Study Data Standards in eCTD: What You Need to Know About the New Technical Rejection Criteria

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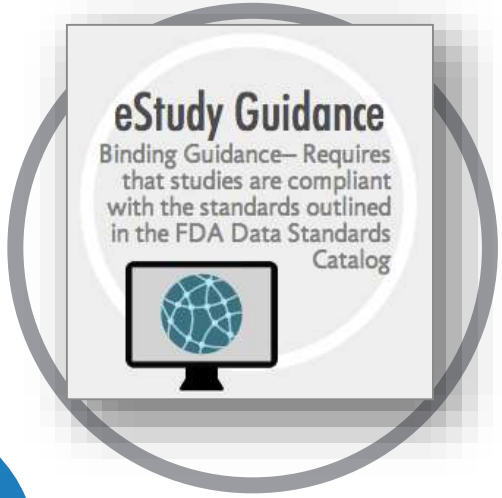
GUIDANCE AND POLICY

STUDY DATA STANDARDS

Study data standards describe a standard way to exchange clinical and nonclinical research data between computer systems.

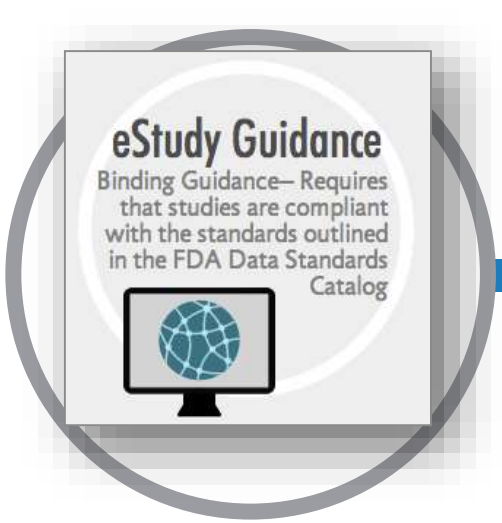


- SDTM (including Therapeutic Areas)
- SEND
- ADaM
- Define-XML

…and more

For the full list of study data standards, see the Data Standards Catalog at www.fda.gov/ForIndustry/DataStandards/StudyDataStandards

When Will Study Data Standards be Required?



Published December 17, 2014

Required for **NDAs, BLAs, ANDAs** **December 17, 2016**

Required for **Commercial INDs** **December 17, 2017**

Compliance ✓

Studies starting **AFTER required date** MUST use the standards in the Data Standards Catalog **(NDAs, ANDAs, BLAs)**

What Study Data Standards Will be Required?

