eCohort Recruitment and Collection of Real-World Data

The Eureka Research Platform

UC BRAID Retreat

Oct 2, 2018

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Department of Epidemiology and Biostatistics, UCSF

Outline

- Real-world data
  - A new buzz word; rationale for EHR and mHealth data
- eCohorts and mHealth data collection
  - Health eHeart Study → Eureka Research Platform
  - Some examples of mHealth data we collect
  - Linking mHealth and EHR data
- Future directions, and ?'s for BRAID

VIEWPOINT

Real-World Evidence and Real-World Data for Evaluating Drug Safety and Effectiveness

Jacqueline Corrigan-Curay, JD, MD
Center for Drug Evaluation and Research, Food and Drug Administration, Silver Spring, Maryland.

Leonard Sacks, MD
Center for Drug Evaluation and Research, Food and Drug Administration, Silver Spring, Maryland.

Janet Woodcock, MD
Center for Drug Evaluation and Research, Food and Drug Administration, Silver Spring, Maryland.

For hundreds of years, the development of new medical treatments relied on "real-world" experience. Discoveries such as citrus fruit curing scurvy described in the 1700s or insulin as a treatment for diabetes in the 1920s long preceded the advent of the modern randomized clinical trial. What these diseases had in common was a reliable method of diagnosis, a predictable clinical course, and a large and obvious effect of the treatment.

In the late 1940s, the medical community began to adopt the use of randomized clinical designs for drug trials.[1] The recognition that anecdotal reports based on clinical practice observations were often misleading led to the nearly complete replacement of this "real-world evidence" (RWE) approach to evidence generated using the modern clinical trial model. Although moving medical science toward greater scientific rigor, this transformation simultaneously diminished the use (and minimized the value) of evidence generated from practice-based observations. Randomization and blinding became the gold standard for determining the effect of treatment. With strict protocol-specified definition of eligible patients, records (EHRs), together with rising costs and recognized limitations of traditional trials, has renewed interest in the use of real-world data (RWD) to enhance the efficiency of research and bridge the evidentiary gap between clinical research and practice. RWD can be defined as data relating to patient health status or the delivery of health care routinely collected from a variety of sources, such as the EHR and administrative data.

Under the 21st Century Cures Act, the Food and Drug Administration is tasked with developing a program to evaluate the use of RWE to support approval of new indications for approved drugs or to satisfy postapproval study requirements.[2] RWE can be defined as the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD. A framework for this program will be published by the end of 2018.

The FDA routinely uses RWD to provide evidence about drug safety, drawing on claims and pharmacy data from more than 100 million individuals in its Sentinel System.[3] In addition, FDA regulations have long recognized that historical controls taken from practice settings can be used as reference groups in

JAMA. 2018 Sep 4;320(9):867-868

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  - Enhance efficiency
  - Reduce problems with generalizability

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- Insisting on “research-grade” measurements is:
  - Expensive
  - Time-consuming/demanding for patients
- Use sources of data that are being collected anyway
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  - Allows us to study “everyone”

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Claims data
EHR data
mHealth data
Other?

Real-World Evidence

- FDA: Types of real-world data
  - Claims and billing activity
  - EHR data
  - Product and disease registries
  - Patient-generated data including in home-use settings
  - Data gathered from other sources that can inform on health status, such as mobile devices

https://www.fda.gov/scienceresearch/specialtopics/realworldevidence/default.htm

Real-World Evidence

- FDA mandate from 21st Century Cure Act (Dec 2016)
  - Develop a program to consider how/when to use real-world evidence for new indications and post-marketing surveillance
  - Framework for program coming by end of 2018
    - Likely to include both observational studies and “pragmatic trials” / “large simple trials”

Real-World Evidence

- How does one collect patient-generated and mHealth data for research studies?

Our team's motivation

Can we use emerging technology to improve health?

- 3 Mechanisms:
  - Do research more efficiently
  - Collect new types of measurements
  - Design and test new types of interventions

The “eCohort” Vision

- eCohort ~= Electronic Cohort Study
  - Approach, consent, enroll over the internet
  - Use online surveys for self-reported data
  - Use electronic health records for health measurements and outcomes
  - Use sensors to collect and transmit real-time/real-life data
  - Use online social networks to collect social data, engage ppts, deliver interventions

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  - U
  - U surements
    a
  - U /real-life
    d
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Cheaper, faster, easier, better?

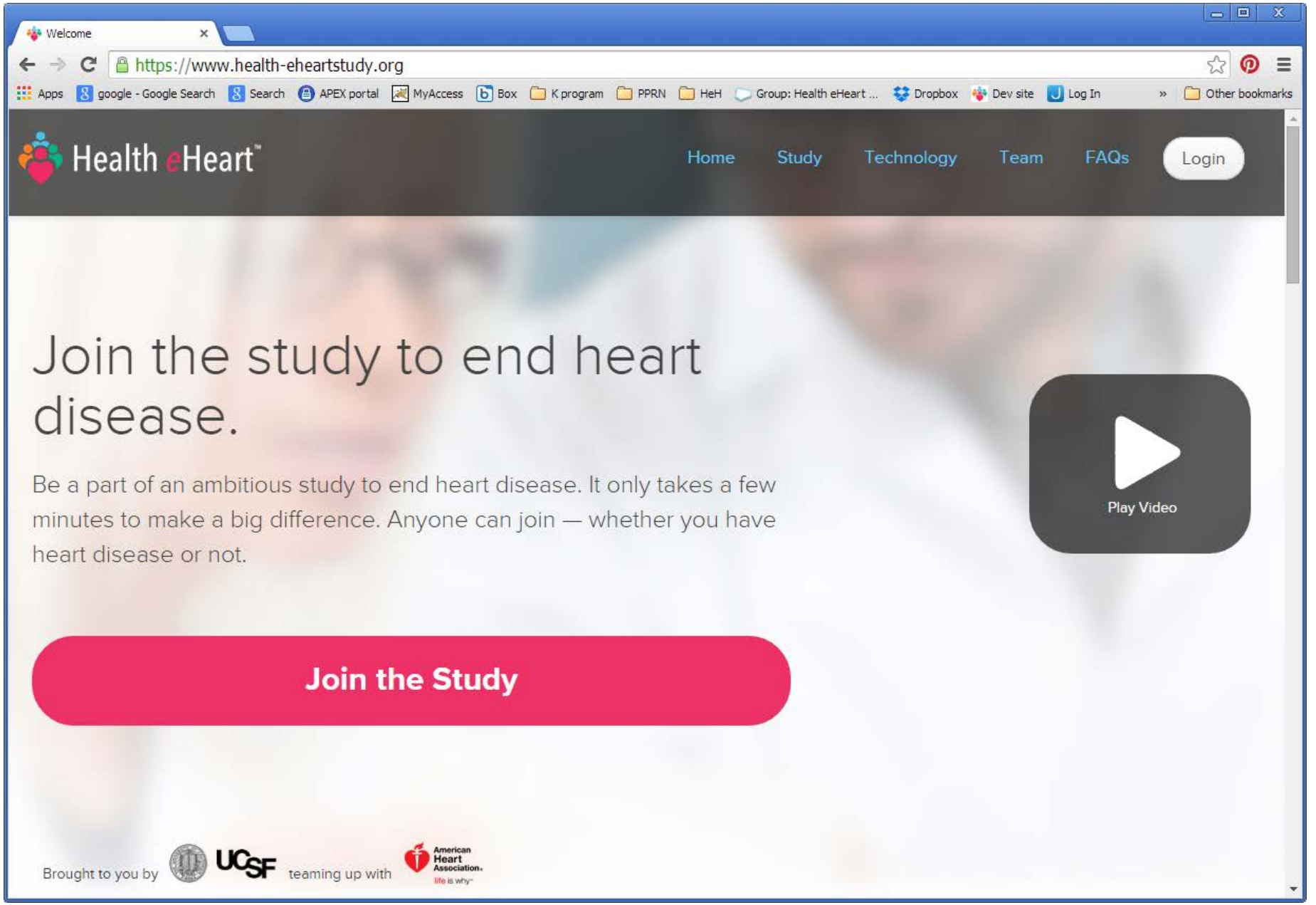
The Health eHeart Study™

Using big data to reduce heart disease

The Health eHeart Study

- Overarching Goal:
  - Do research that improves cardiovascular health

- Approach:
  - Collect “big data”
  - Keep marginal costs low
  - Support ancillary studies, including RCTs


Welcome
https://www.health-eheartstudy.org
Apps
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Search
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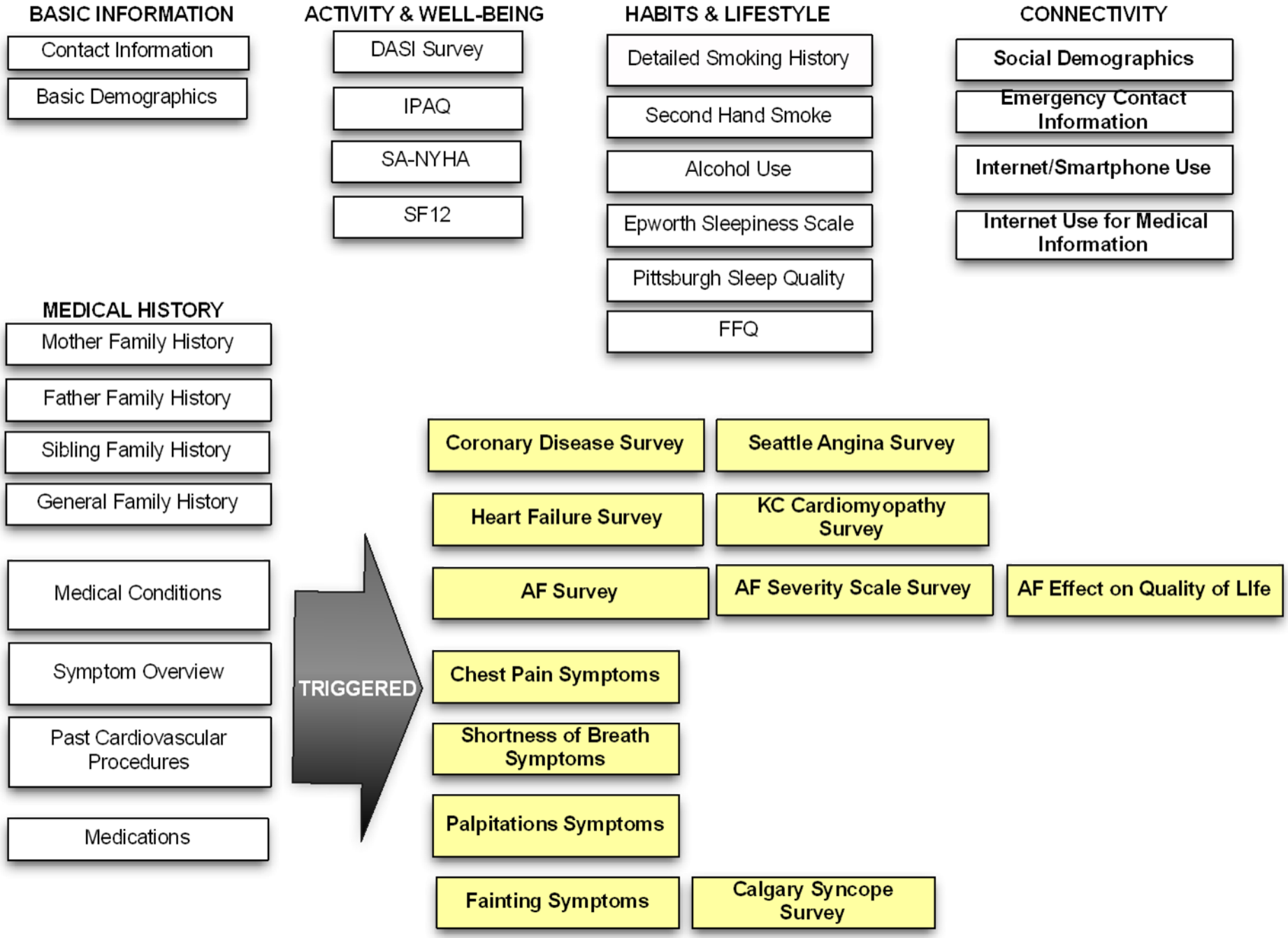
PPRN
HeH
Group: Health eHeart ...
Dropbox
Dev site
Log In
Other bookmarks
Health eHeart
Home
Study
Technology
Team
FAQs
Login
Join the study to end heart disease.
Be a part of an ambitious study to end heart disease. It only takes a few minutes to make a big difference. Anyone can join — whether you have heart disease or not.
Play Video
Join the Study
Brought to you by
UCSF
teaming up with
American Heart Association.
life is why


BASIC INFORMATION
Contact Information
Basic Demographics
ACTIVITY & WELL-BEING
DASI Survey
IPAQ
SA-NYHA
SF12
HABITS & LIFESTYLE
Detailed Smoking History
Second Hand Smoke
Alcohol Use
Epworth Sleepiness Scale
Pittsburgh Sleep Quality
FFQ
CONNECTIVITY
Social Demographics
Emergency Contact Information
Internet/Smartphone Use
Internet Use for Medical Information
MEDICAL HISTORY
Mother Family History
Father Family History
Sibling Family History
General Family History
Medical Conditions
Symptom Overview
Past Cardiovascular Procedures
Medications
TRIGGERED
Coronary Disease Survey
Seattle Angina Survey
Heart Failure Survey
KC Cardiomyopathy Survey
AF Survey
AF Severity Scale Survey
AF Effect on Quality of LIfe
Chest Pain Symptoms
Shortness of Breath Symptoms
Palpitations Symptoms
Fainting Symptoms
Calgary Syncope Survey

AliveCor

GINGER.io

- **Background continuous data collection from smartphone sensors**
  - Mobility & Activity
  - Screen interaction, call/text interaction
  - Behavior modeling
- **Reminders/Messaging**
- **Contextual alerts**

