



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?

| Application Type | Data Type | Modules and Submodules | Expectation by CDER | Expectation by CBER |
|------------------|----------------|--|---|---|
| NDA, BLA, ANDA | Non - Clinical | 4.2.3.1, 4.2.3.2, 4.2.3.4 | <i>Study Start Date: On or prior to 2016-12-17</i> 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) | <i>Study Start Date: On or prior to 2023-03-15</i> 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) |
| NDA, BLA, 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 | <i>Study Start Date: On or prior to 2016-12-17</i> Rejection criteria will be applied; submit a simplified TS if the study contains an xpt dataset (other than the ts.xpt) | <i>Study Start Date: On or prior to 2016-12-17</i> Rejection criteria will be applied; submit a simplified TS if the study contains an xpt dataset (other than the ts.xpt) |
| commercial INDs | Non - Clinical | 4.2.3.1, 4.2.3.2, 4.2.3.4 | <i>Study Start Date: On or prior to 2017-12-17</i> 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) | <i>Study Start Date: On or prior to 2023-03-15</i> 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) |
| commercial 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 | <i>Study Start Date: On or prior to 2017-12-17</i> Rejection criteria will not be applied | <i>Study Start Date: On or prior to 2017-12-17</i> Rejection criteria will not be applied |
| NDA, BLA, ANDA | Non - Clinical | 4.2.3.1, 4.2.3.2, 4.2.3.4 | <i>Study Start Date: After 2016-12-17</i> Rejection criteria will be applied; submit a full TS | <i>Study Start Date: After 2023-03-15</i> Rejection criteria will be applied; submit a full TS |
| NDA, BLA, 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 | <i>Study Start Date: After 2016-12-17</i> Rejection criteria will be applied; submit a full TS | <i>Study Start Date: After 2016-12-17</i> Rejection criteria will be applied; submit a full TS |
| commercial INDs | Non - Clinical | 4.2.3.1, 4.2.3.2, 4.2.3.4 | <i>Study Start Date: After 2017-12-17</i> Rejection criteria will be applied; submit a full TS | <i>Study Start Date: After 2023-03-15</i> Rejection criteria will be applied; submit a full TS |
| commercial 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, | <i>Study Start Date: After 2017-12-17</i> Rejection criteria will not be applied | <i>Study Start Date: After 2017-12-17</i> Rejection criteria will not be applied |