

Embracing the Future: Uninterrupted Data Flows from Protocol Design to Electronic Data Capture

Digital Data Flow for PHUSE US Connect 2024

February 25-28, 2024



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TransCelerate – A Catalyst for Collaboration

We are a not-for-profit entity created to foster collaboration. Our mission is to collaborate across the global biopharmaceutical R&D community on solutions designed to drive the efficient, effective, and high-quality delivery of new medicines.

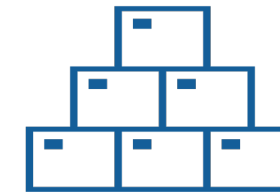
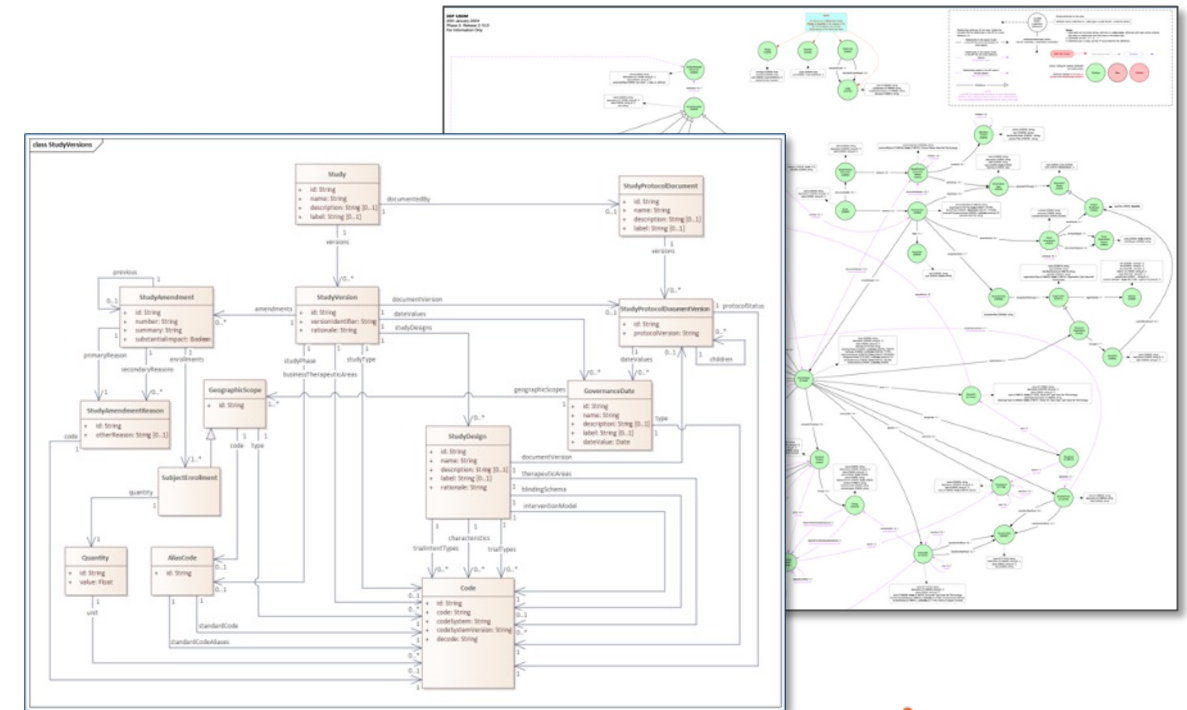
Since inception, TransCelerate has prioritized robust collaboration with key stakeholders across the R&D ecosystem to deliver hundreds of free and publicly available solutions.



