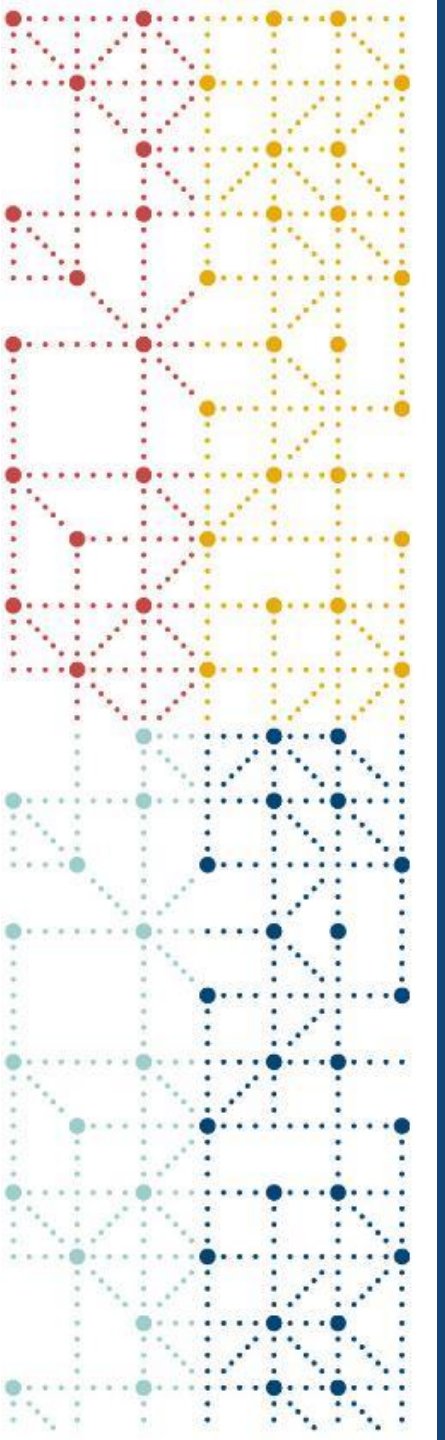
ICH M11 Clinical electronic Structure Harmonized Protocol (CeSHarP) and CDISC: Making the Electronic Protocol a reality

PHUSE US Connect 2024

Peter Van Reusel, Chief Standards Officer, CDISC

Agenda

- ICH M11 Introduction
- CDISC and ICH M11 Engagement
  - Content model
  - Controlled terminology
  - Define Trial Design mappings
  - Conformance rules for M11 model
  - Partner with Vulcan FHIR: exchange standard for ICH M11
- Conclusion



ICH M11

Clinical Electronic Structured Harmonized Protocol

ICH M11 Expert Working Group

- **Regulatory Members**
  - ANVISA, Brazil
  - CDSCO, India
  - EC, Europe
  - FDA, United States
  - Health Canada, Canada
  - HSA, Singapore
  - MHLW / PMDA, Japan
  - National Center, Kazakhstan
  - NMPA, China
  - SFDA, Saudi Arabia
  - TFDA, Chinese Taipei

- **Industry Members**
  - BIO
  - EFPIA
  - IFPMA
  - IGBA
  - JPMA
  - PhRMA

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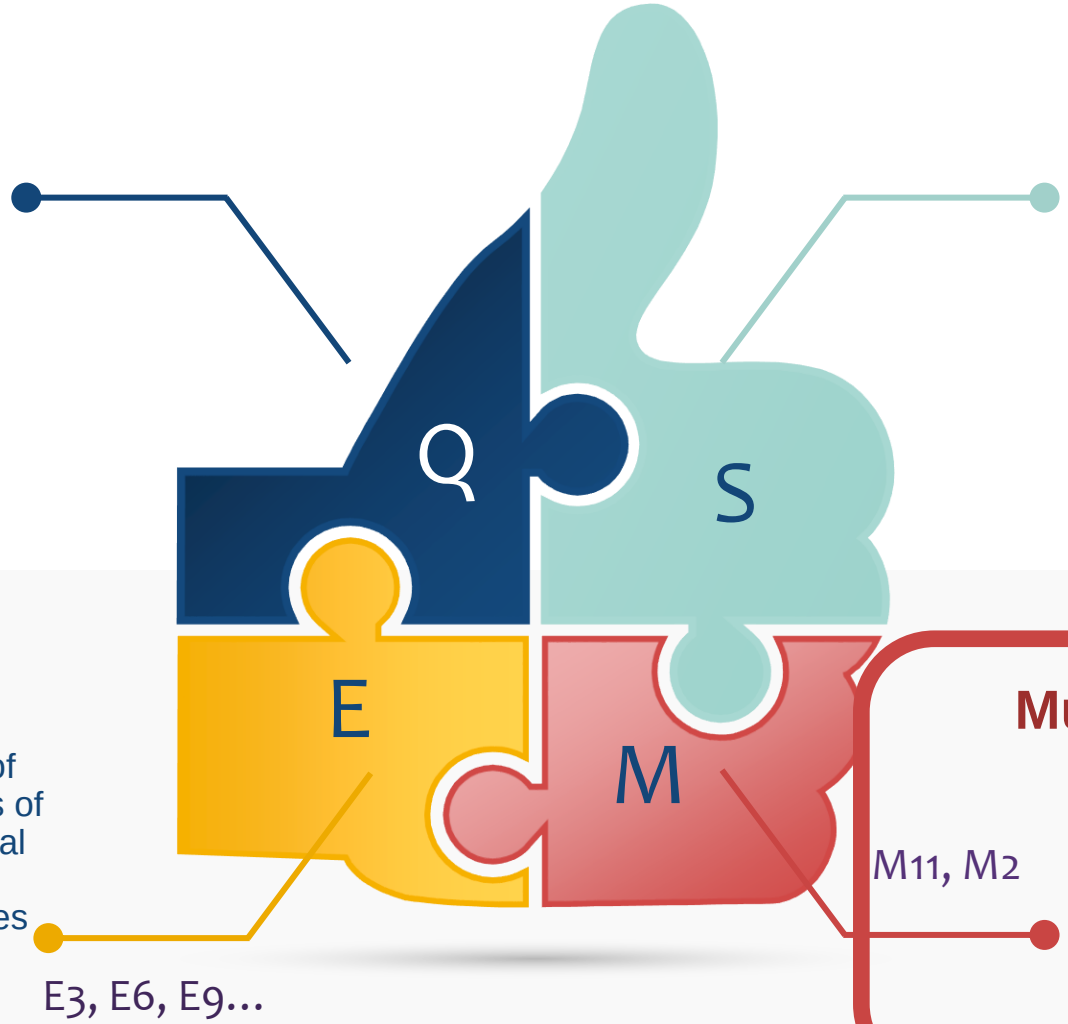
Source: https://ich.org/page/multidisciplinary-guidelines

International Council for Harmonisation (ICH) Guidelines

Topics and Codes

Quality Guidelines

Harmonisation achievements in the Quality area include pivotal milestones such as the conduct of stability studies, defining relevant thresholds for impurities testing and a more flexible approach to pharmaceutical quality based on Good Manufacturing Practice (GMP) risk management.



Safety Guidelines

ICH has produced a comprehensive set of safety Guidelines to uncover potential risks like carcinogenicity, genotoxicity and reprotoxicity. A recent breakthrough has been a non-clinical testing strategy for assessing the QT interval prolongation liability: the single most important cause of drug withdrawals in recent years.

Efficacy Guidelines

The work carried out by ICH under the Efficacy heading is concerned with the design, conduct, safety and reporting of clinical trials. It also covers novel types of medicines derived from biotechnological processes and the use of pharmacogenetics/genomics techniques to produce better targeted medicines.

Multidisciplinary Guidelines

Those are the cross-cutting topics which do not fit uniquely into one of the Quality, Safety and Efficacy categories. It includes the ICH medical terminology (MedDRA), the Common Technical Document (CTD) and the development of Electronic Standards for the Transfer of Regulatory Information (ESTRI).

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Why Clinical electronic Structured Harmonized Protocol (CeSHarP)?

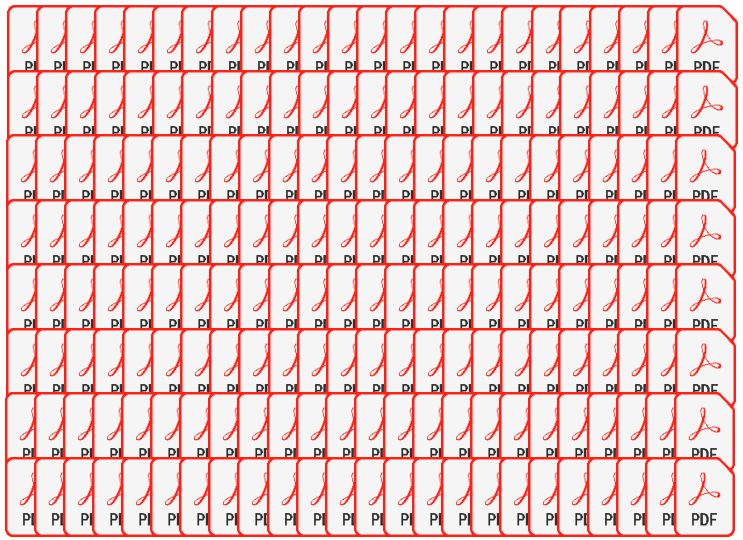
01 | No internationally harmonized standard template for the format and content to support consistency across sponsors and exchange of protocol information.

