



# Leading Edge Acceleration Projects in Health IT

ONC Annual Meeting  
January 28<sup>th</sup> 2020

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The Office of the National Coordinator for  
Health Information Technology



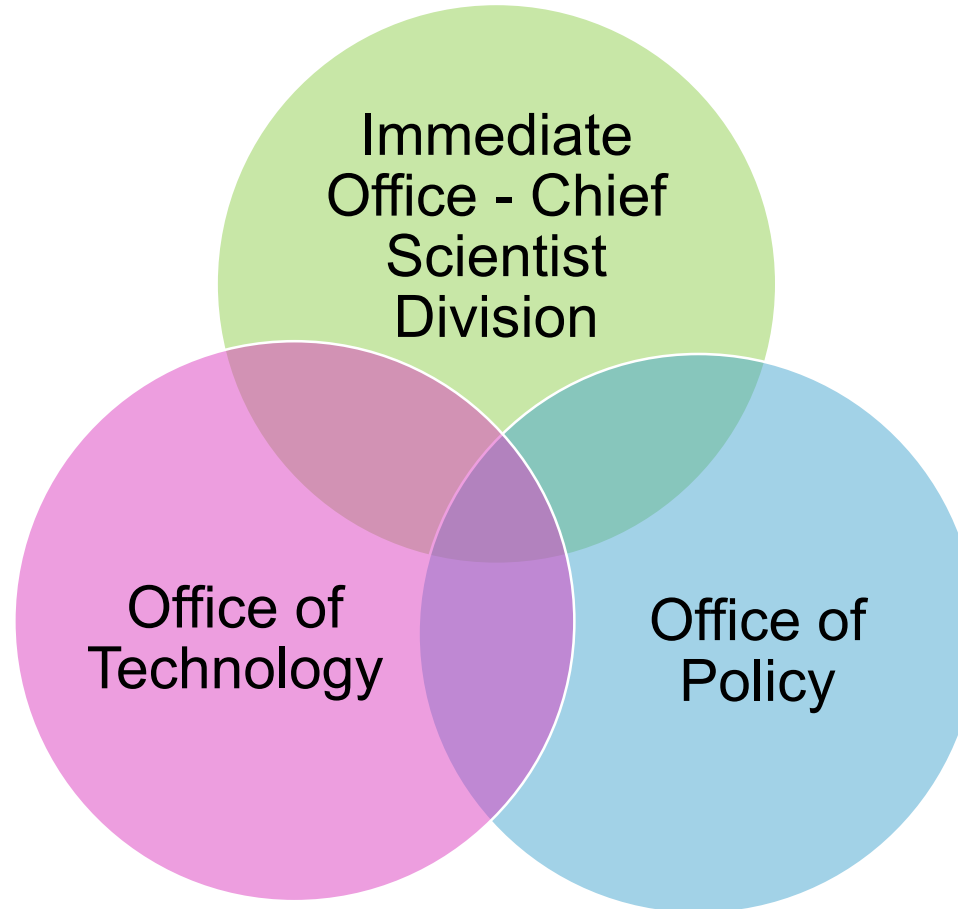
# LEAP in Health IT



Addresses well-documented and emerging challenges inhibiting the development, use and/or advancement of well designed, interoperable health IT scalable across the healthcare industry.

<https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information>

# ONC Coordination for LEAP in Health IT Across Offices



# LEAP Focus Areas

2018

- Expand population-level data-focused APIs
- Advance clinical knowledge at point-of-care

2019

- Implement HL7<sup>®</sup> FHIR<sup>®</sup> Consent Resource
- Enhanced patient engagement technologies for care and research

2020

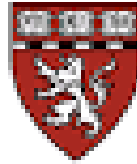
*To Be Determined*

**Significantly enhance the performance of health IT solutions for care and research**

# LEAP 2018 Funded Projects



Boston  
Children's  
Hospital



**Pop Health on FHIR**

**A SMART Approach to  
Universal Healthcare  
Reporting**

**Bulk Data Export**



MedStar Health

**National Center for  
Human Factors in Healthcare**

**Mobilizing a Million Hearts  
- Leveraging Health IT  
Architecture to Advance  
Clinical Knowledge and  
Care Coordination**

# LEAP 2019 Funded Projects



**Scalable Consent  
Framework for the  
Advancement of  
Interoperability with  
FHIR based APIs**



**The University of Texas at Austin**  
**UT Health Austin**

**FHIRRedApp: An API-based  
Patient Engagement  
Platform for the 21st  
Century**



# The Problem



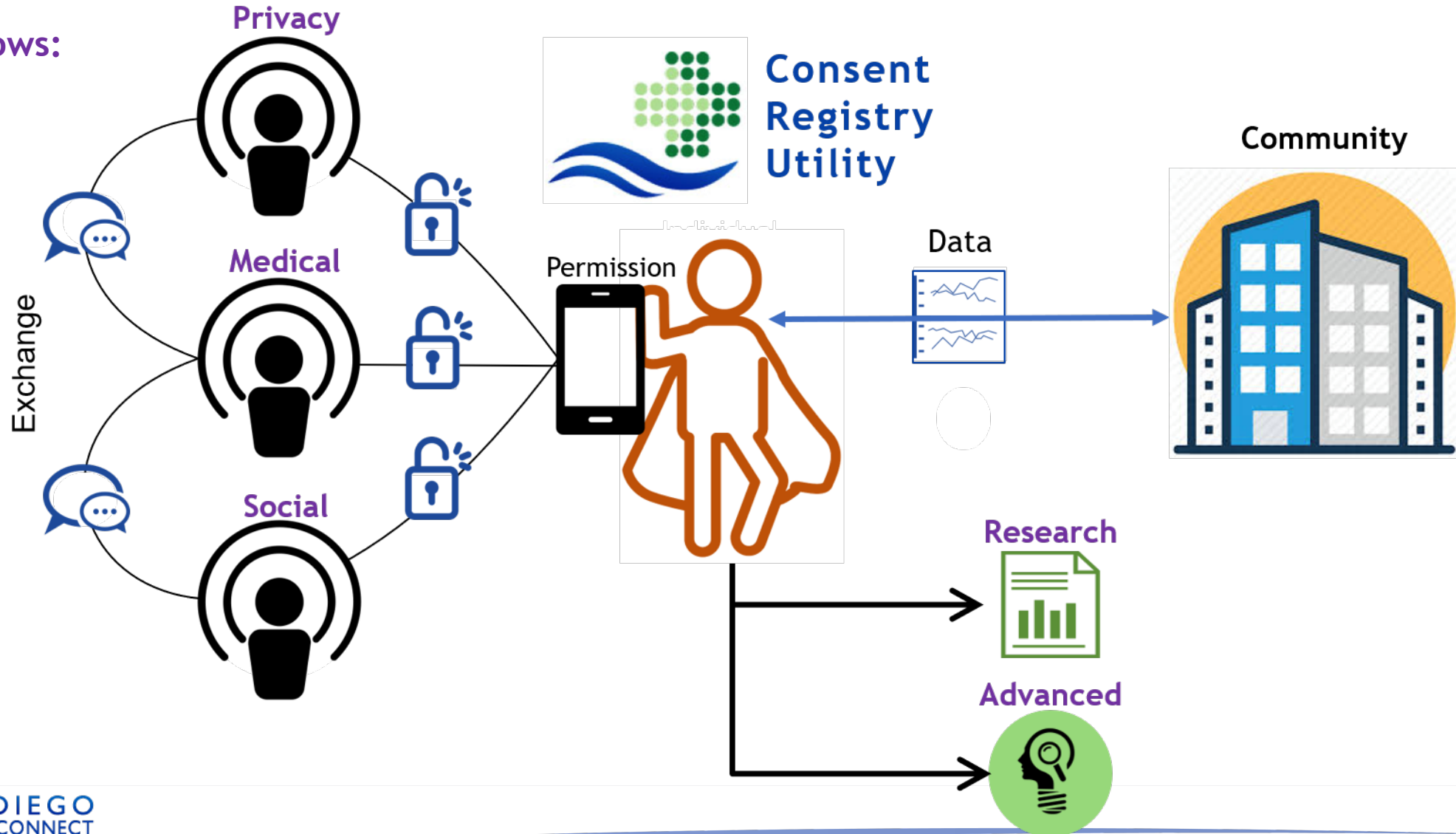
Today, **facilities**, not humans, determine what information is shared with whom, when and under what conditions.





# The Solution

5 Workflows:



# The FHIR Consent Solution

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For each use case will consider applicable CA and Federal laws and regulations governing the form of the:

- Consent
- Contents
- Period of effectiveness
- Description of the info. the consent covers
- Purpose(s) for which the information may be disclosed
- Any restrictions on disclosure
- Timeframe the consent is valid
- Methods for tracking expiration of the consent(or early termination)
- The ability to document additional information necessary to permit the individual to make an informed decision before giving consent



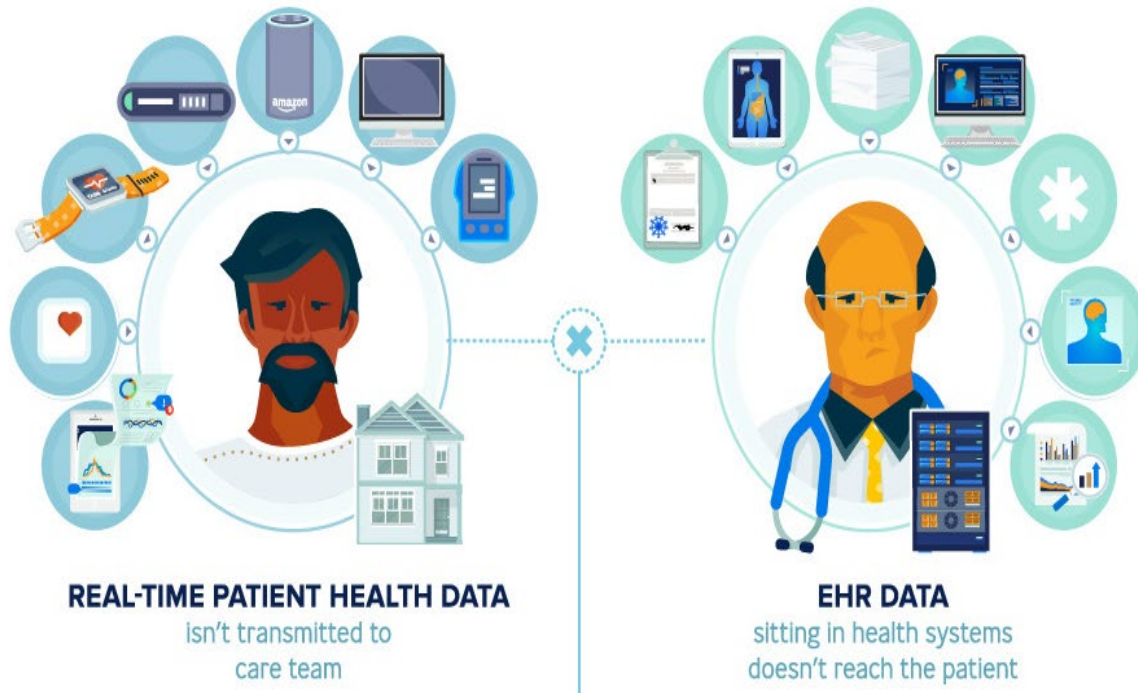
The University of Texas at Austin  
UT Health Austin

# The Problem

Patient's ability to access, share, and contribute relevant healthcare data for medical care and research is limited

Patients and healthcare ecosystems have been largely disconnected for too long.

Patient engagement technologies (PET) are evolving too quickly for patients and providers to keep up with them

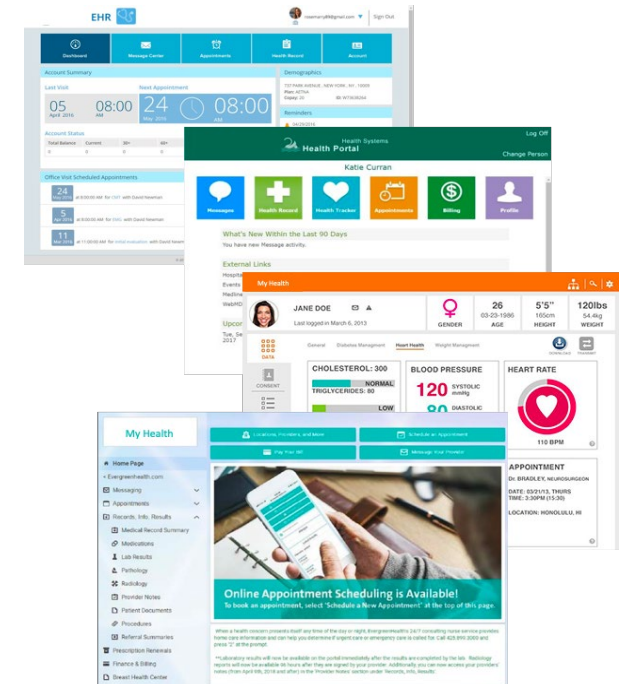


Inconsistent Design  
(lack standardization)

Varied Functionality  
(different info needed)

Multiplicity  
(each provider has one)

Continuously Changing  
(pace of innovation)



# The Solution

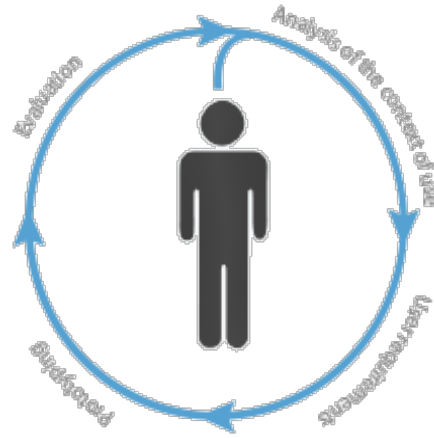
Design, Develop, and Demonstrate patient engagement platform (**FHIRedApp**) to make it **easy** for patients to access and provide access to their data





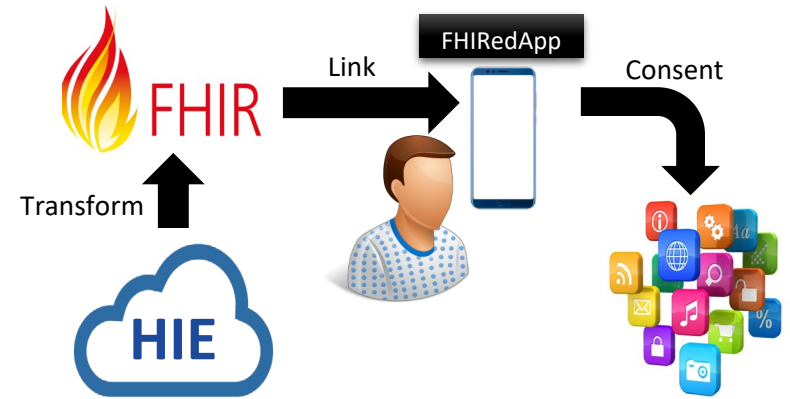
## Community Engagement

- CAB -Community Strategy Team
- CST - Community Advisory Board
- CES - Community Engagement Studios



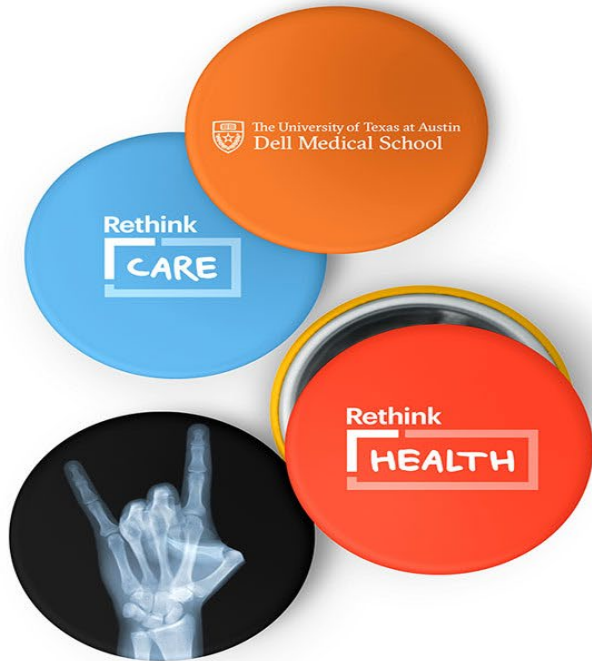
## Use-centered Design

- HIL - Human information interaction Lab
- Generative research phase
- User evaluation phase



## Technical Solution

- Health Information Exchange (HIE) and Patient Reported Outcomes (PRO) data transformed to FHIR
- Use of FHIR APIs
- Privacy Preserving Record Linkage
- Aunt Bertha (social care) + StudyApp (research)



Rethink **COMMUNITY**

Rethink **CARE**

Rethink **HEALTH**

Rethink **Everything**

✉ [anjum.khurshid@austin.utexas.edu](mailto:anjum.khurshid@austin.utexas.edu)

🐦 [@Akhurshid1](https://twitter.com/Akhurshid1)



MedStar Health  
National Center for  
Human Factors in Healthcare



# **ONC LEAP: Mobilizing a Million Hearts: Leveraging Health IT Architecture to Advance Clinical Knowledge and Care Coordination**

**Kristen Miller, DrPH, CPPS**

Scientific Director, National Center for Human Factors in Healthcare, MedStar Health  
Associate Professor of Emergency Medicine, Georgetown University School of Medicine  
Affiliate Faculty, Innovation Center for Biomedical Informatics, Georgetown Medical Center



# Project Aims

ONC Leap addresses well-documented and fast emerging challenges inhibiting the development, use, and/or advancement of well-designed interoperable health information technology. The purpose of the project is to:

1. Support evidence-based clinical cognitive support that prompts management and preventative care.



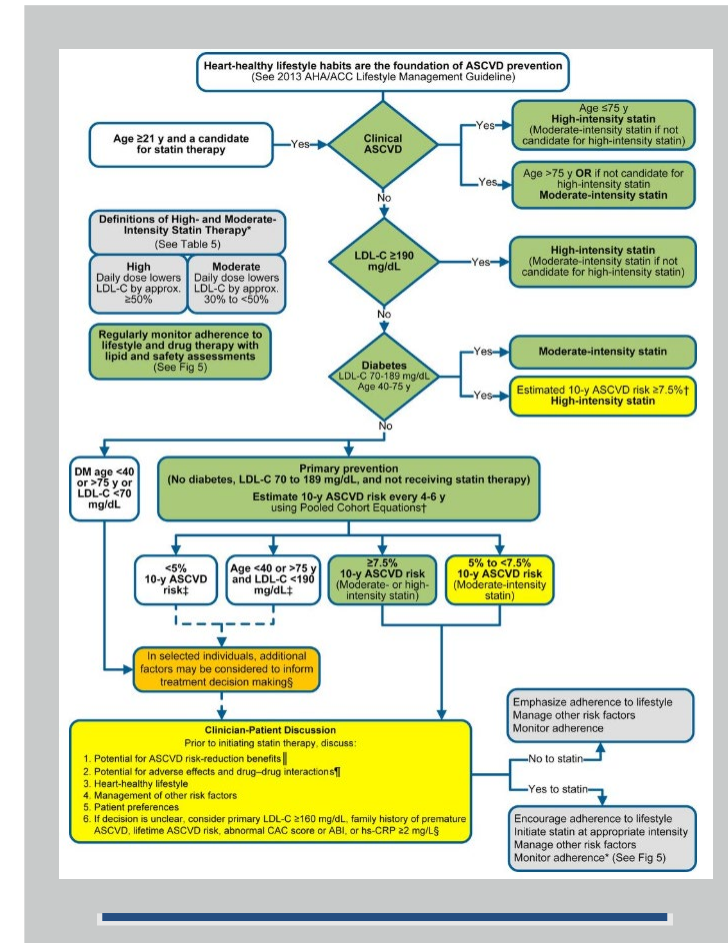
2. Serve as proof-of-concept to transform risk calculators into active surveillance tools leading to guideline based workflow support through SMART on FHIR technology.

