Katie Baca-Motes, MBA
Senior Director, Strategic Initiatives
Scripps Research Digital Trials Center

Transforming the face of research:
Enabling anyone, anywhere, to contribute to—and benefit from—biomedical research

Julia Moore Vogel, MBA, PhD
Program Director, The Participant Center,
All of Us Research Program
Scripps Research Digital Trials Center

Wednesday, December 15
1:00 PM PT/4:00 PM ET

THE FRONT ROW
at Scripps Research

Register at frontrow.scripps.edu
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.”
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.

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.

**mSToPS breaks ground as a ‘pragmatic’ randomized trial**

*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.

**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, Actua, 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.
Commitment and Behavior Change: Evidence from the Field

KATIE BACA-MOTES
CELTIE JOHNSON
AVELIN SIMIERS
ELIZABETH A. NIEHAN
LEIF G. NELSON

Advancing behavioral change by engaging people in understanding, accepting, and practicing health-related behaviors: motivation, self-efficacy, and social support. This approach to healthcare is based on self-determination theory, which highlights the importance of people taking control of their health decisions. It is an approach to health care that is patient-centered, empowering, and promotes health equity. It is an approach to health care that is patient-centered, empowering, and promotes health equity. It is an approach to health care that is patient-centered, empowering, and promotes health equity.
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

2. Research infrastructure & operations

3. Scripps Research

- Inclusive
- Broad & longitudinal data
- Democratizing access
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

Walgreens
BlueCross BlueShield
WebMD
care evolution
Healthcare Technology
DENVER HEALTH.
for life's journey
Quest Diagnostics
MONTAGE MARKETING
National Blood Collaborative
Blood Solutions | Trusted Source
fitbit
San Diego Blood Bank
Foundation
SageBionetworks
Mary's Center
Quality healthcare. Stronger communities.
active minds
Medscape
patientslikeme
SENSIS
SYNC FOR SCIENCE
Urban One
Bloodworks Northwest
ACHA
Gulf Coast Regional Blood Center
Commit for Life.
To enable participation by anyone anywhere…

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

Support throughout
Our Support Center answers all questions, in English and Spanish, via email, phone, or chat.

Research Participant

Learn & join online
Learn about the program and decide whether to join on your own time.

Accessible biosample options
Share saliva from home or go to any Quest, local blood banks, or even have a home visit to provide blood and urine.

Share & visualize data at home
Surveys, electronic health records, digital health technology data, & more can be shared & visualized remotely.
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**
  - 13.4% of the U.S. population (Source: U.S. Census)
  - 5% of clinical trial participants (Source: FDA)
  - 22.3% of All of Us core participants

- **Hispanic or Latino Origin**
  - 18.1% of the U.S. population (Source: U.S. Census)
  - 1% of clinical trial participants (Source: FDA)
  - 17.4% of All of Us core participants
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
Transforming Clinical Research

A New Paradigm in Direct-to-Participant Research
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

Enabling Studies with Robust, Deep Data Capture
And with Unprecedented Speed and Scale

First paper published in fewer than 7 months from launch

October 2021

Over 35,000 participants enrolled in first 4 months

February March July 2020 2021

July September

CONCEPT TO NATIONWIDE LAUNCH IN 4 WEEKS

Wearable sensor data and self-reported symptoms for COVID-19 detection
Gargia Quero, Jennifer M. Rudes, Matteo Galbiati, Katia Roca-Motes, Lauren Aronoff, Edward Ramos, Vik Kheterpal, Eric J. Topol, and Steven R. Steinbuch

Research Letter | Infectious Diseases
Assessment of Prolonged Physiological and Behavioral Changes Associated With COVID-19 Infection
Jennifer M. Rudes, MD; MPH; Gargia Quero, PhD; Edward Ramos, MD; Katia Roca-Motes, MIA; Matteo Galbiati, PhD; Eric J. Topol, MD; Steven R. Steinbuch, MD

ARTICLE OPEN
Passive detection of COVID-19 with wearable sensors and explainable machine learning algorithms
Matteo Galbiati, Jennifer M. Rudes, Katia Roca-Motes, Edward Ramos, Vik Kheterpal, Eric J. Topol, Steven R. Steinbuch, and Gargia Quero

