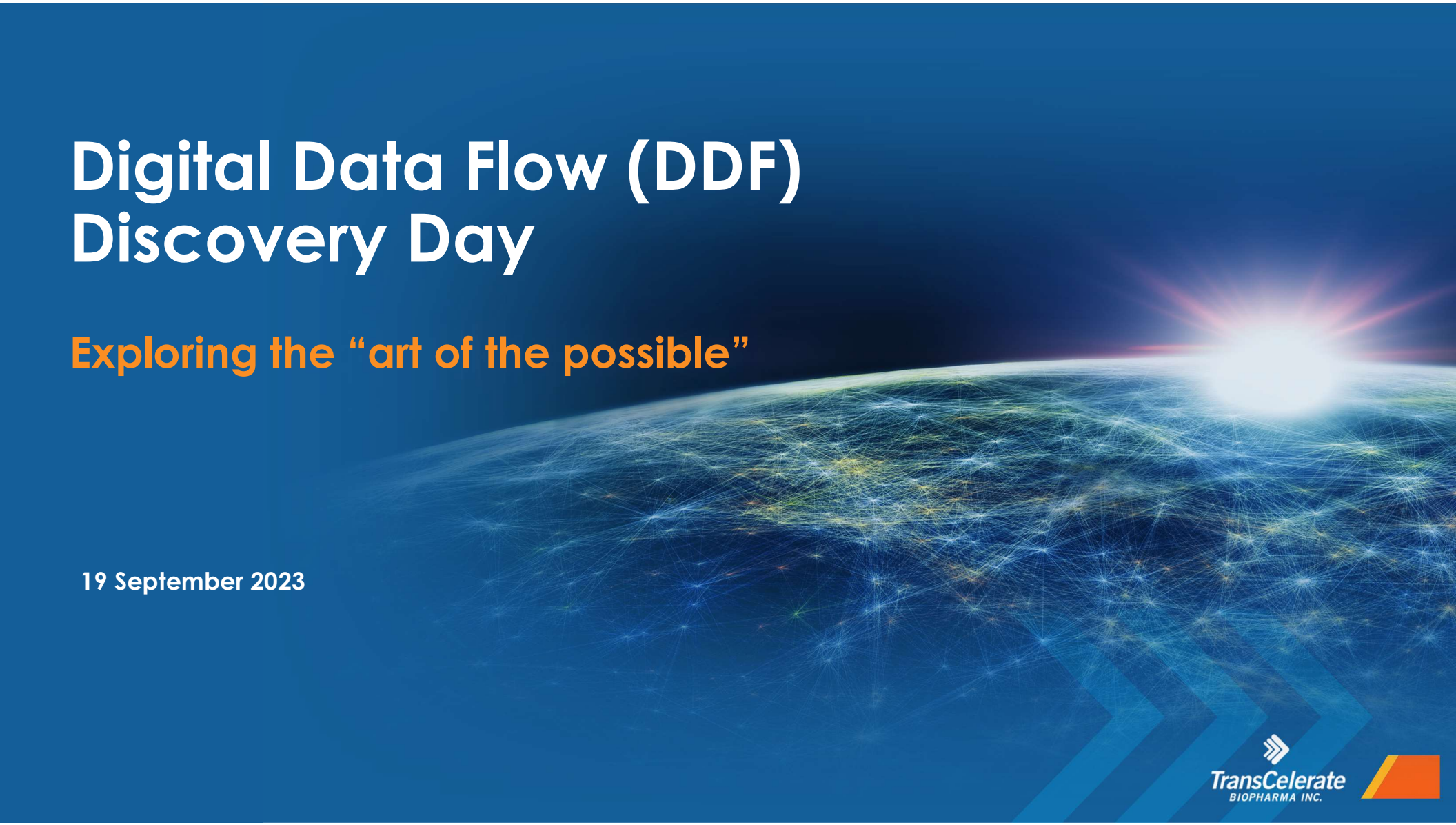
Digital Data Flow (DDF) Discovery Day

Exploring the "art of the possible"

19 September 2023



TransCelerate BIOPHARMA INC.

DDF Discovery Day Agenda

September 19, 2023

Complete the pre-event survey if you haven't already.

Time (EST)	Topic
7:30 – 8:30 AM	**On-site Registration & Networking Breakfast**
8:30 – 8:45 AM	**Welcoming Remarks;** *Kelsey Jakee, TransCelerate*
8:45 – 9:00 AM	**Keynote Speaker;** *Rob DiCicco, TransCelerate*
9:00 – 10:00 AM	**Plenary Session: Industry Convergence in Protocol Digitization and Interoperability** • ***TransCelerate DDF Initiative:*** *Delivering the vision of protocol digitization and automation; William Illis, Novartis* • ***CDISC:*** *USDM alignments to ICH M11 and beyond; Dave Iberson-Hurst, CDISC* • ***Vulcan:*** *Enabling digitization and interoperability of the protocol within research and care (HL7 FHIR & ICH M11); Mike Hamidi, Pfizer; Gustav Vella, Carelane* • ***Panel Q&A;*** *Kelsey Jakee (chair), TransCelerate*
10:00 – 10:15 AM	**Morning Break**
10:15 – 12:15 PM	**Solution Provider Showcase and Q&A**
12:15 – 1:15 PM	**Networking Lunch**
1:15 – 2:00 PM	**[Summer 2] Member Story:** *DDF journey from an early adopter; Nusheen Ditta & Shagun Grover, Roche* **[Summer 1] Solution Provider Debrief & Departure;** *Belinda Griffin (chair), TransCelerate*
2:00 – 3:15 PM	**Interactive Roundtable Discussions:** *Overcoming challenges in digital transformation*
3:15 – 3:30 PM	**Afternoon Break**
3:30 – 4:30 PM	**Roundtable Readout;** *Renu Shukla (chair), JnJ*
4:30 – 5:00 PM	**Reflections & Closing Statements;** *Renu Shukla, JnJ; William Illis, Novartis*

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Ground Rules for the Day

Today's solution provider presentations are about showing the art of the possible when using the USDM/SDR.

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

TransCelerate does not expressly or impliedly endorse any particular software, system, service, or vendor.

Member companies decide independently which DDF deliverables/and or vendor products they will use. Participation in the DDF initiative and today's meeting is entirely voluntary.

Please don't ask member companies which vendors they use or the terms of their arrangements with those vendors. Member companies cannot share this information when there are other member companies present.

If a member company or a vendor is not comfortable answering a question, please do not pursue it.

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Keynote Speaker

Rob DiCicco

Vice President, Portfolio Management,

TransCelerate Biopharma Inc.

TransCelerate was conceived to improve the health of people around the world by accelerating and simplifying the research and development of innovative new therapies

In 2012, after several years of discussion, R&D Leaders formed a non-profit to collaborate using the words **"Transform"** and **"Accelerate"** to create TransCelerate.

Member driven mission to collaborate across the global biopharmaceutical research and development community to **identify, prioritize, design, and facilitate** the implementation of solutions designed to drive the **efficient, effective and high-quality delivery of new medicines**.

TransCelerate has grown from **10 pioneering companies** to **22 Member Companies** working towards improvement in key value drivers in clinical research.

The dedication of TransCelerate members over the last decade has resulted in delivering tangible impact to the ecosystem

Our approach has focused on delivering pragmatic solutions and capturing value across the ecosystem, while prioritizing patient needs.

- Advanced Science through Data Sharing & Reuse
- Accelerated Drug Development
- Captured Benefits for Sponsors
- Improved Quality and Operational Efficiency
- Evolved Practices to Engage Patients as Partners
- Reduced Burden For Clinical Sites
- Catalyzed Innovation Through Digitization
- Modeled Industry Collaboration

Since 2012, we have been on a journey to advance data utilization/reuse

- Clinical Data Standards
- Common Protocol Template
- FDA-NIH Leadership Council
- Template Suite for Reuse (CC&R)
- Automation PoC
- Digital Data Flow
- ICH M11 CeSHarp
- ACRO and EU PEARL Collaborations
- VULCAN HL7 FHIR

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TransCelerate aspires toward a vision of Converging Clinical Care and Clinical Research

CONVENE STAKEHOLDERS TO READY THE ECOSYSTEM FOR CLINICAL TRIALS AT THE POINT OF CARE

ENABLE COMPLETE DIGITIZATION & INTEROPERABILITY OF THE STUDY PROTOCOL ACROSS RESEARCH & CARE

Ecosystem collaboration is fundamental to these goals

- TransCelerate Members
- HCPs / Clinicians
- Community Care
- Patient Groups
- Regulators
- Policy Makers / Agencies
- Technology Community
- Standards Setting Org's
- Other Consortia

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Plenary Session

9:00-10:00AM

Industry Convergence in Protocol Digitization and Interoperability

QR Code: Open the Mentimeter with your phone to ask questions during panelist presentations; Q&A at end

Panel Speakers

William Illis, Novartis

- Global Head of Collaboration / Technology Strategy, Clinical Development & Analytics
- TransCelerate DDF Initiative Lead

Rob DiCicco, TransCelerate

- Vice President, Portfolio Management

Dave Iberson-Hurst, CDISC

- CDISC DDF Product Owner

Kelsey Jakee, TransCelerate (chair)

- DDF Program Director

Mike Hamidi, Pfizer

- Director, Clinical Data Standards Strategy Lead
- Vulcan Operations Committee Co-Chair

