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?

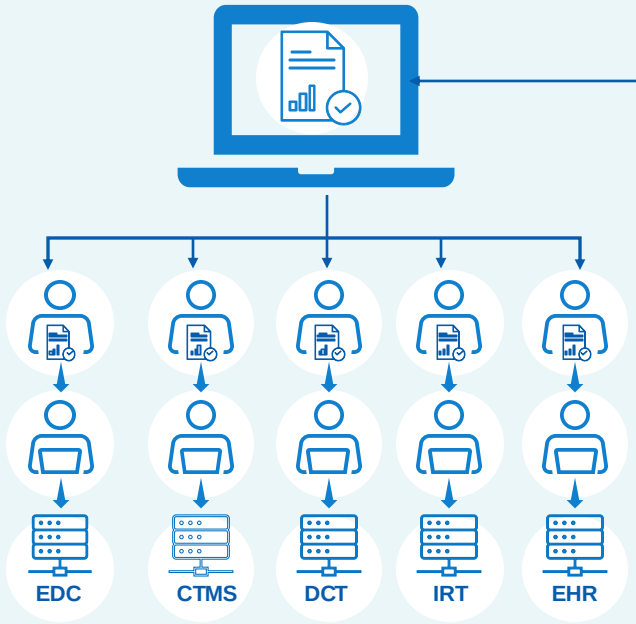
Introduction to the Digital Data Flow Project (DDF) and the Unified Study Definition Model (USDM)

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

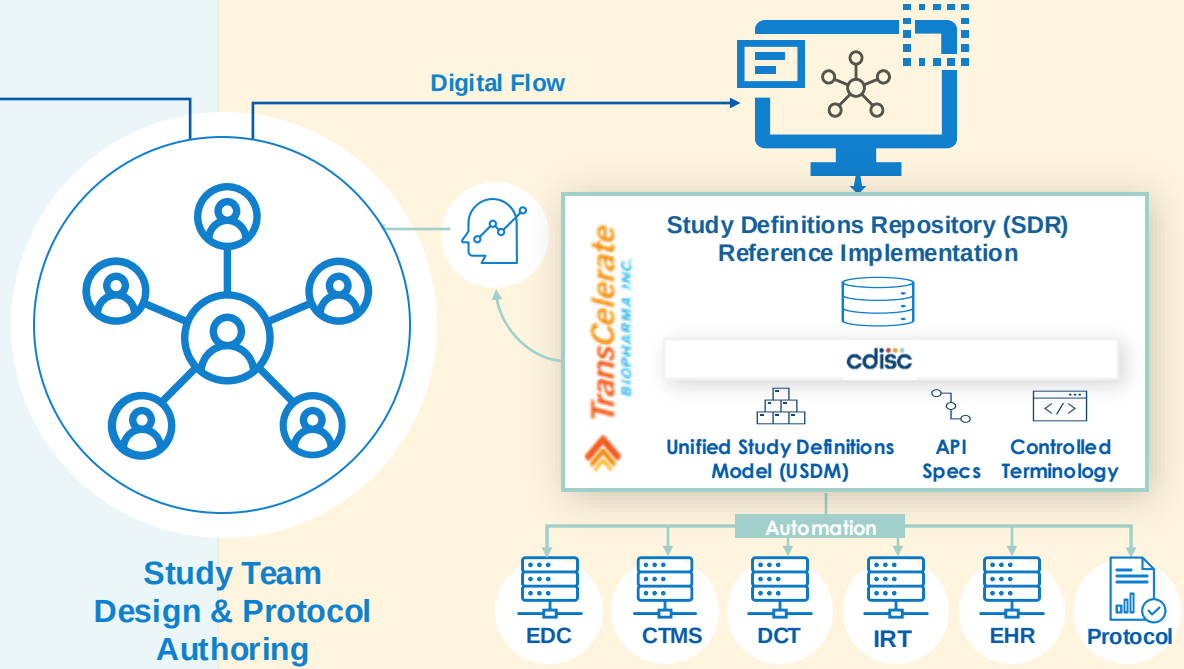
TransCelerate Digital Data Flow (DDF) Ambition

Write Once, Read Many

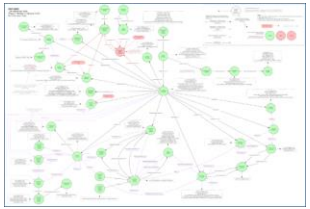
TODAY: Document-based paradigm for protocol creation, interpretation, and transcription into consuming systems



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)

Digital Data Flow Initiative

Suite of DDF Adoption Resources, Videos & Change Management Tools

Continued Industry Collaboration between TransCelerate, CDISC ICH, and HL7

VULCAN HL7 FHIR · cdisc · TransCelerate BIOPHARMA INC. · HL7 International · ICH harmonisation for better health

Growing Solution Collaboration Forum (SCF)*

trials.ai · ZS · InteliNotion · formedix · PHARMASEAL · nurocor · merative · TriNetX · Sycamore Informatics · castor · ORACLE · medidata · TRYAL · REDCAP CLOUD · indegene · Medable · saama · THREAD · Target Health · Taimei Technology

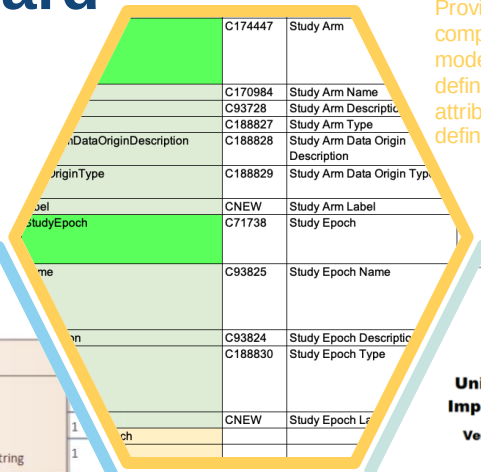
*Company logos illustrate current involvement and are not used to imply endorsement of specific vendors for DDF or to identify a comprehensive list of all actual or potential future participants in DDF.

TransCelerate BIOPHARMA INC.

The USDM Standard

CDISC Controlled Terminology

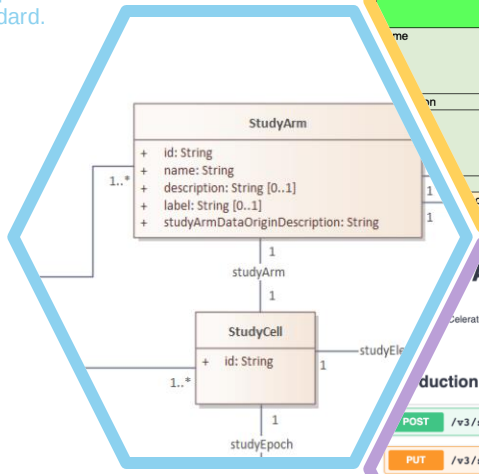
Provides further semantics, complementing the UML model. Includes the definition of classes and attributes along with the definition of value sets



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

Logical Model

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



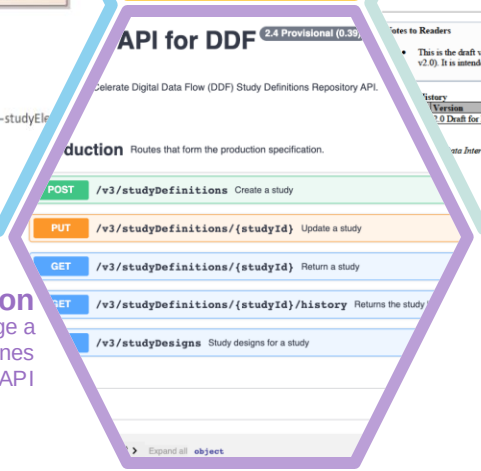
Examples

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

```
tudyArms": [
{
  "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-
```

