

## IEEE-NIH 2017 Special Topic Conference on Healthcare Innovations and Point of Care Technologies (HI-POCT2017)

Breakout and Technical Sessions  
Tuesday, November 7, 2017

Track 1	Track 2	Track 3	Track 4
2.00 – 3:30 PM <b>Breakout Session 1</b> <b>Developing Internal and External Resources for Translation</b> Co-Chairs: Jodi Black, PhD, OER, NIH Matthew McMahon, PhD, NHLBI, NIH	2.00 – 3:30 PM <b>Breakout Session 2</b> <b>Clinical Translational Challenges</b> Co-Chairs: Steven Schechter, MD, CIMIT Edward Livingston, MD, JAMA	2.00 – 3:30 PM <b>Breakout Session 3</b> <b>Technology Translation and Regulatory Issues</b> Co-Chairs: Jeffrey Kaye, MD, OHSU Michael Fisher, MS, GCMI	2.00 – 3:30 PM <b>Breakout Session 4</b> <b>Validation, Standards and Security</b> Co-Chairs: Julian Goldman, MD, MGH Wendy Nilsen, PhD, NSF
3.30 – 3.45 PM <b>Break</b>			
3.45 – 5.30 PM <b>Breakout Technical Session 1</b> <b>Developing Internal and External Resources For Translation</b> Co-Chairs: Jodi Black, PhD, OER, NIH Matthew McMahon, PhD, NHLBI, NIH	3.45 – 5.30 PM <b>Breakout Technical Session 2</b> <b>Clinical Translational Challenges</b> Co-Chairs: Steve Schechter, MD, CIMIT Edward Livingston, MD, JAMA	3.45 – 5.30 PM <b>Breakout Technical Session 3</b> <b>Technology Translation and Regulatory Issues</b> Co-Chairs: Jeffrey Kaye, MD, OHSU Michael Fisher, MS, GCMI	3.45 – 5.30 PM <b>Breakout Technical Session 4</b> <b>Validation, Standards and Security</b> Co-Chairs: Julian Goldman, MD, MGH Wendy Nilsen, PhD, NSF

**Breakout Sessions: Objectives:**

To provide an open forum for all attendees of the IEEE-NIH 2017 Special Topics Conference on Healthcare Innovations and Point-of-Care technologies to discuss challenges to POCT translation in four areas, and brainstorm strategies to overcome these challenges.

**Technical Sessions Objectives:**

To further discuss and prioritize key challenges identified in the previous breakout sessions, and develop a roadmap for NIH and other relevant stakeholders to address the high- priority

challenges for the next 5 to 10 years. Each technical session will have up to two presentations from investigators who have tackled those challenges and can share with the audience lessons learned: what has been working, what hasn't been working, and what would help to overcome the barriers.

**Intended Audience:**

All researchers, clinicians and students engaged in scientific and clinical research related to healthcare applications are invited to attend the breakout sessions of their choice. All stakeholders in healthcare innovations, delivery, maintenance, services and management are specifically encouraged to participate in the conference. Industries and businesses dealing with healthcare products, devices, pharma and payers, along with life-sciences-related sponsoring agencies and foundations are welcome to participate in the collaborative synergy addressing the future of healthcare innovations and point-of-care technologies in medicine.

**Breakout Session 1: Developing Internal and External Resources for Translation**

Topics that will be discussed in this breakout session include exploring funding, infrastructure, human and other resources currently available and identifying resources that need to be developed in the future to accelerate translation.

**Co-Chairs:** Jodi Black, PhD (OER, NIH) and Matthew McMahon, PhD (OTAC, NHLBI)

1. Opening remarks and objectives of the session (10 minutes) - Jodi Black
2. Overview of the NIH Centers for Accelerated Innovations (NCAI) and Research Evaluation and Commercialization Hubs (REACH) programs (20 minutes)- Matthew McMahon
3. Open discussion moderated by the session co-chairs (1 hour)

**Breakout Technical Session 1: Developing Internal and External Resources for Translation**

**Co-Chairs:** Jodi Black, PhD (OER, NIH) and Matthew McMahon, PhD (OTAC, NHLBI)

1. Presentation on the development of non-invasive real-time assessment of coronary stenosis (20 minutes) – REACH grantee, Eric Berson, PhD, University of Louisville
2. Presentation on the development of HemeChip (20 minutes)- NCAI grantee, Umut Gurkan, PhD, Case Western Reserve University
3. Brief introduction of the NIH IC panelists (10 minutes) - Kathleen Rousche (NHLBI), Miguel Ossandon (NCI) and Amit Mistry (FIC).
4. Open discussion/questions (55 minutes).

