What's New, and What's Next

May 2018

Organizational strategy

WHAT IS CDISC'S EMERGING VISION?

CDISC convenes a **global community** to develop and advance data standards of the highest quality. This is our **passion**. We bring together recognized **expertise**. We are **inclusive**. We are **enterprising** in how we approach our work. Our work brings **clarity to data** and is **clearly impactful**.

WHAT DRIVES RECOGNITION AND REVENUE?

All of CDISC's **recognition** and **revenue** flow from the **adoption** and **implementation** of standards.

WHAT ACTIVITIES BEST ENSURE CDISC'S SUSTAINABILITY?

The further **upstream** CDISC standards are implemented by members and stakeholders, the more sure CDISC's **sustainability**.

WHAT IS THE RIGHT STRUCTURE FOR CDISC?

CDISC must balance a high dexterity for **change** with smart view of **stability**. This nimble, evolutionary approach accepts the high stakes of our work while acknowledging the **transparency** and **predictability** our community requires.

2018 Goals

1

Build a customer-centric, stakeholder-centric culture.

2

Generate greater member value.

3

Ensure sustainability of CDISC standards.

4

Optimize standards development and release process.

5

Lay the foundation for CDISC 2.0.

Goal 1 – Build a customer-centric, stakeholder-centric culture

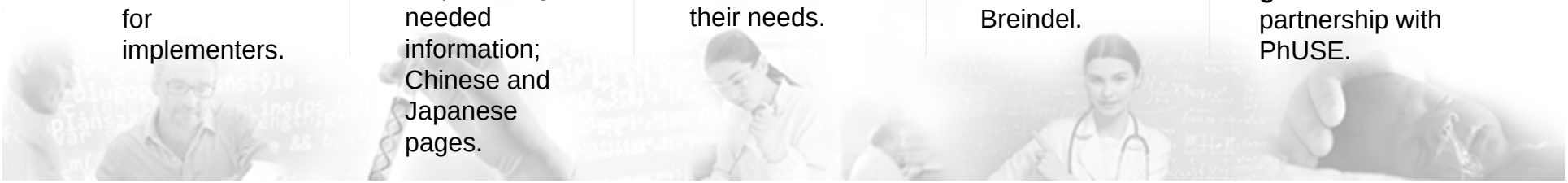
WHAT?

Delight CDISC's stakeholders.

HOW?

Using current data points, and through developing new data and guided conversations, learn what our stakeholders prefer and need from CDISC. Use insights to better inform our decisions.

1	2	3	4	5
Provide three new major **SHARE tools** for implementers.	**Improve** www.cdisc.org emphasizing needed information; Chinese and Japanese pages.	**Survey** our stakeholders to better understand their needs.	**Re-Brand** CDISC through services of DeSantis-Breindel.	Develop a **newcomers guide** in partnership with PhUSE.



Goal 2 – Generate greater member value

WHAT?

Tune up CDISC member offerings to meet member' needs.

HOW?

Provide additional benefits that support member' enterprises, research, and collaboration.

1

Launch **SHARE 2.0** by 31 December 2018

2

Establish a plan for **CDISC Certification.**

3

Generate effective, well-attended **training events** including **excellent Interchanges,** 10% attendance increase.

4

Provide more **content** including webinars in Japanese and Chinese.

Goal 3 – Ensure sustainability of CDISC standards

WHAT?

Provide CDISC with the people resources and financial resources necessary to support the mission long-term.

HOW?

Increase revenue diversity. Become the employer, volunteer opportunity, and partner of choice.

1

Build a strong pipeline and **additional revenue streams**.

2

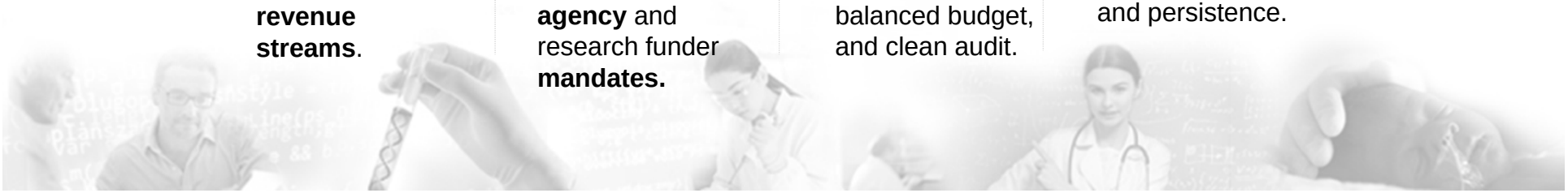
Build momentum for additional **government agency** and research funder **mandates.**

3

Achieve $8.4 million gross revenue, balanced budget, and clean audit.

4

Support **strong employee** performance and persistence.



Goal 4 – Optimize standards development and release process

WHAT?

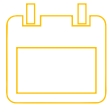
Ensure complete beginning to end standards; predictability and transparency in standards development.

HOW?

Build excellent standards that meet the needs of stakeholders while optimizing available resources.

1

Centralize governance and a commitment to surface and reduce inconsistencies.



2

Support teams with staff project manager; volunteer onboarding; and effective tools.

3

Maintain **website transparency** on all working groups, releases, and updates.

4

Establish a **renewed TA paradigm** building on needs of the community with BTE solutions.

Goal 5 – Lay the foundation for CDISC 2.0

WHAT?

Tap into the global genius of the CDISC community with a temporary Blue Ribbon Commission.

HOW?

Working with well-qualified Co-Chairs and 35+ Commissioners, establish a formal community-based vision for the future of CDISC. From this work, inform development of a new multi-year Strategic Plan.

1

Launch Blue Ribbon Commission, representative of CDISC globally.

2

Generate a white-paper of Commission **advice.**

Accomplishments since April 2017

Foundational Standards

- CDASH v2.1 and the CDASH Model v1.0 – September 2017
- SENDIG-Developmental and Reproductive Toxicology (DART) v1.1 - December 2017
- SDTM v1.6 - December 2017
- SDTMIG v3.3, SDTM v1.7 – soon!
- SDTMIG-Medical Devices v1.1 – soon!