02 | Lack of harmonization contributes to inefficiencies and difficulties in reviewing and assessing clinical protocols by regulators, sponsors, ethical oversight bodies, investigators, and other stakeholders

Why Clinical electronic Structured Harmonized Protocol (CeSHarP)?

- Paper Submissions…
  Not like this anymore…

- …but this isn't much better!



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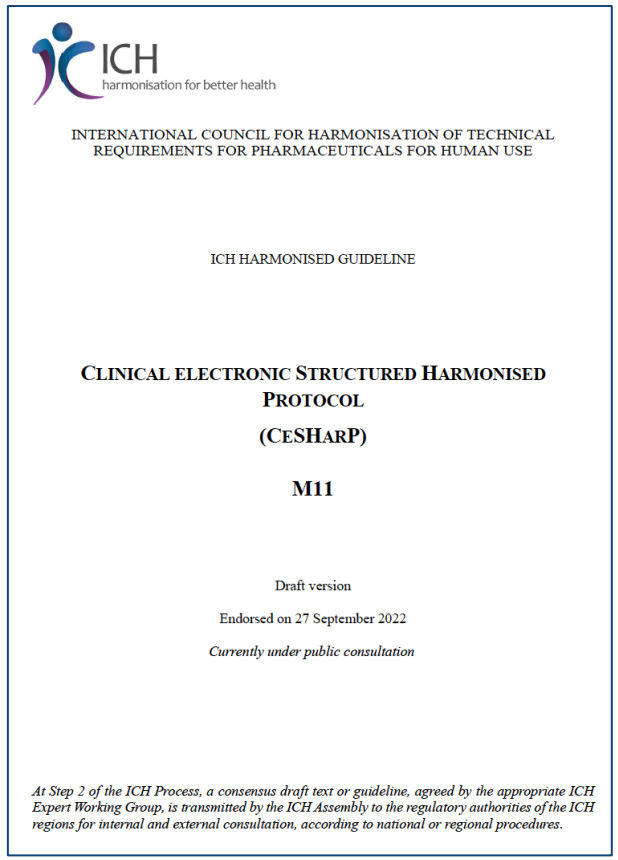
ICH CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHarP)

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



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ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

M11

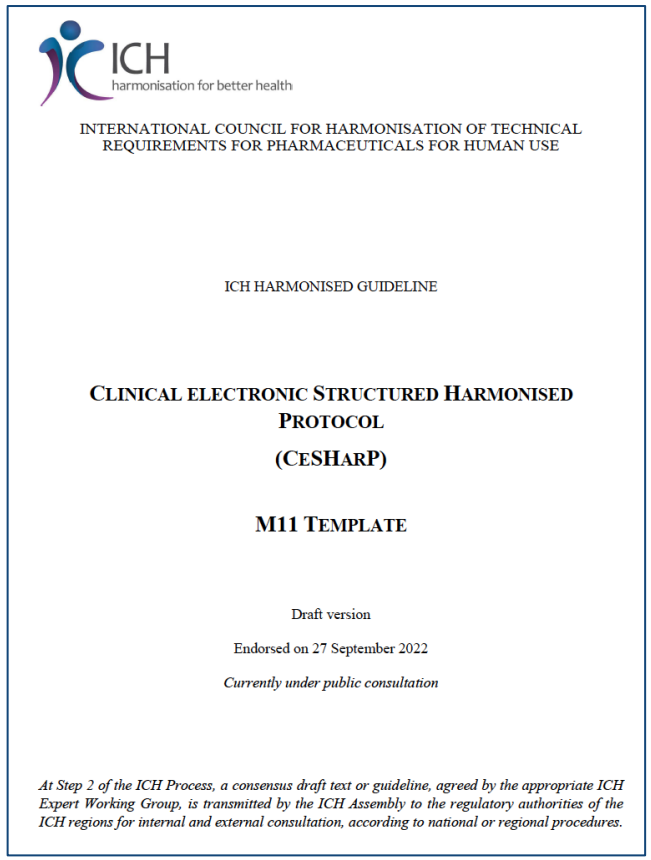
Draft version

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



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M11 TEMPLATE

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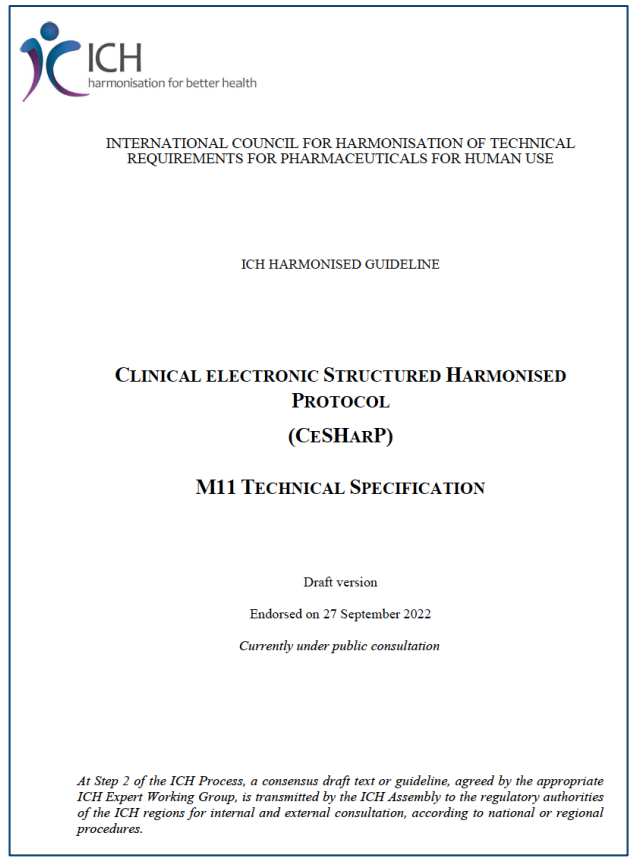
Provides the written format for the Interventional Clinical Trial Protocol Template



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M11 TECHNICAL SPECIFICATION

Draft version

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Provides the technical representation aligned with the guideline and protocol template

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Template for Description of Trial Design

4.1 Description of Trial Design

Describe the trial intervention model (for example, single group, parallel group, cross-over, factorial, sequential), the expected number of participants, and the control method (for example, placebo, active comparator, low dose, historical, standard of care, sham procedure, or none [uncontrolled]).

If applicable, indicate the type of trial (for example, superiority, non-inferiority, dose escalation, or equivalence).

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Technical Specification for Description of Trial Design

Term (Variable)	Type of Trial
Data Type	List
Topic, Value or Header	D
Definition	
User Guidance	
Conformance	Required
Cardinality	
Relationship content from ToC representing the protocol hierarchy	Trial Design
Relationship (reference to high level conceptual model)	
Value	Superiority, non-inferiority, dose escalation, or equivalence
Business rules	**Value Allowed:** Yes **Relationship:** n/a **Concept:** n/a
Duplicate field in other sections	

- Variables
- Concept/Terminology
- Code lists
- Conformance

CDISC M2/M11 Engagement

01 Controlled terminology, code lists, content nomenclature.

02 Define Content model to represent content agnostic of exchange standard.

03 Determine conformance rules for M11 model.

04 Collaborate with ICH M2/M11 on defining mappings between M11 model and CDISC Standards and Artifacts.

05 Joint project with Vulcan FHIR accelerator to deliver an electronic exchange standard for the ICH M11.

VULCAN

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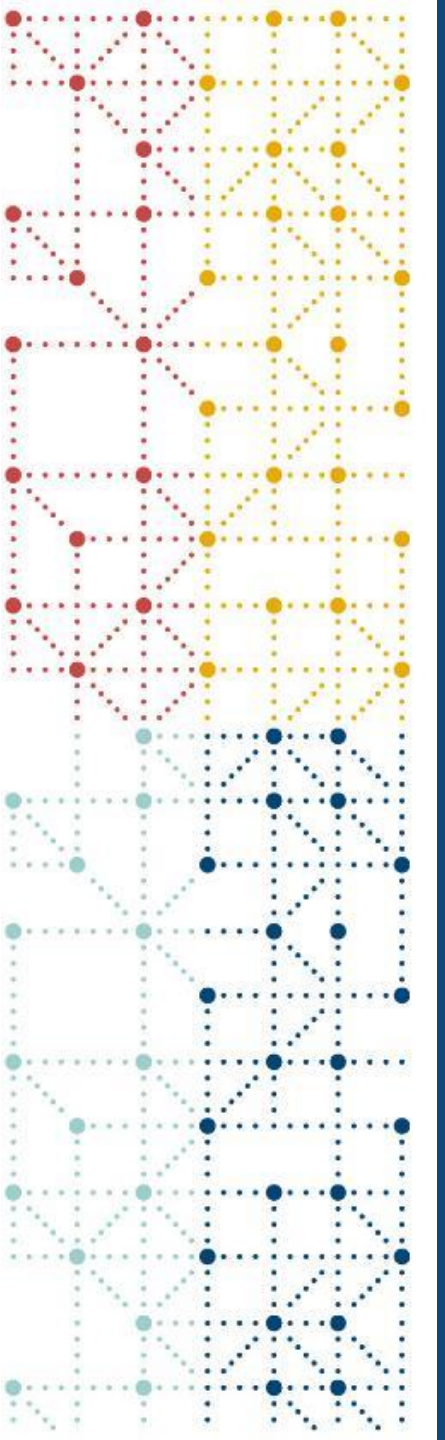