iHealth

Pulse Oximetry

BP

Wt/Body Comp

fitbit

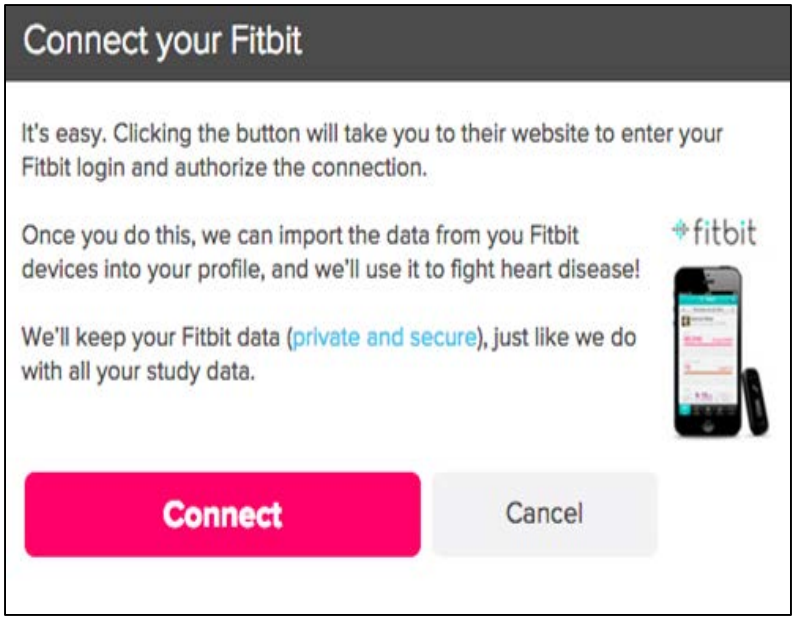
Integrated devices and apps

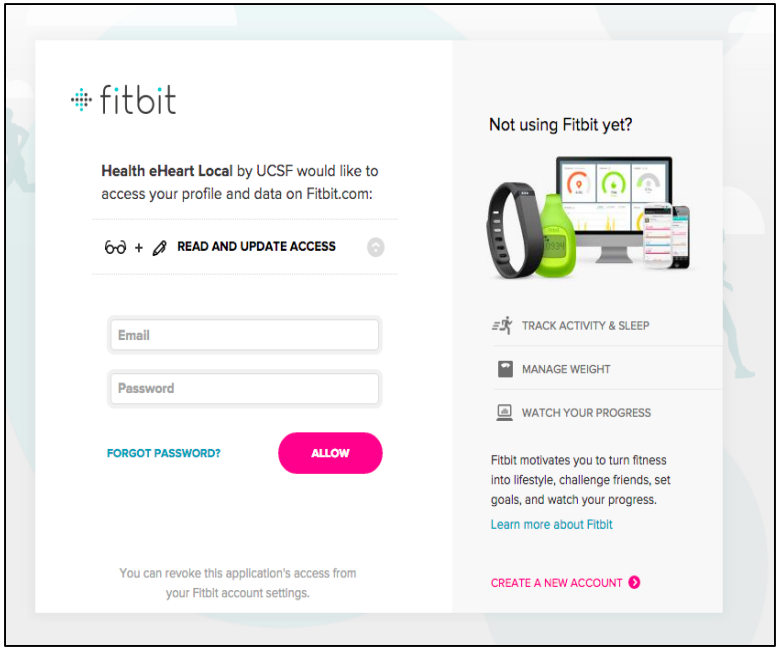
Withings

Modular Consent System

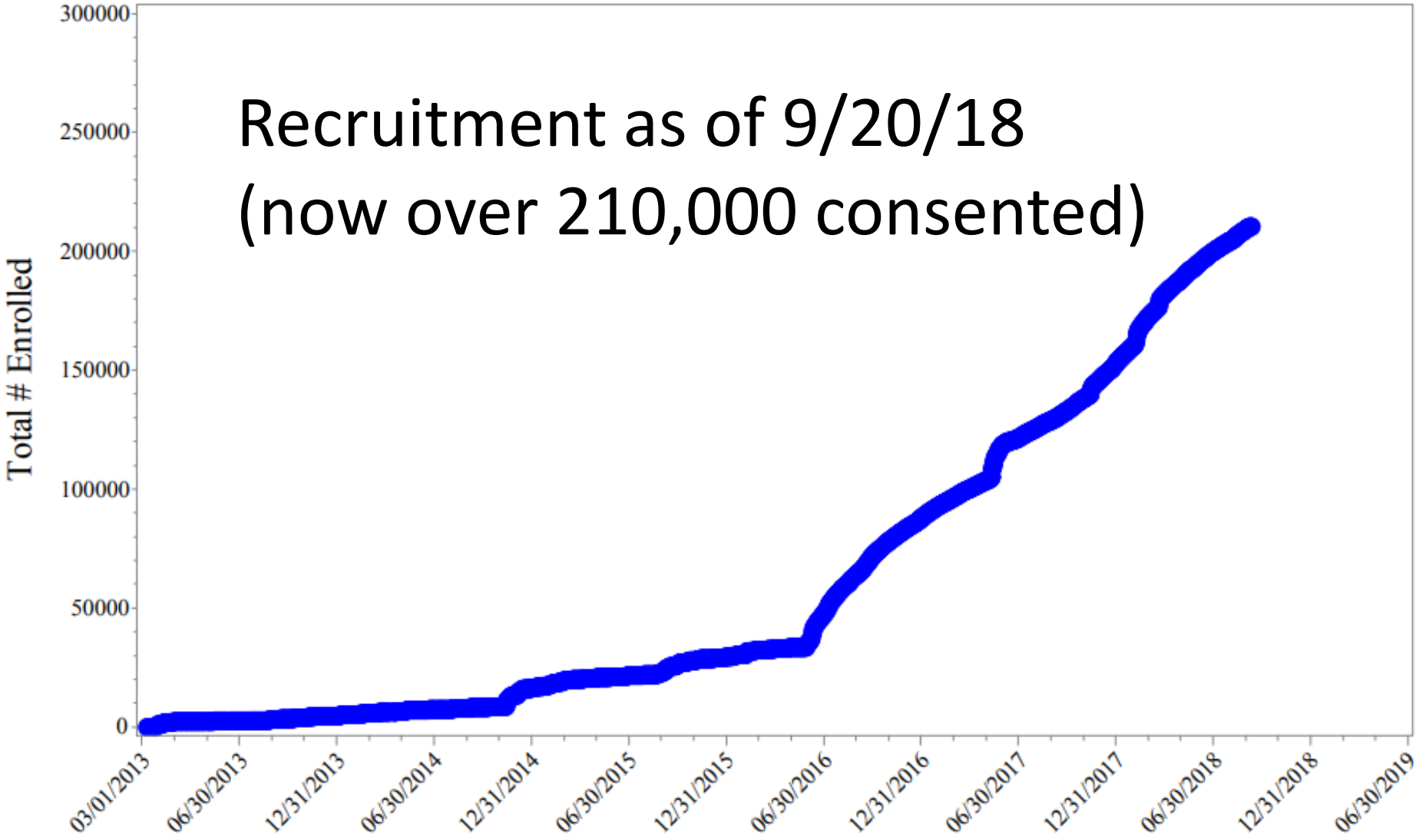
- “Umbrella” consent to answer surveys and use data for research
- Then add short, just-in-time consent modules

2-Step Fitbit Consent Module





- Use API hosted by company
- OAuth 2.0 protocol


Recruitment as of 9/20/18
(now over 210,000 consented)
Total # Enrolled
300000
250000
200000
150000
100000
50000
0
03/01/2013
06/30/2013
12/31/2013
06/30/2014
12/31/2014
06/30/2015
12/31/2015
06/30/2016
12/31/2016
06/30/2017
12/31/2017
06/30/2018
12/31/2018
06/30/2019

Measurements collected
As of 11/10/17

Self report

- 1,453,424 surveys completed (from 61,421 people)
- 242,776 vital signs (from 40,918)
- 87,482 lab results(from 14,221)

Participant-triggered device measurements

- 1,336,158 weights (from 3,656)
- 302,537 blood pressures (from 2100)
- 18,657 EKGs from Alivecor (from xxx)

Passively collected device/app measurements

- 3,244,488 daily step counts (from 7,823)
- 314,519 days of movement/communication patterns (from 2,263)
- 2,429 possible hospitalizations from 179 hospitals

Measurements collected

As of 11/10/17

Variable levels of participation

Self report

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Measurements collected
As of 11/10/17

n/N	
	Weight
1.3	• 48,741 self-reported (from 37,977)
365	• 1,336,158 device (from 3,656)
	Blood pressure
1.6	• 39,847 self-reported (from 25,092)
144	• 302,537 device (from 2,100)

Measurements collected
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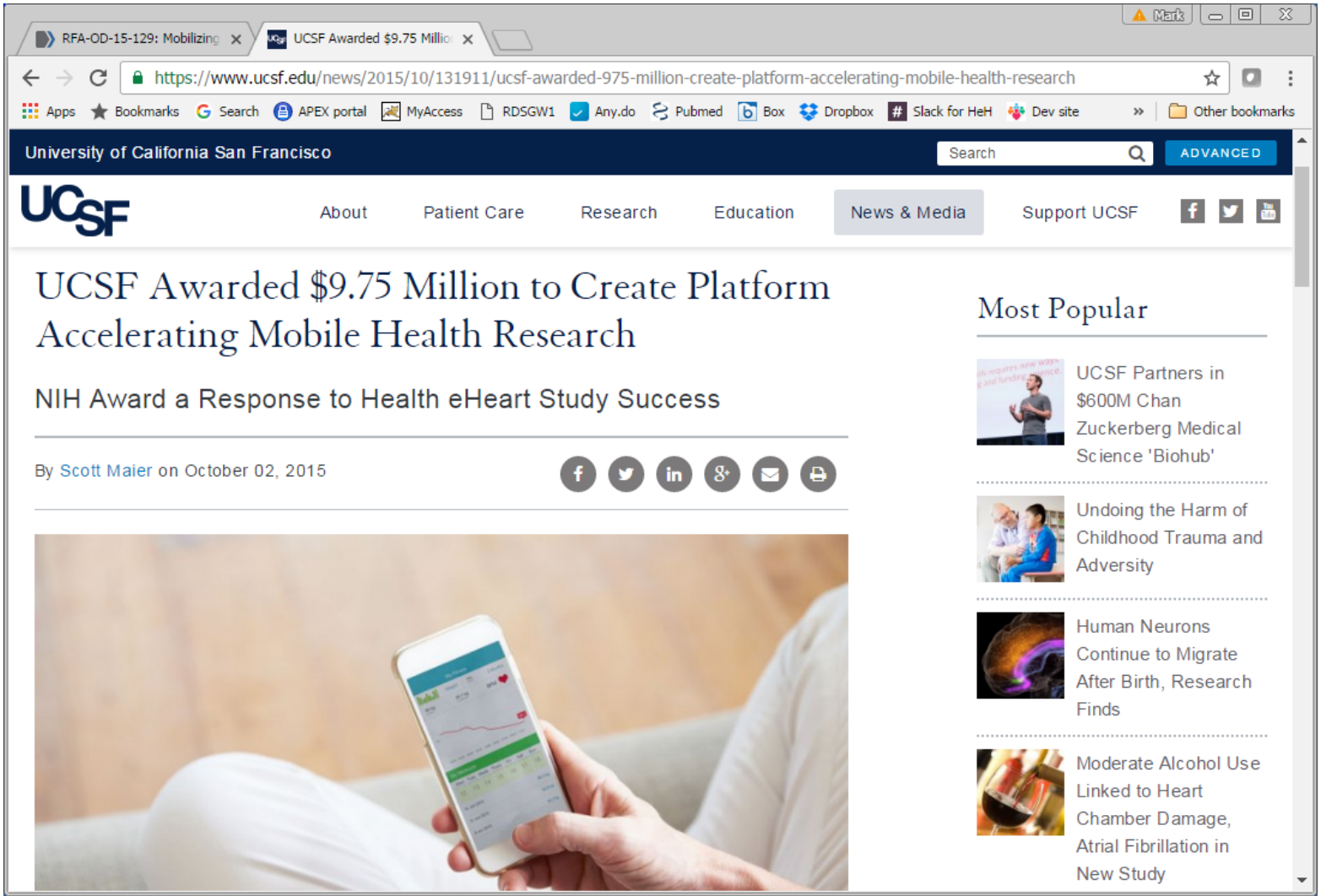
144	• 302,537 device (from 2100)

Much more efficient (and less error-prone) to get measurements directly from a device...

Meanwhile…

- “Mobilizing Research” Award from NIH



Eureka

Discoveries to make the world healthier

Eureka Research Platform

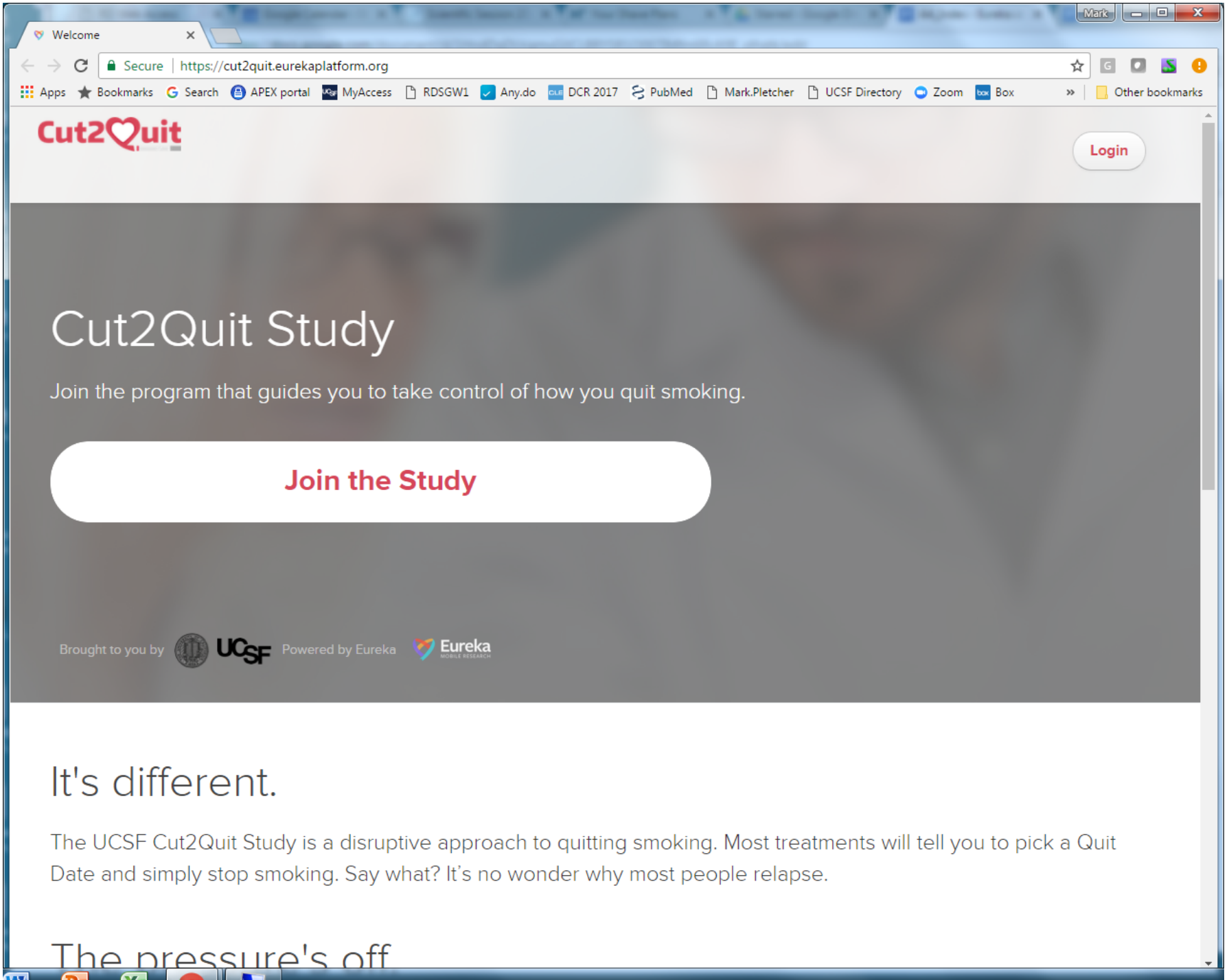
Aims:

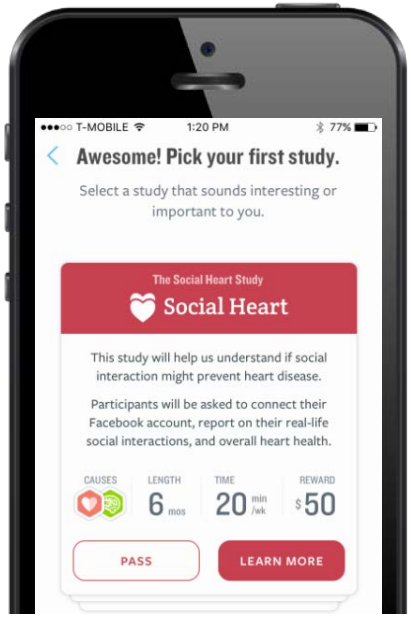
1) Create infrastructure for efficient mHealth research
2) Build cohort of engaged participants willing to volunteer
3) Governance, tech, procedures to support rapid access, data sharing, integration with other projects
4) Financial sustainability

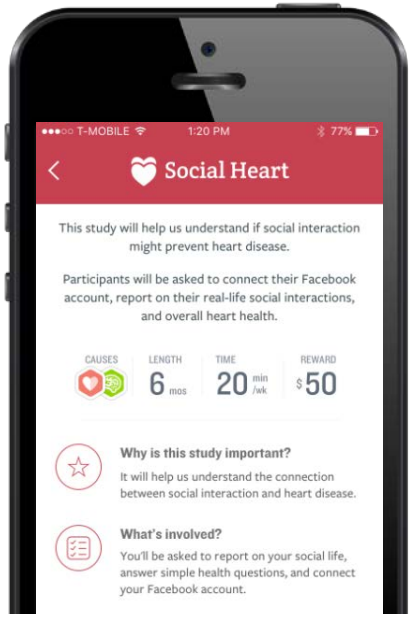
Eureka Research Platform

Features

1) Web portal and app, with synchronized back end


Mark
Welcome
Secure
https://cut2quit.eurekaplatform.org
Apps
Bookmarks
Search
APEX portal
MyAccess
RDSGW1
Any.do
DCR 2017
PubMed
Mark.Pletcher
UCSF Directory
Zoom
Box
Other bookmarks
Cut2Quit
Login
Cut2Quit Study
Join the program that guides you to take control of how you quit smoking.
Join the Study
Brought to you by
UCSF
Powered by Eureka
Eureka
It's different.
The UCSF Cut2Quit Study is a disruptive approach to quitting smoking. Most treatments will tell you to pick a Quit Date and simply stop smoking. Say what? It's no wonder why most people relapse.
The pressure's off


