Navigating ICH M11, CDISC and USDM on the Path to a Digital Protocol

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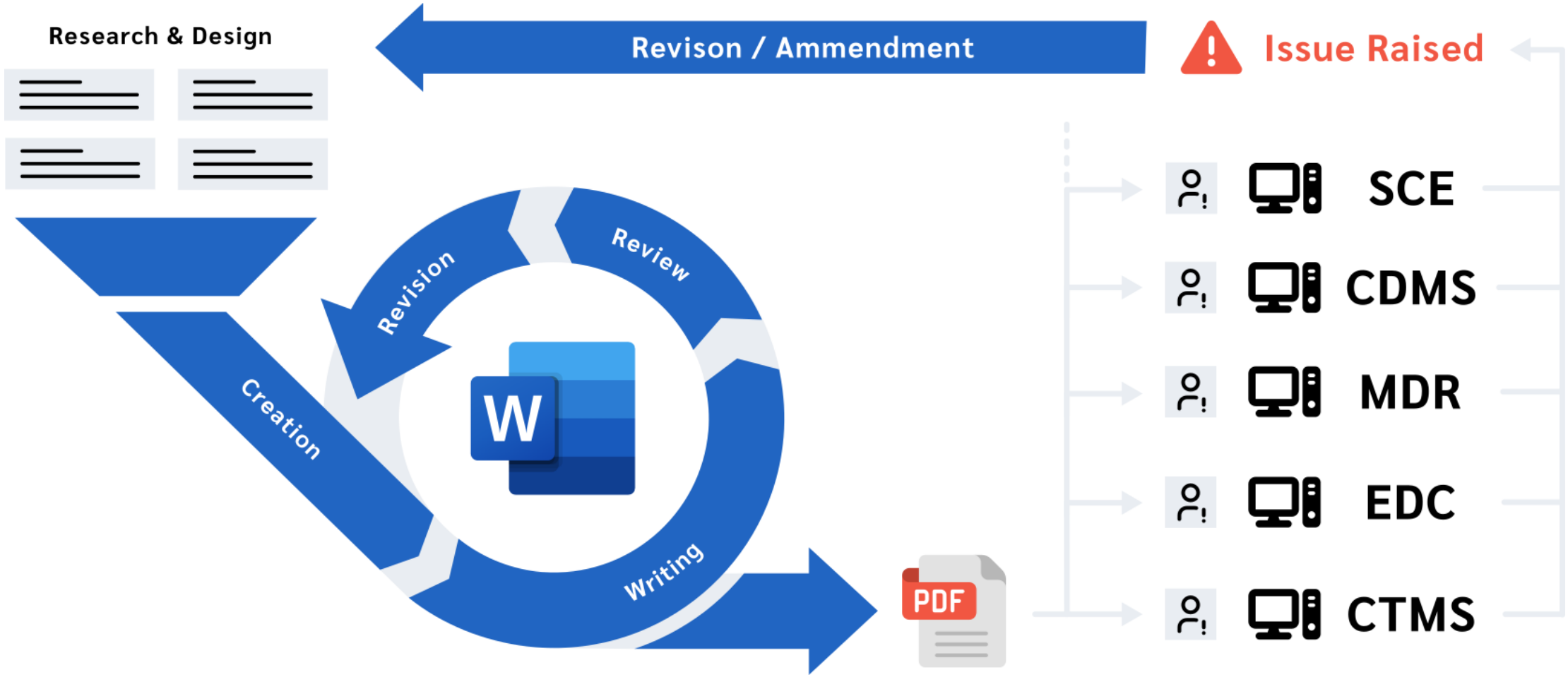
Current Practice

A document centric approach

- It lacks consistency across the industry
- Its unstructured and must be manually transcribed
- It is duplicated and fragmented downstream



What's Happening Now

Changes within the industry

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The Document Model Dichotomy

Dave Iberson-Hurst - Partner at d4k
Clinical Data Standards | Innovative Technologist | Clinical Metadata & Data Expert | Working for Better Data

Regulatory Bodies

FDA

EMA
EUROPEAN MEDICINES AGENCY

Bundesinstitut für Arzneimittel und Medizinprodukte

pmda

MHRA
Regulating Medicines and Medical Devices

.....

