

# CDISC: What's New, and What's Next

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# *Panelists*

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## Question & Answer

- 'Panelist': Question

OR

- 'Presentation': Question

Examples:

- 1) What should be supported by ADaM datasets?
- 2) Is there a limit to the number of variables that can be in ADSL?



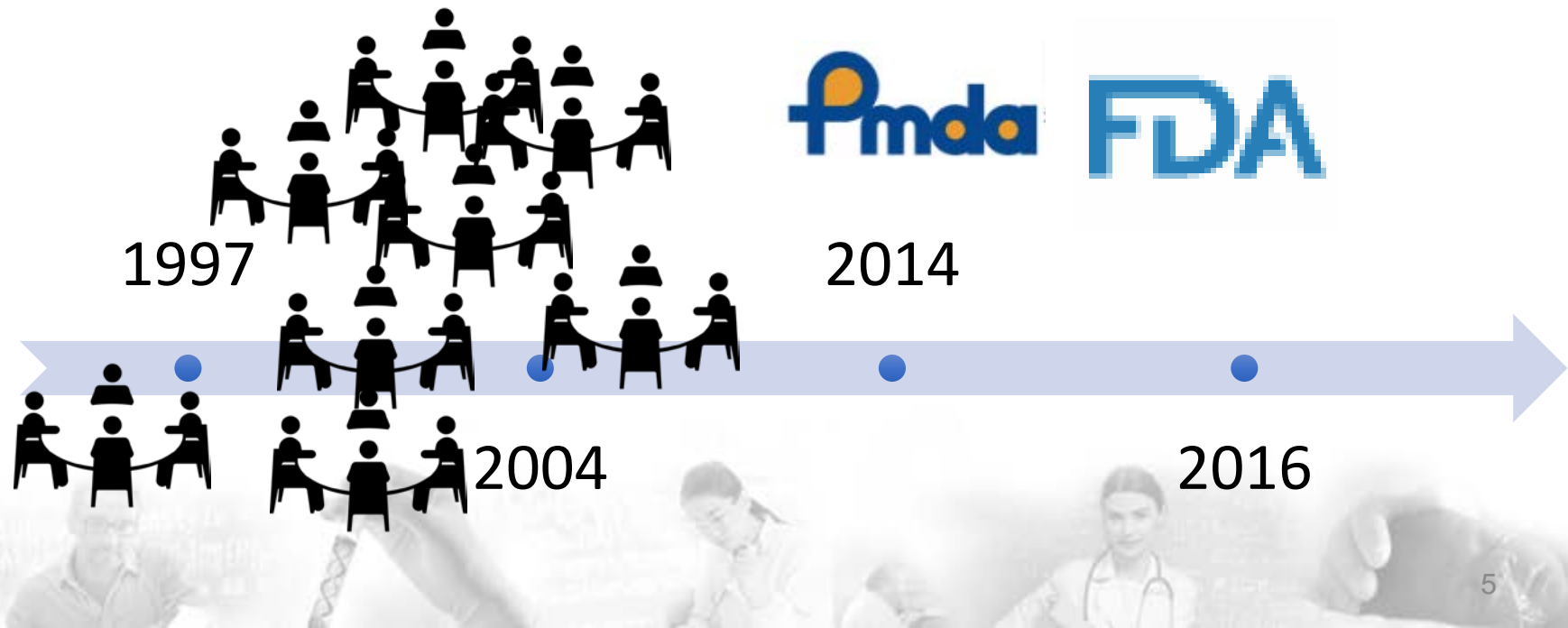
# Content Disclaimer

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# A *very* brief history of CDISC Success



# 1000s of people use CDISC Standards globally for many kinds of medical research



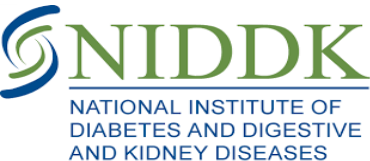
Controlled Terminologies in NCI EVS, BRIDG model, Cloud Commons pilot Adopted CDISC standards for FDA submissions, HIV studies, pharmacovigilance, and meta-analyses



NINDS CDEs used in Parkinson's and TBI TAs for FDA submissions



CDE contributors to Schizophrenia TA, Future CDE alignment to PTS TA



Part of C-Path Polycystic Kidney Disease TA consortium



Pediatric terminologies developed with NCI EVS and CDISC

# 1000s of people use CDISC Standards globally for many kinds of medical research



Vaccines Standard  
Training on collection,  
modeling and  
aggregation  
standards for  
interoperability

TRANSFoRm

Mobile patient  
reported outcomes  
(PRO)



Standards Starter Pack  
Curation pipeline to  
TransMART



Data sharing  
recommendations



Use of standardized  
data for research  
sourced from multiple  
EHRs



Infectious  
Diseases - field  
research data  
collection and  
aggregation  
support

1000s of people use CDISC Standards globally for  
many kinds of medical research

A large, light gray world map serves as a background for the central text. At the bottom of the slide, there is a horizontal strip of faded images showing various people in professional and medical settings, including a man in a lab coat, a woman in a white coat, and a person in a white lab coat with a stethoscope.