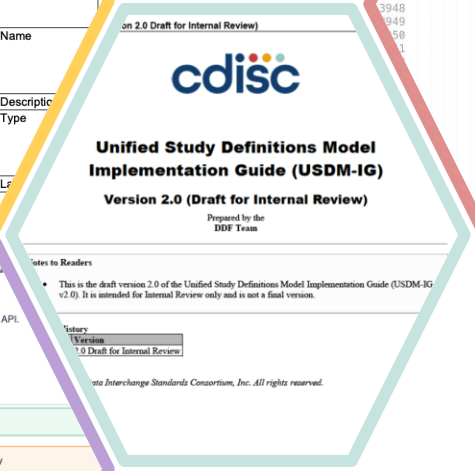
API Specification

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



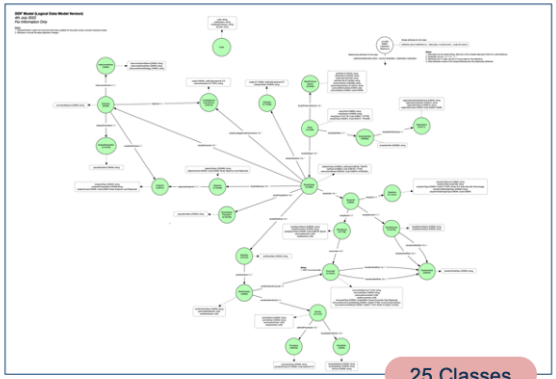
Implementation Guide

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



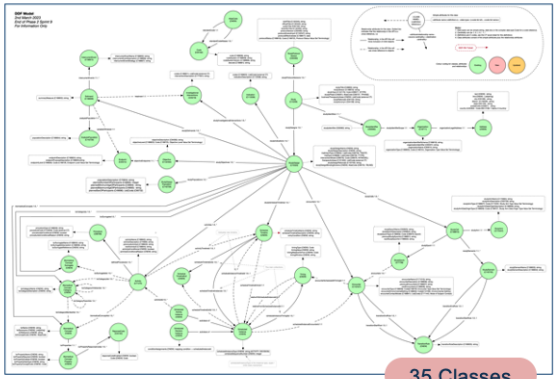
CDISC DDF / USDM: Phases One, Two and Three

Phase One



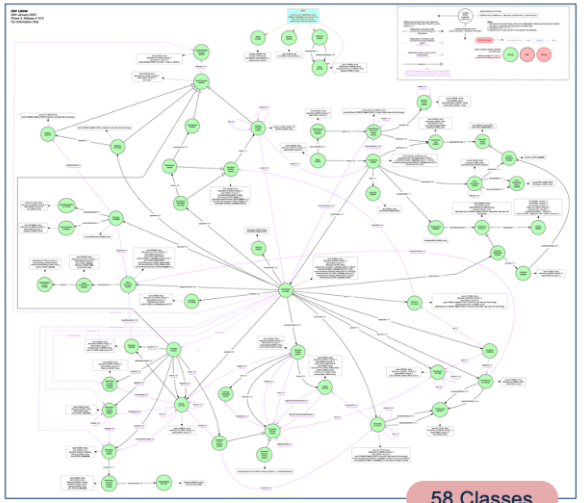
- Solid foundation
- The protocol document was an external entity into which the structured content could be exported

Phase Two



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

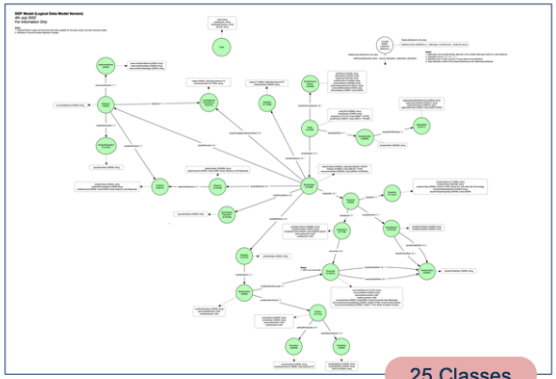
Phase Three



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

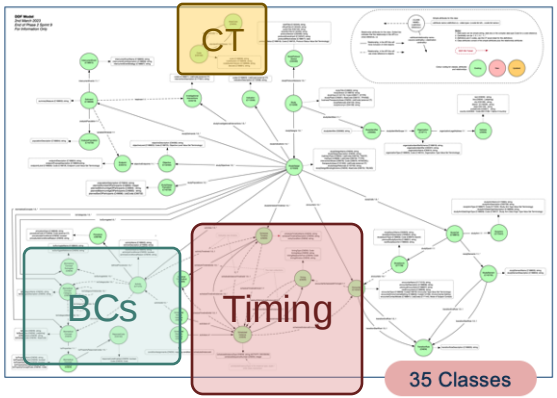
CDISC DDF / USDM: Phases One, Two and Three

Phase One



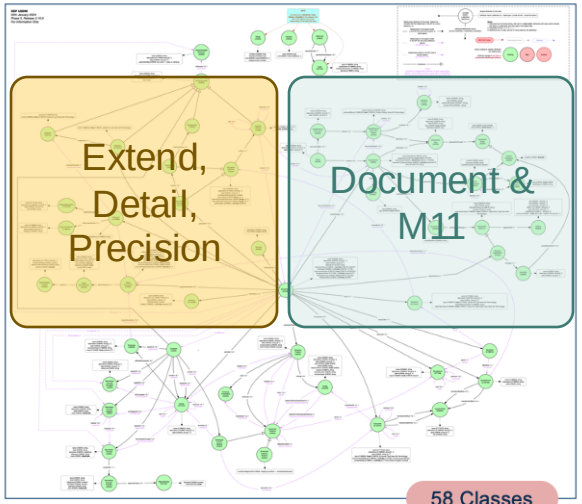
- Solid foundation
- The protocol document was an external entity into which the structured content could be exported

