



## Evolving Data Standards Role in the Digital Age

Jonathan Chainey, Global Head, Data Standards & Governance, Roche  
Miho Hashio, Global Head, Data Standards, GSK

# Meet the Speakers

Jonathan Chainey

Global Head, Data Standards & Governance  
Roche



Miho Hashio

Global Head, Data Standards  
GSK





# Panelists from Pharma Data Standards Heads Community

## On-site:

- Jonathan Chainey (Global Head, Data Standards & Governance, Roche)
- Rhona O'Donnell (VP, Data Standards & Integration, Novo Nordisk)
- Brooke Hinkson (Executive Director, Global Clinical Data Standards, Merck)

## Remote:

- Aatiya Zaidi (Head of Global Clinical Data Standards, Gilead)
- Miho Hashio (Global Head, Data Standards, GSK)
- Nicole Thorne (Head, Standards & Innovation, BMS)
- Tushar Sakpal (Head, Clinical Data Standards & Automation, Novartis)

# Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *{Please disclose any financial relationship or conflict of interest relevant to this presentation here OR}*
- *The author(s) have no real or apparent conflicts of interest to report.*

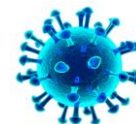
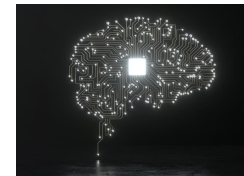


## Agenda

1. Our Journey for Last 25 years
2. CDISC360i – what does it mean for us ?
3. Data Standards Role in Era of AI ? (Panel discussion with Pharma Heads of Data Standards Community )

