



2024 CDISC CHINA INTERCHANGE **SHANGHAI**

30-31 AUGUST: CONFERENCE & EXPO | 28-29 AUGUST: TRAININGS

The banner features a panoramic view of the Shanghai skyline at dusk, with the Oriental Pearl Tower prominently in the center. The text "2024" is on the left, "CDISC CHINA INTERCHANGE" is in the middle, and "SHANGHAI" is on the right. A dark blue bar at the bottom contains the event dates.

**The TransCelerate/CDISC Digital Data Flow Project,
ICH M11 Protocol, and How They Work Together**

Presented by Peter Van Reusel, Chief Standards Officer, CDISC

Meet the Speaker

Peter Van Reusel

Title: Chief Standards Officer

Organization: CDISC



Peter Van Reusel provides executive leadership to the development and implementation of clinical standards in line with CDISC's strategy and operational plans, working closely with the President and CEO, as well as CDISC staff and stakeholders. He has over 20 years' experience in senior roles in pharma and at CROs, providing standards expertise and carrying out other standards work in various organizational settings. A long-time, CDISC-authorized instructor, Peter has helped significantly in developing CDISC training courses.

He previously served as CDISC's European Liaison, shepherding relationships with key European regulatory, academic, and biopharma stakeholders. Peter is also an active PHUSE collaborator.



Agenda

1. Introduction to the Digital Data Flow Project and USDM
2. Overview of M11 and the CDISC/ICH Partnership
3. USDM, M11, and the HL7 UDP – how do they come together?



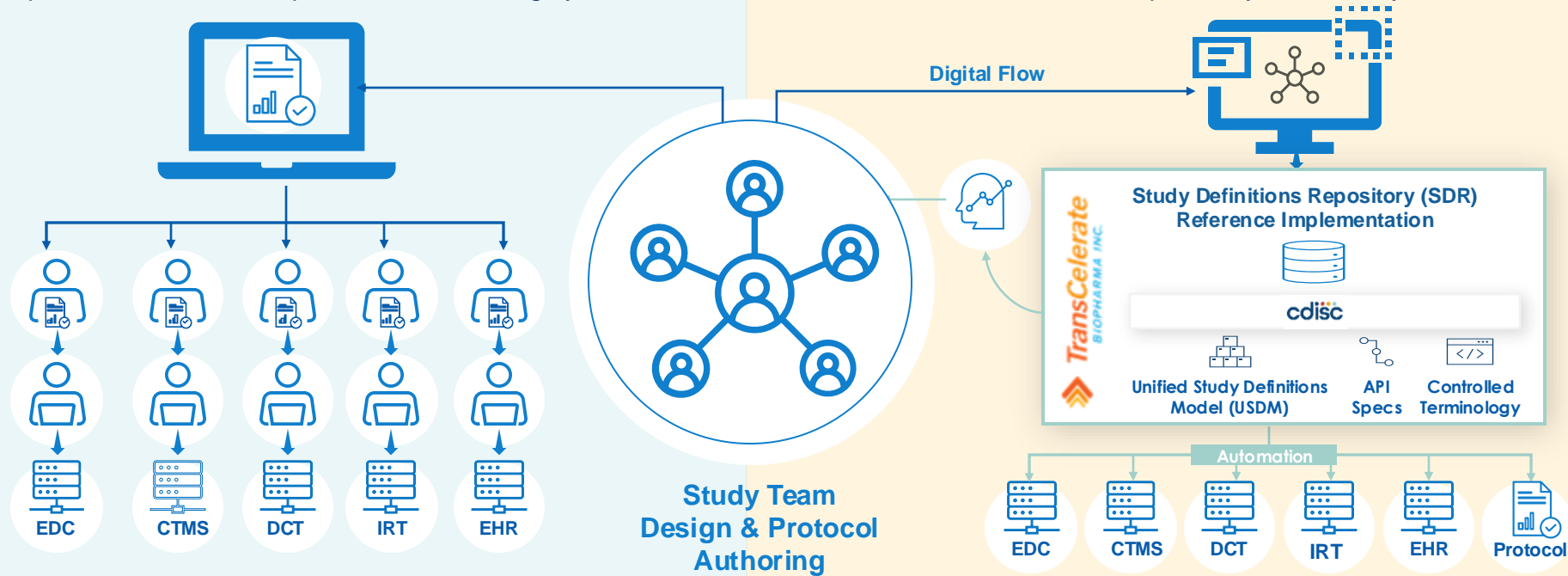
Introduction to the Digital Data Flow Project (DDF) and the Unified Study Definition Model (USDM)

TransCelerate Digital Data Flow (DDF) Ambition

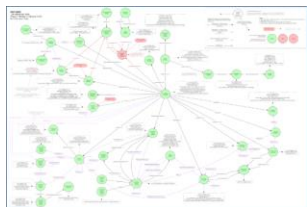
Write Once, Read Many

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



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



cdisc
 Unified Study Definitions Model (USDM) Reference Architecture

TransCelerate's Study Definitions Repository (SDR)

Study ID	Study Name	Phase	Start Date	End Date	Status
101	Study A	Phase 1	2023-01-01	2023-12-31	Active
102	Study B	Phase 2	2023-03-01	2024-06-30	Completed
103	Study C	Phase 3	2023-06-01	2024-09-30	On Hold



Suite of DDF Adoption Resources, Videos & Change Management Tools



Continued Industry Collaboration between TransCelerate, CDISC ICH, and HL7



Growing Solution Collaboration Forum (SCF)*



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

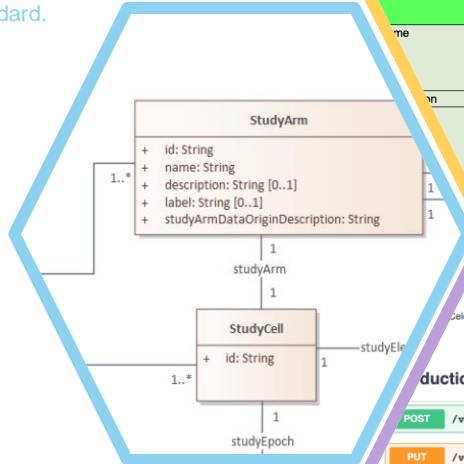
The USDM Standard

CDISC Controlled Terminology

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

Logical Model

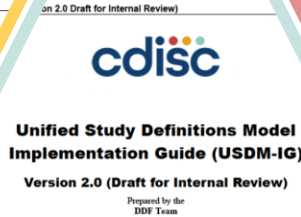
The UML logical model (a class diagram) that provides the basis for the USDM standard.



API Specification

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

C174447	Study Arm
C170984	Study Arm Name
C93728	Study Arm Description
C188827	Study Arm Type
C188828	Study Arm Data Origin Description
C188829	Study Arm Data Origin Type
CNEW	Study Arm Label
C71738	Study Epoch
C93825	Study Epoch Name
C93824	Study Epoch Description
C188830	Study Epoch Type
CNEW	Study Epoch Label



API for DDF 2.4 Provisional (0.3)

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

Introduction Routes that form the production specification.

