TransCelerate Digital Data Flow (DDF)

DISCOVERY DAY 2023

SUMMARY REPORT

ALOFT Hotel Boston Seaport District

September 19th, 2023

8:30 AM – 5:00 PM

A one-day face-to-face event bringing together sponsor member companies, technology solution providers, and key industry stakeholders in an interactive experience to explore the "art of the possible"

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EXECUTIVE SUMMARY

Beginning in 2020, the Digital Data Flow (DDF) initiative set out to establish a foundation for an automated, dynamic future-state aimed at transforming the clinical study planning and execution to a "write once, ready many times" paradigm.

DDF Discovery Day brought together contemporaries from 17 TransCelerate member companies, 7 clinical solution providers, and key industry stakeholders, including CDISC & Vulcan HL7. The event raised awareness & enabled exchanges about the CDISC Unified Study Definitions Model (USDM), TransCelerate Study Definitions Repository (SDR) Reference Implementation, and overall solution implementation for DDF.

The morning began with a keynote speaker, followed by a plenary session and a solution showcase featuring demonstrations by clinical solution providers in attendance. The afternoon featured a member company case study and member company roundtable discussions covering five key topics relevant to change and implementation of DDF (closed to vendors). The agenda allowed multiple opportunities for participants to exchange perspectives, discuss use cases, and learn about tools and resources.

Themes reoccurring throughout the day included: (1) resources exist now and companies need not wait for perfection, (2) each organization's digital transformation journey will be unique to their vision, and (3) change & transformation takes time and iterations.

The event received positive feedback, with 79% indicating at least one of the sessions being very valuable in raising their awareness of the DDF initiative, 96% finding it useful to help them enable and drive protocol digitization in their organizations, and 100% interested in attending a future DDF-sponsored event.

NOTE: Percents in the above summary are based on attendee responses to an anonymized post-event survey

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PARTICIPATION

17

Member Companies Represented

NOVARTIS · sanofi · BAYER · Johnson&Johnson · Lilly · astellas · AstraZeneca · novo nordisk · ucb · REGENERON · Roche · SHIONOGI · GSK · MERCK · abbvie · Pfizer · Bristol Myers Squibb

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Industry Partners Represented

cdisc

VULCAN HL7 FHIR

Solution Provider Companies*

❖ Indegene
❖ Trials.ai by ZS
❖ Medable
❖ Nurocor
❖ Merative
❖ Sycamore Informatics

❖ OpenStudyBuilder by Novo Nordisk

7

Solution Provider Companies*

Note: Providers were selected based on an open call for abstracts followed by a robust assessment and interviews to confirm the intended showcase met the requirements for demonstrating a technical application of the latest version of USDM and/or SDR across one or more use cases.

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Guest Speakers

Rob DiCicco
Vice-President, Portfolio Management, TransCelerate

William Illis, MPH
Global Head, Collaboration/ Technology Strategy & DDF Workstream Lead, Novartis

Kelsey Jakee
Program Director, TransCelerate

Mike Hamidi
Clinical Data Standards Strategy Lead, Pfizer & Vulcan Operations Committee Co-Chair

Gustav Vella
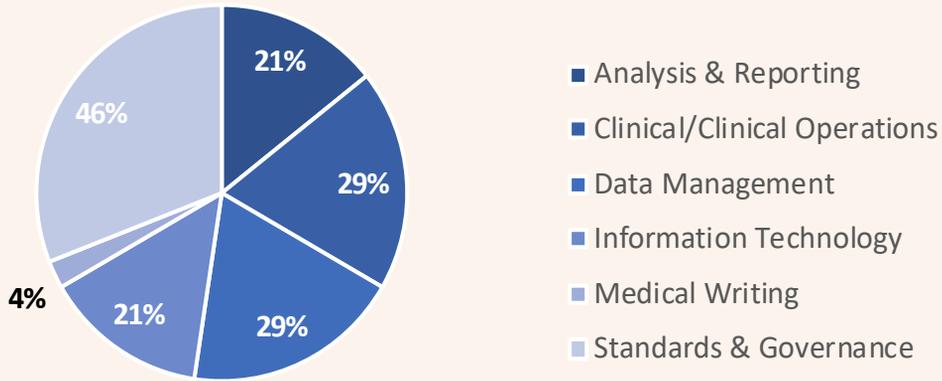Co-founder, Carelane & Vulcan Member, Contributor to Vulcan SoA & Vulcan RWD projects

