



2024 CDISC + TMF
US INTERCHANGE

PHOENIX/SCOTTSDALE

23-24 OCTOBER: CONFERENCE & EXPO | 21, 22, 25 OCTOBER: TRAININGS

Session 3A: Digital Protocol
**Digital Data Flow: Achieving Protocol Digitalization and Clinical
Research Interoperability through Multi-stakeholder Collaboration**

Presented by William Illis, Novartis



Meet the Speaker

Bill Illis

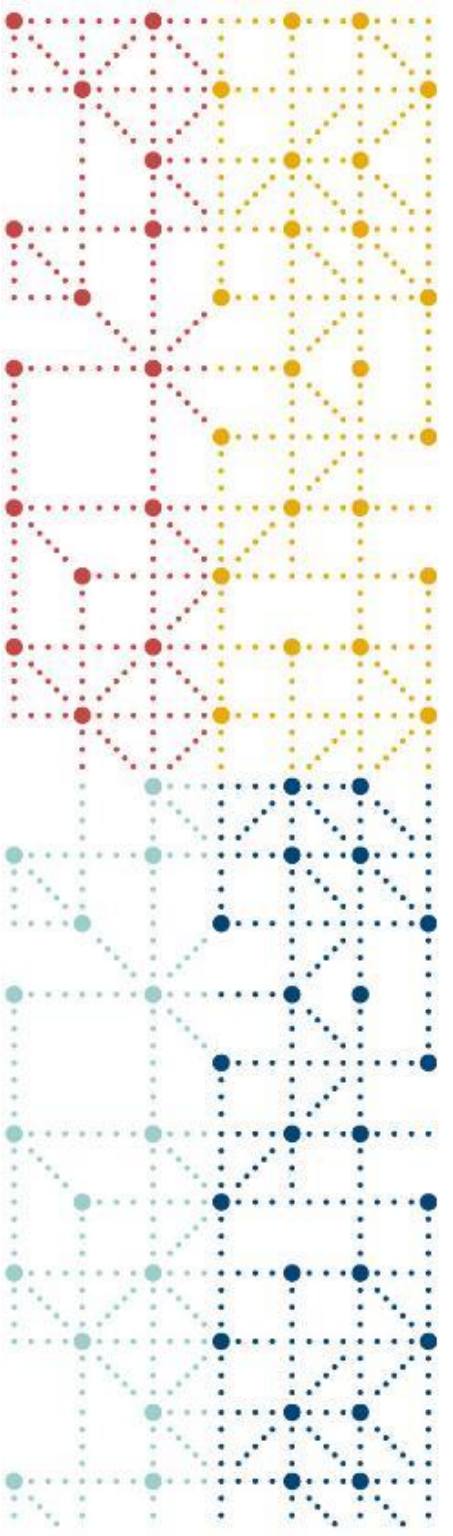
Global Head, Collaboration & Technology Strategy,
Clinical Development & Analytics
Novartis

Bill has > 25 years of experience in the pharmaceutical industry and has provided executive leadership to clinical operations functions of data management, statistical programming, standards management, strategy and operations as well as R&D IT. Recently he led the development and implementation of a strategic technology roadmap for the Analytics team. Since project inception in 2019, Bill has been the workstream lead for TransCelerate BioPharma's Digital Data Flow, protocol digitalization initiative.



