DDF Phase 3 Public Information Webinar

14th September 2023

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TransCelerate's DDF Initiative

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.

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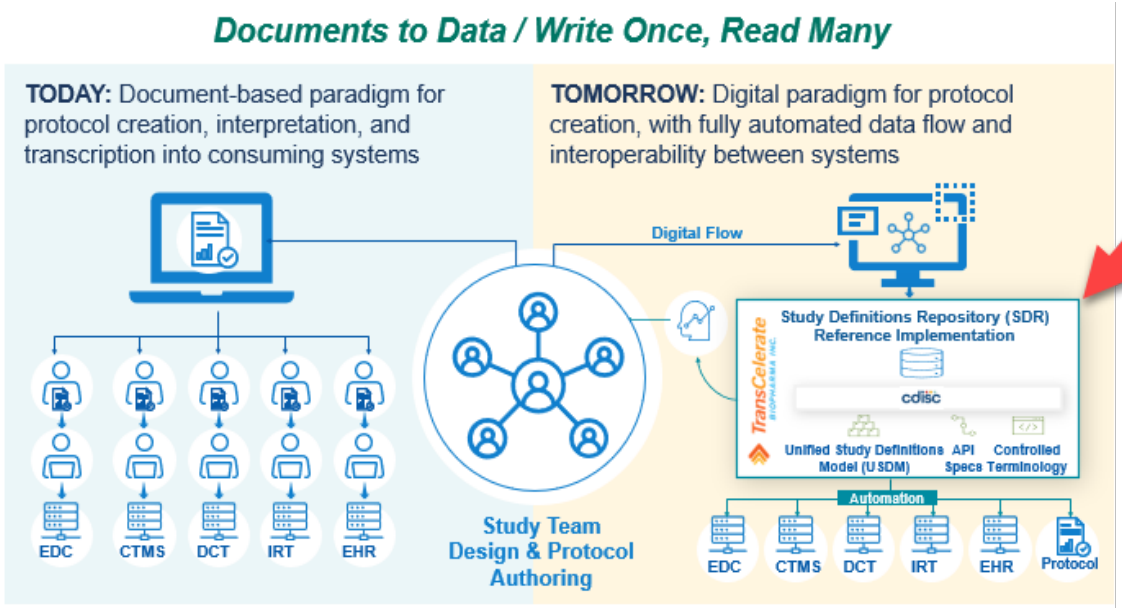
Digital Data Flow Ambition

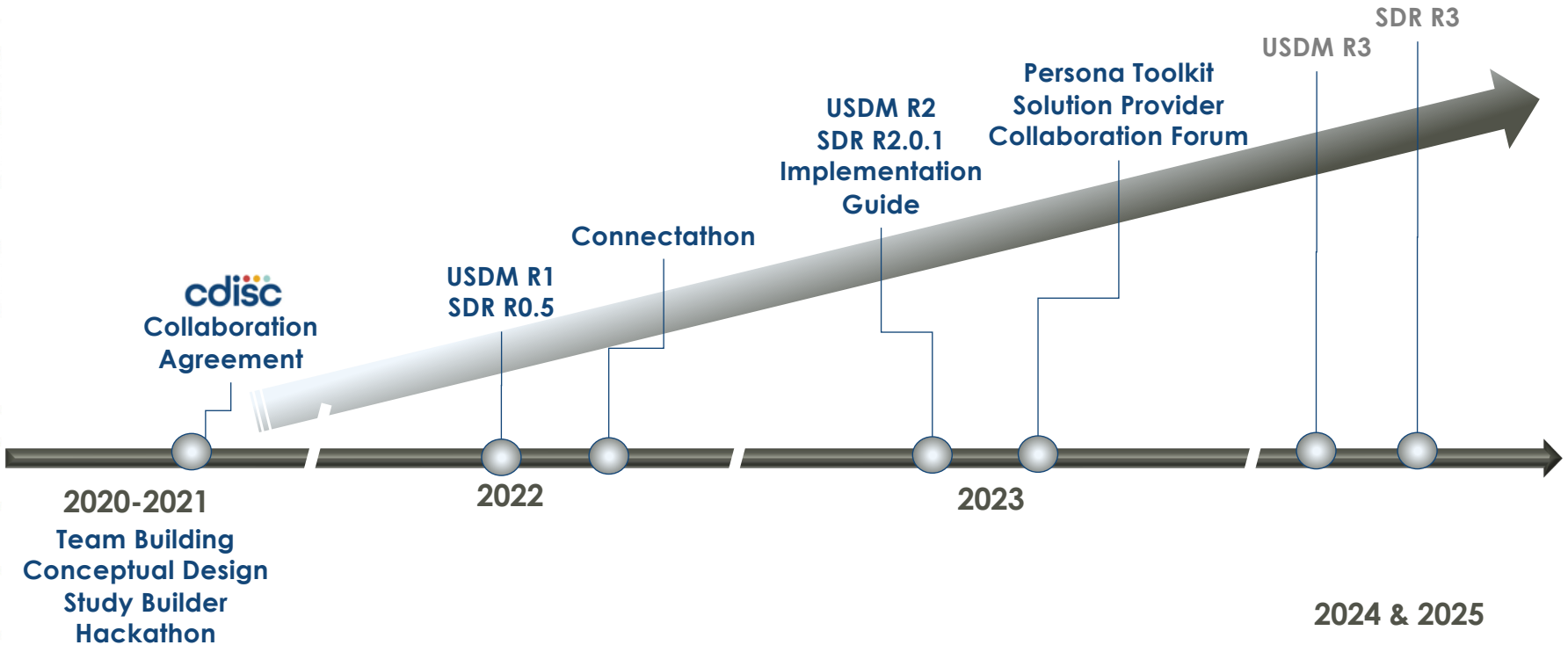
Digital - standard representation of study protocol
- ✓ structured
- ✓ machine readable
- ✓ executable

Data Flow – industry-wide interoperability
- ✓ exchange of data
- ✓ non-cooperating organizations
- ✓ minimal effort



Eliminate non-value added activities, work smarter not harder
Enable automation of downstream study startup and conduct processes
Create foundation for study design analytics insights

DDF Timeline



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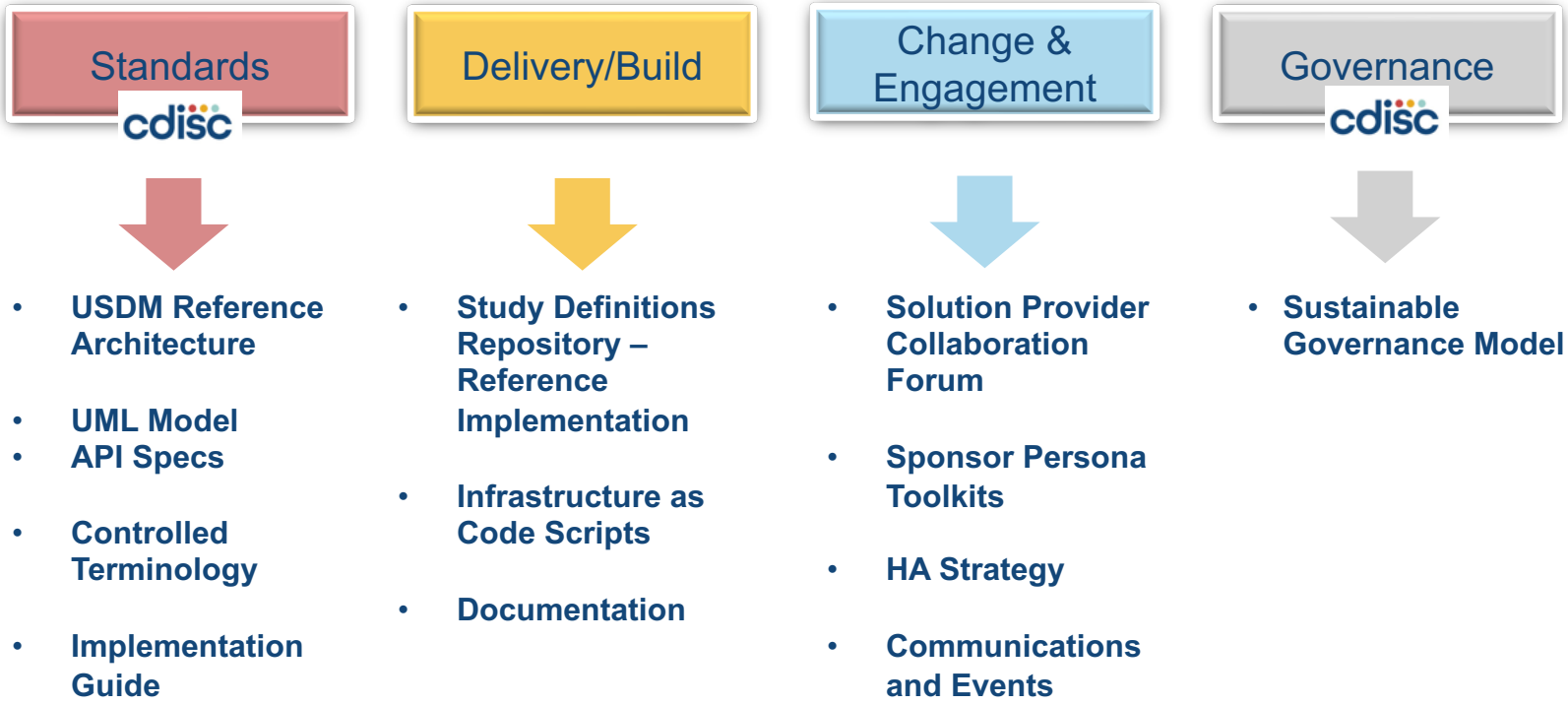
DDF Subteams and Delivery



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DDF Future Value Streams

Complete Protocol Digitization & Regulatory Alignment

- Complete (100%) digitization of all protocol elements in alignment with M11
- Automate production of SDTM Trial Design Domains and Registry Protocol Submission.

Alignment with Point of Care

- Alignment of USDM and FHIR/ResearchStudy resources for study workflow and eSource

Expand Downstream Connectivity

- Data flows to “protocol consuming” operational systems (e.g. CTMS, IVRS, DCT, eConsent)
- Work collaboratively with solution providers identify requirements for USDM

DDF Comms, Events & Webinars

Mark your calendars!

Upcoming Events, Webinars & Conferences	Date
CDISC Webinar: DDF Phase 3 Informational ● ▲ Register Here: Digital Data Flow Project Phase 3 Informational Webinar | CDISC	14 September 2023
DDF Discovery Day (Member Only In-person Event) ◆ Boston, MA, USA	19 September 2023
PHUSE SDE Copenhagen: Automation – Work Smarter Not Harder! ● Novo Nordisk campus Copenhagen, Denmark SDE 2023 (phuse-events.org)	10 October 2023
CDISC US Interchange ◆ Falls Church, VA, USA 2023 US Interchange | CDISC	18-19 October 2023 *(workshops begin 15-17th)*
eClinical Forum Americas ● Janssen in Spring House, PA North America Meetings - eClinical Forum	24-26 October 2023
PHUSE EU Connect (TCB sponsored DDF hands-on workshop) ◆ Birmingham, UK PHUSE EU Connect 2023 | CDISC	5-8 November 2023

