AGENDA

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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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
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)

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

Vulcan
Connecting translational and clinical research with healthcare

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

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

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

HL7 Accelerator Program
Focused Standards Development

FAST
Define a scalable approach to deploying FHIR across interoperability use cases

Argonaut
Advance artifacts foundational to healthcare exchange: CDS Hooks, Bulk Data, Subscriptions, Clinical Notes, and US Core

CARIN
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
Vulcan Vision Statement

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

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.

How will we accomplish this?
• Bridge existing gaps
• Strategically connect industry collaborations
• Maximize collective resources
• Deliver integrated tools and solutions

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

DEVELOPER 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
Vulcan Value Propositions
Why Vulcan?

**REDUCE COSTS**
Exchange data based on a recognized standard reducing site-by-site negotiation.

"Build once, use many"

**REMOVE BARRIERS**
Identify & resolve common barriers to adoption such as privacy, consent and inconsistent data.

"Implement faster"

**INCREASE QUALITY**
Leverage standardized terminologies to reduce ambiguity and increase precision.

"Talk the same language"

**BUILD NETWORK**
Connect with clinical research leaders, innovators and implementers across the sector and around the world.

"Better together"

**THE POWER OF MANY**
Resolve problems that may be difficult to solve within an organization. Others have resolved the same issue.

"Crowd source solutions"

**HARMONIZE STANDARDS**
Develop and implement standards that are already in place in clinical care, but in a clinical research setting.

"Reduce mappings"

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**Vulcan Projects**
July 2023

<table>
<thead>
<tr>
<th>Project</th>
<th>Objectives</th>
<th>Vulcan Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schedule of Activities (SoA)</td>
<td>Represent the schedule of activities in FHIR from a spreadsheet. Enable the consistent description, timing and identification of each activity in a study</td>
<td>Mike Ward (TransCelerate) Geoff Low (PHUSE)</td>
</tr>
<tr>
<td>Real World Data (RWD)</td>
<td>Extract data from EHRs in a standardized format to support clinical research and especially submission to Regulators</td>
<td>Scott Gordon (FDA) [Open Position]</td>
</tr>
<tr>
<td>Phenotypic Data</td>
<td>To increase the availability of high-quality standardized phenotypic information for genomic research and genomic medicine.</td>
<td>Anita Walden (University of Colorado Anschutz) Shahim Essaid (University of Colorado Anschutz)</td>
</tr>
<tr>
<td>Electronic Product Information (ePI)</td>
<td>Define a common structure for product information (monographs) that supports cross-border exchange of data for patients</td>
<td>Craig Anderson (Pfizer) Catherine Chronaki (Secretary General at HL7 Europe)</td>
</tr>
<tr>
<td>Adverse Events (AE)</td>
<td>Support standardizing the reporting and format of an adverse event. Improve the maturity of the relevant FHIR resources</td>
<td>Michelle Casagni (MITRE) Ed Millikan (FDA)</td>
</tr>
<tr>
<td>FHIR to OMOP</td>
<td>Support the development of FHIR to OMOP data transfer for better analysis of clinical data for research</td>
<td>Davera Gabriel (Johns Hopkins) Catherine Diederich (Duke)</td>
</tr>
</tbody>
</table>
Future Vulcan Projects
July 2022

<table>
<thead>
<tr>
<th>Project / Vulcan Leads</th>
<th>Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Data</td>
<td>• Provide sets of data suitable for use in testing Vulcan applications and implementation guides</td>
</tr>
<tr>
<td></td>
<td>• Some data sets to be wholly synthetic, others to be anonymized real data</td>
</tr>
<tr>
<td>MedWatch on FHIR</td>
<td>• Provide a FHIR based equivalent to the FDA MedWatch form for Adverse Event reporting</td>
</tr>
<tr>
<td>ICH CeSHarP</td>
<td>• Demonstrate that FHIR can be used to exchange the CeSHarP representation of a protocol between regulators and between a sponsor and a regulator</td>
</tr>
</tbody>
</table>

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

Vulcan – Moving Forward
Inflection Point

- **Foundation**
  - Implementation Guides for Real World Data, Schedule of Activities, electronic Product Information, Phenotypic Data, Adverse Event FHIR to OMOP (in progress)
  - Connectathons (ongoing)
  - Governance, Membership, Financial models

- **Go Global**
  - Expand outreach into Europe, Asia Pacific and other regions
  - Regional activities, membership & promotion
  - Showcase global HL7 FHIR efforts in clinical research

- **Implement It**
  - Adoption Strategy: Proof of Concept / Pilot, Tooling, Conformance
  - Early adopters
  - Regional & Global plans (by project)

- **New Content**
  - Use Case Map (Big Picture)
  - Additional Use Cases
  - Collaborate with other HL7 FHIR Accelerators
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Infrastructure - People and Processes

- Tech Support
- Operations: Governance
- Advisory: Information
- Steering: Governance
- HL7 Accelerator Program/Project/Version
- Patients
- Research Academia
- Technology Vendors
- Government Agencies
- Industry Streams

Connectathon
Confluence
Meetings
PMO: People/Projects/Process/Technology
Making a Use Case Proposal

- Vulcan actively seeks new use case proposals – contact us at 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.