Phase Two



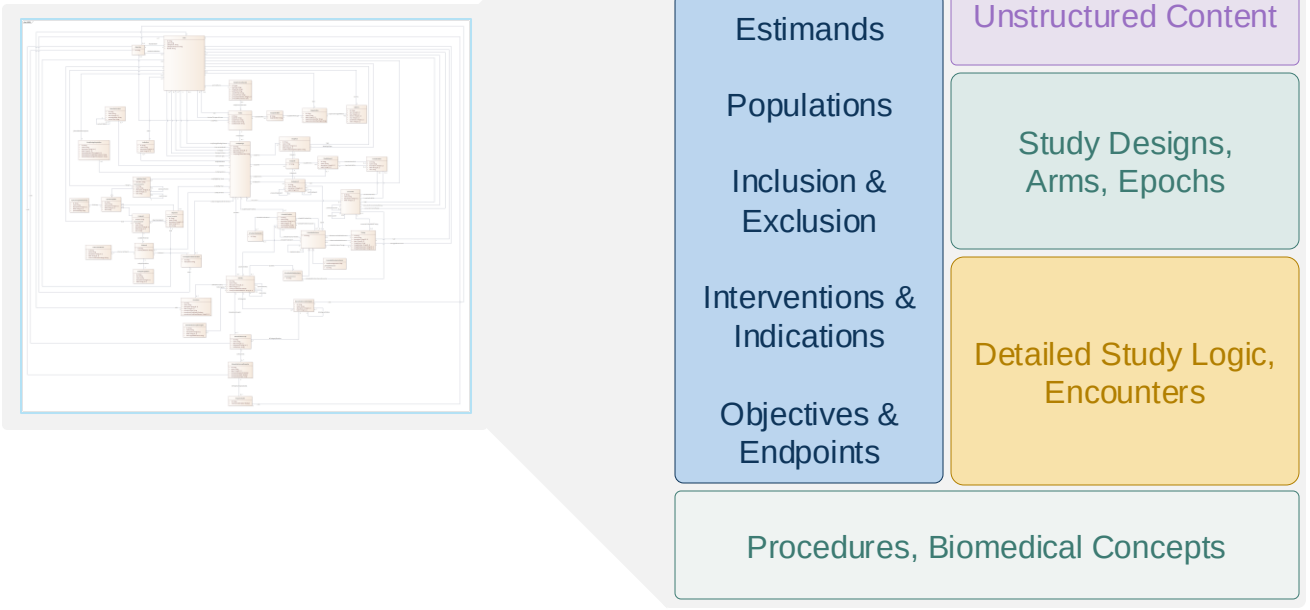
- Focused on the structured elements of the protocol, e.g. the Schedule of Activities (SoA) & Biomedical Concepts (BCs)
- The protocol document still an external entity

Phase Three



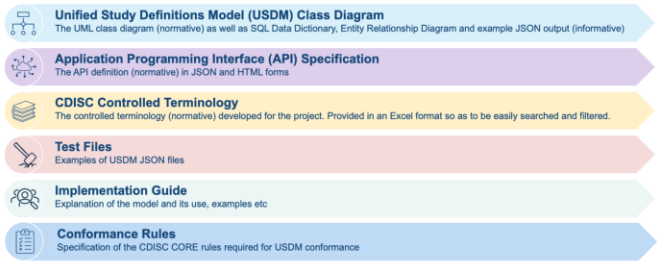
- Now contains structured and unstructured elements
- The entire protocol document can be held within the USDM
- Allows for the protocol document to be generated from the model

USDM Content

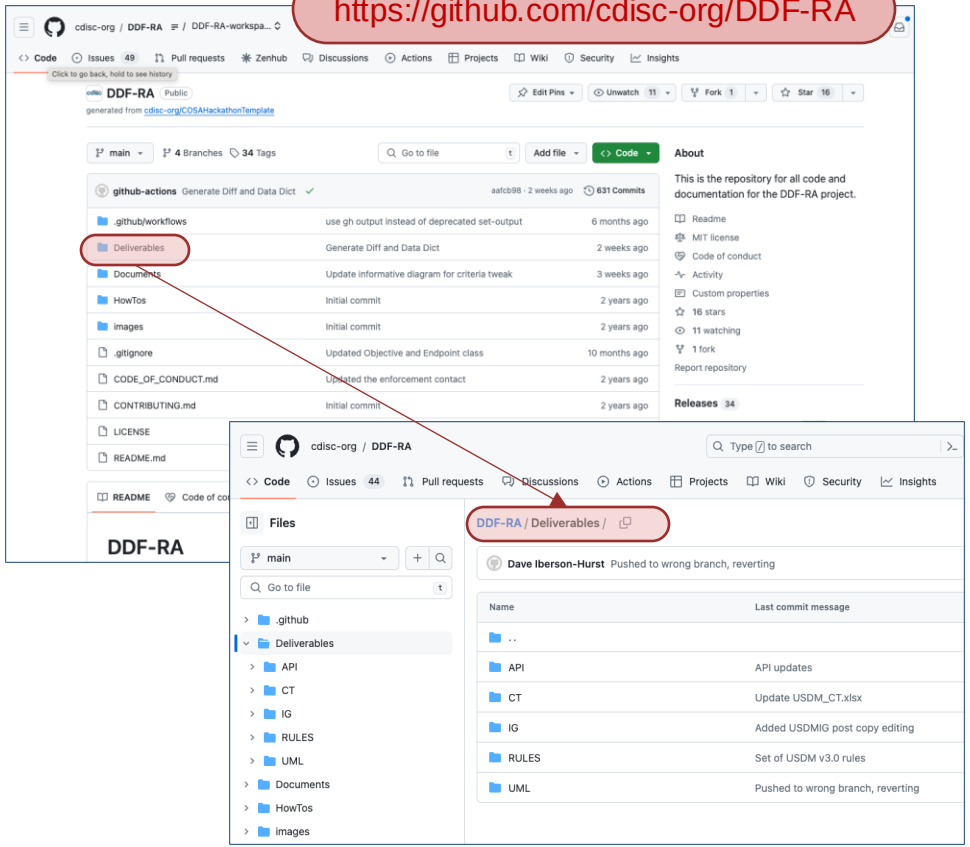


DDF Reference Architecture & Github

- The source of DDF Reference Architecture deliverables

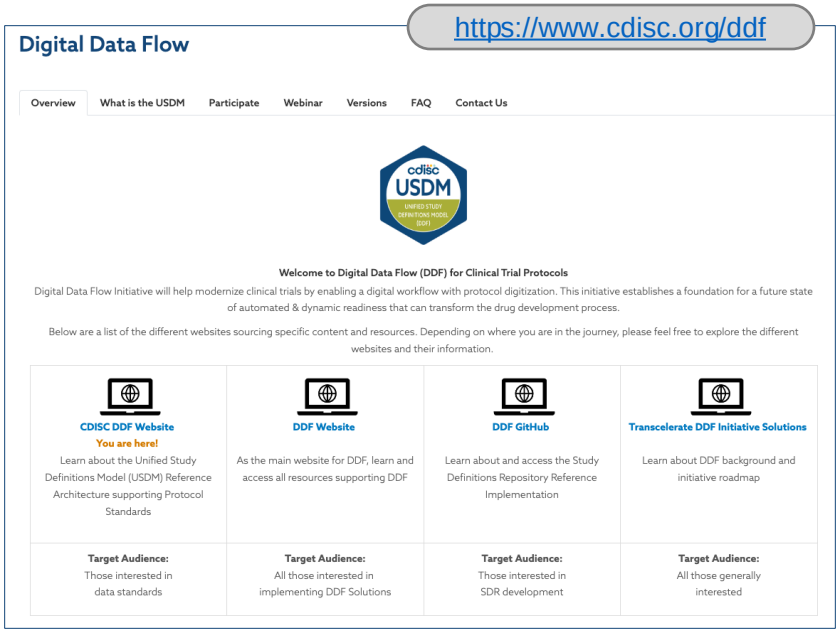


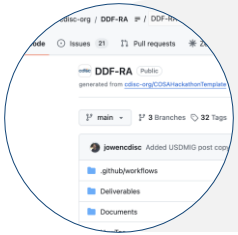
https://github.com/cdisc-org/DDF-RA



Example Resources – CDISC

https://www.cdisc.org/ddf





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.