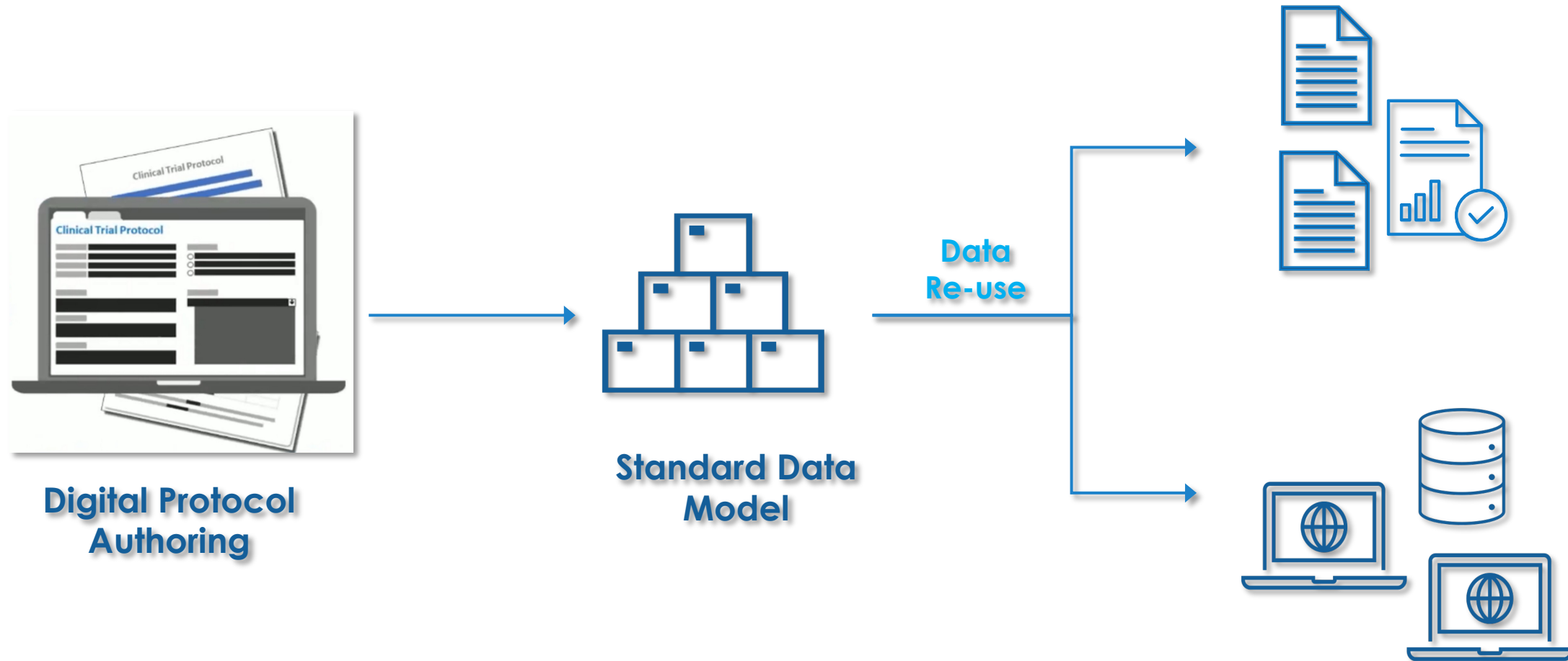
Transformation: Document to Data Centric Approach

Today

Tomorrow

[illegible]

Transformation: Write Once, Read Many Times



Digital Data Flow Ambition: Breaking the Document Paradigm

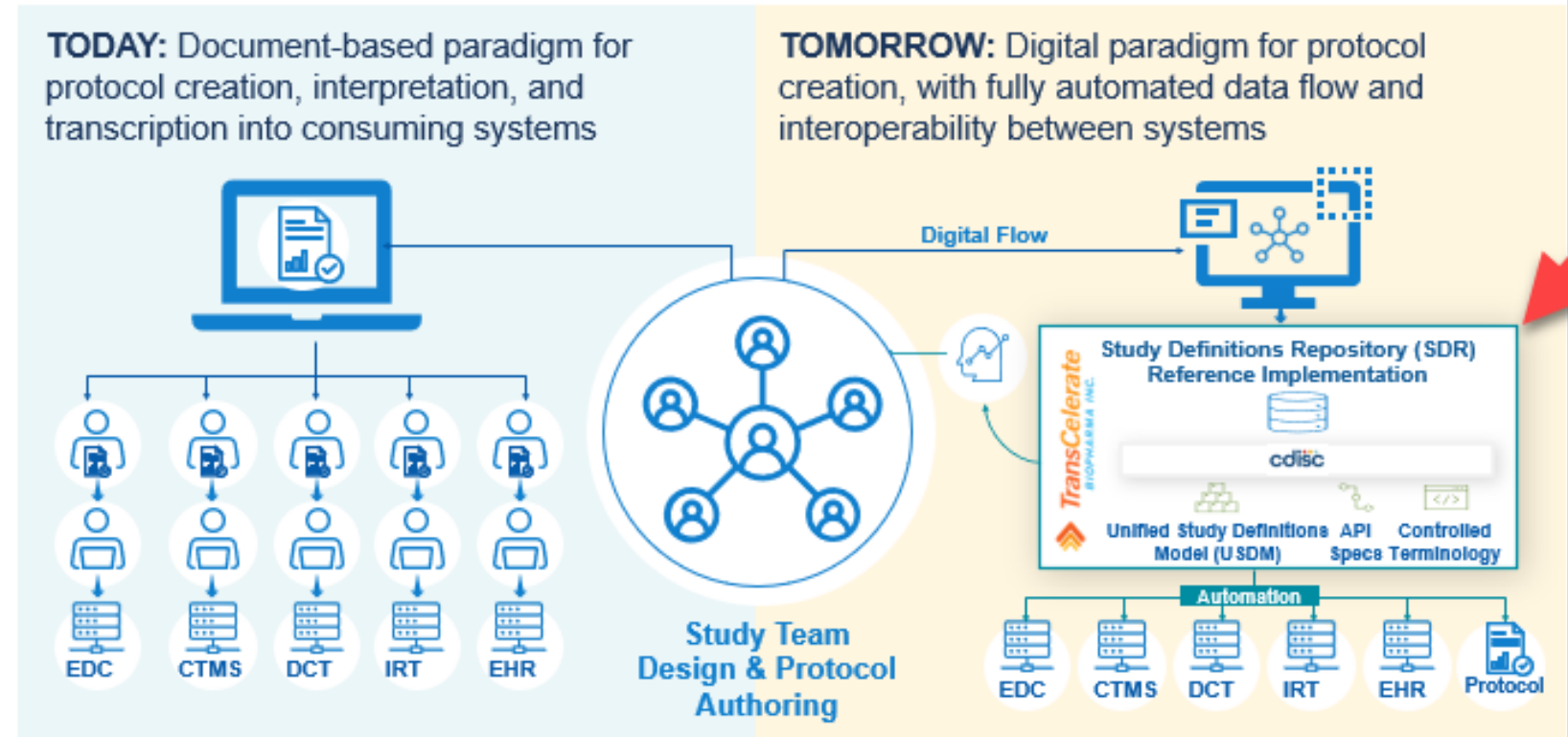
Documents to Data / Write Once, Read Many

