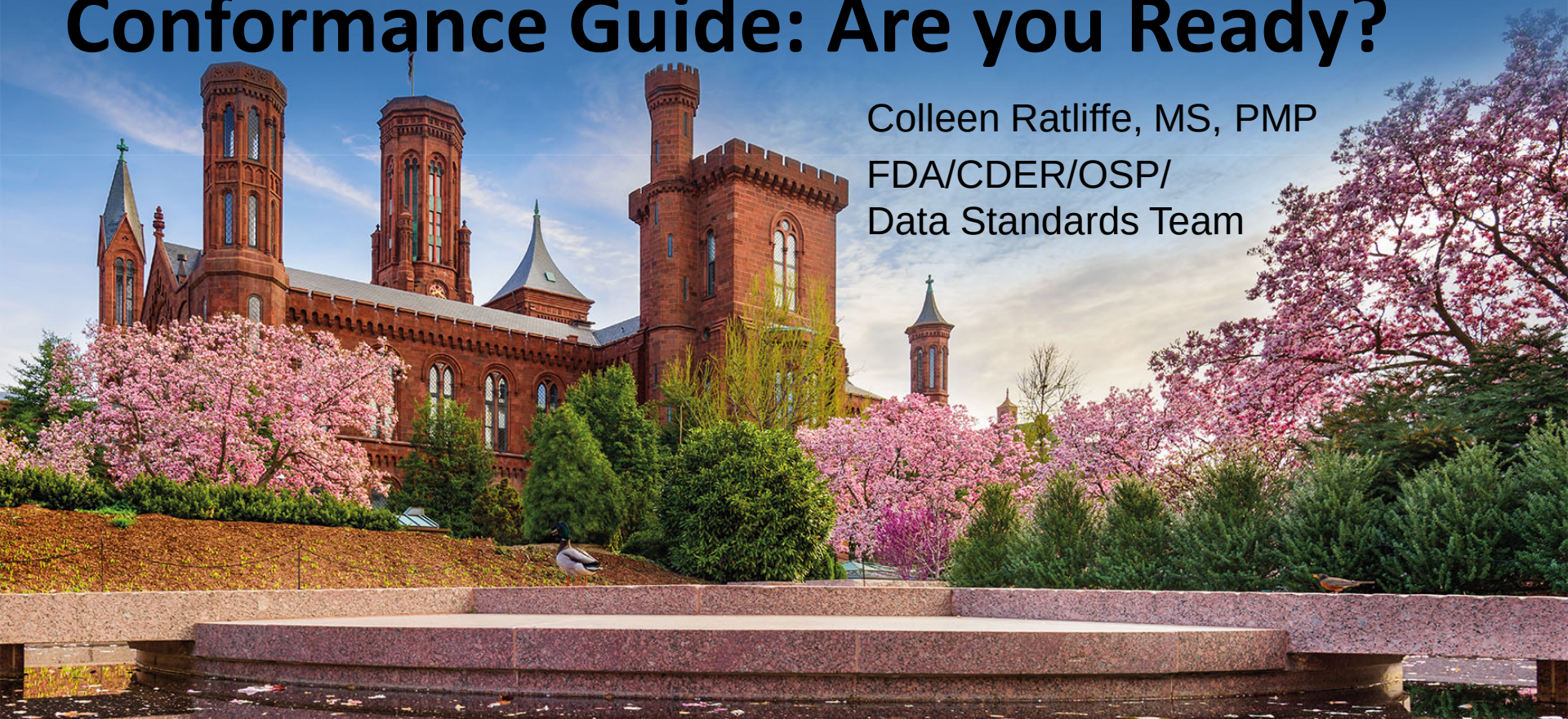
