KEYNOTE SPEAKERS

GARY H. GIBBONS, M.D.
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
MONDAY, 6 NOVEMBER, 2017
8:45AM – 9:45AM

Gary H. Gibbons, M.D., is Director of the National Heart, Lung, and Blood Institute (NHLBI) at the National Institutes of Health (NIH), where he oversees the third largest institute at the NIH, with an annual budget of approximately $3 billion and a staff of nearly 1,000 federal employees. NHLBI provides global leadership for research, training, and education programs to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives.

Since being named Director of the NHLBI, Dr. Gibbons has enhanced the NHLBI investment in fundamental discovery science, steadily increasing the payline and number of awards for established and early stage investigators. His commitment to nurturing the next generation of scientists is manifest in expanded funding for career development and loan repayment awards as well as initiatives to facilitate the transition to independent research awards.

Dr. Gibbons provides leadership to advance several NIH initiatives and has made many scientific contributions in the fields of vascular biology, genomic medicine, and the pathogenesis of vascular diseases. His research focuses on investigating the relationships between clinical phenotypes, behavior, molecular interactions, and social determinants on gene expression and their contribution to cardiovascular disease. Dr. Gibbons has received several patents for innovations derived from his research in the fields of vascular biology and the pathogenesis of vascular diseases.

Dr. Gibbons earned his undergraduate degree from Princeton University in Princeton, N.J., and graduated magna cum laude from Harvard Medical School in Boston. He completed his residency and cardiology fellowship at the Harvard-affiliated Brigham and Women’s Hospital in Boston. Dr. Gibbons was a member of the faculty at Stanford University in Stanford, CA, from 1990-1996, and at Harvard Medical School from 1996-1999. He joined the Morehouse School of Medicine in 1999, where he served as the founding director of the Cardiovascular Research Institute, chairperson of the Department of Physiology, and professor of physiology and medicine at the Morehouse School of Medicine, in Atlanta. While at Morehouse School of Medicine, Dr. Gibbons served as a member of the National Heart, Lung, and Blood Advisory Council from 2009-2012.

Throughout his career, Dr. Gibbons has received numerous honors, including election to the former Institute of Medicine of the National Academies of Sciences (now National Academy of Medicine); selection as a Robert Wood Johnson Foundation Minority Faculty Development Awardee; selection as a Pew Foundation Biomedical Scholar; and recognition as an Established Investigator of the American Heart Association (AHA).
For nearly 70 years, the National Heart, Lung, and Blood Institute (NHLBI) has provided global leadership for research, training, and education programs to promote the prevention and treatment of heart, lung, blood, and sleep (HLBS) diseases and disorders. Throughout this period, NHLBI-supported research discoveries have helped fuel dramatic declines in death and disability from HLBS diseases and disorders and continued improvements in quality of life in the United States and abroad. Despite these successes, heart disease remains the leading cause of death in the United States and at the global level while other diseases in the NHLBI mission areas such as chronic obstructive lung disease, asthma, and sickle cell disease contribute significant mortality, morbidity, and lost economic productivity worldwide. Additionally, disparities in access to quality care based on race, ethnicity, sex, geography, and socioeconomic status remains pervasive in the United States and abroad. Despite these persistent challenges, the NHLBI remains committed to advancing discovery science and related translation to promote precision health for all and enhance human health through several enduring principles that have sustained the NHLBI legacy of excellence. These principles include: valuing investigator-initiated fundamental discovery science; maintaining a balanced portfolio across basic, translational, clinical, population, and implementation science; training a diverse new generation of scientists; supporting implementation science that empowers patients and partners to improve the nation’s health; and innovating an evidence-based elimination of health inequities. Successful pursuit of this endeavor requires the collective effort of a diverse community of partners including patients, researchers, policymakers, care providers, professional organizations, and the private sector. The NHLBI Strategic Vision released in 2016 provides a unique opportunity for a mission-driven focus on building on our past successes, leveraging technological advances, and importantly, taking the next leap forward in precision health for all. This focus addresses both the quality and longevity of life as well as the reduction and elimination of health inequities. In particular, our ability to integrate truly diverse biomedical datasets with social and environmental determinants could usher in a new era of precision health that emphasizes the right treatment, in the right amount, tailored for the right individual patient, delivered at the right time, that yields the right outcomes. Our strategic vision for turning discovery science into precision health is perfectly aligned with the theme of the 2017 NIH-IEEE Special Topics Conference on Healthcare Innovations and Point of Care Technologies: Technology in Translation. We are excited about the opportunity to translate discovery science into health impact and chart our future together with our community of investigators and our key partners – our patients, their family members, and the public. The future has never looked brighter.
George M. Whitesides received his AB degree from Harvard University in 1960, and his PhD from the California Institute of Technology in 1964 (with J.D Roberts). He began his independent career at M.I.T., and is now the Woodford L. and Ann A. Flowers University Professor at Harvard University. His current research interests include physical and organic chemistry, materials science, biophysics, water, self-assembly, complexity and simplicity, origin of life, dissipative systems, affordable diagnostics, and soft robotics.

