RADx Tech
Listening Session:
Accessible COVID-19 At-Home Tests

Zoom Suggestions

To **view the live transcription, select "Live Transcript" button at the bottom of your screen**; you may select either subtitles or a full transcript

Comments and questions are welcome using the **chat function** or **raise hand** button, which can be shown under reactions

Please ensure that you are **muted throughout the meeting when not speaking** to reduce background noise

Kindly **turn on your video when speaking** and **make sure you are facing the camera directly** to make the session more interactive

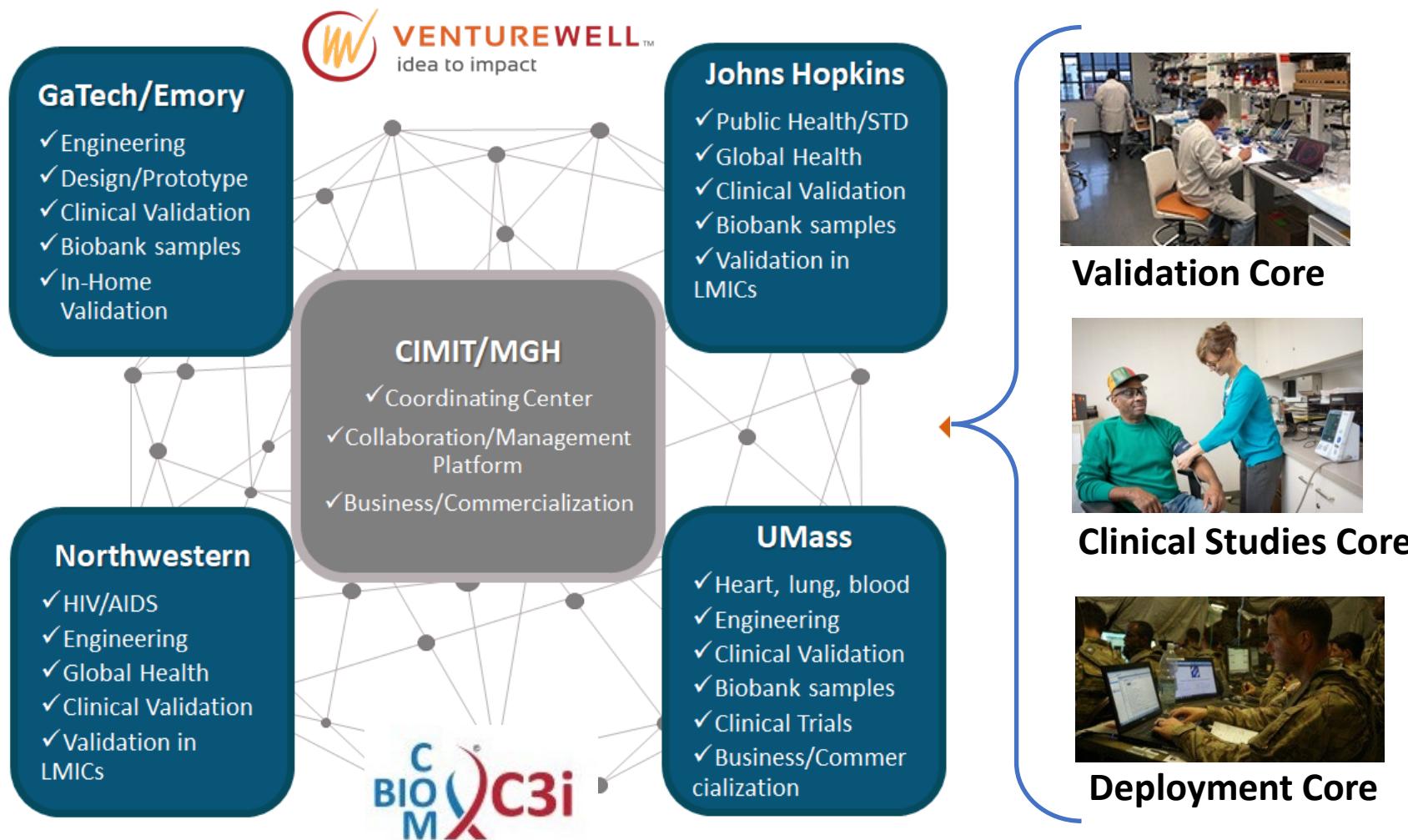If you encounter technical issues, **please contact Michele Liston**

