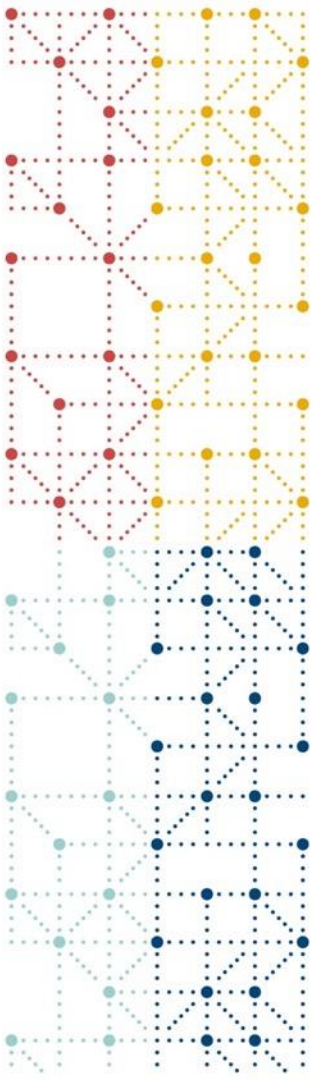**2024** CDISC JAPAN INTERCHANGE TOKYO

12-13 JUNE: CONFERENCE & EXPO | 10-11 JUNE: TRAININGS

CDISC Roadmap: Focus on the First Steps to Realize the Long-Term Vision

Presented by Chris Decker, CEO and President, CDISC

Strategic Pillars and Roadmap

Realizing the CDISC Mission

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	Enable & Automate	Engage & Adopt
Expand, Connect, and Digitalize our Standards	Reduce Variability, Enable Interoperability, and Increase Automation	Focus on Community Needs Deliver Business Value

End to End Study Information Lifecycle

Standards driven automation across the research information lifecycle

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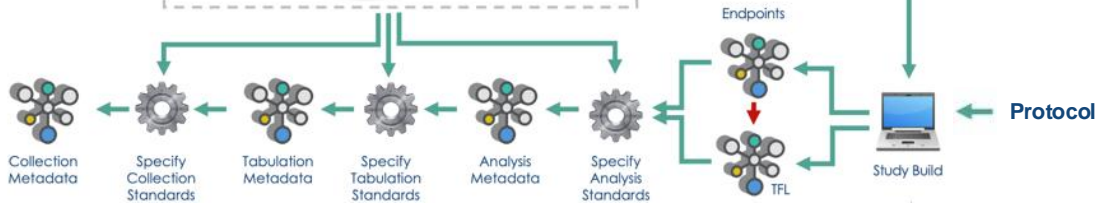Collection ← Tabulation ← Analysis ← Endpoints ← Protocol

← **Design & Build**

Data Sources

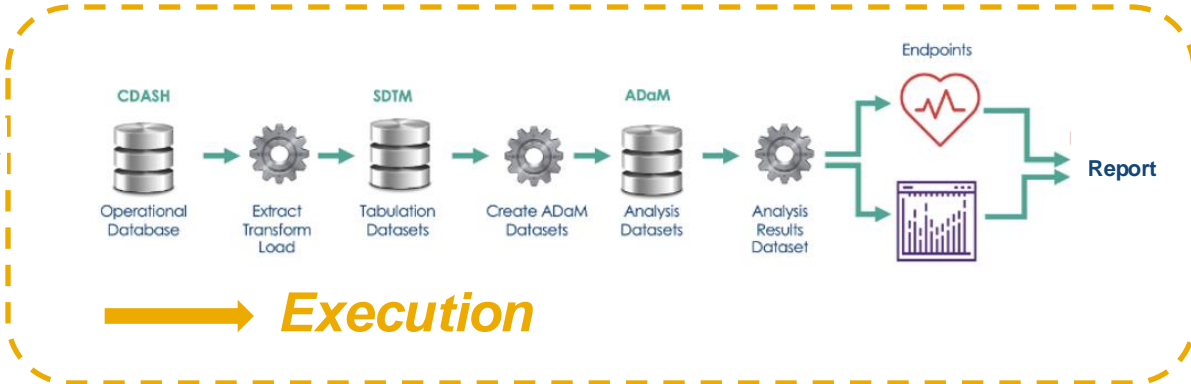Collection → Integration → Tabulation → Analysis → Endpoints → Report

→ **Execution**

CDISC Strategic Goal

Our work has started!

