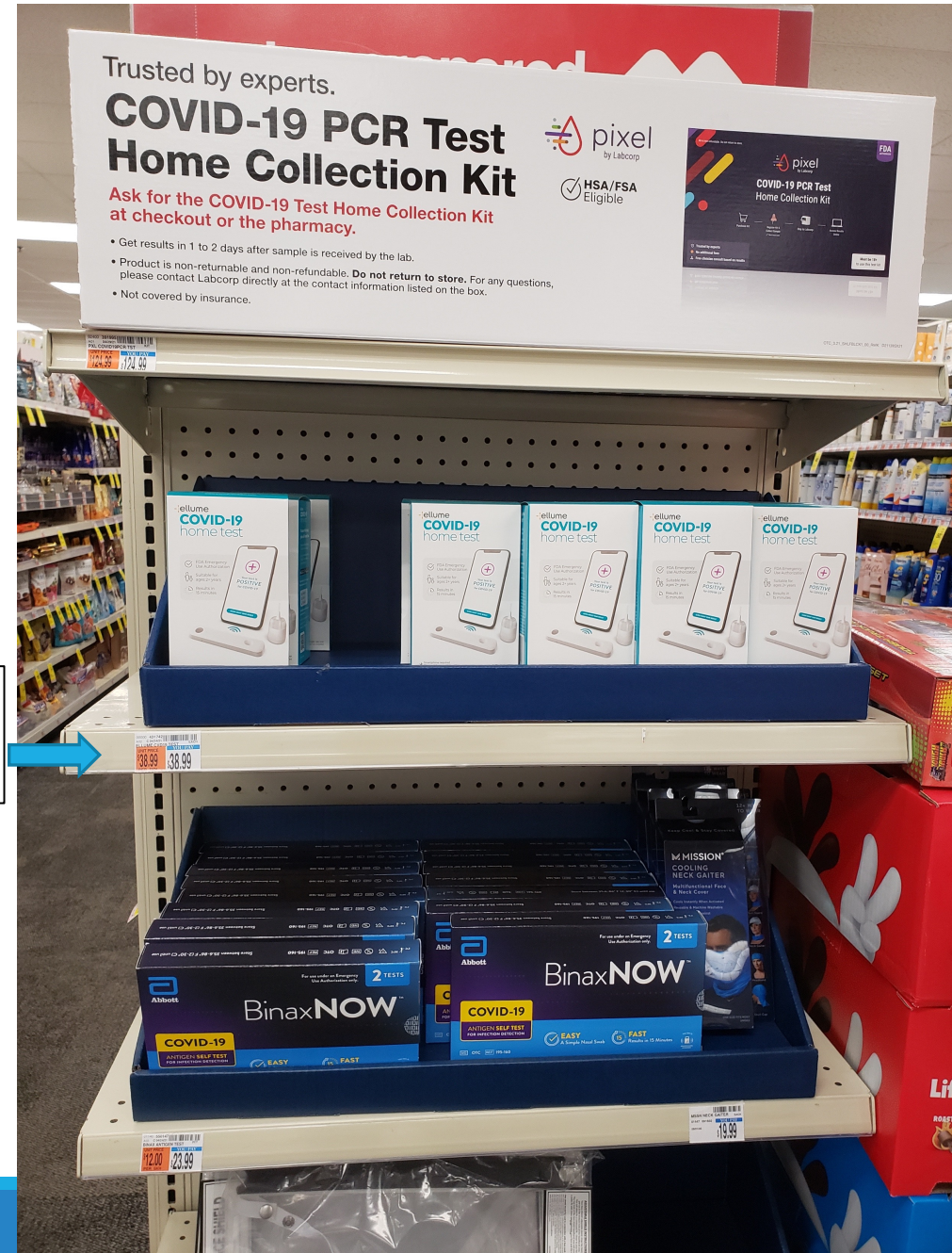
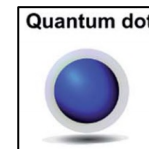


# Bioengineering for COVID-19

Bruce J. Tromberg, Ph.D.

