



# 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

# 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.
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# General Ground Rules

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

- 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.



# General Ground Rules

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

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- The **solution adopter bears all responsibility and liability** for compliance with any and all applicable laws and regulations and for ensuring that any solution (including any DDF implementation) is fit for a particular use.
- 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.



# 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

# 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



# 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...

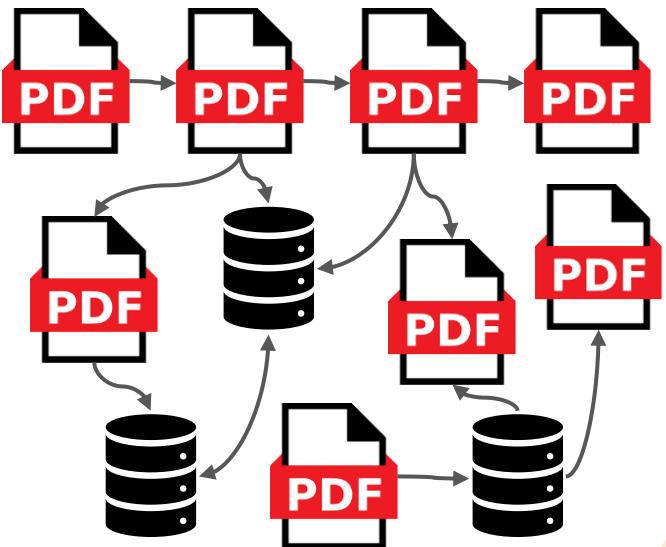
Participate in two days of the DDF experience - listening, ideating and collaborating to understand:

- ✓ 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

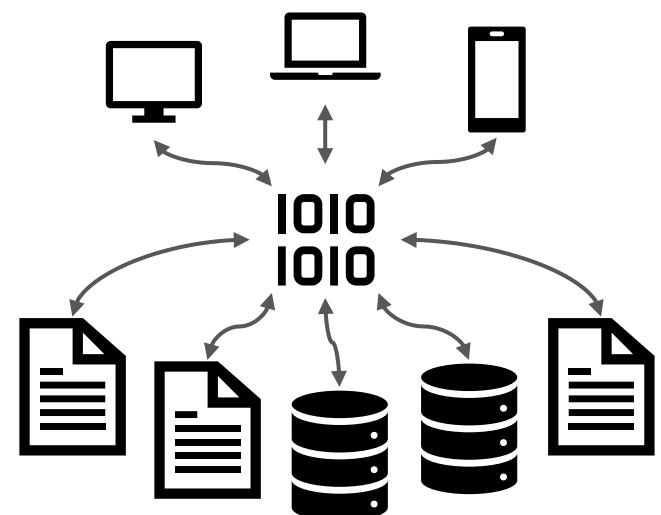
# Why DDF? – The Vision

*Break the Document Paradigm*

From document-first



To data-first

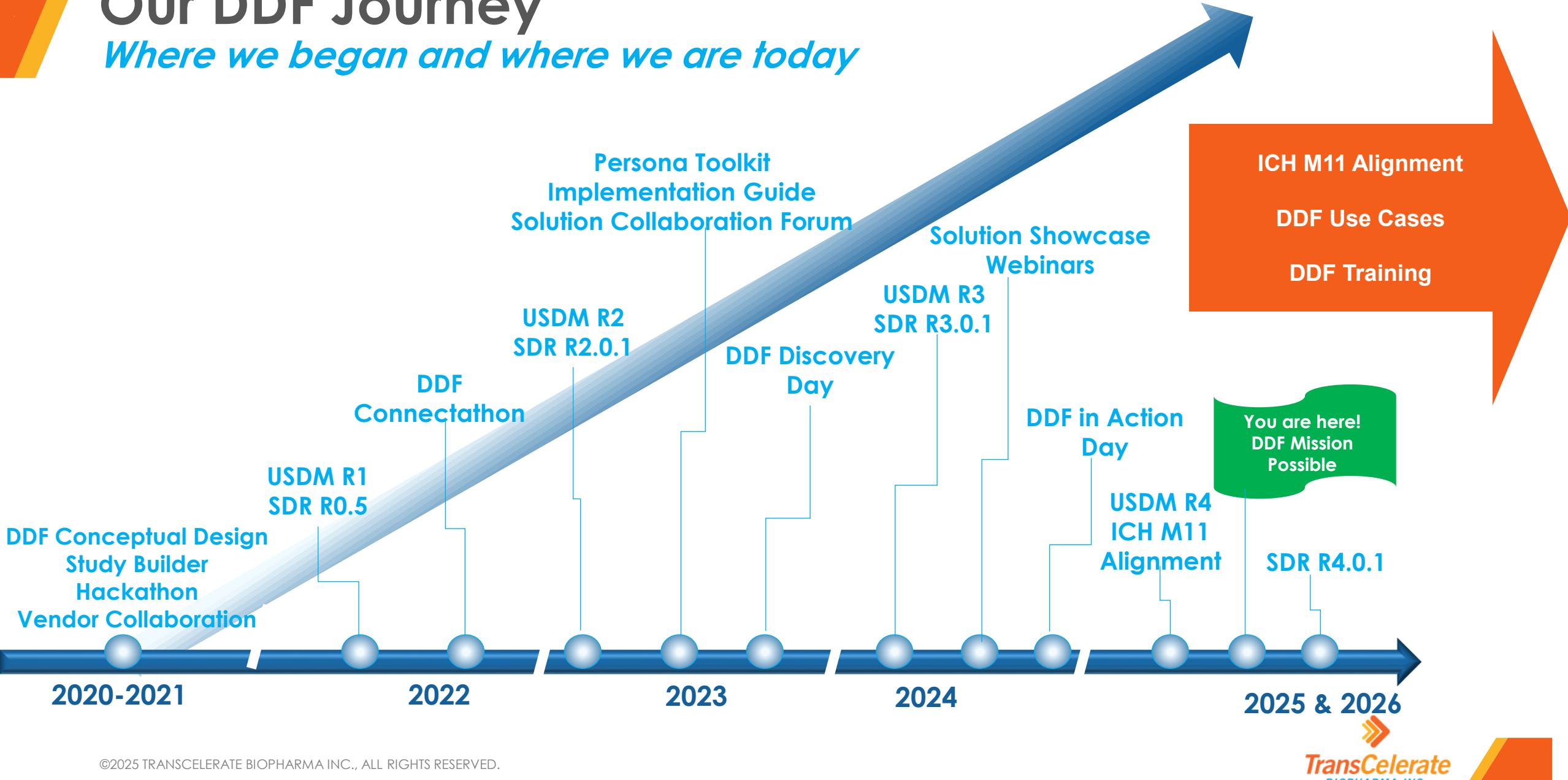


Goal: Increase Clinical Research Velocity

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

# Our DDF Journey

*Where we began and where we are today*



# Stable Technology Now Underpins Digital Data Flow

USDM v4.0 launched in June



The graphic features the CDISC 25th Anniversary logo at the top right. A yellow circle on the left contains the word "NEW!". Below it, the text "USDM v4.0 Now Available" is displayed. In the center is a hexagonal badge with the CDISC logo at the top, "USDM" in large letters, and "UNIFIED STUDY DEFINITIONS MODEL (DDF)" below it. At the bottom left, a blue box lists "Includes:" followed by a bulleted list: "USDM Logical Model", "USDM Controlled Terminology", "USDM API", "USDM Conformance Rules", and "USDM Implementation Guide".



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

# 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)

**TransCelerate**  
BIOPHARMA INC.



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

# Getting Started: Pathways to Implementation

## DDF Use Cases

### Retrospective

#### 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 I 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.

### Prospective

#### 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

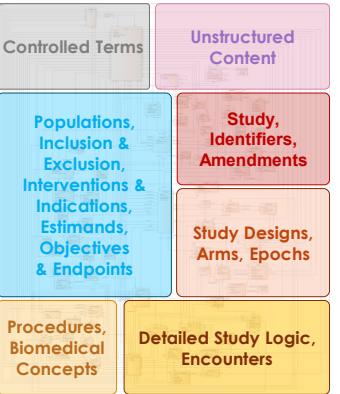
**Submission**  
Preparation of the submission by the sponsor

**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)



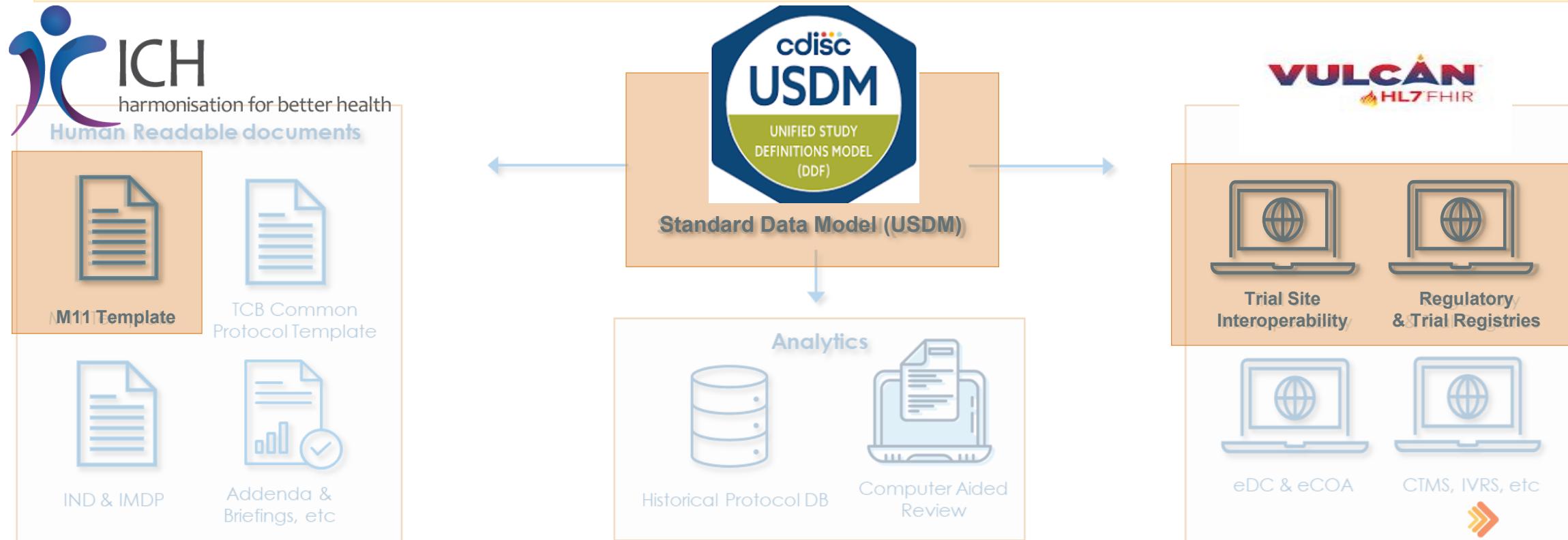
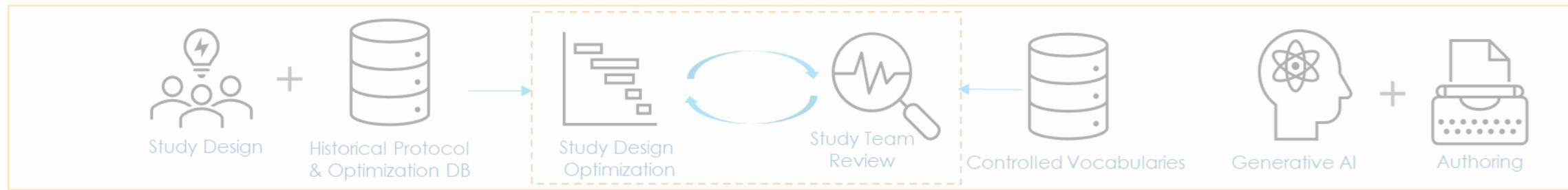
### Across The Lifecycle

**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

# Multiple Stakeholder Collaboration

*CDISC, ICH & HL7-Vulcan*



# Strong Engagement from a Growing Tech Provider Community



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.

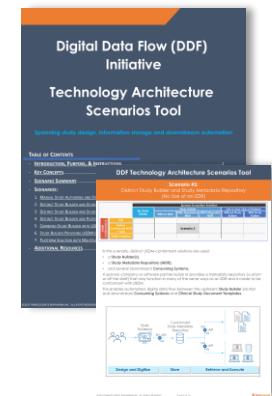
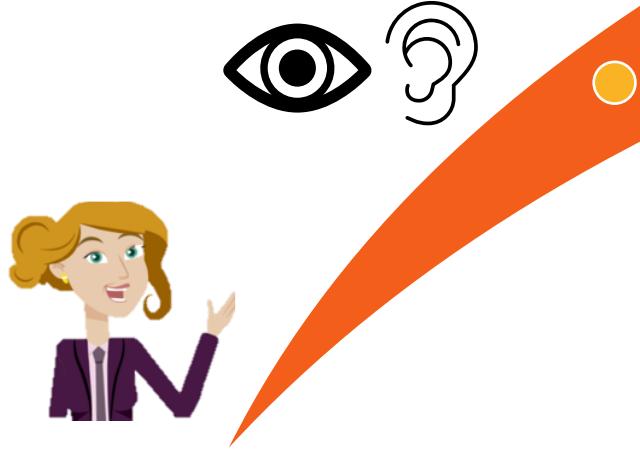


# DDF Change Management Journey

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?

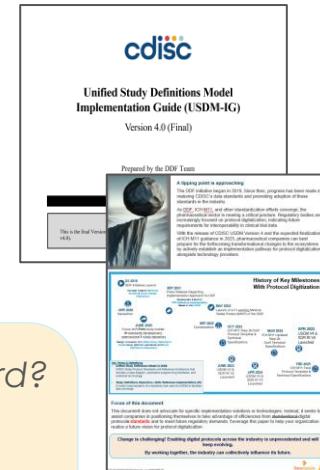
## Commitment?



## 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?

# 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](mailto: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](mailto:info@cdisc.org) for more information

# 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](mailto:DDF@transceleratebiopharmainc.com)

# 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

# TransCelerate Digital Data Flow (DDF)

Mission Possible!

It's not that hard!



# Thank you!

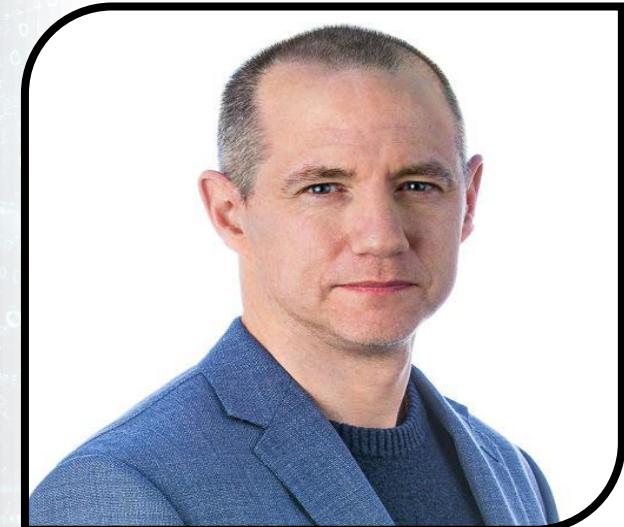




# USDM Updates



**Peter van Reusel**  
**CDISC**  
Chief Standards Officer



**Chris Decker**  
**CDISC**  
President & CEO

# CDISC Digital Protocol Update

DDF Mission Possible Event

24<sup>th</sup> September 2025

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



# Stable Technology Now Underpins Digital Data Flow

USDM v4.0 launched in June



**USDM v4.0  
Now Available**

**Includes:**

- USDM Logical Model
- USDM Controlled Terminology
- USDM API
- USDM Conformance Rules
- USDM Implementation Guide



Alignment with ICH M11



Support for complex studies,  
interventional & observational studies,  
and medical devices



Maximise content re-use and support  
for multiple document templates

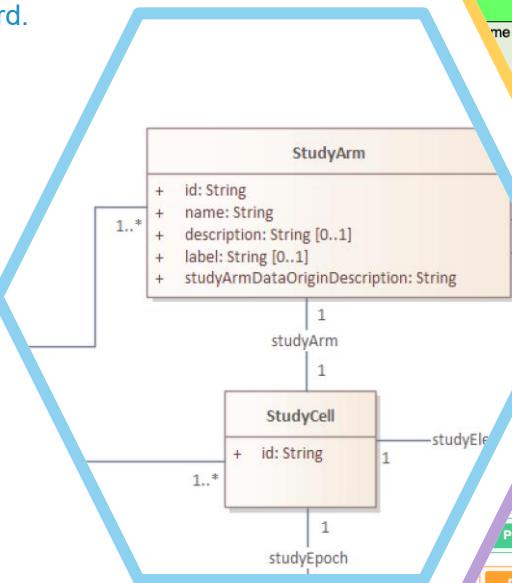


Model Extension mechanism to  
provide flexibility

# The USDM Standard

## Logical Model

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



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

## 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 Description
	C188827	Study Arm Type
	C188828	Study Arm Data Origin Description
	C188829	Study Arm Data Origin Type
	CNEW	Study Arm Label
studyEpoch	C71738	Study Epoch
	C93825	Study Epoch Name
	C93824	Study Epoch Description
	C188830	Study Epoch Type
	CNEW	Study Epoch Label

## API for DDF

Celerate Digital Data Flow (DDF) Study Definitions Repository API.

Production Routes that form the production specification.

**POST** /v3/studyDefinitions Create a study

**PUT** /v3/studyDefinitions/{studyId} Update a study

**GET** /v3/studyDefinitions/{studyId} Return a study

**GET** /v3/studyDefinitions/{studyId}/history Returns the study's history

**PUT** /v3/studyDesigns Study designs for a study

> Expand all object

## CORE Rules

Specification of the rules that define USDM compliance

	A	B	Entity/Value applies
The entity must conform with the USDM schema based on the API specification.			
		Attributes (string, number, boolean) must conform with the USDM schema based on the API specification.	Entity
		Properties must be included as defined in the USDM schema based on the API specification (i.e., all required properties are present and no optional attributes are present).	Error
		Properties must be as defined in the USDM schema based on the API specification (i.e., required properties have at least one value and single-valued properties are not lists).	Error
		Within a study version, all id values must be unique.	Error
		The names of all child instances of the same parent class must be unique.	Error
		The same Biomedical Concept Category must not be referenced more than once from the same activity.	Error
		In specified biomedical concept category is expected to be referenced by an activity.	Error
		Specified biomedical concept surrogate is expected to be referenced by an activity.	Warning
		Specified biomedical concept is expected to be referenced by an activity.	Warning
		Children must not refer to a timeline, procedure, except, biomedical concept category or biomedical concept.	Error
		Procedure is expected to be referenced by an activity.	Warning
		Except, biomedical concept category or biomedical concept must refer to at least 1 procedure, biomedical concept category or biomedical concept.	Warning
		Using the previous and next attributes must refer to children preceding their parents.	Warning

## Implementation Guide

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

## Examples

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

```
studyArms: [
  {
    "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": {
      "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.org",
      "codeSystemVersion": "2022-12-16",
      "decode": "Active Comparator"
    }
  }
]
```

(on 2.0 Draft for Internal Review)



## Unified Study Definitions Model Implementation Guide (USDM-IG)

Version 2.0 (Draft for Internal Review)

Prepared by the DDF Team

### Notes to Readers

- This is the draft version 2.0 of the Unified Study Definitions Model Implementation Guide (USDM-IG v2.0). It is intended for Internal Review only and is not a final version.

History  
Version  
2.0 Draft for Internal Review

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# DDF Phase 5: Accelerate Adoption

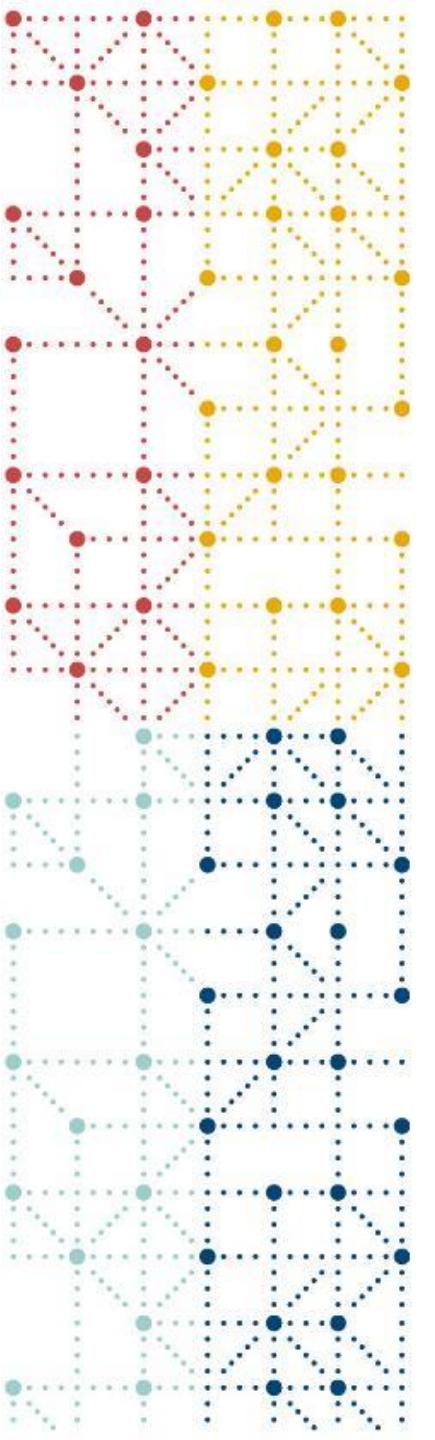
Focus on Community Engagement and Adoption

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

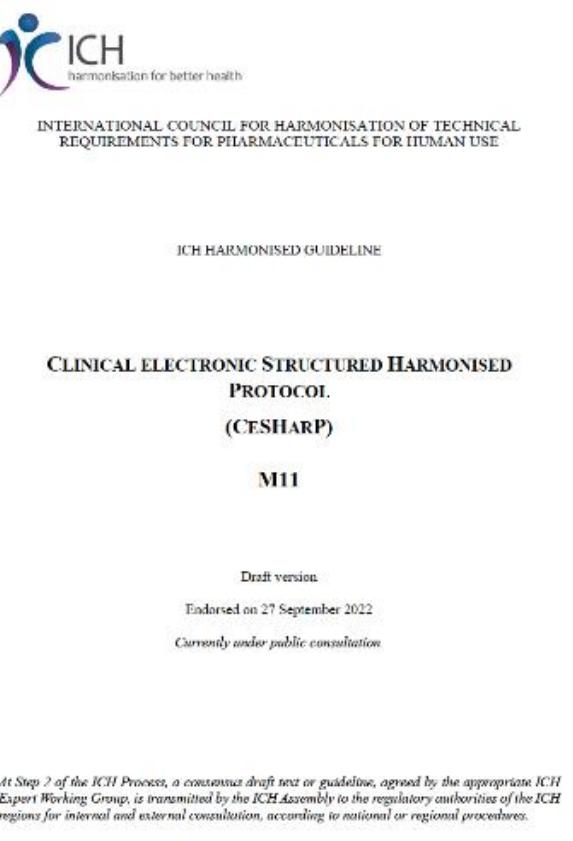


# ICH M11 and USDM: How do they Fit Together

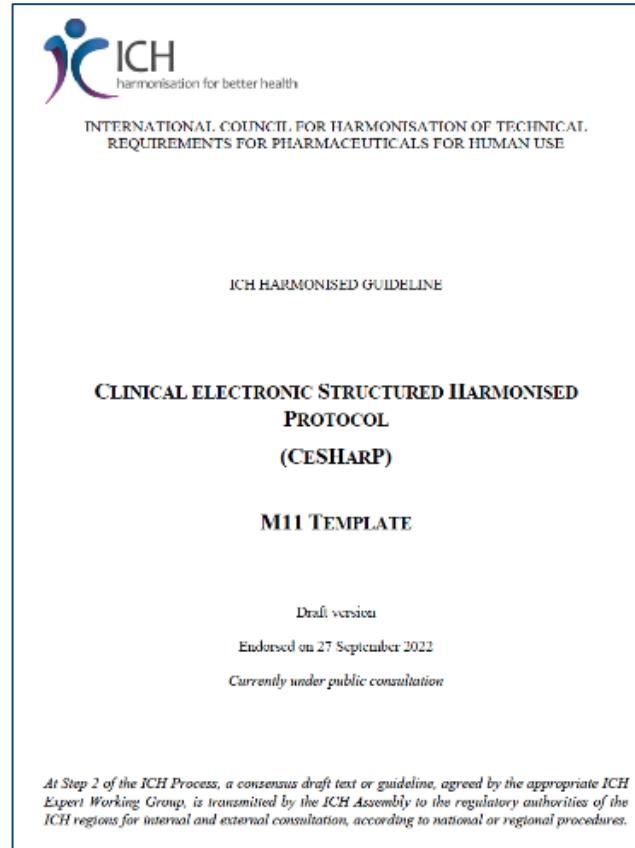
# M11 Is ...

