The NIH Rapid Acceleration of Diagnostics (RADx) Initiative

How you can tap into a share of this $500M for COVID-19 diagnostics development

May 14, 2020
OVERVIEW

- Learn about the ACME POCT, POCTRN, and their roles in RADx
- Define motivation, rationale, and goals for RADx
- Q&A

Use the Q&A feature for all questions
TODAY’S PANEL

Wilbur Lam, MD, PhD
ACME POCT, Principal Investigator
W. Paul Bowers Research Chair & Associate Professor; Department of Pediatrics & Wallace H. Coulter Department of Biomedical Engineering, Chief Innovation Officer; Pediatric Technology Center at Children’s Healthcare of Atlanta and Georgia Institute of Technology

Greg Martin, MD, MSc
ACME POCT, Principal Investigator
President-Elect, Society of Critical Care Medicine; Professor of Medicine; Emory University School of Medicine, Executive Associate Division Director; Division of Pulmonary, Allergy, Critical Care, and Sleep Medicine

Oliver Brand, PhD
ACME POCT, Principal Investigator
Director; Institute for Electronics and Nanotechnology at the Georgia Institute of Technology, Professor, School of Electrical and Computer Engineering

Stacy Heilman, PhD
ACME POCT, Technology Training and Dissemination Core Assistant Professor, Emory University Pediatric Research Operations Director Emory University & Children’s Healthcare of Atlanta

Erika Tyburski, BS
ACME POCT, Director of Operations; Sanguina, Inc., CEO
THE NIH’S POINT-OF-CARE TECHNOLOGIES RESEARCH NETWORK (POCTRN)

- Assessment of clinical and user needs to inform device design
- Evaluation of POC devices for performance and potential for clinical impact
- Completion of clinical testing to facilitate translation and commercialization
- Training and education of relevant stakeholders in the development and utilization of POC technologies
- Development of partnerships with industry and other stakeholders to facilitate commercialization

POCTRN Coordinating Center: Consortia for Improving Medicine with Innovation & Technology (CIMIT) at Harvard

The Center for Advancing Point of Care in Heart, Lung, Blood and Sleep Diseases (CAPCAT) at U Mass

The Center for Innovation in Point of Care Technologies for HIV/AIDS at Northwestern

Center for Point-of-Care Technologies Research for Sexually Transmitted Diseases at Johns Hopkins

Atlanta Center for Microsystems Engineered Point-of-Care Technologies (ACME POCT) at Emory/Georgia Tech/Children’s
The ACME POCT’s Mission

The ACME POCT is focused on the development and translation of microsystems-engineered technologies including microchip-enabled devices such as microelectromechanical systems (MEMs)-based sensors, microfluidics, and smartphone-based systems.

The mission of the ACME POCT is to assist and enable inventors from all over the country who have developed or are developing microsystems-based POC technologies to define their clinical needs, conduct clinical validation, and refine their technology with the objective of accelerating the path to translation and clinical adoption.

Funded by National Institute of Biomedical Imaging and Bioengineering (NIBIB)
Georgia Tech – Institute for Electronics and Nanotechnology

Micro/Nanofabrication and Characterization Core Facilities

≈ 200 installed fabrication/characterization tools
≈ 30 technical staff members + 150 faculty experts
≈ 1,000 core facility users per year
  (85% internal, 15% external from academia & industry)

Member of NSF-funded National Nanotechnology Coordinated Infrastructure
The Georgia CTSA is focused on accelerating the translation of laboratory discoveries into healthcare innovations for patients by supporting Emory University, Morehouse School of Medicine (MSM), the Georgia Institute of Technology (Georgia Tech), and the University of Georgia researchers and their partners.

Resources include:

**Discovery**
- Statewide Network of Adult and Pediatric Clinical Research Sites
- Pilot Grants & Research Technologies

**Education and Training**
- Master of Science in Clinical Research
- KL2
- TL1
- Certificate Program Translational Research

**Expertise, Problem Solving, and Ancillary Support:**
- Biostatistics
- Epidemiology
- Research Study Design
- Biomedical Informatics
- Participant Recruitment & Special Populations
- Clinical Study Start-Up and Closeout
- Ethics
- Technology Transfer
- Community Engagement
- Regulatory Knowledge
- Innovation Catalyst
ACME POCT CENTER CORES AND LEADERSHIP

Administrative (Core 1)
Wilbur Lam, Oliver Brand, Greg Martin, Erika Tyburski
oversee the overall operations of our Center

Technology Development (Core 2)
Oliver Brand, Wilbur Lam, David Gottfried
evaluate and support technological microsystems-based
development/refinement of the selected projects
leveraging IEN facilities, faculty, and staff

Clinical Translational Validation (Core 3)
Greg Martin, Wilbur Lam
comprise clinicians and biostatisticians affiliated with
the Georgia CTSA and will guide clinical validation,
usability, and feasibility testing of microsystems-based
POC diagnostics for those clinical subspecialties

Technology Training and Dissemination Core (Core 4)
David Ku, Stacy Heilman, Eric Nehl, Sathya Gourisankar
will conduct assessments of clinical/user needs and will develop cross-disciplinary training
activities for all stakeholders (clinicians, microsystems engineers, POC
technology developers, patients, general public) and broadly disseminate lessons and best
practices learned
ACME POCT SEED GRANT PROGRAM – YEAR 1 & YEAR 2 PROJECTS

