

“Unlocking the Power of AI in Clinical Trials:
Revolutionising End-to-End Data Processing”



Single Day Event

How CDISC Standards
Will Evolve in the AI Era?

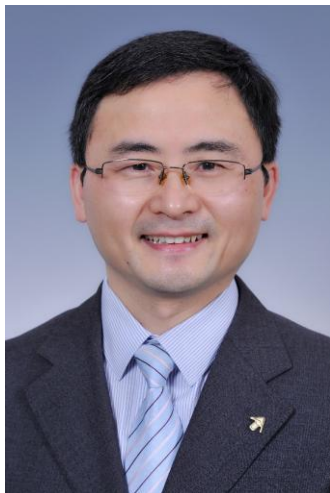
Zibao Zhang
Union Laiya

1 Nov 2024, Shanghai

phuse.global



About the speaker



- GM of Union Laiya, part of Union Lab
- Started in pharma industry since 2001
- PhD in Epi & Biostats, & EMBA

- CDISC user and volunteer since 2004
- CDISC China/APAC Lead 2008-2020

- Biometrics management
- Business development
- VC and Entrepreneurship

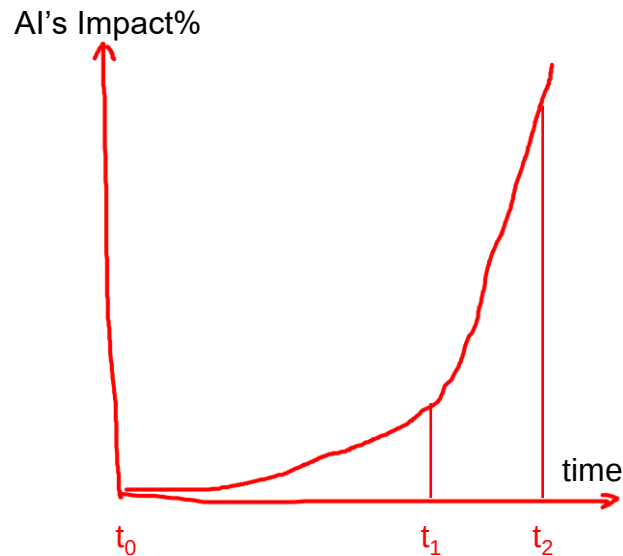


My Viewpoints to the Question

Question: How Will CDISC Standards Evolve in the AI Era?

My responses:

- **Viewpoint 1:** AI's impact on CDISC standards over time (t_0 to t_2) is likely as illustrated in the right chart.
- **Viewpoint 2:** CDISC's ambition is to create **connected** standards to **enable end to end automation from study design to results**. This may be achieved at t_1 .
- **Viewpoint 3:** ... **how long** will it take to t_1 ?
- **Viewpoint 4:** and **how big** could AI impact after t_1 ?



Standards:

Version1

Version2

V3

My talk:

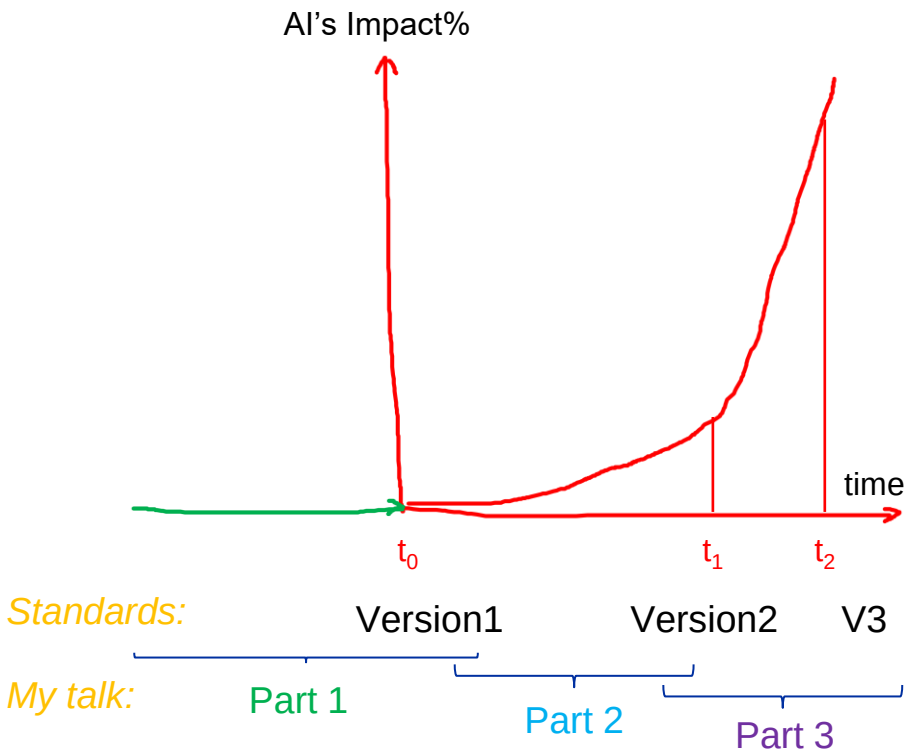
Part 1

Part 2

Part 3



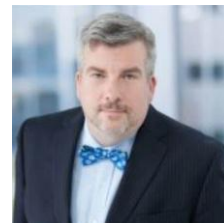
Part 1: CDISC V1.0 ~2000 to ~2020



Rebecca Kush
Founder and
President Emeritus
President & CEO
~2000-2017



Wayne Kubick
Chief Technology
Officer
2012-2016



David R. Bobbitt
President & CEO
2017-2020



Peter Van Reusel
Chief Standards Officer
2018 -



Where We Are

1. Achievements:



2. Problems:

- Standards Incomplete
- Limited automation
- Implemented inconsistently
- Much time needed for study specs...
-

3. Next:
Evolution is
expected...

Source: <https://www.cdisc.org/standards>



CDISC Vision and Mission



VISION

Previous

Inform patient care and safety through higher quality medical research.



