Vulcan UDP (Utilizing the Digital Protocol): Collaborating to Accelerate ICH M11 and End User Value

Welcome to the Utilizing the Digital Protocol Webinar

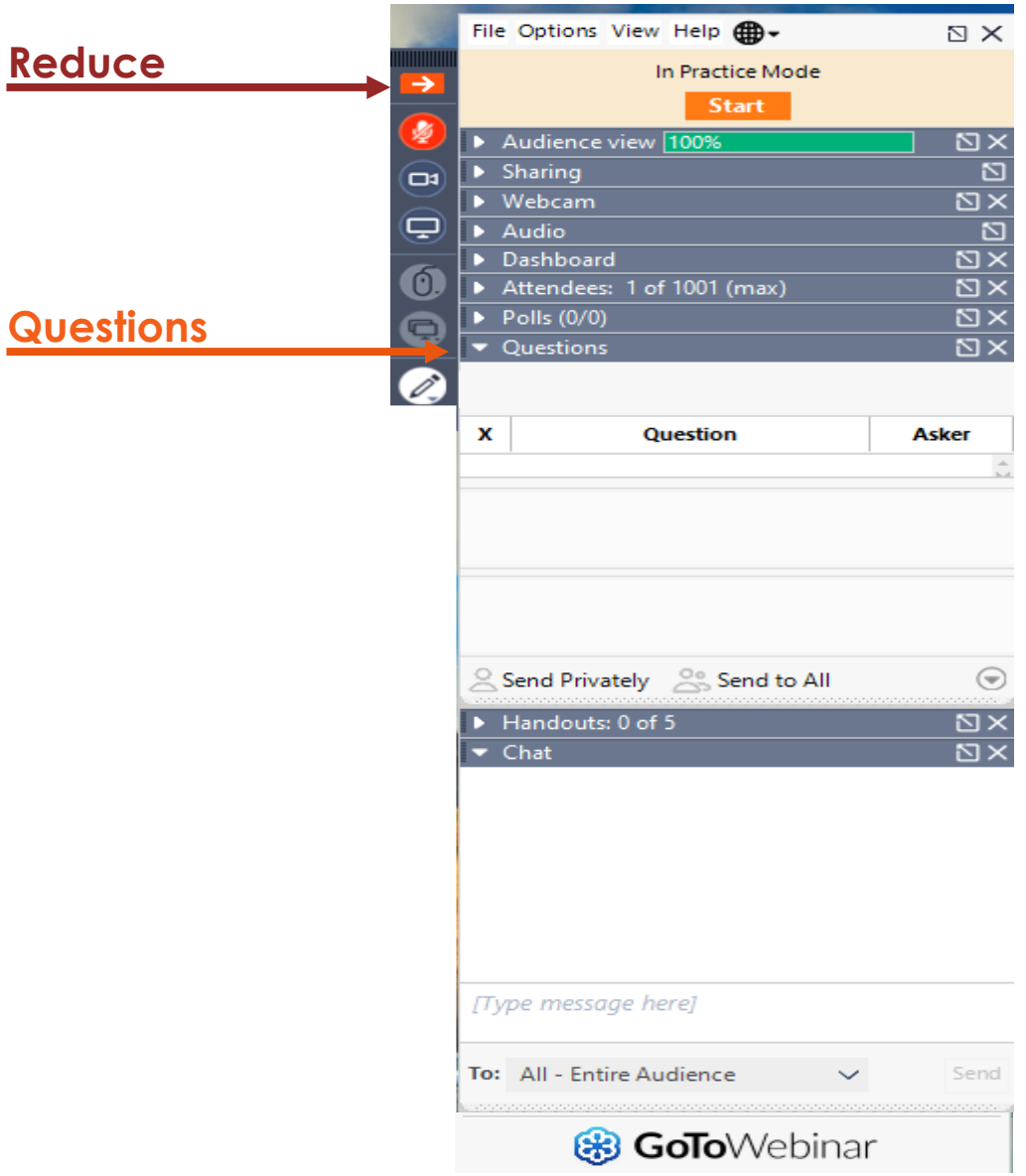
July 11th, 2024 at 09.00 – 10.30am EST

Time	Topic	Speaker
Welcome and Introduction		
5 mins	**Kick-off and ground rules**	Stacy Tegan
10 mins	**Panel introductions and setting the stage**	All
Speaker Presentations		
15 min	**Delivering a Data-Driven ICH M11 Clinical Protocol Template**	Ron Fitzmartin, FDA
10 min	**Regulator Perspective on ICH M11 Deliverables and What the Digitization Will Enable**	Noemie Manent, EMA
10 min	**Overview of the Digital Data Flow Project and the Collaboration with M11 and UDP**	Chris Decker, CDISC
15 min	**UDP Project Overview**	Hugh Glover, Vulcan
10 min	**Pathway to Implementation**	Mary Lynn Mercado, TransCelerate (Novartis)
10 min	**Q&A**	All
Wrap-Up		
5 min	**Close**	Stacy Tegan

VULCAN~UDP

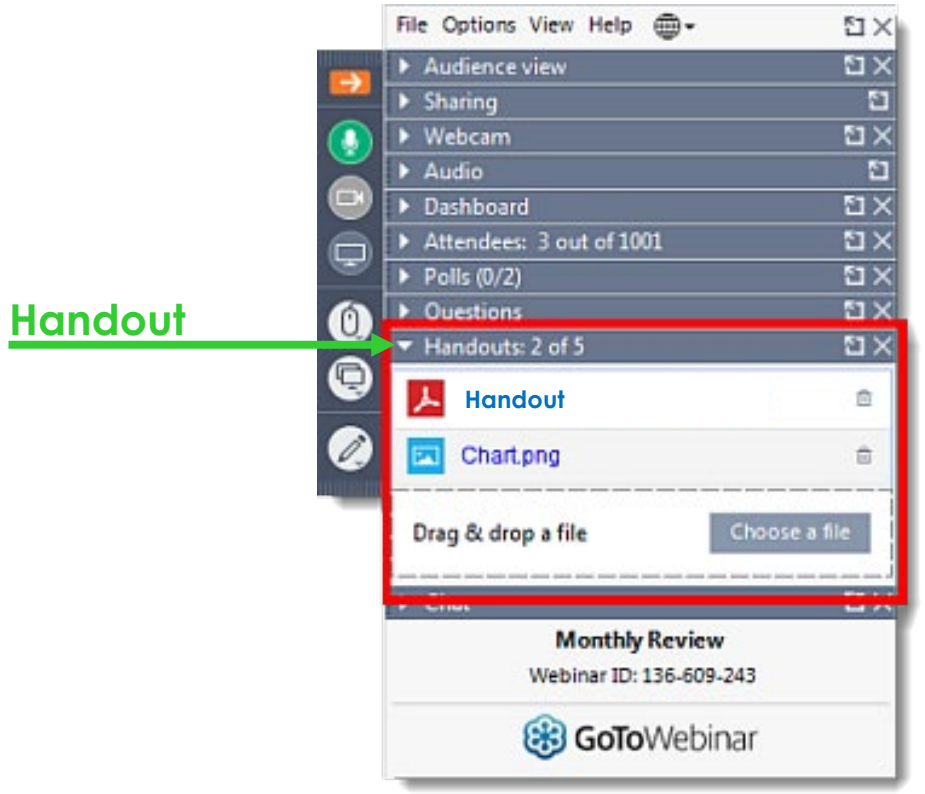
Webinar Logistics

- **All participants will be muted for this call.** Connect to audio to listen to presentations via your computer or phone
- **You can Reduce the control panel** for a better view of the presentation
- **To submit Questions to the presenters,** Type your question in the Questions panel and click Send – Please denote who your question is for



Webinar Logistics

- **Please download the Webinar handout** which contains links to contacts and additional resources
- **Reminder:** This webinar will 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:

- 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 discuss:

- What specific vendors/sites/CROs/sponsors companies are working with
- Any issues companies have with any specific vendors/sites/CROs/sponsors
- Anything related to pricing or costs

TransCelerate BIOPHARMA INC.

LIVE WEBINAR

VULCAN HL7 FHIR

cdisc

Vulcan UDP (Utilizing the Digital Protocol): Collaborating to Accelerate ICH M11 and End User Value

THURSDAY, JULY 11 9 - 10:30 A.M. EST

PANELISTS

HUGH GLOVER
TECHNICAL DIRECTOR
VULCAN

MARY LYNN MERCADO
GLOBAL HEAD PROTOCOL DELIVERY & US SITE HEAD, REGULATORY WRITING & SUBMISSIONS
NOVARTIS

CHRIS DECKER
PRESIDENT AND CEO
CDISC

RON FITZMARTIN
SENIOR ADVISOR, OFFICE OF REGULATORY OPERATIONS
CBER FDA

NOEMIE MANENT
CLINICAL TRIAL TRANSFORMATION, CHANGE MANAGER
EMA

Delivering a Data-Driven ICH M11 Clinical Protocol Template

Ron Fitzmartin, PhD, MBA
Sr. Advisor, Office of Regulatory Operations,
Data Standards Branch
Center for Biologics Evaluation & Research
U.S. Food & Drug Administration

ICH M11 Rapporteur

VULCAN~UDP

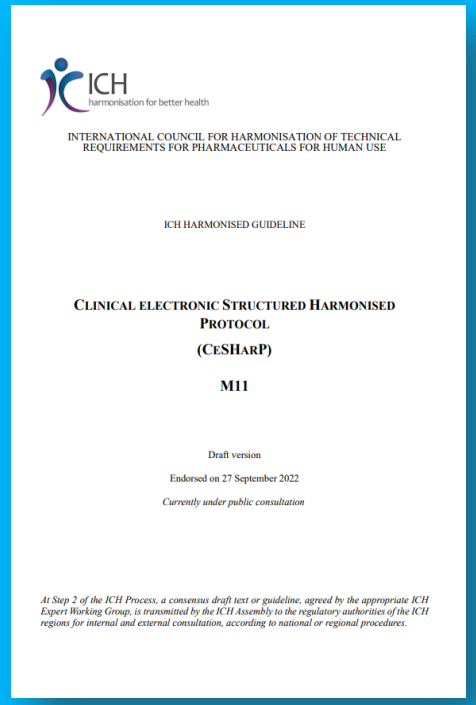
July 11, 2024

FDA Disclaimer

The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.

ICH M11
Clinical electronic Structured Harmonised Protocol

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

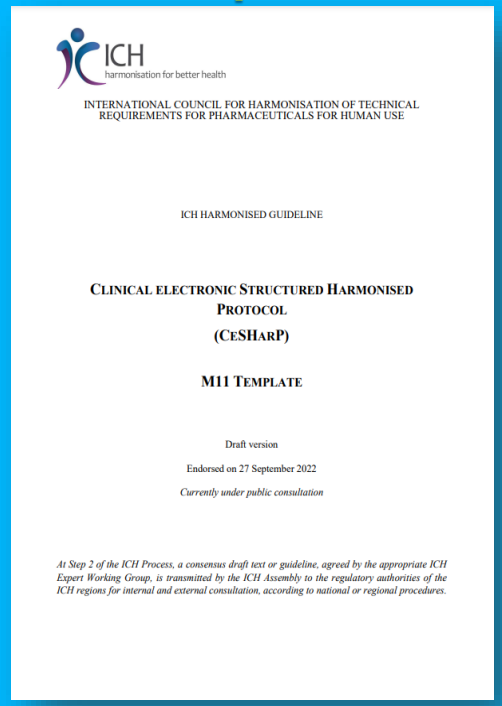
Draft version

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



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M11 TEMPLATE

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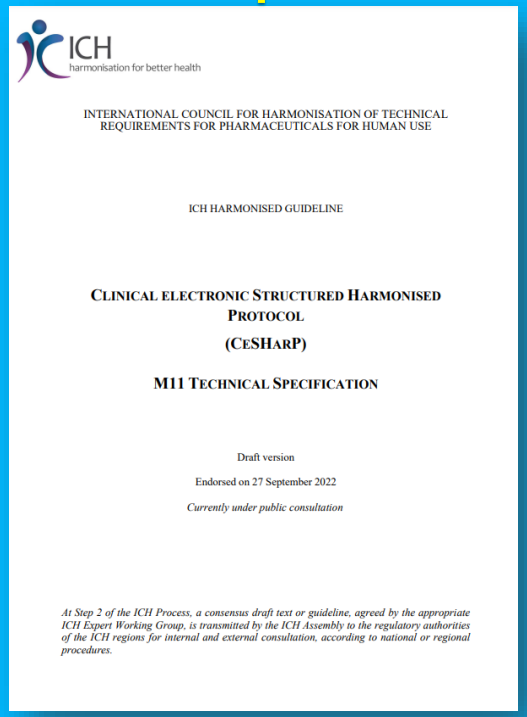
Technical Specification



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ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

M11 TECHNICAL SPECIFICATION

Draft version

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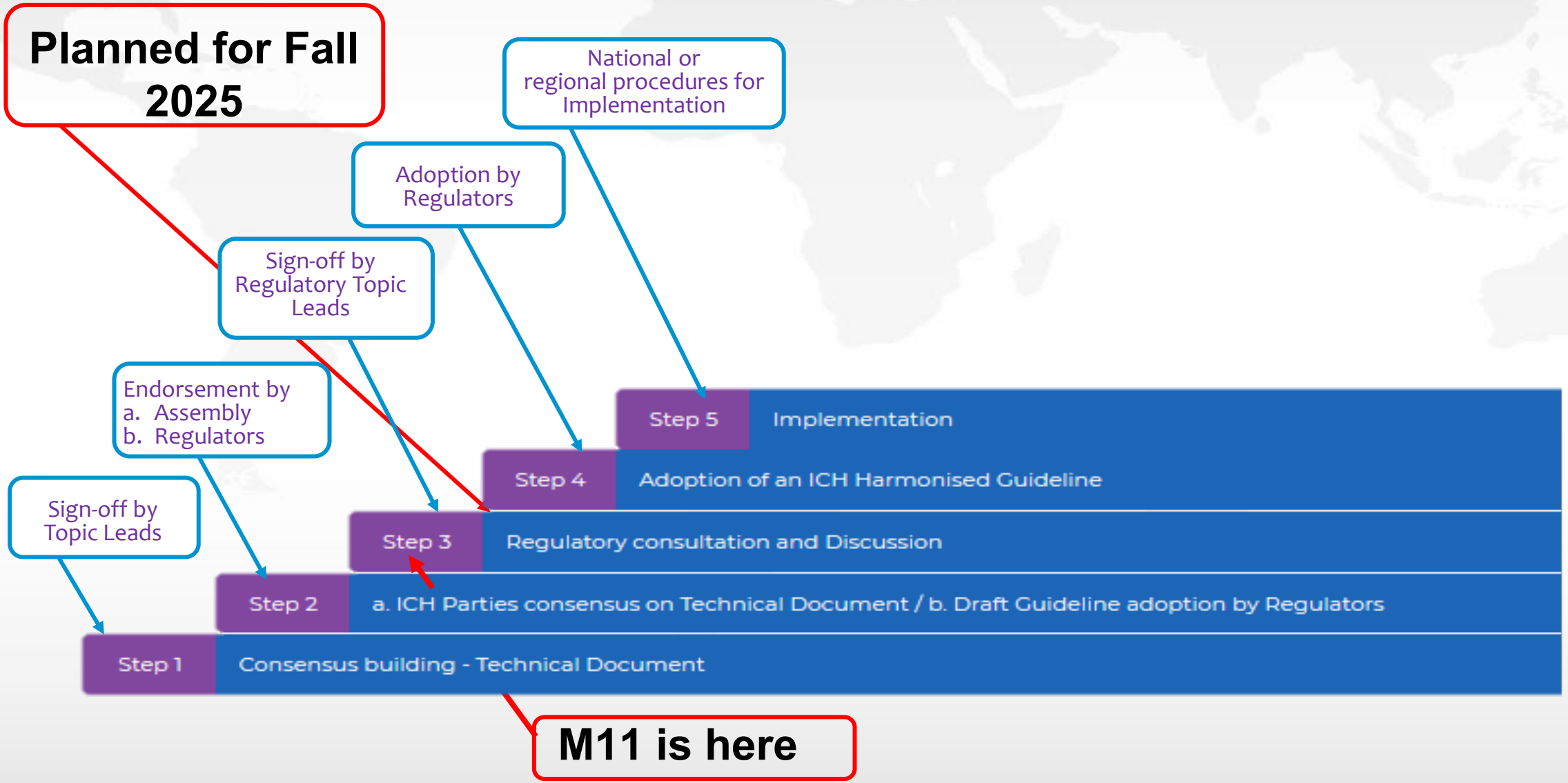
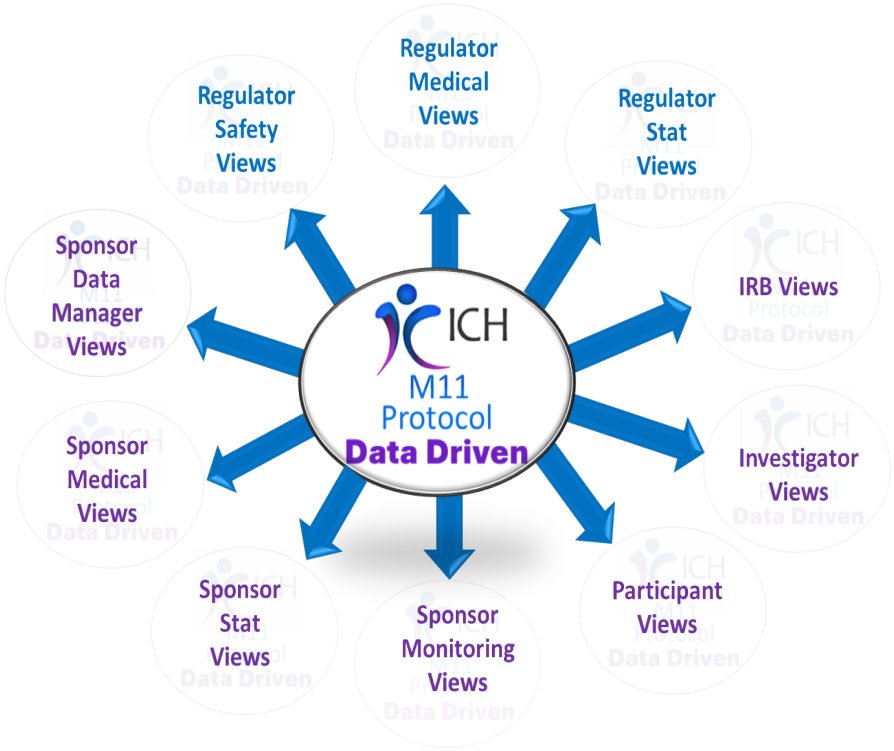
ICH M11: Three deliverables…

