NIBIB and the pandemic response: New opportunities for accelerating innovation from in vitro diagnostics (IVD) to medical imaging

Bruce J. Tromberg, Ph.D.
Director, National Institute of Biomedical Imaging & Bioengineering (NIBIB)
NIBIB Vision: *Engineering the Future of Health*

**Therapeutic Devices**

Monteris Medical, Inc.

**Imaging Technologies**

M. Garwood, UMN

**Engineered Biology**

Cambridge University

**Modeling, Computation & Machine Intelligence**

V. Venugopal, J. Spanier, UCI

https://www.nibib.nih.gov

**Sensors and Point of Care**

S. Xu, UCSD
NIBIB Funding

NIBIB Pandemic Response

1) Imaging and AI
2) In Vitro Diagnostics
3) Digital Health Platforms
NIBIB Funding

NIBIB Pandemic Response

1) Imaging and AI
2) In Vitro Diagnostics
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Medical Imaging and Data Resource Center (MIDRC)

Two-year, $20M contract: Medical Imaging/Data Science
Thoracic imaging and clinical data repository for COVID 19

1) Infrastructure: *Open Discovery Data Repository*
5 Technology Development Projects

Data ingestion, data quality and harmonization

- **Total ingested into MIDRC**: 62,595
- **Undergoing MIDRC Data Quality and Harmonization**: 52,127
- **Released by MIDRC**: 10,468

**Current MIDRC data (Chest Xray & CT)**

- Quality assessment
- Diversity assessment
- Sequestration - algorithm validation (FDA)

**Publicly available curated, high quality, diverse and representative imaging studies**

Access Data: [https://data.midrc.org](https://data.midrc.org)
1) Infrastructure: *Open Discovery Data Repository*
   - 5 Technology Development Projects

   - Data ingestion, data quality and harmonization

   - **Total ingested into MIDRC**
     - # of Imaging Studies: 62,595

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   - **Current MIDRC data (Chest Xray & CT)**

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2) AI/ML development
   - (12 Collaborative Research Projects)
   - >24 algorithms developed /under development.
     - Segmentation of lung and lung opacities
     - Prediction of 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](https://data.midrc.org)
MIDRC: Addressing Major Challenges

Geographic Distribution of Data to Train AI Algorithms


Judy W. Gichoya, et al. arXiv, 2021

Is radiology AI technology racist?
August 6, 2021 -- Artificial intelligence (AI) models can recognize a patient's racial identity on medical images, even though radiologists can't.

3 weeks ago

“...report all results by relevant clinical and demographic group...” => Need for representative dataset
Support Medical Imaging AI/ML
- High quality, representative, trustworthy data
- Culture of collaboration
- Promote standards, sharing, transparency, best practices
- Lower barrier of access

Accelerate translation of AI/ML
- Real-world quantification of algorithm performance (sequestered dataset)
Rapid Acceleration of Diagnostics (RADx Tech)

1) Imaging and AI
2) In Vitro Diagnostics
3) Digital Health Platforms
RADx: Unexpected Opportunity

NIH Office of the Director

RADx Tech – $500M
 Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19

RADx Advanced Technology Platforms (RADx-ATP) – $230M
 Rapid scale-up of advanced technologies to increase rapidity and enhance and validate throughput – create ultra-high throughput machines and facilities

RADx Radical (RADx-Rad) – $200M
 Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing

RADx Underserved Populations (RADx-UP) – $500M
 Interlinked community-based demonstration projects focused on implementation strategies to enable and enhance testing of COVID-19 in vulnerable populations

NIH Office of the Director
Francis Collins Rachael Fleurance Larry Tabak Tara Schwetz

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

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

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

Jill Heemskerk Bruce Tromberg

$307 M Partnership

>12 NIH Institutes, Centers, and Offices

https://www.nih.gov/research-training/medical-research-initiatives/radx
NIBIB Point of Care Tech Network: NHLBI, NIAID, NCCIH, FIC, OBSSR, OAR, ODP

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

https://www.poctrn.org

RADx: Leverage Existing Network (POCTRN)

Operations:
- Review & Fund
- Test & Validate
- Expert Guidance

GaTech/Emory
- Engineering
- Design/Prototype
- Clinical Validation
- Biobank samples
- In-Home Validation

Johns Hopkins
- Public Health/STD
- Global Health
- Clinical Validation
- Biobank samples
- Validation in LMICs

CIMIT/MGH
- Coordinating Center
- Collaboration/Management Platform
- Business/Commercialization

Northwestern
- HIV/AIDS
- Engineering
- Global Health
- Clinical Validation
- Validation in LMICs

UMass
- Heart, lung, blood
- Engineering
- Clinical Validation
- Biobank samples
- Clinical Trials
- Business/Commercialization

Validation Core
- >70 projects complete,
  >3000 participants

Clinical Studies Core
- Standard Trial Design, Digital Health Platform,
  Single IRB, Center Network