Vulcan Project Work Cycle

- Identify Connection Objectives
- Find Connection Participants
- Draft Implementation Guide
- Connectathon
- Lessons Learned
- Showcase

Priorities

Month 0
Month 0
Months 1 to 3
Month 4
Month 5
Project Evolution

Ideas
• How about ...
• This is a form for suggesting new use cases for consideration
• Anyone can make a suggestion

Proposal
• Operations Committee will discuss and vote on whether to adopt
• Steering Committee gives final approval

Discovery
• Many projects start as an “idea” that needs to be developed into a set of project steps
• The exact aims of the project may evolve during this process

Development
• The execution phase of the project where the Implementation Guide is being written and tested through connectathons
• This is an open process

Publishing
• Content goes through the HL7 processes to ballot the Implementation guide and respond to the community issues

HL7 processes

Vulcan internal processes

Phenotypic Data
FHIR to OMOP Adverse Events
Real World Data
Schedule of Activities
Electronic Product Information

Current Vulcan Implementation Guides

Schedule of Activities
Electronic Product Information
Search:
vulcan-schedule history
Search:
emedicinal-product-info history
Search:
vulcan-rwd history
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

**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

**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

**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

**Vulcan Promotion**

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January 2023 Connectathon

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Vulcan Promotion

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Real World Data
Vulcan Connectathons to Date

- Jan 2021
  - SOA
  - RWD
  - Med
  - Pheno

- Sept 2021
  - SOA
  - RWD

- May 2021
  - SOA
  - RWD

- Jan 2022
  - RWD
  - ePI
  - AE

- May 2022
  - SoA
  - ePI

- Sept 2022
  - SoA
  - RWD
  - ePI
  - Pheno

- Jan 2023
  - SoA
  - RWD
  - ePI
  - FHIR 2 OMOP

7 Events
7 Topics
24 Tracks

Evolution
Three Principles

1. Publishing an Implementation Guide is not the end
2. If an Implementation Guide doesn’t get adopted it was a waste of time
3. When an Implementation Guide is adopted it will need to change

Vulcan is at a point of inflection as we go
From start up to production
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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

Vulcan Membership Model

<table>
<thead>
<tr>
<th>Tier</th>
<th>Target Groups</th>
<th>Qualifications</th>
<th>Costs</th>
<th>In-Kind</th>
<th>Lead Project?</th>
<th>Ops Cite Vote?</th>
<th>Implementation Showcase</th>
<th>Education Discount</th>
<th>Strategic Retreat?</th>
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</thead>
<tbody>
<tr>
<td>Consortium / Association</td>
<td>N/A</td>
<td>N/A</td>
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<td>100+ hours</td>
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<td>Yes</td>
<td>Subject to confirmation by PMO</td>
<td>Under Review</td>
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<tr>
<td>Organization</td>
<td>For Profit (Large)</td>
<td>&gt; $25M annual revenue</td>
<td>$50K</td>
<td>100+ hours</td>
<td>Yes</td>
<td>Yes</td>
<td>By Invitation</td>
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<td>Yes</td>
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<tr>
<td></td>
<td>For Profit (Medium)</td>
<td>$5-25M USD annual revenue</td>
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<td>75+ hours</td>
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<tr>
<td></td>
<td>For Profit (Small)</td>
<td>&lt; $5M USD annual revenue</td>
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<td>50+ hours</td>
<td>Yes</td>
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<td>By Invitation</td>
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<tr>
<td></td>
<td>Non-Profit (Large)</td>
<td>&gt; $500M sponsored research</td>
<td>-</td>
<td>200+ hours</td>
<td>Yes</td>
<td>Yes</td>
<td>By Invitation</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td></td>
<td>Non-Profit (Small)</td>
<td>&lt; $500M sponsored research</td>
<td>-</td>
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<tr>
<td>Government Agency</td>
<td>High Impact</td>
<td>&gt; $500M translational research</td>
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<td>Moderate Impact</td>
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<td>100+ hours</td>
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<td>By Invitation</td>
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<tr>
<td>SME (by invitation)</td>
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<td>50+ hours</td>
<td>Yes</td>
<td>Yes</td>
<td>-</td>
<td>-</td>
<td>By Invitation</td>
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</tbody>
</table>
Questions?

To learn more or to get involved

🌐 [http://www.HL7Vulcan.org](http://www.HL7Vulcan.org)

LinkedIn [hl7-vulcan](https://www.linkedin.com/company/hl7-vulcan)

[X] [https://confluence.hl7.org/display/VA/Vulcan+Accelerator+Home](https://confluence.hl7.org/display/VA/Vulcan+Accelerator+Home)

✉️ Vulcan@HL7.org

Thank you!