



Point-of-Care Technology Research Network Science Symposium 2016

June 9, 2016

Natcher Conference Center, Building 45, Room E1 & E2, Bethesda MD

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) Point-of-Care Technology Research Network (POCTRN) symposium will focus on point-of-care technologies and their clinical translation to address challenges in quality healthcare. The POCTRN was created by the NIBIB in 2007 to drive the development of appropriate point-of-care diagnostic technologies through collaborative efforts that merge scientific and technological capabilities with clinical need (<https://www.nibib.nih.gov/research-funding/point-care-technologies-research-network>). The current POCTRN Centers include the Center for Innovation in Point-of-Care Technologies for the Future of Cancer Care at Boston University, the Center for Point-of-Care Technologies Research for Sexually Transmitted Diseases at Johns Hopkins University, and the Point-of-Care Technology Research Center in Primary Care at Massachusetts General Hospital in Boston.

This symposium will highlight posters and presentations by guest speakers and POCTRN centers' scientists about point-of-care technology with the focus on "Co-Inventing the Future Through Collaboration". The keynote speaker will feature Stefanie Akselrod, MT (ASCP) whom will give the talk on "Bringing a POC Test to the US Market-FDA Perspective". During the symposium there will be over 30 electronic poster presentations and demonstrations that were the result of projects supported by POCTRN.

Point-of-Care researchers, clinicians, sponsoring agencies and foundations are invited to attend.

Please Review the Visitor Information prior to attending the symposium. Be sure to read the sections related to Getting to NIH, Campus Access and Security, Parking, Campus Shuttle, and Maps. Also review the list of available services at Building 45, Natcher Building

Agenda

Thursday, June 9th, 2016

8:00 – 8:45 AM: Breakfast (on your own - Natcher Cafeteria)

8:45 – 9:00 AM: Welcome: Roderic I. Pettigrew, Ph.D., M.D., Director, NIBIB

9:00 – 9:15 AM: Introduction: Tiffani Bailey-Lash, Ph.D. Program Director, NIBIB, POCTRN

The Center for Point of Care Tests for Sexually Transmitted Diseases

9:15 – 9:45 AM: Guest Speaker: Dr. Michael Klepser, Pharm D

Title: Best practices for implementing CLIA-waived point-of-care testing services in community pharmacies



9:45 – 10:15 AM: Scientific Talk from the Center: John Clarkson, Ph.D.
Title: Development of a rapid molecular POC diagnostic system for STIs

10:15 – 10:30 AM: Break

Point of Care Technology Research Center in Primary Care

10:30 – 11:00 AM: Guest Speaker: J. Benjamin Crocker, M.D.
Title: Point-of-Care Testing in Primary Care: Facilitators and Barriers to Adoption

11:00 – 11:30 AM: Scientific Talk from the Center: Elizabeth Palaima, Ph.D.
Title: Engineering an Integrated System to Address Unmet Needs in Primary Care

11:30 – 1:00 PM: Poster Session and Lunch (on your own - Natcher Cafeteria)

Center for Future Technologies in Cancer Care

1:00 – 1:30 PM: Guest Speaker: Shivang R. Dave, Ph.D. and Jason Tucker-Schwartz, Ph.D.
Title: Increasing Access to Hematological Cancer Care for the Middle of the Pyramid with a Microscopy-Based Approach

1:30 – 2:00 PM: Scientific Talk from the Center: Catherine Klapperich, Ph.D.

Title: Portable Molecular Diagnosis of HPV

2:00 – 2:45 PM: Keynote Introduction- Charlotte Gaydos, DrPH, Center Director, JHU

Keynote Speaker: Stefanie Akselrod, MT(ASCP)

Title: Bringing a POC Test to the US Market-FDA Perspective

2:45 – 3:00 PM: Closing

3:00 – 4:00 PM: Poster Session

Speakers and Biographies

Roderic I. Pettigrew, Ph.D., M.D.