Data Sources

Design & Build

Execution

CDISC Roadmap

Roadmap Pillars and Objectives

Expand & Connect

- Embrace and adopt digital study design
- Expand and connect standards across the clinical research information lifecycle
- Define clear pipeline for integration of new data sources

Enable & Automate

- Develop ready to use implementation standards
- Create open-source technology enabled standards
- Establish and manage a conformance framework

Engage & Adopt

- Establish a continuous feedback loop across the CDISC community
- Shift focus to producers/consumers needs and lower the barrier to use
- Prioritize communication to enable our stakeholders

Roadmap Pillars and Objectives

Expand & Connect

- Embrace and adopt **digital** study **design**
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Expand & Connect: Digital Study Design
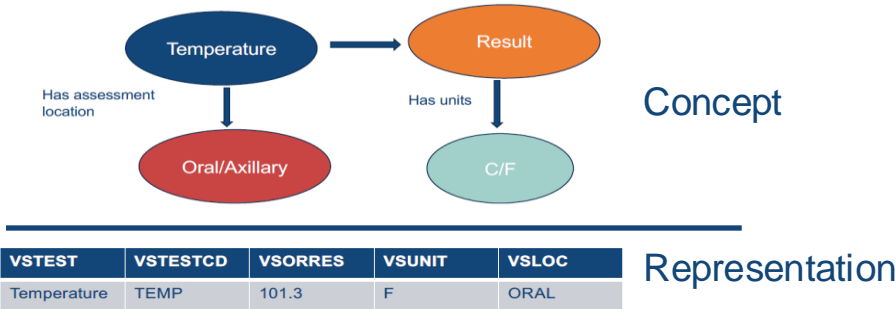
- Unified Study Definitions Model (USDM)
    - Holds many aspects of the study design
    - Facilitates interoperability between systems
    - Schedule of Activities = digital backbone of the protocol
        - Link Schedule of Activities to standard Concepts
    - Support study design activities

Design & Build ←

- ICH M11
    - Provide controlled terminology, aligned with USDM
    - Collaborate with ICH and Vulcan to create exchange mechanism
        - Utilizing Digital Protocol (UDP)
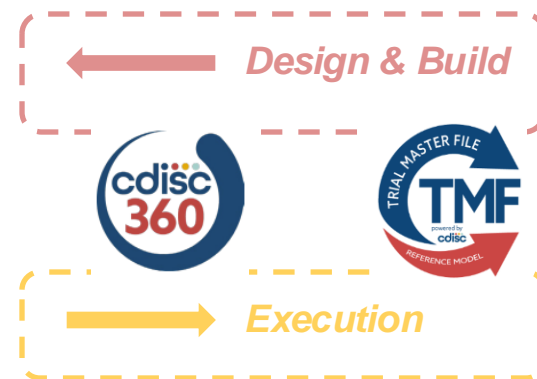   - Support use cases and pilots (e.g. FDA PRISM)

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Connect Design to Results

- Mapping data from various formats often breaks down
  - The meaning and terminology do not match (e.g. eHR to SDTM)
  - Mapping between common data models is only a part of the solution

- We need well defined Concepts
  - Standardize the meaning and semantics of data
  - Regardless of data representation

- Concepts will
  - Link to the **Schedule of Activities**
  - Provide consistent implementation
  - Facilitate automation
  - Prevent AI from hallucinating

Concept

Representation

VSTEST	VSTESTCD	VSORRES	VSUNIT	VSLOC
Temperature	TEMP	101.3	F	ORAL

Close the gaps & Expand the standards

- Ensure standards can represent all data
  - Analysis Results Standards (launched March 2024)
  - Common electronic data transfers (to start)
  - Explore structures to represent objectives & endpoints (to start)

- TMF is now integrated with CDISC
  - Roll out form TMF standards development process
  - TMF Controlled Terminology (in progress)

- Digitalize Trial Master File
  - TMF Art of the Possible to TMF Roadmap
  - TMF systems will integrate digital protocol information
  - Enrich TMF with metadata to support automation

Expand & Connect: Integrate Sources

- Study data is originating from many sources
  - Electronic Data Capture systems and eCRFs
  - Various Data Transfers such as eCOAs, ePROs, eHRs
  - Digital Health technologies

- Provide more standards to ingest data

- Digital Health Technologies initiative
  - Partnership with DiME – Library of digital endpoints
  - Link resources to concepts, device attributes, domains
  - Standardize analysis of DHTs where applicable

Data Sources

EDC   EHR

eDT   DHT

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DHT
DIGITAL HEALTH TECHNOLOGY

DiME
DIGITAL MEDICINE SOCIETY

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Expand & Connect: Integrate Sources

