Director's Report

National Advisory Council
for Biomedical Imaging and Bioengineering

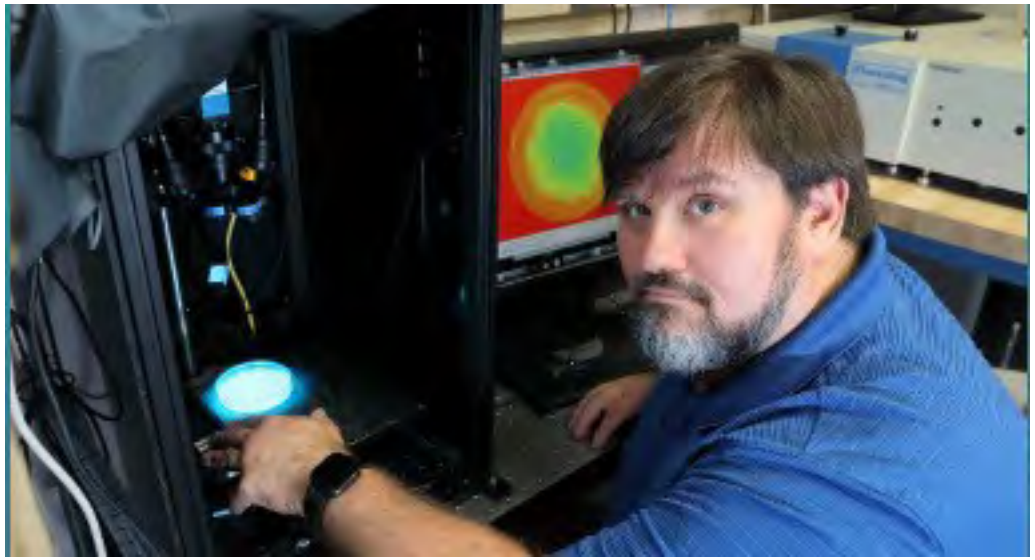
September 14, 2021

Bruce J. Tromberg, Ph.D.

Director

National Institute of Biomedical Imaging and Bioengineering

George H. Patterson, Ph.D. (1970 – 2021)



Senior Investigator and Chief, Section on Biophotonics, NIBIB

https://www.nibib.nih.gov/about-nibib/staff/memoriam-george-harold-patterson-1970-2021

Incoming Council Member

Dr. Manu Platt

- Professor and Walter H. Coulter Distinguished Faculty Fellow in Biomedical Engineering, Ga Tech.
- **Research:** biochemical and mechanical dynamics of tissue remodeling, repair, and regeneration and translation to address global health disparities.
- Recently named Associate Chair for graduate studies and elected to the BMES Board of Directors.
- Nationally-awarded leader in STEM mentorship and director of NIH- and NSF-funded programs to promote diversity, equity, and inclusion in BME.

Incoming Council Member

Dr. Tejal Desai

- Ernest L. Prien Endowed Chair and Professor, Department of Bioengineering and Therapeutic Sciences, UCSF
- **Research:** design, fabrication, and use of micro- and nano-technology to understand how to modulate molecular and cellular behavior, create new therapeutics.
- Multiple patents and startups, including a novel cell encapsulation tech to treat endocrine disorders.
- Current President of AIMBE and Member of the National Academy of Medicine.

New NIBIB Program Staff

Office of the Director (OD)

Taylor Gilliland, Ph.D
Senior Advisor for Innovation Programs

Office of Program Evaluation & Strategic Partnerships (OPESP)

Steven Santos, Ph.D.
HHS Testing Diagnostic Working Group & RADx

Office of Research Administration

Songtao Liu
Scientific Review Officer

Thank You!

Upcoming Retirements

Florence Turska
Lead Grants Management Specialist
Retiring Dec. 31

Angie Eldridge
Grants Management Specialist
Retiring Oct. 2

John Holden
Scientific Review Officer
Retiring Sept. 30

Thank You!

Upcoming Retirements

Holly Taylor

Chief Grants Management Officer
Retiring in October

Kate Egan

Supervisory Public Affairs Specialist
Retiring Oct. 31

Thank You!

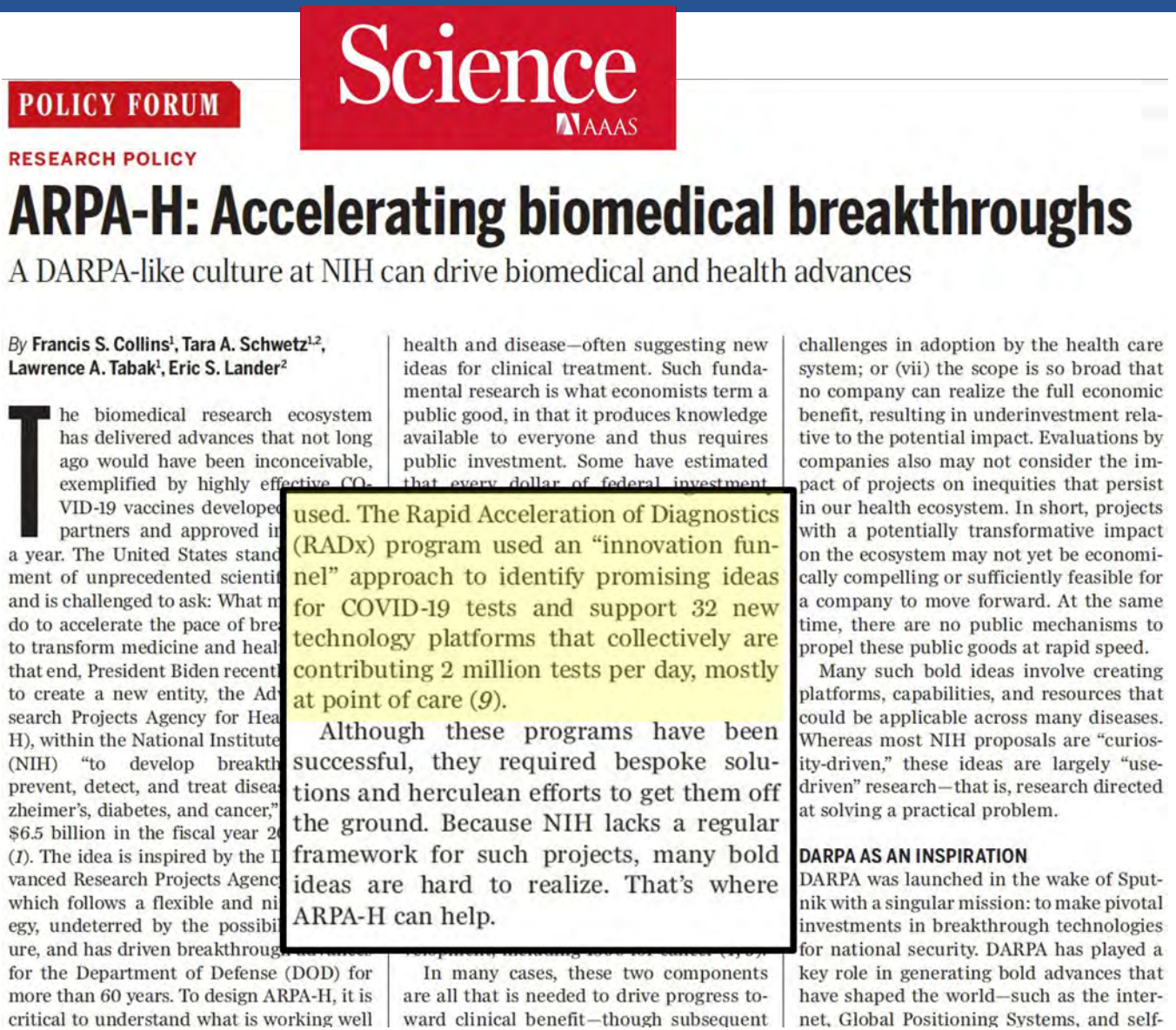
Budget Update

Budget Activities

- House and Senate Appropriations Committee Hearing: 5/25 and 5/26
  NIBIB, NIMHD, NICHD, NIAID, NHLBI, NCI, NIDA
- House Minibus bill FY22 passed in July: ~$49 billion (~$7 billion > FY21)
  - Includes $3B for “ARPA-H”, ~$3.5B for other ICOs
- NIH – pending infrastructure bill: *Vaccines, Therapeutics, Diagnostics*
  - Additional multi-year support for pandemic preparedness

NIBIB Funding

ARPA-H



Science AAAS

POLICY FORUM

RESEARCH POLICY

ARPA-H: Accelerating biomedical breakthroughs

A DARPA-like culture at NIH can drive biomedical and health advances

By Francis S. Collins[1], Tara A. Schwetz[1,2], Lawrence A. Tabak[1], Eric S. Lander[2]

The biomedical research ecosystem has delivered advances that not long ago would have been inconceivable, exemplified by highly effective CO-VID-19 vaccines developed partners and approved in a year. The United States stand ment of unprecedented scientif and is challenged to ask: What m do to accelerate the pace of bre to transform medicine and heal that end, President Biden recentl to create a new entity, the Ad search Projects Agency for Hea H), within the National Institute (NIH) "to develop breakth prevent, detect, and treat disea zheimer's, diabetes, and cancer," $6.5 billion in the fiscal year 2 (*1*). The idea is inspired by the D vanced Research Projects Agenc which follows a flexible and ni egy, undeterred by the possibi ure, and has driven breakthroug for the Department of Defense (DOD) for more than 60 years. To design ARPA-H, it is critical to understand what is working well

health and disease—often suggesting new ideas for clinical treatment. Such fundamental research is what economists term a public good, in that it produces knowledge available to everyone and thus requires public investment. Some have estimated that every dollar of federal investment

used. The Rapid Acceleration of Diagnostics (RADx) program used an "innovation funnel" approach to identify promising ideas for COVID-19 tests and support 32 new technology platforms that collectively are contributing 2 million tests per day, mostly at point of care (*9*).

Although these programs have been successful, they required bespoke solutions and herculean efforts to get them off the ground. Because NIH lacks a regular framework for such projects, many bold ideas are hard to realize. That's where ARPA-H can help.

In many cases, these two components are all that is needed to drive progress toward clinical benefit—though subsequent

challenges in adoption by the health care system; or (vii) the scope is so broad that no company can realize the full economic benefit, resulting in underinvestment relative to the potential impact. Evaluations by companies also may not consider the impact of projects on inequities that persist in our health ecosystem. In short, projects with a potentially transformative impact on the ecosystem may not yet be economically compelling or sufficiently feasible for a company to move forward. At the same time, there are no public mechanisms to propel these public goods at rapid speed.

Many such bold ideas involve creating platforms, capabilities, and resources that could be applicable across many diseases. Whereas most NIH proposals are "curiosity-driven," these ideas are largely "use-driven" research—that is, research directed at solving a practical problem.