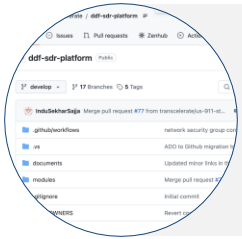
https://usdm-service.fly.dev/

Example Resources – TransCelerate

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

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/



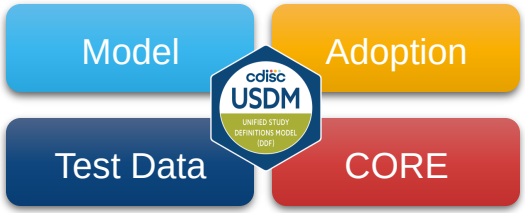
Github housing the source for the Study Definition Repository (SDR) Reference Implementation of the USDM

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

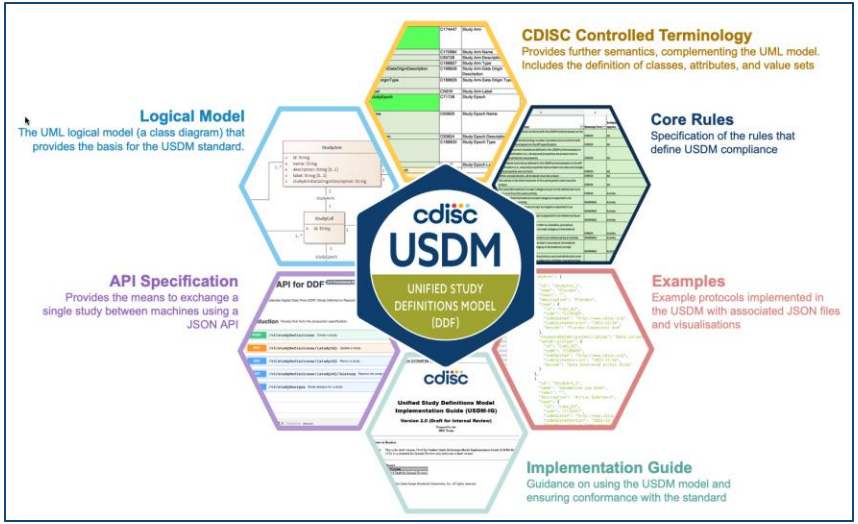
Phase 4 Overview

- 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

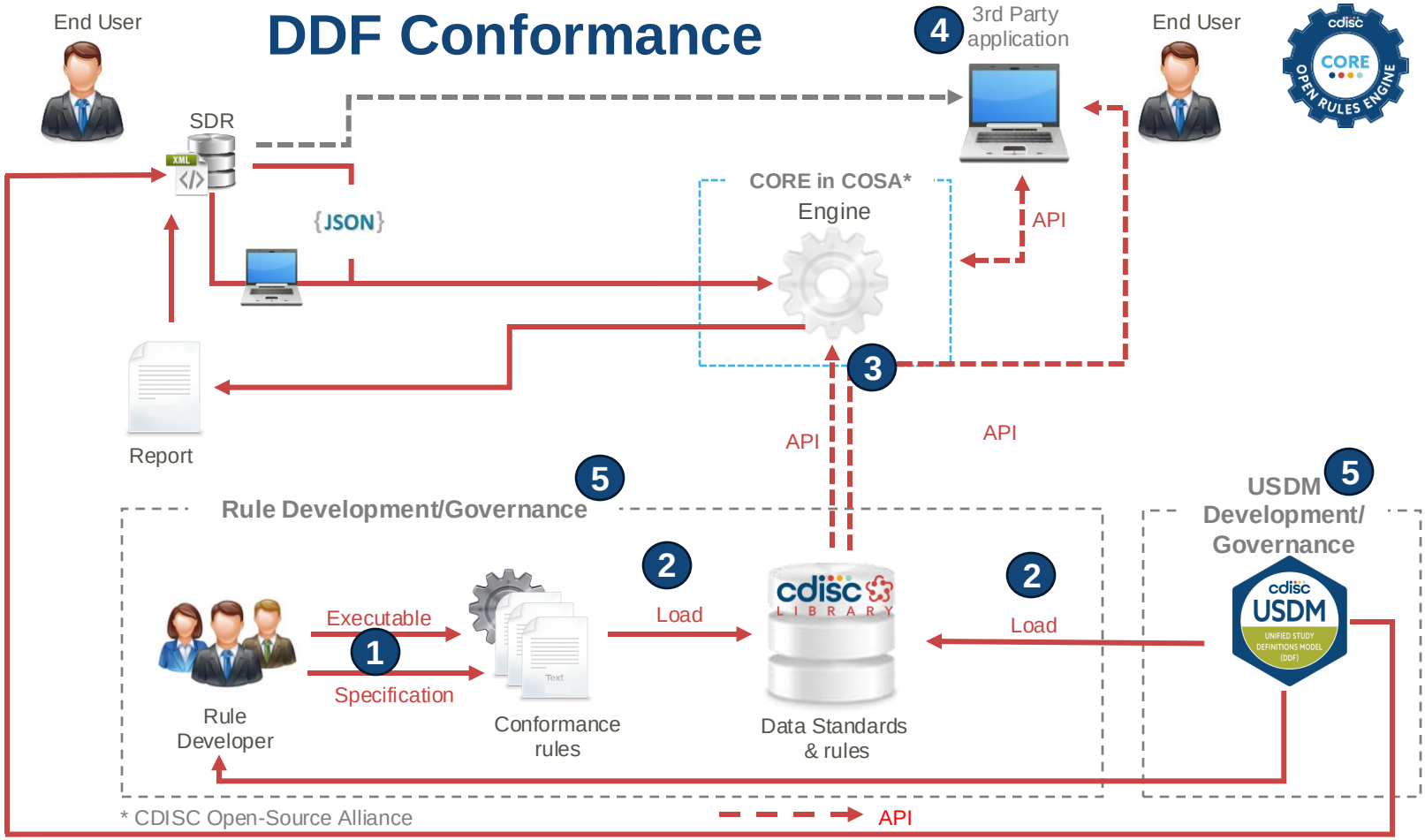


Phase Four Focus

1. USDM 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 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

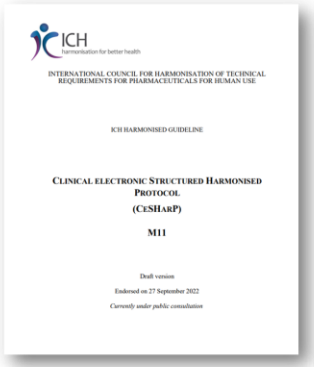


DDF Conformance



USDM generates various formats

Guideline & Template → Tech Spec


ICH harmonisation for better health

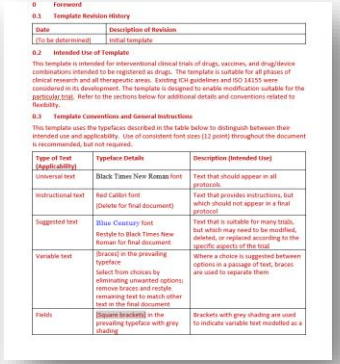
INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL
(CESHARP)

M11

Draft version
Endorsed on 27 September 2022
Currently under public consultation


0 Foreword

0.1 Template Revision History

Date	Description of Revision
(To be determined)	Initial template

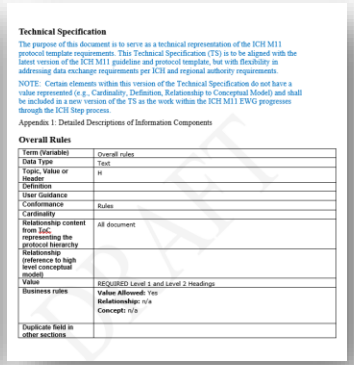
0.2 Intended Use of Template

This template is intended for interventional clinical trials of drugs, vaccines, and drug/device combinations intended to be registered as drugs. 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. The template is designed to enable modification suitable for the particular trial. Refer to the sections below for additional details and conventions related to flexibility.

