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E2E clinical development standards - taking us beyond the silos

Presented by
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Meet the Speakers

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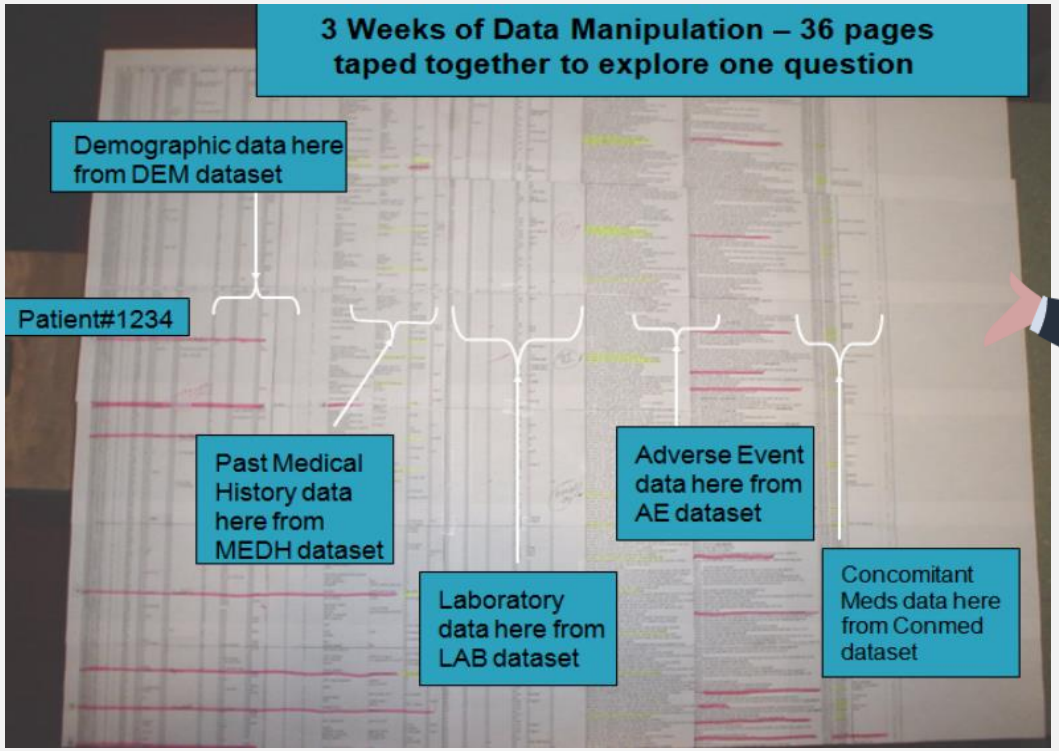
Disclaimer and Disclosures

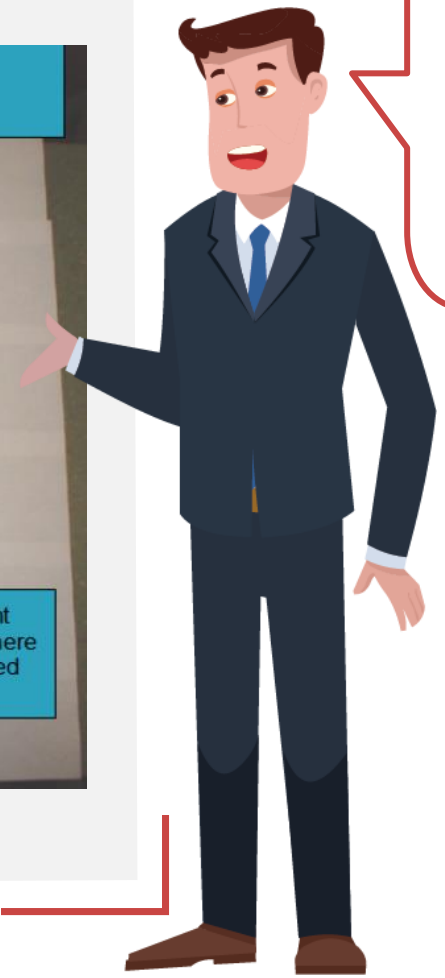
- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author(s) have no real or apparent conflicts of interest to report.*

Data Standards Journey: from manual to E2E automation

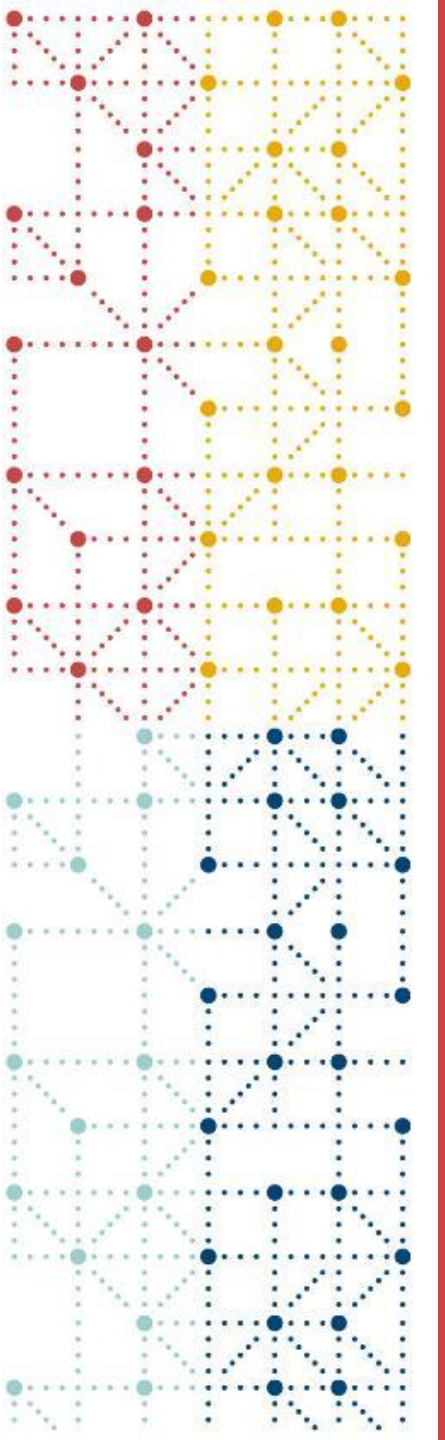
Hey Peter, do you remember when data collection used to be manual and non-standardized?





