Katie Baca Motes
Chief Strategy Officer, Clinical Trials
Scripps Research & CareEvolution

10 years ago, the vision for Digital Medicine was already taking shape

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

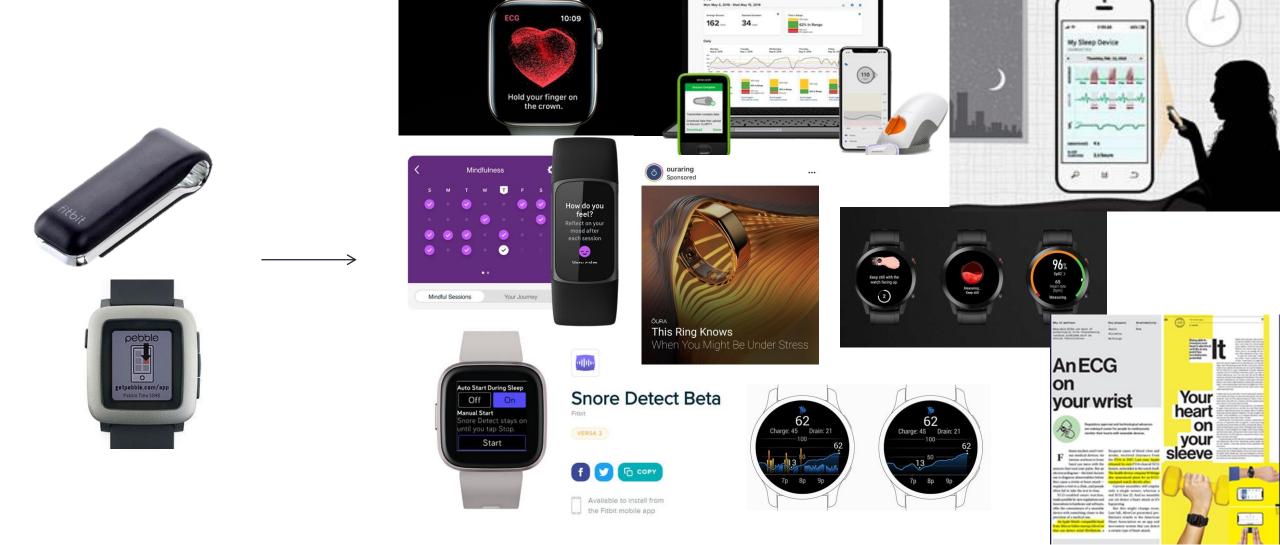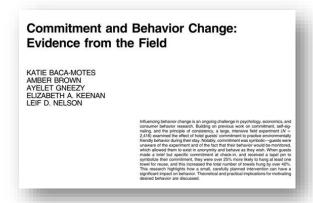By Jonah Comstock | March 26, 2013 | 08:34 pm

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Explosion of Digital Health Technologies

Applying Behavioral Science to Clinical Research

Commitment and Behavior Change:
Evidence from the Field

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

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, MPH[1]; Alison M. Edwards, MStat[3]; 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.
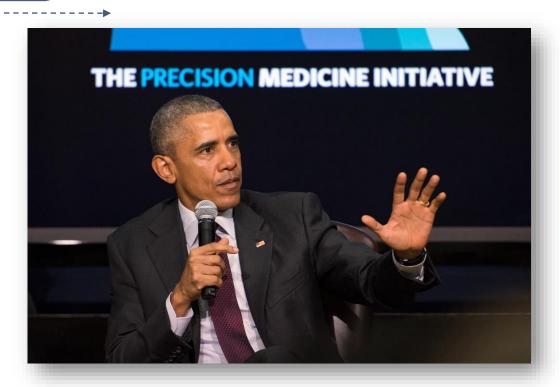
Janssen recently collaborated with Scripps Translational Science Institute, Aetna, and iRhythm Technologies to understand how digital technology can improve large-scale observation and treatment programs. A home-based study of 2,659 volunteers, called mSToPS (short for mHealth Screening To Prevent Strokes), evaluated a wearable electrocardiogram patch as a new way to remotely detect atrial fibrillation.