THE FRONT ROW
at Scripps Research
Global Impact of Our COVID-19 Research

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Parameters Analyzed</th>
<th>Wearable Device(s) Included</th>
<th>Study Population</th>
<th>Key Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Individual-level Viral illness and COVID-19 Detection</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TemPredict[^7]</td>
<td>Skin temp, heart rate, respiratory rate, HRV</td>
<td>Oura ring sensor device</td>
<td>Overall 50</td>
<td>50 Peripheral temperature elevations can be captured by wearable devices and correlate with self-reported fever.</td>
</tr>
<tr>
<td>Stanford consumer smartwatches[^8]</td>
<td>Heart rate, sleep, and activity</td>
<td>Fitbit, Apple Watch, Garmin devices, and other</td>
<td>Overall 5,262</td>
<td>32 83% 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.</td>
</tr>
<tr>
<td>Fitbit Study[^9]</td>
<td>Heart rate, activity, respiration rate, HRV</td>
<td>Fitbit devices</td>
<td>Overall 187,573</td>
<td>2,745 (PCR) and 1117 (serology) Physiological data could predict illness on a specific day with an AUC of 0.77</td>
</tr>
<tr>
<td>DETECT[^10]</td>
<td>RHR, sleep and activity</td>
<td>Data from Fitbits and any devices connected with HealthKit or Google Fit</td>
<td>Overall 30,529</td>
<td>54 Wearable sensors data can significantly improve symptom only based models to distinguish COVID-19 positive versus negative symptomatic infections (AUC=0.80)</td>
</tr>
<tr>
<td>Whoop system[^11]</td>
<td>Respiratory rate, RHR, HRV</td>
<td>WHOOP; wrist-worn strap</td>
<td>Overall 271</td>
<td>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</td>
</tr>
<tr>
<td>Evidation[^12]</td>
<td>RHR, activity, and sleep</td>
<td>Fitbit devices</td>
<td>Overall 6,926</td>
<td>230 Wearable device data showed similar magnitudes in daily changes of steps and heart rate measurements for both flu and COVID-19 cohorts</td>
</tr>
<tr>
<td><strong>Population-Level Viral illness and COVID-19 Detection</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scripps Fitbit study[^13]</td>
<td>RHR and sleep</td>
<td>Fitbit devices</td>
<td>Overall 47,249</td>
<td>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</td>
</tr>
<tr>
<td>Kinsa[^14-15]</td>
<td>temperature</td>
<td>Kinsa smart thermometers</td>
<td>Overall 1,321</td>
<td>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&gt;0.95) in the US</td>
</tr>
<tr>
<td>Corona Data Donation App[^16]</td>
<td>RHR and activity</td>
<td>Wearable fitness devices</td>
<td>Overall 535,298*</td>
<td>N/A Sensor data may predict fever anomalies in Chinese cities (average ρ=0.68)</td>
</tr>
<tr>
<td>Huami Device Users[^17]</td>
<td>Heart rate and sleep</td>
<td>Huami device</td>
<td>Overall 1.3 million</td>
<td>N/A Physiological anomaly rate correlates with COVID-19 case counts in Chinese cities (average p=0.68)</td>
</tr>
</tbody>
</table>

[^7]: Skin temp, heart rate, respiratory rate, HRV
[^8]: Heart rate, sleep, and activity
[^9]: Heart rate, activity, respiration rate, HRV
[^10]: RHR, sleep and activity
[^11]: Respiration rate, RHR, HRV
[^12]: RHR, activity, and sleep
[^13]: RHR and sleep
[^14]: temperature
[^15]: Kinsa smart thermometers
[^16]: RHR and activity
[^17]: Heart rate and sleep
Long COVID (published July 2021)

Research Letter | Infectious Diseases
Assessment of Prolonged Physiological and Behavioral Changes Associated With COVID-19 Infection
Jennifer M. Rodin, PhD, MPH; Giorgio Quer, PhD; Edward Ramos, PhD; Katie Baca-Motes, MBA; Matteo Gaddetta, 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
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.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
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:

To learn more & sign up for updates, visit:

longcovid.scripps.edu
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

**PowerMom**
- Welcome Jane,
  - You are in your 1st Trimester
  - 16 weeks and 3 days pregnant

**PROGRESS**
- Current points 460pts
  - 740 points to next reward
  - Due Date: Dec 17th, 2021
    - 19 weeks and 4 days left
  - Update Pregnancy Status

**REFRESH**
- Good morning

Tasks
- Collect Blood Sample: 190 points | 15 min
- Collect Saliva Sample: 185 points | 15 min
- Collect Microbiome Sample: 225 points | 20 min
- Return Samples: 10 points | 10 min

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

**Infectious Diseases**
- detect.scripps.edu

**Maternal Health**
- powermom.scripps.edu

**Precision Nutrition**
- progress.scripps.edu

**Sleep Medicine**
- refresh.scripps.edu

**Precision Medicine**
- go.joinallofus.org

The Front Row
at Scripps Research
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 Miyasaka
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
Acknowledgements: Scripps Research Partners
Connect with us

Scripps Research
Digital Trials Center

digitaltrials.scripps.edu