ADaM Datasets for Review: An FDA Update

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PhUSE Single Day Event
Chicago, IL
April 30, 2015

Introduction

Common Disclaimer

These presentations reflect the views of the speakers and should not be construed to represent FDA's views or policies

Some Acknowledgements

Regulatory Policy

- Ron Fitzmartin (CDER)

TAUGs

- Boris Brodsky, FDA
- Rhonda Facile and PM team, CDISC
- Nate Freimark, ADaM
- ADaM Volunteers

ADRG

- John Brega, PharmaStat
- Gail Stoner, J&J

Outline

- Introduction (Steve)
- Electronic Submission Requirements (Ben)
- PDUFA V and Therapeutic Area Standards (TAS)
  - TAS Progress and Challenges (Steve)
  - ADaM and Therapeutic Area Standards (Susan)
- PhUSE CSS Optimizing Data Standards Working Group: An ADRG Update (Susan)
- Office of Biostatistics Data Review Committee, and the eData FAQ Team (Weiya)
- FDA/CDER, CDISC and PhUSE (Steve)

Electronic Submission Requirements

Benjamin P. Vali, MS
Office of Biostatistics (OB)

Center for Drug Evaluation and Research (CDER)

Statutory Basis

- Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012

- FDASIA authorized the fifth instance of the Prescription Drug User Fee Act (PDUFA), i.e., PDUFA V

- Section 1136 ('Electronic submission of applications') of FDASIA amended the Federal Food, Drug, and Cosmetic Act (FD&C) to include a new section, i.e., Section 745A

Statutory Basis

- Within this new section, 745A, of the FD&C Act, Congress explicitly authorized FDA to implement statutory electronic submission requirements by specifying the format and timing for such submissions in guidance
  - Unlike our usual 'Guidance for Industry' documents, this guidance is **binding**

- **Section 745A(a)** applies to all drug and biologic submissions
- Section 745A(b) applies to all device submissions

Binding Parent Guidance

- **Providing Regulatory Submissions in Electronic Format – Submissions Under Section 745A(a) for the Federal Food, Drug, and Cosmetic Act**
  - **Guidance finalized on December 17, 2014**

- Establishes the overall requirement for all submissions specified under section 745A(a) to be electronic
  - Describes how FDA interprets and plans to implement (including general timelines) the requirements of section 745A(a)

Binding Parent Guidance

- INDs, NDAs, ANDAs and BLAs all apply
  - Exemptions: Noncommercial INDs, i.e., Investigator INDs and Expanded Access INDs
- Describes the process in which FDA will develop individual binding guidances, each specifying the formats/requirements for a specific type of submission (e.g., a unique guidance for eCTD submissions, a unique guidance for dataset submissions, etc.) and its corresponding timetable for implementation
  - **THESE** are the important guidances
  - Note: Criteria for any waivers will be discussed within these individual submission-specific binding guidance documents

Binding Individual Guidances

- **Providing Regulatory Submissions in Electronic Format – Standardized Study Data**
  - **“eStudy Guidance” finalized on December 17, 2014**

- Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications
  - Finalized guidance is imminent

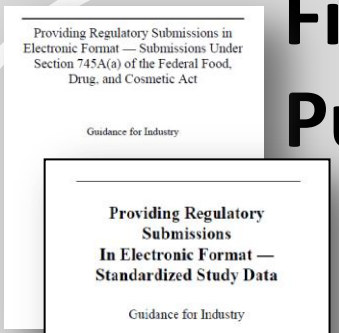
- Binding Guidances still in Development
  - Guidance from the Office of Scientific Investigations (OSI)
  - Guidance from the Office of Prescription Drug Promotion (OPDP)

eStudy Guidance

- Expands on the parent guidance with further detail and implementation of the requirements specifically in regards to study dataset submissions

- Timelines
  - Datasets submitted in NDAs, ANDAs, and BLAs
    - For studies with study start dates on or after 24 Months after the issuance of Final Guidance
      - 24 Months after December 17, 2014 = **December 17, 2016**
  - Datasets submitted to INDs (except Investigator INDs and expanded access INDs)
    - For studies with study start dates on or after 36 Months after the issuance of Final Guidance
      - 36 Months after December 17, 2014 = **December 17, 2017**

When Will Standards Be Required?



Final Published

December 2014

24 Months*

December 2016

Compliance

Studies starting after MUST use the standards within the Data Standards Catalog (NDAs, ANDAs, BLAs)

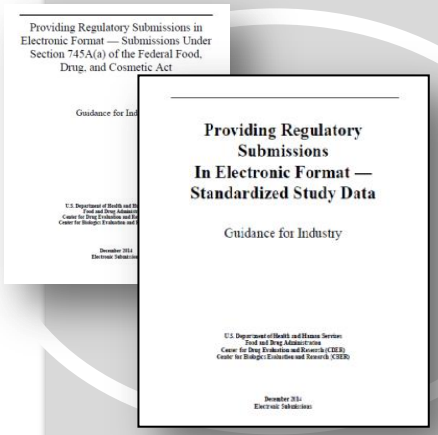
eStudy Guidance
Binding Guidance– Requires that studies are compliant with the standards outlined in the FDA Data Standards Catalog

*36 months for INDs

eStudy Guidance – Standardized Study Data Requirements

- Standards specified within the **Data Standards Catalog**, which is a list of all supported data standards that the Agency can currently process, review, and archive
  - **Exchange Format Standards**
    - Examples from the catalog include SAS XPORT, XML, PDF
  - **Study Data Standards**
    - Examples from the catalog include CDISC SDTM, SEND, and **ADaM**
  - **Controlled Terminology Standards**
    - Examples from the catalog include CDISC Controlled Terminology and MedDRA

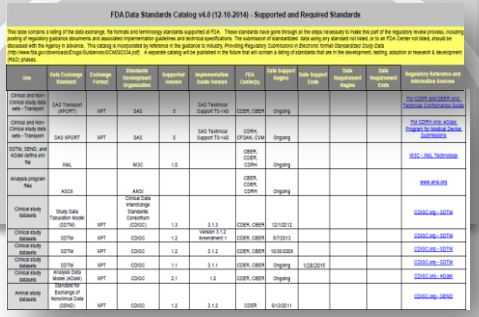
What Standards Will Be Required?



Final Published

December 2016

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



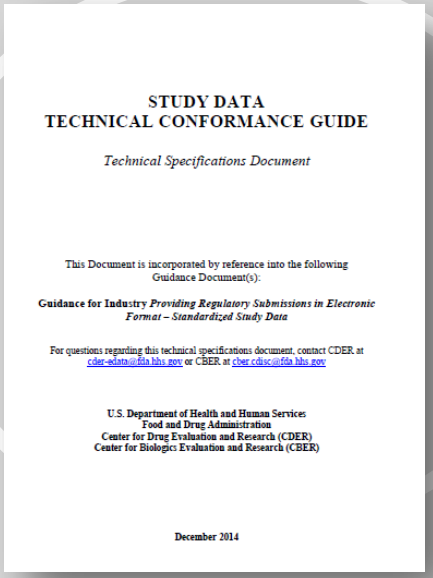
Data Standards Catalog

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

eStudy Guidance – Standardized Study Data Specifications

- The **Study Data Technical Conformance Guide (i.e., Tech Conformance Guide)** is a separate and detailed technical specifications document that supplements the requirements described in the eStudy guidance and is intended to assist sponsors and applicants in the electronic submission of standardized study data
- This document replaces the archaic, and now retired, 'FDA Study Data Specifications' and 'Common Issues' documents in both CDER and CBER
- Note that the **Data Standards Catalog** and **Tech Conformance Guide** are living documents in that each will be updated over time in order to reflect our evolving study data needs

How Standards Will Be Required?


