Will ICH M11 be the Catalyst to the Digital Transformation in Pharma R&D?

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TransCelerate BioPharma Inc.

CDISC Japan Academic Workshop
November 2024

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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**.

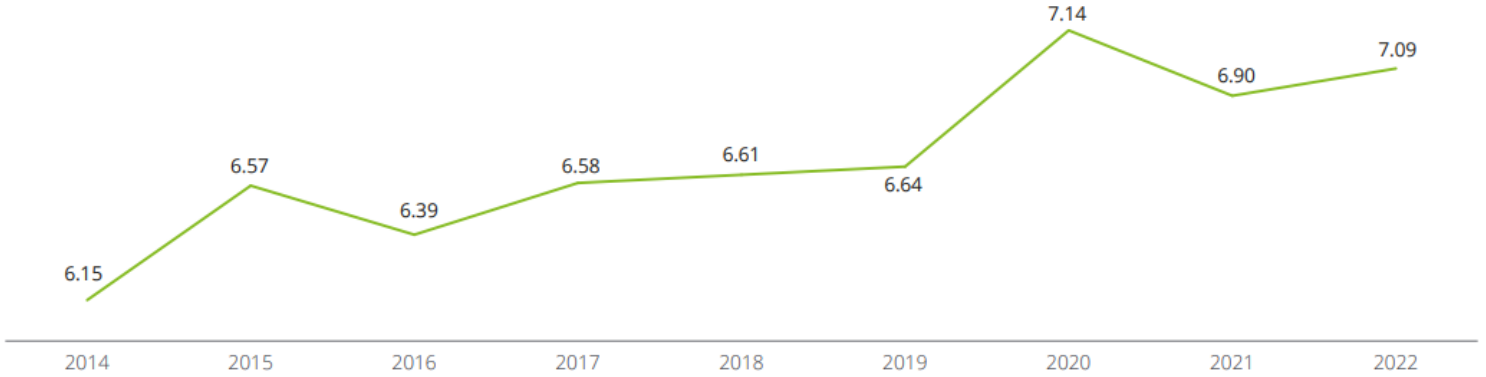
TransCelerate has grown from **10 pioneering companies** to **over 20 Member Companies** working towards improvement in key value drivers in clinical research.

Average Cycle Times Over a 10-year Period

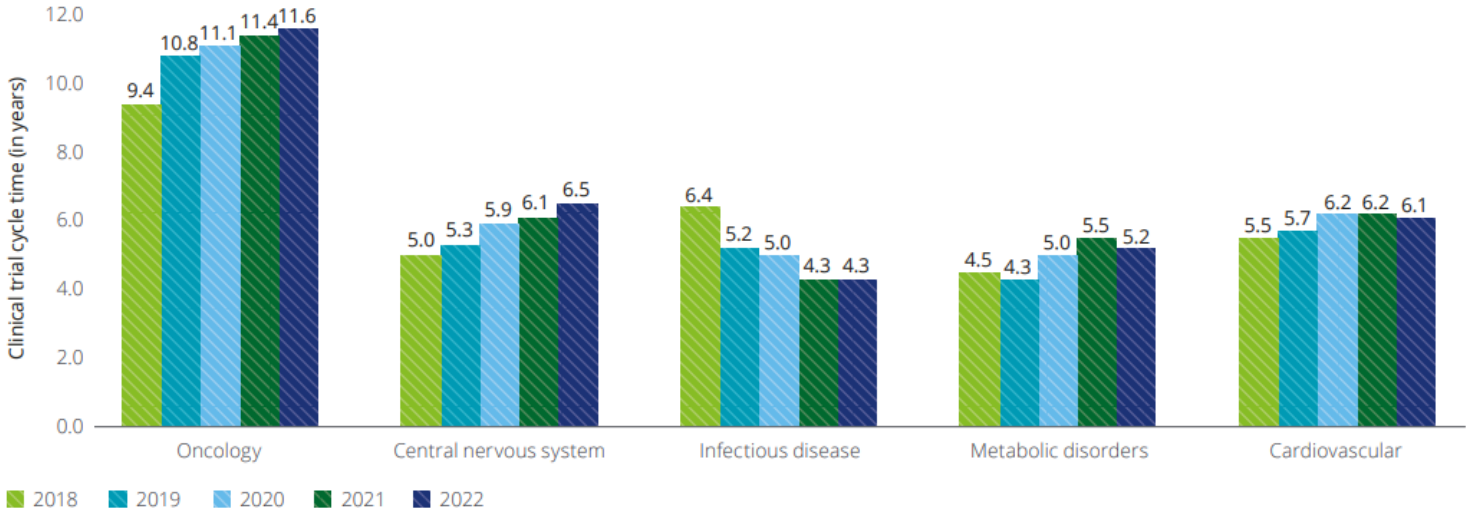
Deloitte: Seize the Digital Momentum – Measuring the return from pharmaceutical innovation 2022

https://www2.deloitte.com/ch/en/pages/life-sciences-and-healthcare/articles/measuring-return-from-pharmaceutical-innovation.html