◆ Major/ Interactive Event ● General Awareness ▲ Virtual option available

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Introduction

Digital Data Flow

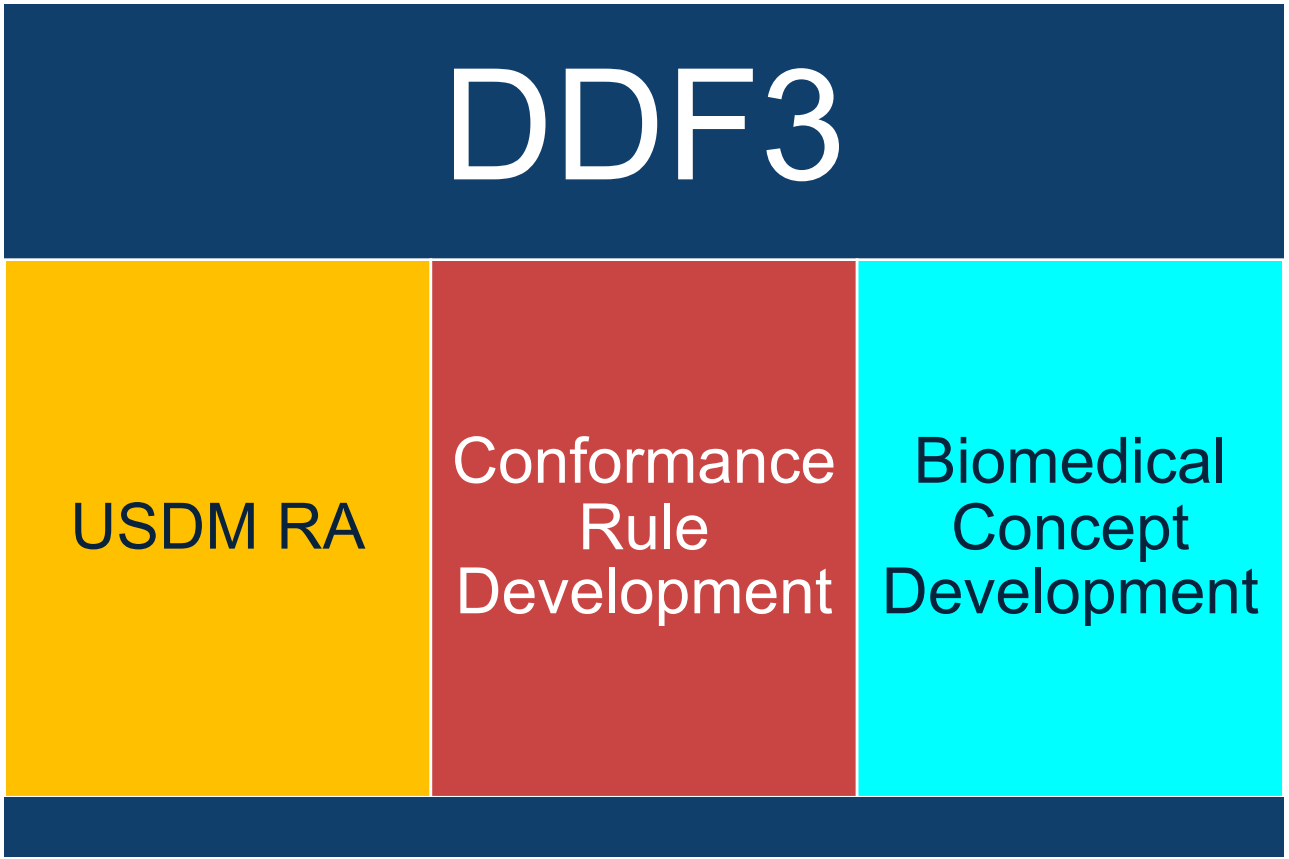
- **Phase 1**
  - Base model design
    - UML
    - API
    - Controlled Terminology
  - Topics
    - Objectives and endpoints
    - High Level Study Design
    - Eligibility criteria
    - Activities and assessments
    - Basic schedule of activities and assessments
    - Basic data collection configuration related to activities and assessments

- **Phase 2**
  - Extended model
    - UML
    - API
    - Controlled Terminology
    - USDMIG
    - Example Data
  - Topics
    - Enable greater population of study set-up elements
    - Represent structured study design information for more complex trials
      - Handling of complex study timing
    - Support electronic data capture (EDC) automation
      - Expand model to include Biomedical Concepts
    - Demonstrate population of the TransCelerate Common Protocol Template (CPT)
    - Demonstrate population of SDTM Trial Design Domains

2021 **2022** **2023**

https://www.cdisc.org/ddf

Work Areas


DDF3
USDM RA
Conformance Rule Development
Biomedical Concept Development

USDM RA

CDISC Study Definition Repository RA Deliverables

Unified Study Definitions Model (USDM) Class Diagram

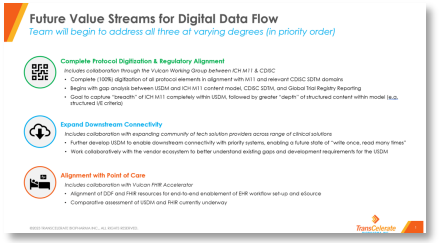
Application Programming Interface (API) Specification

CDISC Controlled Terminology

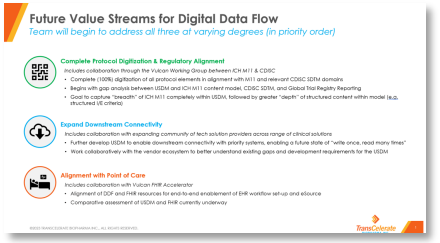
USDM Implementation Guide

DDF 3 USDM Scope

- Represent ICH M11 in USDM
- SDTM Trial Design Population
- Clinical Trial Registry Population
- Complex Studies/Cohorts
- Model Enhancements

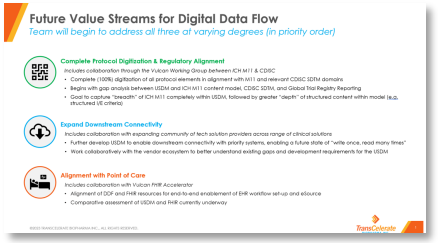


DDF 3 USDM Scope



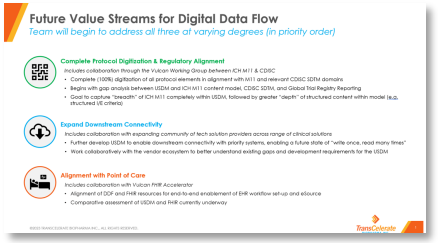
- Include breadth of ICH M11 into the USDM
  - Narrative Content
    - Covers free text parts of the M11 specification (i.e., without data elements)
  - Structured content
    - Using data elements to build sections of text
    - Individual structured elements (e.g., Study acronym, phase)
- SDTM Trial Design Population
  - Population of the planning parts of the SDTM trial design information
  - Some mapping performed in DDF 2
  - Additional mapping to allow population of existing SDTM trail design information (particularly the FDA required parameters)
  - Identification of new alignments between ICH M11 and SDTM trial design artefacts
    - What other trail design elements from the ICH M11 protocol could we represent in SDTM T domains
- Clinical Trial Registry Population
  - Expand on existing CTR.xml standard
  - POC to show population of structured fields from USDM for registering and updating studies in clinical Trial registries

DDF 3 USDM Scope

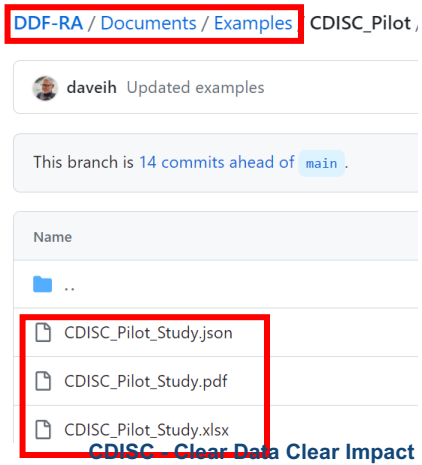


- Complex Studies, Complex Cohorts
  - Enhancements to ensure the model can hold complex study designs with complex cohorts
  - Allow for more modern protocol designs (e.g., basket trials, adaptive trials)
  - Include feedback from users of USDM v2.0
- Model Enhancements
  - Create a true logical data model with logical relationships that are visible and understandable with a separate document that details the API step to enable serialization to produce the required JSON
  - Improve element naming for consistency and standardize some elements within each class (e.g., name, description fields)
  - Improve general readability of the UML model

DDF 3 USDM Supporting Documentation



- USDMIG
  - Improve USDMIG content based on user feedback
  - Add additional Guidance for new elements added to the model
- USDM Test Data
  - Maintain test data developed during DDF2 to include new elements added to the model
  - Develop new test data for more complex study designs

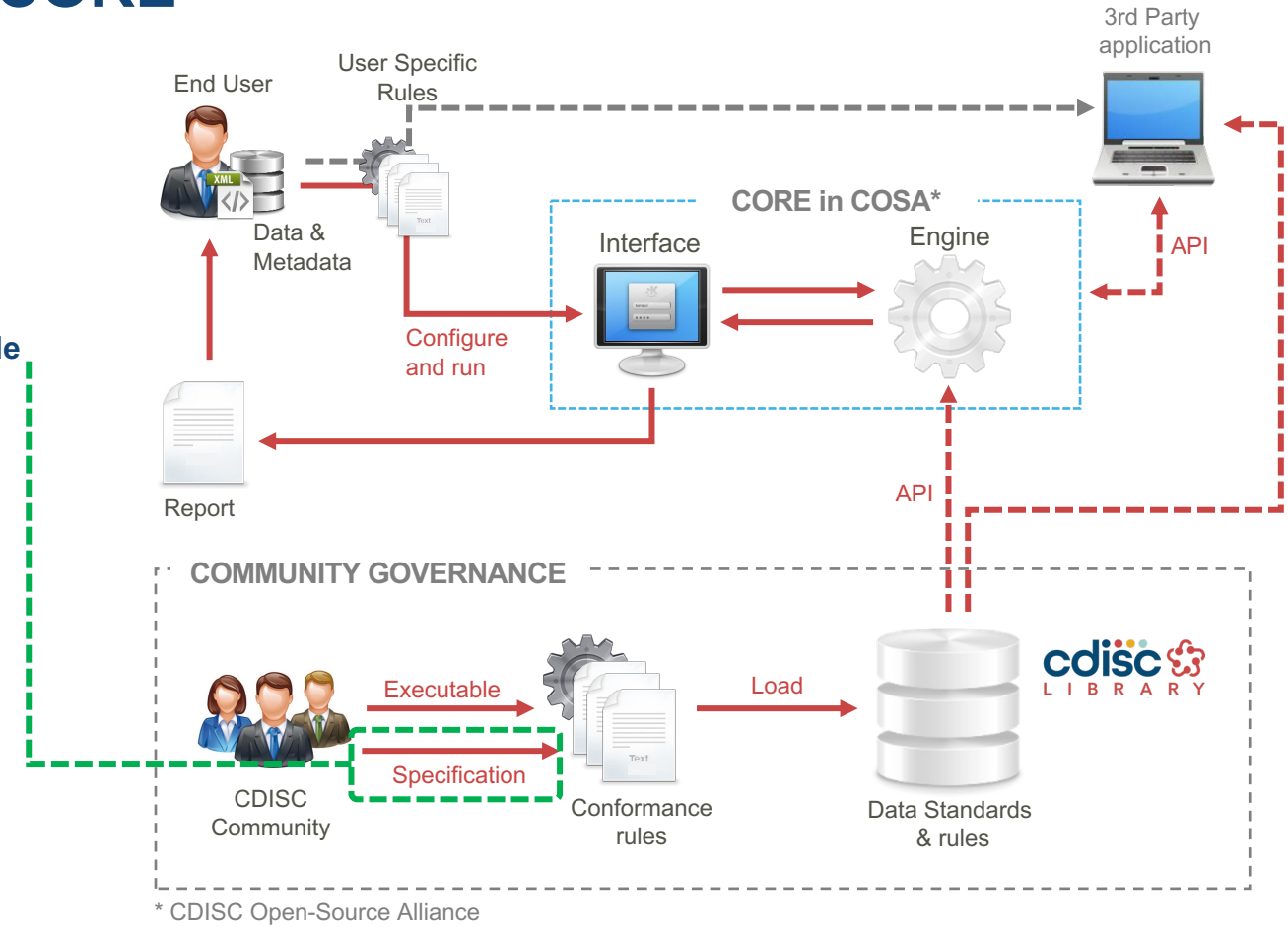


Conformance Rule Development

DDF 3 and CORE

DDF 3 will focus on development of the rule specifications

Later phases will focus on executable conformace rules and adaptation of CORE to work with DDF



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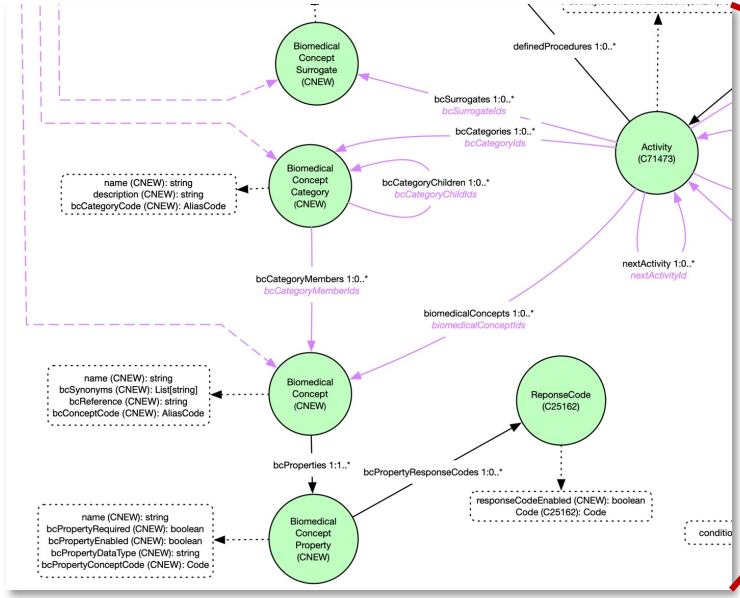
DDF 3 and CORE