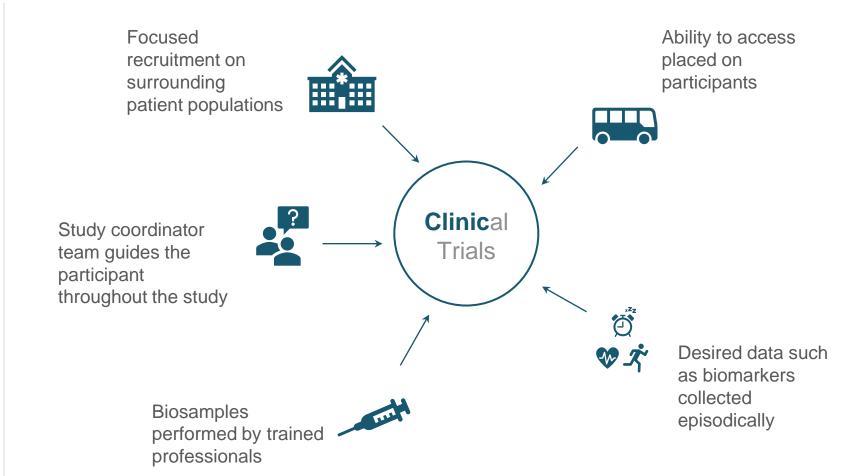# Bringing Digital Research to Precision Medicine

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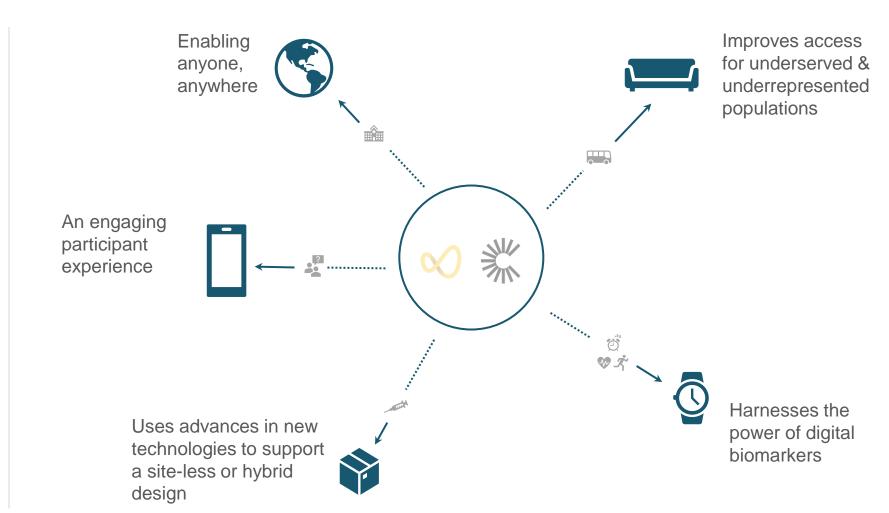

Scripps receives a $200M NIH award to serve as The Participant Center for *All of Us*

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Traditional clinical trial study design

Focused recruitment on surrounding patient populations

Ability to access placed on participants

Study coordinator team guides the participant throughout the study

Clinical Trials

Desired data such as biomarkers collected episodically

Biosamples performed by trained professionals

Beyond the "clinic" in clinical research trials

Enabling anyone, anywhere

Improves access for underserved & underrepresented populations

An engaging participant experience

Uses advances in new technologies to support a site-less or hybrid design

Harnesses the power of digital biomarkers

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All of Us
RESEARCH PROGRAM

The Future of Health Begins With You

Data Snapshots
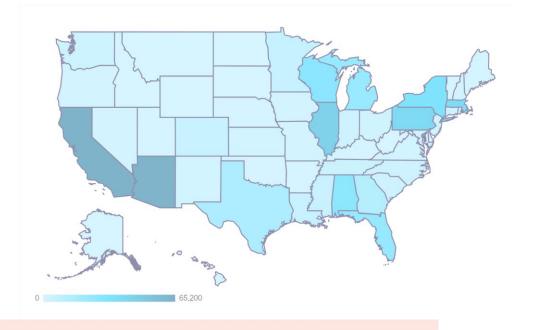
Data Snapshots showcase the breadth and depth of the *All of Us* Research Program dataset. The snapshots provide participant demographics, geographic distribution, and more. We update the snapshots daily.