- **Guideline is a high-level document that:**
  - Provides the background on why a harmonized clinical protocol template is needed, and
  - Describes how the template and technical specification were developed.
- **Template**
  - Includes identification of headers, common text, instructions, data fields and terminologies.
- **Technical Specification**
  - Serves as a technical representation of the ICH M11 protocol template.
  - Aligns with the latest version of the ICH M11 guideline and template standard to enable electronic exchange of the clinical protocol information.
  - The tech spec does not deliver an implementation guide…that's for later

M11 & the ICH Step Process

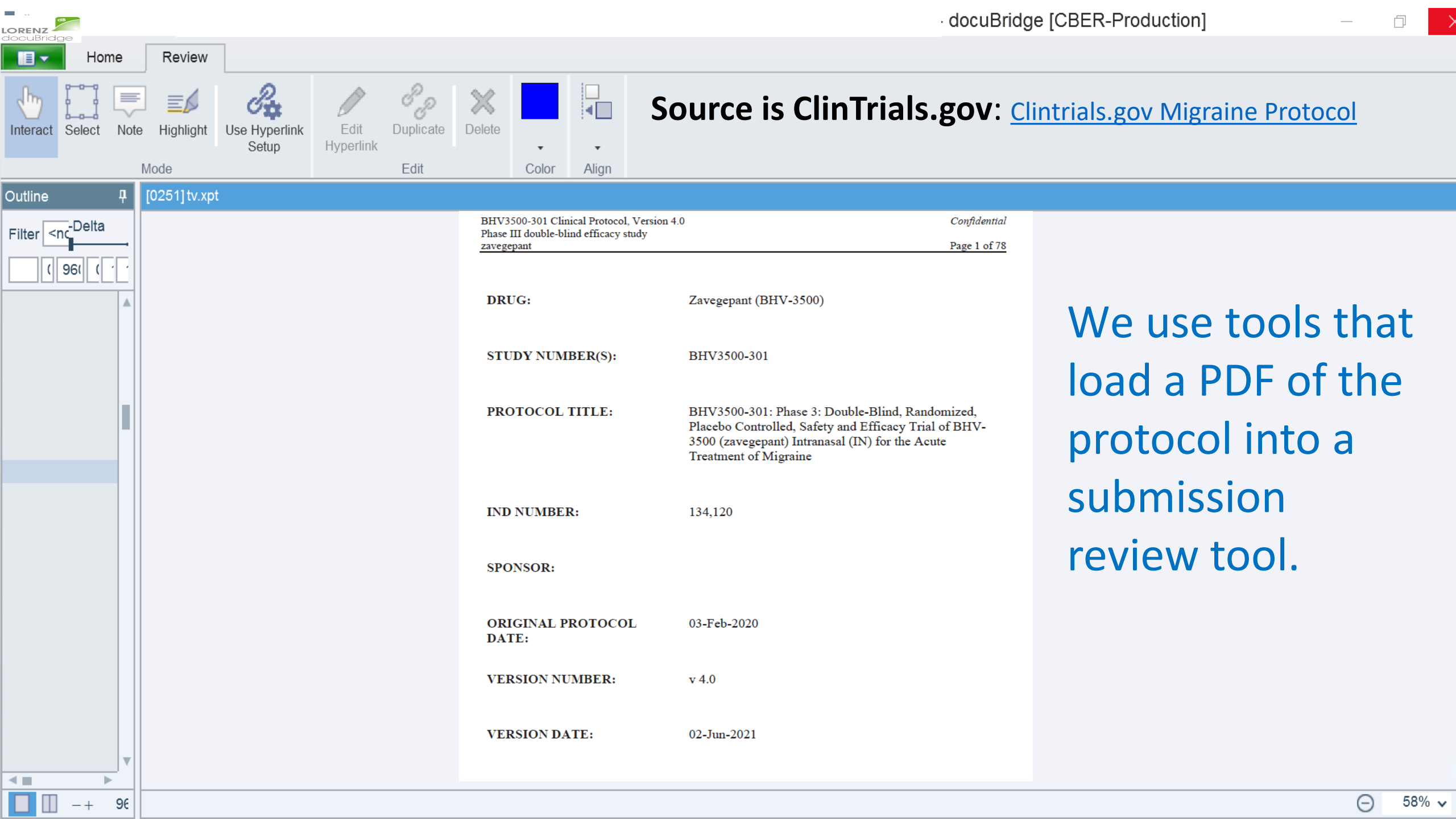


Imagine the Future State…



…where the Protocol is driven by a common data model that enables limitless personalized views of the protocol.

…But now all we have is this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BHV3500-301 Clinical Protocol, Version 4.0
Phase III double-blind efficacy study
zavegepant
Confidential
Page 1 of 78
DRUG: Zavegepant (BHV-3500)
STUDY NUMBER(S): BHV3500-301
PROTOCOL TITLE: BHV3500-301: Phase 3: Double-Blind, Randomized, Placebo Controlled, Safety and Efficacy Trial of BHV-3500 (zavegepant) Intranasal (IN) for the Acute Treatment of Migraine
IND NUMBER: 134,120
SPONSOR:
ORIGINAL PROTOCOL DATE: 03-Feb-2020
VERSION NUMBER: v 4.0
VERSION DATE: 02-Jun-2021
We use tools that load a PDF of the protocol into a submission review tool.
58%

TABLE OF CONTENTS

Or we review the protocol with a PDF reader.

STUDY SUMMARY (SYNOPSIS)

Title:	BHV3500-301: Phase 3: Double-Blind, Randomized, Placebo Controlled, Safety and Efficacy Trial of BHV-3500 (zavegepant) Intranasal (IN) for the Acute Treatment of Migraine
Rationale:	Zavegepant is being developed for the acute treatment of migraine. Effectiveness against migraine was demonstrated in BHV3500-201, a fully powered, pivotal, Phase 2/3, double-blind, randomized, placebo-controlled, dose-ranging study of zavegepant 5 mg, 10 mg, and 20 mg via intranasal (IN) administration. The data from this study will allow characterization of the relative safety and efficacy of IN zavegepant versus placebo in the acute treatment of moderate or severe migraine measuring freedom from pain and freedom from most bothersome system (nausea, photophobia or phonophobia) as reported just prior to treatment of the migraine. Information regarding time to onset of action, the duration of action, and the sustainability of pain freedom in subjects with migraine will also be obtained.
Target Population:	The study will recruit male and female subjects 18 years of age and older with at least a 1-year history of migraine (with or without aura), consistent with a diagnosis according to the International Classification of Headache Disorders 3rd edition[1], including an age of onset prior to 50, migraine attacks that last about 4-72 hours, not more than 8 attacks of moderate or severe intensity per month within the last 3 months and not less than 2 attacks per month.
Number of Subjects:	Approximately 1,750 subjects will be screened to randomize approximately 1,400 subjects (approximately 700 per treatment group). Subjects will be randomized in a 1:1 ratio to the zavegepant or placebo treatment groups. Randomization will be stratified by prophylactic migraine medication use (yes or no).
Primary Objective:	To compare the efficacy of zavegepant with placebo in the acute treatment of migraine, as measured by co-primary endpoints of pain freedom at 2 hours postdose, and freedom from the most bothersome symptom (MBS) associated with migraine at 2 hours postdose.
Secondary Objectives:	1. To compare zavegepant with placebo for pain relief at 2 hours postdose. 2. To compare zavegepant with placebo for return to normal function at 2 hours postdose according to the Functional Disability scale.

Page by page, hyperlinking back and forth

CDISC and M11 Curated Common Terminology enables the Data Driven Clinical Protocol

M11 will break the clinical protocol "document-centric" paradigm

CDISC and M11 Curated Common Terminology enables the Data Driven Clinical Protocol

Possible "Overall Protocol Views"

Term (Variable)	1.1 Protocol Synopsis
Data Type	Text
Topic, Value or Header	H
Definition	Header
User Guidance	The No t
Conformance	Req
Cardinality	
Relationship content from ToC representing the protocol hierarchy	Prot
Relationship (reference to high level conceptual model)	
Value	1.1
Business rules	**Valu** **Rela** **Con**
Duplicate field in other sections	

Section 1.0

Term (Variable)	Trial Schema
Data Type	Image
Topic, Value or Header	D
Definition	Visua featu parti scre rand
User Guidance	Key the t Activ subje rand are p to la

Section 1.0

Term (Variable)	Study Objectives, Endpoints, and Estimands
Data Type	Text
Topic, Value or Header	H
Definition	Heading
User Guidance	In this section, precisely define each clinical question of interest by stating each study objective and specifying the endpoint(s) and estimand(s) that corre to each study objective. Ensure alignment with every other section of the protocol. Include additional level 2 headers under Section 3 Study Objectives, Endp and Estimands as needed.
Conformance	Required / Required
Cardinality	
Relationship content from ToC representing the protocol hierarchy	Study Objectives, Endpoints, and Estimands
Relationship (reference to high level conceptual model)	
Value	Study Objectives, Endpoints, and Estimands
Business rules	**Value Allowed:** Yes **Relationship:** n/a **Concept:** n/a
Duplicate field in other sections	

Section 3.0

Term (Variable)	Study Intervention and Concomitant Therapy
Data Type	Text
Topic, Value or Header	H
Definition	Heading
User Guidance	In this section, describe the study intervention being tested and any control product being used. If multiple study interventions are to be evaluated, Section 6.1, Description of Study Intervention, Section 6.3, Dosing and Administration, and Section 6.5, Preparation, Handling, Storage, and Accountability should differentiate between each product.
Conformance	Required / Required
Cardinality	
Relationship content from ToC representing the protocol hierarchy	Study Intervention and Concomitant Therapy
Relationship (reference to high level conceptual model)	
Value	Study Intervention and Concomitant Therapy
Business rules	**Value Allowed:** Yes **Relationship:** n/a **Concept:** n/a
Duplicate field in other sections	

Section 6.0

M11 Technical Specification, Step 2a/2b version

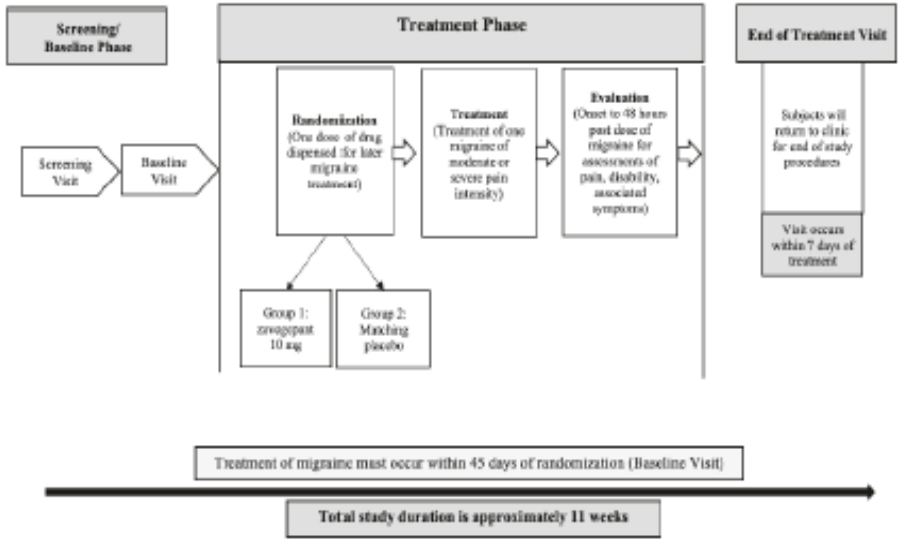
PHASE 3: DOUBLE-BLIND, RANDOMIZED, PLACEBO CONTROLLED, SAFETY AND EFFICACY TRIAL OF BHV-3500 (ZAVEGEPANT) INTRANASAL (IN) FOR THE ACUTE TREATMENT OF MIGRAINE

Overall Design

Intervention Model:	[Parallel]	**Population Type:**	[Adult Participants]
Control Type:	[Placebo]	**Population Diagnosis or Condition:**	[Migraine]
Control Description:	[NA]	**Population Age:**	Minimum: 18 years Maximum: 80 years
Intervention Assignment Method:	[Stratified Randomization]	**Site Distribution and Geographic Scope:**	[Multicentre] [Multiple Countries]
Adaptive Trial Design:	[No]	**Master Protocol Design:**	[No]
Drug/Device Combination Product Indicator:	[No]		

Number of Arms	[2]
Trial Blind Schema	[Triple]
Blinded Roles	[Participant] [Investigator] [Care Provider]
Number of Participants	[1400] / [1750]
Duration	[45] [days]
Independent Committee	[No]

Trial Schema



Overview of Trial Interventions

Arm Name	Arm Type	Intervention Name	Intervention Type	Dose Form	Unit Dose Strength	Dosage Level	Route of Administration	Regimen Treatment Period
Experimental	[Active]	[Zavegepant]	[Drug]	[Spray]	[mg]	[10]	[Intranasal]	[45] [days]
Placebo Comparator	[Placebo]	[Placebo]	[Drug]	[Spray]	[mg]	[10]	[Intranasal]	[45] [days]

Trial Objectives and Associated Estimands

Estimand Characteristic	Description
Population	(<The study will recruit male and female subjects 18 years of age and older with at least a 1-year history of migraine (with or without aura), consistent with a diagnosis according to the International Classification of Headache Disorders 3rd edition1, including an age of onset prior to 50, migraine attacks that last about 4-72 hours, not more than 8 attacks of moderate or severe intensity per month within the last 3 months and not less than 2 attacks per month. >)
Treatment	(<zavegepant 10 mg via intranasal (IN) administration>)
Endpoint	(< Pain freedom at 2 hours postdose will be assessed using the percentage of subjects with a pain intensity of none at 2 hours postdose. Pain intensity will be measured on a 4-point numeric rating scale (0=none, 1=mild, 2=moderate, 3=severe). >)
Population-Level Summary	(< Treatments compared using a Cochran-Mantel Haenszel test to estimate the difference in percentages of subjects achieving the endpoint response criteria (zavegepant-placebo) stratified by prophylactic migraine medication use at randomization (yes or no)>)
Intercurrent Event	(Strategy)
Rescue Medication	(<(The intercurrent event of rescue medication use will be handled using Rescue Medication = Failure (RM=F), i.e., subjects who take rescue medication will be classified as failures for all efficacy assessments that are reported at or after taking rescue medication. The RM=F method will apply to all endpoints listed below, except the secondary endpoint of rescue medication use within 24 hours postdose)>)

CDISC and M11 Curated Common Terminology will Enable the Data Driven Clinical Protocol

Possible "Safety Views"

Term (Variable)	1.1 Protocol Synopsis
Data Type	Text
Topic, Value or Header	H
Definition	Header
User Guidance	The protocol synopsis is a short summary of the key points of the trial.