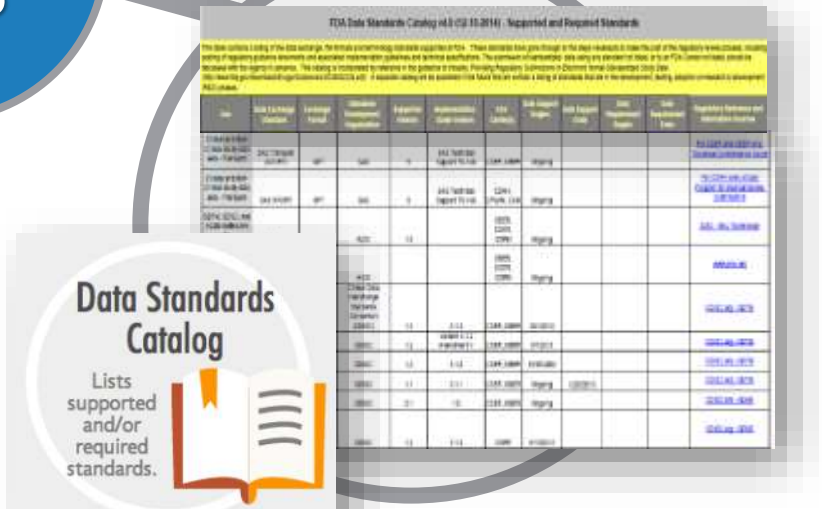
eStudy Guidance

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

December 2016

FDA Data Standards Catalog

Study Data…SDTM, ADaM, SEND, Define.XML

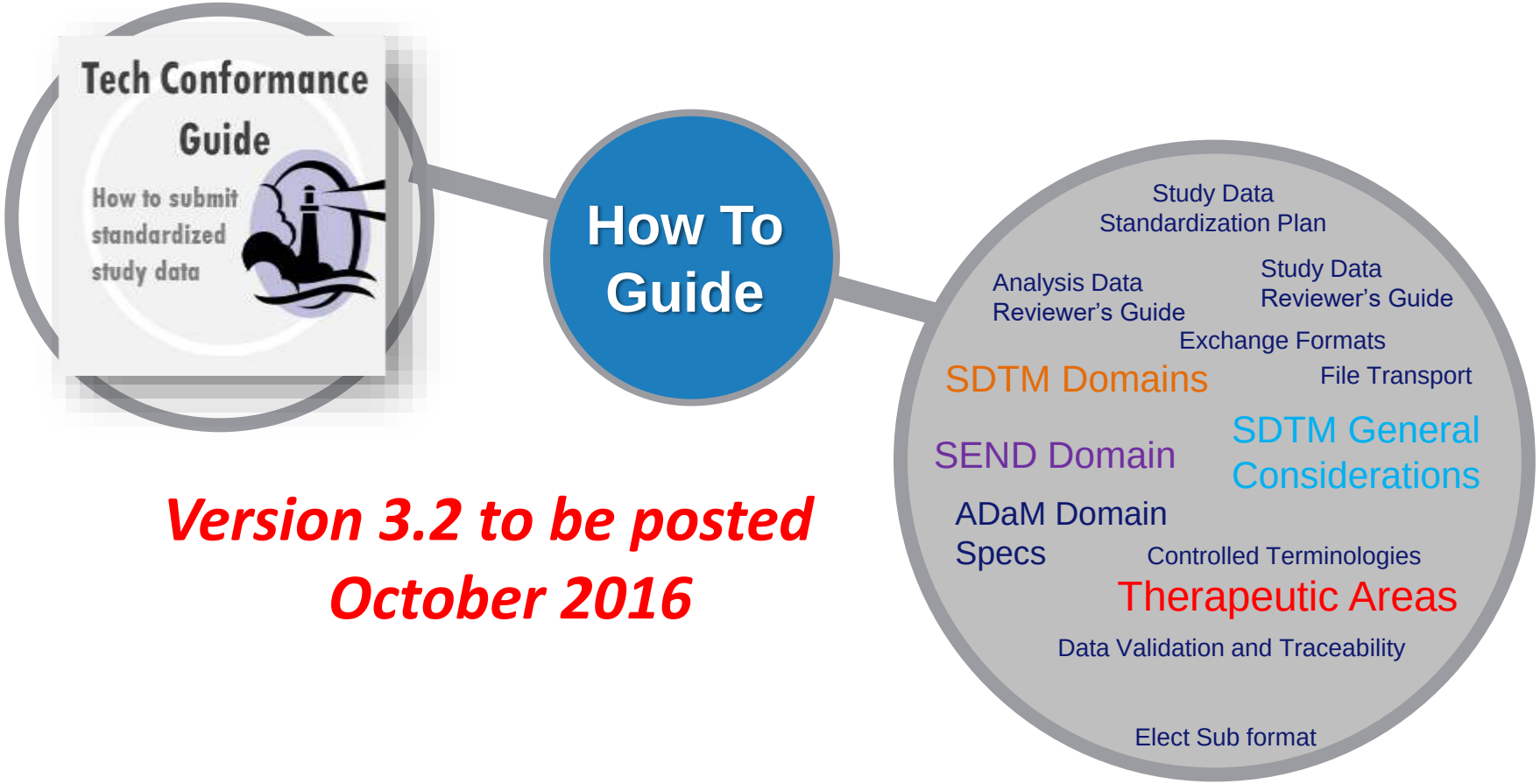


Data Standards Catalog

Lists supported and/or required standards.

