



Closing Summary

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President & CEO
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A panoramic view of the Berlin skyline at sunrise or sunset, with the Spire of Berlin (Fernsehturm) as the central landmark. The sky is a mix of soft orange and light blue.

2024 CDISC + TMF
EUROPE INTERCHANGE

BERLIN

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

CDISC Vision and Roadmap: Reminder and our Ask to You

Presented by Chris Decker, CEO and President, CDISC

CDISC's Vision and Mission



VISION

Amplify Data's Impact to Advance Research



MISSION

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

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
Digitize our
Standards



Enable & Automate

Reduce
Variability,
Enable
Interoperability,
and Increase
Automation



Engage & Adopt

Focus on
Community
Needs
Deliver
Business Value

Preliminary Results are In (20% of the polls reporting)

1. How much do you agree with the CDISC Vision and Mission?

- 1 – Strongly disagree
- 2 – Disagree
- 3 – Neither agree or disagree Sa...
- 4 – Agree
- 5 – Strongly agree

8

2. What resonates the most about the CDISC Vision and Mission?

66
Responses

Latest Responses

- "End to end standards based metadata automation"
- "Digitalize and further standardize already the protocol to start following st..."
- "End-2-end process and Educating the industry on adoption of standards"

Update

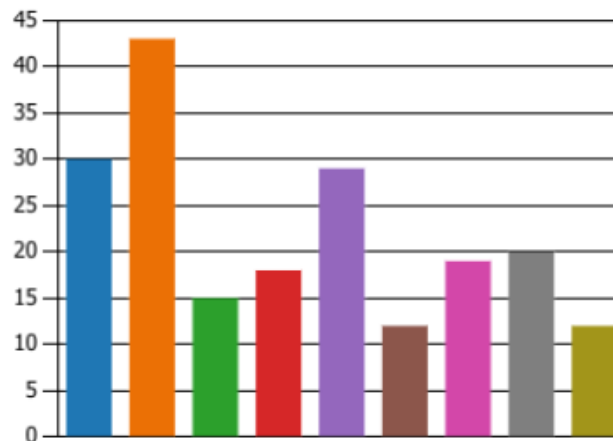
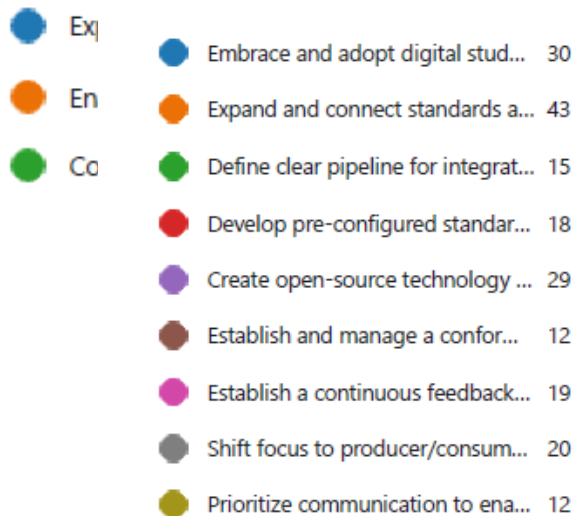
8 respondents (12%) answered **standard** for this question.

data and the Translation
connectivity of data importance of data usage of data
digital study **standard** **Automation**
Connecting and engagement **protocol** **End** data flow Connecting with CAC
data and records Study Design Connecting data raw data
Coherent and connected Connect the information Connecting the pieces
Connect and Communicate

Preliminary Results are In (20% of the polls reporting)