Section 1.0

Term (Variable)	Trial Schema
Data Type	Image
Topic, Value or Header	D
Definition	Visual depiction of the trial design, orienting users of the protocol to the key features of the study design participants through the pr screening, washout/run-in, randomization, crossover, e
User Guidance	Key visits may also be inclu the trial and should corresp Activities. Reviewers will a subjects per treatment grou randomized to treatment gr are presented with time pr to landscape orientation, if

Section 1.0

Term (Variable)	Study Intervention and Concomitant Therapy
Data Type	Text
Topic, Value or Header	H
Definition	Heading
User Guidance	In this section, describe the study intervention being test product being used. If multiple study interventions are t 6.1, Description of Study Intervention, Section 6.3, Dosin and Section 6.5, Preparation, Handling, Storage, and Acc differentiate between each product.
Conformance	Required / Required
Cardinality	
Relationship content from ToC representing the protocol hierarchy	Study Intervention and Concomitant Therapy
Relationship (reference to high level conceptual model)	
Value	Study Intervention and Concomitant Therapy
Business rules	**Value Allowed:** Yes **Relationship:** n/a **Concept:** n/a
Duplicate field in other sections	

Section 6.0

Term (Variable)	Adverse Events of Special Interest
Data Type	Text
Topic, Value or Header	D
Definition	
User Guidance	Include this section, if applicable. Specify any Adverse Eve • Other events tha and regulatory agencies studies). • Other reportable such as cardiovascular a malfunctions), laborator Include the following for • The definition of to report the AESI. • If it is a measura done. If it is a clinical event, s
Conformance	Required / Required
Cardinality	
Relationship content from ToC representing the protocol hierarchy	Study Assessment and P
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	

Section 8.0

Term (Variable)	Safety Assessments and Procedures
Data Type	Text
Topic, Value or Header	H
Definition	
User Guidance	This section describes safety assessments and procedures in this section. Level 3 headings can be added as needed. • Identify any non-investigator party responsible for evaluation of laboratory or other safety assessments (for example, Sponsor or external Independent Data Monitoring Committee). • Include guidelines for the management of relevant laboratory or other safety assessment abnormalities.
Conformance	Optional
Cardinality	
Relationship content from ToC representing the protocol hierarchy	Adverse Events and Serious Adverse Events
Relationship (reference to high level conceptual model)	
Value	Efficacy Assessments and Procedures
Business rules	**Value Allowed:** Yes **Relationship:** n/a **Concept:** n/a
Duplicate field in other sections	

Section 8.0

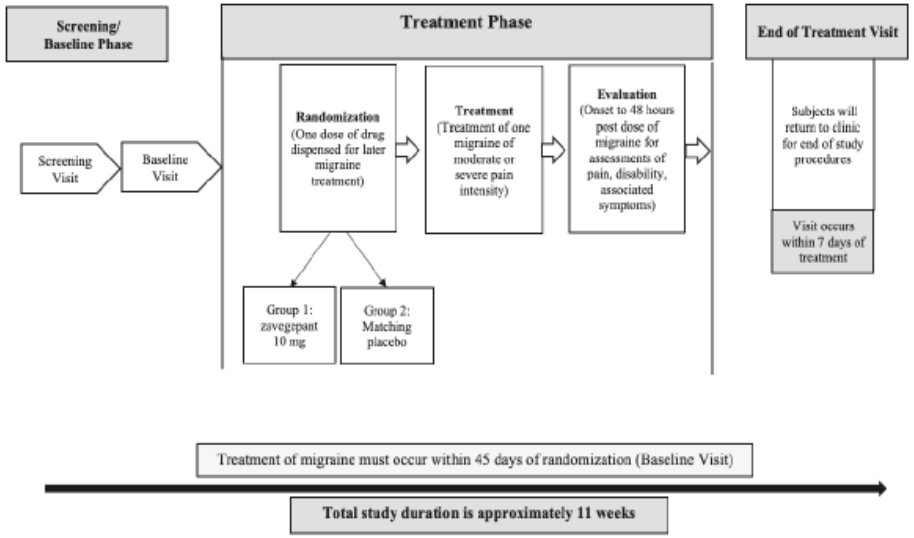
M11 Technical Specification, Step 2a/2b version

PHASE 3: DOUBLE-BLIND, RANDOMIZED, PLACEBO CONTROLLED, SAFETY AND EFFICACY TRIAL OF BHV-3500 (ZAVEGEPANT) INTRANASAL (IN) FOR THE ACUTE TREATMENT OF MIGRAINE

Overview of Trial Interventions

Arm Name	Arm Type	Intervention Name	Intervention Type	Dose Form	Unit Dose Strength	Dosage Level	Route of Administration	Regimen Treatment Period
Experimental	[Active]	[Zavegepant]	[Drug]	[Spray]	[mg]	[10]	[Intranasal]	[45] [days]
Placebo Comparator	[Placebo]	[Placebo]	[Drug]	[Spray]	[mg]	[10]	[Intranasal]	[45] [days]

Trial Schema



Adverse Events of Special Interest

< ***Non-serious Adverse Events***

A ***non-serious AE*** is an AE not classified as serious.

·*Collection and Reporting of Non-Serious Adverse Events*

The collection of non-serious AE information should begin at the Baseline Visit through the EOT Visit.

Non-serious AEs should be followed until conclusion or stabilization, or reported as SAEs if they become serious. Follow-up is also required for non-serious AEs that cause interruption or discontinuation of study drug or those that are present at the end of study treatment.

Laboratory Test Abnormalities

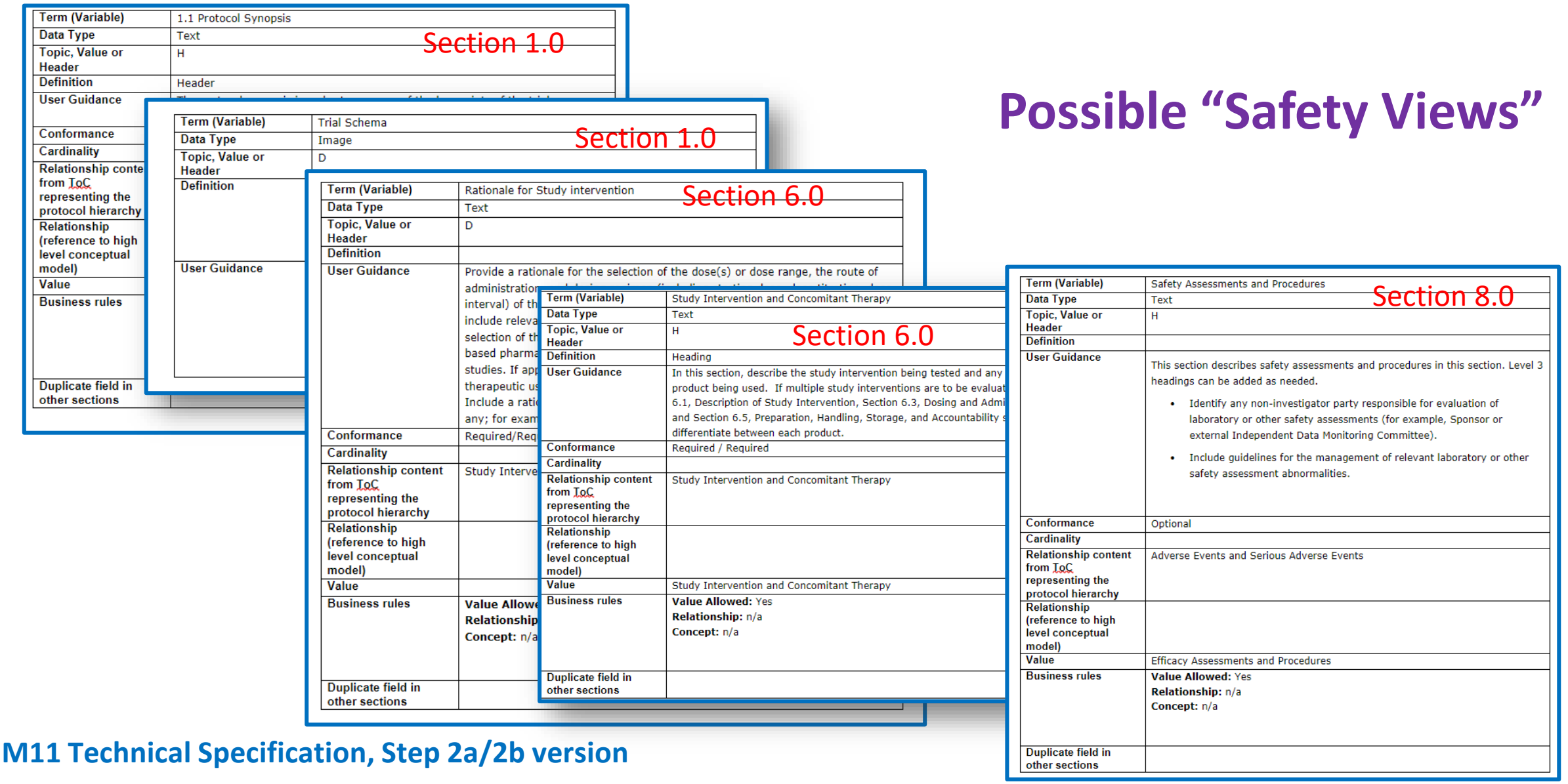
The following laboratory test abnormalities should be captured on the non-serious AE CRF page or SAE Report Form (paper or electronic) as appropriate:

1. Any laboratory test result that is clinically significant or meets the definition of an SAE;
2. Any laboratory abnormality that required the subject to have the study drug discontinued or interrupted;
3. Any laboratory abnormality that required the subject to receive specific corrective therapy.

Safety Assessments and Procedures

Procedure	Screening Visit	Baseline Randomization Visit (Day1)	Moderate or Severe Migraine Before Study Drug Administration	Post Study Drug Administration: 15, 30, 45, 60 & 90 minutes 2, 3, 4, 6, 8, 24 & 48 hours	End of Treatment Visit
Physical Examination	X				X
Nasal Inspection	X	X			X
Vital Signs / Physical Measurements	X	X			X
Adverse Event and Serious Adverse Event Assessment	X	X	X	X	X
Sheehan Suicidality Tracking Scale	X	X			
ECG	X				
Clinical Safety Laboratory Testing	X				
Liver Function Tests	X				
Lipid Panel	X				
FSH, if Applicable	X				
Pregnancy Test	X				
Urinalysis Test	X	X	X		X
Urine Drug Screen for Drugs of abuse	X				X

CDISC and M11 Curated Common Terminology enables the Data Driven Clinical Protocol



Possible "Safety Views"

M11 Technical Specification, Step 2a/2b version

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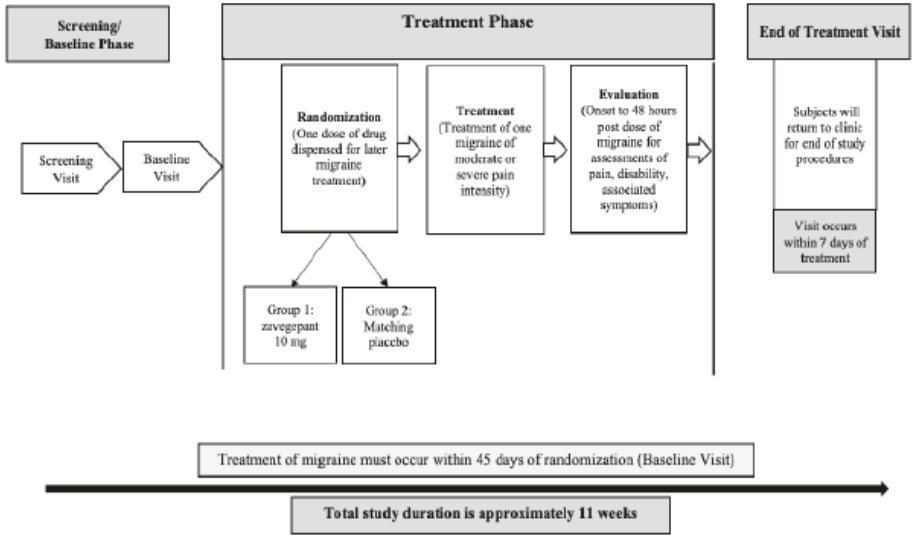
Trial Schema



Rationale for Investigational Trial Intervention Dose and Regime

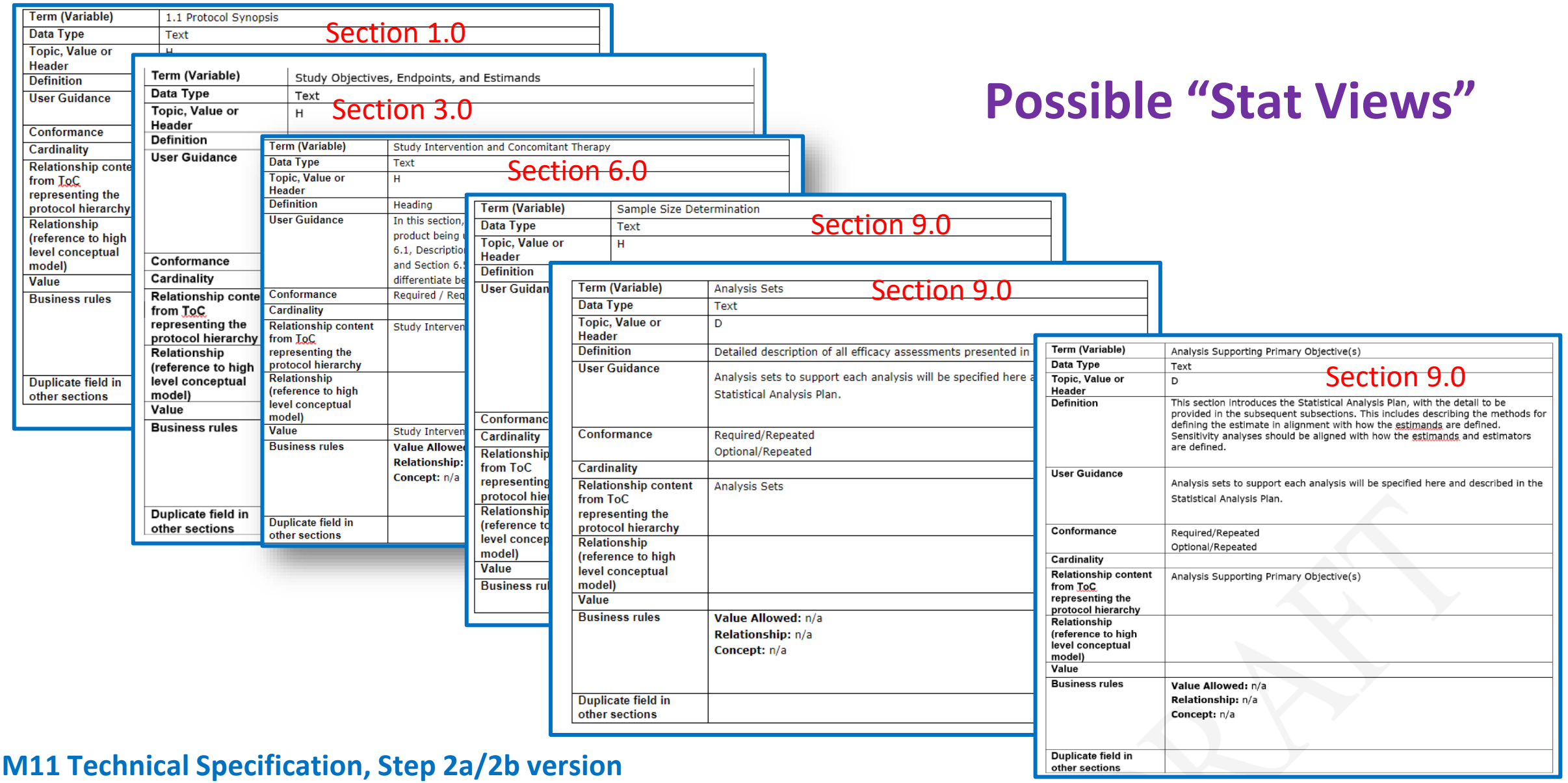
<Safety data are now available from the pivotal Phase 2/3 dose ranging study (BHV3500-201). BHV3500-201 is a concluded, pivotal, Phase 2/3, double-blind, randomized, placebo-controlled dose-ranging (5 mg, 10 mg, or 20 mg) study of zavegepant IN for the acute treatment of migraine. In this study, a total of 1,673 subjects were randomized to receive zavegepant (5 mg, 10 mg, or 20 mg) or matching placebo.

