CDISC China
UG Seminar 2025

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What You Need to Know about eProtocol

eProtocol 进展、路径、挑战和应用场景

By 张子豹

CDISC中国用户群研讨会

2025-08-30

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张子豹 (Bob) 介绍

- 现任有临来雅总经理，负责数据管理/统计/编程等业务规划和管理；
- 20+年生物医药研发行业经验，多个不同管理岗位经验；
  - *曾在多家跨国临床CRO负责创建和管理中国生物统计和编程团队，支持全球临床试验业务*
  - *曾参与创建一家CRO发展成为独角兽，负责技术和商务拓展团队*
  - *短期VC工作经历，参与创业公司融资*
- 多个行业协会志愿者，包括CDISC亚太区和中国区前任主席；上海生物统计论坛主要协调人之一；DIA定量科学论坛和专题组织志愿者；
- 复旦大学流行病与卫生统计博士 (2003)；中欧国际工商学院 Global EMBA课程 (2020-2023) 和中欧创投营 (2022-2023)。

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目录

1. **系统回顾**：行业对临床研究方案（clinical protocol）进行规范化/标准化/数字化的努力，并尝试分析其策略和挑战
2. **重点介绍**：ICH's **M11** (Protocol Template/Tech Spec), CDISC's Unified Study Definitions Model (**USDM)** , TCB's Digital Data Flow (**DDF**) ➔ eProtocol
3. **个人分享**：e-Protocol和DDF可能的应用场景和影响

回顾1：ICH – E6 R1 (1996) to R3 (2019)

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INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED TRIPARTITE GUIDELINE

GUIDELINE FOR GOOD CLINICAL PRACTICE
E6(R1)

Current *Step 4* version
dated 10 June 1996

(including the Post Step 4 corrections)

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

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ICH – M11 (2018-now), Step 4 (2025-2026?)

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M11 Clinical electronic Structured Harmonised Protocol (CeSHarP)

M11 EWG **Clinical electronic Structured Harmonised Protocol (CeSHarP)**

This topic was endorsed by the ICH Management Committee in November 2018. This new guideline is proposed to provide comprehensive clinical protocol organisation with standardised content, with:

- A Template which presents the format and structure of the protocol, including the table of contents, common headers, and contents;
- A Technical Specification which presents the conformance, cardinality, and other technical attributes that enable the interoperable electronic exchange of protocol content.

The Technical Specification document and Template had reached Step 2b on 27 September 2022 and entered public consultation. They have been updated by the M11 EWG following the comments received. The Technical Specification is now being submitted for a second round of public consultations, and the Template is provided as a support to the consultation.

Rapporteur: Dr. Veronica Pei (FDA, United States)

Regulatory Chair: Dr. Noemie Manent (EC, Europe)

Date of *Step 2b*: 13 March 2025

Status: *Step 3*

Public consultation dates:

ANVISA, Brazil - Deadline for comments by 28 April 2025

EC, Europe - Deadline for comments by 22 April 2025

FDA, United States - Deadline for comments by 7 July 2025

HSA, Singapore - Deadline for comments by 25 April 2025

Health Canada, Canada - Deadline for comments by 15 July 2025

MHLW/PMDA, Japan - Deadline for comments by 1 May 2025

NMPA, China - Deadline for comments by 28 April 2025

SFDA, Saudi Arabia - Deadline for comments by 21 April 2025

TFDA, Chinese Taipei - Deadline for comments by 25 April 2025

Guideline

- M11 Draft Guideline
- M11 Updated Template
- M11 Updated Technical Specification

Endorsed Documents

- M11 Concept Paper
- M11 Business Plan
- M11 Work Plan

WG Presentations / Trainings

- M11 Step 2 Presentation
- M11 Step 2 Updated Technical Specification Presentation

WG list

ICH工作办公室

首页 > ICH指导原则征求意见 > ICH指导原则征求意见详情

关于公开征求ICH《M11：临床电子结构化协调方案（CeSHarP）》指导原则草案意见的通知

2023-01-06

ICH工作办公室

首页 > ICH工作动态 > ICH工作动态详情

关于公开征求ICH《M11:电子结构化协调的临床方案》模板文件草案意见的通知

2025-03-21

ICH《M11:电子结构化协调的临床方案》模板文件现进入第3阶段区域公开征求意见阶段。按照ICH相关章程要求，ICH的监管机构成员需收集本地区关于该文件草案的意见并反馈ICH。

M11模板文件草案的英文原文和中文译文见附件，现就该指导原则内容及中文译文向社会公开征求意见。

社会各界如有相关建议，请于2025年4月10日前通过电子邮箱反馈我中心。

邮箱：gkzhqyj@cde.org.cn

附件：1.【英文】M11模板文件（草案）

2.【中文】M11模板文件（草案）

国家药品监督管理局药品审评中心

2025年3月21日

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ICH – M11 Clinical electronic Structured Harmonised Protocol (CeSHarP)

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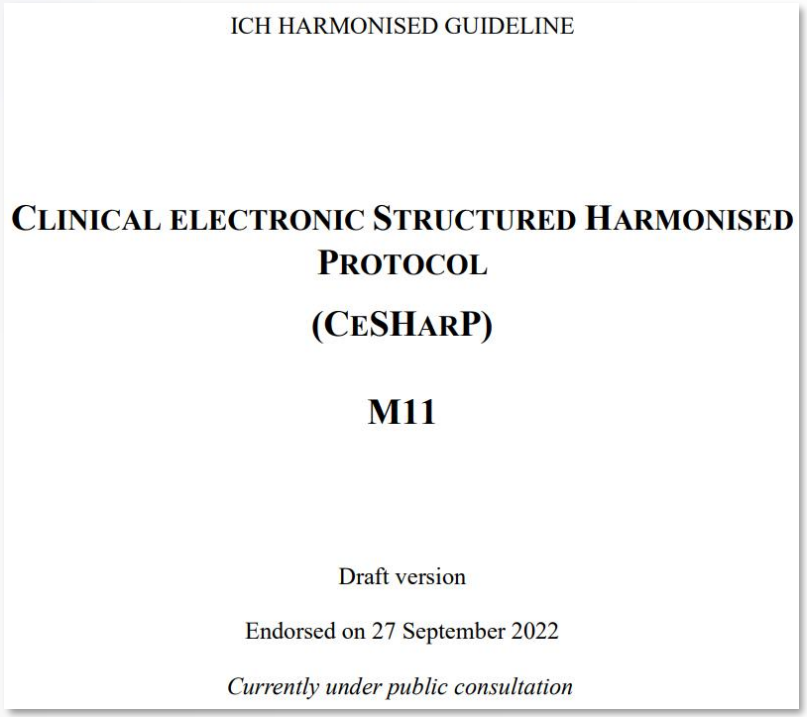
Guideline (7pp)



ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

M11

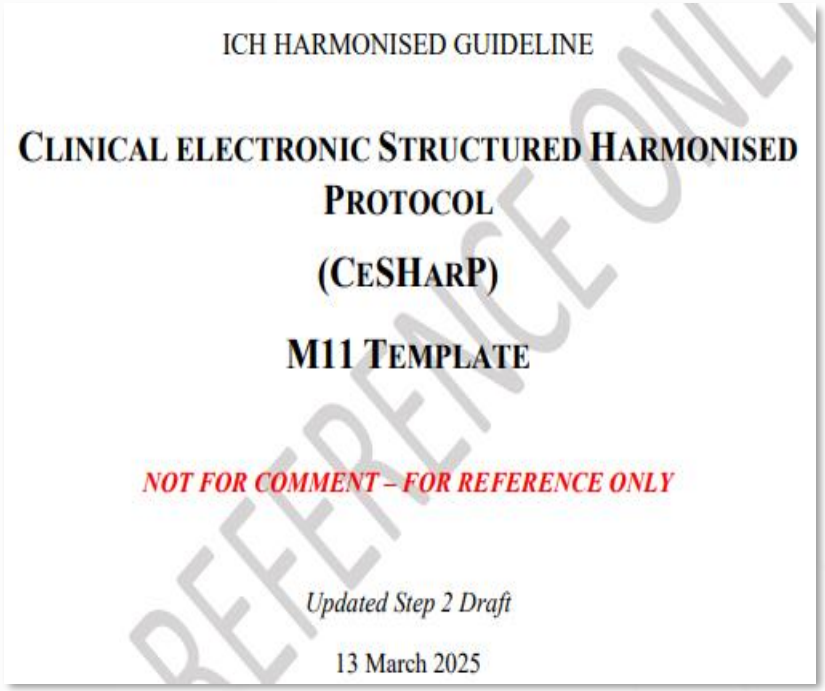
Draft version

Endorsed on 27 September 2022

Currently under public consultation

Defines the background, purpose, scope and principles

Template (64pp)



ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

M11 TEMPLATE

NOT FOR COMMENT – FOR REFERENCE ONLY

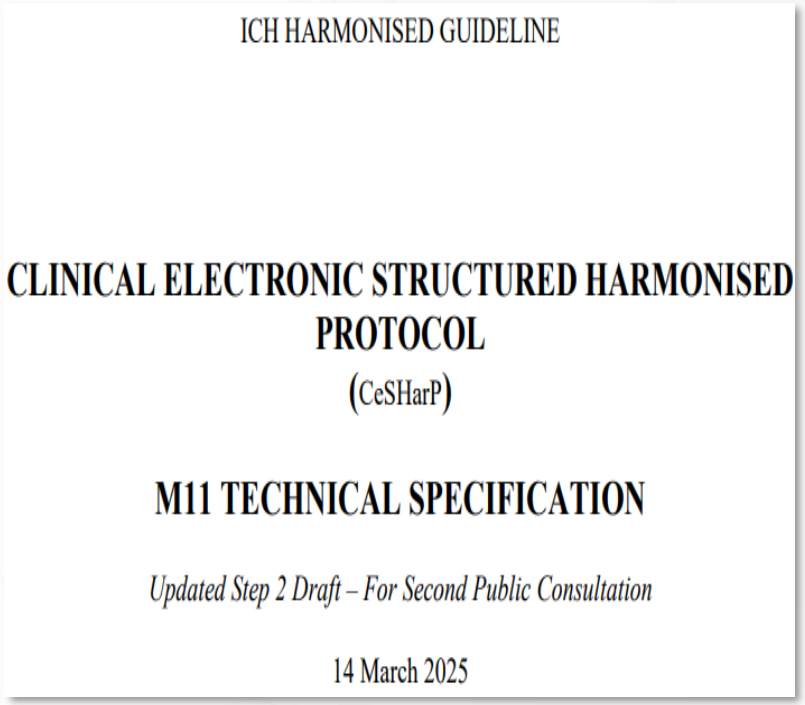
Updated Step 2 Draft

13 March 2025

REFERENCE ONLY

The specification of the Protocol Document Template that contains embedded data elements

Tech Spec (280pp)



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M11 TECHNICAL SPECIFICATION

Updated Step 2 Draft – For Second Public Consultation

14 March 2025

Provides a set of data element definitions aligned with the template specification

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回顾2 – CDISC Protocol相关标准

Protocol相关标准：

- SDTM.TDM (v1.0, 2004 to v2.1, 2024)
- BRIDG (v1.0, 2007 to v5.3.1, 2019)
- PRM (v1.0, 2009)
- USDM (v1.0, 2022 to v4.0, 2025)

CDISC PRM (Protocol Representation Model)

