Advancing Schedule of Activities with USDM

CDISC USDM SoA Project Launch

18th June 2026

John Owen –Senior Director, Standards Operations, CDISC

Peter Van Reusel – Chief Standards Officer, CDISC

Agenda

1. Housekeeping
2. Introduction to CDISC and Digital Data Flow
3. Overview of the USDM Model
4. The USDM SoA Project
5. Become involved in the USDM SoA Project
6. Q&A

Housekeeping

- Audience will be on mute during this session.

Shhhh…

- Please submit via Q&A in the Teams App.

Questions?

- First, restart Teams.
- Second, check your local internet connection strength

Audio Issues?

- A recording of this webinar and slides will be available on Public Webinar Archive on CDISC website.

Recording

Speaker

John Owen
Senior Director, Standards Operations
CDISC

Panel

Peter Van Reusel
Chief Standards Officer
CDISC

Introduction to CDISC

cdisc

Clear Data. Clear Impact.

Standards Transform Clinical Research
Membership Join Our Global Community
Education Learn CDISC From CDISC

Membership Segments by Industry

cdisc®

Alliances
Collective Strength

ACRO
ACRP
ARO協議会 Academic Research Organization
DiME Digital Medicine Society
DIA Develop Innovate Advance
CLYMB Clinical
CodeX
Critical Path Institute
Droice Labs
FHIR
The Leona M. and Harry B. Helmsley Charitable Trust
HL7 International
HIMSS
IDDO Infectious Diseases Data Observatory
innovative health initiative
imi innovative medicines initiative
International Organization for Standardization ISO
AMED Japan Agency for Medical Research and Development
Joint Initiative Council
Lindus Health
Mapi Research Trust
MDIC Medical Device Innovation Consortium
MHLW Ministry of Health, Labour and Welfare of Japan
MRCT Multi-Regional Clinical Trials The MRCT Center of Brigham and Women's Hospital and Harvard
NORD National Organization for Rare Disorders
NIH National Cancer Institute, National Institute On Aging, National Institute Of Allergy and Infectious Diseases, National Library Of Medicine
OHDSI Observational Health Data Sciences and Informatics
OpenClinica
PharmaSUG
phuse
PINNACLE 21
Pistoia Alliance
SNOMED International
REDCap Research Electronic Data Capture
SCDM Society for Clinical Data Management Data Driven
SGS
TransCelerate BioPharma Inc.
Vivli Center for Global Clinical Research Data
VULCAN HL7 FHIR
Uppsala Monitoring Centre

Regulatory Relationships

FDA
Pmda
European Medicines Agency Science Medicines Health
National Medical Products Administration 国家药品监督管理局

Using CDISC Standards in the Research Process

Retrospective Research

Interventional Human Research

Non-Interventional Research

Non-Clinical Research

CDISC Standards Support End to End Traceability

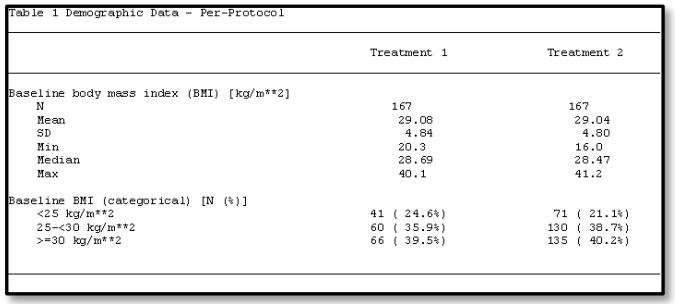


Table 1 Demographic Data – Per-Protocol

	Treatment 1	Treatment 2
Baseline body mass index (BMI) [kg/m**2]		
N	167	167
Mean	29.08	29.04
SD	4.84	4.80
Min	20.3	16.0
Median	28.69	28.47
Max	40.1	41.2
Baseline BMI (categorical) [N (%)]		
<25 kg/m**2	41 (24.6%)	71 (21.1%)
25-<30 kg/m**2	60 (35.9%)	130 (38.7%)
>=30 kg/m**2	66 (39.5%)	135 (40.2%)

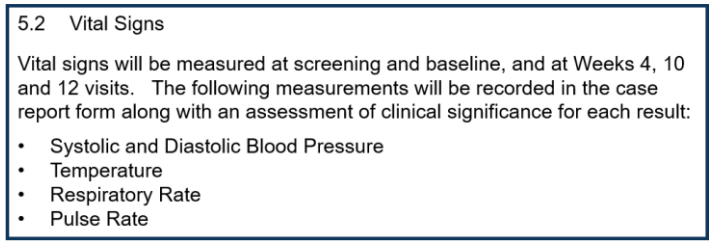
ICH M11 harmonisation for better health

cdisc USDM UNIFIED STUDY DEFINITIONS MODEL (DDF)

cdisc ARS ANALYSIS RESULTS STANDARD

Protocol

cdisc BCs BIOMEDICAL CONCEPTS



5.2 Vital Signs

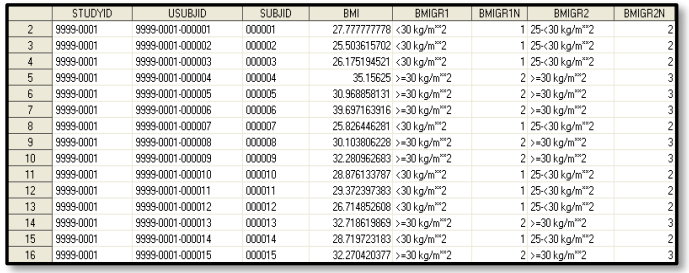
Vital signs will be measured at screening and baseline, and at Weeks 4, 10 and 12 visits. The following measurements will be recorded in the case report form along with an assessment of clinical significance for each result:

- Systolic and Diastolic Blood Pressure
- Temperature
- Respiratory Rate
- Pulse Rate

Analysis Results

Case Report Form

cdisc eCRF ELECTRONIC CASE REPORT FORMS

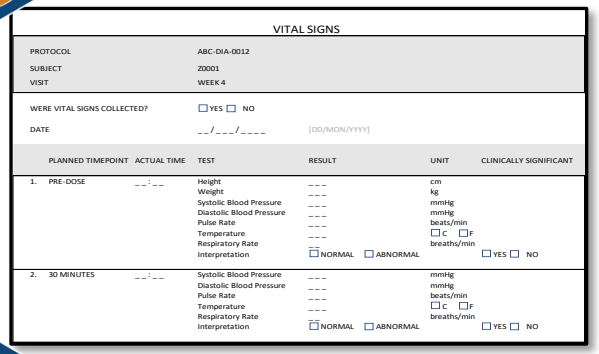


	STUDYID	USUBJID	SUBJID	BMI	BMIGR1	BMIGR1N	BMIGR2	BMIGR2N
2	9999-0001	9999-0001-000001	000001	27.777777778	<30 kg/m**2	1	25-<30 kg/m**2	2
3	9999-0001	9999-0001-000002	000002	25.503615702	<30 kg/m**2	1	25-<30 kg/m**2	2
4	9999-0001	9999-0001-000003	000003	26.175194521	<30 kg/m**2	1	25-<30 kg/m**2	2
5	9999-0001	9999-0001-000004	000004	35.15625	>=30 kg/m**2	2	>=30 kg/m**2	3
6	9999-0001	9999-0001-000005	000005	30.968858131	>=30 kg/m**2	2	>=30 kg/m**2	3
7	9999-0001	9999-0001-000006	000006	39.697163916	>=30 kg/m**2	2	>=30 kg/m**2	3
8	9999-0001	9999-0001-000007	000007	25.826446281	<30 kg/m**2	1	25-<30 kg/m**2	2
9	9999-0001	9999-0001-000008	000008	30.103806228	>=30 kg/m**2	2	>=30 kg/m**2	3
10	9999-0001	9999-0001-000009	000009	32.280962683	>=30 kg/m**2	2	>=30 kg/m**2	3
11	9999-0001	9999-0001-000010	000010	28.876133787	<30 kg/m**2	1	25-<30 kg/m**2	2
12	9999-0001	9999-0001-000011	000011	29.372397383	<30 kg/m**2	1	25-<30 kg/m**2	2
13	9999-0001	9999-0001-000012	000012	26.714852608	<30 kg/m**2	1	25-<30 kg/m**2	2
14	9999-0001	9999-0001-000013	000013	32.718619869	>=30 kg/m**2	2	>=30 kg/m**2	3
15	9999-0001	9999-0001-000014	000014	28.719723183	<30 kg/m**2	1	25-<30 kg/m**2	2
16	9999-0001	9999-0001-000015	000015	32.270420377	>=30 kg/m**2	2	>=30 kg/m**2	3

cdisc CORE OPEN RULES ENGINE

cdisc CT CONTROLLED TERMINOLOGY

cdisc Define-XML METADATA EXCHANGE STANDARD



VITAL SIGNS

PROTOCOL ABC-DIA-0012
SUBJECT Z0001
VISIT WEEK 4

WERE VITAL SIGNS COLLECTED? ☐ YES ☐ NO
DATE __/___/____ (DD/MON/YYYY)

PLANNED TIMEPOINT	ACTUAL TIME	TEST	RESULT	UNIT	CLINICALLY SIGNIFICANT
1. PRE-DOSE	__:__	Height	___	cm	
		Weight	___	kg	
		Systolic Blood Pressure	___	mmHg	
		Diastolic Blood Pressure	___	mmHg	
		Pulse Rate	___	beats/min	
		Temperature	___	☐C ☐F	
		Respiratory Rate	___	breaths/min	
		Interpretation	☐ NORMAL ☐ ABNORMAL		☐ YES ☐ NO
2. 30 MINUTES	__:__	Systolic Blood Pressure	___	mmHg	
		Diastolic Blood Pressure	___	mmHg	
		Pulse Rate	___	beats/min	
		Temperature	___	☐C ☐F	
		Respiratory Rate	___	breaths/min	
		Interpretation	☐ NORMAL ☐ ABNORMAL		☐ YES ☐ NO

