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2023
US
INTERCHANGE

FALLS CHURCH, VA | 18-19 OCTOBER

Breaking the Document Paradigm from Protocol Design to Electronic Data Capture

Presented by William Illis, Novartis and Sumesh Kalappurakal, JnJ

Meet the Speakers

William Illis

Title: Global Head, Collaboration & technology Strategy, Clinical Development & Analytics

Organization: Novartis

William has led the development and implementation of a strategic technology roadmap for the Analytics team (encompassing a state-of-the-art computing environment) and initiating improvement projects at Novartis, including the integration, analysis and reporting of clinical trial data in clinical study reports and health authority submissions, good data science practices, and regulatory compliance. Since project inception, William has been the appointed workstream lead for TransCelerate BioPharma's Digital Data Flow initiative.

Sumesh Kalappurakal

Title: Sr. Director, Clinical & Statistical Programming Technology Solutions

Organization: Johnson & Johnson

Sumesh and his team are at the forefront of developing innovative solutions, employing open-source platforms such as R and Python. They focus on formulating methodologies, setting standards, and crafting web applications to cater to the portfolio requirements in clinical and statistical programming functions. Furthermore, architect a strategy to incorporate the open-source platform, "R" as an analytical tool for all clinical study submission endeavors. Sumesh leads the TransCelerate DDF Change and Engagement Team

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.*

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Agenda

1. Overview of TransCelerate's Digital Data Flow(DDF)
2. DDF Change and Engagement

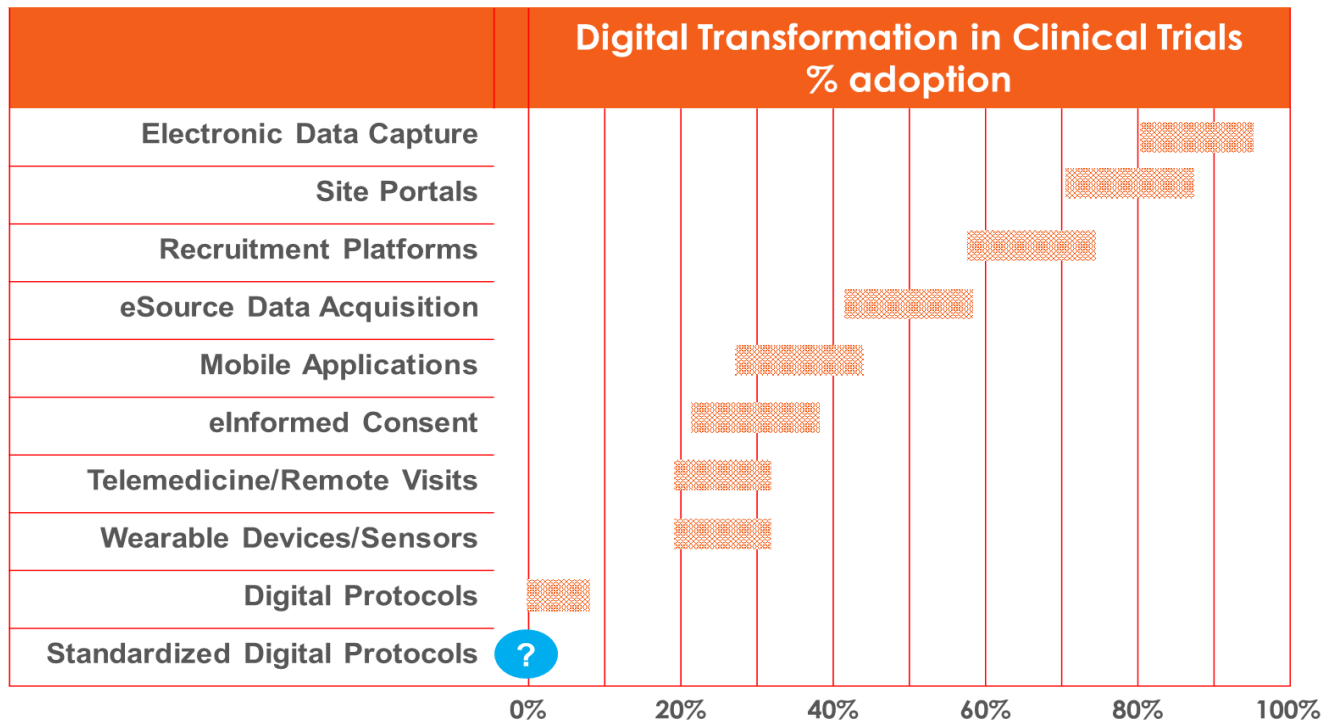# TransCelerate – A Catalyst for Collaboration

We are a not-for-profit entity created to foster collaboration. Our mission is to collaborate across the global biopharmaceutical R&D community on solutions designed to drive the efficient, effective, and high-quality delivery of new medicines.

