

Study Data Technical Rejection Criteria, Validation, and Self-Check Worksheet

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Agenda

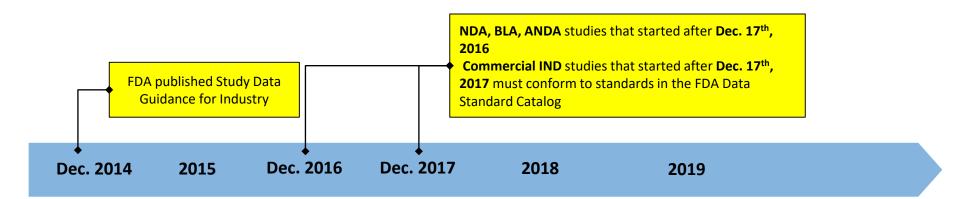


- o FDA Guidance and Data Standards Catalog
- o Study Data Technical Rejection Criteria Conformance Trend
- o Revised Technical Rejection Criteria for Study Data
- o Technical Rejection Criteria Validation Process
- Typical Error Examples and Demo of the Self-Check Worksheet
- o Implementation Timeline



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



CDER Conformance: Validation Error 1789



ANDA, NDA, BLA, and Commercial IND Submissions were assessed for conformance to high-level error, 1789, as defined in the Technical Rejection Criteria for Study Data (Revised Jan. 2019)

	NDA		AN	DA	BLA		Comm. IND		All	
	CY2018	CY2019 (Q1)	CY2018	CY2019 (Q1)	CY2018	CY2019 (Q1)	CY2018	CY2019 (Q1)	CY2018	CY2019 (Q1)
Total Number of Submissions	41,077	11,011	62,695	14,776	11,042	2997	79,473	22,226	194,287	51,010
Error 1789	43	11	225	53	1	0	193	62	462	126
Failure Rate (% among submissions with Study Data)	0.10%	0.10%	0.36%	0.36%	<0.01%	0.00%	0.24%	0.28%	0.24%	0.20%

Notes:

- 1) One drug application could contain multiple submissions throughout its review life-cycle, such as original, supplements, and amendments
- 2) Each submission may contain more than one study
- 3) Analysis includes NDA, BLA, ANDA and Commercial IND submissions received by CDER between 1/1/2018 to 3/31/2019
- 4) Analysis is conducted according to the revised TRC

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

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CDER Conformance: Validation Errors 1734, 1735 & 1736



- ANDA, NDA, BLA, and Commercial IND Submissions were assessed for conformance to three high-level error, 1734, 1735, & 1736, as defined in the Technical Rejection Criteria for Study Data (Revised Jan. 2019)
- Failure Rate for all applications increased 2.3% (average) between 2018 and 2019

	NDA		AN	IDA	BLA		Comm. IND		All	
	CY2018	CY2019 (Q1)	CY2018	CY2019 (Q1)	CY2018	CY2019 (Q1)	CY2018	CY2019 (Q1)	CY2018	CY2019 (Q1)
Total Number of Submissions with Study Data	877	270	1078	243	291	77	649	183	2895	773
Total Number of Submissions with Study Data in TRC Applicable Sections		204		226		57		172		659
Total Number Submissions with Critical Errors	215	71	689	181	54	15	134	42	1092	309
Error 1734	185	52	186	53	48	15	96	24	515	144
Error 1735	34	23	497	130	5	0	26	15	562	168
Error 1736	16	3	88	21	2	0	18	5	124	29
Failure Rate (% among submissions with Study Data)	24.50%	26.30%	63.90%	73.70%	18.60%	19.50%	20.60%	23.00%	37.70%	40.00%
Failure Rate (% among submissions with Study Data in TRC Applicable Sections)		34.80%		80.10%		26.30%		24.40%		46.90%

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 1/1/2018 to 3/31/2019
- 3) Submission with multiple studies can report both Errors 1734, 1735 and 1736
- 4) Validation of errors 1735 and 1736 are not performed if a study has Error 1734
- 5) Analysis is conducted according to the revised TRC

CBER Conformance: Validation Errors 1734, 1735, 1736 & 1789

CBER BLA Submissions were assessed for conformance to four high-level errors, 1734, 1735, 1736 and 1789 as defined in the Technical Rejection Criteria for Study Data (Revised Jan. 2019)

	BLA			
	CY2018	CY2019 (Q1)		
Total Number of studies with Study Data	6062	1644		
Error 1789	6	0		
Failure Rate (% among studies with Study Data)	0.1%	0%		

	BL	A
	CY2018	CY2019 (Q1)
Total Number of studies with Study Data	49	12
Total Number of Submissions with Study Data in TR(Applicable Sections		12
Total Number studies with Critical Errors	15	6
Error 1734	14	5
Error 1735	3	1
Error 1736	1	1
Failure Rate (% among studies with Study Data)	30.6%	50.0%
Failure Rate (% among submissions with Study Data in TRC Applicable Sections)		50.0%

Notes:

- 1) One drug application could contain multiple submissions throughout its review life-cycle, such as original, supplements, and amendments
- 2) Analysis includes BLA submissions received by CBER between 1/1/2018 to 3/31/2019
- 3) Analysis is conducted according to the revised TRC
- 4) Submission with multiple studies can report both Errors 1734, 1735 and 1736
- 5) Validation of errors 1735 and 1736 are not performed if a study has Error 1734

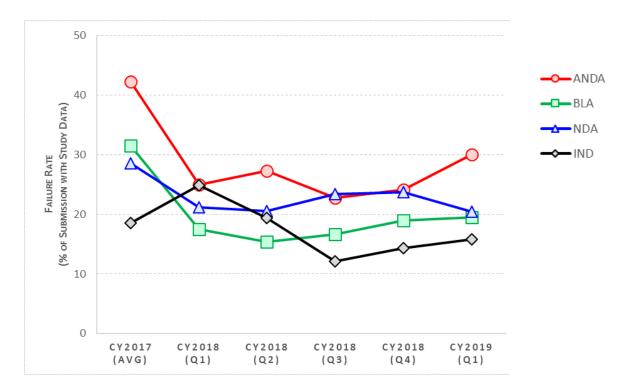
Reference: FDA Study Data Technical Rejection Criteria (Revised Jan. 2019)

