

# Vulcan UDP (Utilizing the Digital Protocol): Complementing ICH M11 with an Interoperable Schedule of Activities (SoA)





# Welcome to the Utilizing the Digital Protocol Webinar

Tuesday February 11<sup>th</sup>, 2025 @ 09.00 – 10.15am EST

Time	Topic	Speaker
<b>Welcome and Introduction</b>		
5 mins	<b>Kick-off and ground rules and Introductions</b>	Stacy Tegan
<b>Speaker Presentations</b>		
30 mins	<b>January Connectathon Spotlight</b> <ul style="list-style-type: none"><li>○ Components of a Connectathon</li><li>○ Progress across Connectathons to date</li><li>○ Connectathon 38: Aims and Objectives</li><li>○ Live demonstration of how the different FHIR resources are used</li></ul>	Hugh Glover & Dave Ibersen-Hurst
15 mins	<b>UDP Impact</b> <ul style="list-style-type: none"><li>○ SoA Business Process Objectives, Opportunities and Challenges</li></ul>	Mary Lynn Mercado
20 mins	<b>Moderated Q&amp;A</b> <ul style="list-style-type: none"><li>○ Live Poll</li></ul>	All
<b>Wrap-Up</b>		
5 min	<b>Close</b>	Stacy Tegan



## Vulcan UDP (Utilizing the Digital Protocol): Complementing ICH M11 with an Interoperable Schedule of Activities (SoA)

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 Technical Director



**Chris Decker**  
President and CEO



**Dave Iberson-Hurst**  
USDM Product Owner



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

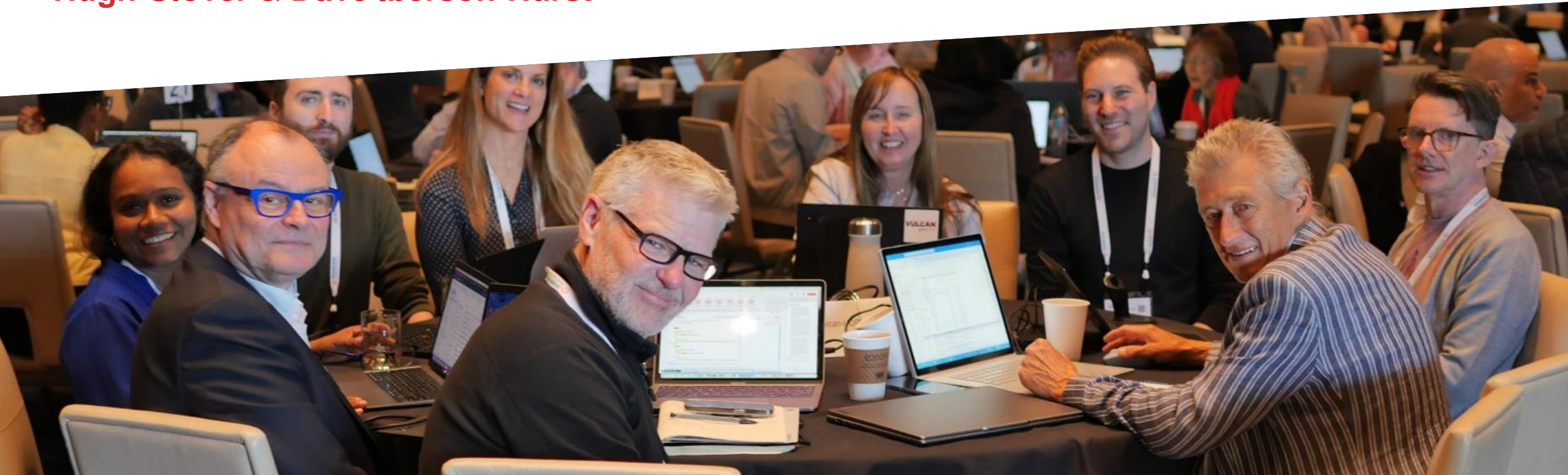




# Vulcan UDP - Utilizing the Digital Protocol Connectathon January 2025 - Summary

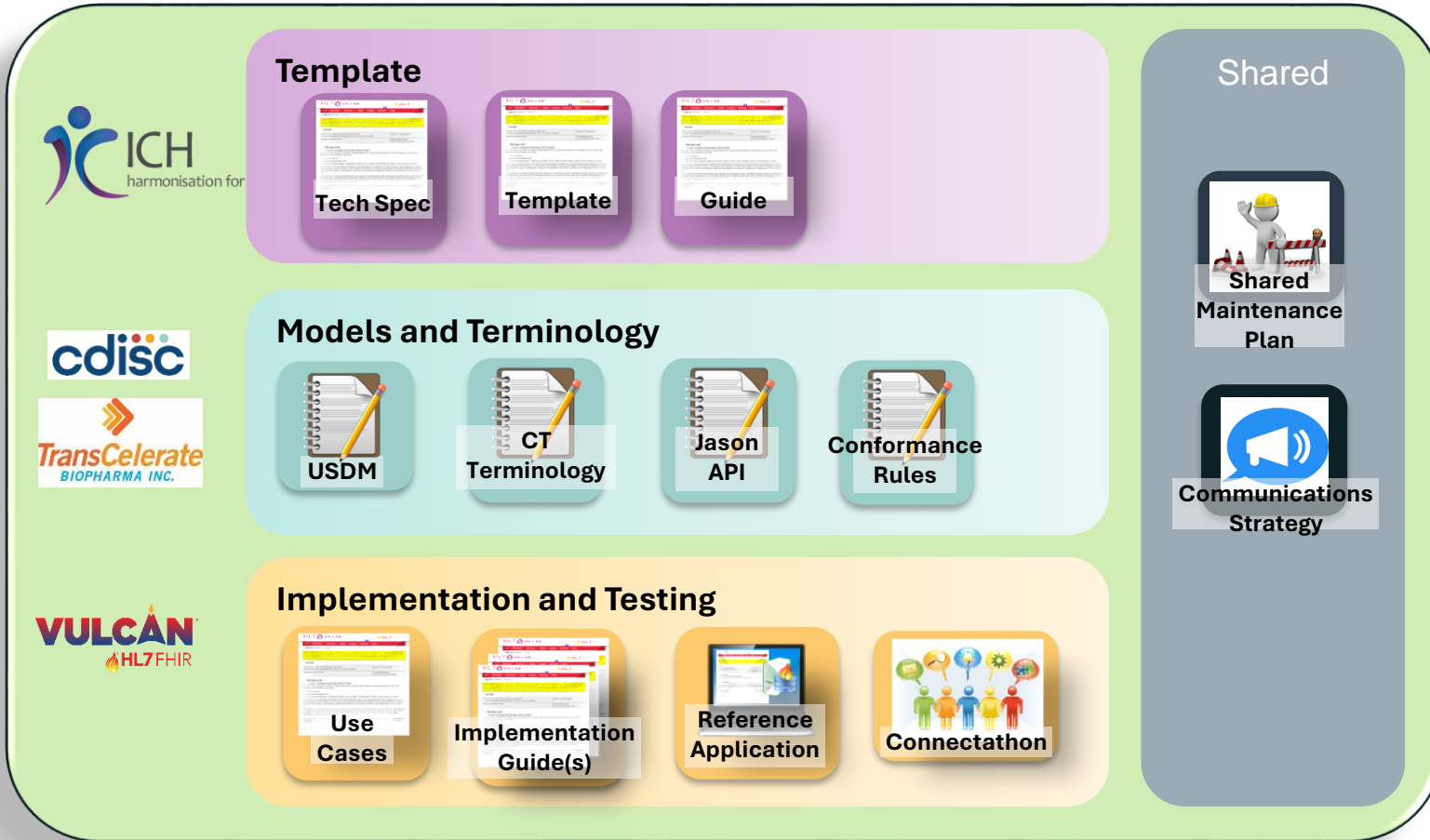
Demonstrating use of Schedule of Activities (SoA) with the  
ICH M11 Clinical Trial Protocol Template