CDISC M2/M11 Engagement

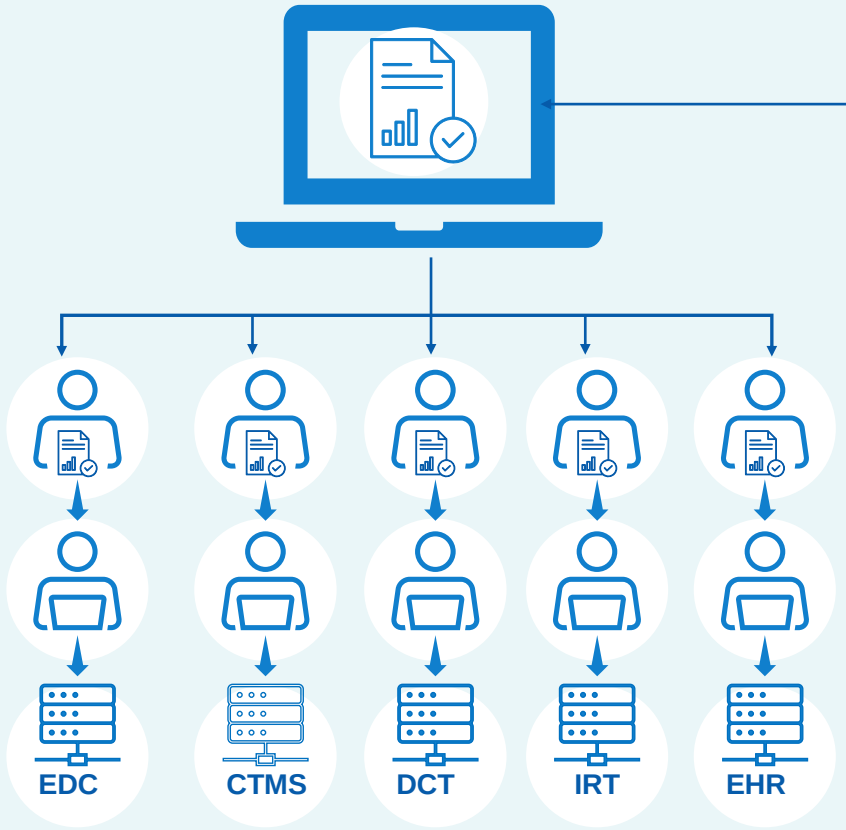
Define Content model to represent content agnostic of exchange standard

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

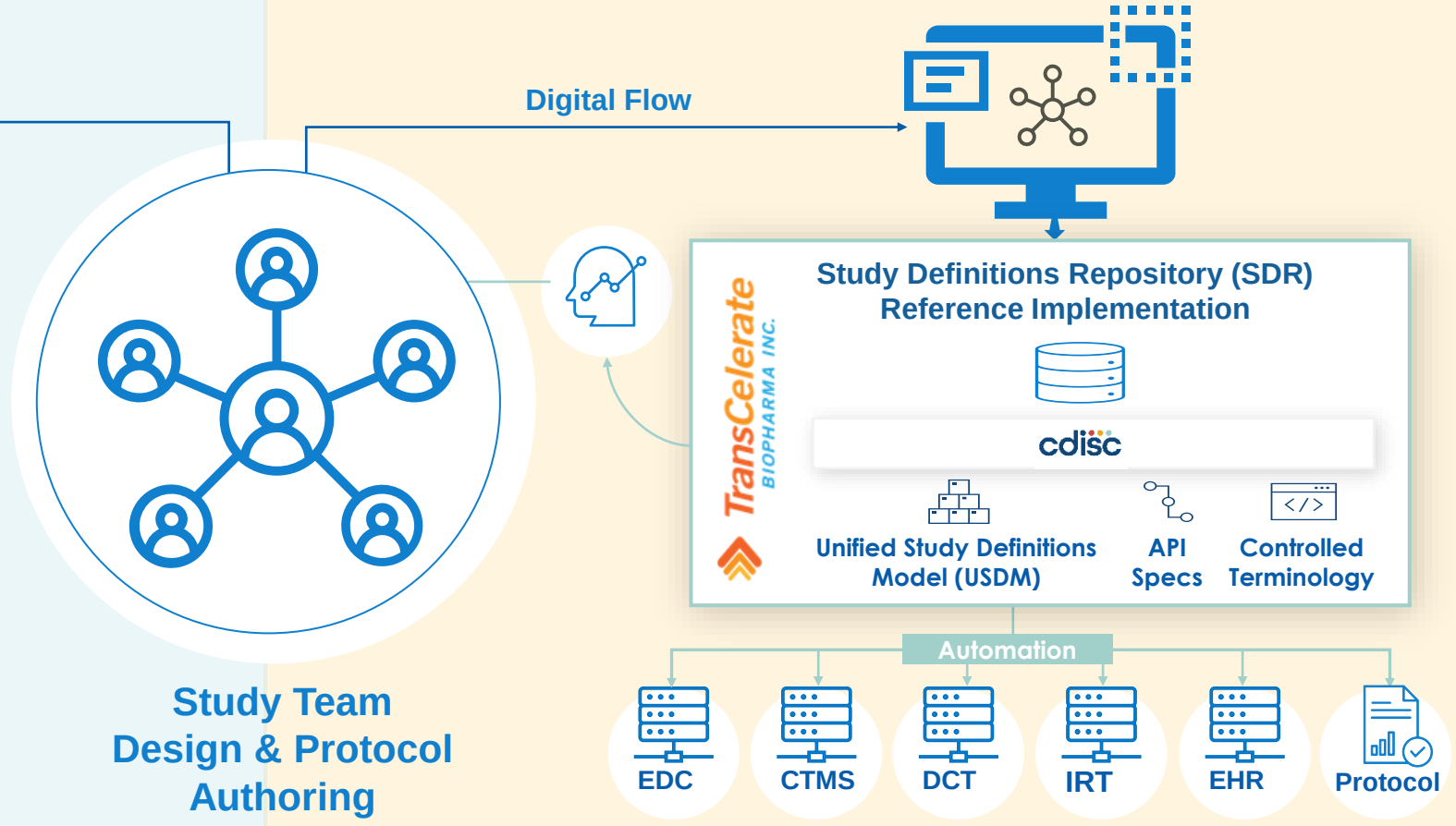
TransCelerate Digital Data Flow (DDF) Ambition

Write Once, Read Many

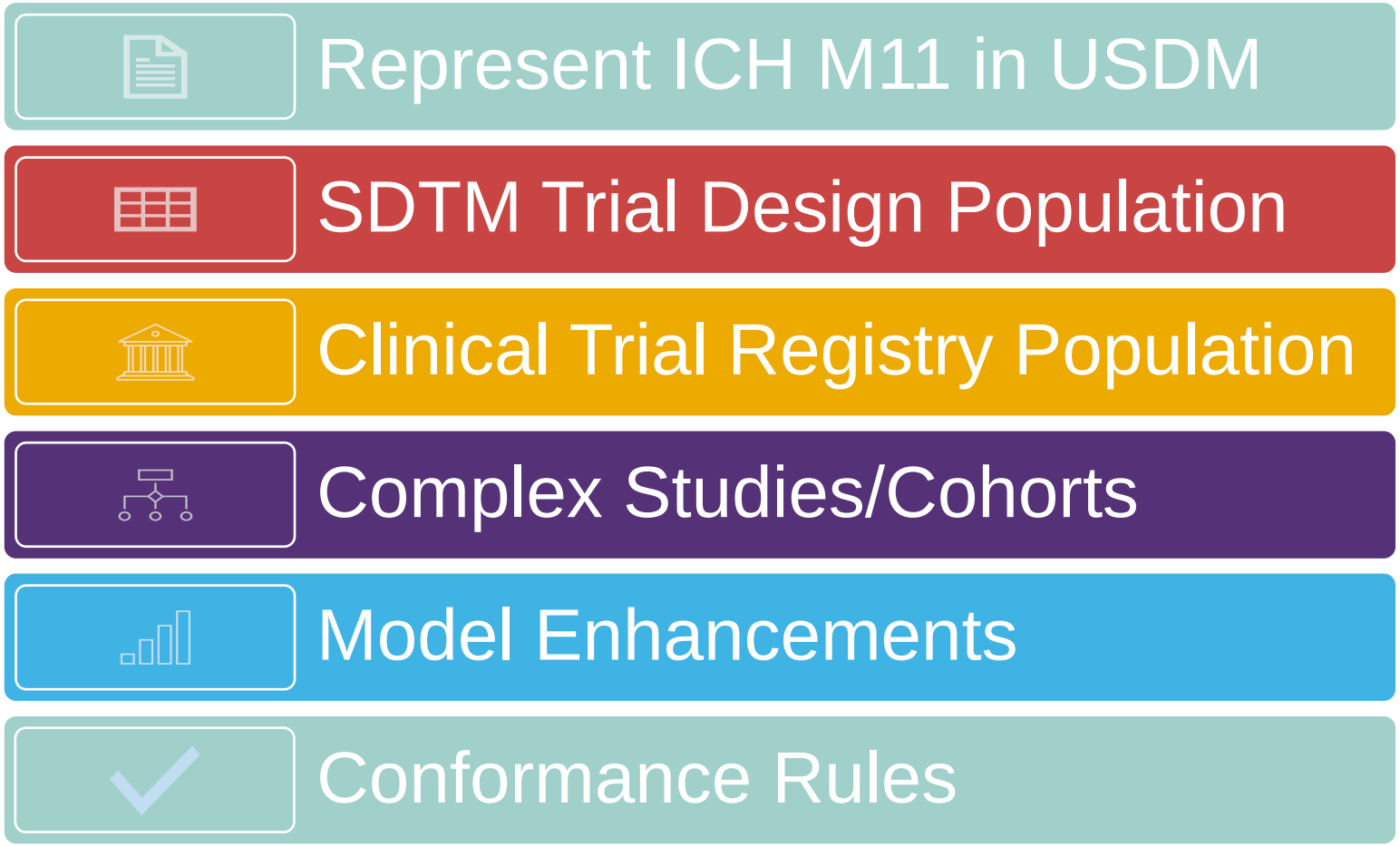
TODAY: Document-based paradigm for protocol creation, interpretation, and transcription into consuming systems