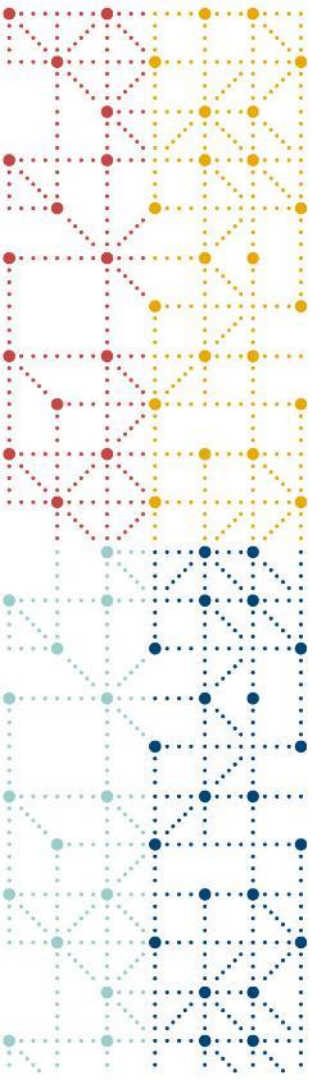
# Our Journey for Last 25 Years

2000	2005	2010	2015	2020	2025
------	------	------	------	------	------



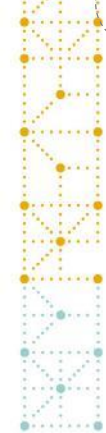
## Data Standards





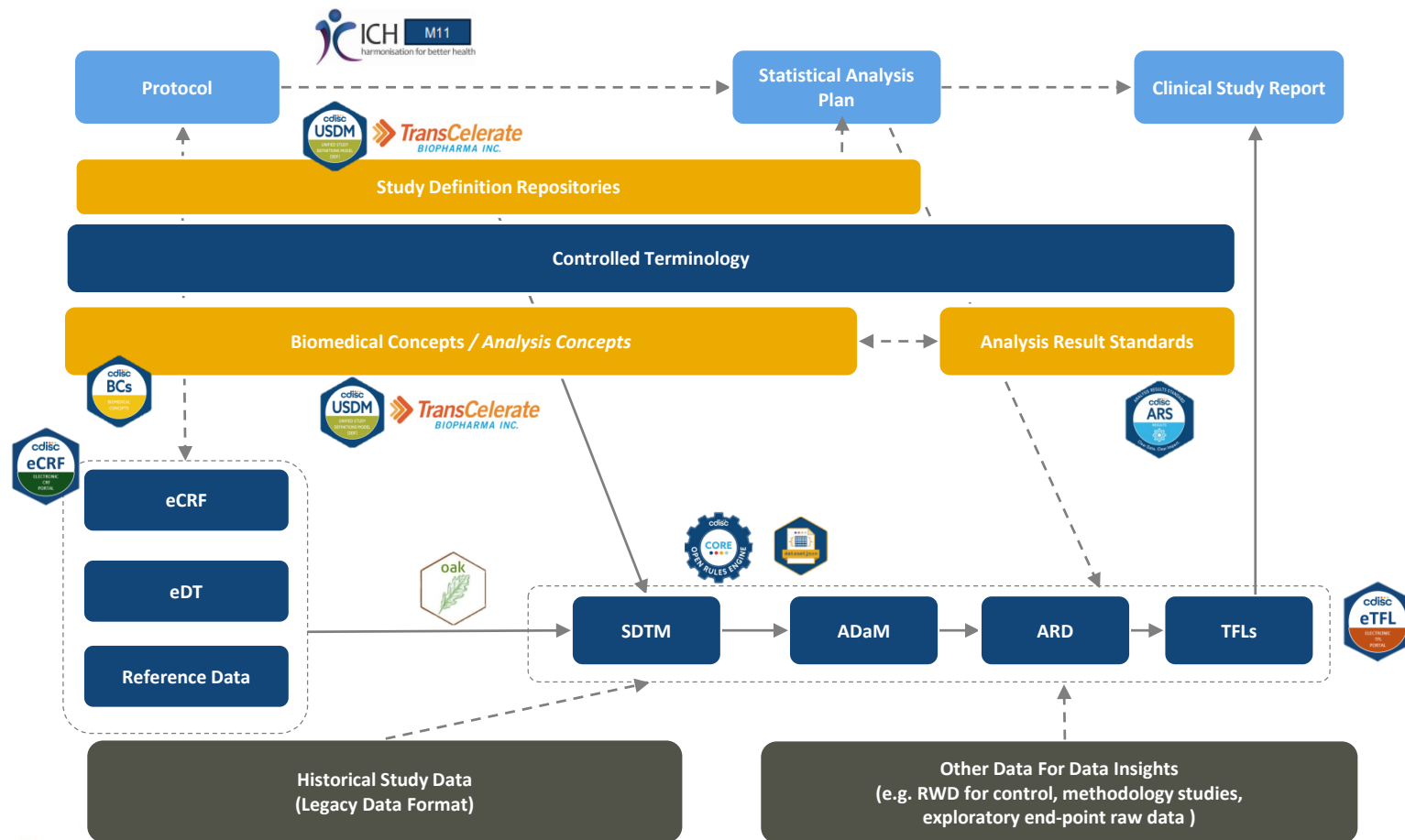
## CDISC360i – What Does It Mean for Us ?