**450+**  
**Global**  
**Members**



# 20 years later...2017



Resolve the inconsistencies

SLOW DOWN!

Tell us what are working

When will you have the next version?

HELP!!!

SPEED UP!

Make the documentation easier to use!

Make it easier for volunteers to participate!

SLOW DOWN!

SLOW DOWN!

We hear you!

Here's what we are doing about it



# 2017: What's New

- More support for volunteers
- Improved standards development process
- Accredited training program



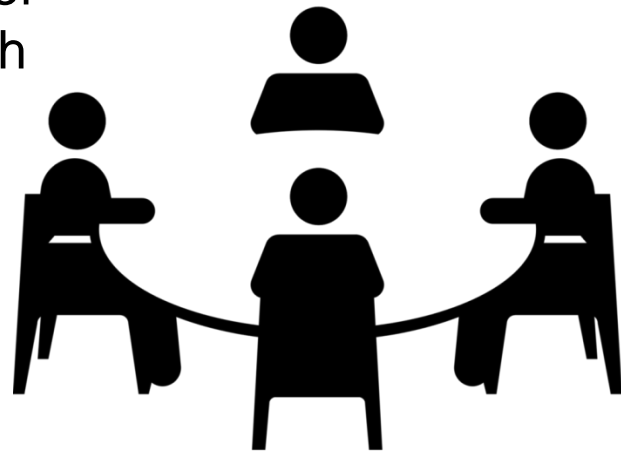
# Making things easier for volunteers

- More consistent experience onboarding
- Training on policies, procedures and tools
- Setting clear expectations
- Avoiding burnout - succession planning for team leadership
- Tracking volunteer hours (legal requirement)

# CDISC Staff Support for Foundational Teams



- One CDISC staff member assigned to support each foundational team
- Provide conduit for consistent two-way communication
- Support team with tools and resources



# Wiki Collaboration Space

wiki.cdisc.org

- Team collaboration space
- Repository of draft standards
- Encourages global participation
- Integration with issue tracker (JIRA)
- Support the use of SHARE tools (e.g., CRF Maker)
- Wiki “how to” training is available on the Wiki



# JIRA Issue Tracking

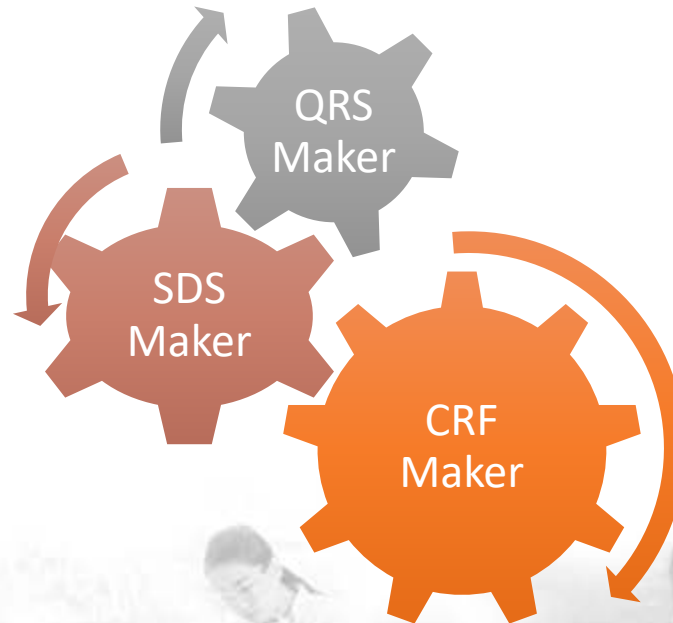
## JIRA.cdisc.org

- Issue tracking tool used for
  - Internal and public review comments
  - Tracking disposition of comments
  - Tracking issues for future development
  - Approvals to publish
- Same login as Wiki





# SHARE Tools Available in Wiki



# CRF Maker

Input: CDASH-compliant metadata\*  
in English and **Japanese** directly in  
the Wiki to support collaboration