3. Leverage the technology to facilitate communication and coordination within providers, and between providers and patients as engaged members of their care with reduced clinical burden.



# Background: Million Hearts

- Cardiovascular disease remains the leading cause of death in the US.
- The American Heart Association and American College of Cardiology recommend use of the Atherosclerotic Cardiovascular Disease (ASCVD) risk estimator: evaluates 10-year and lifetime risk for ASCVD.
- Variables include: age, race, total and high-density lipoprotein (HDL) cholesterol levels, low level lipoprotein (LDL) cholesterol, systolic blood pressure, use of statin therapy, antihypertensive medication, use of aspirin therapy, smoking status, and diabetes status.



# Million Hearts Optimization

ASCVD Risk Estimator\*

10-Year ASCVD Risk: 6.2% calculated risk, 5.2% risk with optimal risk factors\*\*

Lifetime ASCVD Risk: 50% calculated risk, 5% risk with optimal risk factors\*\*

Recommendation Based On Calculation

Gender: Male (selected), Female

Age: 59

Total Cholesterol (mg/dL): 163

HDL - Cholesterol (mg/dL): 80

Treatment for Hypertension: Yes (selected), No

Smoker: Yes, No (selected)

Race: White (selected), African American, Other

Systolic Blood Pressure: 140

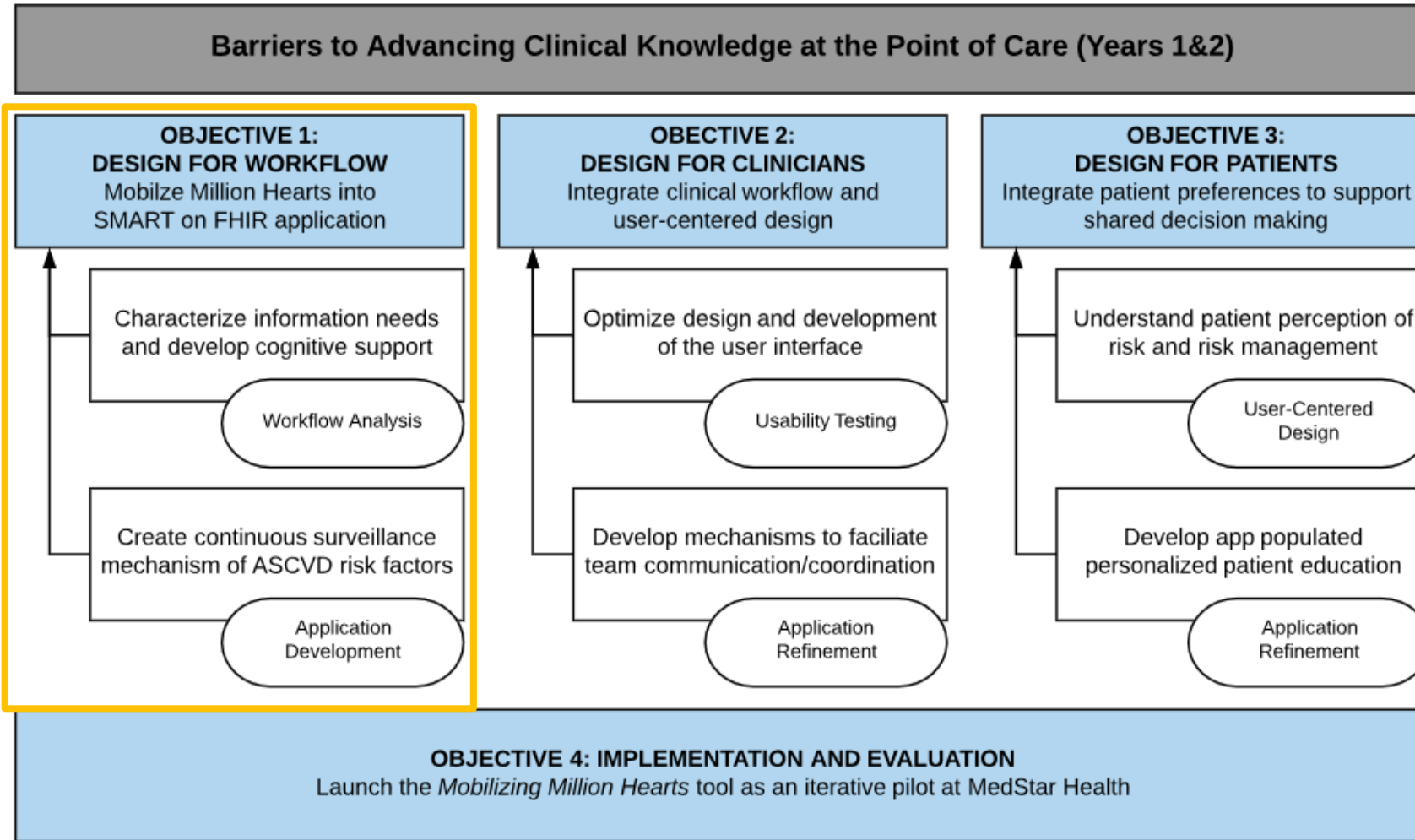
Diabetes: Yes, No (selected)

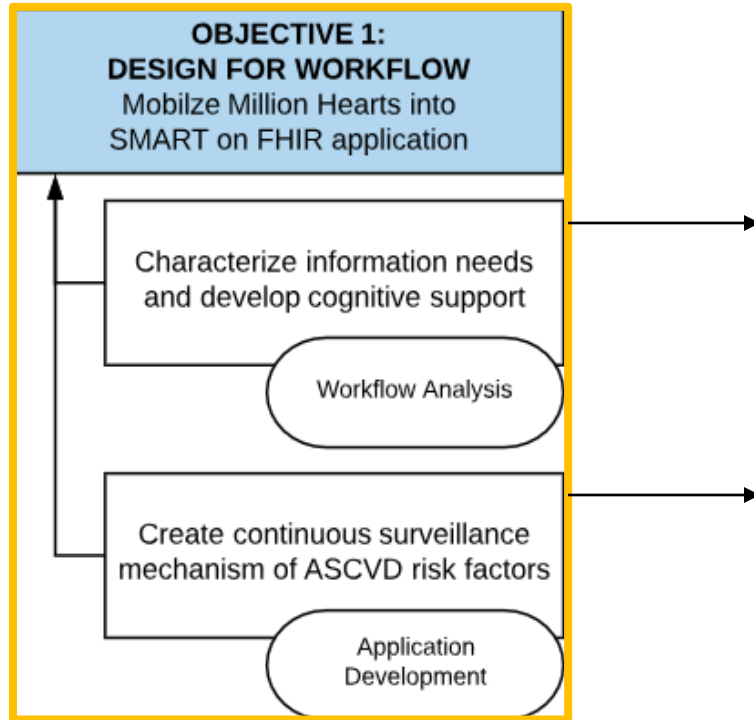
\*Intended for use if there is not ASCVD and the LDL-cholesterol is <190 mg/dL.  
\*\*Optimal risk factors include: Total cholesterol of 170 mg/dL, HDL-cholesterol of 50 mg/dL, Systolic BP of 110 mm Hg, Not taking medications for hypertension, Not a diabetic, Not a smoker

AMERICAN COLLEGE of CARDIOLOGY | American Heart Association  
Published jointly by ACC and AHA | © 2014

Our research addresses the following:

- Optimizing health IT tools that currently exist: removing the burden of active surveillance, pushing technology to bring relevant data to the clinician
- Reducing time required to integrate clinical guidelines at the point of care by leveraging different technological advancements in a single solution
- Developing solutions that are not product centric – our solution sits outside of the EHR and does not rely on the vendor to support modifications
- Developing solutions that are truly integrated into clinician and patient workflow
- Developing scalable solutions that change the way we think about patient data and decision support (multi-layered support and visualizations)

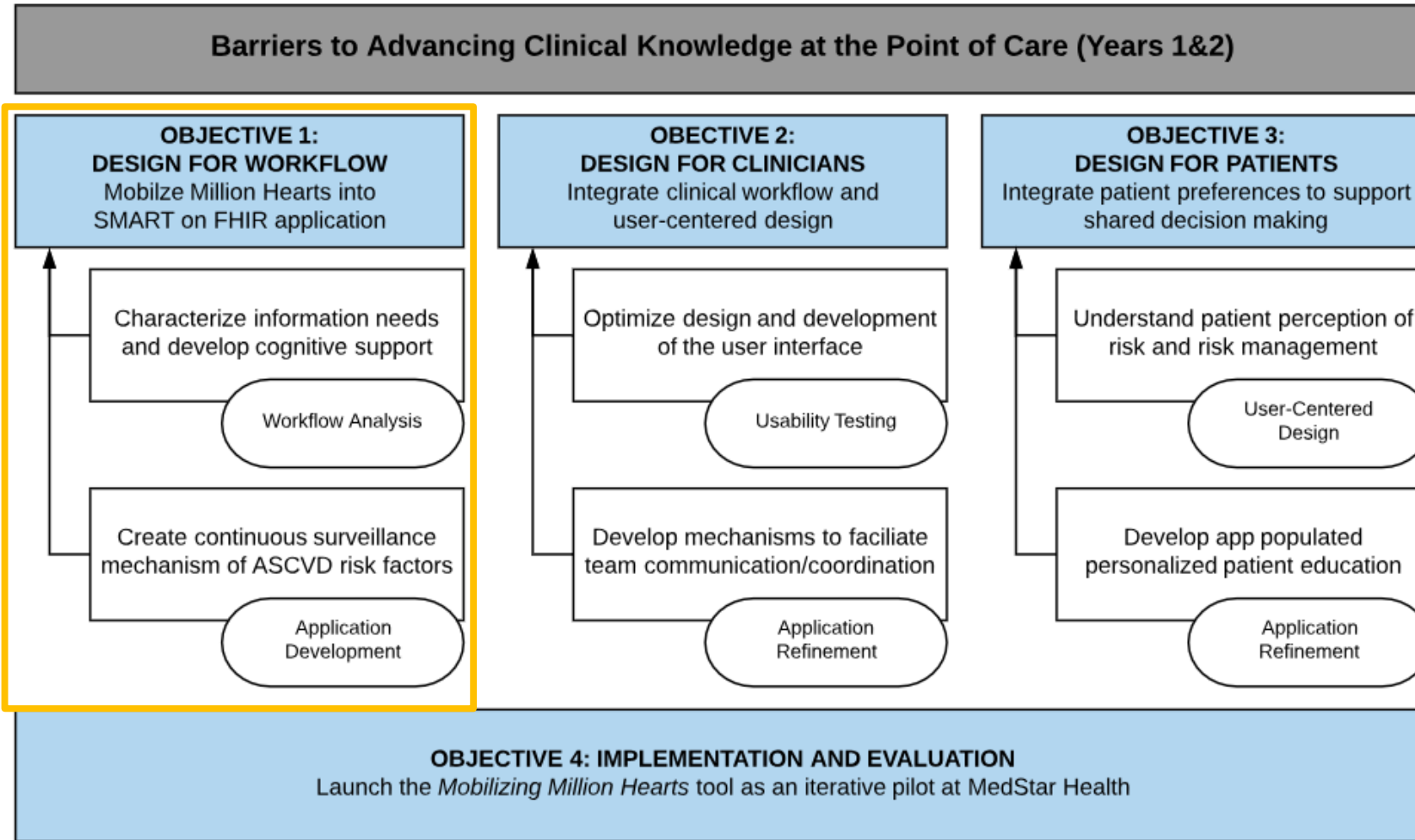




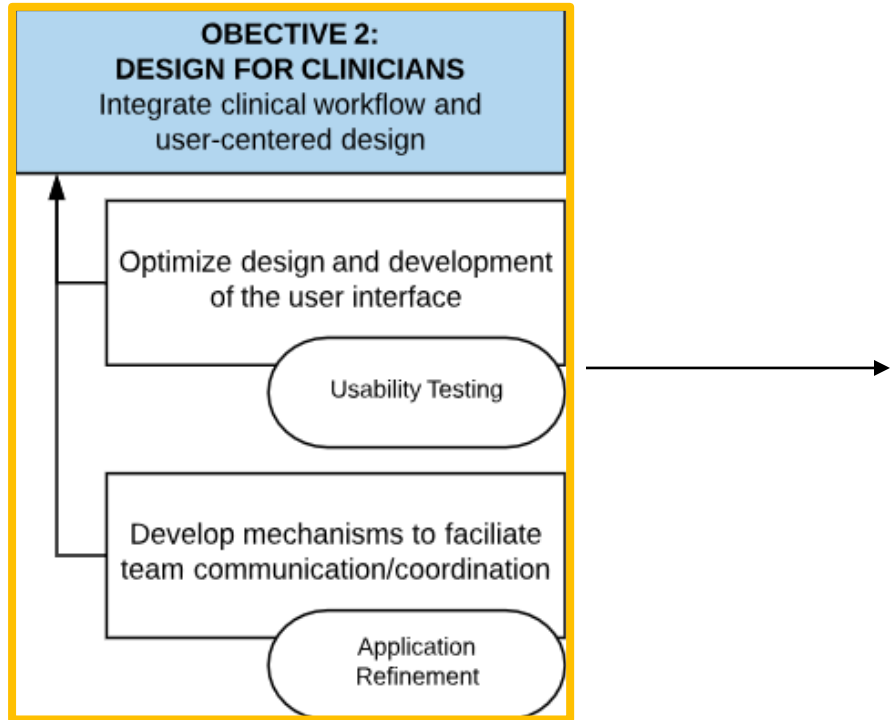
- Systematic literature review initiated of how cardiovascular risk is measured and communicated across various CDS tools.
- Stakeholder interviews and clinical observations to conceptualize and develop thorough workflow analysis.
- Detailed technical specifications mapping desired prototype functions to features to technical capabilities. These specifications were developed by the research team and delivered to the technical team to guide prototyping.
- Finalizing of visual mockups to illustrate UX needs and to incorporate technical specifications into a visual reference for the technical team to guide prototyping.

# Technical Specifications (sample)

Features of Dynamic Risk Educator		
Function	Feature	Tech
<b>Calculate &amp; Recalculate scores</b>	<ul style="list-style-type: none"><li>• Auto populate.<ul style="list-style-type: none"><li>◦ Auto populate risk score and patient values into dynamic risk calculator.</li></ul></li><li>◦ Option for MD to free type and edit value.</li><li>◦ Option for MD to use a slider bar within validated ranges to change values.</li><li>• Auto populate the Yes/No boxes for hypertension treatment, on a statin, etc. have ability when opened.</li></ul>	FHIR and CCL Call, MSH  FHIR and UX
<b>Display</b>	<ul style="list-style-type: none"><li>• Clear indication that this dynamic calculator does NOT write to record.</li><li>• Consider reference ranges tailored to individuals' demographic baseline and comorbidities.</li><li>• Consider different graphic representations of risk besides bar.</li></ul>	*MPage with custom component FHIR
<b>Date stamp</b>	<ul style="list-style-type: none"><li>• Show time frame of when data was captured next to each lab value.</li><li>• Hover over for specific date.</li></ul>	*FHIR
<b>Patient Portal</b>	<ul style="list-style-type: none"><li>• Explore integration potential.</li></ul>	...
<b>Educational Engagement</b>	<ul style="list-style-type: none"><li>• Discharge summaries.</li><li>• Links to education resources (diet, exercise, smoking cessation programs, etc.).</li></ul>	...
<b>Risk Level Indicators</b>	<ul style="list-style-type: none"><li>• Explore risk bar to provide context and “best case” scenario.</li></ul>	App Programming

