

Digital Health: Past, Present and Future

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OPA Annual Conference & Trade Show
April 5-7, 2024



Disclosure Statement

- Mike Dorsch has no relevant financial relationship(s) with ineligible companies to disclose.

Learning Objectives

After this activity, the participant will be able to:

1. Describe digital health.
2. Explain the regulatory landscape for digital health.
3. Identify how a smartphone app or wearable can be used to help patients.
4. Summarize the potential pitfalls of digital health.

In the news...

← [Safety Communications](#)

Do Not Use Smartwatches or Smart Rings to Measure Blood Glucose Levels: FDA Safety Communication

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Date Issued: February 21, 2024

The U.S. Food and Drug Administration (FDA) is warning consumers, patients, caregivers, and health care providers of risks related to using smartwatches or smart rings that claim to measure blood glucose levels (blood sugar)

HealthAffairs



HEALTH AFFAIRS FOREFRONT

RELATED TOPICS:

HEALTH INFORMATION TECHNOLOGY | TECHNOLOGY
| ELECTRONIC MEDICAL RECORDS | REGULATION
| MEDICAL DEVICES | BEST PRACTICES

A Regulation To Promote Responsible AI In Health Care

[Jordan Everson](#), [Jeffery Smith](#),
[Kathryn Marchesini](#), [Micky Tripathi](#)

FEBRUARY 28, 2024

DOI: 10.1377/forefront.20240223.953299

BLEEPINGCOMPUTER



Ransomware gang claims they stole 6TB of Change Healthcare data



By [Sergiu Gatlan](#)

February 28, 2024

02:33 PM



Image: Midjourney

The BlackCat/ALPHV ransomware gang has

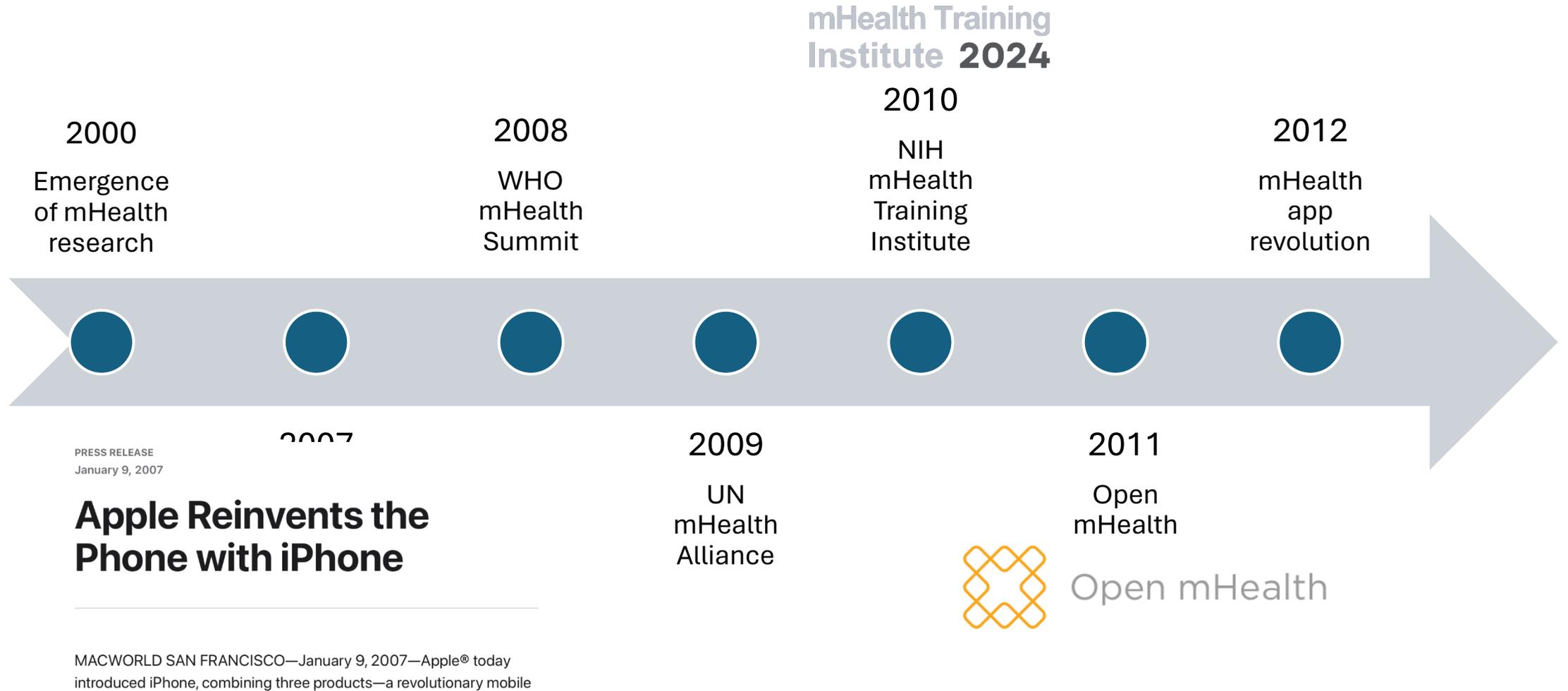
What is digital health?

- Digital health includes mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine.
 - mHealth
 - Health IT
 - Wearable devices

mHealth

- Broadly encompasses mobile telecommunication and multimedia technologies as they are integrated within increasingly mobile and wireless healthcare delivery systems.
- Mobile phones, smartphones, patient monitoring devices, remote data collection software, mobile applications
- Patient-centered clinical decision support

mHealth



MACWORLD SAN FRANCISCO—January 9, 2007—Apple® today introduced iPhone, combining three products—a revolutionary mobile

mHealth

Viewpoint

December 11, 2013

Can Mobile Health Technologies Transform Health Care?

Steven R. Steinhubl, MD¹; Evan D. Muse, MD, PhD¹; Eric J. Topol, MD¹

» Author Affiliations

JAMA. 2013;310(22):2395-2396. doi:10.1001/jama.2013.281078



Perspective

A New Initiative on Precision Medicine

Francis S. Collins, M.D., Ph.D., and Harold Varmus, M.D.

February 26, 2015

N Engl J Med 2015; 372:793-795

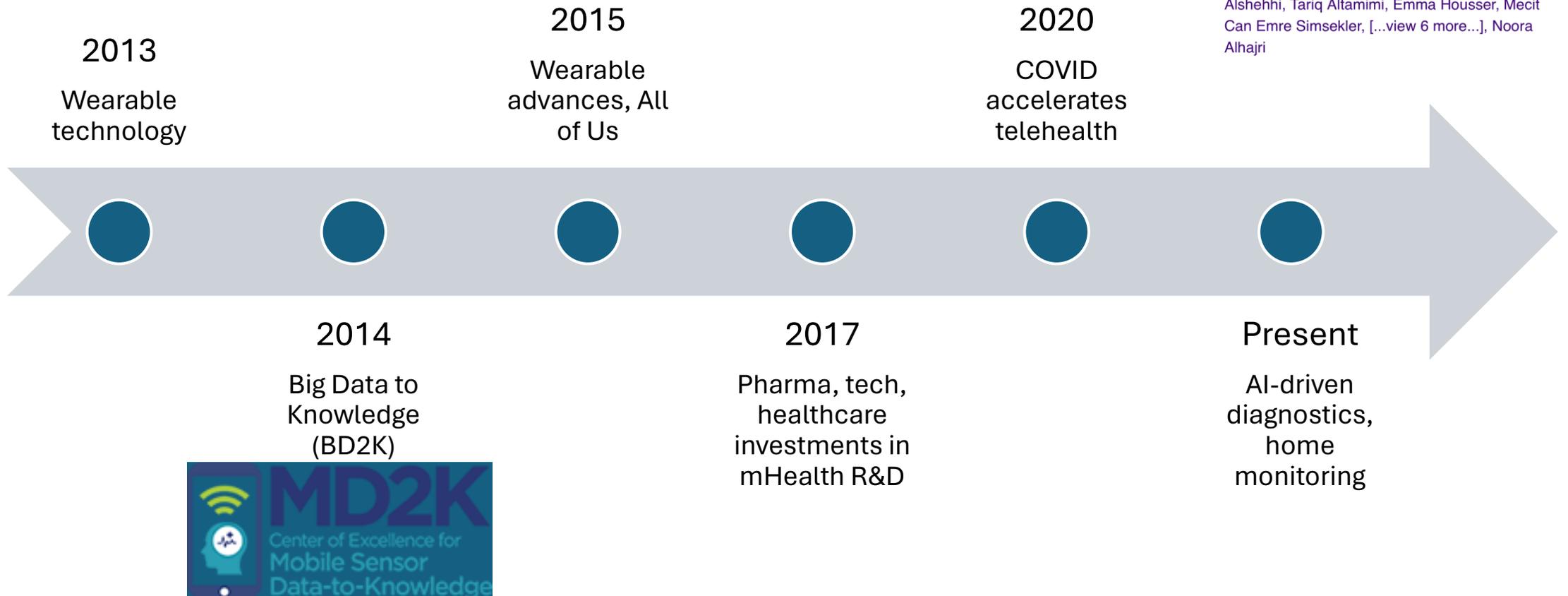
DOI: 10.1056/NEJMp1500523



RESEARCH ARTICLE

The integration of mHealth technologies in telemedicine during the COVID-19 era: A cross-sectional study

Abdul Rahman Taha, Mustafa Shehadeh, Ali Alshehhi, Tariq Altamimi, Emma Housser, Mecit Can Emre Simsekler, [...view 6 more...], Noora Alhajri



Question

You develop a mobile application that analyzes phone data using an algorithm to predict the likelihood of having the flu and recommend when the user should go to the doctor. Which governmental agency oversees this digital health product?

- A. Department of Health and Human Services
- B. Food and Drug Administration
- C. Federal Trade Commission
- D. Securities and Exchange Commission

Health IT

- Health IT uses computer hardware, software, or infrastructure to record, store, protect, and retrieve clinical, administrative, or financial information.
- Health IT can include:
 - Electronic Health Records (EHR)
 - Personal Health Records
 - Electronic Medical Records
 - Electronic prescribing (e-prescribing)

HITECH Act 2009

- Health Information Technology for Economic and Clinical Health Act of 2009
- Provides HHS with the authority to establish programs to improve healthcare quality, safety, and efficiency through promotion of Health IT
 - Mandates for EHR implementation (“meaningful use”)
 - Private and secure health information exchange (HIE)
- Legislatively mandated the Office of the National Coordinator (ONC) for Health IT

Meaningful Use (MU) Stages

- **Stage 1** (2011-2012) establishes the base requirements for electronic capture of clinical data
- **Stage 2** (2014) encourages the use of EHRs for the electronic exchange of health information to improve healthcare
- **Stage 3** (2016) is the use of certified EHR technology to submit clinical quality and other measures

Office of the National Coordinator (ONC)

- Created in 2004 through a presidential executive order
- Mandated in the HITECH Act 2009
- What does the ONC do?
 - Advance the development and use of health IT capabilities
 - Establish expectations for data sharing

