



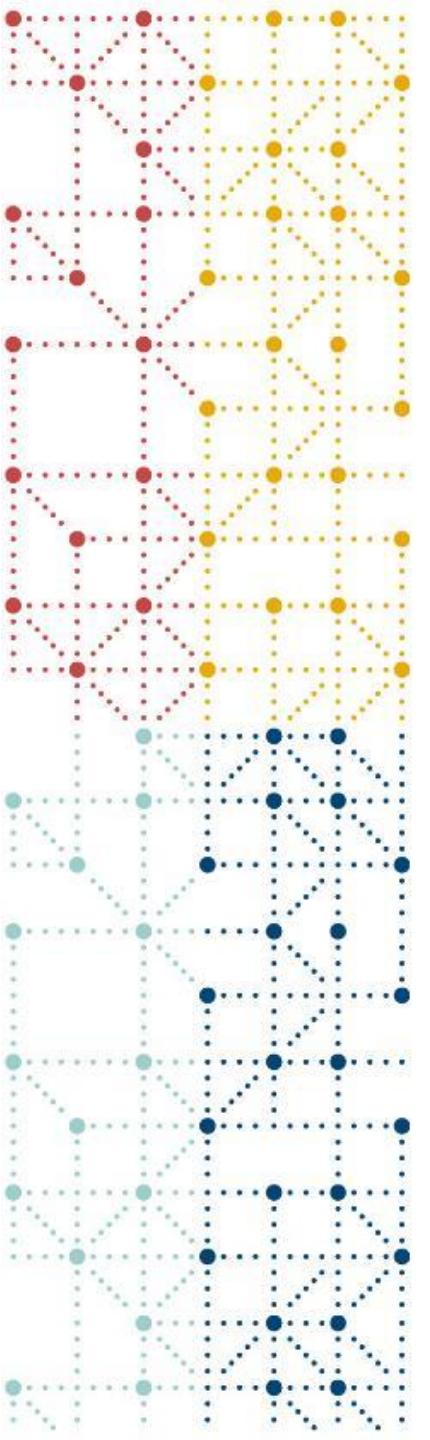
2025

CDISC + TMF
US INTERCHANGE

NASHVILLE

CONFERENCE & EXPO: 13-14 OCTOBER | TRAININGS: 15-17 OCTOBER

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



2001



2006

facebook

2004



2007

YouTube

2005



Dropbox 2008



2009

cdisc

Mobile & Cloud Boom



2006



2007

AI, Apps, & On-AI Expansion & Demand



2010



2016



2011



amazon alexa 2014



zoom

2019



2015



Generative AI & the Metaverse



2020



2021



2022



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

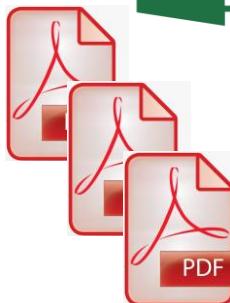
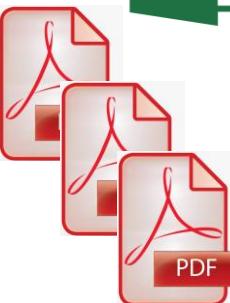
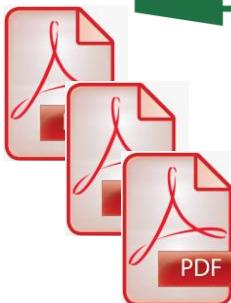
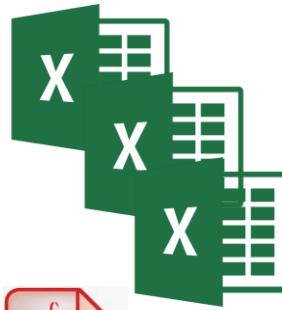
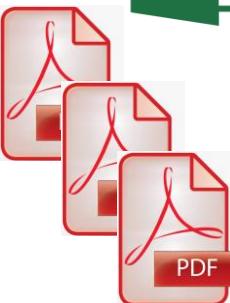
2005

