Director’s Report

National Advisory Council for Biomedical Imaging and Bioengineering

May 19, 2021

Bruce J. Tromberg, Ph.D.
Director
National Institute of Biomedical Imaging and Bioengineering
Thank you, Council Member Gordana!

Dr. Vunjak-Novakovic has completed her term, however, she has agreed to extend serving on NIBIB’s Advisory Council.

Dr. Gordana Vunjak-Novakovic  
*Columbia University*
New NIBIB Staff

Office of Program Evaluation and Strategic Partnership

Julia Ringel
Health Specialist
Tareq Al-Shargabi
Scientific Program Manager

Office of Information Technology

Donna Gregory
Intranet Redesign/Internal Communication Consultant
Stacey Warr
Administrative Assistant

Office of Financial Management

Shanna Frierson
Grants Data Analyst
Imran Omair
Financial Consultant
Naledi Simons
Budget Analyst

Office of Administrative Management

Sonca Hoang
Administrative Assistant
Leticia Noel
Administrative Assistant

Office of Science Policy and Communications

Karen Olsen
Writer

Extramural Science Program

Khalil Chughtai
Scientific Program Analyst- DIDT

Intramural Research Program

Djanira Murchison, Biologist (Molecular Tracer and Imaging Core)
Lale Esven, Staff Scientist (Immuno-Engineering Lab)
Budget Update

FY22 President’s Proposed Budget

- NIH - ~$51 billion (increase of ~$9 billion above FY21 level)
  - Includes $6.5 B for “ARPA-H”
- NIH – pending infrastructure bill: Vaccines, Therapeutics, Diagnostics
  - Additional 6 FY 21-26 support for specific projects
- House and Senate Appropriations Committee Hearing: 5/25 and 5/26
  NIBIB, NIMHD, NICHD, NIAID, NHLBI, NCI, NIDA
# NIBIB Funding FY20/21

<table>
<thead>
<tr>
<th>Projects</th>
<th>Allocation</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 20/21 Annual Appropriation</td>
<td>$815,366,000</td>
</tr>
<tr>
<td>Coronavirus Aid, Relief, and Economic Security (CARES) Act</td>
<td>$60,000,000</td>
</tr>
<tr>
<td>Paycheck Protection Program and Health Care Enhancement Act</td>
<td>$421,727,313</td>
</tr>
<tr>
<td>Coronavirus Response and Relief Supplemental Appropriations Act</td>
<td>$100,000,000</td>
</tr>
<tr>
<td>American Rescue Plan - IDDA</td>
<td>$147,080,643</td>
</tr>
<tr>
<td>Biomedical Advanced Research and Development Authority – IDDA</td>
<td>$238,795,044</td>
</tr>
<tr>
<td>RADxSM-Advanced Technology Program (ATP)</td>
<td>$230,000,000</td>
</tr>
<tr>
<td>Mitigating Threats of SARS-CoV-2 Viral Evolution</td>
<td>$20,000,000</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>$2,032,969,000</strong></td>
</tr>
</tbody>
</table>
## R01 Competing Awards

<table>
<thead>
<tr>
<th>Year</th>
<th>Competing R01 Awards</th>
<th>Payline (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>85</td>
<td>16%</td>
</tr>
<tr>
<td>2018</td>
<td>108</td>
<td>19%</td>
</tr>
<tr>
<td>2019</td>
<td>96</td>
<td>19%</td>
</tr>
<tr>
<td>2020</td>
<td>113</td>
<td>18%</td>
</tr>
<tr>
<td>2021</td>
<td>91</td>
<td>16%</td>
</tr>
</tbody>
</table>

### Payline Adjustments

- **2017**: 16%
- **2018**: 19%
- **2019**: 19%
- **2020**: 18%
- **2021**: 16%

### Annual Appropriation

<table>
<thead>
<tr>
<th>Year</th>
<th>Annual Appropriation</th>
<th>Appropriation Increase Over Prior Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>$356,981,000</td>
<td>$13,984,343</td>
</tr>
<tr>
<td>2018</td>
<td>$376,730,000</td>
<td>$19,749,000</td>
</tr>
<tr>
<td>2019</td>
<td>$388,113,000</td>
<td>$11,383,000</td>
</tr>
<tr>
<td>2020</td>
<td>$404,638,000</td>
<td>$16,525,000</td>
</tr>
<tr>
<td>2021</td>
<td>$410,728,000</td>
<td>$6,090,000</td>
</tr>
</tbody>
</table>