Roderic I. Pettigrew, Ph.D., M.D., is the first Director of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) at the NIH. From 2013-2014, the NIH Director appointed Dr. Pettigrew as the Acting Chief Officer for Scientific Workforce Diversity to establish program oversight of all NIH activities that address the unique diversity and inclusion challenges, to strengthen the national biomedical research workforce.

Prior to his appointment at the NIH, Dr. Pettigrew was Professor of Radiology, Medicine (Cardiology) at Emory University in Atlanta, Georgia, Professor of Bioengineering at the Georgia Institute of Technology, and Director of the Emory Center for MR Research at the Emory University School of Medicine. He is known internationally for his pioneering work at Emory University involving four-dimensional imaging of the cardiovascular system using magnetic resonance (MRI). His current research focuses on integrated imaging and predictive biomechanical modeling of coronary atherosclerotic disease.

Early on at the NIBIB he jointly led a national effort with Howard Hughes Medical Institute to create new interdisciplinary graduate training programs, and established the Quantum Projects program to achieve “medical moon shots” by pursuing high-risk, high-impact projects designed to solve major healthcare problems. Under Dr. Pettigrew’s leadership, national collaborative and international initiatives have been issued to develop low cost and point-of-care medical technologies and at present, he leads an effort to reduce CT radiation dose to background levels. He also leads a recent US-India collaboration to develop unobtrusive technologies for frequent recording of blood pressure to address the world wide problem of hypertension.

Dr. Pettigrew has been elected to membership in two components of the US National Academies: the Institute of Medicine, and the National Academy of Engineering. His awards include Phi Beta Kappa, the Bennie Award for Achievement, Morehouse College, the Most Distinguished Alumnus of the University of Miami (1990), the Hall of Fame of the Miller School of Medicine at the University of Miami, the Herbert Nickens Award of the ABC, the Pritzker Distinguished Achievement Award of the Biomedical Engineering Society, the Distinguished Service Award of the National Medical Association, the Pierre Galletti Award of the American Institute of Medical and Biological Engineering, and the Inaugural Gold Medal Award of the Academy of Radiology Research. He has also been awarded Honorary Professor of the South China University of Technology in Guangzhou on the occasion of commencing their first medical school class.

Tiffani Bailey-Lash, Ph.D.



Dr. Tiffani Bailey Lash serves as a Program Director/Health Scientist Administrator at the National Institutes of Health. She manages the research portfolios for the Biosensors, Platform Technologies, and mHealth programs at the National Institute of Biomedical Imaging and Bioengineering (NIBIB). Dr. Lash is also the Program Director for the NIBIB Point of Care Technologies Research Network, consisting of three centers charged with developing point-of-care diagnostic technologies through collaborative efforts that merge scientific and technological capabilities with clinical need.

Prior to her current position, Dr. Lash worked within the NIH's science policy administration. During that time, she worked at the National Institute of General Medical Sciences and National Heart Lung and Blood Institute, as well as the NIH Office of the Director. Dr. Lash has been selected as a science policy fellow for both the American Association for the Advancement of Science (AAAS) and the National Academy of Engineering. She also has a background in small business innovation and intellectual property. Dr. Lash earned her Ph.D. in Physical Chemistry from North Carolina State University via collaboration between the Departments of Chemistry and Chemical and Biomolecular Engineering. Her interdisciplinary research interests include microfluidics, biopolymers with controlled molecular architecture, and biosensor technologies.

Dr. Michael Klepser



Dr. Michael Klepser, PharmD, FCCP is a professor of pharmacy at the Ferris State University College of Pharmacy in Kalamazoo, Michigan. He received his Doctor of Pharmacy from the University of Michigan and completed a post-graduate residency at Detroit Receiving Hospital and a fellowship in Infectious Diseases at Hartford Hospital. He maintains a clinical practice at the Western Michigan University Homer Stryker M.D. School of Medicine Clinics. Dr. Klepser has been a leader in developing disease management programs utilizing CLIA-waived point-of-care tests in community pharmacies for over a decade. He is a co-developer of the *Community Pharmacy-Based Point-of-Care Testing* certificate program offered by the National

Association for Chain Drug Stores. Dr. Klepser has published extensively regarding the use of CLIA-waived point-of-care tests in community pharmacies and on training pharmacists to utilize these tests appropriately.

John Clarkson, Ph.D.



Dr Clarkson graduated in Genetics and completed PhD studies at the University of London in Microbial Genetics. Following a 15 year career in academia at the University of the West Indies and the University of Bath in the UK, he founded Molecular Sensing in 1997 with a postdoctoral researcher. The company went public in 1999 and was acquired in 2004 by Osmetech plc. After a short period as Director of Instrument Systems, he created Atlas Genetics in 2005 as a joint spin-out from Osmetech and the University of Bath. The company has focused solely on the development of an integrated system for POC molecular diagnostic tests. Following seed and series A financings, the company completed a \$30m series B financing led by the venture funds of Novartis and Johnson & Johnson. This was followed in 2015 by a series C financing led by RMI Partners. John has coordinated all of the financing rounds for Atlas. The company's first product, a rapid POC test for Chlamydia, received European regulatory approval in

2016.

J. Benjamin Crocker, M.D.



J. Benjamin Crocker, MD is a general internist and serves as **Medical Director** of the Ambulatory Practice of the Future (APF). Ben attended Tufts University (B.S. Chemical Engineering 1992) and the University of Massachusetts Medical School (M.D. 1997). He completed his residency training in internal medicine at Boston Medical Center, where he also served as chief resident. In 2001, he joined Internal Medicine Associates (IMA), the largest primary care teaching practice at MGH, where he served on the clinical practice committee for 9 years. While there he led a care team in one of the first team redesign and development projects to improve patient access to care and reduce Emergency Room admissions.

Ben was intimately involved in the hiring and development of the APF team, building and implementing the practice's strategic plan of operations, developing practice guidelines and policies, expanding urgent care services, and designing team building activities and team development processes. He was a co-founder and developer of APF's Innovation Learning Program to bring collaborators together, in the clinical environment, to build solutions to primary care challenges.

Ben has received local fellowship awards at MGH and CIMIT (Center for Integration of Medicine and Innovative Technology) to investigate primary care-based post discharge telephone follow up care, point of care laboratory testing, and point of care population management platforms for chronic disease management.

Elizabeth Palaima, Ph.D.



Elizabeth Palaima, Ph.D. is a Principal Investigator at Ativa Medical in St. Paul Minnesota; Dr. Palaima's education in Molecular Medicine at Boston University focused on carbohydrate based cellular adhesion. Currently, Dr. Palaima directs feasibility projects for diagnostic assays at Ativa.

She also leads the biochemistry development work, including reagent formulation and fluorescence flow cytometry cellular markers for the Ativa Point of Care Diagnostic System.

Shivang R. Dave, Ph.D.



Shivang R. Dave, Ph.D., is a biomedical engineer, nanotechnologist, and entrepreneur. Over the last 15 years he has focused on the development of detection technologies that improve quality of life. His formal studies include a BS in Bioengineering and minor in synthetic chemistry from the University of California, Berkeley (2004) where, under Professor Thomas F. Budinger he worked on the synthesis of targeted PET radiotracers for breast cancer imaging and a low-cost, connected plethysmograph for public health applications. He completed a dual-degree PhD in Bioengineering & Nanotechnology from the University of Washington, Seattle (2011) as Professor Xiaohu Gao's first graduate student, focusing on the development of quantum

dot-based probes for the ultrasensitive, multiplexed detection of soluble cancer biomarkers. In addition, he earned a Technology Entrepreneurship Certificate from the Center for Innovation & Entrepreneurship from the UW Foster School of Business and developed the commercialization plan for a drug delivery technology aimed at improving recovery rates from cataracts surgeries global health settings. Afterwards, he completed a three-year M+Visión Fellowship as part of the inaugural cohort of the Madrid-MIT M+Visión Consortium for Biomedical Imaging & Entrepreneurship, where he co-developed both a novel high-throughput optical cytometry technology aimed at detecting and analyzing rare cells in the blood, and an accurate, low-cost, handheld wavefront aberrometer ("QuickSee") with the aim of addressing uncorrected refractive errors in global health settings. In the summer of 2014, he cofounded PlenOptika, which is commercializing the QuickSee, and has continued to advance and translate the cytometry platform.