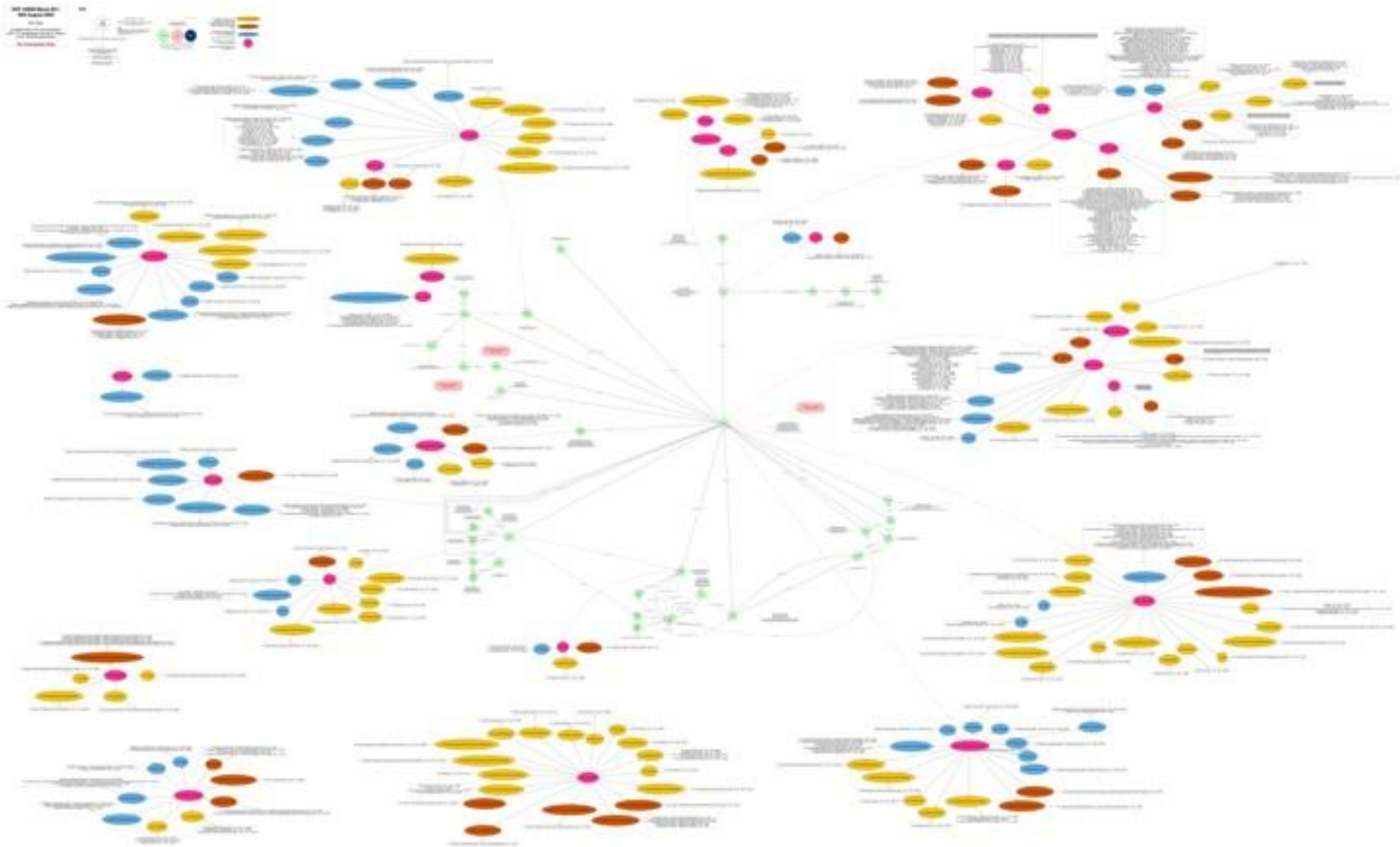
TOMORROW: Digital paradigm for protocol creation, with fully automated data flow and interoperability between systems



DDF 3 USDM Scope

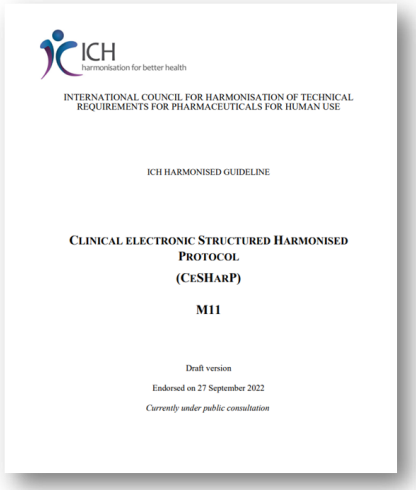


USDM Meets M11



M2/M11 Technical Development Process

Guideline & **Template** → **Tech Spec**



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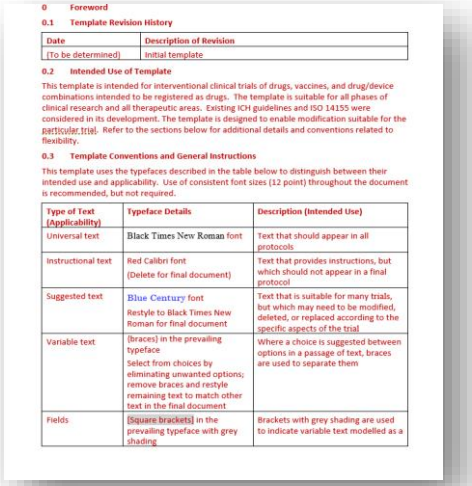


0 Foreword

0.1 Template Revision History

Date	Description of Revision
[To be determined]	Initial template

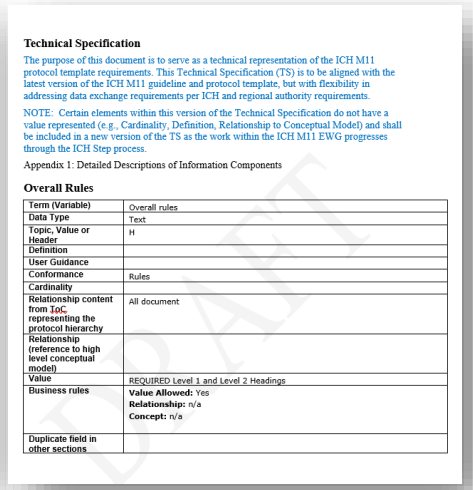
0.2 Intended Use of Template

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

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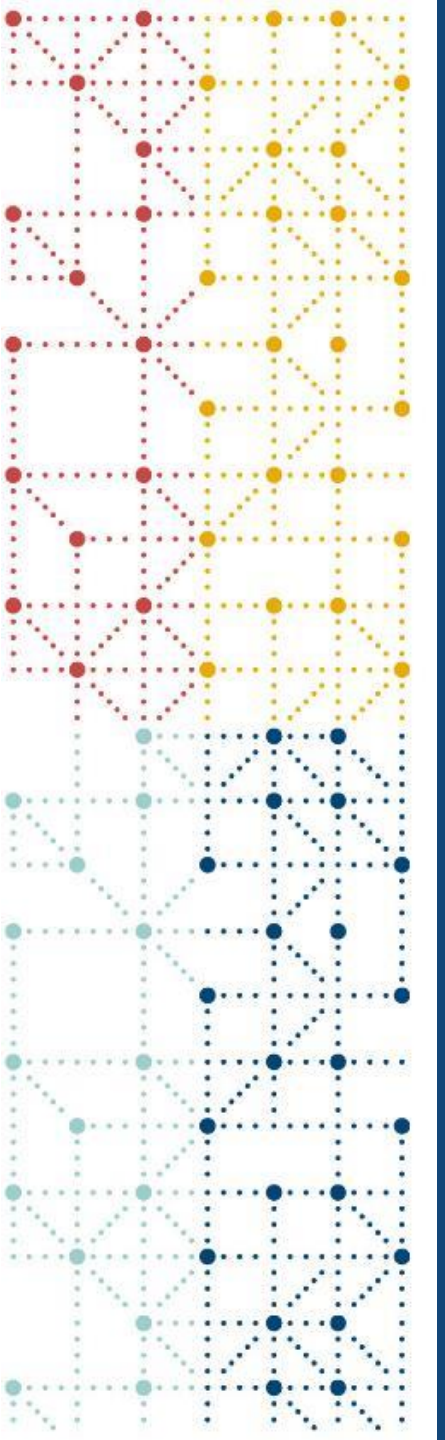
Standard Message Exchange Formats