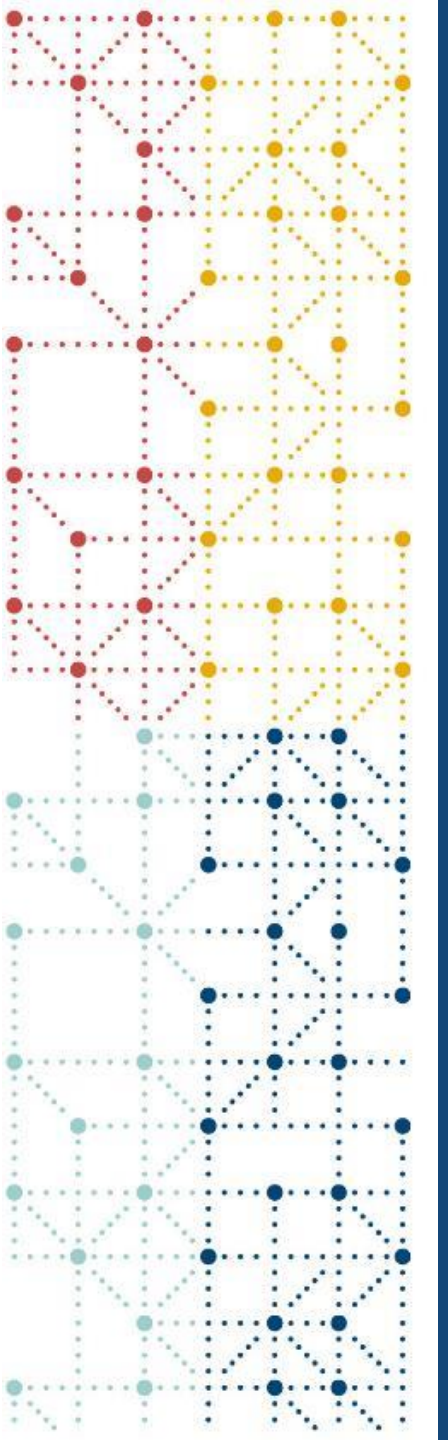
Of course, Emily! Thanks to the E2E standardization and automation efforts, it's much more efficient now.

Image source: The Past, Present, and Future of Clinical Data Standards; Chris Decker



Agenda

1. Our journey so far at UCB
2. What we learnt on the way
3. Our road ahead
4. Summary
5. Our vision for the future



Our journey so far at UCB

Why we focus on E2E clinical data standards?

