

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 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.



PANELISTS



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



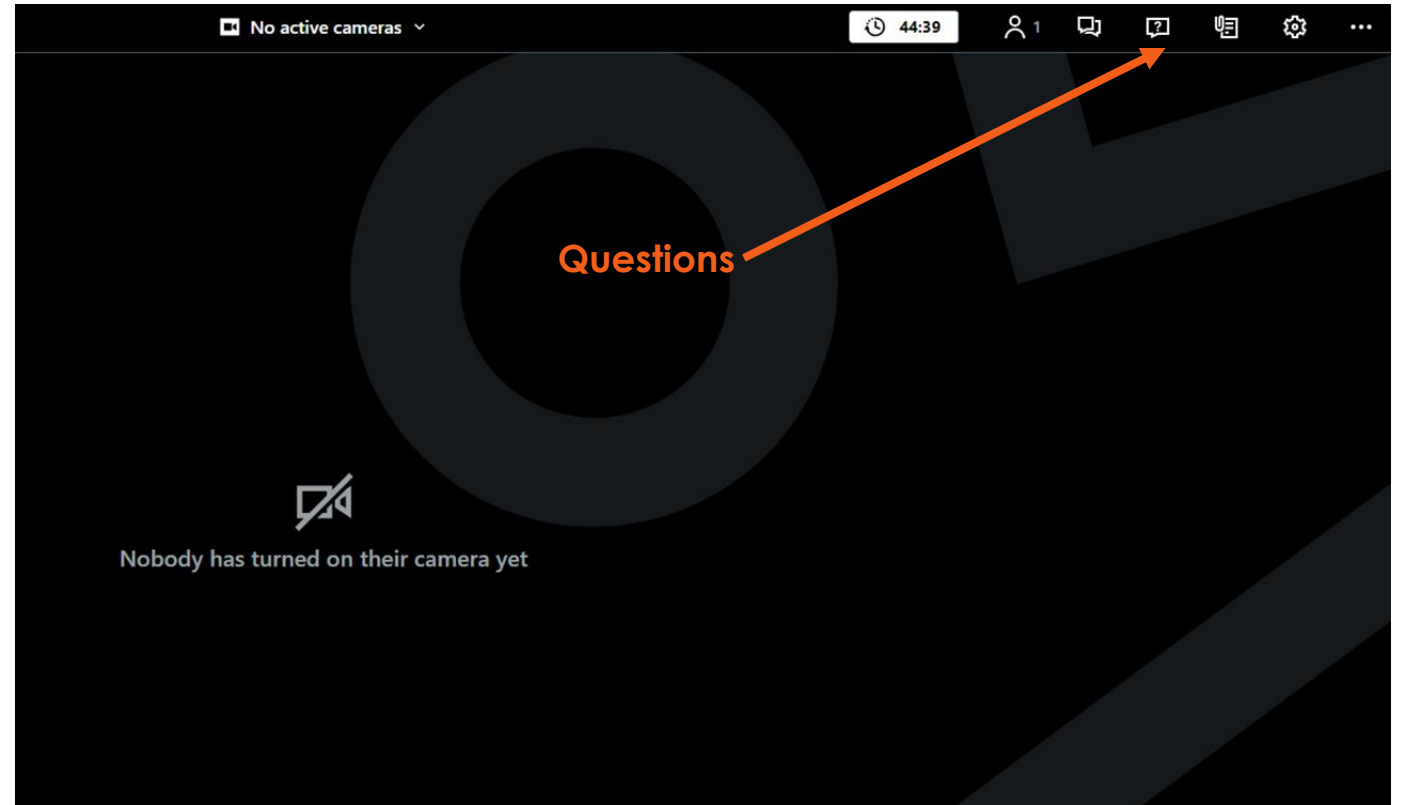
Welcome to the Utilizing the Digital Protocol Webinar

Time	Topic	Speaker
Welcome and Introduction		
5 mins	Kick-off and ground rules and Introductions	Shani Sampson
Speaker Presentations		
10 mins	ICH M11 <ul style="list-style-type: none">Recent progress updateRoadmap to finalization	Mary Lynn Mercado
10 mins	Vulcan UDP Implementation Guide (IG) <ul style="list-style-type: none">Preview of the IG being developed including the inputs from the recent ConnectathonStarting the IG lifecycle now with a vision toward the future	Hugh Glover
10 mins	Balloting the Vulcan UDP IG <ul style="list-style-type: none">The HL7 ballot process and its role in reaching publicationCall to action: How to get involved	Hugh Glover
15 mins	Catalyzing Connections to Accelerate Impact <ul style="list-style-type: none">How Vulcan UDP fits with other protocol-related initiativeGet prepared! Planning for implementation in your organization	Stacy Tegan
20 mins	Moderated Q&A	All
Wrap-Up		
5 min	Close	Shani Sampson

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 of 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