Digital - standard representation of study protocol

- ✓ structured
- ✓ machine readable
- ✓ executable

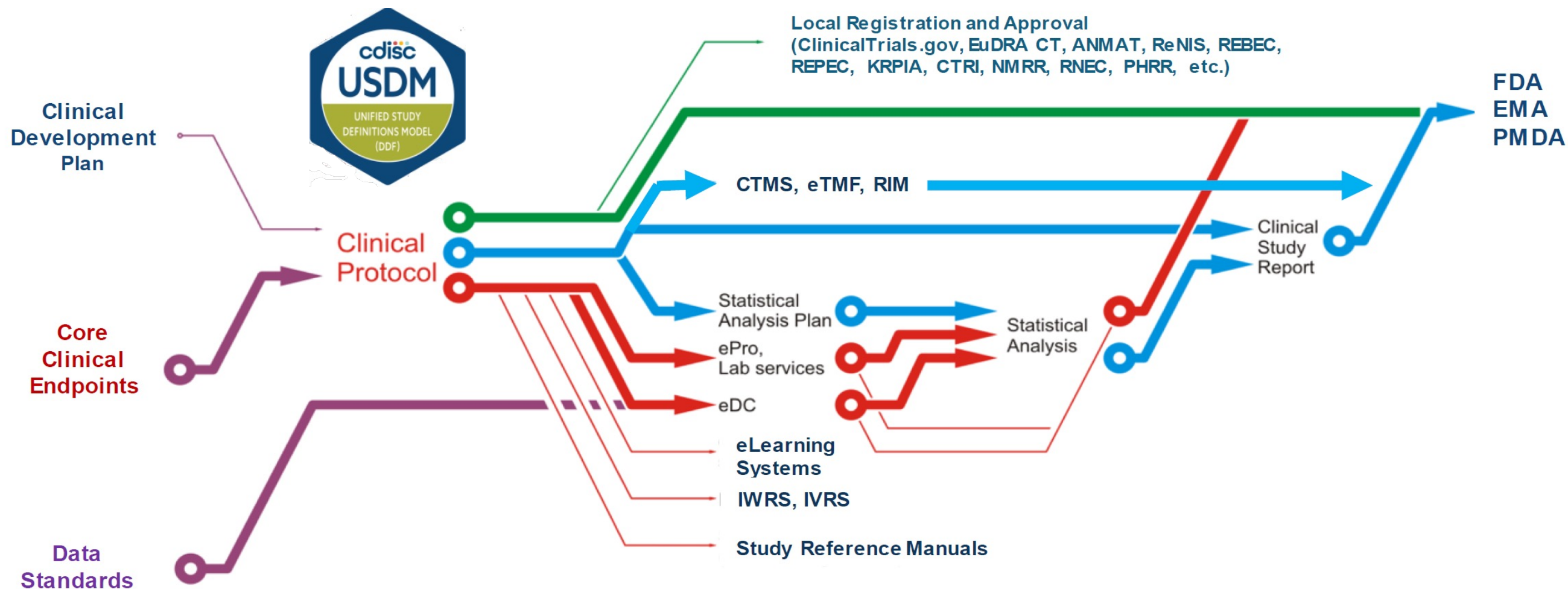
Data Flow – industry-wide interoperability

