Propelling Innovation and Interoperability

HL7 FHIR Accelerators on the Move

7/23/2021
HL7 Webinar Speakers

Speakers:

**HL7 Moderator:** Ticia Gerber, MHS/HP

**The Argonaut Project**
- Brett Marquard, Project Manager, The Argonaut Project; Principal, WaveOne Associates

**The CARIN Alliance**
- Dave Lee, JD, Management Team, The CARIN Alliance; Director, Leavitt Partners

**CodeX**
- Steve Bratt, PhD, Program Manager, CodeX; Principal, Health Standards and Interoperability, The MITRE Corporation
HL7 Webinar Speakers

Speakers:

Da Vinci Project
• Viet Nguyen, MD, Technical Director, Da Vinci Project; Founder, Stratametrics
• Jocelyn Keegan, Program Manager, Da Vinci Project; Payer Practice Lead, Point of Care Partners

Gravity Project
• Evelyn Gallego, MBA, MPH, CPHIMS, Program Manager, Gravity Project; Chief Executive Officer, EMI Advisors, LLC

Vulcan
• Michael van Campen, Vulcan Program Manager, Sr. Consultant, Gevity Consulting Inc.
The HL7 FHIR Accelerator program is designed to assist communities and collaborative groups across the health care spectrum in moving towards global health data interoperability.
Argonaut

Overview and Introduction

Brett Marquard
WaveOne
7/23/2021
What is the Argonaut Project?

The Argonaut Project is an implementation community comprising leading technology vendors and provider organizations to accelerate the use of FHIR and OAuth in health care information exchange.

We are:

- Private sector initiated and funded
- Working collaboratively with other FHIR initiatives such as SMART-on-FHIR, and the Health Systems Platform Consortium (now Logica!)
- Creating open industry Implementation Guides in high priority use cases of importance to patients, providers and the industry as a whole

We are NOT:

- A standards development organization
- A separate legal entity
- A proprietary activity
**Technology Vendors**

- Accenture
- Allscripts
- Apple
- Athenahealth
- Cerner
- Change Healthcare
- eClinicalWorks
- Epic
- Humana
- MEDITECH
- Microsoft
- Optum
- Surescripts

**Provider Organizations**

- Beth Israel Deaconess Medical Center
- Intermountain Health
- Mayo Clinic
- Partners Healthcare
- SMART at Boston Children’s Hospital

**Staff (current and past)**

- Prime contractor: HL7
- FHIR initiatives:
  - Grahame Grieve, Eric Haas, Josh Mandel, Brett Marquard, Gino Canessa, Carl Anderson
- OAuth initiatives: Dixie Baker, Josh Mandel
- Project Management: Brett Marquard (Jennifer Monahan, Micky Tripathi prior to 2021!)
**Argonaut Project Timeline**

**JASON Task Force Recommendations**

- Call to action for APIs and FHIR
- Launch of Argonaut Project
- EHR certification includes API requirement

**S&I Initiative**

- Data Access Framework
- Data Query Implementation Guide published

**HL7 FHIR**

- Argonaut Project
- SMART on FHIR Granular Controls

**Provider Directory**

- Implementation Guide published

**CDS HOOKS**

- CDS Hooks Implementation Guide
- Argonaut R4 + Clinical Notes + Provenance added to US Core!

**Clinical Data Subscriptions**

- Bulk Data
- Patient Lists

**Timeline**

- Oct 2014
- Dec 2014
- Oct 2015
- Dec 2016
- Jun 2017
- May 2018
- Nov 2019
- 2020 and beyond
Four Short Years from Inception to Market Adoption

Jan 2018

Carequality implements Argonaut Provider Directory specification

CommonWell includes Argonaut FHIR specifications in core services – MEDITECH goes live on FHIR

50% of 100+ certified vendors use FHIR APIs

Apple will let you keep your medical records on your iPhone

- Apple is moving deeper into health care with a service that lets users view their medical records.
- CEO Jeff Williams tells CNBC that "Apple doesn’t see the data unless the consumer chooses to share it."
- About a dozen hospitals have signed up, as have medical-record vendors.

