TransCelerate Digital Data Flow (DDF)

Mission Possible!

Practical Approaches for Protocol Digitalization

EVENT SUMMARY REPORT

An interactive in-person event involving sponsor companies, clinical solution providers, and key industry stakeholders to exchange knowledge and ideas with peers on the implementation of digital protocol, standards & solutions.

Hosted at Novartis in New Jersey, USA and Roche in Basel, Switzerland

September 24-25, 2025

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Realizing a future with a digitized clinical study protocol with automated data flow and streamlined analytics insights

EXECUTIVE SUMMARY

Digital Data Flow (DDF) Mission Possible showcased some practical approaches for protocol digitalization. The event brought together industry leaders, experts, and stakeholders to discuss and share advancements in applying digital data flow solutions and their impact on clinical trials & across the industry.

This event was co-hosted in the United States & Switzerland by two sponsor companies, Novartis and Roche, respectively. It was structured to allow simultaneous live-streaming of several sessions, including the sharing of three additional Adoption Stories, and panel discussions about the Future of Protocol Digitalization, and Learnings from Early Adopters.

DDF Mission Possible also featured a solution showcase, where solution providers presented technology solutions for digital data flow and protocol digitalization via a poster session.

Throughout the event, various topics were discussed and shared, such as an overview of DDF, updates on CDISC's Unified Study Definitions Model (USDM), efforts to foster industry-wide collaboration for increased impact, and an introduction to some potential "Use Cases" designed to inspire stakeholders to innovate.

To support further engagements, this event featured breakout sessions that focused on three topics of interest: Change Management Strategy & Approach for Protocol Digitalization, DDF from Ideation to Implementation, and AI in Protocol Digitalization.

DDF Mission Possible highlighted the advancements made in developing solid building blocks for protocol digitalization to realize digital data flow and interoperability across the biopharma industry.

Event attendees had positive feedback across both sites and look forward to next year's event.

Please Note: TransCelerate does not endorse, certify or recommend any solution provider or product. All adoption or use of any solution, deliverable, standard, technology, product, or vendor is purely voluntary.

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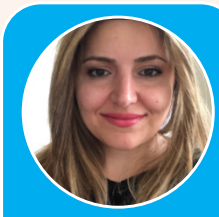

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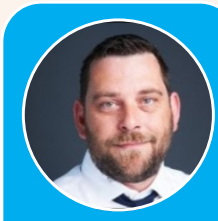

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ATTENDANCE COMPOSITION

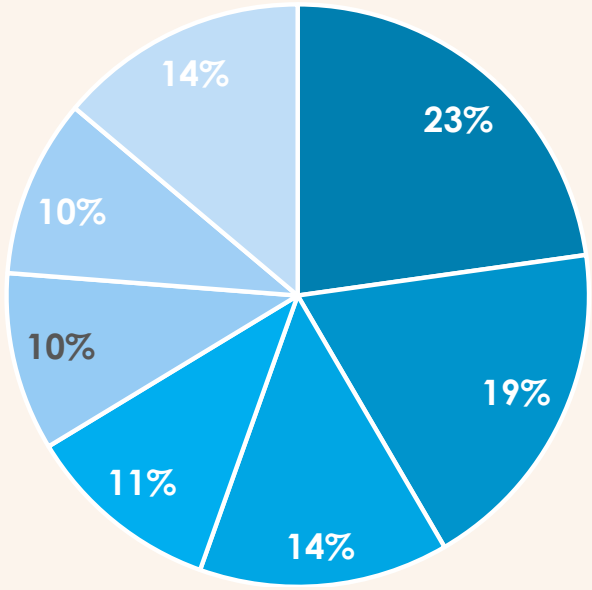
240 Global Attendees

28 Biopharma Companies

40 Solution Providers

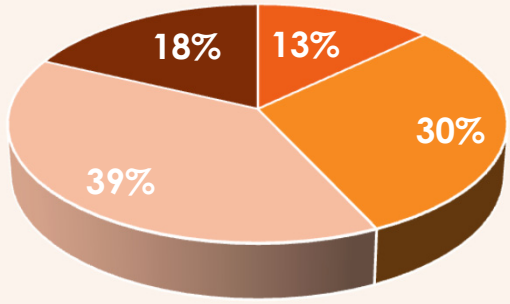
7 Other Industry Stakeholders

Functional Representation*



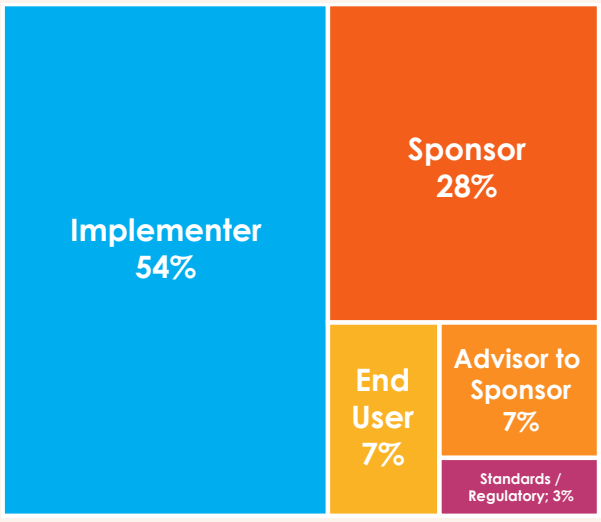
- Analysis & Reporting
- Clinical Operations
- Data Management
- Information Technology
- Medical Writing
- Standards & Governance
- Other

Familiarity with DDF (Pre-Event)*



- Not Familiar
- Slightly Familiar
- Moderately Familiar
- Very Familiar

Role Types



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PARTICIPATING COMPANIES

■ Sponsor Company (blue) ■ Clinical Solution Provider (magenta) ■ Other Stakeholders (green)
❖ Basel, Switzerland ◆ New Jersey, United States

