TransCelerate Digital Data Flow: An Update on DDF Phase 2

Mikkel Traun, Novo Nordisk A/S
Vijay Reddi, Roche Products Ltd.

Meet the Speakers

Vijay Reddi

Title: Regulatory Transformational Lead

**Organization:** Roche Products Ltd

Vijay leads a team which is transforming the Regulatory landscape towards a digital state and has over 20 years' experience in the pharmaceutical industry. Vijay started his career as a statistician, moving into statistical programming and has led teams in oncology and inflammation. A current passion is being a team member of TransCelerate Digital Data Flow within the governance subteam which is focused on delivering a uniform approach model for clinical trials.

Mikkel Traun

Title: Principal System Developer

Organization: Novo Nordisk A/S

Mikkel is one of the product owners for the next generation study builder and data standards repository solution at Novo Nordisk. Mikkel is also an active member of the TransCelerate and CDISC Digital Dataflow project, and previously the CDISC 360 project. He has worked as a principal system developer supporting the clinical data warehouse solution and the CDISC implementation at Novo Nordisk. Previously he has worked on several projects in pre-clinical, clinical and outcome research.
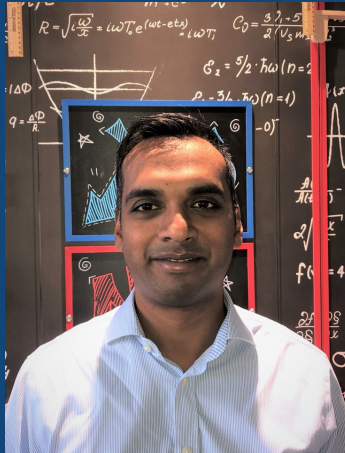
Who is TransCelerate BioPharma Inc.?

A nonprofit entity created to foster collaboration. Our mission is to collaborate across the global biopharmaceutical R&D community to identify, prioritize, design, and facilitate the implementation of solutions designed to drive the efficient, effective, and high-quality delivery of new medicines.
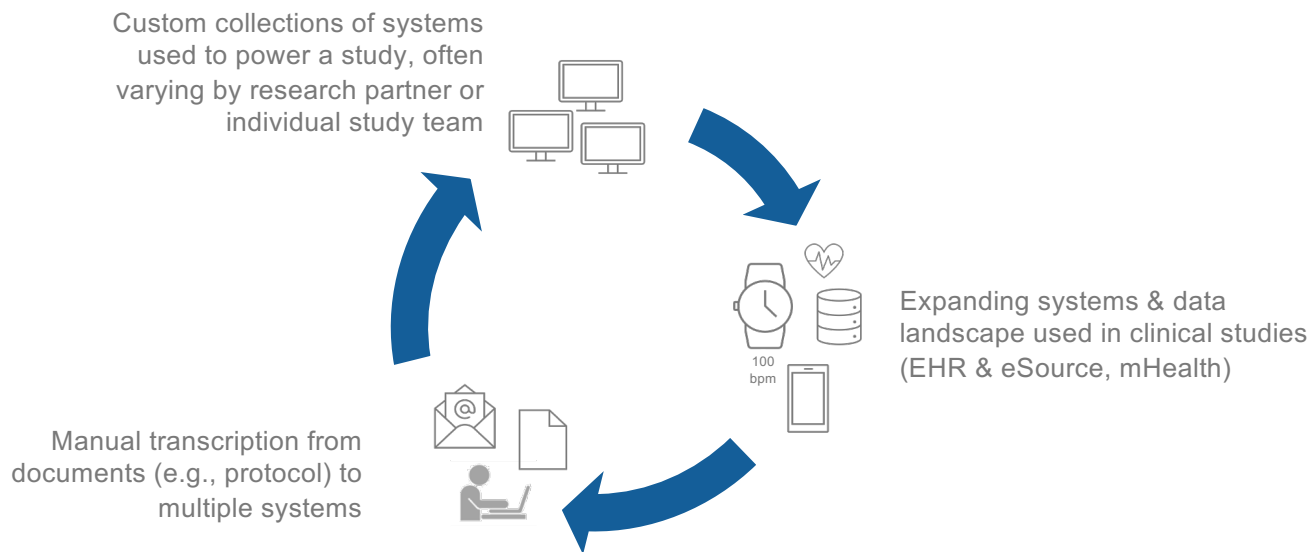
Our Members are passionate about designing solutions to address R&D's most complex challenges related to clinical development & drug safety.