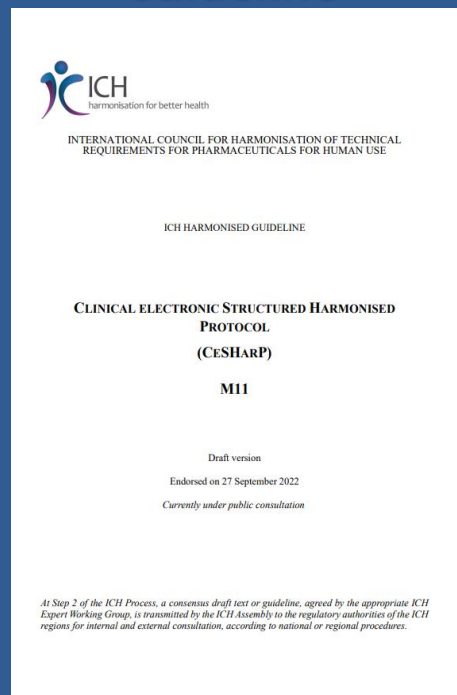
Agenda

Time	Topic	Speaker
Welcome and Introduction		
5 mins	Kick-off and ground rules and Introductions	Shani Sampson
Speaker Presentations		
10 mins	ICH M11 <ul style="list-style-type: none">Recent progress updateRoadmap to finalization	Mary Lynn Mercado
10 mins	Vulcan UDP Implementation Guide (IG) <ul style="list-style-type: none">Preview of the IG being developed including the inputs from the recent ConnectathonStarting the IG lifecycle now with a vision toward the future	Hugh Glover
10 mins	Balloting the Vulcan UDP IG <ul style="list-style-type: none">The HL7 ballot process and its role in reaching publicationCall to action: How to get involved	Hugh Glover
15 mins	Catalyzing Connections to Accelerate Impact <ul style="list-style-type: none">How Vulcan UDP fits with other protocol-related initiativeGet prepared! Planning for implementation in your organization	Stacy Tegan
20 mins	Moderated Q&A	All
Wrap-Up		
5 min	Close	Shani Sampson

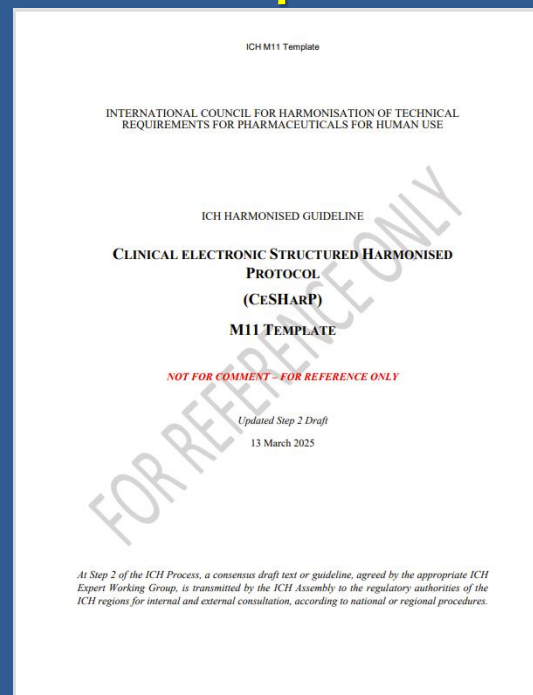
What is ICH M11 and where is it today?

