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Scripps Research Digital Trials Center

Transforming the face of research:

**Enabling anyone, anywhere, to
contribute to—and benefit from—
biomedical research**

Wednesday, December 15

1:00 PM PT/4:00 PM ET



THE FRONT ROW

at Scripps Research

Register at frontrow.scripps.edu

A Clear Path for Digital Medicine

2013

Scripps' Dr. Eric Topol predicting smartphones were going to revolutionize medicine

“Topol explained that the appeal of digital health lies in highly personalized medicine, delivered via the smartphone...

‘Well, you know what is going to be different is that **smartphone is going to be a conduit of data and information about your health, about your medical essence, like you never had before,**’ he said.”



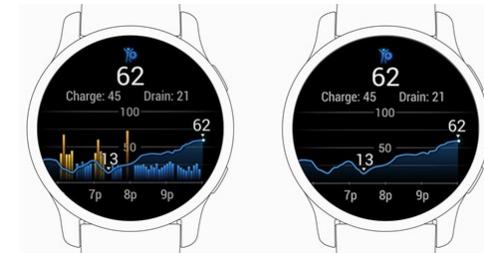
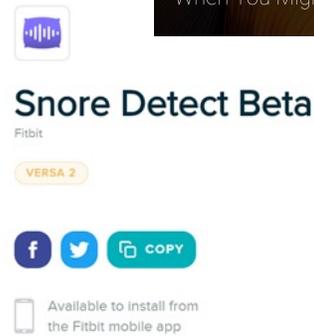
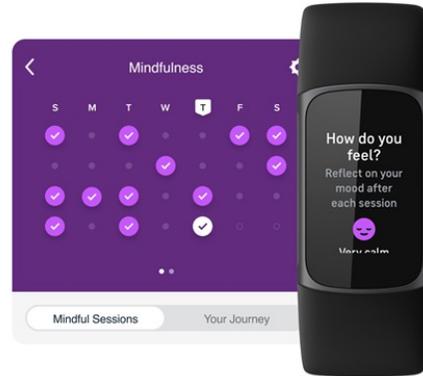
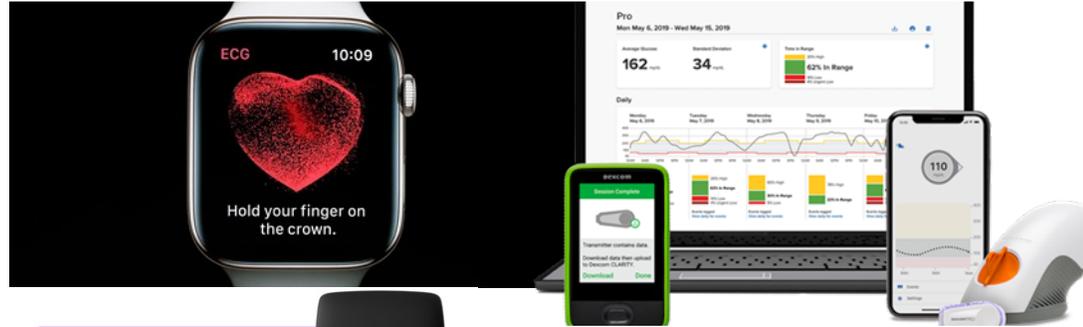
Topol turns Colbert around on digital health

By [Jonah Comstock](#) | March 26, 2013 | 08:34 pm

SHARE [Share](#) 4



Explosion of Digital Health Technologies



Identifying Standards and Other Guidelines for Digital Measures

TOUR OF DUTY: Driving adoption

The Playbook: Digital Clinical Measures

Introducing the essential guide for successful remote monitoring across *clinical research*, *clinical care*, and *public health*.



Digital Medicine Society Convenes Pharmaceutical Leaders to Collaborate on New Digital Endpoint

The collaboration between pharma companies to advance a digital endpoint for use in medical product development marks a profound change for the industry

NEWS PROVIDED BY
[Digital Medicine Society \(DiMe\)](#) →
Nov 02, 2021, 07:00 ET

SHARE THIS ARTICLE
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Bringing together experts in the field to help develop appropriate guidance to address the new frontier of leveraging digital measures.

New capabilities have also transformed the way we can conduct research and clinical trials

2015

FROM THE JOURNALS

mSToPS breaks ground as a 'pragmatic' randomized trial

Publish date: July 10, 2018

By Mitchel L. Zoler, PhD; MDedge News



FROM JAMA

The mSToPS study “represents an innovative example of the potential (and challenges) inherent in a pragmatic information technology trial. The trial “represents a brave new world for clinical research: an innovative, highly commendable, contemporary pragmatic health care information technology study that tested an important question and yielded significant clinical findings,” wrote two leaders in trial design in an editorial about the study.

Effect of a Home-Based Wearable Continuous ECG Monitoring Patch on Detection of Undiagnosed Atrial Fibrillation

The mSToPS Randomized Clinical Trial

Steven R. Steinhubl, MD^{1,2}; Jill Waalen, MD, MPH¹; Alison M. Edwards, MStat³; et al



Bring the trial to the patient

Digital technologies open new possibilities for clinical research. They can, for example, allow patients to participate in trials from their homes. Direct-to-patient trial models, or “[siteless](#)” [clinical trials](#), use tools such as telemedicine along with wearable devices and sensors for remote data collection.

Janssen recently collaborated with Scripps Translational Science Institute, Aetna, and iRhythm Technologies to understand how digital technology can improve large-scale observation and treatment programs. A home-based study of 2,659 volunteers, called mSToPS (short for mHealth Screening To Prevent Strokes), evaluated a wearable electrocardiogram patch as a new way to remotely detect atrial fibrillation.