## ICH CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHarP)

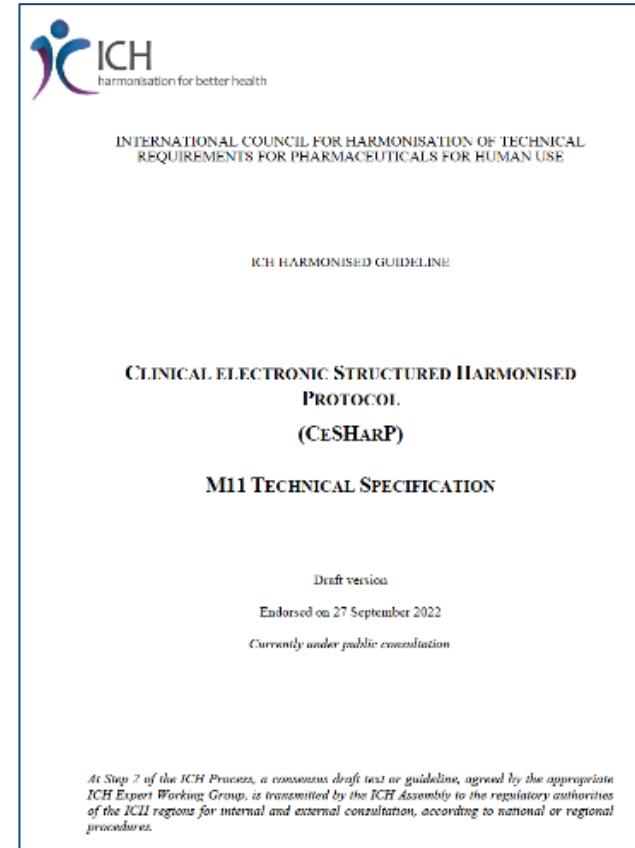
<https://www.ich.org/page/multidisciplinary-guidelines>



Provides background, purpose, and scope as a guideline

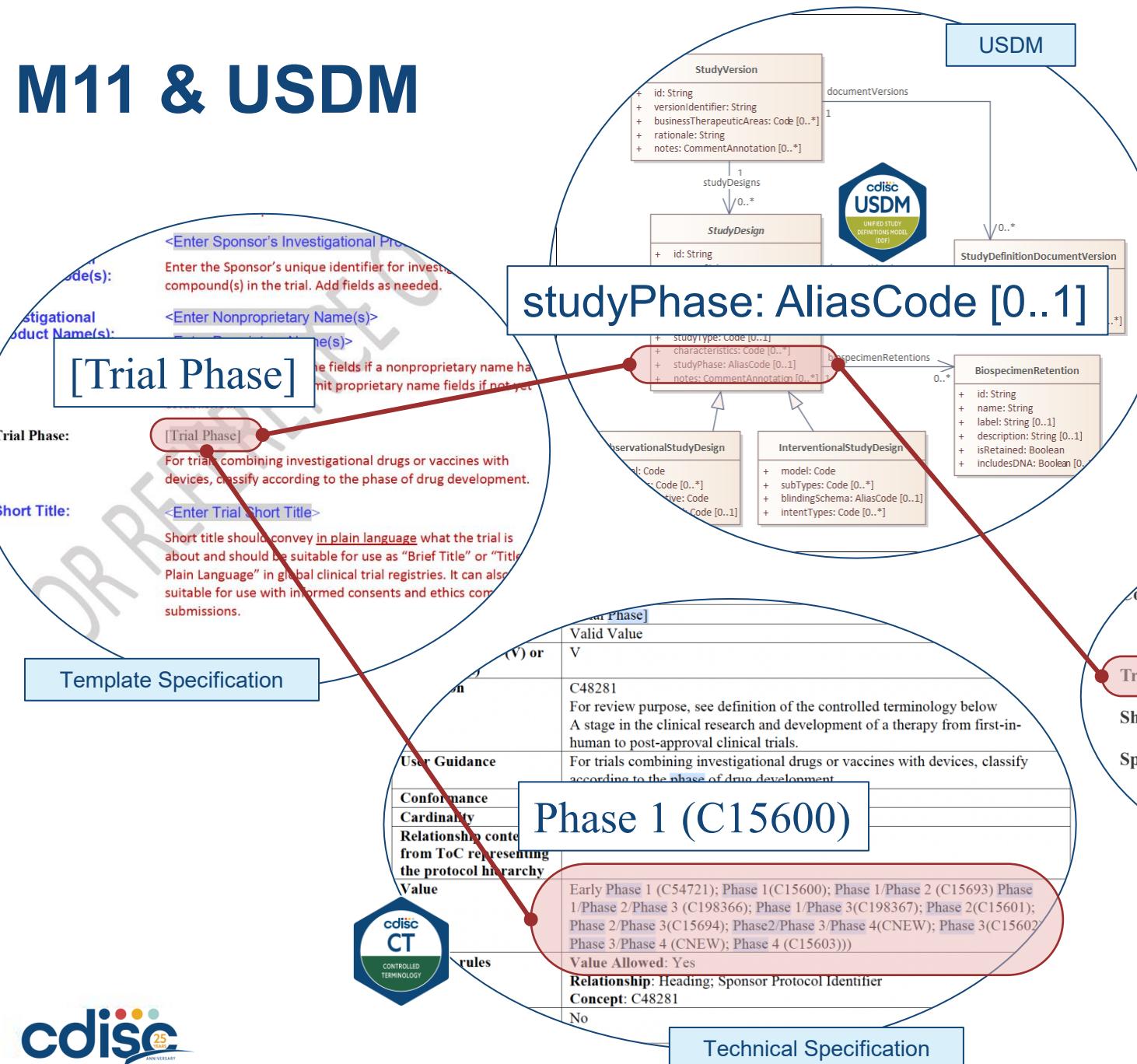


Provides the written format for the Interventional Clinical Trial Protocol Template



Provides the technical representation aligned with the guideline and protocol template

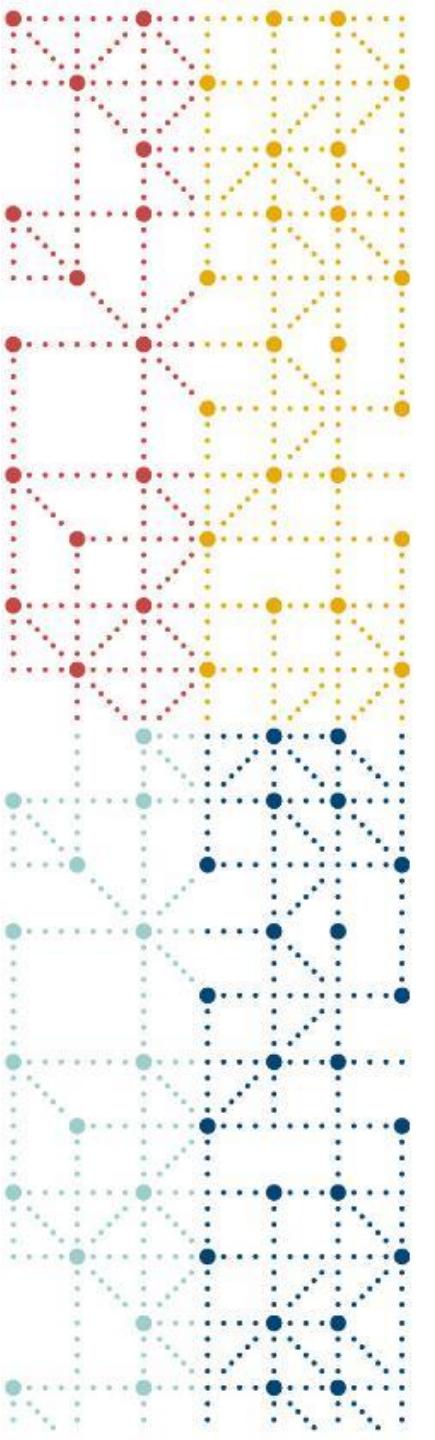
# M11 & USDM



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 *StudyDesign* 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

Client Scope:	Unavailable
Compound Name(s):	Pembrolizumab
	RADVAXTm
Trial Phase:	Phase I
Short Title:	RadVax™: Pembrolizumab & Hypofractionated Radiotherapy
Sponsor Name and Address:	University of Pennsylvania
	Address on File.
Regulatory Agency Identifier:	UPCC# 40914
IRB#:	IRB# 021402
Implementation:	



# **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*



## CDISC Strategic Plan & Roadmap



### Expand & Connect

Expand, Connect, and Digitize Our Standards



### Enable & Automate

Reduce Variability, Enable Interoperability, and Increase Automation



### Engage & Adopt

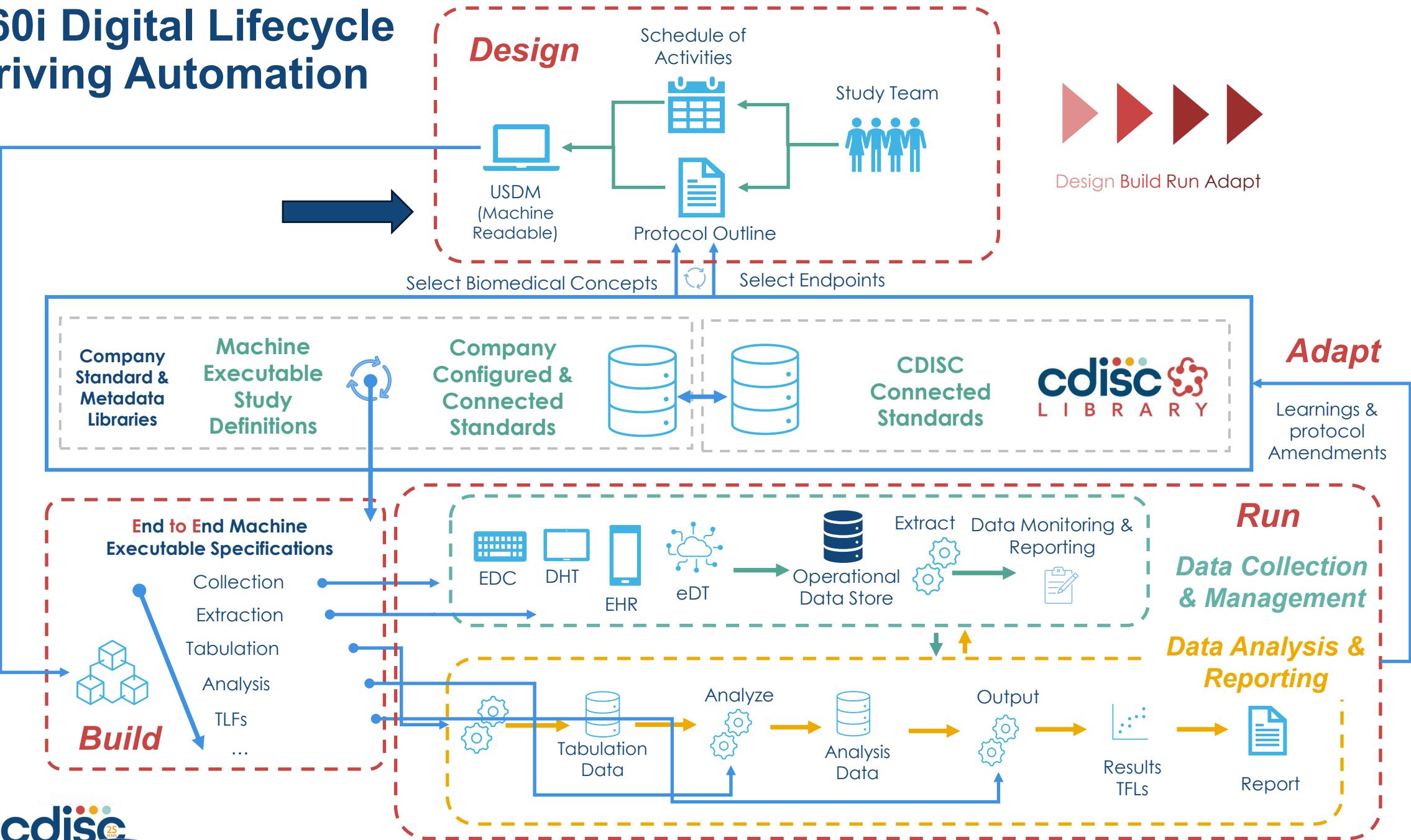
Focus on Community Needs and Deliver Business Value

#### Strategic Goal:

Expand and Enable standards-driven automation across end-to-end study information lifecycle from study design through results.

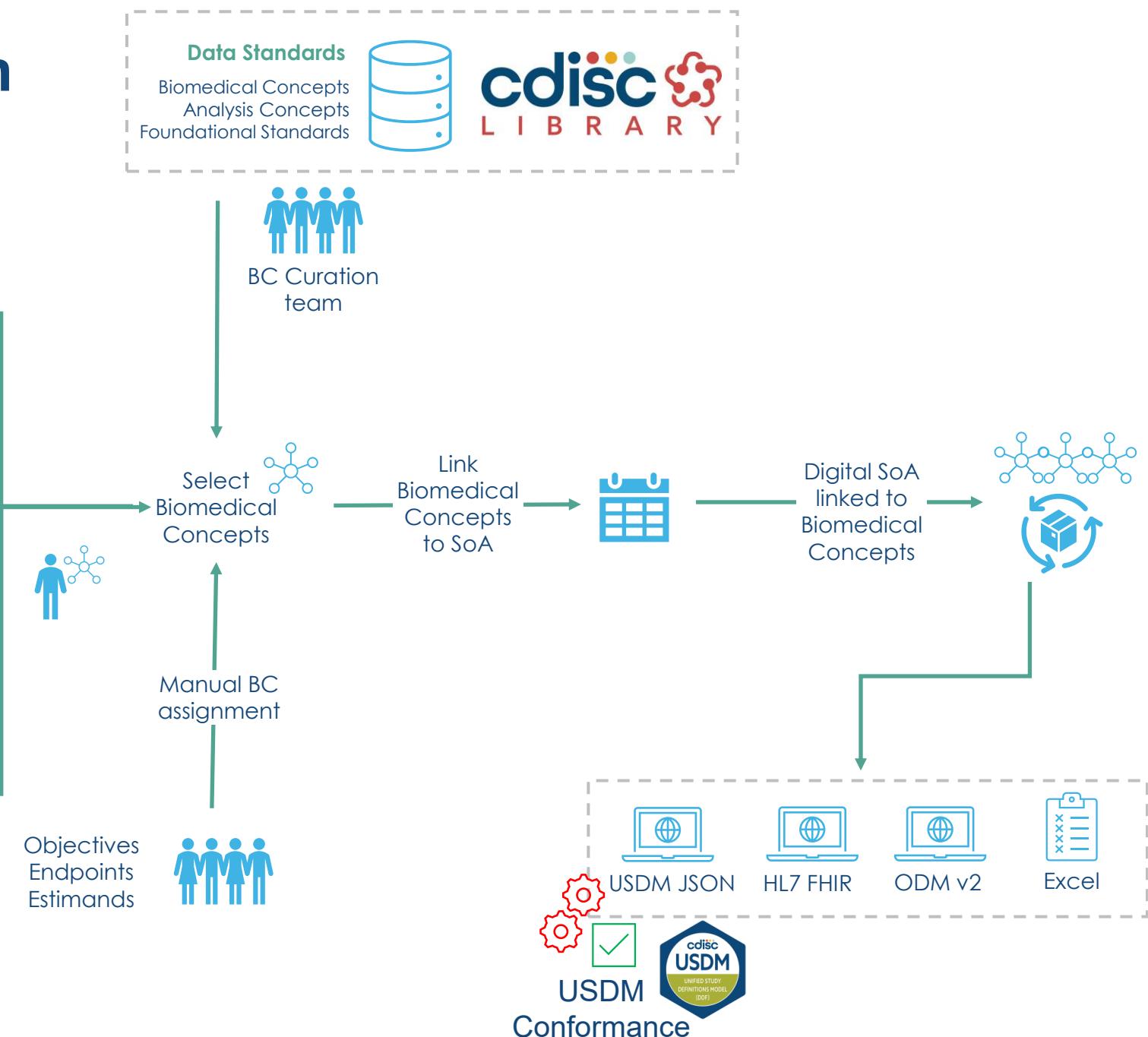
CDISC will expand and realize the original 360 vision.

# 360i Digital Lifecycle Driving Automation

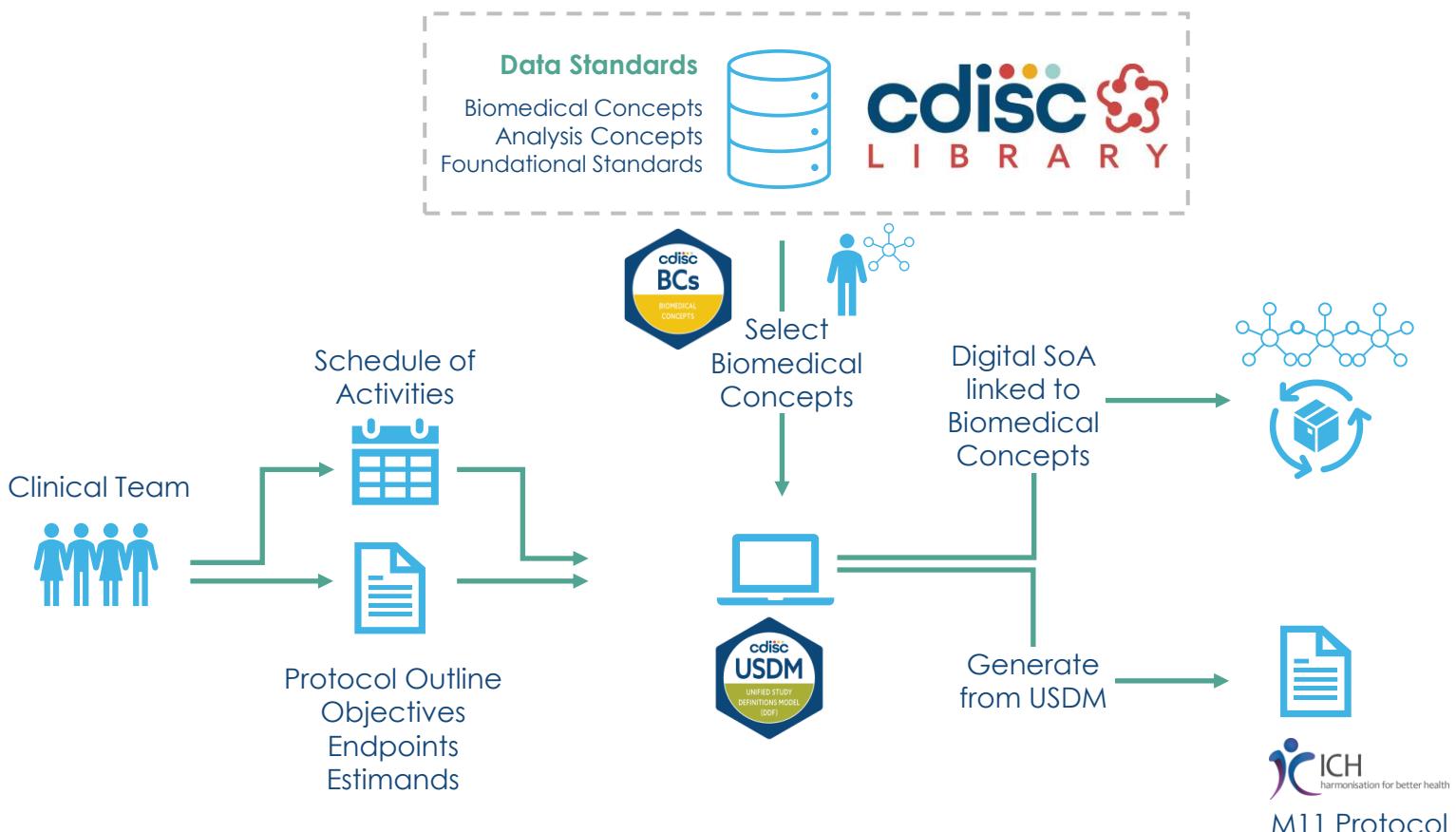


# 360i Study Design

- Safety Assessments**
  - Demography
  - Death Details
  - Adverse Events
    - Overview
    - By SOC and PT
    - By Freq
  - Disposition
  - Change from Baseline Lab
    - Chemistry
    - Hematology
    - Vital Signs
- Safety Assessments**
  - DILI
- Questionnaire**
  - ADAS - COG
- Digital Measure (DHT)**
  - Glucose Monitoring
  - Steps / Movement / Sleep
- Efficacy Endpoint Assessments**
  - Breast Cancer (RECIST)
  - Alzheimer's Disease



# 360i Study Design



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

	WEEK	1	2	3	4	5	7	8	9	10	11	12	13	ET	RT
ACTIVITY															
Informed consent		X													
Patient number assigned		X													
Initial visit		X													
MTM visit 1 to 23		X													
Physical examination		X													
Medical history		X													
Habits		X													
Chest x-ray		X													
Appt 1 (pre-treatment)							X								
Initial blood drawn							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	X
Photos TTS test		X				X									
CT scan (if one within last year and patient passes all other screens)															
Concomitant Medications		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Laboratory (Chem/Hemat)		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Laboratory (Microbiology)						X									
Plasma Specimens (Xnomelaine)						X	X	X	X	X	X	X	X	X	X
Hemoglobin A <sub>1c</sub>						X									
Study drug record							X	X	X	X	X	X	X	X	X
Medication dispensed							X								
Medication returned							X								
TTS Acceptability Survey														X	X
ADAS-Cog		P	X											X	X
CBIC <sup>c</sup>		P	X											X	X
DAD		P	X											X	X
EPP-X		P	X	X	X	X	X	X	X	X	X	X	X	X	X
Adverse events		X	X	X	X	X	X	X	X	X	X	X	X	X	X

Abbreviations: CT = computed tomography; ECG = electrocardiogram  
X = Performed at this visit.  
X\* = Performed at this visit if patient is an industry-dependent participant.  
X# = Performed at this visit if patient is an industry-dependent participant 2 weeks following this visit.  
P = Practice only: it is recommended that a sampling of the CBIC<sup>c</sup>, ADAS-Cog, DAD, and NPS-X is administered at Visit 1. Data from this sampling will not be considered as study data and would not be collected.

Abbreviations: CT = computed tomography; ECG = electrocardiogram  
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## Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease

### 1. Introduction

The M<sub>1</sub> muscarinic-cholinergic receptor is one of five characterized muscarinic-cholinergic receptor subtypes (Fisher and Barak 1994). M<sub>1</sub> 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 antinmrtor 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<sub>1</sub> agonist which has shown high affinity for the M<sub>1</sub> receptor subtype (in transfected cells), and substantially less or no affinity for other muscarinic subtypes. Positron emission tomography (PET) studies of <sup>11</sup>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



Digital SoA

## Safety Assessments

- Demography
- Death Details
- Adverse Events
  - Overview
  - By SOC and PT
  - By Freq
- Disposition
- Change from Baseline Lab
  - Chemistry
  - Hematology
  - Vital Signs

