



Research and Innovation Translation Partnerships In Point of Care Technologies Conference and Technology Showcase—November 27-29, 2023

PROGRAM AGENDA

November 27, 2023

1.00 PM NIH Small Business Program 101
Chair: Kari Ashmont

November 28, 2023

8.30 AM Welcome Remarks and Conference Agenda
Co-chairs: Atam Dhawan, Tiffani Lash

9.00 AM Distinguished Keynote 1: POC Technology Innovations and Applications – Current Status and Challenges
Monica Bertagnolli, Bruce Tromberg

9.30 AM Distinguished Panel-1: POC Technology Innovations – **Clinical Perspective and Challenges**
Developing new point-of-care devices and technologies for clinical care often faces delays and challenges. This panel explores the importance of incorporating the perspective of potential users and stakeholders to determine value, rather than solely focusing on manufacturer performance. Emphasizing value throughout the entire development process, from ideation to launch, can enhance the impact of point-of-care testing on patient outcomes and care delivery.
Chair: David McManus
Panelists: Apurv Soni, Craig Lilly, Yuka Manabe

10.15 AM Break

10.30 AM Distinguished Panel-2: POC Technology Innovations – **Industry Perspective and Challenges**
Point-of-care technology is a promising field that can enhance healthcare by providing fast, accurate, and useful information at or near the site of interest. However, the industry faces many hurdles in developing, validating, integrating, and commercializing point-of-care technology devices, as well as addressing the ethical, social, and legal implications of point-of-care technology.
Chair: Wilbur Lam
Panelists: Erika Tyburski, Erik Engelson, Scott Ferguson

11.15 AM Distinguished Panel-3: POC Technology Innovations – **Regulatory and Standards Compliance**
Discussion of lessons learned from the Rapid Acceleration of Diagnostics (RADx©) initiative, including how the regulatory landscape for over-the-counter (OTC) rapid antigen home tests has evolved, what investigators should be aware of as a result of this shift, and the sustainability of changes made in a non-emergency situation.
Chair: Qi Duan
Panelists: Anuradha Rao, Bill Heetderks, Erika Tyburski

12.00 PM Lunch – Meet w/ NIH staff

1.00 PM Forum – **Research and Innovation Translation Partnerships Hot Topics**
NIBIB and POCTRN, through the RADx Tech program, helped lead the country through the COVID-19 pandemic by accelerating POC and home-based diagnostic development and catalyzing the fundamental shift towards the acceptance and widespread use of self-testing. The RADx Tech program represents a new paradigm by which the NIH, in partnership with others, can drive innovation in medical technology R&D. While the partnership continues to address unmet COVID-19 testing needs, new initiatives that leverage the program’s innovation funnel methodology and novel collaborations have arisen. This Forum will present examples of those efforts representing different partners, technologies, clinical areas, and scales. From postpartum maternal health and HCV to HIV and design principles for accessibility, the panelists will share how partnerships between government agencies, universities, nonprofit organizations, and industry can effectively deliver a diverse array of diagnostic innovation.

Chair: Taylor Gilliland
Panelists: Sally McFall, Antonello Pileggi, Brian Walsh

2.00 PM	Forum – Federal and Non-Federal Resources for Innovators Panel members will share information on a range of resources that innovators may leverage as they develop their products. These in-kind resources may include entrepreneurial training, assistance with customer discovery, networking with other innovators, and access to prototyping and manufacturing partners. The panel will also share insights on how to engage with resource providers and (for NIH grantees) options to add resources to supplement an existing grant. Chair: Michael Wolfson Panelists: Kari Ashmont, Chris Sasiela, Bob Storey, Rebekah Neal
3.00 PM	Break
3.15 PM	POCTRN+ Centers Presentation, Resources, Capabilities, and Q&A Presenters: Tiffani Lash, Jue Chen
4.15 PM	Rapid Pitch Session on e-Poster/Exhibit Session -1 Chair: Susan Moreira
4.45 PM	e-Poster/Exhibit Session -1
5.30 PM	Reception (Optional Networking - Tommy Joe’s Bar and Grill 7940 Norfolk, Ave, Bethesda, MD, 20814 from 6:30 PM)