Membership is available to biopharmaceutical research and development organizations that engage in innovative discovery, development and manufacturing of new medicines*

Bristol Myers Squibb™
Johnson&Johnson
AMGEN
Merck KGaA
Darmstadt, Germany
BAYER
Boehringer Ingelheim
abbvie
astellas
gsk
AstraZeneca
novo nordisk®
ucb
Lilly
MSD INVENTING FOR LIFE
Roche
Pfizer
SANOFI
REGENERON SCIENCE TO MEDICINE®
NOVARTIS
SHIONOGI

The Challenge

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.

Custom collections of systems used to power a study, often varying by research partner or individual study team

Expanding systems & data landscape used in clinical studies (EHR & eSource, mHealth)

Manual transcription from documents (e.g., protocol) to multiple systems

100 bpm

TransCelerate is part of a journey to break down barriers to industry transformation
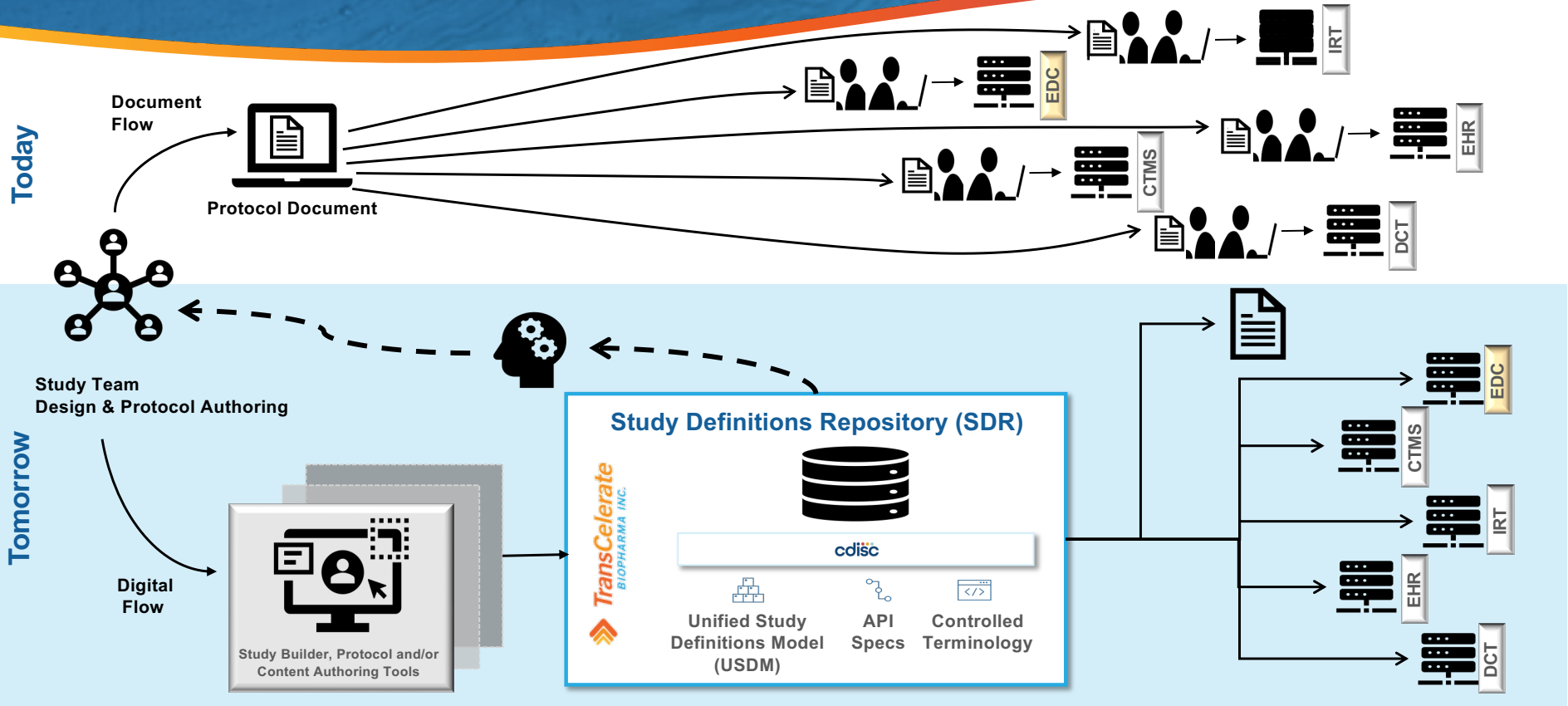
Document-focused