Director, National Institute of Biomedical Imaging  
& Bioengineering (NIBIB)



# Bioengineering for COVID-19

## NIBIB Strategy



- 1) Imaging and AI
- 2) Digital Health Platforms
- 3) Diagnostic Test Technologies

# Medical Imaging and Data Resource Center (MIDRC)



Kris Kandarpa  
*Chair*



Guoying Liu  
*Scientific Program Lead*



Behrouz Shabestari  
*NIBIB National Technology Center Program Director*



Maryellen Giger (PI)  
*AAPM, University of Chicago*

<https://www.nibib.nih.gov/news-events/newsroom/nih-harnesses-ai-covid-19-diagnosis-treatment-and-monitoring>



Two-year, \$20M contract: Medical Imaging/Data Science

Thoracic imaging and clinical data repository for COVID 19

Develop, validate ML/AI for detection, diagnosis, Tx

60,000 curated COVID-19 chest radiographs and CTs+clinical data





# MIDRC

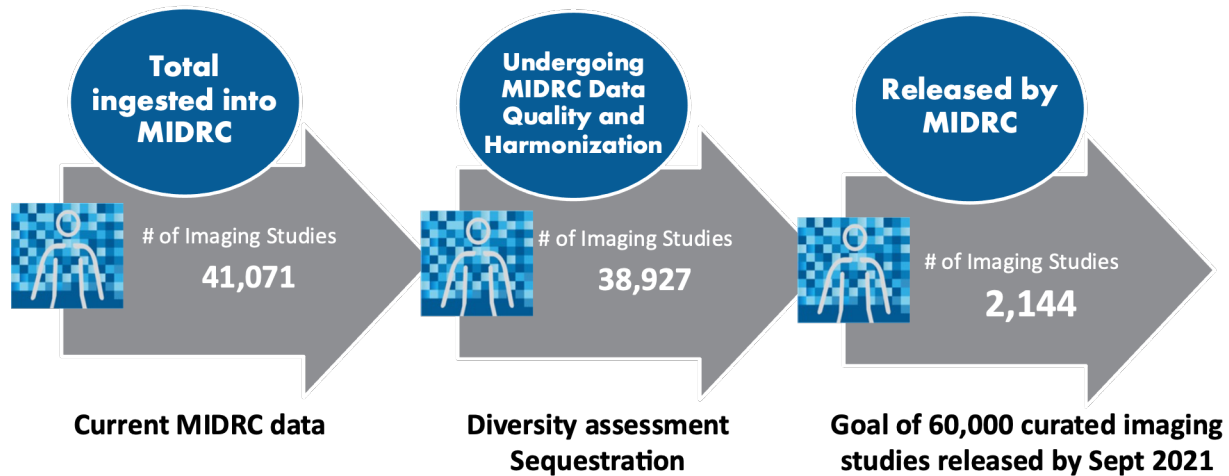
MEDICAL IMAGING AND DATA RESOURCE CENTER.



## Infrastructure

- 5 Technology Development Projects

### Data ingestion, data quality and harmonization



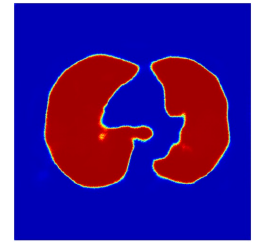
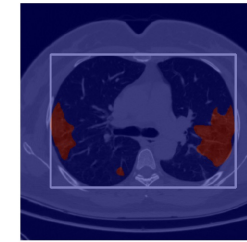
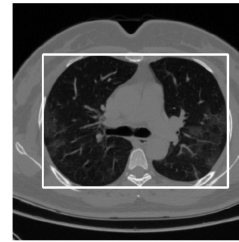
## Operational

## In parallel, AI/ML development

(12 Collaborative Research Projects)

24 algorithms developed /under development.