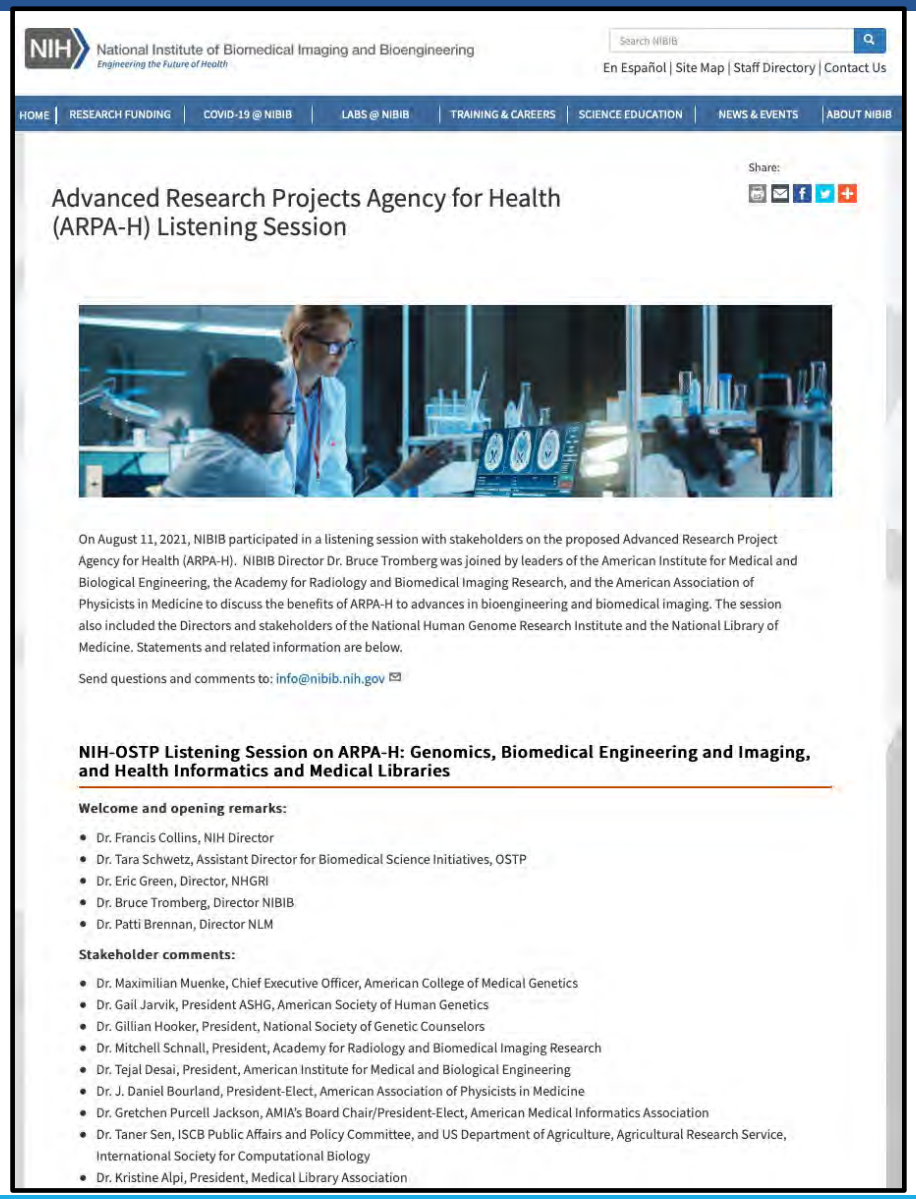
DARPA AS AN INSPIRATION

DARPA was launched in the wake of Sputnik with a singular mission: to make pivotal investments in breakthrough technologies for national security. DARPA has played a key role in generating bold advances that have shaped the world—such as the internet, Global Positioning Systems, and self-

Centered around urgency, nimbleness, and innovation

- Flat, dynamic organization
- Term-limited director with technical and leadership skills
- Creative, diverse cohort of program managers recruited for short terms with broad autonomy to drive transformational change
- Distinct project review and selection processes
- Convergence of scientific disciplines
- Collaborations across academia, industry, government (including ICs)

ARPA-H



National Institute of Biomedical Imaging and Bioengineering
Engineering the Future of Health

Search NIBIB

En Español | Site Map | Staff Directory | Contact Us

HOME | RESEARCH FUNDING | COVID-19 @ NIBIB | LABS @ NIBIB | TRAINING & CAREERS | SCIENCE EDUCATION | NEWS & EVENTS | ABOUT NIBIB

Share:

Advanced Research Projects Agency for Health (ARPA-H) Listening Session

On August 11, 2021, NIBIB participated in a listening session with stakeholders on the proposed Advanced Research Project Agency for Health (ARPA-H). NIBIB Director Dr. Bruce Tromberg was joined by leaders of the American Institute for Medical and Biological Engineering, the Academy for Radiology and Biomedical Imaging Research, and the American Association of Physicists in Medicine to discuss the benefits of ARPA-H to advances in bioengineering and biomedical imaging. The session also included the Directors and stakeholders of the National Human Genome Research Institute and the National Library of Medicine. Statements and related information are below.

Send questions and comments to: info@nibib.nih.gov

NIH-OSTP Listening Session on ARPA-H: Genomics, Biomedical Engineering and Imaging, and Health Informatics and Medical Libraries

Welcome and opening remarks:

- Dr. Francis Collins, NIH Director
- Dr. Tara Schwetz, Assistant Director for Biomedical Science Initiatives, OSTP
- Dr. Eric Green, Director, NHGRI
- Dr. Bruce Tromberg, Director NIBIB
- Dr. Patti Brennan, Director NLM

Stakeholder comments:

- Dr. Maximilian Muenke, Chief Executive Officer, American College of Medical Genetics
- Dr. Gail Jarvik, President ASHG, American Society of Human Genetics
- Dr. Gillian Hooker, President, National Society of Genetic Counselors
- Dr. Mitchell Schnall, President, Academy for Radiology and Biomedical Imaging Research
- Dr. Tejal Desai, President, American Institute for Medical and Biological Engineering
- Dr. J. Daniel Bourland, President-Elect, American Association of Physicists in Medicine
- Dr. Gretchen Purcell Jackson, AMIA's Board Chair/President-Elect, American Medical Informatics Association
- Dr. Taner Sen, ISCB Public Affairs and Policy Committee, and US Department of Agriculture, Agricultural Research Service, International Society for Computational Biology
- Dr. Kristine Alpi, President, Medical Library Association

Stakeholder Statements

The ACADEMY for Radiology & Biomedical Imaging Research

Dr. Mitchell Schnall, Academy for Radiology and Biomedical Imaging Research

- ARPA-H Statement
- Bio
- Academy for Radiology and Biomedical Imaging Research website

AMERICAN INSTITUTE FOR MEDICAL AND BIOLOGICAL ENGINEERING
AIMBE

Dr. Tejal Desai, American Institute for Medical and Biological Engineering

- ARPA-H Statement
- Bio
- American Institute for Medical and Biological Engineering website

AMERICAN ASSOCIATION of PHYSICISTS IN MEDICINE

Dr. J. Daniel Bourland, American Association of Physicists in Medicine

- ARPA-H Statement
- Bio
- American Association of Physicists in Medicine website

White House and National Institutes of Health Close Out Listening Sessions with Over 5,100 Stakeholders on the Proposed Advanced Research Projects Agency for Health

AUGUST 17, 2021 • PRESS RELEASES

Dr. Bruce Tromberg, NIBIB

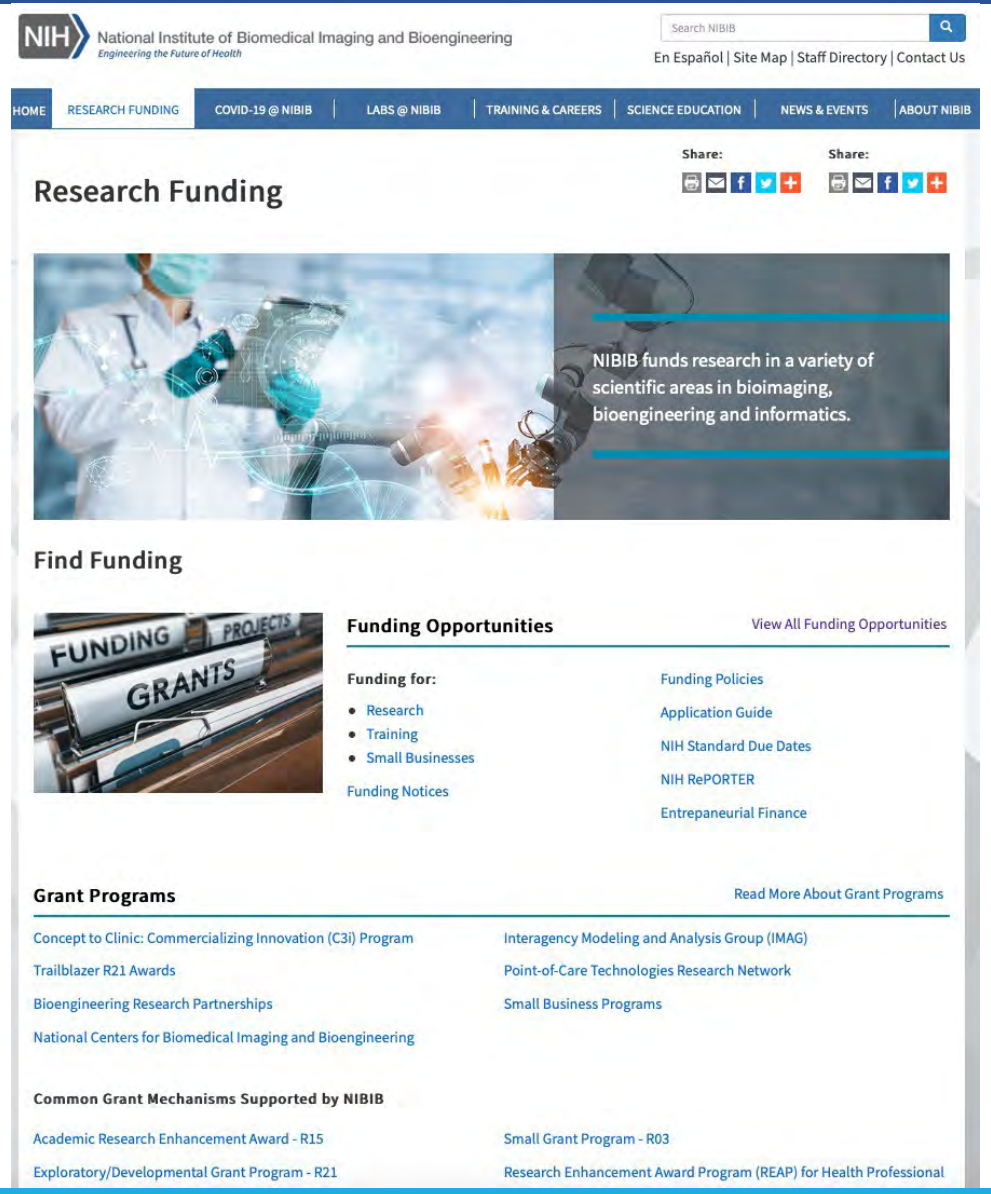
- ARPA-H Statement

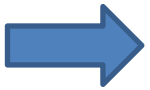
Watch a videocast of ARPA-H Listening Session 9

