CDSIC Evolution and CDISC in China

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TOC

- CDISC Update
- Standards Evolution
- Activity Plan of CDISC China

CDISC Overview

- Founded 1997, incorporated 2000
- Member-supported (>400 organizational members, e.g. academia, bio pharma, service / technology providers
- CDISC Mission: to develop and support *global, platform-independent data standards* that enable information system *interoperability* to improve medical research and related areas of healthcare

What’s New, and What’s Next

2018 Goals

1

Build a customer-centric, stakeholder-centric culture.

2

Generate greater member value.

3

Ensure sustainability of CDISC Standards.

4

Optimize the standards development and release process.

5

Lay the foundation for a CDISC 2.0 vision.

Accomplishments Since end of 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

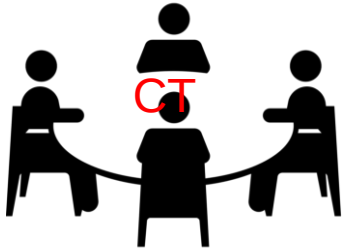
years later…2018

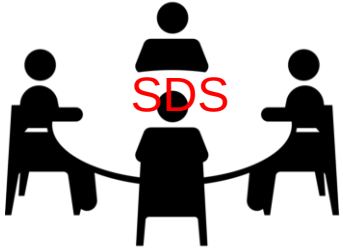

Resolve the inconsistencies!
SLOW DOWN!
Tell us what you are working on!
When will you publish the next version?
SPEED UP!
Make the documentation easier to use!
Make it easier for volunteers to participate!

We hear you!

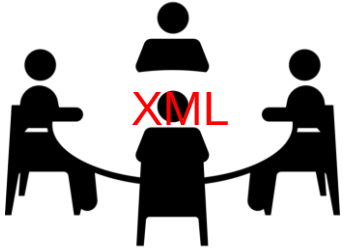
Improving the Standards Development Governance