E2E clinical data standardization boosts patient impact

Faster access to treatments

E2E study automation enables **faster study execution and approvals**

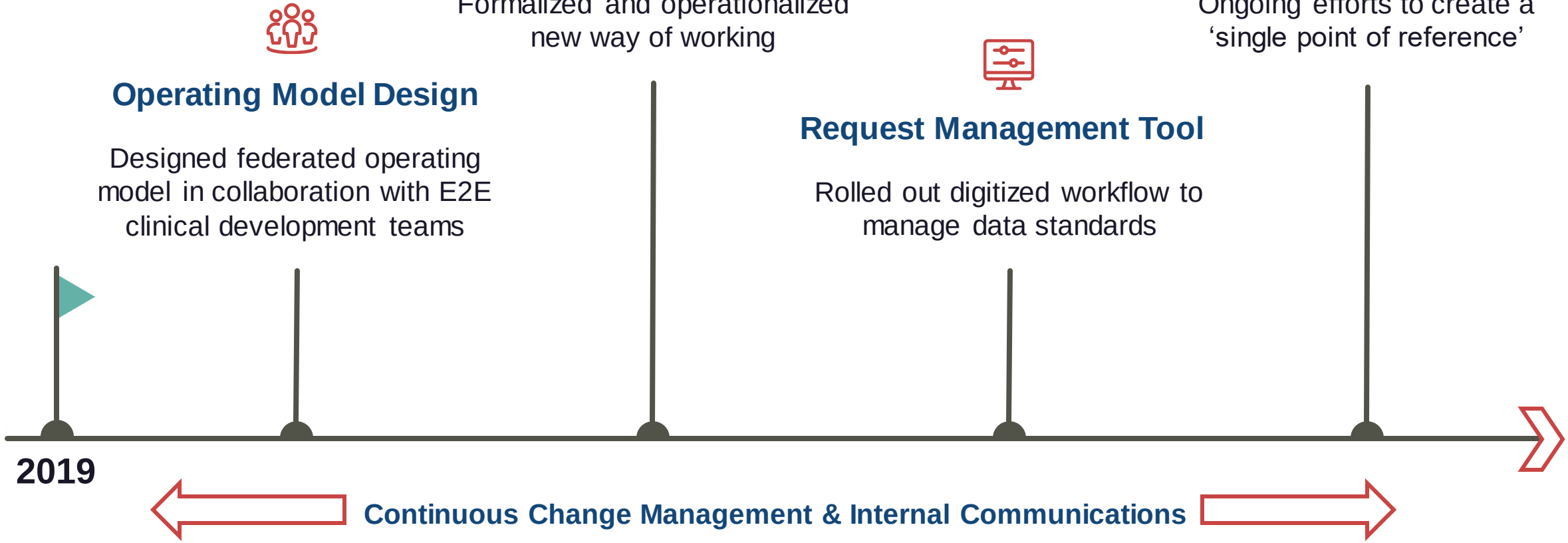
Improved quality of care

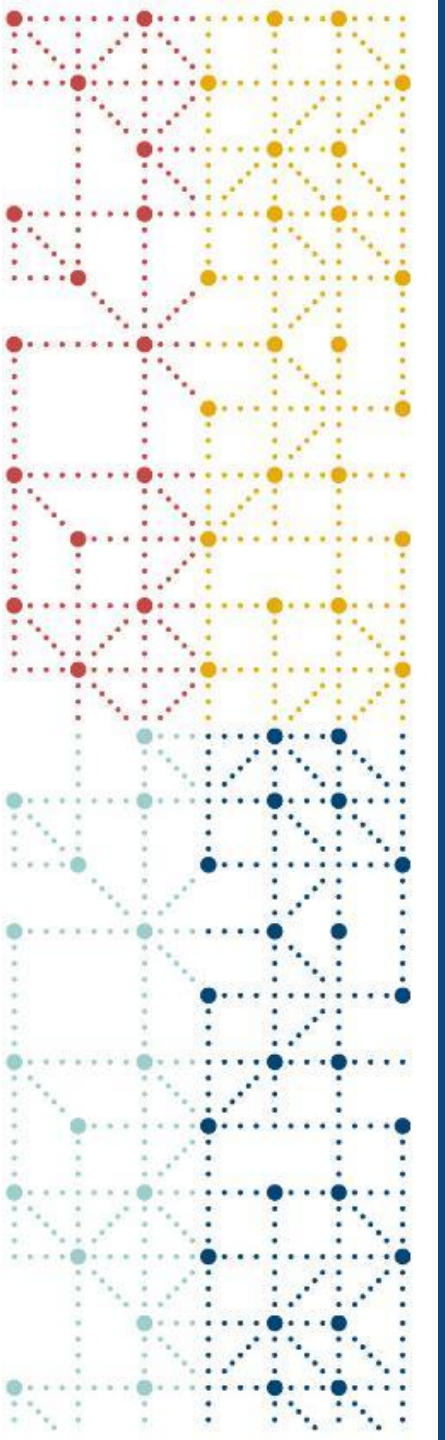
E2E data sharing for more **informed treatment-based decisions**

Patient safety

E2E standardization improves data quality across clinical lifecycle, facilitating **long term outcomes assessments**

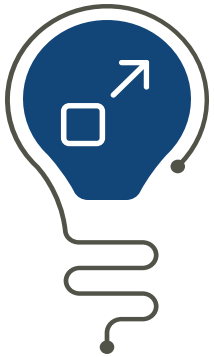
UCB E2E Data Standards Management – Journey so far!





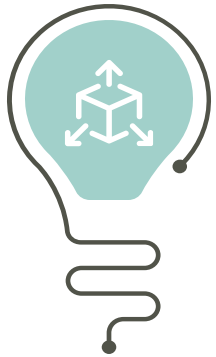
What we learnt on the way

What we've learnt during our journey



01

Move from data collection focus to an **E2E clinical mindset**

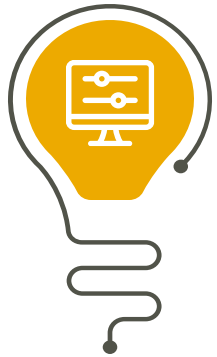


02

For true impact, **think beyond clinical**

03

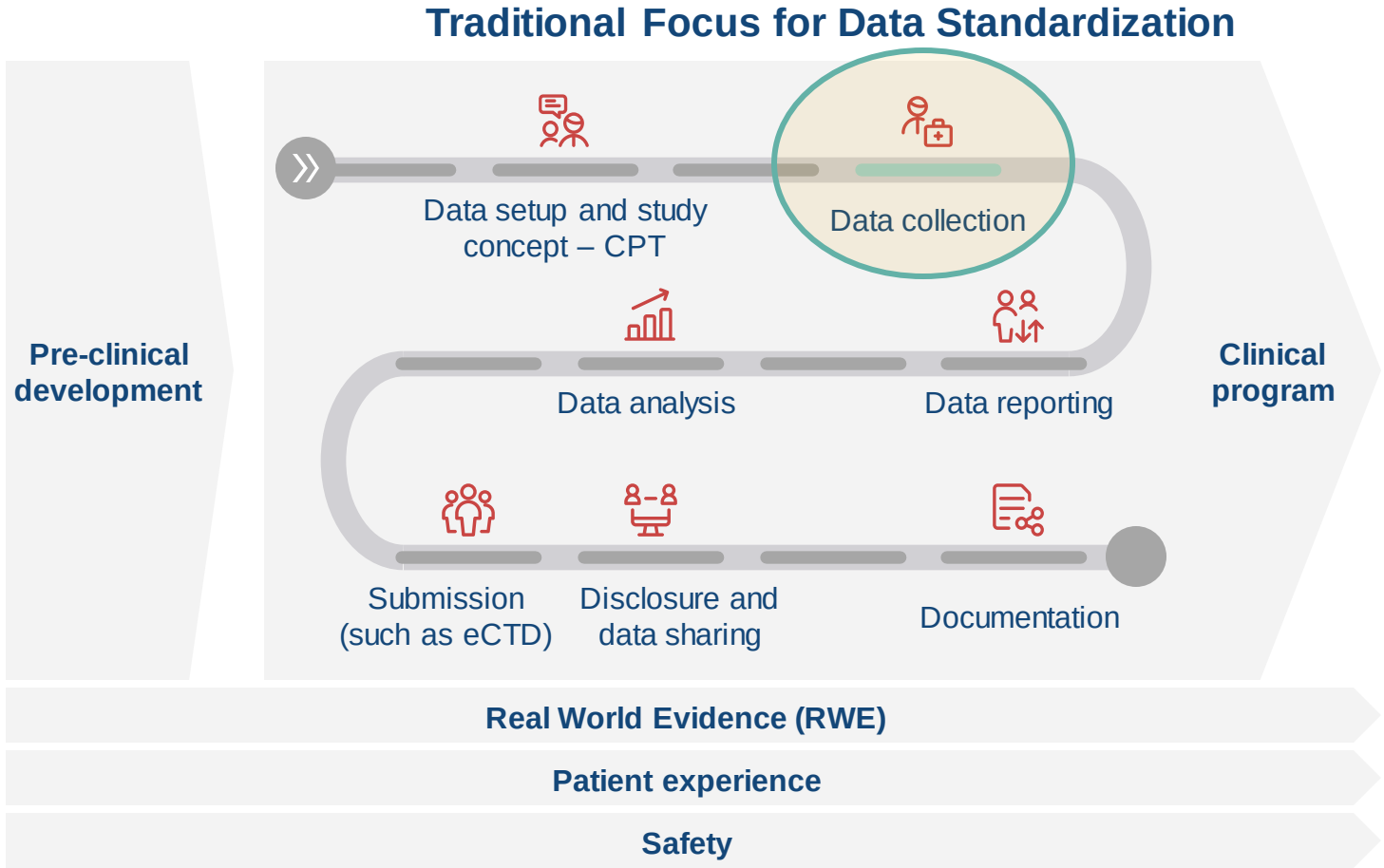
Having your people onboard is key to success



