2021 JAPAN INTERCHANGE

With Standards – Science Will Prevail!

Conference | Trade Show

Live Stream | 10-11 June

State of the CDISC Union

Presented by David A. Evans
President & CEO, CDISC

Session 1 – June 10th, 2021

Meet the Speaker

Dave Evans

Title: President and CEO

Organization: CDISC

Dave Evans is recognized industry-wide as a leading technology visionary for developing and implementing complex process and system solutions and as an expert in the areas of information standards, regulatory compliance and quality governance. He was the architect and developer of the first electronic drug submission to the FDA in 1985 and has been responsible for more than 100 electronic regulatory submissions and complex clinical data warehouse systems. He brings over 40 years' experience to CDISC, serving in various executive-level positions in software development, clinical research, regulatory and healthcare industries. Most recently, he was the Global Head of Quality Governance and Regulatory Compliance for Accenture Life Sciences. Prior to that, he was CIO of Octagon Research Solutions. He has also served on the CDISC Board and has previously chaired the CDISC Advisory Council.

Dave received his MS in Biomedical Engineering from Drexel University and his BS in Biology from Ursinus College.
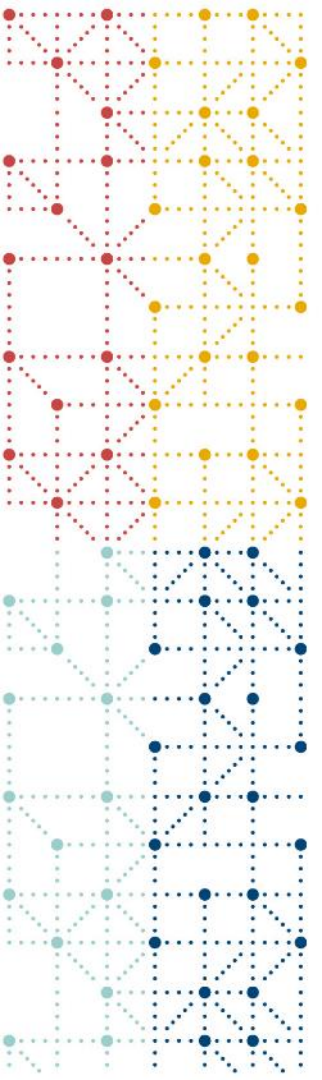
CDISC State of the Union

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Mission: To develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare

- Global Non-profit Consensus-based Standards Development Organization
- 20 Years of Regulatory Clinical Data Standards Development and Implementation
- Experienced Leadership Team and Dedicated Staff of 40+ Professionals and SMEs
- Volunteer Network of 1000+ Industry Experts
- 500+ Member Organizations
- Widely Adopted and Freely Available Clinical Research Data Standards
- Mature Standard Governance Processes
- Innovative Open-Source Technology for Standards Library and Metadata Management
- Involved in a wide range of emerging Industry Initiatives and Projects
- Collaborative Ecosystem of Relationships and Partnerships
  - Members, Regulators, Patient Foundations, Academia, SDOs and Industry
- Healthy Financials

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Alliances and Collaborations

CFAST & Therapeutic Area Partnerships

CDISC collaborates with many organizations to develop Therapeutic Area (TA) standards for multiple disease areas through the Coalition for Accelerating Standards and Therapies (CFAST) initiative, as well as other partnerships.

Regulatory Collaborations

CDISC works closely with regulators around the world to ensure that CDISC standards will 1) streamline research from protocol/study design and trial registration through analysis and reporting; 2) facilitate the eSubmission review process; 3) ensure that clinical research is high quality; and 4) support the approvals of safe and efficacious medicines for patients.

Regulators also contribute to TA standards development

Individual collaborations also part of JIC

Joint Initiative Council (JIC)