Since inception, TransCelerate has prioritized robust collaboration with key stakeholders across the R&D ecosystem to deliver hundreds of free and publicly available solutions.

Patient Advocacy Community

Global Health Authorities

CROs, Technology & Data Providers

Industry Consortia

Clinical Research Sites and Academic Research

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.

	Digital Transformation in Clinical Trials % adoption				
	0%	20%	40%	60%	80%	100%
Electronic Data Capture					▓▓ (90%)
Site Portals					▓▓ (80%)
Recruitment Platforms				▓▓ (65%)	
eSource Data Acquisition			▓▓ (45%)		
Mobile Applications		▓▓ (30%)			
eInformed Consent		▓▓ (27%)			
Telemedicine/Remote Visits		▓▓ (22%)			
Wearable Devices/Sensors		▓▓ (22%)			
Digital Protocols	▓▓ (5%)				
Standardized Digital Protocols	**?**				

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Digital Data Flow Ambition

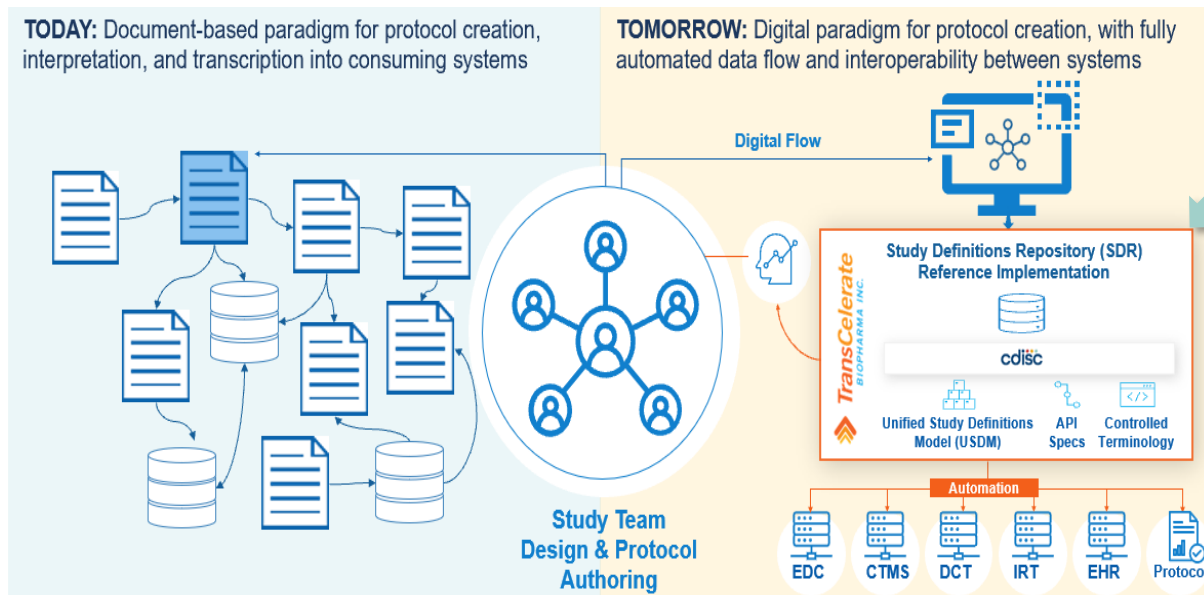**Digital** – standard representation of study protocol
- ✓ structured
- ✓ machine readable
- ✓ executable