Gustav Vella, Carelane

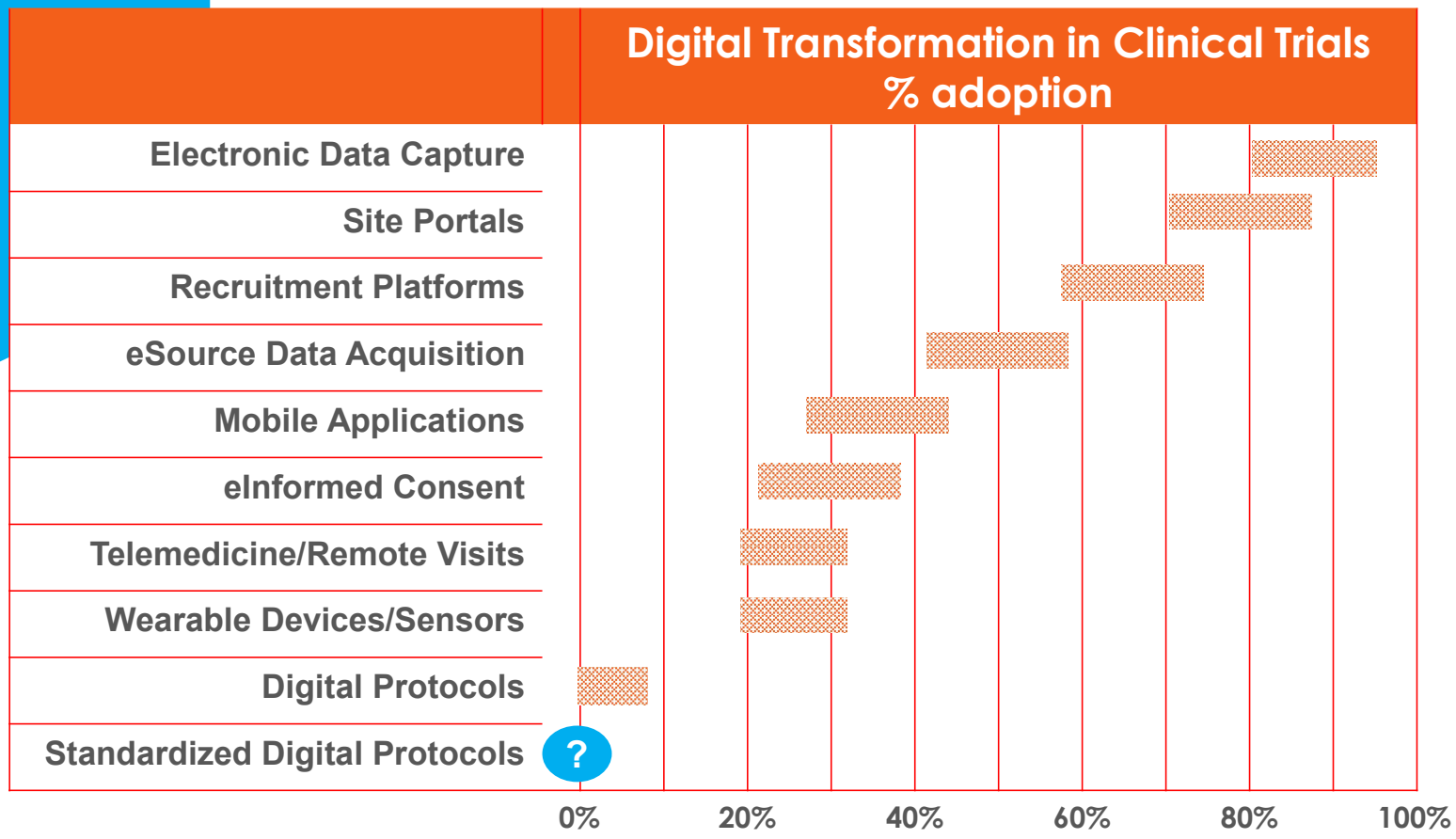
- Cofounder
- Vulcan Member, Contributor to Vulcan Schedule of Activities & Vulcan RWD projects

Digital Data Flow
Protocol Digitalization and Automation

William Illis
DDF Workstream Lead

DDF Discovery Day,
September 19, 2023

Why Digital Data Flow?



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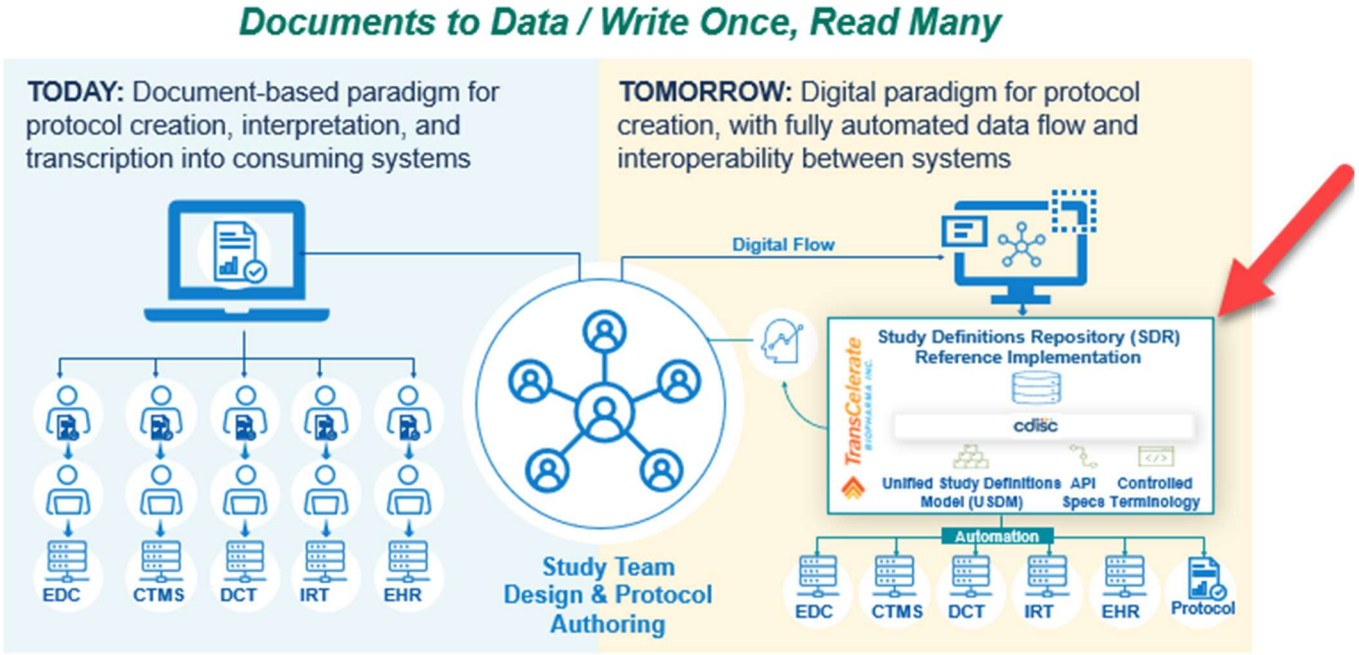
Digital Data Flow Ambition

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

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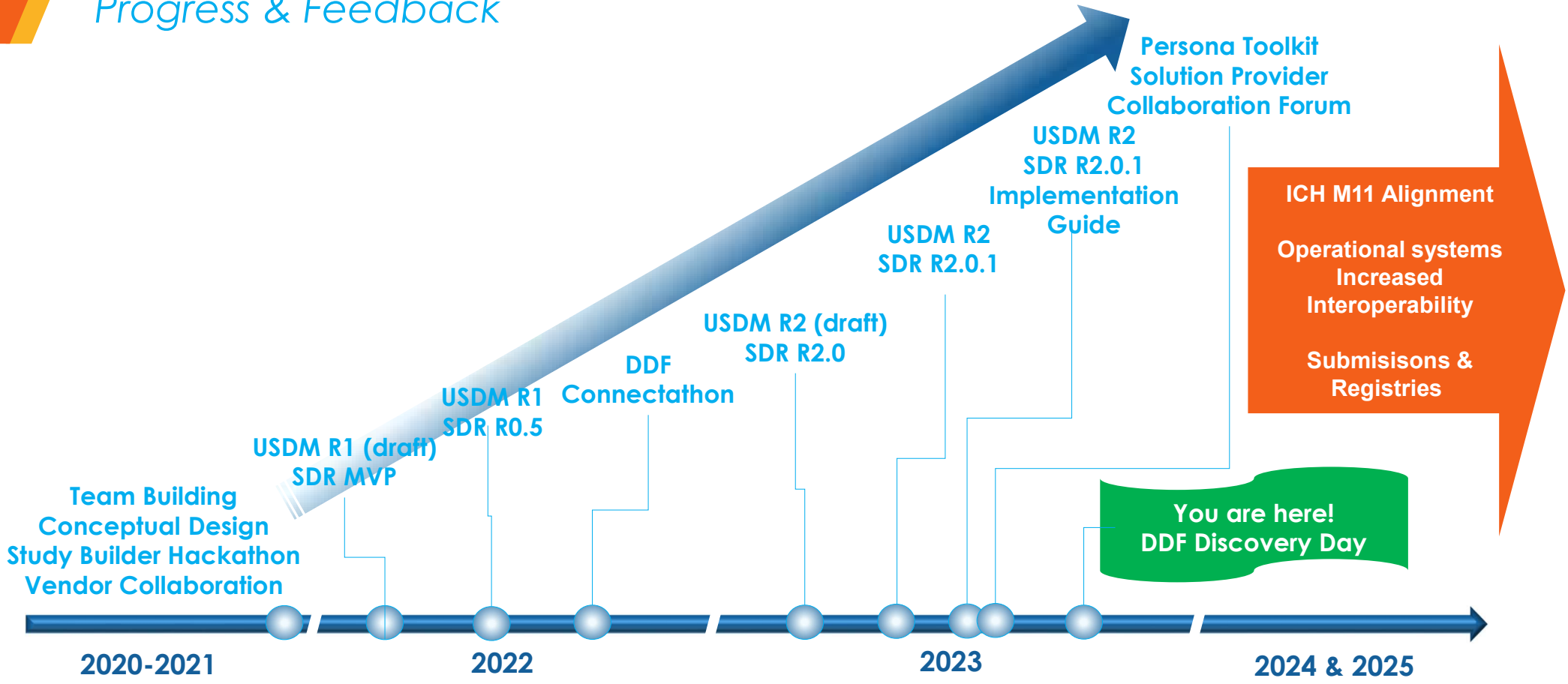
DDF Timeline

Progress & Feedback



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Feedback

"It's too complex."