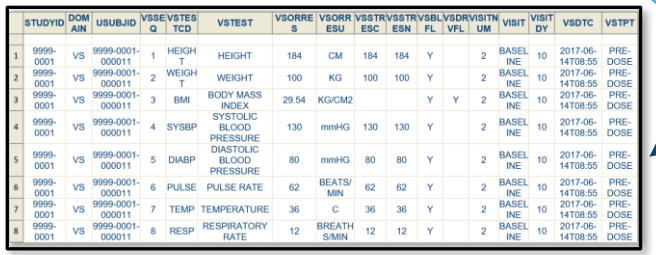
cdisc ADaM ANALYSIS DATA MODEL

Analysis Data

datasetjson

Collected Data

cdisc CDASH CLINICAL DATA ACQUISITION STANDARDS HARMONIZATION

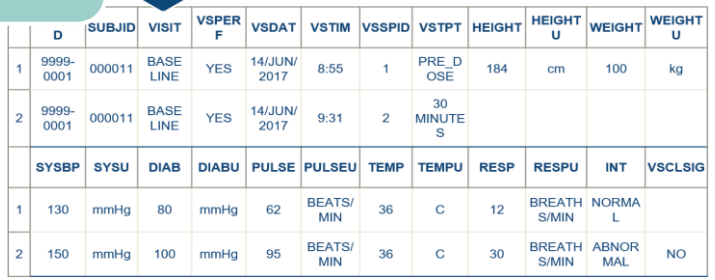


	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSBLFL	VSDRVFL	VISITNUM	VISIT	VISITDY	VSDTC	VSTPT
1	9999-0001	VS	9999-0001-000011	1	HEIGHT	HEIGHT	184	CM	184	184	Y		2	BASELINE	10	2017-06-14T08:55	PRE-DOSE
2	9999-0001	VS	9999-0001-000011	2	WEIGHT	WEIGHT	100	KG	100	100	Y		2	BASELINE	10	2017-06-14T08:55	PRE-DOSE
3	9999-0001	VS	9999-0001-000011	3	BMI	BODY MASS INDEX	29.54	KG/CM2			Y	Y	2	BASELINE	10	2017-06-14T08:55	PRE-DOSE
4	9999-0001	VS	9999-0001-000011	4	SYSBP	SYSTOLIC BLOOD PRESSURE	130	mmHG	130	130	Y		2	BASELINE	10	2017-06-14T08:55	PRE-DOSE
5	9999-0001	VS	9999-0001-000011	5	DIABP	DIASTOLIC BLOOD PRESSURE	80	mmHG	80	80	Y		2	BASELINE	10	2017-06-14T08:55	PRE-DOSE
6	9999-0001	VS	9999-0001-000011	6	PULSE	PULSE RATE	62	BEATS/MIN	62	62	Y		2	BASELINE	10	2017-06-14T08:55	PRE-DOSE
7	9999-0001	VS	9999-0001-000011	7	TEMP	TEMPERATURE	36	C	36	36	Y		2	BASELINE	10	2017-06-14T08:55	PRE-DOSE
8	9999-0001	VS	9999-0001-000011	8	RESP	RESPIRATORY RATE	12	BREATHS/MIN	12	12	Y		2	BASELINE	10	2017-06-14T08:55	PRE-DOSE

Normalized Data Tabulations

cdisc SEND STANDARD FOR EXCHANGE OF NONCLINICAL DATA

cdisc SDTM STUDY DATA TABULATION MODEL



	D	SUBJID	VISIT	VSPERF	VSDAT	VSTIM	VSSPID	VSTPT	HEIGHT	HEIGHTU	WEIGHT	WEIGHTU
1	9999-0001	000011	BASELINE	YES	14/JUN/2017	8:55	1	PRE_DOSE	184	cm	100	kg
2	9999-0001	000011	BASELINE	YES	14/JUN/2017	9:31	2	30 MINUTES				

	SYSBP	SYSU	DIAB	DIABU	PULSE	PULSEU	TEMP	TEMPU	RESP	RESPU	INT	VSCLSIG
1	130	mmHg	80	mmHg	62	BEATS/MIN	36	C	12	BREATHS/MIN	NORMAL	
2	150	mmHg	100	mmHg	95	BEATS/MIN	36	C	30	BREATHS/MIN	ABNORMAL	NO

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Five Year Vision: CDISC 2030

By end of 2030, all CDISC standards are digital, linked, and easily consumable by users and systems.

- Digital, connected standards create the trusted foundation required for scalable automation and responsible AI.
- Digital standards empower experts across the clinical research ecosystem, reducing manual burden, increasing transparency, and enabling better, faster decisions for patients

Digital

Structured, machine-readable standards that reduce manual effort

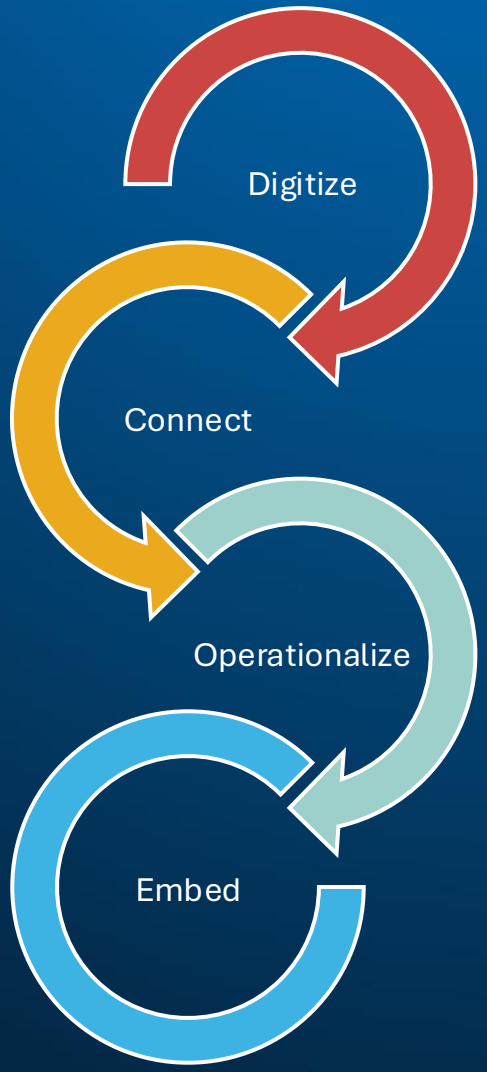
Linked

Unified semantic backbone that provides clarity and context

Accessible

Embedded in workflows to support informed, confident decisions

Path to 2030

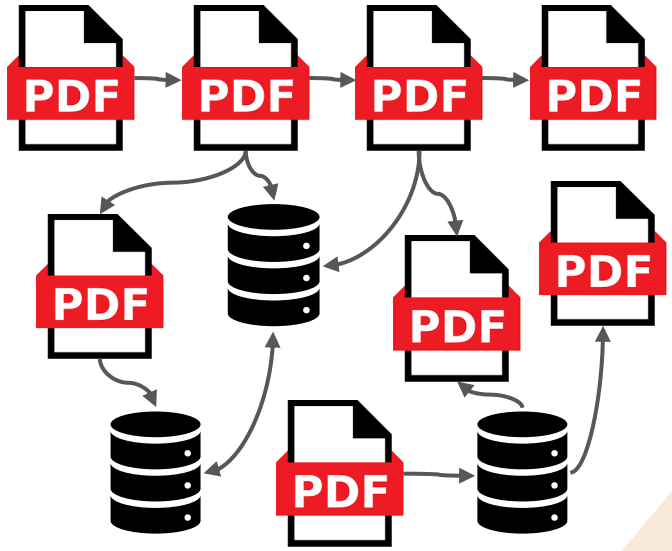


Introduction to Digital Data Flow (DDF)

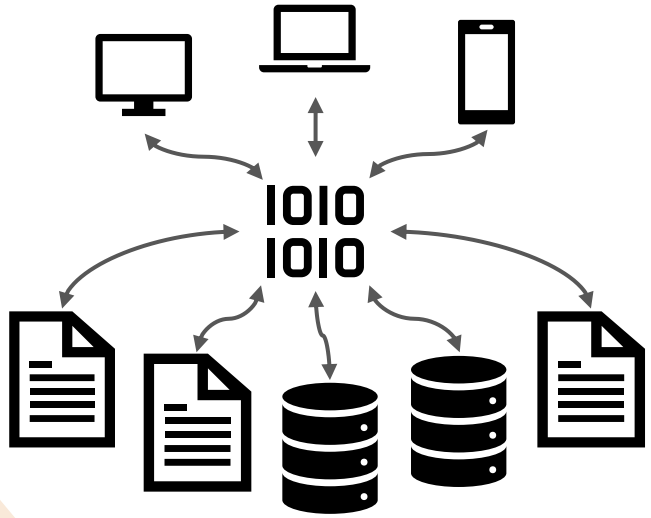
Digital Data Flow: Digital Protocols Power Processes

Structuring and digitizing information within a protocol enables role-based views, machine-readability, and information reuse.

From document-first



To data-first



Faster

Better

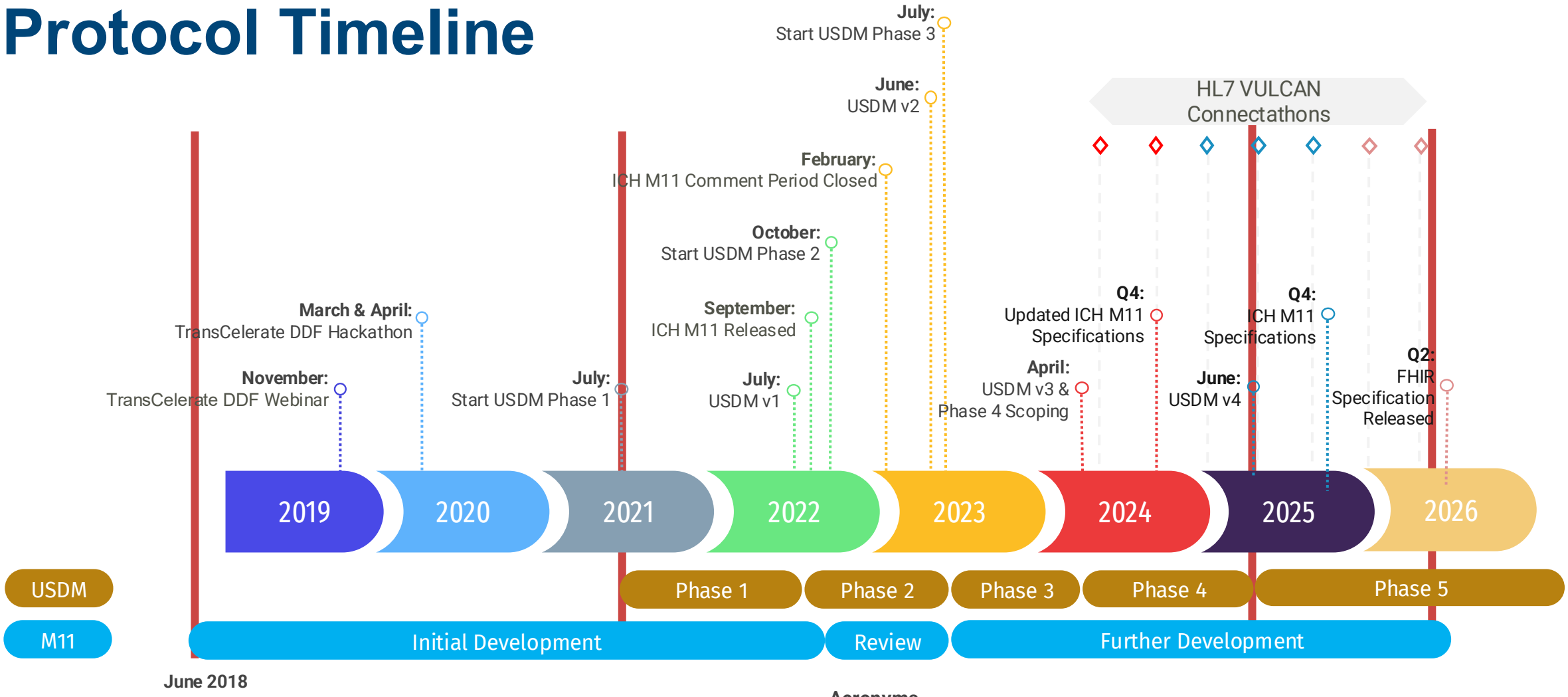
More

Goal: Increase Clinical Research Velocity

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

TransCelerate BIOPHARMA INC.

