Digital Data Flow: Mission Possible!

Practical approaches for protocol digitalization

September 24 – 25, 2025

Hosted by:
Roche – Basel, Switzerland
and
Novartis – East Hanover, New Jersey

TransCelerate BIOPHARMA INC.

Welcome

Welcome – East Hanover, New Jersey

Rachel Zebo

Merck & Co., Inc.

Meeting Moderator, United States

Director, Global Clinical Data Standards

TransCelerate DDF Sponsor Change

Stephen Eason

Novartis

Vice President, Global Head of Regulatory Writing and Submissions

TransCelerate Oversight Committee Member

Rob DiCicco

TransCelerate Biopharma Inc.

Vice President, Portfolio Management

TransCelerate BIOPHARMA INC.

Welcome – Basel, Switzerland

Lissa Morgan

Amgen

Meeting Moderator, Europe

DDF Sponsor Change Team Member

Director, Innovation & Process Improvement

Aditi Kumar

Roche

Head of Product Development Informatics

Janice Chang

TransCelerate Biopharma Inc.

Chief Executive Officer

General Ground Rules

These Ground Rules apply throughout the event, including during any Q&A or open discussions.

At this event:

- ❑ Don't share any information about the **vendors or sponsors with which you do business**.
  - Sponsors – do not identify the vendors/tech companies from which you purchase products or services or any specific brands of products or services that you buy.
  - Vendors – do not identify the sponsors to who you sell or are pitching to sell any tech products or services.
- ❑ Don't share information related to **pricing or costs** regarding any products or services that you sell or buy, *e.g.*, information about what vendors charge, estimated costs for implementation of any system or technology, or a sponsor's budget, anticipated spend, or projected costs savings.
- ❑ Don't discuss **which TransCelerate members have adopted or are planning to adopt** specific TransCelerate solutions.

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General Ground Rules

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- ❑ **Don't mention any criticisms** about other companies or products/services.
- ❑ **TransCelerate does not endorse vendors or product/service offerings.**
  - Vendors – do not state or suggest that TransCelerate endorses you or your products/services or that you are affiliated with TransCelerate.
- ❑ **This event is not a marketing, sales, or procurement opportunity.** Focus on knowledge sharing concerning innovative use cases and examples of how to deploy DDF-related technologies.
- ❑ **A vendor's participation in this event does not mean that its solutions are USDM-compliant.** Companies must do their own diligence to determine whether solutions are compliant.

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General Ground Rules

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- ❑ Participation in the event generally and any specific discussion or break-out session is **purely voluntary**, as is using any TransCelerate asset/tool.
- ❑ In any open discussions or Q&A, you **don't have to identify** what **company** you work for.
- ❑ **TransCelerate does not track and**, even if some anecdotal information might be available, **cannot disclose** which TransCelerate **members have adopted** or may adopt a TransCelerate solution.
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- ❑ Neither TransCelerate nor its member companies bear any liability if any DDF solution fails to comply with any law or regulation or does not meet a company's or customer's needs or expectation.

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Digital Data Flow

About Digital Data Flow – United States

William Illis
Novartis

TransCelerate DDF Initiative Lead

Chris Decker
CDISC

President & CEO

Mary Lynn Mercado
Novartis

TransCelerate Digital Protocol Lead

Global Head Protocol Delivery & US Site Head, Regulatory Writing & Submissions

TransCelerate BIOPHARMA INC.

About Digital Data Flow - Europe

Belinda Griffin

TransCelerate Biopharma

Program Director, TransCelerate Digital Data Flow Initiative

Peter van Reusel

CDISC

Chief Standards Officer

Wafaa Jabert

Merck KGaA

Head of Clinical Data Standards and Integration

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DDF Overview

Belinda Griffin

TransCelerate Biopharma Inc.

Program Director, Digital Data Flow Initiative

Bill Illis

Novartis

TransCelerate DDF Initiative Lead

Welcome to DDF: Mission Possible!

Look around you!

Today we have:

- Study Sponsors
- Technology Providers
- Sites & CROs
- Health Authorities
- Standard Setting Org's
- Consortia

You are joining us from the following functions:

- Medical Writing
- Clinical Operations
- Data Management
- Information Technology
- Standards & Governance
- Analytics & Reporting
- Regulatory Affairs

What awaits you at DDF: Mission Possible!

Over the next two days – your mission, should you choose to accept…

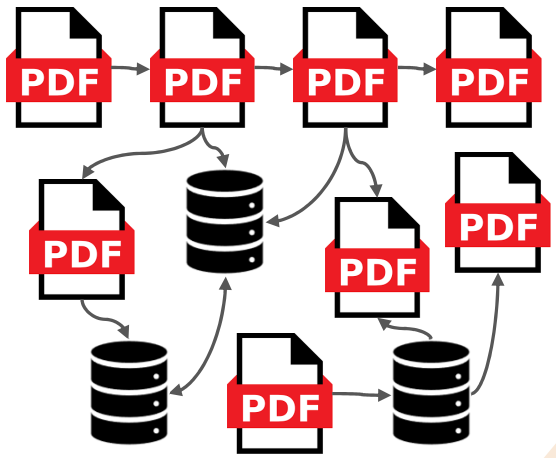
Participate in two days of the DDF experience - listening, ideating and collaborating to understand:

- ✓ what DDF is - the potential and possibility
- ✓ how DDF can help on your data digitalization journey, how others are planning their DDF roadmap and when/where to get started
- ✓ where you can learn more and continue the conversation

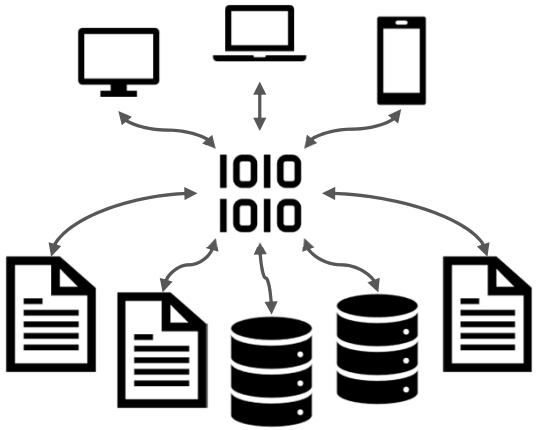
Why DDF? – The Vision

Break the Document Paradigm

From document-first



To data-first



Goal: Increase Clinical Research Velocity

Lower study cycle times ➔ **Faster** trial results
Increased trial throughput ➔ **More** trial bandwidth
Improved study optimization ➔ **Better** trial efficiency

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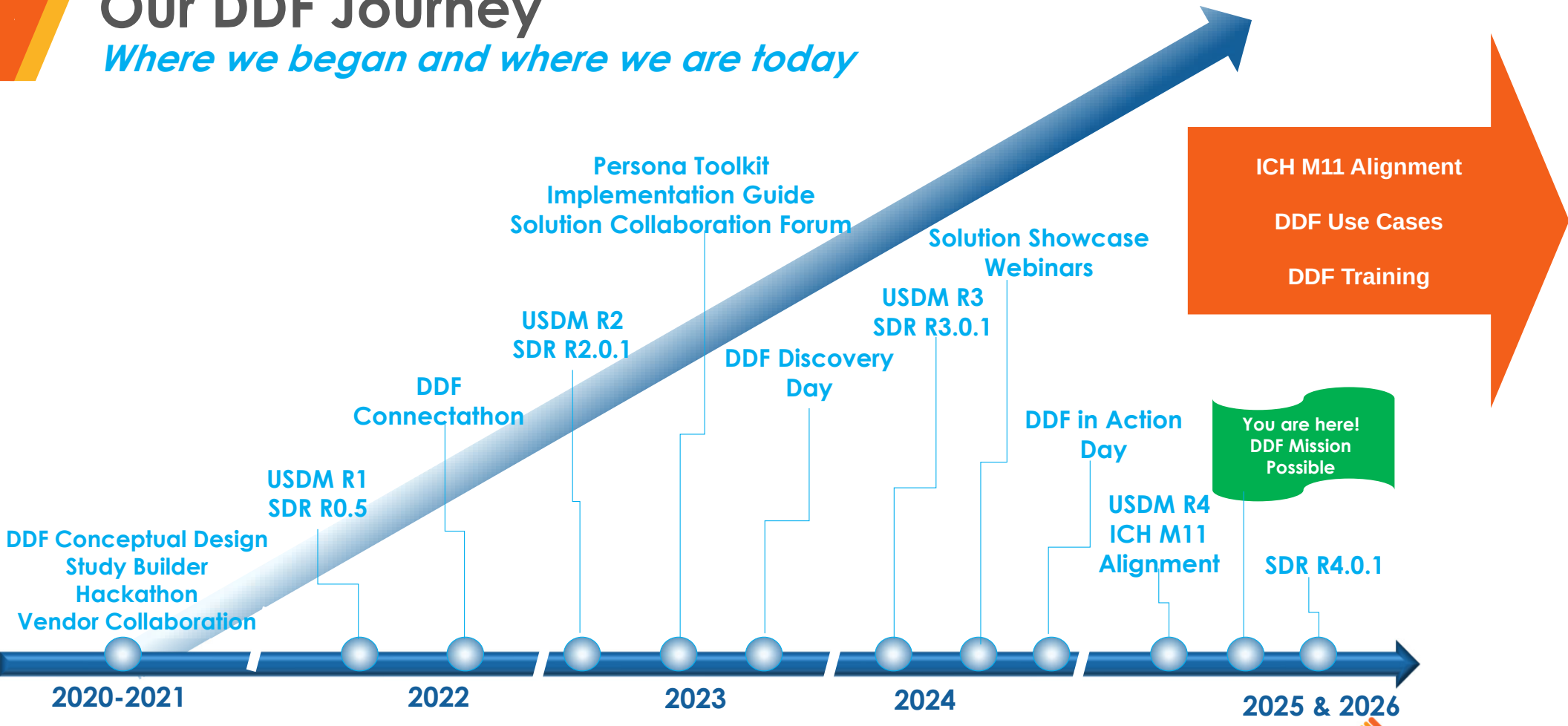
Our DDF Journey

Where we began and where we are today



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Stable Technology Now Underpins Digital Data Flow

USDM v4.0 launched in June

- Alignment with ICH M11
- Support for complex studies, interventional & observational studies, and medical devices
- Maximise content re-use and support for multiple document templates
- Model Extension mechanism to provide flexibility

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How to Actualize the Vision

Conceptual Design

Pathways to Digitalization

- Manual Protocol Authoring
- Historical Protocol & Optimization DB
- Generative AI
- Native Digital Authoring

Documents to Data:
Write Once, Read Many

Digital Data Flow

Study Definitions Repository (SDR)

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cdisc

- Unified Study Definitions Model (USDM)
- API Specs
- Controlled Terminology

Connecting to Downstream Systems

Machine Readable Data

- Trial Site Interoperability
- Regulatory & Trial Registries
- eDC & eCOA
- CTMS, IVRS, etc

Eliminate non-value added activities
Enable automation of downstream study startup and conduct processes
Create foundation for study design analytics insights

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Getting Started: Pathways to Implementation

DDF Use Cases

Retrospective | **Prospective**

Protocol 'Store'

Past Protocols
The storage of a sponsor's past protocols to support a variety of use cases such as:
The particular sponsor's:
- Therapeutic area specific content
- Standard inclusion and exclusion criteria.
- Libraries of objectives, endpoints and estimands.
- Ability to assess the past to prevent protocol amendments.
- General search across the library

Study Design

Protocol Authoring
Support the authoring of new protocols including complex studies such as Master, Umbrella etc.

This would include analysing previous protocol information to inform design choices (see Protocol Store).
Writing associated SAP, Informed Consent, Monitoring Plan, Drug Plan etc via content reuse.

Study Build
Build of the study based on the protocol including all detailed procedures and assessments to allow for immediate deployment.

Feasibility & Cost
Support study feasibility and complexity evaluations.

Determine the cost of the study including such items as vendor and CRO costs and support the laboratory RFP process

Regulatory Reviews
Approval for the execution of the study including IND, CTA etc and discussions with regulatory authorities

Stakeholder Views
Tailored views for stakeholders such as IRB and ethic committees.

Study Start-up

Deployment
Deployment of the study across the enterprise using the USDM to support electronic configuration rather than manual data entry including Data collection systems (incl. EDC), CTMS, IRT, Data transmission specifications and more

TMF
Linking the protocol to the specification of milestones and essential documents

Data Collection Strategy
Ensure all data that is needed for analysis is collected. Remove unnecessary procedures & data collection to reduce trial cost and patient burden.

Trial Registries
Registration of the study with registries such as CT.gov, CTIS etc.

Training
Provision of training materials to those involved in the study including sites

Site Support
Provision of tailored information to sites regarding study execution.

Study Execution

Amendments
Support the amendment process with the ability to indicate the precise changes to the user community.
Ensure fewer amendments (see Protocol Store).

Subject Information
Provision of improved information to subjects regarding study execution, improve expectation management.

Drug & Study Materials
Assist in the planning and provision of study drug, materials and supplies

Subject Recruitment
Support the identification of subjects to help improve subject recruitment to the study. Help support EHR participation identification.

Analysis & Reporting

Automation
Provide a solid foundation for the automation of analysis and reporting outputs such as TLFs and CSRs

SDTM
Creation of 'T' domains. Auto generation of data domains

ADaM
Use the protocol statistical metadata to assist in the derivation of analysis datasets

Statistical Analysis Plan
Use the protocol as the initial source of the SAP to ensure consistency with objectives, endpoints, estimands

Regulatory Submission

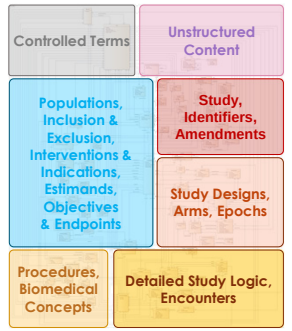
Submission
Preparation of the submission by the sponsor

Regulatory Review
Review of the submission by the regulatory authority and discussions / questions with the sponsor

Statistical and Safety Review
Support the comparison of data by arm or study design.

Allow for the verification of planned (protocol) data versus actual (study data) captured data

Unified Study Definitions Model (USDM)



Across The Lifecycle

Dashboards
The display of protocol related information sourced from one or more protocols in ways which have not been achievable before

Comparison
Compare and verify differences across versions and similar protocols

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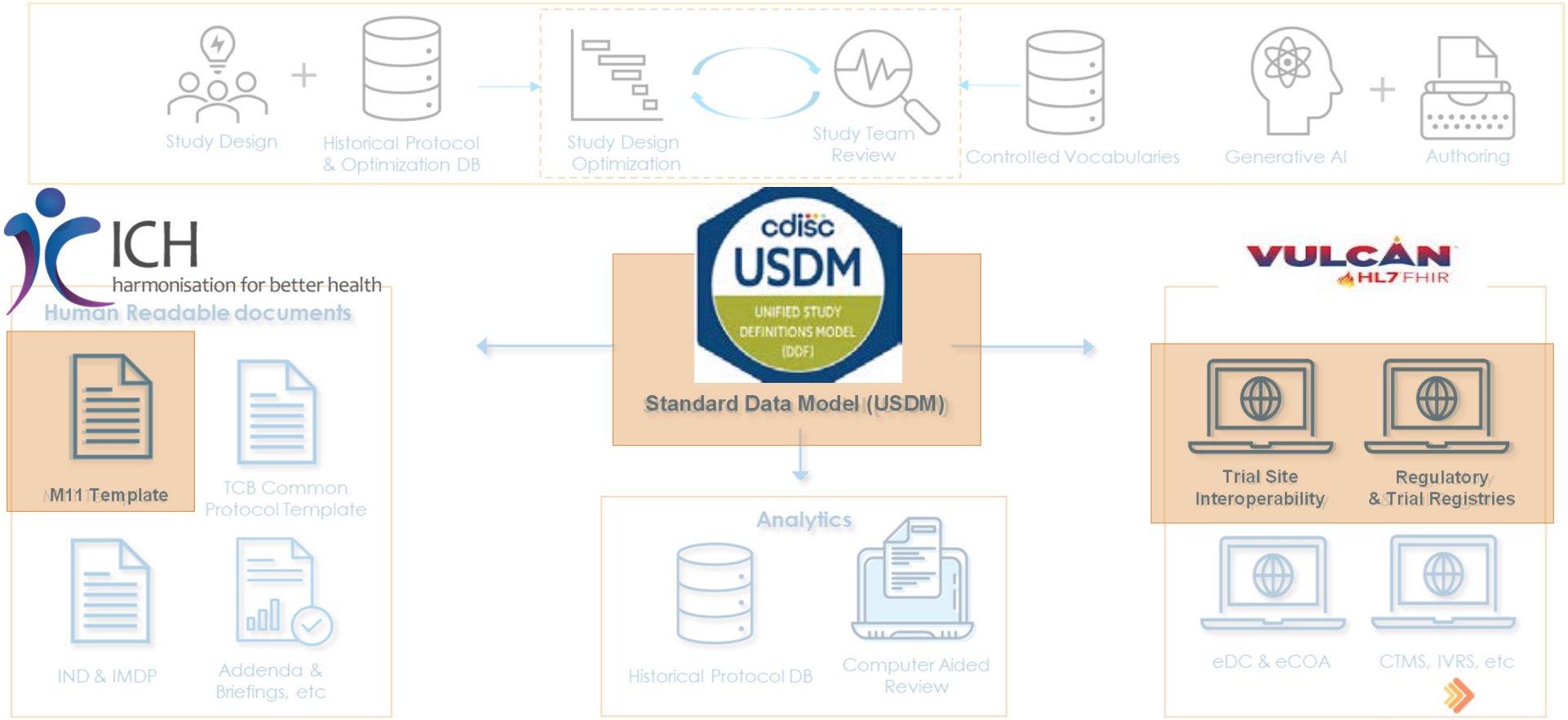
Multiple Stakeholder Collaboration

CDISC, ICH & HL7-Vulcan



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Strong Engagement from a Growing Tech Provider Community

Technical Provider Engagement
Rapid growth in engagement with technical solution providers

Learn more about our technical solution provider engagement and previous webinar recordings-
https://transcelerate.github.io/ddf-home/scf.html

**Company logos are not used to imply endorsement of specific vendors for DDF implementation or endorsement of DDF/USDM by these vendors.*

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DDF Change Management Journey

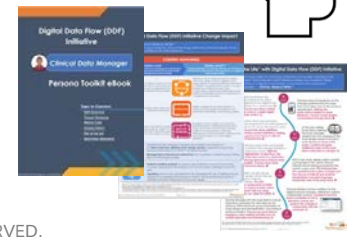
What is a digital protocol?
What can it be used for?

Awareness

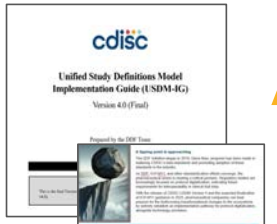
Why is this important?
How can digital protocols improve clinical trials?
What is the business case?

Commitment?

Understanding



What is the USDM standard?
What is it made up of?
How can it be used?
What does this mean for those who work on clinical trials?



Action

?What steps can a company take to implement?
How can you contribute to the industry-wide transformation?

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DDF Training: Getting You Ready!

NEW!

Digital Data Flow & USDM Training

From TransCelerate & CDISC

COMING SOON

DDF Clinical User Training
(provided by TransCelerate)

- On-demand online training
- Available Q4 2025
- Targets clinical research ecosystem roles
- Course Content –
  - Overview of DDF
  - End-to-end clinical data flow use cases from study design to submission

Interested? Email DDF at DDF@transceleratebiopharmainc.com for more information

AVAILABLE NOW

USDM Technical Training
(provided by CDISC)

- On-demand and in-person training opportunities
- Course content –
  - Understanding of USDM structure
  - Schedule of Activities and Study Definition documents
  - hands-on exercises to improve understanding of USDM

Interested? Email CDISC at info@cdisc.org for more information

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Additional Opportunities to Stay Involved with DDF

You can stay involved and learn more about the Digital Data Flow initiative by visiting the following websites:

DDF Website

As the main website for DDF, learn and access all resources supporting DDF

Scan QR Code to explore DDF Website

CDISC DDF Website

Learn about and access the Unified Study Definitions Model (USDM) Reference Architecture supporting Protocol Standards

TransCelerate DDF Initiative Solutions

Learn about DDF initiative background and roadmap

DDF GitHub Repos

Learn about and access the Study Definitions Repository Reference Implementation and supporting codebase

Questions? Feedback? Please email us at DDF@transceleratebiopharmainc.com

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What you think DDF to be…DDF Myths

Only one path to DDF implementation

DDF is still evolving. Better to wait and watch

DDF is a one and done solution to digitize the protocol

It is a lonely road to DDF (we don't know how and where to start)

And what it is…DDF Facts

Many pathways to implementation

Don't wait to start with DDF - technology stable with USDM v4.0

DDF has robust and broad-based ecosystem support (ICH-M11, Vulcan-UDP)

You are not alone! DDF journey offers opportunities to collaborate and lean in

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TransCelerate Digital Data Flow (DDF)

Mission Possible!

It's not that hard!

Thank you!

USDM Updates

Peter van Reusel
CDISC
Chief Standards Officer

Chris Decker
CDISC
President & CEO

CDISC Digital Protocol Update

DDF Mission Possible Event

24th September 2025

Chris Decker (US) / Peter Van Reusel (EU)

Stable Technology Now Underpins Digital Data Flow

USDM v4.0 launched in June

scan for more info

- Alignment with ICH M11
- Support for complex studies, interventional & observational studies, and medical devices
- Maximise content re-use and support for multiple document templates
- Model Extension mechanism to provide flexibility

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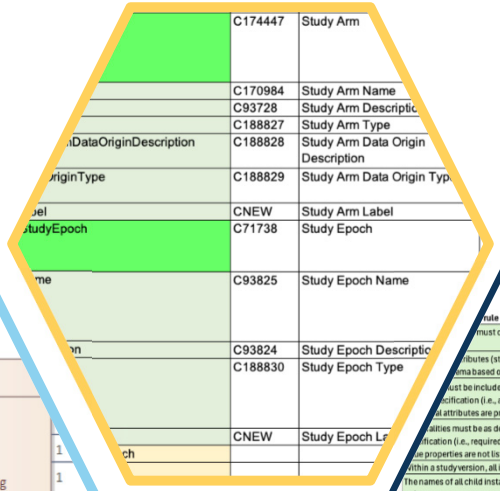
The USDM Standard

CDISC Controlled Terminology

Provides further semantics, complementing the UML model.
Includes the definition of classes, attributes, and value sets



	C174447	Study Arm
	C170984	Study Arm Name
	C93728	Study Arm Descriptic
	C188827	Study Arm Type
DataOriginDescription	C188828	Study Arm Data Origin Description
riginType	C188829	Study Arm Data Origin Typ
el	CNEW	Study Arm Label
tudyEpoch	C71738	Study Epoch
me	C93825	Study Epoch Name
n	C93824	Study Epoch Descriptic
	C188830	Study Epoch Type
	CNEW	Study Epoch La
ch		

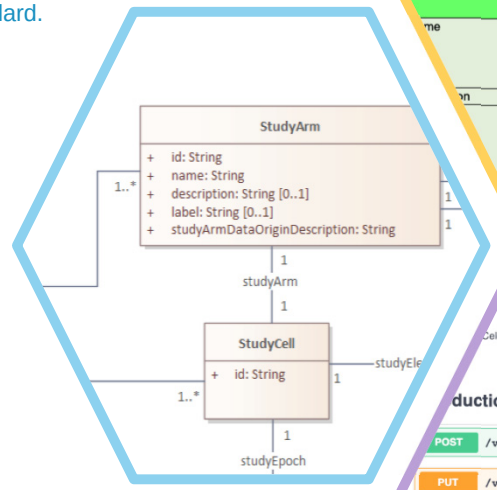
Examples

Example protocols implemented in the USDM with associated JSON files and visualisations


```
tudyArms": [
{
  "id": "StudyArm_1",
  "name": "Placebo",
  "label": "",
  "description": "Placebo",
  "type": {
    "id": "Code_61",
    "code": "C174268",
    "codeSystem": "http://www.cdisc.org",
    "codeSystemVersion": "2022-12-16",
    "decode": "Placebo Comparator Arm"
  },
  "studyArmDataOriginDescription": "Data collec
  "dataOriginType": {
    "id": "Code_62",
    "code": "C188866",
    "codeSystem": "http://www.cdisc.org",
    "codeSystemVersion": "2022-12-16",
    "decode": "Data Generated Within Study"
  }
},
{
  "id": "StudyArm_2",
  "name": "Xanomeline Low Dose",
  "label": "",
  "description": "Active Substance",
  "type": {
    "id": "Code_63",
    "code": "C174267",
    "codeSystem": "http://www.cdisc
    "codeSystemVersion": "2022-12-
```

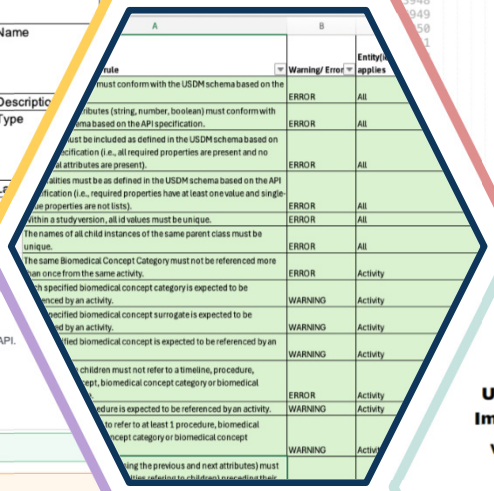

Logical Model

The UML logical model (a class diagram) that provides the basis for the USDM standard.



