

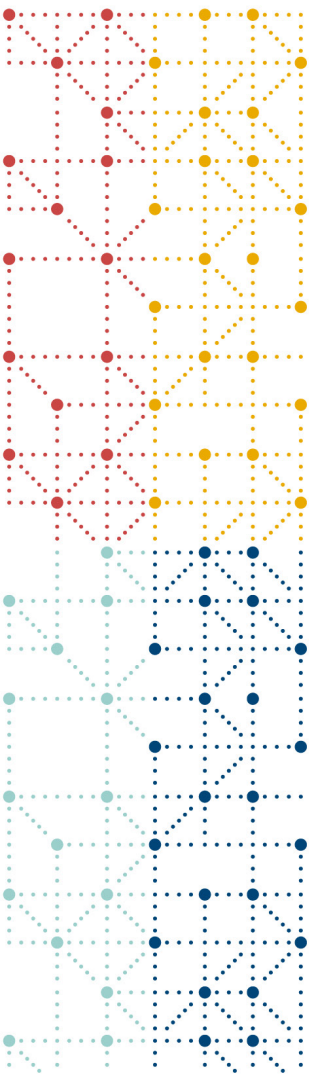


DDF Phase 3 Public Information Webinar

14th September 2023

Bill Illis, Novartis, DDF Workstream Lead
John Owen, CDISC
Dave Iberson-Hurst, CDISC
Berber Snoeijer, CDISC

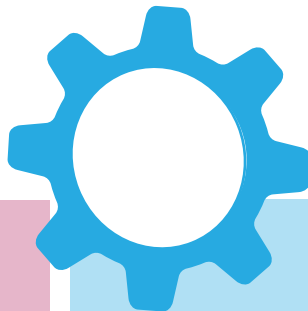
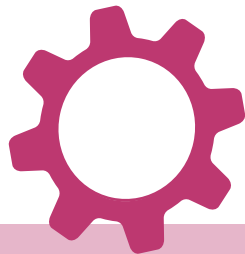
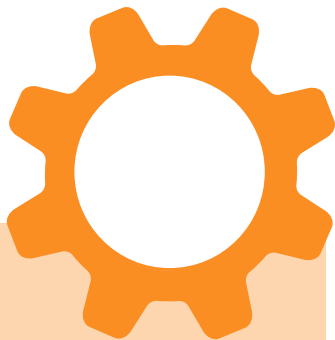




TransCelerate's DDF Initiative

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.



Our Strategic Priorities Guide Us In Achieving Our Goals

Harmonize Process & Share Information

Improve the Patient & Site Experience

Enhance Sponsor Efficiencies & Drug Safety



Digital Data Flow Ambition

Digital - standard representation of study protocol

- ✓ structured
- ✓ machine readable
- ✓ executable

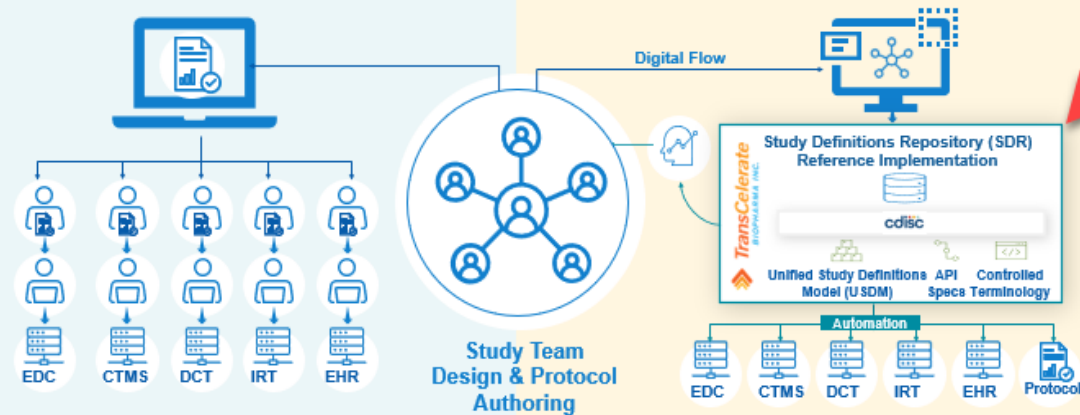
Data Flow – industry-wide interoperability

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

Documents to Data / Write Once, Read Many

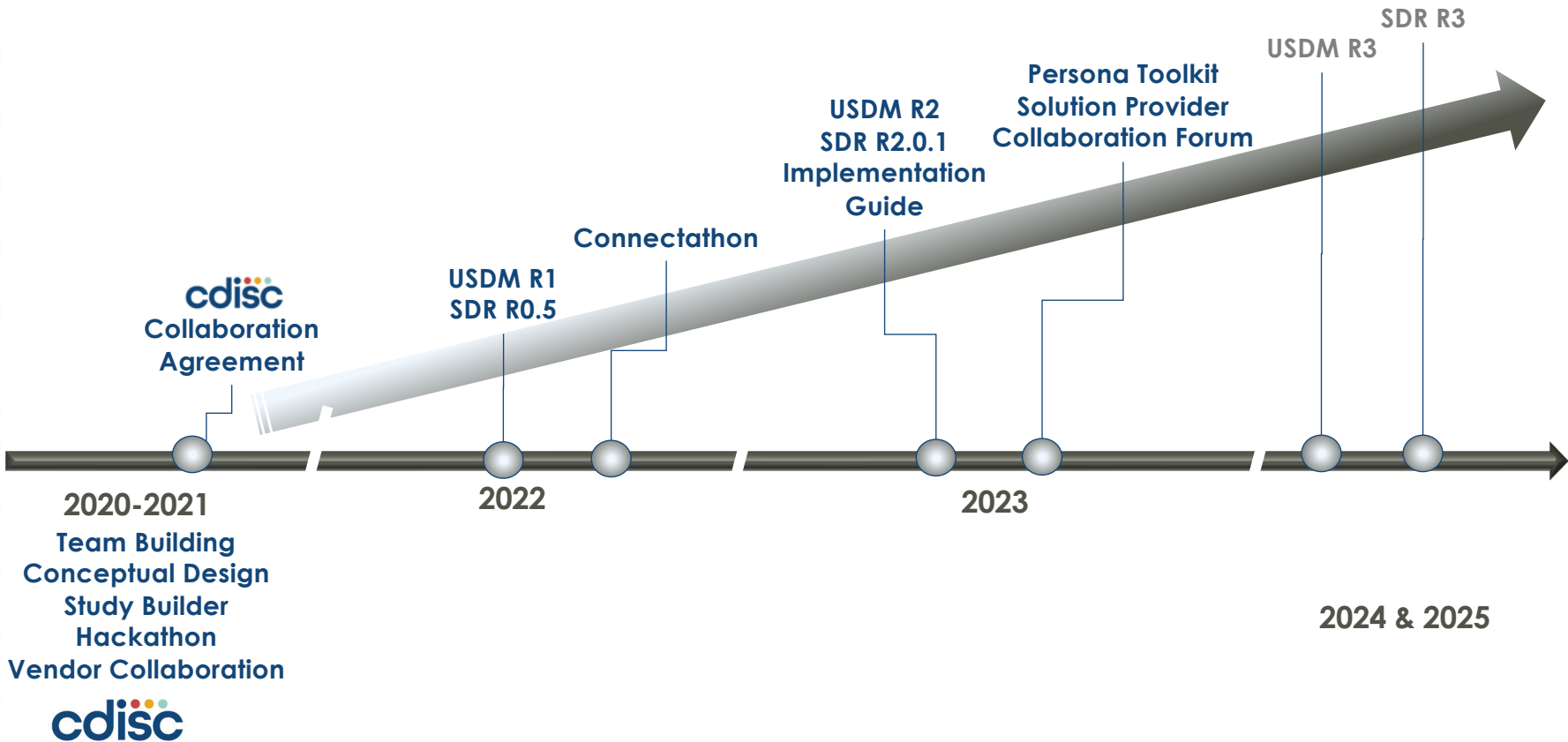
TODAY: Document-based paradigm for protocol creation, interpretation, and transcription into consuming systems

TOMORROW: Digital paradigm for protocol creation, with fully automated data flow and interoperability between systems



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



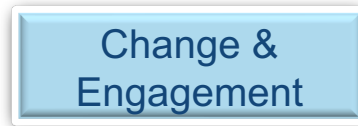
DDF Subteams and Delivery



- **USDM Reference Architecture**
- **UML Model**
- **API Specs**
- **Controlled Terminology**
- **Implementation Guide**



- **Study Definitions Repository – Reference Implementation**
- **Infrastructure as Code Scripts**
- **Documentation**



- **Solution Provider Collaboration Forum**
- **Sponsor Persona Toolkits**
- **HA Strategy**
- **Communications and Events**



- **Sustainable Governance Model**

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 <i>(workshops begin 15-17th)</i>
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