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 cder-edata@fda.hhs.gov or CBER at cber.cdisc@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

Technical Conformance Guide (non-binding)

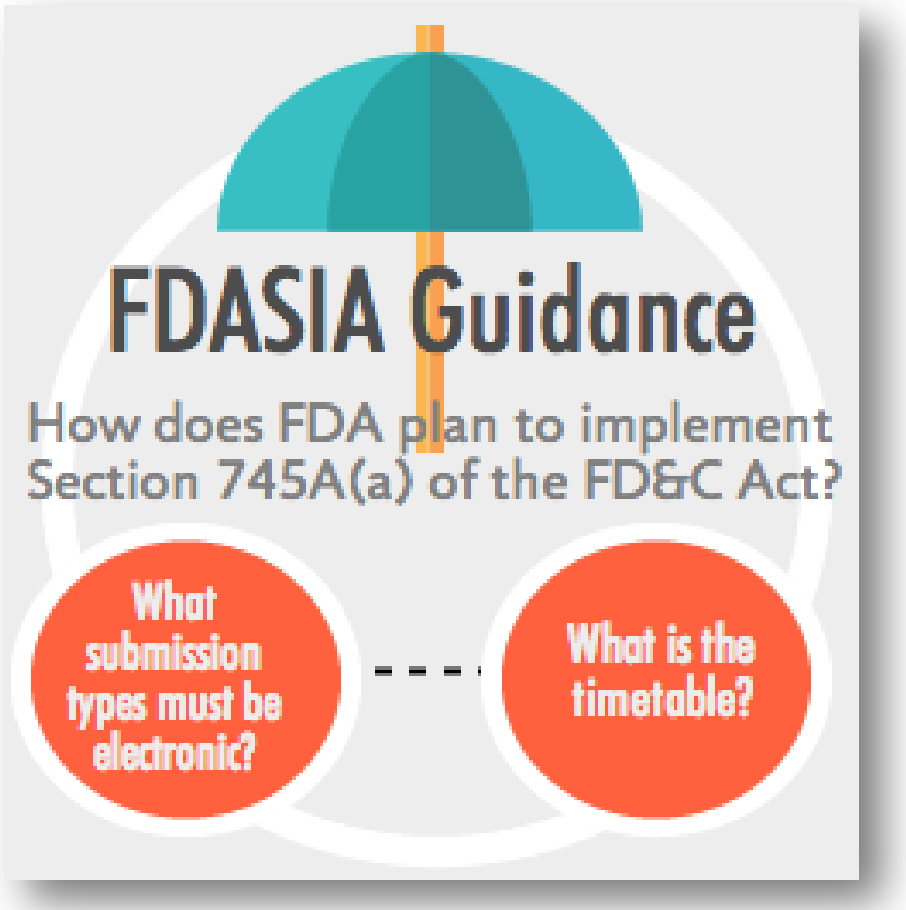
NOW

- Study Data Standardization Plan
- Analysis Data Reviewer's Guide
- Study Data Reviewer's Guide
- SDTM Domain Specs
- Exchange Formats
- File Transport
- SDTM General Considerations
- Efficacy, Safety, Timing Variables
- SEND Domain Specs
- ADaM Domain Specs
- Controlled Terminologies
- Therapeutic Area Standards
- Data Validation & Traceability
- Elect Sub Format

Version 2.1 Published

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

Guidances, Catalog & Tech Guide



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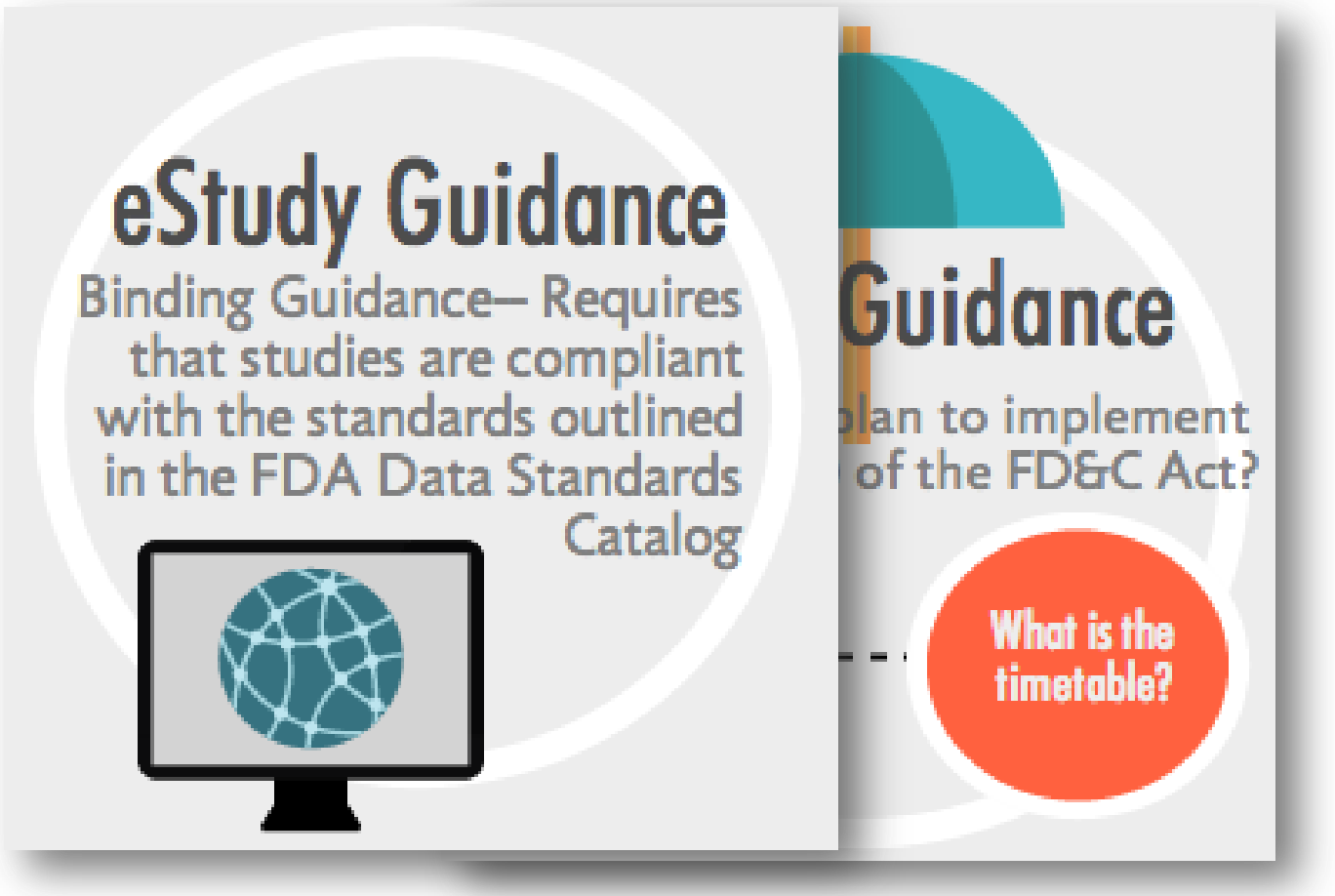
Guidances, Catalog & Tech Guide



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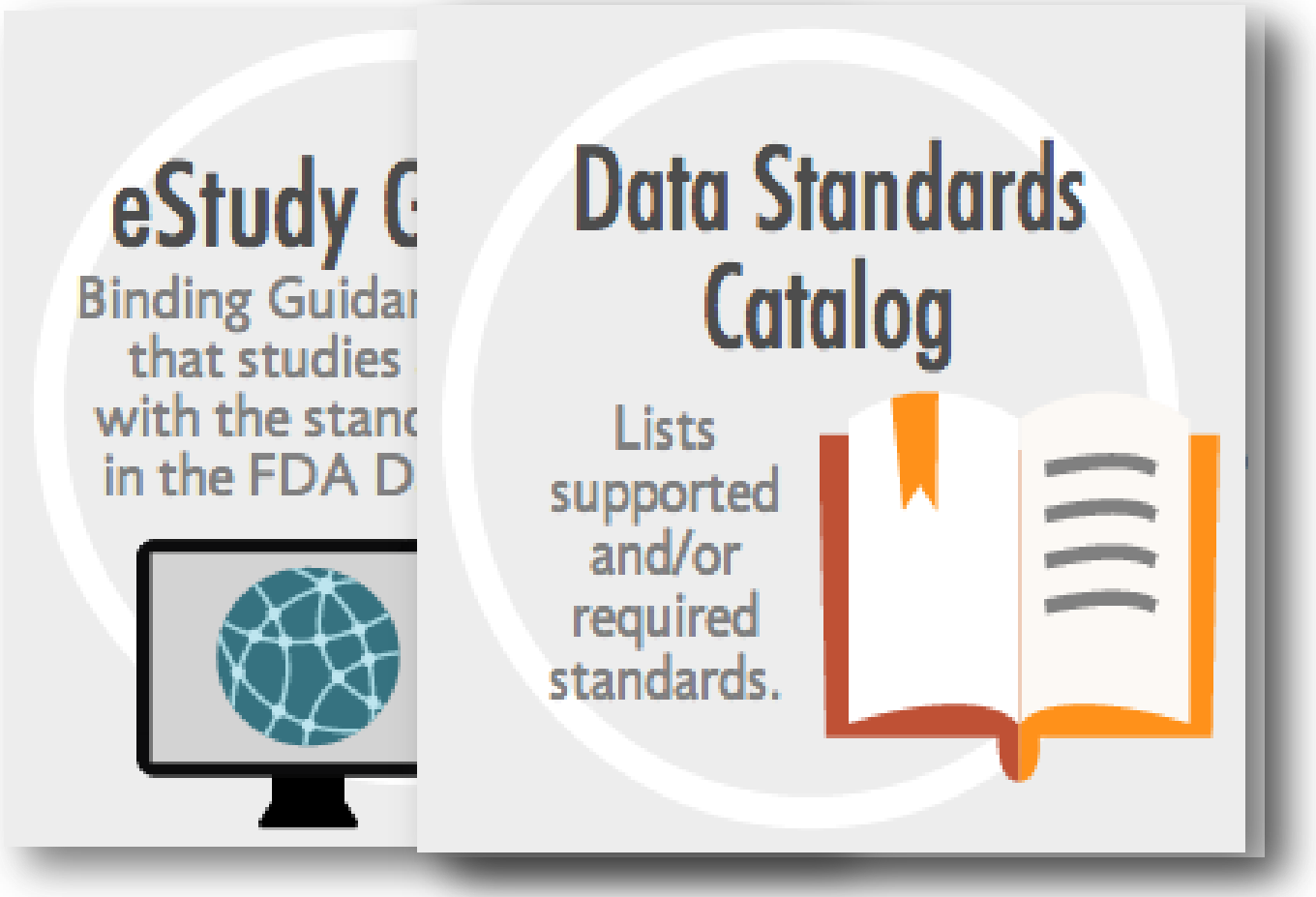
Guidances, Catalog & Tech Guide