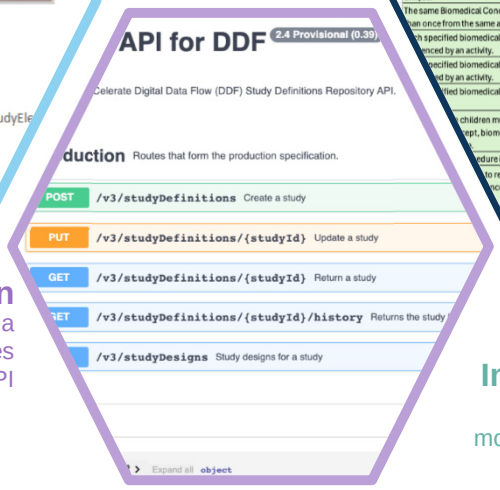
CORE Rules

Specification of the rules that define USDM compliance



	Warning/ Error	Entity(I applies
must conform with the USDM schema based on the	ERROR	All
ibutes (string, number, boolean) must conform with ma based on the API specification.	ERROR	All
ust be included as defined in the USDM schema based on cification (i.e., all required properties are present and no al attributes are present).	ERROR	All
alities must be as defined in the USDM schema based on the API cification (i.e., required properties have at least one value and single- e properties are not lists).	ERROR	All
within a study version, all id values must be unique.	ERROR	All
The names of all child instances of the same parent class must be unique.	ERROR	All
The same Biomedical Concept Category must not be referenced more an once from the same activity.	ERROR	Activity
h specified biomedical concept category is expected to be nced by an activity.	WARNING	Activity
pecified biomedical concept surrogate is expected to be d by an activity.	WARNING	Activity
fied biomedical concept is expected to be referenced by an	WARNING	Activity
children must not refer to a timeline, procedure, ept, biomedical concept category or biomedical	ERROR	Activity
dure is expected to be referenced by an activity.	WARNING	Activity
o refer to at least 1 procedure, biomedical ncept category or biomedical concept	WARNING	Activ
ing the previous and next attributes) must		

API for DDF

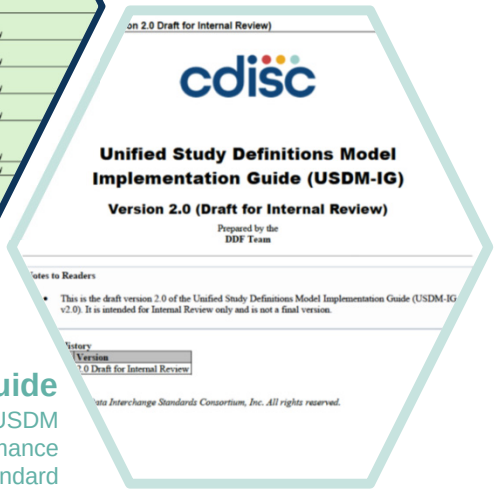


API Specification

Provides the means to exchange a single study between machines using a JSON API

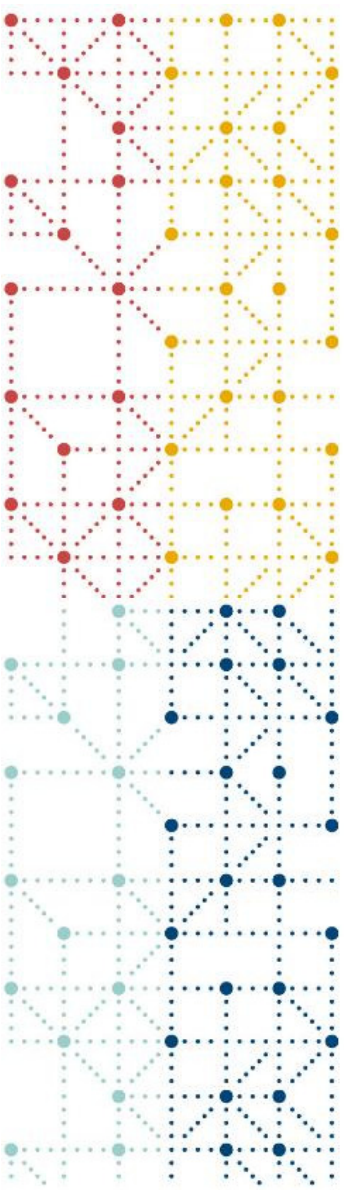
Implementation Guide

Guidance on using the USDM model and ensuring conformance with the standard



DDF Phase 5: Accelerate Adoption

- Focus on Community Engagement and Adoption
- Establishing USDM & DDF Governance
- Scoping for Additional Regulatory Needs
- USDM Release Ensuring Final M11 Alignment
- Target Tangible Use Cases: Patient Matching, Protocol Authoring/M11, and Data Transfer Automation

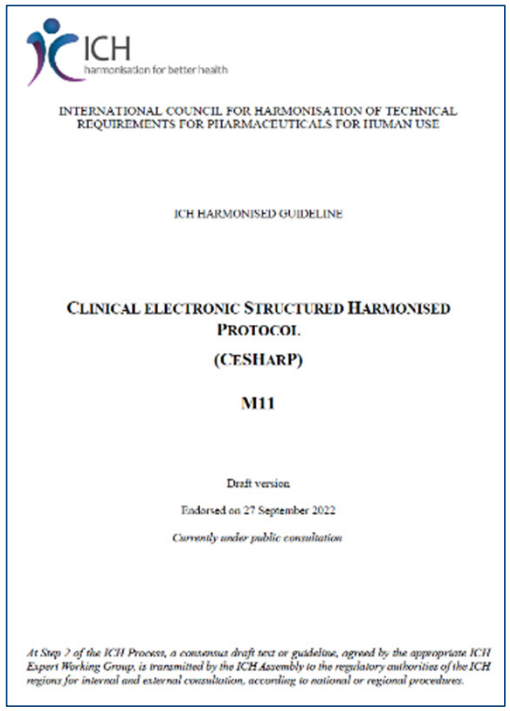


ICH M11 and USDM: How do they Fit Together

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

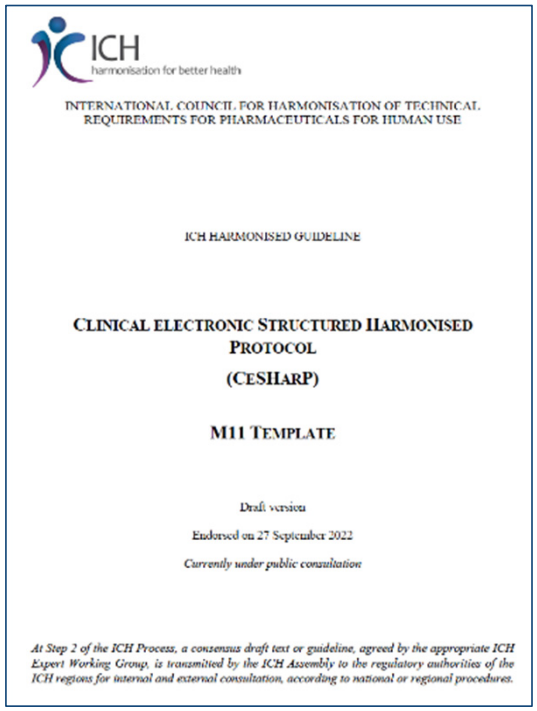
Draft version

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

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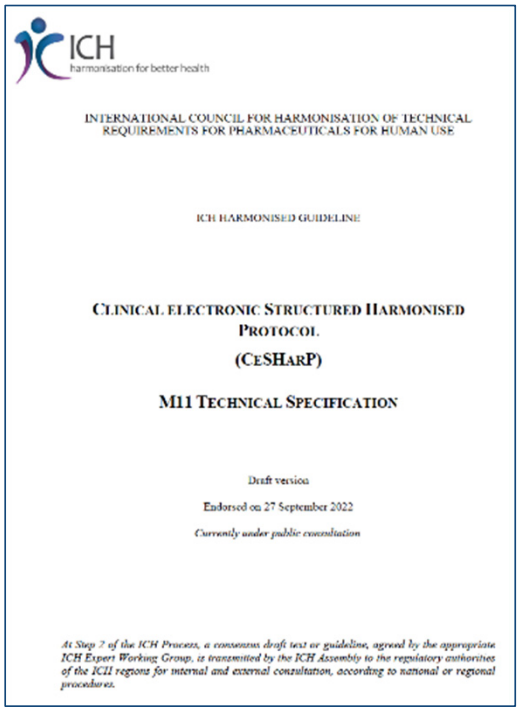
Provides the written format for the Interventional Clinical Trial Protocol Template



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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

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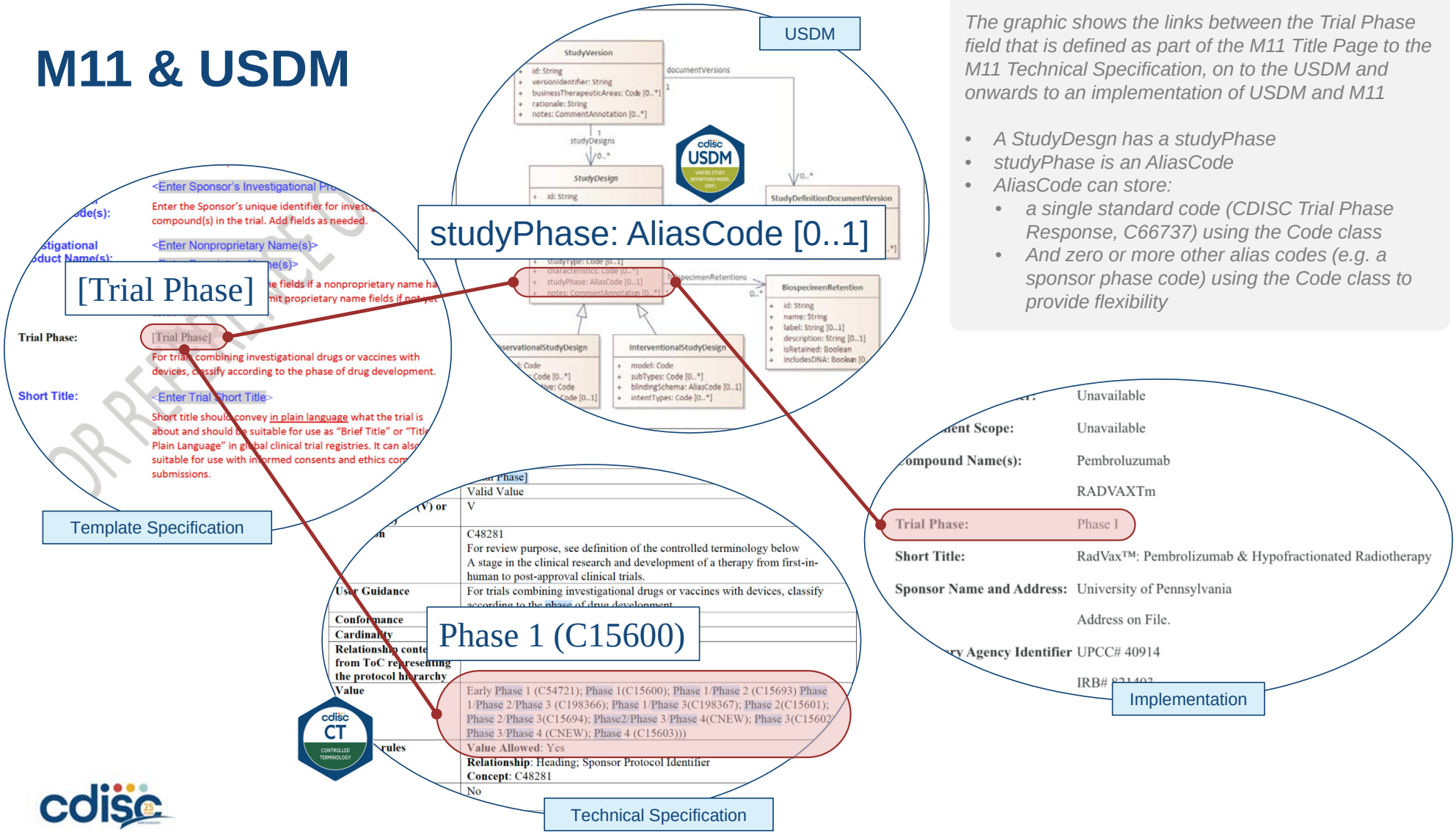
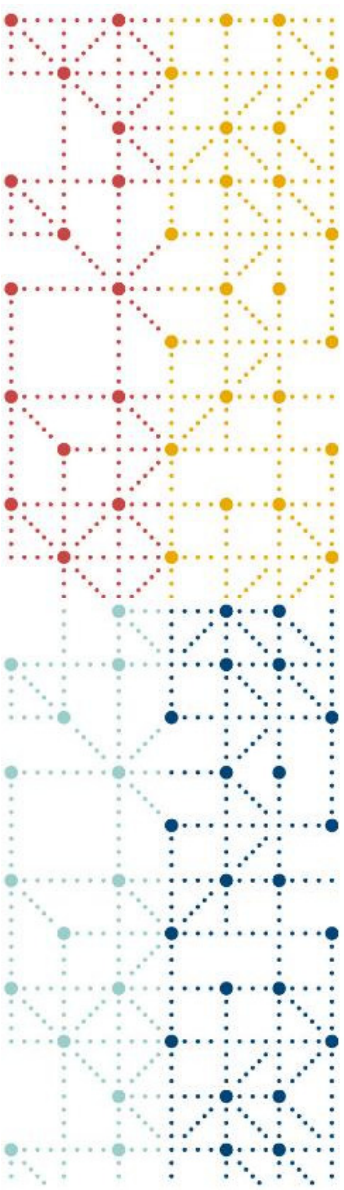
Provides the technical representation aligned with the guideline and protocol template

M11 & USDM



The graphic shows the links between the Trial Phase field that is defined as part of the M11 Title Page to the M11 Technical Specification, on to the USDM and onwards to an implementation of USDM and M11

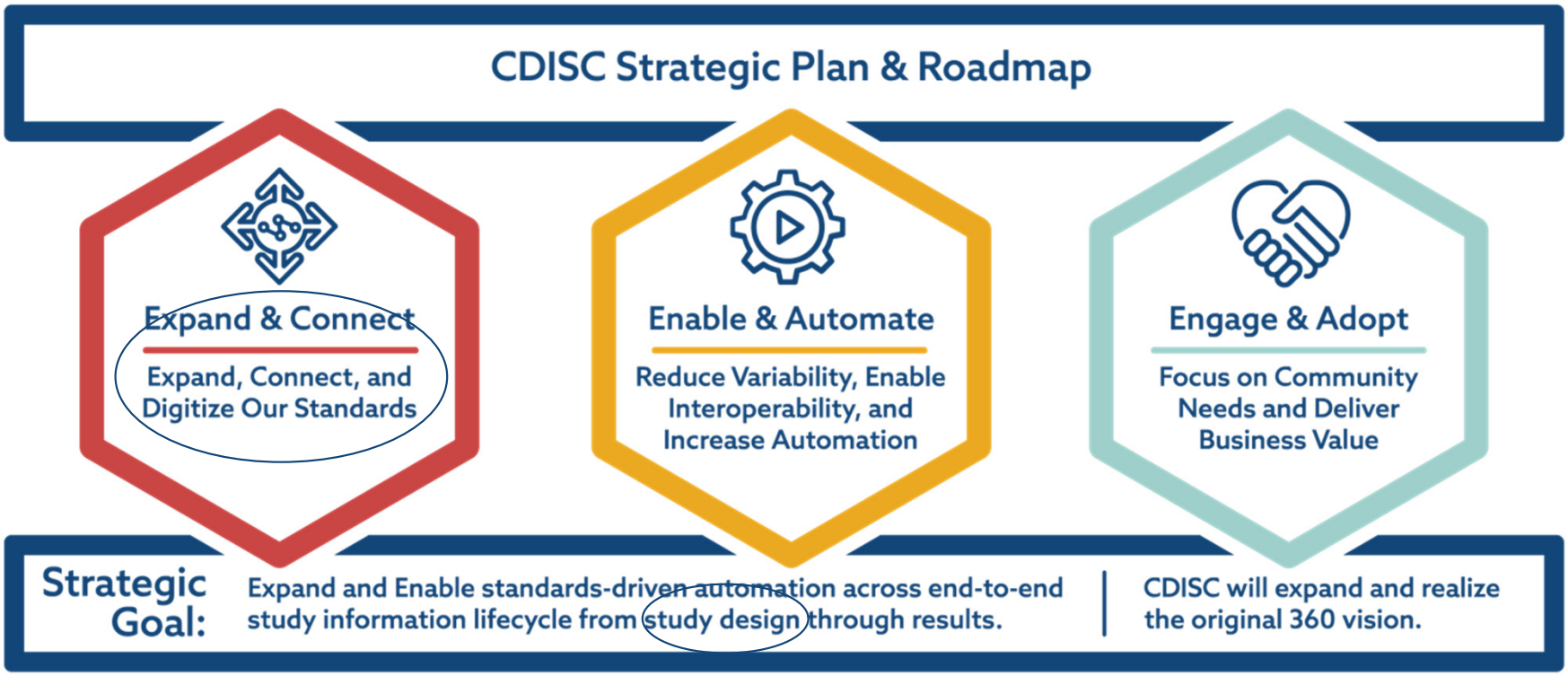
- *A StudyDesgn has a studyPhase*
- *studyPhase is an AliasCode*
- *AliasCode can store:*
  - *a single standard code (CDISC Trial Phase Response, C66737) using the Code class*
  - *And zero or more other alias codes (e.g. a sponsor phase code) using the Code class to provide flexibility*



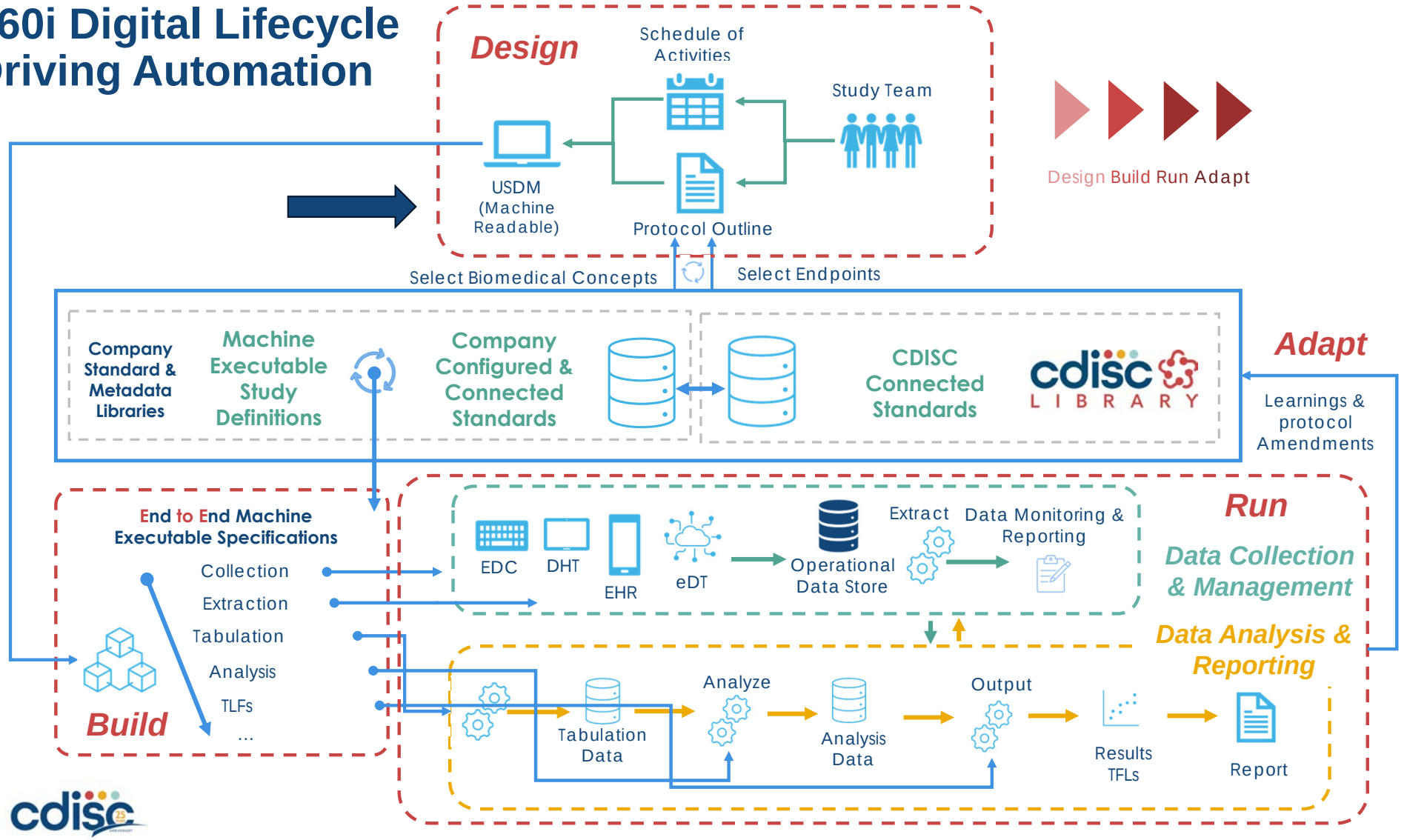
CDISC 360i: Leveraging DDF and USDM to drive Automation Downstream

Realizing CDISC's Mission

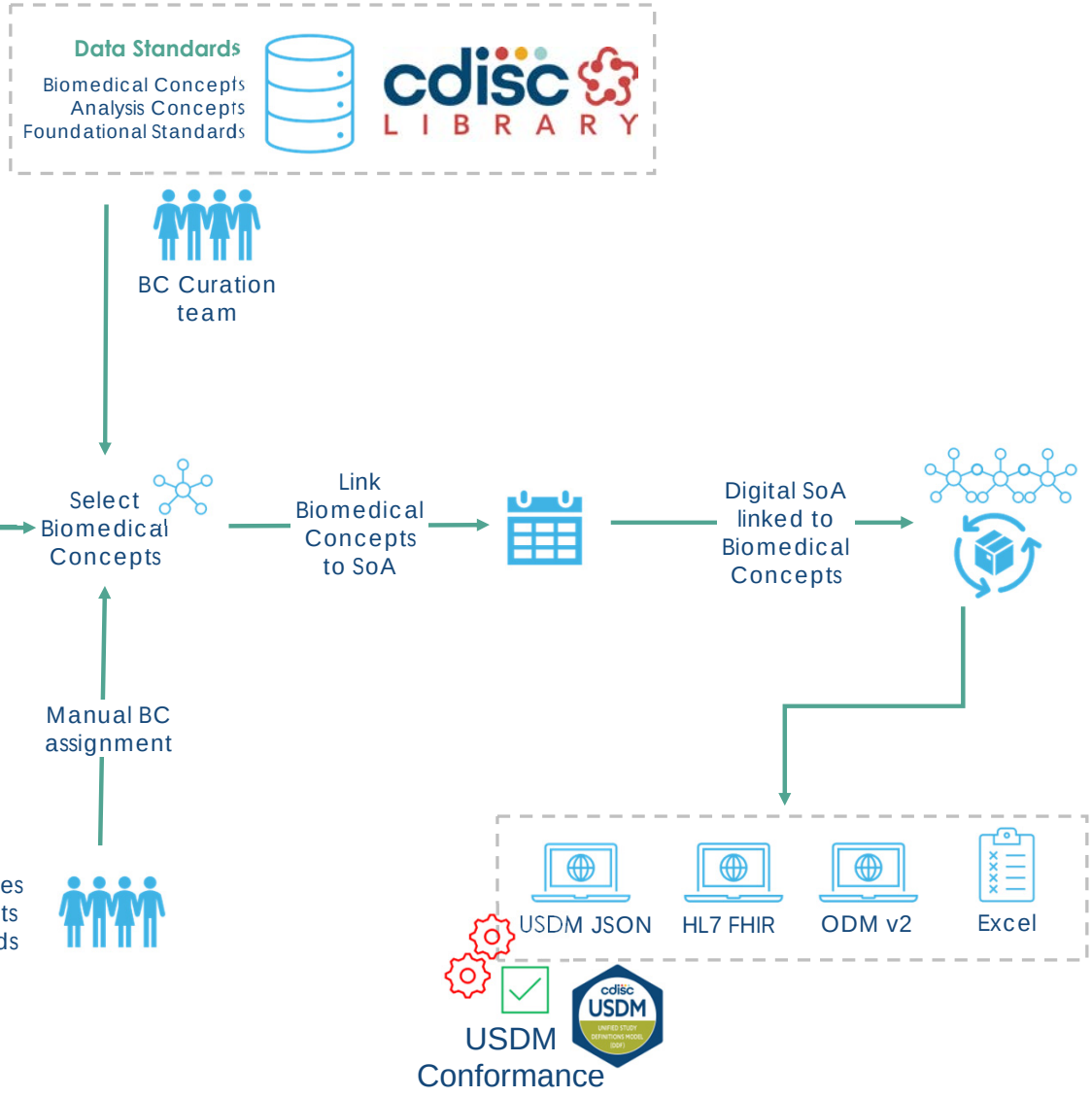
*CDISC's **vision** is to amplify data's impact to advance research by…*
creating connected standards across the study information lifecycle to enable accessible, interoperable, and reusable data for more meaningful and effective research



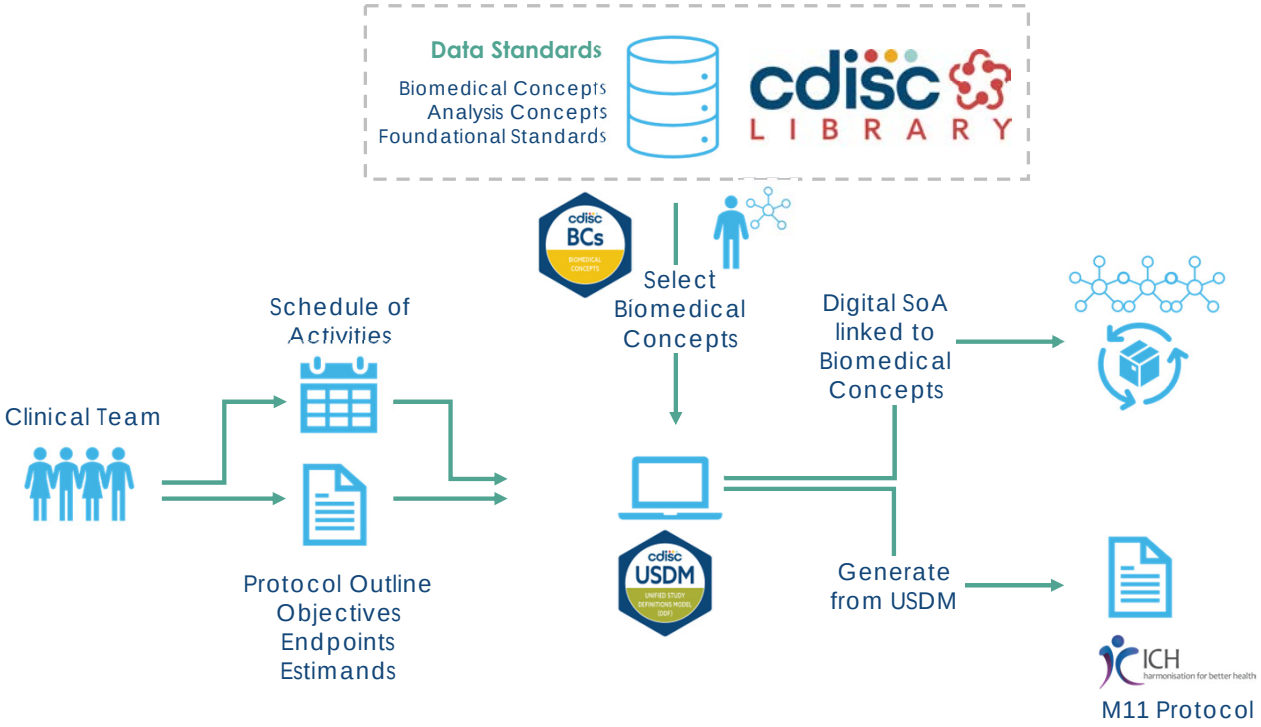
360i Digital Lifecycle Driving Automation

