



# Technology Building Blocks of Rapidly Deployed Public Health Projects

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CareEvolution

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Scripps Research

How do we...

- stay ready for action?
- coordinate efforts/resources?
- ensure access to all?
- organize public and private efforts?
- preempt agreements for quicker response?

Proactive policies, paradigm shifts, novel approaches



## ***Clinical Trials Are Moving Out of the Lab and Into People's Homes***

After the pandemic forced thousands of trials to shut down, researchers found clever ways to conduct human studies remotely — while reaching more people, quickly and cheaply.

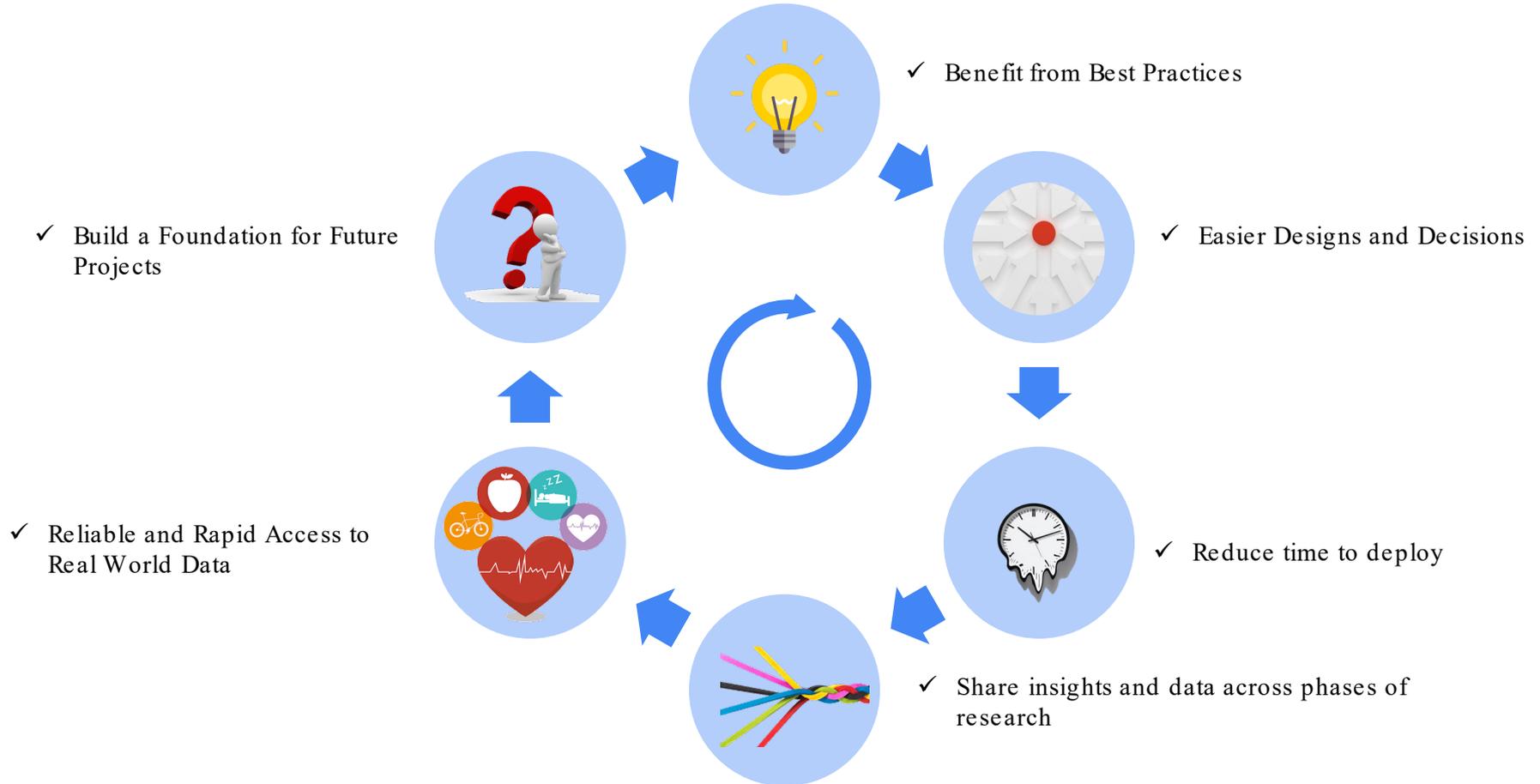
Feb. 18, 2021