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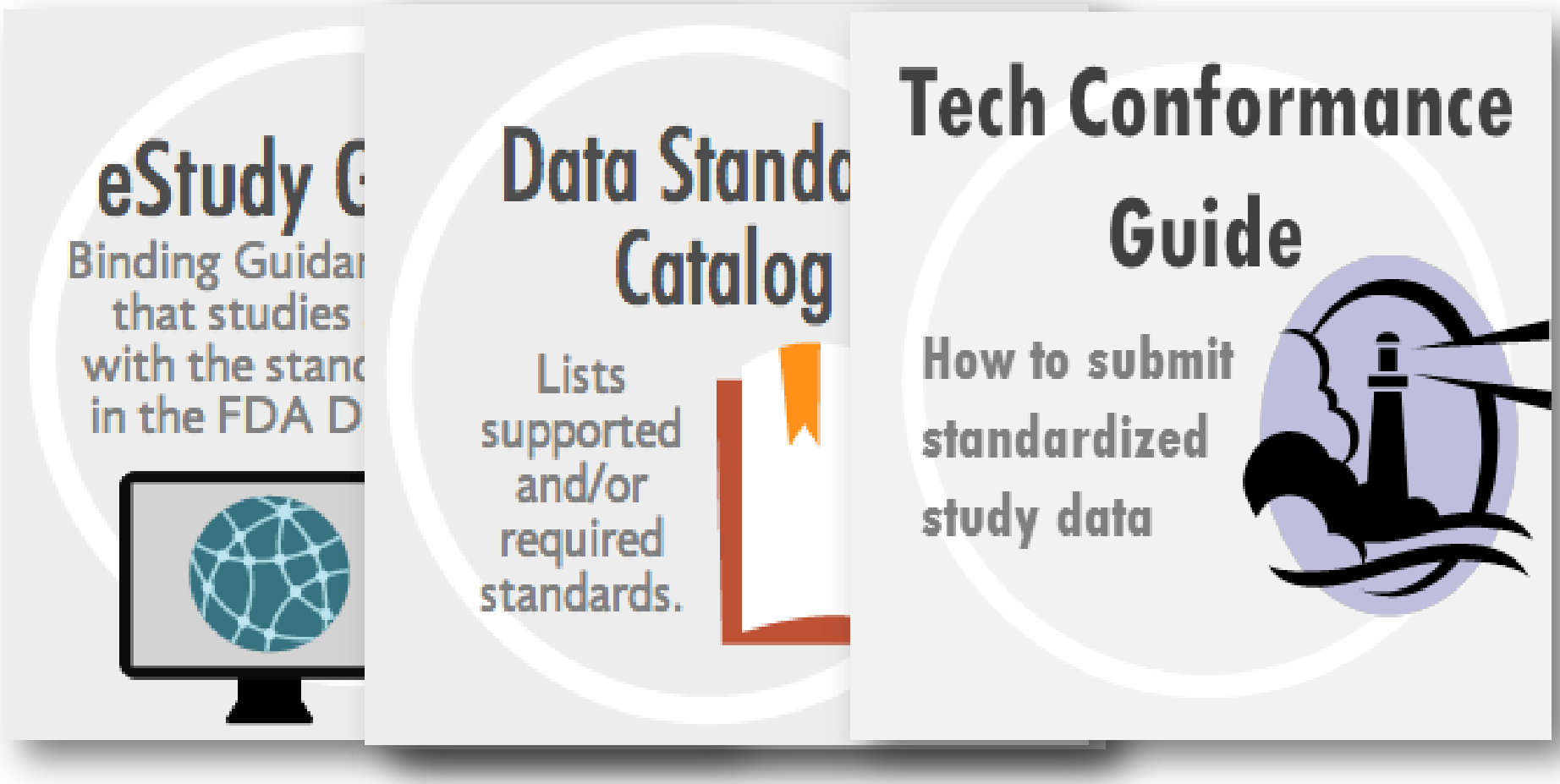
Guidances, Catalog & Tech Guide



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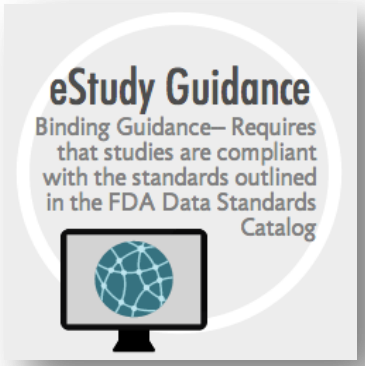
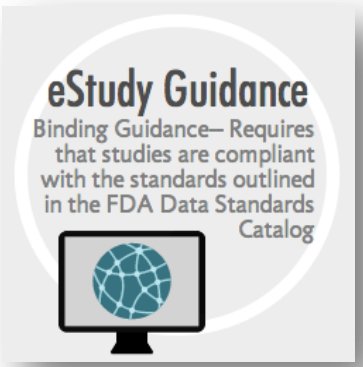


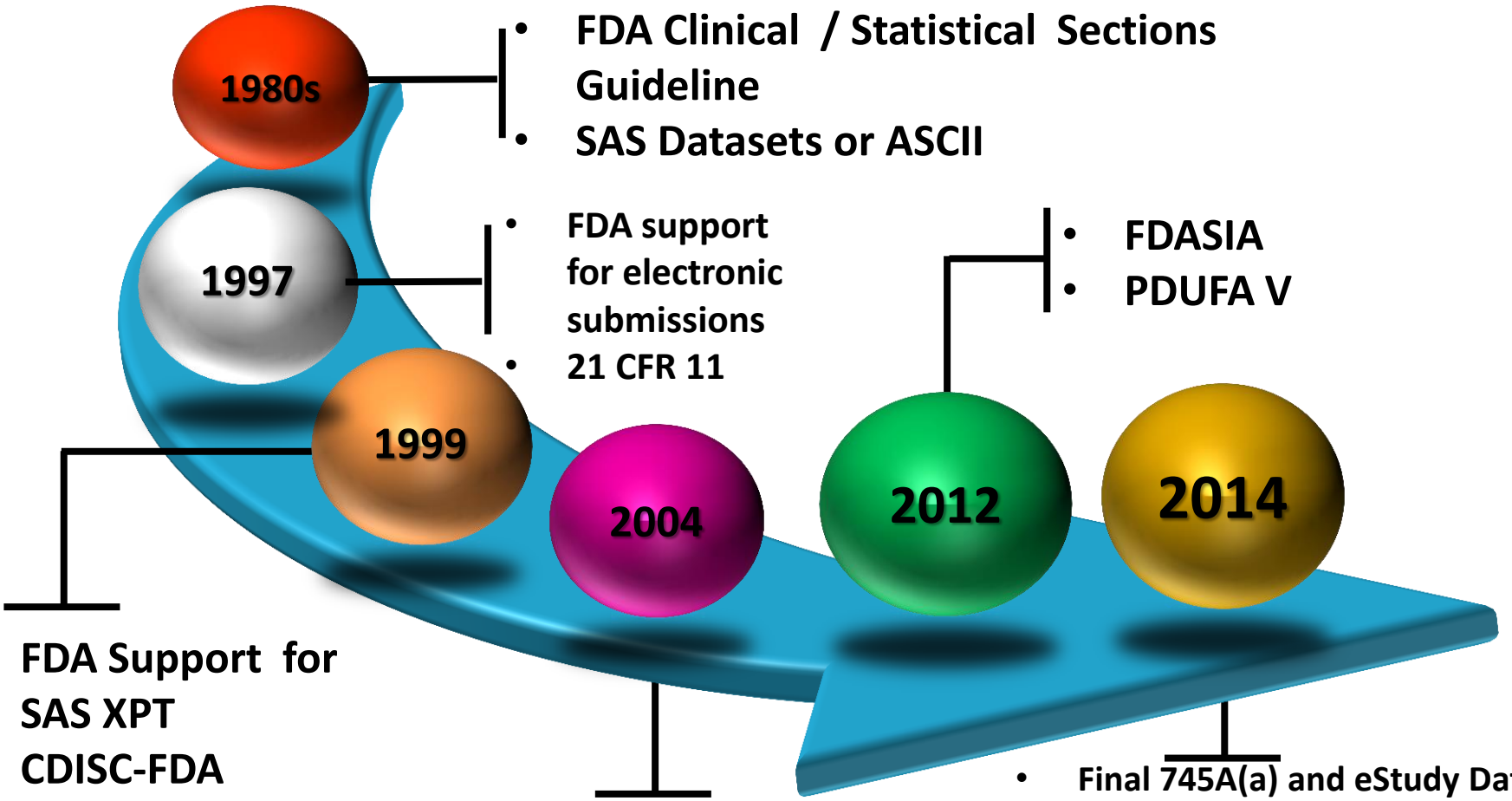
eStudy Guidance – Waivers

Unless it is for a previously supported version of a standard within the Data Standard Catalog, which has been retired/phased out.