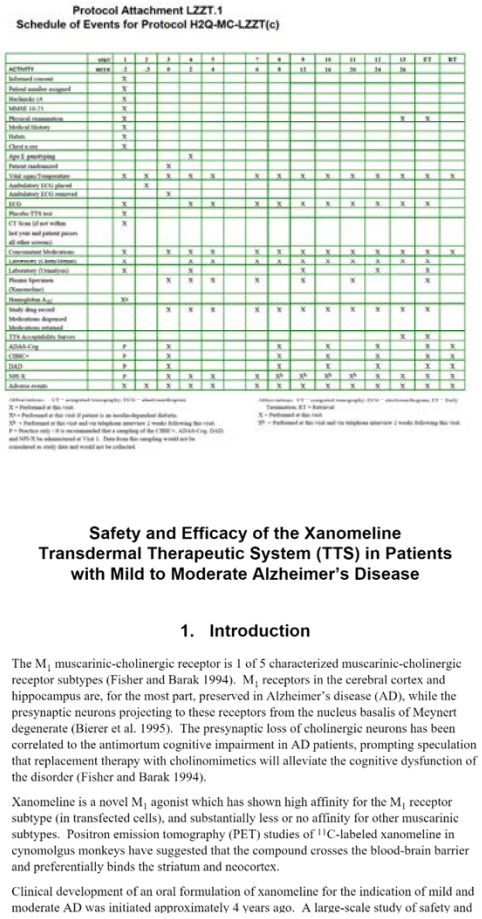


360i Study Design



360i Study Design





Protocol Attachment LZZT.1
Schedule of Events for Protocol H2Q-MC-LZZT(c)

ACTIVITY	VISIT	1	2	3	4	5		7	8	9	10	11	12	13	ET	RT
	WEEK	-2	-1	0	1	4		6	8	12	16	20	24	36		
Informed consent		X														
Patient number assigned		X														
Herlands 14		X														
MMSE 10-71		X														
Physical examination		X												X	X	
Medical history		X														
Habits		X														
Chest x-ray		X														
Age 1 genotyping					X											
Patient randomized				X												
Vital signs/Temperature		X	X	X	X	X		X	X	X	X	X	X	X	X	X
Ambulatory ECG placed			X													
Ambulatory ECG removed				X												
ECG		X			X	X		X	X	X	X	X	X	X		
Placebo TTS test		X														
CT Scan (if not within last year and patient passes all other screens)		X														
Concomitant Medications		X			X	X	X		X	X	X	X	X	X	X	X
Laboratory (Limited)		A			A	A		A	A	X	X	X	X	X		
Laboratory (Urinalysis)		X				X				X			X		X	
Plasma Specimen (Neurochem)					X	X	X		X		X				X	
Hemoglobin A_{1C}		X[b]														
Study drug record Medications dispensed Medications returned					X	X	X		X	X	X	X	X	X	X	
TTS Acceptability Survey														X	X	
ADAS-Cog		P			X				X		X		X		X	X
CIBIC+		P			X				X		X		X		X	X
DAD		P			X				X		X		X		X	X
NPI-X		P			X	X	X		X	X[b]	X[b]	X[b]	X	X	X	X
Adverse events		X	X	X	X	X			X	X	X	X	X	X	X	X

Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease

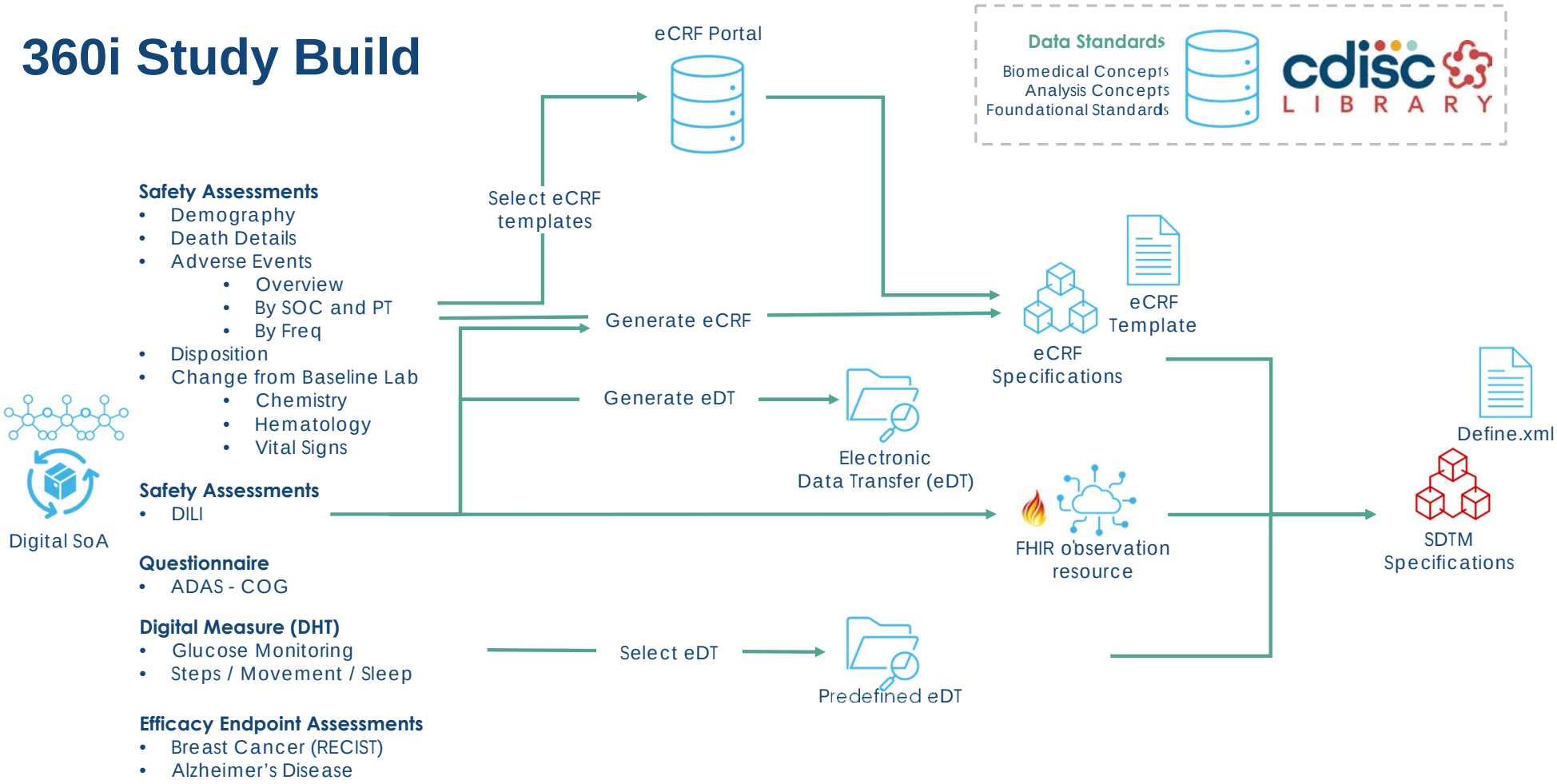
1. Introduction

The M_1 muscarinic-cholinergic receptor is 1 of 5 characterized muscarinic-cholinergic receptor subtypes (Fisher and Barak 1994). M_1 receptors in the cerebral cortex and hippocampus are, for the most part, preserved in Alzheimer's disease (AD), while the presynaptic neurons projecting to these receptors from the nucleus basalis of Meynert degenerate (Bierer et al. 1995). The presynaptic loss of cholinergic neurons has been correlated to the antimortum cognitive impairment in AD patients, prompting speculation that replacement therapy with cholinomimetics will alleviate the cognitive dysfunction of the disorder (Fisher and Barak 1994).

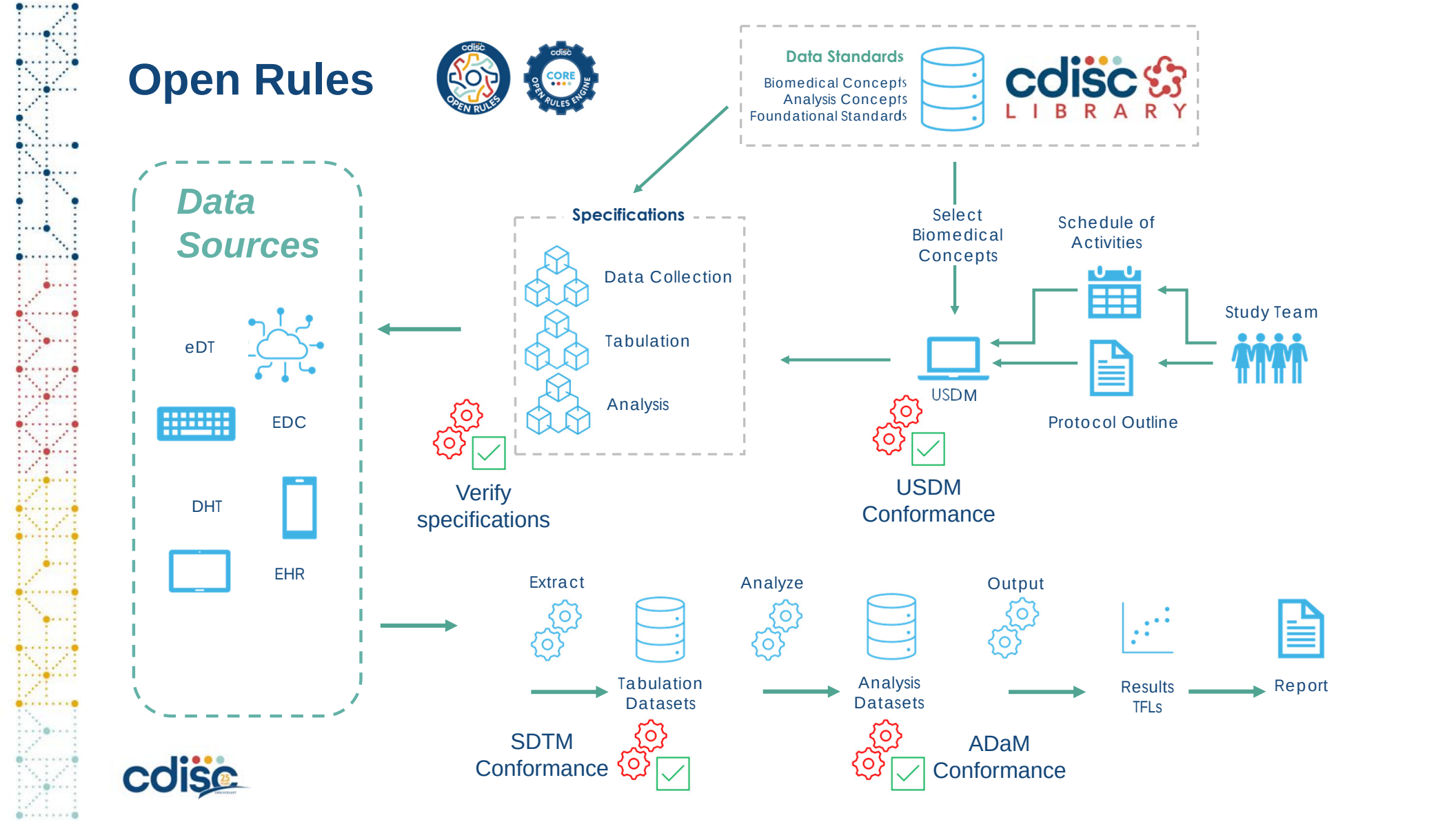
Xanomeline is a novel M_1 agonist which has shown high affinity for the M_1 receptor subtype (in transfected cells), and substantially less or no affinity for other muscarinic subtypes. Positron emission tomography (PET) studies of ^{11}C-labeled xanomeline in cynomolgus monkeys have suggested that the compound crosses the blood-brain barrier and preferentially binds the striatum and neocortex.

Clinical development of an oral formulation of xanomeline for the indication of mild and moderate AD was initiated approximately 4 years ago. A large-scale study of safety and

360i Study Build

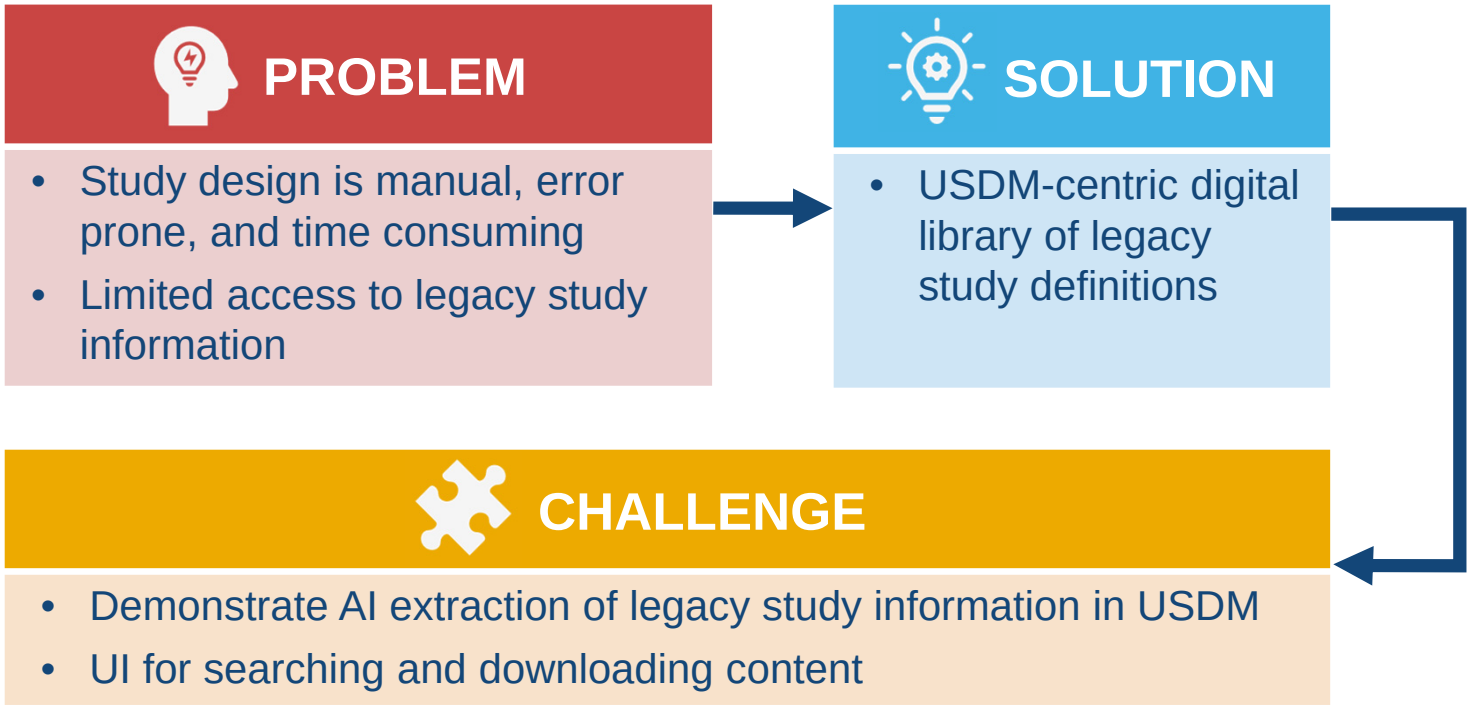


Open Rules

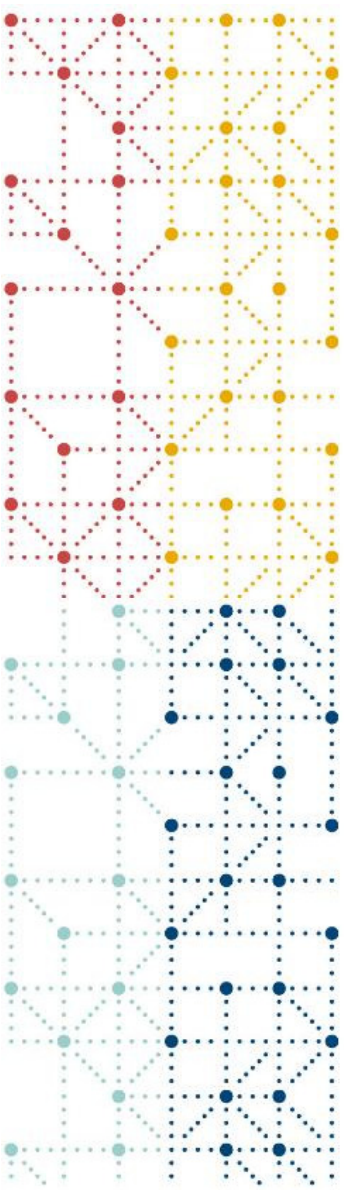

Data Standards
Biomedical Concepts
Analysis Concepts
Foundational Standards
cdisc LIBRARY
Data Sources
eDT
EDC
DHT
EHR
Specifications
Data Collection
Tabulation
Analysis
Select Biomedical Concepts
Schedule of Activities
Study Team
USDM
Protocol Outline
Verify specifications
USDM Conformance
Extract
Tabulation Datasets
SDTM Conformance
Analyze
Analysis Datasets
ADaM Conformance
Output
Results TFLs
Report

CDISC AI Innovation Challenge: Protocol Library

Build a USDM-Centric Repository of Study Definitions from Existing Protocols



NOTE: 30 companies/individuals have submitted intent to participate in this use case.



USDM: Education and Learning Pathways

CDISC USDM Onboarding Package Program (Private Training)

Formal USDM Training

+

USDM Implementation Evaluation

+

Expert USDM Recommendations

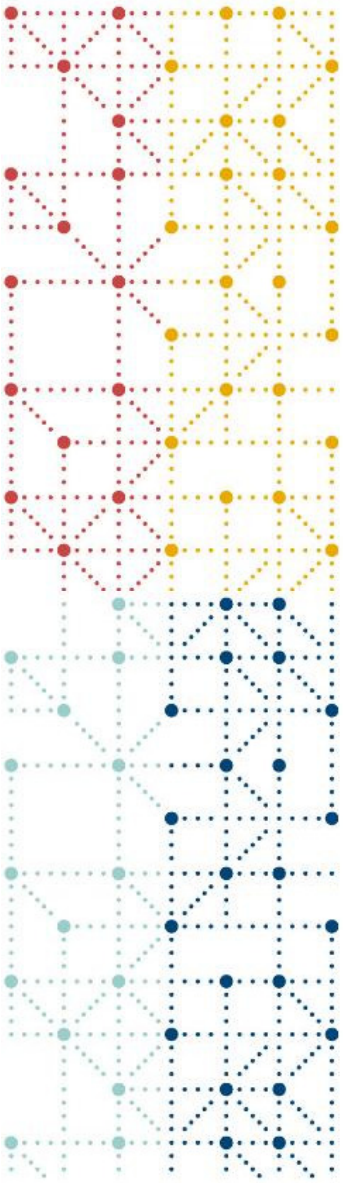
1. Train your employees in the USDM standard.

2. Evaluate your company's implementation needs.

3. Leverage use cases and corresponding requirements sessions tailored to your company's specific needs.

4. Optional additional consultancy from tech experts to guide you through the implementation process.

Public Training	Date	Location	Time
Understanding USDM In-Person Training	16 October 2025	CDISC US Interchange Nashville, TN	9am-6pm US Central Time
Understanding USDM Virtual Training	27-29 January 2026	Virtual	9am-12pm US Eastern Time



Thank You!

cdisc

Catalyzing Connections to Amplify Impact

Wafaa Jabert

Merck KGaA

Head of Clinical Data Standards and Integration

Mary Lynn Mercado

Novartis

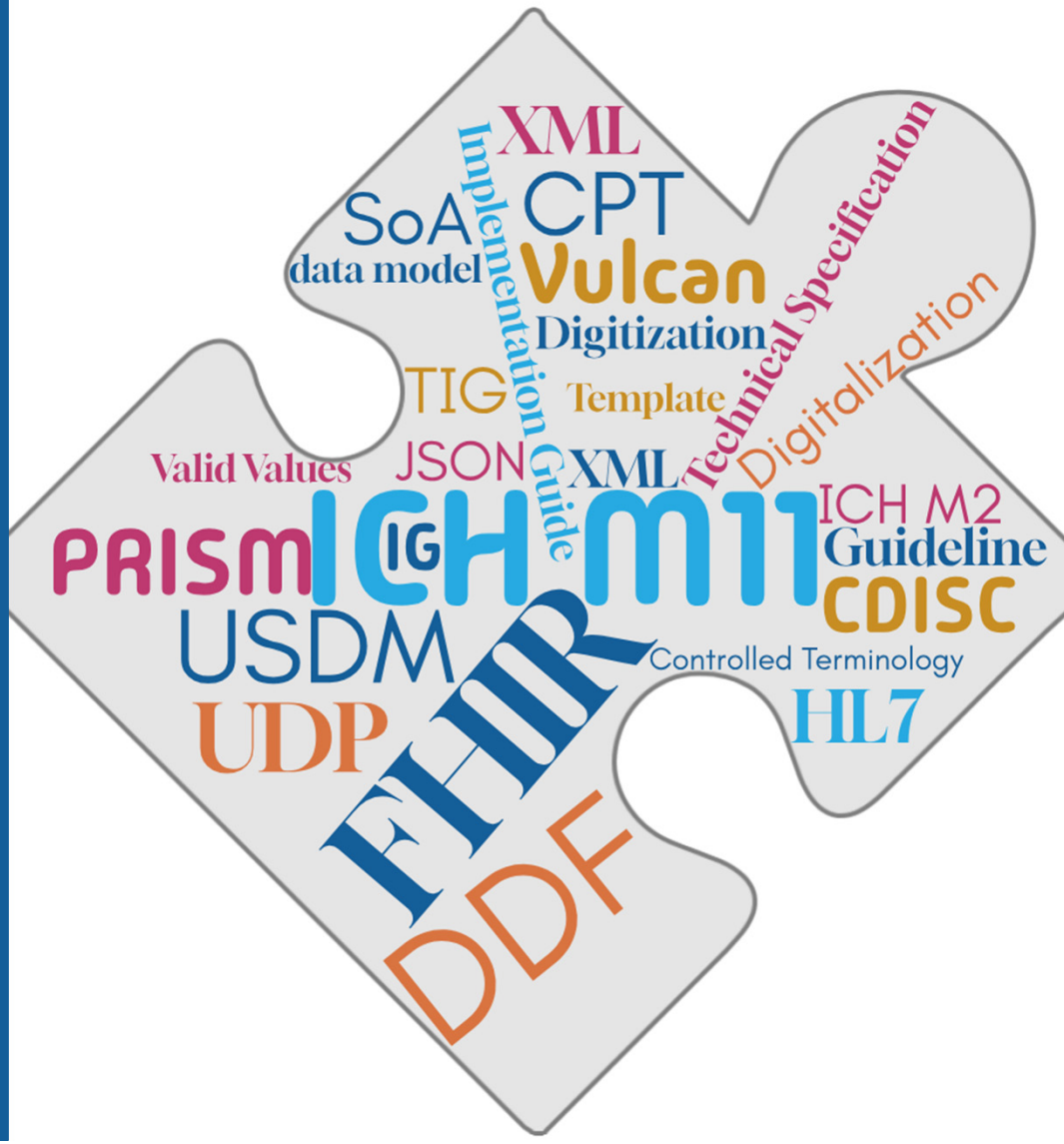
TransCelerate Digital Protocol Engagement Lead

Global Head Protocol Delivery & US Site Head, Regulatory Writing & Submissions

Fostering Connections to enable integration and automated across clinical research and clinical care

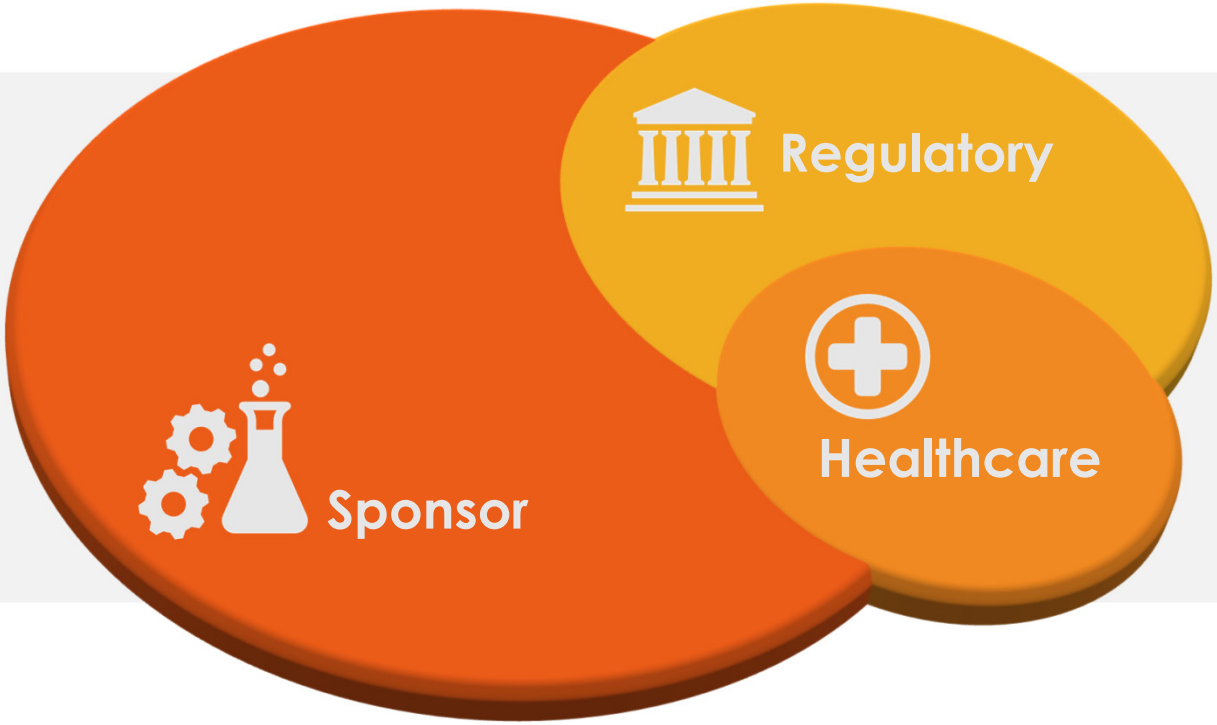
Aim 1: Expand collaboration across protocol-related initiatives and **pursue compatibility** of solutions to **accelerate implementation** and **amplify value** of digital protocols.