Isolated processes

Manual re-entry

Long time lags

Clinical Data Standards Collaborated with CDISC on standards to support exchange of data and metadata

eCPT: Begin Protocol Digitization Introduced structured content within MSWord

eCPT spurred ICH M11 protocol template & technical exchange specification

TransCelerate DDF Hackathon Engage vendor community in demonstrating viability

Collaborative Development of a standards-based study definitions repository a common foundation for industry-wide interoperability

Common Protocol Template (CPT) Harmonized structure, proposed model text, streamlined format

Clinical Template Suite Add SAP & CSR, enable automated content reuse

Digital Data Flow Solution Framework & Conceptual Design Vision for vendor agnostic data flow

Vision on pathway to Digital Data Flow Multi-stakeholder collaboration to create a vendor-agnostic, standards-based technology accessible via an open-source Reference Implementation

Data driven

Connected processes

Automated reuse

Parallel processing

Clinical Study Protocol – Digitization & Data Flow
Enabling Downstream Automation and Analytic Insights

Today

Document Flow

Protocol Document

EDC

IRT

EHR

CTMS

DCT

Tomorrow

Study Team Design & Protocol Authoring

Digital Flow

Study Builder, Protocol and/or Content Authoring Tools

Study Definitions Repository (SDR)

TransCelerate BIOPHARMA INC.

cdisc

Unified Study Definitions Model (USDM)

API Specs

Controlled Terminology

EDC

CTMS

IRT

EHR

DCT

The Digital Data Flow Initiative (DDF) aims to catalyze digital transformation; breaking the document paradigm to enable seamless flow of the data within

Digitized Protocols

Enabling the use of technologies that identify and assemble study elements allows industry to move to digital protocols

Connectivity of Data and Processes

Enabling traceability, automated flow of content to key clinical documents, and automation to clinical & operational systems (e.g.. EDC, CTMS)

Advanced Analytics

Better enabling the use of advanced analytics such as Artificial Intelligence and Machine Learning to improve study designs

Open and Flexible Solution

Developing a dynamic, fully automated solution that is vendor agnostic, open and flexible

---

Development principles to enable broad collaboration, stakeholder input, and sustainability

- Open Source
- Vendor Agnostic
- Agile Development
- Dynamic Alignment to Standards

Minimum Viable Product (MVP) Development Complete
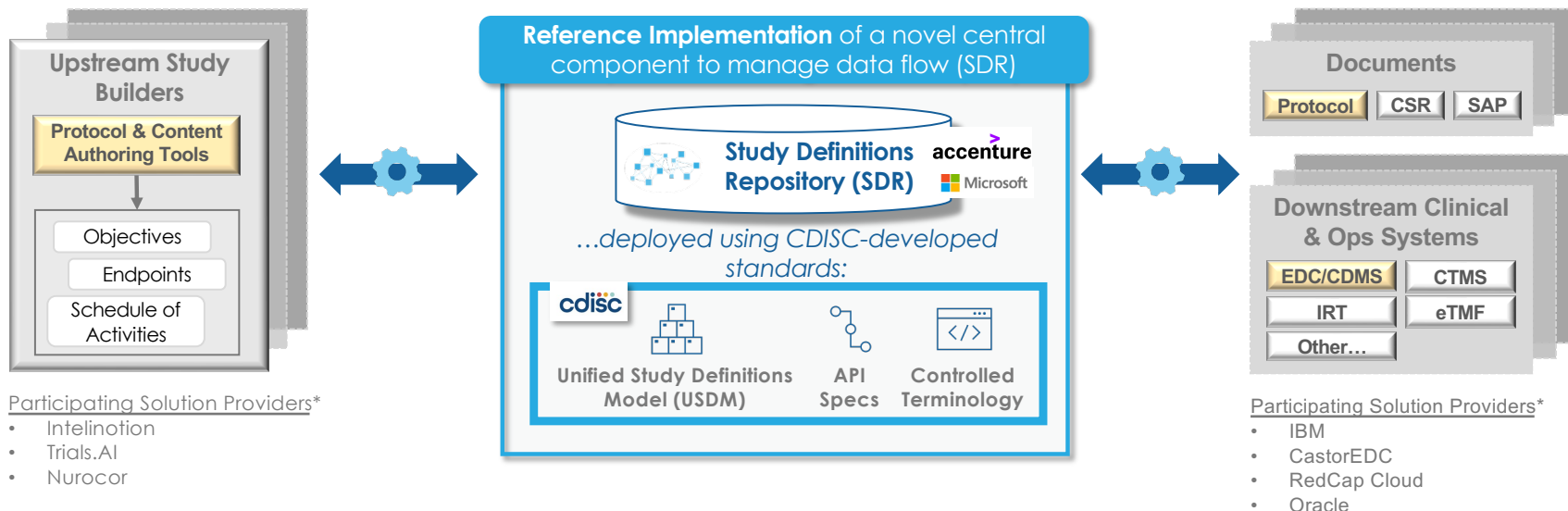April 2022 Release

