Vulcan FHIR Accelerator
Adverse Events Project

September 2022
Objective: Leverage HL7 FHIR standards to enable the collection and exchange of adverse event (AE) data for clinical research

Near term goal: Define FHIR AE profile to support Clinical Research

Activities:
- Mapped FDA MedWatch Forms (3500A, 3500B) to AE base resource and identified gaps
- Leveraged FHIR to CDISC AE mapping and FDA E2B for defining clinical research AE extensions
- Raised gaps with Patient Care WG and incorporated relevant changes to R5 base resource
- Created several clinical research and clinical care AE examples using AE resource
- Defining AE profiles for clinical research and clinical care

Events:
- May 2022 PHUSE/FDA Innovation Challenge
  - Focused on Patient sharing data during clinical trial with FDA for post-market surveillance
  - Leveraged R4 AE base resource and MedWatch 3500B Form
- January 2022 HL7 FHIR Connectathon
  - Focused on data capture using real-world data sources and identified gaps in R4 AE base resource
Going Forward

Complete draft AE IGs (FHIR R5)
  - Primary focus for Vulcan is clinical research IG
  - Clinical care IG a starter to highlight differences in AE meaning and use between the use cases
Harmonize R5 AE IG with R4 to support implementation
Host AE track in 2023 Connectathon(s)
  - Test clinical research AE profile and end-to-end AE workflow
  - Will need participation from downstream users of AE data (e.g., clinical trial sponsors, FDA)
Work towards increasing maturity of AE resource
Target 2023 to ballot clinical research AE IG