## Safety Assessments

- DILI

## Questionnaire

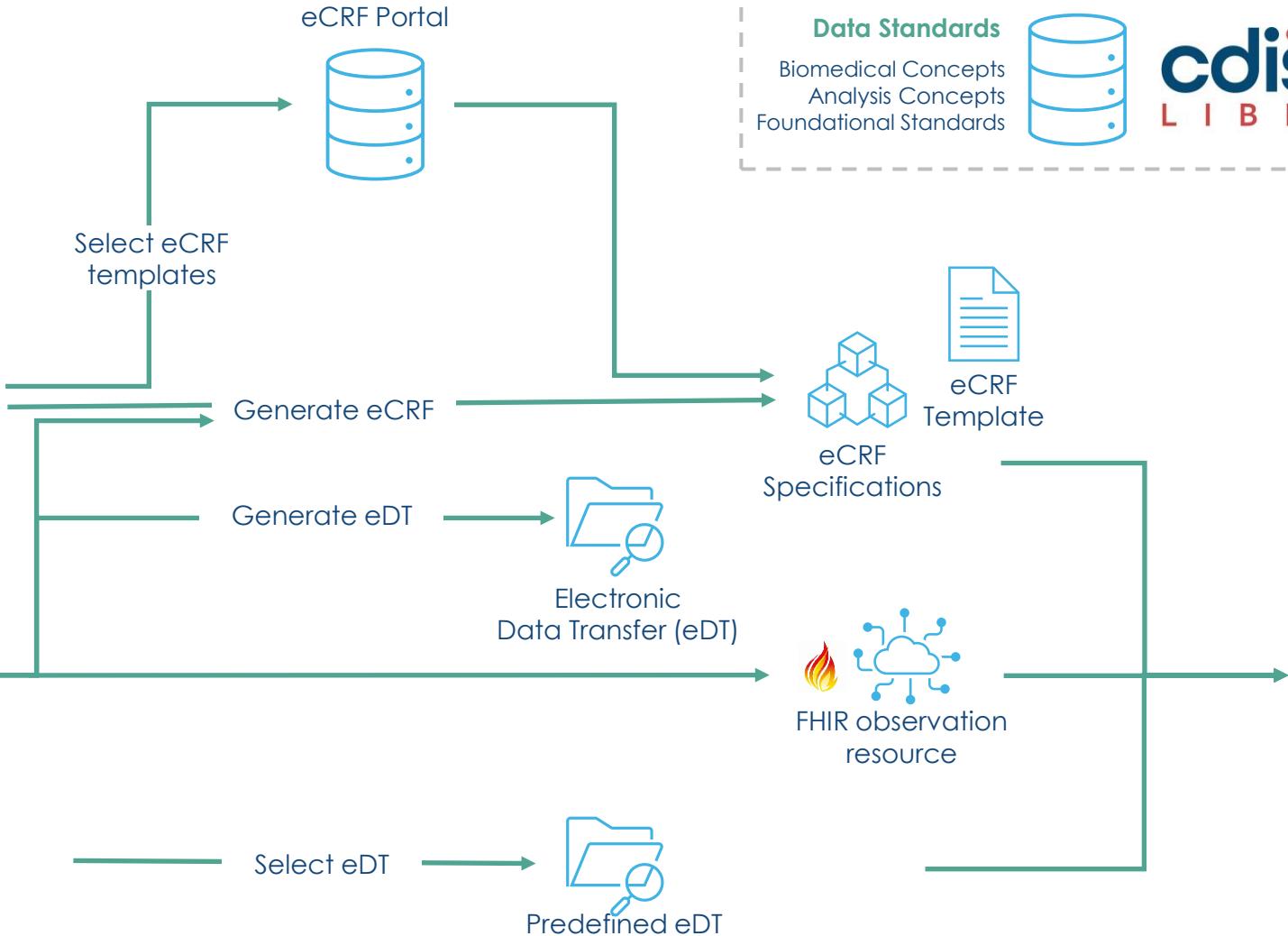
- ADAS - COG

## Digital Measure (DHT)

- Glucose Monitoring
- Steps / Movement / Sleep

## Efficacy Endpoint Assessments

- Breast Cancer (RECIST)
- Alzheimer's Disease



**Data Standards**  
Biomedical Concepts  
Analysis Concepts  
Foundational Standards



# Open Rules

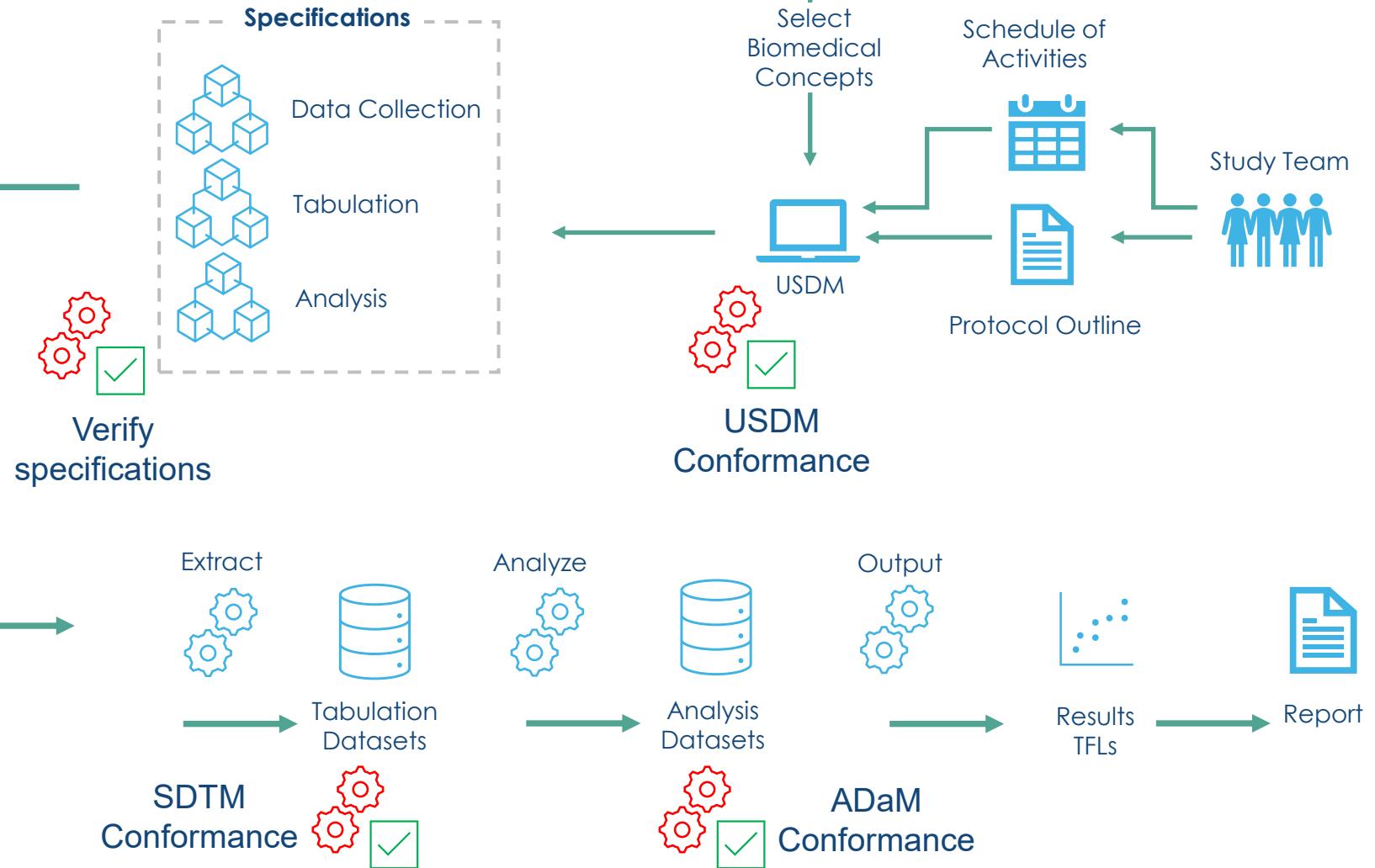


Data Standards

Biomedical Concepts  
Analysis Concepts  
Foundational Standards

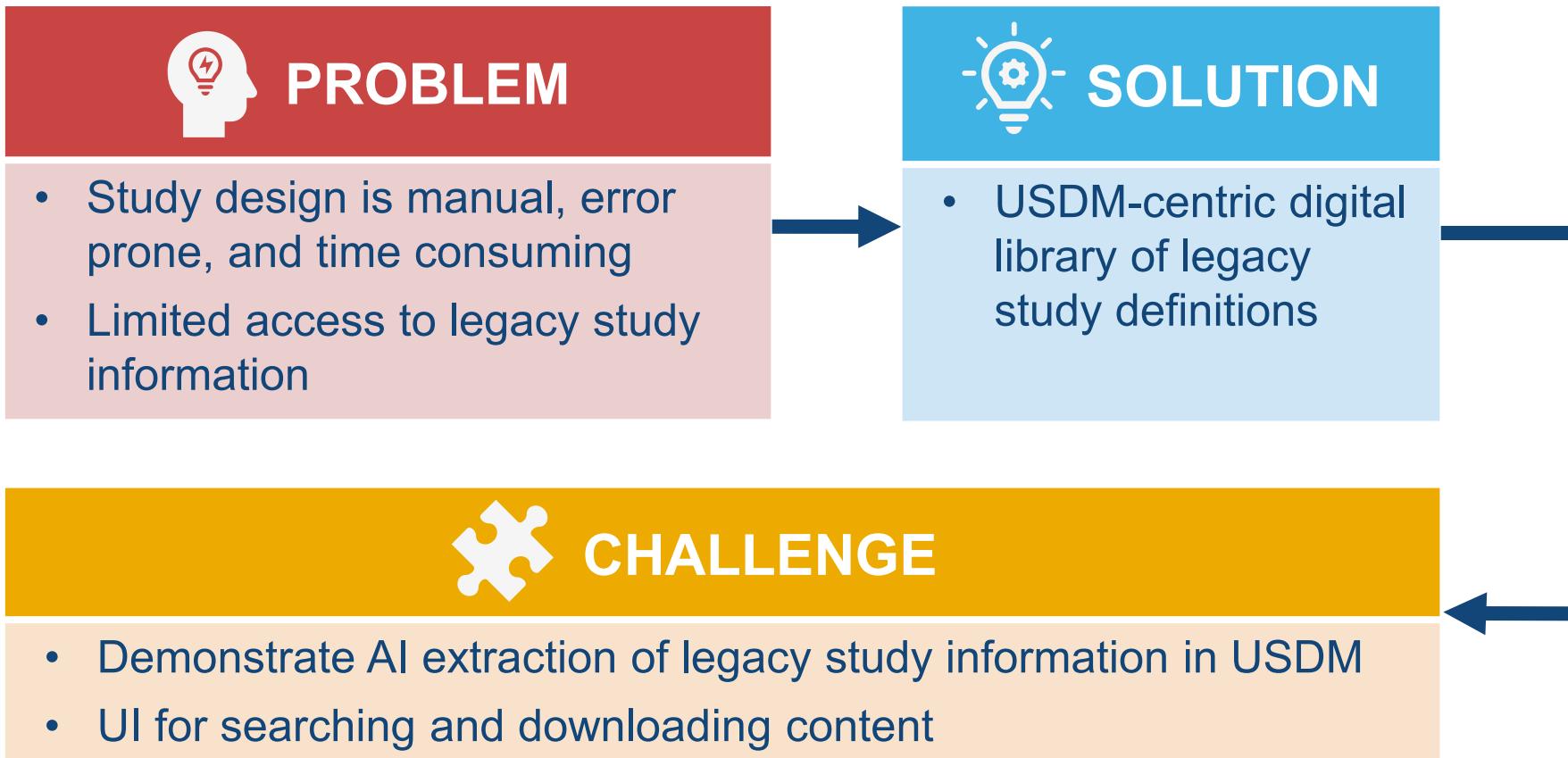


## Data Sources

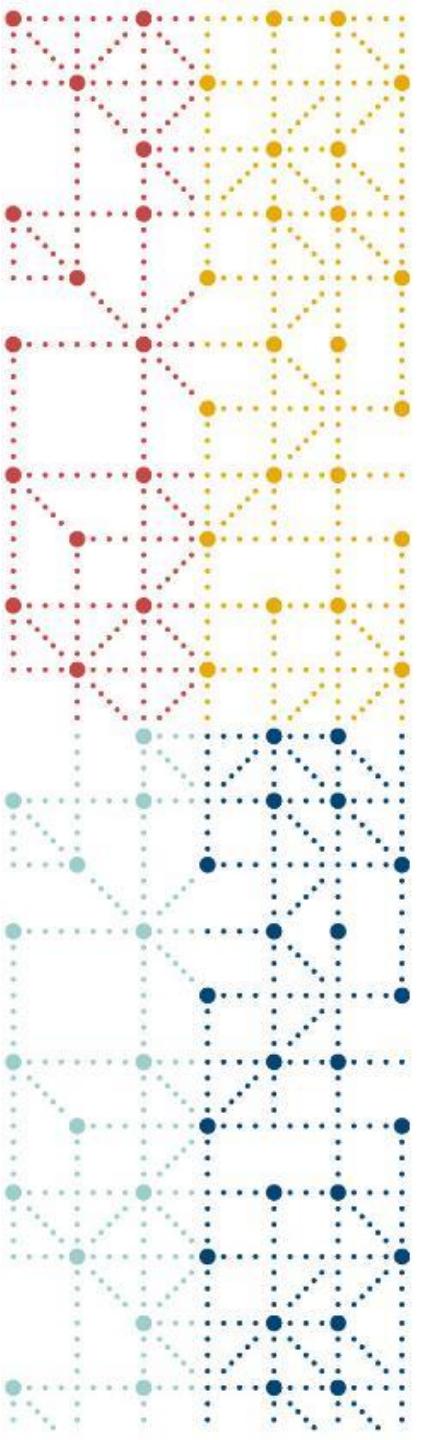


# CDISC AI Innovation Challenge: Protocol Library

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.**

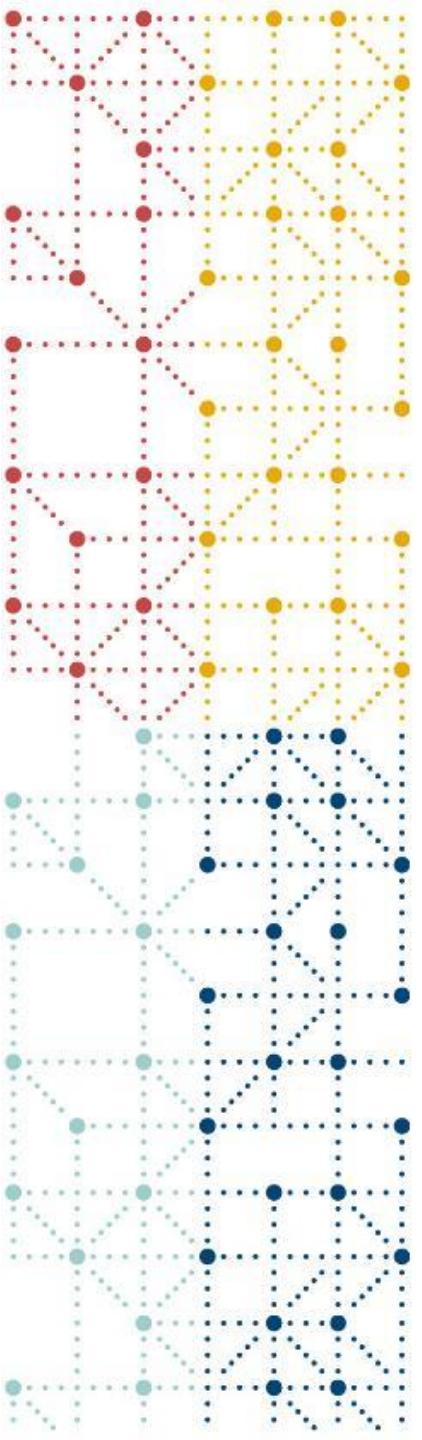
Leverage use cases and corresponding requirements sessions tailored to your company's specific needs.

**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!**





# Catalyzing Connections to Amplify Impact



## Wafaa Jabert

Merck KGaA

Head of Clinical Data  
Standards and Integration



## Mary Lynn Mercado

Novartis

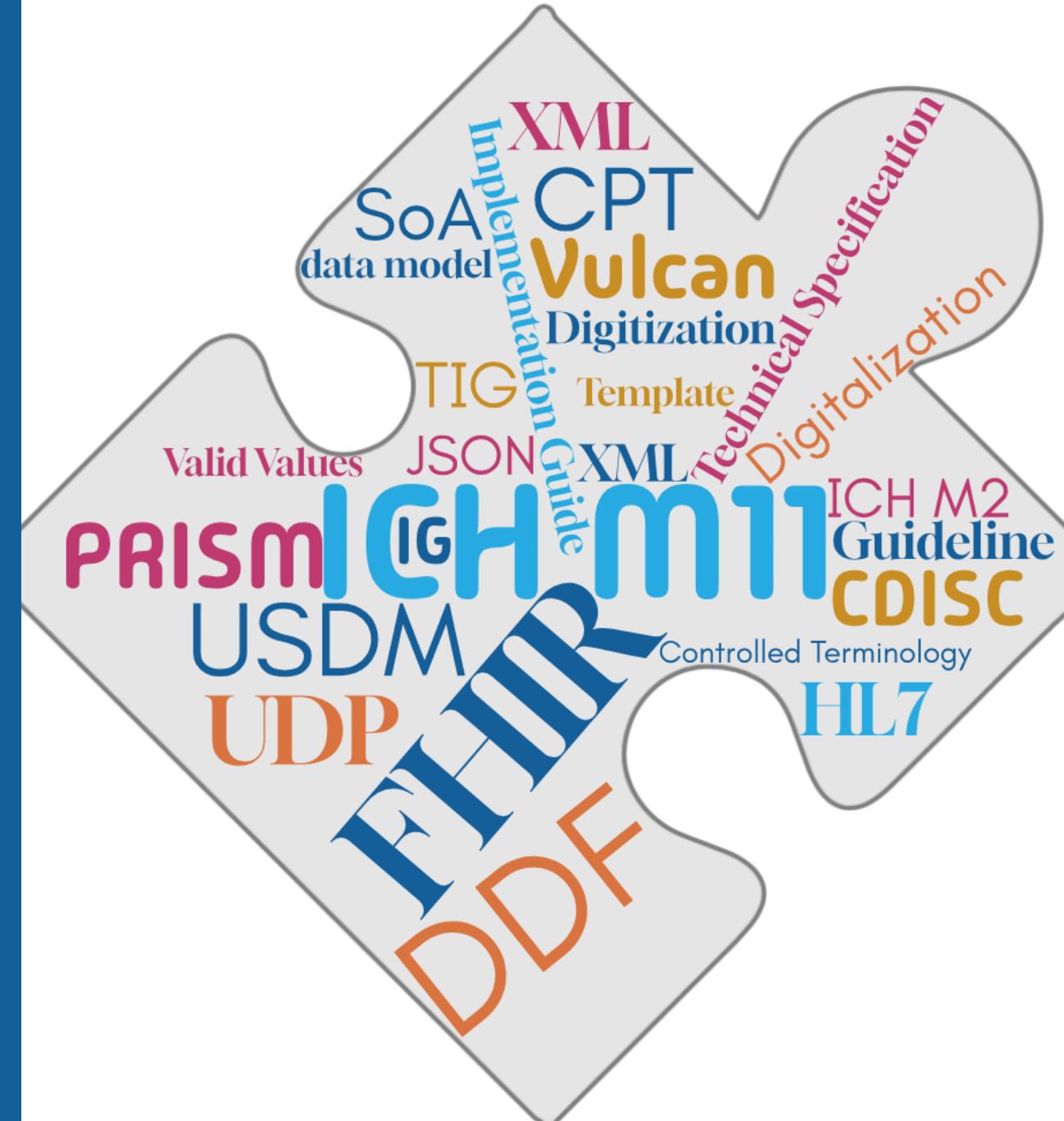
TransCelerate Digital Protocol Engagement  
Lead

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

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

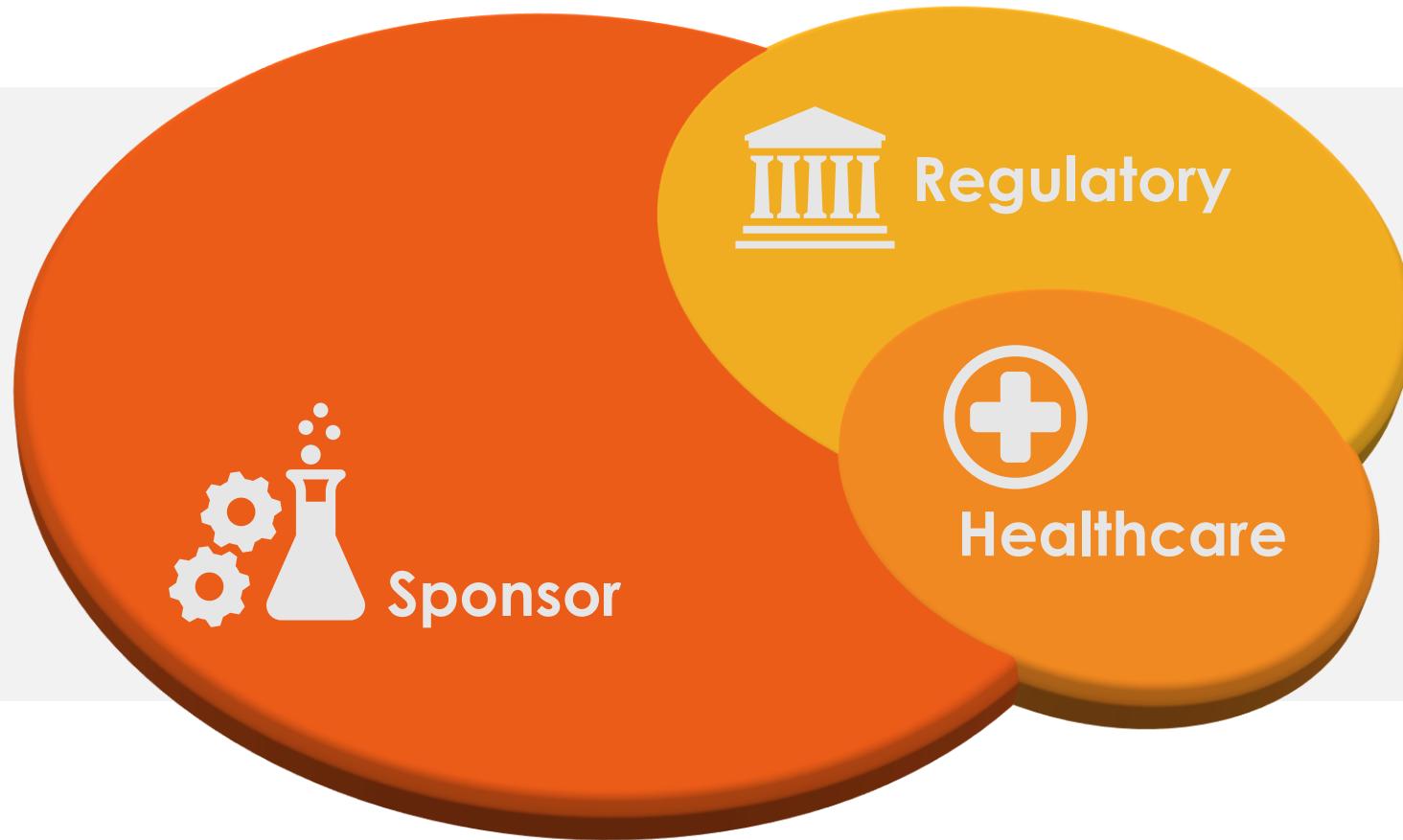
**Aim 1:** Expand collaboration across protocol-related initiatives and pursue compatibility of solutions to accelerate implementation and amplify value of digital protocols.

**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.



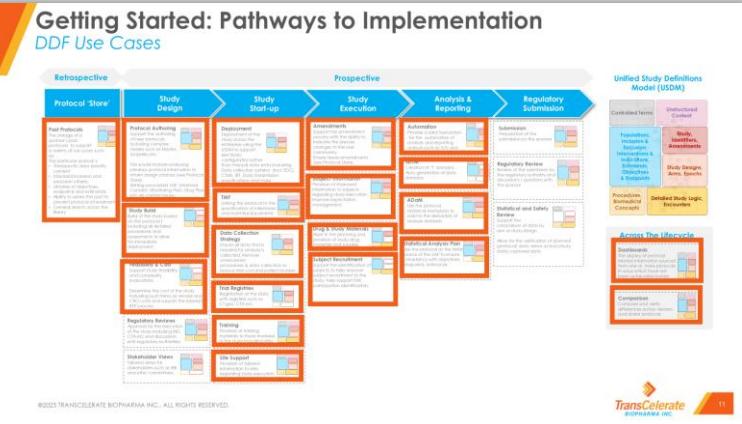
# Digital Protocols Across Domains

*Significant opportunity in the overlap*

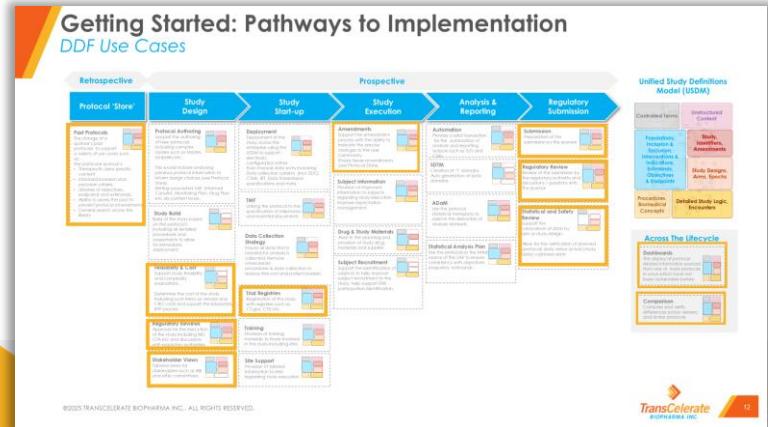
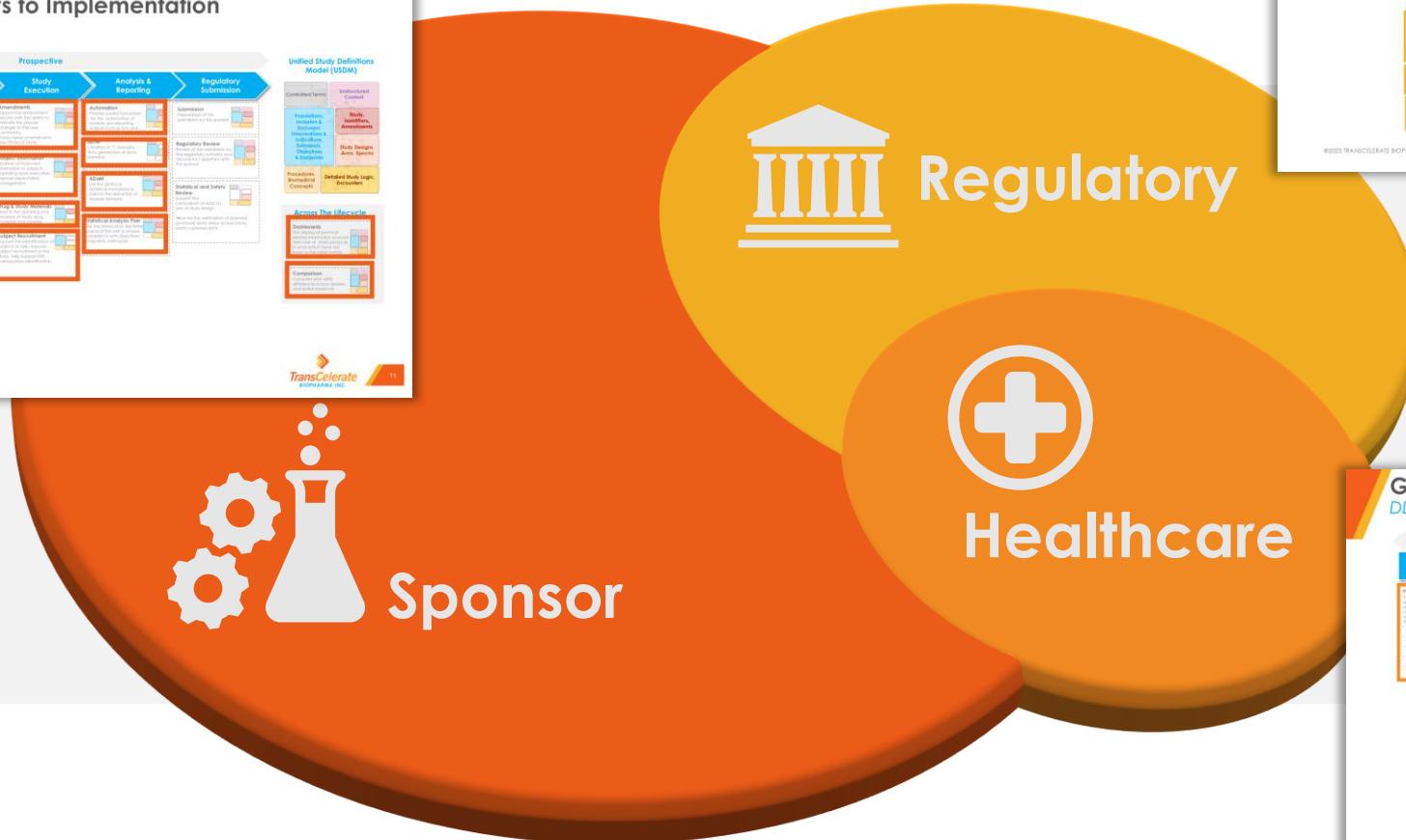