0.3 Template Conventions and General Instructions

This template uses the typefaces 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 (Applicability)	Typeface Details	Description (Intended Use)
Universal text	Black Times New Roman font	Text that should appear in all protocols
Instructional text	Red Calibri font (Delete for final document)	Text that provides instructions, but which should not appear in a final protocol
Suggested text	Blue Century font Restyle 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 aspects of the trial
Variable text	[Braces] in the prevailing typeface Select from choices by eliminating unwanted options; remove braces and restyle remaining text to match other text in the final document	Where a choice is suggested between options in a passage of text, braces are used to separate them
Fields	[Square brackets] in the prevailing typeface with grey shading	Brackets with grey shading are used to indicate variable text modelled 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

Term (Variable)	Overall rules
Data Type	Text
Topic, Value or Header	H
Definition	
User Guidance	
Conformance	Rules
Cardinality	
Relationship content from ToC, representing the protocol hierarchy	All document
Relationship (reference to high level conceptual model)	
Value	REQUIRED Level 1 and Level 2 Headings
Business rules	**Value Allowed:** Yes **Relationship:** n/a **Concept:** n/a
Duplicate field in other sections	

DRAFT

Electronic Document
Human Readable Form

cdisc USDM
UNIFIED STUDY DEFINITIONS MODEL (DDF)

Machine-Readable Form

VULCAN HL7 FHIR

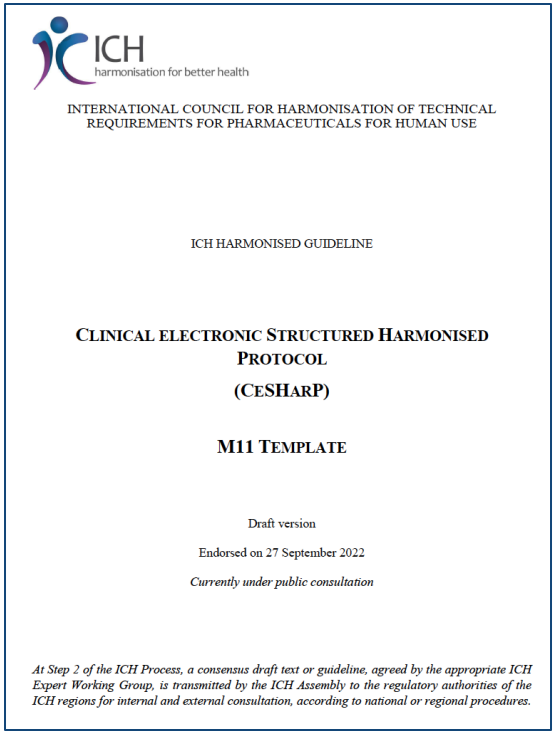
cdisc

Standard Message Exchange Formats

Overview of M11 and the ICH/CDISC Partnership

ICH CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHarP)

Founding Regulatory Members	Founding Industry Members	Standing Regulatory Members	Regulatory Members	Industry Members
• EC, Europe (EMA) • FDA, United States • PMDA, Japan	• EFPIA • JPMA • PhRMA	• Health Canada, Canada • Swissmedic, Switzerland	• ANVISA, Brazil • COFEPRIS, Mexico • EDA, Egypt • HSA, Singapore • MFDS, Republic of Korea • MHRA, UK • NMPA, China • SFDA, Saudi Arabia • TFDA, Chinese Taipei	• BIO • Global Self-Care Federation • IGBA



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

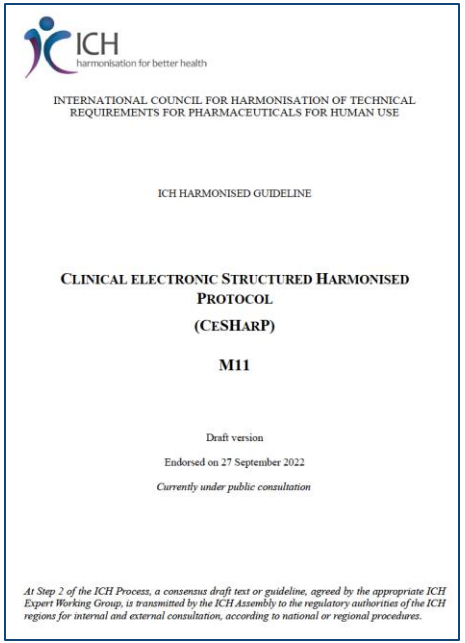
Currently under public consultation

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.