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Overall Conformance Trend for Validation Errors 1734 & 1736

- Submissions with study data shows overall decreases in Validation Error 1734 and 1736 in all application types
- NDAs and INDs are showing the greatest improvements in conformance



Notes:

- 1) CY2017 analysis is conducted according to TRC (Revised May 2018)
- 2) CY2018 & CY2019 (Q1) analysis are conducted according to the TRC (Revised Jan. 2019)

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Study Data Technical Rejection Criteria (SDTRC) Revision (Jan. 2019)



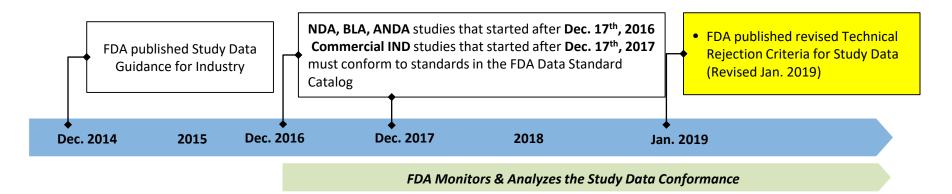
Technical Rejection Criteria for Study Data (Revised 05/01/2018)

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



References:

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

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Update to SDTRC List of High Errors (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

Severity Level Error Description (Reference to FDA Study Data Technical Rejection Criteria Jan. 2019 version) Trial Summary (TS) dataset (ts.xpt) with information on study start date must be present 1734 High for required sections* Correct STF file-tags must be used for all standardized datasets and corresponding 1735 High define.xml files in required sections* For SEND data, a DM dataset and define xml must be submitted in required sections* 1736 For SDTM data, a DM dataset and define.xml must be submitted in required sections* High For ADaM data, an ADSL dataset and define.xml must be submitted in required sections* 1789** Study files must be referenced in a Study Tagging File (STF) 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 www.fda.gov

eCTD Technical Rejection Criteria for Study Data Expectation



Study Start	rt Application			Expectation by Center				
Date	Туре	Data Type	Study Sections	CDER	CBER			
Prior to or on	Commercial	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Rejection oritoria 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			
17-Dec-2017	INDs	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				
After	Commercial	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			
17-Dec-2017	INDs	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 applie	n criteria will not be applied			
Prior to or on	NDA, BLA,	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			
17-Dec-2016	ANDA	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 simplifie contains an xpt dataset (other than the r				
After	NDA, BLA,	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			
17-Dec-2016	ANDA	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			

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Published SDTRC and Self-Check Worksheet



"Technical Rejection Criteria for Study Data"

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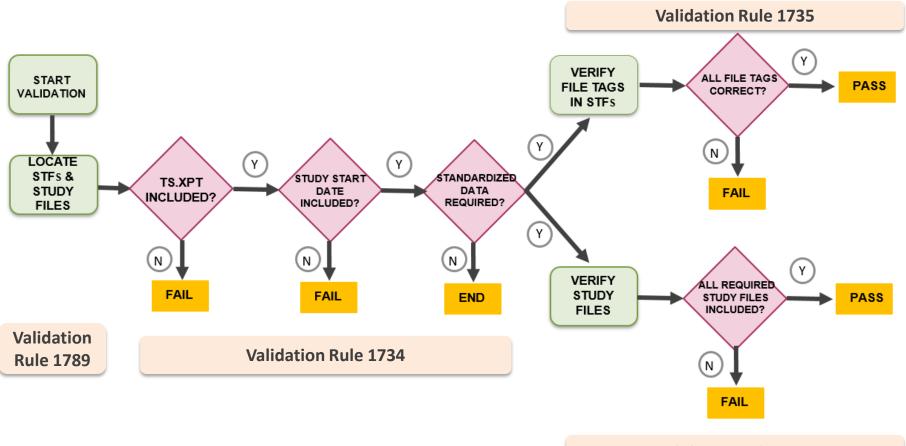
Study Data for Submission to CDER and CBER

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https://www.fda.gov/media/100743/download 👿 Sign up for email updates. 🖉 Study Data Standards "Technical Rejection Criteria Self-Check Worksheet" Resources Data standards enable FDA to modernize and streamline the review process. They also enable more consistent use https://www.fda.gov/media/123098/download Study Data for Submission to Stay Connected of analysis tools to better view drug data and highlight CDER and CBER areas of concern. If you have study data questions for CDER, please contact the CDER eDATA Study Data Research and Study data standards describe a standard way to Team at cder-edata@fda.hhs.gov. Collaborations exchange clinical and nonclinical research data between **"Technical Rejection Criteria Self-Check Worksheet** For electronic submissions, contact the computer systems. These standards provide a consistent Janus Data Repository CDER Electronic Submission (ESUB) general framework for organizing study data, including Support Team at esub@fda.hhs.gov. Instructions" templates for datasets, standard names for variables, and Study Design Standard standard ways of doing calculations with common If you have study data questions for https://www.fda.gov/media/123099/download CBER, please contact CBERvariables. Study Participation Standard edata@fda.hhs.gov. FDA is instituting new requirements for data standards For electronic submissions, contact Subject Data Standard that will apply to most study data submitted to FDA's CBER ESUB at Center for Drug Evaluation and Research (CDER) and esubprep@fda.hhs.gov. 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 not conform to the required standards specified in the FDA Da Catalog. See the Technical Rejection Criteria for Study Data (PDF) for more inform ducted an analysis of study data conformance on submissi specified time period and developed a presentation on the overall conformance results. Study F conformance (PDF) To assist sponsors when submitting study FDA has eated the Technical Rejection Criteria Self-Check Worksheet (PDF) and Worksh Instru (PDF) NDA, BLA, ANDA studies that started after Dec. FDA published Study Data Self-Check Worksheet & Instruction FDA published Study 17th. 2016 Data Guidance for Commercial IND studies that started after Dec. FDA published revised Technical 17th, 2017 must conform to standards in the FDA Industry **Rejection Criteria for Study Data** Data Standard Catalog (Revised Jan. 2019) Dec. 2014 Dec. 2016 Dec. 2017 2018 Jan. 2019 2015

