

# The TransCelerate / CDISC Digital Data Flow Project: Practical Electronic Study Designs

PHUSE EU Connect 2023 (DS02)

Dave Iberson-Hurst, CDISC Product Owner  
7<sup>th</sup> November 2023, Version 3





# Meet the Speaker

## Dave Ibersen-Hurst

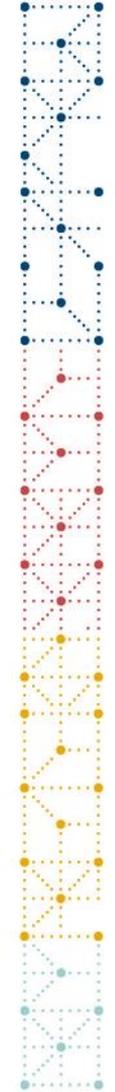
**Title:** Partner

**Organization:** d4k, Copenhagen

*Dave has over 40 years' experience across several industries with the last 20 years spent in the pharmaceutical industry combining his technology and software development experience with clinical data standards.*

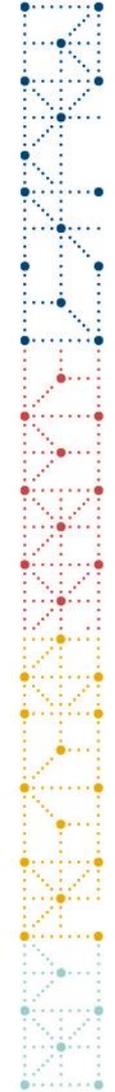
*During this time, he has served as the CDISC CTO, worked on, and led, several CDISC teams, presented in many forums in Europe, the US, and elsewhere across the globe. He has worked closely with the FDA, EMA, HL7, ISO, and other standards organizations and was was a member of CDISC's Blue Ribbon commission. He is currently the CDISC Product Owner for the Digital Data Flow project.*

*He is a partner at data4knoweldge in Copenhagen and is focused on getting greater value and utility from clinical trial data.*



# Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *On contract to CDISC for the DDF work*



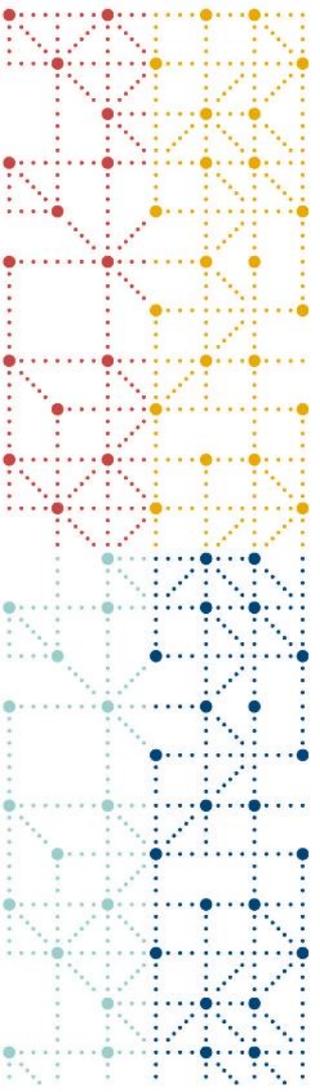
# Abstract

Over the last two years CDISC, in collaboration with Transcelerate, have been working on the Digital Data Flow (DDF) initiative. This initiative aims to “*modernize clinical trials by enabling a digital workflow to allow for the automated creation of study assets and configuration of study systems to support clinical trial execution.*”. The work is focused on the protocol and associated study designs and manifests itself in a new CDISC standard, the Unified Study Definitions Model (USDM), and an open-source implementation of the USDM known as the Study Definitions Repository (SDR).

Now coming to the end of the second phase, with the third phase about to commence, the DDF project delivers a new standard that allows for the digitization of study designs and the foundation of the digital protocol.

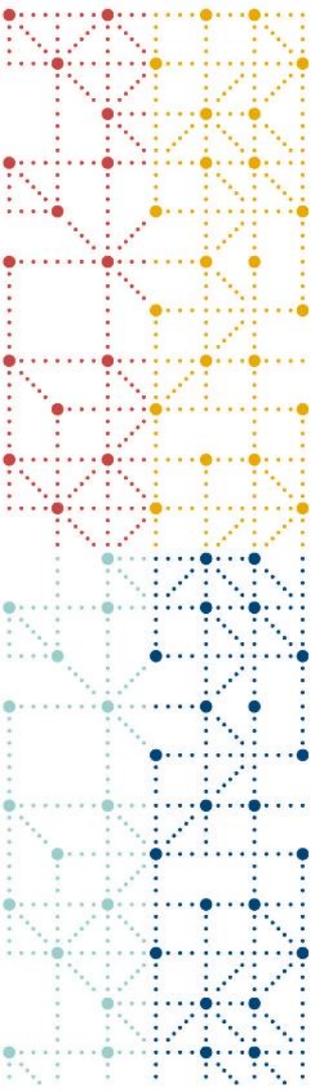
This presentation will detail:

- The work performed in phases one and two.
- The work planned as part of phase three.
- The use cases supported by the model.
- How the model/standard can enable protocol creation, automated data flow and interoperability between systems.
- How the model/standard can be deployed and implemented today.