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.*

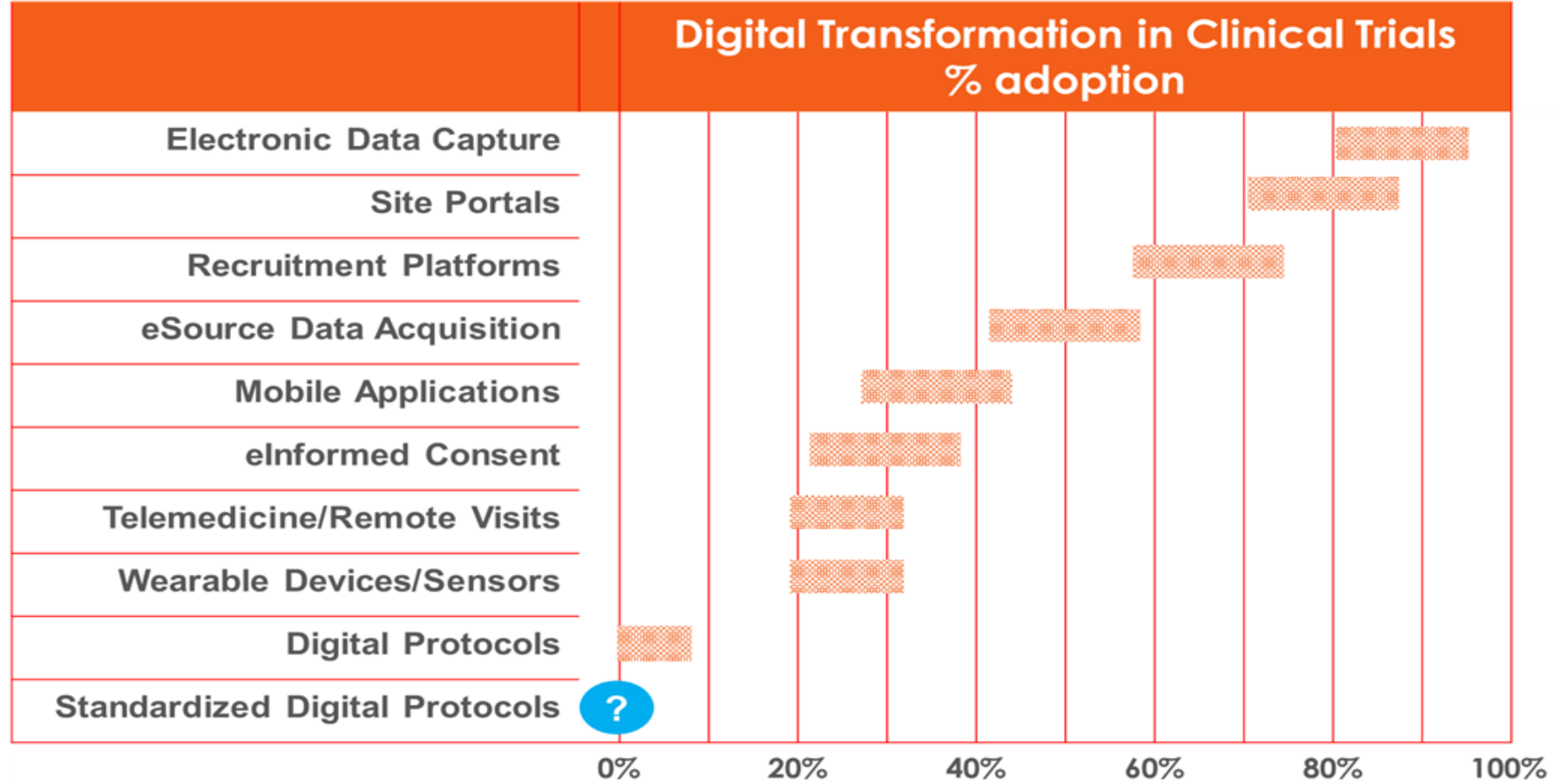


Agenda

1. Why Digital Data Flow?
2. Tools / Multi-stakeholder Change and Engagement

Why Digital Data Flow?

The industry has not kept pace with the complexity of clinical study data or the systems used to manage it. There is opportunity to modernize the manual, slow processes and improve reliability.



Interoperability and standards are all around us

Things that work....



Electrical engineering

IEC GUIDE 111-1:2023

Electric equipment for high-voltage substations - Common recommendations for product and system standards - Part 1: AC (alternating current)

Edition 1.0 ACTAD



Message: SMS/MMS
Encoding: Unicode / UTD-16
Network: 5G / WiMAX / 802.16.t



ISO 13.060

ISO	Standards	Sectors	About ISO	Insights & news	Taking part	Store
13.060.01	Water quality in general					
13.060.10	Water of natural resources					
13.060.20	Drinking water → Mineral water, see 67160.20 → Chemicals for purification of water, see 71100.80 → Drinking water supply systems, see 91140.60					
13.060.25	Water for industrial use Including water for commercial use: for swimming pools, fish breeding, etc.					
13.060.30	Sewage water Including sewage water disposal and treatment → Liquid wastes, see 13.030.20 → Drainage systems, see 91140.80 → Sewage systems, see 93.030					
13.060.45	Examination of water in general Including sampling					
13.060.50	Examination of water for chemical substances					
13.060.60	Examination of physical properties of water					



ISO 668

ISO	Standards	Sectors	About ISO	News	Taking part	Store	Search
ISO Annual Meeting 2024 Check our live page to stay tuned for the latest updates							
Standard and/or project (44) ↑							
ISO 668:2020	Series 1 freight containers — Classification, dimensions and ratings						
ISO 668:2020/Amd 1:2022	Series 1 freight containers — Classification, dimensions and ratings — Amendment 1						
ISO 830:1999	Freight containers — Vocabulary						
ISO 830:1999/Cor 1:2001	Freight containers — Vocabulary — Technical Corrigendum 1						
ISO 830	Freight containers — Vocabulary						
ISO 1161:2016	Series 1 freight containers — Corner and intermediate fittings — Specifications						
ISO 1496-1:2013	Series 1 freight containers — Specification and testing — Part 1: General cargo containers for general purposes						

Clinical Study Protocols Broken....

This collage represents various components of a clinical study protocol. It includes:

- Table 1: Schedule of Events** - A grid showing the timing of various study activities (e.g., randomization, baseline, assessments) across different study visits (V1 to V12).
- Table 2: Schedule of Assessments** - A table detailing the frequency and timing of different types of assessments (e.g., physical exam, vital signs, lab tests) at each visit.
- Text Sections** - Various paragraphs of text, likely describing study objectives, inclusion/exclusion criteria, and assessment procedures.