Renu Shukla
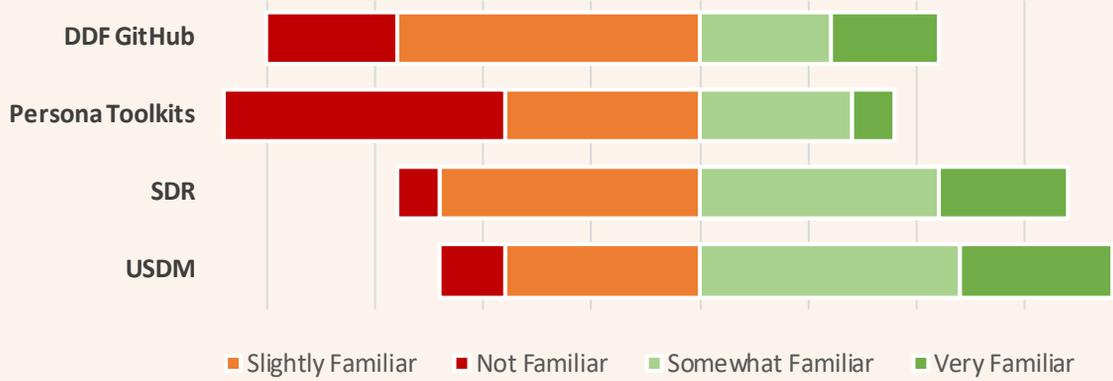TA Head Oncology Stat Programming & DDF Sponsor Change Lead, JnJ

Dave Iberson-Hurst
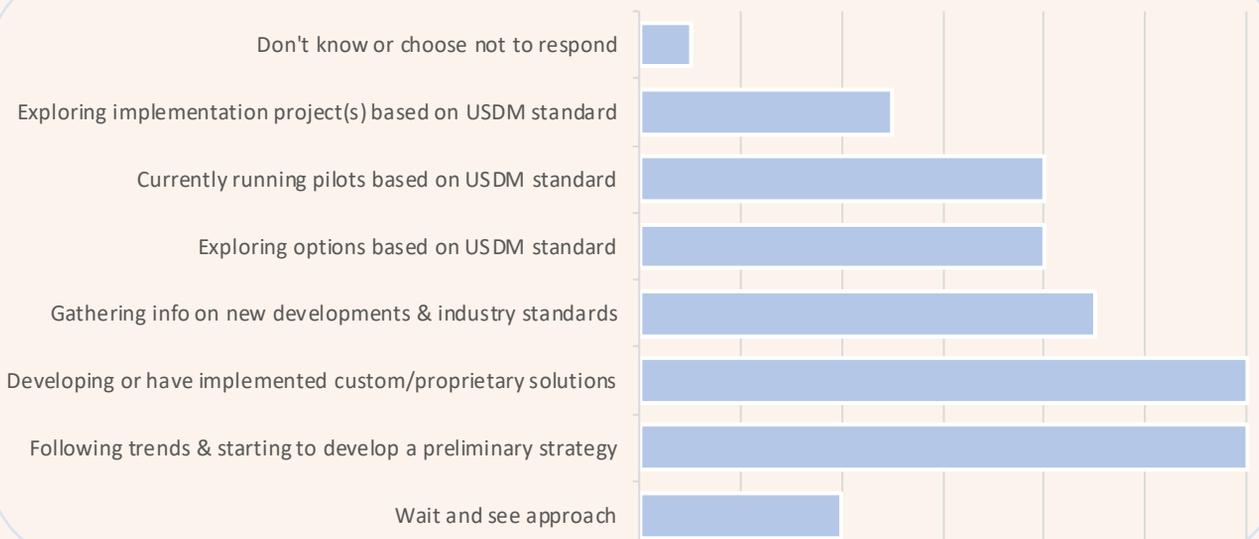DDF Product Owner, CDISC

*Solution Provider presentations do not constitute an endorsement by TransCelerate and/or its member companies.