Based on topline data from this pivotal study, a durable efficacy profile for zavegepant was established. This efficacy profile, together with a favorable safety profile led to the selection of the IN zavegepant 10 mg dose as the lowest fully efficacious dose to support Phase 3 clinical studies.>

Safety Assessments and Procedures

Procedure	Screening Visit	Baseline Randomization Visit (Day1)	Moderate or Severe Migraine Before Study Drug Administration	Post Study Drug Administration: 15, 30, 45, 60 & 90 minutes 2, 3, 4, 6, 8, 24 & 48 hours	End of Treatment Visit
Physical Examination	X				X
Nasal Inspection	X	X			X
Vital Signs / Physical Measurements	X	X			X
Adverse Event and Serious Adverse Event Assessment	X	X	X	X	X
Sheehan Suicidality Tracking Scale	X	X			
ECG	X				
Clinical Safety Laboratory Testing	X				
Liver Function Tests	X				
Lipid Panel	X				
FSH, if Applicable	X				
Pregnancy Test	X				
Urinalysis Test	X	X	X		X
Urine Drug Screen for Drugs of abuse	X				X

CDISC and M11 Curated Common Terminology enables the Data Driven Clinical Protocol



Possible "Stat Views"

M11 Technical Specification, Step 2a/2b version

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Overall Design

Intervention Model:	[Parallel]	**Population Type:**	[Adult Participants]
Control Type:	[Placebo]	**Population Diagnosis or Condition:**	[Migraine]
Control Description:	[NA]	**Population Age:**	Minimum: 18 years Maximum: 80 years
Intervention Assignment Method:	[Stratified Randomization]	**Site Distribution and Geographic Scope:**	[Multicentre] [Multiple Countries]
Adaptive Trial Design:	[No]	**Master Protocol Design:**	[No]

Number of Arms	[2]
Trial Blind Schema	[Triple]
Blinded Roles	[Participant] [Investigator] [Care Provider]
Number of Participants	[1400] / [1750]
Duration	[45] [days]

Overview of Trial Interventions

Arm Name	Arm Type	Intervention Name	Intervention Type	Dose Form	Unit Dose Strength	Dosage Level	Route of Administration	Regimen Treatment Period
Experimental	[Active]	[Zavegepant]	[Drug]	[Spray]	[mg]	[10]	[Intranasal]	[45] [days]
Placebo Comparator	[Placebo]	[Placebo]	[Drug]	[Spray]	[mg]	[10]	[Intranasal]	[45] [days]

Trial Objectives and Associated Estimands

Estimand Characteristic	Description
Population	{<The study will recruit male and female subjects 18 years of age and older with at least a 1-year history of migraine (with or without aura), consistent with a diagnosis according to the International Classification of Headache Disorders 3rd edition1, including an age of onset prior to 50, migraine attacks that last about 4-72 hours, not more than 8 attacks of moderate or severe intensity per month within the last 3 months and not less than 2 attacks per month. >}
Treatment	{<zavegepant 10 mg via intranasal (IN) administration>}
Endpoint	{< Pain freedom at 2 hours postdose will be assessed using the percentage of subjects with a pain intensity of none at 2 hours postdose. Pain intensity will be measured on a 4-point numeric rating scale (O=none, 1=mild, 2=moderate, 3=severe). >}
Population-Level Summary	{< Treatments compared using a Cochran-Mantel Haenszel test to estimate the difference in percentages of subjects achieving the endpoint response criteria (zavegepant-placebo) stratified by prophylactic migraine medication use at randomization (yes or no)>}
Intercurrent Event	{Strategy}
Rescue Medication	{<{The intercurrent event of rescue medication use will be handled using Rescue Medication = Failure (RM=F), i.e., subjects who take rescue medication will be classified as failures for all efficacy assessments that are reported at or after taking rescue medication. The RM=F method will apply to all endpoints listed below, except the secondary endpoint of rescue medication use within 24 hours postdose}>}

Sample Size Determination

It is anticipated that about 90% of the 700 subjects randomized to each treatment group will have a headache in the allotted time period, resulting in approximately 630 subjects evaluable for efficacy in each treatment group.

The sample size calculation is based on results from the Phase 2/3 dose-ranging study BHV3500-201. A total sample size of 1,260 evaluable subjects (630 per group) will provide approximately 91% power for the co-primary endpoint of pain freedom at 2 hours post dose, approximately 88% power for the co-primary endpoint of MBS freedom at 2 hours post dose, and approximately 80% power to detect a difference between treatment groups for both endpoints jointly.

Analysis Sets

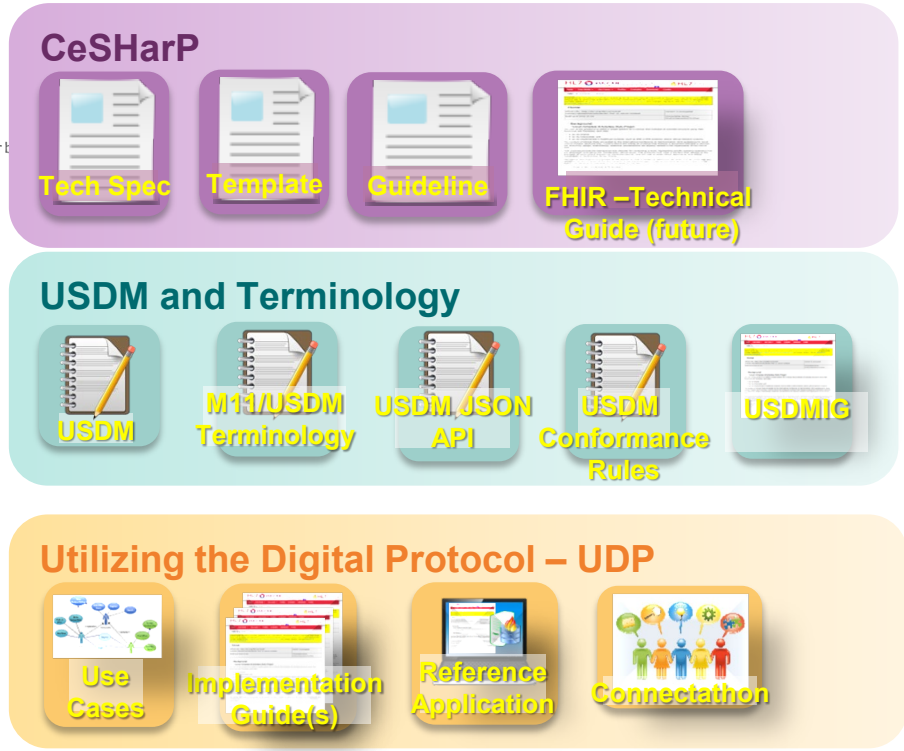
Enrolled: Subjects who sign informed consent and are assigned a subject identification number.

- **Randomized**: Subjects in the enrolled analysis set who receive a randomized treatment group assignment (zavegepant or placebo) from TWRS.
- **Safety**: Subjects in the enrolled analysis set who take study drug (zavegepant or placebo).
- **Efficacy**: Subjects in the randomized analysis set who: (1) are randomized only once; (2) have a migraine of moderate or severe intensity at the time of dosing (3) take study drug; and (4) have post-dose efficacy data.

Analysis Associated with the Primary Objective

Zavegepant will be tested for superiority against placebo at an alpha=0.05 level for both co- primary endpoints using the efficacy analysis set. For each endpoint, treatment groups will be compared using a Cochran-Mantel Haenszel test to estimate the difference in percentages of subjects achieving the endpoint response criteria (zavegepant - placebo) stratified by prophylactic migraine medication use at randomization (yes or no). The percentage of subjects achieving the endpoint response criteria will be presented with a 95% confidence interval (CI) by treatment group.

ICH M11 and Vulcan Utilizing Digital Protocol (UDP): *A Collaboration that will result in…*



- Data driven Protocol that will be personalized to the reviewer's needs
- Standardized data model with CDISC / USDM common terms, definitions and formats
- Improved collaboration / communication among protocol stakeholders
- Facility to exchange the protocol information using multiple formats: DOCX, PDF JSON and FHIR.

Adapted from C. Decker slide, 2024 June

Thank You

Regulator Perspective on ICH M11 Deliverables and What the Digitization Will Enable

Noemie Manent

The European Clinical Trials Regulation

Before the Clinical Trials Regulation

Clinical trial applications were submitted separately to regulators and ethics committees in each EU Member State and recorded in EudraCT

After the Clinical Trials Regulation

Single submission of clinical trial applications, covering regulatory and ethics submission in up to 30 EU/EEA Countries

Applies as of **31 January 2022** supported by the use of the Clinical Trials Information System (CTIS)

The benefits of the Clinical Trials Regulation (CTR)

- CTIS is the register of the **Clinical Trials Regulation**
- CTIS generates substantially **higher quality data** than EudraCT
- Opportunity to capitalise on **technological developments** in *advanced analytics* (i.e., machine learning, AI, NLP)

Image 1.
Since 31 January 2023, sponsors submit all new clinical trial applications in the EU/EEA via CTIS.

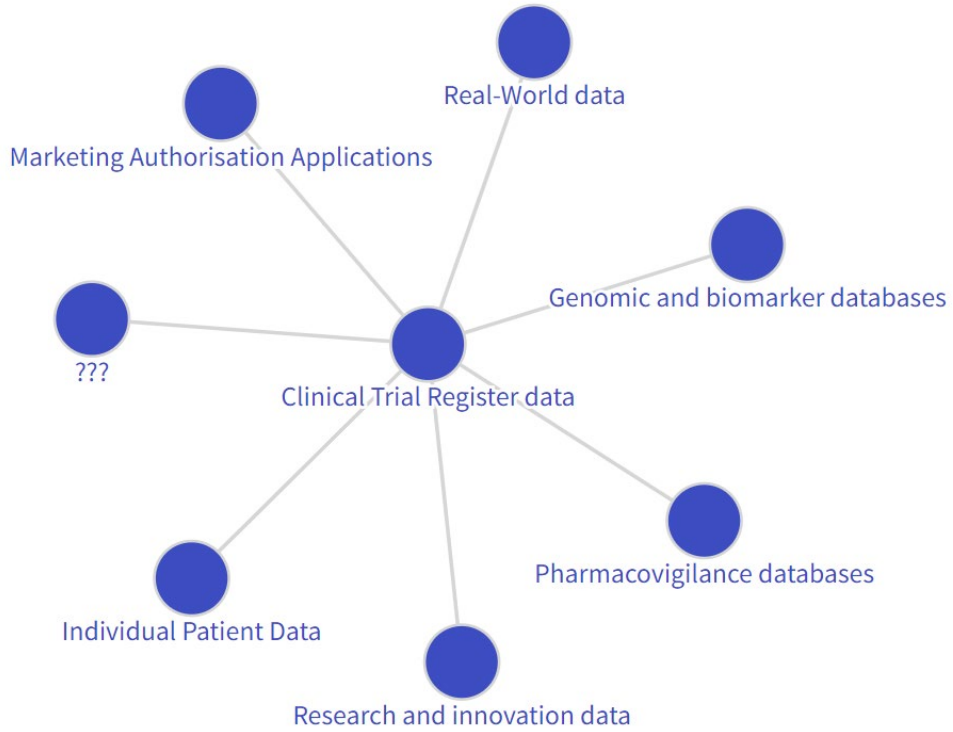
Where should we focus to make better use of the data we collect about clinical trials?

The Clinical Trials Regulation and ICH M11 digitization

- Aligns with EU legislative framework and CTR protocol requirements
- Enhances efficiency under CTR with more structured data
- Improves review and reporting through robust methodologies
- Achieves global consistency with a common Table of Content
- Utilises data to advance drug development and guide policy making

Registers and clinical trials

- *Data about clinical trials* are held in CT registers and contain summary-level information on clinical trials
- *Data from clinical trials* are Individual Patient Data and are not kept in the registers
- CT register data is centrally positioned and play a bridging role, facilitating the link between data sources

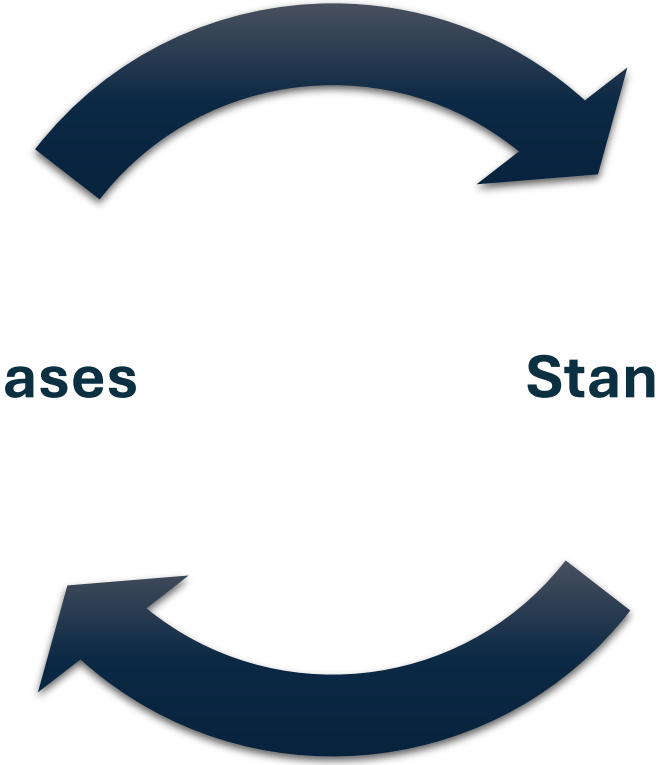


Harnessing clinical trial data for enhanced drug development and policy making

- **Potential**: Clinical trial data is crucial for developing products, shaping policies, and benefiting patients.
- **Objective**: Aim to utilise more data to make drug development more efficient and patient-centered, aiding policy decisions.
- **Resources**: EU regulatory network possesses extensive clinical trial data through EU registers (CTIS and EudraCT).
- **Workshop focus**: Identify use cases to combine various data sources, uncovering new insights to improve EU citizens' health and well-being.

The use cases require data standardisation

- Establish requirements for structuring information



- Enable use cases by making data more accessible

Key takeaways

- **Standardised, harmonised, and interoperable** data are foundational for advancing research methodologies, facilitating effective collaborations, and streamlining regulatory processes.
- **Access to data for patients and patient organisations** is critical for informed decision-making and effective advocacy.
- **Accurate, complete, and timely data** underpin not only the integrity of clinical trials but also the reliability of research outcomes.
- **Open analytics platforms** can optimise research processes, support strategic prioritisation, and guide efficient resource allocation across the research ecosystem.
- **Integrating data** about clinical trials with a variety of other data sources, including real-world data, can optimise trial designs and address challenges in accessibility and inclusivity.

Acknowledgements

- Nick Halsey
- Mumtaz Sultani
- Panagiotis Telonis
- Frank Petavy
- Theo Framke
- IJsbrand den Rooijen
- Ana Zanoletty

Overview of the Digital Data Flow Project and the Collaboration with M11 and UDP

Chris Decker

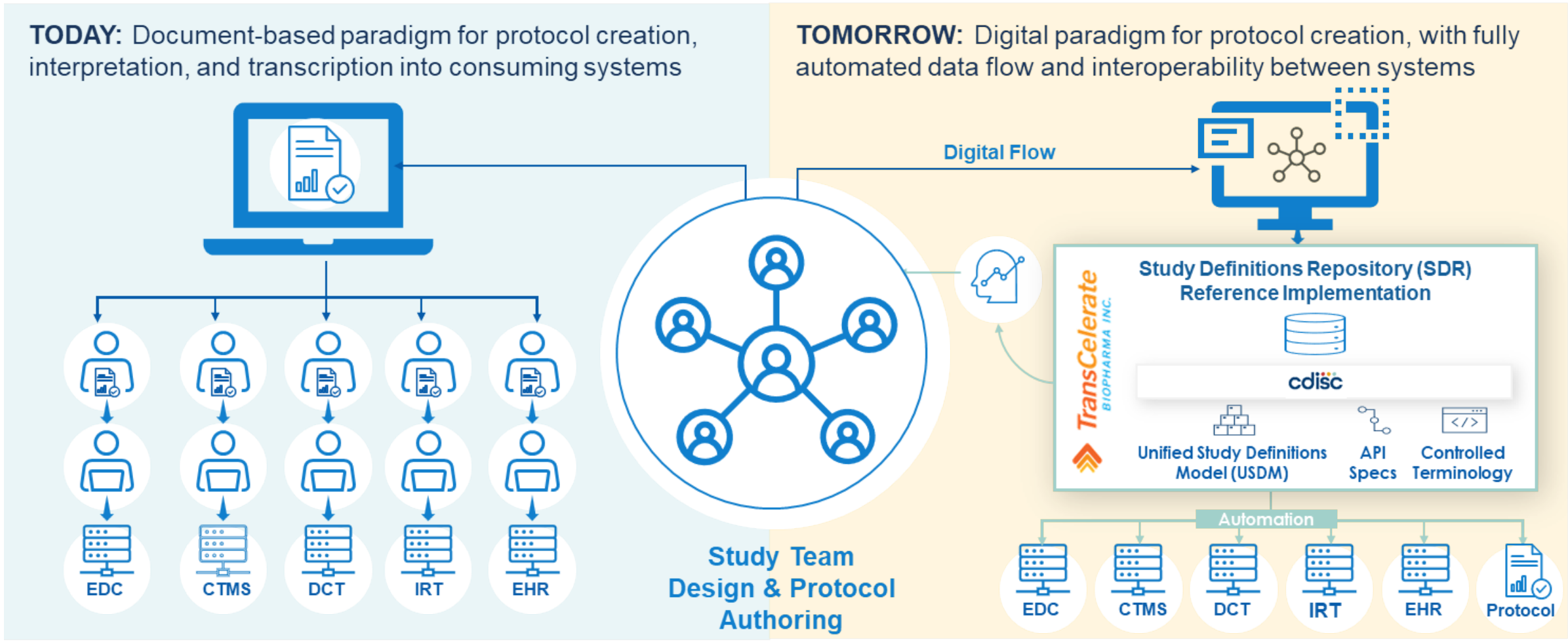
CDISC AGENDA TOPICS

- Introduction to Digital Data Flow (DDF) and Unified Study Definition Model (USDM)
- CDISC/ICH M11 Partnership
- How does USDM, M11, and UDP Come Together