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SDTRC High Level Validation Process (Revised Jan. 2019)



Validation Rule 1736

FDA

Self-Check Worksheet



Section	Contents Application & Submission Information	DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration SELF-CHECK WORKSHEET FOR STUDY DATA PREPARATION Note: This self-check Worksheet is not required for submissions of study data and is designed to help prepare newly submitted study data to FDA, i.e. studies for which no files have been previously submitted. *Required Field
1	 Provides high level information about the application and submission 	Section 1: Application & Submission Information 1a. FDA Center* 1b. Application Type* 1c. Application Number* CDER CBER 1d. eCTD Sequence Number 1e. eCTD Submission Type 1f. eCTD Submission Sub Type
2	 Study Information Provides more detailed information about the specific study 	Note: Repeat Sections 2 through 5 for each study included in the submission. Section 2: Study Information 2a. Study ID*
3	 STF File Information (1789 Validation Error) Provide information about STF file 	If you answered "No" in Field 2b, do not proceed. This self-check worksheet is designed for newly submitted study data. 2c. Title of the Study 2d. Study Section - eCTD Heading (Example: m4-2-1-1)* 2e. Module" 2f. Study Dataset Type(s)*
		Nonclinical (m5) Tabulation Analysis Other Section 3: Study 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 Yes No No No not proceed. No Not proceed. 3b. Is STF File Included?* 3c. Does STF File Reference all Associated Study Files?* Referenced Validation Error Number 1788 Yes No Yes No

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/media/123098/download

"Technical Rejection Criteria Self-Check Worksheet

Instructions" https://www.fda.gov/media/123099/download

3e. Does the Study ID in the STF File Match Field 2a?

Yes No

If you answered "No" in Field 3e, ensure the study ID is consistent across all the files being submitted for the same study.

Fillable Self-Check Worksheet - Coming Soon!



Self-Check Worksheet (1734 Validation Error)

Section	Contents
	TS File Information (1734 Validation Error)
4	 Provide information about ts.xpt file with study start date
Reference:	Rejection Criteria Self-Check Worksheet"
	w.fda.gov/media/123098/download
"Technical	Rejection Criteria Self-Check Worksheet Instructions"
https://www	w fda gov/media/123099/download

