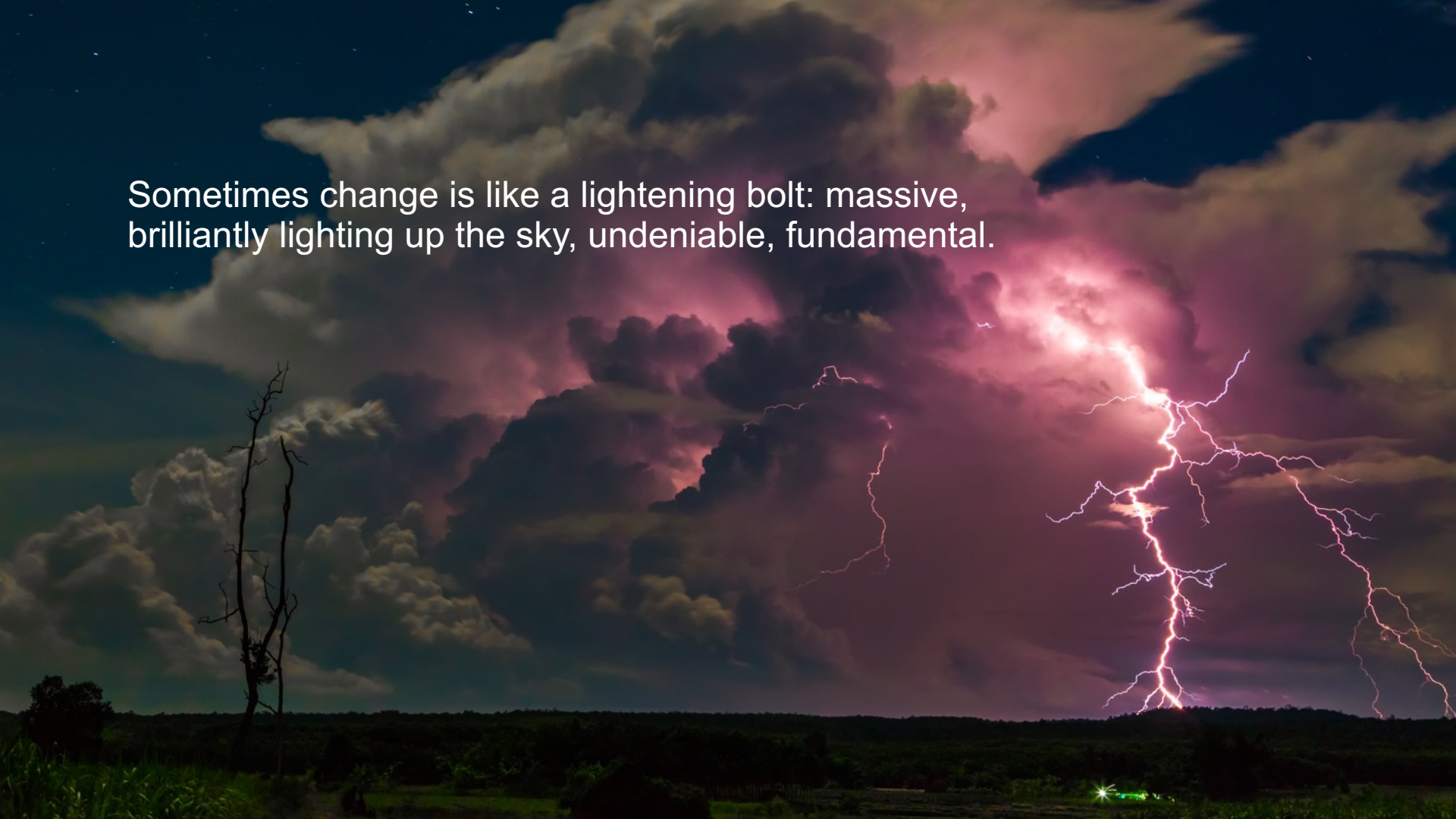# CDISC-Microsoft Industry Workshop

David R. Bobbitt, MSc, MBA
President and CEO
10 September 2020

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Sometimes change is like a lightening bolt: massive, brilliantly lighting up the sky, undeniable, fundamental.