TransCelerate Digital Data Flow (DDF) Ambition

Write Once, Read Many

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

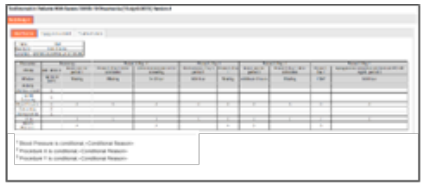


DDF Initiative encompasses technical delivery, change management, and industry engagement

cdisc

Unified Study Definitions Model (USDM) Reference Architecture

TransCelerate's Study Definitions Repository (SDR)



Digital Data Flow Initiative

Suite of DDF Adoption Resources, Videos & Change Management Tools

Continued Industry Collaboration between TransCelerate, CDISC ICH, and HL7

VULCAN HL7 FHIR · cdisc · TransCelerate BIOPHARMA INC. · HL7 International · ICH harmonisation for better health

Growing Solution Collaboration Forum (SCF)*

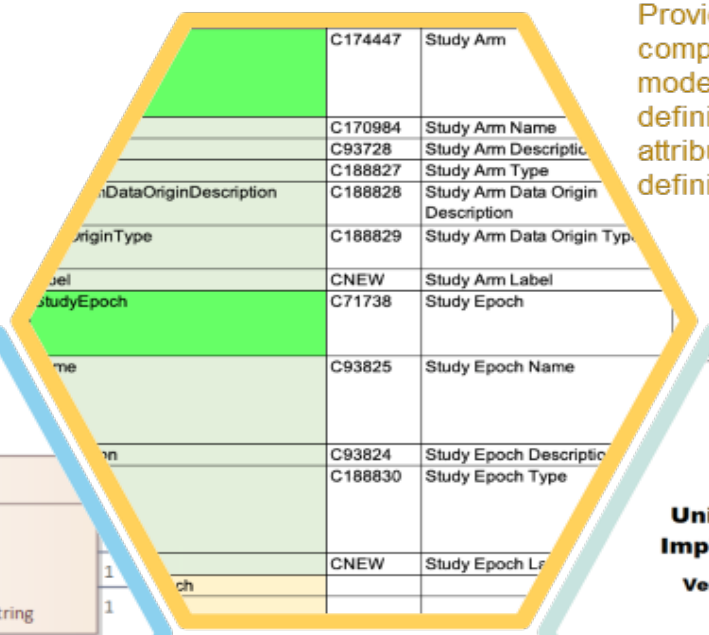
trials.ai · ZS · IntelliNotion · formedix · PHARMASEAL · nurocor · merative · TriNetX · castor · ORACLE · Sycamore Informatics · medidata · TRYAL · REDCAP CLOUD · indegene · Medable · saama · THREAD · Target Health · Taimei Technology

*Company logos illustrate current involvement and are not used to imply endorsement of specific vendors for DDF or to identify a comprehensive list of all actual or potential future participants in DDF.

The USDM Standard

CDISC Controlled Terminology

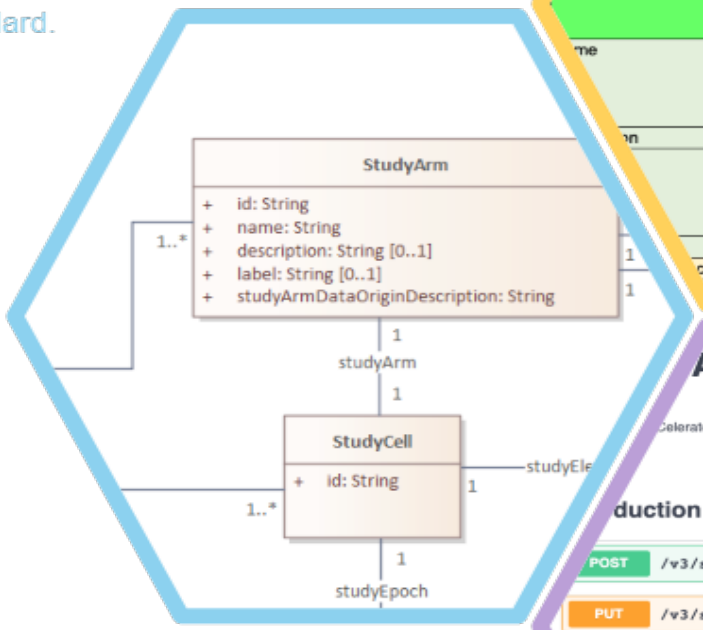
Provides further semantics, complementing the UML model. Includes the definition of classes and attributes along with the definition of value sets



	C174447	Study Arm
	C170984	Study Arm Name
	C93728	Study Arm Descriptic
	C188827	Study Arm Type
nDataOriginDescription	C188828	Study Arm Data Origin Description
riginType	C188829	Study Arm Data Origin Typ
el	CNEW	Study Arm Label
tudyEpoch	C71738	Study Epoch
me	C93825	Study Epoch Name
n	C93824	Study Epoch Descriptic
	C188830	Study Epoch Type
	CNEW	Study Epoch La
ch		

Logical Model

The UML logical model (a class diagram) that provides the basis for the USDM standard.



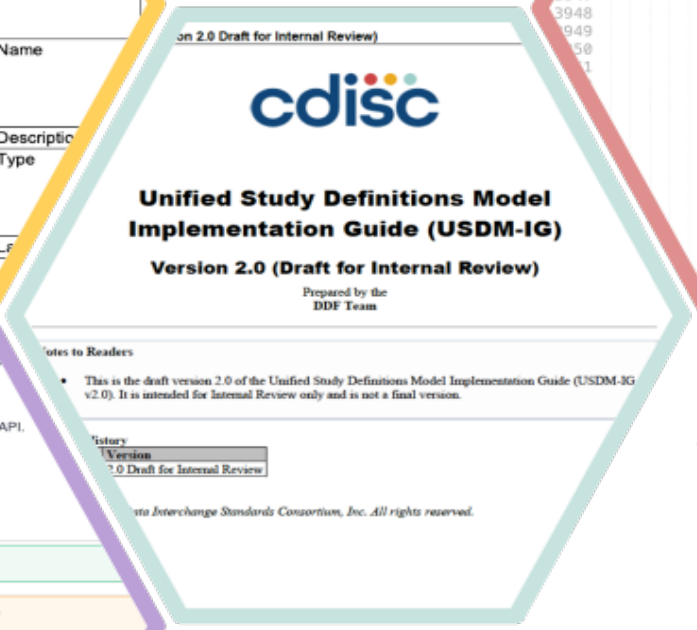
Examples

Example protocols implemented in the USDM with associated JSON files and visualisations

```
tudyArms": [
  {
    "id": "StudyArm_1",
    "name": "Placebo",
    "label": "",
    "description": "Placebo",
    "type": {
      "id": "Code_61",
      "code": "C174268",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2022-12-16",
      "decode": "Placebo Comparator Arm"
    },
    "studyArmDataOriginDescription": "Data collec
    "dataOriginType": {
      "id": "Code_62",
      "code": "C188866",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2022-12-16",
      "decode": "Data Generated Within Study"
    }
  },
  {
    "id": "StudyArm_2",
    "name": "Xanomeline Low Dose",
    "label": "",
    "description": "Active Substance",
    "type": {
      "id": "Code_63",
      "code": "C174267",
      "codeSystem": "http://www.cdisc
      "codeSystemVersion": "2022-12-
```

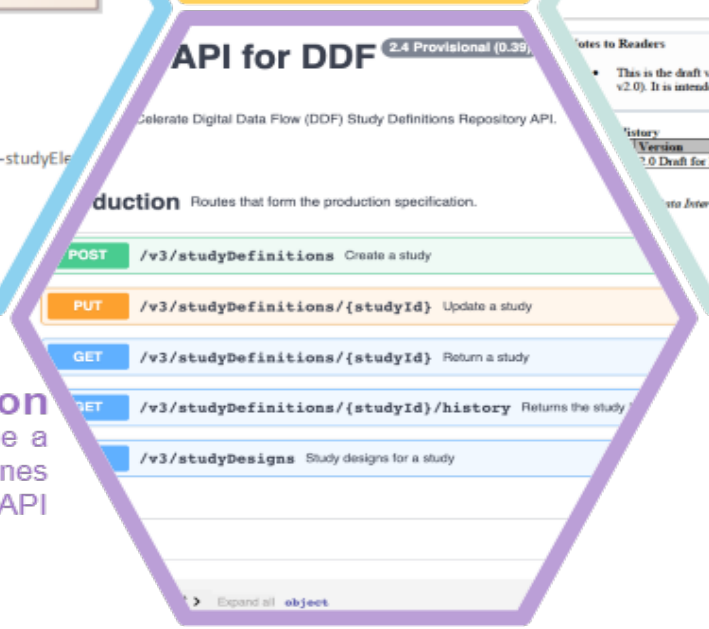
Implementation Guide

Guidance on using the USDM model and ensuring conformance with the standard



API Specification

Provides the means to exchange a single study between machines using a JSON API

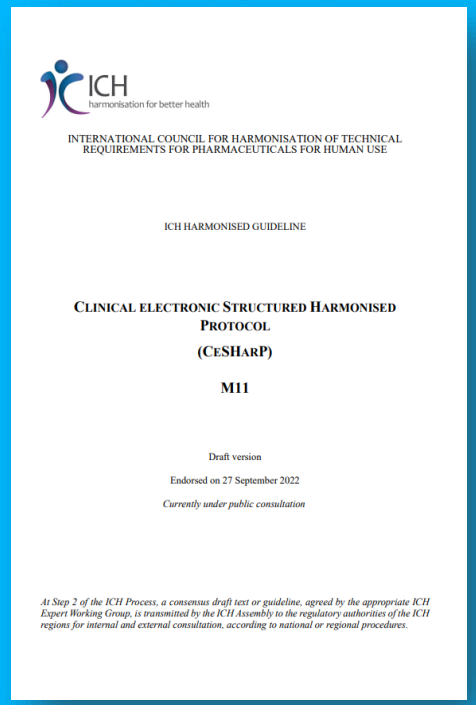


VULCAN~UDP

CDISC/ICH M11 Partnership

ICH M11
Clinical electronic Structured Harmonised Protocol

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

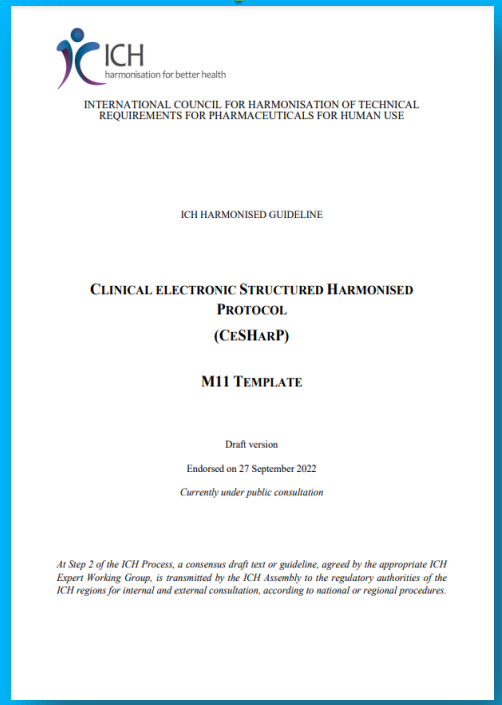
Draft version

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



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ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

M11 TEMPLATE

Draft version

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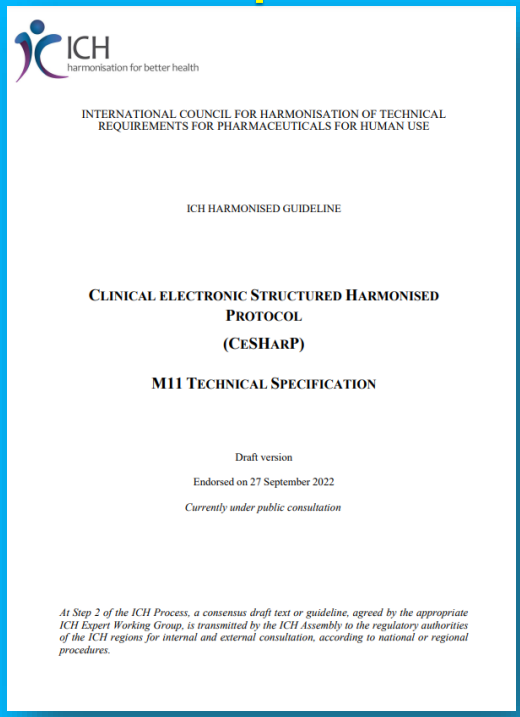
Technical Specification



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 TECHNICAL SPECIFICATION

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.

ICH and CDISC MOU (Memorandum of Understanding)

As a collaboration between ICH and CDISC, the goals of the agreement are to:

- Use a unified governance process and terminology services for the long-term support of ICH controlled terminologies
- Curate and maintain ICH controlled terminologies
- Follow a robust process for the public review and publication of ICH terminologies
- Ensure the terminologies are freely available to the public following public review

Scope

For ICH members to adopt and implement a clinical information standard it is critical that all terminology components, including but not limited to definitions described in the technical specification, are part of a greater international controlled terminology resource managed by an internationally recognized standards development organization (SDO). CDISC has been identified by ICH as a reputable SDO with the qualifications and capabilities to support the maintenance and facilitation of the governance process for ICH controlled terminology.

This Memorandum of Understanding (MOU) sets forth the roles and responsibilities of each party as they relate to the governance of the ICH terms and definitions developed in collaboration with CDISC. This MOU is intended to describe the goals, the high-level governance process, and how each party will collaborate. Specific projects (e.g., M11 controlled terminology) will be defined in detail as part of an annex to this MOU mutually agreed upon by CDISC and ICH.

Goals

As a collaboration between ICH and CDISC, the goals of the agreement are to:

1. Use a unified governance process and terminology services for the long-term support of ICH controlled terminologies.
2. Curate and maintain ICH controlled terminologies.
3. Follow a robust process for the public review and publication of ICH terminologies
4. Ensure the terminologies are freely available to the public following public review.