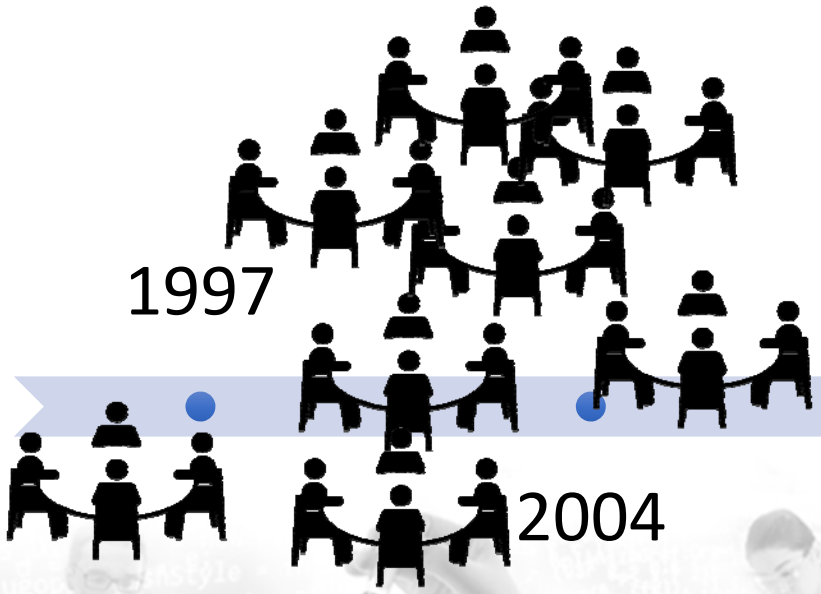
Therapeutic Area Standards

- TAUG-Prostate Cancer – July 2017
- TAUG-Influenza v1.1 – August 2017
- TAUG-Virology v2.1 – August 2017
- TAUG-Duchenne Muscular Dystrophy v1.0 – September 2017
- TAUG-Vaccines - April 2018

CDISC SHARE

- CDISC SHARE API 1.0 available to Platinum members at no cost
  - API 1.0 available to Gold Members
- CDISC SHARE 2.0 & CDISC SHARE API 2.0 Soft launch
  - SEND, CDASH, SDTM, ADaM
- CDISC SHARE 2.0 Full launch
  - Questionnaires, Ratings and Scales, Rules, TAs, Biomedical Concepts, external standards mappings (e.g., LOINC, FHIR)
  - New foundational standards releases

A *very* brief history of CDISC



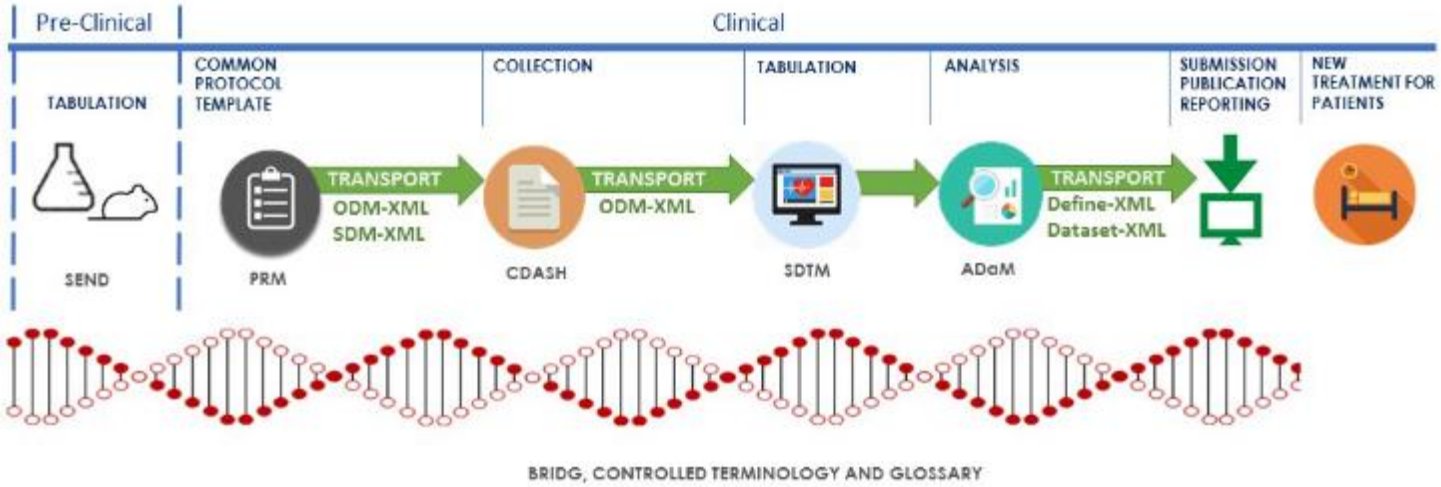
1997

2004

2014

2016

CDISC Standards in the Clinical Research Process



Therapeutic Area Standards

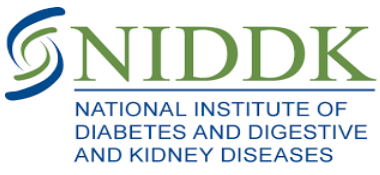
CDISC Standards are used for many kinds of medical research in US

Controlled Terminologies in NCI EVS,
BRIDG model,
Cloud Commons pilot

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

Adopted CDISC standards for FDA submissions, HIV studies, pharmacovigilance, and meta-analyses

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

…and in the EU

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

Standards Starter Pack Curation pipeline to TransMART

Use of standardized data for research sourced from multiple EHRs

Mobile patient reported outcomes (PRO)

Data sharing recommendations

Infectious Diseases - field research data collection and aggregation support

years later…2018


Resolve the inconsistencies!
SLOW DOWN!
Tell us what you are working on!
When will you publish the next version?
SPEED UP!
Make the documentation easier to use!
Make it easier for volunteers to participate!

We hear you!