Data Flow – industry-wide interoperability
- ✓ exchange of data
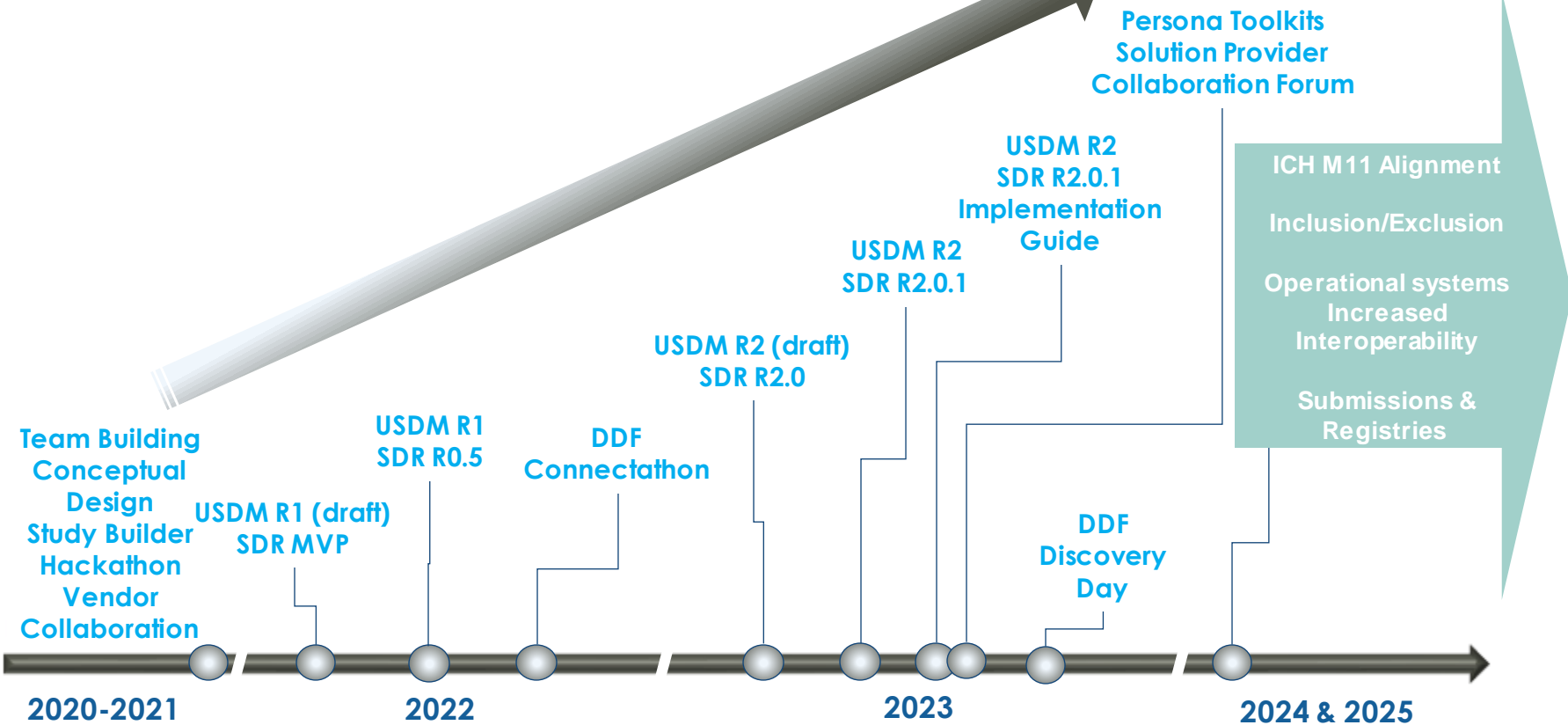- ✓ non-cooperating organizations
- ✓ minimal effort

**Eliminate non-value added activities, work smarter not harder
Enable automation of downstream study startup and conduct processes
Create foundation for study design analytics insights**

DDF Progress Timeline

Team Building
Conceptual Design
Study Builder
Hackathon
Vendor Collaboration

USDM R1 (draft)
SDR MVP

USDM R1
SDR R0.5

DDF Connectathon

USDM R2 (draft)
SDR R2.0

USDM R2
SDR R2.0.1

USDM R2
SDR R2.0.1
Implementation Guide

Persona Toolkits
Solution Provider
Collaboration Forum

DDF Discovery Day

ICH M11 Alignment

Inclusion/Exclusion

Operational systems
Increased Interoperability

Submissions & Registries

2020-2021   2022   2023   2024 & 2025

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Where are we going next?
Key Focus Areas on the Digital Data Flow Roadmap