- Segmentation of lung and lung opacities



- Prediction of Covid-19 severity and length of hospital stay from multi-modal data (EHR and Imaging)

### 1 algorithm undergoing validation

- Comparing AI determination of Covid-19 severity from chest CT data to steroid use during hospitalization (data from Wuhan)

# RADx: Unexpected Opportunity

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

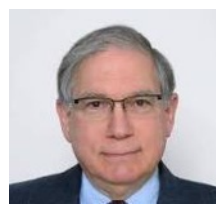
## NIH Office of the Director



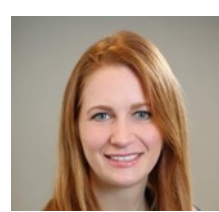
Francis Collins



Rachael Fleurance



Larry Tabak



Tara Schwetz

April 29

- 1) Expand COVID-19 Testing Technologies: *Number, Type and Access*
- 2) Optimize Performance: *Technologic and Operational; Match Community Needs*

### 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*



Jill Heemskerk



Bruce Tromberg

## National Institute of Biomedical Imaging and Bioengineering (NIBIB)

### 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*

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



\$307 M Partnership



# Point-of-Care Technologies Research Network (POCTRN)

## NIBIB National Network: NHLBI, NIAID, NCCIH, FIC, OBSSR, OAR, ODP

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

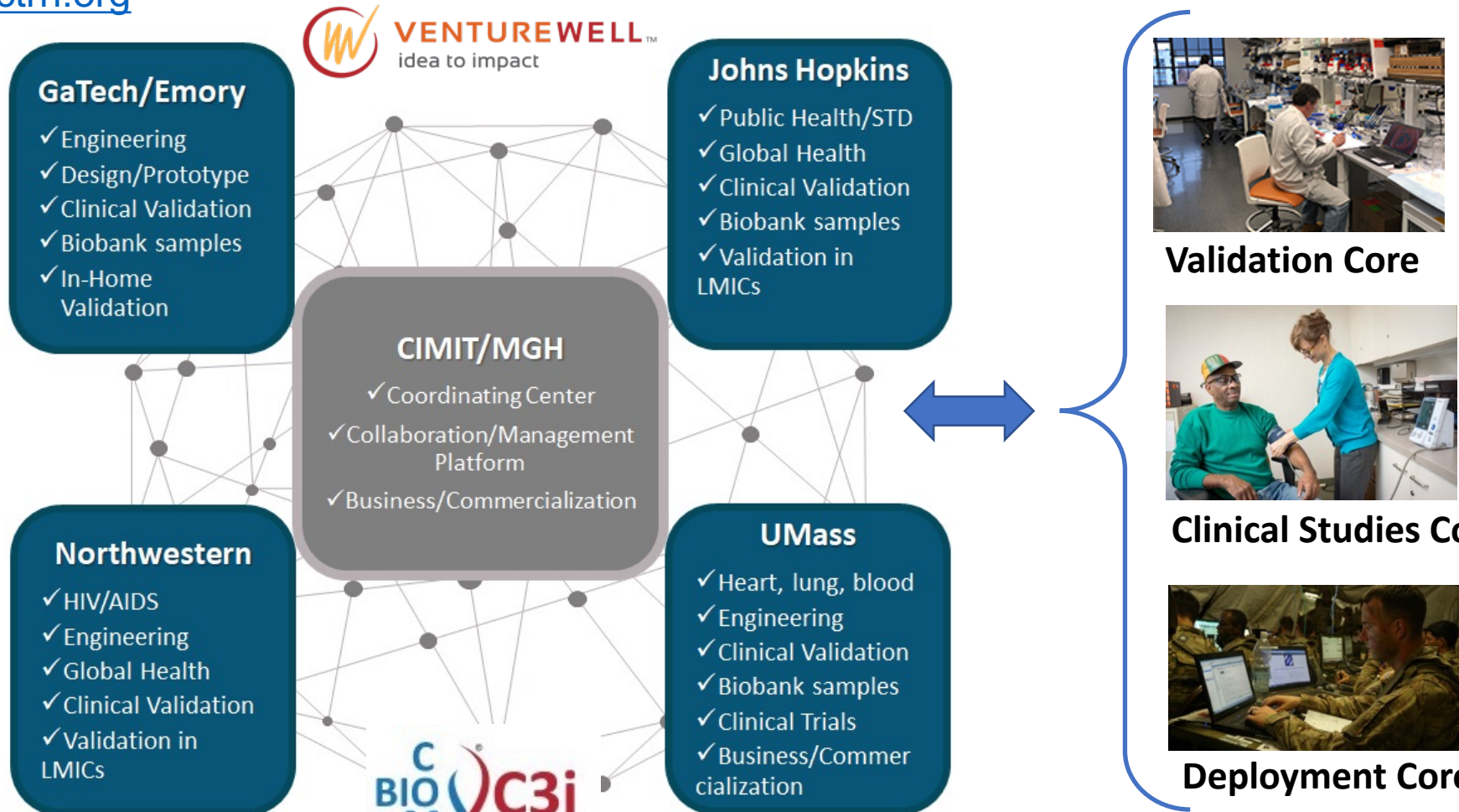


Todd Merchak Tiffany Lash

<https://www.poctrn.org>

### Operations:

- Review & Fund
- Test & Validate
- Expert Guidance



# RADx Tech Innovation Funnel

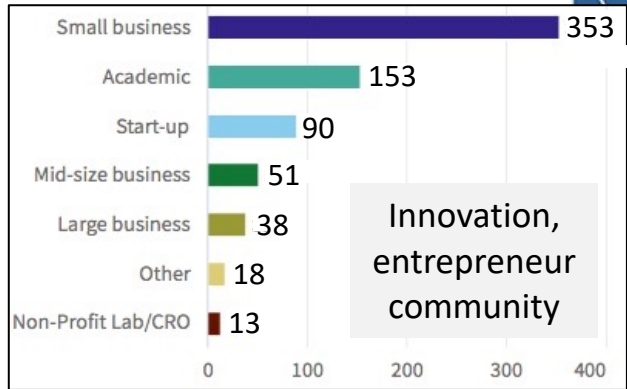


