



**CDISC Closing Session**



# Reflecting on the Past 25 Years... Predicting the Next 25

Chris Decker, CDISC CEO

# Innovation and Disruption in the Last 25 Years...

2000

2005

2010

2015

2020

2025

Digital Dawn

Mobile &  
Cloud Boom

AI, Apps, & On-AI Expansion &  
Demand New Realities

Generative AI &  
the Metaverse



2001



2006



2010



2016



2020



2004



2007



2011



2018



2021



2005



Dropbox 2008

amazon alexa 2014



2019



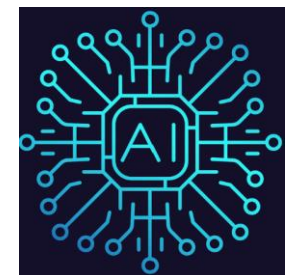
2022



2009



2015





# What Will the Next 25 Years Look Like...

Well let's ask Chat GPT....

*What will be the most disruptive changes in technology and innovation in the next 25 years?*



# What has OUR Last 25 Years Looked Like?

2000

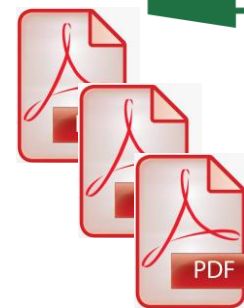
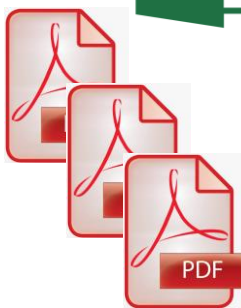
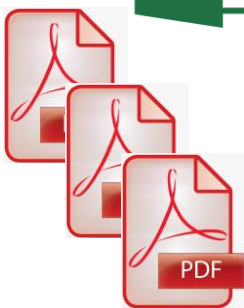
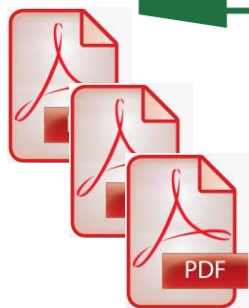
2005