Open Source	Vendor Agnostic	Agile Development	Dynamic Alignment to Standards

Upstream Study Builders

Protocol & Content Authoring Tools

↓

Objectives

Endpoints

Schedule of Activities

Participating Solution Providers*
- Intelinotion
- Trials.AI
- Nurocor

Reference Implementation of a novel central component to manage data flow (SDR)

Study Definitions Repository (SDR)

accenture

Microsoft

...deployed using CDISC-developed standards:

cdisc

Unified Study Definitions Model (USDM)

API Specs

Controlled Terminology

Documents

Protocol | CSR | SAP

Downstream Clinical & Ops Systems

EDC/CDMS | CTMS

IRT | eTMF

Other…

Participating Solution Providers*
- IBM
- CastorEDC
- RedCap Cloud
- Oracle

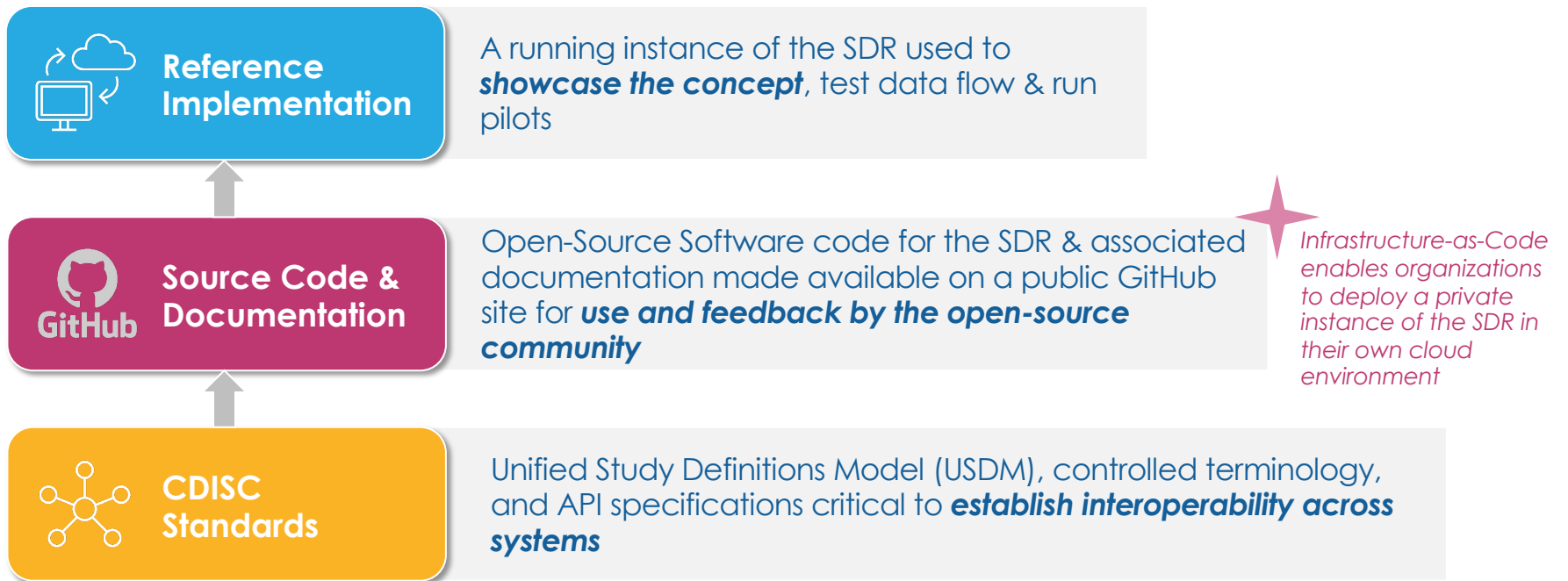**KEY**

System or Tool of Focus for MVP | Potential Future System of Focus

* Solution Providers above have volunteered to participate in DDF design/development in anticipation of making use of DDF solutions in the future. Additional Solution Providers are currently in discussion with TransCelerate. TransCelerate does not endorse nor recommend specific vendors to enable DDF.
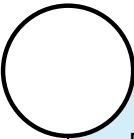
DDF Assets Available Now

Assets available under a permissive open-source license to explore DDF in practice
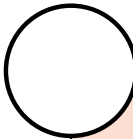
Reference Implementation

A running instance of the SDR used to **showcase the concept**, test data flow & run pilots

Source Code & Documentation
GitHub

Open-Source Software code for the SDR & associated documentation made available on a public GitHub site for **use and feedback by the open-source community**

Infrastructure-as-Code enables organizations to deploy a private instance of the SDR in their own cloud environment

CDISC Standards

Unified Study Definitions Model (USDM), controlled terminology, and API specifications critical to **establish interoperability across systems**

DDF Connectathon - Overview and Purpose

We tailored the event to invite a wide range of innovative solutions
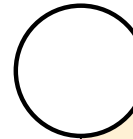
We set out to create an event where we could accomplish all the following:

Innovation
Provide the resources for organizations to expand the application of DDF technology.

Collaboration
Encourage

Feedback
a.

258
Participants

123
Organizations

Organization Category	Organization Count	Participant Headcount
Clinical Solution Vendor	28	62
Non-Member Company Sponsor	20	22
Consulting	18	49
Member Company Sponsor	16	68
General Technology Vendor	16	20
Clinical Research Organization (CRO)	14	22
Academic	11	15

Project Categories and Evaluation Criteria

Categories and criteria were designed to focus on event outcomes

Project Categories