CDISC M2/M11 Engagement

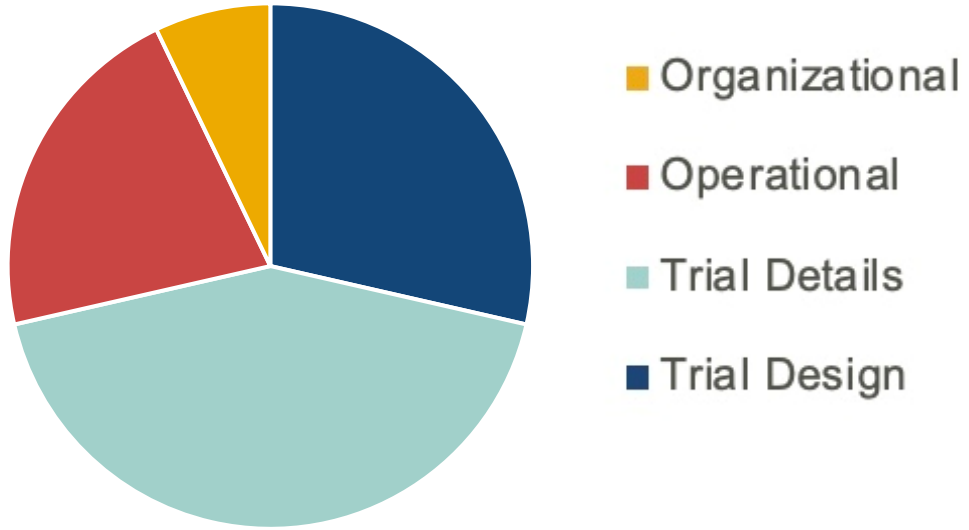
Controlled terminology, code lists, content nomenclature

M11 Document Controlled Terminology Categories

Analysis of CT in M11 Data Element Spreadsheet (n=223)

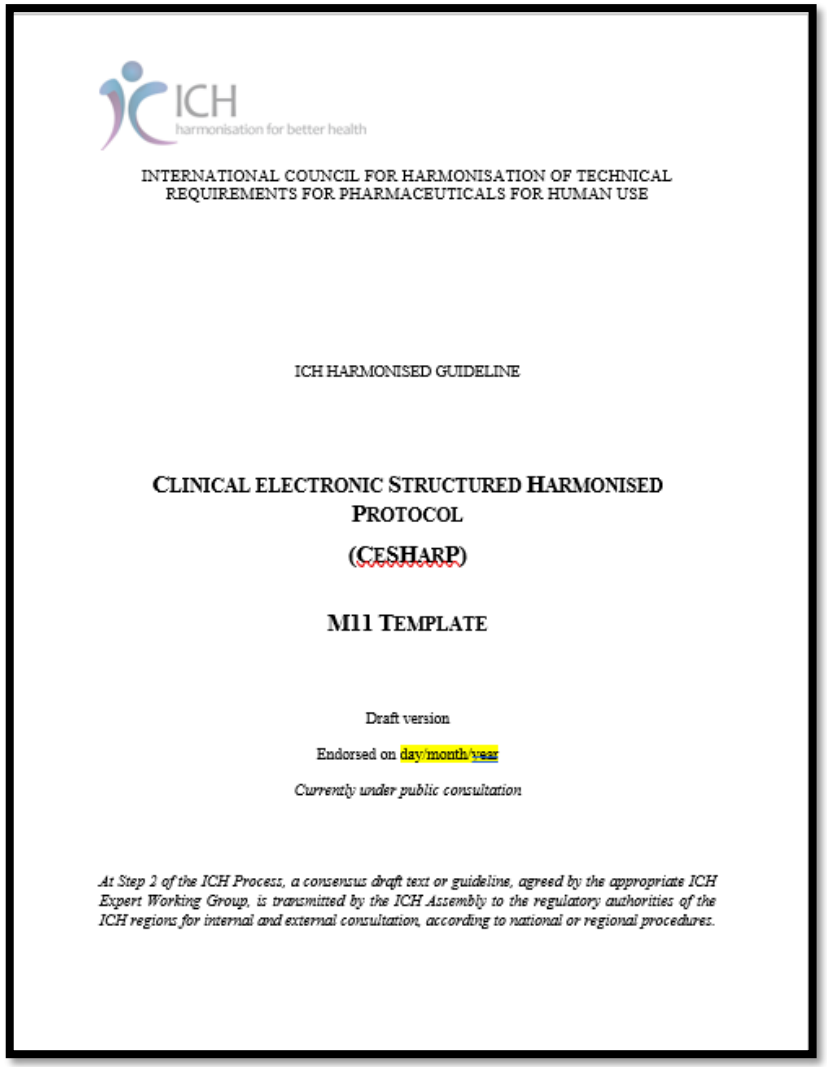
- Organizational provides information on sponsors and committees
- Operational provides details on tasks required (e.g., how to mix drug or handle the drug)
- Trial Details provides explanatory text that would be required for human comprehension
- Trial Design aligns with concepts found discretely in a protocol

Percentage of Data Elements from M11 Concepts



ICH M11 Terminology

- CDISC is working with the ICH M11 working group to create draft semantics for the ***ICH M11 Protocol Template***
  - 257 Data Elements
  - 22 Valid Value Sets comprising 112 terms
- Aligns with/harmonizes to CDISC terminology where appropriate
  - SDTM, DDF, Protocol, Glossary
- Stored with CDISC terminology in the NCI Thesaurus
- Will be undergoing CDISC public review and regulatory review in the next couple of months.



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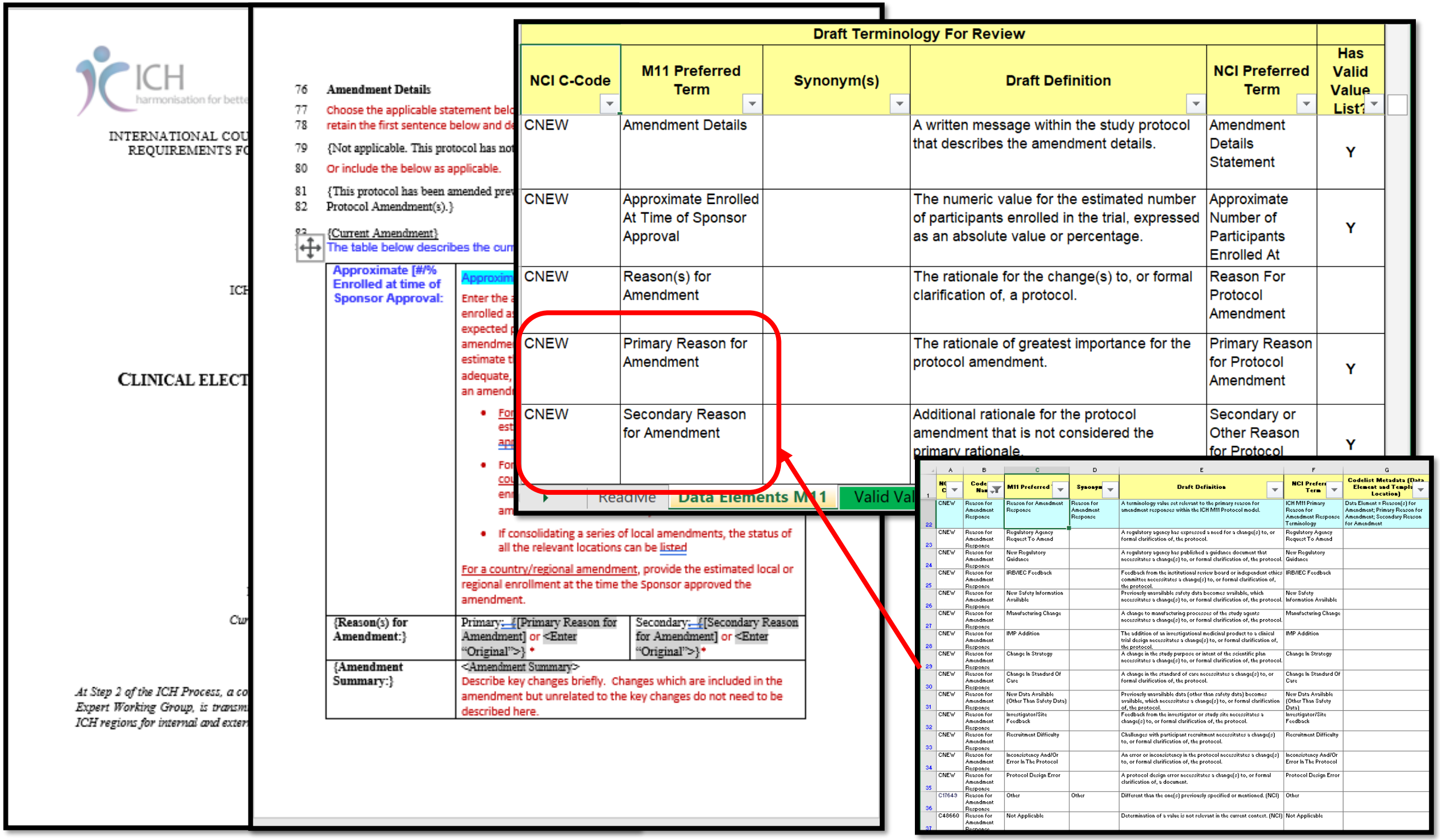

