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







Jill Heemskerk

NIBIB Council Director's Report 01-19-2021



David George Associate Director



Richard Leapman Scientific Director



Kris Kandarpa Strategic Initiatives



Jason Ford
Executive Officer





Pam Glikman

NIBIB Council Director's Report 01-19-2021

(continued)



Alisha Hopkins



Julia Ringel



Asha Storm



Ahmad El Hendawy



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

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

Office of the Director



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

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



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

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 RO1

- 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:
 - 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.

NSF-NIH Smart & Connected Health Program

- Successful NSF-NIH program since 2013; aligns with NIBIB programs/mission
- NOT-OD-21-011: Notice of NIH Participation in Smart Health and Biomedical Research in the Era of Artificial Intelligence and Advanced Data Science
- 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

Qi Duan, Ph.D. *Program Director*



Information Infrastructure

Transformative Data Science

Novel Multimodal Sensor System Hardware

Effective Usability

Automating Health

Medical Image Interpretation



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:

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

Letter of Intent: March 1st, 2021; Application: March 31st, 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

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*

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.



David Rampulla, Ph.D.

Division Director DDST

Program Director – Synthetic Biological Systems

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

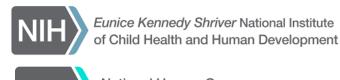














NOT-EB-20-022: Notice of Special Interest (NOSI) Administrative Supplement for Providing Travel Support for Awardees to Attend the Annual NIH Synthetic Biology Consortium Meeting (Admin Supp)



DEBUT Design by Biomedical Undergraduate Teams Challenge

- Challenges undergraduate teams to design technology solutions for unmet health needs
- **Ideation** projects & projects with **Prototypes**
- 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

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 R01
- NIBIB Trailblazer R21



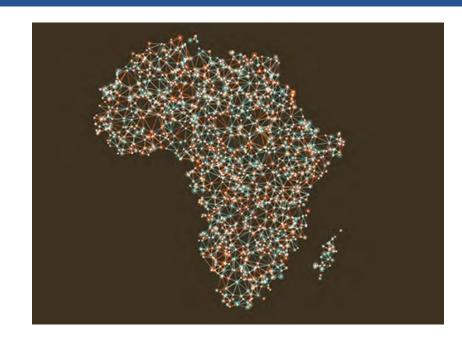
Randy King, Ph.D. *Program Director*



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)

Tiffani Lash, PhD

- 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

Timeline for FOA-RFA-RM-20-018



Judy Wawira, MD, MS

Applications
Due
December 3,
2020



Scientific
Merit
Review
April/May
2021



Advisory Council Review August 2021



Earliest Start
Date
September 1,
2021



Shravani Bobde, MS

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

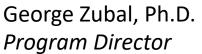
Shumin Wang, Ph.D.

Program Director

Co-chair

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





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



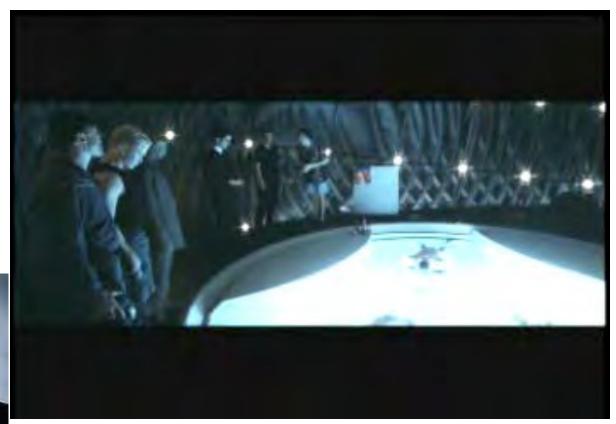
Shumin Wang, Ph.D.

Program Director

Co-chair



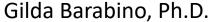
Transformative Non-Invasive Imaging Technologies





Diversity, Equity and Inclusion: NIBIB Community







Roderic Pettigrew, Ph.D., MD

September 2020

NIBIB Community:

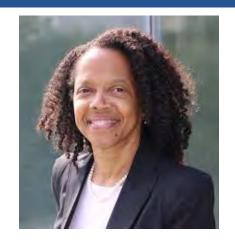
- Intellectually Diverse and Embracing of New Ideas
- Problem Solvers: Blend Technology and Altruism
- Diversity Essential For Growth, Success

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.