https://www.fda.gov/media/123099/download

Secuon 4: 15 Fil	e Information								
4a. What Type of TS	File is Required?* (Refer to guide	elines i	n chart below.)					
Full TS	Full TS Simplified TS Not Required								
Study Start Date	Application Type					Required TS File Type (by Center) CBER			
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Nonclinic	al	4.2.3.1, 4.2.3.2, 4.2.3.4	Simplifie	d TS	Not Required		
Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Clinical	I	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	Simplifie	d TS	Simplified TS		
Prior to or on 17-Dec-17	Commercial IND	Nonclinic	al	4.2.3.1, 4.2.3.2, 4.2.3.4	Simplifie	d TS	Not Required		
Prior to or on 17-Dec-17	Commercial IND	Clinical	1	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	Not Req	uired	Not Required		
After 17-Dec-16	NDA, BLA, or ANDA	Nonclinic	nclinical 4.2.3.1, 4.2.3.2, 4.2.3.4 Full TS N				Not Required		
After 17-Dec-16	NDA, BLA, or ANDA	Clinical	1	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	Full T	s	Full TS		
After 17-Dec-17	Commercial IND	Nonclinic	al	4.2.3.1, 4.2.3.2, 4.2.3.4	Full T	s	Not Required		
After 17-Dec-17	Commercial IND	Clinical	I	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	Not Req	uired	Not Required		
If you answered "No	t Required" in Field 4	la, then Valid	ation R	Pules 1734, 1735, and 1736 do	o not apply.	Do not p	proceed.		
4b. Is TS File Includ	ed?*						enced Validation Number 1734		
If you answered "No	" in Field 4b, Validat	ion Rule 1734	4 FAILS	S. Do not proceed.					
4c. Study ID in TS F	ile*								
4d. Does Study ID ir	n STF (Field 3d) & TS	S Files Match	?				enced Validation Number 1734		
If you answered "No	" in Field 4d, Validat	ion Rule 1734	4 FAIL:	S. Do not proceed.					
4e. Study Start Date	in TS File		_		alid?		enced Validation Number 1734		
4g. If Study Start Date does not Exist, What is the Stated Exception Code?									
Fi	illable Self	-Check	W	orksheet - Com	ing Sc	on!			
	Full TS Study Start Date Prior to or on 17-Dec-16 Prior to or on 17-Dec-16 Prior to or on 17-Dec-17 Prior to or on 17-Dec-17 After 17-Dec-17 After 17-Dec-16 After 17-Dec-17 After 17-Dec-17 After 17-Dec-17 If you answered "No to use the study ID in TS F 4d. Does Study ID in Yes No If you answered "No te. Study Start Date 4g. If Study Start Date	Full TS Simplified TS Study Start Date Application Type Prior to or on 17-Dec-16 NDA, BLA, or ANDA Prior to or on 17-Dec-17 Commercial IND Prior to or on 17-Dec-17 Commercial IND Prior to or on 17-Dec-17 Commercial IND After 17-Dec-16 NDA, BLA, or ANDA After 17-Dec-17 Commercial IND If you answered "Not Required" in Field 40 4b. Is TS File Included?* Yes Yes No If you answered "No" in Field 40, Validat 4c. Study ID in TS File* 4d. Does Study ID in STF (Field 3d) & TS Yes No If you answered "No" in Field 4d, Validat 4e. Study Start Date in TS File 4g. If Study Start Date does not Exist, Wi	Full TS Simplified TS Not if Study Start Date Application Type Data Type Prior to or on NDA, BLA, or Nonclinic Prior to or on NDA, BLA, or Nonclinic Prior to or on NDA, BLA, or Clinical Prior to or on NDA, BLA, or Clinical Prior to or on NDA, BLA, or Clinical Prior to or on Commercial IND Nonclinic Prior to or on Commercial IND Clinical After 17-Dec-16 NDA, BLA, or Nonclinic After 17-Dec-17 Commercial IND Nonclinical After 17-Dec-16 NDA, BLA, or Clinical After 17-Dec-17 Commercial IND Nonclinical After 17-Dec-17 Commercial IND Nonclinical If you answered "Not Required" in Field 4a, then Valid Validation Rule 173- 4c. Study ID in TS File" Study VD in STF (Field 3d) & TS Files Match Yes No No If you answered "No" in Field 4d, Validation Rule 173- 4e. Study Start Date in TS File Matein TS File 4g. If Study Start Date does not Exist, What is the Stat	Full TS Simplified TS Not Required Study Start Date Application Type Data Type Prior to or on 17-Dec-16 NDA, BLA, or ANDA Nonclinical Prior to or on 17-Dec-17 Commercial IND Nonclinical Prior to or on 17-Dec-17 Commercial IND Nonclinical Prior to or on 17-Dec-17 Commercial IND Nonclinical After 17-Dec-18 NDA, BLA, or ANDA Nonclinical After 17-Dec-17 Commercial IND Clinical After 17-Dec-18 NDA, BLA, or ANDA Nonclinical After 17-Dec-17 Commercial IND Clinical If you answered "Not Required" in Field 4a, then Validation Rule 1734 FAIL3 4b. Is TS File Included?* Yes No If you answered "No" in Field 4b, Validation Rule 1734 FAIL3 4c. Study ID in TS File* 4d. Does Study ID in STF (Field 3d) & TS Files Match? Yes Yes No	Study Start Date Application Type Data Type Study Section Prior to or on 17-Dec-18 NDA, BLA, or ANDA Nonclinical 4.2.3.1, 4.2.3.2, 4.2.3.4 Prior to or on 17-Dec-18 NDA, BLA, or ANDA Clinical 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.4, 5.3.3.4, 5.3.3.4, 5	Full TS Simplified TS Not Required Study Start Date Application Type Data Type Study Section Type (by COE Prior to or on NDA, BLA, or Nonclinical 4.2.3.1, 4.2.3.2, 4.2.3.4 Simplifie Prior to or on NDA, BLA, or ANDA Clinical 5.3.1, 5.3.1, 5.3.2, 5.3.3.4, 5.3.3.1, 5.3.3.4, 5.3.5.1, 5.3.5.2 Simplifie Prior to or on NDA, BLA, or Clinical 5.3.1, 1.5.3.1, 2.5.3.3.1, 5.3.2, 4.2.3.4 Simplifie Prior to or on Commercial IND Nonclinical 4.2.3.1, 4.2.3.2, 4.2.3.4 Simplifie Prior to or on Commercial IND Clinical 5.3.1, 5.3.1, 5.3.5.2 Simplifie Prior to or on Commercial IND Clinical 5.3.1, 5.3.1, 5.3.5.4 Full T After 17-Dec-16 NDA, BLA, or Nonclinical 4.2.3.1, 4.2.3.2, 4.2.3.4 Full T After 17-Dec-17 Commercial IND Nonclinical 4.2.3.1, 4.2.3.2, 4.2.3.4 Full T After 17-Dec-17 Commercial IND Nonclinical 4.2.3.1, 4.2.3.2, 4.2.3.4 Full T After 17-Dec-17 Commercial IND Clinical 5.3.1, 6.3.3.5, 5.3.4, 5.3.5.2 Not Requited"in Field 4a, then Val	Full TS Simplified TS Not Required Study Start Date Application Type Data Type Study Section Type (by Center) CDER Prior to or on 17-Dec-16 NDA, BLA, or ANDA Nonclinical 4.2.3.1, 4.2.3.2, 4.2.3.4 Simplified TS Prior to or on 17-Dec-16 NDA, BLA, or ANDA Clinical 5.3.1, 1, 5.3.1, 2, 5.3.3.1, 5.3.3.2, 5.3.3.4, 5.3.5.1, 5.3.5.2 Simplified TS Prior to or on 17-Dec-17 Commercial IND Nonclinical 4.2.3.1, 4.2.3.2, 4.2.3.4 Simplified TS Prior to or on 17-Dec-17 Commercial IND Nonclinical 4.2.3.1, 4.2.3.2, 4.2.3.4 Not Required After 17-Dec-17 Commercial IND Clinical 5.3.1.1, 5.3.1, 2, 5.3.3.1, 5.3.4, 5.3.5, 5.3.3, 4 Full TS After 17-Dec-16 NDA, BLA, or ANDA Clinical 5.3.1.1, 5.3.1, 2, 5.3.3.1, 5.3.4, 5.3.5, 5.3.3, 4 Full TS After 17-Dec-17 Commercial IND Nonclinical 4.2.3.1, 4.2.3.2, 4.2.3.4 Full TS After 17-Dec-17 Commercial IND Nonclinical 5.3.1.1, 5.3.1, 2, 5.3.3.1, 5.3.3.4, 5.3.5.2 Full TS After 17-Dec-17 Commercial IND Clinical 5.3.1, 6.3.2, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2 Not Required If you answere		

Simplified vs Full ts.xpt (Section 4)



- 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)

Study with a valid Study Start Date

STUDYID	TSPARMCD	TSVAL	TSVALNF
Study ID in STF	STSTDTC (Nonclinical) or SSTDTC (Clinical)	yyyy-mm-dd	Can be left blank when valid study start date is provided in TSVAL

Study without a valid Study Start Date

STUDYID	TSPARMCD	TSVAL	TSVALNF
Study ID in STF	STSTDTC (Nonclinical) or SSTDTC (Clinical)	Can be left blank when a study start date is not available	Exception code as specified in the ISO 21090

References:

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

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Applicable Study Sections (Section 4a)



Technical Rejection Criteria is only applicable to Study Sections as specified in Table 1
 eCTD Technical Rejection Criteria for Study Data Expectation

