

From Documents to Digital

Going beyond the “art of the possible”

Rob DiCicco, PharmD
TransCelerate BioPharma Inc.

26 September 2023



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.

Our Collaboration is Worldwide

Since inception, TransCelerate has prioritized robust collaboration with key stakeholders across the R&D ecosystem



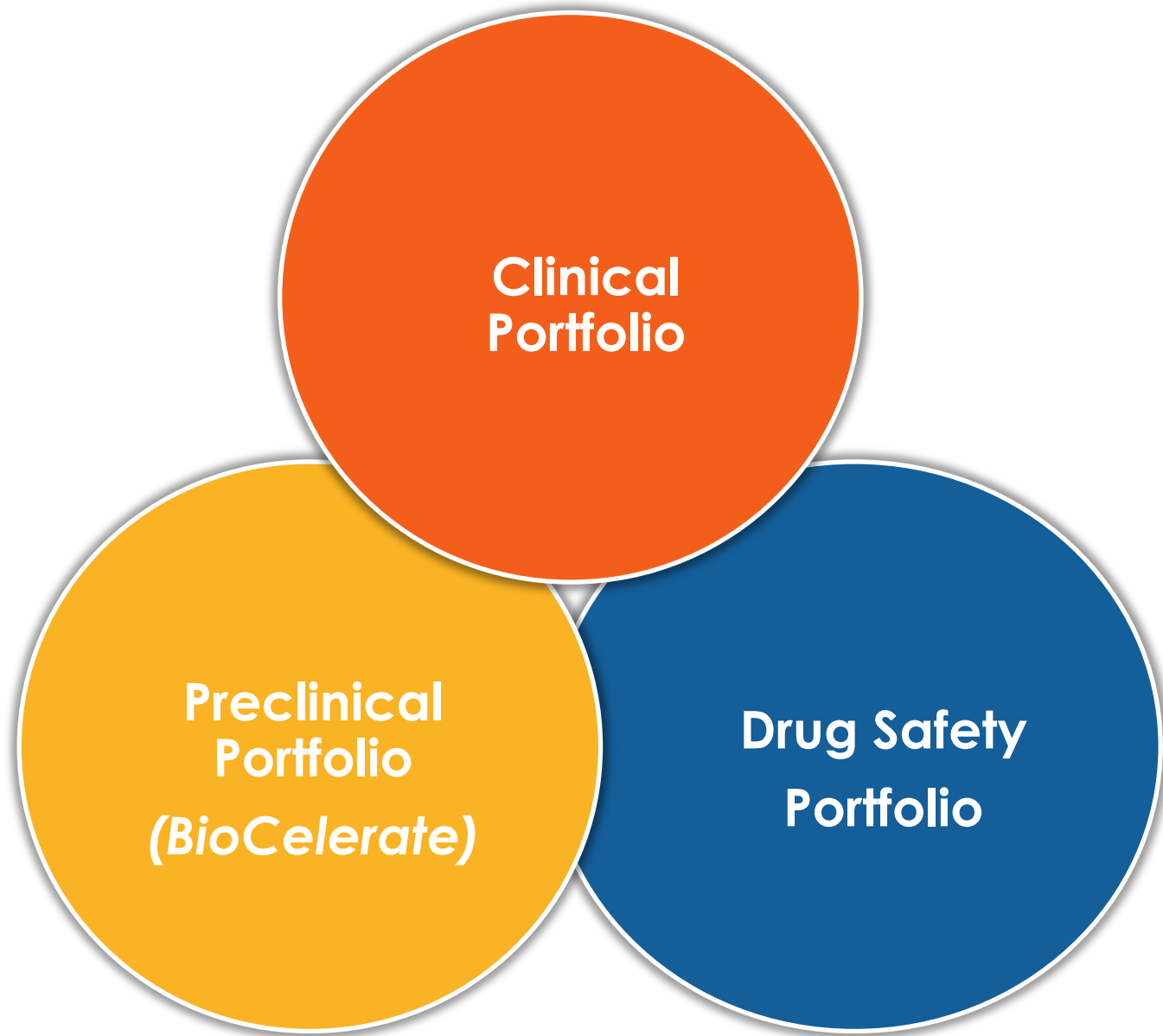
15 GLOBAL HEALTH AUTHORITIES have engaged with TransCelerate

Our Country Network spans **30** COUNTRIES

View select translated solutions [here](#).

