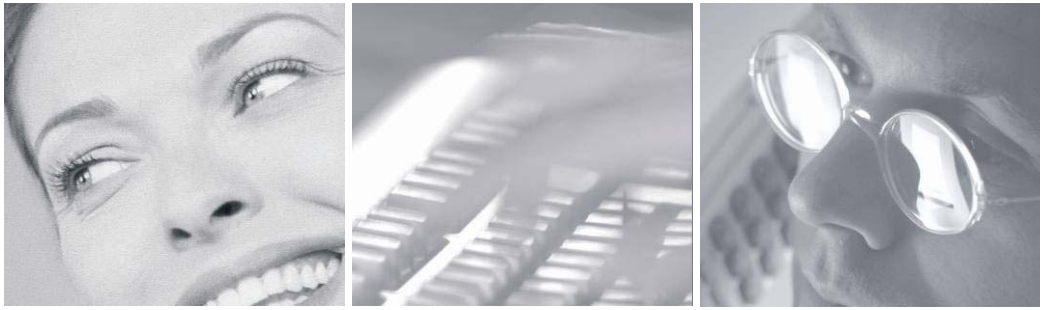
CDISC FSUG Meeting
18-Dec-2013
Paris, France

What's new?
Therapeutic Area Highlights



DRIVE YOUR PERFORMANCE

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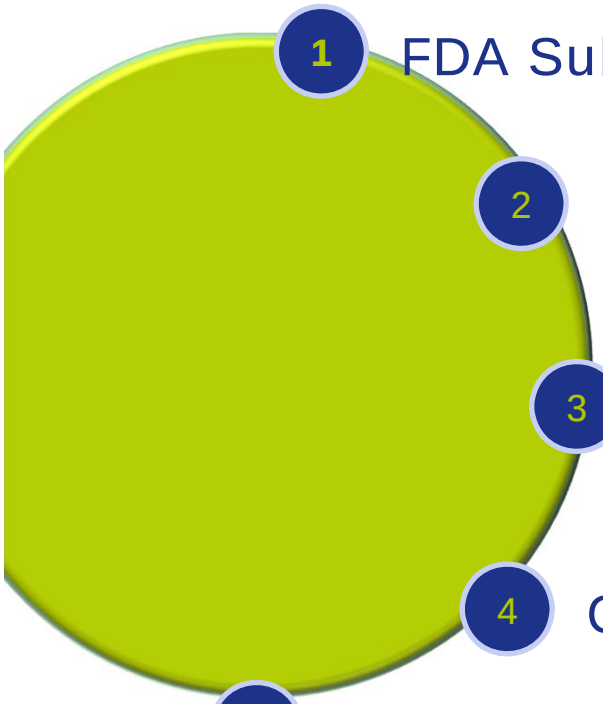
Agenda



1. FDA Submission Landscape
2. Evolution of CDISC Models
3. Development of Standards
4. CDISC SHARE
5. TA highlights

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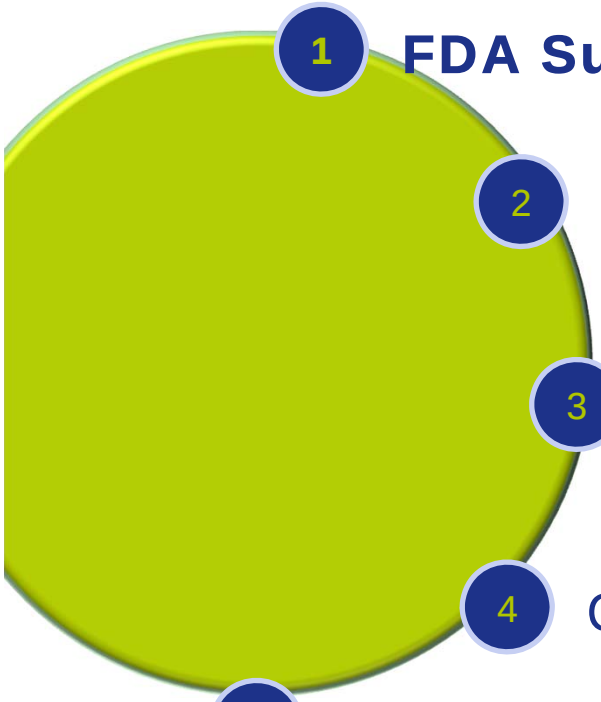
Agenda



1. **FDA Submission Landscape**
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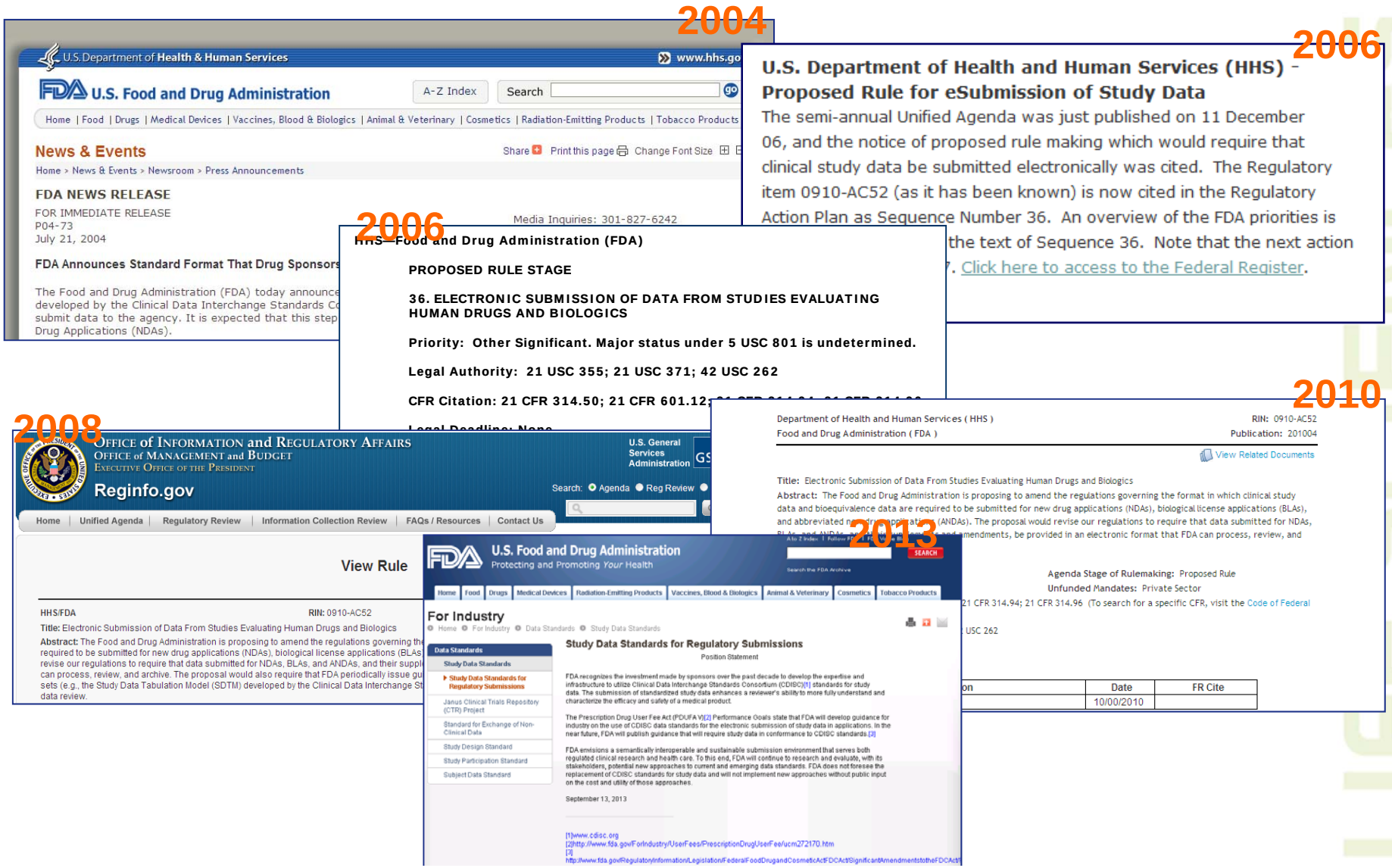
FDA Announcements 2004 - 2013



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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

Join the discussion on Regulatory Exchange

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.

RELATED LINKS

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

http://www.raps.org/focus-online/news/news-article-view/article/2934/

LIFE SCIENCES

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

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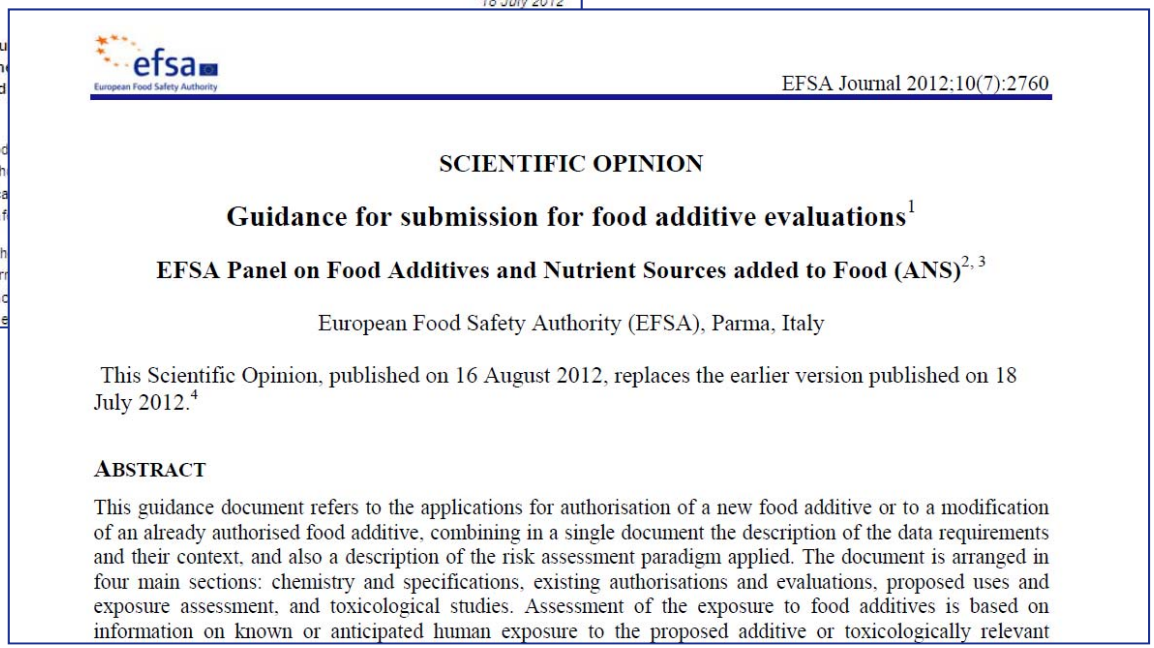
EFSA Announcements



http://www.efsa.europa.eu/en/efsajournal/doc/2760.pdf

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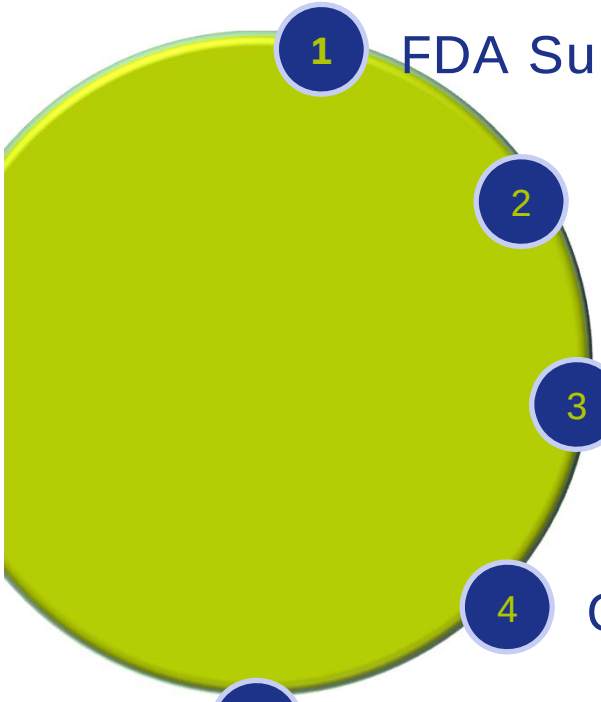
Agenda