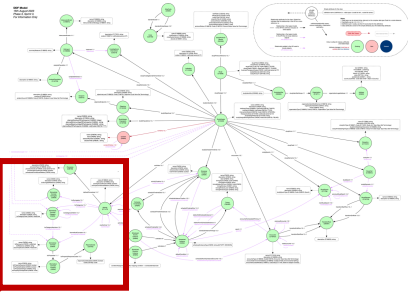
- Conformance currently part of the USDM API specification
- In-line with CDISC strategy for other standards the future intent for DDF is to have conformance rules specified in the library and executable through CORE
- DDF 3 limited to Excel Rule Specification only
  - Develop a representative set of conformance rules covering the breadth of the different types of rules expected to be required for use and several examples of elements using that type of rule required for DDF conformance
- Future phases may include development of a full set of conformance rule specifications alongside executable rules and CORE updates to work with DDF

Biomedical Concept Development

Biomedical Concept Development

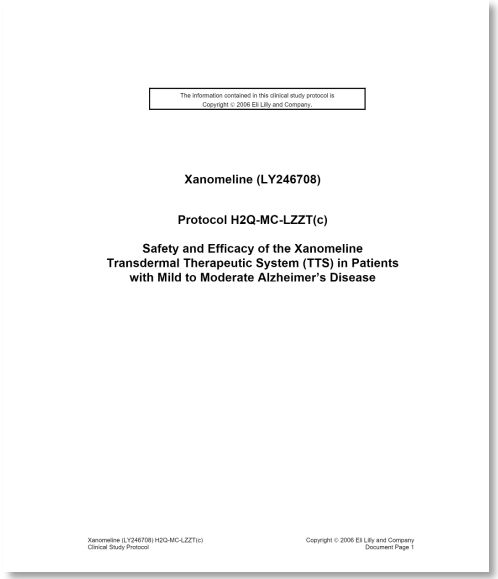
- DDF 2
  - Integration of the CDISC BC model into USDM to support EDC automation
  - Development of BCs to support a COVID protocol





Biomedical Concept Development

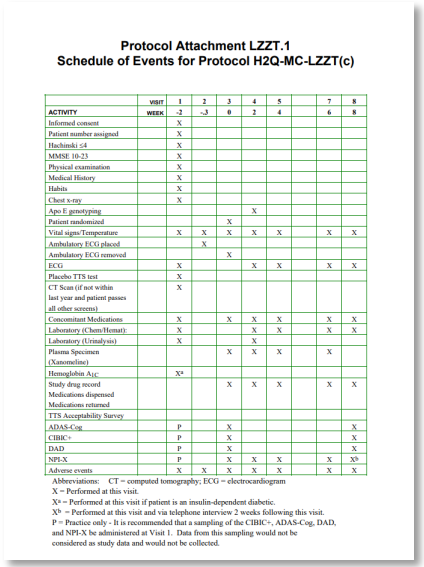
- DDF 3
  - Development of additional biomedical concepts to cover the CDISC Pilot Study (LZZT)
  - Allows for a full exemplar USDM protocol Design
  - LZZT used by other groups so allows for further alignment



Xanomeline (LY246708)

Protocol H2Q-MC-LZZT(c)

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



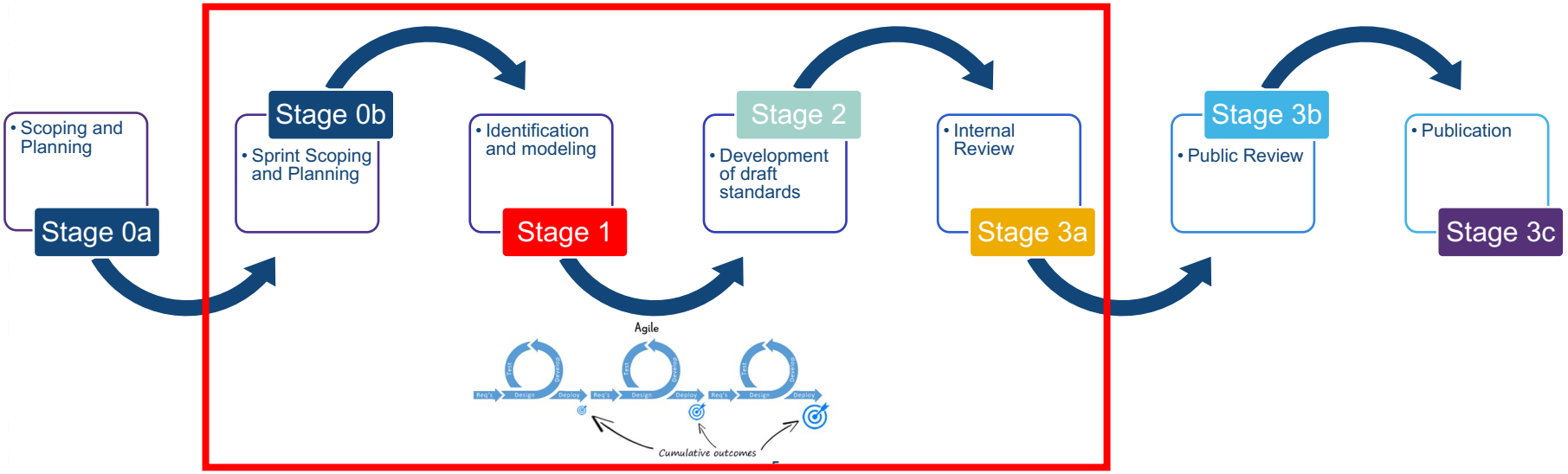
Protocol Attachment LZZT.1
Schedule of Events for Protocol H2Q-MC-LZZT(c)

	VISIT	1	2	3	4	5		7	8
ACTIVITY	WEEK	-2	-3	0	2	4		6	8
Informed consent		X							
Patient number assigned		X							
Hachinski ≤4		X							
MMSE 10-23		X							
Physical examination		X							
Medical History		X							
Habits		X							
Chest x-ray		X							
Apo E genotyping					X				
Patient randomized				X					
Vital signs/Temperature		X	X	X	X	X		X	X
Ambulatory ECG placed			X						
Ambulatory ECG removed				X					
ECG		X			X	X		X	X
Placebo TTS test		X							
CT Scan (if not within last year and patient passes all other screens)		X							
Concomitant Medications		X		X	X	X		X	X
Laboratory (Chem/Hemat):		X			X	X		X	X
Laboratory (Urinalysis)		X			X				
Plasma Specimen (Xanomeline)				X	X	X		X	
Hemoglobin A_{1C}		X[a]							
Study drug record Medications dispensed Medications returned				X	X	X		X	X
TTS Acceptability Survey									
ADAS-Cog		P		X					X
CIBIC+		P		X					X
DAD		P		X					X
NPI-X		P		X	X	X		X	X[b]
Adverse events		X	X	X	X	X		X	X

Abbreviations: CT = computed tomography; ECG = electrocardiogram
X = Performed at this visit.
X[a] = Performed at this visit if patient is an insulin-dependent diabetic.
X[b] = Performed at this visit and via telephone interview 2 weeks following this visit.
P = Practice only - It is recommended that a sampling of the CIBIC+, ADAS-Cog, DAD, and NPI-X be administered at Visit 1. Data from this sampling would not be considered as study data and would not be collected.

Process and Timelines

CDSIC Standards Development Process (COP-001)



<u>Parts of Stage 0b – 3a take place for each draft release.</u>

- After Stage 0a, the sprints begin and a small scoping effort happens as part of the planning for each sprint
- An Inernal review step happens after each draft release.

Development and Review

2023

Date	Week #		Stage	Sprint #
05-Jul-23	1	Scoping	Development Sprints	1
12-Jul-23	2	Scoping	Development Sprints	1
19-Jul-23	3	Scoping	Development Sprints	2
26-Jul-23	4	Scoping	Development Sprints	2
02-Aug-23	5	Scoping	Development Sprints	3
09-Aug-23	6	Scoping	Development Sprints	3
16-Aug-23	7	Scoping	Development Sprints	4
23-Aug-23	8	Scoping	Development Sprints	4
30-Aug-23	9	Scoping	Development Sprints	5
06-Sep-23	10	Scoping	Development Sprints	5
13-Sep-23	11	Scoping	Development Sprints	6
20-Sep-23	12	Scoping	Development Sprints	6
27-Sep-23	13	Scoping	Development Sprints	7
04-Oct-23	14		Development Sprints	7
11-Oct-23	15		Development Sprints	8
18-Oct-23	16		Development Sprints	8
25-Oct-23	17		Development Sprints	9
01-Nov-23	18		Development Sprints	9
08-Nov-23	19		Development Sprints	10
15-Nov-23	20		Development Sprints	10
22-Nov-23	21		Development Sprints	11
29-Nov-23	22		Development Sprints	11
06-Dec-23	23		Development Sprints	12
13-Dec-23	24		Development Sprints	12
20-Dec-23	25		Development Sprints	13
27-Dec-23	26		Development Sprints	13

Development

Continuous Internal Review

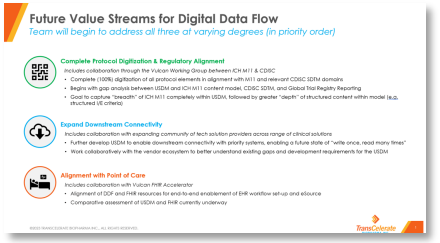
2024

Date	Week #		Stage	Sprint #
03-Jan-24	27		Public Review	14
10-Jan-24	28		Public Review	14
17-Jan-24	29		Public Review	15
24-Jan-24	30		Public Review	15
31-Jan-24	31		Public Review	16
07-Feb-24	32		Public Review	16
14-Feb-24	33		Public Review	17
21-Feb-24	34		Public Review	17
28-Feb-24	35		Public Review	18
06-Mar-24	36		Public Review	18
13-Mar-24	37		Publication	19
20-Mar-24	38		Publication	19
27-Mar-24	39		Publication	20
03-Apr-24	40		Publication	20

Public Review

DDF 3 USDM Scope

- ★ Represent ICH M11 in USDM
- ★ SDTM Trial Design Population
- Clinical Trial Registry Population
- Complex Studies/Cohorts
- Model Enhancements



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Next Steps – Phase Three

Slide from May 2023

USDM

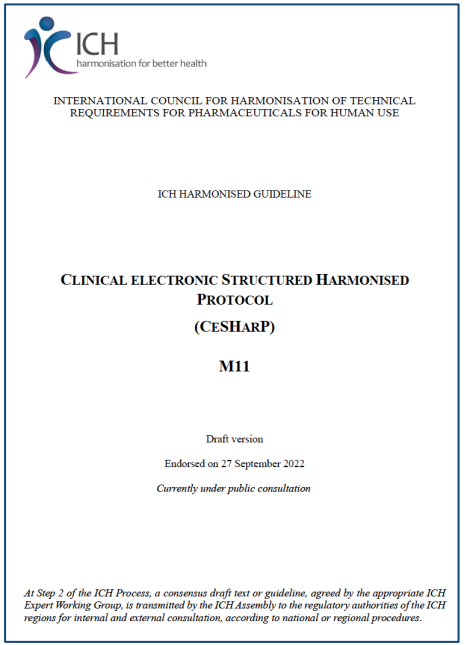
SDR

1	2	3
• Baseline model for specifying a study in digital format • Model supports use of a CRF link to specify which forms to use in EDC. • Handles simple study designs	• Improved support for complex study designs with a fully specified digitized Schedule of Activities (SoA) • Model supports the identification of the appropriate CRFs for data collection to enable automated, faster configuration via use of Biomedical Concepts • Improved CPT alignment • Initial 'T' Domain support	Focus for Phase 3 is currently being determined. Current expectations are: • Expand ability to handle increasingly complex studies • ICH M11 & CPT alignment
• Consume digitized study specification from an upstream source e.g., study builder) • Store, view and search study concepts • Downstream EDC systems may pull study specification to aid in set-up	• Downstream vendors can readily consume the SoA from the SDR • Sponsor system admins can perform a visual check that SoA data received from an upstream system displays an accurate, human-readable SoA table • Opportunity to aggregate robust historical protocol information to support analytics to drive smart design and assess risk	

M11 Is …

ICH CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHarP)

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



ICH harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

M11

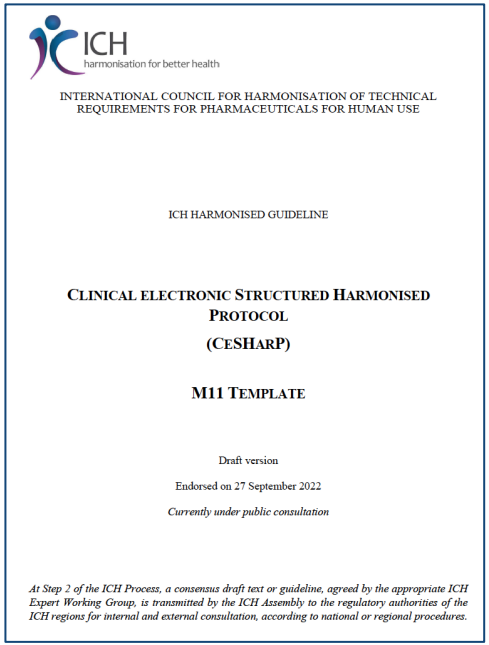
Draft version

Endorsed on 27 September 2022

Currently under public consultation

At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Assembly to the regulatory authorities of the ICH regions for internal and external consultation, according to national or regional procedures.