"Everything should be made as simple as possible, but not simpler."

-Albert Einstein

Feedback

"It doesn't handle this case, it's wrong"

"All models are wrong but some are useful."

-George Box

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Feedback

"Progress is too slow, there are too many stakeholders, and organizations involved"

"If you want to go fast go alone, if you to go far go together."

-African proverb

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Feedback

"It seems like a difficult transformation. I don't know how to get started"

"A journey of 1000 miles begins with a single step."

-Chinese Proverb

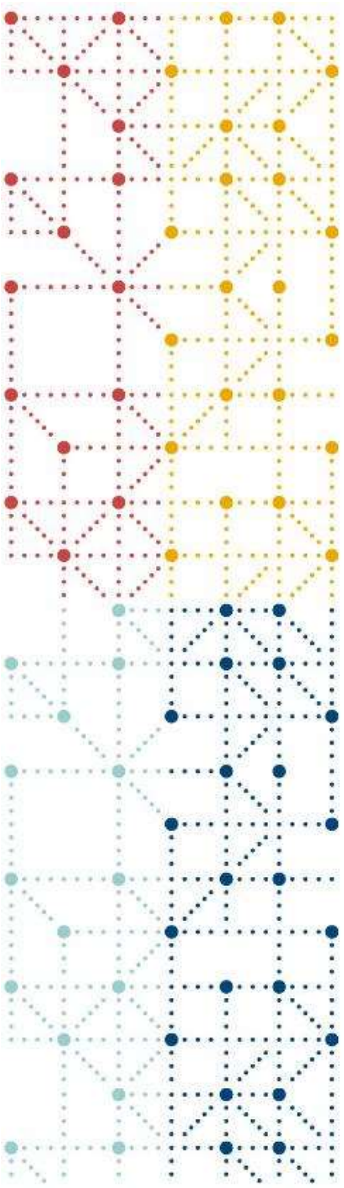
Thank you

USDM meets M11

Dave Iberson-Hurst
CDISC USDM Product Owner

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.*
- *On contract to CDISC for the DDF work*



Agenda

1. Introduction
2. Phases One and Two
3. The Challenges
4. Phase Three: USDM Meets M11
5. Summary

CDISC DDF Phase One

July 2021 – July 2022

Unified Study Definitions Model (USDM) Class Diagram
The UML class diagram (normative) as well as SQL Data Dictionary, Entity Relationship Diagram and example JSON output (informative)

Application Programming Interface (API) Specification
The API definition (normative) in JSON and HTML forms

CDISC Controlled Terminology
The controlled terminology (normative) developed for the project. Provided in an Excel format so as to be easily searched and filtered.

Reference Architecture Conformance Tests
Provided by the functionality provided by tools such as SwaggerHub and Postman

Essential Users Stories
The User Stories. PDF document

Architecture Principles
The architectural principles developed by the project. PDF Document

Supporting Materials
A set of informational materials in PDF format to help understand the deliverables being reviewed. PDF documents or references.

CDISC DDF Phase Two

Oct 2022 – June 2023

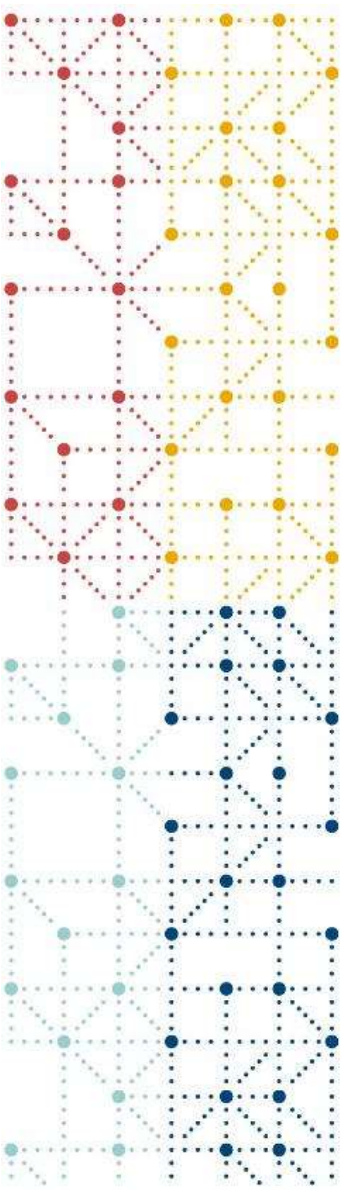
Unified Study Definitions Model (USDM) Class Diagram
The UML class diagram (normative) as well as SQL Data Dictionary, Entity Relationship Diagram and example JSON output (informative)

Application Programming Interface (API) Specification
The API definition (normative) in JSON and HTML forms

CDISC Controlled Terminology
The controlled terminology (normative) developed for the project. Provided in an Excel format so as to be easily searched and filtered.

Test Files
Examples of USDM JSON files

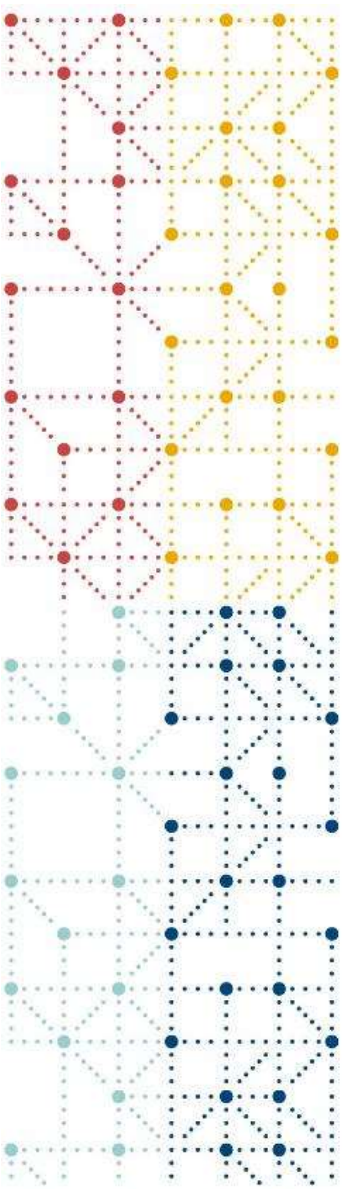
Implementation Guide
Improved explanation of the model and its use, examples etc



The Challenges

Challenges and Choices …

- Choices
  - Recreate the current world or look for something better?
  - How radical do we wish to be?
  - Don’t just want to recreate the “paper world”
- Align with existing CDISC standards but not be constrained by them
- Don’t reinvent the wheel
- Don’t constrain implementations
- The project exposes the complexity of our world



Phase Three: USDM Meets M11

Next Steps – Phase Three

Slide from May 2023

USDM

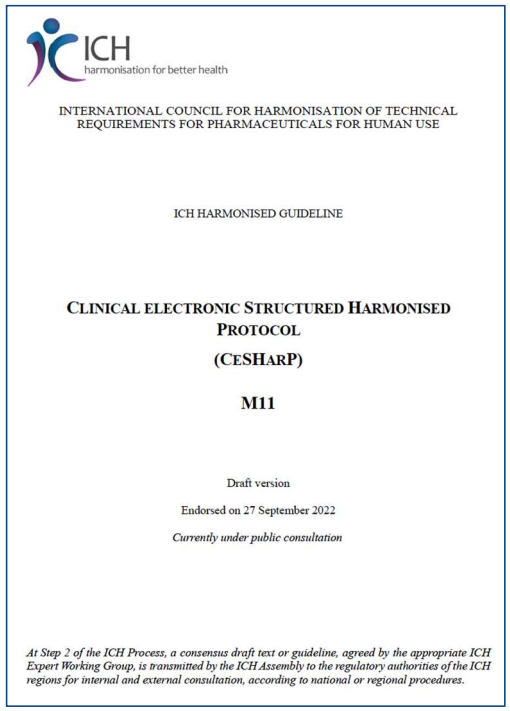
SDR

1	2	3
• Baseline model for specifying a study in digital format • Model supports use of a CRF link to specify which forms to use in EDC. • Handles simple study designs	• Improved support for complex study designs with a fully specified digitized Schedule of Activities (SoA) • Model supports the identification of the appropriate CRFs for data collection to enable automated, faster configuration via use of Biomedical Concepts • Improved CPT alignment • Initial 'T' Domain support	Focus for Phase 3 is currently being determined. Current expectations are: • Expand ability to handle increasingly complex studies • ICH M11 & CPT alignment
• Consume digitized study specification from an upstream source e.g., study builder) • Store, view and search study concepts • Downstream EDC systems may pull study specification to aid in set-up	• Downstream vendors can readily consume the SoA from the SDR • Sponsor system admins can perform a visual check that SoA data received from an upstream system displays an accurate, human-readable SoA table • Opportunity to aggregate robust historical protocol information to support analytics to drive smart design and assess risk	

M11 Is …

ICH CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHarP)

https://www.ich.org/page/multidisciplinary-guidelines



ICH harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

M11

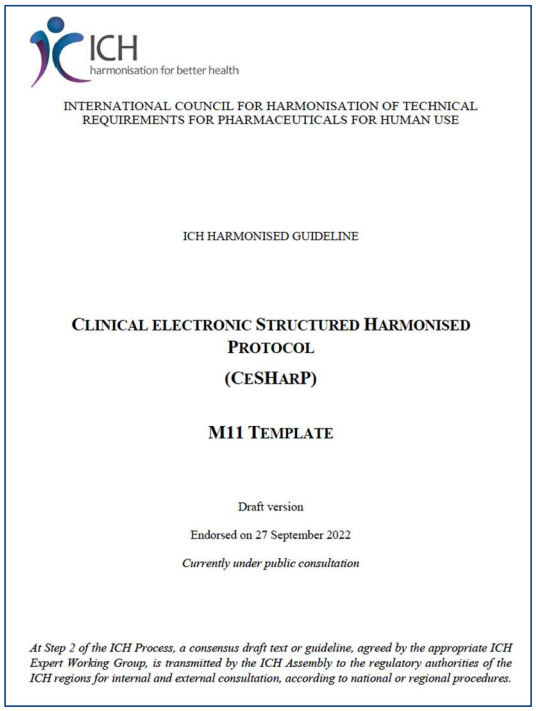
Draft version

Endorsed on 27 September 2022

Currently under public consultation

At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Assembly to the regulatory authorities of the ICH regions for internal and external consultation, according to national or regional procedures.

