Blue Ribbon Commission Insights

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Chief Standards Officer
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Agenda

1. What is the Blue Ribbon Commission?
2. What future do they foresee?
3. Next steps for CDISC and our community

Blue Ribbon Commissioners

- Global reach
- Diversity of CDISC community
  - Pharma, CROs
  - Tech companies
  - Academics
  - Regulatory
  - Nonprofit partners…including PhUSE
  - CDISC staff thought leaders

Commissioners

Co-Chairs
- Joyce Sensmeier, RN (HIMSS)
- Dr. Rob Califf (Verily, Duke University, former US FDA)

Academia
- Dr. Barbara Bierer (Harvard, MRCT, Vivly)
- Dr. Laura Merson (Oxford University, IDDO)
- Dr. Frank Rockhold (Duke University)
- John Speakman (NYU Langone)
- Dr. Sam Volchenboum (University of Chicago, Litmus Health)
- Dr. Anita Walden (University Arkansas for Medical Sciences)

Regulators
- Dr. Yuki Ando (PMDA)
- Dr. Allison Cave (EMA)
- Dr. Lilliam Rosario (US FDA)

Biotech, Devices
- Paul Franson (Medtronic, Inc.)
- Joanna Koft (Biogen)

Nonprofit Partners
- Scott Bahlavooni (PhUSE)
- Dr. Lynn Hudson (C-Path)
- Maria Picone (TREND Community, patient advocate)

Pharmaceuticals
- Jonathan Chainey (Roche, CAC)
- Dr. Hidetoshi Misawa (Pfizer, CDISC J3C)
- Dr. Jennifer O'Callaghan (Eisai Worldwide)
- Dr. Ulo Palm (Allergan)
- Dr. Zibao Zhang (dMed, CDISC C3C)

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Commissioners

Government Agencies
- Dr. Ken Gersing (NIH/NCATS)
- Dr. Tatsuya Maruyama (AMED)
- Dr. Lyuba Remenik (NIH/NCI)

Technology/Services
- Dr. Wenjun Bao (JMP Life Sciences, SAS)
- Dave Evans (Accenture)
- Hugh Glover (Blue Wave Informatics)
- Dr. C. David Hardison (Deloitte)
- Dave Iberson-Hurst (Assero Limited)

CROs/Labs
- Sherry Chou (Parexel)
- Phil Pochon (Covance)

Research Funders
- Dr. Georgina S. Humphries (Wellcome Trust)
- Scott Kahn (Helmsley Charitable Trust)
- Dr. Steven Kern (Gates Foundation)

Healthcare
- Dr. Jeffrey Brown (Harvard University Medical School, Harvard Pilgrims Health Care Institute)

CDISC Staff
- David R. Bobbitt, MSc, MBA
- Anthony Chow
- Dr. Sam Hume
- Rhonda Facile, MS
- Marine Laurent
- Bess LeRoy, MPH
- Peter Van Reusel

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What did they tell us?

#1 Better standards from inception

- Refine the model
  - End-to-end standards unwavering goal
  - Machine readable protocol, in partnership and in context
  - Move from 2D to 3D model
  - Greater insights from real world evidence
  - New technologies, new sources of data
- Improve implementation consistency
  - Improve homogeneity of the standards
  - Transform data across the foundational standards
  - Strive for nimbleness
  - Revisit implementation advice

Moving from 2D to 3D

5 Models for Special-Purpose Domains

Demographics (DM)

