

The Evolution of SDTM

What's new?

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FDA Announcements 2004 - 2013

2004

2006

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U.S. Department of Health & Human Services
FDA U.S. Food and Drug Administration
www.hhs.gov

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FDA NEWS RELEASE
FOR IMMEDIATE RELEASE
P04-73
July 21, 2004

Media Inquiries: 301-827-6242

U.S. Department of Health and Human Services (HHS) - Proposed Rule for eSubmission of Study Data

The semi-annual Unified Agenda was just published on 11 December 06, and the notice of proposed rule making which would require that clinical study data be submitted electronically was cited. The Regulatory item 0910-AC52 (as it has been known) is now cited in the Regulatory Action Plan as Sequence Number 36. An overview of the FDA priorities is the text of Sequence 36. Note that the next action is to publish the rule. [Click here to access to the Federal Register.](#)

U.S. Food and Drug Administration (FDA)

PROPOSED RULE STAGE

36. ELECTRONIC SUBMISSION OF DATA FROM STUDIES EVALUATING HUMAN DRUGS AND BIOLOGICS

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: 21 USC 355; 21 USC 371; 42 USC 262

CFR Citation: 21 CFR 314.50; 21 CFR 601.12; 21 CFR 314.94; 21 CFR 314.96

Legal Deadline: None

OFFICE OF INFORMATION AND REGULATORY AFFAIRS
OFFICE of MANAGEMENT and BUDGET
EXECUTIVE OFFICE of the PRESIDENT

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)

RIN: 0910-AC52
Publication: 201004

[View Related Documents](#)

Title: Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics

Abstract: The Food and Drug Administration is proposing to amend the regulations governing the format in which clinical study data and bioequivalence data are required to be submitted for new drug applications (NDAs), biological license applications (BLAs), and abbreviated new drug applications (ANDAs). The proposal would revise our regulations to require that data submitted for NDAs, BLAs, and ANDAs be submitted in an electronic format that FDA can process, review, and

View Rule

HHS/FDA RIN: 0910-AC52

Title: Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics

Abstract: The Food and Drug Administration is proposing to amend the regulations governing the format in which clinical study data and bioequivalence data are required to be submitted for new drug applications (NDAs), biological license applications (BLAs), and abbreviated new drug applications (ANDAs). The proposal would revise our regulations to require that data submitted for NDAs, BLAs, and ANDAs be submitted in an electronic format that FDA can process, review, and archive. The proposal would also require that FDA periodically issue guidance (e.g., the Study Data Tabulation Model (SDTM) developed by the Clinical Data Interchange Standards Organization (CDISC)) standards for study data.

FDA U.S. Food and Drug Administration
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For Industry
Home For Industry Data Standards Study Data Standards

Study Data Standards for Regulatory Submissions

Janus Clinical Trials Repository (CTRP) Project

Standard for Exchange of Non-Clinical Data

Study Design Standard

Study Participation Standard

Subject Data Standard

Study Data Standards for Regulatory Submissions
Position Statement

FDA recognizes the investment made by sponsors over the past decade to develop the expertise and infrastructure to utilize Clinical Data Interchange Standards Consortium (CDISC) standards for study data. The submission of standardized study data enhances a reviewer's ability to more fully understand and characterize the efficacy and safety of a medical product.

The Prescription Drug User Fee Act (PDUFA) Performance Goals state that FDA will develop guidance for industry on the use of CDISC data standards for the electronic submission of study data in applications. In the near future, FDA will publish guidance that will require study data in conformance to CDISC standards [1].

FDA envisions a semantically interoperable and sustainable submission environment that serves both regulated clinical research and health care. To this end, FDA will continue to research and evaluate, with its stakeholders, potential new approaches to current and emerging data standards. FDA does not foresee the replacement of CDISC standards for study data and will not implement new approaches without public input on the cost and utility of those approaches.

September 13, 2013

[1] www.cdisc.org
[2] http://www.fda.gov/forindustry/UserFees/PrescriptionDrug/UserFees/ucm27170.htm
[3] http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCA/SignificantAmendments/totheFDCA/

Agenda Stage of Rulemaking: Proposed Rule
Unfunded Mandates: Private Sector

21 CFR 314.94; 21 CFR 314.96 (To search for a specific CFR, visit the [Code of Federal Regulations](#))

21 USC 262

on	Date	FR Cite
	10/00/2010	

China's SFDA Announcement February 2013

NEWS

China's SFDA Announces Major Reforms to Drug Regulatory Process

Latest News | Posted: 27 February 2013

By Louise Zornoza, RegLink

0 Likes  

China's State Food and Drug Administration (SFDA) has [announced](#) that it is implementing a series of reforms designed to improve the drug review and approval process, "and to promote the healthy development of China's pharmaceutical industry."

Wang Lifeng, director of the SFDA's drug registration department, said the plan provides incentives for the research and development of innovative clinical drugs, adding that the approval process will be shortened for these drugs.



Join the discussion on [Regulatory Exchange](#)

RELATED LINKS

- [SFDA: "Views on deepening the reform of the drug review and approval to further encourage innovation"](#)
- [Read all *Breaking News* from](#)

EMA « Clinical Data Transparency Initiative »

- Project Scope
 - Clinical reports & data from all clinical studies in Europe
- Timelines
 - Jan 2013 – Apr 2013 : Advisory Groups
 - Patient Confidentiality
 - Clinical Data Formats
 - Rules of engagement
 - Good Analysis Practice
 - Legal Aspects
 - June 2013 : Draft Agency Policy
 - Nov 2013 : Final Agency Policy
 - Jan 2014 : Policy comes into force



Agency moves towards proactive publication of clinical-trial data

EFSA Announcements



efsa
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committed to ensuring that Europe's food is safe

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Food additives: EFSA's new guidance for applicants

News Story
18 July 2012

New guidance for the submission of applications for the latest risk assessments from the European Food Additives and Nutrient Sources Added to Food (ANS).

In the EU, the safety of food additives is assessed by the European Commission for market authorisation. Under EU legislation, applications for authorisation must be supported by data supporting the safety of the additive.

The guidance adopted by the European Commission's for the assessment of food additives. New guidance on the assessment of food additives based on experience in applying the

efsa
European Food Safety Authority

EFSA Journal 2012;10(7):2760

SCIENTIFIC OPINION

Guidance for submission for food additive evaluations¹

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

This Scientific Opinion, published on 16 August 2012, replaces the earlier version published on 18 July 2012.⁴

ABSTRACT

This guidance document refers to the applications for authorisation of a new food additive or to a modification of an already authorised food additive, combining in a single document the description of the data requirements and their context, and also a description of the risk assessment paradigm applied. The document is arranged in four main sections: chemistry and specifications, existing authorisations and evaluations, proposed uses and exposure assessment, and toxicological studies. Assessment of the exposure to food additives is based on information on known or anticipated human exposure to the proposed additive or toxicologically relevant