Provides background, purpose, and scope as a guideline



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ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

M11 TEMPLATE

Draft version

Endorsed on 27 September 2022

Currently under public consultation

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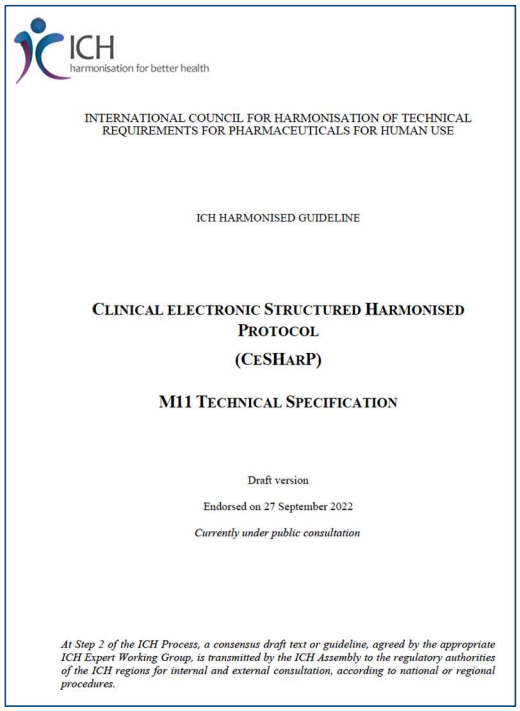
Provides the written format for the Interventional Clinical Trial Protocol Template



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(CESHARP)

M11 TECHNICAL SPECIFICATION

Draft version

Endorsed on 27 September 2022

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Provides the technical representation aligned with the guideline and protocol template

M11 Simple Example

Template Specification

Protocol Full Title:	[Protocol Full Title] The protocol should have a descriptive title that identifies the scientific aspects of the trial sufficiently to ensure it is immediately evident what the trial is investigating and on whom, and to allow retrieval from literature or internet searches.
Sponsor Confidentiality Statement:	[Sponsor Confidentiality Statement] Insert the Sponsor's confidentiality statement, if applicable, otherwise delete.
Protocol Number:	[Protocol Number] A unique alphanumeric identifier for the trial, designated by the Sponsor, is a standard part of trial data, and should be included for most trials.
Version:	[Version] An optional field for use by the Sponsor at their discretion.
Amendment Number:	[Amendment Number] Enter the amendment number. If this is the original instance of
Trial Phase:	[Trial Phase] [Description of Trial Phase Other] Acceptable entries are: "Early Phase 1", "Phase 1", "Phase 1/Phase 2", "Phase 2", "Phase 2/Phase 3", "Phase 3", "Phase 4",
Compound Number(s):	[Compound Number] Enter the Sponsor's unique identifier for investigational compound(s) in the trial. Add or delete additional fields as needed.
Compound Name(s):	[Nonproprietary Name]. [Proprietary Name]. [Additional Proprietary Name] Delete this line from the table if a nonproprietary name has not yet been assigned. Omit proprietary name fields if not yet established.
Trial Phase:	[Trial Phase] [Description of Trial Phase Other] Acceptable entries are: "Early Phase 1", "Phase 1", "Phase 1/Phase 2", "Phase 2", "Phase 2/Phase 3", "Phase 3", "Phase 4",

Technical Specification

Term (Variable)	Trial Phase
Data Type	Pick list
Topic, Value or Header	D
Definition	
User Guidance	For trials combining investigational drugs or vaccines with devices, classify according to the phase of drug development.
Conformance	Required
Cardinality	
Relationship content from ToC representing the protocol hierarchy	Title Page
Relationship (reference to high level conceptual model)	
Value	Early Phase 1 Phase 1 Phase 1/Phase 2 Phase 2 Phase 2/Phase 3 Phase 3 Phase 4 Other
Business rules	**Value Allowed:** yes **Relationship:** n/a **Concept:** Protocol short title
Duplicate field in other sections	

Controlled Terms

Template Specification

Protocol Full Title:	[Protocol Full Title] The protocol should have a descriptive title that identifies the scientific aspects of the trial sufficiently to ensure it is immediately evident what the trial is investigating and on whom, and to allow retrieval from literature or internet searches.
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Business rules	**Value Allowed:** yes **Relationship:** n/a **Concept:** Protocol short title
Duplicate field in other sections	

CDISC CT

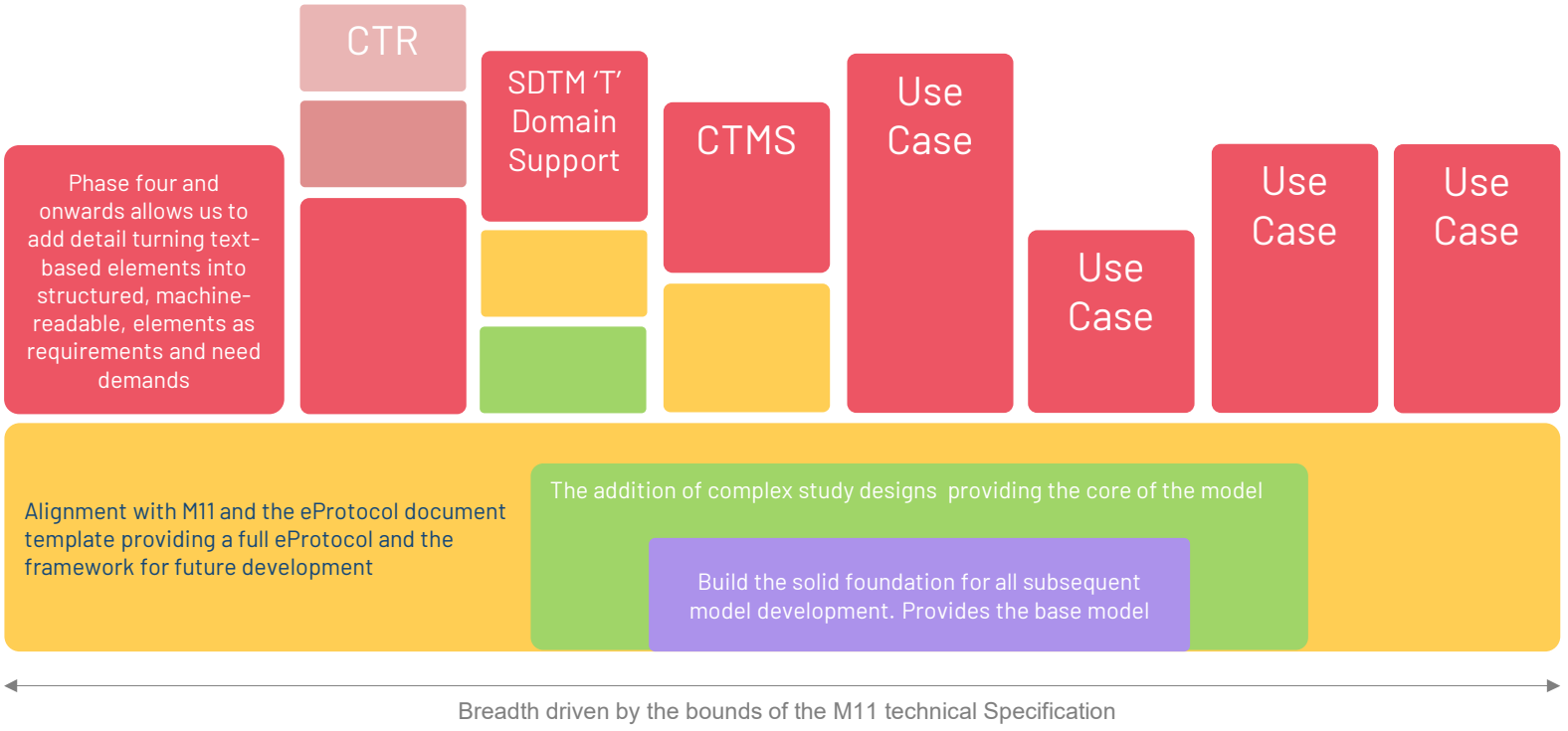
Trial Phase Response (C66737)

NOT APPLICABLE
PHASE 0 TRIAL
PHASE I TRIAL
PHASE I/II TRIAL
PHASE II TRIAL
PHASE II/III TRIAL
PHASE IIA TRIAL
PHASE IIB TRIAL
PHASE III TRIAL
PHASE IIIA TRIAL
PHASE IIIB TRIAL
PHASE IV TRIAL
PHASE V TRIAL

Breadth versus Depth

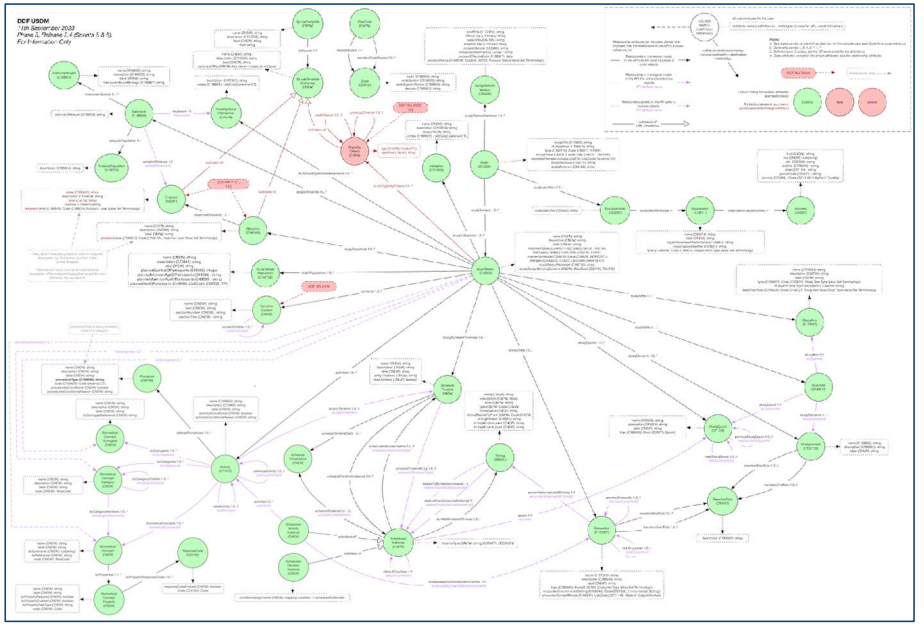
Depth driven by individual use cases.