PRESENTATION ABSTRACT

The Point of Care and the Developing World

This talk will describe bioanalytical/medical methods designed for use in resource-limited environments, for public health, at the point of care, and in related applications in food and water safe, forensics, and others. These methods include paper diagnostics, electrochemical methods, and cell-phone based methods. The talk will also ask what strategies in academic research will be most successful in translating results from university bench science into real solutions to problems in health in the hands of users, and who else must be involved in this translation.
Eric Dishman is the Director of the All of Us Research Program at the National Institutes of Health. In this role, he leads efforts to build a research cohort of one million U.S. participants to advance precision medicine.

Previously, Dishman was an Intel Fellow and Vice President of the Health and Life Sciences Group at Intel Corporation, where he was responsible for driving Intel’s cross-business strategy, research and development, and product and policy initiatives for health and life science solutions.

He is widely recognized as a global leader in health care innovation with specific expertise in home and community-based technologies and services for chronic disease management and independent living. Trained as a social scientist, Dishman is known for pioneering innovation techniques that incorporate anthropology, ethnography, and other social science methods into the development of new technologies. He also brings his own experience as a cancer patient for 23 years—finally cured thanks to precision medicine—to drive a person-centric view of health care transformation.
INVITED SPEAKERS

ERIC BERSON, PH.D. – UNIVERSITY OF LOUISVILLE

Dr. Eric Berson is currently an Associate Professor of Chemical Engineering at the University of Louisville. Dr. Berson’s research program has focused on the development and/or improvement of bio-processes where existing techniques are limited due to complexities with the working media such as multi-phases, high-solids content, and complex flow fields. Integrating computational fluid dynamics with experimental work has been instrumental in overcoming limitations when experimental observations or measurements are difficult or impractical. Example applications include bioreactor design, kinetic and mechanistic modeling of enzymatic reactions, characterization of fluid forces in complex flow fields, correlation of fluid forces to mammalian cellular responses, and most recently a non-invasive technique for detecting and assessing coronary stenosis. The interdisciplinary work has resulted in collaborations with other engineering disciplines, MD’s, and microbiologists from universities in the US and Europe plus national labs and industry. He earned his BS in Chemical Engineering from Florida State University in 1991 and PHD from the University of Louisville in 2000.

JODI BLACK, PH.D. – OFFICE OF EXTRAMURAL RESEARCH, NATIONAL INSTITUTES OF HEALTH

Dr. Jodi Black is the Deputy Director of the Office of Extramural Research, where she oversees and supports initiative development and grants management policy and processes and the small business and extramural technology development programs.

Dr. Black has over 25 years of scientific research and research administration leadership experience with a diverse background in basic and clinical science, and programmatic administration. In her career, she has developed, implemented, and managed large, diverse, multidisciplinary scientific programs in areas including infectious diseases, cancer and genomics and has developed strategic alliances between academic, healthcare and commercial organizations to leverage resources and capacity across institutions. While at the National Heart, Lung, and Blood Institute (NHLBI), she provided leadership and management for initiative development, the peer review process, policy development and implementation, grants and contracts including training, small business and international awards, as well as the development and implementation of programs and partnerships to enhance the translation of innovative technologies from the bench to the market to enhance health.

Dr. Black earned a PhD in pathology and a Masters of Medical Science in infectious diseases from Emory University.
Carole Carey is a senior IEEE member and a member of the IEEE Eta Kappa Nu Honor Society. She currently serves as chair of the EMBS Standards Committee, liaison to the IEEE Standards Association, and was recently selected as a recipient of the 2016 IEEE-SA Standards Medallion Award. She is a former U.S. FDA official in the Center for Devices and Radiological Health (CDRH) with over 23 years of regulatory science experience as a Scientific Reviewer and International Advisor. As a Reviewer, she was team leader of highly complex, innovative cardiovascular devices and a peer-reviewed expert regulatory review scientist. In this capacity, she was also active in the development of industry consensus standards in her areas of specialization, both at the national and international levels. As a Mansfield Fellow, she trained side-by-side and collaborated with regulatory counterparts in Japan’s Ministry of Health, Labour and Welfare (MHLW) and its scientific review arm, the Pharmaceutical and Medical Devices Agency (PMDA) -- on regulatory device issues, scientific matters concerning device safety and effectiveness, the recognition of international standards and global harmonization initiatives. Later, she served as Director of International Staff in FDA CDRH. Furthermore, she conducted device regulatory workshops in Europe, Asia and Latin America. Currently, she is a regulatory consultant providing advice and strategic approaches in premarket submissions, investigational device clinical trials and postmarket issues for regulated industry. Carole earned her engineering degrees from Johns Hopkins University and Loyola University of Maryland.