**~3000**  
Applications  
Started

Rolling submission  
open April 29

5-6 Months

*FAST TRACK FOR ADVANCED DIAGNOSTIC TECHNOLOGIES*

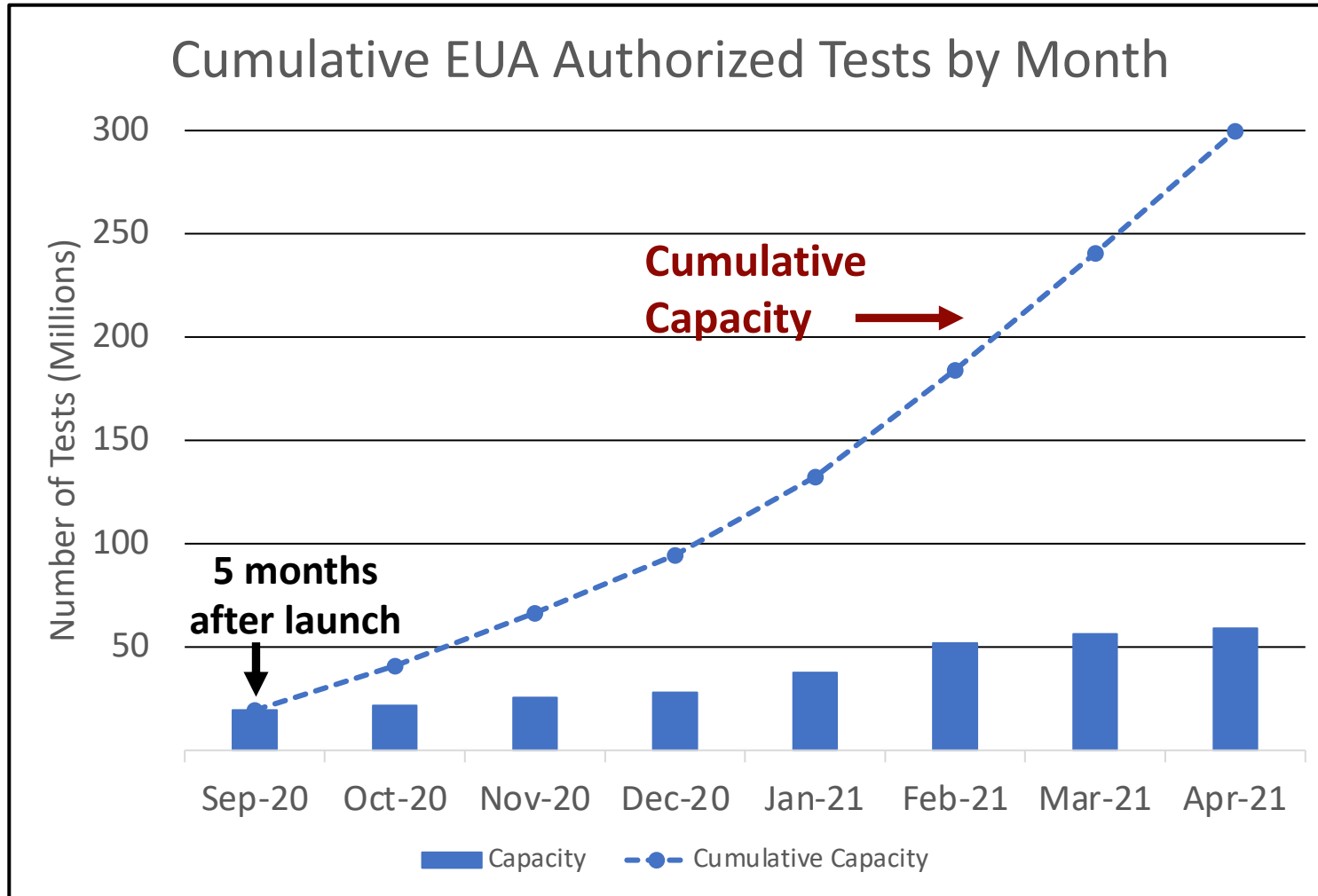


Validation, Clinical Testing,  
Regulatory, Manufacturing,  
Distribution

~\$590M

Projects in  
each Phase

# RADx Impact thru April 2021



## Major Milestones

- **~300 million capacity thru April 2021**
- **~2 M tests and products/day April 2021**
- 23 EUAs; 1st OTC EUA, 2 “at home”
- >100 companies supported

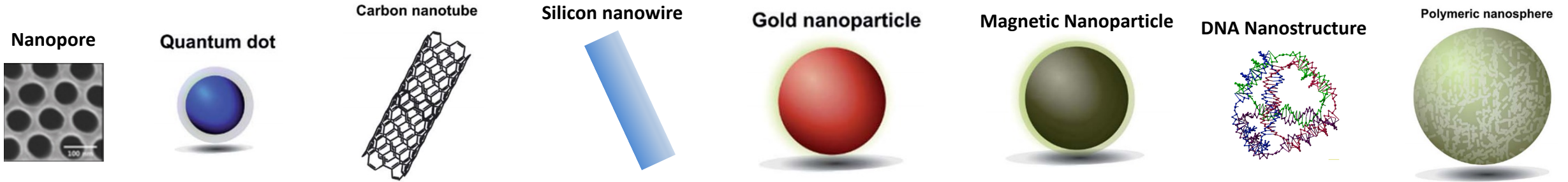
### With FDA studies for:

- Sequential use screening guidance An tests
- Pooling use guidance for POC PCR
- Pediatric use guidance for self swabbing