T-MOBILE 1:20 PM 77%
Awesome! Pick your first study.
Select a study that sounds interesting or important to you.
The Social Heart Study
Social Heart
This study will help us understand if social interaction might prevent heart disease.
Participants will be asked to connect their Facebook account, report on their real-life social interactions, and overall heart health.
CAUSES
LENGTH 6 mos
TIME 20 min/wk
REWARD $50
PASS
LEARN MORE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CAUSES
LENGTH 6 mos
TIME 20 min/wk
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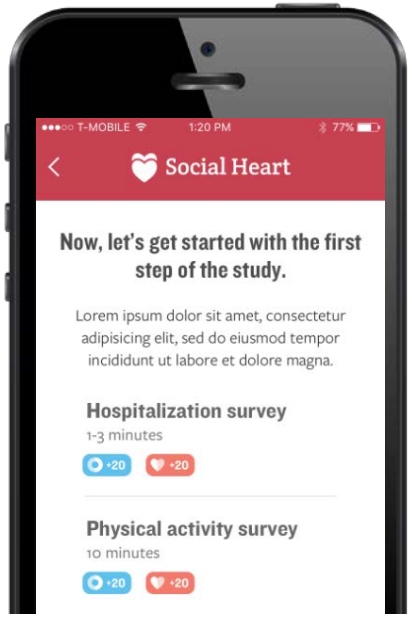
Why is this study important?
It will help us understand the connection between social interaction and heart disease.
What's involved?
You'll be asked to report on your social life, answer simple health questions, and connect your Facebook account.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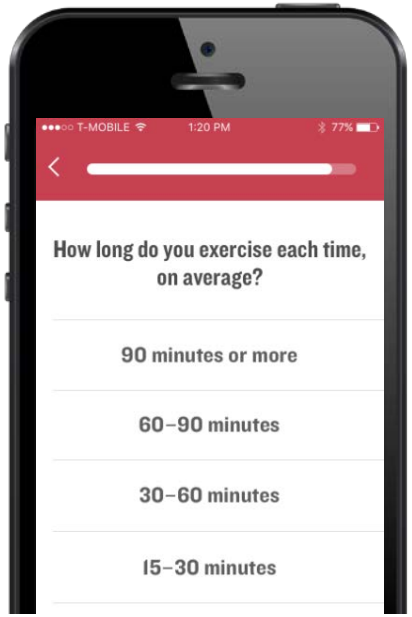
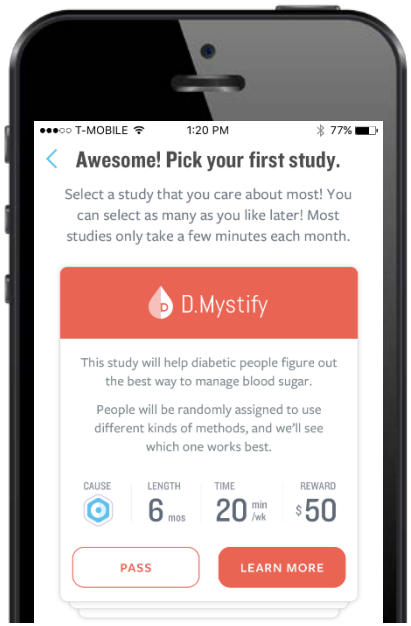
Social Heart
Now, let's get started with the first step of the study.
Lorem ipsum dolor sit amet, consectetur adipisicing elit, sed do eiusmod tempor incididunt ut labore et dolore magna.
Hospitalization survey
1-3 minutes
+20
+20
Physical activity survey
10 minutes
+20
+20


T-MOBILE 1:20 PM 77%
How long do you exercise each time, on average?
90 minutes or more
60–90 minutes
30–60 minutes
15–30 minutes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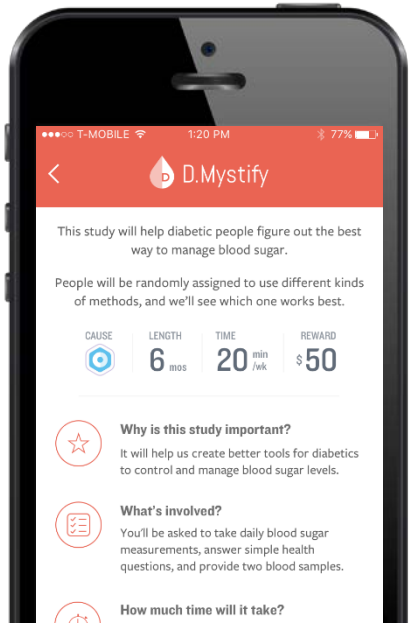
Awesome! Pick your first study.
Select a study that you care about most! You can select as many as you like later! Most studies only take a few minutes each month.
D.Mystify
This study will help diabetic people figure out the best way to manage blood sugar.
People will be randomly assigned to use different kinds of methods, and we'll see which one works best.
CAUSE
LENGTH 6 mos
TIME 20 min/wk
REWARD $50
PASS
LEARN MORE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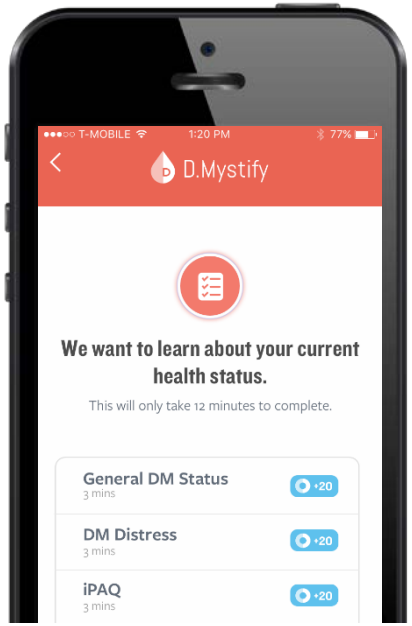
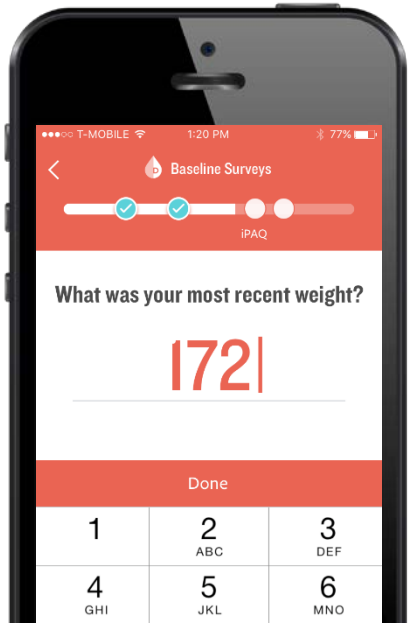
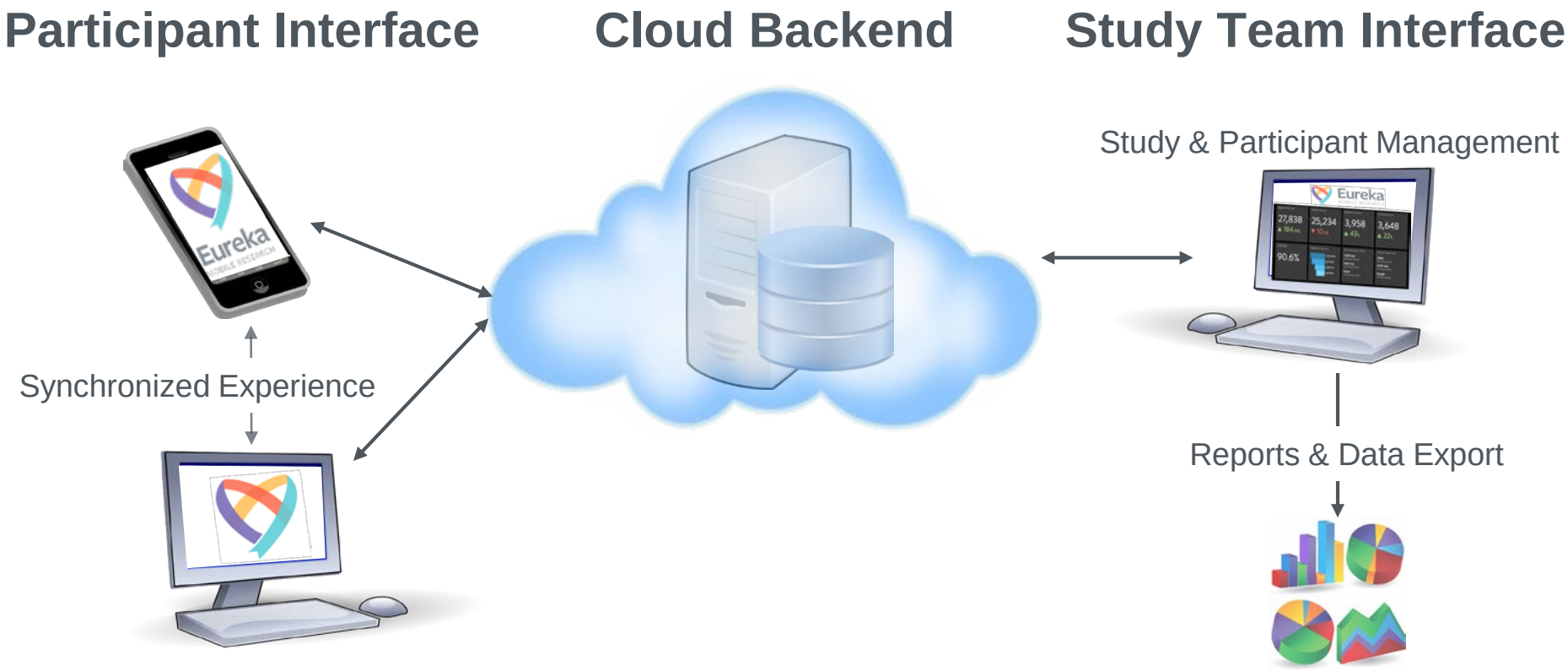
CAUSE
LENGTH 6 mos
TIME 20 min/wk
REWARD $50
Why is this study important?
It will help us create better tools for diabetics to control and manage blood sugar levels.
What's involved?
You'll be asked to take daily blood sugar measurements, answer simple health questions, and provide two blood samples.
How much time will it take?


T-MOBILE 1:20 PM 77%
D.Mystify
We want to learn about your current health status.
This will only take 12 minutes to complete.
General DM Status
3 mins
+20
DM Distress
3 mins
+20
iPAQ
3 mins
+20


T-MOBILE 1:20 PM 77%
Baseline Surveys
iPAQ
What was your most recent weight?
172
Done
1
2 ABC
3 DEF
4 GHI
5 JKL
6 MNO

Synchronized and integrated

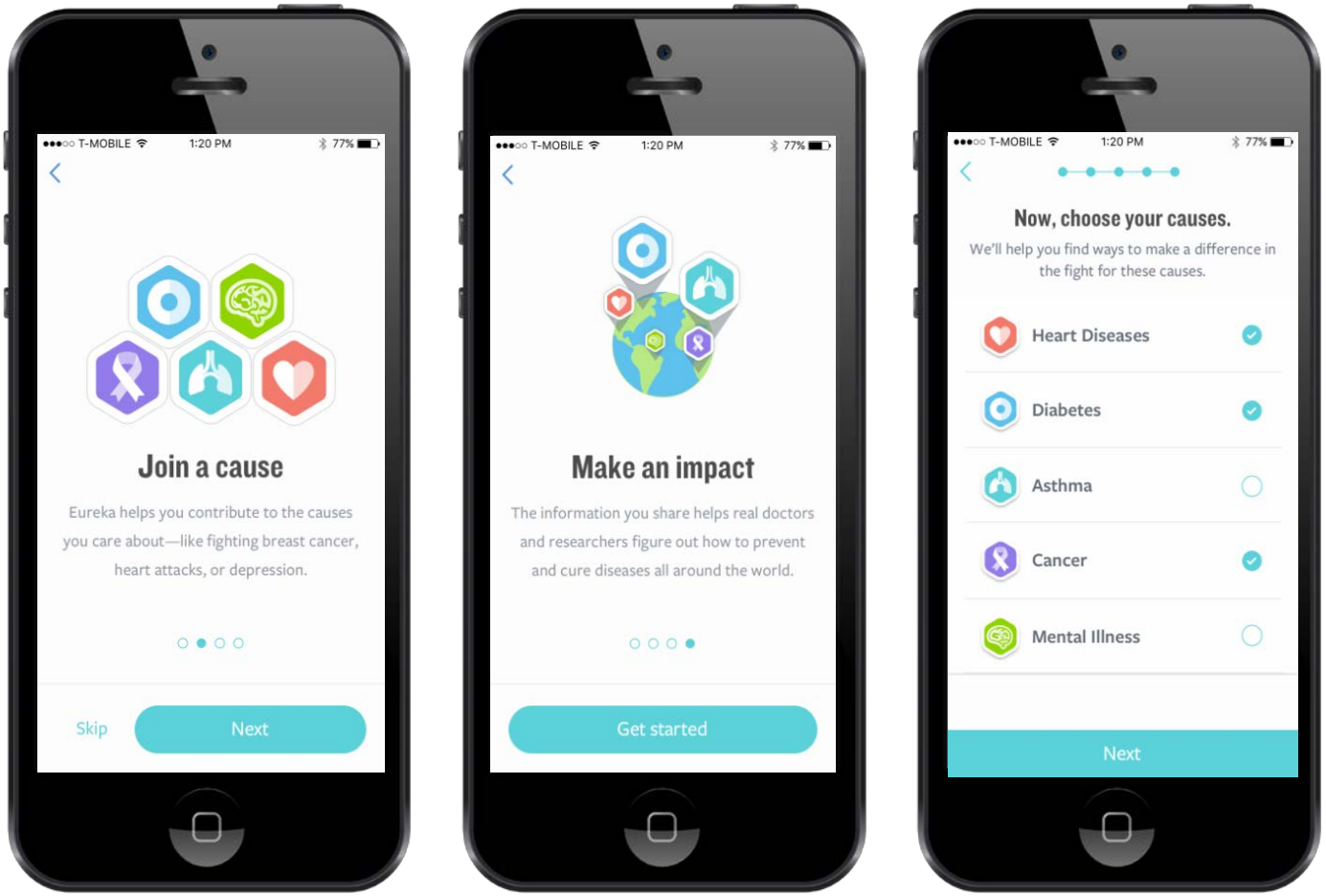


Eureka Research Platform

Features

1) Web portal and app, with synchronized back end
2) Single sign-on registration system

