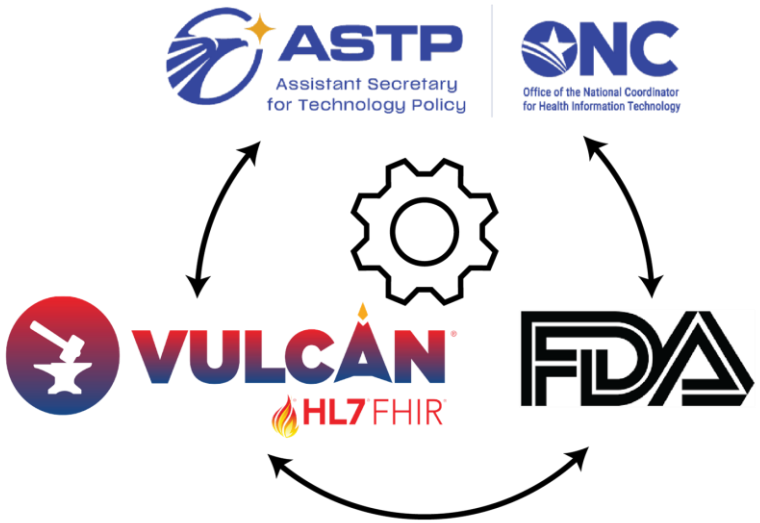
Vulcan Interoperability Bridge Event to Enable Clinical Research Infrastructure Information Session

In collaboration with

ASTP Assistant Secretary for Technology Policy | ONC Office of the National Coordinator for Health Information Technology & FDA

August 21, 2024

Cross-Agency Collaboration



The HL7 Vulcan Accelerator represents a diverse, member-led community, formed in 2019, operating within HL7's FHIR® Accelerator program and dedicated to improving data interoperability by bridging clinical care and research. Vulcan will provide the primary implementation guides and technical guidance on implementing HL7's FHIR®.

The US Office of the National Coordinator (ONC) is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information. ONC supports the Vulcan Interoperability Bridge Event through promotion, event management and aligning resources to strengthen the clinical trials infrastructure and optimize clinical trial data capture.

The Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services, protects public health by regulating human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, cosmetics, dietary supplements, electronic radiation emitting products, and tobacco products. FDA will offer support to the Vulcan Interoperability Bridge by helping to establish use case requirements alongside implementers.

Agenda

- Welcome and Introduction
- Reflections ONC / FDA
- Vulcan Accelerator Overview
- Vulcan Member Perspectives (Site/Pharma)
- VIB Event Details
- Focus Area Deep Dive
- How to Collaborate and Next steps

Background and Landscape

Assistant Secretary for Technology Policy (ASTP) / Office of the National Coordinator for Health IT (ONC)

- **Founded in 2004 by executive order, established in statute in 2009**
- **ASTP is charged with formulating the federal government's health IT strategy to advance national goals for better and safer health care through an interoperable nationwide health IT infrastructure**

Laying the foundation of EHRs across the industry

- $40B CMS investment to subsidize EHRs for hospitals and ambulatory providers
- ONC certification of EHR systems to support CMS and CDC programs
- ONC certification now covers EHRs used by 97% of hospitals and 86% of ambulatory providers

Leveraging EHRs to drive value

- Information blocking: Prohibits providers, technology developers, and health information networks from interfering with access, exchange, and use of electronic health information
- Standards: Requires access to information through APIs "without special effort"
- TEFCA: Requires nationwide governance for health information exchange networks – Trusted Exchange Framework and Common Agreement

ASTP Mission & Vision and Priorities:

Set the Course for the 21st Century Digital Healthcare System

MISSION and VISION

ASTP/ONC is at the forefront of the federal government's digital health efforts. ASTP supports the entire health system with the use of health IT and the promotion of nationwide, standards-based health information exchange.

MISSION: To create systemic improvements in health and care through the access, exchange, and use of data.

VISION: Better health enabled by data.

