



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

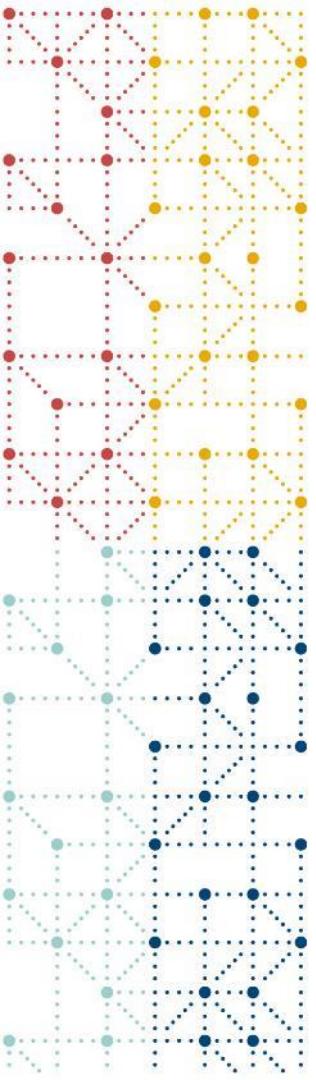
Jonathan Chainey

Global Head, Data Standards & Governance
Roche



Miho Hashio

Global Head, Data Standards
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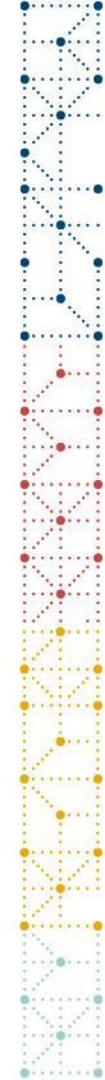
Panelists from Pharma Data Standards Heads Community

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)

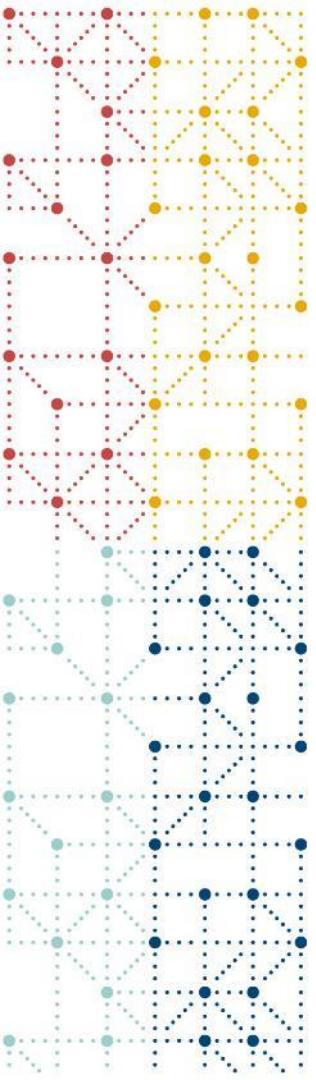
Remote:

- 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)