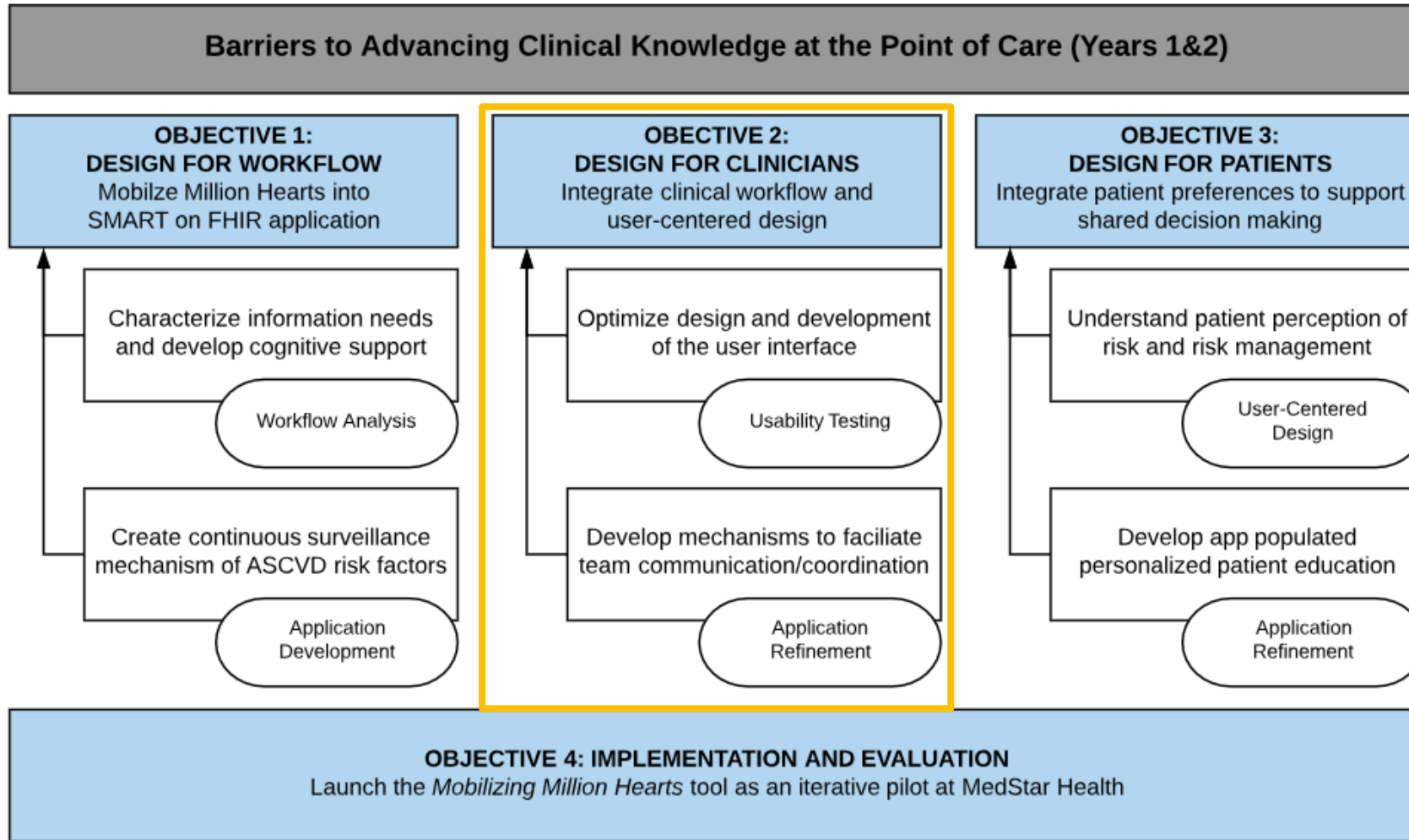


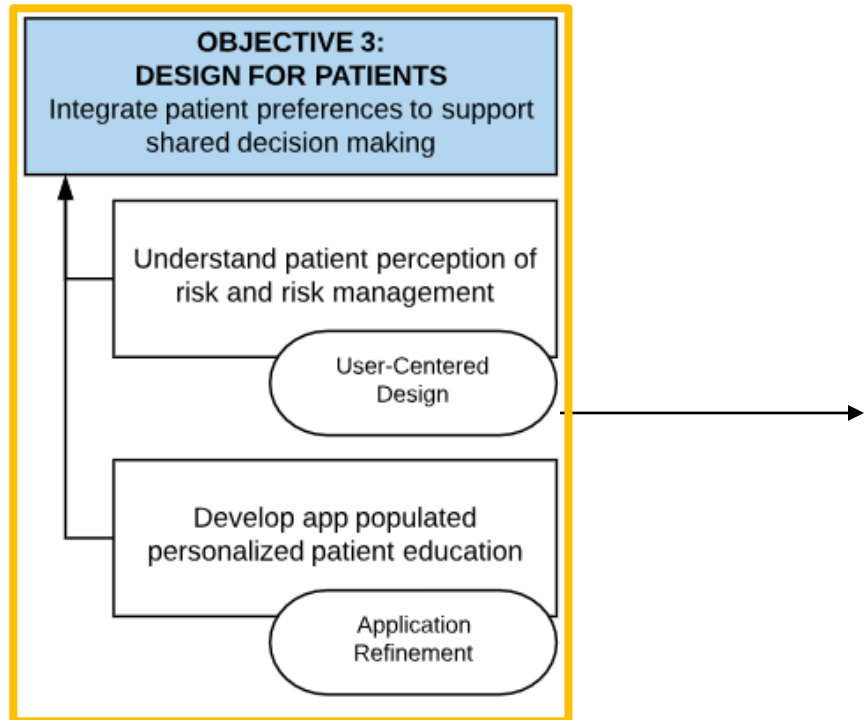




## Usability Testing Methods:

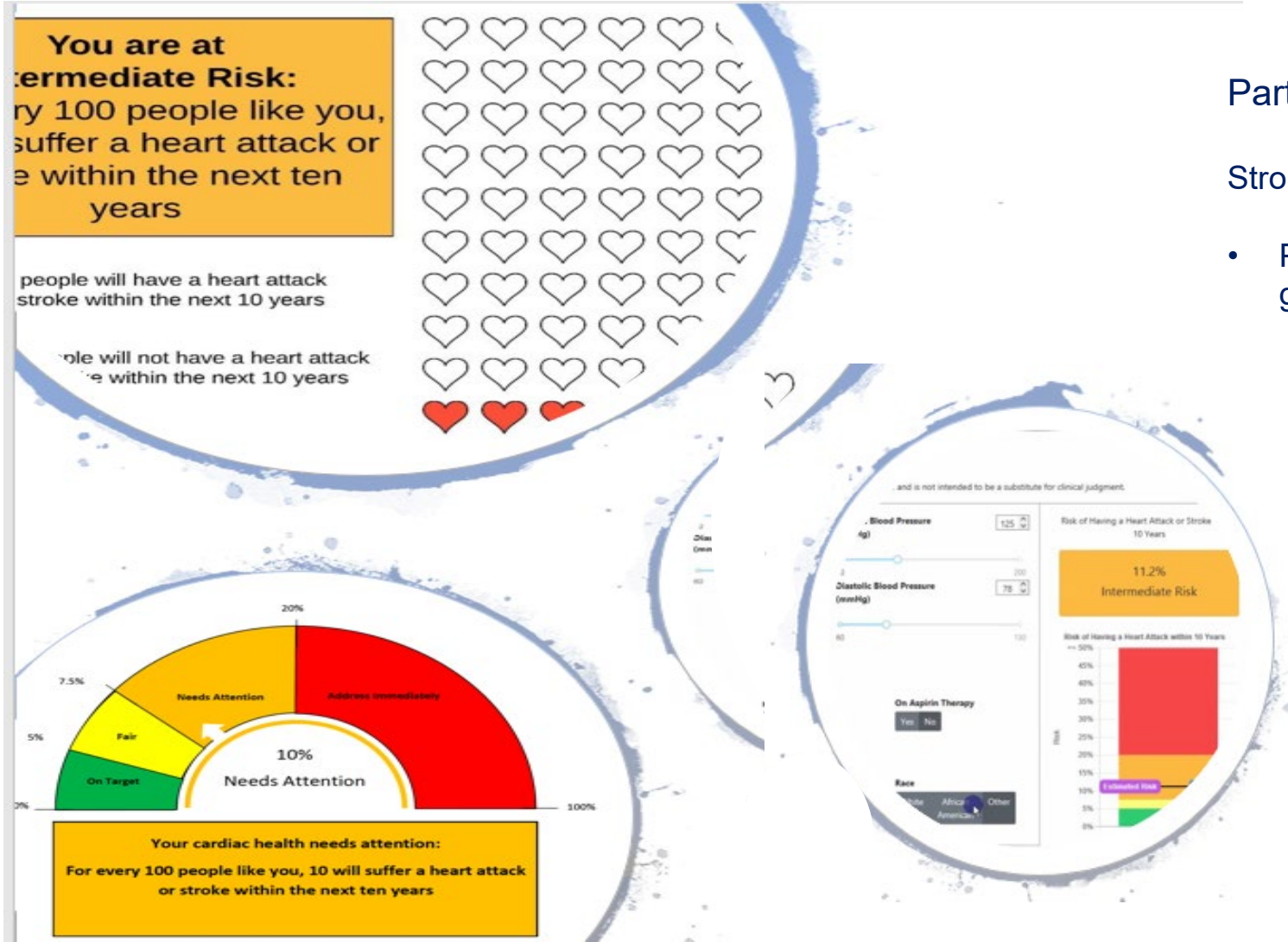
- Stakeholder Interactions with Prototype and Interview
  - 8 Cardiologists
  - 7 Primary Care Physicians
  - Eye Tracking
- Data Analysis
  - Qualitative Coding
  - Video Analysis
- Synthesis
  - Revision of prototype functions and specifications





## User-Feedback Methods

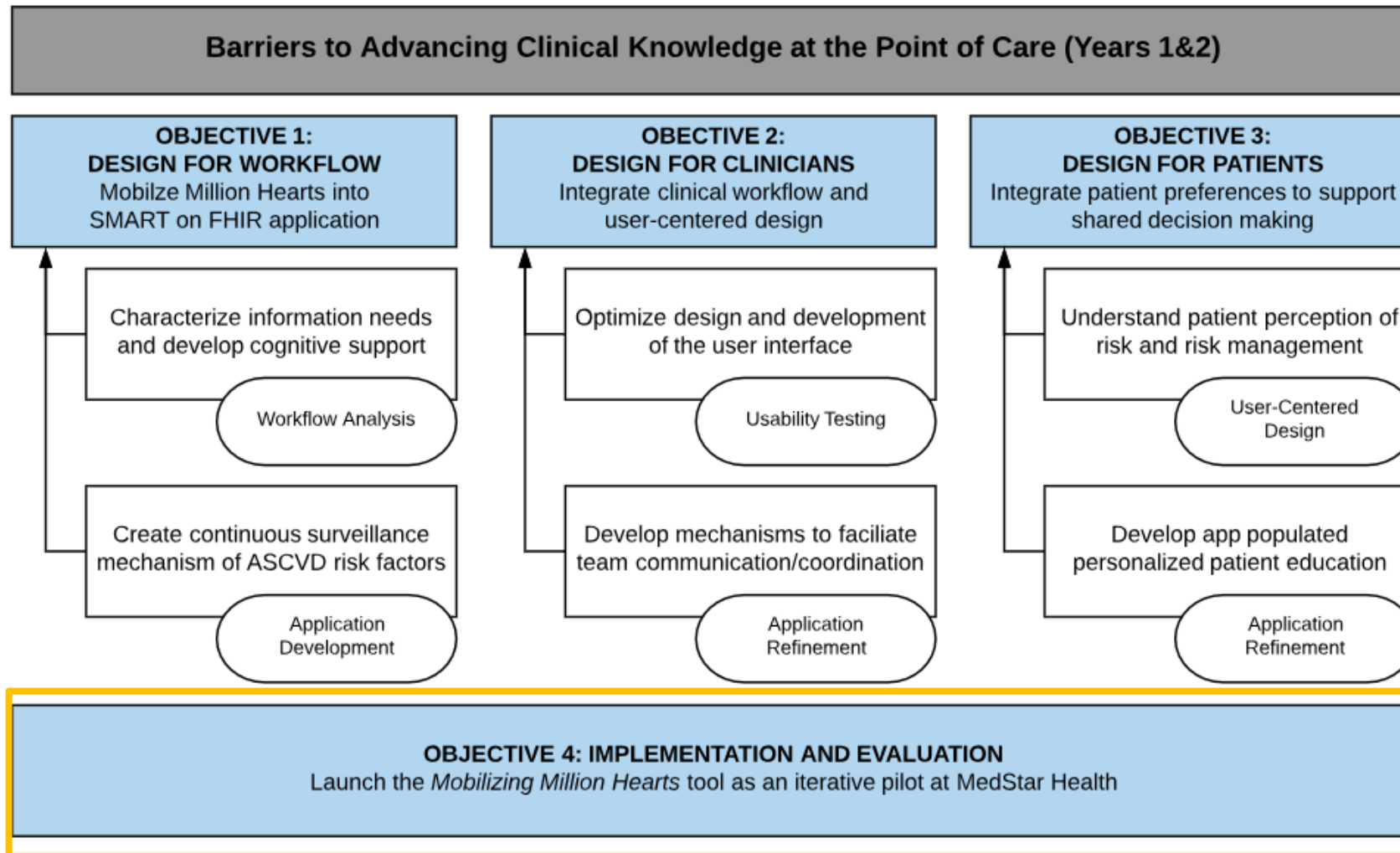
- Stakeholder Interactions with Different Prototypes and Interview
  - 9 Patients
  - 3 Prototypes
- Interviews focused on patient understanding and engagement with their cardiovascular health
- Data Analysis
  - Qualitative Coding
- Synthesis
  - Revision of prototype functions and specifications



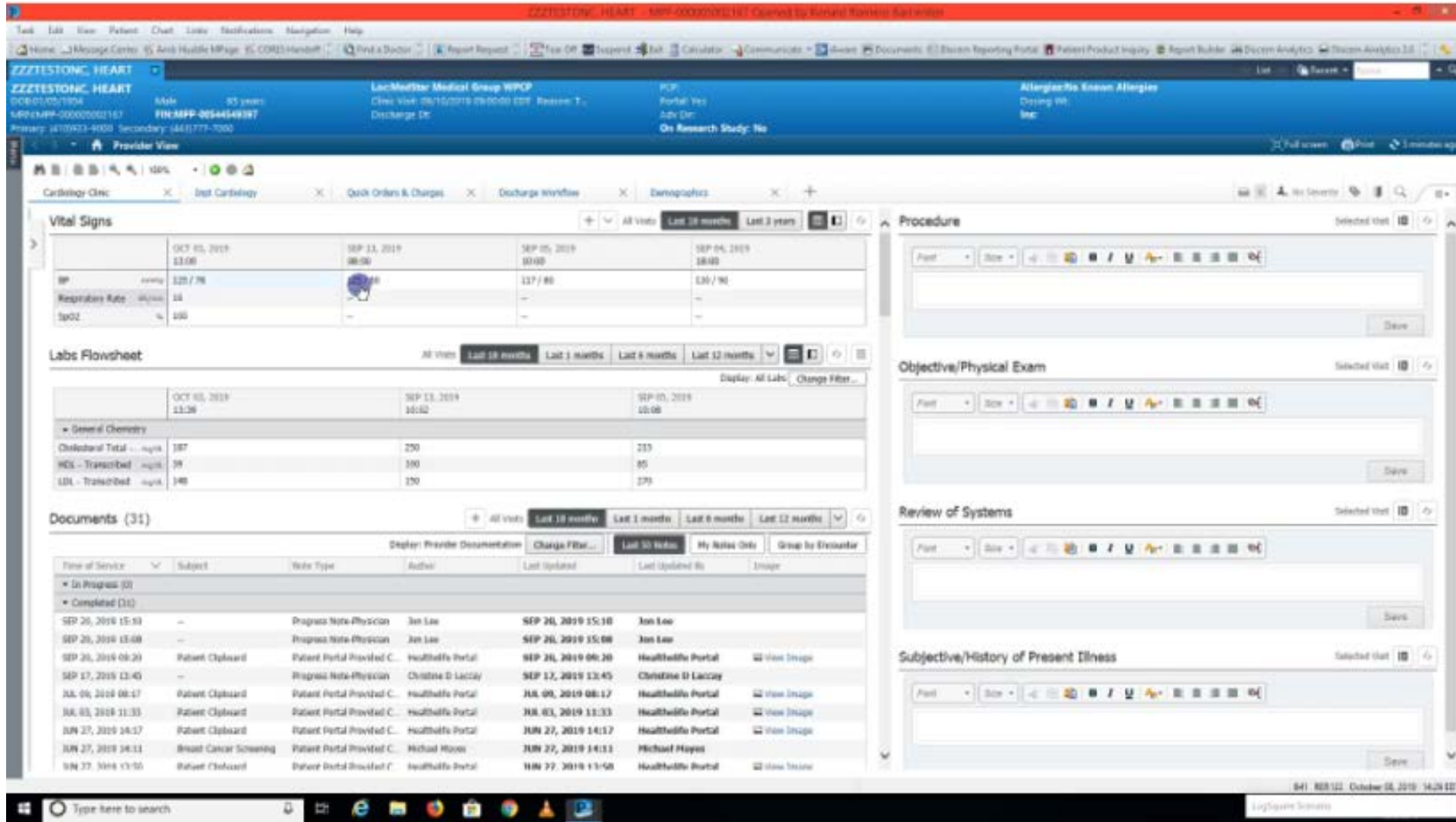
## Participant Feedback

Strong preference for:

- Personalized displays that provide actionable steps and guidance aligning with their care plan
- Translating numeric risk into words (qualitative interpretation of output)
- Access to tools outside of care visit



# Current State ASCVD Risk Calculation



**ZZZTESTONIC, HEART**  
 DOB: 01/05/1954 Male 65 years  
 MRN: MPP-00000001167 FIN: MPP-0004649987  
 Primary: 4410903-9008 Secondary: 4410777-7000

**LachMitar Medical Group WPO**  
 Clin Visit: 09/15/2019 09:00:00 EDT Review: T...  
 Discharge: Dr.

**PCP:** Portal: Yes Adv: Dr. On Research Study: No  
**Allergies:** Known Allergies: Driving Wt, Inc.

**Vital Signs** (All Vitals | Last 12 months | Last 3 years)

	OCT 05, 2019 13:08	SEP 13, 2019 08:06	SEP 05, 2019 03:00	SEP 04, 2019 18:00
BP	120 / 76	110 / 60	137 / 80	130 / 70
Respiratory Rate	14	-	-	-
SpO2	100	-	-	-

**Labs Flowsheet** (All Vitals | Last 12 months | Last 1 month | Last 6 months | Last 12 months)

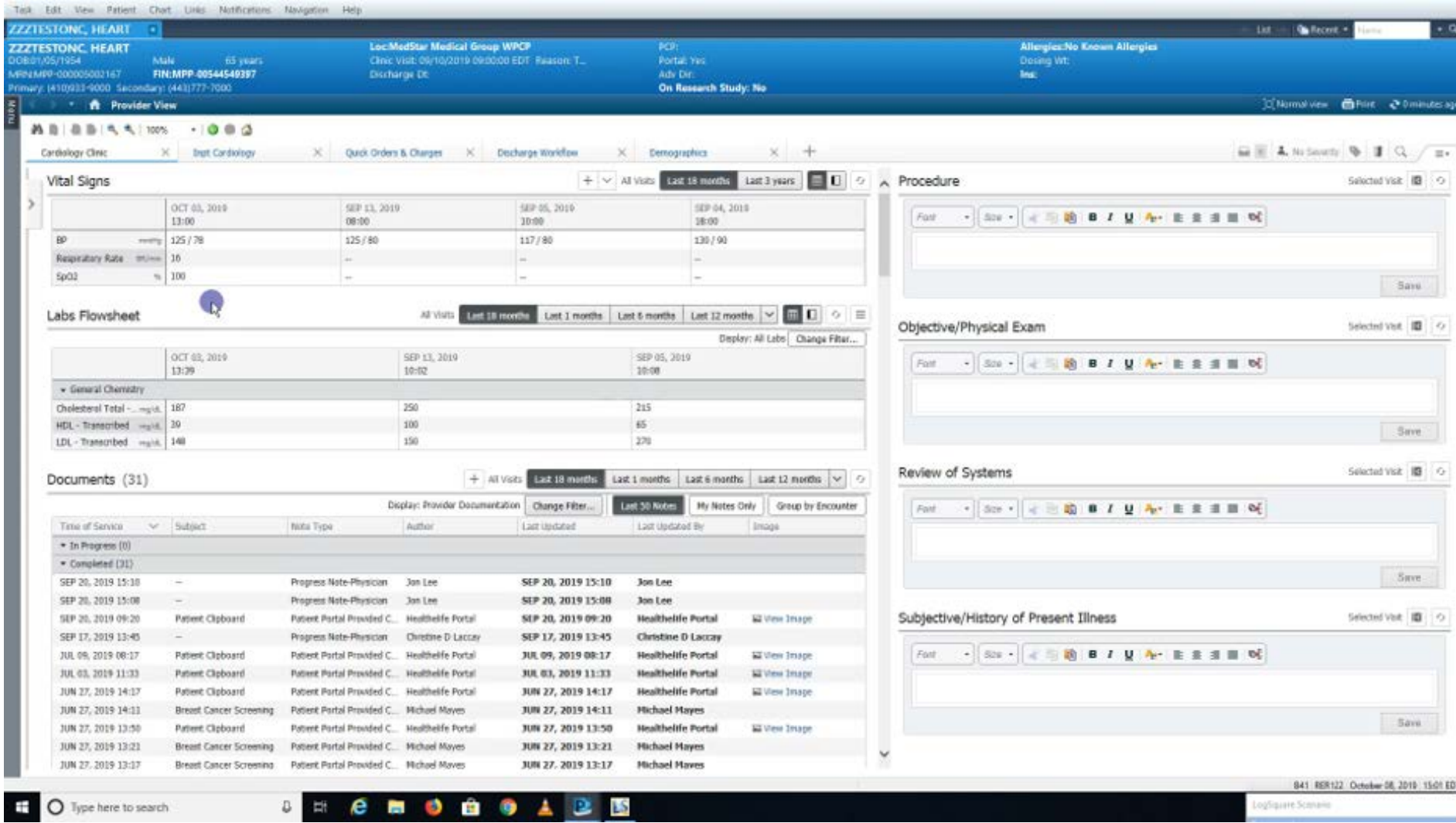
	OCT 05, 2019 13:08	SEP 13, 2019 10:02	SEP 05, 2019 10:00
<b>General Chemistry</b>			
Cholesterol Total	187	200	233
HDL - Transferred	39	100	85
LDL - Transferred	148	100	179