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



Roderic Pettigrew, Ph.D., MD



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

NIBIB Community:

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

- Special Council Working Group, Advisory to Director
- 5 Additional external invitations in progress
- Council member participation encouraged
- Become recognized leadership voice for NIBIB community
- Coordinate with NIH-wide efforts on Diversity (UNITE)



Zeynep Erim, Ph.D. Training Division Director



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

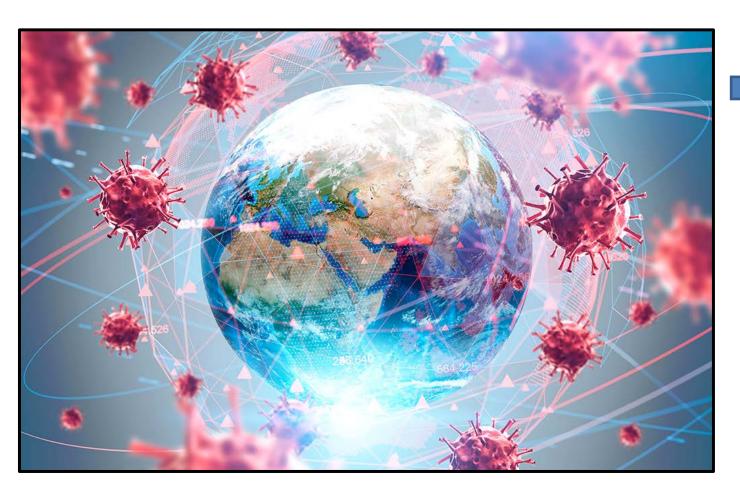




Tiffany Calvert

Asha Storm

COVID-19 Pandemic



Bioengineering

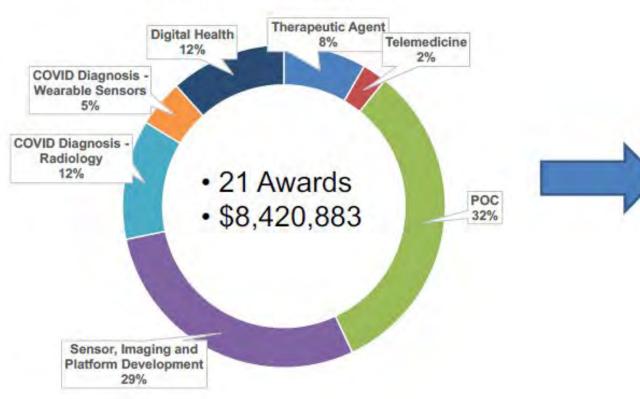


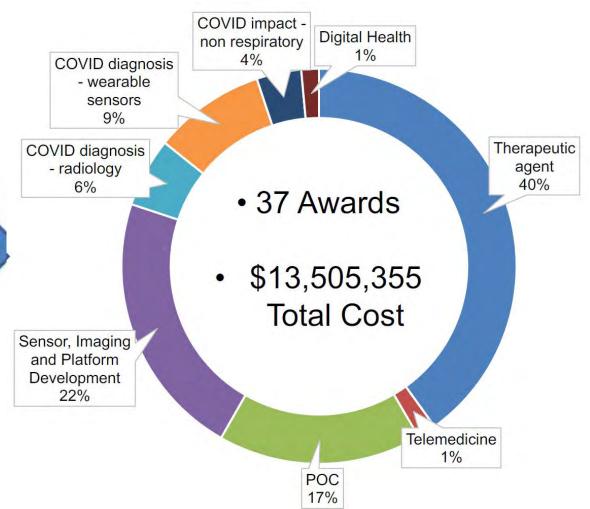
- 1) Imaging and AI
- 2) Digital Health Platforms
- 3) Diagnostic Test Technologies

COVID-19 Supplements: NIBIB Program

Strong response to 3 NOSIs issued 4/10 (~5 mos, now expired)









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



Andrew Weitz, Ph.D.



SAFER-COVID:

isolating yourself.

Safe Release from Isolation

work and other social interactions. None of us want to knowingly spread this dangerous virus to our loved ones, colleagues at work or across our community. This system will provide guidance on what steps you can take to be more certain that you are not

infectious to others before electing to stop

If you are experiencing a life-threatening

emergency, please call 911 immediately. This system is not intended for the diagnosis or treatment of disease or other conditions.