Step 2

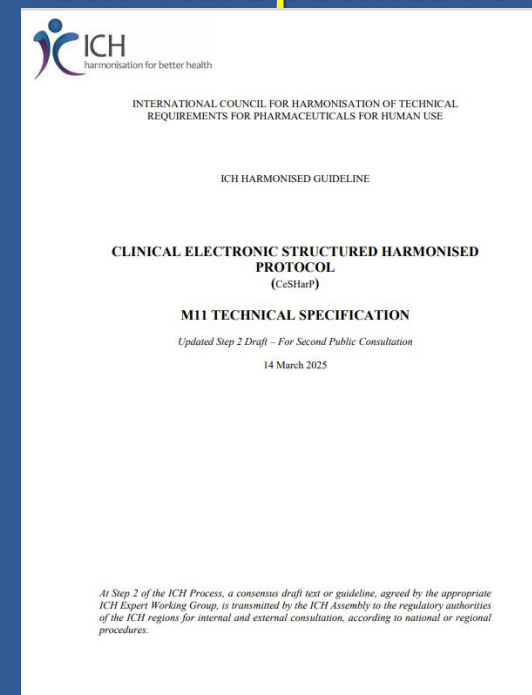
Guideline



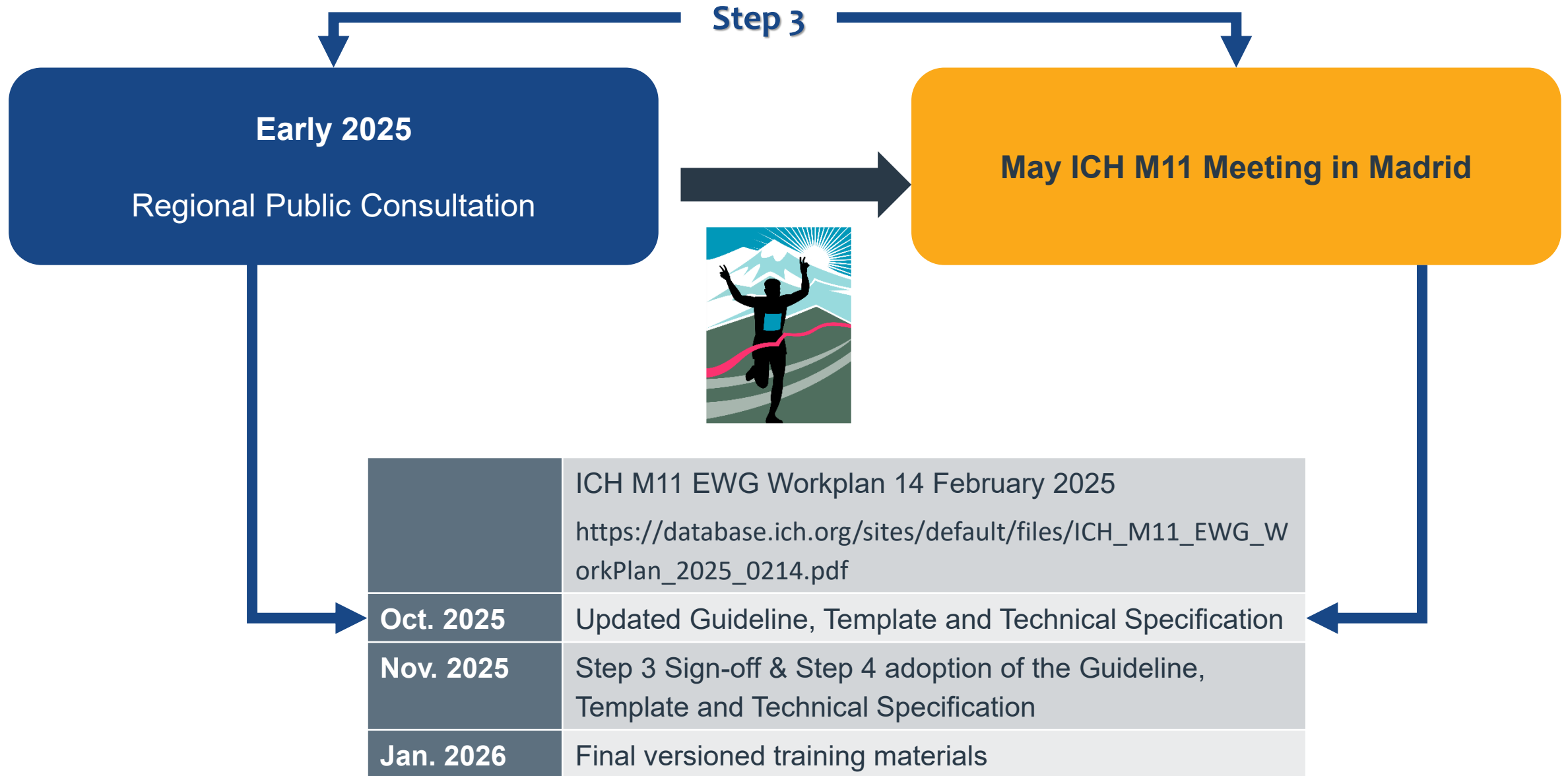
Template



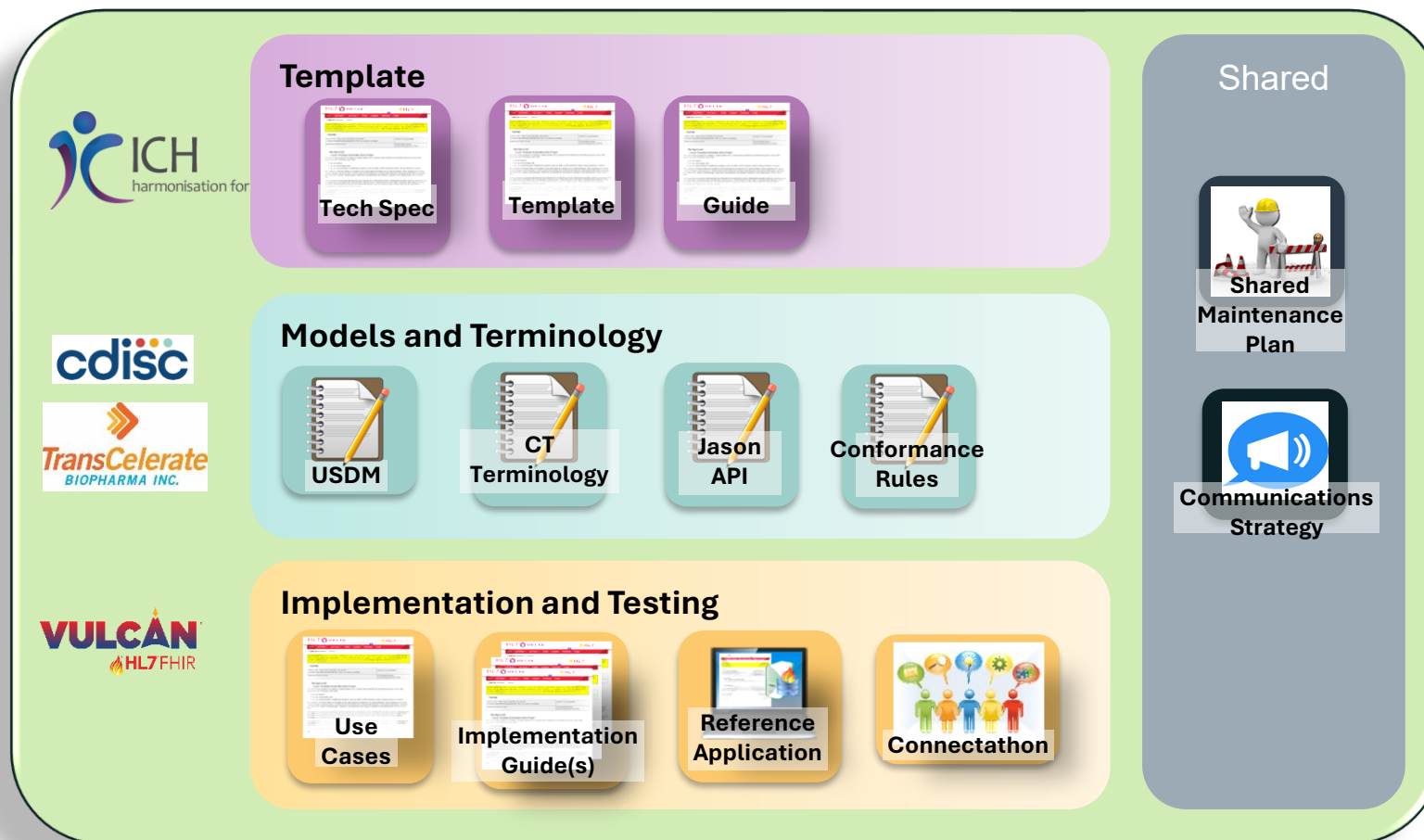
Technical Specification



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



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

Aggregated Timeline (as of June 5, 2025)