Standards Development Organizations (SDO) Collaborations

CDISC collaborates with other SDOs to develop standards that are synergistic to support a learning health system based upon high quality research.
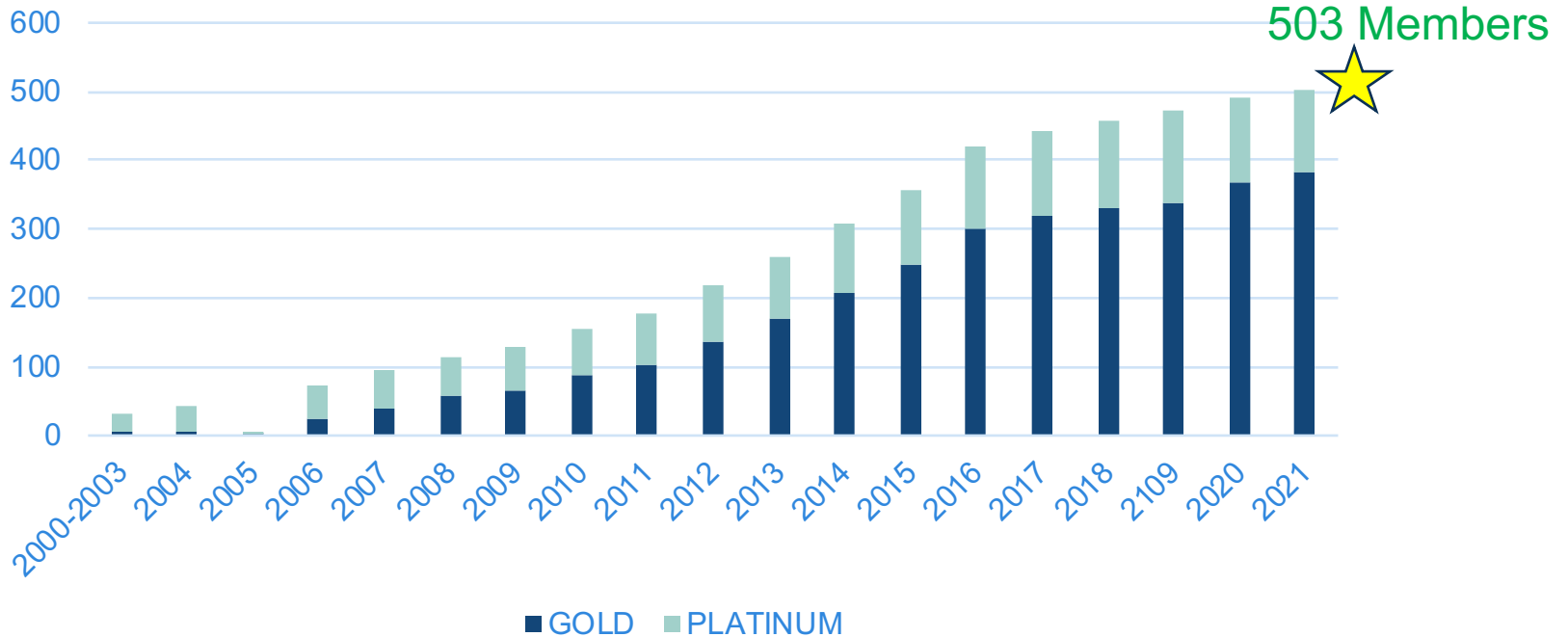
CDISC and PhUSE partner to further the mission of each organization collectively, with CDISC focusing on the development of global, platform-independent data standards, and PhUSE focusing on the implementation and use of the CDISC standards. The two organizations work to combine efforts on key initiatives around end-to-end standards, TA standards, and semantics, strengthening an interdependent process.