PRIORITIES

Build the digital foundation

- Data standards
- Health IT gaps
- HHS Health IT Alignment Policy

Make interoperability easy

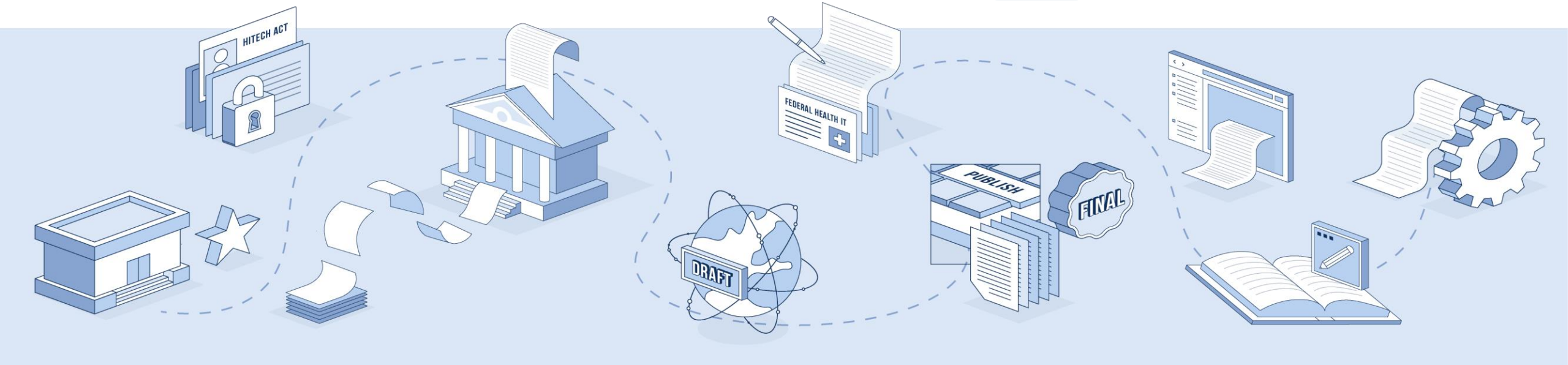
- TEFCA
- APIs
- Expand education and outreach
- Enforce information blocking rules

Ensure proper use of digital information and tools

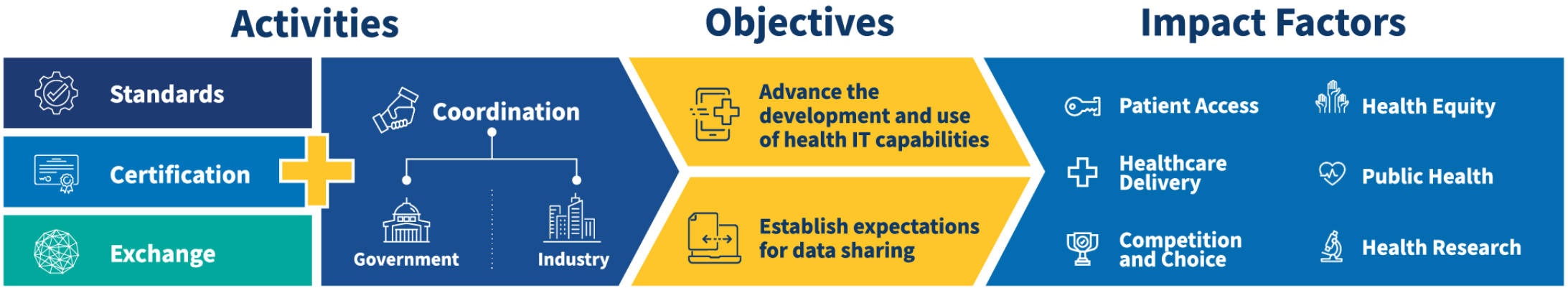
- Health equity by design principles for data capture and use
- Transparency in areas such as algorithm use and safety

ASTP/ONC Significant Milestones

- **2008** — Federal Health IT Strategic Plan 2008-2012
- **2009** — **HITECH Act**
- **2010** — Blue Button Initiative
- **2011** — Meaningful Use Stage 1; Federal Health IT Strategic Plan 2011-2015
- **2014** — Introduced 10-year vision to achieve interoperability health IT infrastructure
- **2015** — Federal Health IT Strategic Plan 2015-2020; Draft Shared Nationwide Interoperability Roadmap 1.0
- **2018** — **21st Century Cures Act signed into law**
- **2019** — The Sequoia Project named as RCE of 4-year award
- **2020** — **Cures Act Final Rule published**
- **2021** — Information Blocking Regulations; PHIT Workforce Development Program
- **2022** — TEFCA published; New EHI definition takes effect
- **2023** — First set of applicant QHIN organizations approved to implement TEFCA; **HTI-1 Final Rule**
- **2024** — **ASTP Reorg**; **HTI-2 Proposed Rule**