eProtocol Timeline



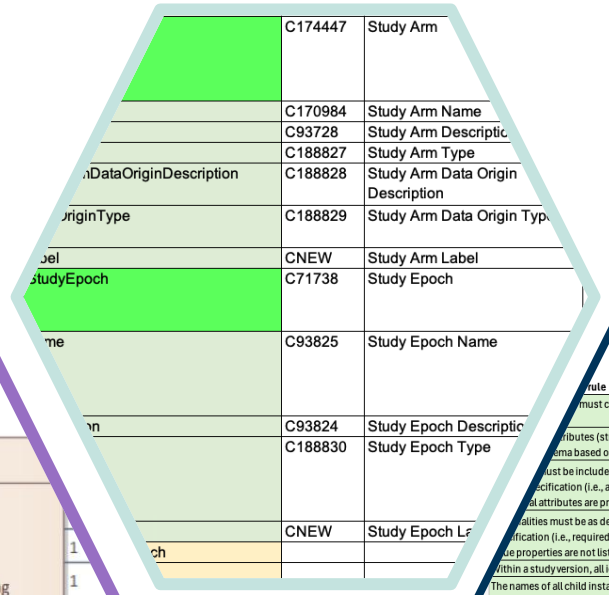
Acronyms
DDF: Digital Data Flow
USDM: Unified Study Definitions Model
ICH: International Council for Harmonisation
M11: Clinical electronic Structured Harmonised Protocol (CeSHarP)

Overview of the USDM Model

The USDM Standard

CDISC Controlled Terminology

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



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

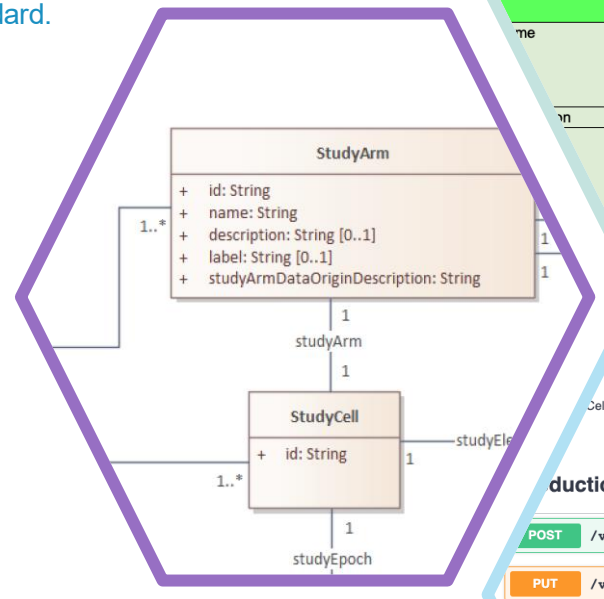
Examples

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

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

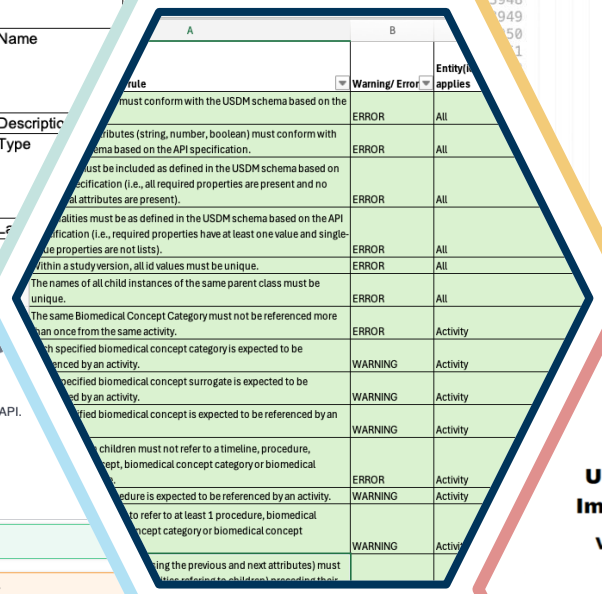
Logical Model

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



CORE Rules

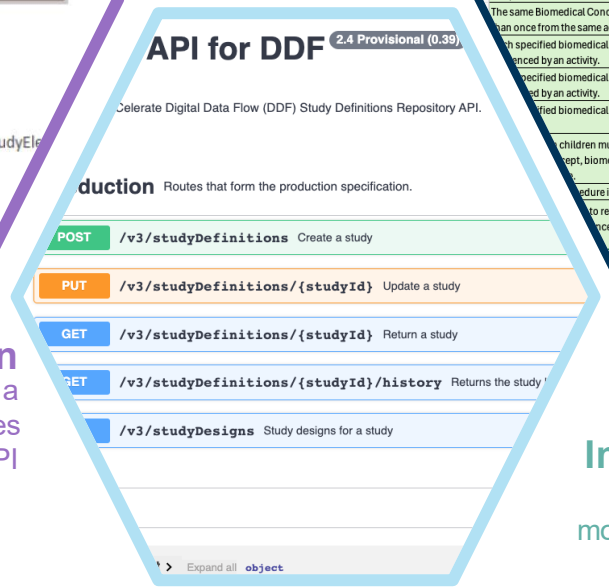
Specification of the rules that define USDM compliance



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

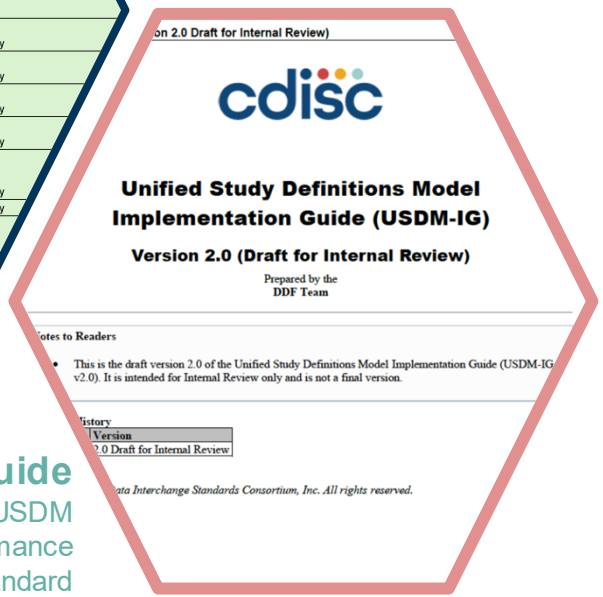
API Specification

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



Implementation Guide

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



Model areas

- Study, Titles and Identifiers
- Amendments
- Roles and Responsibilities
- Study Design, Arms and Epochs
- Population and Eligibility Criteria
- Objectives/Endpoints and Estimands
- Detailed Study Logic/Timelines
- Procedures / Biomedical Concepts
- Interventions
- Unstructured Content

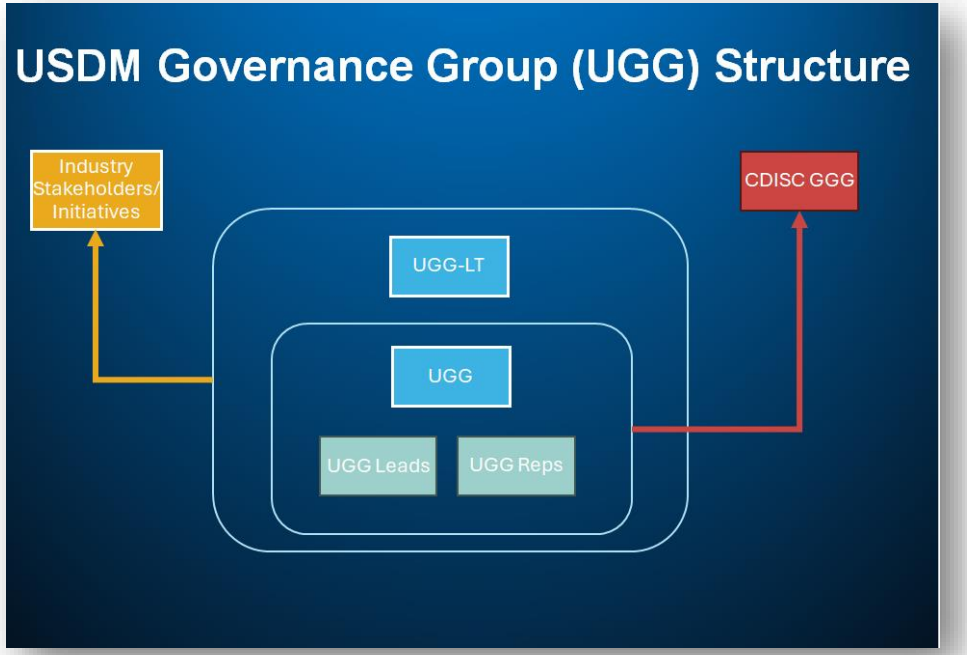
Governance

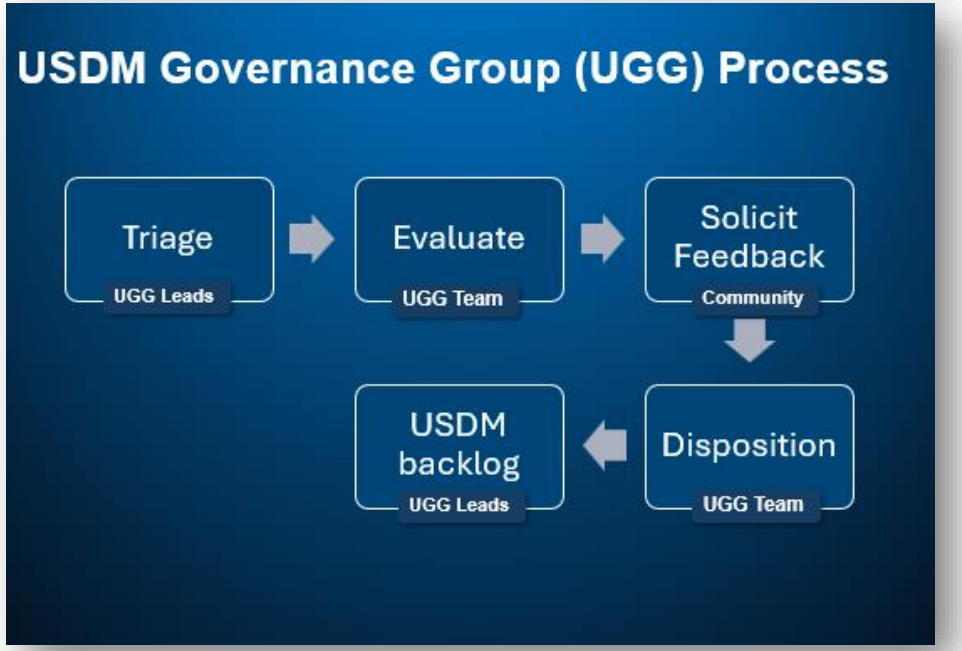
Why do we need USDM Governance?