Defines the background, purpose and scope



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(CESHARP)

M11 TEMPLATE

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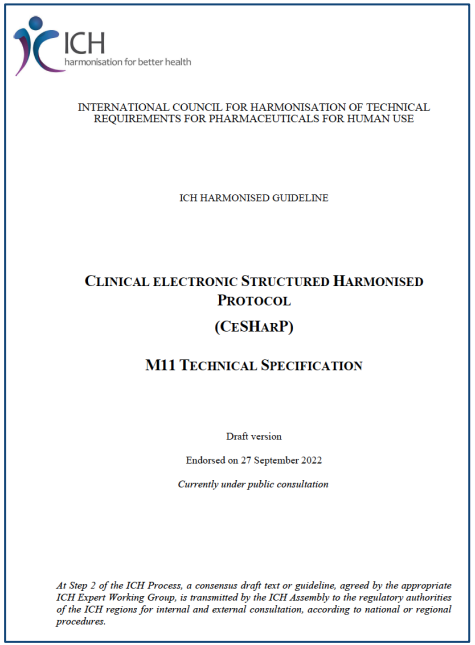
The specification of the Protocol Document Template that contains embedded data elements



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ICH HARMONISED GUIDELINE

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(CESHARP)

M11 TECHNICAL SPECIFICATION

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Provides a set of data element definitions aligned with the template specification

M11 Simple Example

Template Specification

Protocol Full Title:	[Protocol Full Title] The protocol should have a descriptive title that identifies the scientific aspects of the trial sufficiently to ensure it is immediately evident what the trial is investigating and on whom, and to allow retrieval from literature or internet searches.
Sponsor Confidentiality Statement:	[Sponsor Confidentiality Statement] Insert the Sponsor's confidentiality statement, if applicable, otherwise delete.
Protocol Number:	[Protocol Number] A unique alphanumeric identifier for the trial, designated by the Sponsor, is a standard part of trial data, and should be included for most trials.
Version:	[Version] An optional field for use by the Sponsor at their discretion.
Amendment Number:	[Amendment Number] Enter the amendment number. If this is the original instance of
Compound Number(s):	[Compound Number] Enter the Sponsor's unique identifier for investigational compound(s) in the trial. Add or delete additional fields as needed.
Compound Name(s):	[Nonproprietary Name]. [Proprietary Name]. [Additional Proprietary Name] Delete this line from the table if a nonproprietary name has not yet been assigned. Omit proprietary name fields if not yet established.
Trial Phase:	[Trial Phase] [Description of Trial Phase Other] Acceptable entries are: "Early Phase 1", "Phase 1", "Phase 1/Phase 2", "Phase 2", "Phase 2/Phase 3", "Phase 3", "Phase 4",

Trial Phase: [Trial Phase] [Description of Trial Phase Other]

Acceptable entries are: "Early Phase 1", "Phase 1", "Phase 1/Phase 2", "Phase 2", "Phase 2/Phase 3", "Phase 3", "Phase 4",

Technical Specification

Term (Variable)	Trial Phase
Data Type	Pick list
Topic, Value or Header	D
Definition	
User Guidance	For trials combining investigational drugs or vaccines with devices, classify according to the phase of drug development.
Conformance	Required
Cardinality	
Relationship content from ToC representing the protocol hierarchy	Title Page
Relationship (reference to high level conceptual model)	
Value	Early Phase 1 Phase 1 Phase 1/Phase 2 Phase 2 Phase 2/Phase 3 Phase 3 Phase 4 Other
Business rules	**Value Allowed:** yes **Relationship:** n/a **Concept:** Protocol short title
Duplicate field in other sections	

Controlled Terms

Template Specification

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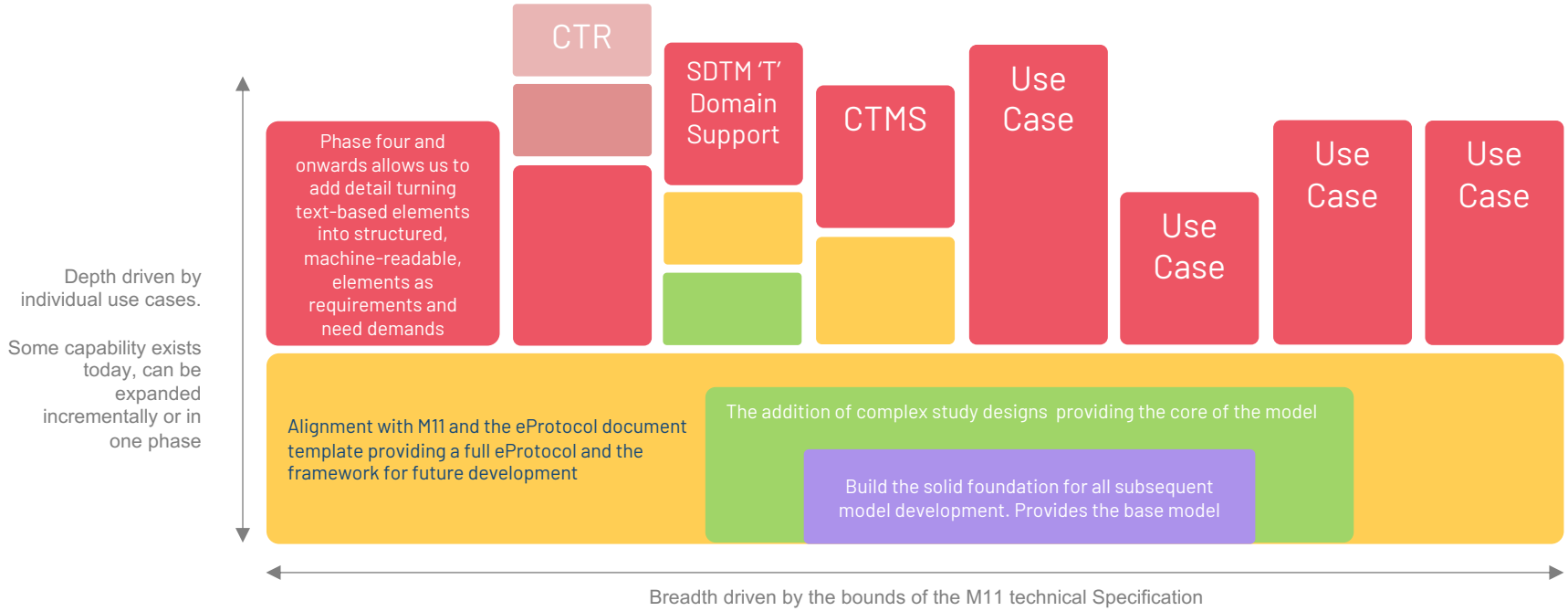
Business rules	**Value Allowed:** yes **Relationship:** n/a **Concept:** Protocol short title
Duplicate field in other sections	

CDISC CT

Trial Phase Response (C66737)

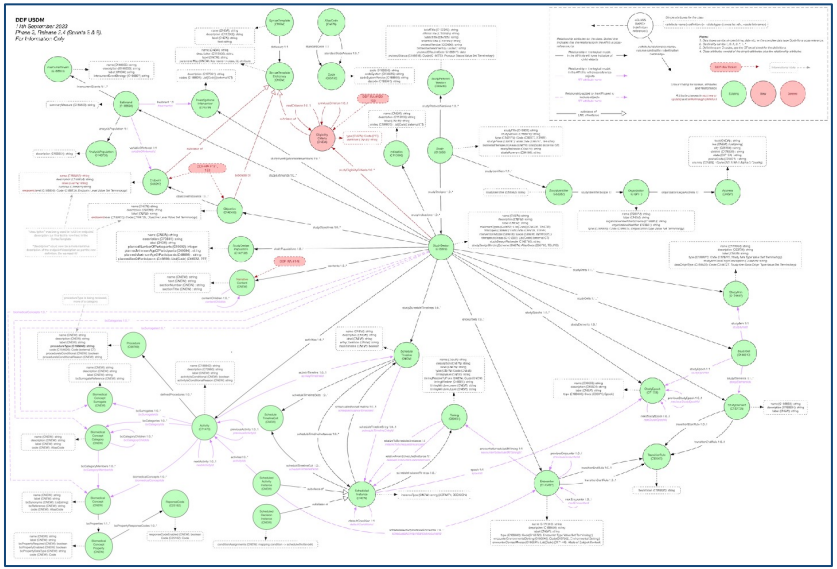
NOT APPLICABLE
PHASE 0 TRIAL
PHASE I TRIAL
PHASE I/II TRIAL
PHASE II TRIAL
PHASE II/III TRIAL
PHASE IIA TRIAL
PHASE IIB TRIAL
PHASE III TRIAL
PHASE IIIA TRIAL
PHASE IIIB TRIAL
PHASE IV TRIAL
PHASE V TRIAL

Breadth versus Depth



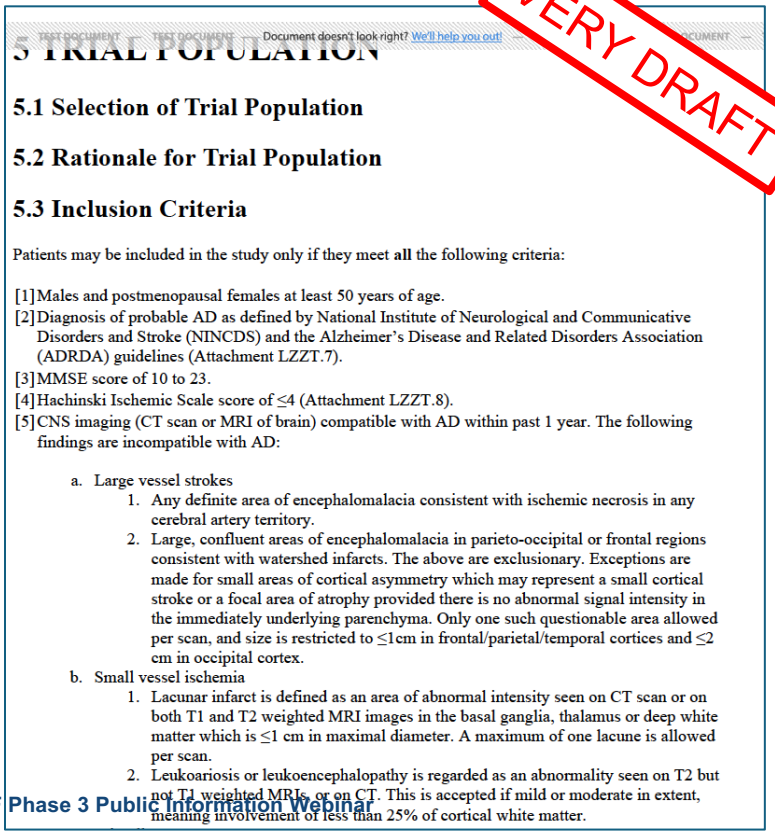
Shift of Focus

- Phases One & Two
  - Focused on the structured elements of the protocol, e.g. the Schedule of Activities (SoA)
  - The protocol document was an external entity into which the structured content could be exported
- Phase Three
  - Now contains structured and unstructured elements
  - The entire protocol document is held within the USDM
  - Allows for the protocol document to be generated from the model



