

A panoramic view of the Berlin skyline at sunset, featuring the TV Tower (Fernsehturm) and various city buildings.

2024 CDISC + TMF  
EUROPE INTERCHANGE

**BERLIN**

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

## **Session 8 - Closing**

Sujit Khune, Novo Nordisk, E3C Co-Chair  
Jamie Marie Toth, Beigene, ET3C

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# E3C



**Nick De Donder**

•Business & Decision Life Sciences



**Sujit Khune**

•Novo Nordisk A/S



**Angelo Tinazzi**

•Cytel



**Silvia Faini**

•Cytel



**Stijn Rogiers**

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**Éanna Kiely**

•Alexion



**Simon Lundberg**

•AstraZeneca



**Johannes Ulander**

•data4knowledge



**Eftychia-Eirini Psarelli**

•EMA



**Kalynn Kennon**

•IDDO



**Wafaa Jebert**

•Merck



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# ET3C



Anne-Noëlle Charles

•GSK



Paul Fenton

•Montrium



Martin Hausten

•Boehringer Ingelheim GmbH  
& Co KG



Joanne Malia

•Regeneron Pharmaceuticals



James E. Martin

•Syneos Health



Lisa Mulcahy

•Mulcahy Consulting



Dawn Niccum

•Inseption Group



Yen Phan

•elderbrook solutions GmbH



Karen Roy

•CDISC



Irina Sargsyan

•Business & Decision Life  
Sciences



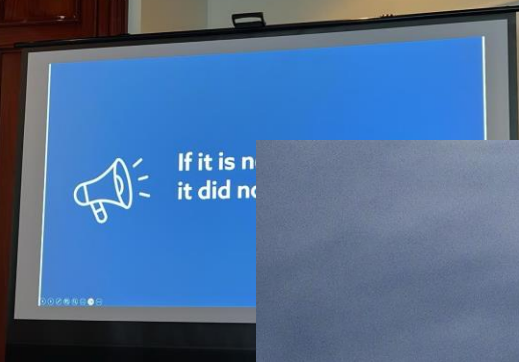
Vittoria Sparacio

•Novartis



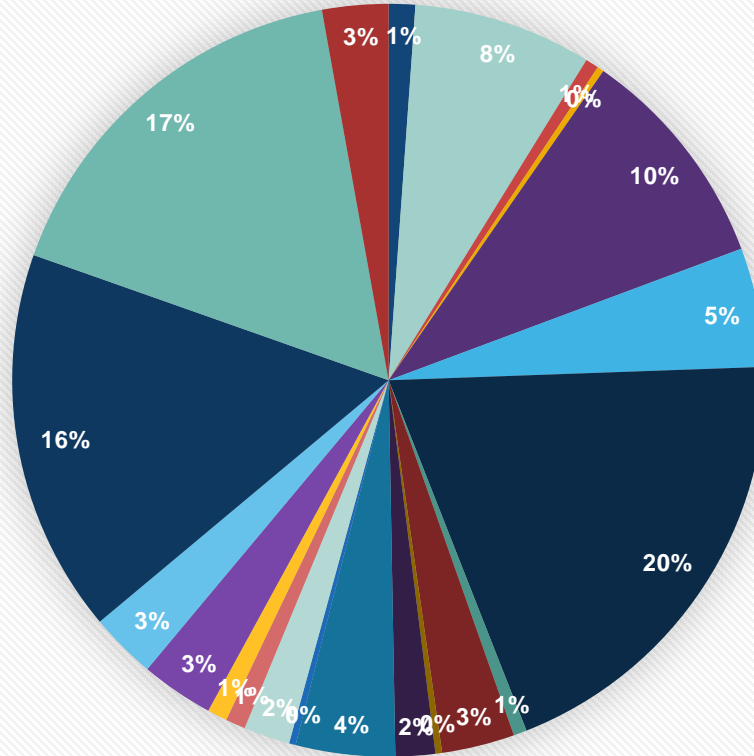
Jamie Marie Toth

•BeiGene

A large screen displaying a "SCHEDULE INTERCHANGE DAY 2" table. The table is organized into columns and rows, with various entries and details. The text is small and difficult to read, but the structure is clear. The screen is part of a collage of images.

