# **Director's Report**

National Advisory Council for Biomedical Imaging and Bioengineering

January 19, 2021

### Bruce J. Tromberg, Ph.D. **Director**

National Institute of Biomedical Imaging and Bioengineering





National Institute of **Biomedical Imaging** and Bioengineering



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#### Jill Heemskerk Deputy Director



David George Associate Director



Richard Leapman Scientific Director



Kris Kandarpa Strategic Initiatives



# NIBIB Council Director's Report 01-19-2021





# NIBIB Council Director's Report 01-19-2021

(continued)



Thank You!

#### **Extramural Science Programs**



Ahmad El-Hendawy Scientific Program Analyst 2018-2021 Division of Interdisciplinary Training

#### **Intramural Research Programs**

Sumit Chaturvedi, Visiting Fellow (Dynamics of Macromolecular Assembly) Yaya Cheng, Special Volunteer (Laboratory of Molecular Imaging and Nanomedicine (LOMIN)) Liangcan He, Special Volunteer (LOMIN) Meijuan Jiang, Special Volunteer (LOMIN) Joseph Lau, Post Doc Visiting Fellow (LOMIN) Yuanyuan Ma, Special Volunteer (LOMIN) Laura Reyes, Post Doc, (Quantitative Medical Imaging) Anandakumar Shunmugavel, Post Doc (Quantitative Medical Imaging) Guocan Yu, Visiting Fellow (LOMIN)

#### **Office of Administrative Management**

Mark Rotariu, Senior Budget Analyst Chuck Benjamin, Security SME IT



Thank You!

#### **Extramural Science Programs**



Ahmad El-Hendawy Scientific Program Analyst 2018-2021 Division of Interdisciplinary Training

#### Council Term ended May 2020 Stayed on thru Jan 2021



David Grainger PhD University of Utah



National Institute of Biomedical Imaging and Bioengineering

New NIBIB Staff

#### Extramural Science Programs





Afrouz Anderson, Ph.D. Program Director – Optical Imaging DAST

Jennifer Jackson, Ph.D. Health Science Policy Analyst OPESP



Judy Wawira Gichoya, M.D., M.S. Data Scholar DS-I Africa



Grace Zhou Fellow DDST



Krishna Juluru, M.D. Presidential Innovation Fellow OD



Rui Carlos Sa, Ph.D. Data Scholar MIDRC

#### Office of Administrative Management



Kimberly Tam Budget Analyst



Hank Durand Grants Analyst

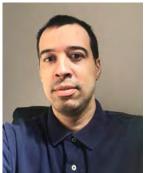


Munir Esmail Program Manager



Eugene Hwang Data Analyst

#### Office of Science Policy and Public Liaison



Che Figueroa-Rodriguez Web Developer

#### **Intramural Research Programs**

Office of the Director

Chineze Egwudo, Post Bac Fellow (Quantitative Medical Imaging) Parinaz Fathi, Post Doc Fellow (Immuno-Engineering) Maria Karkanitsa, Biologist Contractor (Immuno-Engineering) Eric Krueger, Biologist Contractor (High-Resolution Optical Imaging) Alexis Manning, Special Volunteer (Mechanobiology) Tran Ngo, Post Bac Fellow (Immuno-Engineering) Barbara Romero, Post Doc Fellow (Biophotonics) Lixia Zhang, Biologist Contractor (Advanced Imaging and Microscopy)



# **Budget Update**



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#### **FY21** Appropriations Summary

- NIH \$42,934,000,000 (increase of \$1,250,000,000 above FY20 level, or 3% increase)
- NIBIB 410,728,000 (\$7,090,000 above FY20 enacted level of \$403,638,000, 1.8% increase)
- NIH Emergency appropriation (supplement #5): \$1.25B -\$100,000,000 for RADx -\$1.15B for research & trials on COVID-19



# **Budget Update: COVID-19 Funding**

Coronavirus Aid, Relief, and Economic Security (CARES) Act (PL 116-136)	\$60,000,000
Care Enhancement Act (PL 116-139)	\$500,000,000
NIH Office of Director RADx ATP	\$230,000,000
Biomedical Advanced Research and Development Authority - IDDA (PSC-2020-132)	\$307,603,000
Coronavirus Response and Relief Supplemental Appropriations Act	\$100,000,000

**TOTAL** \$1,197,603,000

### RADx Tech program now funded through FY 2021

NIBIB Base Budget FY20/21: 814,366,000 NIBIB Supplemental Budget FY20/21: 1,197,600

2-year doubling

### Goal: Establish RADx as core NIBIB program for FY22+



# Leadership Update



Francis Collins, M.D., Ph.D Reappointed NIH Director

Science Appointments: Eric Lander, PhD: OSTP Director and Presidential Science Advisor

Alondra Nelson, Ph.D.: OSTP Deputy Director for Science and Society

Frances H. Arnold, Ph.D., Co-Chair of the President's Council of Advisors on Science and Technology

Maria Zuber, Ph.D., Co-Chair of the President's Council of Advisors on Science and Technology



# Funding Announcements & Opportunities

- NIH Katz Award
- NIH-NSF Smart and Connected Health
- HEAL Initiative
- NIH FIRST Award
- Music and Health
- Synthetic Biology
- DEBUT
- R21 Mechanism



# New NIH Program: Katz ESI R01

- Investigator-initiated R01
- Early-Stage Investigators (ESI)
- No preliminary data allowed
- New research direction for PI
- Up to 5-years may be requested
- Two Katz FOAs:

National Institute of Biomedical Imaging and Bioengineering

- PAR-21-038 (Clinical Trial Not Allowed)
- PAR-21-039 (Basic Experimental Studies with Humans Required)
  - \*NIBIB is not participating on PAR-21-039\*



Stephen I Katz, M.D., Ph.D. Director NIAMS 1995-2018

#### First due date January 26, 2021



NIH Katz Award Committee Co-chair, David George, Ph.D. Member, Randy King, Ph.D.



