



2024 CDISC + TMF  
EUROPE INTERCHANGE

BERLIN

24-25 APRIL: CONFERENCE & EXPO | 22, 23, 26 APRIL: TRAININGS

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

Presented by Peter Van Reusel, Chief Standards Officer, CDISC

# Meet the Speaker

Peter Van Reusel

**Title:** Chief Standards Officer

**Organization:** CDISC



Peter Van Reusel provides executive leadership to the development and implementation of clinical standards in line with CDISC's strategy and operational plans, working closely with the President and CEO, as well as CDISC staff and stakeholders. He has over 20 years' experience in senior roles in pharma and at CROs, providing standards expertise and carrying out other standards work in various organizational settings. A long-time, CDISC-authorized instructor, Peter has helped significantly in developing CDISC training courses.

He previously served as CDISC's European Liaison, shepherding relationships with key European regulatory, academic, and biopharma stakeholders. Peter is also an active PHUSE collaborator.



## Agenda

- The Strategic Goal
- CDISC Roadmap



# The Strategic Goal

# 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

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



Standards driven automation  
across the research  
information lifecycle



Collection ← Tabulation ← Analysis ← Endpoints ← Protocol

**← Design & Build**

Integration → Tabulation → Analysis → Endpoints → Report

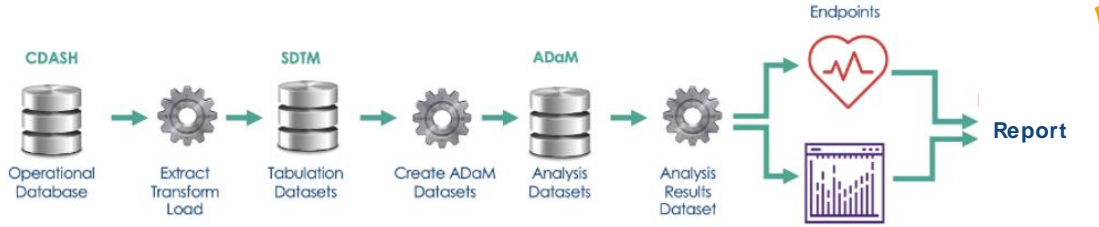
**→ Execution**

# CDISC Strategic Goal

Our work has started!



**Design & Build**



**Execution**





# CDISC Roadmap



# CDISC Roadmap

## Expand & Connect

- Embrace and adopt digital design
- Integrate data sources
- Connect design to results

## Enable & Automate

- Ready to use standards
- Technology enabled standards
- Conformance framework

## Engage & Adopt

Continuous feedback - User focused - Prioritize communication

# CDISC Roadmap

## Expand & Connect

- Embrace and adopt digital design
- Integrate data sources
- Connect design to results

