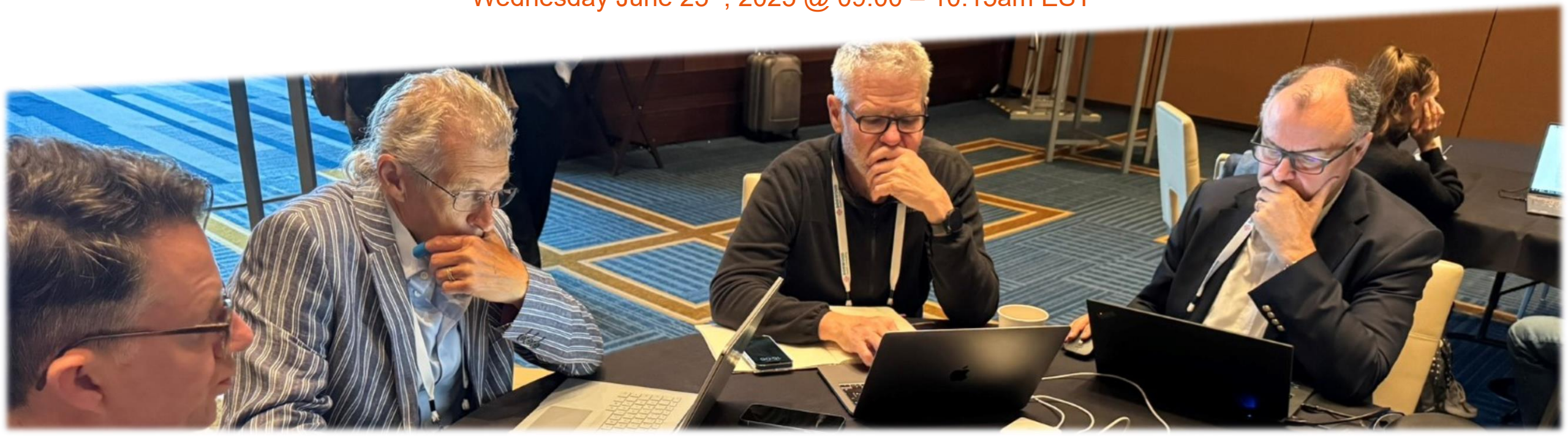
Vulcan UDP (Utilizing the Digital Protocol):

What's Next in Accelerating ICH M11 Adoption:

Vulcan UDP Implementation Guide

Wednesday June 25th, 2025 @ 09.00 – 10.15am EST



VULCAN WEBINAR

HL7 FHIR

Vulcan UDP (Utilizing the Digital Protocol): What's Next in Accelerating ICH M11 Adoption:

Vulcan UDP Implementation Guide

UDP is an umbrella project to accelerate exchange of ICH M11 Clinical electronic Structured Harmonized Protocols through collaboration and integration of work products across Vulcan, CDISC and TransCelerate.

VULCAN HL7 FHIR TransCelerate BIOPHARMA INC. cdisc

PANELISTS

Hugh Glover
Vulcan UDP Technical Lead
VULCAN HL7 FHIR

Mary Lynn Mercado
Global Head Protocol Delivery & US Head, Regulatory Writing Submissions
NOVARTIS TransCelerate BIOPHARMA INC.

Stacy Tegan
TransCelerate Program Director
Vulcan UDP Project Lead
TransCelerate BIOPHARMA INC.

Welcome to the Utilizing the Digital Protocol Webinar

Time	Topic	Speaker
Welcome and Introduction		
5 mins	**Kick-off and ground rules and Introductions**	Shani Sampson
Speaker Presentations		
10 mins	**ICH M11** ○ Recent progress update ○ Roadmap to finalization	Mary Lynn Mercado
10 mins	**Vulcan UDP Implementation Guide (IG)** ○ Preview of the IG being developed including the inputs from the recent Connectathon ○ Starting the IG lifecycle now with a vision toward the future	Hugh Glover
10 mins	**Balloting the Vulcan UDP IG** ○ The HL7 ballot process and its role in reaching publication ○ **Call to action:** How to get involved	Hugh Glover
15 mins	**Catalyzing Connections to Accelerate Impact** ○ How Vulcan UDP fits with other protocol-related initiative ○ Get prepared! Planning for implementation in your organization	Stacy Tegan
20 mins	**Moderated Q&A**	All
Wrap-Up		
5 min	**Close**	Shani Sampson

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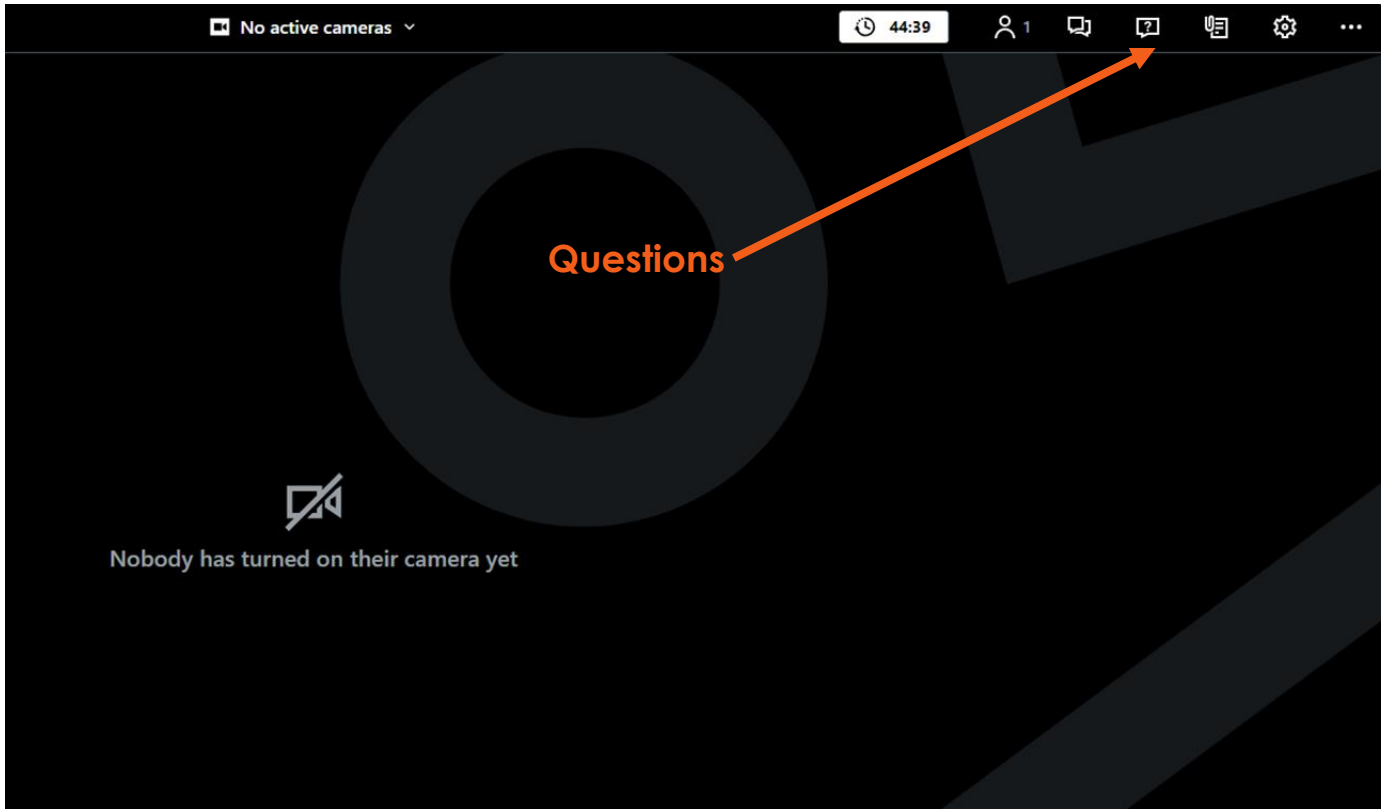
Logistics for the Webinar

- **All participants will be muted for this call.**
- **For audio**: Connect to audio to listen to presentations via your computer or phone
- **To submit a question to the presenters**:
  - Type your question in the Questions panel and click Send.