699,000+
Participants

395,000+
Electronic Health Records

499,000+
Biosamples Received

0 ▬▬▬▬▬▬ 65,200

Diversity

Includes racial and ethnic minorities as well as sexual and gender minorities, people with low income or limited education, and other groups.
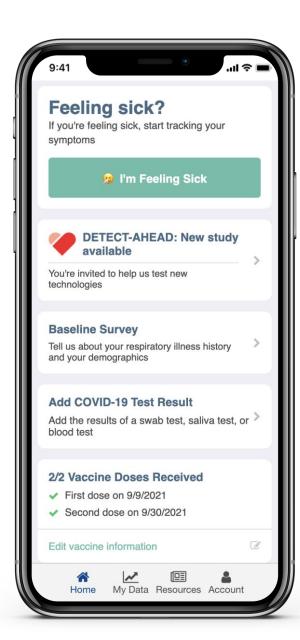
50%+ Racial and Ethnic Minorities
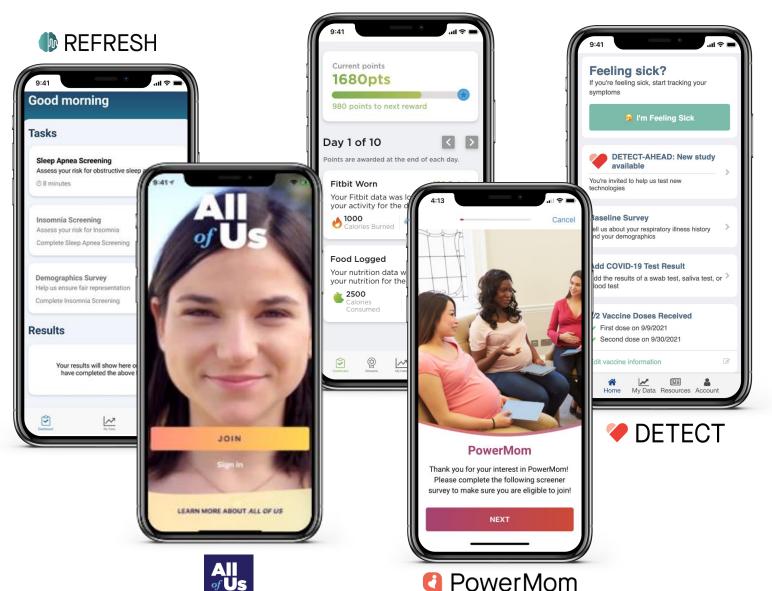
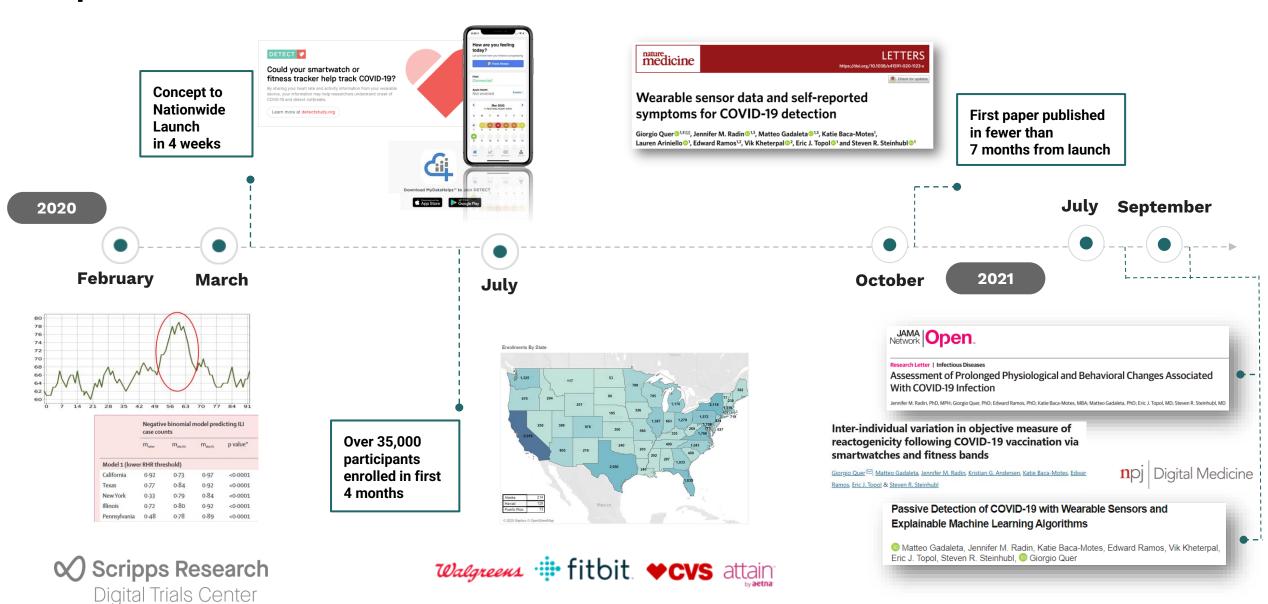**80%+** Underrepresented in Biomedical Research