Aim 2: Articulate the connectivity among ICH M11, DDF, and other protocol initiatives to accelerate **implementation-readiness** especially regarding regulatory and health IT use cases.



Digital Protocols Across Domains

Significant opportunity in the overlap



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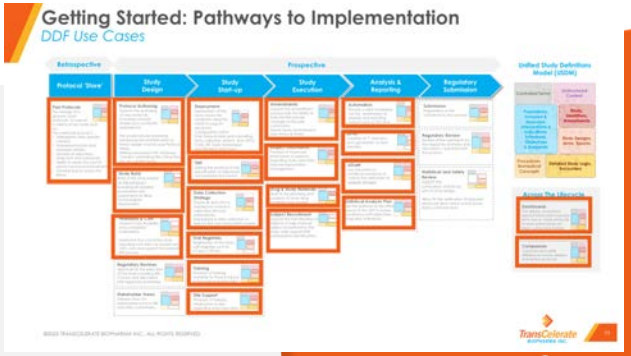
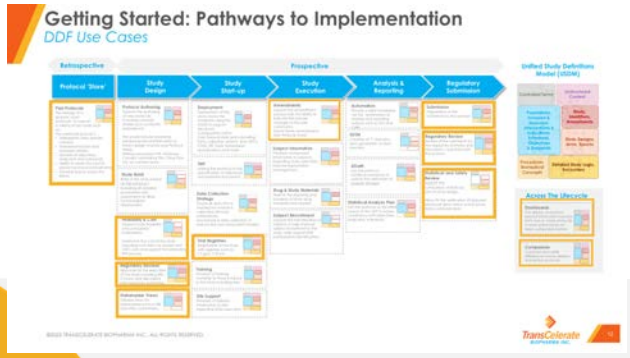
Use Cases and Building Blocks

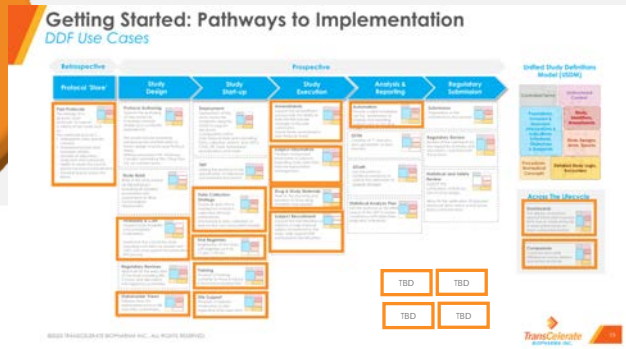
Diverse drivers and perspectives



- CPT
- ICH M11
- USDM



- ICH M11
- USDM
- FHIR



- FHIR

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Collaboration, Compatibility, and Convergence Will Put Patients at the Center

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Catalyzing Connections

Catalyzing Connections

ICH M11 and CPT

Content Alignment and Requirements for Digitization

Global, harmonized clinical trial protocol with requirements for digital trial design elements	**Aim**	Common structure and model language, demonstrates possibilities for content reuse and digitization
Regulator	**Audience**	Investigator
Protocol outline with supporting instruction & minimal sample text, Guideline technical specifications defining requirements for protocol digitization	**Outputs**	M11 heading structure More granular detail & content compared with ICH M11: "Common" (model) text, Example text, detailed instructional text, libraries of additional content eCPT
Addresses global requirements regulators can add regional requirements	**Regions**	Addresses global requirements & regional content requirements

ICH M11 is a harmonized protocol template structure that addresses common global requirements

CPT is an implementable, customizable template

COMING SOON: CPT aligned to Draft M11

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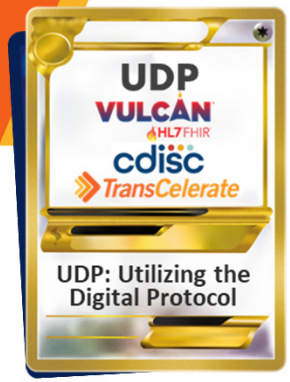
Catalyzing Connections



Utilizing the Digital Protocol (UDP)

HL7 Vulcan FHIR Accelerator

Aim	UDP is an umbrella project to accelerate exchange of ICH M11 aligned protocols through collaboration and integration of work products HL7, CDISC and TransCelerate - Content organized according to ICH M11 - Structured elements adhering to USDM - Exchange in HL7 FHIR
Audience	Technology developers, Sponsors, Regulators, etc.
Approach	Connect and build compatibility with existing related standards and assets. Operates under Vulcan, a FHIR Accelerator in the HL7 community
Outputs	FHIR Implementation Guides, with clear connections to other resources. **Use Case #1:** Sponsor to Regulator Exchange of ICH M11 (for ICH Technical Implementation Guide)

TransCelerate through UDP will ensure M11- aligned protocols in USDM can be exchanged in FHIR

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Bringing it all together: Evolution of Protocol Initiatives

Model structure/content

Common approach for dividing protocol content into structured elements

Common detailed data model that addresses granularity, relationships, etc.

Exchange mechanism that integrates with the information & systems used by various stakeholders

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Catalyzing Connections

ICH M11 Development Testing

Windows into Implementation Readiness

✓ ***COMPLETED***

PRISM Phase 2

- Testing in PrecisionFDA
- tested submission of structured and unstructured ICH M11 protocols

– ***IN PROGRESS***

PRISM Phase 3 ICH M11 testing

- latest M11 draft
- Draft ICH M11 Technical Implementation Guide (Vulcan UDP FHIR for M11)

• ***RECURRING***

UDP Track at HL7 Connectathons

- Held 3 times/year: Jan virtual, May and September in person
- Contribute to development testing
- Optional:
  - Bring Your Own Protocol
  - Bring Your Own Software

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FT1

ICH M11 Development Testing

Windows into Implementation Readiness

COMING SOON

Testing opportunity for TransCelerate Member Companies in Q4

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Slide 58

FT1 Is it just for transCelerate member companies?
Fahmy, Tina, 2025-11-06T17:22:43.379

VD1 0 Testing opportunity is available only for TCB member companies.
Van Dinh, 2025-11-07T17:51:33.255

Catalyzing Connections

ICH M11

Common Protocol Template

Unified Study Definition Model

Digital Data Flow, Protocol Digitization

Clinical Data Standards & Terminology

HL7 FHIR Accelerator Connect Research& Care

UDP: Utilizing the Digital Protocol

Fast Healthcare Interoperability Resources

PRISM

TransCelerate BIOPHARMA INC.

Adoption Stories

Adoption Stories

Noeleen Turner

UCB

Adoption Stories Moderator

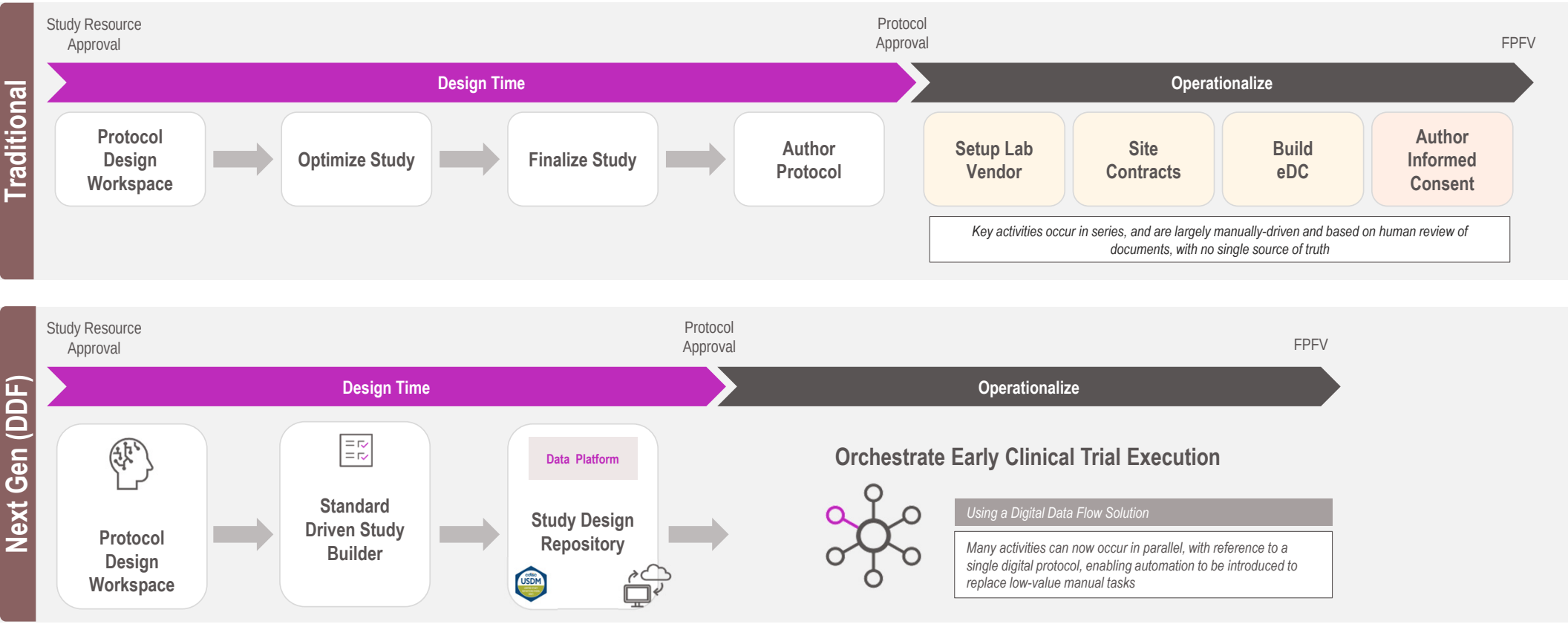
Head of Clinical Data Management

Adoption Story from a Biopharmaceutical Organization

Case Study:
Digital Data Flow Journey

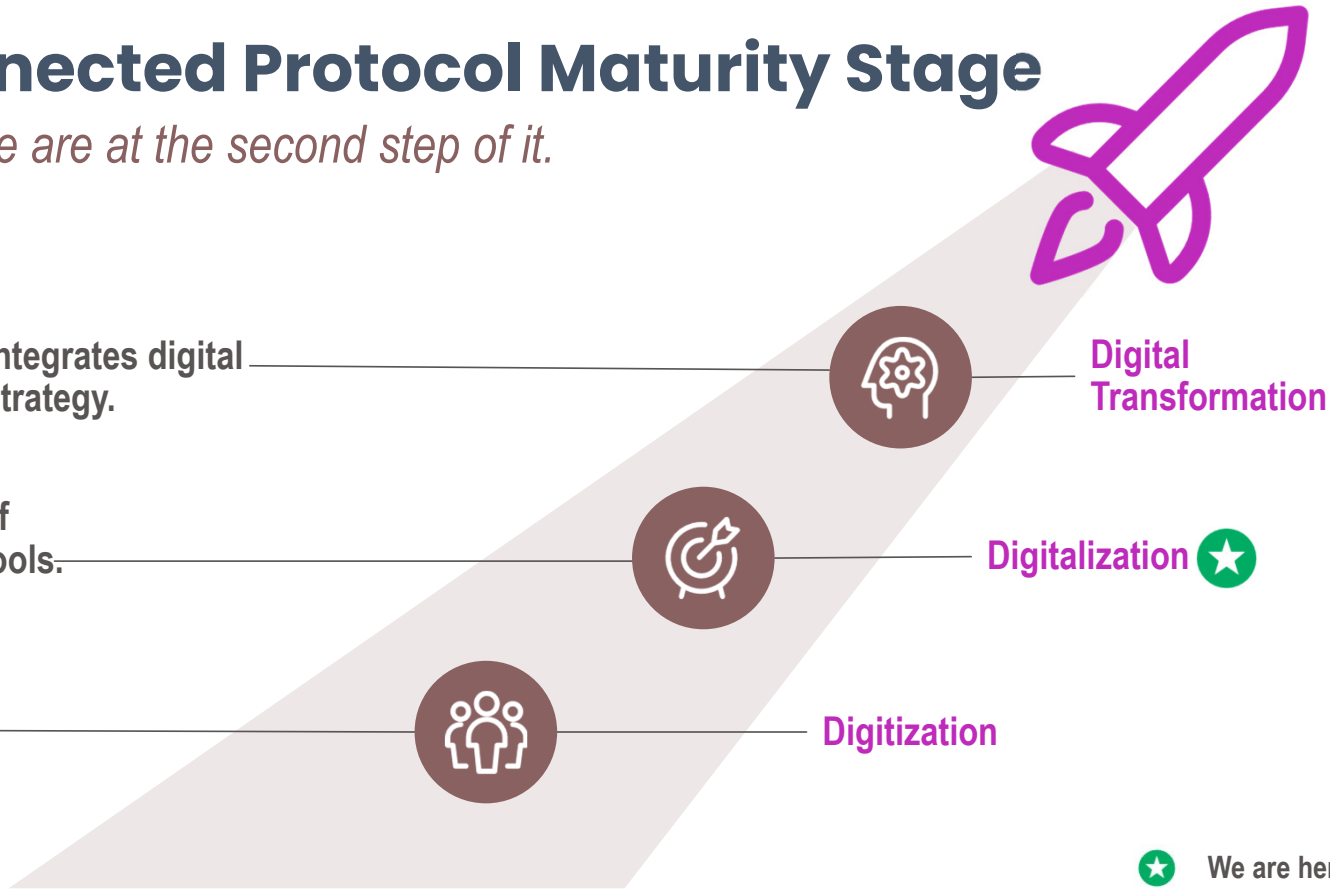
Clinical Development

Leveraging Digital Data Flow to accelerate Clinical Development through a common data model on a technology platform



Our Digitally-Connected Protocol Maturity Stage

Three broader maturity level. We are at the second step of it.



Achieve a holistic transformation that integrates digital protocols into the core organizational strategy.

Digital Transformation

Enhance efficiency and effectiveness of protocol development through digital tools.

Digitalization

Establish a digital foundation by converting paper-based protocols into digital documents

Digitization

We are here

Success So far …

Digital Data Flow has evolved, and is starting to enable automation clinical operations, helping kickstart clinical activities ahead of time

Early Insights

Deliver actionable insights ~2 months earlier in the trial lifecycle**

Specimen Generation Plan

3 to 4 weeks faster study set-up through digitized SOA & Specimen Plan automation

Lab Contracts Generation

Contract negotiation initiated earlier in trial lifecycle

External Data Contracts

~17k hours annually saved by streamlining activities in transfer agreement generation, data review and approvals E2E

Site Contracts Negotiation

Contract negotiation initiated earlier in trial lifecycle accelerating US site contracting for RCO* by 6 to 8 weeks (~50% reduction)

* RCO – Regional Clinical Operations
** Contingent upon the capabilities adopted

Specimen Management Plan Automation

Automation

- ✓ Specimen Planning is Embedded in the SOA
- ✓ Standards-Driven Plan Generation
- ✓ Specimen Testing and Logistics Requirements feed Setup activities

Impact

Faster, more consistent Plan generation, **optimized by Visit**

Digitized Plan captures detail and variability like never before

Quicker lab readiness through customized digital outputs

Site Budget Negotiation Reports

Automation

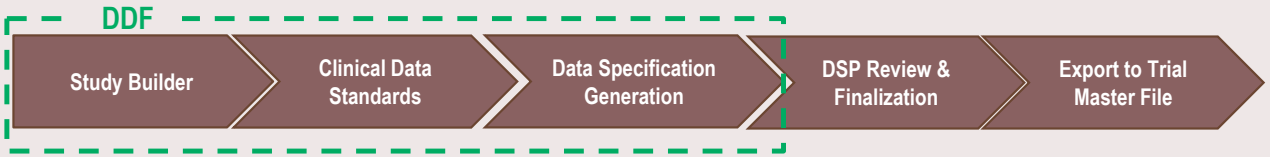
- ✓ All lab-related inputs (test names, frequency, volume) consolidated into one automated, exportable format
- ✓ Accelerates site-ready negotiation packages aligned with protocol and lab plans

Impact

- Accelerates US Site Contracting for RCO
- Accelerates Site Negotiation process
- Improves speed and reduce transcription errors with automated report

External Data Contracts Tracking System

Automation



- ✓ Accelerate DSP creation with digitized study data and clinical data standards, ensuring faster, higher-quality, and consistent data
- ✓ Seamless user experience, allowing easy drafting, finalization, and storage of study Data Specification Packages (DSP) for External Data Acquisition team access

Impact

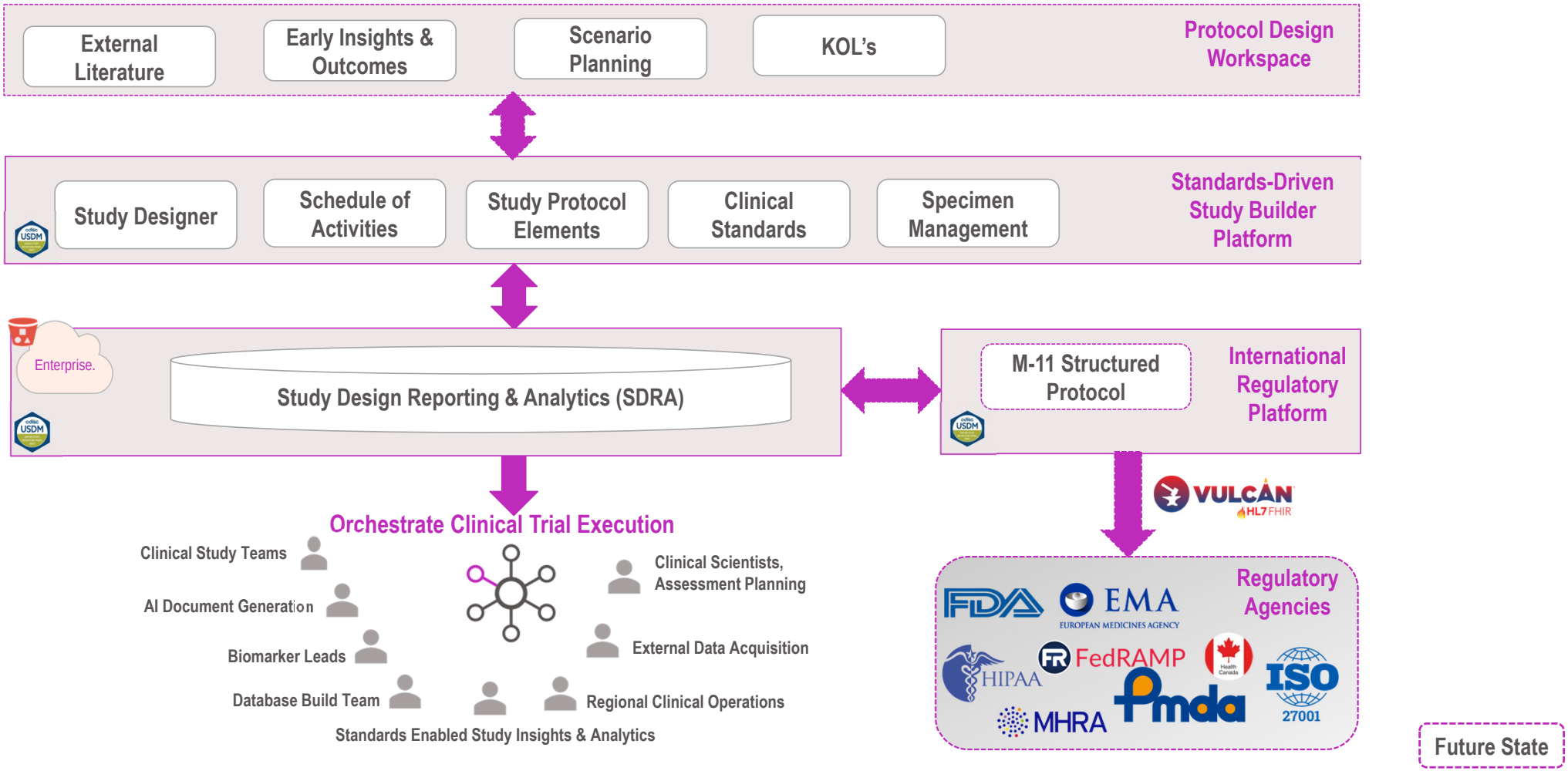
The External Data Acquisition Portal will provide team with ~1000 pre-filled **Data Specification Package(DSP)** annually, resulting in cost savings and efficient vendor engagements

Reduced Manual Work

Higher Consistency Across Data Specification Package

Automated Data Specification Package Creation

Conceptual Overview



Future State

Standards Driven Study Design

Automation

- ✓ Standard design elements such as phase TA, indication, population, and cohort reduces variability and ambiguity in data interpretation
- ✓ Standard Schedule of Activity elements such as visit, epoch, activity, procedure, and biomedical concepts drives downstream automation
- ✓ Data collection elements such as crf name, variable name, and code lists reduces variability and ambiguity

Impact

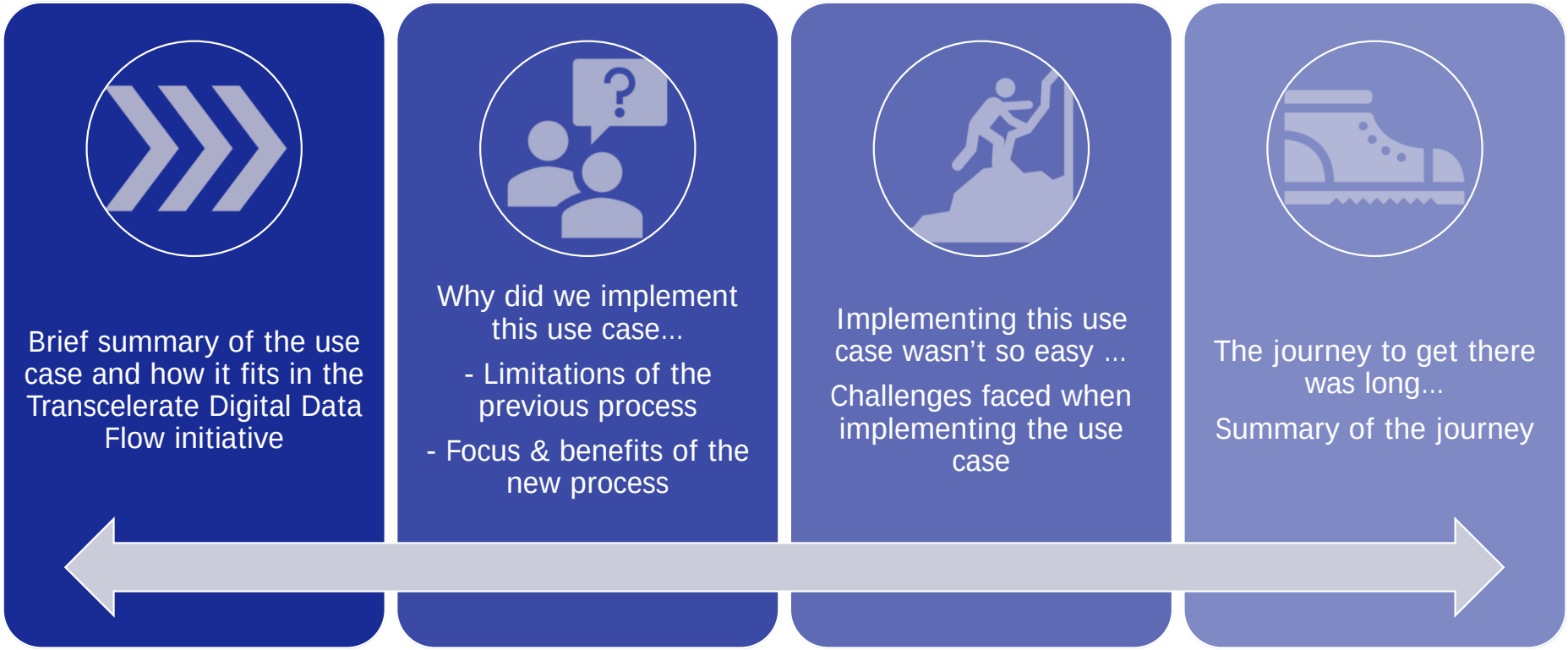
- Improved Data Quality and Consistency ensuring uniformity across sites/studies
- Faster Study Start-Up and Execution via enhanced data integration & reuse
- Regulatory Compliance and Readiness by minimizing delays/rejections

Digital Protocol Transformation Challenges

Adoption Story from a Biopharmaceutical Organization

Case Study:
Integrated Data Journey: From Study Concept to Case Report Form

Agenda


Brief summary of the use case and how it fits in the Transcelerate Digital Data Flow initiative
Why did we implement this use case...
- Limitations of the previous process
- Focus & benefits of the new process
Implementing this use case wasn't so easy ...
Challenges faced when implementing the use case
The journey to get there was long...
Summary of the journey

Before starting: a small Quiz | Protocol Inclusion Criteria

How many variations of this inclusion criteria do you think we have across **35** protocols for the same product?

Female patients of childbearing potential must have a negative serum pregnancy test at screening visit.

Before starting: a small Quiz | Protocol Inclusion Criteria

How many variations of this inclusion criteria do you think we have across **35** protocols for the same product?

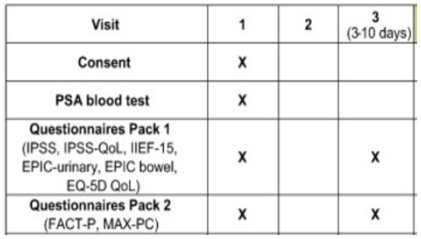
Female patients of childbearing potential must have a negative serum pregnancy test at screening visit.

32

Summary of the use case

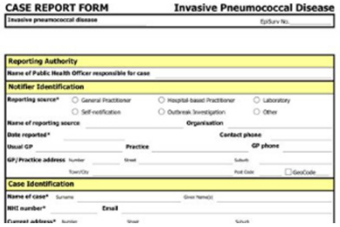
Integrated Data Journey: From Study Concept to CRF

Clinical Document generation using a structured content authoring tool



Visit	1	2	3 (3-10 days)
Consent	X		
PSA blood test	X		
Questionnaires Pack 1 (IPSS, IPSS-QoL, IIEF-15, EPIC-urinary, EPIC bowel, EQ-5D QoL)	X		X
Questionnaires Pack 2 (FACT-P, MAX-PC)	X		X

Creation of machine-readable format schedule of activity



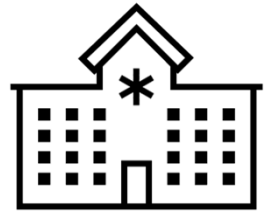
CASE REPORT FORM Invasive Pneumococcal Disease

Reporting Authority

Notifier Identification

Case Identification

Linkage of CRFs to visits and activities



Clinical Data Collection

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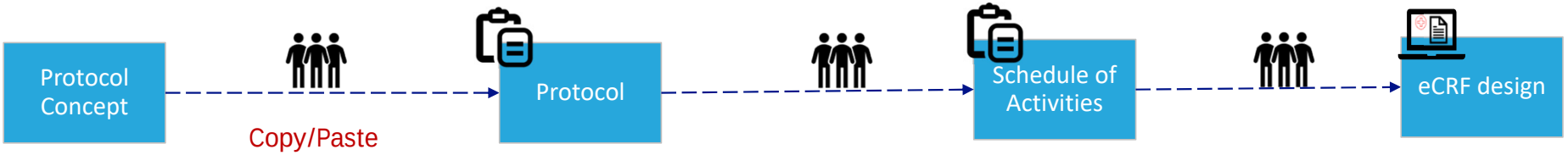
This use case will structure, standardize, and digitize the study protocol content, enabling content reuse across downstream systems and across documents.

