



2024

CDISC JAPAN  
INTERCHANGE

TOKYO

12-13 JUNE: CONFERENCE & EXPO | 10-11 JUNE: TRAININGS

## Overview of HL7 FHIR Accelerator Vulcan, for Bringing Interoperability to Clinical Research

Presented at CDISC Japan Interchange, June 12, 2024



# Meet the Speaker

Mika Ogasawara

**Title:** Overview of HL7 FHIR Accelerator Vulcan, for Bringing Interoperability to Clinical Research

**Organization:** Pfizer R&D Japan, representing HL7 Vulcan

Currently working for Biometrics & DM, Pfizer R&D Japan as the Data Quality Lead and having been assigned as a member of the HL7 Vulcan Operation Committee by Pfizer since its activity started in 2020. She is also a member of Japan Operational Committee of TransCelerate Pharma Inc, especially in charge of engaging Process Harmonization program (i.e, Digital Data Flow, eSource, etc).

As a part of her responsibilities in Pfizer, she is leading eSource project in Japan as a part of global eSource program. She has over 25 years' experience in Pharmaceutical industry and mostly served data management and clinical study data related activities.

# Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *There is no financial relationship or conflict of interest relevant to this presentation*
- *The author has no real or apparent conflicts of interest to report.*



## Agenda

1. HL7 FHIR background
2. Vulcan background
3. Vulcan Use Cases (Projects)
  - Overall
  - Featuring a couple of projects

**Special thanks to**  
Vulcan core members

# What is HL7 FHIR?



FHIR, or **F**ast **H**ealthcare **I**nteroperability **R**esources, is an international Standard for exchanging healthcare information electronically in a consistent fashion.

FHIR R4 is the modernization of and best feature reutilization from HL7's v2, v3, and CDA products. It's also an evolving set of resources that can be expressed as an **80/20 rule**, where 80% is a common starting point and the remaining 20% are in the form of specialized use cases based on third-party extensions.

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.

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?

Flexible standard with 150+ resources to cover a wide array of use cases

Who?

Diverse global community (hospitals, academia, vendors, biopharma, regulators)

Source: <https://www.hl7.org/fhir/overview.html>, <https://www.healthit.gov/sites/default/files/2019-08/ONCFHIREFSWhatIsFHIR.pdf>, R4 is the current version of the FHIR standard

# Interoperability

Interoperability is the ability of computer systems, devices or software to exchange and use data seamlessly, by design.