Average Cycle Time in Years from Start of Phase I to end of Phase III Clinical Trials



Note: Figures indicate time between start of Phase I trial to completion of Phase III trial



Source: Deloitte analysis, 2022

Patients and caregivers continue to navigate two complex, disconnected worlds:
Clinical Research and **Clinical Care**.

Current Day TransCelerate Roadmap

Transforming Connectivity

Modernize ways of working across systems, processes and people

- **Protocol digitization (CC&R, DDF, Vulcan Utilizing the digital protocol)**
- **EHR connectivity**
- **Enabling translational safety**

Information Sharing & Reuse

Use information innovatively, respecting patients, advancing science and medicine,

- **Clinical data sharing via Historical trial data module**
- **Optimizing data collection**
- **Rapid safety signal assessments in (Using RWD)**

Innovative Trial Design

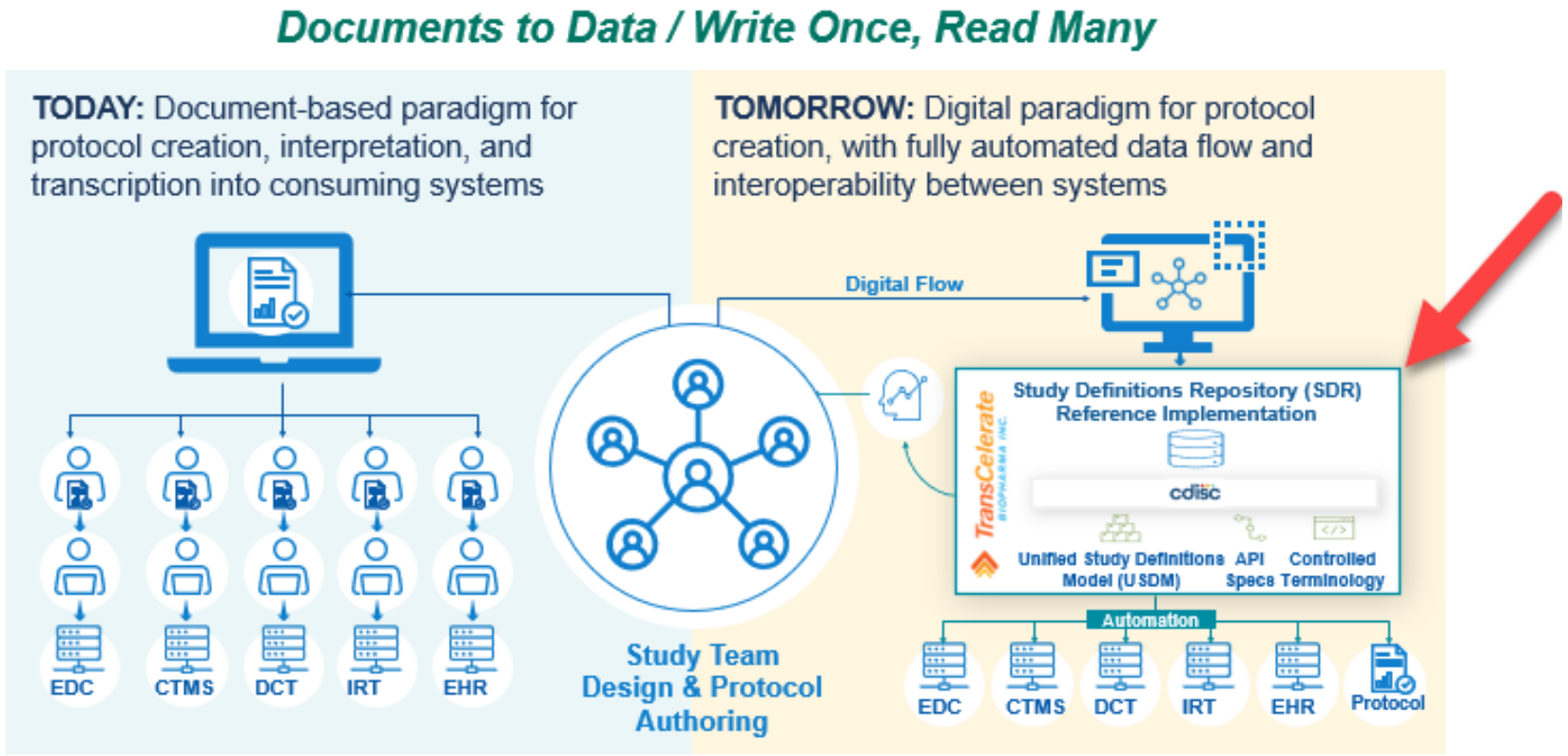
Research designed to fit the lives of patients that delivers safe and effective therapies

