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!

NEW STUDY DATA UPDATE BY FDA

Beginning 15th September 2021, FDA will enforce the **Technical Rejection Criteria (TRC)** for Study Data by **CDER** and **CBER**.

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:

ASPHALION
+34 93 238 5945
+49 89 208 039 280
www.asphalion.coms
ectd@asphalion.com

What studies does TRC apply to? What do I have to submit to comply with TRC?

Study Start Date	Prior to or on 17-Dec-16		Prior to or on 17-Dec-17		After 17-Dec-16		After 17-Dec-17	
Application Type	NDA, BLA, ANDA		Commercial INDs		NDA, BLA, ANDA		Commercial INDs	
Data Type	Non-Clinical	Clinical	Non-Clinical	Clinical	Non-Clinical	Clinical	Non-Clinical	Clinical
Modules	4*	5*	4*	5*	4*	5*	4*	5*
Expectations by CDER	APPLICABLE Simplified TS (1)	APPLICABLE Simplified TS (2)	APPLICABLE Simplified TS (1)	NOT APPLICABLE	APPLICABLE Full TS	APPLICABLE Full TS	APPLICABLE Full TS	NOT APPLICABLE
Expectations by CBER	NOT APPLICABLE	APPLICABLE Simplified TS (2)	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE	APPLICABLE Full TS	NOT APPLICABLE	NOT APPLICABLE

*Module 4, only sections: 4.2.3.1, 4.2.3.2, 4.2.3.4
*Module 5, only sections: 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
(1) TRC 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).
(2) Submit a simplified TS if the study contains an xpt dataset (other than the ts.xpt).

Which validation errors will be checked?

Validation Error	Description
1734	A dataset named ts.xpt with information on study start date must be present for each study in required sections
1735	The 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 Module 4 required sections. For SDTM data, a DM dataset and define.xml must be submitted in Module 5 required sections. For ADaM data, an ADSL dataset and define.xml must be submitted in Module 5 required sections.
1789	A file has been submitted in a study section without providing an STF file. STFs are not required for 4.3 Literature references, 5.2 Tabular listings, 5.4 Literature references and 5.3.6 Postmarketing reports

*Module 4 sections: 4.2.3.1, 4.2.3.2, 4.2.3.4
*Module 5 sections: 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

For further information, check out:

- FDA webpage
- Technical Rejection Criteria for Study Data
- Simplified ts.xpt Creation Guide
- Self-check Worksheet for Study Data Preparation
- TRC Worksheet Instructions

ASPHALION
+34 93 238 5945
+49 89 208 039 280
www.asphalion.com
ectd@asphalion.com