From Documents to Digital

Going beyond the “art of the possible”

Rob DiCicco, PharmD
TransCelerate BioPharma Inc.

5 December 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.

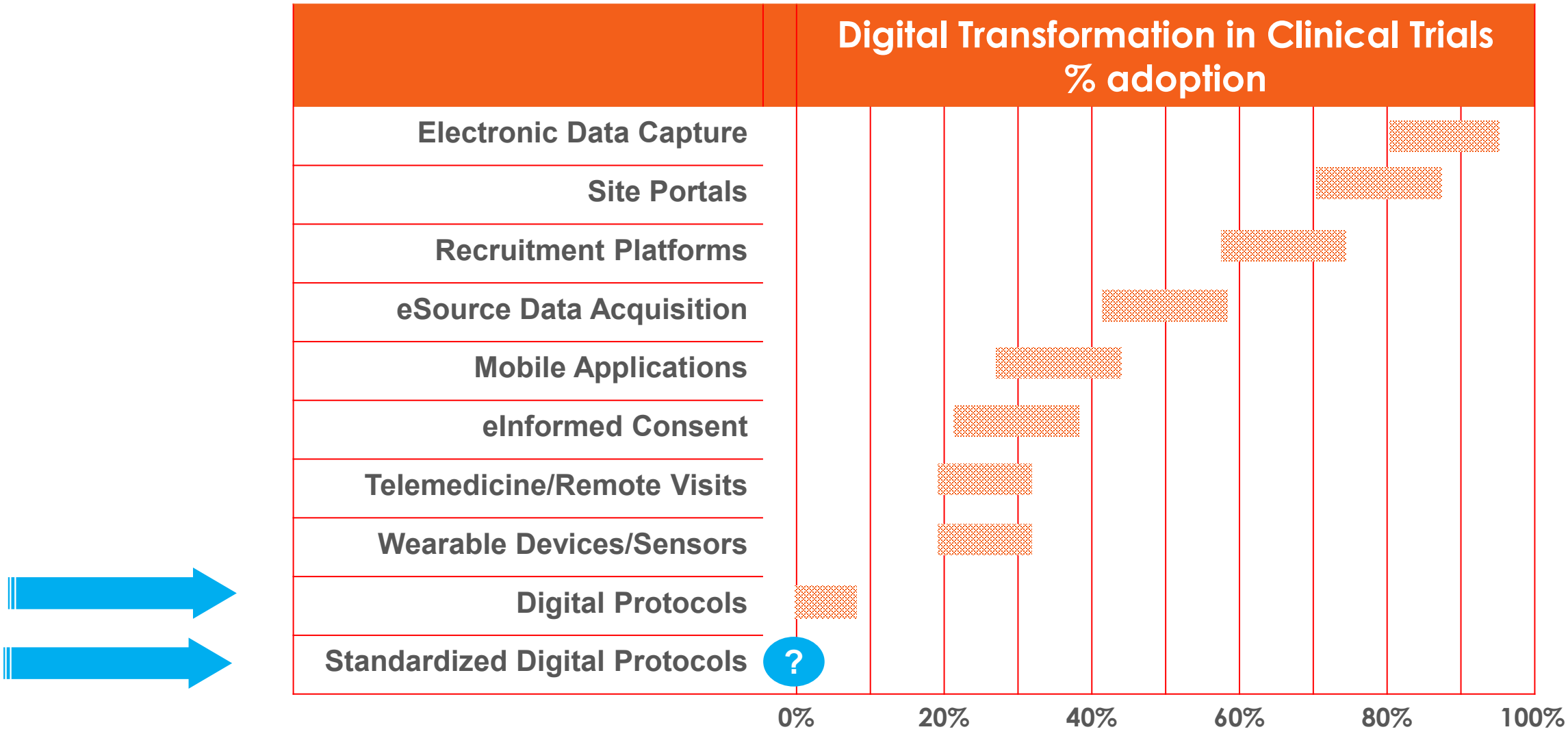
Member driven mission to collaborate across the global biopharmaceutical research and development community to **identify, prioritize, design, and facilitate** the implementation of solutions designed to drive the **efficient, effective and high-quality delivery of new medicines**.

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

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

TransCelerate BIOPHARMA INC.