## Enable & Automate

- Ready to use standards
- Conformance framework
- Technology enabled standards

## Engage & Adopt

Continuous feedback - User Focus - Prioritize communication

# Expand & Connect



## Three Year Roadmap

### Embrace and Adopt Digital Design

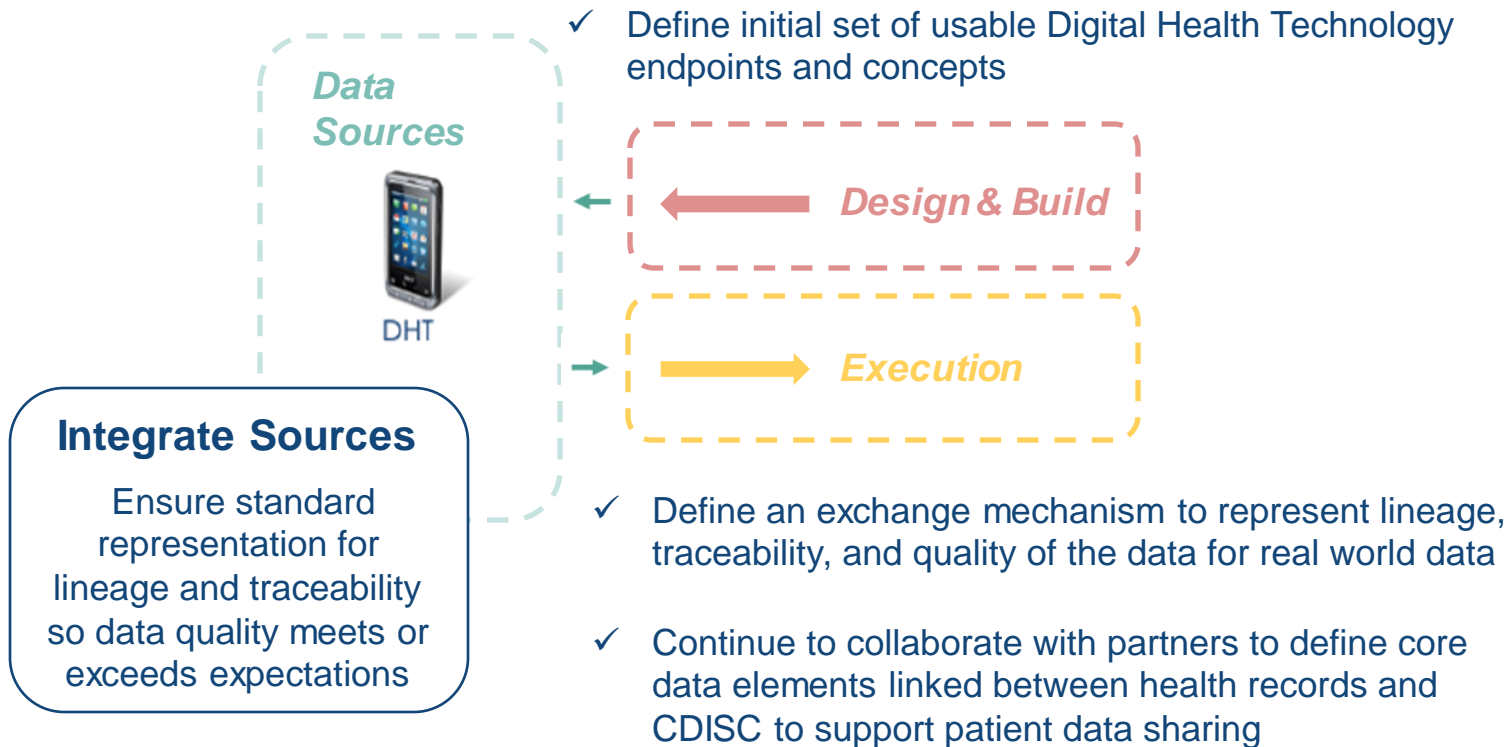
Define study design upfront and leverage downstream to increase automation, improve data quality, and accelerate delivery

- ✓ Establish DDF USDM as industry standard and drive adoption across industry
- ✓ Partner with ICH, Regulatory, and other partners to make M11 standard for submission

← *Design & Build*

- ✓ Define and establish pilots with our community for downstream use

# Expand & Connect



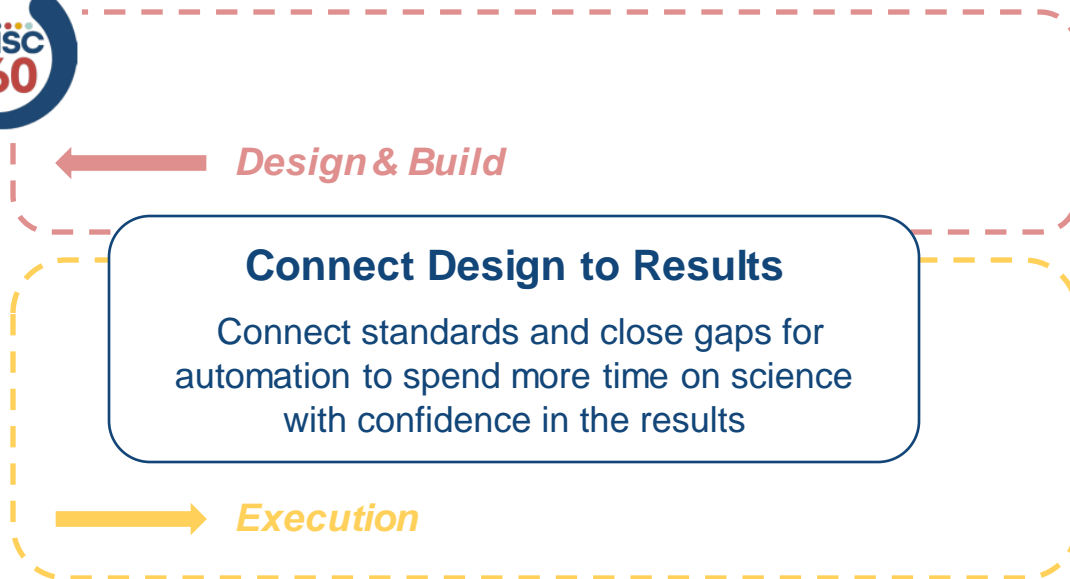
# Expand & Connect



- ✓ Expand 360 initiative to implement the complete the end-to-end Pilot use case