**PRESENTATION ABSTRACT**

**The Role of Standards and Regulations in Translation of Biomedical Technology**

As healthcare is becoming increasingly dependent on new and potentially disruptive technologies, the biomedical engineering community is more engaged in collaborative efforts with academia, clinicians, the health service and industry. Some examples of biomedical engineering developments driving innovation are latest sensors, new biocompatible materials, and novel approaches in measuring techniques. The aspirations are to reduce the cost of medical devices and improve the performance of healthcare technology with reliable products that are safe and effective. The goal of multidisciplinary partnerships is to apply research discoveries and preclinical studies, investigational trials in humans, and finally early access to benefit public health. For medical devices to be marketed legally around the globe, the device industry must overcome many translation challenges in order to seek and obtain regulatory approvals. Innovation, biomedical technology, and use of standards play influential roles in the regulatory process to market a device. They can shorten the translation process and lead to successful commercialization. This presentation will highlight the importance of using consensus standards as well as pursuing the development of new international standards. Examples of existing standards and active projects in development under the IEEE Standards Association (IEEE-SA) and Engineering in Medicine and Biology (EMB) standards committee will be introduced. We will also explain how standards are used and are becoming an important part in carrying out the regulatory mission.
Jue Chen received the Bachelor of Medicine Degree in Preventive Medicine in 2001 and Master Degree in Toxicology in 2004, from Fudan University, Shanghai, China. She obtained her Ph.D. degree in Pharmacology from Emory University in 2011 before joining in the Laboratory of Biochemistry in the Intramural Program of the National Heart, Lung, and Blood Institute (NHLBI). In May 2015, she joined the NHLBI extramural program as a program director in the Division of Cardiovascular Sciences (DCVS).

Dr. Chen’s past research focused on redox signaling and she has expertise in public health, pharmacology, environmental toxicology, and protein chemistry. She currently manages basic and preclinical research grants studying atherosclerosis in the Atherothrombosis and Coronary Artery Disease Branch of the DCVS in the NHLBI.

Jean-Philippe Couderc, Ph.D. – Strong Memorial Hospital, University of Rochester

Short Biographical Sketch Dr. Couderc is a biomedical engineer who obtained his PhD degree with highest honors from the French National Institute of Applied Sciences in Lyon, France in 1997. He is Associate Professor of Medicine in the Cardiology Department of Strong Memorial Hospital (Rochester, NY) and Research Associate Professor of Electrical and Computer Engineering at University of Rochester (NY). He is leading the Telemetric and Holter ECG Warehouse initiative (THEWproject.org), and he is the Assistant Director of the Heart Research Follow-up Program (HRFUP). Dr. Couderc is a principal investigator and a co-investigator in several federal funded research grants involving the development of ECG and wearable technologies. In addition he holds the position of Chief Technology Officer at iCardiac Technology Inc. a Rochester-based research spin-off delivering high-precision ECG-based safety and efficacy metrics to international pharmaceutical companies.

Dr. Couderc has been invited for lectures by universities in US and Europe and by private and national laboratories (NIH and EPA). He is currently holding a position of Special Governmental Employee at the Center for Drug Evaluation and Research (CDER) for the Food and Drug Administration of the US. Department of Health and Human Services. Currently, he has more than 80 publications and his work has been highlighted in the Wall Street Journal.
MICHAEL DEMPSEY, FOUNDER & CEO – SECORA CARE

Mike Dempsey has been working in the field of medical devices for more than 30 years; during this time he has invented or worked on products that have treated over twelve million people. Mike holds over 40 patents on various medical devices and has ten more patents pending. Mike is currently the founder and CEO of Secora.Care, an early-stage company that uses “Big Data” to help older people live safely at home as long as possible.

Mike is also the Entrepreneur in Residence at the Center for the Integration of Medicine and Innovative Technology (CIMIT), the Director of the CIMIT Accelerator Program, the Co-Executive Director of the Center for Biomedical and Interventional Technology (CBIT) at Yale University, and a faculty member at MIT. Mike’s primary responsibilities in these academic settings are to lead academic innovators through the commercialization journey and to teach students the fundamentals of building medical companies. At CIMIT and Yale, Mike leads a team of highly experienced med-tech executives who join the academic team with up to a full-time commitment and for as long as two years, effectively acting as an interim CEO. This intensive, practical, and focused approach to facilitating the academic-to-commercial transition has led to a commercialization success rate of 42% and an average time to commercialize of 18 months. Mike is also the PI on several NIH SBIR grants, a frequent grant reviewer for the NIH, and has received a special citation from the Commissioner of the FDA for “exceptional initiative and leadership to protect the public health.”