Previous Process and its Limitations



Fragmented data flows &
Disconnected tools & workflows
➔ Risk of data discrepancies

Misalignment & inconsistency between protocol content and eCRF

Lack of standardization
&
Difficulty in reusing content across studies

Delays in study design approvals

Integrated Data Journey: use case focus & benefits

Bespoke Structured Content Authoring tool

Study Concept → Protocol → Schedule of Activities

Metadata Repository

Case Report Forms design → SDTM specifications → SDTM Delivery

Case Report Forms design → Data Collection → SDTM Delivery

Schedule of Activities → SAP → TFL Shells → ADAM Specifications → ADAM Dataset Delivery → TFL Delivery → CSR Production

Integrated Data Journey: use case focus & benefits

Bespoke Structured Content Authoring tool

- Supports Scalability & Reusability
- Accelerates Study Start-Up
- Reduces Operational Costs
- Improves Quality & Compliance
- Enhances Cross-Functional Collaboration
- Enables Digital Transformation

Study Concept → Protocol → Schedule of Activities

Standard Libraries being built and grown with each protocol

Metadata Repository

Case Report Forms design → SDTM specifications → SDTM Delivery

Case Report Forms design → Data Collection → SDTM Delivery

SAP → TFL Shells → ADAM Specifications → ADAM Dataset Delivery → TFL Delivery → CSR Production

Integrated Data Journey: use case focus & benefits

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Study Concept → Protocol → Schedule of Activities

Standard Libraries being built and grown with each protocol

Metadata Repository

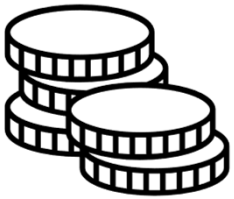
Connection between the structure Content Authoring & metadata repository will allow: Consistency, Fewer Errors & Amendments, Better Traceability & Compliance

Case Report Forms design → SDTM specifications → SDTM Delivery

Case Report Forms design → Data Collection → SDTM Delivery

SAP → TFL Shells → ADAM Specifications → ADAM Dataset Delivery → TFL Delivery → CSR Production

Implementing this use case wasn't easy…
Main challenges



Cost Justification and Return On Investment

Custom tools are expensive, and ROI may be hard to quantify in early stages.

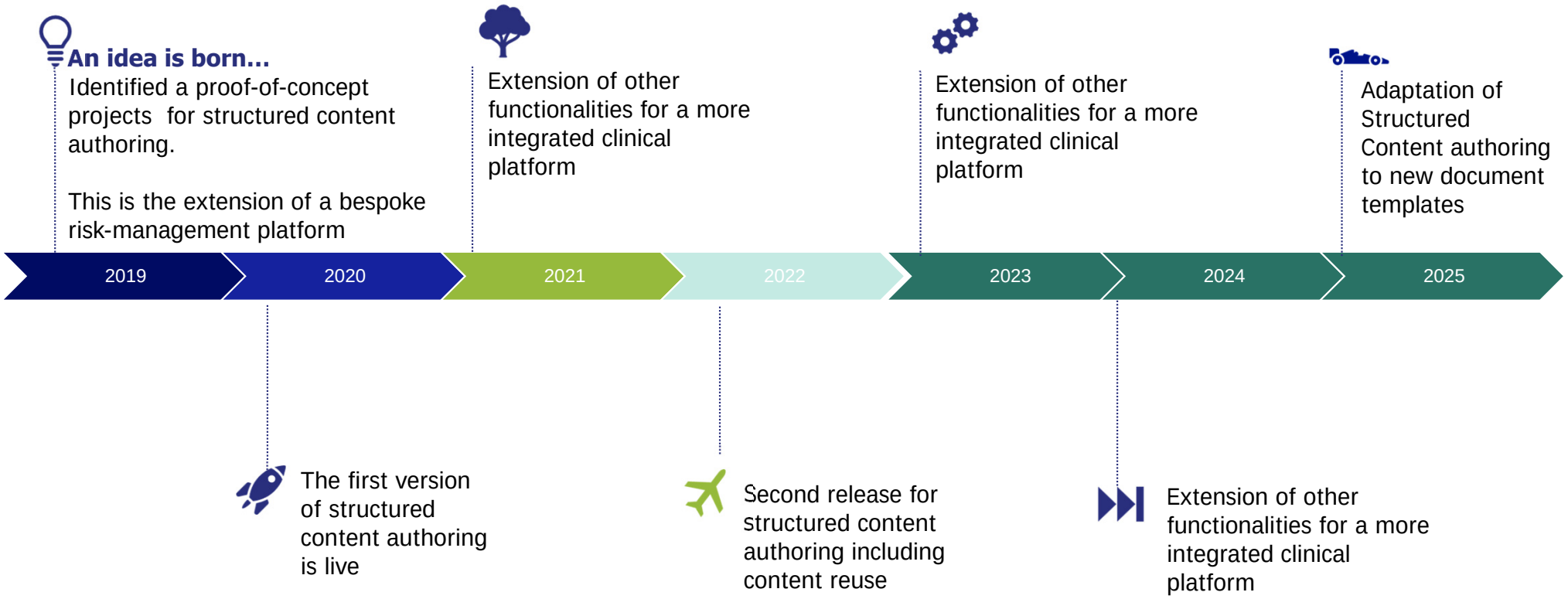
Breaking the silos

A big investment in terms of time & expertise is needed to ensure consistency through the E2E process and digital landscape.

Change Management: Reuse vs. Flexibility

Structured content authoring supports reuse and consistency, but clinical documents often require flexibility. Rigid standards can feel limiting and may not fit all needs. Defining these standards takes time but is key to long-term efficiency.

Summary of the journey



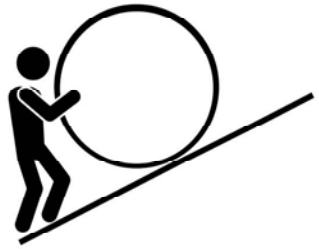
Adoption Story from a Biopharmaceutical Organization

Case Study:
Clinical Content Reuse (CCR) and Document Automation – Key considerations for success

Have we improved clinical trial design and execution?

Process

Consistency



Standardization

Compliance

Industry Challenges

1. Growth in protocol design customizations: 3X the amount of information compared to 10 years ago
    - Approval to FPFV time up by 27%
    - Longer duration of downstream processes eg, EDC build and SDTM creation
    - Phase III trials: 37% increase in total mean endpoints and a 42% increase in total number of procedures from 2016-2021.
2. Increase in the number of PAs = Increase cost burden and drop out rates
    1. Total substantial amendments up by 113%
    2. Average of 4 PAs per study
3. Research sites face increasing burden from protocol complexity
4. Increase in complexity of submission package: how much of the data collected from a clinical trial actually supports the target indication?

Sources:

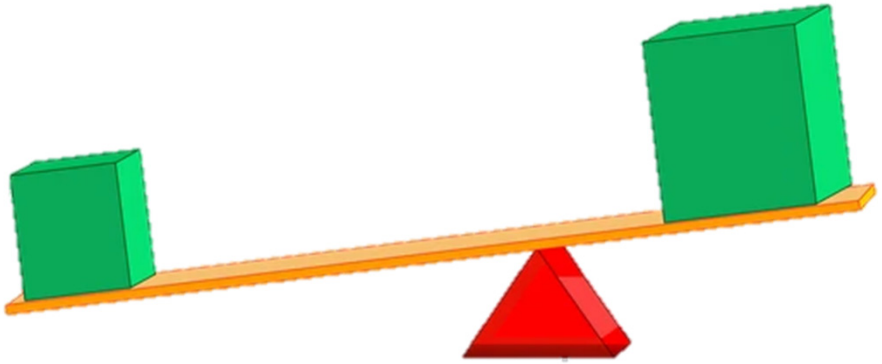
- Getz KA, et al. The Impact of Protocol Amendments on Clinical Trial Performance and Cost. Ther Innov Regul Sci. 2016 Jul;50(4):436-441.
- Getz K, Smith Z, Botto E, Murphy E, Dauchy A. New Benchmarks on Protocol Amendment Practices, Trends and their Impact on Clinical Trial Performance. Ther Innov Regul Sci. 2024 May;58(3):539-548. https://aspe.hhs.gov/reports/examination-clinical-trial-costs-barriers-drug-development-0
- Tufts CSDD Impact Report. Vol 25; 3. May/June 2023
- Quantifying Site Burden to Optimize Protocol Performance https://pubmed.ncbi.nlm.nih.gov/38191957/

Is automation and AI the magical potion that will solve all our industry's problems?

What is the Recipe for Success?

Widely Used/Typical Recipe in the Industry

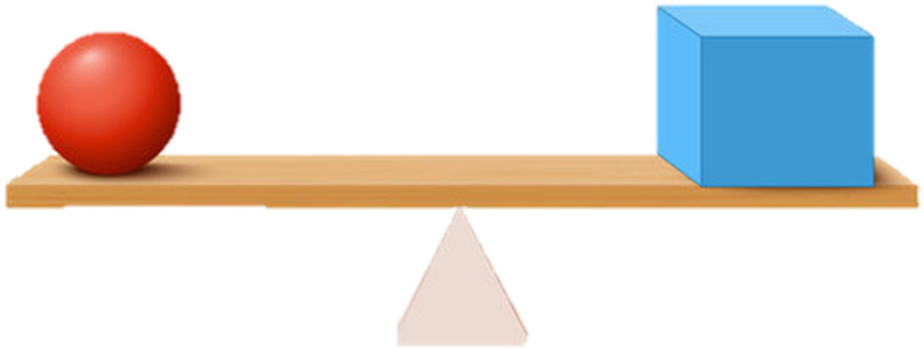
Industry Strategy: AI/ML (discrete, siloed by document type)



Content/data Standardization

Recipe for Success

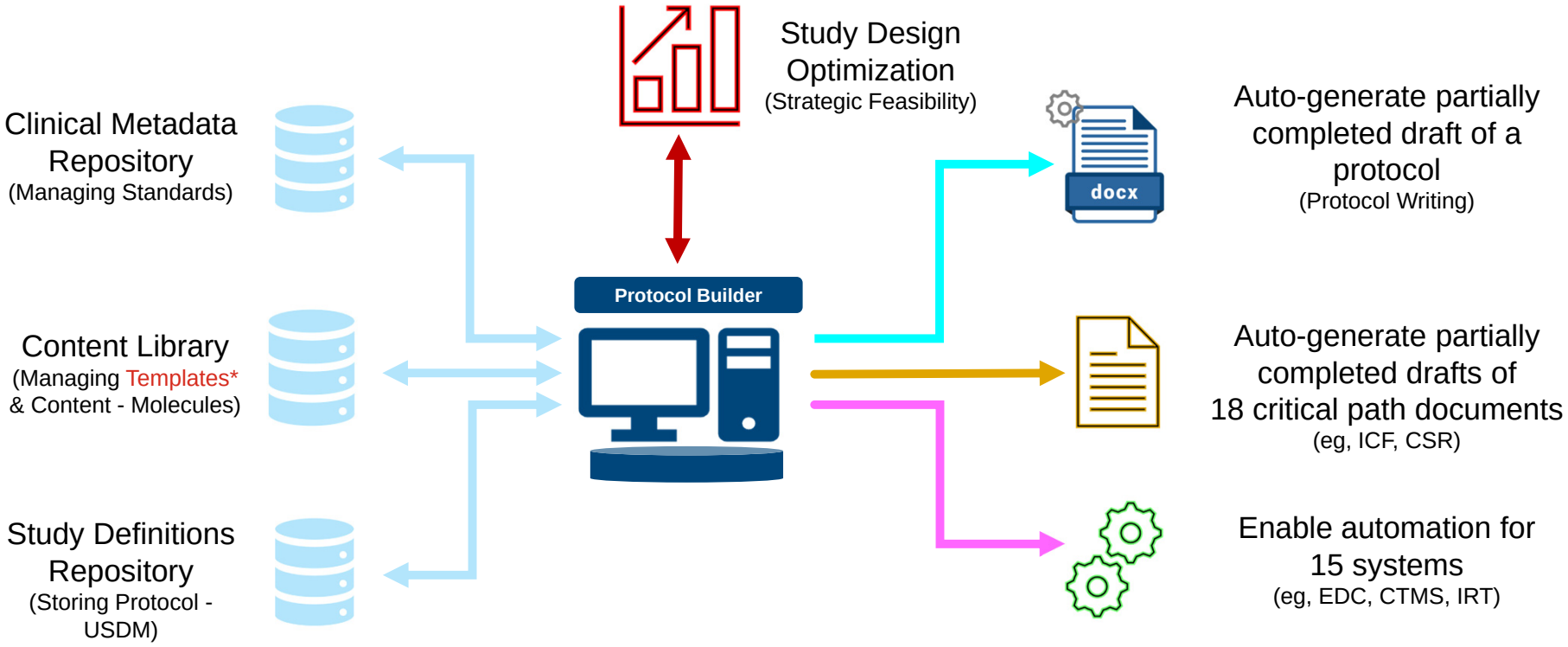
BeOne Strategy: AI/ML (disruptive, CCR connectivity)



Content/data Standardization + Development Data Flow + Building Repository

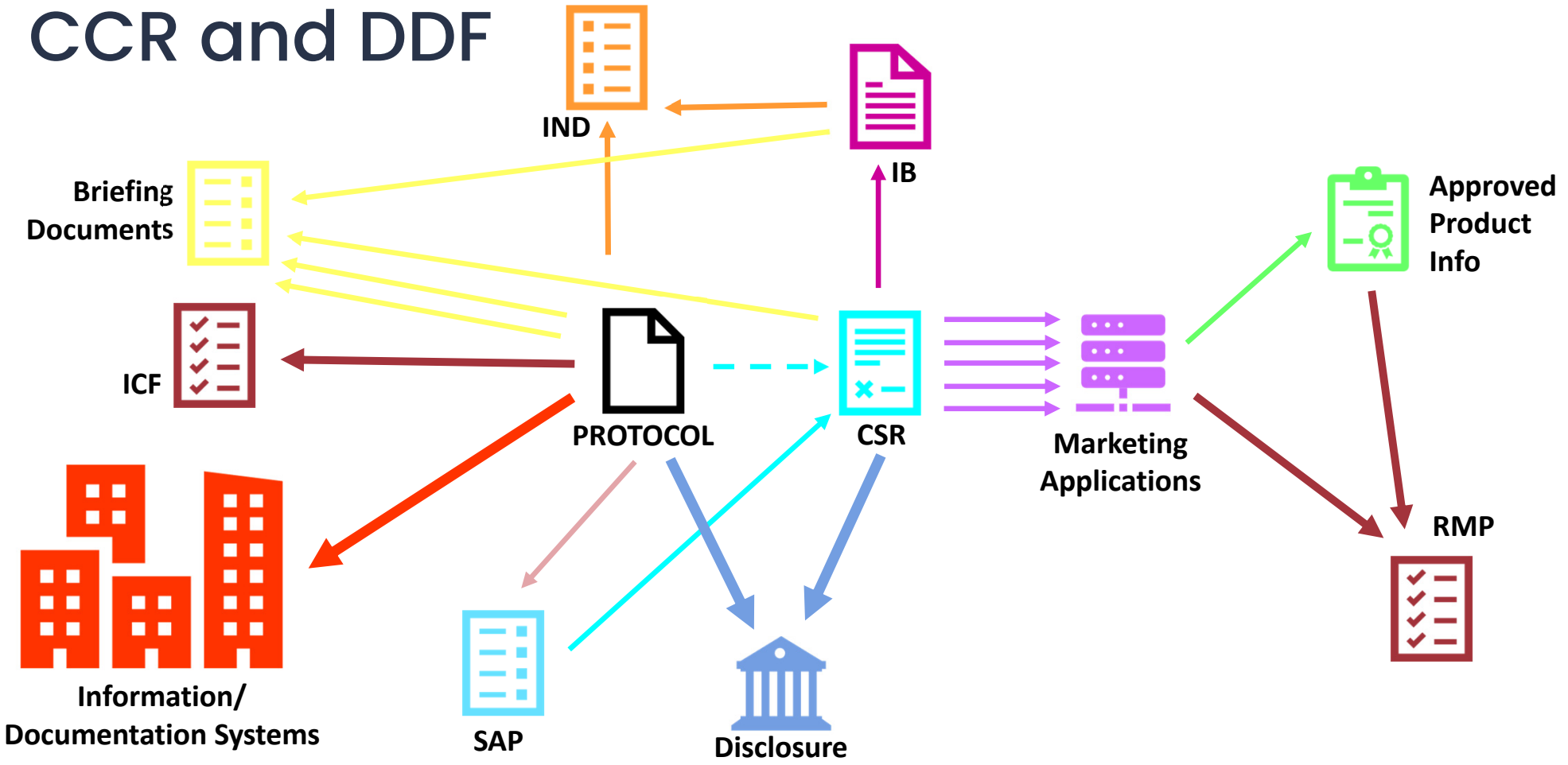
BeOne adoption: Looking ahead to ~18 documents and multiple systems

Protocol Builder Vision



*Template_Protocol based on TransCelerate Common Protocol Template (CPT)

CCR and DDF



Networking effect	Productivity improvement (time & resource)	Better quality (consistency)

Value of Clinical Content Reuse (CCR): Documents and Systems

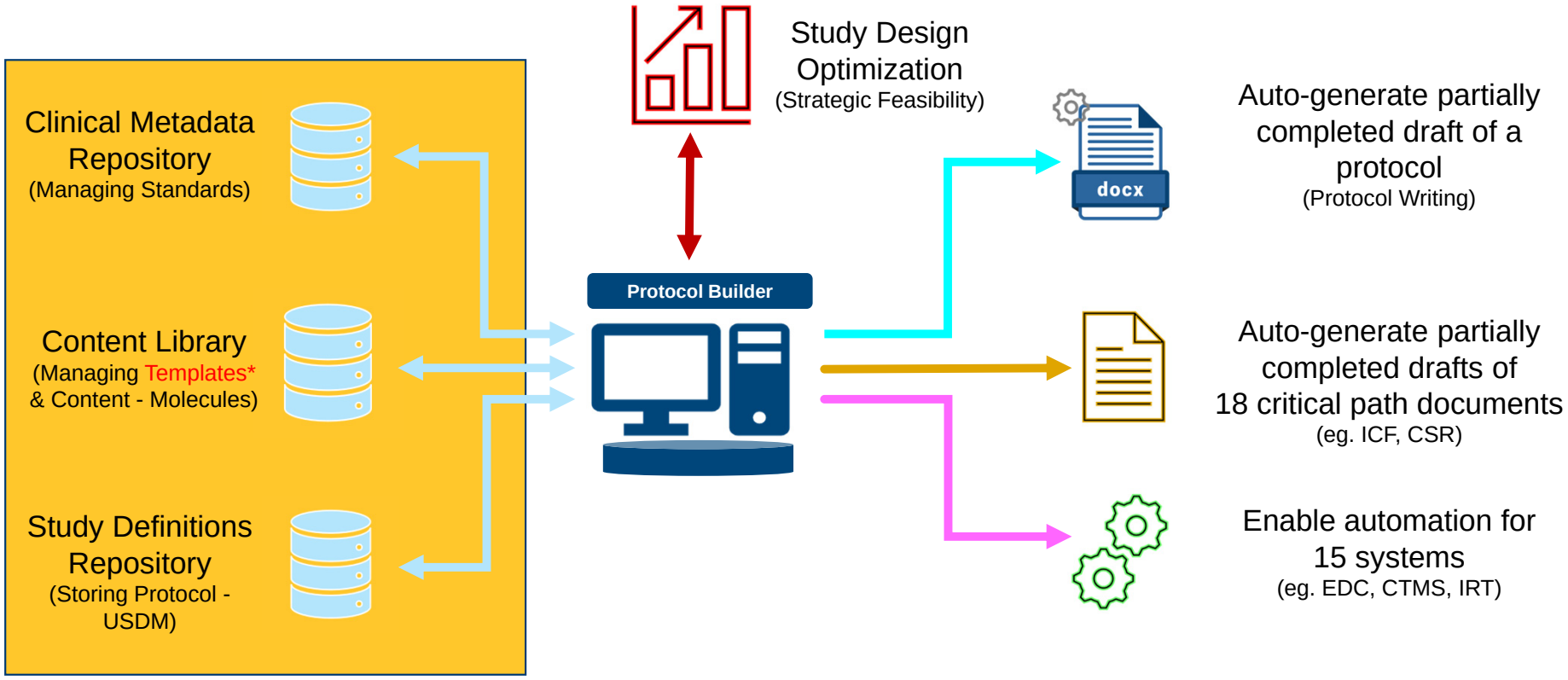
Document Type
IB/IB updated
Original protocol, protocol amendment
CSR (all types)
Module 2 and other documents to support IND, NDA, BLA
ADR, safety reports
Briefing documents
Pediatric documents
RMP

Information/Documentation Systems
Electronic documentation systems
CTMS, IRT
EDC
Safety reporting system
CT.gov, Sponsor → Science → Clinical-Trials
Learning systems
Finance platforms

Understanding the volume and complexity

Exponential Value of CCR = (~18 critical document types) x (~15 key systems) x (No. of Users)

Protocol Builder Vision



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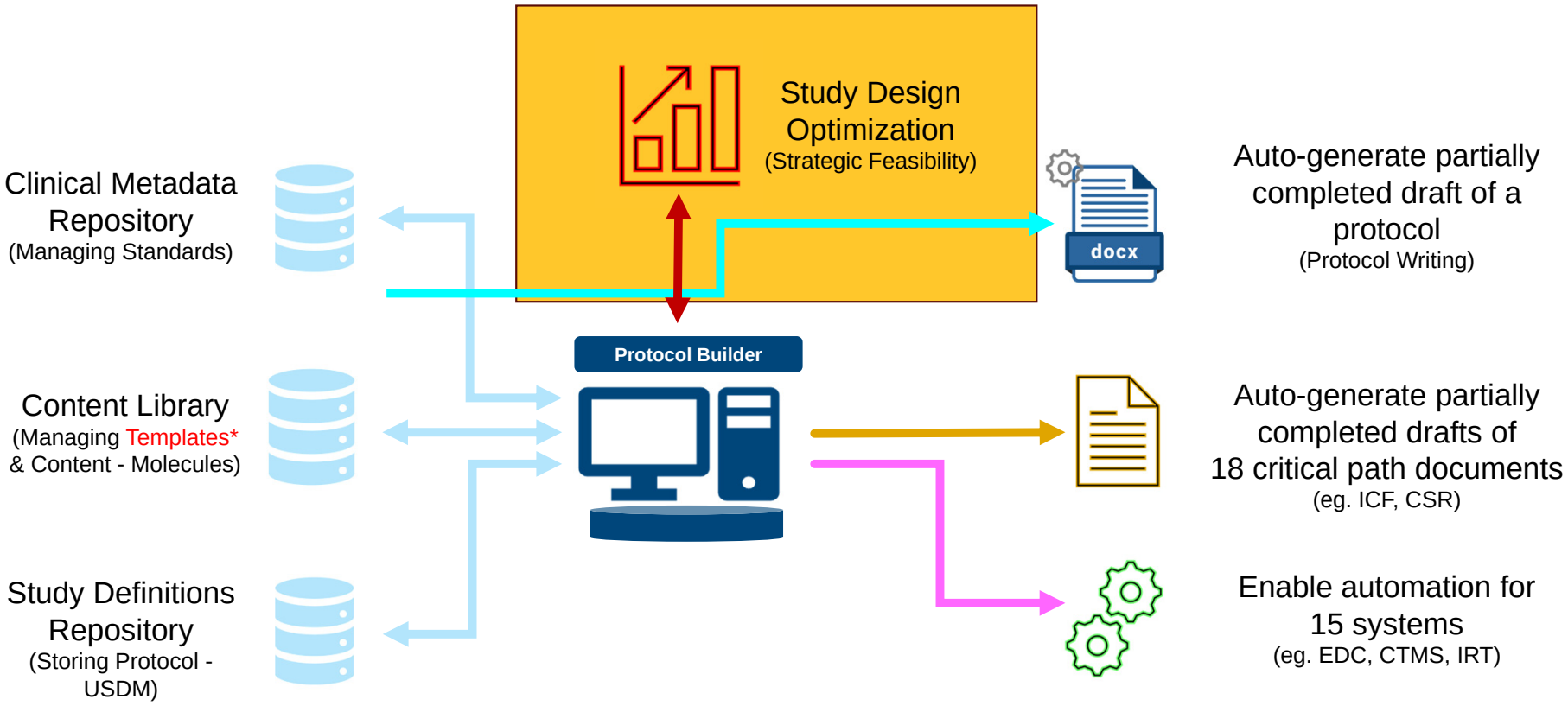