**OSTP and NSC seek input on U.S. capacity for emergency clinical trials, research**

Oct. 25, 2022

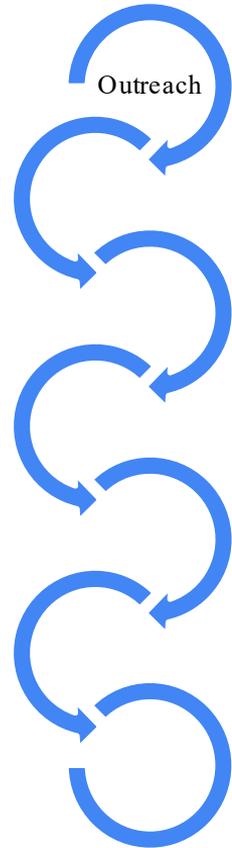
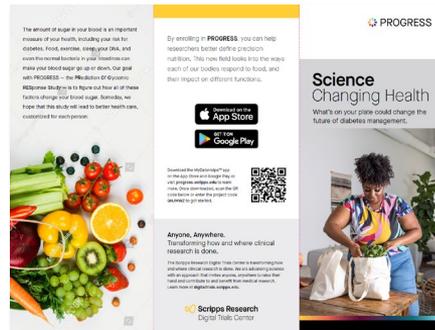
# Advantages of a Reusable Public Health Research Platform



## Participant Outreach:

*Making it easier to connect participants by overcoming geographic and societal boundaries*

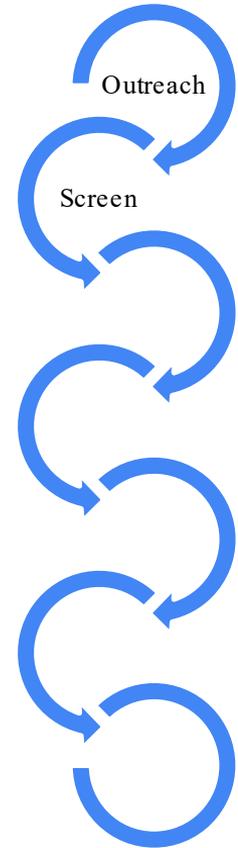
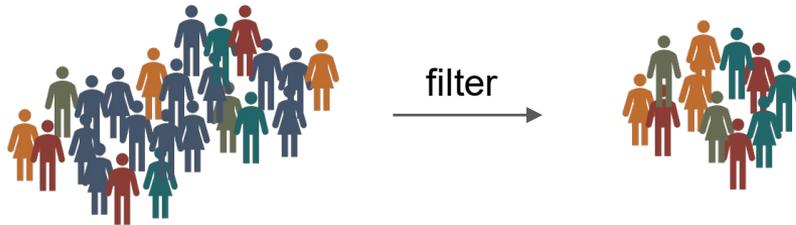
- Social media campaigns
- Clinic/community center outreach with posters and QR Codes
- Culturally appropriate and multilingual
- Tracking outreach to determine best methods by target demographic
- Shareable across phases and projects



## Eligibility Screening:

*Reducing the difficulty to find the best matched participants to control confounders and highlight potentially underserved communities*