An Overview of the Portfolio

A collection of initiatives & programs, aimed at **accelerating & simplifying the research and development** of innovative new therapies, governed & delivered by TransCelerate membership

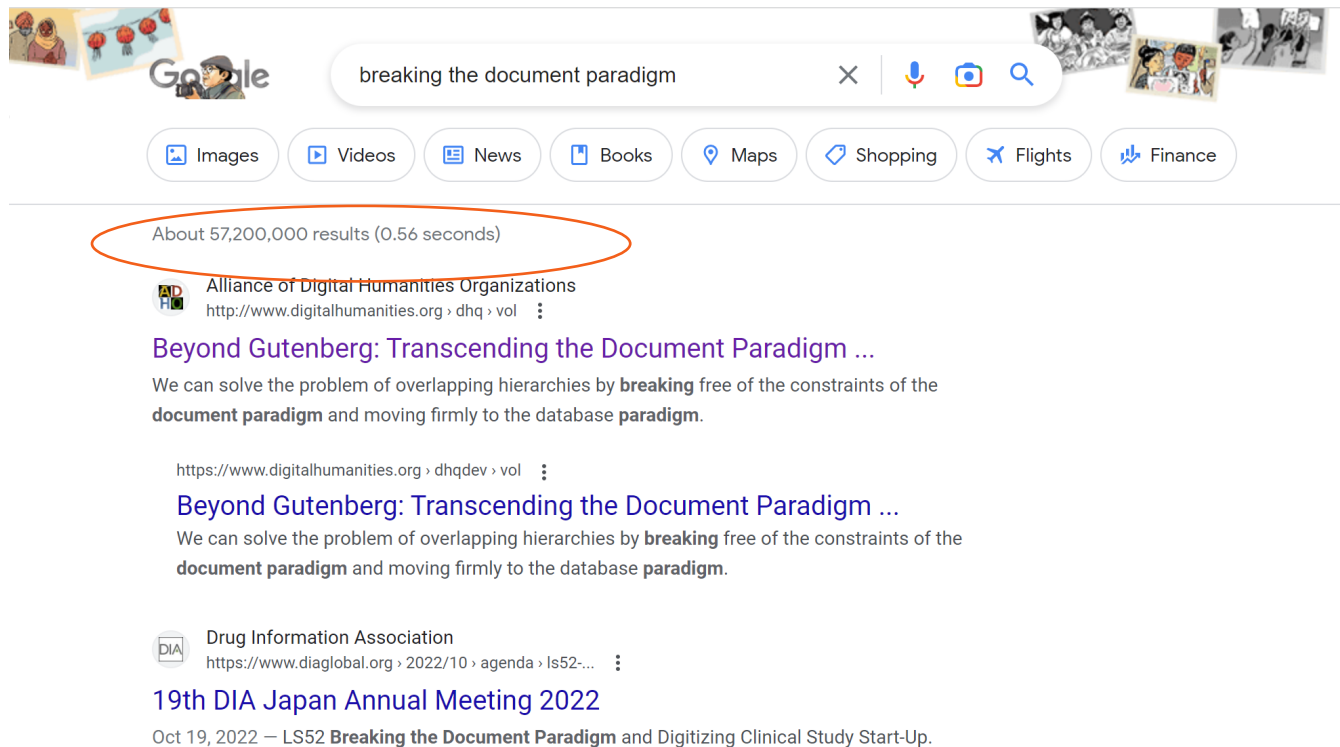


Since 2012, we have been on a journey to advance data utilization/reuse in partnership with **CDISC**



