



2024 CDISC + TMF  
US INTERCHANGE

**PHOENIX/SCOTTSDALE**

23-24 OCTOBER: CONFERENCE & EXPO | 21, 22, 25 OCTOBER: TRAININGS

## **Closing Session**

Nicole Harmon, CDISC COO



# Realizing the CDISC Mission

## CDISC Strategic Plan & Roadmap



### Expand & Connect

Expand, Connect, and Digitize Our Standards



### Enable & Automate

Reduce Variability, Enable Interoperability, and Increase Automation



### Engage & Adopt

Focus on Community Needs and Deliver Business Value

### Strategic Goal:

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

CDISC will expand and realize the original 360 vision.



# CDISC 360i

- Define end to end standards
  - Digitalize information from protocol to reporting
  - Link concepts to representation standards
    - Forms definition, eDTs, DHT, SDTM specs, ADaM specs, TFL specs, ...
  - Enrich with transformation & derivation logic
- Study design & build
  - Select concept and concept groups in digital Schedule of Activities
  - Automates study builds
    - Forms definition, SDTM specs, ADaM specs, TFL specs, ...
  - Provides derivation & transformation algorithms
- Automate data flow
  - Demonstrate end to end automation
    - Starts with linking Schedule of Activities to Concepts (and Concept Groups)
  - Automates transformations & derivation between data states
    - Collection, tabulation, analysis, results



\*Webinar in December

PROVIDE US WITH YOUR INPUT ON THE:

## CDISC 360i Survey





## Pillar 3: Engage & Adopt

To inform our efforts to support the CDISC Global Community and deliver increased value.

To accept feedback on how our organization can most effectively adapt and align with current data standards and interoperability priorities.

# Community Engagement Survey: 7a. How would you sum up what CDISC provides the community that you feel is most useful for you and/or your organization in ~10 words?

“Standardization, Compliance, Training, Collaboration”

“Standards the whole industry adheres to”

“Guidance on submission requirements”

TMF Reference Model and the support that CDISC provides to us

“Making standards available even during DRAFT stage which helps us to incorporate early in our standards”

“Community based standards”

“Standards that realize end-to-end data flow from protocol through submission”

“A single Source of Standards Truth”

“A core set of clinical data standards mandated or accepted by health authorities around the world.”

“The standards themselves. The connection between CDISC, Industry, and FDA is crucial to useful standards development, and CDISC provides that link.”

“Transparent data standards”

“Standardization is crucial when working with multiple vendors”

“Consistency, rules and structure in an evolving landscape.”

An authoritative voice in implementing and maintaining standards across the industry

“Easy to understand advanced data standards that make data collaboration better.”

“A central place to discuss, develop, and implement new data standards”

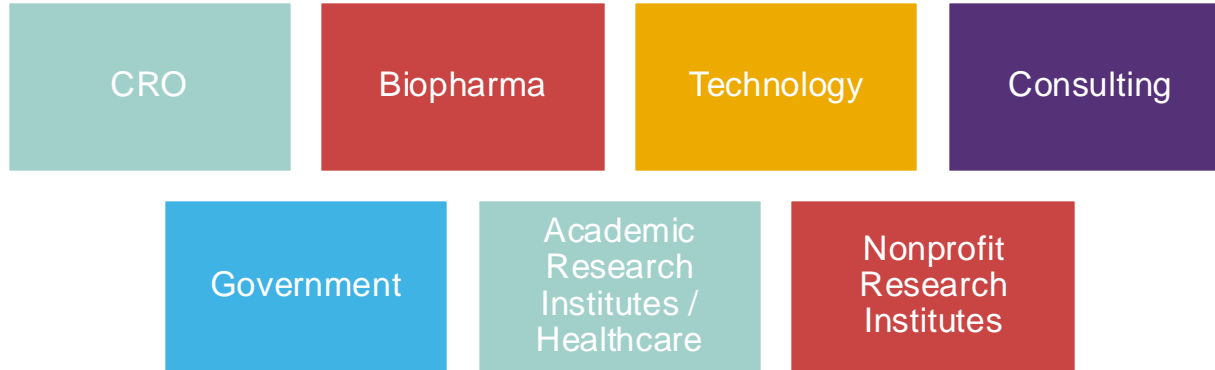


“Connections and network building”

“A standard that can be used across the industry, accepted by regulators.”