- ❖ ◆ AlphaLife Sciences
- ◆ Amazon
- ◆ Ambassador Stealth eClinical
- ❖ ◆ Amgen
- ❖ argenx
- ❖ ◆ Astrazeneca
- ❖ ◆ Bayer
- ◆ BeOne Medicines
- ❖ BioMarin
- ❖ ◆ Boehringer Ingelheim
- ❖ ◆ Bristol Myers Squibb
- ❖ ◆ CDISC
- ❖ CLINIV HEALTH TECH
- ◆ ClinLine
- ◆ Content Rules, Inc.
- ❖ data4knowledge ApS
- ◆ Dauntless eClinical Strategies
- ◆ Decision Analytics
- ◆ DNAnexus
- ◆ Eli Lilly
- ❖ EMA (European Medicines Agency)
- ◆ Ephicacy Consulting Group
- ❖ Eraneos
- ◆ ESPERO
- ◆ Faro Health
- ◆ FDA (U.S. Food and Drug Administration)
- ◆ Florence Healthcare
- ❖ GARDP
- ◆ Gilead Sciences
- ❖ ◆ GlaxoSmithKline
- ◆ HumanTrue
- ◆ ICON
- ❖ Institut de Recherche Pierre Fabre
- ◆ Isha Health
- ◆ Johnson & Johnson Companies
- ❖ Katja Glass Consulting
- ❖ ◆ Medidata Solutions
- ◆ Memorial Sloan Kettering Cancer Center
- ◆ Merative
- ❖ Merck KGaA
- ❖ ◆ Merck Sharp & Dohme
- ❖ ◆ Novartis
- ❖ ◆ Novo Nordisk
- ❖ ◆ Nurocor
- ❖ ◆ ONWARD Health Research
- ◆ Organon
- ◆ Otsuka
- ❖ ◆ PA Consulting
- ◆ Pfizer
- ❖ ◆ PHARMASEAL International Limited
- ❖ Pierre Fabre
- ❖ Pistoia Alliance
- ◆ PKR Health and Life Sciences
- ◆ Regeneron
- ◆ Rider Clinical
- ❖ Risklick
- ❖ Rivia
- ❖ ◆ Roche
- ❖ RWS Group
- ◆ Sanofi
- ❖ Shionogi
- ◆ Simulations-Plus
- ❖ ◆ Sycamore Informatics
- ❖ ◆ Syneos Health
- ◆ Takeda Pharmaceuticals
- ❖ ◆ Tata Consultancy Services
- ❖ Teckro
- ◆ ThoughtSphere
- ◆ Trialynx
- ❖ ◆ UCB
- ❖ University Hospital Basel
- ◆ Verily
- ◆ Vertex Pharmaceuticals
- ◆ Zelta
- ❖ ZS Associates

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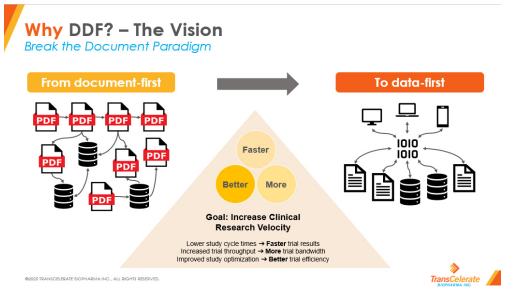
DIGITAL DATA FLOW OVERVIEW

An overview of DDF, USDM and connecting partnerships was provided to set the stage for the event agenda.

Digital Data Flow (DDF) Initiative Overview

DDF looks to emphasize the transition of clinical research from document-based to data-driven processes, in order to accelerate trials, enhance operational efficiency, and promote collaboration.

Important advancements involve USDM publications, harmonization with global standards, and cutting-edge technologies. The approach focuses on collaboration, managing change, and training to ensure DDF implementation is both feasible and scalable.



NOTE: For more information: https://transcelerate.github.io/ddf-home/index.html.

CDISC USDM Overview & Update

A stable version of USDM is now available:

- ICH M11 guideline & USDM v4 technical specification are aligned
- USDM enables machine-readable protocols, API-based data exchange, and automation throughout the clinical trial lifecycle
- CDISC AI Innovation Challenge is building a USDM-centric digital library to improve access to reusable protocol content
- Ongoing collaboration & continuous improvement are driving the expansion of digital protocol standards in clinical trial design.

NOTE: Information is readily available on https://cdisc.org/ddf.

Catalyzing Connections to Amplify Impact

There is ongoing and continued expansion of collaboration across initiatives, aiming to integrate and align solutions like:

- CDISC USDM
- CPT (Common Protocol Template)
- DDF
- ICH M11
- HL7 FHIR

NOTE: See References section for links to solutions

These collaboration supports digital protocol implementation and amplify value for sponsors, regulators, & healthcare providers.

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CROSS-CONTINENT LIVESTREAM SESSIONS

Live-streaming content from different locations can enhance the attendee experience at an in-person event. These benefits include:

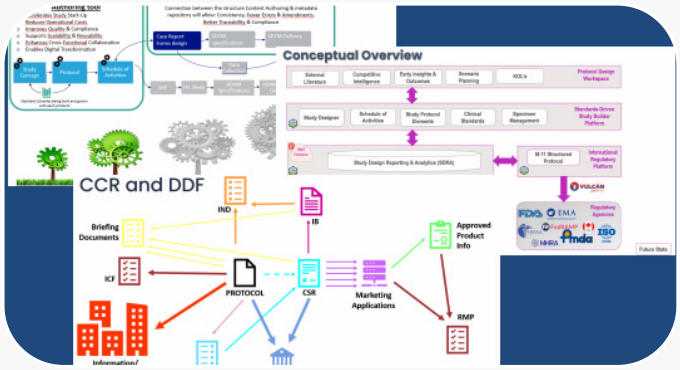
Global Reach and Inclusion

Real-Time Engagement and Interaction

Unified and Collective Experience

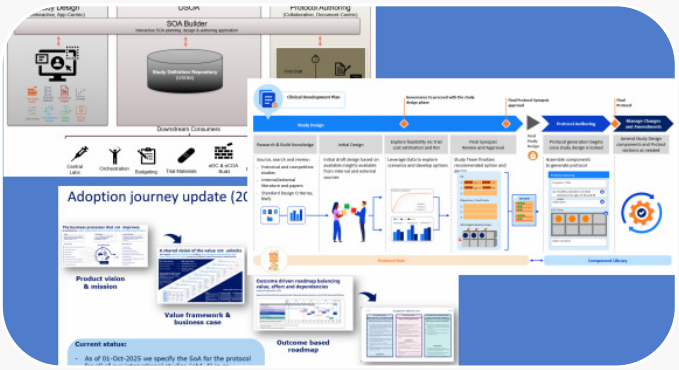
DDF Mission Possible event live-streamed three sessions, connecting stakeholders at the Novartis campus in New Jersey, US, and at the Roche campus in Basel, Switzerland.