DM – Description/Overview for the Demographics Domain Model

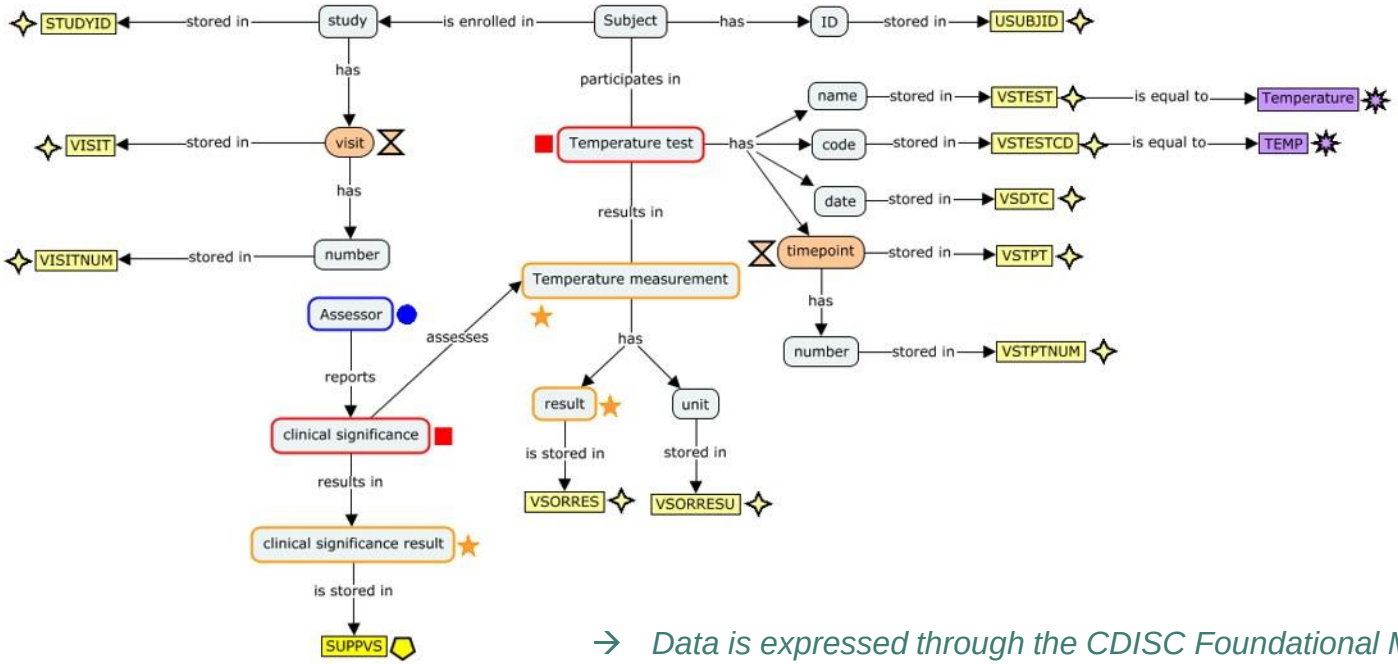
The Demographics domain includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for all other observations for human clinical subjects.

DM – Specification for the Demographics Domain Model

dm.xpt, Demographics — Version 3.2. One record per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DM	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. This must be a unique number, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBJID.	Req
SUBJID	Subject Identifier for the Study	Char		Topic	Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.	Req
RFSTDTC	Subject Reference Start Date/Time	Char	ISO 8601	Record Qualifier	Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. Required for all randomized subjects; will be null for all subjects who did not meet the milestone the date requires, such as screen failures or unassigned subjects.	Exp
RFENDTC	Subject Reference End Date/Time	Char	ISO 8601	Record Qualifier	Reference End Date/time for the subject in ISO 8601 character format. Usually equivalent to the date/time when subject was determined to have ended the trial, and often equivalent to date/time of last exposure to study treatment. Required for all randomized subjects; null for screen failures or unassigned subjects.	Exp
RFXSTDTC	Date/Time of First Study Treatment	Char	ISO 8601	Record Qualifier	First date of exposure to any protocol-specified treatment or therapy, equal to the earliest value of EXSTDTC.	Exp
RFXENDTC	Date/Time of Last Study Treatment	Char	ISO 8601	Record Qualifier	Last date of exposure to any protocol-specified treatment or therapy, equal to the latest value of EXENDTC (or the latest value of EXSTDTC if EXENDTC was not collected or is missing).	Exp

3D biomedical concept map



→ *Data is expressed through the CDISC Foundational Models*
→ *Can map to BRIDG Reference Model*

#2 Optimize the volunteer labor force

- People are CDISC's greatest asset both volunteers and staff
- Volunteers provide irreplaceable knowledge and expertise
- Volunteering is changing and will continue to change

#3 Focus and clarity

- CDISC is a small nonprofit organization with an enormous mission.
- Ignore the “shiny object.” Instead be strategic.
- Overly communicate.
- Reduce barriers to accessing and utilizing the standards
  - Cost as a barrier
  - Knowledge as a barrier
  - Jargon and English-only content as barriers

#4 Build a strong standards ecosystem

- Broaden availability of CDISC Library
- CDISC Certification
- Open source and other tools
- Be multilingual

- Formerly known as SHARE
- Built on a new technology stack based on a linked data model
- Includes an expanded API
- Includes new content not previously available
- Broader membership access to the API
- Launch includes lots of supporting activities