What we are doing about it

2018: What's New

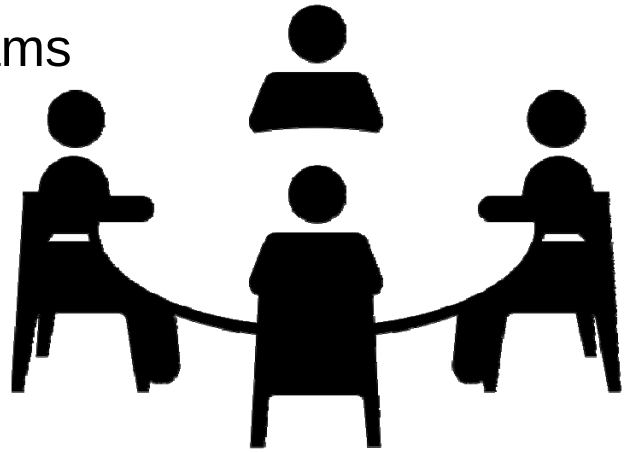
- Support for volunteers
- Improved Standards Development Governance
- Accredited Training Program

Making things easier for volunteers

- Making the volunteer experience more consistent:
  - Onboarding
  - Training on policies, procedures and tools
- Setting clear expectations
- Avoiding burnout - succession planning for team leadership

CDISC Staff Support for Foundational Teams

- Assign CDISC staff to support foundational teams
- Provide conduit for consistent two-way communication
- Support team with tools and resources



Wiki Collaboration Space

- Team collaboration space
- Repository of draft standards
- Encourages global participation
- Integrates with JIRA (issue-tracking tool)
- Supports the use of SHARE tools

➢ Wiki “how to” training is available on the Wiki

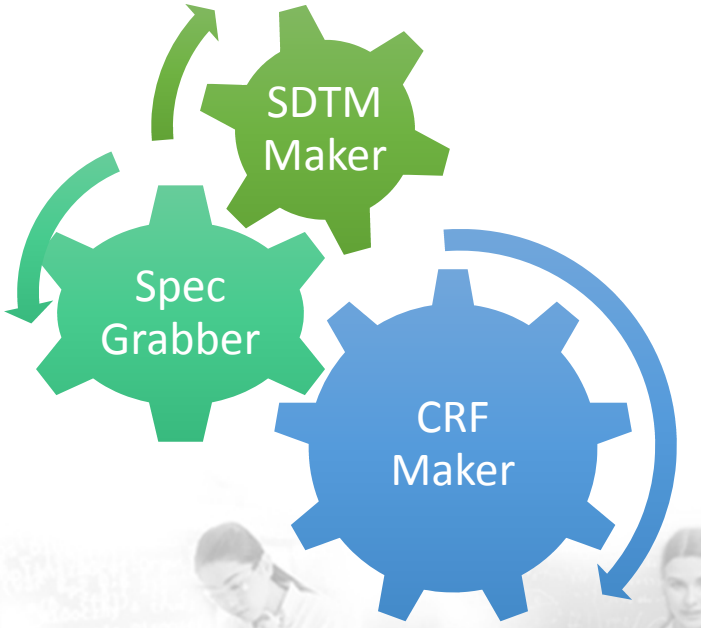
wiki.cdisc.org

JIRA Issue Tracking

JIRA.cdisc.org

- Issue-tracking tool used for:
  - Collecting Internal & 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

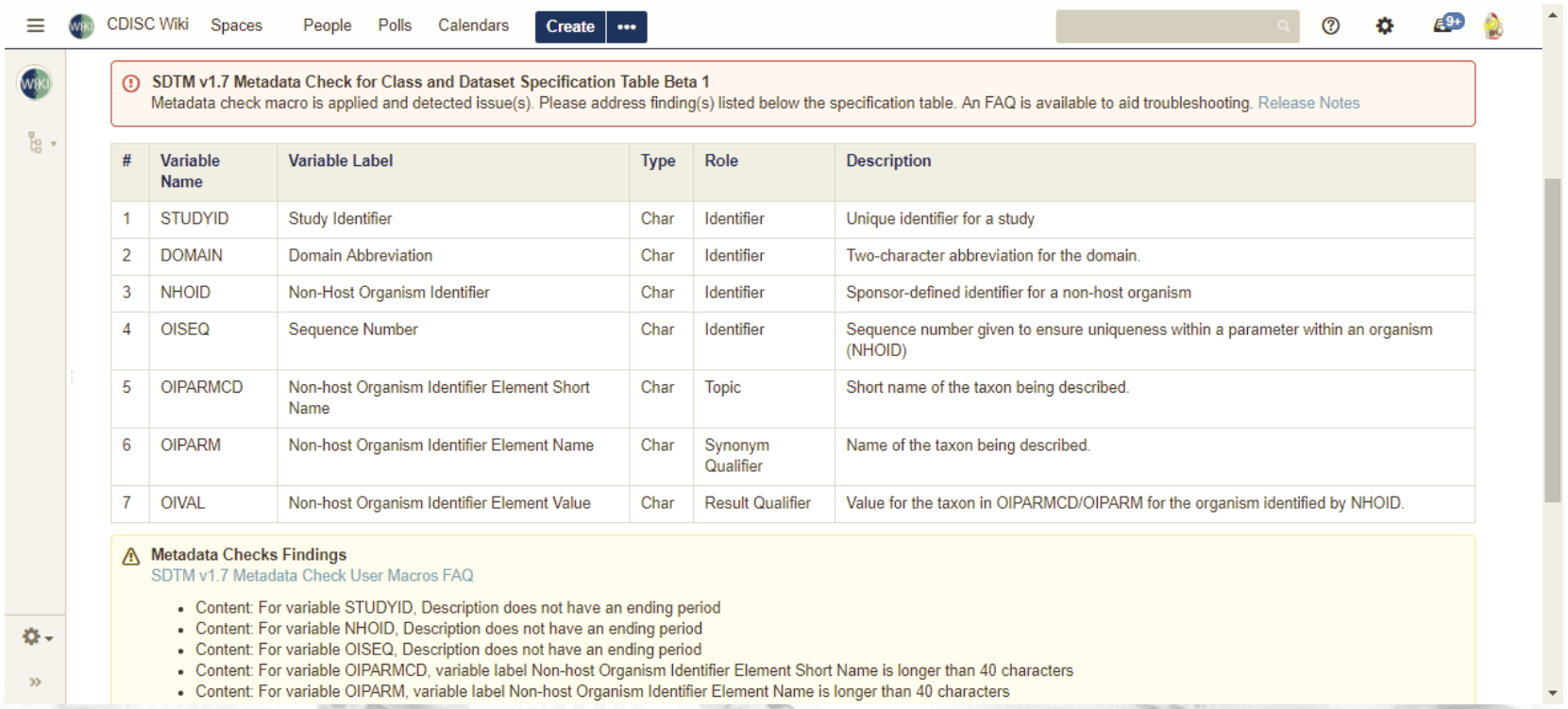
Input: CDASH-compliant metadata* in English and **Japanese** directly in the Wiki to support collaboration