2010

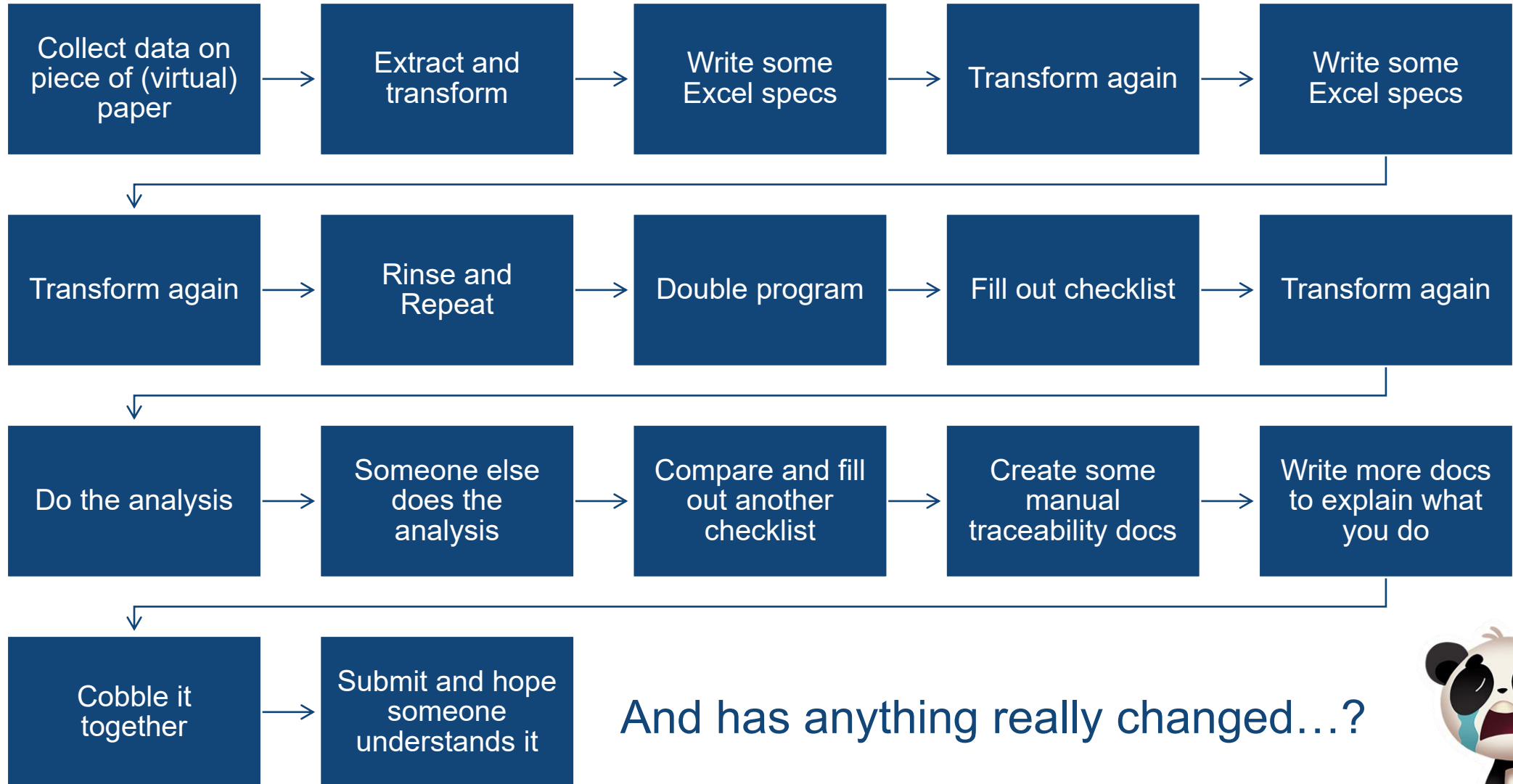
2015

2020

2025



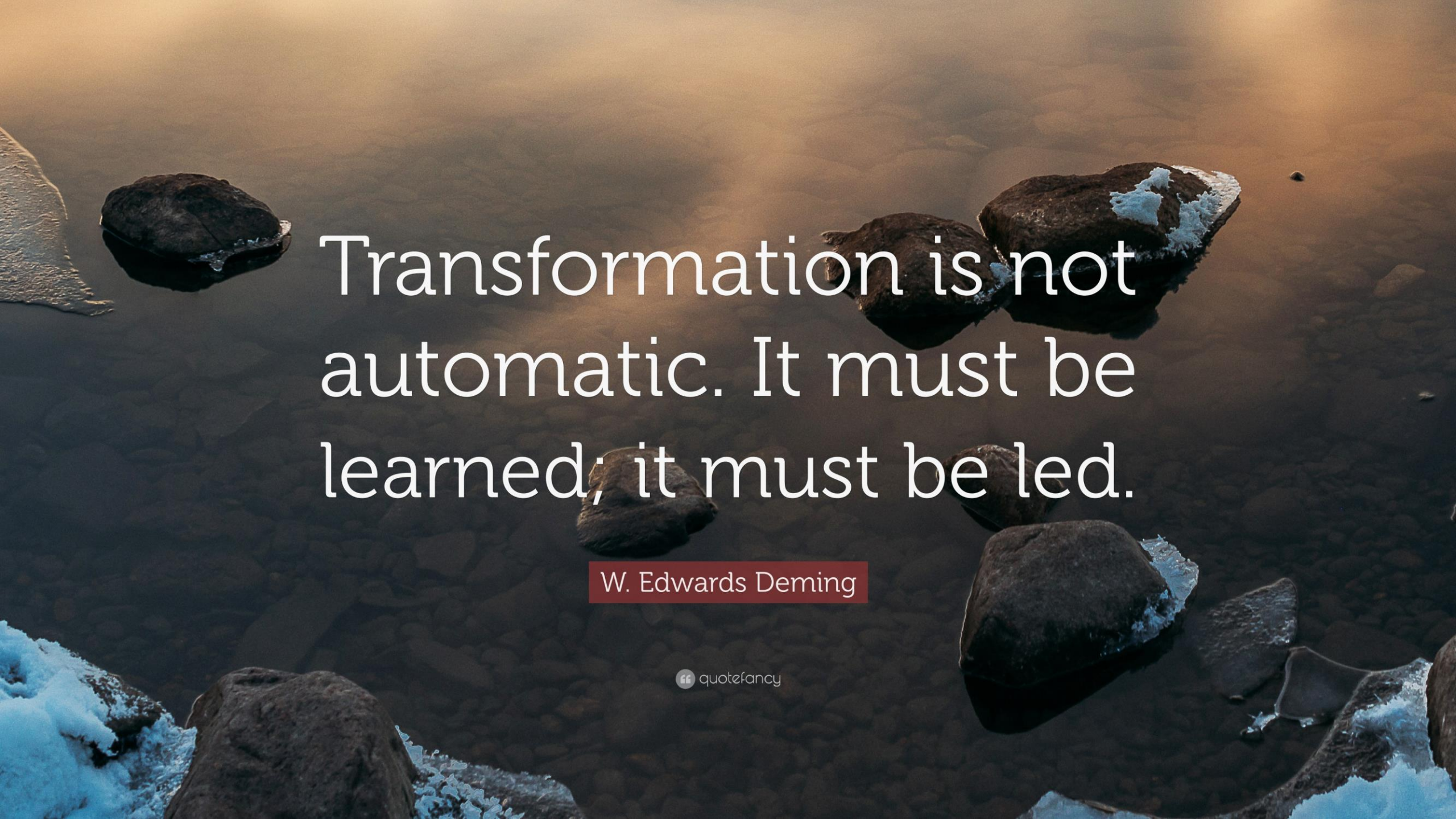
# 30 years ago...



And has anything really changed...?







Transformation is not  
automatic. It must be  
learned; it must be led.

