Chairs Message

Firstly, it’s an honor and privilege to be stepping up as a co-chair and attempting to continue the great work that Rob has done over the past 2 years. Rob Goodwin and Amy Cramer have been very gracious in pulling me into discussions early to support the transition, so I’m feeling ready to go!

I’d like to extend a hearty welcome to our new steering committee members. I’m excited to see the contributions you can all individually and collectively bring to make Vulcan the best it can be. We have so many great minds and resources in Vulcan in addition to so many new members. Maximizing our resources for optimal impact will be a critical success factor as we move into this next chapter.

We have achieved so much, but we have a long way to go, so I’m really looking forward to working with you all as we strive to better integrate translational and clinical research into healthcare.

Darren Westin, Vulcan co-Chair

Outgoing Chairs Message

As my term as co-Chair comes to end, I just wanted to take a moment to reflect on the last two years. I remember like it was yesterday when Amy Cramer brought many of us together to discuss our vision and aspirations to integrate research into clinical care. At the time, I learned about this “thing” called FHIR. I thought it sounded cool but really did not know what it was other than a set of open HL7 standards that could be the pathway to making our vision of integration real. What also impressed me at that meeting was the room of developers working together at round tables to solve real problems. I had never seen anything like that before and thought how wonderful it would be if that same energy went into solving our problems for clinical and translational research.

Since we started, we have established a financially healthy Accelerator with membership growing every quarter. We have six Vulcan projects and a functioning Operations Committee that have been diligently working on the approved use cases and is the heartbeat of Vulcan. We are also continuing to learn what we can do better. Recently we announced changes to the Steering Committee structure, elected a chair for the Advisory Board and have engaged the external community with the Vulcan 101 event amongst a sea of other great accomplishments.

As I walk away, I feel proud of what this Accelerator has accomplished in its short life. I ask each and every one of you to contribute towards the next set of Vulcan accomplishments. I will continue to remain an active supporter of its mission and growth as I still believe this is the pathway to more efficient research and a better experience for patients. Until we meet again, take care of yourselves and thank you for allowing me the honor of being co-Chair for the last two years.

Rob Goodwin, Vulcan co-Chair (past)
Current Members – July 2022

Vulcan membership, as of July 1, 2022.

New Vulcan Members: January-June 2022

Vulcan welcomes the following new members from January to June 2022. Thanks everyone!
Vulcan Project: Adverse Events

Following the January 2022 Connectathon, the Vulcan Adverse Events (AE) project narrowed its focus to clinical research. Using this focus, the team mapped the base FHIR AE resource to other standards: FDA MedWatch forms, FHIR to CDISC Mapping to AE, and FDA E3B set of data elements to identify gaps.

To address the gaps, the team is developing 2 AE profiles, one for clinical research and one for clinical care, to include in the August 2022 R5 ballot. Following development of these profiles, work will begin to retrofit the R5 AE for Clinical Research profile to R4 AE to support current implementations.

Michelle Casagni, Ed Millikan

Vulcan Project: Schedule of Activities

The Vulcan Schedule of Activities (SoA) team are working on the first FHIR Implementation Guide (IG) dealing with the use of FHIR resources for planning and executing a Protocol based Schedule of Activities design in an EHR system.

The core of the model has been planned out and demonstrated at the May 2022 Connectathon, with a special focus on the management of Visit Windowing. We are currently identifying one or two more use cases to develop by the end of the year for inclusion in the first release of the IG.

We are also working on socialising the project through presentations at international events (FHIR DevDays and DIA events in June are recent examples). One other current focus is identification of vendor partners to collaborate and support the publication and implementation of the first IG.

We are aiming to have a first draft Implementation Guide ready for participation in the September 2022 FHIR Connectathon with an intent to ballot the guide in the January 2023 ballot cycle.

Mike Ward, Geoff Low

Vulcan Project: electronic Product Information

The Electronic Product Information (ePI) Project is making great progress towards delivering an international FHIR standard for ePI.

Work is underway to develop a final draft of the FHIR ePI Implementation Guide. After another successful round of testing at the May connectathon, the team has high confidence that this FHIR ePI standard can support any international health authority for any drug product label.

The project is collaborating with Gravitate Health, UNICOM Project, and the European Medicines Agency (EMA) to ensure the project remains aligned with related health authority initiatives.

The project is on schedule to submit the Implementation Guide for testing at the September Connectathon and to HL7 as a candidate standard for the December 2022 ballot cycle.

