Chairs Message

It is my privilege to see the progression of Vulcan, and thanks to each of you, Vulcan has continued to evolve and grow. Chief among the recent achievements include:

- Vulcan 101 continues to provide exciting content that changes with each session.
- The Connectathon participation is impressive, informing implementation guides, as well as moving Vulcan towards delivering tools.
- Kudos to the teams for balloting the implementation guides.
- Some promotions for our PMO team – congratulations Shani and the rest of the PMO.
- In March, the long-awaited EuroVulcan kicked off.
- Vulcan will coordinate a project to pilot the ICH M11 standard for protocol representation.

All these accomplishments are bolstered by the people “behind the curtain.” The Project Management Office (PMO) is the engine behind Vulcan, and I want to thank Hugh Glover for the continued excellent leadership as Technical Director from the start of Vulcan. Congratulations to Stacy Tegan for the new role as Strategy Director, Michael van Campen as Program Director, and Shani Sampson as Associate Technical Director. Maryam Garza and Mike Hamidi, co-Leads of Operations Committee, continue to drive the project teams to success. Operations is the “heartbeat” of Vulcan, and our Advisory Council, under Becky Kush’s leadership, has increased its international perspectives with some key new members. The increased engagement of this council is exciting and will help Vulcan to continue to beneficially disrupt clinical research.

Let’s keep up the great work!

Amy Cramer, Vulcan Co-Chair

Chairs Message

Well, they say time flies when you are having fun, and I cannot believe how quickly the time has gone! I am truly grateful for the hard work and dedication of each and every one of you. Your contributions have been invaluable in driving Vulcan’s success and impact.

I would like to take a moment to express my deep appreciation for the work that has gone into the development of the various balloted implementation guides. I am also pleased with our growing membership and engagement of everyone. These are major accomplishments that demonstrate the group’s commitment and its ability to make a real difference.

I am also excited by the EuroVulcan event in Paris, which was a fantastic opportunity to showcase our work and connect with like-minded individuals from Europe and around the world.

As a co-chair, I am incredibly proud of all that we have achieved together, and I am honored to be a part of this journey. I look forward to continuing to work with all of you as we strive to better integrate translational and clinical research into healthcare.

In the upcoming year, I am confident that we will achieve even more and make an even greater impact. I encourage you all to get involved in specific projects, attend the various events, and share your ideas and suggestions for the group’s future.

Together, we can make Vulcan the best it can be!

Darren Weston, Vulcan Co-Chair
CURRENT MEMBERS

Vulcan membership, as of June 30, 2023

MEMBERS JOINING IN 2022-23...

Throughout 2022-23, we welcomed the following new members to Vulcan. Thanks everyone!
The year ended with all Governance groups, Steering Committee, Advisory Council and Operations Committee, functioning well under direction of the Vulcan Co-Chairs Amy Cramer and Darren Weston.

The **Steering Committee** moved to a balanced representation of Vulcan members and that has worked well to date. The Steering Committee approved an additional co-Chair for Advisory Council, which will be filled during the early part of 2023/24.

The **Advisory Council** has broadened its membership across the globe, filling in gaps in advisory perspectives and moving into a larger role for Vulcan.

Both the Steering Committee and Advisory Council benefited from targeted 1:1 sessions with co-Chairs and members to get better insights into member requirements and understanding methods to improve.

The **Operations Committee**, the heartbeat of the Vulcan Accelerator, continued to provide monthly guidance to members, as well as supporting the launching of new Vulcan projects.

On membership, we do expect to pilot the in-Kind contribution initiative, asking Vulcan members to record time on Vulcan. Stay tuned.

### Vulcan Operations Committee Report

The Vulcan Operations Committee (VOC) aims to realize the many efforts across all Vulcan projects and translate those into formal FHIR IG publications.

Here, we summarize forthcoming publications and their progression. First, the Schedule of Activities (SoA) has tackled a complex area of focus concerning the design, planning, and implementation to initiate clinical trials via the protocols’ SoA. Next, the Real World Data (RWD) defined vital use cases to conduct observational analysis using EHRs using a minimal set of FHIR resources/profiles. Lastly, electronic Product Information (ePI) will help aims to establish a common and interoperable standard for exchanging medicinal product information across international healthcare jurisdictions. The January 2023 ballot included the SoA, RWD, and ePI FHIR IGs, and all three have now been published as Draft for Trial Use (DTU) – congratulations to those project teams!

The VOC is engaged with additional opportunities, which are progressing well, including the Adverse Events in Clinical Research (AECR), Phenopackets, and FHIR-to-OMOP projects teams. Each of those projects will help establish even more value for the industry. Furthermore, the VOC continues collaborating with the Steering Committee and Advisory Council to help identify and prioritize future opportunities within the Vulcan Accelerator. The Vulcan Accelerator will continue to bring continued value and innovation with new ideas, projects, and publications. The VOC will also evaluate how to support those publications in real-world applications (e.g., through education, communication channels, demonstrations, etc.).