Output: Annotated CRF

ID	Order Number	CDASH ID Variable	Question Text	Prompt	Type	Date Report Form Completion Instructions	SDTM Target	Mapping Instructions	Controlled Terminology Code Set Name	Reference Values	Pre-specified Value	Query Display	List Edit	Header
BIRTHDT	4	BIRTHDT	What is the subject's date of birth?	Birth Date	Date	Record the date of birth to the level of precision known (e.g., day/month/year, month/year, etc.).	BIRTHDT	This does not map directly to an SDTM variable. For the SDTM submission, dates, consider all collected CDASH DATE and TIME components and populate the SDTM variable BIRTHDT in ISO 8601 format.	N/A	N/A	N/A	gled	N/A	FALSE
AGE	5	AGE	What is the subject's age?	Age	Integer	Record the age of the subject.	AGE	Maps directly to the SDTM variable, used in the column with the heading "SDTM Target".	N/A	N/A	N/A	gled	N/A	FALSE
AGEU	10	AGEU	What is the age unit used?	Age Unit	Text	Record the appropriate age unit.	AGEU	Maps directly to the SDTM variable, used in the column with the heading "SDTM Target".	AGEU	DAYS, HOURS, MONTHS, WEEKS, YEARS	N/A	gled	edit	FALSE
COLLDT	11	COLLDT	What is the date of collection?	Collection Date	Date	Record the date of collection.	COLLDT	This does not map directly to an SDTM variable. For the SDTM submission, dates, consider all collected CDASH DATE and TIME components and populate the SDTM variable COLLDT in ISO 8601 format.	N/A	N/A	N/A	gled	N/A	FALSE
SEX	12	SEX	What is the sex of the subject?	Sex	Text	Record the appropriate sex.	SEX	Maps directly to the SDTM variable, used in the column with the heading "SDTM Target".	SEX	Female, Male, Unknown, UNDIFFERENTIATED/Intersex	N/A	gled	edit	FALSE

Record the date of birth to the level of precision known (e.g., day/month/year, year, month/year, etc.).

What is the subject's date of birth?

**BIRTHDT** **BIRTHDTG**

Record the age of the subject.

What is the subject's age?

**AGE**

Record the appropriate age unit.

Age Unit

**AGEU**

☐ DAYS  
☐ HOURS  
☐ MONTHS  
☐ WEEKS  
☐ YEARS

<From AGEU code list>

Record the date of collection.

Collection Date

**COLLDT** **COLLDTG**

Record the appropriate sex.

What is the sex of the subject?

**SEX**

☐ Female  
☐ Male  
☐ Unknown  
☐ Intersex

<From SEX code list>

Variables: **BLUE** = Collection **GRAY** = Submission **RED** = Collection & Submission

\* CRF Maker requires a more specific data type than given in CDASH metadata

# SDS Maker: QCs for SDTM & SEND



CDISC Wiki Spaces People Polls Calendars

  
Metadata check macro is applied and detected issue(s). Please address finding(s) listed below the specification table. An FAQ is available to aid troubleshooting. [Release Notes](#) **Metadata Checks Findings**  
[SDTM v1.7 Metadata Check User Macros FAQ](#)

- Content: For variable STUDYID, Description does not have an ending period
- Content: For variable NHOID, Description does not have an ending period
- Content: For variable OISEQ, Description does not have an ending period
- Content: For variable OIPARMCD, variable label Non-host Organism Identifier Element Short Name is longer than 40 characters
- Content: For variable OIPARM, variable label Non-host Organism Identifier Element Name is longer than 40 characters

# QRS Maker

1. Add value domains
2. Add values to each value domain
3. Add measure items

1

### Value Domain

Name*	<input type="text" value="IDSR1-"/>
	<small>Must be unique.</small>
Response Type	<input type="text" value=""/>
Override Label	<input type="text" value=""/>

By default, the table title in Section 4 (SOTM Mapping Strategy) is a list of the test codes for the measures that use this value domain. Specify a label to override the default.

**Add**

2

### Result Value

Original Result*	<input type="text" value=""/>
Standard Result*	<input type="text" value=""/>
	<input type="checkbox"/> Standard result is numeric
Anchor	<input type="checkbox"/> Value is an anchor

**Add**

3

### Measure Item

Coded Value*	<input type="text" value="IDSR1"/>
Display Value*	<input type="text" value="IDSR1-"/>
C-Code	<input type="text" value=""/>
Value Domain	<input type="text" value="Choose from defined:"/> <input type="text" value="or enter manually:"/>
	<input type="checkbox"/> Item has no defined value domain
Dataset only?	<input type="checkbox"/> Item does not appear on the measure