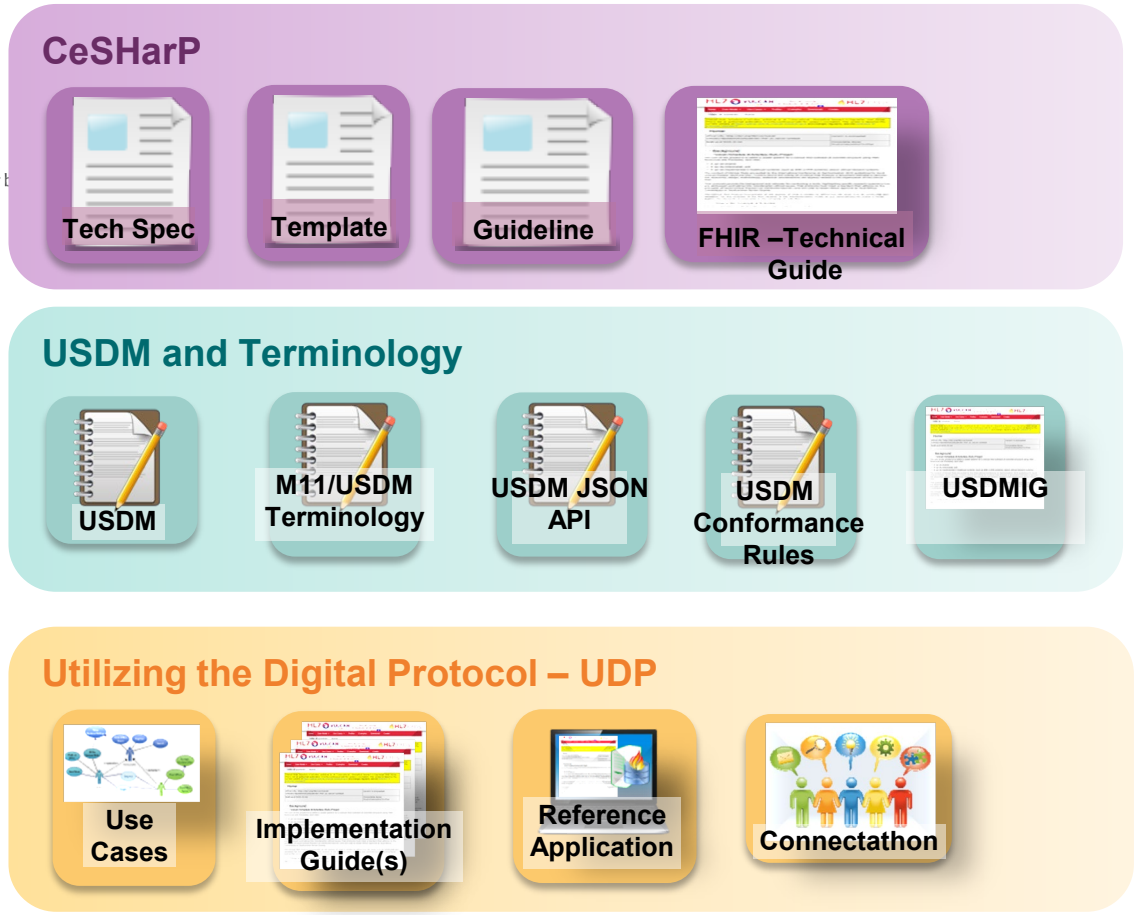
cdisc

ICH harmonisation for better health

VULCAN~UDP

How does USDM, M11, and UDP Come Together

ICH M11 and Vulcan Utilizing Digital Protocol (UDP)



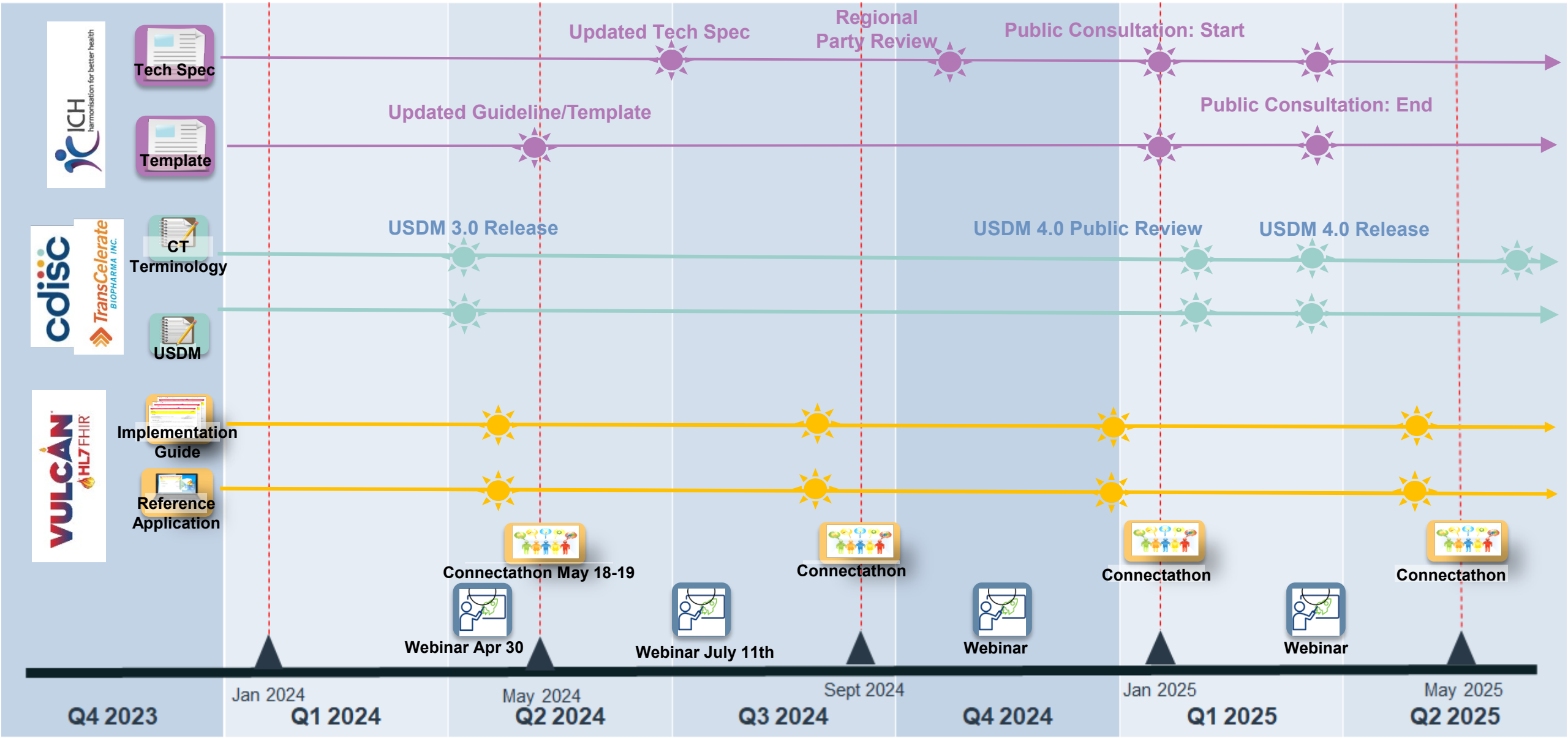
Inputs:

- ICH M11 template
- ICH M11 technical specification
- Models, definitions

FHIR will carry CDISC CT and USDM content

The technical specification can be used to develop other Implementation Guides

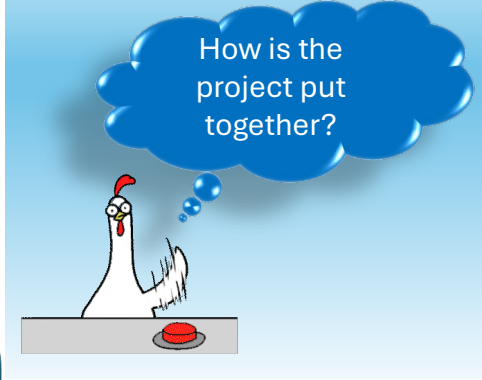
Timelines


Tech Spec
Updated Tech Spec
Regional Party Review
Public Consultation: Start
Template
Updated Guideline/Template
Public Consultation: End
CT Terminology
USDM 3.0 Release
USDM 4.0 Public Review
USDM 4.0 Release
USDM
Implementation Guide
Reference Application
Connectathon May 18-19
Connectathon
Connectathon
Connectathon
Webinar Apr 30
Webinar July 11th
Webinar
Webinar
Jan 2024
May 2024
Sept 2024
Jan 2025
May 2025
Q4 2023
Q1 2024
Q2 2024
Q3 2024
Q4 2024
Q1 2025
Q2 2025

UDP Project Overview

Hugh Glover

UDP is an Umbrella Project with many Use Cases



ICH harmonisation for

Template

- Tech Spec
- Template
- Guide

cdisc

TransCelerate BIOPHARMA INC.

Models and Terminology

- USDM
- CT Terminology
- Jason API
- Conformance Rules

VULCAN HL7 FHIR

Implementation and Testing

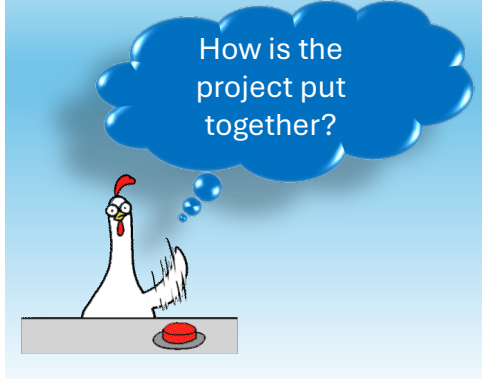
- Use Cases
- Implementation Guide(s)
- Reference Application
- Connectathon

Shared

- Shared Maintenance Plan
- Communications Strategy

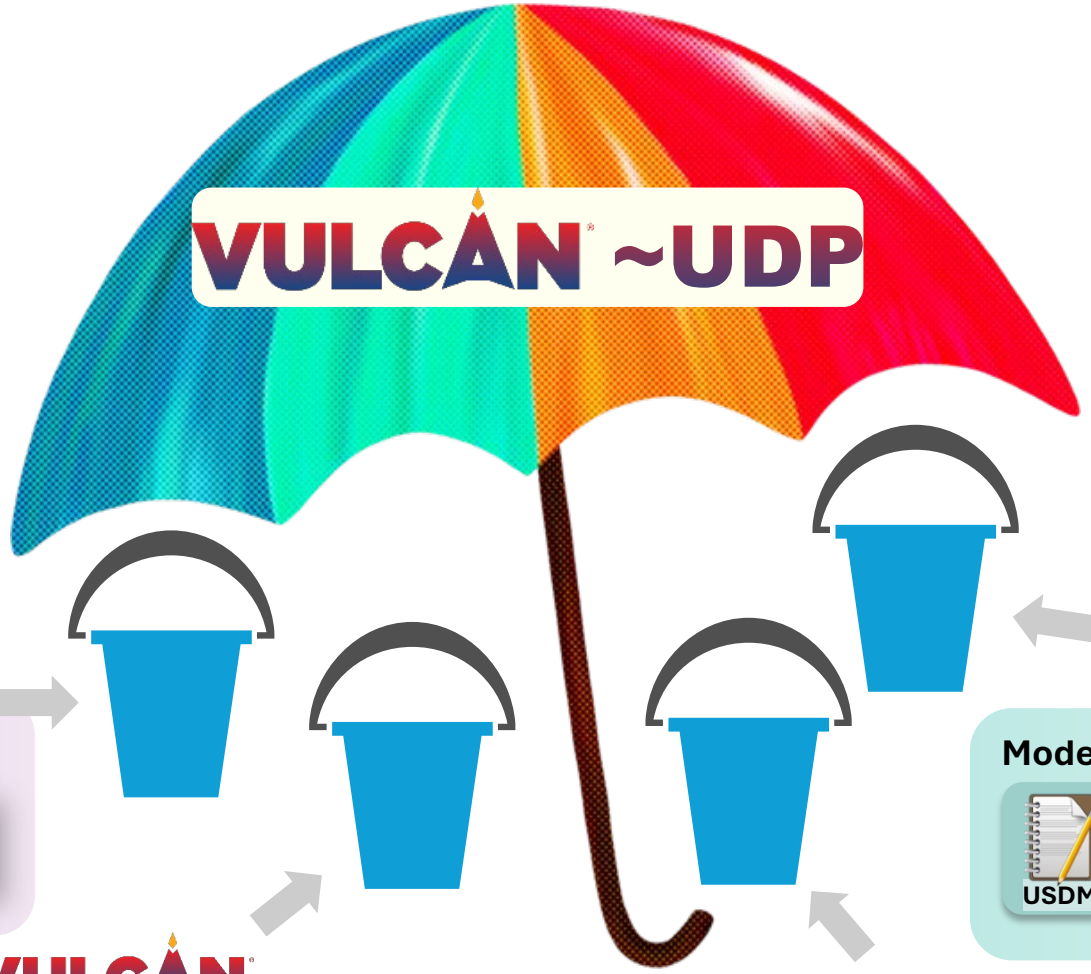
VULCAN~UDP

UDP is an Umbrella Project with many Use Cases



Each bucket contains one or more Use Cases

The ICH starting point is Sponsor to Regulator



ICH harmonisation for better health

Template

- Tech Spec
- Template
- Guide

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Models and Terminology

- USDM
- CT Terminology
- Jason API
- Conformance Rules

VULCAN HL7 FHIR

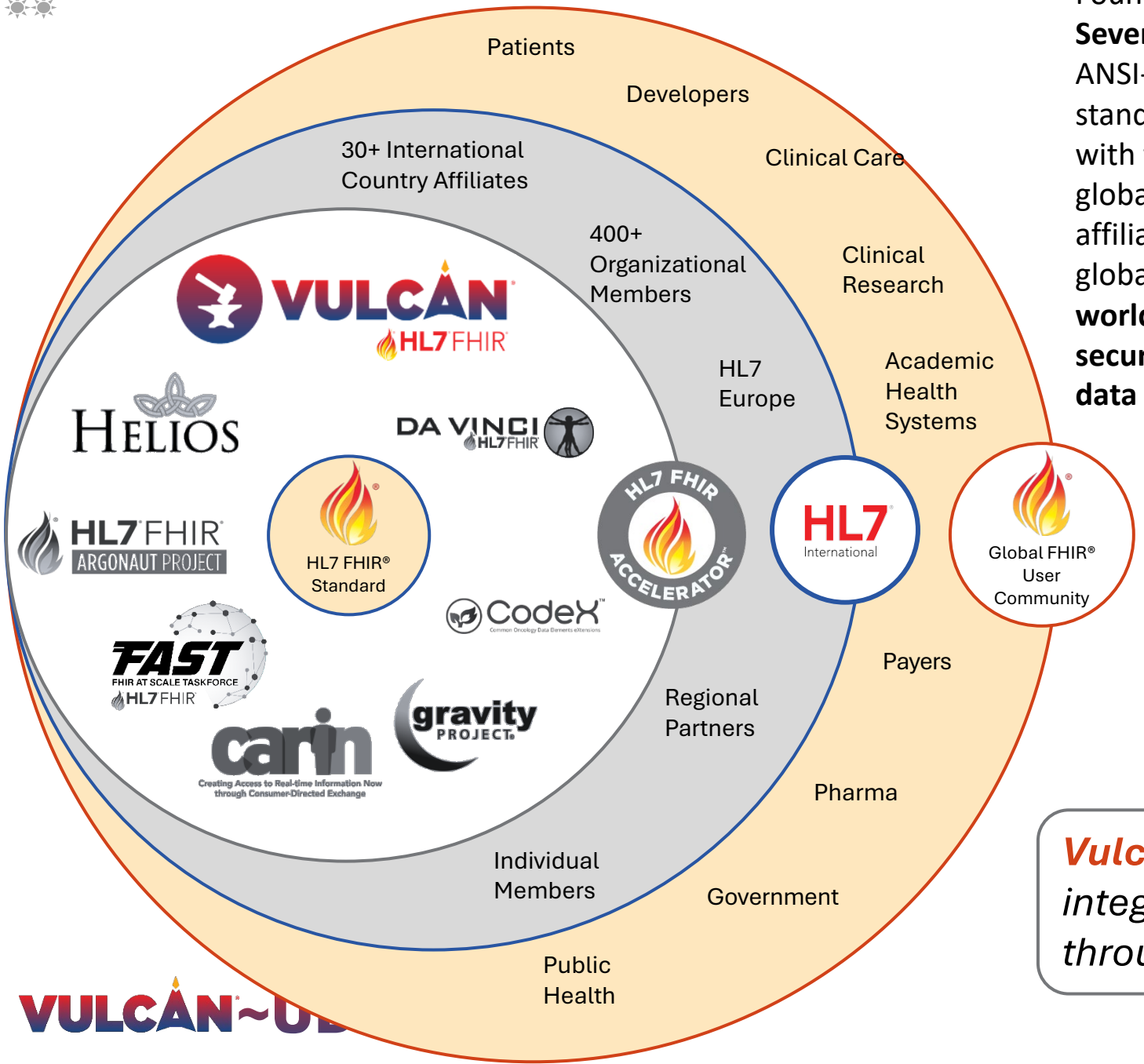
Implementation and Testing

- Use Cases
- Implementation Guide(s)
- Reference Application
- Connectathon

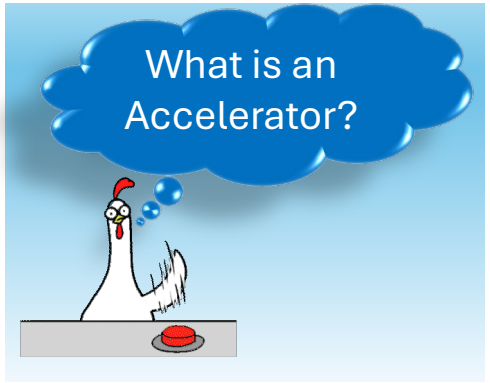
TransCelerate BIOPHARMA INC.

VULCAN~UDP

Vulcan and the HL7 FHIR® Ecosystem



Founded in 1987, **Health Level Seven® International (HL7)** is an ANSI-accredited, not-for-profit standards developing organization with the mission of empowering global health interoperability. With affiliates in over 30 countries, HL7's global membership envisions **a world in which everyone can securely access and use the right data when and where they need it.**



The **HL7 FHIR ACCELERATOR program** is designed to assist communities and collaborative groups across the global health care spectrum in the **creation and adoption of high quality FHIR Implementation Guides or other standard artifacts** to move toward the realization of global health data interoperability.