ICH
harmonisation for better health

M11 Technical Specification & Guidelines

Consistency

VULCAN ~UDP

UDP: Utilising the Digital Protocol

VULCAN HL7 FHIR

Integration Through FHIR

Use Cases & Reference Applications

FHIR Implimentation Guides

cdisc

TransCelerate BIOPHARMA INC.

Digital Data Flow (DDF)

USDM: Operational Model

Controlled Terminology

The ICH M11 Specification

What's included in the template

Clinical Electronic Structured Harmonised Protocol (CeSHarP)

2 INTRODUCTION

No text is intended here (header only).

2.1 Purpose of Trial

Explain why the trial is needed, why the research questions being asked are important. Do not restate the IB.

[Purpose]

Refer to the Section 1.2, Trial Schema, and Section 1.3, Schedule of Activities, for more information about the trial design.

2.2 Summary of Benefits and Risks

Include an assessment of known benefits and potential risks, including the basis of the risk (for example, preclinical studies or prior clinical trials).

Benefit Summary

The benefit summary should be written from the perspective of an individual participant, and should describe any physical, psychological, social, legal, or any other potential benefits to individual participants as a result of participating in the trial, addressing immediate potential benefits and/or long-range potential benefits. Clearly state if no benefits to an individual participant can be anticipated, or if potential benefits are unknown. For early clinical trials such as Phase 1, benefits for an individual participant (other than those of altruism) are expected to be minimal.

Benefits to society in general may also be included but should be discussed separately.

[Benefit Summary]

Risk Summary and Mitigation Strategy

Black: Required Text

Blue: Optional Text

Red: Guidance

3 TRIAL OBJECTIVES, ENDPOINTS AND ESTIMANDS

In this section, precisely define each clinical question of interest by stating each trial objective and specifying the endpoint(s) and estimand(s) that correspond to each objective. Ensure alignment with every other section of the protocol.

Include additional level 2 headers under Section 3 Trial Objectives, Endpoints, and Estimands as needed.

No text is intended here (header only).

3.1 {Primary/Secondary/Exploratory} Objective + Associated Endpoint {and Estimand}

{Primary/Secondary/Exploratory} Objective	{Primary/Secondary/Exploratory} Endpoint
[Objective]	[Endpoint]

{Primary/Secondary/Exploratory} Estimand

Describe the attributes that construct the estimand: the treatment condition of interest, the population of participants targeted by the clinical question of interest, other intercurrent events (if applicable), a population level summary, and the endpoint (or variable) specified in the table above.

[Estimand Description]

The ICH M11 Specification

The technical specification

Clinical Electronic Structured Harmonised Protocol (CeSHarP)

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Term (Variable)	Purpose of Trial
Data Type	Text
Topic, Value or Header	D
Definition	Clear explanation of the research question/hypothesis and the justification of the trial i.e. why the question is worth asking and, through consultation with public and patient groups, why answering this question is worthwhile to patients.
User Guidance	Explain why the trial is needed, why the research questions being asked are important and, where applicable, why closely related questions are not being covered. Do not restate the IB.
Conformance	Required
Cardinality	
Relationship content from ToC representing the protocol hierarchy	Introduction
Relationship (reference to high level conceptual model)	
Value	
Business rules	**Value Allowed:** n/a **Relationship:** n/a **Concept:** n/a
Duplicate field in other sections	

- Here we are following the [Purpose] through to the technical specification which defines it
- The template and technical spec follow the same order