04

Tech / digitization solutions drive scale and efficiency

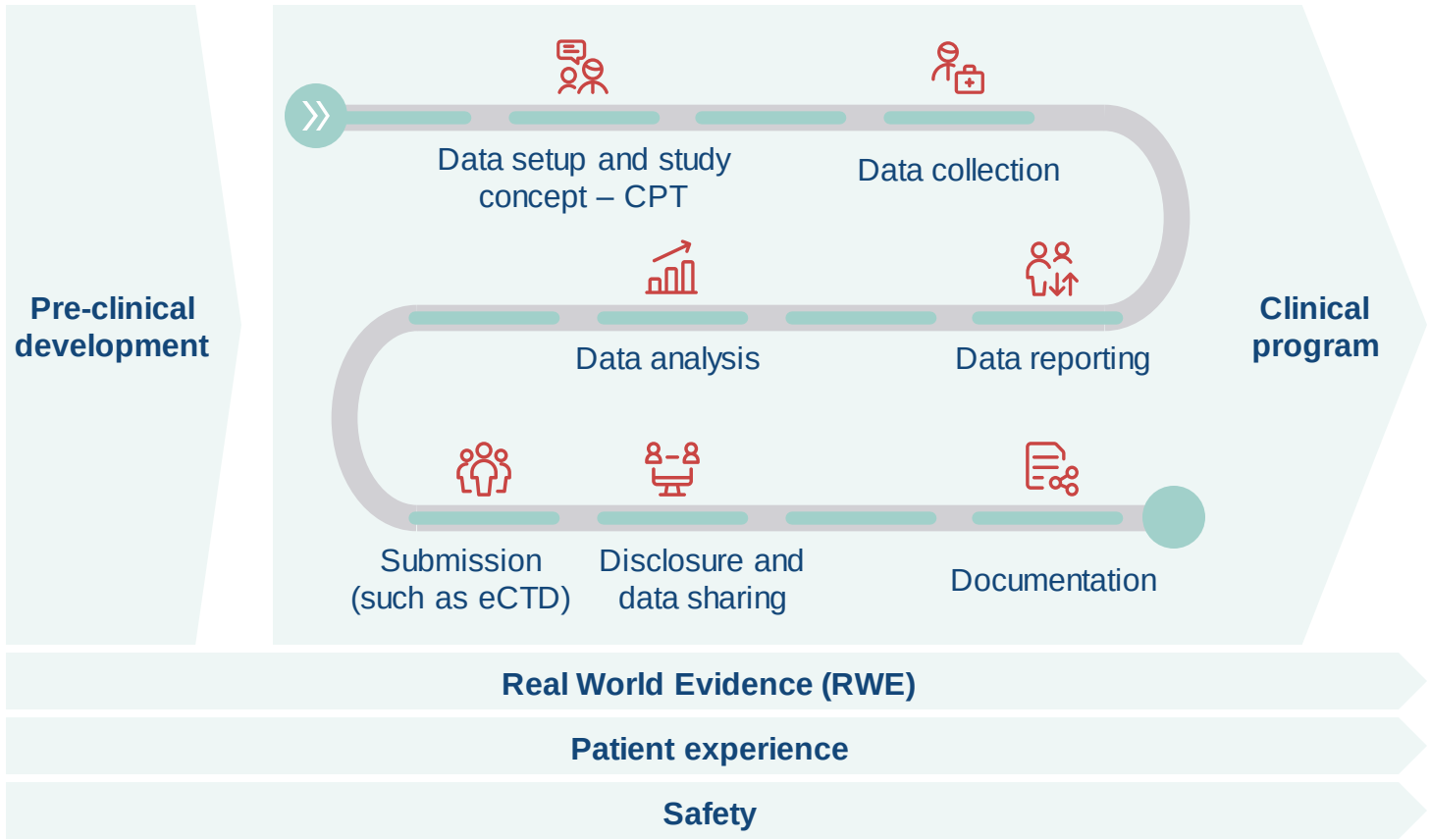
Move from data collection focus…



eCTD = Electronic Common Technical Document
CPT = Common Protocol Template
Standardization step

…to an E2E clinical mindset

Holistic E2E Clinical Data Standardization



Impact

- **Efficient & faster study execution and regulatory submissions**
- **Increased data credibility and analysis reliability**
- **Easier data pooling and rapid analytics**
- **Cross functional alignment and E2E linking of data & processes**

eCTD = Electronic Common Technical Document

CPT = Common Protocol Template

Standardization step

Case Example: Streamlined reporting through data standards enabled automation

Background

Adherence to trial disclosure requirements reporting in public registries

- Manual 'typing over' of data from PDF TFLs into Disclosure system
- Detailed, manual review of transferred info

Approach

- Transfer from ADaM to disclosure standards automated by using macros
- Strong cross-functional collaboration between stats and safety team