ID	Order Number	CDASH IG Variable	Question Text	Prompt	Type	Case Report Form Completion Instructions	SDTMIG Target	Mapping Instructions	Controlled Terminology Codelist Name	Permissible Values	Pre-specified Value	Query Display	List Elements	Hidden
BRTHDAT	4	BRTHDAT	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, year, month/year, etc.).	BRTHDTC	This does not have a direct mapping in SDTMIG Evaluable Form for SDTM submission datasets. Consider using collected CDASH DATE and TIME components and populate the SDTMIG Evaluable BRTHDTC in ISO 8601 format.	NA	NA	NA	gled	NA	FALSE
AGE	6	AGE	What is the subject's age?	Age	integer	Record the age of the subject.	AGE	Maps directly to the SDTMIG Evaluable case in the column with the heading "SDTMIG Target."	NA	NA	NA	gled	NA	FALSE
AGEU	13	AGEU	What is the age unit used?	Age Unit	text	Record the appropriate age unit.	AGEU	Maps directly to the SDTMIG Evaluable case in the column with the heading "SDTMIG Target."	AGEU	DAYS, HOURS, MONTHS, WEEKS, YEARS	NA	gled	auto	FALSE
CMDAT	11	CMDAT	What is the date of collection?	Collection Date	date	Record the date of collection.	DMDTC	This does not have a direct mapping in SDTMIG Evaluable Form for SDTM submission datasets, consider using collected CDASH DATE and TIME components and populate the SDTMIG Evaluable DMDTC in ISO 8601 format.	NA	NA	NA	gled	NA	FALSE
SEX	12	SEX	What is the sex of the subject?	Sex	text	Record the appropriate sex.	SEX	Maps directly to the SDTMIG Evaluable case in the column with the heading "SDTMIG Target."	SEX	F=Female, M=Male, U=Unknown, I=DIFFERENTIATED=Intersex	NA	gled	auto	FALSE

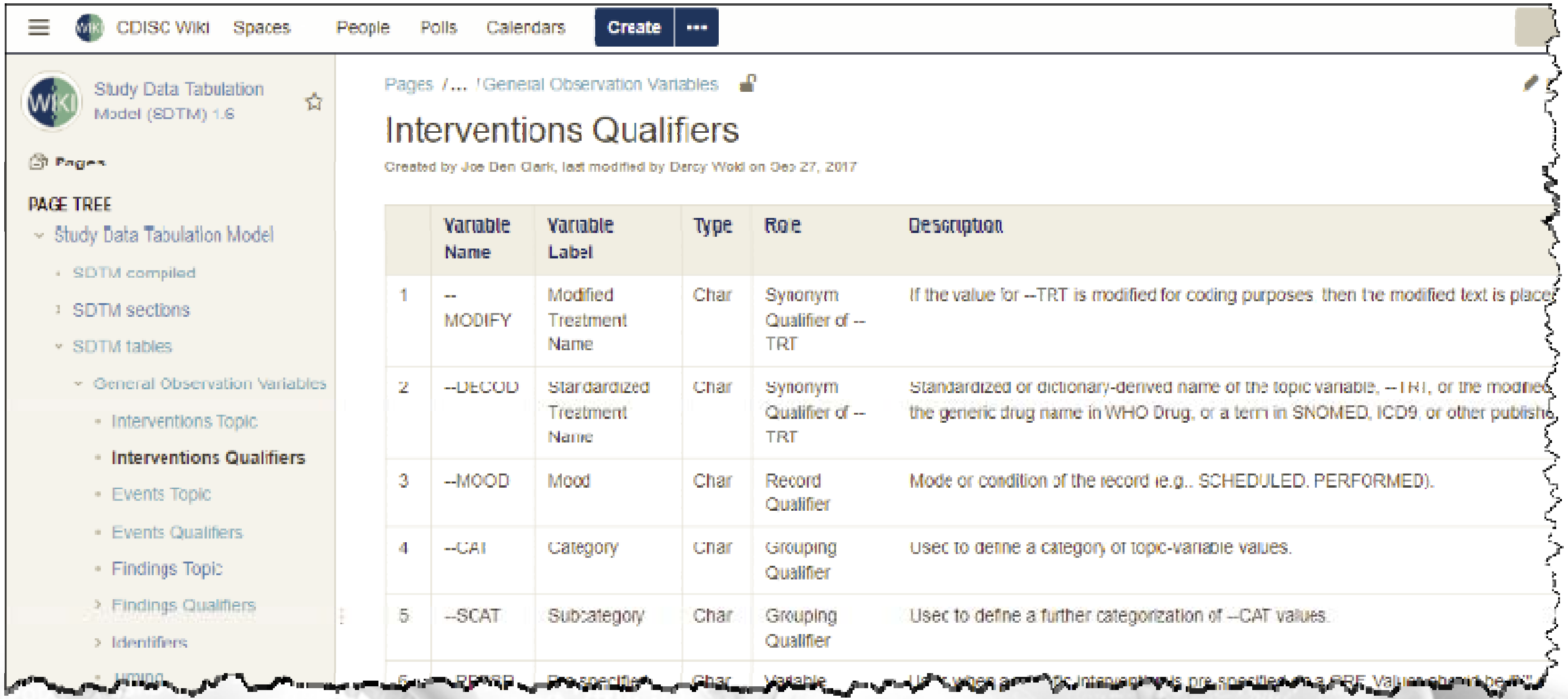
Output: aCRF

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

Metadata QC Checks for SDTM/IG



Spec Grabber: Source Metadata on WIKI



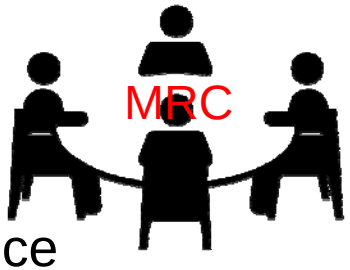
	Variable Name	Variable Label	Type	Role	Description
1	--MODIFY	Modified Treatment Name	Char	Synonym Qualifier of --TRT	If the value for --TRT is modified for coding purposes, then the modified text is place
2	--DECOD	Standardized Treatment Name	Char	Synonym Qualifier of --TRT	Standardized or dictionary-derived name of the topic variable, --TRT, or the modified the generic drug name in WHO Drug, or a term in SNOMED, ICD9, or other publish
3	--MOOD	Mood	Char	Record Qualifier	Mode or condition of the record (e.g., SCHEDULED, PERFORMED).
4	--CAT	Category	Char	Grouping Qualifier	Used to define a category of topic-variable values.
5	--SCAT	Subcategory	Char	Grouping Qualifier	Used to define a further categorization of --CAT values.