Inclusivity
By involving multiple organizations and roles, the governance structure promotes broad stakeholder engagement and balanced decision-making.

Accountability
Defined roles and responsibilities help maintain transparency and accountability within the governance process.

Alignment:
The structure ensures that USDM governance is aligned with both CDISC and Industry initiatives, supporting industry-wide consistency.

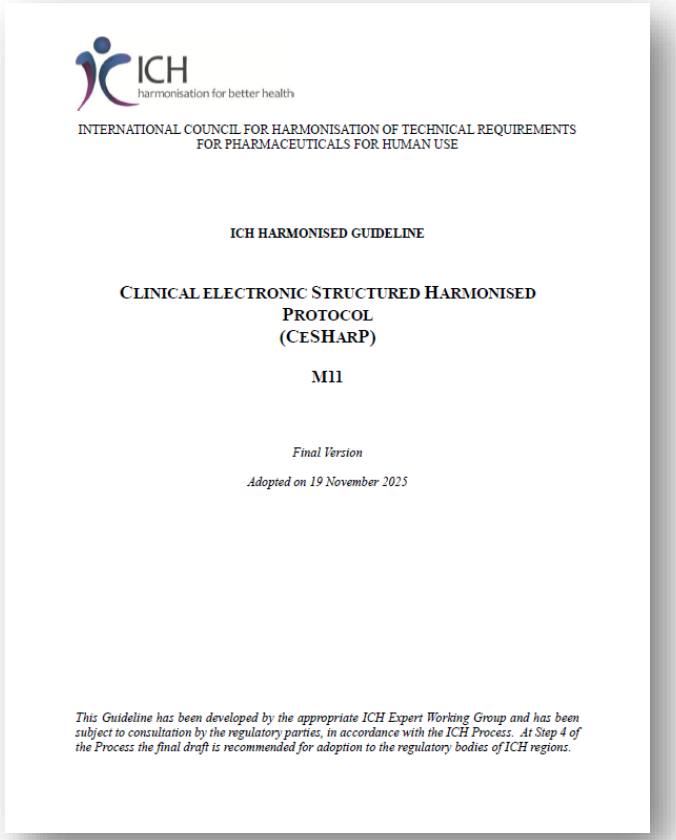




M11 Is …

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)

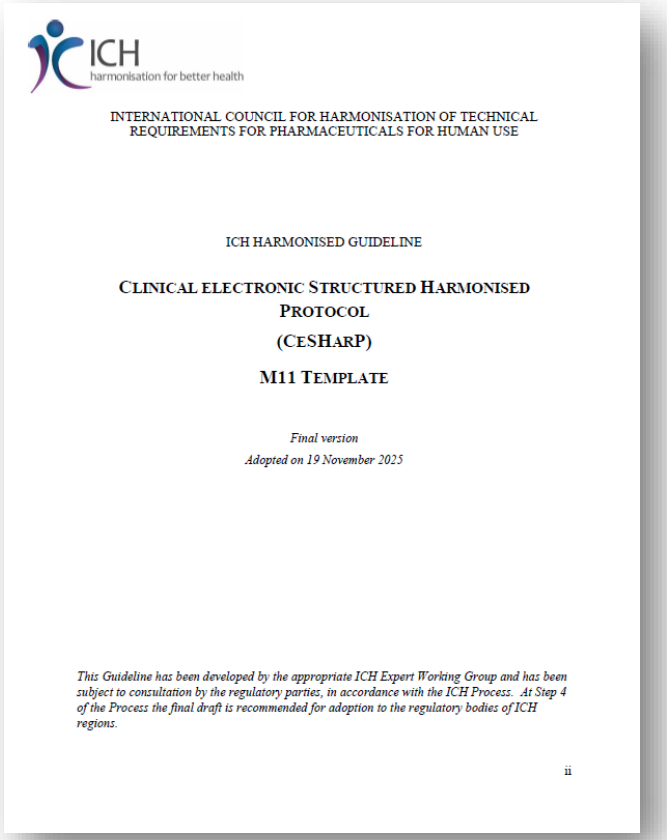
M11

Final Version

Adopted on 19 November 2025

This Guideline has been developed by the appropriate ICH Expert Working Group and has been subject to consultation by the regulatory parties, in accordance with the ICH Process. At Step 4 of the Process the final draft is recommended for adoption to the regulatory bodies of ICH regions.

Provides background, purpose, and scope as a guideline



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 TEMPLATE

Final version

Adopted on 19 November 2025

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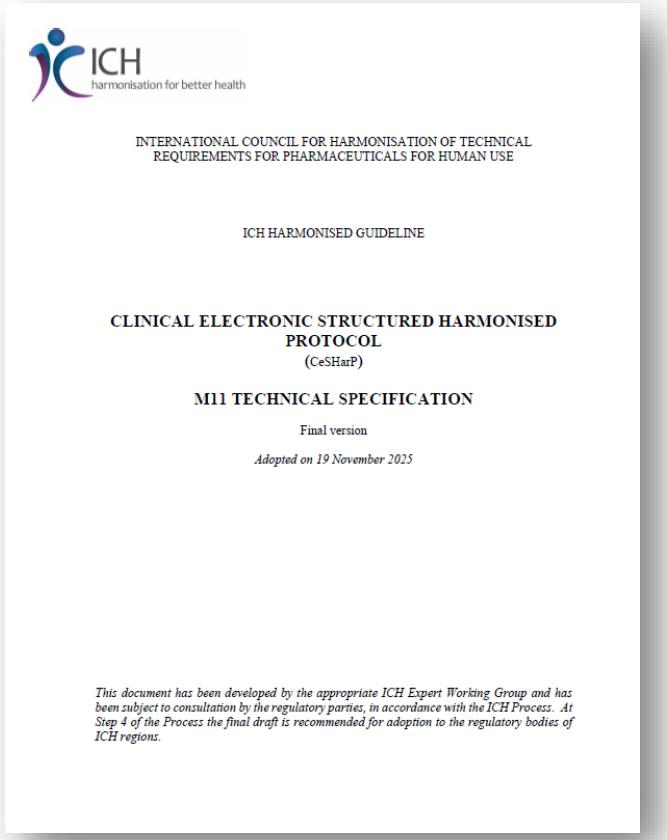
ii

Provides the written format for the Interventional Clinical Trial Protocol Template



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

Final version

Adopted on 19 November 2025

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Provides the technical representation aligned with the guideline and protocol template

USDM in Action
Use Cases Supporting the DDF Vision

Use Cases

Retrospective

Prospective

Protocol 'Store'

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

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

Study Design

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

This would include analyzing previous protocol information to inform design choices (see Protocol Store).

Writing associated SAP, Informed Consent, Monitoring Plan, Drug Plan etc via content reuse.

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

Feasibility & Cost
Support study feasibility and complexity evaluations.

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

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

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

Study Start-up

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

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

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

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

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

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

Study Execution

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

Ensure fewer amendments (see Protocol Store).

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

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

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

Analysis & Reporting

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

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

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

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

Regulatory Submission

Submission
Preparation of the submission by the sponsor

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

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

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

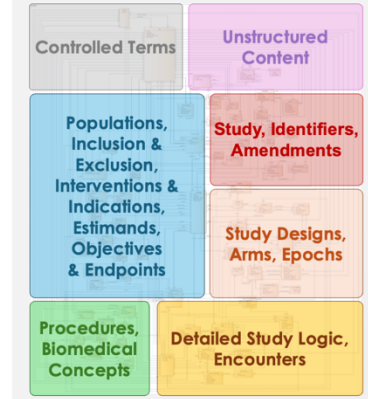
Across The Lifecycle

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

Comparison
Compare and verify differences across versions and similar protocols

NOTE: The use cases presented are illustrative and the list is not intended to be exhaustive.

Unified Study Definitions Model (USDM)



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

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

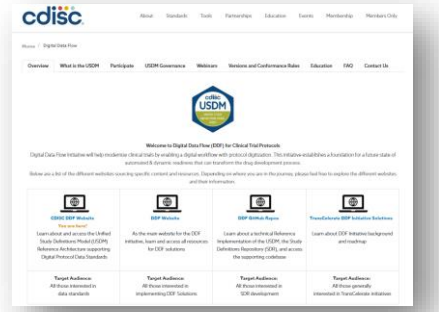
Study Science
The detailed description of the study science: the populations and the associated inclusion and exclusion criteria, the indications being studied, the interventions being used and the objectives, endpoints and the associated estimands.

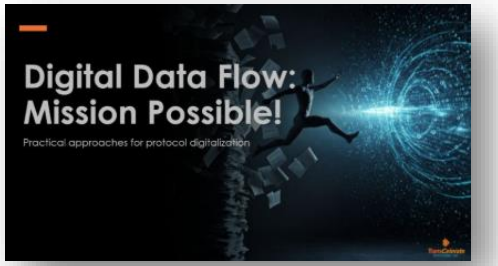
Detailed Study Logic
A precise definition of the study logic including support for the Schedule of Activities.

