Overview

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. The Vulcan Accelerator serves the needs of the clinical and translational research communities through the implementation of HL7 FHIR standardized data exchange.

Introduction

Growing Digitalization 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

Why Vulcan?

**The Need for Standards in Clinical Research**

Data is the Key

- Health data is used across almost every aspect of clinical research and clinical care
- Fidelity for standards and interoperability has been an ongoing challenge over the past several years
- On the positive side, data driven decision making is now the norm for treatment, reimbursement, care delivery and management
- Unique Clinical Research standards are critical for identifying, interpreting and prioritizing data to form a foundation that fully supports health data used by clinical care providers

Vulcan Projects
Real World Data

Utilizing EHR source data to directly populate clinical research data capture systems wherever 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.

Currently working on extracting patient medication data from an EHR FHIR server and generating an SDTM dataset to submit to FDA’s submission Gateway for validation

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.

Currently working on representation of the schedule of activities of a clinical study in ODM-XML format and converting it into FHIR

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 Knowledge bases.

Electronic Product Information (New in 2021)

The current objective of this project is to create a new digital platform that gives patients a more accessible way of acquiring trusted medicinal product information. This will be done by combining information from the International Patient Summary (IPS) document, a selected list of medication list with ePIs for each medication and the associated medicationproductdefinition resources.

Adverse Events (New in 2021)

This use case investigates the feasibility of utilizing the EHR as a mechanism for recording and reporting Adverse Events that occur during a clinical trial. Use of the EHR would provide a common, consistent source for sponsors and regulators.

FHIR to OMOP (New in 2022)

This project supports the development of FHIR to OMOP data transfer for better analysis of clinical data for research.

Membership

Current members

Contact Us at Vulcan@HL7.org to:

- Learn more about Vulcan
- Pursue membership
- Find out more about participation in one or more Vulcan Projects