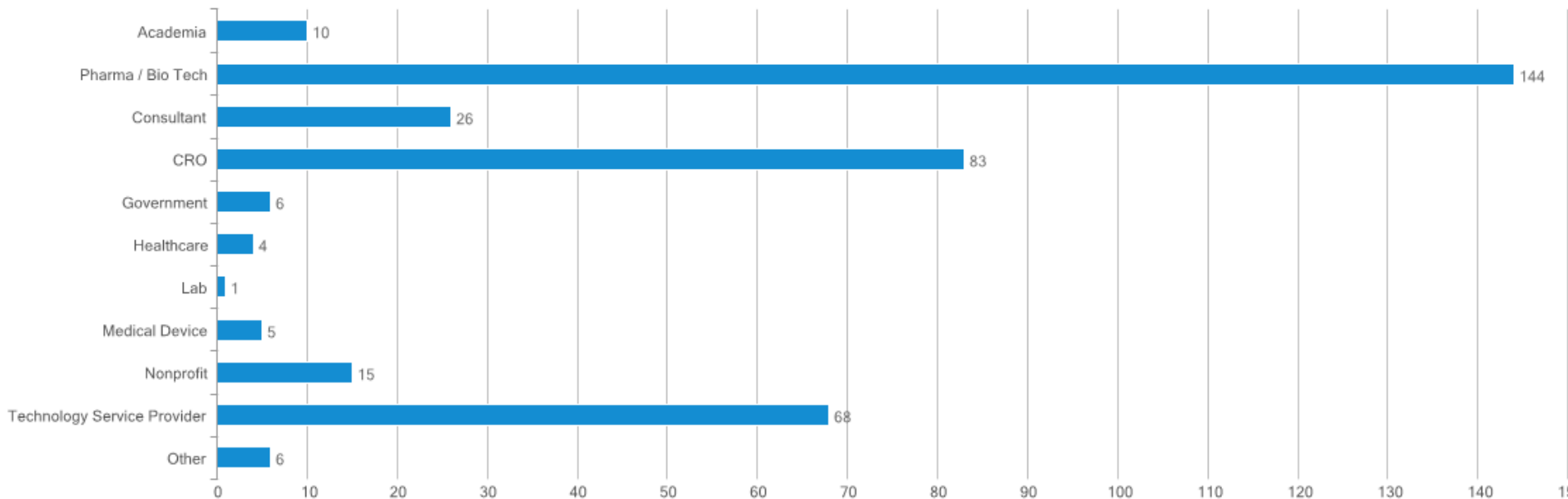
# Attendance

CDISC: 260  
TMF: 92



- Austria
- Belgium
- Canada
- China
- Denmark
- France
- Germany
- India
- Italy
- Israel
- Japan
- Netherlands
- Norway
- Poland
- South Africa
- Spain
- Sweden
- Switzerland
- United Kingdom
- USA
- Ireland

# Attendance per organization type





# Bingo Card Winners

- And the winners are....



C	D	I	S	C

## ENTER TO WIN!

Name: \_\_\_\_\_

Company: \_\_\_\_\_

Email: \_\_\_\_\_

**Prizes:** There will be three prizes, worth \$150, \$100 & \$50, respectively.

**Game Rules:** Visit each booth listed on this card. Booth representatives must put a stamp on their company square. Drop completed Bingo Card at the CDISC Registration Desk by the end of lunch time at 13:30 on **Thursday, 25 April**. Drawings will be after 16:00 (during the Closing Plenary).

Winners must be present to receive their prizes.



## Data quality considerations when providing access to pooled clinical trial data for secondary use Leveraging CDISC Standards for cross-study analysis

Authors: Sid Prabhu, Jonathan Dean, Affiliation: FossilData AI Platform Nova Nordisk A/S  
Contact: qdph@novanordisk.com

### Introduction

Historical clinical trials contain a wealth of information that can be used for insight generation within life-sciences organisations.

Good quality, interoperable data from historical trials fills the gap between high-quality, small-scale pooling on the one hand, and huge datasets full of rather messy real-world data on the other.

It can be used for applications, including data for synthetic control arms, identification of patients of interest for specific disease areas, and for the development and training of AI models.

- There are several challenges to using the data and there is no clear framework to measure the quality of the data.
- Submission-oriented checks like Pinnacle21 focus on compliance within a study, and don't address cross-study quality issues.



