



Are you planning to send a submission to the FDA?
Will this submission contain study data?
If the answer to these 2 questions has been yes, this brochure may be of your interest!

FDA STUDY DATA

(aka. DATASETS)

Since September 15th, 2021, **FDA applies the Technical Rejection Criteria (TRC) for Study Data submitted in eCTD to CDER and CBER FDA divisions**

What is the Technical Rejection Criteria?

The TRC consists in an automated validation that occurs upon receipt of a submission. If the submission fails eCTD validations in TRC, CDER/CBER will reject it. TRC has been created by the FDA to ensure study data compliance with the required electronic standards specified in the FDA Data Standards Catalog.

What procedures does TRC apply to?

NDAs, ANDAs, certain BLAs and commercial INDs.

For regulatory assistance, you can contact us at:

What studies does TRC apply to?

What do I have to submit to comply with TRC?

Data Type	Modules & Submodules	Center	Application Type	Study Start Date	Requirement
Non-clinical	4.2.3.1, 4.2.3.2, 4.2.3.4	CDER	NDA, BLA, ANDA	On/Prior to December 17, 2016	Submit simplified ts.xpt*
				After December 17, 2016	Comply with CDISC standards
			Commercial IND	On/Prior to December 17, 2017	Submit simplified ts.xpt*
				After December 17, 2017	Comply with CDISC standards
		CBER	NDA, BLA, ANDA, Commercial IND	On/Prior to March 15, 2023	Submit simplified ts.xpt*
				After March 15, 2023	Comply with CDISC standards
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	CDER & CBER	NDA, BLA, ANDA	On/Prior to December 17, 2016	Submit simplified ts.xpt if study contains xpt dataset (other than ts-xpt)
				After December 17, 2016	Comply with CDISC standards
		Commercial IND	Rejection criteria not applied		
<p>*Rejection criteria will be applied if a study report with one of the three file tags, "pre-clinical-study-report", "legacy-clinical-study-report", or "study-report-body" is included, and/or an xpt file (other than the ts.xpt) is submitted.</p>					