- ✓ Refine the connected standards business case so stakeholders understand the value and put concepts in the hands of users
- ✓ Enrich concepts with definitions and semantics which will prevent AI from hallucinating



# CDISC Roadmap

## Expand & Connect

- Embrace and adopt digital design
- Connect design to submission
- Integrate data sources

## Enable & Automate

- Ready to use standards
- Technology enabled standards
- Conformance framework

## Engage & Adopt

Continuous feedback - User Focus - Prioritize communication

# Enable & Automate

*Reduce variability, enable interoperability, and increase automation*



## Ready to Use Standards

Deliver community centric standards to simplify management and adoption and reduce variability between studies



## Technology Enabled Standards

Embrace technology integrated as part of standards to automate the research data pipeline and realize the full value of the standards



## Conformance Framework

Deliver a conformance framework as part of the standards to increase data quality and reduce variability

# Enable & Automate



## Ready to Use Standards

Deliver community centric standards to simplify management and adoption and reduce variability between studies

- ✓ Publish a complete preconfigured example study with all components from design to submission
- ✓ Demonstrate and test the example study in Connectathon events with technology providers
- ✓ Collaborate with regulatory to define use cases enabling better use of standards for review



# Enable & Automate



## Technology Enabled Standards

Embrace technology integrated as part of standards to automate the research data pipeline and realize the full value of the standards

- ✓ Develop set of COSA tools with the community to execute and consume the example study
- ✓ Make the complete example study available through the CDISC Library
- ✓ Publish all standards metadata in the CDISC Library and move away from PDF



# Enable & Automate



## Conformance Framework

Deliver a conformance framework as part of the standards to increase data quality and reduce variability

- ✓ Establish CORE as the foundation for defining and governing all CDISC conformance rules
- ✓ Define conformance rules for existing foundational standards including USDM/M11
- ✓ Deliver conformance rules as part of any CDISC standard going forward

# CDISC Roadmap

## Expand & Connect

- Embrace and adopt digital design
- Connect design to submission
- Integrate data sources