Agenda

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FDA Submission Landscape

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Evolution of CDISC Models

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Development of Standards

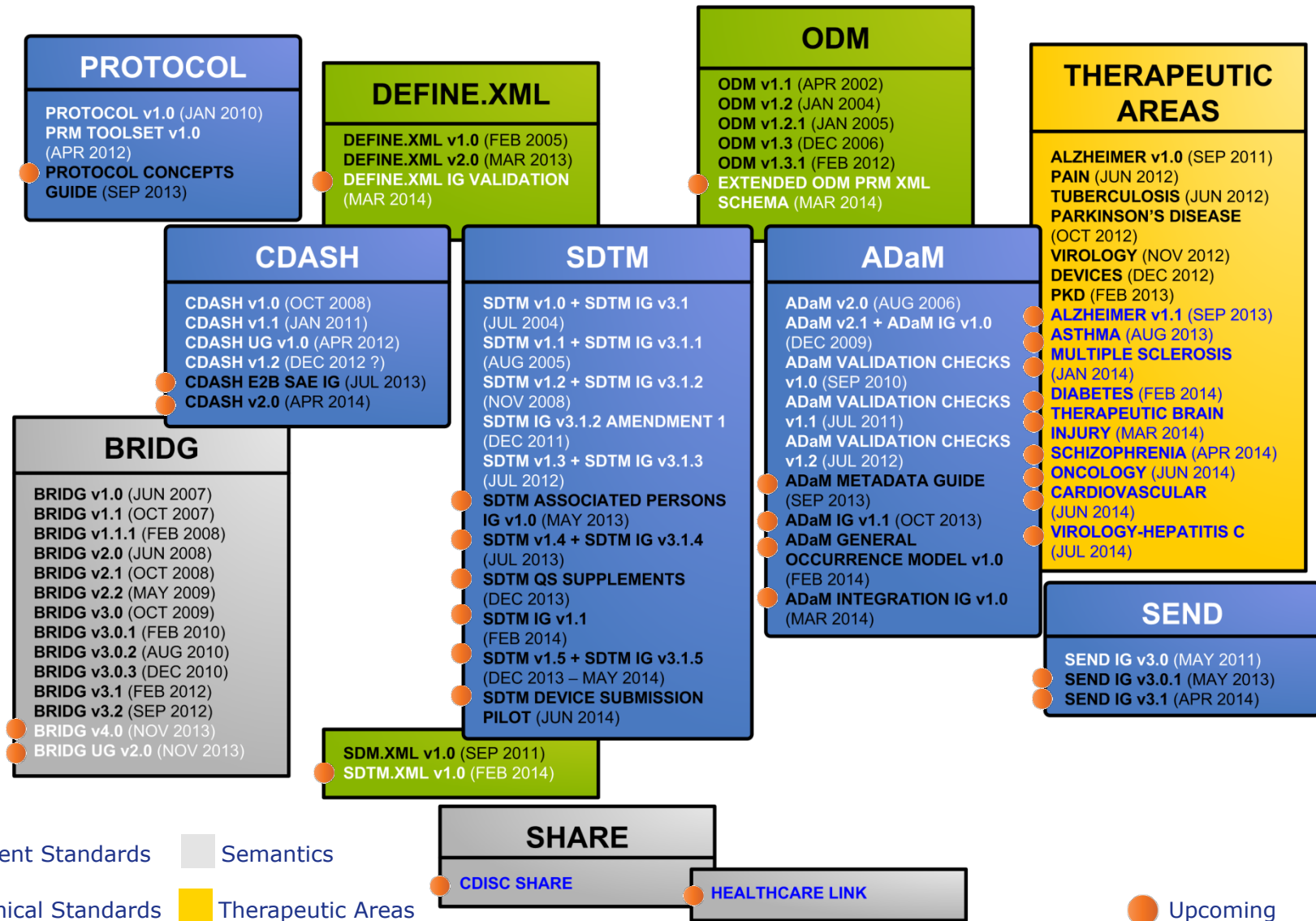
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CDISC SHARE

5

SDTM 3.1.4 Highlights

Overview of CDISC Models SEP 2013

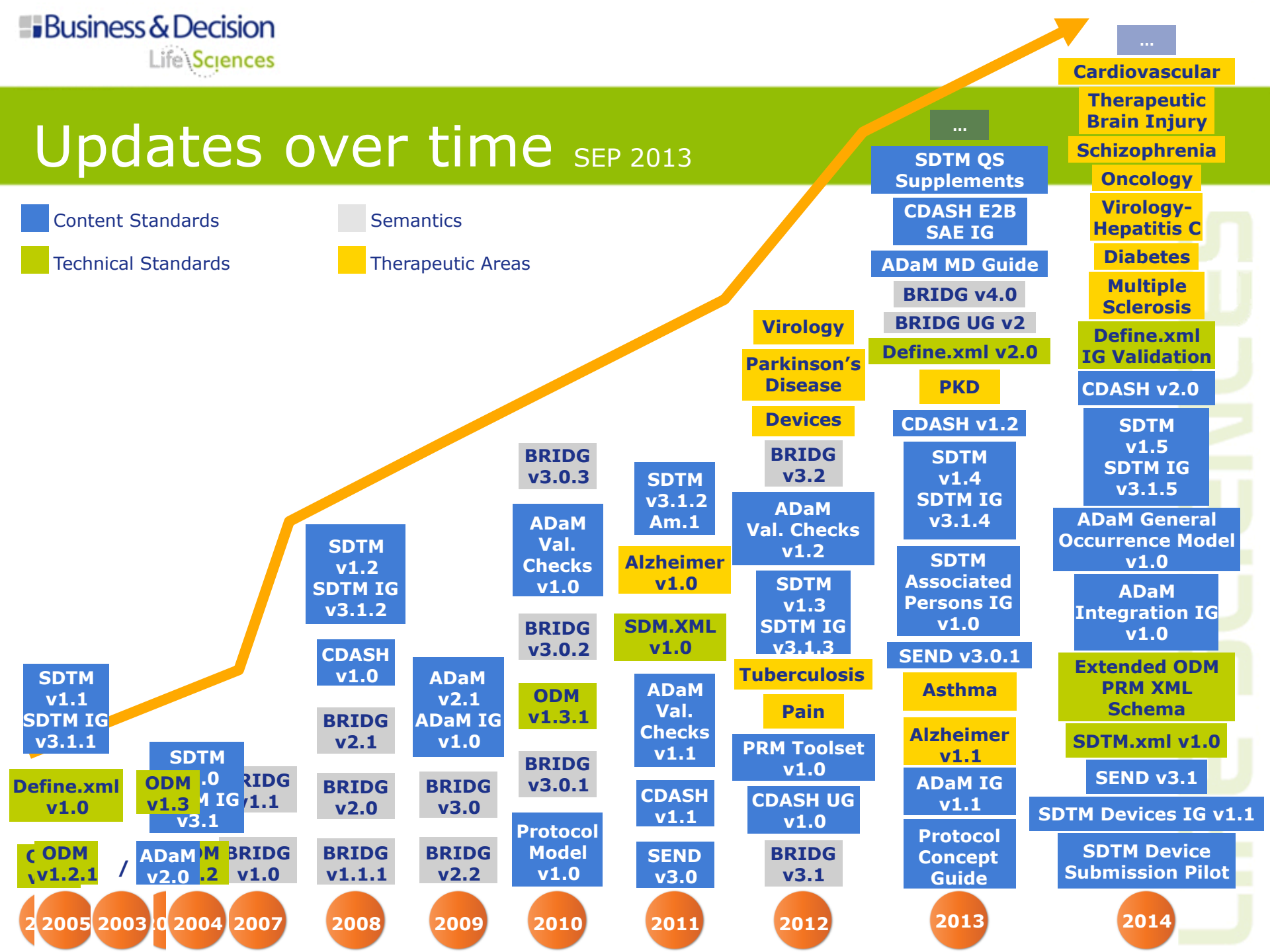


Updates over time

SEP 2013

Content Standards
Technical Standards

Semantics
Therapeutic Areas



The Evolution of SDTM

- SDTM V1.1 and SDTM IG V3.1.1
 - Only for studies initiated prior to 13 Jun 2011
 - Date Support Ends 28 Jan 2015
- SDTM V1.2 and SDTM IG V3.1.2
 - Published Nov 2008
- SDTM V1.2 and SDTM IG V3.1.2 Am. 1
 - Published Dec 2011
- SDTM V1.3 and SDTM IG V3.1.3
 - Published Jul 2012
- SDTM V1.4 and SDTM IG V3.1.4
 - Expected end 2013

5816 Federal Register / Vol. 78, No. 18 / Monday, January 28, 2013 / Notices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA-2012-N-0710]

Electronic Study Data Submission; Data Standard Support End Date

AGENCY: Food and Drug Administration, HHS.