Activities and Targeted Impacts



Interagency Coordination

- Federal Health IT Coordinating Council (FHITCC)
- Health IT Alignment Policy

Non-HHS Federal Agencies

HHS Operational Divisions

HHS Staff Divisions

HL7 FHIR Accelerators

Provider / Provider

Payers / Provider

Public Health

Cancer Care and Research

Consumers

Infrastructure Use Cases

Social Determinants of Health

Clinical Trials

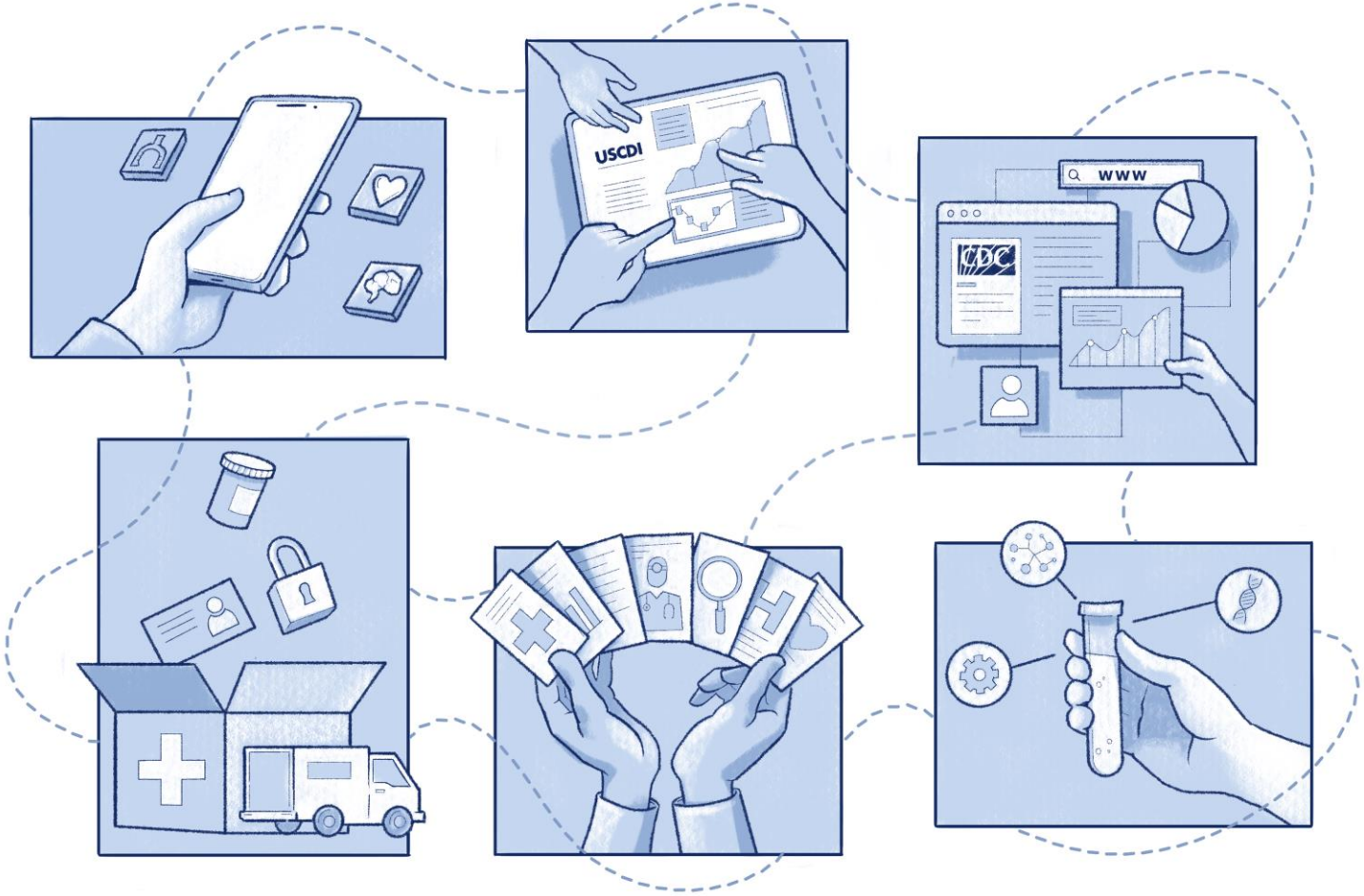
ONC's Impact

Health Equity

- Close-loop referral with social services organizations
- SDOH data capture (i.e., food insecurity, housing insecurity)
- REL and SOGI data standard

Patient Access

- Health record follows patients
- Real-time access to test results
- Ability to use modern smartphone apps to access and use data



Public Health

- CDC's Data Modernization Initiative
- Public health reporting
- Bidirectional exchange with public health

Healthcare Delivery

- Improved patient safety
- Better care coordination
- Reduced medical errors

Health Research

- Clinical trials
- Cancer Moonshot

Competition and Choice

- New services for providers and patients built on a digital health ecosystem

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Current State

U.S Food and Drug Administration

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Health Canada Santé Canada

pmda 独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Future State

FHIR

U.S Food and Drug Administration

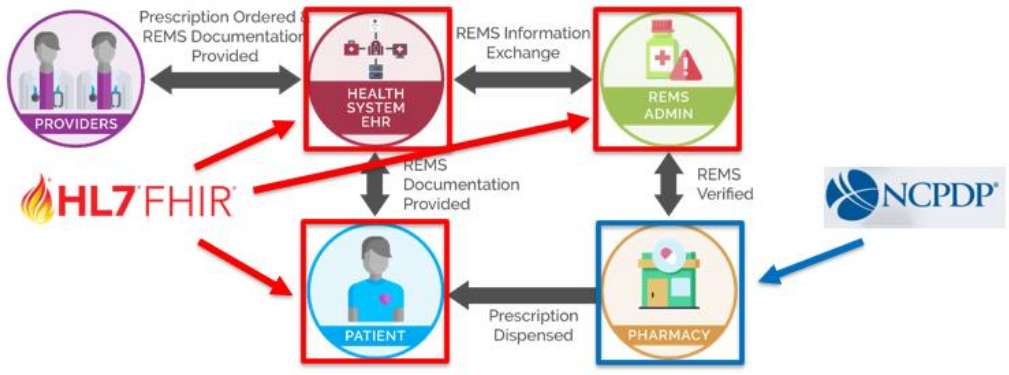
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

