cdisc

2018-2019 Blue Ribbon Commission Insights

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 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 currently used 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 the spring of 2018, CDISC President and CEO David R. Bobbitt with advice and consent of the CDISC Board of Directors under the leadership of Chair Stephen Pyke, an executive at long-time CDISC member company GSK, appointed a Blue Ribbon Commission (Appendix 1). Commissioners were selected to reflect the geographic reach of CDISC standards as well as to 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. These Commissioners served as a strategic think tank for CDISC. The Blue Ribbon Commission was charged with preparing CDISC for the next decade of growth and change by considering what factors would most influence utilization of CDISC standards. Over six months Commissioners met frequently, and these dedicated experts generated more than 200 pages of thoughts and discussion. Their recommendations augmented by some staff comments are incorporated into this 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 improving global health.

Summary of Insights

The Commissioners believe that CDISC standards are, and will remain, relevant for every aspect of the research enterprise; however, they also concluded 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 real world evidence (RWE) 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. The CDISC standards 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, while 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 by supporting a robust clinical data standards ecosystem. Central to this ecosystem is the CDISC SHARE[1] metadata repository. CDISC SHARE 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 build on and 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 and demonstrating value for its members and stakeholders. 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 will always be a gift.

Broad Theme #1: Better standards from inception

Subcomponent Theme 1.A: Refine the model
Commissioners agreed unanimously that CDISC should align all foundational standards around one core model so that CDISC becomes *de facto* one standard. Foundational standards (e.g., SDTM, ADaM, etc.) become views of data that can be accessed and assembled by users according to their requirements. This "refine the model" theme will help ensure the sustainability of CDISC standards. CDISC must address the model as its highest priority. This is the overarching theme of the Blue Ribbon Commission work. In many cases, Commissioners agreed to other priorities yet emphasized that refining the model must come first over other considerations.

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[1] At the time this document is being released for public review, CDISC management is undergoing a process to re-brand the CDISC SHARE metadata repository as CDISC Library. This document utilizes the soon-to-be-legacy name CDISC SHARE.

1.A.1. End-to-end standards

There was clear unanimity that end-to-end (ETE)[2] standardization is the goal, a goal which CDISC has not yet fully achieved. That the disparate foundational standards are not fully interoperable precludes ETE. Not all Therapeutic Area User Guides (TAUGs) are ETE. Commissioners believe a goal of building ETE standards is both worthy and quite ambitious. They had nuanced opinions on what ETE entails and how CDISC should proceed.

CDISC must fundamentally enhance and align around one core model to achieve ETE standards. Commissioners suggested considering BRIDG as this core model, if practicable. CDISC should only generate new TAUGs that are ETE. Eventually CDISC will need to update legacy TAUGs that are not ETE.

1.A.2. Protocol

Commissioners achieved clear consensus that a CDISC Protocol standard makes sense. (See also Broad Theme #5, below.)

- Specifically, a machine-readable protocol standard is needed that is fully interoperable with CDISC foundational standards. Built for machines first, people second to reduce heterogeneity in implementation as well as support good science.
- Any Protocol work should be done in conjunction with TransCelerate BioPharma, the Clinical Electronic Structured Harmonized Protocol (CeSHarP) initiative at ICH, NIH, and PMDA, FDA, among other partners. CDISC should not work solo nor should CDISC duplicate existing work in this area.
- Work on the Protocol standard should not hinder the effort to harmonize across CDISC foundational standards

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

There is a consensus agreement that CDISC ought to move from a 2D model (tabular oriented, siloed model) to a 3D model, focused on biomedical concepts. A 3D model makes implicit relationships, explicit. In such a 3D model, relationships are defined and these relationships dynamically make connections between data elements. CDISC is at a natural inflection point from which the model will evolve into a back-end 3D system, an elegant model that many stakeholders will be wholly unaware of, and a front-end system geared toward researchers and implementers. This is a natural product of the maturation and evolution of the CDISC standards as well as a reflection of the changing world of healthcare informatics.

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[2] Commissioners diverged somewhat on whether CDISC builds beginning to end (BTE) or end-to-end (ETE) standards. Commissioners concluded that BTE is the more common term and that ETE is the more precise term. This report utilizes the term ETE for discussion purposes.