We hope you can join us on the Vulcan Accelerator journey.

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*Maryam Garza, Mike Hamidi, Vulcan Operations Committee Co-Chairs*
The Vulcan Advisory Council members have been busy providing their sage advice to Vulcan in a number of ways over the past several months. This included providing advise to Steering Committee on the development of the new Vulcan Strategic Plan and securing Council member participation & support in the resulting Strategic Working Groups.

As the new Chair, I wanted to try to better understand each member’s areas of expertise and how s/he felt the Advisory Council could best contribute. Hence, during July and August 2022, Michael van Campen and I held individual teleconferences with the original members. We confirmed that the majority of the original members were willing to continue. We have also been able to obtain Steering Committee approval for replacements for those few who felt they could not continue to serve and for several new members, who complement and expand the current Advisory Council (membership is noted below).

With the success of EuroVulcan we are now looking to recruit a second co-Chair to the Advisory Council to reflect the growing importance of international engagement.

Becky Kush, Vulcan Advisory Council Chair

Vulcan Advisory Council Membership

- Becky Kush, Catalysis Research, Chair
- Christel Anderson, HIMSS
- James Cheng, Duke University
- Cal Collins, OpenClinica
- Christel Daniel, Assistance Publique - Hôpitaux de Paris (AP-HP)
- Rob DiCicco, TransCelerate Biopharma
- Toshohiko Doi, Japan National Cancer Centre Hospital East
- Hugh Donovan, Advarra
- David Dorr, Oregon Health & Science University (OHSU)
- Dave Evans, CDISC
- Ron Fitzmartin, FDA
- Jose Galvez, FDA
- Ken Gersing, NIH - National Center for Advancing Translational Sciences (NCATS)
- Charles Jaffe, HL7
- Dipak Kalra, European Institute for Innovation through Health Data (i-HD)
- Pierre-Yves Lastic, French Union of Data Protection Officers; European Federation of Data Protection Officers
- Russ Leftwich, Intersystems
- Craig Lipset, Clinical Innovations Partners
- Cecil Lynch, Accenture
- Josh Mandel, Microsoft
- Kenneth Mandl, Harvard University
- Ben McAlister, Oracle
- Emily Pfaff, University of North Carolina at Chapel Hill
- Rachel Richesson, University of Michigan
- Maryann Slack, FDA
- Nancy Smider, Epic
- Nick Spring, BioVeras
- Pele Yu, Arkansas Children’s Hospital
- Teresa Zayas Caban - NIH - National Library of Medicine (NLM)

Our New (updated) Website!
We have a new website at HL7Vulcan.org – Come See what’s New
Implementation Showcase

Vulcan Implementation Showcases are held every **two months** in mid-February, mid-April, mid-June, mid-October and mid-December (includes a break in summer months).

If your organization is interested in presenting, please contact Vulcan at vulcan@hl7.org.

### October 13, 2022

<table>
<thead>
<tr>
<th>Presentation #1:</th>
<th>Presentation #2:</th>
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<tbody>
<tr>
<td><strong>Source CBERT Best Exchange Platform</strong></td>
<td><strong>Interoperability in Action - Transforming the Future of Clinical Trials Through EHR-to-EDC Data Automation</strong></td>
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**Presenters:** Hussein Ezzeldin (FDA), Ray Duncan, Matthew Sonesen, Renier Estiandan (Cedar-Sinai Health System), Lance Jones, Matthew Deady (IBM)

**Topic:** The Biologics Effectiveness and SafeTy (BEST) Innovative Methods (IM) initiative launched its pilot of the BEST Platform, a FHIR-based, HIPAA-compliant connected platform to semi-automatically detect, validate, and report patients with probable post-biologic adverse events using real-world data (RWD) across the United States. The BEST Platform partnered with eHealth Exchange network to receive interoperable data across healthcare providers, major state and regional health information exchanges in the U.S. Working with our early adopter, Cedars Sinai, we will showcase the two use cases, Pull (validation) and Push (detection) of probable post-biologic AEs. Also, we will briefly demonstrate the platform and the custom developed applications for chart review and reporting.

### December 8, 2022

<table>
<thead>
<tr>
<th>Presentation #1:</th>
<th>Presentation #2:</th>
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<tbody>
<tr>
<td><strong>A Gravitate Health approach to adaptation of product information to individual needs</strong></td>
<td><strong>EMR to EDC (E2e) solution to increase efficiency, improve data quality, and lower site burden in clinical research</strong></td>
</tr>
</tbody>
</table>

**Presenters:** Petter Hurlen (Akershus University Hospital)

**Presenters:** Eva Oakkar, Michael Krupnick (IQVIA), Mike Ward (Eli Lilly & Company)

**Topic:** One of the goals of the Gravitate Health project is to explore how medicinal product information can be adapted to the needs of an individual. This presentation will demonstrate one approach to addressing these challenges, using HL7 standards, the Capable.Life platform and EPIs from The Norwegian Pharmaceutical Product Compendium (Felleskatalogen AS).