Past Governance Model

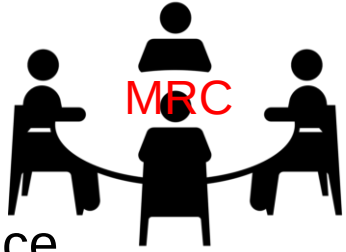




Separate conversations

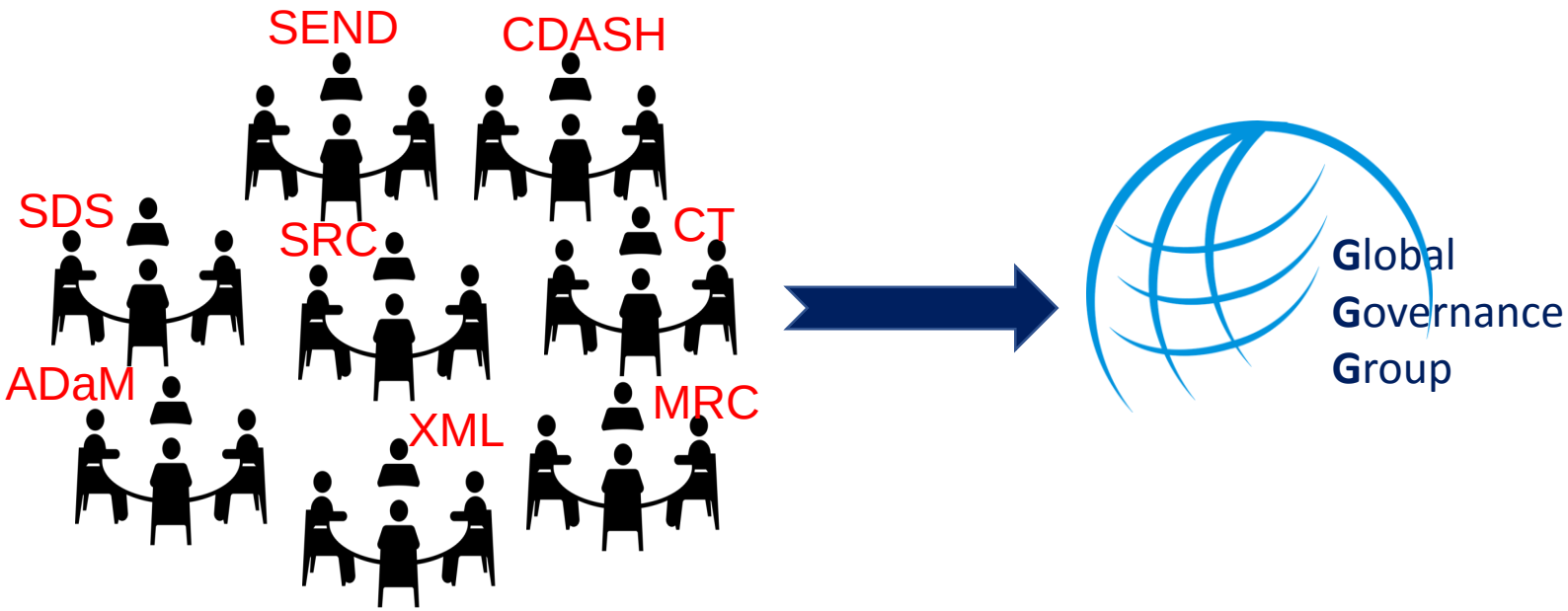


Good governance
But, not all teams represented
And, late in process



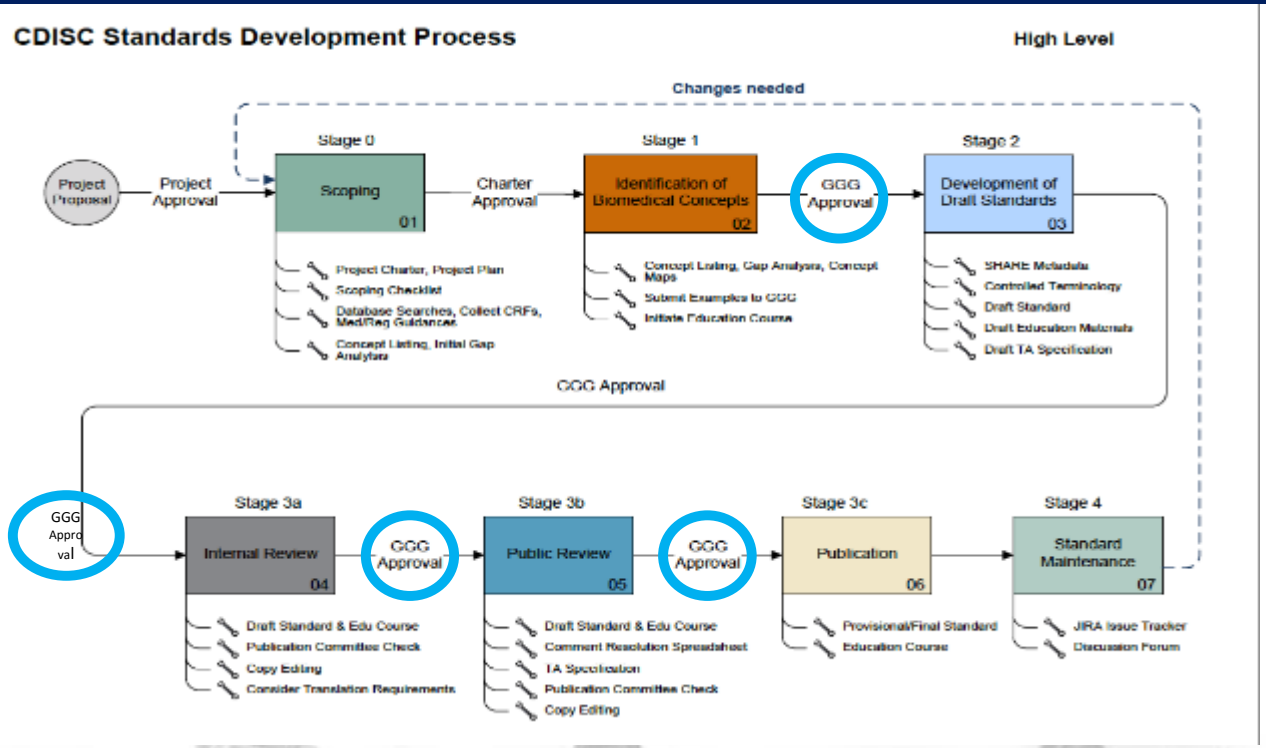
Early advice
Better cross-team conversations
But not actual governance

New Governance Model



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

Standards Development Process



2018-2020: What's Next

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

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

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

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!

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CDISC Standards Evolution

- More and more domains, More and more variables
  - More and more complicated to understand and implement?

- Future?

SDTM IG: 3.1.2 vs 3.2

	IG V3.1.2	IG V3.2
Date	2008-11-12	2013-11-26
Number of Domains	31	50
Number of Unique Standard Variables	145	209 (minus domain prefix)

New Domains

	IG 3.1.2		IG 3.2	
	#	Domains		New Domains
Trial Design	5	TA, TE, TV, TI, TS	7	TD,TX
Special-Purpose	4	DM, CO, SE, SV	4	
Interventions	3	CM, EX, SU	5	EC,PR
Events	5	AE,DS,MH,DV,CE	6	HO
Findings	12	EG, IE, LB, PE, QS, SC, VS, DA, MB, MS, PC, PP	21	DD, IS, MI, MO, RP, RS, SS, TR, TU
Findings About	1	FA	2	SR
Relationship	2	RELREC, SUPPQUAL	4	POOLDEF, RELSUB
Associated Persons			2	APDM, APRELSUB