Christina Farr | @christyfarr
Published 8:31 AM ET Wed, 24 Jan 2018 | Updated 2:21 PM ET Thu, 25 Jan 2018

Apple enables secure iPhone access to medical records using Argonaut Implementation Guide
Prior Initiatives

SMART on FHIR support
Data Query and Document Query
Provider Directory
Scheduling
CDS Hooks support
Bulk Data
Questionnaire and Questionnaire Response
Clinical Provenance

SMART Web Messaging
Clinical Data Subscriptions
US Core Argonaut R4
SMART on FHIR Granular Controls
Patient List
2021 Initiatives

**FHIR Write**
- Currently, very little guidance is provided on writing and updating data in the context of USCDI Core profiles in FHIR
- Provide a standard approach in FHIR, and propose to US Core
- Wed 1-2 PM US Eastern (Zulip: [Argo Write](#))

**Subscriptions**
- Promote adoption of the Subscription framework (R4 & R5)
- Discuss implementation questions / issues / challenges
- Build out testing and reporting
- Wed 2-3 PM US Eastern (Zulip: [Subscriptions](#))

**‘others’ under consideration:**
- Native App Security best practices
- Electronic Health Information (EHI) Export
- USCDI V2 design and testing...
Participation

• Review existing designs and comment using HL7 JIRA
• Zulip Chat Channel - Argonaut
• Argonaut Confluence Page

• Contact: Brett@waveoneasociates.com
HL7 Accelerator Briefing: The CARIN Alliance

JULY 23, 2021
The CARIN Alliance

Our Vision
To rapidly advance the ability for consumers and their authorized caregivers to easily get, use, and share their digital health information when, where, and how they want to achieve their goals.

*Sample list of CARIN members. For a full list of the CARIN board and members go to: https://www.carinalliance.com/our-membership/carin-board-participants/
Key CARIN Workstreams and Deliverables

Trust Framework and Code of Conduct

• Development and industry adoption of a Code of Conduct for third-party applications privacy, security, and consent protocols
• Creation of best practices for application developers’ communication to their users of privacy and security practices and Code of Conduct compliance
• Creation of an application registration guide for how to ensure privacy, security, and consent when accessing payer and provider systems while streamlining how consumer-facing applications access the data

Patient, Care Partner, and Family Caregiver Workgroup

• Dedicated place for patients, consumers, care partners, and family caregivers to meet and advance consumer-directed health information exchange
Key CARIN Workstreams and Deliverables

Payer Workgroup
• Development of the CARIN IG for Blue Button® as an HL7® standard for payers to comply with the CMS Patient Access API requirements
• Creation of a “Digital Insurance Card” FHIR IG for use across payers and platforms

Real-time Pharmacy Benefit Check Workgroup
• Development of the CARIN Real-time Pharmacy Benefit Check FHIR Implementation Guide that may be used by Part D sponsors for their 2023 requirement to create a Real-time Benefit Tool for their enrollees

ID and Authentication Workgroup
• Development of a federated trust framework policy environment for an individual to voluntarily create and use their own digital identity credential across multiple covered entities and non-covered entities to accelerate individual access to clinical and claims data
mCODE™ and the CodeX™ HL7 FHIR Accelerator

Steve Bratt, Ph.D.
Leader, MITRE Health Standards and Interoperability Group
Program Manager, CodeX HL7 FHIR Accelerator
sbratt@mitre.org

July 23, 2021
A FHIR-based core set of common data elements for cancer that is standardized, computable, clinically applicable and available in every electronic health record for patients with a cancer diagnosis.

A **standard health record** for oncology.

The **minimal set of data elements** applicable to all cancers, and collected for:

- Standardized information exchange
- Use-case driven and targeted use

Oncology data element domains: **patient, disease, treatment, outcomes, genomics, lab/vital**

A Member-driven community accelerating interoperable data modeling and implementation around the FHIR and mCODE HL7 standards, leading to substantial improvements in cancer care and research.

http://hl7.org/CodeX
Data are collected and shared via the mCODE standard, and CodeX extensions.
CodeX is a growing, active community of oncology stakeholders, working together to ...