Impact

Reduced manual effort

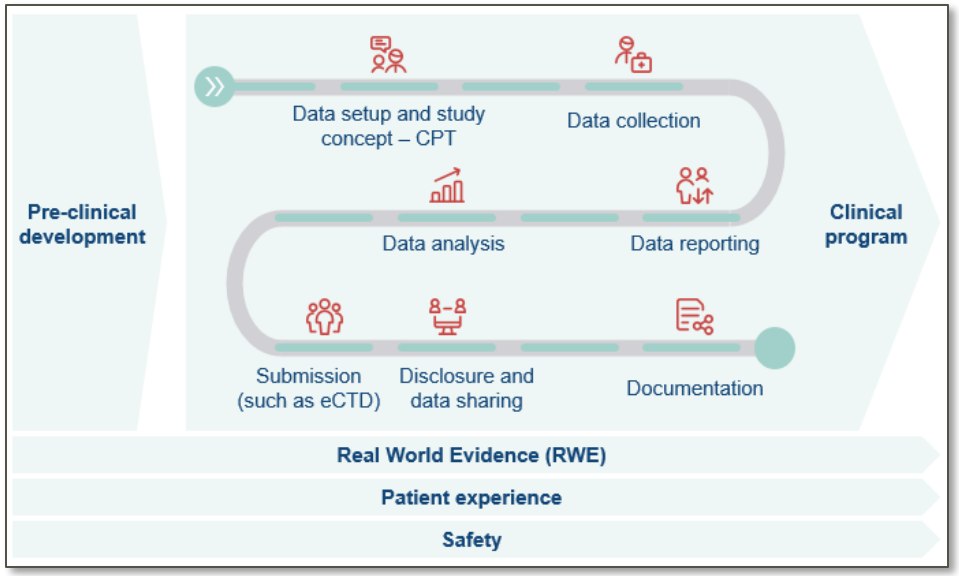
Shortened time to reporting in public registries

Minimal error when transitioning from one standard to other

Implementation of data standards has simplified the linkage between multiple functions

For true impact, think beyond clinical (1/2)

E2E Clinical Data Standardization:



Adoption beyond Clinical Lifecycle:

TAs

- Immunology
- Neurology
- Rare disease

Cross-organization

- Commercial
- Enterprise
- R&D
- Medical

External Collaboration:

Regulatory Bodies

- FDA
- European Medicines Agency

Standards Orgs.

- CDISC
- TransCelerate BIOPHARMA INC.
- HL7 International

Standards Databases

- SNOMED CT
- MedDRA
- ICD-11
- LOINC

For true impact, think beyond clinical (2/2)

Impact

- Enables & supports **E2E automation**
- **Enterprise-wide consistency & transparency** of data standards
- **Proactive response to external shifts**
- Ensures **standardization of** data coming from **external sources**

Case Example: Creating value for patients living with severe diseases now and in the future

Background

Patient Support Programs collect large volume of RWD which

- Use different standards
- Are hosted in siloed environments

Approach

- Aligned standardized patient reported scales to CDISC SDTM structure and meta data standards
- Built harmonized, connected data sets

Impact

Insights into **patient experience** on our products

Provide additional **verifiable evidence for payors**

Support **label expansion**

Understand **performance of our PSPs** adherence, satisfaction

Case Example: Moving 'beyond clinical' has led to unsiloing of reference data for asset names

Background

Historically, multiple functions had their own repository for asset names

Example

"LEV" abbr., used internally by different functions for two different products, leading to confusion

Approach

- Cross-functional alignment on approach
- Created reference table with all known names per product
- Included names used in development and marketing in Product MDM system

Impact

Easier reconciliation and **less ambiguity**

Simpler data sharing between functions

Allows future automation of data alignment across systems

Having your people onboard is key to success

1

Define and Build Operating Model

- **Co-develop**
- **Roles and responsibilities**
- **Choice** of operating **model**: Decentralized / Federated / Centralized

2

Operationalize Model

- Encourage **ownership**
- Provide right **'incentives'**
- Enable **feedback-loop** to evolve model

3

Invest in Change Management

- **Engage → Enable → Empower**
- Ongoing **change management**

Leadership Advocacy

Case Example: Our federated operating model is designed with collaboration and E2E thinking in mind

Centralized Strategy & Governance

Data Standards Teams (DSTs)

- Protocol Team
- Data Collection Team
- Data Analysis Team
- Reference Data Team

Regular communication

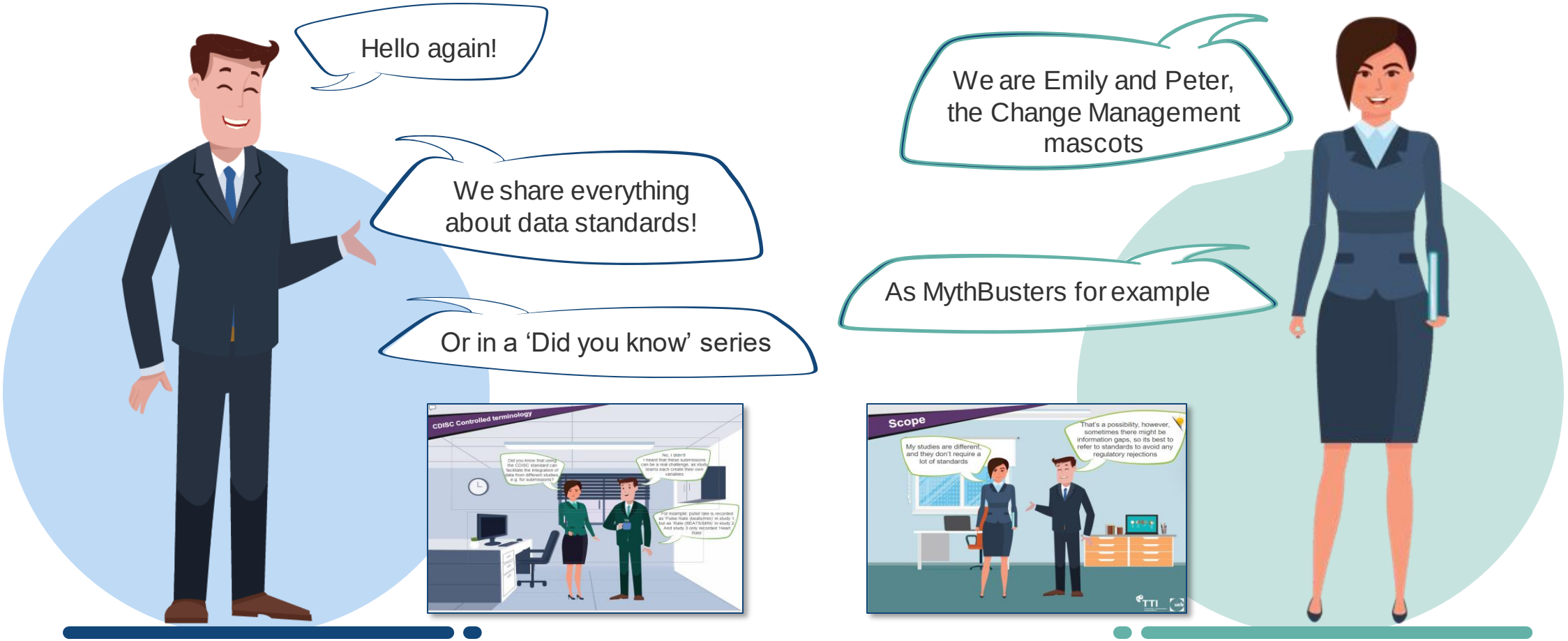
Data Standards Management and Oversight Team (DSMOT)