The purpose of this SAFER-COVID

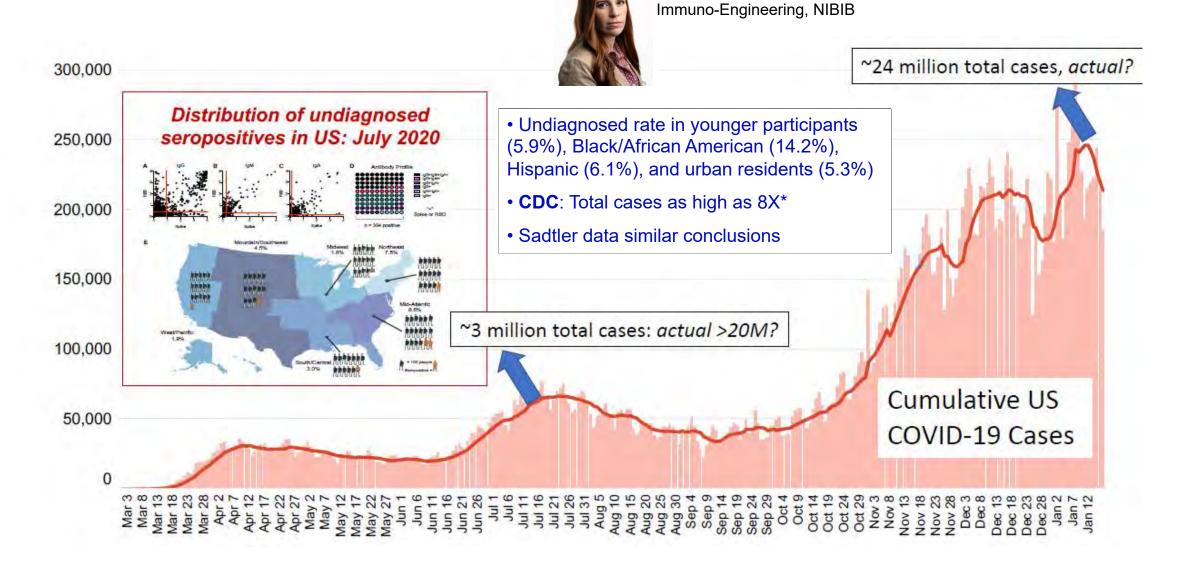
assessment tool is to help you make decisions about when and if it is safe for you to return to regular daily activities such as