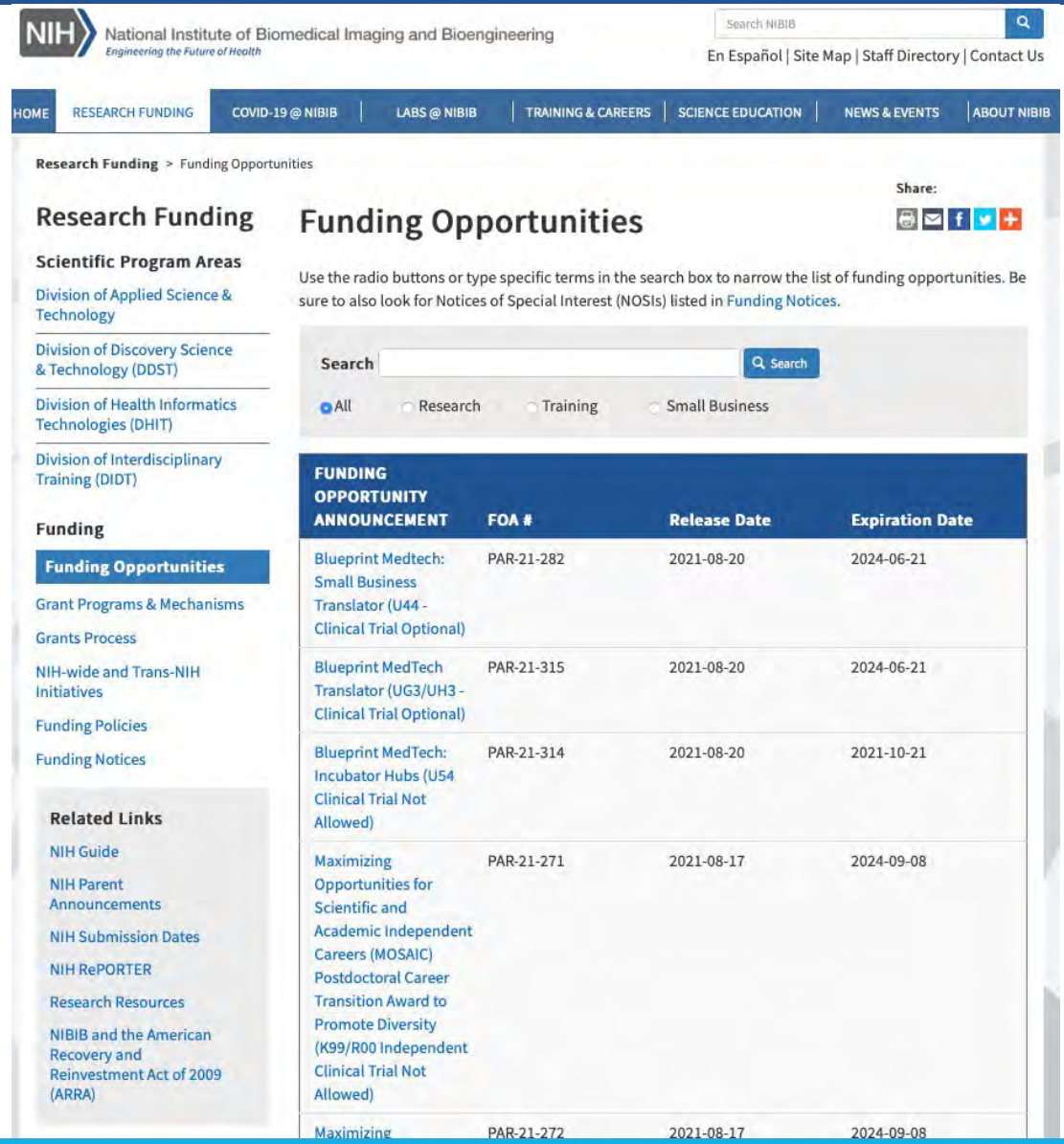
15 sessions

https://www.nibib.nih.gov/arpa-h-listening-session

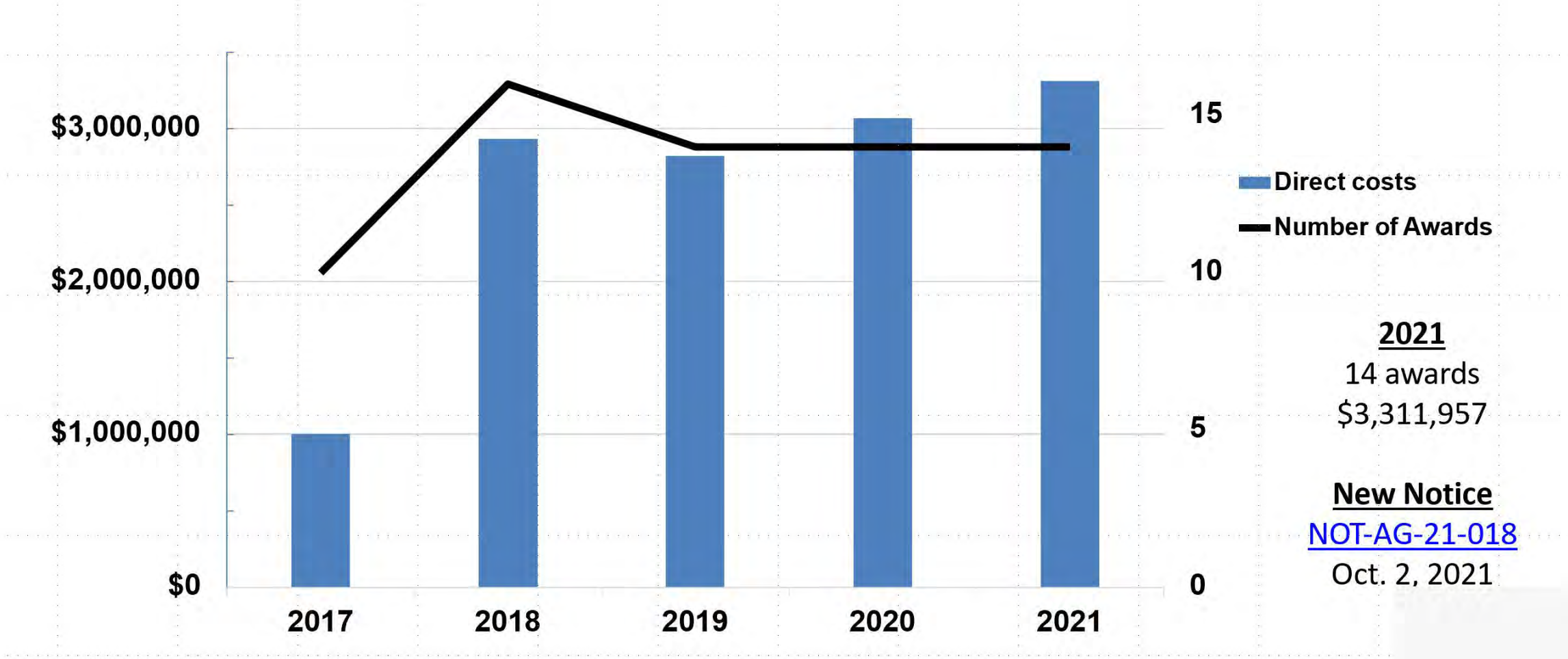
NIBIB: *Opportunities*







Alzheimer's Supplements



2021
14 awards
$3,311,957

New Notice
NOT-AG-21-018
Oct. 2, 2021

Medical Imaging Phantom Library

https://www.nist.gov/programs-projects/nistnibib-medical-imaging-phantom-lending-library

NIBIB National Institute of Biomedical Imaging and Bioengineering

National Institute of Standards and Technology
U.S. Department of Commerce

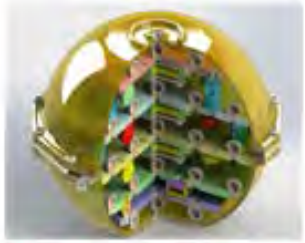
NIBIB/NIST Partnership: A Unique Government Resource to Support a Broad Biomedical Research Community:

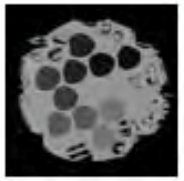
- Access to common standards for round robin testing and validation
- Phantoms are calibrated & traceable to fundamental standards
- Phantoms are curated with stability monitored (including during shipping)
- Open analysis software and image database
- Other Collaborators: RSNA QIBA, NCI QIN, ISMRM, ACR, NPL

NIBIB Program Contact:
Guoying Liu

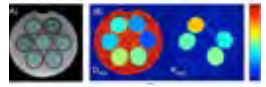
Currently at an Early Stage → Expansion to CT, PET/SPECT, and optical


MRI Breast Phantom


MRI System Phantom



MRI Diffusion Phantom

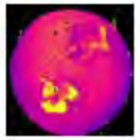

Cardiac T1 Phantom


Kurtosis Phantom


Brain Health Phantom


MRS Phantom

Cone Beam CT Phantom


Biomimetic Tumor Mimic

microCT/MRI Phantom

PET/MRI

OCT Phantom

Organoid Phantom optical/ micoCT/microMRI

Community Requested Phantoms!!

2021: Current Phantoms (60% checked out) 2022 2023 2024

NIH National Institute of Biomedical Imaging and Bioengineering

Community driven: borrow, contribute, request additions

Developing Quantitative Imaging and Other Relevant Biomarkers of Myofascial Tissues for Clinical Pain Management

Co-led by NCCIH and NIBIB

NOT-AT-21-012 Notice of Intent to Publish a FOA for HEAL Initiative

Candidate Imaging Biomarkers:

- Structural Characterization (e.g., MRI, ultrasound)
- Soft tissue mobility and biomechanical properties (e.g., elastography)
- Tissue metabolism, perfusion, pH, oxygenation, and fatty infiltration (e.g., PET, optical, photoacoustic, MR spectroscopic imaging, electrophysiological measurements)
- Multimodal, multiparametric, and multiscale approaches integrating different types of measurements, including dynamic changes in tissue targets

Two-phase Funding Mechanism:

Phase I (2 years): Develop quantitative measures to differentiate myofascial tissue abnormalities in healthy, latent, and active myofascial pain stages that corelate with clinical signs/symptoms

Phase II (3 years): Assess the ability of the measures developed in Phase I to monitor responses and/or predict outcomes in response to therapies in longitudinal interventional studies

Expected Earliest Application Submission Date 12/15/2021

NIH National Center for Complementary and Integrative Health

NIH National Institute of Biomedical Imaging and Bioengineering

NIBIB Program Contact: Guoying Liu

Blueprint MedTech FOAs

The Blueprint MedTech program is an NIH incubator that aims to accelerate the development of cutting-edge medical devices to diagnose and treat disorders of the nervous system.

RADx model

Incubator Hubs

PAR-21-314: Blueprint MedTech: Incubator Hubs (U54) [SINGLE RECEIPT DATE]

RADx-like approach to technology development

Will fund innovators and the resources they'll need to build human-grade prototypes

First-in-human Clinical Studies

PAR-21-315: Blueprint MedTech: Translator (UG3/UH3)

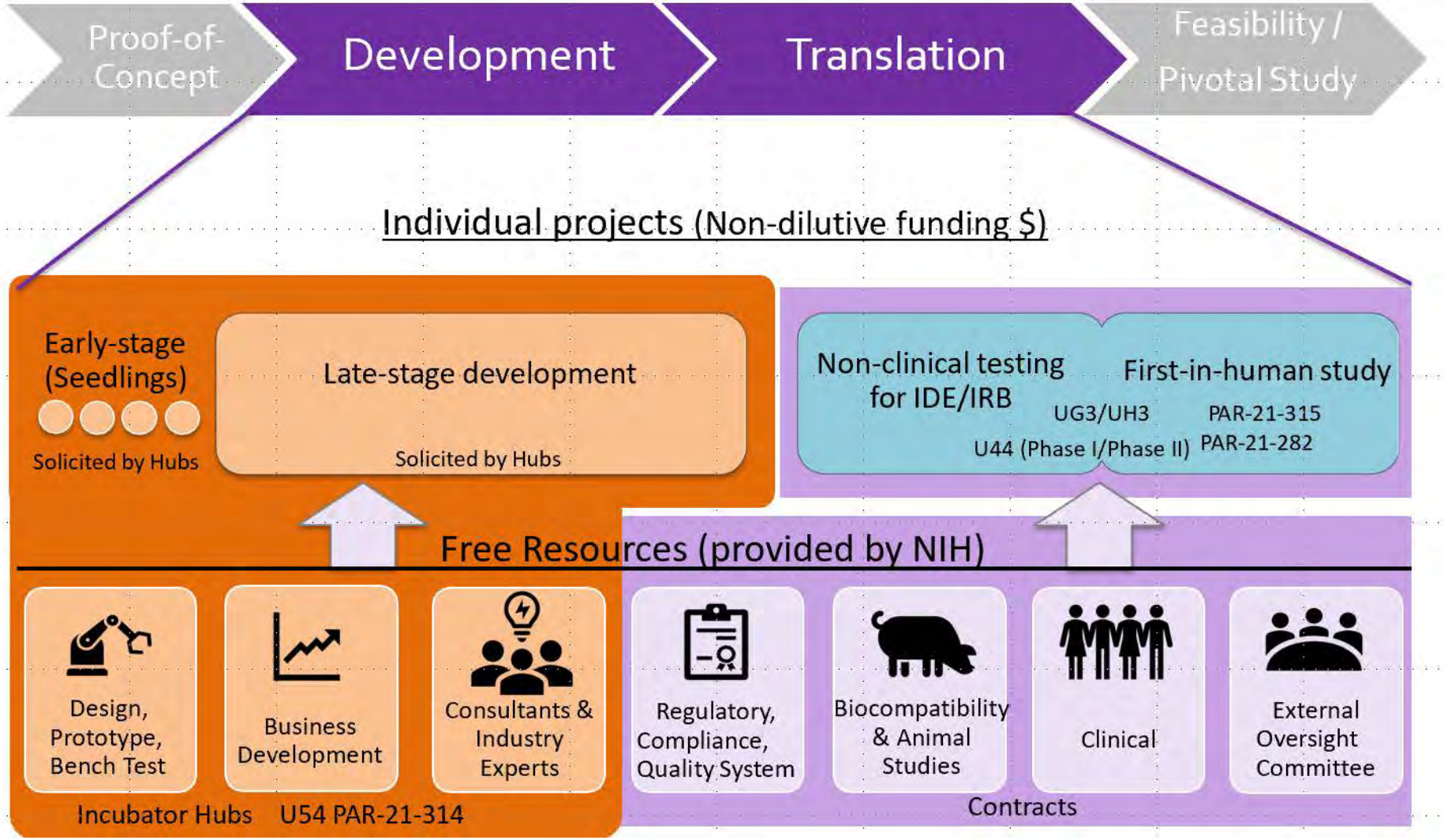
PAR-21-282: Blueprint MedTech: Small Business Translator (U44)