MISSION

*Develop and support **global, platform-independent data standards** that enable information system interoperability to improve medical research and related areas of healthcare.*



Current

Amplify Data's Impact to Advance Research

Create connected standards across the study information lifecycle to enable accessible, interoperable, and reusable data for more meaningful and effective research



CDISC Strategic Goal

*Expand and enable **standards driven automation** across the **end-to-end study information lifecycle** from **study design through results**
(CDISC will expand and realize the original 360 vision)*



Expand & Connect

Expand,
Connect, and
Digitalize our
Standards

Enable & Automate

Reduce
Variability,
Enable
Interoperability,
and Increase
Automation

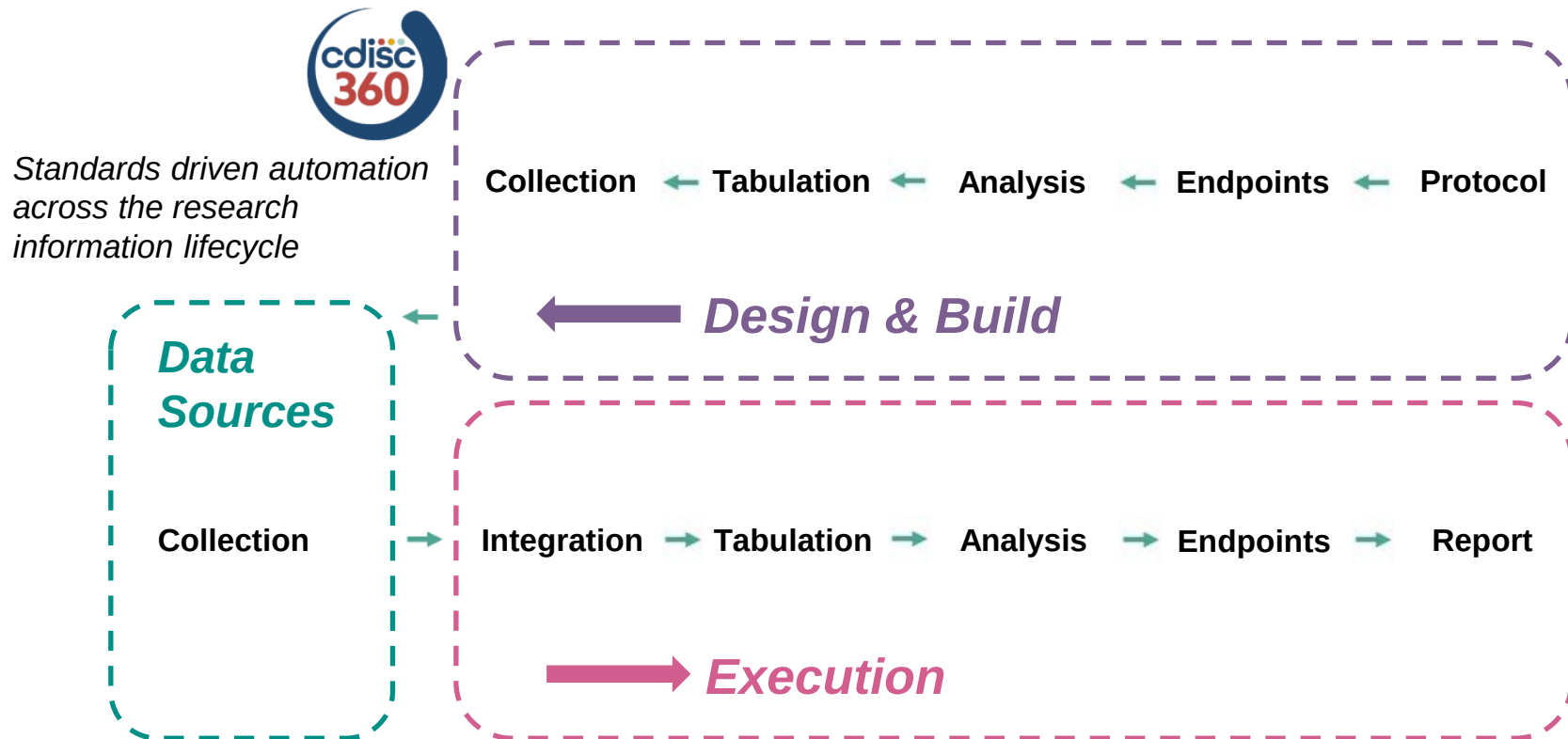
Engage & Adopt

Focus on
Community
Needs

Deliver
Business Value



End to End Study Information Lifecycle

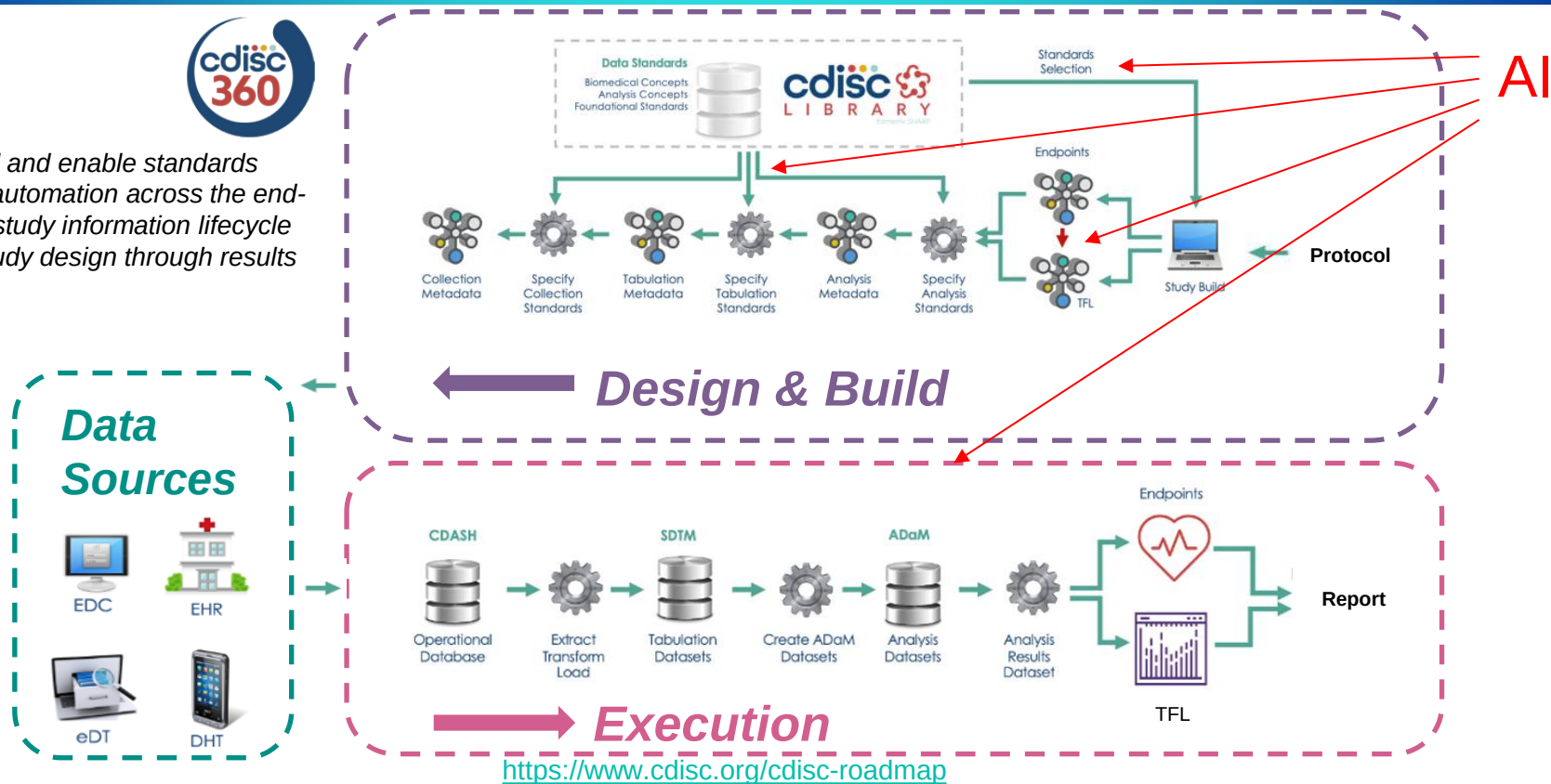




E2E Automation and AI's Involvements



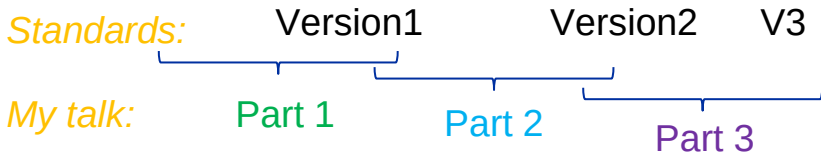
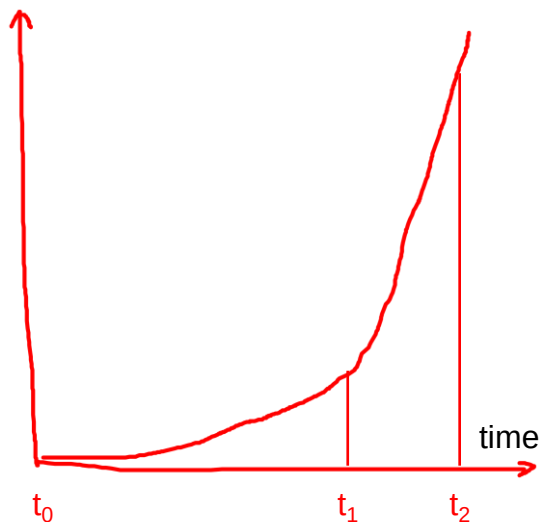
Expand and enable standards driven automation across the end-to-end study information lifecycle from study design through results



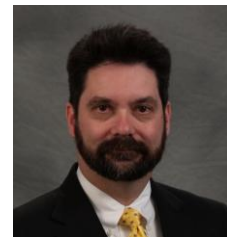


Part 2: CDISC V2.0 ~2020 to 2030?