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

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

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





Version 5, 24th October 2024. Prepared by D Iberson-Hurst for the TransCelerate 'DDF in Action' day.
With thanks to Rob Ferendo (TransCelerate), Bill Illis (Novartos), Jasmine Kestemont (Argenx), Kirsten Langendorf (d4k), Mary Lynn Mercado (Novartis), Lissa Morgan (Amgen), Johannes Ullander (d4k) and Peter Van Reusel (CDISC)

The USDM SoA Project – Bridging the gap

The Future is Connected: Standards and AI Powering Digital Transformation

2026 Europe Interchange

Milan, Italy | Main Conference: 20-21 May | Trainings & Workshops: 18-19 May

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The Problem

Schedule of Activity (SOA) nomenclature varies across protocols resulting in nearly 300 Specimen, Assay, and Visit names manually mapped each month

Leveraging Industry and SOA Standards

1 ICH M11 Template

Modular Sections:

- Objectives
- Endpoints
- Participant Population
- Inclusion/Exclusion Criteria
- Safety
- Visits
- Assessments
- Etc.

Controlled Terminology:

Defines concepts within the protocol & provides standard terms and definitions

- e.g., Adaptive Trial Design, Control Types, Amendment Details, Amendment Scope, Analyses, etc.

3 Structured SOA

- SOA Metadata Model
  - Visits: Structured Timepoints (visits, cycles, days, etc.)
  - Assessments: Standard Nomenclature
- Defines the ontology, data standards, business rules, and operational relationships for SOA representation and authoring within study protocols

2 TransCelerate BIOPHARMA INC. cdisc

Unified Study Definition Model (USDM)

- Machine Readable, standardized framework for clinical trial definitions
- Dynamic, structured, executable protocol

digital study design

How a Harmonized SOA Impacts Stakeholders

The standardized SOA – aligned to USDM – unlocks efficiency across ecosystem

Standardized SOA ⟶ *Digital Study Design* ⟶ *Faster Startup* ⟶ *High Quality Trials*

Study Teams

- Quality protocol development
- Fewer amendments from semantic issues
- Reusable
- Automation ready

Downstream Consumers & Service Providers

- Clear, unambiguous requirements
- Consistent Activities and Specimen definitions
- Enables study start up, service provider alignment

Clinical Sites

- Less confusion and fewer errors due to interpretation burden
- Clearer visit expectations
- Fewer opportunities for deviations

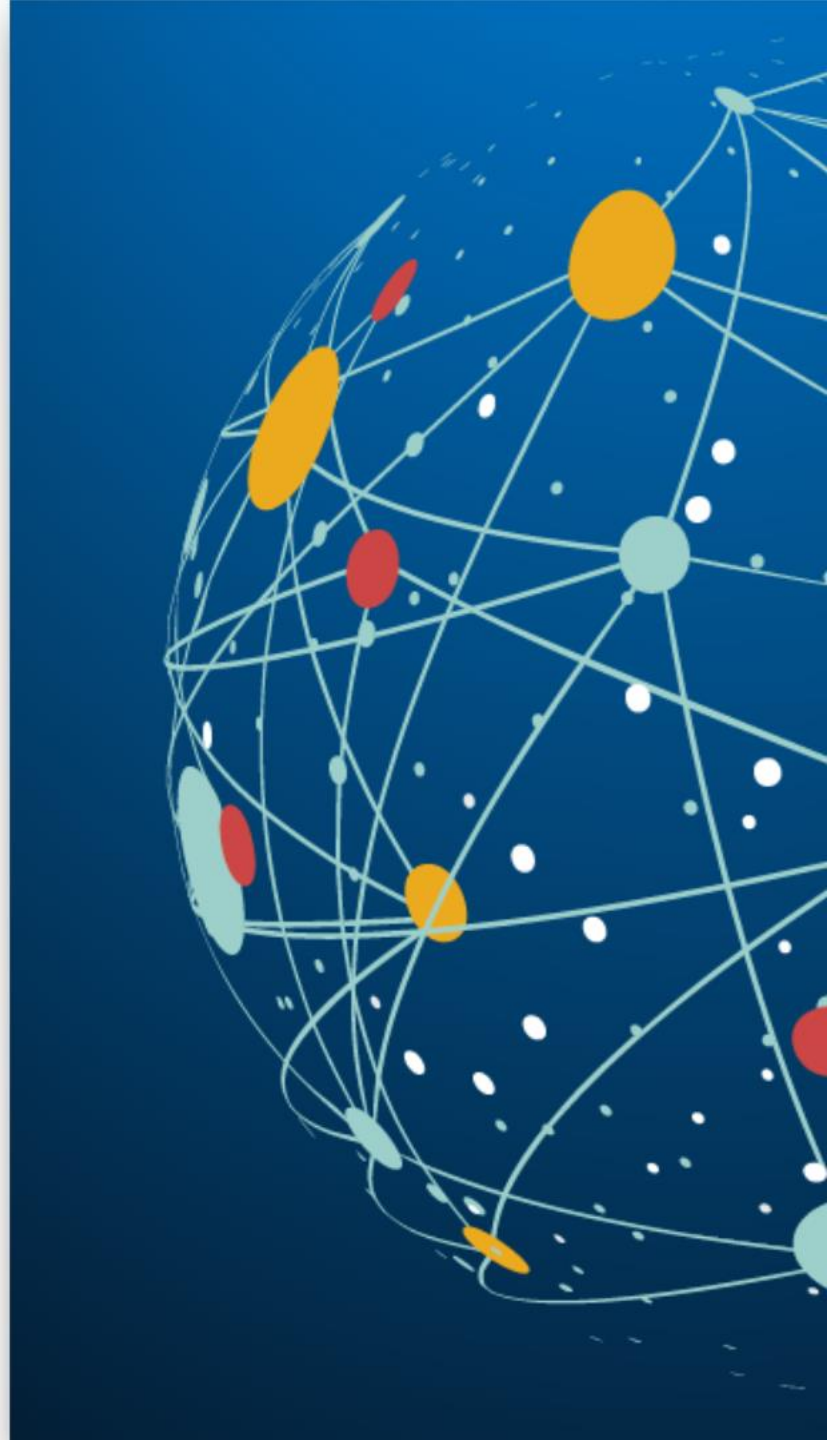
Patients

- Fewer unnecessary visits or procedures
- Clearer understanding of what to expect
- More consistent care across sites

USDM SoA Project

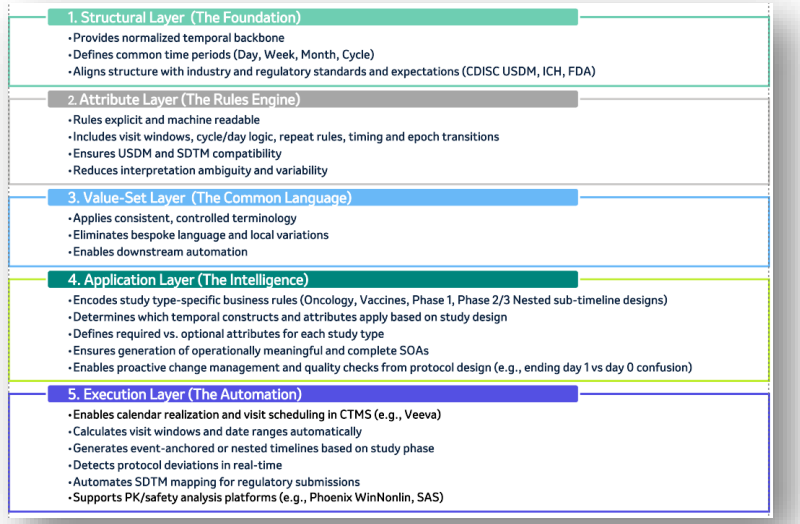
	Screening	Baseline	Allocation	Intervention	Post-intervention		
TIMEPOINT**					1 week	12 weeks	26 weeks
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
OPTIONAL Baseline consultation recording		X					
Allocation			X				
INTERVENTIONS:							
Intervention- eTRIO				←			
Control- NSW Health Website				←			
ASSESSMENTS:							
Clinician demographics		X					
Clinician professional characteristics		X					
***PRIMARY OUTCOME:** Clinician self-efficacy in triadic communication*		X			X	X	X
***SECONDARY OUTCOMES:** Preferences for carer involvement*		X			X	X	X
Carer relevant strategies and policies		X				X	X
Knowledge of strategies		X			X		
OPTIONAL Post intervention consultation recording					X		
Usability					X		
Satisfaction with module/website					X		
User engagement				X			

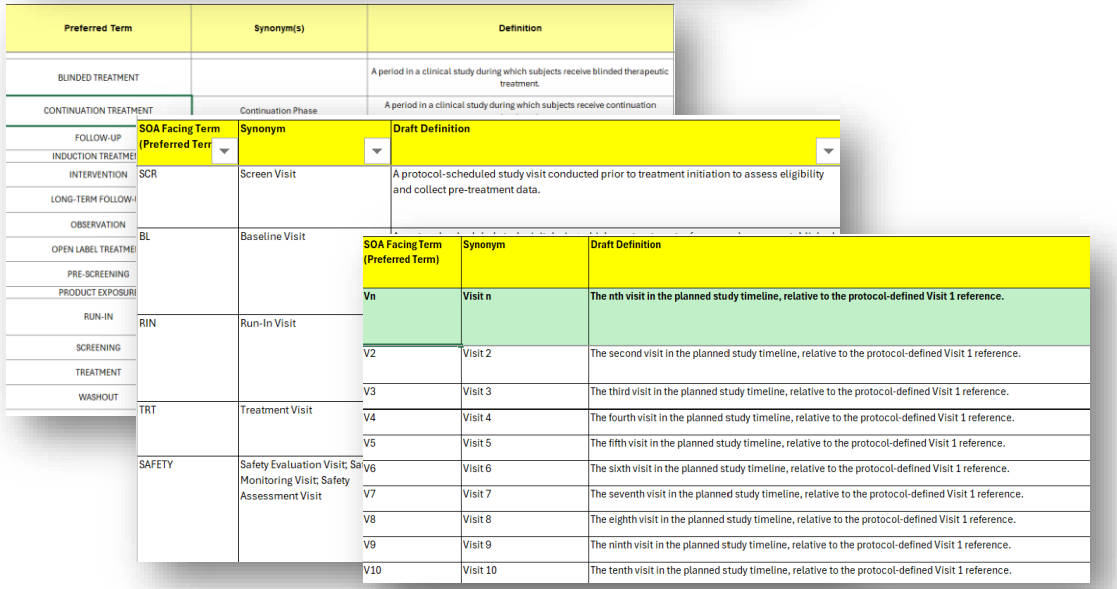
- Define Industry-Aligned Implementation Practices for SoA
- Translate the USDM Model into Real-World Practice
- Standardize SoA Representation to Enable Consistency and Automation
- Drive Cross-Industry Collaboration and Adoption