Katz Program website <u>https://grants.nih.gov/funding/katz-esi-r01.htm</u>

# NSF-NIH Smart & Connected Health Program

- Successful NSF-NIH program since 2013; aligns with NIBIB programs/mission
- <u>NOT-OD-21-011: Notice of NIH Participation in Smart Health and Biomedical Research in</u> <u>the Era of Artificial Intelligence and Advanced Data Science</u>
- Developing technologies to transform health and medicine (\$300K/year, up to 4 years)
- The new program "Smart Health and Biomedical Research in the Era of Artificial Intelligence and Advanced Data Science", was restructured to promote two goals of the NIH's Strategic Plan for Data Science with 23 ICOs' participation

### Application due date February 16, 2021



Information Infrastructure

Transformative Data Science

Novel Multimodal Sensor System Hardware

**Effective Usability** 

Automating Health

Medical Image Interpretation

Qi Duan, Ph.D. Program Director



# HEAL Initiative: HEALthy Brain & Child Development

**Goal:** understand impact of fetal drug exposure, adversities on mental & behavioral health; inform intervention/prevention strategies.

**Longitudinal study:** cognitive, psychosocial assessments + advanced imaging (MRI, EEG, NIRS etc.)

- 7,500 subjects to be scanned from birth to 10 years old.
- Portable imaging tech, e.g. EEG and fNIRS, for infants in motion, baby-caregiver interactions, etc.
- New imaging tech, e.g. novel fMRI and fetal ultrasound, in large-scale study.

#### Four FOAs:

- <u>RFA-DA-21-020 Unlinked Research Project Sites (U01)</u>
- RFA-DA-21-021 Linked Research Project Sites (U01)
- RFA-DA-21-022 Consortium Administrative Core (U24)
- <u>RFA-DA-21-023 Data Coordinating Center (U24)</u>

#### Letter of Intent: March 1<sup>st</sup>, 2021; Application: March 31<sup>st</sup>, 2021



Shumin Wang, Ph.D. Program Director



### Faculty Institutional Recruitment for Sustainable Transformation (FIRST)

#### **Objective**: *Create cultures of inclusive excellence* Common Fund intends to commit **\$241 million over nine years**

#### RFA-RM-20-022: FIRST Cohort (U54 Clinical Trial Optional)

#### **FIRST Faculty Cohort awards:**

- *Hire a diverse cohort:* early-stage research faculty w/multi-level mentoring, professional development.
- *Effect systemic and sustainable institutional culture change:* address bias, equity, mentoring, and work/life issues.

#### RFA-RM-20-023: FIRST Coordination & Evaluation Center (U24 Clinical Trial Not Allowed)

#### **FIRST** Coordination and Evaluation Center:

- *Coordinate and facilitate:* development of strategies with FIRST Cohort awardees
- *Conduct a comprehensive evaluation:* impact of FIRST program

#### Application Due Date: March 1, 2021

Webinar January 25, 2021, 2 - 4 pm EST. https://nci.rev.vbrick.com/#/webcasts/nihfirst.





Hannah Valantine, MD. Chief Officer for Scientific Workforce Diversity 2014-2019

Zeynep Erim, Ph.D. **Division Director** 



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# Music and Health FOA

#### PAR-21-099: Music and Health: Understanding and Developing Music Medicine (R21 Clinical Trial Optional)

#### Goals:

- Increase understanding of how music affects the brain
- Develop evidence-based music interventions to enhance health or treat specific diseases and disorders.

#### **NIBIB Topics of interest** (not limited to):

- Development of non-invasive human imaging tools and technologies to probe music's impact on the brain.
- Effects of music on the quantity of sedatives and/or analgesics as required during image-guided interventions and other minimally invasive procedures.

Guoying Liu, Ph.D. Program Director





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# Synthetic Biology NOSIs

#### NOT-EB-20-017: Notice of Special Interest (NOSI) Synthetic Biology for Biomedical Applications

Goals of this Notice are to:

- 1. develop tools and technologies to control and reprogram biological systems.
- 2. apply synthetic biology approaches for the development of biomedical technologies.
- 3. increase the fundamental understanding of synthetic biology concepts as they relate to human health.
- 4. gain fundamental biological knowledge through the application of synthetic biology approaches.

The NOSI will fund R01, R21, and R35 research projects.

#### The NOSI expands the trans-NIH Synthetic Biology partnership from 3 ICs to 8 ICs



National Institute of Biomedical Imaging and Bioengineering



National Center for Complementary and Integrative Health





Allergy and Infectious Diseases National Institute on Aging

National Institute of



National Institute of General Medical Sciences



*Eunice Kennedy Shriver* National Institute of Child Health and Human Development

David Rampulla, Ph.D. Division Director DDST

Program Director – Synthetic Biological Systems



National Human Genome Research Institute

NOT-EB-20-022: Notice of Special Interest (NOSI) Administrative Supplement for Providing Travel Support for Awardees to Attend the Annual NIH Synthetic Biology Consortium Meeting (Admin Supp)



# **DEBUT** Design by Biomedical Undergraduate Teams Challenge

- Challenges undergraduate teams to design technology solutions for unmet health needs
- **Ideation** projects & projects with **Prototypes** ٠
- Total of **\$115,000** in Prizes!
- Submission Deadline: June 1, 2021
- Winners Announced: August 25, 2021
- Award Ceremony: October 2021, BMES meeting

https://www.nibib.nih.gov/research-programs/DEBUT-challenge





Zeynep Erim, Ph.D. Division Director

Joan Greve, Ph.D. **Program Director** 

#### **NIBIB** Prizes • The Steven H. Krosnick Prize: **\$20,000** • Second Prize: **\$15,000**

- Third Prize: **\$10,000**
- HIV/AIDS Prize: \$15,000
- NIMHD Tech for Low-Resource Settings Prize: \$15,000
- Newlo NCI Technologies for Cancer Prevention, Diagnosis and Treatment Prize: \$15,000
  - 5 Honorable Mentions: **\$1,000** each