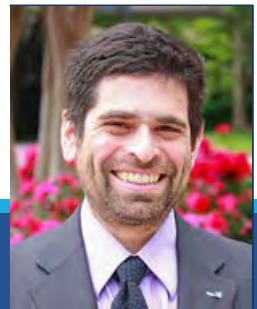
Similar to BRAIN and IC-specific FOAs, with access to resources

Applications Due: October 20, 2021

https://neurosciencebluprint.nih.gov/blueprint-medtech

Blueprint MedTech FOAs





NSF-NIH Smart & Connected Health Program

- Successful NSF-NIH program since 2013 with great alignment with NIBIB's programs

  NSF program solicitation: NSF 21-530
  NIH notice: NOT-OD-21-011
  FY21 PI webinar recording and slides are available on the NSF SCH website

- Developing information technologies to transform health and medicine (Budget: $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

Next application due date: *November 10th, 2021*

- Information Infrastructure
- Transformative Data Science
- Novel Multimodal Sensor System Hardware
- Effective Usability
- Automating Health
- Medical Image Interpretation

Upcoming:

November 4-5, 2021

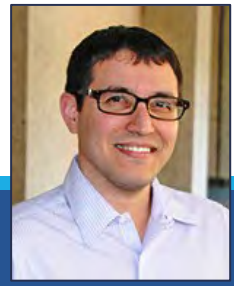
Virtual 2021 Synthetic Biology Consortium Meeting

Focusing synthetic biology for biomedicine

- Engaging with FDA stakeholders
- Showcase of research from Synthetic Biology Consortium grantees
- Networking with NIH Program staff from different ICs
- Trainee-focused grant/technical writing panel

"Re-wire" biology → engineer health

Virtual meeting information available at
https://www.syntheticbiology.nibib.nih.gov/



- Sabbatical-like experience
- w/ NIH extramural
- Scholars engage policymakers
- NIH gains 1st hand interaction
- ODSS-NIH IC cost-matching

NIH Data and Technology Advancement (DATA) National Service Scholar Program

Stay tuned -- next round of calls
April 2022

March 8, 2021

The NIH Office of Data Science Strategy (ODSS) Data and Technology Advancement (DATA) National Service Scholar Program is seeking experienced data and computer scientists and engineers to tackle challenging biomedical data problems with the potential for substantial public health impact.

Applicants should possess technical skills in one or more of the following areas, as relevant to their proposed project area(s):

- Artificial intelligence
- Cloud computing
- Data engineering
- Data science
- Database management
- Project management
- Software design
- Supercomputing
- Bioinformatics

Industry experience is desired. Applicants should have an MD, PhD, or equivalent doctoral degree and have advanced experience in data science or related fields. For program details and eligibility, please visit: https://datascience.nih.gov/data-scholars-2021.
Applications due April 9, 2021.

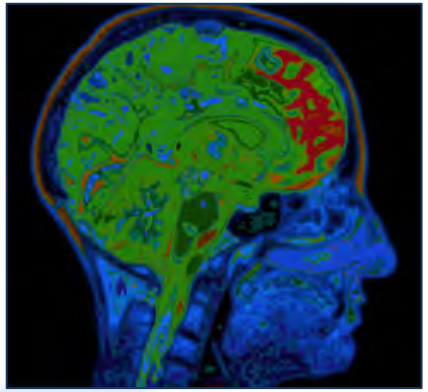
Data and Technology Advancement (DATA) National Service Scholars

First Class!

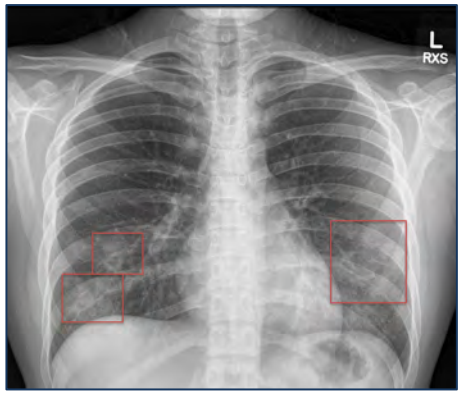
brings talented professionals with experience in and knowledge of data and computer sciences and related fields to advance high-impact programs at NIH

Harnessing Data Science for Health Discovery and Innovation in Africa (DS-I Africa)
Judy Wawira Gichoya, M.D.

BRAIN WORKS
Mohammad M. Ghassemi, Ph.D.

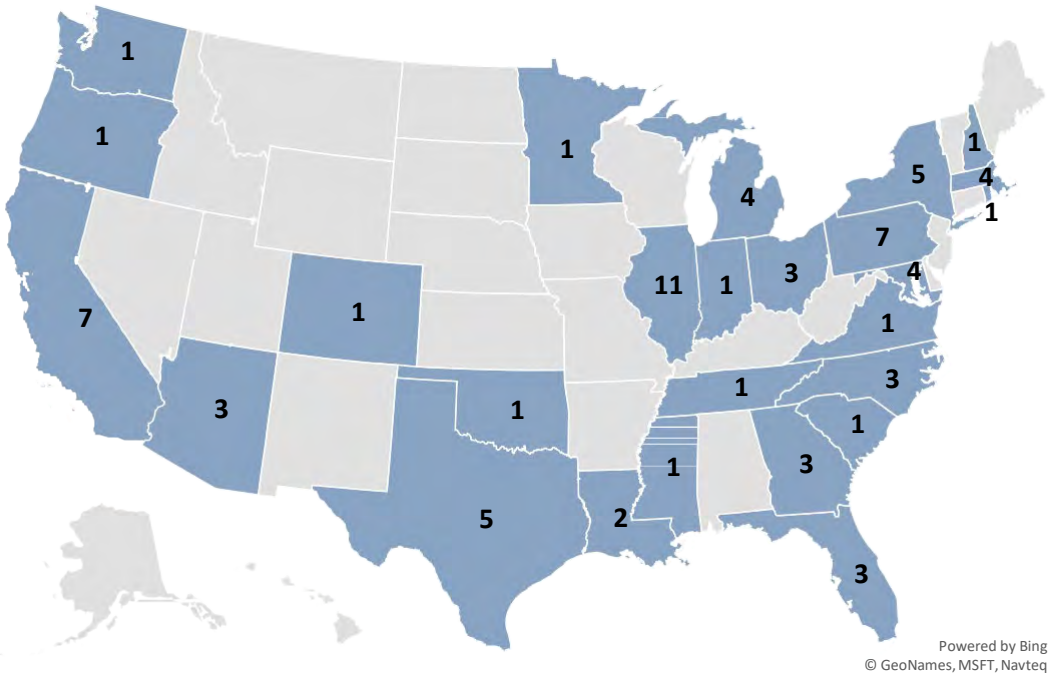


Medical Imaging Data Resource Center (MIDRC)
Rui Carlos Pereira de Sá, Ph.D.



DEBUT Design by Biomedical Undergraduate Teams Challenge

2021



76 applications from **47** universities in **26** states

~400 students engaged

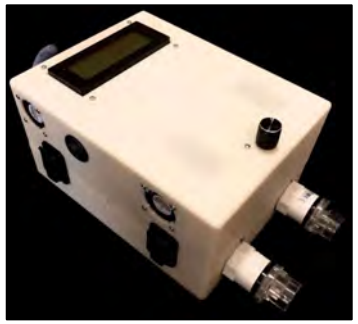
- NIH Total: $95k, VentureWell Total: $20k
  - NIBIB: Steven H. Krosnick 1st $20k, 2nd $15k, 3rd $10k
  - Office of AIDS Research: $15k
  - NIMHD: $15k
  - NCI (*new* in 2021): $15k

$115,000

- 6 additional states
  - Including IDeA states: MS, OK, NH
- Numerous multi-disciplinary teams
- Numerous multi-career level teams, i.e. frosh – senior
- One of the winning teams was all fresh(wo)men
- Holistic approaches to design, e.g. developing educational materials with the community the design team seeks to serve through their device.

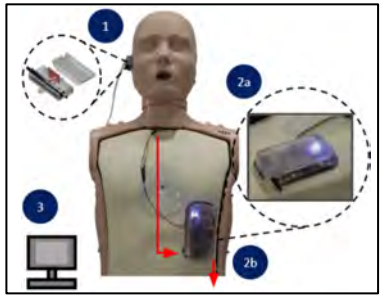
DEBUT Design by Biomedical Undergraduate Teams Challenge

https://www.nibib.nih.gov/news-events/newsroom/debut-challenge-awards-prizes-future-bioengineers



The Steven H. Krosnick Prize- $20,000 *(U of South Florida)*

Eucovent: A ventilator addon that allows multiple patients be ventilated with a single ventilator.



Second Place- $15,000 *(Rice University)*

Cephalopump: An assistive treatment device for low differential pressure hydrocephalus.

Third Place- $10,000 *(Columbia University)*

Eyephone: At-home glaucoma monitoring device with a low-cost VR application.

Award Ceremony

- Biomedical Engineering Society (BMES) Annual Meeting
- October, 2021; Virtual and In-person
- Dedicated parallel session featuring DEBUT winners

NIBIB Program Contacts: Zeynep Erim, Joan Greve

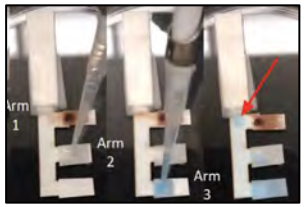
DEBUT Design by Biomedical Undergraduate Teams Challenge

https://www.nibib.nih.gov/news-events/newsroom/debut-challenge-awards-prizes-future-bioengineers

NIH National Institutes of Health Office of AIDS Research

HIV/AIDS Prize- $15,000 *(Texas A&M University)*

Direct Detection of HIV miRNA via SERS using a low-cost 3D printed device and gold nanoparticle-based sensing.



NIH National Institute on Minority Health and Health Disparities

Health Care Technologies for Low Resource Settings Prize- $15,000 *(Lehigh University)*

A low-cost, point-of-care lateral flow device for sickle disease in low to middle income countries.

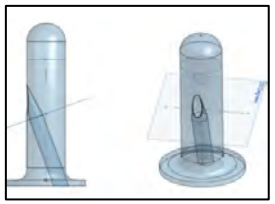
NIH NATIONAL CANCER INSTITUTE

Technologies for Cancer Prevention, Diagnosis and Treatment Prize- $15,000 *(Duke University)*

LowCostomy: An affordable colostomy bag for ostomy patients in low-resource settings

VentureWell, Venture Prize- $15,000 *(Georgia Tech)*

AusculBand: A powerful, yet affordable patient-facing electronic stethoscope that can be marketed at a significantly lower cost than the current competition.