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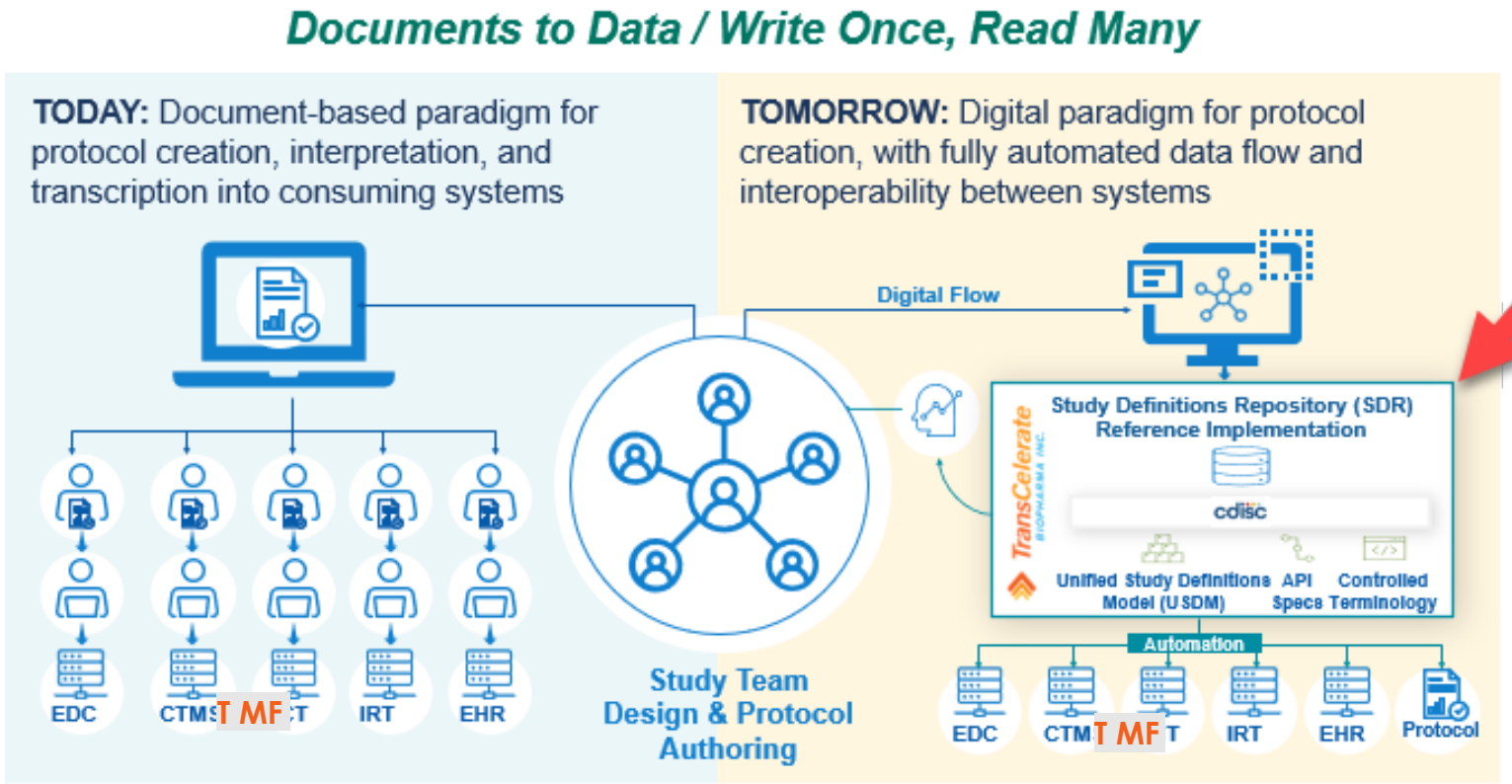
Digital Data Flow Ambition

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
For all stakeholders

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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.