### VentureWell Prizes:

- Venture Prize: \$15,000
- Design Excellence Prize: **\$5,000**





# NIBIB Exploratory/Developmental R21 Update

# PAR-18-433: NIBIB Exploratory/Developmental Research Grant Program (R21 Clinical Trial Optional)

Key Features:

- No preliminary data allowed
- Balancing considerable risk with potential high impact research
- Expires May 8, 2021 (per issuance of NOT-EB-20-013)

NIBIB will be discontinuing this Exploratory/Developmental R21 FOA. Alternatives include:

- R03
- Short-term R01
- Katz RO1
- NIBIB Trailblazer R21



Randy King, Ph.D. Program Director

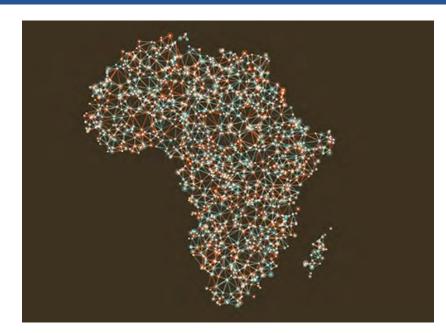


# Program Updates

- DS-I Africa
- BRAIN
- Diversity Working Group
- COVID-19



### Harnessing Data Science for Health Discovery and Innovation in Africa (DS-I Africa)



Over 100 diverse group of applications received for the following FOA's:

- Open Data Science Platform and Coordinating Center (ODSP/CC)
- Ethical, Legal and Social Implications of DS-I Research
- DS-I Research Training Program
- Research Hubs

Applications for ODSP/CC received from South Africa, Nigeria, Ghana, Uganda, Kenya, Sudan, Mali, Egypt, Tanzania, Mauritius and Rwanda

https://www.nibib.nih.gov/research-funding/data-science-initiave-dsi

Judy Wawira, MD, MS

National Institute of

Biomedical Imaging and Bioengineering

#### Timeline for FOA-RFA-RM-20-018





Tiffani Lash, PhD

# **BRAIN Initiative Workshops**

#### **Dissemination of Non-Invasive Imaging Technologies**

- February 18-19, 2021
- Purpose: to feature progress updates from BRAIN Initiative awardees and presentations from industry on potential pathways for follow-on dissemination.
- Agenda and Speaker Information

#### **Transformative Non-Invasive Imaging Technologies**

- March 9-11, 2021
- Purpose: to bring together neuroscientists, tool developers/engineers, and industry partners to identify new non-invasive functional imaging tools that could be realized in the next five to ten years.
- Agenda and Speaker Information



Shumin Wang, Ph.D. Program Director Co-chair



George Zubal, Ph.D. Program Director

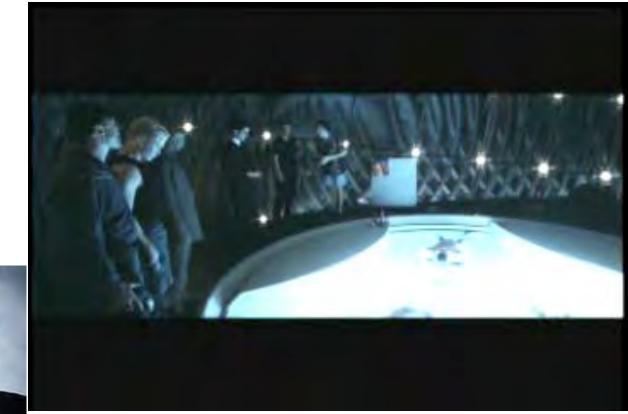


# BRAIN Initiative Workshops

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#### **Transformative Non-Invasive Imaging Technologies**





Shumin Wang, Ph.D. Program Director Co-chair





### Diversity, Equity and Inclusion: NIBIB Community



Gilda Barabino, Ph.D.

Roderic Pettigrew, Ph.D., MD

#### September 2020

#### **NIBIB Community:**

- Intellectually Diverse and Embracing of New Ideas
- Problem Solvers: Blend Technology and Altruism
- Diversity Essential For Growth, Success

### Co-Chairs of New Advisory Council Working Group

- Developing Diverse, Inclusive Workforce and Leadership
- Addressing Structural and Systemic Barriers, Bias
- Advancing Technology for Reducing Disparities, Improving Access



### Diversity, Equity and Inclusion: *NIBIB Community*



Gilda Barabino, Ph.D.



Roderic Pettigrew, Ph.D., MD

Manu Platt, Ph.D. Associate Professor, BME, GaTech

National Institute of Biomedical Imaging and Bioengineering



Greg Washington, Ph.D. President, George Mason University

Intellectually Diverse and Embracing of New Ideas

• Special Council Working Group, Advisory to Director

Problem Solvers: Blend Technology and Altruism

• Diversity Essential For Growth, Success

Zeynep Erim, Ph.D. Training Division Director



**NIBIB Community:** 

## Diversity, Equity and Inclusion: NIH-wide activity

NIH-Wide Approach: From December 11, 2020 Advisory Council to Director (ACD) Presentation

Create trans-NIH committees reporting to the NIH Steering Committee and reporting out to NIH Advisory Committee to the Director (ACD) to address 5 interrelated, but distinct, workstreams

- Understanding stakeholder experiences through listening and learning
- New research on health disparities/inequities
- Internal workforce
- Extramural research workforce
- Talking and communicating with our internal external stakeholders