# We want to hear from YOU!

## Next Up: Focus Groups by Stakeholder

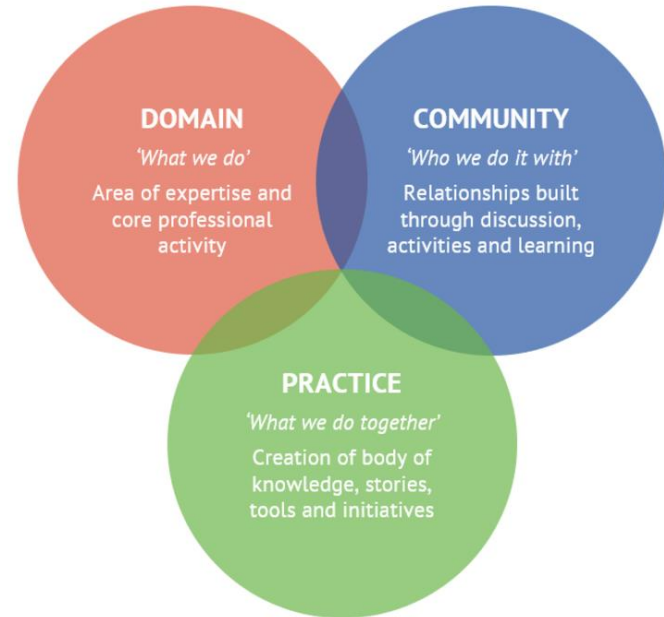


- **Clinical Standards**
- **Product Manager**
- **Solution Engineer**
- **Statistical Programming**
- **Clinical Operations**
- **Clinical Data Management**
- **Trial Planning**
- **Consultant**
- **Project Manager**
- **Business Development**
- **Developer**
- **Program Lead**
- **Clinical Strategy**
- **Clinical Records Management**
- **Researcher**
- **Informatics**
- **Medical Safety & Regulatory**
- **Quality and Compliance**
- **TMF Records**
- **Document Manager**
- **System Analyst**
- **Data Engineer**



# Community of Practice Framework

Mission: Build a robust community of diverse CDISC supporters and partners focused on implementation of CDISC standards to create a continuous feedback loop across stakeholder groups to ensure CDISC understands our community, prioritize what brings the most value, and to communicate transparently across the community.





# Thank You to Our US Program Committee

- Dan Crawford, [Veeva](#)
- Sam Hume, [CDISC](#)
- Harivardhan Jampala, [Fortrea](#)
- Asif Karbhari, [AstraZeneca](#)
- Bron Kisler, [Nurocor](#)
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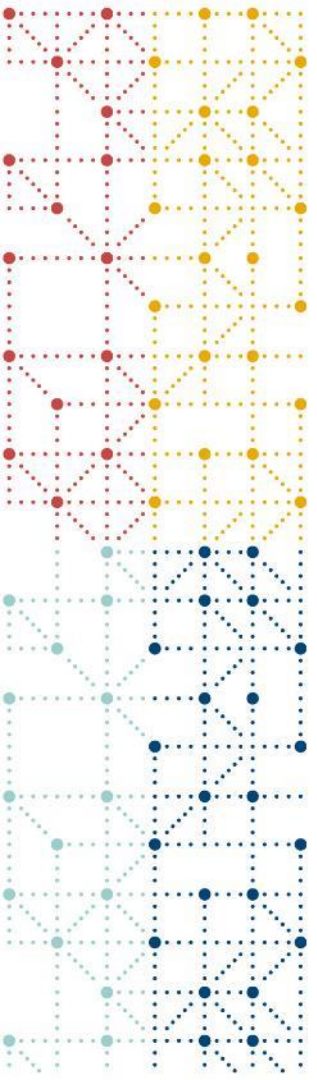


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**REMINDER:**  
**Please complete the US  
Interchange Feedback  
Survey sent by email next  
week and we will send you  
all the  
PRESENTATION SLIDES**

# Upcoming 2025 CDISC Events



**BENGALURU**  
India CDISC Day  
1 March

\*Call for Abstracts  
close  
**TOMORROW**



**GENEVA**  
Europe  
Interchange  
14-15 May

\*Call for Abstracts  
Open in  
**NOVEMBER**



**TOKYO**  
Japan  
Interchange  
25-26 June

\*Host  
Applications  
Open



**BEIJING**  
China  
Interchange  
August

# WE CANT WAIT TO SEE YOU IN NASHVILLE!!!



**cdisc** 25 YEARS ANNIVERSARY

**2025 US Interchange - Nashville**  
Conference: 13-14 Oct. | Trainings: 15-17 Oct.

Join Us in Celebrating 25 Years of Member-Driven CDISC Standards & Data Science Innovation!

**Sign Up as a Sponsor & Exhibitor for a DISCOUNT by Nov 1st!**

Join us in celebrating our 25<sup>th</sup>  
Anniversary in 2025!

*Celebrating our past while  
envisioning our future!*







THANK YOU!!!