- **Modernizing clinical trial conduct: Patient preferences and supporting sites**
- **Embedded pragmatic trials**
- **Operationalizing platform trials**

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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DDF Deliverables

		PHASE ONE *July 2021 – July 2022*	PHASE TWO *Oct 2022 – Sep 2023*	PHASE THREE *July 2023– Apr 2024*	PHASE FOUR *Apr 2024– 1Q 2025*
CDISC's USDM Reference Architecture	**USDM Data Model**	☑	☑	☑	☑
	API Specification	☑	☑	☑	☑
	CDISC Controlled Terminology	☑	☑	☑	☑
	Implementation Guide		☑	☑	☑
	Test Files		☑	☑	☑
	Conformance CORE Rules – POC			☑	*TBD*
TransCelerate's SDR & Implementation Support	**Study Definitions Repository (SDR)**	☑	☑	☑	☑
	Common Protocol Template (CPT) Interface Tool – POC		☑		
	Implementation Architecture Scenarios Toolkit		☑	*Still Applicable*	*Still Applicable*
	Persona Toolkits (MW, DM, IT)		☑	*Still Applicable*	*Still Applicable*
	Kubernetes – POC			☑	☑
	Industry Engagement	*Connectathon*	*Discovery Day Solution Collab Forum*	*Hands-on Workshops Solution Catalog*	*Use Cases, Benefits Case Studies*

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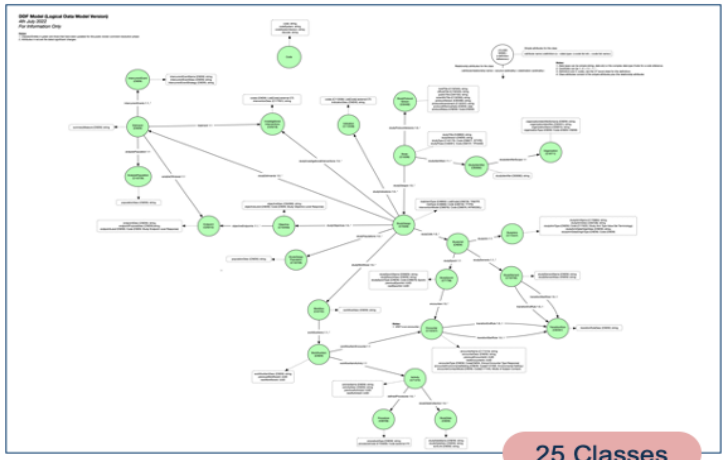
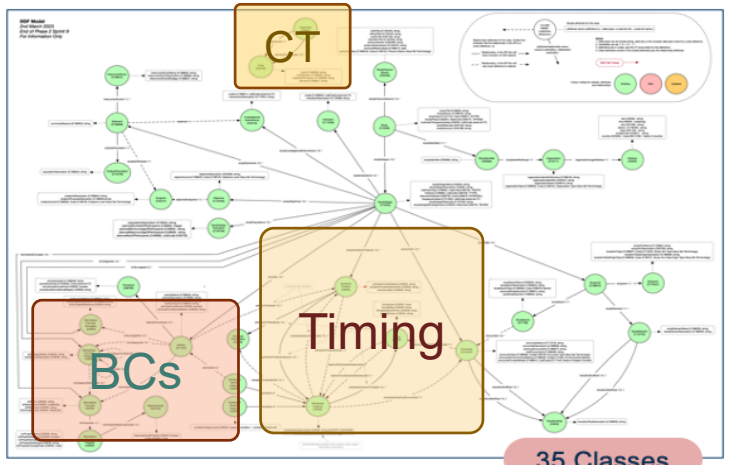
Expansion of the USDM Model