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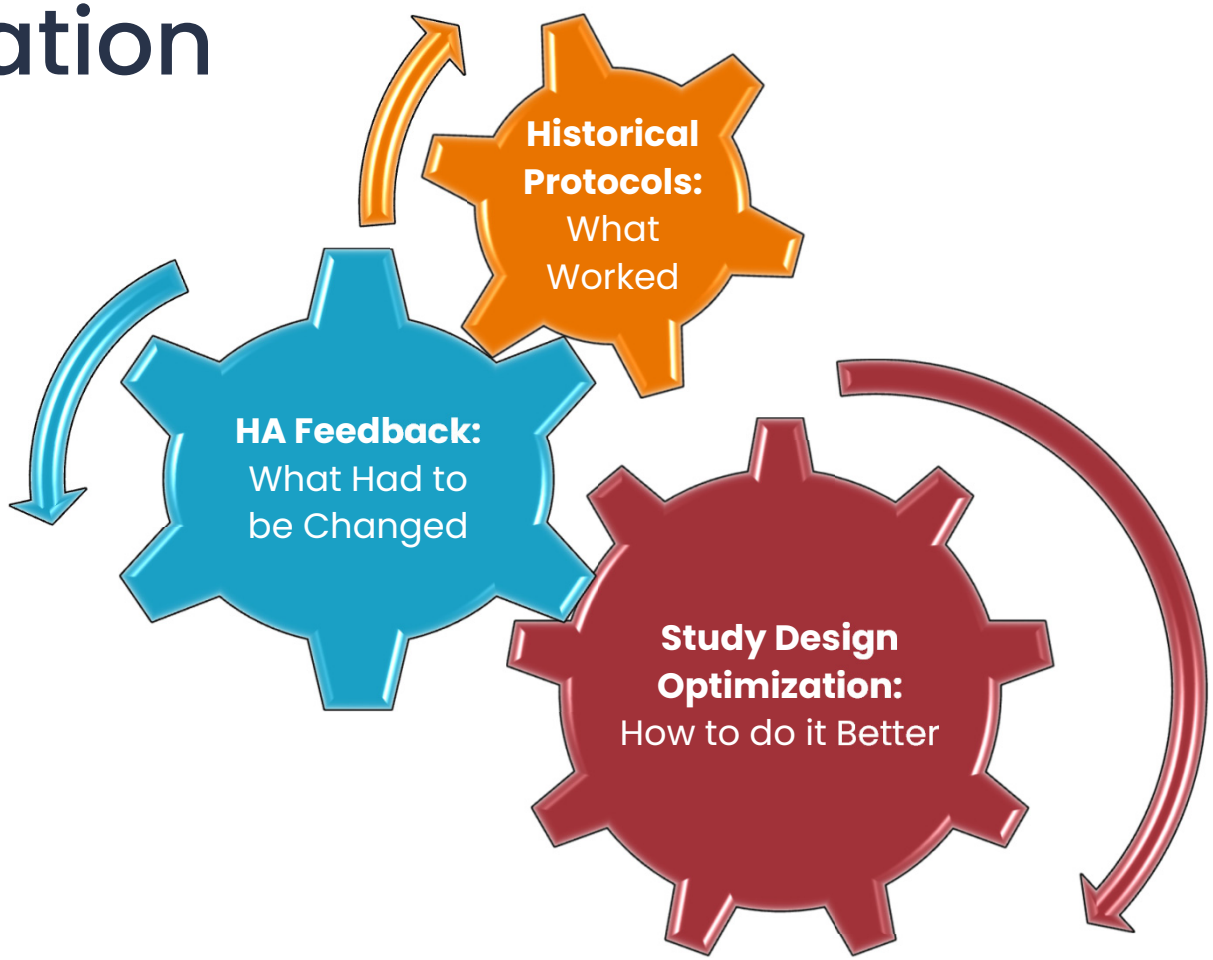
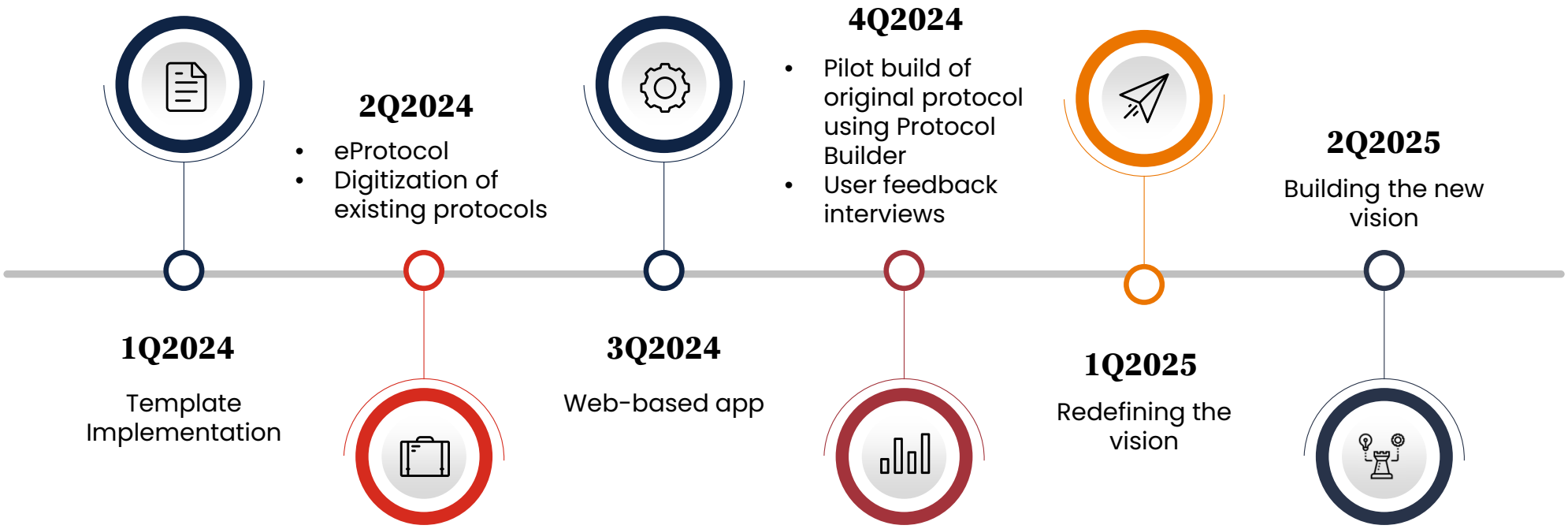
Optimization



Roadmap – Destination 1: Building a Protocol



Modifying the Vision – Looking through the User Lens

Is the platform easy to use?	• Web-based app • MS Word-based environment
How does it facilitate the process?	• What features allow the user to significantly decrease time? • What features are nice to have but not real value added
What is needed for successful change management?	• What does minimum viable product (MVP) mean to the user? • Focus on completion of parts vs. overall benefit picture

Modifying the Vision – Parallel Paths to Achieve More

SoA Builder

Clinical Metadata Content Library Study Definitions
***Repositories**

Per SOP

Draft Protocol

Final Approved Protocol

eProtocol Suite – Microsoft Word Add-in

3 key business needs -- AI assist, manage content library, and template compliance checks

Enable automation for downstream systems
(eg. EDC, CTMS, IRT)

Auto-generate partially completed drafts of critical path documents
(eg. Contracts, ICF, CSR)

Study Startup Activities

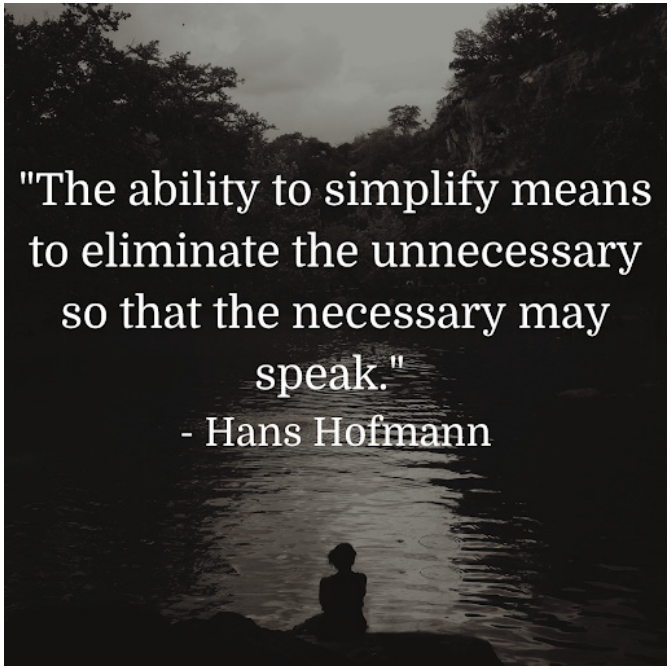
*Repositories – Clinical Metadata Repository managing standards, content library managing templates and content reuse, study definitions storing Protocol Information (TransCelerate/CDISC USDM)

Recipe for Success

- 1 cup AI
- 1 cup Automation
- ¾ cup CCR
- ?
- ?

Strategic Writing

- Strategic Writing is about writing for your Audience
- Write with the reviewer in mind; not just their background but how and why they review
- Documents must be:
  - ✓ Usable: They must be able to easily find what they are looking for
  - ✓ Readable: Electronic reviewing lends itself to skim reading



Source: Cuppan and Bernhardt Writing for the Biopharmaceutical Regulatory Reader https://a.co/fqDdDpp

Strategic Writing

Before

78 patients were included in the Efficacy Analysis set for Primary Analysis. Results of Study [redacted] showed that in patients with [redacted], treatment with [redacted] resulted in high response rate, deep response, and rapid response. In the Efficacy Analysis Set for Primary Analysis excluding 18 patients (N=60) (Table 3):

- The ORR assessed by IRC was high (76.7%), with p value of < 0.0001 to reject the null hypothesis of ORR of 40%.
  - Subgroup analyses showed that benefit in ORR per IRC assessment was generally observed across all predefined subgroups, including subgroups that have traditionally responded poorly to therapy (eg, those with cytogenic abnormalities).
- The complete response rate was 20.0%.
  - Among the patients with CR/CRi as assessed by IRC, 50.0% and 50.0% of patients had best blood and bone marrow MRD negativity ($< 10^{-4}$), respectively.
- Responses occurred rapidly, as evidenced by the medial TTR of 3.70 months.
- DOR, PFS and OS were not mature as of the data cutoff date.
  - The median DOR by IRC was not reached; the event-free rate at 6 months was 87.1%.
  - The median PFS by IRC was not reached; PFS at 6 months was 87.3%.
  - The median OS was not reached; OS at 6 months was 95.0%.
- Efficacy results in the Efficacy Analysis Set for Primary Analysis (N=78) were consistent with those in Efficacy Analysis Set for Primary Analysis excluding 18 patients.
- Efficacy results as assessed by the investigator, including ORR, DOR, TTR, PFS, and OS, were similar to the IRC assessment.

Strategic Writing

- **Make good use of cross-reference to intext tables**
- **Provide key messages**
- **Highlight the important numbers**

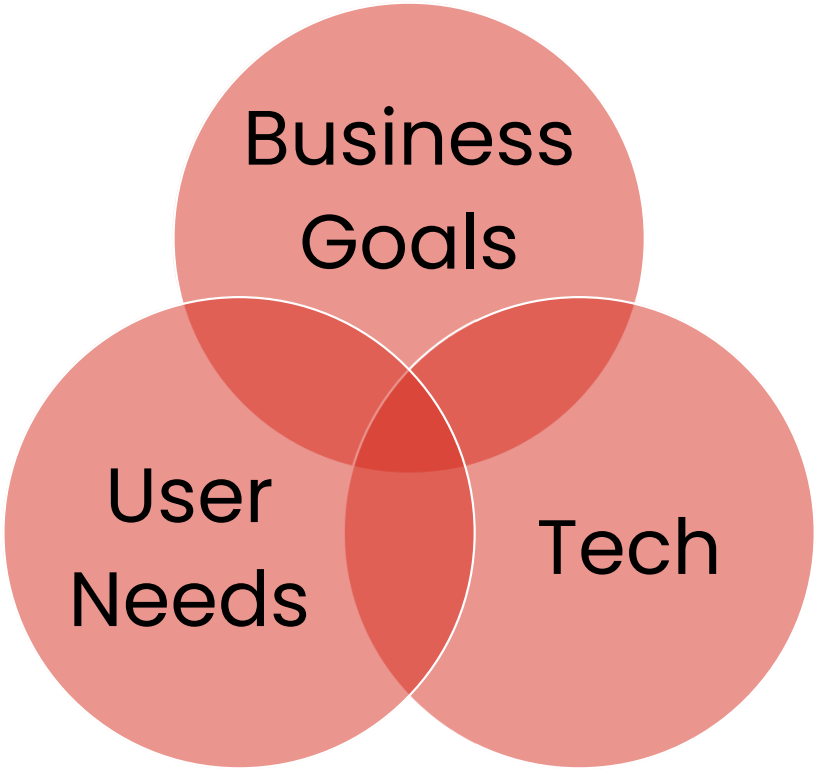
After

Efficacy analyses showed that treatment with [redacted] resulted in high response rates with rapid and deep responses in patients with [redacted] who have failed treatment with [redacted] as evidenced by high ORR, high complete response rate, high best undetectable MRD rate and short time to response in both Efficacy Analysis Set and Efficacy Analysis Set excluding 18 patients (Table 3 and Table 15).

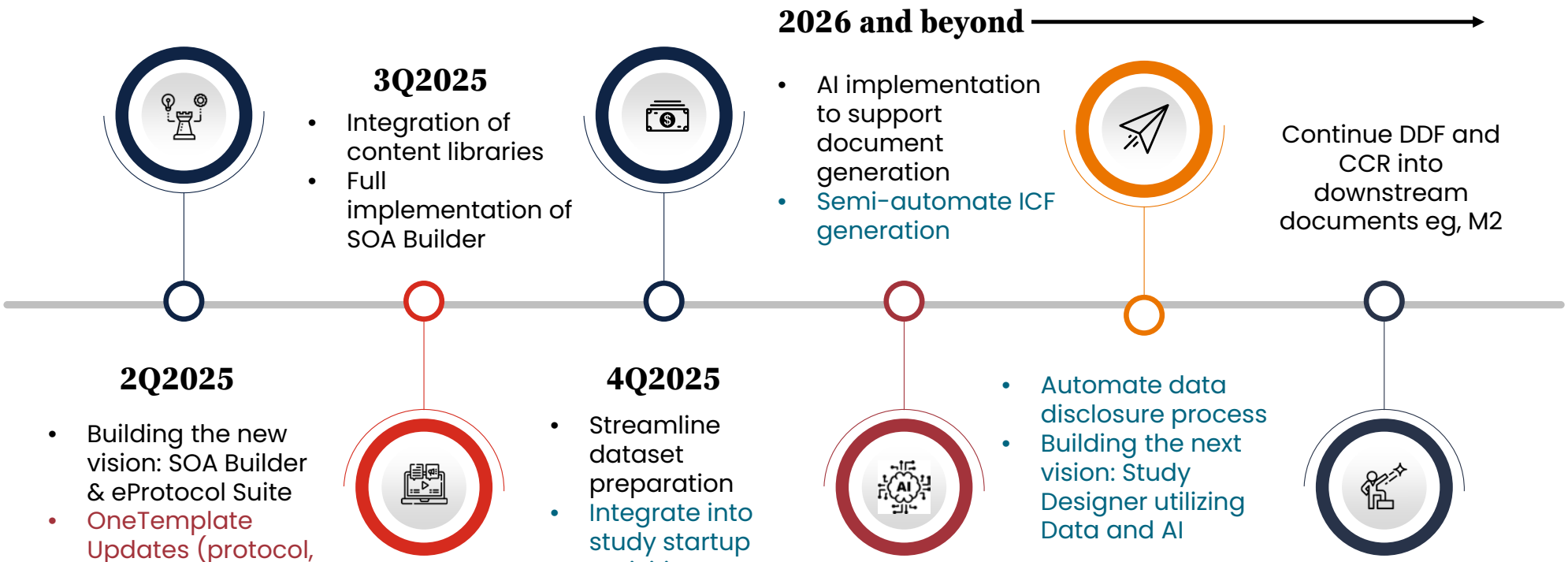
DOR, PFS and OS were not mature as of the data cutoff date, with median DOR, PFS, and OS not being reached. For DOR, event-free rate at 6 months was high (Table 3).

Efficacy results in the Efficacy Analysis Set (N = 100) were consistent with those in Efficacy Analysis Set excluding 18 patients (N = 82).

Technology vs Business Needs



BeOne Roadmap – Parallel Paths to the Pinnacle



People, Process, Technology: Together to the Summit

The People:

- ✓ Clinical Development
- ✓ Clinical Operations
- ✓ Statistics
- ✓ Safety
- ✓ Regulatory
- ✓ Clinical Pharmacology and Biomarkers

The Process:

- ✓ Clear roles and responsibilities
- ✓ Writing and reviewing best practices
- ✓ Standard timelines and steps

The Technology:

- ✓ SoA Builder
- ✓ eProtocol Suite
- ✓ CCR/DDF
- ✓ AI/LLM

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Use Case Overview

Use Case Overview

Chi Vo

Eli Lilly

Data Engineer, Clinical Design & Operations

Don Jennings

Eli Lilly

Senior Director, Digital Trial Foundations and Patient Experience

Digital Study Design Use Case Library

What is it, Why do we need it,
How to use it and Next Steps

Presented by: Don Jennings & Chi Vo

DDF Mission Possible Event
September 24-25, 2025

Please Note

This Presentation and the forthcoming Library are intended to advance further discussion, collaboration and free flow of ideas.

The work presented here details common elements and examples of factors that organizations may encounter when initiating a Digital Study Design/Digital Data Flow transformation. They are not intended to outline the only possibilities for achieving scalable Digital Study Design or to ***do not constitute a recommendation to adopt*** *or approve a particular system or a system with particular elements or features .*

The work presented here describes common elements and examples of factors that organizations may encounter when initiating a Digital Study Design/Digital Data Flow transformation. ***Each organization must decide for itself if different, alternate approaches may work better for its unique circumstances****.*

The decision to consider and to proceed *with a Digital Study Design/Digital Data Flow transformative effort* ***is the sole prerogative and at the complete discretion of individual organizations*** *as informed by their internal strategies, assessments, and approval processes.*

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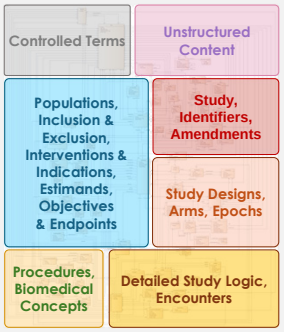
Digital Study Design-USDM Use Case Summary

Unified Study Definitions Model (USDM)



Study Details
The overall study, its various versions, identifiers and associated governance. Also includes the amendments made to the study

Study High Level Design
The single or set of study designs making up the study detailing the epochs, arms etc.

Study Science
The detailed description of the study science: the populations and the associated inclusion and exclusion criteria, the indications being studied, the interventions being used and the objectives, endpoints and the associated estimands.

Detailed Study Logic
A precise definition of the study logic including support for the Schedule of Activities.

Unstructured Content
The ability to support one or more document presentations of the USDM content including the ICH M11 protocol template, sponsor templates and other documents.

Procedures and Biomedical Concepts
The detail around the procedures and observations to be performed as part of the detailed study designs.

Controlled Terms
The controlled terminology needed to define the semantics within the model. Managed in the same manner as all CDISC CT and aligned with the M11 template standard.

Use Cases

Retrospective

Protocol 'Store'

Past Protocols
The storage of past sponsor protocols in to support a variety of use cases such as:

- Therapeutic area specific content
- Standard inclusion and exclusion criteria.
- Libraries of objectives, endpoints and estimands.
- Asses the past to prevent protocol amendments.
- General search across the library

Prospective

Study-Experimental Concept

Analytics
Use information from previous studies to compute & iterate upon study optimization parameters – e.g., patient and site burden scores, resource utilization, enrollment forecasting – making tradeoff decisions to balance technical success with time and resource constraints.

Study Design
Construct the initial set of study design elements – e.g., Estimand, SOA, Inclusion/Exclusion -- and apply the Analytics Use Case output to refine them into a final, optimized set.

Protocol Authoring
Use the study design elements created via The Study Design Use Case to generate an initial Protocol draft document.

Author additional protocol Content – e.g. study design rationale, handling participant discontinuation and adverse events, -- iterating via The Study Design Use Case to update/refine the study design elements, as necessary.

Stakeholder Views
Create tailored views for stakeholders such as IRB and ethics committees.

Study Start-up

Deployment
Deployment of the study across the enterprise using the USDM to support electronic configuration rather than manual data entry including Data collection systems (e.g., EDC, eCOA), CTMS, IRT, Data transmission specifications and more.

Trial Budgets
Create draft budgets for trials based upon the planned study activities.

Trial Registries
Registration of the study with registries such as CT.gov, CTIS etc.

Training
Provision of training materials to those involved in the study including sites

Study Execution

Amendments
Support the amendment process with the ability to indicate the precise changes to the user community.

Ensure fewer amendments (see Protocol Store).

Drug & Study Materials
Assist in the planning and provision of study drug, materials and supplies

Patient Recruitment
Support the identification of subjects to help improve subject recruitment to the study. Help support EHR participation identification.

Site Support
Provision tailored information to sites regarding study execution.

Site Monitoring
Track study subject progression against the SOA and incoming patient data to assess protocol compliance

Analysis & Reporting

SDTM
Creation of 'T' domains. Auto generation of data domains.

ADaM
Use the protocol statistical metadata to assist in the derivation of analysis datasets

Statistical Analysis Plan
Use the protocol as the initial source of the SAP to ensure consistency with objectives, endpoints, estimands

Regulatory Submission

Submission
Preparation of the regulatory submission by the sponsor

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Review of the submission by the regulatory authority and discussions / questions with the sponsor

Statistical and Safety Review
Support the comparison of data by arm or study design.

Allow for the verification of planned (protocol) data versus actual (study data) captured data

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What, Why, How and Next Steps

What is the Digital Study Design Use Case Library?

- A resource that captures current thinking & knowledge on the utility of Digital Study Design Adoption
- Provides a “Rosetta Stone” of definition and taxonomy for sharing concepts between stakeholders

Why do we want a Use Case Library?

- Describe various use cases that industry can deploy to gain value from Digital Study Design
- Give stakeholders an understanding of the potential value created from adoption
- Initiate a proposed framework for considering and capturing the impact of DSD adoption across the broader Healthcare Community – i.e., Providers, Patients, Regulators, Investigators, Sponsors

How to use the Library?

- Up First!

What are the next Steps?

- Up Second!

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How to use the Library
What is a Use Case?

Use cases capture proposed schemas for a Product or *System of Interest* by telling a story about how users interact with it to accomplish something

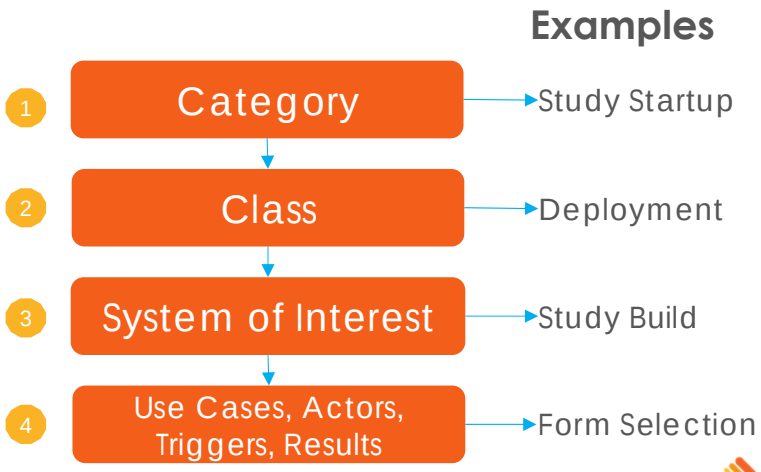
- They describe the expected behavior of the *System of Interest* (the *What*), and not the exact method of making it happen (the *How*).
- They help designers understand the *System of Interest* from the end user's perspective by specifying all externally visible behavior.

The Library organizes use cases into a four-level hierarchy

Each level aggregates – i.e. "contains"-- elements of subsequent levels

Specific use cases are addressed by their full hierarchy name. For Example:

Study Startup: Deployment: Study Build: Form Selection



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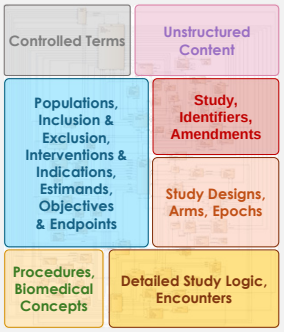
How to Use the Library
Categories

Unified Study Definitions Model (USDM)



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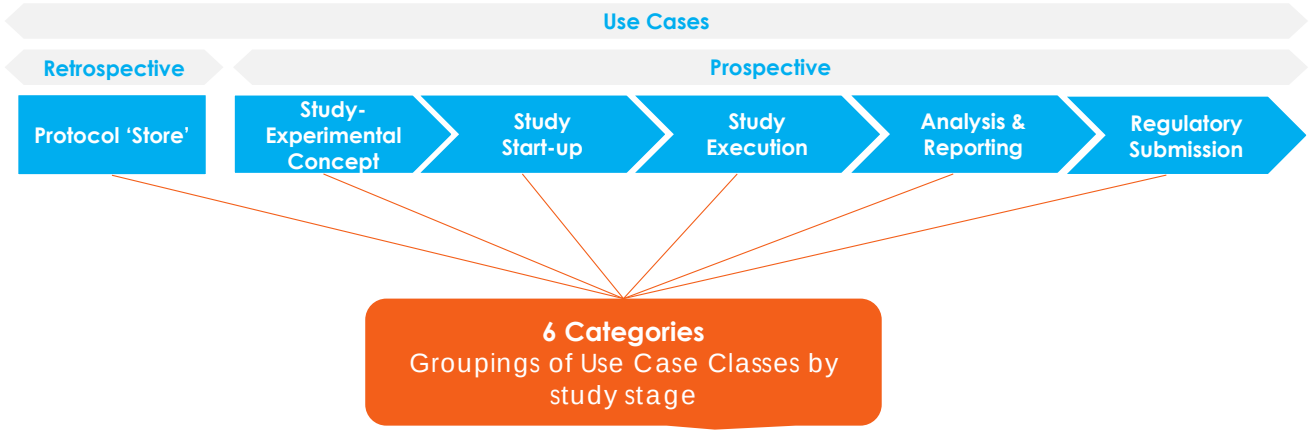
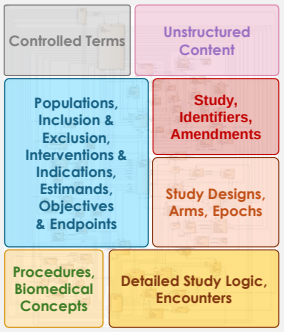


NOTE: The Library is still under development.
Content may change before release.

How to use the Library

Classes

Unified Study Definitions Model (USDM)



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20 Classes
Groupings of Use Case Systems within a study stage

Each Class contains one or more *Systems of Interest*

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How to use the Library

System of Interest Example: Study Startup: Trial Registry: Trial Registries

Upload Study to Registry

Trigger

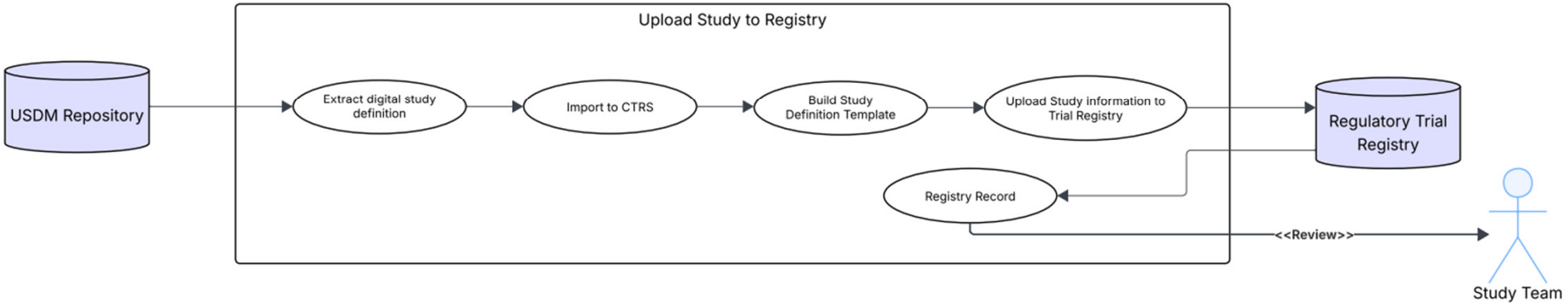
A Sponsor registers a new study with a Regulatory Agency.

