

Technical Rejection Criteria Self-Check Worksheet Videos

Examples:

1. A Commercial IND non-clinical study which began prior to December 17, 2017 is submitted to FDA and the study files are referenced in a Study Tagging File (STF), a ts.xpt dataset is not included in the study. The Study Data Start Date cannot be determined, and the study fails validation 1734. <https://www.youtube.com/watch?v=yT3zCqCv4YQ>
2. An NDA clinical study in standardized format is submitted to FDA and the study files are referenced in a Study Tagging File (STF). The ADaM dataset in Module 5 contains a define.xml file and an adsl.xpt file and they are appropriately tagged in the STF. The study passes validation 1736. https://www.youtube.com/watch?v=jY-9-4H_-NM