VentureWell, Design Excellence Prize- $5,000 *(Stanford University)*

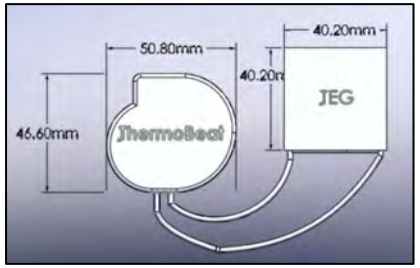
NeedleDelivery: A tool to facilitate transvaginal injection of medicine.

NIH National Institute of Biomedical Imaging and Bioengineering

VENTUREWELL idea to impact

DEBUT Design by Biomedical Undergraduate Teams Challenge

Honorable Mentions - $1,000

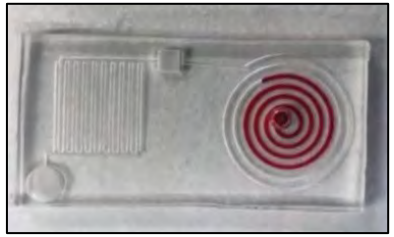


ThermoBeat *(John Hopkins University)*
Pacemaker battery that uses a temperature gradient to greatly extend battery life.

Iris - Concussion Dx
(University of Miami)
Concussion diagnostic tool that utilizes eye tracking.

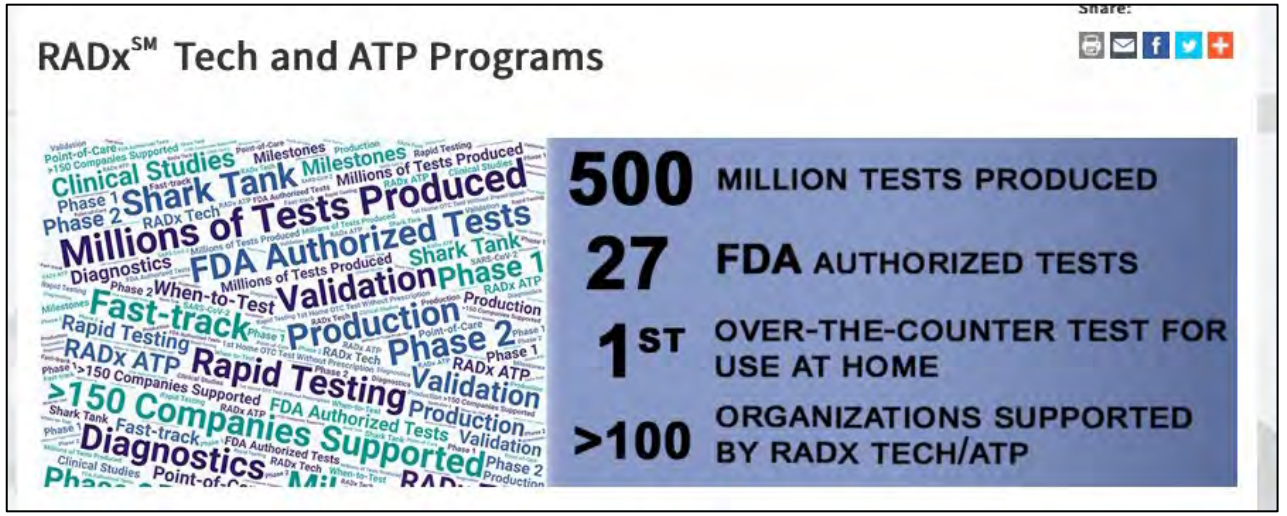
RoboSock *(Harvard College)*
Post-Stroke ankle rehabilitation device.

Coagulation Lab-on-a-Chip
(Western New England University)
Lab-on-a-chip blood clotting timed test.

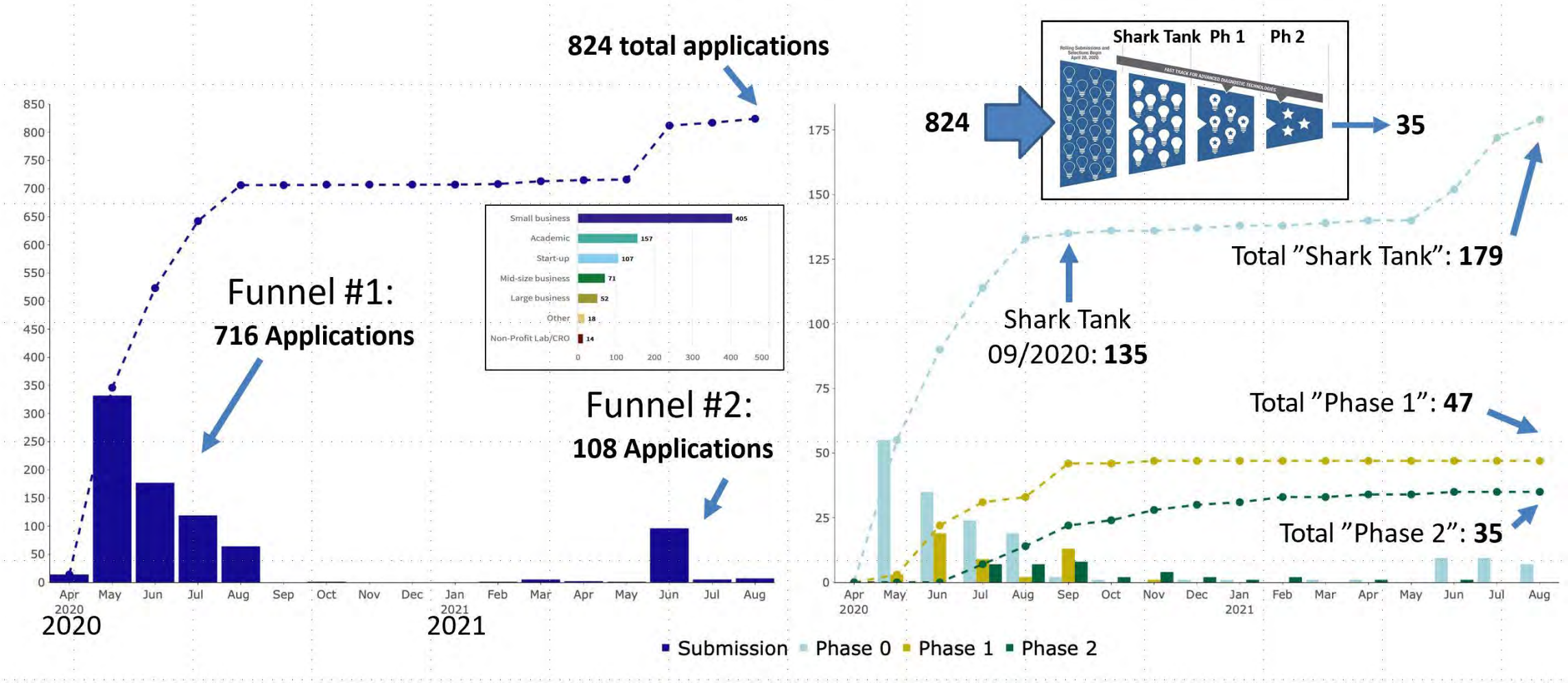


DuoPouch *(University of Minnesota – Twin Cities)*
A calibrated, two-pouch system to diagnose postpartum hemorrhaging.

