

Strategic Conference on Point of Care Technologies for Precision Medicine

November 9-10, 2015

NIAID Conference Center, 5601 Fishers Lane, Bethesda, MD 20852

Monday November 9, 2015

7:30 – 8:30 AM Breakfast
8:30 – 9:30 AM Inauguration and Welcome/Overview/Goals Roderic I. Pettigrew, Ph.D., MD (NIBIB) Keynote – Precision Medicine William Riley, Ph.D. (NCI)
9:30 – 10:30 AM Panel Session I Clinical Needs Driving Technology Innovation for Precision Medicine William Heetderks, MD, Ph.D. (NIBIB) and Jim Gallarda, Ph.D. (BMGF)
10:30 – 10:45 AM Break
10:45 – 11:45 PM Panel Session II Enabling Technologies: Point-Of-Care Devices for non-invasive monitoring of wellness, health, and lifestyles Atam Dhawan, Ph.D. (NJIT) and Erica Forzani, Ph.D. (ASU)
11:45 – 1:45 PM Lunch, Poster Session, POC Technologies Demonstrations
1:45 – 2:45 PM Panel Session III Regulatory Issues for POC Technologies (FDA, CMS, etc.) Katherine Serrano (FDA), Sunita Shukla, Ph.D. (FDA), Shari Ling, MD (CMS), Karen Dyer, MT (ASCP) DLM (CMS)
2:45 – 3:45 PM Panel Session IV Business Models Supporting a Sustainable Global Point of Care Business: From Resource Limited Settings to Your Local Retail Pharmacy Clinic Richard Thayer, MBA (Halteres Associates, LLC, and Catalysis Foundation for Health) and Patrick Arensdorf, MSM (Halteres Associates, LLC)
3:45 – 4:00 PM Break
4:00 – 5:00 PM Federal Funding Opportunities and Resource Showcase Miguel Ossandon, MS (NCI) and Pushpa Tandon, Ph.D. (NCI)
6:00 – 8:00 PM Reception IEEE/EMBS

Tuesday November 10, 2015

7:30 – 8:30 AM Breakfast			
Track 1	Track 2	Track 3	Track 4
8:30 – 10:00 AM Technical Session	8:30 – 10:00 AM Technical Session	8:30 – 10:00 AM Technical Session	8:30 – 10:00 AM Technical Session
10:00 – 10:15 AM Break			
10:15 – 11:45 AM Technical Session: Low-cost POC Technologies for Cervical Cancer Paul Pearlman, Ph.D. (NCI) and Shannon Silkenson, Ph.D. (NCI)	10:15 – 11:45 AM Technical Session: Emerging POC Technologies for Heart, Lung, Blood, and Sleep (HLBS) Disorders Erin Iturriaga, BS, MSN (NHLBI) and Bishow Adhikari, Ph.D. (NHLBI)	10:15 – 11:45 AM Technical Session: Advances in Point-of- Care (POC) Tests for Infectious Diseases Charlotte Gaydos, DrPH, MPH, MS (JHMI) and Samuel Sia, Ph.D. (Columbia University)	10:15 – 11:45 AM Technical Session: Point of Care Interoperability and Informatics Vinay Pai, Ph.D. (NIBIB)
11:45 – 1:30 PM Lunch & Poster Session II			
1:30 – 3:15 PM Breakout Session: Point of Care Technologies in Resource-Limited Settings Jim Gallarda, Ph.D. (BMGF)	1:30 – 3:15 PM Breakout Session: POC- Clinical Use and Acceptance J. Benjamin Crocker, MD (AMF)	1:30 – 3:15 PM Breakout Session: Patient Education and Acceptance Anne Rompalo, MD, ScM (JHMI)	1:30 – 3:15 PM Breakout Session: Comprehensive Diagnostics Evaluation and Validation Bernhard Weigl, Ph.D. (Intellectual Ventures)
3:15 – 3:30 PM Break			
3:30 – 4:30 PM Reports from Breakouts and Drafting for White Papers			
4:30 – 5:00 PM Meeting Wrap Up – Next Steps			

IEEE/EMBS/NIH Strategic Conference on

Point of Care Technologies for Precision Medicine Detailed Information

Panel Sessions:

- **Panel Session I: Clinical Needs Driving Technology Innovation for Precision Medicine**
William Heetderks (NIBIB), Jim Gallarda (Bill and Melinda Gates Foundation), Michael Bates (Cepheid), Mike Mauro (MSKCC) and Erin Zammett Ruddy
Abstract:
This session will highlight how true health advances can be facilitated by technology innovation in various healthcare settings, with an emphasis on clinical needs. Key to achieving improved health outcomes are the requirements for innovators to "begin with the end in mind" by having a clear and comprehensive understanding of the needs of the patient pathway within the broader healthcare ecosystem. With such an understanding, subsequent product development efforts have a clear roadmap in achieving high impact diagnostics.
- **Panel Session II: Enabling Technologies: Point-Of-Care Devices for non-invasive monitoring of wellness, health, and lifestyles**
Atam Dhawan (IEEE/EMBS, NJIT), Erica Forzani (ASU), Jose Gomez-Marquez (MIT), Onur Mudanyali (Holomic LLC), Portia Taylor-Singh (Phillips) and David Erickson (Cornell University)
Abstract:
This session brings the state-of-the-art development and commercialization of Point-Of-Care-Devices, which are geared to bring Point-Of-Care closer to the users, while providing to professionals snapshots of user's life outside the clinical settings for a more comprehensive understanding of patient's health and habits under free-living conditions.
Professionals from academia, and industry gather together their experiences and expertise in the assessment of health parameters with non-invasive or minimally invasive methods to assess metabolic and physiological biomarkers related to health, wellness, fitness, and lifestyle. This strategic point is a key milestone for improvement of patient assessment, prognosis, and treatment; as well as for support of better healthy lifestyles.
- **Panel Session III: Regulatory Issues for POC Technologies (FDA, CMS, etc.)**
Katherine Serrano (FDA), Sunita Shukla (FDA), Shari Ling (CMS), and Karen Dyer (CMS)
Abstract:
This panel focuses on describing the regulatory issues that must be addressed in order to enable point of care technologies to reach the market. A panelist from the FDA will describe the regulatory requirements and pathway for point-of-care devices, as well as describe the resources available to assist in this process. A CMS representative from the Clinical Laboratory Improvement Act (CLIA) program will describe the clinical laboratory

requirements for certain categories of point-of-care tests. Another FDA panelist will discuss the requirements and evaluations needed to achieve “CLIA waiver” status for a point-of-care device. Finally, a CMS representative will discuss reimbursement challenges for these devices. Through an understanding of the regulatory issues associated with point-of-care devices, developers of these technologies can appropriately design and evaluate their devices in a way that will facilitate a more timely and efficient route for these devices to market.

- **Panel Session IV: Business Models Supporting a Sustainable Global Point of Care Business: From Resource Limited Settings to Your Local Retail Pharmacy Clinic**

Richard Thayer (Halteres Associates, LLC and Catalysis Foundation for Health) and Patrick Arensdorf (Halteres Associates, LLC)

Abstract:

Successful Point of Care programs must look beyond creative assay technology solutions to consider sustainability of the business in the target settings and a clear understanding of the information delivery requirements. An integrated model has been developed to help benchmark and guide diagnostic systems development for resource limited settings around the world. The goal is to help diagnostic developers better understand and leverage potential ecosystem partners to achieve financial sustainability without the need for recurring capital investments. Additionally, it is essential to consider the information and communications needs upfront when establishing the system requirements. Data reporting requirements include, for example, patient, clinical, laboratory, service and support information. While point-of-care diagnostics may provide information at the clinician's "point-of-need," in most cases clinical considerations do not stop with a single patient-provider interaction. Continuity of care, health system coordination and public health surveillance are all requirements of the new "connected healthcare" environment.

Technical Sessions:

- **Tracks 1 -4 (8:30 – 10:00am): Sessions of Submitted Abstracts**

- **Track 1 (10:15 – 11:45am): NCI Technical Session:**

Low-cost POC Technologies for Cervical Cancer

Paul Pearlman (NCI), Shannon Silkenson (NCI), Ted Trimble (NCI), Jose Jeronimo (PATH), Rebecca Richards-Kortum (Rice University) and Jean Anderson (JHU)

Abstract:

Cervical Cancer is the fourth most common cancer in women. Approximately 528,000 new cases were estimated in 2012; nearly 85% of those cases occur in less developed regions of the world. Almost nine out of ten (87%) cervical cancer deaths, approx. 266,000, occur in the less developed regions of the world. Screening is an effective means to detect early stage cervical cancer lesions. In many developing countries, access to healthcare is limited and point-of-care (POC) “screen and treat” (SAT)

programs present the best opportunity to reduce cervical cancer mortality. This session includes two timely low-cost, POC cervical cancer screening technologies and one new treatment technology.