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SPONSOR ATTENDANCE COMPOSITION

Functional Representation*

Pie chart values: 21%, 29%, 29%, 21%, 4%, 46%

Legend:
- Analysis & Reporting
- Clinical/Clinical Operations
- Data Management
- Information Technology
- Medical Writing
- Standards & Governance

DDF Solutions Familiarity (Pre-Event)*

Categories: DDF GitHub, Persona Toolkits, SDR, USDM

Legend:
- Slightly Familiar
- Not Familiar
- Somewhat Familiar
- Very Familiar

Company's Current Approach to Adoption of Protocol Digitization Solutions*

Bar chart categories (top to bottom):
- Don't know or choose not to respond
- Exploring implementation project(s) based on USDM standard
- Currently running pilots based on USDM standard
- Exploring options based on USDM standard
- Gathering info on new developments & industry standards
- Developing or have implemented custom/proprietary solutions
- Following trends & starting to develop a preliminary strategy
- Wait and see approach

*% is not reflective of individual headcount. Respondents may have selected one or more of the available options.

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Networking Breakfast

Prior to the official start of the event, a networking breakfast was provided, where attendees were able to informally get acquainted or re-acquainted and connect in a more social setting.

There was a good level of energy, curiosity and excitement about the event, with both member company representatives and solution showcase representatives mingling prior to the start of the event.

Keynote

Kelsey Jakee kicked off the event and introduced the keynote speaker, Rob DiCicco.

Rob summarized TransCelerate's purpose and vision for accelerating and simplifying research and development through an industry-wide pragmatic solution. Highlights of the keynote included:

➢ High-level review of TransCelerate's initiatives over the past decade, with a focus on data use and reuse

➢ Calling out TransCelerate's focus for developing industry solutions that are efficient, effective, and support high-quality delivery of new medicines for patients

➢ Stressing the benefits of industry collaboration and partnerships

➢ Sharing that some executive sponsors consider DDF as the "most important" initiative yet, moving from "documents to digital," and

➢ Compatibility between DDF and TransCelerate's focus on the convergence between clinical care and clinical research

Plenary Session

Kelsey Jakee moderated the plenary session: *Industry Convergence in Protocol Digitization & Interoperability*.

She introduced 3 ongoing initiatives related to data standards that have synergy and alignment opportunities.

Protocol Digitization and Automation with the TransCelerate DDF Initiative

William (Bill) Illis introduced the DDF Initiative and the vision of "write once, read many times." Key takeaways included:

➢ Digitization of the protocol has been neglected compared to digitalization elsewhere in clinical.

➢ Take initiative, the first step in this digitization journey is to actively learn about DDF solutions.

➢ Protocol complexity should not stop the industry from pursuing digitization.

CDISC's USDM and Convergence with ICH M11

Dave Iberson-Hurst recapped CDISC's work on the USDM. Already completed, Phases 1 and 2 focused on defining and refining the data model. Phase 3, planned for 2024, will focus on digitization of both structured and unstructured data, aligning it with the ICH M11 template and model.

Dave briefly introduced ICH M11, which is ICH's guidance on a clinical electronic structured harmonized protocol. There are active efforts to align USDM and ICH M11, an example being codelist values.

A key takeaway is that the application of the USDM is only limited to the imagination, and that "stars are aligning" with both ICH M11 and Vulcan HL7 FHIR, given ongoing effort to align across these standards and bridge information exchange across clinical research and clinical care systems.