**Prioritize**
- *Use cases* around interest and impact on cancer care and research, and where mCODE is central

**Build**
- New *data FHIR IGs needed to supplement* mCODE
- *Reference implementations and updates to products*
- *Test datasets*

**Execute**
- *Pilots to demonstrate feasibility and value enabling early adoption and scale*
CodeX Members
(June 2021)
★ CodeX Founders

Premier

★ AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE
★ ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY FOUNDATION
★ Cancer Action Network
★ ASTRO
★ HL7 International
★ MITRE
★ Pfizer
★ Syntropy
★ UnitedHealthcare

Benefactor

★ CIBMTR
★ Trajectory
★ CDC
★ MCSP
★ Siim

Government Agency

★ COMP
★ OCPM
★ Learning Health Community

Sponsored Member

★ Cancer Insights
★ MassiveBio
★ Mettle Solutions
★ NeuralFrame
★ Principia Health Sciences
★ QLHC
★ Quantum Leap Healthcare Collaborative
★ Varian
★ Wemedoo

Developer/Implementer

★ Patientlink
★ Better Patient Connection - Better Data Collection
Building a **Trusted** Network of Health System Solutions

Brigham and Women’s Hospital
City of Hope
Clearview Cancer Institute
Dana Farber Cancer Institute
Duke University
Grady Health
Heartland Cancer Research
Massachusetts General Hospital
Mayo Clinic
MD Anderson Cancer Center
Metro-Minnesota Community Oncology Research Consortium
Northwell Health
Rush University Medical Center
Saint Joseph Mercy Health System
The Ohio State University
The University of Chicago Medicine
ThedaCare
Trinity Health
UNC Lineberger Comprehensive Cancer Center
University of California San Francisco
University of Michigan
University of Pennsylvania
University of Texas Southwestern
Virginia Commonwealth University
Washington University in St. Louis
Yale University

IC: Active – Committed or actively participating in planning, design, development, piloting
Engaged & Interested – Engaged in multiple conversations and/or in the process of being Active

IC: ICAREdata
RR: Registry Reporting
TM: Trial Matching
RT: Radiation Therapy Treatment Data
CodeX Use-Case-Based Projects

Discovery -> Planning -> Execution

https://confluence.hl7.org/display/COD/CodeX+Use+Cases

0. mCODE++ Extraction
1. EHR Endpoints for Cancer Clinical Trials (future extensions of ICAREdata)
2. Integrated Trial Matching for Cancer Patients and Providers
3. Cancer Registry Reporting
4. Radiation Therapy Treatment Data for Cancer
5. Oncology Clinical Pathways
6. Prior Authorization in Oncology
7. Genomics Data Sharing
Leveraging the mCODE™ standard (minimal Common Oncology Data Elements), CodeX will expand around this core to encompass additional use cases, accelerating opportunities to create a learning health system based on interoperable data and improved patient care.

Learn more [www.hl7.org/codex/](http://www.hl7.org/codex/)
HL7 Da Vinci Project Introduction

July 23, 2021
VBC Programs Drive Focus to Patient Outcomes
Da Vinci members are industry leaders and health IT technical experts who are working together to accelerate the adoption of HL7 Fast Healthcare Interoperability Resources (HL7® FHIR®) as the standard to support and integrate value-based care (VBC) data exchange across communities. VBC programs enable providers to see right data at right time for specific patient coverage, benefits and care coordination.

Focus — Use cases linked to high volume, manual activities that would benefit from automation of portions of the workflow that collect and exchange critical data to improve outcomes.
To ensure the success of the industry’s **shift to Value Based Care**

**Transform out of Controlled Chaos:**
Develop *rapid multi-stakeholder* process to identify, exercise and implement initial use cases.

**Collaboration:**
Minimize the development and deployment of *unique solutions.*
*Promote* industry wide *standards* and adoption.

**Success Measures:**
Use of FHIR®, implementation guides and pilot projects.
Empower End Users to Shift to Value

Project Challenge

Physicians Say Better Data Interoperability Will Save Lives

Physicians recognize the importance of having the right information at the right time.

86% think better data interoperability would significantly cut time to diagnosis.
95% say increased data interoperability will improve patient outcomes.
96% agree that easier access to critical data can save lives.