2010

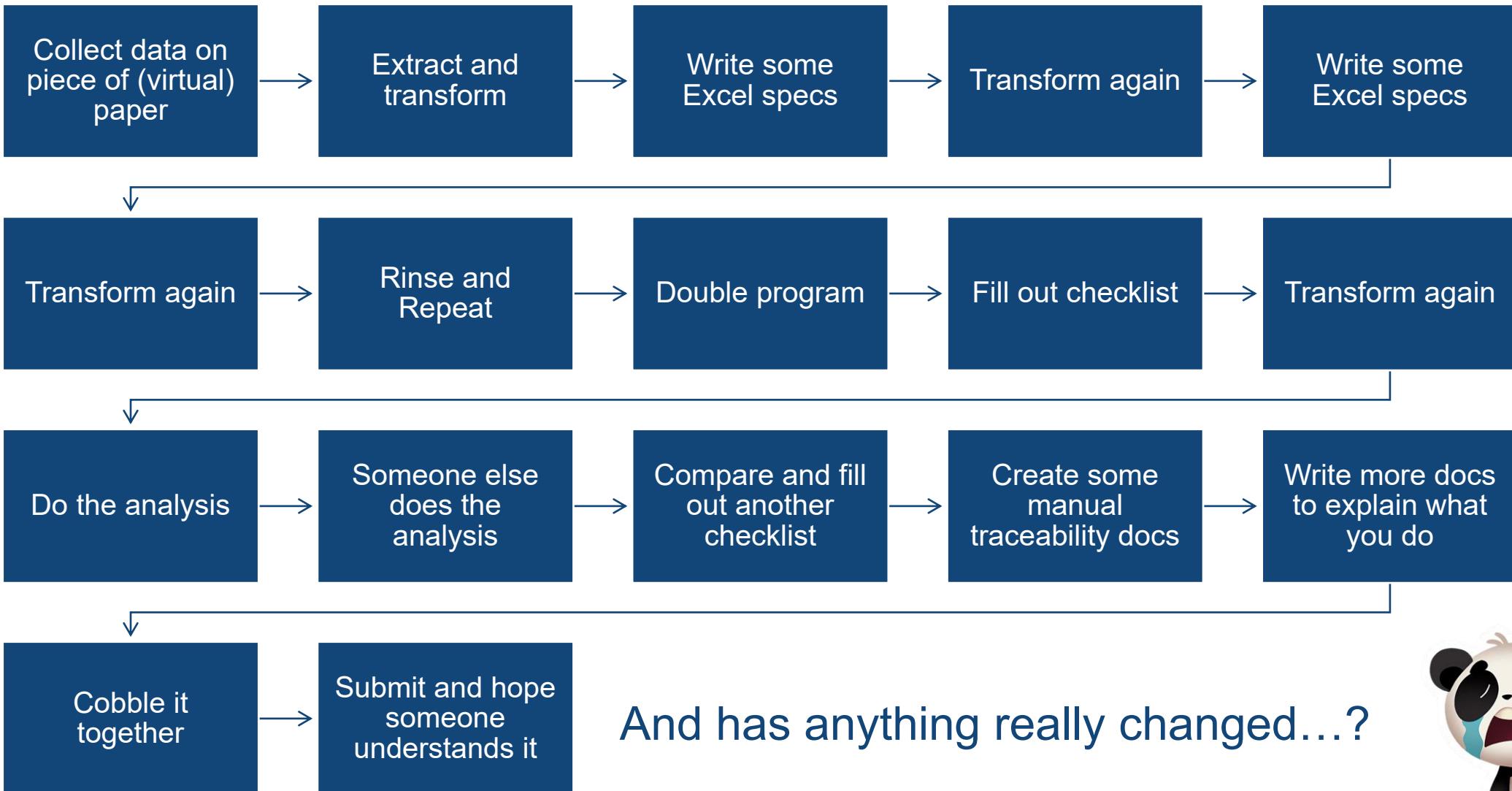
2015

2020

2025

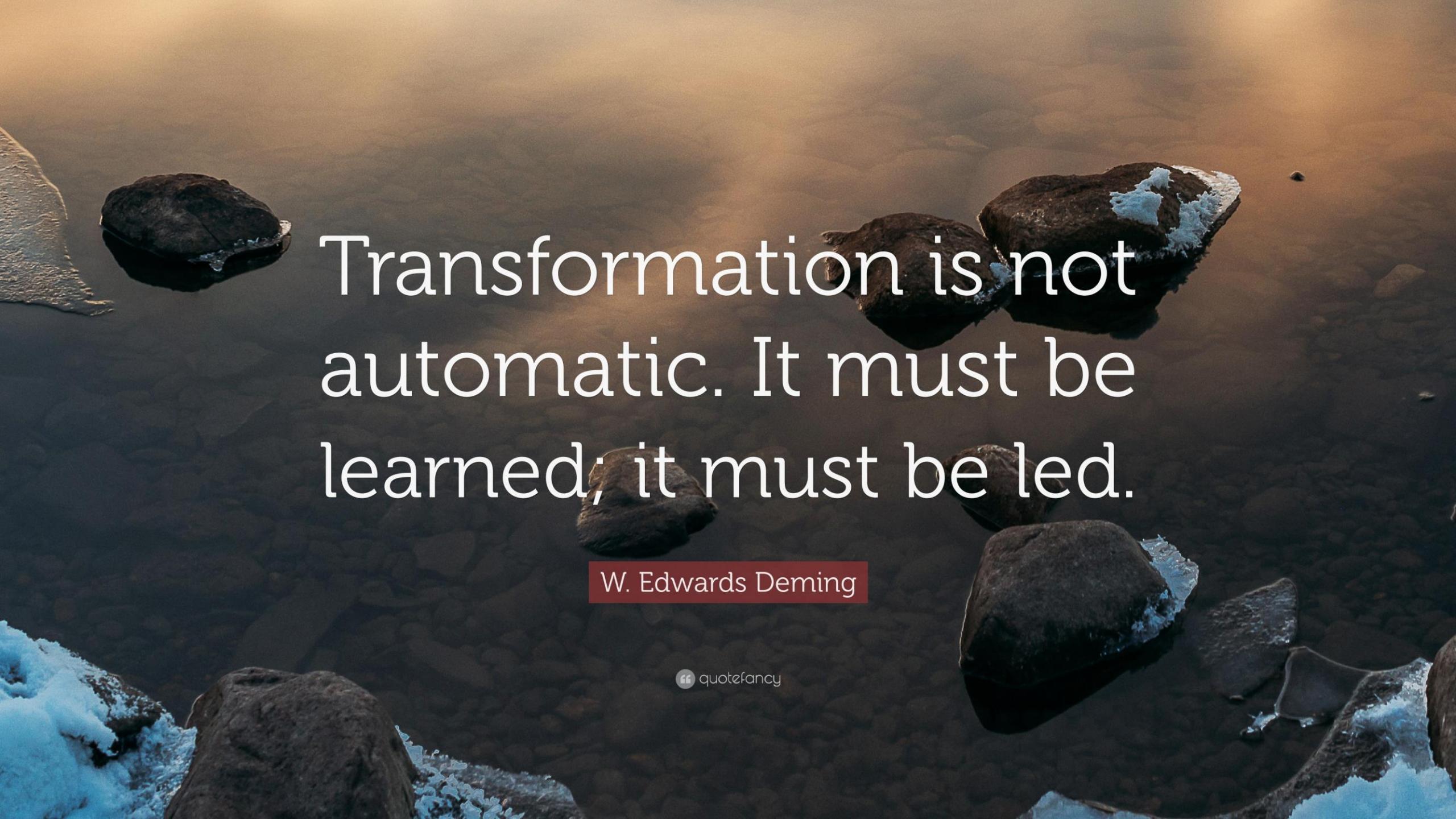


30 years ago...



And has anything really changed...?