AI's Impact%



Dave A. Evans
President & CEO
2021-2023



Chris Decker, MS
President & CEO
2024 -

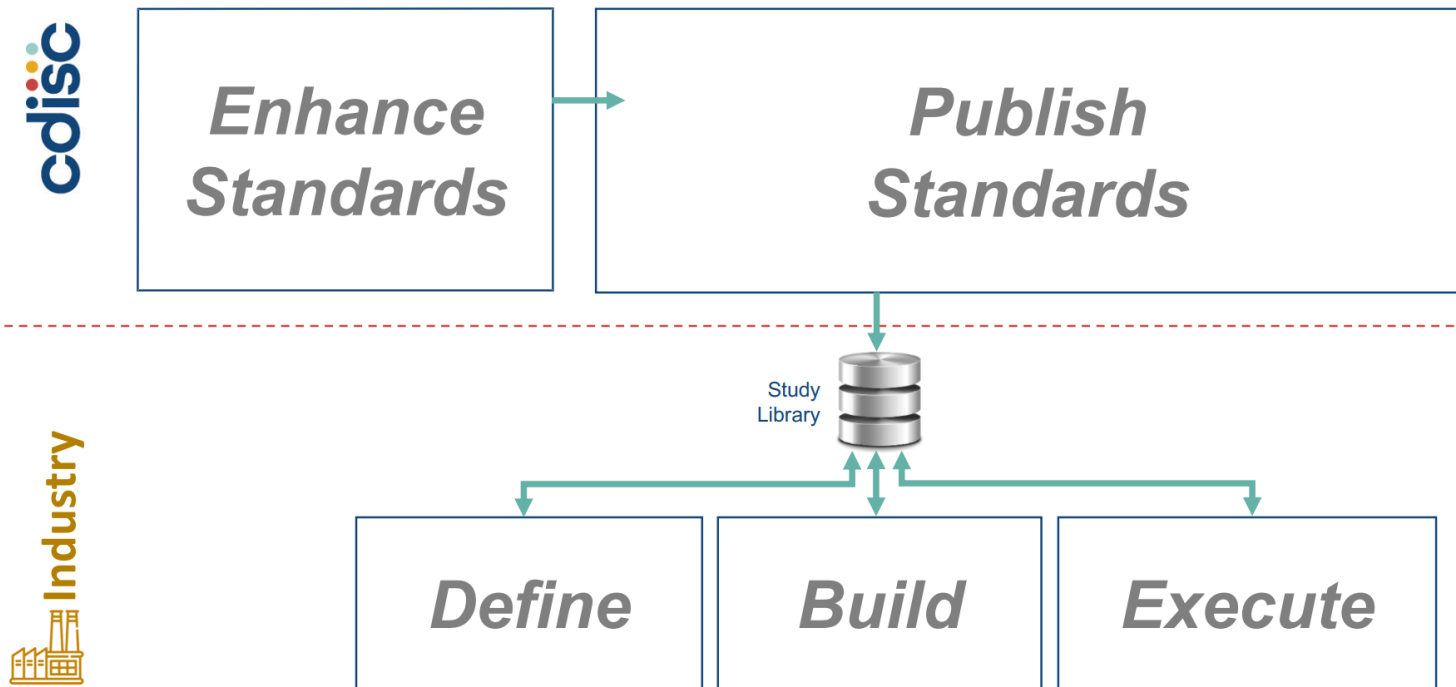


Peter Van Reusel
Chief Standards
Officer
2018 -



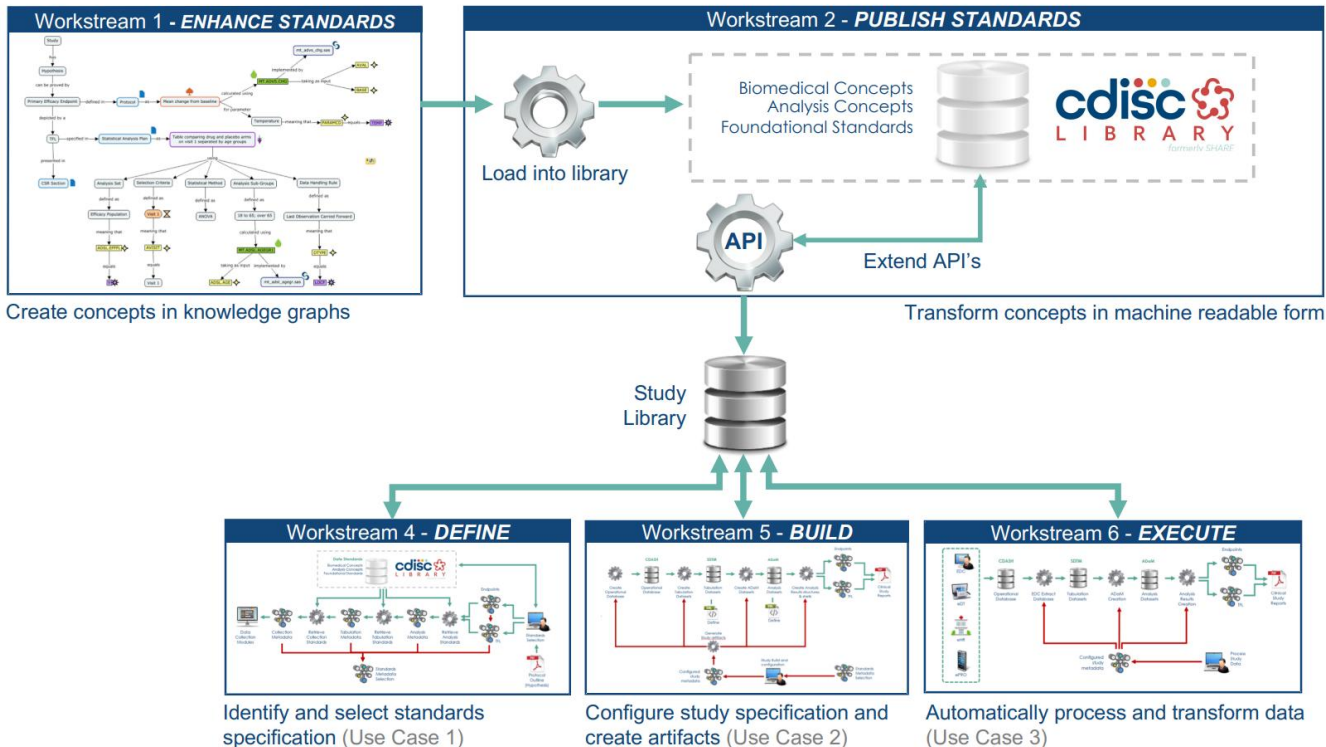


Look Back: CDISC 360 Scope





CDISC 360 Workstreams





CDISC 360 Project Timeline

#	Stage	Start	End
1	Initiation, scoping, and internal staffing	Oct 2018	Nov 2019
2	Planning, recruiting CDISC member participants	Dec 2019	Feb 2019
3	Align with Transcelerate Digital Data Flow Initiative	Oct 2018	Jan 2019
3	Onboarding CDISC member participants	Mar 2019	Apr 2019
5	Kickoff, workstreams briefing	Apr 2019	Apr 2019
6	Execution of agile sprints	Apr 2019	Oct 2019
7	Project evaluation – Stage 1 (CDISC US Interchange)	Oct 2019	Oct 2019
8	Execution of agile sprints	Nov 2019	Mar 2020
9	Project evaluation – Stage 2 (CDISC EU Interchange)	Mar 2020	Mar 2020
10	Execution of agile sprints	Apr 2020	Nov 2020
11	Project evaluation – Stage 3 (CDISC US Interchange)	Nov 2020	Nov 2020

<https://www.cdisc.org/cdisc-360>



CDISC 360 Advisory Committee

CDISC 360 Leadership Team

- **David Bobbitt**
CDISC Chief Executive Officer
- **Peter Van Reusel**
CDISC Chief Standards Officer
- **Sam Hume**
CDISC Vice President Data Sciences