Regular communication and collaboration

Decentralized Execution and Implementation

- Create and Manage Standards
- Create Once
- Library Content Management
- Use Multiple
- Documentation
- Support of Standards Usage

Case Example: Continued change management has been a key enabler behind UCB's impact stories



Tech / digitization solutions drive scale and efficiency

Data Standards Inventory

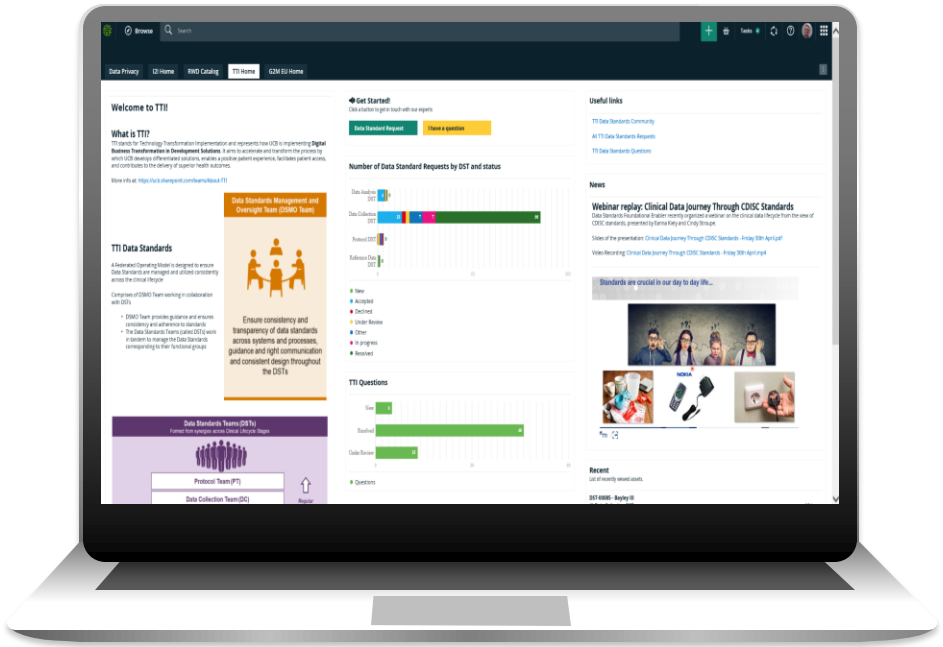
Single point of reference for all requisite standards

Digitized Workflow and Task Management

Maintain overview and keep activities organized across stakeholders

E2E Clinical Automation

Integrate and automate data exchange between multiple systems



Case Example: Implementation of Request Management tool has propelled uptake of standards

Background

One-stop tool to ask questions and raise requests related to data standards

Impact

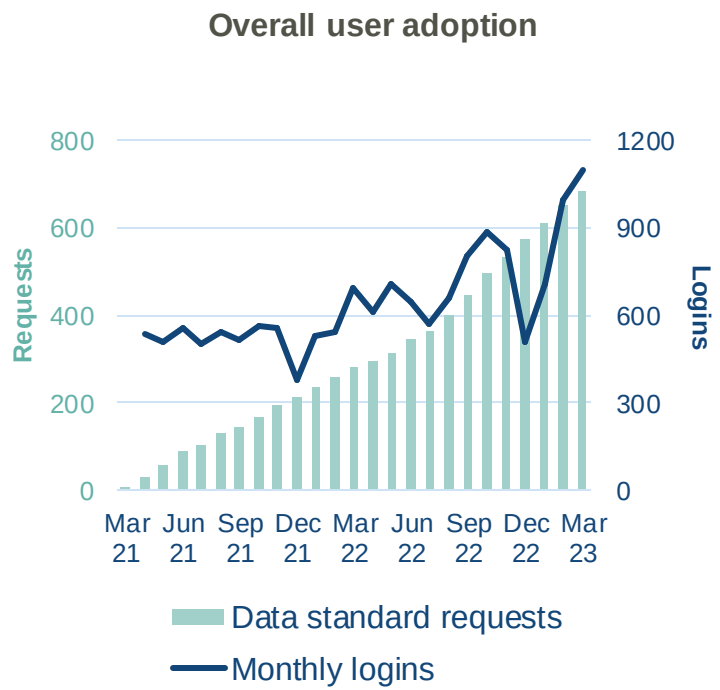
Enables a **centralized process** for request management

Assigns clear roles & responsibilities with increased transparency

Assesses **E2E clinical implications** for all requests

Performance Indicators (Mar'21 – Mar'23)

Affected Dimensions	Requests
ADaM Interpretation Guide	17
CDASH Interpretation Guide	2
Common Protocol Template	135
CRF	256
ePRO/eCOA	10
External Data	4
Lab	46
Late Phase SAP Template	4
Migration	16
Program Convention Documents	1
Reference Data Terminology	2
SDTM	156
SDTM Interpretation Guide	20
TFL Shells	17
Grand Total	**686**