5 Jun 2025

Draft TIG Sep 2025
IG 2Q26

2Q26 Step 4 Adoption
ICH Tech Implementation
Guide for FHIR

Step 2 Testing
ICH Tech Implementation
Guide for FHIR

Step 3 Sign Off
Step 4 Adoption

Training Materials

Updated
Technical Specification

Updated
Guideline/Template

Publish EVS
Controlled

Publish
Controlled

Obtain C
Codes

Update Terms
ICH M11 CT

Public Consultation:
Start

Public Consultation:
End

Party, M2 Review

Party, M2 Review

Public Review: End

Confirm Part 2
Plan

FHIR Protocol

Summary
results

FHIR View
tool upload

USDM 4.0 Public Review

USDM 4.0 Release

USDM 4.1 PC
Mar/APR 2026

USDM 4.1 Release
(M11 Aligned)
May 2026

Ballot opens (Aug 8)

Ballot closes (Sept 8)

Sept Connectathon
proposals

Published

Connectathon
WGM

NIB
Deadline

1st PSS to TSC

Connectathon proposals for
May

Connectathon
1) CTIS
2) UDP

Tech Spec

Template

M11 DE VV

RCA Demo
Case

CT

Terminology

USDM

Balloting

Implementation
Guide

Reference
Application

Webinar Oct

Connectathon Jan

Webinar Feb

Connectathon May

Webinar Jun

Connectathon Sept

Webinar Oct

Connectathon Jan

Q4 2024

Jan 2025

Q1 2025

May 2025

Q2 2025

Q3 2025

Sept 2025

Q4 2025

Jan 2026

Q1 2026



Agenda

Time	Topic	Speaker
Welcome and Introduction		
5 mins	Kick-off and ground rules and Introductions	Shani Sampson
Speaker Presentations		
10 mins	ICH M11 <ul style="list-style-type: none">Recent progress updateRoadmap to finalization	Mary Lynn Mercado
10 mins	Vulcan UDP Implementation Guide (IG) <ul style="list-style-type: none">Preview of the IG being developed including the inputs from the recent ConnectathonStarting the IG lifecycle now with a vision toward the future	Hugh Glover
10 mins	Balloting the Vulcan UDP IG <ul style="list-style-type: none">The HL7 ballot process and its role in reaching publicationCall to action: How to get involved	Hugh Glover
15 mins	Catalyzing Connections to Accelerate Impact <ul style="list-style-type: none">How Vulcan UDP fits with other protocol-related initiativeGet prepared! Planning for implementation in your organization	Stacy Tegan
20 mins	Moderated Q&A	All
Wrap-Up		
5 min	Close	Shani Sampson



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.

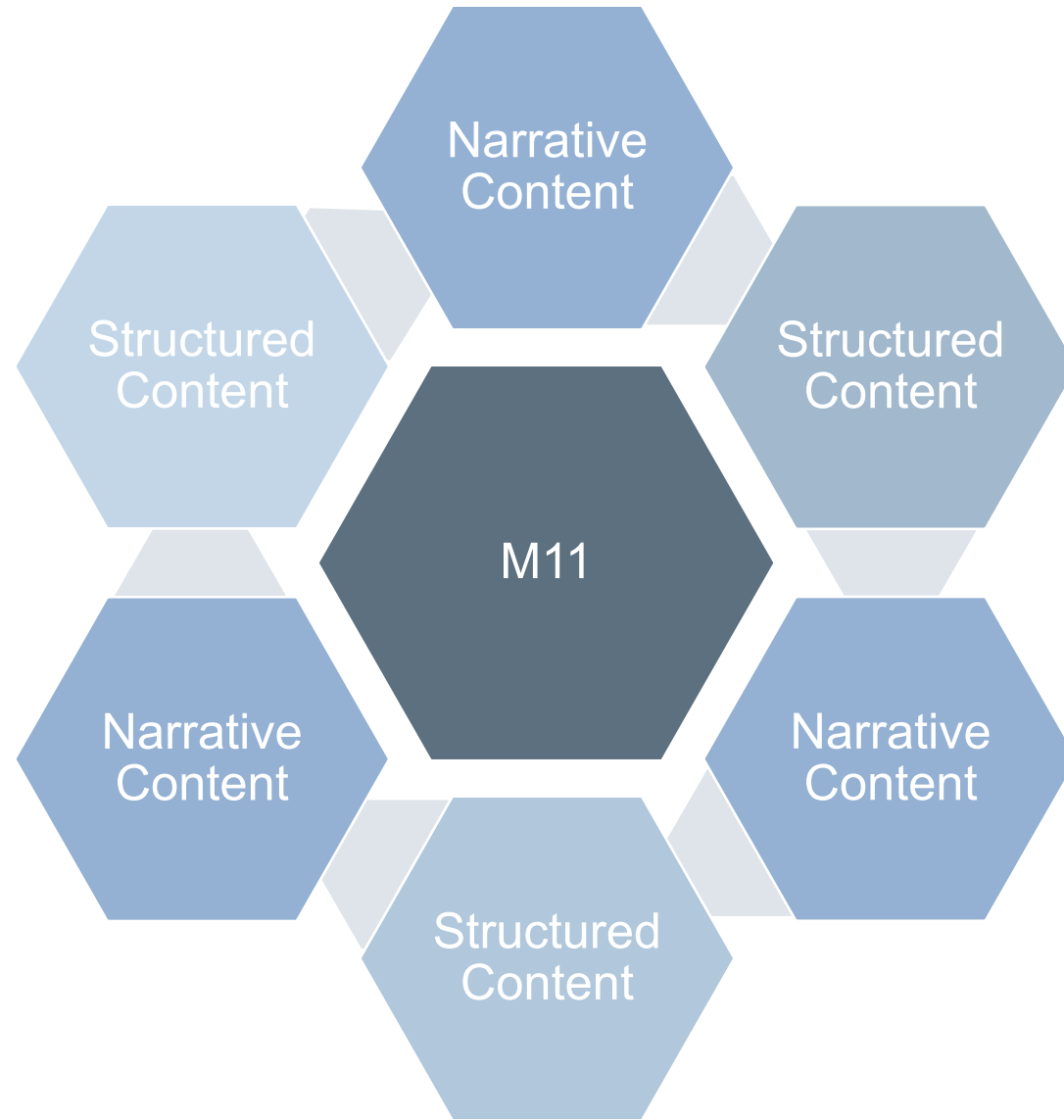
A great strength of FHIR is that creating a new **profile*** or **extension*** DOES NOT require an update to FHIR itself and existing FHIR servers will handle content using the new profiles and extensions without change to the server