- **Barry Cohen**
CDISC 360 Project Manager

CDISC 360 Board Representation

- **Chris Decker** - dWise
- **Dave Evans** - Accenture
- **Dave Hardison** - Deloitte
- **Pandu Kulkarni** - Lilly
- **Steve Rosenberg** - Oracle
- **Ulo Palm** - * Transcelerate

CDISC 360 Committee Members

- **Praveen Garg** - Astra Zeneca
- **Patrick Genyn** - Johnson & Johnson
- **Brooke Hinkson** - Merck
- **Ulo Palm** - Allergan
- **Mike Hamidi** - CDISC



CDISC 360 Lessons Learned

Four pillars of 360 implementation emerge from the 360 lessons learned:

1. **Complete** the E2E foundational standards where they are incomplete
2. **Enrich** the foundational standards with the additional metadata needed for full data meaning and relationships by creating a biomedical concept layer
3. **Extend** the CDISC Library model with implementation level metadata
4. **Collaborate** with industry to standup and curate biomedical concepts



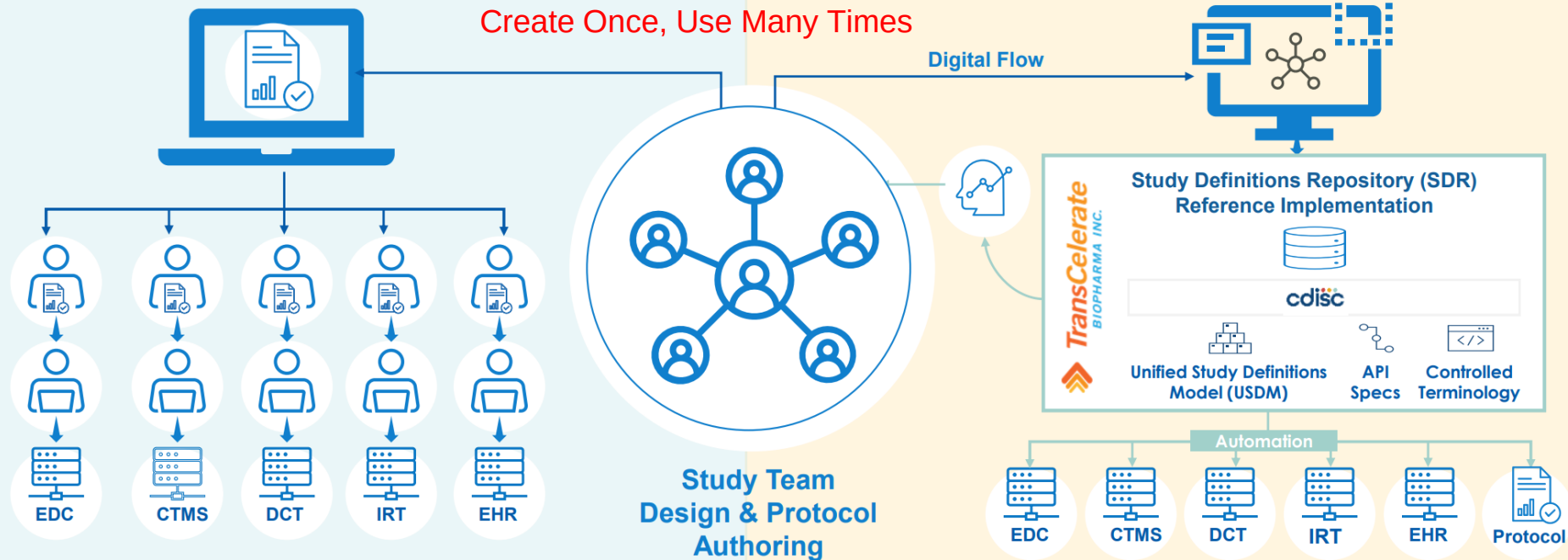
TCB Digital Data Flow (DDF) Initiative

TODAY: Document-based paradigm for protocol creation, interpretation, and transcription into consuming systems

TOMORROW: Digital paradigm for protocol creation, with fully automated data flow and interoperability between systems