- Real-world data provides valuable insights but…

- Concerns about
  - Data quality
  - Data integration issues (fidelity)
  - Traceability

- RWD Lineage
  - Exchange mechanism to represent lineage, traceability and quality
  - Together with the data

- Continue partnering with NIH, IMI and other SDOs
  - Define core data elements

Data Sources

EDC   EHR

eDT   DHT

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Roadmap Pillars and Objectives

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- Develop **ready to use** implementation standards
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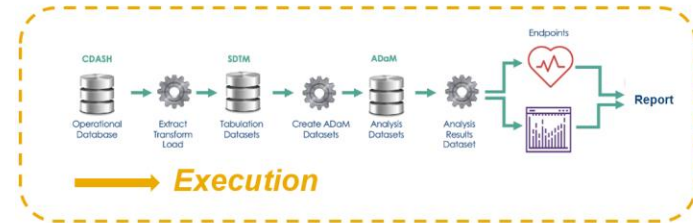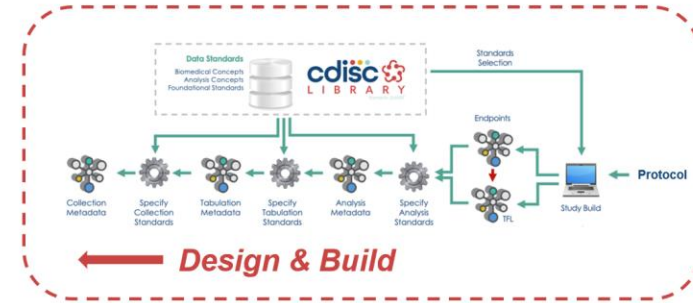- Prioritize communication to enable our stakeholders

Enable & Automate: Ready to Use Standards

- Provide rich resources and examples
  - normative standards with informative content
  - 'easy' to implement and understand

- eCRF portal
  - https://www.cdisc.org/kb
  - 70 eCRF resources and growing
  - Ready to download and use in eDC systems

- eTLF portal
  - Based on the Analysis Results Standard
  - Analysis concept + ADaM metadata + ARS metadata + TFL example
  - Ready to download and implement

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Enable & Automate: Preconfigured example study

- Complete preconfigured example study
  - Include all components from design to submission
  - Understand the normative gaps between standards

- Demonstrate and test the example study
  - Set-up Connectathon events with technology providers

- Collaborate with Regulatory to define use cases
  - Enabling better use of standards for review

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Enable & Automate: Open-Source

- Consider technology and automation upfront

- CDISC Open Source Alliance
  - Support and promote development of open-source software
  - Drive innovation

- Examples
  - Oak Initiative: automate SDTM generation
  - Open Study Builder
  - CDISC Open Rules Engine
  - CDISC Rule Editor

Enable & Automate: Technology enables Automation

- Modernize data transport: Dataset JSON
  - Technology friendly, future proof

- Standards with logical models
  - Both USDM and ARS are published with logical models
  - Enables technical implementation, demonstrate use cases
  - Includes API specifications

- CDISC Library
  - Relevant standards are digitally available via APIs
  - Source for tools and automation

Enable & Automate: Conformance Rules

- Complete conformance rules for all relevant foundational standards
  - SDTM, ADaM, SEND, ARS, …

- Expand to regulatory business rules
  - Current collaboration with FDA, other agencies to follow

- Expand to industry quality rules
  - Quality rules beyond standard conformance
  - Creating conformance rules for USDM to ensure compliance with USDM framework
    - This will enable checking conformance with M11 transport standard

- Going forward
  - Establish rules for all CDISC standards

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Engage & Adopt

- Establish a continuous **feedback** loop across the CDISC **community**
- Shift **focus** to **user needs** and lower the barrier to use
- Prioritize **communication** to enable our stakeholders

Engage & Adopt: Feedback

- Ensure we are **solving the right problems**
  - Understand the needs of end-users

- Establish a transparent feedback framework

- Reform the CDISC Advisory Council
  - Member input

Continuous Feedback

Define and manage community feedback loop to ensure understanding of needs

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Engage & Adopt: User Focus

- Focus to enhance and accelerate standards adoption
  - A standard is only successful when used

- Include impact assessment to significant standard changes
  - Provide a rationale and value for the change
  - Provide implementation considerations where possible

- CDISC education
  - Shift from theory to hands-on experience trainings
  - I do, we do, you do

User Focus

Shift from development to user needs to enhance and accelerate standards adoption

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Engage & Adopt: Communication

- Evaluate on how we make content and information available
  - Website, Social Media, Github, CDISC Library