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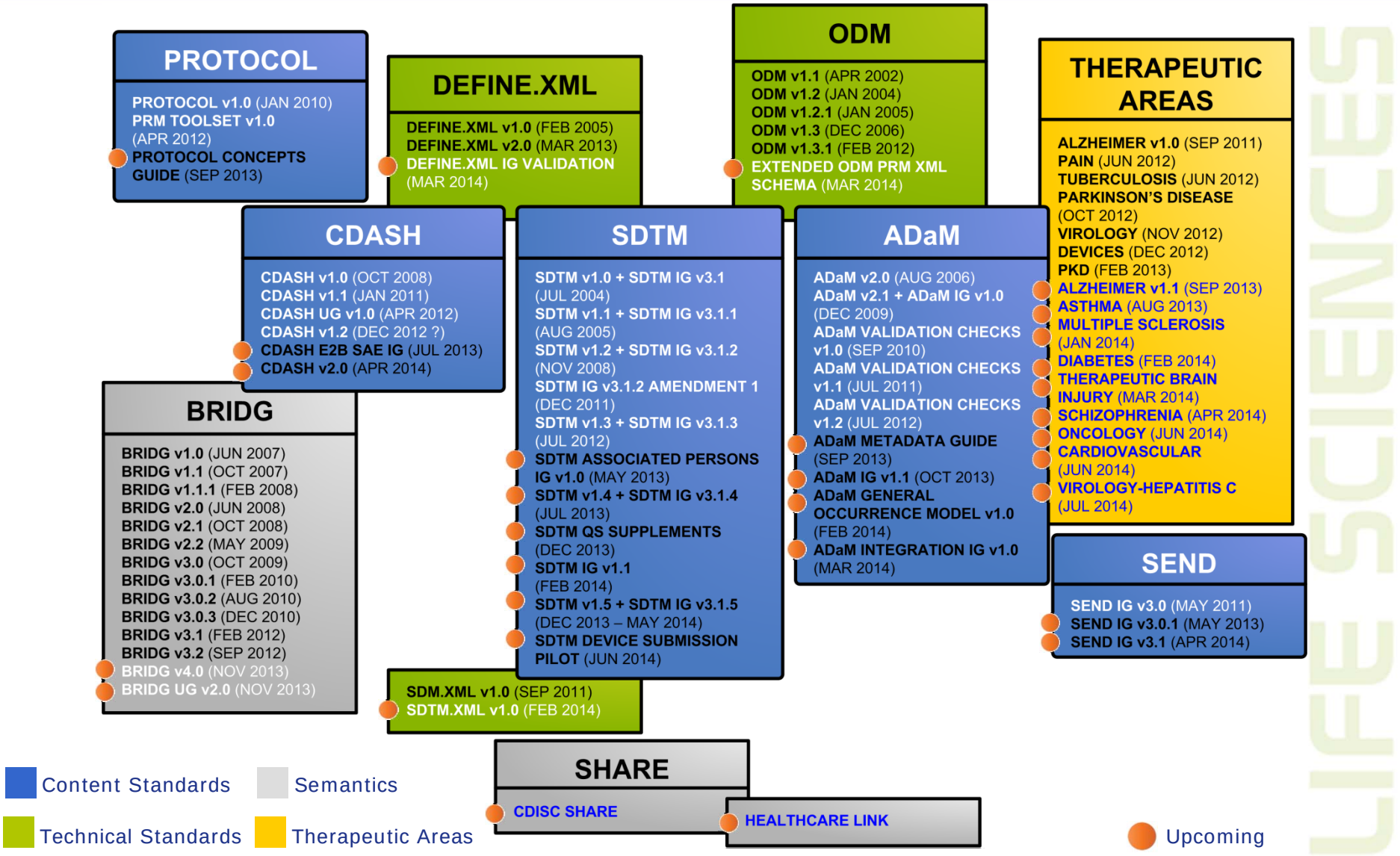
Overview of CDISC Models SEP 2013



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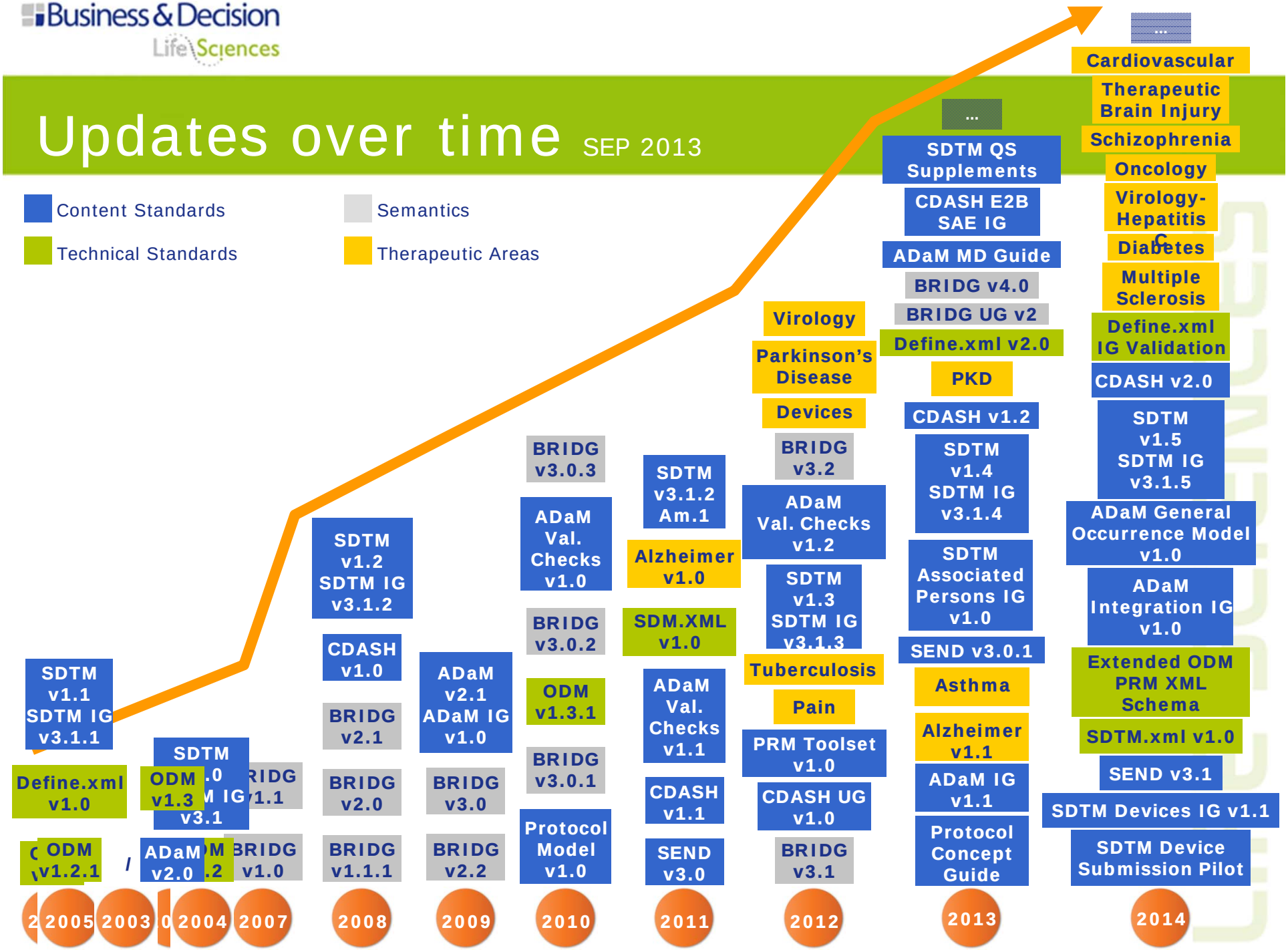
Updates over time SEP 2013

Content Standards | Semantics | Technical Standards | Therapeutic Areas



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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 20993, 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.htm*).[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/FormsSubmissionRequirements/ElectronicSubmissions/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; 8:45 am]

BILLING CODE 4160–01–P

[1] Section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), added by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112–144), requires electronic submission of drug and biologic applications beginning no earlier than 24 months after issuance of a final guidance. The final guidance, to be issued under section 745A of the FD&C Act following public notice and opportunity for comment, will specify the format required for such electronic submissions. The action announced in this notice, although applicable to electronic submission of standardized study data, is not being taken under section 745A of the FD&C Act and is not intended to trigger the mandatory submission requirements under that section.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0082]

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 guidances 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 20993–0002; 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 20993–0002, 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

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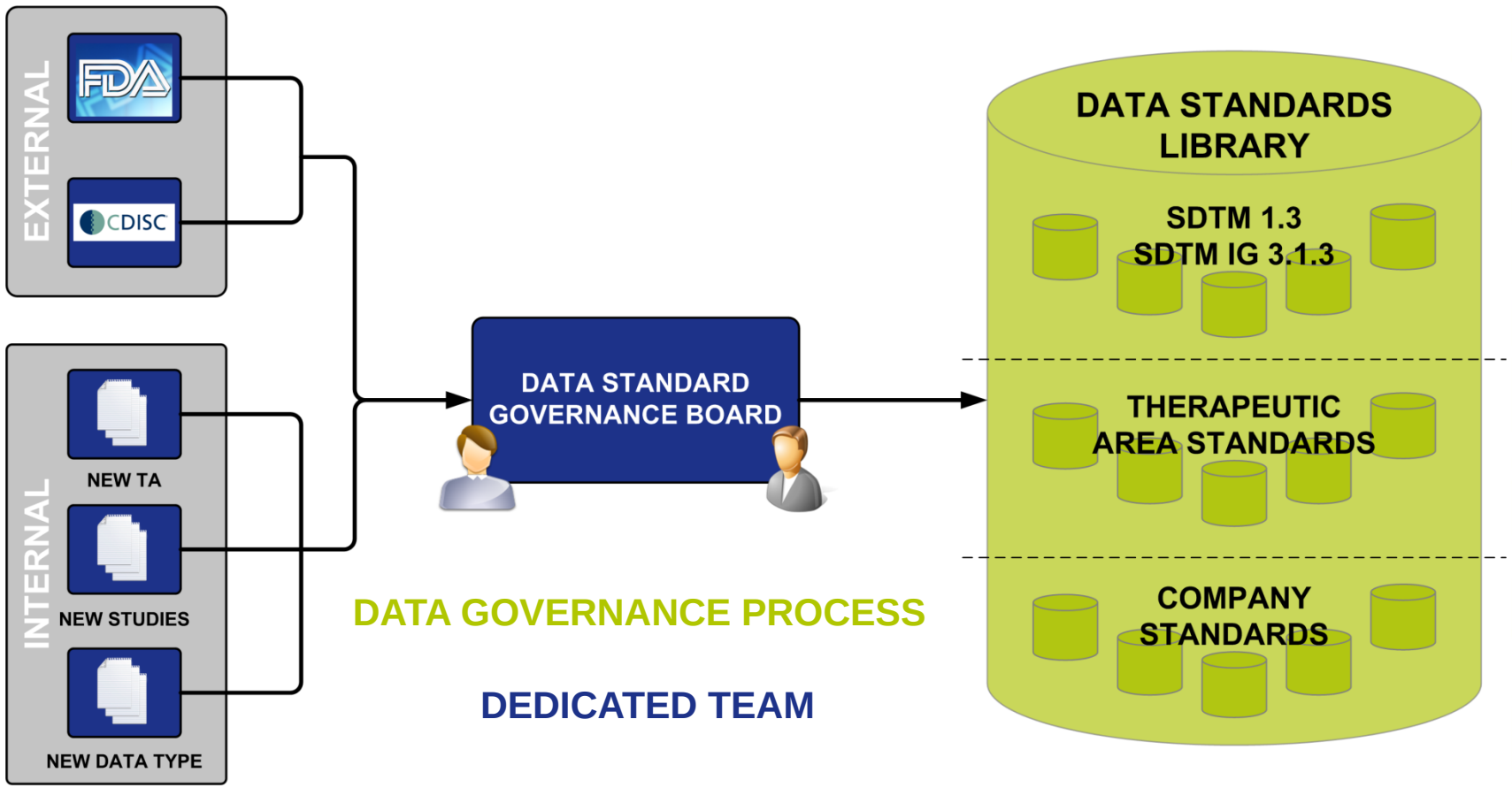
Data Standards Governance



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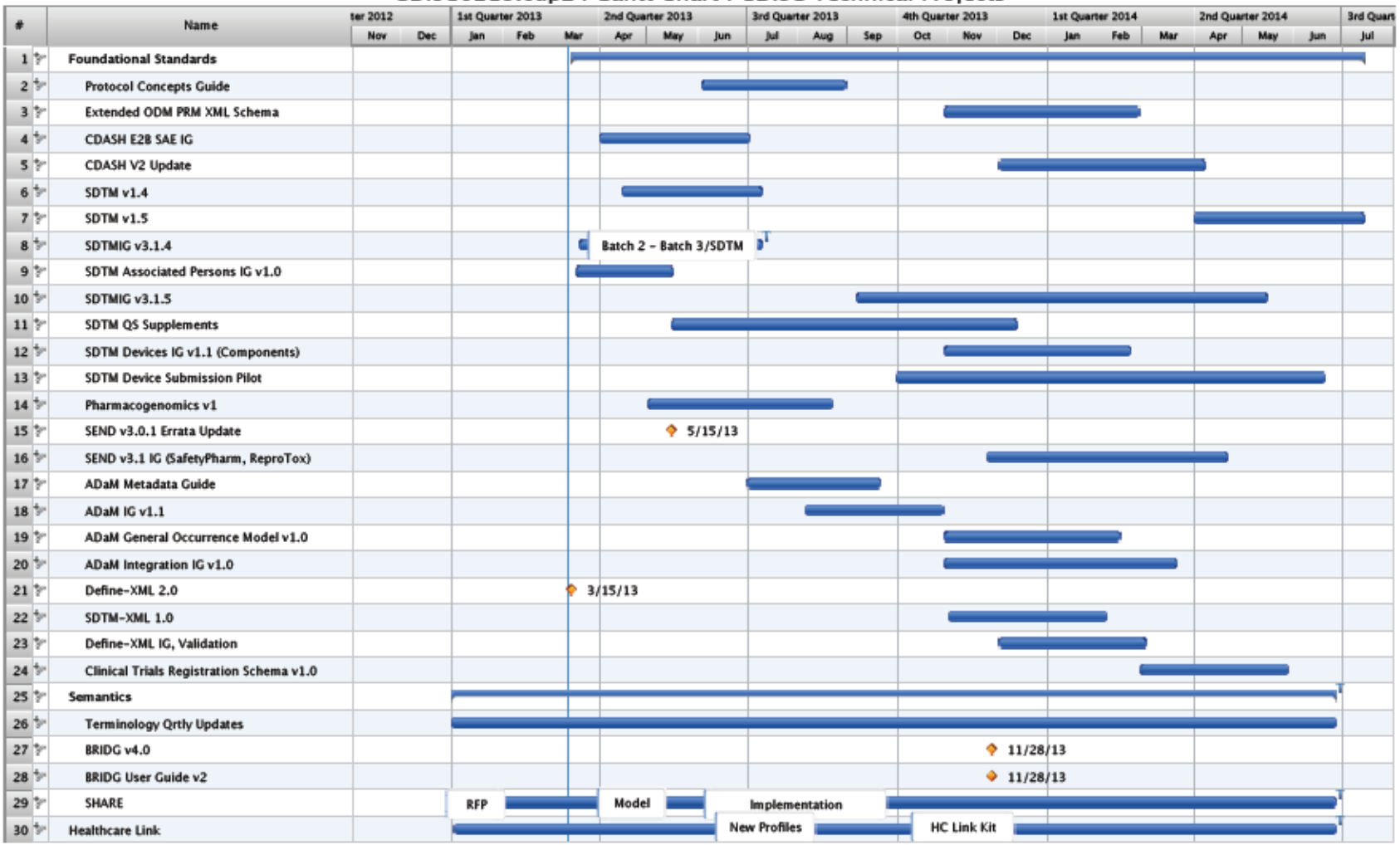
Technical Plan Project Schedule Published March 2013

CDISC0213.cdpz : Gantt Chart : CDISC Technical Projects



http://www.cdisc.org/stuff/contentmgr/files/0/5fbd2b7afd4cc3ae3274d97d44d7a8b0/misc/cdisc0213.pdf

LIFE SCIENCES

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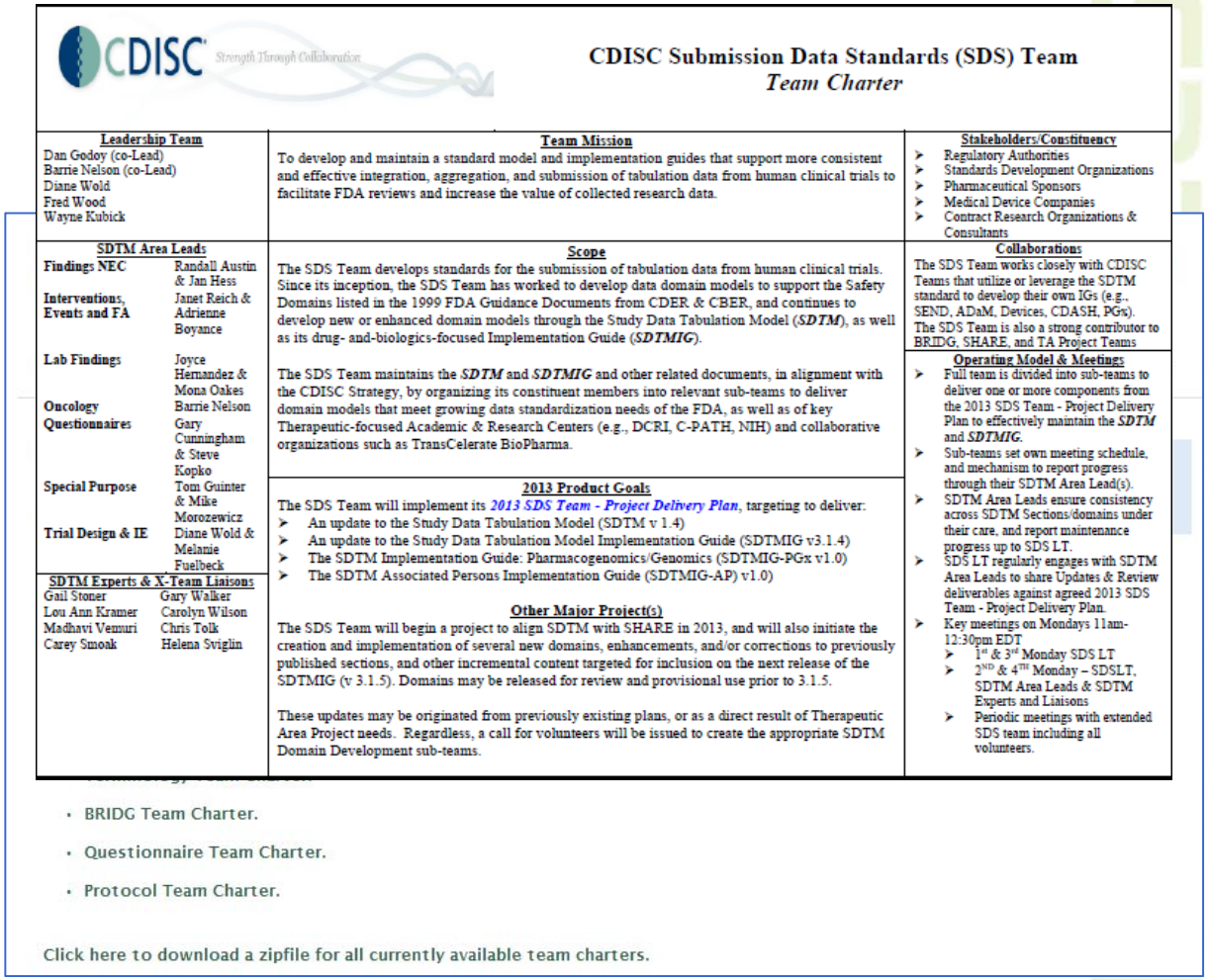
CDISC Team Charters

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



CDISC Strength Through Collaboration

CDISC Submission Data Standards (SDS) Team
Team Charter

Leadership Team
Dan Godoy (co-Lead)
Barrie Nelson (co-Lead)
Diane Wold
Fred Wood
Wayne Kubick

SDTM Area Leads

Findings NEC	Randall Austin & Jan Hess
Interventions, Events and FA	Janet Reich & Adrienne Boyance
Lab Findings	Joyce Hernandez & Mona Oakes
Oncology	Barrie Nelson
Questionnaires	Gary Cunningham & Steve Kopko
Special Purpose	Tom Guinter & Mike Morozewicz
Trial Design & IE	Diane Wold & Melanie Fuelbeck

SDTM Experts & X-Team Liaisons

Gail Stoner	Gary Walker
Lou Ann Kramer	Carolyn Wilson
Madhavi Vemuri	Chris Tolk
Carey Smoak	Helena Sviglin

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.

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 (***SDTM***), as well as its drug- and-biologics-focused Implementation Guide (***SDTMIG***).

The SDS Team maintains the ***SDTM*** and ***SDTMIG*** 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 *2013 SDS Team - Project Delivery Plan*, 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.

Stakeholders/Constituency
- Regulatory Authorities
- Standards Development Organizations
- Pharmaceutical Sponsors
- Medical Device Companies
- Contract Research Organizations & Consultants

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 ***SDTM*** and ***SDTMIG***.
- 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.

http://www.cdisc.org/team-charters

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CDISC Volunteers

NEW

CDISC

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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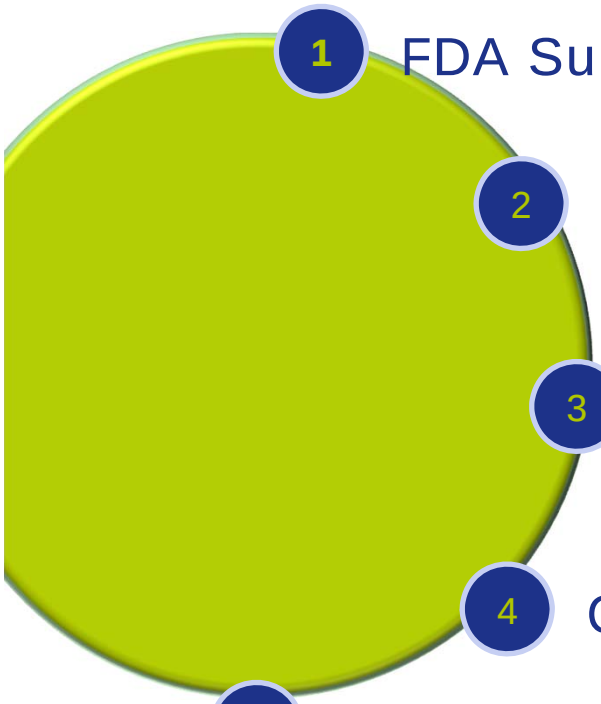
Agenda



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CFAST Therapeutic Area Standards

CFAST
Coalition for the Advancement of Standards and Therapies

- Joint initiative of CDISC & C-Path
- Development of therapeutic area standards along with FDA and TransCelerate Biopharma, Inc.

http://www.cdisc.org/therapeutic

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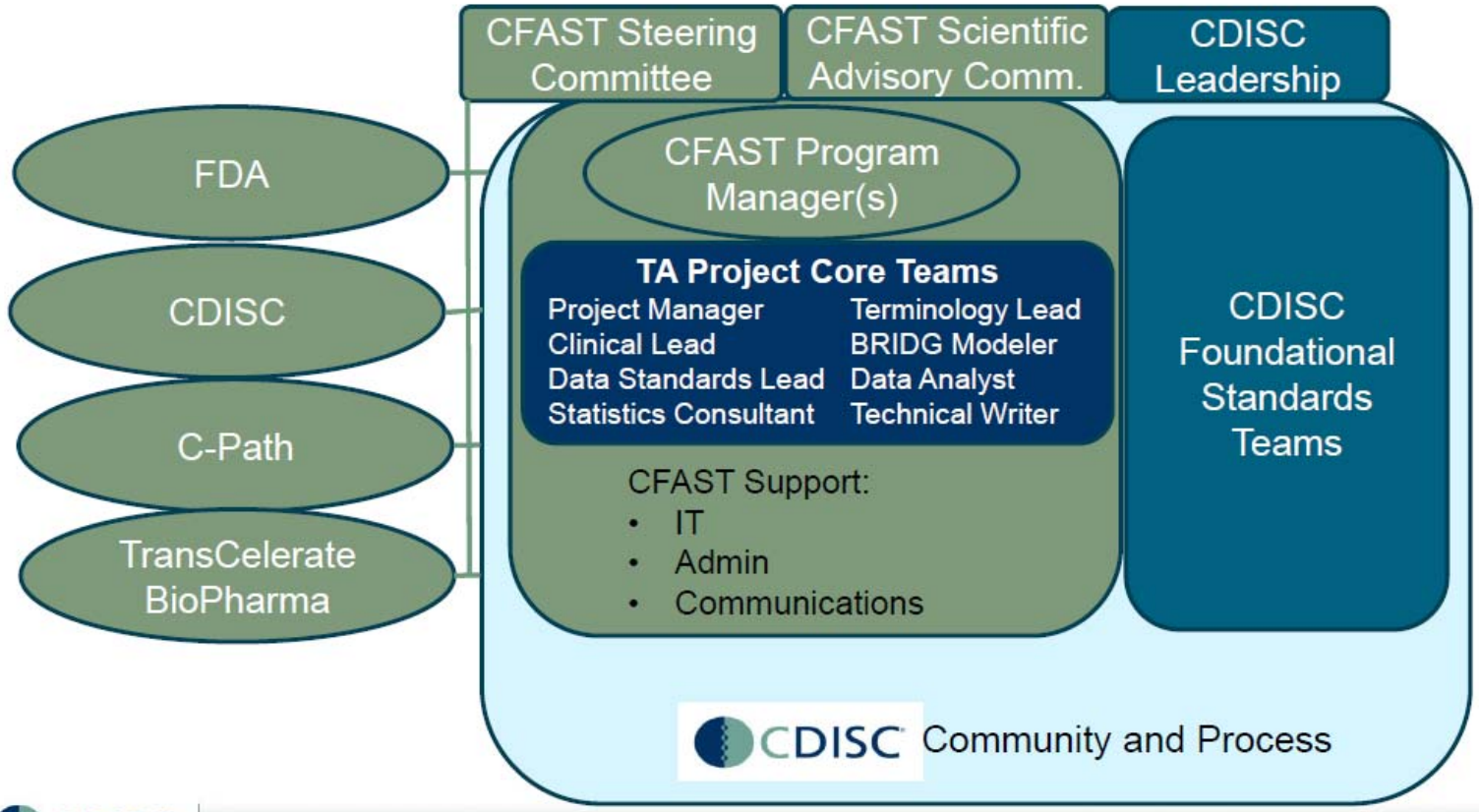
Therapeutic Area Standards Governance Model



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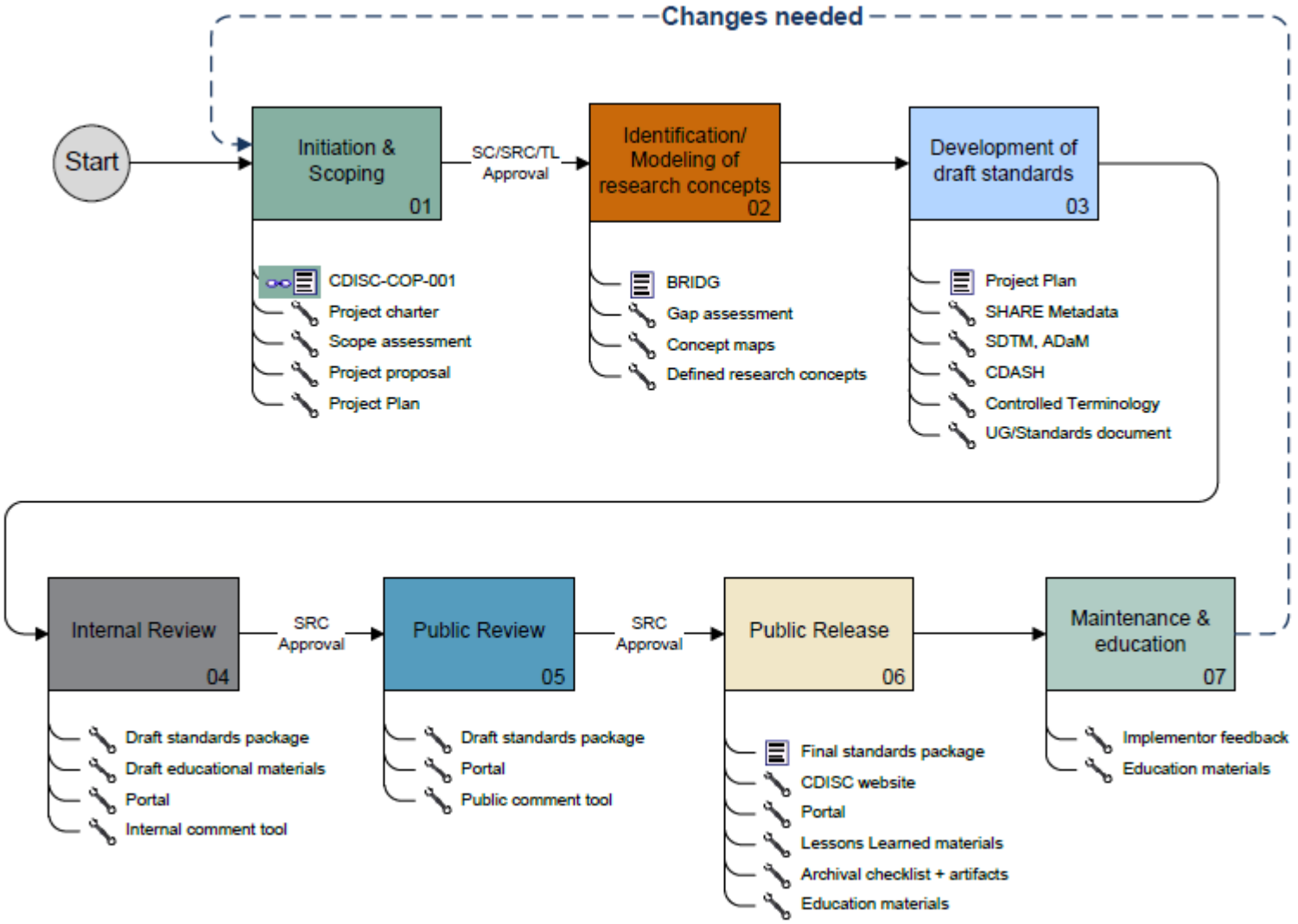
NEW

Enhanced Standards Development Process



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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*	*Concept modeling done prior to standards development step.*
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*						*SAC working to define scope and deliverables.*

Project Status: ● On track ● At risk ● Critical issues ▭ Stage ongoing ▭ Stage completed *Italics = Projected*

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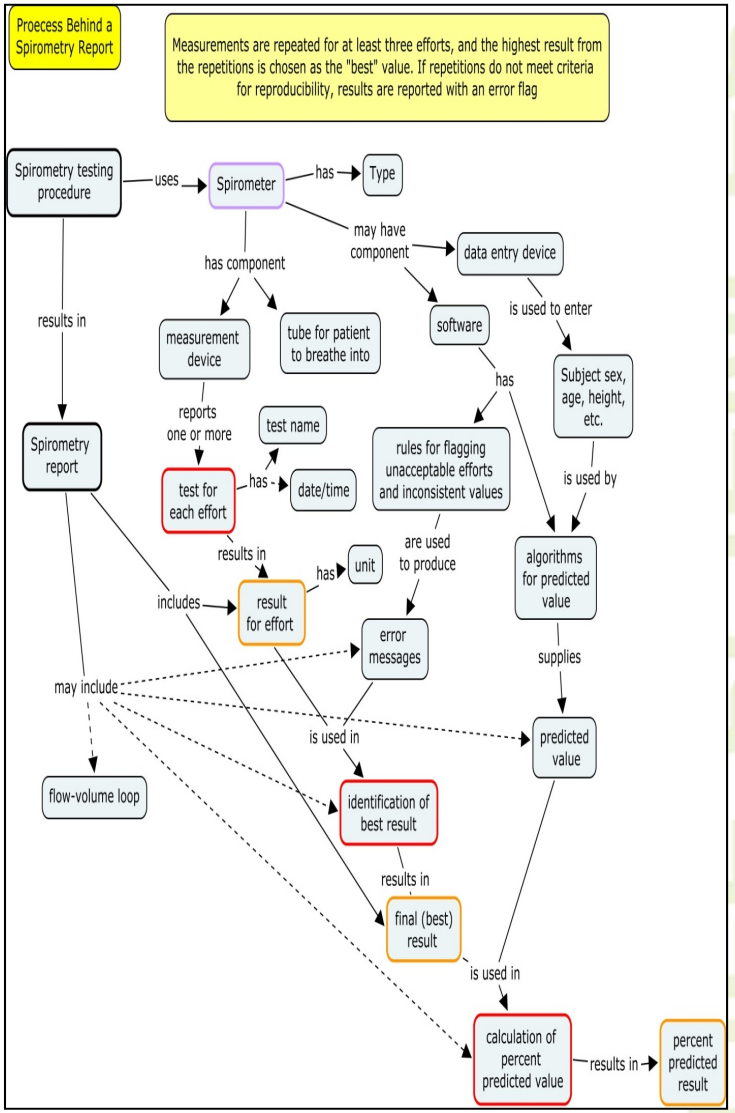
Enhanced Standards Development Process

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



Source : Cdisc Intrachange July 30 2013

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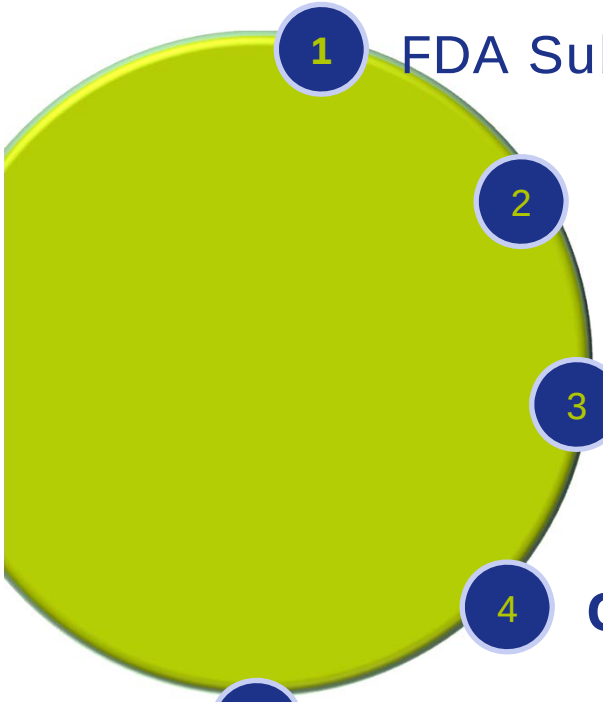
Agenda



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What is CDISC SHARE?

http://www.cdisc.org/cdisc-share

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What is CDISC SHARE?

Watch the video:

http://www.cdisc.org/cdisc-share

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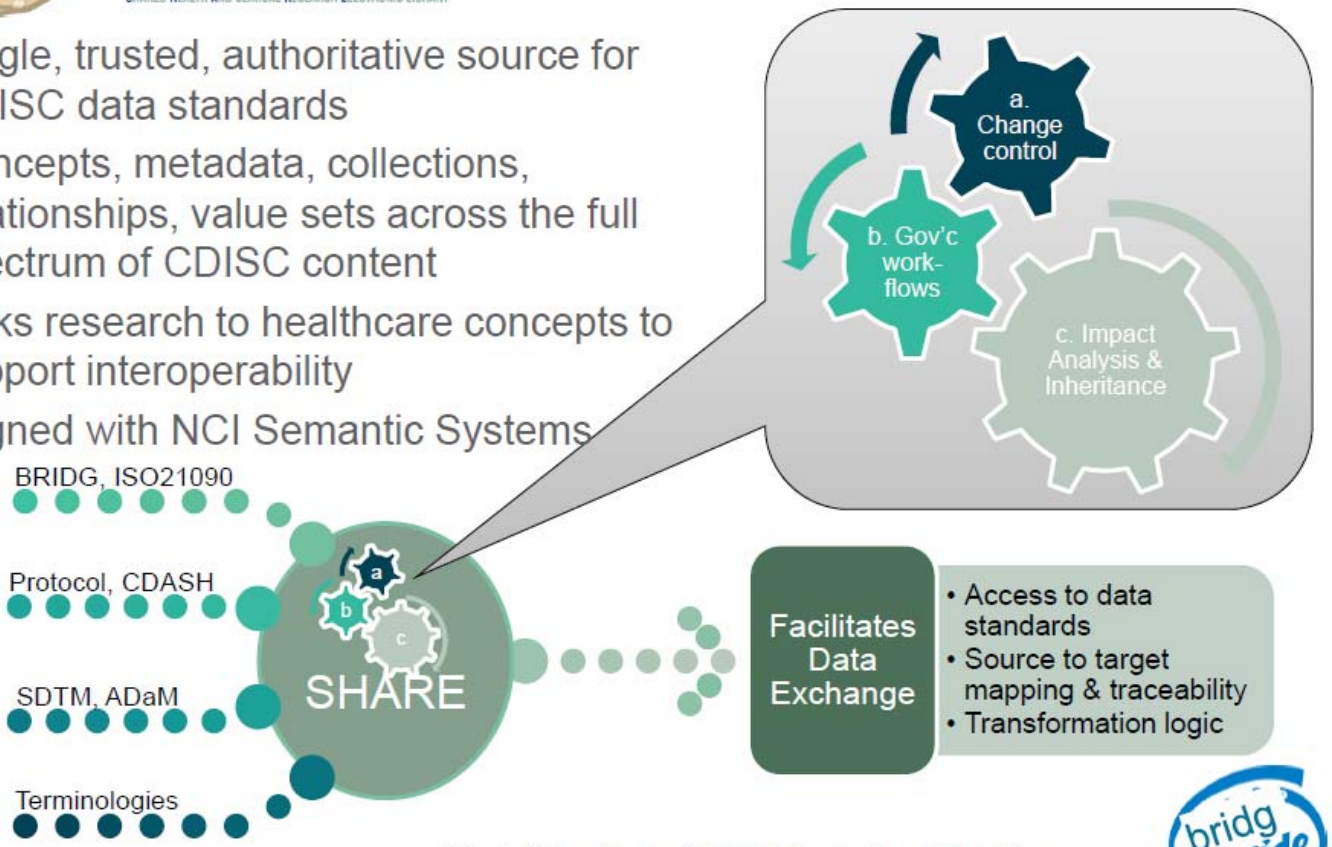
CDISC SHARE

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



Adapted from Source by Sue Dubman, Sanofi-Aventis

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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

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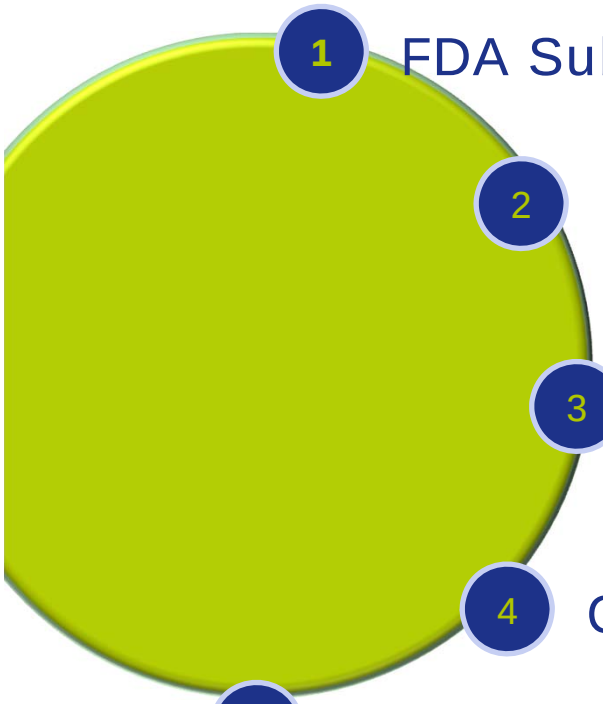
What is the Potential Value of SHARE?

- 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

Source : Cdisc Intrachange July 30 2013

LIFE SCIENCES

Agenda



1. FDA Submission Landscape
2. Evolution of CDISC Models
3. Development of Standards
4. CDISC SHARE
5. **TA highlights**

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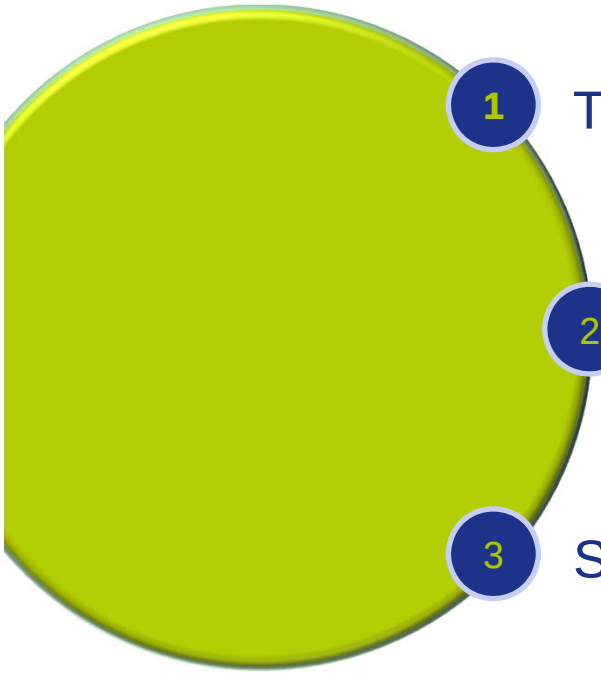
TA highlights



1. Therapeutic Area Overview
2. Questionnaires
3. SDTM 3.1.4 Highlights

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Overview

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

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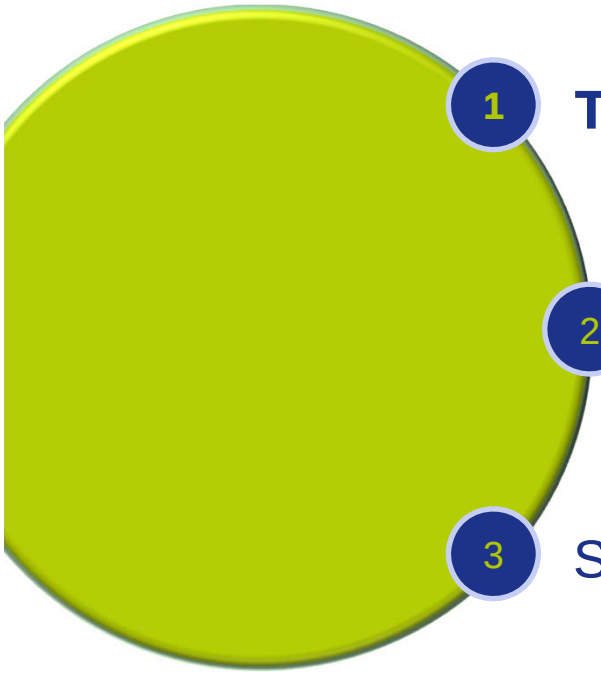
Agenda



1. **Therapeutic Area Overview**
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3. SDTM 3.1.4 Highlights

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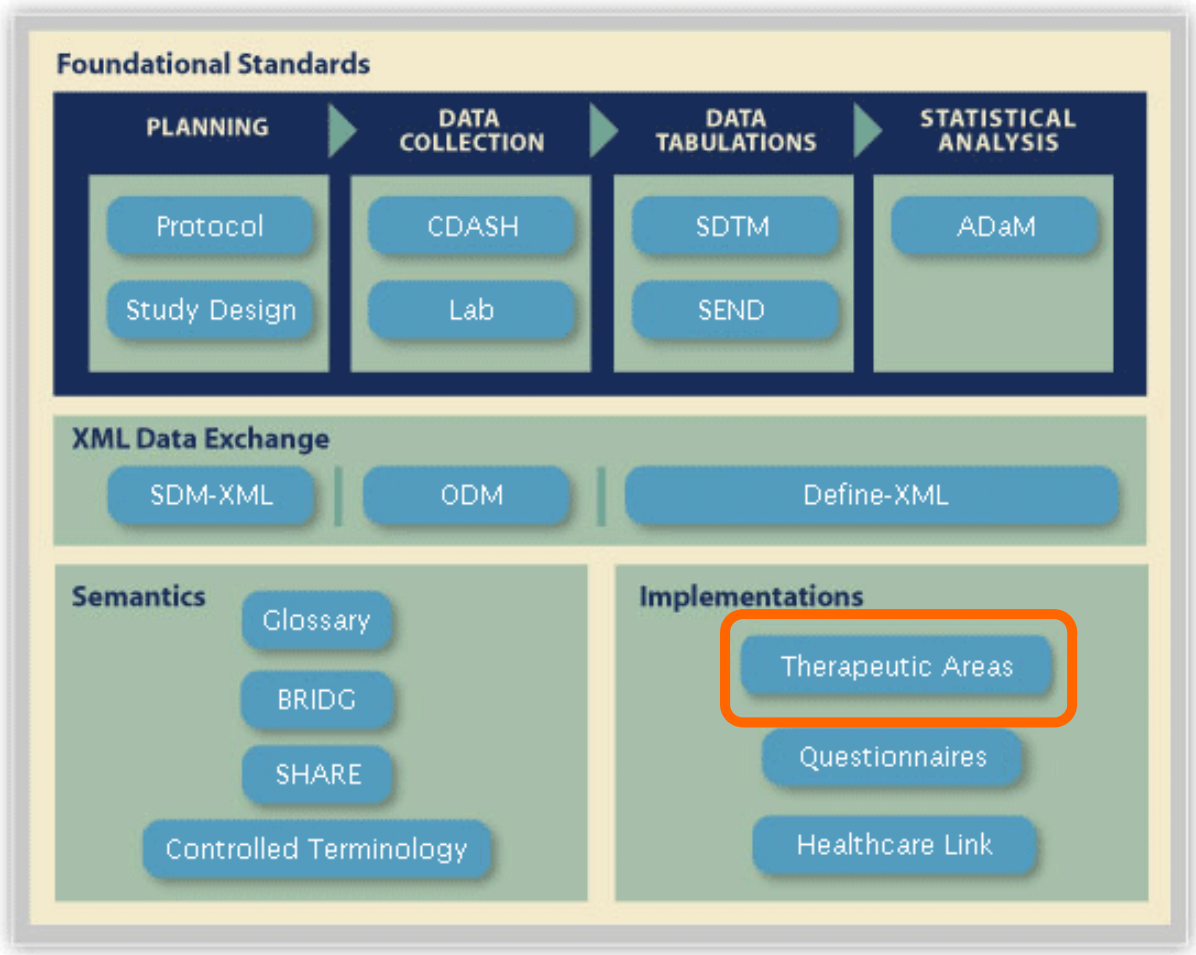
Therapeutic Area

Foundational Standards



http://www.cdisc.org/standards-and-implementations

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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 V1 – *Final*

* *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*

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Therapeutic Area Handling

- Intended as a supplement to the SDTM and SDTM IG
- The document does not replace or supersede the rules of the SDTM or SDTMIG
- Published as User Guides
- Includes:
  - Assumptions to the current SDTMIG
  - Implementation examples
  - Additional domains published in SDTMIG 3.1.4
  - Questionnaires specific for the Therapeutic Area

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Overview -PKD

Therapeutic Areas

Oncology
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Questionnaires

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…

SDTMIG 3.1.3

TU – Tumor Identification
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EC - Exposure as Collected
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PR - Procedures
TD - Trial Disease Assessments
DD - Death Details
SS - Subject Status
SDTM 1.4
SDTMIG for Associated Persons
HO - Healthcare Resource Utilization

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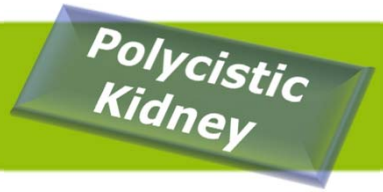
5. Polycystic Kidney Disease 1



The PKD v1.0 User Guide – Provisional version was published on 26 FEB 2013

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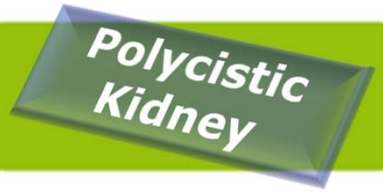
5. Polycystic Kidney Disease 2



The PKD v1.0 User Guide contains:

- Assumptions for existing SDTM standard domains DM, CM, SU, DS, MH, CE, LB, SC, VS, FA and QS
  - All assumptions present in the SDTMIG are applicable
  - Additional assumptions added for special implementations

1. The following SDTM demographic variables are used in PKD studies.
   a. RFSTDTC and RFENDTC values must correspond to the actual Active or Placebo study medication start and stop dates. First and last date of exposure to any protocol-specified treatment should be used to populate these fields. Any drug washout or placebo run-in dates should not be populated in RFSTDTC or RFENDTC. This logic insures that the study reference days derived in the study are based on the initial study drug exposure start date.
   b. DTHFL: Indicates the subject died. The value is either Y or null. It needs to be populated even when the death date is unknown.
   c. DTHDTC: Date/time of death for any subject needs to be in ISO 8601 format. This represents the date/time of death that is captured in the clinical-trial database.

- Examples of implementation in the published domains

mh.xpt

ROW	STUDYID	DOMAIN	USUBJID	MHSEQ	MHTERM	MHCAT	MHDUR	MHPRESP	MHOCCUR	MHSTDTC
1	STUDY01	MH	2324-P0001	1	Autosomal dominant polycystic kidney disease (ADPKD)	PRIMARY DIAGNOSIS		Y	Y	2010-09-28
2	STUDY01	MH	2324-P0001	2	Hypertension	PKD		Y	Y	2010-08-15
3	STUDY01	MH	2324-P0001	3	Infertility	PKD		Y	N	

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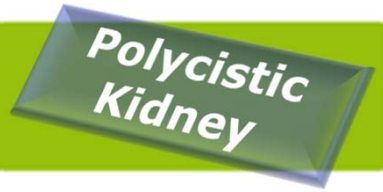
5. Polycystic Kidney Disease 3



The PKD v1.0 User Guide contains:

- Assumptions and examples for SDTM provisional domains:
  - Device Identifiers (DI)
  - Device Subject Relationships (DR)
  - Device Properties (DO)
  - Device in Use (DU)

LIFE SCIENCES

5. Polycystic Kidney Disease 4

The PKD v1.0 User Guide contains:

- SDTM draft domains DD, HO, MO, PF, PR, RP, SS, UR and Associated Persons
  - Briefly described with assumptions and examples
  - Inconsistencies might occur

4.4.1 Assumptions for Death Details Domain Model

All assumptions for the DD domain from the draft DD domain documentation apply for this user guide including those referenced in the CDISC Notes. Additionally, the following assumptions apply to PKD.

1. Terminology
   a. Controlled terminology is still under development for the PKD data standards, thus some values in the examples are not CDISC controlled terms. Verify demonstrated terminology against current standards before adopting it.
   b. See PKD special interest terminology values used for source of death and autopsy information.

4.4.2 Example for PKD Common Data Elements Death Details Domain Model

Example 1
This example shows the source of death and two manifestations from autopsy findings for USUBJECTID=2324-P0001

Row 1: Displays the source of death for USUBJID=2324-P001.
Rows 2-3: Display two separate autopsy findings for USUBJID=2324-P001 with the results categorized as ADPD Manifestations.

dd.xpt

Row	STUDYID	DOMAIN	USUBJID	DDSEQ	DDTESTCD	DDTEST	DDORRES	DDSTRESC	DDRESCAT	DDDTC
1	STUDY01	DD	2324-P0001	1	DTHSRC	Source of Death Information	Medical Records	Medical Records		2012-03-27
2	STUDY01	DD	2324-P0001	2	AUTOPFDG	Autopsy Findings	Kidney Cysts	Kidney Cysts	ADPKD Manifestations	2012-03-27
3	STUDY01	DD	2324-P0001	3	AUTOPFDG	Autopsy Findings	Intracranial Aneurysm	Intracranial Aneurysm	ADPKD Manifestations	2012-03-27

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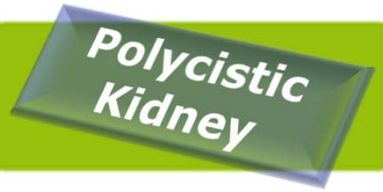
5. Polycystic Kidney Disease 5

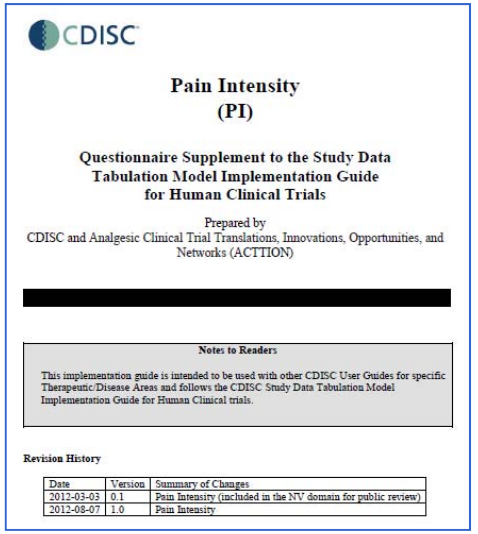


- Common Data Elements (CDE) are used to create the PKD Data Standards

- PKD Labs Terminology Guide has been provided

	A	B	C	D	E	F	G	H
1	**Labs of interest for PKD Mapping**	**Preferred Units**	**CDISC LBTESTCD Terminology**	**CDISC LBTEST TERMINOLOGY**	**LBCAT**	**LBSCAT**	**LBSPEC**	**LBDUR**
2	Urine albumin	mg/dL	ALB	Albumin	URINALYSIS		URINE	
3	Urine albumin	mg/day	ALB	Albumin	URINALYSIS		URINE	PT24H
4	Serum albumin	g/dL	ALB	Albumin	CHEMISTRY		SERUM	
5	Urine albumin/ creatinine ratio	mg/mmol	ALBCREAT	Albumin/Creatinine	URINALYSIS		URINE	
6	Serum:Bicarbonate	mEq/L	BICARB	Bicarbonate	CHEMISTRY		SERUM	
7	Serum bilirubin	mg/dL	BILI	Bilirubin	CHEMISTRY		SERUM	
8	Blood urea nitrogen	mg/dL	BUN	Blood Urea Nitrogen	CHEMISTRY		SERUM	
9	Serum Calcium	mg/dL	CA	Calcium	CHEMISTRY		SERUM	
10	Urine calcium	mg/dL	CA	Calcium	URINALYSIS		URINE	
11	Urine calcium	mg/day	CA	Calcium	URINALYSIS		URINE	PT24H
12	Creatinine clearance estimated by Cockroft-Gault corrected for BSA	mL/min/1.73m^2	CCLCGBSA	Creat Clear Cockroft-Gault Est Corr BSA	URINALYSIS	KIDNEY CLEARANCE ESTIMATES	URINE	

- Specific Questionnaires created for
  - E.g. Pain Intensity



CDISC

Pain Intensity (PI)

Questionnaire Supplement to the Study Data Tabulation Model Implementation Guide for Human Clinical Trials

Prepared by
CDISC and Analgesic Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION)

[redacted]

Notes to Readers

This implementation guide is intended to be used with other CDISC User Guides for specific Therapeutic/Disease Areas and follows the CDISC Study Data Tabulation Model Implementation Guide for Human Clinical trials.

Revision History

Date	Version	Summary of Changes
2012-03-03	0.1	Pain Intensity (included in the NV domain for public review)
2012-08-07	1.0	Pain Intensity

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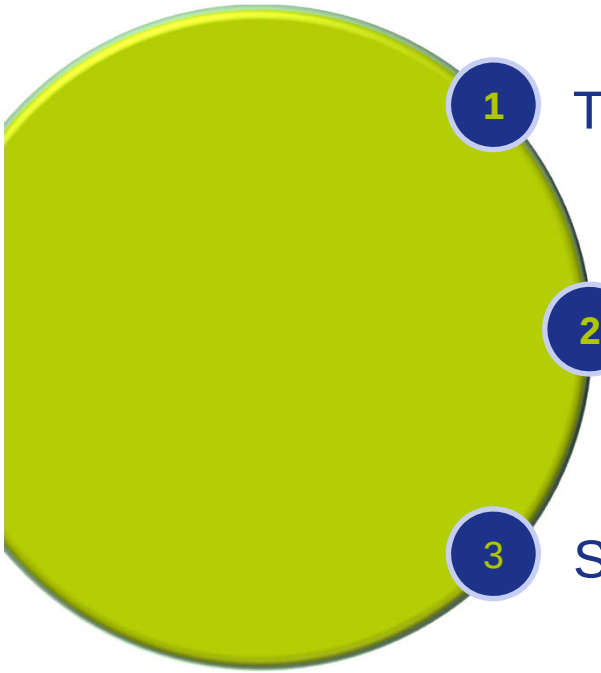
Agenda