**Documents (31)** (All Vitals | Last 12 months | Last 1 month | Last 6 months | Last 12 months)

Time of Service	Subject	Note Type	Author	Last Updated	Last Updated By	Image
SEP 26, 2019 15:11	-	Progress Note-Physician	Jon Lee	SEP 26, 2019 15:18	Jon Lee	
SEP 26, 2019 13:08	-	Progress Note-Physician	Jon Lee	SEP 26, 2019 13:08	Jon Lee	
SEP 26, 2019 09:26	Patient Clipboard	Patient Portal Provided C.	HealthLife Portal	SEP 26, 2019 09:26	HealthLife Portal	View Image
SEP 17, 2019 13:40	-	Progress Note-Physician	Christine D Laccay	SEP 17, 2019 13:45	Christine D Laccay	
JUL 06, 2019 08:17	Patient Clipboard	Patient Portal Provided C.	HealthLife Portal	JUL 09, 2019 08:17	HealthLife Portal	View Image
JUL 03, 2019 11:33	Patient Clipboard	Patient Portal Provided C.	HealthLife Portal	JUL 03, 2019 11:33	HealthLife Portal	View Image
JUN 27, 2019 14:17	Patient Clipboard	Patient Portal Provided C.	HealthLife Portal	JUN 27, 2019 14:17	HealthLife Portal	View Image
JUN 27, 2019 14:11	Breast Cancer Screening	Patient Portal Provided C.	Michael Hayes	JUN 27, 2019 14:11	Michael Hayes	
JUN 27, 2019 13:50	Patient Clipboard	Patient Portal Provided C.	HealthLife Portal	JUN 27, 2019 13:50	HealthLife Portal	View Image

841 808102 October 08, 2019 14:24 EDT  
 Log Square Sciences

# Mobilizing Million Hearts Future State



**ZZZTESTONIC, HEART**  
 DOB: 05/19/54 Male 65 years  
 MRN: MPP-00005002147 RN: MPP-00544540397  
 Primary: (410)933-9000 Secondary: (443)777-7000

Loc: MedStar Medical Group WPCP  
 Clinic Visit: 09/10/2019 09:00:00 EDT Reason: T...  
 Discharge Dc:

PCP:  
 Portal: Yes  
 Adv Dir:  
 On Research Study: No

Allergies: No Known Allergies  
 Dosing Wt:  
 Ins:

**Vital Signs**  
 All Visits | Last 18 months | Last 3 years

	OCT 03, 2019 13:00	SEP 13, 2019 08:00	SEP 26, 2019 10:00	SEP 04, 2019 18:00
BP <small>mmHg</small>	125 / 78	125 / 80	117 / 80	130 / 90
Respiratory Rate <small>breaths/min</small>	16	--	--	--
SpO2 <small>%</small>	100	--	--	--

**Labs Flowsheet**  
 All Visits | Last 18 months | Last 1 month | Last 6 months | Last 12 months | Display: All Labs | Change Filter...

	OCT 03, 2019 13:29	SEP 13, 2019 10:02	SEP 05, 2019 10:08
<b>General Chemistry</b>			
Cholesterol Total <small>mg/dL</small>	187	250	215
HDL - Transferred <small>mg/dL</small>	30	100	65
LDL - Transferred <small>mg/dL</small>	148	150	270

**Documents (31)**  
 All Visits | Last 18 months | Last 1 month | Last 6 months | Last 12 months | Display: Provider Documentation | Change Filter... | Last 30 Notes | My Notes Only | Group by Encounter

Title of Service	Subject	Note Type	Author	Last Updated	Last Updated By	Image
<b>In Progress (0)</b>						
<b>Completed (31)</b>						
SEP 26, 2019 15:10	--	Progress Note-Physician	Jon Lee	SEP 26, 2019 15:10	Jon Lee	
SEP 26, 2019 15:08	--	Progress Note-Physician	Jon Lee	SEP 26, 2019 15:08	Jon Lee	
SEP 26, 2019 09:20	Patient Clipboard	Patient Portal Provided C.	Healthlife Portal	SEP 26, 2019 09:20	Healthlife Portal	
SEP 17, 2019 13:40	--	Progress Note-Physician	Christine D Laccay	SEP 17, 2019 13:45	Christine D Laccay	
JUL 09, 2019 08:17	Patient Clipboard	Patient Portal Provided C.	Healthlife Portal	JUL 09, 2019 08:17	Healthlife Portal	
JUL 03, 2019 11:33	Patient Clipboard	Patient Portal Provided C.	Healthlife Portal	JUL 03, 2019 11:33	Healthlife Portal	
JUN 27, 2019 14:17	Patient Clipboard	Patient Portal Provided C.	Healthlife Portal	JUN 27, 2019 14:17	Healthlife Portal	
JUN 27, 2019 14:11	Breast Cancer Screening	Patient Portal Provided C.	Michael Mayes	JUN 27, 2019 14:11	Michael Mayes	
JUN 27, 2019 13:50	Patient Clipboard	Patient Portal Provided C.	Healthlife Portal	JUN 27, 2019 13:50	Healthlife Portal	
JUN 27, 2019 13:21	Breast Cancer Screening	Patient Portal Provided C.	Michael Mayes	JUN 27, 2019 13:21	Michael Mayes	
JUN 27, 2019 13:17	Breast Cancer Screening	Patient Portal Provided C.	Michael Mayes	JUN 27, 2019 13:17	Michael Mayes	

**Procedure**  
 Selected Visit | Font | Size | Save

**Objective/Physical Exam**  
 Selected Visit | Font | Size | Save

**Review of Systems**  
 Selected Visit | Font | Size | Save

**Subjective/History of Present Illness**  
 Selected Visit | Font | Size | Save

841 RER122 October 08, 2019 15:01 EDT  
 LogSquare Screens

# Clinician-Facing ASCVD Risk Estimator

## ASCVD Risk Estimator

This calculation is based on asymptomatic, normative population samples and is not intended to be a substitute for clinical judgment.

<b>Last Updated:</b>	6 days ago	<b>Last Updated:</b>	6 days ago	Risk of Having a Heart Attack or Stroke within 10 Years
<b>Total Cholesterol (mg/dL):</b>	187	<b>Systolic Blood Pressure (mmHg):</b>	125	
<b>HDL Cholesterol (mg/dL):</b>	39	<b>Diastolic Blood Pressure (mmHg):</b>	78	<b>11.2%</b> Intermediate Risk
<b>LDL Cholesterol (mg/dL):</b>	148			
<b>Age:</b>	65	<b>History of Diabetes:</b>	No	<b>Write Score to Record</b>
<b>Sex:</b>	Male	<b>Smoker:</b>	No	
<b>Race:</b>	Other			
<b>Hypertension Treatment:</b>	No			
<b>Statin:</b>	No			
<b>Aspirin Therapy:</b>	Yes			

Quick Links: [Clinical Guidelines](#) [ASCVD Risk Educator](#)



# Clinician-Facing ASCVD Risk Estimator

## ASCVD Risk Estimator

This calculation is based on asymptomatic, normative population samples and is not intended to be a substitute for clinical judgment.

<b>Last Updated:</b> 6 days ago <b>Total Cholesterol:</b> Thursday, October 03, 2019 187	<b>Last Updated:</b> 6 days ago <b>Systolic Blood Pressure (mmHg):</b> 125	<b>Risk of Having a Heart Attack or Stroke within 10 Years</b>  <b>11.2%</b> <b>Intermediate Risk</b>  <b>Write Score to Record</b>
<b>HDL Cholesterol (mg/dL):</b> 39	<b>Diastolic Blood Pressure (mmHg):</b> 78	
<b>LDL Cholesterol (mg/dL):</b> 148		
<b>Age:</b> 65	<b>History of Diabetes:</b> No	
<b>Sex:</b> Male	<b>Smoker:</b> No	
<b>Race:</b> Other		
<b>Hypertension Treatment:</b> No		
<b>Statin:</b> No		
<b>Aspirin Therapy:</b> Yes		

Quick Links: [Clinical Guidelines](#) [ASCVD Risk Educator](#)

# Clinician-Facing ASCVD Risk Estimator

## ASCVD Risk Estimator

This calculation is based on asymptomatic, normative population samples and is not intended to be a substitute for clinical judgment.

<b>Last Updated:</b> 6 days ago		<b>Last Updated:</b> 6 days ago		Risk of Having a Heart Attack or Stroke within Score Submission
<b>Total Cholesterol (mg/dL):</b> 187	<b>Systolic Blood Pressure (mmHg):</b> 125	<b>HDL Cholesterol (mg/dL):</b> 39	<b>Diastolic Blood Pressure (mmHg):</b> 78	
<b>LDL Cholesterol (mg/dL):</b> 148	<b>Age:</b> 65	<b>History of Diabetes:</b> No	<b>Smoker:</b> No	<input type="button" value="Close"/> <input type="button" value="Submit"/>
<b>Sex:</b> Male	<b>Race:</b> Other	<b>Hypertension Treatment:</b> No	<b>Statin:</b> No	
<b>Aspirin Therapy:</b> Yes	<b>Quick Links:</b> <a href="#">Clinical Guidelines</a>		<a href="#">ASCVD Risk Educator</a>	

# Patient-Facing ASCVD Risk Educator

## ASCVD Risk Educator

[Back to Estimator](#)

This calculation is based on asymptomatic, normative population samples and is not intended to be a substitute for clinical judgment.

**Total Cholesterol (mg/dL)** 206

**Systolic Blood Pressure (mmHg)** 138

**HDL Cholesterol (mg/dL)** 39

**Diastolic Blood Pressure (mmHg)** 78

**LDL Cholesterol (mg/dL)** 148

**On Hypertensive Treatment** Yes No

**On a Statin** Yes No

**On Aspirin Therapy** Yes No

**History of Diabetes** Yes No

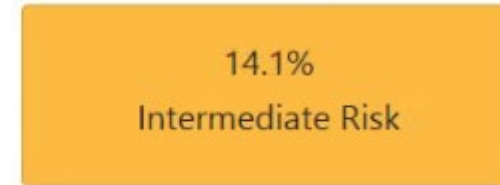
**Smoker** Yes Former No

**Current Age** 65

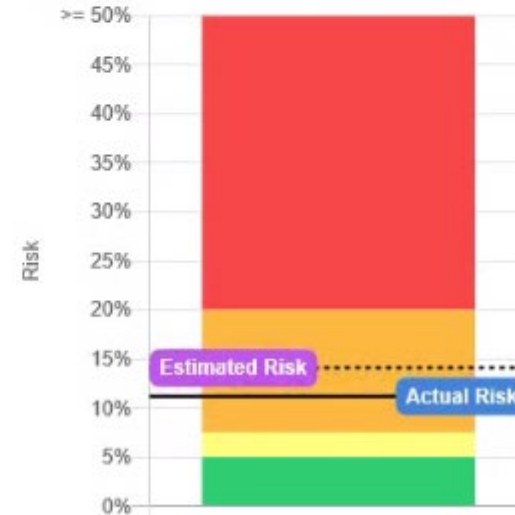
**Sex** Female Male

**Race** White African American Other

Risk of Having a Heart Attack or Stroke within 10 Years



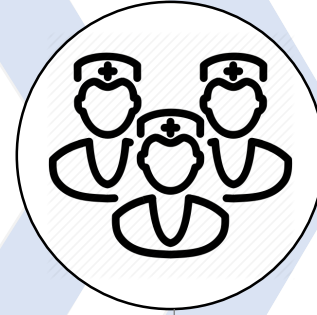
Risk of Having a Heart Attack within 10 Years





### 3 Month Pilot

- **System Outcomes**  
(usage, API calls, load time)
- **Provider Outcomes**  
(surveys, video capture, interviews)



### 6 Month Pilot

- **Developer Outcomes**  
(technical challenges, resources)
- **Patient Outcomes**  
(preference, usability)

**OBJECTIVE 4: IMPLEMENTATION AND EVALUATION**  
Launch the *Mobilizing Million Hearts* tool as an iterative pilot at MedStar Health

# Challenges to Date

## Strategic

- Optimizing inputs from multiple stakeholders and perspectives
- Validation costs and IT security challenges

## Legal/ Ethical

- Personalizing population-level risk prediction
- Legal liability

## Technical

- Applying SMART on FHIR and CDS Hooks solutions to systems that have not (yet) adopted
- Not all the desired data can easily and consistently be found in the FHIR resources (or may be documented in multiple places)
- SMART-on-FHIR apps behave differently within Cerner depending on the “profile”.

### ASCVD Risk Estimator

This calculation is based on asymptomatic, normative population samples and is not intended to be a substitute for clinical judgment.

Last Updated:	6 days ago	Last Updated:	6 days ago
Total Cholesterol (mg/dL):	187	Systolic Blood Pressure (mmHg):	125
HDL Cholesterol (mg/dL):	39	Diastolic Blood Pressure (mmHg):	78
LDL Cholesterol (mg/dL):	148		

Age:	65	History of Diabetes:	No
Sex:	Male	Smoker:	No
Race:	Other		

Hypertension Treatment:	No
Statin:	No
Aspirin Therapy:	Yes

Quick Links: [Clinical Guidelines](#) [ASCVD Risk Educator](#)

Risk of Having a Heart Attack or Stroke within 10 Years

11.2%  
Intermediate Risk

Write Score to Record

### ASCVD Risk Educator

[Back to Estimator](#)

This calculation is based on asymptomatic, normative population samples and is not intended to be a substitute for clinical judgment.

**Total Cholesterol (mg/dL)**    
 130  320

**HDL Cholesterol (mg/dL)**    
 20  100

**LDL Cholesterol (mg/dL)**    
 30  300

**Systolic Blood Pressure (mmHg)**    
 90  200

**Diastolic Blood Pressure (mmHg)**    
 60  130

**On Hypertensive Treatment**  Yes  No

**On a Statin**  Yes  No

**On Aspirin Therapy**  Yes  No

**History of Diabetes**  Yes  No

**Smoker**  Yes  Former  No

**Current Age**

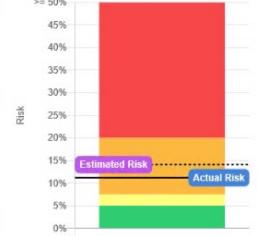
**Sex**  Female  Male

**Race**  White  African American  Other

Risk of Having a Heart Attack or Stroke within 10 Years

14.1%  
Intermediate Risk

Risk of Having a Heart Attack within 10 Years



# Thank you!

Kristen Miller  
 kristen.e.miller@medstar.net



# **ONC LEAP: Mobilizing a Million Hearts: Leveraging Health IT Architecture to Advance Clinical Knowledge and Care Coordination**

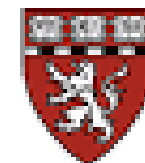
**Kristen Miller, DrPH, CPPS**

Scientific Director, National Center for Human Factors in Healthcare, MedStar Health  
Associate Professor of Emergency Medicine, Georgetown University School of Medicine  
Affiliate Faculty, Innovation Center for Biomedical Informatics, Georgetown Medical Center





Boston Children's Hospital







Leading Edge Acceleration Projects (LEAP)  
SMART/HL7 Bulk Data Export  
**Population  
Health on FHIR**

Kenneth D. Mandl, MD, MPH

Director, Computational Health Informatics Program  
Boston Children's Hospital

Donald A.B. Lindberg Professor of Pediatrics  
Professor of Biomedical Informatics  
Harvard Medical School

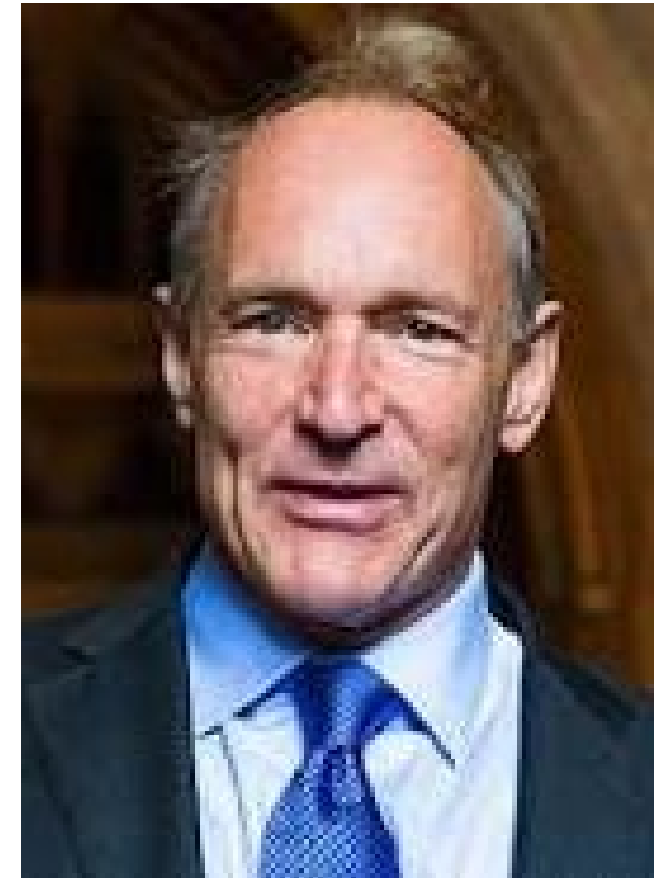
 @mandl

# Disclosure

I and my spouse/partner have no relevant relationships with commercial interests to disclose.

# Invention of the World Wide Web

- Built over the existing TCP and IP protocols, it consisted of 4 building blocks:
- A textual format to represent hypertext documents, the *HyperText Markup Language* (HTML).
- A simple protocol to exchange these documents, the *Hypertext Transfer Protocol* (HTTP).
- A client to display these documents, the first Web browser called *WorldWideWeb*.
- A server to give access to the document, an early version of *httpd*.



# Problem #1

**Apps don't  
connect to health systems data**

But has been hard to use the point of care





## The NEW ENGLAND JOURNAL of MEDICINE

### No Small Change for the Health Information Economy

Kenneth D. Mandl, M.D., M.P.H., and Isaac S. Kohane, M.D., Ph.D.

The economic stimulus package signed by President Barack Obama on February 17 included a \$19 billion investment in health information technology. How can we best take advantage of this unprecedented opportunity to computerize health care and stimulate the health information economy while also stimulating the U.S. economy? A health care system adapting to the effects of an aging population, growing expenditures, and a diminishing primary care workforce needs the support

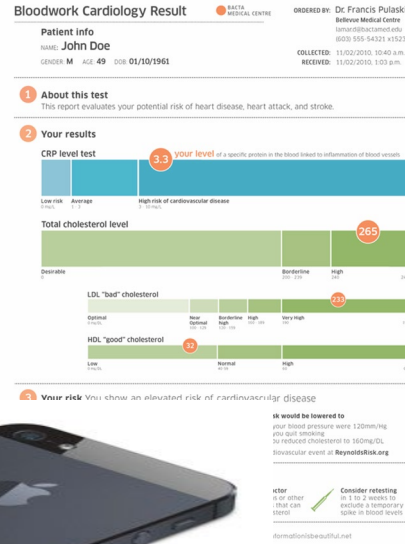
of a flexible information infrastructure that facilitates innovation in wellness, health care, and public health.

Flexibility is critical, since the system will have to function under new policies and in the service of new health care delivery mechanisms, and it will need to incorporate emerging information technologies on an ongoing basis. As we seek to design a system that will constantly evolve and encourage innovation, we can glean lessons from large-scale information-

technology successes in other fields. An essential first lesson is that ideally, system components should be not only interoperable but also substitutable.