Reminder: This webinar may be recorded in whole or in part



Ground Rules

- **We want to make this discussion helpful and answer as many of your questions as we can, so here are some quick ground rules:**
  - Participation is voluntary, as is using TransCelerate assets/tools
  - The responsibility for compliance with laws and regulations is owned by the solution adopter
  - You don't have to identify what company you work for
- **Things we would ask you not to post questions on:**
  - For clinical trial sponsors, what vendors/sites/CROs a company is working with or not working with
  - For tech companies, vendors, CROs, & others, what pharma companies you work with or don't work with
  - Any issues/criticisms companies have with any vendors, tech company, sites, CROs, or sponsors
  - Future and long-term development plans
  - Anything related to pricing or costs -- what you pay for the purchase off or receive for the sale of any goods or services
- **We can't answer questions about:**
  - Specific vendors or other business partners with whom member companies are working
  - Costs of using/implementing TransCelerate assets/tools
  - Which member companies are using or going to use any TransCelerate solution or any commercial product or service

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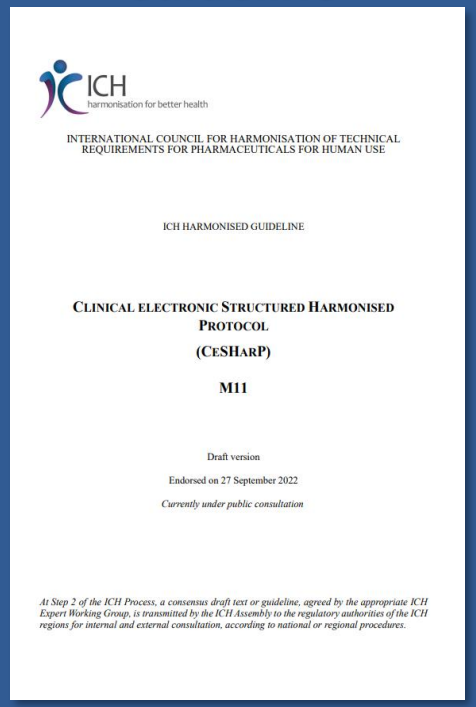
What is ICH M11 and where is it today?

Step 2

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

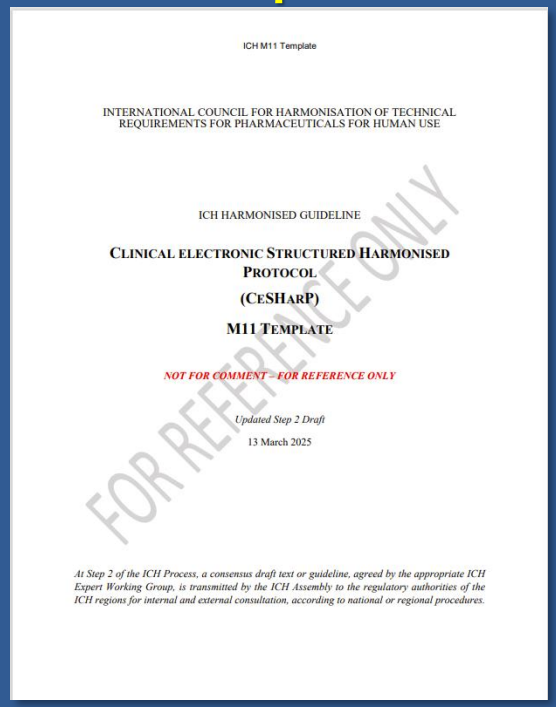
Draft version

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.

Template



ICH M11 Template

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

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

M11 TEMPLATE

NOT FOR COMMENT – FOR REFERENCE ONLY

Updated Step 2 Draft

13 March 2025

FOR REFERENCE ONLY

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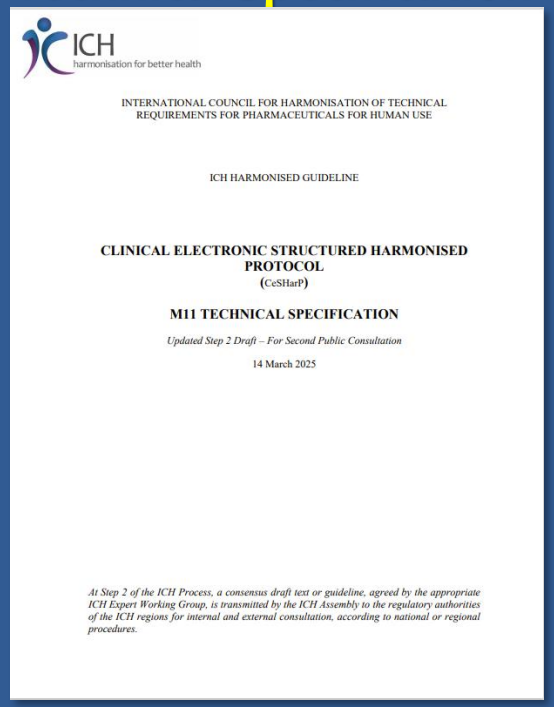
Technical Specification



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(CeSHarP)

M11 TECHNICAL SPECIFICATION

Updated Step 2 Draft – For Second Public Consultation

14 March 2025

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.

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..what we know about ICH progress toward the finish line…

Step 3

Early 2025

Regional Public Consultation

May ICH M11 Meeting in Madrid

	ICH M11 EWG Workplan 14 February 2025 https://database.ich.org/sites/default/files/ICH_M11_EWG_WorkPlan_2025_0214.pdf
Oct. 2025	Updated Guideline, Template and Technical Specification
Nov. 2025	Step 3 Sign-off & Step 4 adoption of the Guideline, Template and Technical Specification
Jan. 2026	Final versioned training materials

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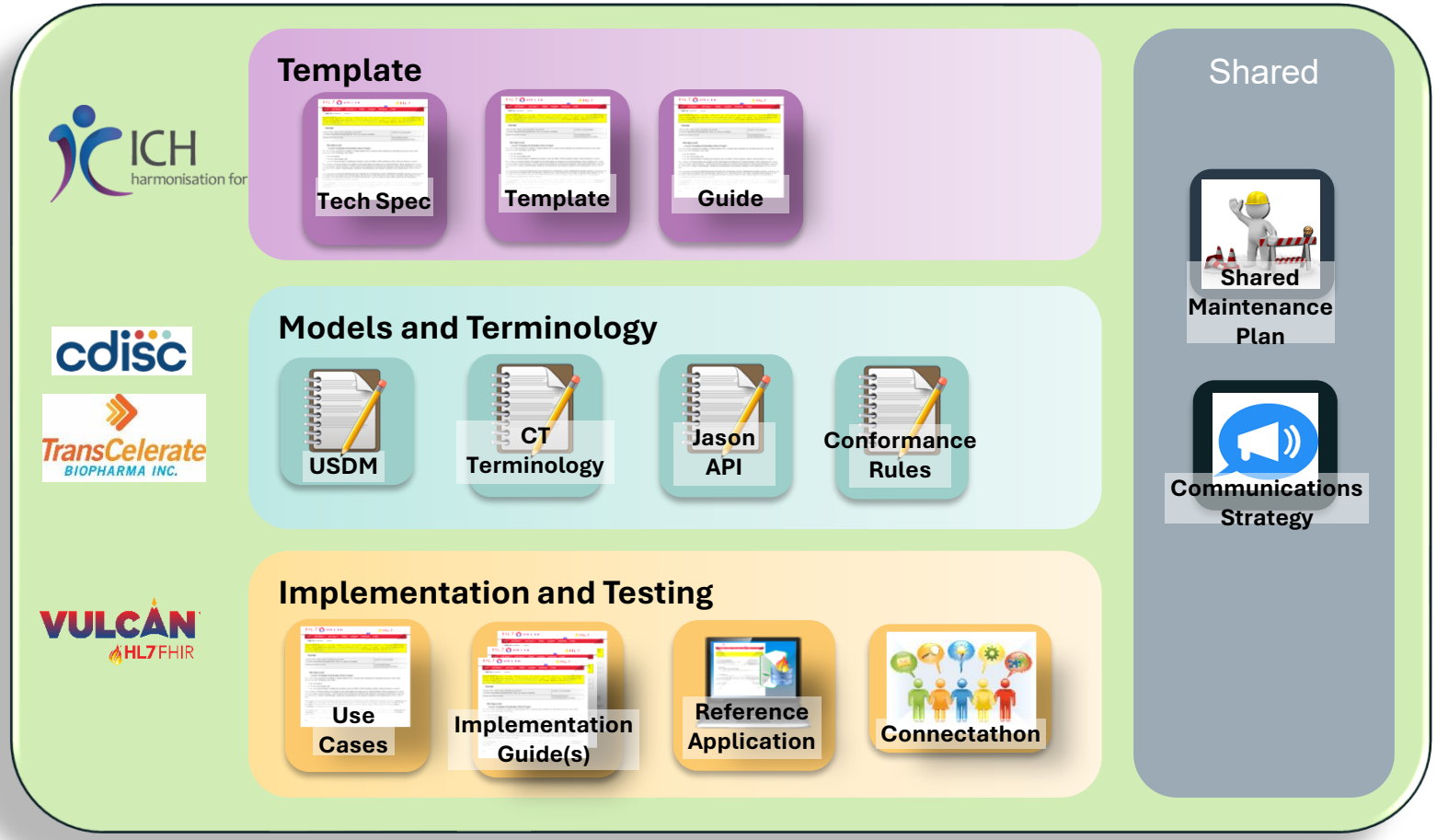
https://www.ich.org/page/multidisciplinary-guidelines

