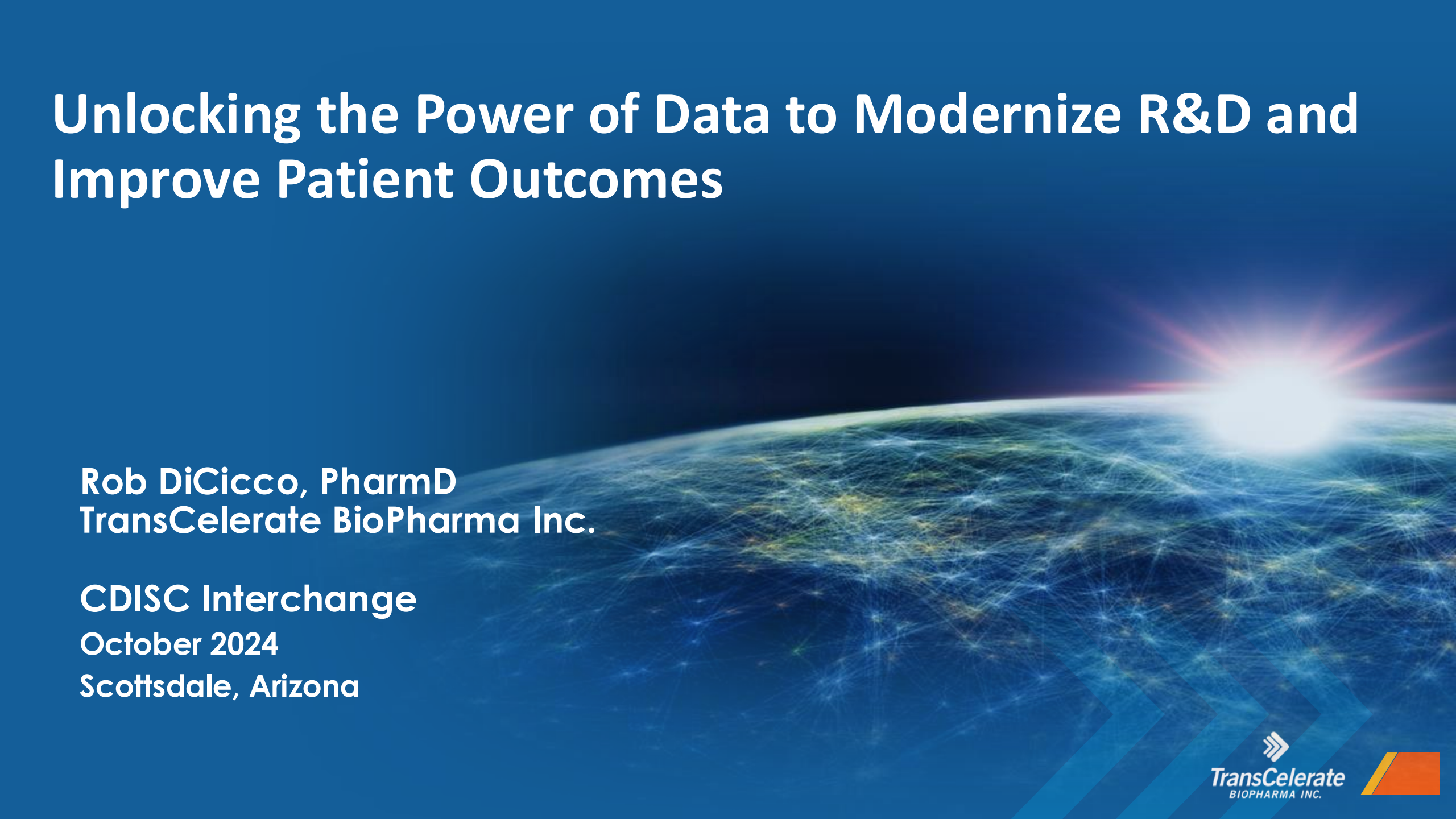
Unlocking the Power of Data to Modernize R&D and Improve Patient Outcomes

Rob DiCicco, PharmD
TransCelerate BioPharma Inc.

