CHAIRS MESSAGE

It’s the end of 2021 and before we step into 2022, Amy and I were hoping to take a few minutes to thank you for all that you have done and continue to do to move Vulcan ahead.

Since our start in late 2020, we have done so much together.

- We established a PMO, Steering, Operations and Advisory committees.
- We have a large and diverse group of stakeholders and continue to bring on new members to support our mission.
- Our Vulcan projects are well established and moving forward.
- We continue to be active in HL7 Connectathons now as we continue on our quest to create HL7 FHIR implementation guides.
- Due to our financial success, and with your support, we are now bringing on resources to assist our project teams to drive the projects at lightspeed.

As part of continuous improvement, we brought on POCP Consulting to provide feedback in areas that could make us better, including communicating our progress on Confluence and input into Vulcan governance and membership structures.

Our goal to integrate translational and clinical research into healthcare is unwavering. Together we will remove the inefficiencies in data collection through the use of HL7 FHIR standards and make participating in all forms of research easier for our HCP community and patients.

Thank you for your unwavering support and participation.

Robert Goodwin & Amy Cramer, Vulcan Co-Chairs

CONNECTATHON RECAP

January 2022 will mark our fourth round of Connectathon tracks – when I first said we were doing multiple tracks for our first Connectathon last year, some eyebrows were raised because this was seen as ambitious for such a new accelerator. However, the teams all did a great job and we had good attendance and general interest in what we were doing – so THANK YOU to everyone who made it work.

The aim of Connectathons is to solve problems by writing code and demonstrating interoperability. As the year has progressed, HL7 has emphasized this by insisting that new attendees attend a training webinar in advance of the event. This covers FHIR and the Connectathon generally, not the individual track objective. This focuses the actual Connectathon on active participation in problem solving, rather than seeing the event as a teaching session.

Standing back and looking at the Connectathons as a whole, it is noticeable how they have matured during the year and how synergies are being formed. For example, the tie up between Real World Data and Schedule of Activities. I’m sure that through 2022 we will see more of this.

Finally, if you haven’t taken part in a Connectathon in the past, it is a great way to gain practical experience exchanging data in an real-world, interoperable way.

Hugh Glover, Technical Director
CURRENT MEMBERS

Vulcan membership, as of November 15, 2021.

MEMBERS JOINING IN 2021...

Throughout 2021, we welcomed the following new members to Vulcan. Thanks everyone!

- Accenture
- CDISC
- EPIC
- Infor
- Medidata
- MITRE
- University of Oslo
- Accenture Federal Services
- Citius Health
- GSK
- InterSystems
- Microsoft
- PHUSE
- Verily
**Vulcan Project: Real World Data**

The project began by attempting to extract concomitant medication information from sample EHRs. A challenge has been the limited use made by EHR systems of the full set of prescribe / dispense / administer / statement resources and the difficulty of getting significant sized sets of real “Real World Data” to use for evaluation and testing. Regardless, progress has been made through the three Connectathons of 2021 to develop an understanding of what is feasible. The “LZZT” data set already being used by the SOA project provides a real world set of data and work is in progress to convert this to FHIR before looking at the feasibility of extracting other sets of information such as Lab Results, Diagnoses or Conditions.

All of the development work has considered an end point of providing data to the FDA in SDTM format using the existing balloted FHIR to SDTM mapping standard.

*Scott Gordon, Lauren McCabe*

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**Vulcan Project: Schedule of Activities**

The original objective was to represent the sequencing of visits in a study as specified by the Protocol using HL7 FHIR. Initial modelling work was exercised in the January Connectathon which showed the need for detailed examples. The “LZZT” study is a real study done about 20 years ago and subsequently put in the public domain – it is being used as the raw material for representation in FHIR and by the September Connectathon, the team was able to represent the study AND then use other tooling to generate a Care Plan for a specific patient. A remaining issue is representation of asymmetric timing windows.

The project is not participating directly in the January Connectathon but is supporting the Real World Data project since there is considerable overlap between the two.

*Mike Ward, Geoff Low*

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**Vulcan Project: electronic Product Information**

Since gaining endorsement from the Steering Committee in September, the team has made significant progress in the following areas: (1) agreed to a FHIR model aligned with the European Medicines Agency’s (EMA) ePI and SPOR projects; (2) developed a process for producing ePI prototypes using FHIR Shorthand, the ClinFHIR Graph Builder tool, and GitHub Workflows; and (3) now have access to the Vulcan FHIR server.