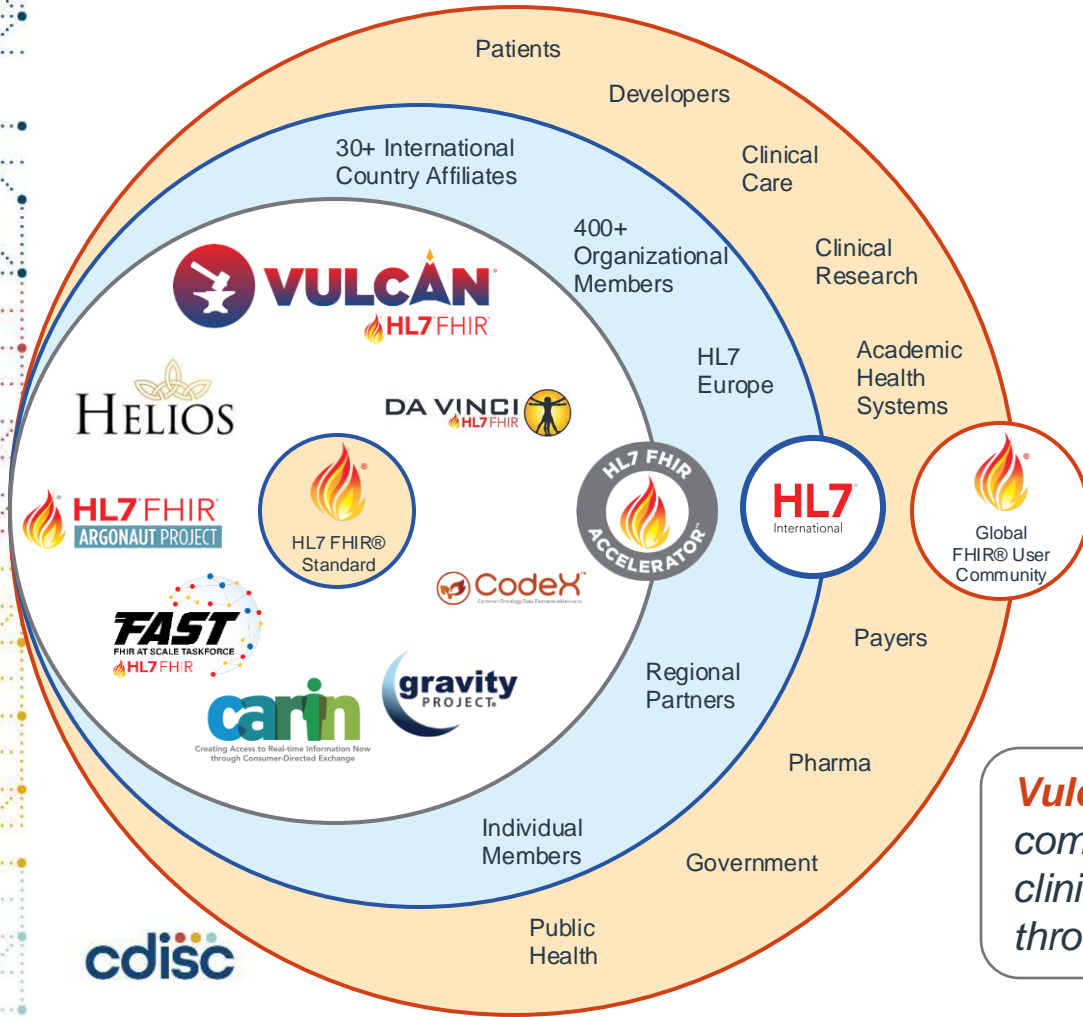
**Electrical power is a great example:**

- generated by multiple sources
- distributed in standard ways
- used by simply plugging in

**Data interoperability: smooth exchange and reuse of data between computer systems to ensure they work together seamlessly and efficiently.**



# 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.**

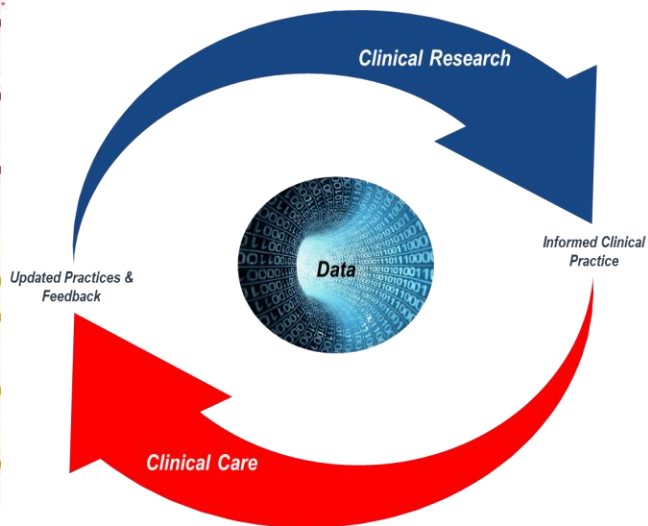
The **HL7 FHIR ACCELERATOR program** is designed to assist communities and collaborative groups across the global health care spectrum in the **creation and adoption of high quality FHIR Implementation Guides or other standard artifacts** to move toward the realization of global health data interoperability.

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

# Vulcan HL7 FHIR Accelerator

## Accelerating Interoperability in Clinical Research

Vulcan is a diverse and global research community collaborating to align care and clinical & translational research by driving standards-based exchange of health and research data.