Vulcan's Enabling Protocol Digitization within Research and Care through HL7 FHIR & ICH M11

Mike Hamidi and Gustave Vella explained that Vulcan is a global membership-based group operating under HL7's FHIR Accelerator Program, with FHIR being the standard for healthcare information exchange. Regarding collaboration between clinical research and clinical care, Vulcan is looking to support USDM / FHIR mapping methodology and aligned messaging and education efforts across the different organizations (ICH, HL7, Vulcan, CDISC, and TransCelerate).

Ultimately, the main driver behind Vulcan and other initiatives and programs is to provide the best connections between various systems used for clinical research and clinical care.

Solution Showcase*

The Solution Showcase featured demonstrations from clinical solution providers of what was coined as "the art of the possible," or use of one or more DDF solutions in a technology platform or system.

The seven providers were selected based on an open call for abstracts. The selection process included a detailed review of the abstract and interviews with the companies to confirm if the abstract and intended event showcase met the requirements for demonstrating a technical application of the latest version of CDISC USDM and/or SDR across one or more use cases.

To provide the opportunity for all showcases to be viewed by all attendees, the audience separated into small groups that rotated from showcase to showcase. Each group was able to get a dedicated demo and a more intimate Q&A setting at each showcase.

Solution showcase demonstrations included potential solutions for the following:

- Middleware platform supporting analytics and reporting from an SDR

- Tool that takes a protocol in PDF format and parsing its content into a USDM-structured format with JSON export capabilities

- AI-focused platforms supporting predictive conversion of biomedical concepts to USDM-based schedule of activities (SOA) to an electronic case report form

- Open-source "OpenStudyBuilder" currently available on GitHub supporting an SDR aligned to the USDM, and interoperability with meta data repositories (MDR) and other libraries

- Framework for linking biomedical concepts to an SOA, aligned with the USDM model as well as CDASH to bridge the protocol to an electronic data capture (EDC) system

- Study builder tool that aligns to the USDM and supports workflow capabilities with export functionality to an SDR

Overall, there was positive feedback on being able to see live demonstrations and visualizations of potential solutions and participate in robust Q&A with the providers.

The solution showcase demonstrated varied use and application of DDF solutions supporting protocol design, data storage, data interoperability across different platforms, and analytics.

Member Story

The Member Story featured a case study describing how the USDM V2 had been applied to a custom in-house solution.

Some key takeaways included the following:

- ❖ The member company has started their protocol digitalization journey leveraging DDF solutions, to drive internal standardization and interoperability, facilitate automation and reduce operational cycle times.

- ❖ Complex protocols such as basket/umbrella studies are not yet well supported by USDM V2.

- ❖ CDISC provided support to the member company and engaged in two-way exchange of information about how best to apply USDM V2 to the company's studies. CDISC will use the feedback to develop updates for the next version of the USDM v3, planned for 2024.

- ❖ As more member companies start exploring the USDM in detail, there are opportunities to share questions, findings, and learnings, which can lead to further community building for the DDF initiative.

Roundtable Discussion

One of the most anticipated sessions of the event was the roundtable discussion. Attendees self-selected their topics of interest for a peer-to-peer dialogue focused on sharing ideas, asking questions, and discussing topics related to digital data flow transformation.

Five topics were moderated by the DDF initiative team. Each table observed very animated conversations around their experiences, learnings and perspectives. A summary readout was conducted at the conclusion of the roundtable discussions so that all attendees could learn about the outcomes of other conversations.
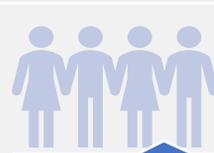
| Getting Started | Impact and Benefits | IT Infrastructure | People and Change Management | USDM and Other Standards |

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Roundtable Discussion cont'

🚀 Getting Started Roundtable: Summary of Discussion*

Ideas on Getting Started

- Understand organizational structure
- Include all stakeholders from the start
- Speak to the value for different stakeholders
- Determine measures of success
- Gauge resource commitments and capacity for absorbing changes
- Don't wait until tools are perfect

