



# Vulcan | OHDSI Community Call

July 18, 2023



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## AGENDA

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### Introductions

|                                  |         |        |
|----------------------------------|---------|--------|
| 1. Vulcan   HL7 FHIR Accelerator | Michael | 10 min |
| 2. Vulcan   How We Work          | Hugh    | 5 min  |
| 3. Vulcan   FHIR to OMOP Project | Davera  | 5 min  |
| 4. Vulcan   Membership           | Michael | 5 min  |
| 5. Q&A                           | All     | 15 min |



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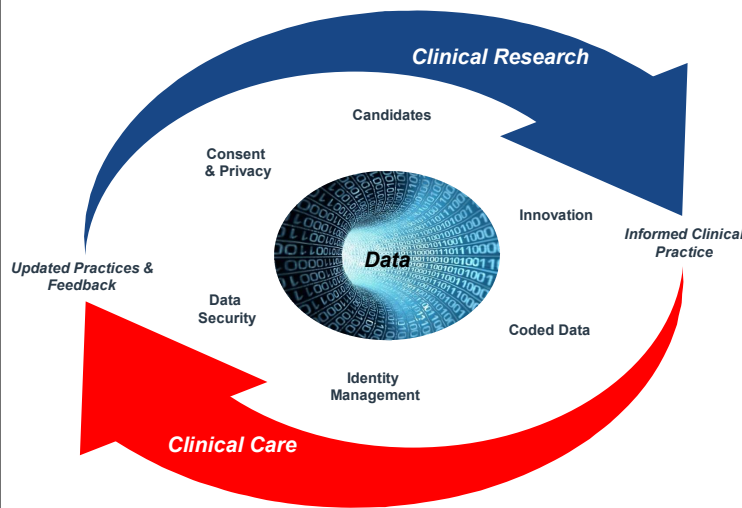
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## The Need for Standards in Clinical Research Data is the Key



- Health data is used for both Clinical Research and Clinical Care purposes
- However, **Clinical Research** has lagged behind other clinical care functions in the definition and use of Standards
- On the positive side, both share many common standards such as consent (to treatment, to research) and identity management
- Unique clinical research standards include candidate identification, clinical trials and phenotypic data (to name a few) that rely on health data curated by clinical care processes



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## Vulcan HL7 FHIR Grew Out of the Increasingly Digital Healthcare Environment



The growing digitalization in healthcare brings along modernized electronic health record standards such as HL7 FHIR.

Maturity in this space varies across the markets; however, the transition to a more digital environment is happening.

Several Accelerators exist already to spur development of digital solutions for healthcare:

- *Project Argonaut* (providers to providers)
- *Project DaVinci* (providers to payers)

### Experts Blazing the Path Forward for Research

The September 2019 HL7 FHIR® Conference in Atlanta included a half-day forum drawing participation across government, academia and industry.



The goal of the forum was to help the research community align toward leveraging HL7 FHIR® for more effective acquisition, exchange and use of data for clinical research.



## The Convening Members of Vulcan Represent a Wide Variety of Expertise



## Current Member Organizations of Vulcan

As of June 2023

★ indicates a convening member of Vulcan

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## HL7 Accelerator Program

### Focused Standards Development

**VULCÁN** HL7 FHIR  
**Vulcan**  
 Connecting translational and clinical research with healthcare

**HELIOS** Helios  
 Equitable and effective use of data for the advancement of public health

**gravity** PROJECT  
**Gravity**  
 Identify and harmonize social risk factor data for interoperable electronic health information exchange

**FAST**  
 FHIR AT SCALE TASKFORCE  
 HL7 FHIR  
 Define a scalable approach to deploying FHIR across interoperability use cases

**Argonaut** HL7 FHIR ARGONAUT PROJECT  
 Advance artifacts foundational to healthcare exchange: CDS Hooks, Bulk Data, Subscriptions, Clinical Notes, and US Core

**CARIN**  
 Creating Access to Real-time Information Now through Consumer-Directed Exchange  
 Advance the ability for consumers and their authorized caregivers to easily get, use, and share their digital health information

**CodeX**  
 Accelerate interoperable data modeling and applications cancer patient care and research

**Da Vinci** DA VINCI HL7 FHIR  
 Adoption of HL7® FHIR® as the standard to support and integrate value-based care (VBC) data exchange across communities

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## Vulcan Vision Statement



### Why Vulcan?

Fully integrate research into the delivery of healthcare by streamlining data collection and exchange into a singular process.