For the full list of study data standards, see the Data Standards Catalog at www.fda.gov/ForIndustry/DataStandards/StudyDataStandards

How Will Data Study Standards be Required?



Version 3.2 to be posted October 2016

http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM384744.pdf

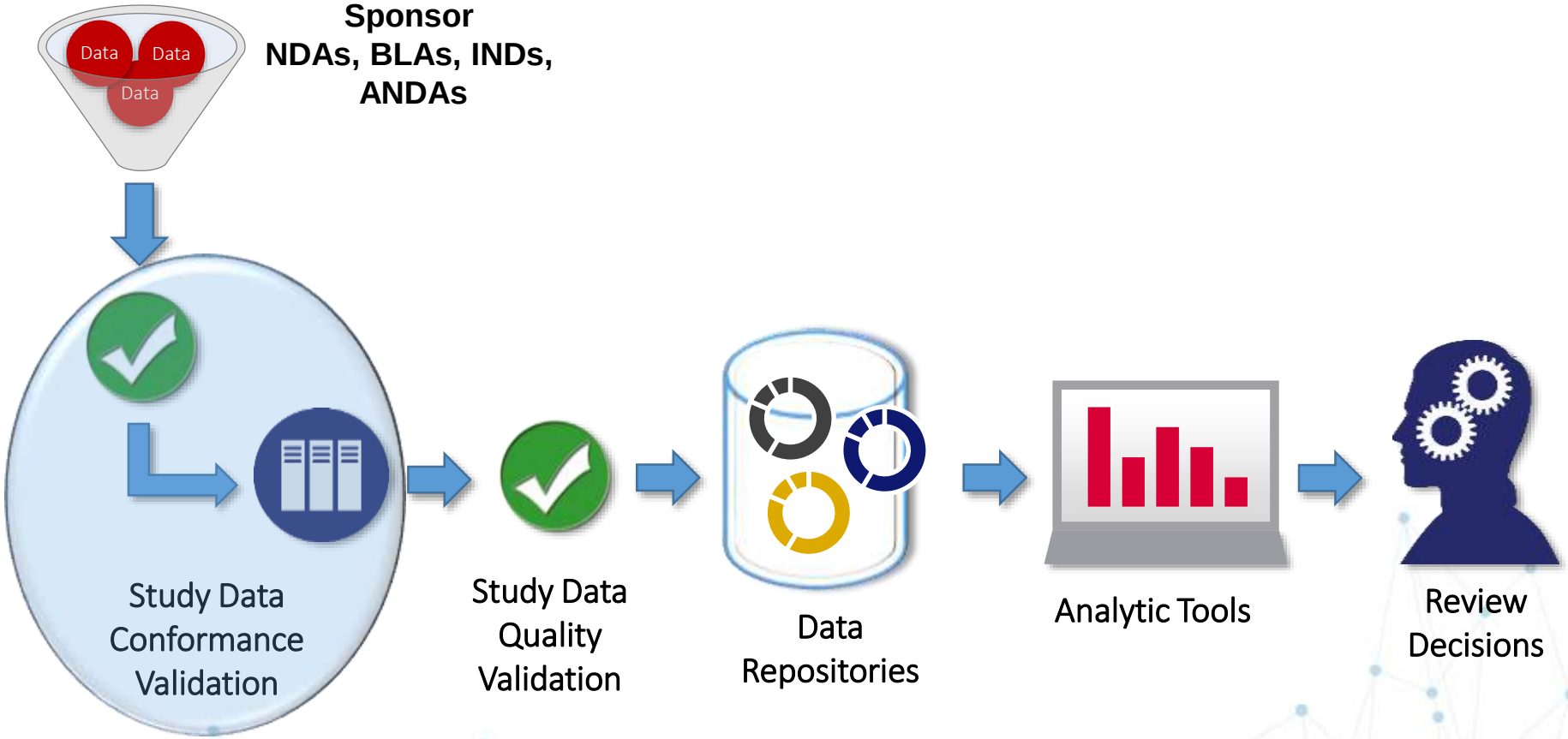
Can FDA RTF / RTR Submissions for Non-conformance?

