

The Technical Rejection Criteria for Study Data document has been incorporated into the Study Data Technical Conformance Guide. The Study Data Technical Conformance Guide is located here: <https://www.fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources>

Details on the validations, including description, effective date, and corrective action, can be found in the Specifications for eCTD Validation Criteria. The Specifications for eCTD Validation Criteria can be accessed through the eCTD Submission Standards catalog here: <https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd>