



SUCCESSFULLY EMBRACING CHANGES TO CDISC STANDARDS

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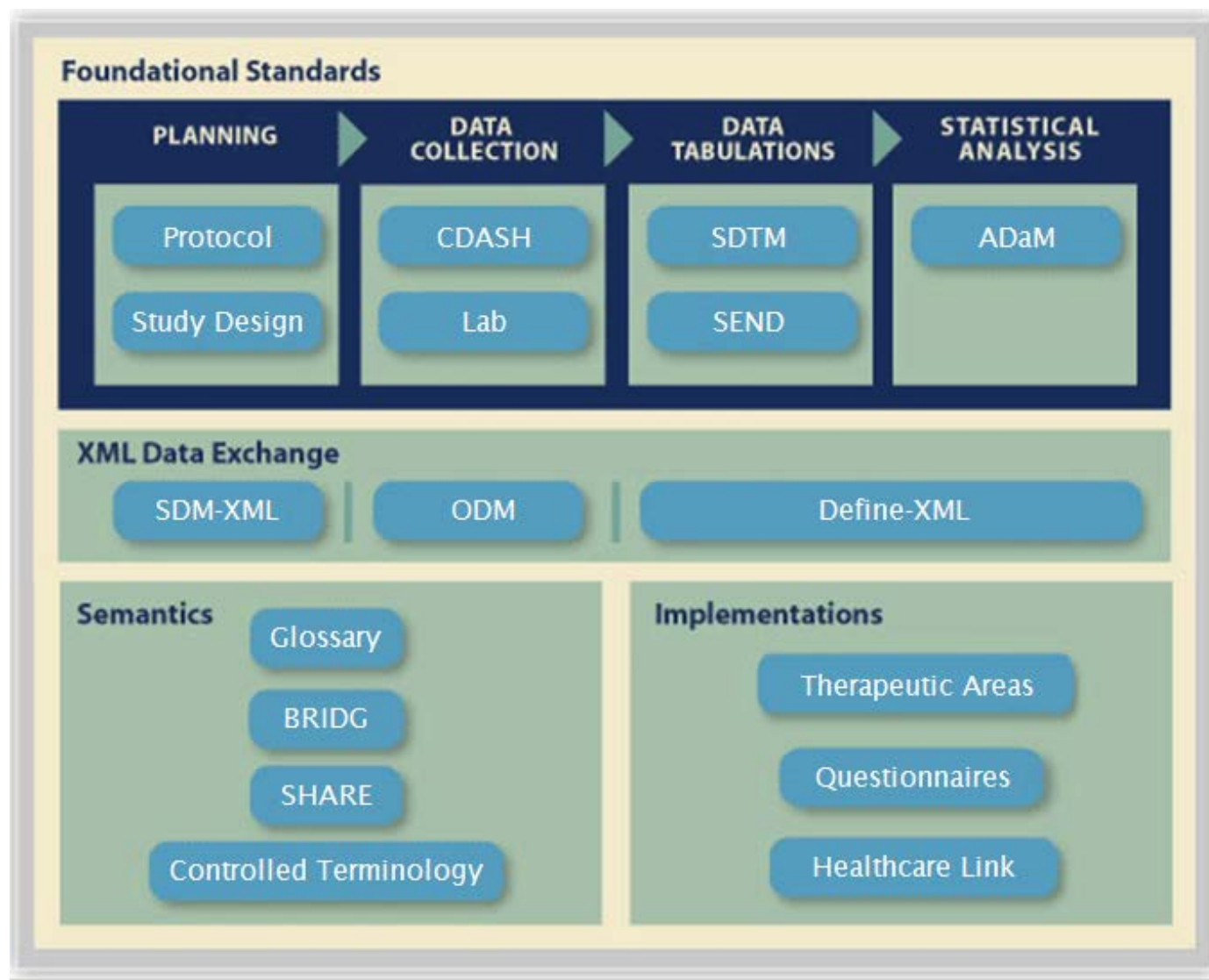
Director, Biometrics Operating Standards Group

WHAT, WHERE, WHEN

What is new?

Where do I find it?

When was/will it being posted?



What's New

CDISC Long-term Contract Position Open in Europe

Terminology Call for Public Review Package 18 - Comments Due by 18 April 2014

FDA Publishes Guidance on Standardized Study Data for Electronic Submissions & Study Data Technical

SDTM v1.4, SDTMIG v3.2 and SDTMIG-AP v1.0 Final Documents Now Available

Alzheimer's Therapeutic Area Data Standard User Guide v2.0 (TAUG-Alzheimer's v2.0) is Now Available

ASTHMA Therapeutic Area Data Standard User Guide v 1.0 (TAUG-Asthma) is Available Here

Job Opportunities Available Here!

CDISC StudyDataSet-XML Draft Standard to be Assessed in FDA Pilot.

CDISC Healthcare Link Profiles Information Available Here.

No longer available!

Study Data Tabulation Model

Team Charters:

- [Click here to view the SDS Team Charter.](#)
- [Click here to view the Devices Team Charter.](#)

**Reference to date of
posting missing!**

CDISC Study Data Tabulation Model (SDTM) v1.4, Study Data Tabulation Model Implementation Guide (SDTMIG) v3.2 and Associated Persons Implementation Guide (SDTMIG-AP) v1.0 Final Documents Released!

The CDISC SDS Team is pleased to announce the release of SDTM v1.4, SDTMIG v3.2, and SDTMIG-AP v1.0. The updates to these documents include:

SDTM: The addition of new variables to the general observation classes for both human clinical trials and SEND;

SDTMIG: A completely re-designed SDTMIG as a PDF Portfolio instead of the traditional single PDF file. 11 New Domains: EC, PR, HO, DD, IS, MI, MO, RP, SR, SS, and TD

SDTMIG-AP: A brand new IG to describe how to represent collected data about persons other than the subject under study, who could be associated with the study itself, a particular study subject, or a device used in the study

Published Therapeutic Area Standards

- New Diabetes User Guide
- TAUG-Alzheimer v2
- TAUG-Asthma v1
- Alzheimer's Disease v2 - Provisional
- Alzheimer's Disease v1- Final
- Asthma v1 - Provisional
- Pain v1 - Provisional
- Parkinson's Disease v1 - Provisional
- Polycystic Kidney Disease v1 - Provisional
- Tuberculosis v1 - Provisional
- Virology v1 - Provisional



Program Overview – September 2014

Approved Therapeutic Area Standards Projects

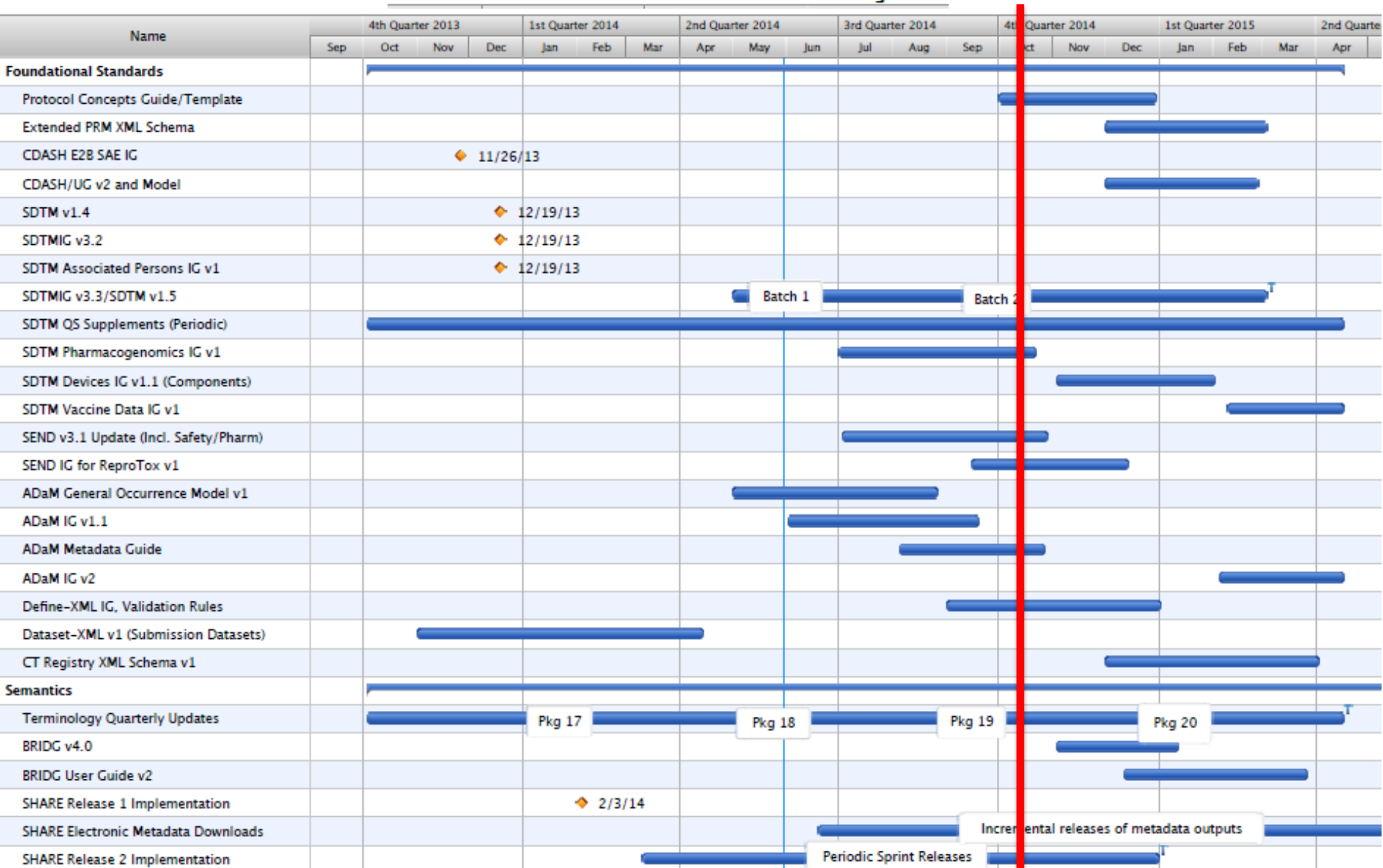
Therapeutic Area	Coordinating Organization(s)	Proposal Approval Date	Stage 0	Stage 1	Stage 2	Stage 3a	*Stage 3b	*Stage 3c
	Project Manager		Scoping & Planning	Concept Modeling	Standards Development	Internal Review	Public Review	**Projected Publication
CV Endpoints v1	CDISC/DCRI Amy Palmer	Jun 13	July	Sep	Nov	Feb	May	Q314
Diabetes v1	TCB Rachael Zirkle	Apr 13	May	Aug	Dec	Apr	May	Q314
QT Studies v1	TCB John Owen	Aug 13	Oct	Feb	Mar	Jul	Sept	Q414
Traumatic Brain Injury v1	CDISC Rhonda Facile	Oct 13	Sept	Oct	Nov			Q215
Chronic Hepatitis C Virus v1	TCB John Owen	Nov 13	Feb	Apr	Jul	Oct	Nov	Q414
Schizophrenia v1	CDISC/DCRI Amy Palmer	Nov 13	May	Jul	Aug	Oct	Nov	Q115
Breast Cancer v1	TCB Pam Harvey	Nov 13	Aug	Sept	Nov			2015
Influenza v1	C-PATH Laura Butte	Feb 14	May	Jul	Aug	Sept	Oct	Q414
Dyslipidemia v1	TCB John Glover	Dec 13	May	Sept	Oct			Q115
COPD v1	TCB John Glover	Nov 13	Aug	Oct	Dec			Q315

Key| ■ Stage completed | ■ Stage ongoing | All months reflect when stage is, or is projected to be, completed.

*The Stage3b concludes at the end of the 30-day review period and Stage 3c concludes when all tasks have been completed and the standard is publically available.
** Specific projected publication dates to be added to the notes section at the conclusion of Stage 3b.

Gantt Chart : CDISC Technical Projects

And More...



Centrally Track Updates

Standard	Item	Description	Date
SDTM	SDTMIG V3.2	Implementation Guide	2013-12-16
SDTM	SDTM V1.4	Study Data Tabulation Model	2013-12-13
CDASH	SAE Supplement V1	Serious Adverse Event Supplement	2013-11-22
ADaM	Validation Checks V1.2	ADaM Validation Checks	2012-08-17

New: Public Comment Tracker

Site Actions ▾

Browse

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Documents

Library

CDISC

PORTAL

Public Comment Tracker ▸ Review Documents ▸ All Documents ▾

Home Portal

Education

CDISC User Networks

OPS ▾

Teams/Project Portals ▾

C3C

Public Comment Tracker

Team Comment Tracker

Therapeutic Area Repository

Help

Review Documents

Comments

Assigned To Me

By Assigned To

By Document Number - Title

By Current State

By Comment Author

By Comment Category

By CDISC Disposition

Recycle Bin

All Site Content

Document Identifier

Type

Name

SDTM IG 001

SDTM IG 002

SDTM IG 003

EX_EC_ExposureDomains_v3 1 4 - Draft NEW

IS_SR_ImmunogenicityDomains_v3 1 4 - Draft NEW

RD_Reproductive Details_v3 1 4 - Draft NEW

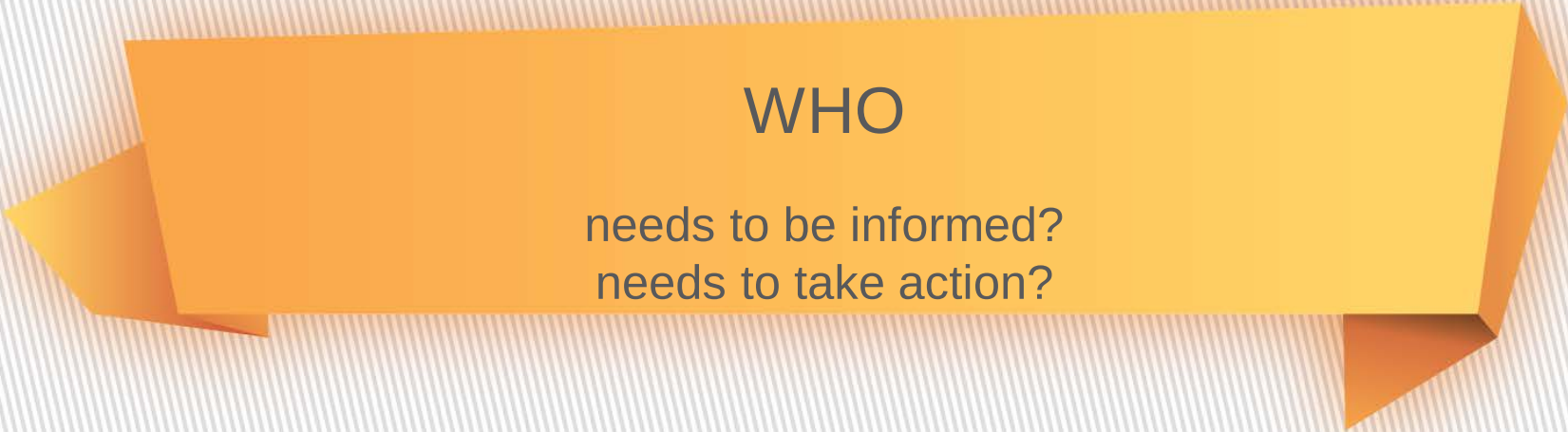
+ Add document

<http://portal.cdisc.org/CT/Review%20Documents/Forms/Active%20Documents.aspx>

The screenshot displays the CDISC Commons web application. At the top, a dark blue navigation bar contains "Site Actions" and a "Browse" button. A red arrow points to the "List Tools" dropdown menu, which has "Items" selected. Below this is a toolbar with icons for "New Item", "New Folder", "View Item", "Edit Item", "Version History", "Item Permissions", "Delete Item", "Attach File", "Alert Me", "Workflows", "Approve/Reject", "I Like It", and "Tags & Notes".

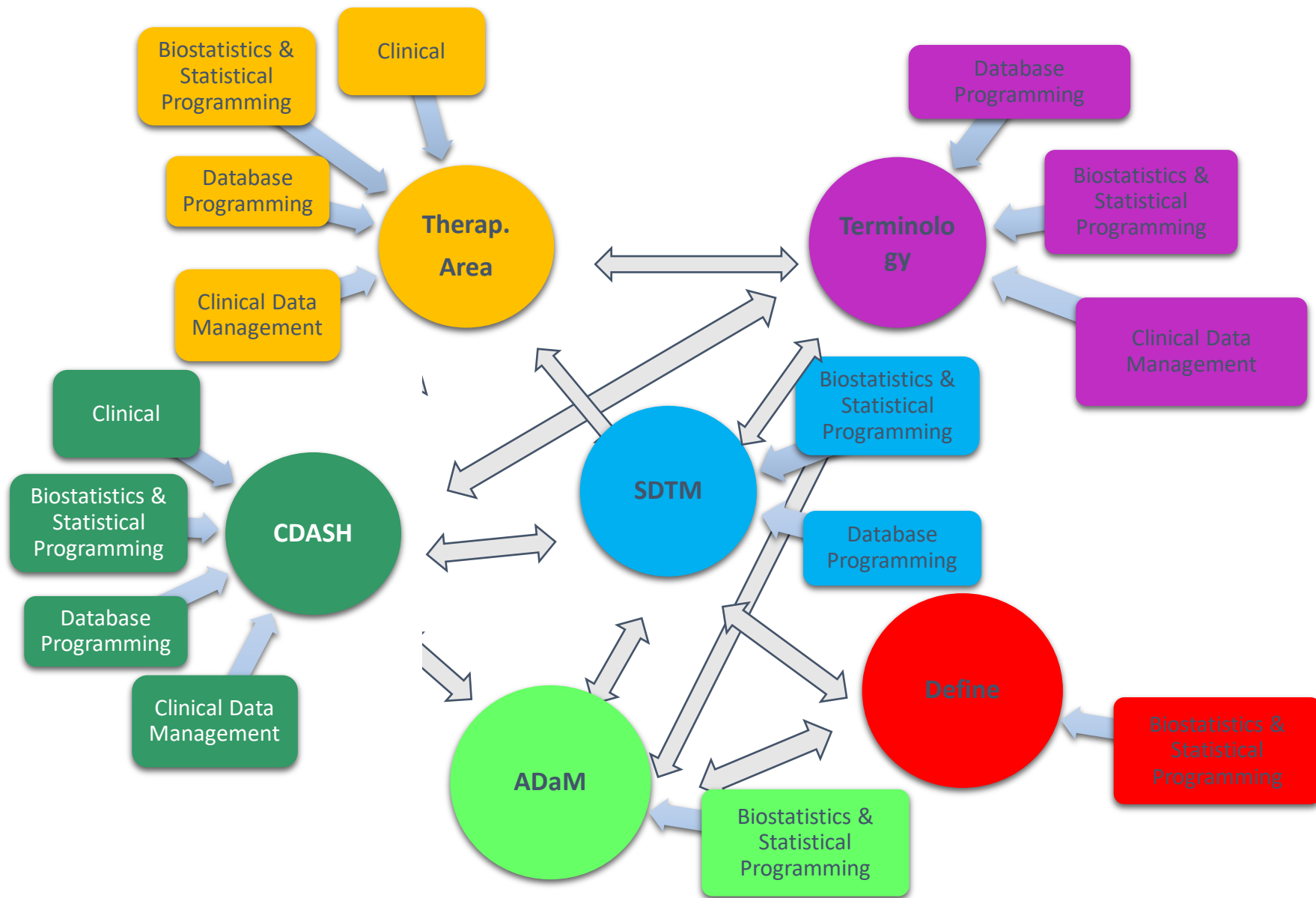
New Item	Comment Title	Comment	Document Section	Current State	Comment Author
Add a new item to this list.	IR Comment	The link is not for the Guidance itself but leads to a webpage showing where the various types of information are located, including guidances and specifications. The eCTD Guidance is among them, and the actual link is: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072349.pdf	2.2, Page 9, 12th bullet	Select or Blank	cratliffe
Comments	FDA/CDER	The link leads to "Study Data Standards for Submission to CDER", not "FDA Study Data Specifications". It is important to note that "FDA" would imply specifications applicable to both CDER and CBER, whereas this page is for CDER. The web page includes a link for "Study Data Specifications (v2.0)", and the actual link for the document is: http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM312964.pdf . Since the document version is likely to further change [currently no longer 1.6 as stated in the DefineXML 2.0.0 Specification Draft], it is better to avoid naming version number.	2.2, Pg 9, 13th bullet	Select or Blank	cratliffe
Assigned To Me	FDA/CDER Comment	"may not" or "should not" instead of "cannot"	3.2, Pg 10, last bullet	Select or Blank	cratliffe
By Assigned To	FDA/CDER Comment	Purpose of DefineXML is to support metadata interchange in a machine-readable format. During the webex on Sept 18, it is clear that reviewers feel that there should be an additional purpose in facilitating review of data for human reading.	4, Pg 13, Parag 1	Select or Blank	cratliffe
By Document Number - Title	FDA/CDER Comment	Text maximum allowed length as 200 characters may be problematic.	4.2.1, Page 18, 1st row	Select or Blank	cratliffe
By Current State					
By Comment Author					
By Comment Category					
By CDISC Disposition					

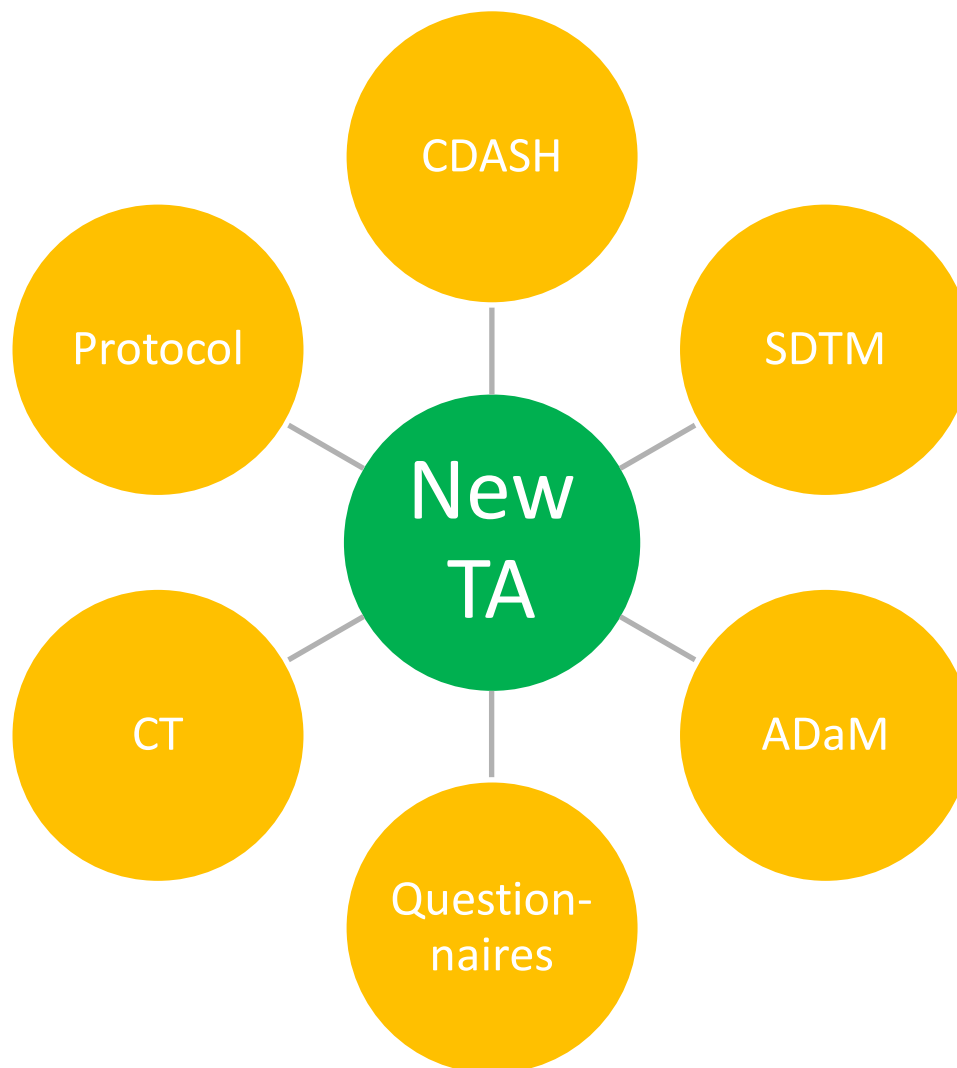
At the bottom left, there are links for "Recycle Bin" and "All Site Content".

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WHO

needs to be informed?
needs to take action?

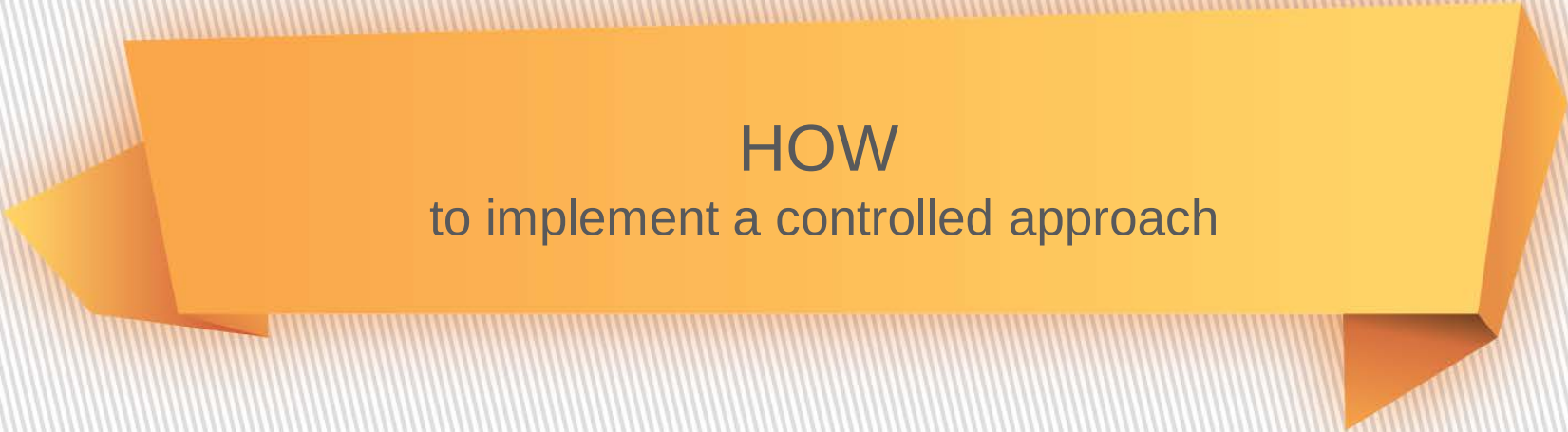




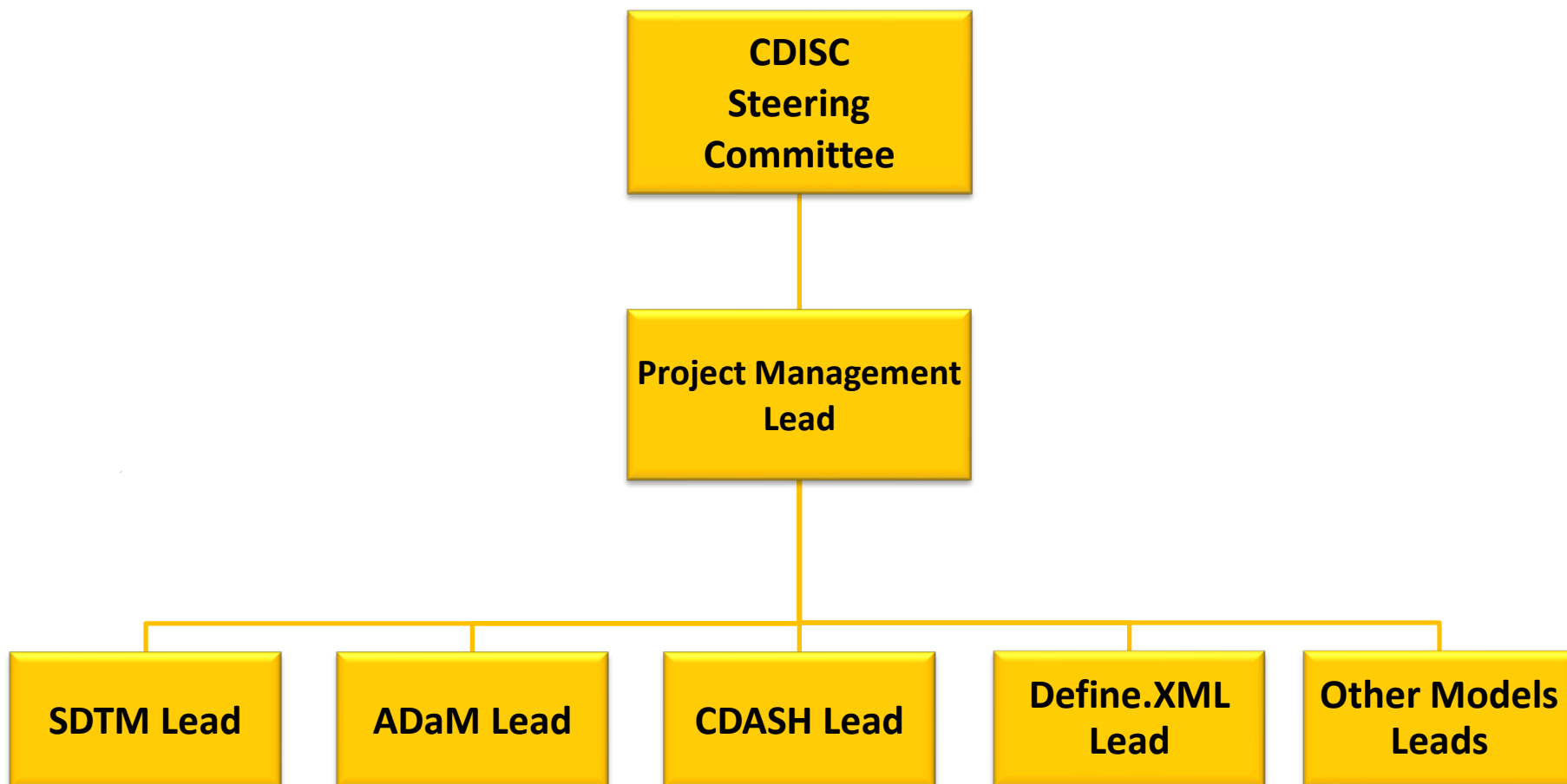
System or Chaos?



- ▶ Have a team structure in place
- ▶ Ensure key personnel is informed
- ▶ Actions to be taken are planned
- ▶ Changes are implemented
- ▶ Transition strategy decided
- ▶ Training material is developed
- ▶ All team members are informed and trained

A large, horizontal, orange ribbon-like graphic with a 3D effect, featuring a gradient from light orange to a darker orange at the edges. It has a central vertical crease and folded ends on both sides, giving it a banner-like appearance. It is positioned in the upper half of the slide.

HOW
to implement a controlled approach



Roles and Responsibilities

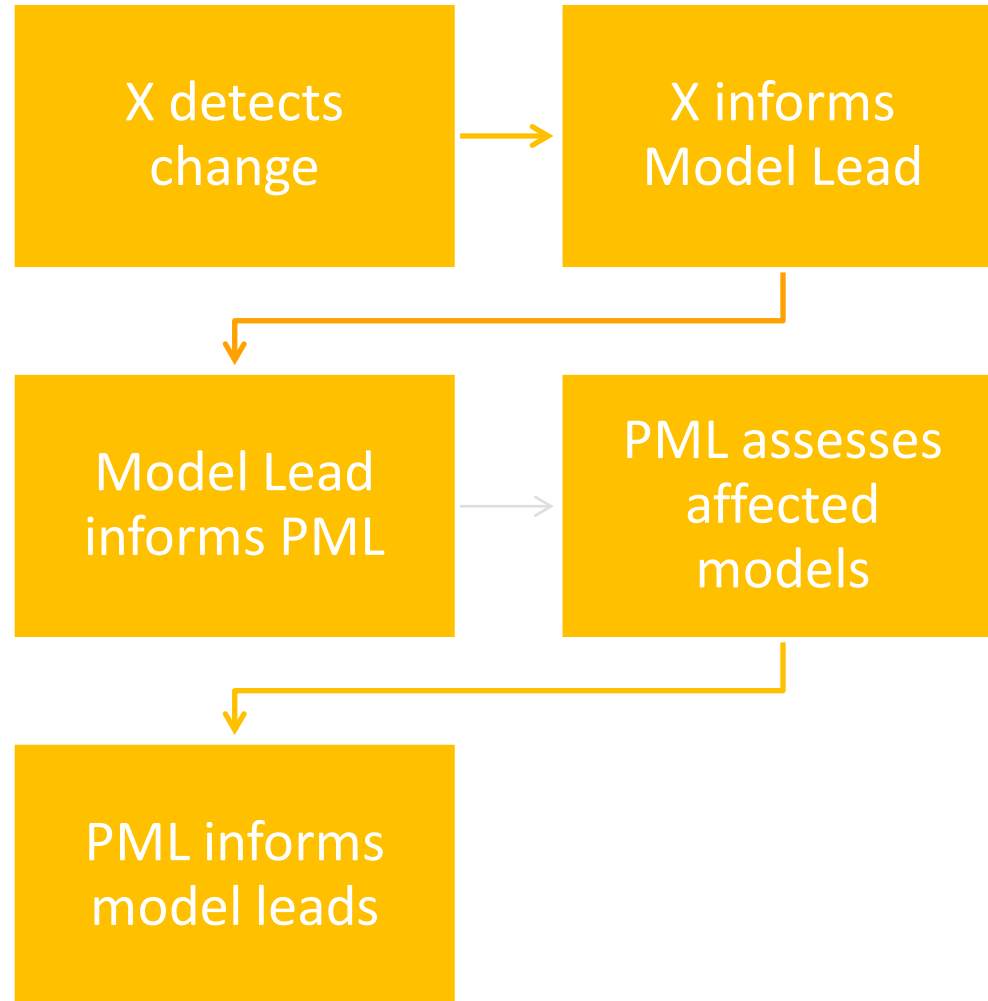
- ▶ Identify the Global Model Leads
- ▶ Commit the necessary resources
- ▶ Remove obstacles
- ▶ Monitor progress of the initiative:
 - Ensures that project deliverables are properly defined
 - Timelines for deliverables are understood and met
 - Project functionality is understood and delivered
 - Committed project benefits are realized

Roles and Responsibilities

- ▶ Coordinate interaction of the model leads
- ▶ Develop an overall project plan
- ▶ Conduct regular meetings with the model leads to determine current status, discuss next steps and identify risks and issues
- ▶ Centrally track changes
- ▶ Provide update information to Steering Committee

- ▶ Main contact for the specific model
- ▶ Set up and lead the Model Project Team
- ▶ Establish tasks and timelines
- ▶ Determine resource needs
- ▶ Work together with other Model Leads and standards team(s)
- ▶ Forward CDISC Review Packages to experts, collect comments and send them to CDISC
- ▶ Report on the progress/difficulties to the Project Management Lead and the Steering Committee

- ▶ Establish communication plan
- ▶ Ensure names of key personnel are known within the company
- ▶ Define responsibilities for regular search for news on the CDISC website



- ▶ Assess change/update
 - Major / minor
 - Relevance for ongoing business
- ▶ Evaluate which models are affected
- ▶ Assess if changes are required to
 - Processes
 - Standard templates
 - Standard macros and programs
- ▶ Prioritize actions needed
- ▶ Develop timelines

- ▶ Allow for different versions to be used by different users
- ▶ Version control
 - processes
 - Specs
 - Macros
- ▶ Establish system to ensure right version is used
 - Include versions used in study set-up
 - Automatically pull in the corresponding standard programs and macros

- ▶ Develop strategy which version should be used for
 - New stand-alone projects
 - New projects of a development program
 - Ongoing projects

- ▶ Submission Strategy
 - Based on
 - Standards and versions applied for individual studies
 - Amount of data to be pooled
 - Time and resource availability
 - Without compromising
 - Quality
 - Traceability

- ▶ Develop training material for different types of users, as needed, e.g.
 - Database programmer
 - Statistical programmer
 - Statistician
 - Therapeutic Director, etc.
- ▶ Address process changes as needed
- ▶ Transition strategy

- ▶ CDISC is a rapidly evolving set of standards
- ▶ Users face new issues through increasing number of annual releases of CDISC standards
- ▶ Look into central tracking tool of new releases, review options, etc.
- ▶ Companies need to develop strategies and controlled approaches for version implementation and control that fit their needs
- ▶ Need to get buy in from management and clinical departments
- ▶ Collaboration and communication between departments is key

Embrace the Change



Thank you!

**Questions?
Ideas?**

Think
THEOREM
CLINICAL RESEARCH™