SUMMARY: The Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH) are announcing the end of support for the 3.1.1 version of Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) Implementation Guide (SDTM IG 3.1.1). SDTM IG 3.1.2, which has been available since October 2009, is the newer standard supported by FDA. Support for SDTM IG 3.1.1 will end on January 28, 2015.

FOR FURTHER INFORMATION CONTACT:
Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1161, Silver Spring, MD 20903, Phone: 301-796-1016, EDATA@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA encourages sponsors to submit standardized study data using Agency-supported data standards (see <http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.html>).¹ An Agency-supported data standard means that FDA has established processes and technology infrastructure to support the receipt, processing, review, and archiving of study data using the standard. As data standards evolve, FDA will periodically end support for old standards in favor of newer standards that are better suited to meet FDA data management and review needs. FDA maintains a catalog of the supported data standards for study data submissions at <http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM292505.xls>.

To facilitate the transition to newer standards, FDA is committed to providing a transition period of 24 months during which both older and newer standards are supported. FDA first began supporting SDTM IG 3.1.2 on October 30, 2009, over 2 years ago.

This notice establishes that CBER, CDER, and CDRH are ending support for SDTM IG 3.1.1 effective January 28, 2015. Effective immediately, submitters are strongly encouraged to use SDTM IG 3.1.2 instead. The support end date is the date past which study data using the standard may not be submitted, unless special arrangements have been made in advance with the Agency.

FDA recognizes the challenges associated with adopting a new standard, particularly because studies are often conducted and study data are standardized months to years before submission to the Agency. Submitters seeking a special arrangement to provide data using SDTM IG 3.1.1 beyond the established support end date should submit a waiver request. A waiver request process will be posted at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ForSubmissions/ucm249979.htm> for CDER and <http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/ucm209137.htm> for CBER by November 1, 2012. The waiver process will be put into place to support the transition and allow for submission of clinical data in SDTM IG 3.1.1 format data in cases where SDTM IG 3.1.2 is otherwise not feasible and/or when such submission has been determined as having no negative impact to the review process.

Dated: January 22, 2013.
Leslie Kux,
Assistant Commissioner for Policy.
[FR Doc. 2013-01641 Filed 1-25-13; 8:43 am]
BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA-2011-D-0062]

Guidance for Industry on Clinical Pharmacogenomics: Premarket Evaluation in Early-Phase Clinical Studies and Recommendations for Labeling; Availability

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Clinical Pharmacogenomics: Premarket Evaluation in Early-Phase Clinical Studies and Recommendations for Labeling." This guidance is intended to assist the pharmaceutical industry and other investigators engaged in new drug development in evaluating how variations in the human genome, specifically DNA sequence variants, could affect a drug's pharmacokinetics (PK), pharmacodynamics (PD), efficacy, or safety. The guidance provides recommendations on when and how genomic principles should be considered and applied in early-phase clinical studies to address questions arising during drug development and regulatory review.

DATES: Submit either electronic or written comments on Agency guidance at any time.

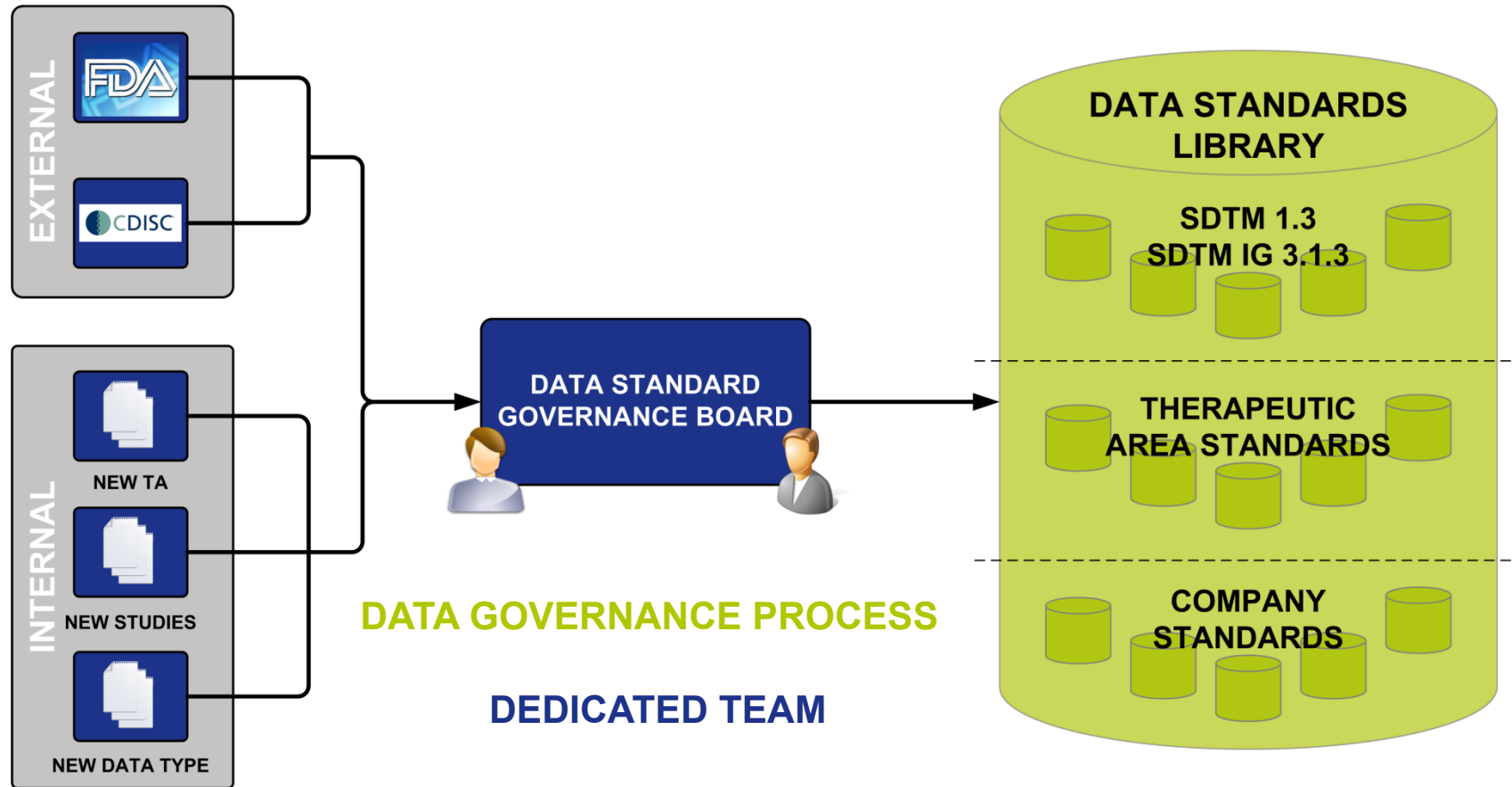
ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20903-0002; or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Issam Zineh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3178, Silver Spring, MD 20903-0002, 301-796-4756; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