POST	/v3/studyDefinitions	Create a study
PUT	/v3/studyDefinitions/{studyId}	Update a study
GET	/v3/studyDefinitions/{studyId}	Return a study
GET	/v3/studyDefinitions/{studyId}/history	Returns the study history
GET	/v3/studyDesigns	Study designs for a study

Expand all object

```

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 collected from external source",
    "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.org",
      "codeSystemVersion": "2022-12-16",
      "decode": "Active Substance"
    }
  }
]

```

Examples

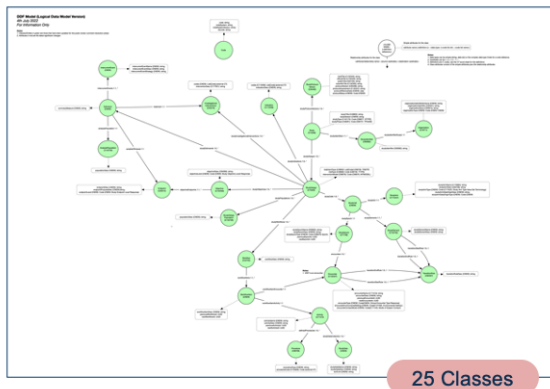
Example protocols implemented in the USDM with associated JSON files and visualisations

Implementation Guide

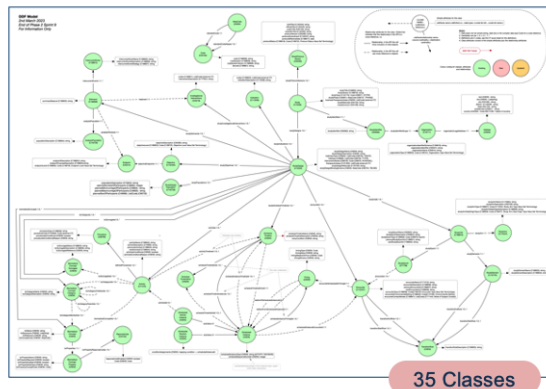
Guidance on using the USDM model and ensuring conformance with the standard

CDISC DDF / USDM: Phases One, Two and Three

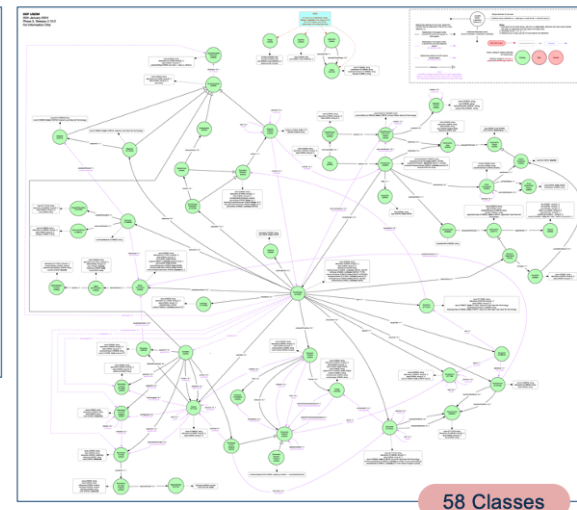
Phase One



Phase Two



Phase Three



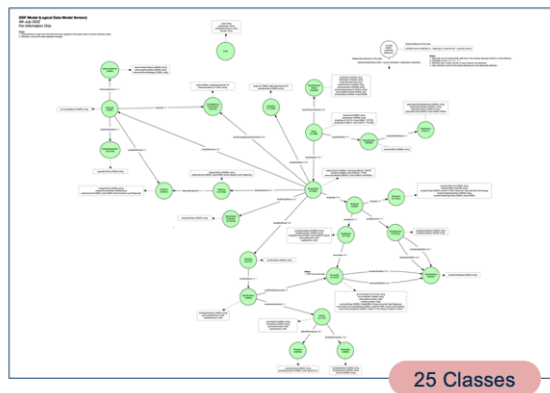
- Solid foundation
- The protocol document was an external entity into which the structured content could be exported

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

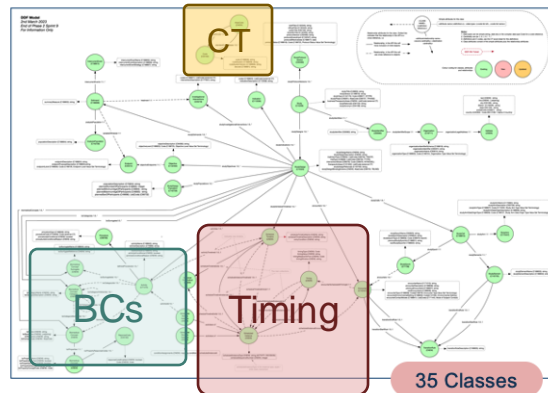
- Now contains structured and unstructured elements
- The entire protocol document can be held within the USDM
- Allows for the protocol document to be generated from the model