Complete Protocol Digitization & Regulatory Alignment (Coming early 2024)
Includes collaboration through the Vulcan Working Group between ICH M11 & CDISC

- Complete (100%) digitization of all protocol elements in alignment with M11 and relevant CDISC SDTM domains

Expand Downstream Connectivity (In Progress)
Includes collaboration with expanding community of tech solution providers across range of clinical solutions

- Further develop USDM to enable downstream connectivity with priority systems, enabling a future state of "write once, read many times"

Alignment with Point of Care (In Progress)
Includes collaboration with Vulcan FHIR Accelerator

- Alignment of DDF and FHIR resources for end-to-end enablement of EHR workflow set-up and eSource

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The DDF Initiative is focused on global transformation

DDF Technical Solutions

Unified Study Definitions Model (USDM) v2.0 – developed with CDISC; this is an industry standard for specifying and structuring study definitions (design & protocol information) in a digital, machine-readable format promulgated and maintained by CDISC.

Study Definitions Repository (SDR) v2.0.1 – Type of repository that is conformant with USDM and acts as a functioning, example approach to store protocol information and connect other producing and consuming systems to achieve interoperability. Source code is available under an open-source license.

DDF Change & Engagement

Sponsor Engagement

Health Authority Engagement

Solution Provider Engagement

Communications & Pulse on Industry

Sponsor Engagement on DDF

2023 Focus: Provider tools and resources for sponsor roles to overcome the change curve

Persona Toolkits
(released in July 2023)

The DDF Persona Toolkits are developed to help specific personas understand and better prepare for how to adapt their role and responsibilities to new ways of working within an automated and digitalized study lifecycle.

Toolkit components include:
- DDF Initiative Overview
- Toolkit Overview
- Persona Profile Card
- DDF Change Impacts
- "Day in the Life" with DDF

Explore the DDF GitHub:
[Home | Digital Data Flow (transcelerate.github.io)](transcelerate.github.io)

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Engaging with solution providers on DDF

2023 Focus: Continue to grow the momentum and greater engagement with tech solution providers following the 2022 Connectathon

SCAN QR Code to Get Involved

Solution Collaboration Forum
(Kicked-off in July 2023)

- Contribute technical and industry expertise, providing input for DDF's next development phase
- Expand DDF use cases to enable greater sponsors and tech solution providers participation and collaboration
- Apply collective provider engagement and enthusiasm in open forum discussions on the DDF GitHub

Current Participation:

Castor EDC	*Tryal Clinical*	*ArborSys*	*Target Health*
Faro Health	*Merative*	*Trials.AI by ZS*	*Medidata*
Oracle	*RedCap Cloud*	*Intellinotion*	*Nurocor*
Pharmaseal	*CGD Health*	*Sycamore Informatics*	*TriNetX*
Medable	*Indegene*	*Thread Research*	*Novo Open-Source Study Builder*
Formedix	*Saama*	*TaiMei Clinical*	

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DDF Discovery Day
September 2023

Sponsors and providers coming together to embrace the "art of the possible"

Event Objectives

- Hands-on Solution Showcase demonstrating practical applications of DDF solutions by the clinical solution provider community

- Openly discuss transformational enablers, change management barriers, and other potential hurdles to adoption

- Deliver better understanding of the future roadmap for DDF and its convergence with other ecosystem initiatives

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Lilly astellas Johnson&Johnson AstraZeneca

ucb REGENERON VULCAN HL7 FHIR

- Indegene
- Medable
- Merative
- Novo Open-Source Study Builder
- Nurocor
- Sycamore Informatics
- Trials.ai by ZS

SHIONOGI Roche MERCK

abbvie Pfizer novo nordisk GSK

Bristol Myers Squibb

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Health Authority Engagement Goals & Priorities

	Focus	Opportunistic
1 Deepen relationships & HA understanding of DDF	FDA, EMA, PMDA JAPAN	Other HAs
2 Identify HA rep to actively participate on the DDF team	FDA	EMA, PMDA JAPAN
3 Explore a pilot project collaboration to demonstrate DDF's value to regulators	FDA	EMA, PMDA JAPAN