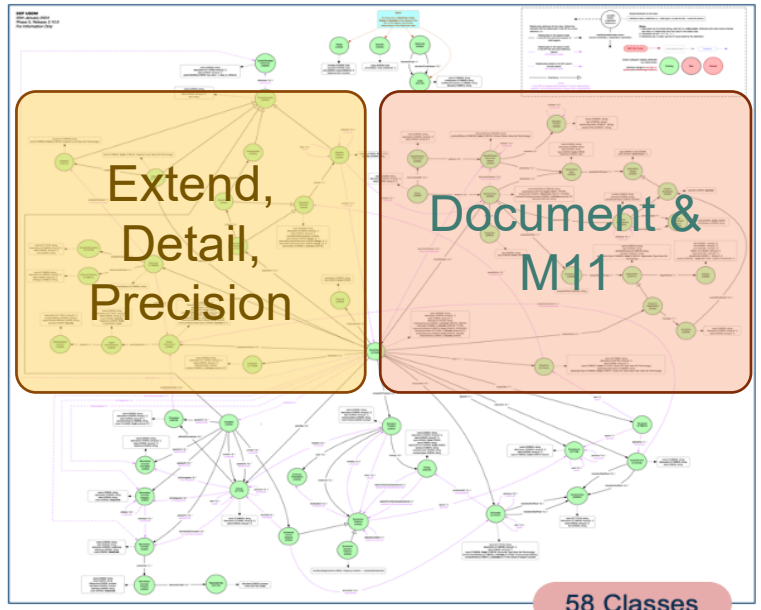
Phase One



Phase Two



Phase Three



- Solid foundation
- The protocol document was an external entity into which the structured content could be exported

- Focused on the structured elements of the protocol, e.g. the Schedule of Activities (SoA) & Biomedical Concepts (BCs)
- The protocol document still an external entity

- **Now contains structured and unstructured elements**
- **The entire protocol document can be held within the USDM**
- **Protocol document generated from the model**

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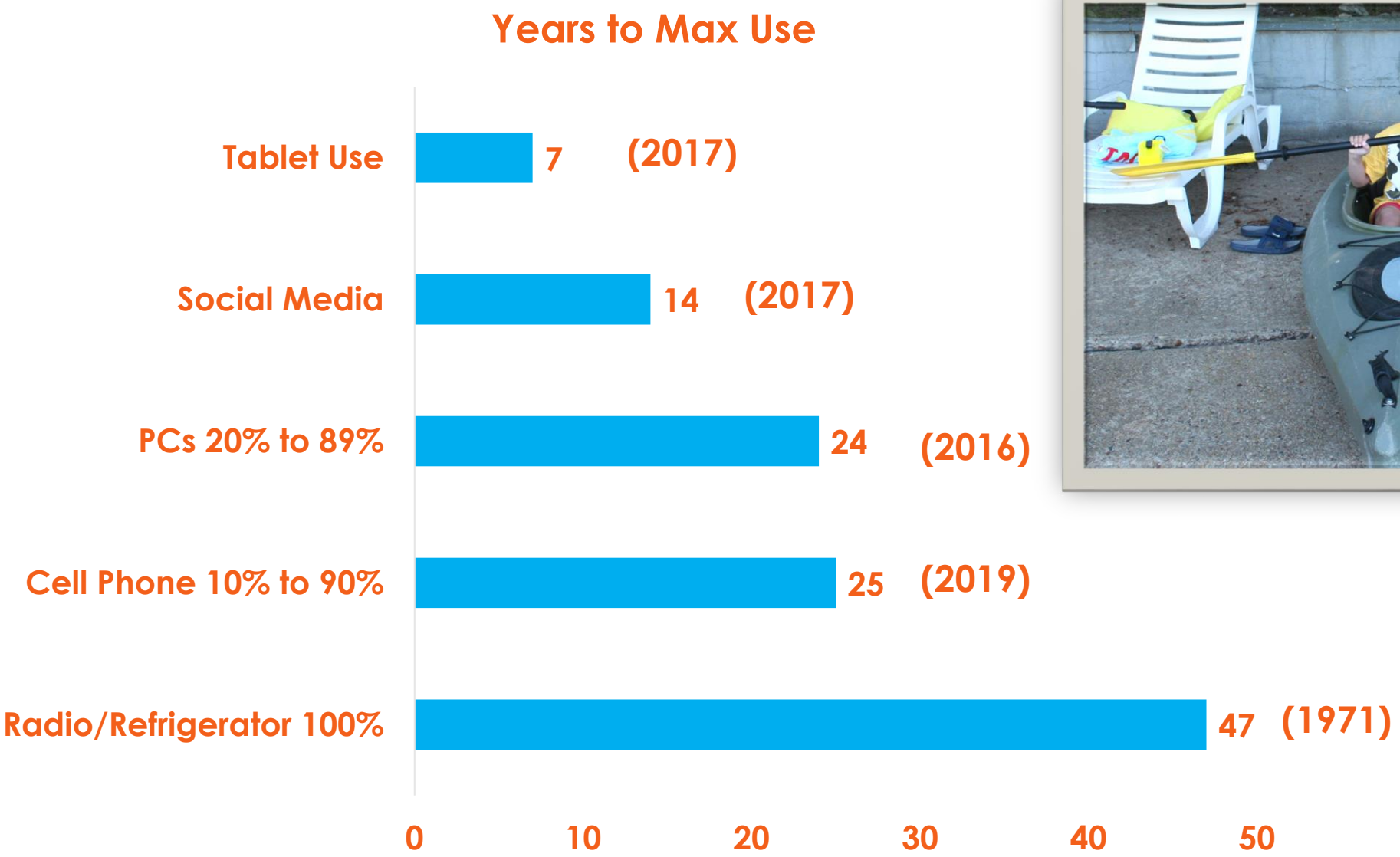
Are we there yet ?