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REFRESH
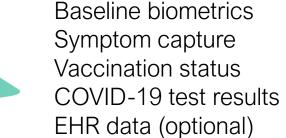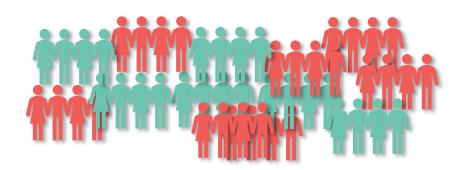
PROGRESS

DETECT

PowerMom

All of Us

DETECT: a showcase for how the infrastructure was leveraged for a nimble respond to the COVID-19 crisis
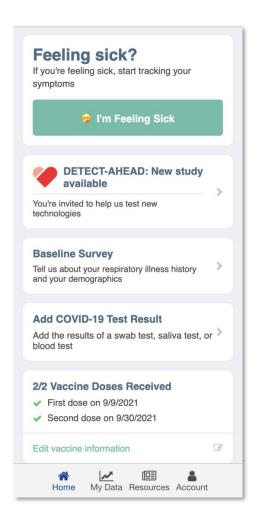
Scalable model developed to enable sub-studies on each platform
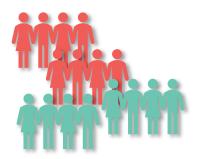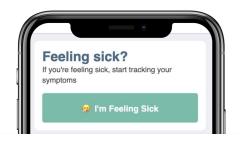

DETECT

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

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

Edit vaccine information

Home   My Data   Resources   Account

Large Baseline Cohort Enabled Smaller, Interventional Studies

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

Add COVID-19 Test Result >
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2/2 Vaccine Doses Received
✓ First dose on 9/9/2021
✓ Second dose on 9/30/2021

Edit vaccine information ✎

🏠 Home   📈 My Data   📰 Resources   👤 Account
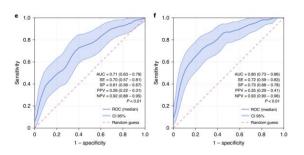
9.5 weeks to complete enrollment (LPI
  n = 450
  30% UBR races/ethnicities
  50% all UBR categories

Observational data collected to set baseline...

$$\text{RHRMetric} = \frac{\max(\text{DailyRHR [test data]}) - \text{median}(\text{DailyRHR [baseline data]})}{4.00}$$

$$\text{SleepMetric} = \frac{\text{mean}(\text{DailySleep [test data]}) - \text{median}(\text{DailySleep [baseline data]})}{56.06}$$

$$\text{ActivityMetric} = \frac{\text{mean}(\text{DailyActivity [test data]}) - \text{median}(\text{DailyActivity [baseline data]})}{2,489.85}$$

Can prediction algorithms lead to quicker diagnosis?

Participants alerted when biomarkers deviate from baseline
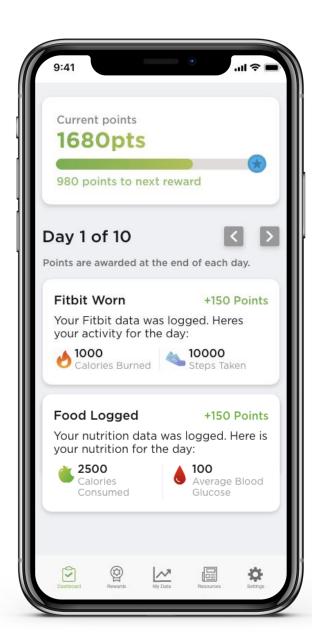
COVID-19 testing prompt coupled with test kit

Symptom reporting for additional contextual data

Wearable sensor data improves prediction of COVID-19 positivity (training).