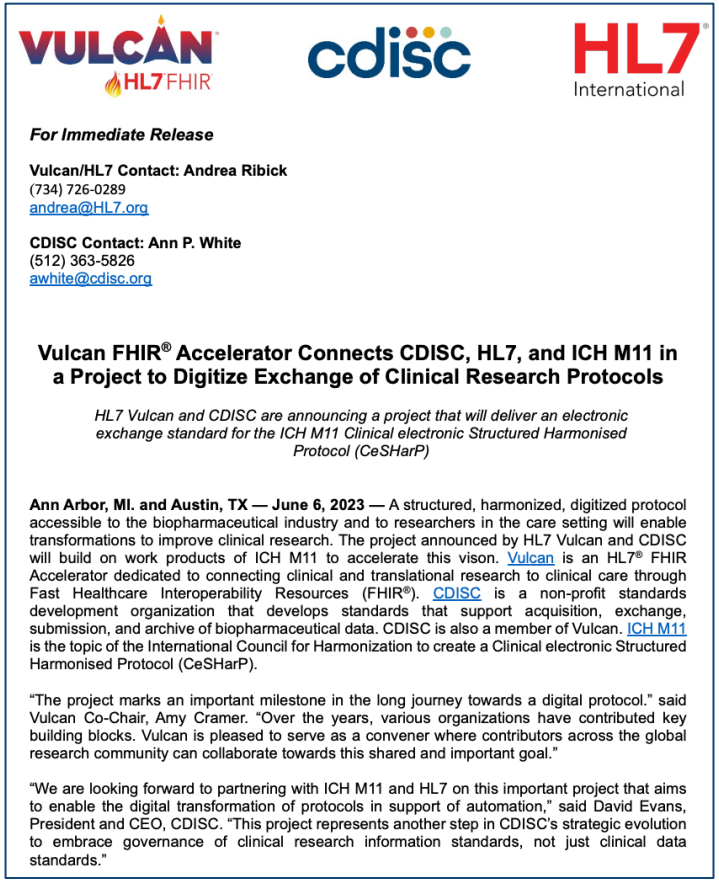
M11 Template Example Document

- First attempt to create a protocol document from the USDM, both structured [non-narrative] and unstructured [narrative text] content.
- Functionality has been added to the Excel test data tool
- More work is needed, this is very much a first draft



ICH M11, CDISC & HL7

- "FHIR-based exchange standard for ICH's Clinical electronic Structured Harmonised Protocol (CeSHarP), aligned to CDISC standards"
- The USDM and CDISC CT will be used in the project
- Initial project discussions have been underway for a few months



For Immediate Release

Vulcan/HL7 Contact: Andrea Ribick
(734) 726-0289
andrea@HL7.org

CDISC Contact: Ann P. White
(512) 363-5826
awhite@cdisc.org

Vulcan FHIR® Accelerator Connects CDISC, HL7, and ICH M11 in a Project to Digitize Exchange of Clinical Research Protocols

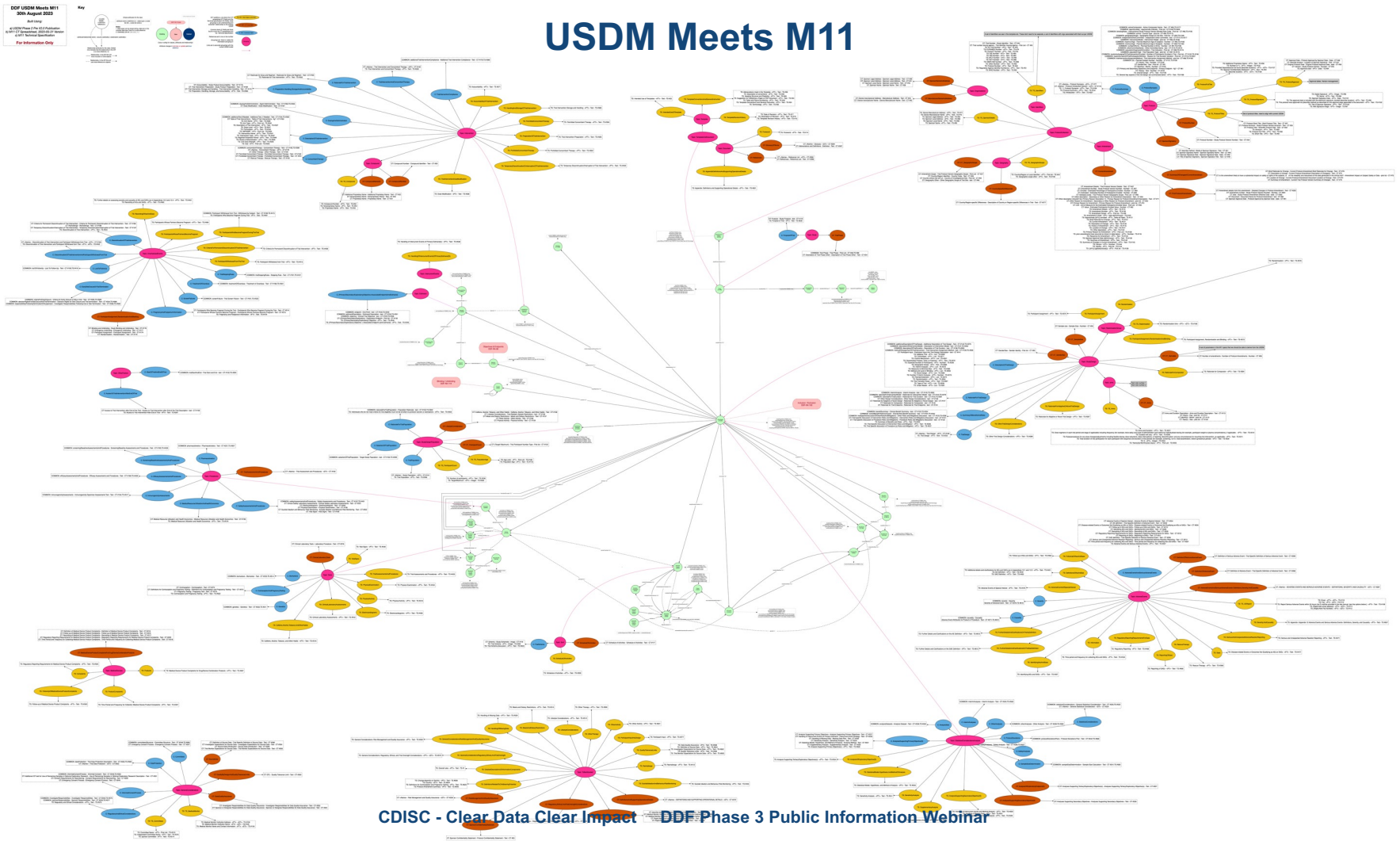
HL7 Vulcan and CDISC are announcing a project that will deliver an electronic exchange standard for the ICH M11 Clinical electronic Structured Harmonised Protocol (CeSHarP)

Ann Arbor, MI. and Austin, TX — June 6, 2023 — A structured, harmonized, digitized protocol accessible to the biopharmaceutical industry and to researchers in the care setting will enable transformations to improve clinical research. The project announced by HL7 Vulcan and CDISC will build on work products of ICH M11 to accelerate this vison. Vulcan is an HL7® FHIR Accelerator dedicated to connecting clinical and translational research to clinical care through Fast Healthcare Interoperability Resources (FHIR®). CDISC is a non-profit standards development organization that develops standards that support acquisition, exchange, submission, and archive of biopharmaceutical data. CDISC is also a member of Vulcan. ICH M11 is the topic of the International Council for Harmonization to create a Clinical electronic Structured Harmonised Protocol (CeSHarP).

"The project marks an important milestone in the long journey towards a digital protocol." said Vulcan Co-Chair, Amy Cramer. "Over the years, various organizations have contributed key building blocks. Vulcan is pleased to serve as a convener where contributors across the global research community can collaborate towards this shared and important goal."

"We are looking forward to partnering with ICH M11 and HL7 on this important project that aims to enable the digital transformation of protocols in support of automation," said David Evans, President and CEO, CDISC. "This project represents another step in CDISC's strategic evolution to embrace governance of clinical research information standards, not just clinical data standards."

USDM Meets M11



SDTM Trial Design

USDM v2 SDTM Trial Design Activities

- Initial investigation into automated creation of SDTM Trial Design datasets.
- USDMIG documented a list of published Trial Summary (TS) parameters and their mapping to USDM elements (entities, attributes, or valid values)

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synony	CDISC Definition	NCI Preferred Term	USDM Entity Name
C101302	C66738		Trial Summary Parameter Test Code	THERAREA	Therapeutic Area	A knowledge field that focuses on research and development of specific treatments for diseases and pathologic findings, as well as prevention of conditions that negatively impact the health of an individual. (NCI)	Therapeutic Area	StudyDesign
C112038	C66738		Trial Summary Parameter Test Code	INDIC	Trial Disease/Condition Indication; Trial Disease/Condition Indication Description	The textual representation of the condition, disease or disorder that the clinical trial is intended to investigate or address.	Trial Indication	Indication
C112038	C66738		Trial Summary Parameter Test Code	INDIC	Trial Disease/Condition Indication; Trial Disease/Condition Indication Description	The textual representation of the condition, disease or disorder that the clinical trial is intended to investigate or address.	Trial Indication	Indication
C142175	C66738		Trial Summary Parameter Test Code	STYPE	Study Type; Study Type Classification	The nature of the investigation for which study information is being collected. (clinicaltrials.gov)	Study Type	Study
C48281	C66738		Trial Summary Parameter Test Code	TPHASE	Trial Phase; Trial Phase Classification	A step in the clinical research and development of a therapy from initial clinical trials to post-approval studies. **Note:** Clinical trials are generally categorized into 4 (sometimes 5) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap 2 different phases. (21 CFR § 312.21; see also ICH Guideline E8[4])	Trial Phase	Study
C49652	C66738		Trial Summary Parameter Test Code	TINDTP	Trial Intent Type	The planned purpose of the therapy, device, or agent under study in the clinical trial.	Clinical Study by Intent	StudyDesign
C49658	C66738		Trial Summary Parameter Test Code	TBLIND	Study Blinding Design; Study Blinding Schema; Study Masking Design; Trial Blinding Design; Trial Blinding Schema; Trial Masking Design	The type of experimental design used to describe the level of awareness of the study subjects and/ or study personnel as it relates to the respective intervention(s) or assessments being observed, received or administered.	Trial Blinding Schema	StudyDesign
C49660	C66738		Trial Summary Parameter Test Code	TTYPE	Trial Scope; Trial Type	The nature of the interventional study for which information is being collected.	Trial Type	StudyDesign