Vulcan has created a community of interested parties that work on common goals, devoid of individual organization bias or commercial interest



### What are we doing to reach that vision?

- Collaborating with the international research community to align clinical data and clinical research data at the point of collection.
- Developing out the HL7 FHIR standard to support the bidirectional flow of data.

FHIR



Clinical Care

Clinical Research



### How will we accomplish this?

- Bridge existing gaps
- Strategically connect industry collaborations
- Maximize collective resources
- Deliver integrated tools and solutions



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## The Goals of Vulcan



### BRIDGE EXISTING GAPS

Work to close gap between clinical care and clinical research to improve patient lives, decrease costs and improve efficiency



### STRATEGICALLY CONNECT COLLABORATORS

Coordinate strategy between stakeholders and leverage existing work within HL7 and other groups including FDA, NCATS, NLM, SCDM, TransCelerate, and academic research sites



### MAXIMIZE COLLECTIVE RESOURCES

Leverage shared community and resources to be able to communicate the return on investment and return on value that a unified network could realize to various parties, and provide comprehensive recommendations to global regulators



### DELIVER INTEGRATED TOOLS AND SOLUTIONS


Develop necessary FHIR Research Resources to maturity. Vulcan will handle identified and prioritized use cases for secondary use of EHR data that meet interested parties needs and goals



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## Vulcan Value Propositions

Why Vulcan?




|                                                                                                             |                                                                                                              |                                                                                                                 |
|-------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|
| <b>REDUCE COSTS</b>                                                                                         | <b>REMOVE BARRIERS</b>                                                                                       | <b>INCREASE QUALITY</b>                                                                                         |
| Exchange data based on a recognized standard reducing site-by-site negotiation.                             | Identify & resolve common barriers to adoption such as privacy, consent and inconsistent data.               | Leverage standardized terminologies to reduce ambiguity and increase precision.                                 |
| <i>“Build once, use many”</i>                                                                               | <i>“Implement faster”</i>                                                                                    | <i>“Talk the same language”</i>                                                                                 |
| <b>BUILD NETWORK</b>                                                                                        | <b>THE POWER OF MANY</b>                                                                                     | <b>HARMONIZE STANDARDS</b>                                                                                      |
| Connect with clinical research leaders, innovators and implementers across the sector and around the world. | Resolve problems that may be difficult to solve within an organization. Others have resolved the same issue. | Develop and implement standards that are already in place in clinical care, but in a clinical research setting. |
| <i>“Better together”</i>                                                                                    | <i>“Crowd source solutions”</i>                                                                              | <i>“Reduce mappings”</i>                                                                                        |



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## Vulcan Projects

July 2023



| Project                              | Objectives                                                                                                                                                | Vulcan Lead                                                                                                     |
|--------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|
| Schedule of Activities (SoA)         | 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)<br><b>Geoff Low</b> (PHUSE)                                                    |
| Real World Data (RWD)                | Extract data from EHRs in a standardized format to support clinical research and especially submission to Regulators                                      | <b>Scott Gordon</b> (FDA)<br>[Open Position]                                                                    |
| Phenotypic Data                      | To increase the availability of high-quality standardized phenotypic information for genomic research and genomic medicine.                               | <b>Anita Walden</b> (University of Colorado Anschutz)<br><b>Shahim Essaid</b> (University of Colorado Anschutz) |
| Electronic Product Information (ePI) | Define a common structure for product information (monographs) that supports cross-border exchange of data for patients                                   | <b>Craig Anderson</b> (Pfizer)<br><b>Catherine Chronaki</b> (Secretary General at HL7 Europe)                   |
| Adverse Events (AE)                  | Support standardizing the reporting and format of an adverse event. Improve the maturity of the relevant FHIR resources                                   | <b>Michelle Casagni</b> (MITRE)<br><b>Ed Millikan</b> (FDA)                                                     |
| FHIR to OMOP                         | Support the development of FHIR to OMOP data transfer for better analysis of clinical data for research                                                   | <b>Davera Gabriel</b> (Johns Hopkins)<br><b>Catherine Diederich</b> (Duke)                                      |


