

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

HIMSS 2023 Global Health Conference

HIMSS ²³

HEALTH+TECH

17-21 April | Chicago, IL





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.

WHAT DO RESEARCHERS NEED?

NEED

An accurate & complete high-quality patient profile

Socio-demographics



Drug Exposures



Symptoms

Events & Endpoints



Procedures & Surgeries

Labs & Biomarkers



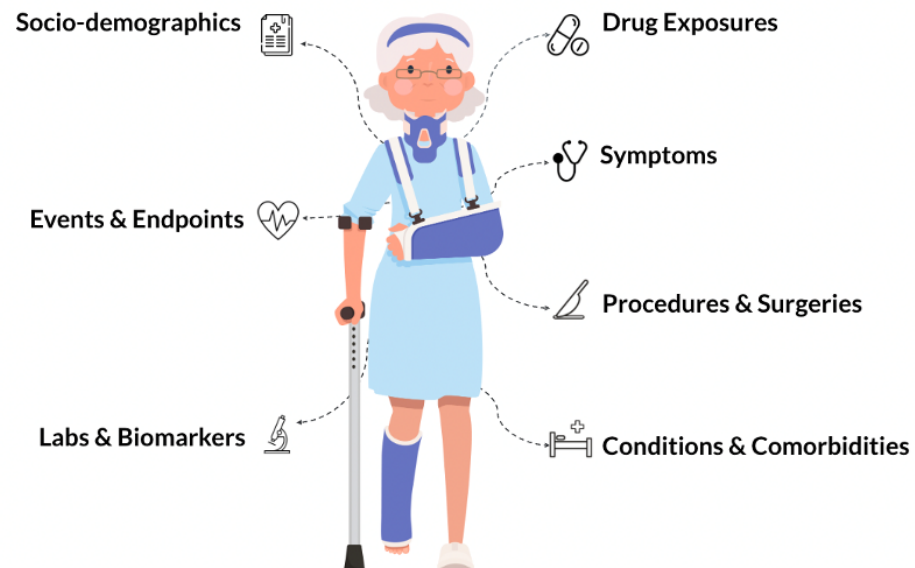
Conditions & Comorbidities



WHAT DO RESEARCHERS NEED?

NEED

An accurate & complete high-quality patient profile



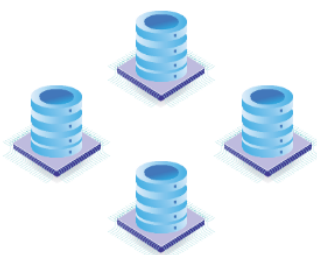
REALITY

Unreliable; missing critical pieces of information



TYPICAL DATA JOURNEY

Real world data



- EMR
- Labs
- ...
- Claims
- Devices
- ...



Data preparation



Use case data



Critical variables
are missing

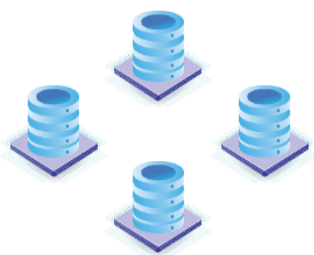


Applications



REAL WORLD PATIENT DATA CHALLENGES

Real world data



- EMR
- Labs
- ...
- Claims
- Devices
- ...

⊗ Imperfect Input



Data preparation



📋 Ad Hoc Process



Use case data



Critical variables
are missing

📋 Low Quality Output

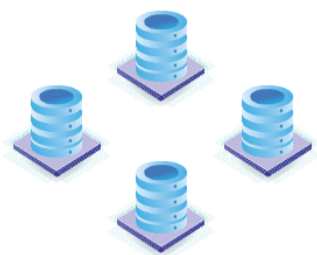
Applications



VULCAN - ENABLING DATA FOR RESEARCH



Real world data



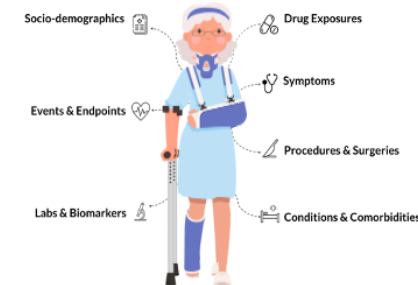
- EMR
- Labs
- ...
- Claims
- Devices
- ...