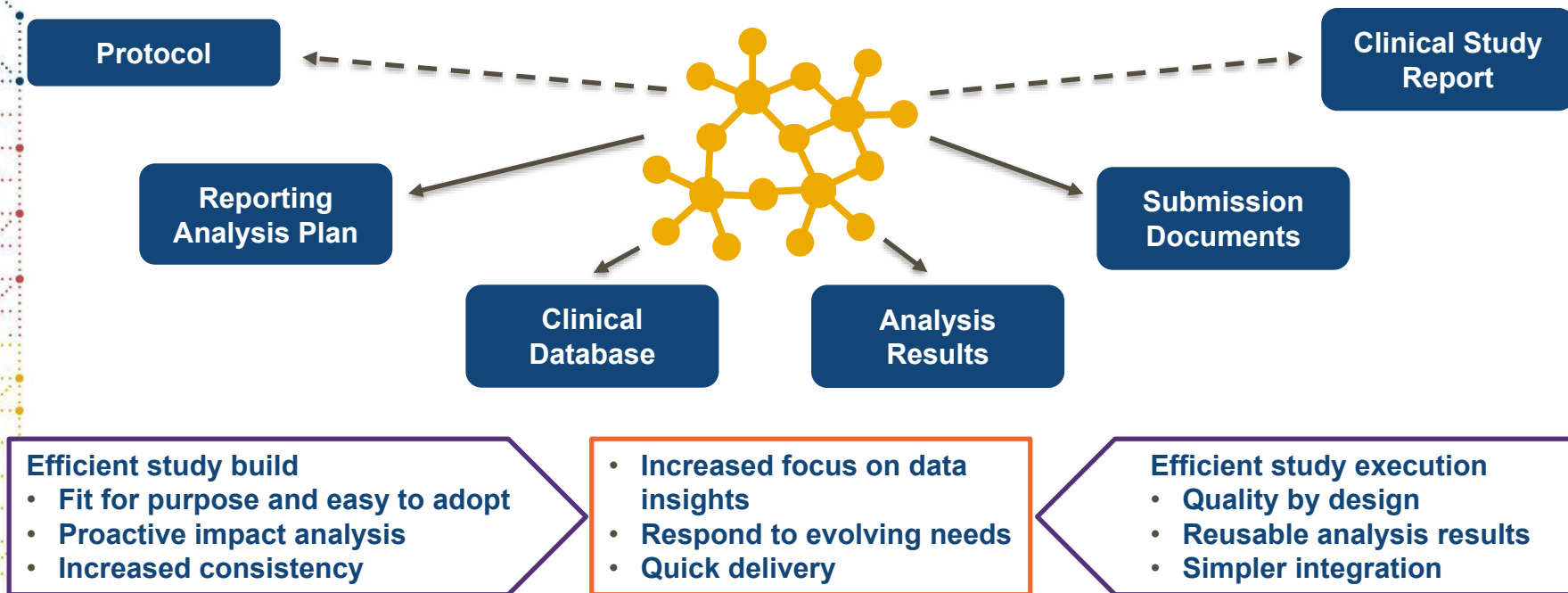


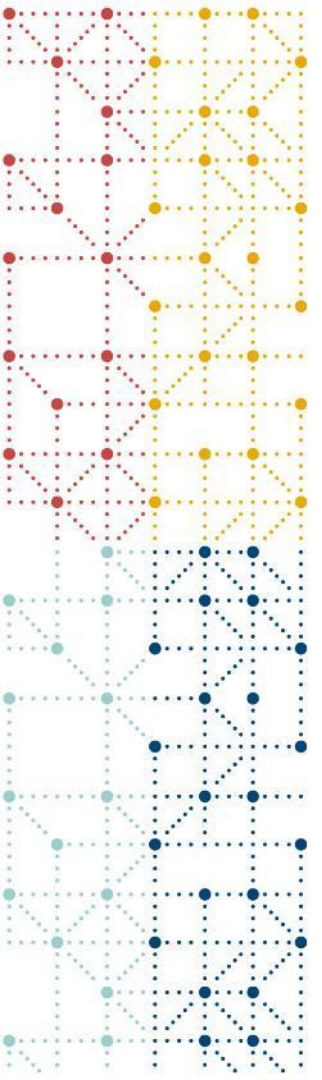


# The "Golden Thread" - Connected Granular Standards



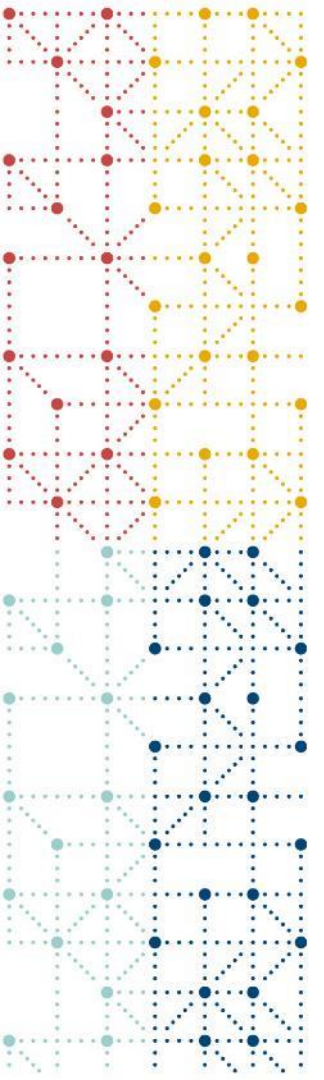
# Upstream Shift: Powered by Semantic Connected Standards





# Data Standards Role in the Era of AI

Panel Discussion



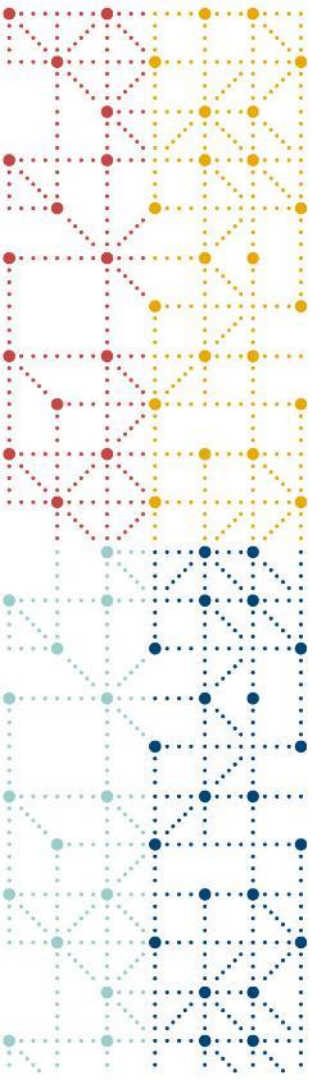
# Foundation and Current State

# Q1 The "Why" of Standardization

Beyond