- Publish and maintain a dashboard with current CDISC activities and progress

- Publish the Annual Report
  - Summarize progress on strategic objectives
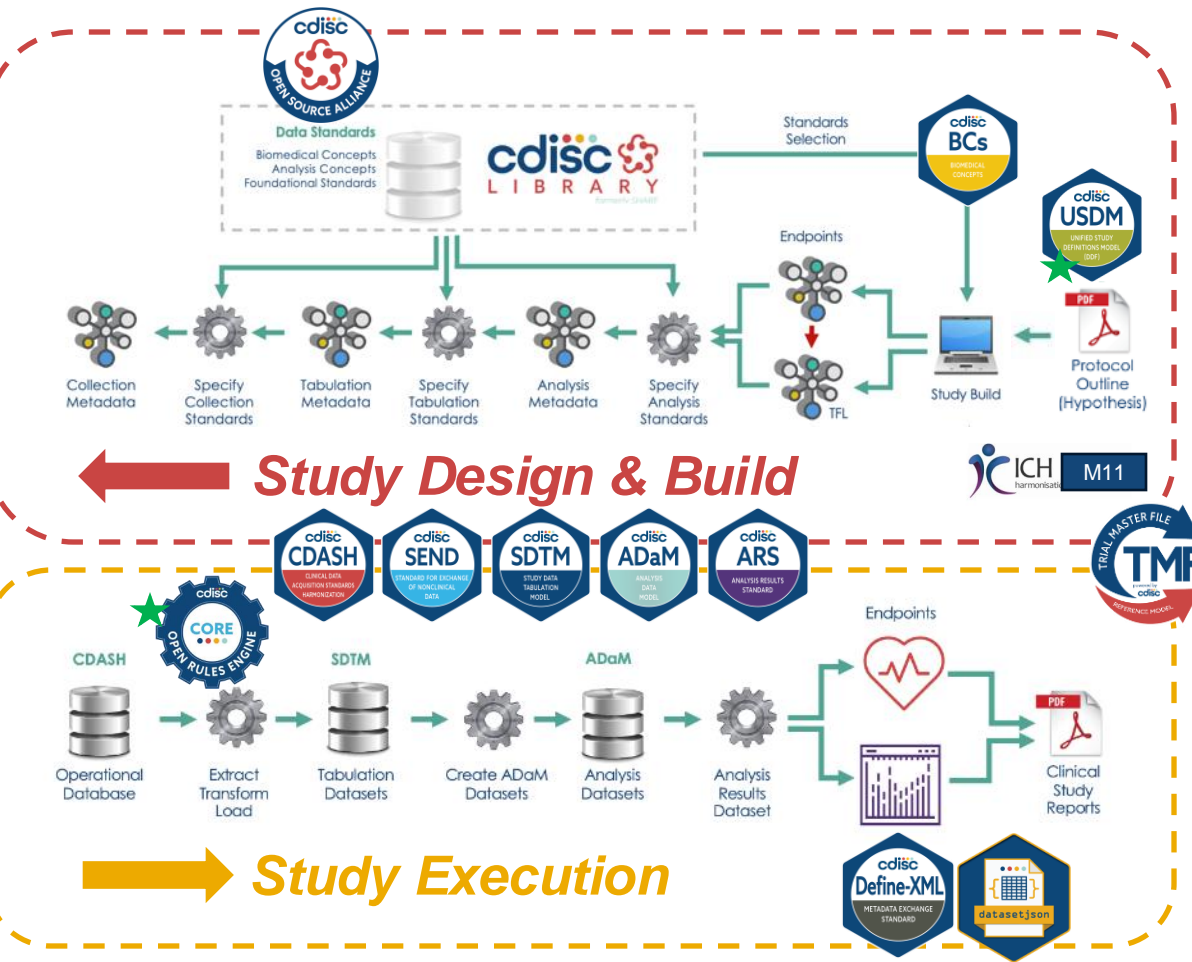 - How is CDISC using membership fees to create value

