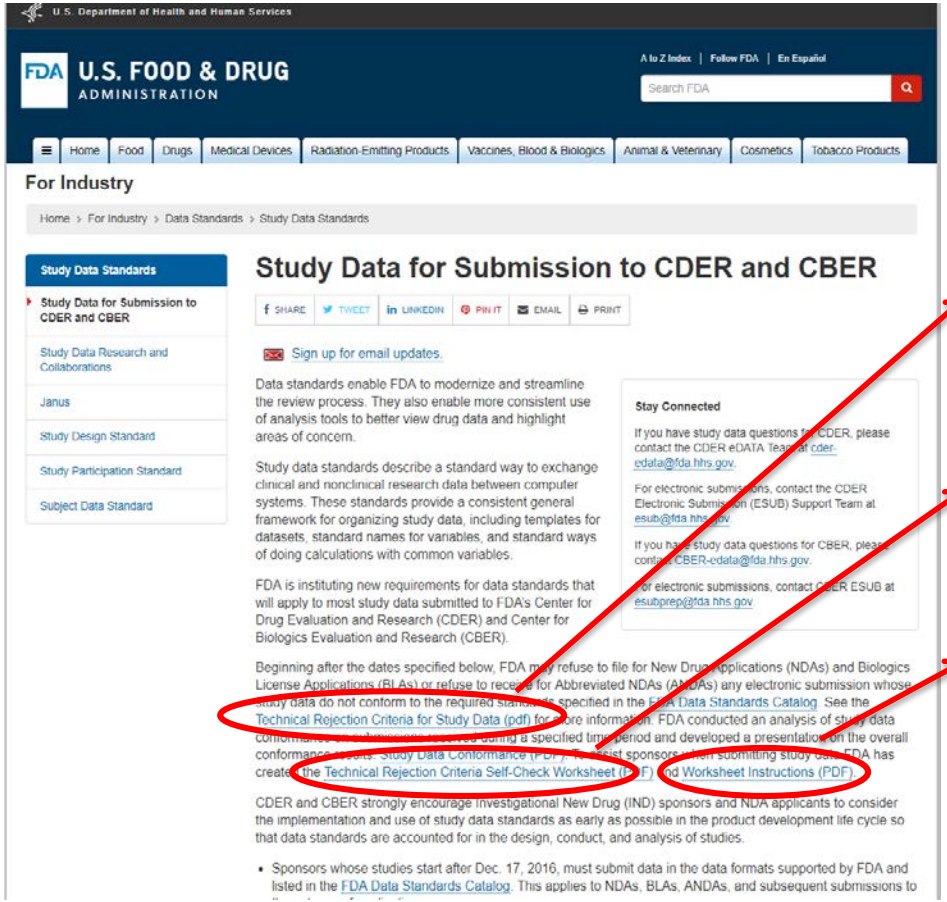
**2. TRC Self-Check Worksheet & Instruction**

**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




**Study Data for Submission to CDER and CBER**
https://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/ucm587508.htm

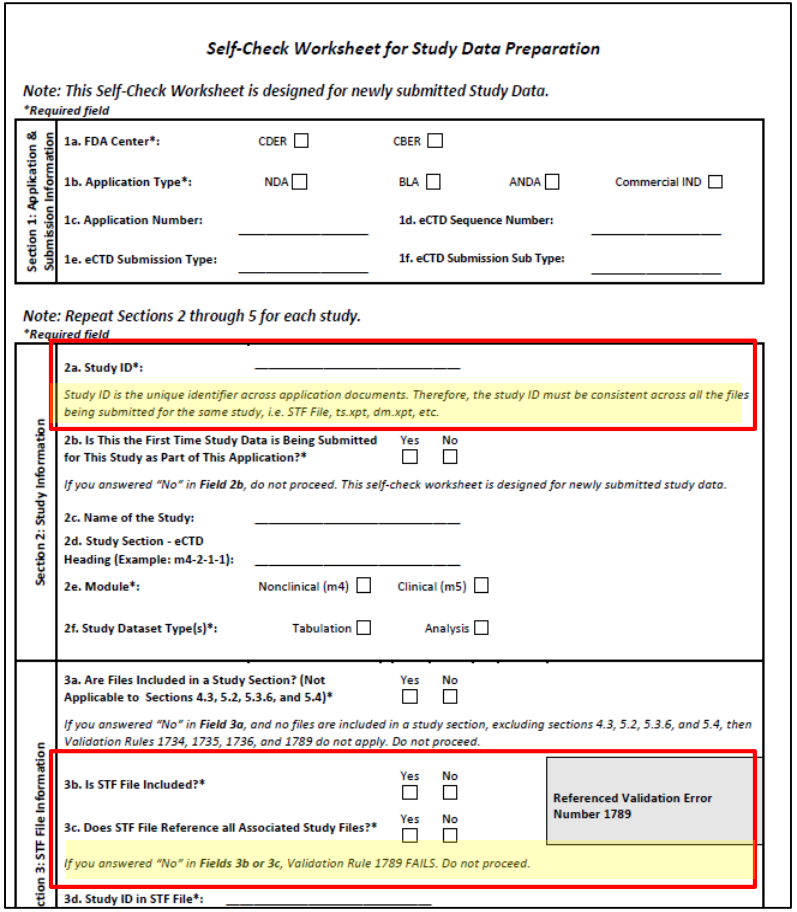
**"Technical Rejection Criteria for Study Data"**
https://www.fda.gov/downloads/forindustry/datastandards/studydatastandards/ucm630740.pdf"