The Apple iPhone, for example, uses a software platform with a published interface that allows software developers outside Apple to create applications; there are now nearly 10,000 applications that consumers can download and use with the common phone interface. The platform separates the system from the functional-

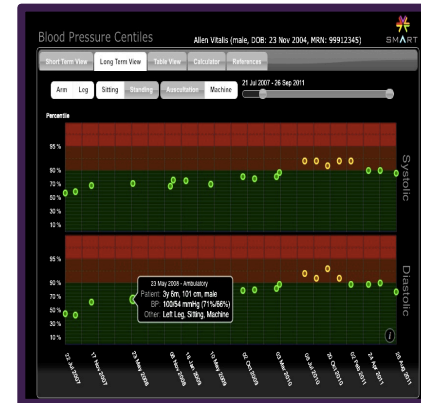
# Designing the app store for health



## No Small Change for the Health Information Economy

Kenneth D. Mandl, M.D., M.P.H., and Isaac S. Kohane, M.D., Ph.D.

The economic stimulus package signed by President Barack Obama on February 17 included a \$19 billion investment in health information technology. How can we best take advantage of this unprecedented opportunity to computerize health care and stimulate the health information economy while also stimulating the U.S. economy? A health care system adapting to the effects of an aging population, growing expenditures, and a diminishing primary care workforce needs the support of a flexible information infrastructure that facilitates innovation in wellness, health care, and public health. Flexibility is critical, since the system will have to function under new policies and in the service of new health care delivery mechanisms, and it will need to incorporate emerging information technologies on an ongoing basis. As we seek to design a system that will constantly evolve and encourage innovation, we can glean lessons from large-scale information technology successes in other fields. An essential first lesson is that ideally, system components should be not only interoperable but also substitutable. The Apple iPhone, for example, uses a software platform with a published interface that allows software developers outside Apple to create applications; there are now nearly 10,000 applications that consumers can download and use with the common phone interface. The platform separates the system from the functional-





regulation, and Policy > Notice of Proposed Rulemaking to Improve the Interoperability of Health Inform



## Notice of Proposed Rulemaking to Improve the Interoperability of Health Information

The U.S. Department of Health and Human Services (HHS) recently proposed a new rule to support seamless and secure access, exchange, and use of electronic health information (EHI).

The proposed rule is designed to increase innovation and competition by giving patients and their healthcare providers secure access to health information and new tools, allowing for more choice in care and treatment. It calls on the healthcare industry to adopt standardized application programming interfaces (APIs), which will help allow individuals to securely and easily access structured EHI using smartphone applications.



The proposed rule places a strong focus on a patient's ability to access their health information through a provision requiring that patients can electronically access all of their EHI (structured and/or unstructured) at no cost. Finally, to further support access and exchange of EHI, the proposed rule implements the information blocking provisions of the Cures Act. The rule proposes seven exceptions to the definition of information blocking.

**The public comment period is now open for the proposed rule.** We value all of your feedback – both positive and negative as it helps inform the rulemaking process. Below are the steps to submitting your comments:

[Download the Proposed Rule \[PDF - 3.2 MB\]](#)

[Comment on the Proposed Rule](#)

*Comments on the proposed rule are due by 11:59 pm ET on May 3, 2019.*

### Fact Sheets on the Proposed Rule



Implementation of Cures Act and Executive Orders [PDF - 1.4 MB]



Conditions and Maintenance of Certification Requirements [PDF - 805 KB]



Information Blocking – Summaries of the 7 Exceptions [PDF - 578 KB]



# Parsimonious Standards to Create Interop



1.  
SUBSTITUTABLE  
APPS



2. TRIGGER-ABLE  
DECISION  
SUPPORT



3. PATIENT-  
GENERATED  
DATA



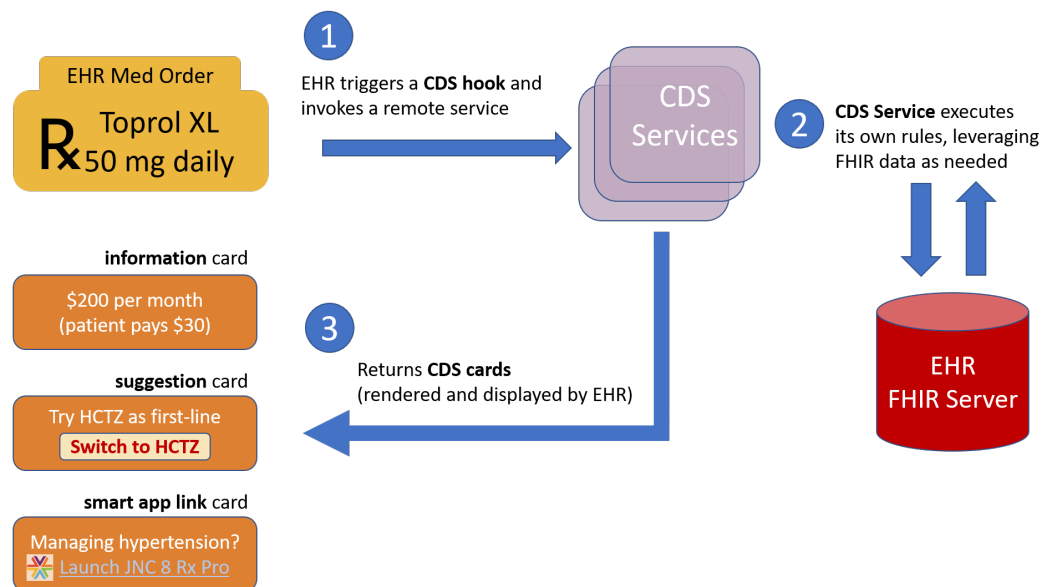
4. PUSH BUTTON  
POPULATION  
HEALTH

## Problem #2

**Can't launch apps  
at just the right moment**

# Triger-able decision support

## CDS HOOKS®

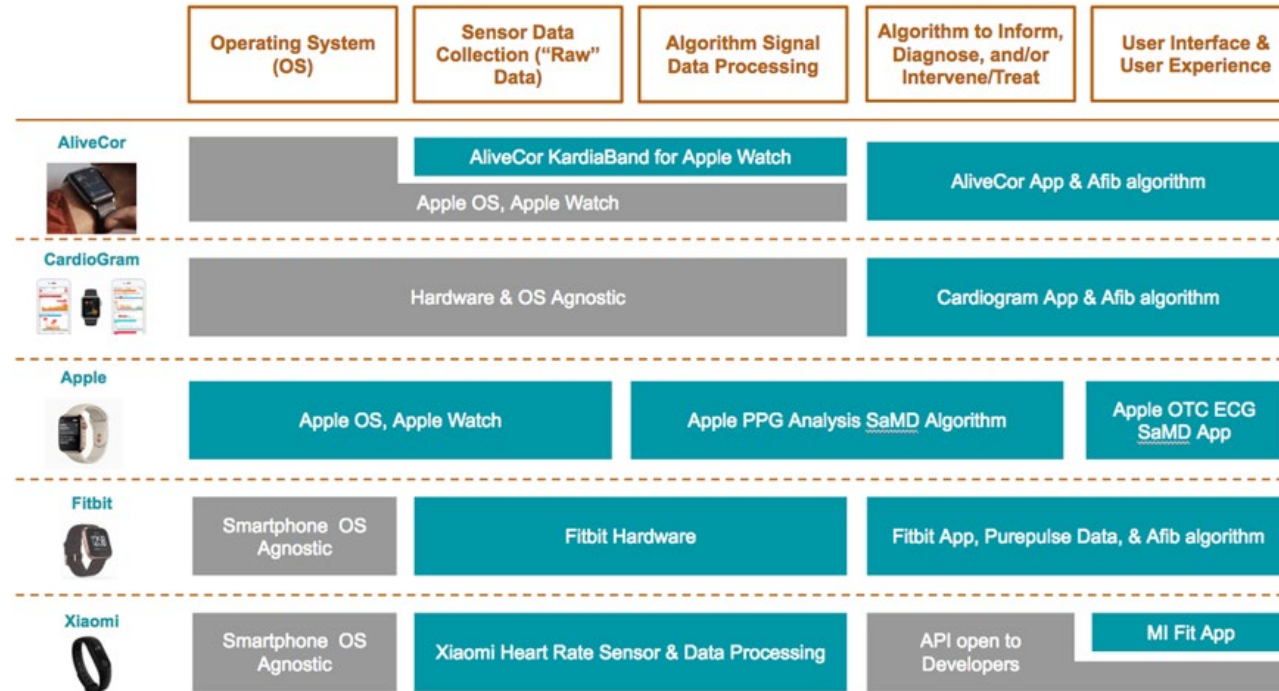


## Problem #3

**Patient generated data are  
non-standardized and in a separate silo**

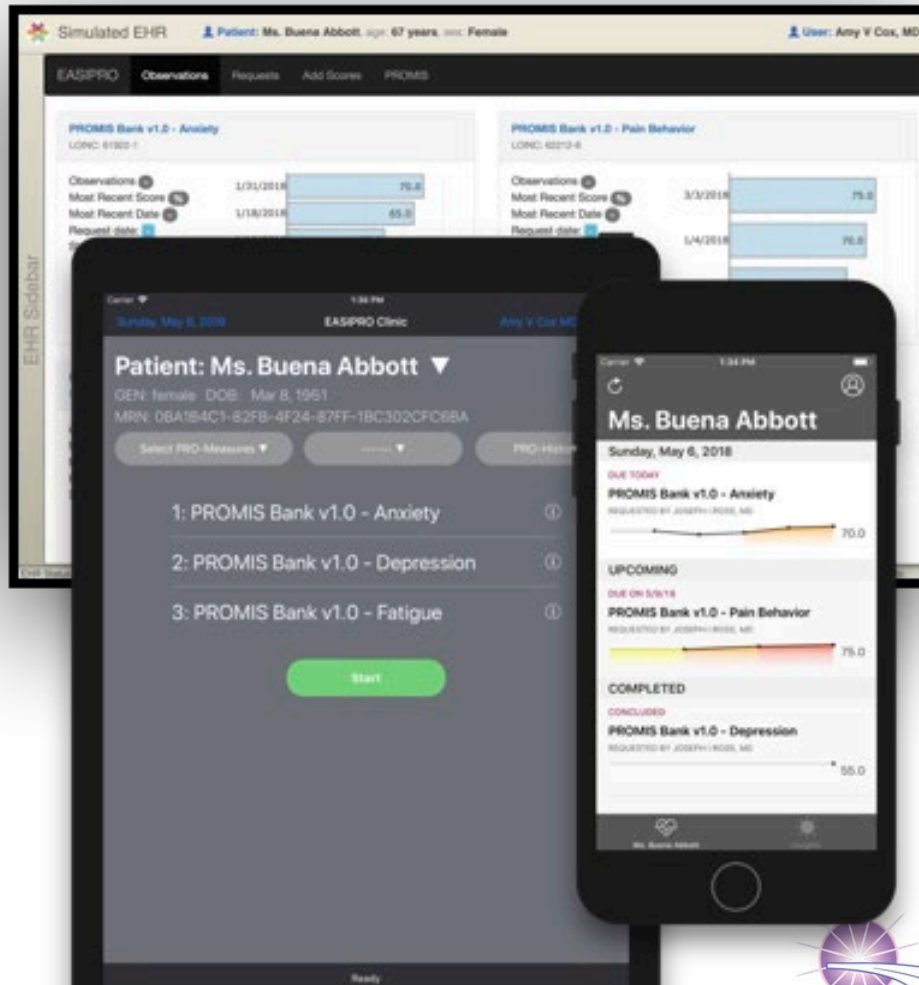
**Modularity of software and sensor products to detect atrial fibrillation through connected technologies**

■ Software built and maintained by listed manufacturer  
 ■ Software built and maintained by third party

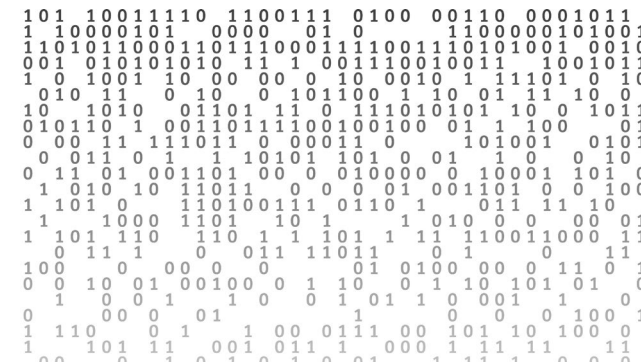


**NPG Digital Medicine 2019**

# Interoperable, PRO apps—patient or provider generated



SMART Markers  
(coming soon)



## Problem #4

**Getting data out of EHRs**

**into analytic platforms tends to require specialized teams**

# Manual Reporting, Duplication

- Hospital IT needs to create reports on the same data in hundreds of different formats (many of those data are in the [USCDI](#))



## Genomics research effort to use \$8.5M grant to expand data sharing

By Fred Bazzoli

October 24, 2019, 2:54 p.m. EDT



Three large pediatric hospitals plan to use proceeds of a National Institutes of Health grant to expand and extend their data-sharing collaboration to other facilities.

The \$8.5 million grant to the Genomics Research and Innovation Network (GRIN) will covers several years of efforts to expand it into a larger federation of medical centers that are able to share large amounts of genomic information while protecting patient privacy.

The grant comes from NIH's National Center for Advancing Translational Sciences.



Open

ARTICLE | Genetics in Medicine



## The Genomics Research and Innovation Network: creating an interoperable, federated, genomics learning system

Kenneth D. Mandl, MD, MPH <sup>1,2,3</sup>, Tracy Glauser, MD <sup>4,5</sup>, Ian D. Krantz, MD <sup>6,7</sup>, Paul Avillach, MD, PhD <sup>1,2</sup>, Anna Bartels, MScPH <sup>8</sup>, Alan H. Beggs, PhD <sup>3,9,10</sup>, Sawona Biswas, MS, CGC <sup>6</sup>, Florence T. Bourgeois, MD, MPH <sup>1,3,10</sup>, Jeremy Corsmo, MPH <sup>5,11</sup>, Andrew Dauber, MD, MMSc <sup>5,12</sup>, Batsal Devkota, PhD <sup>13</sup>, Gary R. Fleisher, MD <sup>3,10</sup>, Allison P. Heath, PhD <sup>13</sup>, Ingo Helbig, MD <sup>7,14,15</sup>, Joel N. Hirschhorn, MD, PhD <sup>3,16,17</sup>, Judson Kilbourn <sup>1</sup>, Sek Won Kong, MD <sup>1,3</sup>, Susan Kornetsky, MPH <sup>18</sup>, Joseph A. Majzoub, MD <sup>3,10,16</sup>, Keith Marsolo, PhD <sup>19</sup>, Lisa J. Martin, PhD <sup>5,20</sup>, Jeremy Nix, BS <sup>21</sup>, Amy Schwarzhoff, MS, MBA <sup>23</sup>, Jason Stedman, BA <sup>2</sup>, Arnold Strauss, MD <sup>5,24</sup>, Kristen L. Sund, PhD, MS <sup>20</sup>, Deanne M. Taylor, PhD <sup>7,14</sup>, Peter S. White, PhD <sup>5,21,22</sup>, the Genomics Research and Innovation Network

**Purpose:** Clinicians and researchers must contextualize a patient's genetic variants against population-based references with detailed phenotyping. We sought to establish globally scalable technology, policy, and procedures for sharing biosamples and associated genomic and phenotypic data on broadly consented cohorts, across sites of care.

**Methods:** Three of the nation's leading children's hospitals launched the Genomic Research and Innovation Network (GRIN), with federated information technology infrastructure, harmonized biobanking protocols, and material transfer agreements. Pilot studies in epilepsy and short stature were completed to design and test the collaboration model.

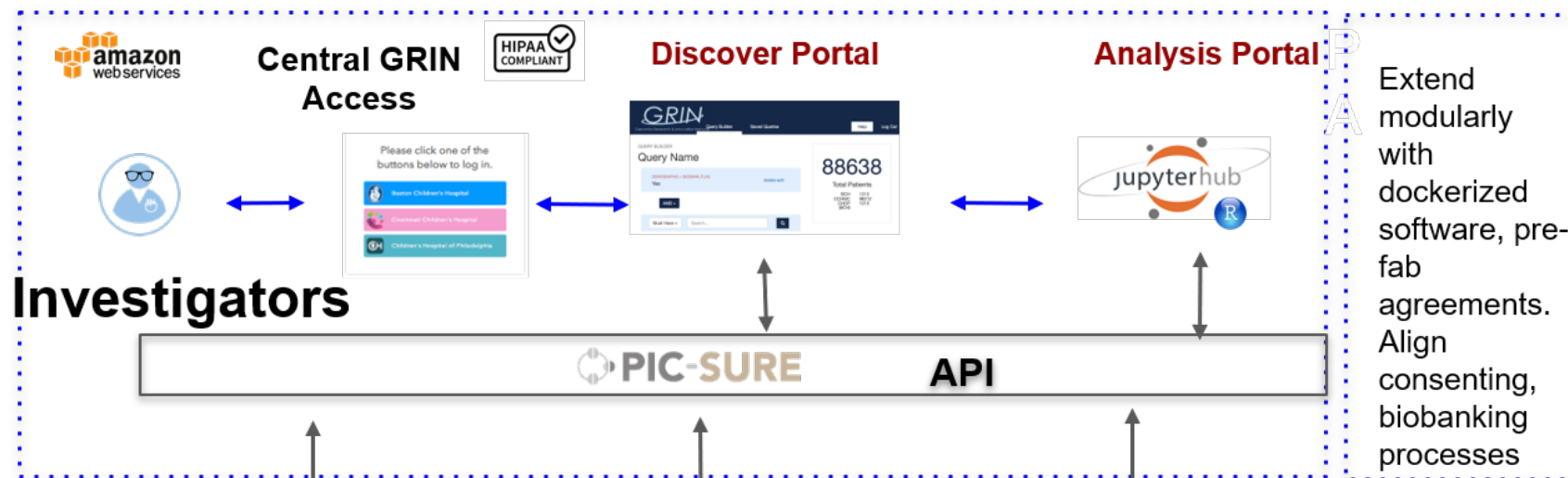
**Results:** Harmonized, broadly consented institutional review board (IRB) protocols were approved and used for biobank enrollment, creating ever-expanding, compatible biobanks. An open source federated query infrastructure was established over

genotype-phenotype databases at the three hospitals. Investigators securely access the GRIN platform for prep to research queries, receiving aggregate counts of patients with particular phenotypes or genotypes in each biobank. With proper approvals, de-identified data is exported to a shared analytic workspace. Investigators at all sites enthusiastically collaborated on the pilot studies, resulting in multiple publications. Investigators have also begun to successfully utilize the infrastructure for grant applications.

**Conclusions:** The GRIN collaboration establishes the technology, policy, and procedures for a scalable genomic research network.