# Use Cases and Building Blocks

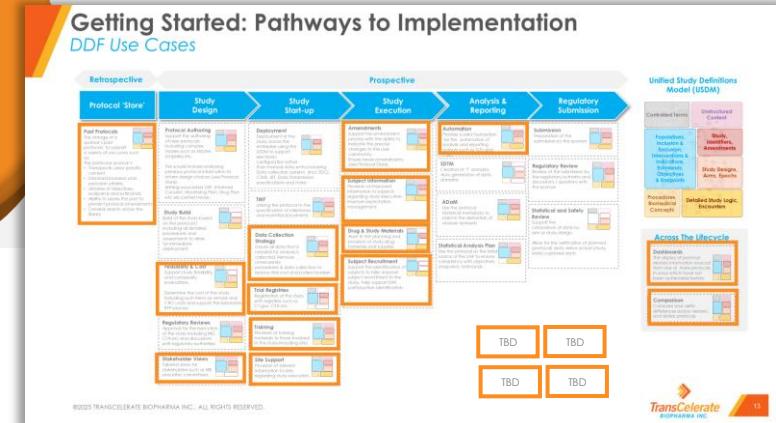
## Diverse drivers and perspectives



- CPT
- ICH M11
- USDM



- ICH M11
- USDM
- FHIR



- FHIR

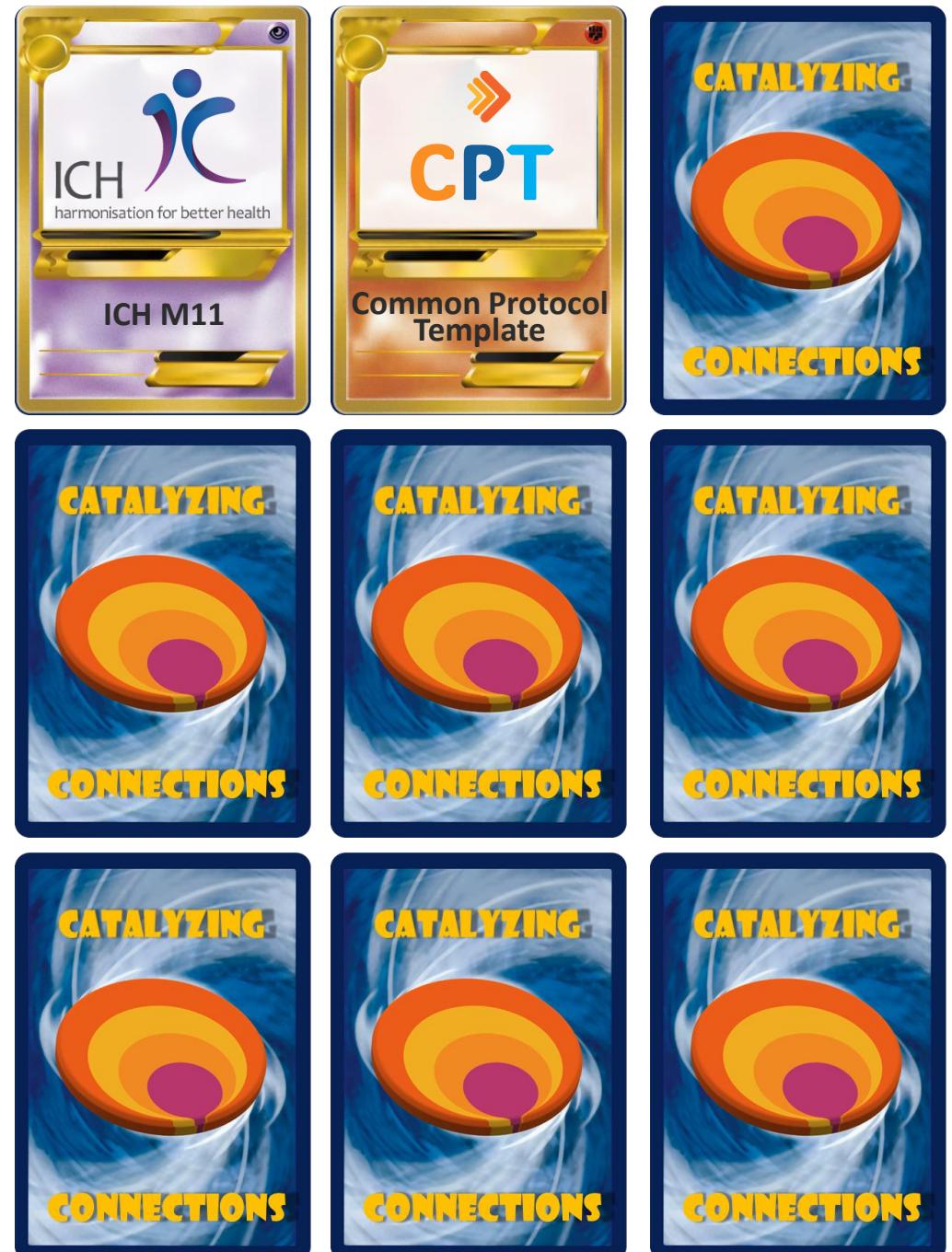
# Collaboration, Compatibility, and Convergence Will Put Patients at the Center



# Catalyzing Connections



# Catalyzing Connections





# ICH M11 and CPT

## *Content Alignment and Requirements for Digitization*



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

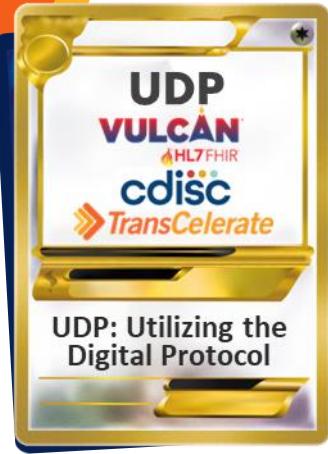
Global, harmonized clinical trial protocol with requirements for digital trial design elements	<b>Aim</b>	Common structure and model language, demonstrates possibilities for content reuse and digitization
Regulator	<b>Audience</b>	Investigator
Protocol outline with supporting instruction & minimal sample text, Guideline technical specifications defining requirements for protocol digitization	<b>Outputs</b>	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	<b>Regions</b>	Addresses global requirements & regional content requirements

**CPT is an implementable, customizable template**

**COMING SOON:  
CPT aligned to Draft M11**

# 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 <ul style="list-style-type: none"><li>- Content organized according to ICH M11</li><li>- Structured elements adhering to USDM</li><li>- Exchange in HL7 FHIR</li></ul>
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. <b>Use Case #1:</b> 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

# 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

# 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

# ICH M11 Development Testing

## Windows into Implementation Readiness



 COMING SOON

Testing opportunity for TransCelerate Member Companies in Q4



# Catalyzing Connections





# Adoption Stories



# Adoption Stories



**Noeleen Turner**

UCB

Adoption Stories Moderator

Head of Clinical Data  
Management



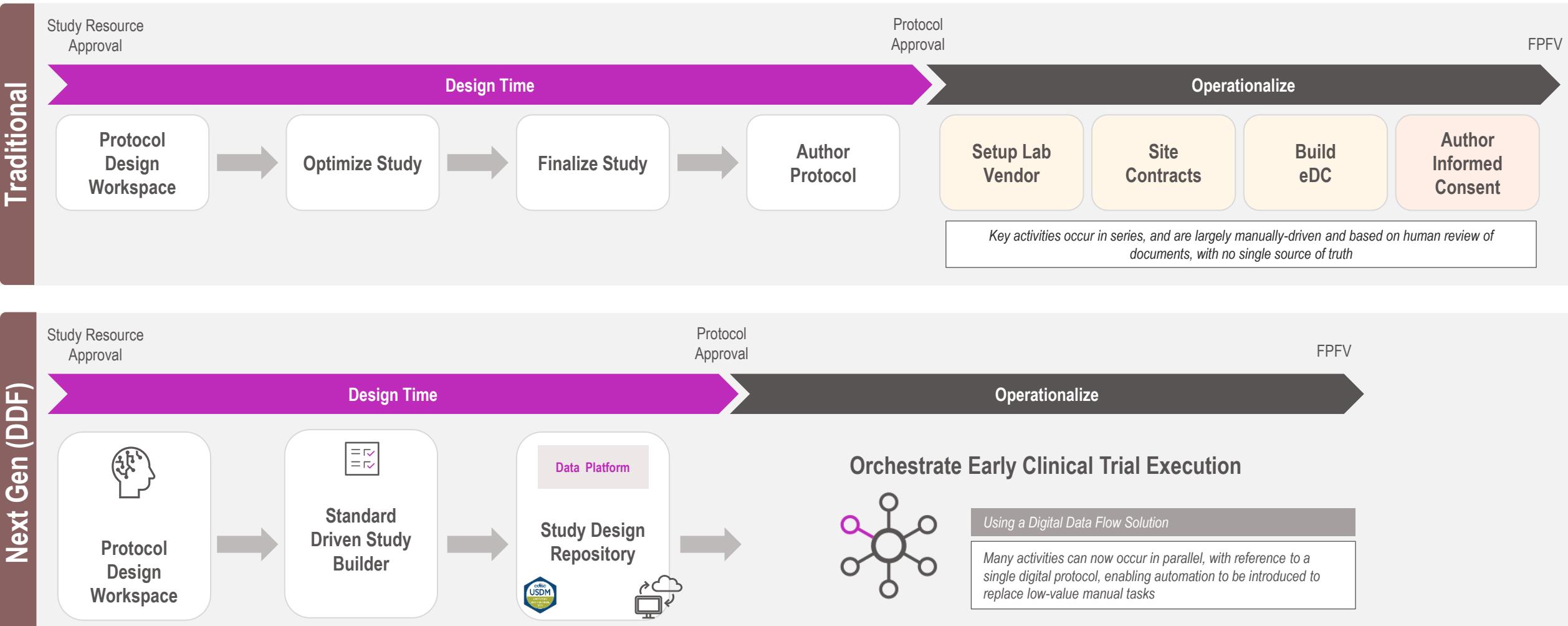
# Adoption Story from a Biopharmaceutical Organization

A woman in a white leotard is shown in mid-stride, running away from a massive, dark stack of papers that are flying off her back like a comet's tail. She is moving towards a bright, glowing tunnel composed of swirling blue binary code (0s and 1s). The background is a dark, textured surface.

**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



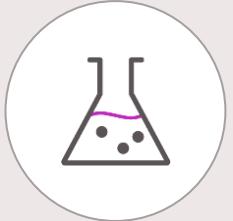
## Early Insights

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



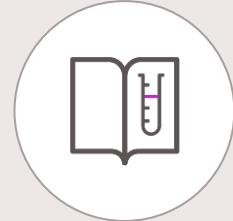
## Specimen Generation Plan

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**



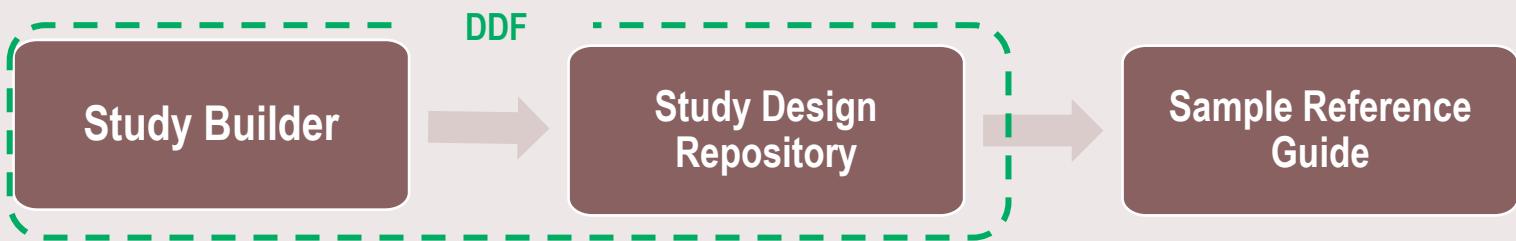
Digitized Plan captures detail and variability like never before



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

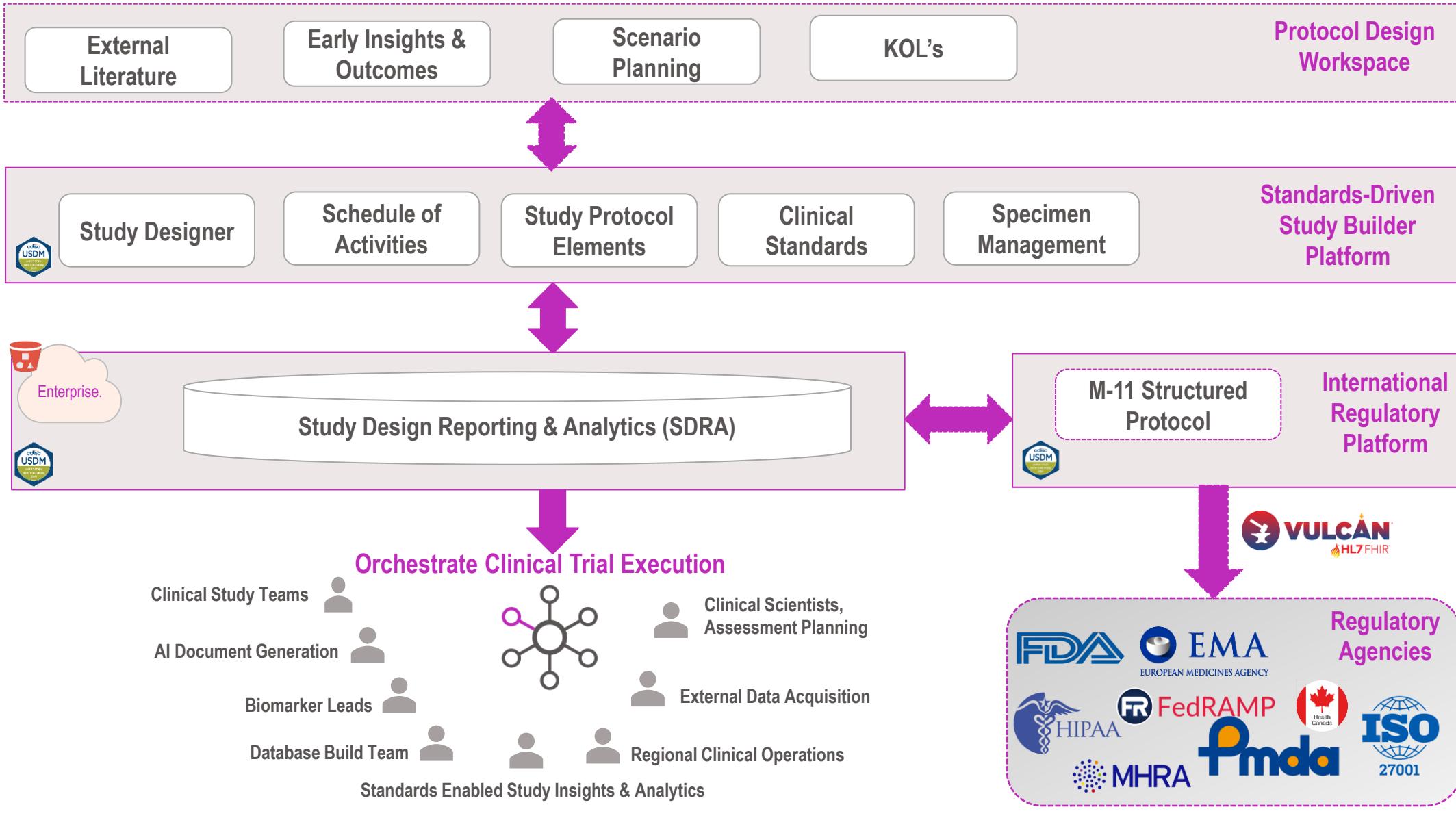


Higher Consistency  
Across Data Specification Package



Automated Data Specification Package Creation

# Conceptual Overview



# 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

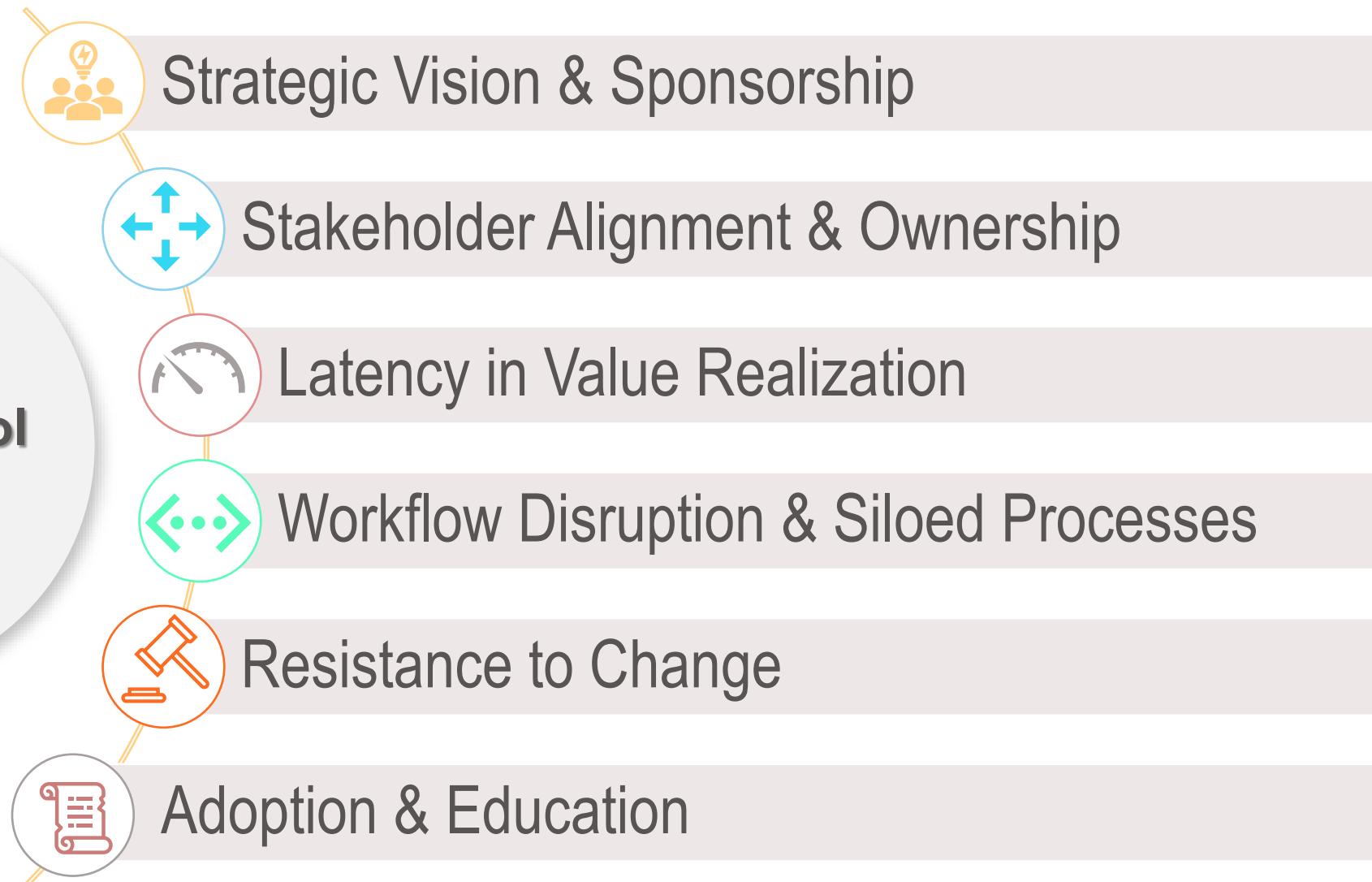


Faster Study Start-Up and Execution via enhanced data integration & reuse



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

---

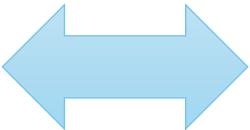
How many variations of this inclusion criteria do you think we have across **35** protocols for the same product?

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

32

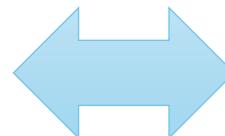
# Summary of the use case

## Integrated Data Journey: From Study Concept to CRF



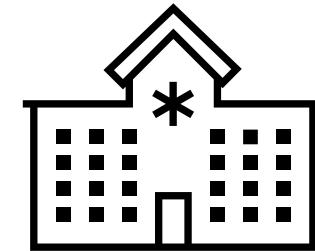
Visit	1	2	3 (3-10 days)
Consent	X		
PSA blood test	X		
Questionnaires Pack 1 (IPSS, IPSS-QoL, IIEF-15, EPIC-urinary, EPIC bowel, EQ-5D QoL)	X		X
Questionnaires Pack 2 (FACT-P, MAX-PC)	X		X

Clinical Document generation using a structured content authoring tool

A screenshot of a 'CASE REPORT FORM' for 'Invasive Pneumococcal Disease'. It includes sections for 'Reporting Authority', 'Notifier Identification', 'Case Identification', and contact information.

