Vulcan, an HL7 FHIR Accelerator Connecting Clinical Care and Clinical Research

HIMSS 2023 Global Health Conference
Speakers

Dr. Qi Li
Physician Executive, InterSystems

As physician executive at InterSystems, Qi leads the product innovation in the areas of real world evidence, life science, research, precision medicine, NLP, and AI. Qi brings his years of expertise and dedication to healthcare innovation to support Vulcan’s Real World Data and Schedule of Activities projects.

Mayur Saxena, PhD
CEO & co-Founder, Droice Labs

Mayur leads cross-functional teams at the intersection of strategy, medicine, business, technology, and research in building AI technologies to unlock the potential of noisy real-world patient data for high quality evidence generation in clinical care and research use cases. Mayur’s team has joined Vulcan and are integral to the success of the Real World Data project.

https://www.linkedin.com/in/qilimd/

https://www.linkedin.com/in/mayursaxena1/
WHAT DO RESEARCHERS NEED?

NEED

An accurate & complete high-quality patient profile

- Socio-demographics
- Drug Exposures
- Events & Endpoints
- Symptoms
- Procedures & Surgeries
- Labs & Biomarkers
- Conditions & Comorbidities
WHAT DO RESEARCHERS NEED?

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**REALITY**

Unreliable; missing critical pieces of information
TYPICAL DATA JOURNEY

Real world data
- EMR
- Labs
- ...

Data preparation
- Claims
- Devices
- ...

Use case data
- Critical variables are missing

Applications
- Financial
- Operational
- Research
REAL WORLD PATIENT DATA CHALLENGES

Real world data

- EMR
- Labs
- ...

Data preparation

- Claims
- Devices
- ...

Data preparation with HL7 FHIR

Use case data

- Critical variables are missing

Applications

- Financial
- Operational
- Research

Imperfect Input + Ad Hoc Process = Low Quality Output
VULCAN - ENABLING DATA FOR RESEARCH

Real world data
- EMR
- Labs
- ...
- Claims
- Devices
- ...

Data preparation

Use case data
- Socio-demographics
- Events & Outcomes
- Labs & Biomarkers
- Conditions & Comorbidities

Applications
- Financial
- Operational
- Research

Standardization

High Quality Output

Deep patient profile
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.

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 April 2023

accenture
ACRO
BioVeras
Cedars Sinai
cdisc
CROHN'S & COLITIS FOUNDATION

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Duke University School of Medicine
Droice Labs
Epic
FDA
FELLESKATALOGEN

GSK
HL7 International
IgniteData
iHD
The European Institute for Innovation through Health Data

infor
InterSystems
Health | Business | Government

JOHNS HOPKINS SCHOOL of MEDICINE
Johnson & Johnson
medidata
Microsoft
MITRE
National Cancer Center Hospital East

NIH
National Center for Advancing Translational Sciences

NIH
U.S. National Library of Medicine

OpenClinica
ORACLE

Oregon Health & Science University

parexel
PatientLink
MyLinks

Pfizer
phuse
Roche

SCDM
Society for Clinical Data Management
DATA DRIVEN

TransCelerate Biopharma Inc.
UAMS
University of Colorado Anschutz Medical Campus
University of Oslo

UT Health San Antonio

VANDERBILT UNIVERSITY

VULCAN

* indicates a convening member of Vulcan
# Current Member Organizations of Vulcan

As of April 2023

<table>
<thead>
<tr>
<th>Category</th>
<th>Organizations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Academia</strong></td>
<td>Cedars Sinai, Duke University School of Medicine, Johns Hopkins School of Medicine, UT Health San Antonio, Vanderbilt University, Oregon Health &amp; Science University, UAMS, University of Colorado Anschutz Medical Campus, University of Oslo</td>
</tr>
<tr>
<td><strong>Consortia</strong></td>
<td>iHD, phuse, Society for Clinical Data Management, Transcend Biopharma Inc.</td>
</tr>
<tr>
<td><strong>Government Agencies</strong></td>
<td>Lægemiddelstyrelsen, Danish Medicines Agency, FDA, NIH, NIH, U.S. National Library of Medicine</td>
</tr>
<tr>
<td><strong>Implementers</strong></td>
<td>Accenture, BioVera, Droice Labs, Epic, Fujitsu, IgniteData, InterSystems, Mylinks, Oracle, Parexel, PatientLink, Infor, Medidata, Microsoft, MITRE, OpenClinica</td>
</tr>
<tr>
<td><strong>Pharma</strong></td>
<td>GSK, Johnson &amp; Johnson, Pfizer, Roche</td>
</tr>
<tr>
<td><strong>SDOs</strong></td>
<td>cdisc, HL7 International</td>
</tr>
<tr>
<td><strong>Others</strong></td>
<td>ACRO, Crohn's &amp; Colitis Foundation, Felleskatalogen</td>
</tr>
</tbody>
</table>