Vulcan *serves a user community focused on integrating clinical research and clinical care through the adoption of FHIR.*

VULCAN~UD

Vulcan is a membership-based group operated under HL7's FHIR Accelerator Program

VULCAN HL7 FHIR

BRIDGE CLINICAL RESEARCH AND CLINICAL CARE

STRATEGICALLY CONNECT COLLABORATORS

MAXIMIZE COLLECTIVE RESOURCES

ENABLE THE DEVELOPMENT OF TOOLS & SOLUTIONS

Patients

Developers

Clinical Care

Clinical Research

Academic Health Systems

Global FHIR® User Community

Payers

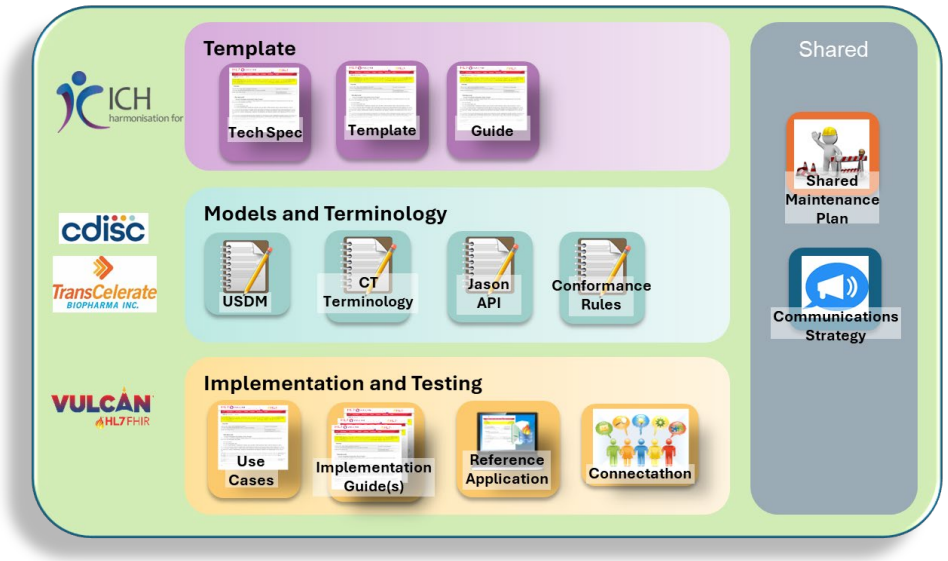
Pharma

Government

Public Health

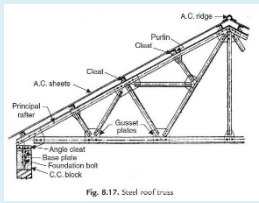
VULCAN~UDP

Design Layers – House Building

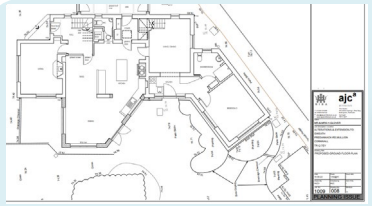


Increasing Constraint

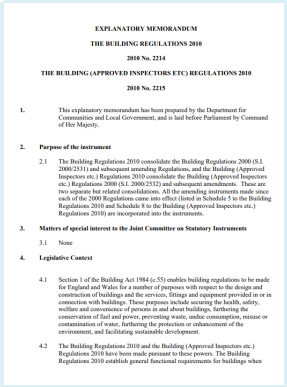
Physical Building



Construction Details



Specific Plan


EXPLANATORY MEMORANDUM

THE BUILDING REGULATIONS 2010

2010 No. 2214

THE BUILDING (APPROVED INSPECTORS ETC) REGULATIONS 2010

2010 No. 2215

1. This explanatory memorandum has been prepared by the Department for Communities and Local Government, and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The Building Regulations 2010 consolidate the Building Regulations 2000 (S.I. 2000/2531) and subsequent amending Regulations, and the Building (Approved Inspectors etc.) Regulations 2010 consolidate the Building (Approved Inspectors etc.) Regulations 2000 (S.I. 2000/2532) and subsequent amendments. These are two separate but related consolidations. All the amending instruments made since each of the 2000 Regulations came into effect (listed in Schedule 5 to the Building Regulations 2010 and Schedule 8 to the Building (Approved Inspectors etc.) Regulations 2010) are incorporated into the instruments.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 Section 1 of the Building Act 1984 (c.55) enables building regulations to be made for England and Wales for a number of purposes with respect to the design and construction of buildings and the services, fittings and equipment provided in or in connection with buildings. These purposes include securing the health, safety, welfare and convenience of persons in and about buildings, furthering the conservation of fuel and power, preventing waste, undue consumption, misuse or contamination of water, furthering the protection or enhancement of the environment, and facilitating sustainable development.

4.2 The Building Regulations 2010 and the Building (Approved Inspectors etc.) Regulations 2010 have been made pursuant to these powers. The Building Regulations 2010 establish general functional requirements for buildings when

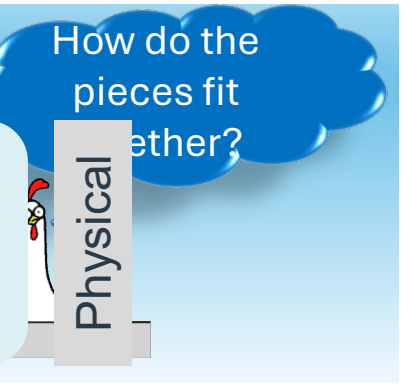
Building Regulations

Planning Regulations

Physical

Logical

Conceptual



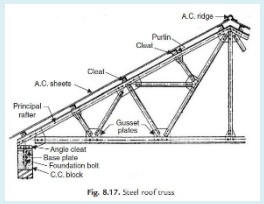
VULCAN~UDP

Design Layers – House Building

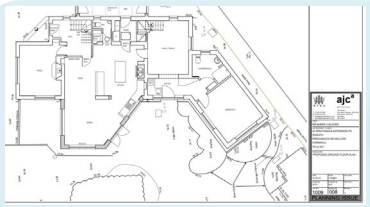
Digital Protocol

Increasing Constraint

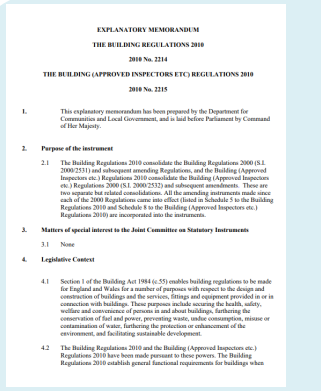
Physical Building



Construction Details



Specific Plan



EXPLANATORY MEMORANDUM

THE BUILDING REGULATIONS 2010

2010 No. 2214

THE BUILDING (APPROVED INSPECTORS ETC) REGULATIONS 2010

2010 No. 2215

1. This explanatory memorandum has been prepared by the Department for Communities and Local Government, and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The Building Regulations 2010 consolidate the Building Regulations 2000 (S.I. 2000/2531) and subsequent amending Regulations, and the Building (Approved Inspectors etc.) Regulations 2010 consolidate the Building (Approved Inspectors etc.) Regulations 2000 (S.I. 2000/2532) and subsequent amendments. These are two separate but related consolidations. All the amending instruments made since each of the 2000 Regulations came into effect (listed in Schedule 5 to the Building Regulations 2010 and Schedule 8 to the Building (Approved Inspectors etc.) Regulations 2010) are incorporated into the instruments.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 Section 1 of the Building Act 1984 (c.55) enables building regulations to be made for England and Wales for a number of purposes with respect to the design and construction of buildings and the services, fittings and equipment provided in or in connection with buildings. These purposes include securing the health, safety, welfare and convenience of persons in and about buildings, furthering the conservation of fuel and power, preventing waste, undue consumption, misuse or contamination of water, furthering the protection or enhancement of the environment, and facilitating sustainable development.

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Building Regulations

Planning Regulations

Physical

Logical

Conceptual

Physical I
Model, Database

FHIR

Implementation

Architecture Specific Model (Platform Specific)

Architecture

Use Case Specific

USDM + CT

M11 CeSHarP

Use Case

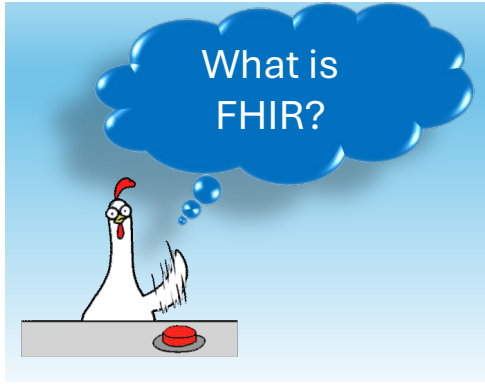
Domain Information Model

Reference Information Model

Semantics

VULCAN

What is FHIR?



Why?	Interoperability out-of-the-box (bridge clinical research and clinical care)
How?	Built on web standards (e.g., XML, JSON, HTTP, and Oauth)
What?	150+ resources (building blocks) to cover a wide array of use cases
Who?	Diverse global community (hospitals, academia, vendors, biopharma, regulators)

FHIR (**F**ast **H**ealthcare **I**nteroperability **R**esources), a specification, which is a standard for exchanging healthcare information electronically. FHIR R4 is the modernization of and best feature reutilization from HL7s v2, v3, and CDA products. Development of resources supposedly follows an 80/20 rule and aims to focus on what is required in 80% of existing systems and to regard the remaining 20% as edge cases. The 20% can then be dealt with through the extension mechanism built into FHIR.

FHIR 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.

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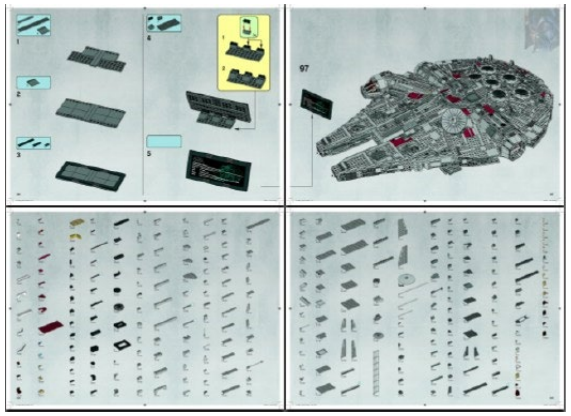
Implementation Guides are Key

FHIR Resources
(components – like Lego blocks)



Implementation Guides

Data Transport Models –
(the finished Lego structure)

- Open Source – No membership required
- FHIR makes no assumptions about the architectural design of systems
- The **content** is the same structure whatever the interoperability paradigm

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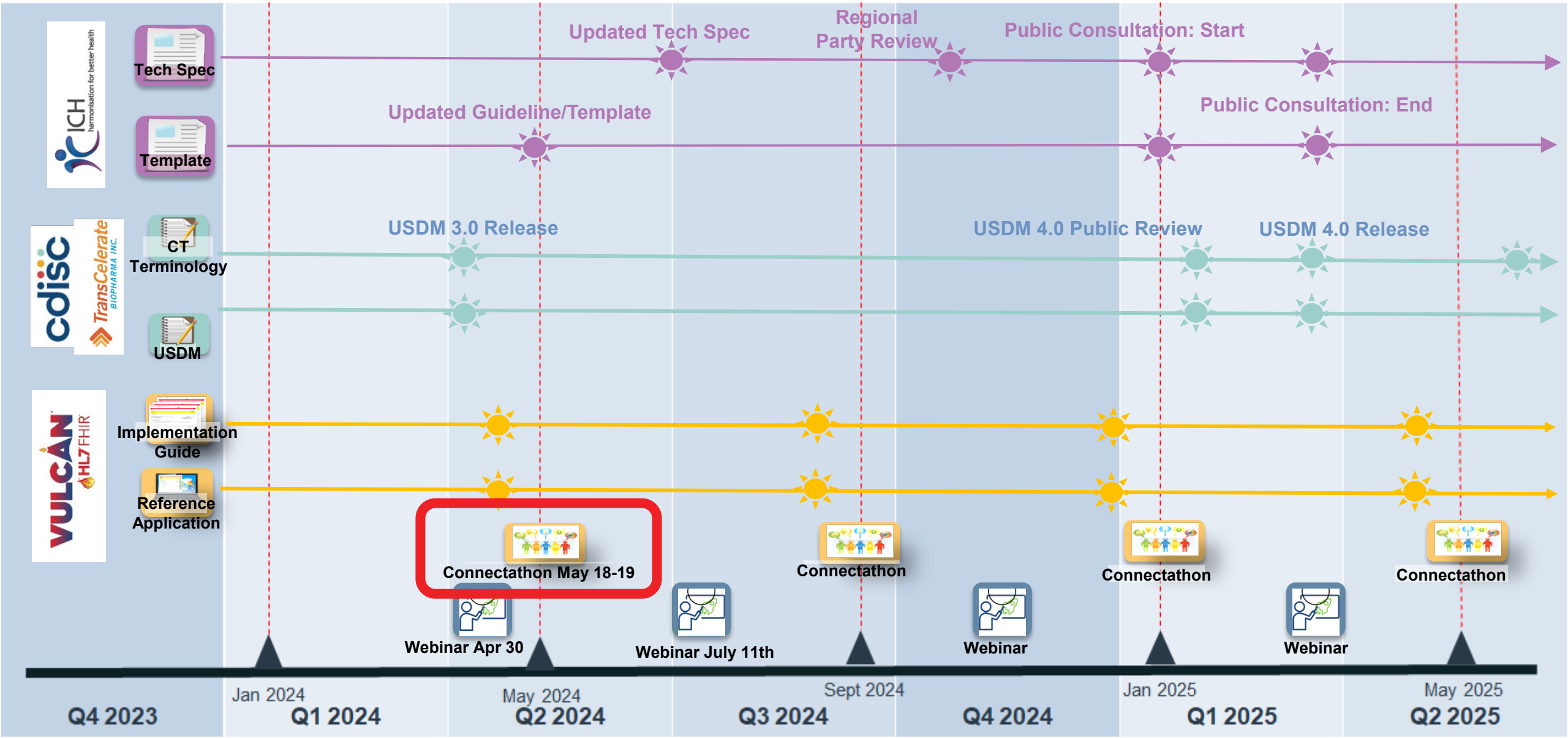
Connectathons are a key feature of FHIR



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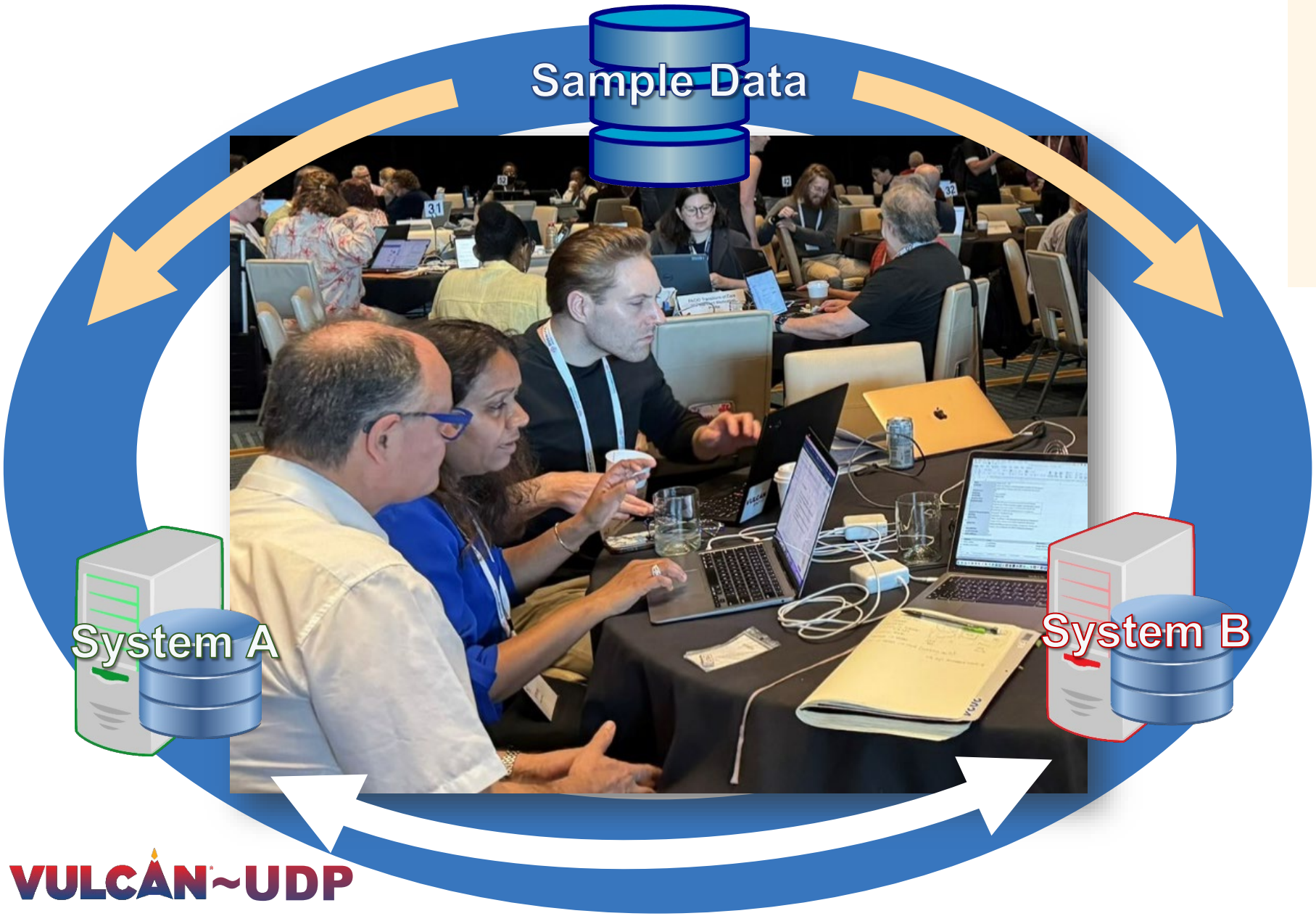
Components of a Connectathon