- **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

Breaking the document paradigm

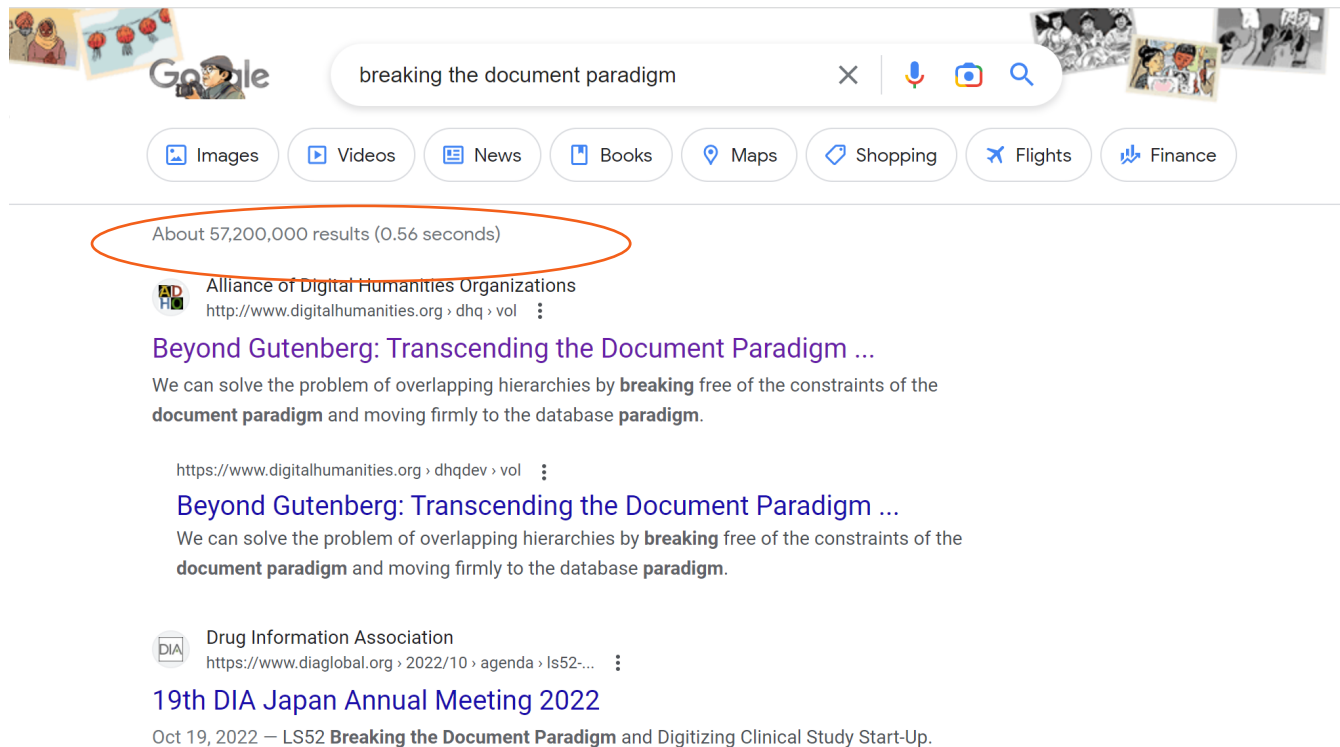


The image shows a Google search interface. The search bar contains the text "breaking the document paradigm". Below the search bar, there are navigation buttons for Images, Videos, News, Books, Maps, Shopping, Flights, and Finance. The search results are displayed below, with the first result circled in red. The circled text reads "About 57,200,000 results (0.56 seconds)". The first search result is from the Alliance of Digital Humanities Organizations, with the title "Beyond Gutenberg: Transcending the Document Paradigm ..." and a snippet: "We can solve the problem of overlapping hierarchies by **breaking** free of the constraints of the **document paradigm** and moving firmly to the database **paradigm**." The second search result is from the Drug Information Association, with the title "19th DIA Japan Annual Meeting 2022" and a snippet: "Oct 19, 2022 – LS52 **Breaking the Document Paradigm** and Digitizing Clinical Study Start-Up."