We are on schedule to have two prototypes and the infrastructure needed to perform testing and capability demonstrations at the January Connectathon.

*Craig Anderson*

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**Vulcan Project: Adverse Events**

The Vulcan Adverse Events (AE) project kicked off in October this year, following a roundtable in June that identified some active AE projects. The Vulcan AE project seeks to address the constraints and barriers that were observed in the roundtable such as the maturity of the FHIR AE resources. We will leverage the HL7 FHIR standard, EHRs and other types of real-world data (RWD) electronic sources to collect adverse events that occur during clinical trials and identify gaps between data elements in these sources and artifacts.

The HL7 Connectathon in January 2022 will be the first activity in which the Vulcan AE project will test capturing and exchanging adverse events to evaluate the downstream utility of this data and identify gaps. As the work of the Vulcan AE project progresses, we will expand our use cases to include standard of care scenarios, other global regions beyond the United States, and expanding to AE reporting standards such as ICH E2B r3 (Individual Safety Case Report (ICSR)) and Identification of Medical Products (IDMP).

*Michelle Casagni*

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**Vulcan Project: Phenopackets**

In January the team demonstrated representing some genetic assessment of a subject using HBO codes and then attaching this coding to an EHR. The project is currently re-evaluating its objectives and deciding on the next challenge to tackle.

*Anita Walden, Melissa Haendel*
I was new to HL7 participation, and I was not sure what to expect. But Vulcan participation as a Steering Committee member and active member in Operations Committee and RWD track has been a positive learning experience. Trust is developing among the varied stakeholders, allowing us to be honest about our varying experience levels with and understanding of FHIR, as well as that of our home organizations, and about the various compelling and sometimes competing interests that we members inevitably have. In turn, this means that we’re becoming more agile in figuring out how to add value to the collective conversation and move the bar forward for all in a pragmatic way.

One such outcome of this dialog for me is that I’ve been working closely with Hugh Glover and Michael van Campen to fold in expertise from academic medical institution colleagues regarding development of a de-identification service and other architectural parameters that will facilitate contributions of EHR data. Honesty, patience, growing camaraderie, and a desire to see scientific gains from Vulcan’s FHIR-for-research work are seeing us through the challenges.

I encourage more stakeholders of all kinds to join us in these early accelerator efforts; you will be welcomed.

Many of you will be aware that Vulcan is still early in its evolution – we’re barely into our 2nd year. One of the key activities over the past year was a review of our initial Governance and Membership models. We contracted POCP Consulting to offer insights into our existing models, review other HL7 Accelerators to gain insights, and to leverage best practices to form recommendations for adjusting our models into 2022.

Fall 2021 saw the PMO move forward on these recommendations through reviews and approvals by the Operations Committee and Steering Committee. The new Governance Model, to be fully implemented in 2022, provides a number of new capabilities, among them:
- New co-Chairs for Operations Committee
- Rotating Chairs for Steering Committee and Operations Committee
- Balanced representation on Steering Committee amongst Vulcan membership
- Call for nominations for standing for the Steering Committee

The revised Membership Model, which is being fine tuned by the Steering Committee and expected to be rolled out for 2022 year end in July, includes:
- New membership category for smaller, for-profit organizations
- Addition of criteria to recognize in-kind contribution for non-profit organizations
- New membership category recognizing individuals who are Subject Matter Experts

As Vulcan has grown, so our Operations Committee has grown during the year; our potential attendee list is now well over 100 and we get up to 50 on any one call. The monthly meetings have aimed to provide a regular report back from each Vulcan Project and from the Connectathons, but also be an initial venue for discussion of new topics.

Moving into 2022 we intend to provide special discussion topics; we encourage you to propose topics you would like to see Vulcan work towards.

Our Advisory Council met in July and provided insights into Adverse Events (now a Vulcan Project), provided input towards establishing a clinician researcher group for Vulcan and provided input into new potential use cases for Vulcan.

In 2022, we expect to engage the council at least twice, in January and early September on a range of topics, including OMOP, Sample Data and other topics.

Thanks to our Advisory Council members for your contributions in 2021.

The Steering Committee met monthly over 2021 to tackle strategic issues with the program. This included reviewing and approving recommendations for governance and membership changes, approving new Vulcan projects (ePI, AE), overseeing procurement activities, and monitoring progress of the various Vulcan projects. Thanks to members of the Steering Committee for your contributions in 2021.
2021 was a busy year for Vulcan members to present on the progress of the program, as noted below. A big thanks to all that presented – you are our ambassadors, and our members appreciate your efforts. We hope to be present for additional conferences in 2022.