CDISC DDF / USDM: Phases One, Two and Three

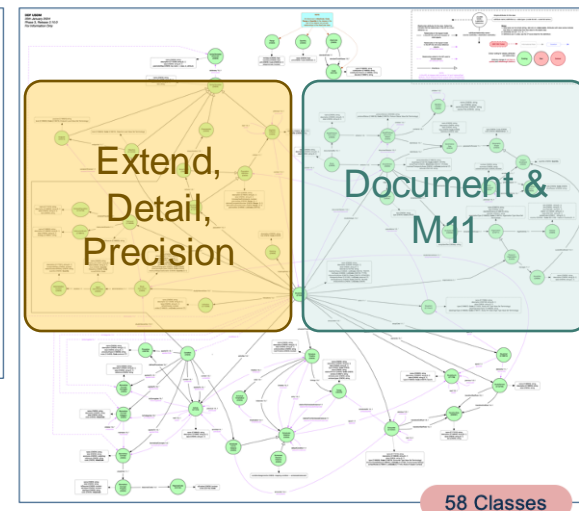
Phase One



Phase Two



Phase Three

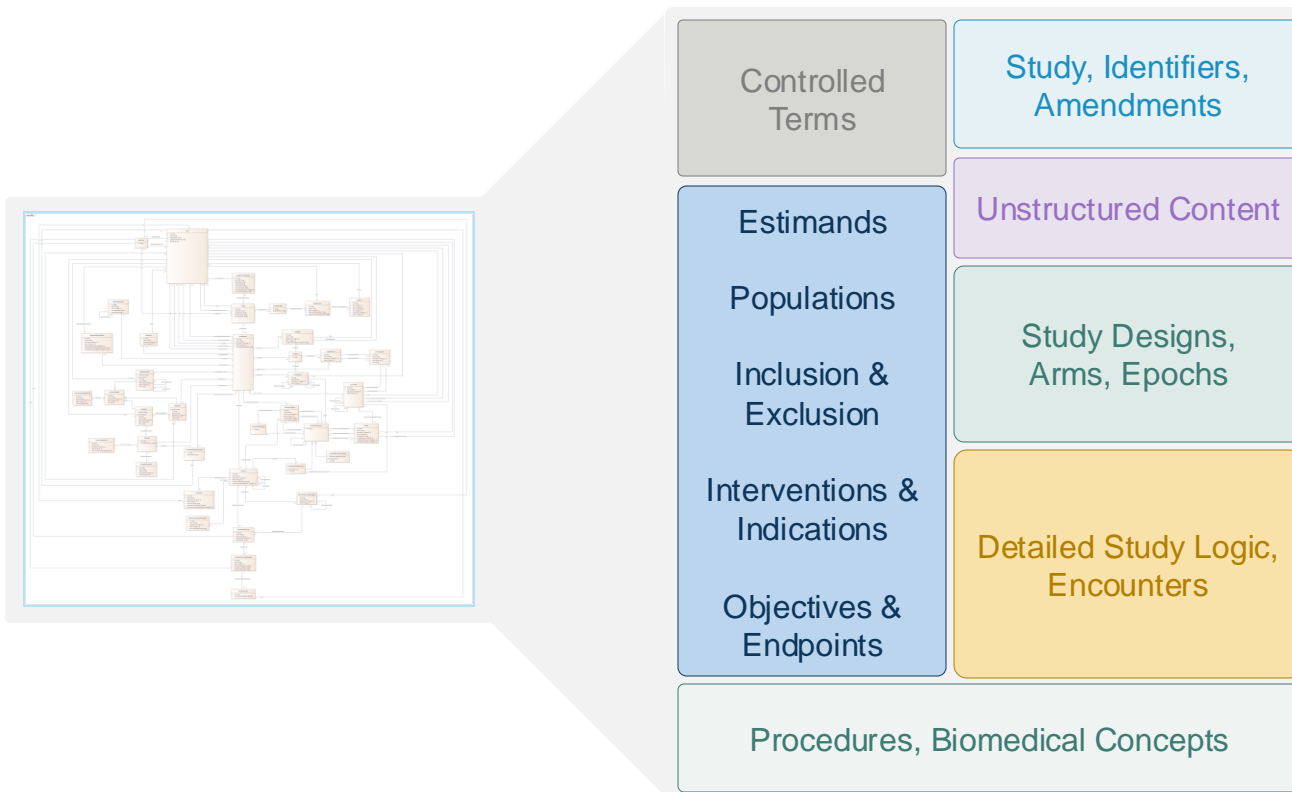


- Solid foundation
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- Focused on the structured elements of the protocol, e.g. the Schedule of Activities (SoA) & Biomedical Concepts (BCs)
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- Now contains structured and unstructured elements
- The entire protocol document can be held within the USDM
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USDM Content



DDF Reference Architecture & Github

- The source of DDF Reference Architecture deliverables

- Unified Study Definitions Model (USDM) Class Diagram**
The UML class diagram (normative) as well as SQL Data Dictionary, Entity Relationship Diagram and example JSON output (informative)
- Application Programming Interface (API) Specification**
The API definition (normative) in JSON and HTML forms
- CDISC Controlled Terminology**
The controlled terminology (normative) developed for the project. Provided in an Excel format so as to be easily searched and filtered.
- Test Files**
Examples of USDM JSON files
- Implementation Guide**
Explanation of the model and its use, examples etc
- Conformance Rules**
Specification of the CDISC CORE rules required for USDM conformance

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

cdisc-org / DDF-RA

Code Issues 49 Pull requests Zenhub Discussions Actions Projects Wiki Security Insights

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

main 4 Branches 34 Tags

File	Description	Updated
github-actions	Generate Diff and Data Dict	saftc98 - 2 weeks ago
github/workflows	use gh output instead of deprecated set-output	6 months ago
Deliverables	Generate Diff and Data Dict	2 weeks ago
Documents	Update informative diagram for criteria tweak	3 weeks ago
HowTos	Initial commit	2 years ago
images	Initial commit	2 years ago
gitignore	Updated Objective and Endpoint class	10 months ago
CODE_OF_CONDUCT.md	Updated the enforcement contact	2 years ago
CONTRIBUTING.md	Initial commit	2 years ago
LICENSE		
README.md		

DDF-RA

cdisc-org / DDF-RA

Code Issues 44 Pull requests Discussions Actions Projects Wiki Security Insights

Files

main

Deliverables

- API
- CT
- IG
- RULES
- UML
- Documents
- HowTos
- Images


DDF-RA / Deliverables

Name	Last commit message
..	
API	API updates
CT	Update USDM_CT.xlsx
IG	Added USDMIG post copy editing
RULES	Set of USDM v3.0 rules
UML	Pushed to wrong branch, reverting

Example Resources – CDISC

Digital Data Flow <https://www.cdisc.org/ddf>





Overview | What is the USDM | Participate | Webinar | Versions | FAQ | Contact Us

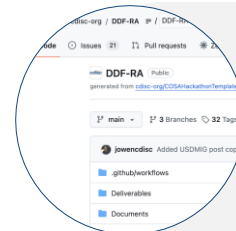


Welcome to Digital Data Flow (DDF) for Clinical Trial Protocols

Digital Data Flow Initiative will help modernize clinical trials by enabling a digital workflow with protocol digitization. This initiative establishes a foundation for a future state of automated & dynamic readiness that can transform the drug development process.

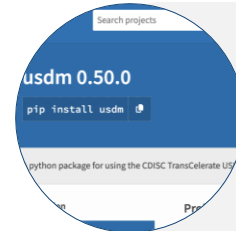
Below are a list of the different websites sourcing specific content and resources. Depending on where you are in the journey, please feel free to explore the different websites and their information.

 CDISC DDF Website <i>You are here!</i> Learn about the Unified Study Definitions Model (USDM) Reference Architecture supporting Protocol Standards	 DDF Website As the main website for DDF, learn and access all resources supporting DDF	 DDF GitHub Learn about and access the Study Definitions Repository Reference Implementation	 Transcelerate DDF Initiative Solutions Learn about DDF background and initiative roadmap
Target Audience: Those interested in data standards	Target Audience: All those interested in implementing DDF Solutions	Target Audience: Those interested in SDR development	Target Audience: All those generally interested



CDISC Github housing the USDM deliverables (model, CT, API etc) along with examples of protocols placed into USDM.

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



Open-source python package that implements USDM V3. Can be used by anyone to build test data

<https://pypi.org/project/usdm/>



Web-based version of the USDM test tooling.

<https://usdm-service.fly.dev/>

Example Resources – TransCelerate

<https://www.transceleratebiopharmainc.com/initiatives/digital-data-flow/>

BACK TO OUR SOLUTIONS

Digital Data Flow

This initiative aims to move the drug development process from a current state of manual study start-up asset creation (i.e., Case Report Forms, Procedure Manuals, Statistical Analysis Plans, and Schedule of Activities) to a future state of fully automated dynamic, study start-up readiness via an open-sourced, vendor agnostic technical solution that will reduce cycle times and improve data quality for sponsors, third-party providers, sites and regulators.

INITIATIVE SOLUTIONS

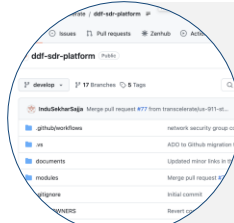
KEY RESOURCES

- INITIATIVE OVERVIEW
- NEWS ARTICLE: DEVELOPMENT OF DIGITAL DATA FLOW
- DIGITAL DATA FLOW OVERVIEW VIDEO



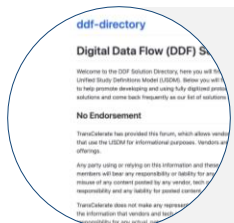
TransCelerate web page holding a significant number of DDF and USDM resources including the persona guides

<https://www.transceleratebiopharmainc.com/assets/digital-data-flow-solutions/>



Github housing the source for the Study Definition Repository (SDR) Reference Implementation of the USDM

<https://github.com/transcelerate/ddf-sdr-platform>

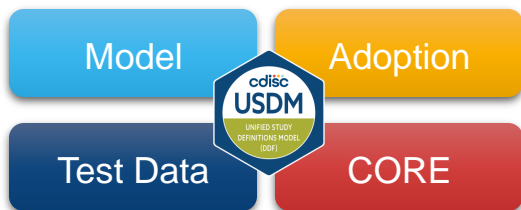


DDF solutions directory. A growing list of self-reported solutions which utilize and follow the DDF Unified Study Definitions Model (USDM)