Commissioners noted:
- The move from 2D to 3D should be incremental and should build on current CDISC strengths.
- Build in transparency so that regulators and others who require access to the back-end model can attain needed insight.
- This transition will take several years to accomplish.
- 2D representations of the standards should continue to be available as most implementers continue to work in a 2D world. The 3D model should be available for implementers (e.g., programmers, technologists) who can utilize the 3D model for implementation.
- Training will be critical for the community to fully benefit from a core 3D model.
- CDISC should work with technology vendors and open source communities to ensure new machine-based software tools can be built on the 3D model, from CDISC SHARE.
- The 3D model should link domains, variables, terminology, as well as commonly utilized, external code lists.
- CDISC SHARE 2.0 should offer the platform to build the 3D model.
- Buy-in is critical. The broader community must understand this process. CDISC staff should consider a pilot or proof of concept to make the effort transparent and to reach as broadly and deeply into the community as possible in order to (1.) draw on expertise from the community and (2.) obtain early adoption within the community that can prod broad adoption.

1.A.4. Greater insights from RWE
Commissioners agreed that real world evidence (RWE) derived from real world data (RWD) is of growing importance to industry and to regulators as a source of actionable insights. Commissioners agreed that CDISC standardization is necessary to unlock insights from RWD and recommended that CDISC:
- Continue to engage regulators and industry as their needs for RWD to support decision-making evolves.
- Be mindful of RWD in evolving the model, (above), and 3D model/biomedical concepts (above) to ensure that the community has adequate tools to plan for, collect, represent, manage, archive, document, and analyze RWD.
- Continue to build SHARE tools (below) that can accurately curate and represent RWE.
- Provide mappings with RWD resources including terminologies and other standards (e.g., LOINC and FHIR elements) in a machine-readable format in CDISC SHARE.
- Cultivate nimbleness, (below), as an organizational strategy to be more prepared to respond to the evolving landscape of RWD.

<u>1.A.5. New technologies and new sources of data</u>
Commissioners agreed unanimously that CDISC's best approach to new technologies and new sources of data begins with further refining the current foundational standards model, noting that:

- CDISC has limited resources to impact the development of new technologies and new sources of data.
- A better-refined model will support greater consistency in standardizing data from new sources and provides working groups clear direction for considering data derived from new technologies.
- The rate of technological change is too great for CDISC to be intimately involved in every opportunity. Commissioners recommended that CDISC should observe and engage (in order of priority) with:
  - HL7 FHIR/ EHR data
  - Internet of things
  - Medical device and wearables data
  - Bring-your-own-device data

Subcomponent Theme 1.B.: Improve implementation consistency
Commissioners agree that CDISC ought to build standards that are even more implementable from inception and that CDISC must support implementers through training and education as well as through key partnerships.

<u>1.B.1. Improving homogeneity</u>
- Staff have recommended taking a pause in developing new versions of foundational standards for up to 18 months to completely reassess the current domain and variable structure in the CDISC standards model. This assessment is likely to suggest structural changes to simplify domains and variables. This assessment should also include a path to resolve discrepancies among domains or variables that are utilized in different CDISC standards. Commissioners agreed with this pause and the strategy behind it. When done successfully, this effort will reduce heterogeneity of implementations.
- Utilize CDISC SHARE 2.0 tools to determine where inconsistencies across the foundational standards exist.

<u>1.B.2. Transform data across the foundational standards</u>
- Commissioners saw significant value in developing a standard way of utilizing examples to transform data across the foundational standards. Such an effort would require CDISC staff and the broader user community to collaborate on a defined use case that incorporates real anonymized data. This effort is highly related to the 3D model transformation work (above).
- Make this work broadly available to the user community.

- Build a structure to allow sponsors and others to share insights and anonymized examples of transforming data across the foundational standards. Commissioners noted that this effort would be labor-intensive, and likely outside the current staff capacity, in order to be executed successfully.

1.B.3. Completeness of new versions of standards

Commissioners achieved a consensus agreement that each major standard version update must include changes to the model, complete rules, examples, compliance/conformance rules, and an accompanying implementation guide. That being said, Commissioners believe that getting the model right first makes this process much easier. Commissioners noted that PDF documents are an insufficient and outdated platform to communicate components of updates like implementation guides when hyperlinked data are more efficient and consumer-friendly for end users of all types. CDISC must move consciously into a new era where standards are build first as machine-readable artefacts.

1.B.4. Nimbleness

Commissioners agreed that CDISC should become a nimbler organization in order to become more responsive to a rapidly changing milieu of technologies, research protocols, and data sources as well as growing demand for new use cases of the CDISC standards. As a result of refining the model and building a 3D core model, CDISC will become nimbler and better able to respond to new technologies and new use cases of the CDISC standards. CDISC should utilize agile methods to develop and scale up new initiatives.