W. Edwards Deming

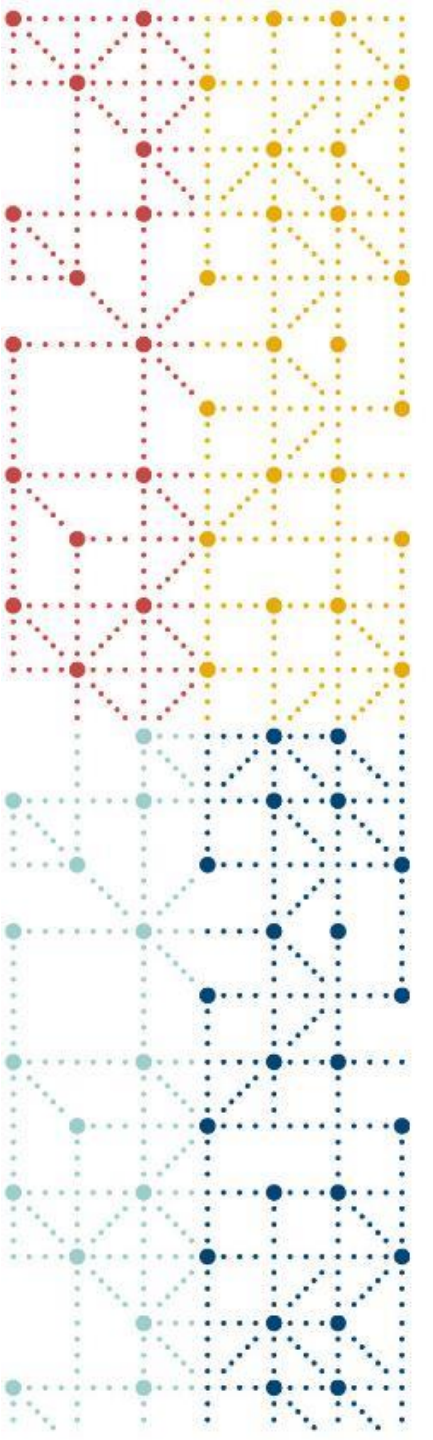




## Building the Future: CDISC 360i Phase 2

Peter Van Reusel  
Chief Standards Officer  
CDISC



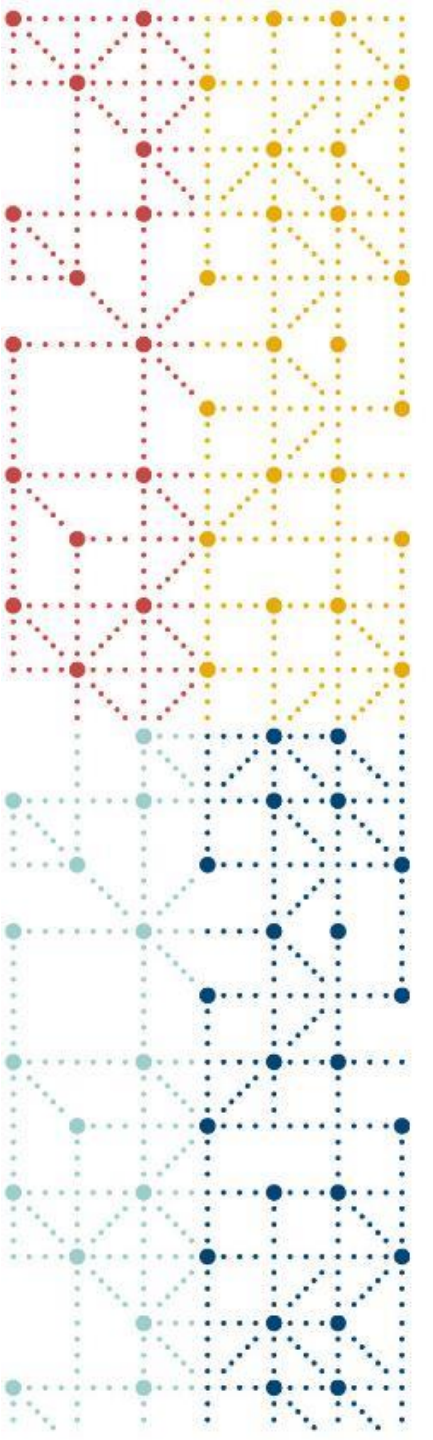


# 360i Goals

# 360i Goals

- 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 build
    - Forms definition, SDTM specs, ADaM specs, TFL specs, ...
- Automate data flow
  - Demonstrate end to end automation
    - Starts with linking Schedule of Activities to Concepts (and Concept Groups)
  - Automate transformations & derivation between data states
    - Collection, tabulation, analysis, results





# Art of the Possible





## Welcome Back!

Enter your credentials to access your account

User Name

Password


[Forgot password?](#)

[Sign In](#)

[Don't have an account? Sign up](#)

The Future of the Clinical Study Design is Digital

# Is Your Organization Ready?

[Get Started with USDM Onboarding](#) 

# Plan Schedule of Activities

Review the generated Schedule of Activities for the **Breast Cancer Randomized Study** and make any necessary adjustments.

## Schedule of Activities

[Import](#)[Add Visit](#)[Add Concept Group](#)

Fullscreen		Screening	Baseline (Cycle 1)	Cycle 1 Day 8	Cycle 1 Day 15
ECOG PS		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<div>Associated Biomedical Concepts</div> <div><ul style="list-style-type: none"><li>• C54706 Blood Pressure</li><li>• C49677 Heart Rate</li><li>• C17444 Body Temperature</li><li>• C49678 Respiratory Rate</li><li>• C60832 Oxygen Saturation</li></ul></div>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vitals		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Clinical Procedures and Assessments					
AE SAE Review		<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
ECG		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

[Back](#)[Save & Continue](#)

# Configure Analysis

Review the recommended analyses for the **Breast Cancer Randomized Phase III Trial**. You can make necessary adjustments or add additional analyses as needed. The currently selected endpoints for this study are: **Overall Survival** and **Progression Free Survival**.