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

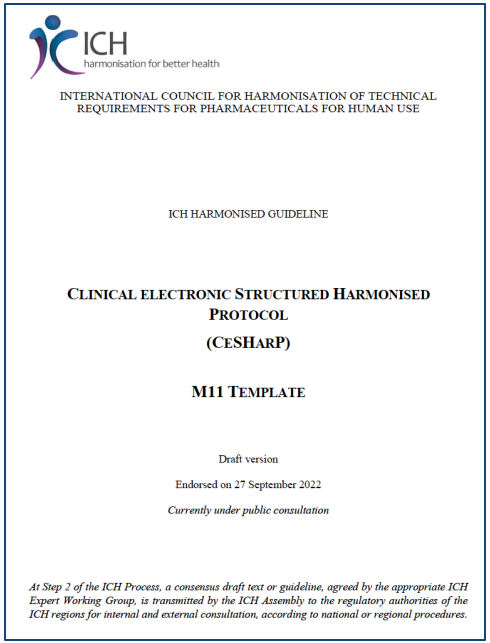
Draft version

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

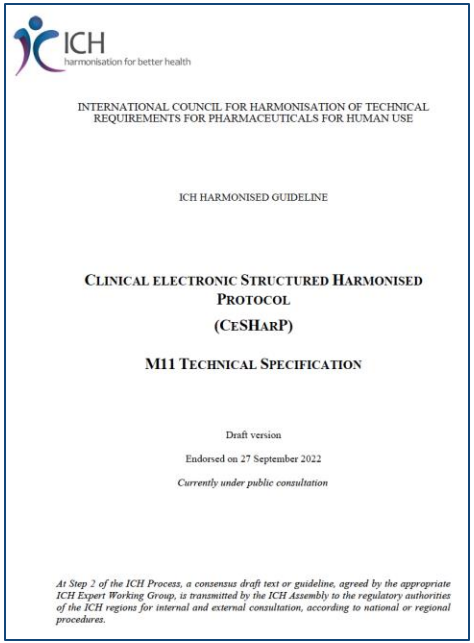
Draft version

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

cdisc

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

Template Specification

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

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

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

Technical Specification

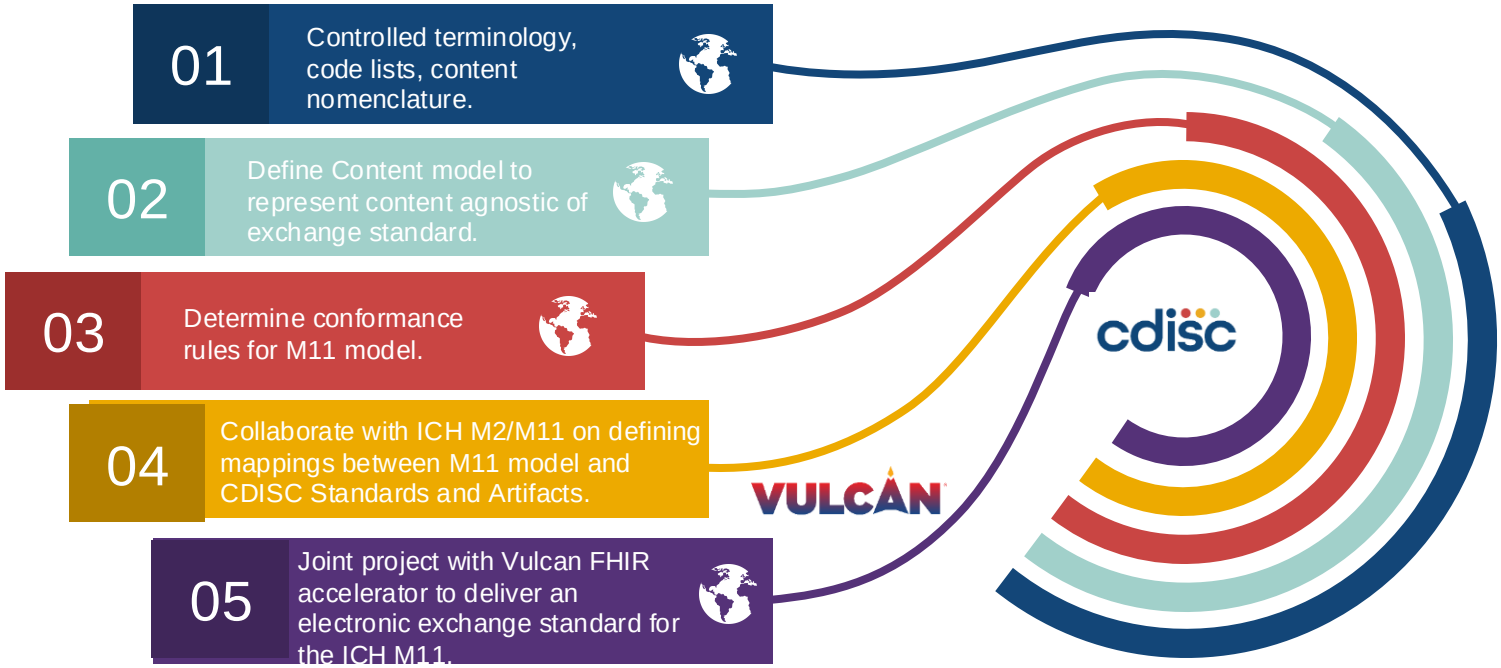
Term (Variable)	Trial Phase
Data Type	Pick list
Topic, Value or Header	D
Definition	
User Guidance	For trials combining investigational drugs or vaccines with devices, classify according to the phase of drug development.
Conformance	Required
Cardinality	
Relationship content from ToC representing the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

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

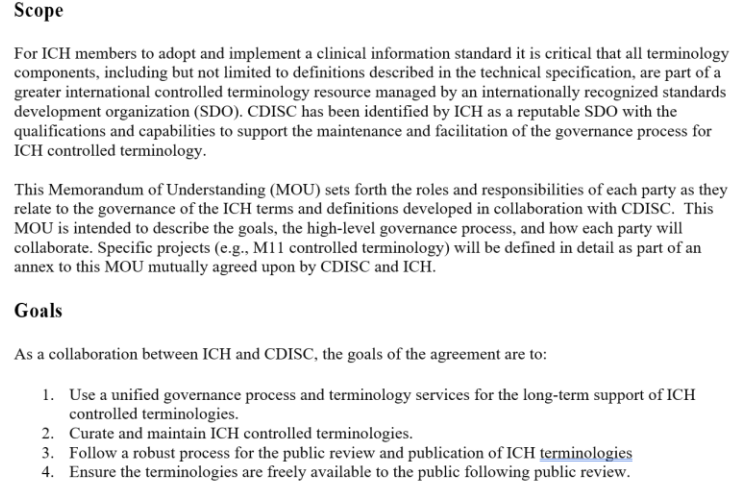
CDISC M2/M11 Engagement



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:

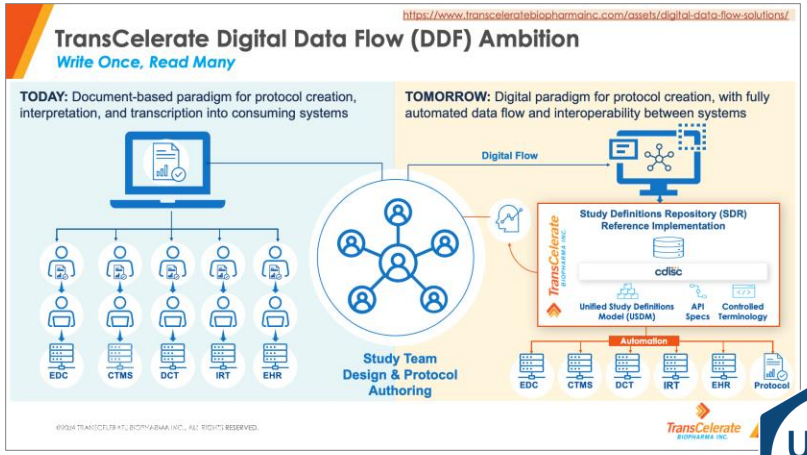
1. Use a unified governance process and terminology services for the long-term support of ICH controlled terminologies.
2. Curate and maintain ICH controlled terminologies.
3. Follow a robust process for the public review and publication of ICH terminologies
4. Ensure the terminologies are freely available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

