VITA DATA SCIENCES
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Think Data! Think CDISC! Think Submission!
Think Patient!

PhUSE SDE - Boston
April 27, 2017
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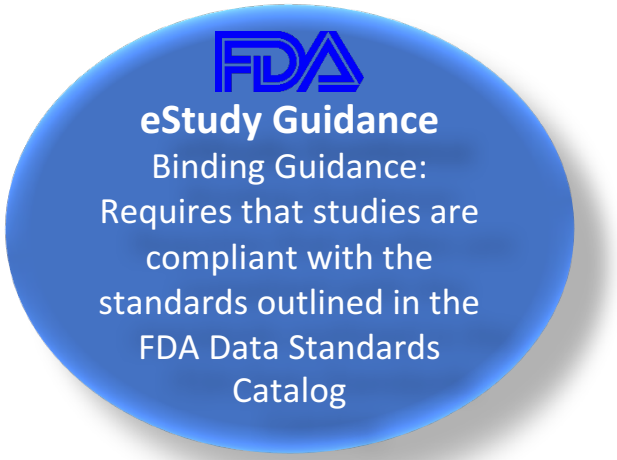
Think Patient!

Think Submission!

- FDA Requirements for Data Submissions
  - eStudy Data Guidance
    - Study Data Standards
  - Study Data Technical Conformance Guide (TCG)
  - Metadata Submission Guidelines
  - eCTD Guidance and Technical Specifications

Think CDISC!

- Starting December 18, 2016: All clinical and nonclinical trials, regardless of study type, must use the standards in the FDA Data Catalog

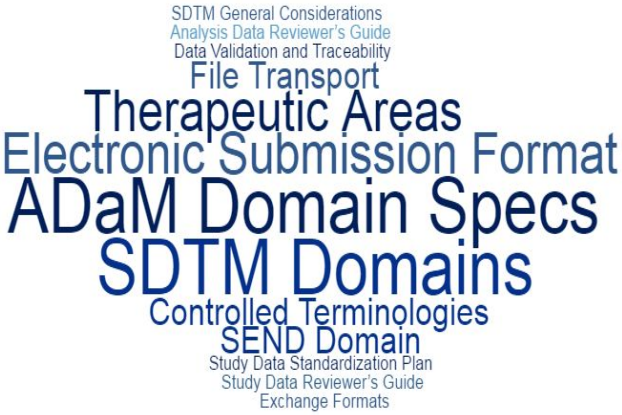


….and more

Study data standards listed in the FDA Data Standards Catalog

Study Data Technical Conformance Guide

- Study Data Standardization Plan
- Reviewers Guide
- Exchange format & Dataset Requirements
- Study Data Submission Formats
- Trial Design Domains
- Data Definition Files (define) & aCRF
- Terminologies
- FDA Business Rules & Validation Rules
- eCTD File Directory Structure
- Conformance to Standards
- Technical Rejection Criteria



‘Submission-ready’ Datasets Package

- SDTM Datasets:
  - XPT Files (including Trial Design Domains)
  - define.xml and define.xsl
  - cSDRG.pdf
  - aCRF.pdf

- ADaM Datasets:
  - XPT Files
  - define.xml and define.xsl
  - ADRG.pdf
  - Program codes in ASCII format

Recommendation # 1

- Generate define.xml and aCRF upfront and during the CDISC datasets development life cycle

- Use define.xml to generate utilities towards:
  - SDTM annotated CRF using SAS®
  - Metadata shells in XPT format using SAS

- Added advantages:
  - Make the SDTM datasets generation and validation process more efficient
  - define.xml and SDTM aCRF will always be in sync

Recommendation # 2

- Incorporate compliance requirements early in the datasets development life cycle
  - Train and educate programmers on SDTM/ADaM IG + compliance/conformance checks
  - Implement metadata driven approach, i.e. generate define.xml upfront
  - Stay current with SDTM/ADaM IG and FDA released business rules + validation rules

Recommendation # 3

- Build SAS-based utility macros to automate generation and QC of SDTM & ADaM Datasets, e.g.:
  - ISO date
  - Study Day
  - Reference Start and End Dates
  - Baseline flags
  - Epoch
  - Sequence variable
  - Unscheduled Visit convention
  - Log checks
  - Proc Compare
  - Convert .sas to .txt format
  - Generation of define.pdf
  - eCTD folder structure

Take Home Message

- Think Patient!
- Think Submission!
- Think CDISC!
- Think Data!

Contact Information

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