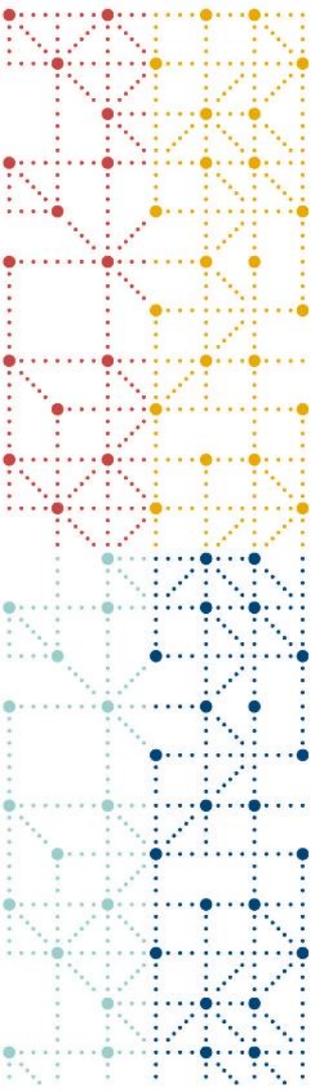
# Agenda

1. Introduction
2. Digital Data Flow – The Project
3. Use Cases
4. Phase Three: USDM Meets M11
5. Summary



# Introduction





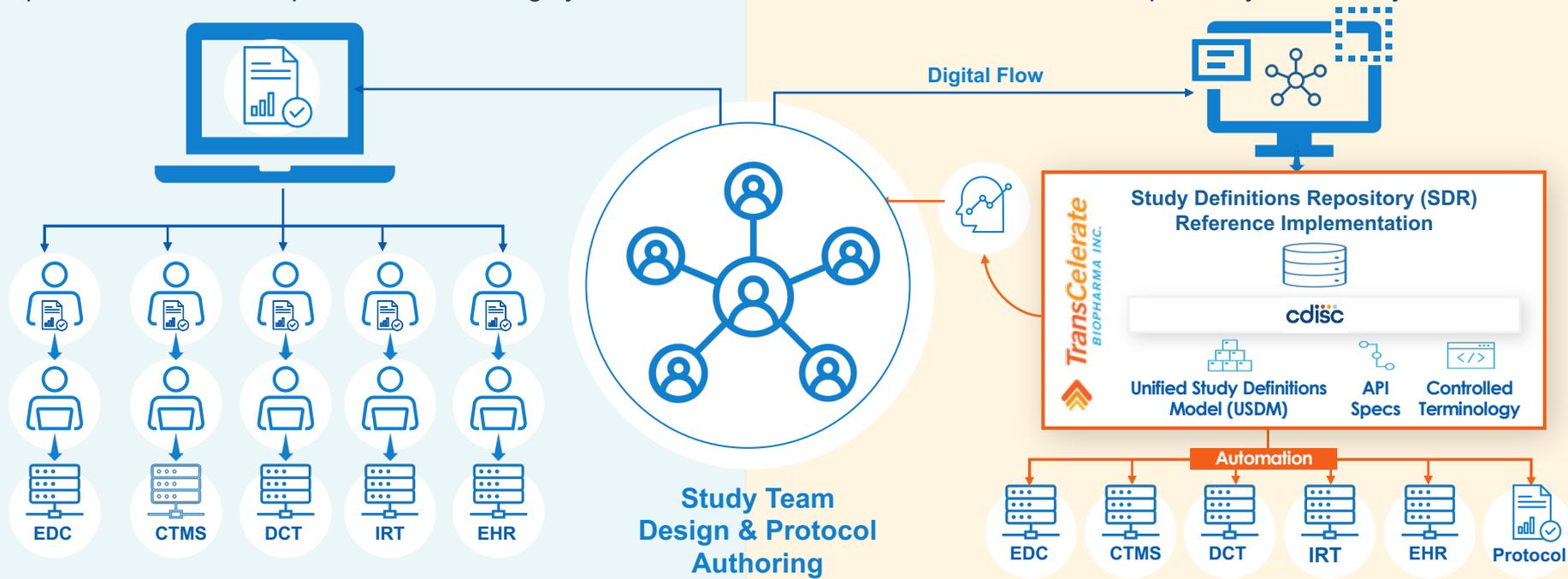
# Digital Data Flow - The Project

# 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



# CDISC DDF Deliverables



	PHASE ONE <i>July 2021 – July 2022</i>	PHASE TWO <i>Oct 2022 – June 2023</i>	PHASE THREE <i>July 2023– Apr 2024</i>
Unified Study Definitions Model (USDM)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Application Programming Interface (API) Specification	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
CDISC Controlled Terminology	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Reference Architecture Conformance Tests	<input checked="" type="checkbox"/>		<i>Replaced by CORE rules</i>
Essential Users Stories	<input checked="" type="checkbox"/>		
Architecture Principles	<input checked="" type="checkbox"/>	<i>Still applicable</i>	<i>Still applicable</i>
Test Files		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Implementation Guide		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

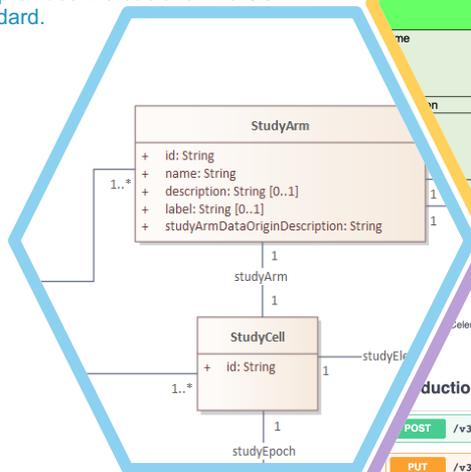
# The USDM Standard

## 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
DataOriginDescription	C188828	Study Arm Data Origin Description
OriginType	C188829	Study Arm Data Origin Type
Label	CNEW	Study Arm Label
StudyEpoch	C71738	Study Epoch
Name	C93825	Study Epoch Name
Description	C93824	Study Epoch Description
Type	C188830	Study Epoch Type
Label	CNEW	Study Epoch Label