Build on the work donated by Merck

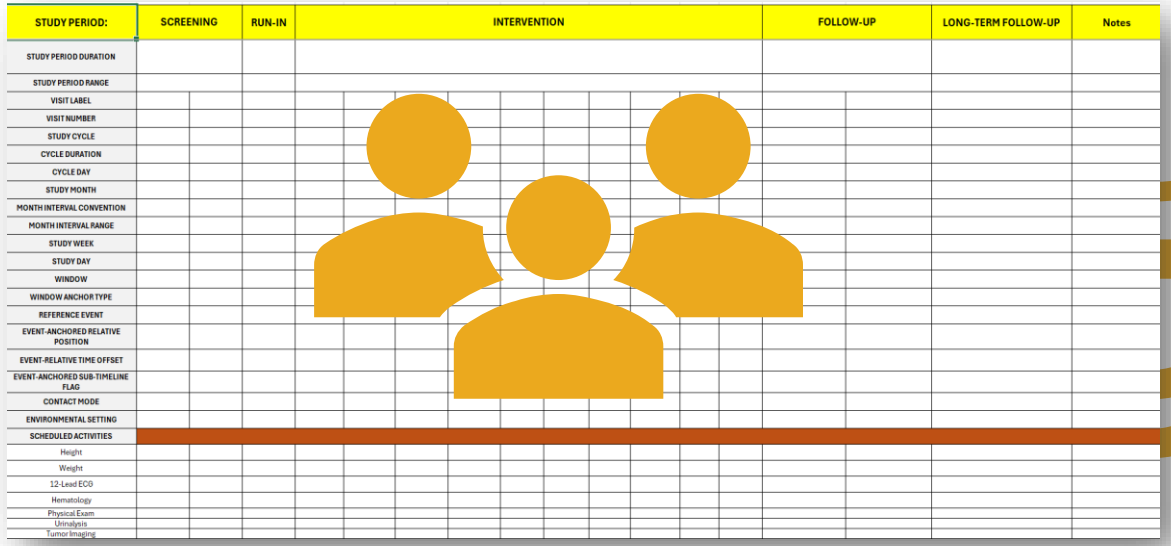
Structured SOA Attributes	Has Controlled Valueset	Control Input Format
STUDY PERIOD DURATION	No	Yes
STUDY PERIOD RANGE	No	Yes
PARTICIPANT PLANNING	Yes	
VISIT LABEL	Yes	
VISIT NUMBER	Yes	
STUDY CYCLE	Yes	
CYCLE DURATION	No	Yes
CYCLE DAY	Yes	
STUDY MONTH	Yes	
MONTH INTERVAL CONVENTION	Yes	
MONTH INTERVAL RANGE	No	Yes
STUDY WEEK	Yes	
STUDY DAY	Yes	
WINDOW	Yes	
WINDOW ANCHOR TYPE	Yes	
DISPOSITION AND MILESTONE EVENT	Yes	
ANCHOR EVENT	Yes	
EVENT-ANCHORED RELATIVE POSITION	Yes	
EVENT-RELATIVE TIME OFFSET	Yes	
EVENT-ANCHORED SUB-TIMELINE FLAG	Yes	
CONTACT MODE	Yes	
ENVIRONMENTAL SETTING	Yes	
SCHEDULED ACTIVITIES	Yes - Pending List	

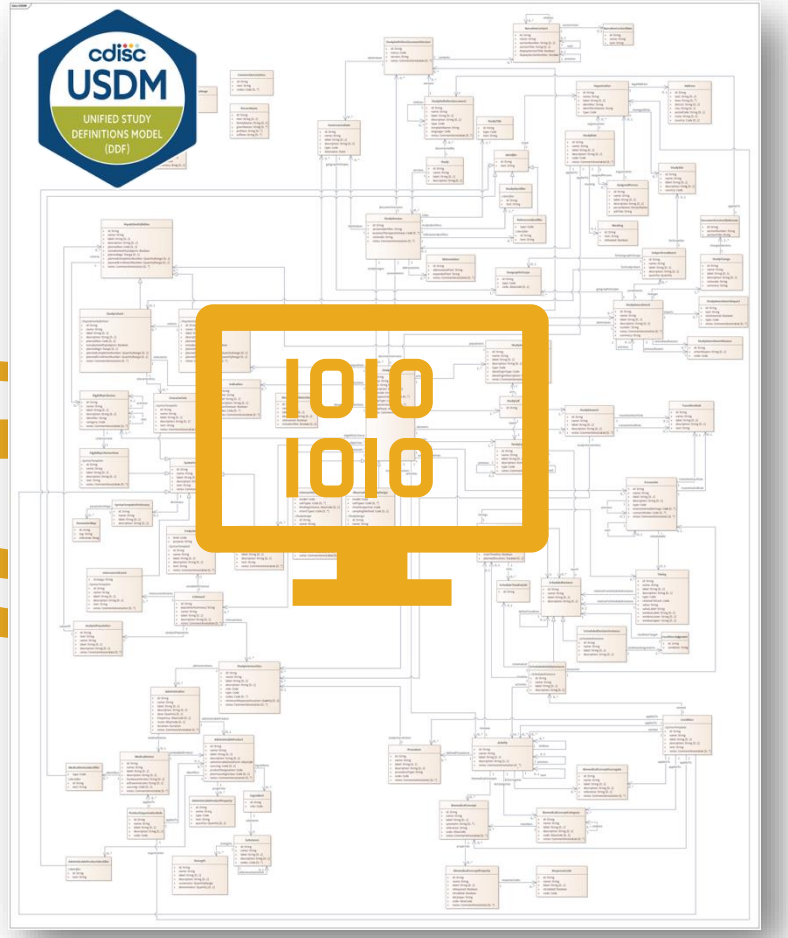




Bridge the gap

"converting SoAs into structured, computable data"



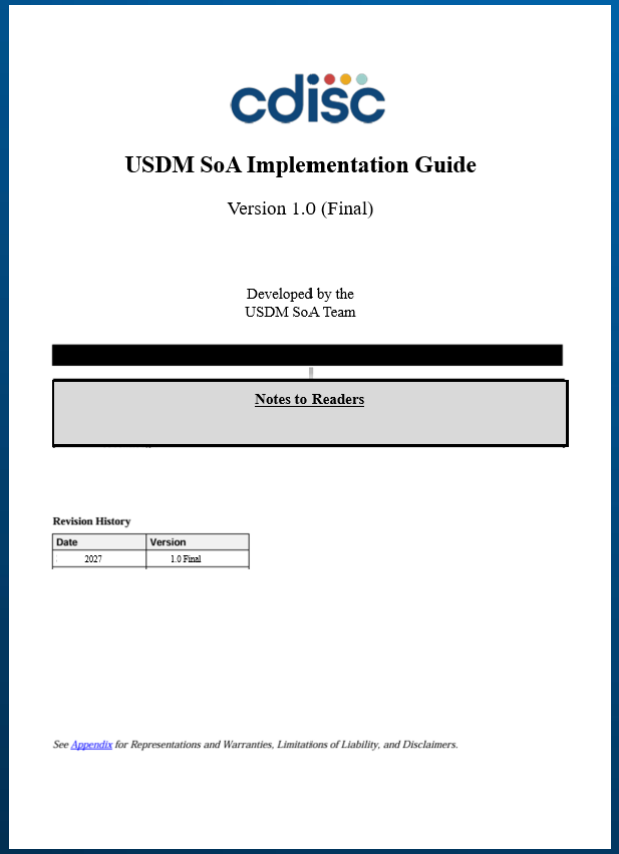


Deliverables

- USDM SoA Implementation Guide
  - Standardize SoA representation using USDM
  - Provide practical, consensus-based guidance
  - Maintain USDM as the normative model

- Supporting artifacts:
  - Example SoA datasets/templates
  - Mapping examples to USDM

- Contribution of USDM change proposals to be filtered through USDM Governance



USDM SoA Implementation Guide

Version 1.0 (Final)

Developed by the
USDM SoA Team

Notes to Readers

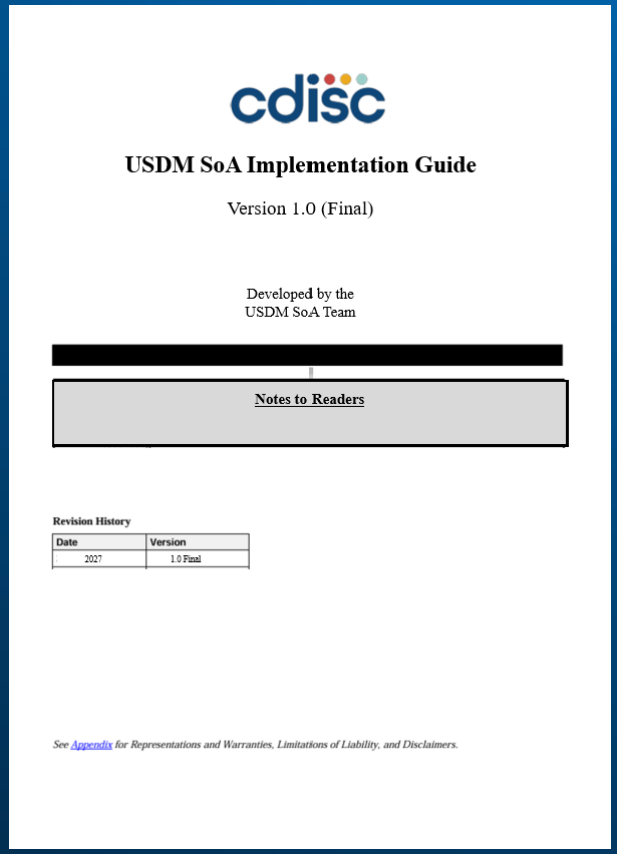
Revision History

Date	Version
2027	1.0 Final

See Appendix for Representations and Warranties, Limitations of Liability, and Disclaimers.