CDISC Interchange
October 2024
Scottsdale, Arizona



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, 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

TransCelerate BIOPHARMA INC.

Imagine a future world where **clinical research converges with clinical care**

A world where…

Clinical research and care is **normalized** for patients and care support

The patient's experience is **seamless** across both clinical research and care

Clinical practice continuously **improves and progresses**

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…?

TransCelerate BIOPHARMA INC.

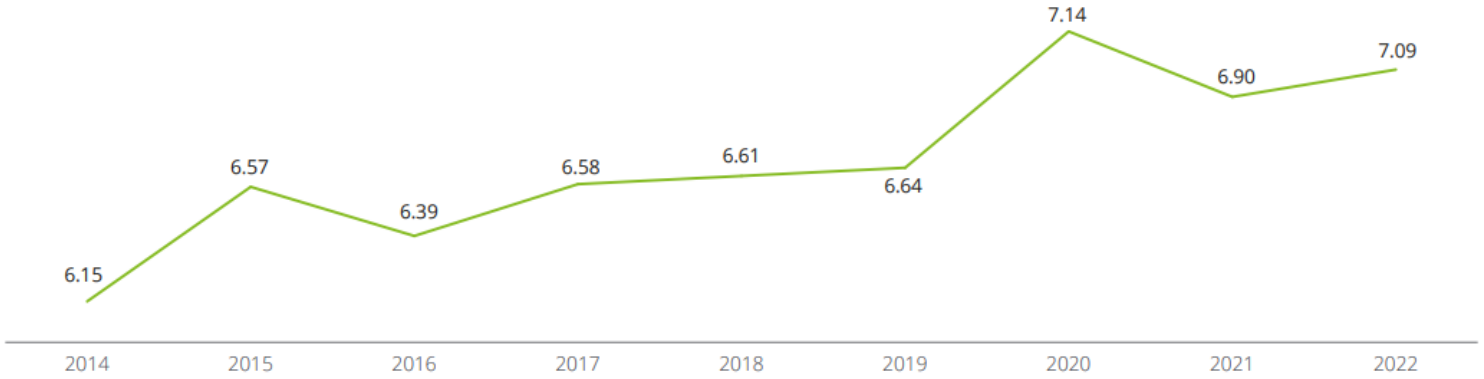

What is the big picture?

Average Cycle Times Over a 10-year Period

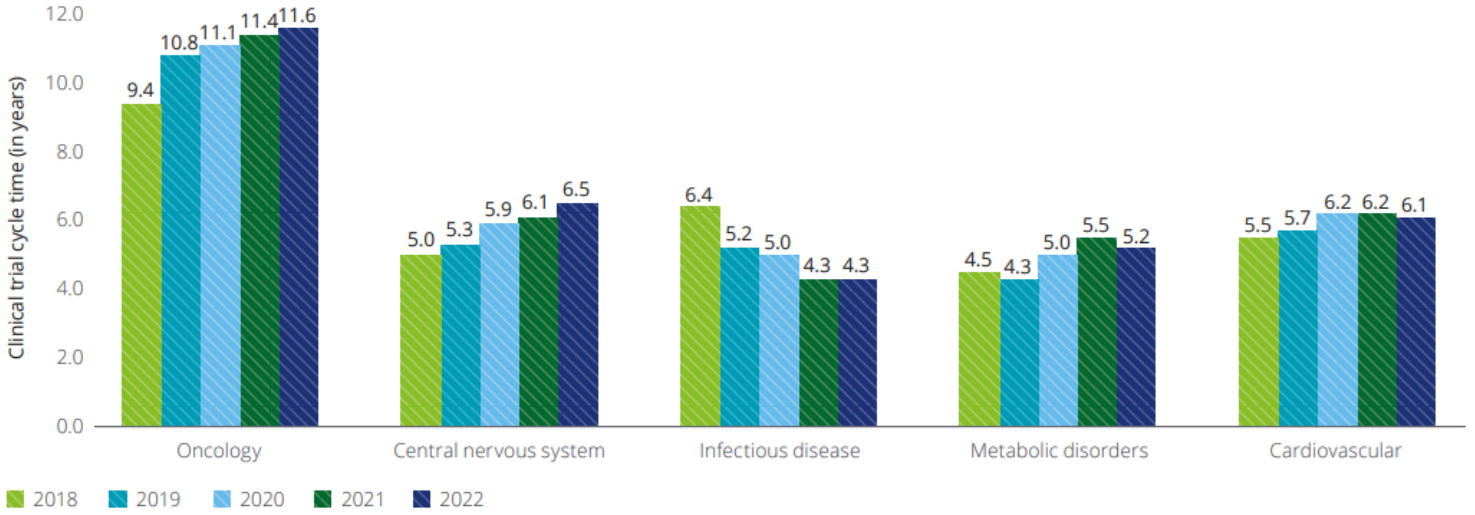
Deloitte: Seize the Digital Momentum – Measuring the return from pharmaceutical innovation 2022