Some capability exists today, can be expanded incrementally or in one phase



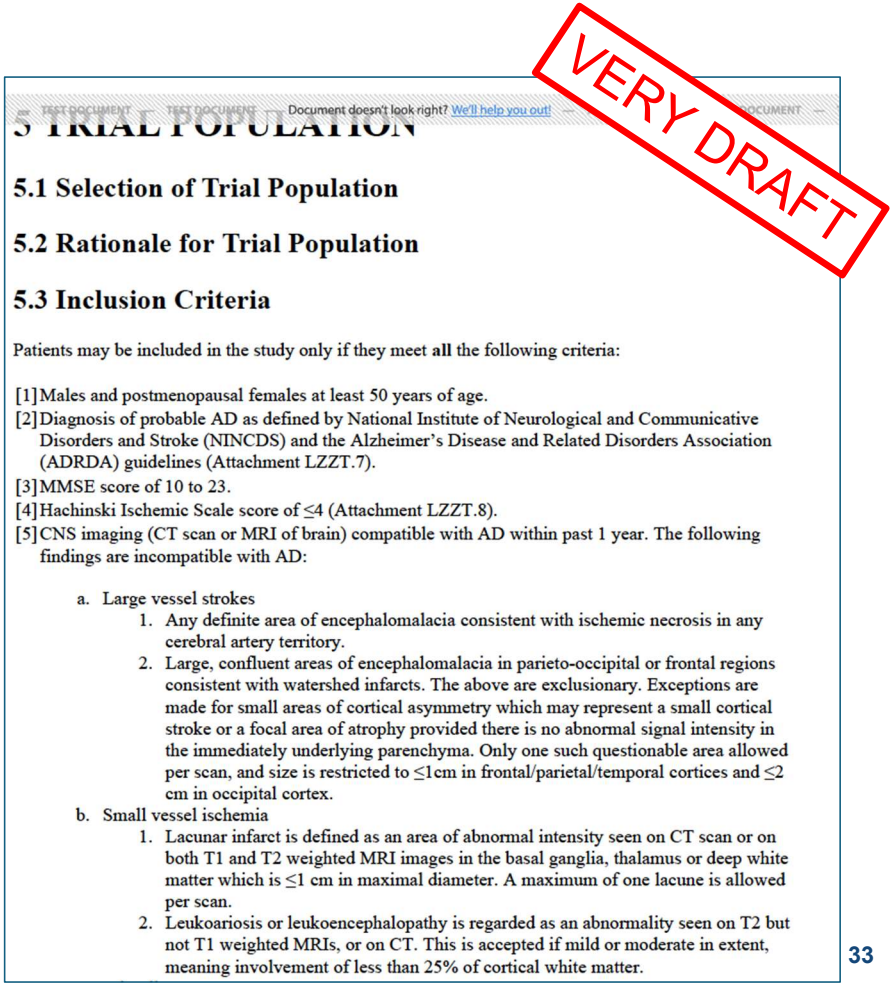
Shift of Focus

- Phases One & Two
  - Focused on the structured elements of the protocol, e.g. the Schedule of Activities (SoA)
  - The protocol document was an external entity into which the structured content could be exported
- Phase Three
  - Now contains structured and unstructured elements
  - The entire protocol document is held within the USDM
  - Allows for the protocol document to be generated from the model



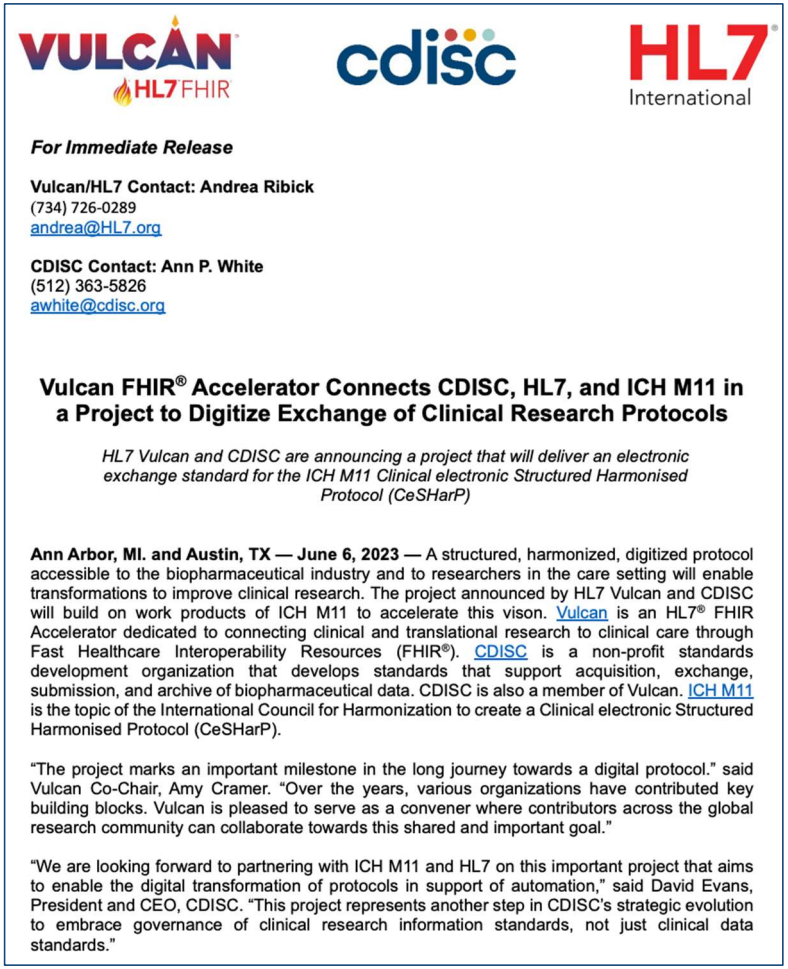
M11 Template Example Document

- First attempt to create a protocol document from the USDM, both structured [non-narrative] and unstructured [narrative text] content.
- Functionality has been added to the Excel test data tool
- More work is needed, this is very much a first draft



ICH M11, CDISC & HL7

- "FHIR-based exchange standard for ICH's Clinical electronic Structured Harmonised Protocol (CeSHarP), aligned to CDISC standards"
- The USDM and CDISC CT will be used to in the project
- Initial project discussions have been underway for several months



For Immediate Release

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CDISC Contact: Ann P. White
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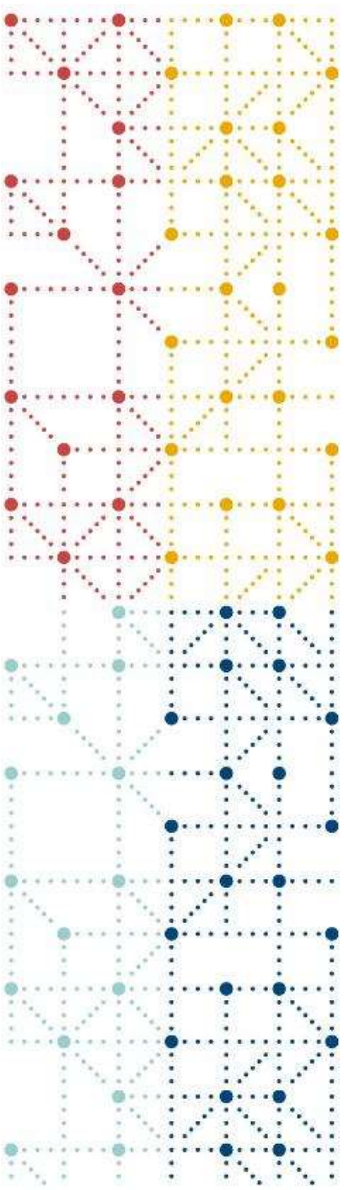
Vulcan FHIR® Accelerator Connects CDISC, HL7, and ICH M11 in a Project to Digitize Exchange of Clinical Research Protocols

HL7 Vulcan and CDISC are announcing a project that will deliver an electronic exchange standard for the ICH M11 Clinical electronic Structured Harmonised Protocol (CeSHarP)

Ann Arbor, MI. and Austin, TX — June 6, 2023 — A structured, harmonized, digitized protocol accessible to the biopharmaceutical industry and to researchers in the care setting will enable transformations to improve clinical research. The project announced by HL7 Vulcan and CDISC will build on work products of ICH M11 to accelerate this vison. Vulcan is an HL7® FHIR Accelerator dedicated to connecting clinical and translational research to clinical care through Fast Healthcare Interoperability Resources (FHIR®). CDISC is a non-profit standards development organization that develops standards that support acquisition, exchange, submission, and archive of biopharmaceutical data. CDISC is also a member of Vulcan. ICH M11 is the topic of the International Council for Harmonization to create a Clinical electronic Structured Harmonised Protocol (CeSHarP).