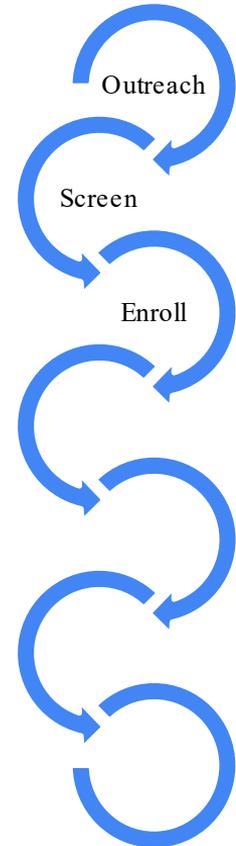
- Mobile and web friendly screening surveys
- Using claims and EHR data to confirm eligibility
- Emphasize high risk or underrepresented cohorts



## Enrollment and Consent:

*Reduce the burden for both coordinators and participants to understand, consent and enroll in a study.*

- Virtual enrollment & consent: improve access and reduce resource needs
- Menu of standard study element templates
- Support “branching logic” to enhance experience
- Methods to educate and confirm participant comprehension



## Data Access and Integration:

*Making it easier to bring “healthcare data” into public health protocols*

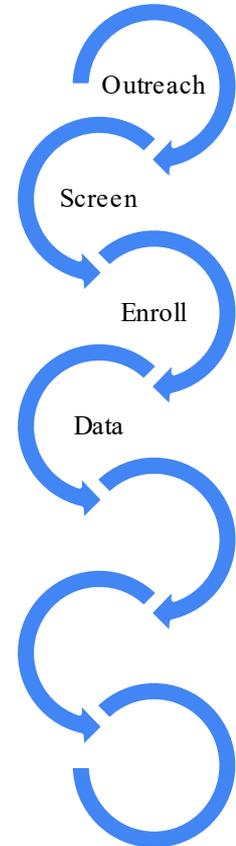
Standardized workflows for retrieving electronic health data

- EHR and claims data
- Wearable data
- Guided by TEFCA principles



Kitting and Fulfillment

- Allow for self-administered collection of other types of data (e.g., saliva for genomics analyses)



## Assessments and Engagement:

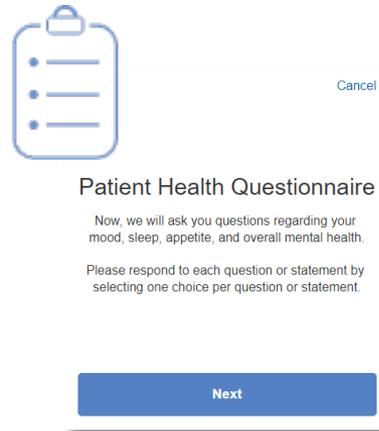
*Getting reliable insights from participants while they go about their daily lives*

### Assessments

- Deploy validated survey instruments such as PHQ9
- Reusable surveys for PROs
- Active tasks
- Ecological Momentary Assessments

### Engagement

- Survey schedules and reminders
- Notifications for new tasks and task dashboard
- Training, education, and resources



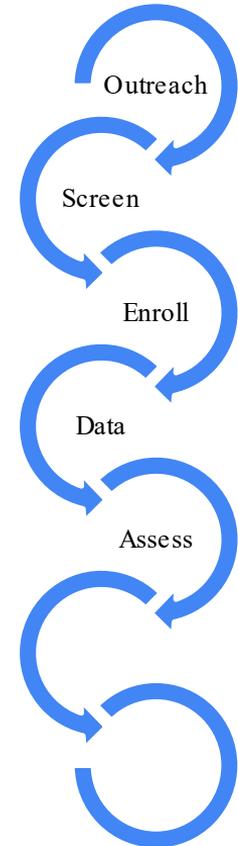
Cancel

**Patient Health Questionnaire**

Now, we will ask you questions regarding your mood, sleep, appetite, and overall mental health.

Please respond to each question or statement by selecting one choice per question or statement.