#### **NIBIB** Representation





Zeynep Erim

Shaun Sims





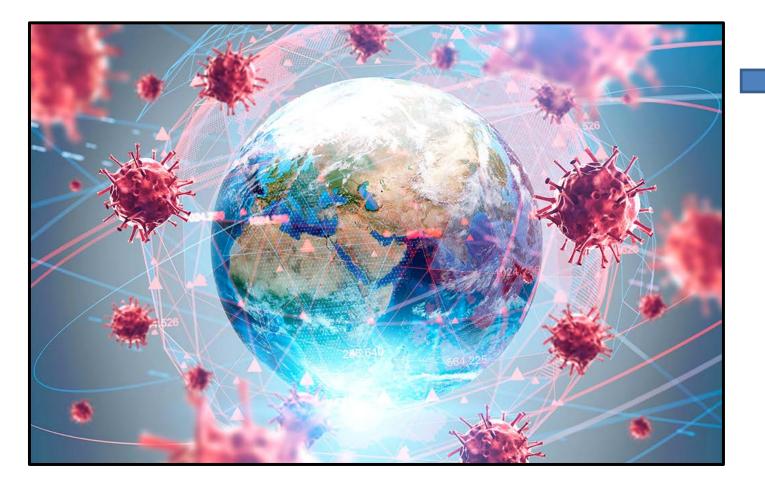
Tiffany Calvert

Asha Storm



### **COVID-19 Pandemic**

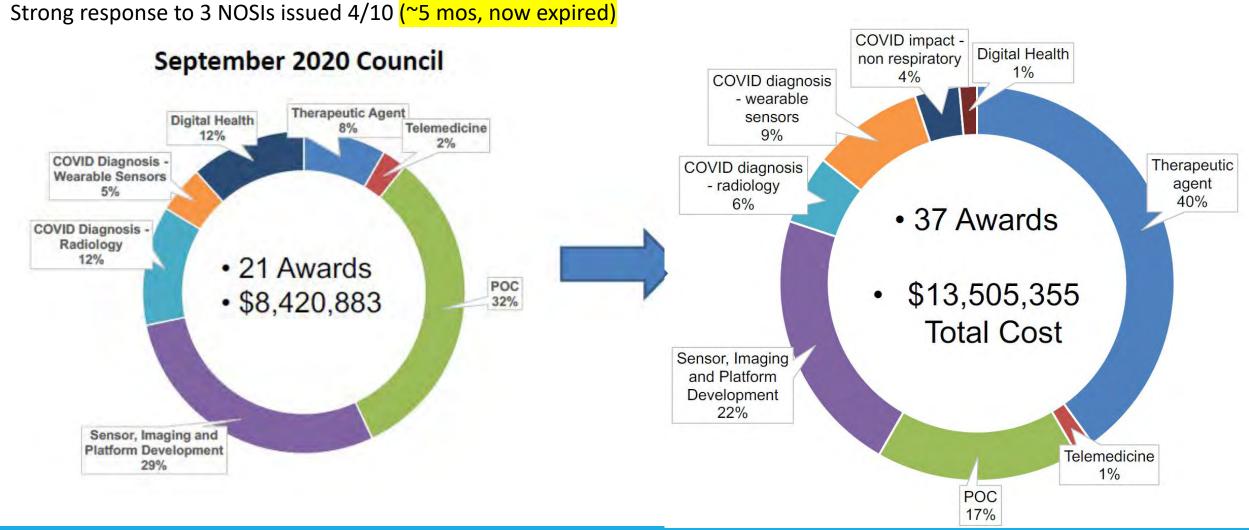




1) Imaging and AI
2) Digital Health Platforms
3) Diagnostic Test Technologies



### COVID-19 Supplements: NIBIB Program



National Institute of Biomedical Imaging and Bioengineering



MEDICAL IMAGING AND DATA RESOURCE CENTER.

Aug 2020: 2-year \$20M National Network

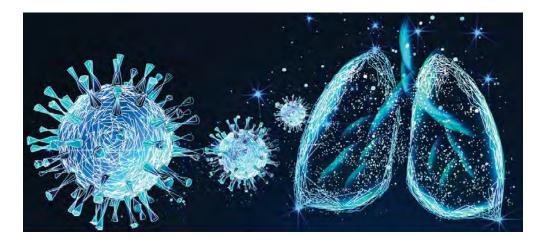
#### Accomplishments (~5 months)

- MIDRC management/advisory structure (23 institutions)
- Data infrastructure, harmonization, evaluation, security and privacy requirements and processes
- Data model & data elements to enable use in AI development
- Contractual agreements with institutions interested in contributing data
- First MIDRC investigators meeting held in December 2020
- Actively link with NCATS N3C (National COVID Cohort Collaboration) for accessing COVID clinical data
- Recent RSNA publication re COVID chest images released to the public (S. Simpson et al. Radiology: Cardiothoracic Imaging 2021, 2(2))

#### In Progress

- 11 institutions to donate data through RSNA (RICORD) and ACR (CIRR)
- 15,000+ cases being processed for MIDRC ingestion
- 10,000+ more cases being processed for donation
- First users/data contributors meeting being planned for March 2021

1,240 COVID imaging studies available for users.





# **Digital Health Solutions for COVID-19**

- **SAFER-COVID** became NIH's official return-to-work app
- More than **150K people** have used the tool to date (NIH and non-NIH)
- Activity risk calculator was featured on CNN (https://safercovid.org/myrisk)
- Tool is being configured to assist with **at-home** COVID-19 testing



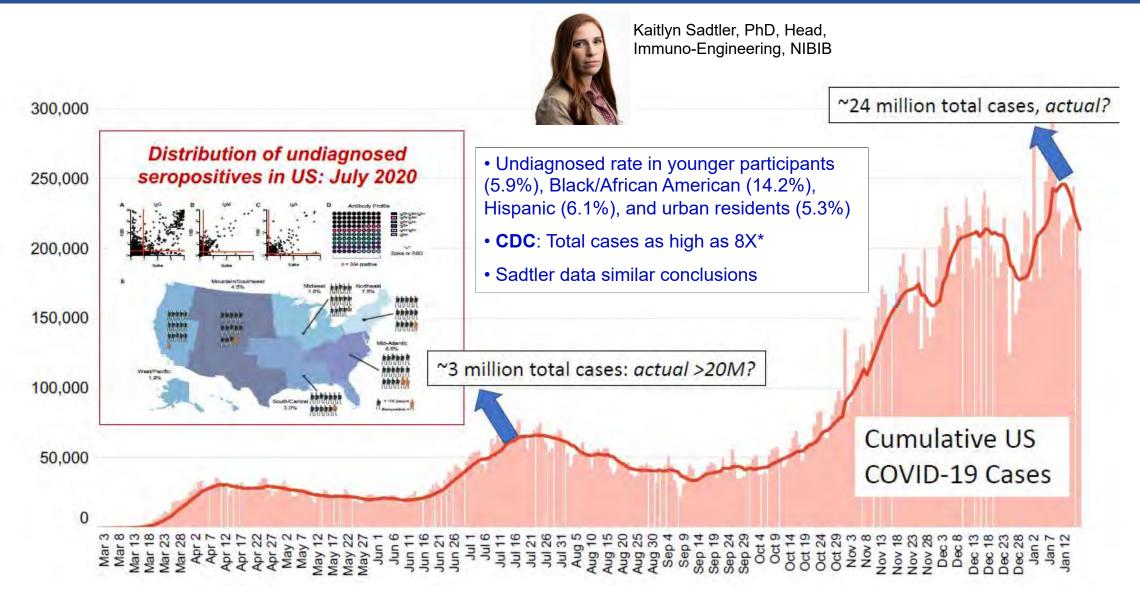
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Andrew Weitz, Ph.D.