Example	Self-Check Worksheet							
 Study Files and/or datasets submitted in m5-3-5- (TRC not applicable study section) TRC Requirement: No ts.xpt is needed 	Section 4: TS Fi 4a. What Type of TS	le Information S File is Required?" (/ Simplified TS	Refer to guidelines ⊠ Not Requir	· · ·				
 ⊕ ⊕ 5.3.3. Reports of Human Pharmacokinetic (PK) Studies ⊕ ⊕	Study Start Date	Application Type	Data Type	Study Section		equired TS File pe (by Center) CDER	Required TS File Type (by Center) CBER	
5.3.5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication [Type of Control]	Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2	2.3.4 S	Simplified TS	Not Required	
- 1 5.3.5.3. Reports of Analyses of Data from More than One Study [Study ID - Study Title]	Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Clinical	5.3.1.1, 5.3.1.2, 5.3 5.3.3.2, 5.3.3.3, 5.3 5.3.4, 5.3.5.1, 5.3.	3.3.4, S	Simplified TS	Simplified TS	
	Prior to or on 17-Dec-17	Commercial IND	Nonclinical	4.2.3.1, 4.2.3.2, 4.2	2.3.4 S	Simplified TS	Not Required	
No Further Validation Needed	Prior to or on 17-Dec-17	Commercial IND	Clinical	5.3.1.1, 5.3.1.2, 5.3 5.3.3.2, 5.3.3.3, 5.3 5.3.4, 5.3.5.1, 5.3	.3.4, N	Not Required	Not Required	
	After 17-Dec-16	NDA, BLA, or ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2	2.3.4	Full TS	Not Required	
	After 17-Dec-16	NDA, BLA, or ANDA	Clinical	5.3.1.1, 5.3.1.2, 5.3 5.3 3 2, 5 3 3 3, 5 3 5.3.4, 5.3.5.1, 5 3	1.3.4,	Full TS	Full TS	
	After 17-Dec-17	Commercial IND	Nonclinical	4.2.3.1, 4.2.3.2, 4.2	2.3.4	Full TS	Not Required	
	After 17-Dec-17	Commercial IND	Clinical	5.3.1.1, 5.3.1.2, 5.3 5.3.3.2, 5.3.3.3, 5.3 5.3.4, 5.3.5.1, 5.3	.3.4, N	Not Required	Not Required	



Simplified vs Full ts.xpt Examples (Section 4a)

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

Example	Self-Check Worksheet					
 2. Study Files and/or datasets submitted in m5-3-5- 1 (TRC applicable study section) Study Start Date: 2010-01-01 		le Information S File is Required?" (/ Simplified TS	Refer to guidelines	· · · ·		
TRC Requirement : <u>Simplified TS is needed</u>	Study Start Date	Application Type	Data Type	Study Section	Required TS File Type (by Center) CDER	Required TS File Type (by Center) CBER
	Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Simplified TS	Not Required
5.3.5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication [Type of Control]	Prior to or on 17-Dec-16	NDA, BLA, or ANDA	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	Simplified TS	Simplified TS
⊕ 🥩 5.3.5.3. Reports of Analyses of Data from More than One Study [Study ID - Study Title]	Prior to or on 17-Dec-17	Commercial IND	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Simplified TS	Not Required
	Prior to or on 17-Dec-17	Commercial IND	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	Not Required	Not Required
	After 17-Dec-16	NDA, BLA, or ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Full TS	Not Required
	After 17-Dec-16	NDA, BLA, or ANDA	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	Full TS	Full TS
	After 17-Dec-17	Commercial IND	Nonclinical	4.2.3.1, 4.2.3.2, 4.2.3.4	Full TS	Not Required
	After 17-Dec-17	Commercial IND	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	Not Required	Not Required
		·				



Simplified vs Full ts.xpt Examples (Section 4a)

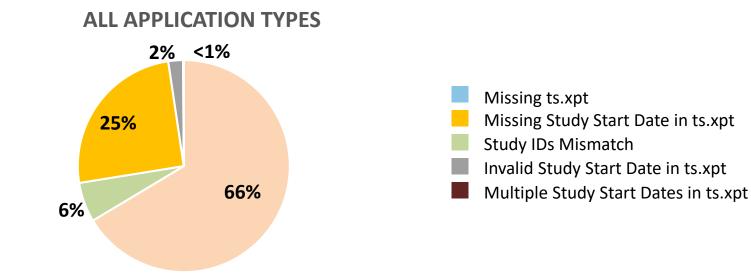
Trial Summary (TS) dataset (ts.xpt) with information on study start date must be present for required sections

Example	Self-Check Worksheet					
 3. Study Files and/or datasets submitted in m5-3-5- 1 (TRC applicable study section) Study Start Date: 2018-01-01 	Section 4: TS Fi 4a. What Type of TS		Refer to guidelines	· · ·		
TRC Requirement : <u>Full TS is needed</u> ÷ ^(J) 5.3.3. Reports of Human Pharmacokinetic (PK) Studies	Study Start Date	Application Type	Data Type	Study Section	Required TS File Type (by Center) CDER	Required TS File Type (by Center) CBER
5.3.5. Reports of Efficacy and Safety Studies [Indication]	Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2	2.3.4 Simplified TS	Not Required
	Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Clinical	5.3.1.1, 5.3.1.2, 5.3 5.3.3.2, 5.3.3.3, 5.3 5.3.4, 5.3.5.1, 5.3	3.3.4, Simplified TS	Simplified TS
⊕ 🥩 5.3.5.3. Reports of Analyses of Data from More than One Study [Study ID - Study Title]	Prior to or on 17-Dec-17	Commercial IND	Nonclinical	4.2.3.1, 4.2.3.2, 4.2	2.3.4 Simplified TS	Not Required
	Prior to or on 17-Dec-17	Commercial IND	Clinical	5.3.1.1, 5.3.1.2, 5.3 5.3.3.2, 5.3.3.3, 5.3 5.3.4, 5.3.5.1, 5.3	3.3.4, Not Required	Not Required
	After 17-Dec-16	NDA, BLA, or ANDA	Nonclinical	4.2.3.1, 4.2.3.2, 4.2	2.3.4 Full TS	Not Required
	After 17-Dec-16	NDA, BLA, or ANDA	Clinical	5.3.1.1, 5.3.1.2, 5.3 5.3.3.2, 5.3.3.3, 5.3 5.3.4, 5.3.5.1, 5.3	3.3.4, Full TS	Full TS
	After 17-Dec-17	Commercial IND	Nonclinical	4.2.3.1, 4.2.3.2, 4.2	2.3.4 Full TS	Not Required
	After 17-Dec-17	Commercial IND	Clinical	5.3.1.1, 5.3.1.2, 5.3 5.3.3.2, 5.3.3.3, 5.3 5.3.4, 5.3.5.1, 5.3	3.3.4, Not Required	Not Required
	-					