The live-streamed sessions covered these three topics:



Adoption Stories from Sponsor Companies

Future of Digital Protocols



Learnings from Early Adopters

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ADOPTION STORIES SUMMARY

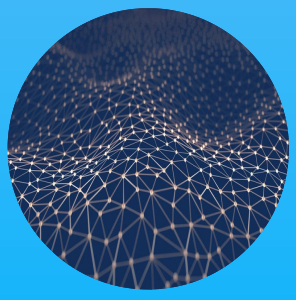
An exploration of additional case studies from three sponsor companies on their digital data flow journey

Adoption stories can be a powerful tool to help the community understand the ***possibilities*** through real-life examples and lessons learned.

As each company has different processes, technology ecosystems, and organization structures. When learning about how DDF solutions can be applied successfully, it is highly recommended to:

- Reflect on your company's specific processes, technologies, and structure
- Consider different areas and situations inclusive of an end-to-end data flow, and
- Focus on the greatest value-add for your specific company.

Common Themes Across Adoption Stories



Digital Transformation

A shift from manual, document-based processes to digital, automated, and standardized clinical data flows improves clinical trial operations.

Templates & Content Reuse

Structured protocol content and using templates enable content reuse, improve consistency, and support automation.

Operational Efficiency & Automation

Automation is one way to accelerate study startup, streamline operations, and improve data quality across clinical trials.

Change Management & Adoption Challenges

Successful digital transformation requires leadership, stakeholder buy-in, and effective change management to promote adoption.

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ADOPTION STORIES DETAILS

#1: Common Data Model on a Technology Platform

Approach to Implementing Digital Data Flow

Create a standards-driven study builder platform with a unified data model aligned with the TransCelerate DDF initiative

Why Focus on a Standards-Driven Study Builder Platform?

A digitized, standards-based study design ensures **consistent data from the start**, enabling teamwork through quality-by-design. This enabled enhanced data transparency and supported improvements with time-consuming start-up tasks.

How Was it Done?

There are three broad maturity levels, and the company is currently at "Digitalization".

1. Digitization
Establish a digital foundation by converting paper-based protocols into digital documents

2. Digitalization
Enhance efficiency and effectiveness of protocol development through digital tools

3. Digital Transformation
Achieve holistic transformation that integrates digital protocols into core strategy.

Successes to Date

Early Insights

Provide insights two months ahead in the trial timeline.

Specimen Plan Generation

Digitized Schedule of Activities (SOA) & Specimen Plan automation enabling 3 to 4 weeks faster study setup

Lab Contracts Generation

Contract negotiation initiated earlier in trial lifecycle

Contracting Support

Earlier contract starts; time saving with automation

Learnings & Key Takeaways

There were implementation challenges. To succeed, consider:

- A **clear vision** with leadership support
- **Stakeholder buy-in** and transparent communication
- A **solid execution planning**
- Solid **execution strategy** and process optimizations

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ADOPTION STORIES DETAILS

#2: Integrated Data Journey: From Study Concept to CRF

Approach to Implementing Digital Data Flow

Create an integrated data journey, from study concept to Case Report Form (CRF), leveraging a bespoke structured content authoring tool and a digital schedule of activities (SoA).

Why Focus on this use case for an integrated data journey?

Having an implementation of an integrated data journey will structure, standardize, and digitize the study protocol content, **enabling content reuse across downstream systems and across documents**.

How Was it Done?

Focused on 2 areas in the company's digital ecosystem:

Bespoke Structured Content Authoring Tool

- Allows for study concept and protocol development to use standardized libraries
- Generates a digital SoA

Meta Data Repository

- CRF design can leverage the digital SoA

What's Been Done To-Date and What's Planned for the Future

This journey started in 2019 with a proof of concept for structured content authoring.

Each year since then, there have been updated versions of the tool, expanding functionality to be a more integrated clinical platform and other document templates.

There are additional opportunities with other systems integrations, beyond CRF design, such as data analysis and reporting.

Learnings & Considerations

There were implementation challenges:

- Custom tools are expensive, and ROI may be hard to justify in early stages
- **Big investment needed in terms of time and expertise** to ensure consistency end-to-end across the process as well as the digital landscape
- **Change management is needed** to balance the need for data re-use and being flexible with the clinical documents.

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ADOPTION STORIES DETAILS

#3: Clinical Content Reuse (CCR) & Document Automation

Approach to Implementing Digital Data Flow

Create an approach that leverages and balances AI/Machine Learning in conjunction with content & data standardization, with development data flow & building a repository.

Why Focus on a Protocol Builder?

With the volume of critical clinical trial document types (~18), and the number of key systems (~15) in the digital landscape, and the total number of users across the ecosystem, the value of having a mechanism for clinical content reuse is significant.

How Was it Done?

Focus was on several components in the process and digital landscape, with a goal to auto-generate partial drafts of key documents and automation across 15 systems

Clinical Metadata Repository	Content Library	Study Definitions Repository	Study Design Optimization
Managing standards	Managing templates & content	Storage of protocol data via USDM design	Strategic Feasibility

What's Been Done To-Date and Plans for the Future

To-Date

- Protocol template implementation
- Digitization of existing protocols
- Developed & implemented web-based protocol builder application
- Redefining vision based on user feedback

Future

- Expansion to having a separate digital SoA and protocol builder
- Continuous improvements on the protocol template
- Integration of content libraries
- Integration of study startup
- Incorporate AI & automation

Learnings & Considerations

To succeed, consider a **balance between People, Process and Technology**.

- People needs to include all stakeholders across the clinical operations landscape
- Process needs to clearly define roles & responsibilities with expectations on timelines
- Technology needs to support various user needs and be integrated

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FUTURE OF DIGITAL PROTOCOLS
Regulatory & Health IT Perspectives

The CDISC USDM was introduced in 2022, and since then, progress has been made in maturing the USDM and promoting adoption of these standards. Recent efforts, including the introduction of ICH M11, a guidance for Clinical Electronic Structured Harmonized Protocol, and HL7 Vulcan Utilizing the Digital Protocol (UDP) initiative, are generating even more awareness across the industry.

The livestream panel introduced insights & perspectives from regulatory and heath IT perspectives on the future of digital protocols under five high-level categories.

CATEGORY	KEY INSIGHTS FROM PANEL PARTICIPANTS
Current Challenges	• Regulators struggle with data inconsistency across documents and want to have content standardized to support quick access and consumption to do the analysis. • Regional considerations can be challenging; alignment to standards can support better universal harmonization. • Sites struggle with handling thousands of data points across various studies and working with sponsors to have structured data increases efficiencies from both sides. • Sponsors want to improve the process to allow regulators and sites to access and consume the information about the protocol as quickly and easily as possible.