- **Lowest base increase in 5 yrs**
FY21 Financial Management Plan

Funding Plan Goals:
• Sustain number of competing R01 awards
• Protect Early-Stage Investigators (ESIs)

Policy changes:
Deeper administrative reductions for higher-cost competing awards
• 15% - R01s and U01s for established PIs with non-modular budgets
• 10% - P41s

Small reduction for non-competing awards
• 2% - R01s, U01s, P41s

Full details available at NIBIB Financial Management Site
Dr. Cato Laurencin Elected to National Academy of Sciences

- Dr. Laurencin was previous NIBIB grantee and Council Member
- First surgeon in history to be elected to the National Academy of Engineering, the National Academy of Medicine, the National Academy of Sciences, and the National Academy of Inventors.

Cato Laurencin, M.D., Ph.D. CEO, Connecticut Convergence Institute for Translation in Regenerative Engineering, UCONN Health
NIBIB’s Dr. Ranu Jung to be Featured on PBS

Dr. Ranu Jung, Ph.D.
Florida International University

- PBS’ Human: The World Within
  - Episode 6: React
    “...go deep into the universe of the most powerful machine on earth: the human brain and the vast nervous system it controls.”

- Dr. Jung will be discussing work from her grant, “Enhancing Sensorimotor Integration Using a Neural Enabled Prosthetic Hand System”

- Dr. Jung also recently received an Honorary Doctorate from Aalborg University, Denmark

June 2nd, 2021

Check out: Human: The World Within | PBS
You probably already know that some animals have the amazingly awesome ability to regrow their bodily tissues, like how lizards can grow new tails or sharks can replace their teeth. You probably also know that we humans, unfortunately, can’t do the same. Bummer!

But that’s not entirely true. Your body does heal tissue all the time, which is why a cut or bruise on your skin usually heals itself.

**Wonder Women of Science: How 12 Geniuses Are Rocking Science, Technology, and the World**
Ginger Rue & Tiera Fletcher (authors)
Sally Wern Comport (Illustrator)
Novel, complete, trustworthy datasets - ethically sourced, following FAIR principles, motivated by biomedical and behavioral grand challenges

Tools to accelerate the creation of data sets for AI/ML analysis (intelligent annotators, metadata-filling instruments)

Community evaluation of datasets -- culture change to embrace data preparation -- for AI/ML analysis

Interdisciplinary AI/ML-BioMed Community

Lead ICs: NIBIB, NEI, NLM, NHGRI, NCCIH

Data Generation Projects ROA – Just Published!
- $96M over 4 years
- 5-8 awards
- July 20, 2021: LOI Due
- August 20, 2021: Applications Due

NOITP: Integration, Dissemination, and Evaluation (BRIDGE) Center (U54)

Grand Challenge Team Building Activities

Bridge2AI Program Town Hall
June 9, 2021
2:00-3:30pm ET

Bridge2AI Data Generation Project Module Microlabs
June 14, 16, and 18, 2021
2:00-4:00pm ET each day

Bridge2AI Grand Challenge Team Building Expo
June 23, 2021
11:00am-5:00pm ET
The Blueprint MedTech program is an NIH incubator, inspired by RADx℠, that will accelerate the development of cutting-edge medical devices to diagnose and treat disorders of the nervous system.

Collaboration between 14 NIH Institutes and Centers plus OD.

Upcoming FOAs will support:
- U54 center to coordinate and manage program’s resources
- U18 projects to support development of human-grade medical device prototypes
- UG3/UH3 projects that support late-stage technology development/optimization and first-in-human clinical studies
- U44 projects to support late-stage technology development/optimization and first-in-human clinical studies in small businesses.

Four new NOITPs:
- NOT-EB-21-018
- NOT-EB-21-019
- NOT-NS-21-057
- NOT-DA-22-050

Estimated FOA & Due Dates: 07/15 and 10/20
Small Business Initiatives for Innovative Diagnostic Technology for Improving Outcomes for Maternal Health

**NOT-EB-21-001**
First Due Date: April 5, 2021

**Development of innovative technologies to quantitatively predict an increased risk for maternal morbidity and mortality (MMM)**

- Identification, phenotyping, subtyping, and stratification of patients at greater risk of MMM.
- Multi-level interventions to address racial disparities in MMM
- Clinical decision-making that considers social and cultural biases
- Wearable, point-of-care, portable, or clinical devices