<https://transcelerate.github.io/ddf-directory/directory/directory.html>

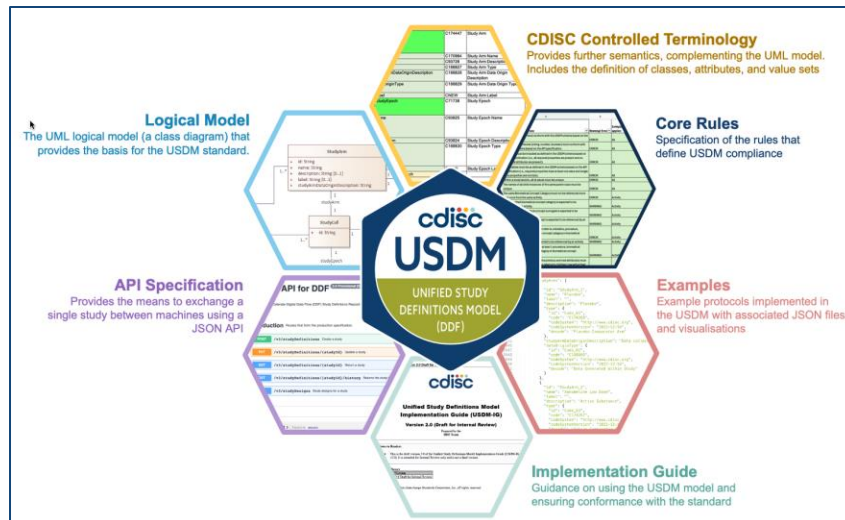
Phase 4 Overview

- More focus on refinement rather than new content
- Need to pay attention to backward compatibility
- Maximum alignment with ICH M11
- Conformance Rules now part of the standard

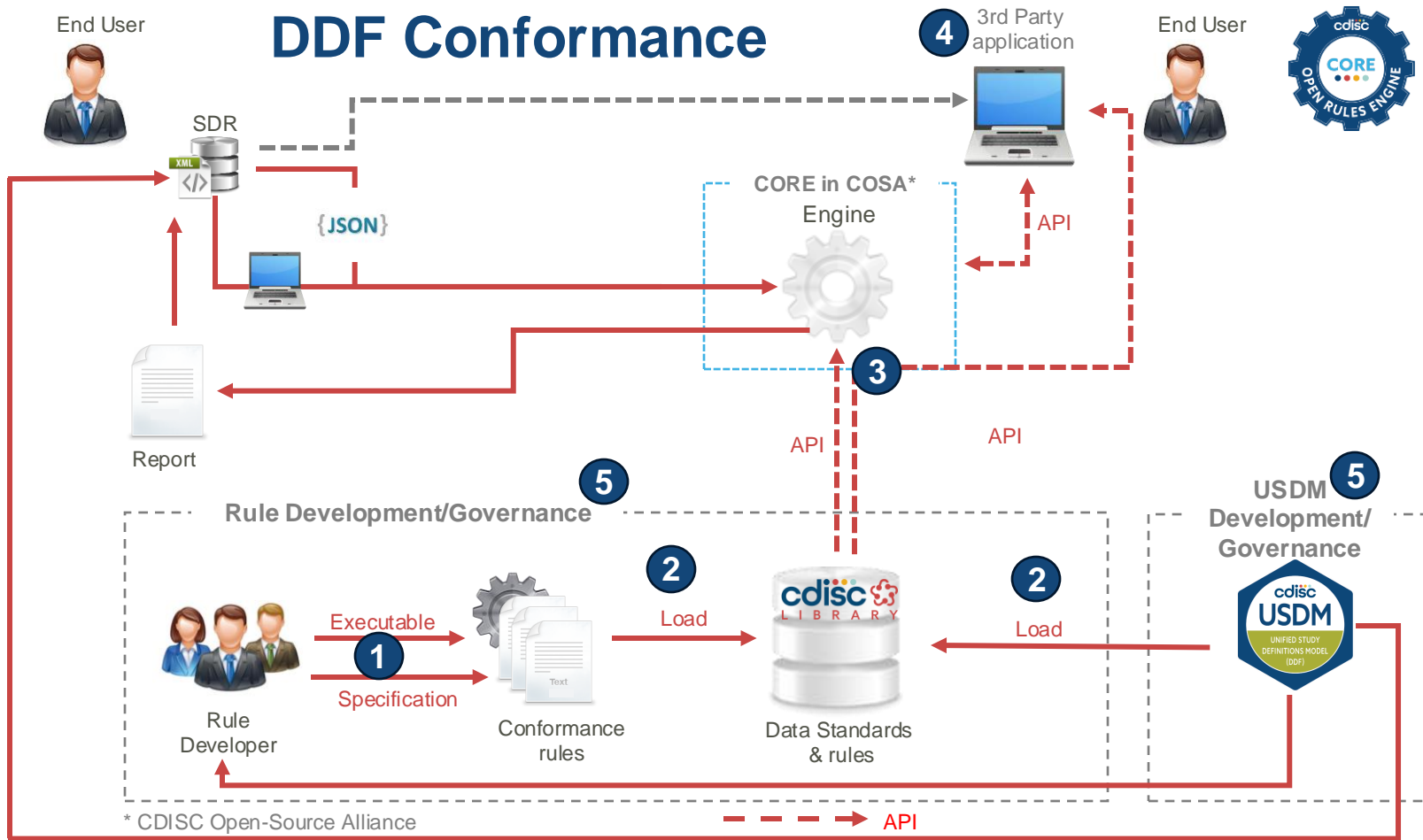


Phase Four Focus

- 1 **USDAM Enhancements** Further IDMP Alignment, M11 amendments and versions, complex studies designs such as multiphase seamless designs, additional trial registration mappings, and statistical / estimands enhancements
- 2 Continued alignment of USDAM with ICH M11
- 3 Participation in the Utilizing the Digital Protocol (UDP) project with TransCelerate, ICH and HL7 Vulcan
- 4 Continue development of USDAM Conformance Rules to support USDAM v3.0 and v4.0
- 5 Continue support and development of test data and test tools
- 6 Development of training and, education materials in conjunction with TransCelerate's Change and Engagement team to foster adoption of DDF



DDF Conformance



USDM generates various formats

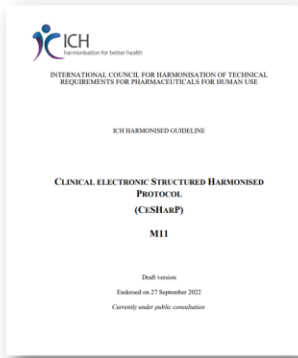
Guideline

&

Template



Tech Spec



0 Foreword

0.1 Template Revision History

Date	Description of Revision
11/16/2020	Initial template

0.2 Intended Use of Template

This template is intended for interventional clinical trials of drugs, vaccines, and drug/device combinations intended for registered use. The template is suitable for all phases of clinical research and all therapeutic areas. Existing ICH guidelines and ISO 14155 were considered in its development. This template is designed to enable modification suitable for the ICH/EMA/CDISC. Refer to the sections below for additional details and conventions related to usability.

0.3 Template Conventions and General Instructions

This template uses the typographic described in the table below to distinguish between their intended use and applicability. Use of consistent font sizes (12 point) throughout the document is recommended, but not required.