- ✓ exchange of data
- ✓ non-cooperating organizations
- ✓ minimal effort

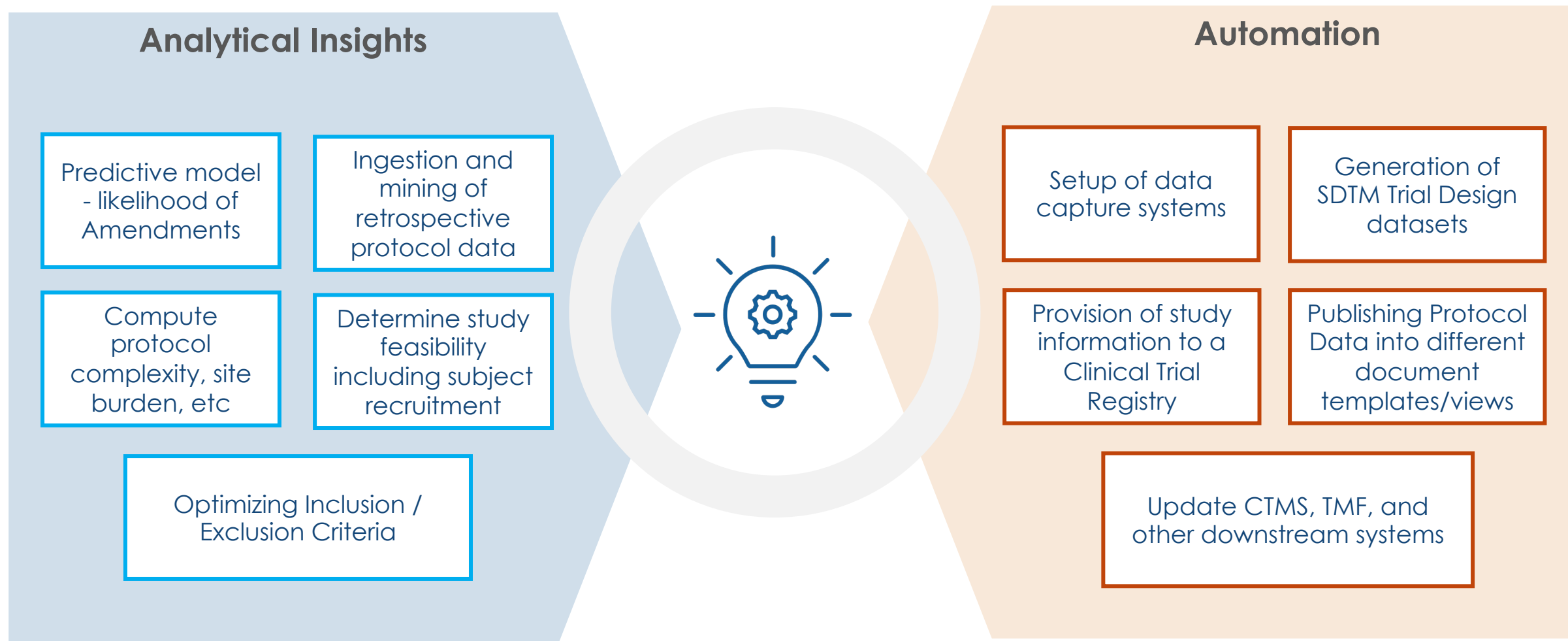


Eliminate non-value added activities
Enable automation of downstream study startup and conduct processes
Create foundation for study design analytics insights

Clinical Data Flows



Use Cases



The Data Capture Use Case (EDC)

Increasing Detail

Provide precision on the data to be captured to the capture systems in a generic manner to facilitate automation. The data precision has not, typically, been in the “paper” protocol. It is SoA “plus”, SoA+

PROTOCOL

TITLE: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE SAFETY AND EFFICACY OF TOCILIZUMAB IN PATIENTS WITH SEVERE COVID-19 PNEUMONIA

PROTOCOL NUMBER: WA42380

VERSION NUMBER: 3

EUDRACT NUMBER: 2020-001154-22

IND NUMBER: 148225

NCT NUMBER: NCT04320615

TEST PRODUCT: Tocilizumab (RO4877533)

MEDICAL MONITOR: [REDACTED], M.D.