ATAM P DHAWAN, PHD – NEW JERSEY INSTITUTE OF TECHNOLOGY

Atam P. Dhawan obtained his bachelor’s and master’s degrees from the Indian Institute of Technology, Roorkee, and Ph.D. from the University of Manitoba, all in Electrical Engineering. From 1985-2000, he held faculty positions in Electrical & Computer Engineering, and Radiology departments at University of Houston, University of Cincinnati, University of Texas, University of Texas Medical Center (Dallas) and University of Toledo. In July 2000, he joined NJIT where he served as the Chair of the Department of Electrical and Computer Engineering for nine years. Currently he is Distinguished Professor of Electrical & Computer Engineering and Executive Director of Undergraduate Research and Innovation. He is also an Adjunct Professor of Radiology at the University of Medicine and Dentistry of New Jersey.

Dr. Dhawan is a Fellow of the IEEE for his contributions in medical imaging and image analysis. He has published more than 215 research articles in refereed journals, books, and conference proceedings. His current research interests are medical imaging, multi-modality medical image analysis, adaptive learning and pattern recognition. His research work has been funded by NIH, NSF and several industries.

Dr. Dhawan is a recipient of Martin Epstein Award (1984), National Institutes of Health FIRST Award (1988), Sigma-Xi Young Investigator Award (1992), University of Cincinnati Faculty Achievement Award (1994) and the prestigious IEEE Engineering in Medicine and Biology Early Career Achievement Award (1995) and University of Toledo Doermann Distinguished Lecture Award (1999). He served as the Senior Editor of IEEE Transactions of Biomedical Engineering and Editor-In-Charge of IEEE TBME Letters (2007-2012). He is Co-Editor-In-Chief of the new open-access IEEE Journal of Translational Engineering in Health and Medicine.
He has served on many IEEE EMBS professional committees and has delivered several Workshops on Intelligent Biomedical Image Analysis in IEEE EMBS International Conferences (1996, 1997, 2000, 2003). He served as the Chair of the “Emerging Technologies Committee” of the IEEE-EMB Society from 1997-99, and 2009-11. He is also a member of the IEEE Life Sciences Committee. He was the Chair of the “New Frontiers in Biomedical Engineering” Symposium at the World Congress 2000 on Medical Physics and Biomedical Engineering. He was the Conference Chair of the IEEE 28th International Conference of Engineering in Medicine and Biology Society, New York in 2006. He has initiated and served as the Conference Chair/Co-Chair of the series of IEEE-NIH Special Topics Conferences on Healthcare Innovations and Point-of-Care Healthcare Technologies held in Bangalore, India (2013), Seattle (2014), Bethesda (2015), and Cancun, Mexico (2016).

Dr. Dhawan has chaired numerous NIH special emphasis and review panels including the NIH Chartered Study Section on Biomedical Computing and Health Informatics (2008-11). He is listed in Who’s Who in the World, Who’s Who in America, Who’s Who in Engineering, and Who’s Who Among America’s Teachers.

Echezona Ezeanolue, M.D., MPH – UNIVERSITY OF NEVADA

Echezona Ezeanolue, MD, MPH is Professor of Pediatrics and Public Health at the University of Nevada, Las Vegas. He is a Nigeria-born Infectious Disease specialist and physician-epidemiologist with an extensive record of community-based maternal and child health research. His research focuses on the use of implementation science to enhance the effectiveness and quality of health services. He serves as the Director of the HRSA-funded comprehensive maternal-child HIV program in Nevada (H12HA24832) and PI on multiple NIH-funded grants including the Baby Shower Trial (R01HD075050; R21TW010252; R01HD087994; R01HD089871) that seek to identify feasible, acceptable, and sustainable approaches to test, engage and retain individuals with HIV infection to achieve viral suppression and improve health outcomes. Dr. Ezeanolue has been recognized as Nevada Public Health Leader of the Year (2007), Nevada Health Care Hero (2008), Nevada Immunization Champion (2009) and AAP Local Hero (2010) for his contributions to public health.

PRESENTATION ABSTRACT

Patient-Held Smartcard to Increase Data Quality and Improve Health Outcome

Despite the availability of evidence-based interventions for prevention, HIV and hepatitis B virus (HBV) infections remain endemic in sub-Saharan African countries. To implement evidence based interventions to prevent these infections, pregnant women need to be screened during pregnancy and infected women identified and treated. Additionally, maternal information including laboratory test results should be available at the point-of-delivery (POD) to enhance implementation of evidence-based interventions to improve health outcomes. Until recently, the use of information technology to make prenatal data available at the POD has been limited to high-income countries due to poor infrastructure in developing countries. Fortunately, the unprecedented spread of mobile technology has made it possible to develop mHealth platforms that provide similar services to hard-to-reach communities in resource-limited settings. This has led to improved quality of care, decreased rate of unnecessary testing and allowed for early institution of evidence-based interventions that improve birth outcomes. We developed an integrated mHealth platform that can: (1) store prenatal data obtained from community- and facility-based screening programs including laboratory test results for HIV, HBV and genotype in a secure, web-based database, (2) encrypt this data into a “smartcard”, and (3) make these data available at the POD using a mobile-phone based application to read the card.
Mike Fisher has 20 years of experience developing and commercializing medical products, managing sustaining engineering efforts, performing International manufacturing scale-up, achieving regulatory concurrence, navigating patent landscapes, and executing development plans. He is a named inventor on over 20 issued US patents with almost twice as many applications in prosecution. In 2015, Mike joined GCMI, a not-for-profit medical device development company that is affiliated with Georgia Tech. Here, he gets to develop disruptive medical technologies and mentor med tech entrepreneurs. Prior to GCMI, Mike spent 17 years working for CR Bard, Johnson & Johnson’s DePuy Franchise, the Orthopaedic Research Lab at the University of Virginia, and several start-up companies in the tissue engineering industry. He earned BS and MS degrees in engineering mechanics from Virginia Tech where he met his wife. When Mike is not working on medical products, he enjoys spending time with his wife, children, and Boy/Cub Scouts across Northwestern Georgia.

Brian Fitzgerald was educated in England and received his engineering degree from University College Cardiff in Wales. He became a US citizen in 2003.

He left the private sector in 1992 after a multidisciplinary engineering career, and joined Underwriters Laboratories (UL) in Raleigh, NC helping to start their software safety initiative. He has contributed to the development of several national and international standards for programmable systems UL 1998, IEC 60601-1-4, AAMI SW68 and most recently IEC 62034, IEC 80001 and IEC ACSEC Guide for Privacy and Security. He was nominated as a US National Expert by AAMI to WG22 of IEC SC62a dealing with programmable systems, to ISO TC210 WG1 dealing with quality systems and to JWG7 of IEC and ISO for Medical IT networks.

He is a member of the AAMI software committee, the AAMI IT committee and the AAMI Cybersecurity committee. Prior to joining FDA he was an accredited software expert and lead auditor for two European notified bodies. He continues to conduct public seminars in software safety, risk management, medical device cybersecurity, software related regulatory affairs and medical quality systems. He is a member of the US National Council of the International Electro-technical Commission.

He joined FDA’s CDRH in October 2003 in the Office of Science and Engineering Laboratories to specialize in systems, software evaluation and safety research activities. He is currently Senior Technical Advisor for Cybersecurity and High-Performance Computing.

Current projects include researching the use of formal methods as they relate to generalized ‘assurance cases’ including safety cases and compliance cases, and the development of forensic techniques for detecting and investigating software failure. He leads the technical and research aspects of the FDA cybersecurity team. He is active in the internal governance structures of FDA computational science and remains active in both the
FDA’s new high-performance computing center and semantic text mining activities. He continues to contribute to FDA Guidance development, product review activities and works with several other Federal Regulatory Agencies in the field of cybersecurity.

**CINDY J. FLACKS, MPH, M.T., ASCP – CENTERS FOR MEDICARE AND MEDICAID SERVICES**

CDR Flacks serves as Medical Technologist/MLS Regulatory Compliance Lead for the Centers for Medicare and Medicaid Services (CMS), Survey and Certification Group/Division of Laboratory Services where she oversees several projects, to include the oversight of CLIA certified International Laboratories. She also served as a member of the IQCP Planning team which was charged with creating and implementing IQCP policy nationwide; Co-authored an educational workbook for laboratories implementing IQCP; and co-wrote and helped to produce a 20-minute video on the CLIA survey process, among other notable accomplishments.

CDR Flacks was commissioned as an officer in the United States Public Health Service in June 2003 and worked in the Federal Bureau of Prisons before joining CLIA in March 2008. She was deployed to New Orleans in February 2006 to lead a Public Health Service clinic in support of the first Mardi Gras celebration post Hurricane Katrina.

A native of Petersburg, Illinois CDR Flacks received her MPH, with Honors from American Military University and a BS, Summa Cum Laude in Clinical Laboratory Science from UMass, Lowell. CDR Flacks is a Certified Medical Technologist by the American Society of Clinical Pathologists.

Currently residing in Downtown Baltimore, MD with her husband, daughter and two dogs, CDR Flacks enjoys Yoga, cross-training, and watching professional football, specifically the NY Football Giants. She is also involved on the board of her daughter’s school Parent Teacher Organization.

**JOHN J. GARGUİLO, M.S. – NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY**

John J. Garguilo is a supervisory computer scientist at the National Institute of Standards and Technology (NIST) of the United States Department of Commerce. John’s the Group Leader of the Systems Interoperability Group and leader of the Semantic Interoperability of Medical Devices (SIMD) project focused on medical device communication research and testing and aimed at enabling the adoption of medical device communication standards by acute, point-of-care, and personal health medical device manufacturers.