## Included Analyses

### #1 - Progression Free Survival Recommended

This analysis was recommended because the **Progression-Free Survival** endpoint is currently auto-configured using historical patterns.

✓ Endpoints ✓ Estimands

### #2 - Overall Survival Recommended

This analysis was recommended because the **Overall Survival** endpoint is currently auto-configured using historical patterns from similar analyses.

✓ Endpoints ✓ Estimands

### #3 - Evaluation for Drug-induced Severe Hepatotoxicity (eDIS) Not Recommended

✓ Endpoints ⚠ Estimands

[Add Analysis](#)
[Back](#)

## Edit Analysis



### Analysis Info

#### Analysis Type \*

Progression Free Survival

#### Analysis Method \*

Kaplan-Meier X

#### Analysis Set \* ?

Intention-to-treat

#### Intervention \*

Investigational drug

#### Comparator \*

Standard chemotherapy

#### Associated Endpoint(s) \*

Progression Free Survival X

### Intercurrent Events (ICEs) [+ Add Event](#)

Event	Handling	Action
Death	Composite	<a href="#">Edit</a> <a href="#">Delete</a>
New Anti-cancer therapy	Composite	<a href="#">Edit</a> <a href="#">Delete</a>

[Cancel](#)
[Save](#)



# Preview Output

Progression Free Survival ▾

Sort A-Z ▾

Generate Artifact ▾

- Analysis Result
- Data Analysis
- Data Tabulations
- Data Collection
- Auxiliary Data

Protocol Violation	XXX	XXX	-
--------------------	-----	-----	---

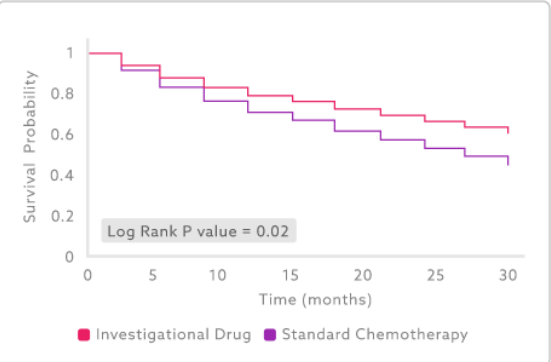
Cox Regression Adjusted for Age

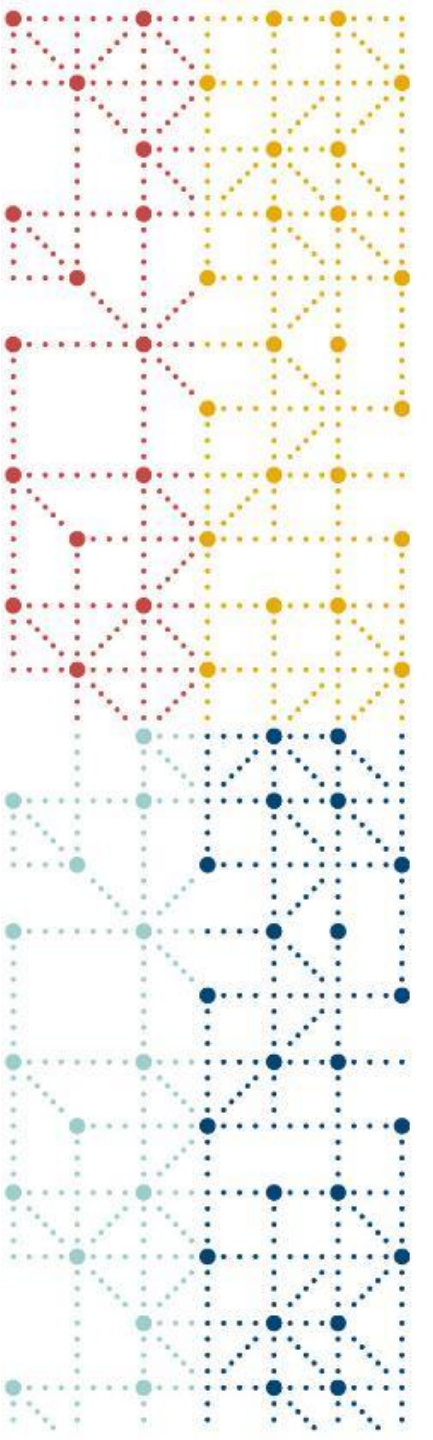
View Code

Variable	Hazard Ratio	95% CI Lower	95% CI Upper	P-value
Investigational Drug vs Standard Chemotherapy	XX.XX	XX.XX	XX.XX	XX.XX
Age (per year increase)	XX.XX	XX.XX	XX.XX	XX.XX