Additional Collaborations

- Academic Institutions
- Accumulus Synergy
- BioPharmaceutical Statistics Leaders Consortium
- Clinical Data Privacy Consortium
- Learning Health Community
- Oxford University
- Phuse
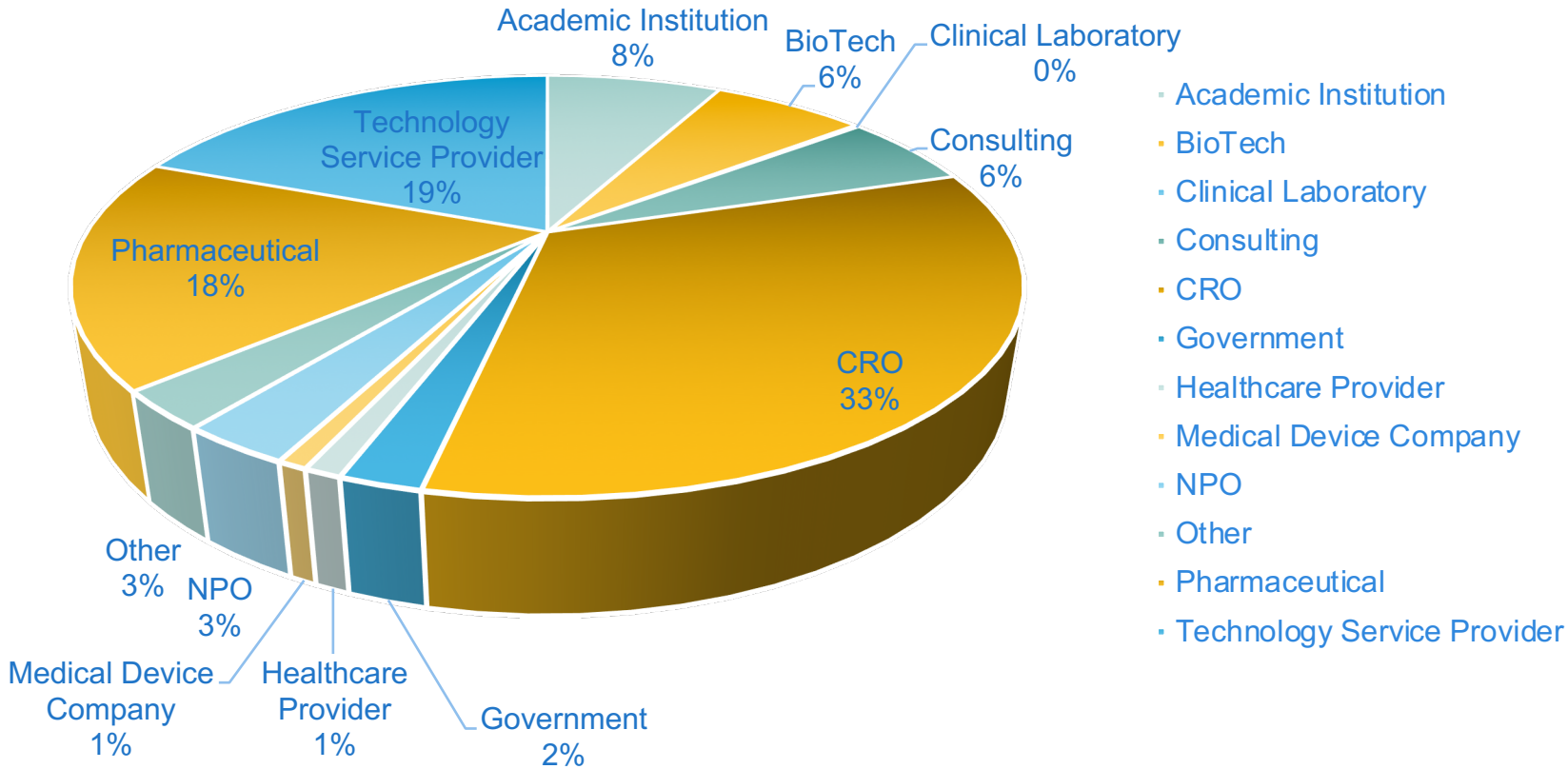- Pharmaceutical Data Standards Leaders
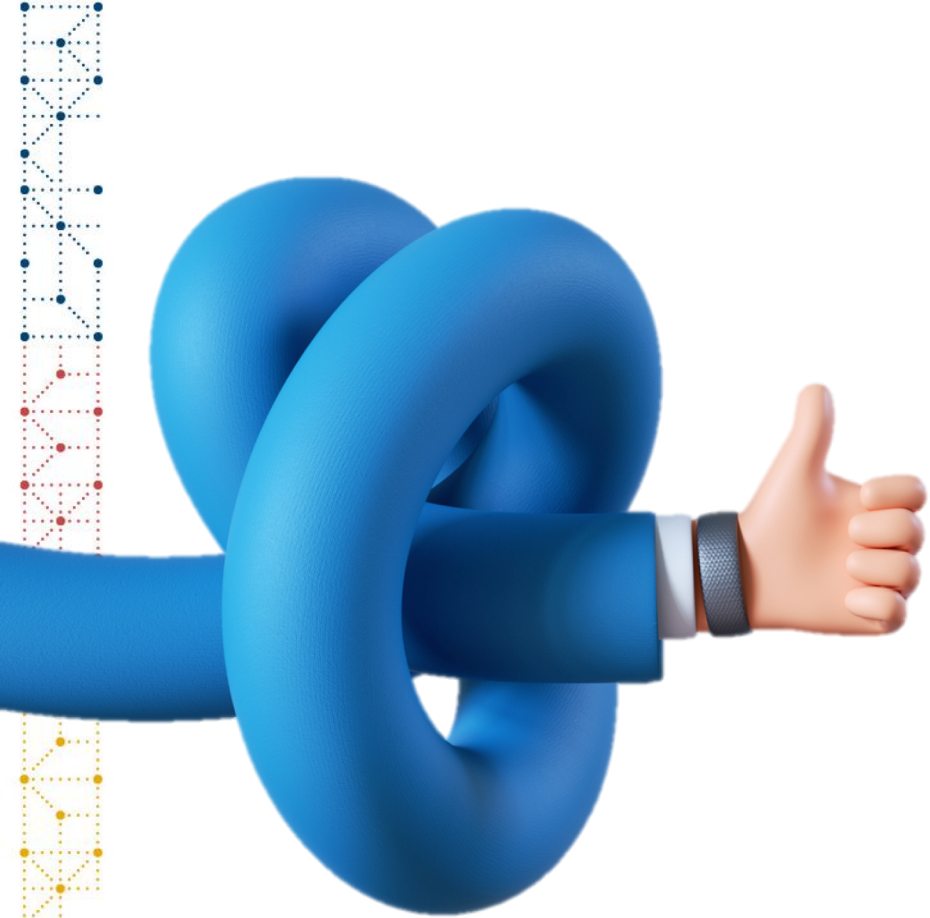- Vivli