eStudy Guidance

Path to Electronic Standardized Data



- FDA Clinical / Statistical Sections Guideline
- SAS Datasets or ASCII

- FDA support for electronic submissions
- 21 CFR 11

- FDASIA
- PDUFA V

- FDA Support for SAS XPT
- CDISC-FDA Collaboration

- FDA Support for CDISC Submissions

- Final 745A(a) and eStudy Data Guidances
- Data Standards Catalog
- Tech Conformance Guide

- Guidance for Industry – Providing Regulatory Submissions in Electronic Format – Submissions Under 745A(a) of the FD&C Act
- Guidance for Industry - Providing Regulatory Submissions in Electronic Format — Standardized Study Data
- Data Standards Catalog v4.1
- Study Data Technical Conformance Guide v2.1

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

PDUFA V and Therapeutic Area Standards (TAS):
Progress and Challenges

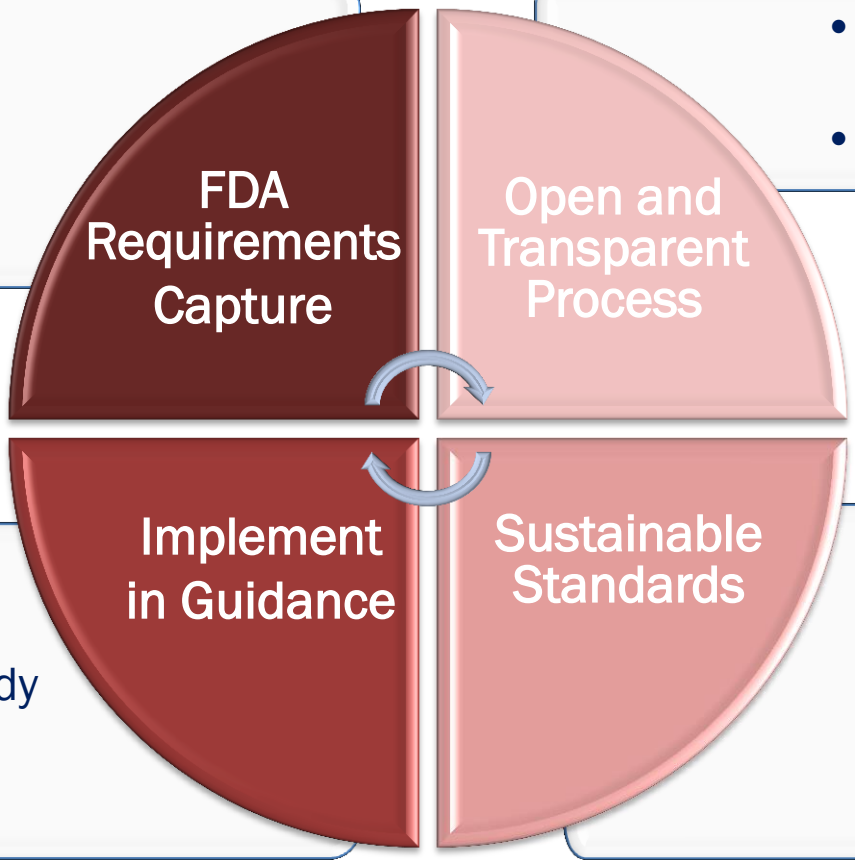
Steve Wilson
Director, Division of Biometrics III
FDA/CDER/OTS/OB

PDUFA V

- **P**rescription **D**rug **U**ser **F**ee **A**ct
- With FDASIA (FDA Safety and Innovations Act)
- From the PDUFA "Performance Goals"
- E. Clinical Terminology Standards: Using a public process that allows for stakeholder input, FDA shall develop standardized clinical data terminology through open standards development organizations (i.e., the Clinical Data Interchange Standards Consortium (CDISC)) with the goal of completing clinical data terminology and detailed implementation guides by FY 2017.

