Bioengineering for COVID-19

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Director, National Institute of Biomedical Imaging & Bioengineering (NIBIB)
Bioengineering for COVID-19

NIBIB Strategy

1) Imaging and AI
2) Digital Health Platforms
3) Diagnostic Test Technologies
Two-year, $20M contract: Medical Imaging/Data Science

Thoracic imaging and clinical data repository for COVID-19

Develop, validate ML/AI for detection, diagnosis, Tx

60,000 curated COVID-19 chest radiographs and CTs+clinical data

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)

Operational

Access Data: https://data.midrc.org
RADx: Unexpected Opportunity

NIH Office of the Director

Francis Collins  Rachael Fleurance  Larry Tabak  Tara Schwetz

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

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

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

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

Jill Heemskerk, Bruce Tromberg

$307 M Partnership

https://www.nih.gov/research-training/medical-research-initiatives/radx
Point-of-Care Technologies Research Network (POCTRN)

NIBIB National Network: NHLBI, NIAID, NCCIH, FIC, OBSSR, OAR, ODP

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

https://www.poctrn.org

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

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

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

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

Validation Core
>60 projects complete,
>2000 participants

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

Deployment Core
Supply chain, Manufacturing,
User Community,
whentotest.org solutions

Todd Merchak  Tiffany Lash
RADx Tech Innovation Funnel

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

5-6 Months

~3000 Applications Started

Rolling submission open April 29

Projects in each Phase

716

140

47

33

~$590M

Validation, Clinical Testing, Regulatory, Manufacturing, Distribution

DEPLOY MILLIONS of tests per week

Validation, Clinical Testing, Regulatory, Manufacturing, Distribution

NIH

National Institute of Biomedical Imaging and Bioengineering

Innovation, entrepreneur community

Small business 353
Academic 153
Start-up 90
Mid-size business 51
Large business 38
Other 18
Non-Profit Lab/CRO 13
RADx Impact thru April 2021

Cumulative EUA Authorized Tests by Month

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

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

Nano applications to RADx-Tech

Images from Chudasama et al., Chemical Science 2016, Lim et al., Nanoscale 2015, Wikipedia

RADx-Tech Applications and Funded Proposals

112 Total Nano: ~16% of total
26 Funded Nano: ~18% of phase 2
57M tests w/nano produced thru April

WP2 = ★

Quantum Dots on the shelves at CVS
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)


**SAY YES!**

**COVID TEST**

JOIN THE FREE AT-HOME TESTING CHALLENGE

RADx UP

NIH | National Institutes of Health
---|---
Duke Clinical Research Institute | UNC School of Medicine
CDC | Center for Health Equity Research
New Infrastructure: Personal and Public Health

- RADx POC Test
- Wearables
- Symptom Surveys
- How to Use
- Cell Phone Reader
- e.g. OpenRDT (Audere)
- Data Hubs
- State and Federal
  - Contact Tracing
  - Health status
- PCR
- LFA
- EHR & Claims
- HLR FHIR
- Need Standards
- Need Standards
- Data Hubs
- e.g. VCI
- https://vaccinationcredential.org

Contact Tracing Health status

NIH National Institute of Biomedical Imaging and Bioengineering
Andrew Weitz Krishna Juluru
RADx and MIDRC: *New process for acceleration and impact*
- Leverage existing networks w/added capabilities for evaluation, validation, funding
- Connect with partners to meet regulatory, policy, and deployment goals

**Nano: Tech, materials, manufacturing huge drivers of RADx**
- ~15-20% of total RADx investment, # of applications, cumulative test capacity
- Tech de-risked, validated, accelerated to market

**Diagnostic Technology future**
- Leverage semi-conductor & telecom w/nano-tech and biomaterials
- Multiplexed tests with other pathogens, variants, diseases