SPONSOR: F. Hoffmann-La Roche Ltd

APPROVAL DATE: See electronic date stamp below

PROTOCOL AMENDMENT APPROVAL

NN1218-3854	Protocol section	Screening	4-week Run-in				Randomisation	0-16 weeks treatment period																End of treatment	Follow up 1	Follow up 2	Premature discontinuation of trial product		
			Blinded trial product																										
			V 1	V 2	V 3	V 4	V 5	V 6	V 7	V 8	V 9	V 10	V 11	V 12	V 13	V 14	V 15	V 16	V 17	V 18	V 19	V 20	V 21	V 22	V 23	V 24	V 22A	V 22B	
Visit (V)	8.1.5																												
Phone contact (P)	8.1.6																												
Time of visit (weeks)			-6	-4	-3	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	20			
Visit window (days)			+10	+3	+3	+3	0	+3	+3	+3	+3	+3	+3	+3	+3	+3	+3	+3	+3	+3	+3	+3	+3	+5	+5	+3	+3		
CGM data transfer	8.3.1.3							X																			X	X	
Change of infusion set and reservoir	8.3.2.3		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	
PRO questionnaire	8.3.3		X																										
TRIAL MATERIAL																													
IV WBS	10		X						X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Dispensing visit (drug)	8								X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Dosing	8								X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Drug accountability	8.4									X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
REMINDERS																													
Hand-out Subject participation card	8.1.2		X																										
Pointing of Subjects Pump and Subject Number in CareLink	8.1.1			X																									
Hand out and instruct in use of BG meter	8.3.2.2			X																									
Hand out and instruct in use of back-up kit	8.3.2.2			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Hand out and instruct in use of diary	8.3.2			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Hand out of infusion set and reservoir	8.3.2			X																									
Amend visit fasting	8.1.7			X																									
Training in diabetes and carbohydrate counting	8.3.3.3			X																									
Training in pump use (and trial procedures)	8.3.3.3			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Remind Subject to bring BG meter to site visit	8.1.1			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Upload pump and BG meter data	8.3.4			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Instruct in use of trial product	8.2.2.1							X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
End of treatment	8.1.2																								X		X	X	