Deployment Core
- Supply chain, Manufacturing,
  User Community, whenotest.org
  ASU testing common
  Project N95

Todd Merchak  Tiffany Lash
RADx: Tech Innovation Funnel Process

NATIONAL CALL FOR INNOVATIVE TECHNOLOGIES

PHASE 0: "Shark Tank" Like Rapid Selection Process

PHASE 1: Validation and Risk Review

PHASE 2: Clinical Tests, Regulatory Approval, and Scaling Up

END OF SUMMER/FALL 2020

Rolling submission open April 29

~3000 Applications Started

~$600M

Funnel 1 May 2020: 3.5 mos.
Funnel 2 June 2021: 1 month

Projects in each Phase

Small business 1457
Academic 107
Start-up 72
Mid-size business 52
Large business 18
Other 14
Non-Profit Lab/CRO 0

Innovation, entrepreneur community

Validation, Clinical Testing, Regulatory, Manufacturing, Distribution
Cumulative EUA Authorized Tests by Month

- Laboratory
- Point of Care
- Home

5 months after launch

Major Milestones

- 815 million capacity thru August 2021
- ~4 M tests and products/day August 2021
- 31 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

Impact: National Policy

The Washington Post  September 11, 2021

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

RADx tests
SYCT program

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

https://sayyescovidtest.org
https://whentotest.org
The biomedical research ecosystem has delivered advances that not long ago would have been inconceivable, exemplified by highly effective COVID-19 vaccines developed in a year. The United States stands at a moment of unprecedented scientific urgency, and it is challenged to act. What must we do to accelerate the pace of research to transform medicine and heal that end?President Biden recently proposed to create a new entity, the Advanced Research Projects Agency for Health (ARPA-H), within the National Institutes of Health (NIH) to develop breakthroughs that prevent, detect, and treat diseases such as Alzheimer’s, diabetes, and cancer. $3.5 billion in the fiscal year 2022.

The idea is inspired by the Advanced Research Projects Agency, which follows a flexible and agile approach, underpinned by the possibility of significant returns, and has driven breakthroughs for the Department of Defense (DOD) for more than 60 years. To design ARPA-H, it is critical to understand what is working well

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

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 scale 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-driving cars. These ideas all share a common thread: they are bold, fundamental, and entirely "use-driven." This is not the same as curiosity-driven research. DARPA's approach is to fund these ideas by giving them a practical goal and ensuring that the resources are deployed in a way that makes them a success. ARPA-H could adopt a similar approach to transform medicine and health.
On August 13, 2021, NIBIB participated in a listening session with stakeholders on the proposed Advanced Research Projects 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 Physicians in Medicine to discuss the benefits of ARPA-H to advance biomedical engineering 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 Schwartz, Assistant Director for Biomedical Science Initiatives, OSTP
- Dr. Eric Green, Director, NHGRI
- Dr. Bruce Tromberg, Director NIBIB
- Dr. Paul Brennan, Director NHLBI

Stakeholder comments:
- Dr. Rachael Berman, Chief Executive Officer, American College of Medical Genetics
- Dr. Gail Javrick, President AMIA, American Society for Medical Informatics
- Dr. Jillian 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. David Boulard, President- Elect, American Association of Physicians in Medicine
- Dr. Greeten Purcell Jackson, ARPA-H Board Chair-Pres/President-Elect, American Medical Informatics Association
- Dr. Teter S. S. CEO & Public Affairs and Policy Committee, and US Department of Agriculture, Agricultural Research Service, International Society for Computational Biology
- Dr. Kristine Alis, President, Medical Library Association

ARPA-H Statement:
- ARPA-H Statement

Watch a video cast of ARPA-H Listening Session 9:
- ARPA-H Listening Session 9

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

Stakeholder Statements

Dr. Mitchell Schnall, Academy for Radiology and Biomedical Imaging Research
- ARPA-H Statement

Dr. Tejal Desai, American Institute for Medical and Biological Engineering
- ARPA-H Statement

Dr. Daniel Bourland, American Association of Physicians in Medicine
- ARPA-H Statement

American Institute for Medical and Biological Engineering

American Association of Physicians in Medicine
New Opportunities: IVDs to Medical Imaging

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 community testing may be even more profound.

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 community testing may be even more profound. Over thepast year, the US National Institutes of Health (NIH) Rapid Acceleration of Diagnostics (RADx) program has invested hundreds of millions of dollars into the development of new diagnostic products. However, the promise of RADx is being made available for testing, contact tracing, surveillance and containment in the coming year.

These are eye-popping numbers, especially when one considers that the entire global market for clinical diagnostics in 2020 was $29.5 billion. Now is the time to walk the walk.

Call to action...

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 outmoded diagnostic-led 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 is not a time for joust, to...