- **Track 2 (10:15 – 11:45am): NHLBI Technical Session:**

Emerging POC Technologies for Heart, Lung, Blood, and Sleep (HLBS) Disorders

Erin Iturriaga (NHLBI), Bishow Adhikari (NHLBI), Chi On Chui (University of California), Brian Jamieson (Diagnostic Biochips, Inc.) and Tony Jun Huang (The Pennsylvania State University)

Abstract:

The purpose of the National Heart, Lung, and Blood Institute (NHLBI) Technical Panel is to present and discuss several examples of emerging technologies that may be utilized to develop innovative point-of-care (POC) tools and devices for advancing the diagnosis, monitoring, treatment and management of HLBS disorders. The convergence of more precise biomarker discoveries and advances in POC related technologies (e.g., miniaturized bioprocessing and sensing, information technology, bioinformatics, and access to large clinical datasets) offers unprecedented opportunities to improve diagnosis, monitoring and management of these disorders at the point of care. Major benefits such as faster time to intervention have been demonstrated when the results of POC testing are utilized in conjunction with Electronic Health Records or mobile technology, and when combined with goal directed therapy. These technologies have the potential to play a pivotal role in personalizing medicine, improving healthcare delivery, and, ultimately, reducing healthcare costs.

- **Track 3 (10: 15 – 11:45am): NIAID Technical Session:**

Advances in Point-of-Care (POC) Tests for Infectious Diseases

Charlotte Gaydos (Johns Hopkins University), Robert Garry (Tulane University), Samuel Sia (Columbia University) and Fed Tenover (Cepheid)

Abstract:

In the NIAID panel, we will hear three presentations about recent developments on the rapidly evolving POC device landscape for infectious disease agents. These detection devices highlight the potential to rapidly identify the causative agents of specific diseases to guide appropriate treatment and allow timely control measures to limit the spread of infectious diseases whenever they occur. The presentations will cover (1) challenges to develop a rapid field diagnostic for Ebola virus in Africa, a significant public health threat due to the severity of the disease and the high risk of mortality; (2) A Smartphone plug-in diagnostic device to detect exposure to HIV or syphilis; and (3) The use of PCR-based testing for STIs, tuberculosis, and facilitating clinical trials.

- **Track 4 (10:15 – 11:45am): NIBIB Technical Session:**

Enabling Interoperable Informatics in Point-of-Care Systems

Vinay Pai (NIBIB), Shawn Murphy (Partners), Yohan Lee (Booz Allen Hamilton), Charles Jaffe (Health Level 7 International), Katherine Kim (UC Davis) and Julian Goldman (MGH, MD PnP Interoperability Program, and Partners HealthCare)

Abstract:

The purpose of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) Technical Panel is to understand the dynamics for enabling interoperability for the informatics in point-of-care systems. Informatics in POC systems range from information content available from medical devices, to the information content in the electronic health records. When looked at from the paradigm of patient-first, there is an increasing need to determine the constraints limiting interoperability of information content among the various software and hardware components that affect health and healthcare. This panel, which incorporates academic and industrial points-of-view, is an attempt to see what all has been achieved in interoperability and what approaches can be used to tackle the hurdles that remain in ensuring that precision medicine utilizes “precision informatics”.

Breakout Sessions:

- **Track 1 (1:30 – 3:15pm): POCT in Resource Limited Settings**

Jim Gallarda (Bill and Melinda Gates Foundation)

- **Track 2 (1:30 – 3:15pm): POC -Clinical Use and Acceptance**

J. Benjamin Crocker (Ambulatory Practice of the Future) and Kent Lewandrowski (MGH Harvard)

- **Track 3 (1:30 – 3:15pm): Patient Education and Acceptance**

Anne Rompalo (Johns Hopkins University)

- **Track 4 (1:30 – 3:15pm): Comprehensive Diagnostics Evaluation and Validation**

Bernhard Weigl (Intellectual Ventures/Global Good)