Data & Procedures

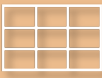


SoA+

Visits & Activities

Arms & Epochs

Study Design

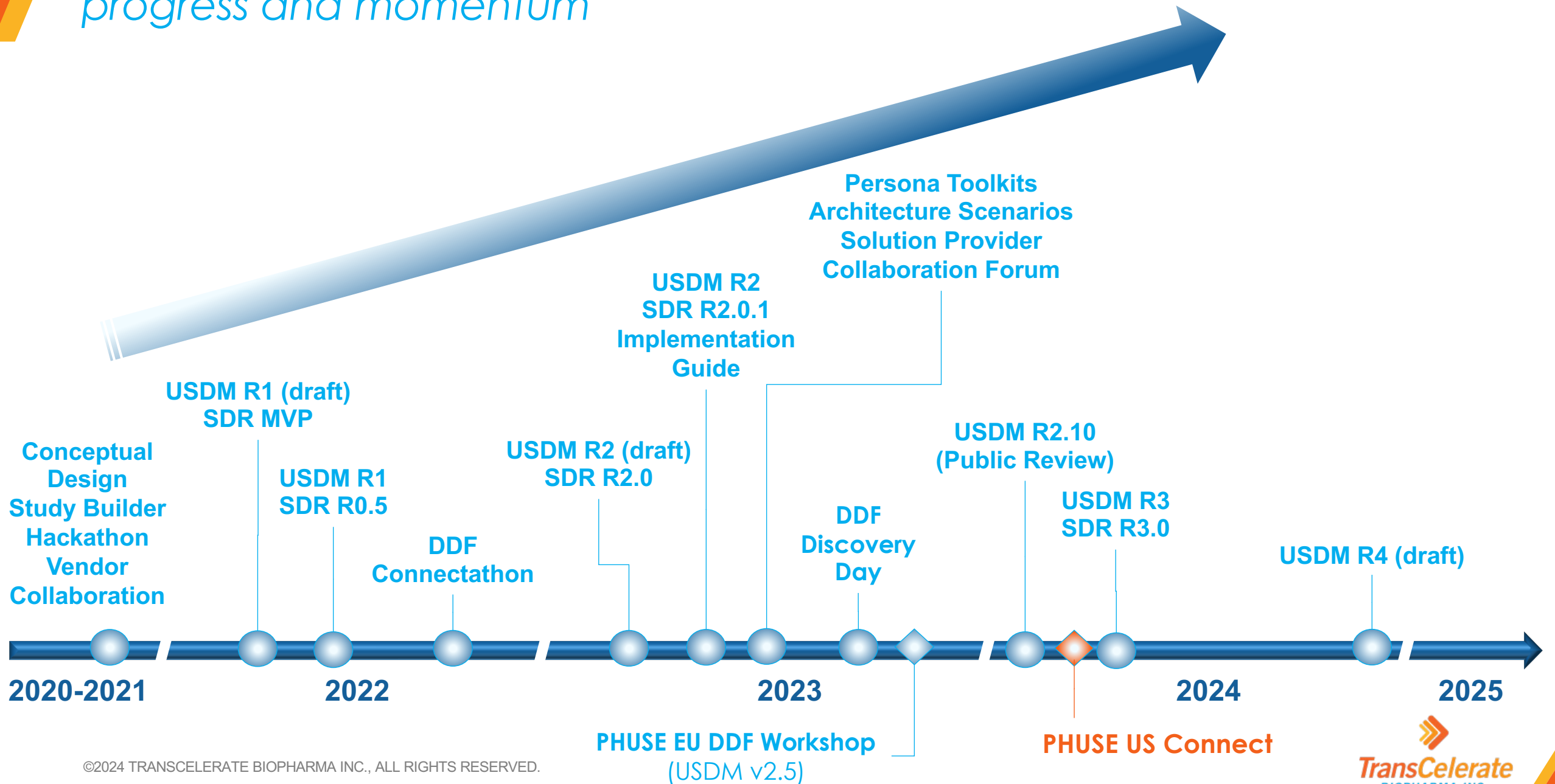


SoA



Digital Data Flow Timeline

progress and momentum

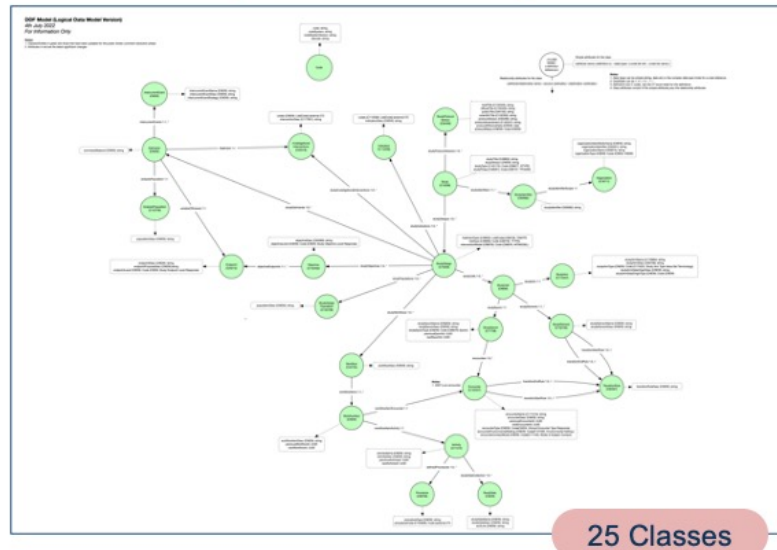


DDF Deliverables

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

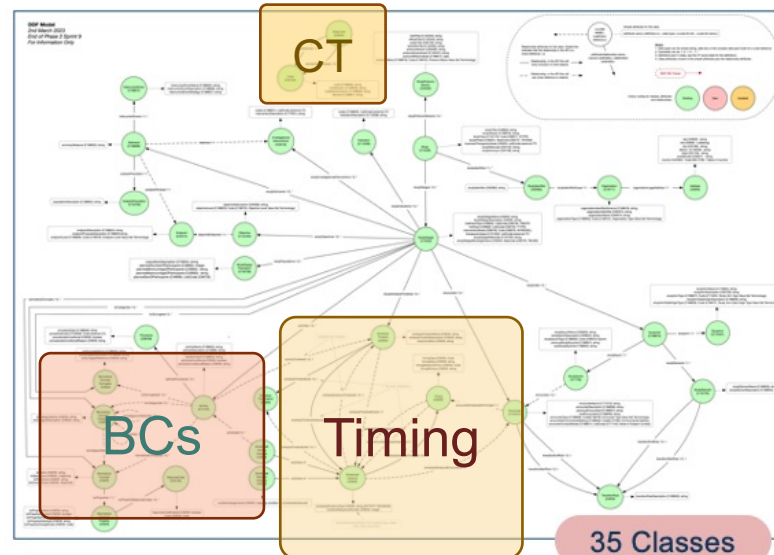
CDISC Development / USDM: Phases One, Two and Three