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

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.

ResearchStudy

+ NarrativeContent

Composition

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*.

ResearchStudy	+ ResearchStudyStudyAmendment • scope
---------------	--

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

- ✓ 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 Implementation Guide

Discussion:

- Background
- Context
- Best Practice

Technical:

- Profiles
- Extensions
- Terminology
- Examples

This is the home page – basic introduction and navigation

Discussion:

- Background
- Context
- Best Practice

Technical:

- Profiles
- Extensions
- Terminology
- Examples

Home - Vulcan UDP IG v0.3.0

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

HL7 VULCAN International
Vulcan UDP IG 0.3.0 - ci-build

IG Home Guidance Artifact Index Downloads Change Log

Table of Contents > Home

Vulcan UDP IG, published by Vulcan. This guide is not an authorized publication; it is the continuous build for version 0.3.0 built by the FHIR (HL7® FHIR® Standard) CI Build. This version is based on the current content of <https://github.com/HL7/vulcan-udp-ig/> and changes regularly. See the [Directory of published versions](#)

1 Home

Official URL: http://hl7.org/fhir/uv/VulcanUdpIg/ImplementationGuide/hl7.fhir.uv.VulcanUdpIg	Version: 0.3.0
IG Standards status: Draft	Maturity Level: 0
Computable Name: VulcanUdpIg	

1.1 Introduction

[input/pagecontent/index.xml](#)

This guide is not complete - most of the discursive sections have only placeholders while the technical content is being developed

What is this IG about (in non-expert friendly terms).

1.2 Technical Overview

Additional detail/context setting for those who have significant background in the domain. (Try to make as understandable as you can, but set important context).

The main sections of this IG are:

- This home page which sets out basic introduction and background
- The following sections under **Guidance** that provide detail explanation and guidance:
 - **Use Cases and Work Flows** - describes intended uses of a digital protocol that follows this specification.
 - **Information Models** - The structure of Protocol Information seen from different viewpoints
 - **Mappings** - Guidance converting the sections of a protocol into FHIR
- **Artifacts** - The technical components (Profiles, Extensions, Value Sets etc) of the Implementation Guide

IG © 2025+ Vulcan. Package hl7.fhir.uv.VulcanUdpIg#0.3.0 based on FHIR 6.0.0-ballot3. Generated 2025-06-17

Links: [Table of Contents](#) | [QA Report](#) | [Version History](#) | [PUBLIC DOMAIN](#) | [Propose a change](#)

“Artifacts Summary” – The Technical Content

Artifacts Summary - Vulcan UDP IG

build.fhir.org/ig/HL7/vulcan-udp-ig/artifacts.html

HL7 VULCAN International HL7 FHIR Vulcan UDP IG 0.3.0 - ci-build

IG Home Guidance Artifact Index Downloads Change Log

Table of Contents > Artifacts Summary

Vulcan UDP IG, published by Vulcan. This guide is not an authorized publication; it is the continuous build for version 0.3.0 built by the FHIR (HL7® FHIR® Standard) CI Build. This version is based on the current content of <https://github.com/HL7/vulcan-udp-ig/> and changes regularly. See the [Directory of published versions](#)

14 Artifacts Summary

This page provides a list of the FHIR artifacts defined as part of this implementation guide.

14.0.1 Structures: Resource Profiles

These define constraints on FHIR resources for systems conforming to this implementation guide.