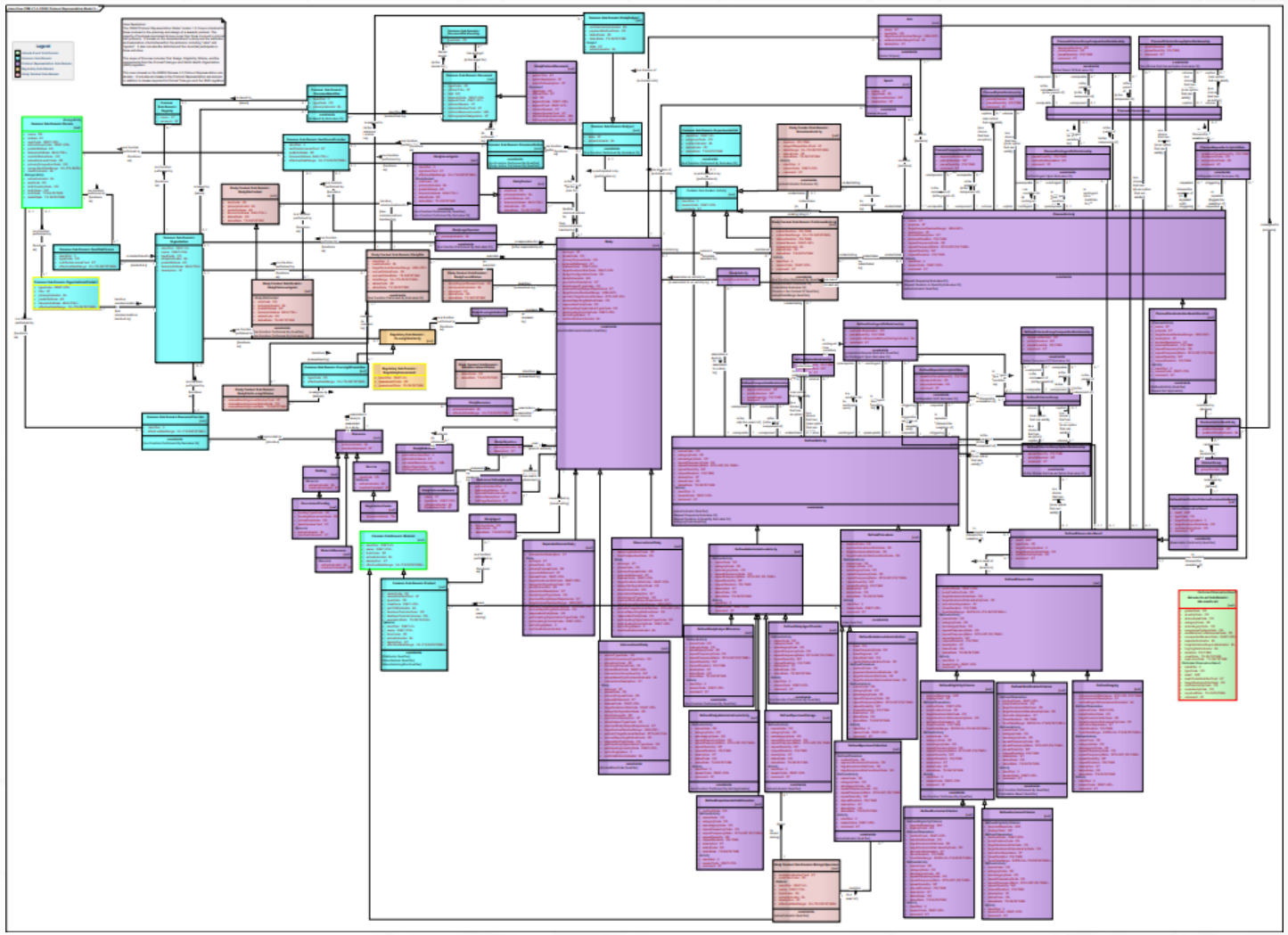
CDISC

The Protocol Representation Model
Version 1.0

Prepared by:

The CDISC Protocol Representation Group (PRG)

© CDISC, 2009 27/Jan/2010



CDISC New Strategic Goal

Expand and enable standards driven automation across the end-to-end study information lifecycle from study design through results
(CDISC will expand and realize the original 360 vision)

Expand & Connect

Expand, Connect, and Digitalize our Standards

Enable & Automate

Reduce Variability, Enable Interoperability, and Increase Automation

Engage & Adopt

Focus on Community Needs

Deliver Business Value

https://www.cdisc.org/cdisc-roadmap

End to End Study Information Lifecycle

Standards driven automation across the research information lifecycle

Collection ← Tabulation ← Analysis ← Endpoints ← Protocol

← **Design & Build**

Data Sources

Collection → Integration → Tabulation → Analysis → Endpoints → Report

→ **Execution**

https://www.cdisc.org/cdisc-roadmap

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回顾3 – TCB：Common Protocol Template (CPT)

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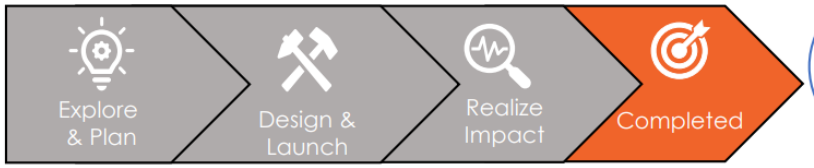
Clinical Content & Reuse (CC&R)

Formerly Common Protocol Template (CPT)

Create a common template suite for clinical trial information to ease interpretation and use, enable downstream automation of clinical processes and align to industry data standards

Project Life Cycle Phase:



Benefits:

- Develops harmonized format and streamlined content of key clinical trial documents
- Enables content reuse to downstream documents and registries
- Enables ease of review & interpretation
- Enables end-to-end use of metadata and traceability
- Improves access to protocol information
- Increases quality of clinical development

Solutions:

TransCelerate Clinical Template Suite (CTS) (2015-2024):
Basic Word Edition of the CPT(2015), SAP & CSR editions added in 2018

eCPT (2015-2024), eSAP, and eCSR (2019-2024):
Technology-enabled versions of the Clinical Template Suite.

CTS Implementation Toolkit (2015-2024):
Support materials for evaluation and implementation of solutions

Innovation & Collaboration
Procedures Library White Paper (2022), SoA Point of View Blog (2024), TransCelerate/ACRO: CSR Points to Consider for Disrupted Clinical Trials (2023), Master Protocol Design Considerations (2024)

回顾总结：eProtocol - ICH, CDISC, TCB

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ICH.E6
1996

ICH.E6
R2
2016

ICH改组
再出发

ICH.M11
2018

ICH.M11
2025-26?

CDISC
SDTM
开始
2002

CDISC
SDTM
v1.0
2004

CDISC
SDTM
v2.1
2024

2000 2005 2010 2015 2020 2025

CDISC
BRIDG
开始
2002

CDISC
BRIDG
v1.0
2007

CDISC
BRIDG
V5.3.1
2019

CDISC
PRG
开始
2004?

CDISC
PRG
v1.0
2009

cdisc USDM
UNIFIED STUDY DEFINITIONS MODEL (DDF)

TCB
CPT
开始
2005

TCB
CPT
结束
2024

Digital Data Flow

ROI
Use cases
Business
People

eProtocol – Industry Collaboration

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③

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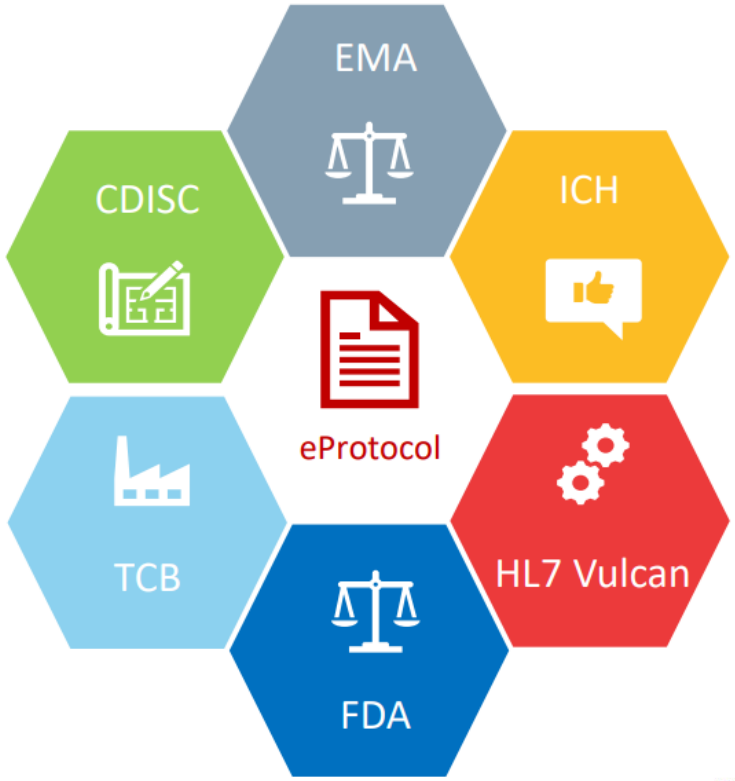
Unified Study Definitions Model (USDM) Reference Architecture