Apply through the NIBIB SBIR website
[https://www.nibib.nih.gov/research-program/small-business-programs](https://www.nibib.nih.gov/research-program/small-business-programs)

Ilana Goldberg
NIBIB will sign back onto the Parent R21 Grant Program

After discussion with Council
NIBIB will sign back onto the R21 Parent Grant Program

- **NOT-EB-21-015** – Clinical Trail Required
- **NOT-EB-21-016** – Clinical Trail Not Allowed
  - Project duration- 2 years
  - Two-year budget $275,000 direct cost
  - Preliminary Data will be Allowed

Randy King, Ph.D.
Program Director
BRAIN Initiative Workshops

• Dissemination of Non-Invasive Imaging Technologies Workshop
  • February 18-19, 2021
  • A two-day virtual event with 25 presentations and over 200 on-line attendees.
  • Videos are available at:
    • Day 1: https://videocast.nih.gov/watch=40173
    • Day 2: https://videocast.nih.gov/watch=40174

• Transformative Non-Invasive Imaging Technologies Workshop
  • March 9-11, 2021
  • A three-day virtual event with 44 presentations and over 200 on-line attendees.
  • Videos are available at:
    • Day 1: https://videocast.nih.gov/watch=40182
    • Day 2: https://videocast.nih.gov/watch=40183
    • Day 3: https://videocast.nih.gov/watch=40184
Design by Biomedical Undergraduate Teams Challenge

**NIBIB Prizes**
- The Steven H. Krosnick Prize: $20,000
- Second Prize: $15,000
- Third Prize: $10,000
- HIV/AIDS Prize: $15,000
- Healthcare Technologies for Low-Resource Settings Prize: $15,000
- Diagnosis and Treatment Prize: $15,000
- 5 Honorable Mentions: $1,000 each

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

- Challenges undergraduate teams to design technology solutions to unmet health needs
- Ideation projects considered in addition to projects with Prototype
- Total of $115,000 in Prizes!
- Submission Deadline: June 1, 2021
- Winners Announced: August 25, 2021
- Award Ceremony: October 2021, BMES Conference

https://venturewell.org/debut/
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.

Infrastructure

- 5 Technology Development Projects
  - Data ingestion, data quality and harmonization

In parallel, AI/ML development
(12 Collaborative Research Projects)
24 algorithms developed /under development.
  - Segmentation of lung and lung opacities
  - Prediction of Covid-19 severity and length of hospital stay from multi-modal data (EHR and Imaging)

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

Access Data: https://data.midrc.org
A quiet healthcare revolution is taking place, driven by an urgent national need and fueled by cutting-edge technologies. Prior to the COVID-19 pandemic, in vitro diagnostic tests were primarily confined to laboratories, required days to return results, and were designed to evaluate the presence of disease in symptomatic individuals. Today, laboratory tests are just part of a diverse landscape of accurate, reliable, and accessible SARS-CoV2 tests, designed not just for detecting disease in individuals, but also for screening and surveillance in large populations. Diagnostics have changed, and more COVID-19 tests are now performed in point of care (POC) and home settings than in central labs. Looking forward, our goal is to leverage this unprecedented transformation into a new, modernized infrastructure that helps us realize the promise of personalized medicine, not just for COVID 19, but for the entire spectrum of pathogens and diseases.

Looking back on lessons learned

The Rapid Acceleration of Diagnostics (RADx) initiative was launched just one year ago to expand SARS-CoV2 testing capacity, performance, and access. As the 2020 quarantine dragged on for many, behind the scenes of RADx it seemed there weren’t enough hours in the day. All those hours dedicated by more than 900 individuals in government, academia, and the private sector have helped advise and support about 150 companies over the past year. Currently, 32 companies have progressed through the development pipeline to RADx.
Cumulative EUA Authorized Tests by Month

5 months after launch

Number of Tests (Millions)

Cumulative Capacity

Major Milestones

• ~300 million capacity thru April 2021
• ~2 M tests and products/day April 2021
• 23 EUAs; 1st OTC EUA, 2 “at home”
• >100 companies supported, 32 WP2 ($590M)
• June 2021: Project >5M tests/day

With FDA:
• Sequential use screening guidance An tests
• Pooling use guidance for POC PCR
• Pediatric use guidance for self swabbing

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

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

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

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

RADx Tech: April 29 Anniversary Event

Special Thanks to:

Katharine Egan  Raymond MacDougall
Thomas Johnson  Jessica Meade
Karen Olsen  Scott Kim
RADx Tech: Thank You!
May 17: Senate Appropriations Committee NIH Visit

RADx Tech: Under the Big Tent

Thank you for having us. Our country’s world-class research efforts and highly skilled @NIH personnel have helped solve incredible public health challenges this past year. Having the opportunity to learn more about this work up-close was informative and encouraging. @NIHDirector

NIH was honored to share results of taxpayers’ investment in COVID19 testing technologies with members of the U.S. Senate, including Senators @rogerMarshallMD, @joeyLankford, & @JohnBoozman.
Radical solutions

The US RADx program has spawned a phalanx of diagnostic products to market in just 12 months. Its long-term impact on point-of-care, at-home and population testing may be even more profound.

devices, loop-mediated amplification tests, paper-based diagnostics, rapid lateral flow assay (LFA) antigen tests, smartphone readers, next-generation sequencing (NGS) and machine-learning-assisted diagnostics—in a matter of months. This combination of RADx technologies, together with structural changes to healthcare during the pandemic, has the potential to radically change diagnostics, opening up the point-of-care (POC), at-home and community testing settings.

RADx was established by the NIH at the end of April 2020 as part of $5.3 billion appropriated for SARS-CoV-2 testing by US Congress in the Paycheck Protection Program and Health Care Enhancement Act. The US National Institute of Biomedical Imaging and Bioengineering established programs to build testing capacity for school and university re-opening (RADx Tech and RADx ATP), galvanize innovative diagnostic and surveillance development (RADx:Rad) and jump-start efforts to reach vulnerable and underserved populations (RADx-UP). By matching developers with experts from a pool of ~600 academicians, entrepreneurs and regulators, RADx aims to not only galvanize simultaneous development of assay and devices, but also parallelize performance assessment, regulatory interactions, manufacturing capacity and supply chain logistics to compress into a single year what is typically a five-year product development cycle.

To date, RADx has awarded a total of $520 million in grants (from a starting set of 716 applications)—complementing another ~$157 million in funding from the Biomedical Advanced Research and Development Authority. And, with the December passage of the Consolidated Appropriations Act, 2021 and signing of the American Rescue Plan Act of 2021 last month, another $71.55 billion was invested in SARS-CoV-2 testing—enough to make an impact on point e, at-home and population testing may be even more profound.

digital medicine increasingly intersects with diagnostics. Last month, another EUA was given to a Car. Health home test kit with a reusable cartridge reader and app, opening the door to repeat home testing.

This text has implications for low, low-income and remote populations. For example, as COVID-19 becomes endemic, handheld devices developed by Mesa Biotech or Mammoth Biologies could speed patient triage to emergency rooms, enabling rapid distinction among viruses causing respiratory infections, such as SARS-CoV-2, influenza A or B, and respiratory syncytial virus. Similarly, greater uptake of molecular tests in clinical microbiology can supersede culturing approaches carried over from the nineteenth century, returning lab results in minutes or hours rather than days.

But it is the $29.5 billion POC market (using trained personnel in physician offices and pop-up labs) and the massively underpenetrated-at-home-direct-to-consumer (DTC) market that seem likely to see the most change.

The RADx program is supporting numerous POC applications, including 14 PCR tests and 7 LFA antigen tests. The use of artificial intelligence for pattern recognition of test readouts and support received from non-experienced technicians in areas like ultrasound will also broaden market opportunities. Similarly, Medicare reimbursement for COVID-19 testing will drive test uptake, even if private payer coverage remains variable.

Post-pandemic, increasing use of telehealth and remote care is likely to further drive diagnostic access into community or home settings. In December, RADx awarded Ellume’s multiplexed quantum dot fluorescence test and smartphone app received Emergency Use Authorization (EUA) for home use. The app allows test data readout to be automated and returned to the physician or other provider, illustrating how home testing can be connected to the healthcare infrastructure as more people in remote settings lacking clinical infrastructure—although the digital divide remains a concern.

A final area where RADx has targeted funding is the use of NGS platforms as an early warning system for potential outbreaks. Surveillance can be used for spot sampling of surfaces, air, urban wastewater and long-haul flight waste. The use of sample pooling is likely to prove extremely useful in opening schools and screening employees. It will also galvanize testing for SARS-CoV-2 variants circulating in the population and enable test, trace and isolate efforts during community transmission.