As a private industry project under HL7 International, Da Vinci work is unleashing critical data and workflows between payers and providers required for VBC workflows leveraging HL7® FHIR®

### Da Vinci 2021 Multi-Stakeholder Membership

#### PROVIDERS
- *YAMA Medical Group*
- *Cedars-Sinai*
- *HCA Healthcare*
- *Sutter Health*
- *MultiCare* Connected Care
- *OrthoVirginia*
- *Providence* St. Joseph Health
- *OHSU*
- *Texas Health Resources*
- *UC Davis Health*
- *UNC Health Care*
- *Weill Cornell Medicine*

#### EHRs
- *athenahealth*
- *Cerner*
- *Epic*
- *healow | Insights*
- *veradigm.*

#### DEPLOYMENT
- *Availity*
- *MiHIN*
- *CHANGE HEALTHCARE*
- *Cognizant*

#### PAYERS
- *Anthem*
- *Blue Cross Blue Shield of Alabama*
- *Blue Cross Blue Shield Association*
- *Blue Cross of Idaho*
- *CAMBIA*
- *Cigna*
- *GuideWell*
- *Humana*
- *Independence*
- *UnitedHealthcare*

#### VENDORS
- *casenet*
- *cognosante*
- *edifeq*
- *infor*
- *InterSystems*
- *juxly*
- *mcg*
- *OPTUM*
- *surescripts*
- *ZeOmega*

#### INDUSTRY PARTNERS
- *HIMSS*
- *HL7 International*
- *NCQA*

*Indicates a founding member of the Da Vinci Project. Organization shown in primary Da Vinci role. Many members participate across categories.*
ANSI Antitrust Policy

ANSI neither develops standards nor conducts certification programs but instead accredits standards developers and certification bodies under programs requiring adherence to principles of openness, voluntariness, due process and non-discrimination. ANSI, therefore, brings significant, procompetitive benefits to the standards and conformity assessment community.

ANSI nevertheless recognizes that it must not be a vehicle for individuals or organizations to reach unlawful agreements regarding prices, terms of sale, customers, or markets or engage in other aspects of anti-competitive behavior. ANSI’s policy, therefore, is to take all appropriate measures to comply with U.S. antitrust laws and foreign competition laws and ANSI expects the same from its members and volunteers when acting on behalf of ANSI.

Approved by the ANSI Board of Directors May 22, 2014
Da Vinci Program Manager:
Jocelyn Keegan, Point of Care Partners
jocelyn.keegan@pocp.com

https://confluence.hl7.org/display/DVP/Da%2B+Vinci%2B+Welcome

Da Vinci Technical Director:
Dr. Viet Nguyen, Stratametrics LLC
vietnguyen@stratametrics.com
Consensus-driven Standards on Social Determinants of Health

HL7 FHIR Accelerators on the Move | July 23, 2021
Evelyn Gallego, EMI Advisors LLC
Slide developed by Laura Gottlieb, MD, MPH with permission from Jack Maypole, MD
Challenges in SDOH Data Capture and Exchange

- Consent Management
- Standardization of SDOH Data Collection and Storage
- Data Sharing Between Ecosystem Parties
- Access & Comfort with Digital Solutions
- Concerns about Information Collection and Sharing
- Social Care Sector Capacity and Capability
- Unnecessary Medicalization of SDOH

Enter the Gravity Project...

**Goal** – Foster equitable health and social care using consensus-driven data standards to support the use and exchange of social determinants of health (SDOH) data.

Domains grounded by those listed in the NASEM “*Capturing Social and Behavioral Domains in Electronic Health Records*” 2014
In May 2019, the **Gravity Project** was launched as a multi-stakeholder public collaborative with the goal to develop, test, and validate standardized SDOH data for use in patient care, care coordination between health and human services sectors, population health management, public health, value-based payment, and clinical research.

**Gravity Project Scope:** Develop data standards to represent patient level SDOH data documented across four clinical activities: screening, assessment/diagnosis, goal setting, and treatment/interventions.

https://confluence.hl7.org/display/GRAV/The+Gravity+Project
Project Founders, Grants, and In-Kind Support To-Date

https://confluence.hl7.org/display/GRAV/Gravity%2BProject%2BSponsors
### Gravity Overview: Two Streams

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**Key:***
- ▲ LOINC Code Submissions (MAR/ OCT)
- ★ SNOMED Code Submissions (MAY/DEC)
- ◆ ICD-10 Code Submissions (JUN/DEC)
- ------ Goals/Interventions