CONFIDENTIAL Protocol (protocol number), (sponsor name) and (site(s))

Title Page

Protocol Title: [Sponsor name] (primary phase), (study phase), (disease) (condition) with study to investigate (health assessment outcome) with (non-interventional) (interventional) (intervention type) (population) (age) (years of age) with (condition/disease)

Protocol Number: (protocol number)

Assessment Number: (assessment number)

Assessment Scope: Global/Continent-specific/Regional

Assessment Region Identifier: (ISO 3166 country identifier)

Component: (positive or active)

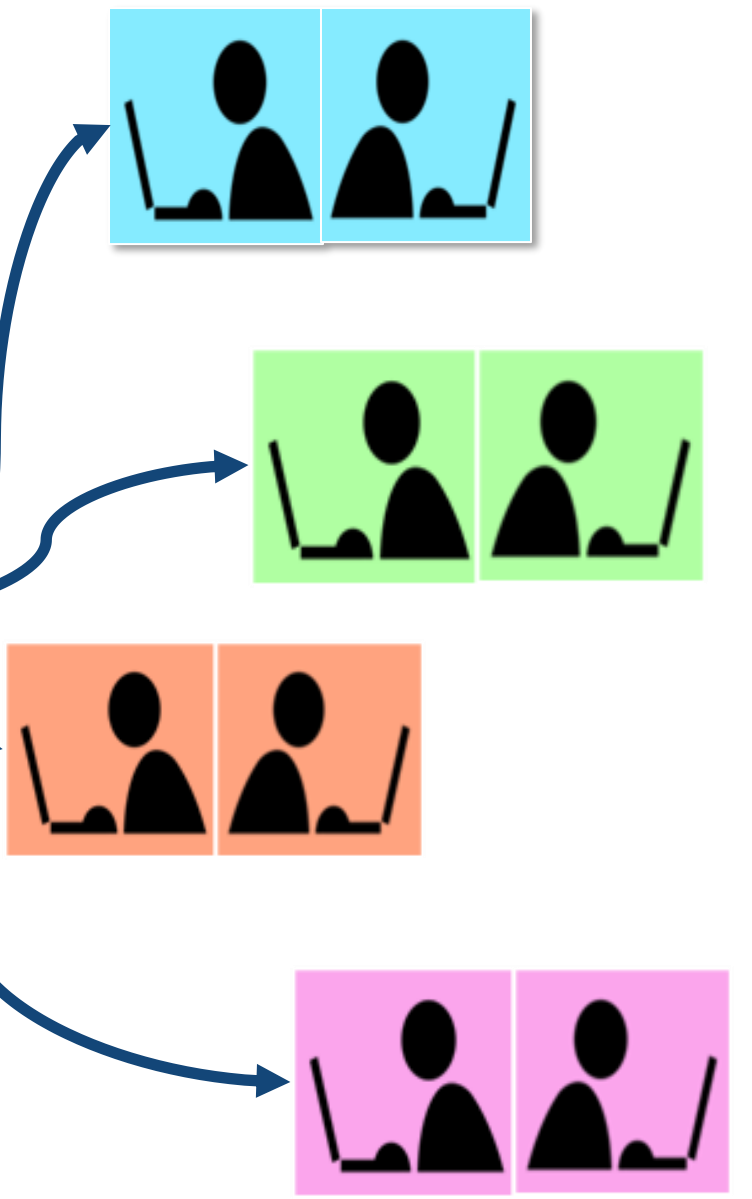
Study Title: [Sponsor name] (primary phase), (study phase), (disease) (condition) with study to investigate (health assessment outcome) with (non-interventional) (interventional) (intervention type) (population) (age) (years of age) with (condition/disease)

Study Phase: (study phase)

Sponsor Name:

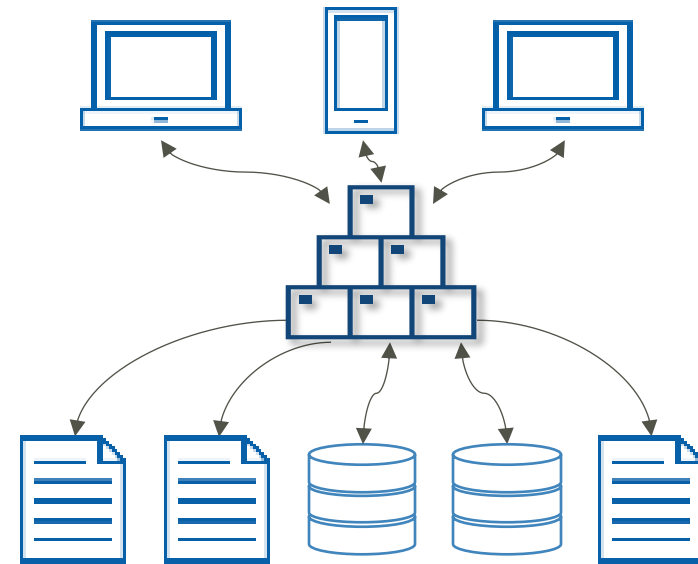
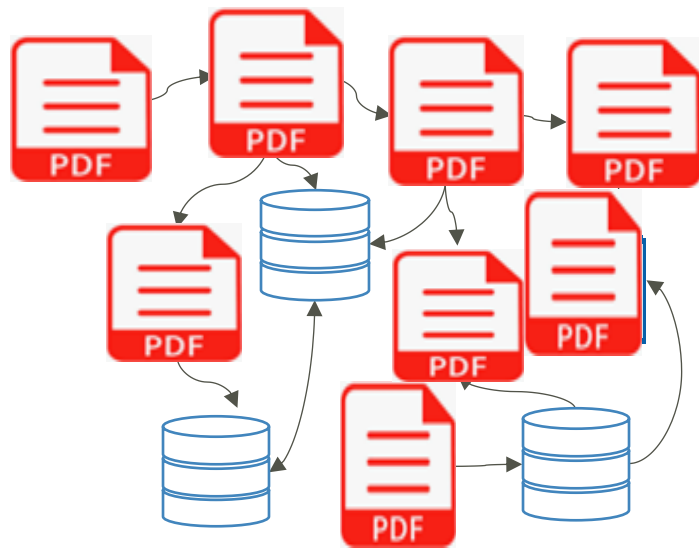
Legal Registered Name: (sponsor name)