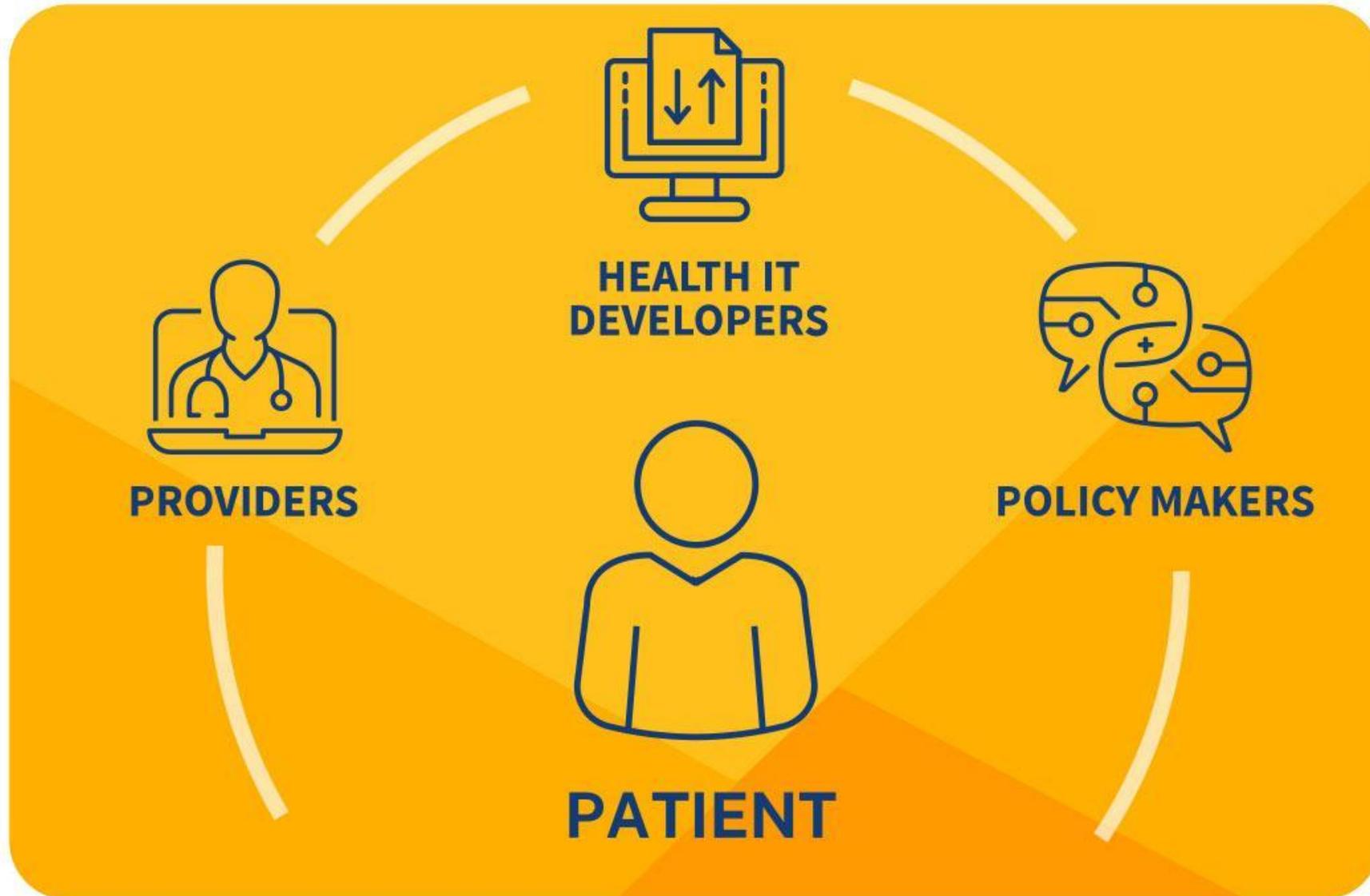
FDASIA of 2012

- Food and Drug Administration Safety and Innovation Act of 2012
- Directed HHS and FDA, in consultation with the ONC and FCC, to develop a report for the regulatory framework of health IT
- Promote innovation, protect patient safety, and avoid regulatory duplication

21st Century Cures Act 2016

- Empowering Patients with Their Health Record in a Modern Health IT Economy
- Putting the patient first in health technology enables the healthcare system to deliver:
 - Transparency into the cost and outcomes of their care
 - Competitive options in getting medical care
 - Modern smartphone apps to provide them convenient access to their records
 - An app economy that provides patients, physicians, hospitals, payers, and employers with innovation and choice
- **INTEROPERABILITY**

21st Century Cures Act 2016



21st Century Cures Act 2016

- Give patients and their healthcare providers secure access to health information
- Increase innovation and competition by fostering an ecosystem of new applications to provide patients with more choices in their healthcare
- Patients can electronically access all of their electronic health information (EHI), structured and/or unstructured, at no cost

TEFCA 2022

- Trusted Exchange Framework and Common Agreement - January 18th, 2022
- Entities will be able to apply and be designated as Qualified Health Information Networks (QHINs)
 - QHINs will connect to one another and enable their participants to engage in health information exchange across the country.

TEFCA 2022

- Goals for TEFCA are:
 - Establish a universal policy and technical floor for nationwide interoperability.
 - Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value.
 - Enable individuals to gather their health care information.
- TEFCA will accelerate HL7 FHIR adoption using APIs (like the banking industry)

Qualified Health Information Networks (QHINs)

INTEROPERABILITY & HIE > TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT (TEFCA)

HHS Names First Six QHINs to Participate in TEFCA

‘Our vision is that TEFCA can get us out of this collective learned helplessness that we’re in’ regarding interoperability challenges, says Micky Tripathi, Ph.D., M.P.P., national coordinator for health IT

[David Rath](#)

Feb. 13, 2023

In a significant milestone in the history of health data interoperability, representatives from the CommonWell Health Alliance, eHealth Exchange, Health Gorilla, Konza, Epic Systems, and Kno2 were on hand in Washington, D.C., to be recognized by HHS Secretary Xavier Becerra in the Great Hall at the HHS building.

FOR IMMEDIATE RELEASE

February 12, 2024

Contact: HHS Press Office

202-690-6343

media@hhs.gov

HHS Expands TEFCA by Adding Two Additional QHINs

Seven QHINs will now safely and securely exchange critical health information for patient care

The U.S. Department of Health and Human Services (HHS), through the Office of the National Coordinator for Health Information Technology (ONC), announced today that two additional organizations—CommonWell Health Alliance and Kno2—have been designated as Qualified Health Information Networks™ (QHINs™) capable of nationwide health data exchange governed by the Trusted Exchange Framework and Common AgreementSM (TEFCASM). ONC has led a multi-year, public-private process alongside its Recognized Coordinating Entity®, The Sequoia Project, Inc., to implement TEFCA, which was envisioned by the 21st Century Cures Act to support nationwide interoperability. TEFCA [became operational](#) in December 2023 with the designation of the first five QHINs—eHealth Exchange, Epic Nexus, Health Gorilla, KONZA, and MedAllies.

Entities



Pharmacy



Call center



Payer



EMS



Government



Patient



Primary care



Lab

Health Level Seven (HL7)

- Non-profit organization
- Creates the standards and framework for exchange, integration, sharing and retrieval of electronic health information
- International standard (ISO approved)
- Gold standard for transmitting healthcare data
- Three standards currently supported:
 - V2, CDA, FHIR
- **EHRs must use HL7 interfaces**

HL7 Clinical Document Architecture (CDA)

- CDA is a document markup standard that specifies the structure and semantics of "clinical documents" for exchange between healthcare providers and patients.
- A CDA can contain any clinical content -- typical CDA documents would be a Discharge Summary, Imaging Report, Admission & Physical, Pathology Report and more.
- The most popular use is for inter-enterprise information exchange, as envisioned for a **US Health Information Exchange (HIE)**.

HL7 FHIR



- Fast Healthcare Interoperability Resources
- FHIR is an **interoperability** standard intended to facilitate the exchange of healthcare information between healthcare providers, patients, caregivers, payers, researchers, and any one else involved in healthcare.
- FHIR combines the best features of HL7's existing solutions, while leveraging the latest web technologies and applying a critical focus on implementation.

HL7 FHIR



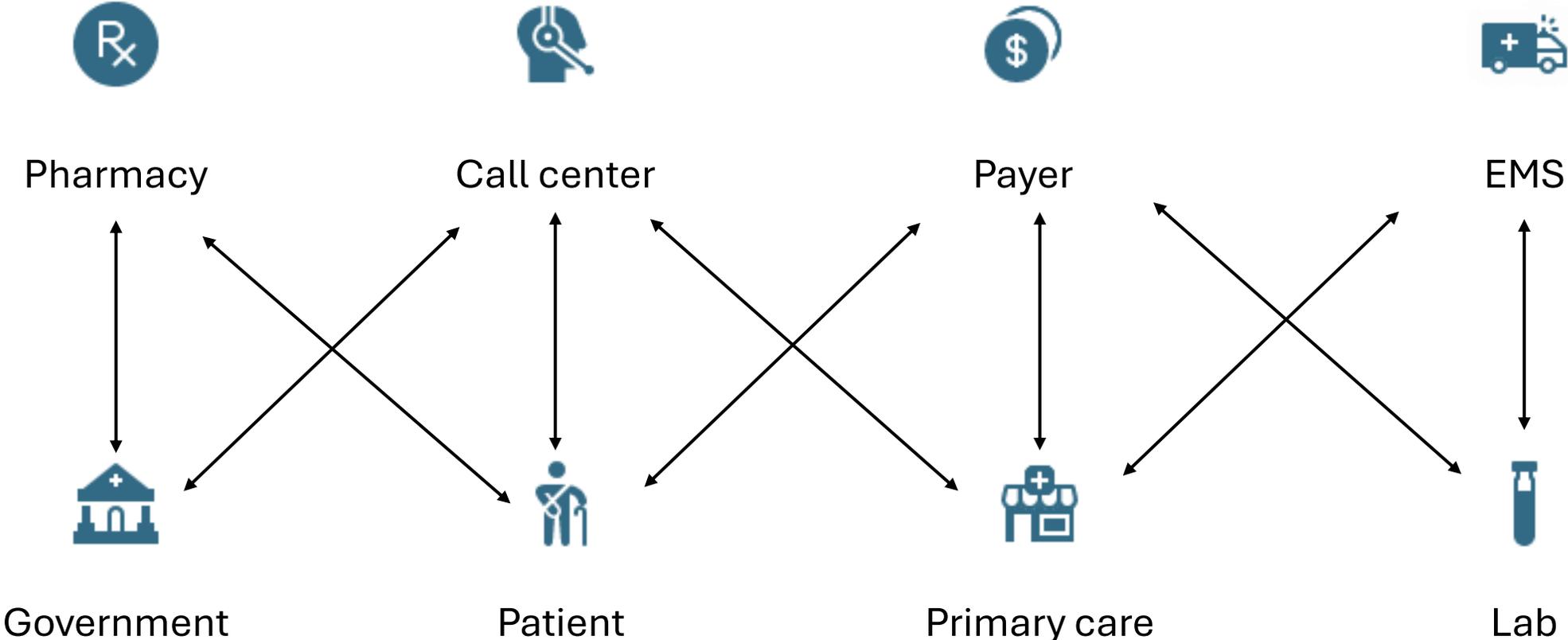
- FHIR is suitable for use in a wide variety of contexts, including uses for mobile devices, cloud communications, EHR-based data sharing, server communication in large institutions, and much more.
- The FHIR platform can serve as a clinical model for analytics and machine learning.
- Apple Health integration

Question

Which of the following organizations creates the international standard formatting for healthcare data?