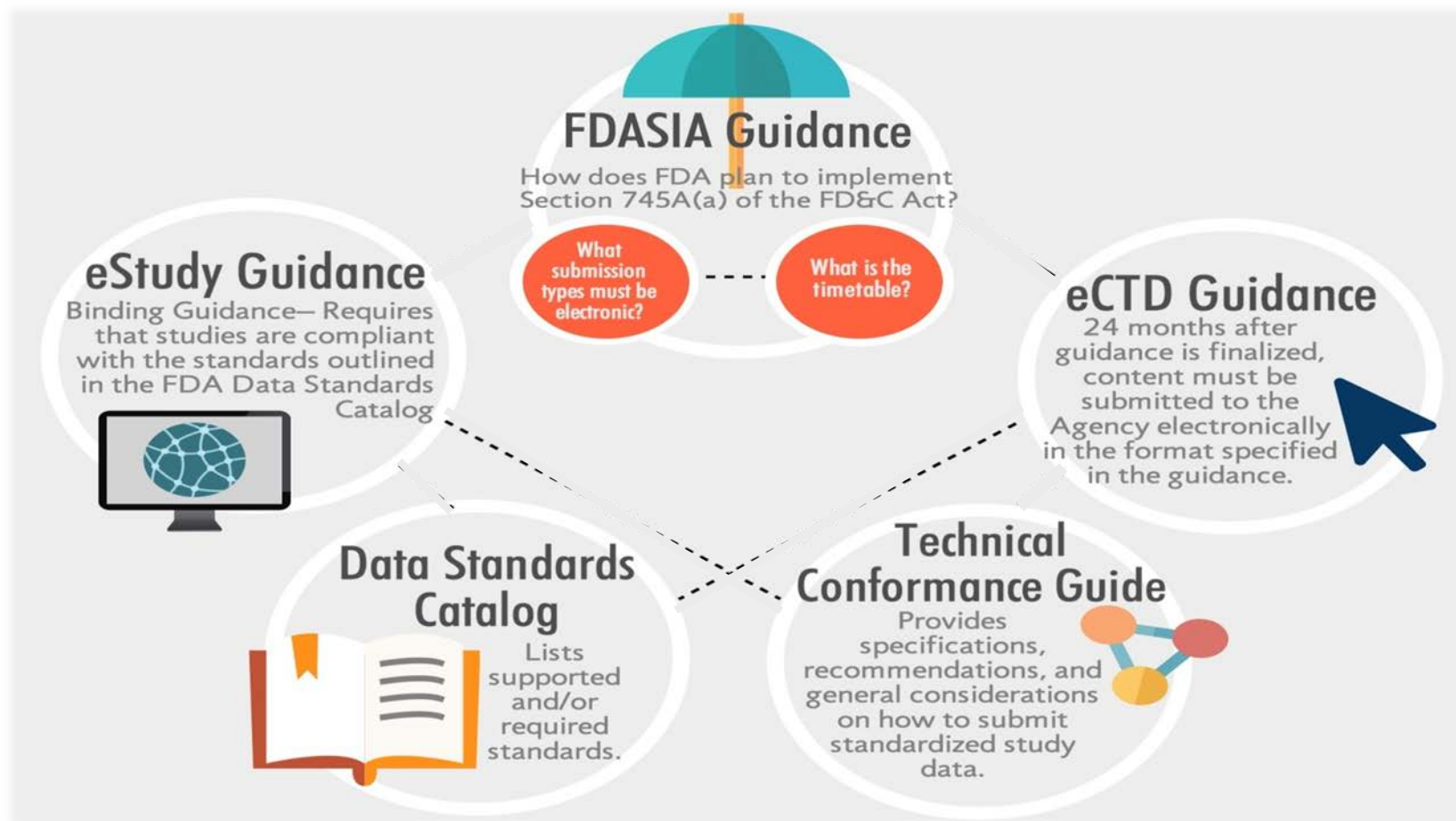