**Hugh Glover & Dave Iberson-Hurst**



# Utilizing the Digital Protocol

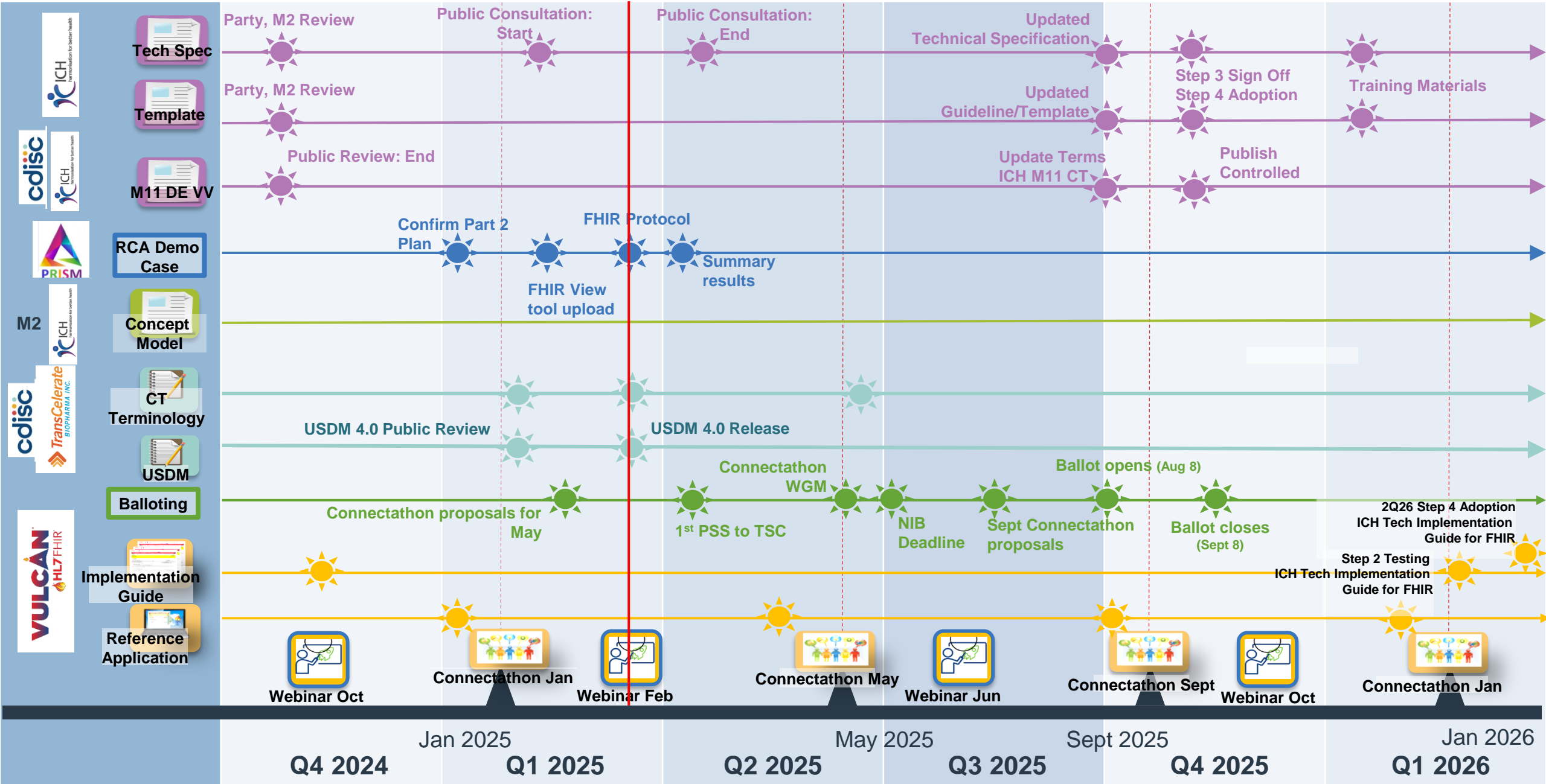
## UDP is an Umbrella Project with many Use Cases