Prioritize Communication

Create frequent and accessible information for CDISC and community alignment

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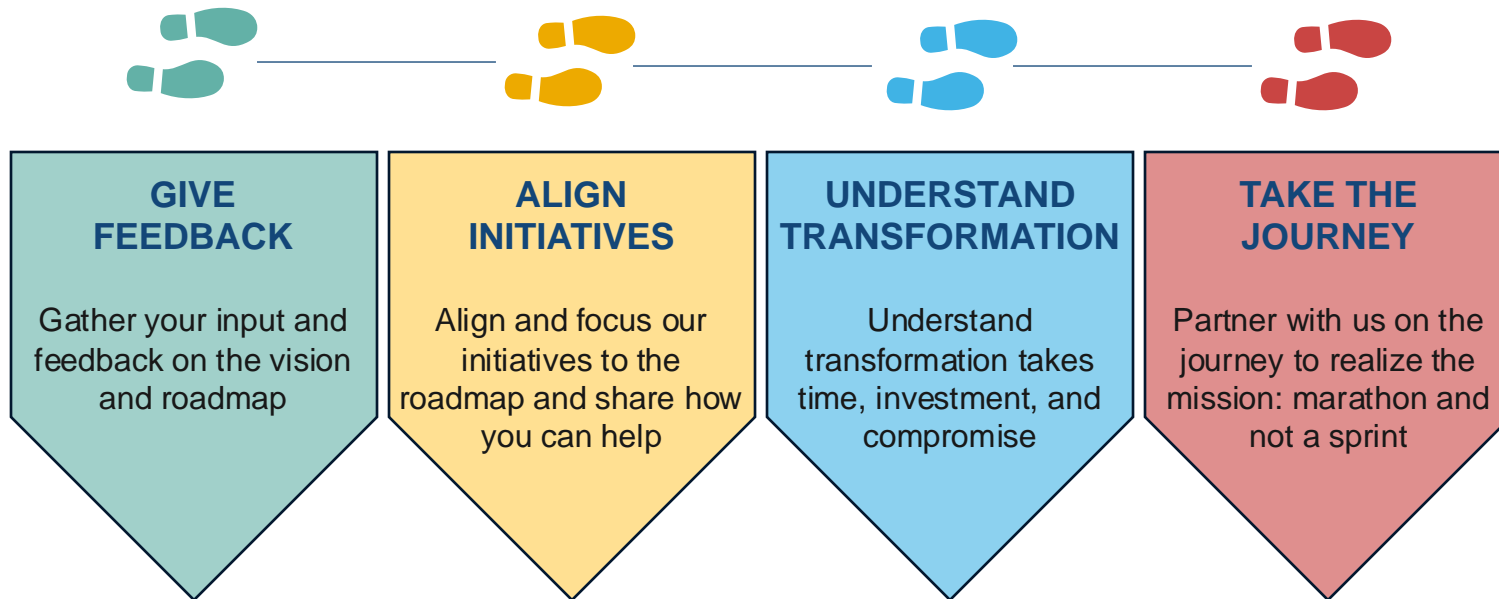Standards driven automation across the research information lifecycle

Study Design & Build

Data Sources

Study Execution

Where do we go next?

GIVE FEEDBACK

Gather your input and feedback on the vision and roadmap

ALIGN INITIATIVES

Align and focus our initiatives to the roadmap and share how you can help

UNDERSTAND TRANSFORMATION

Understand transformation takes time, investment, and compromise

TAKE THE JOURNEY

Partner with us on the journey to realize the mission: marathon and not a sprint

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We Want Your Feedback!

Opportunities:

- Plenary presentation Q & A
- Speak to CDISC leadership team members at the event
- Survey with QR Code
- May Webinar to share message with broader CDISC community
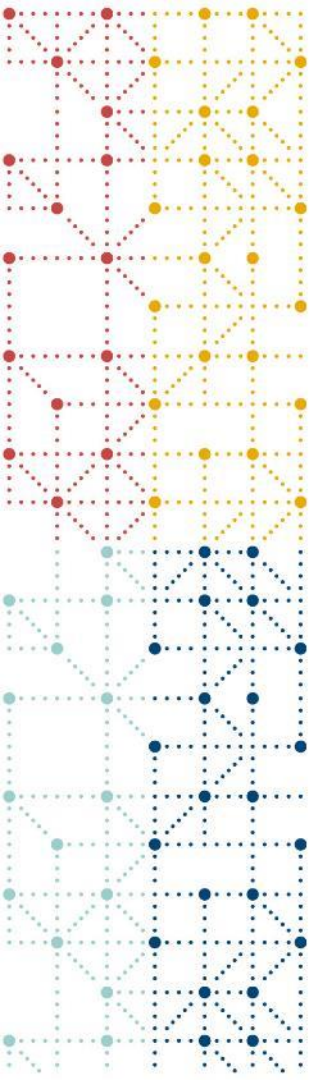- Listening Groups in May and June

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Never doubt that a small group of thoughtful committed citizens can change the world; Indeed, it's the only thing that ever has.

--- Margaret Mead

#RelentlessCollaboration

#ClearDataClearImpact

Domo Arigatou Gozaimasu!

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