#### Mapping a Pandemic: SARS-CoV-2 Seropositivity in the United States





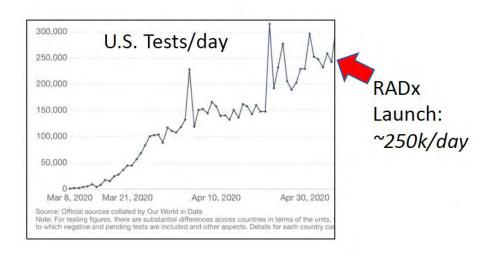
\*Heather Reese, et al., Clinical Infectious Diseases, ciaa1780, https://doi.org/10.1093/cid/ciaa1780

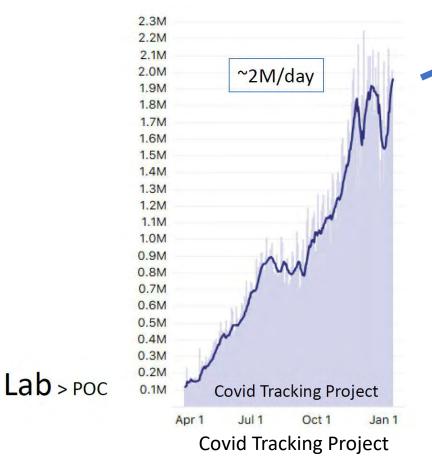
### RADx Tech & ATP Goals

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

**Test Settings** 

- Home-based
- Point of Care (POC)
- Laboratory (CLIA, research)



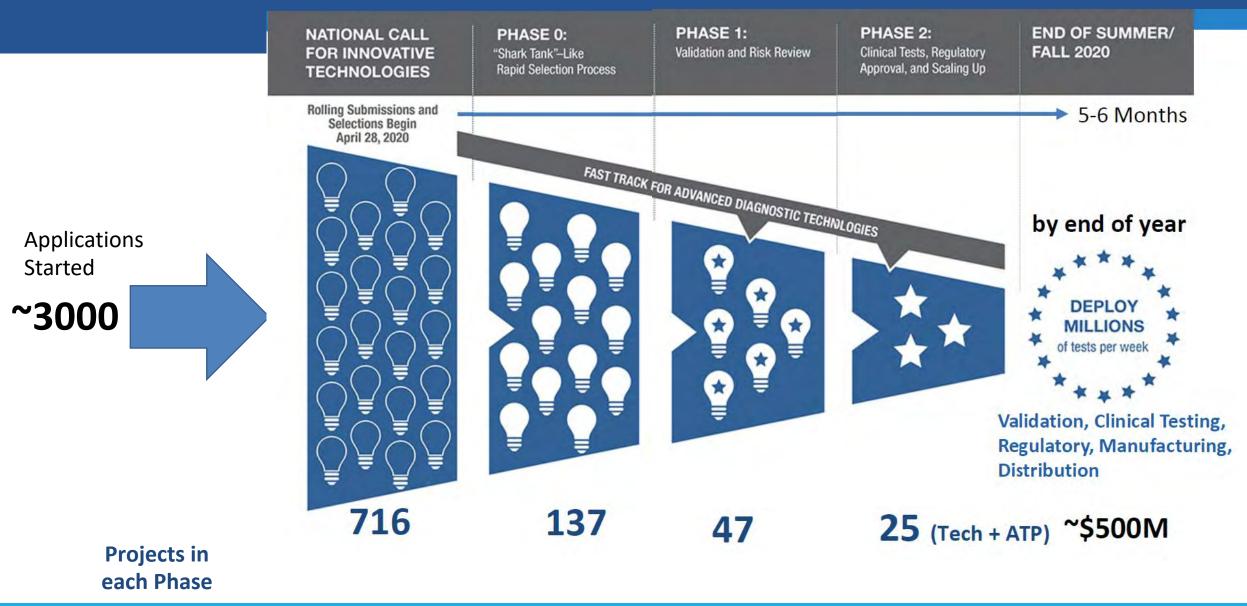


+ >2 million/day LFA antigen tests unreported

POC > Lab

https://www.theatlantic.com/health/ar chive/2021/01/rapid-antigen-covid19tests-unreported/617668/