FDA Therapeutic Area Study Data Standards Project

- Identify efficacy endpoints
- Manageable increments

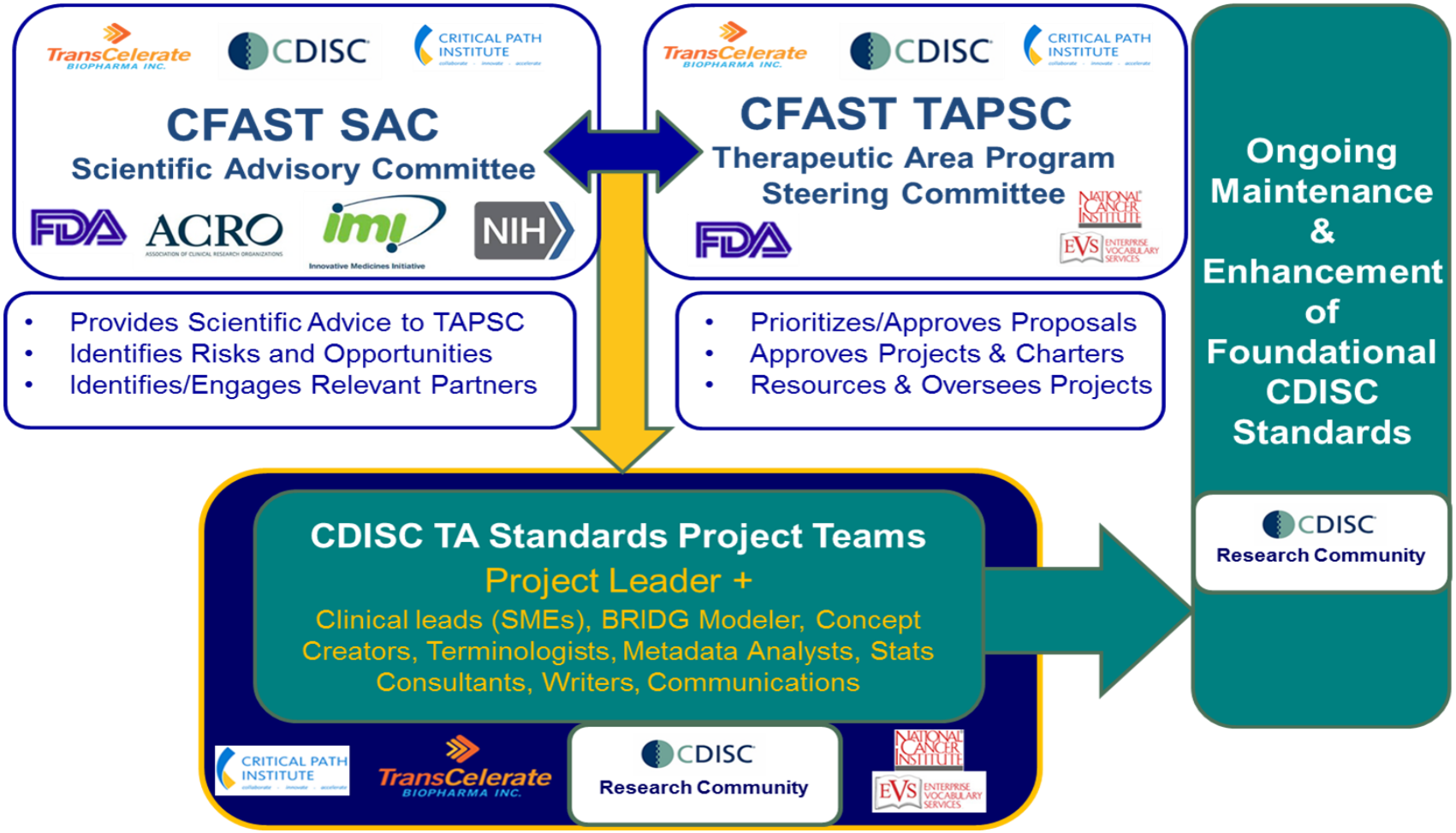


- Collaborate with SDOs & TA Experts
- Ensure Public Comment

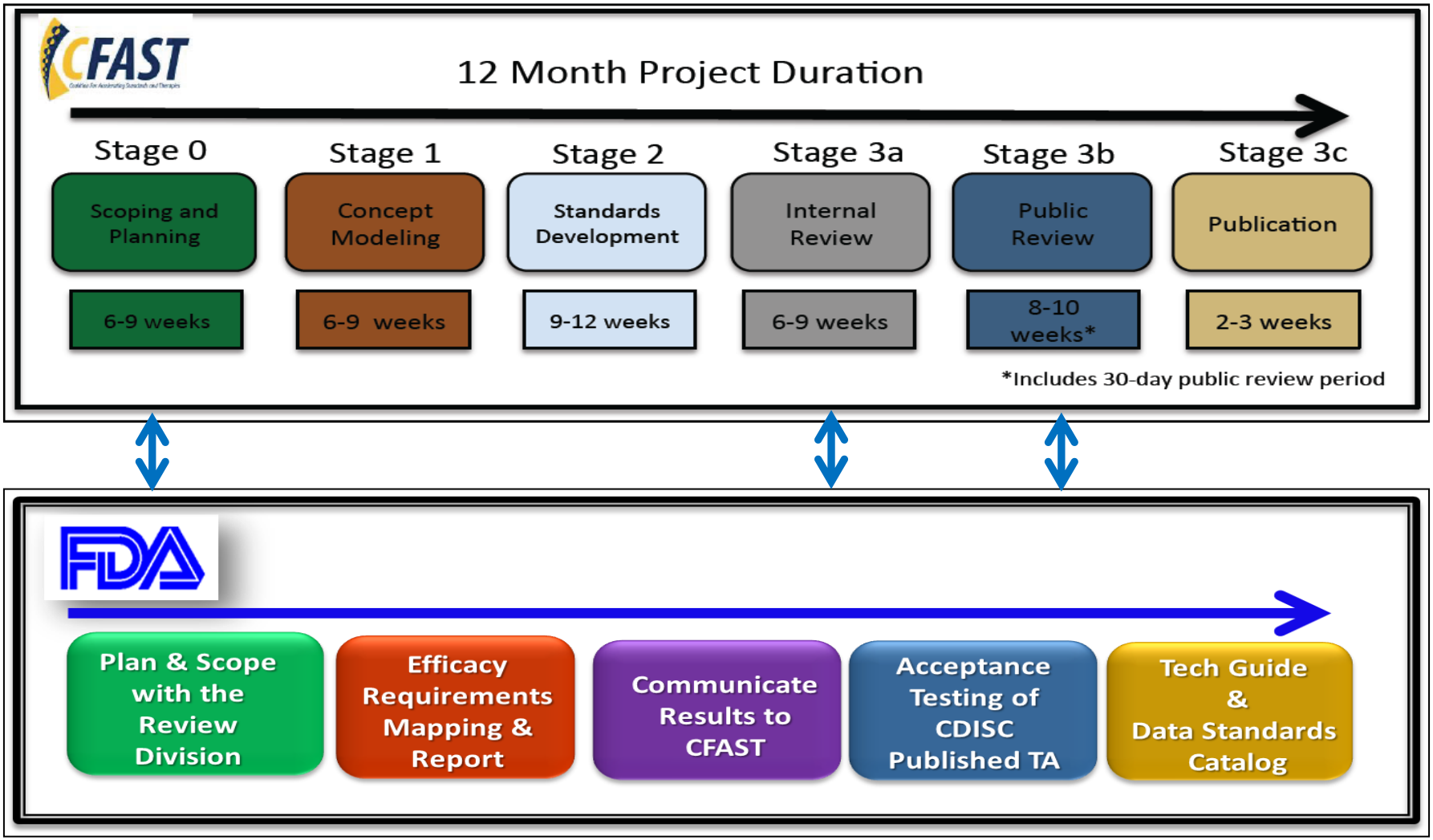
- Guidance Implementation
- Standardized Study Data will become Binding

- Adopt or adapt existing TA data elements
- Harmonize with healthcare standards, as possible

Therapeutic Area Standards Governance



FDA's Role in the TA Standards Initiative

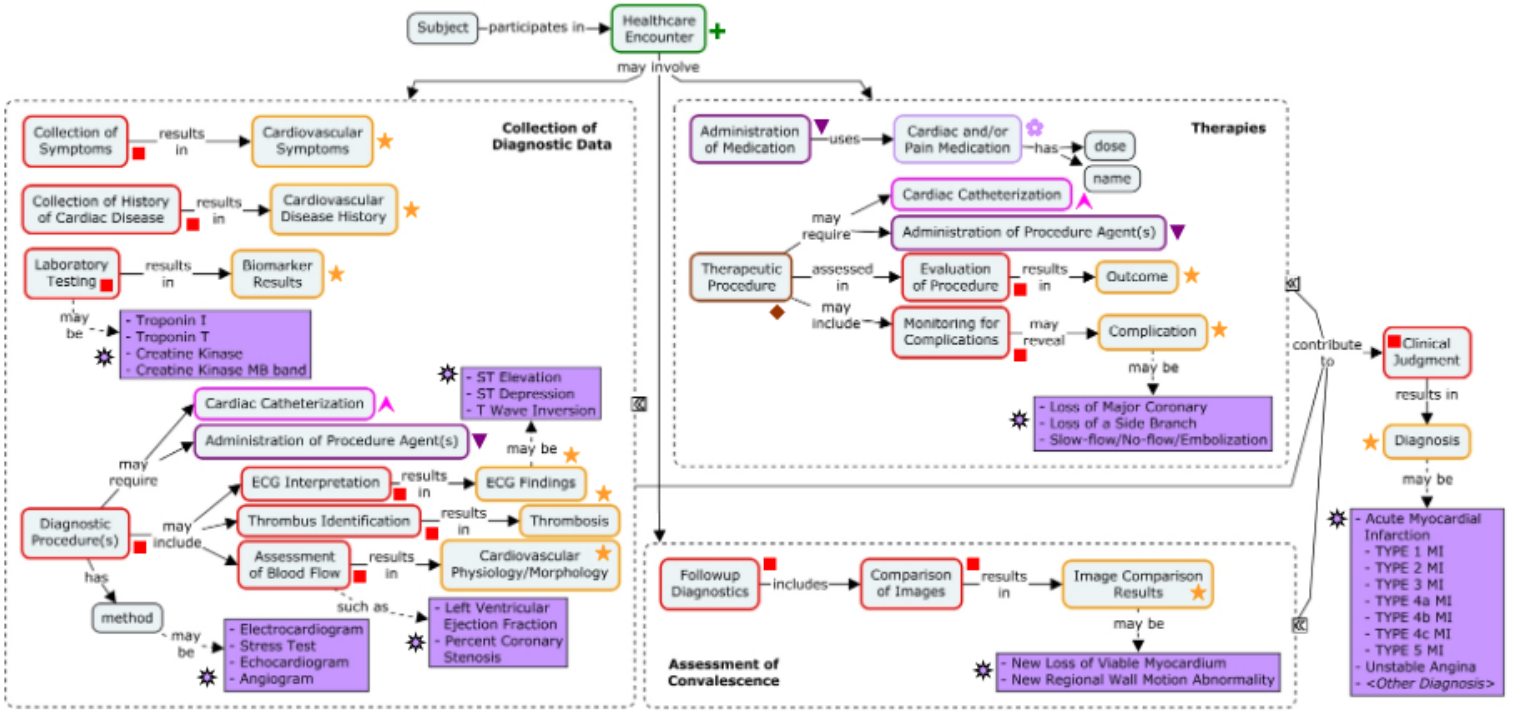


TAUGs – Regulatory Science

http://www.cdisc.org/system/files/members/standard/PDF/TAUG-CV_v1.pdf

These common data elements and definitions for the ACS data elements can be found on the HL7 website.

The concept map below shows what happens to a patient experiencing ACS. For example, a patient presents cardiac problems to his doctor that may result in investigating the patient's medical history, symptoms of the problems, cardiac biomarkers, diagnostic procedures and therapeutics. This may result in sending the patient to the emergency room for further evaluation. Based on the applicable cardiac disease guidelines, this may lead to further testing that is assessed with clinical judgment in determining a diagnosis and course of action in correcting the problem.



Concept Map 1: Acute Coronary Syndrome

Not included in this concept map: Disease Guidelines and Appropriate Use Criteria help to direct what diagnostic tests are performed, what therapies are indicated, and other courses of action. For additional information on myocardial infarction, see Section 3.2.4. For examples of therapeutic procedures, see Sections 3.2.5 and 3.2.6.