Registration Agency ID:

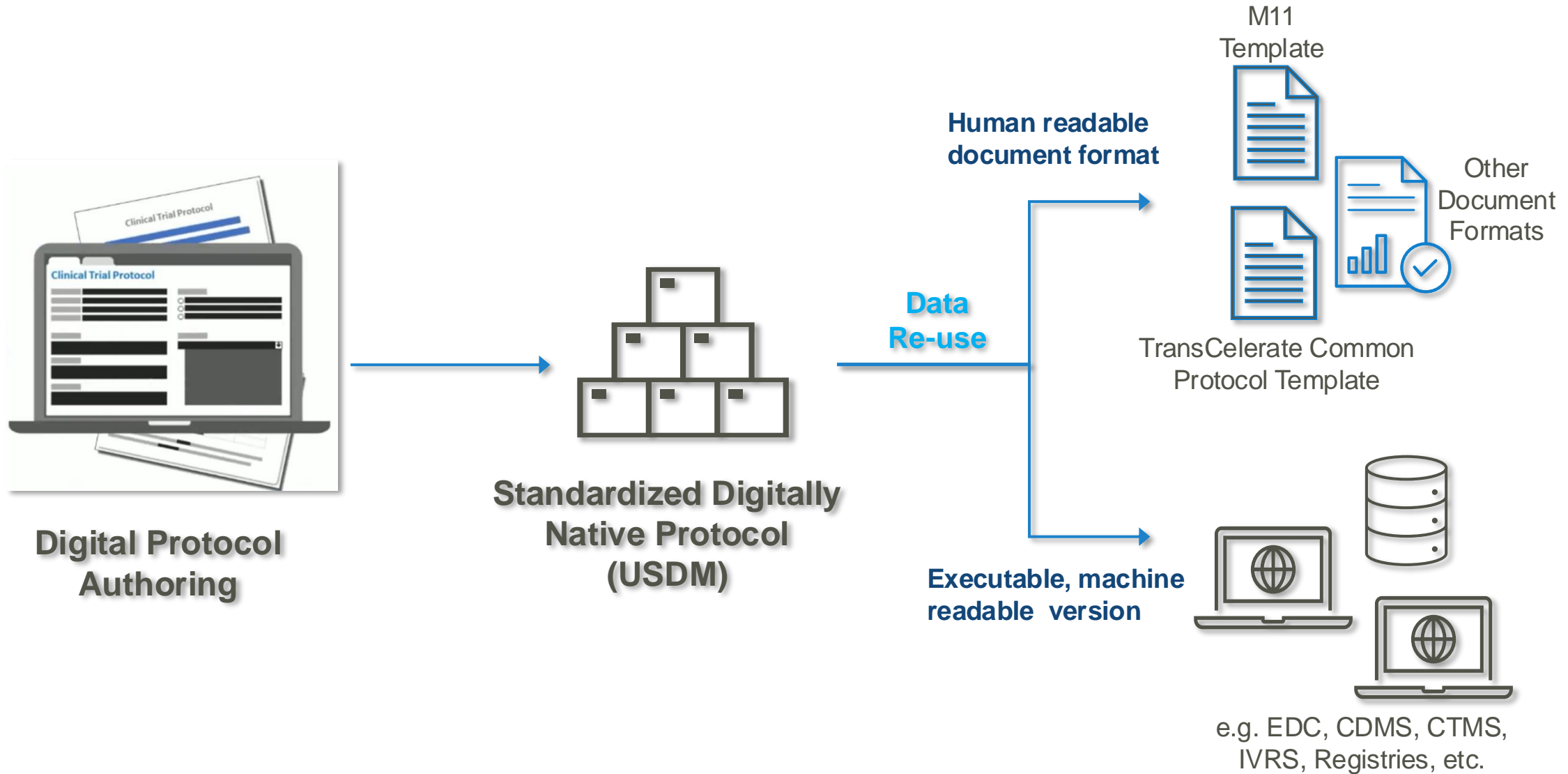


Protocol Digitalization Vision

Shift from “document-first” to “data-first” paradigm for clinical study setup, unlocking value through seamless integration, process automation and data-based insights