RADx Tech: *Update*

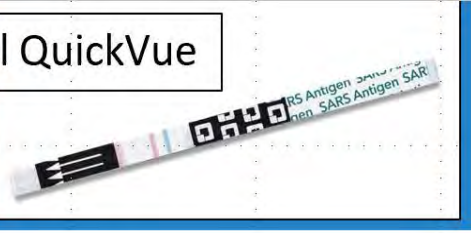


RADx Tech: *Innovation Funnel v2.0*



Mesa BioTech

Quidel QuickVue



Meridian

Quidel Sophia

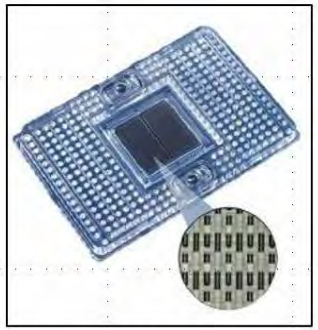
Genbody

Visby Medical

Quanterix Simoa

Ellume

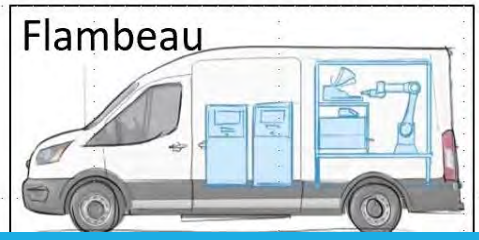
ANP



Fluidigm

Luminostics

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

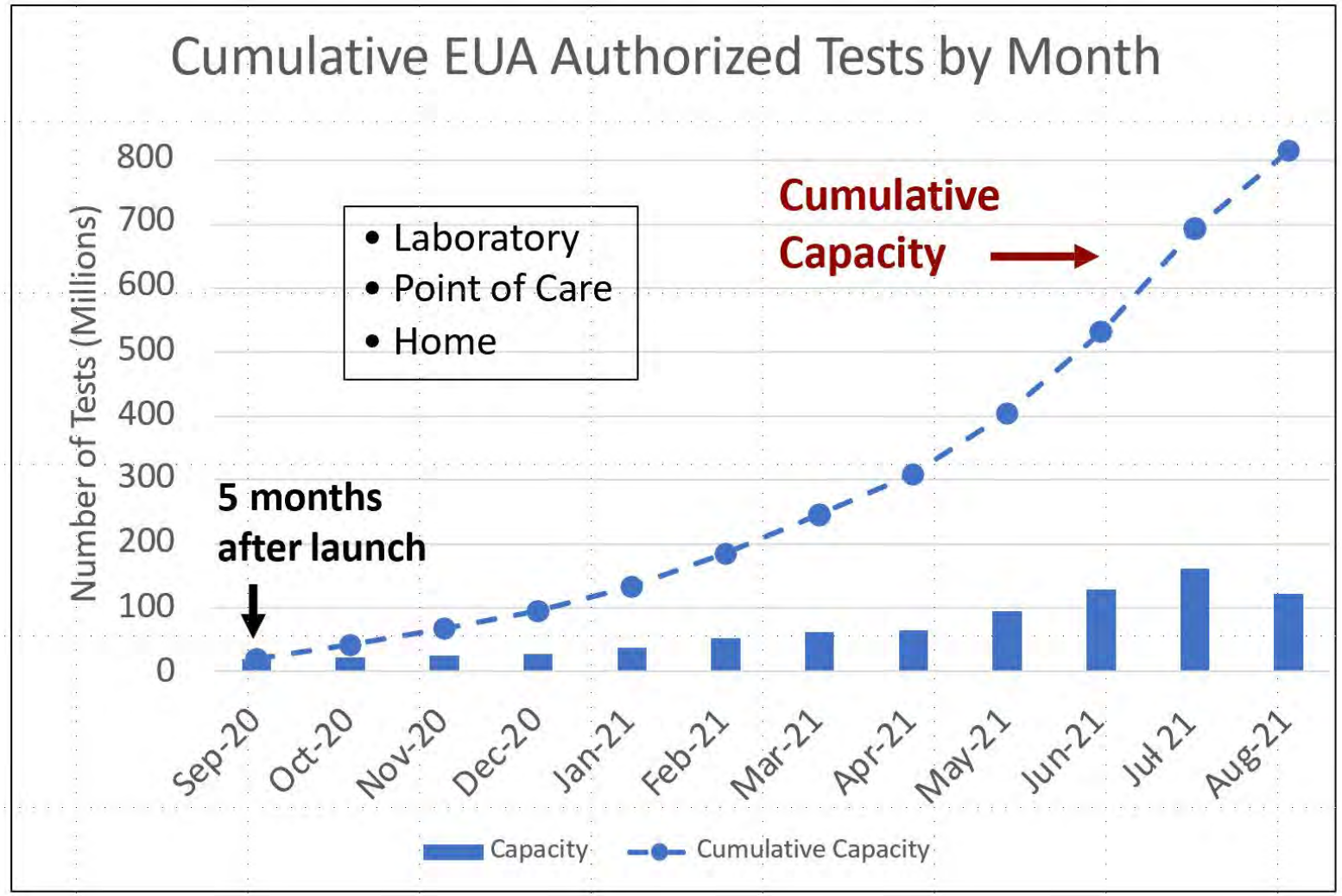
Home OTC

Home OTC

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

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

RADx Impact thru August 2021



Major Milestones

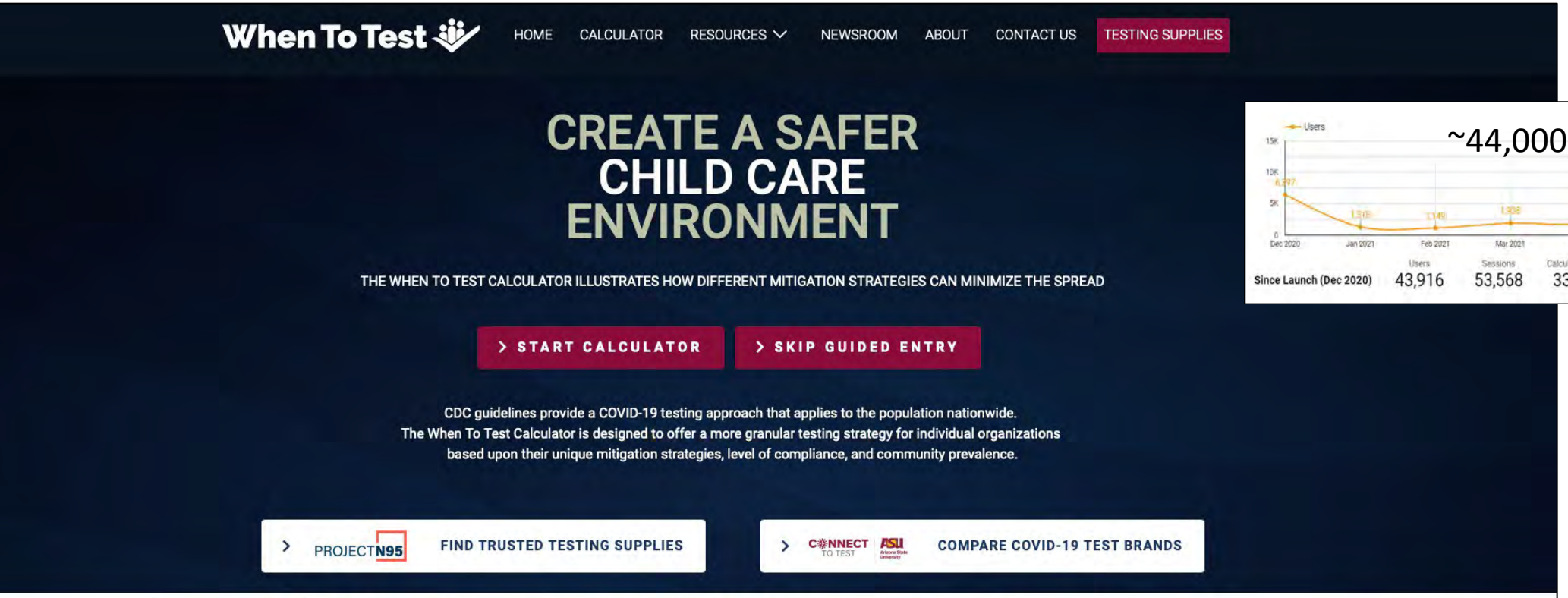
- **814.7 million capacity thru August 2021**
- ~4 M tests and products/day **August 2021**
- 28 EUAs; 1st OTC EUA, 3 "at home"
- >100 companies supported

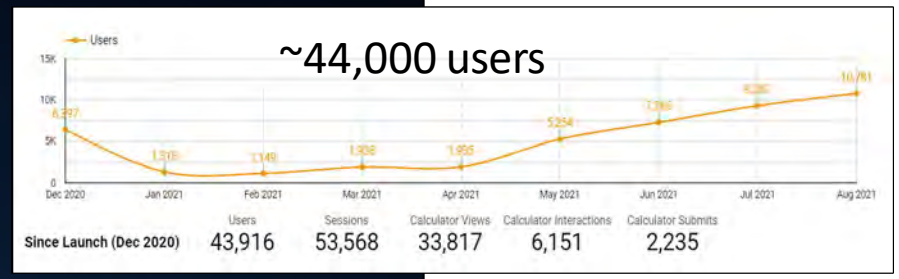
~$1.1 Billion: *Special Congress Authorization* (~$600M in Phase 2)

~1.3 Billion: *Private Capital Raised*

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

RADx Impact: *whentotest.org*





- **Vaccination rates**
- **R0 altered for Delta**
- **Pooling guidance**
- **K-12 playbook (CDC)**
- **Individual risk calculator (mid sept)**
- **Link purchase, guidance**

~2 million free tests

Pitt Co, NC; Hamilton Co, TN; Washtenaw Co, MI


Rachael Fleurance


Mike Lauer


Bill Riley

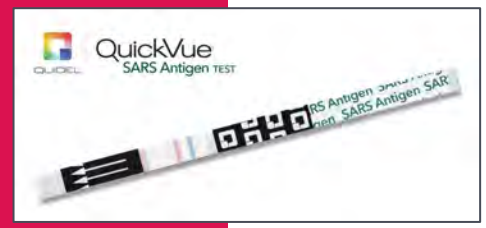
Assess ***efficacy*** and ***effectiveness*** of at-home testing 2-3 X/week

Outcome measures:

- SARS-CoV-2 prevalence and incidence
- % test positivity, volume
- 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 (MI, TN)



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

RADxUP

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

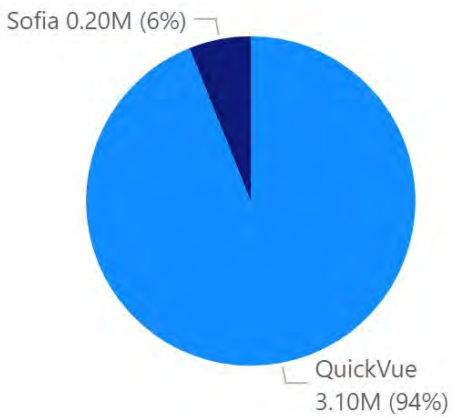
RADx Total Test Distribution

This report reflects tests purchased directly by NIH to support specified projects. Tests purchased separately by awardees are not shown.

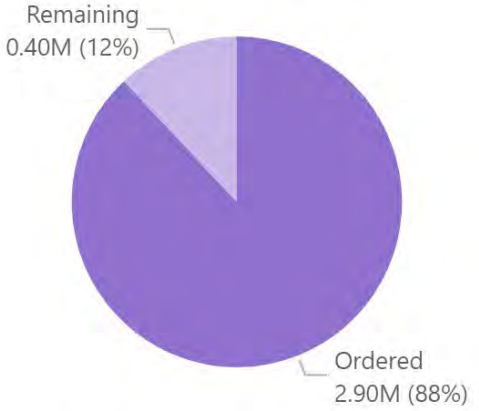
3.3M
Tests purchased

2.9M	395.3K
Ordered	Remaining

Tests Purchased



Tests ordered and remaining

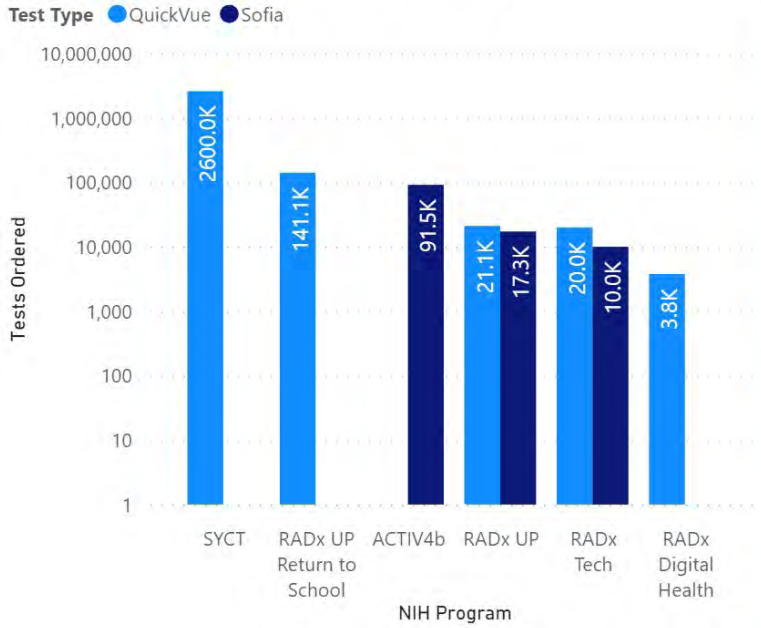


Remaining = Purchased - Ordered

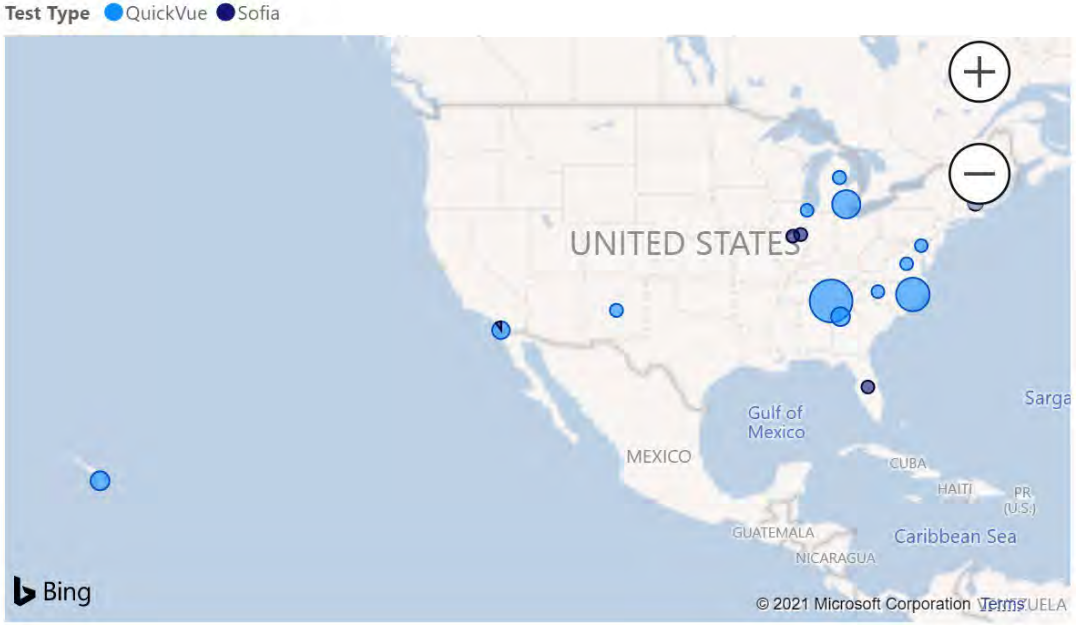
Awardee

- Activ Public / Private Partnership
- Duke University
- Johns Hopkins University
- Public Health Intervention
- Rush University
- San Diego State University
- U Massachusettes
- UIUC
- University of Chicago
- University of Hawaii
- University of New Mexico
- Vibrent Health