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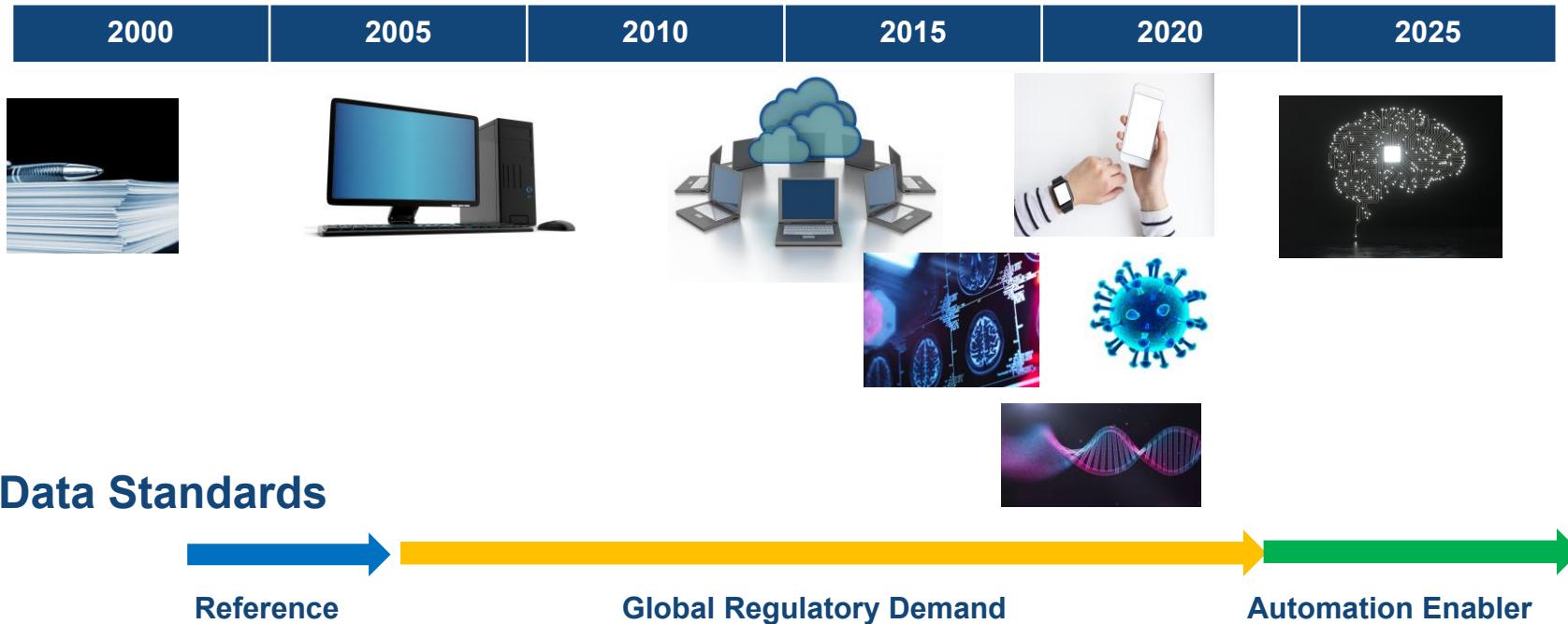
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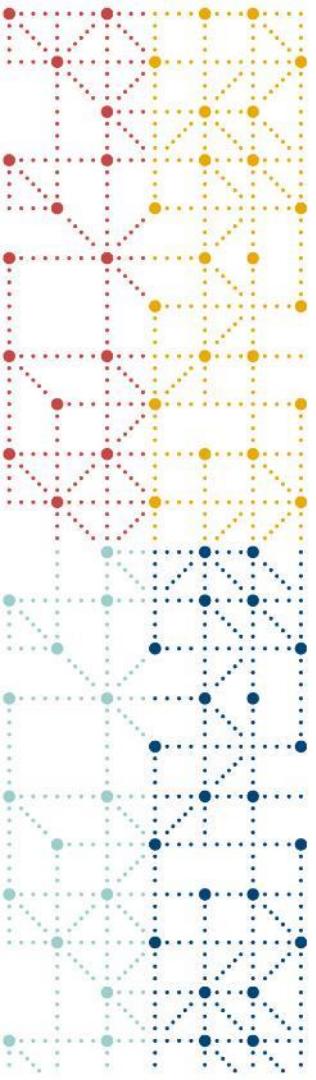


Agenda

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)