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



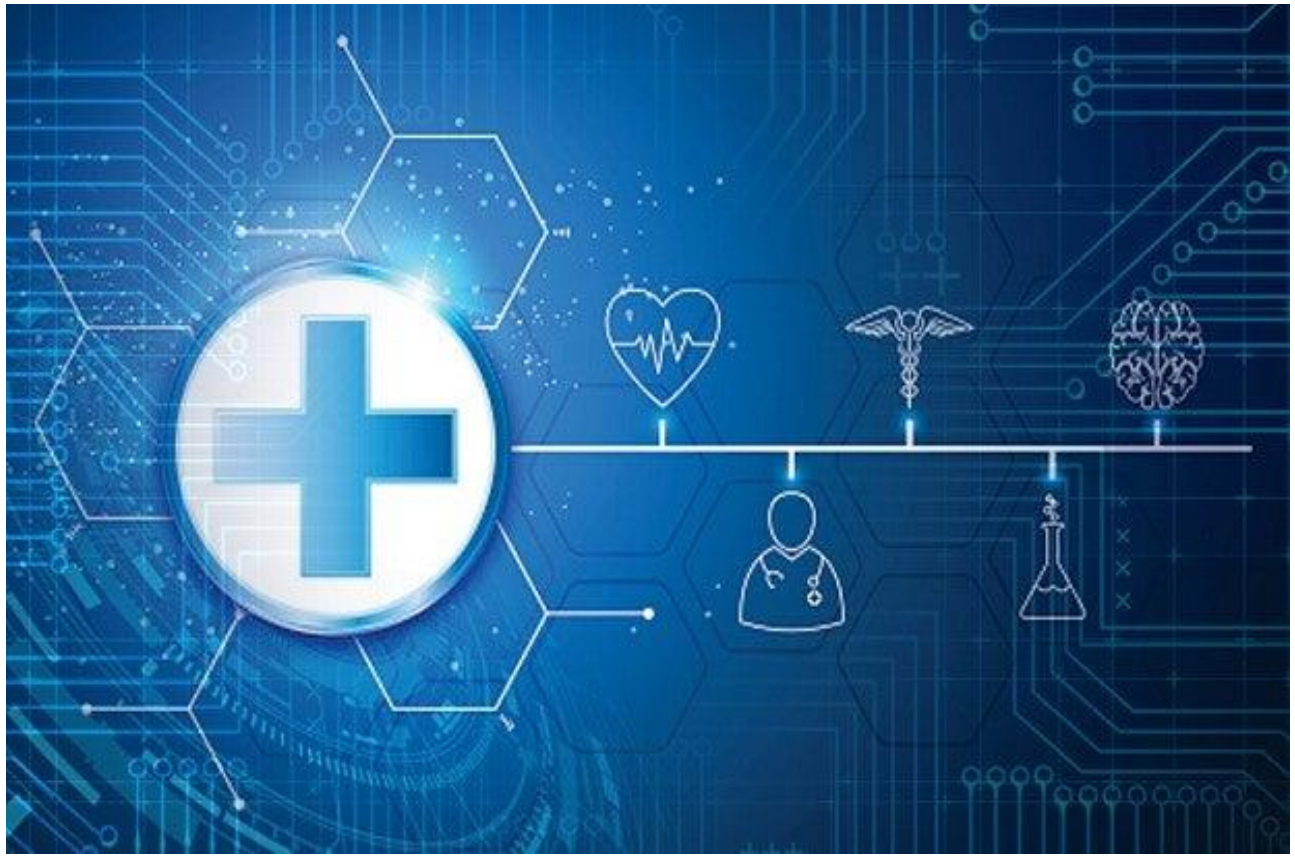
Note: Figures indicate time between start of Phase I trial to completion of Phase III trial