The evolution of the standards ecosystem

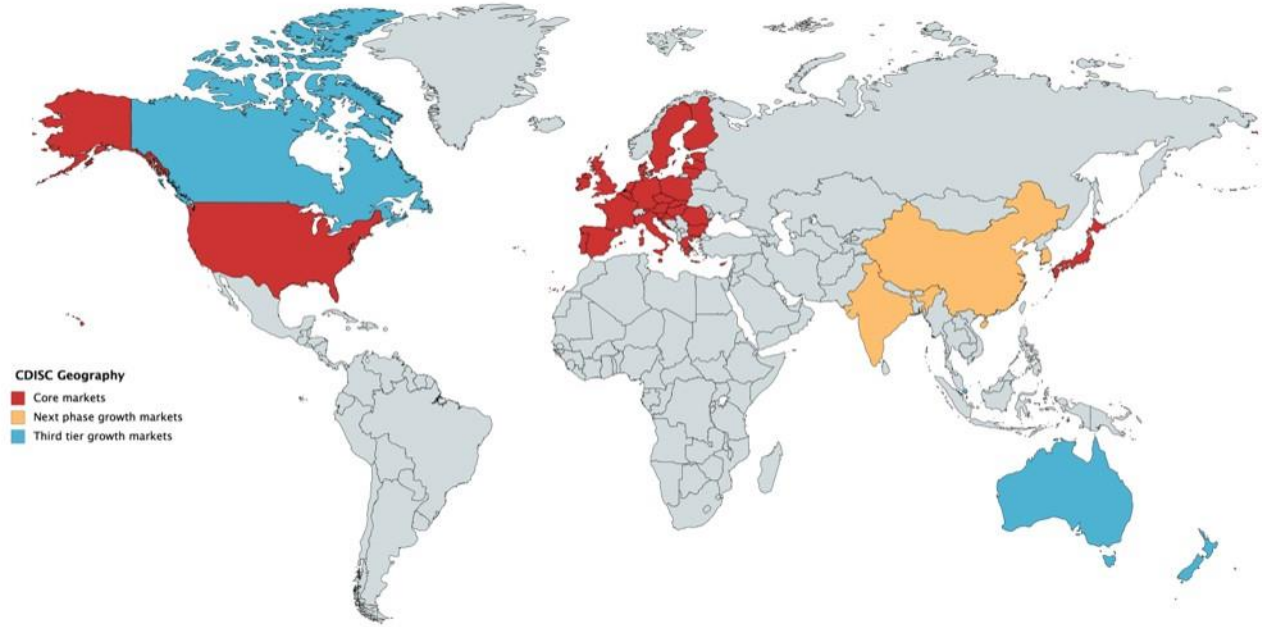
	Yesterday	Today	Tomorrow
Standards	Standards are PDF and paper- based.	Standards are machine-readable and exposed via API.	Standards are built for machines first, people second.
Implementers	Implementers work in highly bespoke, labor-intensive environments. Implementers must be standards experts.	Implementers have a single source of truth to improve homogeneity.	Implementers curate tools based on a deep understanding of standards.
Tools	Tools are site-specific and workplace-specific, narrow in scope, and frequently expensive.	Tools are scalable and more reliable, but there are gaps. Broad-scope tools are available.	Tools allow non-standards experts to attain benefits of standardization. Quality derivative products abound.
Semantic Interoperability	Interoperability requires laborious mapping between standards.	A higher degree of interoperability reduce barriers to meta-analysis.	Broad interoperability is achieved. Standards truly become views of data.

#5 Rely on key partnerships

…and be a good partner!

#6 Growth

- Growth in use case: academic research
- Growth geographically



#7 Membership

Explore new models while maintaining current strengths

(Some) Areas where we didn't achieve consensus

- Interoperability of real world data
  - This is complex, and still unfolding.
- Deprecation
  - Not everyone wants it, and there's no simple way to do it.
- Versioning
  - Everyone wants it simplified. We could not agree how.

What happens next?

Next steps

February-March 2019

Insights document out for public review and comment

April 2019

CDISC staff review comments and draft new multi-year strategic plan

May 2019

CDISC Board of Directors finalizes a new multi-year strategic plan.

Final comments

We don't predict the future.

We make the future, together.

CDISC is a small organization with a vast reach. At the same time, CDISC is a community filled with people of goodwill who want to ensure benefits of standardization reach all of humanity.

We should built the world where we would want to be sick. We should build the world where we would want to age.

Data is a precious resource, never to be squandered, ignored, or wasted.

Thank You!

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