Kaplan-Meier Survival Curve

View Code

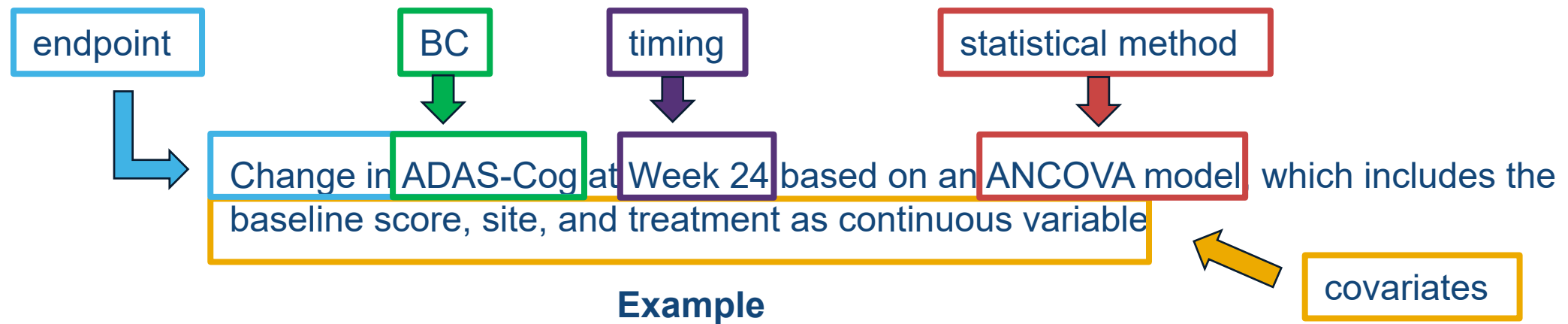




## 360i Phase 2: draft plan

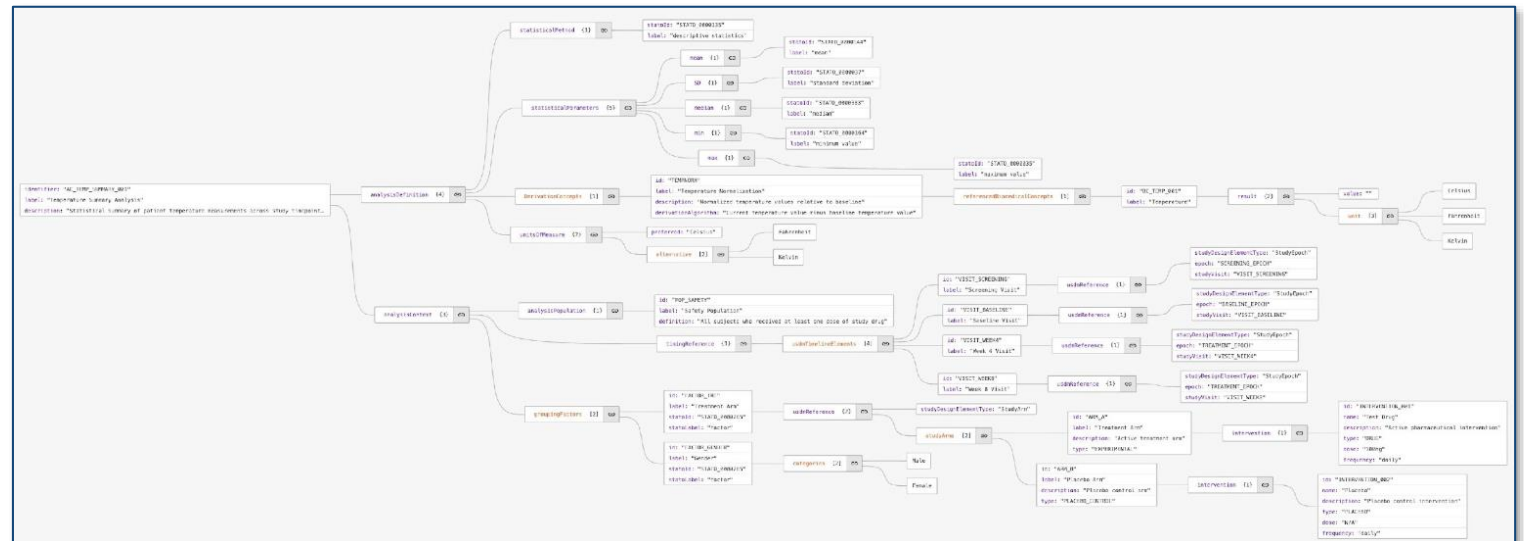
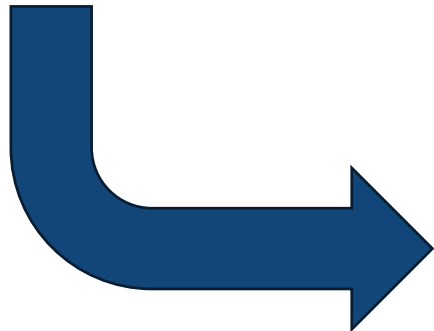
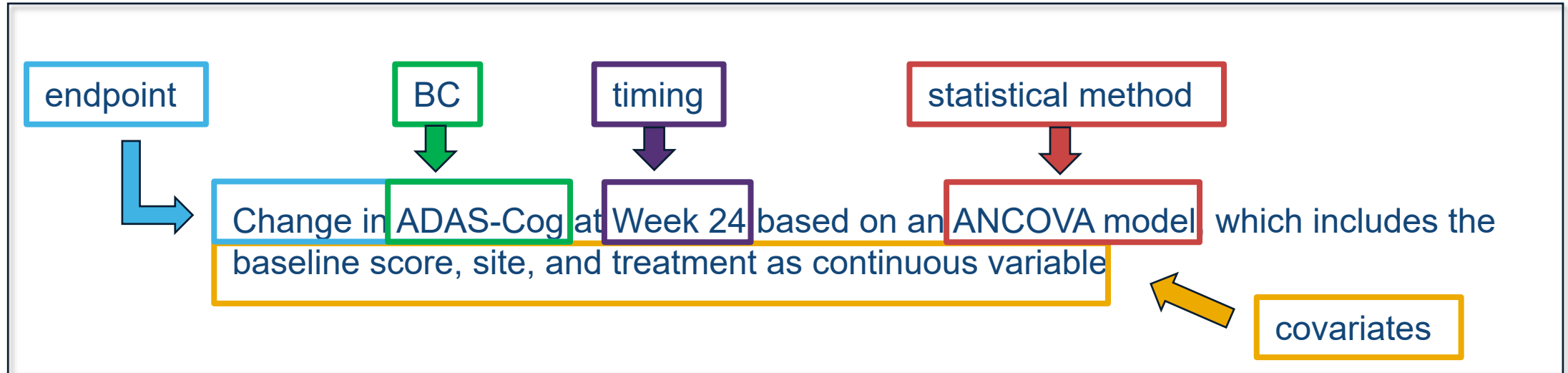
# Analysis Concepts