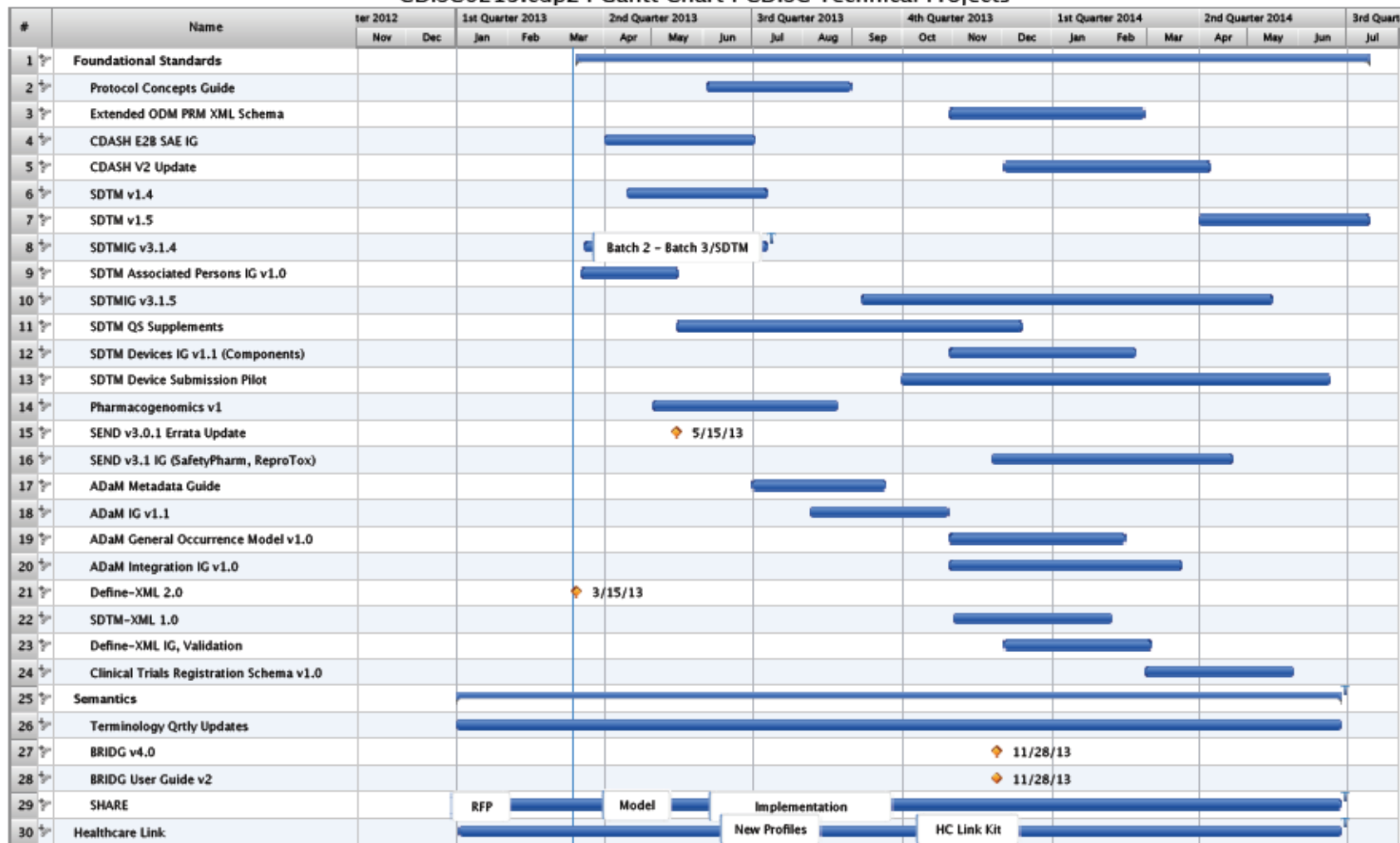
SUPPLEMENTARY INFORMATION:
I. Background
FDA is announcing the availability of a guidance entitled "Clinical Pharmacogenomics: Premarket

Data Standards Governance



Technical Plan Project Schedule Published March 2013

CDISC0213.cdpz : Gantt Chart : CDISC Technical Projects



CDISC Team Charters

- CDASH Team
- SDS Team
- Device team
- ADaM Team
- XML Technologies Team
- Terminology team
- BRIDG Team
- Questionnaire Team
- Protocol Team

 CDISC Submission Data Standards (SDS) Team <i>Team Charter</i>		
Leadership Team Dan Godoy (co-Lead) Barrie Nelson (co-Lead) Diane Wold Fred Wood Wayne Kubick	Team Mission To develop and maintain a standard model and implementation guides that support more consistent and effective integration, aggregation, and submission of tabulation data from human clinical trials to facilitate FDA reviews and increase the value of collected research data.	Stakeholders/Constituency ➤ Regulatory Authorities ➤ Standards Development Organizations ➤ Pharmaceutical Sponsors ➤ Medical Device Companies ➤ Contract Research Organizations & Consultants
SDTM Area Leads Findings NEC Randall Austin & Jan Hess Interventions, Events and FA Janet Reich & Adrienne Boyance Lab Findings Joyce Hernandez & Mona Oakes Oncology Questionnaires Barrie Nelson Special Purpose Gary Cunningham & Steve Kopko Trial Design & IE Tom Guinter & Mike Morozewicz SDTM Experts & X-Team Liaisons Diane Wold & Melanie Fuelbeck Gail Stoner Lou Ann Kramer Madhavi Vemuri Carey Smoak Gary Walker Carolyn Wilson Chris Tolk Helena Sviglin	Scope The SDS Team develops standards for the submission of tabulation data from human clinical trials. Since its inception, the SDS Team has worked to develop data domain models to support the Safety Domains listed in the 1999 FDA Guidance Documents from CDER & CBER, and continues to develop new or enhanced domain models through the Study Data Tabulation Model (<i>SDTM</i>), as well as its drug- and-biologics-focused Implementation Guide (<i>SDTMIG</i>). The SDS Team maintains the <i>SDTM</i> and <i>SDTMIG</i> and other related documents, in alignment with the CDISC Strategy, by organizing its constituent members into relevant sub-teams to deliver domain models that meet growing data standardization needs of the FDA, as well as of key Therapeutic-focused Academic & Research Centers (e.g., DCRI, C-PATH, NIH) and collaborative organizations such as TransCelerate BioPharma. 2013 Product Goals The SDS Team will implement its <i>2013 SDS Team - Project Delivery Plan</i> , targeting to deliver: ➤ An update to the Study Data Tabulation Model (SDTM v 1.4) ➤ An update to the Study Data Tabulation Model Implementation Guide (SDTMIG v3.1.4) ➤ The SDTM Implementation Guide: Pharmacogenomics/Genomics (SDTMIG-PGx v1.0) ➤ The SDTM Associated Persons Implementation Guide (SDTMIG-AP) v1.0 Other Major Project(s) The SDS Team will begin a project to align SDTM with SHARE in 2013, and will also initiate the creation and implementation of several new domains, enhancements, and/or corrections to previously published sections, and other incremental content targeted for inclusion on the next release of the SDTMIG (v 3.1.5). Domains may be released for review and provisional use prior to 3.1.5. These updates may be originated from previously existing plans, or as a direct result of Therapeutic Area Project needs. Regardless, a call for volunteers will be issued to create the appropriate SDTM Domain Development sub-teams.	Collaborations The SDS Team works closely with CDISC Teams that utilize or leverage the SDTM standard to develop their own IGs (e.g., SEND, ADaM, Devices, CDASH, PGx). The SDS Team is also a strong contributor to BRIDG, SHARE, and TA Project Teams. Operating Model & Meetings ➤ Full team is divided into sub-teams to deliver one or more components from the 2013 SDS Team - Project Delivery Plan to effectively maintain the <i>SDTM</i> and <i>SDTMIG</i>. ➤ Sub-teams set own meeting schedule, and mechanism to report progress through their SDTM Area Lead(s). ➤ SDTM Area Leads ensure consistency across SDTM Sections/domains under their care, and report maintenance progress up to SDS LT. ➤ SDS LT regularly engages with SDTM Area Leads to share Updates & Review deliverables against agreed 2013 SDS Team - Project Delivery Plan. ➤ Key meetings on Mondays 11am-12:30pm EDT ➤ 1st & 3rd Monday SDS LT ➤ 2nd & 4th Monday - SDSLT, SDTM Area Leads & SDTM Experts and Liaisons ➤ Periodic meetings with extended SDS team including all volunteers.