<p><b>BRIDGE CLINICAL RESEARCH AND CLINICAL CARE</b></p>	<p>Identify areas of opportunity.</p>	<p><b>EDUCATION</b></p> <p>Educate the community</p>
<p><b>STRATEGICALLY CONNECT COLLABORATORS</b></p>	<p><u>Convene</u> the research community</p>	
<p><b>MAXIMIZE COLLECTIVE RESOURCES</b></p>	<p>Achieve more together.</p>	
<p><b>ENABLE INTEGRATION OF TOOLS &amp; SOLUTIONS</b></p>	<p>Develop FHIR Implementation Guides for Research.</p>	



# Vulcan is a Diverse, Global Community with 45 Member Organizations

As of May 2024

★ indicates a convening member of Vulcan

## Academia



## Consortia



## Government



## Implementers



## Pharma



## SDOs



## Others



# Vulcan – Moving Forward

## Inflection Point







# Vulcan Accomplishments - Highlights

- ✓ 3 Projects complete and Implementation Guide Published (RWD, SoA, ePI)
- ✓ 1 Project nearing complete (AE)
- ✓ 2 Projects Ongoing (Phenotypic data, FHIR to OMOP)
- ✓ 3 Projects in Discovery (Sample data, UDP, ACTR)
- ✓ Track at every connectathon since Jan 2021 (nearly 30 tracks on 7 topics)
- ✓ Large and small events organised
  - Vulcan 101 (multiple)
  - EuroVulcan (x2)
  - Implementation Showcase (multiple)
  - Conference presentations / presence (MIE, JAMI, FHIR DevDays, etc.)

# Vulcan HL7 FHIR® Accelerator Projects at-a-glance



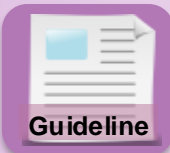
Has an IG published

Project	Objectives	Vulcan Leads
<b>Schedule of Activities (SoA)</b> 	Represent the schedule of activities in FHIR from a spreadsheet. Enable the consistent description, timing and identification of each activity in a study	<b>Mike Ward</b> (TransCelerate) <b>Geoff Low</b> (PHUSE)
<b>Real World Data (RWD)</b> 	Extract data from EHRs in a standardized format to support clinical research and especially submission to Regulators	<b>Scott Gordon</b> (FDA) <b>Alex Cheng</b> (Vanderbilt)
<b>Phenomics Exchange for Research and Diagnostics</b>	To increase the availability of high-quality standardized phenotypic information for genomic research and genomic medicine.	<b>Anita Walden</b> (University of Colorado Anschutz) <b>Shahim Essaid</b> (University of Colorado Anschutz)
<b>Electronic Product Information (ePI)</b> 	Define a common structure for product information (monographs) that supports cross-border exchange of data for patients	<b>Craig Anderson</b> (Pfizer) <b>Catherine Chronaki</b> (Secretary General at HL7 Europe)
<b>Adverse Events (AE)</b> 	Support standardizing the reporting and format of an adverse event. Improve the maturity of the relevant FHIR resources	<b>Michelle Casagni</b> (MITRE) <b>Ed Millikan</b> (FDA)
<b>FHIR to OMOP</b>	Support the development of FHIR to OMOP data transfer for better analysis of clinical data for research	<b>Davera Gabriel</b> (Evidentli)
<b>Sample Data</b>	Provide sets of data suitable for use in testing Vulcan applications and implementation guides  Some data sets to be wholly synthetic, others to be anonymized real data	<b>Catherine Craven</b> (Independent, SME) <b>Russell Leftwich</b> (InterSystems)

# ICH M11 and Vulcan Utilizing Digital Protocol



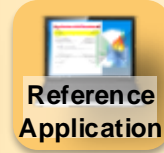
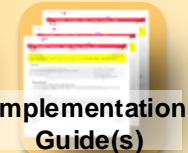
## CeSHarP