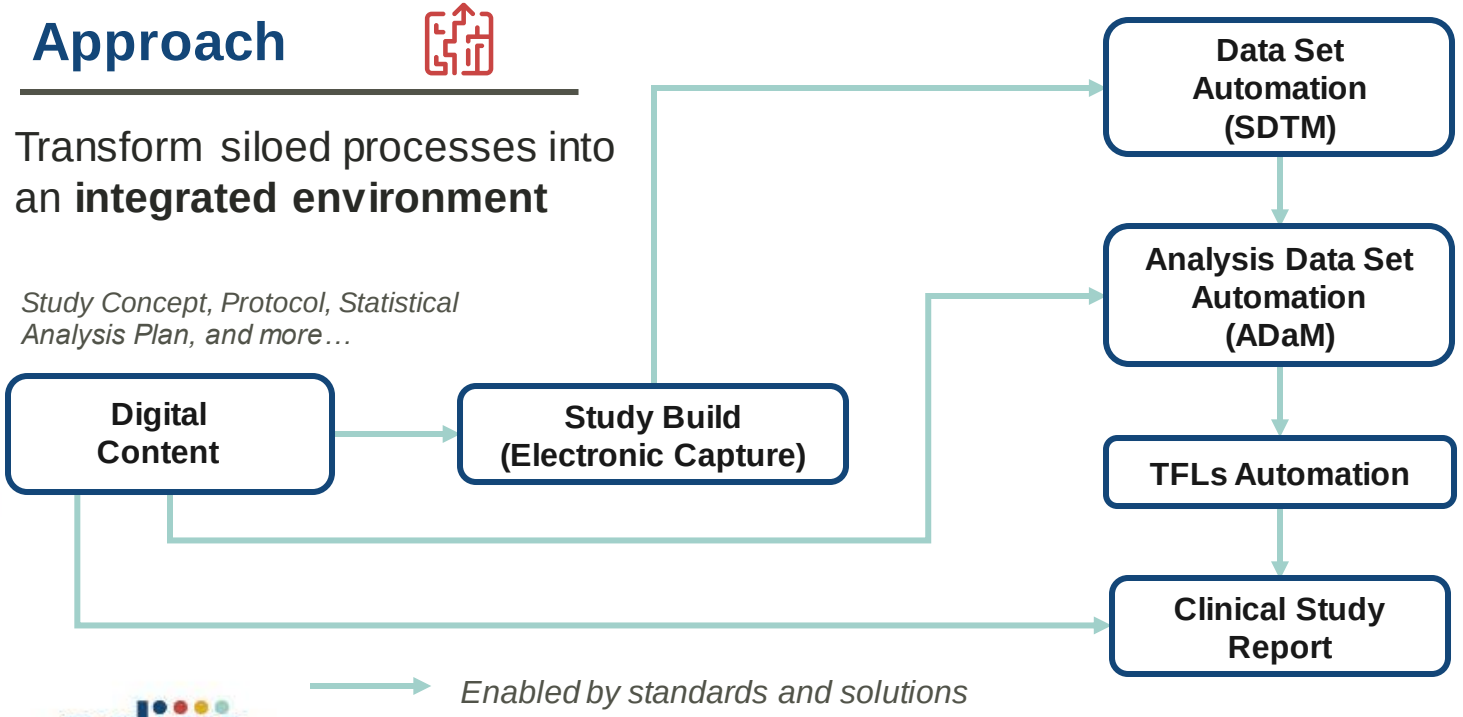
Case Example: E2E clinical study automation enabled by standards

Background

Historically, clinical study processes were manual and siloed, involving significant amounts of paperwork, manual data entry and tracking of data

Approach

Transform siloed processes into an **integrated environment**

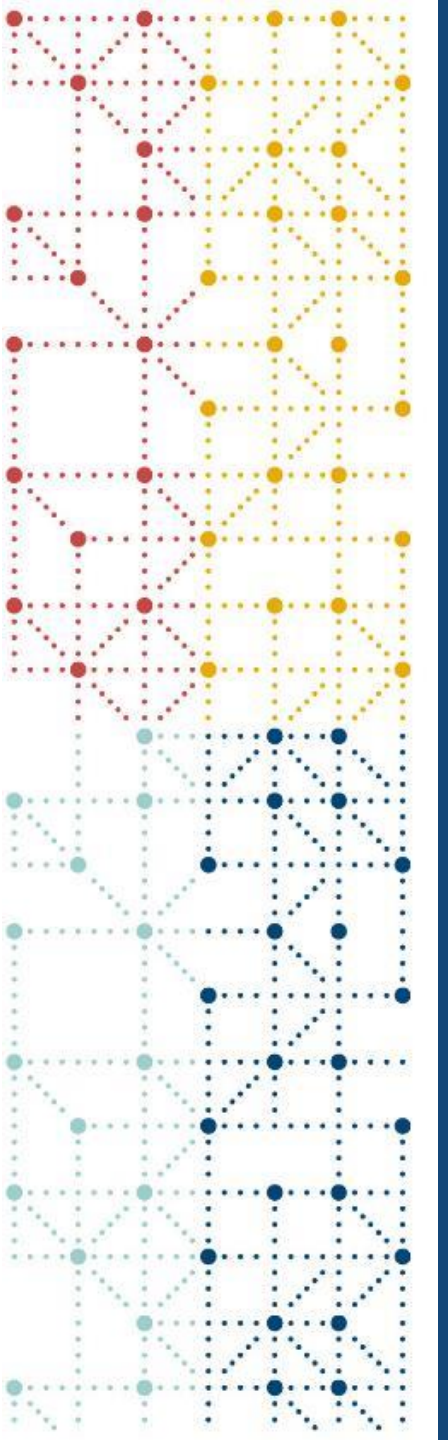


Impact

Increased E2E mindset within teams

Ensures **consistency & quality** from study planning & definition to study closeout **facilitating automated data flow**