eStudy Guidance and Technical Conformance Guide: Are you Ready?

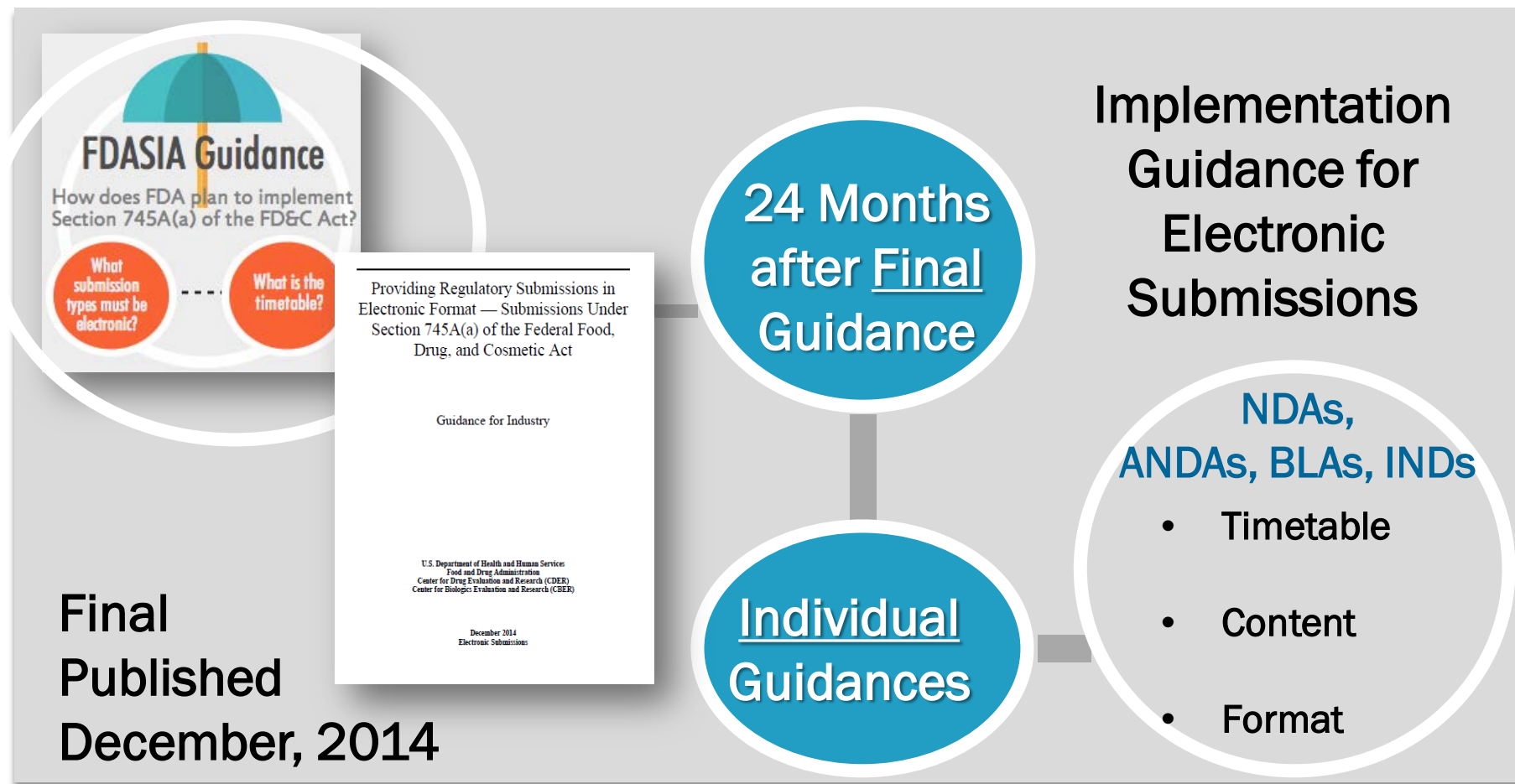
Colleen Ratliffe, MS, PMP
FDA/CDER/OSP/
Data Standards Team