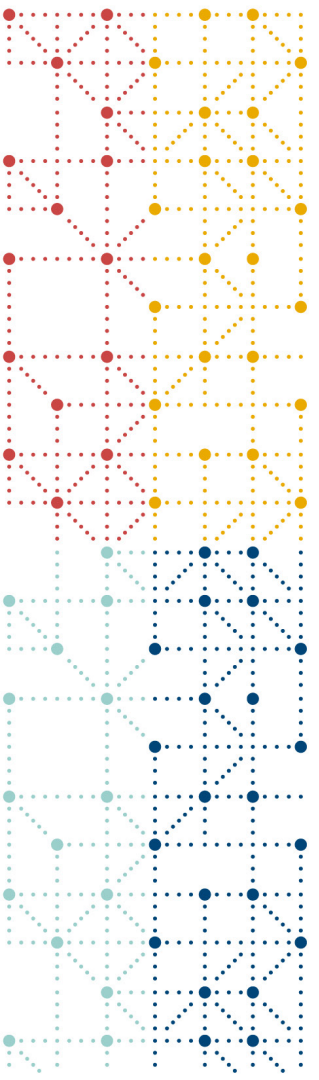
Major/
Interactive
Event



General
Awareness



Virtual option
available



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

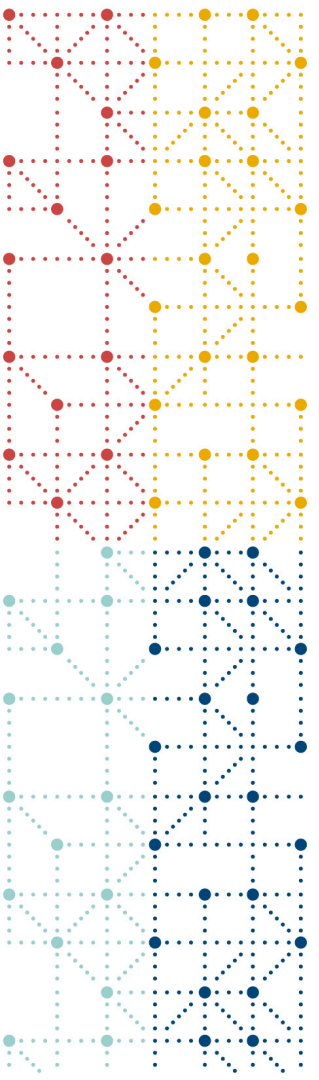
Work Areas

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

Future Value Streams for Digital Data Flow
Team will begin to address all three of varying degrees (in priority order)

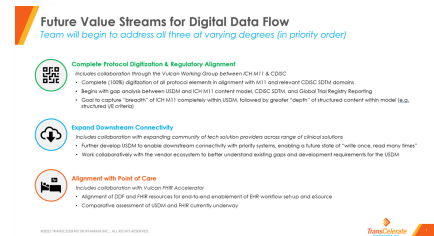
- Complete Protocol Digitization & Regulatory Alignment**
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 - Complete CDISC digitization of all protocol elements in alignment with M11 and relevant CDISC SDTM domains
 - Begin with gap analysis between ICH M11 and ICH M11 content model, CDISC SDTM, and Global Trial Registry Reporting
 - Goal to explore "breakout" of ICH M11 compliance when SDTM follows to greater "depth" of structured content within model (i.e., structured ICH content)
- Expand Datastream Connectivity**
 - Includes collaboration with expanding community of tech solution providers across range of clinical solutions
 - Further explore SDTM to enable openstream connectivity with ancillary systems, enabling future state of "white circle, read many times"
 - Work collaboratively with the vendor ecosystem to better understand existing gaps and development requirements for the USDM
- Alignment with Point of Care**
 - Includes collaboration with Vision PDR Accelerator
 - Alignment of CDISC and PDR resources to enable end-to-end implementation of PDR workflow setup and source
 - Comprehensive assessment of SDTM and PDR current connectivity

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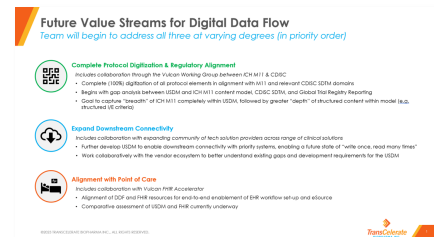
DDF 3 USDM Scope

- 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 trial design information (particularly the FDA required parameters)
 - Identification of new alignments between ICH M11 and SDTM trial design artefacts
 - What other trial 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



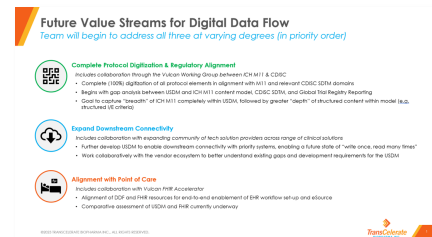
DDF 3 USDM Supporting Documentation

• 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



[DDF-RA / Documents / Examples](#) CDISC_Pilot ,

daveih Updated examples

This branch is 14 commits ahead of [main](#) .