FDA

CY2018 CDER Error Reasons for Validation Rule 1734

- A dataset named ts.xpt with information on Study Start Date (SSD) must be present for each study
- Common error reason across all application types:
 - missing ts.xpt file (66% of studies with error 1734)
 - missing study start date in the ts.xpt (25% of studies with error 1734)



TRC Validation Rule 1734 (Section 4b)



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

Example	Self-Check Worksheet
 2. Study Files and/or datasets submitted in m5-3-5- 1 (TRC applicable study section) Study Start Date: 2018-01-01 TRC Requirement: Full TS is needed 	Section 4: TS File Information
S.3.3. Reports of Human Pharmacokinetic (PK) Studies S.3.5. Reports of Efficacy and Safety Studies [Indication] S.3.5. Treatment chronic iron overload due to blood transfusion S.3.5. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication [Type of Controlled Clinical Studies [Study ID - Study Title] S.3.5. Study Reports of Analyses of Data from More than One Study [Study ID - Study Title] S.3.5. Study reports of Analyses of Data from More than One Study [Study ID - Study Title] S.3.5. Neports of Analyses of Data from More than One Study [Study ID - Study Title] S.3.5. Neports of Analyses of Data from More than One Study [Study ID - Study Title] S.3.5. Neports of Analyses of Data from More than One Study [Study ID - Study Title] S.3.5. Neports of Analyses of Data from More than One Study [Study ID - Study Title] S.3.5. Neports of Analyses of Data from More than One Study [Study ID - Study Title] If you answered "No" in Field 4b, Validation Rule 1734 FAILS. Do not proceed.	4a. What Type of TS File is Required?* (Refer to guidelines in chart below.) ▲ Full TS Simplified TS 4b. Is TS File Included?* Referenced Validation ▲ Yes No If you answered "No" in Field 4b, Validation Rule 1734 FAILS. Do not proceed 4c. Study ID in TS File* 4d. Does Study ID in STF (Field 3d) & TS Files Match? ▲ Yes No If you answered "No" in Field 4d, Validation Rule 1734 FAILS. Do not proceed. 4d. Does Study ID in STF (Field 3d) & TS Files Match? ▲ Yes No If you answered "No" in Field 4d, Validation Rule 1734 FAILS. Do not proceed. 4e. Study Start Date in TS File 4f. If Study Start Date Exists, Is it Valid? ▲ Study Start Date in TS File 4f. If Study Start Date Exists, Is it Valid? ▲ If Study Start Date does not Exist, What is the Stated Exception Code?

Study ID Match Requirements

- 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.

	riable	Variable Label	Comments	Included in:
Na	mo			
ST	UDYID	Study ID	Uniquely identifies a study within a particular submission.	All files
SIT	TEID	Shell	Some sponsors may use INWID	At least one of these
INV	VID	Investigator ID	instead of or in addition to a SITEID.	variables must be included in all files
US	UBJID	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) (<u>http://estri.ich.org/STF/STFV2-6-1.pdf</u>) CDISC Submission Metadata Model

(https://www.cdisc.org/system/files/all/reference_material_category/application/pdf/submissionmetadatamodelv2.pdf)



TRC Validation Rule 1734 (Section 4c)



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

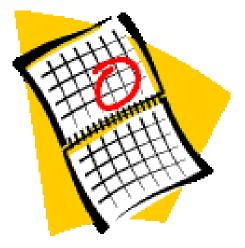
Example	Self-Check Worksheet
 2. Study Files and/or datasets submitted in m5-3-5- 1 (TRC applicable study section) Study Start Date: 2018-01-01 TRC Requirement: Full TS is needed 	Section 4: TS File Information
 5.3.3. Reports of Human Pharmacokinetic (PK) Studies 5.3.5. Reports of Efficacy and Safety Studies [Indication] 5.3.5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication [Type of Control] 5.3.5.2. Study Reports of Uncontrolled Clinical Studies [Study ID - Study Title] 5.3.5.3. Reports of Analyses of Data from More than One Study [Study ID - Study Title] 	4a. What Type of TS File is Bequired?* (Befor to quidelines in chart below) ✓ Full TS Sim 3d. Study ID in STF File* 4b. Is TS File Included?* Yes No If you answered "No" in Field 4b."
[Study IDs Match Requirement]	4c. Study ID in TS File* ABC
<pre><title> <title> <</th><th>4d. Does Study ID in STF (Field 3d) & TS Files Match? Referenced Validation Yes No If you answered "No" in Field 4d, Validation Rule 1/34 FAILS. Do not proceed. 4e. Study Start Date in TS File 4f. If Study Start Date Exists, Is it Valid? Yes No</th></tr><tr><td>Fail Rule 1734</td><td>4g. If Study Start Date does not Exist, What is the Stated Exception Code?</td></tr></tbody></table></title></pre>	



Top Error for Rule 1734: Incorrect Study Start Date Format

A missing study start date (TSVAL) in the ts.xpt (25% of studies with error 1734)

Correct Study Start Date Format						
yyyy-mm-dd						
Incorrect Study Start Date Format						
yyyy-mm	dd-mmm-yyyy					
SAS Date Format	dd-mm-yyyy					
mm/dd/yyyy	ddmmmyyyy					
dd-mmm-yy	dd.mm.yyyy					
уууу	month-yyyy					
mm/dd/yy						