## USDM and Terminology



## Utilizing the Digital Protocol – UDP



## Inputs:

ICH M11 template

ICH M11 technical specification

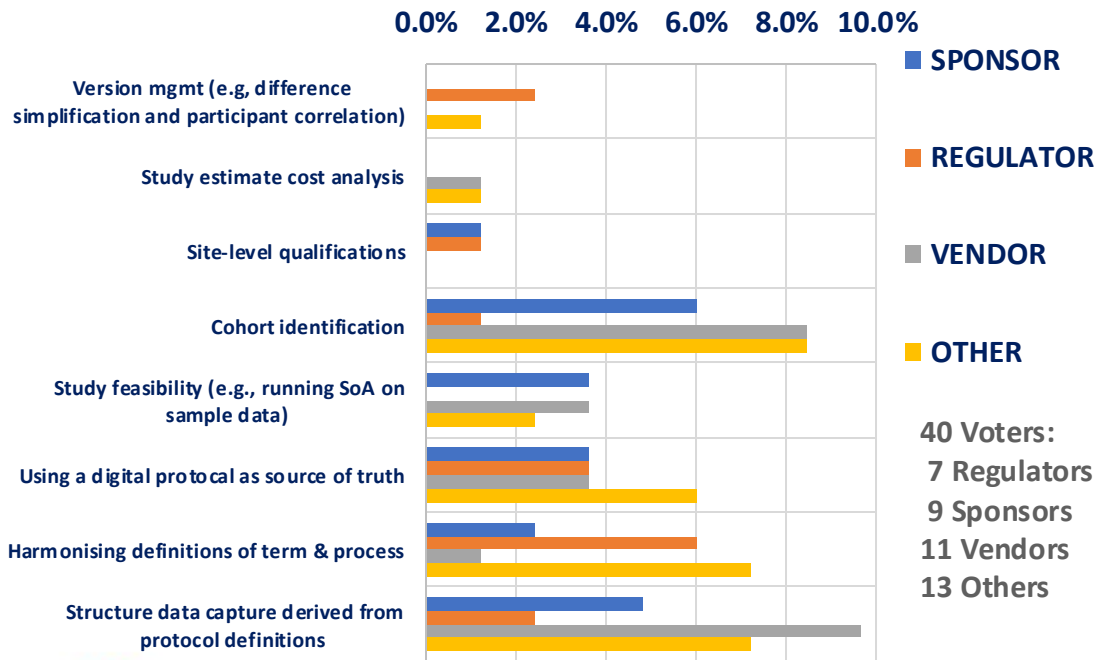
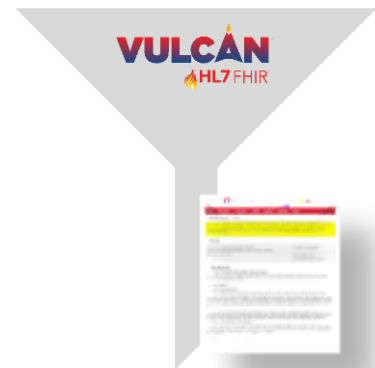
Models, definitions

**FHIR will carry CDISC CT and USDM content**

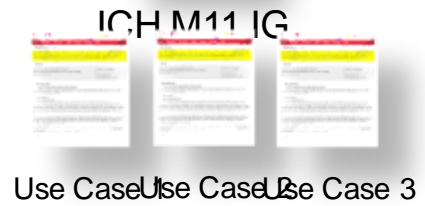
**The technical specification can be used to develop other Implementation Guides**

# Connecting Collaborators and Cross-Sector Use Cases for Digital Protocol

## VULCAN HL7 FHIR Preliminary Pulse Check Survey Distribution Across All Groups



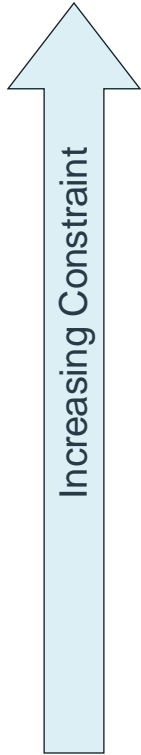
40 Voters:  
7 Regulators  
9 Sponsors  
11 Vendors  
13 Others



Use Case 1 Use Case 2 Use Case 3



# Design Layers – House Building



	<h2>Physical Building</h2>	Physical
	<h2>Construction Details</h2>	Logical
	<h2>Specific Plan</h2>	Conceptual
	<h2>Building Regulations</h2> <h2>Planning Regulations</h2>	

# Digital Protocol



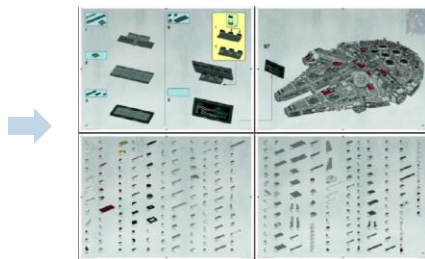
	<h2>Physical Model</h2> <p>(Transport Model, Database Definition)</p>		Implementation	
	<h2>Architecture Specific Model</h2> <p>(Platform Specific)</p>		Architecture	
	<h2>Use Case Specific</h2> <p>(Platform Independent)</p>			Case
	<h2>Domain Information Model</h2>		Semantics	
	<h2>Reference Information Model</h2>			