CDISC – a look at this year so far

- **New Standards Initiatives from Regulatory Agencies**
- **Ongoing Therapeutic Area Projects**
- **Ongoing Activities and Projects on RWD/RWE & Data Sharing**
- **Actively extending the content and functionality of the CDISC Library with our technology and industry partnerships**
- **The next phase of development for Biomedical Concepts**
- **Continue to add content to eCRF Portal and QRS Library**
- **Continue to curate and develop Foundational Standards**
- **Standards Implementation for Registries and Academic Use**
- **New Collaborative Industry Projects in the Pipeline**
- **Active Partnerships with other SDOs on emerging Industry Initiatives**

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Membership

503 Members

2000: **18**   2010: **154**   2020: **490**   2021: **503**

Members by Industry

- Academic Institution 8%
- BioTech 6%
- Clinical Laboratory 0%
- Consulting 6%
- CRO 33%
- Technology Service Provider 19%
- Pharmaceutical 18%
- Other 3%
- NPO 3%
- Medical Device Company 1%
- Healthcare Provider 1%
- Government 2%

Legend:
- Academic Institution
- BioTech
- Clinical Laboratory
- Consulting
- CRO
- Government
- Healthcare Provider
- Medical Device Company
- NPO
- Other
- Pharmaceutical
- Technology Service Provider

The Great 2020 Virtual

Pivot

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2021 CDISC Events

Global Interchanges

Europe Interchange & TechniCon
28 – 30 April
Virtual with 300 Attendees

Japan Interchange
10 – 11 June
Virtual

China Interchange
6 – 7 August
Beijing, China

US Interchange
18 – 22 October
Hybrid | Washington, DC

Korea Interchange (Tentative)
8 – 9 November
Seoul/Daegu, South Korea

CDISC Webinars

A Numbers Snapshot for 2020:

- CDISC held **32 webinars**
- A grand total of 4,272 people attended
- Average of 56.5% of registrants attended a webinar

A Numbers Snapshot for 2021:

- CDISC has held **11 webinars** to date
- A 35% increase in attendance from 2020
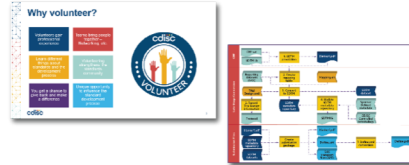- Average of 60% of registrants attended a webinar this year

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CDISC Communications

CDISC Education

2020 CDISC Training by the Numbers

- 🎓 **8,704 Course Enrollments**
- 💻 **2,555 New Training Accounts**
- 👥 **4,725 Webinar Attendees**
- 📚 **11 New Trainings Published**

CDISC Standards in the Clinical Research Process

CDISC Standards

FOUNDATIONAL STANDARDS ← built on — **THERAPEUTIC AREAS**

CDASH — Standard for data collection — Described in CDASH Implementation Guide

SDTM — Standard for structuring/formatting data — Described in SDTM Implementation Guide