-what does it mean?



Is it the document paradigm or the document mindset?



A screenshot of a Google search interface. The search bar contains the text "breaking the document paradigm". Below the search bar, there are navigation buttons for Images, Videos, News, Books, Maps, Shopping, Flights, and Finance. The search results show "About 57,200,000 results (0.56 seconds)" circled in red. The first result is from the Alliance of Digital Humanities Organizations, titled "Beyond Gutenberg: Transcending the Document Paradigm ...". The second result is from the Drug Information Association, titled "19th DIA Japan Annual Meeting 2022".

breaking the document paradigm

Images Videos News Books Maps Shopping Flights Finance

About 57,200,000 results (0.56 seconds)

Alliance of Digital Humanities Organizations
<http://www.digitalhumanities.org> > dhq > vol

Beyond Gutenberg: Transcending the Document Paradigm ...
We can solve the problem of overlapping hierarchies by **breaking** free of the constraints of the **document paradigm** and moving firmly to the database **paradigm**.

<https://www.digitalhumanities.org> > dhqdev > vol

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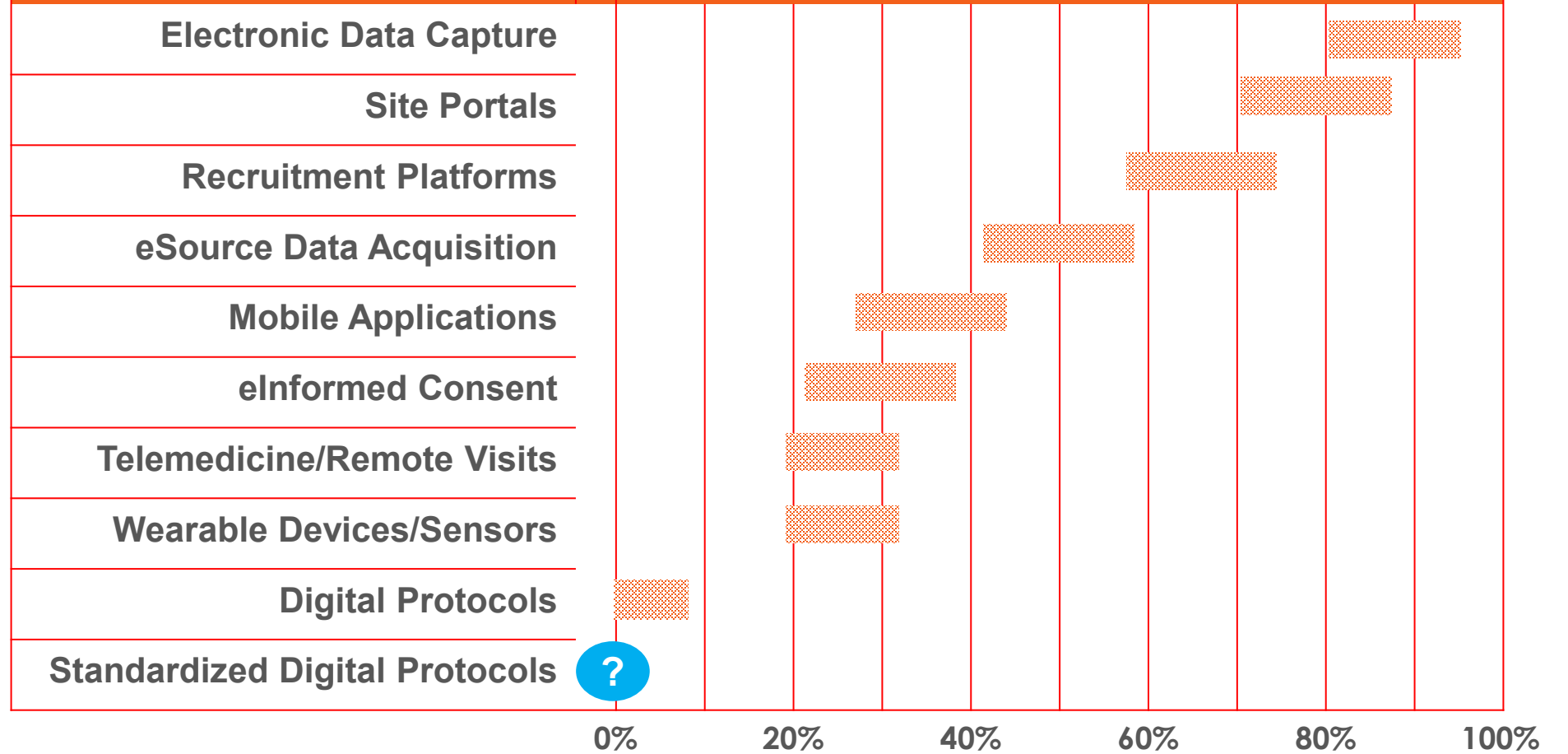
Drug Information Association
<https://www.diaglobal.org> > 2022/10 > agenda > ls52-...