4. Which pillar of the CDISC Vision is most compelling to you?

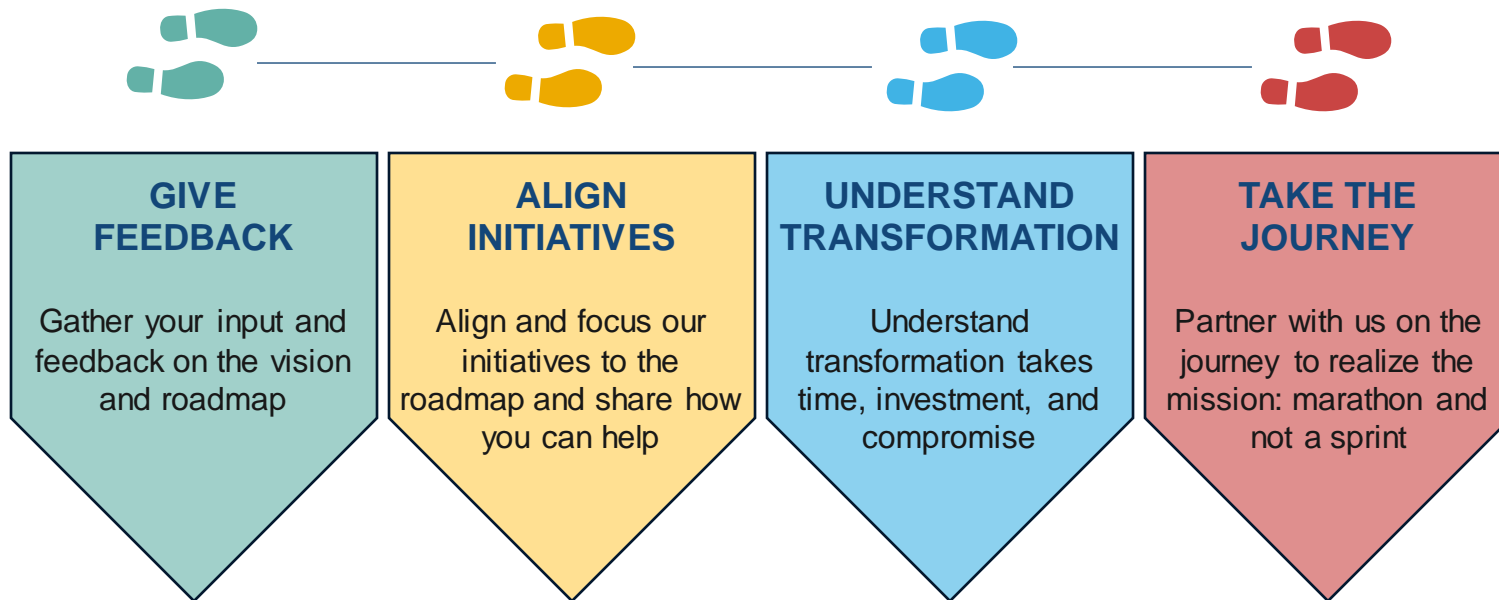
5. What do you think are the most important three objectives described on the CDISC Roadmap?



Imagine If... Ideas

- PDF will be forbidden
- Imagine if in 3 years DDF is fully integrated and adopted by industry :)
- Imagine if we can leverage automation in newer ways to help us prepare study TMFs for inspections (tying in expected document lists and standardizing risk based approaches for TMF reviews)
- All data changes are instantly known across the clinical trial ecosystem by all systems that need it.
- Protocol design and development becomes a “digital first” process
- By implementing standards across the clinical research landscape, we will achieve our dream of efficiency and moving therapeutics earlier to patients.
- Imagine if you start to treat your TMF as a source of data rather than a static repository
- You could create your protocol and then everything else would just “happen”
- Imagine if no documents existed, but were only manifestations of clinical trial data elements
- Standardization where possible and flexibility where needed go hand in hand
- Imagine if the roles in our industry that think standards don't impact them realized their influence
- Imagine if regulators talked together and aligned their needs and requirements to submissions and standards
- If all skill areas in the clinical development data flow have a basic shared understanding of concepts based standards then this will enable digitalised collaboration in the clinical data flows
- The faster horse is now an autonomous car
- We could stop over complicating everything
- We built the button that is required to “push the button”

Where do we go next?



Where we are going....



We Want Your Feedback!

Opportunities:

- Speak to CDISC leadership team members at the event
- Survey with QR Code
- Future Webinar to share message with broader CDISC community
- Listening Groups in the next few months



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