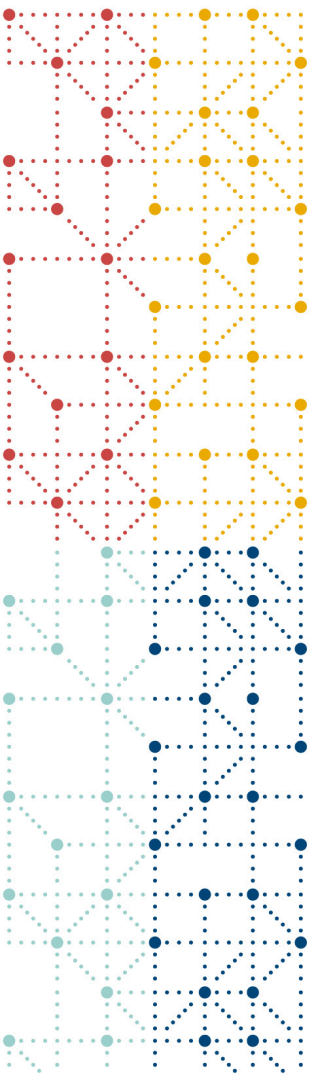
Name

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CDISC_Pilot_Study.json

CDISC_Pilot_Study.pdf

CDISC_Pilot_Study.xlsx

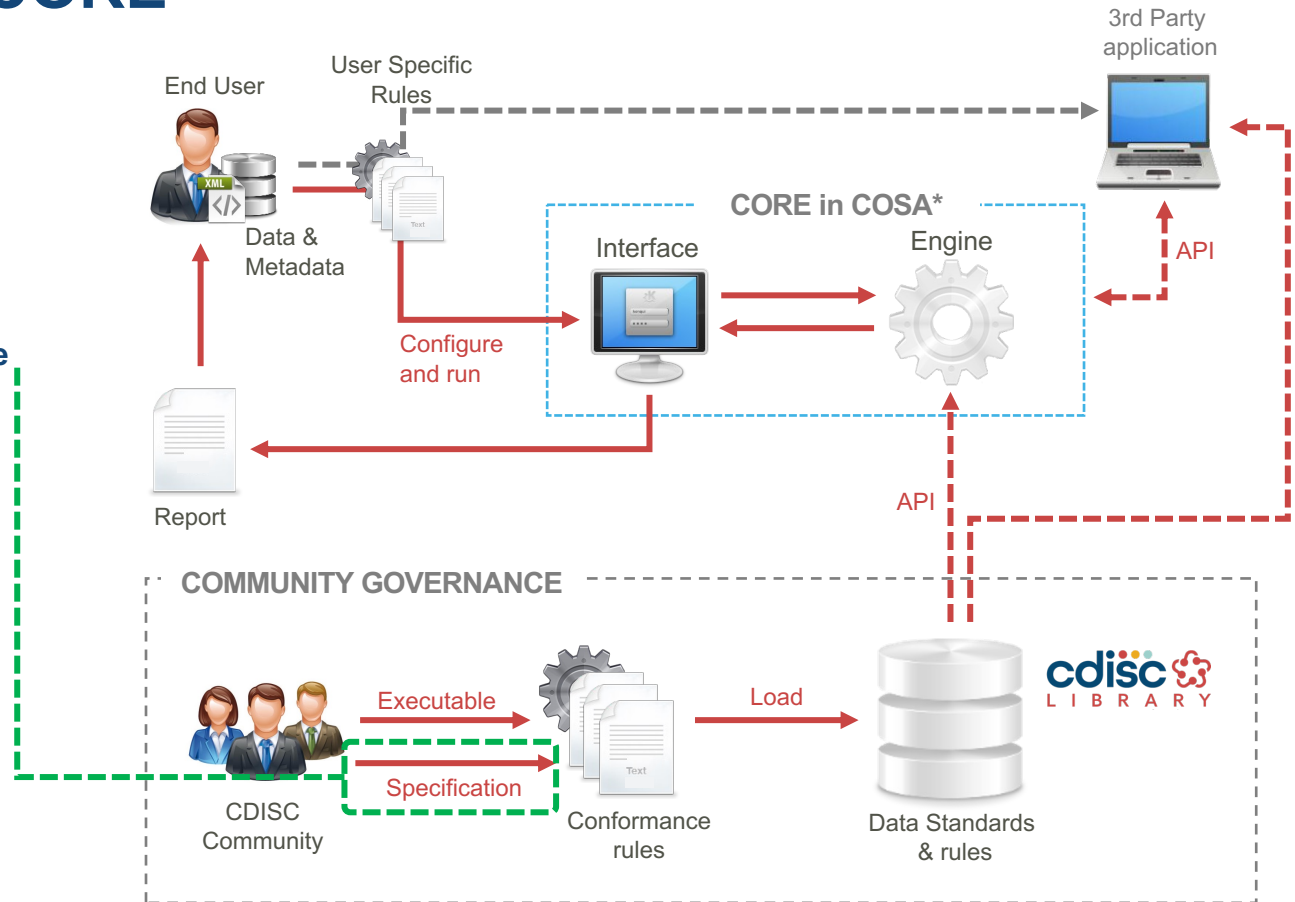


Conformance Rule Development

DDF 3 and CORE

DDF 3 will focus on development of the rule specifications

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

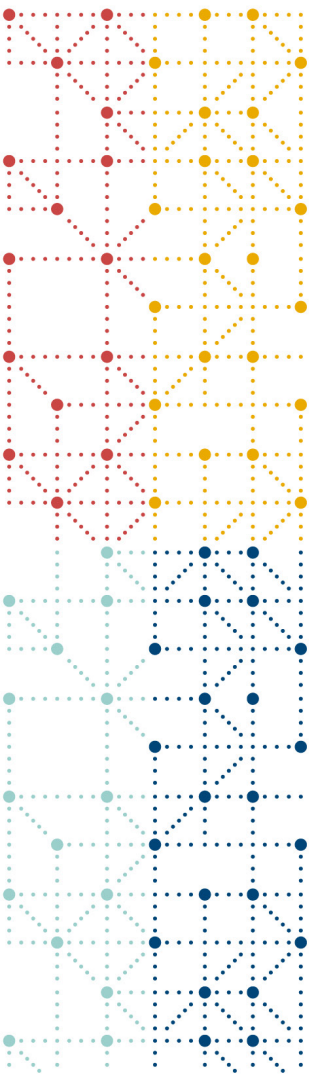


* CDISC Open-Source Alliance



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

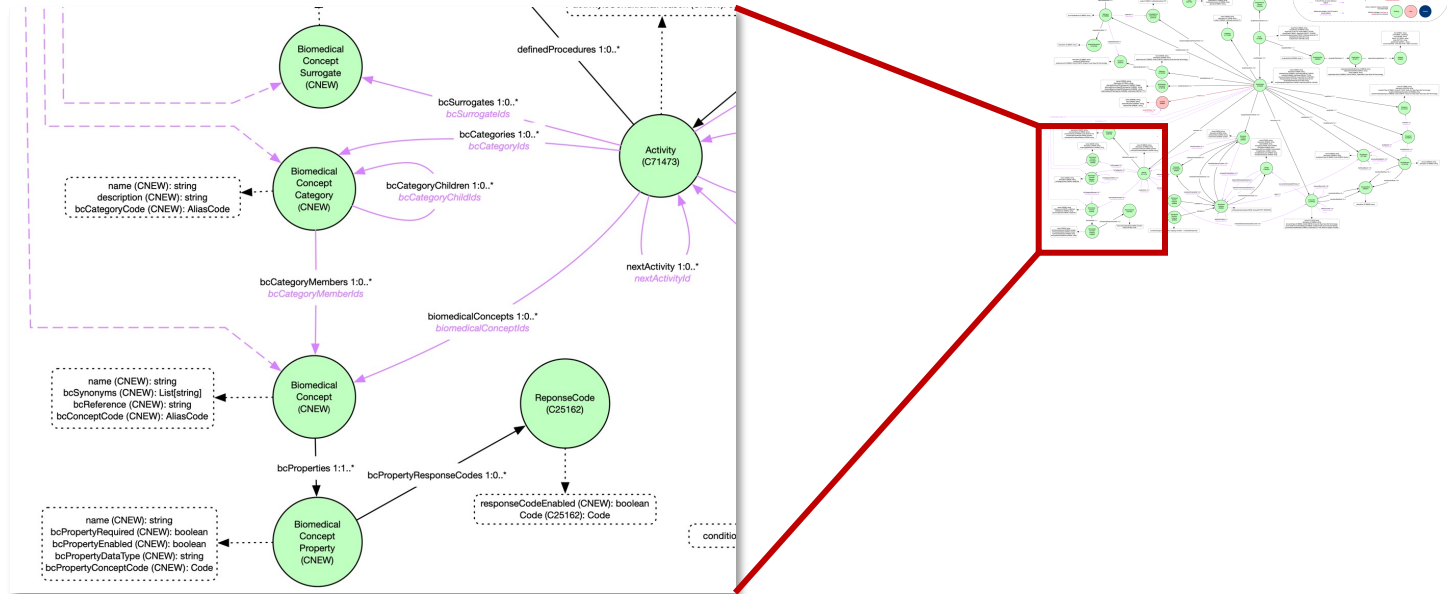


Biomedical Concept Development

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

The information contained in this clinical study protocol is
Copyright © 2008 Eli Lilly and Company.

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

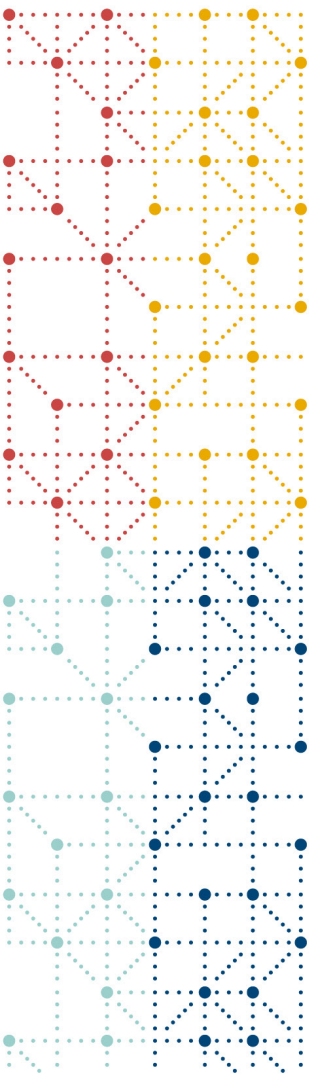
Xanomeline (LY246708) H2Q-MC-LZZT(c)
Clinical Study Protocol

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Document Page 1

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

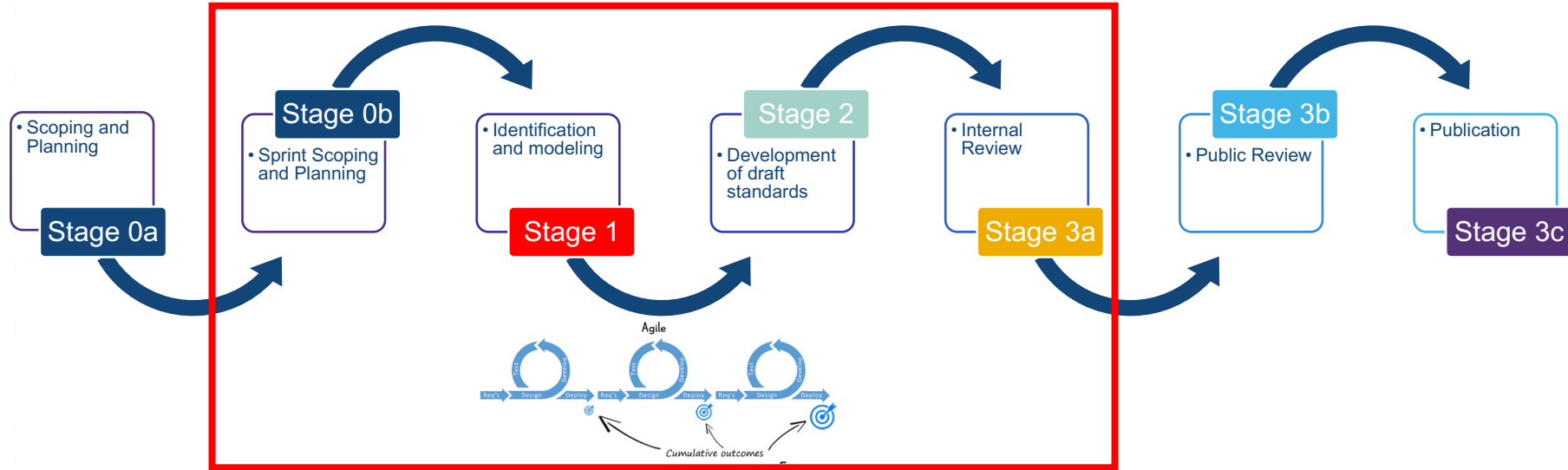
	WEEK	1	2	3	4	5	7	8
ACTIVITY	WEEK	-2	-1	0	2	4	6	8
Informed consent	X							
Patient number assigned	X							
Hitchhiker CA	X							
MMSSE 10-23	X							
Physical examination	X							
Medical History	X							
Habits	X							
Chest x-ray	X							
Signs of genotoxicity				X				
Patient randomized			X					
Vital signs/Temperature	X	X	X	X	X	X	X	X
Antibiotics/ECG/abdominal		X						
Ambulatory ECG removed		X						
ECG	X			X	X	X	X	X
Practice TTS test	X							
CT Scan (if not within last year and patient passes all other screens)	X							
Concomitant Medications	X	X	X	X	X	X	X	X
Laboratory (Chem/Hemat)	X		X	X	X	X	X	X
Laboratory (Urine/vis)	X		X					
Plasma Specimen (Xanomeline)			X	X	X	X	X	X
Hemoglobin A1c	X*							
Study drug record			X	X	X		X	X
Medications dispensed			X	X	X		X	X
Medications returned								
TTS acceptability survey								
ADAS-Cog	P	X						X
CBIB+	P	X						X
DAD	P	X						X
NPI-X	P	X	X	X	X	X	X	X*
Adverse events	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 insulin-dependent diabetic.
X# = Performed at this visit and via telephone interview 2 weeks following this visit.
P = Practice only - It is recommended that a sampling of the CBIB+, ADAS-Cog, DAD, and NPI-X be administered at Visit 1. Data from this sampling would not be considered in study data and would not be collected.