Cardiac catheterization, which is shown as a surgical intervention in the concept map above, is actually a complex procedure which may combine diagnostic assessments and therapeutic interventions. It is a surgical procedure in which a catheter is threaded from an incision in the groin or wrist through the arteries into

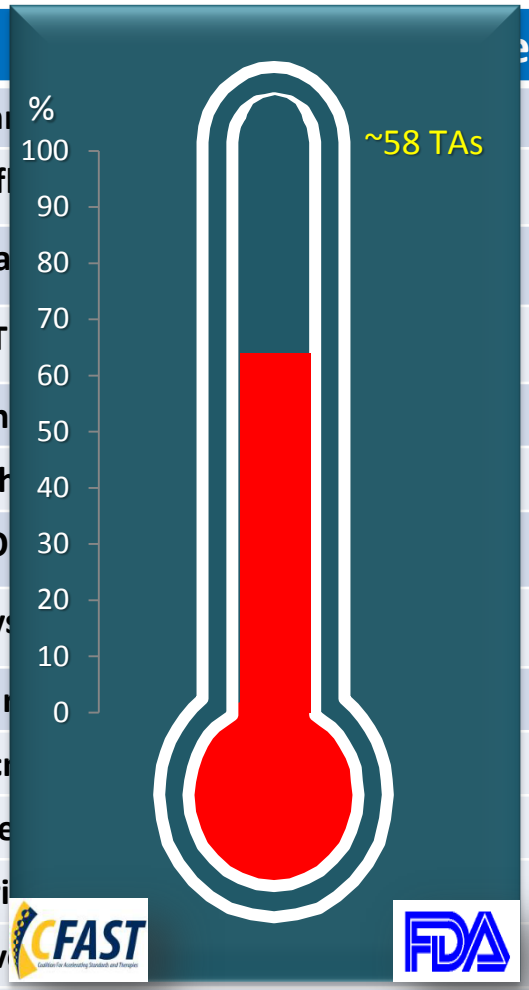
Therapeutic Area Standards: Status to Date*

CDISC Released	Work in Progress or Planned Projects	
Alzheimer's Disease v1 & v2	Chronic Hepatitis-C Virus	Oncology v2 – Prostate Cancer
Pain	Influenza (and Vaccines)	Duchenne Muscular Dystrophy
Parkinson's Disease	Traumatic Brain Injury	Rheumatoid Arthritis
Polycystic Kidney Disease	QT Studies	Tuberculosis v2 (pediatrics)
Tuberculosis	Oncology v1 - Breast Cancer	Solid Organ Transplant (Renal)
Virology	Schizophrenia	Psoriasis
Asthma	COPD	Post-menopausal Osteoporosis
Multiple Sclerosis	Dyslipidemia	Major Depressive Disorder
Cardiovascular Endpoints	Cardiovascular Imaging	Diabetic Kidney Disease
Diabetes	Acne	Parkinson's v2; Oncology v3
	Prevention of Pregnancy	ADHD
	Irritable Bowel Disorder	Anticonvulsants
	Overactive Bladder	Comp. Urinary Tract Infection
		Comp. Skin Structure Infections

* November, 2014

Therapeutic Area Standards: Status to Date*

CDISC Released		ess or Planned Projects
Alzheimer's Disease v1 & v2	Chr	Oncology v2 – Prostate Cancer
Pain	Infl	Duchenne Muscular Dystrophy
Parkinson's Disease	Tra	Rheumatoid Arthritis
Polycystic Kidney Disease	QT	Tuberculosis v2 (pediatrics)
Tuberculosis	On	Solid Organ Transplant (Renal)
Virology	Sch	Psoriasis
Asthma	CO	Post-menopausal Osteoporosis
Multiple Sclerosis	Dys	Major Depressive Disorder
Cardiovascular Endpoints	Car	Diabetic Kidney Disease
Diabetes	Acr	Parkinson's v2; Oncology v3
	Pre	ADHD
	Irri	Anticonvulsants
	Ov	Comp. Urinary Tract Infection
		Comp. Skin Structure Infections



* November, 2014

Including Analysis Data Standards (CDISC/ADaM) In the Therapeutic Area Standards Initiative

PhRMA / Bio Public (Docket) Comments to the TA Project Plan

- "No mention of CDASH or ADaM standards which are needed to support the end-to-end TA standards model."
- More emphasis on [ADaM] given that the "TA standards development initiative focuses primarily on requirements for the efficacy review and evaluation of new medical products."
- "…where composite endpoints exist and the data is originating across multiple SDTM domains the inclusion of ADaM will be particularly relevant."

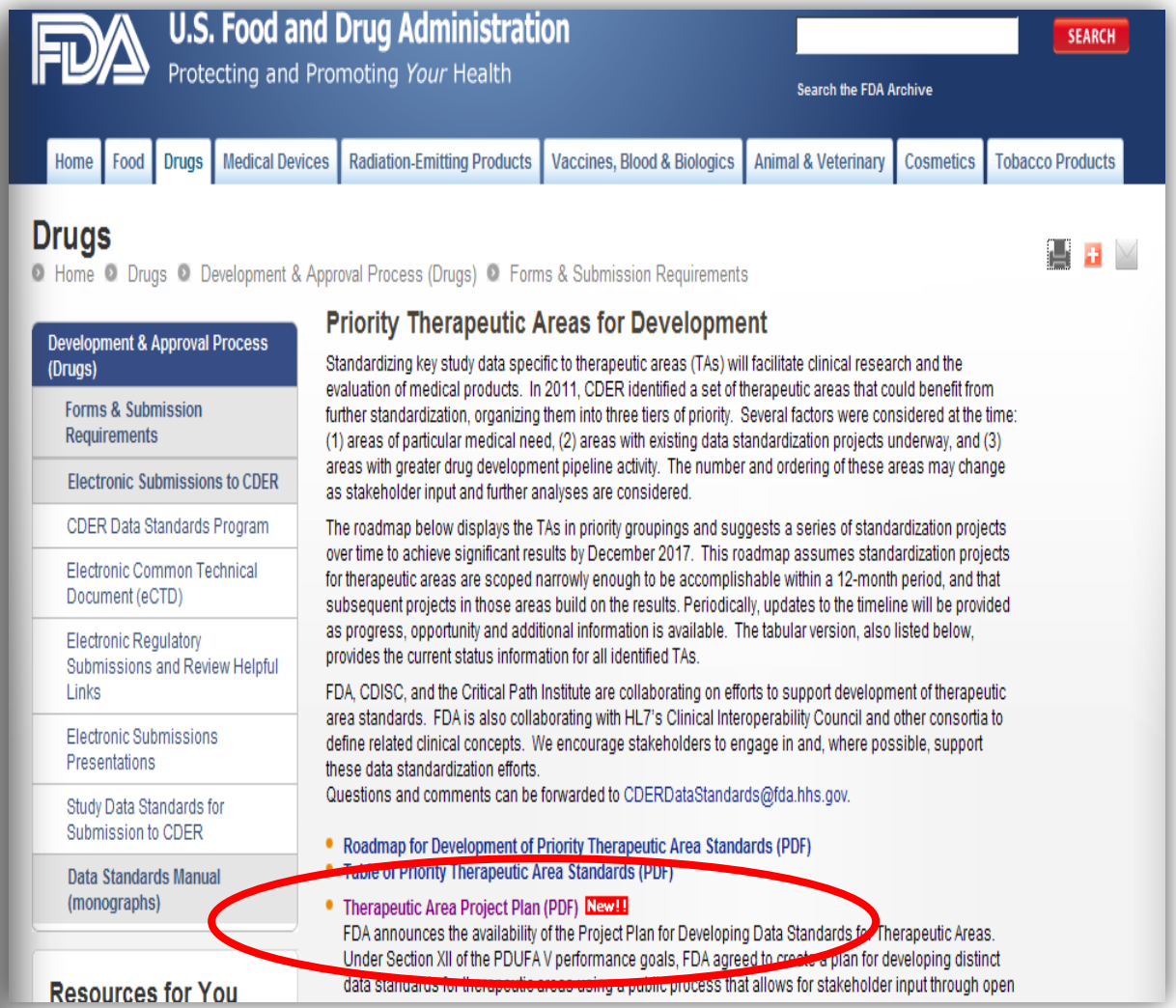
Therapeutic Area Standards Project Plan

Therapeutic Area Standards (TAS) Initiative

Project Plan

Version: 1.0

Document Date: September, 2013



ADaM and Therapeutic Area Standards

Susan Kenny, PhD
Consultant
Center for Drug Evaluation and Research (CDER)

Analysis Standards for Therapeutic Areas

- CDISC / C-PATH / FDA are working together to address the need to develop TA specific standards
  - Very ambitious timeline to produce standards for a large number of TA's in 5 years
- These are published in the Therapeutic Area User Guides (TAUG) and represent effort of large team of volunteers
- TAUG provides models of CDISC implementation of TA specific data that cannot be found in existing CDISC documentation
  - TAUG development identifies gaps in CDISC models which are then taken back to respective team for consideration and incorporation