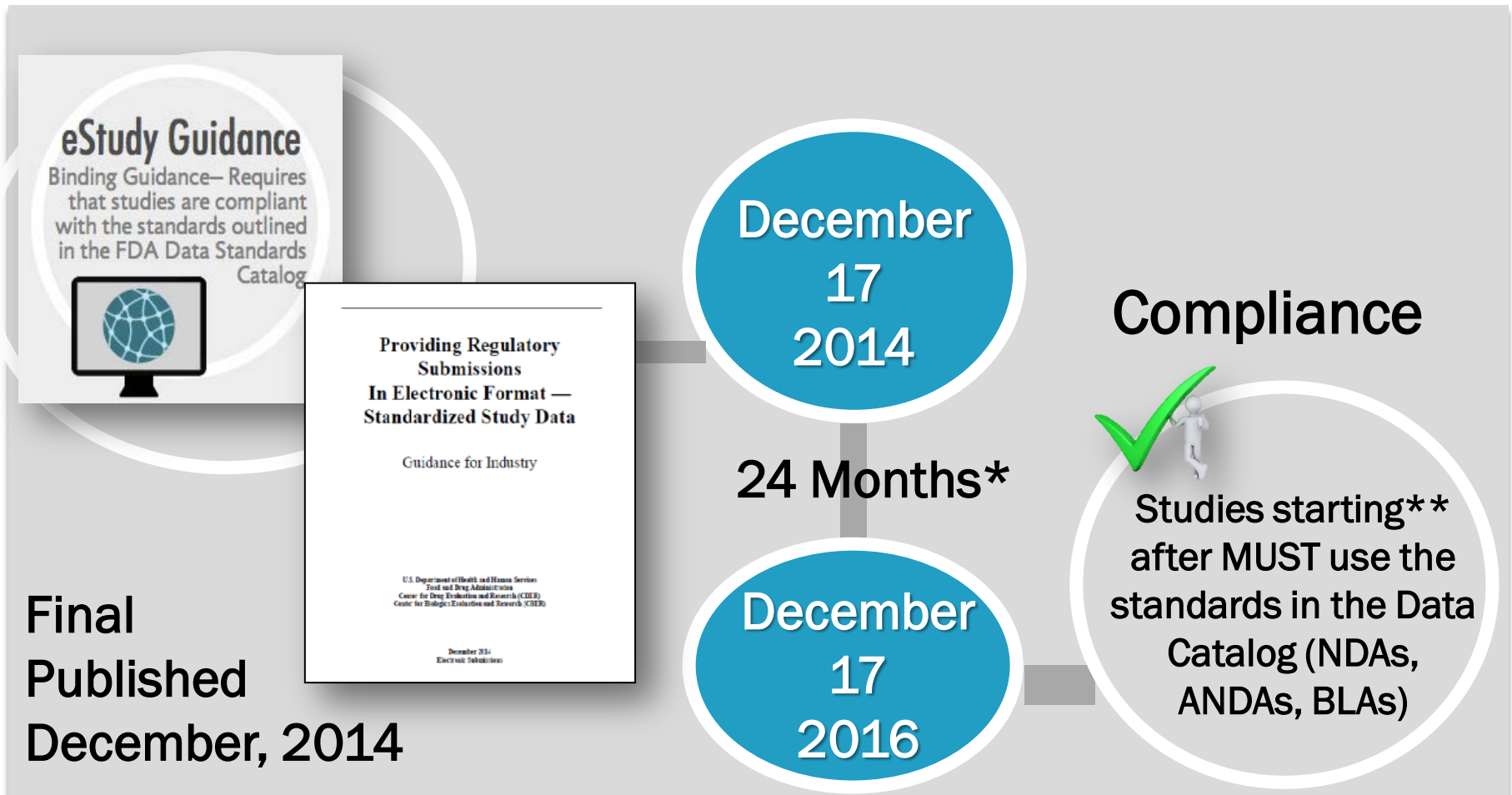
eStudy Data Framework



How will eSubmissions be Implemented?



When will Study Data Standards be Required?



*36 months for INDs

**Study Start Date in the SDTM Trial Summary Domain (TSPARMCD = SSTDTC).



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

Providing Regulatory Submissions In Electronic Format — Standardized Study Data

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

December 2014
Electronic Submissions

December 2016

Data Standards Catalog

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

Data Standards Catalog

Lists supported and/or required standards.



FDA Data Standards Catalog v4.0 (12-10-2016) - Supported and Required Standards

This book contains a listing of the data standards, file formats and terminology standards supported at FDA. These standards have gone through an FDA review process to make the list of the regulatory review process, including listing of regulatory guidance documents and available implementation guidance and service questions. The submission of standards data only are standard for most, and in FDA Center for most, and are associated with the agency's review process. This listing is intended to inform the public of the standards in use, including Agency submission of standards data, and to inform the public of the standards in use, including Agency submission of standards data, and to inform the public of the standards in use, including Agency submission of standards data.

ID#	File Extension	Standard Name	Standard Version	Standard Format	Standard Category	File Category	File Format	File Type	File Subtype	File Description	File Location
101	SDTM	SDTM	1.0	1.0	SDTM	SDTM	SDTM	SDTM	SDTM	SDTM	SDTM
102	ADaM	ADaM	1.0	1.0	ADaM	ADaM	ADaM	ADaM	ADaM	ADaM	ADaM
103	SEND	SEND	1.0	1.0	SEND	SEND	SEND	SEND	SEND	SEND	SEND
104	Define.XML	Define.XML	1.0	1.0	Define.XML	Define.XML	Define.XML	Define.XML	Define.XML	Define.XML	Define.XML

Final Published December, 2014

**Final
Published
December, 2014**

<http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>

Data Standards Catalog

FDA Data Standards Catalog v4.1 (04-09-2015) - Supported and Required Standards

This table contains a listing of the data exchange, file formats and terminology standards supported at FDA. These standards have gone through all the steps necessary to make this part of the regulatory review process, including posting of regulatory guidance documents and associated implementation guidelines and technical specifications. The submission of standardized data using any standard not listed, or to an FDA Center not listed, should be discussed with the Agency in advance. This catalog is incorporated by reference in the guidance to industry, *Providing Regulatory Submissions in Electronic format-Standardized Study Data* (<http://www.fda.gov/downloads/Drugs/Guidances/UCM292334.pdf>). A separate catalog will be published in the future that will contain a listing of standards that are in the development, testing, adoption or research & development (R&D) phases.