Craig Anderson, Catherine Chronaki

Vulcan Project: Real World Data

The Vulcan Real World Data track is currently developing a first draft FHIR Implementation Guide (IG) with FHIR profiles that can be used to retrieve relevant research data from EHR systems to facilitate downstream use (directly or after transformation) for submissions to pharmaceutical regulatory agencies.

For the current phase of work, the scope of this Implementation Guide is limited to the use of Electronic Health Record (EHR) systems as sources of RWD and limited to the use of EHR data for retrospective analysis of data which already exists as part of normal healthcare encounters.

We are developing the IG using an iterative use case approach, with repeated cycles of identifying the minimal set of EHR-based information needed to answer a small set of research questions and creating a set of FHIR profiles for representing this needed information in an EHR. We are aiming to have a first draft Implementation Guide ready for participation in the September 2022 FHIR Connectathon with an intent to ballot the guide in the January 2023 ballot cycle.

Scott Gordon, Damion Nero
**Vulcan Project: Phenotypic Data**

The Phenotypic Data project is designed to exchange a set of EHR phenotypic abnormalities, diseases, age, sex, onset, evidence and other information about a patient that could support genomic analysis and interpretation in the context of cancer and rare disease. However, it is a general framework for profiling the clinical picture of a patient for a specific use case based on existing clinical information from one or more sources.

The group is currently working with a commercial vendor to prototype the integration of their current system's output into FHIR based representations that are conformant with an independently evolving Implementation Guide. This IG is iteratively representing various elements of the native Phenopackets schema, and our work will be one of the first attempts to put this IG to use for a real system. We are also preparing to participate in an upcoming HL7 Connectathon.

*Anita Walden, Shahim Essaid*

**Vulcan Project: FHIR to OMOP**

Approved for launch in April 2022, the FHIR to OMOP project is working with the OMOP & FHIR Collaboration within the Terminologies Subgroup to develop a canonical set of maps for FHIR to OMOP for core health data elements established in the US Core Data for Interoperability (USCDI) and the SNOMED CT International Patient Summary (IPS).

The goal of this project is to reduce the variability and cost of data transformations to health delivery and research organizations. Rather than begin anew, the project team is leveraging an environmental scan of prior FHIR to OMOP transformations, outreaching to these projects to obtain use of their work products curating content to evaluate concordance, conflicts, and gaps, and then develop. The team will have then reviewed the obtained prior works to propose a set of maps representing the “best practice” examples of FHIR to OMOP transformations, and curate only those elements that prior works do not address.

*Davera Gabriel, Catherine Diederich*

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**Member Spotlight – Kristina Schwartz**

"The most pressing difficulty with interoperability right now is connecting to health systems," said Maria Kristina Schwartz, Intern at Vulcan Accelerator.

**A little about Kristina**

I am an international medical graduate with advanced clinical psychiatry clerkship training from Harvard Medical School in substance use disorder, addiction, and mood disorders. Since then, I’ve consulted for anti-opioid pharmacies in the Virginia Tidewater area to promote non-opioid alternative medicine therapy to reduce habit formation.

More recently, I worked as a clinical research specialist with the University of Maryland’s Department of Pharmaceutical Health Services Research on an FDA-funded feasibility and usability mHealth study that used wearable fitness trackers and an app to see if psychotropic medications affect youth. I recall experiencing difficulties obtaining consented protected health information from medical practitioners to expedite the research recruitment process in our study.

I believe there ought to be a more efficient way to organize information transfer between physicians, healthcare organizations, and clinical research teams. I was drawn to HL7 because I saw it as a way to contribute to an exciting movement aimed at generating new medical insights, particularly with the FHIR to OMOP initiative, which will allow for more efficient processing of existing data sources by standardizing universal and comprehensive clinical terminology.

My favorite aspect is working with HL7 members, who inspire me daily with their demonstrated enthusiasm and impact. I am now pursuing a Master of Science degree in Health Information Management & Technology to get involved in the development of a more robust interoperability application. I want to expand my knowledge and skills so that I can inspire health professionals to investigate how digital technologies might be used in their own practices to easily engage and communicate the transfer of health information.
The Vulcan governance committees were updated last year, which includes a few leadership roles. Please welcome:
- Darren Weston, Steering Committee co-Chair (2 year term)
- Maryam Garza, Operations Committee co-Chair (2 year term)
- Mike Hamidi, Operations Committee co-Chair (1 year term)
- Becky Kush, Advisory Council Chair (2 year term)
Amy Cramer continues as Steering Committee co-Chair for year 2 of her 2 year term.