### Solution

#### Align Data Standards

We chose the Study Data Tabulation Model (SDTM) developed by CDISC for cross-study pooling and analysis of data as it allows us to pool the data without prior knowledge of the analysis needs.

#### Measure Data Quality

We devised quality metrics that assess aspects such as:

- Cross-align consistency of the data against code lists and dictionaries (CDISC, MedDRA, etc.)
- Format of the data (SD Dates, etc.)

These metrics allow experts to govern and improve the overall quality of the data.

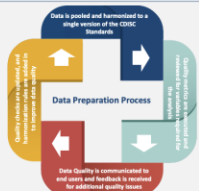
#### Implement Standards

We standardised all the studies to a single version of the SDTM, a single version of the code lists for the controlled terminology, and a single version of dictionaries (e.g., MedDRA).

#### Improve Data Quality

We share the history of the execution of our quality metrics so that Data Engineers can compare and quantify the improvement in the quality of the data over time.

### Iterative process to provide data for secondary analysis



### Results

#### 1 Global overview of metrics that can be leveraged by experts to monitor and improve data quality



#### 2 Example queries that are executed to produce quality metrics



Supplementing technical checks on data quality with functional checks helps ensure clinical trial data is "analysis-ready" for secondary purposes. CDISC standards provide a perfect framework for implementation of these checks.

# Poster Session Winner

- And the winner is.....

- Thank you to all of the submitters!



# Best Presentation Winners

- CDISC

- Navigating Data Package Submission in the Chinese Regulatory Landscape -Rebecca Moretti & Emanuele Rocco Calabrò, Chiesi Farmaceutici S.p.A

- TMF

- For 'The EU CTR and Its Impact on TMF' - Karla Navera-Andersen, Ascendis Pharma A/S



**We are going to Geneva.....!**

Tentative Dates: 14-15 May 2025



## Closing Summary

*Chris Decker*  
*President & CEO*  
*CDISC*



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## 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

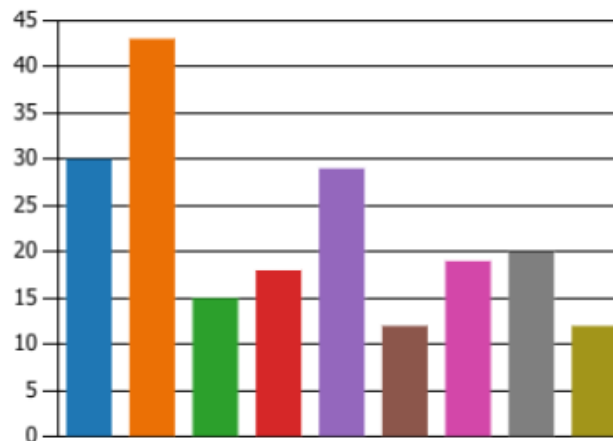
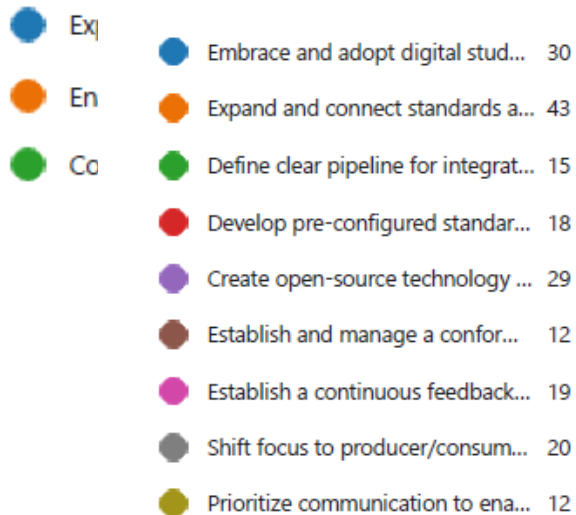
8 respondents (12%) answered **standard** for this question.

data and the Translation  
connectivity of data importance of data usage of data  
digital study **standard** Automation  
Connecting and engagement protocol **standard** 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?