M11 Specific Research Study Narratives	Further constraint of ResearchStudyNarratives profile to force use of M11 heading. The ICH M11 CeSHarP template for a study protocol specifies the headings to be used to organise protocol content. For a FHIR representation of the protocol to be compliant with this template each of the narrative sections must be organised using these headings. Only if there is material that does not properly belong under one of the M11 headings can additional codes be created. ///TODO Add example of creating custom code/section
Research Study Narratives	Narrative elements associated with a research study. Use this profile when the ordering of the narrative sections is not intended to comply with the ICH M11 CeSHarP template otherwise use the M11ResearchStudyNarratives profile. For narrative that is not arranged according to the M11 template create a value set to use in place of the M11SectionCodesVS. ///TODOProvide pointers to construction of a non M11 value set

Contents:

- Structures: Resource Profiles
- Structures: Extension Definitions
- Terminology: Value Sets
- Example: Example Instances
- Other

Artifacts Summary - Vulcan UDP IG

build.fhir.org/ig/HL7/vulcan-udp-ig/artifacts.html

HL7 VULCAN International HL7 FHIR Vulcan UDP IG 0.3.0 - ci-build

IG Home Guidance Artifact Index Downloads Change Log

Table of Contents > Artifacts Summary

Vulcan UDP IG, published by Vulcan. This guide is not an authorized publication; it is the continuous build for version 0.3.0 built by the FHIR (HL7® FHIR® Standard) CI Build. This version is based on the current content of <https://github.com/HL7/vulcan-udp-ig/> and changes regularly. See the [Directory of published versions](#)

14 Artifacts Summary

This page provides a list of the FHIR artifacts defined as part of this implementation guide.

14.0.1 Structures: Extension Definitions

These define constraints on FHIR data types for systems conforming to this implementation guide.

Narrative Elements	Narrative content for the ResearchStudy.
ResearchStudyStudyAmendment	Amendment to a study protocol. This is originally from EBM.

14.0.2 Terminology: Value Sets

These define sets of codes used by systems conforming to this implementation guide.

M11 Section Codes Value Set	Codes representing sections of M11. The codes are an interim mock up until the proper set is available from ICH.
-----------------------------	--

14.0.3 Example: Example Instances

These are example instances that show what data produced and consumed by systems conforming with this implementation guide might look like.

IGBJ Protocol Narrative 2.1	2.1 Purpose of Trial
IGBJ Protocol Narrative 5.1	5.1 Description of Trial Population and Rationale
IGBJ Protocol Narrative 9	9 ADVERSE EVENTS, SERIOUS ADVERSE EVENTS, PRODUCT COMPLAINTS, PREGNANCY AND POSTPARTUM INFORMATION
IGBJ Research Study with narrative	Illustration of a protocol with some parts in narrative form and some in granular form. The same example can also be viewed on the server by following this link https://vhewer.com/display-product?url=https://fs-01.azurewebsites.net/Bundle/ICH-M11-Template-IGBJ-Bundle

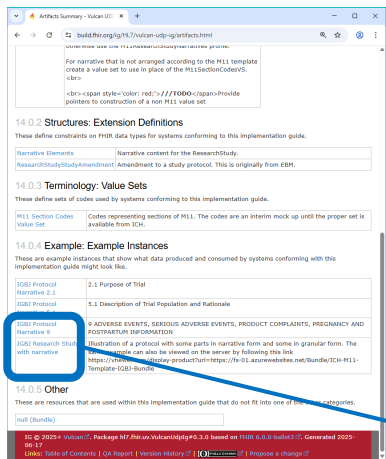
14.0.5 Other

These are resources that are used within this implementation guide that do not fit into one of the other categories.

null (Bundle)

IG © 2025+ Vulcan. Package hl7.fhir.uv.VulcanUdpIg#0.3.0 based on FHIR 6.0.0-ballot3. Generated 2025-06-17

Links: [Table of Contents](#) | [QA Report](#) | [Version History](#) | [Public Domain](#) | [Propose a change](#)



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 the study in place of any preceding version of the protocol. The overall changes and rationale for the