- **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**

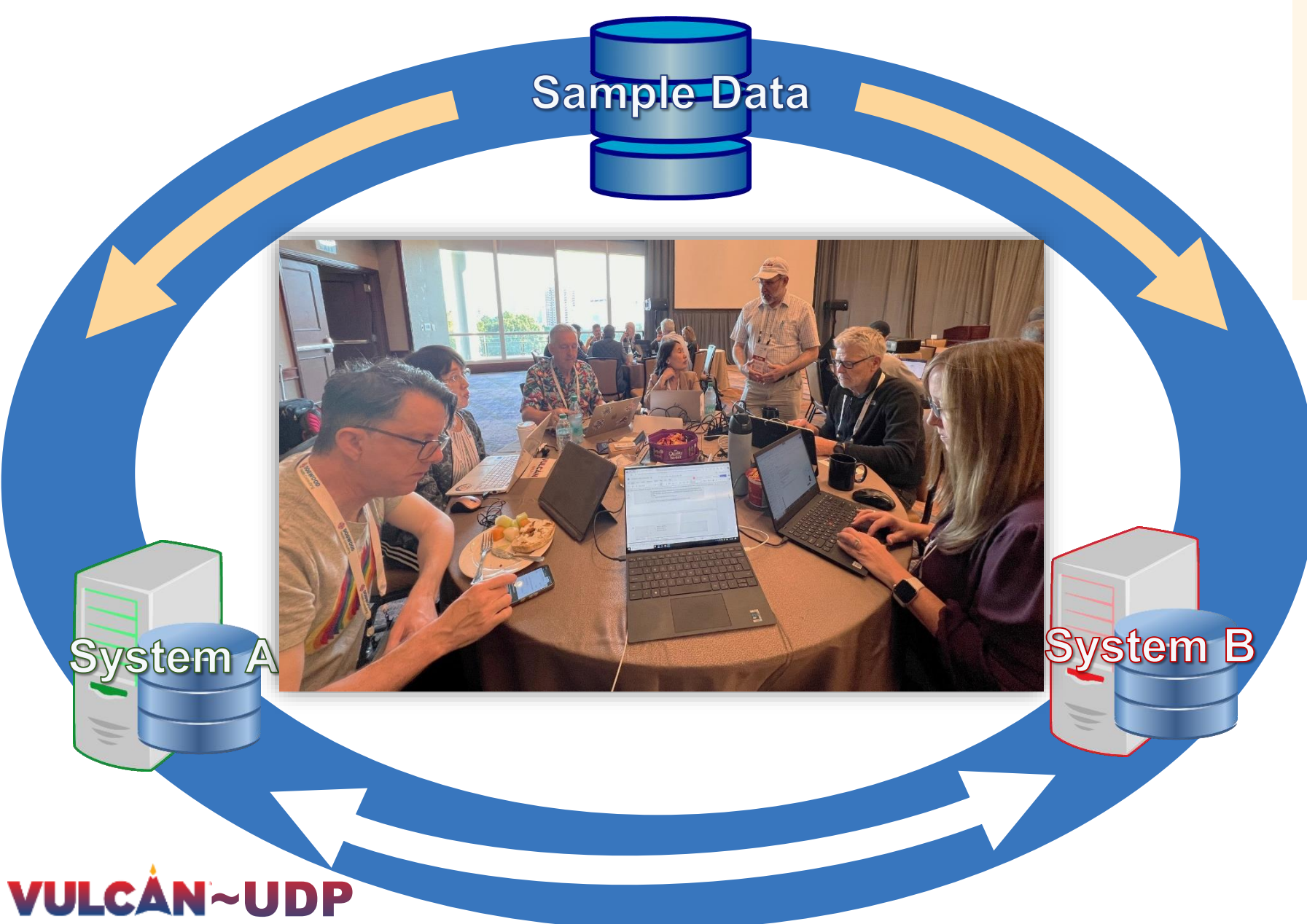
# Planned Aggregate Timeline

11 Feb 2025





# 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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**Review progress across Connectathons ...**

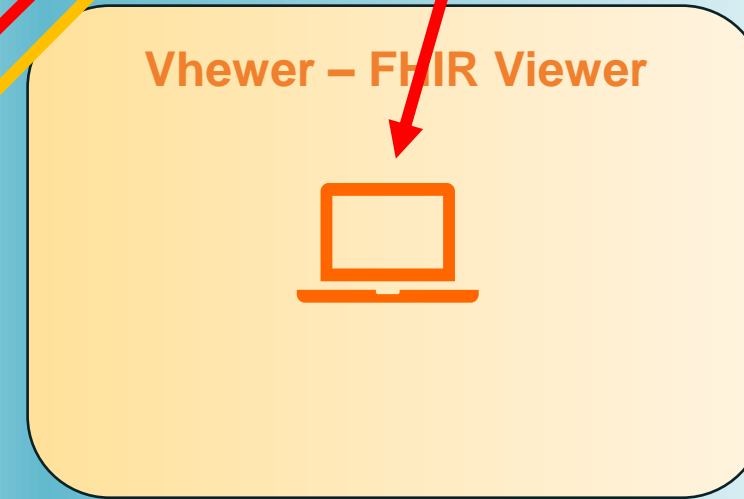
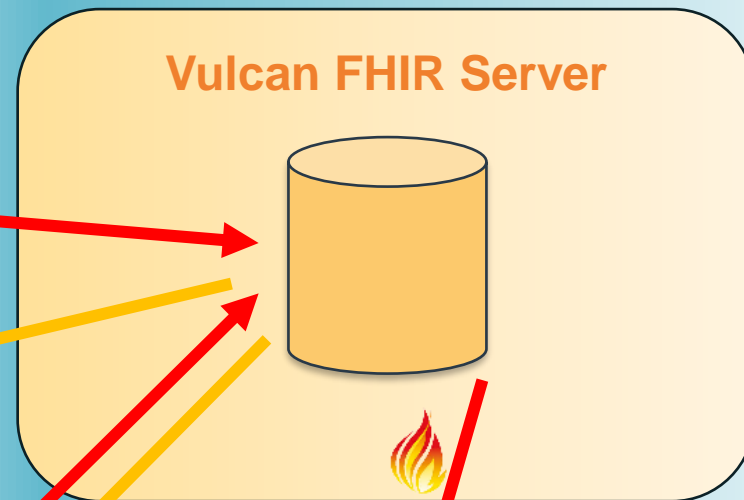
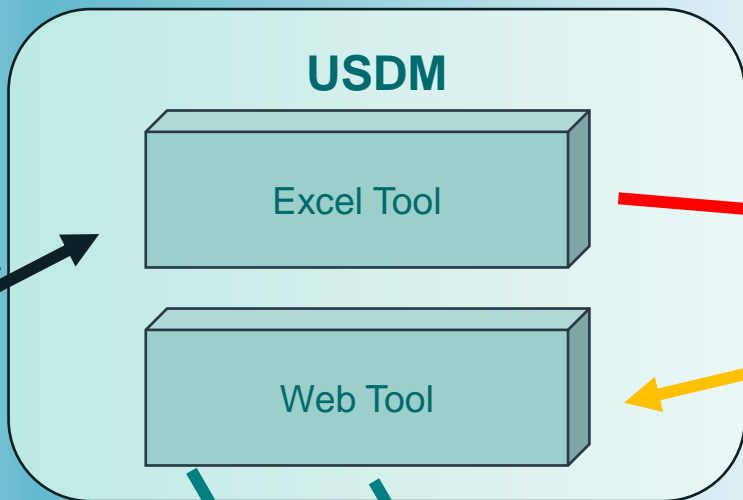
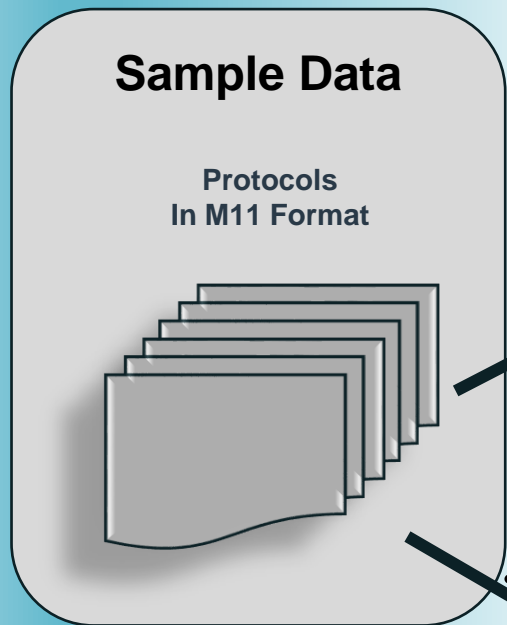


# UDP Participating System Types

## Sources

## Custom Tools

## FHIR Tools



Connectathon	Key Accomplishments and Learnings
<p><b>Connectathon 36</b></p> <p>May 18-19, 2024</p> <p>Dallas, Texas</p>	<ul style="list-style-type: none"> <li>• This Connectathon focused on the <b>transfer of clinical trial protocols from sponsor to regulator</b>, in line with the developments by ICH M11/M2, CDISC, and TransCelerate. This event was the first iteration exploring a document-centric approach, using FHIR Composition resources to enable the transfer of protocol document sections.</li> <li>• Key activities included testing the design of resources, validating implementation guides, and educating development teams on these new frameworks.</li> </ul>
<p><b>Connectathon 37</b></p> <p>September 21-22, 2024</p> <p>Atlanta, Georgia</p>	<ul style="list-style-type: none"> <li>• For the September 2024 Connectathon, the focus was on refining the document-centric approach used in the previous event. <b>It expanded to structure selected portions of the clinical trial protocol to make them more machine-processable.</b></li> <li>• Specifically, portions of the unstructured composition, including title page elements, eligibility criteria, and objectives/endpoints/estimands, were targeted for transfer in structured data form.</li> </ul>

## Composition

identifier {xxx}

title {xxx}

### **section**

> code{1. Protocol Summary}

> > **section**{1.1 Protocol Synopsis} {text}

> > > **section**{1.1.1 Objectives & Estimands} {text}

...