Accelerates **submission readiness**



Our road ahead

Where we're heading next in our journey

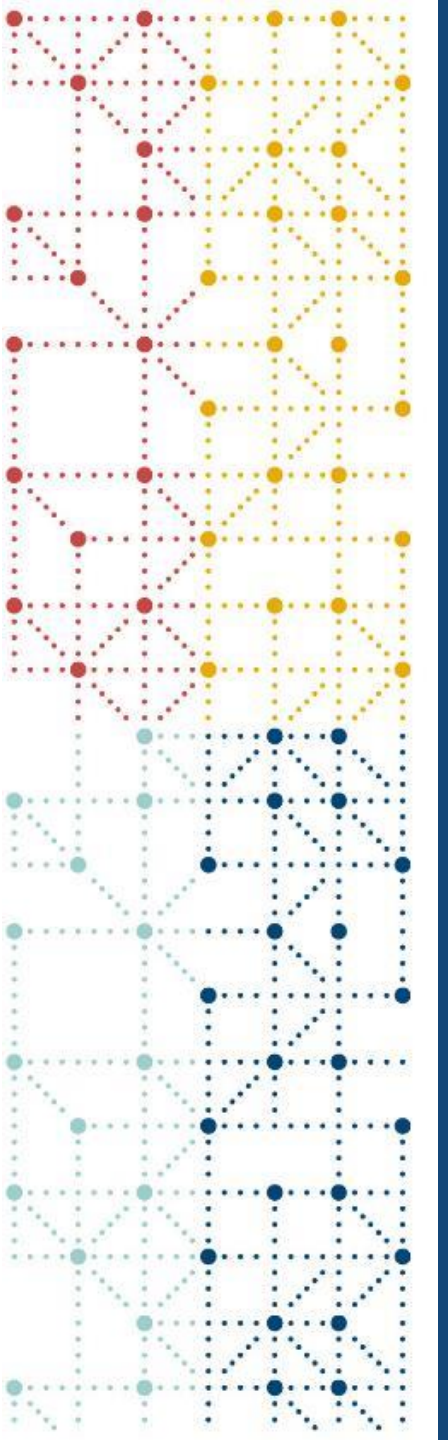
Extended Integration of Functions/Teams

- **Intensify cross-functional collaboration with teams** like RWE, PCOR* and specific therapeutic areas to develop granular standards tailored to their needs

Standards-Driven Automation

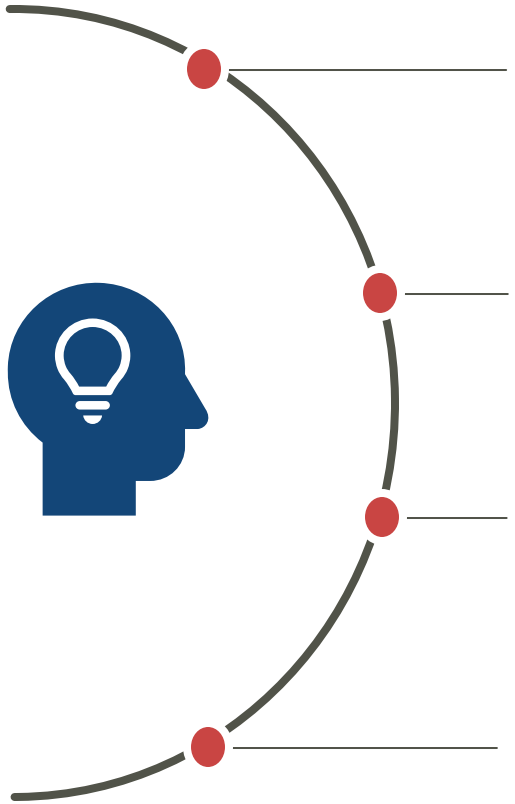
- Compile standards into a central repository (standards inventory), as an exhaustive **single source of truth**
- Create **knowledge graph / ontologies** based on standards inventory
- Link standards in inventory to request management tool and **automate impact assessment** based on defined ontologies

*PCOR – Patient-Centered Outcomes Research



Summary

We learnt successful E2E clinical data standardization is achievable, with dedicated effort



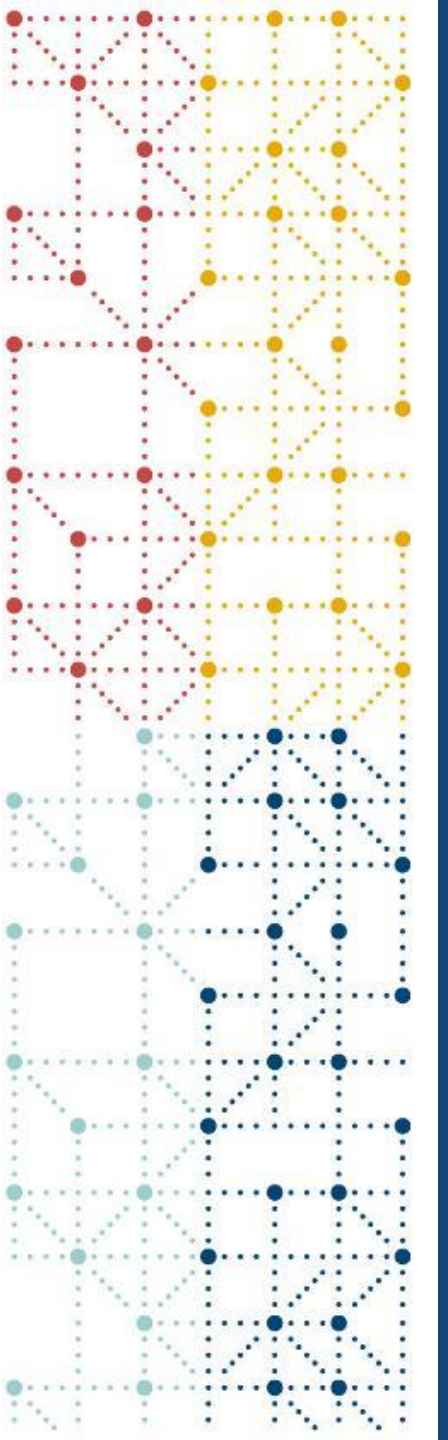
Managing data standards requires an overarching **E2E approach**

Think beyond clinical - data standards are transversal across the enterprise

Maximize collaboration - people make the initiative successful

Use **technology/automation** to support people

CDISC plays a crucial role in facilitating end-to-end standardization of clinical data



Our vision for the future

Future of clinical data standards – Scope expansion

Spotlight on RWE

- Increased **importance** of **RWE** in evolving evidence landscape
- **Standardization efforts** need to acknowledge the **heterogeneous** nature of **real-world data**

Big data to deep data

- Explosion of **healthcare data** in terms of **volume, variety** and **granularity**
- Clinical data **standards** need to **accommodate new data archetypes**

Standardizing free text

- Currently **document-based** templates are largely **unstructured** and **subjective**
- Need to **shift** to **standardization** and **digitization** of these templates, enabling **structured creativity** in an E2E environment

Thank You!