Process and Timelines

CDSIC Standards Development Process (COP-001)



Parts of Stage 0b – 3a take place for each draft release.

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

Development and Review

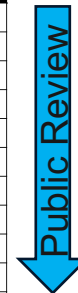
2023

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



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



DDF 3 USDM Scope



Represent ICH M11 in USDM



SDTM Trial Design Population



Clinical Trial Registry Population



Complex Studies/Cohorts




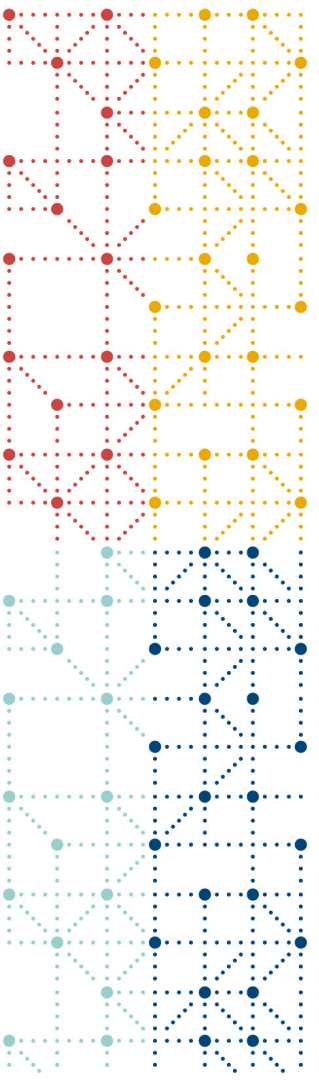
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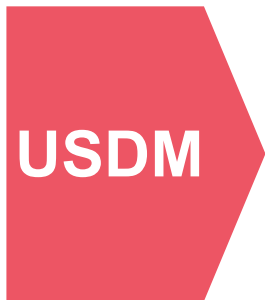




M11

Next Steps – Phase Three

Slide from May 2023



1

- 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

2

- 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

3

Focus for Phase 3 is currently being determined. Current expectations are:

- 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

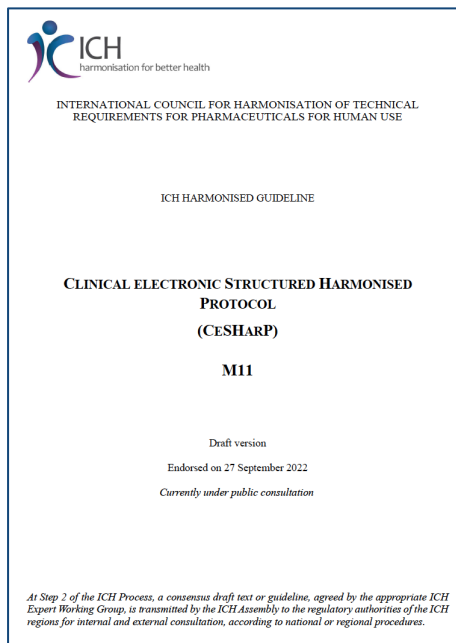
- Downstream vendors can readily consume the SoA from the SDR
- Sponsor system admins can perform a visual check that SoA data received from an upstream system displays an accurate, human-readable SoA table
- Opportunity to aggregate robust historical protocol information to support analytics to drive smart design and assess risk

- Expand ability to handle increasingly complex studies
- ICH M11 & CPT alignment

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

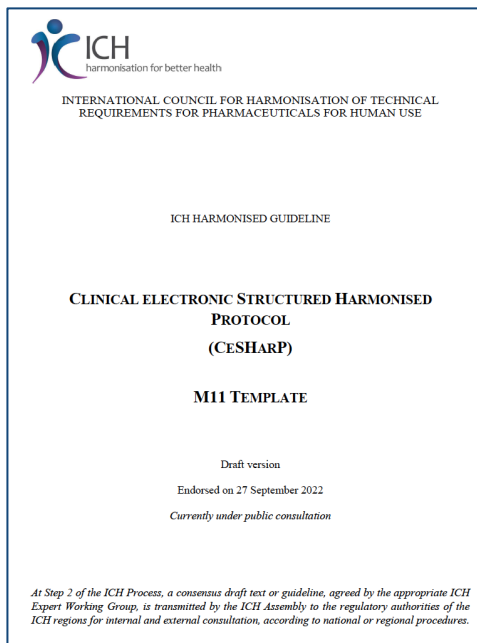
CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL
(CESHARP)

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



ICH
harmonisation for better health

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

ICH HARMONISED GUIDELINE

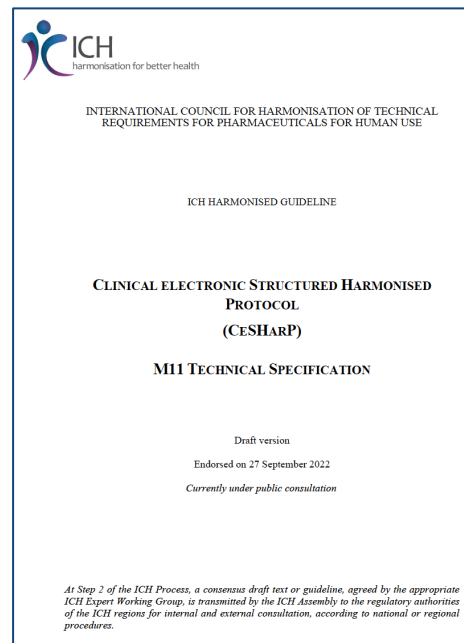
CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL
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M11 TEMPLATE

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



ICH
harmonisation for better health

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

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL
(CESHARP)

M11 TECHNICAL SPECIFICATION

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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

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",

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",

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

Technical Specification

Template Specification

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Amendment Number:	[Amendment Number] Enter the amendment number. If this is the original instance of

Term (Variable)	Trial Phase
Data Type	Pick list
Topic, Value or Header	D
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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	

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",

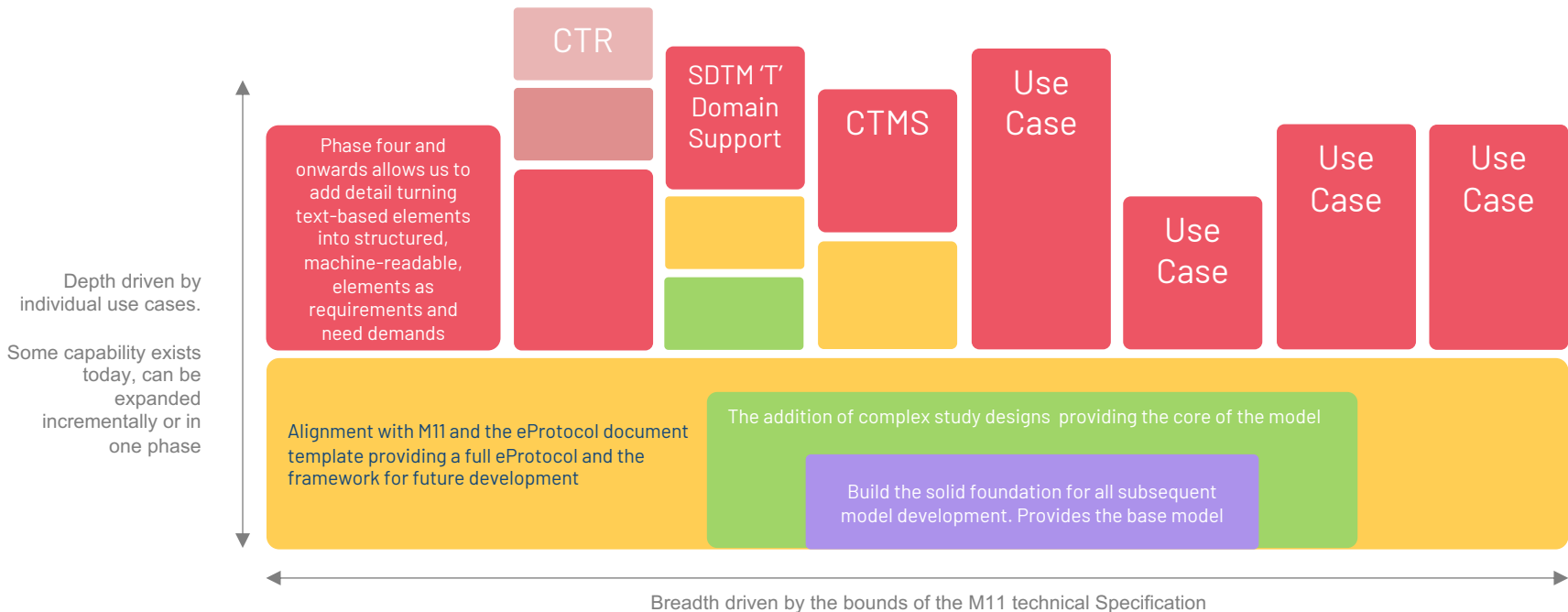
Compound Number(s):	[Compound Number] Enter the Sponsor's unique identifier for investigational compound(s) in the trial. Add or delete additional fields as needed.
Compound Name(s):	[Nonproprietary Name], [Proprietary Name], [Additional Proprietary Name] Delete this line from the table if a nonproprietary 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",