Algorithms trained on these data can then be used to inform an ML model used for future prediction (new).

Enabling studies with robust, deep data capture

PROGRESS

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

HbA1c

genomics

microbiome
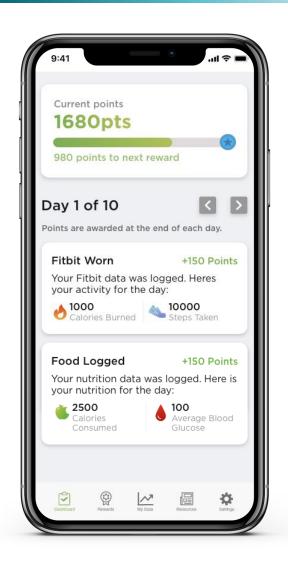
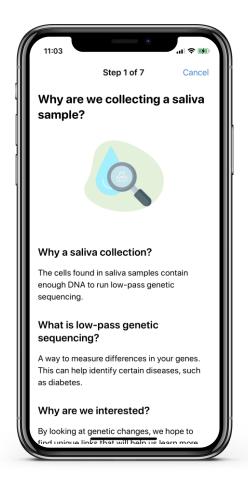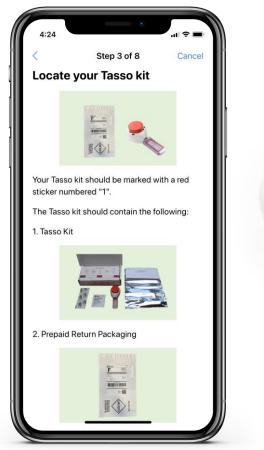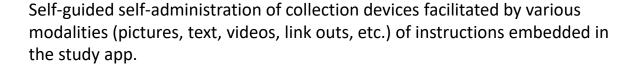*biometrics*

nutritional intake

glucose response

Current points
1680pts
980 points to next reward

Day 1 of 10
Points are awarded at the end of each day.

Fitbit Worn   **+150 Points**
Your Fitbit data was logged. Heres your activity for the day:
🔥 **1000** Calories Burned   👟 **10000** Steps Taken

Food Logged   **+150 Points**
Your nutrition data was logged. Here is your nutrition for the day:
🍎 **2500** Calories Consumed   **100** Average Blood Glucose

