ACCOVION

A CLINIPACE WORLDWIDE Company

Submission of Programs

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21st German CDISC UG Meeting

Submission of programs - FDA

- FDA Study Data Technical Conformance Guide
  - Sponsors should provide programs used to create
    - → all ADaM datasets
    - → tables and figures associated with primary and secondary efficacy analyses
  - Programs do not need to be executable but need to be sufficiently documented
  - Possible formats: *.pdf or *.txt

➢ http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM384744.pdf - June 2015

Submission of programs - PDMA

- Sponsors should provide programs used to create
  - → ADaM datasets
  - → Analyses programs
- Consult with PMDA to decide which specific programs/macros to submit prior to submission
- Programs do not need to be executable but need to be sufficiently documented
- the main purpose for PMDA is to check algorithm of datasets creation and analyses. If providing programs/macros is not possible, the documents explaining algorithm of analyses is also acceptable.

➢ http://www.pmda.go.jp/files/000153708.pdf- June 2014

Recommended reading

- Non-Executable SAS-Code for the FDA - Background, Examples and Experiences from an Oncology Filling, *Christoph Ziegler, Roche*

http://www.phusewiki.org/docs/Germany%202015%20SDE%20Presentations/Non-Executable-SAS-Code-for-the-FDA.pdf