Next



## Rewards and Feedback:

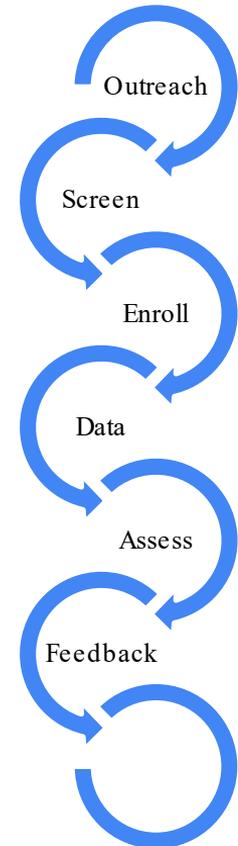
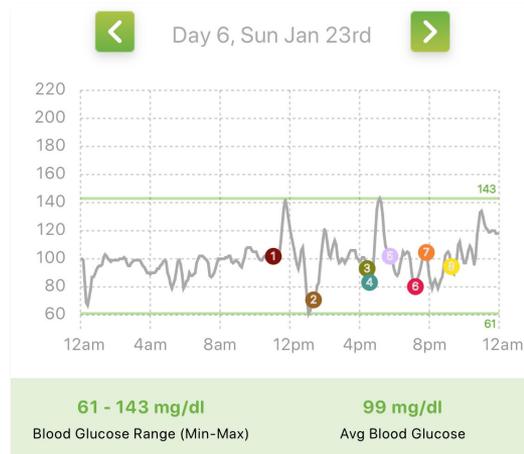
*Motivating participants to follow through and get benefit from participation*

### Rewards

- Pointbased systems
- Gamification
- Automated gift cards

### Feedback

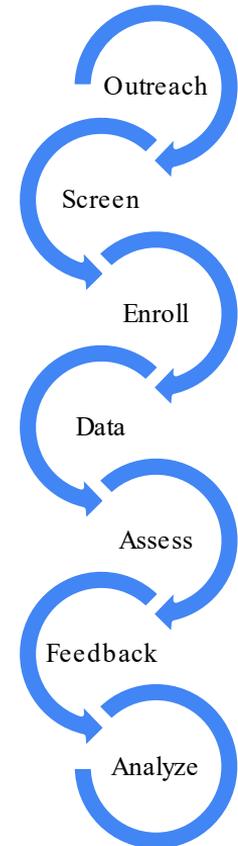
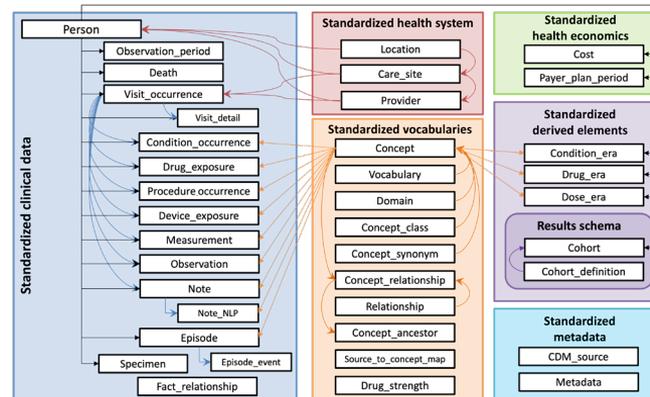
- Visualize the data being collected
- Provide health insights



## Data Preparation for Analysis:

*Make the data analysis phase faster and more reliable with standard data formats and consistent representation of meaning*

- Consistent terminology and structure across every study making it easier to analyze
- Support for common formats such as OMOP
- Integration with RedCap