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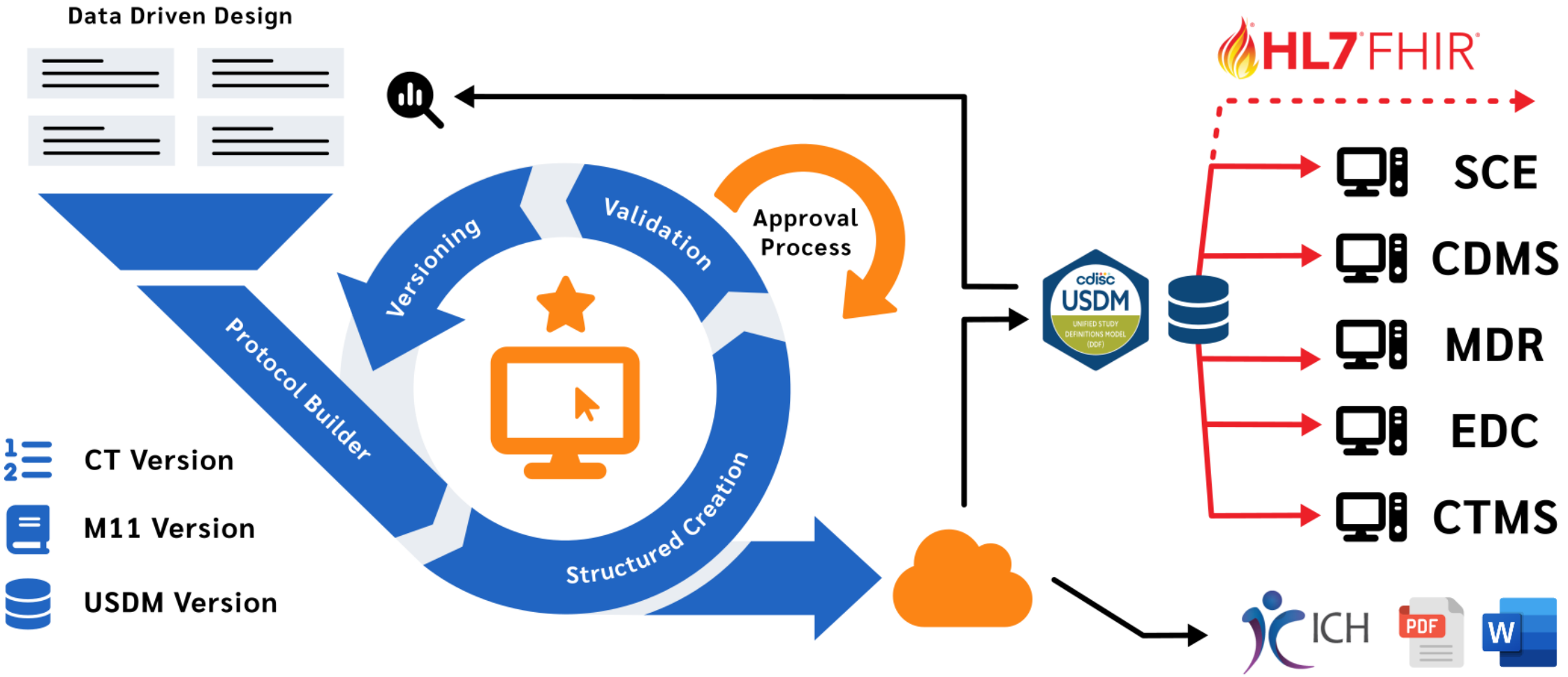
What We Have Explored