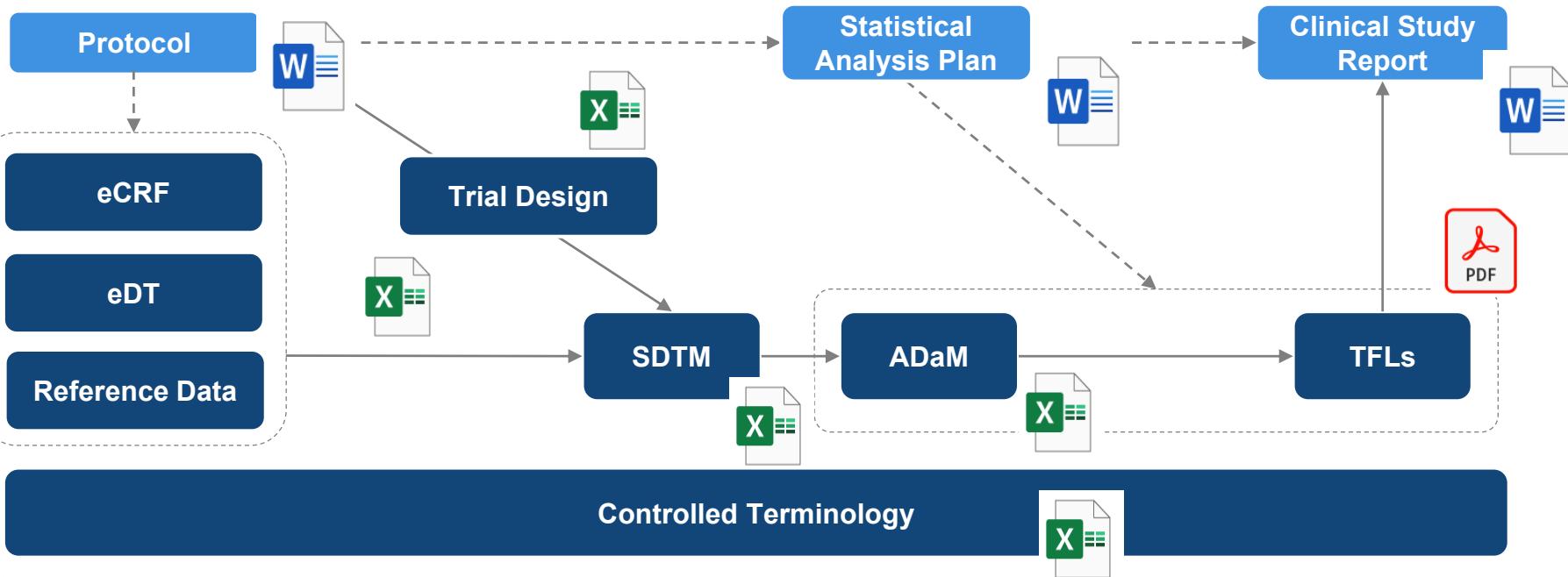
Our Journey for Last 25 Years



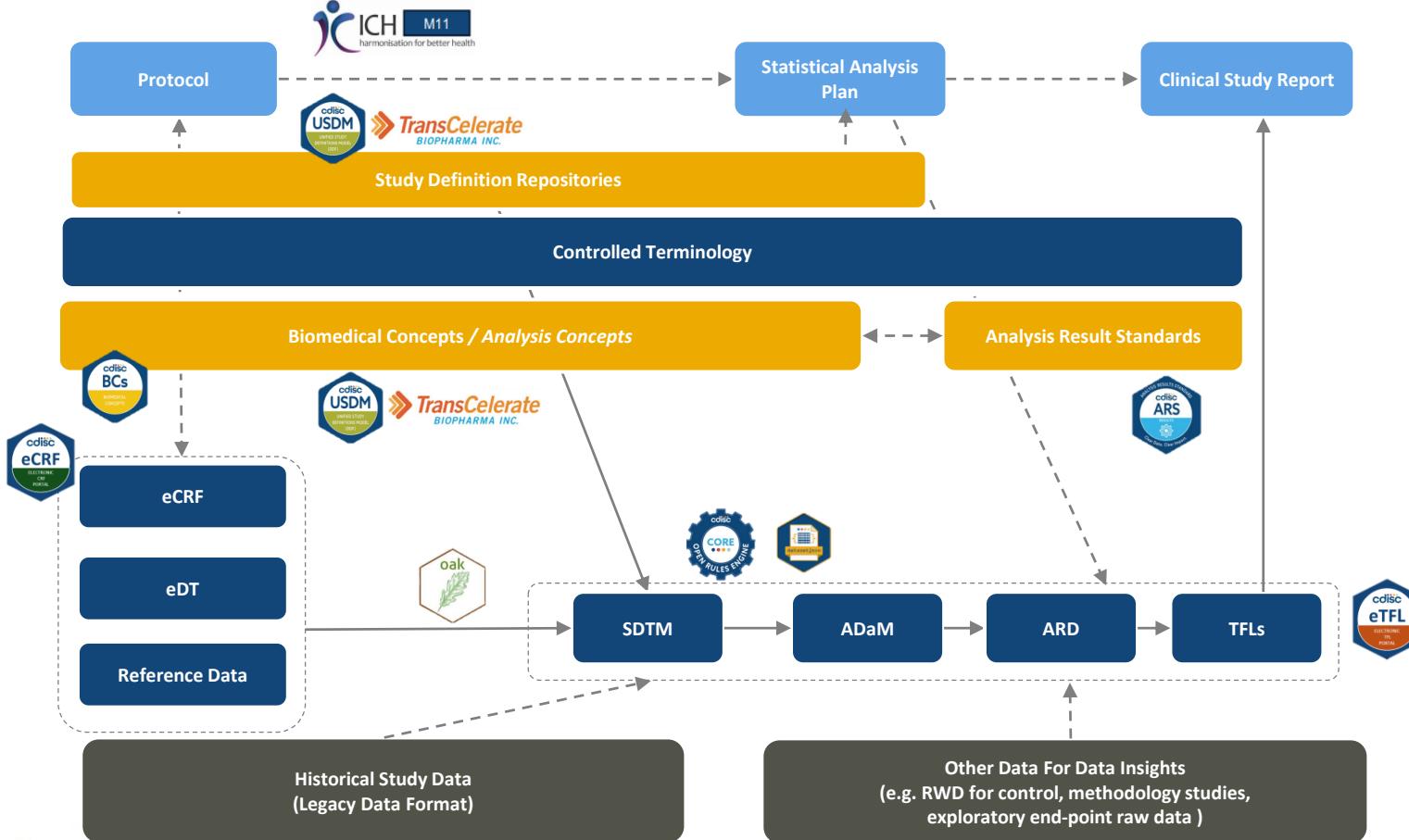