Data Interoperability   Of the complete set of data elements within the USDM, how many elements are you able to store and transfer (up and/or down)
User Interface/Experience   Demonstrates solution features around displaying relevant data in an easy to use and understand format
Analytics/Reporting   Demonstrates solution features focused on performing background analysis of relevant DDF data
Supplemental Data and Standards   Demonstrates solution features dedicated to layering additional data or incorporating additional standards in addition to what is described with the USDM
Process Automation   Demonstrates solution features related to workflow and process automations, both for input and output of the solution
SDR Host Migration   Proven ability to migrate, deploy, validate and successfully connect to a hosted SDR instance on a novel system architecture

Evaluation Criteria
Data Coverage   How much of the total set of data elements were you able to transfer?
Executed Integrations   How many integrations to foreign systems were you able to practically demonstrate?
Personas Impacted   How many of the expected user persona workflows does your solution improve?
Technical Implementation   How elegantly is your solution technically implemented/executed in its current state?
Solution Usability   How user friendly is your solution, based on the understanding of the end user?
Open Innovation   How well does your solution capitalize on innovative and emerging technologies/ideas?

Final Project Submissions

Our team is encouraged by the variety and quality of submitted projects

Over the course of the event, we had 15 projects drafted and submitted for final judging...

Bioveras	Deloitte	Intelinotion	Trials.ai	C&R Research
"Patient Screening with DDF"	*"CognitiveSpark for Clinical"*	*"Intelinotion: Interactive Study Definitions Form"*	*"Trials.ai"*	*"Verifying Metadata Schema For Study Protocols"*
ZS Associates	**Nurocor**	**EvidentIQ**	**Oracle**	**Sycamore Informatics**
"SOA Optimization With DDF"	*"NCP Connector To SDR"*	*"Constraint Modeling with Schemas"*	*"SDR Driven EDC/IRT/Analytics Study Setup Automation"*	*"Accelerate Study Startup with Structured Protocol Authoring"*
Indegene	**Novartis**	**Novo Nordisk + EvidentIQ + Neo4J + RedCap Cloud**	**Oracle + Nurocor**	**Trials.ai + Merative**
"Analysis & Automation of Protocol Submissions Using DDF"	*"Digital Protocol to Automate/Digitize the Clinical Trials"*	*"Open Study Builder"*	*"API Enabled Interoperability & Digital Data Flow Automation"*	*"Study Design To EDC in 4 Easy Steps"*

Thank you to all project submitters. On behalf of the entire DDF team, we are extremely impressed with the quality and originality of your work and look forward to working with you all as part of the larger DDF community!