19th DIA Japan Annual Meeting 2022
Oct 19, 2022 – LS52 **Breaking the Document Paradigm** and Digitizing Clinical Study Start-Up.

“The alternative to the document paradigm is the database paradigm, which is characterized by data structures that transcend the position-dependent structure of pre-digital documents.” – Digital humanities quarterly

But current thinking about documentation hasn't kept up with the pace of innovation. It's a mistake, however, to point to technology alone as the way forward. ...we need to shift from “document” the noun to document the verb. – Michelle Vuolo, Pharmaceutical Engineering –Dec 2020

Digital Transformation in Clinical Trials % adoption



Digital Data Flow Ambition

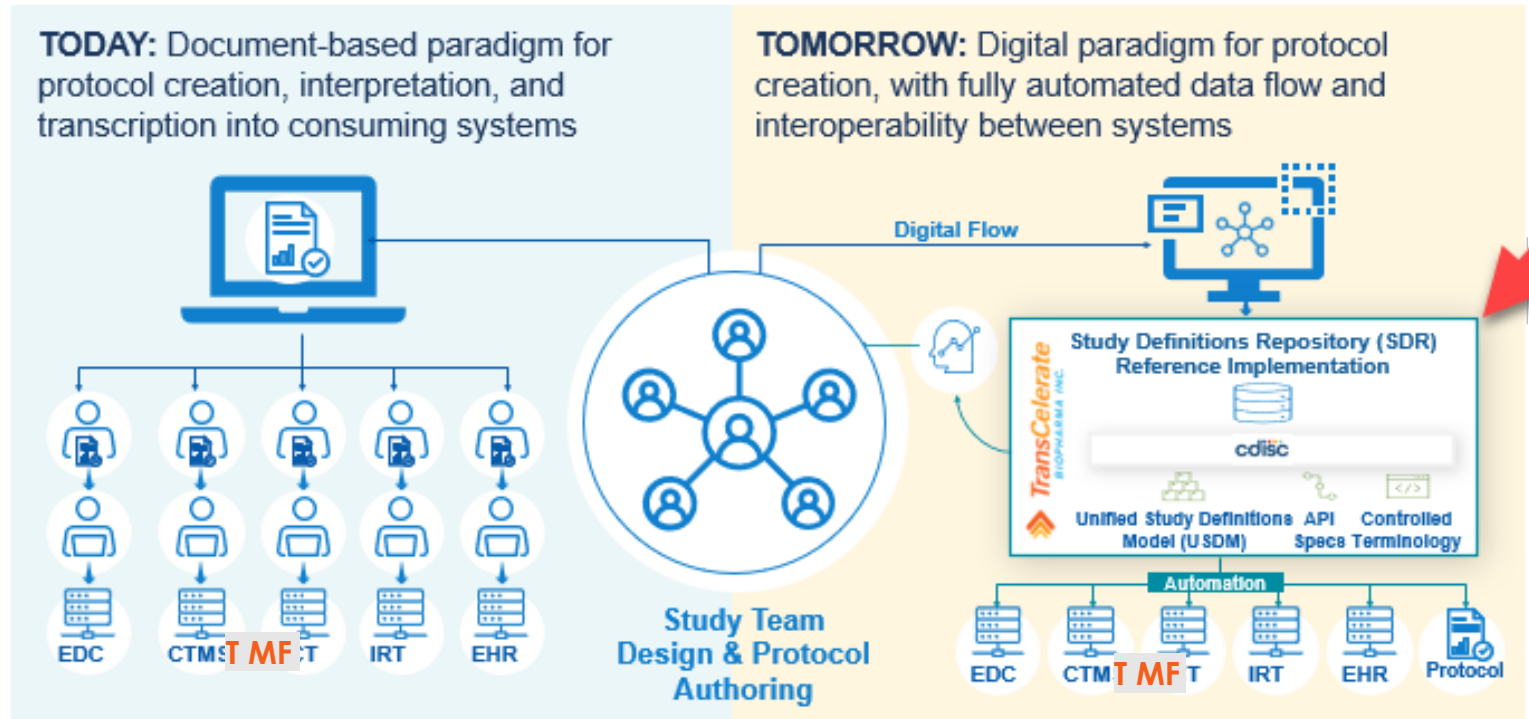
Digital - standard representation of study protocol