CDISC360i – What Does It Mean for Us ?

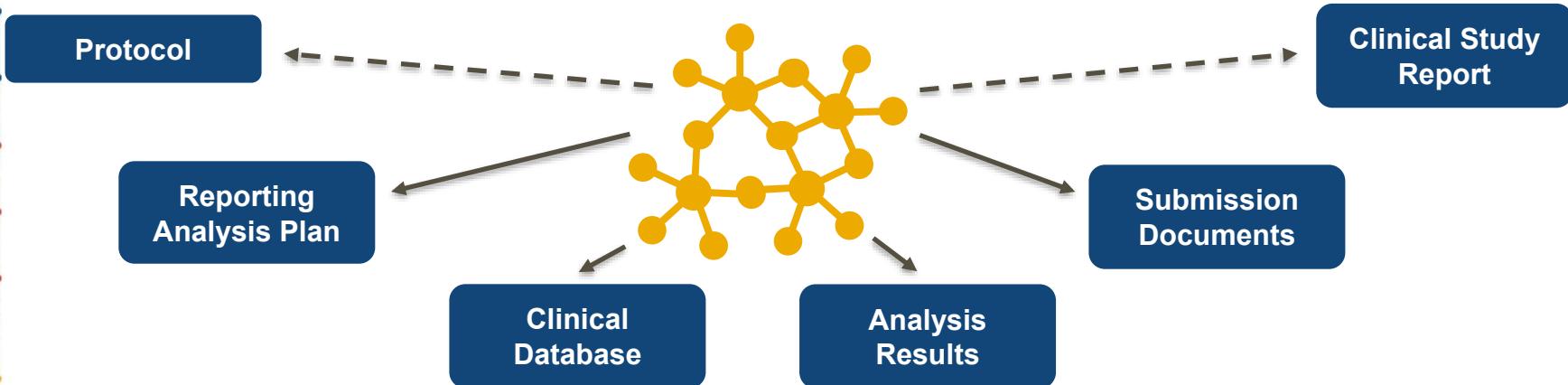
Traditional Data Standards for Clinical Trials