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## Future Vulcan Projects

July 2022



| Project / Vulcan Leads | Objectives                                                                                                                                                                                                                         |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Sample Data            | <ul style="list-style-type: none"> <li>Provide sets of data suitable for use in testing Vulcan applications and implementation guides</li> <li>Some data sets to be wholly synthetic, others to be anonymized real data</li> </ul> |
| MedWatch on FHIR       | <ul style="list-style-type: none"> <li>Provide a FHIR based equivalent to the FDA MedWatch form for Adverse Event reporting</li> </ul>                                                                                             |
| ICH CeSHarP            | <ul style="list-style-type: none"> <li>Demonstrate that FHIR can be used to exchange the CeSHarP representation of a protocol between regulators and between a sponsor and a regulator</li> </ul>                                  |

*This is one among several Vulcan projects working with aspects of the protocol – not all can be shared at present*



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## Vulcan – Moving Forward

Inflection Point



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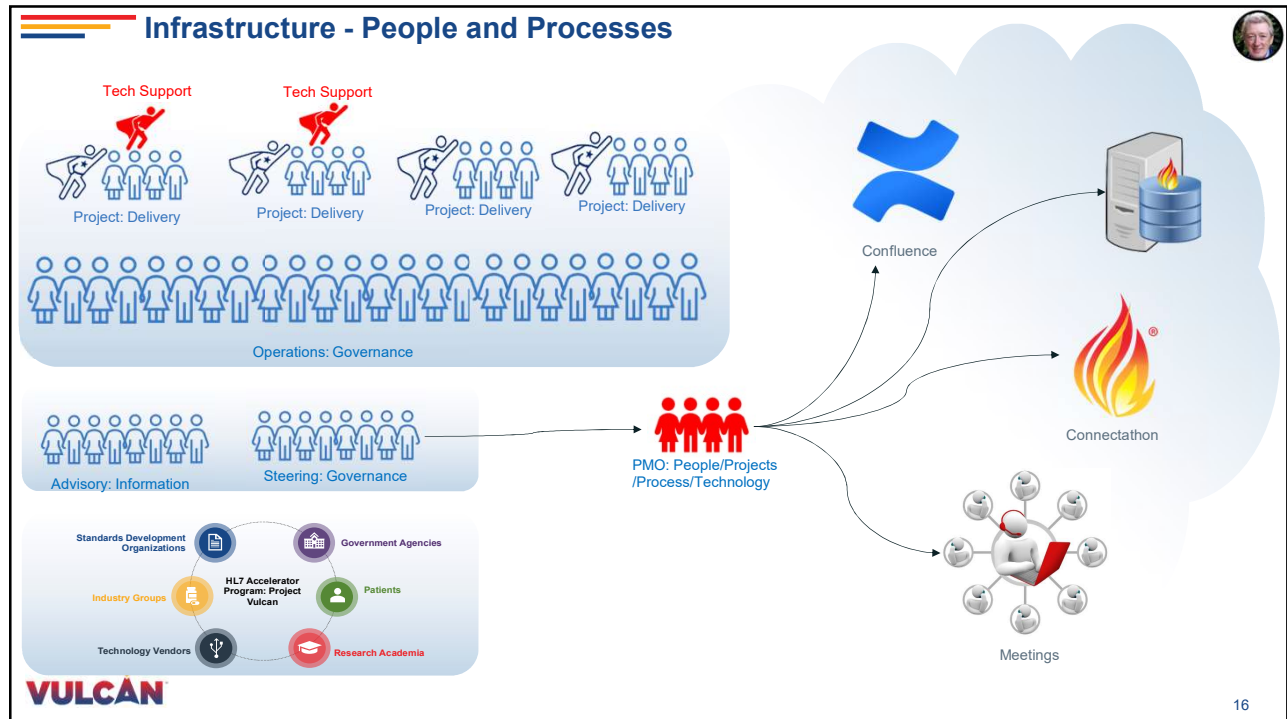


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## Making a Use Case Proposal

- Vulcan actively seeks new use case proposals – contact us at [Vulcan@HL7.org](mailto:Vulcan@HL7.org) or use the form shown here – Search **Vulcan Use Case Submission**
- Proposals are initially considered by the Project Management Office and we may seek further input from you, particularly if the suggestion appears to overlap with an existing proposal.
- New proposals are then added to the project backlog for consideration and **prioritization by the Operations Committee** and subsequent recommendation to the **Steering Committee for final approval and any funding**.
- Adoption of new projects depends on priority and availability of resources.