ADaM — Standard for analysis datasets — Described in ADaM Implementation Guide

Demonstrate high-level implementation across broad use cases

Organized by domain/dataset

Therapeutic areas: Alzheimer's, Diabetic Kidney Disease, Malaria, Asthma, Schizophrenia, Kidney Transplant, Breast Cancer, Ebola, Pain, Tuberculosis, MS, Diabetes, Hepatitis C, Prostate Cancer, PKD, CV Endpoints, Influenza, Dyslipidemia, TBI, Parkinson's, Major Depressive Disorder, COPD, Rheumatoid Arthritis, Virology

Demonstrate implementation of disease-specific use cases

Organized by biomedical concept

*The full list of foundational and therapeutic area standards are available at https://www.cdisc.org/standards

CDISC Library

Connect with Digital Data Processes through Open-API

Biomedical Concepts	**Codelist Subsets**	**Tables, Listings, and Figures**	**Implementation Guide Text**	**FHIR to CDISC Mappings**
Analysis Concepts	**TAUG metadata**	**Derivations and Mappings**	**Machine-readable Examples**	**LOINC Code Mappings**
Templates	**Study design metadata**		**CRF Collection**	**Diff Content Between Versions**
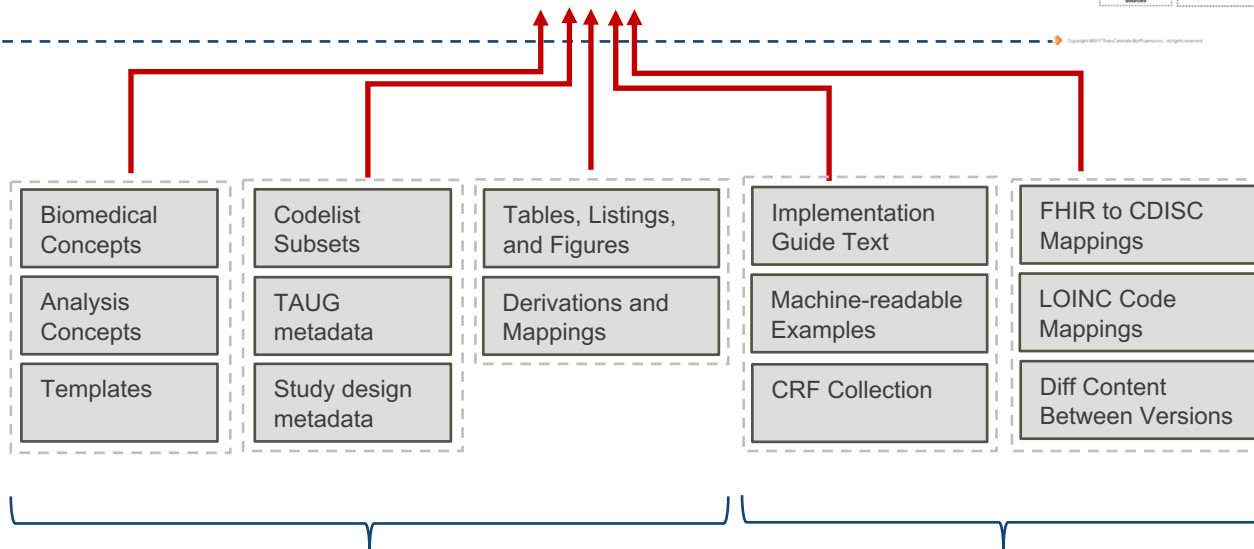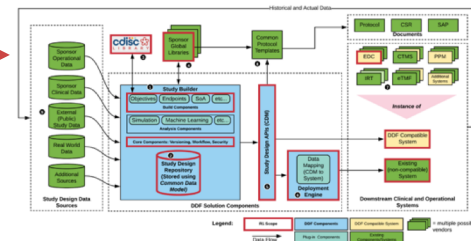
CDISC Standards   *Informative Content*