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

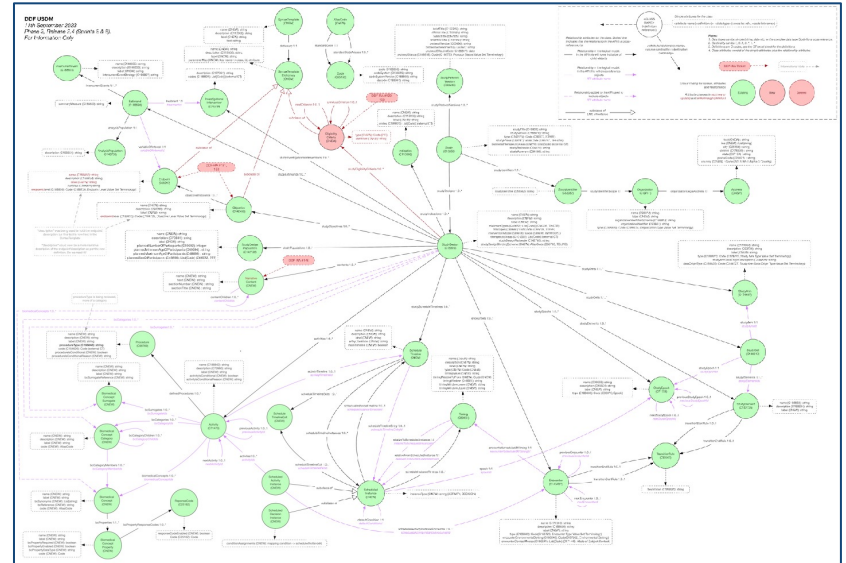


Breadth versus Depth



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

VERY DRAFT

TEST DOCUMENT TEST DOCUMENT Document doesn't look right? We'll help you out! TEST DOCUMENT

5 TRIAL POPULATION

5.1 Selection of Trial Population

5.2 Rationale for Trial Population

5.3 Inclusion Criteria

Patients may be included in the study only if they meet **all** the following criteria:

- [1] Males and postmenopausal females at least 50 years of age.
- [2] Diagnosis of probable AD as defined by National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) and the Alzheimer's Disease and Related Disorders Association (ADRDA) guidelines (Attachment LZTZ.7).
- [3] MMSE score of 10 to 23.
- [4] Hachinski Ischemic Scale score of ≤ 4 (Attachment LZTZ.8).
- [5] CNS imaging (CT scan or MRI of brain) compatible with AD within past 1 year. The following findings are incompatible with AD:
 - a. Large vessel strokes
 - 1. Any definite area of encephalomalacia consistent with ischemic necrosis in any cerebral artery territory.
 - 2. Large, confluent areas of encephalomalacia in parieto-occipital or frontal regions consistent with watershed infarcts. The above are exclusionary. Exceptions are made for small areas of cortical asymmetry which may represent a small cortical stroke or a focal area of atrophy provided there is no abnormal signal intensity in the immediately underlying parenchyma. Only one such questionable area allowed per scan, and size is restricted to ≤ 1 cm in frontal/parietal/temporal cortices and ≤ 2 cm in occipital cortex.
 - b. Small vessel ischemia
 - 1. Lacunar infarct is defined as an area of abnormal intensity seen on CT scan or on both T1 and T2 weighted MRI images in the basal ganglia, thalamus or deep white matter which is ≤ 1 cm in maximal diameter. A maximum of one lacune is allowed per scan.
 - 2. Leukoariosis or leukoencephalopathy is regarded as an abnormality seen on T2 but not T1 weighted MRI, or on CT. This is accepted if mild or moderate in extent, meaning involvement of less than 25% of cortical white matter.

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)

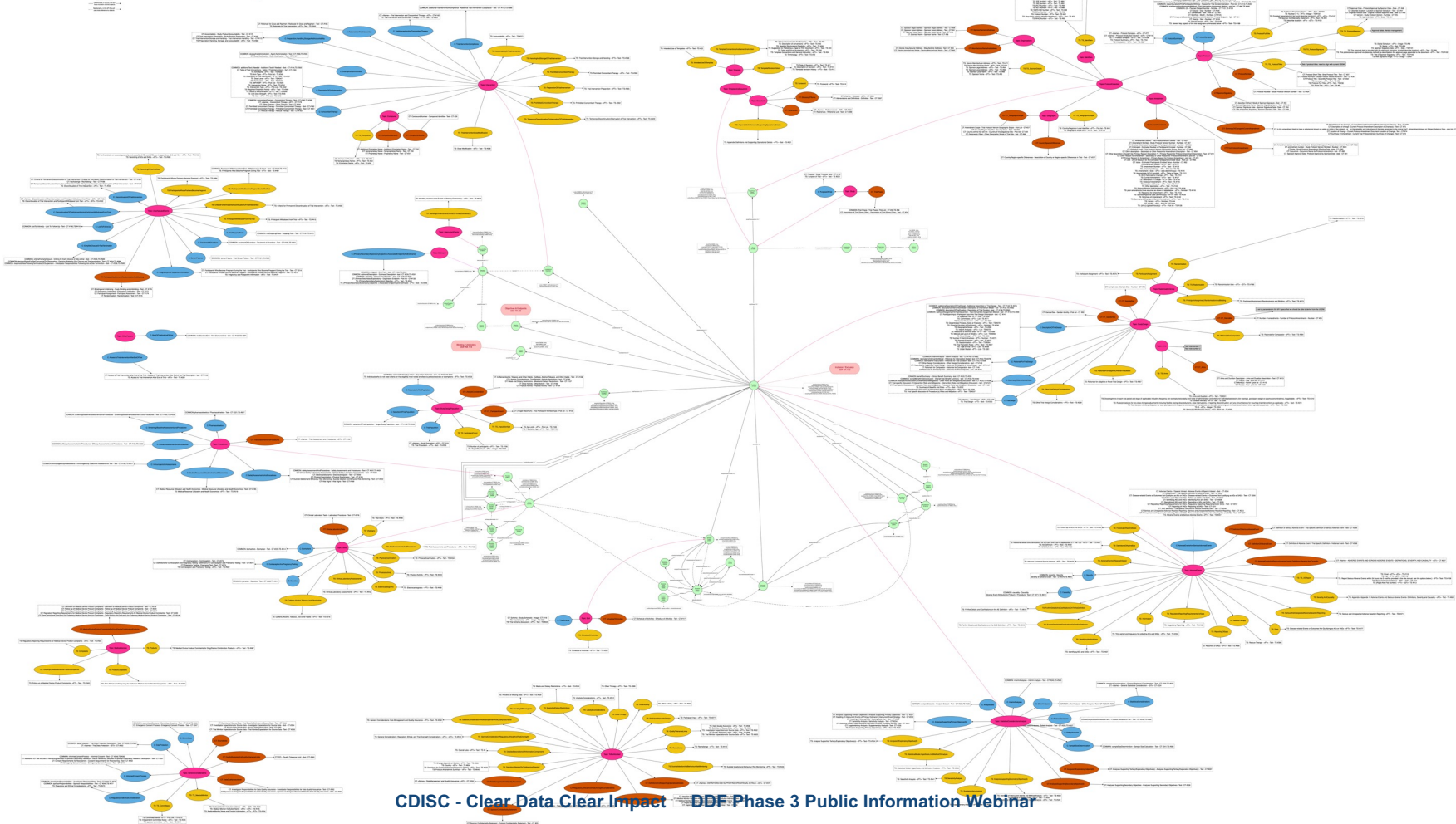
Ann Arbor, MI. and Austin, TX — June 6, 2023 — A structured, harmonized, digitized protocol accessible to the biopharmaceutical industry and to researchers in the care setting will enable transformations to improve clinical research. The project announced by HL7 Vulcan and CDISC will build on work products of ICH M11 to accelerate this vision. [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).