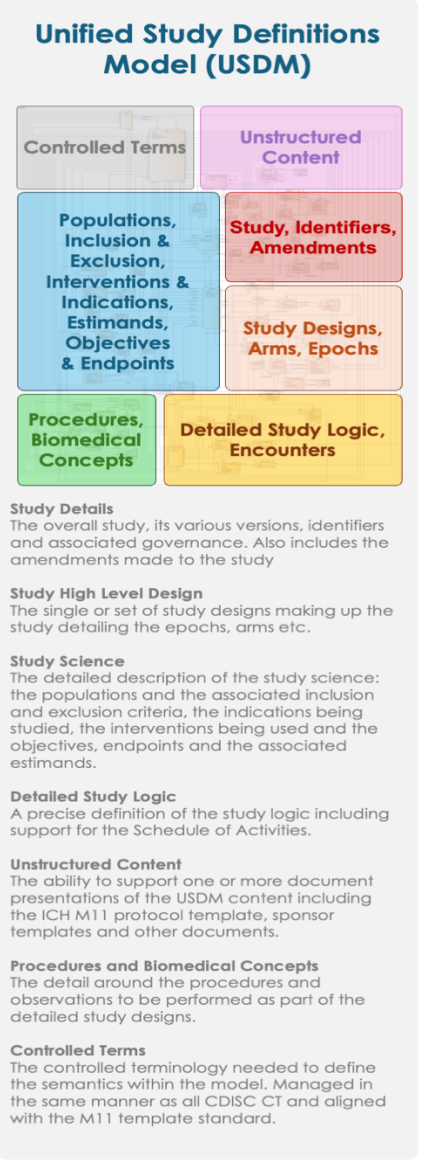
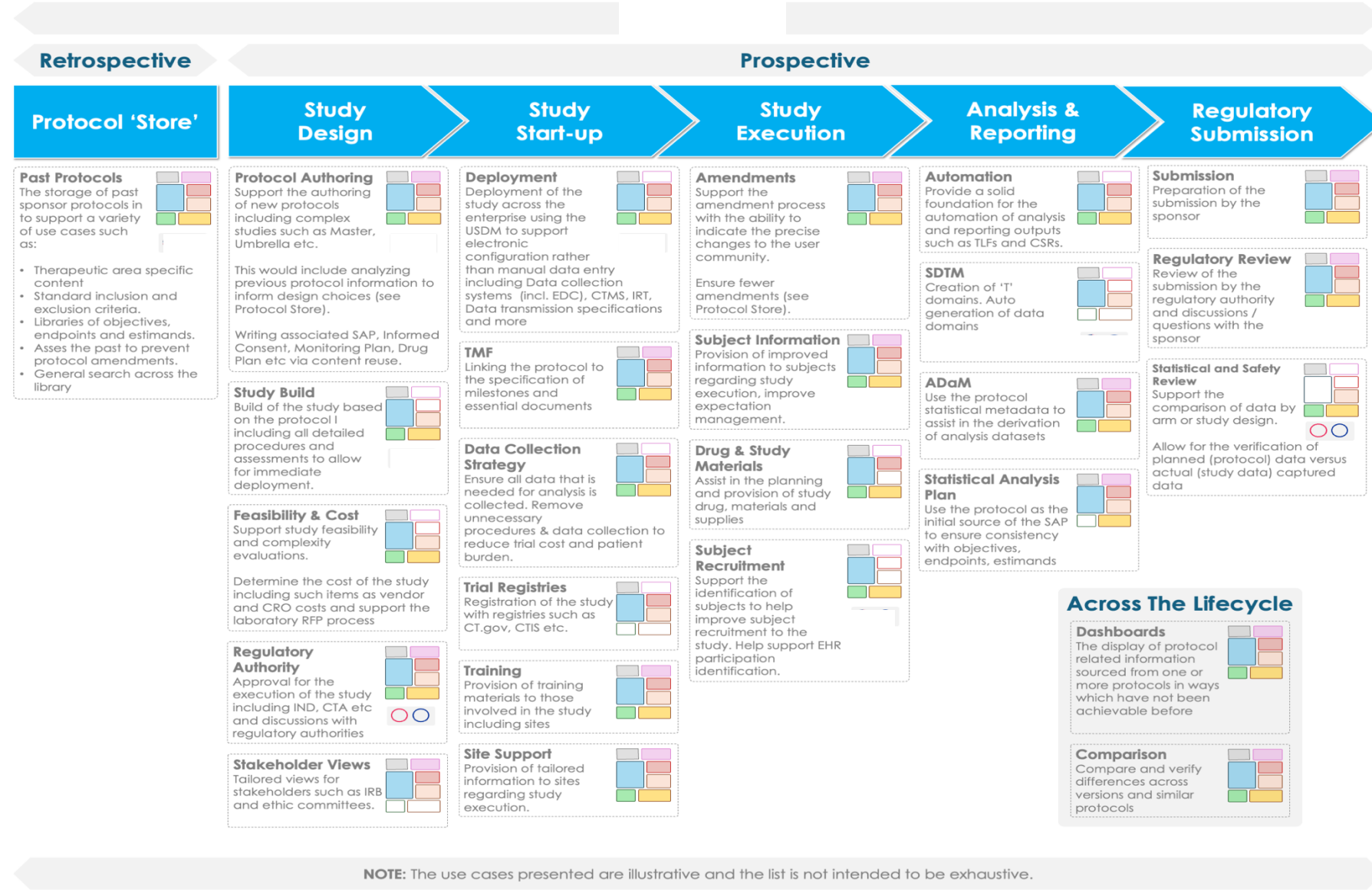