### API for DDF 2.4 Provisional (0.39)

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

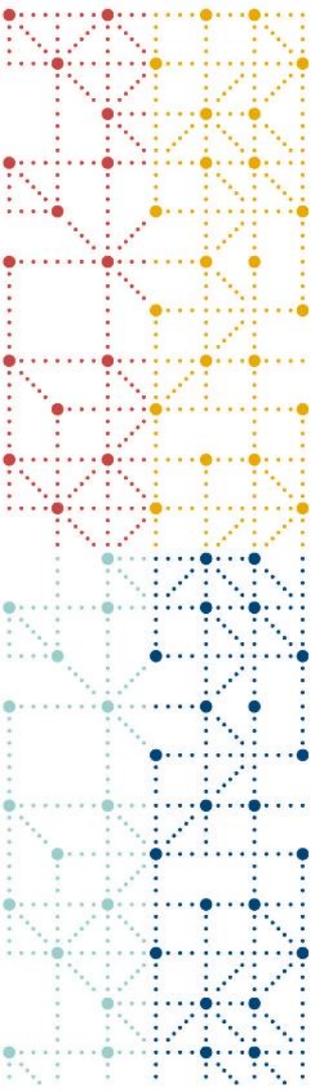
> Expand all object

```

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"
    }
  },
  {
    "id": "StudyArmDataOriginDescription": "Data collected within study",
    "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 Comparator"
    }
  }
]
    
```

**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



# Use Cases

# Use Cases: USDM with BCs allows for ...

Data Capture

Automate the setup of data capture systems, incl. RWE, and capture the data.

SoA

Use the study design to build the FHIR SoA message.

Data Import

Import data from a variety of sources. Can be re-exported thus allowing for conversion across versions.

Common Protocol Template (CPT)

Generation of the CPT from a study design.



Data Decay

Re-import data using the USDM as a framework to rebuild a study design & data using the SDTM Trial Design Domains.

Scoring

The "scoring" of a study for such purposes as site impact, subject impact, environmental impact etc.

Feasibility

The use of the design to determine study feasibility including subject recruitment. A study data template.

CT Registry

The provision of study information to a CT registry.

FAIR Data

The use of the design to aid Findability, Accessibility, Interoperability, and Reusability.

CTMS, TMF ...

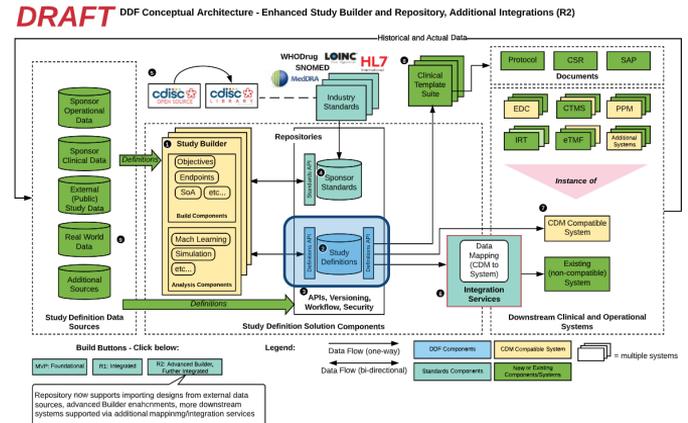
The provision of protocol information to downstream systems needing "study" information.

Query

Having multiple studies that have a common structure allows for data export and query across the set of studies.

SDTM

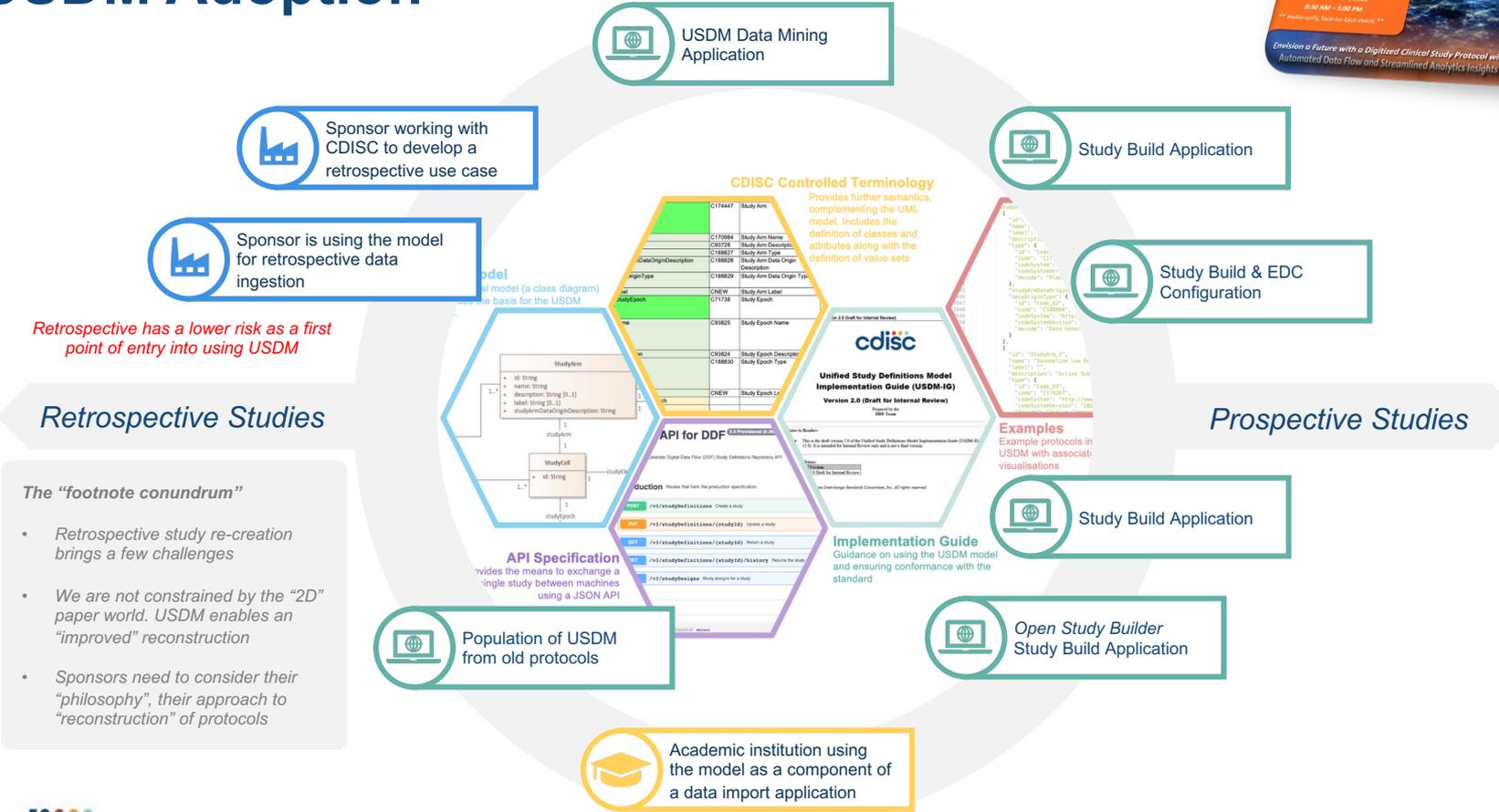
Automate the generation of SDTM datasets using the study design and BCs, including the "T" Domains.