TransCelerate's Study Definitions Repository (SDR)

TCB Digital Data Flow ②



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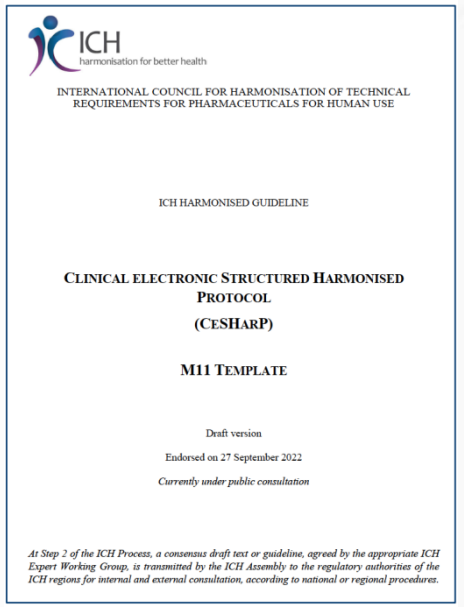

ICH
harmonisation for better health

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

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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.

PROJECT PRISM

A Regulatory Cloud Collaborative Initiative

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

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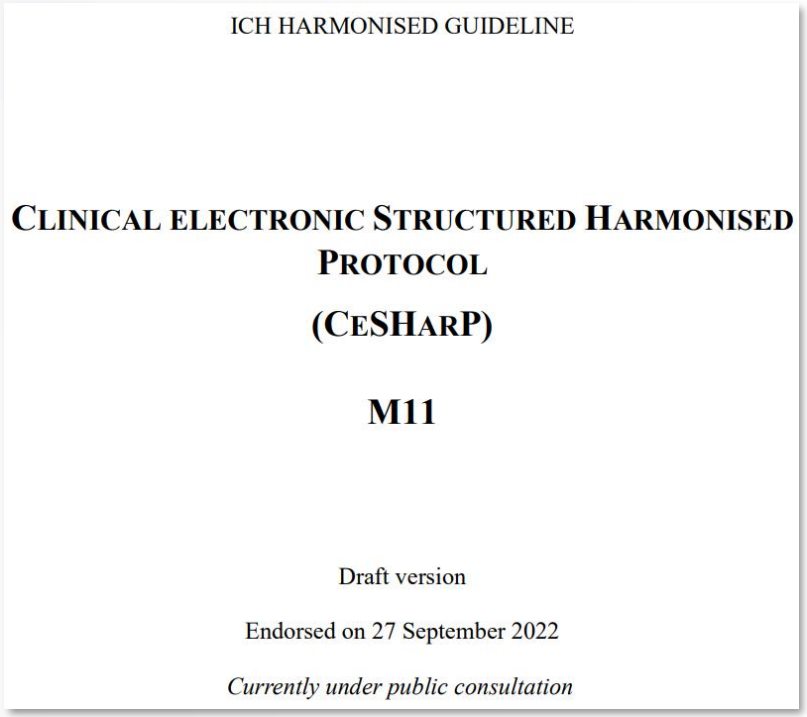
① ICH – M11 Clinical electronic Structured Harmonised Protocol (CeSHarP)

Guideline (7pp)



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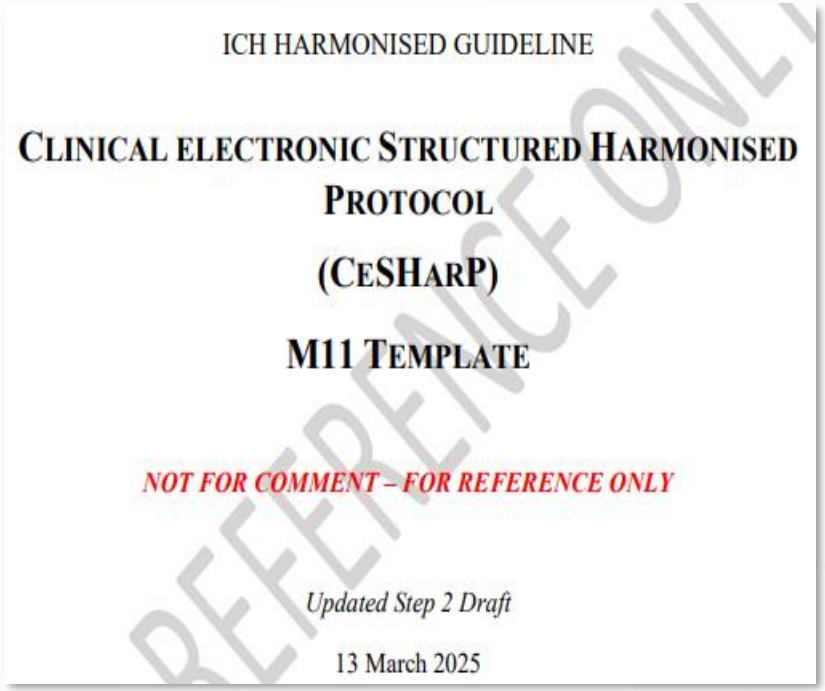

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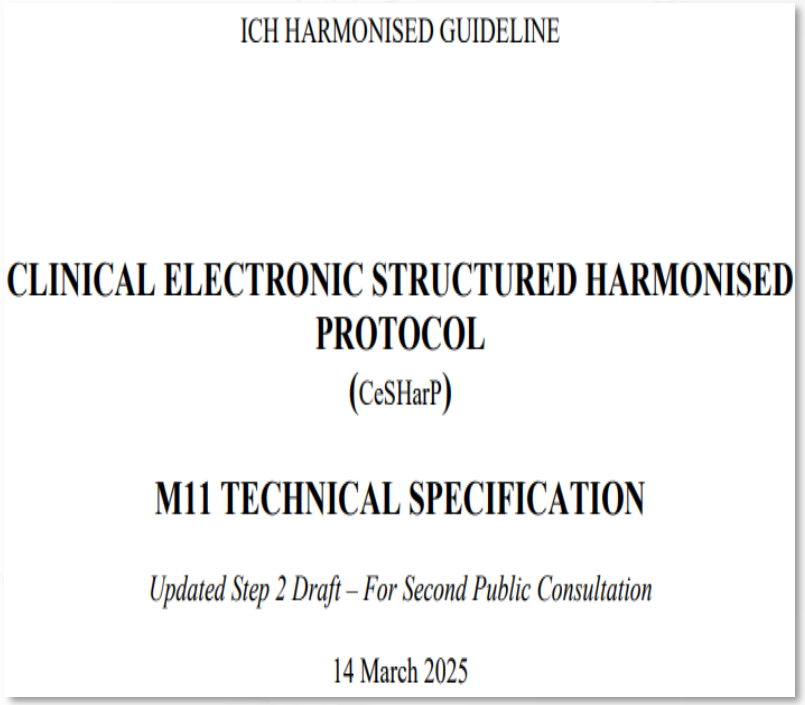