Create Once, Use Many Times

Digital Flow

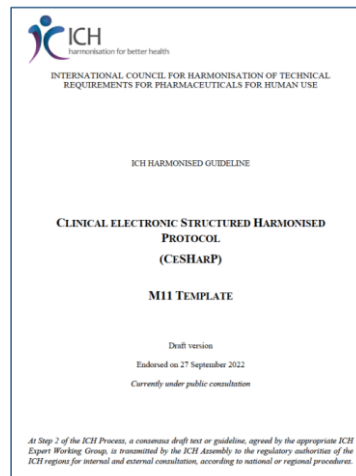
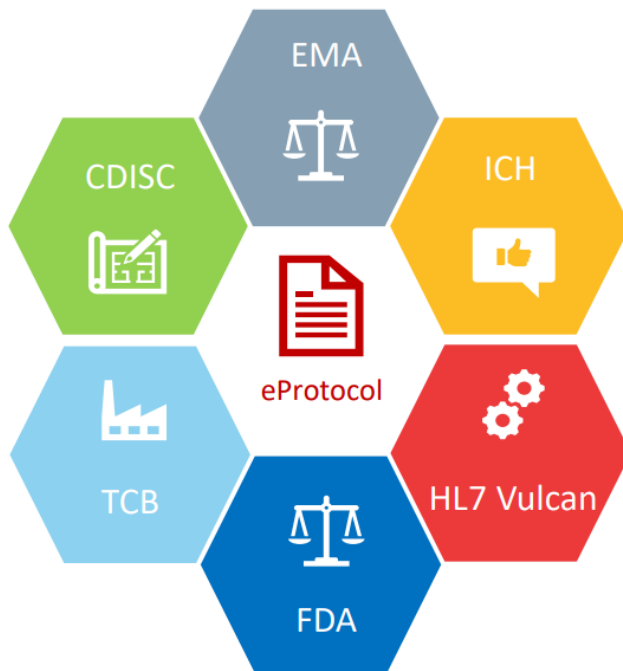




Digital Protocol – Industry Collaboration



cdisc
Unified Study
Definitions Model
(USDM) Reference
Architecture

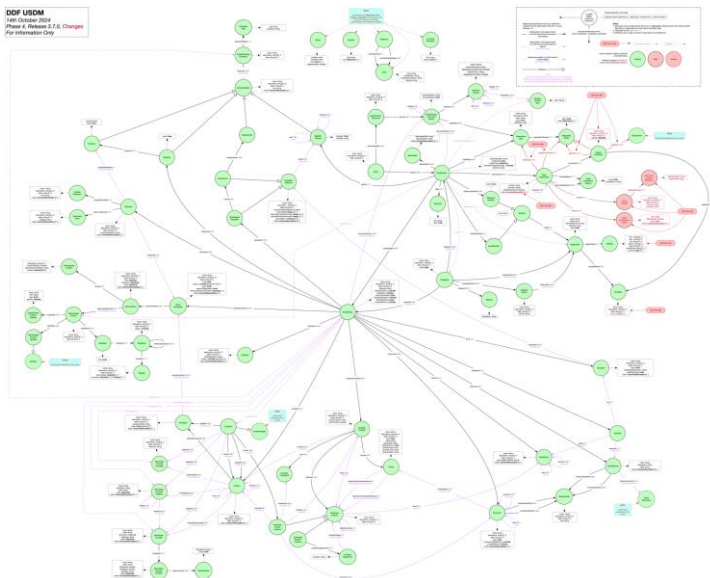


TransCelerate's
Study Definitions
Repository (SDR)

PROJECT PRISM
A Regulatory Cloud Collaborative Initiative

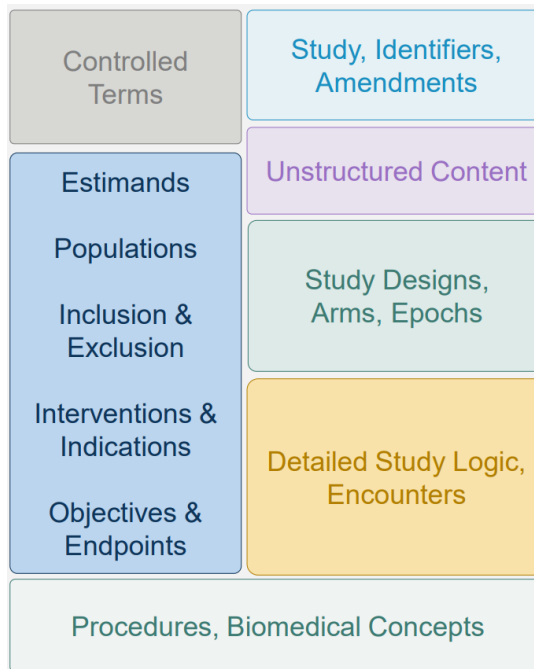
precisionFDA Regulatory Information Service Module
FDA-Industry Research Collaboration Agreement
(Public-Private Partnership)

<https://www.cdisc.org/ddf>



Unified Study Definitions Model (USDM) Phase 4 Graphic

Source: <https://github.com/cdisc-org/DDF-RA>



Downstream Use Cases

- Protocol Authoring (incl. ICH M11)
- Clinical trial registries
- EDC/IRT
- aCRF
- SDTM data
- Define.XML
-



CDISC Analysis Results Standard (ARS)