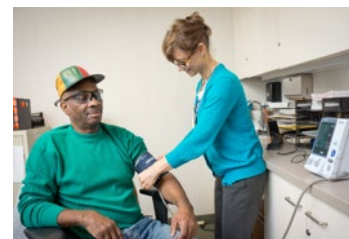# COVID-19 Accessible Tests Listening Session

March 24, 2022

Jill Heemskerk, Ph.D.

Deputy Director

National Institute of Biomedical Imaging & Bioengineering
(NIBIB)

Rapid Acceleration of Diagnostics (RADx Tech)

Leverages the NIBIB Point of Care Technology Research Network (POCTRN)

VENTUREWELL — idea to impact

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

CBIOM C3i

Validation Core
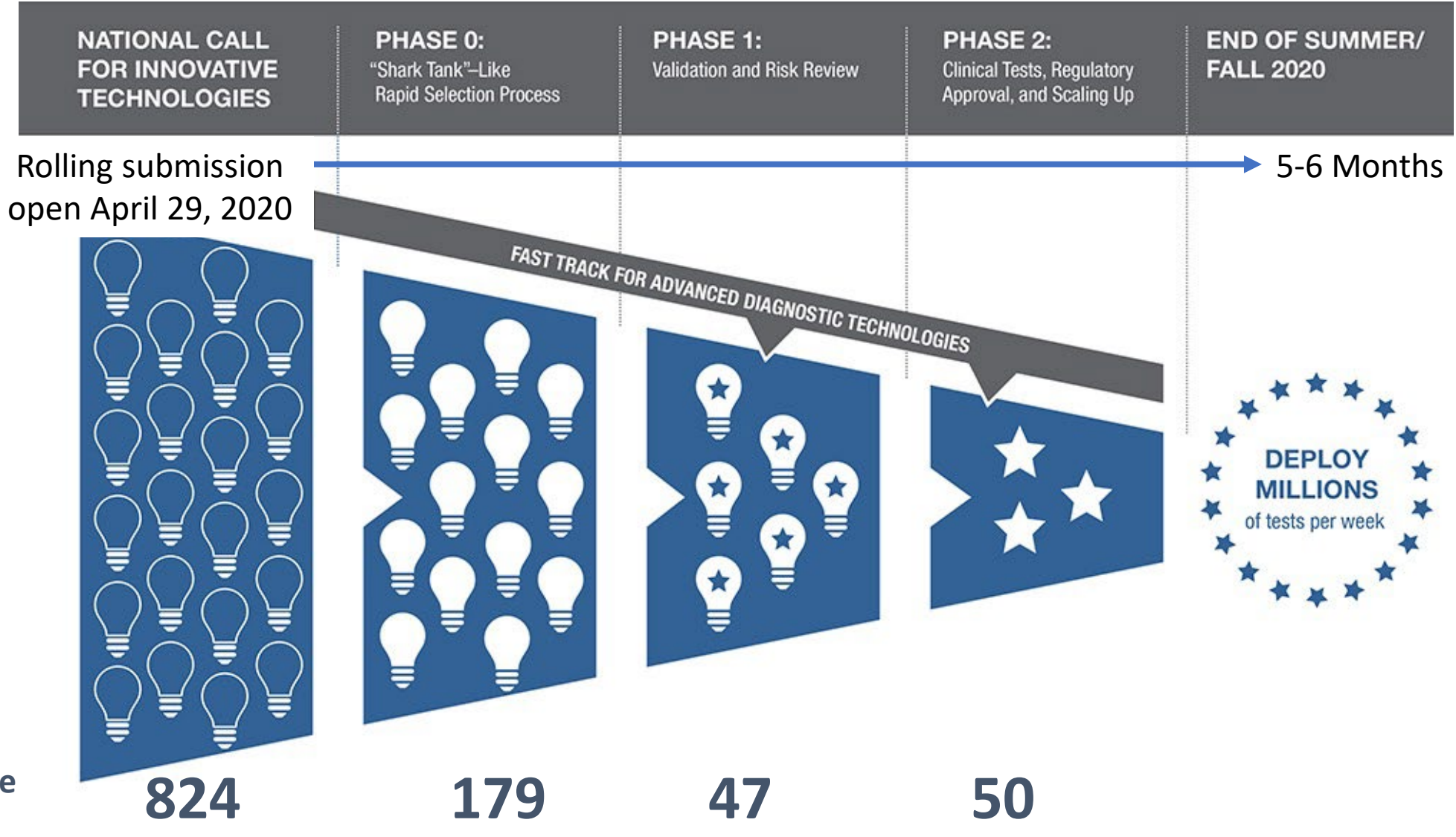
Clinical Studies Core

Deployment Core

RADx Operations:
- Review and fund
- Test and validate
- Give expert guidance

~900 RADx Contributors:
- USG
- Academia
- Industry
- Non-profits

https://www.poctrn.org

4

| 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, 2020

5-6 Months

FAST TRACK FOR ADVANCED DIAGNOSTIC TECHNOLOGIES

DEPLOY MILLIONS of tests per week

Projects by Phase as of Feb. 2022

824   179   47   50

RADx Tech Impact

Major Milestones

- 1.8 billon total capacity thru January 2022

- 41 EUAs: 7 over-the-counter

- > 100 companies supported

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

Ongoing Challenges

1) Increase Accessibility: *modified and next generation at-home tests that can be used independently by more people*

2) Improve Performance: *next generation accessible point of care/home tests w/lab performance*

3) Increase Information: *tests for variants and other respiratory diseases; measures of response to vaccines, treatments, prognosis*

4) Reduce cost: *innovations in manufacturing, packaging, distribution, reagents → **$2-$4 retail***

5) Test to Treat Networks: *digital reporting for at-home tests + telemedicine infrastructure*

Listening Session Goals