Components required

1. People
2. The FHIR standard
3. Implementation Guides
4. Sample Data
5. Test Systems

Test that “things” work

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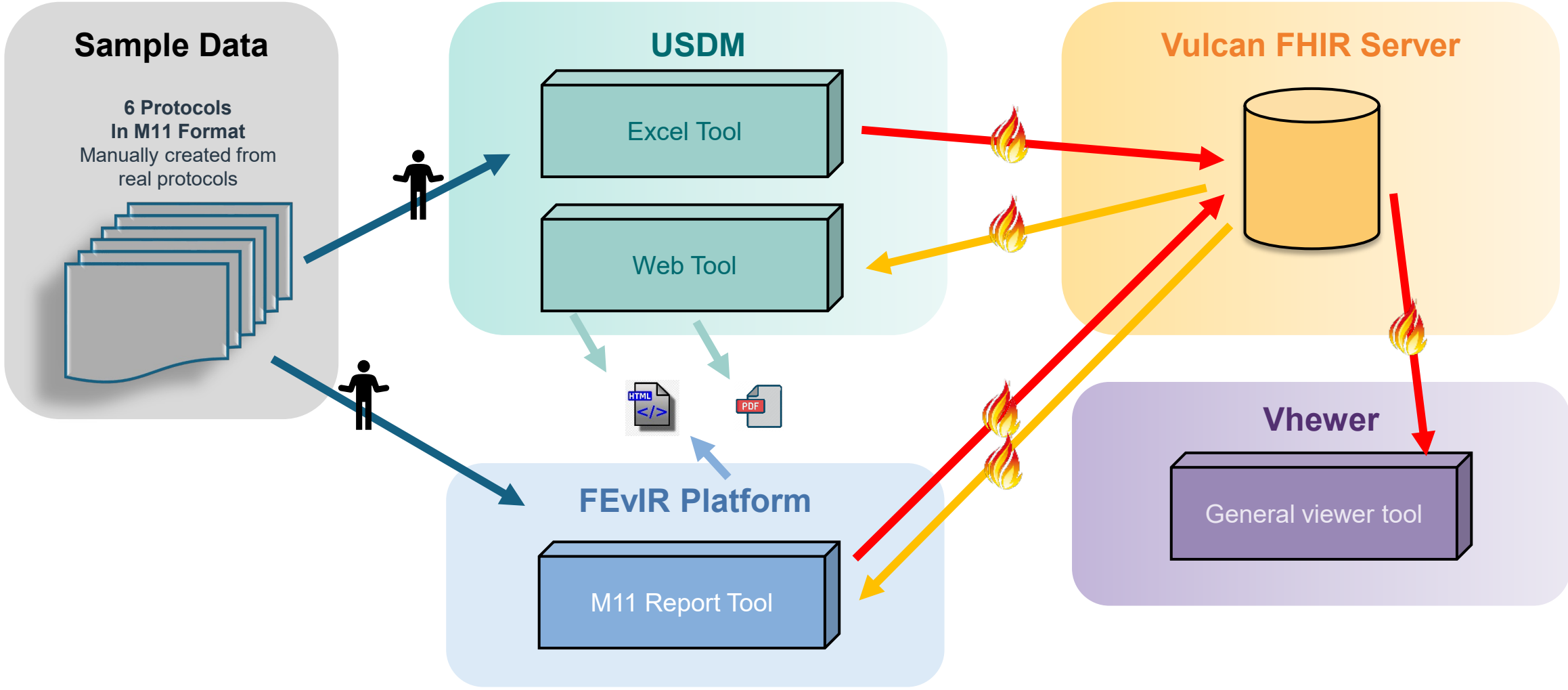
- Demonstrate FHIR based exchange of a Protocol **Document**
- Get the connectathon process running

UDP Connectathons May: Systems Participating



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Manual flow

FHIR flow

The connectathon demonstrated successful Protocol representation in FHIR following M11 document template and began to identify more granular representations

- Had 6 sample protocols created and in FHIR format
- Connected USDM to FHIR for first time
- Exercised tools from participants to create sets of data and load to the server using multiple tools as identified in the drawing

UDP Connectathons Future Plans

September Connectathon

- **Structured title page (highest-level protocol metadata)**
- **Inclusion / Exclusion Criteria**
- **Expand vendor participation**

Early thinking on 2025 Connectathon Topics

- Objectives and Endpoints
- Schedule of Activities
- Mapping to data capture tools
- Utilization of ODM

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Community Involvement

True success for UDP will come only with involvement from the widest possible community …

Connectathons

- HL7 Events January (virtual), May, September
- Specific UDP events
- **Search:** HL7 Connectathon

- Open to all
- Influence development
- Gain experience and insight

Webinar Series

- Regular cadence of Webinars next one planned in the fall

- Information and Progress updates
- Connectathon reports

Community of Interest

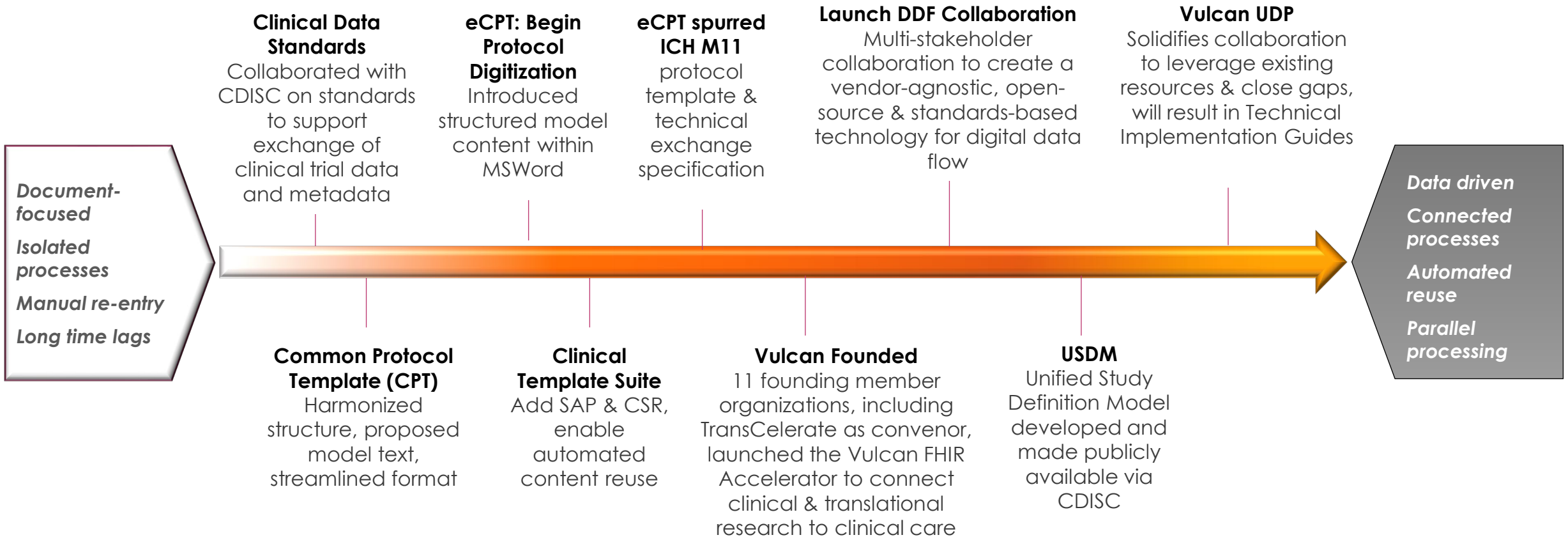
- Open forum for users
- We need to hear real business processes

- Active engagement
- Forefront of application development

Pathway to Implementation

Mary Lynn Mercado

TransCelerate is part of a journey to break down barriers to data/digital transformation in R&D



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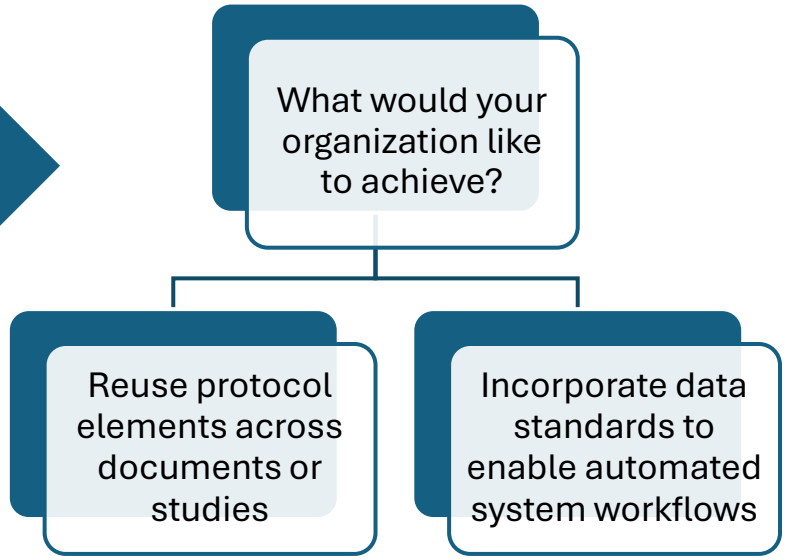
* *Public, open-source assets from the DDF project are accessible at: https://transcelerate.github.io/ddf-home/*

Don’t wait to chart your pathway to implementation

1. **Prioritize use cases for a digital protocol**
   - How could your organization benefit from a digital protocol?
   - What are your protocol process-related pain points?

For example…



2. **Learn more about the building blocks that will enable a digital protocol**
   - ICH M11, TransCelerate, CDISC, HL7, Vulcan

3. **Engage early and often with stakeholders who will be impacted by and/or benefit from availability of a digital protocol**
   - Decision-makers within your organization
   - Internal stakeholders
   - Vendor community
   - External stakeholders creating guidelines and tools

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Implementation starts with prioritizing a business problem to be solved with the digital protocol

- Automated creation of CRFs
- Automated clinical trial pricing
- Schedule of Assessments that does not have to be manually translated for use by a site
- Real-time regulatory review of clinical trial protocols
- Single source of truth for clinical trial protocol elements
- Automated study design analytics
- Automated population of downstream clinical documents
- Automated population of clinical trial applications and registries
- Automated generation of fit-for-purpose views of clinical trial protocol information

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Understanding the value of components will be foundational to your unique implementation strategy

ICH M11 Template

- Enables content fit for regulators and sites
- Harmonized structure

ICH M11 Technical Specification

- Structured elements
- Valid values lists

USDM

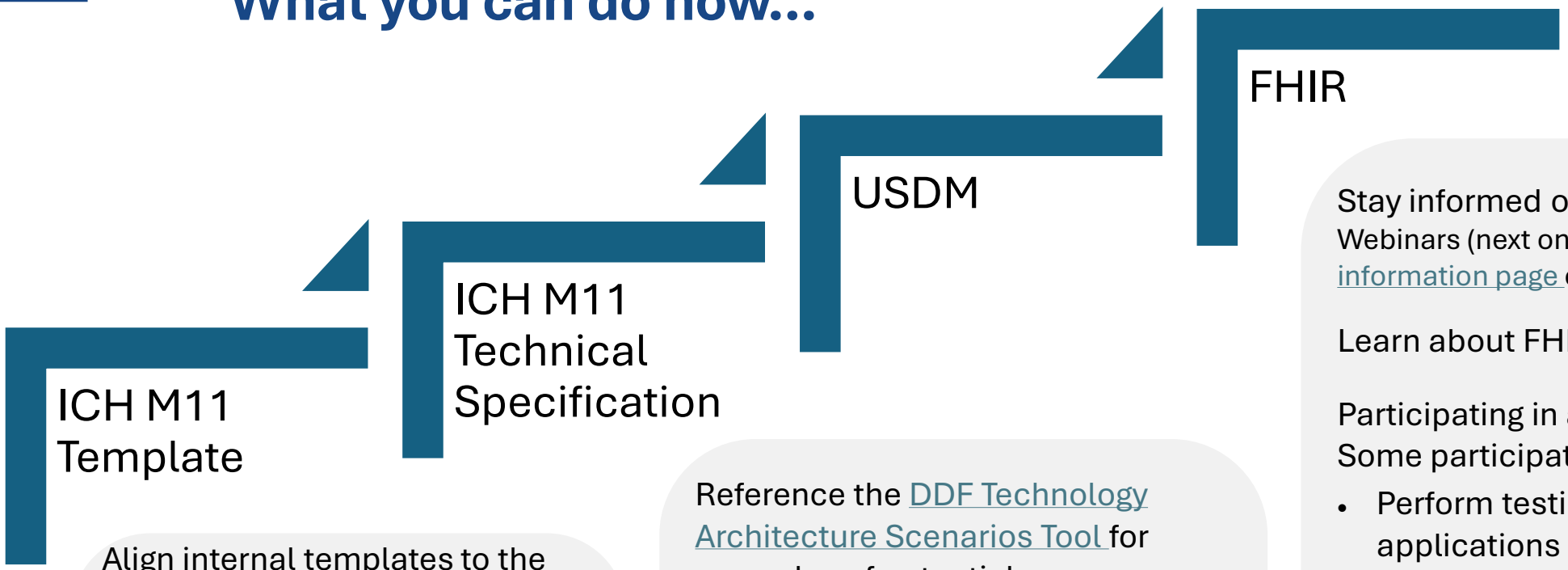
- Additional structured elements
- Critical context
- Computable

FHIR

- Open exchange
- Offers bridge between clinical research and clinical care

VULCAN~UDP

What you can do now…



Align internal templates to the CPT (Common Protocol Template) which ICH has drawn from

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

Participate in public reviews

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

Consider upcoming events:

- 26 Sept: DDF Vendor Showcase Webinar Series
- 10 Oct: "DDF in Action" Day
- 21-25 Oct: CDISC US Interchange INFO

Participate in CDISC public reviews

Stay informed on UDP:
Webinars (next one in the fall), Vulcan UDP information page on HL7's Confluence

Learn about FHIR: Reference HL7 Vulcan

Participating in a 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 Connectathon in Atlanta: onsite only or via virtual prep 1-2 months ahead, Jan to be virtual

VULCAN~UDP

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
TECHNICAL DIRECTOR
VULCAN

MARY LYNN MERCADO
GLOBAL HEAD PROTOCOL DELIVERY & US SITE HEAD, REGULATORY WRITING & SUBMISSIONS
NOVARTIS

CHRIS DECKER
PRESIDENT AND CEO
CDISC

RON FITZMARTIN
SENIOR ADVISOR, OFFICE OF REGULATORY OPERATIONS
CBER FDA

NOEMIE MANENT
CLINICAL TRIAL TRANSFORMATION (CTT), CHANGE MANAGER
EMA

Upcoming Events

- **Connectathon in September**
- **Future UDP Webinar in the fall**
  - Report out from the September Connectathon

Contacts & Resources

VULCAN HL7 FHIR

hl7-Vulcan

www.HL7Vulcan.org

Vulcan@HL7.org

TransCelerate BIOPHARMA INC.

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Stay Connected:
Sign Up for our Awareness & Implementation Community!

Events Calendar:
To find out more about our events click here

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ddf@cdisc.org

ICH M11

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 (Draft):https://database.ich.org/sites/default/files/ICH_M11_Template_Step2_2022_0904.pdf

ICH M11 Technical specification (draft):https://database.ich.org/sites/default/files/ICH_M11_TechnicalSpecification_Step2_2022_1014.pdf

Thank you!

If you have any questions about the UDP Project please reach out to:
Vulcan@HL7.org

For any questions about the Webinar or issues with the recording please reach out to:
Events@transceleratebiopharmainc.com