Creation of machine-readable format schedule of activity

Linkage of CRFs to visits and activities

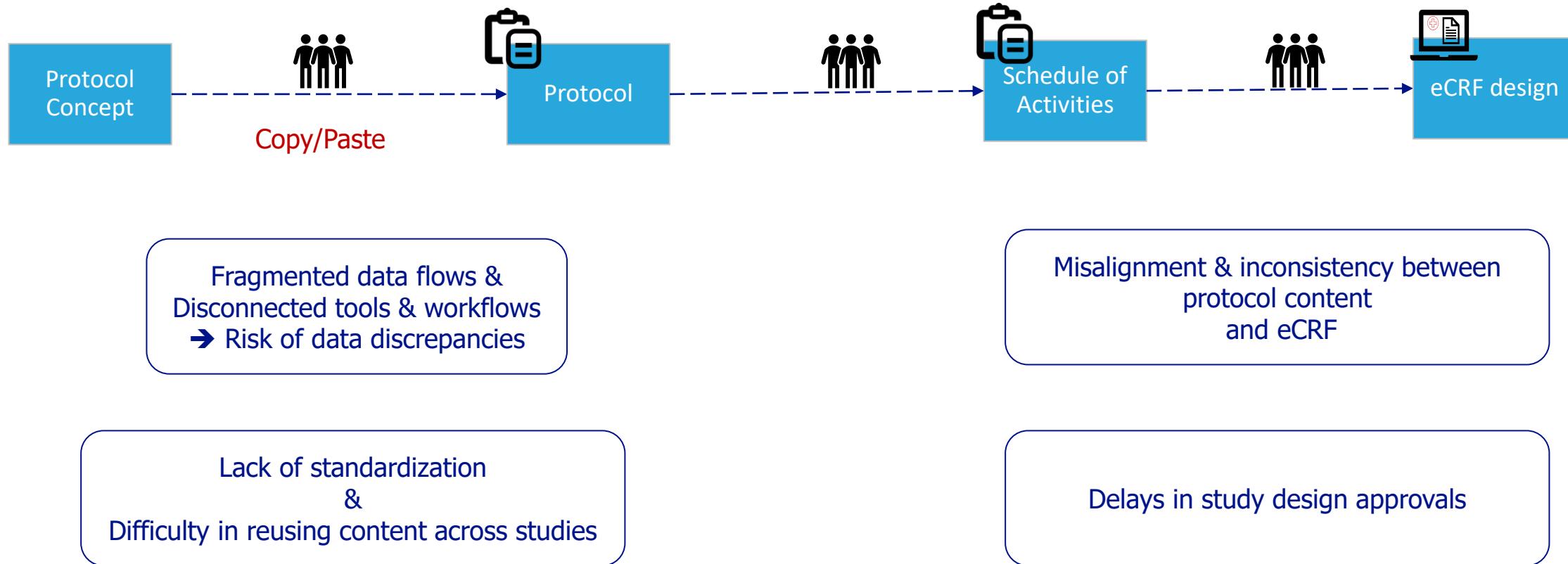


Clinical Data Collection



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

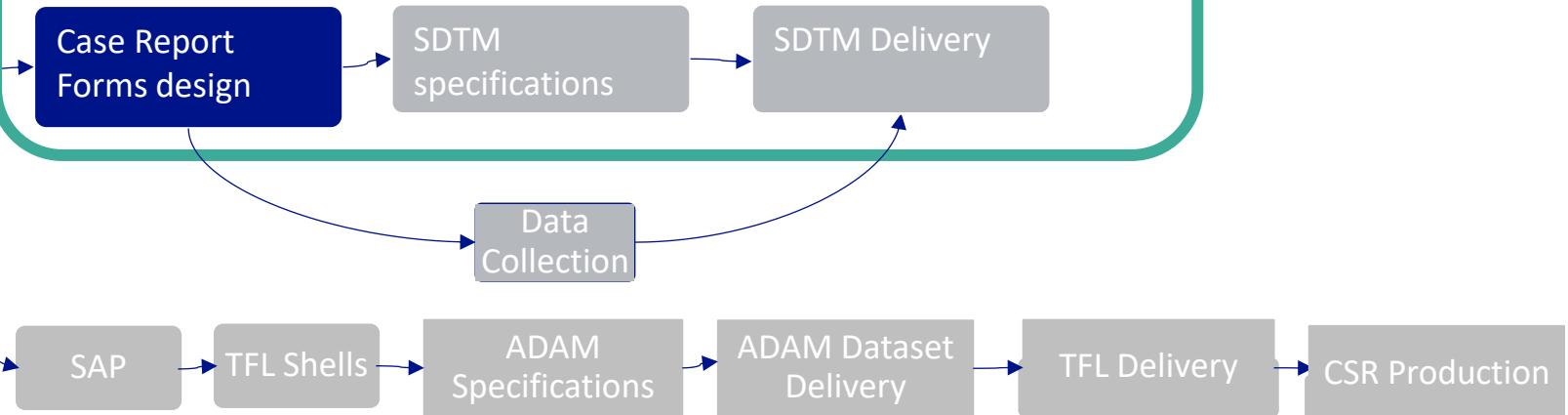


# Integrated Data Journey: use case focus & benefits

## Bespoke Structured Content Authoring tool



## Metadata Repository

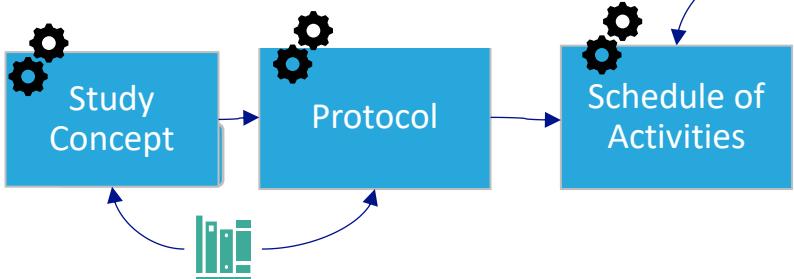


# Integrated Data Journey: use case focus & benefits

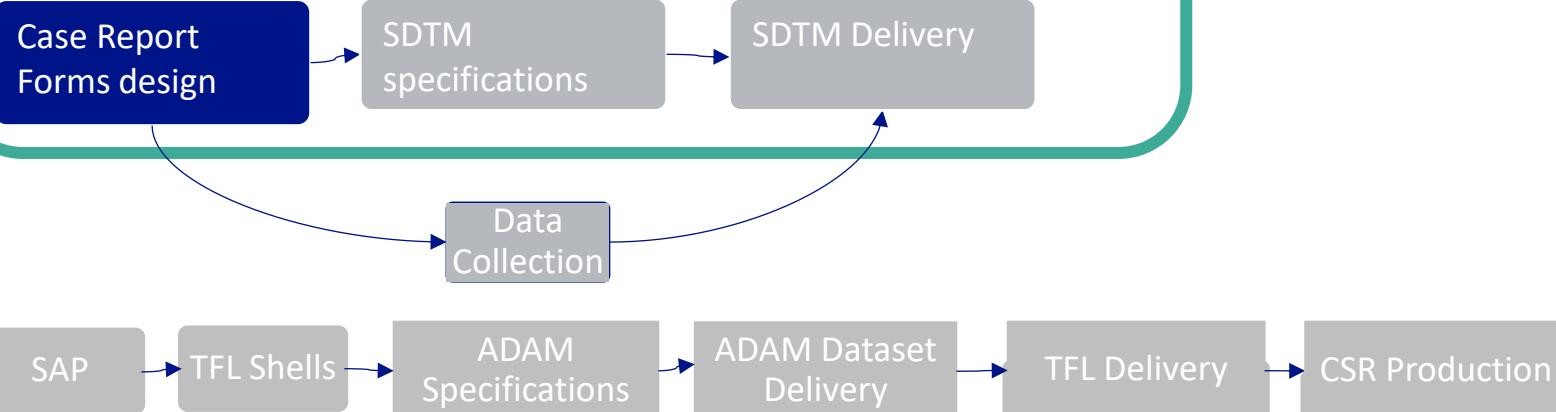
## Bespoke Structured Content

### Authoring tool

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



## Metadata Repository

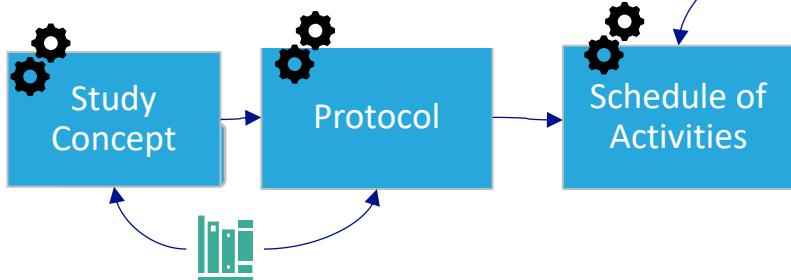


# Integrated Data Journey: use case focus & benefits

## Bespoke Structured Content

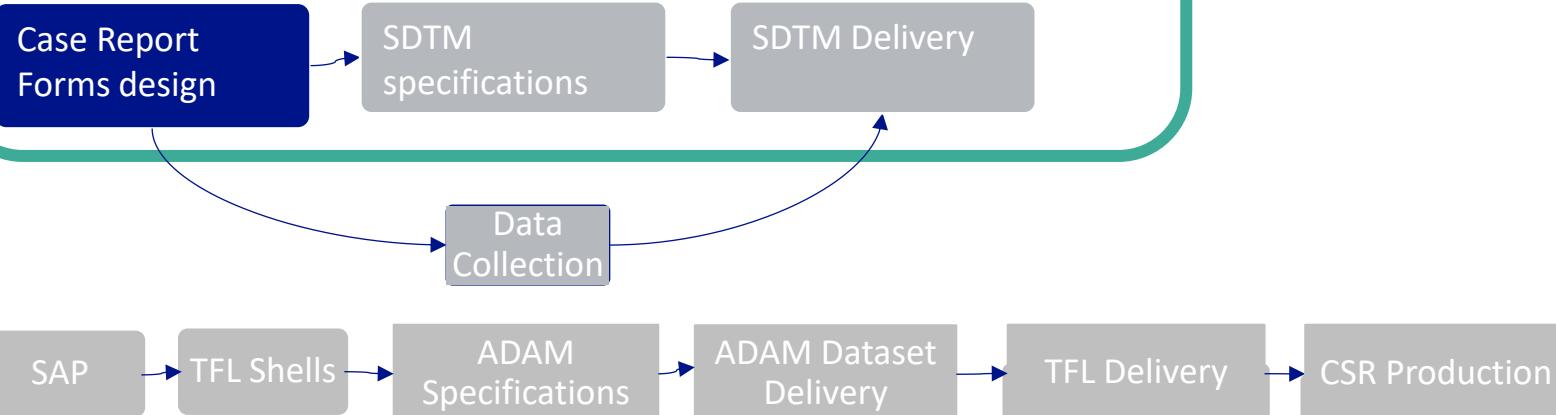
### Authoring tool

- Accelerates Study Start-Up
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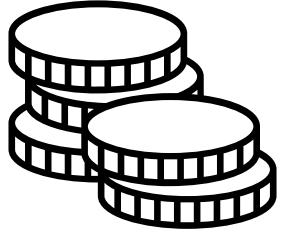


## Metadata Repository

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



# Implementing this use case wasn't easy... Main challenges



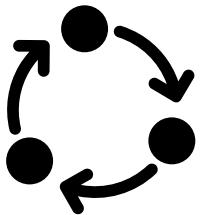
## Cost Justification and Return On Investment

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



## An idea is born...

Identified a proof-of-concept projects for structured content authoring.

This is the extension of a bespoke risk-management platform

2019

2020

2021

2022

2023

2024

2025



Extension of other functionalities for a more integrated clinical platform



Extension of other functionalities for a more integrated clinical platform



Adaptation of Structured Content authoring to new document templates



The first version of structured content authoring is live



Second release for structured content authoring including content reuse



Extension of other functionalities for a more integrated clinical platform



# Adoption Story from a Biopharmaceutical Organization

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

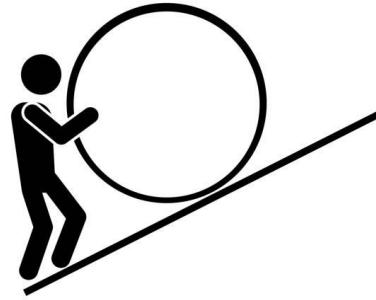
# Have we improved clinical trial design and execution?



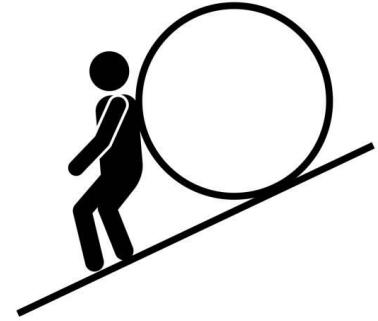
**Process**



**Consistency**



**Standardization**



**Compliance**

# Industry Challenges



- I. 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/>

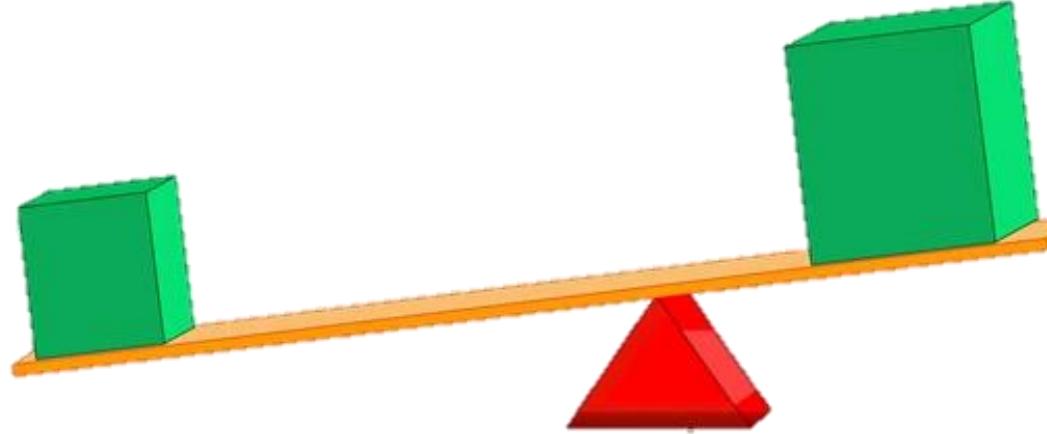
**Is automation and AI the magical potion that will solve all our industry's problems?**



**What is the Recipe for Success?**

# Widely Used/Typical Recipe in the Industry

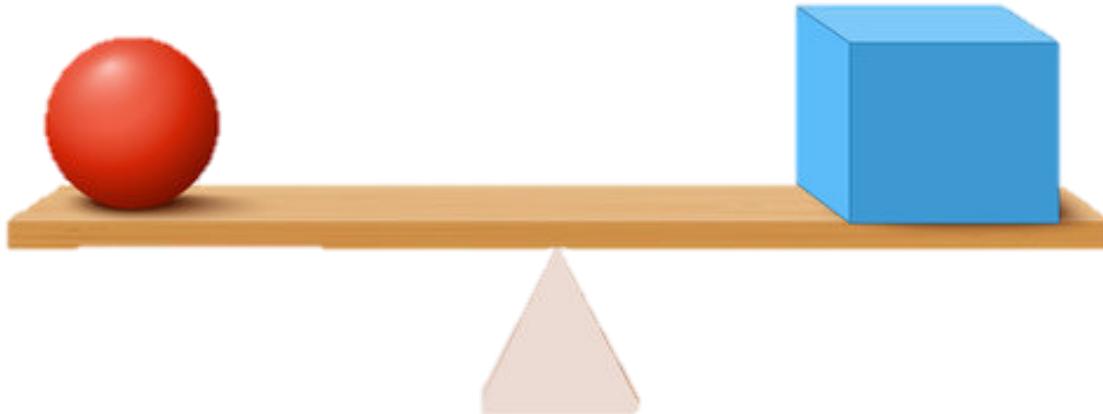
**Industry Strategy:**  
**AI/ML (discrete, siloed  
by document type)**



**Content/data  
Standardization**

# Recipe for Success

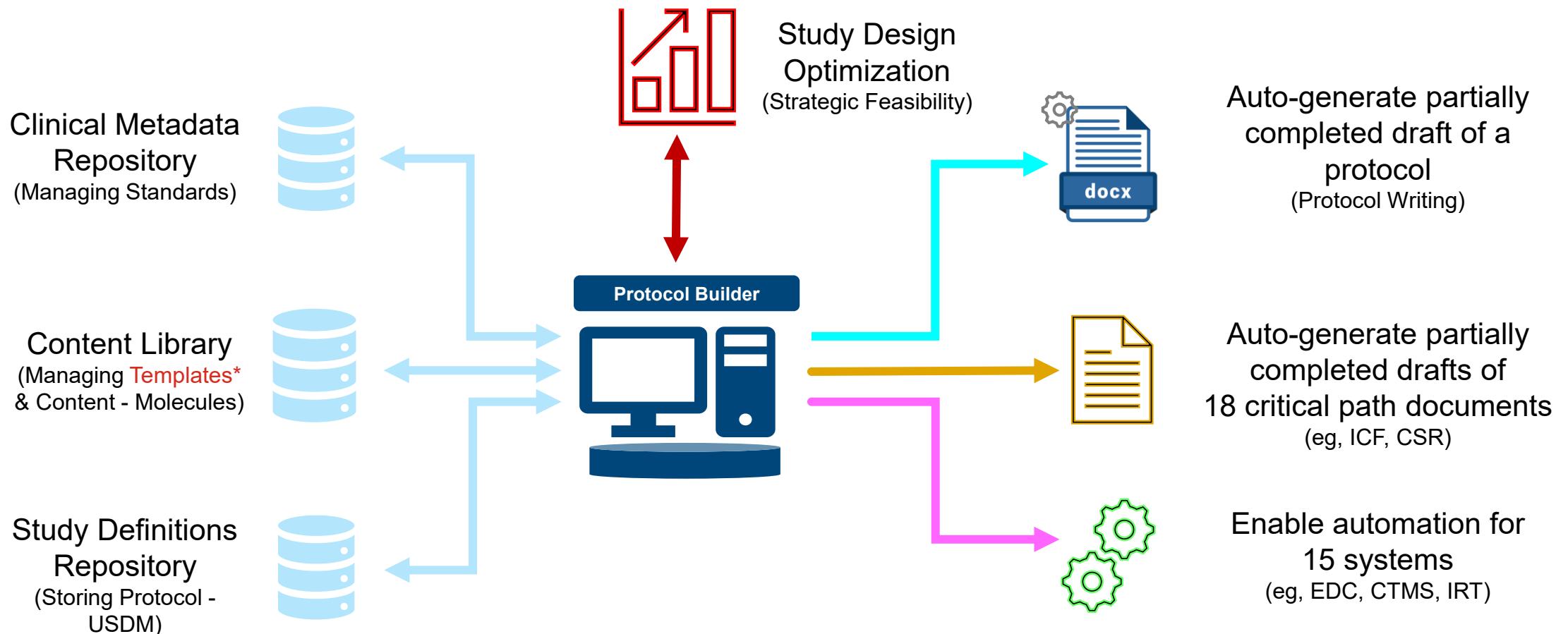
**BeOne Strategy:**  
AI/ML (disruptive,  
CCR connectivity)



**Content/data  
Standardization +  
Development Data  
Flow  
+  
Building Repository**

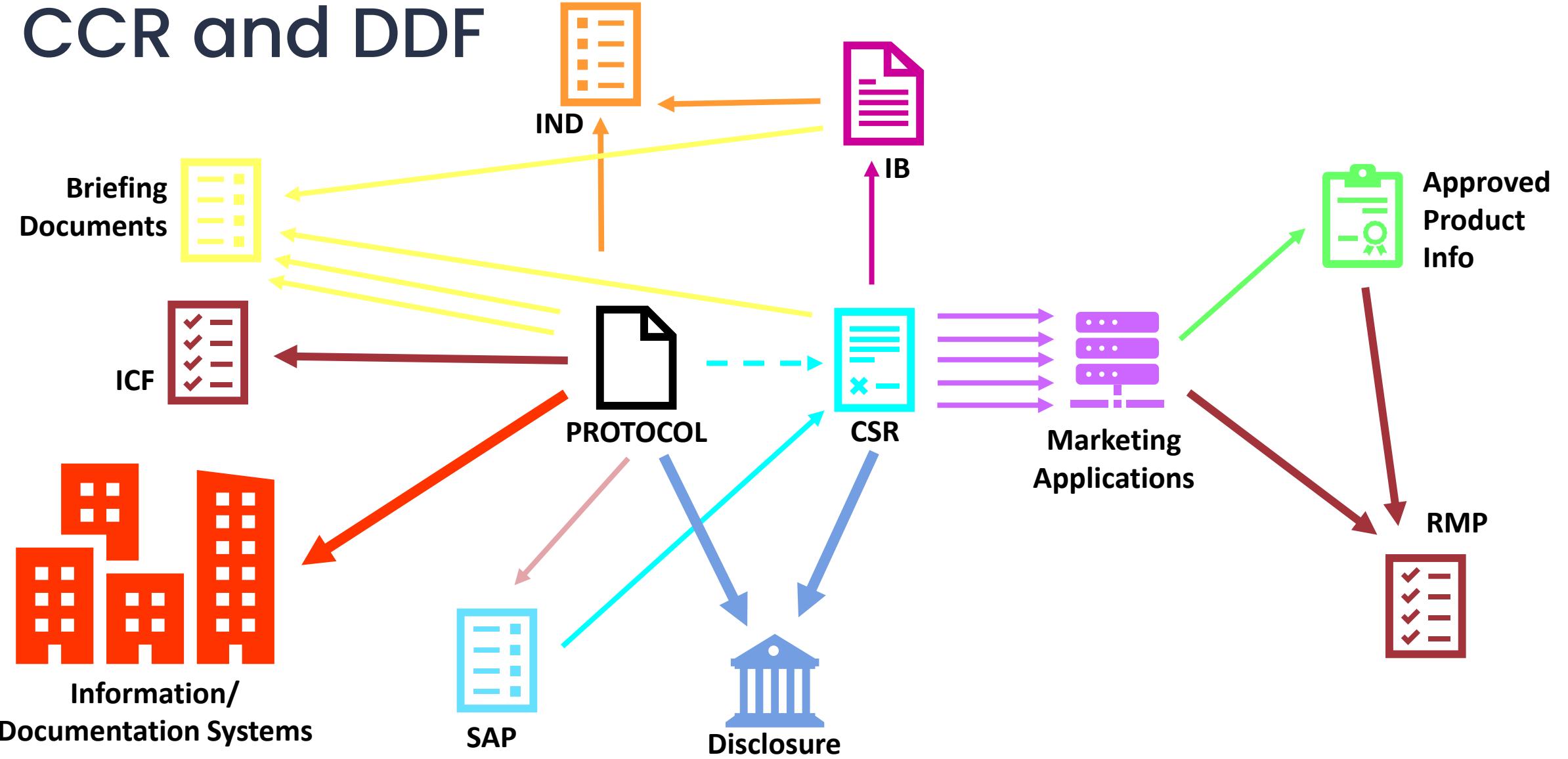
*BeOne adoption: Looking ahead to ~18 documents and multiple systems*

# Protocol Builder Vision



\*Template\_Protocol based on TransCelerate Common Protocol Template (CPT)

# CCR and DDF



Networking effect

Productivity improvement (time & resource)

Better quality (consistency)

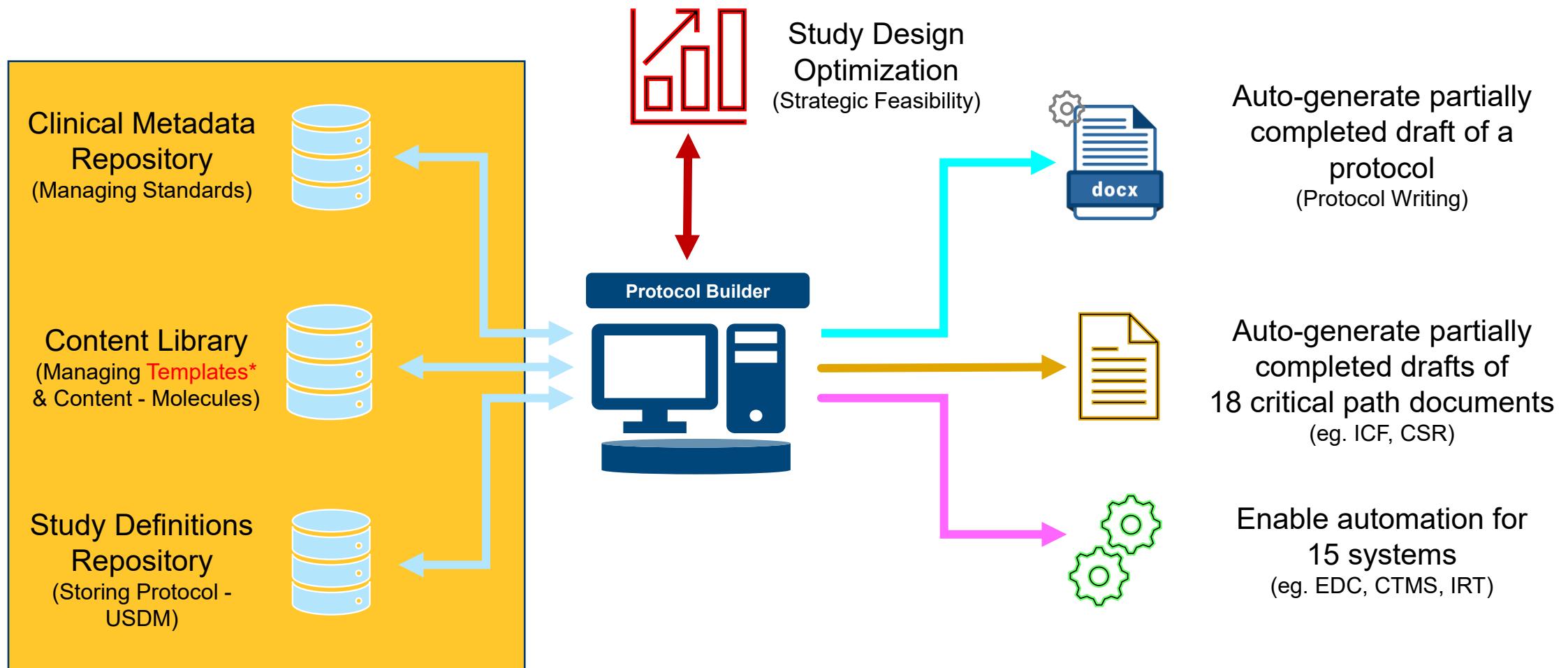
# Value of Clinical Content Reuse (CCR): Documents and Systems

Document Type	Information/Documentation Systems
IB/IB updated	Electronic documentation systems
Original protocol, protocol amendment	CTMS, IRT
CSR (all types)	EDC
Module 2 and other documents to support IND, NDA, BLA	Safety reporting system
ADR, safety reports	CT.gov, Sponsor → Science → Clinical-Trials
Briefing documents	Learning systems
Pediatric documents	Finance platforms
RMP	

Understanding the volume and complexity

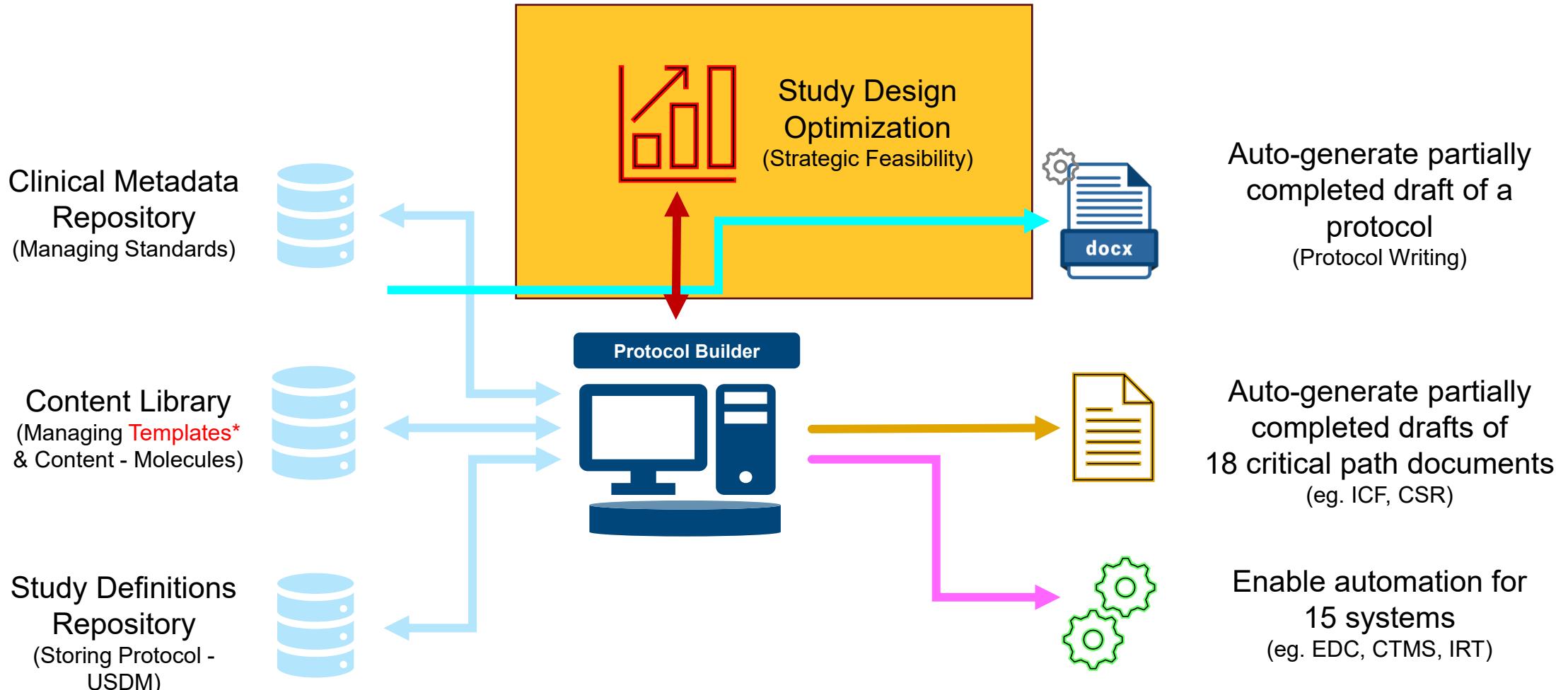
Exponential Value of CCR = (~18 critical document types) x (~15 key systems) x (No. of Users)