- DDF Phase 3 will expand on this initial work

SDTM Trial Design - activities

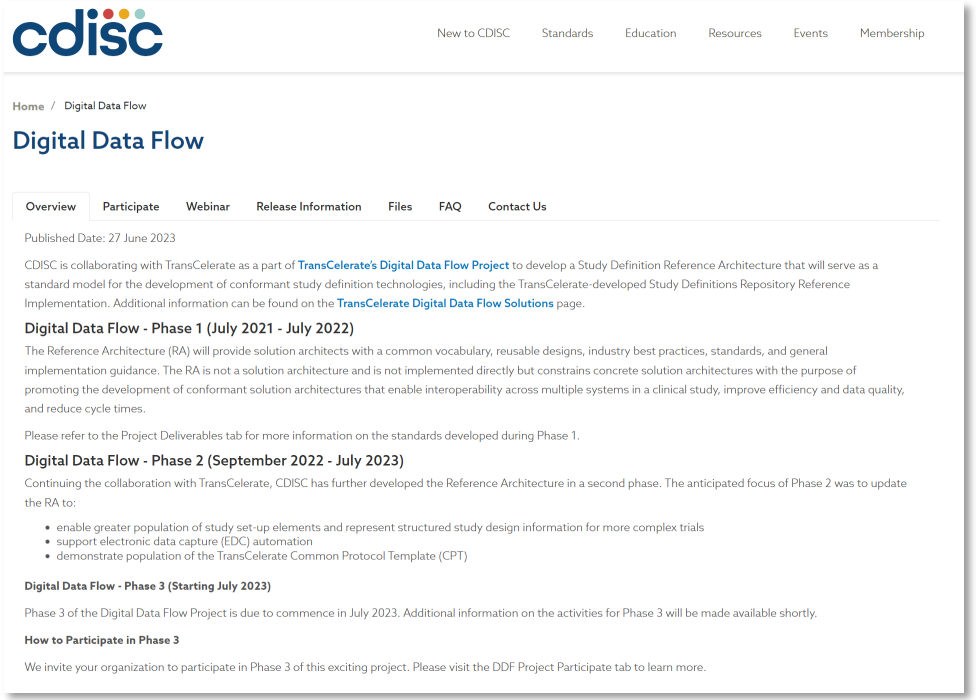
- Weekly alignment meetings
- Mutual education of SDTM vs USDM specialists
- Explore SDTM trial design domains
- Check current overlap and mapping from USDM to SDTM Trial Design domains
- Check corresponding M11 requirements and overlap with SDTM
- Suggest additions to USDM

USDM recommendations

- SDTM TS domain
  - Add current TS parameters that are required by FDA to USDM
  - Add additional corresponding M11 parameters to USDM
  - The following USDM classes are affected
    - Study / Study Design
    - Population
    - Intervention
    - Indication
- SDTM TI domain
  - Include Eligibility Criteria in USDM and align with TI
- Other trial design domains
  - Alignment in progress

Available Resources

CDISC DDF Web Site Page



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Home / Digital Data Flow

Digital Data Flow

Overview | Participate | Webinar | Release Information | Files | FAQ | Contact Us

Published Date: 27 June 2023

CDISC is collaborating with TransCelerate as a part of **TransCelerate's Digital Data Flow Project** to develop a Study Definition Reference Architecture that will serve as a standard model for the development of conformant study definition technologies, including the TransCelerate-developed Study Definitions Repository Reference Implementation. Additional information can be found on the **TransCelerate Digital Data Flow Solutions** page.

Digital Data Flow - Phase 1 (July 2021 - July 2022)

The Reference Architecture (RA) will provide solution architects with a common vocabulary, reusable designs, industry best practices, standards, and general implementation guidance. The RA is not a solution architecture and is not implemented directly but constrains concrete solution architectures with the purpose of promoting the development of conformant solution architectures that enable interoperability across multiple systems in a clinical study, improve efficiency and data quality, and reduce cycle times.

Please refer to the Project Deliverables tab for more information on the standards developed during Phase 1.

Digital Data Flow - Phase 2 (September 2022 - July 2023)

Continuing the collaboration with TransCelerate, CDISC has further developed the Reference Architecture in a second phase. The anticipated focus of Phase 2 was to update the RA to:

- enable greater population of study set-up elements and represent structured study design information for more complex trials
- support electronic data capture (EDC) automation
- demonstrate population of the TransCelerate Common Protocol Template (CPT)

Digital Data Flow - Phase 3 (Starting July 2023)

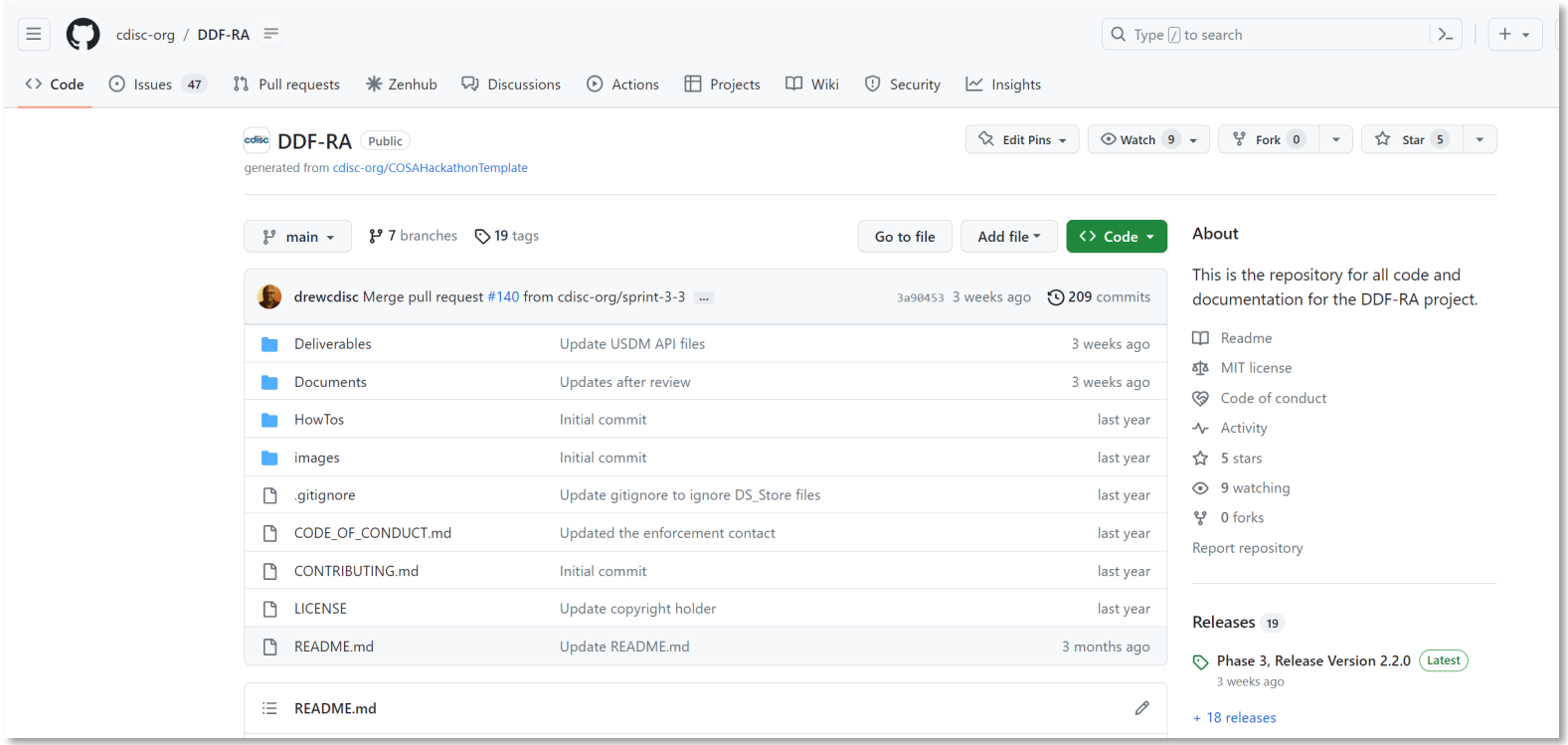
Phase 3 of the Digital Data Flow Project is due to commence in July 2023. Additional information on the activities for Phase 3 will be made available shortly.

How to Participate in Phase 3

We invite your organization to participate in Phase 3 of this exciting project. Please visit the DDF Project Participate tab to learn more.

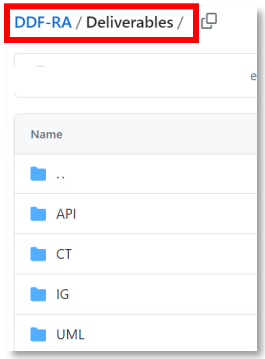
https://www.cdisc.org/ddf

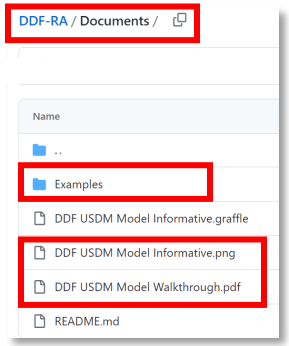
GitHub

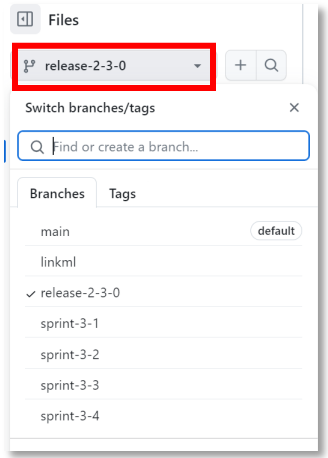


https://github.com/cdisc-org/DDF-RA

GitHub







https://github.com/cdisc-org/DDF-RA

PUBLIC

DDF USDM Model Information Graphic

DDF-RA / Documents /

daveih Updates after review

Name

..

