Update on the Study Data Technical Conformance Guide

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July 13, 2017

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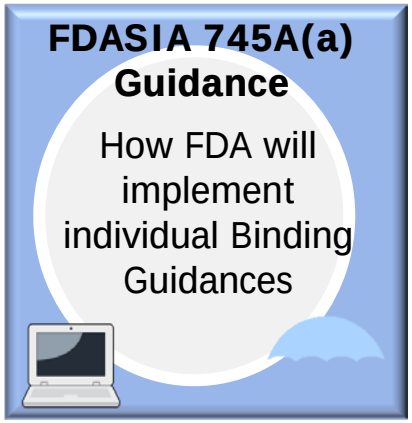
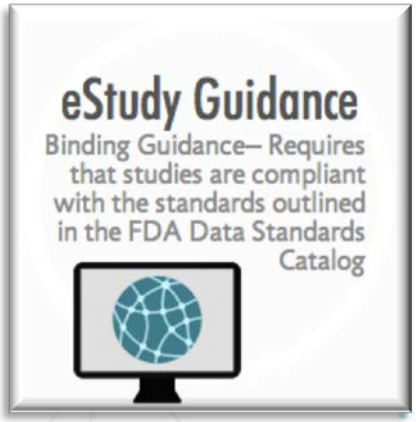
The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.

Study Data Standards:
Road Ahead and the Road Left Behind

FDA Statute to Require Data Standards

2012 FDASIA amended FD&C Act added Sec 745A (21 USC 379 k-1(a))





Study Data Technical Conformance Guide (TCG)

- Focus is on helping sponsors & applicants to submit better standardized data.
- Most up-to-date guide on standardized study data submissions to CBER / CDER.
- Posted at least twice per year: March / October.

Study Data Technical Conformance Guide (TCG)

- **2.3** An ADRG for clinical data should be called an ADRG and the document should be a PDF file 'adrg.pdf' upon submission.

- **4.1.1.3** When there is more than one disposition event, the EPOCH or DSSCAT variable should be used. This will allow identification of the EPOCH in which each event occurred or DSSCAT to differentiate if the disposition is for treatment or study.

- **4.1.2, 4.1.3.3, 4.1.4.1** Clarifications for SEND

- **5.1** Updated & clarified that TAs are not data standards but rather extensions of the CDISC foundational standards.

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- **5.2** FDA now supports *Diabetic Kidney Disease*, *Ebola*, *Kidney Transplant*, and *Malaria*, and *Rheumatoid Arthritis*

- **8.0 Types of Study Data Validation Rules**

  1. Standards Development Organizations (e.g., CDISC) provide rules that assess conformance to its published standards (See www.CDISC.org).

  2. FDA eCTD Technical Rejection Criteria for Study Data that assess conformance to the standards listed in the FDA Data Standards Catalog (See above).

  3. FDA Business and Validator rules to assess that the data support regulatory review and analysis.

- **8.3.1 & 8.3.2** Added paragraphs on SEND

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Selected KEY Points

- **2.1:** SDSP should be located in the eCTD M1,Section 1.13.9 (General Investigational Plan)

- **4.1.1.2:** Each submitted SDTM dataset should have its contents described with complete metadata in the **define.xml**. Not PDF!

- **4.1.1.3:** ts.xpt must be in *legacy studies* that started prior to 12/17/2016.

- FDA has not yet published the 30 day notice date for technical rejection due to non-standardized study data.

For questions please contact the CDER eData Team at: eDATA@fda.hhs.gov