Innovations for Tackling Tuberculosis in the Time of COVID-19 Virtual Workshop, September 14-16, 2021

Rapid Acceleration of Diagnostics Technology *(RADx Tech)*

Matthew McMahon, Ph.D.
Director, SEED Office, NIH

National Institutes of Health
Office of Extramural Research

RADx Tech Leads: Jill Heemskerk, Tiffani Lash, Todd Merchak, Mike Wolfson, Doug Sheeley, Rachael Fleurance, David George, Gene Civillico, Bill Heetderks, Charles Anamelechi, Matt McMahon, Felicia Qashu, Tony Kirilusha, Mark Snyder, Andrew Weitz, Krishna Juluru, Ilana Goldberg, Taylor Gilliland, Kate Egan, Ray MacDougall, Patty Wiley, Jennifer Jackson

RADx: *Unexpected Opportunity*

April 24, 2020: $1.5B to NIH
$500 Million to NIBIB

NIH Office of the Director

Francis Collins   Rachael Fleurance   Larry Tabak   Tara Schwetz

1) **Expand COVID-19 Testing Technologies:** *Number, Type and Access*

2) **Optimize Performance:** *Technology Matched to Community Needs*

April 29

RADx Tech – $500M
Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19

RADx Advanced Technology Platforms (RADx-ATP) – $230M
Rapid scale-up of advanced technologies to increase rapidity and enhance and validate throughput – create ultra-high throughput machines and facilities

Bruce Tromberg   Jill Heemskerk

NIH National Institute of Biomedical Imaging and Bioengineering
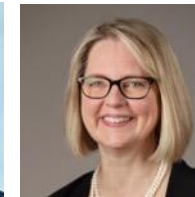
RADx Radical (RADx-Rad) – $200M
Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing

RADx Underserved Populations (RADx-UP) – $500M
Interlinked community-based demonstration projects focused on implementation strategies to enable and enhance testing of COVID-19 in vulnerable populations