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TRC Validation Rule 1734 (Section 4c)



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

	Example	Self-Check Worksheet				
1 (TRC applicabl Study Start Date	d/or datasets submitted in m5-3-5 le study section) e: 2018-01-01 nt: <u>Full TS is needed</u>	Section 4: TS File Information 4a. What Type of TS File is Required?* (<i>Refer to guidelines in chart below.</i>)				
[Study Date Foryyyy-mm-dd	mat Requirement]	West in Field 4b, Validation Rule 1734 FAILS. Do not proceed.				
SSTDTC	Study Start Date 42622	4c. Study ID in TS File*				
Stu	dy Start Date in SAS Date Format	4d. Does Study ID in STF (Field 3d) & TS Files Match? Referenced Validation Yes No If you answered "No" in Field 4d, Validation Rule 1734 FAILS. Do not proceed.				
E	nil Rule 1734	4e. Study Start Date in TS File 4f. If Study Start Date Exists, Is it Valid? 42622 ∑ Yes No 4g. If Study Start Date does not Exist, what is the Stated Exception Code? No				

Self-Check Worksheet (1735 & 1736 Validation Error)



Cention	Contonto	Section 5: Standardized Datasets (SEND, SDTM, ADaM)						
Section	Contents	5a. Are Standardized	Datasets Required?*					
	Standardized Dataset Information	🛛 Yes 📃 No	Study Start Date	Application Type	Standardized Datasets Required?	1		
	(1735 & 1736 Validation Error)		Prior to or on 17-Dec-16	NDA, BLA, or ANDA	Not Required			
5	Provide information about SEND or STDM		After 17-Dec-16	NDA, BLA, or ANDA	Required			
	and/or ADaM dataset and define.xml		Prior to or on 17-Dec-17 After 17-Dec-17	Commercial IND Commercial IND	Not Required Required	-		
]		
	Provide information about STF File-tags	If you answered "No" Do not proceed.	in Field 5a, standardized dat	tasets are not required and l	Validation Rules 1735 and 17	36 do not apply.		
			licable to nonclinical tabulatio 5j-5m are applicable to clinica		5f-5i are applicable to clinical	l tabulation datasets		
			a in Commercial INDs standa lechnical rejection criteria will		l if the study start data is after er notice.	the date stated,		
		Tabulation (SDTM da	tasets)					
		5f. Is DM File Include Yes No	d?* 5g. Is Define File			ferenced Validation or Number 1738		
		If you answered "No"	in Fields 5f or 5g, Validation	Rule 1736 FAILS. Proceed	to Fields 5h and 5i for Valida	ation Rule 1735.		
		5h. Are the STF File- Yes No	Tags for the SDTM Datasets	*data-tabulation-dataset-sdt		ferenced Validation		
		5i. Is the STF File-Tag	g for the Define File "data-tab	oulation-data-definition?*	Err	or Number 1735		
		lf you answered "No" Analysis (ADaM data	in Fields 5h or 5i, Validation sets)	Rule 1735 FAILS.				
		5j. Is ADSL File Inclue	ded?* 5k. Is Define File			ferenced Validation or Number 1736		
		If you answered "No"	in Fields 5j or 5k, Validation	Rule 1736 FAILS. Proceed	to Fields 5I and 5m for Valid	lation Rule 1735.		
Reference: "Technical Po	jection Criteria Self-Check Worksheet"	5I. Are the STF File-T	ags for the ADaM Datasets "	analysis-dataset-adam"?*				
		5m. Is the STF File-ta	g for the Define File "analysis	s-data-definition"?"		ferenced Validation or Number 1735		
	fda.gov/media/123098/download	Yes No	- •					
	jection Criteria Self-Check Worksheet Instructions"							
<u>https://www.f</u>	fda.gov/media/123099/download	Fillab	le Self-Chec	k Workshee	t - Coming S	oon!		

www.fda.gov



TRC Validation Rule 1735 and 1736 (Section 5a)

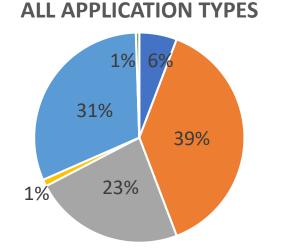
- Rule 1735: Correct STF file-tags must be used for all standardized datasets and corresponding define.xml files in required sections
- Rule 1736: For SEND data, a DM dataset and define xml must be submitted in required sections
 - For SDTM data, a DM dataset and define.xml must be submitted in required sections
 - For ADaM data, an ADSL dataset and define.xml must be submitted in required sections

Example	Self-Check Worksheet				
Study Files and/or datasets submitted in m5-	Section 5: Standardized Datasets (SEND, SDTM, ADaM)				
3-5-1 (clinical)	5a. Are Standardized Datasets Required?* ⊠ Yes □ No				
Study Start Date: 2018-01-01		Study Start Date	Application Type	Standardized Datasets Required?	
Dataset Type: Tabulation (SDTM)		Prior to or on 17-Dec-16 After 17-Dec-16	NDA, BLA, or ANDA NDA, BLA, or ANDA	Not Required Required	
		Prior to or on 17-Dec-17	Commercial IND	Not Required	
		After 17-Dec-17	Commercial IND	Required	



CY2018 CDER Error Reasons for Validation Rule 1736

- Rule 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
 - For ADaM data, an ADSL dataset and define.xml must be submitted
- Common error reason across all application types:
 - missing define.xml file (39% of studies)
 - missing define.xml, dm.xpt, and adsl.xpt files (31% of studies)
- Common error reason for NDAs:
 - missing define.xml and adsl.xpt files







TRC Validation Rule 1735 and 1736 (Section 5f-5g)