Reuse: Write Once, Execute Many Times

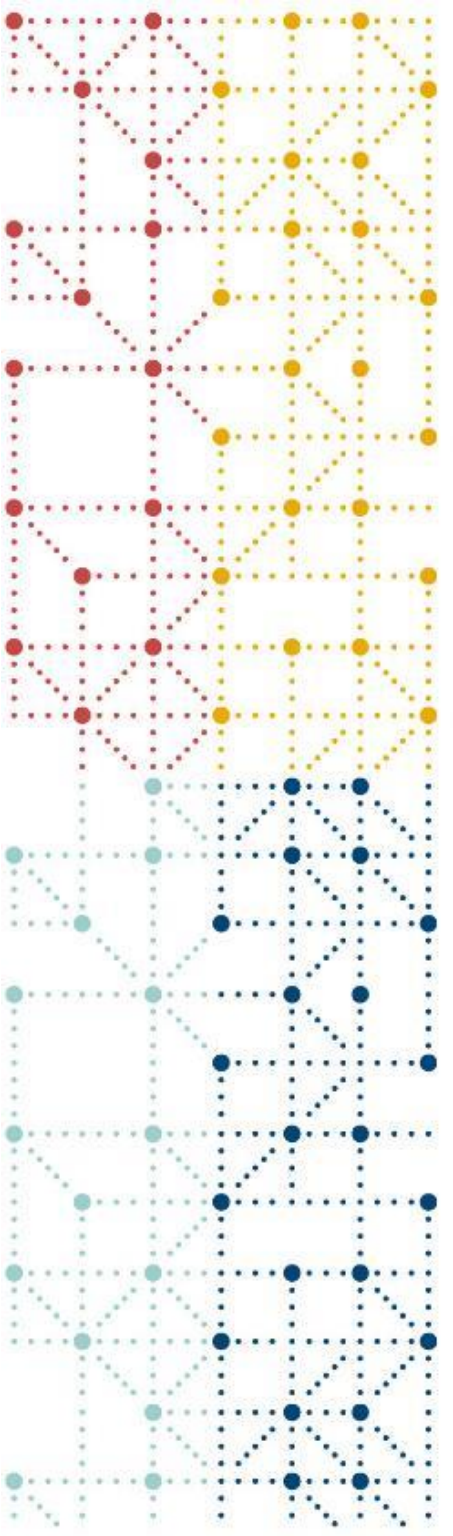


USDM in Action

Use Cases Supporting the DDF Vision

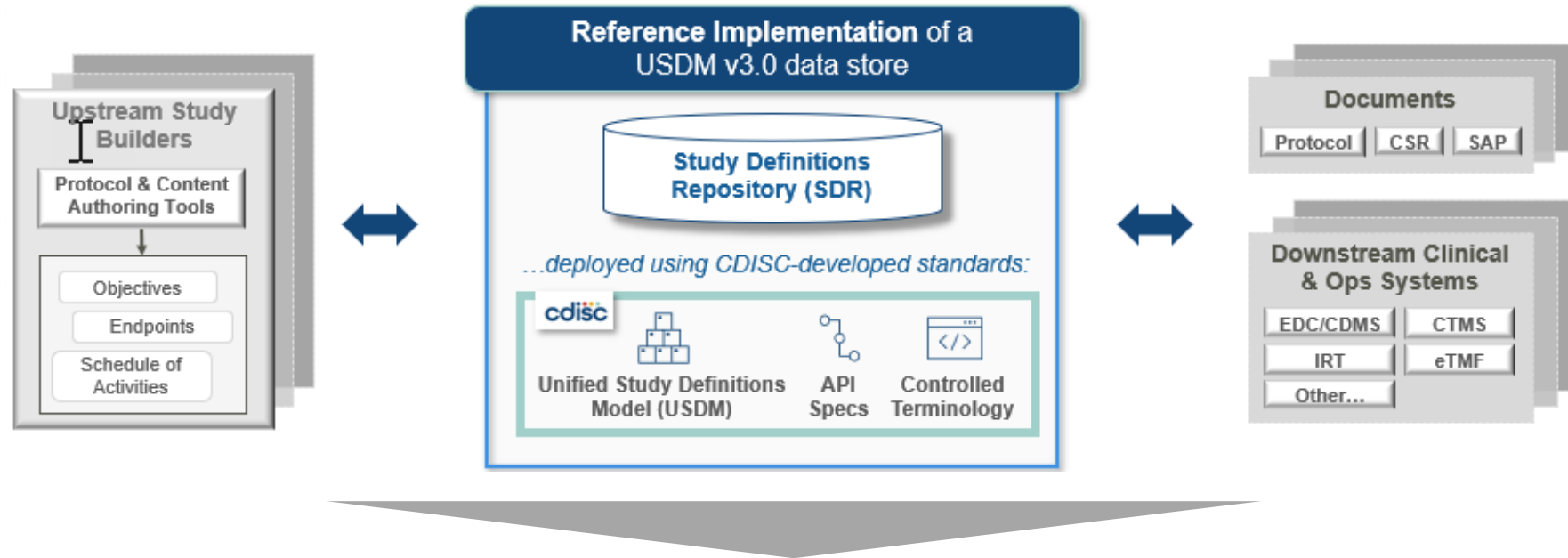


Version 3, 10th October 2024. Prepared by D Iberson-Hurst for the TransCelerate 'DDF in Action' day.
With thanks to Rob Ferendo (TransCelerate), Bill Illis (Novartis), Jasmine Kestemont (Argenx), Kirsten Langendorf (d4k), Mary Lynn Mercado (Novartis), Lisa Morgan (Amgen), Johannes Ullander (d4k) and Peter Van Reusel (CDISC)