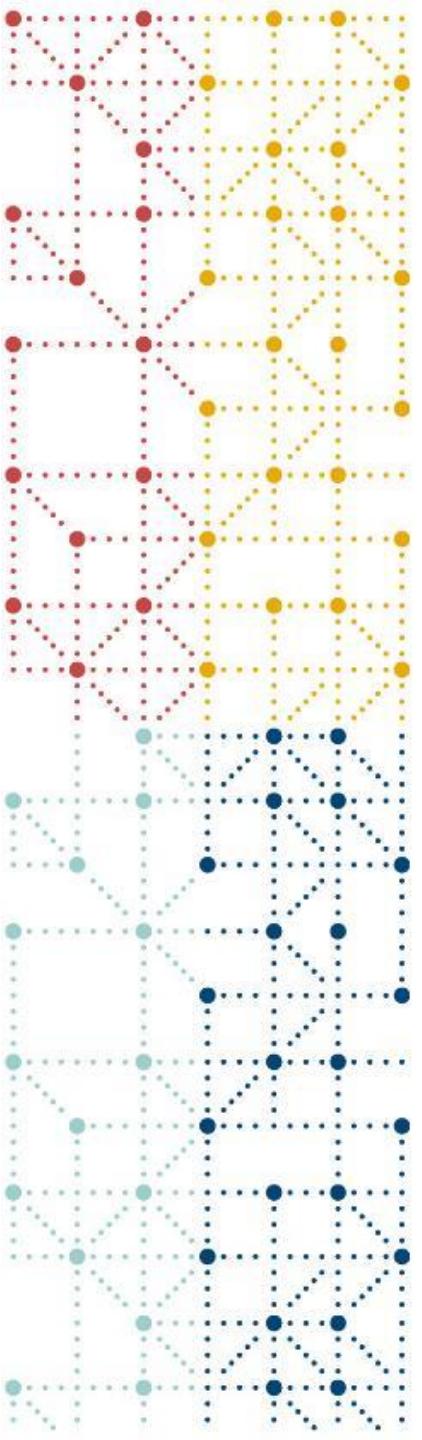
Transformation is not
automatic. It must be
learned; it must be led.

W. Edwards Deming



Building the Future: CDISC 360i Phase 2

Peter Van Reusel
Chief Standards Officer
CDISC



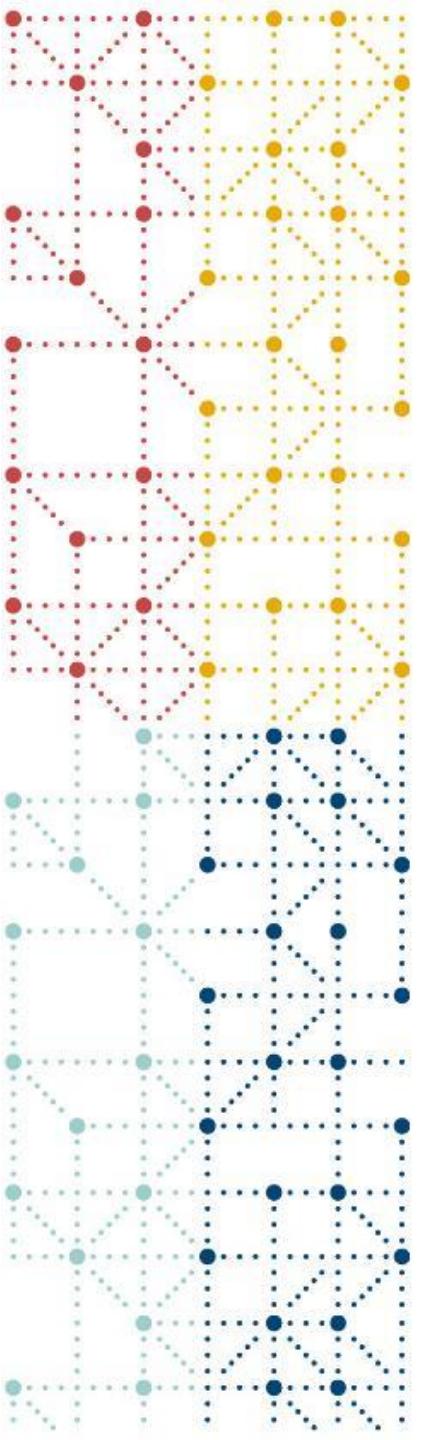
360i Goals

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



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JSmith@company.com

Password

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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	Cycle 1 Day 28
		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Back

Save & Continue

Configure Analysis

Review the recommended analyses for the **Breast Cancer Randomized Control Trial**. Make necessary adjustments or add additional analyses as needed. The 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 was selected. The analysis parameters are currently auto-configured using historical patterns.

✓ Endpoints ✓ Estimands

#2 - Overall Survival Recommended

This analysis was recommended because the Overall Survival endpoint was selected. The analysis parameters are currently auto-configured using historical patterns from similar analyses.

✓ Endpoints ✓ Estimands

#3 - Evaluation for Drug-induced Severe Hepatotoxicity (eDIS)

✓ Endpoints ⚠ Estimands

[Add Analysis](#)

[Back](#)

Edit Analysis

X

Analysis Info

Analysis Type *

Progression Free Survival

Analysis Method *

Kaplan-Meier

Analysis Set * ?