Enables multi-study engagement

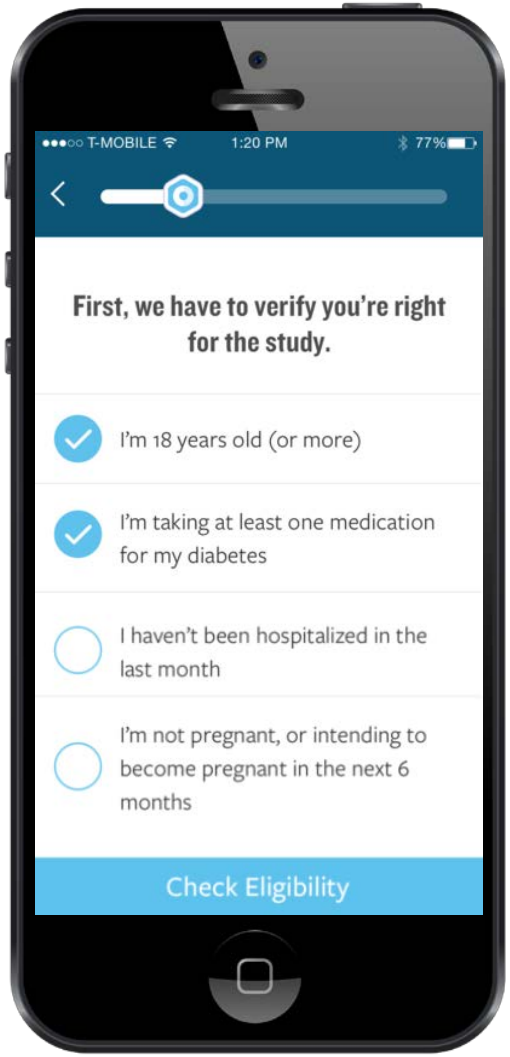


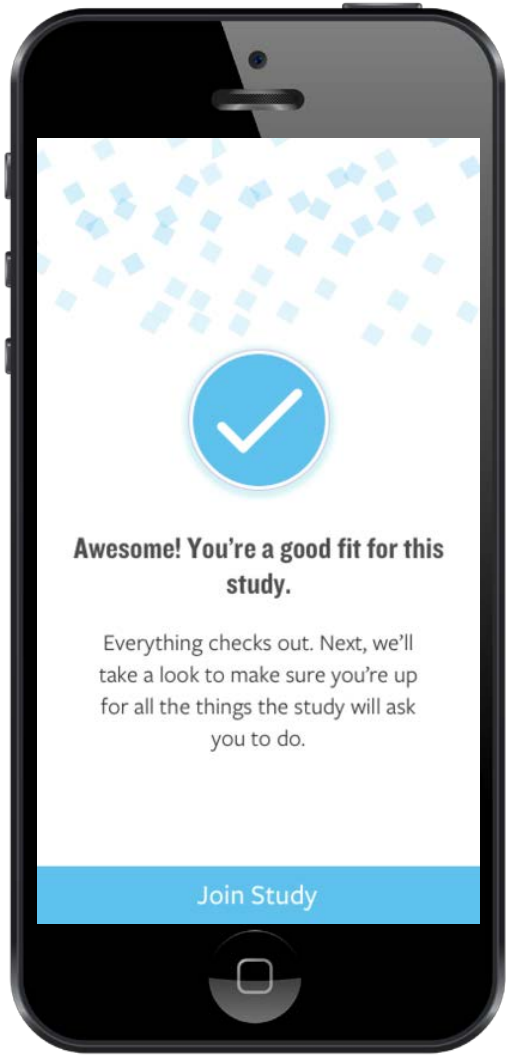
Eureka Research Platform

Features

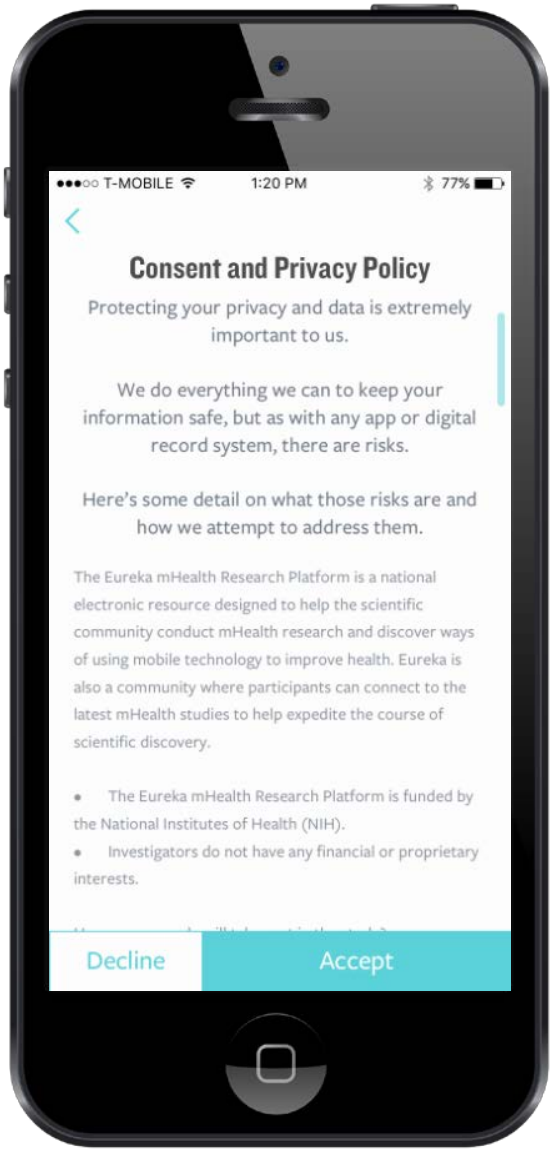
1) Web portal and app, with synchronized back end
2) Single sign-on registration system
3) Flexible consent sequencing

Eligibility/Understanding Check

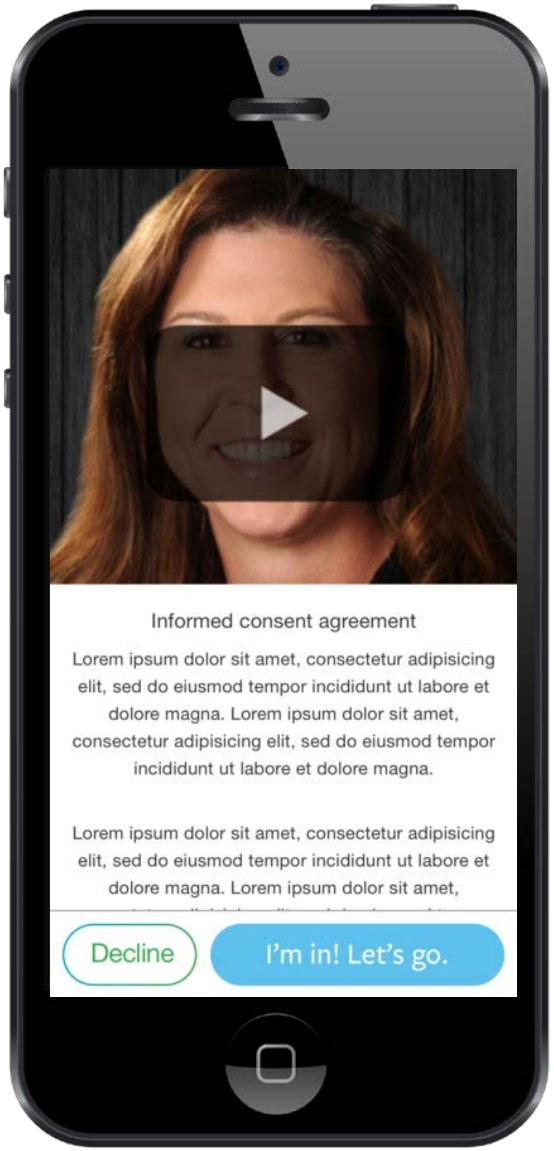




Simple Consent



Video Consent



Signed Consent

Eureka Research Platform

Features

1) Web portal and app, with synchronized back end
2) Single sign-on registration system
3) Flexible consent sequencing
4) Deliver online surveys, eVisits, randomization

sputnik

Alcohol Use

Did you drink any alcoholic beverages in the past year?

- No
- Yes
- Don't know
- I refuse to answer

Do you believe alcohol is good for your heart?

- Yes
- No
- Don't know

Do you believe the type of alcoholic drink matters to the health of your heart?

- Yes
- No

How does your understanding of the potential health effects of alcohol influence the amount of alcohol you drink?

- There is no influence.
- I drink more alcohol than I otherwise would for what I perceive to be health benefits.
- I drink less alcohol than I otherwise
- Other

Eureka Research Platform

Features

1) Web portal and app, with synchronized back end
2) Single sign-on registration system
3) Flexible consent sequencing
4) Deliver online surveys, eVisits, randomization
5) Email/text/app-based programmable messaging

Messaging

- Timed vs. event-triggered
- Modality options
  - Email/text/app push notification
  - Participant preferences (text messaging enabled?)
- Reminders or actual study interventions

Eureka Research Platform

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2) Single sign-on registration system
3) Flexible consent sequencing
4) Deliver online surveys, eVisits, randomization
5) Email/text/app-based programmable messaging
6) App- and sensor-based data collection

RFA-OD-15-129: Mobiliz | UCSF Awarded $9.75 Mi | sputnik-launch | UCSF H | Sputnik Launch Feedbac | Mark's Profile | What's New

https://www.fitbit.com/whats-new#new-edition

Apps | Bookmarks | Search | APEX portal | MyAccess | RDSGW1 | Any.do | Pubmed | Box | Dropbox | Slack for HeH | Dev site | PPRN | HeH | Ethan | Other bookmarks

fitbit

Products | Experiences | Fun | Help | Dashboard | Store

Everyday Fitness

Fitbit Zip® | Fitbit One® | Fitbit Flex 2™ | Fitbit Alta™

Active Fitness

Fitbit Charge 2™ | Fitbit Blaze™

Performance Fitness

Fitbit Surge™

Wi-Fi Smart Scale

Fitbit® Aria®

Not sure which product is right for you? FIND YOUR FIT

New Trackers

Meet our newest fitness trackers—Fitbit Charge 2 & Fitbit Flex 2.

Gold Series

Special edition Fitbit Blaze & Fitbit Alta trackers & accessories.

Enhanced Experiences

Start Adventures, try guided breathing & understand your cardio fitness.

More Accessories

New bands and styles available for Blaze & Alta.

Blaze Updates

Three new reasons to love our smart fitness watch.

RFA-OD-15-129: Mobilizing | UCSF Awarded $9.75 Millio | sputnik-launch | UCSF Hea | Sputnik Launch Feedback | Mark's Profile | Health Monitoring Devices

https://ihealthlabs.com

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- iHealth View Wireless Wrist Blood Pressure Monitor
- Wireless Blood Pressure Wrist Monitor
- Wireless Blood Pressure Monitor
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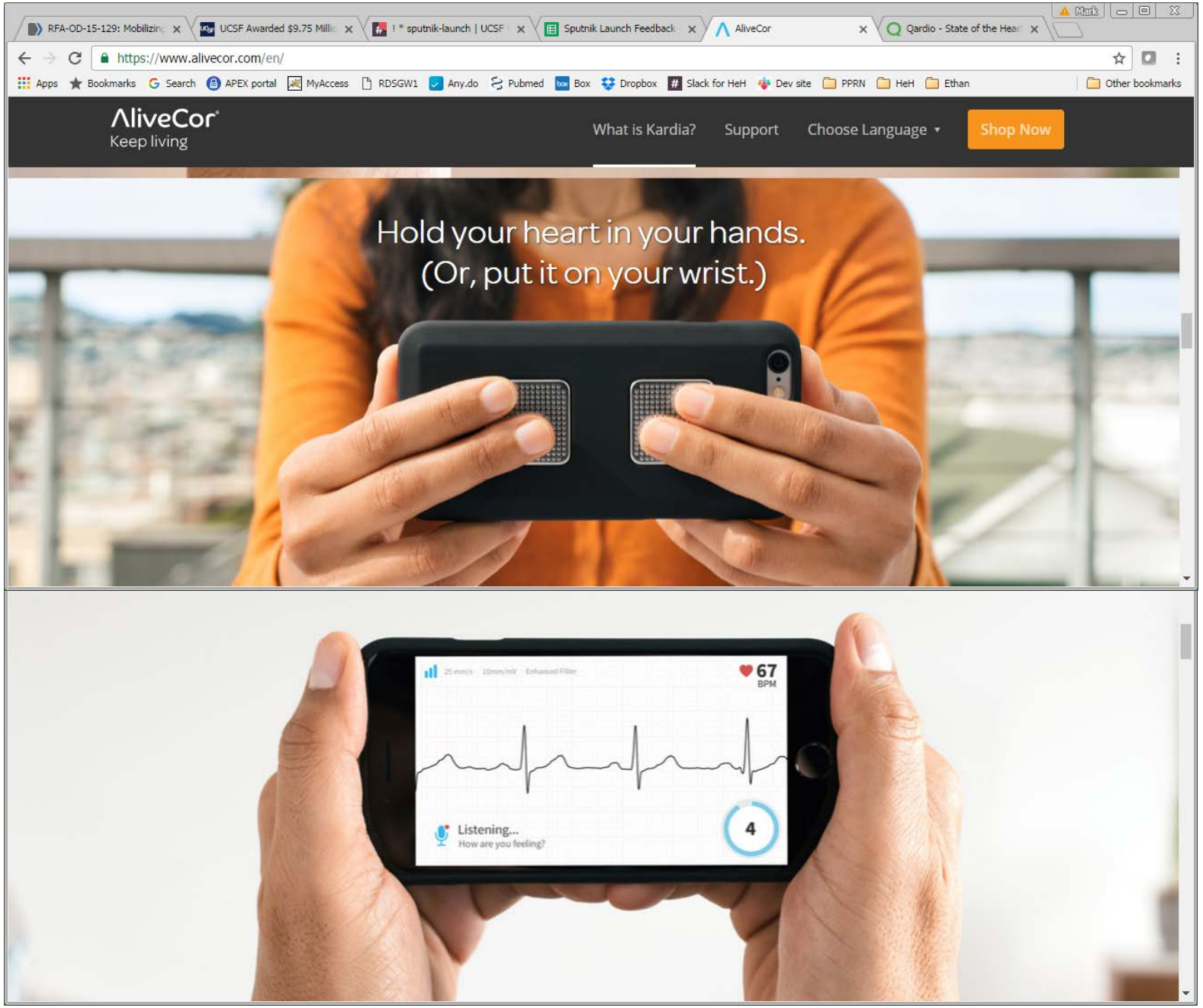
RFA-OD-15-129: Mobilizing
UCSF Awarded $9.75 Millio
! * sputnik-launch | UCSF
Sputnik Launch Feedback
AliveCor
Qardio - State of the Heart
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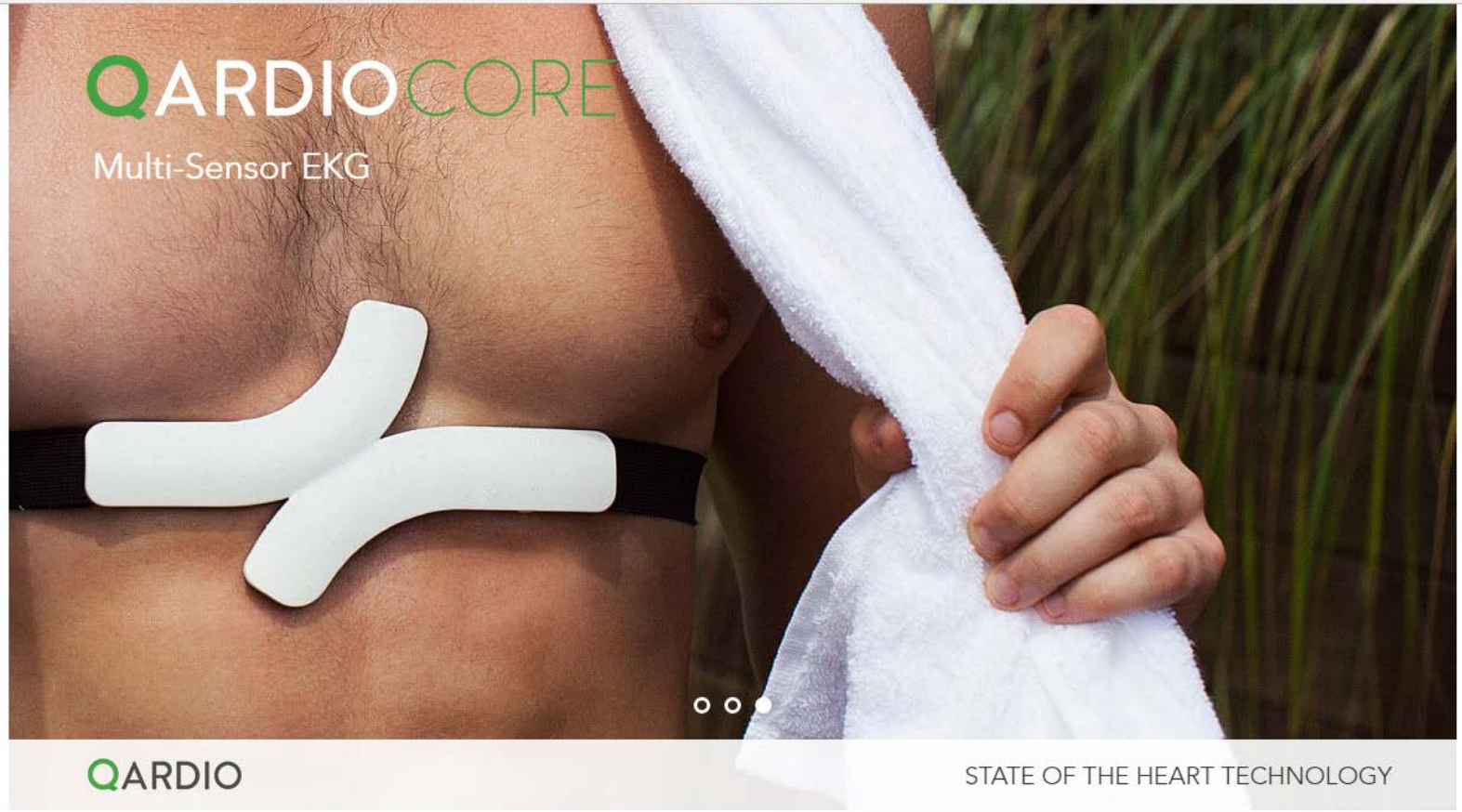
Slack for HeH
Dev site
PPRN
HeH
Ethan
Other bookmarks
AliveCor
Keep living
What is Kardia?
Support
Choose Language
Shop Now
Hold your heart in your hands.
(Or, put it on your wrist.)
67
BPM
Listening...
How are you feeling?
4

RFA-OD-15-129: Mobilizing | UCSF Awarded $9.75 Millio | ! * sputnik-launch | UCSF | Sputnik Launch Feedback - | Mark's Profile | Qardio - State of the Heart

Qardio, Inc [US] | https://www.getqardio.com

Apps | Bookmarks | Search | APEX portal | MyAccess | RDSGW1 | Any.do | Pubmed | Box | Dropbox | Slack for HeH | Dev site | PPRN | HeH | Ethan | Other bookmarks



QARDIO

STATE OF THE HEART TECHNOLOGY

QARDIOARM

The smart blood pressure monitor
that fits your daily life.