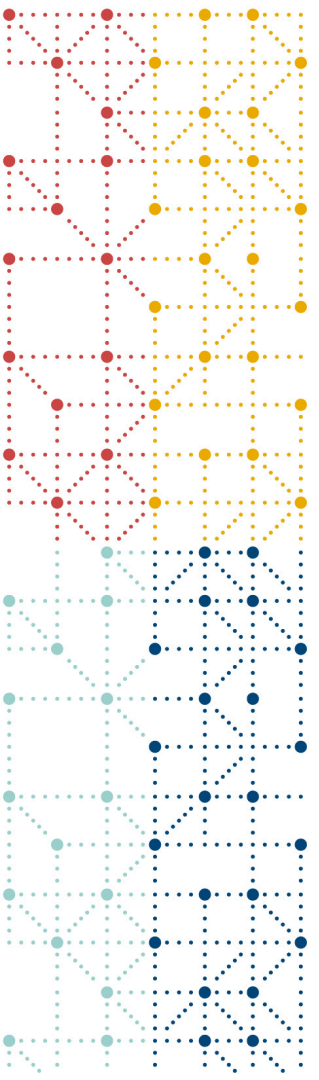
“The project marks an important milestone in the long journey towards a digital protocol,” said Vulcan Co-Chair, Amy Cramer. “Over the years, various organizations have contributed key building blocks. Vulcan is pleased to serve as a convener where contributors across the global research community can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

DDF USDM Meets M11
20th August 2022
For Information Only





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 Syntax	CDISC Definition	NCI Preferred Term	USDM Entry Name
C101302	C66738		Trial Summary Parameter Test Code	THERAREA	Therapeutic Area	A knowledge field that focuses on research and development of specific treatments for disease and pathological findings, as well as prevention of conditions that negatively impact the health of an individual. (NCI)	Therapeutic Area	Study/Design
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	TYPHASE	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 E6(A4))	Trial Phase	Study
C48652	C66738		Trial Summary Parameter Test Code	TINDIP	Trial Intent Type	The planned purpose of the therapy, device, or agent under study in the clinical trial.	Clinical Study by Intent	Study/Design
C49658	C66738		Trial Summary Parameter Test Code	TBLIND	Study Blinding Design: Study Blinding Scheme: Trial Blinding Design: Trial Blinding Scheme: 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 Scheme	Study/Design
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	Study/Design

- DDF Phase 3 will expand on this initial work



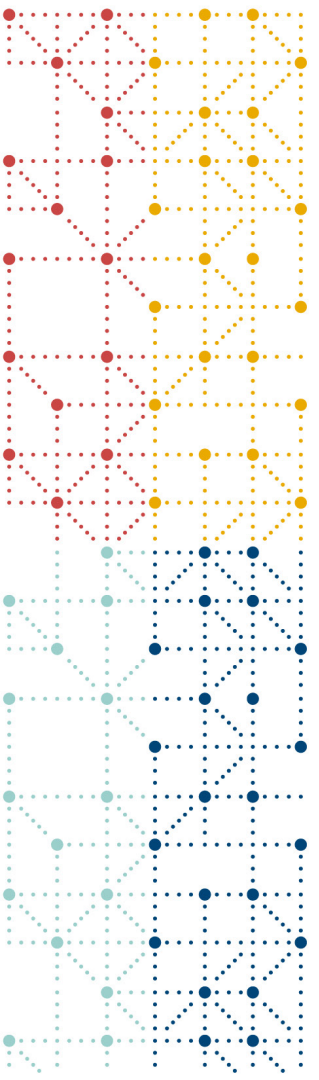
SDTM Trial Design - activities

- 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



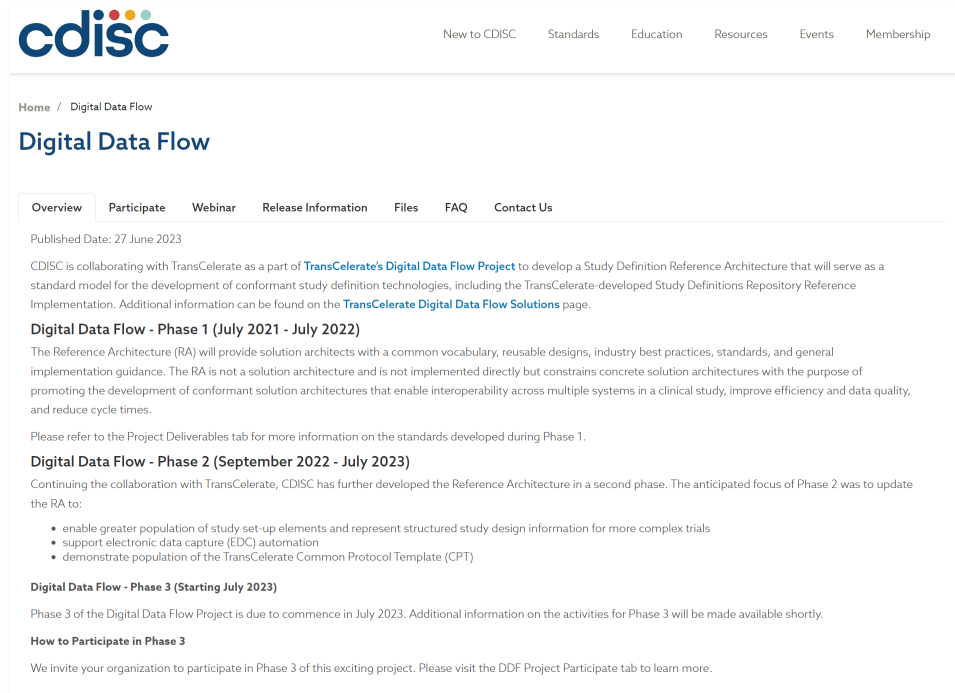
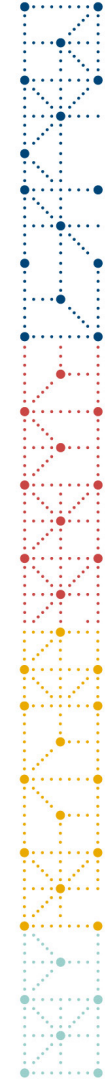
USDM recommendations

- 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



cdisc [New to CDISC](#) [Standards](#) [Education](#) [Resources](#) [Events](#) [Membership](#)

[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.

GitHub

cdisc-org / DDF-RA

Issues 47 Pull requests Zenhub Discussions Actions Projects Wiki Security Insights

DDF-RA (Public) generated from cdisc-org/COSAHackathonTemplate

main 7 branches 19 tags

Go to file Add file Code

drewcdisc Merge pull request #140 from cdisc-org/sprint-3-3 ... 3a90453 3 weeks ago 209 commits

Deliverables	Update USDM API files	3 weeks ago
Documents	Updates after review	3 weeks ago
HowTos	Initial commit	last year
images	Initial commit	last year
.gitignore	Update gitignore to ignore DS_Store files	last year
CODE_OF_CONDUCT.md	Updated the enforcement contact	last year
CONTRIBUTING.md	Initial commit	last year
LICENSE	Update copyright holder	last year
README.md	Update README.md	3 months ago

README.md

About

This is the repository for all code and documentation for the DDF-RA project.