- A. ONC
- B. TEFCA
- C. HL7
- D. EPIC

Connections



Health Information Exchanges



- HIE is the mobilization of healthcare information electronically across organizations within a region, community or hospital system
- HIE provides the capability to move clinical information among different healthcare information systems electronically
- The goal of HIE is to facilitate access to and retrieval of clinical data to provide safer and more timely, efficient, effective, and equitable patient-centered care

Health Information Exchanges



- There are currently three key forms of health information exchange:
 - **Directed Exchange** – ability to automatically send and receive secure information electronically between care providers to support coordinated care
 - **Query-based Exchange** – ability for providers to find and/or request information on a patient from other providers, often used for unplanned care
 - **Consumer Mediated Exchange** – ability for patients to aggregate and control the use of their health information among providers

Health Information Exchanges

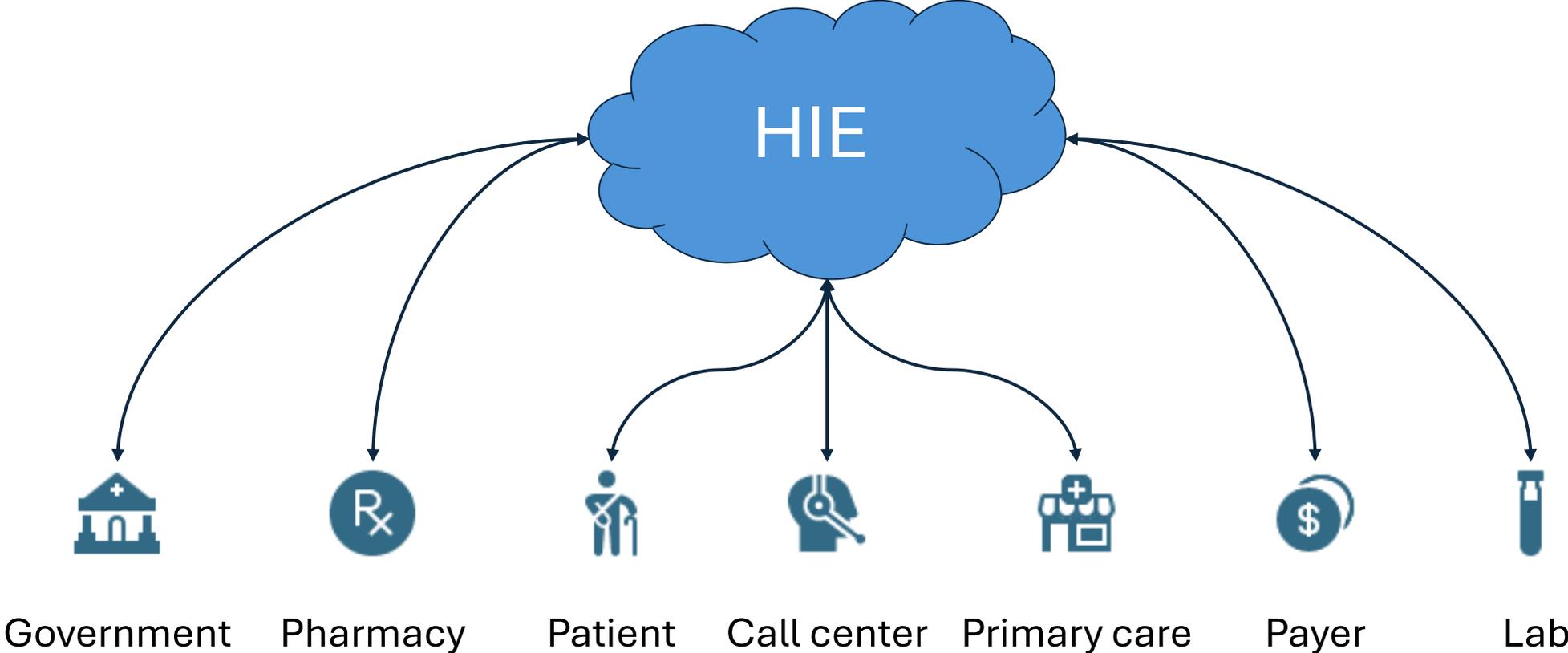


- HIE systems facilitate physicians' and clinicians' efforts to meet high standards of patient care through electronic participation in a patient's continuity of care with multiple providers.
- Secondary health care provider benefits include reduced expenses associated with:
 - the manual printing, scanning and faxing of documents, including paper and ink costs, as well as the maintenance of associated office machinery
 - the physical mailing of patient charts and records, and phone communication to verify delivery of traditional communications, referrals, and test results
 - the time and effort involved in recovering missing patient information, including any duplicate tests required to recover such information

Health Information Exchanges



Direct Exchange



HIE Direct Exchange

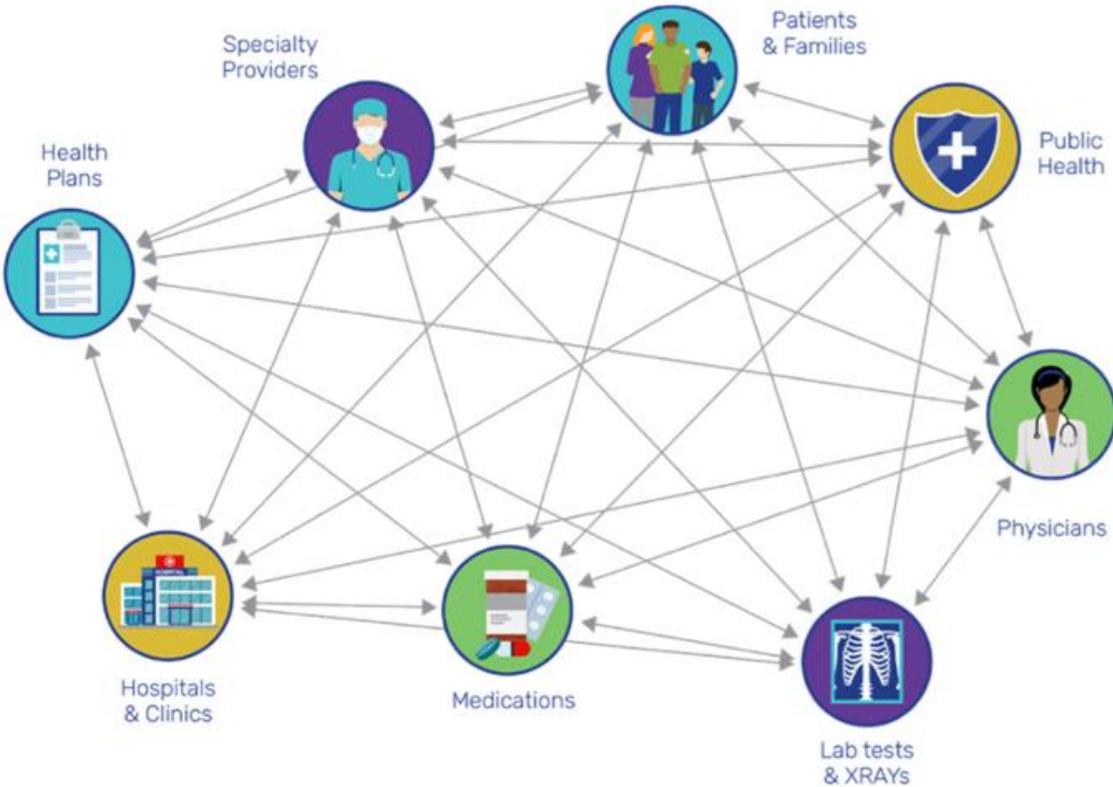


- Two models for HIEs
 - Federated - no central (master) database
 - Decentralized - central database with a full patient record
- Hybrid model
- Michigan Health Information Network (MiHIN)
- Patient consent for HIEs comes from HIPAA
- Mostly use HL7 CDA format to exchange data
- EHR vendors are required to provide tools to interact with HIEs

Statewide Health Information Exchange Creates Efficiency

BEFORE:

Duplication of effort, waste and expense



NOW:

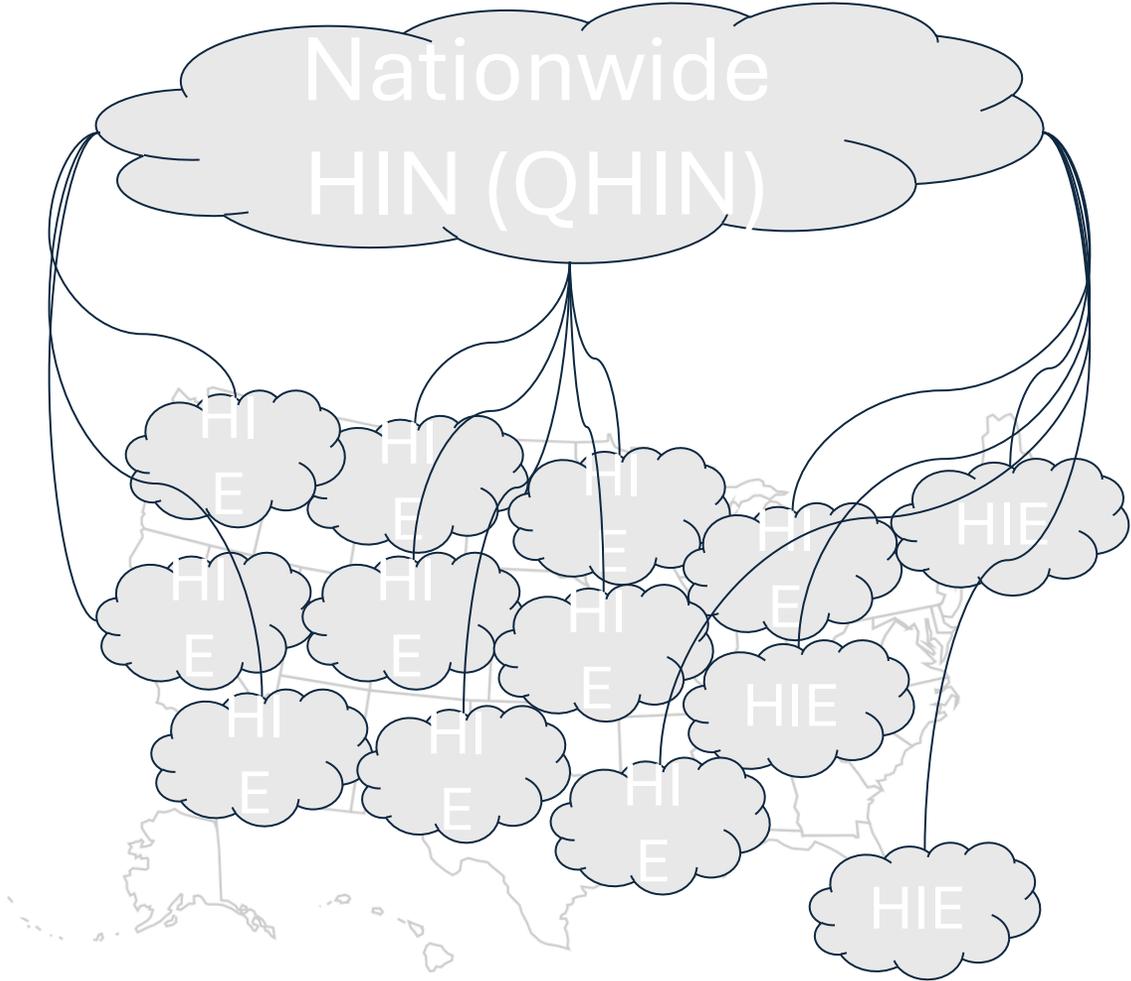
Connect once to access shared services



Health Information Exchanges



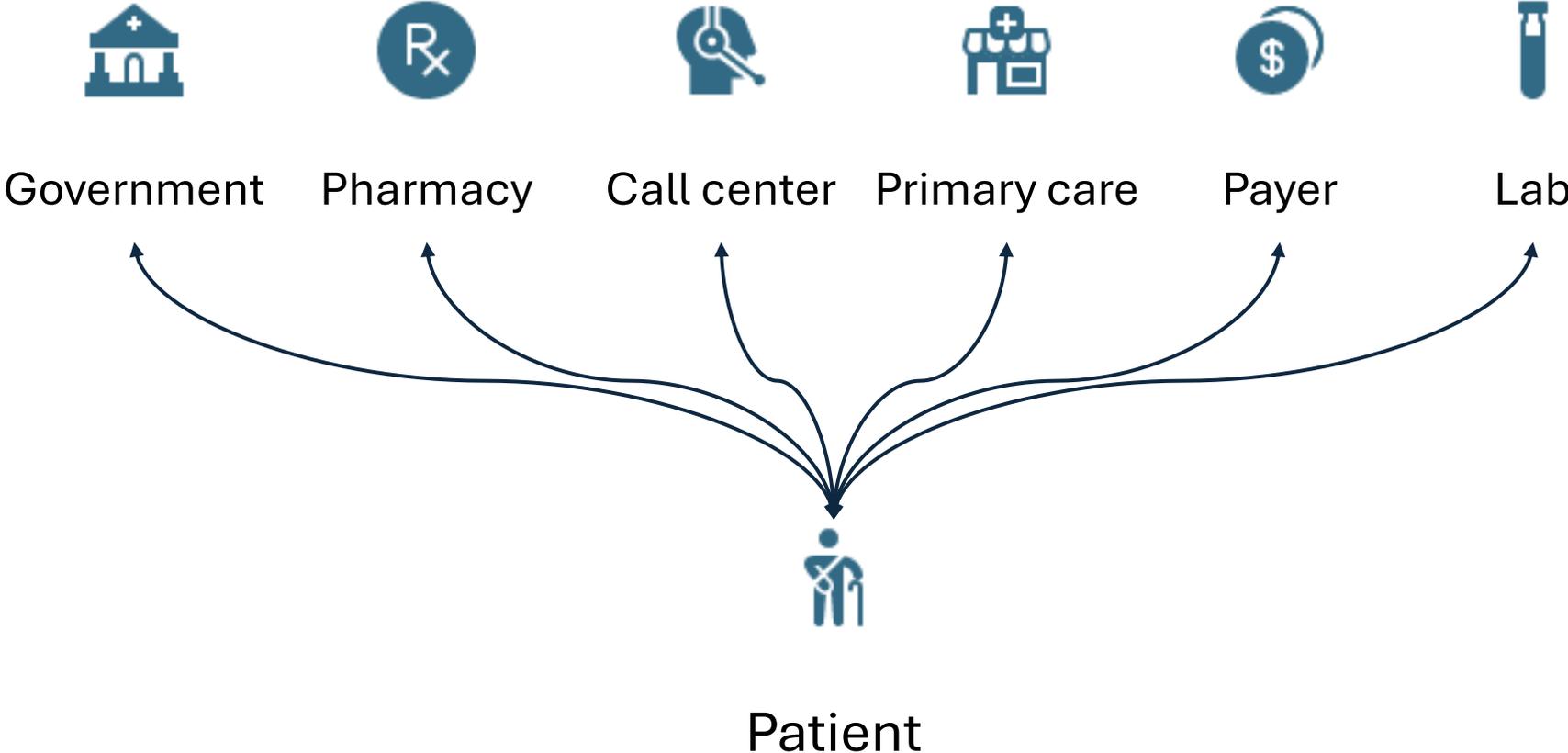
Direct Exchange



Health Information Exchanges



Consumer Mediated Exchange



HIE Consumer Mediated Exchange

- United States Core Data for Interoperability (USCDI) - 21st Century Cures
 - a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange
- Use of the USCDI standard is required as part of the new application programming interface (API) certification criterion, “standardized API for patient and population services”

Welcome Mike

Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua.



Connect Devices

Share data from your wearables, apps, and other devices.



Fitbit

[Connect](#)



Garmin

[Connect](#)



Apple Health

[Download MyDataHelps](#)



Google Fit

[Download MyDataHelps](#)



Connect Provider or Health Plan

Your electronic health records are an important source of information. They could help researchers make new discoveries. Connect your provider or health plan (ex: Medicare) with PROJECT.

[Connect Provider or Health Plan](#)

Welcome Mike

Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua.

Medications

atorvastatin 10 MG Oral Tablet
Metformin hydrochloride 500 MG Oral Tablet
atorvastatin 40 MG Oral Tablet

[67 >](#)

Lab Results

[53 >](#)

WBC COUNT

16.6 **H**

03/03/21



CHOLESTEROL

135.0

02/27/21



HDL

45.0

02/27/21



LDL

152.0 **H**

02/27/21



S M T W T F S



Tasks

Mood Survey

3 minutes

Overdue

[Start](#)

Pregnancy: Followup

3 minutes

Overdue

[Resume](#)

Alcohol and Tobacco

5 minutes

Overdue

[Start](#)

Activity Today

STEPS

3,995



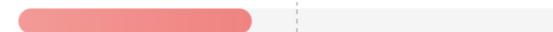
SLEEP TIME

8h 12m



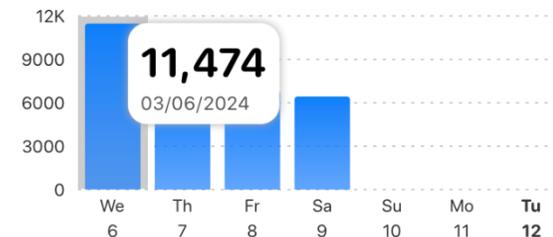
MAX HEART RATE

90 bpm



30 Day Average

Steps

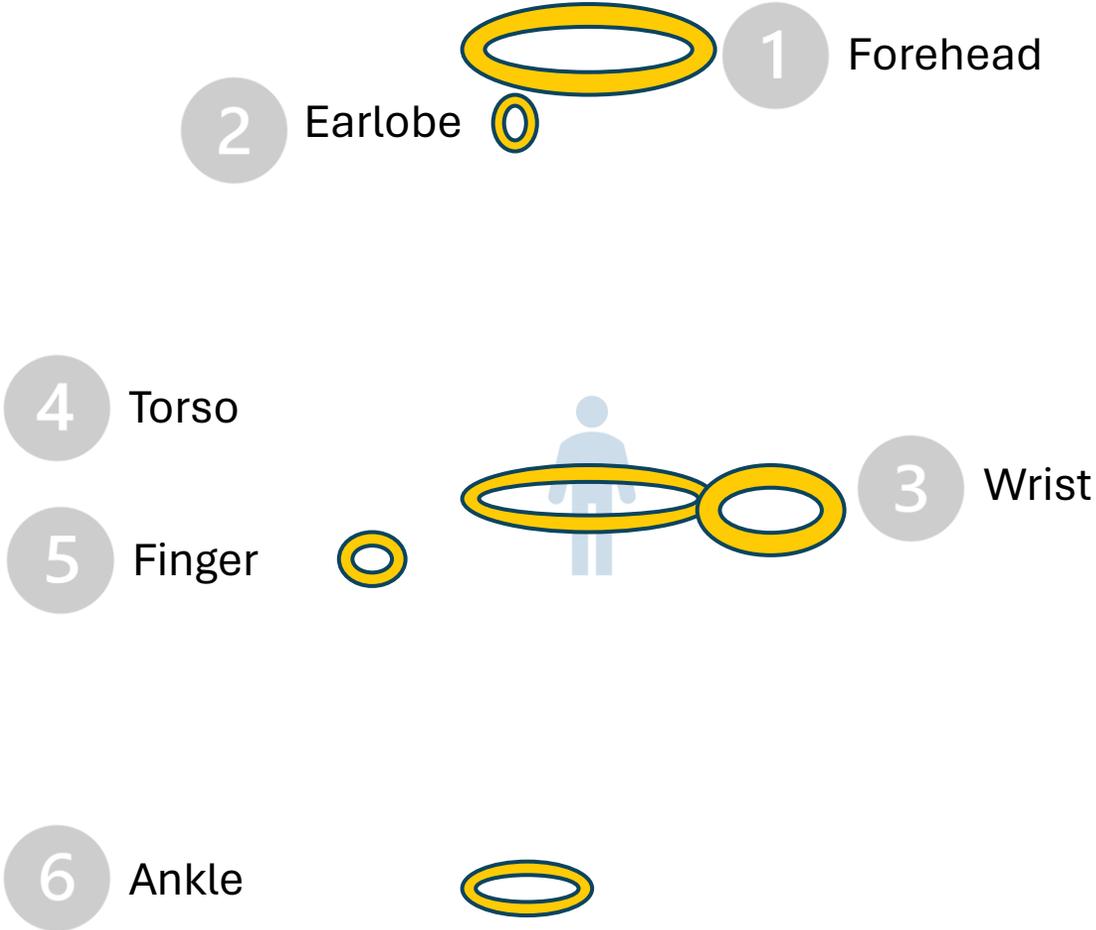


Question

You develop an algorithm within your EHR that analyzes data using an algorithm to predict the likelihood of having the flu and recommends when to call patients for therapy. Which governmental agency oversees this digital health product?

- A. Department of Health and Human Services
- B. Food and Drug Administration
- C. Federal Trade Commission
- D. Securities and Exchange Commission

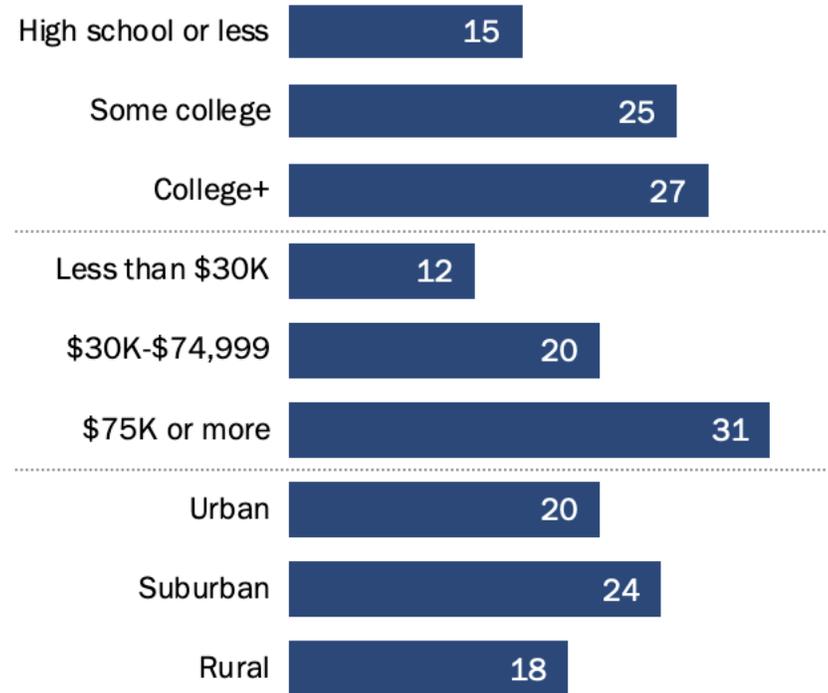
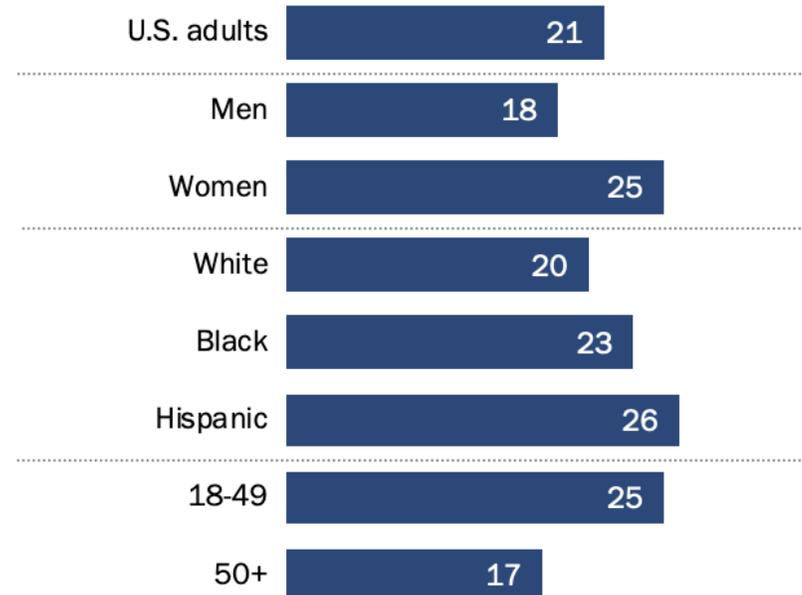
What is a wearable?



