What is Vulcan?

The vision for an Accelerator dedicated to connecting clinical research and healthcare was solidified in September 2019 by a group of invested representatives from government agencies, academia, technology companies, standards development organizations, patients, and industry consortiums. Vulcan brings together stakeholders across the translational and clinical research community in order to bridge existing gaps between clinical care and clinical research, strategically connect industry collaboratives, maximize collective resources, and deliver integrated tools and resources.

Growing Digitization in Healthcare: 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, it is already happening.

Standard data elements and controlled terminology for data collection forms have been in use by many organizations for multiple decades. Common data models for regulatory decision-making and secondary use of EHR data are not new. However, the acquisition and use of EHR data for prospective clinical research has remained largely separate from routine care. This then requires manual chart review to collect data, increasing study timelines and creating opportunity for error. Through standards these processes can be modernized. All stakeholders across the research enterprise stand to benefit from accelerating further development, refinement, and use of these standards toward optimizing the design, conduct and reporting of clinical studies.

1. **Bridge Existing Gaps**: Work to close gap between clinical care and clinical research to improve patient lives, decrease costs and improve efficiency
2. **Strategically Connect Industry Collaborations**: Coordinate strategy between stakeholders and leverage existing work within HL7 and other groups including FDA, HL7, NCATS, NLM, Danish Medicines Agency, SCDM, TransCelerate Bio Pharma, and others
3. **Maximize Collective Resources**: Leverage shared community and resources to be able to communicate the return on investment and return on value that a unified network could realize to various parties, and provide comprehensive recommendations to global regulators
4. **Deliver Integrated Tools and Solutions**: Develop necessary FHIR Research Resources to maturity. Accelerator program will handle identified and prioritized use cases for secondary use of EHR data that meet interested parties needs and goals

Who is involved in Vulcan?

As of April 2021, the organizational members of Vulcan are:

- Accenture
- The Association of Clinical Research Organizations (ACRO)
- CDISC
- Crohn’s & Colitis Foundation
- Danish Medicines Agency *
- Duke University School of Medicine *
- Epic
- FDA *
- HL7 International *
How can you get involved with Vulcan?

The success of Vulcan will depend on the involvement of volunteers who are eager to make rapid progress on the acceleration of further development, refinement, and use of the FHIR standards toward optimizing the design, conduct, and reporting of clinical studies. We will need experts to contribute towards the creation and development of uses cases. If you are interested in learning more about joining Vulcan please email us at Vulca n@HL7.org or fill out the form on our website.

Click here to download the Vulcan SOU.

What is Vulcan working on?

Phenopackets
Phenopackets is a GA4GH standard for exchanging phenotype data to support de-identified case level patient information that can be shared broadly and used in a wide variety of settings, such as EHRs, Journals, Clinical Labs, Patient Registries, and Knowledgebases.

Project Leads:
- Anita Walden, Oregon Health & Science University
- Davera Gabriël, John Hopkins University

Real World Data
Utilizing EHR source data to directly populate clinical research data capture systems whenever feasible would save cost and time. The July 2018 FDA guidance Use of Electronic Health Record Data in Clinical Investigations encourages this and there is a clear need to develop HL7 FHIR capabilities to fulfill this requirement.

Current goal of the project focuses on extracting patient medication data from an EHR FHIR server and generating an SDTM dataset to submit to FDA's submission Gateway for validation.

Project Leads:
- Scott Gordon, FDA
- Lauren McCabe, Pfizer

Schedule of Activities
Adoption of a FHIR based representation of the Schedule of Activities in a study will introduce consistency, avoid repeated data entry, and enable automation.

Current goal of the project is to take the representation of the schedule of activities of a clinical study in CDM-XML format and convert it into FHIR.

Project Lead:
- Mike Ward, TransCelerate

Other Information and Related Publications
Check out the video below for more information on why Vulcan matters now.
Related Publications

- Article: Semantic integration of clinical laboratory tests from electronic health records for deep phenotyping and biomarker discovery
  - Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6527418/

- Final report from the Advancing Standards for Precision Medicine project which is part of ONC’s portfolio of projects under the Precision Medicine Initiative. The project was conducted in collaboration with standards development organizations, key stakeholders, and demonstration sites with the goal of advancing standardized sharing of mobile health, sensor, wearable data and social determinants of health data – to help further precision medicine and research.
  - Link: https://www.healthit.gov/topic/advancing-standards-precision-medicine

Recent Space Activity

Gideon S. Gordon
- Vulcan RWD - IG content Background and overview updated Aug 19, 2021 • view change

Hugh Glover
- Project Checklist updated Aug 19, 2021 • view change

Mike Hamidi
- Real World Data Overview commented Aug 10, 2021

Lauren McCabe
- Real World Data Overview updated Aug 10, 2021 • view change

Hugh Glover
- Vulcan Expectations created Jul 20, 2021

Space Coordinators

Madeleine Brennan

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