Source: Deloitte analysis, 2022

Hospital systems are investing to provide a digital experience

American Hospital Association Innovation Market Scan



- 77% investing in portals and mobile
- >50% plan to invest in SMS
- 40% automated workflows

- Telemedicine
- EHR Capabilities
- Patient portals and communication

https://www.aha.org/aha-center-health-innovation-market-scan/2022-02-22-3-principles-seamless-patient-digital

TransCelerate BIOPHARMA INC.

The refreshed roadmap is based on greater connectivity aiming for bigger impact

Transforming Connectivity

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

Information Sharing & Reuse

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

Innovative Trial Design

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

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

TransCelerate BIOPHARMA INC.

Can we make M11 the Catalyst to go Digital

Mature protocol template implementation and alignment

Maturing Data Model and Control Terminology

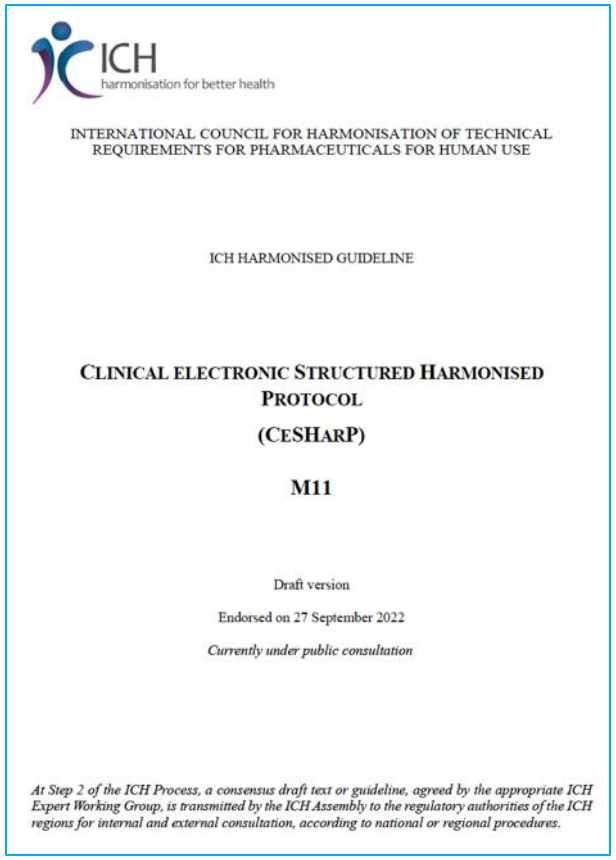
Regulatory Imperative

TransCelerate BIOPHARMA INC.