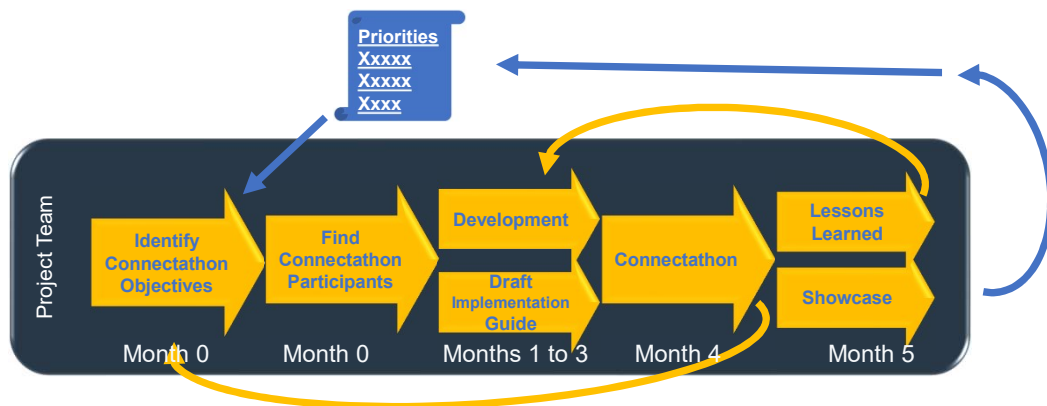
<https://confluence.hl7.org/display/VA/Vulcan+Use+Case+Submission+Form>



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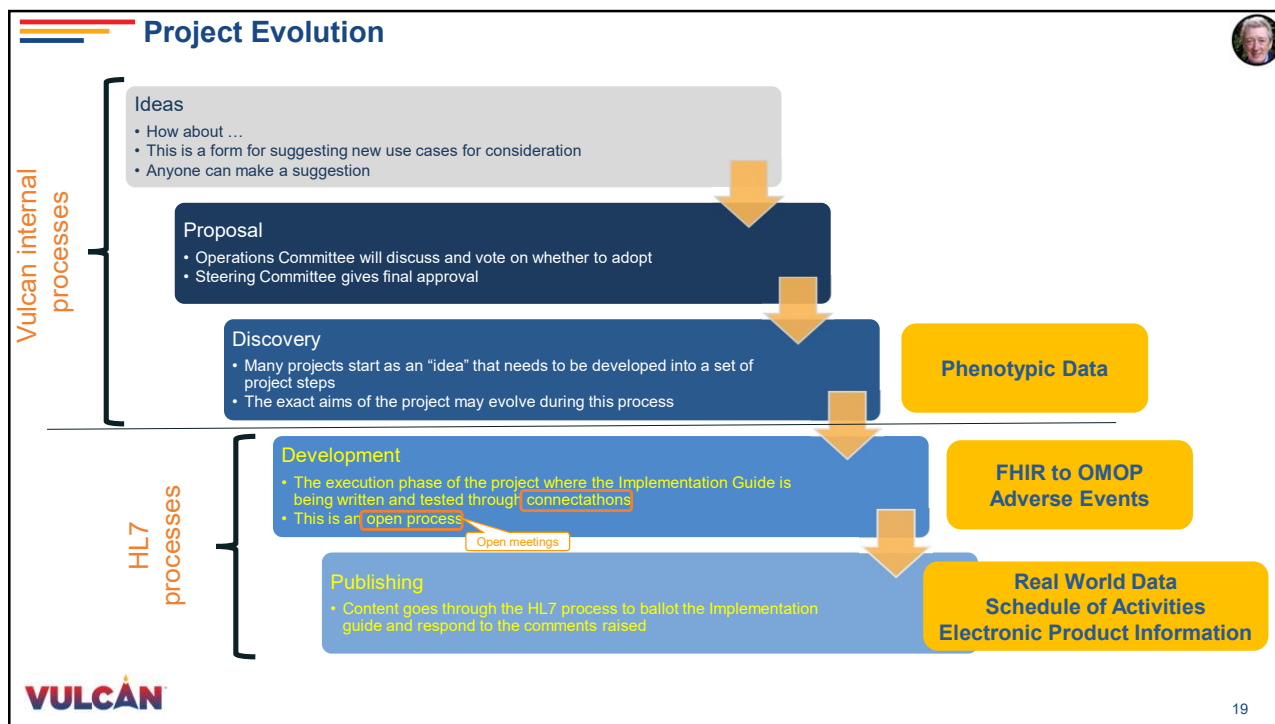
## Vulcan Project Work Cycle