Applying Behavioral Science to Clinical Research

2016



Commitment and Behavior Change: Evidence from the Field

KATIE BACA-MOTES
AMBER BROWN
AYELET GNEEZY
ELIZABETH A. KEENAN
LEIF D. NELSON

Influencing behavior change is an ongoing challenge in psychology, economics, and consumer behavior research. Building on previous work on commitment, self-signaling, and the principle of consistency, a large, intensive field experiment (N = 2,416) examined the effect of hotel guests' commitment to practice environmentally friendly behavior during their stay. Notably, commitment was symbolic—guests were unaware of the experiment and of the fact that their behavior would be monitored, which allowed them to exist in anonymity and behave as they wish. When guests made a brief but specific commitment at check-in, and received a lapel pin to symbolize their commitment, they were over 25% more likely to hang at least one towel for reuse, and this increased the total number of towels hung by over 40%. This research highlights how a small, carefully planned intervention can have a significant impact on behavior. Theoretical and practical implications for motivating desired behavior are discussed.



The **most diverse**
medical research
program. **Ever.**

LEARN MORE >



 **Scripps Research**
Digital Trials Center

Bringing Digital Research to Precision Medicine

2016



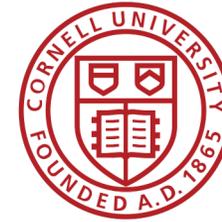
President Obama convenes a roundtable to help kickoff the White House Precision Medicine Initiative that later became the *All of Us* Research Program.

Scripps receives a \$200M NIH award to serve as The Participant Center for *All of Us*



Implementing scalable, participant-centric health research

1. Education & research training



Cornell University®



2. Research infrastructure & operations



SCIENCE FOR THE BENEFIT OF HUMANITY

3. Scripps Research



- Inclusive
- Broad & longitudinal data
- Democratizing access





THE FRONT ROW
at Scripps Research

All of Us
RESEARCH PROGRAM | The
Precision
Medicine
Initiative

The Participant Center Mission

Making it as easy as possible for interested individuals living **anywhere in the US** to join and remain **enthusiastic** participants in the *All of Us* Research Program.



All of Us Participant Center Partners



To enable participation by anyone anywhere...

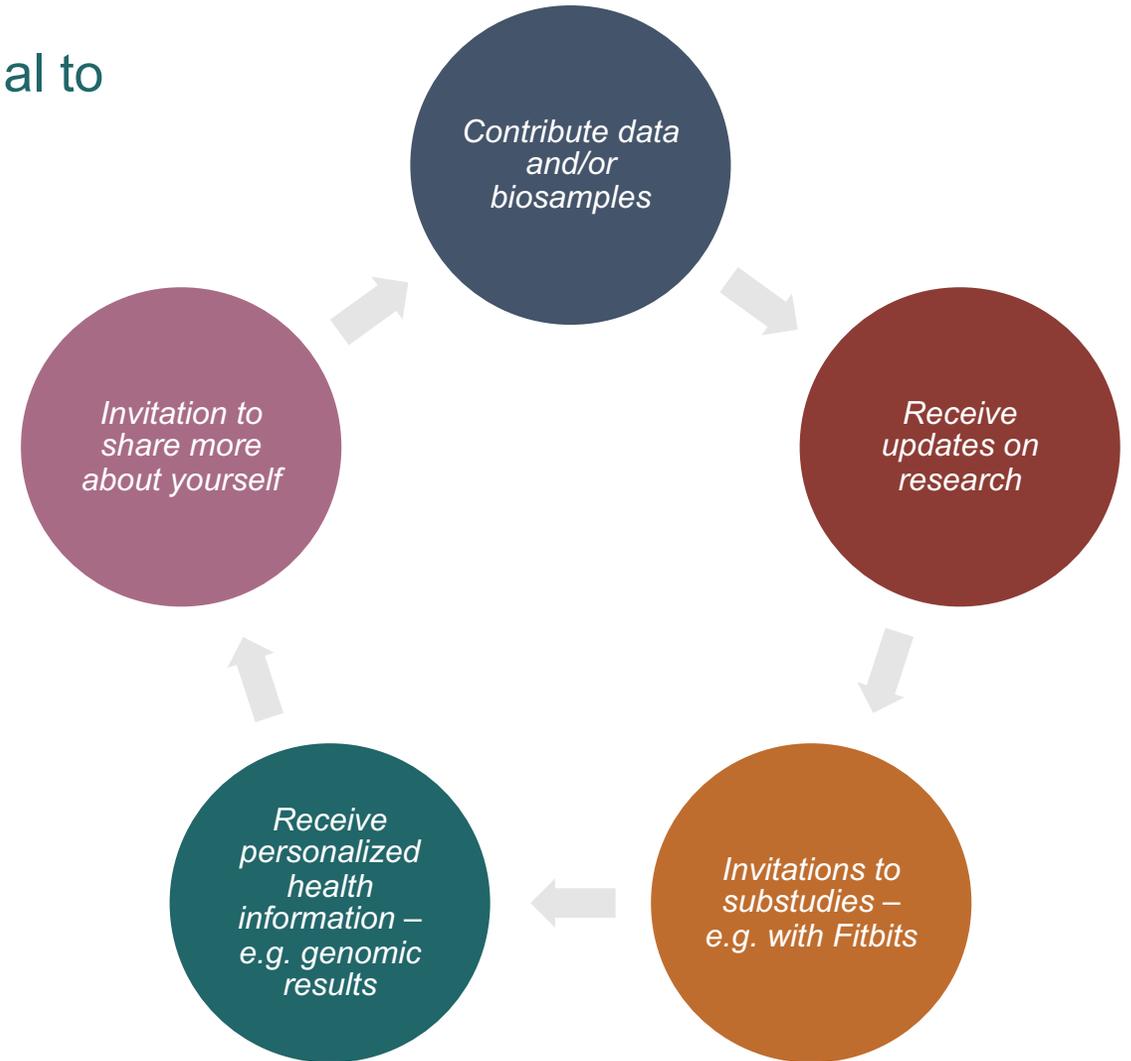
...we re-engineered the research participation experience to center on the participant.