Examples

Narrative Content

XML

JSON

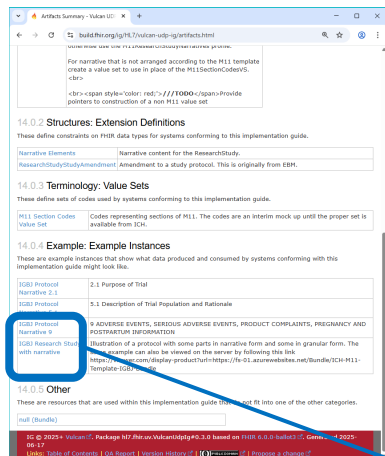
TTL

14.9.8 : IGBJ Research Study with narrative - XML Representation

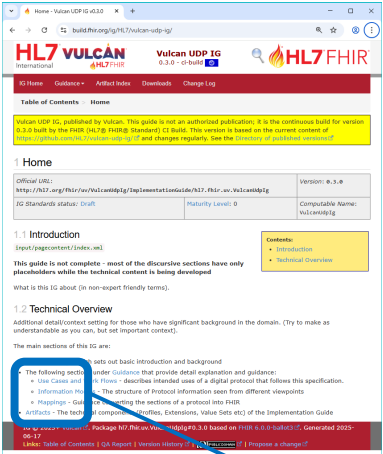
Page standards status: Informative

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: Resear</b>
  </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
    url="http://hl7.org/fhir/uv/VulcanUdpIg/StructureDefinition/narrative-elements">
    <valueReference>
```



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 = IBR-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

Part of Mapping

M11		FHIR		
Section Title	ElementName	Path	Sample XML	Example Value(s)
Title Page	Full Title	ResearchStudy.title	<code><title value=%VALUE/></code>	%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	<pre> <identifier> <use value="usual"/> <type> <text value="Sponsor Identifier"/> </type> <system value=\$SpID/> <value value=%VALUE/> </identifier> </pre>	%VALUE = I8R-JE-IGBJ
Title Page	Amendment Scope	ResearchStudy.extension[\$ext-amd].extension[scope]	<pre> <extension url=\$ext-amd> <extension url="scope"> <valueString value=%VALUE/> </extension> </extension> </pre>	%VALUE = Global
Title Page	Trial Phase	ResearchStudy.phase	<pre> <phase> <coding> <system value="\$FHIR/research-study-phase"/> <code value=%CODE /> <display value=%DISPLAY /> </coding> </phase> </pre>	%CODE = phase-3 %DISPLAY = Phase 3
Title Page	Trial Short Title	ResearchStudy.label	<pre> <label> <type> <coding> <system value="http://hl7.org/fhir/title-type"/> <code value="short-title"/> <display value="Short title"/> </coding> </pre>	%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



Agenda

Time	Topic	Speaker
Welcome and Introduction		
5 mins	Kick-off and ground rules and Introductions	Shani Sampson
Speaker Presentations		
10 mins	ICH M11 <ul style="list-style-type: none">Recent progress updateRoadmap to finalization	Mary Lynn Mercado
10 mins	Vulcan UDP Implementation Guide (IG) <ul style="list-style-type: none">Preview of the IG being developed including the inputs from the recent ConnectathonStarting the IG lifecycle now with a vision toward the future	Hugh Glover
10 mins	Balloting the Vulcan UDP IG <ul style="list-style-type: none">The HL7 ballot process and its role in reaching publicationCall to action: How to get involved	Hugh Glover
15 mins	Catalyzing Connections to Accelerate Impact <ul style="list-style-type: none">How Vulcan UDP fits with other protocol-related initiativeGet prepared! Planning for implementation in your organization	Stacy Tegan
20 mins	Moderated Q&A	All
Wrap-Up		
5 min	Close	Shani Sampson

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



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.

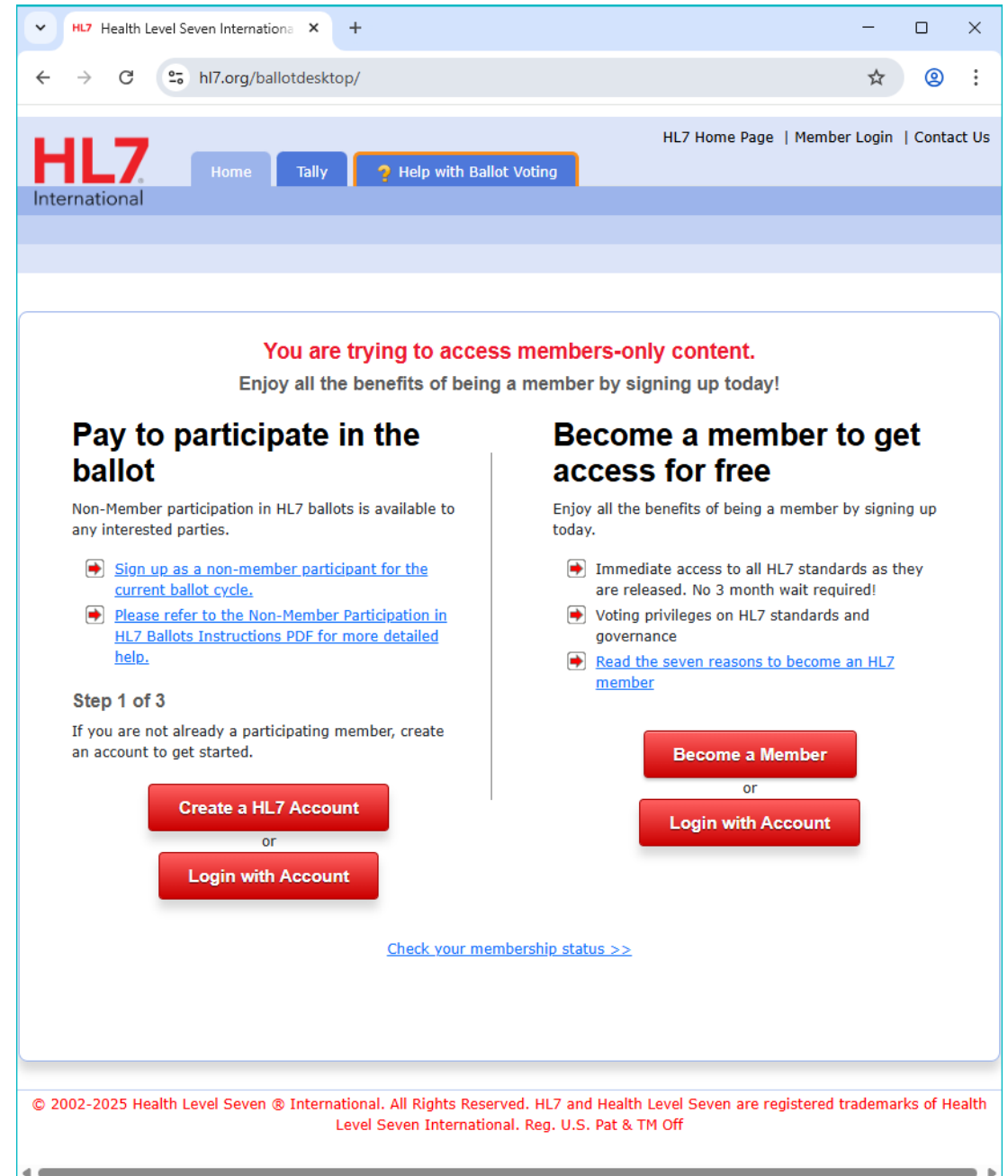
You can read more here: [Jira Ballot Process - HL7 - Confluence](#)

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.



The screenshot shows a web browser window with the URL [hl7.org/ballotdesktop/](https://www.hl7.org/ballotdesktop/). The page header includes the HL7 International logo and navigation links: Home, Tally, and Help with Ballot Voting. The main content area displays a red banner stating "You are trying to access members-only content. Enjoy all the benefits of being a member by signing up today!". Below this, there are two columns of information. The left column, titled "Pay to participate in the ballot", explains that non-member participation is available and provides two links: "Sign up as a non-member participant for the current ballot cycle." and "Please refer to the Non-Member Participation in HL7 Ballots Instructions PDF for more detailed help." The right column, titled "Become a member to get access for free", lists benefits of membership: immediate access to all HL7 standards, voting privileges, and a link to "Read the seven reasons to become an HL7 member". At the bottom of each column are buttons: "Create a HL7 Account" and "Login with Account" on the left, and "Become a Member" and "Login with Account" on the right. A footer section contains copyright information: "© 2002-2025 Health Level Seven © International. All Rights Reserved. HL7 and Health Level Seven are registered trademarks of Health Level Seven International. Reg. U.S. Pat & TM Off".

