FDA Guidance on Standards

CDISC User Network Meeting
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Overview and Political Process

- **2012-07-09 President Obama signs FDASIA**

  ➔ **authorizes FDA to demand data standards** **(and more fees…)**

- **2014-12-18 FDA publishes the package of 6 documents:**

http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm

- **In the Federal Register:**

https://www.federalregister.gov/articles/2014/12/18/2014-29609/guidance-for-industry-on-providing-regulatory-submissions-in-electronic-format-submissions-under

Overview and Political Process

- **2014-12-18 FDA publishes the package of the 6 documents:**
  - **Providing Regulatory Submissions In Electronic Format – Submission Under Section 745 A (a) of the Federal Food, Drug and Cosmetic Act.**
  - **Providing Regulatory Submissions In Electronic Format – Standardized Study Data**
  - **Study Data Technical Conformance Guide**
  - **FDA Data Standards Catalog**
  - **FDA specific SEND Validation Rules**
  - **FDA specific SDTM Validation Rules**

- **YYYY-MM-DD Which Components Will Be a Must and When?**

Providing Regulatory Submissions In Electronic Format – Submission Under Section 745 A (a) of the Federal Food, Drug and Cosmetic Act.

- Which types of submissions are target?
- Which not?
- How to obtain a waiver
- How will requirements be implemented?
  - By creating individual guidelines for various topics
  - By publishing new/updated guidelines in the Federal Register
- This doc has been issues “in December 2014”
  - Thus, valid after a period of 24 months by Jan 1st 2017 (?)

Providing Regulatory Submissions In Electronic Format – Standardized Study Data

- Main document of the guidance – sub-documents:
  - Data Standard Catalog
  - Study Data Technical Conformance Guide
  - FDA specific SEND Validation Rules
  - FDA specific SDTM Validation Rules

- Repeats sections/keywords from the high-level doc
  - Rules about time axis after issue date (=entry into catalog)
    - 24 months for eSub Requirements
    - March 15 of following year plus 12 / 24 / 36 months
- Discuss and agree with “your” FDA reviewer.

Study Data Technical Conformance Guide

List of the standard file formats, data tables and single details

Keywords:

Reviewers guide SDRG & ADRG

XML – PDF – XPT

Dataset size – column length – SAS limitations

CDISC data models SDTM and ADaM

All (?) details from "the FDA Issue Document", including but not limited to:

Treatment-emergent – USUBJID – EPOCH – split big LB – ISO/numeric dates

Baseline flag – define.xml – aCRF – TAUGs – CT – eCTD locations

Validation rules – traceability – legacy data – interoperability

FDA Data Standards Catalog

Tabular overview of all supported standards:

www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM340684.xlsx