$307 M Partnership

BARDA   OASH   FDA   DEPARTMENT OF DEFENSE   THE WHITE HOUSE   CDC

>12 NIH Institutes, Centers, and Offices

https://www.nih.gov/research-training/medical-research-initiatives/radx

RADx: *Leverage Existing Network (POCTRN)*

Point-of-Care Technologies Research Network

Established 2007, Expanded 2020: >900 RADx experts & contributors
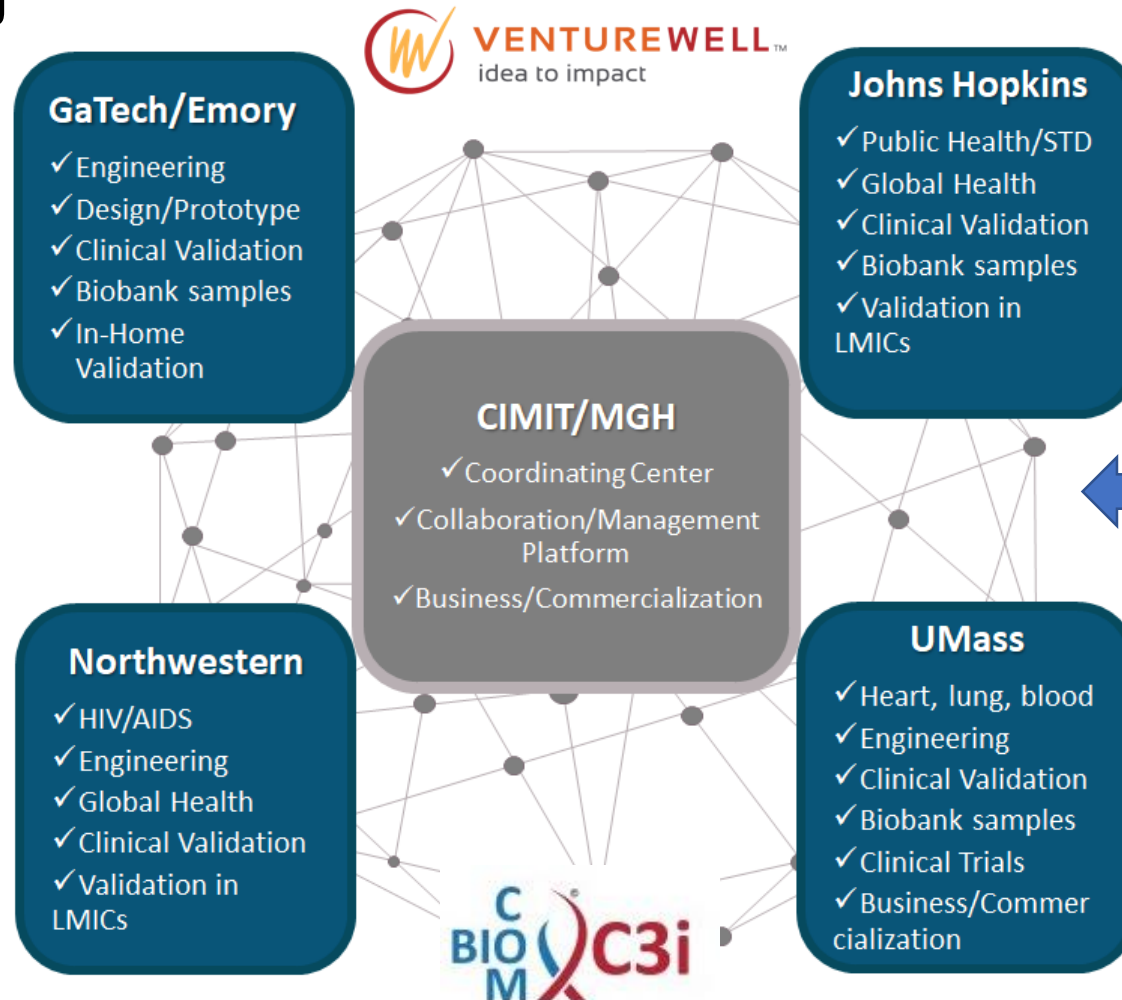
(Government, Academia, Industry)

www.poctrn.org

Todd Merchak   Tiffany Lash

Operations:

- Review & Fund
- Test & Validate
- Expert Guidance

VENTUREWELL™
idea to impact

GaTech/Emory
- ✓ Engineering
- ✓ Design/Prototype
- ✓ Clinical Validation
- ✓ Biobank samples
- ✓ In-Home Validation

Johns Hopkins
- ✓ Public Health/STD
- ✓ Global Health
- ✓ Clinical Validation
- ✓ Biobank samples
- ✓ Validation in LMICs

CIMIT/MGH
- ✓ Coordinating Center
- ✓ Collaboration/Management Platform
- ✓ Business/Commercialization

Northwestern
- ✓ HIV/AIDS
- ✓ Engineering
- ✓ Global Health
- ✓ Clinical Validation
- ✓ Validation in LMICs

UMass
- ✓ Heart, lung, blood
- ✓ Engineering
- ✓ Clinical Validation
- ✓ Biobank samples
- ✓ Clinical Trials
- ✓ Business/Commercialization