# RADx Tech/ATP Innovation Funnel



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Mesa BioTech

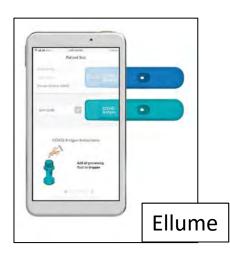


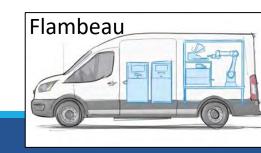


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Control Line

#### Quidel Sophia





### 14 EUAs issued



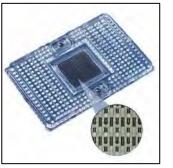


Point of Care & Home	
Visby	RTPCR
Mesa	RTPCR
Microgem	RTPCR
Talis	ISO-PCR
MatMaCorp	RTPCR
Ubiquitome	RTPCR
Quidel Sophia	An-LFA
Quidel QuickView	An-LFA
Luminostics	An-LFA
ANP	An-LFA
Ellume	An-LFA
Laboratory	
Flambeau	PCR-mobile
Fluidigm	RTPCR
Broad Inst	RTPCR
Illumina	NGS
Helix	NGS/RTPCR
Gingko	NGS/RTPCR
Sonic Healthcare	RTPCR
PathGroup	RTPCR
Aegis	RTPCR
Quanterix	SIMOA (An)
Lab Products	
Mammoth Biosci	CRISPR
Ceres Nanosciences	Beads/Conc
Yukon	Swabs





Visby Medical



Fluidigm

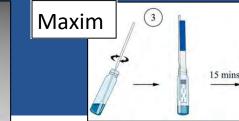


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Luminostics

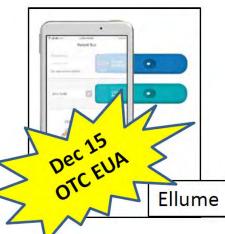


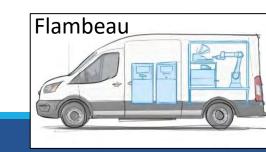




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#### Quidel Sophia





# 14 EUAs issued





Point of Care & Home	
Visby	RTPCR
Mesa	RTPCR
Microgem	RTPCR
Talis	ISO-PCR
MatMaCorp	RTPCR
Ubiquitome	RTPCR
Quidel Sophia	An-LFA
Quidel QuickView	An-LFA
Luminostics	An-LFA
ANP	An-LFA
Ellume	An-LFA
Laboratory	
Flambeau	PCR-mobile
Fluidigm	RTPCR
Broad Inst	RTPCR
Illumina	NGS
Helix	NGS/RTPCR
Gingko	NGS/RTPCR
Sonic Healthcare	RTPCR
PathGroup	RTPCR
Aegis	RTPCR
Quanterix	SIMOA (An)
Lab Products	
Mammoth Biosci	CRISPR
Ceres Nanosciences	Beads/Conc
Yukon	Swabs

#### Mesa BioTech





Visby Medical



Fluidigm



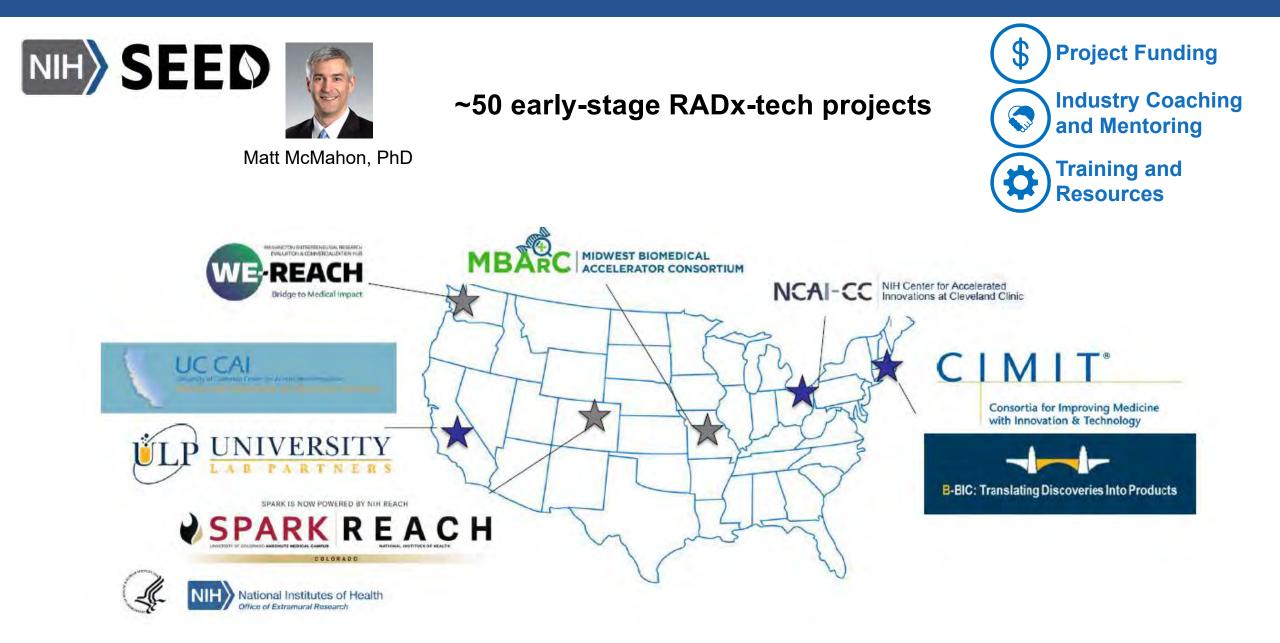
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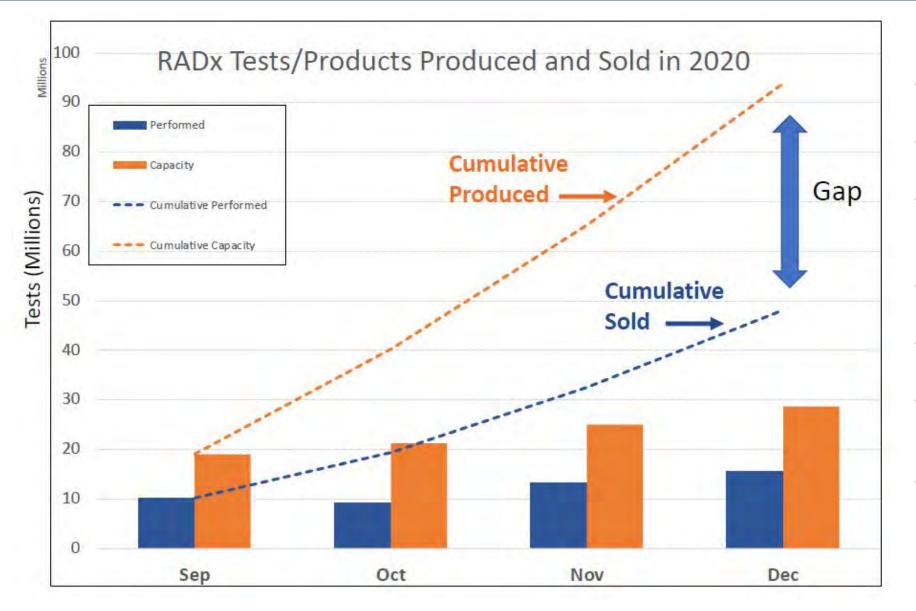
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Ubiquitome