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M11 - Guideline

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3. TEMPLATE CONVENTIONS AND DESIGN 4

M11 – Guideline – Design Principles

Protocol Template – Principles

- **Build common core content**
- Serve the needs of stakeholders
- **Define content for electronic exchange**
- Design for content re-use
- Maintain flexibility

Protocol Tech Specs – Principles

- **Promote structured common core content**
- Define content specifications for electronic exchange
- **Develop a data model based on specifications**
- Focus on relevant content use and re-use
- **Use an open, non-proprietary exchange message standard**
- Maintain flexibility for technical innovation and region-specific use

ICH – M11 eProtocol TEMPLATE & Tech Spec

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5.6 Screen Failures
6 TRIAL INTERVENTION AND CONCOMITANT THERAPY
6.1 Description of Trial Intervention

1 PROTOCOL SUMMARY

No text is intended here (header only).

1.1 Protocol Synopsis

The protocol synopsis is a short summary of the key points of the trial.

No text is intended here (header only).

Primary and Secondary Objectives and Endpoints

Include a copy of the Objectives/Endpoints Table including primary and secondary endpoints only from Section 3 of the protocol and follow all the same instructions. Not all trials will have a complete estimand. Do not include exploratory endpoints in the synopsis.

[Primary and Secondary Objectives and Endpoints]

Overall Design

Several key aspects of the trial design are summarised below.

Intervention Model:	[intervention model]	**Population Type:**	[population type]
Control:	[control]	**Population Diagnosis or Condition:**	[diagnosis or condition]
Active Comparator:	[comparator]	**Population Age:**	Minimum: [minimum age] – Maximum: [maximum age]
Trial Intervention Assignment Method:	[intervention assignment method]	**Site Distribution:**	[geographic scope]

Briefly state the following:

- Intervention model (for example, single group, parallel group, cross-over, factorial, sequential).
- Control (for example, placebo, active comparator, low dose, historical, standard of care, sham procedure, or none [uncontrolled]).
- Active comparator, if applicable; indicate N/A if not applicable.
- Trial intervention assignment method (for example, randomisation, stratification, or both). Do NOT state block size. If assignment to intervention is by randomisation, describe when randomisation occurs relative to screening.

Term (Variable)	Intervention Model
Data Type	Pick List
Topic, Value or Header	D
Definition	
User Guidance	Intervention model (for example, single group, parallel group, cross-over, factorial, sequential, other)
Conformance	Required
Cardinality	
Relationship content from ToC representing the protocol hierarchy	Protocol Summary
Relationship (reference to high level conceptual model)	
Value	Single group, parallel group, cross-over, factorial, sequential, other
Business rules	**Value Allowed:** Yes **Relationship:** n/a **Concept:** n/a
Duplicate field in other sections	

Term (Variable)	Control
Data Type	Pick List
Topic, Value or Header	D
Definition	
User Guidance	Control method (for example, placebo, active comparator, low dose, historical, standard of care, sham procedure, or none [uncontrolled])
Conformance	Required
Cardinality	
Relationship content from ToC representing the protocol hierarchy	Protocol Summary
Relationship (reference to high level conceptual model)	
Value	placebo, active comparator, low dose, historical, standard of care, sham procedure, or none [uncontrolled]
Business rules	**Value Allowed:** Yes **Relationship:** n/a **Concept:** n/a
Duplicate field in other sections	

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② TCB Digital Data Flow (DDF) Initiative

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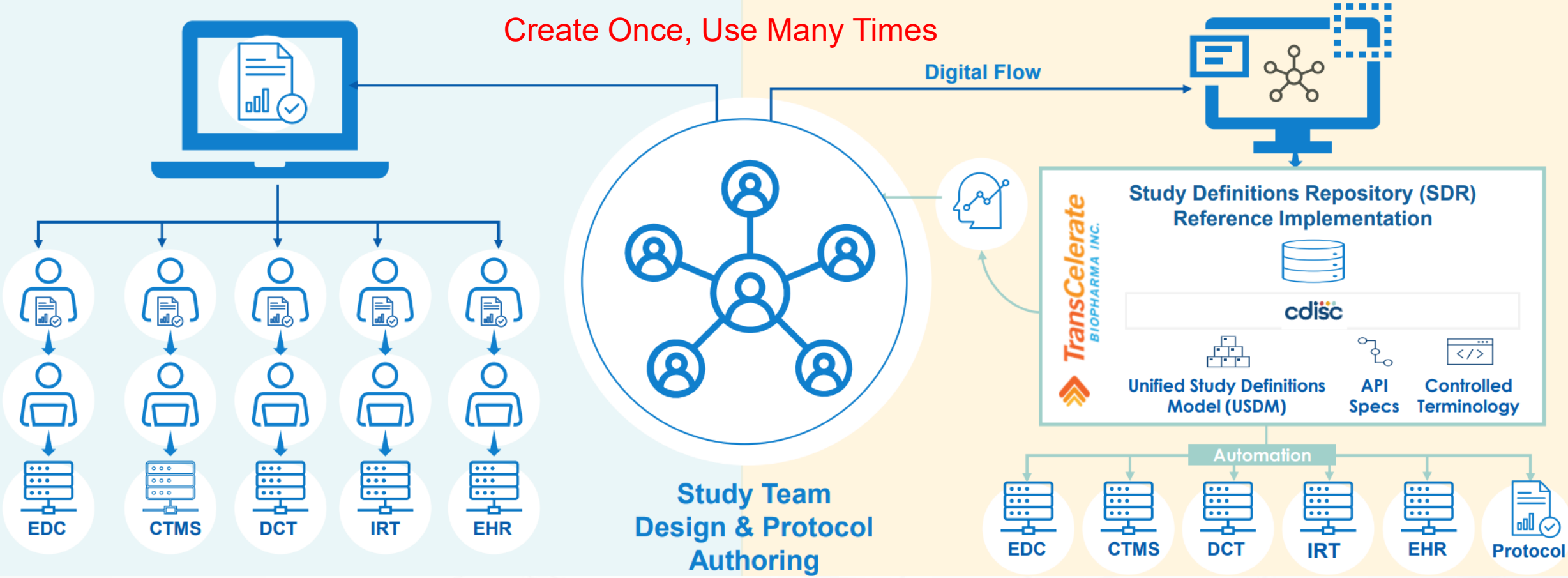
TODAY: Document-based paradigm for protocol creation, interpretation, and transcription into consuming systems

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

Create Once, Use Many Times



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

TCB DDF Initiative Three Key Principles

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Engage with critical stakeholders

- Sponsors
- Solution Providers
- CROs
- Health authorities
- Clinical study sites