- **Auscultech Dx, LLC**
  - Mobile phone stethoscope

- **RePreDx**
  - Detection of heart failure
  - Detection of normal

- **ThrombusCheck**
  - A diagnostic device to personalize medication for heart patients

- **UC Irvine**
  - XHale Patch & XStolic Patch
  - Band Aid-like Sensors for Continuous Vital Signs

- **ResonanceDx**
  - Creatinine Sensor
  - for Kidney Function

- **Aptitude Medical Systems**
  - TrueFib Fibrinogen Sensor
  - for Coagulopathy Detection

- **Seismowatch**
  - Cardiovascular screening & management

- **Cytovale**
  - Microfluidic Sepsis Detection

- **ACME POCT SEED GRANT PROGRAM – YEAR 1 & YEAR 2 PROJECTS**

- **RePreDx**
  - Detection of heart failure
  - Detection of normal

- **Aptitude Medical Systems**
  - TrueFib Fibrinogen Sensor
  - for Coagulopathy Detection
AND THEN THINGS CHANGED…

BEFORE COMMON ERA (BCE)      COMMON ERA (CE)
AND THEN THINGS CHANGED…
An accelerated and comprehensive multi-pronged effort by NIH to make SARS-CoV-2, the virus that causes COVID-19, testing readily available to every American.

Supports development and commercialization of innovative technologies to significantly increase the U.S. testing capacity for SARS-CoV-2 up to 100-fold above what is achievable with standard approaches.

Structured to deliver innovative testing strategies to the public as soon as late summer 2020 to provide the information needed to make decisions about returning to normal activities and to help reduce the risk of future outbreaks.

RADx supports innovative approaches that introduce new test platforms as well as strategies for solving problems that limit current tests.

The NIBIB is urgently soliciting proposals, on a rolling submission process, and can provide up to $500M across multiple projects to rapidly produce innovative SARS-CoV-2 diagnostic tests.
Rapid Acceleration of Diagnostics (RADx)

- RADx is specifically for **diagnostics that test for the presence of the SARS-CoV-2 virus, not serology/immunity**

- Development of new tests with improved technical performance and convenience, such as **point-of-care, home-based, and community-based devices**, as well as innovations that **make current lab tests faster, more efficient, and more widely accessible** will be supported

- Tests developed through RADx will be validated, be proven clinically effective, and obtain Emergency Use Authorization (EUA) and/or clearance through the FDA

- Innovations at all stages of readiness will be considered, including:
  - **Early stage**: transformative innovations based on novel testing strategies that have potential for major scale up
  - **Advanced stage**: modification and optimization of existing SARS-CoV-2 testing approaches, including clinical laboratory tests, that can dramatically increase testing capacity

- Review criteria will include: **Technical** (performance, usability), **Clinical**, **Commercial**, and **Regulatory** aspects
NIH Rapid Acceleration of Diagnostics (RADx) Initiative for COVID-19

**NATIONAL CALL FOR INNOVATIVE TECHNOLOGIES**
- Rolling Submissions and Selections Begin April 29, 2020

**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

**FAST TRACK FOR ADVANCED DIAGNOSTIC TECHNOLOGIES**

- ~1 week
  - Investigators receive $25k

- ~1 month
  - Investigators receive $1M

- Multiple months
  - No budget limit for investigators

**DEPLOY MILLIONS**
- of tests per week
ACME POCT WILL SERVE AS RADx’S TEST VALIDATION CORE

**Emory/Children’s Laboratory for Innovative Assay Development (ELIAD)**

- John Roback, MD, PhD (Emory) and Sunita Park, MD (Children’s)
- CLIA-certified clinical “testing” laboratory dedicated to assessing and validating novel diagnostic tests, including those for COVID-19
- >1300 COVID-19 patient biospecimens (nasopharyngeal, sputum, other oral, blood/plasma/serum, etc.) curated with clinical information
- Conduct different tiers of test validation (contrived SARS-CoV-2 “spiked in” samples, banked patient samples, fresh patient samples, community testing), can be used for EUA submission

**HomeLab (Georgia Tech)**

- Brad Fain, PhD and Sarah Farmer, PhD
- Network of >600 Atlanta-area households available to evaluate medical technologies in their homes & communities
- Conduct usability assessments (including human factors analysis & heuristics evaluation) of COVID-19 tests
- Performed in intended use locations (home, school, clinical labs, public areas, etc.)

**IEN (Georgia Tech)** – Technology & Manufacturing Readiness Level Assessments
THANK YOU!

- https://www.poctrn.org/-/acme-poct
- application website: https://www.poctrn.org/radx
- Contact: erika.acmepoct@gmail.com

any questions?
NIH Rapid Acceleration of Diagnostics (RADx) Initiative for COVID-19

NATIONAL CALL FOR INNOVATIVE TECHNOLOGIES
Rolling Submissions and Selections Begin April 29, 2020

PHASE 0: “Shark Tank”-Like Rapid Selection Process
~1 week Investigators receive $25k

PHASE 1: Validation and Risk Review
~1 month Investigators receive $1M

PHASE 2: Clinical Tests, Regulatory Approval, and Scaling Up
Multiple months No budget limit for investigators

END OF SUMMER/FALL 2020

FAST TRACK FOR ADVANCED DIAGNOSTIC TECHNOLOGIES

DEPLOY MILLIONS of tests per week