Plus many more ...



# USDM Adoption



Sponsor working with CDISC to develop a retrospective use case

Sponsor is using the model for retrospective data ingestion

*Retrospective has a lower risk as a first point of entry into using USDM*

## Retrospective Studies

- The "footnote conundrum"**
- Retrospective study re-creation brings a few challenges
  - We are not constrained by the "2D" paper world. USDM enables an "improved" reconstruction
  - Sponsors need to consider their "philosophy", their approach to "reconstruction" of protocols

USDM Data Mining Application

Study Build Application

Study Build & EDC Configuration

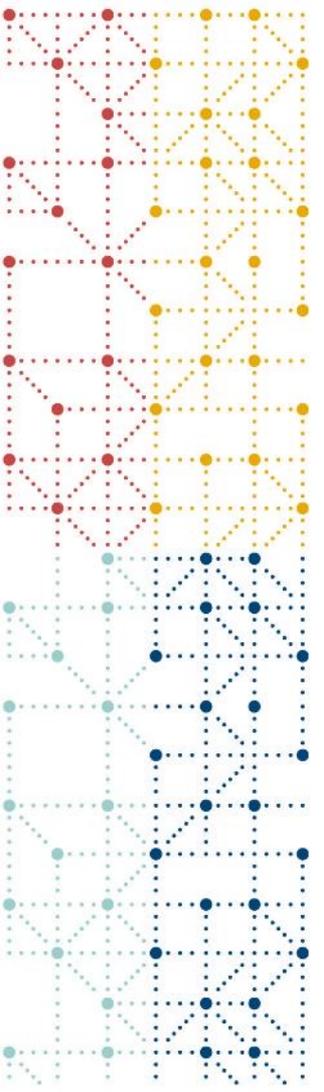
Study Build Application

Open Study Builder  
Study Build Application

Population of USDM from old protocols

Academic institution using the model as a component of a data import application





## Phase Three: USDM Meets M11

# Next Steps – Phase Three

Slide from May 2023

USDM

SDR

1

- Baseline model for specifying a study in digital format
- Model supports use of a CRF link to specify which forms to use in EDC
- Handles simple study designs

- Consume digitized study specification from an upstream source e.g., study builder)
- Store, view and search study concepts
- Downstream EDC systems may pull study specification to aid in set-up

2

- Improved support for complex study designs with a fully specified digitized Schedule of Activities (SoA)
- Model supports the identification of the appropriate CRFs for data collection to enable automated, faster configuration via use of Biomedical Concepts
- Improved CPT alignment
- Initial 'T' Domain support

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

3

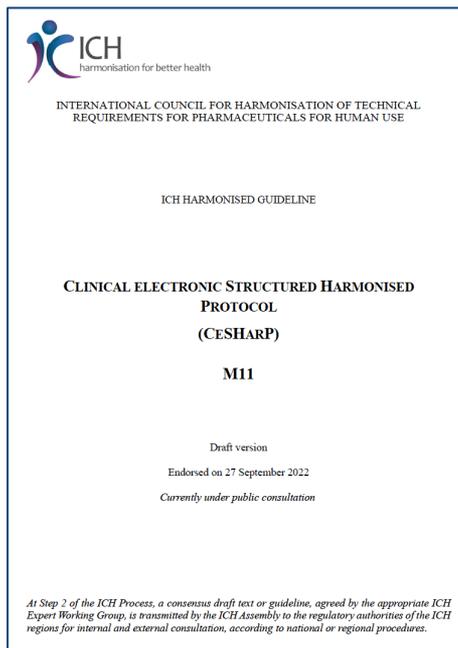
Focus for Phase 3 is currently being determined. Current expectations are:

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

# M11 Is ...

## ICH CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHarP)

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



ICH  
harmonisation for better health

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

ICH HARMONISED GUIDELINE

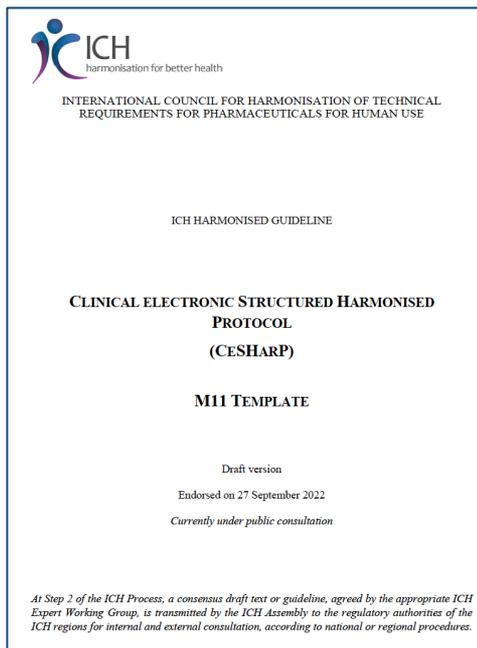
CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CESHARP)

M11

Draft version  
Endorsed on 27 September 2022  
Currently under public consultation

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

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

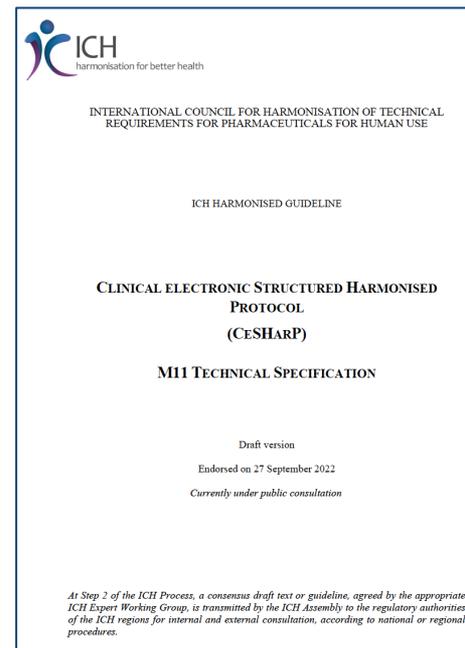
CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CESHARP)

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

<b>Protocol Full Title:</b>	[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.
<b>Sponsor Confidentiality Statement:</b>	[Sponsor Confidentiality Statement] Insert the Sponsor's confidentiality statement, if applicable, otherwise delete.
<b>Protocol Number:</b>	[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.
<b>Version:</b>	[Version] An optional field for use by the Sponsor at their discretion.
<b>Amendment Number:</b>	[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",

<b>Compound Number(s):</b>	[Compound Number] Enter the Sponsor's unique identifier for investigational compound(s) in the trial. Add or delete additional fields as needed.
<b>Compound Name(s):</b>	[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.
<b>Trial Phase:</b>	[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",

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

# Controlled Terms

Technical Specification

Template Specification

<b>Protocol Full Title:</b>	[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.
<b>Sponsor Confidentiality Statement:</b>	[Sponsor Confidentiality Statement] Insert the Sponsor's confidentiality statement, if applicable, otherwise delete.
<b>Protocol Number:</b>	[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.
<b>Version:</b>	[Version] An optional field for use by the Sponsor at their discretion.
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<b>Term (Variable)</b>	Trial Phase
<b>Data Type</b>	Pick list
<b>Topic, Value or Header</b>	D
<b>Definition</b>	
<b>User Guidance</b>	For trials combining investigational drugs or vaccines with devices, classify according to the phase of drug development.
<b>Conformance</b>	Required
<b>Cardinality</b>	
<b>Relationship content from ToC representing the protocol hierarchy</b>	Title Page
<b>Relationship (reference to high level conceptual model)</b>	
<b>Value</b>	Early Phase 1 Phase 1 Phase 1/Phase 2 Phase 2 Phase 2/Phase 3 Phase 3 Phase 4 Other
<b>Business rules</b>	<b>Value Allowed:</b> yes <b>Relationship:</b> n/a <b>Concept:</b> Protocol short title
<b>Duplicate field in other sections</b>	