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# Current Vulcan Implementation Guides

**Schedule of Activities**

Search: vulcan-schedule history

**Electronic Product Information**

Search: emedicinal-product-info history

**Real World Data**

Search: vulcan-rwd history

**VULCÁN**

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## Connectathon January 2023

### 4 Vulcan Tracks



#### Schedule of Activities

- Updated React app that displays activities in visit windows to incorporate administrations and unscheduled activities
- Additionally, progressed
  - Investigational Product Administration
  - Unscheduled Activities

#### Real World Data

- Created a synthetic data set to help develop EHR queries
- Successfully queried the data using inclusion / exclusion criteria for patients of interest
- Compared retrieved data to source data to confirm that queries were working correctly
- Compared queried data to other EHR sources

#### FHIR to OMOP

- Fixed various infelicities in the existing IG, for instance, adding severity and modifiers and specific named component slices
- Wrote HAPI FHIR Java code to convert GA4GH Phenotypic Data (JSON) to FHIR version, post this to a FHIR server, search and retrieve the FHIR message and translate back to GA4GH JSON
- Coordination FHIR Genomics Reporting IG version 2

#### Electronic Product Information

- Developed plans on how to handle allergens and interactions as a priority
- Decided to compare the patients' drugs with the list of interactions between those drugs.
- Decided on an operation to provide the EMA ePI in the full 'US style' format by combining the ePI plus SPOR product data
- Clarified how we plan to incorporate more SPL profile data into the Vulcan IG



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## January 2023 Connectathon