John currently serves as the Health Level Seven (HL7) Healthcare Device Working Group Co-Chair and over ten years as the test lead as well as four years as the Technical Committee Co-chair for the Integrating the
Healthcare Enterprise – Patient Care Device (IHE-PCD) domain. John has recently been elected to a two-year term as the Secretary of the IEEE 11073 Medical Device Communications Point of Care (PoCD) working group. John’s focus over the past ten years has been on developing conformance test tooling in support of standardization of medical device information exchange and working with device standard and Standards Development Organizations (including HL7 V2 and ISO/IEEE 11073). His work includes testing and promoting adoption of standards for medical device communications throughout the healthcare enterprise as well as integrating it into the electronic health record. John works and is closely engaged with medical device experts within the HL7, IHE-PCD domain, and ISO/IEEE Healthcare Devices and Personal Health Devices working groups. John also leads the HL7 message validation test tooling effort and development of an industry adopted harmonized medical device terminology database containing ISO/IEEE 11073 terminology.

John holds a Master’s degree from the Johns Hopkins University and Undergraduate degree from the State University of New York, Potsdam, both in computer science. John has extensive experience over the past 30 years working on and managing software systems to support research, testing, automating work flow applications, data communications, and electronic commerce.

**PRESENTATION ABSTRACT**

**Testing Semantic Interoperability of Medical Device Communication Information**

John Garguilo, computer scientist at the National Institute of Standards and Technology, will present applied black-box test methods and research approaches based on well recognized international standards used to help chip away at device to device interoperability and integrating device data throughout the healthcare enterprise including electronic health records. Conformance test tooling will be described - built in support of common exchange of information - via standardization and working with medical device domain and Standards Development Organizations (including Health Level Seven [HL7] and ISO/IEEE 11073 – Medical Device Communication Family of Standards). Core to the described approach are informational modeling techniques and a harmonized medical device nomenclature; and a foundational health information technology test framework used to provide users implementation guide and test case authoring and management capabilities leading to automatic test tool generation. Such approaches to testing and communication research is aimed at enabling the adoption of medical device communication standards by acute, point-of-care, and personal health medical device manufacturers thus affecting improved healthcare including patient safety, clinical decision support, and semantically intact retrospective data, as well as financial impact through more informed medical device and system procurement practices.

**CRISTINA GIACHETTI, PH.D. – BILL AND MELINDA GATES FOUNDATION**

Cristina Giachetti is the Deputy Director of Diagnostics at the Bill and Melinda Gates Foundation, where she oversees the development and implementation of diagnostic tools to support the Foundation’s programs in Global Health. Previously, she was Senior Vice President, Research and Development for the Diagnostics Division of Hologic and Vice President, Research and Development for Gen-Probe, with responsibilities over Research, Development, Clinical, Medical and Scientific Affairs. During her tenure at Gen-Probe/Hologic she oversaw the development of numerous molecular diagnostics and blood-screening tests that were successfully commercialized worldwide for the TIGRIS and Panther instruments under the APTIMA and PROCLEIX brand names. In particular, she led the technical team that developed the first FDA licensed blood-screening test for detection of HIV-1 and HCV nucleic acids, and her work in increasing the safety of the blood supply awarded Gen-Probe the National Medal for Technology from the US President. Cristina received her degrees in Clinical Analysis and
Biochemistry, and Ph.D. in Biochemistry from the University of Buenos Aires. She completed postdoctoral training in molecular virology and rapid viral evolution at the University of California, San Diego, Department of Biology and at the University of California, Irvine, Department of Microbiology and Molecular Genetics.

**PRESENTATION ABSTRACT**

**Critical Considerations When Introducing Diagnostics in Global Health**

Nascent health care markets in low-resource settings can present considerable challenges in the design, implementation, and impactful scale-up of diagnostic products. Diagnostics developers often face significant challenges introducing products to these settings because they may lack a clear understanding of the multiple customers and their needs, the restricted physical infrastructure and resources available, the regulatory and policy frameworks, and the dynamics of these emerging markets. While technology innovation is profuse, scale-up of diagnostic interventions has not been particularly successful, and this is especially true with POC diagnostics, where many new ideas and proofs of concept with the intent of overcoming infrastructural hurdles abound, but the true realization of their value is lacking.

Unlike vaccines and drugs, the utility and ultimate impact of diagnostic products depend on many intricacies of the health system (e.g., health-professional skill-set and training, quality, treatment availability, and linkage to care), and the confounded delivery logistics (e.g., supply chain, procurement mechanisms, funding agencies), not all of which are under complete control of the diagnostics developer or able to be solved by technology alone.

The objective of this talk is to highlight some of the critical aspects a developer of a new technology would need to address upfront—and continuously throughout the development process, to be successful in global health.

**JULIAN GOLDMAN, M.D. – PARTNERS HEALTHCARE**

Dr. Goldman is the Medical Director of Biomedical Engineering for Partners HealthCare, an anesthesiologist at the Massachusetts General Hospital, and Director/PI of the Program on Medical Device Interoperability (MD PnP) – a multi-institutional research program founded in 2004 to advance medical device interoperability to improve patient safety and HIT innovation.