CORE Concept
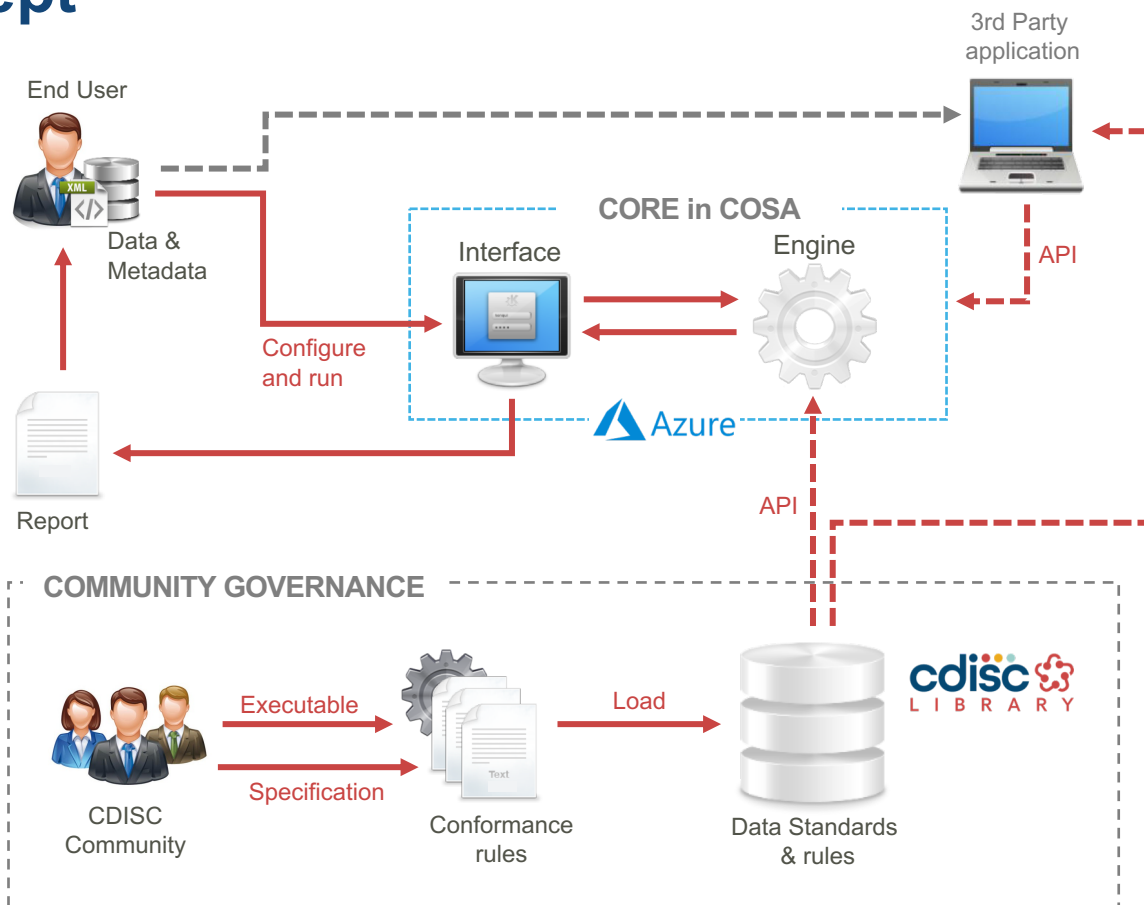
Looking forward…

- Standards Development, Curation, Management, Governance and Implementation
- Standards Certification
- eCRF Portal and QRS Portal
- Analysis Results Standard
- Safety User Guide
- CDISC 360 Implementation– Biomedical Concepts
- CDISC Library – expansion of content and functionality
- COSA – CDISC Open-Source Alliance
- Machine readable and executable Conformance Rules
- Digital Data Flow Standards
- TAUGs, QRS, Digital Biomarkers
- Standards of the Standards

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Standards of the Standards

- Standards Governance Process for Industry Initiatives

- Portal or Marketplace for industry-developed standards and tools
  - Validated instruments - Questionnaires Ratings and Scales (QRS)
  - Biomarker implementation data standards
  - Open-source utilities and tools
  - Industry collaboratively developed use cases
  - Templates of standards implementations
  - eCRFs
  - Interoperability mappings

- Academic and Registry Implementation Standards

- Vaccine Administration Project

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Harmonized Vaccine Administration Standard

- This project is a joint collaboration with Learning Health Community (LHC)
  - https://www.learninghealth.org
- Harmonized set of ~20 core elements.
- Based on:
  - **European eHealth Network**
  - Digital Green Certificate
  - CDC Endorsed Data Elements
  - CDISC, HL7, ISO
- Followed the CDISC standards development process
- Produced a short understandable Implementation Guide
- Published for comments - May 2021
- Comments Received and being addressed
- To be Finalized - Mid-June 2021
- Socialized with industry and regulators for adoption

Photo by National Cancer Institute on Unsplash

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With Standards, Science will Prevail!

Thank you!

Dave Evans

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