# Implementation Guides are Key



**FHIR Resources**  
(components – like Lego blocks)

- 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



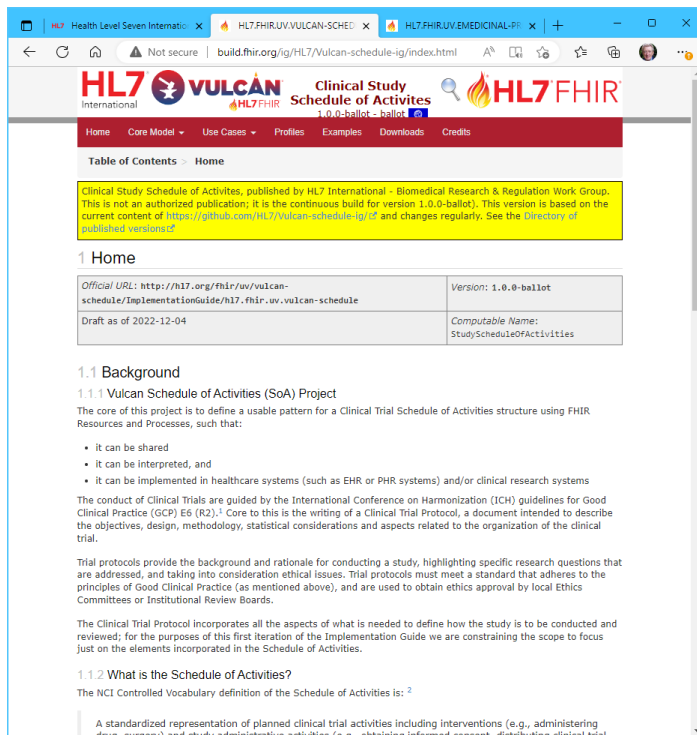
**Implementation Guides**



**Data Transport Models –**  
(the finished Lego structure)



# Example Vulcan Implementation Guide

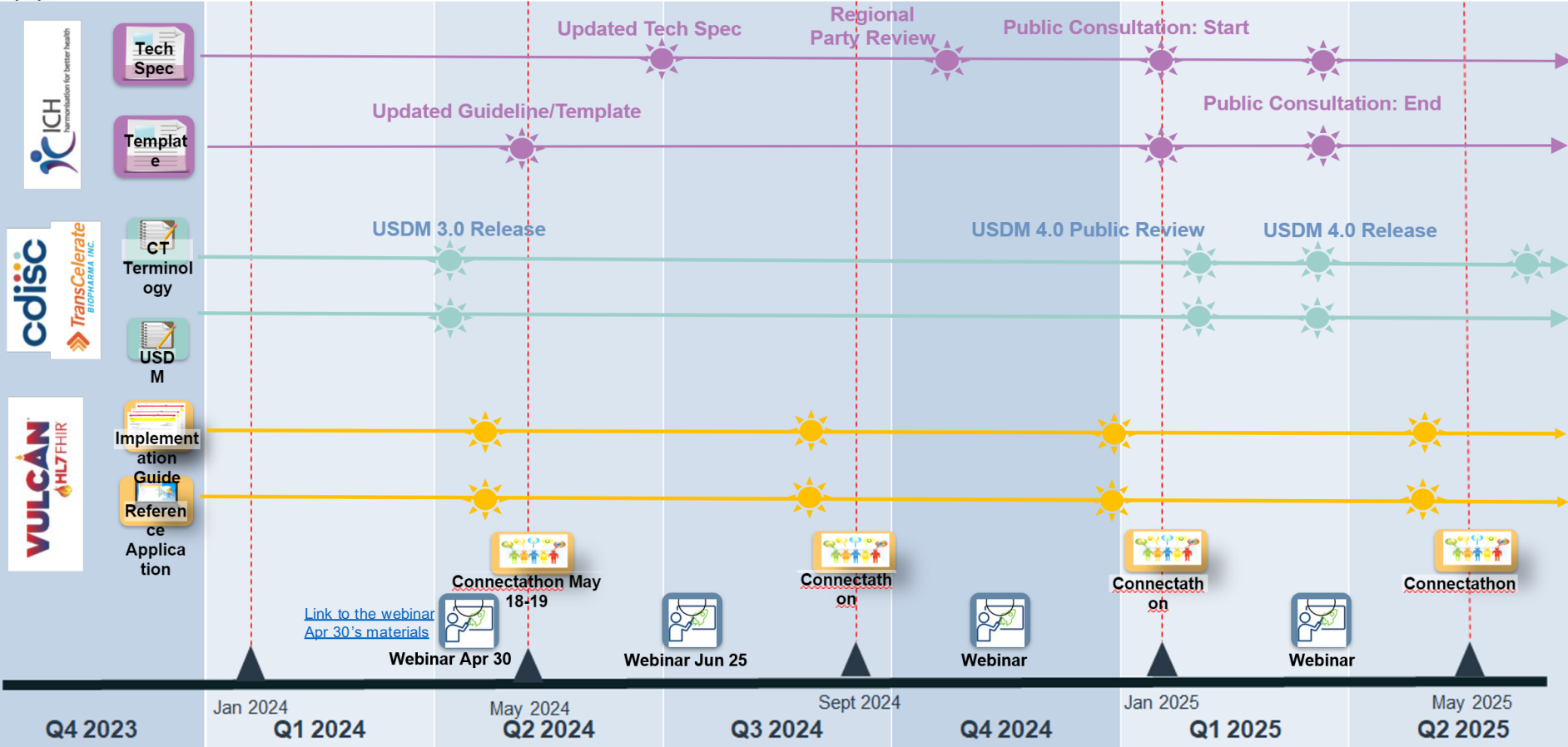


The screenshot shows a web browser displaying the HL7 FHIR Vulcan Schedule of Activities Implementation Guide. The page features a navigation menu with options like Home, Core Model, Use Cases, Profiles, Examples, Downloads, and Credits. A prominent yellow warning box states: "Clinical Study Schedule of Activities, published by HL7 International - Biomedical Research & Regulation Work Group. This is not an authorized publication; it is the continuous build for version 1.0.0-ballot. This version is based on the current content of https://github.com/HL7/vulcan-schedule-ig/ and changes regularly. See the Directory of published versions." Below this, a table provides metadata: Official URL (http://hl7.org/fhir/uv/vulcan-schedule/ImplementationGuide/hl7.fhir.uv.vulcan-schedule), Version (1.0.0-ballot), Draft as of (2022-12-04), and Computable Name (StudyScheduleOfActivities). The main content area begins with the section "1.1 Background" and "1.1.1 Vulcan Schedule of Activities (SoA) Project", explaining the project's goal to define a usable pattern for Clinical Trial Schedule of Activities structure using FHIR Resources and Processes.