Longitudinal engagement

Building a mutually beneficial relationship is essential to sustain a 10+ year commitment

- We aim to **return value** to participants **each time** they return value to the program.
- We believe a personal medicine program should include **personalized engagement**.



Innovating throughout the participant journey

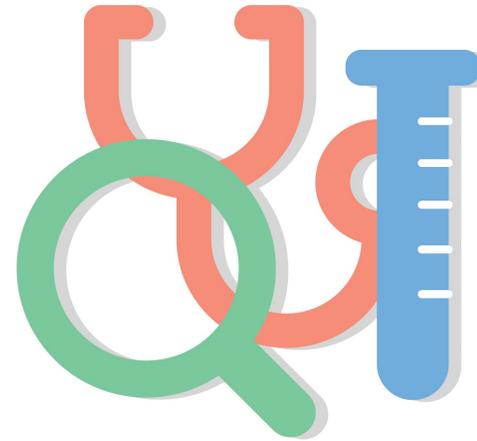
Innovation focus areas:



Enrollment



Engagement & retention



Sample collection



Sensor, EHR & other data collection



Well on our way to recruiting 1 million individuals who reflect the diversity of the US



442,000+

Participants



332,000+

Shared Biosamples



264,000+

Electronic Health
Records



1,000+

Researchers



900+

Research Studies

Data from researchallofus.org

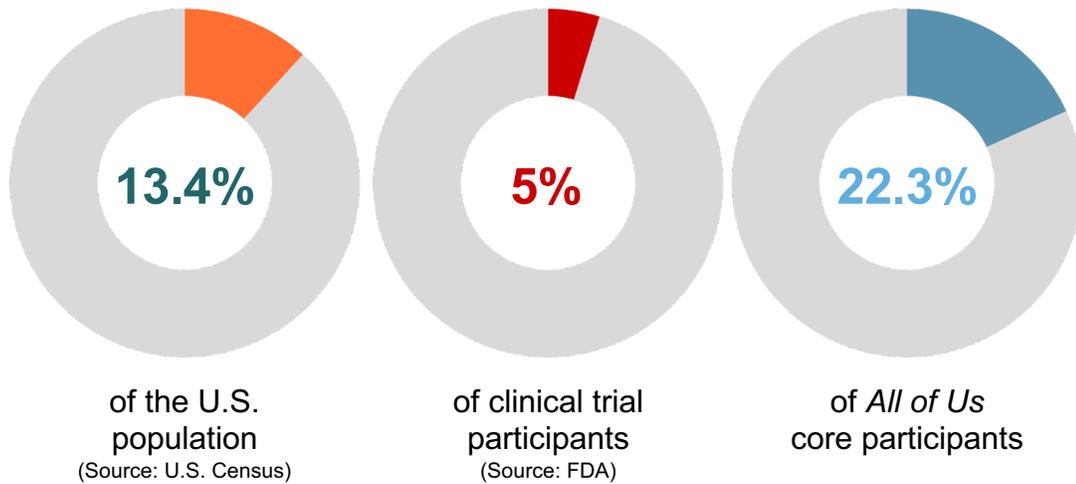


Representing the historically underrepresented

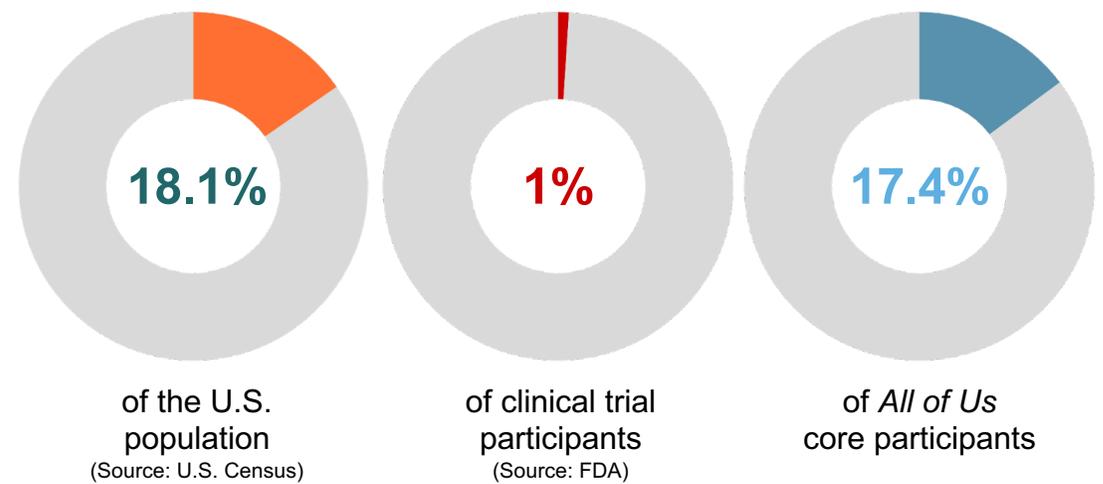
Over 50% of participants are from racial/ethnic groups that have been historically underrepresented in medical research

Over 80% of participants are from groups that have been historically underrepresented in medical research.