CDASH



SDTM



ADaM



Results
Display1

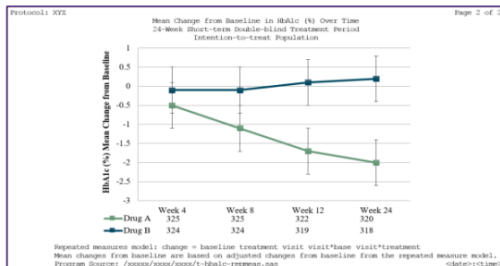


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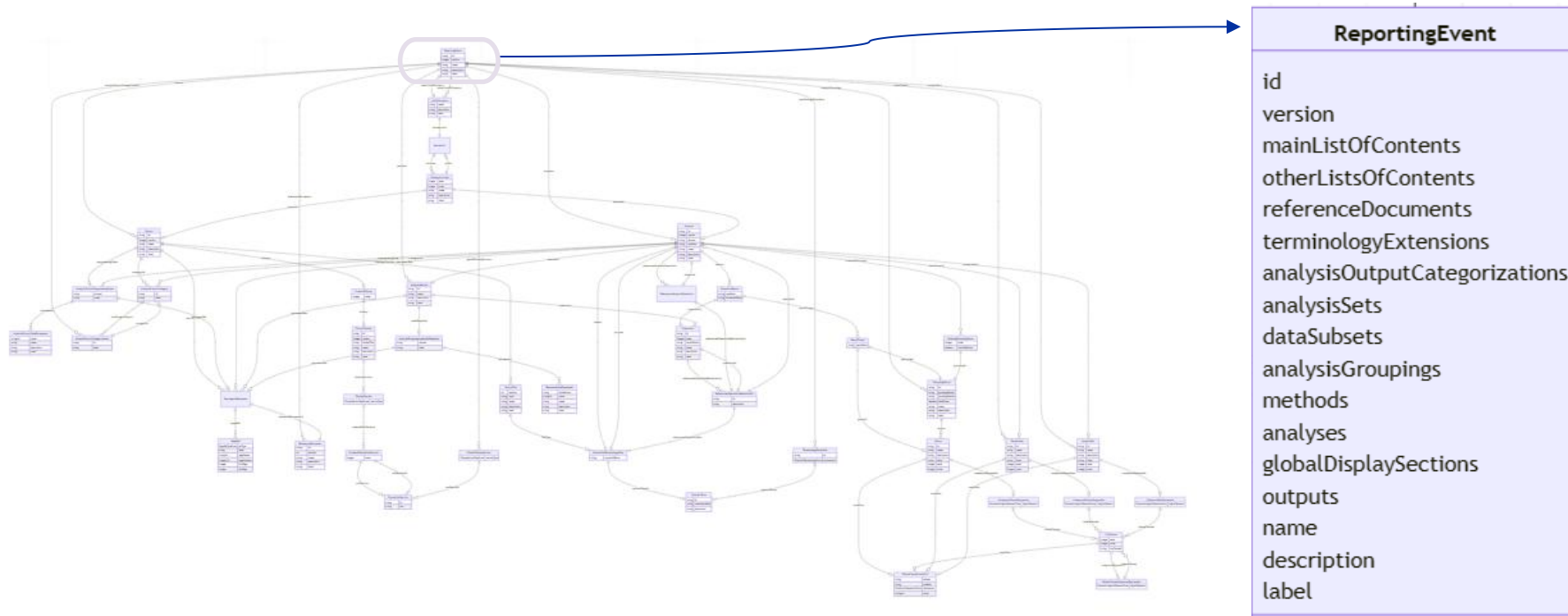
Analysis Results Dataset



Results
Display2



CDISC ARS Schema Diagram



CDISC Analysis Results Standard (ARS) Schema Diagram

Source: <https://cdisc-org.github.io/analysis-results-standard/#schema-diagram>



CDISC ARS Example

Reporting Event

Analysis

Analysis Set

Analysis Grouping

Analysis Method

Output

.....

.....

Interim Analysis 1

Study = CDISC 360

Page x of y

Table 14.1.1
Summary of Demographics
Safety Population

Characteristics	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)	p-value [1]
Age (years)				
n	XX	XX	XX	X.XXXX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	
Median	XX.X	XX.X	XX.X	
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
Min, Max	XX, XX	XX, XX	XX, XX	
Age Group, n (%)				
< 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
≥ 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Gender, n (%)				
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Ethnicity, n (%)				
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	

[1] P-values are results of ANOVA treatment group comparison for continuous variable and Pearson's chi-square test for categorical variables.

Source dataset: adsl, Generated on: DDMONYYYY:HH:MM

Program: <pid>.sas, Output: <pid><oid>.rtf, Generated on: DDMONYYYY:HH:MM



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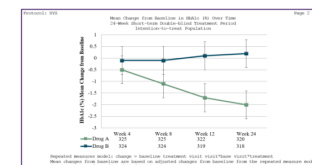
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01-701-1023	Placebo	64	<65	YEARS	WHITE	M
01-701-1028	Xanomeline High Dose	71	65+	YEARS	WHITE	M
01-701-1033	Xanomeline Low Dose	74	65+	YEARS	WHITE	M
01-701-1034	Xanomeline High Dose	77	65+	YEARS	WHITE	F
01-701-1047	Placebo	85	65+	YEARS	WHITE	F

Create Once, Use Many Times

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Analysis Results Dataset



Results Display x



Some Other CDISC 360 Projects

- *Biomedical concepts (BC)*
- *eCRF portal*
- *eTFL Shell portal*
- *Open source tech & tools*
- *E2E use cases*





Data Standards
Biomedical Concepts
Analysis Concepts
Foundational Standards



cdisc
LIBRARY

Standards Selection



Protocol
Outline
(Hypothesis)