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76 **Amendment Details**

77 Choose the applicable statement belo
78 retain the first sentence below and de

79 {Not applicable. This protocol has not

80 Or include the below as applicable.

81 {This protocol has been amended prev
82 Protocol Amendment(s).}

83 {Current Amendment}
The table below describes the cur

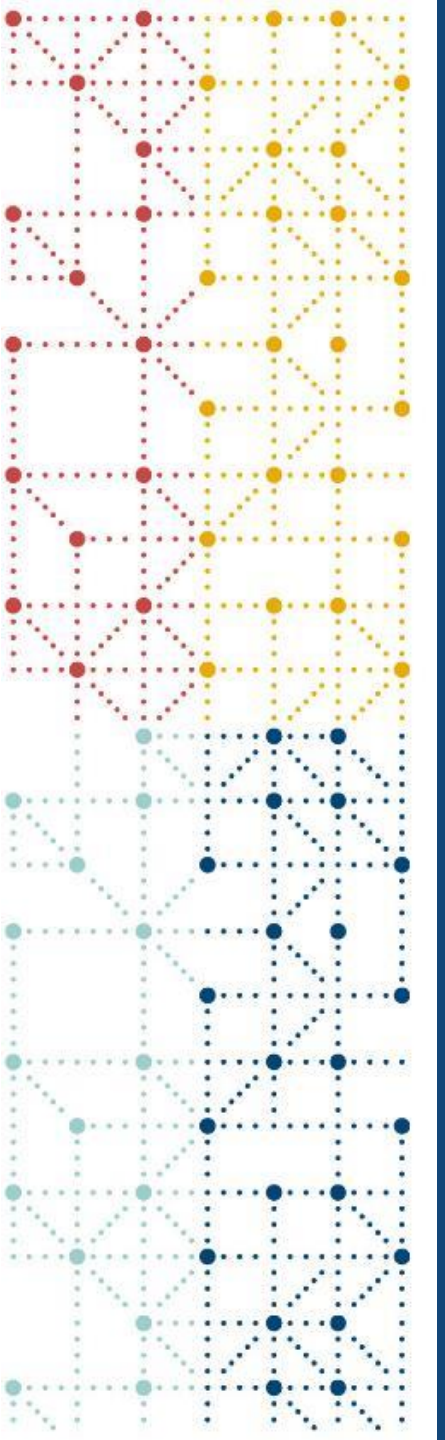
Approximate [#/% Enrolled at time of Sponsor Approval:	Approxim Enter the a enrolled a expected p amendme estimate t adequate, an amendr • For est app • For cou ent am • If consolidating a series of local amendments, the status of all the relevant locations can be listed For a country/regional amendment, provide the estimated local or regional enrollment at the time the Sponsor approved the amendment.
{Reason(s) for Amendment:}	Primary: {[Primary Reason for Amendment] or <Enter "Original">} • Secondary: {[Secondary Reason for Amendment] or <Enter "Original">} •
{Amendment Summary:}	<Amendment Summary> Describe key changes briefly. Changes which are included in the amendment but unrelated to the key changes do not need to be described here.

Draft Terminology For Review

NCI C-Code	M11 Preferred Term	Synonym(s)	Draft Definition	NCI Preferred Term	Has Valid Value List?
CNEW	Amendment Details		A written message within the study protocol that describes the amendment details.	Amendment Details Statement	Y
CNEW	Approximate Enrolled At Time of Sponsor Approval		The numeric value for the estimated number of participants enrolled in the trial, expressed as an absolute value or percentage.	Approximate Number of Participants Enrolled At	Y
CNEW	Reason(s) for Amendment		The rationale for the change(s) to, or formal clarification of, a protocol.	Reason For Protocol Amendment	
CNEW	Primary Reason for Amendment		The rationale of greatest importance for the protocol amendment.	Primary Reason for Protocol Amendment	Y
CNEW	Secondary Reason for Amendment		Additional rationale for the protocol amendment that is not considered the primary rationale.	Secondary or Other Reason for Protocol	Y

ReadMe | Data Elements M11 | Valid Val

	A	B	C	D	E	F	G
1	NC C	Code Nam	M11 Preferred	Synonym	Draft Definition	NCI Preferr Term	Codelist Metadata (Data Element and Templ Location)
22	CNEW	Reason for Amendment Response	Reason for Amendment Response	Reason for Amendment Response	A terminology value set relevant to the primary reason for amendment responses within the ICH M11 Protocol model.	ICH M11 Primary Reason for Amendment Response Terminology	Data Element = Reason(s) for Amendment; Primary Reason for Amendment; Secondary Reason for Amendment
23	CNEW	Reason for Amendment Response	Regulatory Agency Request To Amend		A regulatory agency has expressed a need for a change(s) to, or formal clarification of, the protocol.	Regulatory Agency Request To Amend	
24	CNEW	Reason for Amendment Response	New Regulatory Guidance		A regulatory agency has published a guidance document that necessitates a change(s) to, or formal clarification of, the protocol.	New Regulatory Guidance	
25	CNEW	Reason for Amendment Response	IRB/IEC Feedback		Feedback from the institutional review board or independent ethics committee necessitates a change(s) to, or formal clarification of, the protocol.	IRB/IEC Feedback	
26	CNEW	Reason for Amendment Response	New Safety Information Available		Previously unavailable safety data becomes available, which necessitates a change(s) to, or formal clarification of, the protocol.	New Safety Information Available	
27	CNEW	Reason for Amendment Response	Manufacturing Change		A change to manufacturing processes of the study agents necessitates a change(s) to, or formal clarification of, the protocol.	Manufacturing Change	
28	CNEW	Reason for Amendment Response	IMP Addition		The addition of an investigational medicinal product to a clinical trial design necessitates a change(s) to, or formal clarification of, the protocol.	IMP Addition	
29	CNEW	Reason for Amendment Response	Change In Strategy		A change in the study purpose or intent of the scientific plan necessitates a change(s) to, or formal clarification of, the protocol.	Change In Strategy	
30	CNEW	Reason for Amendment Response	Change In Standard Of Care		A change in the standard of care necessitates a change(s) to, or formal clarification of, the protocol.	Change In Standard Of Care	
31	CNEW	Reason for Amendment Response	New Data Available (Other Than Safety Data)		Previously unavailable data (other than safety data) becomes available, which necessitates a change(s) to, or formal clarification of, the protocol.	New Data Available (Other Than Safety Data)	
32	CNEW	Reason for Amendment Response	Investigator/Site Feedback		Feedback from the investigator or study site necessitates a change(s) to, or formal clarification of, the protocol.	Investigator/Site Feedback	
33	CNEW	Reason for Amendment Response	Recruitment Difficulty		Challenges with participant recruitment necessitates a change(s) to, or formal clarification of, the protocol.	Recruitment Difficulty	
34	CNEW	Reason for Amendment Response	Inconsistency And/Or Error In The Protocol		An error or inconsistency in the protocol necessitates a change(s) to, or formal clarification of, the protocol.	Inconsistency And/Or Error In The Protocol	
35	CNEW	Reason for Amendment Response	Protocol Design Error		A protocol design error necessitates a change(s) to, or formal clarification of, a document.	Protocol Design Error	
36	C17649	Reason for Amendment Response	Other	Other	Different than the one(s) previously specified or mentioned. (NCI)	Other	
37	C48660	Reason for Amendment Response	Not Applicable		Determination of a value is not relevant in the current context. (NCI)	Not Applicable	