Black and African Americans

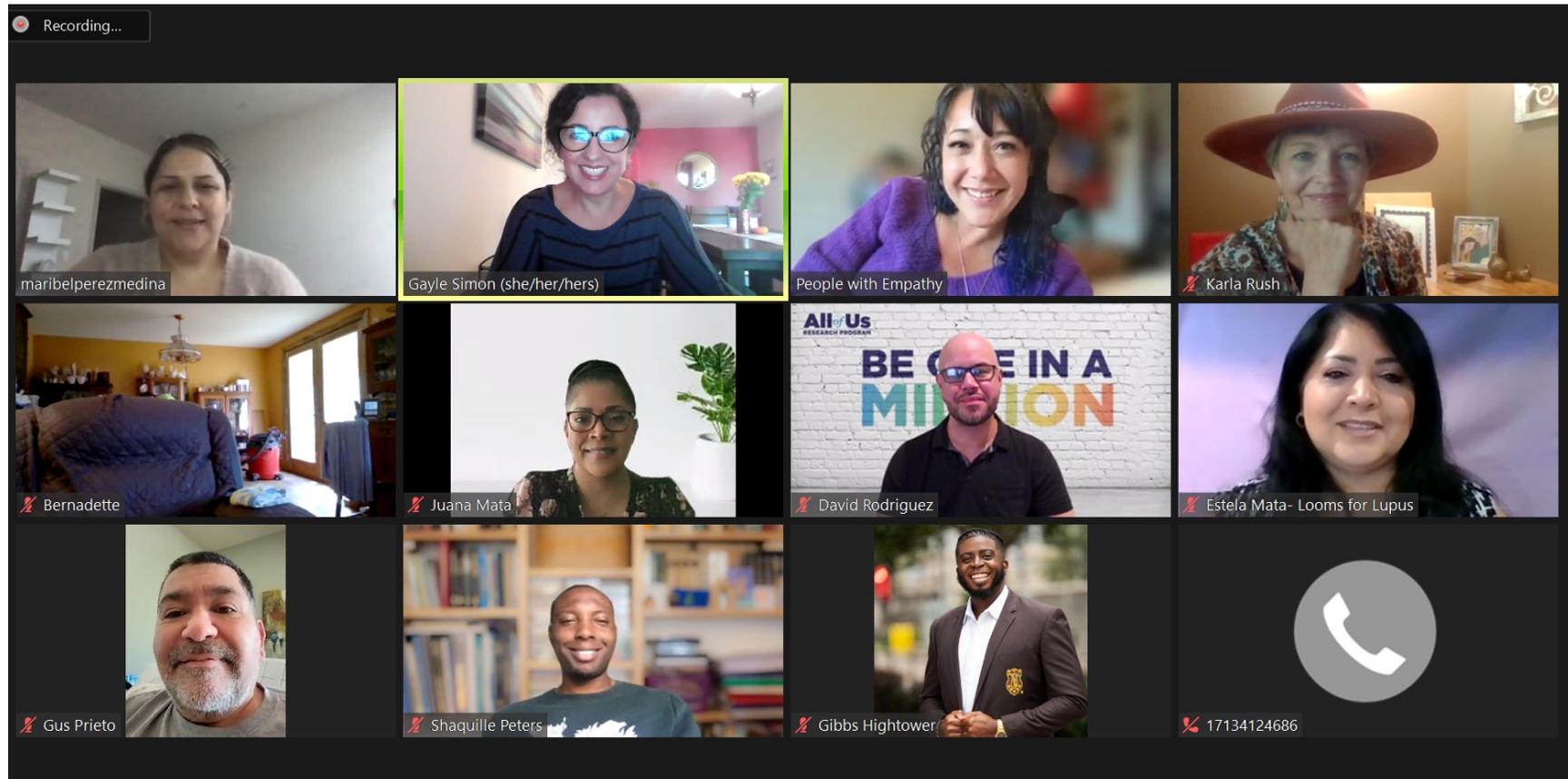


Hispanic or Latino Origin



Partnering with participants

Consulting a diverse group of 20+ advisors helps keep our efforts inclusive



To learn more about participating in the *All of Us* Research Program, visit go.joinallofus.org



THE FRONT ROW
at Scripps Research

Transforming Clinical Research

A New Paradigm in Direct-to-Participant Research



2020

E.g., partnering with 1,000 participants—500 people with type 2 diabetes, and 500 without—to understand individual level glycemic response.