You are trying to access members-only content.
Enjoy all the benefits of being a member by signing up today!

Pay to participate in the ballot
Non-Member participation in HL7 ballots is available to any interested parties.

- ➡ [Sign up as a non-member participant for the current ballot cycle.](#)
- ➡ [Please refer to the Non-Member Participation in HL7 Ballots Instructions PDF for more detailed help.](#)

Step 1 of 3
If you are not already a participating member, create an account to get started.

[Create a HL7 Account](#)
or
[Login with Account](#)

Become a member to get access for free
Enjoy all the benefits of being a member by signing up today.

- ➡ Immediate access to all HL7 standards as they are released. No 3 month wait required!
- ➡ Voting privileges on HL7 standards and governance
- ➡ [Read the seven reasons to become an HL7 member](#)

[Become a Member](#)
or
[Login with Account](#)

[Check your membership status >>](#)

© 2002-2025 Health Level Seven © International. All Rights Reserved. HL7 and Health Level Seven are registered trademarks of Health Level Seven International. Reg. U.S. Pat & TM Off



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 <ul style="list-style-type: none">Recent progress updateRoadmap to finalization	Mary Lynn Mercado
10 mins	Vulcan UDP Implementation Guide (IG) <ul style="list-style-type: none">Preview of the IG being developed including the inputs from the recent ConnectathonStarting the IG lifecycle now with a vision toward the future	Hugh Glover
10 mins	Balloting the Vulcan UDP IG <ul style="list-style-type: none">The HL7 ballot process and its role in reaching publicationCall to action: How to get involved	Hugh Glover
15 mins	Catalyzing Connections to Accelerate Impact <ul style="list-style-type: none">How Vulcan UDP fits with other protocol-related initiativeGet prepared! Planning for implementation in your organization	Stacy Tegan
20 mins	Moderated Q&A	All
Wrap-Up		
5 min	Close	Shani Sampson

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

?

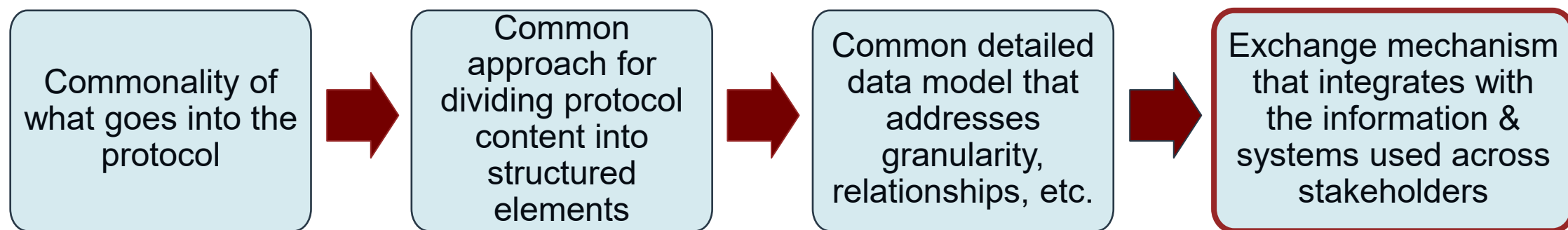
?

?

?

?

Evolution of Protocol Initiatives Towards a Common Vision



**TransCelerate's
Common Protocol
Template (CPT)**

ICH M11

**CDISC USDM
(TransCelerate sponsored
& informed)**

ICH M11

**CDISC USDM
(TransCelerate sponsored
& informed)**

ICH M11

**Vulcan UDP:
creating the
FHIR IG for ICH M11
in collaboration with
CDISC &
TransCelerate**

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.



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

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

Contacts & Resources



[hl7-Vulcan](#)



www.HL7Vulcan.org



Vulcan@HL7.org



[TransCelerate](#)



[TransCelerate Biopharma Inc](#)



Stay Connected:
[Sign Up](#) for our Awareness
& Implementation Community!



Events Calendar:
To find out more about our
events click [here](#)



[cdisc](#)



cdisc.org



ddf@cdisc.org



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



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



Digital Data Flow (DDF) Solution Showcase: July 2025



THURSDAY, JULY 10



9 - 10:30 A.M. EST

PANELISTS



SYLVAIN BERTHELOT

VP STRATEGY & MARKETING



CRScube



ROBERT HAY

MARKETING & SOLUTIONS CONSULTANT



CRScube



ELLIS HIROKI BUTTERFIELD

CHIEF EXECUTIVE OFFICER



studyOS



SCAN QR CODE TO
REGISTER

THANK YOU