regulatory compliance, what are the most compelling benefits and real-world impacts of robust clinical data standards in the current digital landscape?

## Q2. What are the Drivers of Change ?





# The Impact of AI on Data Standards



## Q3. The Challenge

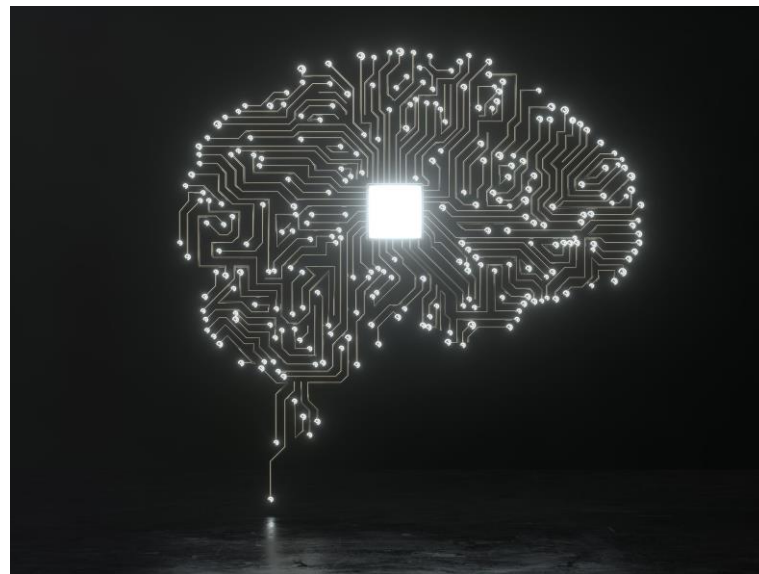
Are Data Standards required in the era of AI?

What are the most significant challenges for colleagues working in Data Standards?