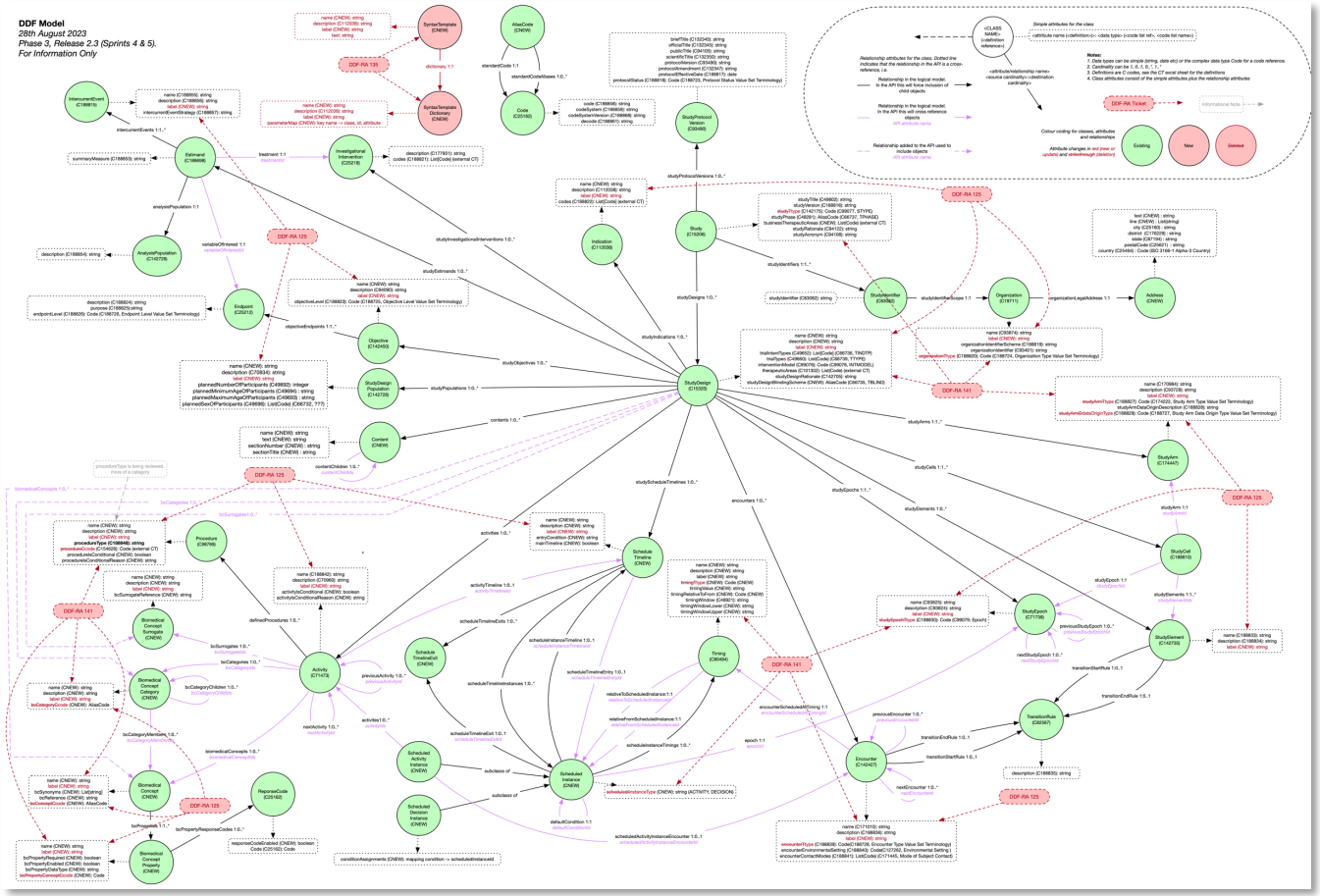
Examples

DDF USDM Model Informative.graffle

DDF USDM Model Informative.png

DDF USDM Model Walkthrough.pdf

README.md



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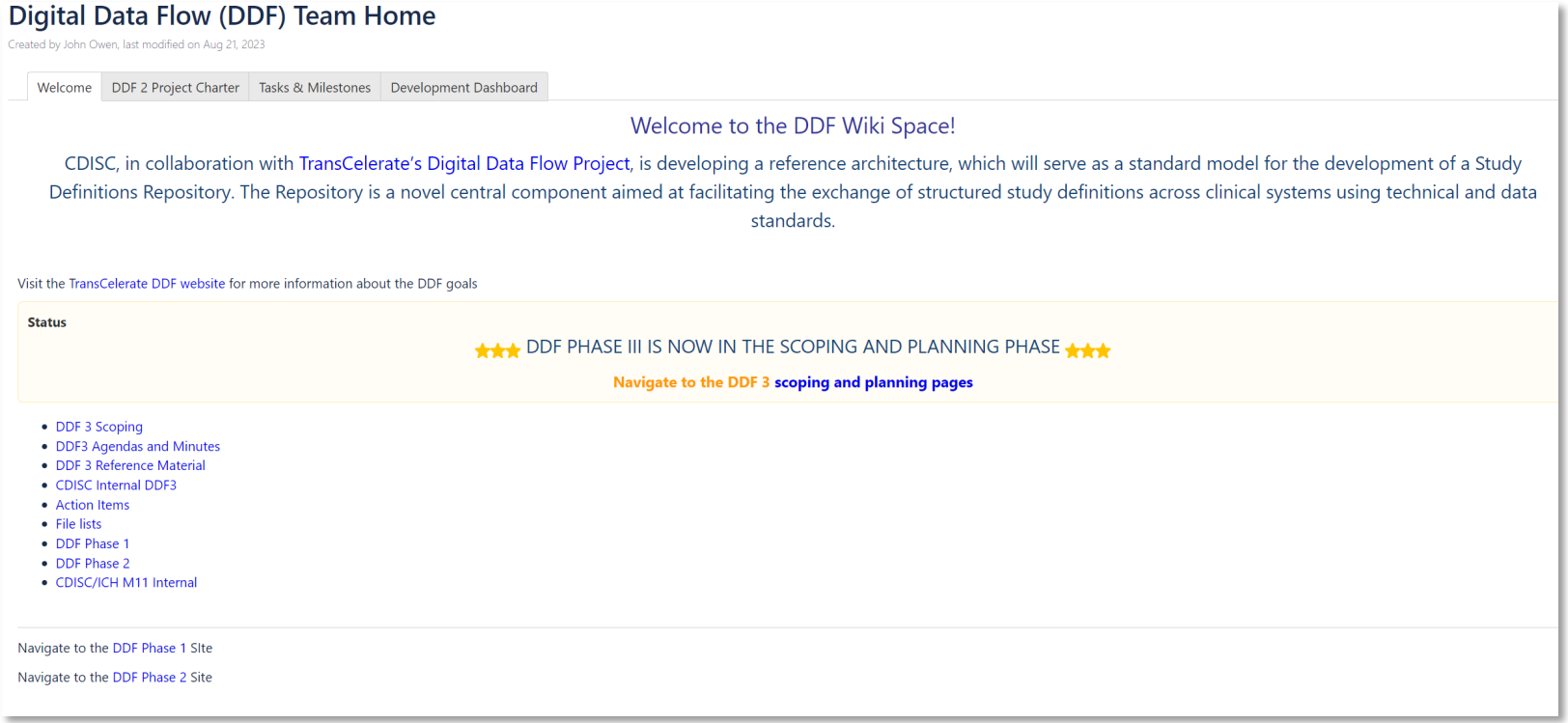
CDISC WIKI ACCOUNT REQUIRED

WIKI Team Space



Digital Data Flow (DDF) Team Home

Created by John Owen, last modified on Aug 21, 2023

Welcome | DDF 2 Project Charter | Tasks & Milestones | Development Dashboard

Welcome to the DDF Wiki Space!

CDISC, in collaboration with TransCelerate's Digital Data Flow Project, is developing a reference architecture, which will serve as a standard model for the development of a Study Definitions Repository. The Repository is a novel central component aimed at facilitating the exchange of structured study definitions across clinical systems using technical and data standards.

Visit the TransCelerate DDF website for more information about the DDF goals

Status

⭐⭐⭐ DDF PHASE III IS NOW IN THE SCOPING AND PLANNING PHASE ⭐⭐⭐

Navigate to the DDF 3 scoping and planning pages

- DDF 3 Scoping
- DDF3 Agendas and Minutes
- DDF 3 Reference Material
- CDISC Internal DDF3
- Action Items
- File lists
- DDF Phase 1
- DDF Phase 2
- CDISC/ICH M11 Internal

Navigate to the DDF Phase 1 SIte

Navigate to the DDF Phase 2 Site

https://wiki.cdisc.org/display/TEAMDDF/Digital+Data+Flow+%28DDF%29+Team+Home

CDISC WIKI ACCOUNT REQUIRED

WIKI Team Space – Development Dashboard for SMEs

Digital Data Flow (DDF) Team Home

Created by John Owen, last modified on Aug 21, 2023

Welcome | DDF 2 Project Charter | Tasks & Milestones | Development Dashboard

Link to the draft USDM Implementation Guide (USDM-IG) v3.0

Link to USDM GitHub https://github.com/cdisc-org/DDF-RA

› Internal Review Instructions

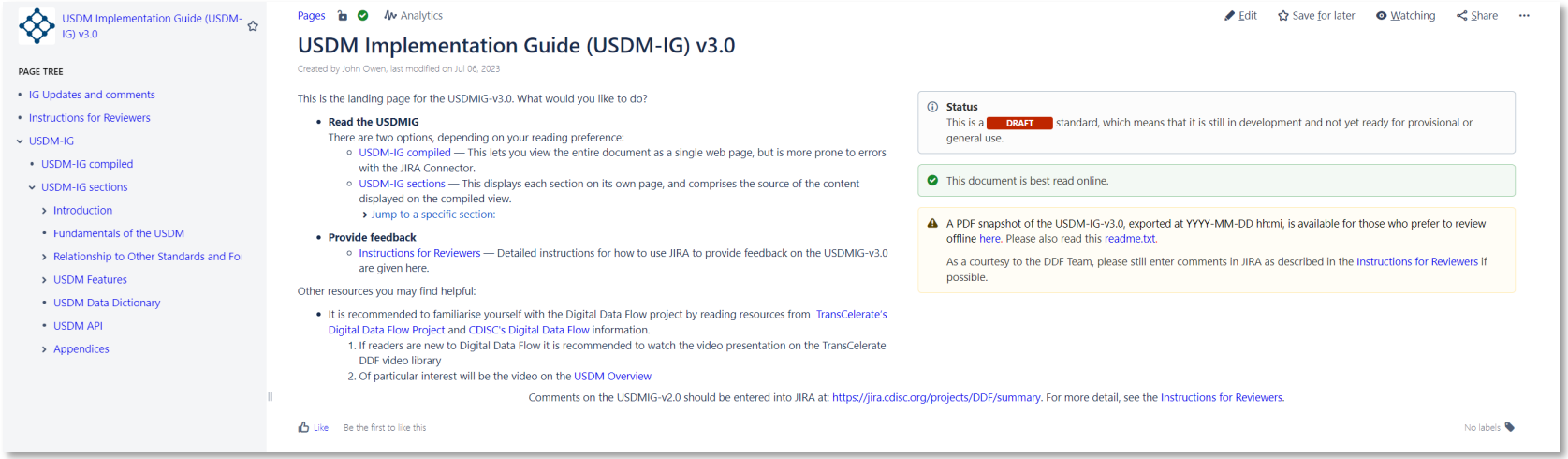
Sprint Deliverables

Release	Summary	Link to Materials	UML Changes	CT Changes	API Changes	USDMIG Changes	Test Data Changes	Other Changes	SME Meeting Link	Internal Review Start	Internal Review End	Internal Review Status
2.1	• The UML model has been updated to make it a more logical model and remove he API implementation elements and links. • Also some naming changes have been implemented to make the naming more consistent between classes	• UML/CT/API • USDM-IG sections • Test Data • Green Dot Diagram (informational only)	Model Split and rename (Delta File)	Model split and rename (Change File)	rename (model split had no impact on the API) (use diff program to compare yaml API v2.0 versus API v2.1)	Updated sections to support model split and rename) (Revision History)	Align examples with Model split and rename	None	• Detailed walkthrough of changes ◦ SME Meeting slides 2nd August ▪ Reference slides 8-26 ◦ SME Meeting Recording 2nd August ▪ 17:58 - 45:40	Wednesday 02 Aug 2023	Tuesday 15 Aug 2023	CLOSED
2.2	• M11 blinding/unblinding content can be represented using the new content class to handle text "blobs" (This content class will also be used to handle other M11 narratives) • Additional naming changes have been implemented to make the naming more consistent between classes (focussed on name and description changes) • API fixed to restore mandatory items (error fixed from release 2.1 where the following JIRA Issue was raised DDF-473 TEAM APPROVED)	• UML/CT/API • Green Dot Diagram (informational only)	• Addition of content class • Additional Names changes (Delta File 2.1>v2.2)	• Addition of content class • Additional Names changes (Change File)	• Addition of content class • Additional Names changes • API mandatory field correction (use diff program to compare yaml API v2.0 versus API v2.2)	No USDMIG changes for this release	No test changes for this release	None	• Detailed walkthrough of content class changes ◦ SME Meeting slides 8th August ▪ reference slides 12-16 ◦ SME Meeting Recording 15th August ▪ 11:27 - 36:21 • Additional Name Changes ◦ SME Meeting slides 8th August ◦ SME Meeting Recording 15th August ▪ 17:02 - 32:13	Thursday 21 Aug 2023	Tuesday 01 Sep 2023	ACTIVE

https://wiki.cdisc.org/display/TEAMDDF/Digital+Data+Flow+%28DDF%29+Team+Home

CDISC WIKI ACCOUNT REQUIRED

WIKI – USDMIG

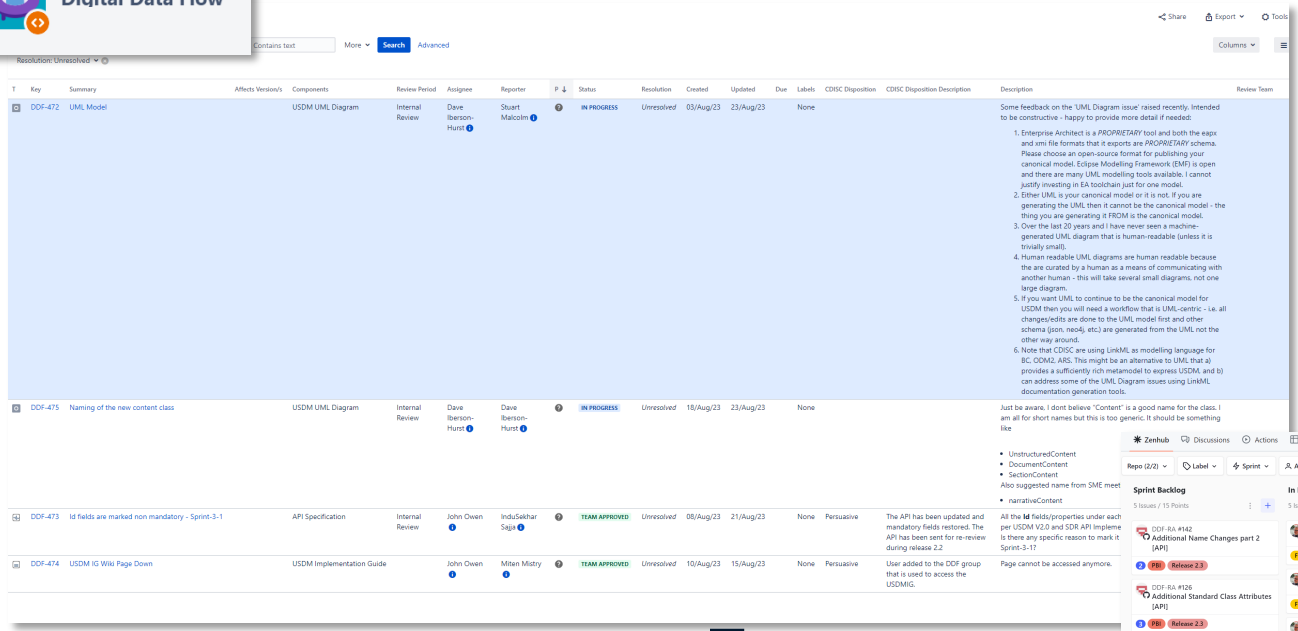


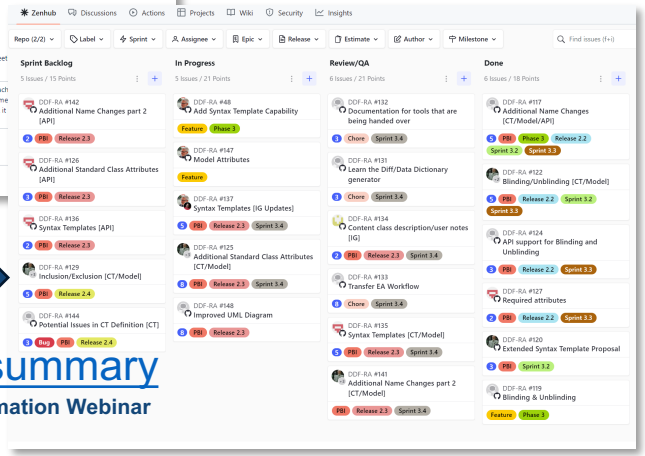
https://wiki.cdisc.org/display/USDMIGv3/USDM+Implementation+Guide+%28USDM-IG%29+v3.0