Importance of wearables in healthcare

21% of Americans say they use smart watches or fitness trackers

% of U.S. adults who say they regularly wear a smart watch or wearable fitness tracker



Note: Whites and blacks include only non-Hispanics. Hispanics are of any race. Those who did not give an answer are not shown.

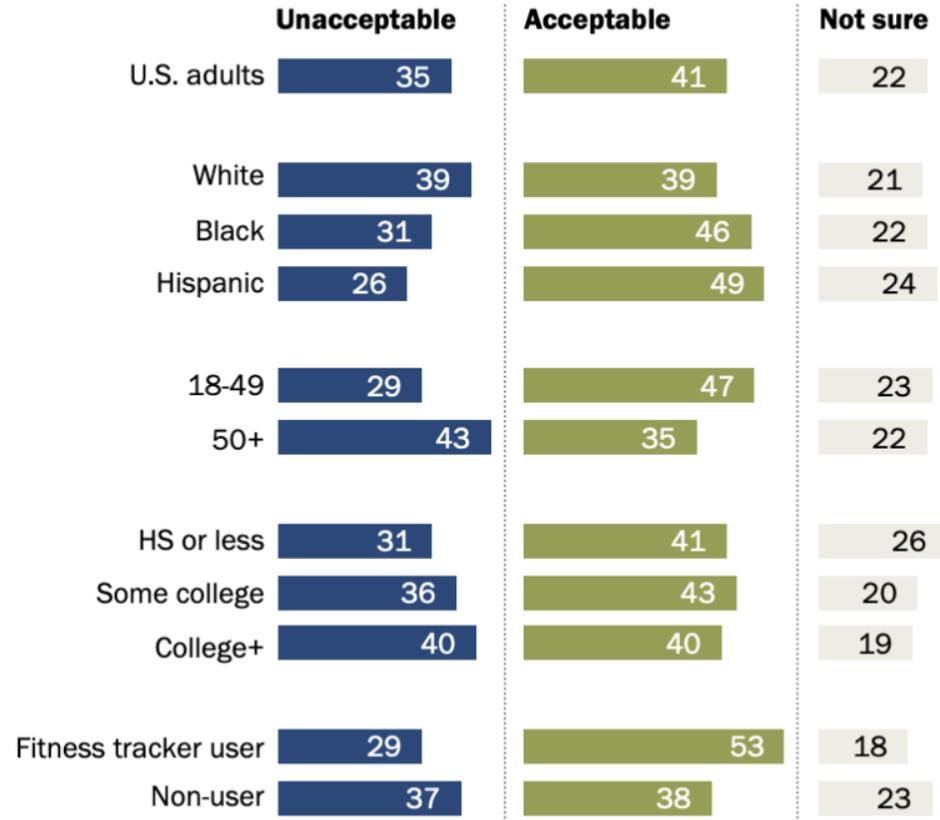
Source: Survey conducted June 3-17, 2019.

PEW RESEARCH CENTER

Importance of wearables in healthcare

About four-in-ten Americans approve of fitness tracker data being used for heart disease research

% of U.S. adults who say that makers of a fitness tracking app sharing their users' data with medical researchers seeking to better understand the link between exercise and heart disease is ...



Currently available wearables



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What sensors are inside most wearable?

- Accelerometer
- Gyroscope
- Magnetometer
- Barometer
- Temperature
- Humidity
- GPS
- Cellular
- Wi-Fi
- Bluetooth
- Photoplethysmography (PPG)
- ECG



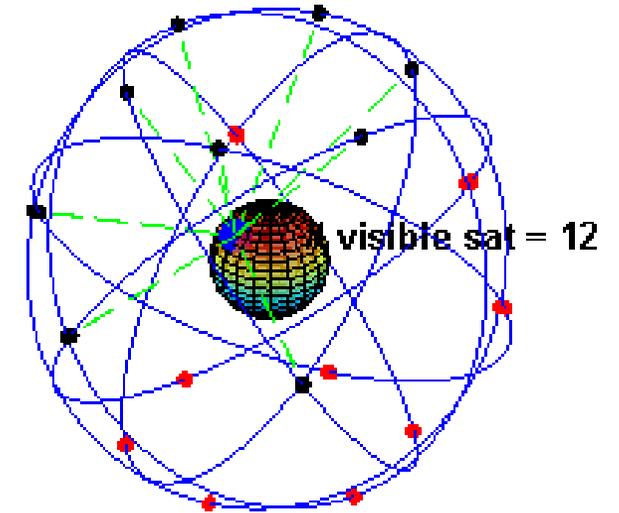
What data come from the sensors?

- Accelerometer – changes in the speed of the device
- Gyroscope – changes in the position of the device
- Magnetometer – magnetic field (compass)
- Barometer – measures air pressure
- Temperature
- Humidity – concentration of water in the air (perspiration)



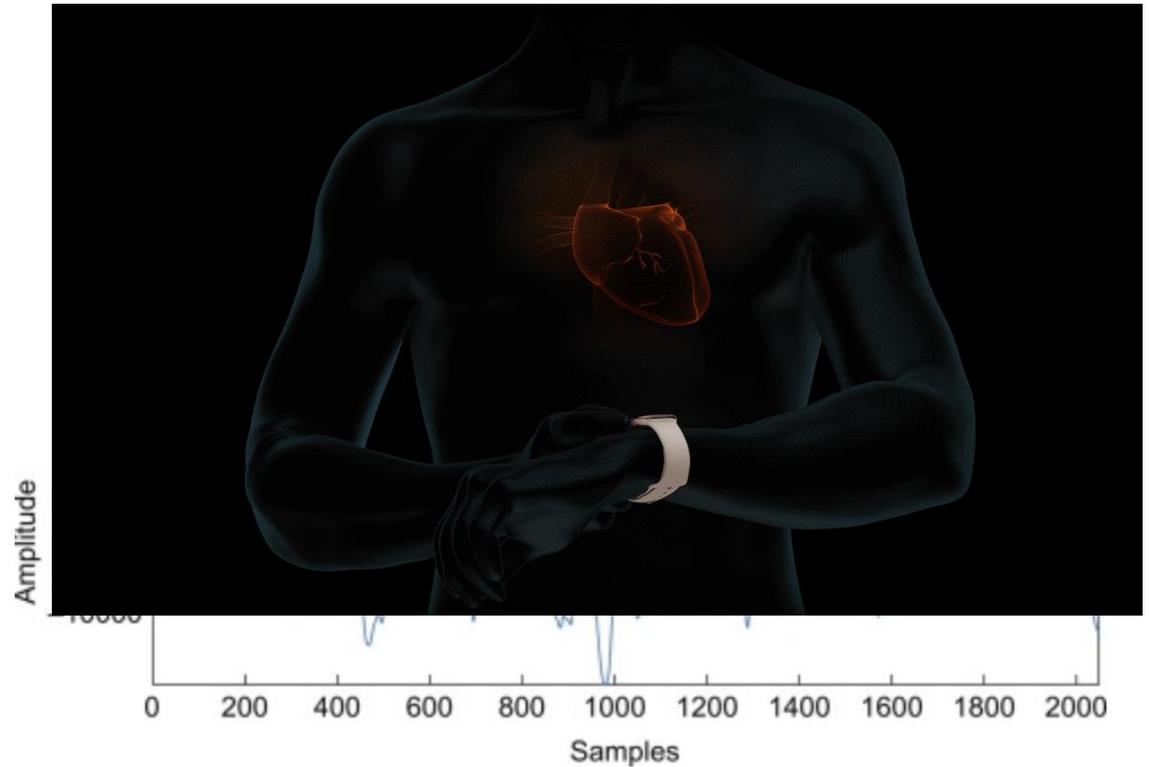
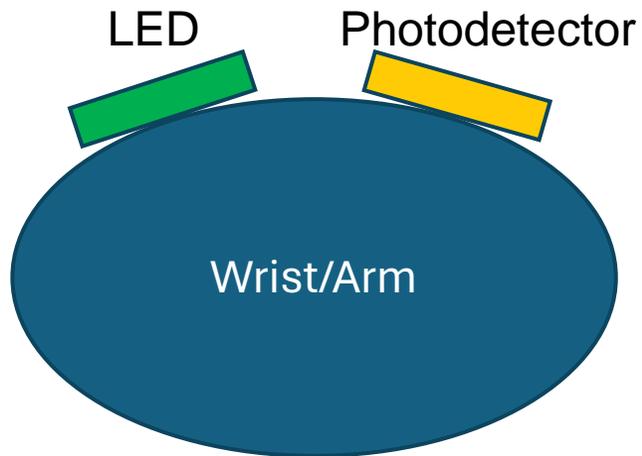
What data come from the sensors?

- GPS – satellite-based location
- Cellular – data transfer over cellular towers
- WiFi – data transfer
- Bluetooth – near field data transfer



What data come from the sensors?