*Genetics in Medicine* (2019) <https://doi.org/10.1038/s41436-019-0646-3>

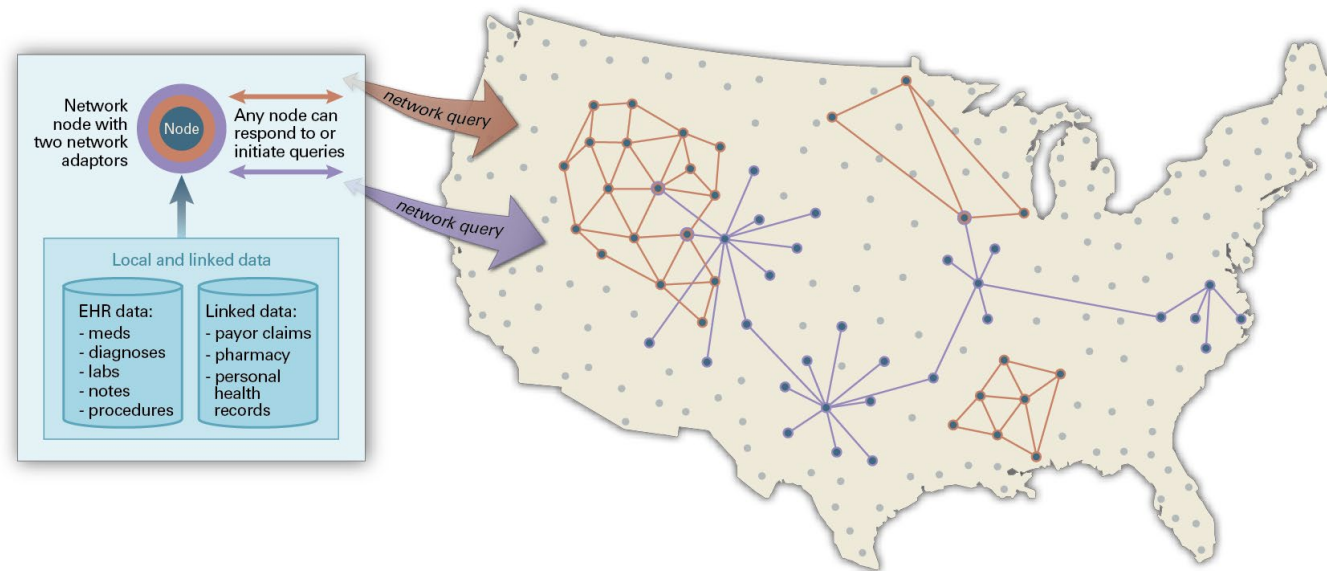
**Keywords:** genomic medicine; federated networks; electronic health records; biobanking; information technology



# Existing Genomic Research and Innovation Network (GRIN)

## Scaling-up

# Federated EHR Networks: engaging health systems by making the data important to them

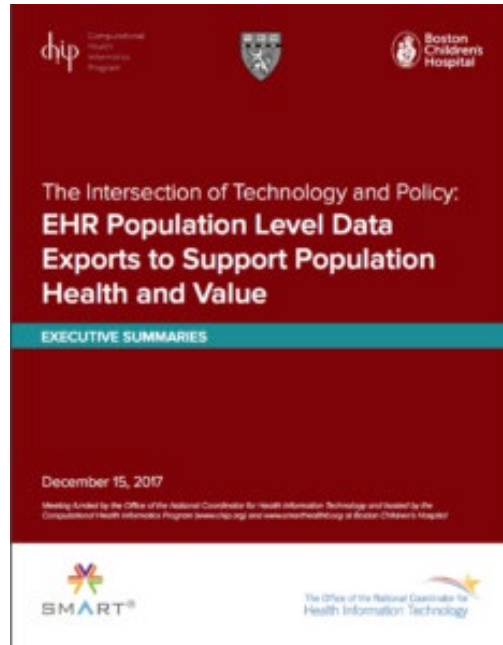


**Federalist Principles for Federated Networks**  
**Mandl, Nature Biotechnology**



- Don Rucker: "If the health system is going to care about the data, they should be about payment."

# Push button population health /FLAT FHIR



December 2017 Enhancing FHIR to support Bulk Data access

November 2019 Follow-up meeting

# SMART/HL7 FHIR Bulk Data



- Reuse as much of existing FHIR semantics as possible
  - Data models
  - API format and data types
  - Implementation guide structure
- Use existing standards based authentication and authorization
  - Base on widely used OAuth (SMART) standard
- Structure for efficiently generating and loading large datasets
  - Asynchronous operation
  - One data type per file
  - Streaming data



## The NEW ENGLAND JOURNAL of MEDICINE

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# A 21st-Century Health IT System — Creating a Real-World Information Economy

Kenneth D. Mandl, M.D., M.P.H., and Isaac S. Kohane, M.D., M.P.H.

Data generated as a by-product of the day-to-day work of delivery systems are a fundamental currency of the 21st Century Cures Act. How efficiently

of real-world evidence to advance treatment and research.

Fortunately, lawmakers included in the 21st Century Cures Act a provision that could transform

contains hundreds of thousands of apps because developers have a well-documented API that enables them to create software that seamlessly integrates with the op-

## Focus on BCH ACO

- Each organization uses an internal data model and architecture for reporting

```
CREATE TEMP TABLE T50XYFWT0MQ000 as
select a11.MRN mrnchar
from CONS_CURRENT_PATIENT_DIM a11
  left outer join CONS_ENCOUNTER_DIM a12
    on (a11.PATIENT_KEY = a12.PATIENT_KEY)
  left outer join CONS_INSURANCE_FACT a13
    on (a12.ENCOUNTER_KEY = a13.ENCOUNTER_KEY)
  left outer join CONS_INSURANCE_PLAN_DIM a14
    on (a13.PLAN_KEY = a14.PLAN_KEY)
where (a11.INSURANCE_PLAN_KEY in (2407)
  or (a14.PLAN_ID in (24501))
  and a12.LATEST_CSN_FLAG in ('Y'))
group by a11.MRN
```

```
CREATE TEMP TABLE T1ZL5FW2SMQ001 as
select a11.DATE_OF_BIRTH DATE_OF_BIRTH,
  a13.EVENT_END_DT_TM EVENT_END_DT_TM,
  a11.MRN mrnchar
from CONS_CURRENT_PATIENT_DIM a11
  left outer join CONS_ENCOUNTER_DIM a12
    on (a11.PATIENT_KEY = a12.PATIENT_KEY)
```



# Resulting Output

- This is the outgoing report to MassHealth for Adolescent Childhood Immunizations
- The output from the internal BCH data warehouse SQL query is below

Current Age	General PCP Name	Last Primary Care Appt Date	Last Primary Care Appt Clinic	Meningococcal Count	Meningococcal Last	Tdap Count	Tdap Last	HPV Count	HPV1	HPV2	HPV3	Measure Met
13	Joseph, Luc	10/19/2018	PCL	1	08/25/2017	1	08/25/2017	1	08/25/2017			N
13	Shah, Snehal N	03/29/2018	PCL									N
13	Spindel, Chelsea	12/01/2018	PCL	1	03/04/2016	1	03/04/2016	2	03/04/2016	08/23/2016		Y
13	Roth, Emily	05/03/2005	PCM									N
13	Badrinath, Seeta D	08/08/2018	PCL	1	06/02/2016	1	06/02/2016	3	10/29/2015	01/27/2016	06/02/2016	Y

## Query with FHIR Bulk Data Analytics

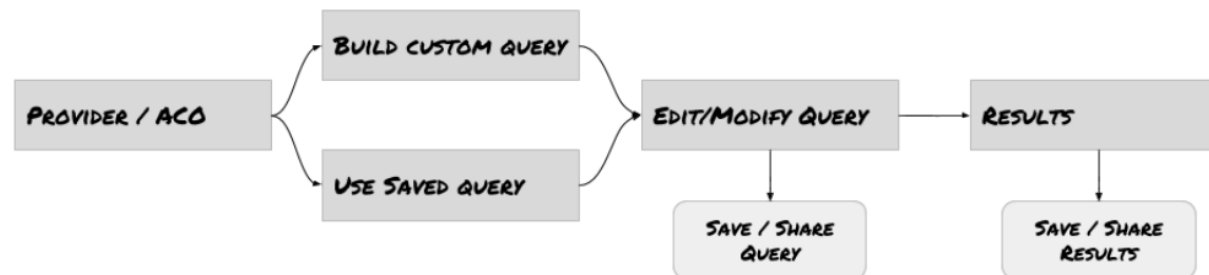
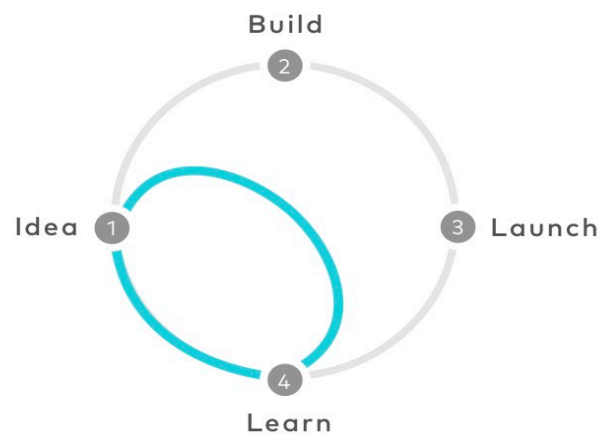
- Here's a query on top of FHIR using Bulk Data Exports as the data source
- The query is written on the Presto SQL query engine
- The output is exactly the same as the one that BCH currently runs

```
WITH patientVaccineRows as (SELECT
  json_extract_scalar(p.json, '$.id') AS patientId,
  json_extract_scalar(p.json, '$.name[0].family[0]') AS familyName,
  json_extract_scalar(p.json, '$.name[0].given[0]') AS givenName,
  json_extract_scalar(dr.json, '$.name.family[0]') AS drFamilyName,
  json_extract_scalar(dr.json, '$.name.given[0]') AS drGivenName,
  json_extract_scalar(i.json, '$.vaccineCode.coding[0].code') AS code,
  json_extract_scalar(i.json, '$.vaccineCode.text') AS text,
  split_part(json_extract_scalar(i.json, '$.date'), 'T', 1) AS date
```

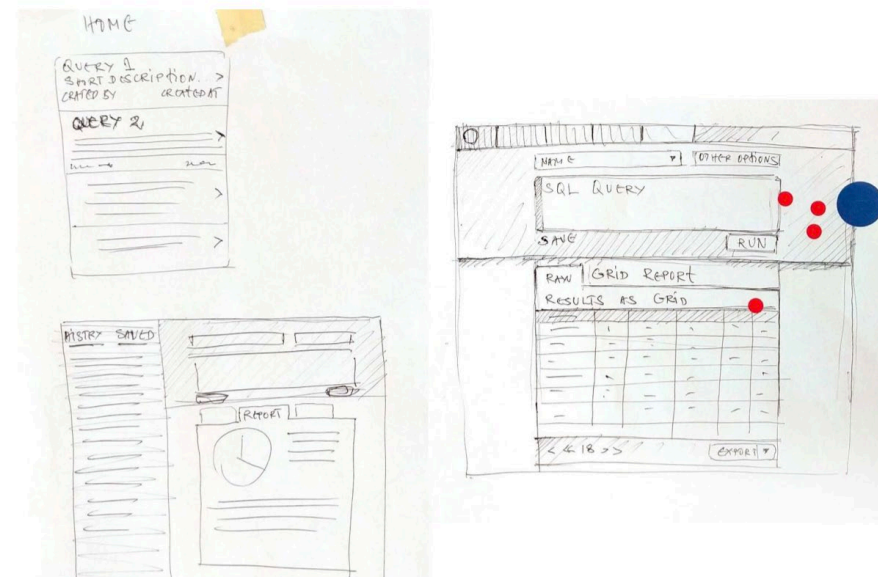
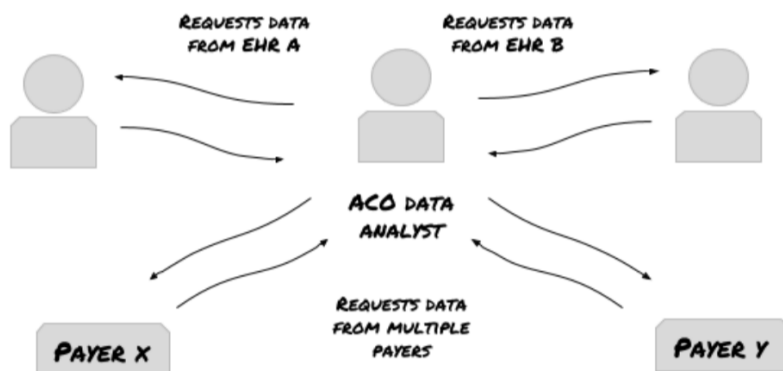
# The proposition

- Bulk data exports in a consistent, standardized format
- Generalizable analytics on top

# Design Sprint Process



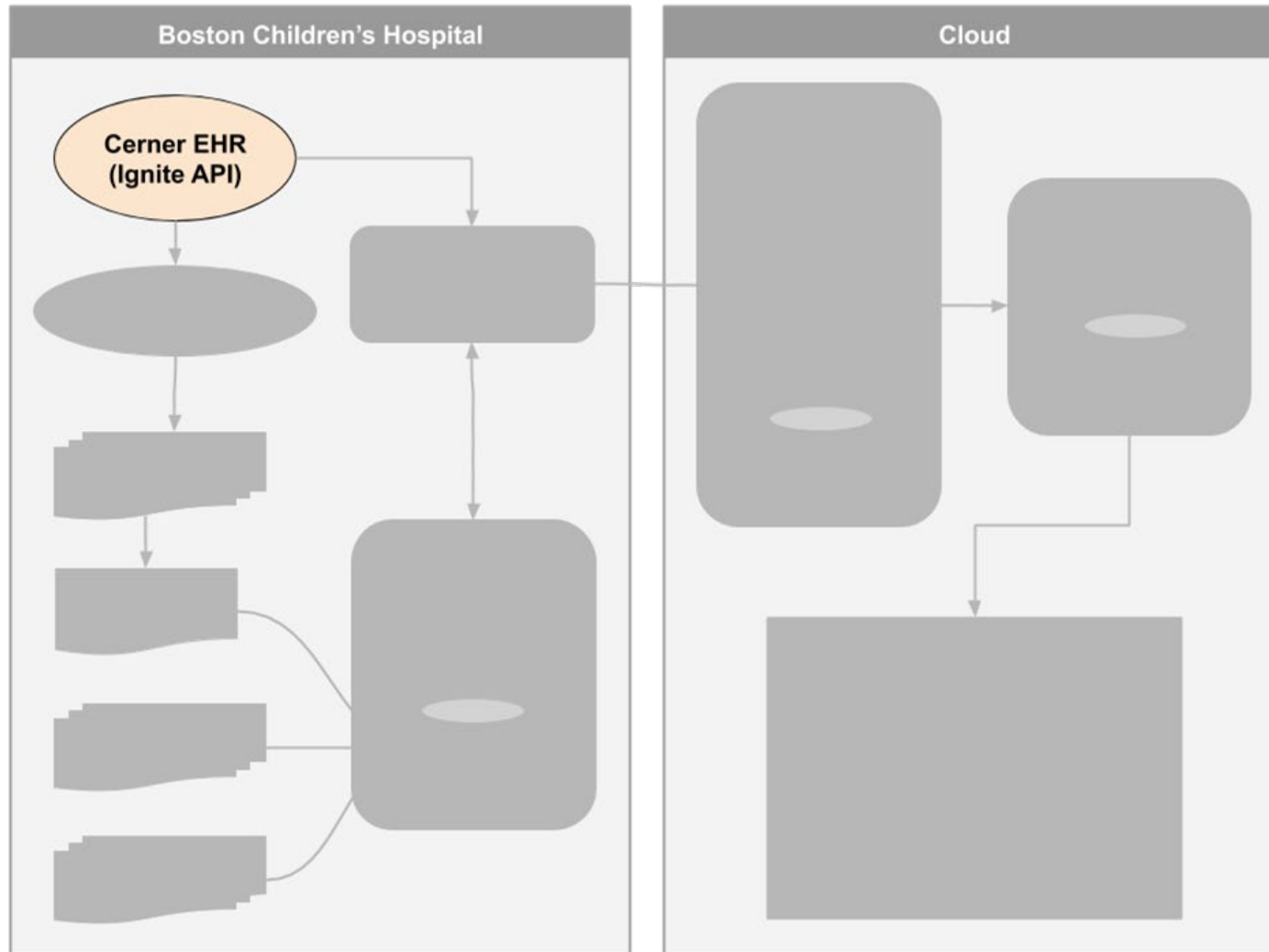
The sprint gives teams a shortcut to learning without building and launching.