Collaboration for Connectivity and Compatibility



- ICH M11 Foundation
  - ICH M11 template
  - ICH M11 technical specification
  - Models, definitions
- FHIR will carry CDISC Controlled Terminology and content aligned to USDM
- The technical specification can be used to develop other Implementation Guides

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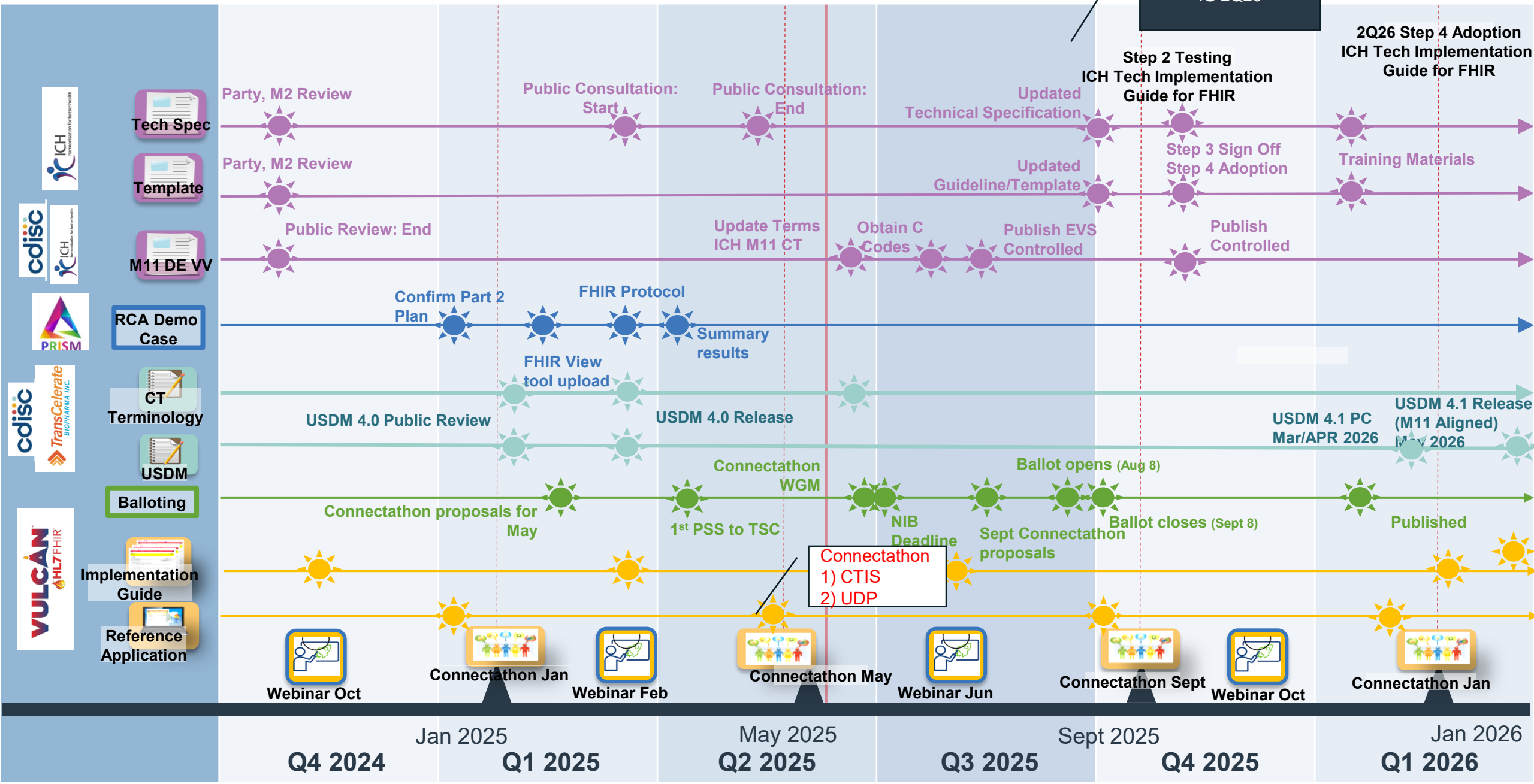
Aggregated Timeline (as of June 5, 2025)



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Leveraging FHIR to represent M11

FHIR (**F**ast **H**ealthcare **I**nteroperability **R**esources) is a standard for exchanging healthcare information electronically. It aims to simplify implementation without sacrificing information integrity. It leverages existing logical and theoretical models to provide a consistent, easy to implement, and rigorous mechanism for exchanging data between healthcare applications.

A great strength of FHIR is that creating a new **profile*** or **extension*** DOES NOT require an update to FHIR itself and existing FHIR servers will handle content using the new profiles and extensions without change to the server

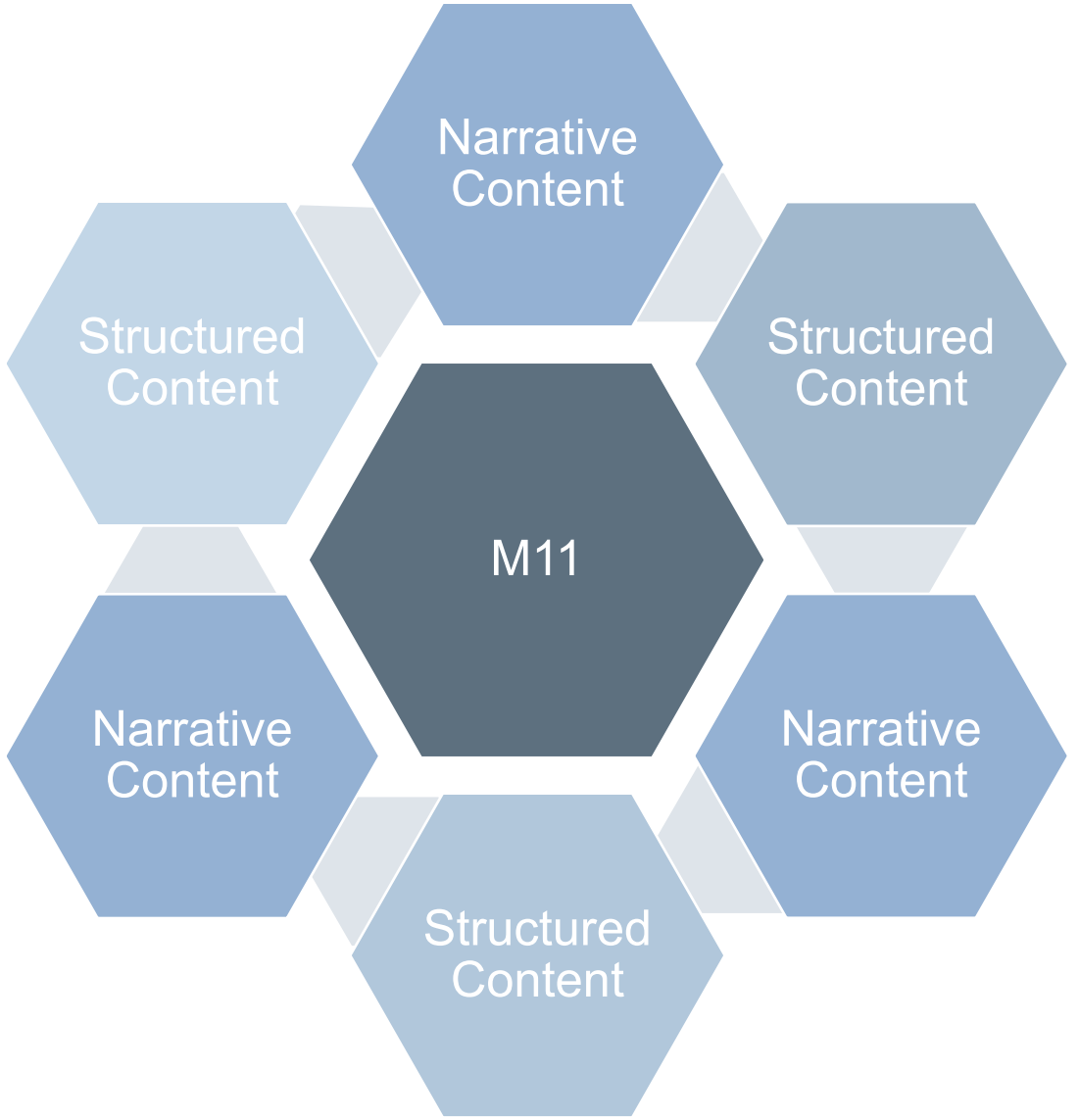
Use of **profiles and **extensions** are keys to success in UDP*