Scope

- Implementation guidance for representing SoA using USDM
- Temporal constructs (Study Day, Cycle, Month, Event-based timing)
- Visit scheduling, windows, and anchor concepts
- Controlled terminology and metadata conventions
- Minimum viable metadata requirements
- Examples across study types (cyclic, non-cyclic, event-driven)
- Mapping guidance to USDM



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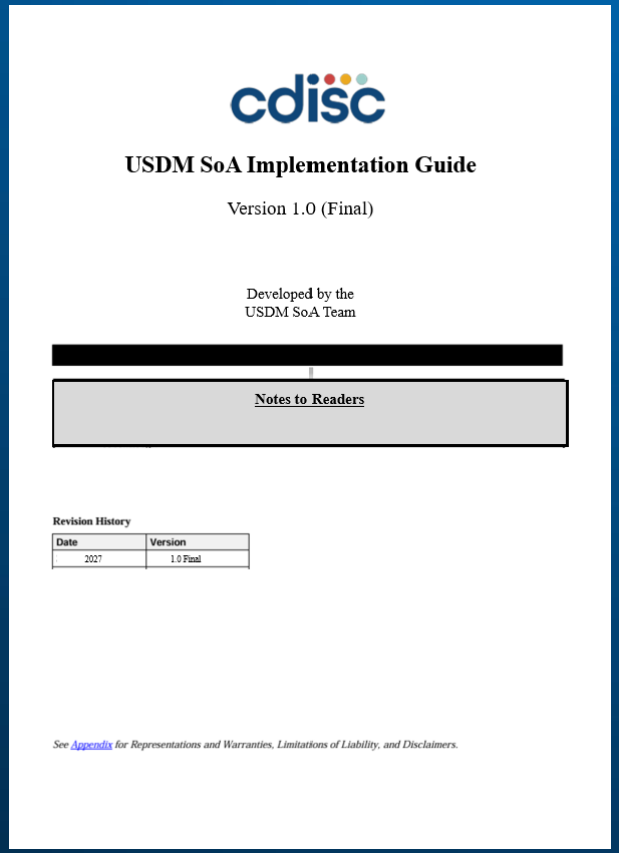
Key Value

- Consistent, unambiguous SoA representation
- Reduced reliance on protocol footnotes and free text
- Improved interoperability across systems (CTMS, EDC, SDTM)
- Enables automation (e.g., scheduling, deviation detection)
- Supports cross-study and cross-sponsor consistency



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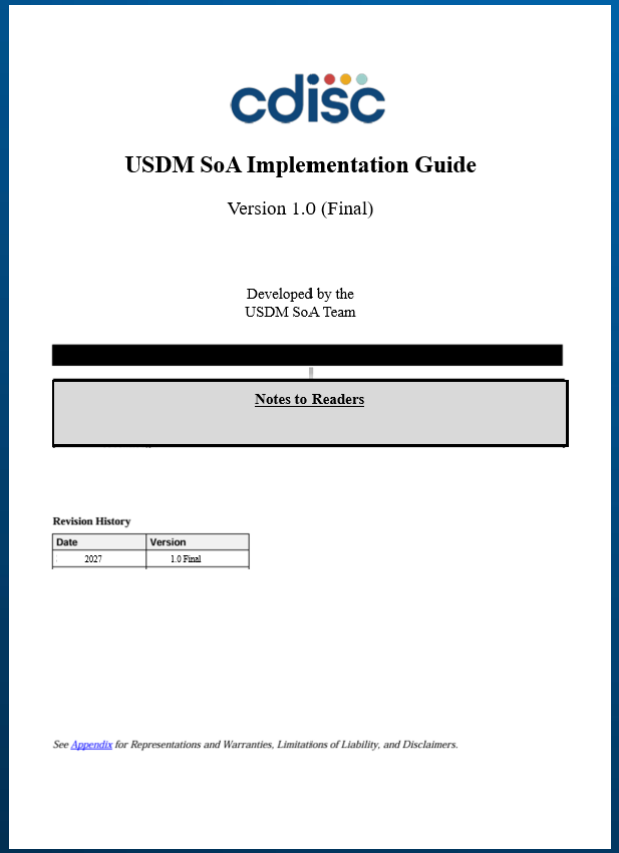
Strategy

- Harmonise core SoA elements.
- Design for complex, adaptive, and evolving study needs
- Create a strong common foundation that supports extension and tailored application
- Enable innovation by design—without limiting new approaches or thinking
- Structure for consistency, while remaining simple and practical to use in the real world



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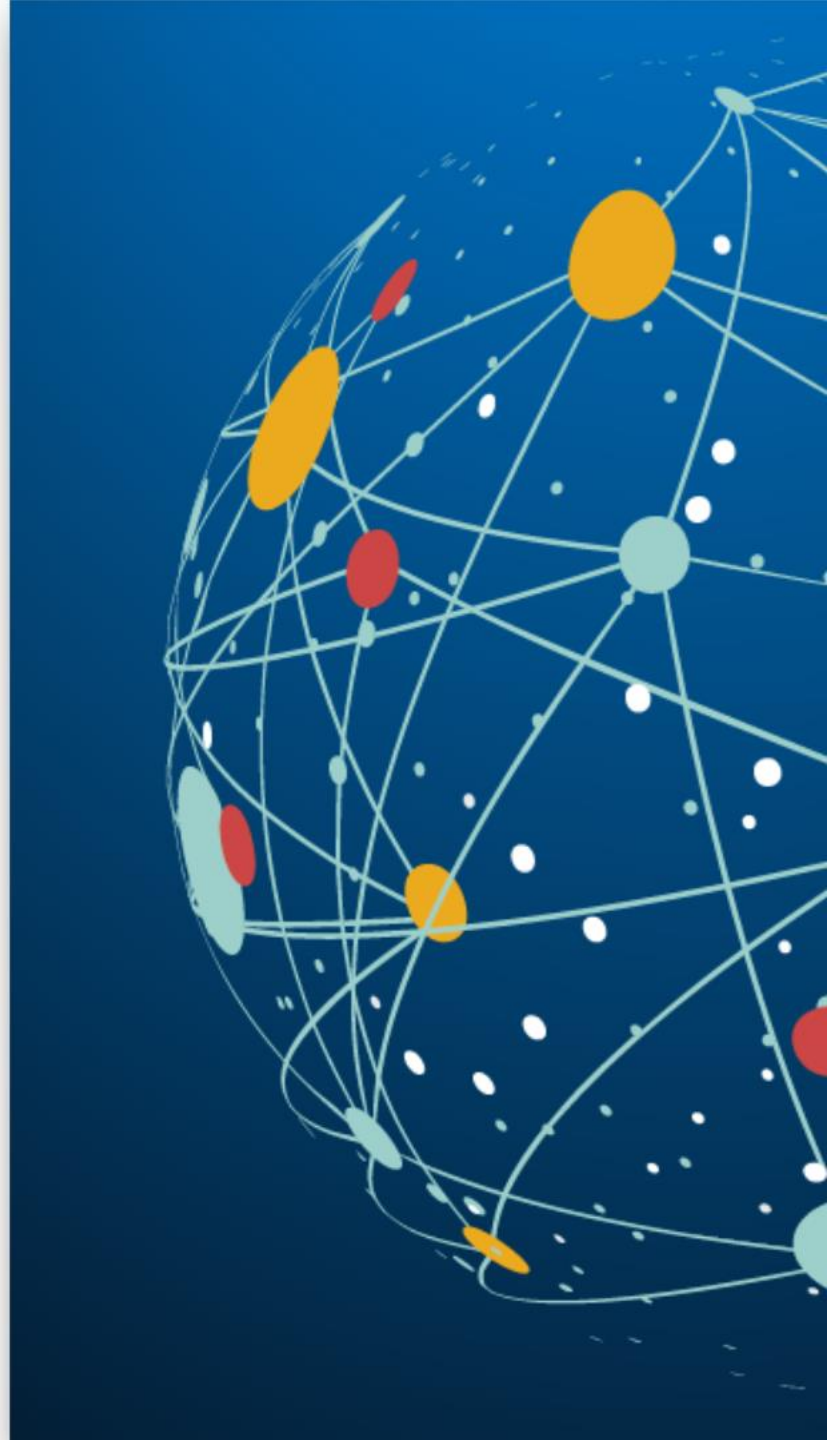
How to get Involved

Collaboration

- Led by CDISC under the formal Standards Development process (COP-001)
- Industry co-lead
  - Merck
  - 2nd Industry co-lead open
- Engagement support from TransCelerate
- Multi stakeholder involvement
- Consensus-driven development across industry with a Focus on:
  - standardization
  - clarity
  - reusability
  - machine computability



Why we need you

Medical Writing	Plays a critical role in translating structured study design into clear, compliant protocol content. With a digitised SoA, medical writers can reduce manual effort, improve consistency, and reuse structured content across documents.
Clinical Development/Operations	Plans and uses the Schedule of Activities to plan and execute studies effectively across sites. A standardised, structured SoA enables clearer study timelines, improved feasibility assessments, and more efficient trial delivery.
Data Management	Relies on accurate and consistent definitions of study activities to design data collection and ensure data quality. A computable SoA reduces ambiguity and supports smoother downstream processes such as database setup and SDTM mapping.
Statistics	Ensures that study design and data collection support robust and reliable analysis. A structured SoA provides clarity on timing, endpoints, and assessments, enabling more efficient derivation of analysis datasets and stronger statistical interpretation.
IT	Enables the integration and automation of systems that support clinical research. Structured SoA data allows IT teams to connect platforms like CTMS, EDC, and analytics tools, driving interoperability and reducing manual data transfer.
Vendors / Researchers / Sponsors/CROs	Collaborate across the study lifecycle to design, run, and analyse clinical trials. A standardised SoA improves alignment between partners, supports data reuse, and accelerates study start-up and execution across organisations.