Starting from the beginning

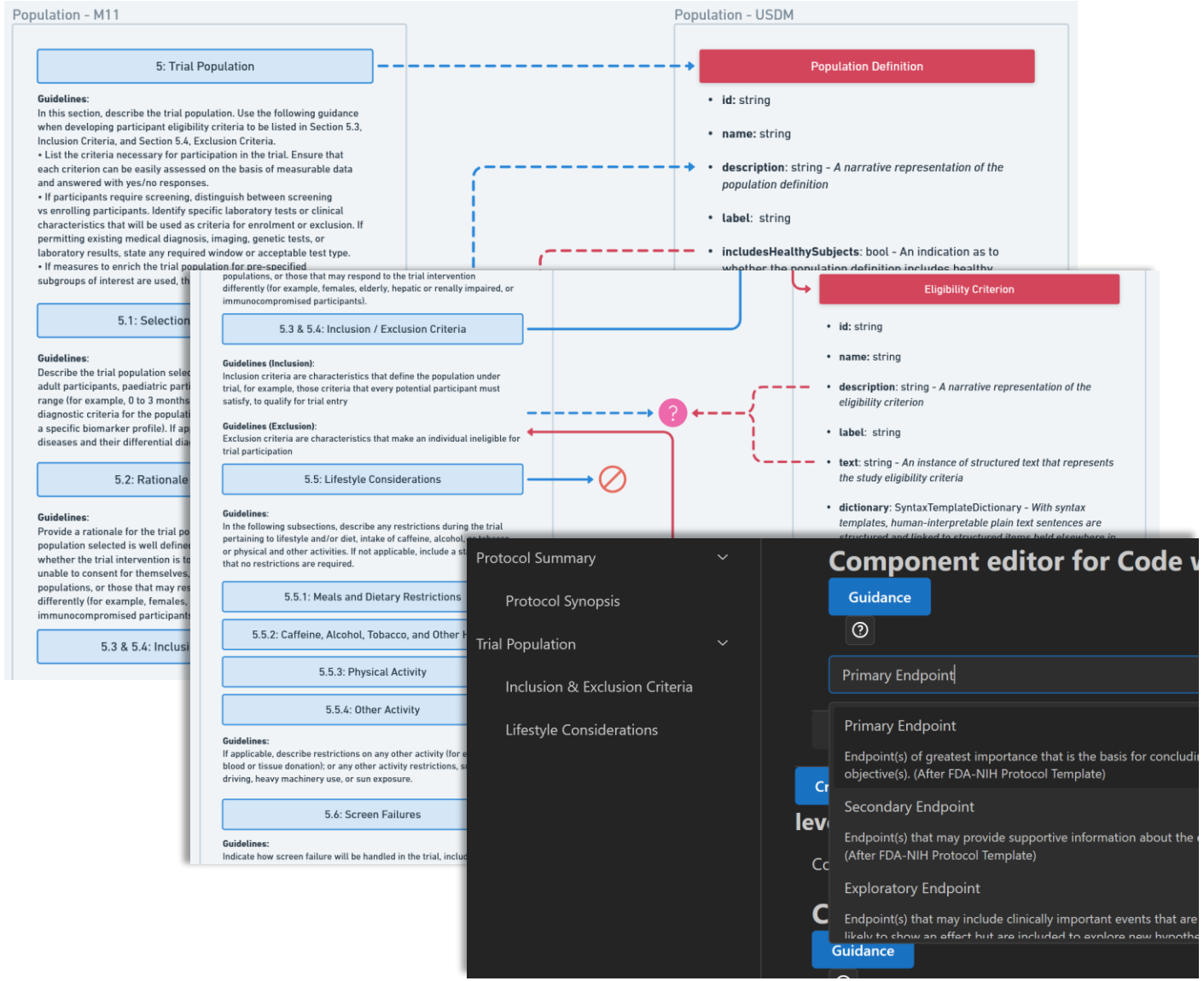
- The pain points of protocol creation
- Using the draft M11 specification in practice
- Harmonise USDM, M11, CT and guidance



What We Found

Rome wasn't built in a day

- The path from M11 to USDM is unclear (So far!)
- The M11 specification has further to go (Coming soon!)
- USDM has further to go (Coming soon!)
- A digital protocol presents many opportunities for innovation
- We can do a lot to improve the user experience of protocol writing



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Vision of the Future

What could the digital protocol lead to?

Maturation of the Digital Protocol

Machine-readable protocols become the norm, boosting efficiencies and reducing manual transcription errors

A Fully Digitized, End-to-End Trial Process

Study design, regulatory submission, and execution are fully digitized, enabling real-time updates, dynamic adaptation and new insights.

Wearables and digital tools empower patients with continuous monitoring, deeper insights, and greater involvement in their own care

The Protocol Document Becomes an Artifact

The operational model for protocol data becomes the authoritative source of truth, shifting from a static document to an intelligent data model that drives innovation.

These standardised data models form the basis for a new chapter in healthcare interoperability.

AI-Driven Analytics and Decision Support

Digitization forms the backbone of AI-powered insights and optimisations, driven by new models.

Leveraging AI and historical trial data, patient demographics, and real-world evidence drives a new approach to research.

A Fully Connected Ecosystem

Digital twins and virtual trials emerge driven by advances in quantum computing, simulated trials become the standard starting point for clinical research…