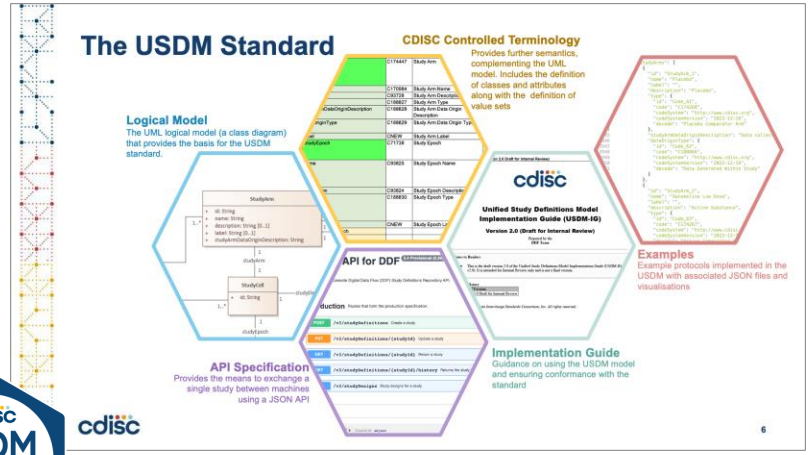
cdisc

ICH harmonisation for better health

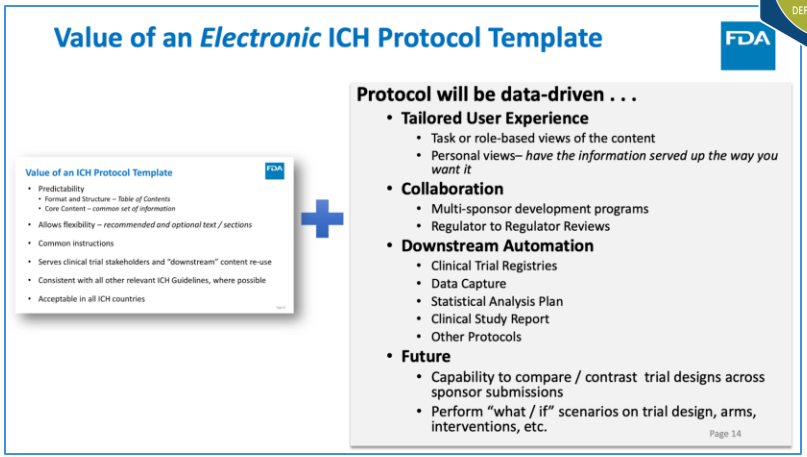
cdisc

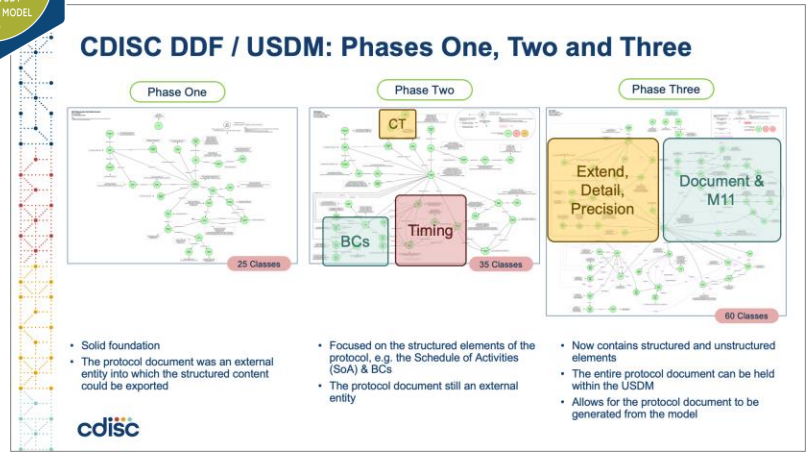
USDM, M11, and the HL7 UDP – how do they come together?





cdisc USDM
UNIFIED STUDY DEFINITIONS MODEL (DDF)





cdisc

Example Use Cases I

Authoring

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

Provide a solid foundation for study execution

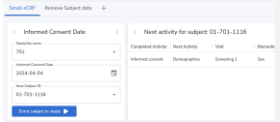
A standard for protocol information re-use during and after study execution

Regulatory

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

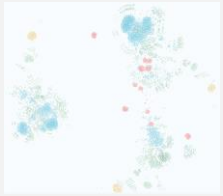
Data Capture

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

Define.xml

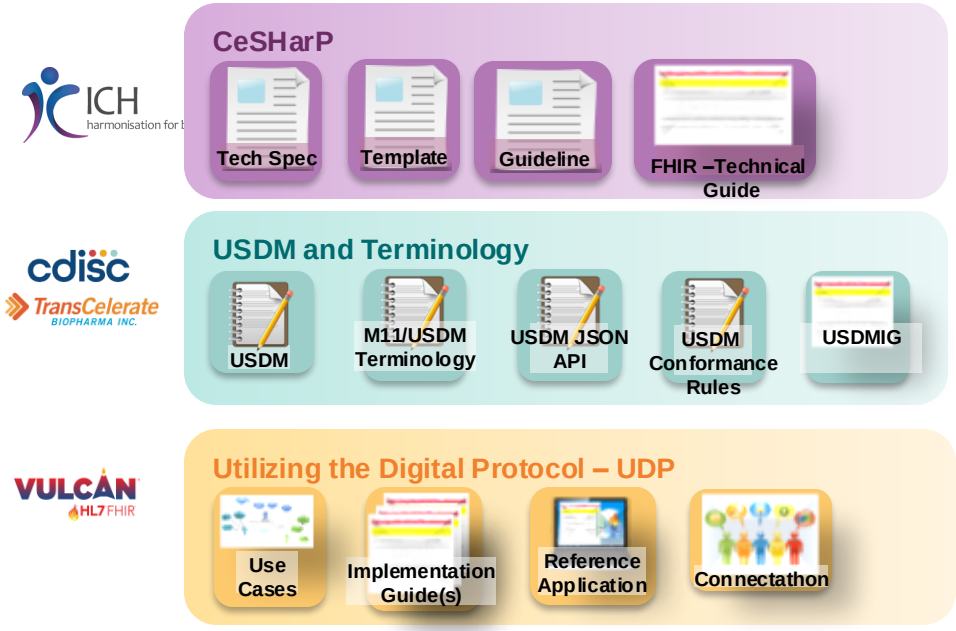
Use of the detailed study design to create a define.xml for the study

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)



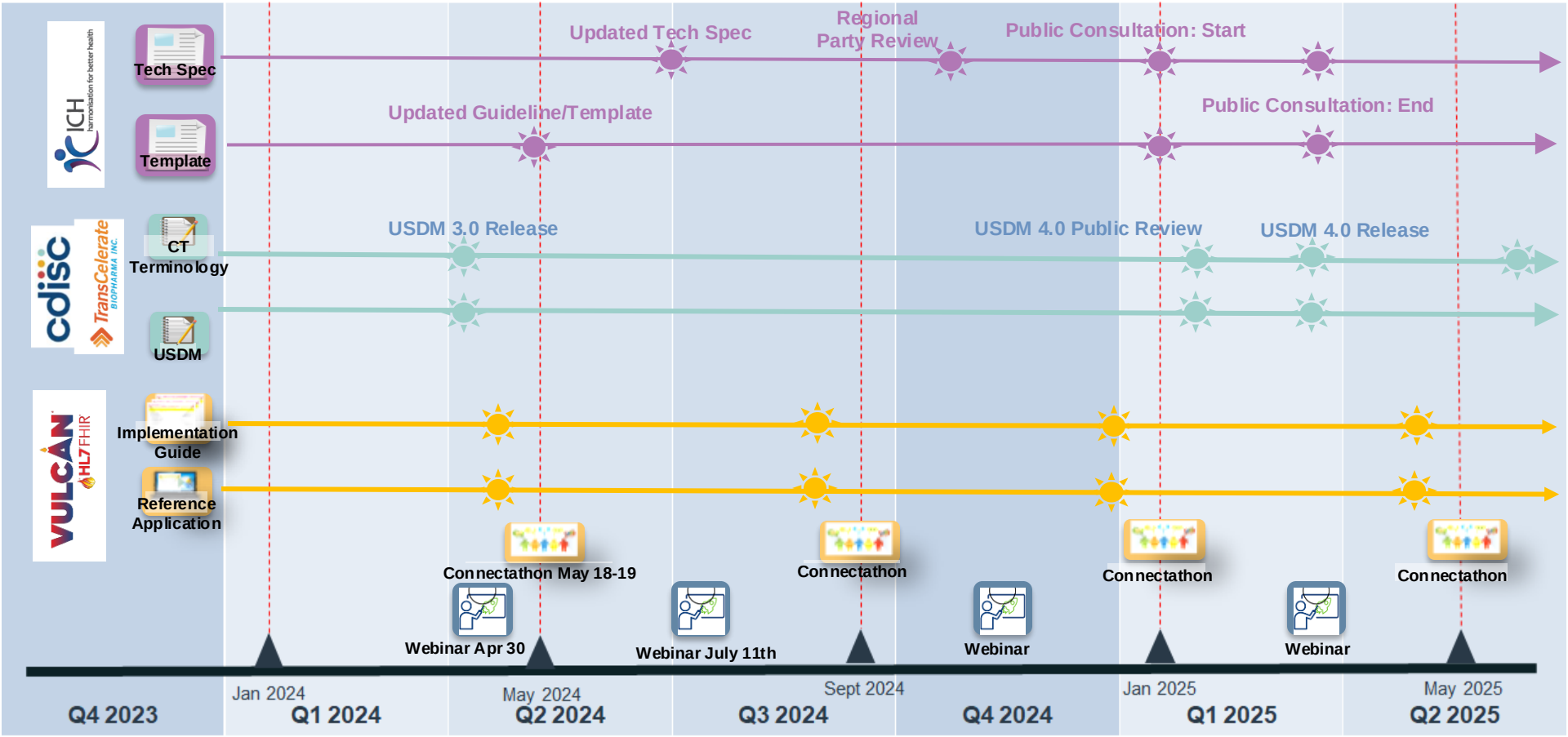
Inputs:

- 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


Tech Spec
Template
CT Terminology
USDM
Implementation Guide
Reference Application
Updated Tech Spec
Regional Party Review
Public Consultation: Start
Updated Guideline/Template
Public Consultation: End
USDM 3.0 Release
USDM 4.0 Public Review
USDM 4.0 Release
Connectathon May 18-19
Connectathon
Connectathon
Connectathon
Webinar Apr 30
Webinar July 11th
Webinar
Webinar
Jan 2024
May 2024
Sept 2024
Jan 2025
May 2025
Q4 2023
Q1 2024
Q2 2024
Q3 2024
Q4 2024
Q1 2025
Q2 2025

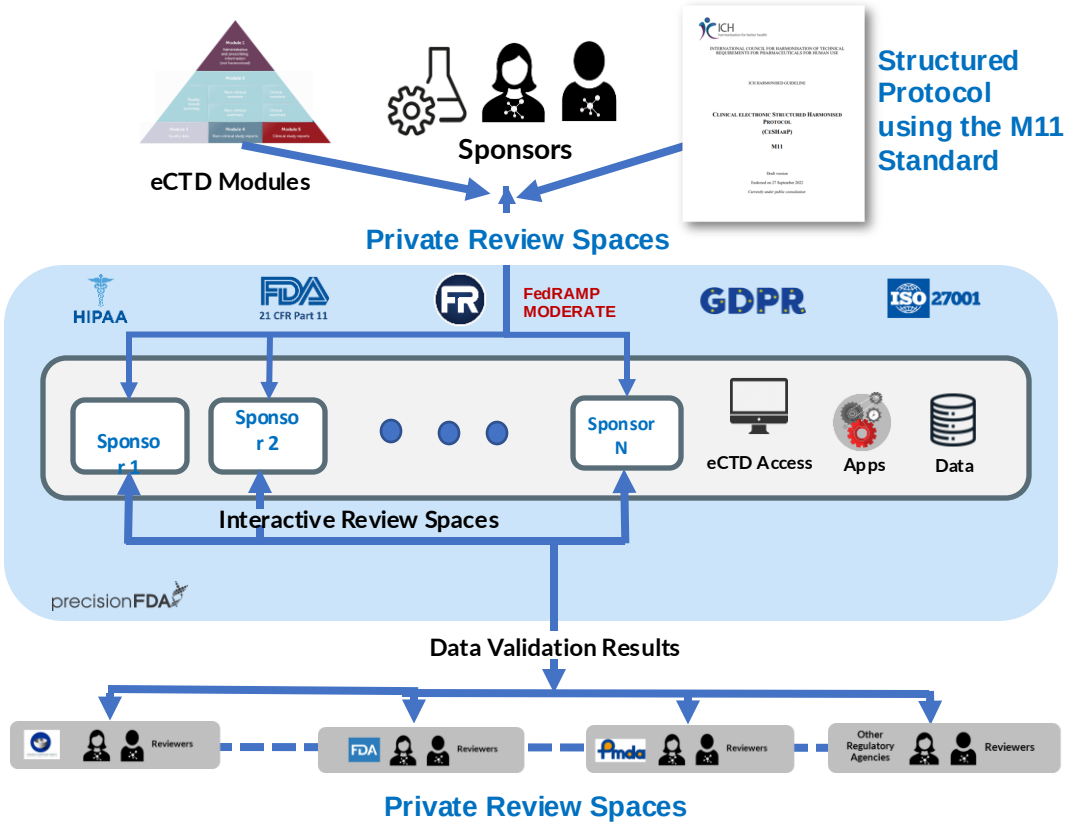
PROJECT PRISM

A Regulatory Cloud Collaborative Initiative

precisionFDA **R**egulatory **I**nformation **S**ervice **M**odule
FDA-Industry Research Collaboration Agreement
(Public-Private Partnership)

U.S. FOOD & DRUG ADMINISTRATION
DNAnexus
Boehringer Ingelheim
BAYER
EMD SERONO
Takeda
Bristol Myers Squibb™

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



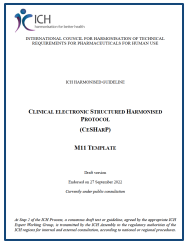
M11-conformed eProtocols…

- 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

Note: This is only an example, the regulatory agencies noted above does not imply their participation

Status

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


ICH

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

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CESHARP)

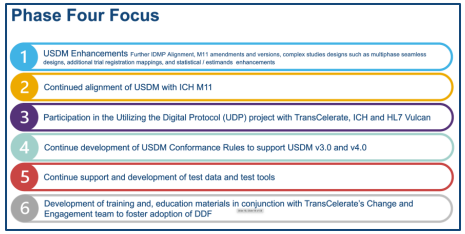
M11 TEMPLATE

Draft version

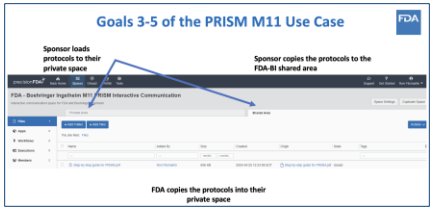
Endorsed on 27 September 2022

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.



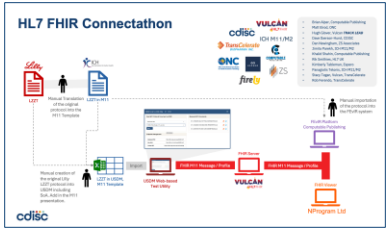
USDM Phase 4
Refine, improve, adopt



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

cdisc USDM
UNIFIED STUDY DEFINITIONS MODEL (DDF)

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



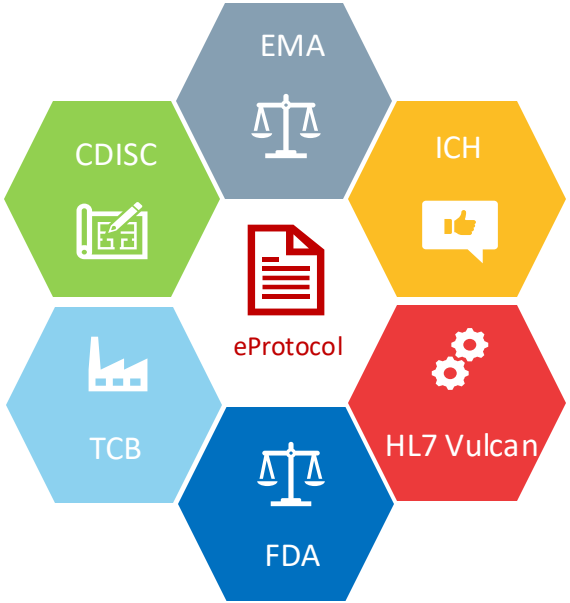
EMA & CTIS
Working with EMA to align USDM with CTIS to faciliate work such as dashboards

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

cdisc

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!