1.B.5. Implementation advice

CDISC has historically declined to offer implementation advice to members. Reasons for this decision include the potential liability if advice fails to produce desired results and the potential for competition with members. The Commissioners were of a consensus that CDISC Board and management should revisit this historic decision and find ways to offer implementation advice, even if in a limited manner, as a benefit of membership. Commissioners perceive provision of implementation advice primarily as a way to improve adoption of the standards and implementation consistency.

Broad Theme #2: Optimize the volunteer labor force
CDISC has been, and will remain, a volunteer-driven organization. Volunteering has changed over the first 20 years of CDISC's existence and will likely continue to evolve; yet the core commitment of volunteers pooling their expertise and knowledge to fundamentally improve human health through well-crafted standards will remain unchanged in the coming decade.

- Ask member organizations explicitly to commit to volunteers, but do not make such a commitment a condition of membership as it could likely be too high a threshold for some companies to agree to.
- Long-term volunteers are the most valuable resources to help build and maintain strong standards. CDISC should do more to recognize and encourage long-term volunteers.
- Encourage subject matter experts (SMEs) who volunteer on TAUGs to remain CDISC volunteers after the TAUG development process is complete.
- Train volunteers to utilize CDISC SHARE as a tool to build and maintain standards.
- Utilize volunteers at key points in the standards development process. Utilize staff at critical points to remove bottlenecks, provide overall strategic direction for teams, and serve as a conduit of communication between the team and CDISC headquarters.
- Commissioners were pleased to see that CDISC uses Wiki and Jira with working groups and encourages broad use of modern electronic tools to foster the work of teams.

Broad Theme #3: Focus and clarity

CDISC is a small nonprofit organization with an enormous mission. Commissioners agreed that CDISC must be focused and clear in articulating goals and strategies in order to be successful, especially to achieve success in influencing the mightily powerful entities that CDISC must regularly engage.

- Be both overly communicative and transparent: share messages about versioning, deprecation, training, certification, and other community-relevant matters many times over a variety of communications channels to ensure community members have access to decisions and can have their voices heard with decisions impact on their work or research. Provide realistic lead times. Articulate clearly why decisions have been made.
- Ignore the "shiny object." This includes not being sidetracked by the promise of new technologies. Focus on the model and implementation, Broad Theme #1 (above).
- Make implementation support a key activity of CDISC. Consider ways that the implementable-ness of a change is considered when making that change (e.g., adding domains, up-versioning, generating new TAUGs).
- Reduce barriers to entry for accessing and utilizing the CDISC standards, including updated educational offerings and an organizational commitment to de-jargoning whenever and wherever possible. Ensure that new users and new implementers can quickly gain sufficient understanding to benefit from standardization.
- Market the many benefits of data standardization and focus less on marketing CDISC. Once a potential stakeholder recognizes the many benefits of standardization, CDISC as an entity will naturally benefit.
- CDISC staff should not feel pressured to engage in every opportunity or pursue every potential partnership. Rather, decisions to prioritize activities and partnerships should flow from a well-considered strategic plan that is updated every few years. CDISC is not as effective when the staff are spread too thin across too many priorities.

- Scoping[3] is the critical phase for every project's success or failure. CDISC should continue to cultivate staff and volunteers who are exceptionally strong in scoping projects.

Broad Theme #4: Build a strong standards ecosystem

While this theme was not identified in response to any discrete question, Commissioners generally perceive CDISC standardization to be a critical resource, which like any resource must be deployed judiciously and sustained. Commissioners agreed that a strong standards ecosystem grows from a healthy community of standards creators and standards implementers. Each member of this community has a critical role. CDISC is central to a healthy standards ecosystem.

- Resist the urge to achieve total interoperability. Instead, focus on use cases that benefit CDISC stakeholders and have the opportunity to improve global health in a significant way.
- Make CDISC SHARE API access free for CDISC members to ensure broader use of the metadata repository.
- Establish a highly functional professional certification program that incorporates pragmatic implementation of the standards, not just learning theory and rules. Require regular knowledge updates to maintain certification credentials. Individual certification (1.) improves homogeneity of implementation; (2.) expands the pool of qualified job candidates available to the community; and (3.) may provide a substrate for company-level certification demonstrated by a critical mass of individual certifications.
- Allow no-charge access to the CDISC SHARE API to developers of open-source tools and solutions. Encourage robust and consistent tools built for the user community, regulators, and implementers through allowing no-charge, pre-commercial access to the CDISC SHARE API by developers to develop tools and related derivative products. Commissioners agreed that after the developer monetizes the tool or other product, CDISC can and should receive revenue in some manner
- Support the development of a SHARE-derived, visual, web-based, natural-language search tool for standards with traceability and mapping to help implementers improve consistency of standards implementation.
- Whenever practicable in release of new versions, moving to the 3D model, or other changes to the standards, provide support for backwards compatibility through either mapping, decision trees, or other tools. Provide updates of existing examples.
- Consciously include the voice of the patient in standards development, especially in TAUG development.