"The project marks an important milestone in the long journey towards a digital protocol." said Vulcan Co-Chair, Amy Cramer. "Over the years, various organizations have contributed key building blocks. Vulcan is pleased to serve as a convener where contributors across the global research community can collaborate towards this shared and important goal."

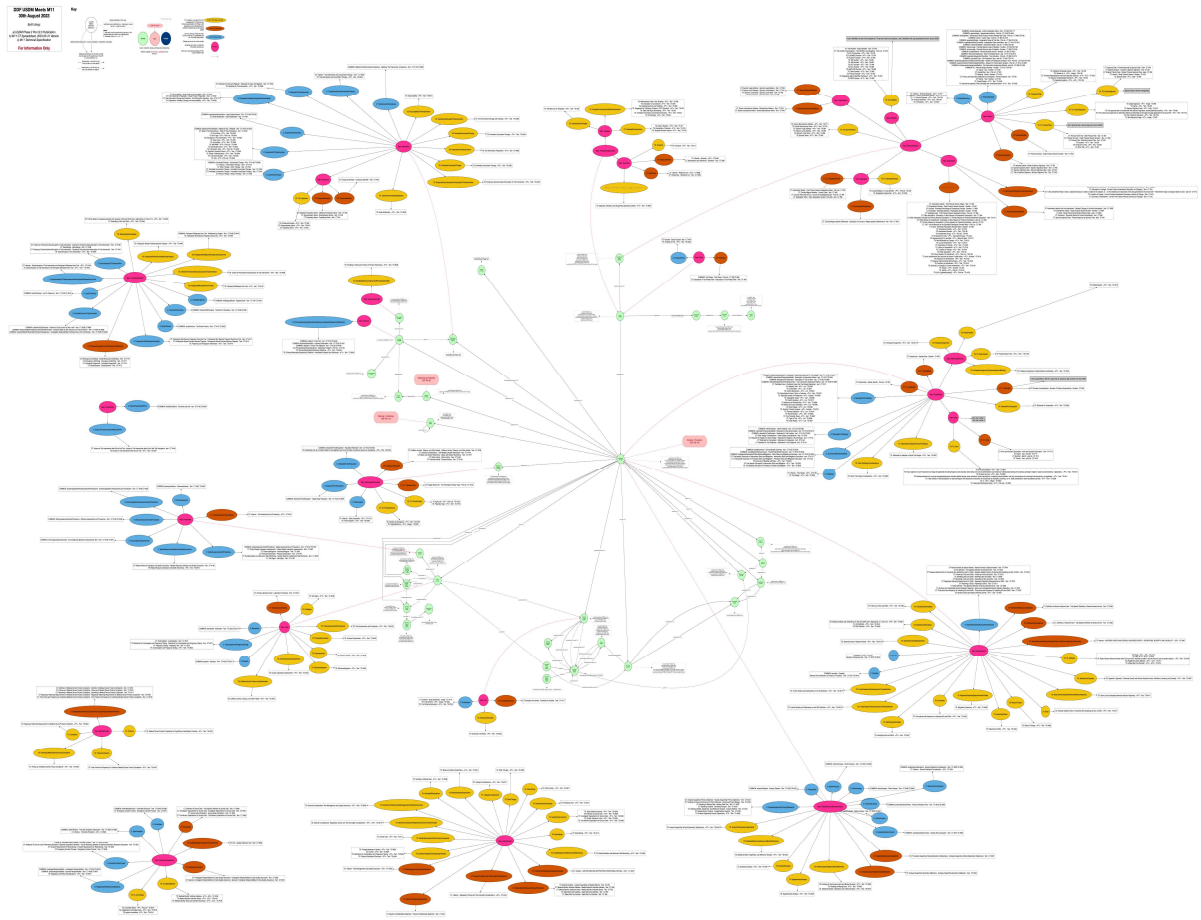
"We are looking forward to partnering with ICH M11 and HL7 on this important project that aims to enable the digital transformation of protocols in support of automation," said David Evans, President and CEO, CDISC. "This project represents another step in CDISC's strategic evolution to embrace governance of clinical research information standards, not just clinical data standards."

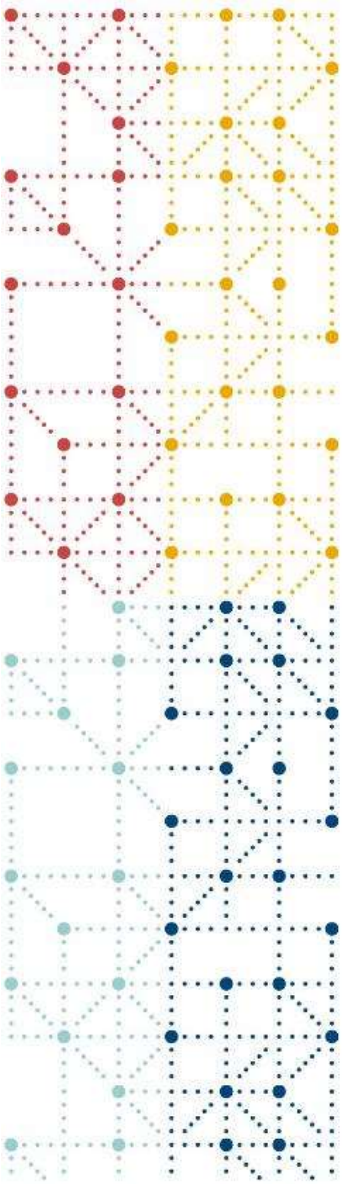


Summary

Summary

- Digital Data Flow / Unified Study Definitions Model (DDF/USDM) fills an important gap
- A single source of truth
- [First] Use of Biomedical Concepts brings precision
- Can support various use cases
  - Prospective v Retrospective
- The stars are aligning, ICH, Transcelerate, CDISC & HL7





Thank You

Contacts

Dave Iberson-Hurst: diberson-hurst.external@cdisc.org
John Owen: jowen@cdisc.org

Links

Github: https://github.com/cdisc-org/DDF-RA

cdisc

What is FHIR?

FHIR (**F**ast **H**ealthcare **I**nteroperability **R**esources), a specification, which is a standard for exchanging healthcare information electronically. FHIR R4 is the modernization of and best feature reutilization from HL7s v2, v3, and CDA products. It's also an evolving set of resources that can be expressed as a **60/40 rule**, where 60% is a common starting point and the remaining 40% are in the form of specialized use cases based on third-party extensions.

FHIR aims to simplify implementation without sacrificing information integrity. It leverages existing logical and theoretical models to provide a consistent, easy to implement, and rigorous mechanism for exchanging data between healthcare applications.

Why?	Interoperability out-of-the-box (bridge clinical research and clinical care)
How?	Built on web standards (e.g., XML, JSON, HTTP, and Oauth)
What?	Flexible standard with 150+ resources to cover a wide array of use cases
Who?	Diverse global community (hospitals, academia, vendors, biopharma, regulators)

VULCAN

Source: https://www.hl7.org/fhir/overview.html, https://www.healthit.gov/sites/default/files/2019-08/ONCFHIRFSWhatIsFHIR.pdf , R4 is the current version of the FHIR standard

Vulcan: Enabling digitization and interoperability of the protocol within research and care (HL7 FHIR & ICH M11)

TransCelerate DDF Discovery Day

Presented by: Mike Hamidi

What is Vulcan?

Vulcan is a membership-based group operated under HL7's FHIR Accelerator Program.

Through Vulcan, diverse members of the research community collaborate to align care and clinical & translational research by driving standards-based exchange of health and research data.

The Goals of Vulcan

Elements of Vulcan

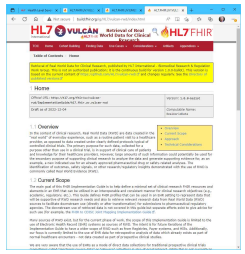
WHY

- FHIR is an enabling technology for harmonising and processing data.
- Vulcan exists to help Clinical and Translational Research start using FHIR to manage the vast amount of data they have to work with.
- Vulcan also exists to bring Clinical and Translational Research and Clinical Care closer together through FHIR.

HOW

Vulcan:

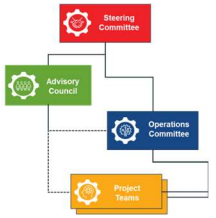
- Creates a community
- Supports projects that have a clear and practical objective and short timescale
- Creates Implementation Guides (IGs)
- Uses connectathons to test the Implementation Guides
- Provides Events & Education



Schedule of Activities, RWD, Electronic Product Information (ePI), Adverse Events, FHIR to OMOP, Phenotypic Data