- ✓ structured
- ✓ machine readable
- ✓ executable

Data Flow – industry-wide interoperability

- ✓ exchange of data
- ✓ non-cooperating organizations
- ✓ minimal effort

Documents to Data / Write Once, Read Many



**Eliminate non-value added activities, work smarter not harder
Enable automation of downstream study startup and conduct processes
For all stakeholders**

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



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Test Files

Examples of USDM JSON files



Implementation Guide

Improved explanation of the model and its use, examples etc



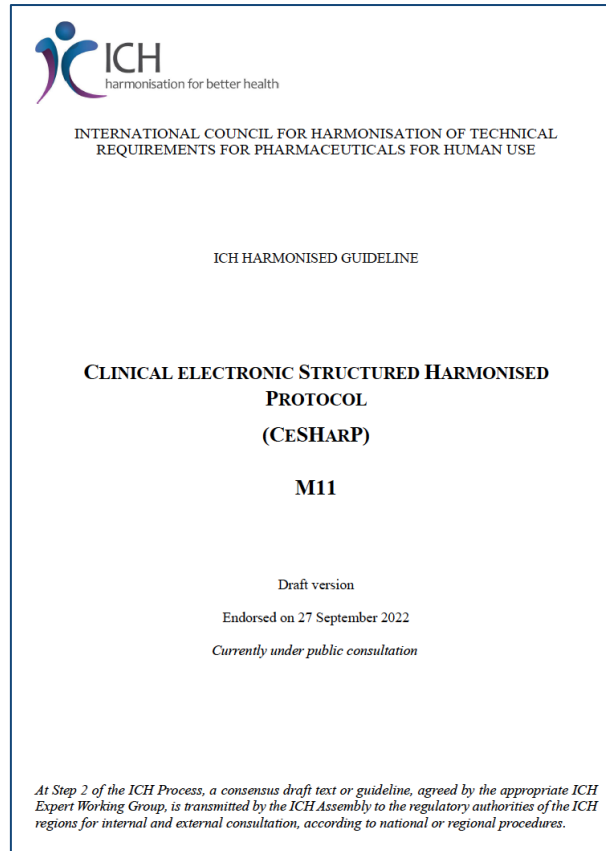


But where is the puck going ?