**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",

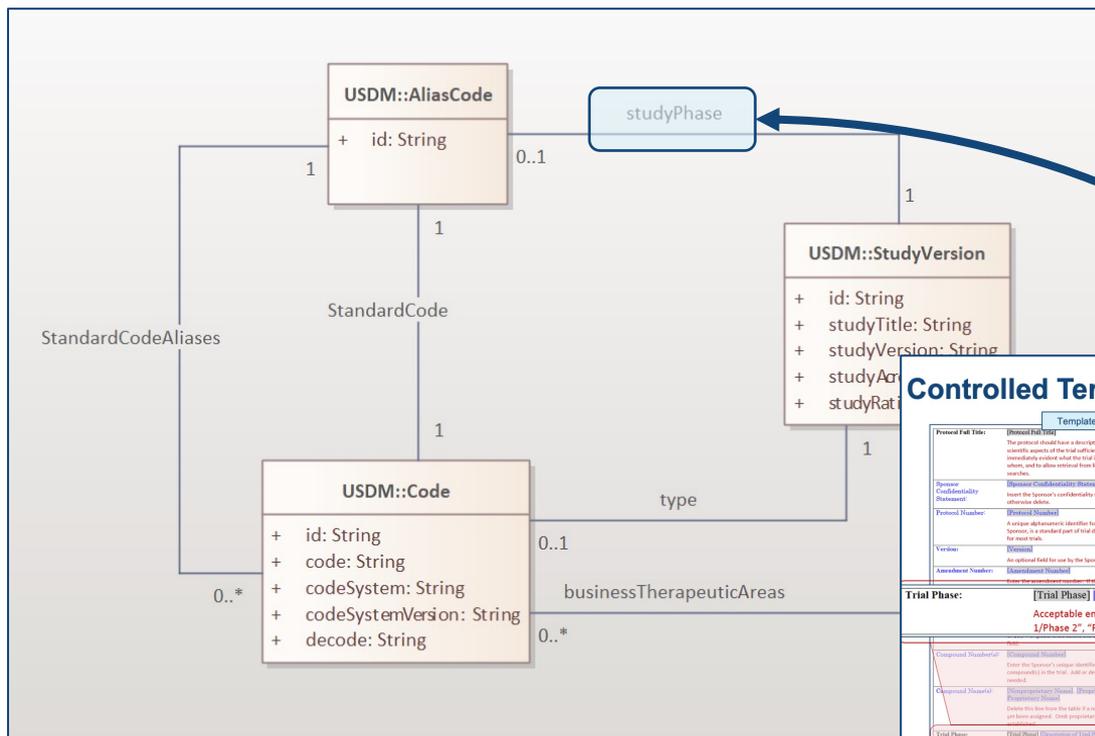
<b>Compound Number(s):</b>	[Compound Number] Enter the Sponsor's unique identifier for investigational compound(s) in the trial. Add or delete additional fields as needed.
<b>Compound Name(s):</b>	[Nonproprietary Name], [Proprietary Name], [Additional Proprietary Name] Delete this line from the table if a nonproprietary name has not yet been assigned. Omit proprietary name fields if not yet established.
<b>Trial Phase:</b>	[Trial Phase] [Description of Trial Phase Other] Acceptable entries are: "Early Phase 1", "Phase 1", "Phase 1/Phase 2", "Phase 2", "Phase 2/Phase 3", "Phase 3", "Phase 4",

CDISC CT

Trial Phase Response (C66737)

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

# Put Into Context ... the USDM



## Walkthrough

- A StudyVersion has a studyPhase
- Linked to the AliasCode class via the relationship studyPhase
- AliasCode can store:
  - a single standard code (CDISC Trial Phase Response, C66737) using the Code class
  - And zero or more other alias codes (e.g. a sponsor phase code) using the Code class to provide flexibility

## Controlled Terms

**Template Specification**

**General Full Title:** [Protocol Full Title]  
The protocol should have a descriptive title that identifies the scientific aspects of the trial sufficiently to ensure that it is readily identifiable to those who are investigating and on whom, and to those involved from literature or internet searches.

**Sponsor/Confidentiality Statement:** [Sponsor/Confidentiality Statement]  
Insert the sponsor's confidentiality statement, if applicable, otherwise delete.

**Formal Identifier:** [Formal Identifier]  
A unique alphanumeric identifier for the trial, designated by the sponsor. It 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]  
[See the amendment section of the CDISC Terminology Manual]

---

**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".

**Composed Number:** [Composed Number]  
Enter the sponsor's unique identifier for investigational compounds in the trial. Additional defined fields as needed.

**Conceptual Source:** [Conceptual Source]  
Identify the source from which a conceptual source has not yet been assigned. Check appropriate source fields if not applicable.

**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".

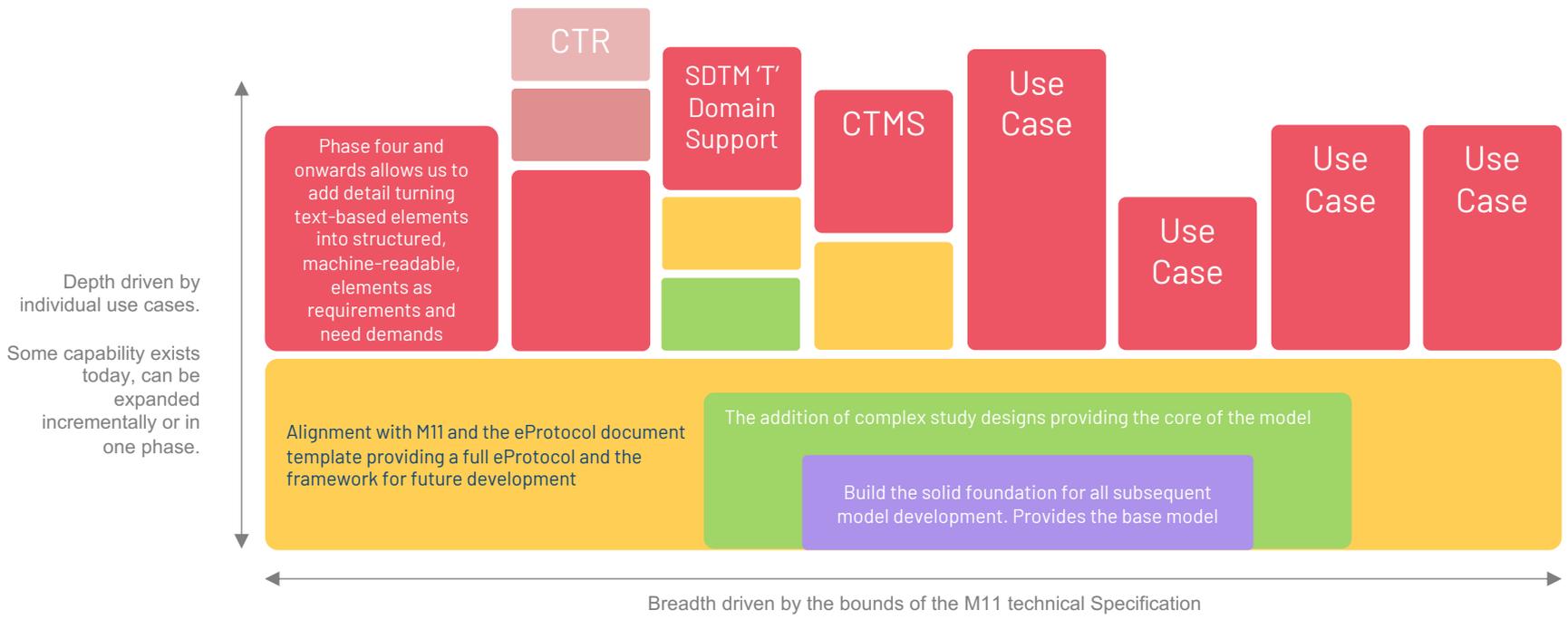
Term (Variable)	Trial Phase
<b>Data Type</b>	Pick list
<b>Topic, Value or Header</b>	D
<b>Definition</b>	
<b>User guidance</b>	For trials combining investigational drugs or vaccines with devices, classify according to the phase of drug development.
<b>Conformance</b>	Required
<b>Cardinality</b>	
<b>Relationship content from ToC representing the protocol hierarchy</b>	Title Page
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<b>Duplicate field in other sections</b>	