---

**Terminology:***

- Social Isolation
- Stress
- Elder Abuse
- Intimate Partner Violence (IPV)
- Material Hardship

**Technical:**

- HL7 FHIR Connectathons
- Gravity FHIR IG Ballot
- IG Ballot Reconciliation
- Reference Implementation Development
- Reference Implementation Update
- Final updates/IG Publication
- IG Updates from Testing & Piloting Activities

**Pilots:**

- Gravity Pilots Recruitment
- Gravity Pilots Testing (6 to 12 months)

**Goals/Interventions:**

- Food Deserts
- Neighborhood Safety
- Unemployment
- Education
- Veterans

---

**Note:**

- WE ARE HERE

---

Terminology Workstream
**Terminology Workstream**

Data Element and Coding Gap Analysis

- All data are sorted across four activities into a master set.
- For data within each domain, we ask:
  - What concepts need to be documented across the four activities?
  - What codes reflecting these concepts are currently available?
  - What codes are missing?
# SDOH Domain Code Dashboard

<table>
<thead>
<tr>
<th>Domain</th>
<th>Activities (Aligns with USCDI SDOH Data Class)</th>
<th>Select Codes Present</th>
<th>Comprehensive List of Codes Present</th>
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[https://confluence.hl7.org/display/GRAV/Coding+Submissions](https://confluence.hl7.org/display/GRAV/Coding+Submissions)
NEW! 2022 Release of ICD-10 CM

Gravity Project submission for new and updated **education**, **food insecurity**, and **housing** ICD-10 CMS codes were approved for implementation beginning October 1, 2021.

[https://confluence.hl7.org/display/GRAV/ICD-10+Coding+Submissions](https://confluence.hl7.org/display/GRAV/ICD-10+Coding+Submissions)

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**2022 release of ICD-10-CM**

The 2022 ICD-10-CM codes are to be used from October 1, 2021 through September 30, 2022.

**Note:** This replaces the FY 2021 – January release. These files listed below represent the FY 2022 ICD-10-CM. The FY 2022 ICD-10-CM is available in both PDF (Adobe) and XML file formats. Most files are provided in compressed zip format for ease in downloading. These files have been created by the National Center for Health Statistics (NCHS), under authorization by the World Health Organization. Any questions regarding typographical or other errors noted on this release may be reported to [nchsicd10cm@cdc.gov](mailto:nchsicd10cm@cdc.gov).

A new version of the ICD-10-CM tabular addenda FY2022 file has been added. If you have downloaded the previous file (prior to June 30, 2021) you will need to download it again. This corrects the missing IS5A, Non-ischemic myocardial injury (non-traumatic) code for the addenda.

Also a new version of the FY2022 Conversion table has been added. If you have downloaded the previous file (prior to June 30, 2021) you will need to download it again.

- [ICD-10-CM FY2022 Full PDF 2022](https://www.cdc.gov/nchs/icd/icd10cm.htm)
- [ICD-10-CM FY2022 XML 2022](https://www.cdc.gov/nchs/icd/icd10cm.htm)
- [ICD-10-CM FY 2022 Addenda PDF 2022](https://www.cdc.gov/nchs/icd/icd10cm.htm)
- [ICD-10-CM FY2022 List of codes and Descriptions 2022](https://www.cdc.gov/nchs/icd/icd10cm.htm)
- [ICD-10-CM FY2022 Order Files 2022](https://www.cdc.gov/nchs/icd/icd10cm.htm)
- [ICD-10-CM FY2022 Conversion Table 2022](https://www.cdc.gov/nchs/icd/icd10cm.htm)
Technical Workstream
HL7 SDOH Clinical Care
FHIR Implementation Guide

1. This is a framework Implementation Guide (IG) and supports multiple domains

2. IG support the following clinical activities
   • Assessments
   • Health Concerns / Problems
   • Goals
   • Interventions including referrals
   • Consent
   • Aggregation for exchange/reporting

3. Completed January 2021 ballot as a Standard for Trial Use Level 1 (STU1)

4. Completed submission for publication through HL7—July 2021

http://hl7.org/fhir/us/sooh-clinicalcare/2021Jan
Interoperability Glide Path: Domain Data Sets & Implementation Guides

SDOH Data Sets

Develop and test coded value sets for use in FHIR

Refine, test, and ballot HL7® FHIR® SDOH Implementation Guide(s)

Regulators

EHR Vendors

Payers & Providers

Patients

Clinicians

Registries/Researchers

http://www.hl7.org/about/fhir-accelerator/
Accomplishments & Success Factors
Policy Integration: Gravity USCDIv2 Submission

- The Gravity Project formally made a submission to the ONC U.S. Core Data for Interoperability (USCDI) version 2 in October 2020.