Representing M11 in FHIR

The M11 template details both narrative content and structured content

Implementers will vary in their desired use of M11: some will treat as a document, others will leverage structured content, others will utilize for machine processing

The FHIR implementation must therefore cover both narrative and structured content



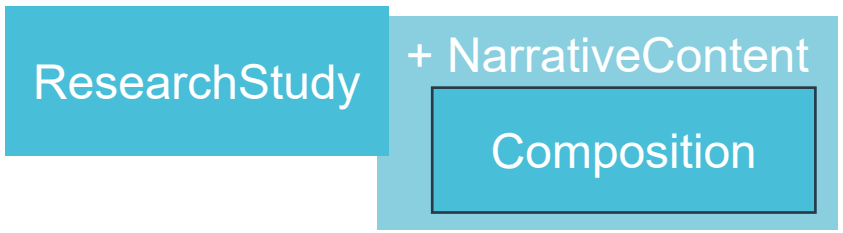
Narrative Content Representation

ResearchStudy

ResearchStudy has many structured attributes to describe a protocol and it is the correct starting point to use.
BUT It does not have provision to carry narrative text

Composition

Composition is designed to carry narrative content and the content can have sections, sub-sections, sub-sub-sections etc.



We created a **NarrativeContent** extension to **ResearchStudy** which is essentially a pointer to a **Composition**.

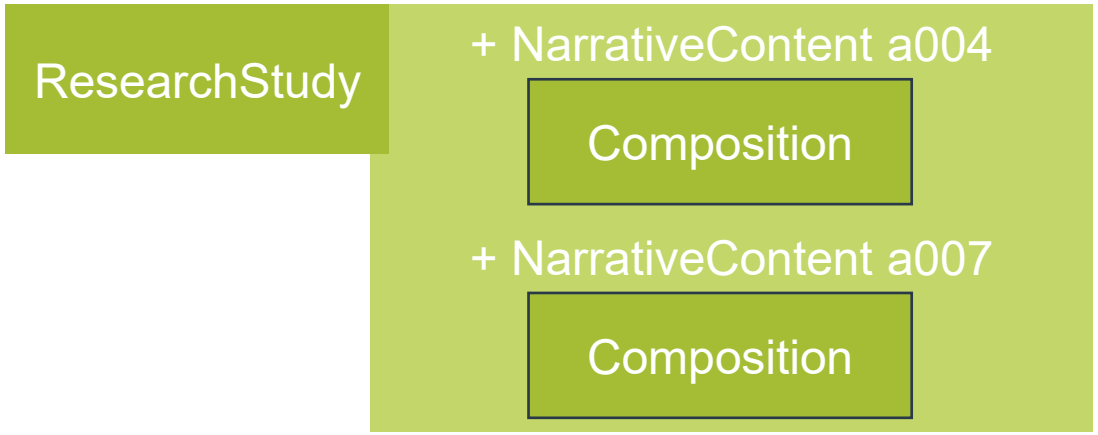
Content Hierarchy and Context (Outline) Representation

Code	Display
a0000	M11 Template Headings
a0001	1 PROTOCOL SUMMARY
a0002	1.1 Protocol Synopsis
a0003	1.1.1 Primary and Secondary Objectives and Estim
a0004	1.1.2 Overall Design
a0005	1.2 Trial Schema
a0006	1.3 Schedule of Activities
a0007	2 INTRODUCTION
a0008	2.1 Purpose of Trial
a0009	2.2 Assessment of Risks and Benefits

To properly reflect the M11 template, the sections and sub-sections in the **Composition** need to match those in the template.

The template sections can be defined in terminology

Specific narrative instances can then use the codes to specify which parts of the M11 Template they represent



In the illustration here **ResearchStudy** has two **NarrativeContent** sections attached. One with code *a004* which is *1.1.2 Overall Design* and one with code *a007* which is *2 INTRODUCTION* and this would then have all the sub-sections within the *INTRODUCTION*.

Structured Representation

ResearchStudy already has many attributes to describe a protocol but not everything required by M11 is present.

For example M11 requires a field to describe Amendment Scope.

To accommodate this, we create another extension called **ResearchStudyStudyAmendment** and amongst the attributes present in this extension we have one called scope

Representing M11 in FHIR

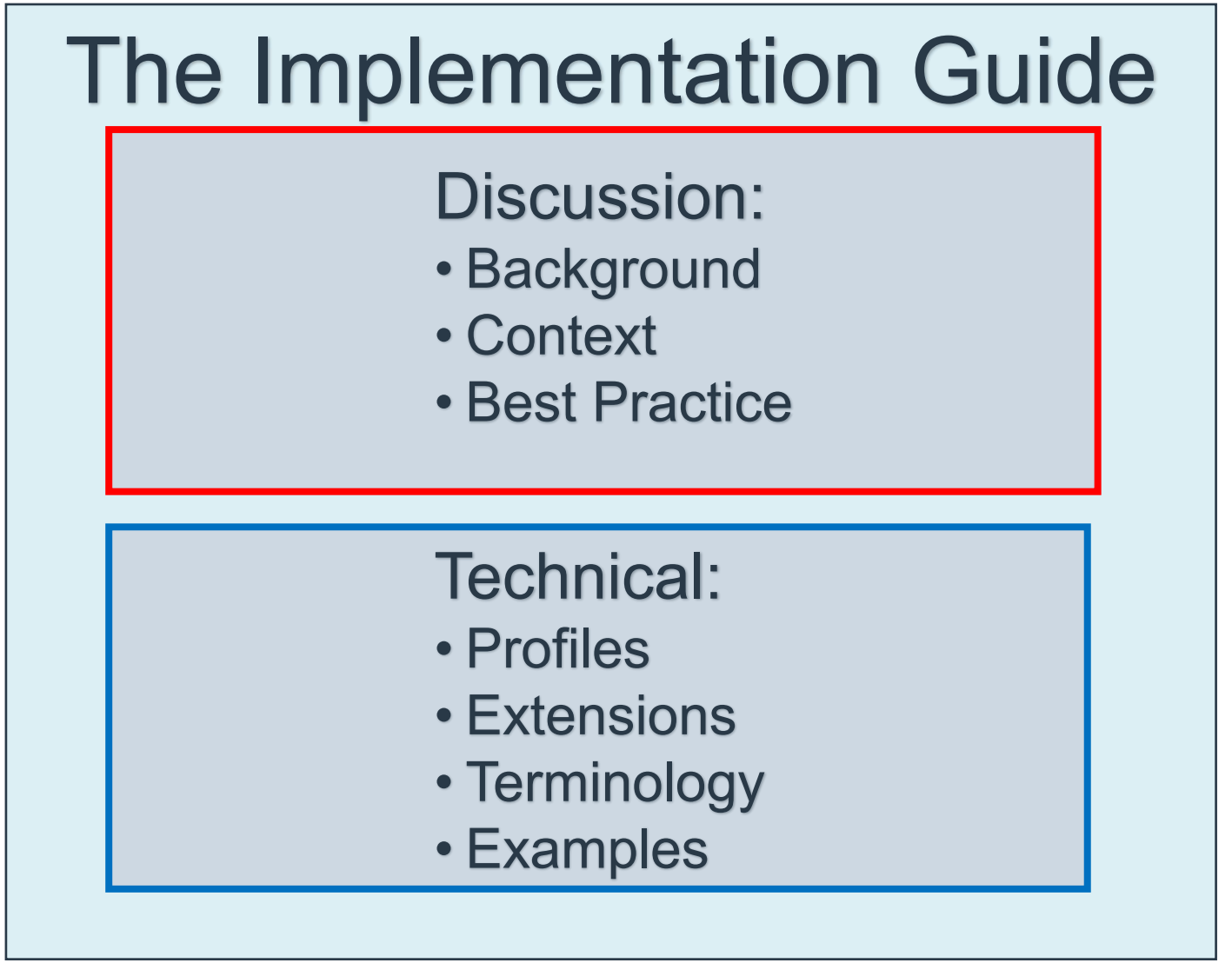
- ✓ M11 Template: Part narrative content, part structured content
- ✓ Implementers: Some want Document Model some want Machine Processable (granular)
- ✓ FHIR implementation must therefore cover both narrative and structured content.