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FUTURE OF DIGITAL PROTOCOLS

Regulatory & Health IT Perspectives cont'

CATEGORY	KEY INSIGHTS
Opportunities with Standards 	• ICH M11 is currently in draft and will be finalized soon. Using both ICH M11 and USDM can help folks get started. • ICH M11, USDM, FHIR are all good building blocks and support various pieces of the puzzle with structure, format, data details & storage, and transmission. • Recommend focusing on specific use cases (e.g., push labs, vitals, adverse events, etc.) vs. attempting to do everything at once.
Taking Action 	• Building blocks are ready now – just need to start to test, learn, and adjust. • Collaboration and sharing learning is important for everyone to benefit from having a protocol digitalization that can support digital data flow. • Work is ongoing with various industry collaborations to test, connect the dots and demonstrate results for streamlined data flow and automation.
Blue Sky Thoughts 	• Collaborative partnerships between sites and sponsors can support more focused data collection and what is needed for regulators in obtaining approvals. • Leverage technology, including AI, with the human in the loop, and standards which include content libraries, etc. to really become more efficient in creating documents and reducing errors. • Having standardized formats and digital protocols can support early discussions with regulators and real-time feedback for streamlined protocols. • With standardized content and formats, there would be more opportunities for regulators to provide more aligned insights and feedback by therapeutic areas. • The future is now! Collaborate, automate, and require to realize the benefits.

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LEARNINGS FROM EARLY ADOPTERS

1. Digital Schedule of Activities (DSoA)

DDF Solution Application from 2024

Creation of Study Definitions Repository (SDR) to better support new studies by digitizing the Schedule of Activities (SoA).

★ 2025 UPDATE ★

- DSOA Target State: Scale
- SOA Builder to connect with Study Design and Protocol Authoring
- Expansion of SDR to downstream systems

2. Digitization of Existing Protocols

DDF Solution Application from 2024

Creation of an SDR to store and contain historical protocols, with an interface for searching stored content.

★ 2025 UPDATE ★

Expansion toward a digital study designer, offering:

- Collaboration across multiple functions
- Real-time data driven insights supporting comprehensive study design
- Data-drive build of a digital SOA

3. A Study Builder

DDF Solution Application from 2024

Creation of sharable open-source code used to develop a Study Builder with an SDR to enable the digitalization of new protocols.

★ 2025 UPDATE ★

- Focus on digital SOA, with usage across all interventional studies
- Expansion toward data collection enablement
- Plans for end-to-end metadata linking

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BREAKOUT SESSIONS OVERVIEW

To support and allow for more personal interactions and engagement, breakout sessions were held at both sites on specific topics of interest.

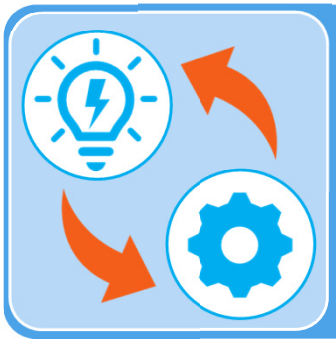
Attendees self-selected one of three topics for a peer-to-peer dialogue focused on sharing ideas, asking questions, and discussing themes related to digital data flow transformation and protocol digitalization.

Breakout sessions were moderated by the DDF initiative team and program volunteers. Each table had animated conversations around their experiences, learnings and perspectives.

A summary readout was conducted at the conclusion of the breakout sessions so that all attendees could learn about the outcomes of other conversations.

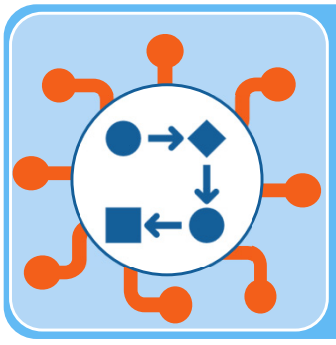
Breakout Session Topics

Change Management Strategy and Approach for Protocol Digitalization: *Considerations Across Assessment, Planning And Implementation*



DDF from Ideation to Implementation:

Developing Capabilities to Realize the Vision of Protocol Digitalization



AI In Protocol Digitalization:

Leveraging Artificial Intelligence to Enhance Trial Design and Execution

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BREAKOUT SESSION
Topic 1: Change Management

Discussion Summary

These breakouts emphasized the necessity of a **clear value proposition**, the **significant challenges** posed by organizational and emotional resistance, and the need for a sustained, strategic implementation **roadmap**.

Selling the Change and Stakeholder Buy-in

A core requirement is clearly **defining the "why" and "What's In It For Me" (WIIFM)** for all stakeholders, including end users. A business case must focus on showing impact and value for the proposed changes.

Leaders need to understand that the initiative links to broader digitization efforts and fits into the company's long-term strategy.

External landscape assessments can help secure buy-in by demonstrating peer activity and showing why action is needed now.

Significant Risks and Resistance

Change management faces high risks related to **resistance** and **resources**.

Resistance is organizational and individual, stemming from people being "set in their ways" and preferring familiar tools where they felt ownership. Many users may perceive the change as an extra step or more upfront work. Fear of job displacement is particularly acute for Medical Writers, who feel threatened, obsolete, and made redundant by technology. Furthermore, decentralized, siloed organizations struggle to "mandate" change, complicating sponsorship buy-in.

There is also a **risk of underestimating** the cost and resource investment, making the initial Return on Investment (RoI) challenging to demonstrate.

Implementation Strategy

Successful adoption requires alignment on a **common vision & strategic goals** across business units. It is recommended to start with a small Minimum Viable Product (MVP), such as digitizing the protocol or Schedule of Activities (SoA), to provide high business value quickly.

Since implementation is a multi-year journey, organizations must **"be in it for the long haul"** by staggering implementation, celebrating small wins, and continually refining the approach based on user feedback.

Transparency is critical: risks must be identified and mitigated to prevent the initiative from losing credibility.

Organizations must also **evolve capabilities**, potentially creating new roles like a "digital architect," and ensure upskilling for existing functions like medical writing to shift from administrative to strategic tasks.

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BREAKOUT SESSION
Topic 2: Ideation to Implementation

Discussion Summary

The breakout discussions on DDF implementation, spanning Ideation to Implementation, provided strategic, tactical, and organizational guidance for realizing protocol digitalization

Strategy and Goals

Successful implementation can be aided by clear objectives defined by **determining an end point** and output to ensure a measurable Return on Investment (ROI).