<table>
<thead>
<tr>
<th>Conference Name</th>
<th>Date</th>
<th>Participants</th>
<th>Overview</th>
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<tbody>
<tr>
<td>Learning Health Community eSource Symposium</td>
<td>March 31, 2021</td>
<td>• Amy Cramer</td>
<td>The Learning Health Community invited Vulcan to present at their quarterly eSource symposium. Amy presented on the current membership of Vulcan, as well as the projects that are underway. Thanks, Amy!</td>
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<tr>
<td>e-Clinical and Data Management Forum</td>
<td>June 2, 2021</td>
<td>• Greg Jones • Jonathan Chainey • Maryam Garza • Scott Gordon</td>
<td>Greg, Jonathan, Maryam, and Scott participating in a round table presentation to the e-Clinical and Data Management Forum. Each participant represented a different stakeholder group of Vulcan: technology vendors, pharma, academia, and regulators. The presentation was dynamic and very well done. Thanks to this group for their involvement!</td>
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<tr>
<td>SCDM 2021 Global Virtual Conference</td>
<td>September 29, 2021</td>
<td>• Jesper Kjær • Maryam Garza • Lauren McCabe • Linda King</td>
<td>Similarly to the presentation made at the e-Clinical and Data Management Forum, the four participants at the SCDM Global Virtual Conference represented four of the different stakeholder groups of Vulcan. Jesper, Maryam, Lauren, and Linda did a fantastic roundtable discussion on the current state and future of Vulcan. Thanks to this team for their participation. Job well done!</td>
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<tr>
<td>JIS2021</td>
<td>November 17, 2021</td>
<td>• Michael Van Campen</td>
<td>JIS Go Live is the largest healthcare informatics event in the LATAM region. This event was created by the Hospital Italiano de Buenos Aires and is co-organized and sponsored by HL7 Argentina. Michael presented an overview of Vulcan to meeting participants, including key activities underway and how organizations in the Latin America region can participate in Vulcan.</td>
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<tr>
<td>eClinical Forum</td>
<td>November 17, 2021</td>
<td>• Darren Weston • Meredith Zozus</td>
<td>Darren and Meredith began the presentation with a brief overview of Vulcan and then segued into a fantastic question and answer forum with the audience. Darren and Meredith proved to be quite the dynamic duo. A big thank you to both of them for participating.</td>
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The Project Management Office (PMO) saw great progress in process, structure and accomplishments in 2021. This included:

- Adding Michael van Campen as Program Manager
- Realizing new Governance & Membership Models, with some work still to be completed in 2022
- Initiating regular touch points with HL7 International, ensuring a strong relationship and partnership
- Supporting the various committees and projects in their respective pursuits, including Connectathon and HL7 Working Group engagement
- Commencing regular monthly check-ins with Vulcan Project Leads, as well as monthly All Leads meetings to share best practice and solve common problems consistently
- Developing a procurement strategy that will allow Vulcan to bring on additional resources to support our Vulcan Projects
- Conducting a Request for Proposals to bring on technical assistance for SoA and RWD projects

More is in store for 2022, including touch points with each Vulcan member, implementing the new Governance & Membership Models, supporting Vulcan projects as they continue to progress their Implementation Guides and related deliverables, outreach to the research community and supporting Vulcan leadership. We look forward to working with you in 2022!

Michael van Campen, Hugh Glover, Stacy Tegan, Madeleine Brennan, Sowmya Surapur

FAREWELL & THANKS
We have been fortunate to have Madeleine (or Maddie) Brennan in the PMO since the inception of Vulcan. Madeleine has been instrumental in providing structure, organization and support for Vulcan; her ability to *get it done* is unparalleled, and she brings an uplifting attitude to every encounter.

We’ll miss you Madeleine but wish you the best in your new endeavors.

Best of Luck and Thanks!

WELCOME
We’d like to introduce you to Sowmya Surapur, our newest member of the Vulcan PMO, who will take over from Madeleine and act as a Project Manager. Sowmya brings a wealth of project management experience and has already hit the ground running.

Welcome Sowmya!

“The progress of Vulcan as a FHIR Accelerator for Translational Research *has* already benefited that community, with a program of work trajectory that will be transformative. Simplifying the conduct, reducing the cost, and increasing the efficiency around the conduct of translational research through Vulcan deliverables are of benefit to all.”

*Chris Chute, John Hopkins University*

WISHING YOU A SAFE & PROSPEROUS 2022!

Contact us: vulcan@hl7.org