New Variables in Finding Class

	IG 3.1.2		IG 3.2	
	#	Variables		New Variables
Findings	54	STUDYID, DOMAIN, USUBJID, SEQ, GRPID, REFID, SPID, TESTCD, TEST, CAT, SCAT, POS, ORRES, ORRESU, STRESC, STRESN, STRESU, STAT, REASND, XFN, NAM, LOC, METHOD, BLFL, DRVFL, EVAL, VISITNUM, VISIT, VISITDY, DTC, DY, TPT, TPTNUM, ELTM, TPTREF, RFTDTC, ORNRLO, ORNRHI, STNRLO, STNRHI, STNRC, NRIND, LOINC, SPEC, SPCCND, FAST, TOX, TOXGR, ENDTC, MODIFY, BODSYS, EVLINT, RESCAT, LLOQ	68	LEAD, TSTDTL, LAT, DIR, LNKID, PORTOT, ANMETH, ULOQ, STINT, ENINT, LNKGRP, EVALID, ACPTFL, EPOCH

Finding Class Domains

- Old:
  - ✓EG, IE, LB, PE, QS, SC, VS, DA, MB, MS, PC, PP
- IG 3.2 New:
  - ✓DD, IS, MI, MO, RP, RS, SS, TR, TU
- Draft:
  - ?: CV, RE, NV,MK, OE, UR, QT, PF, FT, CC

Variables related to Test and results

- OLD:
  - -- TESTCD, -- TEST,
  - -- POS,
  - -- ORRES, -- ORRESU, -- STRESC, -- STRESN, -- STRESU,
  - --ORNRLO, --ORNRHI, --STNRLO, --STNRHI, --STNRC, --NRIND
  - --RESCAT, --LLOQ
  - --LOC, --METHOD, --SPEC
- IG3.2 New:
  - --TSTDTL,
  - --ULOQ
- Draft:
  - --RESTRG (Pre-Specified Result Targeted by Test)

Confusion and Thinking -personal view

- Do we need that many domains?

- Do we need that many Variables?

--TSTDTL

- Further description of --TESTCD and --TEST.
- Example:
  - “The percentage of cells with +1 intensity of staining” when MITESTCD = TTF1.

MITEST	MITSTDTL	MIORRES	MISTRESC	MIRESCAT	MISPEC	
Human Epidermal Growth Factor Receptor 2	Reaction Score	0	0	NEGATIVE	TISSUE	
Human Epidermal Growth Factor Receptor 2	Reaction Score	2+	2+	POSITIVE	TISSUE	

--OBJ

- ***Can we expand using it in all findings Domain?***

	SRTEST	SROBJ	SRORRES
	Reaction Grade	Dog Epi IgG 0 mg	NEGATIVE
	Reaction Grade	Dog Epi IgG 0.1 mg	NEGATIVE
	Reaction Grade	Dog Epi IgG 0.5 mg	ERYTHEMA, INFILTRATION, POSSIBLY DISCRETE PAPULES
	Reaction Grade	Dog Epi IgG 1 mg	ERYTHEMA, INFILTRATION, PAPULES, VESICLES
	Reaction Grade	Dog Epi IgG 1.5 mg	ERYTHEMA, INFILTRATION, PAPULES, VESICLES
	Reaction Grade	Dog Epi IgG 2 mg	ERYTHEMA, INFILTRATION, PAPULES, COALESCING VESICLES

MIOBJ?

MITEST?

MITEST	MITSTDTL	MIORRES	MISTRESC	MIRESCAT	MISPEC	
Human Epidermal Growth Factor Receptor 2	Reaction Score	0	0	NEGATIVE	TISSUE	
Human Epidermal Growth Factor Receptor 2	Reaction Score	2+	2+	POSITIVE	TISSUE	

--RESTRG

- the variable --RESTRG (Pre-Specified Result Targeted by Test) is used when the imaging finding is pre-specified on the case report form, and it should populated with the pre-specified finding of interest.

--PRESP=Y and RETEST?

Proposed

RETEST	RERESTRG	REORRES	RESTRESC	RELOC	REMETHOD
Targeted Respiratory Examination	Volume Loss	ABSENT	ABSENT	LUNG	X-RAY
Targeted Respiratory Examination	Volume Collapse	ABSENT	ABSENT	LUNG	X-RAY
Targeted Respiratory Examination	Cavitation	PRESENT	PRESENT	LUNG	X-RAY

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Activity Plan of CDISC China

- **CDISC Interchange, China 2018**
  - Sep7-8, 2018
  - Beijing
  - Public training
- **CDISC Seminar**
  - >=3 times
  - Beijing, Shanghai, Guangzhou
- **CDISC webinar**
  - every 2 months
  - Presented in Chinese

- CDISC Standards Translation
  - CDASH, SDTM, ADaM
  - PRM, ODM, Define
- Draft Guidance on Data Submission

Contact us:
if you are interested

Email: cdiscChina@cdisc.org

MEMBERSHIP

If you are a CDISC Member, we Thank You!

It is our members' support which enables us to develop standards, keeping it free and accessible to all. CDISC Members Drive Global Standards.

Not a member?

Join over 450 member organizations to work together in Unlocking Cures to Benefit All Patients

Email: Membership@cdisc.org

Acknowledgement

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Strength *through collaboration.*

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