Type of Text (Typographic)	Typographic Details	Description (Intended Use)
Universal text	Black Times New Roman font	Text that should appear in all protocols
Instructional text	Red Courier font (Delete for final document)	Text that provides instructions, but which should not appear in a final protocol
Suggested text	Blue Courier font (Highlight to Black Times New Roman for final document)	Text that is suitable for many trials, but which may need to be modified, deleted, or replaced according to the specific context of the trial
Variable text	Brackets in the prevailing typographic (Select from choices by eliminating unwanted options; remove brackets and replace remaining text to match other text in the final document)	Where a choice is suggested between options in a passage of text, brackets are used to separate them
Fields	Shaded (Shaded) in the prevailing typographic with grey shading	Brackets with grey shading are used to indicate variable text resolved as a

Technical Specification

The purpose of this document is to serve as a technical representation of the ICH M11 protocol template requirements. This Technical Specification (TS) is to be aligned with the latest version of the ICH M11 guideline and protocol template, but with flexibility in addressing data exchange requirements per ICH and regional authority requirements.

NOTE: Certain elements within this version of the Technical Specification do not have a value represented (e.g., Cardinality, Definition, Relationship to Conceptual Model) and shall be included in a new version of the TS as the work within the ICH M11 EWG progresses through the ICH Step process.

Appendix 1: Detailed Descriptions of Information Components

Overall Rules

Form Variability	Overall rules
Form Type	Text
Topic, Value or Header	N/A
Definition	
Text Guidance	Rules
Conformance	
Cardinality	All document
Relationship context from ICD representing the practical hierarchy	
Relationship inference to high level conceptual model	
Value	REQUIRED Level 1 and Level 2 Headings
Business rules	Value Allowed: Y/N Relationship: N/A Concept: N/A

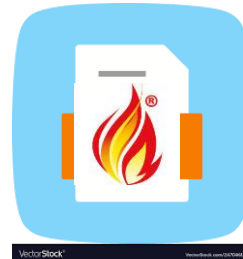
Duplicate field in other sections



Electronic Document
Human Readable Form



Machine-Readable Form



Standard Message Exchange Formats





Overview of M11 and the ICH/CDISC Partnership

ICH CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHarP)



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

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CESHARP)

M11 TEMPLATE

Draft version

Endorsed on 27 September 2022

Currently under public consultation

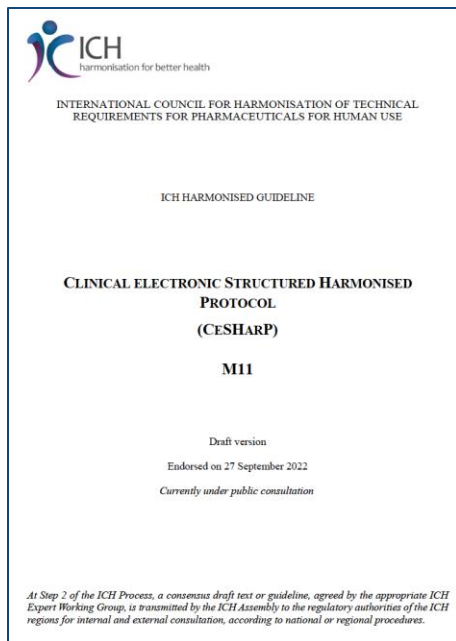
At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Assembly to the regulatory authorities of the ICH regions for internal and external consultation, according to national or regional procedures.

Founding Regulatory Members	Founding Industry Members	Standing Regulatory Members	Regulatory Members	Industry Members
<ul style="list-style-type: none">• EC, Europe (EMA)• FDA, United States• PMDA, Japan	<ul style="list-style-type: none">• EFPIA• JPMA• PhRMA	<ul style="list-style-type: none">• Health Canada, Canada• Swissmedic, Switzerland	<ul style="list-style-type: none">• ANVISA, Brazil• COFEPRIS, Mexico• EDA, Egypt• HSA, Singapore• MFDS, Republic of Korea• MHRA, UK• NMPA, China• SFDA, Saudi Arabia• TFDA, Chinese Taipei	<ul style="list-style-type: none">• BIO• Global Self-Care Federation• IGBA

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

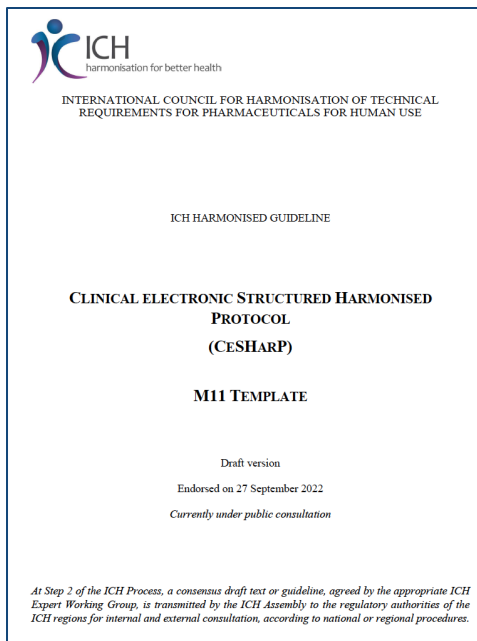
CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CESHARP)

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.

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

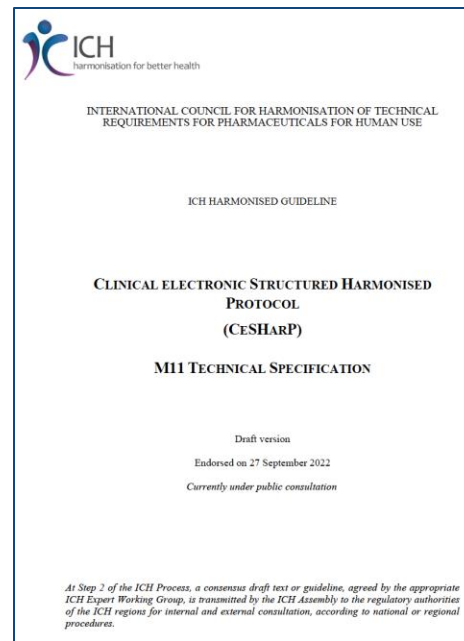
CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CESHARP)

M11 TEMPLATE

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.

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

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.

Provides the technical representation aligned with the guideline and protocol template

M11 Simple Example

Technical Specification

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",

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

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

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	

CDISC CT
Trial Phase Response (C66737)