Analysis Standards for Therapeutic Areas

- First wave of TAUG's did not have any analysis section
- Over the ~18 months, ADaM content has been included in many of the TAUGs
- For concept development, the survey that is sent to pharmaceutical companies was updated
  - Survey is used to decide on scope and main content of TAUG
  - Early version of survey had solicitation for clinical endpoints but not how those clinical endpoints were analyzed (statistical endpoints)
  - Now survey requests brief description of analyses and requests table shells where possible
  - We will also be reviewing publically available FDA summaries

Analysis Standards for Therapeutic Areas

- For all TA's, there is seldom just one clinical endpoint nor is there just one statistical endpoint
- We can't model all of them
- Endpoints are chosen so we can demonstrate:
  - an example of currently available ADaM implementation that has not been shown
  - an example that provides a provisional addition to the current ADaM model
  - an example of something particularly complex
    - ADaM involves process as well as standards implementation
- We include variable level metadata and analysis results metadata when possible

Analysis Standards for Therapeutic Areas

- ADSL concepts are important but not necessarily tied to the clinical/statistical endpoint
  - Many cross-TA issues with ADSL variables
  - Area where we have noted gaps in current ADaM standards
    - Stratification factors and values
    - Representation of Co-morbidities
    - Representation of Concomitant medications
- The TAUG's do not discuss or provide guidance on statistical methodology
  - TAUG may present table shells with analysis results metadata but should be viewed as an example, not a requirement

ADaM Content in TAUG's

Published or Soon to be Published

- QT
  - Full Analysis Section (BDS)
  - The analysis of QT trials is highly specific to this area so ADaM section has less broad applicability
- Hepatitis C
  - Textual section describing analysis issues and approaches to implementation with discussion on use of BDS
- Dyslipidemia
  - Full Analysis section (BDS)

ADaM Content in TAUG's

Soon to be Released for Public Review:

- Breast Cancer
  - Full Analysis section (BDS and TTE)
- Diabetes ADaM Supplement
  - (ADSL, ADCM, BDS, OccDS
  - Most comprehensive showing models that correspond to 3 clinical endpoints
- COPD
  - Full Analysis Section (BDS and OccDS)

ADaM Content in TAUG's

Nearing Internal Review:

- Virology (V2.0)
  - Analysis content in this TAUG is unique and reflects 'niche' area of pharmacogenomic analysis
  - The need of FDA reviewers is for analysis data that is a 'curated view'

A New Concept

- A curated view is somewhere between SDTM and ADaM
- A curated view is an ADaM 'Other' and could serve as an intermediate dataset in some cases
- For Virology, this view is:
  - Join of 2-3 SDTM domains (by study day / date)
  - Add in a few ADSL variables
  - Add in a few additional record level or subject level variables
    - Running accumulation of amino acid changes at a given position
    - Flag to indicate whether subject achieved efficacy endpoint ('efficacy responder')

ADaM Content in TAUG's

In Early Development:

- Diabetes Kidney Disease
  - In scoping stage
- Rheumatoid Arthritis
  - In scoping stage

ADaM Content in TAUG's

- We need more volunteers!
  - ADaM implementation experience is more important that knowledge of therapeutic area (though that helps also)
  - Work in a small team to develop content
  - ADaM leadership is available to help with any problems
  - Please contact Nate Freimark and/or myself

Analysis Data Reviewer's Guide
ADRG

Update on ADRG

- Released one year ago
- Endorsed by FDA, along with SDRG
- Please read completion guidelines
  - Document template is standard but much of content can be customized by sponsor
  - Duplication of content between protocol, SAP, SDRG and ADRG is minimal but it serves a purpose

- Released updated version in early 2015
  - Largely formatting
  - Some clarification in completion guidelines

Office of Biostatistics Data Review Committee and the eData FAQ Team

Weiya Zhang, Ph.D.
Office of Biostatistics (OB)

Center for Drug Evaluation and Research (CDER)

Introduction of OB/SPC/Data Review Committee (DRC)

- Office of Biostatistics / Statistical Policy Council
- Chaired by Steve Wilson
- 15 committee members with representatives from each Division and Immediate Office
- Meets monthly since January 2015

Introduction of OB/SPC/Data Review Committee (DRC)

Initial charges includes:

- Assess OB practice for the handling of review data
- Evaluate compliance with CDER policies
- Collaborate with internal (i.e., CDER and FDA) data standards committees and working groups
- Liaise with outside organizations (e.g., CDISC, PhUSE, PharmaSUG, TransCelerate, CPath Institute, CFAST, DIA, HL7, SCDM and ASA)
- SOPs/guidelines
- Training

DRC Activities in the PhUSE CSS and CDISC IntraChange - March 2015

PhUSE Computational Science Symposium (CSS)

Eight DRC members attended and were actively involved in PhUSE CSS working groups

- Optimizing use of data standards
  - Study Data Standardization Plan
  - Traceability and Data Flow
- Standard scripts for reporting and analysis
- Non-clinical roadmap and implementation
- Semantic technology
- Emerging trends and technologies

CDISC Winter IntraChange

- DRC members covered CDASH, SDTM, ADaM, and CFAST
- Primarily serve as observers / liaisons to the CDISC working groups
- Share statistical reviewers' experience with the working groups

The eData FAQ Team

edata@fda.hhs.gov

The eData Team

Development & Approval Process (Drugs)

Forms & Submission Requirements

Electronic Submissions to CDER

CDER Data Standards Program

Electronic Common Technical Document (eCTD)

Electronic Regulatory Submissions and Review Helpful Links

Electronic Submissions Presentations

Study Data Standards for Submission to CDER

Electronic Regulatory Submission and Review

This page provides information about the electronic submission of regulatory information to the Center and the review of it by CDER staff. The Electronic Common Technical Document (eCTD) is the standard, accepted electronic format for the following submission types:

- New Drug Application (NDA)
- Abbreviated New Drug Application (ANDA)
- Investigational New Drug Application (IND)
- Biologics License Application (BLA)
- Master files: Drug Master File (DMF) and Biologics Master File (BMF)

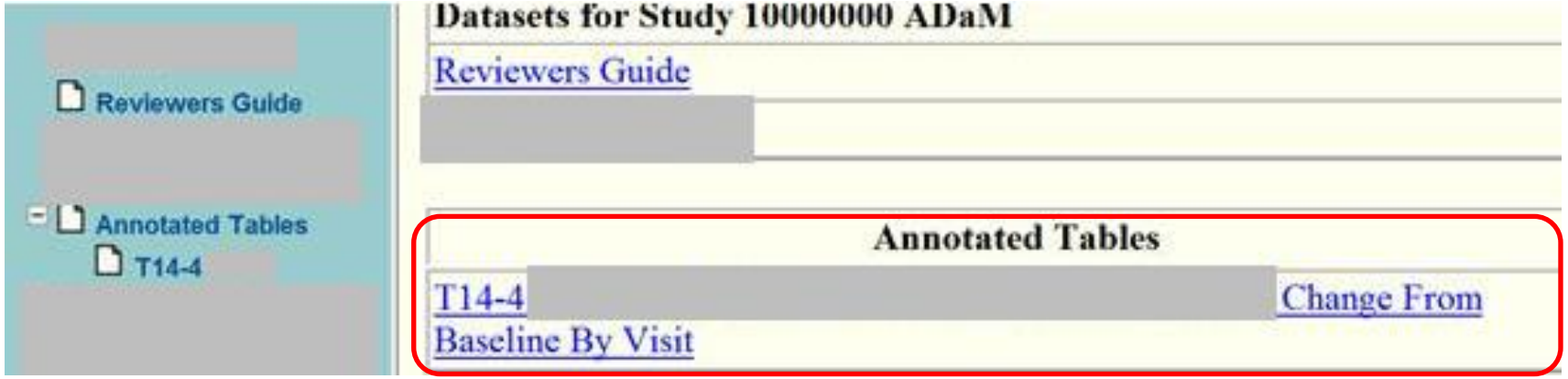
Please visit the Electronic Common Technical Document (eCTD) web page to access a wide variety of resources and support regarding eCTD submissions.

Questions and general information regarding the preparation of submissions in electronic format may be directed to CDER at esub@fda.hhs.gov or CBER at esubprep@cber.fda.gov. Questions regarding submission of datasets to CDER may be sent to edata@fda.hhs.gov.

Sample Questions Received through edata@fda.hhs.gov

Q1: What is Regulatory Reviewer's preference for analysis results metadata?

Option 1



Q1: What is Regulatory Reviewer's preference for analysis results metadata?