Jason Tucker-Schwartz, Ph.D.



Jason Tucker-Schwartz, Ph.D., is a biomedical engineer with experience in device development and biomedical photonics. He holds bachelor's (2008) and master's (2010) degrees in biomedical engineering from the University of Virginia and a PhD (2015) in biomedical engineering from Vanderbilt University. At Virginia, he worked with advisers Dr. George Gillies and Dr. Srijoy Mahapatra to develop a novel pericardial access device that increases safety of epicardial electrophysiology procedures. Based on this research, Jason and his advisers started a medical device company, EpiEP Inc., which is working towards commercial release of the technology and has already achieved FDA 510(k) clearance in the United States. During his PhD, Jason worked with Dr. Melissa Skala to develop optical imaging instrumentation and signal analysis techniques for photothermal optical coherence tomography (OCT), a functional extension of OCT that allows for three-dimensional high resolution imaging of contrast agents in tissue. In 2014, Jason was selected to join the M+Visión Fellowship program at MIT, an accelerated translational research program aimed at developing technologies to address currently unmet needs in healthcare. Through this fellowship Jason has been an integral member of three teams developing technologies in the fields of imaging cytometry, chemotherapy monitoring, and skin cancer diagnosis.

Catherine Klapperich, Ph.D.



Dr. Catherine Klapperich is the Associate Dean for Research in the College of Engineering the Director of the [NIBIB POCTRN Center for Future Technologies in Cancer Care \(CFTCC\)](#) at Boston University. She is a Professor of Biomedical Engineering and holds appointments in the Division of Materials Science and Engineering and the Department of Mechanical Engineering. Dr. Klapperich's research is focused on engineering medical devices for use in low resource settings and at the point of care. Current projects include the early diagnosis and treatment of sexually transmitted diseases and cancer. Dr. Klapperich became Associate Dean in 2015 and is working to streamline grants administration, increase the breadth of interdisciplinary work, and diversify the funding portfolio of the College.

Charlotte Gaydos, DrPH



Dr. Charlotte Gaydos is a Professor in the Division of Infectious Diseases, Johns Hopkins University, president-elect of International Union Against Sexually Transmitted Infections (IUSTI), and member of the Johns Hopkins Global Health Center. Her MPH and DrPH in immunology and infectious diseases were received from Johns Hopkins University School of Public Health. She is the Director of the Johns Hopkins University International STI Research Laboratory. She has 45 years laboratory expertise in microbiology, has authored 27 book chapters, 400 research articles, and >600 abstracts/oral presentations. Dr. Gaydos has conducted multiple FDA clinical trials for new diagnostics for STIs. She has experience in the development and evaluation of molecular amplification tests, as well as epidemiology expertise. She serves on the editorial board of the STD journal and is P.I. of an NIH Center to develop point-of-care tests for STIs, as well as a co-investigator for a NIH Center for Influenza.

Stefanie Akselrod, MT(ASCP)



Stefanie Akselrod is a Scientific Reviewer in the Division of Microbiology Devices in the Office of *in Vitro* Diagnostics and Radiological Health at the U.S. Food and Drug Administration (FDA), in Silver Spring, MD. Stefanie joined FDA in 2007 and has since been focused on the regulatory issues related to diagnostic devices intended for use in near-patient settings and in CLIA waived environments. Her primary area of expertise resides with devices intended for detection of sexually transmitted infections and respiratory pathogens. Stefanie has been on the forefront of developing study designs that capture the risk considerations of devices based on the newest technologies when used in point-of-care

settings.

Stefanie's prior work experience includes various aspects of the diagnostics field, including manufacturing practices, assay development for the pharmaceutical industry and diagnostic testing in a clinical laboratory at a healthcare institution.

Stefanie received her Bachelor of Science degree in Health Sciences from Hunter College in New York and completed her Laboratory Science internship at Lenox Hill Hospital in New York City.