Data preparation



Standardization

Use case data



Deep patient profile



High Quality Output

Applications



Financial



Operational



Research

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

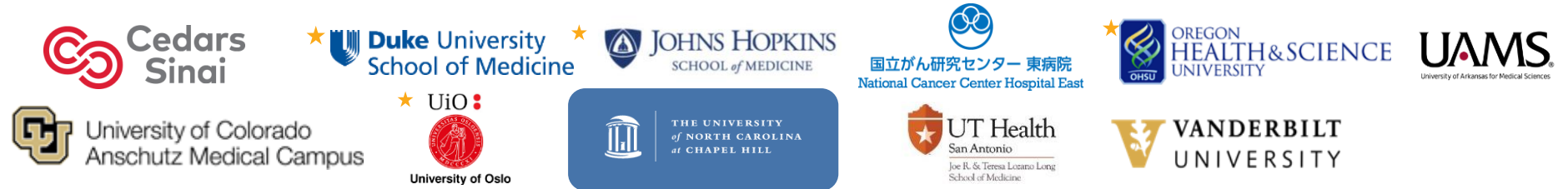


★ indicates a convening member of Vulcan

Current Member Organizations of Vulcan

As of April 2023

Academia



Consortia



Government Agencies



Implementers



Pharma



SDOs



Others

(e.g., thought leaders, SMEs, CROs, Patient Advocates)



★ 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



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	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>

REalWorld Insights on the INitiation and Treatment Duration of ticagrEloR & Other Oral Antiplatelets (OAP) in Patients With Acute Coronary Syndrome (ACS) in Be/Lux. (REWINDER)



The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT02190123

[Recruitment Status](#) ⓘ : Completed

[First Posted](#) ⓘ : July 15, 2014

[Last Update Posted](#) ⓘ : January 8, 2016

[View this study on Beta.ClinicalTrials.gov](#)

Sponsor:

AstraZeneca

Information provided by (Responsible Party):

AstraZeneca



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

2023 & Beyond

To learn more or to get involved



Visit our website <http://www.hl7vulcan.org>



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



Email us at Vulcan@HL7.org

Thank you!

Reference

HL7 Accelerator Program

Focused Standards Development



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



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

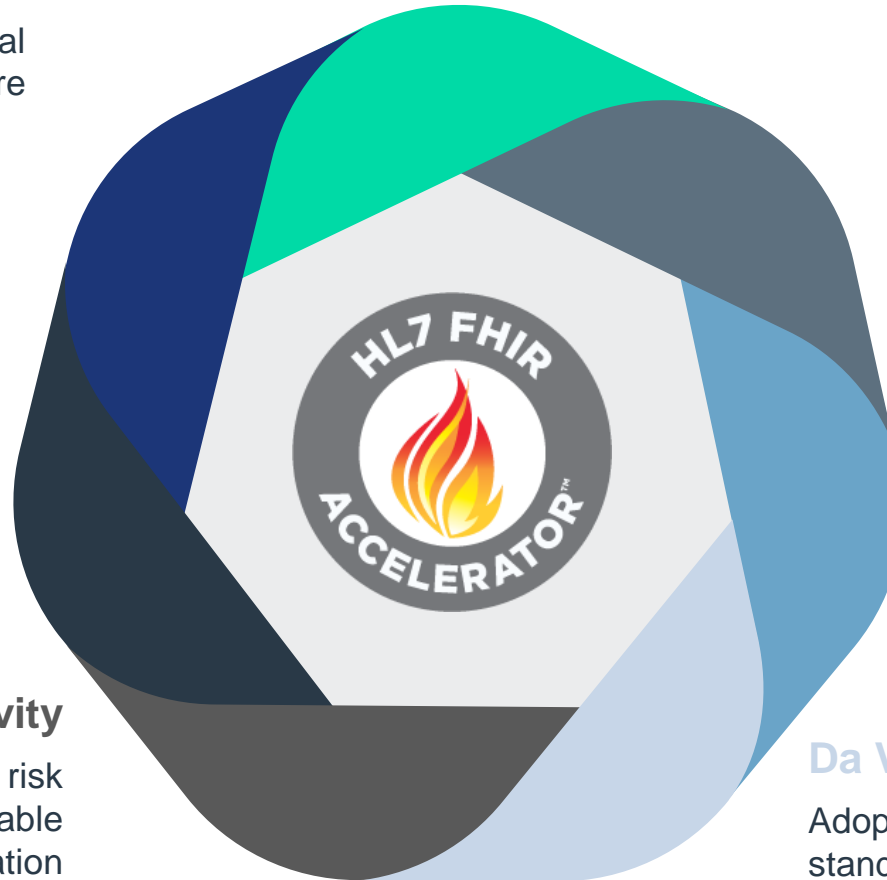


Accelerate interoperable data modeling and applications cancer patient care and research

Da Vinci



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



Vulcan Membership Model

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

Vulcan Events and Educational Opportunities

Vulcan provides valuable opportunities to engage across the research community