Phase One



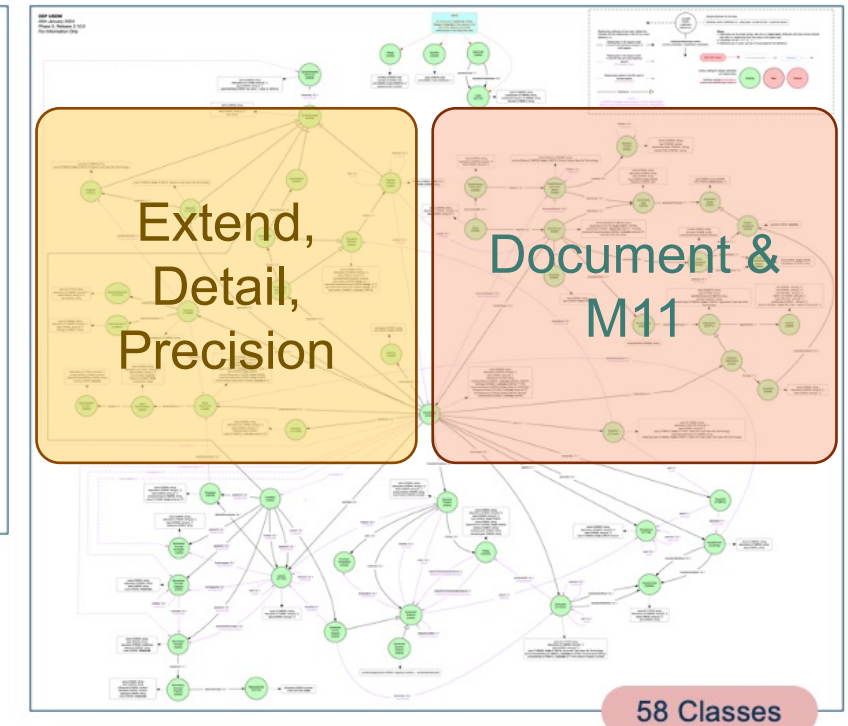
- Solid foundation
- The protocol document was an external entity into which the structured content could be exported

Phase Two



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

Phase Three



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

Where are we going?

TECHNICAL DELIVERY GOALS



Release 3.0 of USDM and SDR (2024)

- **Regulatory Alignment via collaboration between CDISC, ICH M11 and the Vulcan Working Group** – Complete (100%) digitization of all protocol elements in alignment with M11.
- **Expand Downstream Connectivity** – generation of SDTM Trial Design Domains, and Trial Registry data.



Alignment with Point of Care – Aligning DDF and Vulcan FHIR Accelerator resources for end-to-end enablement of site workflows and eSource configuration.

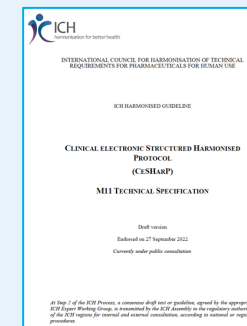
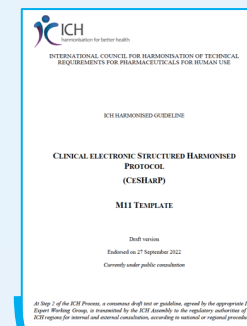


Explore use of CDISC CORE engine for USDM conformance check - MVP development with subset of rules.

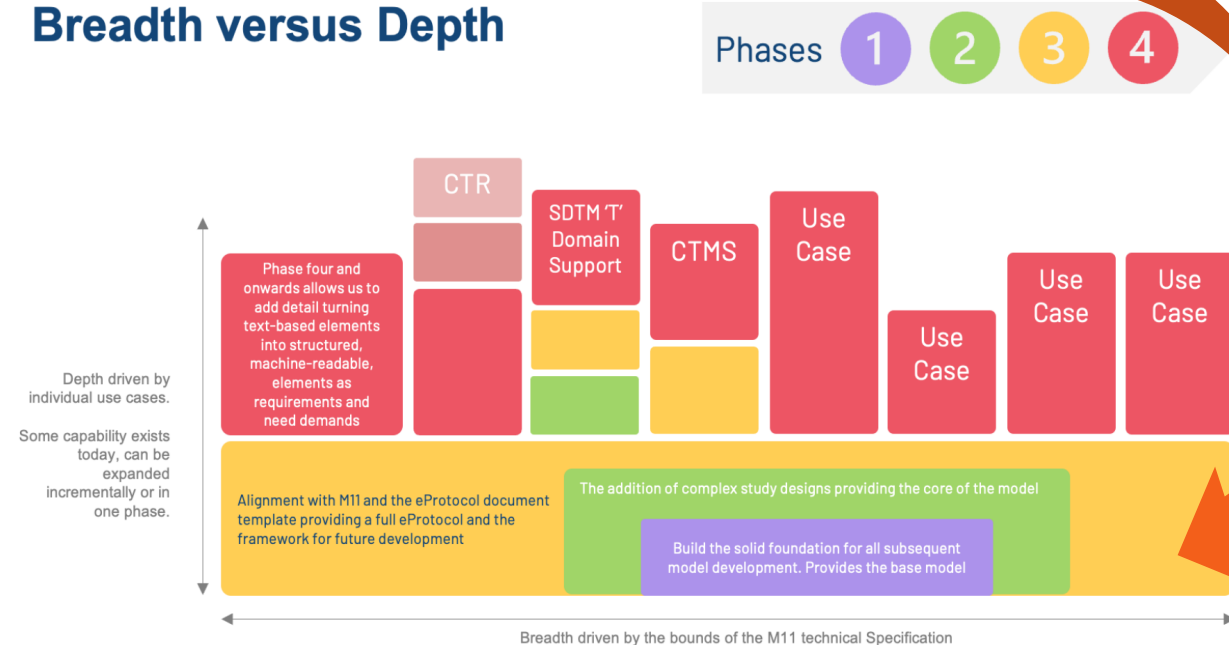
M11 is ...