# Protocol Builder Vision



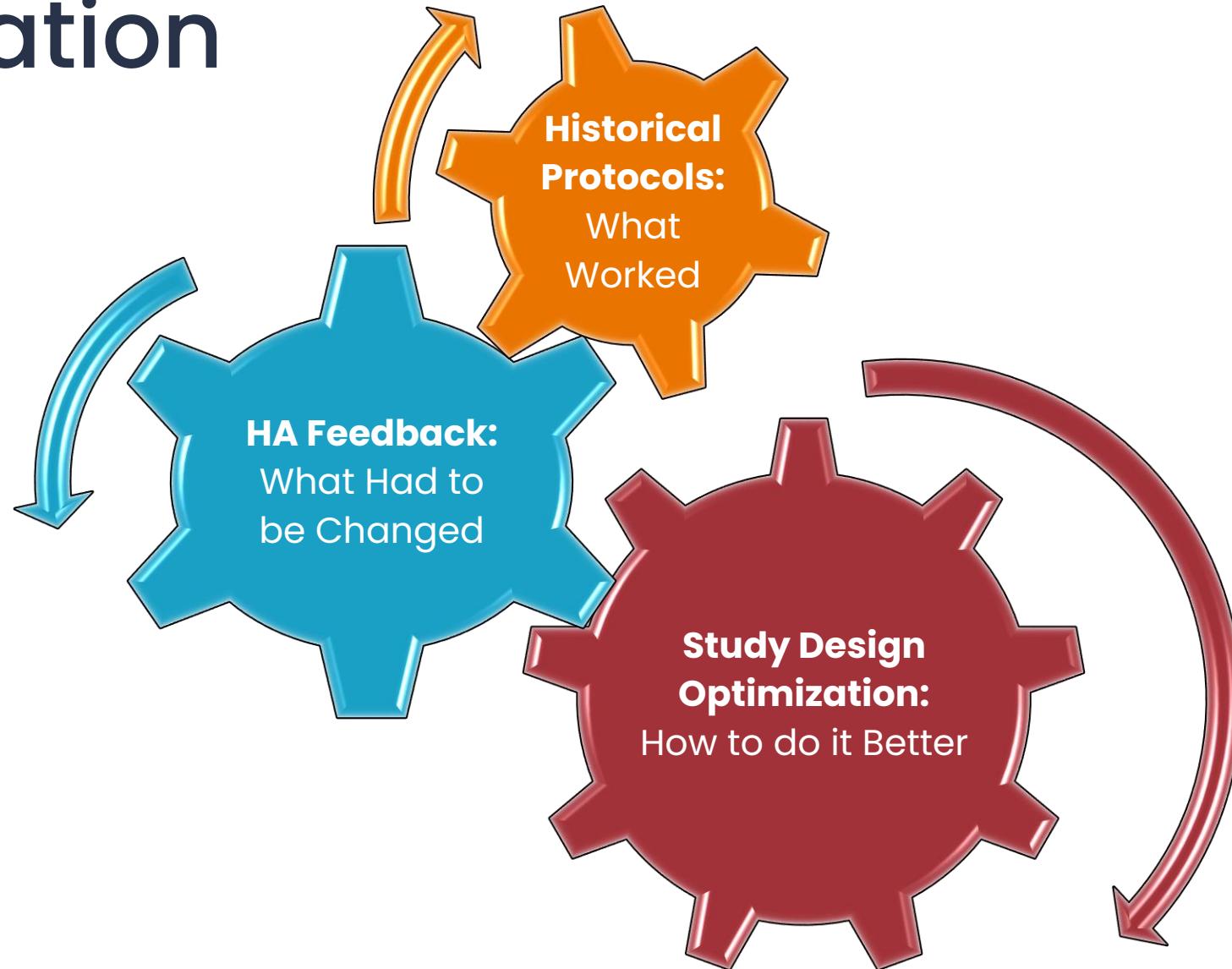
\*Template\_Protocol based on TransCelerate Common Protocol Template (CPT)

# Protocol Builder Vision

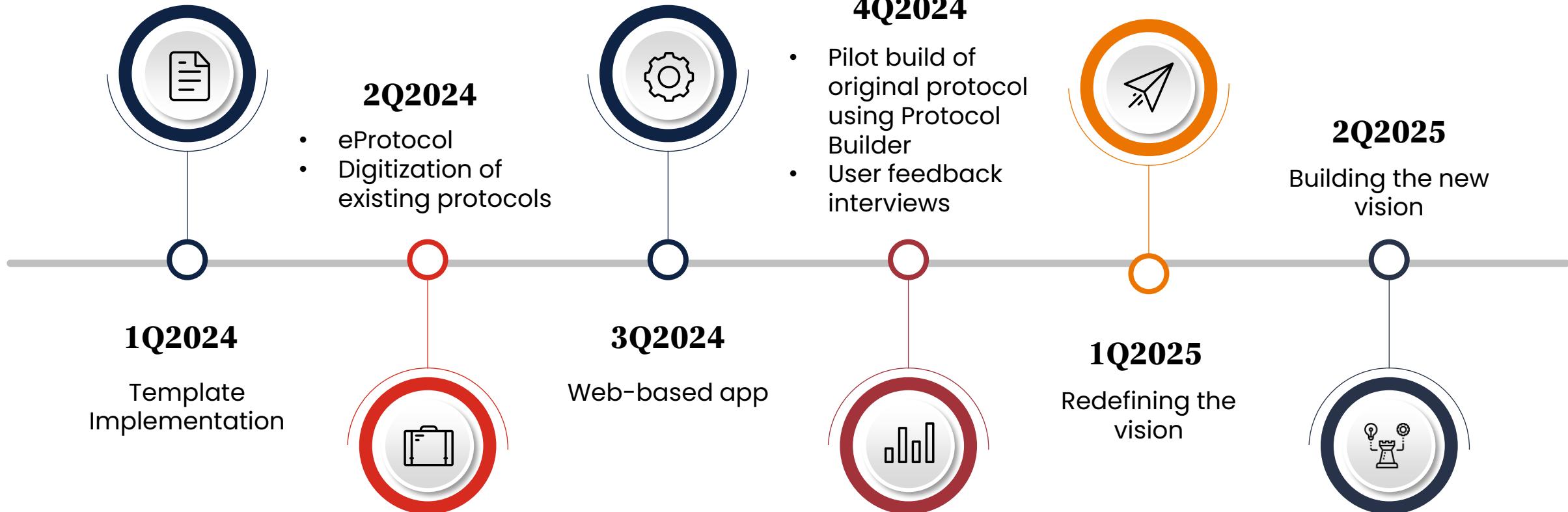


\*Template\_Protocol based on TransCelerate Common Protocol Template (CPT)

# 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?

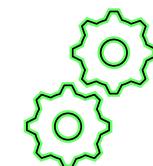
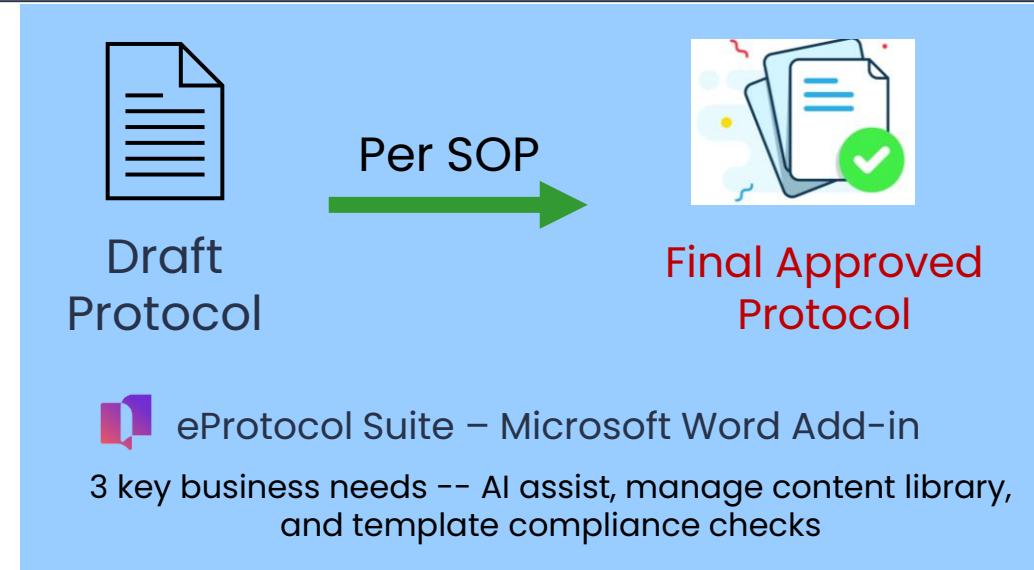
- What does minimum viable product (MVP) mean to the user?
- Focus on completion of parts vs. overall benefit picture

# Modifying the Vision – Parallel Paths to Achieve More

SoA Builder



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



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)

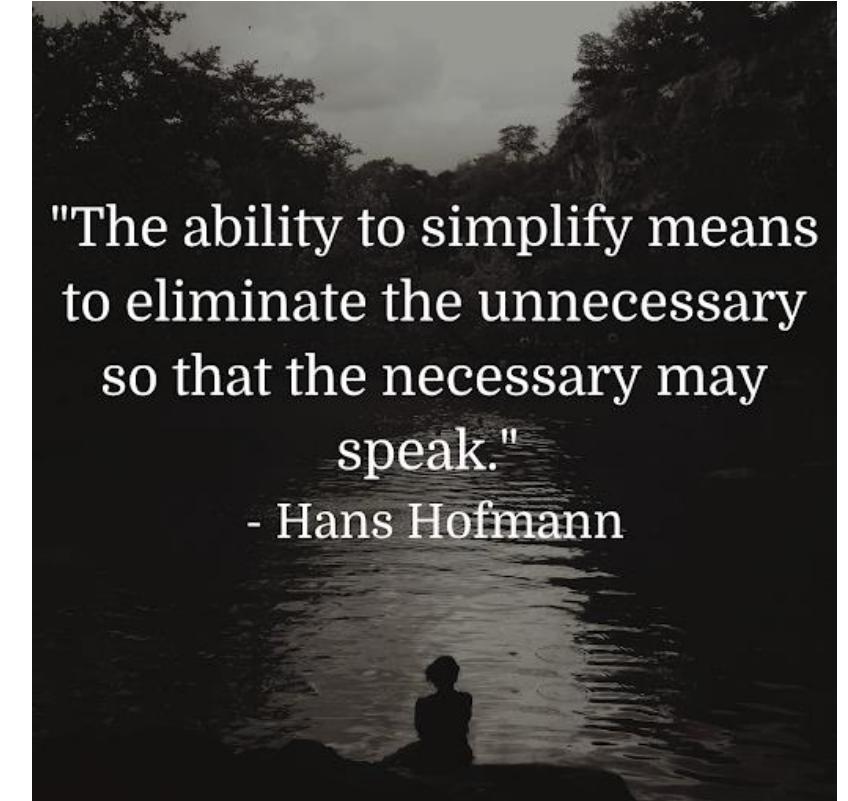
# Recipe for Success



- 1 cup AI
- 1 cup Automation
- $\frac{3}{4}$  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



"The ability to simplify means to eliminate the unnecessary so that the necessary may speak."

- Hans Hofmann

# Strategic Writing

## Before

78 patients were included in the Efficacy Analysis set for Primary Analysis. Results of Study █ showed that in patients with █, treatment with █ 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 cytogenetic 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<sup>-4</sup>), respectively.
- Responses occurred rapidly, as evidenced by the median 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**

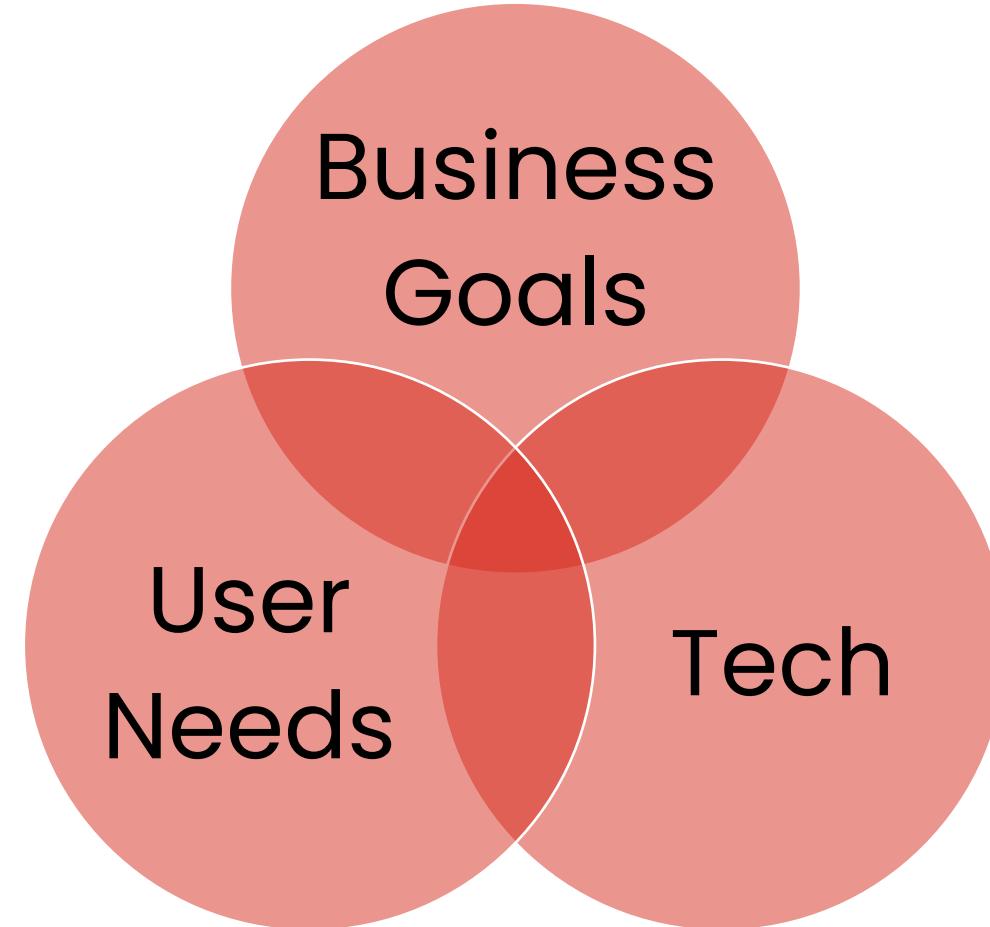
## After

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](#)).

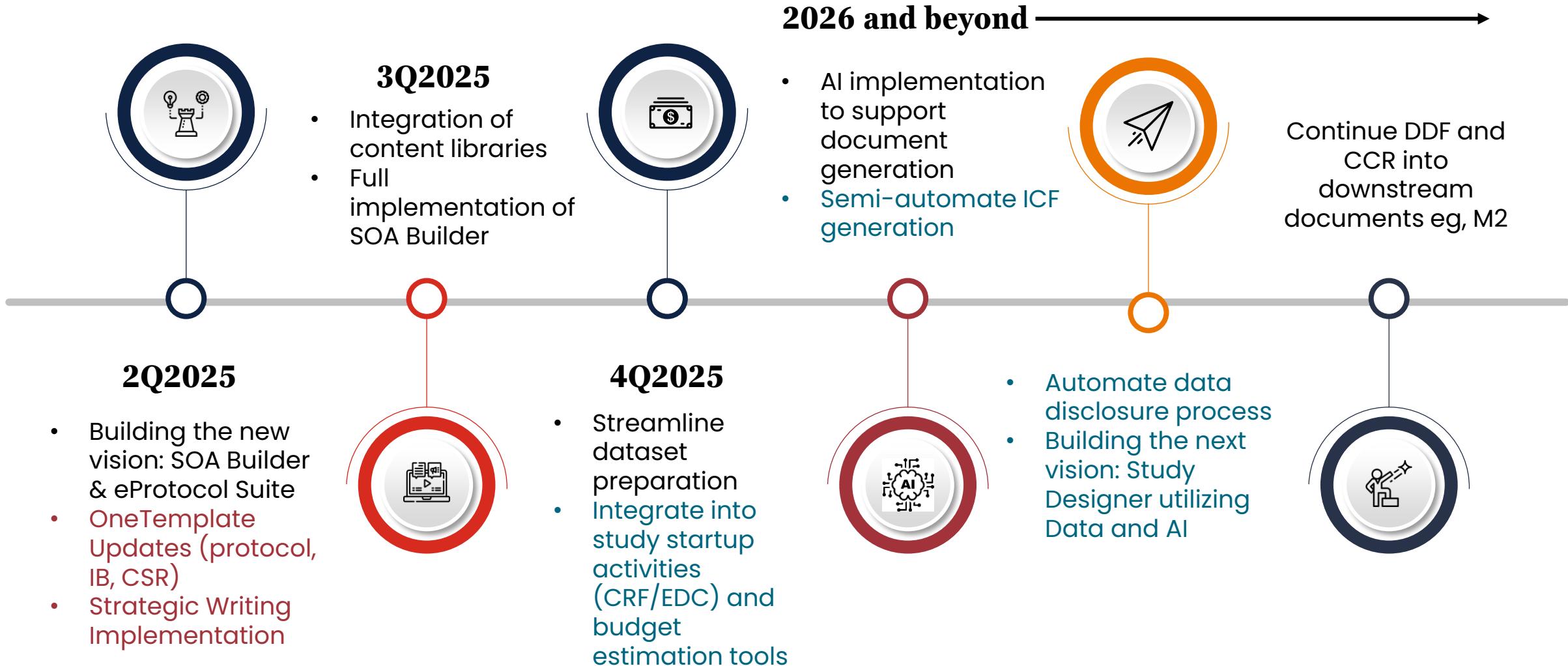
DOR, PFS and OS were not mature as of the data cutoff date, with median DOR, PFS, and OS not being reached. For DOR, event-free rate at 6 months was high ([Table 3](#)).

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



# 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

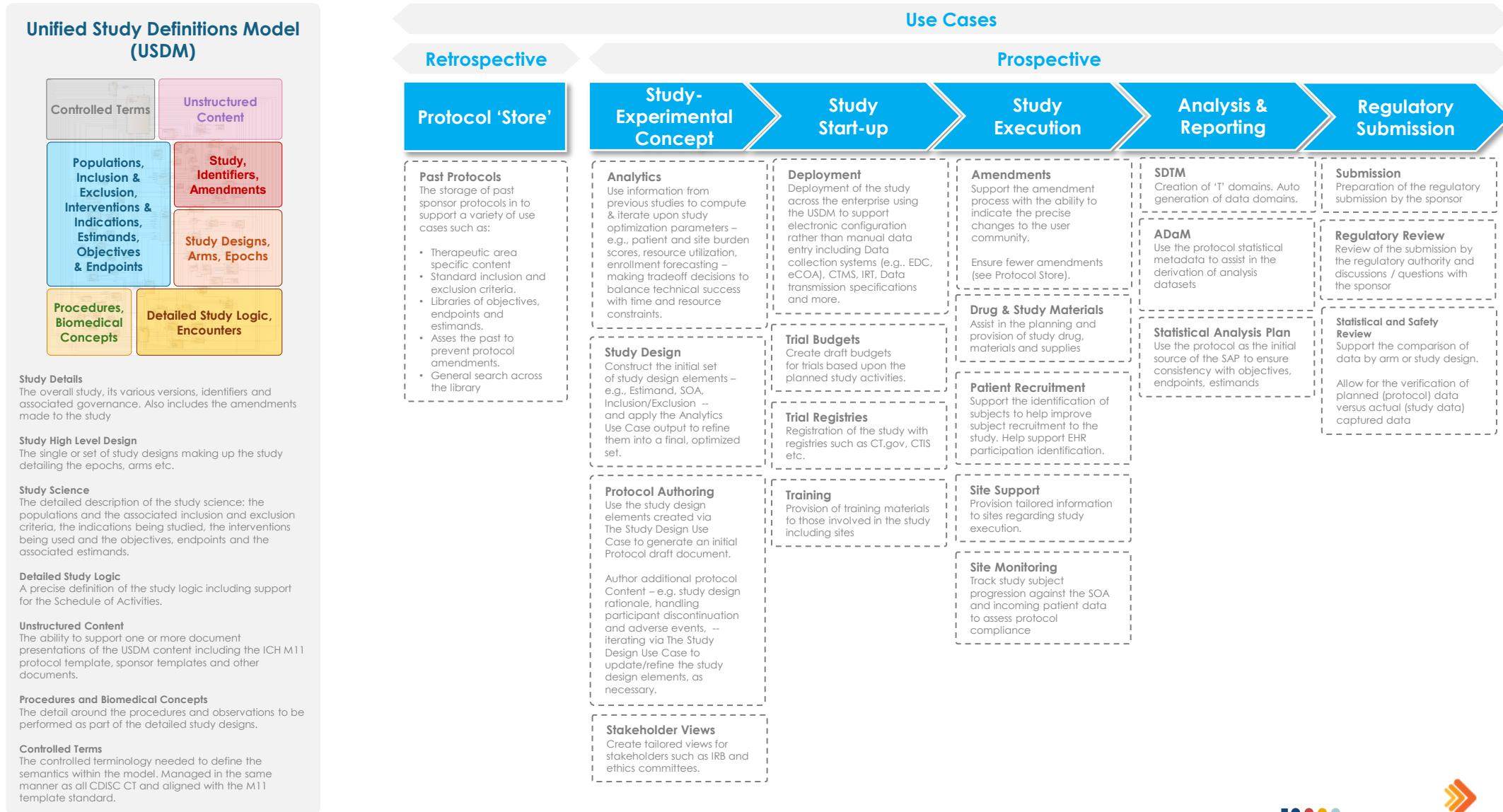
This Presentation and the forthcoming Library are intended to advance further discussion, collaboration and free flow of ideas.

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.

# Digital Study Design-USDM Use Case Summary



# 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!

# 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

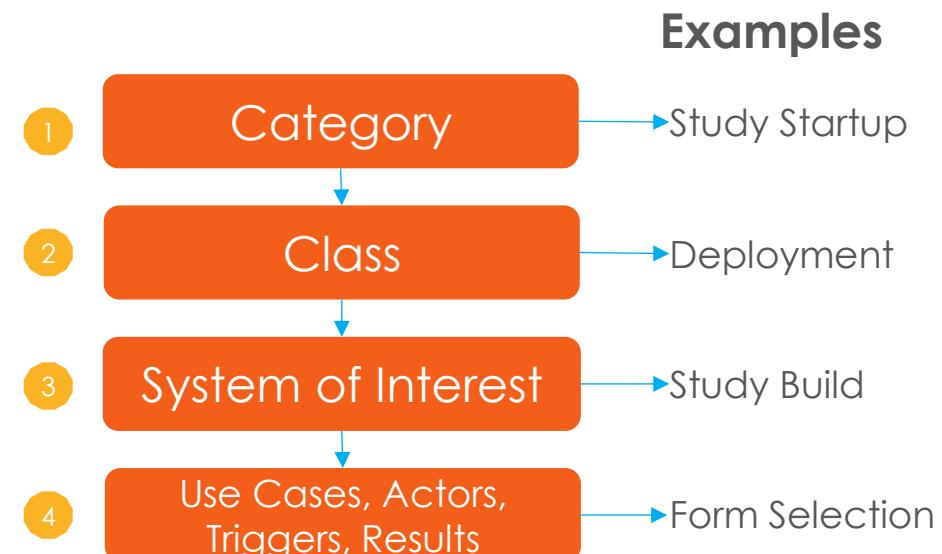
- They describe the expected behavior of the *System of Interest* (the *What*), and not the exact method of making it happen (the *How*).
- They help designers understand the *System of Interest* from the end user's perspective by specifying all externally visible behavior.