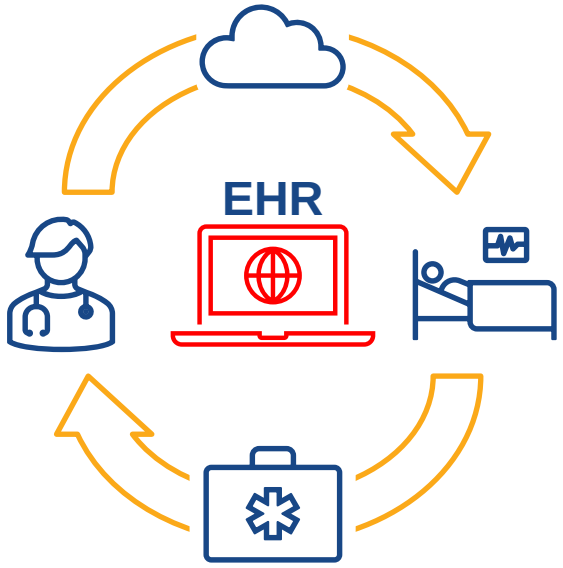
Health Canada Santé Canada

pmda 独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

The Difficult becomes Trivial

FHIR's shared data model allows both agencies and systems vendors to easily interoperate.

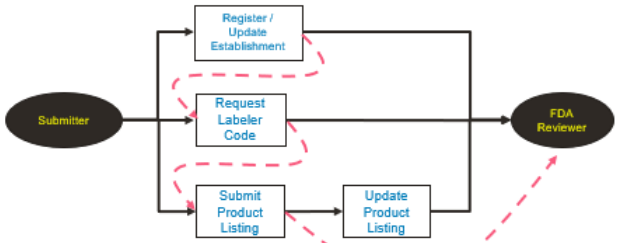




SPL FHIR (FDA)

SPL is used for many activities at FDA

High-level processes (example use case):
Establishment Registration and Product Listing



Submit, Request, Register:
- Drug/Biologic Label
- NDC Labeler code
- Establishment information
- GDUFA Self-Identification
- REMS
- Etc.

For:
- Drugs
- Biologics
- Veterinary
- Devices
- Medical Food and Supplements
- Cosmetics

Vulcan Accelerator Overview

A Global Community with 40+ Member Organizations

Membership as of August 2024

VULCAN® HL7® FHIR®

Vulcan has convened diverse members of the global research user community to align care and clinical & translational research through the adoption of FHIR

Guiding Principles

- **Bridge Clinical Research and Clinical Care**
- **Strategically Connect Collaborators**
- **Maximize Collective Resources**
- **Enable Tools and Solutions Development**

accenture, asc, Docuvera, Assistant Secretary for Technology Policy (ASTP), BioVeras, CARELANE, cdisc, Cedars Sinai, Crohn's & Colitis Foundation, ★ Lægemiddelstyrelsen Danish Medicines Agency, ★ Duke University School of Medicine, Droice Labs, Epic, evidentli, ★ FDA, Felleskatalogen, Fujitsu, GSK, ★ HL7 International, IgniteData, iHD The European Institute for Innovation through Health Data, infor, Interoperability Institute, ★ Johns Hopkins School of Medicine, Johnson&Johnson, medidata, Microsoft, MITRE, Memorial Sloan Kettering Cancer Center, 国立がん研究センター 東病院 National Cancer Center Hospital East, ★ National Institutes of Health (NIH) National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH) National Cancer Institute (NCI), National Institutes of Health (NIH) National Library of Medicine (NLM), NIHR National Institute for Health Research, OpenClinica, ORACLE, ★ Oregon Health & Science University, patientlink MyLinks, Pfizer, phuse, Roche, Scientific Knowledge Accelerator Foundation (SKAF), ★ SCDM Society for Clinical Data Management DATA DRIVEN, ★ TransCelerate BIOPHARMA INC., UAMS, University of Colorado Anschutz Medical Campus, UiO University of Oslo, ★ UT Health San Antonio Joe R. & Teresa Lozano Long School of Medicine, The University of North Carolina at Chapel Hill, Vanderbilt University

★ *indicates a convening member of Vulcan*

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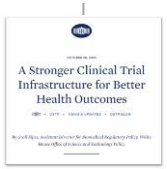
How did we get here?