**Topic:** IQVIA, in collaboration with Eli Lilly & Company, conducted a successful pilot of an EMR to EDC solution powered by IQVIA’s AppScript technology which has been deployed to several EMR environments. AppScript taps into real-time data from the EMR, extracts targeted data elements needed for a specific research study, allows for verification of the data by the user (e.g., Investigator) and pre-fills case report forms in the study EDC. AppScript is launched from within a patient’s record in the EMR leveraging SMART on FHIR, thus, seamlessly integrating into the clinical workflow. This technology prevents “swivel chair” data entry, reduces the site burden as it eliminates the need for manual data entry, improves study data quality as it mitigates the risk for data entry errors and decreases time to data availability as it allows research coordinators to initiate the data transfer on demand through the click of a button.
February 9, 2023

**Presentation #1:**

**Ellie for Patient Screening with SMART on FHIR**

**Presenters:** Nick Spring (BioVeras), Dan Newingham (BioVeras), JeanMarie Markham (BioVeras)

**Topic:** Ellie was created with clinical researchers and built to streamline the patient screening process for CRCs, PIs, and CRAs. This presentation will include a demonstration of Ellie and highlight important considerations for stakeholders looking to leverage FHIR for patient eligibility and automated data entry in clinical research.

**Presentation #2:**

**The Open-Source Sandbox for Healthcare – Meld**

**Presenters:** Kendra Baker (Interoperability Institute), Chit Zin Win (Interoperability Institute), Joel Gruenberg (Interoperability Institute)

**Topic:** Meld is an open-source, FHIR® based sandbox that was developed for the healthcare community. During this presentation, we will go over what the Meld sandbox is, how to utilize it for your own business needs, and how you can get involved in the community working together to improve the Meld sandbox.

April showcase was not held

June 22, 2023

**Presentation #1:**

**Efforts for social implementation of FHIR in Japan**

**Presenters:** Hisashi Osanai (Fujitsu)

**Topic:** In this presentation, Fujitsu, the largest EMR vendor in Japan, will introduce its newly developed platform for exchanging healthcare data in the cloud. The new platform enables the automatic conversion of medical data from medical institutions’ electronic medical records to HL7 FHIR and secure aggregation of health-related data including patient’s personal health information such as vital data and step counts. The platform supports medical institutions and pharmaceutical companies to perform data analysis and R&D activities to accelerate the development of individualized healthcare and the discovery of new drugs.

**Presentation #2:**

**Structured Authoring - Supporting IDMP Submissions using HL7 FHIR Standard**

**Presenters:** Susie Winn (Author-IT), John Jones (Entitech), Murali Menon (Author-IT)

**Topic:** This presentation will highlight the use of Structured Authoring with Docuvera in a Regulatory Setting, discuss current Docuvera IDMP FHIR Export Capabilities, show FHIR Composition Export Capabilities to Support ePI & explain findings from FHIR Composition Generation. Time permitting, we’ll show production Use Cases of FHIR Compositions Beyond Regulatory.

Vulcan 101

Vulcan 101, an educational day highlighting HL7 FHIR and deep dive into Vulcan project briefs, was held on December 14th. Participation was excellent and included many Vulcan members and a cross section of topics.

Vulcan 101 sessions are planned for 2 times per year: spring and fall. The Spring 2023 edition was replaced by EuroVulcan (see the report below). We will be adding new content for future sessions, so please plan to attend future events.

**Vulcan 101 Topics**

- HL7 FHIR basics
- Reading an Implementation Guide
- HL7 Ballot process
- Vulcan: Context
- Regulator Viewpoint
- Vendor Viewpoint
- Vulcan Project Deep Dives
- Vulcan Roadmap
Looking Forward in 2023/24

2022 Foundation

The end of calendar year 2022 marked remarkable achievements by Vulcan members, including:

- 3 Implementation Guides that have been balloted (reviewed) by HL7 International. This is a formal step that will establish baseline standards known as a Standard for Trial Use (STU) for electronic Product Information (ePI), Schedule of Activities (SoA) and Real World Data (RWD).
- New governance and membership models this past 6 months, positioning the program for member-driven priorities & engagement, as well as stability in a balanced membership.

These foundational results act as foundational elements of the Vulcan Program, proving a scalable program that can deliver. However, there is much more to be done, and hence why Vulcan is at an Inflection Point.

2023 Ambitions

Moving forward in 2023 and beyond, there are 3 major thrusts that will guide the program (opposite). 2023 is a pivotal year for Vulcan.