- BRIDG Team Charter.
- Questionnaire Team Charter.
- Protocol Team Charter.

Click here to download a zipfile for all currently available team charters.

CDISC Volunteers



New Volunteer Form

1

CDISC Project Teams and Sub-teams

2

Contact Information

CDISC depends on volunteers like you to develop, use and maintain our open standards. The goal is to create a responsive community that can efficiently review and comment on draft standard documents as they become available as well as to build up membership on teams that develop new standards. Participating in the public review process is a necessary first step to becoming involved in CDISC team activities. Standards open for public review and new standards available for use are available on the CDISC website: www.cdisc.org.

What additional activities can you expect to be involved in as a CDISC volunteer? In addition to reviewing draft standards, you may be asked or decide to participate in any of the following:

- Actively participate during scheduled team teleconferences and take action items
- Evaluate and help resolve internal and external review comments on draft standards documents
- Participate in the development of new and updated standards documentation
- Help identify new versions of standards or new domains and align development with other standards teams
- Provide subject matter expertise and consultation
- Contribute to the development of team training materials

Click [here](#) to see the latest CDISC Technical Plan which shows major project deliverables for the year. For more information on Therapeutic Area standards, click [here](#).

If you think you're interested in contributing 8 or more hours a month to help, please fill out the form below and someone will follow up with you.

Thank you for considering volunteering for CDISC!

Italics indicate team is not currently recruiting new volunteers.

Please list where you would like to contribute to the CDISC mission (at least one selection is required):

- ☐ ADAM (Analysis Domain Model)
- ☐ BRIDG (Biomedical Research Integrated Domain Group)
- ☐ CDASH (Clinical Data Acquisition Standards Harmonization)
- ☐ Define.XML (Define Specifications)
- ☐ Healthcare Link
- ☐ ODM (Operational Data Model)

<http://cdisc.wufoo.com/forms/m7p6r7/>

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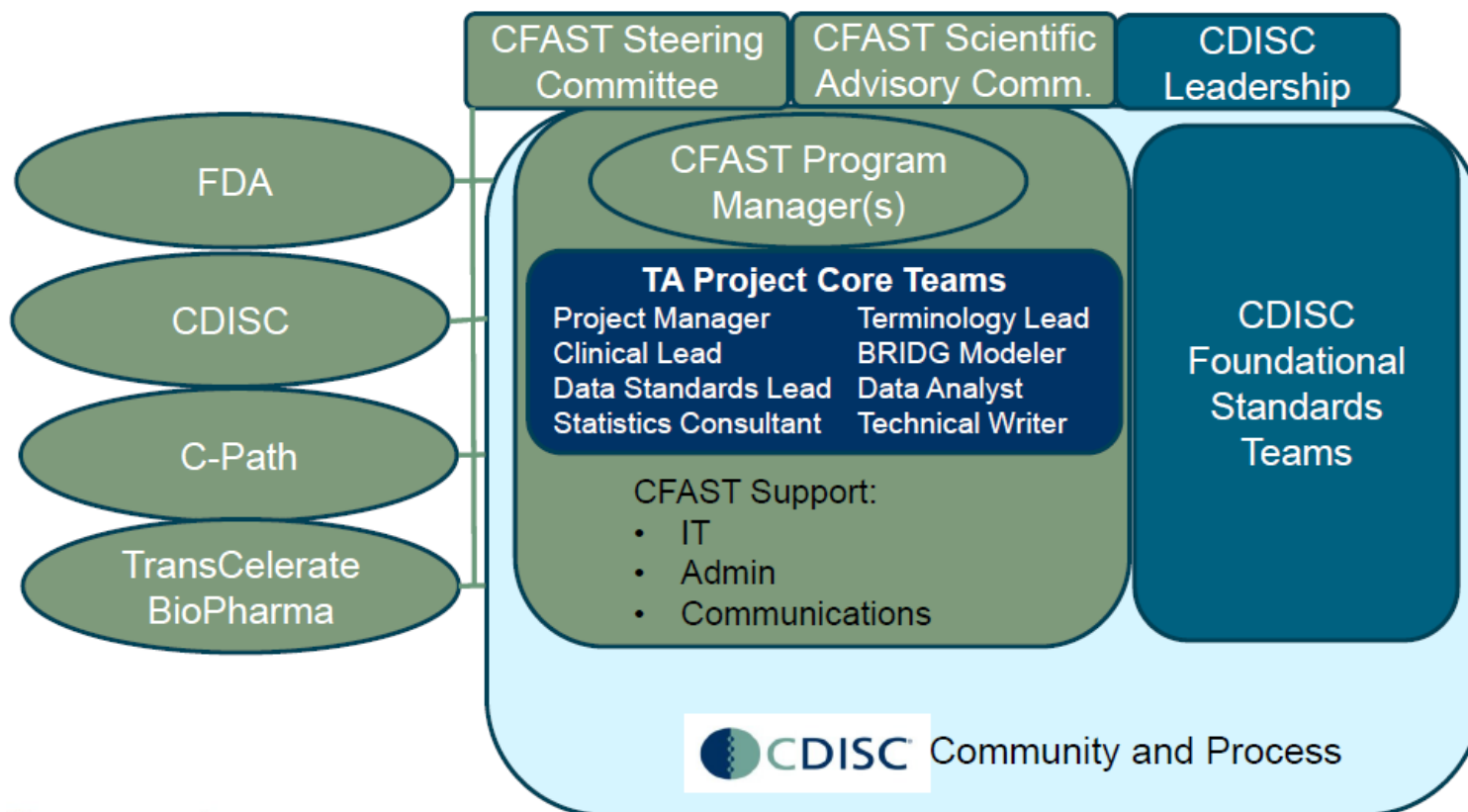
Published Therapeutic Areas SEP 2013