eStudy Guidance requires the electronic submission of NDAs, BLAs, ANDAs, INDs in standardized format

BUT FDA DOES NOT WISH TO RTF / RTR FOR NON-CONFORMANCE… *SO*

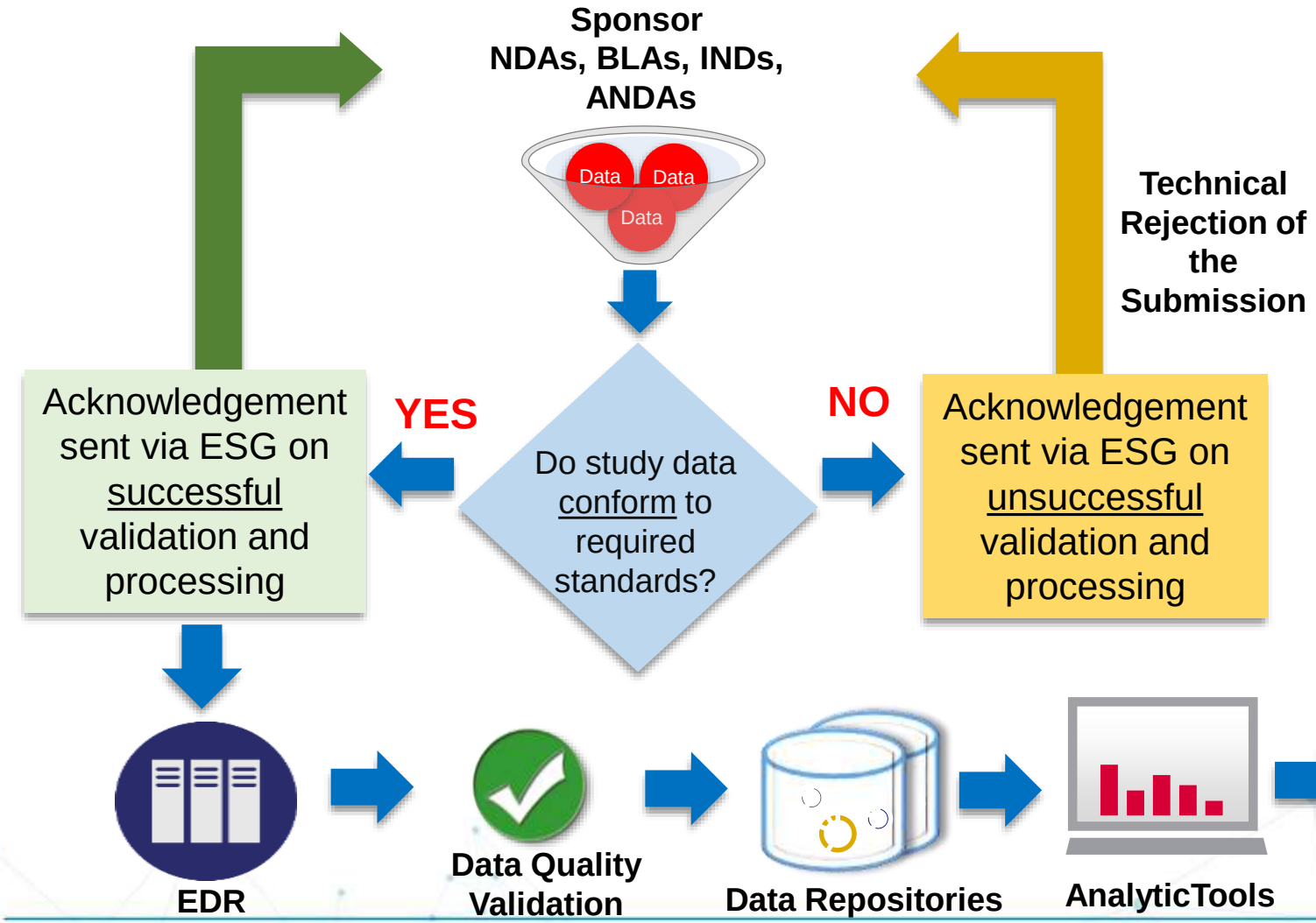
FDA
will implement
a process for rejection of
submissions that do not
conform to the required
study data standards