By using **Profiles** and **Extensions** we can do a comprehensive mapping from the M11 template to FHIR that comprehensively covers the Document approach and approaches that leverage Structured Content.

These same components also enable more granular mappings from USDM to FHIR and reuse what has been done for M11 to FHIR.

> *A great strength of FHIR is that creating a new **profile** or **extension** DOES NOT require an update to FHIR itself and existing FHIR servers will handle content using the new Profiles/Extensions without change to the server*

The IG – Basic Orientation

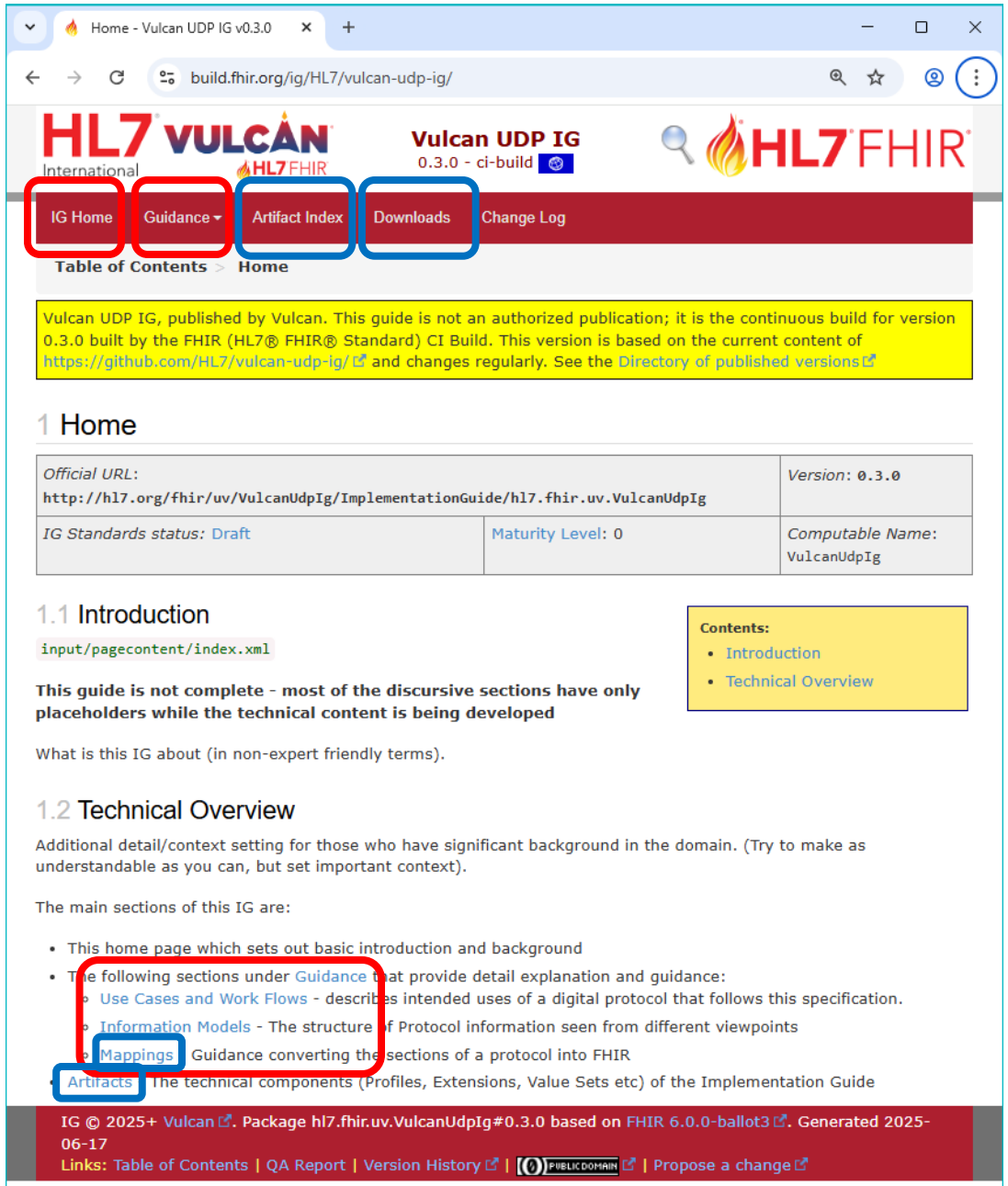


https://build.fhir.org/ig/HL7/vulcan-udp-ig

This is the home page – basic introduction and navigation

Discussion:
- Background
- Context
- Best Practice

Technical:
- Profiles
- Extensions
- Terminology
- Examples



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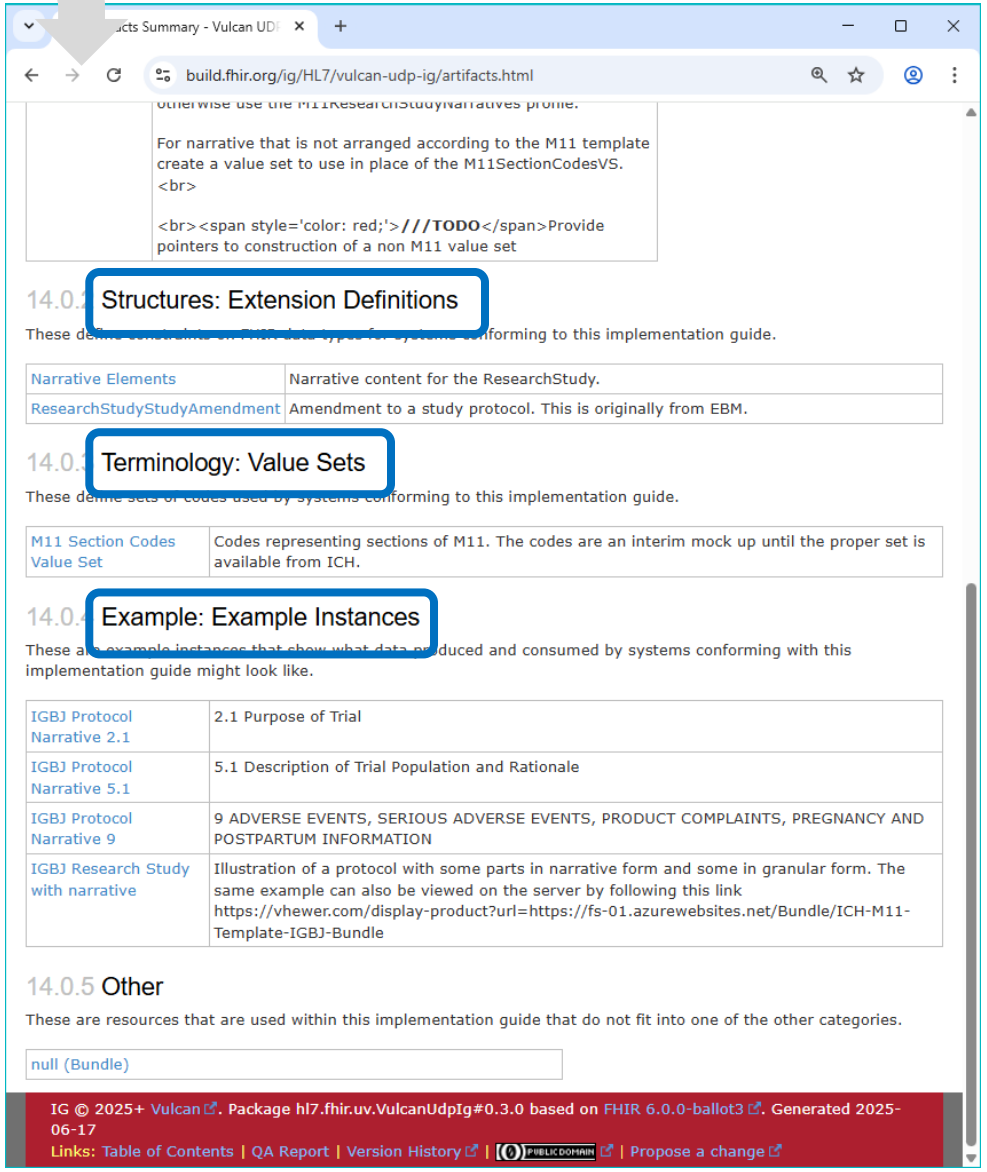
“Artifacts Summary” – The Technical Content