Organizations could start by assessing the current Schedule of Activities (SoA), optimizing it, and estimating potential impact.

Use cases can be evaluated through an **Assessment of Effort vs. Impact vs. Value** to identify potential quick wins or high-risk/high-reward initiatives.

Ultimately, it may help if the initiative is added to the company strategy.

Implementation Steps & Tactics

Teams could **start with something bite-sized and more tangible**, such as content reuse among templates, site enablement, or specimen tracking plans.

It is helpful to map the process from end-to-end, understand existing pain points, and harmonize the core content.

A key advice: **Don't try to fit new technology into old processes**. For pilots, starting with a retrospective study is recommended.

People and Change Management

Implementation success involves balancing process, technology, & **people**, alongside securing **Leadership Buy-In**.

Participants suggested elevating Change Management to **transformation management** to facilitate greater business involvement and stakeholder discussion.

This transition should involve **Subject Matter Experts (SMEs) upfront** and identifying or expanding a **transformation agent role**.

Existing roles, such as Medical Writer, could be expanding to cover new scopes, including understanding the biomedical concepts (BCs).

Data Considerations

While historical data can inform decisions, teams should use it with care.

Discussions emphasized the potential risk of "garbage in, garbage out" and the need to check the **applicability of historical data**, given potential inconsistencies (e.g., 32 variations of inclusion criteria).

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BREAKOUT SESSION
Topic 3: AI in Protocol Digitalization

Discussion Summary

The Digital Data Flow breakout sessions on AI in Protocol Digitalization focused on the goal of **harnessing AI to streamline and enhance clinical trial protocol creation, design, execution, and review**, ultimately making subject matter experts more productive.

Importance of Standards

During the sessions, participants discussed the concept of developing a Protocol Content Library organized by indication and phase. Examples shared included libraries that incorporate regulatory-approved protocols, public data sources (such as ClinicalTrials.gov and PubMed/DRACT), and internal organizational knowledge.

These types of efforts require integrating formats and standards such as USDM, CDISC BCs, and M11 standards, though it was noted that USDM is "not there yet".

AI-Driven Study Design and Structured Data Integration

During Study Design and Planning, AI could be used to suggest design options and draft the Schedule of Activities (SoA) by incorporating historical evidence and cost association.

Linkage between objectives, endpoints, and data points would be important to enable the AI to construct the first draft SoA.

AI could auto-generate protocol text following design selection and map the SoA to CRFs, supporting the subsequent creation of SDTM specifications.

All information could benefit from being **stored in a structured way** with adaptable presentations for various end users, such as clinicians and nurses.

Human in the Loop With AI

Another discussion was focused on **Validation, Quality Control, and Traceability**.

The consensus was that the **"human in the loop is essential"** for reviewing, approving, and building trust in the AI-assisted process.

Although there will be cases where humans can be removed from the loop, a risk-based approach to review should be implemented.

Managing Risks with AI

Risks identified include **data issues** (inconsistency, duplicate history), the challenge of **demonstrating traceability and lineage**, and the **lack of trust or varied knowledge** among end users.

Therefore, key decisions to manage risks should include maintaining clear accountability, audit trails, and ensuring terminology harmonization and robust governance.

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USE CASE OVERVIEW

Introducing the Digital Study Design Use Case Library

WHAT

What is the Digital Study Design Use Case Library?

- ✓ A draft resource that captures definition and taxonomy for current thinking of concepts shared between stakeholders from the Sponsor and Solution Provider communities

WHY

Why do we want a Use Case Library?

- ✓ Describes a sample of some use cases
- ✓ Initiates a proposed framework for considering and capturing the impact of DSD adoption across the broader Healthcare Community – i.e., Providers, Patients, Regulators, Investigators, Sponsors

HOW

How to use the Library?

- ✓ Leverage the "categories" and "classes" of how the use cases are organized
- ✓ Review the specific use cases of interest to understand the various components of the use case

NEXT STEPS

What is next?

- ✓ Digital Study Design Use Case Library to be shared by end of 2025
- ✓ Expand scope, add new Categories & Collaborators
- ✓ Establish Governance & appoint Domain Experts to Steward

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CLINICAL SOLUTION PROVIDER SHOWCASE DETAILS

A dedicated poster session where clinical solution provider representatives shared different protocol digitization technology solutions.

NOTE: TransCelerate does not endorse or recommend solutions by any vendor.

Clinical solution providers varied by location. Providers and their posters were selected based on an open call for abstracts. The criteria for selection included:

- Information about how the USDM and DDF Solutions, have been applied in practice to achieve protocol digitization or protocol digitalization
- Demonstrated ability and/or application of a protocol digitalization use case with USDM and/or pathway for USDM incorporation in the solution in the future

Review list of Clinical Solution options in the **DDF Solution Directory**

https://transcelerate.github.io/ddf-directory/directory/directory.html

Provider Name	Description		
AlphaLife Sciences	The solution bridges the gap between human-centric regulatory narratives and machine-centric structured data. By combining generative AI with USDM, the solution generates both digital protocols and context-rich narratives, creating a bi-directional bridge between structured data and regulatory submissions.		
	Standards	**Use Cases**	**Attributes**
	USDM, SDTM, ADaM	• Study Design (Protocol Authoring, Analytics) • Study Start-up (Deployment) • Regulatory Submission (Preparation)	• Digitalization
CDISC 360i	DDF CDISC USDM is a core component to CDISC 360i, providing the standards, architecture, and automation capability required to realize a fully digital, interoperable, and efficient clinical research ecosystem.		
	Standards	**Use Cases**	**Attributes**
	USDM, SDTM, ADaM, CDASH, HL7 FHIR, ICH M11	All lifecycle phases (Protocol Store → Submission)	• Automation enabler • Digitalization

Legend CDISC Analysis Data Model; CDISC Biomedical Concepts; CDISC Clinical Data Acquisition Standards Harmonization; CDISC Study Data Tabulation Model; CDISC Unified Study Definitions Model; HL7 FHIR; ICH M11

TransCelerate does not endorse, certify or recommend any specific actions based on discussion outputs. All adoption or use of any solution, deliverable, standard, technology, product, or vendor is purely voluntary.