TransCelerate Public Webinars

Change Enablement Support for the R&D Ecosystem

NEW WEBINAR ANNOUNCEMENT:

Digital Data Flow (DDF): Connectathon Results and Outcomes

DATE & TIME:

NOVEMBER 1, 2022, 11:00 AM – NOON ET

PRESENTATION OVERVIEW:

TransCelerate's Digital Data Flow (DDF) initiative aims to transform clinical studies by enabling end-to-end digital exchange of study definition information. The DDF Initiative recently hosted a three-week Connectathon event to experiment and demonstrate how stakeholder applications integrate and deploy the CDISC Unified Study Definitions Model (USDM) and the connectivity and interoperability of these applications to the Study Definitions Repository Reference Implementation (SDR RI).

By attending this webinar, you will: 1. Hear an overview of the DDF Connectathon, participants, and what the Connectathon entailed **2.** Learn about the innovative solutions, demonstrations, and experiment outcomes related to the SDR RI and the DDF system.

IDEAL ATTENDEES:

- **Functional and Technology Vendors involved in clinical trials**
- **Sponsors and CROs**

R&D Ecosystem Learning

This is a unique and free learning opportunity. Session are open to anyone interested in learning about this TransCelerate topic.

Insights into Action

Webinars are led by subject matter experts. Their insights could aid your organization in making decisions on how best to leverage TransCelerate solutions.
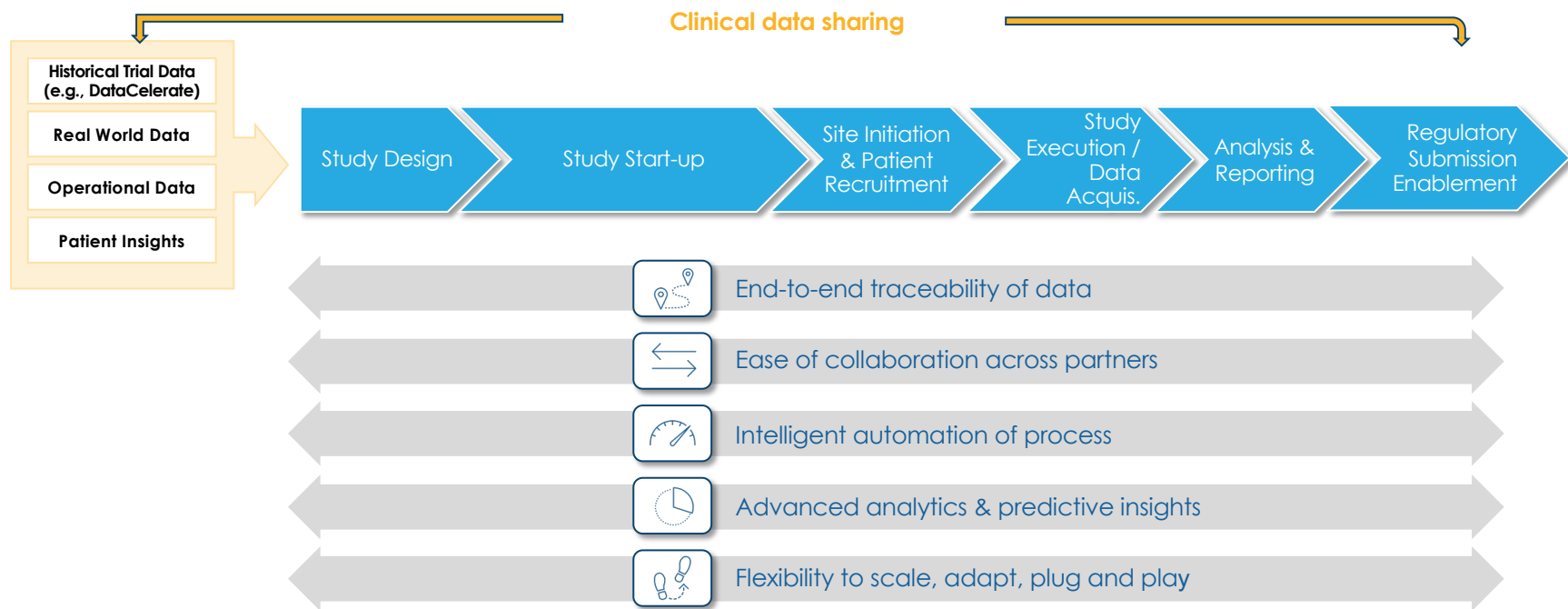
Secure your Spot Now!