# An Evolving Research Platform for an Evolving Pandemic

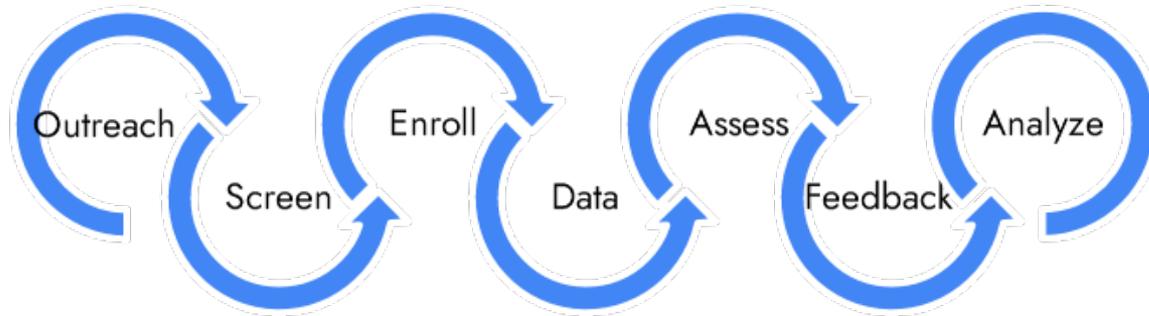


DETECT:  
Wearable  
detection of Ill

TUAH & ITAP:  
Shifting testing  
from lab to home

Test to Stay:  
Testing at home  
to stay in school

Test to Treat: Testing  
to provide therapy to  
those at highest risk



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## COVID-19: the ultimate use case



# DETECT: Early detection of COVID-19 infection

## Wearable sensor data and self-reported symptoms for COVID-19 detection

nature  
medicine

Giorgio Quer<sup>1,2,3,5</sup>, Jennifer M. Radin<sup>1,3</sup>, Matteo Gadaleta<sup>1,3</sup>, Katie Baca-Motes<sup>1</sup>, Lauren Ariniello<sup>1</sup>, Edward Ramos<sup>1,3</sup>, Vik Khetarpal<sup>1,3</sup>, Eric J. Topol<sup>1,3</sup> and Steven R. Steinhilb<sup>1,3</sup>

First paper published in fewer than 7 months from launch

2021-2022

**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. Steinhilb, MD

**ARTICLE OPEN**  
**Passive detection of COVID-19 with wearable sensors and explainable machine learning algorithms**  
 Matteo Gadaleta<sup>1</sup>, Jennifer M. Radin<sup>1</sup>, Katie Baca-Motes<sup>1</sup>, Edward Ramos<sup>1,3</sup>, Vik Khetarpal<sup>1,3</sup>, Eric J. Topol<sup>1,3</sup>, Steven R. Steinhilb<sup>1,3</sup> and Giorgio Quer<sup>1,2,3,5</sup>

Inter-individual variation in objective measure of reactivity following COVID-19 vaccination via smartwatches and fitness bands  
 Giorgio Quer<sup>1,2,3</sup>, Matteo Gadaleta<sup>1</sup>, Jennifer M. Radin<sup>1</sup>, Kristen G. Anderson<sup>1</sup>, Katie Baca-Motes<sup>1</sup>, Edward Ramos<sup>1,3</sup>, Eric J. Topol<sup>1,3</sup> and Steven R. Steinhilb<sup>1,3</sup>

Sensor-based surveillance for digitising real-time COVID-19 tracking in the USA (DETECT): a multivariable, population-based, modelling study  
 Jennifer M. Radin, Giorgio Quer, Eric J. Topol, Matteo Gadaleta, Katie Baca-Motes, Edward Ramos, Vik Khetarpal, Katie Quinovic, Vik Khetarpal and Steven R. Steinhilb, Eric J. Topol