These trends lead to an unexpected collision of previously disparate diagnostic realms. NGS already has a foothold in clinical settings, steering therapeutic interventions via multiplexed assays for cancer, infectious agents, antimicrobial resistance genes and microbiome profiling. If the slow of funding for surveillance bears fruit outside COVID-19, the divisions between public health surveillance and individual/patient-oriented clinical diagnostics may start to blur.

Overall, RADx has both radically shifted the funding available for innovative diagnostics and greatly foreshortened product development times. But it will all be for naught if the current outdated one-test, one-person paradigm isn’t exchanged for a robust infrastructure and rational reimbursement system that actually empowers community testing and diagnostic-led medicine. For too long, we have talked the talk of precision medicine. Now is the time to walk the walk.
• Intro to NIBIB Activities: Dr. Bruce Tromberg
• NIH and NIBIB Initiatives, Concept Clearance: Dr. Zeynep Erim
• Council DEI Working Group Discussion: Co-Chairs Drs. Gilda Barabino and Roderic Pettigrew
Advisory Council Working Group on DEI (September 2020)

- Recommend mechanisms and strategies to advance DEI and end structural racism in NIBIB extramural community.
- Provide recommendations for increasing NIBIB’s support of accessible technologies for ending health disparities

NIBIB Working Group on DEI

- Internal Working Group consisting of NIBIB staff from a variety of divisions/business areas to complement the Advisory Council WG
- Scope: NIBIB/NIH workforce and DEI initiatives for extramural institutions
NIBIB New Positions

Director, Center for Biomedical Engineering and Technology Acceleration, Associate NIBIB Director for DEI

- Senior Intramural Investigator, Molecular Imaging research program, Bioengineering Center Director
- Executive-level leadership, reports to NBIB director:
  1. Build Center for BME: lead Molecular Imaging Program, Engineering tech resource, CC Radiology Fellows; Collaborations within NIBIB, other ICs, and CC
  2. Provide guidance, leadership on DEI initiatives within NIBIB and the extramural community

Diversity Programs Leader

- Responsible for implementing NIBIB's DEI efforts, working group activities, and UNITE coordination
  1. NIBIB workforce
  2. NIBIB Extramural community
  3. All NIH ICs will hire and coordinate activities
NIBIB: National Advisory Council + Working Group

Working group meeting: May 3, 2021

Samuel Achilefu, Ph.D.
Washington University School of Medicine
Professor of Radiology and Medicine

Maryellen Giger, Ph.D.
University of Chicago
Professor of Radiology

Jennifer Kehlet Barton, Ph.D.
University of Arizona
Professor of Biomedical, Biosystems, Electrical & Computer Engineering

Simon Cherry, Ph.D.
University of California, Davis
Professor of Biomedical Engineering

Ranu Jung, Ph.D.
Florida International University
Professor of Biomedical Engineering

Gordana Vunjak-Novakovic, Ph.D.
Columbia University
Professor of Biomedical Engineering and Medicine

Amy Elizabeth Herr, Ph.D.
University of California, Berkeley
Professor of Bioengineering

Paula T. Hamond, Ph.D.
Massachusetts Institute of Technology
Professor of Engineering

Kathryn R. Nightingale, Ph.D.
Duke University
Professor of Biomedical Engineering

Bruce Rosen, M.D., Ph.D.
Harvard Medical School
Professor of Radiology

Gilda Barabino, Ph.D.
Olin College of Engineering
President, Olin College of Engineering
Professor of Biomedical & Chemical Engineering
Co-Chair Diversity, Equity, and Inclusion Working Group

Roderic Pettigrew, Ph.D., MD
Texas A&M University
Executive Dean, School of Medicine
Co-Chair Diversity, Equity, and Inclusion Working Group

Manu Platt, Ph.D.
Associate Professor, Biomedical Engineering
Georgia Tech
Diversity, Equity, and Inclusion Working Group

Greg Washington, Ph.D.
President, George Mason University
Diversity, Equity, and Inclusion Working Group
The NIH UNITE Initiative

Understanding stakeholder experiences through listening and learning

New research on health disparities/minority health/health equity

Improving the NIH Culture and Structure for Equity, Inclusion, and Excellence

Transparency, communication, and accountability with our internal and external stakeholders

Extramural Research Ecosystem: Changing Policy, Culture, and Structure to Promote Workforce Diversity

nih.gov/ending-structural-racism