Tests Ordered by NIH Program and Test Type



Program locations

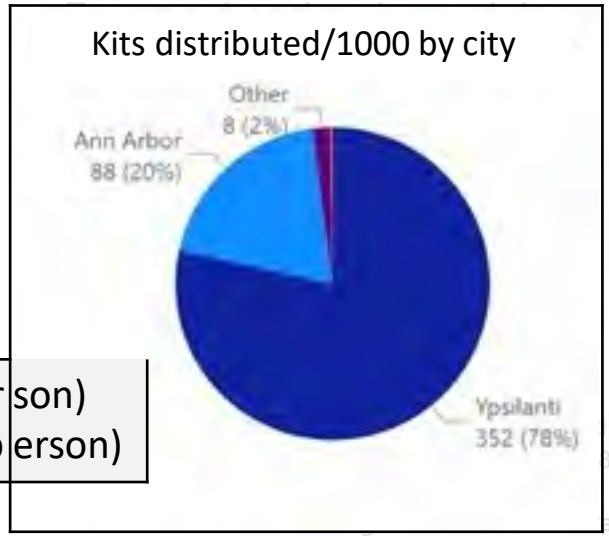


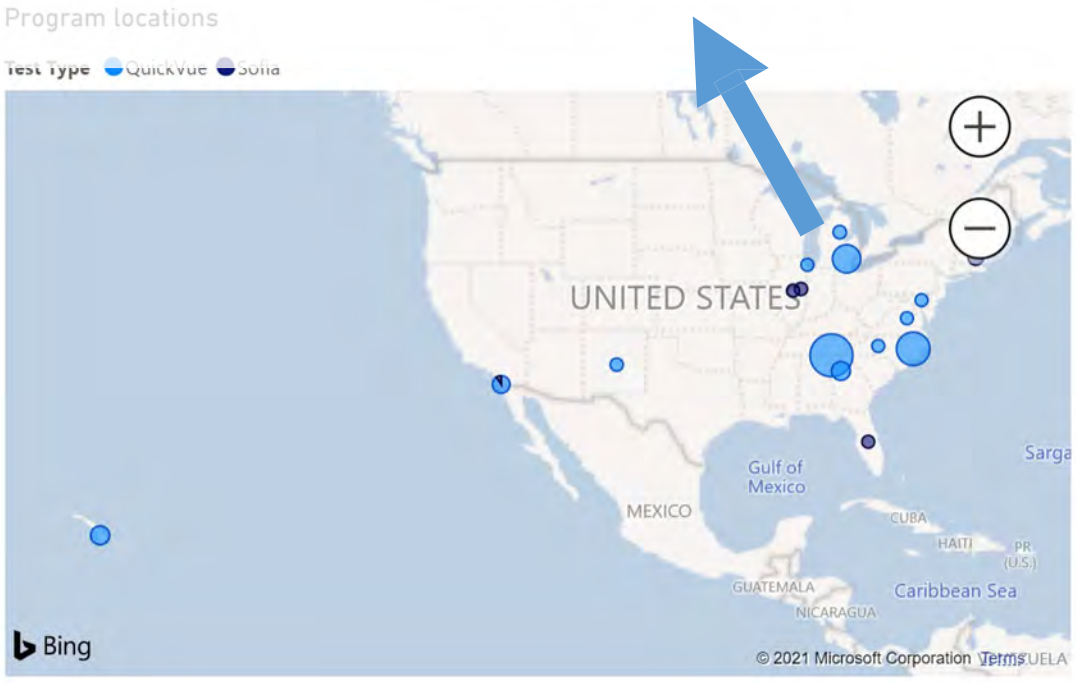
RADx Total Test Distribution

Hawaii, Georgia

- Up to 4 additional SYCT sites approved
- ~4 Million home/OTC tests
- Supported by WH pandemic testing board
- Partner with HHS surge teams

Ypsilanti (~8 tests/person)
Ann Arbor (~2 tests/person)

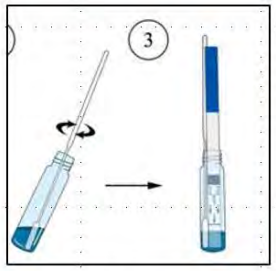




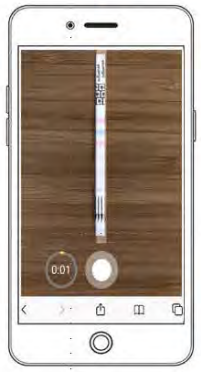
Digital Health Infrastructure


Andrew Weitz Krishna Juluru

RADx POC Test

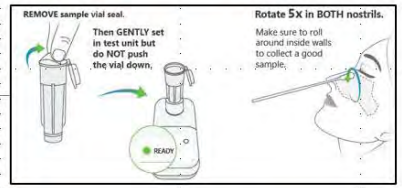


LFA

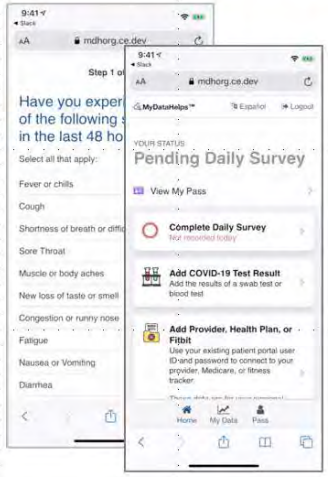


Cell Phone Reader

How to Use



Symptom Surveys



careevolution HEALTHCARE TECHNOLOGY

EHR & Claims

SYNC FOR SCIENCE

HL7 FHIR

Blue Button Download My Data

Need Standards

Need Standards

HealthIT.gov

APHL

State and Federal

Contact Tracing

Health status

e.g. VCI

RADx Variant Task Force *(est Jan 2020)*

RADx Team

Richard Creager
Eric Lai
John Blackwood
Mia Cirrincione
Dale Gort
Emily Kennedy
D'lynne Plummer
Thomas Pribyl
Adam Samuta
Megan Shaw
Brian Walsh

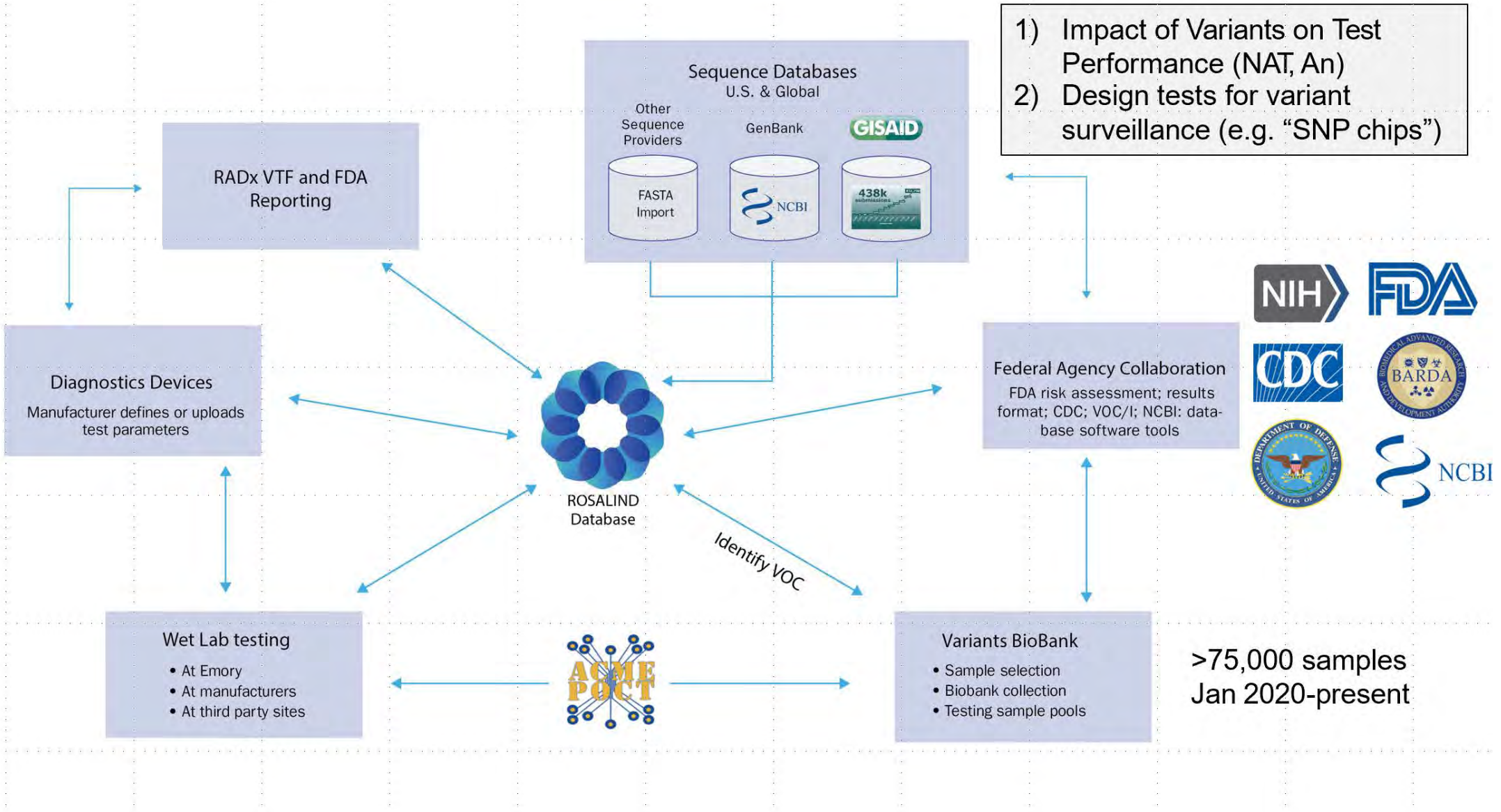
Emory

Leda Bassit
Filipp Frank
Morgan Greanleaf
Wilbur Lam
Cangyuan Li
Eric Ortlund
Anuradha Rao
Raymond Schinazi
Allie Suessmith
Julie Sullivan
Thomas Vanderford

Univ of WA

Alex Greninger

1) Impact of Variants on Test Performance (NAT, An)
2) Design tests for variant surveillance (e.g. "SNP chips")



>75,000 samples
Jan 2020-present

RADx Variant Surveillance: “SNP Chip”

RADx Team

Richard Creager
Eric Lai
John Blackwood
Mia Cirrincione
Dale Gort
Emily Kennedy
D’lynne Plummer
Thomas Pribyl
Adam Samuta
Megan Shaw
Brian Walsh

Emory

Leda Bassit
Filipp Frank
Morgan Greanleaf
Wilbur Lam
Cangyuan Li
Eric Ortlund
Anuradha Rao
Raymond Schinazi
Allie Suessmith
Julie Sullivan
Thomas Vanderford

Univ of WA

Alex Greninger

“Project Rosa”

ROSALIND GISAID NCBI

Helix, Thermo-Fisher, CDC

48 Markers:

1) Positivity of sample
2) Lineage (>95% sens and spec for all WHO variants)
3) Mutations of biological interest

Genotyping Validation (TaqMan, TF), 10k sample study, 4 weeks

Submit RADx FDA EUA: early/Mid-Nov

“SNP Chip” Advantages

Speed: no reflex, “real time” 1000s/day vs NGS ~4 weeks
Cost: CapX and price/test << NGS
Access: Adaptable to most labs: >50% vs 5% current NGS
Modify: New variant integration ~4-6 weeks

1) Impact of Variants on Test Performance (NAT, An)
2) Design tests for variant surveillance (e.g. “SNP chips”)

Ongoing Challenges

1) Reporting infrastructure

POLITICO

Inside America's Covid-reporting breakdown

Crashing computers, 3-week delays tracking infections, lab results delivered by snail mail: State officials detail a vast failure to identify hotspots quickly enough to prevent outbreaks

by ERIN BANCO
08/15/2021 07:00 AM EDT

Illustrations by Glenn Harvey

There were too many cases to count.