- Photoplethysmography (PPG)

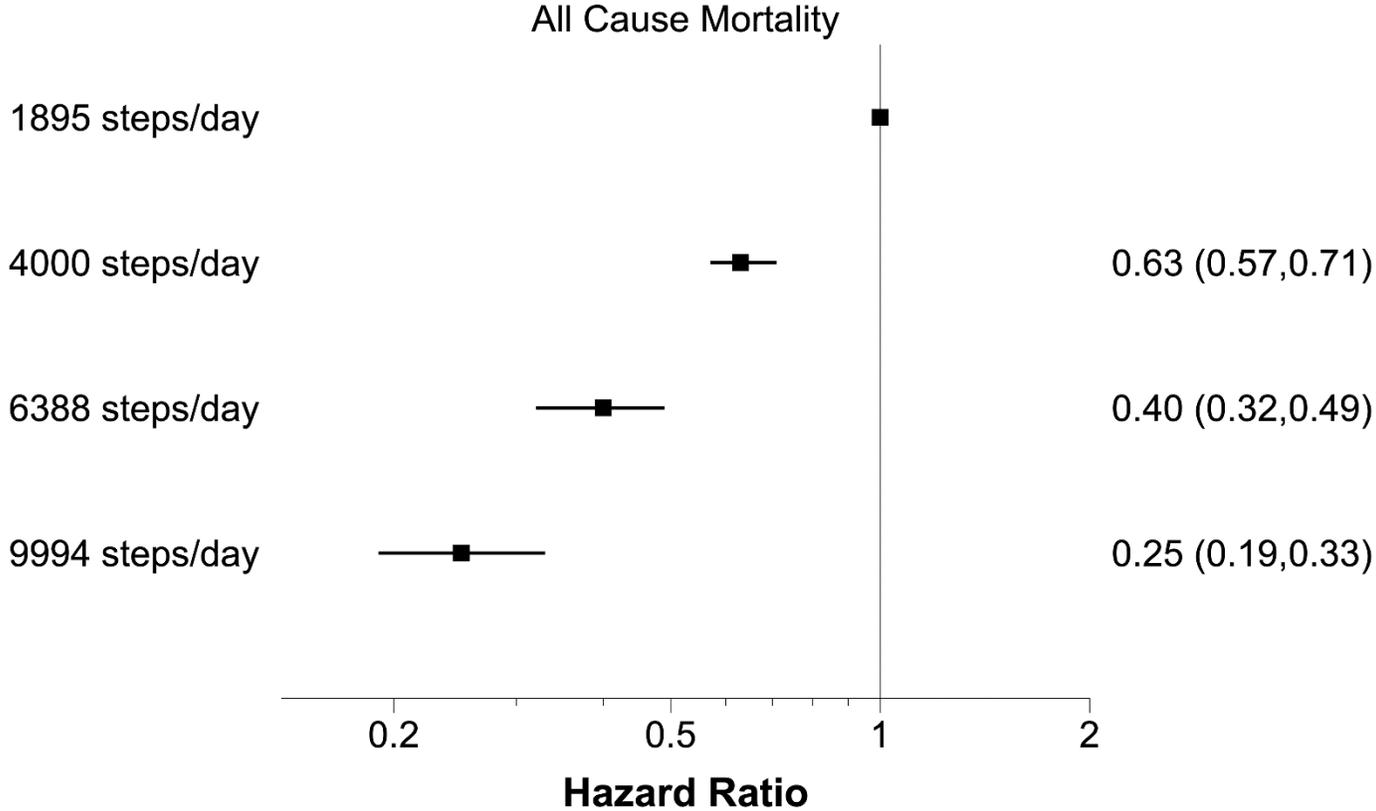


<https://physionet.org/content/wrist/1.0.0/>



How do these measurements relate to health?

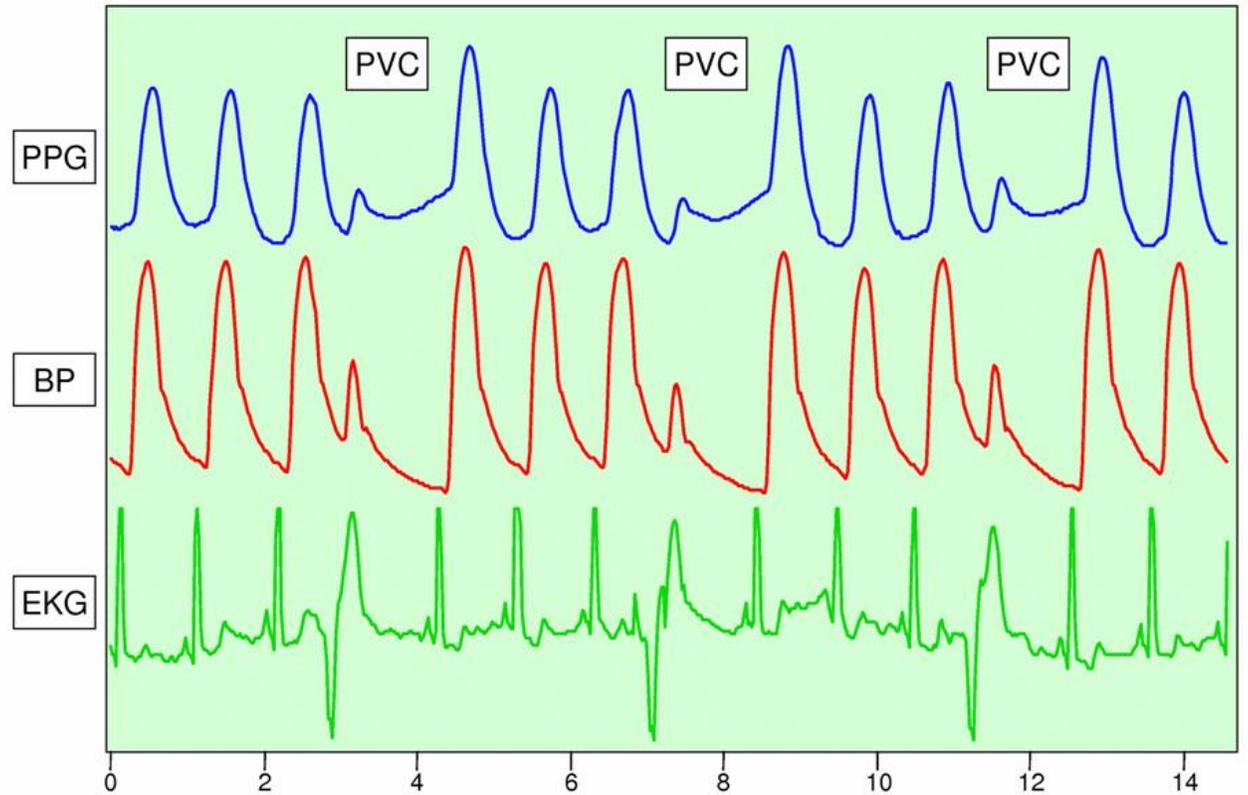
- Steps, Gait = accelerometer, gyroscope, magnetometer





How do these measurements relate to health?

- Heart rate, arrhythmias, O2 sat = PPG

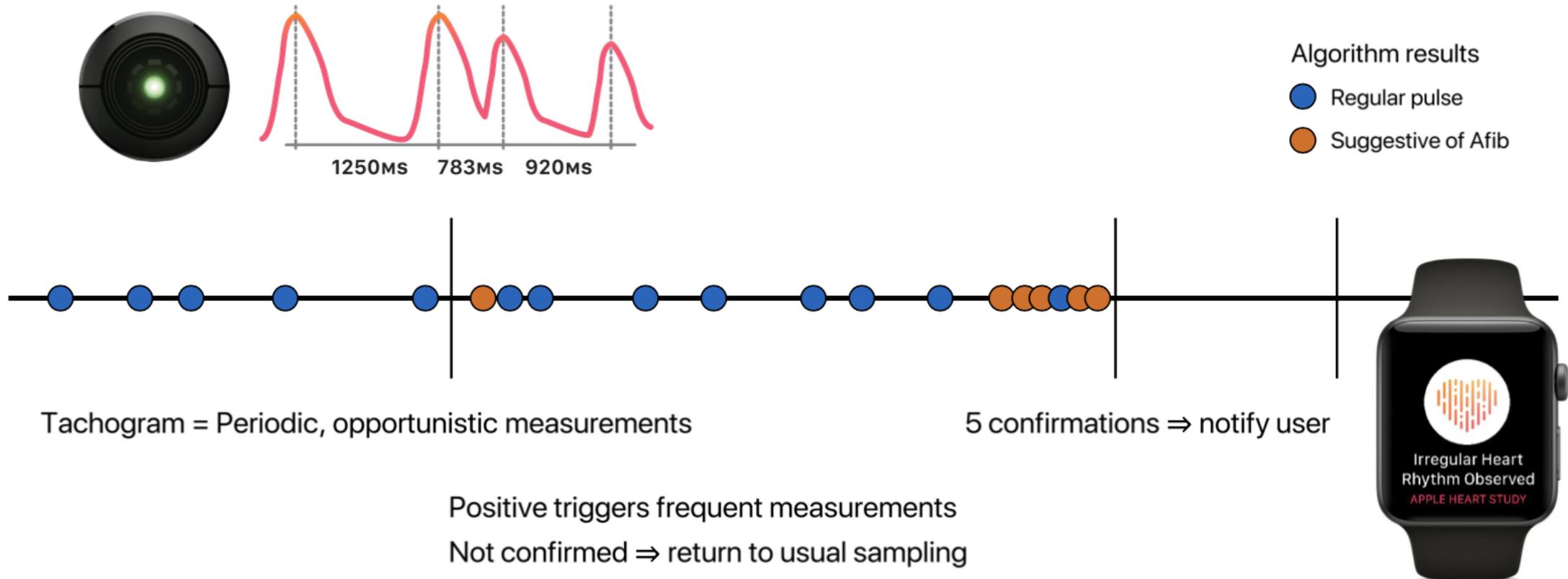


https://upload.wikimedia.org/wikipedia/commons/3/3b/PVC_detectionUsing_PGG.png

The original figure was provided by Kirk Shelley, Yale Medical School and modified by Stephen Linder, Dartmouth College.