## **Breakout Session 2: Clinical Translational Challenges**

Topics that will be discussed in this breakout session include placing POCTs in the context of the healthcare innovation cycle, definition of unmet clinical needs for POCTs, challenges in moving POCTs forward to the clinic, and the role of federal agencies in the development and commercialization of POCTs.

**Co-Chairs:** Steven Schechter, MD (CIMIT, MGH) and Ed Livingston, MD (JAMA)

1. Opening remarks and two objectives of the session (5 minutes) – Steven Schachter and Edward Livingston
  - a. POCTs in the context of the healthcare innovation cycle – Steve to introduce
  - b. Case study: Medication reconciliation – Ed to introduce
2. Understanding and measuring the healthcare innovation cycle and POCTs (20 minutes) – Michael Dempsey (CIMIT)
3. Medical complications that result from inaccurate medication reconciliation during transitions of care and current methods used to reduce errors, unmet needs (20 minutes) – Shoshana Herzig, MD (Beth Israel Deaconess Medical Center, Harvard Medical School)
4. Open discussion moderated by the session co-chairs (45 minutes)

## **Technical Session 2: Clinical Translational Challenges**

**Co-Chairs:** Steven Schechter, MD (CIMIT, MGH) and Ed Livingston, MD (JAMA)

1. Opening remarks and two objectives of the session (5 minutes) – Steven Schachter and Edward Livingston
    - a. Challenges of moving point-of-care projects forward: case study
    - b. Role of federal funding agencies
  2. Presentation on addressing clinical translation challenges when developing diagnostic tests for infectious diseases (20 minutes)- Nira Pollock (Boston Children’s Hospital)
  3. Overview of [PRISMS](#) program (20 minutes) – Michael Dellarco, NIBIB, NIH
  4. Brief introduction of the NIH IC panelists (10 minutes) - Jue Chen (NHLBI), Tiffani Lash (NIBIB), Rao Divi (NCI), Maria Giovanni (NIAID), Randall Kincaid (NIAID), Paul Pearlman (NCI), Pushpa Tandon (NCI) and Laura Povlich (FIC).
  5. Open discussion/questions (50 minutes).
-

### **Breakout Session 3: Technology Translation and Regulatory Issues**

Topics that will be discussed in this breakout session include identifying challenges in regulatory approval of POCTs and exploring efficient regulatory pathways to move POCT to the market, including compliance with regulatory bodies both nationally and internationally.

**Co-Chairs:** Jeffrey Kaye, MD (OHSU) and Michael Fisher, MS (GCMI)

1. Opening remarks and objectives of the session (10 minutes) – Michael Fisher
2. Overview of the [CART](#) program (10 minutes) – Jeffrey Kaye
3. Open discussion moderated by the session co-chairs (1 hour 10 minutes)

### **Technical Session 3: Technology Translation and Regulatory Issues**

**Co-Chairs:** Jeffrey Kaye, MD (OHSU) and Michael Fisher, MS (GCMI)

1. Presentation on a project supported by the CART (20 minutes) – Jeffrey Kaye
  2. Presentation on development of a POCT for detection of atrial fibrillation (20 minutes) – [Jean-Philippe Couderc](#), PhD, MBA, University of Rochester
  3. Brief introduction of the NIH IC panelists (10 minutes) - Erin Iturriaga (NHLBI), Nina Silverberg (NIA), Maureen Beanan (NIAID) and other IC representatives.
  4. Open discussion/questions (55 minutes).
- 

### **Breakout Session 4: Validation and Integration: Today and into the Future**

Topics that will be discussed in this breakout session include exploring the handoffs between basic and applied researchers in developing POC technologies in validating these technologies and creating devices that can be integrated into existing and future systems.

**Co-Chairs:** Julian Goldman, MD (MGH) and Wendy Nilsen, PhD (NSF)

1. Opening remarks and objectives of the session (5 minutes) – Julian Goldman
2. A story of the translation of a POCT to the market (15 minutes) - [Anand Iyer](#), PhD, MBA, WellDoc Inc.
3. Standards and security (15 minutes) - Brian Fitzgerald, PhD, FDA

4. Open discussion moderated by the session co-chairs (55 minutes)

#### **Technical Session 4: Validation and Integration: Today and into the Future**

**Co-Chairs:** Julian Goldman, MD (MGH) and Wendy Nilsen, PhD (NSF)

Three presenters sharing their experience in overcoming challenges of validating and integrating POC devices.

1. Clifford Dacso, MD, Baylor College of Medicine (20 minutes)
  2. Ki Chon, PhD, University of Connecticut (20 minutes)
  3. Robert Taylor, PhD, the Gates Foundation (20 minutes)
  4. Brief introduction of the NIH IC panelists (5 minutes) - James Luo (NHLBI), and other IC representatives.
  5. Open discussion/questions (45 minutes)
-