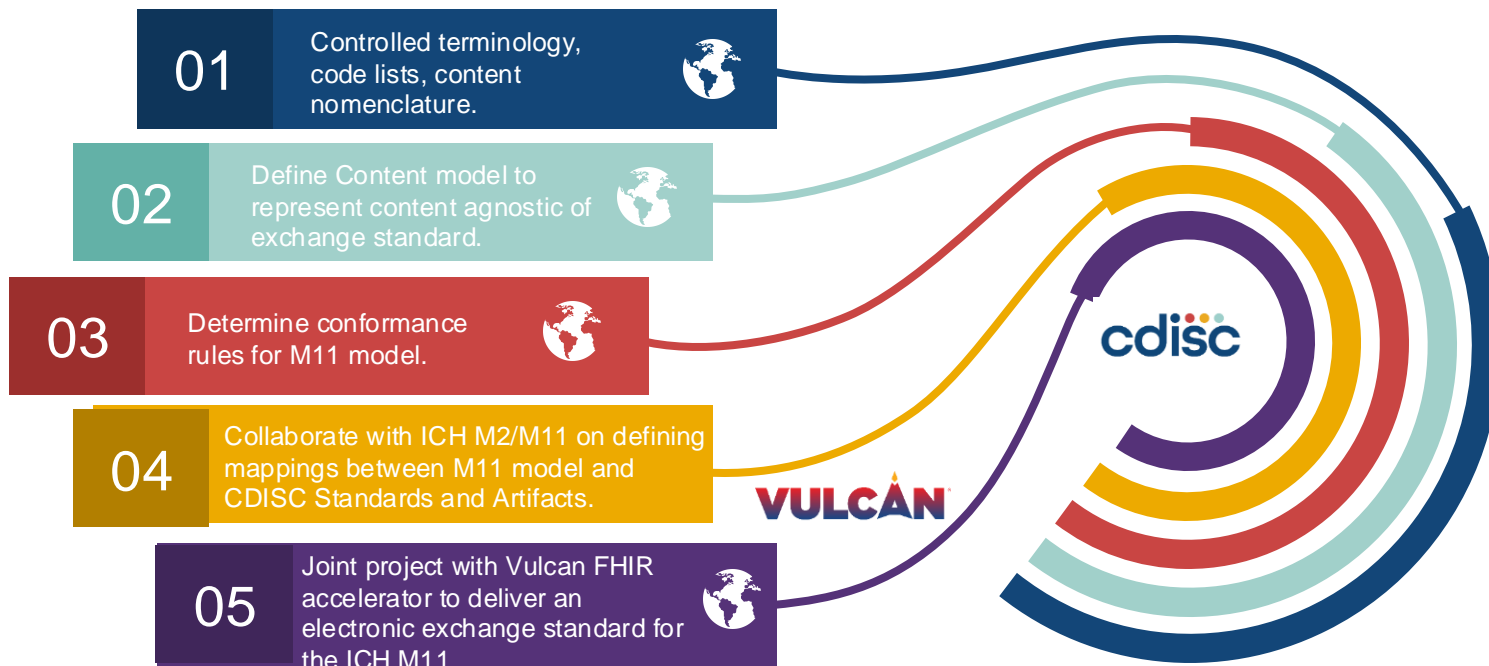
NOT APPLICABLE
PHASE 0 TRIAL
PHASE I TRIAL
PHASE I/II TRIAL
PHASE II TRIAL
PHASE II/III TRIAL
PHASE IIA TRIAL
PHASE IIB TRIAL
PHASE III TRIAL
PHASE IIIA TRIAL
PHASE IIIB TRIAL
PHASE IV TRIAL
PHASE V TRIAL

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 M2/M11 Engagement



ICH and CDISC MOU (Memorandum of Understanding)

As a collaboration between ICH and CDISC, the goals of the agreement are to:

- Use a unified governance process and terminology services for the long-term support of ICH controlled terminologies
- Curate and maintain ICH controlled terminologies
- Follow a robust process for the public review and publication of ICH terminologies
- Ensure the terminologies are freely available to the public following public review

Scope

For ICH members to adopt and implement a clinical information standard it is critical that all terminology components, including but not limited to definitions described in the technical specification, are part of a greater international controlled terminology resource managed by an internationally recognized standards development organization (SDO). CDISC has been identified by ICH as a reputable SDO with the qualifications and capabilities to support the maintenance and facilitation of the governance process for ICH controlled terminology.

This Memorandum of Understanding (MOU) sets forth the roles and responsibilities of each party as they relate to the governance of the ICH terms and definitions developed in collaboration with CDISC. This MOU is intended to describe the goals, the high-level governance process, and how each party will collaborate. Specific projects (e.g., M11 controlled terminology) will be defined in detail as part of an annex to this MOU mutually agreed upon by CDISC and ICH.

Goals

As a collaboration between ICH and CDISC, the goals of the agreement are to:

1. Use a unified governance process and terminology services for the long-term support of ICH controlled terminologies.
2. Curate and maintain ICH controlled terminologies.
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4. Ensure the terminologies are freely available to the public following public review.

The CDISC logo consists of the word "cdisc" in a bold, blue, lowercase sans-serif font. Above the letters "i", "d", and "c" are three small colored dots: a red dot above the "i", a yellow dot above the "d", and a green dot above the "c".The ICH logo features a stylized human figure icon on the left, composed of a blue head and a purple body with arms and legs. To the right of the icon, the letters "ICH" are written in a large, bold, black sans-serif font. Below "ICH", the tagline "harmonisation for better health" is written in a smaller, black, lowercase sans-serif font.The CDISC logo consists of the word "cdisc" in a bold, blue, lowercase sans-serif font. Above the letters "i", "d", and "c" are three small colored dots: a red dot above the "i", a yellow dot above the "d", and a green dot above the "c".



USDM, M11, and the HL7 UDP – how do they come together?

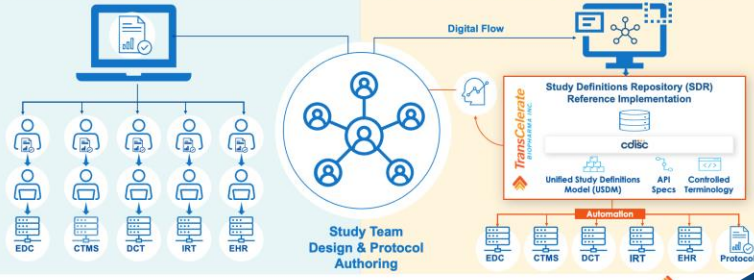
TransCelerate Digital Data Flow (DDF) Ambition

Write Once, Read Many

<https://www.transceleratebiopharm.com/assets/digital-data-flow-solutions/>

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



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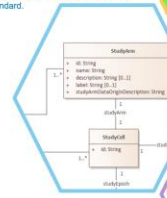
TransCelerate
EXPERIENCE THE DIFFERENCE



The USDM Standard

Logical Model

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



API Specification

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



API for DDF



Implementation Guide

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

cdisc

Unified Study Definitions Model Implementation Guide (USDM-IG) Version 2.0 (Draft for Internal Review)

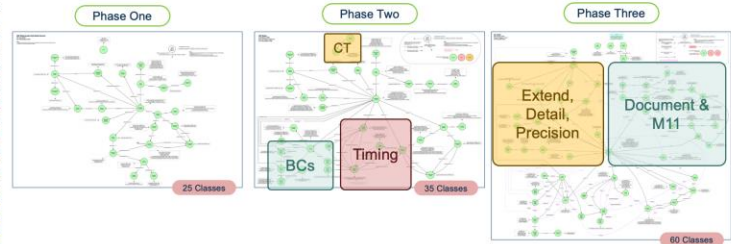
CDISC Controlled Terminology

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

Examples

Example protocols implemented in the USDM with associated USDM files and visualizations

CDISC DDF / USDM: Phases One, Two and Three



- Solid foundation
- The protocol document was an external entity into which the structured content could be exported
- Focused on the structured elements of the protocol, e.g. the Schedule of Activities (SOA) & BCs
- The protocol document still an external entity
- Now contains structured and unstructured elements
- The entire protocol document can be held within the USDM
- Allows for the protocol document to be generated from the model

Value of an Electronic ICH Protocol Template



- Value of an ICH Protocol Template
- Predictability
 - Format and Structure – Table of Contents
 - Core Content – common set of information
 - Allows Flexibility – recommended and optional text / sections
 - Common Instructions
 - Serves clinical trial stakeholders and “downstream” content re-use
 - Consistent with all other relevant ICH Guidelines, where possible
 - Acceptable in all ICH countries



- Protocol will be data-driven . . .
- **Tailored User Experience**
 - Task or role-based views of the content
 - Personal views – have the information served up the way you want it
 - **Collaboration**
 - Multi-sponsor development programs
 - Regulator to Regulator Reviews
 - **Downstream Automation**
 - Clinical Trial Registries
 - Data Capture
 - Statistical Analysis Plan
 - Clinical Study Report
 - Other Protocols
 - **Future**
 - Capability to compare / contrast trial designs across sponsor submissions
 - Perform “what / if” scenarios on trial design, arms, interventions, etc.