Improving the Standards Development Governance

Past Governance Model

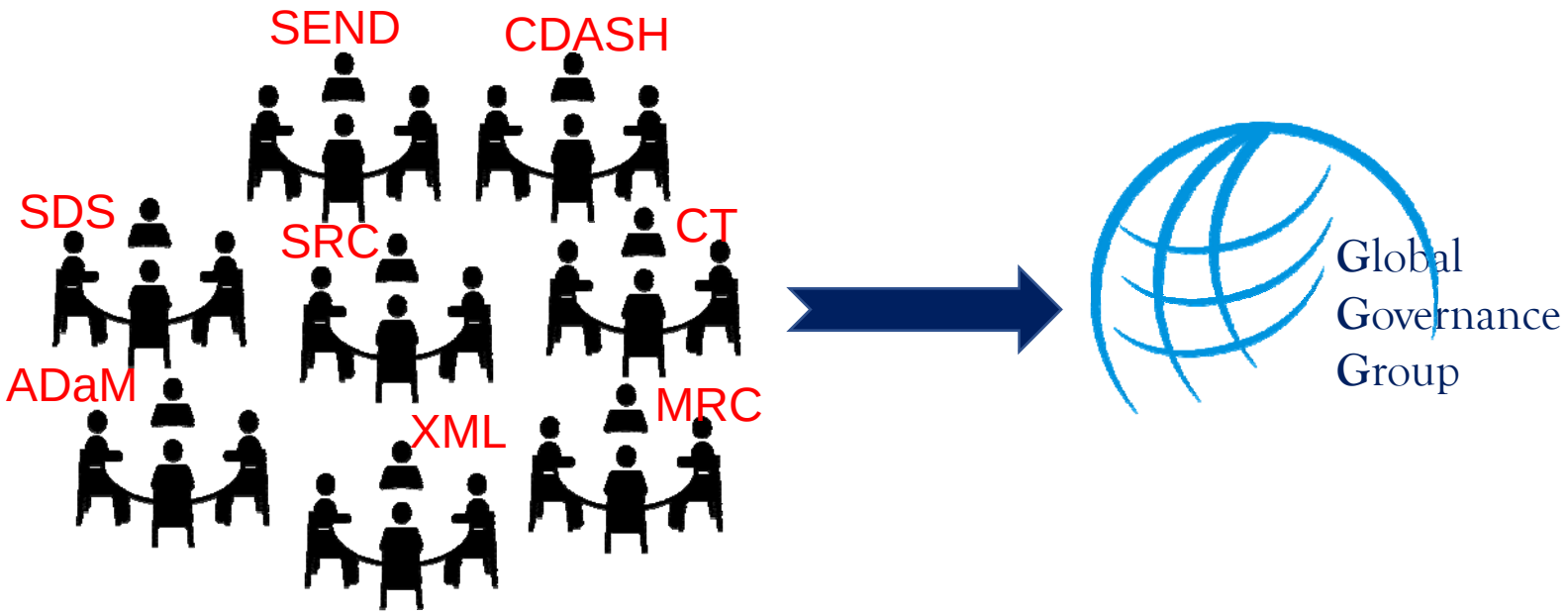
Separate conversations

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



Early advice
Better cross-team conversations
But not actual governance

New Governance Model



All governance groups now consolidated into **one** decision making body

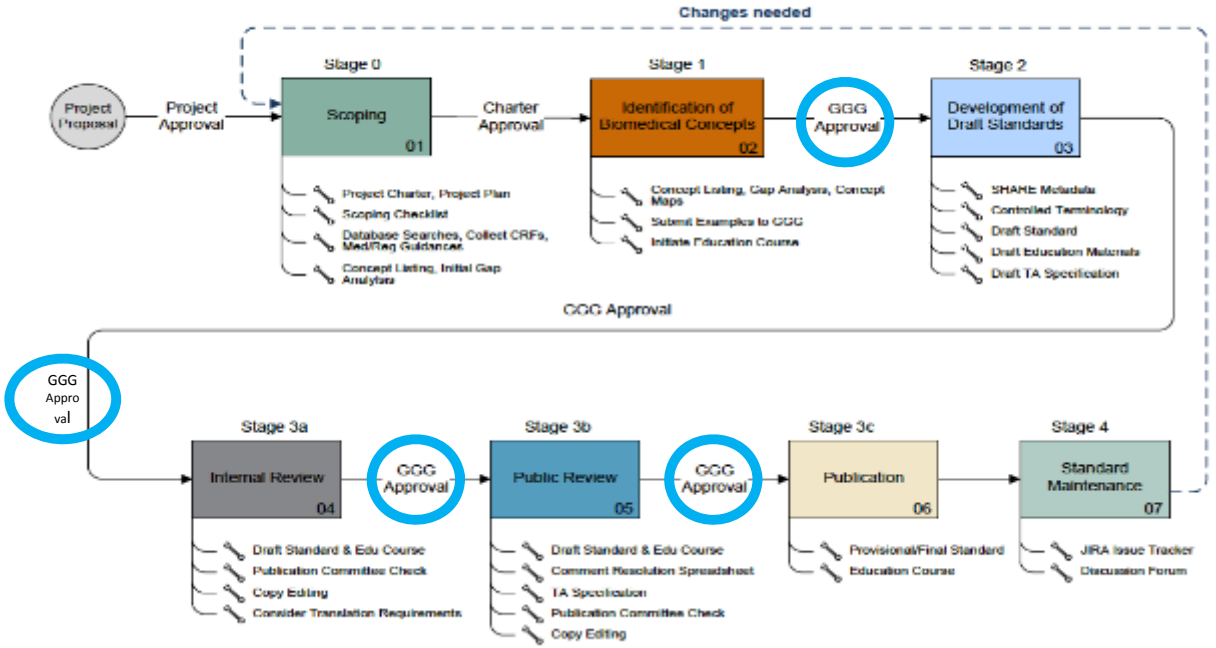
Benefits

- Reducing siloed decision-making by moving to a central governing body
- Consolidating governance into one decision making body
- Decision making more transparent with documentation of decisions in one place

Global Governance Group

- Consistency across teams and standards
- Representation (1-2) from each Foundational team
- Ensuring early input from all teams to reduce future rework