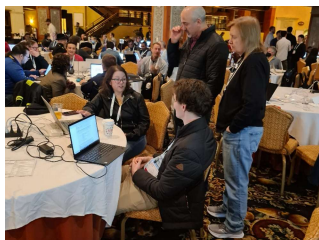
Schedule of Activities



Vulcan Promotion



Electronic Product Information



FHIR to OMOP



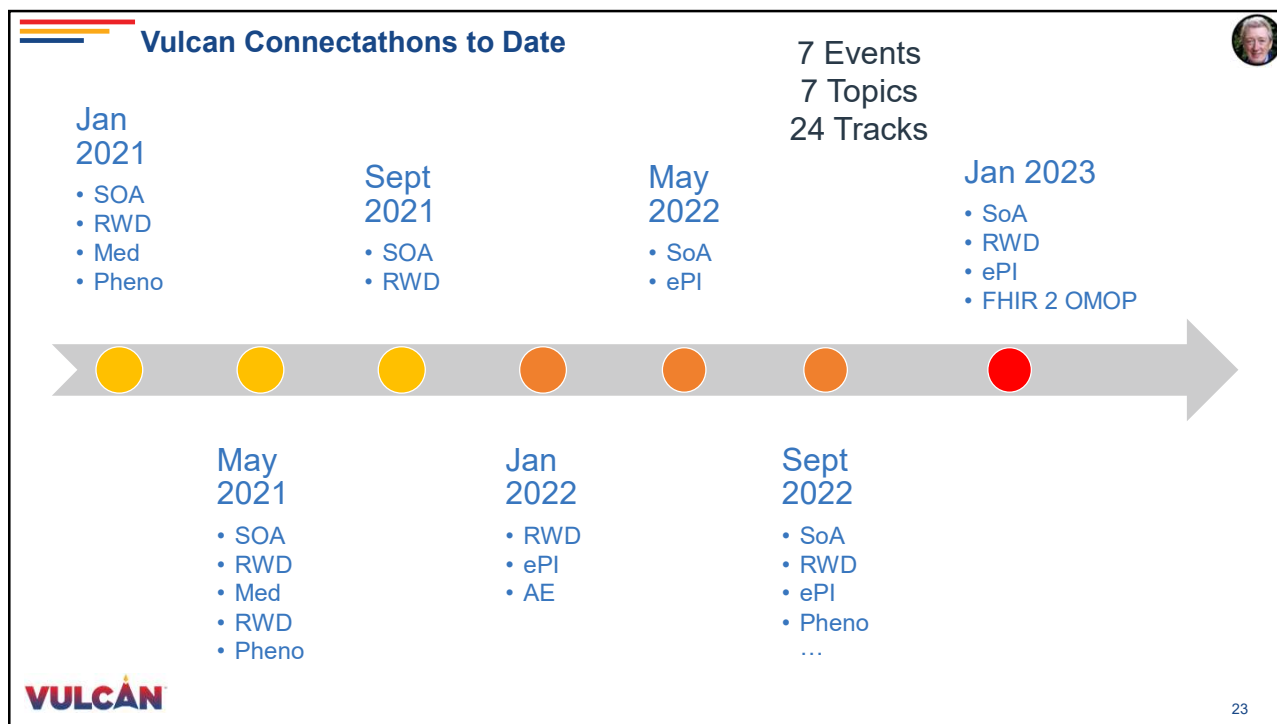
Real World Data



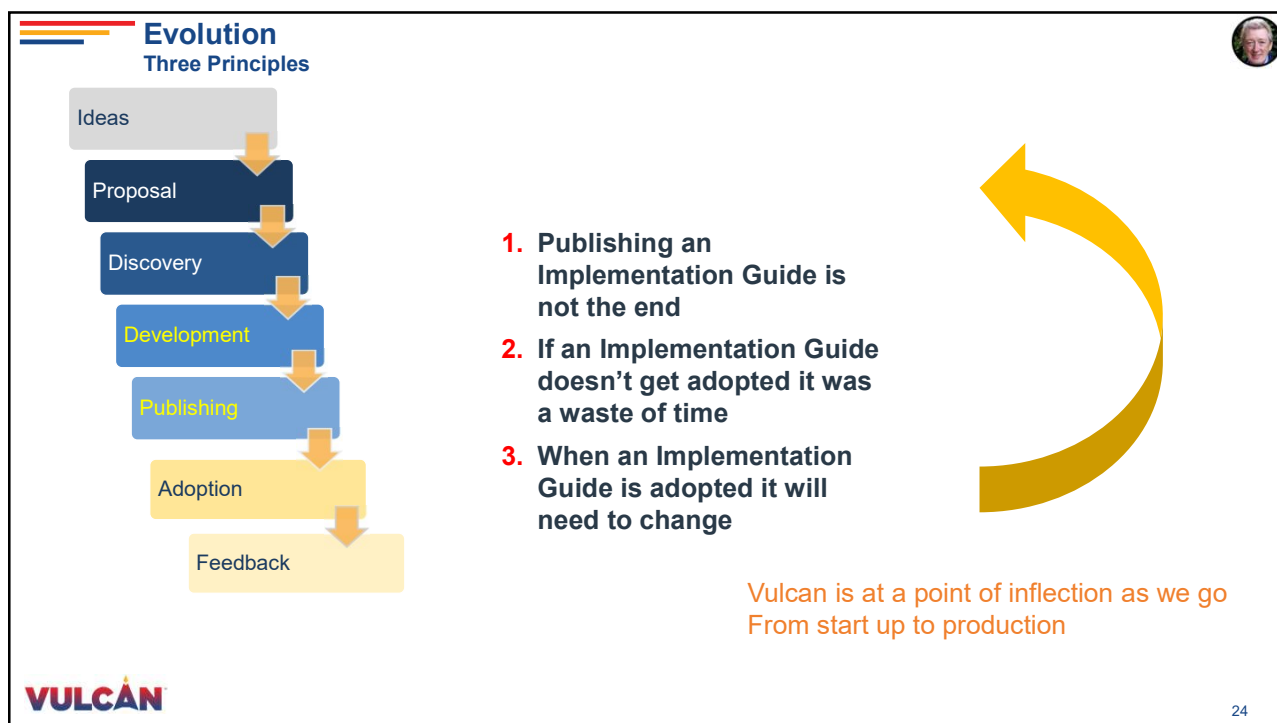
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## Vulcan | HL7 FHIR Accelerator FHIR to OMOP Project



- **Takes advantage of a “win-win” scenario, leveraging**
  - FHIR adoption breadth
  - Vulcan’s diverse membership
  - OMOP Harmonization & Data Quality
  - OHDSI’s advanced analytics capabilities
- **Decreases individual site data transformation costs**
- **Increases the quality & consistency of transformed data**