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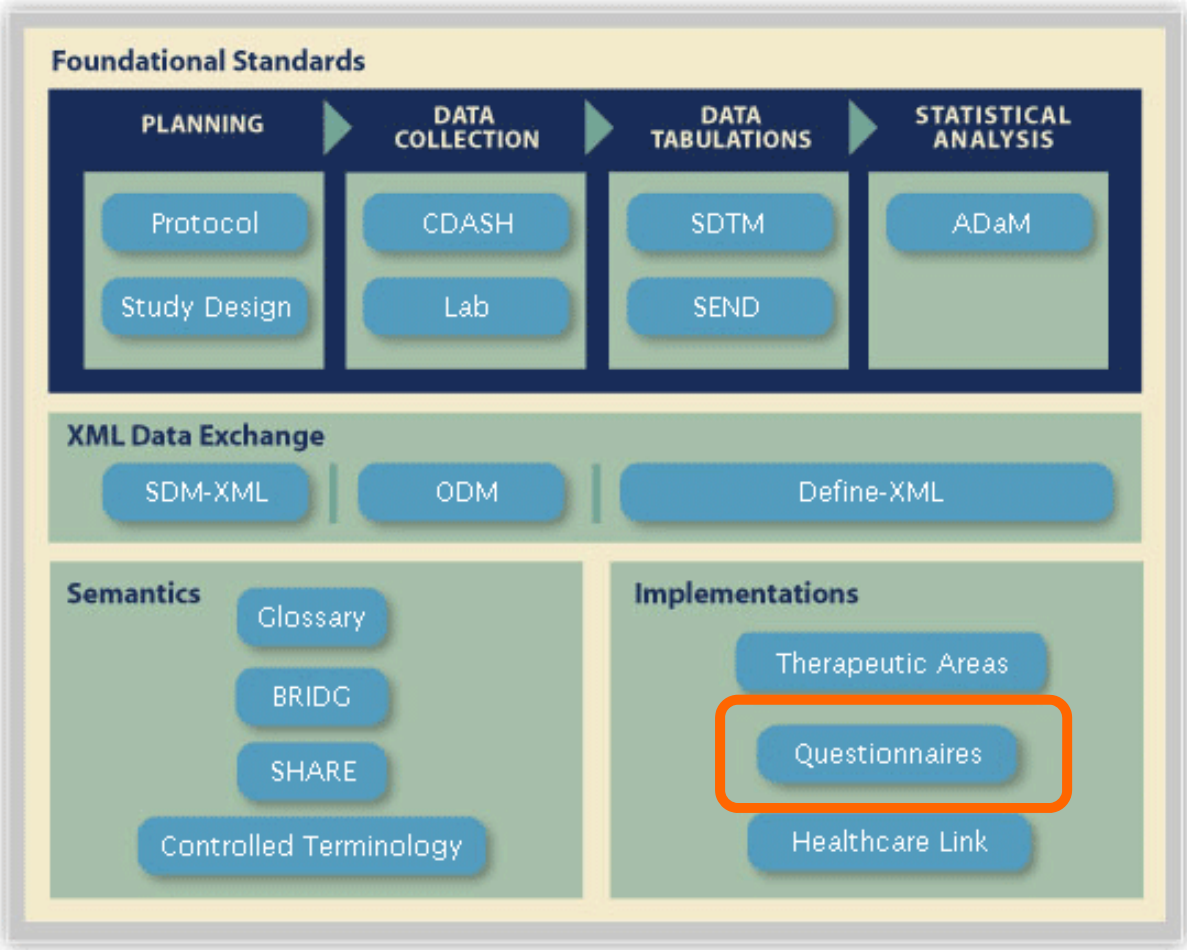
Questionnaires

Foundational Standards



http://www.cdisc.org/standards-and-implementations

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CDISC Questionnaire Supplements

Questionnaire	Version	Short Name (QSCAT)	Permission	Release Date
General Clinical Global Impression	V1.0	GENERAL CLINICAL GLOBAL IMPRESSIONS	Public Domain	August 7, 2012
Geriatric Depression Scale (GDS)	V1.0	GDS	Public Domain	May 22, 2013
Geriatric Depression Scale Short Form (GDS SHORT FORM)	V1.0	GDS SHORT FORM	Public Domain	May 22, 2013
General-Pain Intensity	V1.0	PAIN INTENSITY	Public Domain	August 7, 2012
General-Pain Relief	V1.0	PAIN RELIEF	Public Domain	August 7, 2012
Hamilton Anxiety Rating Scale (HAM-A)	V1.0	HAM-A	Public Domain	May 16, 2013
Hamilton Depression Rating Scale 17-Item (HAMD 17)	V1.1	HAMD 17	Public Domain	May 15, 2013
Hamilton Depression Rating Scale 21-Item (HAMD 21)	V1.0	HAMD 21	Public Domain	May 29, 2013
Karnofsky Performance Scale	V1.0	KPS SCALE	Public Domain	August 7, 2012
McGill Pain Questionnaire (Short-Form) MPQ 2	V1.0	SHORT-FORM MPQ-2	Granted	August 7, 2012
Michigan Neuropathy Screening Instrument (MNSI)	V1.0	MNSI	Public Domain	August 7, 2012
Mini Mental Scale (MMSE)	V1.0	MMSE	Not Permitted	August 7, 2012
Movement Disorder Society Version of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS)	V1.0	MDS-UPDRS	Granted	December 18, 2012
Roland-Morris Disability Questionnaire (RDQ)	V1.0	RDQ	Public Domain	August 7, 2012
Screener and Opioid Assessment for Patients with Pain (SOAPP-R)	V1.0	SOAPP-R	Granted	August 7, 2012
Short Form 36 health survey standard, US Version 1.0 (SF36 v1.0 Standard)	V1.0	SF36 v1.0 STANDARD	Not Permitted	August 7, 2012
Unified Parkinson's Disease Rating Scale (UPDRS)	V1.0	UPDRS	Granted	December 18, 2012
Work Productivity and Activity Impairment Questionnaire - Specific Health Problem (WPAI-SH)	V1.0	WPAI-SHP	Public Domain	August 7, 2012

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Difficulties

- Questionnaires are either in the public domain or have copyright requirements
  - ***Public Domain*** → available without further permission
  - ***Copyright*** → CDISC obtain permission from holders before implementing
    - *Copyright only relates to the creation of CDISC QS Data Standard, not the use of the questionnaire in clinical studies*
- Some Questionnaires did not get permission for publication (EQ-5D, SF-36, …) so no standardization can be done

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SF-36 Health Survey
Hamilton Depression Scale
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SDTMIG 3.1.3

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TR – Tumor Results
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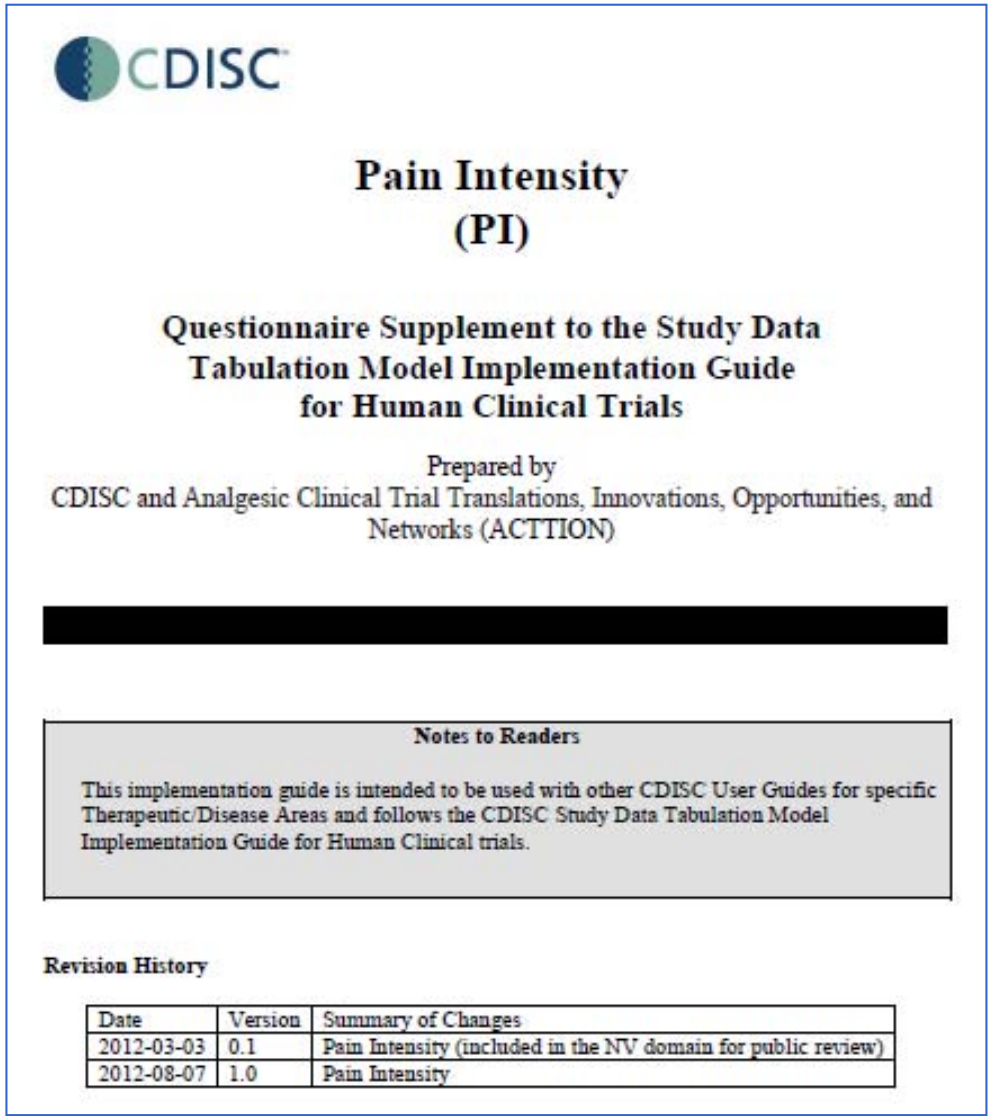
PR - Procedures
TD - Trial Disease Assessments
DD - Death Details
SS - Subject Status
SDTM 1.4
SDTMIG for Associated Persons
HO - Healthcare Resource Utilization

Business & Decision Life Sciences

Pain Intensity Questionnaire



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2012-08-07	1.0	Pain Intensity

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Business & Decision Life Sciences

Important

- Controlled terminology is still under development thus some values in the examples are not CDISC controlled terms

- Verify demonstrated terminology against current standards before adopting it
  - Last version 2013-06-28 present at the NCI EVS website
  - http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc

- QSTEST should be created according to the Questionnaire Naming Rules

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Questionnaire Naming Rules

QSCAT Codelist Rules	Notes	Comments
Submission Value: A name that uniquely identifies an individual instrument. Where possible, use the most common name that the questionnaire is known by. This may be an acronym or a complete name of the questionnaire. *Upper case text only.*		
Synonym: A short code name for the questionnaire used as the basis of the QSTESTCD and QSTEST. It should be no more than 6 characters but may need to be shortened depending upon how many items are included in a questionnaire. The version number should start with 01, but may be shortened to 1 to accommodate 8 characters within the QSTESTCD value. *Upper case text only.*	All questionnaires should have a version number even if there is only one version.	
Definition: The full name of the questionnaire including the version if available, followed by the questionnaire acronym in parenthesis, and the citation (for public domain instruments) or copyright details (for copyrighted instruments) in parentheses. *Sentence case text format.*		

Rules for Questionnaires	Notes	Comments
QSTESTCD: A code limited to 8 characters beginning with the QSCAT Synonym followed immediately by the item number. Where item numbers are included on the original questionnaire, the QSTESTCD faithfully represents the questionnaire with alpha-numeric characters as provided. In the absence of item numbers on the original questionnaire, sequential numbering is used beginning with 01. *Upper case text only.*		
QSTEST: A brief description of each questionnaire item's intent. Beginning with the QSCAT Synonym, followed by a hyphen, with no spaces before or after the hyphen. Item text may be shortened to maintain the 40 character limit as needed, but should faithfully retain the question intent. *Title case text format after the hyphen.*	Title Case: use lower case text for the following words: a, an, and, as, at, but, by, for, in, nor, of, on, or, per, to, the	The following rules are intended primarily to facilitate consistency: - *Capitalize the first and last words in titles except as part of a name, and capitalize all other major words (nouns, pronouns, verbs, adjectives, adverbs, and some conjunctions.* - *Lowercase prepositions of 3 characters or less, except when used adverbially or adjectivally (down in Turn Down, on in The On Button, to in Come To, etc.) or as part of a Latin expression used adjectivally or adverbially (De Facto, In Vitro, etc.).*
Definition: The full questionnaire name and reproduction of each questionnaire item. The full name of the questionnaire is followed by a hyphen with a space before and after the hyphen. The verbatim item text, including punctuation, follows. For clarity, text faithful to the item intent can be substituted where questionnaire formatting leaves verbatim item text ambiguous. Instructions, information in italics or a list of valid responses are not included. All definitions end with punctuation; either as it appears in the questionnaire or defaulted with a period. *Sentence case text format.*		