Standards Development Process



CDISC Education IACET Accreditation

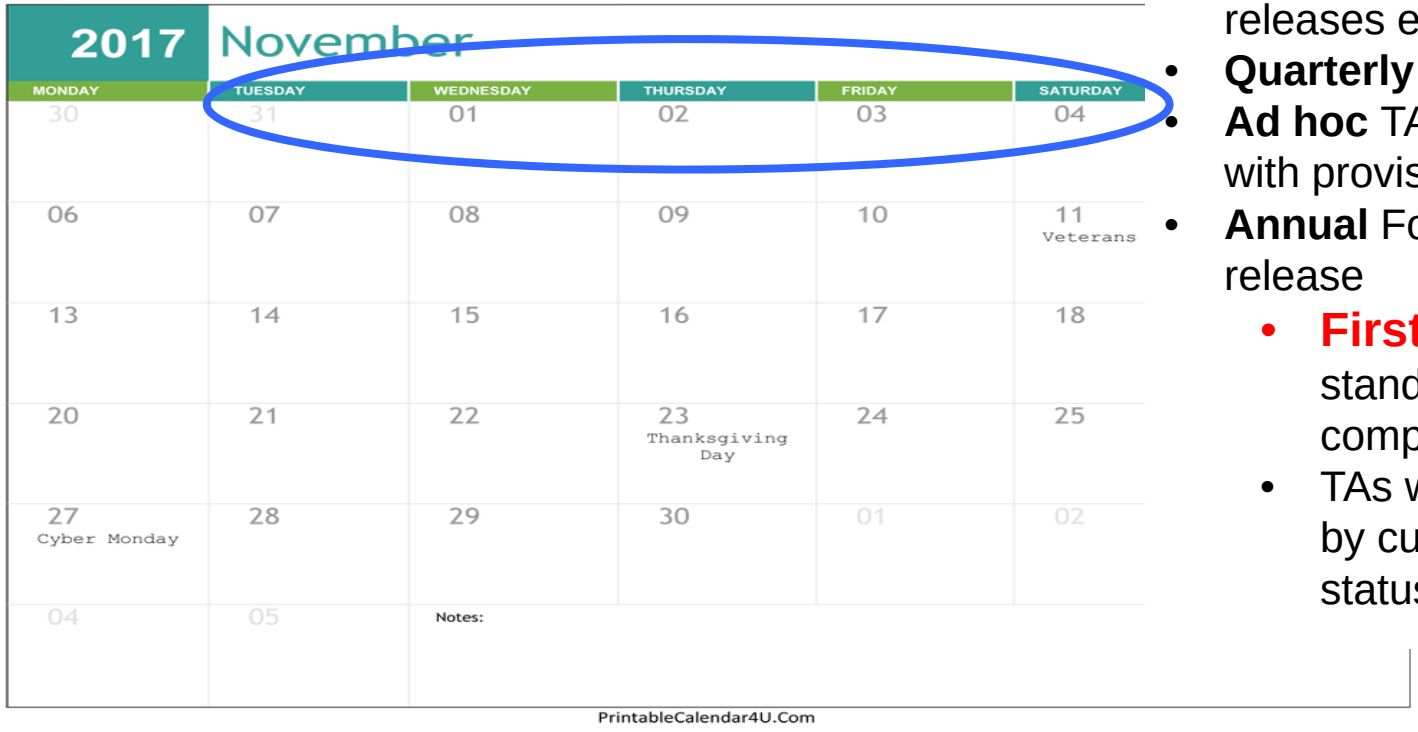
- CDISC Education received accreditation from the International Association of Continuing Education and Training (IACET)
  - Independent assessment and confirmation of a high quality, well controlled training program
- Continuing Education Units (CEUs) will be offered for most CDISC courses
  - CEUs 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

- Annual release schedule
- New publishing formats
- Transparency and Predictability
- Preparing for the future

Annual Release Schedule

Annual Product Release Schedule



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

“Final” is defined as:

- All public review comments dispositioned
- All changes made, QC’ed and approved for publication by the GGG
- Conformance Rules reviewed and ready
- Controlled terminology needed to support the standard is final
  - Is released, or has reached the post-public review stage
- Metadata loaded into SHARE and ready to export
- Education components developed (e.g., learning outcomes)

Result - More Implementable Standards

New Publishing Formats

New Publishing Formats

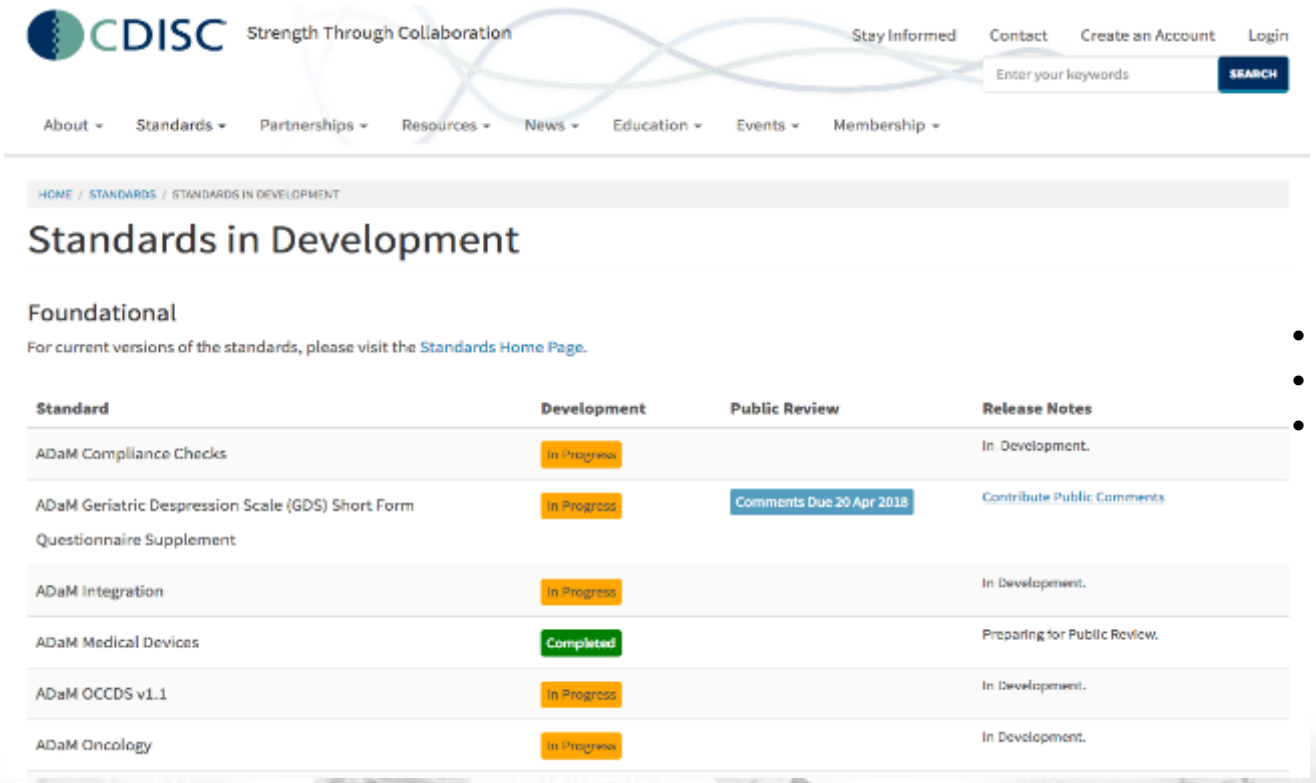
- Piloted release of CDASHIG v2.0, CDASH Model v1.0 in HTML – success!
  - Don’t worry ☺
    - You can still download as a file to your desktop
    - You can still bookmark sections
- Benefits
  - Much shorter publication time
  - More universally readable than PDF