- What is an Analysis Concept?
  - Collection of standardized configurable elements & methods that are needed to describe a final output or answer a clinical question
  - Standard definitions in a digital statistical analysis plan
- What is the purpose of an Analysis Concept?
  - Supports configuration and automation of analysis
  - Informs what needs to be collected to answer the clinical question





# Working Towards a Logical Model



# 360i Phase 2 draft plan

- Address **gaps** identified in Phase 1 to connect Biomedical concepts to **operational artifacts**
  - Decide how and where to handle operational metadata
  - Identify requirements for the next generation CDISC Library
- Define and **pilot analysis concepts** to generate analysis artifacts (ADaM datasets, TFLs, eSAP, ...)
- Establish **digital data transfer agreements** 'standard' and **pilot** the generation from USDM
- Partner with vendors and open-source community to create a basic open-source **tool to author the digital Schedule of Activities** and linking to **Biomedical Concepts** from the CDISC Library
- Create and publish all content for an **end-to-end digital TAUG** and playbook on how to implement
- Partner with community to define an operational model for **BC collaborative curation**
- **Accelerate development** of concepts (BCs, ACs, end to end TAUGs,...)



# Relentless Collaboration





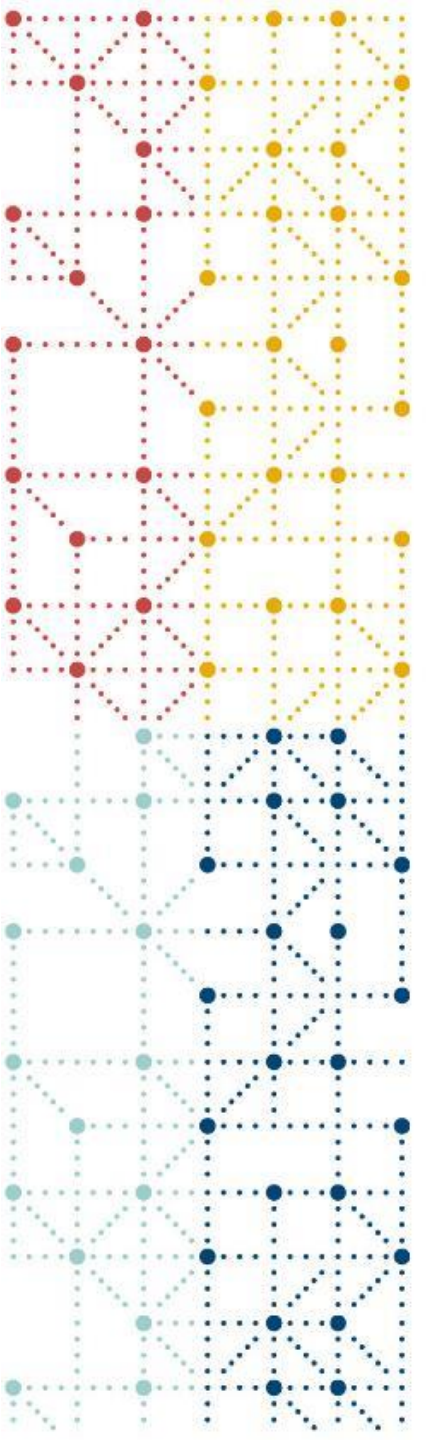


# CDISC Leadership Q&A

# Q & A Session

Scan this QR code  
to submit questions  
real time via your  
phone or laptop.