HbA1c



genomics



microbiome



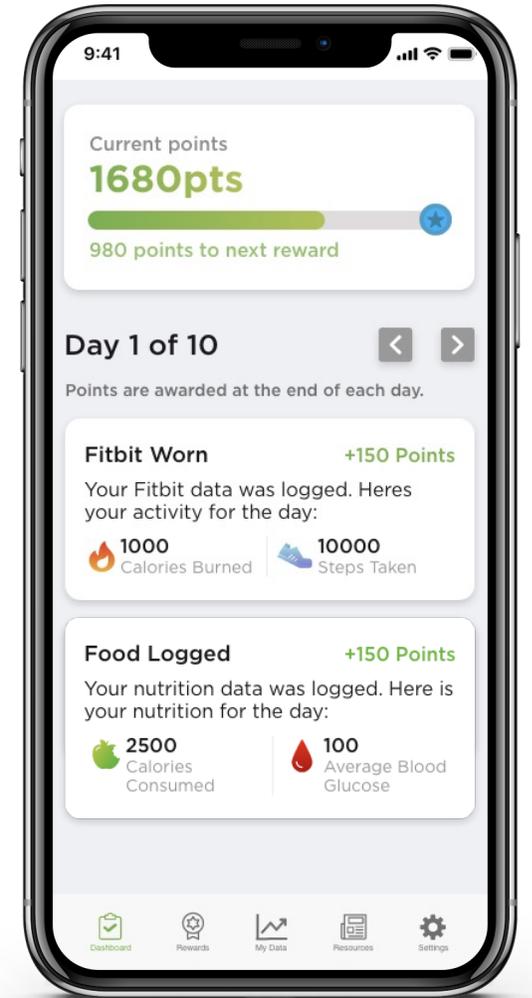
biometrics



nutritional intake



glucose response



Global Impact of Our COVID-19 Research

Study Name	Parameters Analyzed	Wearable Device(s) Included	Study Population		Key Finding
			Overall	Number COVID+	
Individual-level Viral Illness and COVID-19 Detection					
TemPredict ³⁷	Skin temp, heart rate, respiratory rate, HRV	Oura ring sensor device	50	50	Peripheral temperature elevations can be captured by wearable devices and correlate with self-reported fever.
Stanford consumer smartwatches ³⁵	Heart rate, sleep, and activity	Fitbit, Apple Watch, Garmin devices, and other	5,262	32	81% of COVID-19 cases had changes in their heart rate, steps or sleep. Retrospectively, 63% of COVID-19 cases could be detected pre-symptoms onset using extreme elevations in RHR.
Fitbit Study ³⁶	Heart rate, activity, respiration rate, HRV, sleep	Fitbit devices	187,573	2,745 (PCR) and 1117 (serology)	Physiological data could predict illness on a specific day with an AUC of 0.77
DETECT ²⁵	RHR, sleep and activity	Data from Fitbits and any devices connected with HealthKit or GoogleFit	30,529	54	Wearable sensors data can significantly improve symptom only based models to distinguish COVID-19 positive verses negative symptomatic infections (AUC=0.80)
Whoop system ⁵³	Respiratory rate, RHR, HRV	WHOOP; wrist-worn strap	271	81	Model identified 20% of COVID-19 positive cases in 2 days prior to symptom onset and 80% of positive cases by third day of symptoms
Evidation ³⁸	RHR, activity, and sleep	Fitbit devices	6,926	230	Wearable device data showed similar magnitudes in daily changes of steps and heart rate measurements for both flu and COVID-19 cohorts
Population-Level Viral illness and COVID-19 Detection					
Scripps' Fitbit study ⁵⁴	RHR and sleep	Fitbit devices	47,249	N/A	The weekly proportion of users with anomalous Fitbit data significantly improved models using CDC ILI data from 3 weeks prior to predict current ILI at the state level ($r=0.84-0.97$) in the US
Kinsa ^{29,31}	temperature	Kinsa smart thermometers	1,321 counties	N/A	Fever anomalies are significantly correlated ($r=0.54, 0.55$) with COVID-19 case counts at the county and state level, respectively, and with national ILI activity ($r>0.95$) in the US
Corona Data Donation App ²⁷	RHR and activity	Wearable fitness devices	535,298*	N/A	Sensor data may predict fever anomalies in Germany
Huami Device Users ⁵⁶	Heart rate and sleep	Huami device	1.3 million	N/A	Physiological anomaly rate correlates with COVID-19 case counts in Chinese cities (average $\rho=0.68$)

nature biomedical engineering ARTICLES
<https://doi.org/10.1038/s41551-020-00640-6>

Pre-symptomatic detection of COVID-19 from smartwatch data

Tejaswini Mishra¹, Amir Bahmani^{1,3}, A Susan Kirkpatrick¹, Ariel B. Ganz^{1, B}

npj | Digital Medicine www.nature.com/npjdigitalmed

ARTICLE OPEN

Assessment of physiological signs associated with COVID-19 measured using wearable devices

Aravind Natarajan^{1,3}, Hao-Wei Su¹ and Conor Heneghan¹

scientific reports

OPEN **Feasibility of continuous fever monitoring using wearable devices**

Benjamin L. Smarr^{1,2}, Kirstin Aschbacher^{2,3}, Sarah M. Fisher⁴, Anoushka Chowdhary⁴, Stephan Dilchert⁵, Karena Puldon⁶, Adam Rao⁶, Frederick M. Hecht^{4,8} & Ashley E. Mason^{4,7,8}

Patterns

Characterizing COVID-19 and Influenza Illnesses in the Real World via Person-Generated Health Data

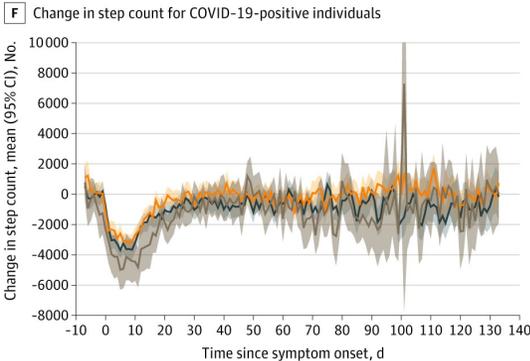
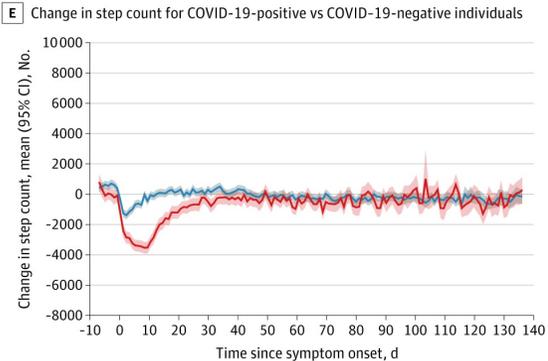
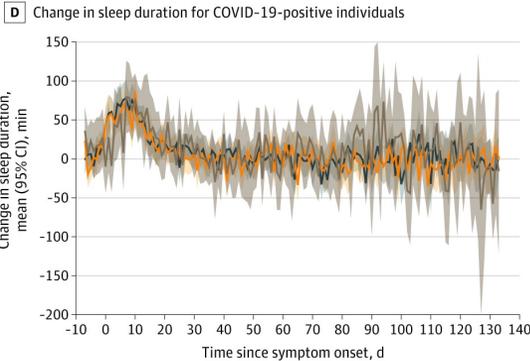
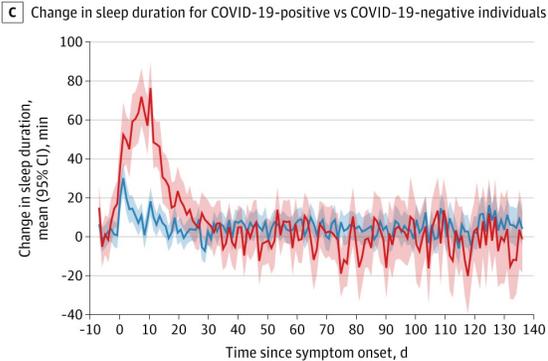
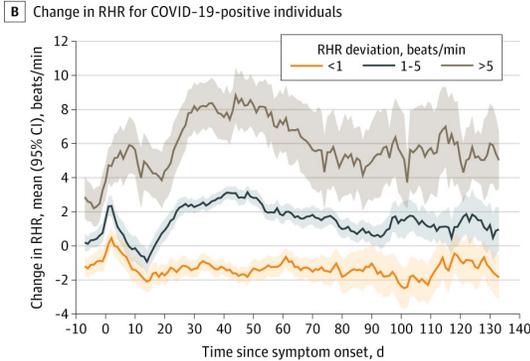
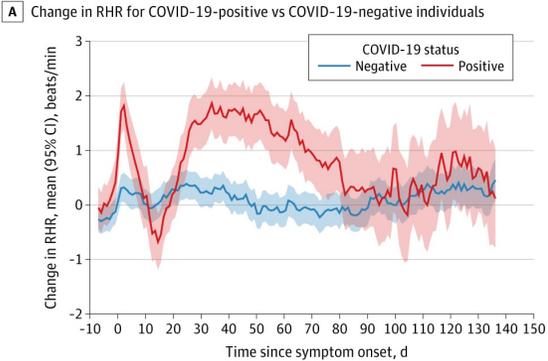
RESEARCH ARTICLE