*indicates a convening member of Vulcan*
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
<table>
<thead>
<tr>
<th>Project</th>
<th>Objectives</th>
<th>Vulcan Lead</th>
</tr>
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</table>
| 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  | **Mike Ward** (TransCelerate)  
**Geoff Low** (PHUSE)                                                                 |
| Real World Data (RWD)   | Extract data from EHRs in a standardized format to support clinical research and especially submission to Regulators                                                                                                                                                                                                                   | **Scott Gordon** (FDA)  
[Open Position for Co-Lead]                                                                 |
| Phenotypic Data         | To increase the availability of high-quality standardized phenotypic information for genomic research and genomic medicine.                                                                                                                                                                                                            | **Anita Walden** (University of Colorado Anschutz)  
**Shahim Essaid** (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                                                                                                                                                                                                                   | **Craig Anderson** (Pfizer)  
**Catherine Chronaki** (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                                                                                                                                                                                                                  | **Michelle Casagni** (MITRE)  
**Ed Millikan** (FDA)                                                                 |
| FHIR to OMOP            | Support the development of FHIR to OMOP data transfer for better analysis of clinical data for research                                                                                                                                                                                                                               | **Davera Gabriel** (Johns Hopkins)  
**Catherine Diederich** (Duke)                                                                 |
HL7 FHIR Vulcan RWD Use Case Example

Identify
• A cohort of patients: dx, demo, lab, EKG
• Condition under study: procedures (PCI) and medication (antiplatelets)
• Concomitant medications (18 months)

Retrieve study data points
• Medical history, vital signs, hospitalization, transfusion

Example study: https://clinicaltrials.gov/ct2/show/NCT02190123
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
<table>
<thead>
<tr>
<th><strong>To learn more or to get involved</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit our website <a href="http://www.hl7vulcan.org">http://www.hl7vulcan.org</a></td>
</tr>
<tr>
<td>Visit our confluence page <a href="https://confluence.hl7.org/display/VA/Vulcan+Accelerator+Home">https://confluence.hl7.org/display/VA/Vulcan+Accelerator+Home</a></td>
</tr>
<tr>
<td>Email us at <a href="mailto:Vulcan@HL7.org">Vulcan@HL7.org</a></td>
</tr>
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Thank you!
Reference
HL7 Accelerator Program
Focused Standards Development

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

**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

**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

**Da Vinci**
Adoption of HL7® FHIR® as the standard to support and integrate value-based care (VBC) data exchange across communities
<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 Ctte Vote?</th>
<th>Implementation Showcase</th>
<th>Education Discount</th>
<th>Strategic Retreat?</th>
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<tr>
<td><strong>Consortia / Association</strong></td>
<td>N/A</td>
<td>• Industry associations • SDOs</td>
<td>N/A</td>
<td>100+ hours</td>
<td>By Invitation and Subject to confirmation by PMO</td>
<td>Yes</td>
<td>Yes</td>
<td>Under Review</td>
<td>Yes</td>
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<tr>
<td><strong>Organization</strong></td>
<td>For Profit (Large)</td>
<td>• Pharma • Implementers • CROs • MedTech</td>
<td>&gt; $25M annual revenue</td>
<td>$50K</td>
<td>100+ hours</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td>Yes</td>
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<tr>
<td></td>
<td>For Profit (Medium)</td>
<td></td>
<td>$5-25M USD annual revenue</td>
<td>$25K</td>
<td>75+ hours</td>
<td>Yes</td>
<td>Yes</td>
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<td></td>
<td>For Profit (Small)</td>
<td></td>
<td>&lt; $5M USD annual revenue</td>
<td>$10K</td>
<td>50+ hours</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td>By Invitation</td>
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<td></td>
<td>Non-Profit (Large)</td>
<td>• Academia • Researchers</td>
<td>&gt; $500M sponsored research</td>
<td>-</td>
<td>200+ hours</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td>Yes</td>
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<tr>
<td></td>
<td>Non-Profit (Small)</td>
<td>• Academia • Researchers</td>
<td>&gt; $500M sponsored research</td>
<td>-</td>
<td>100+ hours</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td><strong>Government Agency</strong></td>
<td>High Impact</td>
<td>• Clinical Trial Regulators • Regulators</td>
<td>&gt; $500M translational research</td>
<td>-</td>
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<tr>
<td></td>
<td>Moderate Impact</td>
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<td>&lt; $500M translational research</td>
<td>-</td>
<td>100+ hours</td>
<td>Yes</td>
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<td><strong>SME (by invitation)</strong></td>
<td>N/A</td>
<td>• SMEs (HL7 FHIR experts, thought leaders, etc.) • Patient Advocacy</td>
<td>N/A</td>
<td>50+ hours</td>
<td></td>
<td>-</td>
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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