Dr. Goldman performed his clinical anesthesia and research training at the University of Colorado, and is Board Certified in Anesthesiology and Clinical Informatics. He served as a Visiting Scholar in the FDA Medical Device Fellowship Program as well as an executive of a medical device company. At MGH, Dr. Goldman served as a principal anesthesiologist in the “OR of the Future” – a multi-specialty OR that studies diverse technologies and clinical practices to enable broad adoption.

Dr. Goldman chairs the international standardization committee for the safety and performance of anesthesia and respiratory equipment (ISO TC 121), and serves in leadership positions of AAMI, UL, and IEC standardization committees. He Co-Chaired the HHS HIT Policy Committee FDASIA Regulations Subcommittee and the FCC mHealth Task Force, and co-chairs the healthcare task group of the Industrial Internet Consortium. He was recently appointed as a Distinguished Lecturer for the IEEE EMBS.
Dr. Goldman’s awards include the AAMI Technology in Health Care Clinical Application Award, the International Council on Systems Engineering Pioneer Award, the American College of Clinical Engineering award for Professional Achievement in Technology, and American Society of Anesthesiologists awards for advanced technology applications to improve patient safety.

E-card: www.jgoldman.info

Umut A. Gurkan holds BS degrees in Chemical Engineering and Mechanical Engineering from Middle East Technical University, and a PhD degree in Biomedical Engineering from Purdue University. He completed his Postdoctoral Training in Medicine at Brigham and Women’s Hospital (Harvard Medical School) and Harvard-MIT Health Sciences and Technology after which he joined Case Western Reserve University as Assistant Professor of Mechanical and Aerospace Engineering. Dr. Gurkan is leading the CASE Biomanufacturing and Microfabrication Laboratory (CASE-BML). CASE-BML’s mission is to improve human health and quality of life by a fundamental understanding of cell biomechanics, and through innovations in micro/nano-engineering, microfluidics, biosensors, and point-of-care systems. Dr. Gurkan has received national and international recognitions and awards for research and education, including, NSF CAREER Award, “Rising Star” Award from Biomedical Engineering Society (Cellular and Molecular Bioengineering and Advanced Biomanufacturing Divisions), MIT Technology Review Innovator Under 35 Award (Turkey), Case-Coulter Translational Research Partnership Award, Clinical and Translational Science Collaborative Award, Case School of Engineering Research Award, Doris Duke Innovations in Clinical Research Award, Belcher-Weir Family Pediatric Innovation Award, Translational Research Featured New Investigator Award from Central Society for Clinical and Translational Research, and Glennan Fellowship from the University Center for Innovation in Teaching and Education. Dr. Gurkan has authored over 55 research and review articles in leading peer-reviewed journals, in addition to numerous book chapters and patents. Three of his patents have been licensed for commercialization, one of them being on a microchip electrophoresis system for point-of-care diagnosis of hemoglobin disorders in low resource settings. Dr. Gurkan is a member of the following societies: American Society of Hematology, American Society of Mechanical Engineers, IEEE Engineering in Medicine and Biology Society, and Biomedical Engineering Society.  Email: umut@case.edu  Web: http://www.case-bml.net

Shoshana Herzig, MD, MPH, FACP is a hospitalist and Director of Hospital Medicine Research in the Division of General Medicine at Beth Israel Deaconess Medical Center, an Assistant Professor of Medicine at Harvard Medical School, and a Senior Deputy Editor at the Journal of Hospital Medicine. Her research focuses on the interplay between medication decisions and adverse outcomes in the hospital setting in an effort to inform development of clinical decision rules and computer-based interventions to promote evidence-based prescribing practices and reduce complications from medical care.
**Erin Iturriaga – National Heart, Lung, and Blood Institute**

Erin Iturriaga serves as a Program Officer and Clinical Trials Specialist at the National Heart, Lung, and Blood Institute (NHLBI). She led an RFA called Onsite Tools and Technologies for Heart, Lung, and Blood Clinical Research Point-of-Care and has an interest in technology for home use especially in the aging population. She led a workshop with the Computer Research Association’s Computing Community Consortium (CCC) funded by the National Science Foundation to discuss the use and development of technologies for assisting older adults and people with chronic diseases to live independently. She brings a strong background in clinical research, including clinical trials management, education, and regulatory responsibilities.

**Zachary Ives, Ph.D. – University of Pennsylvania**

Zachary Ives is a Professor of Computer and Information Science at the University of Pennsylvania, where he also serves as the Associate Dean for Masters and Professional Programs in Penn’s School of Engineering and Applied Science. His research interests include data integration and sharing, managing “big data,” sensor networks, and data provenance and authoritativeness. He has worked extensively in applying these techniques in scientific applications, especially in the field of neuroscience (where he and collaborators built the IEEG.org portal for sharing epilepsy data). He is a recipient of the NSF CAREER award, and an alumnus of the DARPA Computer Science Study Panel and Information Science and Technology advisory panel. He is a co-author of the textbook Principles of Data Integration, and received an ICDE 2013 ten-year Most Influential Paper award. He has been an Associate Editor for Proceedings of the VLDB Endowment (2014) and a Program Co-Chair for SIGMOD (2015). He is also a co-founder of Blackfynn, Inc., a company focused on providing infrastructure for biomedical data science.