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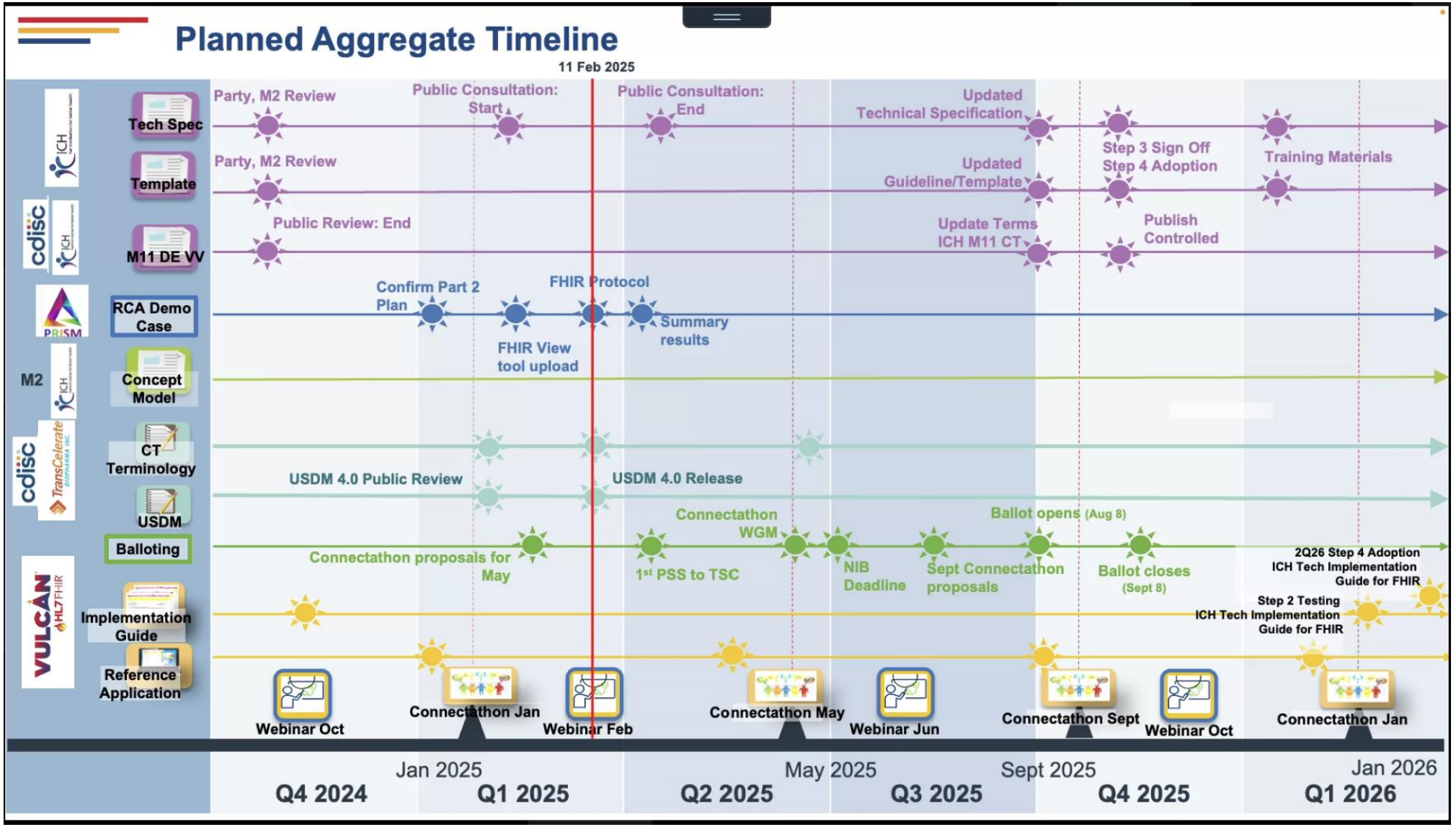
Industry Timeline Vulcan UDP

UDP Webinar

Vulcan UDP webinar timeline



Industry Timeline Highlights

Events and releases to watch for

ICH M11 Work Plan & Endorsed Documents

Feb 2025

USDM V4 Release

The latest version of USDM, bringing additional attention to backwards compatibility, alignment with the evolving ICH M11 standard and support for a wider range of study types.

March 2025

End of M11 public consultation

The latest public consultation period for M11 ends in the run up to the new M11 release. Keep an eye out for the latest overview of comments received on the EMA website.

Jun 2025

Vulcan UDP Webinar

HL7 Vulcan - Utilising the Digital Protocol (UDP) webinar with updates from industry experts & regulators

Sept 2025

M11 Revision Release

Release of revised controlled terminology, protocol template and technical specification based on feedback from public consultation.

Feb 2026

ICH IG for FHIR

Testing of the latest FHIR implementation guide begins

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Thank you!

Learning Objectives

1. Current practice is very “document” centric and consequently is fragmented, unstructured and lacks consistency
2. There is collaborative development work going on around ICH M11 “the standard protocol” by Vulcan, Transcelerate & CDISC
3. Identify some of the practical implications of putting this into practice, as there are many hurdles
4. Be aware of the future implications of a digital protocol

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