ASTP Assistant Secretary for Technology Policy

Progress and Promise:
Piecing Together the Future of Clinical Trials Infrastructure

2024 ASTP Annual Meeting

December 5th, 2024

Progress and Promise:
Piecing Together the Future of Clinical Trials Infrastructure

Dr. Kamal Menghrajani
White House – Office of Science and Technology
Health Outcomes Division

Panel Discussion
Progress and Promise: *Piecing Together the Future of Clinical Trials Infrastructure*

Moderator: Stephen Konya, ASTP

Panelist: Dr. Kamal Menghrajani, WH/OSTP

Panelist: Dr. Jose Galvez, FDA

Panelist: Paula Braun, ARPA-H

Panelist: Dr. Shannon Silkensen, NIH/NCI

Panelist: Amy Cramer, JnJ / Vulcan

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Audience Q&A

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

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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

VULCAN®
Interoperability Bridge

Office of Science and Technology Policy

HealthIT.gov USCDI+

THE WHITE HOUSE WASHINGTON

Advancing Clinical Trial Readiness

FDA

ASTP Assistant Secretary

VULCAN® In collaboration with **ASTP** Assistant Secretary for Technology Policy & **FDA**

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
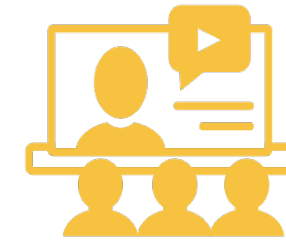- Gather input for Implementer Resources

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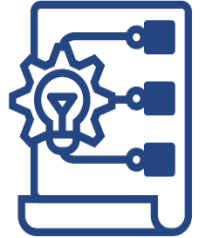- Convene stakeholders at ASTP/ONC Annual Meeting

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

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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

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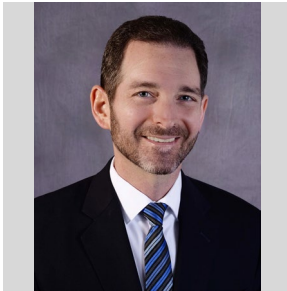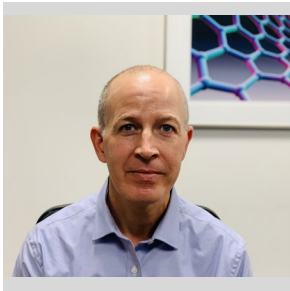
VIB Champions and Participating Implementers

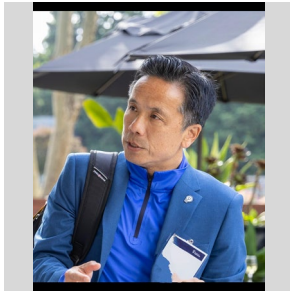| 1) Patient	2) Health Information Exchange (HIE)	3) Researcher to Sponsor		4) Regulatory AE Investigations		5) Internal Sponsor Systems
Debi Willis MyPatientLink	**Qi Li** InterSystems	**Rich Yeatman** Ignite Data	**Mike Buckley** MSKCC	**Mitra Rocca** FDA	**Scott Gordon** FDA	**Cal Collins** OpenClinica

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!

- ❖ Register for the Vulcan Interoperability Bridge Event on February 5th

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HHS | ASTP

Reach out via phone or web

📱 202-690-7151

💬 Feedback Form: https://www.healthit.gov/form/healthit-feedback-form

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in Office of the National Coordinator for Health Information Technology

▶ https://www.youtube.com/user/HHSONC

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2024 ANNUAL MEETING

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Washington, DC | December 4 - 5

Agenda

My Sessions

Meet the Speakers

Floor Plan

Area Dining

App Tutorial

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24 MEETING

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ASTP Better health enabled by data