Analyzing changes in respiratory rate to predict the risk of COVID-19 infection **PLOS ONE**

Dean J. Miller^{1*}, John V. Capodilupo², Michele Lastella¹, Charli Sargent¹, Gregory D. Roach¹, Victoria H. Lee², Emily R. Capodilupo²



Long COVID (published July 2021)



JAMA Network | **Open**

Research Letter | Infectious Diseases

Assessment of Prolonged Physiological and Behavioral Changes Associated With COVID-19 Infection

Jennifer M. Radin, PhD, MPH; Giorgio Quer, PhD; Edward Ramos, PhD; Katie Baca-Motes, MBA; Matteo Gadaleta, PhD; Eric J. Topol, MD; Steven R. Steinhubl, MD

The New York Times

Fitbits Detect Lasting Changes After Covid-19

Some people recovering from a coronavirus infection had an elevated heart rate for months, according to a new study.

The Economist

Fitbit for purpose

A new study using wearable devices could help to define long covid

14% of covid-19 patients have elevated heart rates for months after infection





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at Scripps Research

Long COVID Wearable Study

An effort to help the millions of individuals with Long COVID better manage their symptoms



The massive scale & scope of Long COVID

Scale

- An estimated **17M** individuals in the **US**
- Estimated over **70M** individuals **worldwide**
- And **growing** every day...

Scope

- Over **200 symptoms**
- Affecting **10 organ systems**
- **22% cannot work**; an **additional 45%** work at a **reduced capacity**

References:

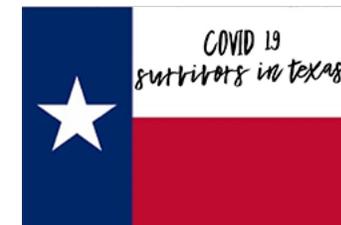
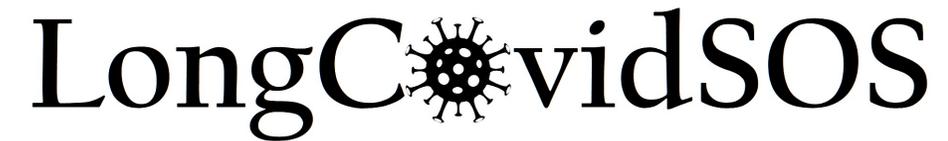
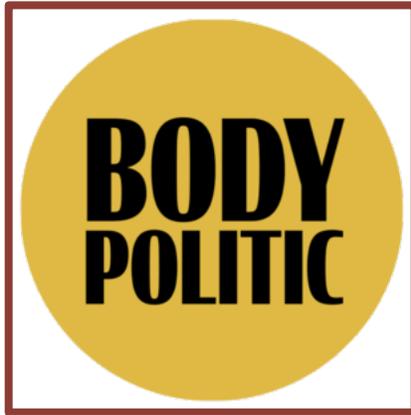
[https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(21\)00299-6/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00299-6/fulltext)