The Library organizes use cases into a four-level hierarchy

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

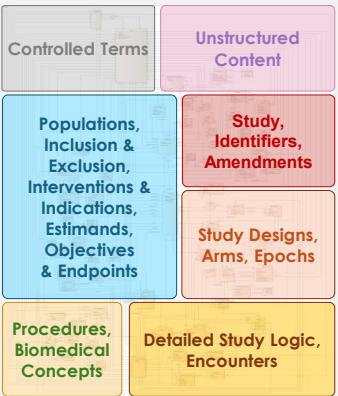
Specific use cases are addressed by their full hierarchy name. For Example:

*Study Startup: Deployment: Study Build: Form Selection*



# How to Use the Library Categories

## 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

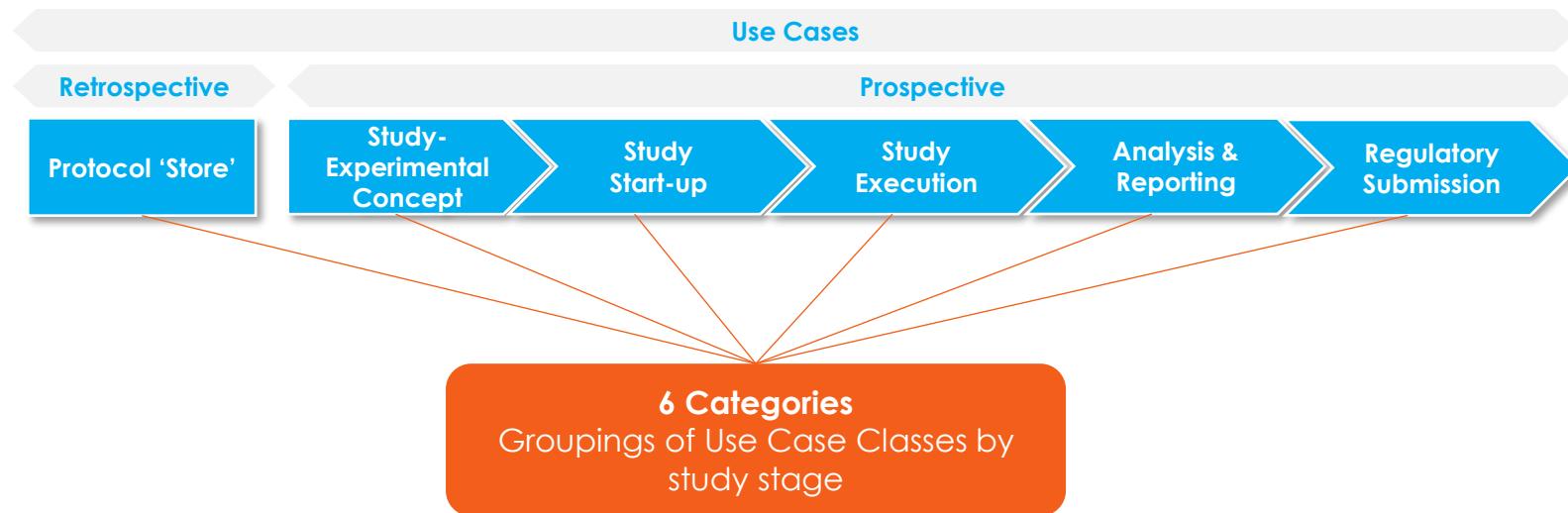
The ability to support one or more document presentations of the USDM content including the ICH M11 protocol template, sponsor templates and other documents.

### Procedures and Biomedical Concepts

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

### Controlled Terms

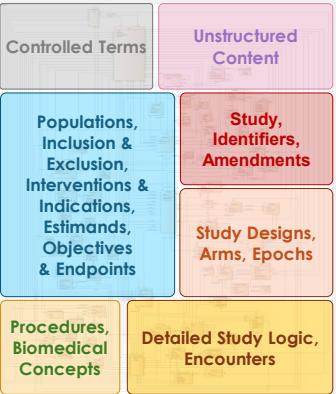
The controlled terminology needed to define the semantics within the model. Managed in the same manner as all CDISC CT and aligned with the M11 template standard.



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

# How to use the Library Classes

## 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.

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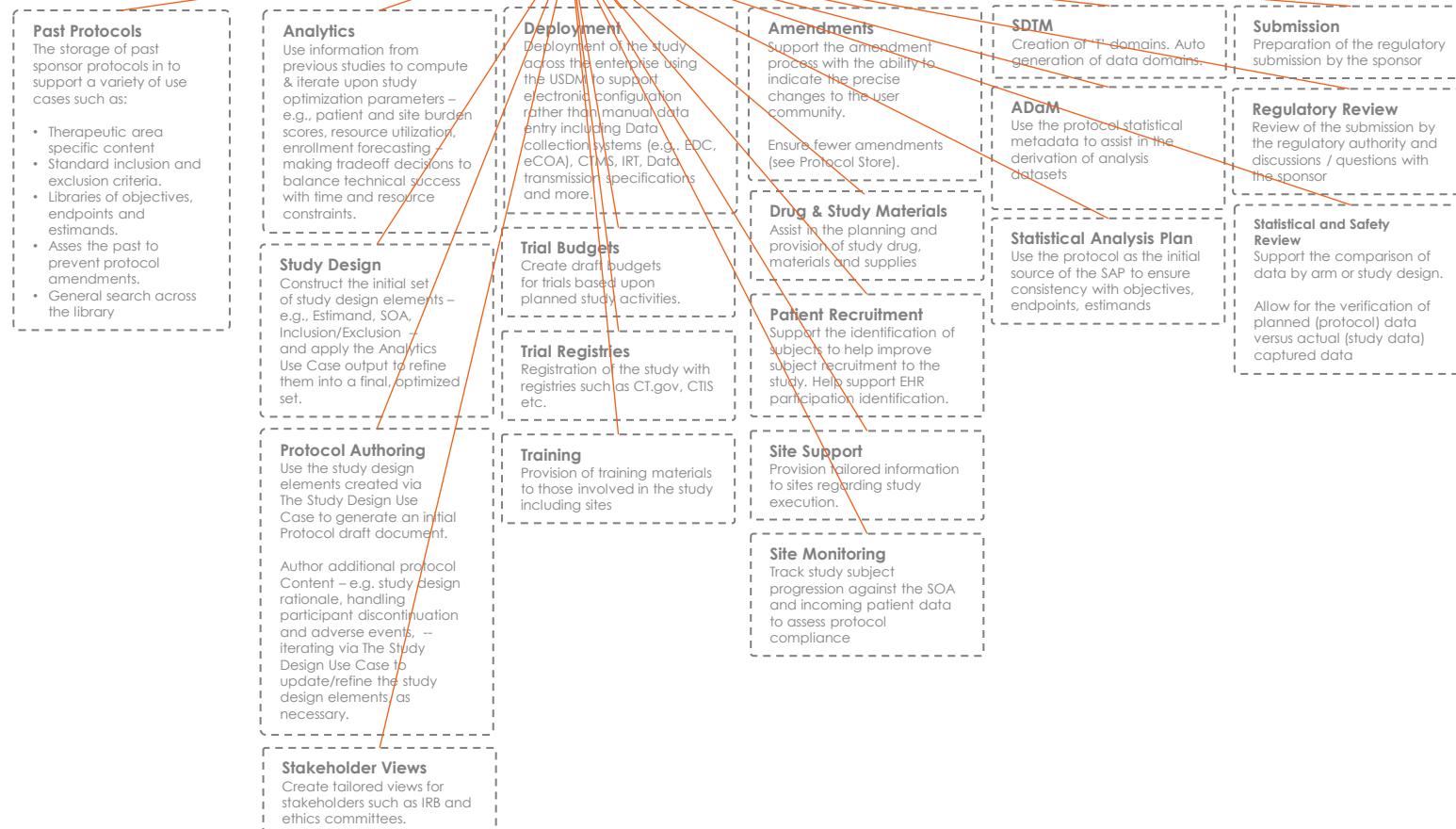
The detail around the procedures and observations to be performed as part of the detailed study designs.

### 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.

**20 Classes**  
Groupings of Use Case Systems  
within a study stage

Each Class contains one or more  
Systems of Interest



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

# How to use the Library

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

### Upload Study to Registry

#### Trigger

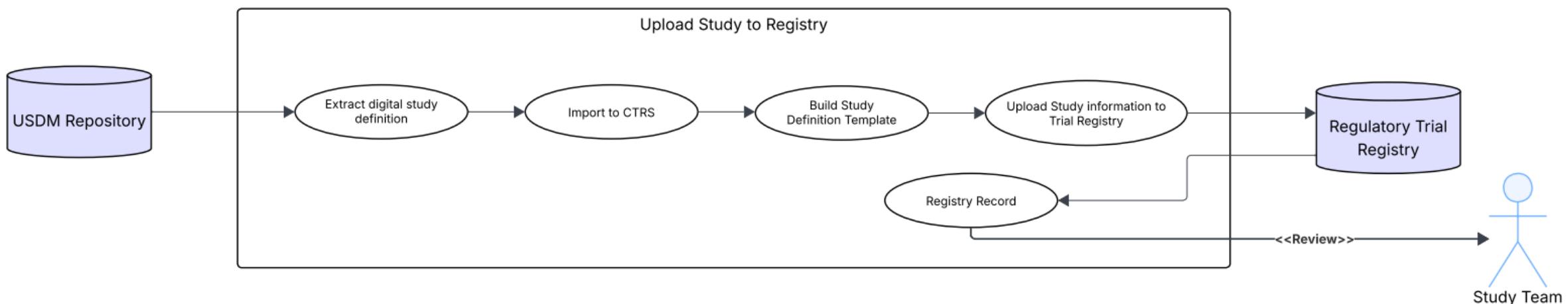
A Sponsor registers a new study with a Regulatory Agency.

#### Primary Scenario

The System selects a study and study version from the USDM Repository, imports 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.



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

# 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 Name

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



### Upload Study to Registry

#### Trigger

A Sponsor registers a new study with a Regulatory Agency.

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#### Result

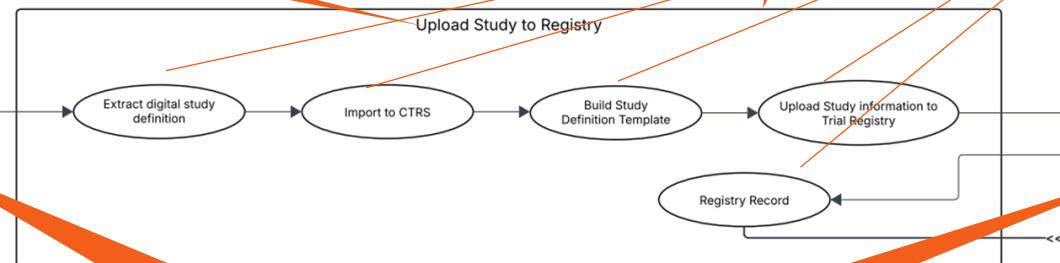
The Sponsor's Study Team reviews the Registry Record, along with any returned errors, to determine if the study's registry is as expected.

### System of Interest Boundary

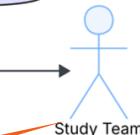
Groups Use Cases into clinical functions that define a given Scenario

### Use Cases

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



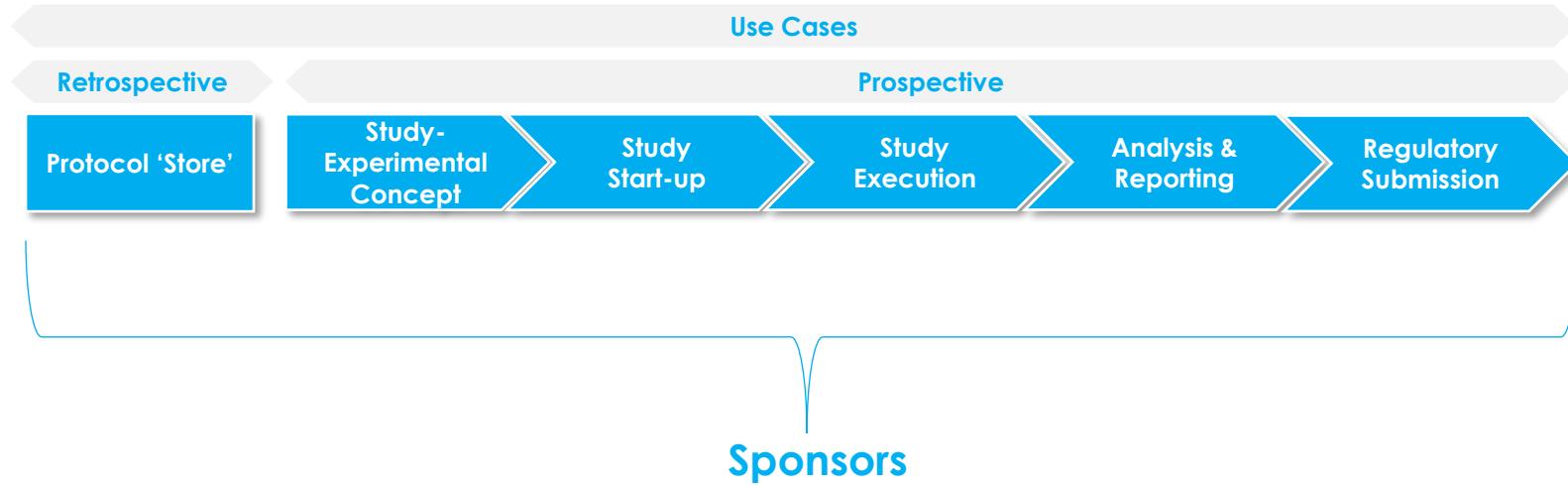
Typically  
Actors that expect outputs are  
drawn on the Right



### Actors

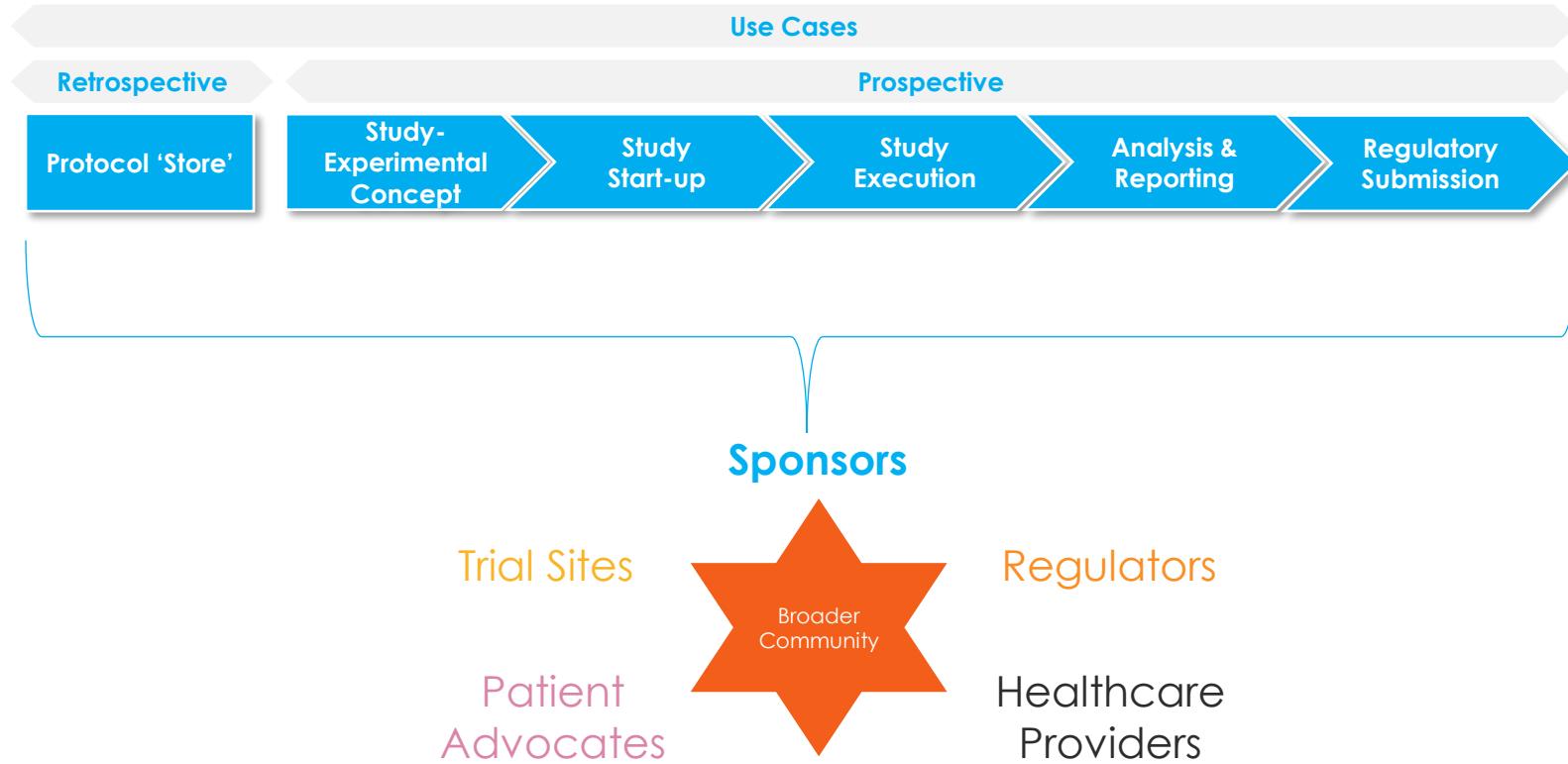
Someone or thing that interacts with the System, either having a responsibility (inputs) or expectations (outputs)

# What is next? Sponsor-centric perspective

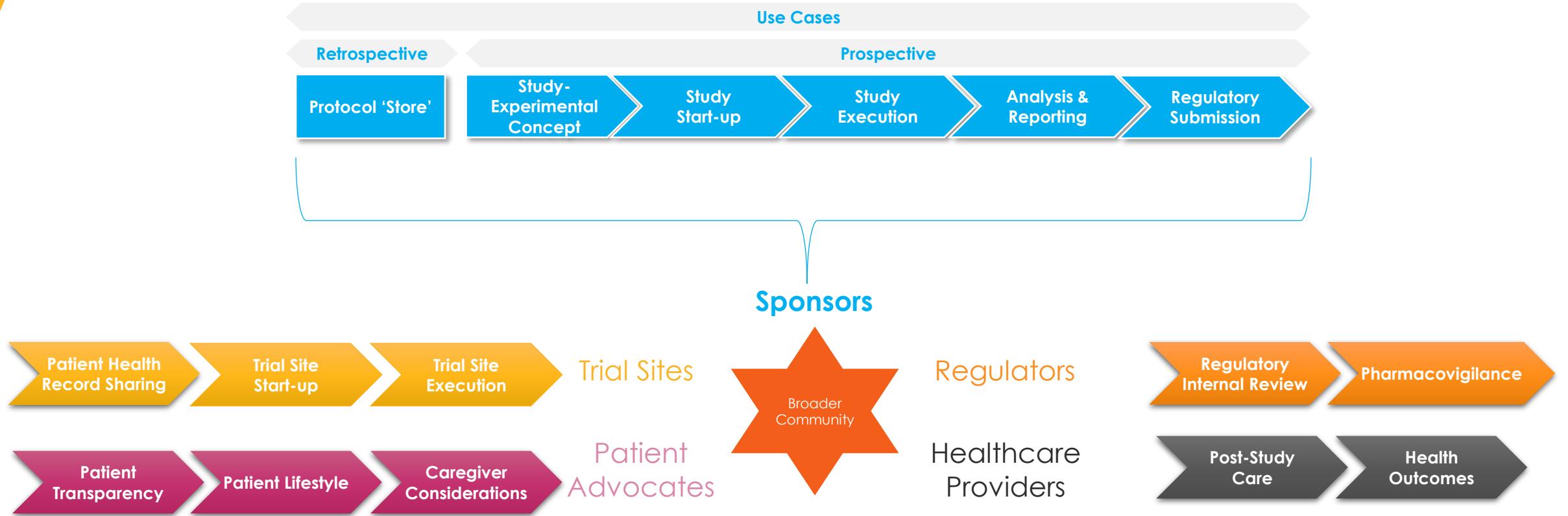


# What is next?

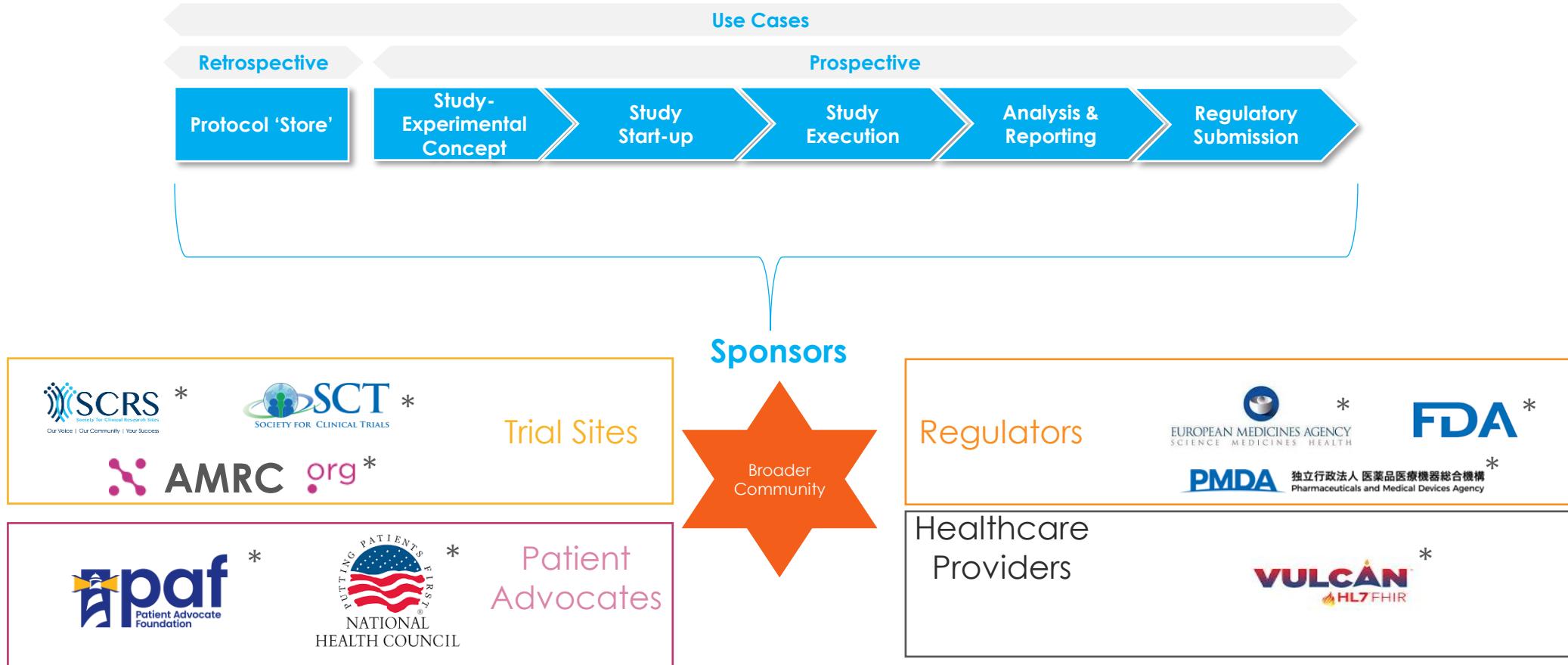
## Expansion to the Broader Community



# What is next? Possible New Categories



# What is next? Possible New Collaborators

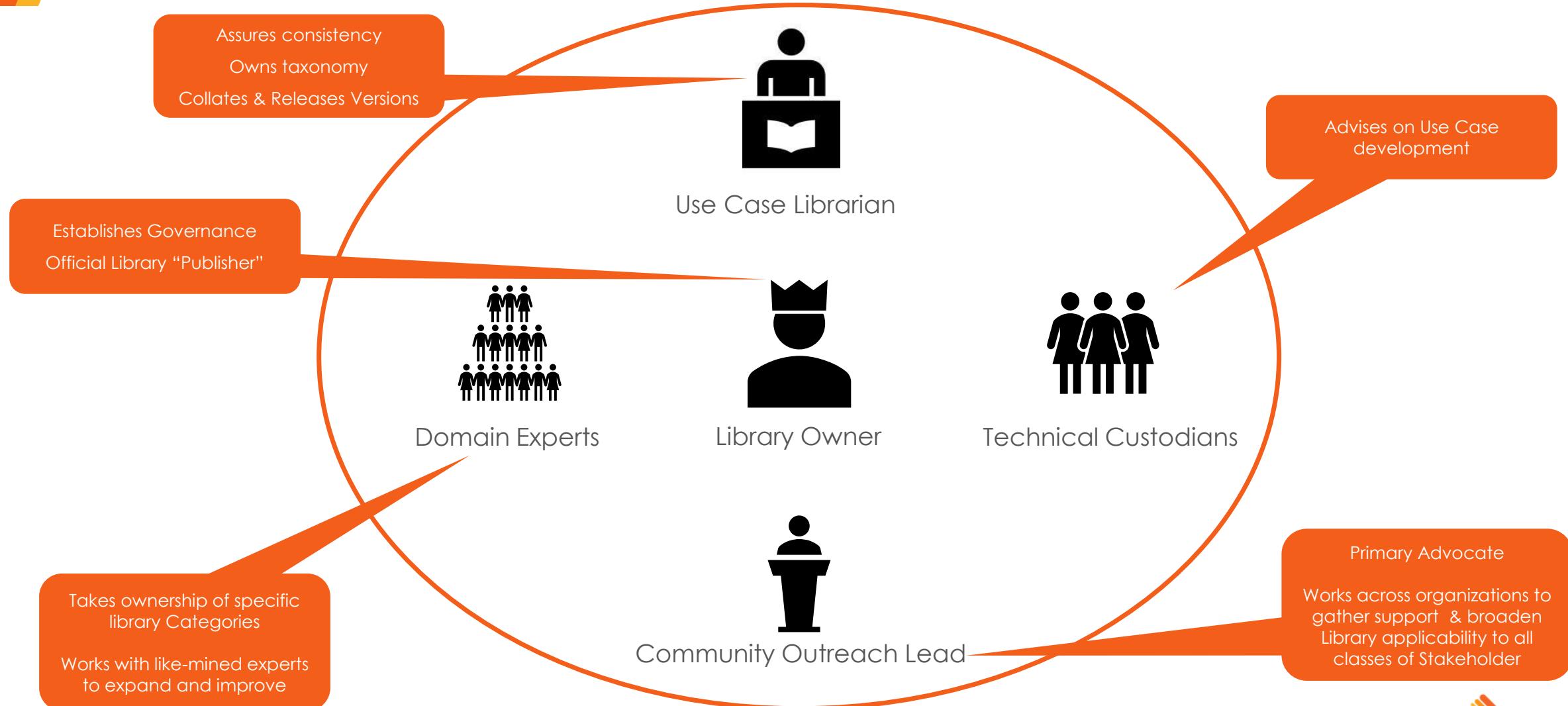


\*Organization Names provided as examples only and imply neither a preference for nor a pre-existing relationship with Transcelerate