Development of clinical protocol standards

- CDISC
- ICH M11
- CC&R initiative (Common Protocol Template)
- Vulcan HL7 FHIR

Encourage development of technical solutions

- Vendor-agnostic, platform-independent framework for end-to-end digitalization
- Eventual industry-led governance for long-term sustainability of DDF solutions

TCB DDF Initiative Roadmap

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Introduce clinical trial protocol standards

- Partnered with CDISC for standards development (USDM)
- USDM encapsulates all sections of a protocol allowing for the generation of an entire protocol document

Introduce reference implementation for end-to-end digitalization

- Study Definitions Repository (SDR) Reference implementation of a novel central component to manage data flow
- SDR open-source code available on a public GitHub site for use and feedback by the open-source community

Introduce mechansims for industry adoption

- Toolkits development
- Solutions forum
- Community meetings
- Other efforts (not exhaustive)

Setup a long-term sustainable governance model for DDF

- Industry-run governance model

DDF Evolution: Phases One to Four

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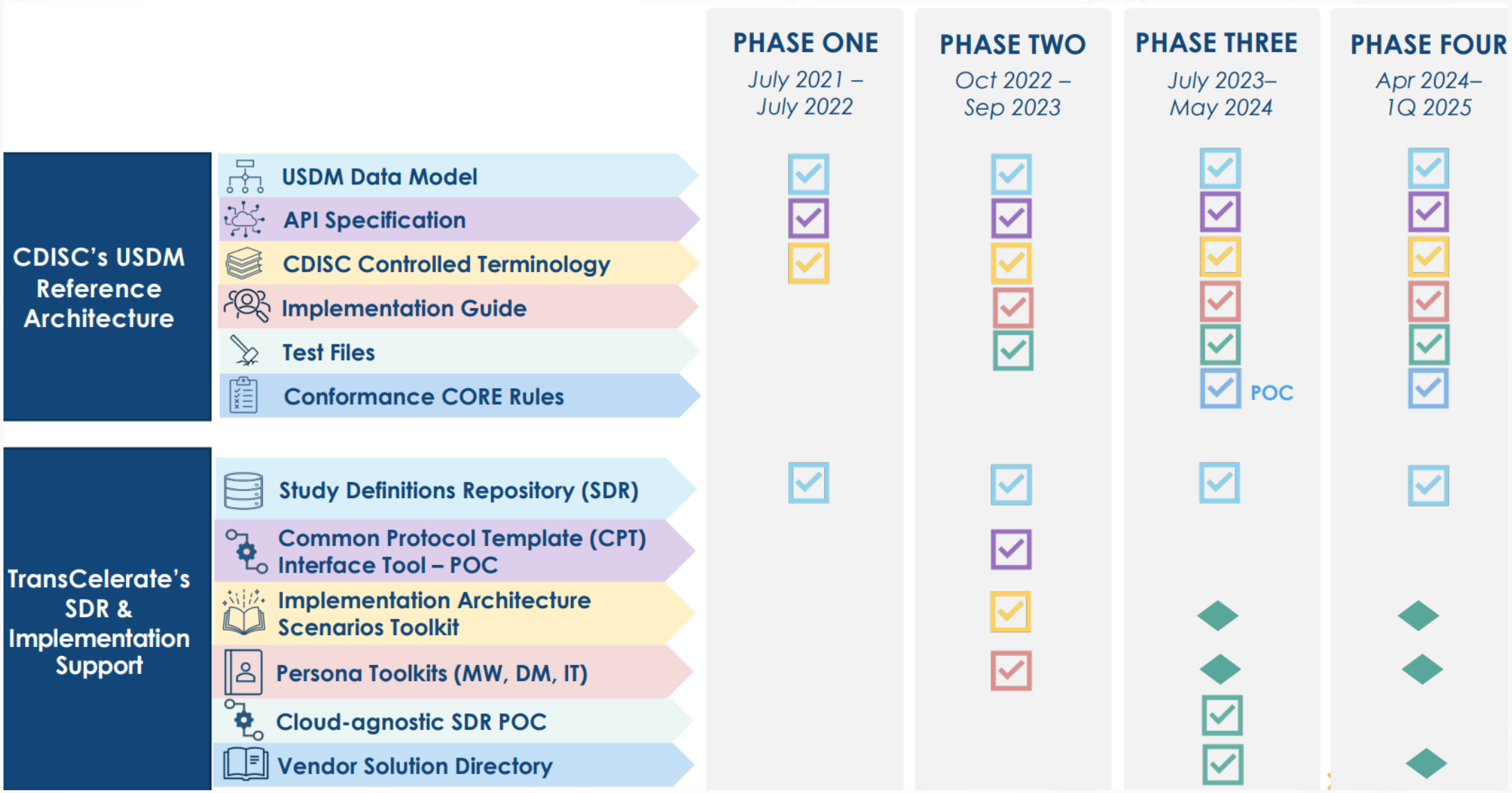

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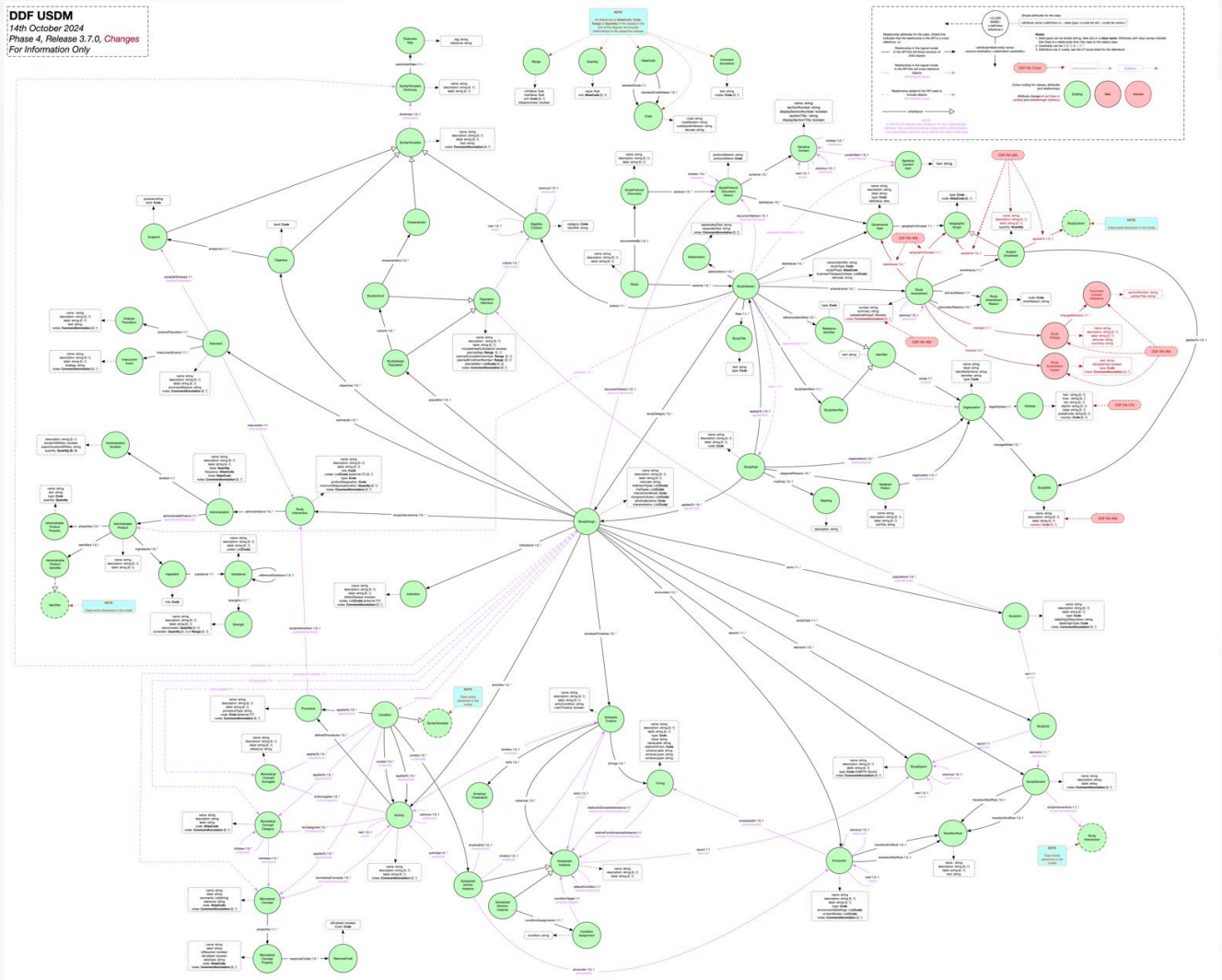
③ CDISC - USDM Standard & DDF