careevolution

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

Kaitlyn Sadtler, PhD, Head,



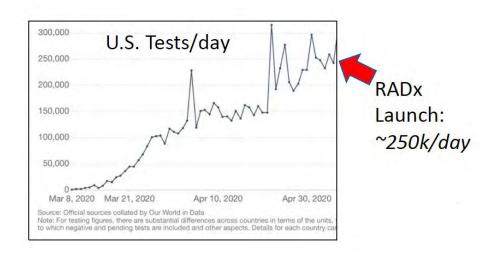


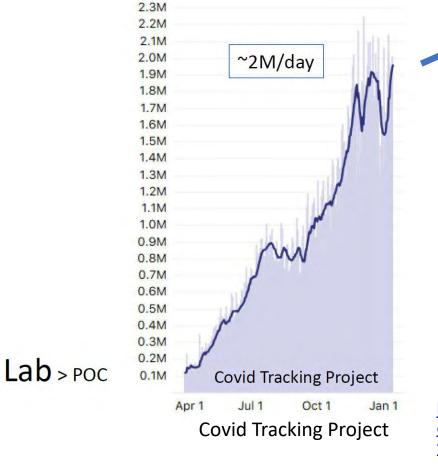
RADx Tech & ATP Goals

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

Test Settings

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



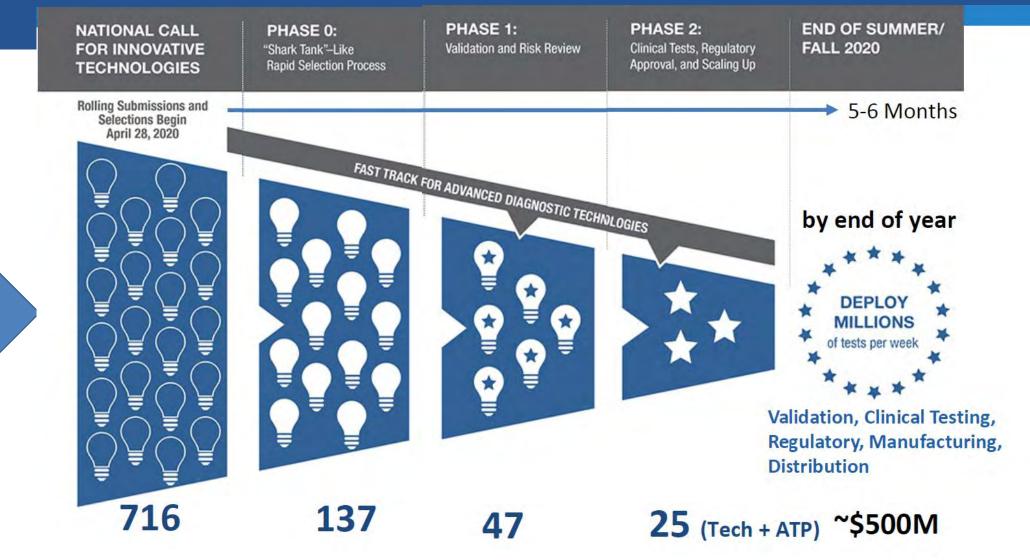


+ >2 million/day LFA antigen tests unreported

POC > Lab

https://www.theatlantic.com/health/archive/2021/01/rapid-antigen-covid19-tests-unreported/617668/