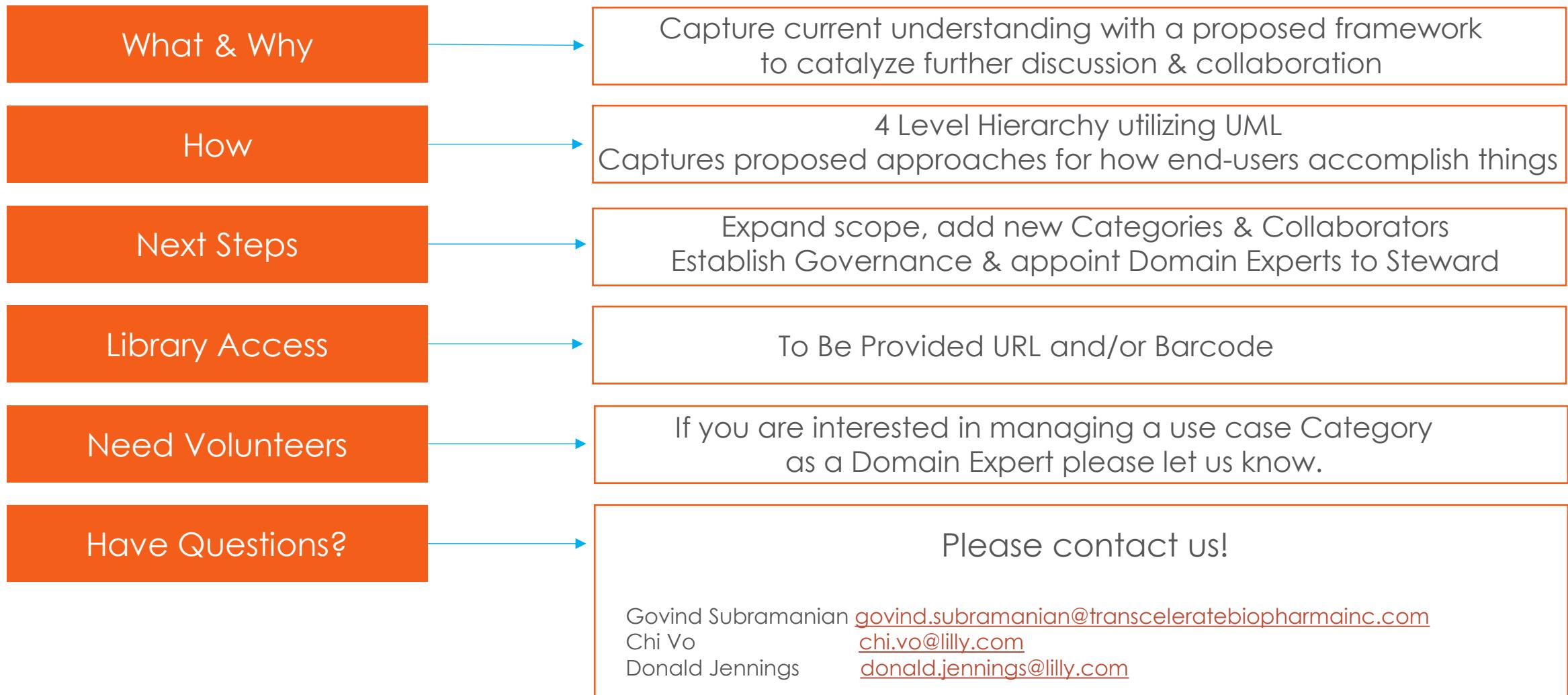
NOTE: The Library is still under development.  
Content may change before release.

# What is next?

## Potential Future Governance & Continuous Improvement of Use Cases



# Summary & Closing Remarks





# Digital Data Flow: Mission Possible!

Practical approaches for protocol digitalization

Day 2 – September 25, 2025



**TransCelerate**  
BIOPHARMA INC.



# 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



# 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



## Start with pre-submitted questions:

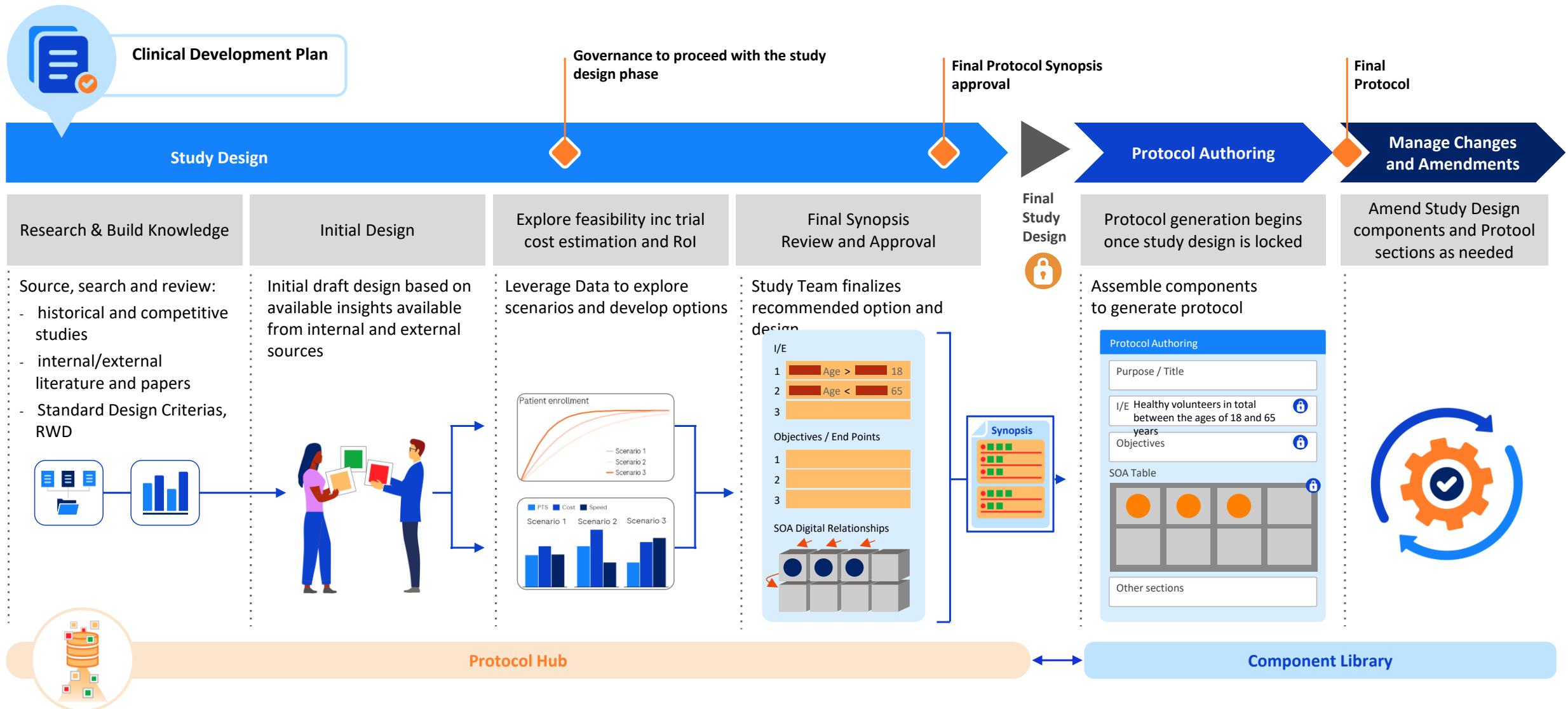
1. Summarize what you presented last year.
2. What progress has your organization made over the last year?
3. What are the barriers that have been addressed or removed?
4. What challenges to implementation remain?
5. What are your organization's aspirations moving forward?



# Case Study Recap:

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





## Digitization

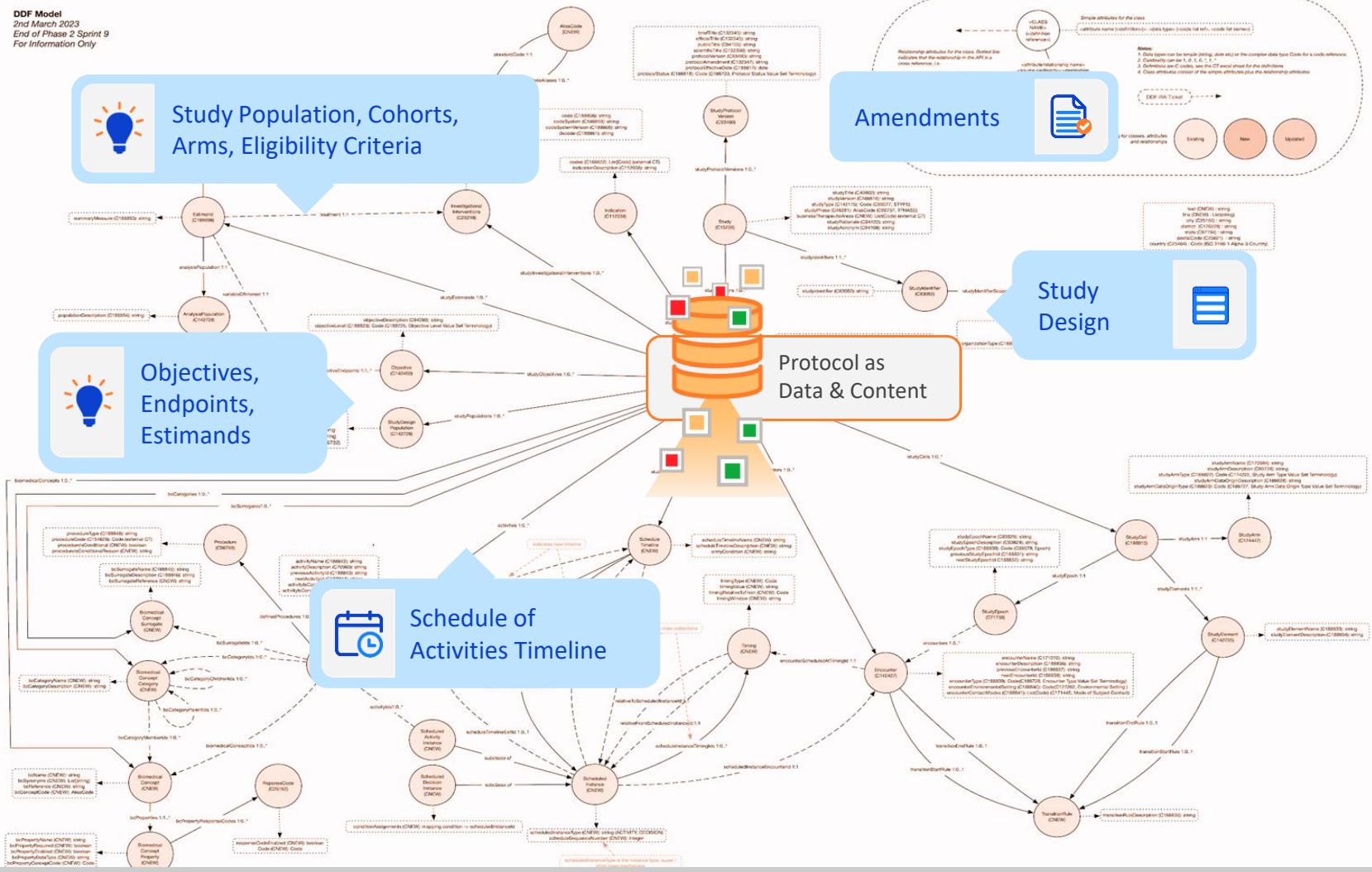


**Converts existing documents into digital data by extracting and deconstructing sentences or paragraphs**

## Digitalization



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



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.

**Digital Platform: Study Designer**

Study Designer Concept

JBH G043693\_v1

- Study Information
- Protocol Summary
- Objectives and Endpoints
- Trial Objectives
- Trial Design
- Trial Population
- Trial Intervention
- Trial assessments and procedures
- Trial assessments
- Real Time Insights
- Amendment Decision Framework

Study Information Phase 2 G043693\_v1

Additional info

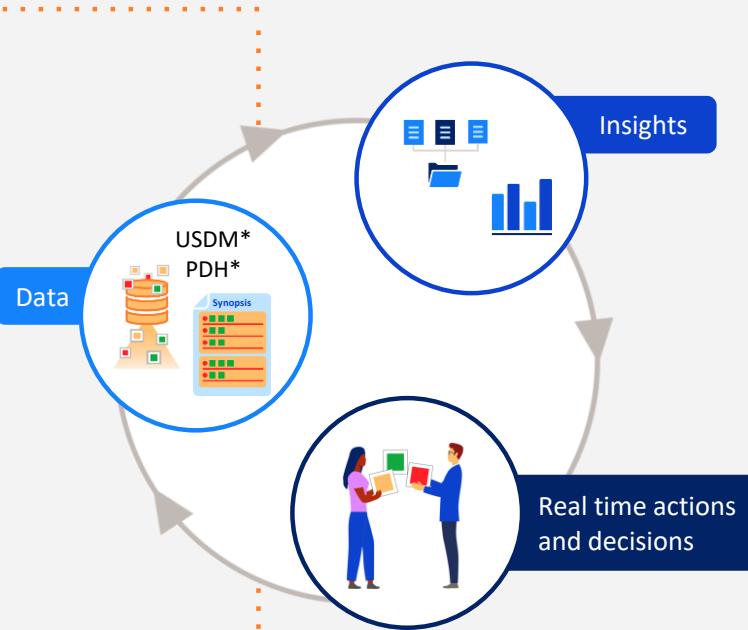
Full Name	
What is your role/job title?	
Email	
Study ID	
Protocol Version	
How many countries will be affected by this change?	
Product Name	

Create Substantial Protocol Amendment (SOP-0105C)

- This is a **USDM/DIL**, submit within 14 days and include information included in DIL.
- Include in the amendment ONLY information included during RIs. If PCL(s) were issued prior to this amendment, these PCLs should NOT be included now, but in the next amendment if it was agreed upon by the health authority.
- Document the decision (upload the pdf file) in the next amendment.

Field Value

Full Name	Zoya
Role	SME
Email	volynska@pRED
Organization	pRED



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

**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)

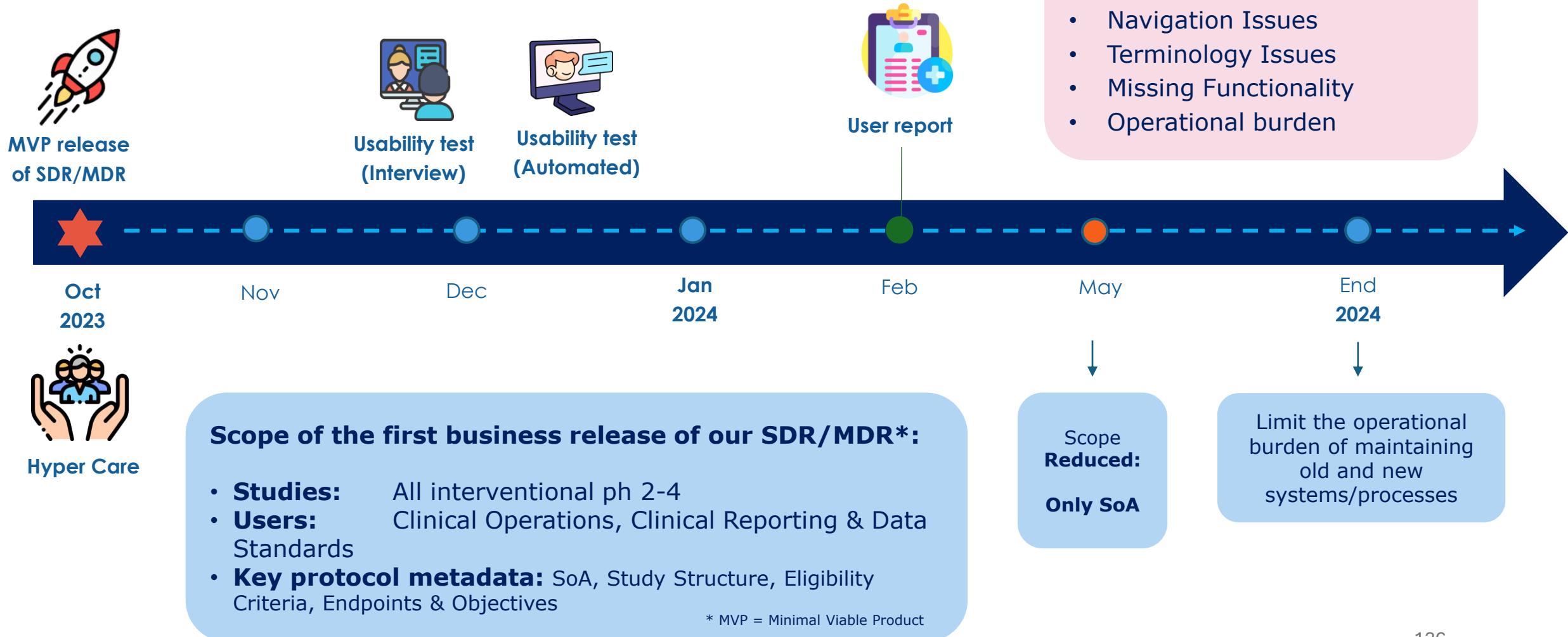


# Case Study Recap:

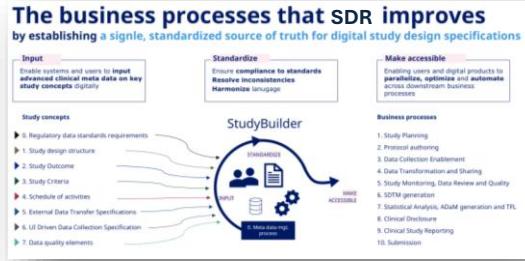
Adoption of Digital Data Flow



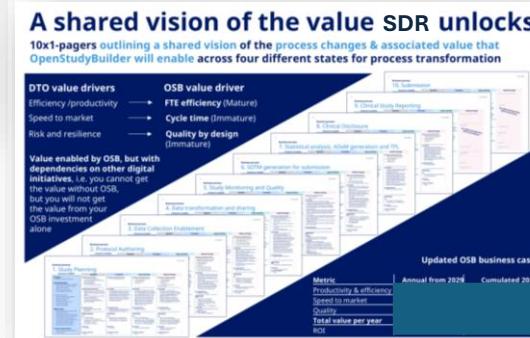
# Adoption journey 2024



# Adoption journey update (2025)



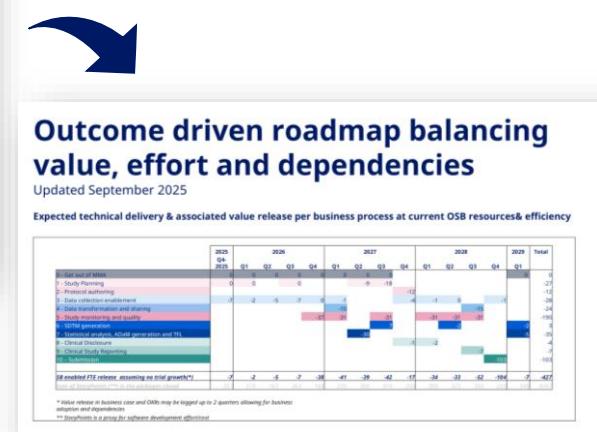
## Product vision & mission



## Value framework & business case

### Current status:

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



## Outcome based roadmap



## Defined Objectives & Key Results

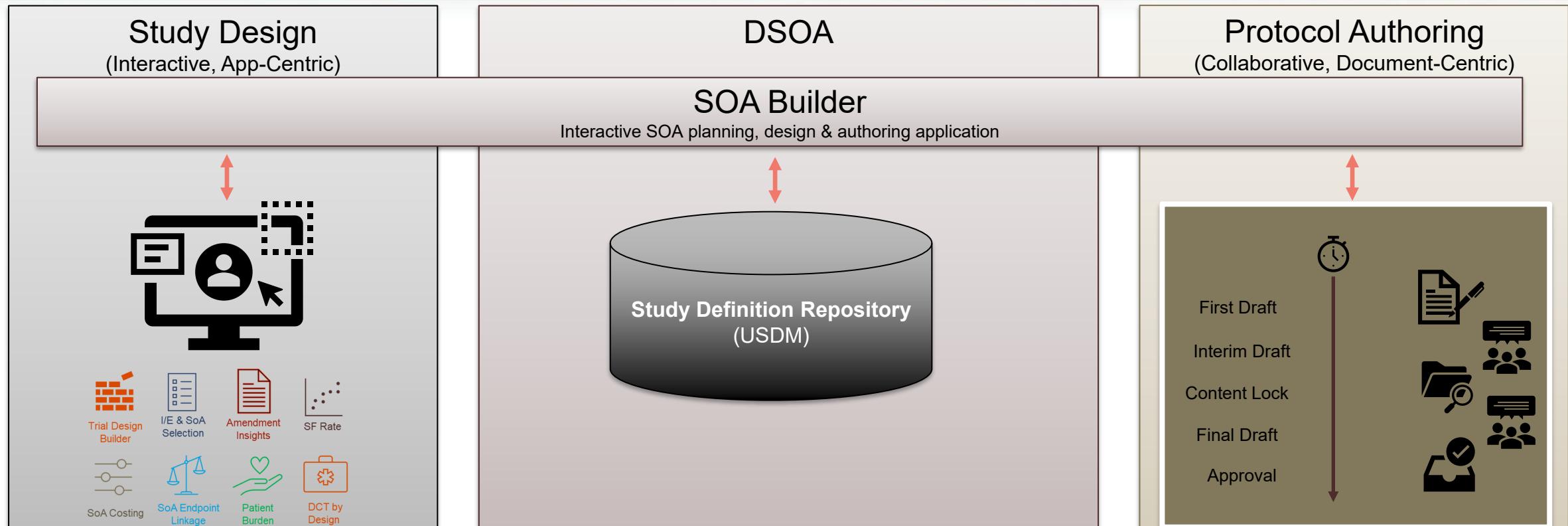


# Case Study Recap:

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



# DSOA Target State (Scale)



Central  
Labs



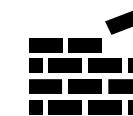
Orchestration



Budgeting



Trial Materials



eDC & eCOA  
Build



Monitoring



Pharmaceutical  
Dispensing



# Ask a Question

Scan the QR code or go to:  
[novartis.pigeonhole.at](http://novartis.pigeonhole.at)

Enter passcode:  
**MCPMK3T2**

LEARNINGS FROM  
EARLY ADOPTERS



SCAN ME



# Solution Provider Orientation





# AlphaLife Sciences

ALPHA<sup>X</sup>LIFE Sciences



Mike Liang



Bogong Zhu



**CDISC**



**Peter Van  
Reusel**



**Julie Smiley**



# ClinLine



**Berber  
Snoeijer**



# Data4knowledge



**Johannes  
Ulander**



**Dave Iberson-  
Hurst**

A large stack of papers falls from the top left, with a person running away from it towards a digital binary code landscape.

**DNA**nexus

**DNA**nexus®



**Jimita Parekh**



**Sanchit  
Thakrar**





**HumanTrue**



**Bill Lynch**



**Merative**



**Jennifer Duff**



# Novonordisk OSB



Nicolas  
deSaint Jorre



Jeremy Cronin



# Nurocor



**Bob Brindle**



**Barrie Nelson**



# Onward Health



**Martin Lim**



# Pharmaseal



Ricky Lakhani



Daljit Cheema



# RWS & Contentrules



**content rules®**  
the global content experts®



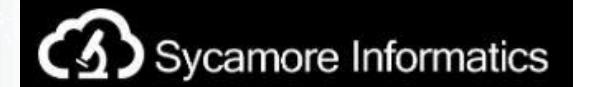
**Todd Georgieff**



**Regina Lynn  
Preciado**



# Sycamore Informatics



Kairav  
Tarmaster



Joel Hoffman



# TransCelerate SDR



**Belinda Griffin**



**Mike Rippin**



# Trialynx & Cliniv



Ram S.



Angie Schwab



# Verily



**Brandon  
GoldBlatt**



# Solution Provider Poster Session





# Action Toolkit & Survey





# 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 Reference Implementation.*



**TransCelerate**  
BIOPHARMA INC.

GIVE  
US  
YOUR  
FEEDBACK



SCAN ME



# 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

**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

Join our LinkedIn community dedicated to protocol digitalization, fostering connections, and sharing DDF-related information in a clear and accessible manner.



Follow the DDF LinkedIn Page!



# Digital Data Flow: Mission Possible!

Practical approaches for protocol digitalization



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# TransCelerate Digital Data Flow (DDF)

Mission Possible!

***"Impossible is temporary,  
impossible is nothing"***

The Transformation is on!