> > **section**{1.3 Schedule of Activities} {text}

- **Composition is a FHIR Resource**
- **M11Report is a profile of a Composition**
- **This slide illustrates an Instance of a Composition according to an M11Report profile not the definition of it**

Connectathon	Key Accomplishments and Learnings
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# M11 Report Profile

## Composition

```
identifier {xxx}  
title {xxx}  
section  
> code{1. Protocol Summary}  
> > section{1.1 Protocol Synopsis} {text}  
> > > section{1.1.1 Objectives & Estimands} {text}  
...  
> > section{1.3 Schedule of Activities} {text}  
...
```

## ResearchStudy Resource

### ResearchStudy

```
identifier {xxx}  
version {xxx}  
title {xxx}  
label {xxx}  
protocol.Reference( PlanDefinition )  
associatedParty.Reference(... Organization )  
recruitment  
> eligibility.Reference(Group ...)
```

### Organization

XXX

sponsor

### Group

XXX

eligibility criteria

- Continued with the M11Report profile
- Also started to explore use of the ResearchStudy resource
- ResearchStudy starts to pull in other FHIR Resources

## Summary

### Demonstrate the use of Schedule of Activities (SoA) with the ICH M11 clinical trial protocol template

- Take one or more of the clinical trial protocols and demonstrate the ability to transmit using the SoA message and render on the receiving system as a SoA table (as seen in the protocol document) and potentially other useful forms
- This track follows on from recent successful Connectathons for Vulcan UDP (May and September 2024), and Vulcan SoA Connectathons (January, May and September 2021), which produced the SoA IG (link below). This event aims to pull the two workstreams together.

## Aims

- 1) Demonstrate SoA with ICH M11 clinical trial protocol data.
- 2) Demonstrate ability to represent the data for the SoA, which is based on FHIR PlanDefinition. Use FHIR PlanDefinition to represent some of the dummy ICH M11 clinical trial protocols
- 3) Creator/sender system creates the data and sends to another system to consume.
- 4) Receiver can consume and represent the data in one or more visual ways (e.g., display as a table or turn it into a single patient's calendar view or load it into a system that can automatically do this)

## 1. Create SoA for an M11 study

### Precondition:

- M11 document with suitable SoA

### Action:

- Create a SoA for a Study based on an example M11 document

### Success Criteria:

- Able to represent SoA as structured FHIR data, with M11 FHIR data.  
Load FHIR data to a server

## 2. Consume SoA for an M11 study, for display

### Precondition:

- FHIR M11 representation with SoA

### Action:

- Fetch M11, decode SoA data and display, in:
  - a) Tabular format
  - b) Other formats e.g. list

### Success Criteria:

- Able to represent SoA from the structured FHIR data, within M11 FHIR data

## OPTIONAL. Create input form for collecting data for a study participant

### Precondition:

- FHIR M11 representation with SoA

### Action:

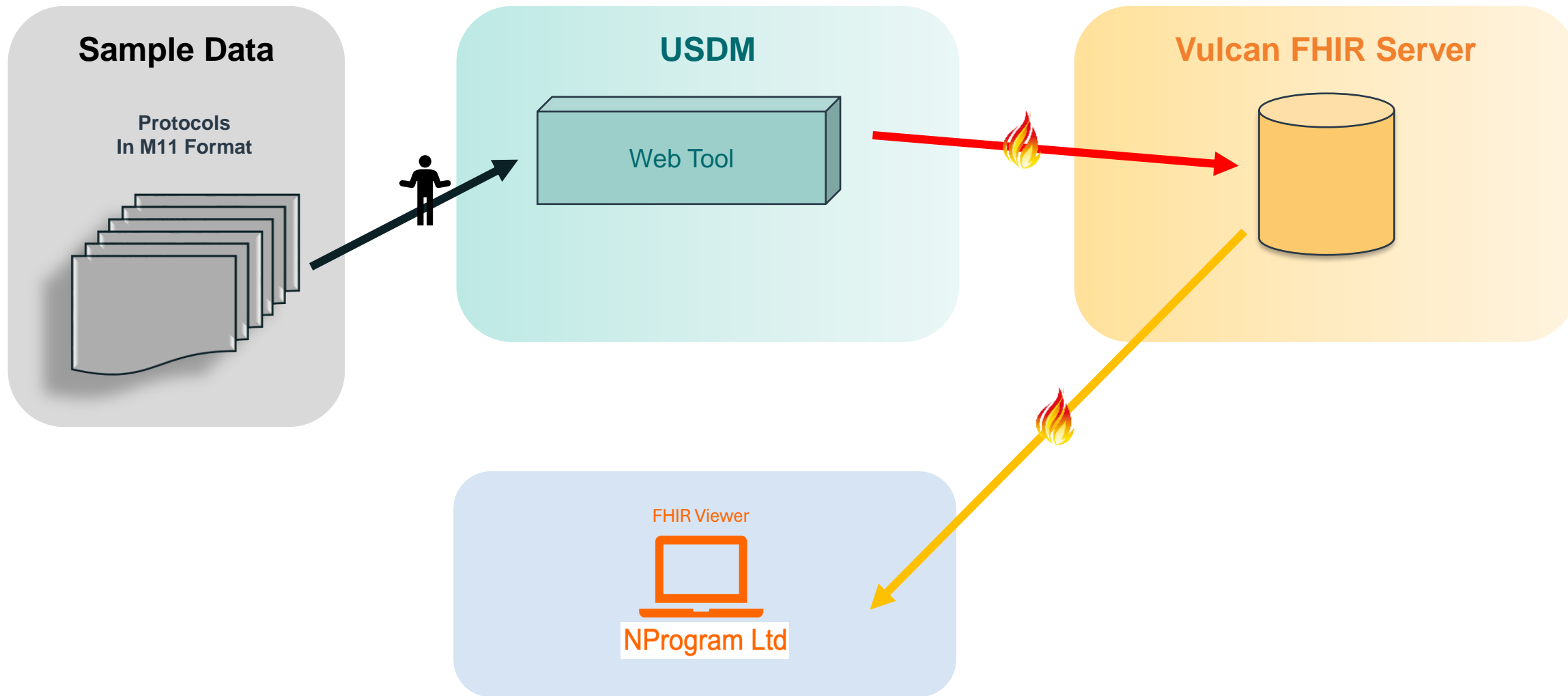
- Creation of data input form

### Success Criteria:

- Able to display a data entry form for collection of data required for a stud participant

Security and Privacy Considerations: NA

# Connectathon 38 Jan 2025 : UDP Participating System Types





# ResearchStudy Structure

## ResearchStudy

identifier {xxx}  
version {xxx}  
title {xxx}  
label {xxx}  
protocol.*Reference*( *PlanDefinition* )  
associatedParty.*Reference*(... *Organization* )  
recruitment  
> eligibility.*Reference*( *Group* ... )