Use	Data Exchange Standard	Exchange Format	Standards Development Organization (SDO)	Supported Version	Implementation Guide Version	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY)	Date Requirement Ends	Regulatory Reference and Information Sources
Clinical and Non-Clinical study data sets - Transport	SAS Transport (XPORT)	XPT	SAS	5	SAS Technical Support TS-140	CDER, CBER	Ongoing		12/17/2016 [1] 12/17/2017 [2]		<u>For CDER and CBER only: Technical Conformance Guide</u>
Clinical and Non-Clinical study data sets - Transport	SAS XPORT	XPT	SAS	5	SAS Technical Support TS-140	CDRH, CFSAN, CVM	Ongoing				<u>For CDRH only: eCopy Program for Medical Device Submissions</u>
SDTM, SEND, and ADaM define.xml file	XML		W3C	1.0		CBER, CDER, CDRH	Ongoing				<u>W3C - XML Technology</u>
Analysis program files	ASCII		ANSI			CBER, CDER, CDRH	Ongoing				<u>www.ansi.org</u>
Clinical study datasets	Study Data Tabulation Model (SDTM)	XPT	Clinical Data Interchange Standards Consortium (CDISC)	1.3	3.1.3	CDER, CBER	12/01/2012		12/17/2016 [1] 12/17/2017 [2]		<u>CDISC.org - SDTM</u>
Clinical study datasets	SDTM	XPT	CDISC	1.2	Version 3.1.2 Amendment 1	CDER, CBER	08/07/2013		12/17/2016 [1] 12/17/2017 [2]		<u>CDISC.org - SDTM</u>
Clinical study datasets	SDTM	XPT	CDISC	1.2	3.1.2	CDER, CBER	10/30/2009		12/17/2016 [1] 12/17/2017 [2]		<u>CDISC.org - SDTM</u>
Clinical study datasets	SDTM	XPT	CDISC	1.1	3.1.1	CDER, CBER	Ongoing	01/28/2015	12/17/2016 [1] 12/17/2017 [2]		<u>CDISC.org - SDTM</u>
Clinical study datasets	Analysis Data Model (ADaM) Standard for Exchange of Nonclinical Data (SEND)	XPT	CDISC	2.1	1.0	CDER, CBER	Ongoing		12/17/2016 [1] 12/17/2017 [2]		<u>CDISC.org - ADaM</u>
Animal study datasets		XPT	CDISC	1.2	3.0	CDER	06/13/2011		12/17/2016 [1] 12/17/2017 [2]		<u>CDISC.org - SEND</u>
Clinical study data definition	Define	XML	CDISC	1.0	N/A	CDER, CBER, CDRH	Ongoing		12/17/2016 [1] 12/17/2017 [2]		<u>CDISC.org - Define-XML</u>
Clinical study data definition	Define	XML	CDISC	2.0	N/A	CDER, CBER, CDRH	08/07/2013		12/17/2016 [1] 12/17/2017 [2]		<u>CDISC.org - Define-XML</u>



How to Submit Standardized Study Data Standards

Tech Conformance Guide

How to submit
standardized
study data

Non-binding
guidance

STUDY DATA TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

This Document is incorporated by reference into the following
Guidance Document(s):

*Guidance for Industry Providing Regulatory Submissions in Electronic
Format - Standardized Study Data*

For questions regarding this technical specifications document, contact CDER at
cdet-studdata@hhs.gov or CDER at cdet.cder@fda.hhs.gov

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

December 2014

December
17
2014

Use it
NOW

TCG supersedes the
Study Data Specs &
Common Issues

<http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>

eStudy Guidance and Technical Conformance Guide:

Are you Ready?



FDA Webpage

<http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm>

CDER OBI eDataTeam

eData@fda.hhs.gov

**The premier community for people
working in the biometric area**



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