1. Oncology Domains – *Included in SDTMIG 3.1.3*
2. Alzheimer's Disease V1 - *Final*
3. Pain V1 - *Provisional*
4. Parkinson's Disease V1 - *Provisional*
5. Polycystic Kidney Disease V1 - *Provisional*
6. Tuberculosis V1 - *Provisional*
7. Virology V1 – *Provisional*
8. Asthma – *Open for public review*

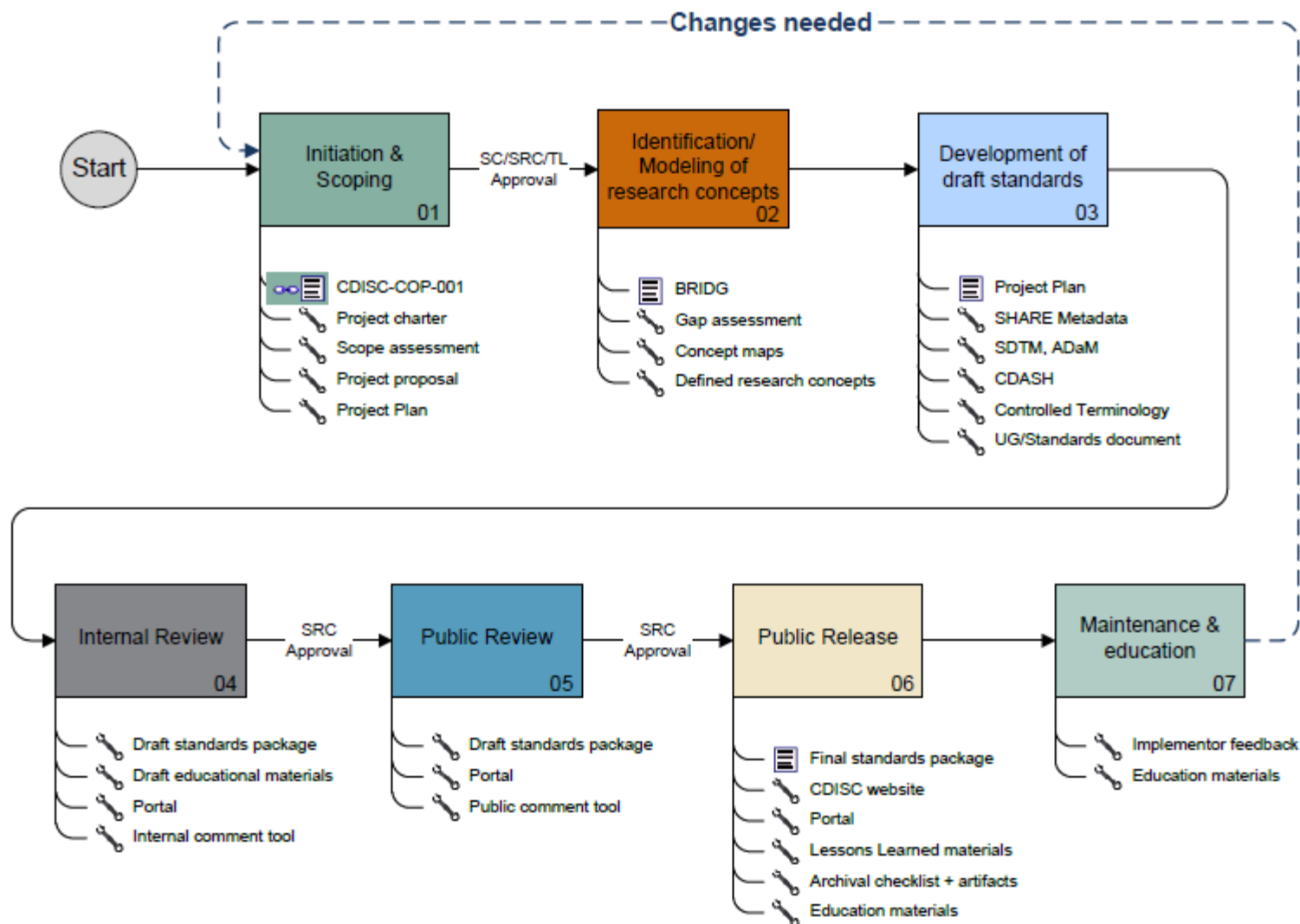
* *A CDISC provisional release is defined as a proposed standard that has completed a public review within the CDISC user community and is available for initial use; but subject to modification for some component parts still in process*



Therapeutic Area Standards Governance Model



Enhanced Standards Development Process



CFAST Program Overview July 2013

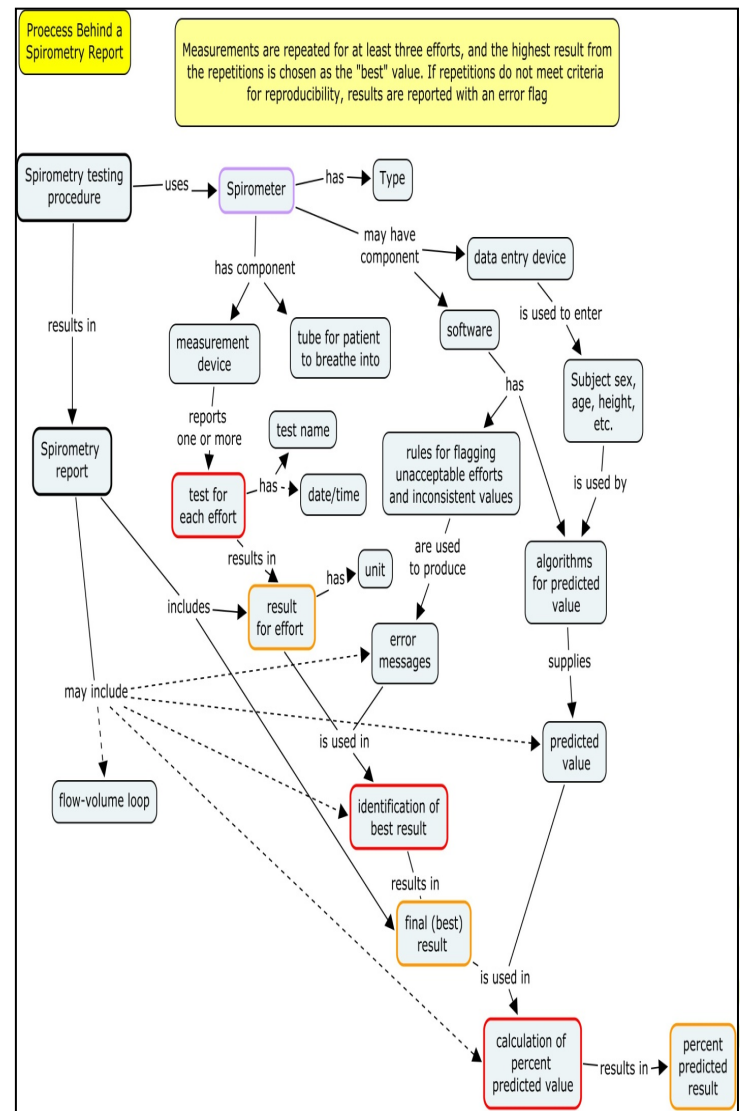
Therapeutic Area Standards Under Development