CDISC WIKI ACCOUNT REQUIRED

JIRA – Internal and Public Review Comment Tracking

Digital Data Flow





https://jira.cdisc.org/projects/DDF/summary

CDISC DDF Workgroups

DDF SME Group

- Meet Weekly
- Provide Expertise
- Discuss USDM Modelling
- Review Draft USDM Releases

CT Registry Population

Structured Text

SDTM Trial Design Population

Complex Studies/Cohorts

Conformance Rules

Biomedical Concepts

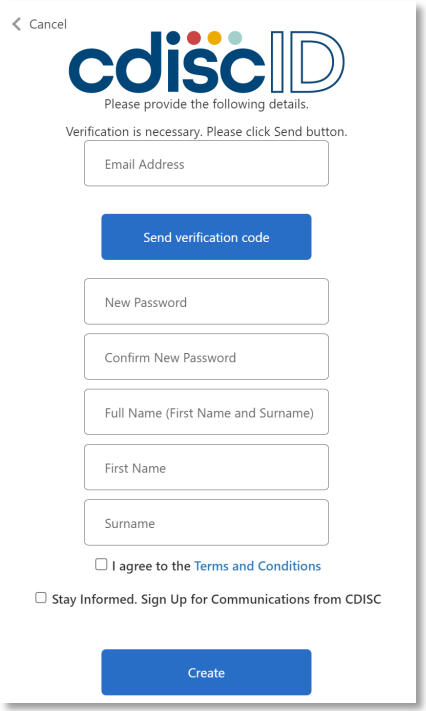
Test Data

Onboarding as a volunteer to the CDISC DDF Team

How to get involved

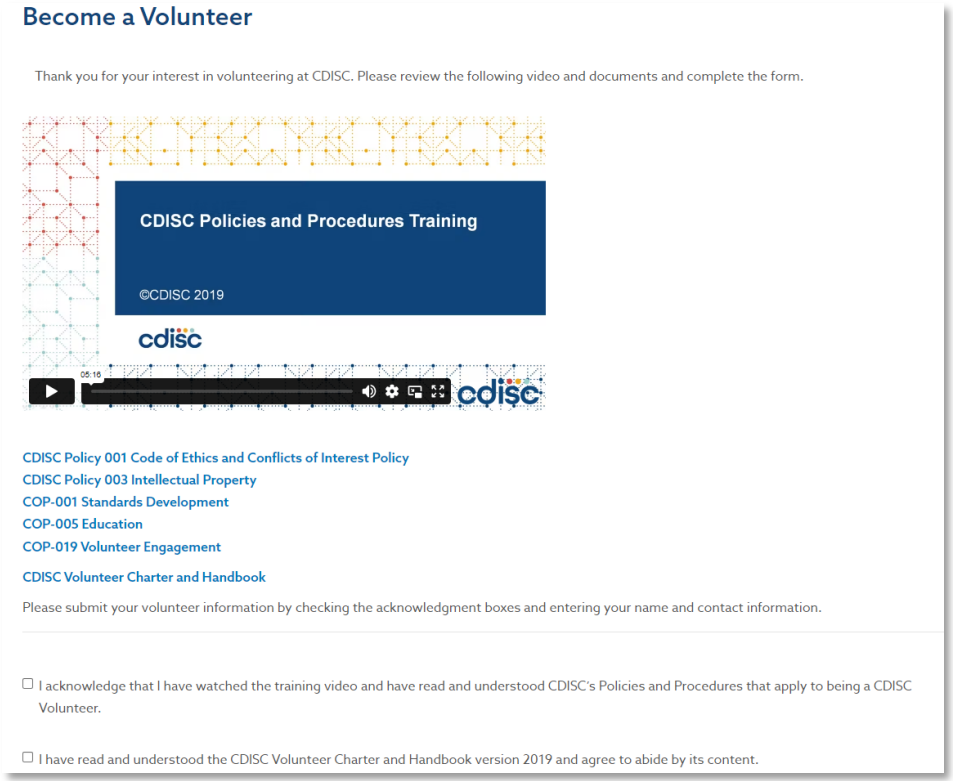
Process to Request a CDISC Wiki Account

- Create a free cdiscID (if you don't have one already)



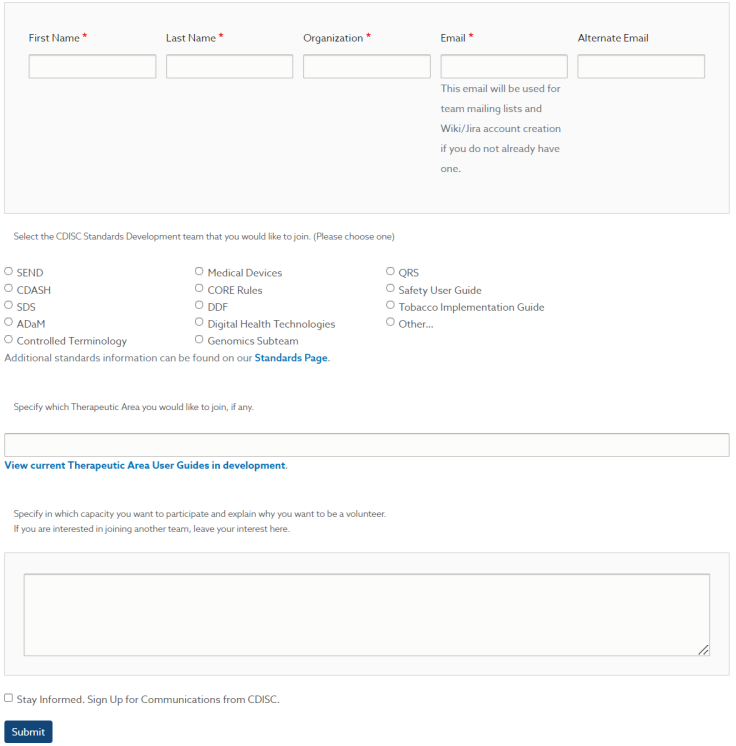
Process to Request a CDISC Wiki Account

- Navigate to the CDISC Volunteer form
  - https://www.cdisc.org/volunteer/form
  - Review of volunteer information



Process to Request a CDISC Wiki Account - DDF

- Navigate to the CDISC Volunteer form
  - Enter your contact information
  - Choose DDF from the team selection
  - Leave TA box blank
  - Enter brief text into the “Specify in which capacity….” box
  - Click Submit



Process to Request a CDISC Wiki Account - DDF

- The CDISC Volunteer coordinator will process your request
  - A CDISC WIKI and JIRA account will be created (if you don’t have one already)
  - You will be added to the DDF mailing list
  - Your request will be forwarded to the DDF PM who will add you to the DDF WIKI group
  - You will then be able to access the DDF WIKI materials and submit comments in JIRA

DDF 3 CDISC US Interchange

https://www.cdisc.org/

Events Membership

Conferences
2023 CDISC TMF Interchange
2023 US Interchange
2023 Japan Academic Workshop
2023 Korea Interchange
2024 Europe Interchange

Webinars
Upcoming Webinars
Public Webinars Archive

Day 2
19 October 2023

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

Chair: Bron Kisler, Nurocor

11:00 - 11:30
Automating Study Set-up through Digitalized Protocol
Frederik Malfait, Nurocor

11:30 - 12:00
From Medical Writing to Data Management: Key Considerations for Successfully Adopting the Unified Study Definitions Model (USDM) and Enabling Digital Data Flow (DDF)
Akash Trivedi, Accenture

12:00 - 12:30
Digital Data Flow: Breaking the Document Paradigm with Digital Data Flow from Protocol Design to Electronic Data Capture
Sumesh Kalappurakal and William Illis, Novartis

https://www.cdisc.org/events/interchange/2023-us-interchange/program

DDF PHUSE EU Connect

Sunday 5 November

Time (GMT)	Hall 7	Hall 9	Media Suite	Time (GMT)
From 14:00	**Registration**			From 14:00
14:30–16:00	**Hands-on Workshop** Dazzled and Delighted by Define-XML: Creating Define-XML with Pinnacle 21 PINNACLE 21 BY CERTARA	**Hands-on Workshop** Mastering USDM Standards with an Interactive Demo and Hands-on Workshop cdisc TransCelerate BIOPHARMA INC.	**Hands-on Workshop** Setting Sail for Synergy: Navigating the Biostatistician–Statistical Programmer Partnership AliraHealth	14:30–16:00

Tuesday 7 November

Time (GMT)	Hall 6a	Hall 7	Hall 9	Hall 10A
06:30	**PHUSE 5k Run Around Birmingham – Meet Outside the ICC** *All abilities welcome*			
09:00–10:30	**Keynote Speaker – Gareth Thomas** | Plenary Room – Hall 1			
10:30–11:00	**Morning Break**			
11:00–11:30	**TT11: Building a Scalable Utility Service to Make Multi lingual Applications Available to the Masses!** *Ferring Pharmaceuticals*	**PM04: Navigating Unprecedented Challenges: Journey Through a Pandemic and International Conflict** *Veramed*	**AR01: Analytical Risk-Based Monitoring (ARBM) – How Central Monitors Detect the Ripple in the Dataflow that Hides Danger On Site** *ICON*	**Connect Theme Presentations (DS)** Digital Data Flow – From Vision to Reality **DS01: ICH M11 Clinical Electronic Structured Harmonized Protocol (CeSHarP) and CDISC: Making the Electronic Protocol a Reality** *CDISC* **DS02: The TransCelerate/CDISC Digital Data Flow Project: Practical Electronic Study Designs** *data4knowledge* **DS03: The Digital Protocol Is Just the Beginning. Or Is It?** *Instem*
11:30–12:00	**TT12: From Legacy to the Cloud: Novo Nordisk's Journey Towards a Modern Statistical Computing Environment** *Novo Nordisk*	**PM05: An Agile Approach to Onboarding** *GSK*	**AR02: Advanced Analytics for Data Quality Assessment in Countries and Regions Affected by Crisis** *Janssen Research & Development*	
12:00–12:30	**TT13: InnerSource: A Stepping Stone Towards Open Source in Statistical Programming** *Novo Nordisk*	**PM06: Statistical Programming – Hiring Mission Made Possible** *Janssen Research & Development*	**AR03: Quality Tolerance Limits – More Critical Aspects of Clinical Trials with Much Less Visibility** *Fortrea*	

https://phuse.s3.eu-central-1.amazonaws.com/Events/2023/EU+Connect+%E2%80%93+Birmingham/Agenda/EU+Connect+Agenda.pdf

2023 US INTERCHANGE

FALLS CHURCH, VA | 18-19 OCTOBER

CDISC - Clear Data Clear Impact DDF Phase 3 Information Webinar

phuse·connect
connect·share·advance

EU 2023

The Clinical Data Science Conference

5-8 November
ICC Birmingham

Questions