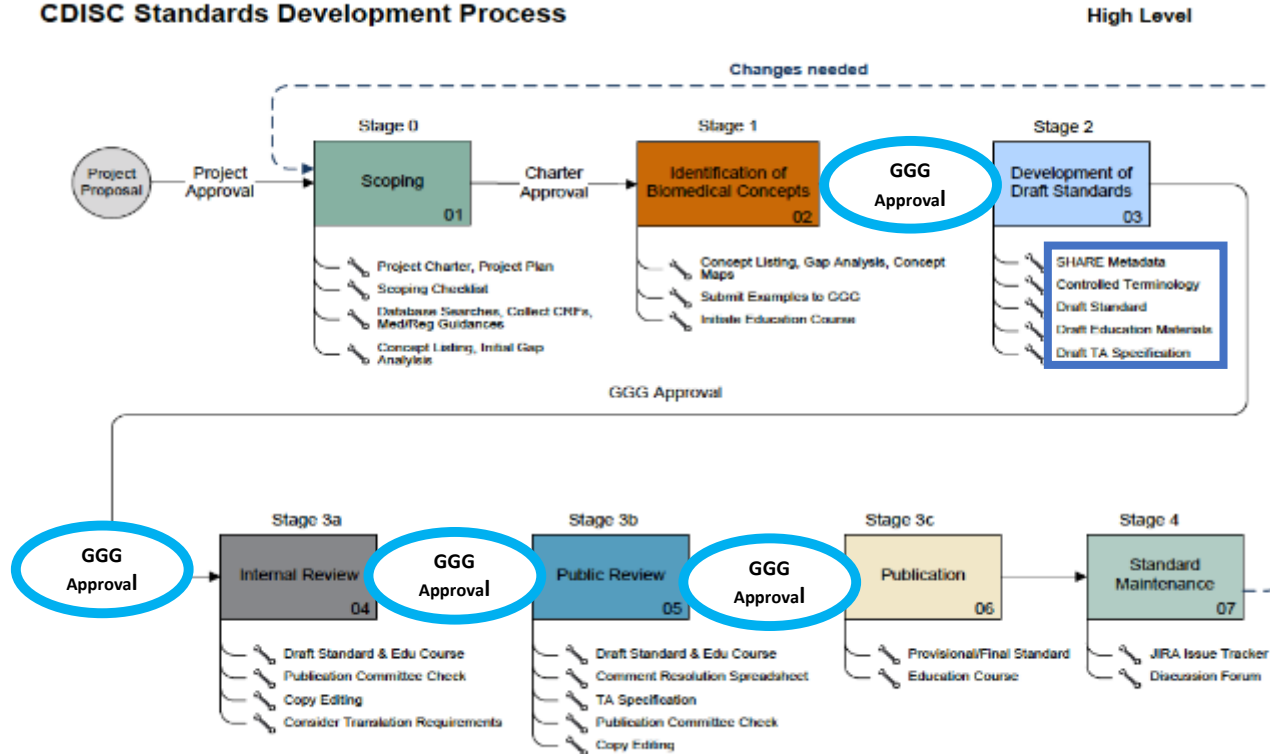
**Add**

# Improving the Standards Development Process

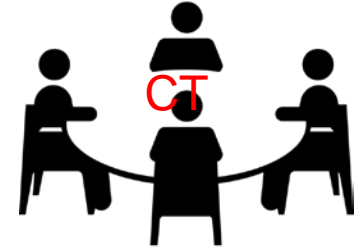


# Improved Standards Development Procedure

## CDISC Standards Development Process



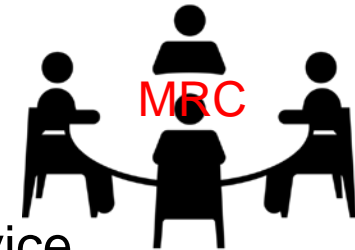
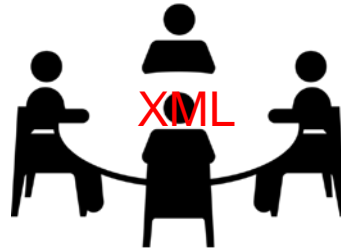
- Expanded, more details
- Highlights Education and SHARE deliverables
- Defines status of standards documentation
  - Draft
  - Provisional
  - Final
- Introduces early, **cross-team modeling governance**