RADx Tech/ATP Innovation Funnel



Applications Started

~3000

Projects in each Phase

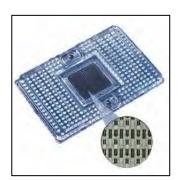




Mesa BioTech



Ubiquitome

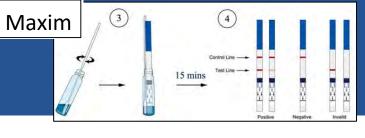


Visby Medical

Fluidigm



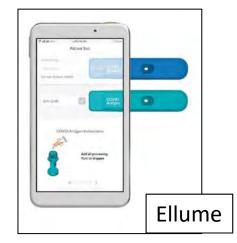
Luminostics

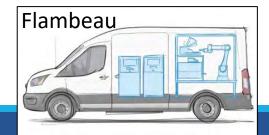


14 EUAs issued



Quidel Sophia

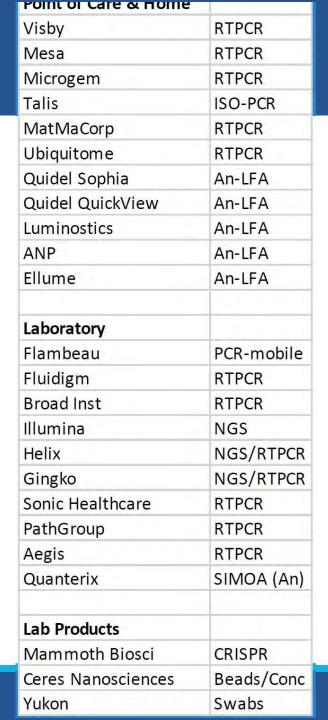














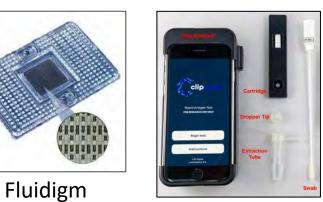


Mesa BioTech

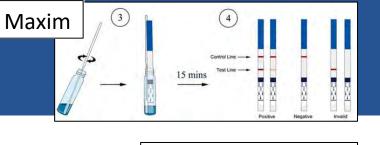
COVID-19



Visby Medical Ubiquitome

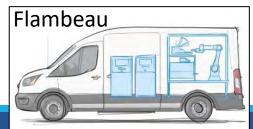


Luminostics



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



RADx Leveraging NIH Proof of Concept (PoC) Network



~50 early-stage RADx-tech projects

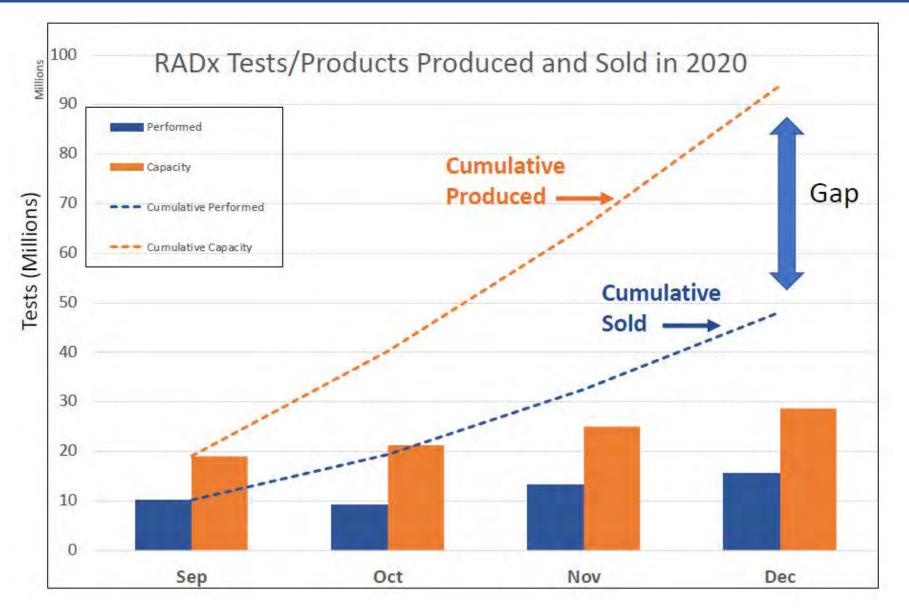






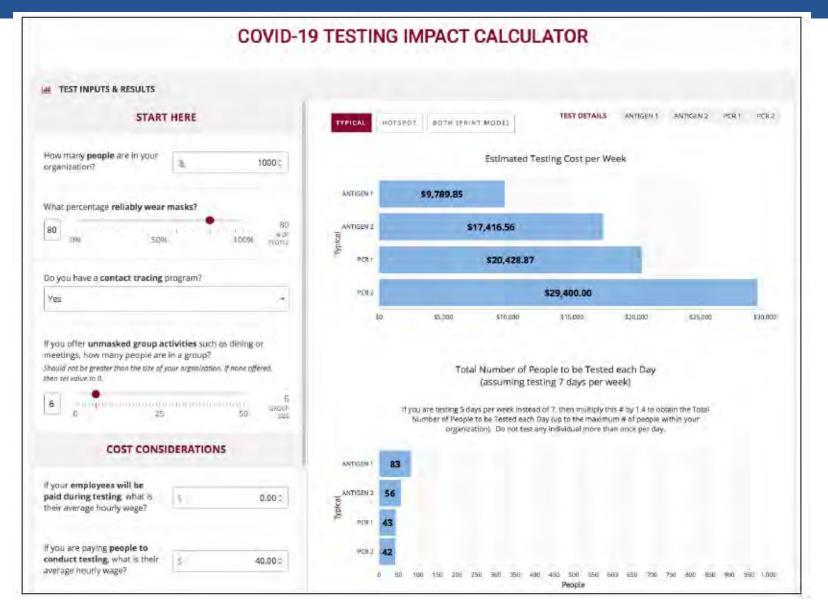


RADx Impact in 2020



- ~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/



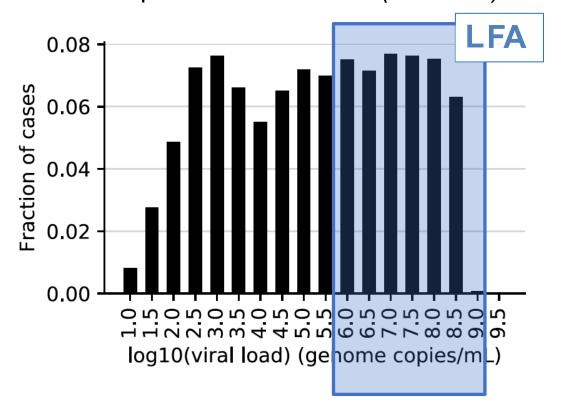
Anette Hosoi MIT



Paul Tessier, CIMIT/MGH

Challenges: Screening/Surveillance LFA Performance

Wide Population Viral Loads (n = 4774)



Typical LOD ~10⁶ Copies/mL Sensitivity ~40% vs. RTPCR for all (symptomatic + asymptomatic)*

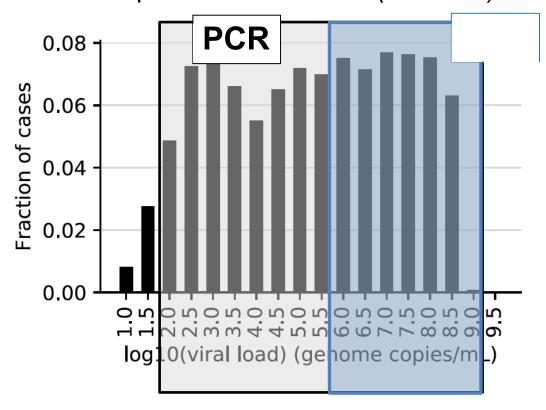
Vs.