Intention-to-treat

Intervention *

Investigational drug

Comparator *

Standard chemotherapy

Associated Endpoint(s) *

Progression Free Survival

Intercurrent Events (ICEs) + Add Event

Event	Handling	Action
Death	Composite	 
New Anti-cancer therapy	Composite	 

[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

-

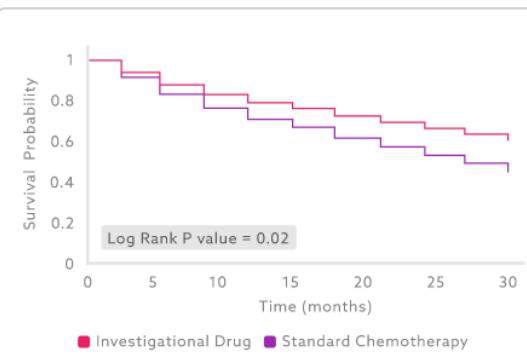
Cox Regression Adjusted for Age

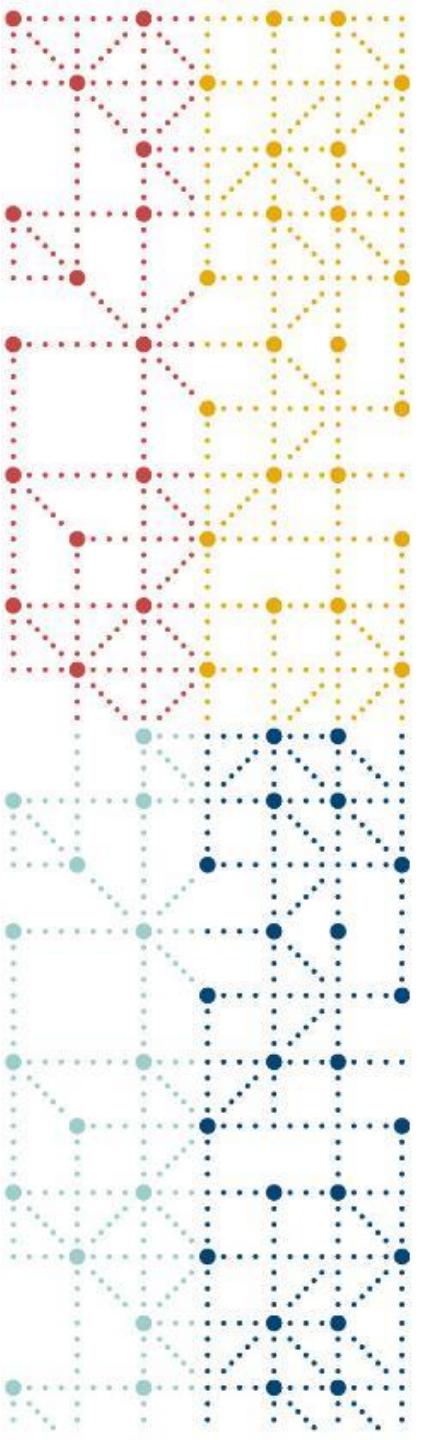
[View Code](#)

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](#)