Unified Study Definitions Model (USDM) Phase 4 Graphic, source: https://github.com/cdisc-org/DDF-RA

Controlled Terms	Study, Identifiers, Amendments
Estimands Populations Inclusion & Exclusion Interventions & Indications Objectives & Endpoints	Unstructured Content
	Study Designs, Arms, Epochs
	Detailed Study Logic, Encounters
Procedures, Biomedical Concepts	

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CDISC - USDM IG (V4.0 final, 119pp)

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Unified Study Definitions Model Implementation Guide (USDM-IG)

Version 4.0 (Final)

Prepared by the DDF Team

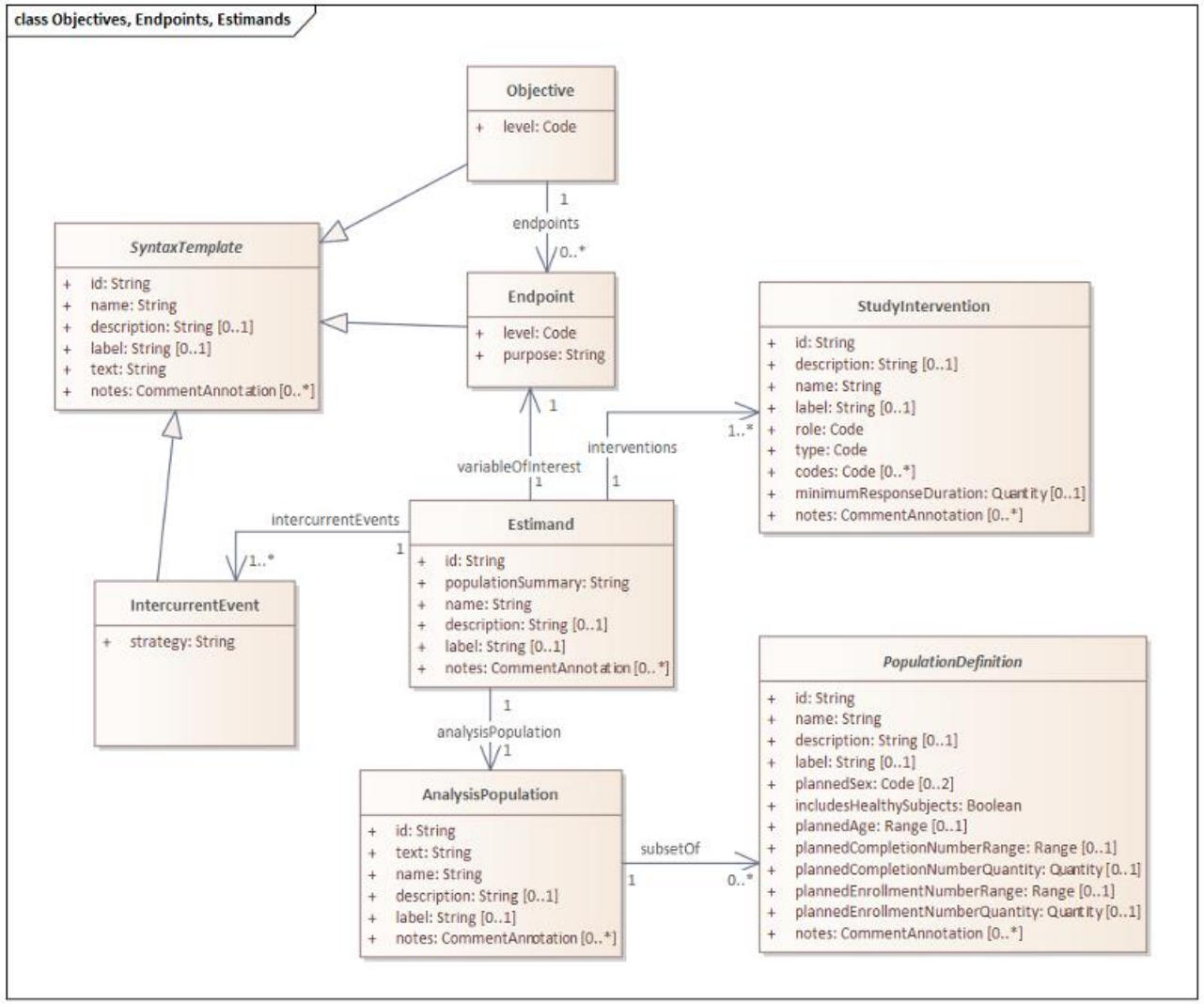
Notes to Readers

This is the final Version 4.0 of the Unified Study Definitions Model Implementation Guide (USDM-IG v4.0).

Revision History

Date	Version
2025-06-03	4.0 Final
2024-04-16	3.0 Final
2023-06-07	2.0 Final
Not applicable*	1.0

*No USDM-IG was developed for USDM Version 1.0.