JAMA NETWORK | Open.  
 npj | Digital Medicine  
 THE LANCET Digital Health

Concept to nationwide launch in 4 weeks

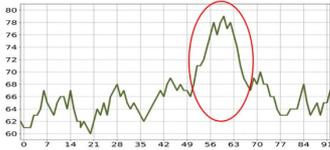
2020

February

March

July

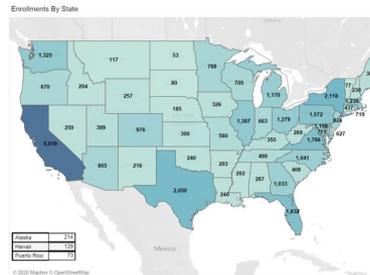
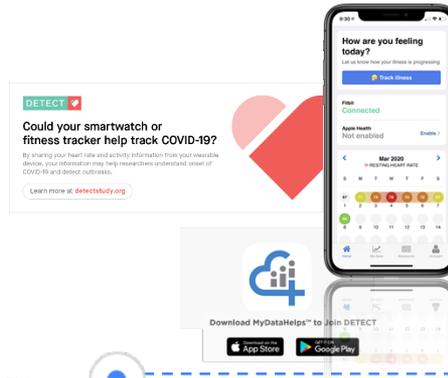
October



Negative binomial model predicting ILI case counts

	$\mu_{low}$	$\mu_{high}$	$\mu_{ratio}$	p value*
Model 1 (lower RHR threshold)				
California	0.92	0.73	0.97	<0.0001
Texas	0.77	0.84	0.92	<0.0001
New York	0.33	0.79	0.84	<0.0001
Illinois	0.72	0.80	0.92	<0.0001
Pennsylvania	0.48	0.78	0.89	<0.0001

Over 35,000 participants enrolled in first 4 months



# Validation of At-home Testing for COVID

## Test us at Home (TUAH) & Independent Testing Assessment Program (ITAP): Validation and FDA EUA

TUAH: 3600 participants over 6wks—launch to preprint 4 mos.

- Email Invitations/ QR Code Enrollment
- Eligibility Verification/ Screening Surveys
- Serial at-home testing + data collection

ITAP: Expanded to 47 states on the same mobile platform

- From protocol approval to launch in 2 wks
- Kitting and fulfilment of tests for OTC investigational, OTC Standard of Care and PCR Test sent to Lab
- Quick expansion to support FDA EUA

### FDA announces recommendations based on new study highlighting serial testing with rapid antigen tests

UMass Chan-led research forms basis for recommendation

By Susan E.W. Spencer  
UMass Chan Medical School Communications

August 11, 2022



Findings from a new study led by UMass Chan Medical School researchers are the basis for a [safety communication issued by the U.S. Food and Drug Administration \(FDA\)](#) Aug. 11 regarding serial use of at-home antigen tests for COVID-19.

# Expansion of At-home Testing for COVID

## Say Yes! COVID Test (SYCT): Expansion to State Level Initiatives for Mass Testing

15 million test distributed across 5 states with support for 38 languages

Demonstrated the ability to *raise and scale outreach procurement fulfillment instruction and reporting* across three different state programs



### Procurement

- 1a. State PO with OEM and OEM shipment to Amazon
- 1b. State inventory shipped to Amazon



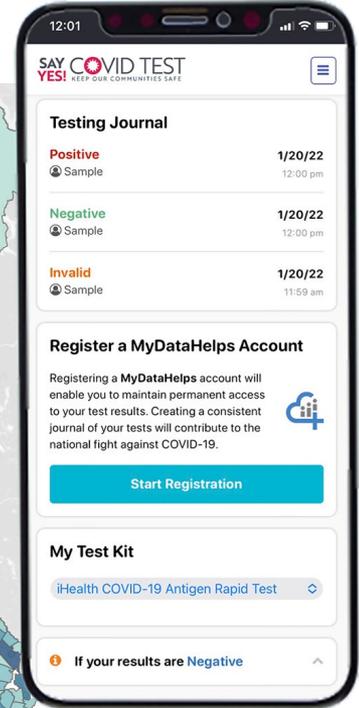
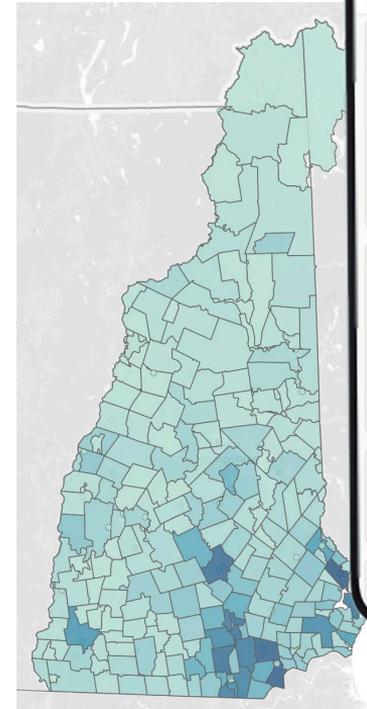
### Fulfillment