Study Data Standards Validation



Conformance Validation…

How will it work?



eCTD Data Validation Criteria and Severity

High	Demographic dataset (DM) and the define.xml must be submitted in Module 4 for nonclinical data; DM dataset, the Subject level analysis dataset (ADSL) and define.xml must be submitted in Module 5 for clinical data
High	Trial Summary (TS) dataset must be presented for each study in Module 4 or 5
Medium	Correct STF file-tags must be used for all standardized datasets • Data-tabulations-dataset-sdtm • Data-tabulations-dataset-send • Analysis-dataset-adam
Medium	For each study, no more than one dataset of the same type should be submitted as new

SO WHICH IS BETTER?

What are the Current Metrics?

Standardized Study Data

76%
of **study data** submitted within all NDA submissions are in standardized SDTM format**

85%
of **study data** submitted in support of NEW NDAs are in standardized SDTM format**

*FY2016
Source: Office of Business Informatics, CDER - **One or more explicitly stated SDTM studies (or study data structure that resembled SDTM).

TECHNICAL CONFORMANCE GUIDE

TRIAL DESIGN DOMAIN

In Study Data Technical Conformance Guide (TCG)

- **4.1.1.3 SDTM Domain Specifications**

- **Trial Design Model (TDM) - All TDM datasets should be included in the submissions and Trial Summary (TS) dataset will be used to determine the time of study start. TS should include TSPARMCD = SSTDTC and TSVAL="yyyy-mm-dd" (ISO8601)**

TRIAL DESIGN DOMAIN

❖ 4.1.3.3 SEND Domain Specification

- **Trial Design (TDM) – All TD datastes should be included in the submissions and TS dataset will be used to determine the time of study start. TS should include TSPARMCD = STSTDTC and TSVAL="yyyy-mm-dd" (ISO8601)**

TRIAL DESIGN DOMAIN

❖ **Legacy data submissions**

- **TS should be submitted and should include TSPARMCD = SSTDTC or STSTDTC(non-clinical data) and TSVAL="yyyy-mm-dd" (ISO8601)**

TRIAL DESIGN DOMAIN

❖**Example**

- **TS for clinical data**

	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
1	UX003-CL201	TS	1		SSTDTC	Study Start Date	2013-11-18			ISO 8601	

- **TS for non-clinical data**

	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
1	UX003-CL201	TS	1		STSTDTC	Study Start Date	2017-01-03			ISO 8601	

SUMMARY & KEY POINTS

- **Starting 12/18/2016: ** All ** clinical and nonclinical trials, regardless of study type, must use the standards in the FDA Data Catalog**
- **FDA will validate submissions upon receipt and will assess conformance to required study data standards**
- **A technical rejection notice will be sent if the submission fails validation**
- **Technical Conformance Guide…. is key document to help you get it right**
- **FDA will provide 30 days' notice prior to the validation criteria being effective**

INFORMATION FOR INDUSTRY

Click for:

- Data Standards Catalog
- Study Data Technical Conformance Guide
- PDF of today's slides
- Contact the CDER eData Team for assistance related to study data and standards:

edata@fda.hhs.gov

Questions about material presented during this webinar?
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