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

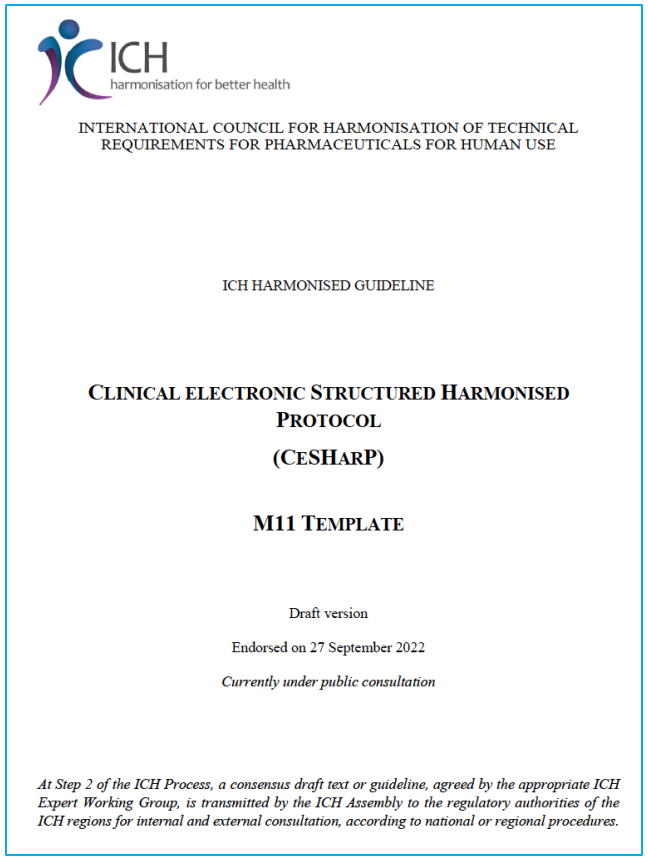
Draft version

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



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 TEMPLATE

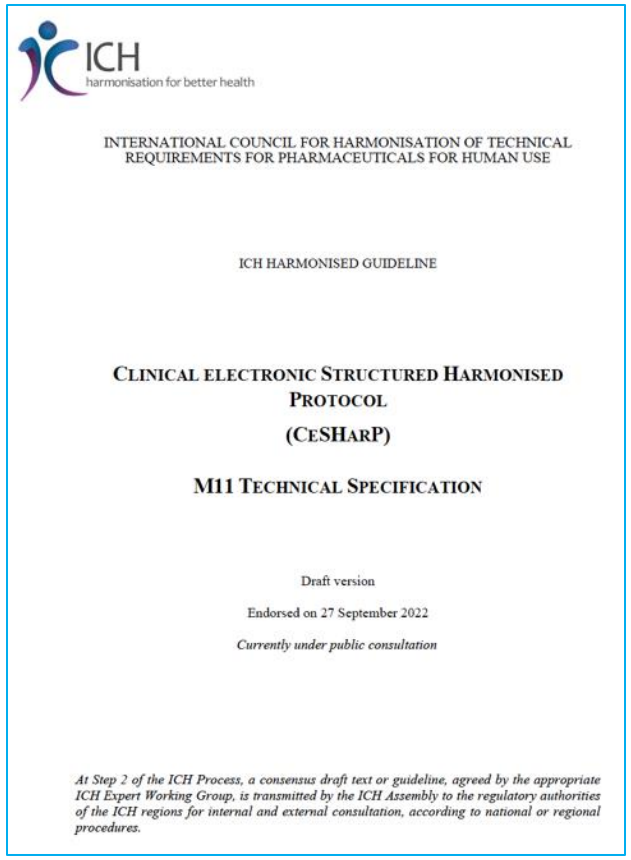
Draft version

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.

Written format for the Interventional Clinical Trial Protocol Template



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 TECHNICAL SPECIFICATION

Draft version

Endorsed on 27 September 2022

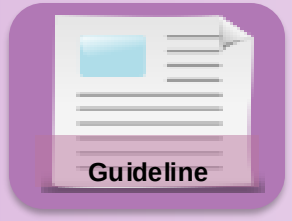
Currently under public consultation

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.