January 2023

Vulcan provided response to OSTP's RFI - "Request for Information on Data Collection for Emergency Clinical Trials and Interoperability Pilot"

October 2023

White House/ OSTP blog "A Stronger Clinical Trial Infrastructure for Better Health Outcomes"



May 2024

USCDI+ Cancer Research Data Exchange Summit – Vulcan plenary session

FHIR Published Implementation Guides (IG)

April 2023 – Clinical Study Schedule of Activities (SoA)

May 2023 – Retrieval of RWD for Clinical Research

July 2023 – Electronic Medicinal Product Information (ePI)

April 2024 – Adverse Events for Clinical Research

"Optimizing Data Capture for Clinical Trials, an OSTP/ONC listening session"

December 2023

Vulcan provided response to "Request for Information on Advancing Clinical Trial Readiness (ACTR) Initiative, ARPANET-H"

Late 2024-Early 2025

Collaboration between Vulcan and ASTP/ONC to produce "Vulcan Interoperability Bridge event (VIB)"

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Motivating factors, initiatives, and related themes

USCDI+ Cancer use cases

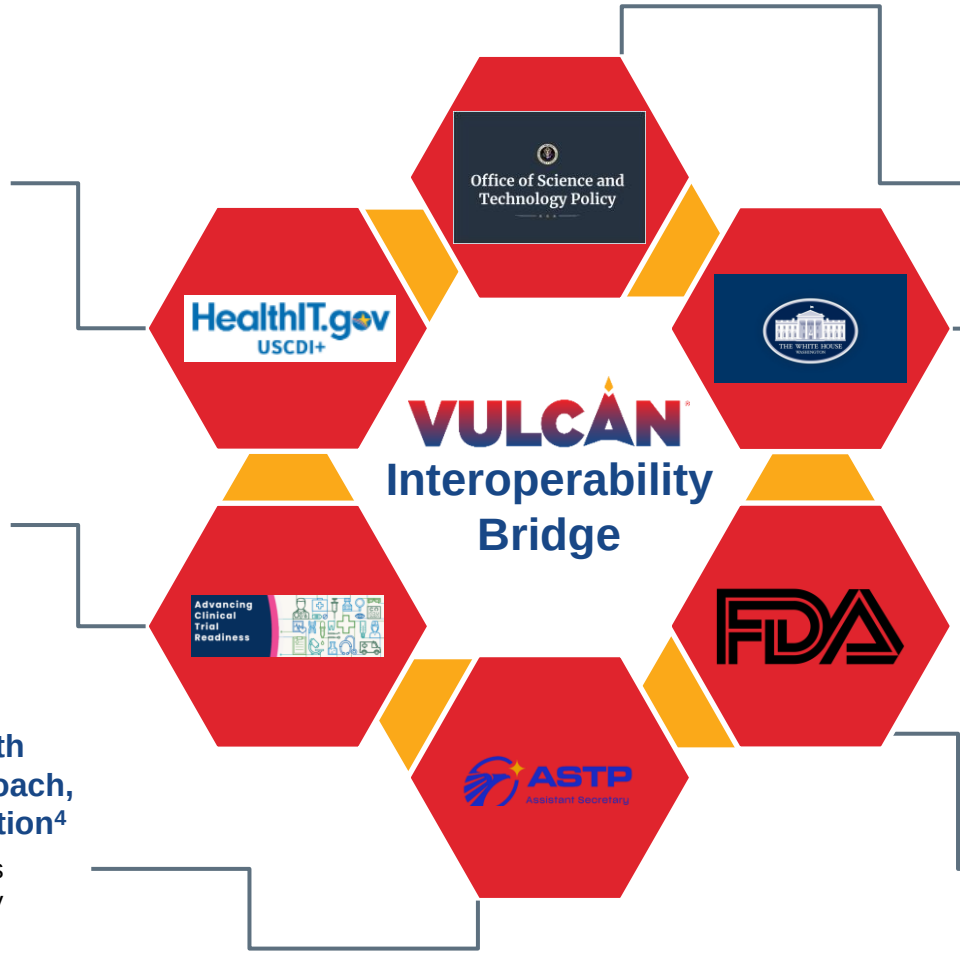
- The USCDI+ Cancer Program[1] will define real-world data (RWD) elements to further cancer prevention, diagnosis, treatment, research, and care
- Clinical Trial Recruitment / Matching
- Immune Related Adverse Event (irAE) tracking

ARPA-H – Advancing Clinical Trial Readiness Project (ACTR)

- Enable 90% of all eligible Americans to take part in a clinical trial within a half hour of their home
- Improve access for under-represented populations and communities
- Move trials closer to the point of care

ONC – Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input, and Call to Action[4]

- Focus on the steps and results needed to address health inequities and advance the health equity by design of health IT
- Reduce, not exacerbate, health disparities



OSTP – RFI on Data Collection for Emergency Clinical Trials and Interoperability Pilot

- Clinical trial protocol for broad distribution across clinical trial networks and sites
- Participant enrolment enhanced by trial matching 'alerts'
- Clinical trial data to the sponsor

White House/OSTP – "A Stronger Clinical Trial Infrastructure for Better Health Outcomes"[2]

- Standardizing approaches to data exchange
- Strengthening our clinical trials infrastructure
- Leveraging electronic health records systems, and making data available to researchers more rapidly

FDA – Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies[3]

- Enable clinical trial diversity by design
- Reduce participant burden and increase access to the clinical study

1 LINK *3* LINK
2 LINK *4* LINK

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Vulcan Member Perspectives

Vulcan Interoperability Bridge Event

What is the Vulcan Interoperability Bridge Event?