- **Focus on only FHIR-to-OMOP transformations**
  - Goal: Validate & Publish SME-curated maps
- **Only leverage prior work**
  - NOT generating new maps, unless missing
- **Scope limited EMR “core” data**
  - Use established FHIR IG Profiles (IPA, or IPS / US Core)
- **Project findings report**
  - Environmental scan: breadth of prior work discovered
- **Iterative Connectathon Engagement**
  - Validate & Refine SME-curated maps`



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## Vulcan Events and Educational Opportunities



Vulcan provides valuable opportunities to engage across the research community



**Conferences**

Vulcan event to convene interested parties to share thought leadership, Vulcan progress, and implementation opportunities

EuroVulcan held March 2023



**Connectathons**

Event centered on developing and testing use of FHIR for a Vulcan use case

This is a critical step in developing Vulcan Implementation Guides



**Round Tables**

Topical discussions to connect groups and inform Vulcan direction

Round tables held on Electronic Product Information, Adverse Events, FHIR to OMOP



**Vulcan 101**

Full day course, in depth review of HL7 FHIR & the Vulcan Projects

Held 2-3 times/year

Open to non-members, Vulcan members receive two complimentary passes



**Implementation Showcases**

Forum for Vulcan members to learn of innovative solutions using FHIR in clinical & translational research

Non-members can present solutions

There are many opportunities to engage with the Vulcan community



## Vulcan Membership Model



| Tier                           | Target Groups       | Qualifications                                                                                                             | Costs                           | In-Kind | Lead Project? | Ops Ctte Vote?                 | Implementation Showcase | Education Discount | Strategic Retreat? |               |
|--------------------------------|---------------------|----------------------------------------------------------------------------------------------------------------------------|---------------------------------|---------|---------------|--------------------------------|-------------------------|--------------------|--------------------|---------------|
| <b>Consortia / Association</b> | N/A                 | <ul style="list-style-type: none"> <li>Industry associations</li> <li>SDOs</li> </ul>                                      | N/A                             | -       | 100+ hours    | By Invitation                  | Yes                     | Yes                | Under Review       | Yes           |
| <b>Organization</b>            | For Profit (Large)  | <ul style="list-style-type: none"> <li>Pharma</li> <li>Implementers</li> <li>CROs</li> <li>MedTech</li> </ul>              | > \$25M annual revenue          | \$50K   | 100+ hours    | Subject to confirmation by PMO | Yes                     | Yes                |                    | Yes           |
|                                | For Profit (Medium) |                                                                                                                            | \$5-25M USD annual revenue      | \$25K   | 75+ hours     |                                | Yes                     | Yes                |                    | By Invitation |
|                                | For Profit (Small)  |                                                                                                                            | < \$5M USD annual revenue       | \$10K   | 50+ hours     |                                | Yes                     | Yes                |                    | By Invitation |
|                                | Non-Profit (Large)  | <ul style="list-style-type: none"> <li>Academia</li> <li>Researchers</li> </ul>                                            | > \$500M sponsored research     | -       | 200+ hours    |                                | Yes                     | Yes                |                    | Yes           |
|                                | Non-Profit (Small)  |                                                                                                                            | < \$500M sponsored research     | -       | 100+ hours    |                                | Yes                     | Yes                |                    | By Invitation |
| <b>Government Agency</b>       | High Impact         | <ul style="list-style-type: none"> <li>Clinical Trial Regulators</li> <li>Regulators</li> </ul>                            | > \$500M translational research | -       | 200+ hours    | Yes                            | Yes                     | Yes                |                    |               |
|                                | Moderate Impact     |                                                                                                                            | < \$500M translational research | -       | 100+ hours    | Yes                            | Yes                     | By Invitation      |                    |               |
| <b>SME (by invitation)</b>     | N/A                 | <ul style="list-style-type: none"> <li>SMEs (HL7 FHIR experts, thought leaders, etc.)</li> <li>Patient Advocacy</li> </ul> | N/A                             | -       | 50+ hours     | -                              | -                       | By Invitation      |                    |               |



 Questions?

*To learn more or to get involved*



<http://www.HL7Vulcan.org>



hl7-vulcan



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



[Vulcan@HL7.org](mailto:Vulcan@HL7.org)



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Thank you!

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