

# FDA Study Data Standards

Update

Nov-2014 – Sep-2015

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21<sup>st</sup> German CDISC UG Meeting

# FDA Study Data Standards - Website

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## For Industry

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### Important Notices:

- [Data Standards Catalog v4.3](#) (September 3, 2015)
- [Study Data Technical Conformance Guide v2.2](#) (June 12, 2015)
- [eStability Position Statement](#) (May 28, 2015)
- [DS-XML Pilot Final Report](#) (April 20, 2015)
- [FDA Specific SEND Validation Rules v2.1](#) (Feb 13, 2015)
- [Guidance for Industry - Providing Regulatory Submissions in Electronic Format — Standardized Study Data](#) (Dec 17, 2014)
- [FDA Specific SDTM Validation Rules v1.0](#) (Nov 18, 2014)

[CBER/CDER Study Data Standards for Regulatory Submissions Position Statement](#)

[CDER/CDER Position on Use of SI Units for Lab Tests](#)

[Statistical Software Clarifying Statement](#)

## FDA Study Data Standards – Important Notices I

- Data Standards Catalog v4.3 (03-Sep-2015)

Typo: der Link verweist auf v4.4 (17-Aug-2015)

### Updates:

v4.0: Erweiterter Support für Terminologien SRS/UNII, NDF-RT

v4.1: Terminologie WHO-DD wurde ergänzt

v4.2: Terminologie LOINC wurde ergänzt

v4.3: „Date Requirement Begins“ hinzugefügt für eCTD Data Exchange Standard (05-Mai-2017 bzw. 2018)

v4.4: FDA Support von SDTM v1.4 / IG v3.2 wurde ergänzt; Einfügen eines „Date Requirement Begins“ für LOINC (15-März-2018 bzw. 2019)

weitere Änderungen/Details – s. Change History

## FDA Study Data Standards – Important Notices II

- Study Data Technical Conformance Guide v2.2  
(12-Juni-2015)

### Updates:

- 2.1 Study Data Standardization Plan: Hinweis auf Beispiel + Link
  - 3.3.2: Splitten von Domains soll in SDRG/ADRG beschrieben werden
  - 4.1.1.3 SDTM Domain Specifications: EC + DD ergänzt
  - 4.1.4.5 Data Definition Files: neu formuliert, define.pdf / printable define.xml
  - 4.1.2 Analysis Data Model: Updates bei Timing und Core Variables
  - 5 Therapeutic Area Standards: 5.1 General ist neu (Hinweis, dass einige SDTM Domains in Verbindung mit verschiedenen TA User Guides noch nicht getestet und akzeptiert sind)
  - 6.7 Laboratory Data / LOINC: neu hinzugefügt
  - 7 Electronic Submission Format: Hinweis ergänzt, dass kein zusätzliches define.xml für splitted domains nötig ist
- + Änderungen in Formulierungen, Ergänzungen im Glossary, ...

## FDA Study Data Standards – Important Notices III

- eStability Position Statement (28-Mai-2015)
- DS-XML Pilot Final Report (20-April-2015)
- FDA Specific SEND Validation Rules v2.1 (13-Februar-2015)
- **Guidance for Industry – Providing Regulatory Submissions in Electronic Format – Standardized Study Data (17-Dezember-2014)**

Dieser Guide beschreibt die geplante Implementation der Anforderungen für eSubmissions von standardisierten Studiendaten durch die FDA.

## FDA Study Data Standards – Important Notices IV

- FDA Specific SDTM Validation Rules v1.0  
(18-November-2014)

FDA spezifische „Validation Rules for SDTM Formatted Studies“ stehen als Excel File zur Verfügung. Sie beinhalten eine Beschreibung der Validierungsregeln.

## Federal Register

<https://www.federalregister.gov/>



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NOAA's National Ocean Service

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### Electronic Study Data Submission; Data Standards ; Support for Study Data Tabulation Model Implementation Guide Version 3.2



... Exceptions) of Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model Implementation ... Electronic Format— Standardized Study Data (eStudy Data ) posted on FDA's Study Data Standards Resources ... implement the FDA-supported study data standards should contact and work with ...

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## Federal Register – Search Results I

- **Electronic Study Data Submission; Data Standards; Support for Study Data Tabulation Model Implementation Guide Version 3.2 (18-Aug-2015)**

Der SDTM IG 3.2 wird jetzt von der FDA akzeptiert (required ab 15-Mar-2018).

Ausnahmen:

Domains DD und EC sowie die TA standards, die in SDTM IG 3.2 enthalten sind.

**Diese Notice erscheint mittlerweile nicht mehr; diese Info ist jetzt im Data Standards Catalog v4.4 eingefügt.**

## Federal Register – Search Results II

- **Electronic Study Data Submission; Data Standards; Study Data Standardization Plan Recommendations (18-May-2015)**

Es gibt einen Draft mit Empfehlungen für die Erstellung eines Study Data Standardization Plans. Dieser Draft ist im Study Data Technical Conformance Guide enthalten (Kommentare dazu waren bis zum 02-Jul-2015 möglich).

- **Electronic Study Data Submission; Data Standards; Support for the Logical Observation Identifiers Names and Codes (14-May-2015)**

Die FDA unterstützt LOINC codes in den Labordaten, die im Rahmen von Submissions an CDER/CBER geschickt werden.

**Diese Info ist im Data Standards Catalog v4.4 eingefügt.**

## Federal Register – Search Results III

- **Electronic Study Data Submission; Data Standards; Recommending the Use of the WHO Drug Dictionary (31-Mar-2015)**

Die FDA empfiehlt die Benutzung von WHO-DD.

- **Intent to Review a Study Data Reviewer's Guide Template (23-Jul-2015)**

In einer PhUSE Arbeitsgruppe wurde ein SDRG Template erstellt. In Zusammenarbeit mit der PhUSE hat die FDA Kommentare dazu gesammelt (abgeschlossen)