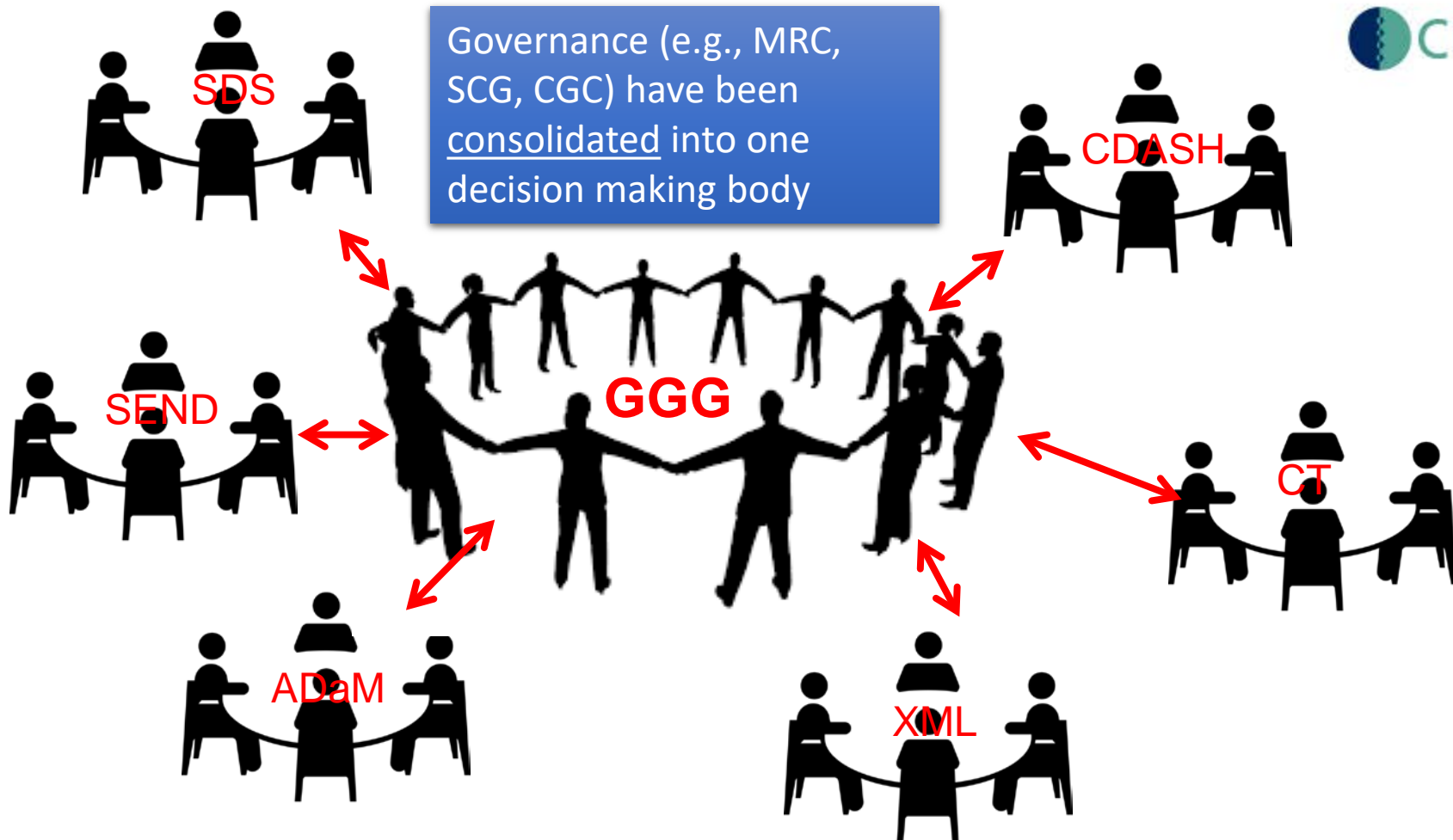
Separate conversations  
No central governance  
Creates inconsistencies



Good governance  
But, not all teams represented  
And, late in process



Early advice  
Better cross-team conversations  
But not actual governance





# Benefits of Global Governance Group (GGG)

- Reducing siloes by moving decision-making to a central governing body
- Transparent decision making with documentation in single place



- Alignment and consistent decision making across teams and standards
- Early input from all teams will reduce future rework
- Clear, consistent documentation of decisions





# Accredited Training Program

*to encourage and support consistency*



# CDISC Education IACET Accreditation



- CDISC Education recently received accreditation from the International Association of Continuing Education and Training (IACET)
  - Independent assessment and confirmation of a high quality, well controlled training program
- Continuing Education Units (CEUs) will be offered for most CDISC courses
  - CEUs can be used to re-certify (CCDM, CCRA, CCRP, etc)
- *IACET course development methodology lays the groundwork for certification in CDISC standards - coming soon!*



# 2018-2020: What's Next

- Transparency and Predictability
- Annual release schedule
- New publishing formats
- Retooling to prepare for the future