<https://www.medrxiv.org/content/10.1101/2021.11.15.21266377v1>



With insufficient medical support, patients turn to each other

Our collaborators



...and many more



The most helpful thing I learned from other Long COVID patients

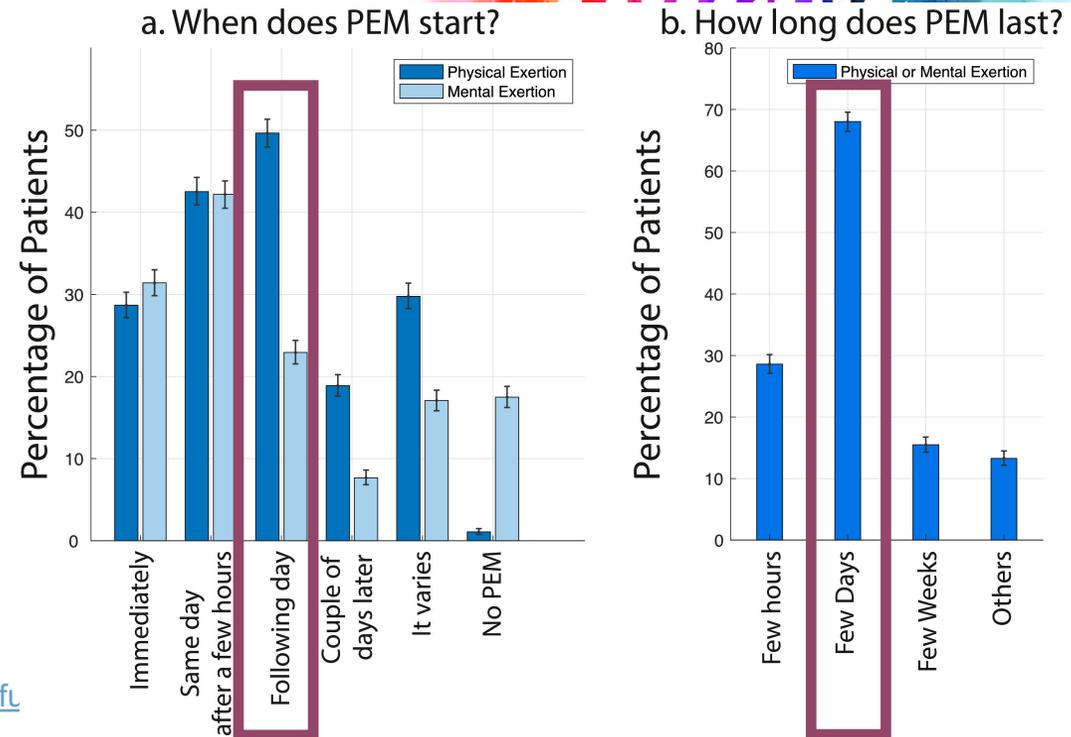
How to manage symptoms

Every Monday my symptoms were the strongest. Why?

Post-exertional malaise (PEM)

Reference:

[https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(21\)00299-6/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00299-6/fulltext)



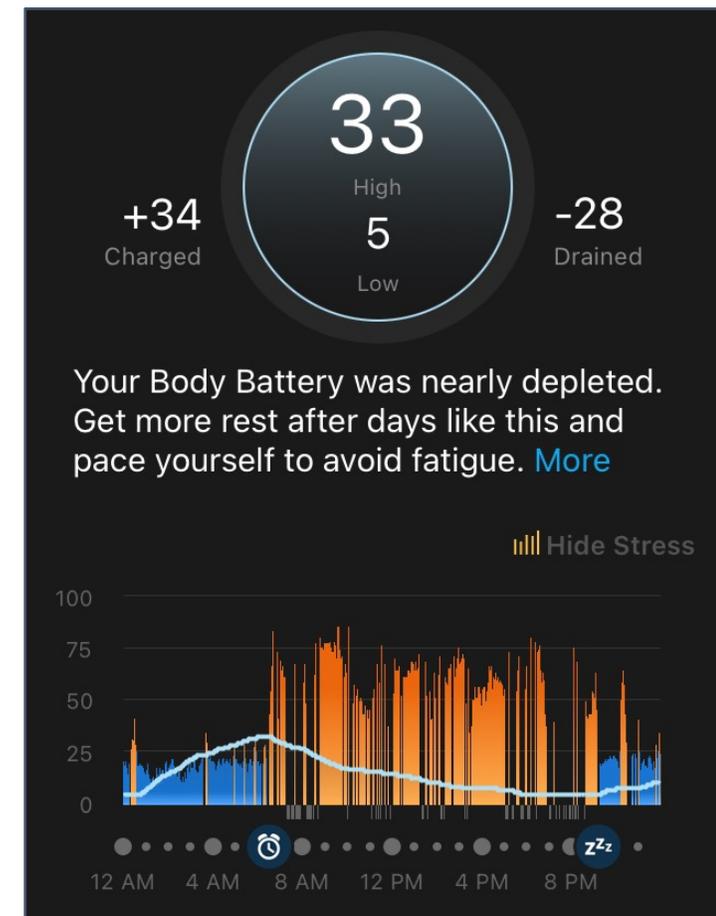
The most helpful thing I learned from other Long COVID patients

How to manage symptoms using a wrist-worn wearable

How can we avoid PEM?

Pacing.

We aim to teach participants how to use wearable devices to pace & lessen the severity of their symptoms.



What do we hope to show?

We hypothesize that with a Garmin device and advice about how to use it to pace participants will...

1

Have **fewer**
relapses

2

Have **less severe**
relapses

3

Possibly **recover**
from Long COVID



Early feedback from Long COVID patients

- **86%** found the study **helpful for symptom management**
- Of the 86% who experienced a “relapse” or worsening of symptoms, **83%** said the study **reduced the severity and/or duration.**



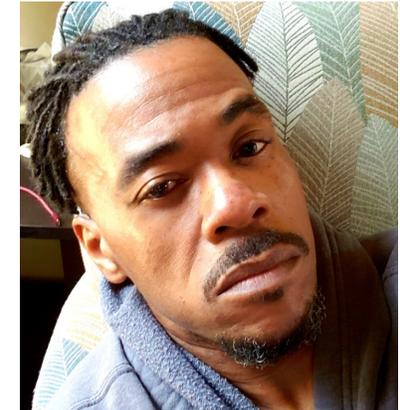
"Through this wearables study...I have made adjustments and accommodations in my lifestyle, **empowering me to care for myself in a more proactive way.**"

- Heather-Elizabeth Brown



"Doctors don't know much about Long COVID...We are feeling alone, and **any information would be great.**"

- Estela Mata



"My participation...has **greatly helped in managing the fatigue,** along with many other things."