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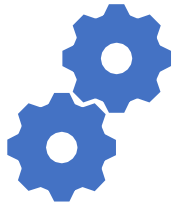
TransCelerate in Partnership with CDISC on Digital Data Flow

Unified study definitions model (USDM) + Study Definitions Repository + APIs

Use cases advanced by member companies and tech companies



Cloud portability

.Analytic capabilities

Vendor agnostic automated flow of data across platforms

EHR connectivity for screening. Assessment of patient burden.

- **35+ Tech Companies have volunteered to inform development and sustainability** (i.e., EDC and eCOA, Analytics, System integrators and software development, RWD companies)

- **16 Member Companies in some stage of implementation or implementation planning**

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DDF Use Cases

From machine actionable Protocol authoring to automation of downstream connectivity

Study Design → **Study Start-up** → **Study Execution** → **Analysis & Reporting** → **Regulatory Submission**

Study Design and Analytics

- Predict and avoid protocol amendments
- Improve study design with comparative analysis
- Automate for complexity and patient burden scoring
- Optimize Inclusion / Exclusion Criteria
- Determine study feasibility

Downstream Process Automation and E2E Traceability

- Auto-configure execution systems
- Auto-generate SDTM trial design datasets
- Auto-populate trial registries
- Publish user-specific protocol views
- Feed study updates into all study execution systems

*"**As a medical writer**, the digitalization of data flows enables me to work faster with my team on one dedicated system, accessing study content in a single digital study design system."*

*"**As a data manager**, the digitalization of end-to-end processes from study design to EDC generates structured data that can be leveraged to track outcomes and progress made."*

*"**As a technical expert**, the digitalization of data flows reduces tedious manual work freeing up time for more complex projects that cannot be automated (value-added activities focus)."*

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Since 2012, we have been on a journey to advance data utilization/reuse in partnership with CDISC, Health Authorities & Others

- 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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Can we make M11 the Catalyst to go Digital

Mature protocol template implementation and alignment

Maturing Data Model and Control Terminology

Regulatory Imperative

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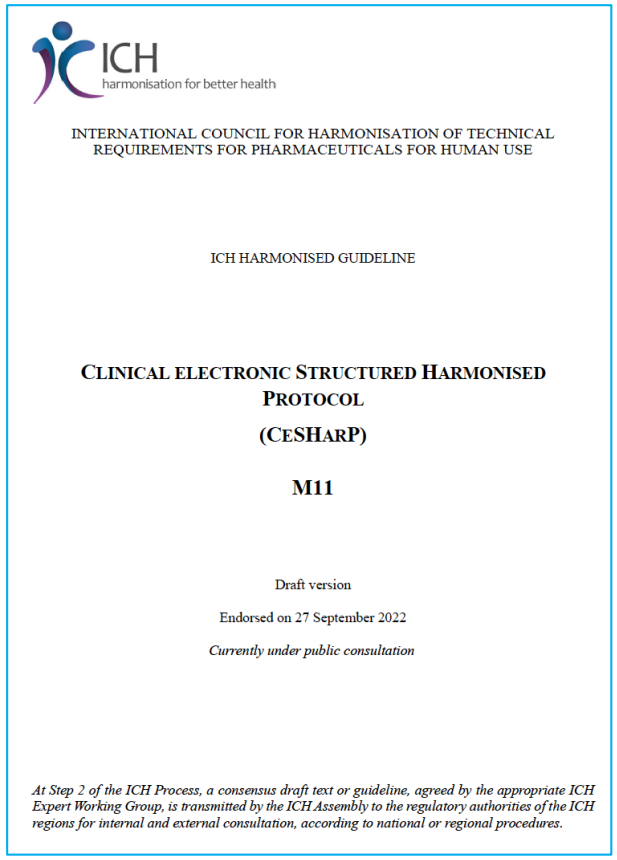
M11 Is …