CBIOMX C3i

Validation Core

>60 projects complete

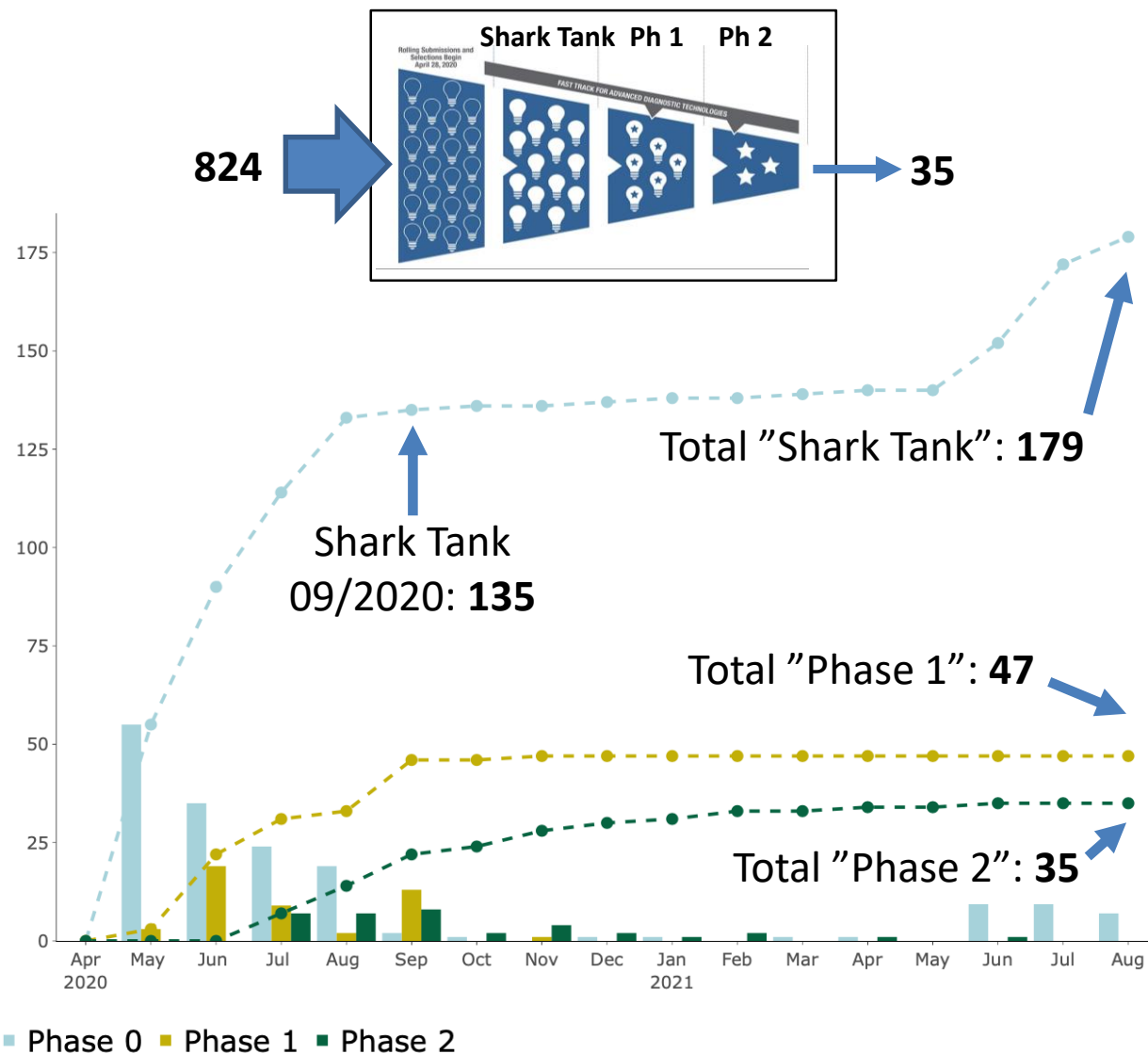