- Clinical research community comes together to test and demonstrate the power of HL7 FHIR to move the needle on Clinical Research data use
- Demonstrations in focus areas that represent improved end to end data flows in the clinical research space and how the use of FHIR APIs can improve data quality, efficiency, and overall cost to conduct research
- On February 5, 2025, the clinical research community will come together to provide feedback, questions and comments on live demonstrations of multi-stakeholder pilot implementations of FHIR
- A resource guide for the rest of the clinical research community to advance their FHIR initiatives

Vulcan Interoperability Bridge Outcomes

01. Faster adoption of interoperability between health care and research

02. Increased understanding and use of FHIR Implementation Guides

03. Increased maturity of FHIR resources with a goal of aligning with USCDI / USCDI+

04. Increased exposure of the opportunities to drive more solutions

05. Identification of additional interoperability capabilities for clinical research

06. Increase the community of interested and engaged parties

07. Evolve to a framework that could be implemented globally

08. Identification of able implementers for HL7 FHIR Implementation Guides

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Vulcan Interoperability Bridge Timeline

August 2024

ASTP/ONC to host Informational Webinar to share the plan

Establish a team of early adopters to implement Vulcan IGs

September 2024

Develop workflows that compel adoption of implementation guides

October-December 2024

Provide technical support for implementers

October

- Begin biweekly office hours for technical implementation support
- Fill implementer gaps

November

- Continue to work through implementation
- Refine use case story lines
- Gather input for Implementer Resources

December

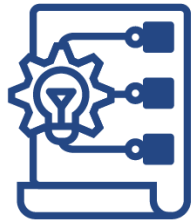
- Continue testing and documentation
- Launch webinar registration and marketing campaign
- Convene stakeholders at ASTP/ONC Annual Meeting

January 2025

Develop Guidance to Improve Clinical Research Infrastructure such as recorded demos and resource guides to Share Across Multiple Events

February 2025

Bring government and the research community together in a virtual environment to demonstrate the future of clinical research infrastructure



2025 Reusable Resources

1.End to end workflow demonstrations

2.Roadmap for implementation

3.Registry of who has implemented the IGs

Implementer Benefits of Participation

1

Contribute

Work side-by-side with other research and industry leaders as story lines are defined through collaborative iteration.

2

Support

Receive expert technical input from the Vulcan team leading up to the event.

3

Access

Get access to engage with other participants and recorded content for their own use.

4

Visibility

Be featured in related Vulcan demonstrations.

5

Preemption

Gain visibility to their involvement and contributions

- In event promotions and demo webpage
- Featured in implementer resource recordings and documents
- At ONC Annual Meeting in December where the work will be featured

Implementer Participation

Technology Solution Providers who want to better support clinical trials with FHIR APIs**:**
Electronic Health Records or Data Capture Systems, Intermediary systems, Clinical Trial Management Systems, among others

Clinical Research Sponsors who initiate, manage, or finance clinical studies or trials and want to improve the efficiency of their data collection**:**
Pharmaceutical Companies, Academic Medical Centers, among others

Clinical Research Sites who wish to improve their compatibility with Clinical Research Sponsors**:**
Clinical Research Hospitals, Academic Medical Centers, Retail Clinics, Community Based Locations, among others

Focus Areas

Intro to Focus Area Leads

1) Patient	2) Health Information Exchange (HIE)	3) Researcher to Sponsor		4) Regulatory AE Investigations		5) Internal Sponsor Systems
						
Debi Willis MyPatientLink	**Qi Li** InterSystems	**Rich Yeatman** Ignite Data	**Mike Buckley** MSKCC	**Mitra Rocca** FDA	**Scott Gordon** FDA	**Cal Collins** OpenClinica

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1) Patient Focus Area

What

Explore ways to engage patients to allow them to directly share their RWD (EHR data, PROs, AE, etc.) with clinical research.

Patient engagement gives sponsors and CROs an opportunity to gain invaluable data input and feedback from stakeholders who have traditionally not been viewed as a core part of the study team – patients.

Patient Engagement

Why

- Enhanced patient empowerment
- Streamlined data sharing
- Reduces manual data entry burden
- Enriches data quality
- Expands safety surveillance
- Improves patient experience
- Facilitates longitudinal studies
- Supports regulatory decisions
- Enables decentralized clinical trials
- Provides a secure pathway for return of data from sponsors
- Accelerates research and innovation

Improves Data Flow & Quality

Benefits

NIH studies found patient engagement technology:

- Helps reduce barriers to clinical trial participation
- Improves retention (particularly under-represented populations)
- Provides a more complete understanding of the impact of an intervention, therapy, or service

Sharing RWD provides the research team with a broad set of data in near real time, improving patient surveillance / safety while minimizing data errors and reducing study costs.