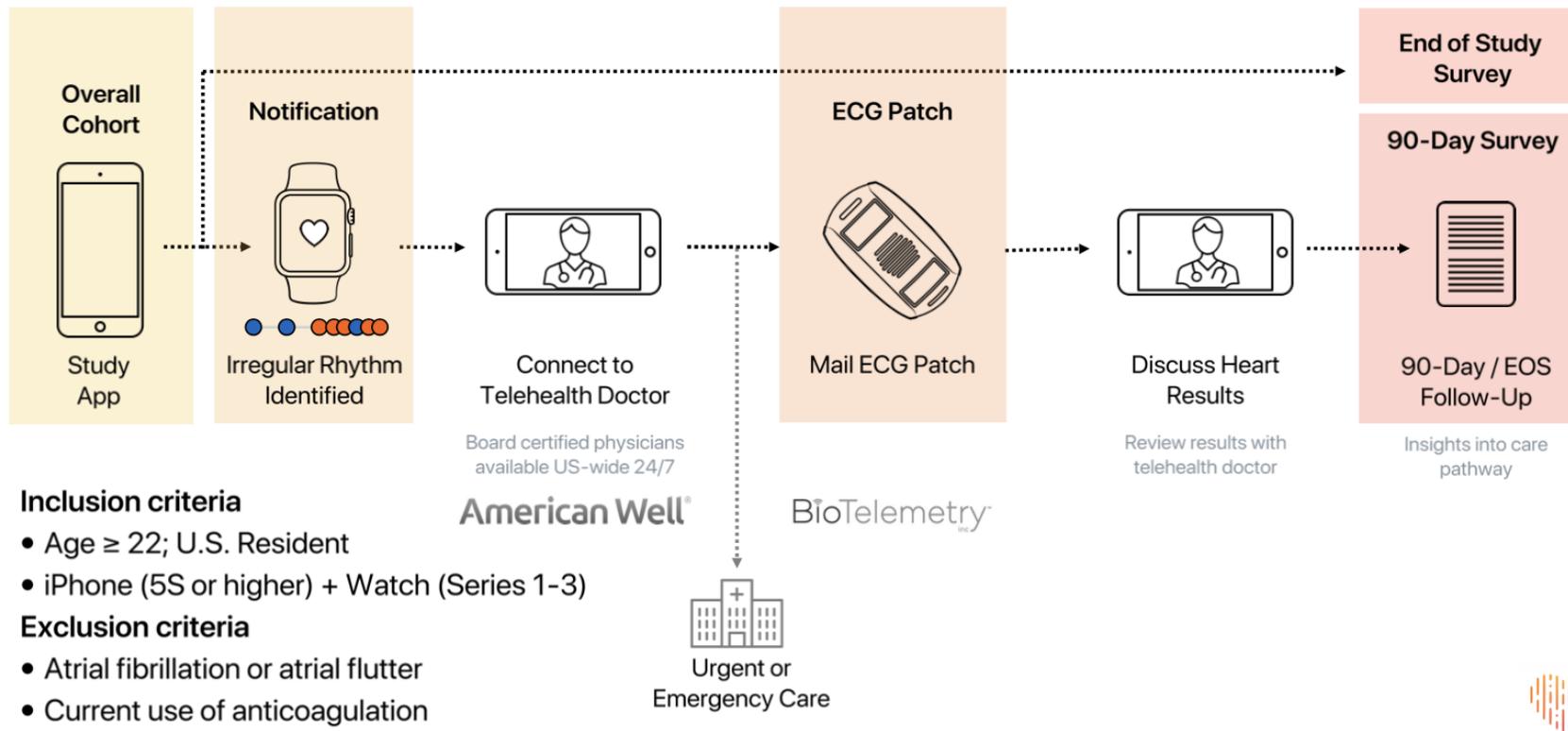
Apple Heart Study – AFib Detection

Irregular Pulse Notification Algorithm



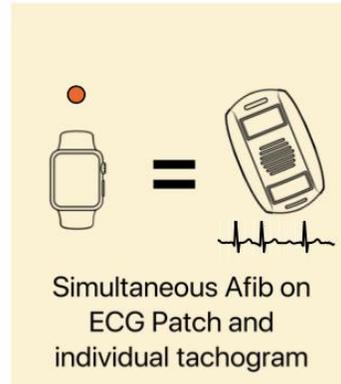
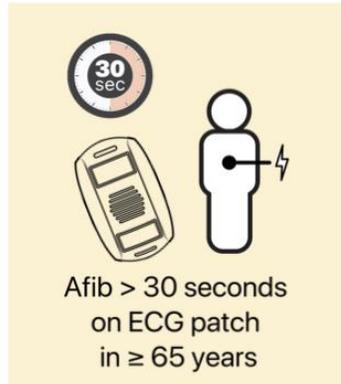
Apple Heart Study – AFib Detection

Prospective, Single Arm, Open Label Study

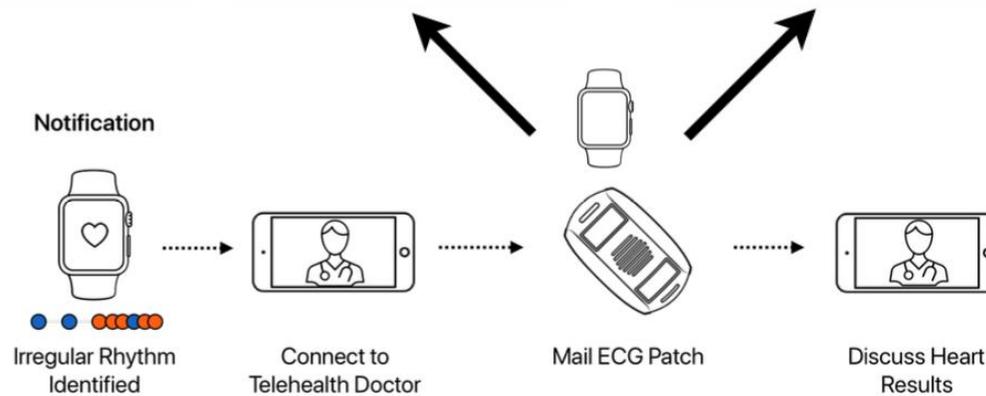
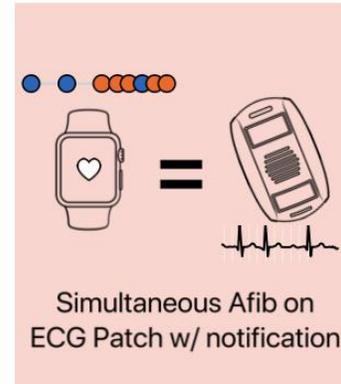


Apple Heart Study – AFib Detection

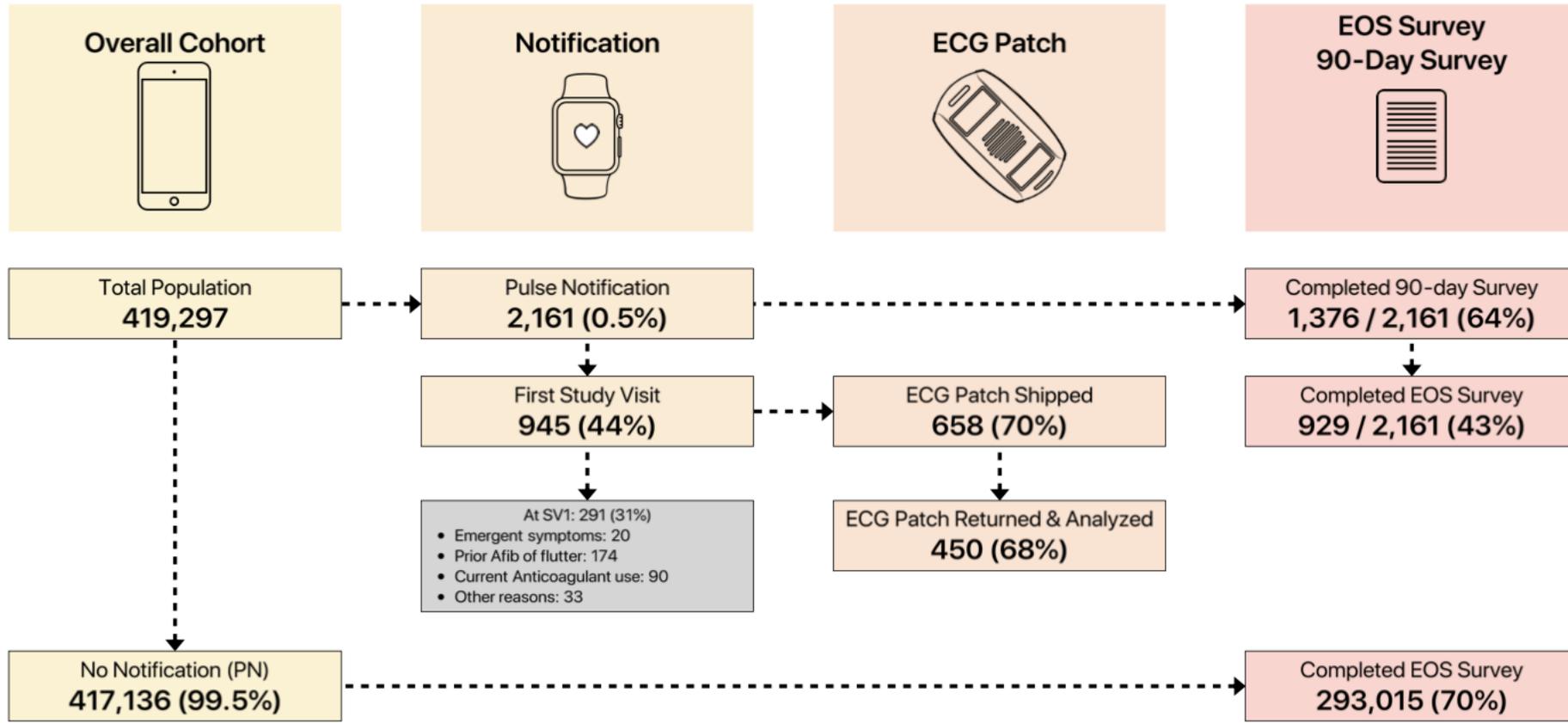
Primary Endpoints



Secondary Endpoints

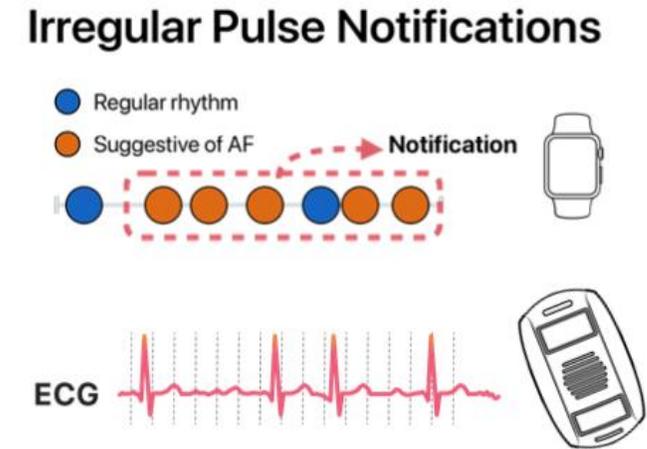
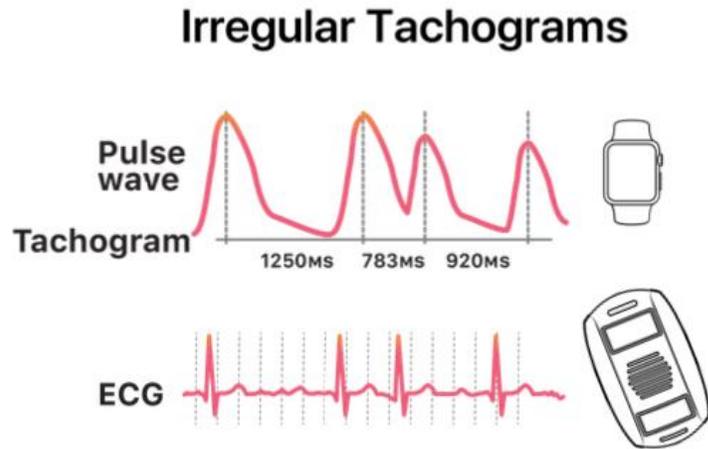


Apple Heart Study – AFib Detection



Apple Heart Study – AFib Detection

Positive Predictive Values



	Afib on ECG Patch	Positive Tachograms	PPV* (97.5% CI)
Overall	1,489	2,089	0.71 (0.69–0.74)
Age ≥ 65	548	914	0.60 (0.56 – 0.64)

	Afib on ECG Patch	Positive Notifications	PPV (95% CI)
Overall	72	86	0.84 (0.76–0.92)
Age ≥ 65	25	32	0.78 (0.64 – 0.92)

Apple Heart Study – AFib Detection

End of Study Survey

Variable	Notification group (n=929)	Non-notification group (n=293,015)
Atrial Fibrillation	404 (43%)	3070 (1%)
Warfarin	20 (2.2%)	321 (0.1%)
DOAC	202 (22%)	996 (0.3%)
Aspirin	338 (36%)	40,774 (14%)

Apple vs. Fitbit Comparison

	Apple Heart Study	Fitbit Heart Study
Total Population	419,297	455,699
Received Notification	2161 (0.5%)	4728 (1%)
Returned Patch Data	450 (20.8%)	1057 (22.3%)
Patch Confirmed AFib	153 (34%)	340 (32%)
Irregular Pulse Notifications while wearing the ECG patch, pts	86	225
Irregular Pulse Notifications while wearing the ECG patch that says AFib, pts	72 (PPV 0.84)	221 (PPV 0.98)