Study Build

Endpoints



AI

Study Design & Build



M11



Data
Sources



EDC



EHR



eDT



DHT



CDASH



Operational
Database



Extract
Transform
Load



Tabulation
Datasets



SDTM



Create ADaM
Datasets



Analysis
Datasets



Analysis
Results
Dataset



ADaM



Analysis
Results
Dataset



Analysis
Results
Dataset



Analysis
Results
Dataset

Endpoints



Clinical
Study
Reports

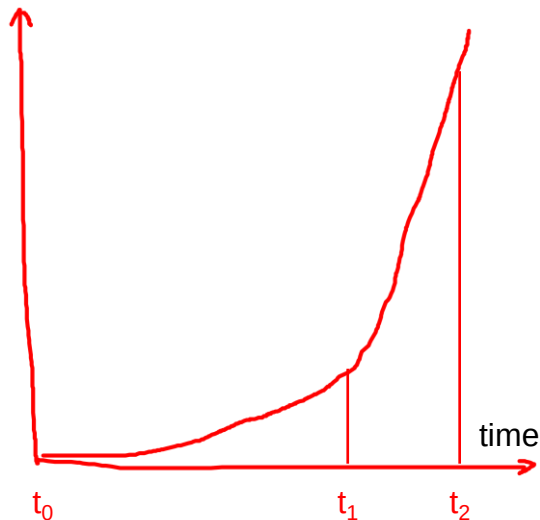


Study Execution



Part 3: CDISC 3.0 ~2030 to ?

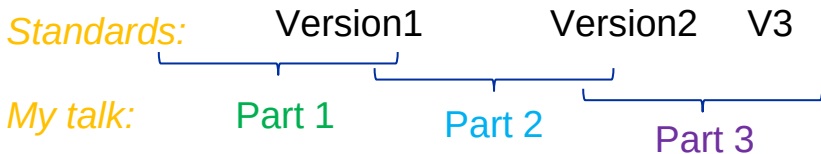
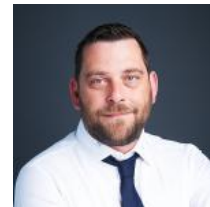
AI's Impact%



Chris Decker, MS
President & CEO
2024 -



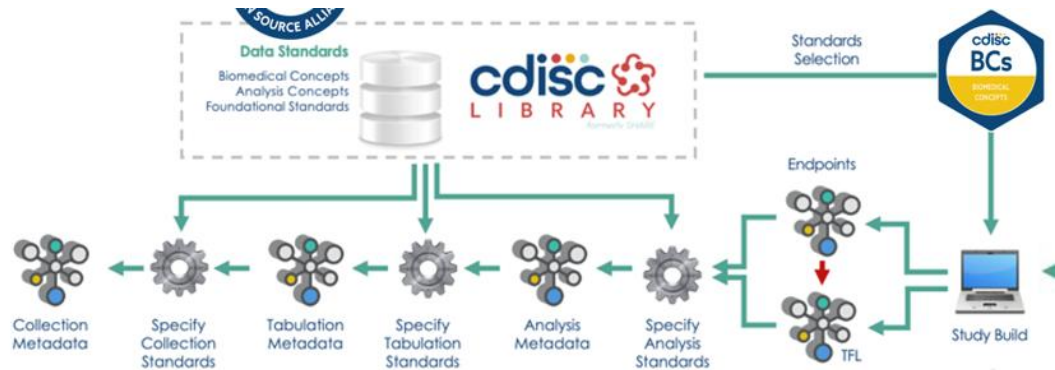
Peter Van Reusel
Chief Standards
Officer
2018 -





How Will AI Impacts on CDISC Standards?

1. AI empowers the CDISC standards use – configuration, metadata selection.



2. AI supports to fine tune and further develop the CDISC standards – Feedback from millions of data through end-to-end automation.

3. AI enables to explore the value of huge clinical data from end to end.



Ask AI for the following questions:

1. What's the upper limit of standardization in clinical trials?
2. How will the AI and standardization impact biometrics professional's job?
3. Any opportunities for capital investment and business start-up?

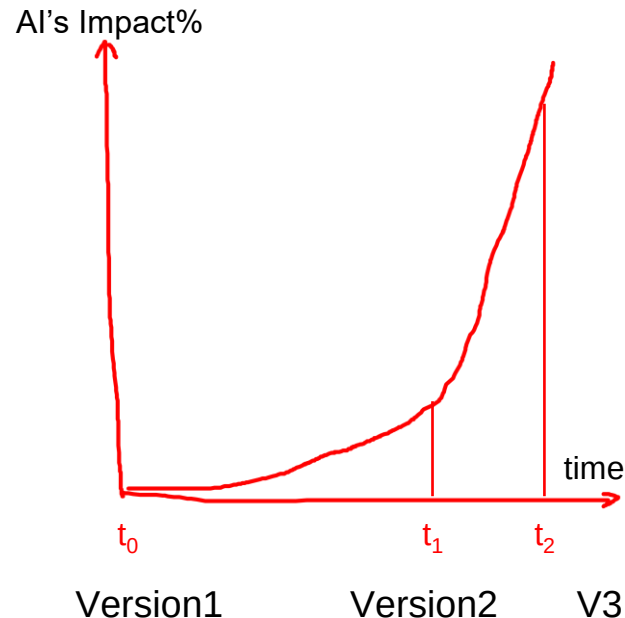


Summary & Take-away Messages

Question: How Will CDISC Standards Evolve in the AI Era?

My responses:

- **Viewpoint 1:** AI's impact on CDISC standards over time (t_0 to t_2) is likely as illustrated in the right chart.
- **Viewpoint 2:** CDISC's ambition is to create **connected** standards to **enable end to end automation from study design to results**. This may be achieved at t_1 .
- **Viewpoint 3:** it will take **long** time. $t_1 = 5-10$ years.
- **Viewpoint 4:** **AI's impact %** after t_1 is expected huge, and also depends on **connected standards** development and **use** (to produce millions or billion of high-quality data).



Thanks for your attention!

Acknowledgements: hundreds of CDISC volunteers who developed and are developing the standards, and CDISC speakers whose insights and presentation slides are referenced.



**The Global Healthcare
Data Science Community**

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