💡 *Consider a DDF "Process Hackathon"*

Potential Roadblocks and Recommendations

- No regulatory mandate to change → Leadership advocacy would play a more important role in promoting changes
- How to get started? → Work closely with CDISC, TransCelerate, etc. to learn more and leverage materials
- No in-house tools to understand DDF Solutions → Can demo TransCelerate SDR Reference Implementation sandbox
- Limited capacity to explore → Get buy-in from leadership
- "Options Overload" with solution showcase → Identify specific company needs vs. solution showcase capabilities
- Difficulty for getting DDF solutions approved as a "new" initiative → Incorporate solutions into existing programs

🌱 Impact and Benefit Roundtable: Summary of Discussion*

Broad, Multiple Stakeholders

- While DDF has many benefits across stakeholder groups, this can complicate articulating its benefits across stakeholders.
- Impacted stakeholders may not be the ones who realize the most benefit.
- Decision-makers should be high enough to transcend functional silos. Champions would help.

Starting Change versus Realizing Benefits

- A lag between starting the change and realizing its benefits will occur.
- Change likely will not be a "big bang" but iterative. Having a roadmap will help communicate the vision for the changes.
- To help guide progress, define up-front what success pathways could look like.

Value and Messaging

- Value proposition should be iterative and tailored as new use cases emerge.
- Not one-size-fits-all. To inform a roadmap, each company should understand the value for their organization.
- Focus on "What's in it for me." For greatest stakeholder impact, tailor messages and anchor to relatable anecdotes.

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Roundtable Discussion cont'

IT Infrastructure Roundtable: Summary of Discussion*

IT Landscape

- "Data streaming" concept: Think about working differently to push data for consumption across a network when required rather than relying on bespoke interfaces.

Meta-Data Repository (MDR) for Digital Protocols

- Standards applied to MDR would be critical for achieving consistency downstream.

- Each company has their own approach to MDR use and related standards.

Data Integration and Governance Best Practices

- Focus on starting, even though standards may not be 100% developed for every use case.

- Governance committees may help communicate standards updates to stakeholders.

- Standards should adapt to data collection realities.

- Standards may highlight end-to-end impacts of collecting "nice-to-have" data and fuel data optimization efforts.

General Challenges

- Organizational change management and ongoing business process changes are difficult to keep up with.

- Driving toward actively using digital study design is a mindset shift.

- Include clinical & medical writing stakeholders in technology solution discussions so they see the benefits and value.

People and Change Management Roundtable: Summary of Discussion*

Key Stakeholder and Impacts

- As key stakeholders, clinical and medical writing should be more involved in the DDF change journey.

- Continuous technical updates could cause data management to experience change fatigue.

- Ideally, focus on cross-functional alignment to better understand impacts and benefits.

- Service organizations or vendors may already be a step ahead on this journey.

Consider a DDF Initiative Community of Practice within sponsor companies

Change Management Strategies

- Apply best practices: identify clear goals, change leadership, "connect the dots," "big picture," tailored messaging, champions, and a roadmap with milestones.

- Before implementation, apply early change management approaches to ensure cross-functional leadership aligns on the vision, business case, and value.

Skills and Training Considerations

- Not everyone has a data or technical background. Data and digital transformation education may be valuable.

- Explicit, relatable examples of benefits of data standards can promote understanding and get buy-in on value.

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🪑 Roundtable Discussion cont'

⚜ USDM and Other Standards Roundtable: Summary of Discussion*

How to Drive Success in Standards Implementation

- A top-down mandate is most effective.

- Promote an understanding of standards interoperability.

- Promote an agile mindset so your organization is comfortable re-visiting decisions.

- Offer a clear return on investment, especially if it's not a regulatory requirement.

- Challenges in standards implementation:
  - ➤ Breaking down silos
  - ➤ Harmonization and alignment
  - ➤ Model changes seem too large

Managing End-to-End Data (E2E) Standards

- Can see E2E standards as a set. Highlight key interdependencies and relationships.

- Consider data categories and supportive standards governance.