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

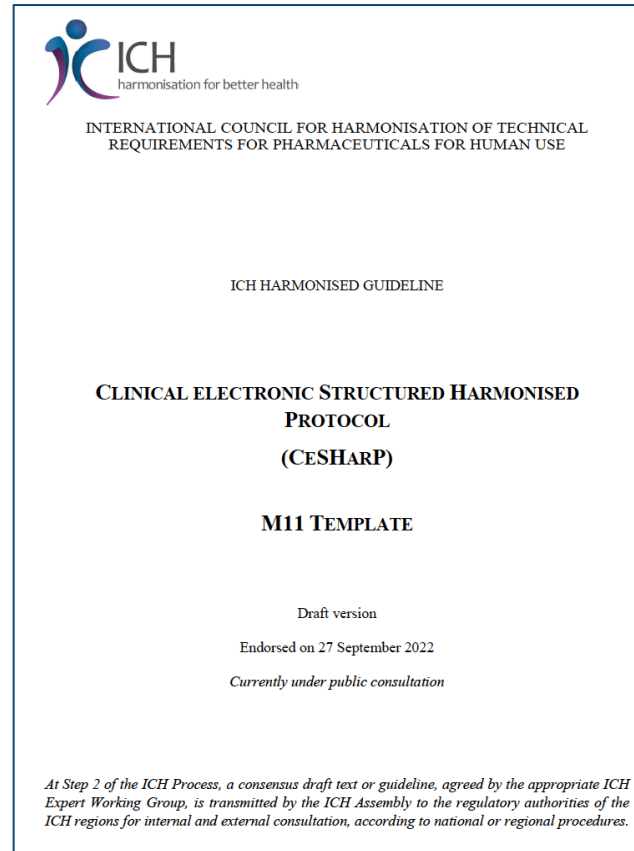
CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CESHARP)

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

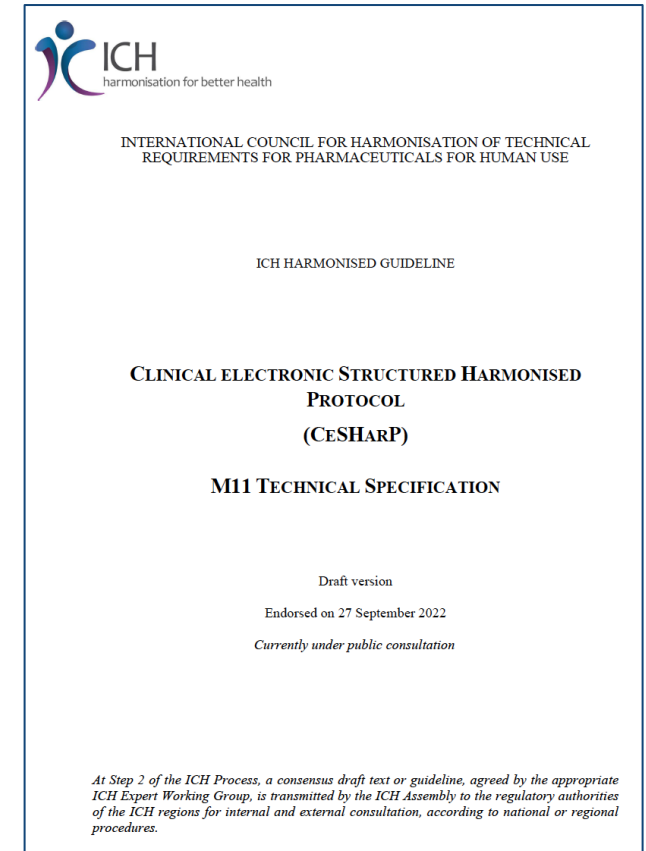
CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CESHARP)

M11 TEMPLATE

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Provides the written format for the Interventional Clinical Trial Protocol Template



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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 TECHNICAL SPECIFICATION

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Provides the technical representation aligned with the guideline and protocol template

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
- What is the implication of all this ?