2. Order placed via SYCT
3. Fulfilled by Amazon



### Reporting

- 4a. Daily aggregate ordering reports
- 4b. Weekly orders by zip code reports



# Changing Behaviors Based on COVID-19 Testing

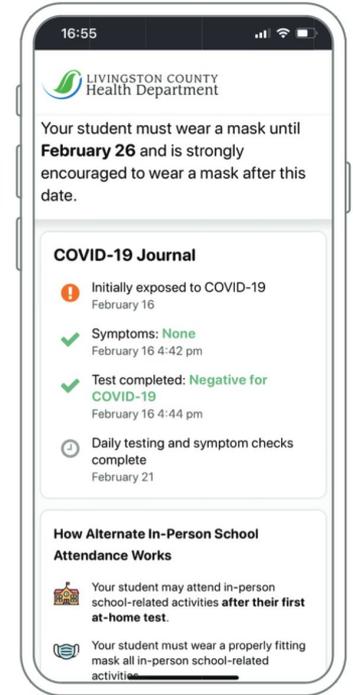
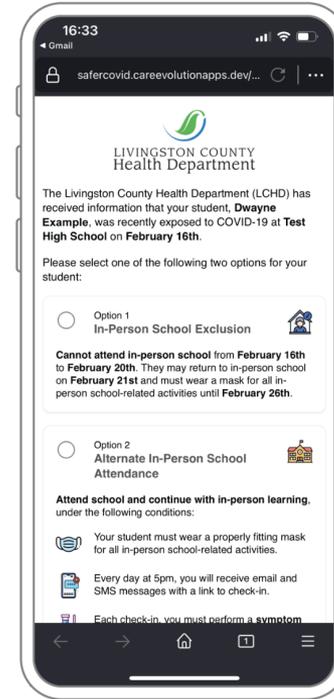
Digitally Enabled Test-to-Stay: Supporting in School Learning during the Pandemic



Reliable testing and symptom screening enabled in-person school attendance resulting in 3,653 days of instruction saved.

Experience and reusable components enabled:

- Guardian consent management
- Kit distribution to students' homes
- Symptom screening
- Instructions to assist with reliable at-home testing
- Reporting individual antigen test results via summary dashboards.



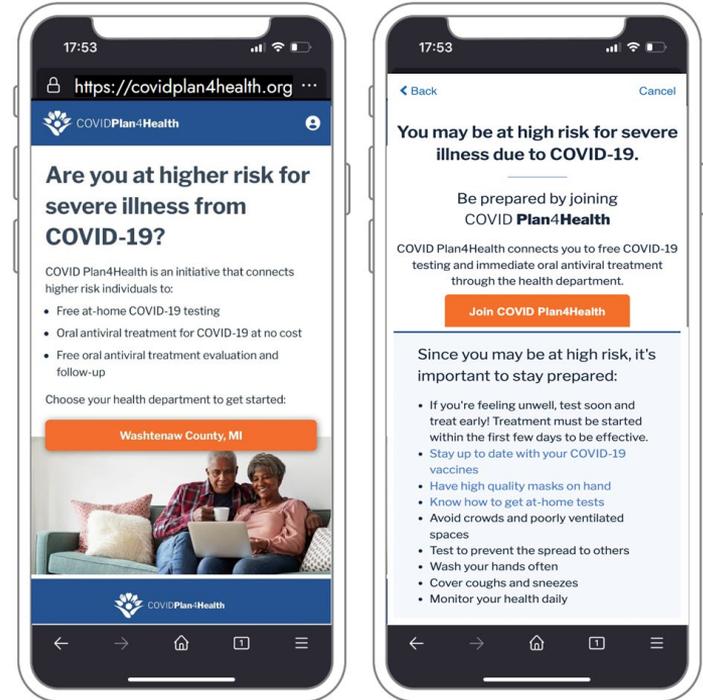
# Providing Therapy for At-risk Individuals