QARDIOBASE

Wireless smart scale.
Weight management redefined.

QARDIOCORE

Medical-grade ECG
unlike any other.

ARGUS by Azumio

https://www.azumio.com/s/argus/index.html

Apps | Bookmarks | Search | APEX portal | MyAccess | RDSGW1 | Any.do | Pubmed | Box | Dropbox | Slack for HeH | Dev site | PPRN | HeH | Other bookmarks

azumio

LOG IN HOME PRODUCTS BLOG HELP & SUPPORT ABOUT

- ARGUS
- INSTANT HEART RATE
- SLEEP TIME
- FITNESS BUDDY
- GLUCOSE BUDDY

IT'S ALL A

Argus is all about getting to know the rhythm of your own lifestyle.
Doctors recommend at least **30 active minutes** every day.

Eureka Research Platform

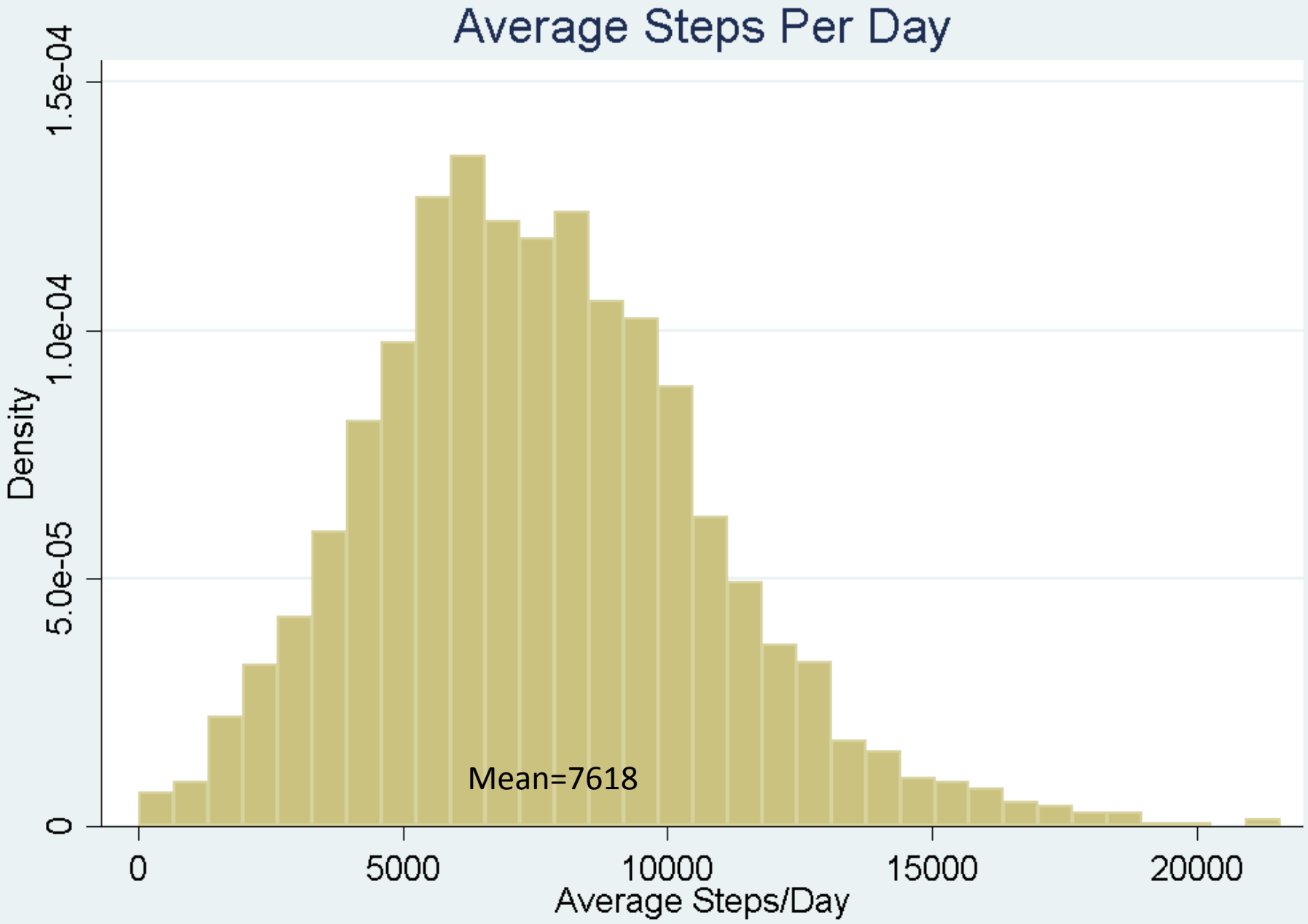
- 10 studies launched
- 7 slated for launch by end of year
- 43 more in pipeline

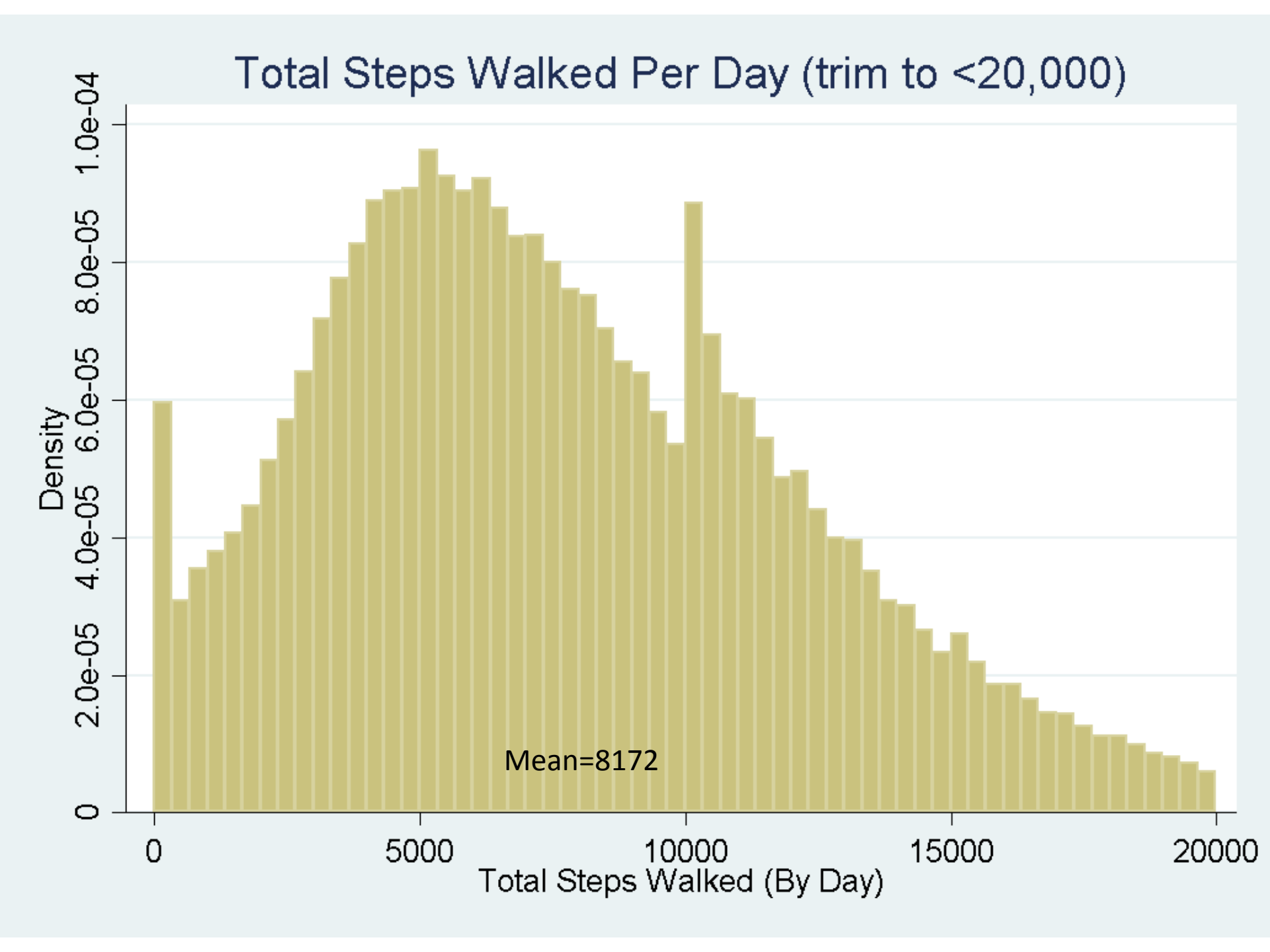
- Ready for business! (though some hiccups)
  - http://info.eurekaplatform.org/

Activity data

- Is step count data useful?

- 4668 consented to connect Fitbit account with Health eHeart Study

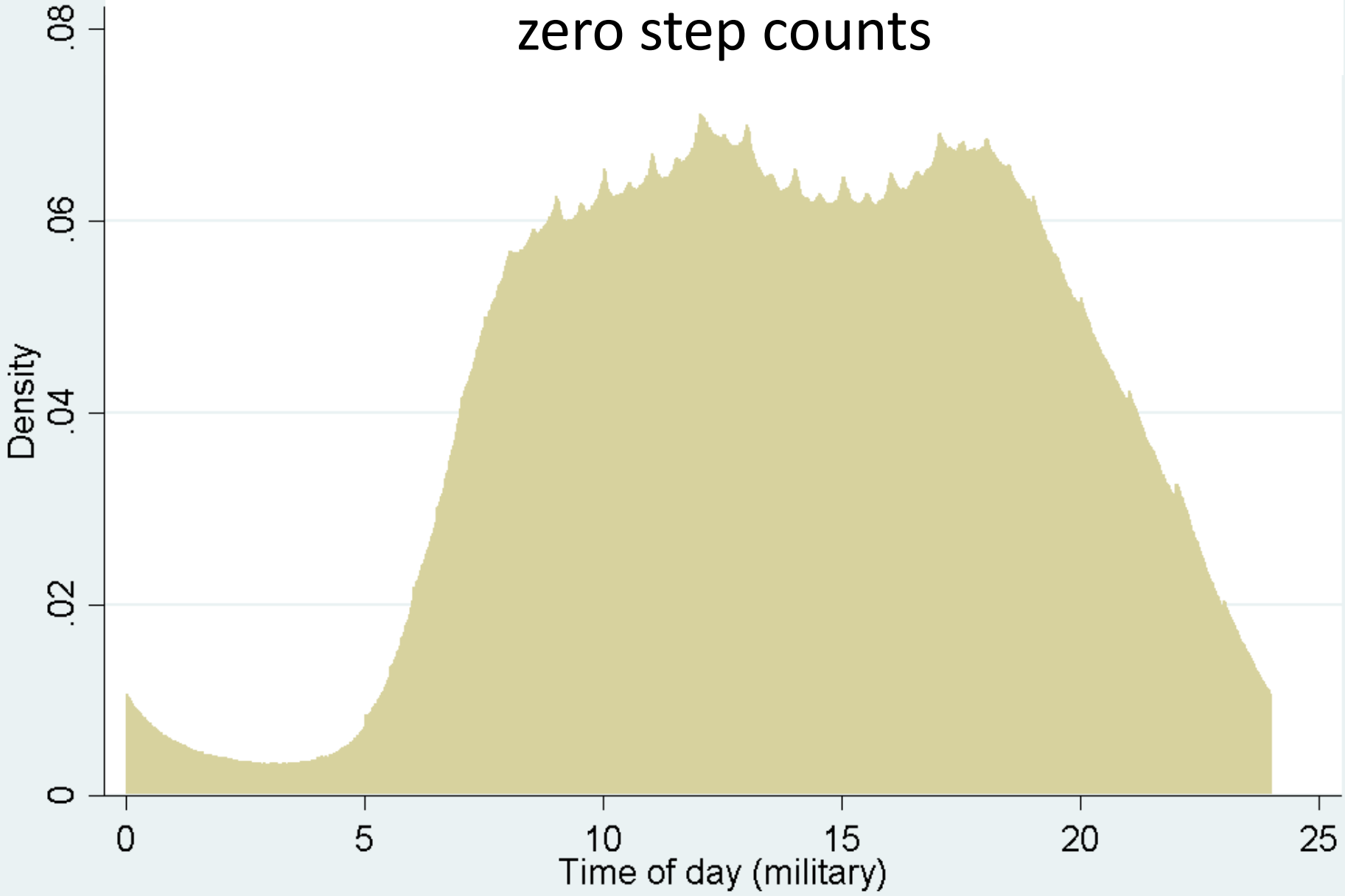

Average Steps Per Day
Density
0
5.0e-05
1.0e-04
1.5e-04
Mean=7618
0
5000
10000
15000
20000
Average Steps/Day


Total Steps Walked Per Day (trim to <20,000)
Density
0
2.0e-05
4.0e-05
6.0e-05
8.0e-05
1.0e-04
Mean=8172
0
5000
10000
15000
20000
Total Steps Walked (By Day)

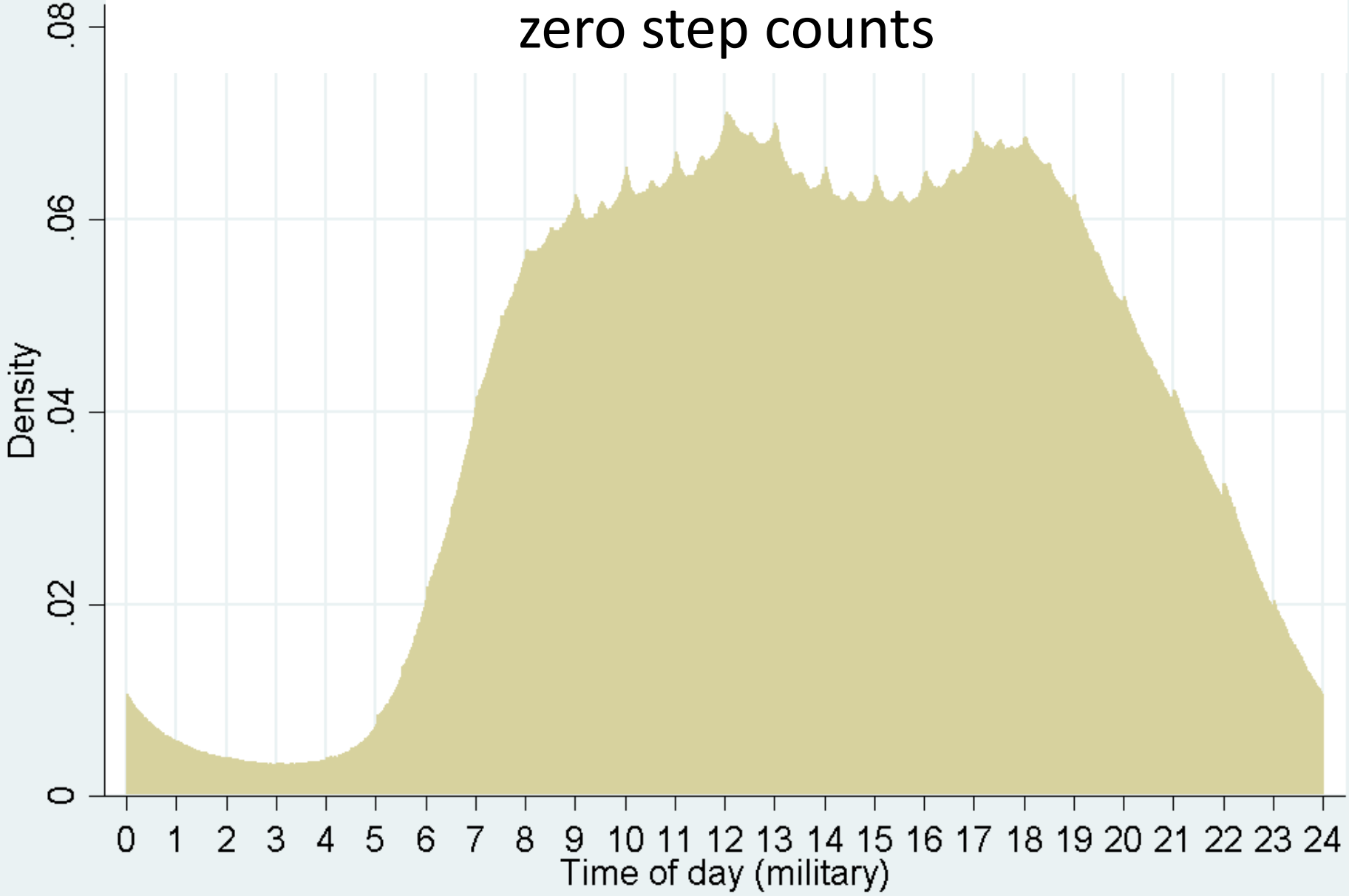
Steps by the minute

- Fitbit also provides step counts by the minute for researchers through their API