Sign up here

Future Roadmap: Digital Data Flow Across the Study Lifecycle

Breaking the Document Paradigm to Catalyze End-to-End
Digital Transformation

Clinical data sharing

Historical Trial Data
(e.g., DataCelerate)

Real World Data

Operational Data

Patient Insights

Study Design

Study Start-up

Site Initiation
& Patient
Recruitment

Study
Execution /
Data
Acquis.

Analysis &
Reporting

Regulatory
Submission
Enablement

End-to-end traceability of data

Ease of collaboration across partners

Intelligent automation of process

Advanced analytics & predictive insights

Flexibility to scale, adapt, plug and play

* "Study definitions data" describe the design & definition of a study and include information such as objectives, endpoints, schedule of activities, I/E criteria, or other information typically found in a protocol document

What is Next For Digital Data Flow in 2023
Downstream Automation

The next phase of work will focus on reaching a tangible value proposition both for sponsor companies/CROs and for technology vendors:
- Greater automation of downstream system set-up through collaboration across the EDC, study builder, and broader technology community
- Expanded support for complex study types
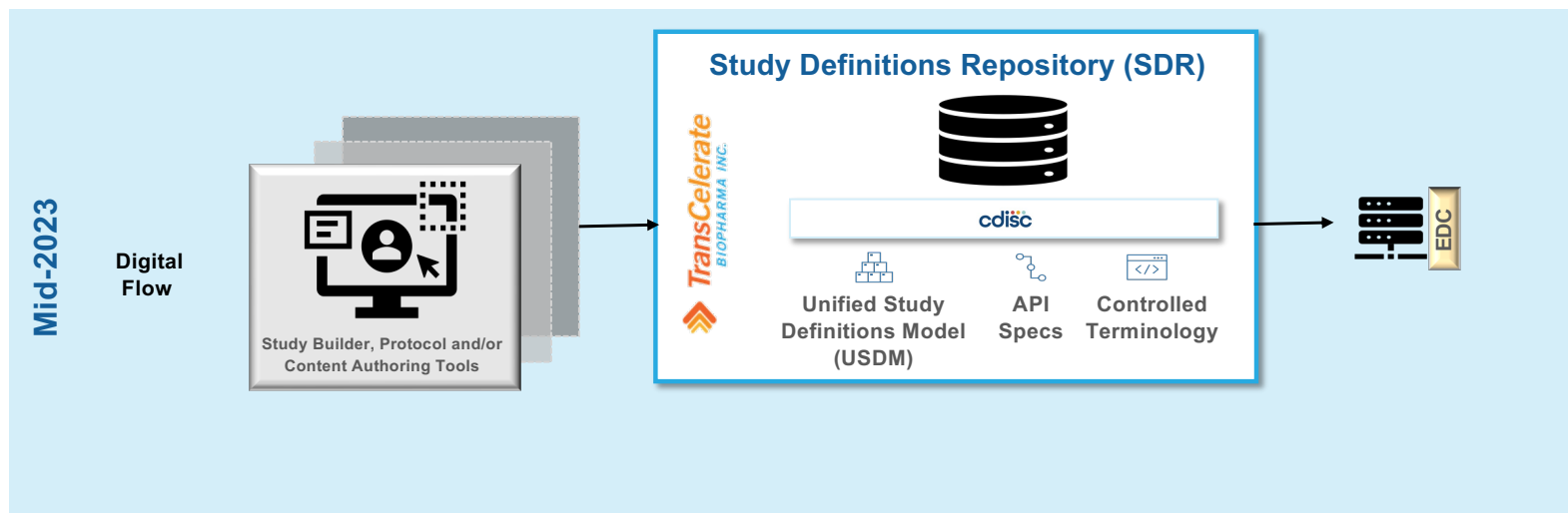
Thank You

Questions? Email DDF at
DDF@transceleratebiopharmainc.com

Learn more on the collaborative Digital Data Flow solution at the DDF website.