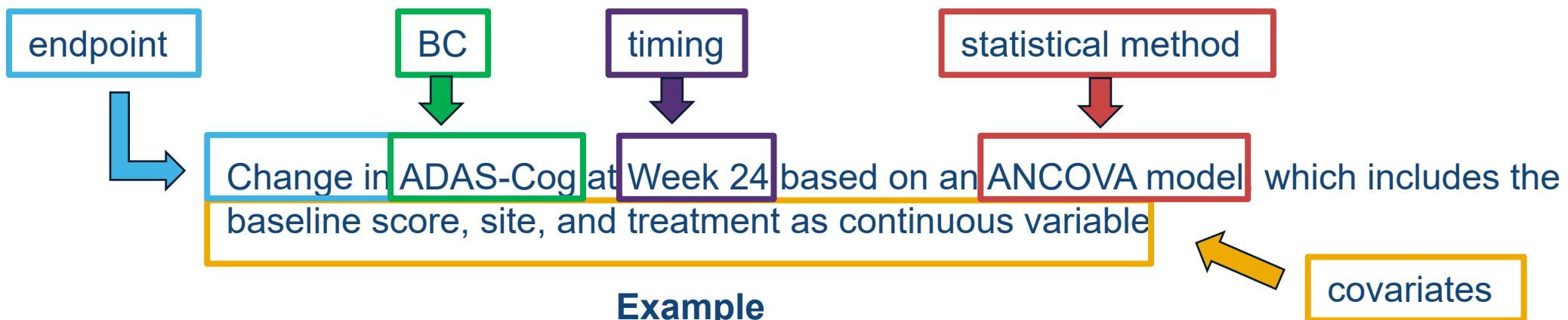




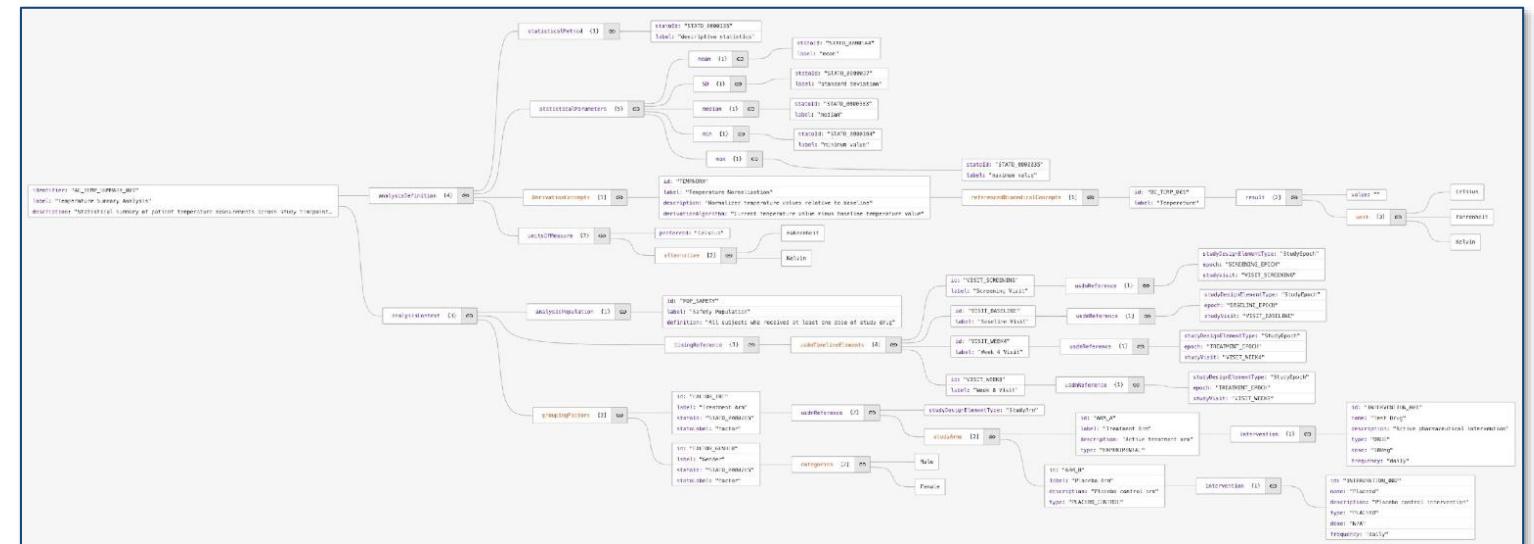
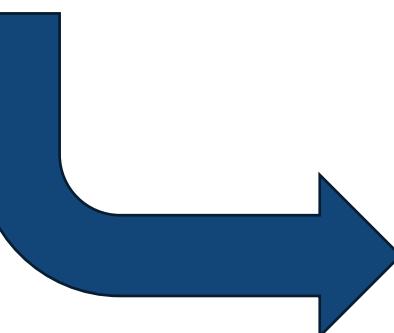
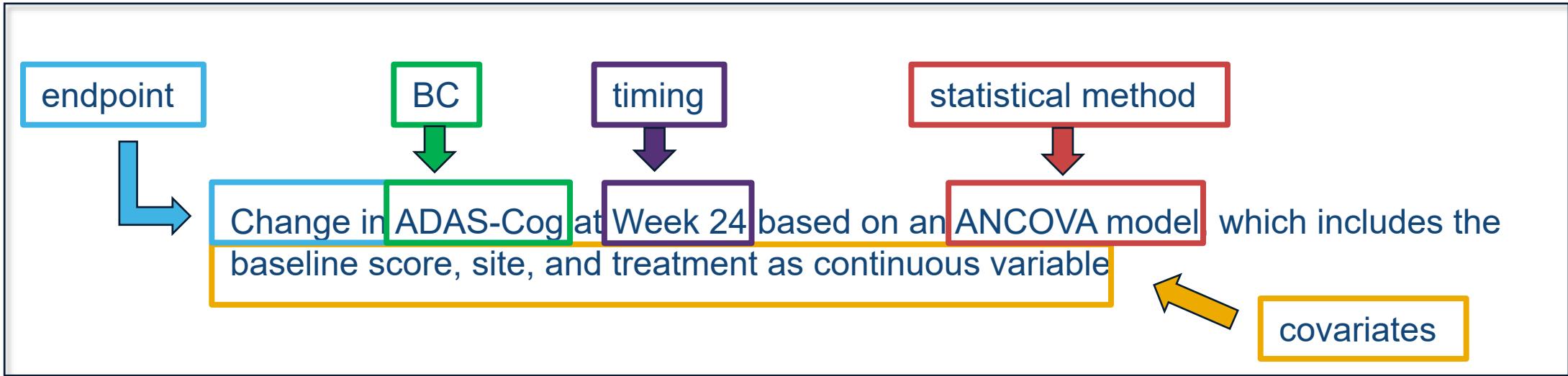
360i Phase 2: draft plan