- Upskilling/Capability development e.g. New technology, evolving scientific knowledge to define standards, data modeling
- Interoperability
- Various "Standards" for different domain/data sources

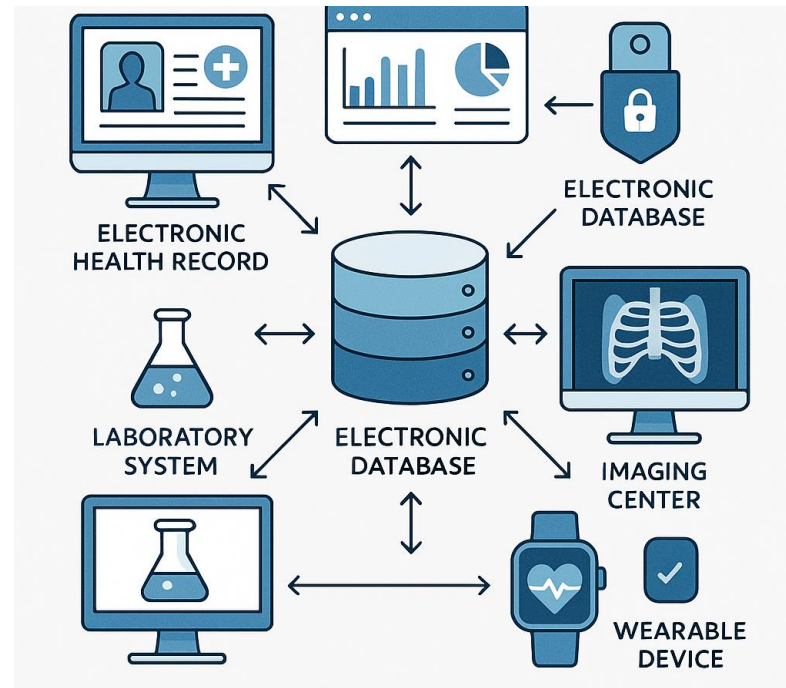
## Q4. AI Demands

- Are current standards sufficient for training and deploying reliable AI models?
  - Unstructured Data and Natural Language Processing
  - Bias and Fairness
  - Explainability and Interpretability
  - Synthetic Data and Data Augmentation



## Q5. Digitalization and Data Generation

- How can clinical data standards truly enable seamless, secure, and bidirectional data flow between different systems (e.g., EHRs, EDC systems, AI platforms, wearables) throughout the entire patient journey?



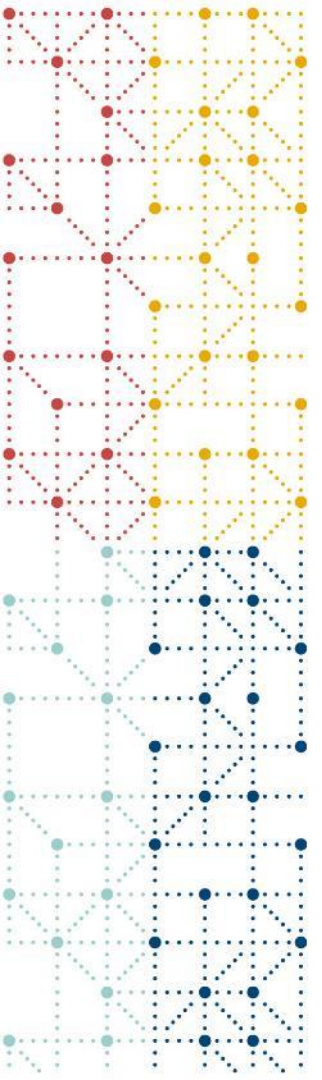


# Regulatory, Ethical and Implementation Considerations

## Q6. Global Harmonization

Given the global nature of clinical research, what are the biggest hurdles to achieving international harmonization of clinical data standards in the age of digitalization and AI?

- Regulatory adoption
- Economic Impact
- Data Governance and Stewardship



# Looking Ahead

## Q7. The North Star

- What is the ultimate vision for clinical data standards in a fully digital and AI-integrated healthcare and research ecosystem?
- What will our success look like?







**Thank You!**