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CDISC USDM & DDF Resources

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

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

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

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

CDISC DDF Website	**DDF Website**	**DDF GitHub Repos**	**TransCelerate DDF Initiative Solutions**
You are here! Learn about and access the Unified Study Definitions Model (USDM) Reference Architecture supporting Digital Protocol Data Standards	As the main website for the DDF initiative, learn and access all resources for DDF solutions	Learn about a technical Reference Implementation of the USDM, the Study Definitions Repository (SDR), and access the supporting codebase	Learn about DDF Initiative background and roadmap
Target Audience: All those interested in data standards	**Target Audience:** All those interested in implementing DDF Solutions	**Target Audience:** All those interested in SDR development	**Target Audience:** All those generally interested in TransCelerate initiatives

https://www.cdisc.org/ddf

DDF Use Cases

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From machine actionable Protocol authoring to automation of downstream connectivity

Study Design → Study Start-up → Study Execution / Data Acquisition → Analysis & Reporting → Regulatory Submission Enablement

Protocol development to approval

Connectivity to downstream systems

Use cases to improve study design and analytics

- Predictive model - likelihood of Amendments
- Ingestion and mining of retrospective protocol data
- Compute protocol complexity, site burden, etc
- Optimizing Inclusion / Exclusion Criteria
- Determine study feasibility including subject recruitment

Use cases to automate downstream processes and enable E2E traceability

- Setup of data capture systems
- Generation of SDTM Trial Design datasets
- Provision of study information to a Clinical Trial Registry
- Publishing Protocol Data into different document templates/views
- Update CTMS, TMF, and other downstream systems

"As a medical writer, the digitalization of data flows enables me to work faster with my team on one dedicated system, accessing study content in a single digital study design system.

"As a data manager, the digitalization of end-to-end processes from study design to EDC generates structured data that can be leveraged to track outcomes and progress made.

"As a technical expert, the digitalization of data flows reduces tedious manual work freeing up time for more complex projects that cannot be automated (value-added activities focus).

e-Protocol潜在应用场景和可能影响

- Protocol Authoring (incl. ICH M11)
  Tools for protocol authoring, review, analysis etc

- Clinical trial registries (ct.gov, CDE临床试验注册平台)
- EDC/IRT
- CTMS/TMF

- SDTM.TDM
- Define.XML
- …

Business
Use cases
ROI
People

CDISC E2E Standards Driven Automation

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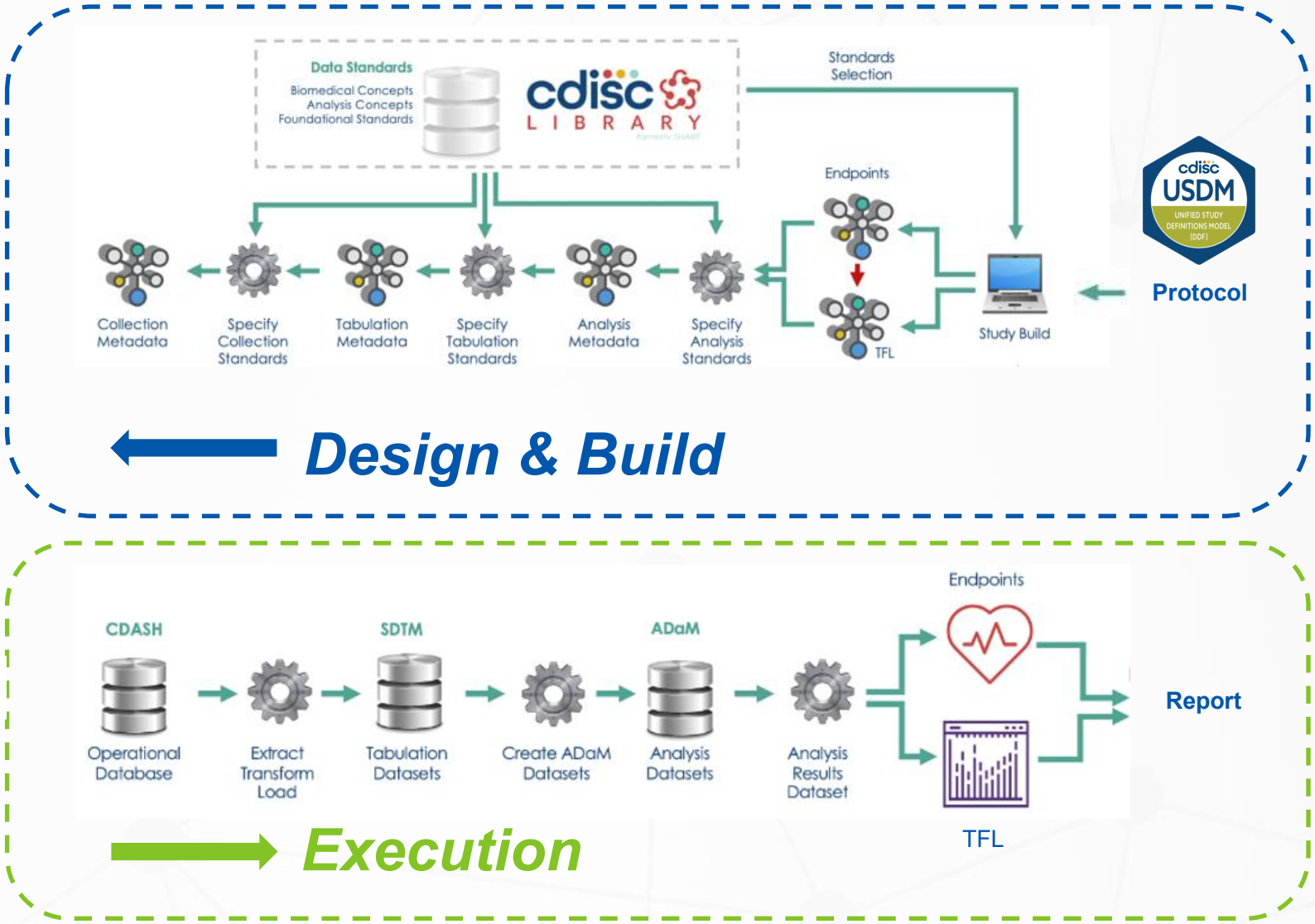
Expand and enable standards driven automation across the end-to-end study information lifecycle from study design through results



Summary – Key Messages

1. Learn hard and think hard - how to put it into business
2. Use cases – need strong evidence for implementation
3. ROI
4. Data – Tools – AI
5. China

References

1. **ICH** E6 (GCP), M11 (eProtcol) https://www.ich.org/page/ich-guidelines
2. **CDISC** SDTM.TDM, BRIDG, PRM, USDM https://www.cdisc.org/ddf
3. **TCB** CPT, DDF https://www.transceleratebiopharmainc.com/initiatives/digital-data-flow/
4. **HL7** Vulcan.FHIR https://www.hl7vulcan.org/
5. **US FDA** Project PRISM https://www.fda.gov/about-fda/office-digital-transformation/precisionfda

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Q&A