Technical representation aligned with the guideline and protocol template

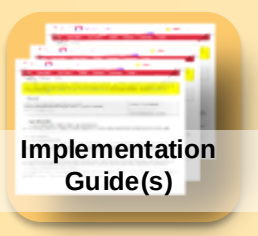
ICH M11 Creates A Unique Opportunity

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

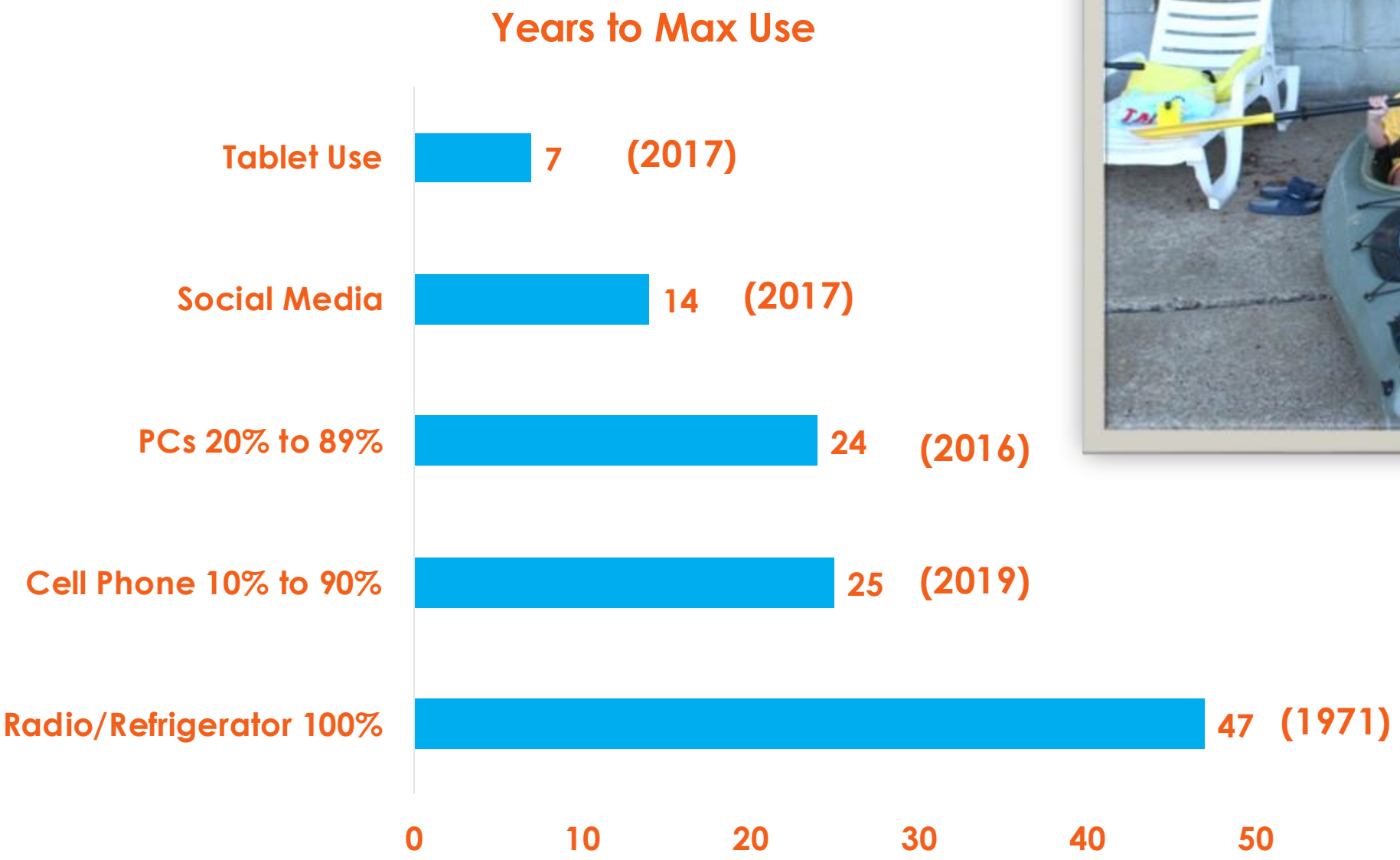
collaborating to maximize synergies & collective resources