## RADx Leveraging NIH Proof of Concept (PoC) Network

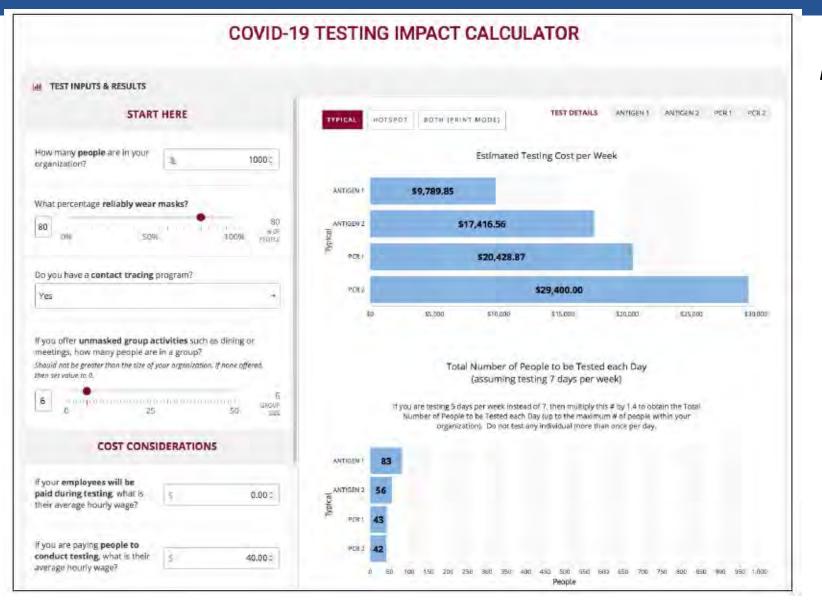


### RADx Impact in 2020



- ~94 million capacity in 2020
- ~48 million sold in 2020
- ~950k tests/day produced Dec 2020; ~550k/day sold
- ~14 EUAs and 1st OTC EUA
- ~190 Companies supported
- Feb 2021: Project millions OTC LFA tests/day
- March 2021: Project >2.5M tests/day

# Deployment Core: CIMIT/MGH (close gap)



Bridging NIH/USG, non-profit Foundations, Academia, and Industry



Nancy Gagliano, MD CIMIT/MGH

**"When-to-Test"** modeling tool: Match tests w/needs; evaluate impact of risk reducing activities.

#### https://whentotest.org/

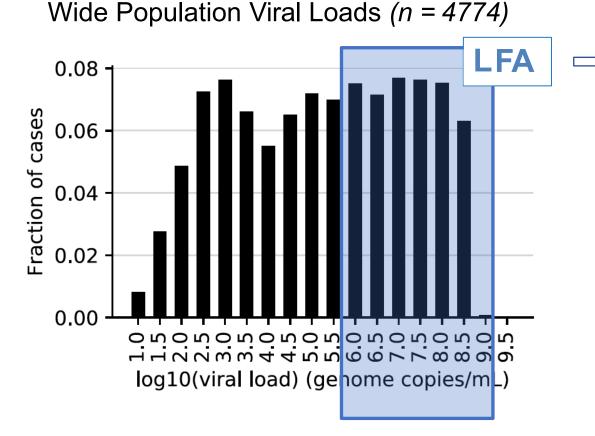




Anette Hosoi Paul MIT CIMI

Paul Tessier, CIMIT/MGH

## Challenges: Screening/Surveillance LFA Performance



Typical LOD ~10<sup>6</sup> Copies/mL Sensitivity ~40% vs. RTPCR for all (symptomatic + asymptomatic)\*

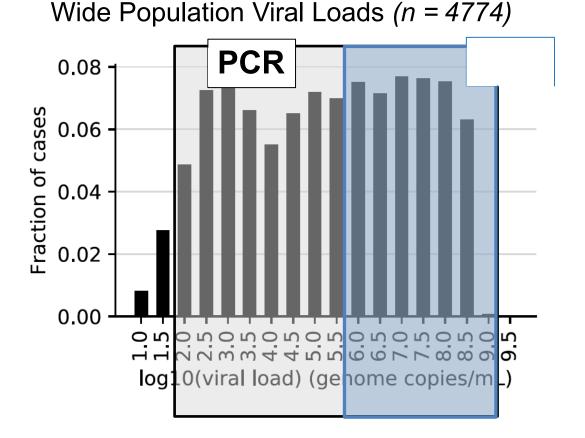
Vs.