## Enable & Automate

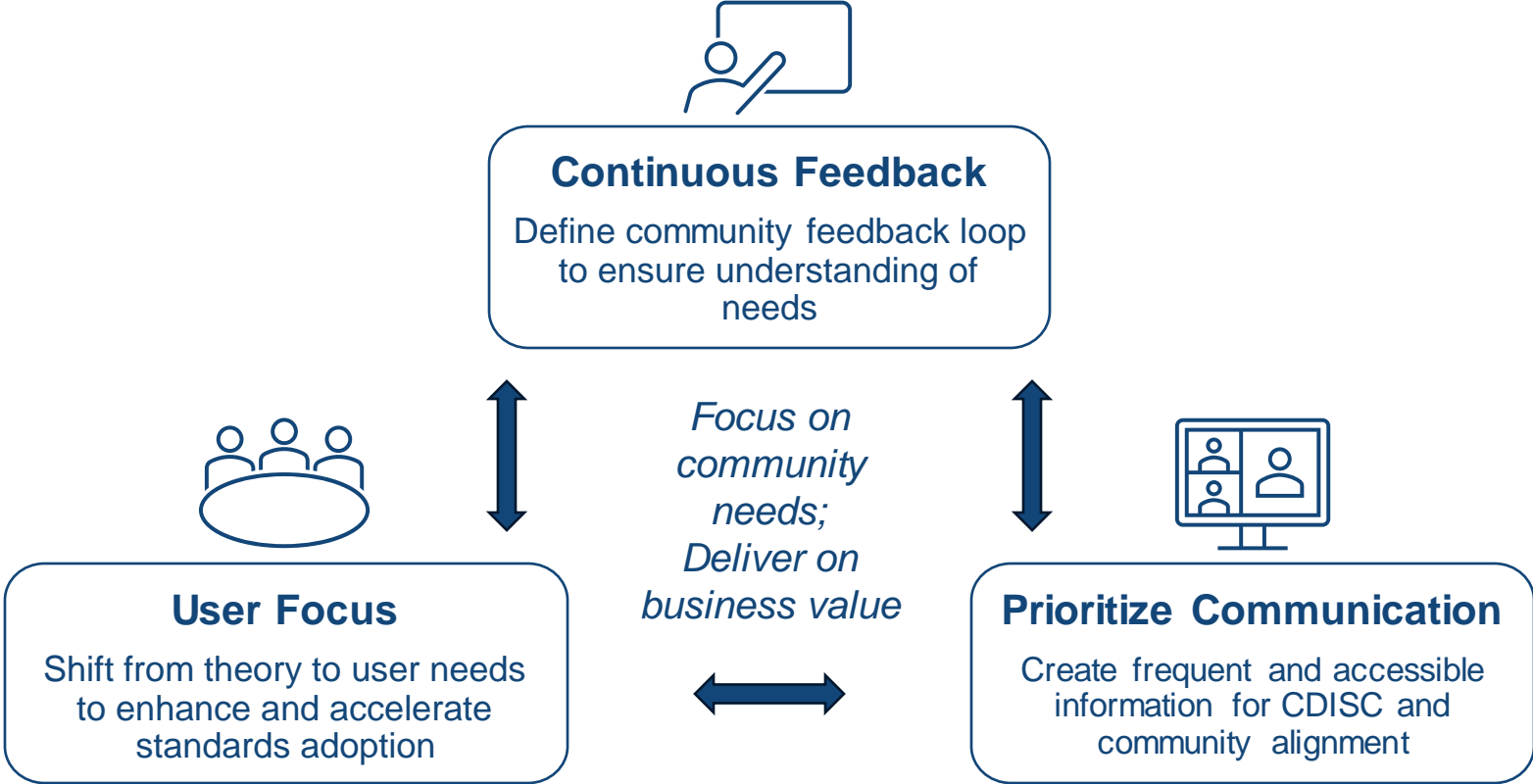
- Ready to use standards
- Conformance framework
- Technology enabled standards

## Engage & Adopt



Continuous feedback - User Focus - Prioritize communication

# Engage & Adopt



# Engage & Adopt



## Continuous Feedback

Define and manage community feedback loop to ensure understanding of needs

- ✓ Establish formal, transparent, and robust industry, regulatory, and academic feedback framework
- ✓ Rebuild the CDISC Advisory Council to optimize input from our members
- ✓ Proactively publish all feedback and decisions made through our feedback loops

# Engage & Adopt



## User Focus

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

- ✓ Include scientific and business value impact assessment to significant standard changes
- ✓ Shift our training from theory to producer and consumer centric with hands on experience
- ✓ Continuously review and optimize the standards development process in collaboration with users

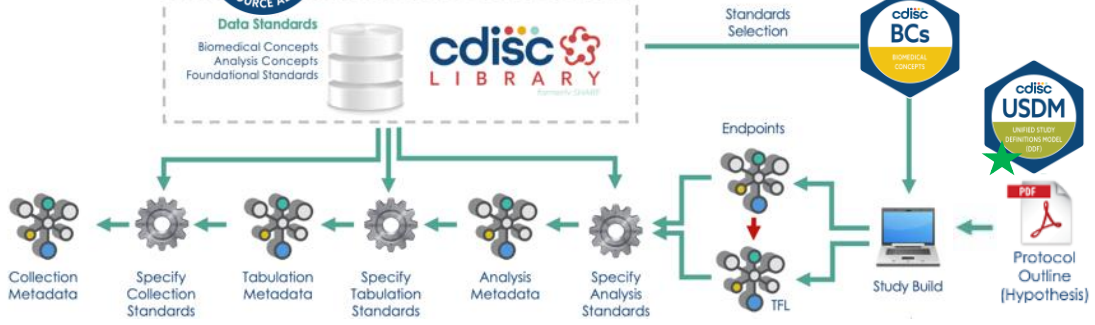
# Engage & Adopt



## Prioritize Communication

Create frequent and accessible information for CDISC and community alignment

- ✓ Evaluate and redesign the CDISC content delivery streams (e.g., website) to provide valuable information to our consumers
- ✓ Publish and maintain dashboard of the most current CDISC activities and progress
- ✓ Publish Annual Report summarizing progress of our strategic objectives and how we are using our membership fees to create value.



## Study Design & Build



## Data Sources



## Study Execution





# 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





**Thank You!**

**cdisc**