- The industry seems to lack an E2E solution.

Skills and Training Needed

- Deliver stakeholder-specific training that articulates E2E impact.

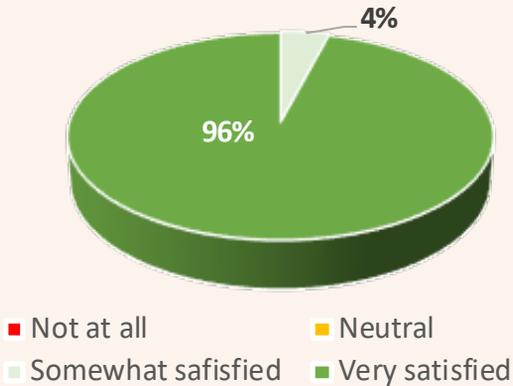- Focus on the importance of USDM and its relationship to other standards, such as SDTM and ADaM.

Summary of common themes from roundtable discussions*

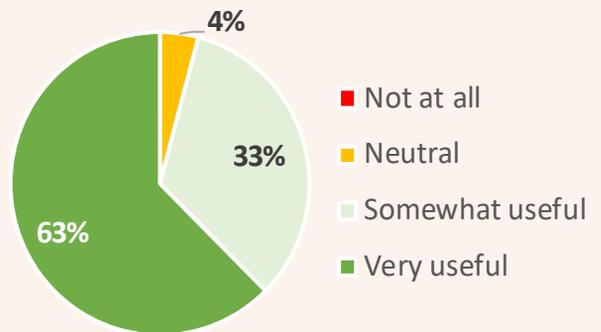|			
Leadership is key. Leaders from different groups may need to work together.	Because a regulatory mandate isn't driving this change, a clear **business case** or ROI may be necessary to get started.	**Buy-in** from both strategic and tactical perspectives is important. These may differ with different stakeholders.	Break down silos. Because the DDF initiative crosses functions, **cross-functional collaboration** is key.
Because the data flow starts with **clinical and medical writing**, their involvement and buy-in is critical.	To better bridge clinical research and clinical care, keep the **relationship between standards** in mind.	**Tailored messaging**. Use the "What's In It For Me?" approach and focus on what specific stakeholders need to know.	Tailored education and training are important, as are **continuous training and messaging**.

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SUCCESS MEASURES AND OUTCOMES*

100%
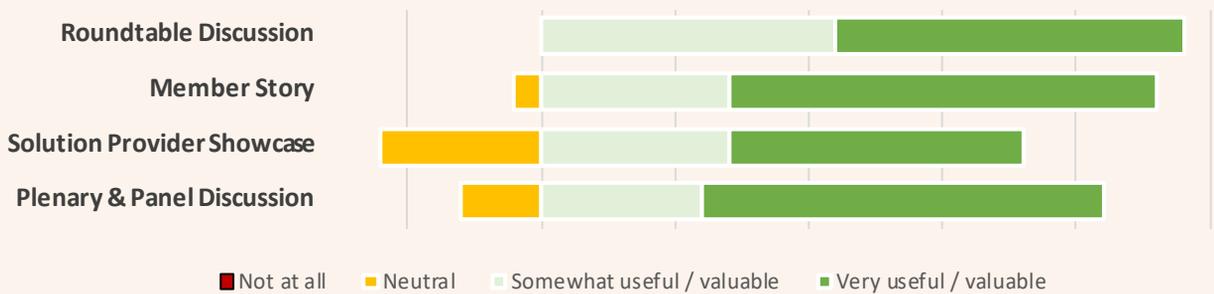of survey responses indicated interest in attending another DDF-Sponsored event like DDF Discovery Day

Agenda, Content and Conduct of DDF Discovery Day Satisfaction

96%
4%

- Not at all
- Neutral
- Somewhat safisfied
- Very satisfied

Usefulness of Agenda / Content in Enabling You to Help Lead or Drive Protocol Digitization

