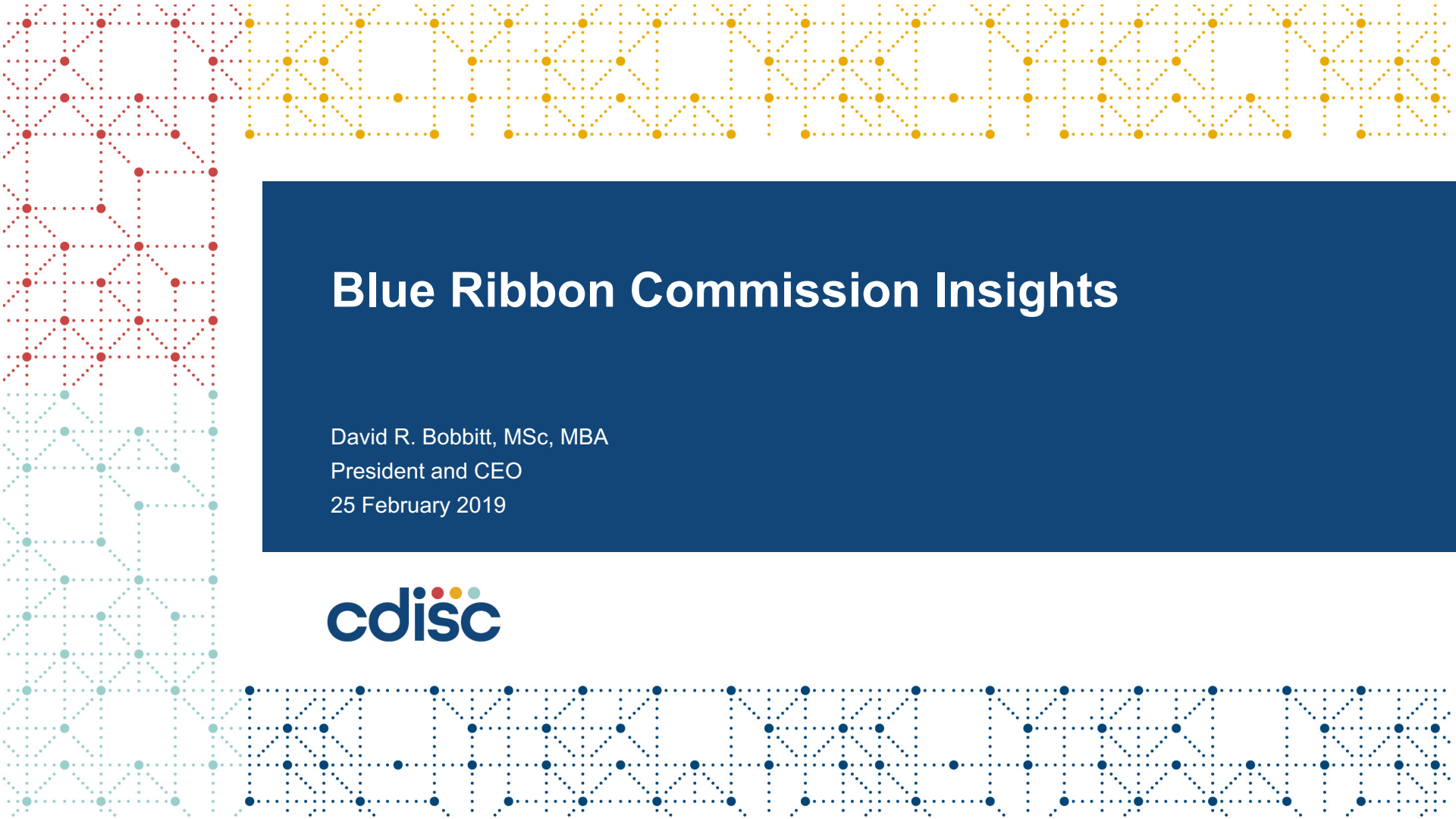




Blue Ribbon Commission Insights

David R. Bobbitt, MSc, MBA

President and CEO

25 February 2019





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 Volchenboun (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)

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

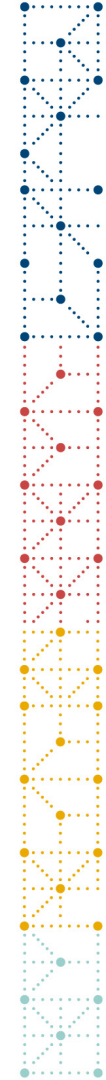
- Dr. Jeffrey Brown (Harvard University Medical School, Harvard Pilgrims Health Care Institute)

CDISC Staff

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

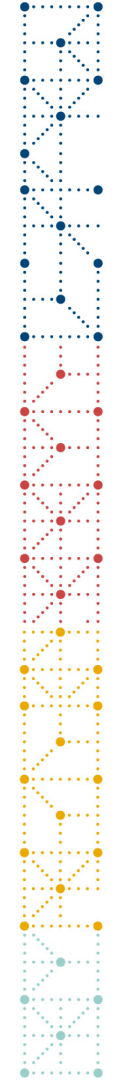


What did they tell us?