# Transparency and Predictability



# Pipeline - Volunteer View (Wiki)



Standard	Scoping	Development	Internal Review	Prep for Public Review	Public Review	Resolving Public Review Comments	Prep for Publication	Published	Published Status
TAUG-Vaccines v1						<b>COMPLETE</b> GGG to sign off		Estimate Q1 2018	Provisional
TAUG-Colorectal Cancer v1						<b>COMPLETE</b> GGG to sign off		Estimate Q1 2018	Provisional
SDTMIG v3.3						<b>COMPLETE</b>	<b>ONGOING</b>	Estimate Q1 2018	Provisional
SDTMIG-MD v1.1					N/A	N/A GGG to sign off		Estimate Q1 2018	Final
SDTM v1.7					<b>COMPLETE</b>	<b>ONGOING</b>		Estimate Q1 2018	Final
Define-XML v2.1					<b>COMPLETE</b>	<b>ONGOING</b>		Estimate Q1 2018	Final
TAUG-PTSD v1					<b>COMPLETE</b>	<b>ONGOING</b>		Estimate Q2 2018	Provisional
TAUG-Huntington's Disease v1					<b>COMPLETE</b>	<b>ONGOING</b>		Estimate Q2 2018	Provisional
TAUG-Asthma v1.1						<b>COMPLETE</b>	<b>ONGOING</b>	Estimate Q2 2018	Final
RDF Reference Guide v1.1					<b>COMPLETE</b>	<b>ONGOING</b>		Estimate Q2 2018	Final
ADaMIG v1.2					<b>COMPLETE</b>	<b>ONGOING</b>			

# Pipeline - Public View *Prototype*

(coming soon to website)

Standard	In Development	Public Review	Est. Publication Date	Publication Status
SDTM v1.7	Completed	Ongoing	Q12018	Final
SDMTIG v3.3	Completed	Completed	Q12018	Final
SDTMIG-MD v1.1	Completed	Ongoing	Q12018	Final
ADaMIG v1.2	Completed	Ongoing		Final
TAUG-Nutrition	Ongoing			Provisional
TAUG-Lung Cancer	Ongoing			Provisional

# Annual Release Schedule





# Annual Product Release Schedule



November 2018						
Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
			1	2	3	4
5	6	7	8	9	10	11
					Marine Corps Day	Veterans Day
12	13	14	15	16	17	18
19	20	21	22	23	24	25
			Thanksgiving			
26	27	28	29	30		

- Early notice of expected product releases each year
- **Quarterly** CT releases
- **Ad hoc** QRS Supplements
- **Ad hoc** TA User Guide releases with Provisional status
- **Annual Foundational Standards release**
  - **First Week November** for standards with finalized components by cut-off date
  - Provisional standards with all content finalized by cut-off date also gain Final status

# “Final” = More **Implementable** Standards

## Final now means:

- Public review completed on
  - Normative standard
  - Informative examples & text
  - Conformance Rules
  - Referenced controlled terminology
- Publication-ready updates made
- Metadata loaded into CDISC SHARE
- Education chapter-level learning outcomes developed

# New Publishing Formats



# New Publishing Formats

- Have started publishing standards in HTML
  - CDASHIG v2.0
  - CDASH Model v1.0
- Benefits
  - Aiming for a shorter publication time from Wiki to HTML
  - HTML more universally readable than PDF
  - But...you can export a PDF if you want one, or save the HTML file for offline use

# Retooling to Prepare for the Future



# Documenting Development Principles

- Guides and improves understanding of the standard
- Increases awareness about the manner in which team members should act in various situations
- Facilitates decision making
- Helps to optimum utilization of resources
- Helps to manage change
- Builds knowledge base for future development



# Alignment of Standards

- Variable definitions
- Core designations
- Metadata review (for consistency)
- IG Text review
  - What can be written as a rule?



# Future of CDISC Standards

- Expand use cases beyond regulatory submissions
- Align models with Real World Data (RWD)
- Refine the standards to build more support for new technologies





# Traditional View of Data: Domains/Files

dm.xpt

Row	STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTCT	RFENDTCT	RFN
1	ABC123	DM	ABC12301001	001	2006-01-12	2006-03-10	200
2	ABC123	DM	ABC12301002	002	2006-01-15	2006-02-28	200
3	ABC123	DM	ABC12301003	003	2006-01-16	2006-03-19	200
4	ABC123	DM	ABC12301004	004			
5	ABC123	DM	ABC12302001	001	2006-02-02	2006-03-31	200
6	ABC123	DM	ABC12302002	002	2006-02-03	2006-04-05	200

Row	SITEID	INVTNAM	BRTHDTCT	AGE	AGEU	SEX
1 (cont)	01	JOHNSON, M	1948-12-13	57	YEARS	M
2 (cont)	01	JOHNSON, M	1955-03-22	50	YEARS	M
3 (cont)	01	JOHNSON, M	1938-01-10	68	YEARS	F
4 (cont)	01	JOHNSON, M				
5 (cont)	02	GONZALEZ, J				
6 (cont)	02	GONZALEZ, J				