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

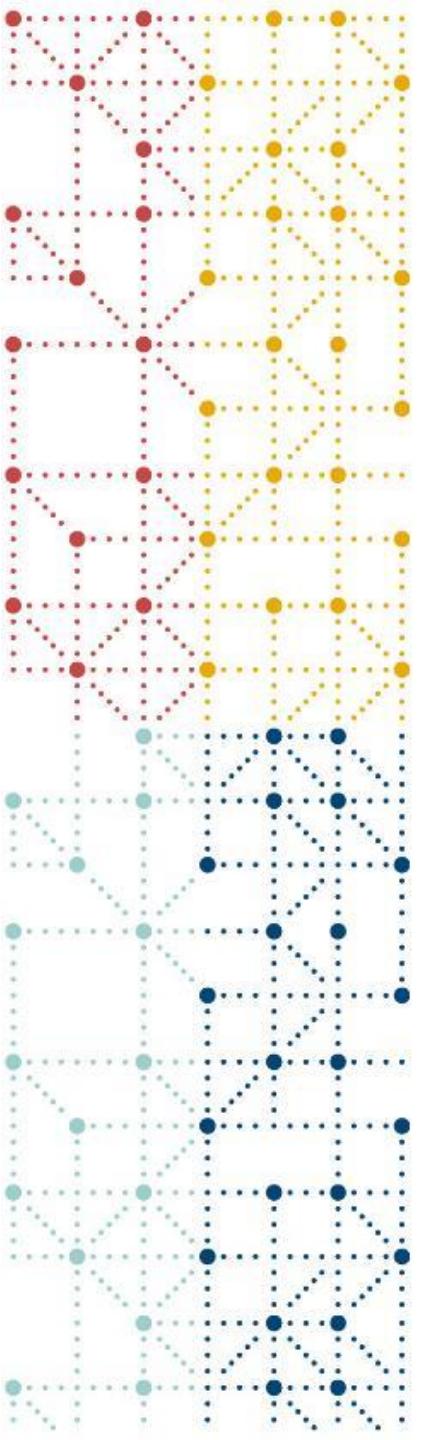


360i Phase 2 draft plan

- 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



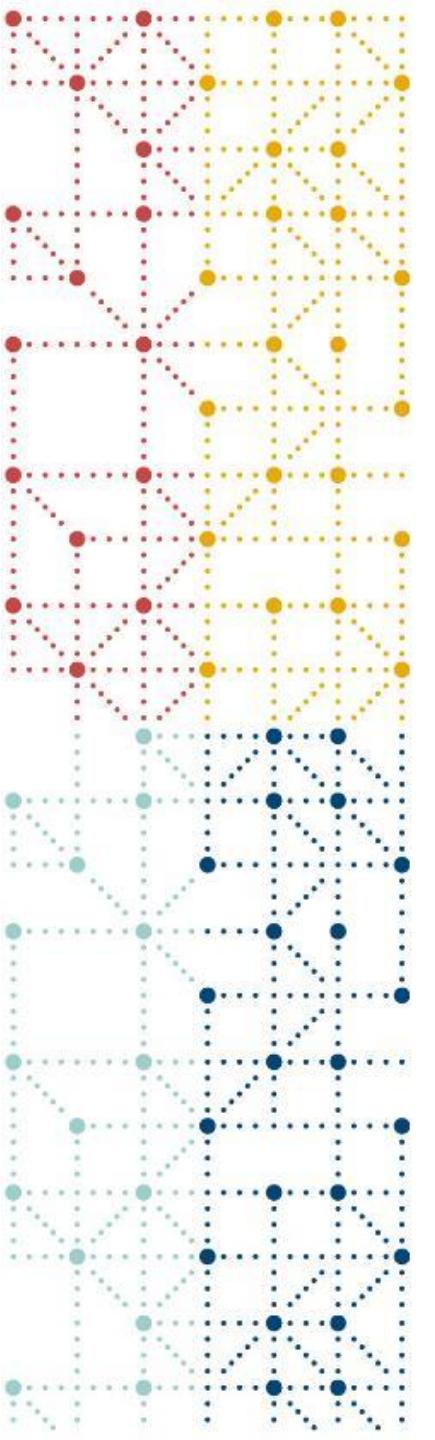


CDISC Leadership Q&A

Q & A Session

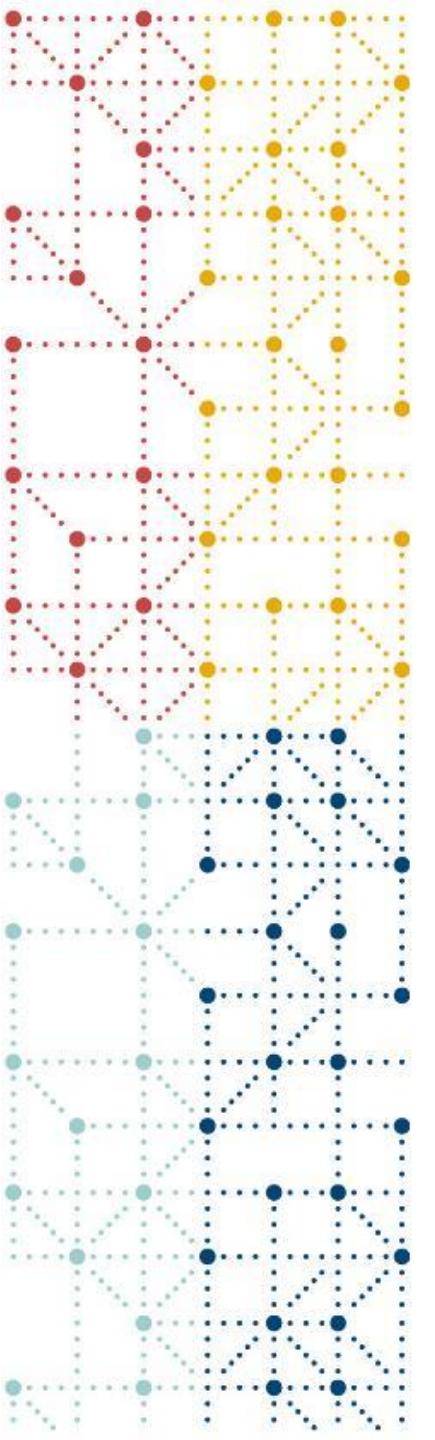
Scan this QR code
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Reflections from a CDISC Board Member

Brooke Hinkson, 2025 CDISC Board Chair

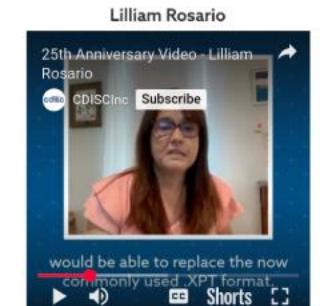
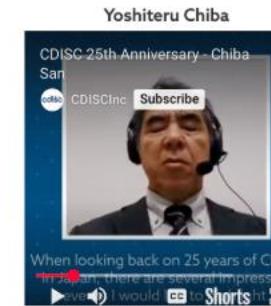
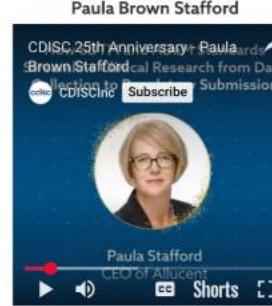
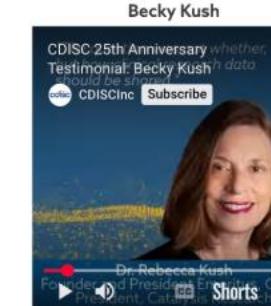


Thank You and Parting Words

Nicole Harmon, PhD, CDISC COO



Celebrating 25 Years...
All Year!



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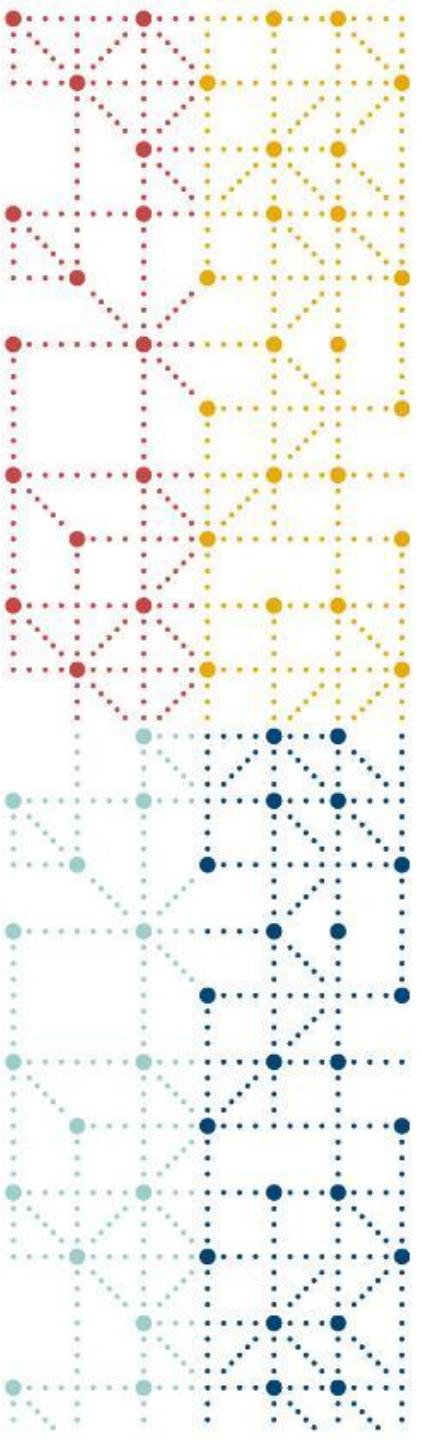
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EXHIBITORS