- 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

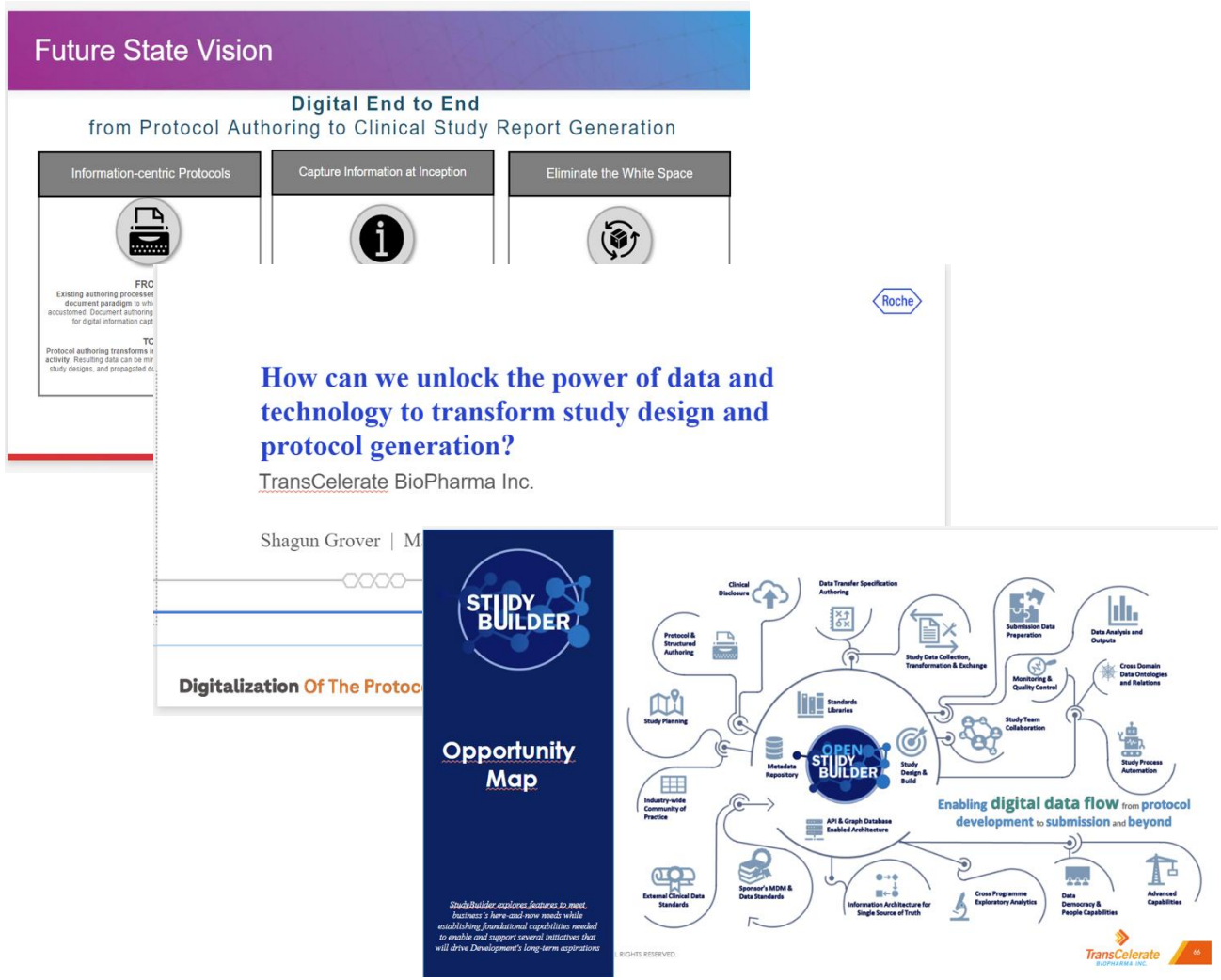
Are we there yet ?



TransCelerate BIOPHARMA INC.

DDF user stories are maturing

DDF in Action Day October 10, 2024



- Number of attendees **increased 3X**
- International
- Number of active ***sponsor companies*** increased from **9-17**
- Increase in vendor participation overall
- All 3 member company user stories have the same ***vision*** for end-to-end interoperability across the study lifecycle

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).*

TransCelerate BIOPHARMA INC.

How You can Contribute

- Collaborate with the DDF team to capture your organization's DDF case studies and adoption stories
- Explore, identify and share USDM, DDF solutions use cases
- Partner with others in the ecosystem to identify ways to build USDM into solutions to achieve protocol digitalization
- Evangelize DDF within your organization, educate your teams on Digital Data Flow and update on latest technical releases, use cases

TransCelerate BIOPHARMA INC.

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. Continued investment in technology / data
3. A need to digitalize the patient experience
4. Sustainability
5. New frontiers in drug discovery
6. Cycle time pressures
7. Industrializing what we learned from COVID
8. Focus on streamlined protocol design
9. Diversity in clinical trials
10. Developing alternative clinical sites

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/