Row	ARMCD	ARM
1 (cont)	A	Drug A
2 (cont)	P	Placebo
3 (cont)	P	Placebo
4 (cont)	SCRNFAIL	Screen Fail
5 (cont)	P	Placebo
6 (cont)	A	Drug A

pr.xpt

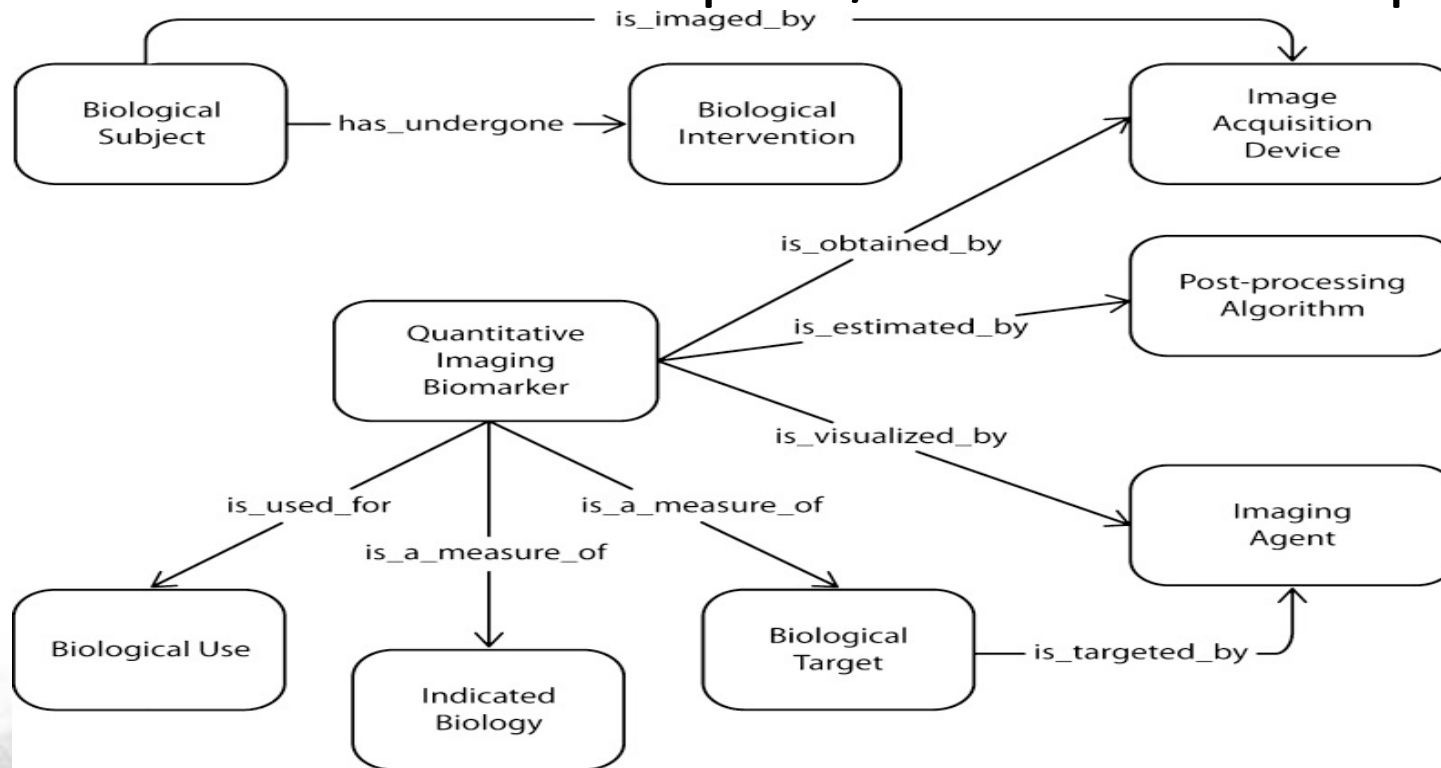
Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRTRT	PRSTDTCT	PRENDTCT
1	XYZ	PR	XYZ789-002	1	Wisdom Teeth Extraction	2010-06-08	2010-06-08
2	XYZ	PR	XYZ789-002	2	Reset Broken Arm	2010-08-06	2010-08-06
3	XYZ	PR	XYZ789-002	3	Prostate Examination	2010-12-12	2010-12-12
4	XYZ	PR	XYZ789-002	4	Endoscopy	2010-12-12	2010-12-12
5	XYZ	PR	XYZ789-002	5	Heart Transplant	2011-08-29	2011-08-29