Sometimes change is like lightening bugs on a summer evening: small, building slowly, not necessarily following a pre-planned pathway.

To achieve sustainable change, CDISC is pursuing both:

A lightening bolt strategy… 3D standards build for machines first and available freely via an API built by volunteers who collaboratively curate standards with CDISC staff and SMEs virtually around the globe.

A lightening bug strategy… tools, demonstrations, pilot projects, and trainings to help our stakeholders absorb and benefit from these significant changes.

The partnership with Microsoft fundamentally moves CDISC forward with both strategies.

Why will Microsoft build the next generation CDISC Library?

How did we get here?

- Blue Ribbon Commission
  - Build a nimble, agile organization
  - New sources of data: RWD, IoT, genomics, imaging, medical devices
  - Noted the changing nature of volunteerism
  - Utilize technology

- Strategic Plan
  - Demonstrate that 3D standards are achievable
  - Deliver standards via API
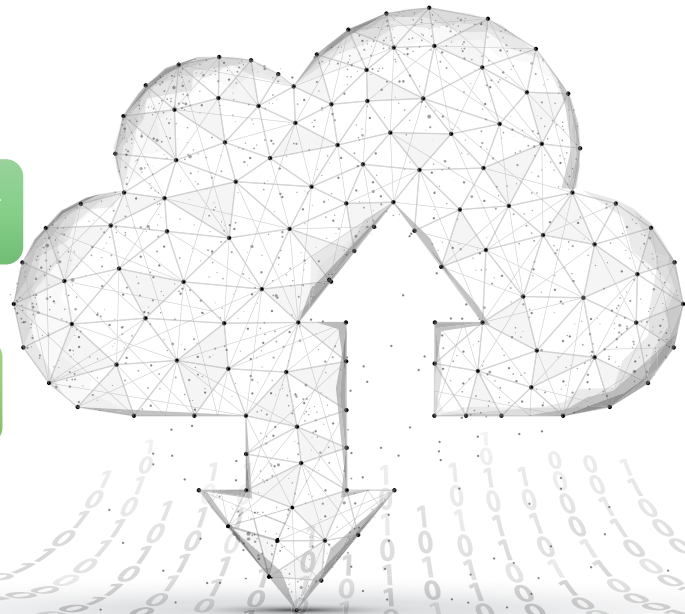 - Develop and deliver standards more rapidly
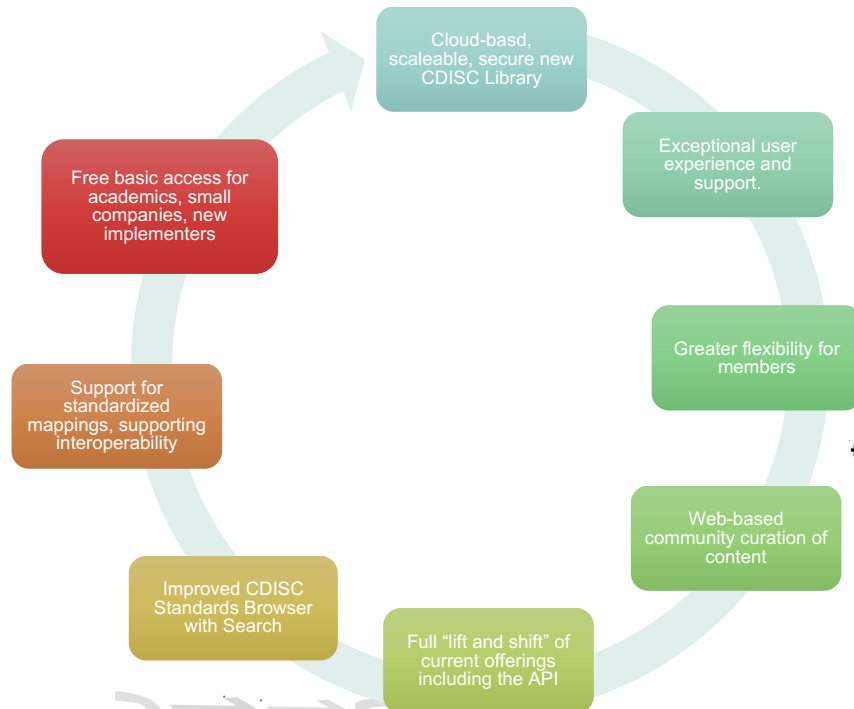 - Support implementers