Thank you to our TMF Program Committee & NA3C

Dawn Niccum Inception
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
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Rob Jones Cencorra
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Harivardhan Jampala Fortrea
Asif Karbhari AstraZeneca
Erin Mulhbradt NCI EVS
Donna Sattler

Nominations open for NA3C
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

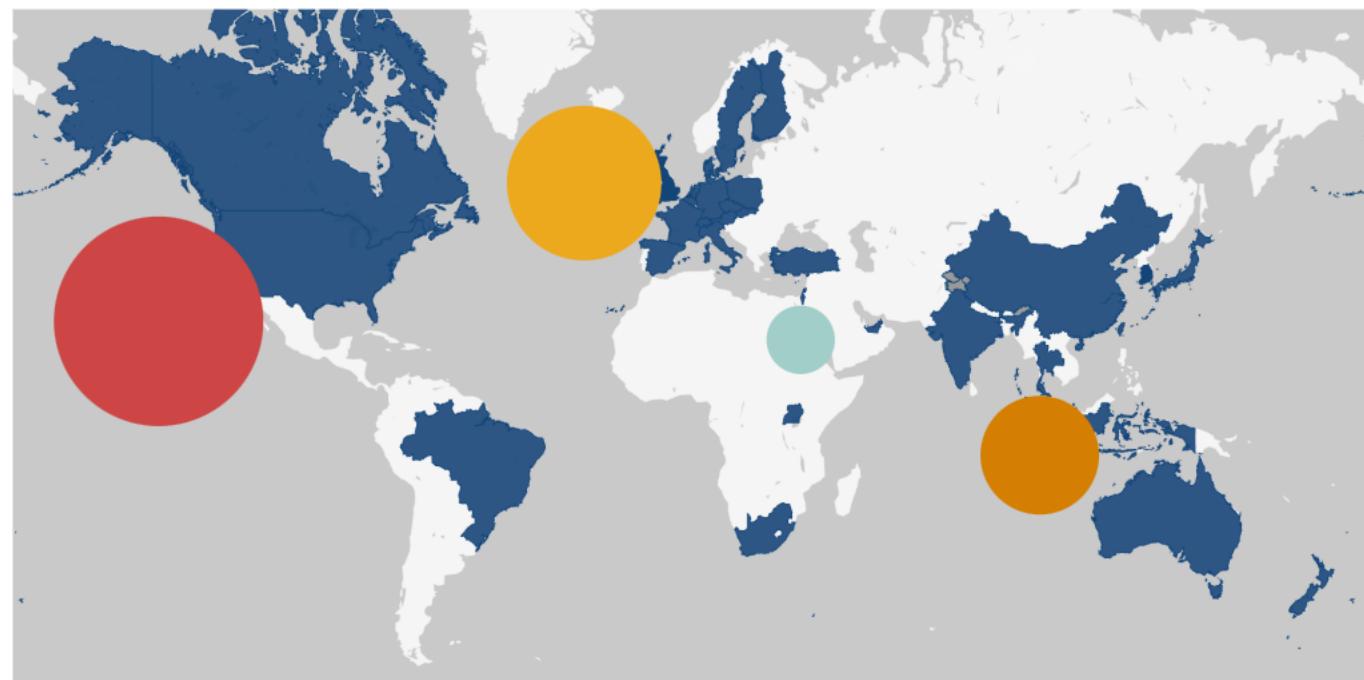
450+ Members impacting global health across **30+ Countries**.