The "Golden Thread" - Connected Granular Standards



Upstream Shift: Powered by Semantic Connected Standards



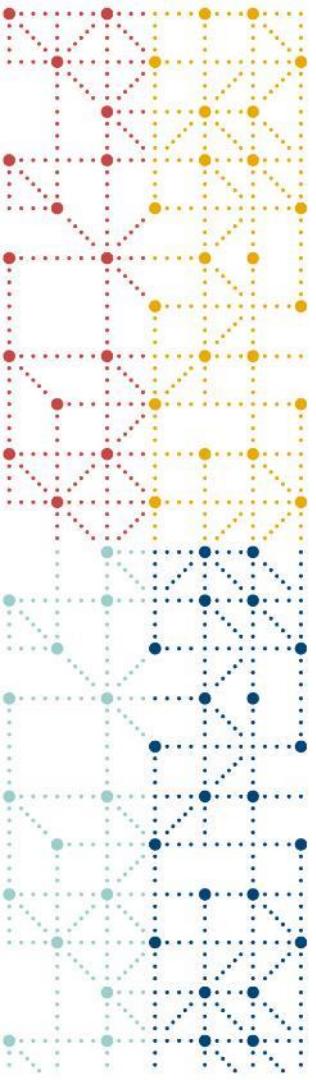
Efficient study build

- Fit for purpose and easy to adopt
- Proactive impact analysis
- Increased consistency