Transparency

Interactive View of Standards

https://www.cdisc.org/standards

Project Status on the Website



- Foundational Standards
- Data Exchange
- Therapeutic Areas

https://www.cdisc.org/standards/in-development

Project Status on Wiki for Volunteers

Pages / Teams Home Edit Save for later Watch Share

Standards Updates Table

Created by Diane Wold, last modified by Steve Wilson on Apr 13, 2018

All Projects

Standard	Scoping	Development	Internal Review	Prep for Public Review	Public Review	Resolving Public Review Comments	Prep for Publication	Pu
Controlled Terminology Package 33							COMPLETE	30 20
TAUG-Vaccines v1.1						COMPLETE	ONGOING	Es Q:
SDTMIG v3.3						COMPLETE	ONGOING	Es Q:
SDTMIG-MD v1.1					N/A	N/A	ONGOING	Es Q:
SDTM v1.7					COMPLETE	ONGOING		Es Q:
TAUG-Colorectal Cancer v1						COMPLETE	ONGOING	Es Q:
TAUG-PTSD v1					COMPLETE	ONGOING		Es Q:
Define-XML v2.1					COMPLETE	ONGOING		Es Q:
RDF Reference Guide v1.1					COMPLETE	ONGOING		Es Q:
ADaMIG v1.2					COMPLETE	ONGOING		E Q:
TAUG-Huntington's Disease v1					COMPLETE	ONGOING		Es Q:
TAUG-Asthma v1.1						COMPLETE		Es Q:
2018 - Above this line, standards are Grandfathered into old process - (foundational standards published as "Final" and TAs as "Provis								
TAUG-CDAD v1				COMPLETE	ONGOING until 10 April			
QRS GDSSF ADaM Supplement				COMPLETE	ONGOING until 20 April			
Controlled Terminology Package 34				COMPLETE	ONGOING until 20 April			
ADaM Medical Devices			COMPLETE	ONGOING				
TAUG-HIV v1			COMPLETE	ONGOING				
TAUG-TCM Coronary Artery Disease/Angina v1			COMPLETE	ONGOING				
TAUG-QT Studies v1.1			N/A for updates	ONGOING				

https://wiki.cdisc.org/display/TEAM/Standards+Updates+Table

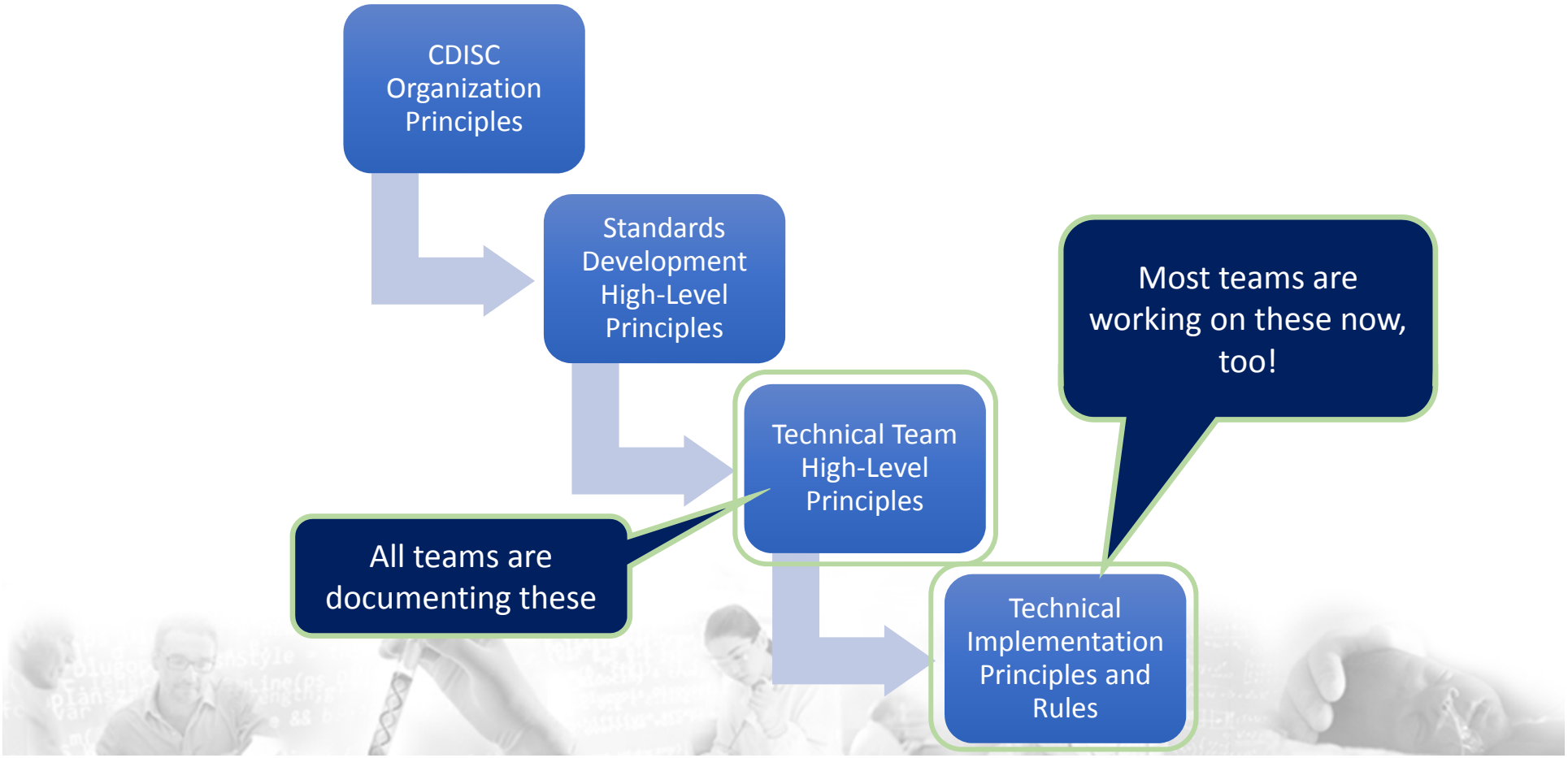
Preparing for the Future

Development Principles

Why do we need them?