## PlanDefinition

xxx

SoA

- **Mainly focussed on Schedule of Activities and existing Implementation Guide**
- **Doesn't mean content from earlier connectathons is dropped**

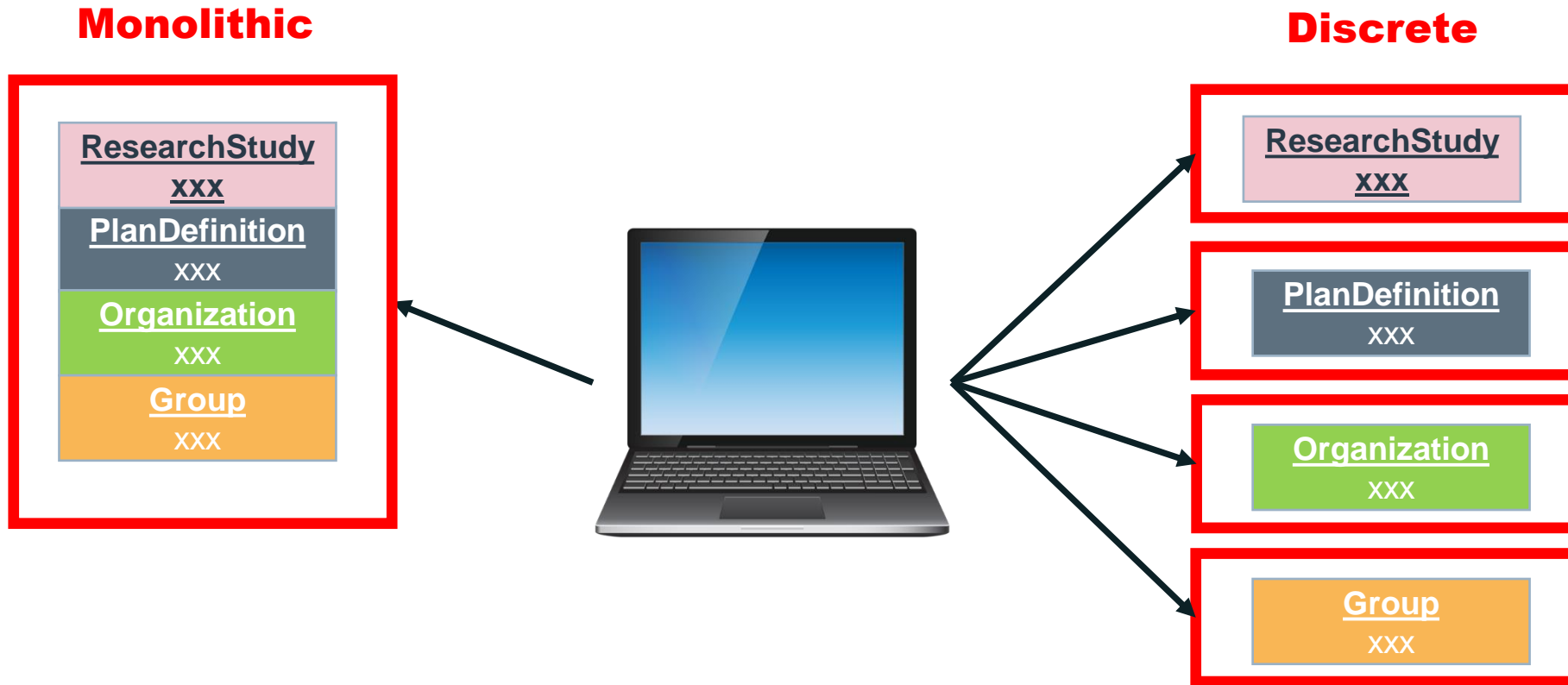
### Successes

- Used the SoA IG as the means of representing the SoA within the entire Protocol
- Transferred multiple SoA instances from USDM representation to a FHIR server and then displayed them in human readable form
- Continued to build business process models

### Key Challenges / Complicating factors

- Issue identified: A bundle containing all content suits approval use case but loading distinctly addressable resources better suits utilization use cases.
- Adoption considerations: The IG will have to lay out multiple methods of adoption that work with the existing applications. (This is a reflection of the issue above)

# Packaging Resources – Alternative Patterns

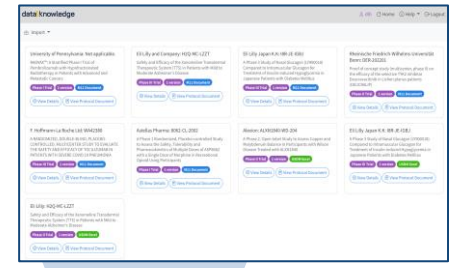


# HL7 FHIR Connectathon

## Atlanta, September 2024



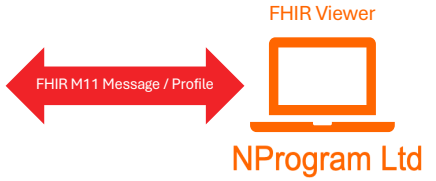
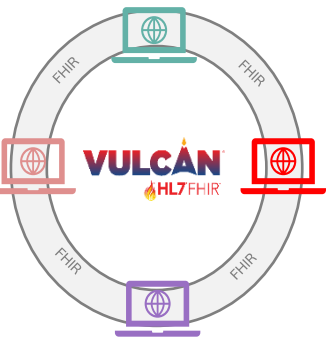
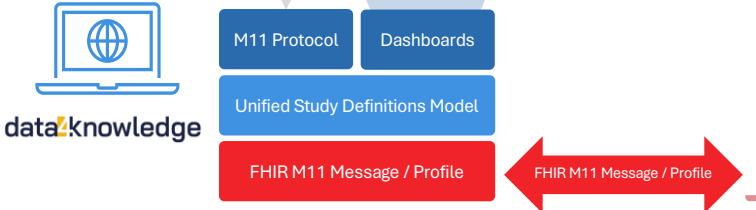
- Brian Alper, Computable Publishing
- Hugh Glover, Vulcan TRACK LEAD
- Dave Iberson-Hurst, CDISC
- Khalid Shahin, Computable Publishing
- Rik Smithies, HL7 UK
- Stacy Tegan, Vulcan, TransCelerate
- Rob Ferendo, TransCelerate
- Mary Lynn Mercado, Novartis
- Enam Rahman, TransCelerate
- Mihoko Okada, Idial