WHITE	NOT HISPANIC OR LATINO
BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO

ho.xpt

Row	STUDYID	DOMAIN	USUBJID	HOSEQ	HOTERM	HOSDTCT	HOENDTCT	HODUR
1	ABC	HO	ABC123101	1	HOSPITAL	2011-06-08	2011-06-13	
2	ABC	HO	ABC123101	2	NURSING HOME			PdD
3	ABC	HO	ABC123102	1	GENERAL WARD	2011-08-06	2011-08-08	
4	ABC	HO	ABC123102	2	INTENSIVE CARE	2011-08-08	2011-08-15	
5	ABC	HO	ABC123102	3	REHABILITATION FACILITY	2011-08-15	2011-08-20	
6	ABC	HO	ABC123103	1	HOSPITAL	2011-09-09	2011-09-11	
7	ABC	HO	ABC123103	2	HOSPITAL	2011-09-11	2011-09-15	
8	ABC	HO	ABC123104	1	CARDIAC CATHETERIZATION LABORATORY	2011-10-10	2011-10-10	
9	ABC	HO	ABC123105	1	CARDIAC CATHETERIZATION LABORATORY	2011-10-11	2011-10-11	
10	ABC	HO	ABC123105	2	HOSPITAL	2011-10-11	2011-10-15	
11	ABC	HO	ABC123106	1	CARDIAC CATHETERIZATION LABORATORY	2011-11-07	2011-11-07	
12	ABC	HO	ABC123106	2	HOSPITAL	2011-11-07	2011-11-09	

# Real World View of Data: Individual Concepts / Relationships



# Support for New Technologies

- Connect CDASH (and SDTM) with FHIR and other healthcare standards to support eSource
- Align SDTM Pharmacogenomics with global genomics initiatives
  - GA4GH, HL7 Clinical Genomics, ISA-Tab & Workflow initiatives
- Provide standards in new formats - RDF
- Refine the models to support machine readable standards
  - Single instance of each concept, well defined
  - Build biomedical concept templates

# 2018-2019

## Roadmap for Refining the Standards

**Focus** foundational standards development teams to:

- Finalize development of the following for consistency
  - Development principles
  - Conformance rules
- Do an in-depth review and refinement of metadata to ensure consistency within and across standards
- Develop template & process of biomedical concept maps
- Load all of the above into CDISC SHARE
- Build and publish SHARE tools to support future development



# Expected Results

- Alignment and consistency within and across models
- Clearly defined concepts to reduce ambiguity and help identify gaps
- Documented principles will guide future development
- Better alignment with RWD, 'omics data and other standards
- Better support for tool development
- Higher quality standards
- Better support for machine-readability, semantic interoperability
- Gain efficiencies in future standards development
  - Pause and re-tool
  - Slow down now to be able to speed up and get higher quality later



# Conclusions

- We've come a long, long way together since 1997
- We hear your concerns and are addressing them
- CDISC staff are committed to doing everything we can to support our community and to make the standards sustainable

**Join us on this  
journey!**

# Q&A



# UPCOMING NORTH AMERICA PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends:	Late fees kick(ed) in:	Host
Los Angeles, CA	26-30 March 2018	SDTM, CDASH, Controlled Terminology, ADaM Primer, ADaM T&A, Define-XML	26 Dec 2017	26 Feb 2018	 <b>nurocor</b> bringing order to clinical data
Audubon, PA	2-6 April 2018	SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML	2 Jan 2018	2 Mar 2018	 <b>BIOCLINICA</b> SEE MORE CLEARLY

Visit [cdisc.org/public-courses](http://cdisc.org/public-courses) for information on other CDISC Public Training events.





# UPCOMING EUROPE PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends	Late fees kick(ed) in:	Host
Europe Interchange, Berlin, DE	23-27 April 2018	SDTM, ADaM Primer, ADaM T&A, CDASH, Define-XML, Controlled Terminology, SEND, Standards from the Start	23 Feb 2018	23 Mar 2018	
Milan, Italy	14-18 May 2018	SDTM, ADaM Primer, ADaM T&A, CDASH, Define-XML	14 Feb 2018	14 April 2018	

Visit [cdisc.org/public-courses](https://cdisc.org/public-courses) for information on other CDISC Public Training events.

# UPCOMING ASIA PUBLIC COURSES

Location	Dates	Courses Offered	Discount period ends:	Late fees kick(ed) in:	Host
Tokyo, Japan	5-9 Mar 2018	SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML	5 Dec 2017	5 Feb 2018	
Seoul, South Korea	5-14 Mar 2018	Standards from the Start, SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML	5 Dec 2017	5 Feb 2018	

Visit [cdisc.org/public-courses](http://cdisc.org/public-courses) for information on other CDISC Public Training events.

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Thank you!