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Controlled Terminology

Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
Questionnaire Category	PI	PI01	The Pain Intensity (PI) questions were created by STANDARDS (Standardized Analgesic Database for Research, Discovery, and Submissions) and sponsored by ACTTION (Analgesic Clinical Trial Translations, Innovations, Opportunities, and Networks) www.acttion.org; 2012-08-07 v1.	STANDARDS Pain Intensity Questionnaire
Codelist Name	**CDISC Submission Value**	**CDISC Synonym(s)**	**CDISC Definition**	**NCI Preferred Term**
Pain Intensity Questionnaire Test Name	PI TEST	Pain Intensity Questionnaire Test Name	Pain Intensity test name.	CDISC Questionnaire PI v1 Test Name Terminology
Pain Intensity Questionnaire Test Name	PI01-Pain Intensity	PI01-Pain Intensity	Pain Intensity - Pain intensity for various time periods of evaluation.	PI - Pain Intensity For Various Time Periods of Evaluation
Pain Intensity Questionnaire Test Name	PI01-Average Pain Intensity	PI01-Average Pain Intensity	Pain Intensity - Average pain intensity for various time periods of evaluation.	PI - Average Pain Intensity For Various Time Periods of Evaluation
Pain Intensity Questionnaire Test Name	PI01-Minimum Pain Intensity	PI01-Minimum Pain Intensity	Pain Intensity - Minimum pain intensity for various time periods of evaluation.	PI - Minimum Pain Intensity For Various Time Periods of Evaluation
Pain Intensity Questionnaire Test Name	PI01-Maximum Pain Intensity	PI01-Maximum Pain Intensity	Pain Intensity - Maximum pain intensity for various time periods of evaluation.	PI - Maximum Pain Intensity For Various Time Periods of Evaluation
Pain Intensity Questionnaire Test Name	PI01-Least Pain Intensity	PI01-Least Pain Intensity	Pain Intensity - Least pain intensity for various time periods of evaluation.	PI - Least Pain Intensity For Various Time Periods of Evaluation
Pain Intensity Questionnaire Test Name	PI01-Worst Pain Intensity	PI01-Worst Pain Intensity	Pain Intensity - Worst pain intensity for various time periods of evaluation.	PI - Worst Pain Intensity For Various Time Periods of Evaluation
Pain Intensity Questionnaire Test Code	PI TESTCD	Pain Intensity Questionnaire Test Code	Pain Intensity test code.	CDISC Questionnaire PI v1 Test Code Terminology
Pain Intensity Questionnaire Test Code	PI0101	PI01-Pain Intensity	Pain Intensity - Pain intensity for various time periods of evaluation.	PI - Pain Intensity For Various Time Periods of Evaluation
Pain Intensity Questionnaire Test Code	PI0102	PI01-Average Pain Intensity	Pain Intensity - Average pain intensity for various time periods of evaluation.	PI - Average Pain Intensity For Various Time Periods of Evaluation
Pain Intensity Questionnaire Test Code	PI0103	PI01-Minimum Pain Intensity	Pain Intensity - Minimum pain intensity for various time periods of evaluation.	PI - Minimum Pain Intensity For Various Time Periods of Evaluation

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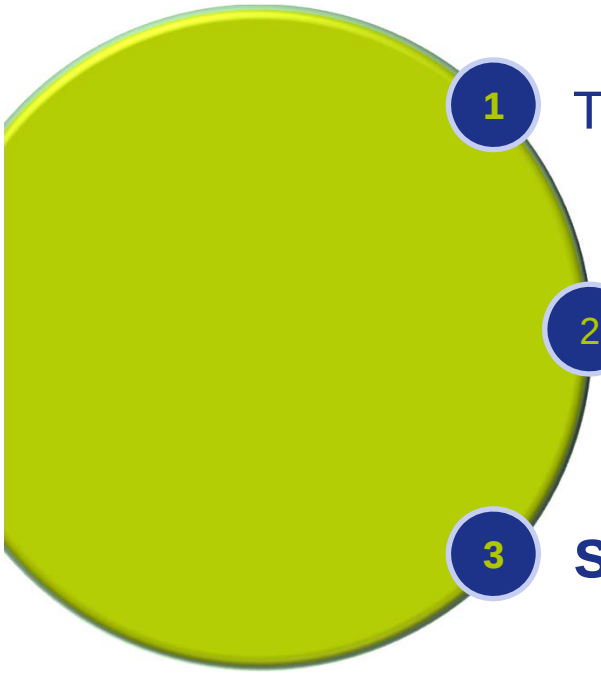
Agenda



1. Therapeutic Area Overview
2. Questionnaires
3. **SDTM 3.1.4 Highlights**

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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

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Overview PKD

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**

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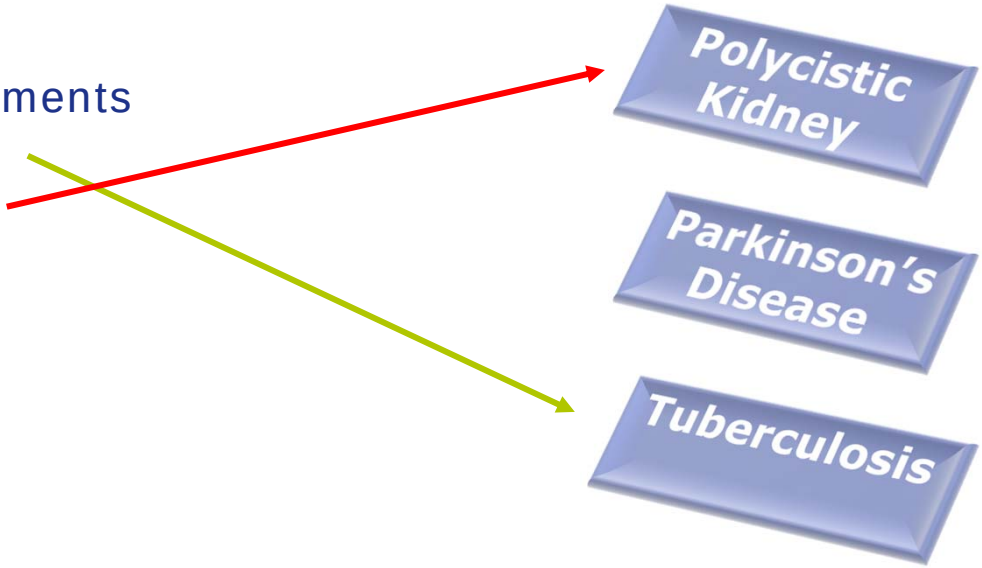
SDTM IG V3.1.4 Batch 1

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



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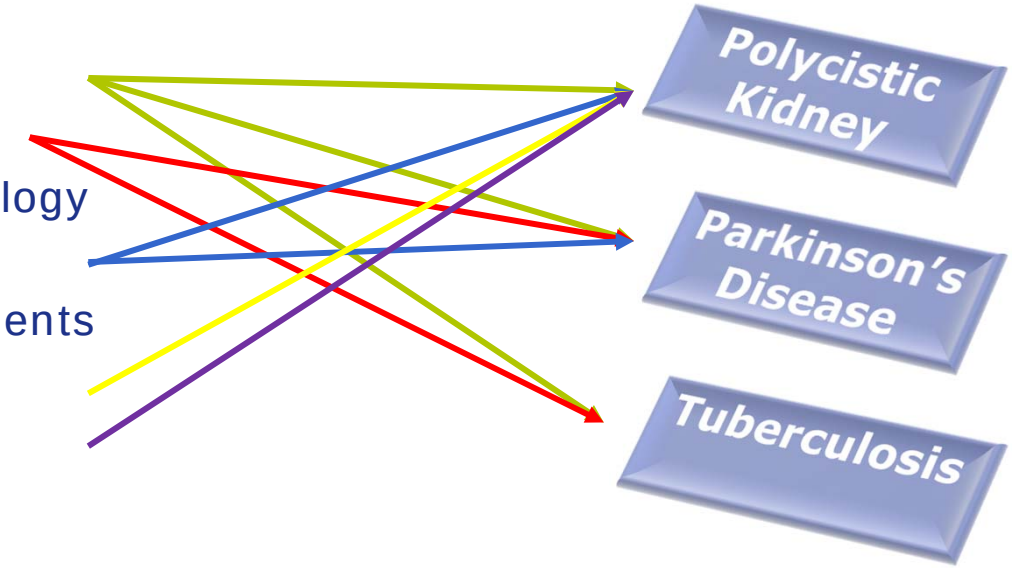
SDTM IG V3.1.4 Batch 2

- 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



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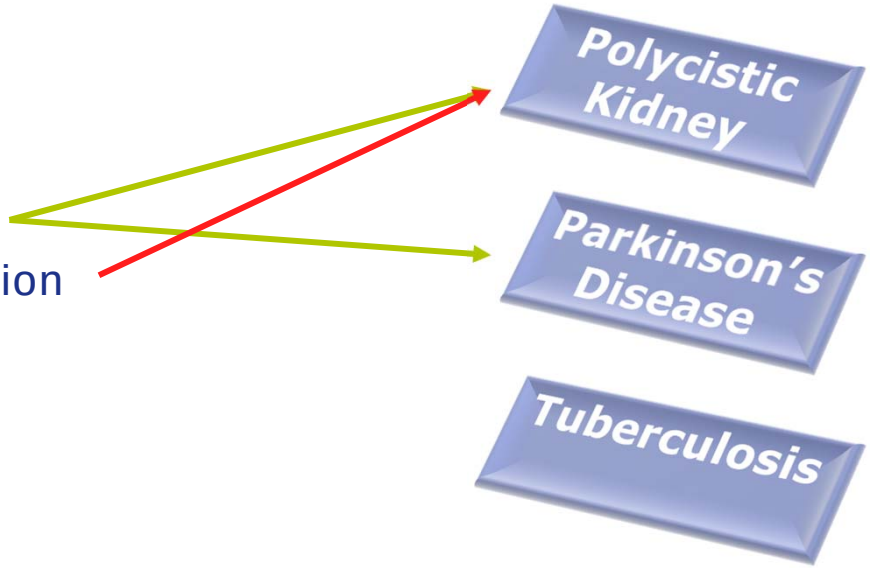
SDTM IG V3.1.4 Batch 3

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



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Questions ?

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Thank you for your attention

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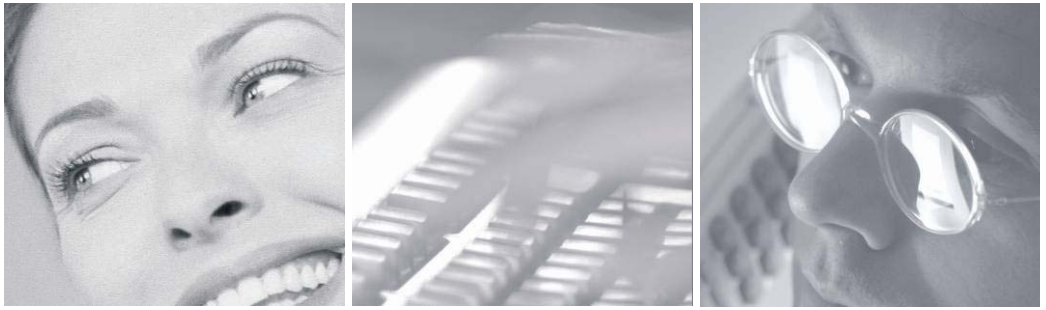

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