**“Sponsor”**

1

• M11 ‘.docx’ → USDM → FHIR M11

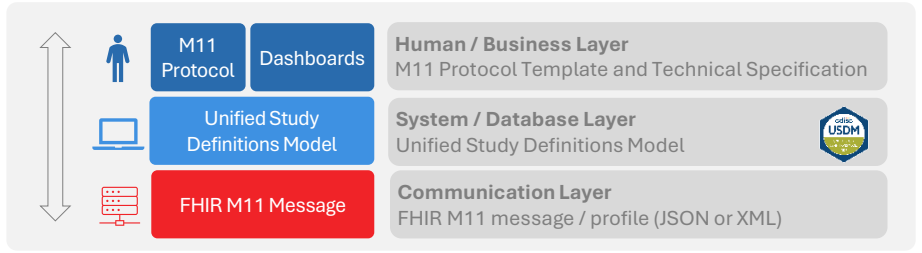


**“Regulator”**

2

• FHIR → M11 Presentation

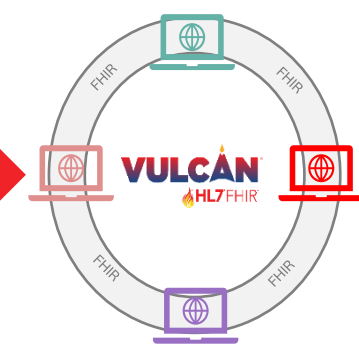
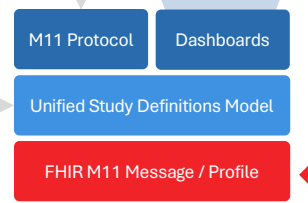
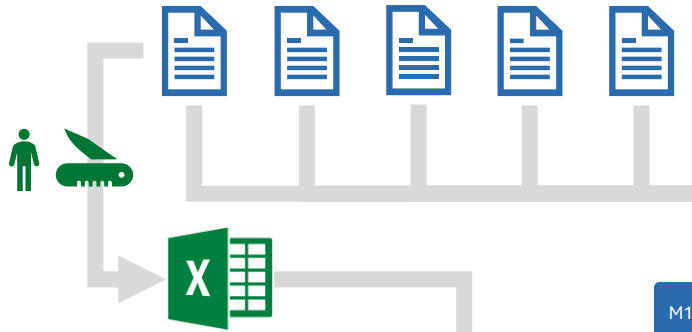
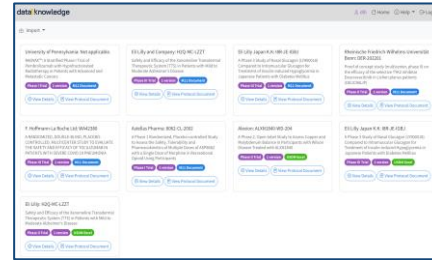
- Structure parts of the M11 Template:**
- Title Page
  - Inclusion / Exclusion
  - Estimands, Objectives and Endpoints
  - Amendments







- Hugh Glover, Vulcan TRACK LEAD
- Rob Ferendo, TransCelerate
- Patrick Genyn, fhir4pharma
- Dave Ibersen-Hurst, CDISC
- Geoff Low, Medidata
- Keiko Ota, Osaka Metropolitan University Hospital
- Rik Smithies, HL7 UK
- Stacy Tegan, TransCelerate, Vulcan



**“Sponsor”**

- M11 ‘.docx’ → USDM → FHIR M11
- USDM ‘.xlsx’ → USDM → FHIR SoA



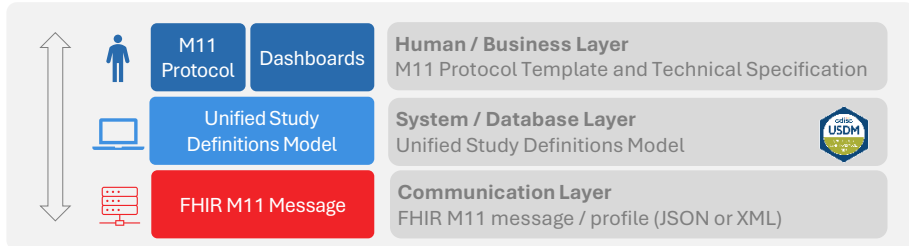
- Structure the SoA**
- Visits
  - Activities
  - Timing

**“Regulator”**

- FHIR → M11 Presentation

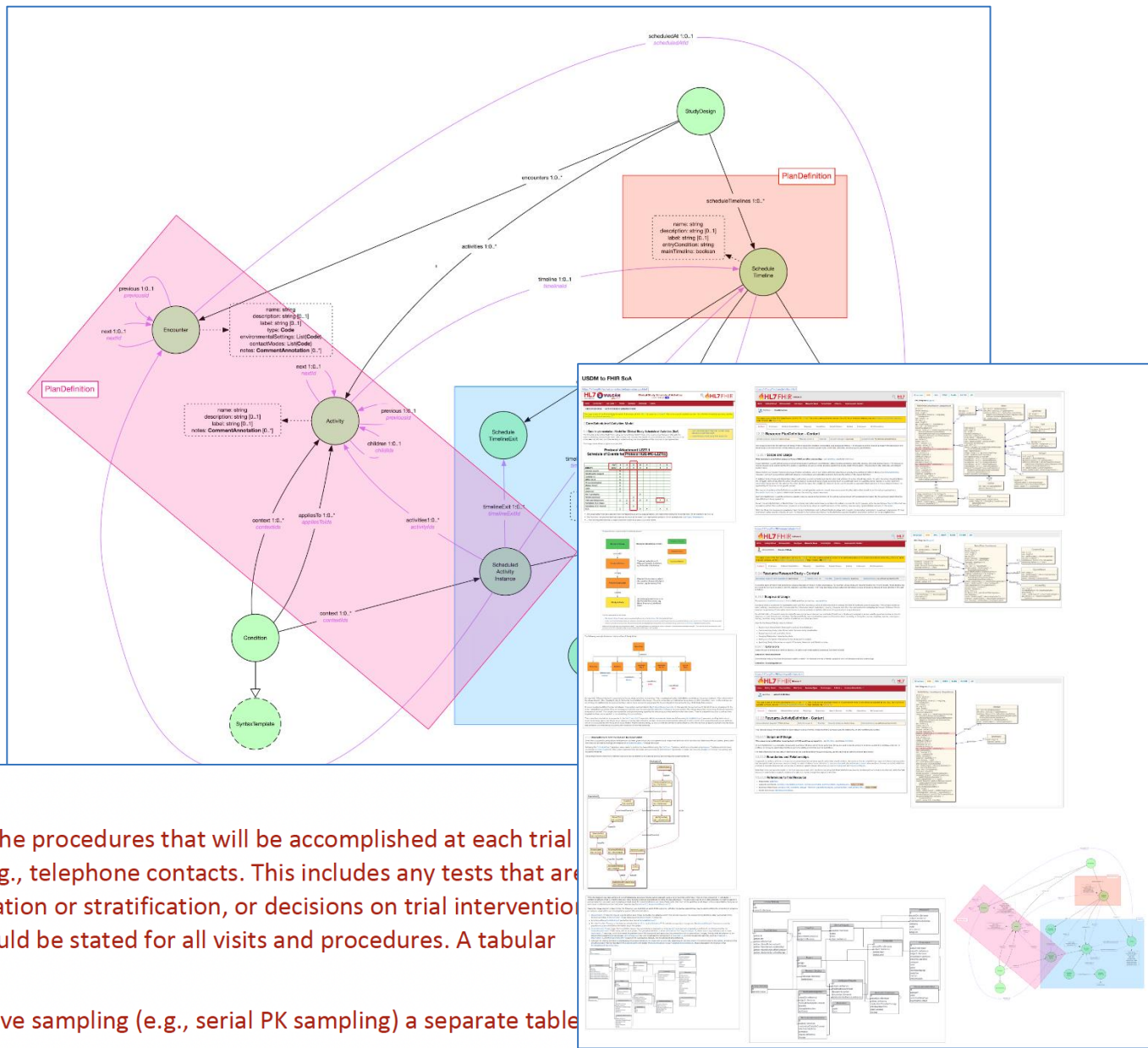
**“Operational Environment”**

- FHIR → SoA Presentation



# Protocols, SoA, USDM & FHIR

- M11 does not specify any structure for a SoA; we need structured data for data exchange.
- We are all well aware of the various SoA formats used within 'paper' protocols
- This Connectathon was the first [successful] bridging of that gap and transporting the SoA in a FHIR message
- The Connectathon demonstrated that USDM connects well with the FHIR representation
- Work on taking 'paper' SoAs into USDM is in progress, building the 'inner' layer, and closing the gap.