Primary Scenario

The System selects a study and study version from the USDM Respository, imports the the digital study definition into its Clinical Trial Reporting System (CTRS), and populates a registry template. The template is uploaded to the Regulator's Trial Registry system and a Registry Record, along with any potential errors, is returned to the Sponsor.

Result

The Sponsor's Study Team reviews the Registry Record, along with any returned errors, to determine if the study's registry is as expected.



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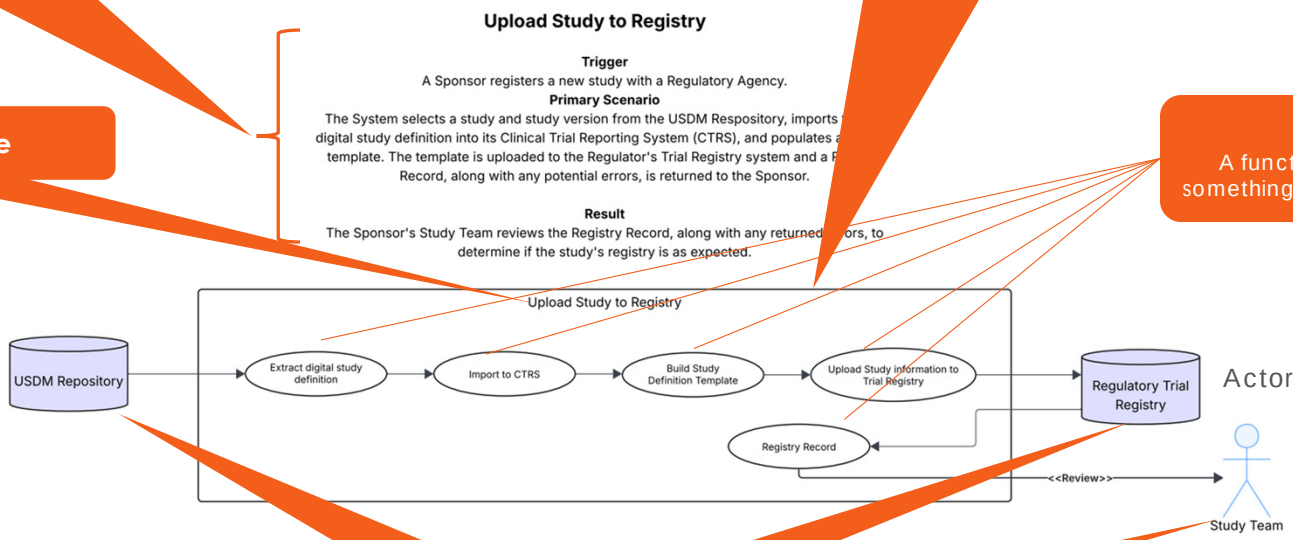
How to use the Library
Use Case Components

Scenario
A textual description of the sequence of executed functions from input to output, including the Triggering event and Result

System of Interest Boundary
Groups Use Cases into clinical functions that define a given Scenario

System of Interest Name

Use Cases
A function of the System that does something in the execution of a Scenario



Typically
Actors that trigger or Provide inputs are drawn on the Left

Typically
Actors that expect outputs are drawn on the Right

Actors
Someone or thing that interacts with the System, either having a responsibility (inputs) or expectations (outputs)

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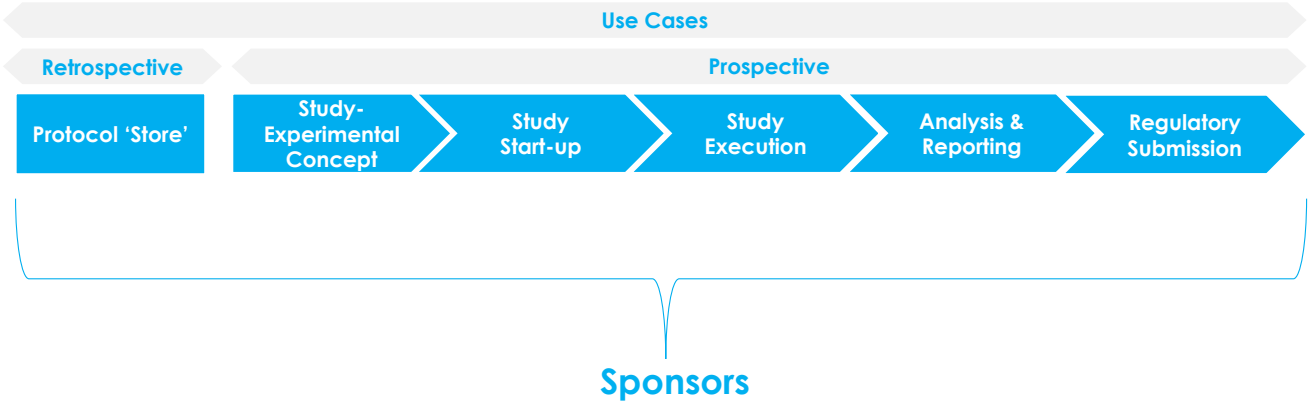
What is next?
Sponsor-centric perspective



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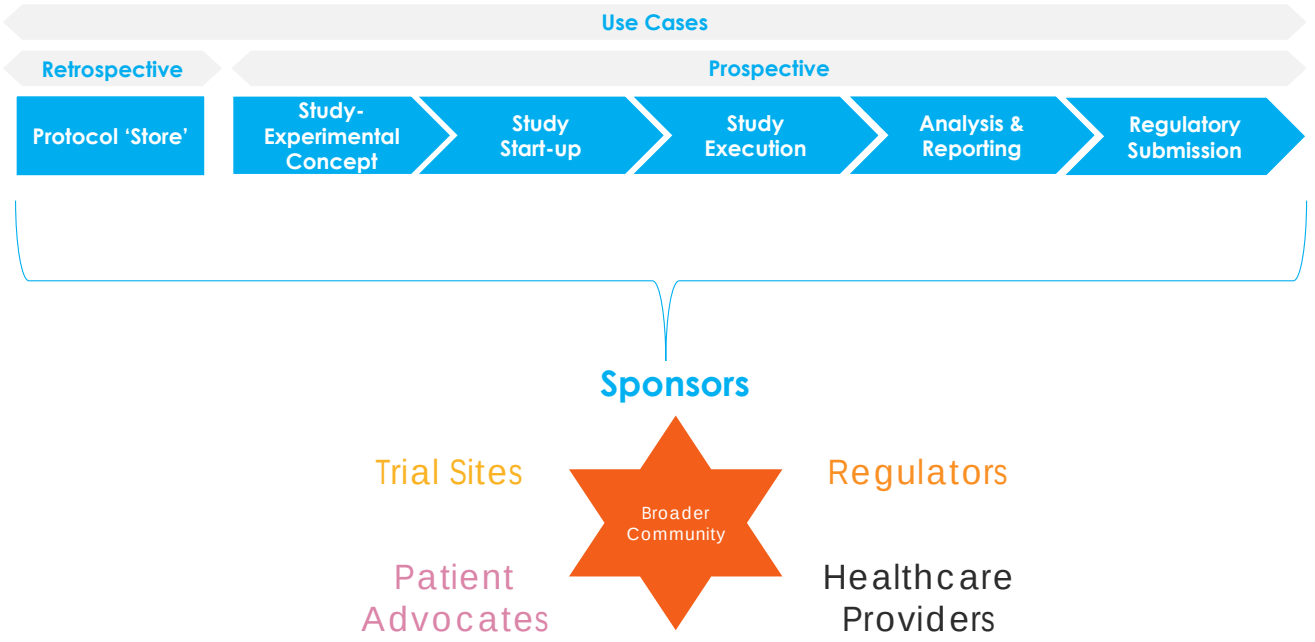
What is next?

Expansion to the Broader Community



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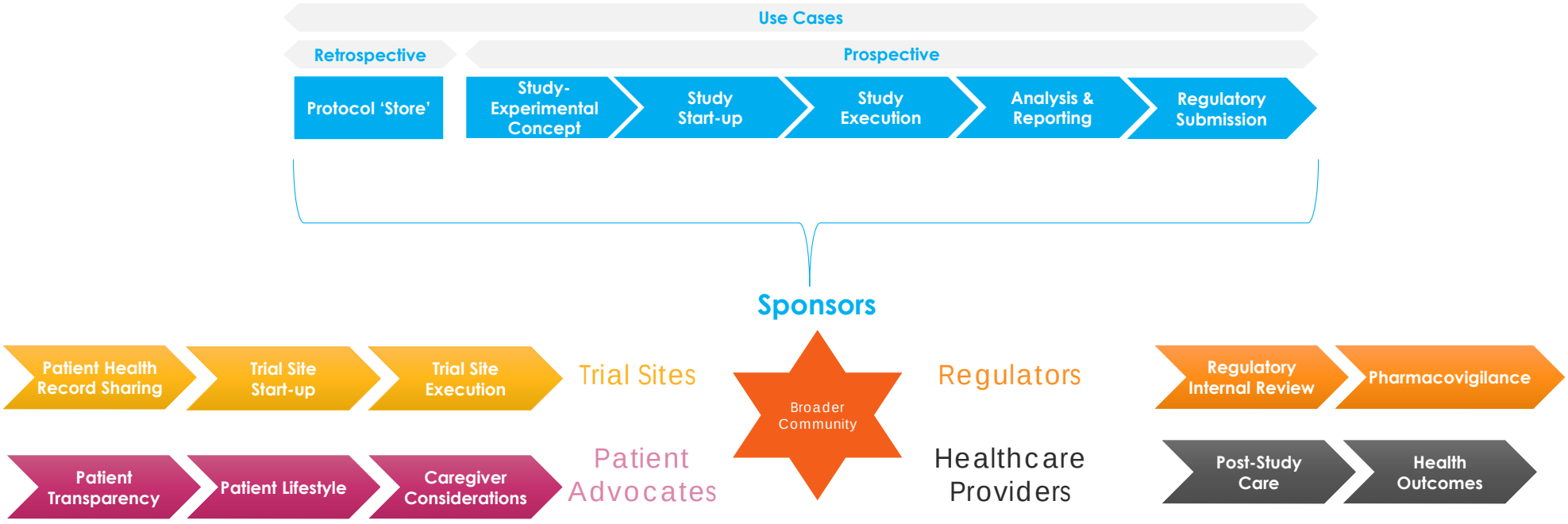
What is next?
Possible New Categories



NOTE: The Library is still under development.
Content may change before release.

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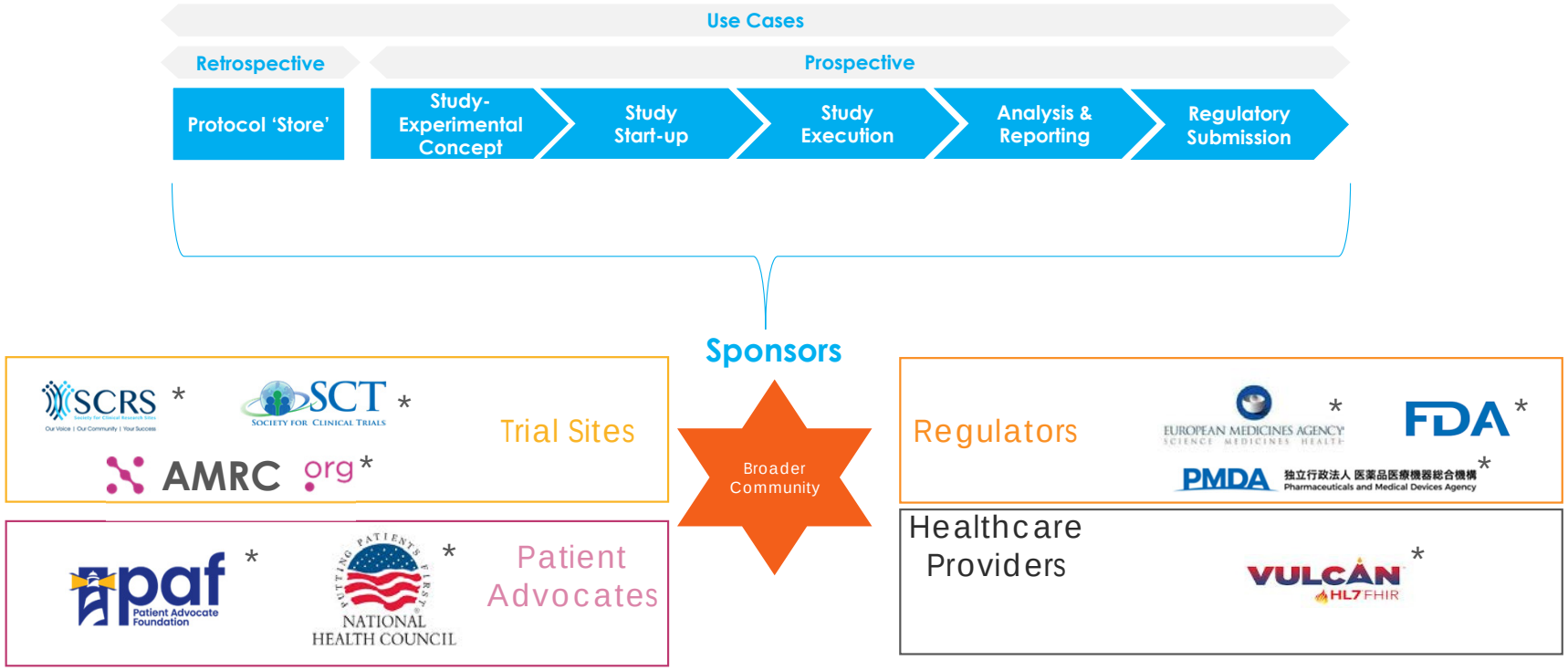
What is next?
Possible New Collaborators



*Organization Names provided as examples only and imply neither a preference for nor a pre-existing relationship with Transcelerate

NOTE: The Library is still under development.
Content may change before release.

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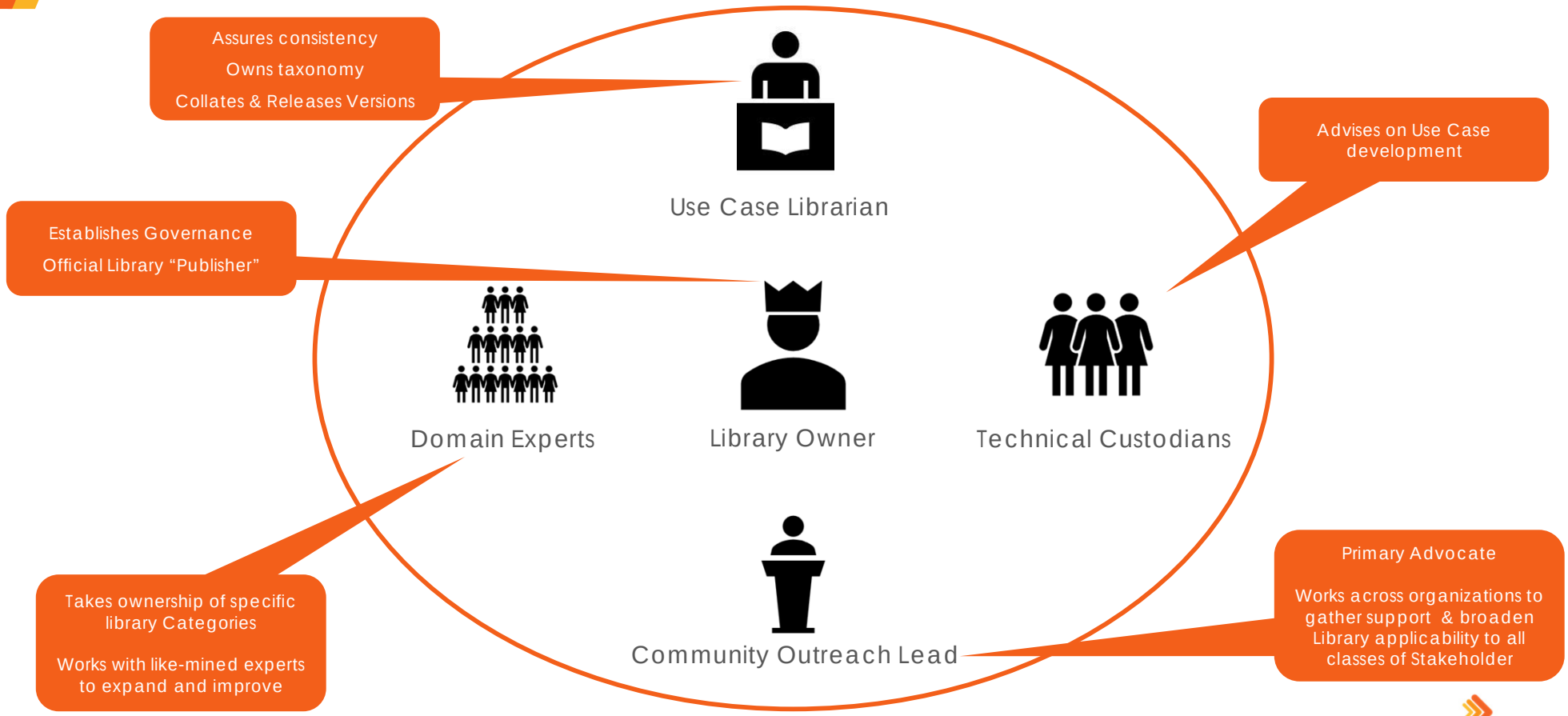
What is next?

Potential Future Governance & Continuous Improvement of Use Cases



Unclear at this time what organizations or groups would assume responsibility for any role

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Summary & Closing Remarks

What & Why	Capture current understanding with a proposed framework to catalyze further discussion & collaboration
How	4 Level Hierarchy utilizing UML Captures proposed approaches for how end-users accomplish things
Next Steps	Expand scope, add new Categories & Collaborators Establish Governance & appoint Domain Experts to Steward
Library Access	To Be Provided URL and/or Barcode
Need Volunteers	If you are interested in managing a use case Category as a Domain Expert please let us know.
Have Questions?	Please contact us! Govind Subramanian govind.subramanian@transceleratebiopharmainc.com Chi Vo chi.vo@lilly.com Donald Jennings donald.jennings@lilly.com

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Digital Data Flow: Mission Possible!

Practical approaches for protocol digitalization

Day 2 – September 25, 2025

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The Future of Digital Protocols: Regulatory and Health IT Perspectives

The Future of Digital Protocols

Mike Buckley

MSKCC

Leading teams who translate user needs into transformative digital products
HL7 Vulcan Schedule of Activities Co-Lead

Ron Fitzmartin

Decision Analytics

Regulatory and industry veteran working with sponsors and health authorities to adopt and implement global regulatory data standards

Nick Halsey

EMA

ICH M2 EU Topic Lead

Mary Lynn Mercado

Novartis

TransCelerate Digital Protocol Lead
ICH M11 (PhRMA)
Vulcan UDP Advisor

Veronica Pei

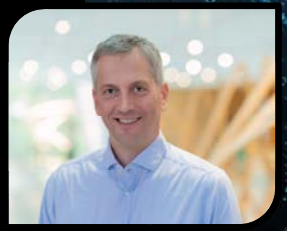
FDA

ICH M11 Rapporteur

Vada Perkins

Boehringer Ingelheim

PRISM Principal Investigator
ICH M2 EFPIA Topic Leader
ICH M11-M2 SDO Leadership Group Chair



Guillaume Schoch

Roche

ICH M11 EFPIA Topic Lead

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Learnings from Early Adopters

Learnings from Early Adopters

Lissa Morgan

Amgen

Director, Innovation & Process Improvement

Donald Jennings

Eli Lilly

Senior Director, Digital Trial Foundations and Patient Experience

Camilla Kehler

Novo Nordisk

Principal Product Owner, OpenStudyBuilder

Shagun Grover

Roche

Senior Director, Digitalization of Protocol Initiative

Yann Nouet

Roche

Digital Innovation Lead

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Start with pre-submitted questions:

1. Summarize what you presented last year.
2. What progress has your organization made over the last year?
3. What are the barriers that have been addressed or removed?
4. What challenges to implementation remain?
5. What are your organization's aspirations moving forward?

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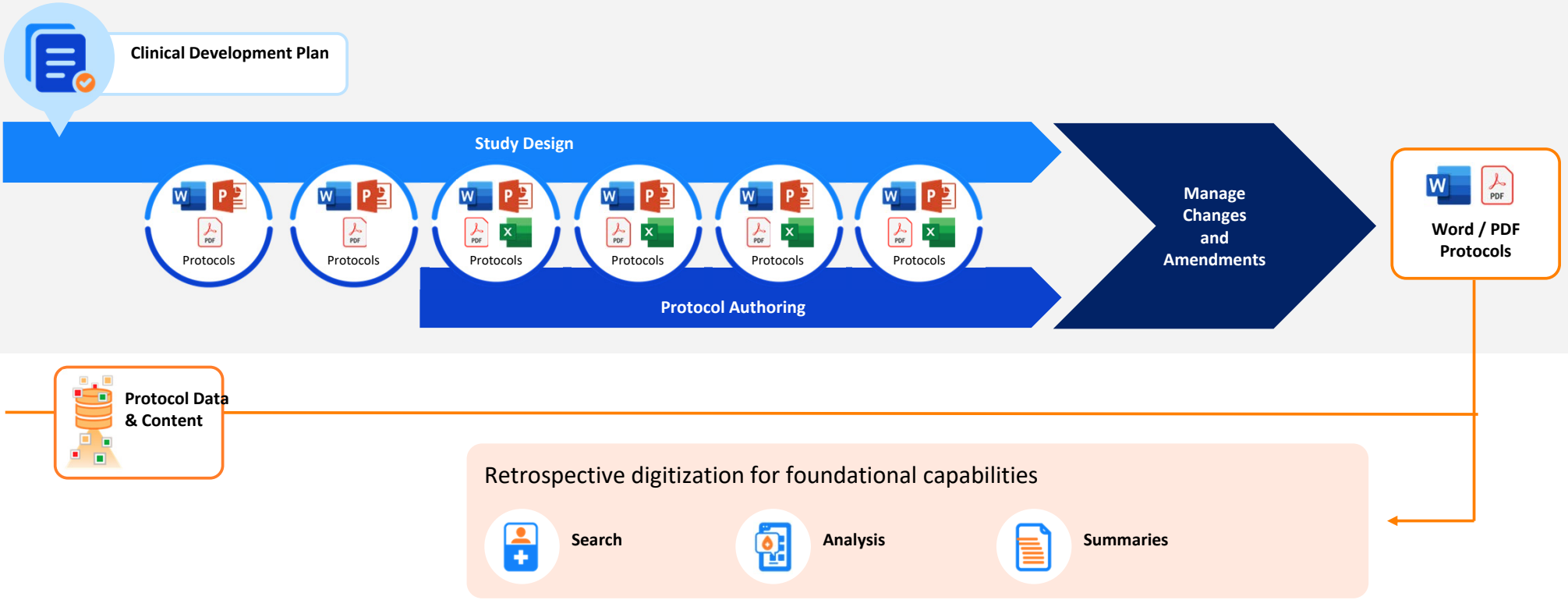
Case Study Recap:

How can we unlock the power of data and technology to transform study design and protocol generation?