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

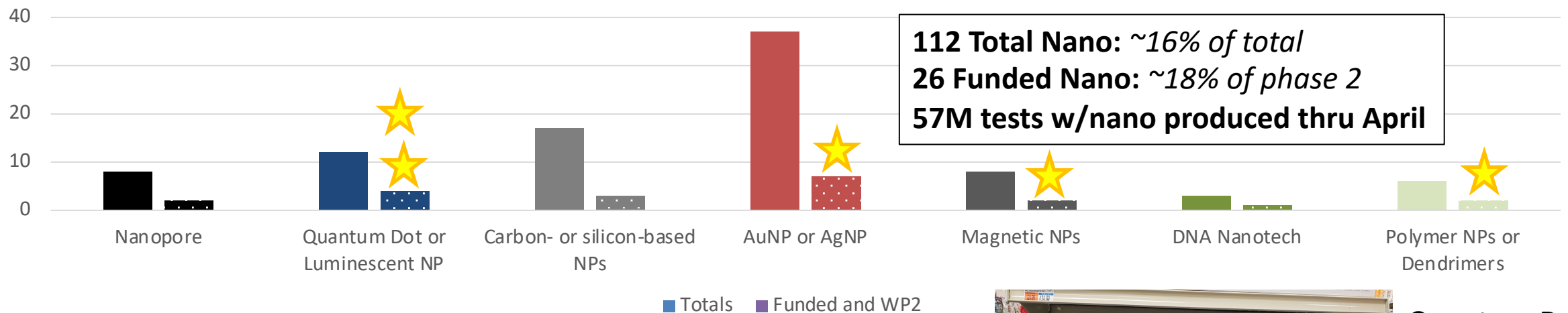


# Nano applications to RADx-Tech



Images from Chudasama et al., *Chemical Science* 2016, Lim et al., *Nanoscale* 2015, Wikipedia

## RADx-Tech Applications and Funded Proposals



**112 Total Nano: ~16% of total**  
**26 Funded Nano: ~18% of phase 2**  
**57M tests w/nano produced thru April**

■ Totals ■ Funded and WP2

WP2 = ★



Quantum Dots on the shelves at CVS



Mesa BioTech

Quidel QuickVue



Xtrava Health



Quidel Sophia

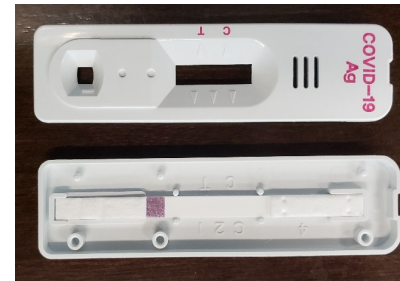
Meridian



Ellume



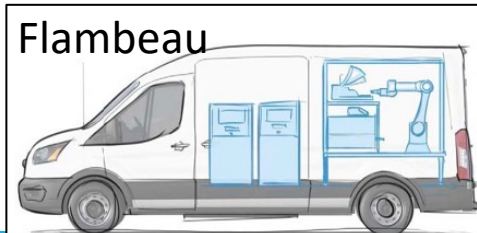
Genbody



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	Home Rx & OTC	An-LFA
ANP		An-LFA
Ellume	←	An-LFA
Xtrava	Home OTC	An-LFA
Qorvo		An-BAW
Mologic		An-LFA
Maxim		An-LFA

**Laboratory**

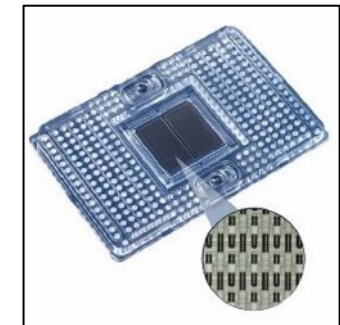
Flambeau	PCR-mobile-lab
MatMaCorp	RTPCR-mini-lab
Fluidigm	RTPCR
Broad Inst	RTPCR
Illumina	NGS
Helix	NGS/RTPCR
Ginko	NGS/RTPCR
Sonic Healthcare	RTPCR
PathGroup	RTPCR
PathogenDx	RTPCR
Aegis	RTPCR
Quanterix	SIMOA (An)
Minute Molecular	RTPCR

**Lab Products**

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



Visby Medical



Fluidigm



Luminostics

Assess the effectiveness of at-home testing 3 times a week in reducing community transmission over 4 weeks

**2 million free home tests**  
*Greenville, NC; Chattanooga, TN*

Outcome measures:

- SARS-CoV-2 prevalence and incidence
- % test positivity
- Cell phone mobility
- Wastewater surveillance

Optional app used for:

- Ordering tests (partnership with Amazon)
- Reminders and instructions
- Interpretation & guidance when positive
- Reporting results to the state (TN only)