- On April 15, 2021, HITAC approved and forwarded recommendation to ONC

- On July 9, 2021 ONC included the SDOH data class in the USCDI V2 publication

https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#uscdi-v2
Policy Integration: CMS State Health Official Letter

On January 7th, CMS released guidance for states on opportunities under Medicaid and CHIP to address SDOH.

The guidance acknowledges that states can leverage Medicaid resources to support data integration and data sharing to assist state health systems to identify individuals with SDOH needs and link them to appropriate medical and social supports.

States are required to design technical infrastructure for Mechanized Claims Processing, Information Retrieval Systems, and care coordination hubs that are interoperable with human services programs, HIEs, and public health agencies, as applicable.

States must ensure alignment of the claims processing and IRS systems with CEHRT.

States are encouraged to review ISA SDOH standards and review and participate in the Gravity Project.

Grants Integration: ACL Challenge Grant & ONC LEAP Grant

• Administration of Community Living (ACL) Social Care Challenge Grant:
  o All 12 will demonstrate use of Gravity defined data elements

• ONC Leading Edge Acceleration Projects (LEAP) in Health IT Notice of Funding Opportunity: Referral Management to Address Social Determinants of Health Aligned with Clinical Care
  o https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information
How to Engage!
Join the Gravity Project!

Learn More
https://confluence.hl7.org/display/GRAV/Join+the+Gravity+Project

• Public Collaborative meets weekly on Wed
• Workgroup meets bi-weekly on Thursdays’ 4:00 to 5:30 pm ET
• SDOH FHIR IG Workgroup s. 3:00 to 4:00 pm ET

• Give us feedback on the Data Principles:
  https://confluence.hl7.org/display/GRAV/Gravity+Data+Principles

• Submit SDOH domain data elements (especially for Interventions):
  https://confluence.hl7.org/display/GRAV/Data+Element+Submission

Help us with Gravity Education & Outreach

Use Social Media handles to share or tag us to relevant information

@thegavityproj
https://www.linkedin.com/company/gravity-project

Help us find new sponsors and partners
Partner with us on development of blogs, manuscripts, dissemination materials
Questions?

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Additional questions? Contact: gravityproject@emiadvisors.net or visit https://thegravityproject.net
HL7 Accelerators Webinar – Vulcan

July 23, 2021

Michael van Campen, Vulcan Program Manager
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, the transition to a more digital environment is happening.

Several Accelerators exist already to spur development of digital solutions for healthcare:

- *Project Argonaut* (providers to providers)
- *Project DaVinci* (providers to payers)

The goal of the forum was to help the research community align toward leveraging HL7 FHIR® for more effective acquisition, exchange and use of data for clinical research.
The need for standards in clinical research

• Health data is used for both Clinical Research and Clinical Care purposes

• However, Clinical Research has lagged behind other clinical care functions in the definition and use of Standards

• On the positive side, both share many common standards such as consent (to treatment, to research) and identity management

• Unique clinical research standards include candidate identification, clinical trials and phenopackets (to name a few) that rely on health data curated by clinical care processes
Vulcan Vision Statement

Why Vulcan?
Fully integrate research into the delivery of healthcare by streamlining data collection and exchange into a singular process.

What are we doing to reach that vision?
• Collaborating with the international research community to align clinical data and clinical research data at the point of collection.
• Developing out the HL7 FHIR standard to support the bidirectional flow of data.

How will we accomplish this?
• Bridge existing gaps
• Strategically connect industry collaborations
• Maximize collective resources
• Deliver integrated tools and solutions
Vulcan Member Organizations

*indicates a convening member of Vulcan
The Goals of Vulcan

BRIDGE EXISTING GAPS

Work to close gap between clinical care and clinical research to improve patient lives, decrease costs and improve efficiency.