		Coordinating Organization(s)							Issues
		Project Manager	Scoping & Input	Concept Modeling	Standards Development	Internal Review	Public Review	Publication	
Alzheimer's V1.1		CPATH/CDISC Jon Neville	Jan	Mar	Jun	Jul	Sep	Q313	
Asthma V1		CDISC Rhonda Facile	Jan	Mar	Jun	Jul	Sep	Q413	
Cardiovascular Endpoints V1		DCRI/CDISC Amy Palmer	Jun	Jul	Aug			Q114	
Multiple Sclerosis V1		CPATH/CDISC Bess Leroy	May	Aug	Jul			Q114	<i>Concept modeling done prior to standards development step.</i>
Diabetes V1		TCB/CDISC Rachael Zirkle	Mar	Jun	Aug			Q114	
QT Studies V1		TCB/CDISC John Owen	Jul	Sep				Q214	
Traumatic Brain Injury V1		CDISC TBD	Aug					Q214	
Hepatitis C V1		TBD	Sep					Q314	
Schizophrenia V1		DCRI/CDISC Amy Palmer	Oct					Q314	
Oncology		TBD	Oct						<i>SAC working to define scope and deliverables.</i>
Project Status:  On track  At risk  Critical issues  Stage ongoing  Stage completed <i>Italics = Projected</i>									

Enhanced Standards Development Process

CFAST Deliverables:

1. Mindmap visualization of disease area clinical concepts
2. Essential core data elements of the disease
3. Definitions
4. Data types (simple & ISO 21090)
5. BRIDG and SDTM mappings
6. SDTM domains and examples
7. Minimum value sets (from code lists) with definitions and C-Codes
8. User/Implementation Guide with permissions statement
9. Standard CDASH CRFs with SDTM annotations, as appropriate



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What is CDISC SHARE?



CDISC
SHARE

SHARED HEALTH AND CLINICAL RESEARCH ELECTRONIC LIBRARY



- Single, trusted, authoritative source for CDISC data standards
- Concepts, metadata, collections, relationships, value sets across the full spectrum of CDISC content
- Links research to healthcare concepts to support interoperability
- Aligned with NCI Semantic Systems

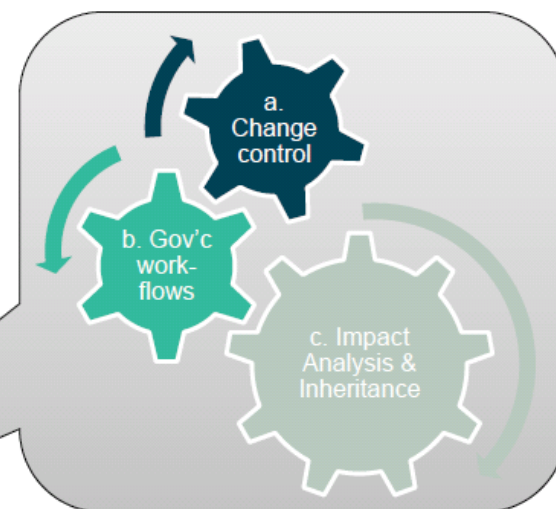
BRIDG, ISO21090

Protocol, CDASH

SDTM, ADaM

Terminologies

SHARE



Facilitates
Data
Exchange

- Access to data standards
- Source to target mapping & traceability
- Transformation logic

CDISC SHARE R1 Implementation Plan

SHARE SM Implementation R1

2013-08-14

All Inclusive Report. Report Period: 2013-06-12 - 2014-02-01

ID	Name	Duration	Start	Finish	Complete	Man-hour	Resource Name	Notes
1	SM Solution Familiarization	3.0 d	6/13/13	6/17/13	100 %	0.0		
2	Assessment	41.0 d	6/13/13	8/8/13	100 %	216.0		
3	Answer assessment questions	31.0 d	6/13/13	7/25/13	100 %	0.0		
4	Author assessment document	2.0 d	7/25/13	7/26/13	100 %	0.0		
5	Review assessment document	8.0 d	7/29/13	8/7/13	100 %	192.0	A&M Team, Governance Team, Content Team	
6	Finalize and approve assessment document	1.0 d	8/8/13	8/8/13	100 %	24.0	A&M Team, Governance Team, Content Team	
7	Assessment Complete	0.0 d	8/8/13	8/8/13	0 %	0.0		
8	R1 SM Implementation	108.0 d	8/14/13	1/10/14	0 %	2,848.0		
9	Sprint 1 (metamodel configuration, customer queries, and validation scripts)	21.0 d	8/14/13	9/11/13	0 %	296.0		
10	Development / Configuration	15.0 d	8/14/13	9/3/13	0 %	120.0	SOA Team	
11	Training (F2F / WebEx)	2.0 d	9/4/13	9/5/13	0 %	16.0	SOA Team	
12	Informal testing	4.0 d	9/6/13	9/11/13	0 %	96.0	A&M Team, Governance Team, Content Team	shortened due to the F2F training
13	Test script development	4.0 d	9/6/13	9/11/13	0 %	32.0	A&M Team	
14	Sprint retrospective & planning	1.0 d	9/10/13	9/10/13	0 %	32.0	Governance Team, A&M Team, Content Team, SOA Team	
15	Sprint 1 Complete	0.0 d	9/11/13	9/11/13	0 %	0.0		
16	Sprint 2 (governance and customer scripts)	21.0 d	9/12/13	10/10/13	0 %	352.0		
17	Development / Configuration	16.0 d	9/12/13	10/3/13	0 %	128.0	SOA Team	
18	Demo / Walkthrough	1.0 d	10/3/13	10/3/13	0 %	8.0	SOA Team	
19	Informal testing	6.0 d	10/3/13	10/10/13	0 %	144.0	A&M Team, Governance Team, Content Team	
20	Test script development	5.0 d	10/4/13	10/10/13	0 %	40.0	Governance Team	
21	Sprint retrospective & planning	1.0 d	10/10/13	10/10/13	0 %	32.0	A&M Team, Content Team, Governance Team, SOA Team	
22	Sprint 2 Complete	0.0 d	10/10/13	10/10/13	0 %	0.0		
23	Sprint 3 (User / role management & reports)	21.0 d	10/11/13	11/8/13	0 %	344.0		
24	Development / Configuration	15.0 d	10/11/13	10/31/13	0 %	120.0	SOA Team	
25	Demo / Walkthrough	1.0 d	10/31/13	10/31/13	0 %	8.0	SOA Team	

Initial Release of CDISC SHARE is planned early 2014

What is the Potential Value of SHARE?

- Improves **data quality** based upon better definitions, change control
- Improves **data consistency**, encourages data re-use and facilitates aggregation of data and comparisons across organizations
- Improves **data exchange**, sharing, workflow and collaboration among multiple parties with clear, unambiguous standardised definitions
- Supports ability for 2 computers to understand information without direct human interpretation (**interoperability**)
- Provides **reduction in costs** resulting from maintaining individual (and different) dictionaries within research organizations
- **Improves the speed** by which we develop new standards among all stakeholders with consistent, reliable governance
- Maintains version traceability, **change control** to allow impact analysis