- Readme
- MIT license
- Code of conduct
- Activity
- 5 stars
- 9 watching
- 0 forks

Report repository

Releases 19

Phase 3, Release Version 2.2.0 (Latest) 3 weeks ago

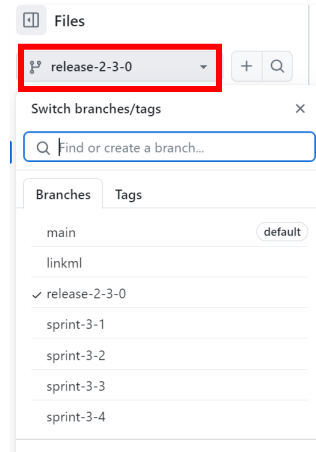
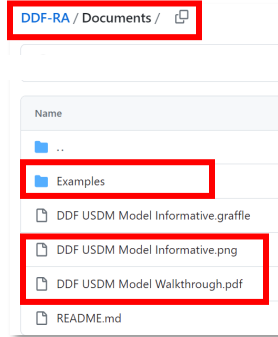
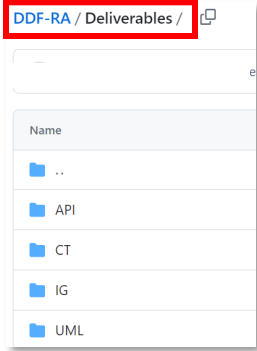
+ 18 releases



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

CDISC - Clear Data Clear Impact DDF Phase 3 Public Information Webinar

GitHub



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>

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](#)

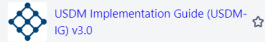
Sprint Deliverables

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	<ul style="list-style-type: none"> The UML model has been updated to make it a more logical model and remove the API implementation elements and links. Also some naming changes have been implemented to make the naming more consistent between classes 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Detailed walkthrough of changes <ul style="list-style-type: none"> SME Meeting slides 2nd August <ul style="list-style-type: none"> Reference slides 8-26 SME Meeting Recording 2nd August <ul style="list-style-type: none"> 17:58 - 45:40 	Wednesday 02 Aug 2023	Tuesday 15 Aug 2023	CLOSED
2.2	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> UML/CT/API Green Dot Diagram (informational only) 	<ul style="list-style-type: none"> Addition of content class Additional Names changes (Delta File 2.1>v2.2) 	<ul style="list-style-type: none"> Addition of content class Additional Names changes (Change File) 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Detailed walkthrough of content class changes <ul style="list-style-type: none"> SME Meeting slides 8th August <ul style="list-style-type: none"> reference slides 12-16 SME Meeting Recording 15th August <ul style="list-style-type: none"> 11:27 - 36:21 Additional Name Changes <ul style="list-style-type: none"> SME Meeting slides 8th August SME Meeting Recording 15th August <ul style="list-style-type: none"> 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>

WIKI – USDMIG



PAGE TREE

- IG Updates and comments
- Instructions for Reviewers
- ▼ USDM-IG
 - USDM-IG compiled
 - ▼ USDM-IG sections
 - > Introduction
 - Fundamentals of the USDM
 - > Relationship to Other Standards and Fo
 - > USDM Features
 - USDM Data Dictionary
 - USDM API
 - > Appendices

Pages Analytics

USDM Implementation Guide (USDM-IG) v3.0

Created by John Owen, last modified on Jul 06, 2023

This is the landing page for the USDMIG-v3.0. What would you like to do?

- **Read the USDMIG**

There are two options, depending on your reading preference:

 - **USDM-IG compiled** — This lets you view the entire document as a single web page, but is more prone to errors with the JIRA Connector.
 - **USDM-IG sections** — This displays each section on its own page, and comprises the source of the content displayed on the compiled view.
 - > [Jump to a specific section:](#)
 - **Provide feedback**
 - **Instructions for Reviewers** — Detailed instructions for how to use JIRA to provide feedback on the USDMIG-v3.0 are given here.
- Other resources you may find helpful:
- It is recommended to familiarise yourself with the Digital Data Flow project by reading resources from [TransCelerate's Digital Data Flow Project](#) and CDISC's [Digital Data Flow](#) information.
 1. If readers are new to Digital Data Flow it is recommended to watch the video presentation on the TransCelerate DDF video library
 2. Of particular interest will be the video on the [USDM Overview](#)

Comments on the USDMIG-v2.0 should be entered into JIRA at: <https://jira.cdisc.org/projects/DDF/summary>. For more detail, see the [Instructions for Reviewers](#).

Like Be the first to like this

Edit Save for later Watching Share ...

Status
This is a **DRAFT** standard, which means that it is still in development and not yet ready for provisional or general use.

This document is best read online.

A PDF snapshot of the USDM-IG-v3.0, exported at YYYY-MM-DD hh:mm, is available for those who prefer to review offline [here](#). Please also read this [readme.txt](#).
As a courtesy to the DDF Team, please still enter comments in JIRA as described in the [Instructions for Reviewers](#) if possible.

No labels



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

JIRA – Internal and Public Review Comment Tracking



Resolution: Unresolved

Contains text More Search Advanced Columns

T	Key	Summary	Affects Version/s	Component/s	Review Period	Assignee	Reporter	P	Status	Resolution	Created	Updated	Due	Labels	CDISC Disposition	CDISC Disposition Description	Description	Review Team
4	DDF-472	UML Model		USDM UML Diagram	Internal Review	Dave Ibarson-Hurst	Shawn Malcolm	3	IN PROGRESS	Unresolved	05/Aug/23	23/Aug/23		None			<p>Some feedback on the "UML Diagram issue" raised recently. Intended to be constructive - happy to provide more if needed.</p> <ol style="list-style-type: none"> Enterprise Architect is a PROPRIETARY tool and both the exap and xml file formats that it exports are PROPRIETARY schema. Please choose an open-source format for publishing your canonical model. Eclipse Modelling Framework (EMF) is open and there are many UML modelling tools available. I cannot justify investing in EA toolset just for one model. Either UML is your canonical model or it is not. If you are generating the UML then it cannot be the canonical model - the thing you are generating it FROM is the canonical model. Over the last 20 years and I have never seen a machine-generated UML diagram that is human-readable (unless it is trivially small). Human readable UML diagrams are human readable because they are created by a human as a means of communicating with another human - this will take several small diagrams, not one large diagram. If you want UML to continue to be the canonical model for USDM then you will need a workflow that is UML-centric, i.e. all changes/edits are done to the UML model first and other schema (json, mecd, etc) are generated from the UML not the other way around. Note that CDISC are using LinkML as modelling language for BC, CDISC, and SD. This might be an alternative to UML that it provides a sufficiently rich metamodel to access USDM, and it can address some of the UML Diagram issues using LinkML documentation/generation tools. 	
5	DDF-475	Naming of the new content class		USDM UML Diagram	Internal Review	Dave Ibarson-Hurst	Dave Ibarson-Hurst	3	IN PROGRESS	Unresolved	18/Aug/23	23/Aug/23		None			<p>Just to aware: I don't believe "Content" is a good name for the class. I am all for short names but this is too generic, it should be something like</p> <ul style="list-style-type: none"> UnstructuredContent DocumentContent SectionContent <p>Also suggested name from SME meet</p> <ul style="list-style-type: none"> narrativeContent 	
6	DDF-473	14 fields are marked non mandatory - Sprint 3-1		API Specification	Internal Review	John Owen	Indu/Sahar Sajja	3	TEAM APPROVED	Unresolved	08/Aug/23	21/Aug/23		None	Persuasive	The API has been updated and mandatory fields restored. The API has been sent for re-review during release 2.2.	All the 14 fields/properties under each per USDM V2.0 and SDR API implement is there any specific reason to mark it Sprint 3.	
7	DDF-474	USDM IG Wiki Page Down		USDM Implementation Guide		John Owen	Milan Misty	3	TEAM APPROVED	Unresolved	10/Aug/23	15/Aug/23		None	Persuasive	User added to the DDF group that is used to access the USDMIG.	Page cannot be accessed anymore.	



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

CDISC - Clear Data Clear Impact DDF Phase 3 Public Information Webinar



Zenhub Discussions Actions Projects Wiki Security Insights

Reps (2/2) Label Sprint Estimate Release Author Milestone Find Issues (4)

Sprint Backlog 5 Issues / 15 Points

- DDF-RA-#142 Additional Name Changes part 2 (API) (PBI) Release 2.2 Sprint 3.0
- DDF-RA-#125 Additional Standard Class Attributes (API) (PBI) Release 2.3 Sprint 3.0
- DDF-RA-#136 Syntax Templates (API) (PBI) Release 2.3 Sprint 3.0
- DDF-RA-#125 Inclusion/Exclusion (CT/Mode) (PBI) Release 2.4 Sprint 3.0
- DDF-RA-#144 Potential Issues in CT Definition (CT) (PBI) Release 2.4 Sprint 3.0

In Progress 5 Issues / 21 Points

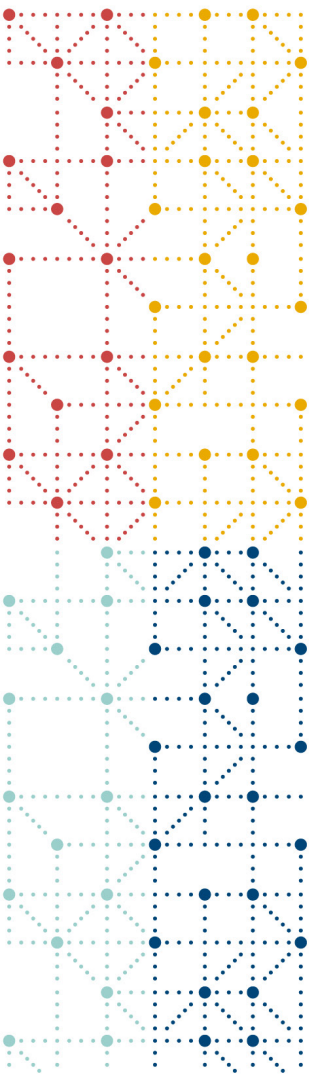
- DDF-RA-#448 Add Syntax Template Capability (Feature) Phase 3
- DDF-RA-#147 Model Identifier (Feature) Phase 3
- DDF-RA-#137 Syntax Templates (IG Updates) (PBI) Release 2.3 Sprint 3.4
- DDF-RA-#125 Additional Standard Class Attributes (CT/Mode) (PBI) Release 2.3 Sprint 3.4
- DDF-RA-#148 Improved UML Diagram (PBI) Release 2.3 Sprint 3.4