4%
33%
63%

- Not at all
- Neutral
- Somewhat useful
- Very useful

Usefulness & Value of Sessions in Raising Awareness for DDF Solutions**

- Roundtable Discussion
- Member Story
- Solution Provider Showcase
- Plenary & Panel Discussion

- Not at all
- Neutral
- Somewhat useful / valuable
- Very useful / valuable

Interest in Further DDF Related Engagements**

Familiarize yourself with Persona Toolkits and other sponsor transformation tools

Connect with stakeholders across your organization about impact of DDF

Deep dive into USDM resources

Engage in more hands-on experience with USDM and/or SDR

Explore internal, external, and/or collaborative projects relating to DDF and/or DDF solutions

Explore protocol digitalization strategies; i.e. USDM, SDR, or other E2E data flow solutions

Engage with DDF GitHub and supporting content

Learn more about future DDF governance and the roadmap for USDM and/or SDR

Connect with your DDF SPOC

Other

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QUOTES & FEEDBACK ON DDF DISCOVERY DAY

"I had very little understanding of DDF before today so each session gave a **different perspective** and deeper dive. I thoroughly enjoyed it"

"Always great and educational to hear from sponsors and vendors who are doing new and sometimes **unanticipated things** with DDF and USDM"

"It was helpful to get **direct exposure** to the content and to peers in the industry as well as related vendors."

"Superb"

"Would like to see **more on value stories and potential impact** from DDF "

Great to learn more about new/up and coming developments with DDF, especially related to **CDISC, ICH M11 and FHIR.** Appreciated the different vendor solutions and hearing how different sponsors are implementing."

"I now understand why my boss sent me to this conference!"

"For someone who has just started the DDF journey from my organization, this single day event helped me get a better understanding and perspective. Some great ideas were exchanged on having a **community of sponsor companies**"

"Vendor demos were very informative in representing the **art of the possible**."

"I know change is coming and I want to be part of the dialogue"

"Enjoyed the discussions both in session and in passing and definitely learned quite a bit while also **sparking questions** for our team"

"The energy level of members and the enthusiasm to share success stories was great to see - Getting some sneak preview on vendors and the areas they are focusing on in terms of tech enablers to drive DDF was **refreshing and thought provoking**."

"Glad I was here!"

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CONCLUSION AND FINAL THOUGHTS

DDF Discovery Day's objective was to convene TransCelerate Member Companies, clinical solution providers, and key industry stakeholders for an interactive experience to raise awareness and exchange knowledge about DDF solution implementation.

To create a robust experience, DDF Discovery Day included explorations of practical applications of DDF solutions, moderated discussions of transformational enablers & potential hurdles, and presentations on the future roadmap for DDF as the initiative is converging with many standards-related efforts in the ecosystem, including advancement of ICH M11 CeSHarP and research-to-care interoperability through the Vulcan FHIR Accelerator under HL7.

Per results of a post-event survey, DDF Discovery Day was successfully able to increase awareness of DDF solutions and its potential applications, promote attendees to learn more and share learnings with other industry peers and colleagues, and create heighten interest in the DDF initiative's progress moving forward.

The DDF Initiative project team is very energized by the positive results of the event. With 2024 around the corner, all the feedback and ideas shared during the event will be taken into consideration for next year's DDF Initiative objectives.

In closing, the event was only made possible by the meticulous preparation and planning by members of the DDF Initiative project team, as well as tight coordination across the program management office, sub-team leads, and project team members regarding the logistics and facilitation of the event. A very sincere 'thank you' to all that supported DDF Discovery Day, and hopefully this event will be the first of many other future events that can support the transformation journey toward Digital Data Flow.

To learn more about the DDF Initiative, CDISC, and Vulcan, access the links & QR Codes below.

TransCelerate DDF Website
https://www.transcelerate biopharmainc.com/assets/ digital-data-flow-solutions/

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

CDISC & Digital Data Flow
https://www.cdisc.org/ddf

Vulcan
HL7 FHIR
https://hl7vulcan.org/