Enhanced Health Management

Technology Solution Providers	Clinical Research Sponsors	Clinical Research Sites	Government	Patient Persona	Subject Matter Experts
✓	✓	✓	✓	✓	✓

Expected roles to support and enable Focus Area

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2) Health Information Exchange Focus Area

What

Allow federated data compilation of data into a single set that can be used for real world research questions that are approved by an honest broker.

Data Compilation

Why

Data is often contained in separate sources utilizing different schema and coding requiring significant workload to harmonize the data, creating a longitudinal record, across various systems.

Data Harmonization

Benefits

- Single data source allows for more robust scientific exploration and ability to track long-term outcomes
- Wider visibility of signals and trends
- Reduction in harmonization effort, time, and costs
- Honest brokers have established governance, processes, and technical infrastructure that enable access to RWD
- Fair and equitable data representative of varying demographics

Better RWD Access

Technology Solution Providers	Clinical Research Sponsors	Clinical Research Sites	Government	Patient Persona	Subject Matter Experts
✓	✓	✓	✓		✓

Expected roles to support and enable Focus Area

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3) Researcher to Sponsor Focus Area

What

Advance site and research interoperability by leveraging clinical trial protocols to guide structured data collection.

This approach enhances data accessibility, streamlines processes, and accelerates research timelines, delivering substantial ROI for both sites and sponsors, particularly within electronic data capture systems.

Data Accessibility

Why

Increased the productivity of an existing clinical trial data transfer process by decreasing data latency, transcription errors, and queries. It allows for the more efficient use of both sponsor, CRO, and site staff time and effort.

Study start-up is time consuming and streamlining data exchange will improve this.

Improve Productivity / Reduce Cost

Benefits

- Improved data collection efficiency
- Enhanced data accuracy and reliability
- 1.5x faster than manual process
- Reduces data entry error by 99%
- Increased user satisfaction
- Strengthened interoperability
- More efficient and reduces effort
- Conversion from paper to electronic standards-based formats establishes a framework for multiple innovations such as AI/ML

Enhanced Interoperability

Technology Solution Providers	Clinical Research Sponsors	Clinical Research Sites	Government	Patient Persona	Subject Matter Experts
✓	✓	✓			✓

Expected roles to support and enable Focus Area

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4) Regulatory AE Investigations Focus Area

What

Investigate how to connect interoperable structured **drug labeling** information (e.g., adverse reactions section, ingredients) with structured **Adverse Event** (AE) identification and reporting, and data from the **pharmacy information systems** to support rapid investigation of new or increased adverse events related to medical products.

Support AE investigations with interoperable Label/AE/Pharmacy information systems

Why

Ability to identify source of adverse events (e.g., specific ingredient, manufacturer or drug-drug interaction) is limited because:

- Medical product information (labeling data) is siloed, if structured, or unstructured
- AE identification and reporting is a highly manual process
- Pharmacy information are typically siloed
- No interoperable standards exist to support a harmonized data ecosystem for AE investigations

Transform fragmented sources of AE investigations into a harmonized interoperable ecosystem

Benefits

Enhance speed, accuracy, and comprehensiveness of:

- Detection of new and/or increased medical products-related adverse events
- Investigation of the source of medical product adverse events

Integration of healthcare, pharmacy and public health information systems.

Promotes rapid public health actions to reduce and prevent adverse events, improving health outcomes.

Reduce unnecessary health issues and save more lives

Technology Solution Providers	Clinical Research Sponsors	Clinical Research Sites	Government	Patient Persona	Subject Matter Experts
✓	✓	✓	✓	✓	✓

Expected roles to support and enable Focus Area

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5) Internal Sponsor Systems Focus Area

What

Sponsors can achieve internal research system interoperability by adopting FHIR for R&D information exchange, including:

- Digitized clinical trial protocols
- Structured Schedules of Activities
- Adverse event data sharing
- RWD utilization

Interoperability Between Parties

Why

Research systems used by sites and sponsors (e.g., EDCs, CTMS, IVRS, Trial Master Files, etc.) can move beyond point-to-point integrations and manual duplication of data.

Increased industry alignment with the rest of the healthcare ecosystem will benefit from ongoing investment in FHIR-based Health IT tools in pursuit of a "write once, run anywhere" ecosystem.

Streamline Research Processes

Benefits

- Improved data quality and data collection efficiency
- Streamline study planning, startup, and execution
- Alignment of clinical care and clinical research to benefit patients and reduce site burden
- Move from siloed systems into a cohesive infrastructure, with improved ROI and ability to leverage AI/ML

A More Cohesive Infrastructure

Technology Solution Providers	Clinical Research Sponsors	Clinical Research Sites	Government	Patient Persona	Subject Matter Experts
✓	✓				✓

Expected roles to support and enable Focus Area

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Call for participation

Vulcan's Call for Research Community Collaboration

Research Community Innovators

- Join with other non-technical, technical and business colleagues via an ASTP/ONC hosted webinar to witness demonstrations of the impact of interoperability on the flow of data
- Collect intelligence on the opportunities for innovation
- Learn new capabilities and systems
- See the real functionality to bridge clinical care and clinical/translational research
- Provide anonymous feedback
- Attend a **FREE** webinar in February 2025 to witness the work of the "Implementers" at the Vulcan Interoperability Bridge (VIB) Event