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CLINICAL SOLUTION PROVIDER SHOWCASE DETAILS

Provider Name	Description	Standards	Use Cases	Attributes
ClinLine	An open-source mapping tool that automates SDTM design domains based on USDM. Having this information digitized and structured in the study design phase, including all the relevant coding, has the potential to reduce programming and alignment time for creating these domains.		• Study Design (Study Construction, Analytics) • Analysis & Reporting (SDTM generation)	• Digitalization
Data4knowledge	Demonstration of time savings, with full traceability and consistency by combining USDM with CDISC BCs and ICH M11 standards to transform protocol PDFs into SDTM datasets, and CRFs.		• Protocol Store (Historical Protocol Conversion) • Study Design (Analytics) • Analysis & Reporting (Traceability)	• Demonstration of DDF potential
DNAnexus	Converts an original protocol into an ICH M11 structured protocol for an IND, enabling simultaneous, real-time review by multiple agencies—all within Trusted Regulatory Spaces (TRS). Authors, submission specialists, publishers, and health-authority reviewers can work in a shared workspace.		• Regulatory Submission (Preparation, Regulatory Review) • Study Design (Protocol Authoring)	• Digitization
Faro Health	Faro's AI-powered platform helps clinical teams design smarter, more efficient trials by transforming protocols into structured, machine-readable data. Involves a study builder, an SDR, and an AI authoring assistant.		• Study Design (Authoring, Stakeholder Views) • Study Start-up (Deployment)	• Digitalization
HumanTrue	The solution is an AI application that uses large language models (LLMs) to understand and interpret clinical trial protocols.		• Study Start-up (Deployment, Training) • Study Execution (Site Support)	• Digitization

Legend CDISC Analysis Data Model · CDISC Biomedical Concepts · CDISC Clinical Data Acquisition Standards Harmonization · CDISC Study Data Tabulation Model · CDISC Unified Study Definitions Model · HL7 FHIR · ICH M11

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CLINICAL SOLUTION PROVIDER SHOWCASE DETAILS

Provider Name	Description
Merative	Zelta is a cloud-based unified clinical data management and acquisition platform with customizable modules that can be tailored to meet the unique needs of various clinical trials.

Standards	Use Cases	Attributes
	• Study Start-up (Deployment) • Study Execution (Amendment Management) • Analysis & Reporting (SDTM/ADaM)	• Digitization

Provider Name	Description
Novonordisk OSB	The solution provides a dedicated API endpoint that retrieves the metadata as they have been defined in the OpenStudyBuilder and generates a JSON file using the version 3.11 of the DDF-USDM specifications.

Standards	Use Cases	Attributes
	• Protocol Store (Metadata Library) • Study Design (Construction) • Study Execution (Amendment Tracking)	• Digitalization

Provider Name	Description
Nurocor	Metadata & clinical platform enabling digital protocol development, automation, and lifecycle traceability across CDISC standards. Provides structured authoring, downstream integration, and regulatory traceability within a unified metadata repository.

Standards	Use Cases	Attributes
	• Protocol Store • Study Design (Authoring, Construction) • Study Start-up (Deployment) • Regulatory Submission (Preparation)	• Digitalization

Provider Name	Description
Onward Health	ONWARDAccess is no-code, customizable eSource/eCOA/ePRO solution which has a system admin module that is used to configure an end-user study build UI and database.

Standards	Use Cases	Attributes
	• Study Start-up (Deployment)	• Digitalization

Provider Name	Description
Pharmaseal	Automated system set-up and intelligent system set-up leveraging USDM using Engility® Clinical Management System. EDC, CTMS, eTMF automation.

Standards	Use Cases	Attributes
	• Study Start-up (Deployment) • Study Execution (CTMS, eTMF)	• Automation enabler

Legend CDISC Analysis Data Model; CDISC Biomedical Concepts; CDISC Clinical Data Acquisition Standards Harmonization; CDISC Study Data Tabulation Model; CDISC Unified Study Definitions Model; HL7 FHIR; ICH M11

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CLINICAL SOLUTION PROVIDER SHOWCASE DETAILS

Provider Name	Description
RWS & Content Rules	RWS offers a Structured Content Authoring platform that uses AI, Component Content Management, and localization for clinical trial protocols and other uses. Content Rules consulting services help Pharma and other industries with content strategy and prepare content for automation and optimization with GenAI and LLMs.

Standards	Use Cases	Attributes
USDM	• Structured Content Authoring • Structured Component Management	• Digitalization

Provider Name	Description
Sycamore Informatics	The Sycamore Structured Protocol Authoring (SPA) app streamlines protocol creation by using Microsoft Word with templates and tools. It helps users design and export study protocols and Clinical Development Plans in standard formats while aligning with study design and organizational standards via integration with the Sycamore Metadata Repository (MDR).

Standards	Use Cases	Attributes
USDM, HL7 FHIR	• Study Design (Authoring, Construction)	• Digitization/ Digitalization

Provider Name	Description
TransCelerate SDR	The Study Definition Repository (SDR) Reference Implementation is a model implementation of a repository that uses a Unified Study Definitions Model to facilitate data exchange. The source code and configurations are available by means of an open-source license.

Standards	Use Cases	Attributes
USDM	• Centralized repository	• Digitalization

Provider Name	Description
Trialynx & Cliniv	Trialynx employs AI to convert study synopses into digital protocols, which are sent to Cliniv for database creation and data collection, and then returned to Trialynx for automated clinical study report creation.

Standards	Use Cases	Attributes
USDM	• Study Design (Construction) • Study Start-up (Deployment) • Regulatory Submission (Preparation)	• Digitization/ Digitalization

Provider Name	Description
Verily	The Verily Precision Health Platform supports the digitization of clinical trial protocols into USDM-based formats, enabling dynamic data use, better integration, and faster clinical workflows.

Standards	Use Cases	Attributes
USDM, HL7 FHIR	• Study Design (Authoring, Construction)	• Digitization

Legend

- CDISC Analysis Data Model
- CDISC Biomedical Concepts
- CDISC Clinical Data Acquisition Standards Harmonization
- CDISC Study Data Tabulation Model
- CDISC Unified Study Definitions Model
- HL7 FHIR
- ICH M11

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EVENT FEEDBACK & SUCCESS MEASURES

Common Themes from Event Feedback

Value of Networking & Collaboration

Participants appreciated the chance to connect with peers, share ideas, and learn from others' experiences in implementing DDF solutions.