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

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

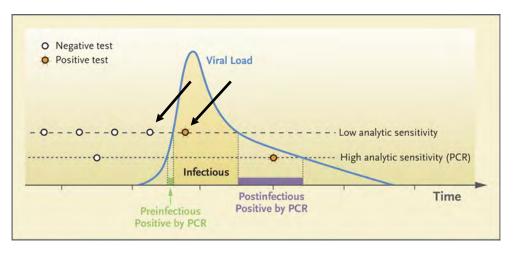
Challenges: Screening/Surveillance LFA Performance

Wide Population Viral Loads (n = 4774)



- 1) 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?





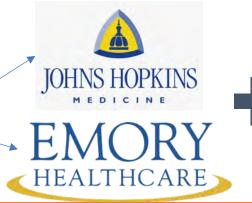
Laura Gibson, MD David McManus, MD





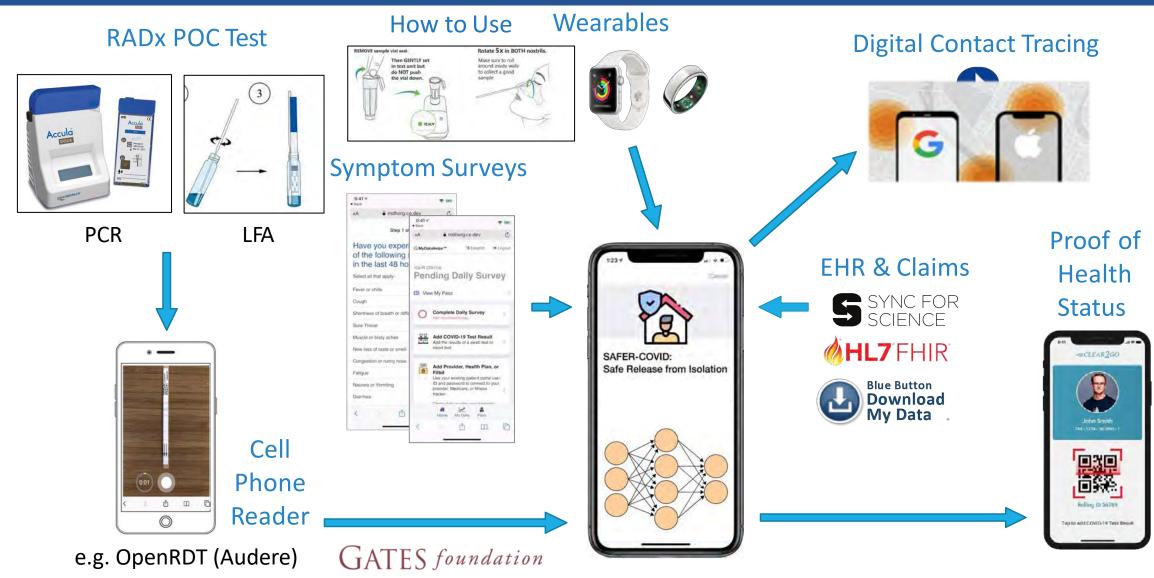








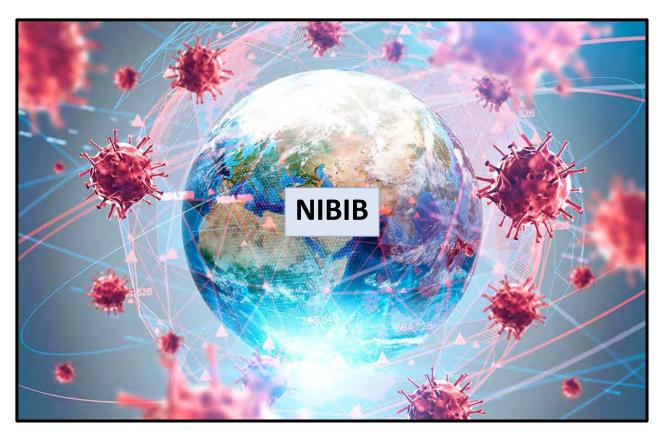
POC/Home Challenges: Digital Health







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!



COVID19.nih.gov

NIH COVID-19 Website

- ✓ Get trusted, up-to-date, accurate information about NIH research.
- ✓ Learn about vaccines, treatments, and testing that are readily available.
- ✓ Find out how to join clinical trials and view resources from other federal agencies.