Dashboard   Rewards   My Data   Resources   Settings

Biosample collection

Self-guided self-administration of collection devices facilitated by various modalities (pictures, text, videos, link outs, etc.) of instructions embedded in the study app.
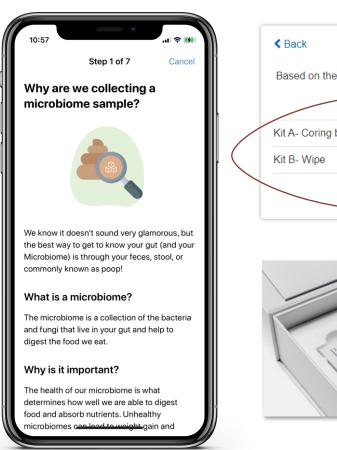
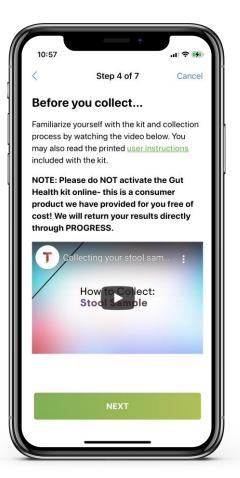# Adaptability to accommodate workflow changes
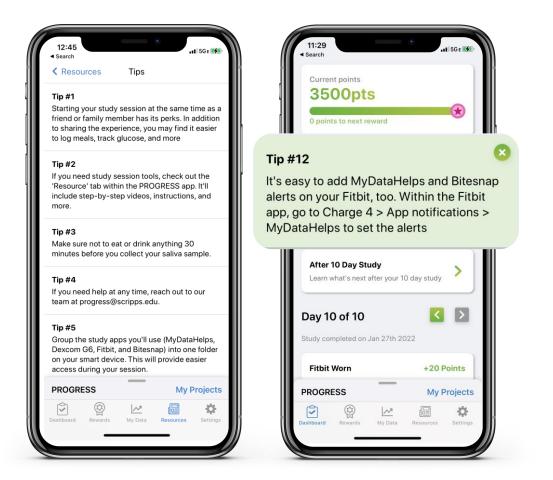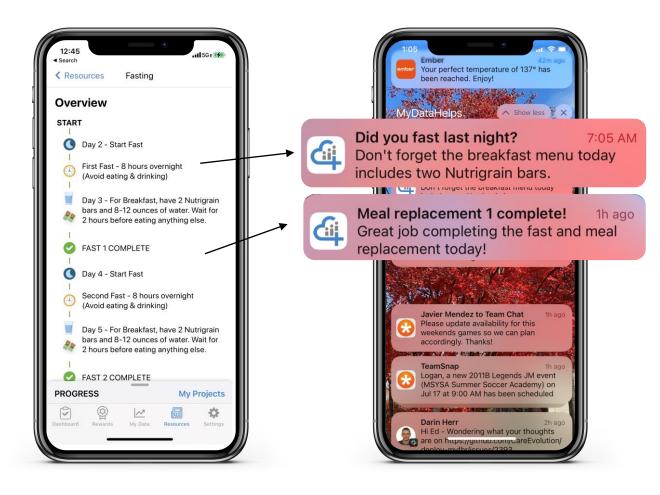
Backend designer tool allows for easy modification to address changes in operational workflows.

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Flexibility in notification and reminder options
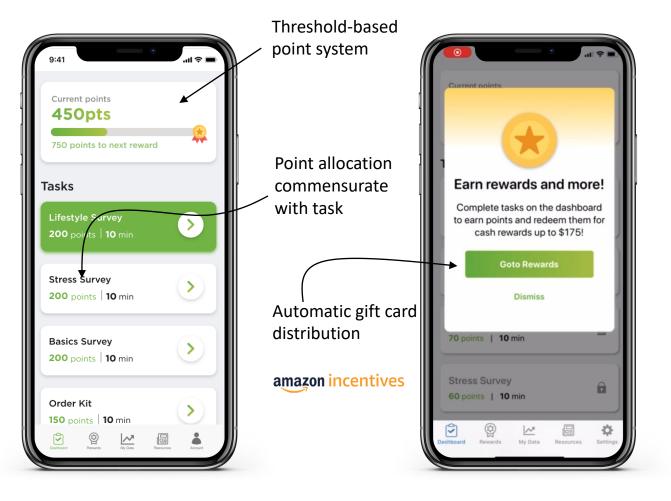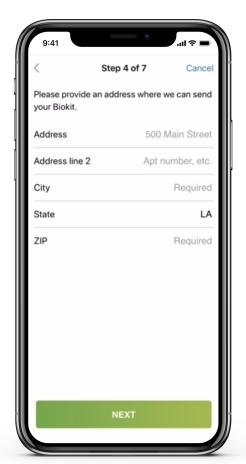
Ability to build participant "tips" and customized reminders to match task sequencing.

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Dynamic incentive system and In-App kit ordering

Threshold-based point system
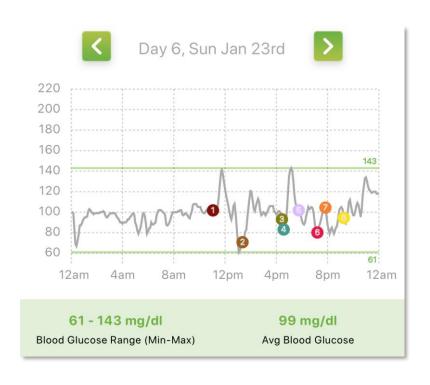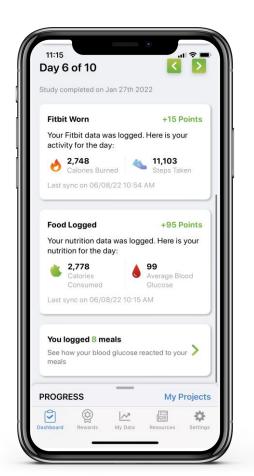
Point allocation commensurate with task