Sens/Spec ~90/95% for symptomatic population (EUA: ~5 days post-onset)

Ramy Arnaout, James E. Kirby, et al., **SARS-CoV2 Testing:The Limit of Detection Matters** bioRxiv 2020.06.02.131144; doi: <u>https://doi.org/10.1101/2020.06.02.131144</u>

\*Pray IW, et al. Morb Mortal Wkly Rep 2021;69:1642–1647. DOI: http://dx.doi.org/10.15585/mmwr.mm695152a3

# Challenges: Screening/Surveillance LFA Performance



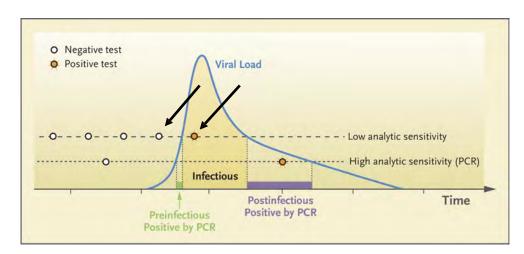
Ramy Arnaout, James E. Kirby, et al., **SARS-CoV2 Testing:The Limit of Detection Matters** bioRxiv 2020.06.02.131144; doi: <u>https://doi.org/10.1101/2020.06.02.131144</u>

Use LFA within ~5-7 days of symptoms
Elevated viral load (>90% sens, spec)

2) "Off Label" LFA in Asymptomatics:

- Backup PCR w/positive in low prevalence
- Backup PCR w/negative recently exposed

#### 3) Sequential LFA tests



M. Mina et al, NEJM, DOI: 10.1056/NEJMp2025631

## RADx Clinical Studies Core (UMass)

**Mission:** Evaluate RADx platforms that advance to Phase 2 in rigorous clinical studies w/ diverse populations and settings.

- Quidel Multisite study: UMass, UIUC, JHU in progress (n=200)
  - Longitudinal sequential Lateral Flow Assay (LFA) assessment (2 weeks)
  - RTPCR, saliva, + viral infectiousness assay
- LFA home testing study: UMass and Northwestern, Jan 25 (n=100)
  - At home, Self sampling, Digital health platforms
- LFA large population study, planning w/public health (n>200,000)
  - Regular frequent tests break chain of transmission?

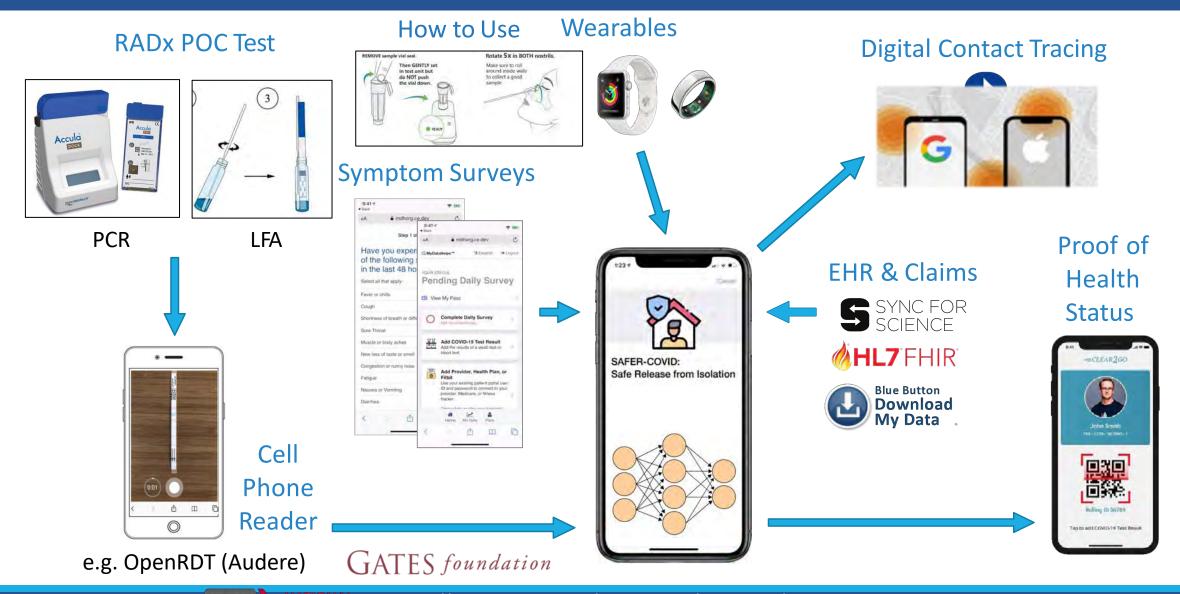


Laura Gibson, MD David McManus, MD

COVID-19 TestUS



## POC/Home Challenges: Digital Health



https://www.nibib.nih.gov/news-events/newsroom/nih-awardscontracts-develop-innovative-digital-health-technologies-covid-19

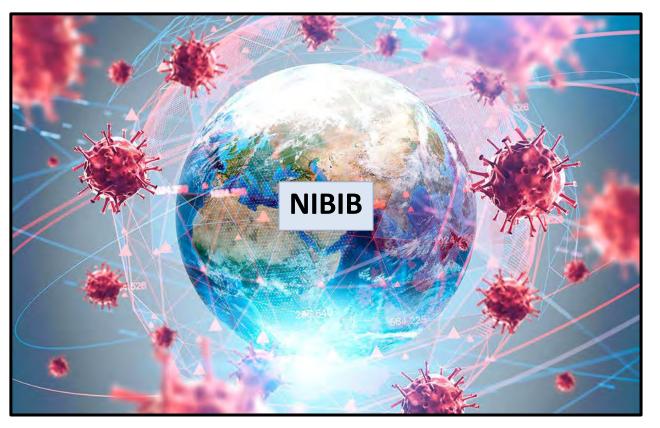
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and Bioengineering

NIH

## COVID-19 Pandemic



### **Summary & Future**

Pandemic demands can't be addressed by "off the shelf" solutions: *Be ready with new, purpose-driven tech.* 

Bioengineers are multi-lingual integrators: Urgent need to work closely with Public Health

Leveraging existing networks by expanding is key for speed, impact: *Build in efficiencies to counter the natural growth of bureaucracy.* 

Technology development relatively easy: *Adoption, guidance, modifying human behavior for surveillance* & *screening are hard.* **Partnerships, stakeholders!** 

**RADx general platform for acceleration, impact:** embedding in NIBIB structure, disseminating to NIH & beyond



### Thank You!



National Institute of Biomedical Imaging and Bioengineering

### Manu O. Platt, Ph.D.

Seventh Annual Lopez Lecture + January 19, 2021

In Memory of NIBIB Program Director Hector Lopez, Ph.D. (1947-2014)

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- ✓ Find out how to join clinical trials and view resources from other federal agencies.