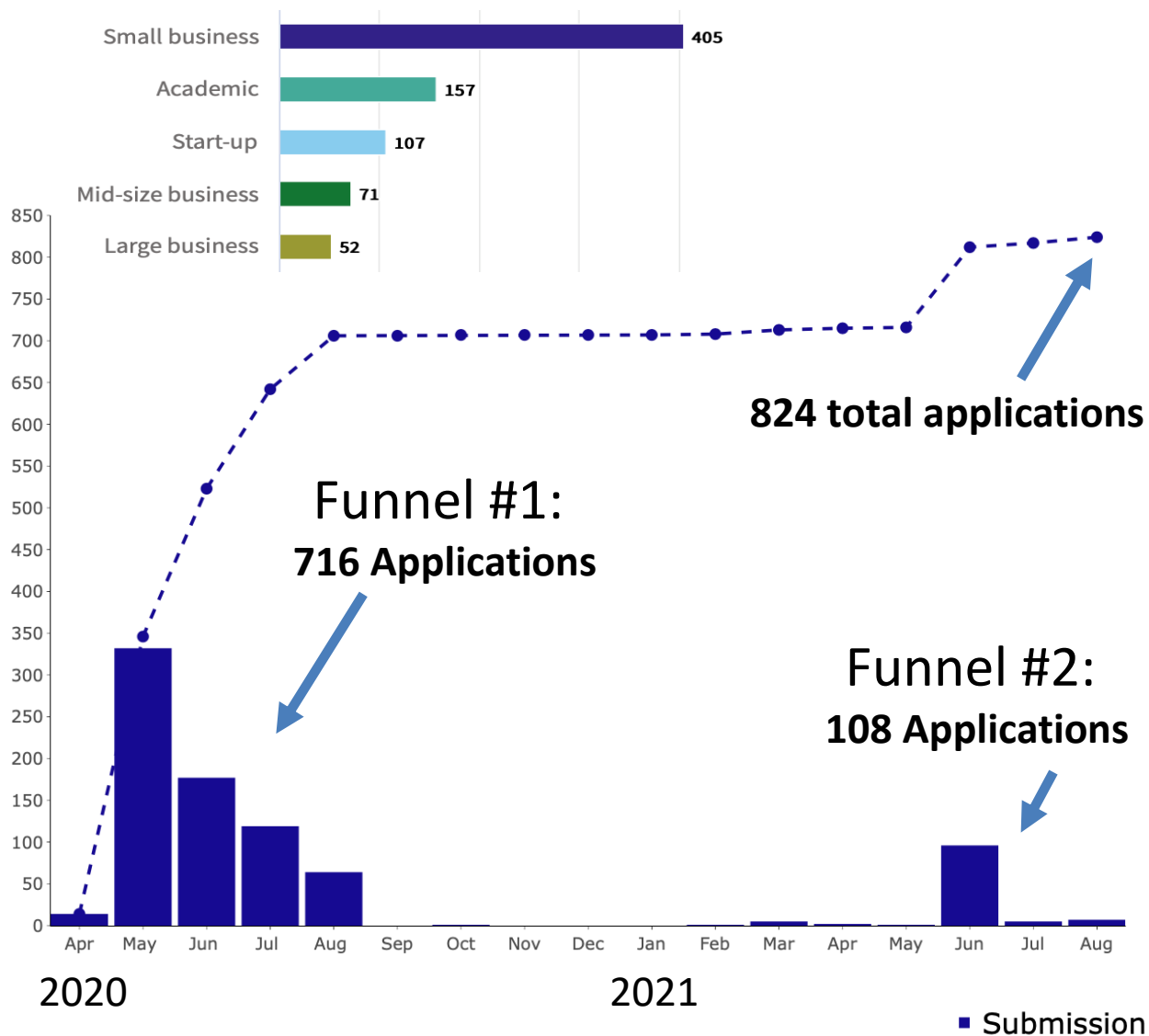>2500 participants