Covid-19 was spreading rapidly throughout the United States, as cold winter weather began to drive people indoors, but the Centers for Disease Control and Prevention was flying blind: The state agencies that it relied on

2) Insufficient screening, surveillance

Nearly 5 out of 6 coronavirus cases were undetected in pandemic's early months

LA Times, June 25, 2021

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

K. Sadtler et al. Sci. Transl. Med, June 22, 2021

Ongoing Challenges

Impact: ***Guidance and policy decisions made based on lagging and incomplete test data***

Innovation Funnel v2.0

Solutions:

- **Real-time COVID 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)*

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

Ongoing Challenges

RADx tests
SYCT progra

The Washington Post
Democracy Dies in Darkness

September 11, 2021

Health

How at-home coronavirus testing is becoming part of Biden's plan for managing the pandemic

A Pitt County Health Department worker passes out at-home coronavirus test kits April 21 in Greenville, N.C. (Melissa Sue Gerrits for The Washington Post)

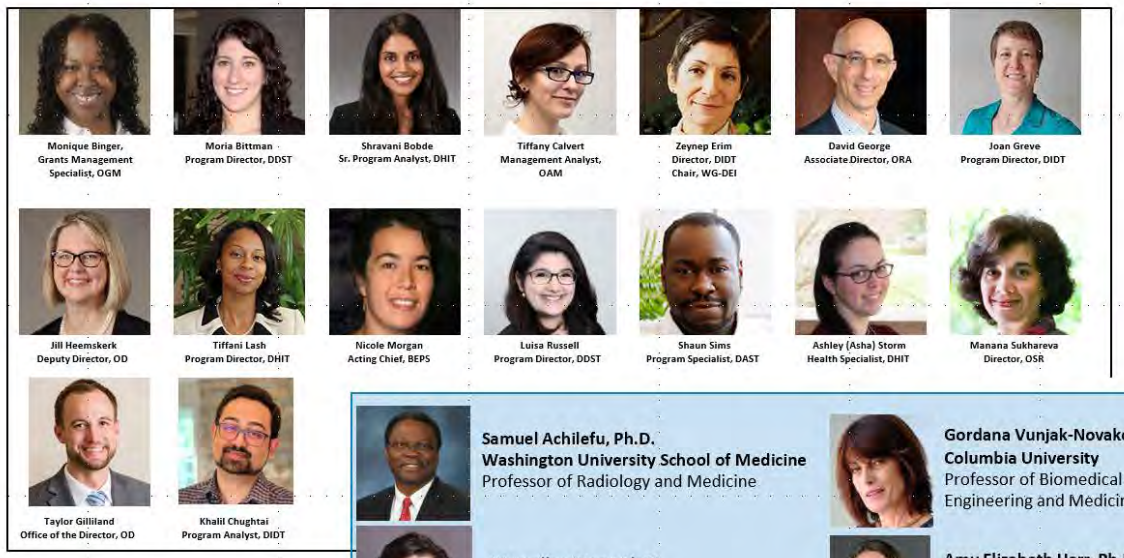
By Derek Hawkins and Fenit Nirappil

395

Work (OSHA): vaccine, weekly testing
Entertainment: show negative test
School: regular testing
Procurement: $2B OTC/POC tests, DPA
Retailers: sell OTC at cost, Medicaid reimbursement
Community: distribute OTC to high SVI regions
Pharmacy: Expand free POC to 10k

September 9. 2021

NIBIB: *National Advisory Council + Working Group*



Combined Working Group Meeting: August 30, 2021

- Center update
- Themes from May 2021 Council
- Landscape of current mechanisms
- New programs to fill gaps, expand

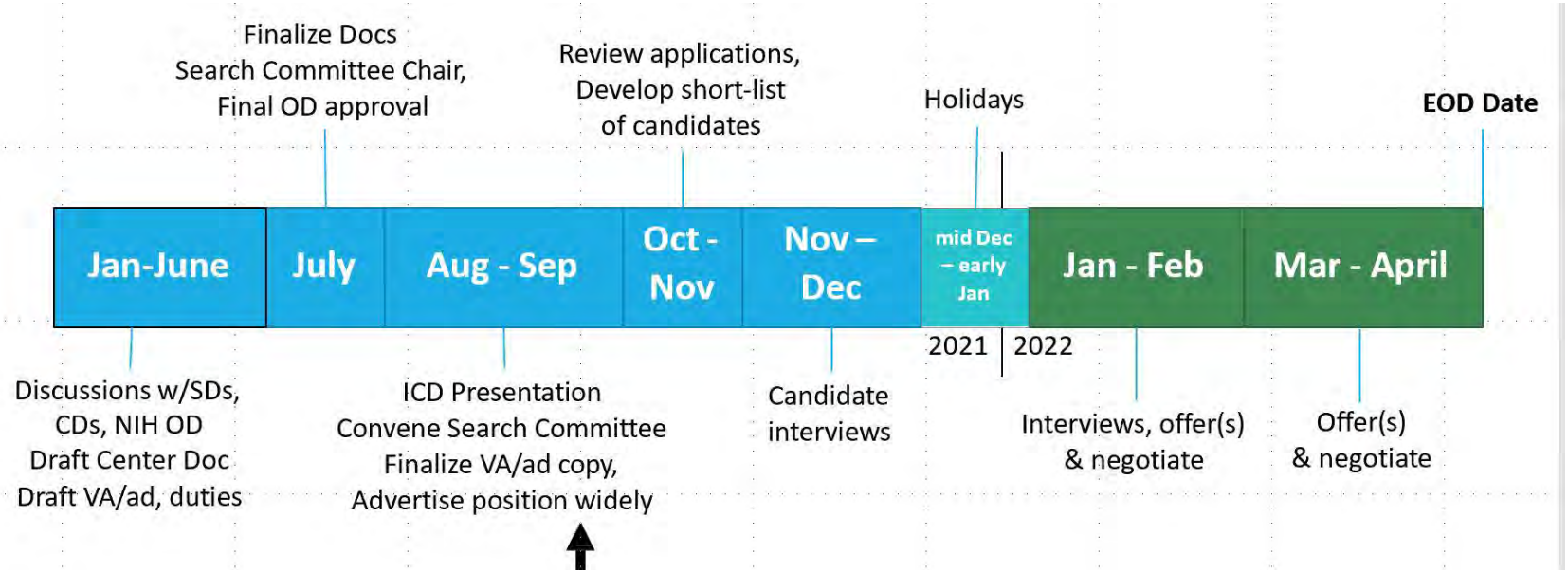
- Expand and Extend the pipeline/pathway
- Resources/training for students and researchers
- Grant review and funding considerations
- Improving outreach, including via social media
- Prizes (eventually certification)
- Connect to industry
- Connect to other agencies

βETA Center: *Director Search Committee*

βETA = *Biomedical Engineering & Technology Acceleration*

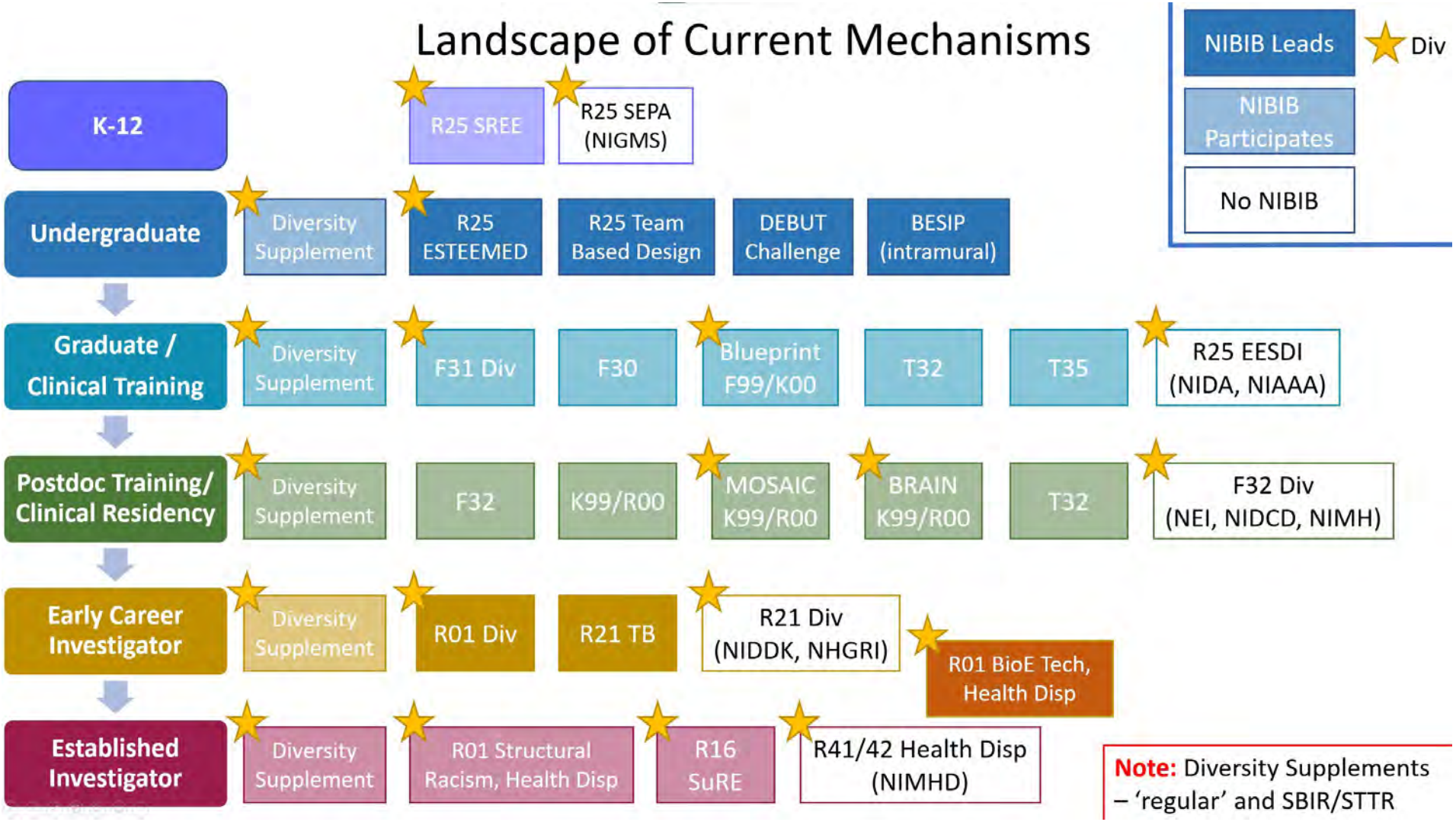
Dual position with NIBIB Associate Director for Scientific Diversity, Equity, and Inclusion

Griffin P. Rodgers, M.D., M.A.C.P.
Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK): *Committee Chair*



Search Committee Approved and Formed
Dr. Gilda Barabino, outside member

Landscape of Current Mechanisms



Update on FOAs to Address Workforce Diversity and Health Disparities

F31 Kirschstein NRSA Predoctoral Fellowship to Promote Diversity in Health-Related Research, PA-21-052	Due: Standard Dates… Dec, 2021, NIBIB Contact: joan.greve@nih.gov • NIBIB supports post quals, 2 years
K99/R00 Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Award to Promote Diversity, PAR-21-271	Due: Oct 27, 2021 NIBIB Contact: joan.greve@nih.gov ; Standard Dates • W/in 4 years of starting postdoc, citizenship requirement.
NEW! Support for Research Excellence **R16** SuRE, PAR-21-169 **R16** SuRE FIRST, PAR-21-173 **U24** SuRE Resource Center, PAR-21-227	Due: May, 2021-23; no current NIH funding, $125k/year, Due: Nov, 2021-23; Never had any NIH funding, $100k/year, NIBIB Contact: joan.greve@nih.gov Due: Sept, 2021 •Institutions that enroll significant numbers of students from backgrounds nationally underrepresented in biomedical research.
NEW! **R01** Impact of Structural Racism and Discrimination on Minority Health and Health Disparities, RFA-MD-21-004	Due: Aug 2021, Review: Nov 2021, Earliest Start: Apr 2022
NEW! NIBIB Leads **R01** New Investigators to Promote Workforce Diversity in Genomics, Bioinformatics, or Bioengineering and Biomedical Imaging Research, RFA-HG-21-041	Due: Feb 22, NIBIB Contacts: zeynep.erim@nih.gov, joan.greve@nih.gov • Early stage and new investigators
NEW! NIBIB Leads **R01** Bioengineering Technologies for Ending Health Disparities	• Concept Clearance May 2021 Council • Investigators