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

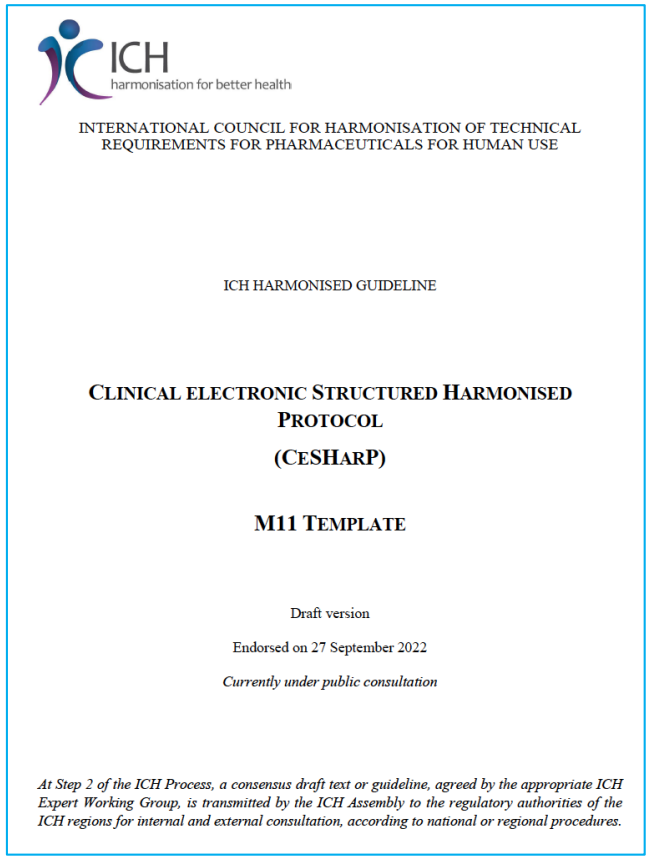
Draft version

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.

Background, purpose, and scope as a guideline



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CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

M11 TEMPLATE

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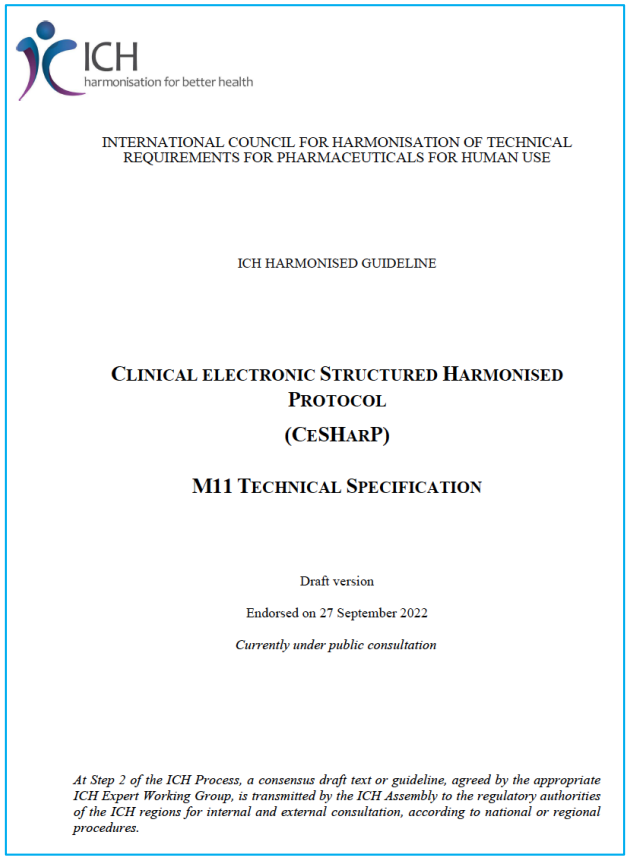
Written format for the Interventional Clinical Trial Protocol Template



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(CESHARP)

M11 TECHNICAL SPECIFICATION

Draft version

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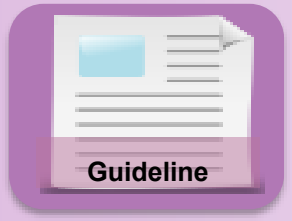
Technical representation aligned with the guideline and protocol template