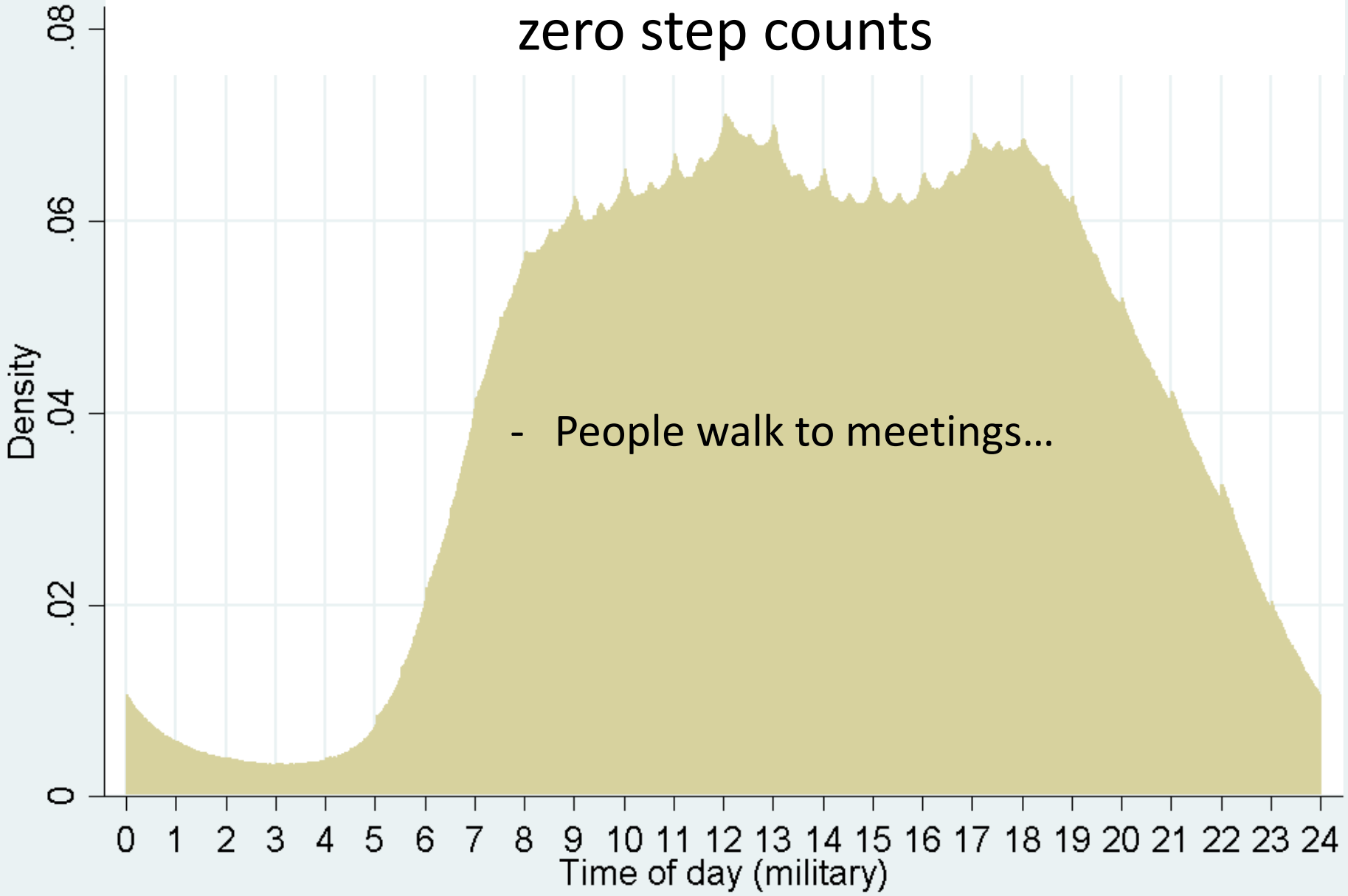
Distribution of minutes in the day with non-zero step counts



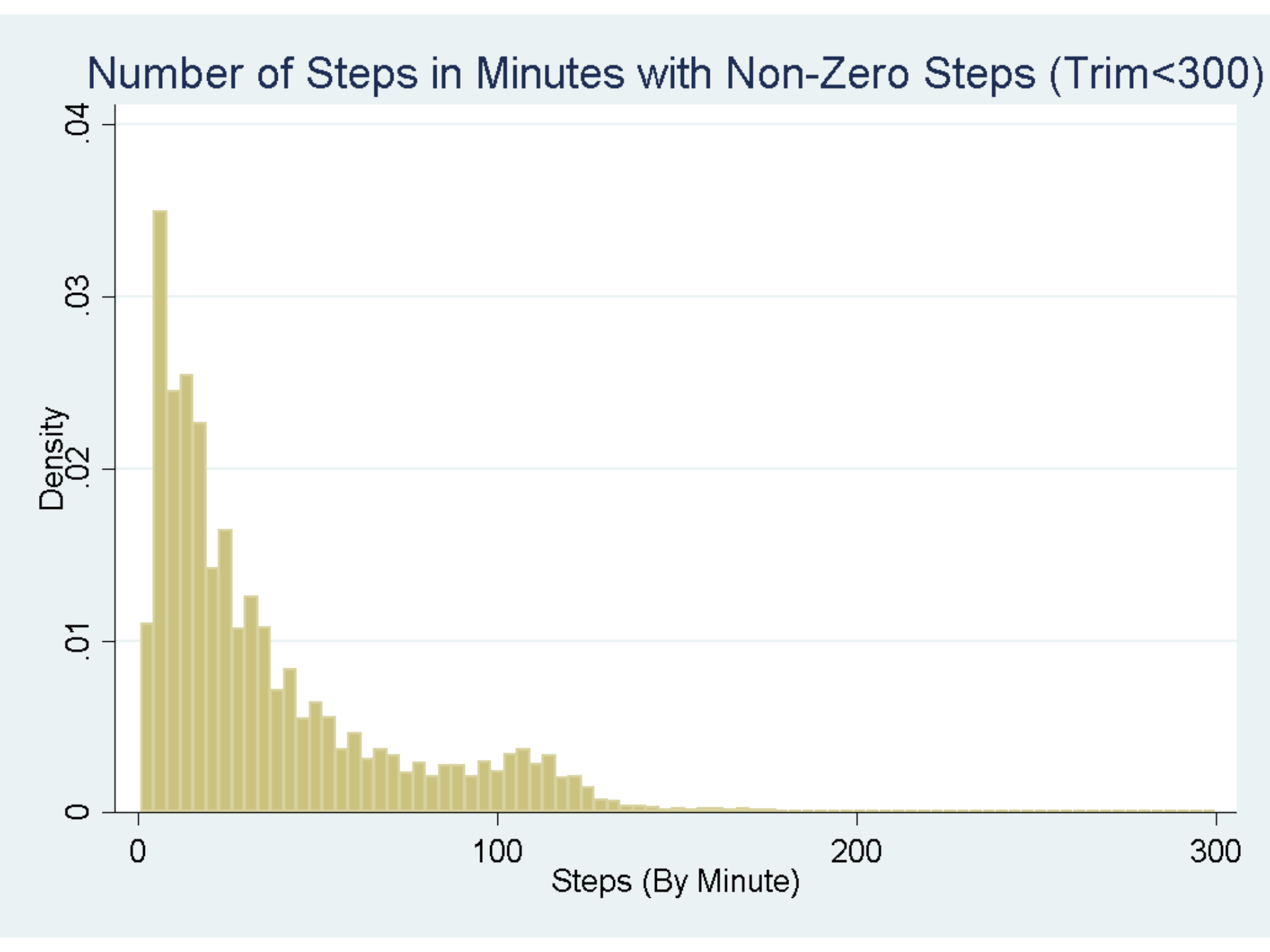
Distribution of minutes in the day with non-zero step counts

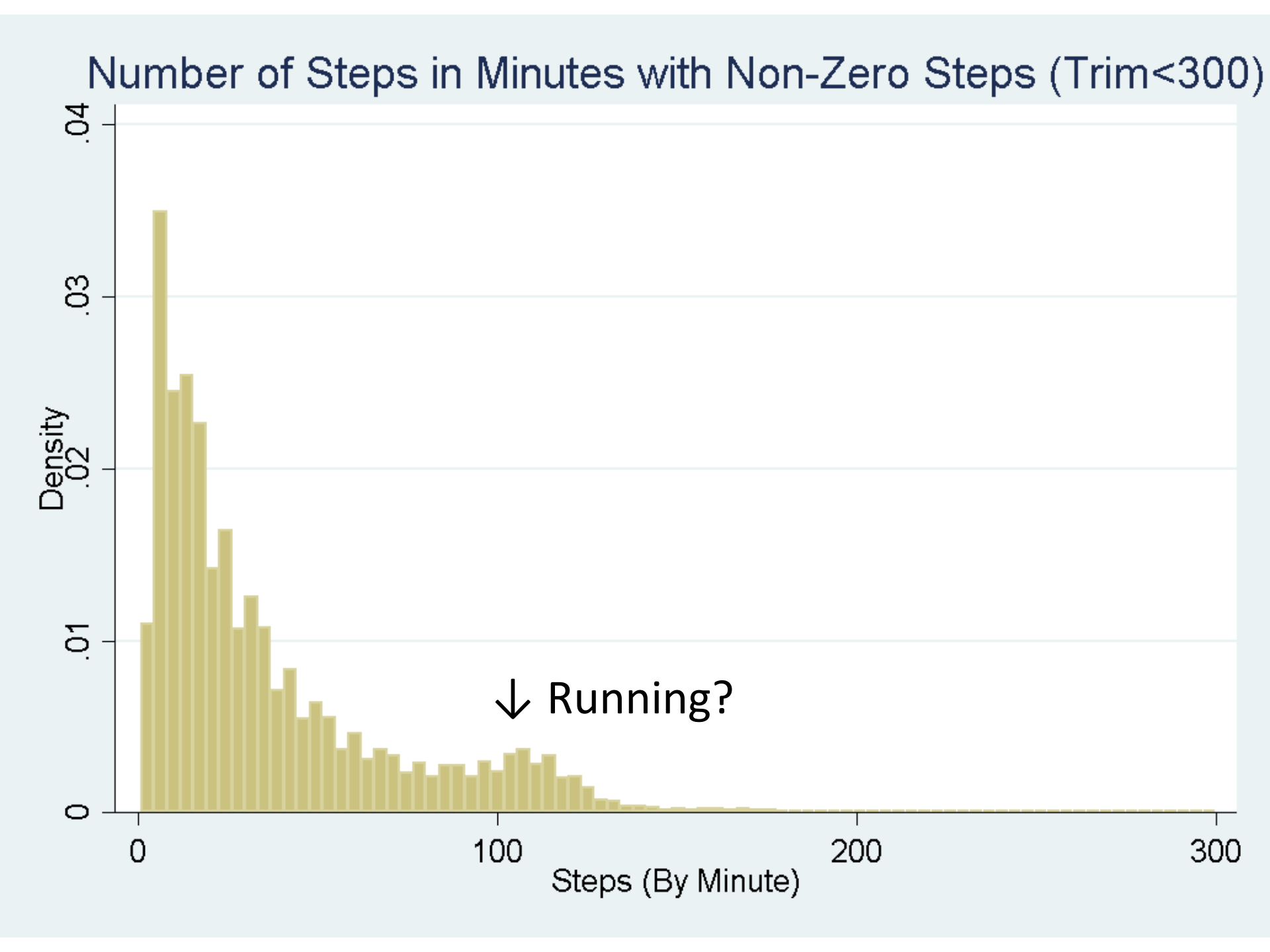


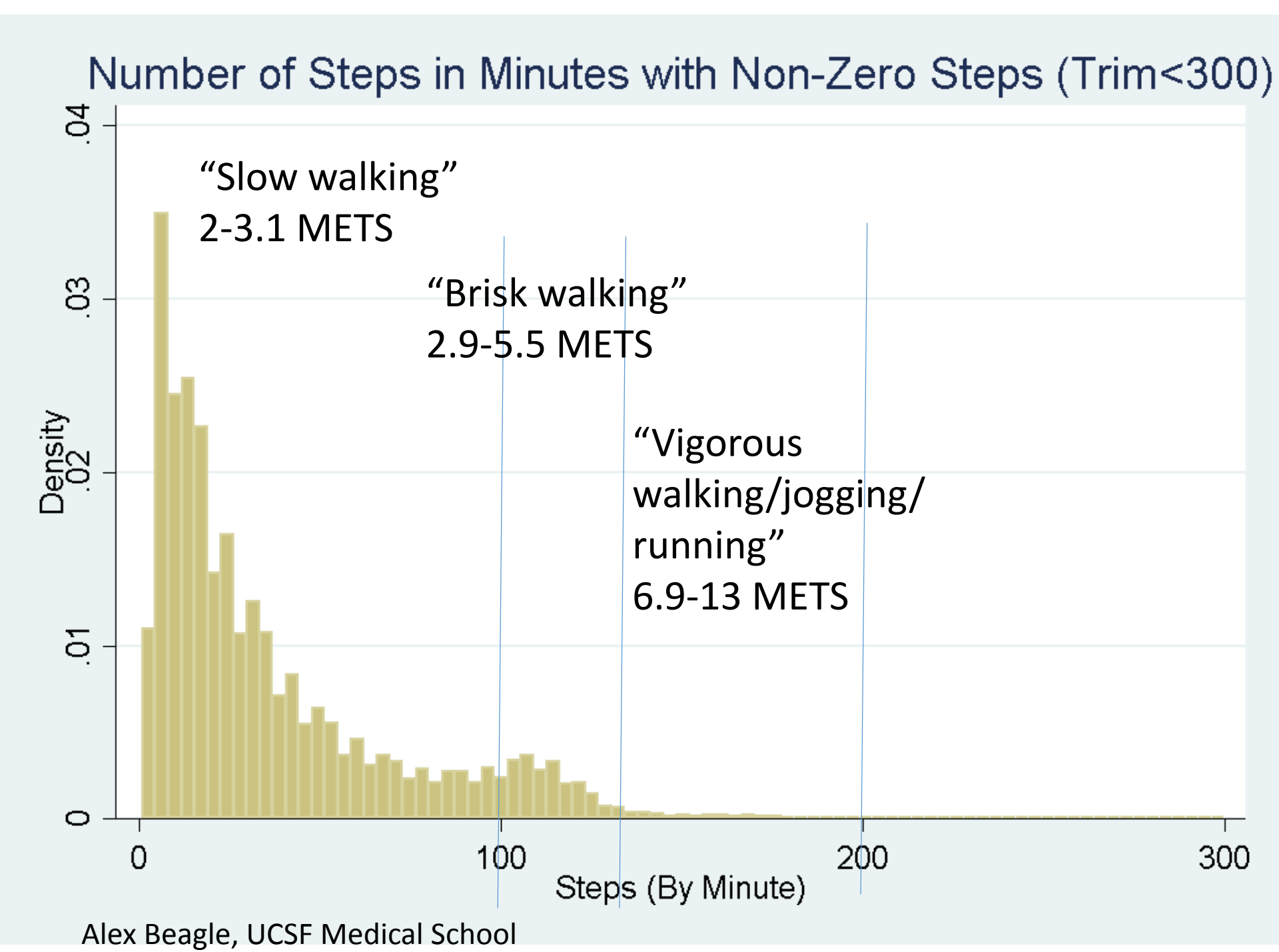
Distribution of minutes in the day with non-zero step counts



- People walk to meetings…


Number of Steps in Minutes with Non-Zero Steps (Trim<300)
Density
0
.01
.02
.03
.04
0
100
200
300
Steps (By Minute)


Number of Steps in Minutes with Non-Zero Steps (Trim<300)
Density
.04
.03
.02
.01
0
↓ Running?
0
100
200
300
Steps (By Minute)