<https://www.nih.gov/news-events/news-releases/cdc-nih-bring-covid-19-self-testing-residents-two-locales>



**SAY YES!**  
**COVID TEST**

JOIN THE FREE AT-HOME TESTING CHALLENGE



RADx UP

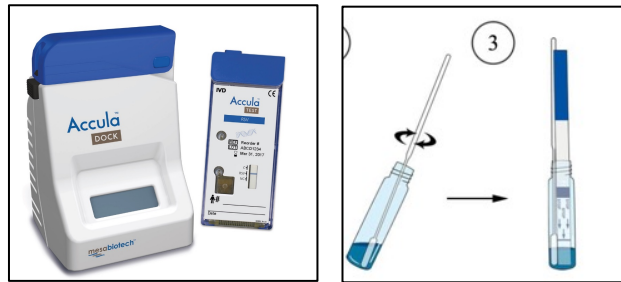


# New Infrastructure: *Personal and Public Health*



Andrew Weitz Krishna Juluru

## RADx POC Test



PCR

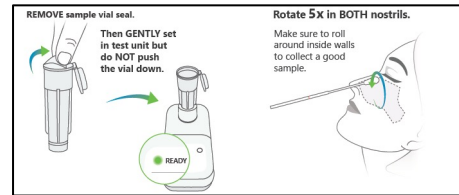
LFA



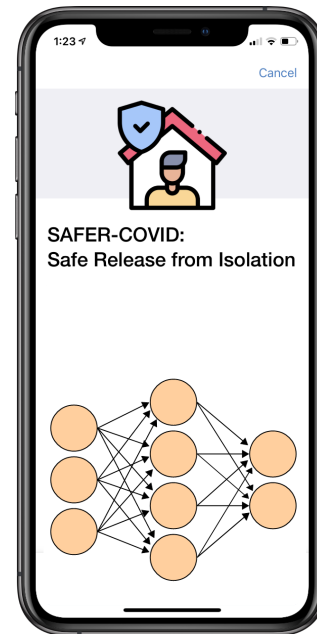
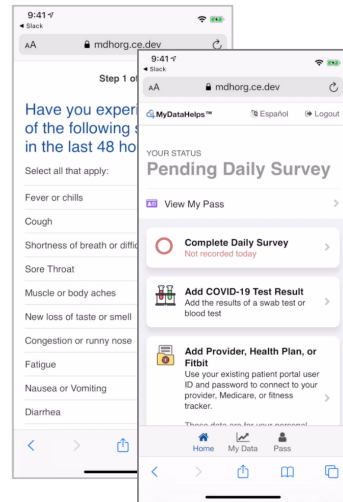
Cell Phone Reader

e.g. OpenRDT (Audere)

## How to Use Wearables



## Symptom Surveys

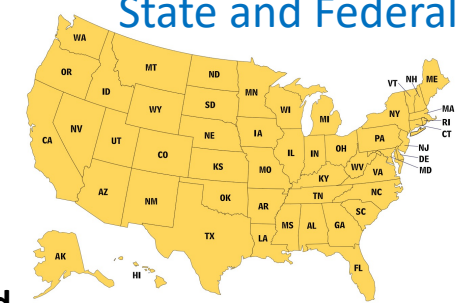


GATES foundation

## EHR & Claims



## State and Federal



## Need Standards

## Contact Tracing



## Health status



e.g. VCI



Data Hubs



<https://vaccinationcredential.org>

# Summary

## **RADx and MIDRC: *New process for acceleration and impact***

- Leverage existing networks w/added capabilities for evaluation, validation, funding
- Connect with partners to meet regulatory, policy, and deployment goals

## **Nano: *Tech, materials, manufacturing huge drivers of RADx***

- ~15-20% of total RADx investment, # of applications, cumulative test capacity
- Tech de-risked, validated, accelerated to market

## **Diagnostic Technology future**

- Leverage semi-conductor & telecom w/nano-tech and biomaterials
- Multiplexed tests with other pathogens, variants, diseases