# LEAP POP-HEALTH APP

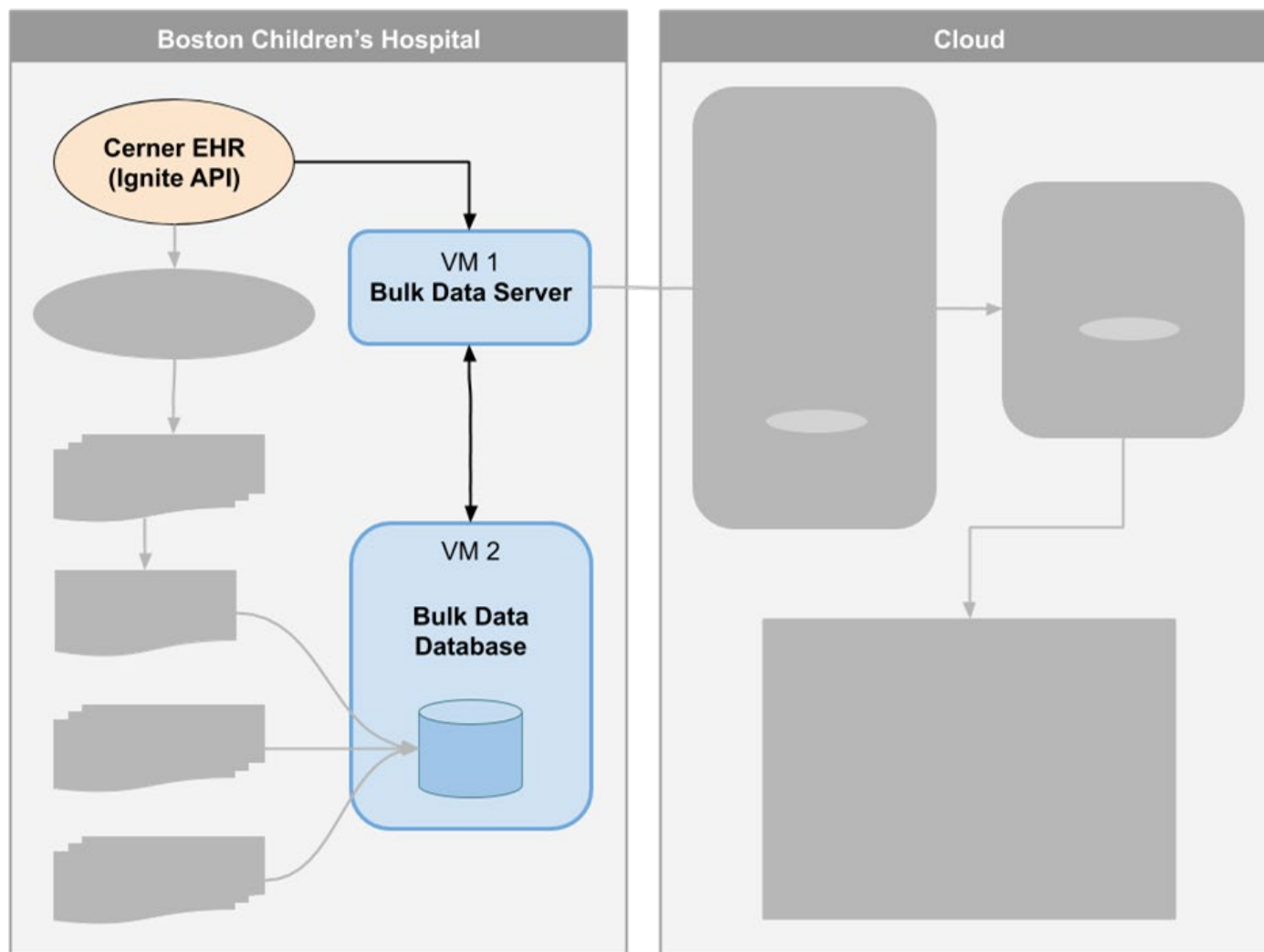
Population-level app based on bulk data

# BOSTON CHILDREN'S HOSPITAL EHR



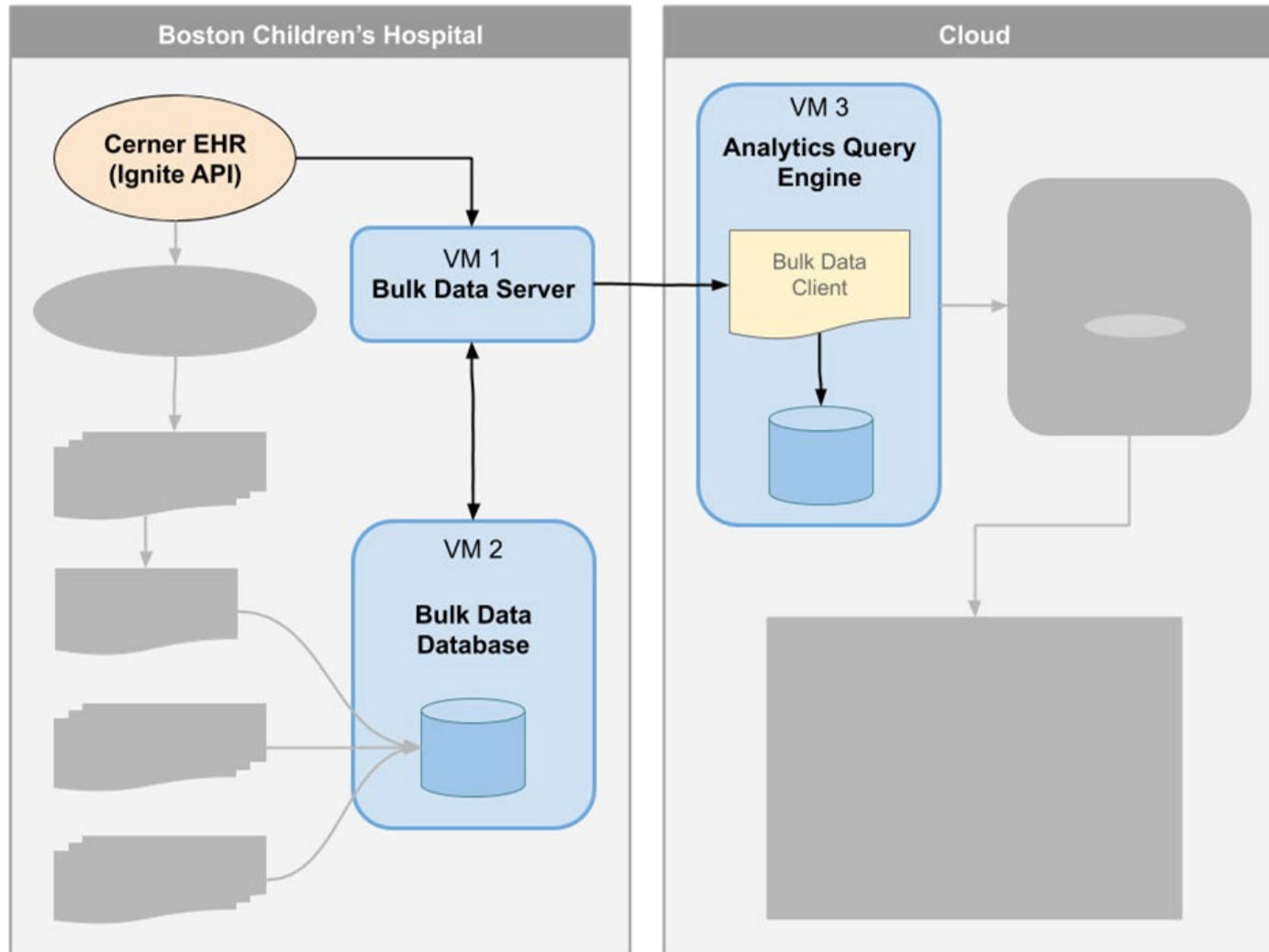
- Boston Children's Hospital Cerner EHR
- Cerner Ignite API
- FHIR DSTU-2 and R4
- Does NOT support bulk data

# BULK DATA SERVER



- Connects to any FHIR-enabled EHR
- Exposes standard bulk-data API
- Can act as a proxy
- Synchronizes automatically
- Caches data
- Acts as data aggregator

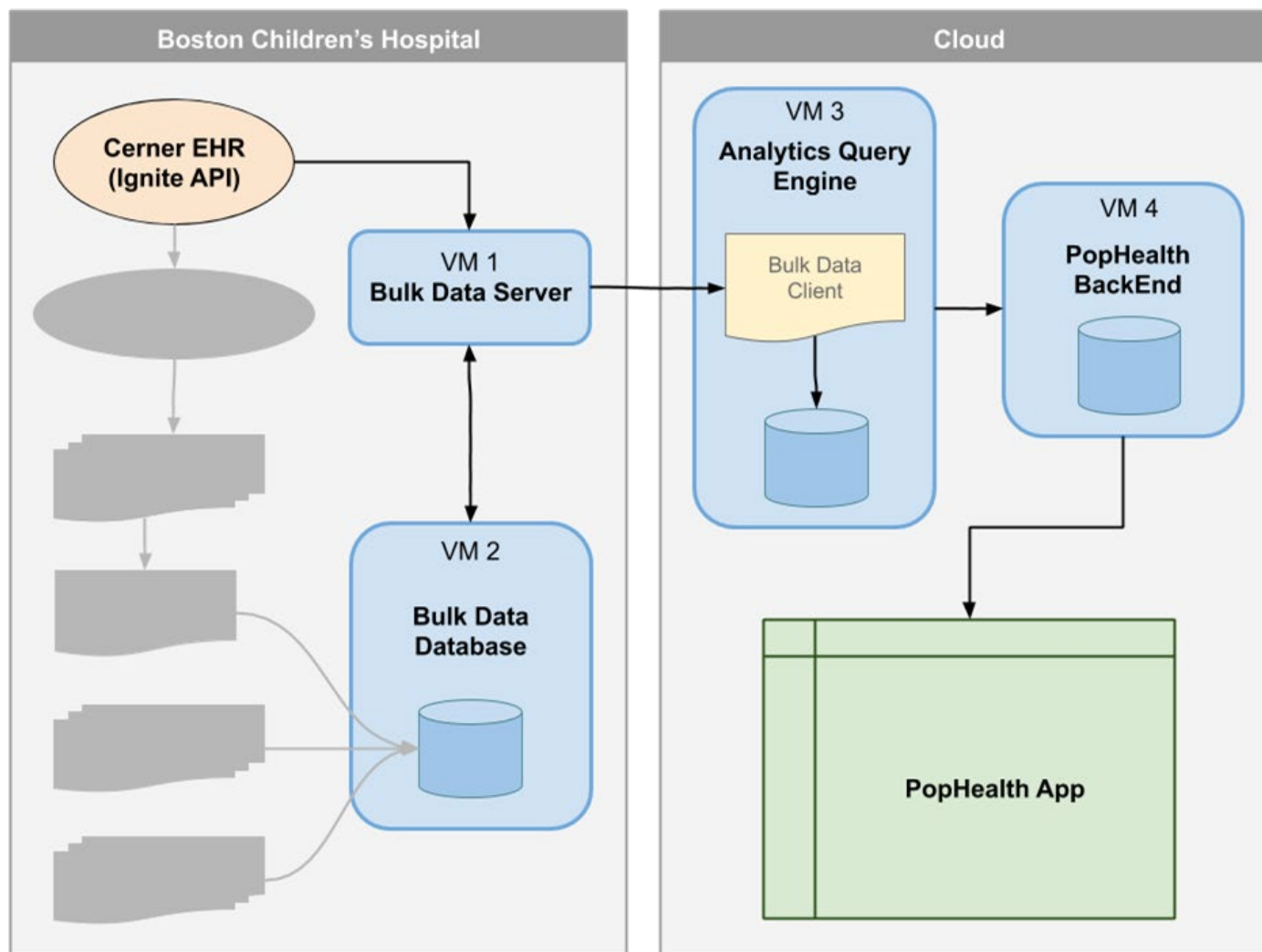
# ANALYTICS QUERY ENGINE



- Consumes standard bulk-data NDJSON
- Converts and stores data in Presto
- Improves performance in large datasets
- Exposes SQL interface

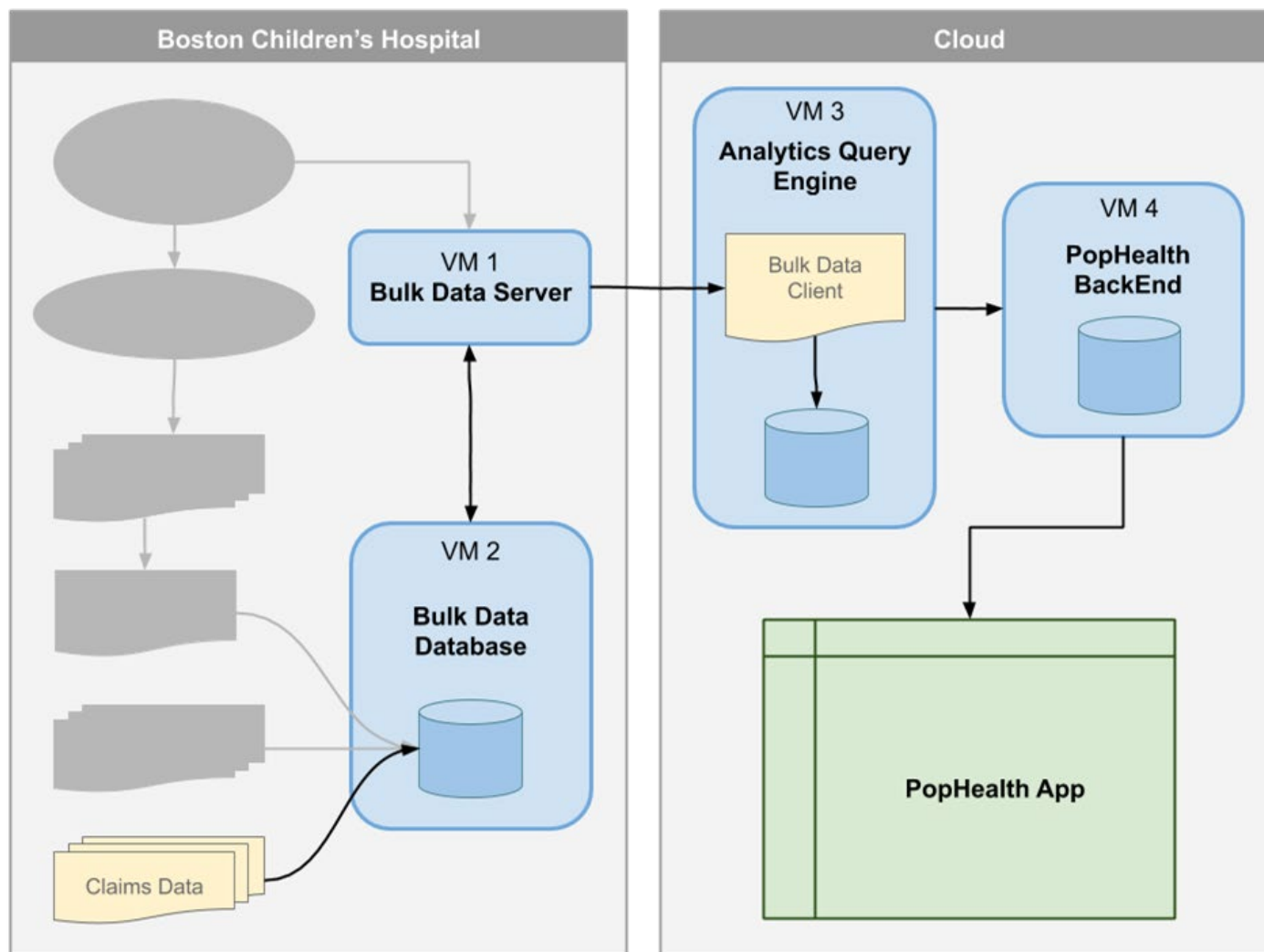


# POP-HEALTH APP



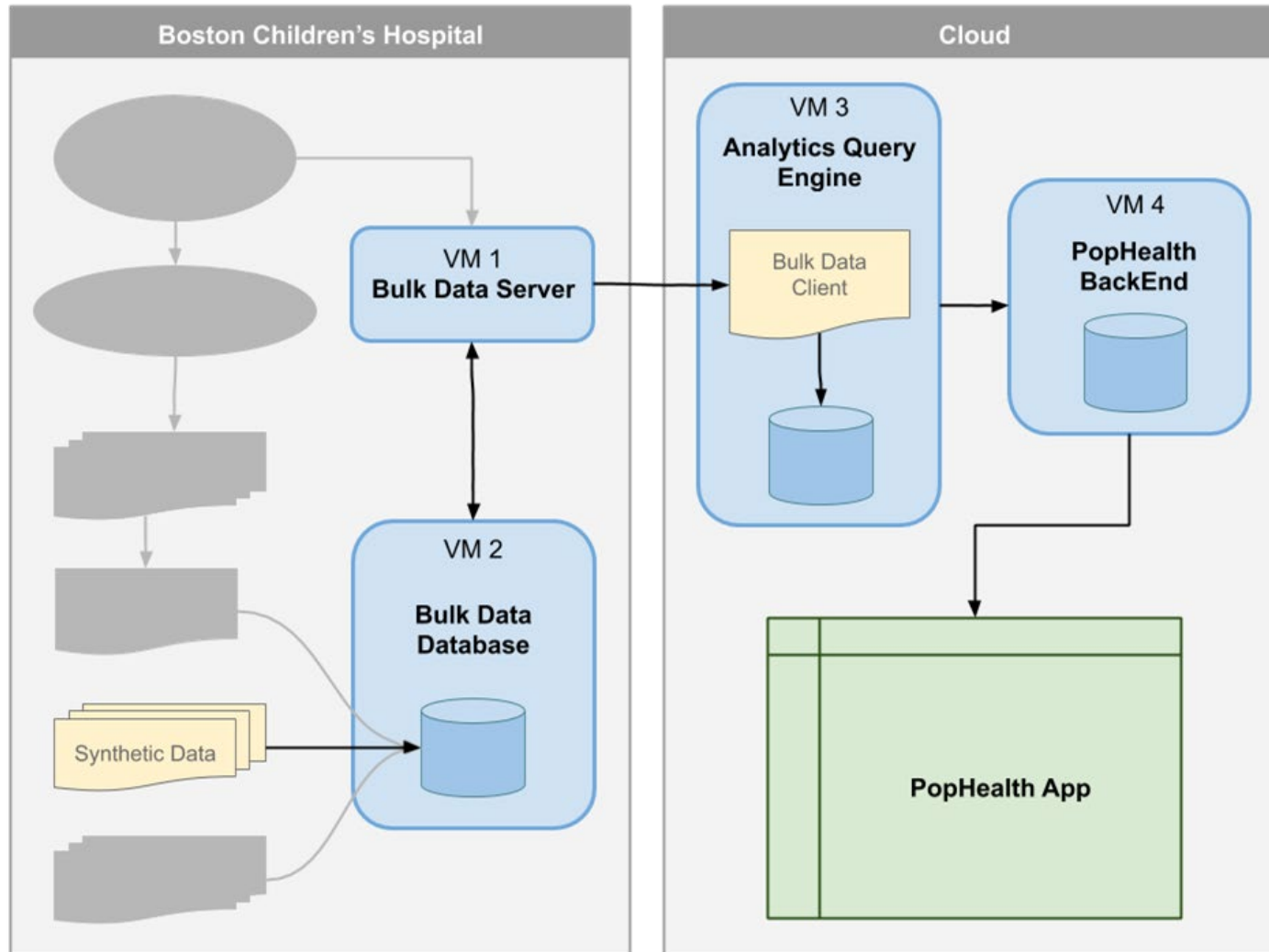
- Sends SQL queries to AQE
- Caches historical data
- Provides user management
- Supports multiple pre-configured QMs
- Includes SQL query builder

# CLAIMS DATA



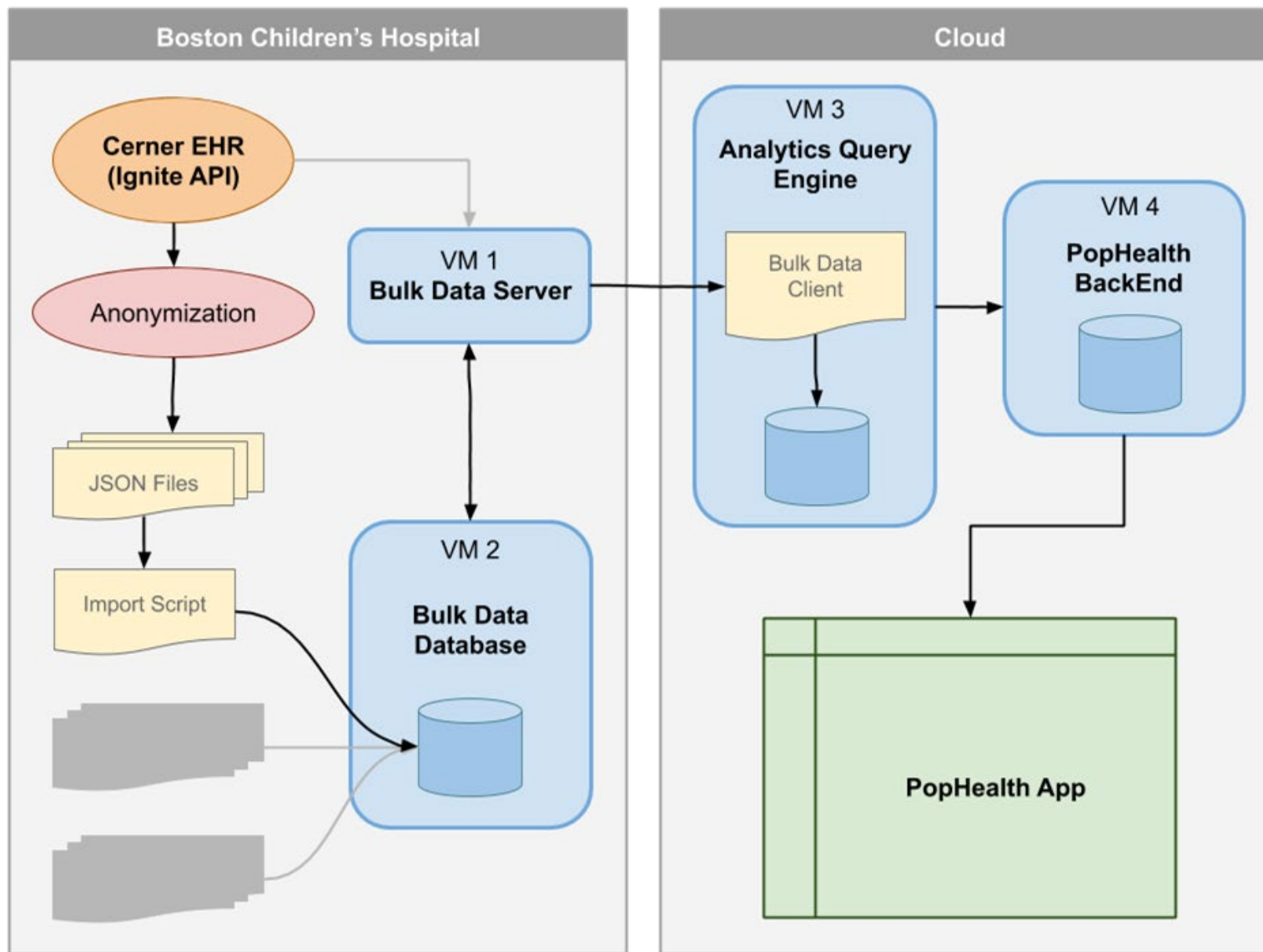
- Claims data from various sources can be merged into the bulk-data database.