Please welcome our new Steering Committee:
- Amy Cramer, Chair, part of Vulcan Leadership team
- Darren Weston, Chair, part of Vulcan Leadership team
- Stephen Bamford, J&J
- Priya Gopal, Roche (Flatiron)
- Jorine Putter, GSK
- Rajya Bhaiya, Microsoft
- Debi Willis, Patientlink
- Emily Bachman, TransCelerate BioPharma (Astellas)
- Linda King, SCDM (Astellas)
- Joachim Luithle, TransCelerate BioPharma (Bayer)
- Chris Chute, Johns Hopkins
- Ed Hammond, Duke
- Anne Moen, University of Oslo
- Jesper Kjar, Danish Medicines Agency
- Cal Collins, OpenClinica
- Irene Joseph, Microsoft
- Tom Yosick, Epic
- Dave Evans, CDISC
- Chuck Jaffe, HL7

plus Operations Committee co-Chair(s) & Advisory Council Chair.

We would also like to thank our outgoing Steering Committee members:
- Catherine Craven
- Cathy Critchlow
- Jose Galvez
- Kenneth Gersing
- Rob Goodwin
- Paul Lynch
- Clem McDonald
- Viet Nguyen
- Karen VanHentenryk

The Governance Model is available on the Vulcan Confluence site at: [Vulcan Governance Model](#).
The Membership Model is also available on the Vulcan Confluence site: [Vulcan Membership Model](#).

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**Vulcan Convener**

*A big thanks to TransCelerate BioPharma for taking on the role of Vulcan Convener for 2022-23!*

*Your support and enthusiasm for Vulcan is appreciated by all Vulcan members!*
Vulcan Operations Committee Report

Mike Hamidi and Maryam Garza, the new Vulcan Operations Committee co-Chairs, are excited to lead the way in 2022. Since Vulcan’s inception, members have tirelessly worked to drive the use cases forward (Adverse Events, Schedule of Activities, Phenotypic Data, Real World Data, electronic Product Information and newly added FHIR to OMOP) and test them via Connectathons. As the year progresses, Vulcan will start delivering on these use cases with formalized FHIR Implementation Guides (IGs) that will evolve incrementally to expand its coverage.

As importantly, the Operations Committee will evaluate how to support members on ongoing use case activities (e.g., sample data, showcases, tooling assessments, etc.). Looking forward to 2022-23.

Maryam Garza, Mike Hamidi

Vulcan Advisory Council Report

Adoption was the topic of the Vulcan Advisory Council call on 23 February. The comments and suggestions from Advisory Council members on the topic were wide-ranging and thoughtful. Michael Van Campen compiled these and proposed we do a deeper dive into this topic on our next Advisory Council call, which took place on 19 May. As we all know, adoption (preferably global adoption) is at the heart of any standards-related initiative; without adoption, the development efforts are for naught. The Council provided additional insights on this topic at the May call after an opening session during which Craig Anderson requested specific advice from the Council on the Vulcan Electronic Product Information (ePI) project.

Based upon suggestions to have more frequent Advisory Council meetings, we will target holding these quarterly going forward. I look forward to having 1 on 1 conversations with willing members of the Advisory Council to obtain more direct suggestions for future meeting topics and to ensure continuing commitment to and optimal composition of this important Vulcan entity.

Becky Kush

Readouts from January & May 2022 Connectathons

Since the last newsletter there have been HL7 Connectathons in January and May and Vulcan has again had projects using them to drive progress forward.

Real World Data

In January the RWD team looked at “round tripping” data. Posing the question “can we start with an existing set of submission data, convert it to FHIR and then re-extract the data we started with?” This has the added advantage of providing sample data to work with which has been a challenge throughout the project. The team also wanted to move away from the initial focus on Concomitant Medication to look at the full range of real world data elements.

Fortunately, the round tripping was a success, but it made clear the extent to which the context in which data elements sit in a FHIR message and the context of the terminology used provide a depth of expression that is lost in simple tabular data. It underscores the need for “mapping” to be more than just single element to single element.

On the basis of this experience the team is now developing the first draft of an implementation guide which should go for balloting in January 2022.