Option 1 (Con't)

Table 14-4 [redacted] **Change From Baseline At Month 36**

ANCOVA

AS[redacted].FULLSET="Y" → **(Full Analysis Set [redacted])**

[redacted]

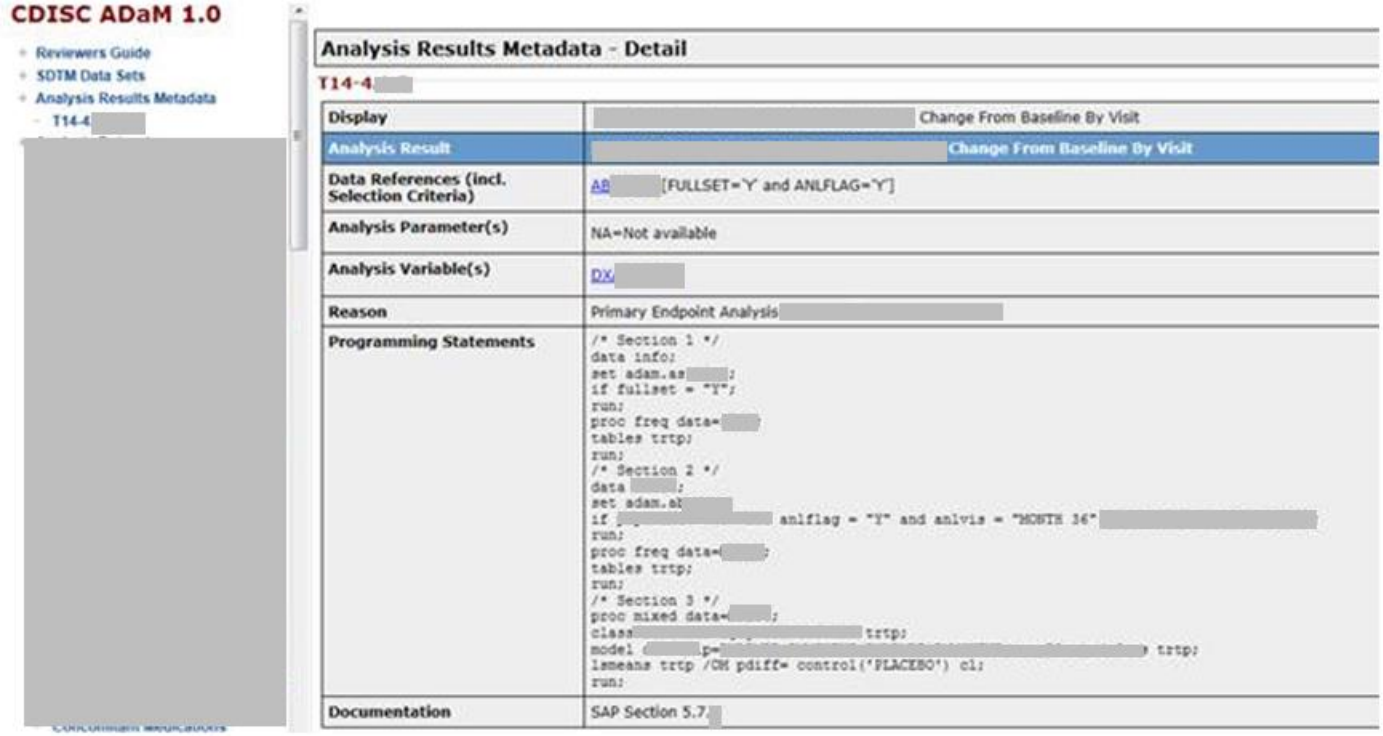
	n	% Change From Baseline[a] LS Mean	95% CI	Difference From Placebo[a] LS Mean	95% CI	p-value
Section 1 / Section 2 / Section 3						
Month 36						
Placebo (N = xxx) AS[redacted].TRTP						
[redacted] (N = xxx)						

ABL[redacted]LP WHERE AB[redacted].ANLVIS="MONTH 36"

```
data [redacted];
set adam.a[redacted];
if [redacted] anlflag = "Y" and anlvis = "MONTH 36" [redacted];
run;
proc mixed data=[redacted];
class [redacted] trtp;
model [redacted]lp=[redacted] trtp;
lsmeans trtp /OM pdiff= control('PLACEBO') cl;
run;
```

Q1: What is Regulatory Reviewer's preference for analysis results metadata?

Option 2



CDISC ADaM 1.0

- Reviewers Guide
- SDTM Data Sets
- Analysis Results Metadata
  - T14-4

Analysis Results Metadata - Detail

T14-4

Display	Change From Baseline By Visit
Analysis Result	Change From Baseline By Visit
Data References (incl. Selection Criteria)	AB [FULLSET='Y' and ANLFLAG='Y']
Analysis Parameter(s)	NA=Not available
Analysis Variable(s)	DX
Reason	Primary Endpoint Analysis

Programming Statements	/* Section 1 */
	data info;
	set adam.as ;
	if fullset = "Y";
	run;
	proc freq data=
	tables trtp;
	run;
	/* Section 2 */
	data ;
	set adam.ab
	if anlflag = "Y" and anlvis = "MONTH 36"
	run;
	proc freq data=
	tables trtp;
	run;
	/* Section 3 */
	proc mixed data= ;
	class trtp;
	model p= trtp;
	lsmeans trtp /CM pdiff= control('PLACEBO') cl;
	run;

Documentation	SAP Section 5.7

Q2: What detail does the FDA require us to go in the ADaM define.xml, taking into consideration that the SAPs are pretty detailed?

Email:

The CDISC ADaM define.xml metadata contains a column with a description of derived variables. There is a large variation in how this information is provided.

- Variety 1: shows a basic reference to the SAP which contains all definitions and derivation rules.
- Variety 2: shows the actual derivation rules in a very detailed fashion.

Q2: What detail does the FDA require us to go in the ADaM define.xml, taking into consideration that the SAPs are pretty detailed?

Potential response:

As the CDER Study Data Technical Conformance G*uide* states, "An insufficiently documented define file is a common deficiency that reviewers have noted," therefore, clear, detailed descriptions of the derivations used to create the submitted analysis files help us better understand how the SAP was actually implemented in producing the derived variables.

As we have found that in many cases relying on references to the SAP may not provide us with the clear/complete documentation that we need for review, we recommend that this detailed description of the derived variables be included in the define.xml.

BOTTOM LINE:
Communicate with Review Divisions and Reviewers! INCLUDING YOUR STATISTICAL REVIEWER!

FDA/CDER, CDISC and PhUSE

Steve Wilson
Director, Division of
Biometrics III
FDA/CDER/OTS/OB

FDA/CDER and PhUSE

CDISC/PhUSE MOU

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CDISC Strength Through Collaboration

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CDISC and PhUSE Announce Signed Partnership in Support of Ongoing Collaboration

February 19, 2015

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Austin, TX – 19 February 2015 – The Clinical Data Interchange Standards Consortium (CDISC), and the Pharmaceutical Users Software Exchange (PhUSE) announced today the signing of a Memorandum of Understanding (MOU), strengthening the partnership for the benefit of stakeholders conducting regulated clinical research and product development.

The CDISC–PhUSE MOU furthers the mission of each organization collectively with (1) CDISC focusing on development of global, platform-independent data standards; and (2) PhUSE focusing on the implementation and use of CDISC standards. The two organizations will combine efforts and seek to collaborate on key initiatives such as the PhUSE Computational Science Symposium (CSS) Working Group projects, many of which already directly involve the testing and implementation of CDISC standards. The Working Groups are a collaborative effort between PhUSE, the FDA, industry and the CDISC community. In addition to these projects, CDISC and PhUSE will cooperate on joint marketing and communications activities, particularly around CDISC Interchanges and PhUSE annual events.

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PhUSE CS Dashboard

The PhUSE CS Working Groups bring together academia, industry, technology providers and regulatory agencies including the FDA to collaborate on projects to address unmet computational science needs. This dashboard provides a single point of reference for active working groups and projects that are part of the PhUSE Collaboration. The content developed by the CS Working Group projects can be accessed via the PhUSE CS Deliverables Catalog.

Optimizing the Use of Data Standards

Traceability and Data Flow : Discuss and define traceability considerations and best practices for study-level and integrated dataset conversions for different data flow scenarios.

Best Practices for DataStandards Implementation:
Identify ambiguities within CDISC documentation and draft best practice documentation for handling these ambiguities .

Semantic Technology

Representing CDISC Protocol Representation Model (PRM) in RDF : Represent the concepts in the PRM in RDF including elements related to a schedule of events and activities, a study's experimental design, subject eligibility, and clinical trial registry.

Modeling Analysis Results Metadata to Support Clinical and Non-Clinical Applications : Development of standard models

PhUSE and FDA … Making It Work!

Sect 2: Planning & Providing Standardized Study Data

- **Study Data Standardization Plan**

  For clinical and nonclinical studies, a plan (e.g., in the IND) describing the submission of standardized study data to FDA.

- **Study Data Reviewer's Guide (SDRG)**

  Describes any special considerations or directions that may facilitate reviewer's use of and understanding of the relationships between the study report and the data.

- **Analysis Data Reviewer's Guide (ADRG)**

  Provides context for analysis datasets and terminology, received as part of a regulatory product submission, additional to what is presented within the data definition file (i.e., define.xml).

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

THANK YOU!