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[3] Scoping, Phase 0 in the CDISC standards development process, refers to an initial assessment and documentation of specific project goals, deliverables, tasks, required subject matter expertise, and deadlines in a project.

- In all matters, present CDISC as a global community. Share materials in multiple languages. Ensure that the diversity of this global community is represented in decision-making.

Broad Theme #5: Rely on key partnerships

CDISC is not an island. Everything CDISC does affects others. Commissioners encouraged CDISC to be a good partner and to cultivate key partnerships. Commissioners noted certain partnerships, which are core to CDISC's future vision:

- Regulators as well as ICH
- HL7
- C-PATH
- TransCelerate BioPharma
- Industry associations including EFPIA, ACRO, and JPMA

As a consequence of Focus and Clarity (Broad Theme #3, above) Commissioners recommended against some activities as a priority for CDISC. Commissioners instead recommended that CDISC should be supportive of these activities, yet find a partner entity to lead the effort on the following topics:

- Curation of donated data to generate examples for community use.
- Production of derivative tools and related products to support users specifically in low and middle-income countries (for whom machine-readable materials are a high barrier to implementation)
- Development of a machine-readable Protocol standard (above).
- Development of ways to share data back with patients, who are often eager to understand how their own data have been utilized in research
- Efforts to make CDISC standards more accessible to researchers working on rare diseases; to researchers in low and middle-income countries; and to researchers working on emergent infectious diseases

Broad Theme #6: Growth

The Commission recommended growth from two perspectives: use cases and geographic growth.

Subtheme 6.1: Grow Use Case

Commissioners acknowledged CDISC standards are growing in use-cases beyond the original use case of regulatory approvals. Commissioners agreed that the most important use case for CDISC to support above and ahead of all others in the foreseeable future is standardization of academic research, observational research, patient-reported outcomes, and real world evidence. Support could include:

- Academic-user-specific education
- Visual, web-based, natural-language search for academic users

- Success stories and case studies
- Provide accessible training (accessible in terms of both cost and content)
- Explore a new membership pricing model at the researcher-led organizational level (a.k.a. the lab level, and not full university level) for academic users of CDISC standards.
- Leverage the growing data-sharing movement and support the movement's need for standardization

Subtheme 6.2: Grow geographically

The Commission recognizes that CDISC standards are used globally and that mandates are useful to support further adoption of the standards. Yet the Commission cautioned that CDISC standards should be chosen for quality more than merely mandated. CDISC should be opportunistic whenever a regulatory agenda is interested in a closer relationship with CDISC. Any plan from geographic growth will rapidly deteriorate in value as time passes yet current thinking is as follows:

- Priorities for the next 1-3 years:
  - China—An important and growing market for both healthcare product discovery and consumption. Also, China is a market many developing nations look to for guidance. Pursue closer relationship with National Medical Products Agency (NMPA, formerly China FDA).
  - India—Growing market for outsourcing data management. Perhaps a market for training/education growth and additional user groups.
  - EU—Will at some point likely accept electronic data submissions. Remain engaged with the European Medicines Agency (EMA.)
  - UK—May select electronic data submissions rapidly post-Brexit. Remain attentive.
- Additional markets to bear in mind:
  - South Korea, Australia, New Zealand, Singapore
  - Canada, Central American nations, South American nations
  - Eastern European nations
  - Middle Eastern nations
  - African nations
- Continue to support major markets of USA and Japan.

In addition, CDISC should consider the following to consolidate or expand its current geographic reach:
- Provide more support to local user groups where practicable.
- Consider a global health perspective when prioritizing new TAUGs for development.
- Build relationships with funders of trials in low to moderate income nations, including the Bill and Melinda Gates Foundation and WHO, to ensure CDISC standards are recognized and standardization is funded within their grants.