For Immediate Release

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awhite@cdisc.org

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)

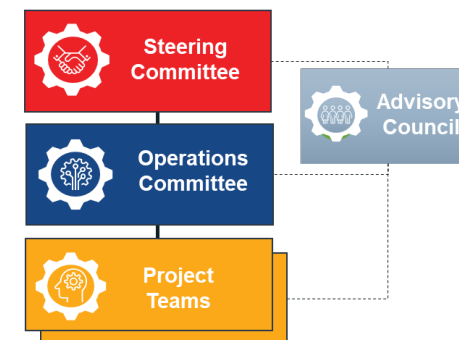
Ann Arbor, MI. and Austin, TX — June 6, 2023 — A structured, harmonized, digitized protocol accessible to the biopharmaceutical industry and to researchers in the care setting will enable transformations to improve clinical research. The project announced by HL7 Vulcan and CDISC will build on work products of ICH M11 to accelerate this vision. [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.”

Vulcan HL7 FHIR Accelerator: Advancing interoperability of health data to integrate clinical and translational research with clinical care

TransCelerate serves as the Convener and engages across all levels of Vulcan governance



- Vulcan works strategically to connect collaborators, maximize impact from collective resources
- Develop the necessary FHIR research resources to accelerate the convergence of clinical care and clinical research to improve patient lives, decrease costs and improve efficiency.



Harmonization and Standards Implementation

Keys to innovation

- **The so what behind TMF Reference Model and Development of the Digital Data Flow Project are the same**
- **The future state of automated document exchange and automated data exchange depend on the implementation and adoption of standards**
- **Model development is intended to need dynamic**
- **The focus is on better not perfect**
- **Collaboration across stakeholders and organizations is a critical success factor**



What is the big picture?



The dedication of TransCelerate members have delivered the foundation to lean into the future state

We embrace the potential to enable the convergence of clinical care and clinical research

**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**

The what and the how

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



Ecosystem collaboration is fundamental to these goals



TransCelerate Members



HCPs / Clinicians



Community Care



Patient Groups



Regulators



Policy Makers / Agencies



Technology Community



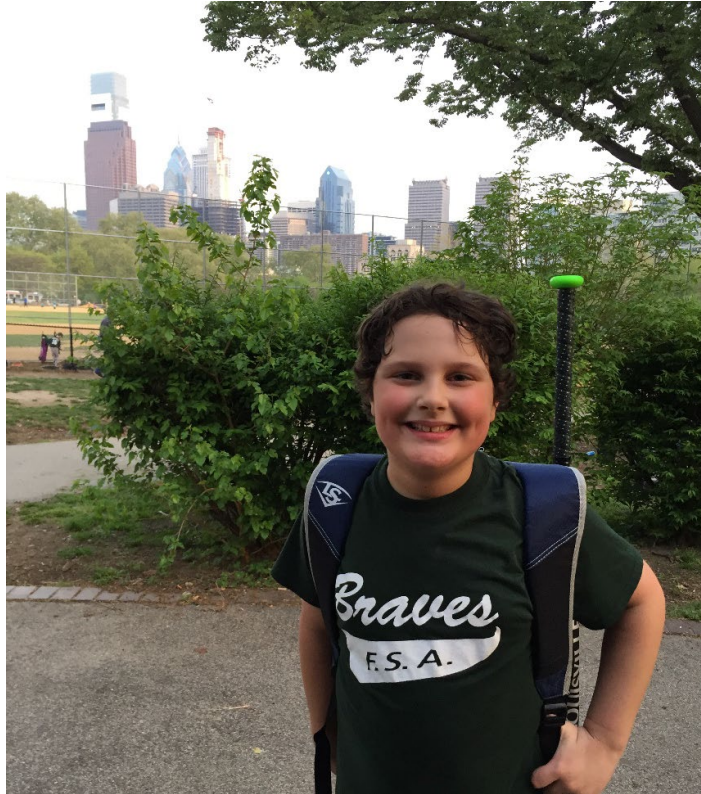
Standards Setting Org's



Other Consortia

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





What does baseball have to do with it?



Acknowledgements