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

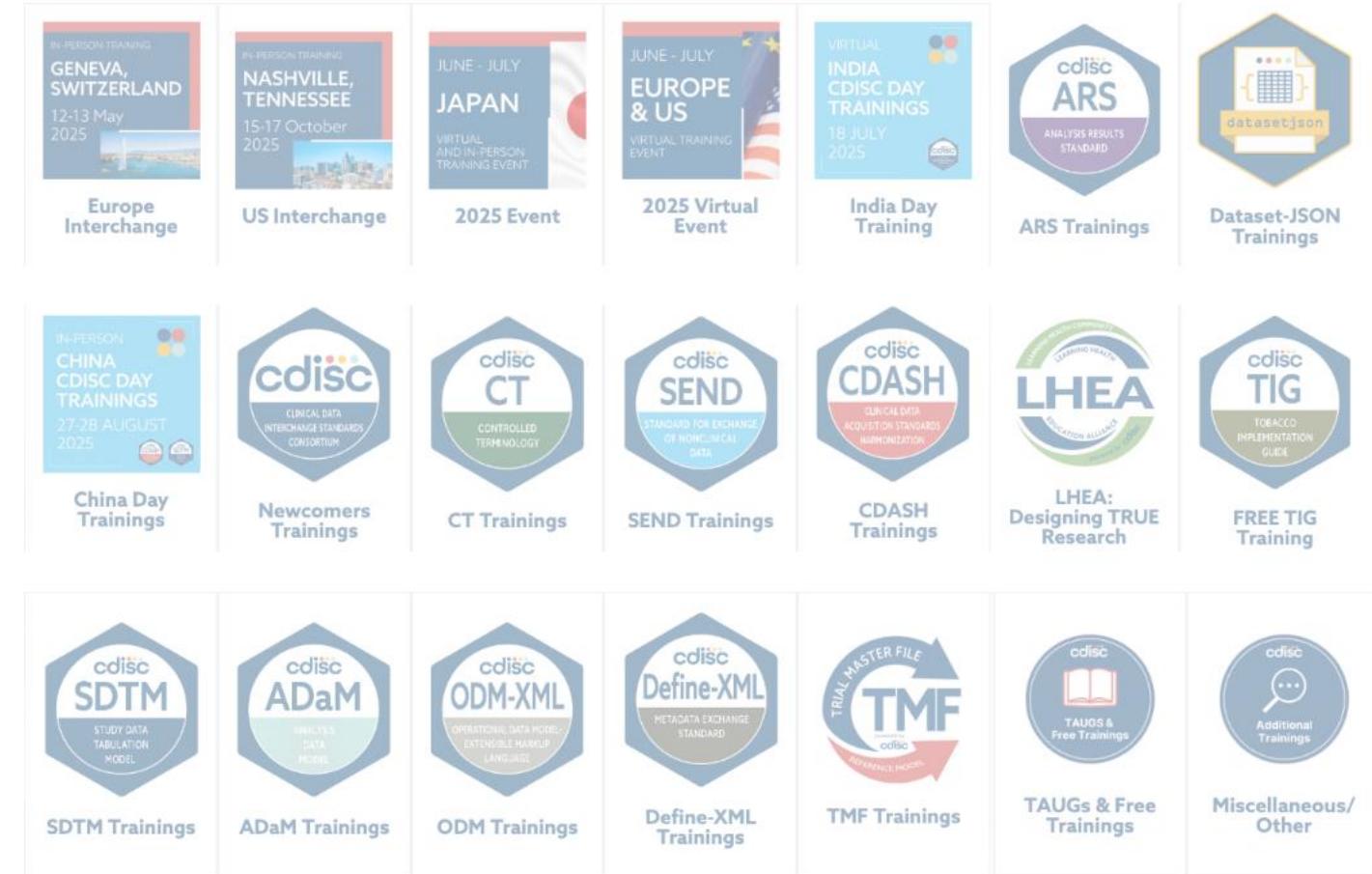
Education Virtual, On-Demand, In-Person

Learn from Standards
Experts and Developers.

Enroll in English, Mandarin, or
Japanese Language Trainings.

Member Credits and Discounts.

Learn More training@cdisc.org



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.*



#ClearDataClearImpact

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 to sign up

Alliances

Collective Strength

Regulatory
Relationships

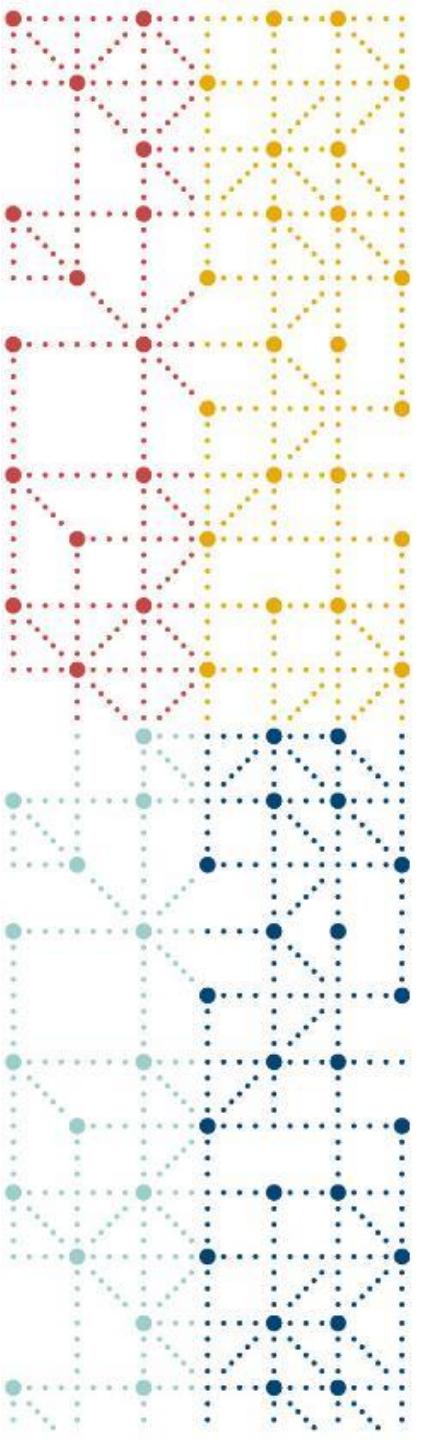


Feedback Survey

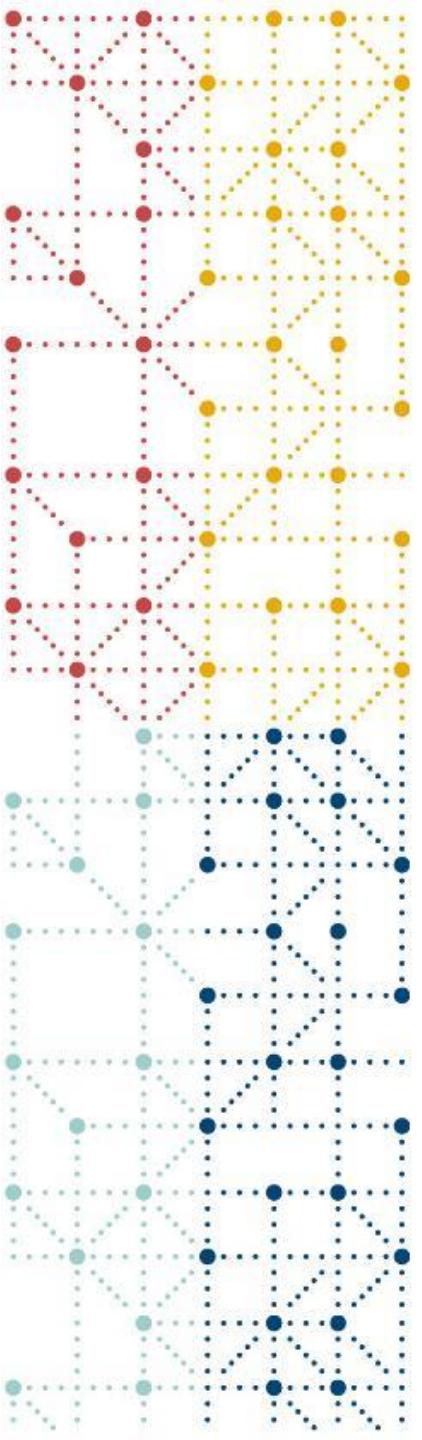
Please complete
US Interchange
Feedback Survey
(to be sent via email
next week) and we
will send you the

Presentation Slides!





POSTER WINNERS



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*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!