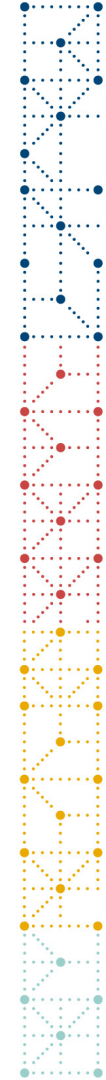
#1 Better standards from inception

- 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



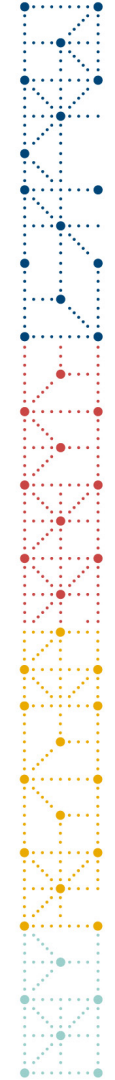
#2 Optimize the volunteer labor force

- 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



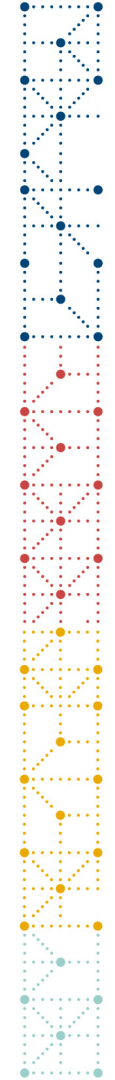
#4 Build a strong standards ecosystem

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

The evolution of the standards ecosystem



Phase 1: Last 20 years	Phase 2: Today	Phase 3: Tomorrow
Standards are PDF and paper-based.	Standards are machine-readable and exposed via API.	Standards are built for machines first, people second.
Implementers work in highly bespoke, labor-intensive environments.	Implementers have a single source of truth to improve homogeneity.	Implementers curate tools based on a deep understanding of standards.
Tools are site-specific and workplace-specific, narrow in scope, and frequently expensive.	Tools are scalable and reliable. Broad-scope tools are available.	Tools allow non-standards experts to attain benefits of standardization. Quality derivative products abound.
Interoperability requires laborious mapping between standards.	A higher degree of interoperability allows true meta-analysis.	Broad interoperability is achieved. Standards truly become views of data.

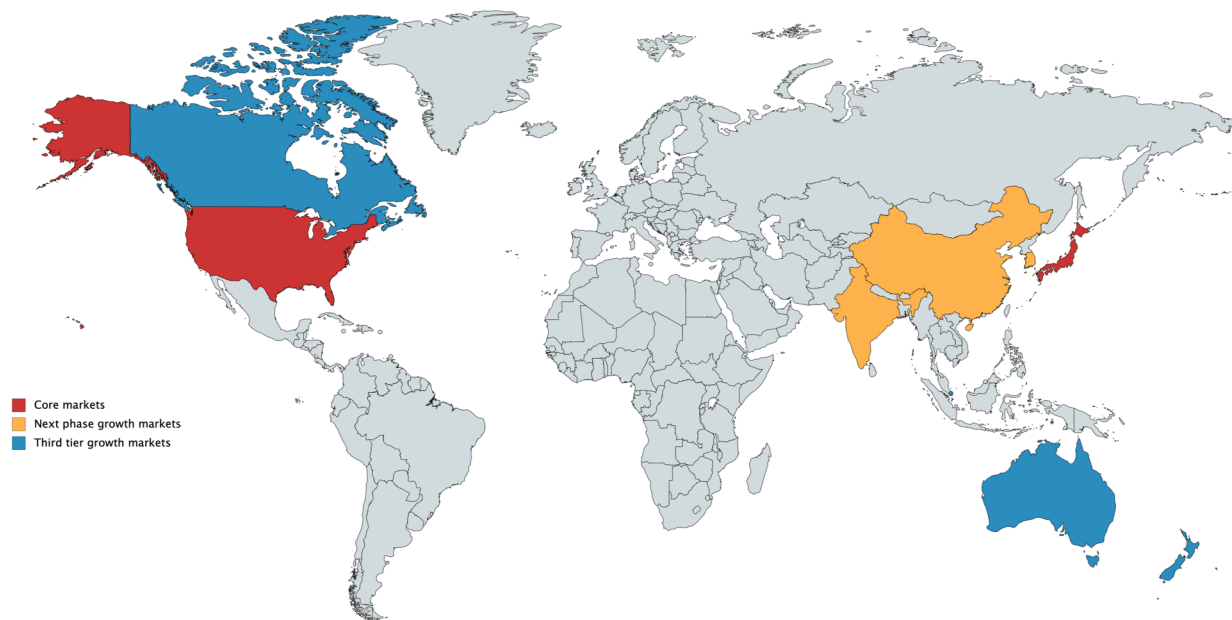


#5 Rely on key partnerships

...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

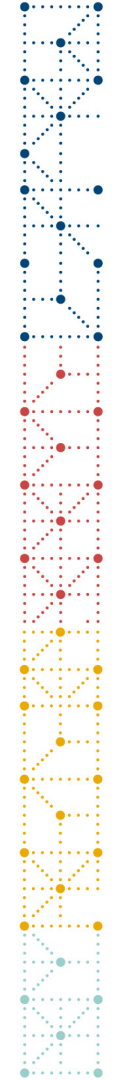
Insights document
out for public
review and
comment

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 see CDISC succeed.

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.



More information...

<https://www.cdisc.org/about/blue-ribbon-commission>