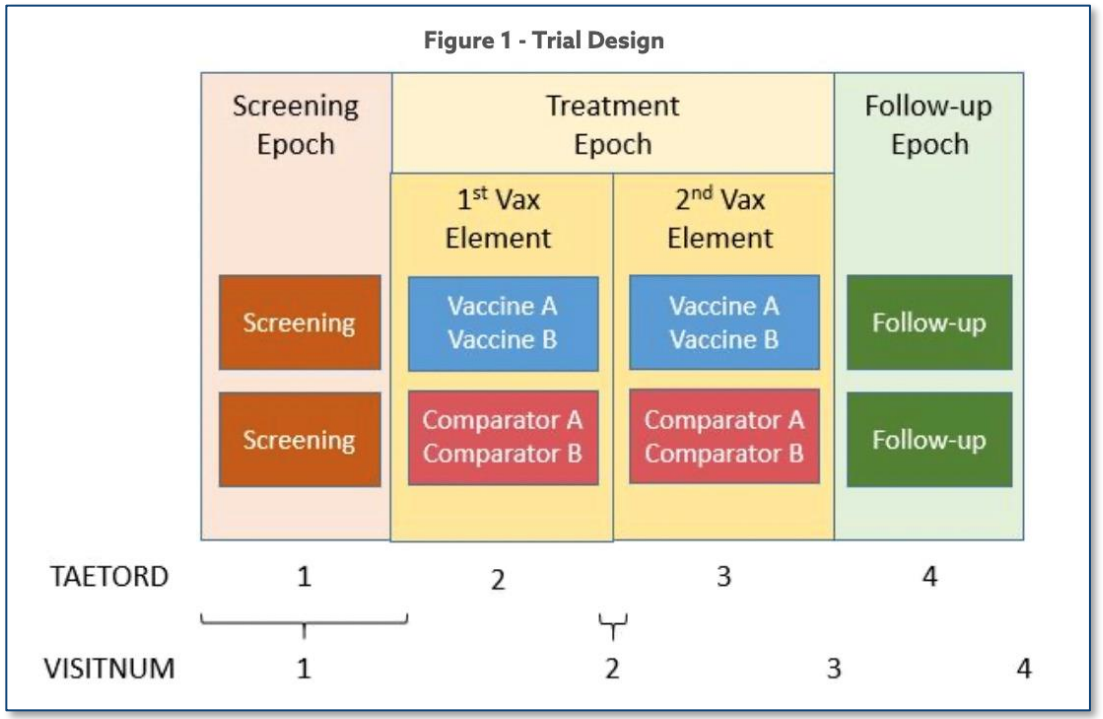


CDISC M2/M11 Engagement

Defining Trial Design mappings for M11 model

Generate SDTM Trial Design Datasets

- Demonstrate how an M11 protocol represented in USDM will be used to generate SDTM Trial Design datasets
- For Trial Arms, Trial Elements, Trial Visits, Trial Inclusion
  - Domain specifications supplemented with sources in USDM
- For Trial Summary
  - Assessed whether and how FDA-required parameters could be generated



Identify new Trial Summary Parameters from M11

- M11 terminology is evolving, so a definitive list is not yet possible

- Examples of possible new trial summary parameters
  - A set of parameters to describe top-level characteristics of each amendment
  - Parameters to represent compound names and numbers
  - Parameter(s) to represent various committees overseeing aspects of study conduct

ts.xpt

Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM
1	XYZ	TS	1		ADDON	Added on to Existing Treatments
2	XYZ	TS	1		AGEMAX	Planned Maximum Age of Subjects
3	XYZ	TS	1		AGEMIN	Planned Minimum Age of Subjects
4	XYZ	TS	1		LENGTH	Trial Length
5	XYZ	TS	1		PLANSUB	Planned Number of Subjects
6	XYZ	TS	1		RANDOM	Trial is Randomized
7	XYZ	TS	1		SEXPOP	Sex of Participants
8	XYZ	TS	1		STOPRULE	Study Stop Rules
9	XYZ	TS	1		TBLIND	Trial Blinding Schema
10	XYZ	TS	1		TCNTRL	Control Type
11	XYZ	TS	1		TDIGRP	Diagnosis Group
12	XYZ	TS	1		INDIC	Trial Disease/Condition Indication
13	XYZ	TS	1		TINDTP	Trial Intent Type
14	XYZ	TS	1		TITLE	Trial Title
15	XYZ	TS	1		TPHASE	Trial Phase Classification
16	XYZ	TS	1		TTYPE	Trial Type
17	XYZ	TS	2		TTYPE	Trial Type

Possible Future Modifications to SDTM Trial Design

- **Trial Visits**
  - Add planned contact mode and include other than in-person visits
  - Add planned visit windows
- **New Trial Timepoints**
  - Fill gap in representing schedule of activities
  - Structure similar to Trial Visits
- **Trial Interventions**
  - Separate duration of treatment from duration of elements (assessment of trial effects)
  - Based on study interventions, allows denormalized representation of dosing data currently in normalized form in Trial Summary
  - Enhance Trial Elements by linking Trial Interventions to treatment elements
- **Trial Inclusion/Exclusion**
  - Link tests/biomedical concepts to criteria
- **New Trial Organizations**
  - Represent roles and contact information

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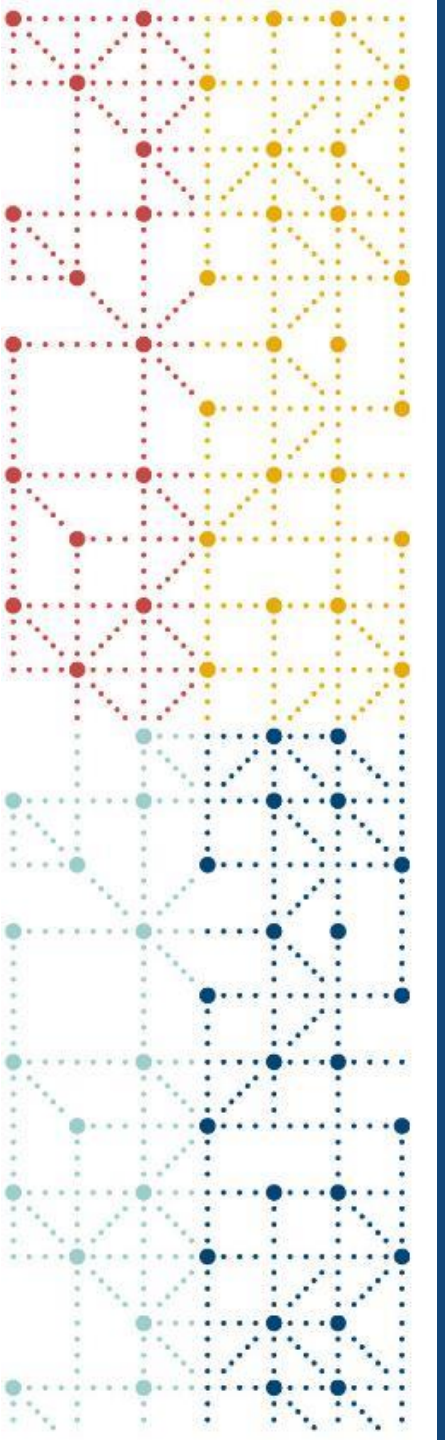


CDISC M2/M11 Engagement

Determine conformance rules for M11 model

The Conformance Rule Challenge

A single source of truth for all conformance rules

Consistency across conformance rule implementations

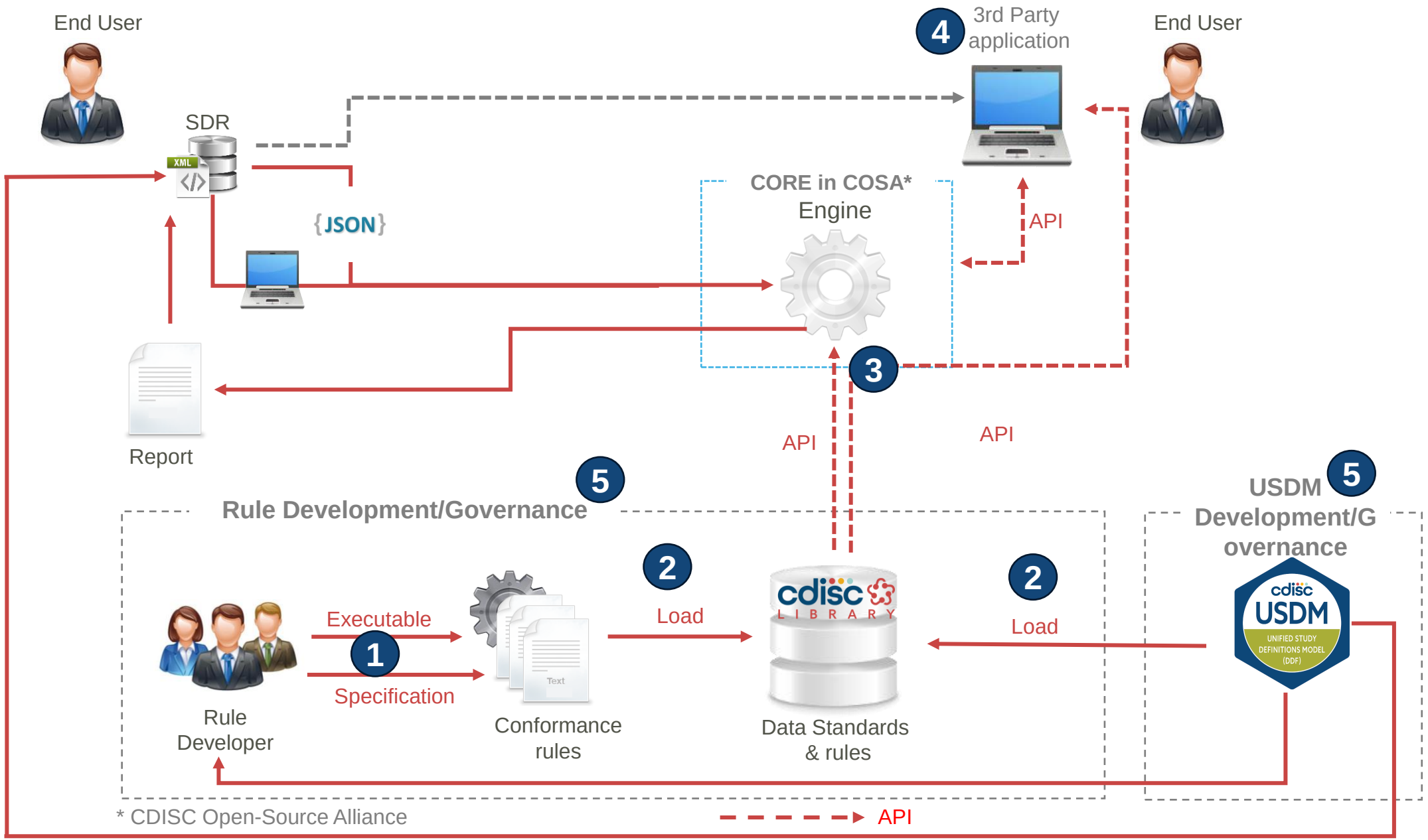
Central management and governance of rule specifications, regardless of source:

- CDISC – rules in the foundational standards
- FDA Validator Rules
- PMDA Validation Rules
- Community – proposed new/updated rules

Development, central management and governance of machine-executable rules from specifications

Efficient and transparent process for the community to

- Access specifications
- Access executable rules
- Propose new/updated rules


End User
SDR
XML
{JSON}
4
3rd Party application
End User
CORE in COSA* Engine
API
3
Report
API
API
5
Rule Development/Governance
5
USDM Development/Governance
2
Load
2
Load
Executable
1
Specification
Rule Developer
Conformance rules
Data Standards & rules
cdisc LIBRARY
cdisc USDM
UNIFIED STUDY DEFINITIONS MODEL (DDF)
* CDISC Open-Source Alliance
API

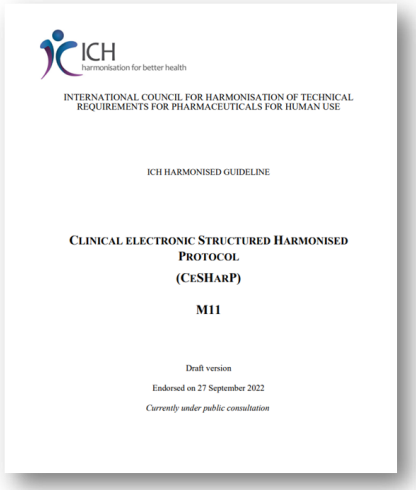
CDISC M2/M11 Engagement

Joint project with Vulcan FHIR accelerator to deliver an electronic exchange standard for the ICH M11

CDISC and HL7 FHIR Vulcan Collaboration

M2/M11 Technical Development Process

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

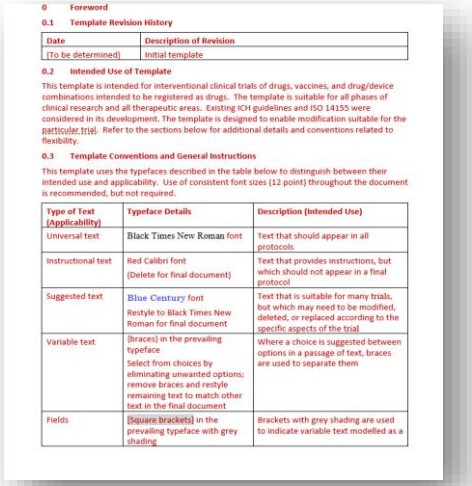
(CeSHarP)

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

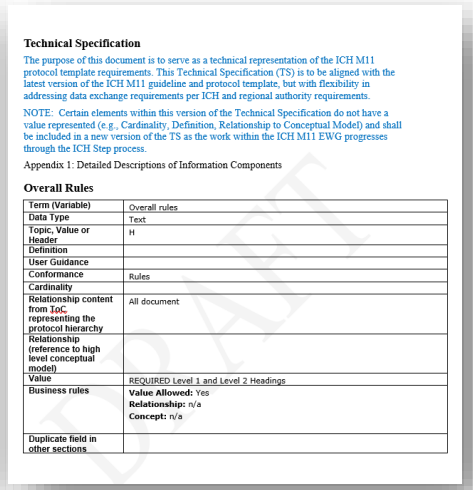
0.2 Intended Use of Template

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

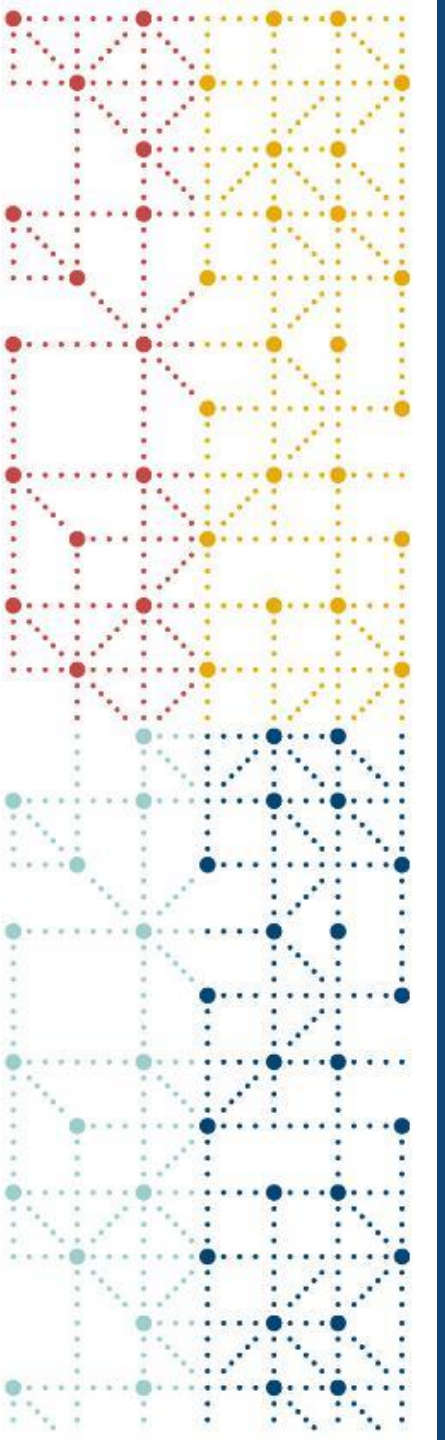
cdisc USDM UNIFIED STUDY DEFINITIONS MODEL (DDF)

Machine-Readable Form

VULCAN HL7 FHIR

cdisc

Standard Message Exchange Formats

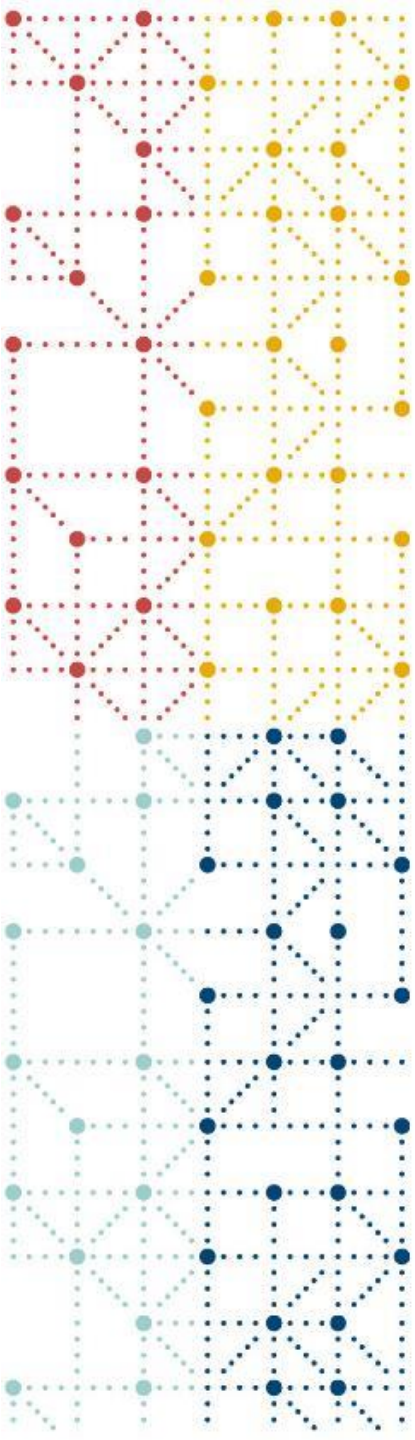


Conclusion

Next steps

What to expect

- It’s time to start paying attention
- Transcelerate and CDISC will accelerate the operationalization of the digital protocol
- We expect to engage in industry and regulatory pilots soon



Thank You!

cdisc