FHIR Implementers

- Co-develop the future with technical and standards development colleagues representing multiple stakeholders from patient advocacy groups, pharma, sites, vendors and government agencies (ASTP/ONC and FDA)
- Collaborate elbow to elbow with other actors to create a use case story to demonstrate improved patient journey through the use of the HL7 FHIR® standards and the capability of systems
- Build interoperability capabilities with other actors to exchange (mock) data in real time at a live webinar demonstration – the Vulcan Interoperability Bridge (VIB) Event

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How to Get Involved

NEXT STEPS

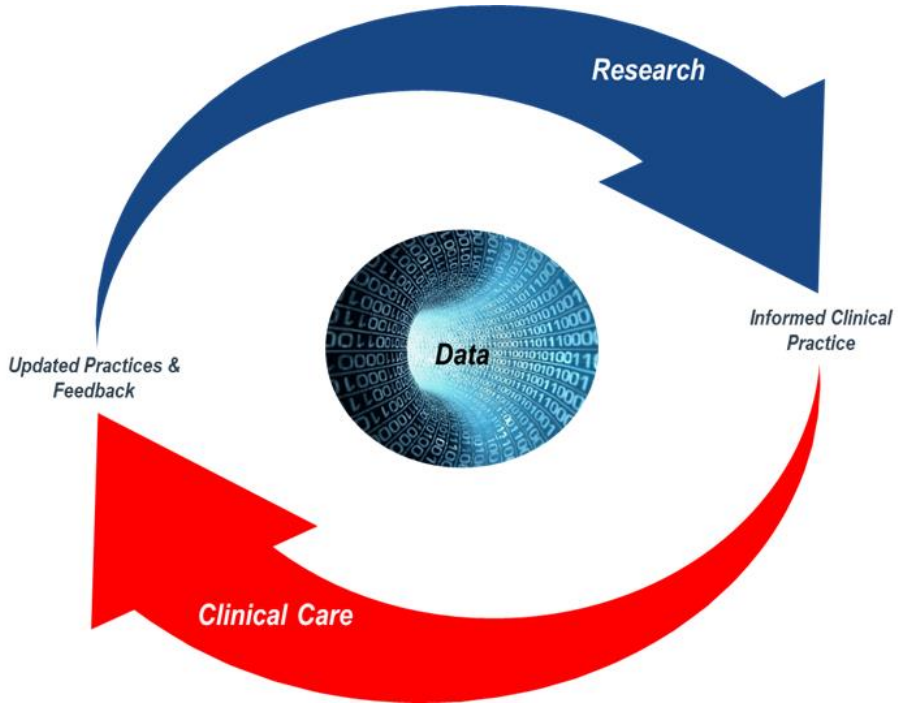
- **Express your interest by emailing VIB@hl7vulcan.org**
- **Stay in touch with Vulcan Interoperability Bridge Team by providing feedback or supporting one of the use case demonstrations!**

APPENDIX

Role Definitions

Technology Solution Provider	Clinical Research Sponsor	Clinical Research Site	Government	Patient Persona	Subject Matter Expert
Ensures sites can receive and implement schedule of activity guidelines to develop data collection forms, enabling sharing with sponsors and government entities.	Receives clinical research safety data and questionnaire responses from sites.	Aligns data collection forms and safety data with schedule of activity guidelines.	Utilizes clinical research safety data from sites for surveillance and reporting.	Completes the form with relevant responses	Provides clinical and FHIR-specific expertise to ensure use case success.

Our member-led projects are key to bridging research and care



Project	Objectives	Status
Adverse Events (AE)	Leverage EHRs and other types of real-world data (RWD) as electronic source to collect adverse events that occur during clinical trials.	**Published:** Clinical Research AdverseEvent IG Clinical Research AdverseEvent R4 Backport IG
Electronic Product Information (ePI)	Develop a FHIR standard that makes ePI more accessible; improves patient experience; and supports cross-border exchange of data for patients.	**Published:** Electronic Medicinal Product Information (ePI) FHIR Implementation Guide
Real World Data (RWD)	Extract data from EHRs in a standardized format to support clinical research including submission to Regulators.	**Published:** Retrieval of Real World Data for Clinical Research
Schedule of Activities (SoA)	Use FHIR to communicate a clinical protocol's Schedule of Activities. Enables care providers to plan and execute encounters and activities compliant with the protocol.	**Published:** Clinical Study Schedule of Activities
FHIR to OMOP	Support the development of FHIR to OMOP data transfer for better analysis of clinical data for research.	**Ongoing**
Phenotypic Data	To increase the availability of high-quality standardized phenotypic information for genomic research and genomic medicine.	**Ongoing**
Utilizing the Digital Protocol (UDP)	Demonstrate that FHIR can be used to exchange the CeSHarP representation of a protocol between regulators and between a sponsor and a regulator.	**Ongoing**