1. Go Global: Efforts to ensure that Implementation Guides are applicable across the globe will benefit health systems far and wide. More efforts are required for outreach, to increase participation and to implement Vulcan Implementation Guides in numerous markets.

2. Implement It: The work of Vulcan is not limited to the development of Implementation Guides. Implementation of those guides, with appropriate feedback mechanisms, will be the true test of success. Whether implementation is a pilot, proof of concept, limited implementation or full scale implementation, all of these efforts will provide the proof that Vulcan is making a difference.

3. New Content: Additional use cases are everywhere. Adding new use cases that result in Implementation Guides to support clinical research will provide benefit to more stakeholders and expand Vulcan’s appeal. Efforts are underway with the Operations & Steering committees to identify and prioritize new opportunities for Vulcan.

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Stay Connected to Vulcan

Look for news and updates throughout the year and follow us on our LinkedIn page (#HL7vulcan).
EuroVulcan was our first ever face to face Conference & Connectathon and it was a resounding success!

Almost 100 attendees and nearly 30 speakers participated over the two days. We were able to bring to a European Audience a strong sense of the current extent of FHIR adoption in clinical research and to lay the basis for a more international flavour to Vulcan projects. We have already seen an increase in interest in Vulcan membership from Europe.

The first day began with scene setting through an overview of Vulcan and of FHIR before going on to presentations on production implementation from regulators and vendors in the afternoon.

The first day also saw our first Connectathon in Europe, where we hosted tracks for Electronic Product Information, Schedule of Activities and Real World Data.

The second day picked up on the implementation theme with reports from the Connectathon tracks before moving on the discuss development of Vulcan – particularly for Europe during the afternoon.

During lunch on the first day, we had 5 tables set aside for tackling the problem facing the clinical and translational industry. There was enthusiastic participation – it was hard to get attendees to stop talking and get back to the conference agenda!

Overall attendees were very positive about the event with many asking when the next on would be! Look out for announcements!

Presentations from the event are available on our website at https://HL7Vulcan.org/eurovulcan
Connectathon Report – January 2023

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
Connectathon Report – September 2022

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

Phenotypic Data

- 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
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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

General Observations

- 350 participants
- Many participants from Vulcan member organizations – thanks to all who travelled to attend

Vulcan Observations

- Each of the 4 Vulcan Tracks made real, tangible progress at the Connectathon, especially towards completing respective Implementation Guides and clarity on use cases
- Connections were made in person that will help make progress on virtual platforms a little easier
Vulcan is honored to have been approached by ICH M11 to coordinate a project that will produce a FHIR Implementation Guide for the ICH M11 CeSHarP (Clinical electronic Structured Harmonised Protocol) standard for digital representation of the protocol for a study. This work will be done in conjunction with CDISC who, along with TransCelerate Biopharma, have developed the USDM (Unified Study Definition Model).

This work will dovetail into existing Vulcan projects and the program of Connectathons.

ICH M11 CeSHarP Press Release
2022-23 saw each of 3 Vulcan projects conduct HL7 International ballots, resolve comments from the broad HL7 standards community and publish IGs as Draft for Trial Use. These are the first set of published standards for Vulcan and will be used to guide pilot and production implementations.

Vulcan Real World Data (RWD) IG
http://hl7.org/fhir/uv/vulcan-rwd/  (Search for vulcan-rwd history)

Vulcan Schedule of Activities (SoA) IG
http://hl7.org/fhir/uv/vulcan-schedule/  (Search for vulcan-schedule history)

Vulcan electronic Product Information (ePI) IG
The Project Management Office (PMO) continued its progress in process, structure and accomplishments since the last newsletter. This included:

- Shani has been a wonderful addition to the PMO and has been promoted to Associate Technical Director
- Connectathon tracks are continuing
- Excellent technical support has been provided by Jean Duteau and Bret Heale
- We have published 3 Implementation Guides (IGs): RWD, SoA and ePI
- The AE project revised the AdverseEvent resource for the FHIR R5 ballot and is building separate profiles for AE in Clinical Care and AE in Clinical Research. We are aiming to ballot Implementation Guides for these in September 2023 and to hold a related Connectathon.
- FHIR to OMOP continues to make progress building a catalog of mappings
- Vulcan only Showcase continues every 2 months, and a second Vulcan 101 has been held
- Future developments:
  - EuroVulcan – and maybe an APACVulcan for Asia/Pacific later this year
  - Putting together a project on Sample data – please get in touch if interested in participating
  - Looking at possibility of having a Vulcan terminology server
  - Starting to explore feasibility of supporting pilot implementations (aka reference implementations) – please get in touch if interested in participating

Michael van Campen, Hugh Glover, Stacy Tegan, Shani Sampson

Contact us: vulcan@hl7.org