ICH CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHarP)

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



Breadth versus Depth



Where are we going?



Sponsor
Engagement



Health Authority
Engagement



Solution Provider
Engagement



Communications &
Pulse on Industry

ENGAGEMENT GOALS



Increase Solution Provider Engagement

Continue to grow Solution Collaboration Forum and provide opportunity for providers to showcase how they are applying DDF solutions



Publish Sponsor Case Studies to share experiences among industry peers

Includes case studies in exploration and execution of related protocol digitization value and/or adoption



Strengthen industry understanding of DDF via congresses, webinars, and training

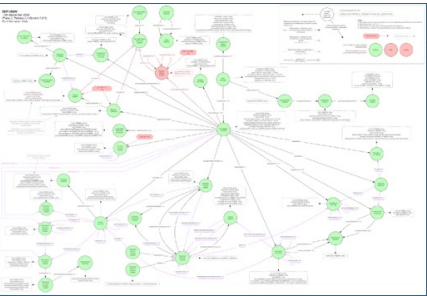
Workshops, panels/presentations, and modular education that can provide hands-on experience and showcase case studies



Prepare for long-term governance transition

Design long term governance model and prepare for a future transition of the DDF initiative to a 3rd party(ies) by year-end 2025

DDF Initiative encompasses technical delivery, change management, and industry engagement



cdisc
Unified Study
Definitions Model
(USDM) Reference
Architecture

TransCelerate's Study
Definitions Repository
(SDR) Reference
Implementation

**Digital Data
Flow Initiative**

Suite of DDF Adoption
Resources, Videos &
Change Management Tools

Continued Industry Collaboration
between TransCelerate, CDISC
ICH, and HL7



Growing Solution
Collaboration Forum (SCF)*



*Company logos illustrate current involvement and are not used to imply endorsement of specific vendors for DDF or to identify a comprehensive list of all actual or potential future participants in DDF.

CDISC EU Interchange 2024

Tuesday 23rd April

CDISC Workshops

Digital Data Flow Workshop

9:00 AM-3:00 PM CET

- Deep dive into all aspects of the model and how study protocols and designs can be represented using the USDM
- Focused sessions covering the theory on an individual aspect of the model combined with hands-on exercises and discussion
- Timing, biomedical concepts, interventions, versioning, links with other standards such as SDTM, ICH M11, Trial Registries

<https://www.cdisc.org/events/interchange/2024-cdisc-tmf-europe-interchange>



cdisc

Day 2
25 April 2024



11:00 - 12:30
Session 6A: Digital Data Flow

Stijn Rogers, argenx
Europa 5

11:00 - 11:30
ICH M11 Presentation
Peter Van Reusel, CDISC

11:30 - 12:00
DDF Presentation
Dave Iberson-Hurst, CDISC

12:00 - 12:30
DDF: The Art of the Possible Becomes a Reality
Bron Kisler, Nurocor

13:30 - 15:30
Session 7A: Digital Data Flow

Sujit Khune, Novo Nordisk A/S
Europa 5

13:30 - 13:50
Development of Unified Studies Definition Model (USDM) Through Translation of the Human-Readable Protocols
Jasmine Kestemont, Innovion

13:50 - 14:10
Ripping up the Protocol: Pairing up USDM and ICH M11 to Inform Real-Time Study Builds
Zaid Al-Jubouri, Lindus Health

14:10 - 14:40
Demonstrating e2e Study Data Automation Using Extended USDM Model
Kirsten Walther Langendorf, data4knowledge ApS

14:40 - 15:00
From OpenStudyBuilder to the Digital Data Flow- USDM Format
Maurizio Mazzel, Neo4J

15:00 - 15:30
Panel Discussion

Additional Opportunities to Stay Involved with DDF



Scan QR Code to explore DDF GitHub

- Review the videos, newsletters and other archived materials available
- Find links to the USDM RA, and other assets
- Download the SDR RI source code available
- Contribute and interact on the open discussion forums
- If you work for a TransCelerate member company, volunteer to join our core team
- If you work for a technology vendor join our Solution Collaboration Forum
- Volunteer to join the CDISC USDM team (via CDISC website)



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

Thank you!