- 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 optimize utilization of resources
- Helps to manage change
- Builds knowledge base for future development

Principles Hierarchy



Conceptual Examples*

Standard	Development Principles	Conformance Rules
Controlled Terminology	Within a code list, there cannot be duplicate CDISC submission values.	When two or more CDISC submission values within VSTESTCD are identical, display error.
CDASH	Data collection fields that will map SDTM variables that require controlled terminology should use the same terminology to collect the data.	If value list for AEACN contains any value not found in ACN codelist, display error.
SDTMIG	Variables in any domain are limited to those described for the Observation Class on which the domain is based	If a Findings Class domain contains --TERM or --TRT, display error.

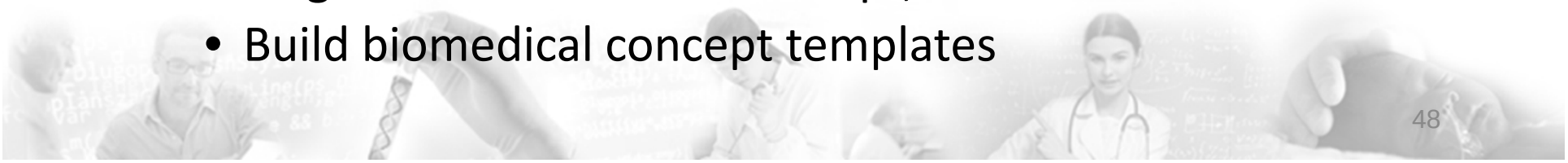
(*not real -just examples to illustrate the concepts)

Future of CDISC Standards

- Expanding use cases beyond regulatory submissions
- Aligning models with Real World Data (RWD)
- Refining the standards to build more support for new and emerging technologies

Support for New Technologies

- Connect CDASH (and SDTM) with FHIR and other healthcare standards to support eSource
- Provide standards in new formats (RDF, OWL)
- Refine the models to support machine readable standards
  - Single instance of each concept, well defined
  - Build biomedical concept templates



Roadmap for Refining the Standards

- Finalizing documentation of development principles that support future consistency within and across standards
- Finishing developing the associated conformance rules for model-based standards
- In-depth review and refinement of metadata to ensure consistency within and across standards
- Developing template biomedical concept maps based on the documented principles
- Load the refined models and templates into SHARE
- Build and publish SHARE tools to support future development

Expected Results

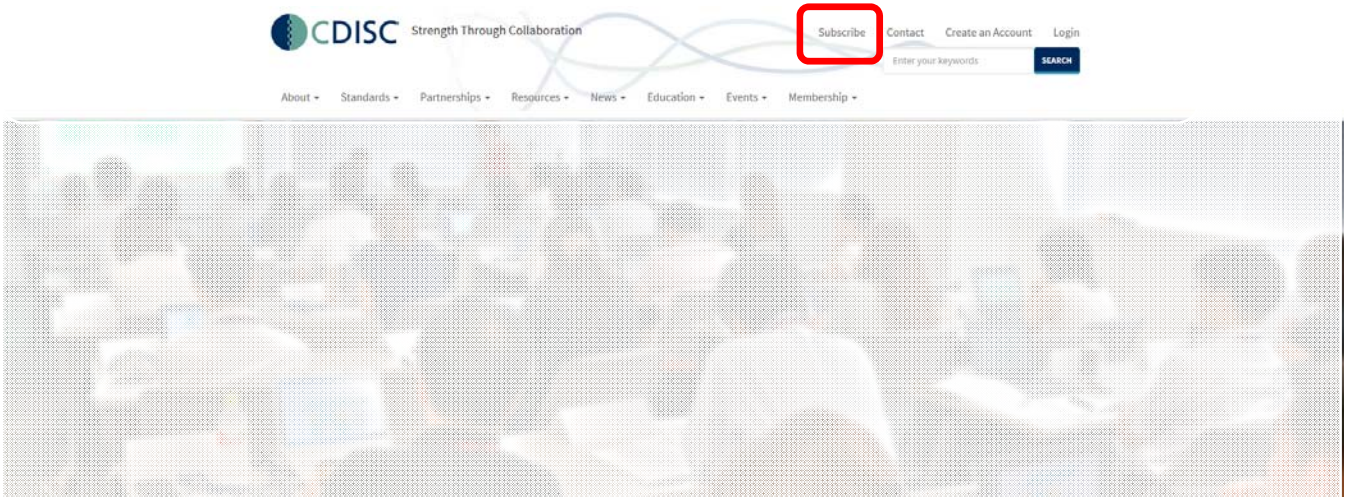
- Alignment within and across models
- Clearly defined concepts
- Better alignment with RWD
- Better support for tool development
- Higher quality standards
- Better support for machine-readability, semantic interoperability
- Gain efficiencies in future standards development
  - Pause and re-tool
  - Slow down now to be able to speed up and get higher quality later

As a CDISC newcomer, you may want to

- Subscribe to the newsletter
- Find information on the CDISC website
- Attend a CDISC training course or conference
- Become a member
- Participate in public review
- Volunteer on a standards development team

Announcements

- On the website
- E-mail “blasts” to our mailing list



MEMBERSHIP

Join over 450 member organizations who collaborate through CDISC to foster *Smarter Research to Unlock Cures*
www.cdisc.org

Conclusion

- We've come a long way since 1997
- Important work remains to be done
- CDISC will continue to evolve to
  - include new use cases
  - enhance the standards
  - move towards connected B2E concepts
  - respond and adapt to new technologies
  - meet the needs of the global community

Thank you for your continued collaboration!

Extra Slides

CDISC Standards Required for Regulated Research in the US and Japan

BINDING DOCUMENTS

US FDA & Japan's PMDA Require CDISC Standards, China's CFDA and EMA Recommend CDISC Standards

Real World View of Data