Clinical Studies Core

Trial Design, Digital Health Platform, Single IRB

Deployment Core

Supply chain, Manufacturing, User Community
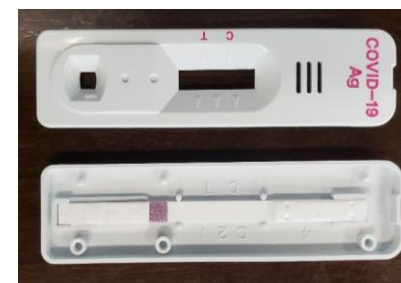
RADx: *Tech Innovation Funnel*

Small business **405**
Academic **157**
Start-up **107**
Mid-size business **71**
Large business **52**

824 total applications

Funnel #1:
716 Applications

Funnel #2:
108 Applications

2020 — 2021

824 → Shark Tank → Ph 1 → Ph 2 → **35**

Total "Shark Tank": 179

Shark Tank 09/2020: 135

Total "Phase 1": 47

Total "Phase 2": 35

Legend: ■ Submission ■ Phase 0 ■ Phase 1 ■ Phase 2

Mesa BioTech

Quidel QuickVue

Meridian

Quanterix Simoa

Quidel Sophia

Visby Medical

Ellume

Genbody

Fluidigm

Luminostics

ANP
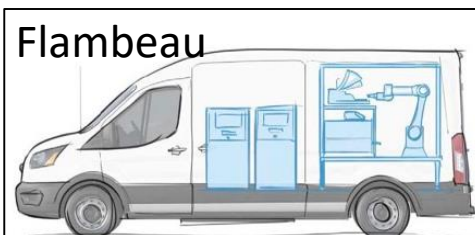
Flambeau
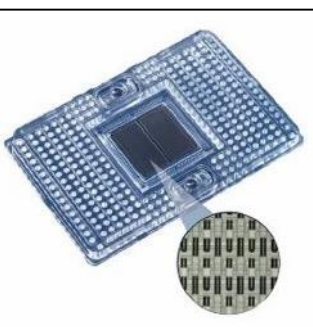
Point of Care & Home	
Visby	RTPCR
Mesa	RTPCR
MicroGem	RTPCR
Talis	ISO-PCR
Ubiquitome	RTPCR
Meridian	RTPCR
GenBody	An-LFA
Quidel Sophia	An-LFA
Quidel QuickView	An-LFA
Luminostics	An-LFA
ANP	An-LFA
Ellume	An-LFA
Xtrava	An-LFA
Qorvo	An-BAW
Mologic	An-LFA
Maxim	An-LFA
Salignostics	An-LFA
BD Veritor	An-LFA

Home Rx & OTC

Home OTC

Home OTC

Laboratory	
Flambeau (+Saliva Direct)	PCR-mobile-lab
MatMaCorp	RTPCR-mini-lab
Fluidigm	RTPCR
Quanterix	SIMOA (An)
Minute Molecular	RTPCR
PathogenDx	RTPCR
Broad Inst	RTPCR
Illumina	NGS
Helix	NGS/RTPCR
Gingko	NGS/RTPCR
Sonic Healthcare	RTPCR
PathGroup	RTPCR
Aegis	RTPCR
Octant	NGS/RTPCR

Tech

Labs

Lab Products	
Mammoth Biosci	CRISPR
Ceres Nanosciences	Beads/Conc
Oasis	Saliva Collect
Yukon	Swabs