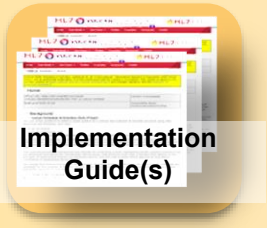
ICH M11 Creates A Unique Opportunity

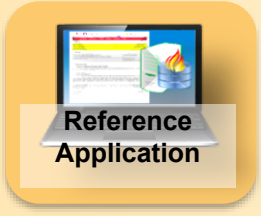
CeSHarP



USDM and Terminology

Utilizing the Digital Protocol – UDP





Collaboration to amplify value of multiple initiatives

ICH M11, Vulcan, CDISC, TransCelerate Collaborate on Digital Protocol

Capabilities, expertise, and relationships built to date across multiple projects

- Partnership Model with SDOs
- Data Model Development
- Relationships with Tech
- Architecture Foundation for Interoperability

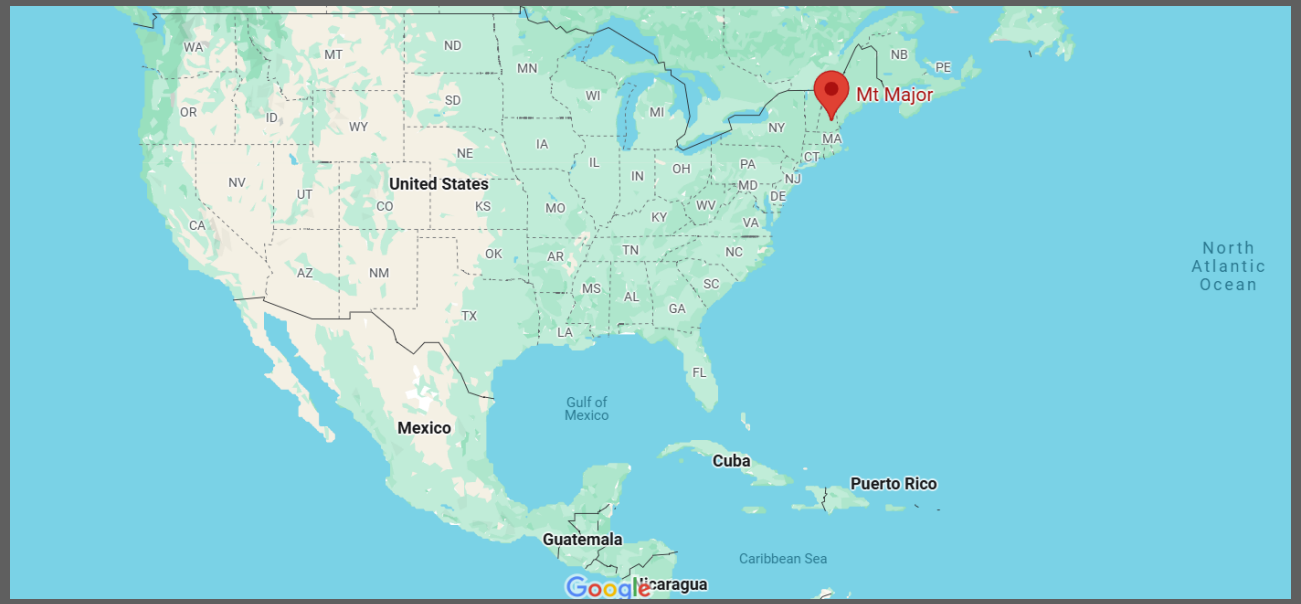
collaborating to maximize synergies & collective resources

- ICH M11
- Protocol Digitization

will extend the value of multiple initiatives across the ecosystem

- Regulatory-driven implementation of Harmonized Protocol Guideline
- Regulator Receipt of Digitized Protocol (USDM + FHIR)
- Operational & EHR-related Uses of Digitized Protocols

The road to the top of Mt. Major is paved with a lot of complaining from both my daughter and me



There will be challenges to achieve the aspiration of converging clinical research and clinical care.

SHIFTING MINDSET across the ecosystem with a need to take a more collaborative approach

ACHIEVING MORE CONNECTIVITY across our systems, processes, and people – without sacrificing quality and time.

ENGAGING PLAYERS IN THE HEALTHCARE ECOSYSTEM to collectively support each other in advancing towards this aspiration

ADOPTING NEW WAYS OF WORKING which may feel uncomfortable at first but on a greater scale are more practical and effective

This sounds hard.

So, why take this journey…?