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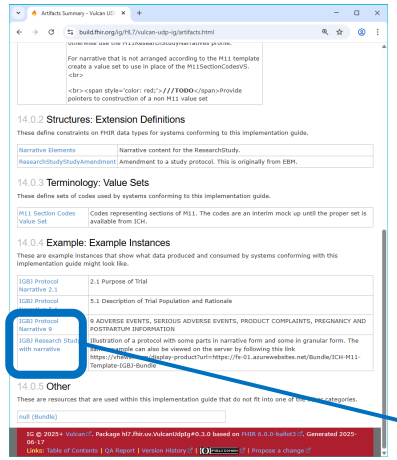
Examples



Narrative Content | XML | JSON | TTL

14.9.1 Example ResearchStudy: IGBJ Research Study with narrative

Page standards status: Informative

Narrative Elements: Composition IGBJ Protocol Narrative 2.1

Narrative Elements: Composition IGBJ Protocol Narrative 5.1

Narrative Elements: Composition IGBJ Protocol Narrative 9

ResearchStudyStudyAmendment

- scope: Global

ResearchStudyStudyAmendment

- details: This protocol has not been amended previously.

ResearchStudyStudyAmendment

- description: Protocol I8R-JE-IGBJ A Phase 3 Study of Nasal Glucagon (LY900018) Compared to Intramuscular Glucagon for Treatment of Insulin-induced Hypoglycemia in Japanese Patients with Diabetes Mellitus has been amended. The new protocol is indicated by Amendment (a) and will be used to conduct

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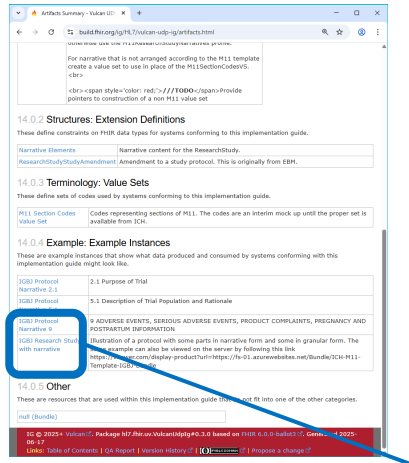
Examples