STRATEGICALLY CONNECT COLLABORATORS

Coordinate strategy between stakeholders and leverage existing work within HL7 and other groups including FDA, NCATS, NLM, SCDM, TransCelerate, and academic research sites.

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.

DELIVER INTEGRATED TOOLS AND SOLUTIONS

Develop necessary FHIR Research Resources to maturity. Vulcan will handle identified and prioritized use cases for secondary use of EHR data that meet interested parties needs and goals.
Vulcan Project Structure

Advisory Council
- Comprised of thought leaders who serve for a voice of their area of expertise and/or the health sector they represent (and not their own organization)
  - Members nominated by Steering Committee

Steering Committee
- Sets strategic direction for Vulcan
- Prioritizes activities and approves use cases and projects
- Makes financial decisions
- Comprised of convening member organizations

Operations Committee
- Develops and recommends use case proposals
- Oversees operations and delivery of use case projects
- Comprised of all member organizations of Vulcan

Project Teams
- Formed to carry out use case projects
- All organizations have the opportunity to participate in the project teams of their choosing
Vulcan Team Membership

**Leadership**
- Rob Goodwin: Vulcan co-Chair
- Amy Cramer: Vulcan co-Chair

**PMO**
- Michael van Campen: Program Manager
- Madeleine Brennan: Project Manager
- Hugh Glover: Technical Director
- Stacy Tegan: Membership Program Manager

**HL7**
- Karen Van Hentenryck: HL7 Liaison
## Vulcan Project Updates – July 2021

### Real World Data

**May Connectathon**
- Continuing the work from January – identifying concomitant medication from an EHR
- PatientLink kindly provided an update of the reference implementation
- Good attendance (core of about 12) – FDA / Parexel / Epic / Edetek / Pfizer
- Discussion moved on to mapping and conversion of data - code got written!
- Starting detailed discussion …

**General**
- Established as a project and generally self-directing

### Schedule of Activities

**May Connectathon**
- Continuing from January
- Good attendance (core of about 8) – strong PHUSE involvement
- Looking at modelling some of the detail of planning – especially timing and clinical measurement
- Reference implementation was extended to import ODM
- More focus on writing implementation notes

**General**
- Established as a project and generally self-directing
- Need to balance Writing Implementation Guides and providing a Reference Implementation

### PhenoPackets

**May Connectathon**
- Track withdrawn – not sufficient clarity on “business problem to solve”

**General**
- Still in the “Forming/Storming” phase as a Vulcan project
- Involvement of Epic will bring some application experience
- Currently arranging external FHIR SME involvement to review and advise
- Will need to engage much more with relevant WGs
New Vulcan Projects (1 of 2)
Adverse Events

Roundtable #1, June 1, 2021

- Projects we knew in this space were invited to present (opposite)
- Key objective: **Raising Awareness**

![Raising Awareness](image)

- Key Output: Landscape Map (opposite)
  - Link: [https://confluence.hl7.org/display/VA/AE+Landscape](https://confluence.hl7.org/display/VA/AE+Landscape)

- Observations:
  - Some use of ICSR, but US focused

Use Case Approval Process

- Proposed to Steering Committee; seeking approval in July
New Vulcan Projects (2 of 2)  
E-Labeling (under assessment)

<table>
<thead>
<tr>
<th>Topic (Proposed)</th>
<th>Notes / Discussion</th>
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<tbody>
<tr>
<td></td>
<td>• Gravitate-Health Consortium, part of the Innovative Medicines Initiative (IMI)</td>
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**Initiator**

- Gravitate-Health Consortium, part of the Innovative Medicines Initiative (IMI)

**Use Case**

- Structuring product information

**Rationale for Use Case**

- e-Labeling is an area of interest in many geographical regions
- Following Vulcan guiding principles to strategically connect and maximize resources to develop a single pathway for interoperable exchange of data

**Initial Plans**

- Connectathon in September
- Roundtable in October

*How can we apply an open access digital platform with trusted Digital health information to transform the way patients access and understand health information, and apply this in personal health for adherence to treatment, risk minimization and quality of life?*
Thank you!

Michael van Campen
mvancampen@gevityinc.com
Q & A

THANK YOU!