

PhUSE US Connect 2019

CDISC Blue Ribbon Commission Insights

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Context

CDISC is a global community united by a vision to bring clarity to data. Volunteers founded CDISC more than two decades ago because they saw the future clearly, a future where standardized data improves the critical conversation between sponsors of regulated research and government regulators charged to ensure the public health.

That future is reality today. CDISC foundational standards (i.e. SDTM, SEND, CDASH, and ADaM) are utilized by sponsors of regulated research to submit data to regulatory bodies including US Food and Drug Administration (FDA) and Japan Pharmaceuticals and Medical Devices Agency (PMDA). Therapeutic Area User Guides (TAUGs) help researchers plan and structure studies to benefit from standardization. CDISC standards are utilized in ways the founders may not have fully imagined, including to support data sharing platforms, to build patient registries, and to standardize academic research.

In spring 2018, CDISC CEO David R. Bobbitt with advice and consent of the CDISC Board of Directors under the leadership of Chair Dr. Stephen Pyke, an executive at long-time CDISC member company GSK, appointed a Blue Ribbon Commission, Appendix 1. Commissioners were selected to represent the geographic reach of CDISC standards as well as represent the industries and users of CDISC standards. Joyce Sensmeier, HIMSS executive and CDISC Board member, and Dr. Robert Califf, former Commissioner of the US FDA, co-chaired the Commission. The Blue Ribbon Commission was charged with preparing CDISC for the next decade of growth and change by considering what factors will most influence utilization of CDISC standards. Commissioners served as a strategic think tank for CDISC. Over six months Commissioners met frequently and generated more than 200 pages of discussion. Their recommendations augmented by some staff comments were incorporated into a high level report. Commissioners connected, as members of the CDISC community so often do, over their shared passions: bringing clarity to data, reducing human suffering, curing diseases, supporting automation, enhancing interoperability, and a commitment to global health.

Summary of Insights

Commissioners believe that CDISC standards are and will remain relevant for every aspect of the research enterprise; however, CDISC must be prepared for significant changes as the research world is undergoing substantial changes. New technologies combined with data from new sources will require CDISC to become nimbler and more rapidly responsive to change. The

core CDISC foundational standards model must be fine-tuned both to support implementation through better internal alignment and to better reflect the core biomedical concepts common to research protocols. As the use of real world data (RWD) in clinical research grows, CDISC standardization remains necessary to maximize the value of RWD in research datasets. CDISC must fundamentally change its historically hands-off approach to implementation. One key effort to support implementation is to build a new content layer that standardizes the transformation of data across the CDISC foundational standards. CDISC will become *de facto* one standard, evolving to one well-refined model on the back end where foundational standards, and therapeutic area specific extensions, become views of data, and developing on the front end a more accessible profile so that non-experts can leverage the benefits of standardization.

CDISC must be prepared for future global growth through supporting a robust clinical data standards ecosystem. Central to this ecosystem is the CDISC SHARE metadata repository. CDISC SHARE is a standards library which offers new ways to expose and implement the CDISC standards as well as a new technology-based platform from which to build and update CDISC standards. As part of this robust ecosystem, CDISC as an organization should extend efforts beyond the sponsor-regulator focus to include the broader research landscape, with a renewed emphasis on support for academic researchers' effective utilization of the CDISC standards.

Above all, CDISC must remain a focused and productive global community, providing value for its members. This community is a welcoming place for volunteers where each member of the community can bring their personal gifts and talents. This community builds solid partnerships with other stakeholders and entities: there is much work to do and more hands and minds to do this work are always a gift.

Public Comments and Next Steps

The Commissioners agreed on a several broad themes, below, which are further developed in a Blue Ribbon Commission document. This document will be available for public review and input at www.cdisc.org. The public comment period will begin in February 2019 and is expected to extend at least 60 days. Guided by the final document and those comments, CDISC leadership will develop a new multi-year strategic plan.

#1: Better standards from inception

1.A: Refine the model

1.A.1. End to End Standards

1.A.2. Protocol

1.A.3. 3D Model/Biomedical Concepts

1.A.4. Greater insights from RWE

1.A.5. New technologies and new sources of data

1.B.: Improve implementation consistency

1.B.1. Improving homogeneity

1.B.2. Transform data across the foundational standards

1.B.3. Completeness of New Versions of Standards

1.B.4. Nimbleness

1.B.5. Implementation advice

#2: Optimize the volunteer labor force

#3: Focus and clarity

#4: Build a strong standards ecosystem

#5: Rely on key partnerships

#6: Growth

6.1: Grow Use Case: Standardization of Academic Research

6.2: Grow Geographically

#7: Explore new models for membership and revenue while maintaining current strengths

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Appendix 1: Blue Ribbon Commissioners

Joyce Sensmeier, RN, Co-Chair HIMSS	Dr. C. David Hardison Deloitte	Dr. Lyubov Remennik NIH National Cancer Institute Enterprise Vocabulary Services
Dr. Robert Califf, Co-Chair Duke University, former Commissioner, US FDA	Dr. Lynn Hudson Critical Path Institute, CFAST	Dr. Frank Rockhold Duke University
Dr. Yuki Ando PMDA	Dr. Georgina S. Humphries Wellcome Trust	Dr. Lilliam Rosario US FDA
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Dr. Wenjun Bao JMP Life Sciences, SAS Institute Inc.	Scott Kahn Helmsley Charitable Trust	Dr. Sam Volchenbom University of Chicago, Litmus Health
Dr. Barbara Bierer Harvard University, Brigham and Women's Hospital, MRTG, Vivly	Dr. Stephen Kern Bill and Melinda Gates Foundation	Dr. Anita Walden University of Arkansas for Medical Sciences
Dr. Jeffrey Brown Harvard University Medical School, Harvard Pilgrims Health, FDA Sentinel	Joanna Koft Biogen	Dr. Zibao Zhang dMed Pharmaceuticals, AP3C, C3C
Dr. Alison Cave EMA	Dr. Tatsuya Maruyama Keio University and formerly AMED	David R. Bobbitt, MSc, MBA CDISC
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Dave Evans Accenture	Jennifer O'Callaghan Eisai Worldwide	Dr. Sam Hume CDISC
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Dr. Ken Gersing National Institutes of Health	Maria Picone TREND Community, patient advocate	Bess Leroy, MPH CDISC
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