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DDF Upcoming Events

Major/ Interactive Event ◆   General Awareness ●   Virtual option available ▲
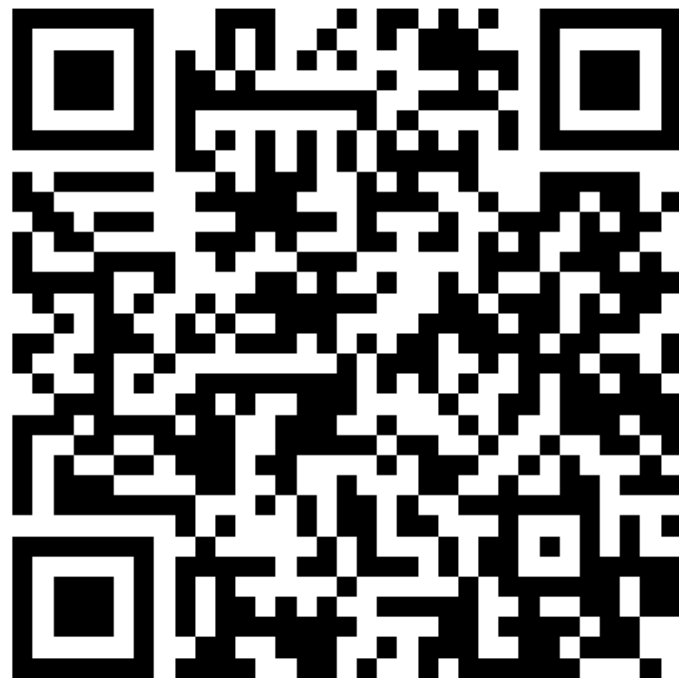
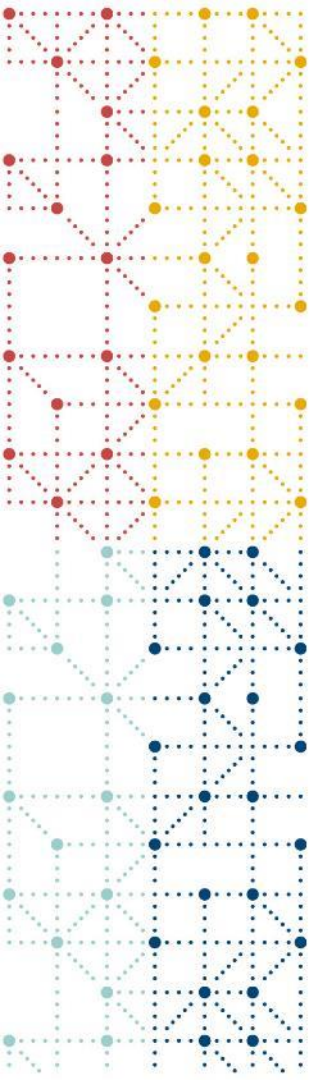| Upcoming Events of 2023	Date
eClinical Forum Americas ● Janssen in Spring House, PA USA North America Meetings - eClinical Forum	24-26 October 2023
PHUSE EU Connect ◆ (TCB sponsored DDF hands-on workshop in collaboration with CDISC) Birmingham, UK PHUSE EU Connect 2023 | CDISC	5-8 November 2023 *(workshop on Nov 5th)*
DIA Japan Annual Meeting 2023 ● Ariake Central Tower Hall DIA Japan 2023 - About DIA Japan 2023 (diaglobal.org)	5-7 November 2023
TransCelerate DDF Webinar ▲ Modernizing Clinical Trials Using Digitized Protocol Information: An Exploration of New Tools for Digital Transformation	13 December 2023 10-11 AM EST
Anticipated Events for 2024	**Date**
SCOPE 2024 ●	11-14 February 2024
PHUSE US Connect 2024 ◆	25-28 February 2024

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How to Get Involved with DDF?

Scan QR Code to explore DDF GitHub

- Check out the CDISC USDM

- Download the SDR source code

- Upscale your knowledge with the DDF short educational videos

- Download the persona toolkits

- Contribute and interact on the open discussion forums

- Signup for the DDF Newsletter

- Get involved in the discussion page

https://transcelerate.github.io/ddf-home/

GitHub

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Thank You!

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