- Increased focus on data insights
- Respond to evolving needs
- Quick delivery

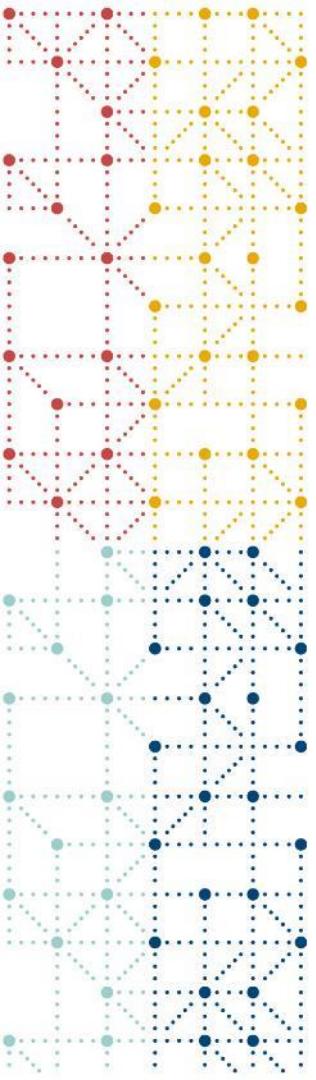
Efficient study execution

- Quality by design
- Reusable analysis results
- Simpler integration



Data Standards Role in the Era of AI

Panel Discussion



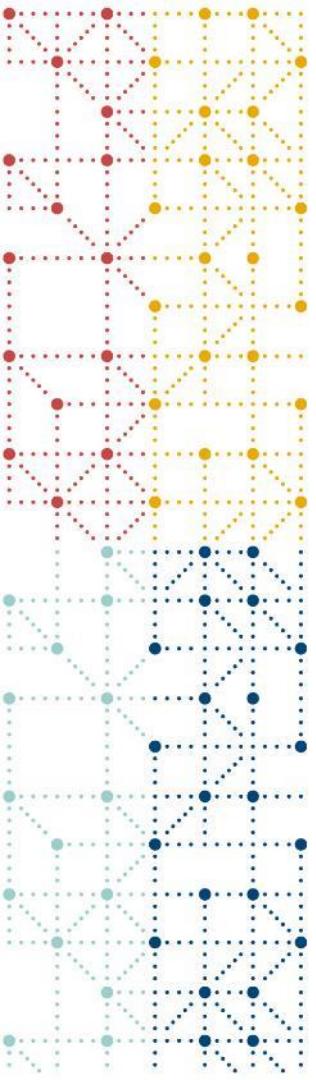
Foundation and Current State

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

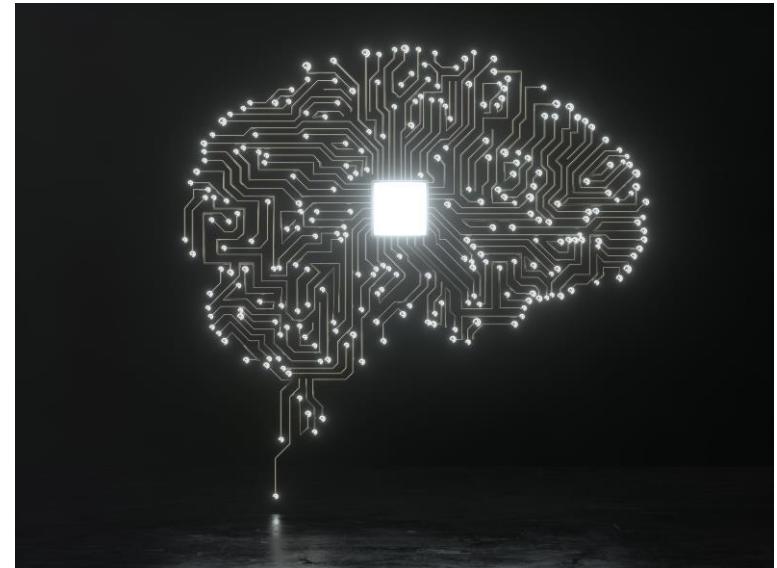
Are Data Standards required in the era of AI?