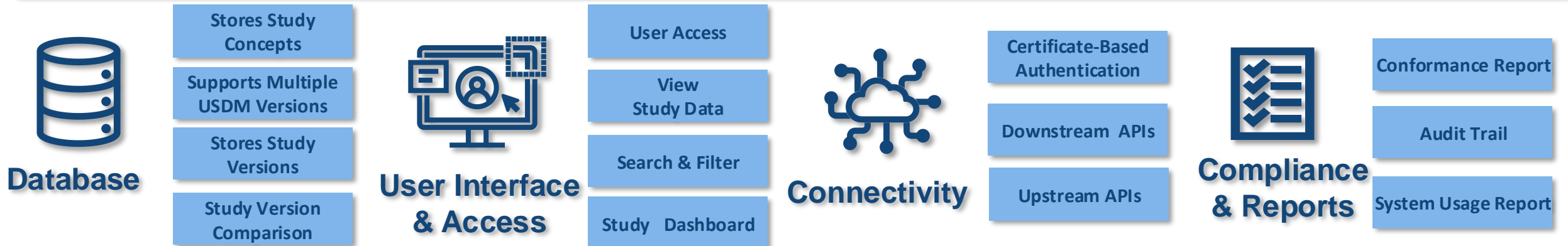


Tools / Multi-Stakeholder Change and Engagement

Technology Tools: Study Definitions Repository



Features



Tools and Resources

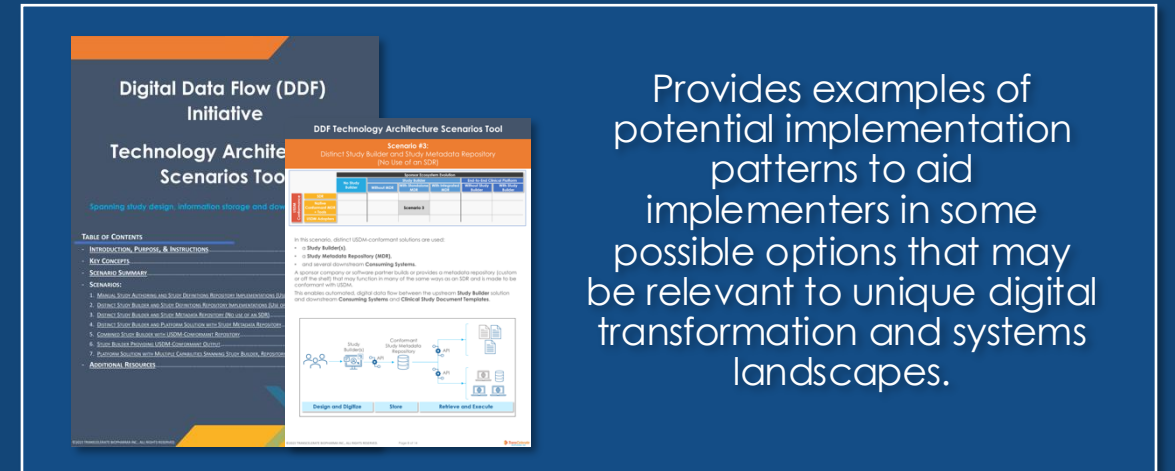
Persona Toolkits for Transformational Change

Available for Data Managers, Protocol Medical Writers, IT Leadership and IT Technical Experts



A packet of change resources that aims to help a specific persona role understand the potential impacts and changes in a DDF-enabled future state.

DDF Technology Architecture Scenarios Tool



Provides examples of potential implementation patterns to aid implementers in some possible options that may be relevant to unique digital transformation and systems landscapes.

DDF's Growing Solution Provider Engagement



1 Solution Collaboration Forum

35+ Solution Providers: focus on use cases, adoption and further development of USDM.

2 Solutions Directory

Catalog of technology products which utilize and follow the DDF Unified Study Definitions Model (USDM).

3 Solution Showcase

Quarterly Webinars – deep dive with solution providers



October 10, 2024

DDF in Action Day

Transforming Clinical Trials with Standards and Digitalization

“Continuing the Journey, Charting the Future”

Full day in-person public event with biopharma, solution providers and others held across two locations - J&J, New Jersey and Novo Nordisk, Copenhagen



Highlights

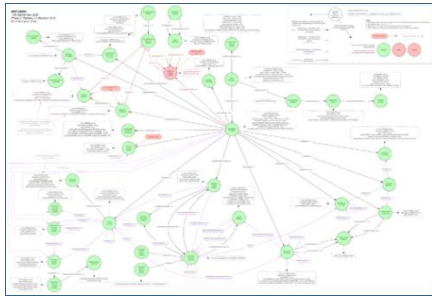
- Explore pathways and proofs of concept to implement DDF solutions
- **Agenda topics included** pharma adoption stories, use cases, solution provider poster session and panel discussion, as well as networking opportunities.
- **Two common themes** surfaced through the day:
 - Leadership engagement and organizational change management (OCM) are critical to success
 - Change is coming. Don't wait to get started