Review/QA 6 Issues / 21 Points

- DDF-RA-#117 Documentation for tools that are being handed over (CT/Mode/ADR) (PBI) Release 2.2 Sprint 3.0
- DDF-RA-#112 Learn the CDISC Data Dictionary generator (PBI) Release 2.2 Sprint 3.0
- DDF-RA-#134 Content class descriptor/user notes (IG) (PBI) Release 2.3 Sprint 3.4
- DDF-RA-#133 Transfer EA Workflow (PBI) Release 2.3 Sprint 3.4
- DDF-RA-#117 Required attributes (PBI) Release 2.2 Sprint 3.0
- DDF-RA-#120 Extended Syntax Template Proposal (PBI) Sprint 3.0
- DDF-RA-#119 Blinding & Unblinding (Feature) Phase 3

Done 6 Issues / 18 Points

- DDF-RA-#117 Additional Name Changes (CT/Mode/ADR) (PBI) Release 2.2 Sprint 3.0
- DDF-RA-#112 Blinding/Unblinding (CT/Mode) (PBI) Release 2.2 Sprint 3.0
- DDF-RA-#134 API support for Blinding and Unblinding (PBI) Release 2.3 Sprint 3.4
- DDF-RA-#127 Required attributes (PBI) Release 2.2 Sprint 3.0
- DDF-RA-#120 Extended Syntax Template Proposal (PBI) Sprint 3.0
- DDF-RA-#119 Blinding & Unblinding (Feature) Phase 3



CDISC DDF Workgroups



DDF SME Group

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

CT Registry Population

Structured Text

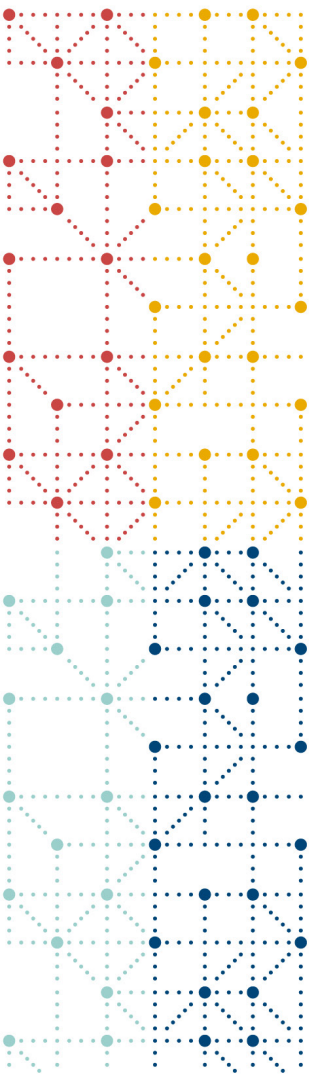
SDTM Trial Design Population

Complex Studies/Cohorts

Conformance Rules

Biomedical Concepts

Test Data

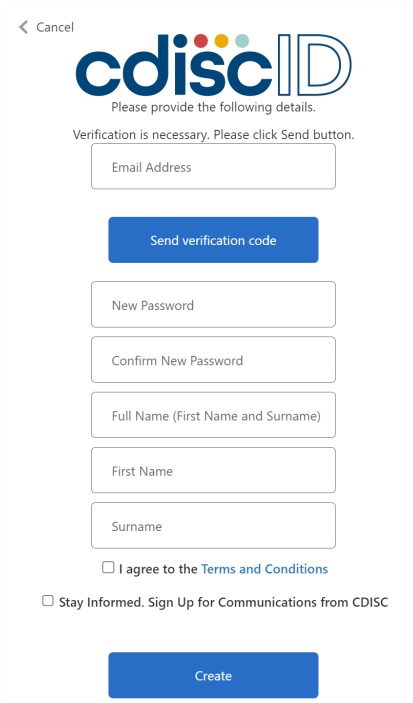


Onboarding as a volunteer to the CDISC DDF Team

How to get involved

Process to Request a CDISC Wiki Account

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



The screenshot shows a mobile-style registration form for a CDISC ID. At the top left is a back arrow and the word "Cancel". The CDISC ID logo is centered, with the text "Please provide the following details." and "Verification is necessary. Please click Send button." below it. The form contains several input fields: "Email Address", "New Password", "Confirm New Password", "Full Name (First Name and Surname)", "First Name", and "Surname". There are two checkboxes at the bottom: "I agree to the Terms and Conditions" and "Stay Informed. Sign Up for Communications from CDISC". A blue "Create" button is at the bottom.

Process to Request a CDISC Wiki Account

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

Become a Volunteer

Thank you for your interest in volunteering at CDISC. Please review the following video and documents and complete the form.



[CDISC Policy 001 Code of Ethics and Conflicts of Interest Policy](#)

[CDISC Policy 003 Intellectual Property](#)

[COP-001 Standards Development](#)

[COP-005 Education](#)

[COP-019 Volunteer Engagement](#)

[CDISC Volunteer Charter and Handbook](#)

Please submit your volunteer information by checking the acknowledgment boxes and entering your name and contact information.

I acknowledge that I have watched the training video and have read and understood CDISC's Policies and Procedures that apply to being a CDISC Volunteer.

I have read and understood the CDISC Volunteer Charter and Handbook version 2019 and agree to abide by its content.

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

First Name * Last Name * Organization * Email * Alternate Email

This email will be used for team mailing lists and Wiki/Jira account creation if you do not already have one.

Select the CDISC Standards Development team that you would like to join. (Please choose one)

<input type="radio"/> SEND	<input type="radio"/> Medical Devices	<input type="radio"/> QRS
<input type="radio"/> CDASH	<input type="radio"/> CORE Rules	<input type="radio"/> Safety User Guide
<input type="radio"/> SDS	<input type="radio"/> DDF	<input type="radio"/> Tobacco Implementation Guide
<input type="radio"/> ADaM	<input type="radio"/> Digital Health Technologies	<input type="radio"/> Other...
<input type="radio"/> Controlled Terminology	<input type="radio"/> Genomics Subteam	

Additional standards information can be found on our [Standards Page](#).

Specify which Therapeutic Area you would like to join, if any.

[View current Therapeutic Area User Guides in development.](#)

Specify in which capacity you want to participate and explain why you want to be a volunteer. If you are interested in joining another team, leave your interest here.

Stay Informed. Sign Up for Communications from CDISC.

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

Conferences

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

Webinars

- Upcoming Webinars
- Public Webinars Archive

DDF 3 CDISC US Interchange

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



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 	Hands-on Workshop Mastering USDM Standards with an Interactive Demo and Hands-on Workshop 	Hands-on Workshop Setting Sail for Synergy: Navigating the Biostatistician–Statistical Programmer Partnership 	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 <i>All abilities welcome</i>			
09:00–10:30	Keynote Speaker – Gareth Thomas Plenary Room – Hall 1			
10:30–11:00	Morning Break			
11:00–11:30	TT1: Building a Scalable Utility Service to Make Multi-lingual Applications Available to the Masses! <i>Ferring Pharmaceuticals</i>	PM04: Navigating Unprecedented Challenges: Journey Through a Pandemic and International Conflict <i>Veramed</i>	AR01: Analytical Risk-Based Monitoring (ARBM) – How Central Monitors Detect the Ripple in the Dataflow that Hides Danger On Site <i>ICON</i>	Connect Theme Presentations (DS) Digital Data Flow – From Vision to Reality DS01: ICH M11 Clinical Electronic Structured Harmonized Protocol (CeSHaP) and CDISC: Making the Electronic Protocol a Reality <i>CDISC</i>
11:30–12:00	TT12: From Legacy to the Cloud: Novo Nordisk's Journey Towards a Modern Statistical Computing Environment <i>Novo Nordisk</i>	PM05: An Agile Approach to Onboarding GSK	AR02: Advanced Analytics for Data Quality Assessment in Countries and Regions Affected by Crises <i>Janssen Research & Development</i>	DS02: The TransCelerate/CDISC Digital Data Flow Project: Practical Electronic Study Designs <i>data4knowledge</i>
12:00–12:30	TT13: InnerSource: A Stepping Stone Towards Open Source in Statistical Programming <i>Novo Nordisk</i>	PM06: Statistical Programming – Hiring Mission Made Possible <i>Janssen Research & Development</i>	AR03: Quality Tolerance Limits – More Critical Aspects of Clinical Trials with Much Less Viability <i>Fortrea</i>	DS03: The Digital Protocol Is Just the Beginning. Or Is It? <i>InSTEM</i>



2023 US INTERCHANGE

FALLS CHURCH, VA | 18-19 OCTOBER



EU 2023



CDISC - Clear Data Clear Impact

DDF Phase 3 Public Information Webinar

5-6 December
ICC Birmingham

The Clinical Data
Science Conference



Questions

cdisc