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

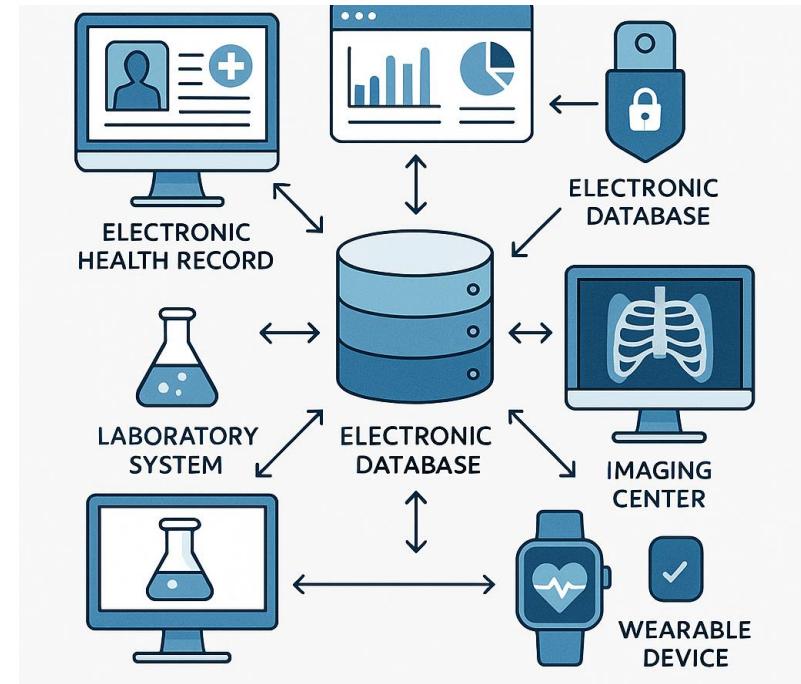
Q4. AI Demands

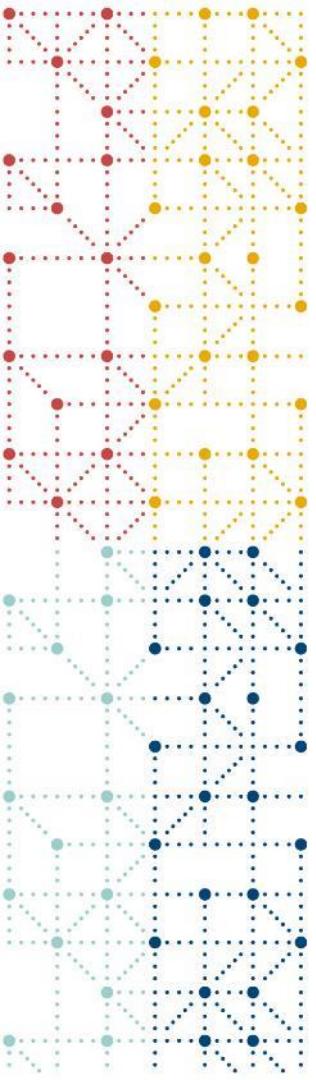
- Are current standards sufficient for training and deploying reliable AI models?
 - Unstructured Data and Natural Language Processing
 - Bias and Fairness
 - Explainability and Interpretability
 - Synthetic Data and Data Augmentation



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?



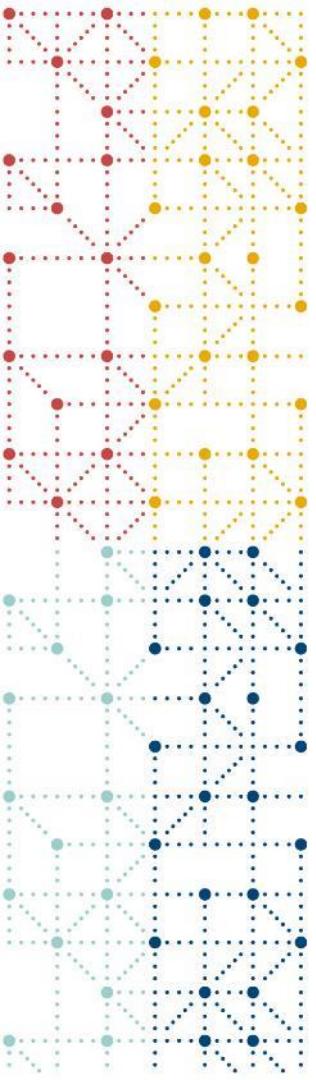


Regulatory, Ethical and Implementation Considerations

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

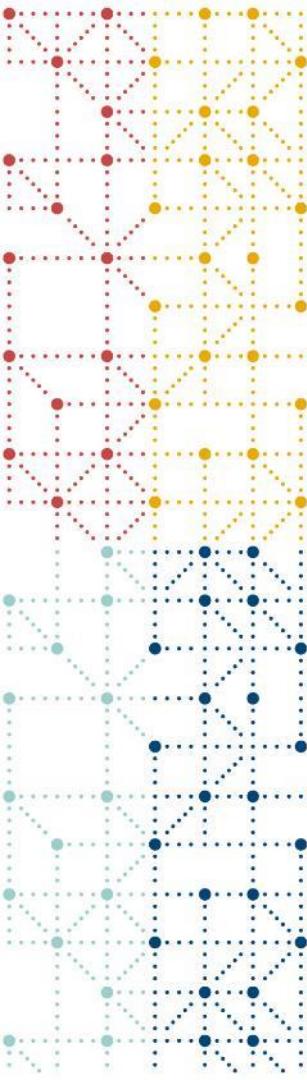


Looking Ahead

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!