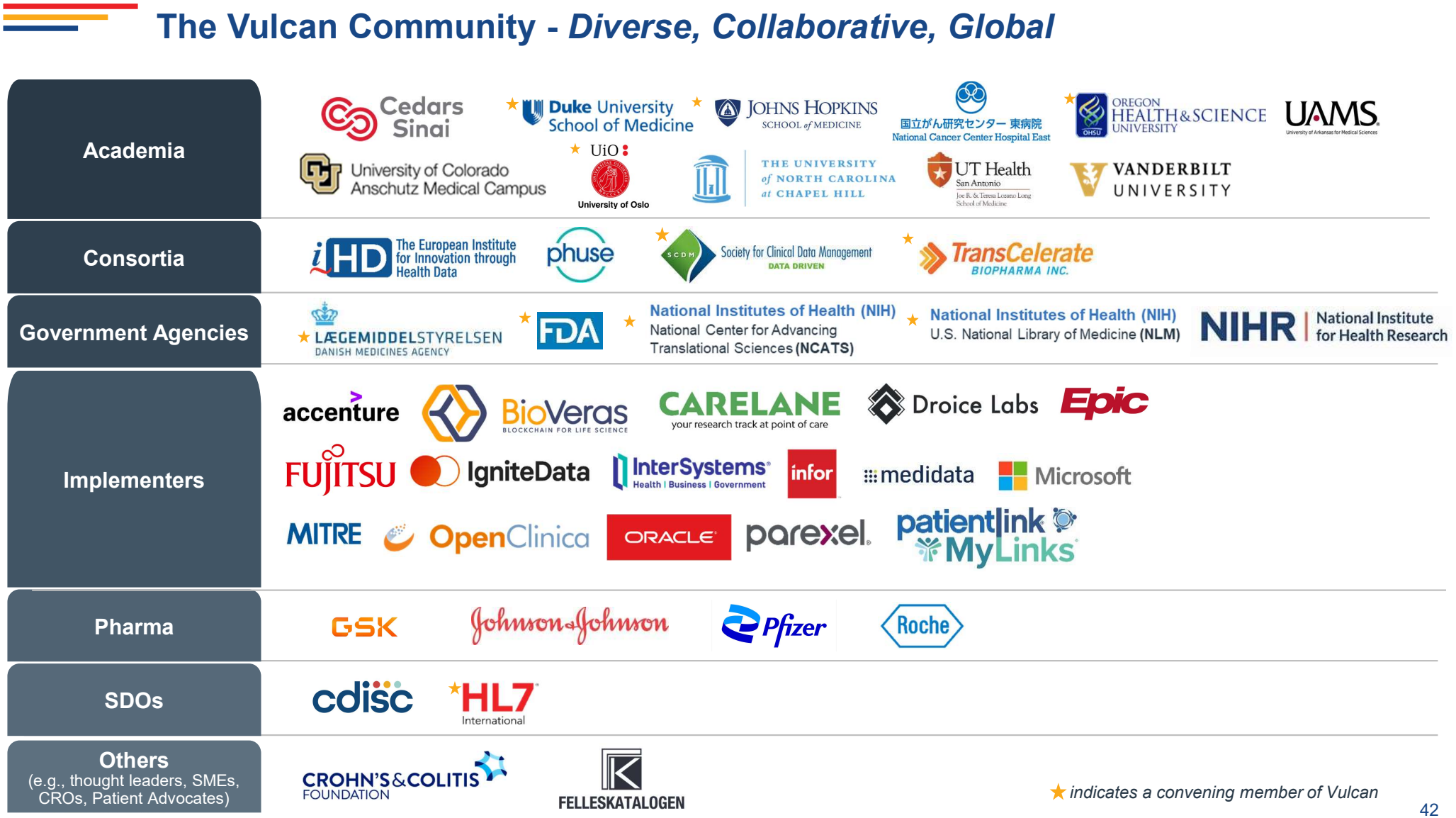
WHO

- Over 40 members drawn from Pharma, Academic, Vendors, Regulators, SDOs.
- Operations Committee formed from Members
- Supported by Project Management Office
- International scope



VULCAN

The Vulcan Community - *Diverse, Collaborative, Global*



★ *indicates a convening member of Vulcan*

Vulcan: M11 Concept

Software Engineers, Medical Writers, Clinicians, Statisticians, etc.

ICH M11 Package → CDISC USDM → Vulcan M11 FHIR IG → M11 on FHIR Solutions → FHIR Protocol → Protocol Exchange

HL7® FHIR®

- Healthcare Institutions
- Academic Institutions
- Biopharma / Medical Devices
- Health Authorities
- Health Data Sharing Platforms

Server Side Implementations

DHTs EHRs PHRs CTPs Others

DHT=Digital Health Technologies; EHR=Electronic Health Records; PHR=Personal Health Record; CTP=Clinical Trial Platforms (e.g., CTMS, EDC, MDR, DBMS)

Opportunity Use Cases

Interoperable Data Exchange | Patient Care | Practitioner Clarity | Persistent Data Analysis | Clinical Reports | Clinical Decisions | Site Qualification | Cost Est. Analysis | Care Plan Workflows | Clear Guidelines | Gen AI Solutions

VULCAN

What is Vulcan's Role in the Joint ICH M11 Project?

Vulcan's Role

- **Infrastructure:** Host Connectathons to test and demonstrate protocol exchange
- **Technical expertise & process support** for FHIR Implementation Guide(s)
- **Enable convergence of regulatory and EHR-related use cases** to broaden & accelerate implementation
  - USDM-FHIR mapping methodology
  - Current Vulcan work packages: Adverse Events, Schedule of Activities
  - New site/EHR-focused work packages (e.g., eligibility)
- **Governance:** define a shared maintenance plan of the FHIR IG(s) with the ICH Expert Working Group content experts
- **Communications:** Support joint and aligned messaging and education efforts across partnering organizations (ICH M11, Vulcan, HL7, CDISC, TransCelerate)

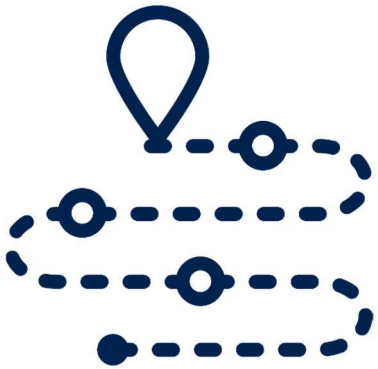
VULCAN

Vulcan Opportunities

- FHIR enables interoperable protocol exchange into clinical care ecosystem (e.g., EHRs)
- Emphasis on semantic understanding of protocol information (e.g., common coding systems → SNOMED-CT, CPT, HCPS, LOINC, RxNorm)
- Transforming static to computable SoA (i.e., expedite study start-up at sites)
- Utilizing the protocol SoA to estimate study cost analysis (e.g., chemistry lab panel costs)
- Allowing for protocol stylesheets to render different views or language (e.g., participant vs. investigator)
- Dynamic integration of referenced guidelines, publications, etc.
- Enabling structured inclusion/exclusion criteria to achieve eligibility matching automation (i.e., candidate pooling via healthcare system or network)
- Leveraging syntactic and semantic content to enable LLMs for GenAI (e.g., generate relevant content using existing protocols to create efficiency and consistency in protocol development)
- A consistent set to agnostic requirements for technology solutions (e.g., protocol authoring software)
- Flexibility to accommodate the 60/40 rule (i.e., 60% international commonality with 40% specific to regional, national, or local regulations and laws)
- Future FHIR opportunities can include statistical analysis plans, endpoint models w/ computable expressions, disease and medicinal ontologies, or source data collection methodologies

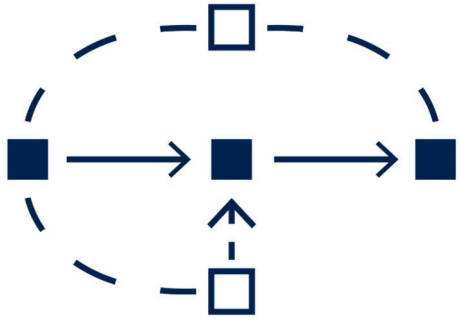
VULCAN

Thank You



This is a journey

Collaboration is important



Manage challenges together

VULCAN

Plenary Session

9:00-10:00AM

Industry Convergence in Protocol Digitization and Interoperability

QR Code: Open the Mentimeter to ask additional questions

Panel Speakers

William Illis, Novartis

- Global Head of Collaboration / Technology Strategy, Clinical Development & Analytics
- TransCelerate DDF Initiative Lead

Rob DiCicco, TransCelerate

- Vice President, Portfolio Management

Dave Iberson-Hurst, CDISC

- CDISC DDF Product Owner

Kelsey Jakee, TransCelerate (chair)

- DDF Program Director

Mike Hamidi, Pfizer

- Director, Clinical Data Standards Strategy Lead
- Vulcan Operations Committee Co-Chair

Gustav Vella, Carelane

- Cofounder
- Vulcan Member, Contributor to Vulcan Schedule of Activities & Vulcan RWD projects

Break
10:00-10:15

DDF Discovery Day Agenda

September 19, 2023

Time (EST)	Topic	
7:30 – 8:30 AM	**On-site Registration & Networking Breakfast**	
8:30 – 8:45 AM	**Welcoming Remarks;** *Kelsey Jakee, TransCelerate*	
8:45 – 9:00 AM	**Keynote Speaker;** *Rob DiCicco, TransCelerate*	
9:00 – 10:00 AM	**Plenary Session: Industry Convergence in Protocol Digitization and Interoperability** • ***TransCelerate DDF Initiative:*** *Delivering the vision of protocol digitization and automation; William Illis, Novartis* • ***CDISC:*** *USDM alignments to ICH M11 and beyond; Dave Iberson-Hurst, CDISC* • ***Vulcan:*** *Enabling digitization and interoperability of the protocol within research and care (HL7 FHIR & ICH M11); Mike Hamidi, Pfizer* • ***Panel Q&A;*** *Kelsey Jakee (chair), TransCelerate*	
10:00 – 10:15 AM	**Morning Break**	
10:15 – 12:15 PM	**Solution Provider Showcase and Q&A**	
12:15 – 1:15 PM	**Networking Lunch**	
1:15 – 2:00 PM	**[Summer 2] Member Story:** *DDF journey from an early adopter; Nusheen Ditta, Roche*	**[Summer 1] Solution Provider Debrief & Departure;** *Belinda Griffin (chair), TransCelerate*
2:00 – 3:15 PM	**Interactive Roundtable Discussions:** *Overcoming challenges in digital transformation*	
3:15 – 3:30 PM	**Afternoon Break**	
3:30 – 4:30 PM	**Roundtable Readout;** *Renu Shukla (chair), JnJ*	
4:30 – 5:00 PM	**Reflections & Closing Statements;** *Renu Shukla, JnJ; William Illis, Novartis*	