Adverse Event

This project only got off the ground at the end of 2021 so participating in the January Connectathon was a stretch but one they rose to admirably, helped by enthusiastic support from our Vendor members.

The work tried using the existing Adverse Event resource to exchange data from a Collector (patient or clinician) into a Repository (EHR) and then sent on to the Consumer (Regulator). This basic experience equipped the team to begin detailed gap analysis between the needs of these systems and the FHIR R4 Adverse Event resource and to propose standardised extensions to bridge the gaps.

The team are currently working on recommendations for data points that should be added to recommended minimum data sets such as US Core and are also making some revisions to the base resource to meet the requirements of Clinical Research more directly.
Electronic Product Information

This project is following an aggressive path to achieve first publication of an Implementation Guide in January 2023. In the January Connectathon they loaded a range of example products into the appropriate FHIR resources including support material such as instruction videos. This exercise gave the team confidence that the resources were able to cope with anything that might be required.

In the May Connectathon the emphasis shifted to different languages by loading Japanese and Norwegian data in the original text and character sets.

This experience puts the team in a strong position to be able to generate a base Implementation Guide with regional profiles for the various regulators around the world.

Schedule of Activities

The team is also on track to produce an Implementation Guide for January 2023. At the May Connectathon they tackled the question of fitting general events in the EHR to the pattern of visits dictated by the study design – all represented in FHIR of course. This lead to discussion of the intricacies of the allowed date window for a visit and how that should be represented.

There is a close association between this and the RWD questions and the two teams are in close collaboration.

Vulcan 101 Feedback

Specific Feedback

“I attended the Vulcan 101 one-day tutorial and found it to be very well-conceived and executed. This educational webinar provided a fascinating introduction and overview of Vulcan accelerator and its overall progress.”

Becky Kush

Anonymous Feedback

“Update on the Vulcan projects and specifically the tools and techniques. these helped me a lot.”

“Learning how Vulcan sees the various standards working together to support a variety of use cases.”

“I am excited about the progress in every project.”

“FDA perspective and learning about the individual projects, and FHIR intro. Really, it was all very informative. Thank you for putting this event on.”

Vulcan Shout Out

A special shout out to Craig McClendon and the Accenture team who have been providing technical support to our Vulcan projects at numerous HL7 Connectathons. More specifically, Craig and his team have set up a FHIR server and made it publicly accessible for use by any Connectathon participants for testing against which was then curated by the project team for the adverse events use case.

A big thanks to Craig and his team at Accenture!

Vulcan Implementation Showcase

Every 2 months Vulcan hosts an Implementation Showcase where Vulcan members can demonstrate real-world (semi-commercial) applications of HL7 FHIR to other Vulcan members. There have been 3 showcases to date, with participation from Microsoft, OpenClinica, Accenture, Computable Publishing, Vanderbilt & FDA. If you or your organization is interested in presenting at an upcoming Vulcan Implementation Showcase, please send an email to vulcan@hl7.org.
The Project Management Office (PMO) continue to support the Vulcan accelerator through the individuals noted opposite. The following activities are undertaken, to name a few:

- Providing secretariat support (agendas, schedules, presentations, minutes, etc.) for the Vulcan governance committees / council
- Providing administrative assistance to each of the Vulcan projects
- Organizing and hosting the Vulcan Implementation Showcase, as well as Vulcan 101
- Liaison with HL7 working groups such as BR&R & Patient Care, as well as working with HL7 to manage the accelerator’s financials
- Member recruitment, onboarding and renewals
- Procuring technical resources for Vulcan projects to develop and ballot HL7 Implementation Guides
- Aligning and harmonizing processes, methods and procedures with other HL7 FHIR accelerators
- Regular touch points with each Vulcan project to gauge project health, identify collaboration opportunities and continue to move projects forward towards goals and expected outcomes (e.g. identifying project leadership)

Stay tuned – more to come in 2022-23.

Vulcan Roster

The Vulcan Project Management Office (PMO) maintains a roster of interested individuals from member organizations. On occasion, emails go out to this list for our Implementation Showcase, newsletter, Vulcan 101 and upcoming Connectathons, to name a few reasons. If you would like others in your member organization to receive these notices OR want to be removed, please send a note to Vulcan@hl7.org and we will action your request.

Welcome

Shani Sampson has joined the PMO team as Project Manager. Shani has already made a positive impact with each of the Vulcan project teams and is organizing the PMO. Welcome Shani!

For more information, contact us: vulcan@hl7.org