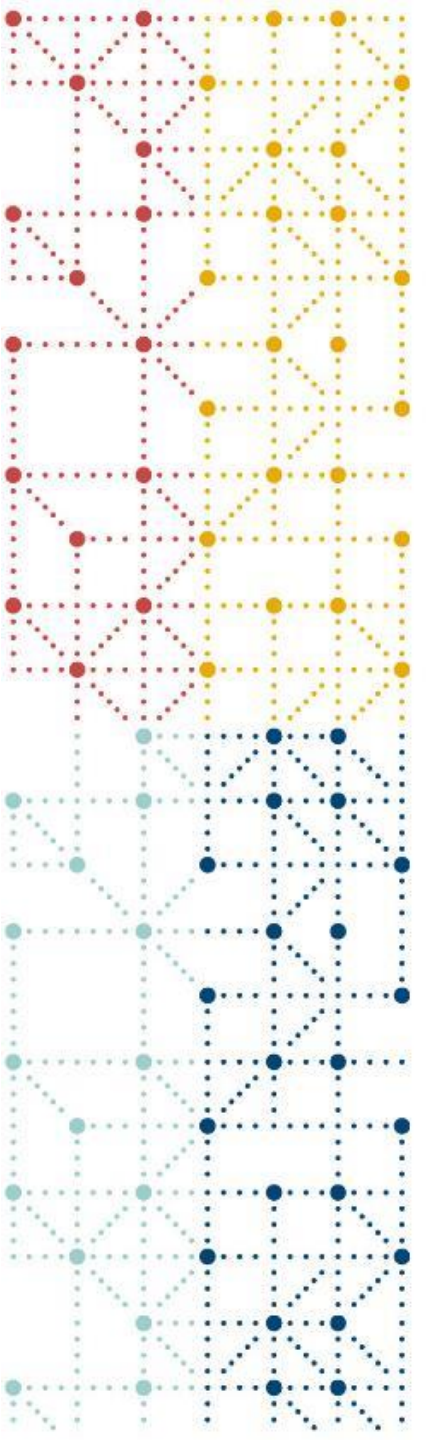




# Reflections from a CDISC Board Member

Brooke Hinkson, 2025 CDISC Board Chair





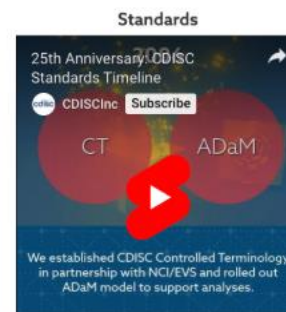
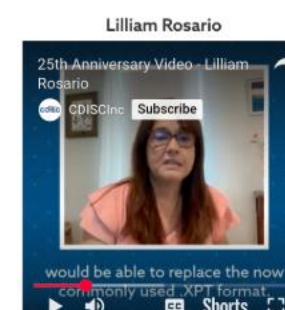
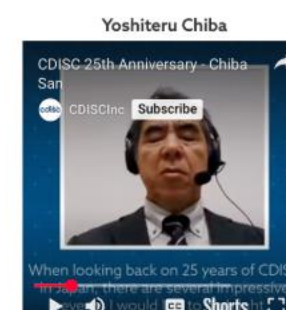
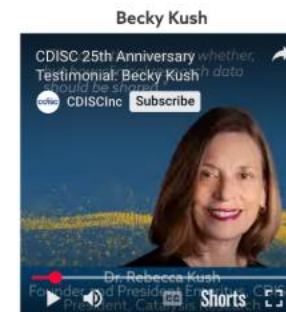
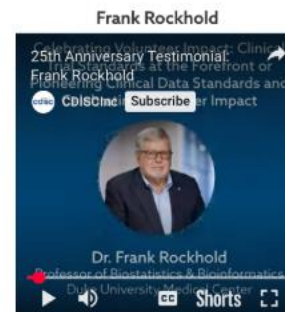
# Thank You and Parting Words

Nicole Harmon, PhD, CDISC COO





Celebrating 25 Years...  
All Year!



# Thank You To Our Sponsors & Exhibitors

#cdisc2025us



## SPONSORS

GLOBAL RUBY SPONSOR



RUBY



RUBY



SAPPHIRE



SAPPHIRE



EMERALD



SESSION SPONSOR



TOTE BAG SPONSOR



## EXHIBITORS







# Thank you to our TMF Program Committee & NA3C

**Dawn Niccum** Inseption  
**Donna Dorozinsky** Just In Time GCP  
**Gillian Gittens** Transperfect  
**Jamie Toth** BeOne Medicines USA Inc.  
**Jim Horstmann** Veeva  
**Joanne Malia** Regeneron  
**Karen Roy** n/a  
**Lisa Mulcahy** Mulcahy Consulting  
**Paul Fenton** Montrium  
**Suzanne Turner** Ice Consulting  
**Wendy Trimboli** Acadia Pharmaceuticals  
**Bryan Souder** Merck  
**Liz Farrell** Agios  
**Richard Shore** Eraneos  
**Rob Jones** Cencorra  
**Nick Hargaden** Merus  
**Kathleen Mellet** Just in Time GCP

**Jennifer Duff** Merative  
**Kent Letourneau** ICON  
**Mary Dolegowski** SAS  
**Srinivasa Rao Mandava** Merck  
**Harivardhan Jampala** Fortrea  
**Asif Karbhari** AstraZeneca  
**Erin Mulhbradt** NCI EVS  
**Donna Sattler**

**Nominations open for NA3C**  
**[Nominations@cdisc.org](mailto:Nominations@cdisc.org)**

ENGAGING OUR GLOBAL COMMUNITY



**Standards** Transform Clinical Research  
**Membership** Join Our Global Community  
**Education** Learn CDISC From CDISC