# SYNTHETIC DATA



- More than 1.22M Patients
- Close to 200M Observations
- Close to 380M Resources
- About 49M Claims
- About 24GB data
- About 2.2GB data with gzip

# REAL-WORLD DIAGRAM



# POP-HEALTH APP

SMART<sup>®</sup> PopHealth App
MEASURES REPORT LOGOUT


**DATA SOURCES**

- BCH Epic
- BCH Cerner
- Aetna Claims
- MassHealth Claims
- BCBS Claims

Payer: MassHealth Organization: All Organizations Clinic: None Selected Update

### Immunizations for Adolescents

Boston Children's Hospital



	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Childhood Immunization Status	1%	1%	12%	22%	34%	34%	39%	40%	45%	55%	53%	56%
Immunizations for Adolescents	11%	17%	18%	29%	37%	49%	60%	71%	77%	83%	84%	90%
Depression Screening and Follow-up Plan	5%	13%	14%	22%	32%	32%	34%	36%	36%	47%	71%	72%
Depression Remission or Response	9%	20%	32%	33%	41%	42%	49%	59%	65%	69%	68%	77%

### BCH Physicians Organization

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Childhood Immunization Status	3%	6%	15%	22%	23%	27%	39%	50%	57%	59%	72%	74%
Immunizations for Adolescents	3%	3%	8%	13%	25%	26%	36%	37%	40%	42%	57%	60%
Depression Screening and Follow-up Plan	4%	8%	16%	27%	34%	37%	44%	53%	61%	72%	67%	73%

SMART<sup>®</sup> PopHealth App
MEASURES REPORT LOGOUT

**DATA SOURCES**

- BCH Epic
- BCH Cerner
- Aetna Claims
- MassHealth Claims
- BCBS Claims

## Cohort Builder

REPORT BUILDER

```

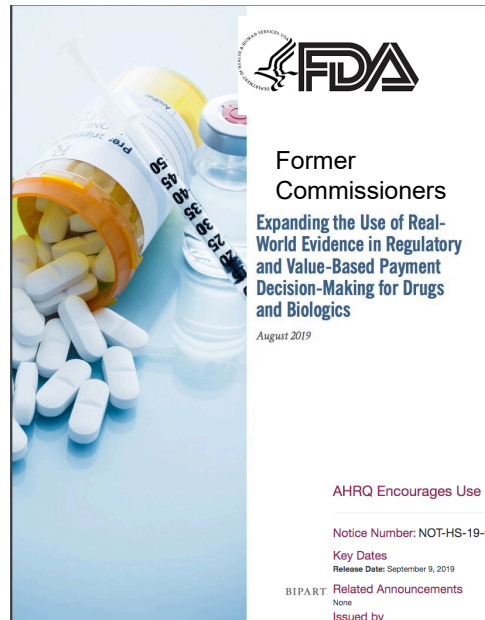
select
  json_extract_scalar(json,'$.name[0].family[0]') as "Family Name",
  json_extract_scalar(json,'$.name[0].given[0]') as "Given Name",
  json_extract_scalar(json,'$.address[0].line[0]') as "Address",
  json_extract_scalar(json,'$.gender') Gender,
  json_extract_scalar(json,'$.birthDate') DOB
from patient p
WHERE json_extract_scalar(json,'$.name[0].family[0]') = 'Schuppe920'
  AND json_extract_scalar(json,'$.name[0].given[0]') = 'Jean712'
```

Total time: 6 seconds and 166 ms  
Result rows: 1000

Preview DOWNLOAD CSV

Family Name	Given Name	Address	Gender	DOB
Schuppe920	Christopher407	620 Marvin Road Unit 24	male	1984-10-05
Schuppe920	Jeffrey461	371 Mitchell Avenue Unit 82	female	1976-06-29
Schuppe920	Mervin111	123 Block Mews	male	1963-06-08
Schuppe920	Anabel269	886 MacGyver Gardens	female	1954-07-03
Schuppe920	Jorge203	816 Stanton Orchard	male	1954-01-13
Schuppe920	William805	444 Fritsch Camp Unit 93	female	1966-03-26
Schuppe920	Keenan632	876 Schuster Quay Apt 92	male	1969-08-01
Schuppe920	Angel97	881 Reynolds Mews Suite 77	male	1954-08-02
Schuppe920	Leonor133	150 Prosacco Meadow Unit 82	female	1980-03-16
Schuppe920	Sam879	139 Homenick Bypass	male	1971-05-20
Schuppe920	Oswaldo857	722 Stiedemann Skyway	male	1997-06-19

# Federal Health Agencies Coming Aboard



**Former Commissioners**  
Expanding the Use of Real-World Evidence in Regulatory and Value-Based Payment Decision-Making for Drugs and Biologics  
August 2019

**FDA**

## Fast Healthcare Interoperability Resources (FHIR®) Standard

Notice Number: NOT-OD-19-122

Key Dates  
Release Date: July 30, 2019

Related Announcements  
NOT-OD-19-014  
NOT-OD-19-154  
NOT-OD-19-150

Issued by  
OFFICE OF THE DIRECTOR, NATIONAL INSTITUTE

### Purpose

The purpose of this notice is to encourage NIH researchers to explore the use of the Fast Healthcare Interoperability Resources (FHIR®) standard to capture, integrate, and exchange clinical data for research purposes and to enhance capabilities to share research data.

### Background

Once research is approved and compliant with human subjects protections, the FHIR format can accelerate the use of clinical data for research. FHIR is a standardized way of transmitting health data from one health information system to another through an application programming interface (API). It is being widely promoted and adopted for use in clinical care. In addition, FHIR provides a way to structure data generated from research in a manner that protects patient privacy and fosters interoperability and interchange of both research and clinical data. FHIR benefits from relative ease of implementation, availability of open source implementation tools, considerable industry support, and an American National Standards Institute consensus development process. It is also compatible with analytic resources used in biomedical research, such as R and Python.

Several Federal health agencies are promoting the use of FHIR in electronic health record (EHR) systems. The 21st Century Cures Act requires that a health information technology developer or entity "allow health information...to be accessed, exchanged, and used without special effort through the use of application programming interfaces (APIs)...including providing access to all data elements of a patient's electronic health record."<sup>1</sup> To implement this provision, the Department of Health and Human Services, Office of the National Coordinator for Health Information Technology (ONC) has proposed a new rule to support seamless and secure access, exchange, and use of electronic health information.<sup>2</sup> Specifically, the proposed rule calls on the health care industry to adopt standardized APIs by using the FHIR standard to share patient data.

Concurrently, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule with requirements for Medicaid, the Children's Health Insurance Program, Medicare Advantage plans, and Qualified Health Plans in the federally facilitated exchanges to provide enrollees with immediate electronic access to medical claims and other health information electronically by 2020 by adopting and implementing openly published APIs.<sup>3</sup> CMS would also require these health care providers and plans to implement open data sharing technologies that are consistent with the FHIR standard in ONC's notice of proposed rulemaking (NPRM). Both NPRMs also support the use of specific content and vocabulary standards to achieve

at least one third of developers certified under the 2015 Edition<sup>4</sup> of ONC's Health Information Technology (IT) Certification that approximately 80% of hospitals and 74% of clinicians have EHR systems with some FHIR API capabilities. In addition, CMS developed the Blue Button 2.0 FHIR API to enable exchange of claims data with software applications, on-site data sharing using FHIR under the Da Vinci Project.<sup>5</sup> The broader IT sector has also begun adopting FHIR, for instance, EHR systems or to support the uploading of data to cloud-based services. Pharmaceutical companies are also using FHIR for clinical trial management with EHRs.<sup>6</sup>

ected in the course of clinical care. For example, while monitoring cardiovascular, renal, and kidney function during the trial, a clinician could use the FHIR framework to provide instructions to access an authorized participant's electronic health records, and then transmit this information directly into a clinical trial management system or other research data

and CMS align with and facilitate many of the objectives asserted in the NIH Strategic Plan for Data Science,<sup>7</sup> as well as the National Library of Medicine, in its Strategic Plan, 2017-2027.<sup>8</sup> Additionally, the National Library of Medicine, in its Strategic Plan, 2017-2027,<sup>9</sup> proposes technical and scientific approaches to support the use of FHIR in biomedical research, as well as implementation challenges and opportunities they foresee in using

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## Regulation, and Policy > Notice of Proposed Rulemaking to Improve the Interoperability of Health Information

### Notice of Proposed Rulemaking to Improve the Interoperability of Health Information

The U.S. Department of Health and Human Services (HHS) recently proposed a new rule to support seamless and secure access, exchange, and use of electronic health information (EHI).

The proposed rule is designed to increase innovation and competition by giving patients and their healthcare providers secure access to health information and new tools, allowing for more choice in care and treatment. It calls on the healthcare industry to adopt standardized application programming interfaces (APIs), which will help allow individuals to securely and easily access structured EHI using smartphone applications.

The proposed rule places a strong focus on a patient's ability to access their health information through a provision requiring that patients can electronically access all of their EHI (structured and/or unstructured) at no cost. Finally, to further support access and exchange of EHI, the proposed rule implements the information blocking provisions of the Cures Act. The rule proposes seven exceptions to the definition of information blocking.

The public comment period is now open for the proposed rule. We value all of your feedback – both positive and negative as it helps inform the rulemaking process. Below are the steps to submitting your comments:

[Download the Proposed Rule \(PDF - 3.2 MB\)](#)

[Comment on the Proposed Rule](#)

Comments on the proposed rule are due by 11:59 pm ET on May 3, 2019.

### Fact Sheets on the Proposed Rule



Implementation of Cures Act and Executive Orders [PDF - 1.4 MB]



Conditions and Maintenance of Certification Requirements [PDF - 805 KB]



Information Blocking - Summaries of the 7 Exceptions [PDF - 578 KB]

## AHRQ Encourages Use of Fast Healthcare Interoperability Resources (FHIR®) Standard

Notice Number: NOT-HS-19-020

Key Dates  
Release Date: September 9, 2019

Related Announcements  
None

BIPART

Issued by  
AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

### Purpose

The purpose of this notice is to encourage the Agency for Healthcare Research and Quality (AHRQ)-funded researchers to explore the use of the Fast Healthcare Interoperability Resources (FHIR®) standard to capture, integrate, and exchange healthcare data for research purposes and to enhance capabilities to share research data.

### Background

The Health Level Seven International (HL7®) FHIR is a standard for exchanging health information electronically. FHIR specifies the content of the data exchanged between healthcare applications, and how the exchange is implemented and managed, typically through an application programming interface (API). Software developers can seamlessly connect their application to another through a FHIR API to transmit electronic healthcare data. FHIR enables the exchange of many different healthcare data types such as clinical information, demographics, and billing and claims data.

FHIR is broadly used in healthcare. As of mid-April 2019, approximately one third of developers certified under the 2015 Edition<sup>1</sup> of the Office of the National Coordinator for Health Information Technology's (ONC's) Health Information Technology (IT) Certification Program published that they are using a FHIR API.<sup>2</sup> It is estimated that approximately 96% of hospitals and 74% of clinicians have electronic health record (EHR) systems with some FHIR API capabilities. In addition, federal agencies are using FHIR to exchange data. For example, the Centers for Medicare & Medicaid Services (CMS) developed the Blue Button 2.0 FHIR API to enable exchange of claims data with software applications.<sup>3</sup> Payors, including CMS, and providers are working together to automate data sharing using FHIR under the Da Vinci Project.<sup>4</sup> The broader IT sector has also begun adopting FHIR, for example, to enable individuals to import their health records from providers' EHR systems or to support the uploading of data to cloud-based services. Pharmaceutical companies are also active in FHIR development efforts,<sup>5</sup> including to use FHIR to integrate clinical trial management with EHRs.<sup>6</sup>

AHRQ believes that the use of FHIR in healthcare has gained sufficient momentum to warrant the encouragement of its use for health services research. The FHIR standard could, for example, accelerate the research uses of data collected in the course of clinical care. Toward that end, AHRQ recently partnered with ONC to support and test the development of FHIR specifications for patient-reported outcomes (PROs). The mechanisms to exchange PROs for research purposes using FHIR are now available. Also, AHRQ's clinical decision support (CDS) initiative has been leveraging FHIR to increase the interoperability of CDS knowledge resources and using FHIR in demonstration projects.<sup>7</sup> The CDS Connect project has developed open source, FHIR-based software packages in clinical domains such as cholesterol management, chronic pain, and preventive care.<sup>8</sup> An open source CDS Outsourcing Tool is also available that allows researchers and developers to build interoperable CDS logic using FHIR data models.<sup>9</sup>

Through this Notice, AHRQ encourages funded researchers to explore the use of the FHIR standard to capture and integrate patient- and population-level data from clinical information systems for research purposes and to use it as common structure for sharing research data. As with all AHRQ-funded or supported research involving human participants, and as is currently the expectation using FHIR, investigators must obtain participant consent and follow applicable national, tribal, and state laws and regulations, as well as relevant institutional policies, for the protection of human subjects.

The National Institutes of Health also released a Notice<sup>10</sup> encouraging its funded researchers to use the FHIR standard to capture, integrate, and exchange clinical data for research purposes and to enhance capabilities to share research data.

[1] <https://www.healthit.gov/topic/certification-ehrs-2015-edition>

[2] <https://chip.healthit.gov/#research>

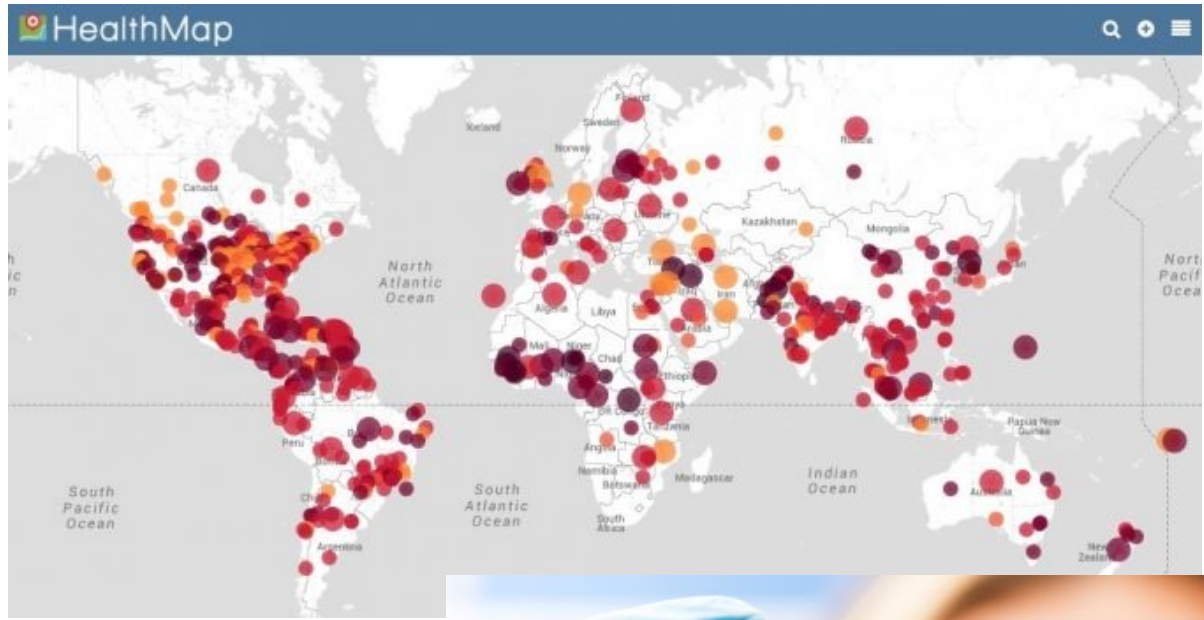
[3] <https://bluebutton.cms.gov/>

[4] <http://www.hl7.org/about/davinci/>

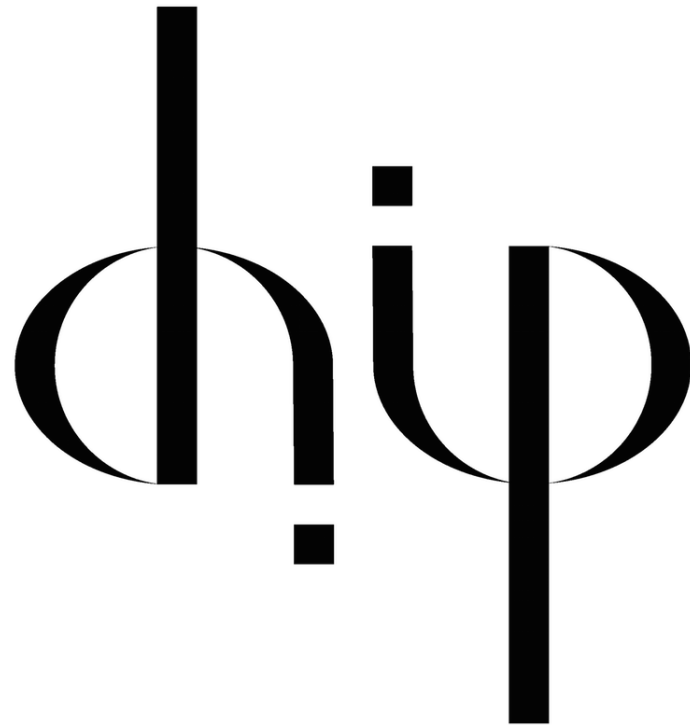
[5] <https://transceleratebiopharm.com/resource-connection-challenge-recap/>

[6] <https://www.healthleadersmedia.com/innovation/ochone-and-pfizer-constructing-digital-superhighway-clinical-trials>

[7] <https://www.ahrq.gov>



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# LEAP Focus Areas

2018

- Expand population-level data-focused APIs
- Advance clinical knowledge at point-of-care

2019

- Implement HL7<sup>®</sup> FHIR<sup>®</sup> Consent Resource
- Enhanced patient engagement technologies for care and research

2020

*To Be Determined*

- Consent for regulated vs. unregulated research?
- Security of data at rest and transit?

**Significantly enhance the performance of health IT solutions for care and research**

## Discussion: LEAP Areas for 2020?

- Data anonymization
- Digital footprint
- Data security at rest and transit
- Unregulated vs. regulated research
- Patient education and misinformation
- Open source tools for health research apps





The Office of the National Coordinator for  
Health Information Technology

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