Agenda

1

FDA Submission Landscape

2

Evolution of CDISC Models

3

Development of Standards

4

CDISC SHARE

5

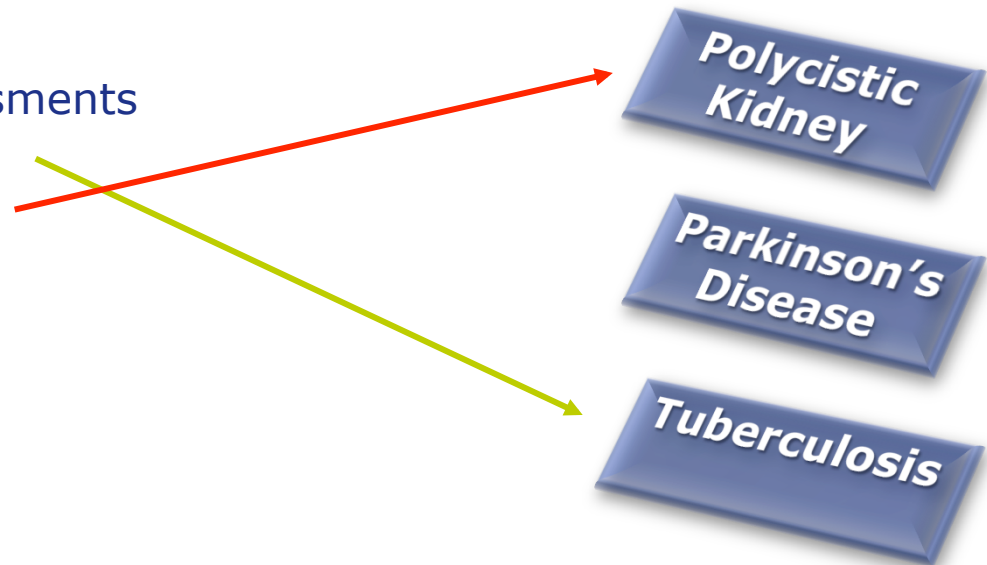
SDTM 3.1.4 Highlights

General Releases SEP 2013

- Public Review Period ended
 - SDTM IG v3.1.4 Batch 1
 - SDTM IG v3.1.4 Batch 2
 - SDTM IG v3.1.4 Batch 3

SDTM IG V3.1.4 Batch 1

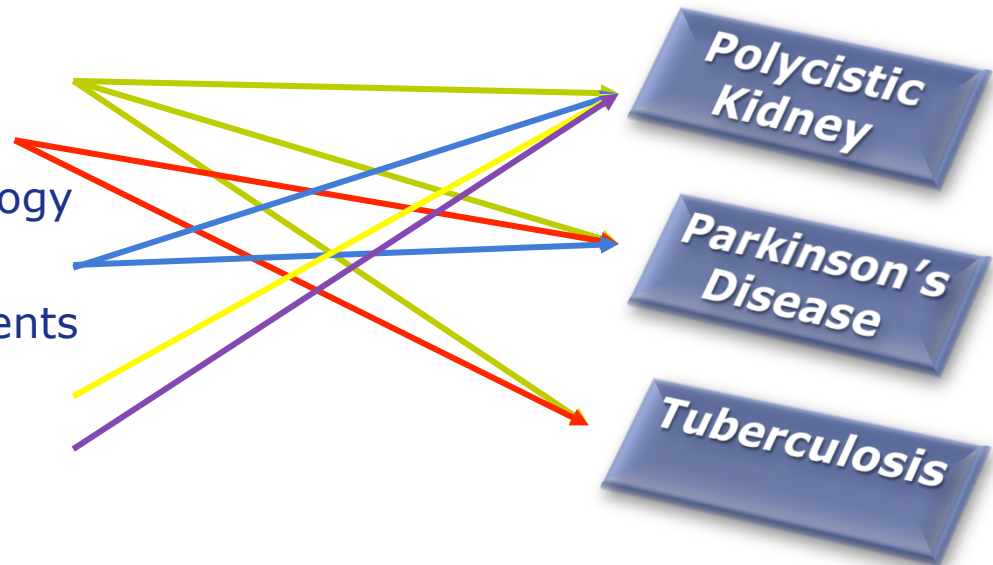
- Specifications for representing exposure data, Immunogenicity and Reproductive data
 - EC - Exposure as Collected
 - IS - Immunogenicity Assessments
 - SR - Skin Response
 - RD - Reproductive Details



SDTM IG V3.1.4 Batch 2

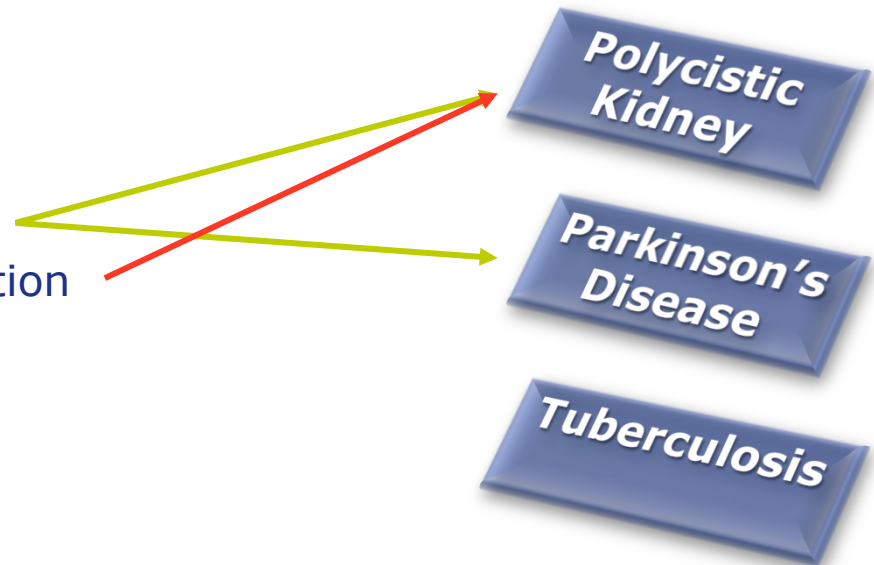
- Specifications for representing morphology, histopathology and physiology data

- MO - Morphology
- MI - Microscopic Findings
- CV - Cardiovascular Physiology
- PR - Procedures
- TD - Trial Disease Assessments
- DD - Death Details
- SS - Subject Status



SDTM IG V3.1.4 Batch 3

- Draft SDTM Domain, SDTM Model Document and SDTMIG for AP
 - SDTM 1.4
 - SDTMIG for Associated Persons
 - HO - Healthcare Resource Utilization



Link TA – QS – SDTMIG domains

Therapeutic Areas

- Oncology
- Alzheimer's Disease
- Pain
- Parkinson's Disease
- Polycystic Kidney Disease
- Tuberculosis
- Virology

Questionnaires

- Alzheimer's disease Assessment Scale – Cognitive (ADAS-Cog)
- Mini Mental Scale (MMSE)
- Audio Verbal Learning Test Version A (AVLTvA)
- Pain Intensity
- Brief Pain Inventory (BPI)
- EuroQol (EQ-5D)
- Karnofsky Performance Status Scale
- SF-36 Health Survey
- Hamilton Depression Scale
- Faces Pain Scale
- Mini Mental State Examination (MMSE)
- ...

SDTMIG 3.1.3

- TU – Tumor Identification
- TR – Tumor Results
- RS – Disease Response
- RELREC – Related Records

SDTMIG 3.1.4

- EC - Exposure as Collected
- IS - Immunogenicity Assessments
- SR - Skin Response
- RD - Reproductive Details
- MO - Morphology
- MI - Microscopic Findings
- CV - Cardiovascular Physiology
- PR - Procedures
- TD - Trial Disease Assessments
- DD - Death Details
- SS - Subject Status
- SDTM 1.4
- SDTMIG for Associated Persons
- HO - Healthcare Resource Utilization

Questions ?



Thank you for your attention

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