# Global Reach

## A World Of Opportunity

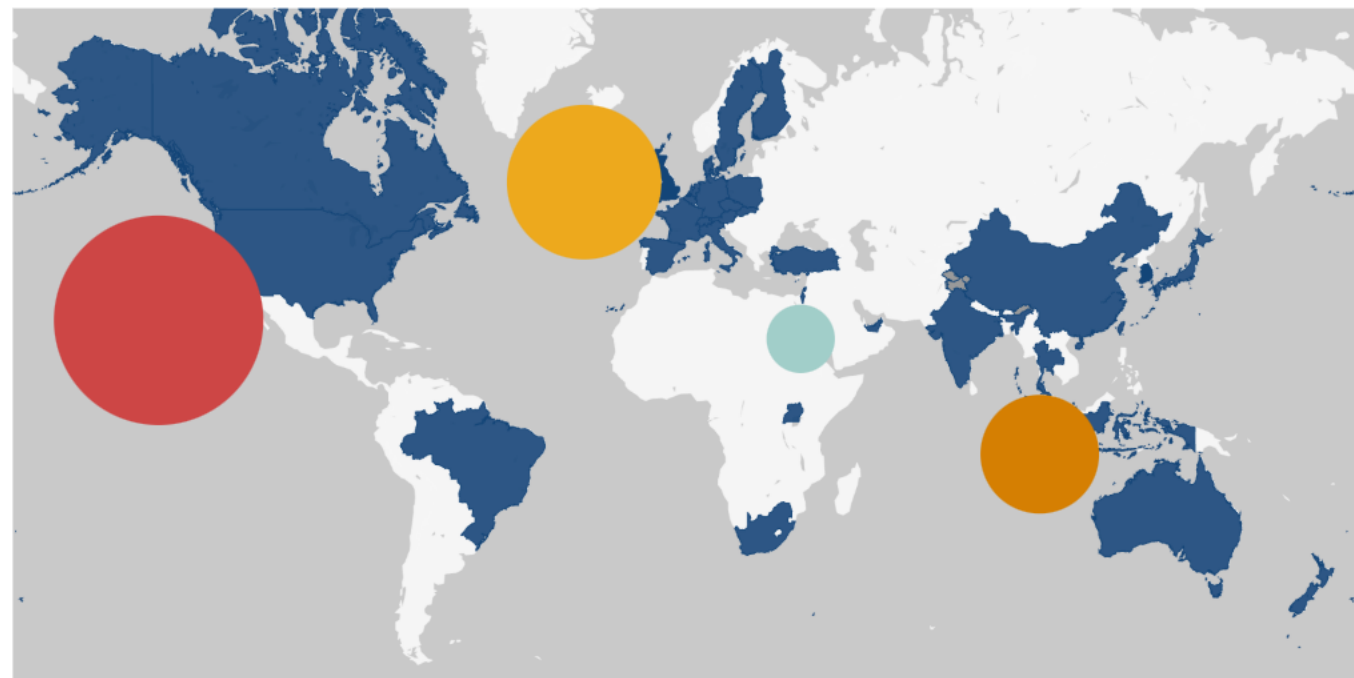
**450+ Members** impacting global health across **30+ Countries**.

**90+ Countries** where standards are downloaded and used.

**6 Regions** providing support through CDISC Coordination Committees (3Cs).

**User Groups** across Asia, Africa, Europe, and North America.

## Member Map



● Americas - 237

● Europe, UK, Ireland - 121

● Asia, Oceania - 90

● Africa, Middle East - 4

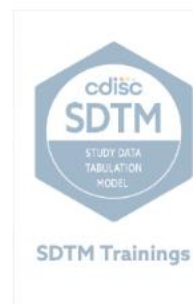
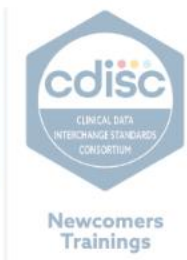
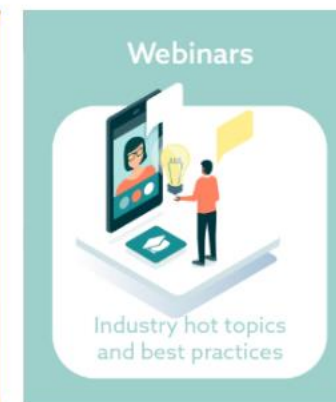
# Education Virtual, On-Demand, In-Person

Learn from Standards  
Experts and Developers.

Enroll in English, Mandarin, or  
Japanese Language Trainings.

Member Credits and Discounts.

**Learn More** [training@cdisc.org](mailto:training@cdisc.org)



# Education Focus Groups October 28 and November 5

*CDISC is focused on listening and engaging with our Global Community in many ways. We invite you to **nominate a participant** from your company to join a **strategic, small-group discussion** focused on shaping the future of CDISC education and training.*



## Discussion:

- Explore supporting evolving industry needs.
- Seek diverse perspectives for future of CDISC Education.
- Gain insight into emerging training needs and engagement strategies.
- Identify barriers to training participation

## Participants:

Heads of Standards, Heads of Statistical programming, Heads of Data Management, Head of Data Science, Head of Digital Technologies, Head of Clinical Operations, Head of Biometrics

## Details:

Two virtual, small-group sessions

Email [membership@cdisc.org](mailto:membership@cdisc.org) to sign up



# Alliances Collective Strength



## Regulatory Relationships





# Feedback Survey

Please complete  
US Interchange  
Feedback Survey  
(to be sent via email  
next week) and we  
will send you the

**Presentation Slides!**





# POSTER WINNERS



# BINGO WINNERS



# Upcoming Global Events

*Announcing  
Dates Soon:  
Asia Pacific  
CDISC  
Events!*



*"CDISC Interchange is a great opportunity  
to learn and grow professionally."*



2026 CDISC + TMF  
Europe Interchange  
Milan, Italy | 20 - 21 May



2026 CDISC + TMF  
US Interchange  
Salt Lake City, Utah  
19 - 20 October

*"CDISC Interchange is not to be missed  
and is my pinnacle conference of the year."*



# Thank You So Much for Joining Us This Year!