- **Understand challenges to accessibility of at-home tests**

- **Prioritize top concerns to be addressed**

- **Discuss potential improvements**

- **Identify near-term and longer-term solutions**

- **Open lines of communication for ongoing partnership**

Assumed Requirements for Accessible Tests

- Low Cost, no surcharge for accessible tests

- Available as quickly as possible

- All will require a new FDA submission

Potential Solutions: Short-Term

Short-term solutions:

- Modifications to existing products

Potential Solutions: Long-Term

Long-term solutions:

- Develop a new solution
- New technology
- Update diagnostic development process to address accessibility from day one

Breakout Participation Tips: Speaking

- Make sure your camera is on
- Introduce yourself to the audience with your name and affiliation each time you begin speaking
- Periodically pause so that the facilitators can respond to or voice comments made in the chat and call on individuals with raised hands
- Speak at a slow, smooth pace for the interpreters to keep up with the conversation

Breakout Participation Tips: Video

- Check the level of natural sunlight and close blinds/shades slightly if needed
- Raise your laptop to elevate your camera to eye level, face the camera with a frontal view, and ensure part of your upper body is visible
- Ensure your mouth is not obstructed by hand gestures or by looking down

Breakout Discussion Agenda

3:40-3:45pm   Background and Experience with at-home COVID Tests

3:45-4:05pm   Understanding Barriers to Accessibility

4:05-4:15pm   Identifying Good Models

4:15-4:20pm   Recommended Collaborators

4:20-4:35pm   Recap of Discussion Findings

Please refer to the agenda attachment for the breakout discussion questions