November 29, 2023

8.30 AM	Welcome Remarks and Conference Agenda Co-chairs: Atam Dhawan, Tiffani Lash
9.00 AM	Day-1 Recap chairs: Atam Dhawan, Tiffani Lash
9.30 AM	Distinguished Panel-4: POC Technology Innovations – Technology Innovation, and Collaborative Partnership The journey from technologic concept to a commercially available product can take many paths, but all share common elements: 1) A need must be met with a product of sufficient quality; 2) The idea must be cultivated into a design to be prototyped, optimized, validated, and verified/authorized/cleared; 3)The product must be manufactured at consistently high quality, packaged, and shipped; 4) and finally, the product must be marketed, sold, and used. Many hands are required to traverse this pathway and this panel will explore the interdependence of partnerships at several key inflection points, as well as ways to optimize them. Topics to be discussed include the push/pull of technology capability vs. identified need at inception; how market opportunity and size relate to the incentive to join the market and who funds the project; and the balance between regulatory requirements and product needs both before authorization and after market entry. Chair: Shawn Mulvany Panelists: Eric Lai, Teresa Abraham, Stephanie Calderwood
10.15 AM	Break
10.30 AM	Distinguished Panel-5: POC Technology Innovations – Technology Translation, Validation, and Business Model for Commercialization Discussion of best practices and lessons learned from the Point-of-Care Technologies Research Network (POCTRN) and Rapid Acceleration of Diagnostics (RADx©) initiative. Topics will cover translational research frameworks, analytical and clinical validation protocols, and resources for commercialization assistance. Chair: Todd Merchak Panelists: *
11.15 AM	Distinguished Panel-6: POC Technology Innovations – Translation in Low Resource Settings This panel will provide a cross-cutting overview of translational global health technology research supported by the POCTRN network, resources and capabilities offered by the centers, and highlight experiences with developing, validating, and implementing technology solutions in low-resource settings, globally. Emphasis will be placed on the unique challenges and opportunities posed in such settings; the role of design thinking to ensure usability and acceptability in local systems; and approaches for reciprocal innovation based on bidirectional, mutually beneficial

research, where the resultant technologies are designed for broad applicability across high-income country as well as low- and middle-income country settings.

Chair: Robert Murphy

Panelists: David Erickson, Rebecca Richards-Kortum, Yuka Manabe

12.00 AM Lunch

1.00 PM Forum: **Digital Health**

In recent years, diagnostic testing has experienced a massive shift out of laboratories and into the point-of-care and home settings. Widespread adoption of home testing has been a welcome change for consumers, enabling new opportunities for home-based care, but also presenting challenges related to diagnostic data capture. This panel will highlight several of those opportunities and challenges, with an eye towards how digital health technologies can be used to unlock the full potential of at-home tests. Panelists from industry and government will discuss efforts to augment at-home testing with telehealth, mobile apps, and other digital health tools

Chair: Andrew Weitz

Discussants: Vik Kheterpal, Michael Mina, Pooja Jani

2.00 PM Distinguished Keynote 2: POC Technology Innovations and Applications – Future Trends, Objectives and Funding Programs

Keynote speaker: Renee Wegrzyn

2.30 PM Forum: **Future of POC Technology Innovation, Translation, Commercialization and Clinical-Patient-Payor Acceptances**

This panel will delve into the future of Point of Care (POC) technologies, covering advancements in various areas. These include the development of innovative tools, enhancement of translation processes, efficiency improvements in commercialization, and strategies to boost acceptance among key stakeholders such as clinicians, patients, and payors.

Chair: Tiffani Lash

3.00 PM Break

3.15 PM Rapid Pitch Session on e-Poster/Exhibit Session -2

Chair: Rao Divi

4.00 PM e-Poster/Exhibit Session -2

5.30 PM Reception and Closing Remarks- Day 2

* The process of selecting panelists is currently underway.