- 360 Pilot
  - 3D standards and ETE standards are achievable
  - Requires a different paradigm for how standards are built and deployed.
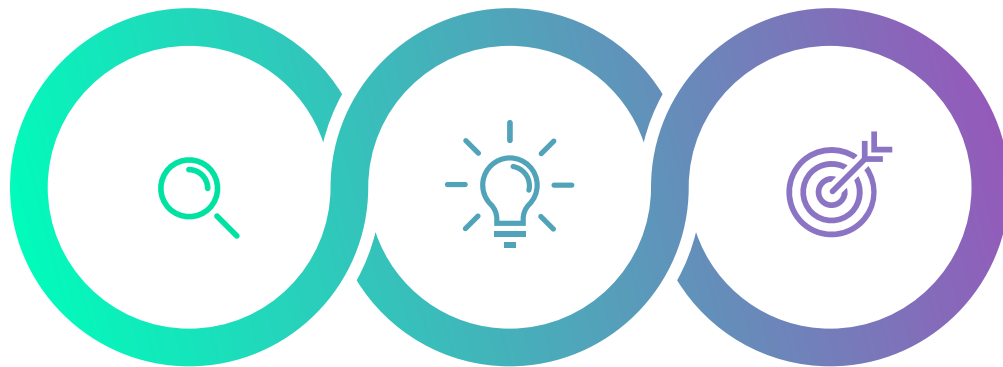 - CDISC Library must be the platform for both building and deploying.

Microsoft gets CDISC there faster

- Cloud-basd, scaleable, secure new CDISC Library
- Exceptional user experience and support.
- Greater flexibility for members
- Web-based community curation of content
- Full "lift and shift" of current offerings including the API
- Improved CDISC Standards Browser with Search
- Support for standardized mappings, supporting interoperability
- Free basic access for academics, small companies, new implementers

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Three phases of CDISC data standards

Founding
"Foundational standards"
- Collect the best practices of the industry
- Organize volunteers in teams
- Limited staffing required

Collaboration
"IGs and TAUGs"
- Extend foundational standards
- Collaborate with a breadth of SMEs and orgs
- Staffing requires project managers

Curation
"CDISC 360, Browser, API"
- Build machine-readable, 3D standards
- Community curation iterates standards development with implementation
- Staffing requires data science experts and modeling experts

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What is Titanium?

What's in a name?

New category: **Titanium membership**

New adjective: **Titans**

New advisory board: **Titan Council**

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Benefits

- New revenue will be committed to fully engaging the work of CDISC 360 and implementing change across the organization and the community.

- Establishes new Titan Council.

- Offers Titanium members a voice in priorities and decisions for CDISC Library and CDISC 360 next steps via the Titan Council.

- Ensures a high level of commitment by CDISC and by the Titanium members.

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Benefits

- Supports maturation of the technology section building tools for sponsors, CROs, and even academics.

- Provides resources for standardized mappings to other standards (HL7 FHIR) and code lists (LOINC) and full access to this metadata for Titans.

- Challenges inherent in flattening data for current submission requirements may be overcome, with regulator engagement.

- This structure mitigates risk for both CDISC and member companies by eliminating antitrust issues.

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Pricing

Founding Titanium members discount
First year membership until 30 June 2021: $250,000
Second year: 100,000
Third year: 100,000

Regular Titanium membership fee after Founding period
First year membership beginning 1 July 2021: $350,000
Second and subsequent years: 150,000

replaces Platinum membership fee: ~$42,000-58,000 per year

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What happens next?

Pathway forward

- Sorry, not for us.
  No problem! We will update you in a year or so.

- Yes, we are in!
  Sheila Leaman in Membership will follow up.
  Sleaman@cdisc.org for immediate response.

- We are interested and need more discussion.
  Individual and group conversations will be scheduled.

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Discussion