Great Learning Opportunity

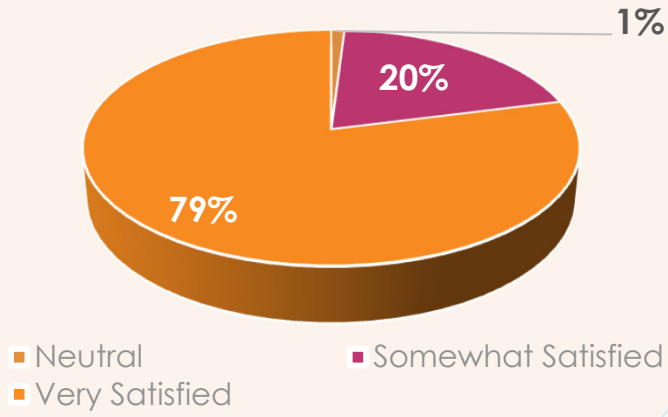
Participants noted that tools like Persona Toolkits, Technology Architecture Scenarios, and USDM/SDR RI materials can help organizations with their digital data flow journey

Desire for More Interaction & In-Depth Content

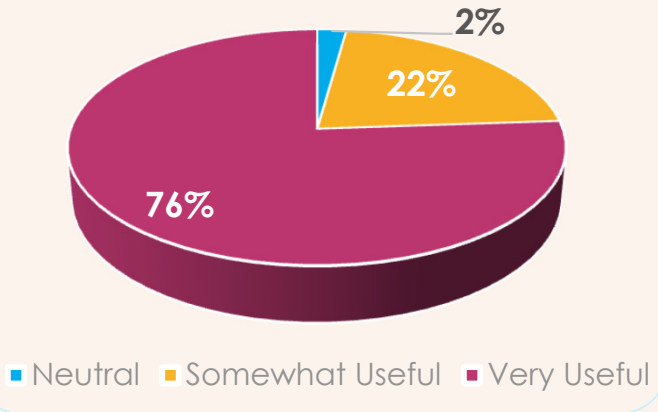
Participants would like more time for interactive sessions, deeper dives into use cases, and practical demonstrations from early adopters and solution providers.

SUCCESS MEASURES AND OUTCOMES*

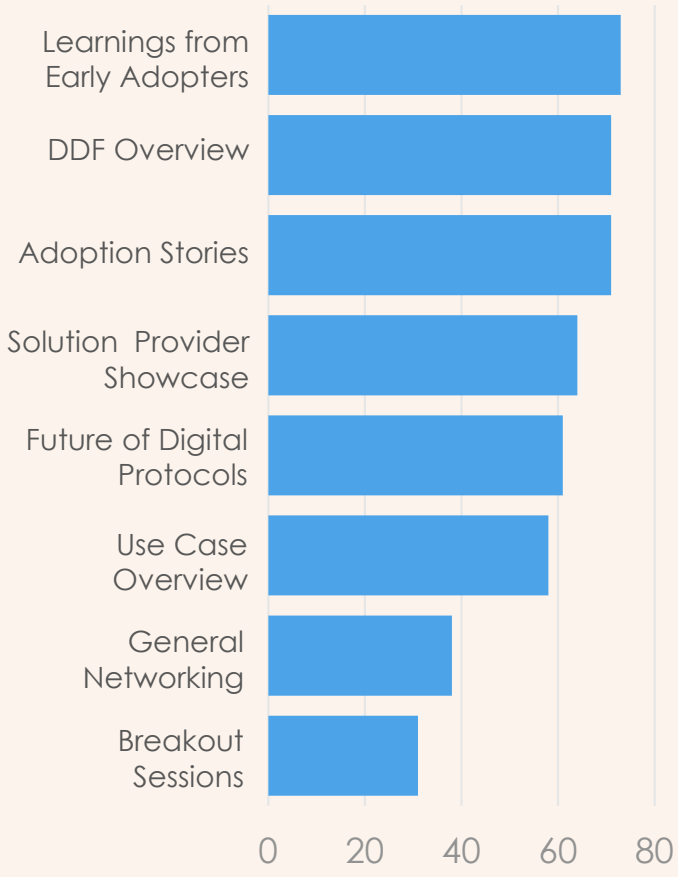
Agenda, Content and Conduct of DDF Mission Possible Satisfaction



DDF Content Usefulness in Enabling You to Drive/Lead/Champion within Your Org



Sessions Most Useful to You in Applying DDF within Your Organization (Total counts of multiple responses)



* Based on post-survey event. Some respondents may have selected one or more of the available options, per question

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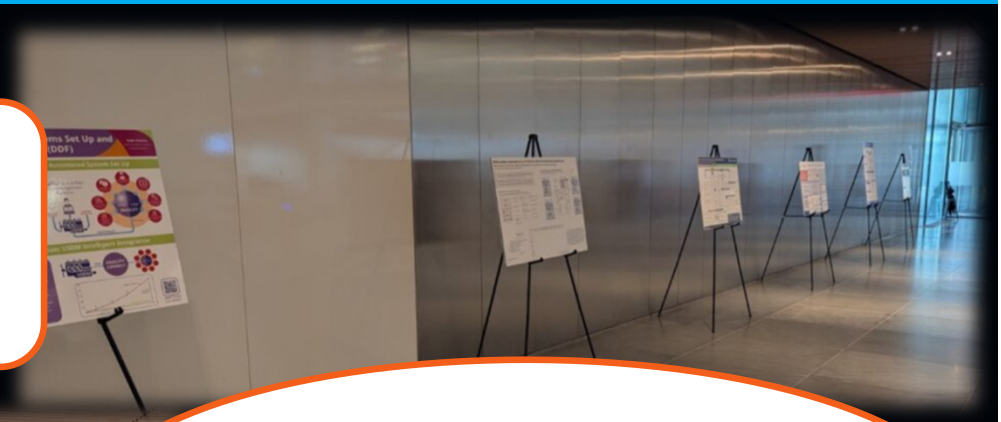
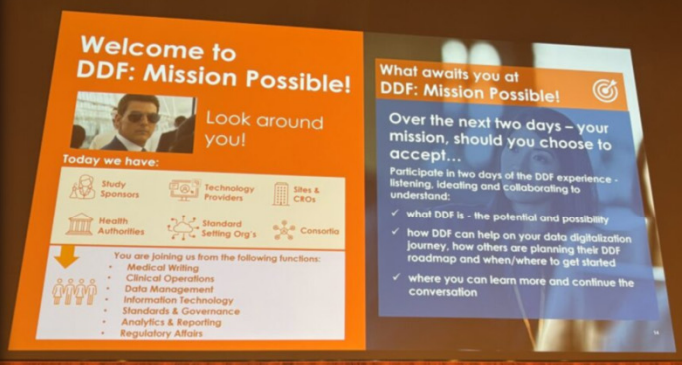
Celebrating People & Perspectives

Very inspiring and engaging experience. Thank you for organizing this event. Learnt a lot!