- Diago Walker



Next steps: secure study funding & launch

Current collaborators:



**PATIENT-LED
RESEARCH
COLLABORATIVE**



care evolution
HEALTHCARE TECHNOLOGY

GARMIN®

To learn more & sign up for updates, visit:

longcovid.scripps.edu



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Upcoming Areas of Focus

What's Next for the Center

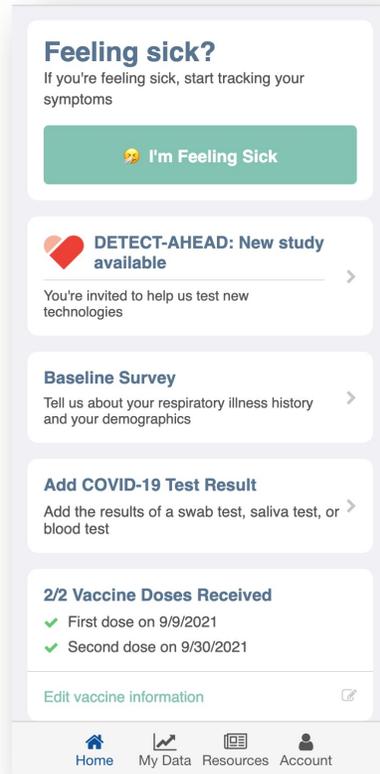


Scalable model developed to enable dozens of studies on each platform

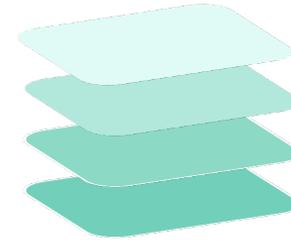
Lightweight, foundational protocol



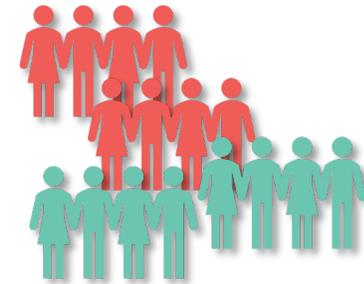
Baseline biometrics
Symptom capture
Vaccination status
COVID-19 test results
EHR data (optional)



Layered, targeted sub-studies



At-home COVID-19 testing
Acoustic signaling
Personalized biometric triggers
Long COVID



The Scripps Digital Trial Center: Looking Ahead

DETECT

Feeling sick?
If you're feeling sick, start tracking your symptoms

I'm Feeling Sick

DETECT-AHEAD: New study available
You're invited to help us test new technologies

Baseline Survey
Tell us about your respiratory illness history and your demographics

Add COVID-19 Test Result
Add the results of a swab test, saliva test, or blood test

2/2 Vaccine Doses Received
First dose on 9/9/2021
Second dose on 9/30/2021

Home My Data Resources Account

detect.scripps.edu

Infectious
Diseases

PowerMom

Welcome Jane,

You are in your 1st Trimester
10 weeks and 3 days Pregnant

Dec 17th Due Date: Dec 17th, 2021
29 weeks and 4 days left

Update Pregnancy Status

Your Fitbit is on the way!
Keep an eye out for an email from Fitbit regarding tracking information for your device.

Tasks
Health History Survey
10 - 15 minutes

Dashboard My Data Resources Settings

powermom.scripps.edu

Maternal
Health

PROGRESS

Current points
460pts
740 points to next reward

Tasks

Collect Blood Sample
190 points | 15 min

Collect Saliva Sample
185 points | 15 min

Collect Microbiome Sample
225 points | 20 min

Return Samples
90 points | 10 min

Prediction of Glycemic RESPONSE Study (PR... My Projects

Dashboard Rewards My Data Resources Settings

progress.scripps.edu

Precision
Nutrition

REFRESH

Good morning

Tasks

Sleep Apnea Screening
Assess your risk for obstructive sleep apnea
8 minutes

Insomnia Screening
Assess your risk for insomnia
Complete sleep apnea screening

Demographics Survey
Help us ensure fair representation
Complete insomnia screening

Results

Your results will show here once you have completed the above tasks.

Dashboard My Data Account

refresh.scripps.edu

Sleep
Medicine



Getting Started

Welcome to All of Us - to get started, please tell us some basic information about yourself.

START THE BASICS

0/6 Surveys 0/2 Biosample 0/2 Health Records 0/1 Digital Health

7/22/2019 Consent

Not started The Basics Survey

Not started Order Salivary Kit

Not started Return Salivary Kit

Not started EHR Consent

Not started Link Health Records

Not started Share Digital Health Data

Not started Lifestyle Survey

Not started Overall Health Survey

Dashboard Tasks My Data Profile

go.joinallofus.org

Precision
Medicine



Acknowledgements: Scripps Research Digital Trials Center Team

Eric Topol

Amanda Schneider

Andrea Goosen

Ann Batt

Anna Andersen

Christina Orlovsky

Colleen McShane

Dana Deighton

Daniel Oran

Danielle Chiang

David Rodriguez

Diana Ho

Dina Hamideh

Ed Ramos

Emily Spencer

Erin Coughlin

Evan Muse

Felipe Delgado

Gabe Neri

Gail Ebner

Gayle Simon

Giorgio Quer

Gwynne Davis

Isa Rector

Jairo Rodriguez

Janna Ter Meer

Jasmine Rezai

Jason Burg

Jay Pandit

Jeff Pawelek

Jennifer Radin

Jill Waalen

Julia Moore Vogel

Katie Baca-Motes

Katie Quartuccio

Kendall Laycock

Kristina Haro

Lase Ajayi

Lauren Ariniello

Lauren Serpico

Lena Miyasaki

Maria Benjamin

Maribel Perez-Medina

Matin Nazari

Matteo Gadaleta

Matthew Tombs

Meagan Sharp

Michael Djobi

Michael Hung

Michelle Miller

Nicole Phoenix

Romina Foster-Bonds

Royan Kamyar

Sasri Dedigama

Scott Parish

Shaquille Peters

Shiri Warshawsky

Steven Steinhubl

Stuti Jaiswal

Tanya Hearne

Tyler Peters

Wendy Wong



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