Automatic gift card distribution
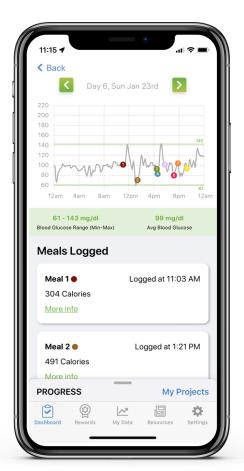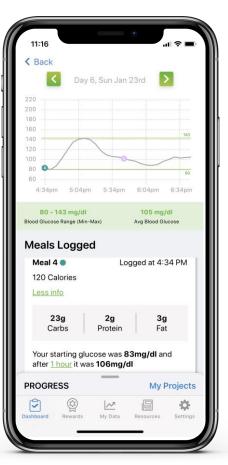
Self-service, study coordinator reporting tools allow for coordination with third-party logistic vendors.

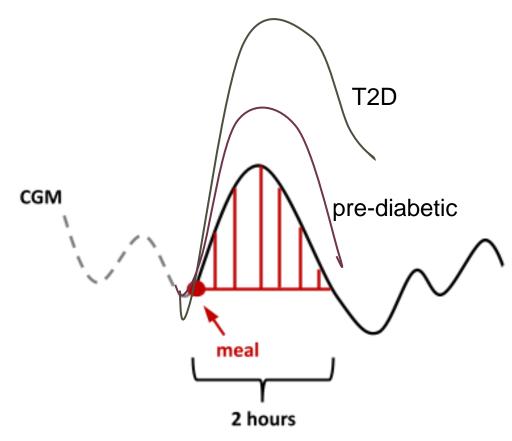Scripps Research
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Personalized visualization populated by data collected from Fitbit, Dexcom G6, and Bitesnap recorded food log entries.

**What factors contribute
to glycemic response?**

Features include:
macronutritional data, sleep, activity,
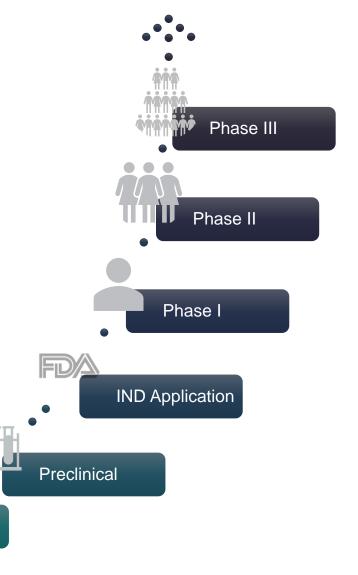blood parameters, CGM data,
microbiome data, genomic data

T2D

pre-diabetic

CGM

meal

2 hours

ML models seek to establish an AUC for prediction of
glycemic spike within a 2-hour postprandial window

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2023

Significant investments in clinical trials

Among top 20 pharma, average cost for developing a new drug was $2.3 billion in 2022.

There is significant incentive to reduce cost and time to market.

Phase III

Phase II

Phase I

IND Application

Preclinical

Discovery

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Source: Deloitte. "Measuring the return from pharmaceutical innovation 2022" (2023)

ROI on DCT

Implementation of digital health technology in clinical trials: the 6R framework

"A reduction in the number of in-person clinic visits can reduce the overall cost of the study."

DAPA-MI trial

43% ↓
25$M saved

"Remote data collection can capture information more frequently than traditional clinic visits"

CRESCENDO trial

15% ↓ **trial duration**

"Digital health solutions in clinical R&D can enable a shift from the traditional physical site-based model…"

All trial assessments

74-85% **collected remotely**

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AstraZeneca

A DCT can be designed to collect multimodal data used for analyses that can inform prediction algorithms.

DCTs can help compare virtual care delivery models to traditional in-person visits.

DCTs can inform the path to hospital-at-home through validating measure and approaches to remote monitoring.

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Acknowledgement of our partners

Scripps Research Digital Trials Center

Care Evolution™

Katie Baca-Motes
Co-founder, Digital Trials Center,
Scripps Research
Chief Strategy Officer, CareEvolution

https://www.linkedin.com/in/katiebaca/