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

Commissioners generally perceived CDISC as doing a good job in building an effective membership model and supporting the community through a well-staffed and well-managed organization. Commissioners recognized that CDISC must reassess membership offerings from time to time to ensure relevance, and that CDISC in the course of good management ought to consider new and additional revenue streams. Commissioners provided a range of advice on these matters including:

- Consider a "freemium" model for CDSIC SHARE where some basic content is freely available (to encourage more utilization of CDISC SHARE and therefore upstream implementation of the standards) and where more advanced content comes only with paid membership.
- Explore revenue-sharing options with developers who have built tools from no-charge, pre-commercial access to SHARE
- Approach funders of academic research that support open science and data sharing to request grant dollars to support the expansion of CDISC for academics, the 3D evolution, and support for free access to CDISC SHARE API by academics.
- Consider a different membership model for academics where specific researchers and labs can join CDISC for a modest annual cost—that can be paid from grants for example—rather than charging larger memberships fees at the institutional level. Explore a mechanism to earn revenue from offering implementation services and/or answering implementation questions.
- Consider a "fit for use" revenue model where CDISC verifies that derivative products for use cases other than regulatory submissions generally fit the CDISC model and charge for this "fit for use" endorsement. This could also be a joint effort of CDISC with another entity to be funded by grants, in cases where the target audience is researchers in low and middle-income countries for example.
- Build a professional certification program (above) and charge for certification.
- Consider a company-level certification program where companies wanting to demonstrate depth of competence can obtain a company-wide certification after a sufficient number of staff are individually certified. Charge a fee for this additional company-level certification.

Areas Where Consensus Could Not Be Reached

#1 Balancing timeliness and completeness of work

Commissioners spoke to a desire for CDISC to work more rapidly on updating standards as well as for updates to include contemporaneous release of rules and implementation guides. At the same time, Commissioners desire to allow longer lead time for implementers to adjust to changes in standards. Commissioners acknowledged that it will be difficult for CDISC to

accomplish all three: rapid work, complete releases, and long lead times in a resource-limited environment.

Recommendation: Commissioners believe CDISC requires sufficient resources to support timeliness and completeness of up-versioning and of development of a 3D model. CDISC will consider ways to update to a segment of a standard (e.g., a 3D unit in the 360 Project). Since stakeholders have diverging interests, CDISC must make clear, well-communicated decisions when resources are insufficient and choices must be made.

#2 Interoperability of Real World Data

Commissioners agreed on the need to leverage the CDISC standards for real world data (RWD), where feasible. They differed on how best to achieve full interoperability of RWD into CDISC standards. Commissioners' opinions fell into two groups broadly:

- RWD is collected within disparate and complex health care systems for clinical care and reimbursement and not research; therefore, it is operationally difficult and potentially misleading to map such data to CDISC standards without significant manipulation of the data.
- Clinical data from all sources, including RWD, should be first organized via interoperable mapping and subsequently decisions on quality and utility can be made.

RWD data is a complex topic. CDISC staff and community members currently work in a variety of consortia on eSource and other efforts that attempt to make use of RWD reliable and scalable. This brief outline of Commission insights lacks space to address this topic in depth.

Recommendation: Report both positions. In addition, recommend the following:
1. *Consider the feasibility of a new "source quality" qualifier added onto specific SDTM variables only for RWD so that data mapped from RWD sources into CDISC format can be noted as coming from a source other than traditional randomized controlled clinical trials.*
2. *Begin using RWD as an eSource input into study eCRFs and track the use of the same edit checks used in today's research to assess the quality of research data populated using RWD sources. Metrics generated based on study experience will provide empirical support for claims regarding EHR data quality and suitability for research.*
3. *Provide no-cost access to the CDISC SHARE machine-readable standards for researchers attempting to scale-up eSource and other convergences of clinical and observational data sources as a concrete way to support practical use of RWD for clinical research.*
4. *If resources allow, and in partnership with key stakeholders, build toolkits and APIs for registries and other new sources of RWD so that new RWD can be established from the start already built in to the extent possible in CDISC standardization.*

#3 Branding of the foundational standards

A large majority of Commissioners believe the standards names would be improved and simplified through de-jargoning by renaming SDTM to CDISC-Tabulate and ADaM to CDISC-

Analyze, for example. A minority of Commissioners do not see much value in changing the names either because most users are currently familiar with these acronyms and/or because some systems utilize the current names.