COVID Plan4Health: Test-Treat Broadening equitable access to Paxlovid for higher risk individuals

Provides Test Kits, evaluation and therapy for high risk individuals

Platform enables:

- Broad population outreach
- Kitting and fulfilment direct-to-home to test kits
- Follow up for positive results and eligibility for Paxlovid
- Individual management between health department and eligible positive individuals to obtain treatment and follow up



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# Applying the Platform Beyond COVID-19



## **Scripps Research** Digital Trials Center



Ed Ramos



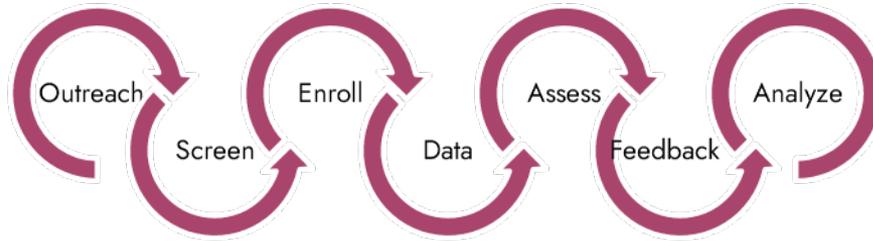
Katie Baca-Motes

**Co-founders**





# PowerMom



Among developed countries, U.S. is ranked **1<sup>st</sup> in maternal mortality**

**↑ 200%**

Cases of severe maternal morbidity (SMM) have dramatically increased in the last 20 years



17.2 deaths per 100,000 live births



Only developed country to not guarantee access for home visits

**Pregnant women of color at highest risk**

**3.4 X**

Black women more likely to die giving birth compared to white women in the U.S.

**↑ 19%**

Since 2018, Hispanic women seeing the highest increase in SMM rates



Black and Hispanic women are more likely to have risk factors for SMM

**Lack of research and knowledge gaps**



Pregnant woman excluded from medical research



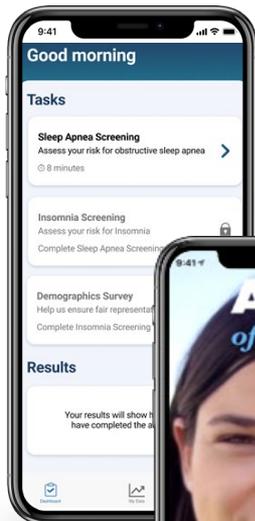
Disparities in representation



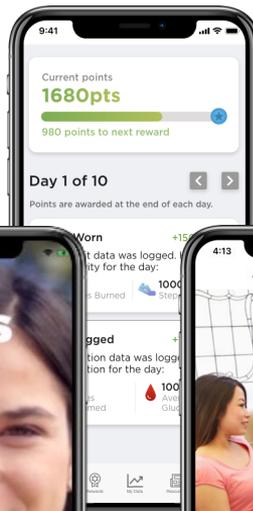
Variations in care creates adverse outcomes and higher costs

# Research Efforts to Solve Today's Pressing Challenges

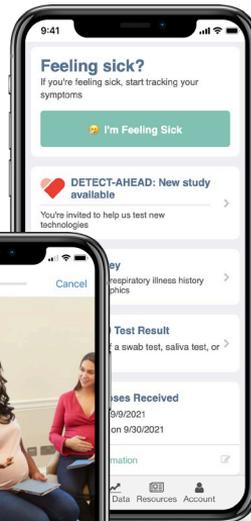
REFRESH



PROGRESS



DETECT



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Thank you!