**"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



*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

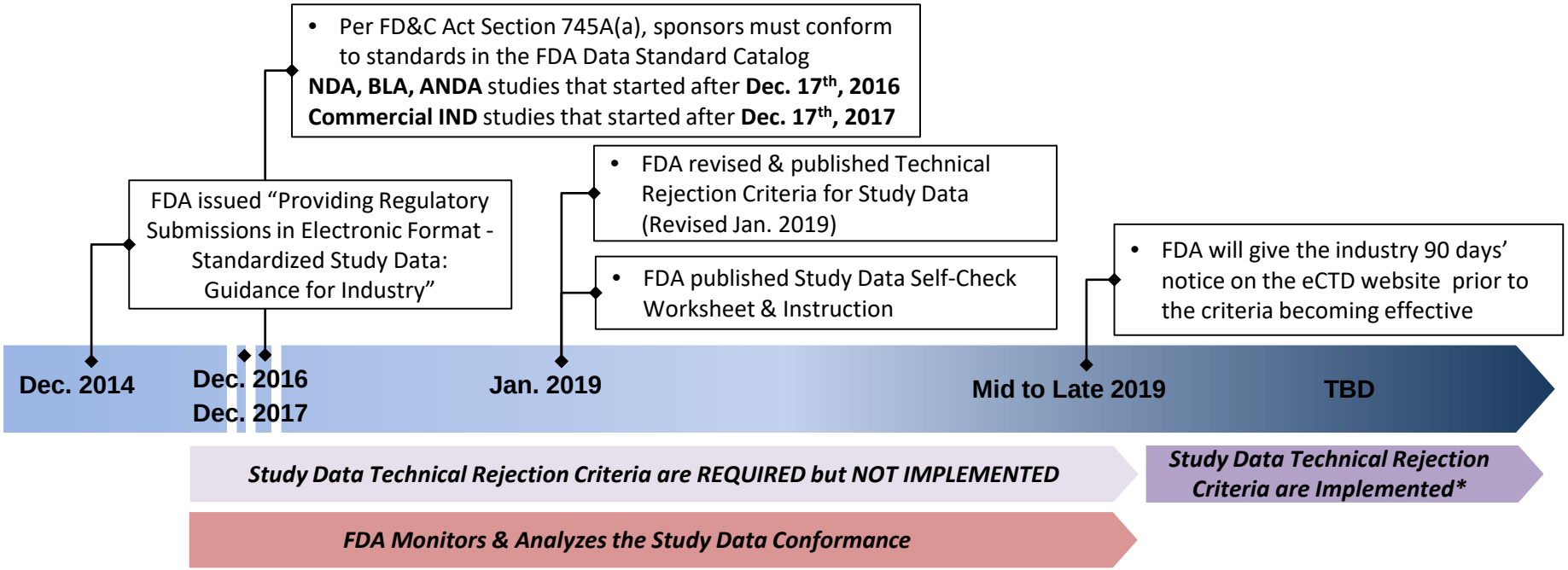
| Section | Contents | Example(s) |
|---|---|---|
| 1 | **Application & Submission Information**<br>• Provides high level information about the application and submission | 1a. FDA Center*: CDER ☐ CBER ☐ |
| 2 | **Study Information**<br>• Provides more detailed information about the specific study | 2a. Study ID*:<br>2f. Study Dataset Type(s)*: Tabulation ☐ Analysis ☐ |
| 3 | **STF File Information** (1789 Validation Error)<br>• Provide information about STF file | 3b. Is STF File Included?* Yes ☐ No ☐<br>3c. Does STF File Reference all Associated Study Files?* Yes ☐ No ☐ |
| 4 | **TS File Information** (1734 Validation Error)<br>• Provide information about ts.xpt file with study start date | 4c. Study ID in TS File*: _____<br>4d. Does Study ID in STF & TS Files Match?* Yes ☐ No ☐ |
| 5 | **Standardized Dataset Information**<br>(1735 & 1736 Validation Error)<br>• Provide information about SEND or STDM and/or ADaM dataset and define.xml<br>• Provide information about STF File-tags | 5f. Is DM File Included?* Yes ☐ No ☐<br>5g. Is Define File Included?* Yes ☐ No ☐<br>5h. Are the STF File-Tags for the SDTM Datasets "data-tabulation-dataset-sdtm"?* Yes ☐ No ☐<br>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.***

**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.**

# Questions

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

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

# 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
- **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

# Acknowledgments

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