**CDISC CT**

**Trial Phase Response (C66737)**

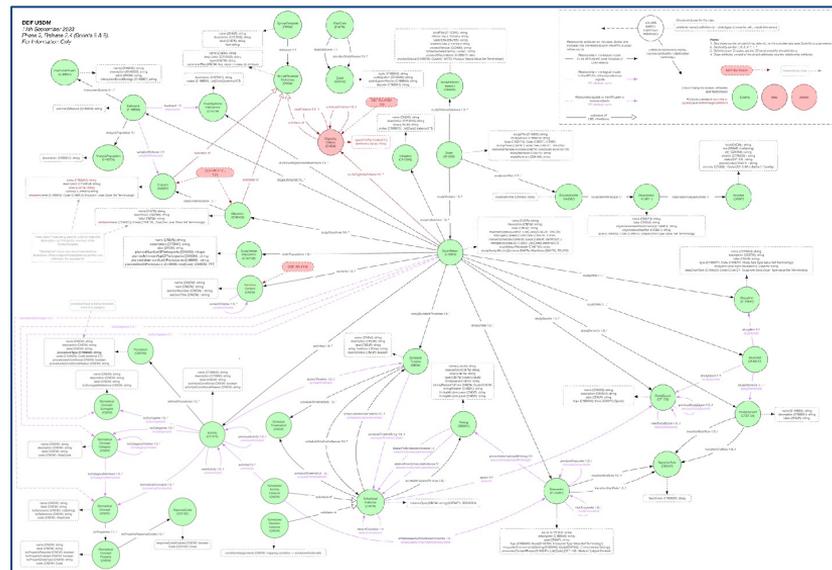
NOT APPLICABLE  
PHASE 0 TRIAL  
PHASE I TRIAL  
PHASE III TRIAL  
PHASE II TRIAL  
PHASE I/III TRIAL  
PHASE II TRIAL  
PHASE III TRIAL  
PHASE IIIB TRIAL  
PHASE IV TRIAL  
PHASE V TRIAL

# Breadth versus Depth



# Shift of Focus

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



# M11 Template Example Document

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

Document doesn't look right? [We'll help you out!](#)

## 5 TRIAL POPULATION

### 5.1 Selection of Trial Population

### 5.2 Rationale for Trial Population

### 5.3 Inclusion Criteria

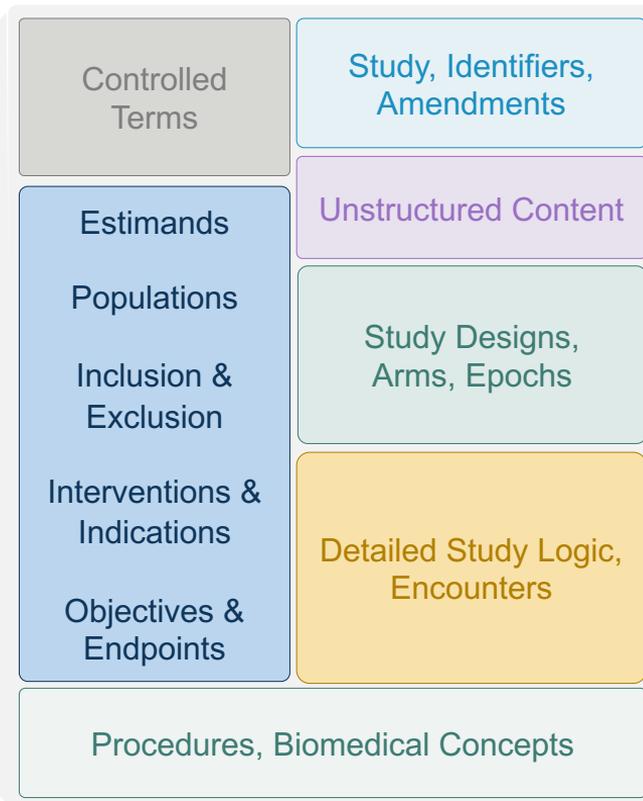
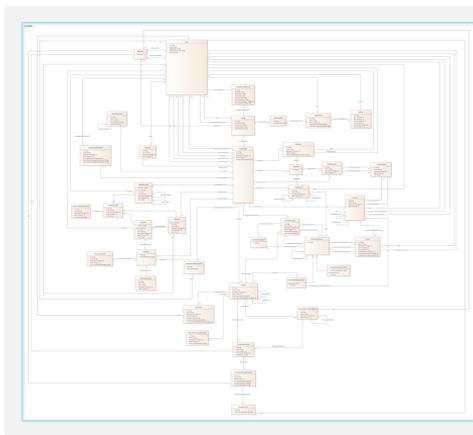
Patients may be included in the study only if they meet **all** the following criteria:

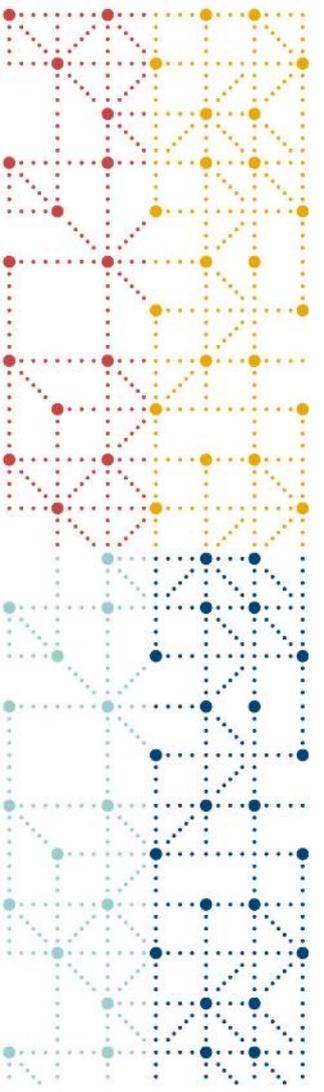
- [1] Males and postmenopausal females at least 50 years of age.
- [2] Diagnosis of probable AD as defined by National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) and the Alzheimer's Disease and Related Disorders Association (ADRDA) guidelines (Attachment LZTZ.7).
- [3]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

**VERY DRAFT**

# USDM Summary

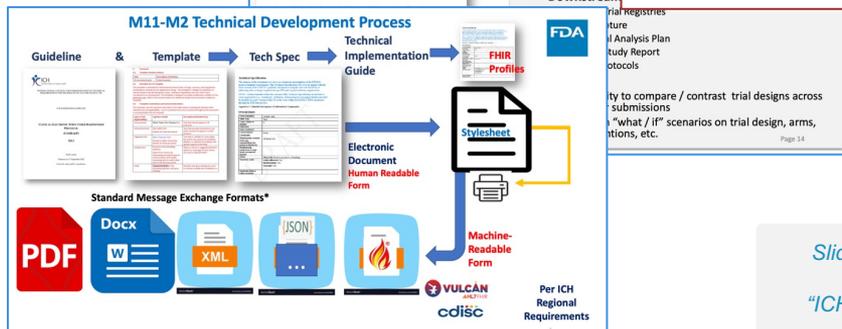
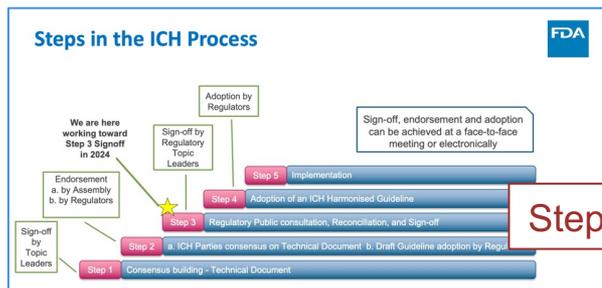
- Structured content along with the ability to hold unstructured content





# Summary

# ICH & The CDISC Project



## Phase Three Timeline

January 2024

Phase 3 development sprints complete

February 2024

Phase 3 public review

April 2024

Version 3 USDM published

Dates may be adjusted to align with ICH M11 publication dates.

Slides taken from CDISC US Interchange 2023 Presentation

"ICH M11 Clinical Electronic Structured Harmonized Protocol"

Ron Fitzmartin, PhD, MBA  
Center for Biologics Evaluation and Research  
Food and Drug Administration

# Summary

- We are “understanding” the complexity
- We can start to remove the silos and join the dots
- Digital Data Flow / Unified Study Definitions Model (DDF/USDM) fills an important gap
- USDM is but one building block, but an important one
- USDM alignment with ICH M11 will be an important step forward
- Can support various use cases, the prospective versus the retrospective
- We are only limited by our imagination



**CDISC Controlled Terms**  
Provides further s... complementing th... model. Includes th... definition of classe... attributes along w... definition of value...

C174447	Study Arm
C170984	Study Arm Name
C93728	Study Arm Descriptio...
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 Descriptio...
C188830	Study Epoch Type
CNEW	Study Epoch L...

**API for DDF** 2.4 Provisional (0.39)  
Generate Digital Data Flow (DDF) Study Definitions Repository API.

- 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
- POST** /v3/studyDesigns Study designs for a study

**Unified Study Definitions Model Implementation Guide**  
Version 2.0 (Draft for Internal Review)  
Prepared by CDISC  
DDF T...

**Implementing the Standard**  
Guidance on... and ensuring... standard

# Thank You

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## Link:

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

## CDSIC Team:

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- Drew Mills
- Erin Muhlbradt
- John Owen
- Jared Schreibman
- Berber Snoeijer
- Craig Zwickl

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API (a class diagram)  
for the USDM

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	C188830	Study Epoch Type
	CNEW	Study Epoch L

API for DDF



API Specification

means to exchange a  
study between machines  
using a JSON API

Method	Endpoint	Description
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

on 2.0 Draft for Internal Review



Unified Study De  
Implementation C

Version 2.0 (Draft fo

Prepared for  
DDF T

Notes to Readers

This is the draft version 2.0 of the Unified Study D  
v2.0). It is intended for Internal Review only and

History

Version  
2.0 Draft for Internal Review

Interchange Standards Consortium, A

Impleme

Guidance on

and ensuring

standard