Page 14



Example Use Cases I



Authoring

Protocol authoring and sharing including the providing a **tailored user experience**.

Provide a solid foundation for study execution

A standard for protocol information re-use during and after study execution



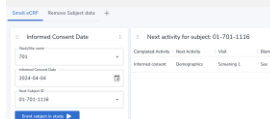
Regulatory

Automate or ease the process of providing protocols and protocol information to regulators and clinical trial registries



Data Capture

The use of detailed study design information to ease the configuration data capture systems



Insights

Use of protocol information to gain insights into past performance to improve future outputs and processes




Subject Impact

Use of protocol information to assess impact on subjects such as subject burden, time and risk

There are many use cases, these are just a few examples


Example Use Cases 2



SDTM T Domains



Use of protocol information to generate SDTM trial design domains

Can also read trial design domains to assist in rebuilding studies




SDTM Data

Use of the detailed study design information available within USDM to provide a solid foundation for the automated generation of SDTM data domains



aCRF



Use of the detailed study design to create an annotated Case Report Form for the study



<ODM>


Define.xml

Use of the detailed study design to create a define.xml for the study



Data Decay

Use of the detailed study design information available within USDM to provide a framework for ingesting old study data

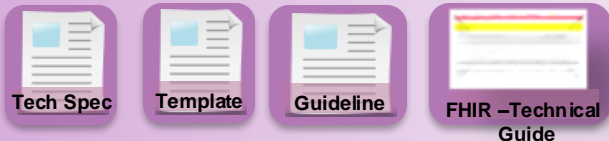


There are many use cases, these are just a few examples

ICH M11 and Vulcan Utilizing Digital Protocol (UDP)



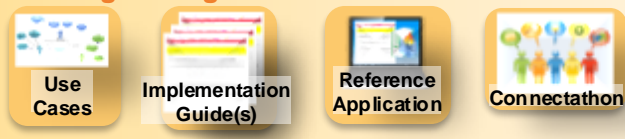
CeSHarP



USDM and Terminology



Utilizing the Digital Protocol – UDP



Inputs:

ICH M11 template

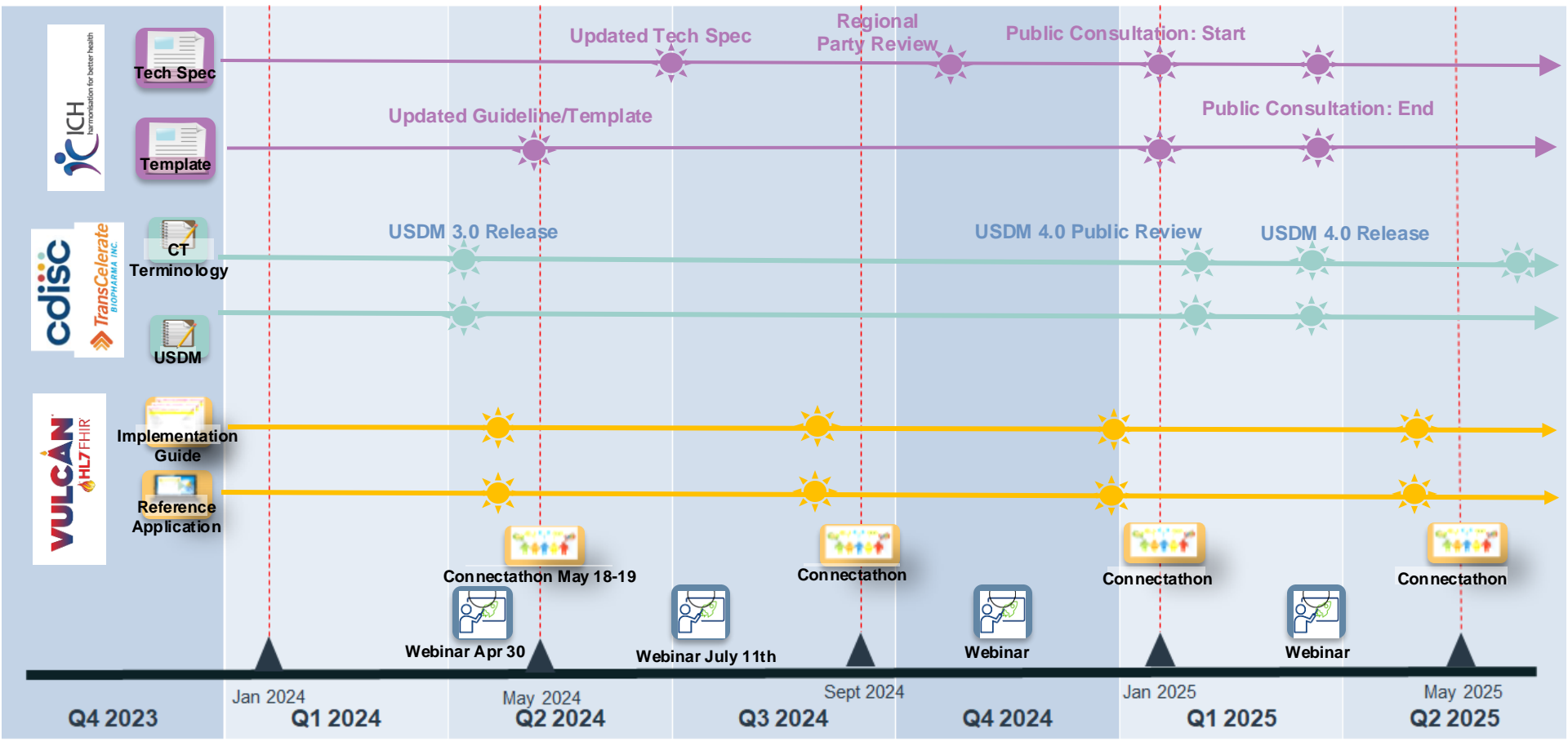
ICH M11 technical specification

Models, definitions

FHIR will carry CDISC CT and USDM content

The technical specification can be used to develop other Implementation Guides

Timelines



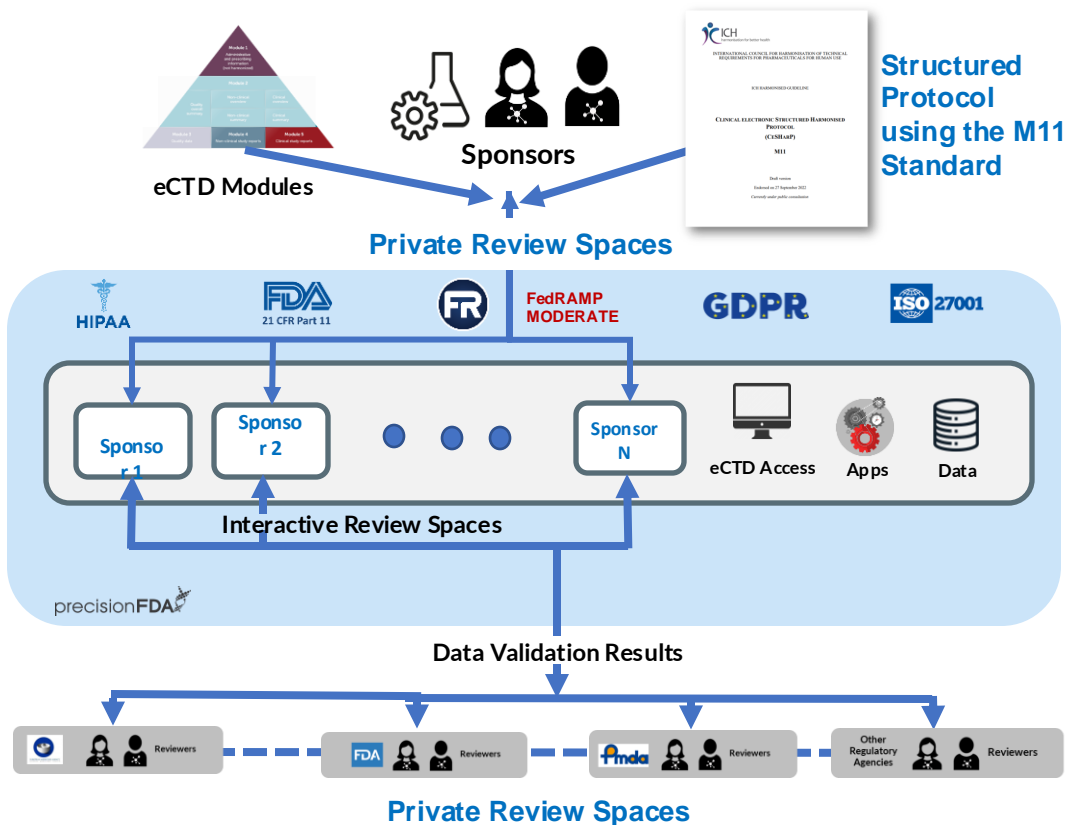
PROJECT PRISM



A Regulatory Cloud Collaborative Initiative

precisionFDA Regulatory Information Service Module
FDA-Industry Research Collaboration Agreement
(Public-Private Partnership)

Implementation of the M11 Protocol Standard for Interactive Activities in the Cloud

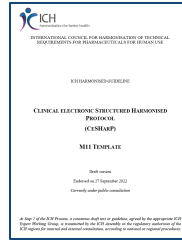


M11-conformed eProtocols...

- Use a common data model & standards (e.g., CDISC)
- Can be exchanged using multiple standards: FHIR, XML, MS Word, PDF
- Can use common tools to access data repositories
- Can be real-time quality-checked
- Ensure consistency across protocol sections
- Ensure line of sight of trial objectives, endpoints, procedures and design.
- Facilitate downstream processes, e.g., SAP, CSR, Registries

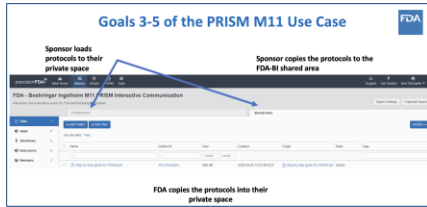
Status

ICH & M11 Specifications
USDM being kept aligned with the ICH M11 work via close communication and development of M11 CT



- ### Phase Four Focus
- 1 USDM Enhancements: Further CDMP Alignment, M11 amendments and versions, complex studies designs such as multiphase seamless design, additional trial registration mappings, and statistical estimands enhancements
 - 2 Continued alignment of USDM with ICH M11
 - 3 Participation in the Utilizing the Digital Protocol (UDP) project with TransCelerate, ICH and HL7 Vulcan
 - 4 Continue development of USDM Conformance Rules to support USDM v3.0 and v4.0
 - 5 Continue support and development of test data and test tools
 - 6 Development of training and education materials in conjunction with TransCelerate's Change and Engagement team to foster adoption of DDF

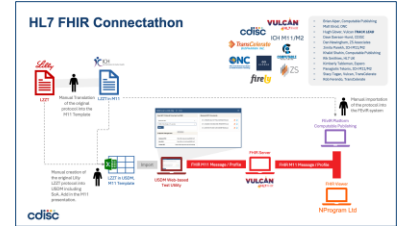
USDM Phase 4
Refine, improve, adopt



FDA & PRISM
Working with FDA to pilot first electronic transfer of an M11 protocol as well as tooling to support



HL7 Vulcan & UDP
Working with HL7 Vulcan to build FHIR message to support exchange of USDM / M11 content. Next connection is Atlanta, Sept 2024



EMA & CTIS
Working with EMA to align USDM with CTIS to facilitate work such as dashboards



ABSTRACT SUBMISSIONS ARE NOW OPEN!

Abstracts are due on July 19. Learn more about the submission process [here](#).

DDF VENDOR SHOWCASE
26 September

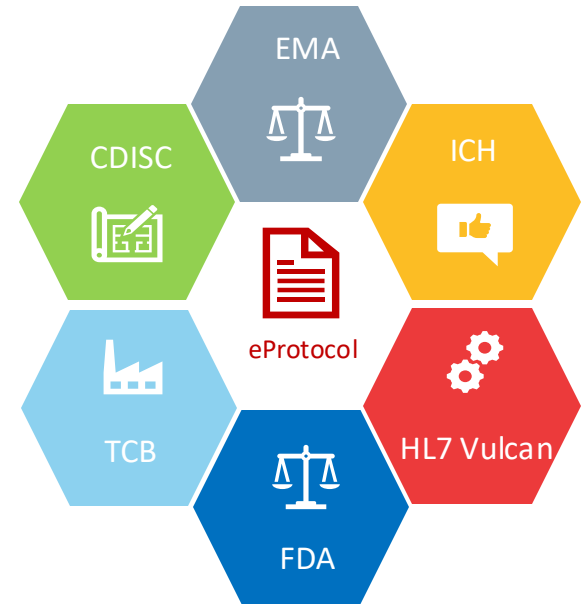
DDF IN ACTION DAY
10 October

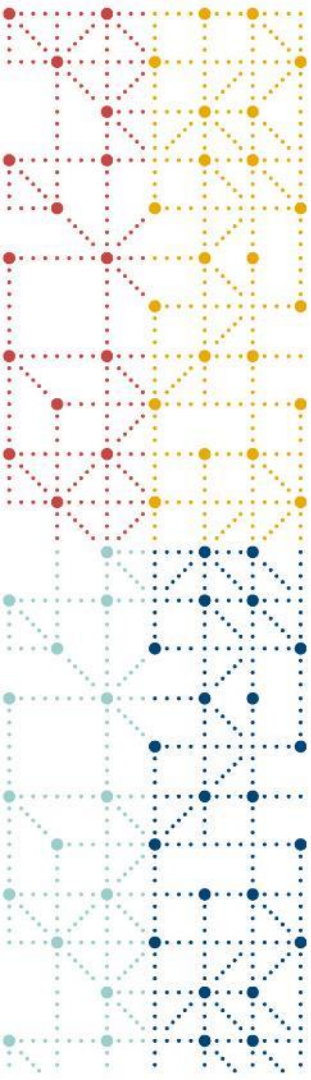
TransCelerate & Adoption
Several sponsors and vendors working with USDM. Latest adoption will be visible at the TransCelerate 'DDF in Action' day



Summary

- Digitalizing protocol is well underway
- This collaboration will accelerate the operationalization of the digital protocol
- Sponsors and vendors have started to pilot and implement





Thank You!

cdisc