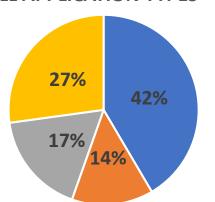
- Rule 1735: Correct STF file-tags must be used for all standardized datasets and corresponding define.xml files in required sections
- Rule 1736: For SEND data, a DM dataset and define xml must be submitted in required sections
 - For SDTM data, a DM dataset and define.xml must be submitted in required sections
 - For ADaM data, an ADSL dataset and define.xml must be submitted in required sections

	Example				Self-Check Worksheet				
Study Files and/or datasets submitted in m5- 3-5-1 (clinical) Study Start Date: 2018-01-01 Dataset Type: Tabulation (SDTM)					ardized Datasets (S d Datasets Required?* Study Start Date Prior to or on 17-Dec After 17-Dec-16 Prior to or on 17-Dec	Application Type 16 NDA, BLA, or ANDA NDA, BLA, or ANDA 17 Commercial IND	Standardized Datasets Required? Not Required Required Not Required		
뿣 acrf.pdf	Files Referenced in stf.xml mh.xpt suppda.xpt suppmh.xpt tv.xpt				Clinical (m5) Tabulation (SDTM da	After 17-Dec-17	Commercial IND	Required	
ae.xpt cm.xpt co.xpt	dv.xpt pe.xpt eg.xpt sc.xpt	suppdm.xpt suppds.xpt suppeg.xpt	sv.xpt ta.xpt te.xpt	vs.xpt	5f. Is DM File Include	ed?* 5g. Is Defi	e File Included?*		Referenced Validation Error Number 1736
sodrg.pdf				Yes No		asets "data-tabulation-dataset-s ta-tabulation-data-definition?*		Referenced Validation Error Number 1735	
Fail Rule 1736						" in Fields 5h or 5i , Val	dation Rule 1735 FAILS.		

FDA

CY2018 CDER Error Reasons for Validation Rule 1735

- The correct STF file tags must be used for all standardized datasets and corresponding define.xml files
- Common error reason for ANDAs:
 - incorrect file tag for a define.xml file (42% of ANDA studies with error 1735)
- Common error reason for NDAs:
 - dataset tagged as legacy when standardized datasets are required (80% of NDA studies with error 1735)



ALL APPLICATION TYPES

Incorrect define.xml file tag Incorrect define.xml & XPT dataset file tags Incorrect XPT dataset file tag Legacy Datasets Submitted When Standardized Required



TRC Validation Rule 1735 and 1736 (Section 5h-5i)

- Rule 1735: Correct STF file-tags must be used for all standardized datasets and corresponding define.xml files in required sections
- Rule 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

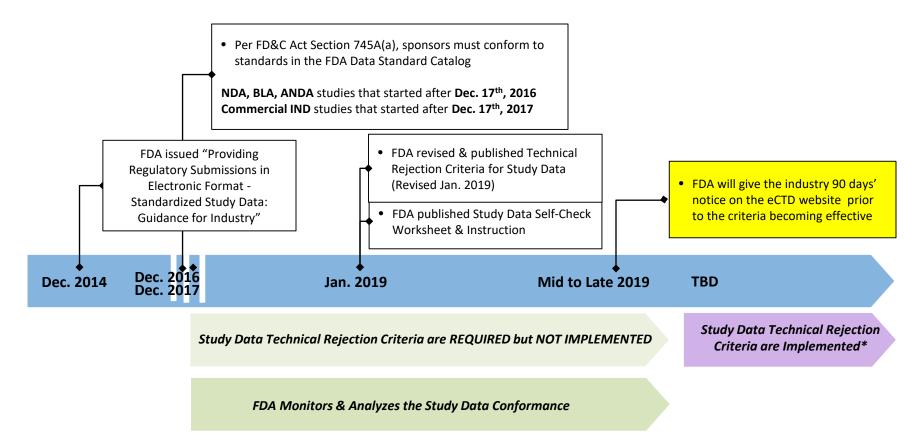
	Example				Self-Check Worksheet				
Study Files ar	nd/or datasets sub	mitted in m5 -							
3-5-1 (clinica	l)		Section 5: Standa	rdized Datasets (SEND,	SDTM, ADaM)				
Study Start D	ate: 2018-01-01		Yes No			Standardized Datasets	l		
Dataset Type	: Tabulation (SDTN	/1)		Study Start Date Prior to or on 17-Dec-16 After 17-Dec-16	Application Type NDA, BLA, or ANDA NDA, BLA, or ANDA	Required? Not Required Required			
🔁 acrf.pdf	ae.xpt	i cm.xpt		Prior to or on 17-Dec-17 After 17-Dec-17	Commercial IND Commercial IND	Not Required Required			
co.xpt	🕵 define2-0-0.xsl	define.pdf	Clinical (m5) Tabulation (SDTM da	tasets)					
i ds.xpt ex.xpt	ा dv.xpt ा ie.xpt	eg.xpt	5f. Is DM File Included	d?* 5g. Is Define File ⊠ Yes □ No			eferenced Validation rror Number 1736		
<pre><doc-content """"""""""""""""""""""""""""""""""<="" td="" xlink:href=""><td>stf.xml</td><td>0003"><file_tag name="</td"><td><u> </u></td><td>-</td><td></td><td>d to Fields 5h and 5i for Vali</td><td>dation Rule 1735.</td></file_tag></td></doc-content></pre>	stf.xml	0003"> <file_tag name="</td"><td><u> </u></td><td>-</td><td></td><td>d to Fields 5h and 5i for Vali</td><td>dation Rule 1735.</td></file_tag>	<u> </u>	-		d to Fields 5h and 5i for Vali	dation Rule 1735.		
data-tabulation-dataset-	<pre>sdtm"pinfo type="us" /></pre>	🛛 Yes 📃 No	Tags for the SDTM Datasets		E	eferenced Validation			
"data-tabulation-dataset-sdtm" info-type="us" /> define.xml is tagged as "data-tabulation-dataset-sdtm"			5i. Is the STF File-Tag for the Define File "data-tabulation-data-definition?" Yes X				rror Number 1735		
	I Rule 1735	asersulli	lf you answered "No"	in Fields 5h or 5i, Validation	n Rule 1735 FAILS.				



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

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