## Closing The Gap

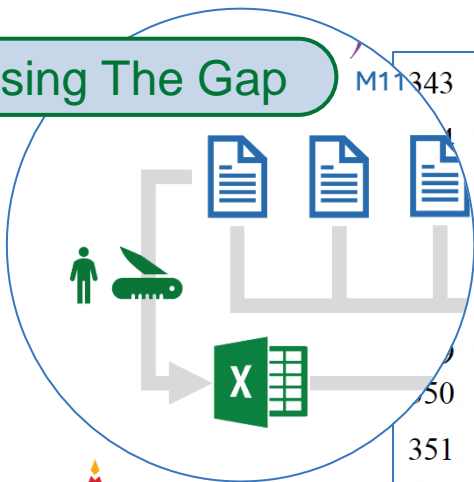
M11 343

### 1.3 Schedule of Activities

The schedule of activities must capture the procedures that will be accomplished at each trial visit, and all contact with participants, e.g., telephone contacts. This includes any tests that are used for eligibility, participant randomisation or stratification, or decisions on trial intervention discontinuation. Allowable windows should be stated for all visits and procedures. A tabular format is recommended.

When applicable for studies with extensive sampling (e.g., serial PK sampling) a separate table may be added.

<Enter Schedule of Activities>



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**Live Demonstration ...**

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## UDP Impact



# The Schedule of Activities must answer many questions



## Patients

When will I have appointments?  
 What tests will I have to have?  
 Do I have to fast for blood draws?  
 Are there a lot of questionnaires?



## Sponsors

Will I have the data needed to answer the research question and support a label claim?  
 Is this study too burdensome for patients or for the sites?  
 What will it cost?

1.3. Schedule of Activities (SoA)

Procedure	Screening (up to X days before Day 1)	Intervention Period [Days or Weeks, etc.]								E/D	Follow-up (X days after last dose)	Notes E/D = Early Discontinuation	
		-1	1	2	3	4	5	6	7				8
Informed consent	X												
Inclusion and exclusion criteria	X												[Recheck clinical status before randomization and/or 1st dose of study intervention.]
Demography	X												
Full physical examination including height and weight	X												
Medical history (includes substance usage [and family history of premature CV disease])	X												Substances: [drugs, alcohol, tobacco, and caffeine]
Past and current medical conditions	X												
[Highly sensitive serum OR urine] pregnancy test (WOCBP only)	X	X								X	X		[refer to section 8.2.5 – pregnancy testing for instruction on timepoints]
[HIV, Hepatitis B, and C screening]	X												
Laboratory tests (include liver chemistries)	X	X					X			X			
12-lead ECG	X		X		X					X	X		



## Sites

Can I manage what is required to conduct this study (i.e., staff, cost)?  
 What data needs to be collected & how does it need to be coded?  
 Is this study feasible for my patient?  
 When do I need to schedule my staff and my patients?



## Regulators

Do the procedures support the objectives?  
 Does the reported data trace back to procedures in the SoA? Was there compliance?



# Digitizing the Schedule of Activities will allow for clarity and the opportunity for additional value with additional layers of detail



The overall digital protocol contains layers of detail - each serving a specific purpose

## Document Exchange

The Schedule of Activities in a common location within a protocol document

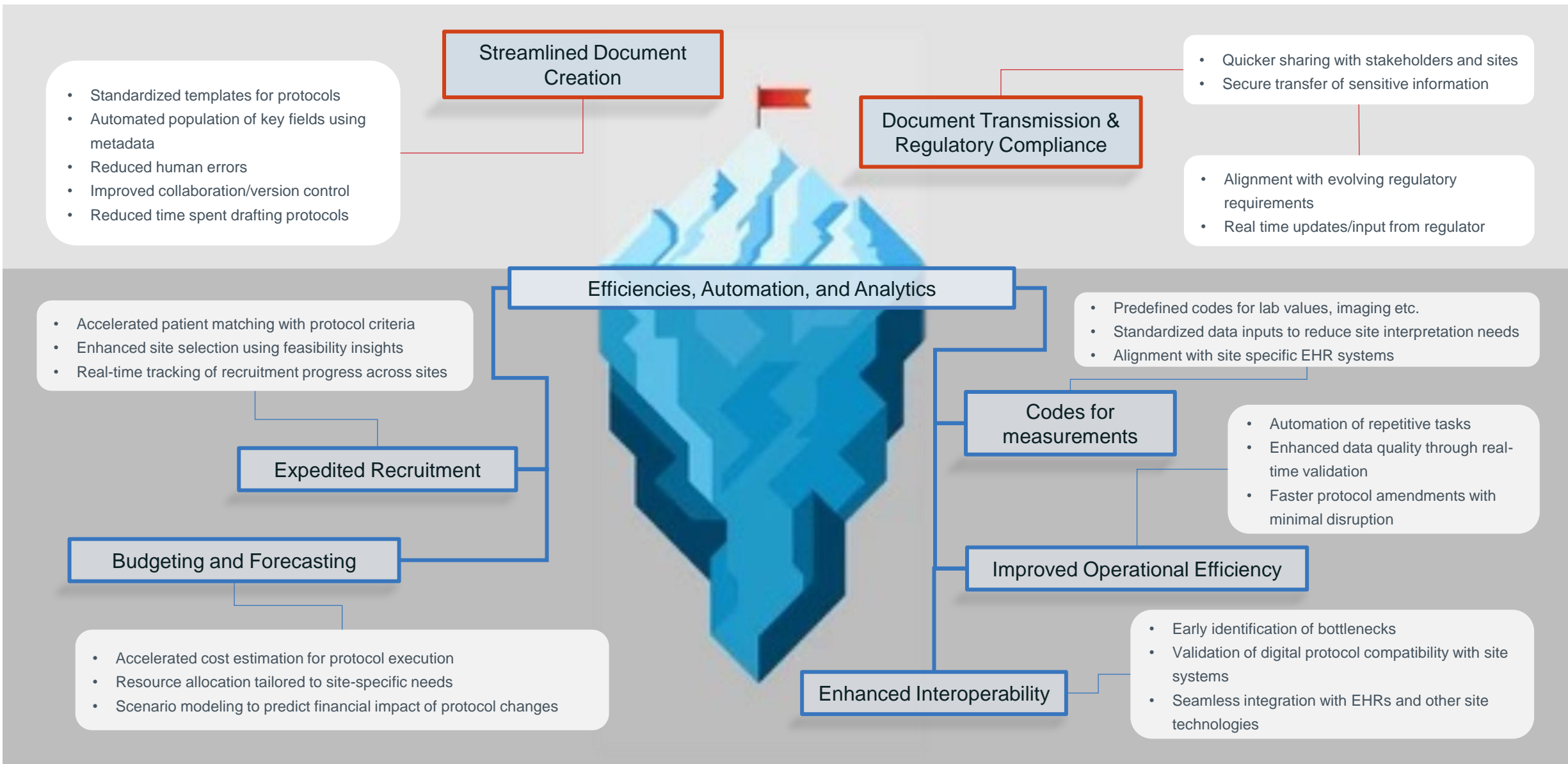
## Structured Exchange

Digitized and structured visits, activities, and details often found in footnotes today