Schedule of Activities

Search:  
Vulcan-schedule-ig

# Development Timeline



# The White House Office of Science & Technology Policy (OSTP) Announcement



***“Vulcan, together with CodeX and others, is stepping up to speed the development of standardized approaches to data exchange, with the goal of piloting faster and more inclusive data capture for multi-site clinical trials.”***

<https://www.whitehouse.gov/ostp/news-updates/2023/10/26/a-stronger-clinical-trial-infrastructure-for-better-health-outcomes/>

# OSTP Blog Announcement

## – What Does it Mean for Vulcan?

- Existing Vulcan IG's and ongoing projects can be leveraged to reach these goals:
  - ✓ Adverse Events for clinical research (AE)
  - ✓ Real world Data (RWD)
  - ✓ UDP
- Development of new open standards is envisaged – e.g. Modular Protocols
- Testing and demonstration is key – Vulcan can enable this through Connectathons and Reference Implementations
- It will generate momentum that matches Vulcan objectives
- US developments often travel the world – Vulcan can be the messenger through its global network and membership



# Get Involved!

## *To learn more or to get involved*



Visit our website <http://www.hl7.org/vulcan/>



Visit our confluence page  
<https://confluence.hl7.org/display/VA/Vulcan+Accelerator+Home>



Email us at [Vulcan@HL7.org](mailto:Vulcan@HL7.org)

Thank You!