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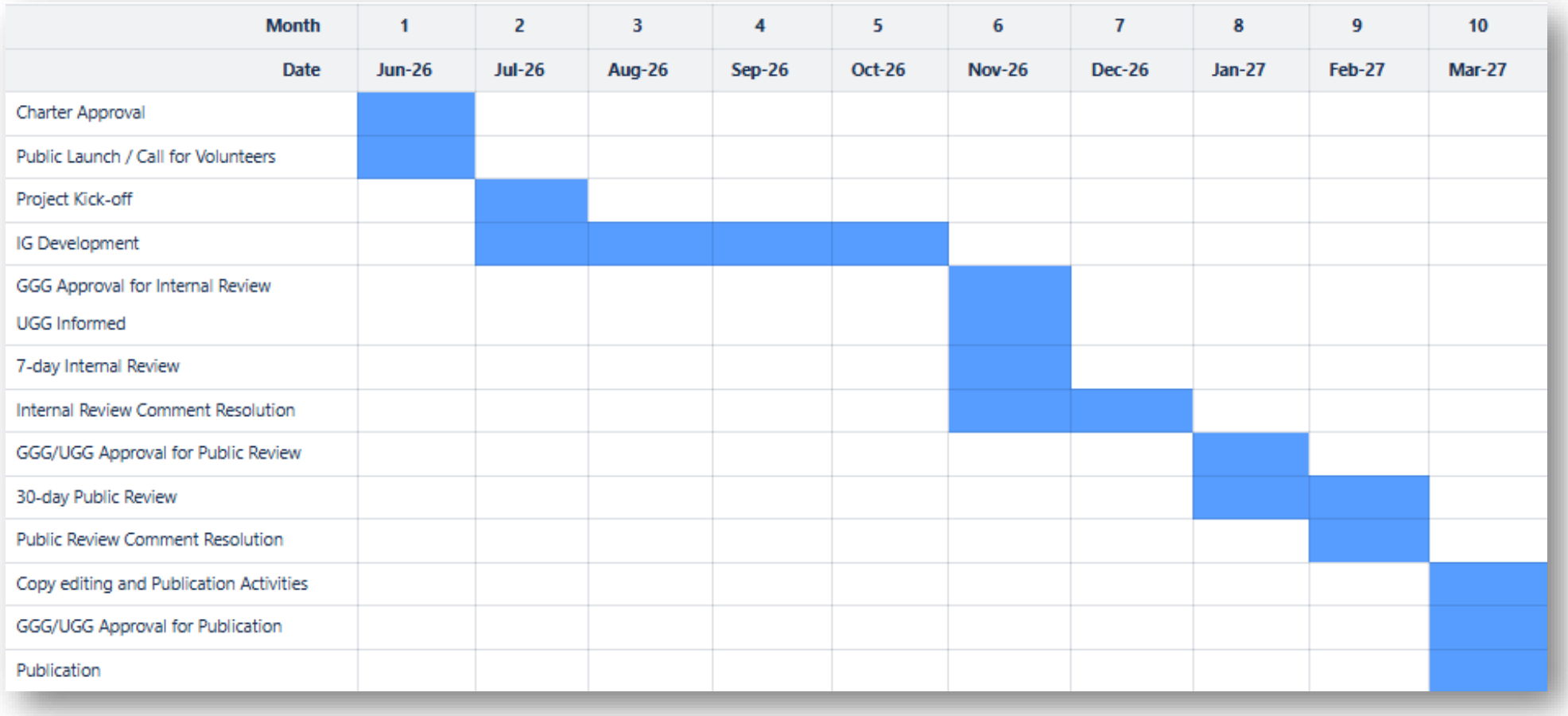
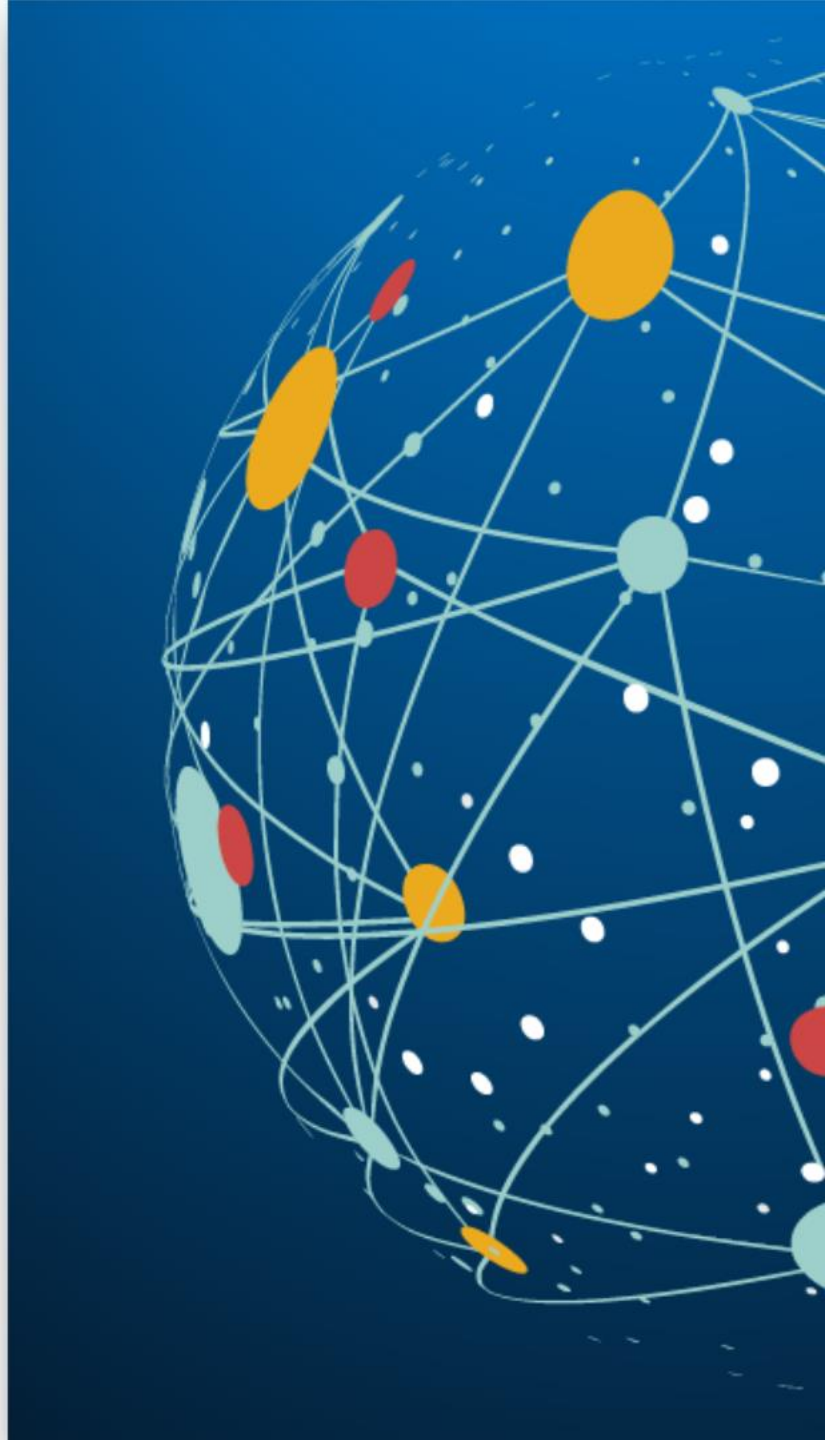
Indicative timelines



Month	1	2	3	4	5	6	7	8	9	10
Date	Jun-26	Jul-26	Aug-26	Sep-26	Oct-26	Nov-26	Dec-26	Jan-27	Feb-27	Mar-27
Charter Approval										
Public Launch / Call for Volunteers										
Project Kick-off										
IG Development										
GGG Approval for Internal Review UGG Informed										
7-day Internal Review										
Internal Review Comment Resolution										
GGG/UGG Approval for Public Review										
30-day Public Review										
Public Review Comment Resolution										
Copy editing and Publication Activities										
GGG/UGG Approval for Publication										
Publication										

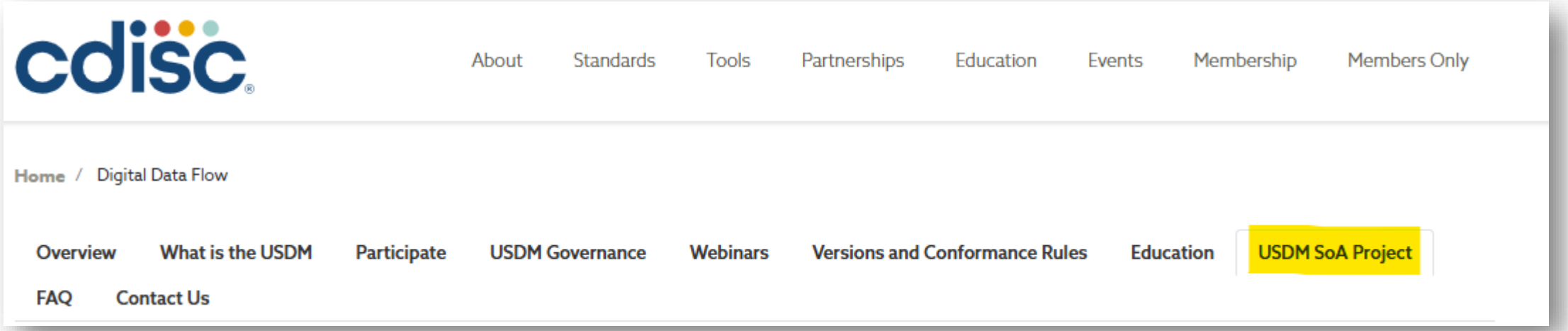
We need your expertise

- **Industry co-lead** (~20% FTE)
  - Actively work with CDISC lead to plan and progress the project to publication
  - Plan and attend weekly team and monthly all-hands meetings
  - Provide expertise in the development of the standard
- **Active Contributor** (~3-4 hours/week)
  - Attend weekly team and monthly all-hands meetings
  - Provide expertise in the development of the standard
  - Participate in the Internal and Public Review of the standard
- **Reviewer** (~1 hour/week)
  - Attend Monthly all-hands meetings
  - Provide expertise in the Internal and Public Review of the standard



How to volunteer

- Visit https://www.cdisc.org/ddf and navigate to the “USDM SoA” Tab



This page will provide information on the project and instructions to direct you to the Volunteer page where you can select the “USDM SoA” Team

Get Involved

Success depends on broad community participation. The project is actively seeking contributors with expertise in:

- Clinical operations and study design
- Data standards (CDASH, SDTM, ADaM)
- Digital health technologies and data collection
- Systems implementation and integration

By participating, you can:

- Help shape the future of digital clinical trials
- Contribute to industry-wide standards
- Ensure practical, real-world applicability

Levels of Involvement

- **Industry co-lead** (~20% FTE)
  - Actively work with CDISC lead to plan and progress the project to publication
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- **Reviewer** (~1 hour/week)
  - Attend Monthly all-hands meetings
  - Provide expertise in the Internal and Public Review of the standard

If you would like to participate in this exciting effort, please sign up on the **CDISC Volunteer page** and indicate "USDM SoA" as the Standards Development team. Please enter some information about your interest in the project in the "Specify in which capacity you want to participate."

How to volunteer

- A Wiki account will be created for you (if you do not already have one).
- You will be added to the USDM SoA Project email distribution list.
- As part of your volunteer welcome email, you will receive a link to complete a short questionnaire about your experience and your expected involvement in the project.
- You will be granted access to the USDM SoA Wiki space.
- You will receive an invitation to the project kick-off meeting scheduled for July 2026.

Q&A

cdisc Education

Learn from Standards Experts and Developers.

In-Person, Virtual, On-Demand, and Private Training options.

Enroll in English, Mandarin, or Japanese Language Trainings.

Member Credits and Discounts.

Learn More *training@cdisc.org*

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Clear Data. Clear Impact.

Standards Transform Clinical Research
Membership Join Our Global Community
Education Learn CDISC From CDISC

Helpful Links

- CDISC website www.cdisc.org
- CDISC Digital Data Flow https://www.cdisc.org/ddf
- CDISC Events https://www.cdisc.org/events
- CDISC Webinars https://www.cdisc.org/events/webinars/upcoming
- CDISC membership inquiries, contact membership@cdisc.org
- CDISC education inquiries, contact training@cdisc.org
- CDISC general inquiries, contact info@cdisc.org