

Update on the Study Data Technical Conformance Guide

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FDA DISCLAIMER

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

REQUIRED

A conceptual image of a road at sunset. The road is paved and has the year '2017' painted on it in large, white, block letters. A white road marker is placed on the road, and a red stamp with the word 'REQUIRED' in white capital letters is placed on top of the marker. The background shows a sunset over a horizon, with the sun low and the sky in shades of orange and blue.


FDA Statute to Require Data Standards



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


**FDASIA 745A(a)
Guidance**

How FDA will
implement
individual Binding
Guidances




eStudy Guidance

Binding Guidance— Requires
that studies are compliant
with the standards outlined
in the FDA Data Standards
Catalog



eCTD Guidance

Binding Guidance
requires the
electronic submission
of NDAs, BLAs,
ANDAs, INDs, DMFs in
eCTD Format



**Draft / Proposed
Binding Guidances**

- Promo / Advertising
- Pharm Quality / CMC
- Manuf. Establishments



Study Data Technical Conformance Guide (TCG)

FDA

Tech Conformance Guide

How to submit standardized study data



Version 3.3, March 2017

- 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.

Study Data Technical Conformance Guide (TCG)



- **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