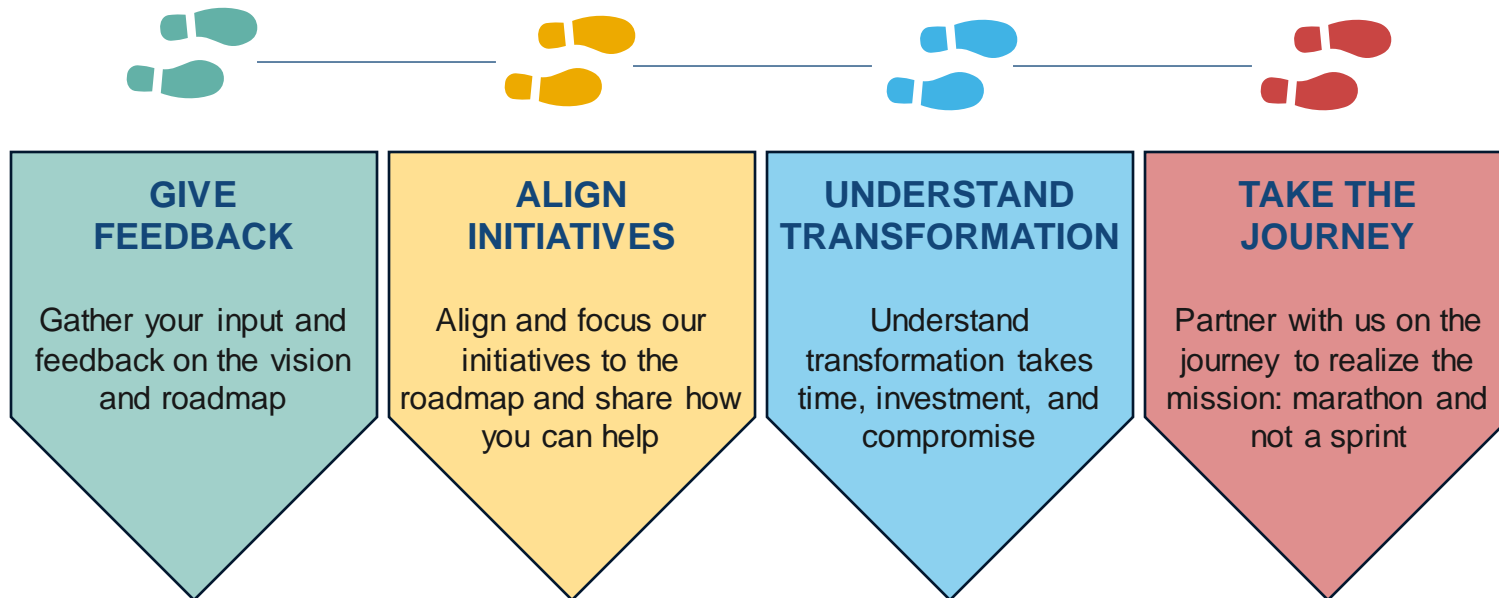
5. What do you think are the most important three objectives described on the CDISC Roadmap?



# 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



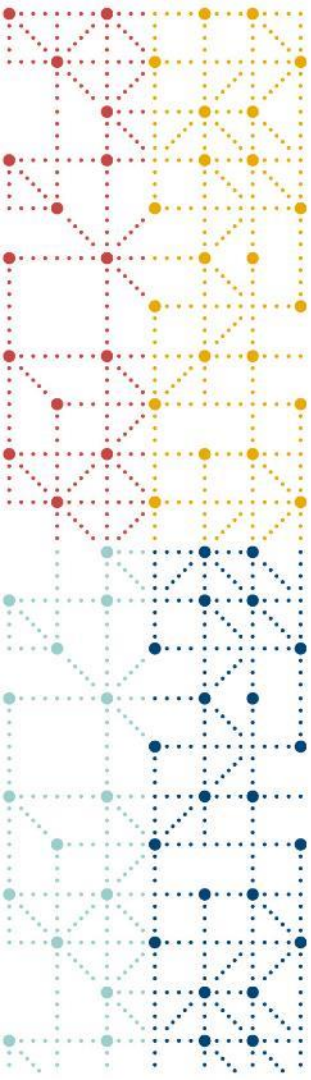
**Never doubt that a small group of thoughtful committed citizens can change the world; Indeed, it's the only thing that ever has.**

**--- Margaret Mead**



**#RelentlessCollaboration**

**#ClearDataClearImpact**



**Thank You!**

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