

# Steps & Slides

Poster title: Steps & Slides of Implementing Global Standards

References by square number:

- 5) CDISC website, for SDTM documentation including:
  - a) Study Data Tabulation model, Version 1.4
  - c) Study Data Tabulation Model Implementation Guide: Human Clinical Trials Versions 3.1.1, 3.1.2, 3.2  
[www.cdisc.org/sdtm](http://www.cdisc.org/sdtm)
- 9) U.S. Department of Health and Human Services Food and Drug Administration, Study Data Standards Resources.  
<http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm>
- 11) FDA Guidance for Industry - Providing Regulatory Submissions in Electronic Format — Standardized Study Data (Dec 17, 2014)  
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM292334.pdf>
- 14) FDA Data Standards Catalog (Version 4.0; (2014-12-10) – Supported and Required Standards  
<http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM340684.xls>
- 20) Analysis Data Reviewer's Guide (ADRG), Version 1.1, (2015-01-26)  
[http://www.phusewiki.org/wiki/index.php?title=Analysis\\_Data\\_Reviewer%27s\\_Guide](http://www.phusewiki.org/wiki/index.php?title=Analysis_Data_Reviewer%27s_Guide)
- 21) OpenCDISC Open Source Validator for CDISC  
<http://www.opencdisc.org/>
- 25) Study Data Reviewers Guide (SDRG), Version 1.2, (2015-01-26)  
<http://www.phusewiki.org/wiki/index.php?title=SDRG>
- 27) National Cancer Institute at the National Institutes of Health, Cancer Topics, CDISC Terminology  
<http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>
- 28) FDA Study Data Technical Conformance Guide, Version 2.2 (June 2015)  
<http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM384744.pdf>
- 29) CDISC Analysis Data Model Version 2.1, Dec. 17, 2009  
CDISC Analysis Data Model (ADaM) Implementation Guide Version 1.0, Dec. 17, 2009  
<http://www.cdisc.org/adam>
- 32) PhUSE Standard Script Index  
[http://www.phusewiki.org/wiki/index.php?title=Standard\\_Script\\_Index](http://www.phusewiki.org/wiki/index.php?title=Standard_Script_Index)
- 35) CDISC Define-XML Specification, Version 2.0, March 5, 2013  
<http://www.cdisc.org/define-xml>