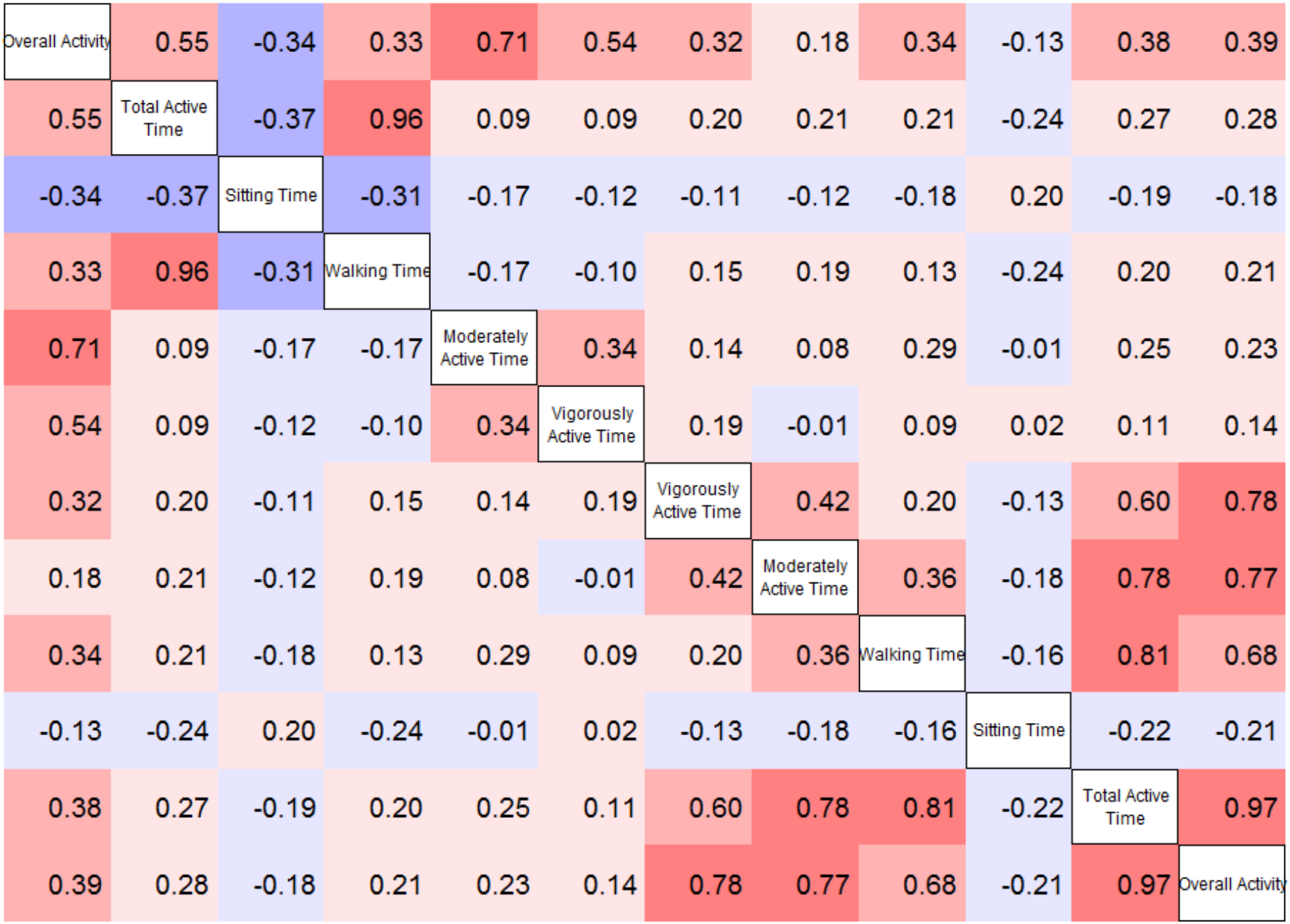


Alex Beagle, UCSF Medical School

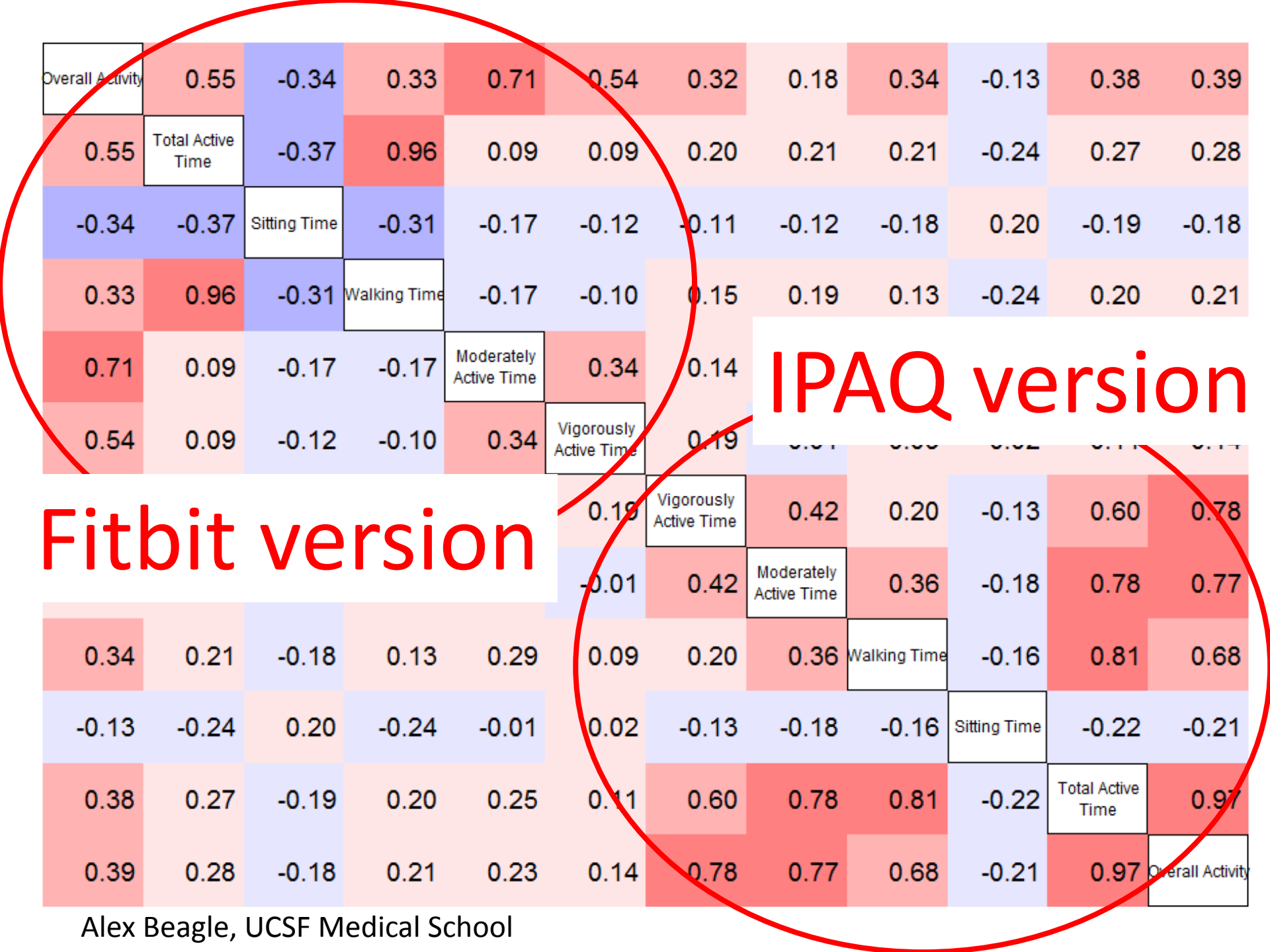
Activity, con't

- We also have survey data
- IPAQ – International Physical Activity Questionnaire
  - Minutes sitting, walking, moderate and vigorous activity per week
  - METS/day

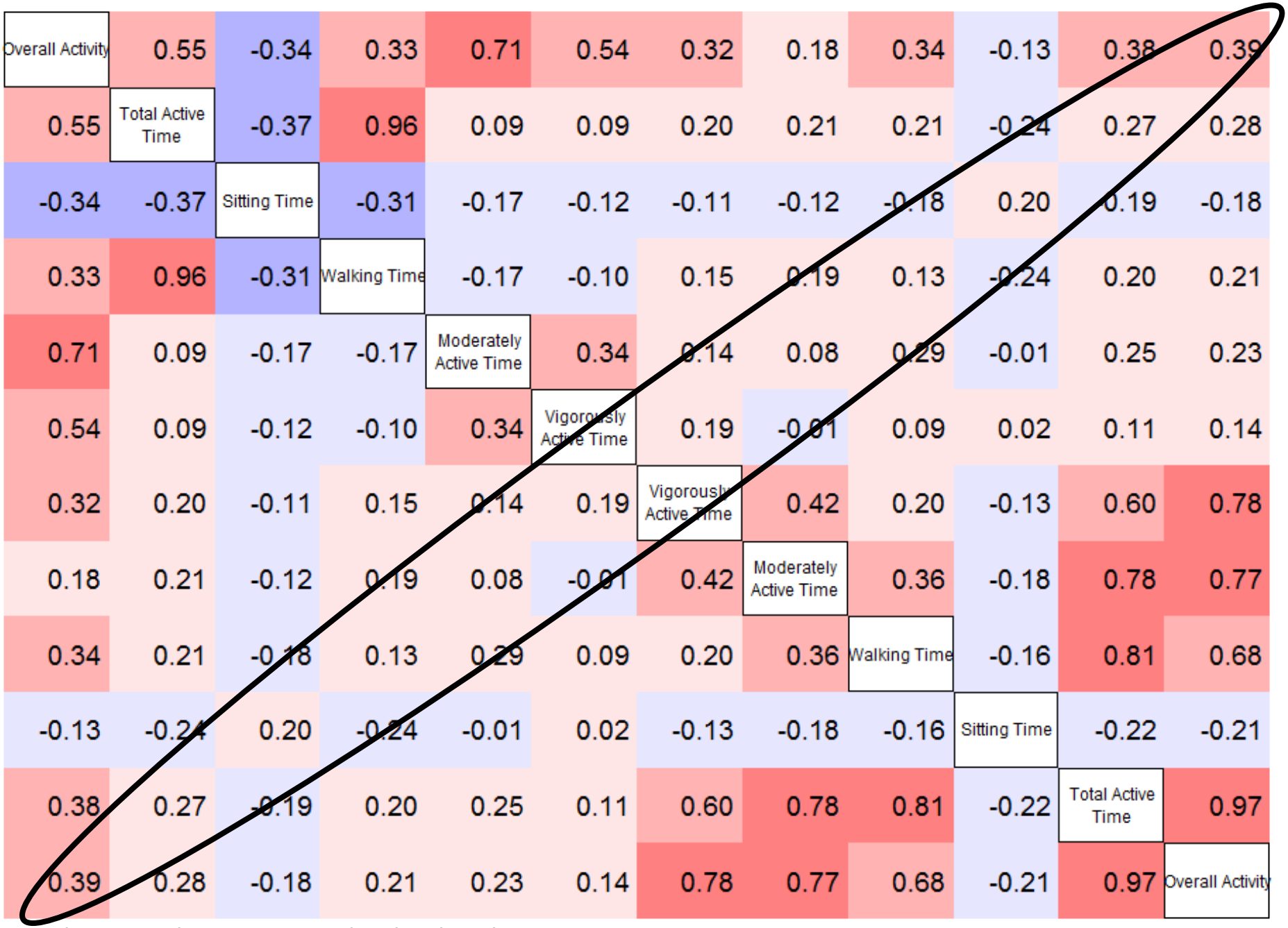
- Does Fitbit data correlate?
- Which is "better"?



Alex Beagle, UCSF Medical School



Alex Beagle, UCSF Medical School



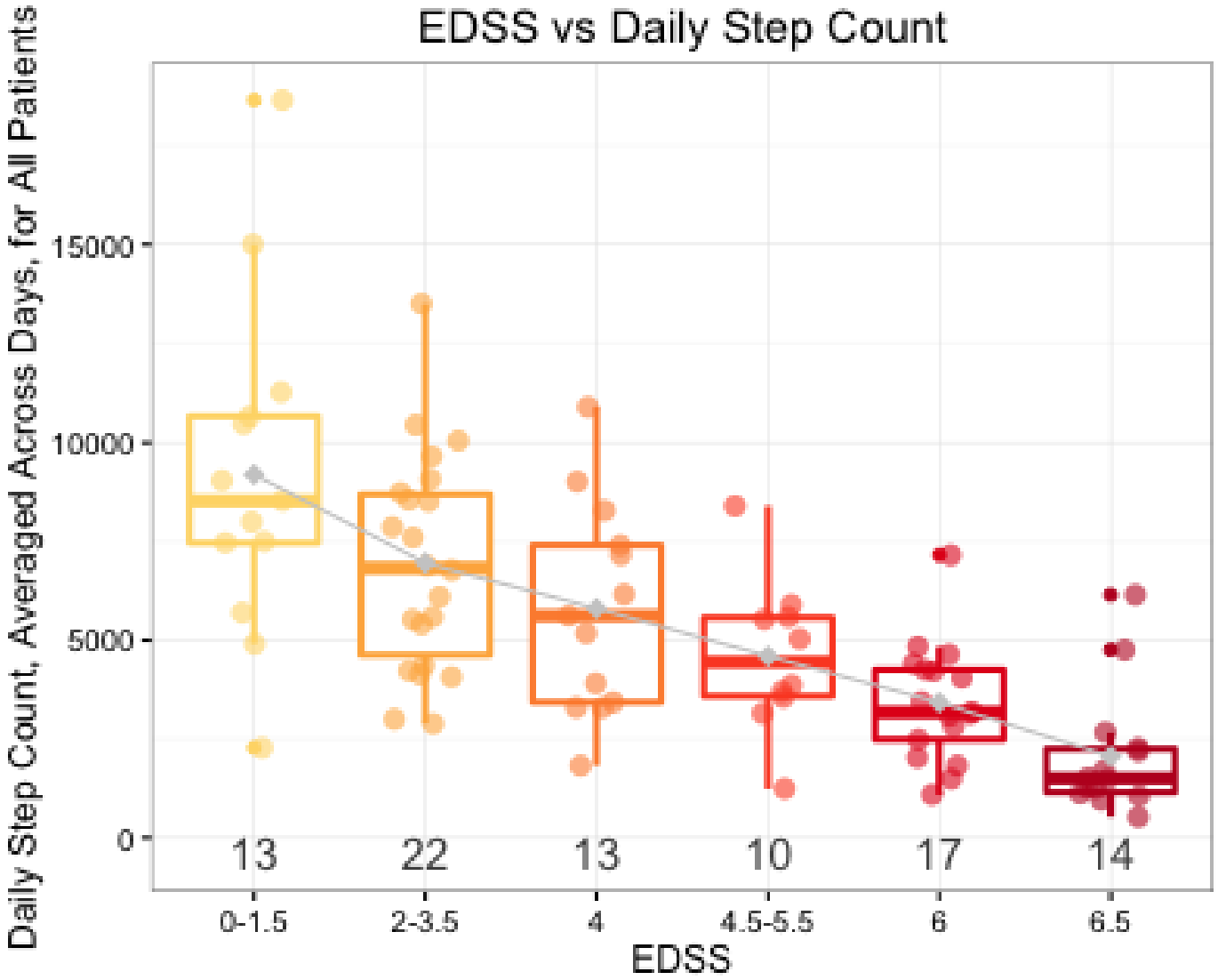
Alex Beagle, UCSF Medical School

Which predicts BMI more strongly?