- Most Commissioners felt renaming is a low-priority issue compared to other issues on the Commission docket.
- Virtually all Commissioners agreed that rebranding needs a long lead-time with old and new names existing side by side or otherwise with clear allowance for old names.
- Many Commissioners perceive re-branding as a material demonstration of the changes the Blue Ribbon Commission will charge CDISC to make.

Recommendation: Report the varied opinions of Commissioners. Choose a compromise to support a dual system wherein the official names of foundational standards remain SDTM, SEND, CDASH, and ADaM and where for training and other ease-of-use reasons, the names of CDISC-Tabulate, CDISC-Collect, CDISC-NonClinical, CDISC-Analyze can exist in parallel.

#4 New system of versioning

Commissioners agreed unanimously that CDISC's system of versioning needs improvement and that a more intuitive and simplified system is highly desirable. Commissioners did not agree on a system to recommend. Commissioners noted that once the 3D model is in place, versioning could be moved to the domain level or the concept level. Commissioners also noted:

- An updated versioning system could include a reliability rating.
- Moving standards development into the CDISC SHARE metadata repository (MDR) should help narrow options for creating an updated versioning system.

Recommendation: Staff should make updating the versioning system a goal in the coming 1-3 years and utilize a public review and comment period, including review by regulators.

#5 Deprecation

Commissioners did not agree unanimously that CDISC should engage in a system of deprecating old versions of standards.

- A majority of Commissioners agreed that a deprecation system is desirable and reasonable, and expressed specific goals and that the process to select a deprecation system be public, subject to regulatory input, and thoroughly communicated within the community after selection.
- A minority of Commissioners believe that deprecation is unnecessary as there are few costs to CDISC, in their opinion, to maintain old versions of standards and because some studies are in flight for so long, there will always be laggard studies.

Recommendation: Accept the majority position and build a deprecation system for old versions of standards since staff note there are concrete expenses associated with ongoing support for all standards. Utilize the CDISC Operational Data Model (ODM) to archive the old standards so they can be made available with advance notice to community members on request, likely for a nominal fee. For deprecating controlled terminology, add a discouraged state, so the term is available for studies in flight for a period of time but is not available for new studies.

Appendix 1: Blue Ribbon Commissioners

Joyce Sensmeier, RN, Co-Chair
HIMSS

Dr. Robert Califf, Co-Chair
Duke University, former
Commissioner, US FDA

Dr. Yuki Ando
PMDA

Scott Bahlavooni
d-Wise, PhUSE

Dr. Wenjun Bao
JMP Life Sciences,
SAS Institute Inc.

Dr. Barbara Bierer
Harvard University, Brigham
and Women's Hospital, MRTC,
Vivly

Dr. Jeffrey Brown
Harvard University Medical
School, Harvard Pilgrims Health
Care Institute

Dr. Alison Cave
EMA

Jonathan Chainey
Roche, CDISC Advisory Council

Sherry Chou
Parexel

Dave Evans
Accenture

Paul Franson
Medtronic

Dr. Ken Gersing
National Institutes of Health

Hugh Glover
Blue Wave Informatics

Dr. C. David Hardison
Deloitte

Dr. Lynn Hudson
Critical Path Institute, CFAST

Dr. Georgina S. Humphries
Wellcome Trust

Dave Iberson-Hurst
Assero, former CTO CDISC

Scott Kahn
Helmsley Charitable Trust

Dr. Stephen Kern
Bill and Melinda Gates
Foundation

Joanna Koft
Biogen

Dr. Tatsuya Maruyama
Keio University and formerly
AMED

Dr. Laura Merson
Oxford University

Hidetoshi Misawa
Pfizer, J3C

Jennifer O'Callaghan
Eisai Worldwide

Dr. Ülo Palm
Allergan

Maria Picone
TREND Community, patient
advocate

Phil Pochon
Covance

Dr. Lyubov Remennik
NIH National Cancer Institute
Enterprise Vocabulary Services

Dr. Frank Rockhold
Duke University

Dr. Lilliam Rosario
US FDA

John Speakman
New York University

Dr. Sam Volchenboum
University of Chicago, Litmus
Health

Dr. Anita Walden
University of Arkansas for
Medical Sciences

Dr. Zibao Zhang
dMed Pharmaceuticals, AP3C,
C3C

David R. Bobbitt, MSc, MBA
CDISC

Anthony Chow
CDISC

Rhonda Facile, MS
CDISC

Dr. Sam Hume
CDISC

Marine Laurent
CDISC

Bess Leroy, MPH
CDISC

Peter Van Reusel
CDISC