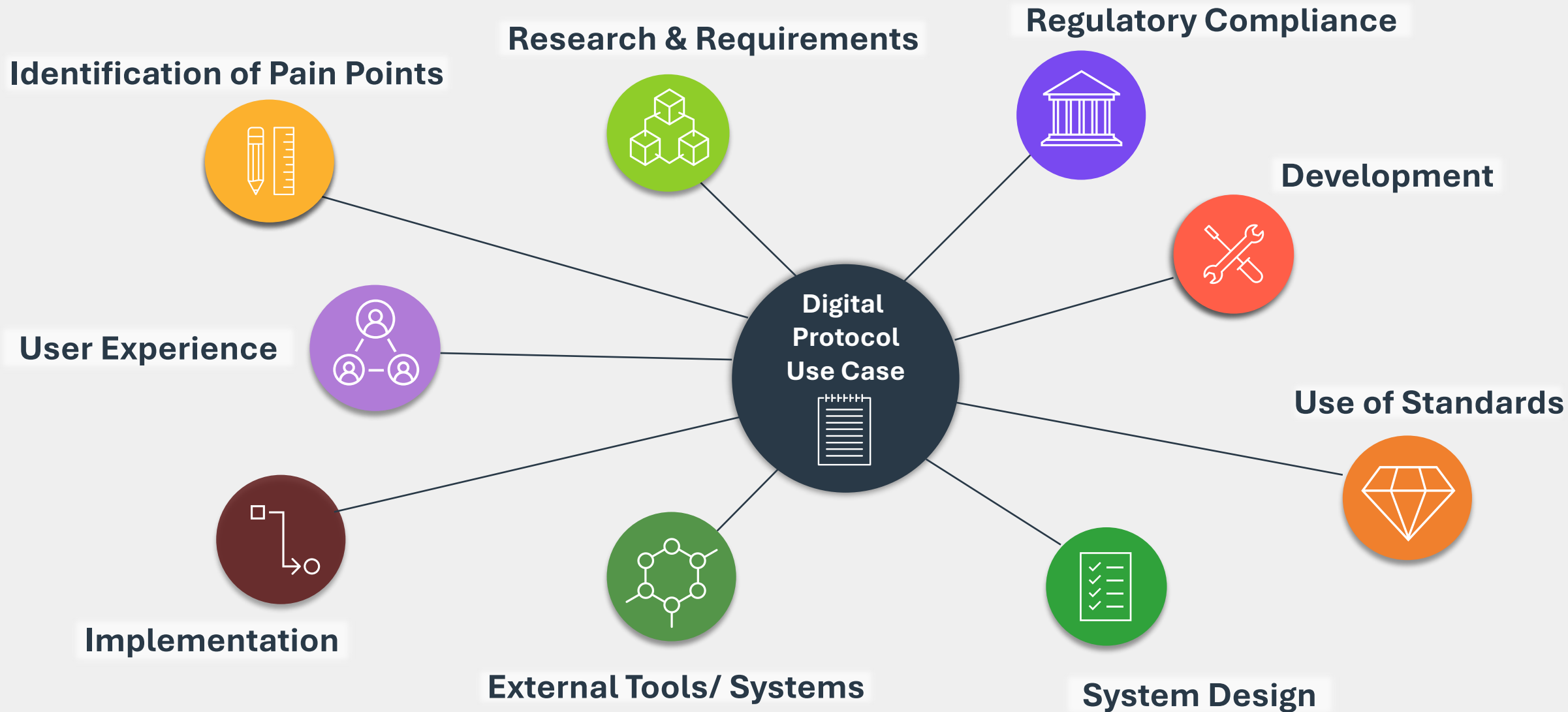
## Opportunities for additional detail

- ✓ Study-specific details (e.g., timelines, endpoints)
- ✓ Acceptable coding for data collection
- ✓ Detailed metadata for interoperability

# Digital Protocol Uses Cases



# Complexity Behind Each Use Case



# Connectathon Discussions on Business Process Opportunities

Alongside technical work, discussions explored business process challenges from different stakeholder perspectives to understand future process evolution and potentially inform technical requirements.

## Study Design

## Study Execution

## Reporting & Review

### Key Challenges

- Today's protocols do not contain sufficient detail (e.g. specification of observations and acceptable coding requirements)
- Sponsors don't have sufficient knowledge of coding systems to specify detail during protocol design
- Protocol designs need to work for sites with various capabilities

- It is a manual process to confirm semantic interoperability
- There is extensive variability among sites (i.e.. Sites may use different units of measure depending on global location; who carries responsibility to of unit conversion to site

- There is a need for common definitions that allow comparison across (i.e., biomedical concepts)
- When standards exists often the level of detail allows for interpretation

### UDP Actions

- Develop a catalog of sample protocols for digitization use cases
- Pinpoint protocols with detailed data (e.g., tests, demographics)

- Test workflows to refine processes

- Create structured implementation guides for clear, repeatable reporting



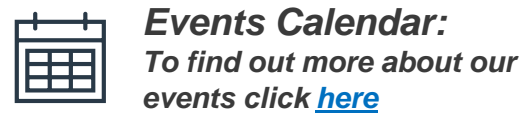
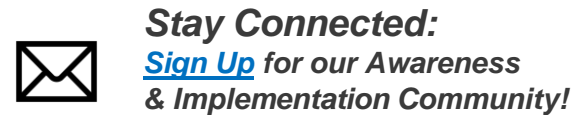


# What's Next and Upcoming Events

- Gather additional Business Process Requirements to inform the technical design
- Prepare for balloting in August
- Plan for additional Use Cases
- Planning underway for the May Connectathon (Madrid)

1. <i>Inclusion/Exclusion</i>	<i>A focus on criteria or mechanisms for inclusion and exclusion. Ensuring clarity on how eligibility criteria are structured within digital protocols</i>
2. <i>Joined-up protocol across previous Connectathons</i>	<i>Ensuring that the work done in past Connectathons ties together cohesively</i>
3. <i>Use of Bundles (Multiple vs. Single)</i>	<i>Exploring different approaches to structuring and exchanging data</i>
4. <i>USDM with FHIR Resources</i>	<i>Clarity of Mapping, ensuring that mappings between USDM and FHIR elements are clearly defined and functionally robust</i>
5. <i>Clarifying the Mapping of Terminology Across Standards</i>	<i>Ensure that terminology is well-defined and aligned across M11, USDM, and FHIR to prevent inconsistencies</i>
6. <i>Exploring the Use of FHIR Extensions for Uncovered Use Cases</i>	<i>Using FHIR extensions and profiles to handle specific use cases that go beyond what the IG currently defines. This would allow for more detailed implementations without altering the core IG</i>

# Contacts & Resources



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](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](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](https://database.ich.org/sites/default/files/ICH_M11_TechnicalSpecification_Step2_2022_1014.pdf)



[Vulcan UDP \(Utilizing the Digital Protocol\) Track](#)

[UDP Project Background and Overview Video](#)