V1.0.0

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

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

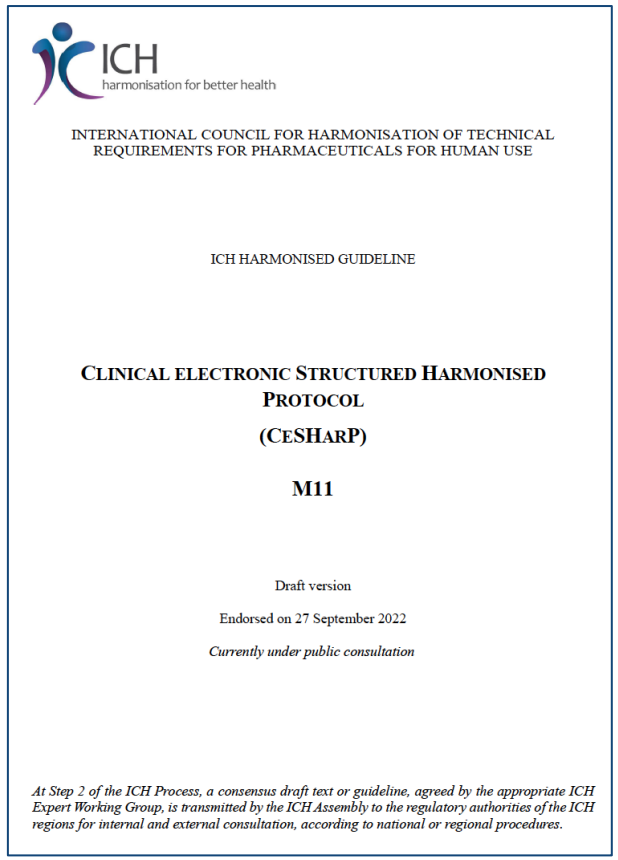
V2.0.0

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

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

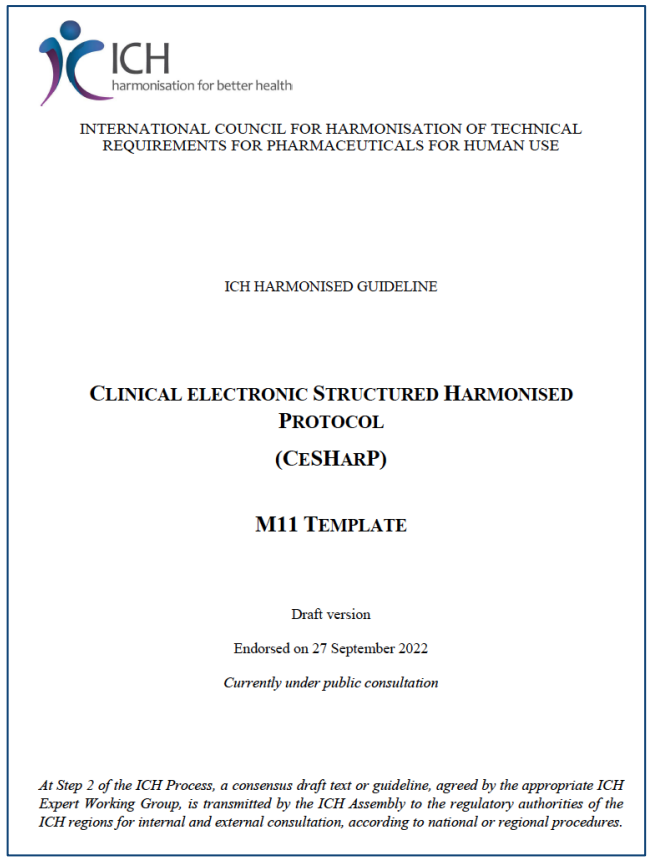
Draft version

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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(CESHARP)

M11 TEMPLATE

Draft version

Endorsed on 27 September 2022

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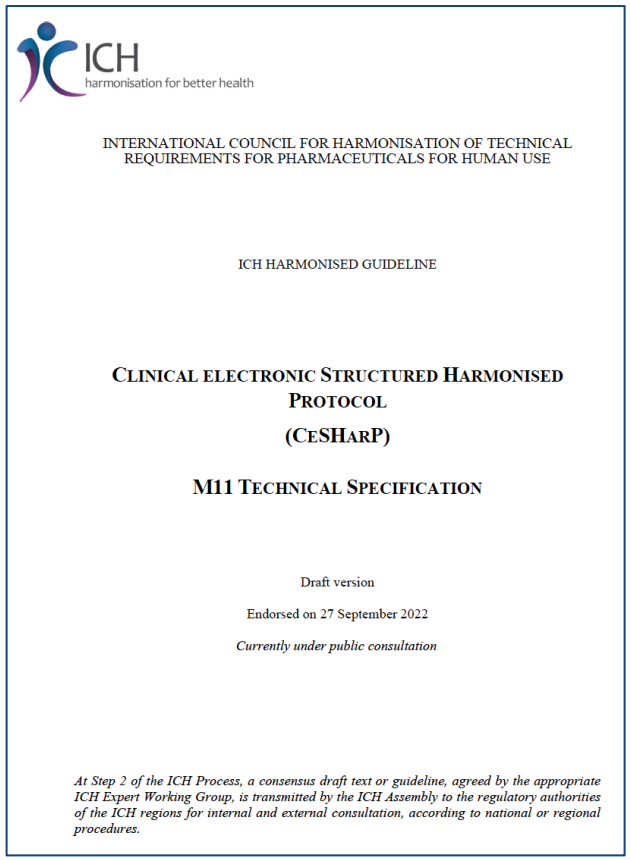
Provides the written format for the Interventional Clinical Trial Protocol Template



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(CESHARP)

M11 TECHNICAL SPECIFICATION

Draft version

Endorsed on 27 September 2022

Currently under public consultation

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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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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)

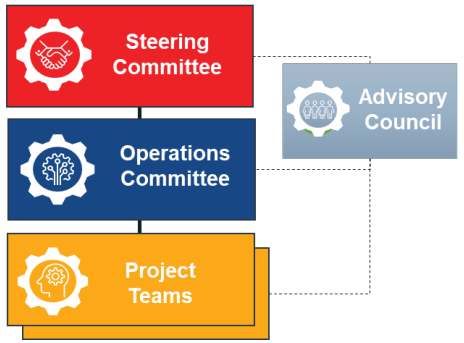
Ann Arbor, MI. and Austin, TX — June 6, 2023 — A structured, harmonized, digitized protocol accessible to the biopharmaceutical industry and to researchers in the care setting will enable transformations to improve clinical research. The project announced by HL7 Vulcan and CDISC will build on work products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

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.

Vulcan members represent diverse perspectives across the international research community

For more information, see https://hl7vulcan.org/

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 what and the how

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

Acknowledgements