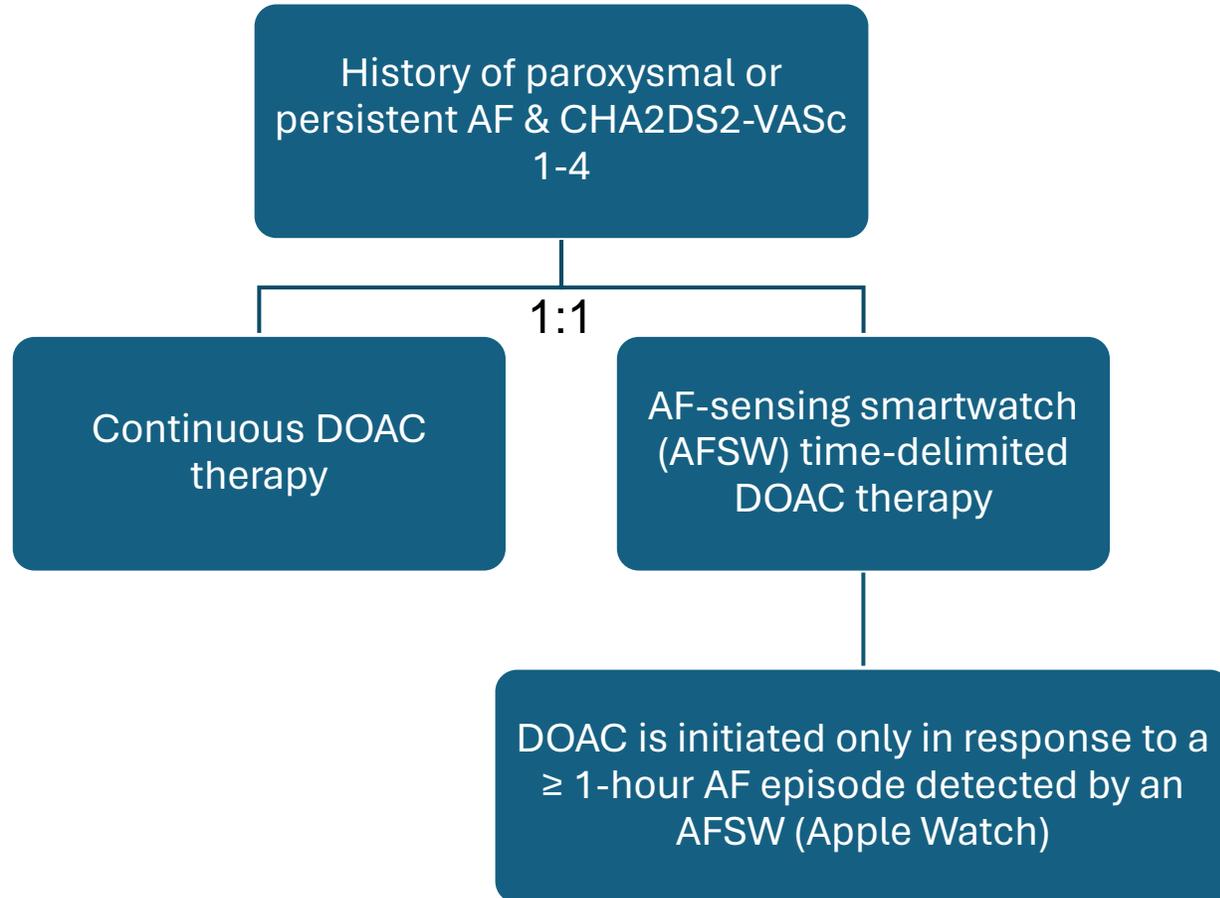
Apple vs. Fitbit Comparison

	Apple Heart Study	Fitbit Heart Study
Devices	Apple Watch	Fitbit devices
Algorithm	Intermittent and passive PPG sampling at rest	Intermittent and passive PPG sampling at rest
	Discrete 1-min sampling windows up to every 2 h followed by up to every 15 min if initial tachogram is irregular	Overlapping 5-min sampling windows
Signal Processing	Watch-based	Server-based
Time Frame	November 2017 to August 2018	May 6, 2020 to February, 2021
Regulatory implications (US)	FDA De Novo application and authorization	FDA De Novo application and authorization

Implications for AFib Detection

The Fitbit PPG-based algorithm and Irregular Heart Rhythm Notifications feature will soon be available to consumers in the U.S. across a range of heart-rate enabled devices. We want to make AFib detection as accessible as possible to help reduce the risk of potentially life-threatening events — like stroke — and ultimately improve overall heart health for everyone. We'll continue to work with the [BMS-Pfizer Alliance](#) to develop educational content for patients and healthcare providers that will help identify and support people in the U.S. with irregular heart rhythms consistent with atrial fibrillation.

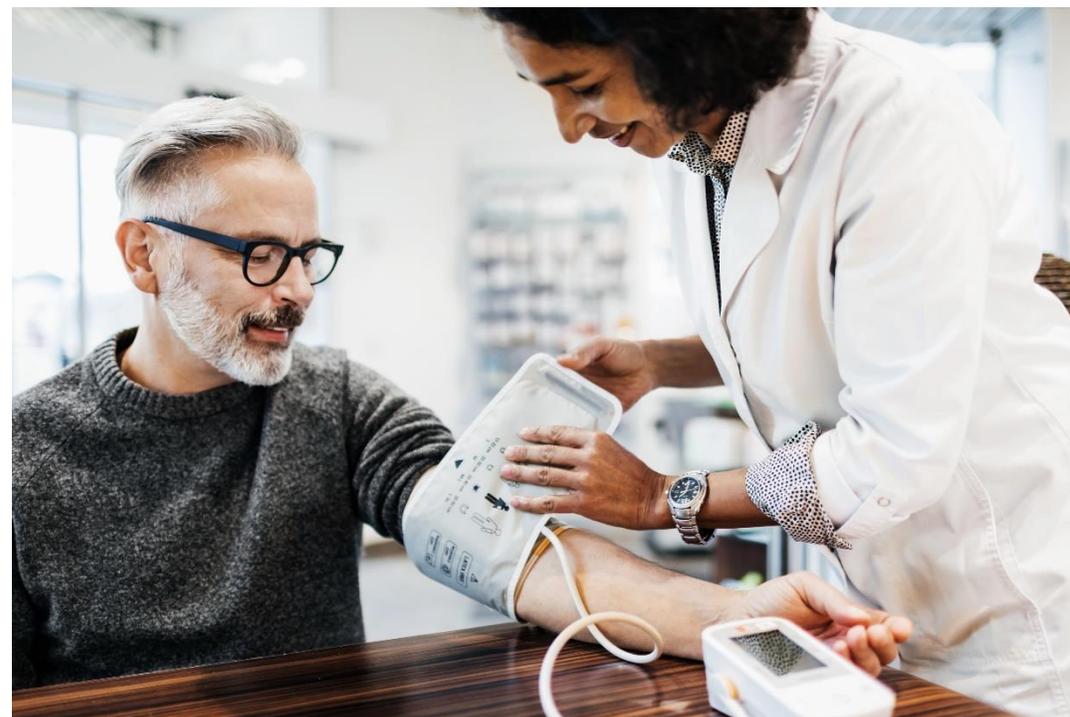
REACT-AF Trial



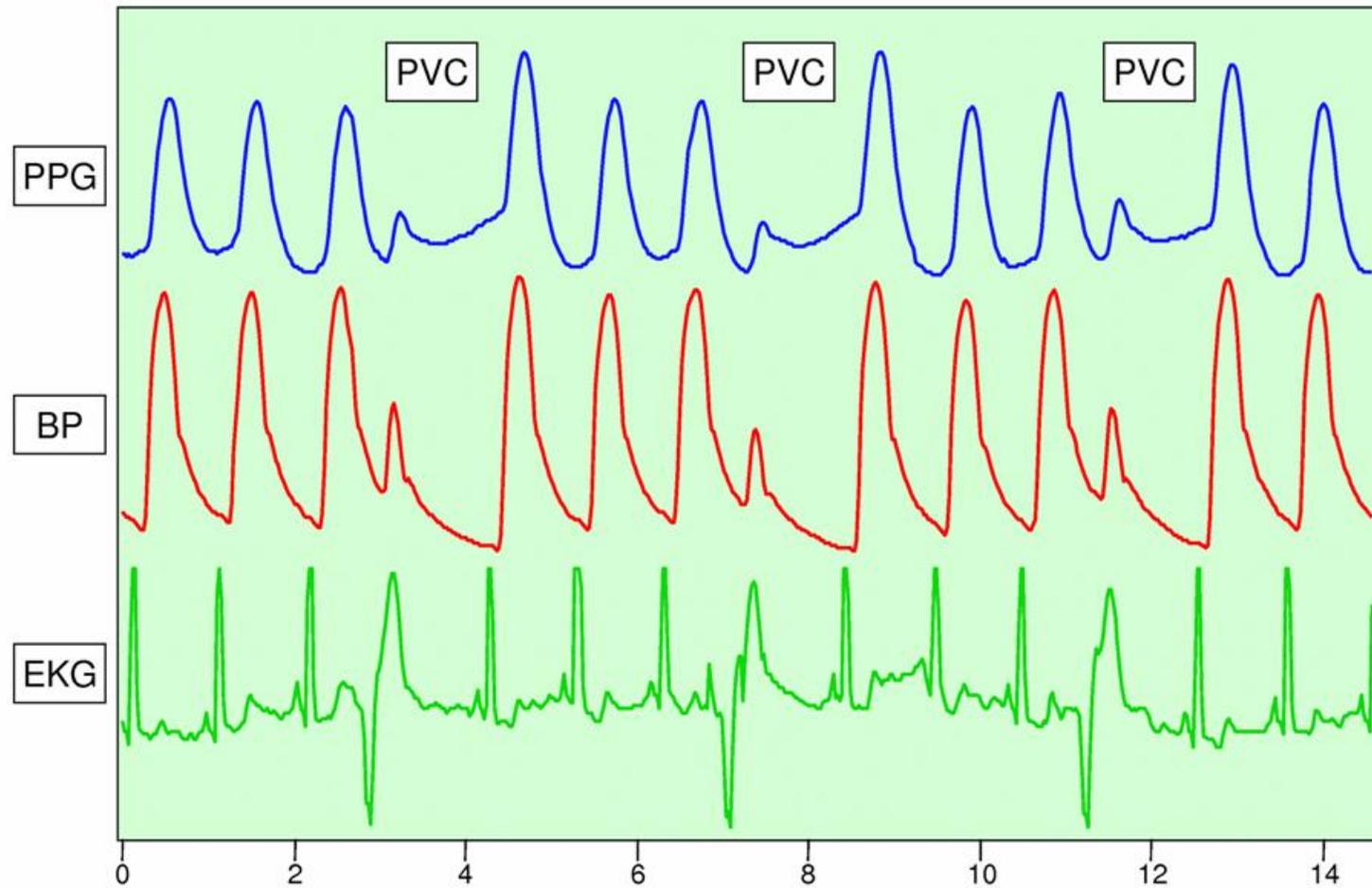
Efficacy Outcome: non-inferior composite endpoint that includes: (1) Ischemic Stroke; (2) Systemic embolism; (3) All-cause mortality

Safety Outcome: major bleeding

Blood Pressure



Blood Pressure



https://upload.wikimedia.org/wikipedia/commons/3/3b/PVC_detectionUsing_PGG.png

The original figure was provided by Kirk Shelley, Yale Medical School and modified by Stephen Linder, Dartmouth College.

Implications for HTN

- Nocturnal BP measurements
- Medication titration
- Patient management
- Medication adherence

What does the future hold for digital health?

- **mHealth** – more patient-centered clinical decision support
 - Motivating patients to improve their health
- **Health IT** – more provider-centered clinical decision support
 - Improving provider workload and workflow
 - Integration of EHR data into mHealth
- **Wearables** – integration into the EHR
 - PPG sensor arrhythmia detection and blood pressure

Need More Information?

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@DorschMike



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