RADx Impact thru July 2021

Cumulative Emergency Use Authorized Tests
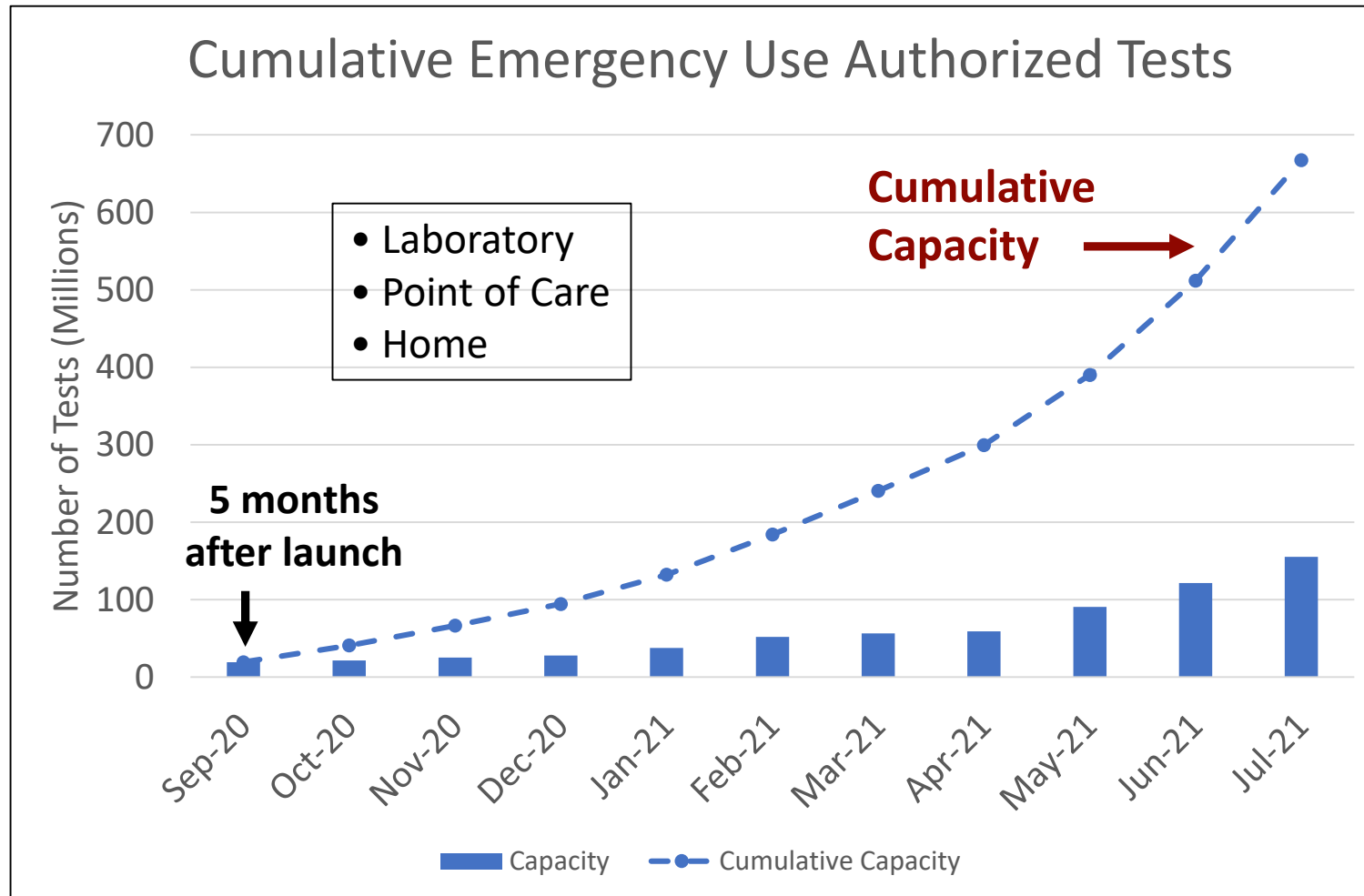
Major Milestones

- **667 million capacity thru July 2021**

- ~5 M tests per day **July 2021**

- 28 EUAs; 1st OTC EUA, 3 "at home" tests

- >100 companies supported

~$1.1 Billion: *Special Congress Authorization* (~$600M in Phase 2)

~1.3 Billion: *Private Capital Raised*

https://www.nibib.nih.gov/covid-19/radx-tech-program/radx-tech-dashboard

2 million free, at-home tests

Pitt County, NC
Hamilton County, TN
Washtenaw County, MI

Up to 4 additional sites approved   *(Hawaii, Georgia)*
Supported by WH Pandemic Testing Board

Assess *efficacy* and *effectiveness* of at-home testing 2-3 times per week

Outcome measures:

- SARS-CoV-2 prevalence and incidence
- % test positivity, volume
- Community cell phone mobility
- Wastewater surveillance

Optional digital assistant used for:

- Reminders and instructions
- Interpretation & guidance when positive
- Reporting results to the state (MI, TN)

sayyescovidtest.org

QUIDEL QuickVue· SARS Antigen TEST

SAY YES!
COVID TEST
JOIN THE FREE AT-HOME TESTING CHALLENGE

RADx UP

Duke Clinical Research Institute   UNC SCHOOL OF MEDICINE | Center for Health Equity Research
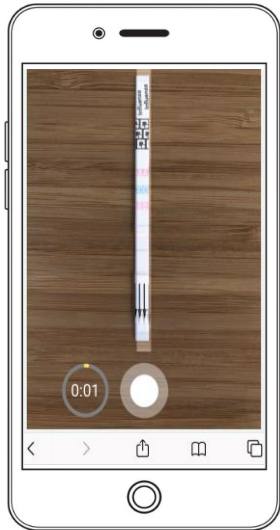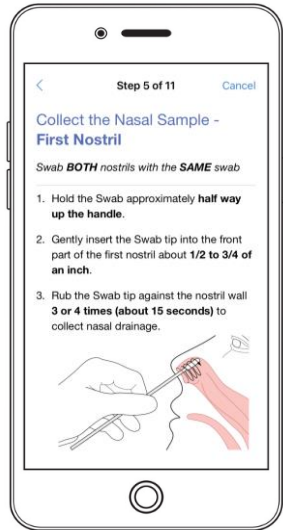
NIH National Institutes of Health
Turning Discovery Into Health

CDC Centers for Disease Control and Prevention
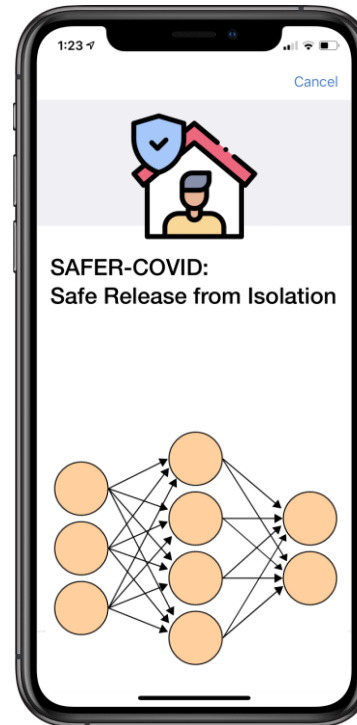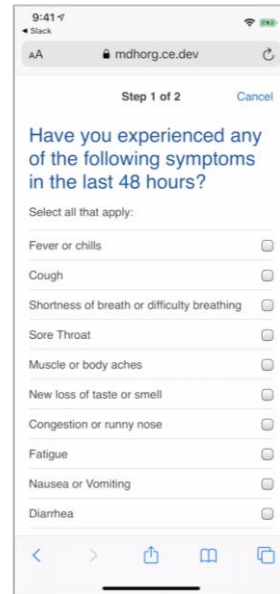
Ongoing Challenges

1) Reporting infrastructure

POLITICO
Inside America's Covid-reporting breakdown

State officials detail a vast failure to identify hotspots quickly enough to prevent outbreaks

2) Insufficient screening, surveillance

Months into the pandemic, the U.S. had six times as many cases as reported, an N.I.H. study finds.

New York Times, June 24, 2021

Nearly 17M Americans May Have Went Undiagnosed With COVID Last Year: Why These Cases Matter

International Business Times, June 24, 2021

Future: *Leverage RADx process and networks for other pathogens, preparedness*

- **Real-time data:** Modernize/expand digital health/reporting *(lab, POC, OTC)*
- **Better, accessible fast tests:** Direct to public: internet disruption to distribute & report *(OTC, POC)*
- **Multiplex tests:** COVID, flu A/B, RSV, etc. for differential Dx *(POC, lab)*
- **Fast, accurate, cost-effective surveillance:** Genotyping w/Informatics *(lab, POC)*