- Head to head comparisons in adjusted models:

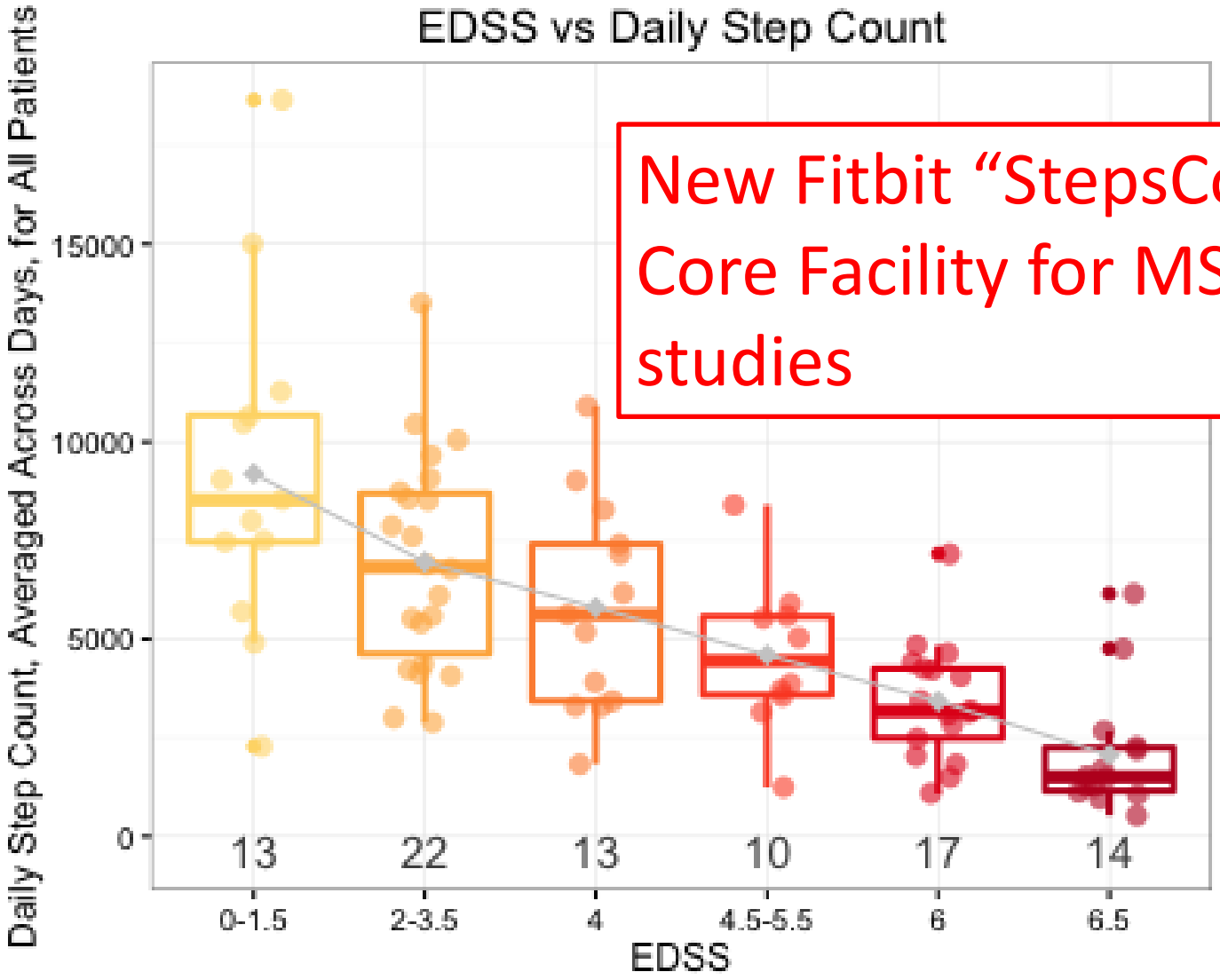
	BMI units per 1 SD change in activity	
	Overall	R^2 added
Fitbit	-1.19 (-1.82- -0.56)	.044
IPAQ	-0.29 (-0.18- -0.23)	.003

Fitbit steps versus MS disability



Block VJ et al. Journal of Neurology 2017;264:316-26 https://www.ncbi.nlm.nih.gov/pubmed/27896433

Fitbit steps versus MS disability



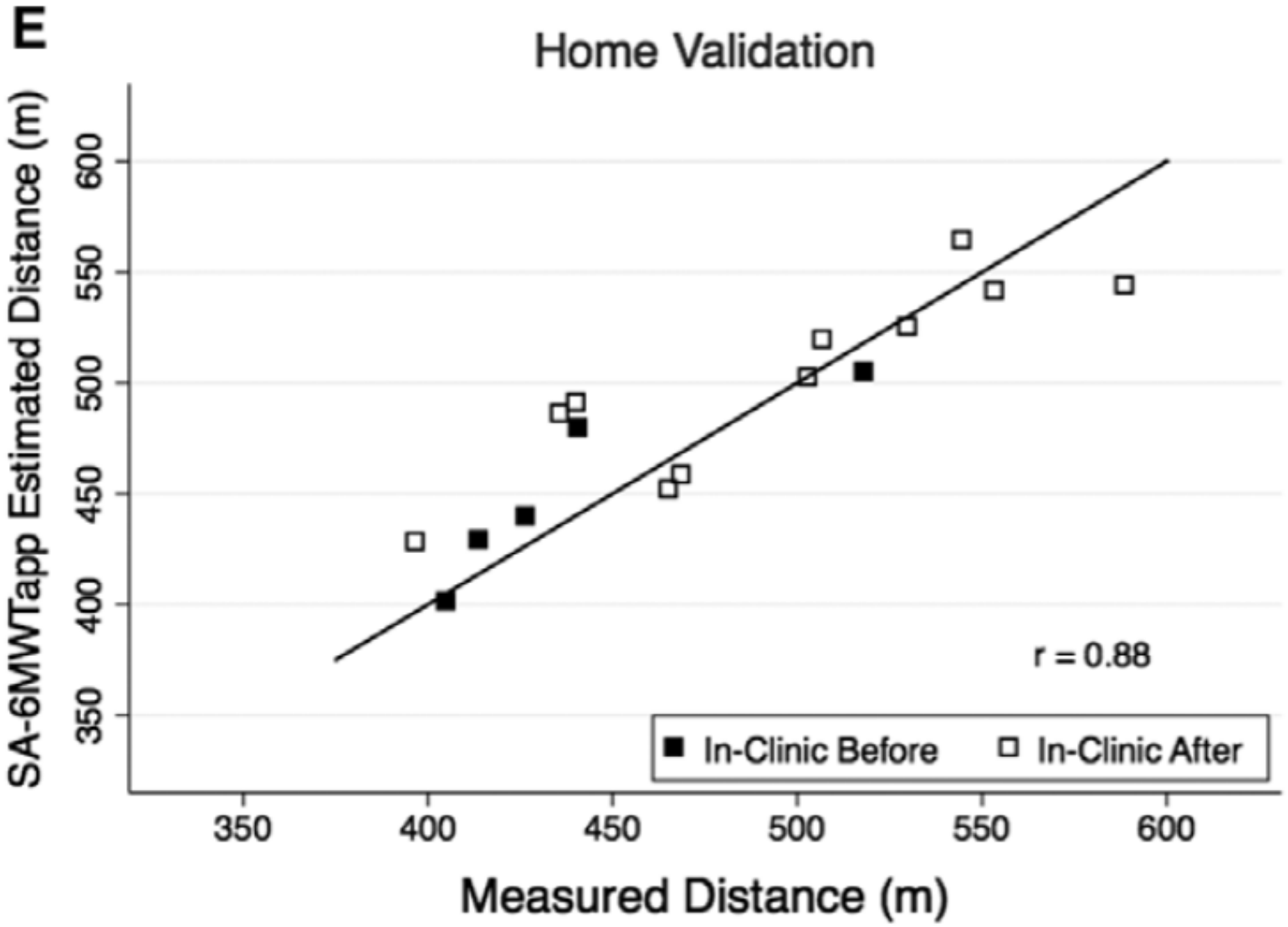
New Fitbit "StepsCore" Core Facility for MS studies

Block VJ et al. Journal of Neurology 2017;264:316-26 https://www.ncbi.nlm.nih.gov/pubmed/27896433

Using smartphone sensors

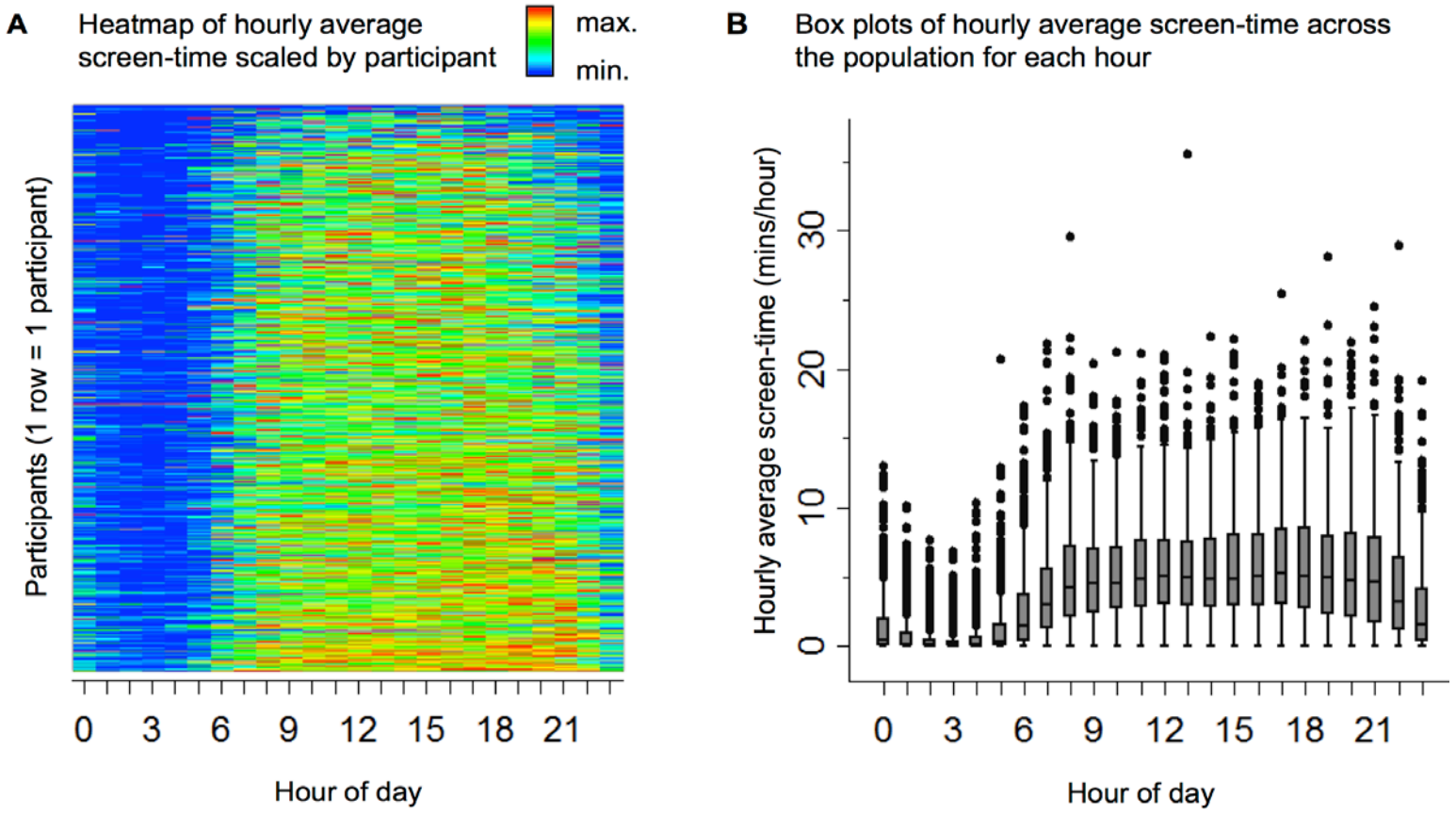
- Everybody has a smartphone (?), and they have built in sensors
  - Location, accelerometers, camera, use indicators
- And they are programmable
- Can we use smartphones to collect useful data for research?

Validation of a 6MWT app



Brooks et al. Circ Heart Fail 2015;8(5):905-13. PMID 26283292

Smartphone screen time



Higher average screen time in African-Americans than Whites

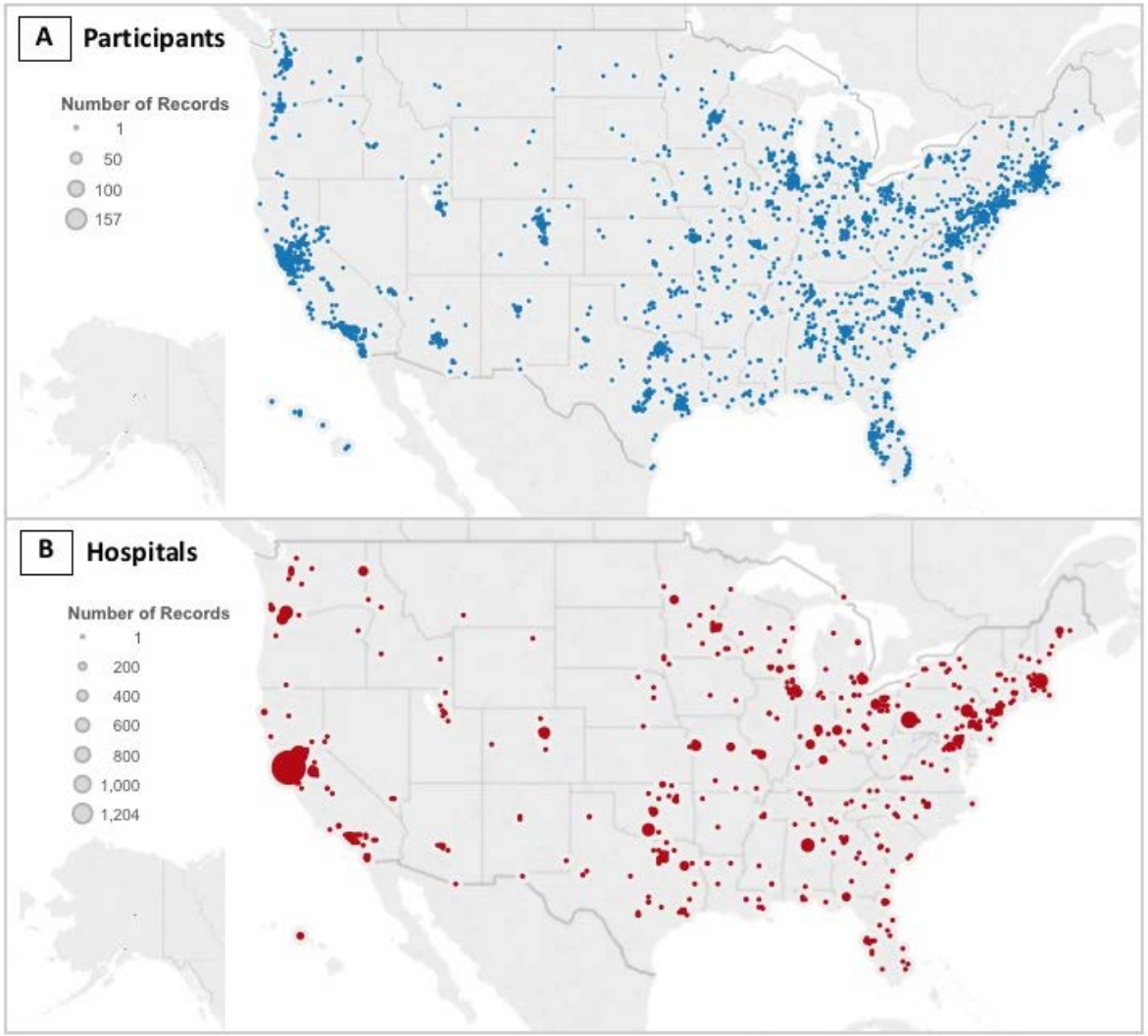
Christensen et al. PLoS One 2016; 11(11): e0165331

App-detected hospitalizations

3443 ppts with app
in all 50 states

243 hospitalizations
at 119 hospitals

PPV = 65% (57%-72%)



Nguyen et al. Circ Cardiovasc Qual Outcomes 2017;10(3):e003326

- Can we use mHealth data together with EHR data?

mHealth + EHR data

- Synergy
  - In medical center + out of medical center
  - mHealth data to fill in the blanks between visits
  - Patient-reported outcomes along with physician-reported outcomes

mHealth + EHR data

- Synergy
  - In medical center + out of medical center
  - mHealth data to fill in the blanks between visits
  - Patient-reported outcomes along with physician-reported outcomes
- Main challenge
  - How do we access both, and link

mHealth + EHR data

- Example: The PCORnet Blood Pressure Control Laboratory

The PCORnet Blood Pressure Control Laboratory

- Goal: Enable efficient RCTs of blood pressure control

- Aim 1: An EHR-based BP control registry
  - Clinic-level stats on BP control and process measures

- Aim 2: A cluster-RCT comparing 2 versions of a QI intervention
  - Clinic-level stats will be the outcomes for the trial

- Aim 3: An individual-level RCT comparing 2 different home BP monitoring devices (with and without smartphone linkage)
  - Need to link EHR data with mHealth data

- How will we link EHR data with mHealth data?

mHealth + EHR data

- “Golden Ticket” System
  - EHR data search to find eligible ppts
  - Send individualized invitations with a Golden Ticket
    - Unique linkage ID on ticket or email
  - Individual enters Golden Ticket # when they enroll in Eureka

mHealth + EHR data

- Experimenting with “Eureka on FHIR”
    - FHIR API at UCSF now enabled
    - Eureka can pull FHIR data for UCSF patients

mHealth + EHR data

- Experimenting with “Eureka on FHIR”
  - FHIR API at UCSF now enabled
  - Eureka can pull FHIR data for UCSF patients
  - Could we do a multicenter Eureka on FHIR study?

Collecting Real-World Evidence at UC

- PCORnet 2.0 continues to develop; we are no longer formally involved
- Will CTSA Consortium efforts reach fruition?
  - New CD2H has some momentum? ACT?
- How can we use our Cross-UC data warehouse to support pragmatic trials?
  - EHR queries + Recruitment + Eureka/other
  - Governance, services, contracting
  - Lessons to be learned from others…

Thanks

- Questions or comments?