Clinical Development Plan
Study Design
Protocols
Protocols
Protocols
Protocols
Protocols
Protocols
Protocol Authoring
Manage Changes and Amendments
Word / PDF Protocols
Protocol Data & Content
Retrospective digitization for foundational capabilities
Search
Analysis
Summaries

Clinical Development Plan

Governance to proceed with the study design phase

Final Protocol Synopsis approval

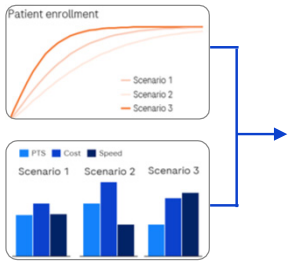
Final Protocol

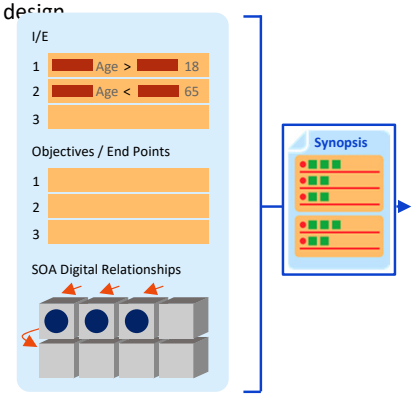
Study Design

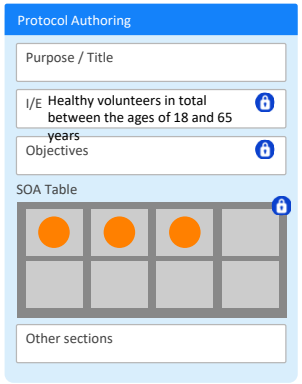
Protocol Authoring

Manage Changes and Amendments

Research & Build Knowledge	Initial Design	Explore feasibility inc trial cost estimation and RoI	Final Synopsis Review and Approval	Final Study Design	Protocol generation begins once study design is locked	Amend Study Design components and Protool sections as needed
Source, search and review: - historical and competitive studies - internal/external literature and papers - Standard Design Criterias, RWD	Initial draft design based on available insights available from internal and external sources	Leverage Data to explore scenarios and develop options	Study Team finalizes recommended option and design		Assemble components to generate protocol	



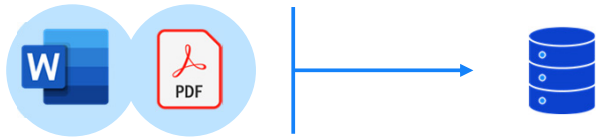




Protocol Hub

Component Library

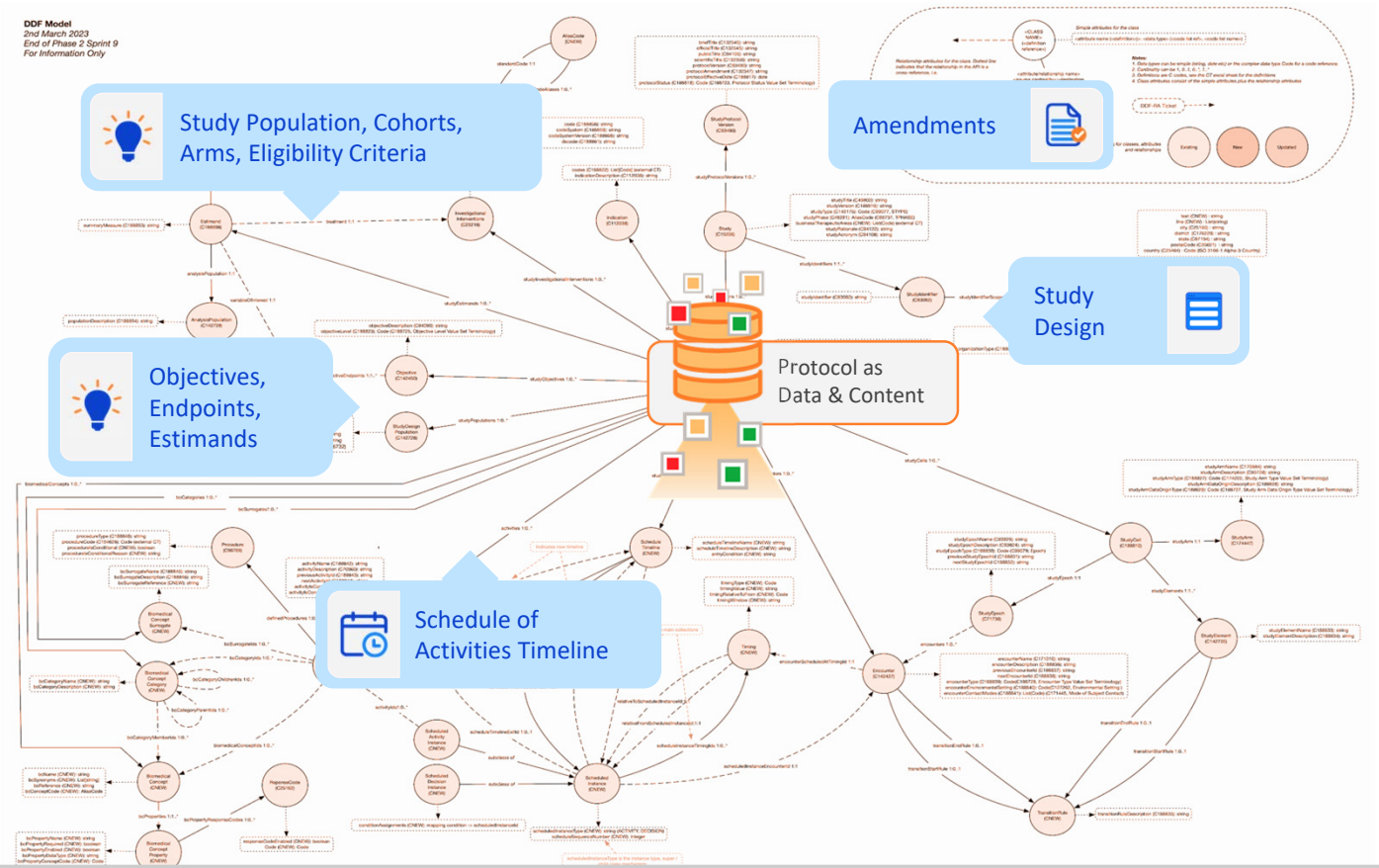
Digitization



Converts existing **documents into digital data** by extracting and deconstructing sentences or paragraphs

Digitalization

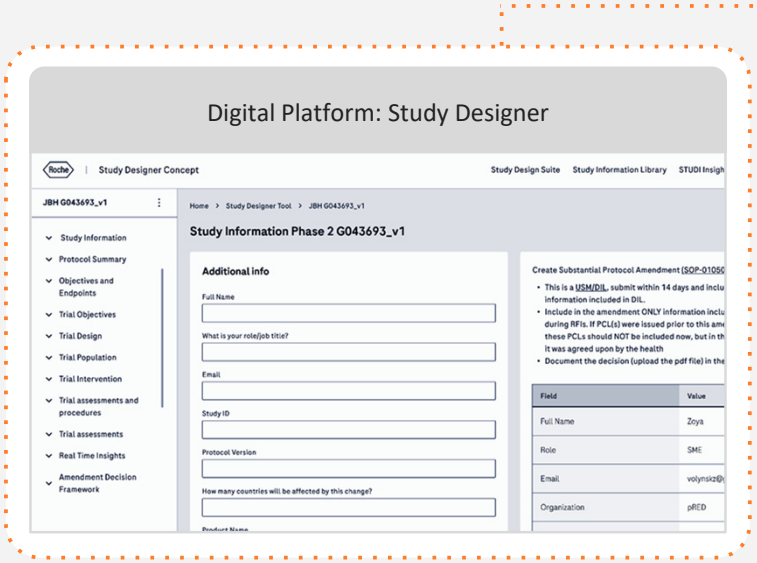
Real-time data acquisition and **integration** into digital processes using digital tools

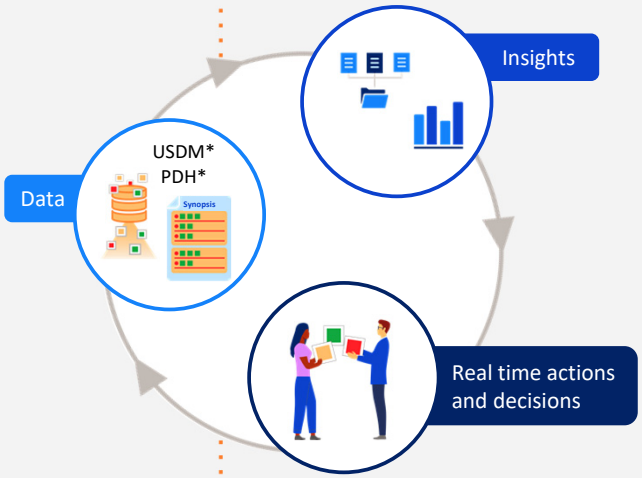


One Roche Template M11 Compliant

500+
Design Elements
derived from
30
Section/
Subsections

Leverages Unified Study Definitions Model (USDM):
A standardized model developed by Transcelerate and CDISC, USDM enables Roche to achieve interoperability between multiple solutions within the organization that require protocol data.





- **Digitalized** study designs from inception
- **Actionable insights** to inform decisions
- **Real-time refinement** of study designs using available insights

USDM *Unified Study Definitions Model*
PDH *Protocol Data Hub*

So can we think of a Study Designer that offers….

Easy to Use and Ready for Collaboration across multiple functions

Comprehensive Study design

Real-Time Data-Driven Insights from SOA to optimize Study design

Interoperability of Study Design Data & Content

Building Data-Driven Schedule of Assessments (SOA)

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Case Study Recap:

Adoption of Digital Data Flow

Adoption journey 2024

Early earnings:
- System Performance
- Navigation Issues
- Terminology Issues
- Missing Functionality
- Operational burden

MVP release of SDR/MDR

Usability test (Interview)

Usability test (Automated)

User report

Oct 2023 | Nov | Dec | Jan 2024 | Feb | May | End 2024

Hyper Care

Scope of the first business release of our SDR/MDR*:

- **Studies:** All interventional ph 2-4
- **Users:** Clinical Operations, Clinical Reporting & Data Standards
- **Key protocol metadata:** SoA, Study Structure, Eligibility Criteria, Endpoints & Objectives

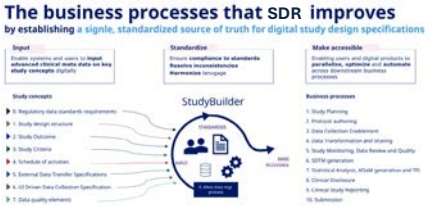
* MVP = Minimal Viable Product

Scope **Reduced:**

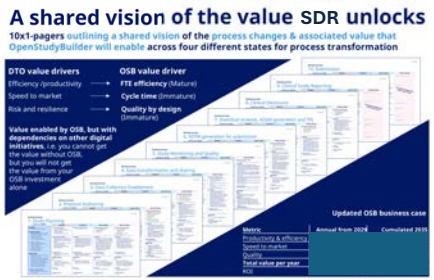
Only SoA

Limit the operational burden of maintaining old and new systems/processes

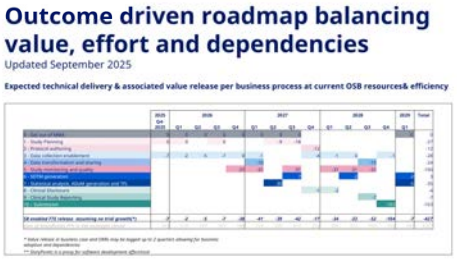
Adoption journey update (2025)



Product vision & mission



Value framework & business case



Outcome based roadmap

Defined Objectives & Key Results

Current status:

- As of 01-Oct-2025 we specify the SoA for the protocol for all of our intervetional studies (ph1-4) in or SDR/MDR
- Data collection enablement soon a reality
- End2End metadata linking the focus of 2026

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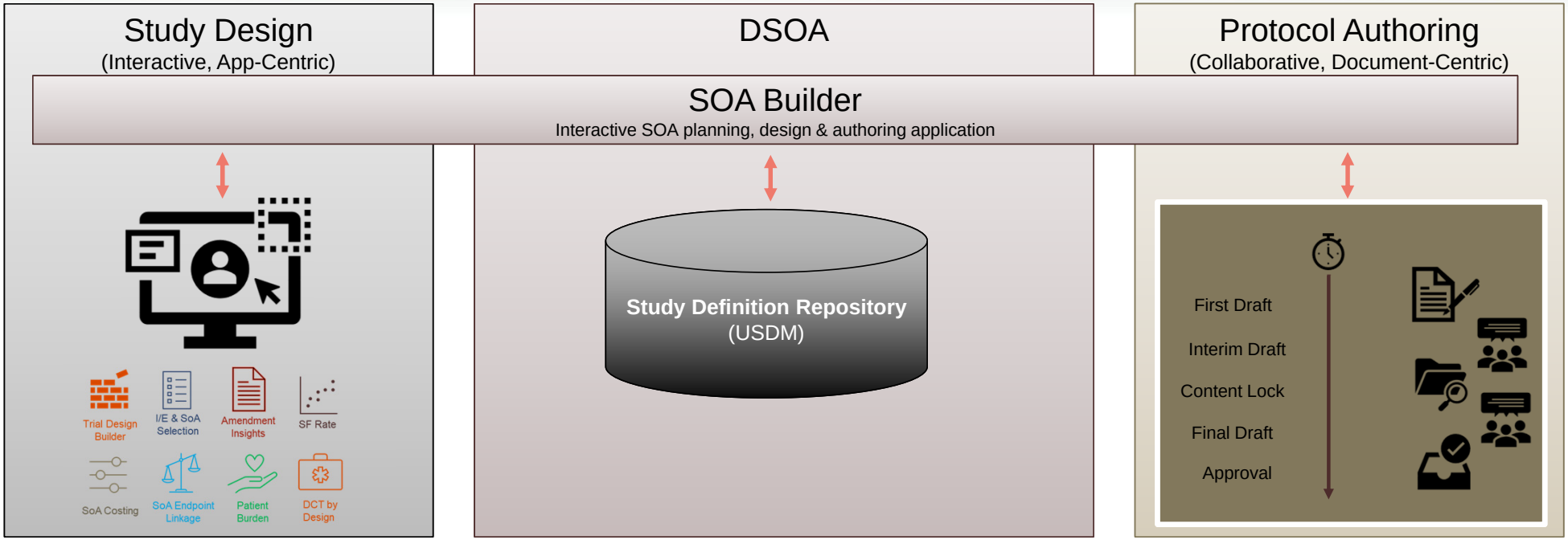
Case Study Recap:

The Digital Schedule of Activities (DSOA) – Using Digital Dat Flow for Portfolio Acceleration

DSOA Target State (Scale)



Downstream Consumers

Central Labs

Orchestration

Budgeting

Trial Materials

eDC & eCOA Build

Monitoring

Pharmaceutical Dispensing

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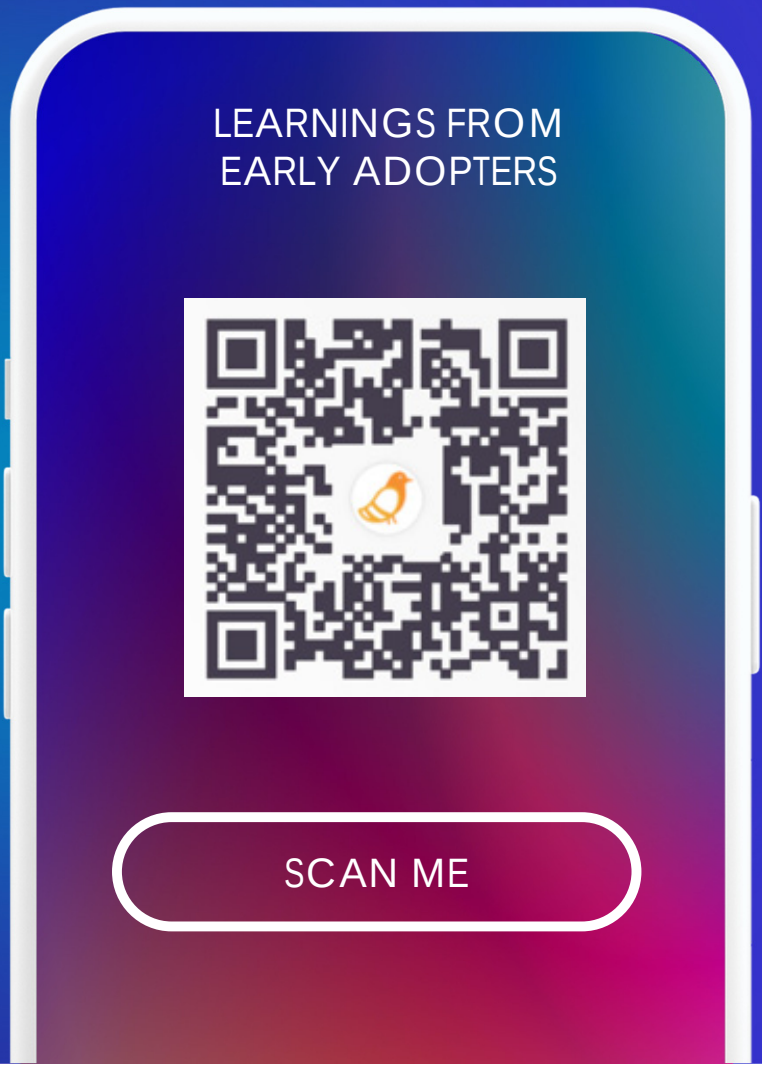
Ask a Question

Scan the QR code or go to:
novartis.pigeonhole.at

Enter passcode:
MCPMK3T2



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Solution Provider Orientation

AlphaLife Sciences

ALPHALIFE Sciences

Mike Liang

Bogong Zhu

CDISC

Peter Van Reusel

Julie Smiley

ClinLine

Berber Snoeijer

Data4knowledge

Johannes Ulander

Dave Iberson-Hurst

DNAnexus

DNAnexus®

Jimita Parekh

Faro Health

faro

Sanchit Thakrar

HumanTrue

HumanTrue

Bill Lynch

Merative

Zelta
by merative

Jennifer Duff

Novonordisk OSB

Nicolas deSaint Jorre

Jeremy Cronin

Nurocor

nurocor™
Digitalized Clinical Development

Bob Brindle

Barrie Nelson

Onward Health

ONWARD
Health Research

Martin Lim

Pharmaseal

PHARMASEAL

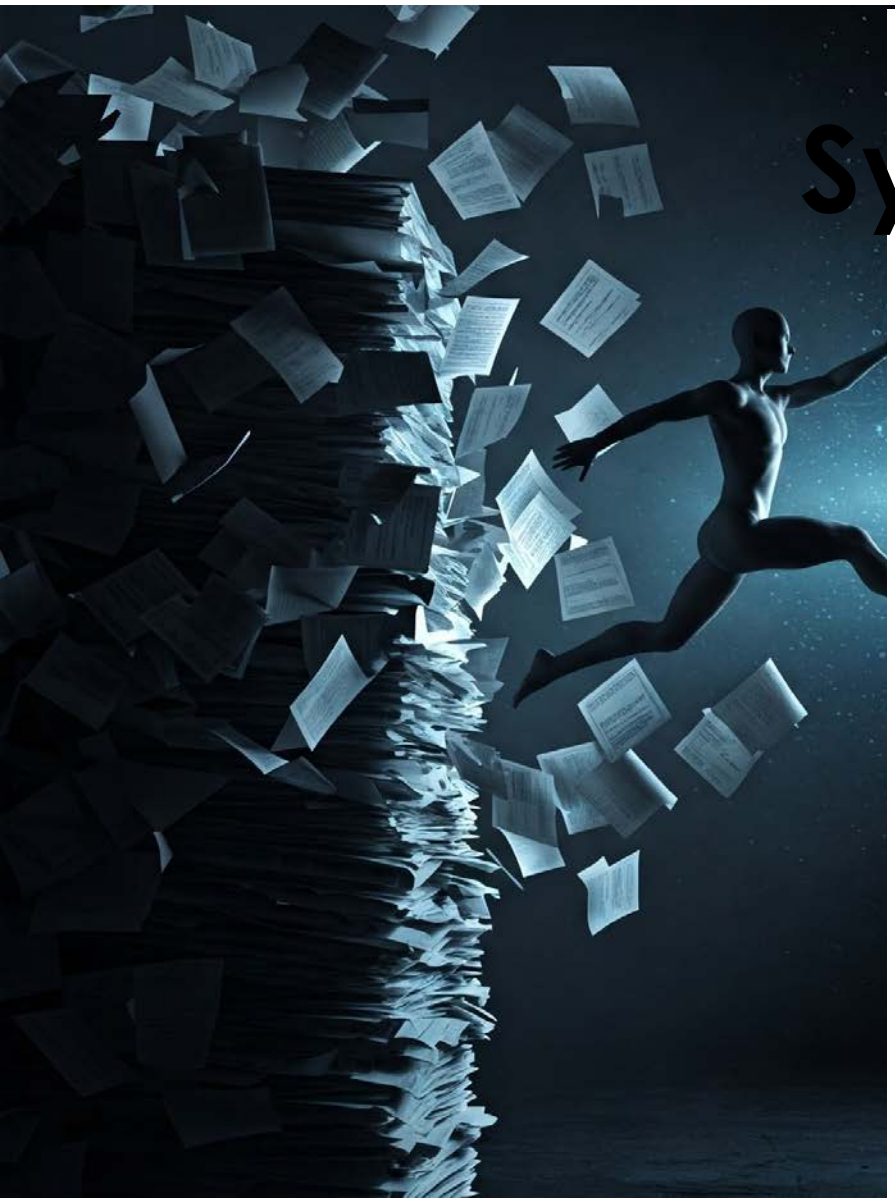
Ricky Lakhani

Daljit Cheema

RWS & Contentrules

Todd Georgieff

Regina Lynn Preciado



Sycamore Informatics

Sycamore Informatics

Kairav Tarmaster

Joel Hoffman

TransCelerate SDR

TransCelerate BIOPHARMA INC.

Belinda Griffin

Mike Rippin

Trialynx & Cliniv

Ram S.

Angie Schwab

Verily

Brandon GoldBlatt

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Solution Provider Poster Session

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Action Toolkit & Survey

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Action Toolkit

Digital Data Flow (DDF) Website

Primary website for DDF

CDISC DDF Website

Explore & access the USDM

TransCelerate DDF Initiative

Discover the initiative background

DDF GitHub Repository

Review & access the SDR Refence Implementation.

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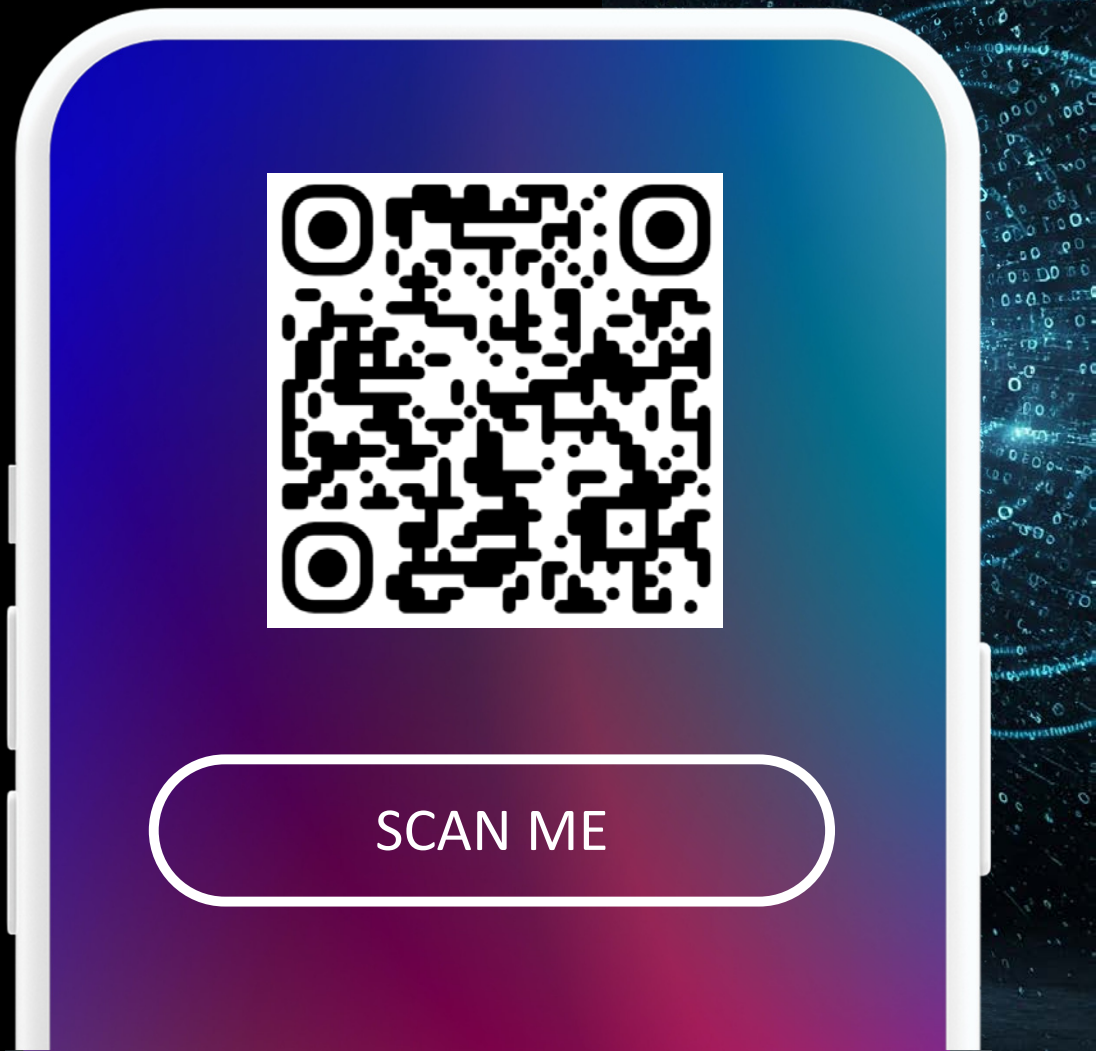
GIVE US YOUR FEEDBACK



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Announcements & Close

Announcing the TransCelerate- SCOPE ClinEco Solve Challenge!

The SCOPE-ClinEco Solve challenge is designed to crowdsource innovative solutions from across the clinical research ecosystem

Problem Statement:
Protocol review today is cumbersome and inefficient. Reviewers must navigate lengthy, complex documents, manually extract relevant information and transcribe it into downstream solutions leading to errors, delays and unnecessary amendments. The challenge is to demonstrate how digital protocols in USDM standard format can enable more efficient, accurate and stakeholder specific review processes.

How to Participate:
Participants will submit a short written abstract outlining what they would like to showcase relative to the challenge. These abstracts will then be used as the basis to select a set of finalists who will be invited to submit a short video that demonstrates how their solution meets the challenge.

Winners will be announced at the SCOPE Summit 2026 plenary in February 2026 and featured on the ClinEco platform!

TransCelerate Protocol Review Challenge: Reimagining How We Review Clinical Protocols

Sponsored by

TransCelerate BIOPHARMA INC.
Accelerating Answers.

Submission deadline: Oct 24, 2025

Today's protocol review process is cumbersome and inefficient. Reviewers navigate lengthy, complex documents, extract relevant details manually, and re-enter information into downstream systems. This creates errors, delays, and unnecessary amendments.

Challenge: Demonstrate improved review capabilities that can be realized utilizing a USDM digital protocol providing certain stakeholder groups with a dynamic and digital protocol review solution. Consider the review process by sponsors, CRO's, sites, patients and/or health authorities. Solutions might include, but are not limited to:

- Persona specific views e.g. medical writer, clinician, medical expert, safety scientist, statistician, regulatory manager, PK scientist, data manager, drug supply manager, clinical project manager
- Automated content consistency checks against protocol content review guidelines or best practices e.g. ICH E6 (R3), SPIRIT Protocol Checklist
- The ability to publish the digital protocol in different standard document formats e.g. following the ICH M11 Template, the TransCelerate Common Protocol Template, NIH FDA Protocol Template with links between the native digital and document views
- Connections to relevant external data sources and the provision of insights or recommendations relevant to a given reviewer
- Computation of study design scores (e.g. complexity, patient burden, site burden) and comparison to relevant benchmarks
- Amendment impact analysis and ability to automate downstream updates based on amendments

How to Participate

1. **Submit an Abstract**
   - Provide a clear summary of what your solution.
   - Any/all identifying company information in the abstract will be blinded before presentation to the judging panel.
2. **Finalist Invitation**
   - Selected abstracts will advance to the finalist round.
   - Finalists will be asked to prepare a **short video (up to 5 minutes)** demonstrating their solution in action.
3. **Judging & Recognition**
   - A panel of judges assembled by TransCelerate will review blinded submissions.
   - Finalists and winners will be announced on ClinEco and highlighted across SCOPE 365 channels.
   - Winning entries will be recognized at the SCOPE Summit plenary session, with opportunities for further visibility.

Propose Solution

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Digital Data Flow (DDF) Initiative on LinkedIn

dIn community
ocol digitalization,
tions, and sharing
ation in a clear and
e manner.

Follow the DDF LinkedIn Page!

Digital Data Flow: Mission Possible!

Practical approaches for protocol digitalization

TransCelerate Digital Data Flow (DDF)

Mission Possible!

"Impossible is temporary, impossible is nothing"

The Transformation is on!