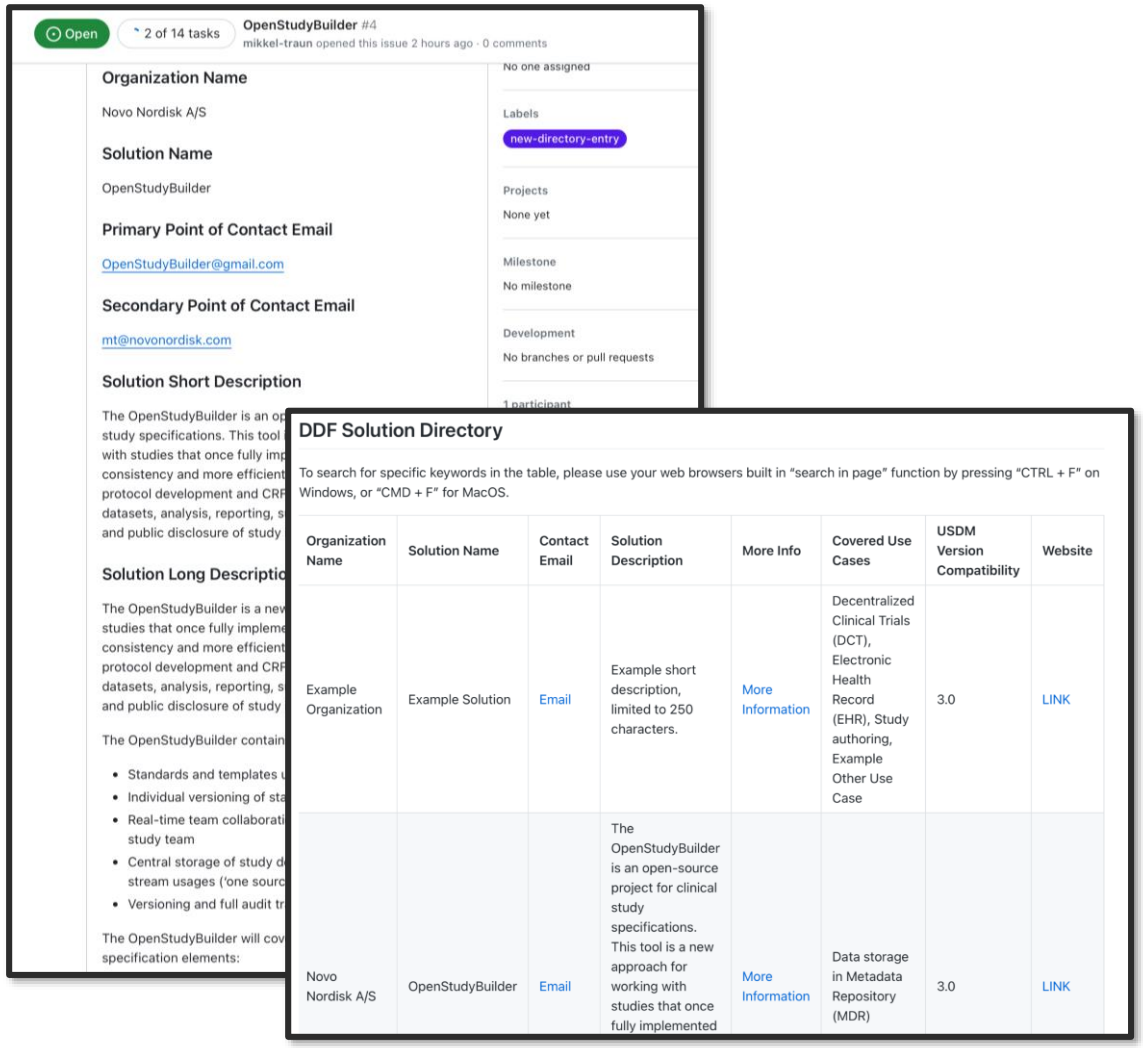
The road to interoperability is paved with a ton of hard work

Can digital first help realize everyone's hope to put patients first ?

1. Collaboration will be increasingly necessary
2. A need to digitalize the patient experience
3. Sustainability
4. New frontiers in drug discovery
5. Cycle time pressures
6. Industrializing what we learned from COVID
7. Focus on streamlined protocol design
8. Diversity in clinical trials
9. Developing alternative clinical sites

Solution Directory on DDF GitHub

Overview and Links



We want to find more ways for solution providers and sponsors within the larger DDF community to share information about use cases and technology development to support innovation.. This tool is a first step to enable this connectivity.

- **Based on direct feedback from vendors and other community members.**
- **Created to be compatible with and open to all variety of solutions.**
- **Should serve as a starting point for additional conversations**

Solution Directory Page*

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Acknowledgements

- CDISC
- TransCelerate DDF Team
- Vulcan Accelerator Utilizing Digital Protocol (UDP) Team
- ICH

For more information:

www.transceleratebiopharmainc.com

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

https://www.linkedin.com/in/rob-dicicco-66815415/