The implementation case studies and breakout discussions were particularly valuable.

Excellent facilitation and moderator. **Keep advocating.**



First time joiner with target to learn. **I have learned more than expected.**

It triggered ideas about potential **change management strategy** and increased my understanding of DDF.

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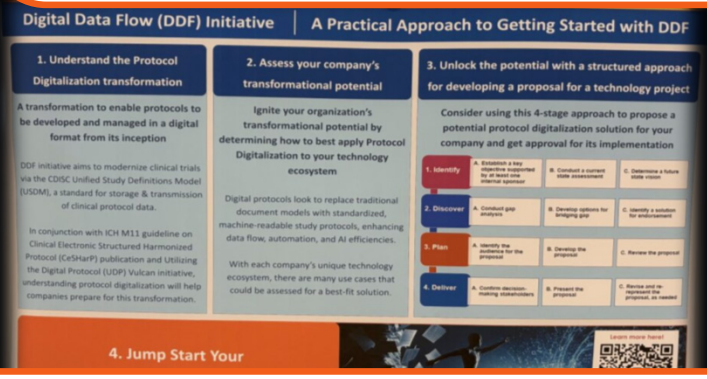
Celebrating People & Perspectives

[The event made me realize] where we are as an organization and what questions we could be asking.

As a medical writer with limited knowledge on this topic, the event provided **good training.**

It helped me better understand details of **DDF and how it related to current activities in my organization**. It was also very helpful to hear from other sponsors and see concrete use cases.



Presenters covered **use cases** very well. They highlighted the **potential of USDM.**

Seeing that so many pharma's are looking into USDM and M11 format showed me that we need to implement them more and more. Those 2 days helped me review how we have integrated the USDM. More work is needed but **we are on the best track**!

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CONCLUSION

The 2-day DDF Mission Possible convened sponsor companies, clinical solution providers, and key industry stakeholders to forge connections, explore DDF solution options, and gain valuable insights into protocol digitization.

Given the advancements in the past year with protocol digitalization, the event emphasized industry momentum toward digital transformation, with an aim to reduce inefficiencies and improve data quality across clinical development ecosystem.

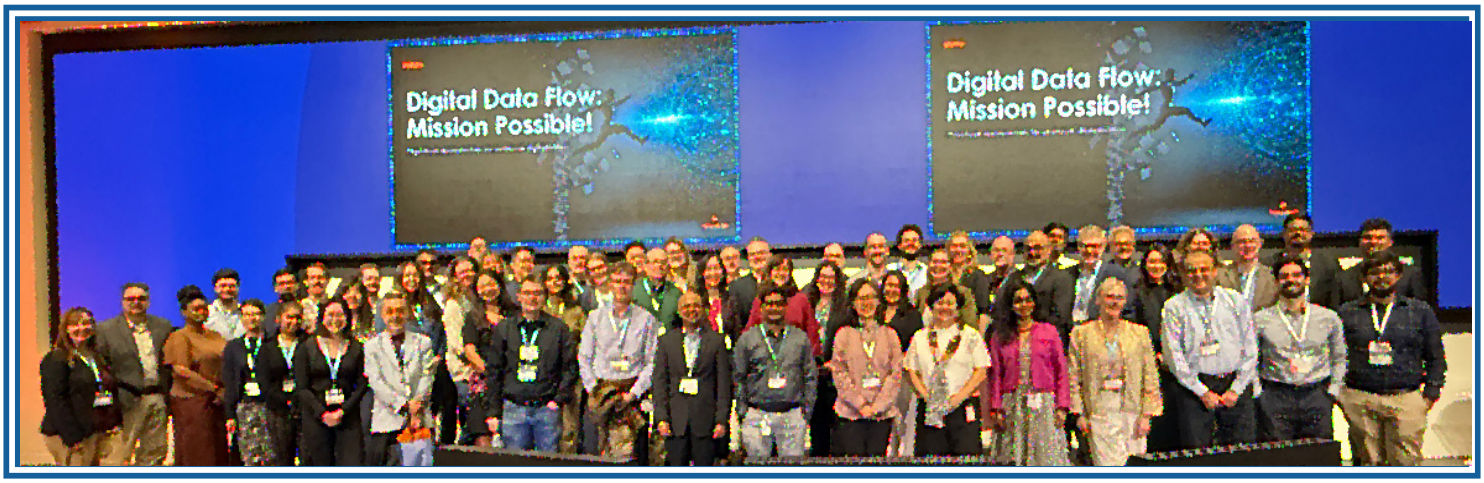
Based on the breath & depth of topics and opportunities for interactive engagement and networking, the event was successful in:

- **Connecting** industry peers on the approach to protocol digitalization
- **Sharing** various potential pathways from transformative enablers across the industry
- **Imparting** lessons learned via adoption stories & available tools to support various efforts

This was the largest DDF event to date, highlighting growing cross-industry collaboration among pharma companies, CROs, regulators, and technology partners. The DDF Initiative project team is very thankful to all for the active participation, insightful contributions, and collaborative engagement.

The excellent facilitation and seamless logistics of a dual continent event was only made possible by the meticulous planning from members of the DDF Initiative project team, as well as extremely thorough coordination and extensive preparation between the DDF Initiative program management office and the host companies' representatives, coordinators, and AV production teams from both Novartis and Roche. Thank you!

By working together, we can break free from the old document paradigm and embrace a smarter, faster future.



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REFERENCES

To learn more about DDF, access the links & QR Codes below.

DDF Website

Primary website for DDF

https://transcelerate.github.io

CDISC DDF Website

Explore & access the USDM

https://cdisc.org/ddf

TCB DDF Initiative

Discover the initiative background

https://www.transceleratebiopharmainc.com/initiatives/digital-data-flow

DDF GitHub Repos

Review & access the SDR Refence Implementation.

https://github.com/transcelerate

To learn more about other related initiatives, access the links & QR Codes below.

ICH M11

Explore & access ICH M11

https://www.ema.europa.eu/en/ich-m11-guideline-clinical-study-protocol-template-and-technical-specifications-scientific-guideline

Utilizing the Digital Protocol (UDP)

Learn more about this umbrella initiative

https://www.hl7vulcan.org/udp-project

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