Organizations Represented

Solution Providers

- ❖ Tata Consultancy Services
- ❖ Nurocor
- ❖ NNIT
- ❖ Open-Source Study Builder
- ❖ Sycamore Informatics
- ❖ EZ Research Solutions
- ❖ PFMD and CTDN
- ❖ Contentrules and Futurpositif
- ❖ EQTY Lifesciences and ClinLine
- ❖ Data4knowledge

DDF Initiative encompasses Technical Standards & Solutions, Change Management, and Industry Engagement



cdisc
 Unified Study Definitions Model (USDM) Reference Architecture

TransCelerate's Study Definitions Repository (SDR) Reference Implementation



Suite of DDF Adoption Resources, Videos & Change Management Tools



Continued Industry Collaboration between TransCelerate, CDISC ICH, and HL7



Growing Solution Collaboration Forum (SCF)*



*Company logos illustrate current involvement and are not used to imply endorsement of specific vendors for DDF or to identify a comprehensive list of all actual or potential future participants in DDF.



What's Next?

2025 Protocol Digitization Objectives

Enable Digitization & Interoperability Of The Study Protocol Across Research & Clinical Care

Enable stakeholders to easily share digital protocol information and insights

Promote hands-on engagement with protocol digitization solutions

Educate and update stakeholders on implementation paths

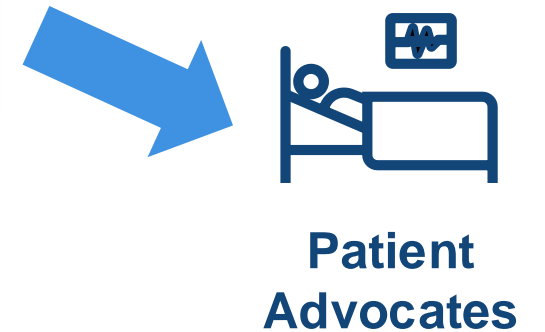
This includes:

- Release of:
 - ✓ CDISC's USDM v4 + Conformance Rules
 - ✓ Study Repository v4
 - ✓ Additional open-source tools
- Scoping for CDISC's USDM Phase 5
- Supporting and sponsoring business case development with adoption case studies.
- Organizing events, webinars, trainings to build awareness, understanding, action, commitment

What about you?

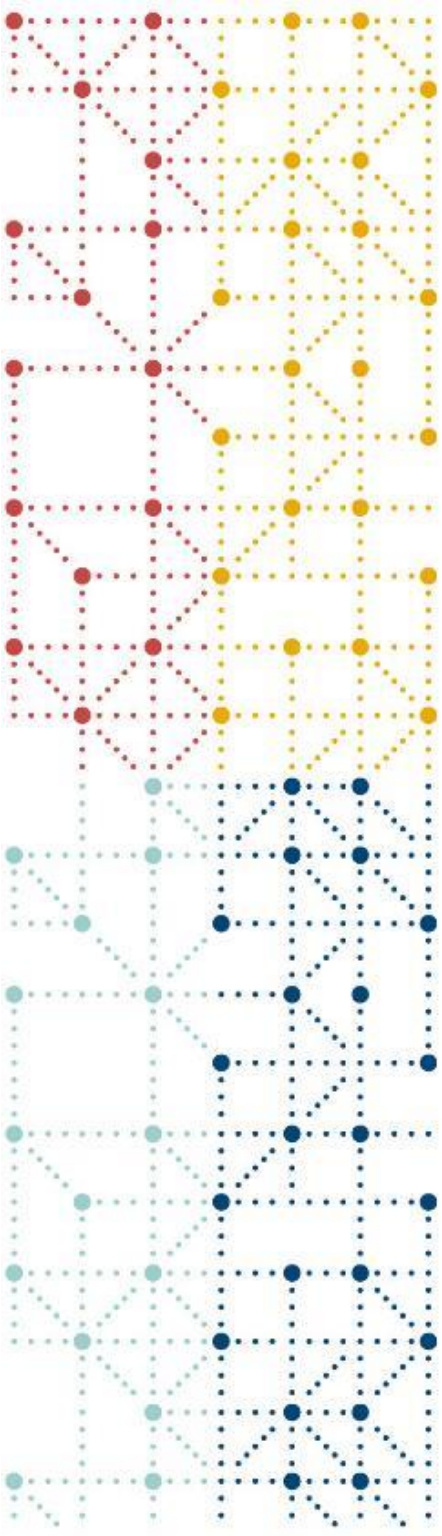


**Ask yourself –
what can I do to
support protocol
interoperability?**



Upcoming Events

2024 & 2025 Q1 Events	Date
SCOPE Europe 2024 Digital Data Flow: Digitalising Clinical Protocol Information to Accelerate Clinical Research and Enable Healthcare Interoperability	29-30 October 2024
PHUSE EU Connect 2024 PHUSE EU Connect 2024 (phuse-events.org)	10-13 November 2024
DDF Solution Showcase Webinar Series #2	5 December 2024
SCOPE US 2025 Going with the (Digital Data) Flow: Reduce Time & Effort on Study Start-Up	3–6 February 2025
PHUSE US Connect 2025 PHUSE US Connect 2025 (phuse-events.org)	16-19 March 2025



Thank You!