Narrative Content | XML | JSON | TTL

14.9.8 : IGBJ Research Study with narrative - XML Representation

Page standards status: Informative

Raw xml | Download

```
<ResearchStudy xmlns="http://hl7.org/fhir">
  <id value="IGBJ-ResearchStudy"/>
  <text>
    <status value="extensions"/>
    <div xmlns="http://www.w3.org/1999/xhtml"><p class="res-header-id"><b>Generated Narrative: Resea
  </text>
  <extension
            url="http://hl7.org/fhir/uv/VulcanUdpIg/StructureDefinition/narrative-elements">
    <valueReference>
      <reference value="Composition/IGBJ-Narrative-2.1"/>
    </valueReference>
  </extension>
  <extension
            url="http://hl7.org/fhir/uv/VulcanUdpIg/StructureDefinition/narrative-elements">
    <valueReference>
      <reference value="Composition/IGBJ-Narrative-5.1"/>
    </valueReference>
  </extension>
  <extension
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```

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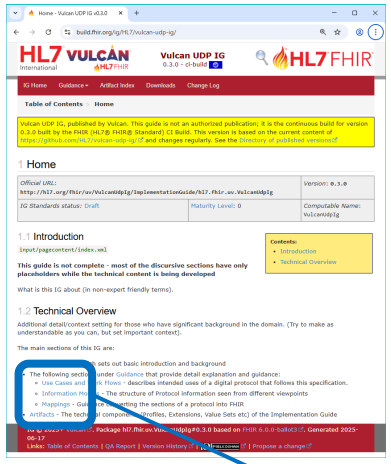
Mappings



Follow the Download Link …

M11		FHIR		
Section Title	**ElementName**	**Path**	**Sample XML**	**Example Value(s)**
Title Page	Full Title	ResearchStudy.title	<title value=%VALUE/>	%VALUE = A Phase 3 Study of Nasal Glucagon (LY900018) Compared to Intramuscular Glucagon for Treatment of Insulin-induced Hypoglycemia in Japanese Patients with Diabetes Mellitus
Title Page	Sponsor Protocol Identifier	ResearchStudy.identifier	<identifier> <use value="usual"/> <type> <text value="Sponsor Identifier"/> </type> <system value=$SpID/> <value value=%VALUE/> </identifier>	%VALUE = I8R-JE-IGBJ
Title Page	Amendment Scope	ResearchStudy.extension[$ext-amd].extension[scope]	<extension url=$ext-amd> <extension url="scope"> <valueString value=%VALUE/> </extension> </extension>	%VALUE = Global
Title Page	Trial Phase	ResearchStudy.phase	<phase> <coding> <system value="$FHIR/research-study-phase"/> <code value=%CODE /> <display value=%DISPLAY /> </coding> </phase>	%CODE = phase-3 %DISPLAY = Phase 3
Title Page	Trial Short Title	ResearchStudy.label	<label> <type> <coding> <system value="http://hl7.org/fhir/title-type"/> <code value="short-title"/> <display value="Short title"/> </coding>	%VALUE = A Phase 3 Study of Nasal Glucagon (LY900018) Compared to Intramuscular Glucagon for Treatment of Insulin-induced Hypoglycemia in Japanese Patients with Diabetes Mellitus

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Part of Mapping

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Title Page	Sponsor Protocol Identifier	ResearchStudy.identifier	<identifier> <use value="usual"/> <type> <text value="Sponsor Identifier"/> </type> <system value=$SpID/> <value value=%VALUE/> </identifier>	%VALUE = I8R-JE-IGBJ
Title Page	Amendment Scope	ResearchStudy.extension[$ext-amd].extension[scope]	<extension url=$ext-amd> <extension url="scope"> <valueString value=%VALUE/> </extension> </extension>	%VALUE = Global
Title Page	Trial Phase	ResearchStudy.phase	<phase> <coding> <system value="$FHIR/research-study-phase"/> <code value=%CODE /> <display value=%DISPLAY /> </coding> </phase>	%CODE = phase-3 %DISPLAY = Phase 3
Title Page	Trial Short Title	ResearchStudy.label	<label> <type> <coding> <system value="http://hl7.org/fhir/title-type"/> <code value="short-title"/> <display value="Short title"/> </coding>	%VALUE = A Phase 3 Study of Nasal Glucagon (LY900018) Compared to Intramuscular Glucagon for Treatment of Insulin-induced Hypoglycemia in Japanese Patients with Diabetes Mellitus

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UDP and the HL7 September 2025 Ballot Cycle

The Vulcan UDP project will enter this September's ballot cycle… what to know.

What is balloting?

- ✓ Balloting is the process by which content becomes an official standard.
- ✓ This is the formal, scheduled period where IG authors actively seek feedback (Ballot Comments) on a proposed standard, ensuring that the community that will be governed by that standard is in agreement with the expectations set by the standard.

How can you make an impact?

- ✓ By joining the ballot pool, you or your organization can directly influence the final version of this IG via commenting. Ballot Comments cannot be ignored and must be resolved to the satisfaction of the person who placed the comment.
- ✓ Your vote counts! Cast your vote in favor of the advancement of the IG - or vote to call attention to issues that you determine should be addressed prior to approval.

Who should participate?

- ✓ All implementers of the digital protocol
- ✓ Stakeholders invested in the potential of downstream end user applications of the digital protocol (e.g. sites, sponsors, regulatory)
- ✓ **Both** technical and non-technical evaluators

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The Ballot Process

- **Sign up to the September 2025 Ballot Pool (July 7th – August 7th) and submit your Ballot Comments during the designated period (August 8th – September 8th)**

✓ This is essential as signing up for the current Ballot Pool enables you to comment/vote in the **current** cycle and is required for participation in **future** ballots of the same content.

- **All comments must then be addressed by Vulcan UDP and the sponsoring HL7 Work Group [Biomedical Research and Regulation (BR&R)]. Comments cannot be ignored or rejected out of hand.**

✓ The September Connectathon (September 13th and 14th) will explore comments raised

✓ If substantive changes to the content are made, the IG will be re-balloted between December 19th, 2025 and January 19th, 2026. Remember: You can only vote in this re-ballot if you signed up to the original ballot pool.

You can read more here: Jira Ballot Process - HL7 - Confluence

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Ballot Access - https://www.hl7.org/ballotdesktop/

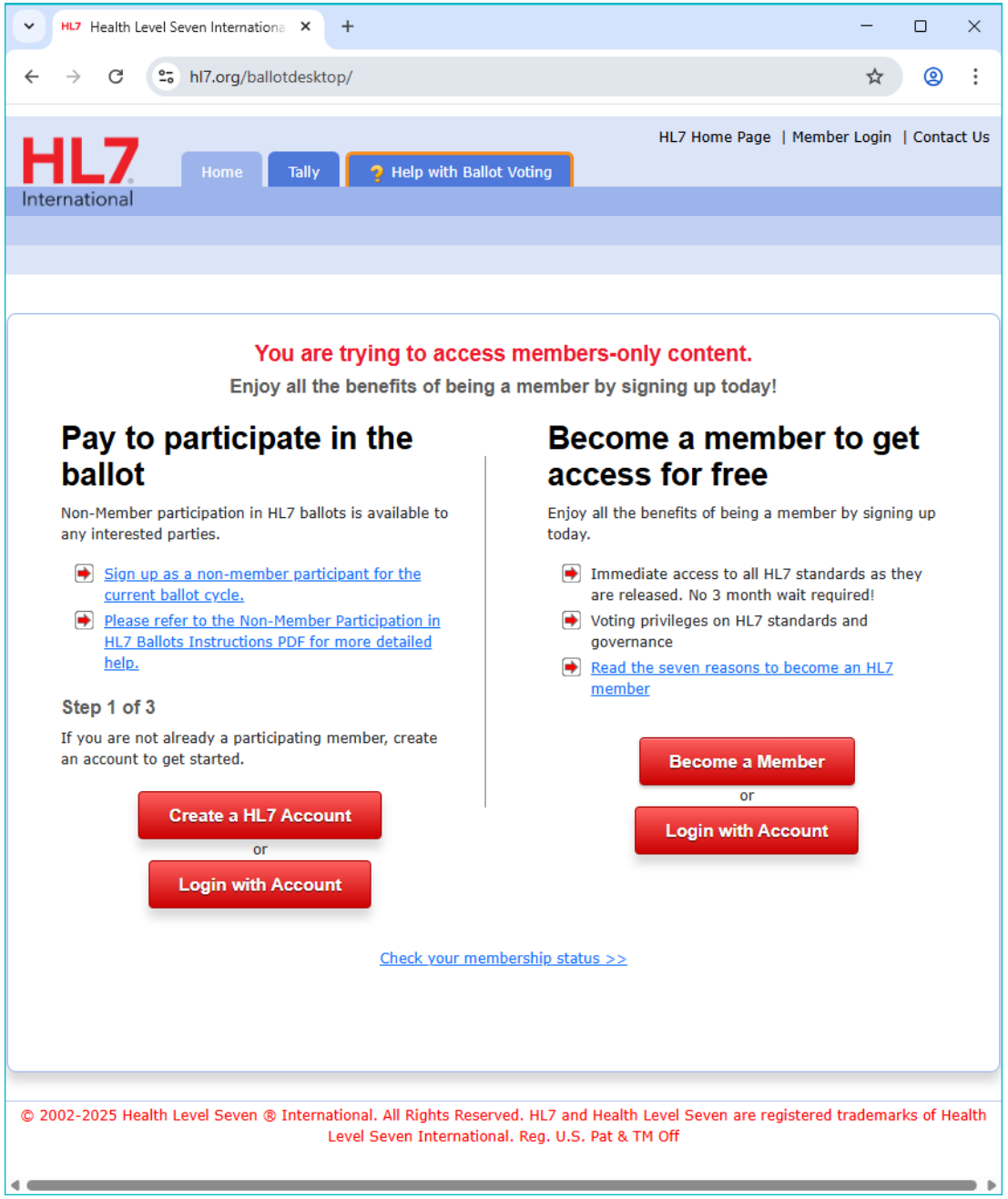
If you are not an HL7 member, and you don't have an HL7 account this is what you will see

You can create an HL7 account without becoming a member, but if you are not a member there is a fee to participate.

*Vulcan membership does not automatically include HL7 membership – those members must assess if their home organizations have an HL7 membership or explore the non-member option.

If you need help with any part of balloting please ask:

UDP@HL7Vulcan.org and we will do our best to provide guidance.



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The IG is too technical for me – how can I comment?

The implementation guide is a technical specification for use of the FHIR standard in a particular set of circumstances so it is inevitably written in FHIR speak. If you have FHIR experts available, get them to go through the technical parts

BUT

There are multiple sections in the IG that are written to explain background, context and potential use.

- ❑ **Does this content make sense?**
- ❑ **Are the uses ones which you recognise? And do the uses match your experience?**
- ❑ **Is something unclear or missing in the explanations?**

The examples are the key to making comments and the Mapping sheet is probably the easiest way to look at an example in detail. Go through the sheet line by line, again ask yourself:

- ❑ **Does this content make sense?**
- ❑ **Do I need more granularity for this item?**
- ❑ **Is this mapping what I would expect?**
- ❑ **Are there other examples you want to see to know how to use FHIR?**

Agenda

Time	Topic	Speaker
Welcome and Introduction		
5 mins	**Kick-off and ground rules and Introductions**	Shani Sampson
Speaker Presentations		
10 mins	**ICH M11** ○ Recent progress update ○ Roadmap to finalization	Mary Lynn Mercado
10 mins	**Vulcan UDP Implementation Guide (IG)** ○ Preview of the IG being developed including the inputs from the recent Connectathon ○ Starting the IG lifecycle now with a vision toward the future	Hugh Glover
10 mins	**Balloting the Vulcan UDP IG** ○ The HL7 ballot process and its role in reaching publication ○ **Call to action:** How to get involved	Hugh Glover
15 mins	**Catalyzing Connections to Accelerate Impact** ○ How Vulcan UDP fits with other protocol-related initiative ○ Get prepared! Planning for implementation in your organization	Stacy Tegan
20 mins	**Moderated Q&A**	All
Wrap-Up		
5 min	**Close**	Shani Sampson

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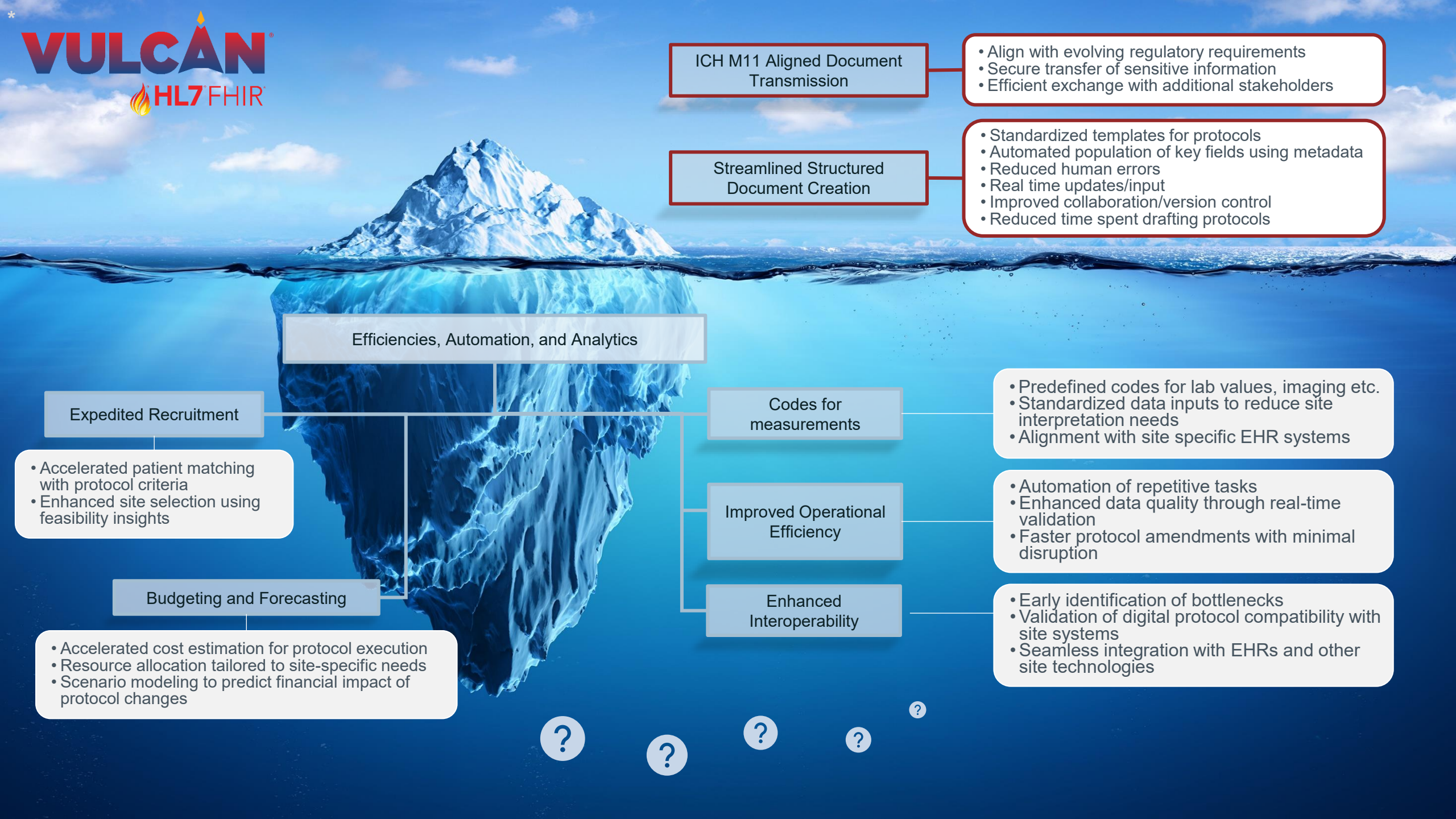
VULCAN

HL7 FHIR



ICH M11 Aligned Document Transmission

- Align with evolving regulatory requirements
- Secure transfer of sensitive information
- Efficient exchange with additional stakeholders

Streamlined Structured Document Creation

- Standardized templates for protocols
- Automated population of key fields using metadata
- Reduced human errors
- Real time updates/input
- Improved collaboration/version control
- Reduced time spent drafting protocols

Efficiencies, Automation, and Analytics

Expedited Recruitment

- Accelerated patient matching with protocol criteria
- Enhanced site selection using feasibility insights

Budgeting and Forecasting

- Accelerated cost estimation for protocol execution
- Resource allocation tailored to site-specific needs
- Scenario modeling to predict financial impact of protocol changes

Codes for measurements

- Predefined codes for lab values, imaging etc.
- Standardized data inputs to reduce site interpretation needs
- Alignment with site specific EHR systems

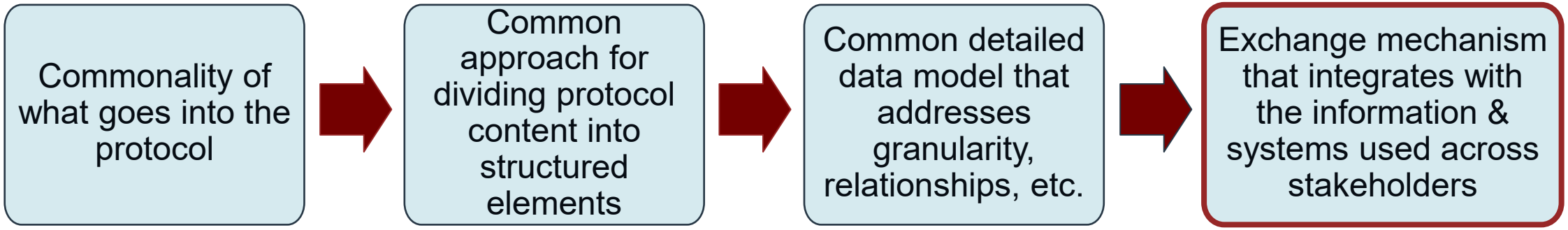
Improved Operational Efficiency

- Automation of repetitive tasks
- Enhanced data quality through real-time validation
- Faster protocol amendments with minimal disruption

Enhanced Interoperability

- Early identification of bottlenecks
- Validation of digital protocol compatibility with site systems
- Seamless integration with EHRs and other site technologies

Evolution of Protocol Initiatives Towards a Common Vision



TransCelerate's Common Protocol Template (CPT)	**CDISC USDM (TransCelerate sponsored & informed)**	**CDISC USDM (TransCelerate sponsored & informed)**	**Vulcan UDP: creating the FHIR IG for ICH M11 in collaboration with CDISC & TransCelerate**
ICH M11	**ICH M11**	**ICH M11**	

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Making the Common Vision a Reality Across Clinical Research & Clinical Care Will Require Compatibility

Imagine a standard shipping container that allows universal exchange. Inside the container, contents can be loosely or highly organized, depending on the needs of the sender & receiver.

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Don’t wait to chart your pathway to implementation

1. **Start discussions now! Implementation starts with prioritizing a business problem**
2. **Learn more about the building blocks that will enable a digital protocol**
3. **Explore technical infrastructure requirements EARLY in the process**
   - Understand internal capabilities... what works for your business process
   - Levering available learning opportunities:
     - There are high quality FHIR Servers and APIs freely available – find out what would work in your environment, use the to gain experience
   - Explore rather than eliminate the options
     - Do you really need a FHIR server? For example, submission to a regulator’s server doesn’t require you to have a server of your own – there may be less to do than you think

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What you can do now...

ICH M11 Template

Familiarize yourself with the DRAFT Template, Guideline, Technical Specification: https://www.ich.org/page/multidisciplinary-guidelines

Prepare to align internal templates (consider leveraging the TransCelerate CPT (Common Protocol Template) which ICH has drawn from.

Participate in public reviews

ICH M11 Technical Specification

USDM

Reference the DDF Technology Architecture Scenarios Tool for examples of potential implementation patterns.

Consider upcoming events:

- 23 Sept: USDM training
- 24-25 Sept: DDF: Mission Possible

Participate in CDISC public reviews

FHIR

Stay informed on UDP:

UDP Monthly Project Meetings

Overview video

Learn about FHIR – this video covers FHIR basics and how to read an IG

Participating in a UDP Connectathon*!
Some participation options:

- Perform testing (test protocols and applications provided)
- "Bring-your-own" protocols
- "Bring-your-own" software
- Contribute business process insights (non-technical)
- Send your R&D IT rep or vendor
- Contribute test protocols, convert protocols to M11/USDM – share learnings

* Sept 2025 Connectathon in Pittsburgh, PA, USA - onsite only

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Contacts & Resources

VULCAN HL7 FHIR

hl7-Vulcan

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Vulcan@HL7.org

TransCelerate BIOPHARMA INC.

TransCelerate

TransCelerate Biopharma Inc

Stay Connected:
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Events Calendar:
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ICH harmonisation for better health

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

ICH M11 guideline (Draft): https://database.ich.org/sites/default/files/ICH_M11_draft_Guideline_Step2_2022_0904.pdf

ICH M11 Protocol Template: https://database.ich.org/sites/default/files/ICH_M11_Template_Updated%20Step%202_ForReferenceOnly_2025_0203.pdf

ICH M11 Technical Specification: https://database.ich.org/sites/default/files/ICH_M11_Technical%20Specification_Updated%20Step%202_2025_0203.pdf

Confluence

UDP Project Background and Overview Video

Expert Panel Discussion with Q&A

Stacy Tegan
TransCelerate
Program Director

As a reminder, we can't answer questions about:

- Specific vendors with whom organizations are working
- Costs of using/implementing TransCelerate assets/tools
- Which member companies are using the assets/tools

Please state to whom your question is directed

Hugh Glover
Vulcan UDP Technical Lead

Mary Lynn Mercado
Global Head Protocol Delivery & US
Head, Regulatory Writing Submissions

Stacy Tegan
TransCelerate Program Director
Vulcan UDP Project Lead

TransCelerate BIOPHARMA INC.

LIVE WEBINAR

cdisc

Digital Data Flow (DDF) Solution Showcase: July 2025

THURSDAY, JULY 10

9 - 10:30 A.M. EST

SCAN QR CODE TO REGISTER

PANELISTS

SYLVAIN BERTHELOT

VP STRATEGY & MARKETING

CRScube

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studyOS

THANK YOU