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Lunch
12:15 – 1:15

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Roundtable Discussions

Overcoming challenges in business transformation and technical implementation

Session Duration: 75 mins

Introductions: 10 mins

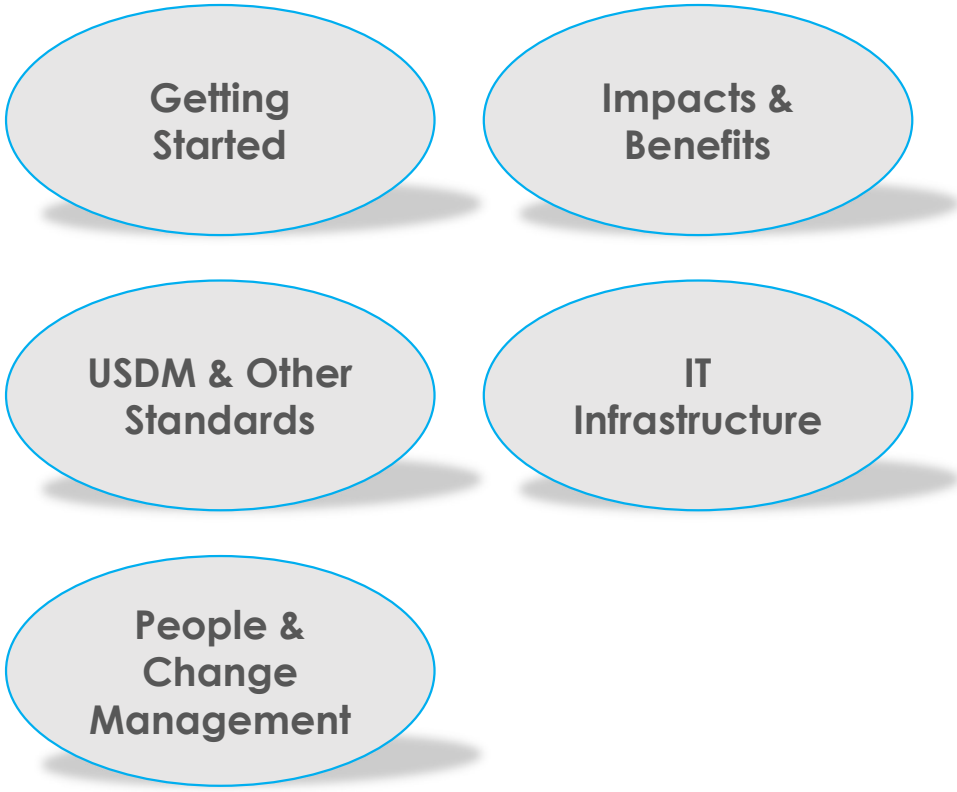
Discussion: 50 mins

Summarize: 15 mins

✓ **Capture your discussion**

- ❖ Key highlights
- ❖ Common themes
- ❖ Group learnings
- ❖ Interesting anecdote

✓ **Identify an individual to present your group recap**



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Break
3:15-3:30

Roundtable Readout

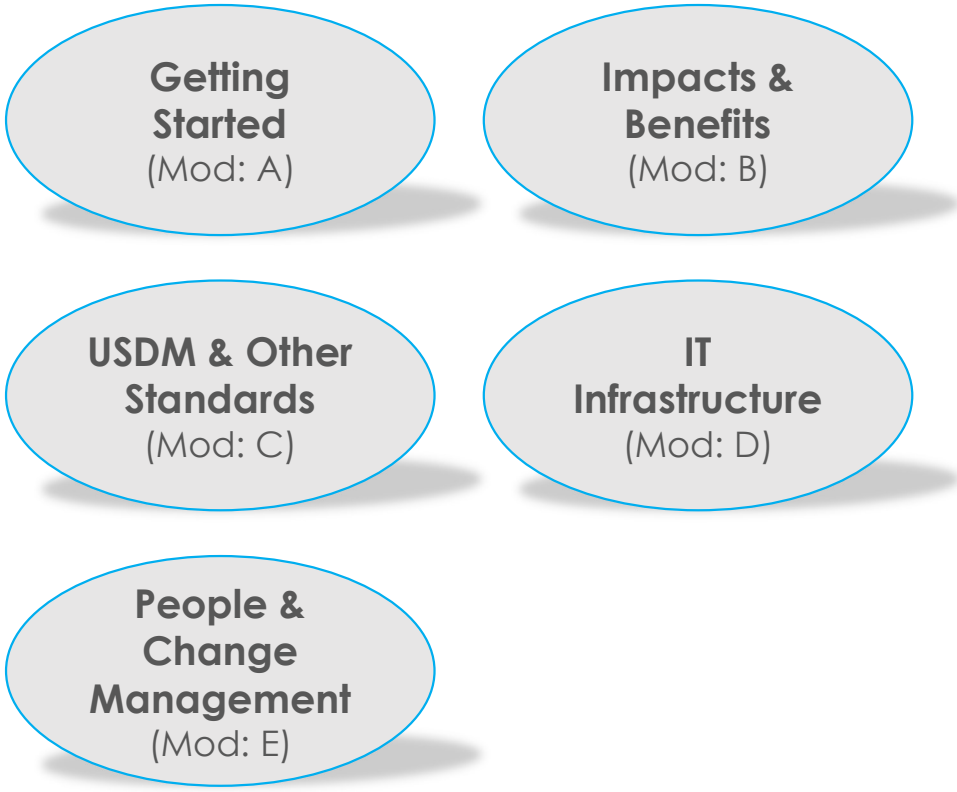
Overcoming challenges in business transformation and technical implementation

Duration: 60 mins

~10 mins per group

Please share:

- Key highlights
- Common themes
- Group learnings
- Interesting anecdote



Reflections

Renu Shukla and Bill Illis

DDF Comms, Events & Webinars

Mark your calendars!

Upcoming Events, Webinars & Conferences	Date
PHUSE SDE Copenhagen: Automation – Work Smarter Not Harder! ● Novo Nordisk campus Copenhagen, Denmark SDE 2023 (phuse-events.org)	10 October 2023
CDISC US Interchange ◆ ● Falls Church, VA, USA 2023 US Interchange | CDISC	18-19 October 2023 *(workshops begin 15-17th)*
eClinical Forum Americas ● Janssen in Spring House, PA 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

◆ Major/ Interactive Event ● General Awareness ▲ Virtual option available

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Thank you for joining DDF Discovery Day!

DDF Discovery Day Post-Event Survey

We would love to hear your feedback.

Appendix: Details of Upcoming Events

CDISC US Interchange

DDF-related events

Tuesday October 17, 2023 – COSA Biomedical Concept & OpenStudyBuilder Workshop - 9:00 AM-3:00 PM ET

- Similar to the workshop at the EU Interchange earlie this year, this workshop will dive into what Biomedical Concepts (BC) are, and how they can be applied within a MDR data standards repository and a SDR study definitions repository – illustrated within the OpenStudyBuilder (OSB) solution. CDISC will relate to how BC's are defined within COSMoS, DDF, d4k and other models. There will be a shared introduction followed by 4 breakout sessions, leading to a shared reflection and discussion on how we can support and bring these initiatives forward. The 4 breakout sessions are currently defined as:
  1. Setup BC's in OSB SoA for a new study, run various queries to learn how BC's can be utilised
  2. Learn and understand the BC model in OSB versus the COSMoS, DDF, d4k and other models
  3. Create and curate OSB BC content via the OSB Library and NeoDash reports
  4. Mining BC's from existing data sources like SDTM

Wednesday October 18, 2023 - Session 2: Second Opening Plenary - 11:00 AM-12:30 PM ET

- 11:00 – 11:30 **ICH M11 Initiative;** Dr. Ron Fitzmartin, FDA
- 11:30 – 12:00 **Digital Data Flow, Phase 3: The USDM meets M11;** Dave Iberson-Hurst, data4knowledge
- 12:00 – 12:30 **Dataset-JSON as Alternative Transport Format for Regulatory Submission;** Sam Hume, CDISC; Jesse Anderson, FDA

Thursday October 19, 2023 - Session 6A: Digital Data Flow - 11:00 AM-12:30 PM ET

Chair: Bron Kisler, Nurocor

- 11:00 – 11:30 **Automating Study Set-up through Digitalized Protocol;** Frederik Malfait, Nurocor
- 11:30 – 12:00 **From Medical Writing to Data Management: Key Considerations for Successfully Adopting the Unified Study Definitions Model (USDM) and Enabling Digital Data Flow (DDF);** Akash Trivedi, Accenture
- 12:00 – 12:30 **Digital Data Flow: Breaking the Document Paradigm with Digital Data Flow from Protocol Design to Electronic Data Capture;** Sumesh Kalappurakal, Janssen and William Illis, Novartis

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PHUSE EU Connect: DDF Workshop Abstract

Title: Mastering USDM Standards with an interactive demo and Hands-on Workshop

Digital data's efficient and seamless flow has become paramount in today's data-driven world. The TransCelerate Digital Data Flow initiative aims to automate the data flow from study design and protocol development to downstream systems and processes by using the power of CDISC's Unified Study Definitions Model (USDM). The primary goal of USDM is to establish a unified language and structure for representing study design data in alignment with SDTM and ICH M11, enabling interoperability and seamless data flow across disparate systems and applications.

The workshop will begin with an overview of the TransCelerate Digital Data Flow (DDF) initiative and its role in promoting USDM, followed by a deeper exploration into USDM fundamentals, and its relationship to other standards, including ICH M11, HL7 FHIR SOA, SDTM, etc. Attendees will gain a clear understanding of the USDM principles, including its core components, such as the data model, metadata schema, and API specifications, and how USDM enables interoperability, promotes data governance, and facilitates the integration of diverse data sources, making it an invaluable tool for organizations seeking to harness the full potential of their data.

Following the overview, the workshop will demonstrate USDM standards through practical examples and interactive visualizations. The event will then conclude with hands-on exercises, allowing participants to work with datasets and apply USDM standards to store and exchange complex study designs, such as schedules of activities. Through these exercises, participants will gain a better understanding of the USDM model and how it can be used in practice.

In summary, by attending this workshop, participants will gain insights into the significance of study protocol digital data flow and the transformative capabilities of the USDM standard. Attendees will learn how USDM can be used in practice to improve data quality and speed up data initiatives. Regardless of one's background, attendees will gain the skills and motivation to use standardized data flow to maximize your organization's data potential.