**Jeffrey Kaye, M.D. – Oregon Health and Science University**

Jeffrey Kaye is the Layton Endowed Professor of Neurology and Biomedical Engineering at Oregon Health and Science University (OHSU). He directs ORCATECH – the National Institute on Aging (NIA) – Oregon Center for Aging and Technology and the NIA – Layton Aging and Alzheimer’s Disease Center at OHSU. Dr. Kaye’s research has focused over the past two decades on the question of why some individuals remain protected from functional decline and dementia with advancing age while others succumb at much earlier times. This work has relied on a number of approaches ranging across the fields of genetics, neuroimaging, physiology and continuous life
activity monitoring. He leads several longitudinal studies on aging and clinical trials including the ongoing Oregon Brain Aging Study, the Intelligent Systems for Detection of Aging Changes (ISAAC), the Life Laboratory, the Ambient Independence Measures for Guiding Care Transitions, and the Collaborative Aging (in Place) Research using Technology (CART) studies using ubiquitous, unobtrusive technologies for assessment of older adults in their homes to detect changes signaling imminent functional decline. He is co-principal investigator for the Integrated Analysis of Longitudinal Studies of Aging (IALSA), a worldwide effort to harmonize aging and dementia data for improved analysis. Dr. Kaye has received the Charles Dolan Hatfield Research Award for his work. He is listed in Best Doctors in America. He serves on many national and international panels and review boards in the fields of geriatrics, neurology and technology including as a commissioner for the Center for Aging Services and Technology (CAST), on the Advisory Council of AgeTech West, the International Scientific Advisory Committee of AGE-WELL Canada, and Past Chair of the International Society to Advance Alzheimer’s Research & Treatment (ISTAART). He is an author of over 400 scientific publications and holds several major grant awards from federal agencies, national foundations and industrial sponsors.

MONICA KERRIGAN, MPH – JHPIEGO

Monica Kerrigan serves as Jhpiego’s Vice President for Innovations, leading a multidisciplinary team to identify novel solutions and harness the power of innovations to accelerate progress in preventing needless deaths among the world’s most vulnerable women, girls and their families. Ms. Kerrigan brings together global and country experts, innovators and “unlike minds” from diverse backgrounds in public, private, technology and non-government organizational sectors to address intractable problems in reproductive, maternal, newborn and adolescent health. In her role, she is forging new partnerships with governments, private sector entities, donors and philanthropists to advance innovative products, policies and processes that transform health through positive disruption.

Ms. Kerrigan is a pioneering leader and expert in family planning, maternal health and sexual and reproductive health and rights. Prior to joining Jhpiego, she worked at the Bill and Melinda Gates Foundation from 2007–2016, serving most recently as Deputy Director of Family Planning. In that position, she played a pivotal role in launching the London Summit on Family Planning in 2012. She worked in partnership with the Department of International Development (DFID), United States Agency for International Development (USAID) and United Nations Population Fund (UNFPA) to promote the long-term goal of universal access to reproductive health and support the rights of an additional 120 million women and girls to access quality family planning information, services and supplies. At the Gates Foundation, Ms. Kerrigan also energized the landscape of family planning by developing partnerships with governments, donors and private sector and civil society organizations, which resulted in the design and implementation of the Urban Reproductive Health Initiative; seminal launch of the Ouagadougou Partnership for Francophone Africa; coordination of the first Implant Volume Guarantee; and inauguration of global strategies and investments in postpartum family planning.

Prior to joining the Bill and Melinda Gates Foundation, Ms. Kerrigan served as Team Leader for Maternal and Newborn Health at UNICEF in Indonesia. For more than a decade at USAID, she served as a Senior Technical Advisor in the Office of Family Planning/Reproductive Health, where she led initiatives on frontline provider performance, commodity security and post-abortion care. In the early 1990s, Ms. Kerrigan led Jhpiego’s Africa Office, developing the capacity of countries to deliver high-quality training and services in reproductive and maternal health.

She earned her Master of Public Health degree in maternal and child health from the University of North Carolina at Chapel Hill. She is a former Peace Corps Volunteer, where she served as a primary health care trainer in rural Mali.
Shawna Khouri, MBID – Georgia Institute of Technology

Shawna Khouri, MBID is the Managing Director of the Coulter Translational Fund at Georgia Institute of Technology and Emory University where she provides business leadership and commercialization strategy at the intersection of academia, medicine, investment and industry to successfully bridge early-stage technologies into successful start-ups and licenses to industry. In addition, Shawna provides commercialization coaching to national clients, including the NIH-C3i Commercialization Training Program, where she mentors R01 and SBIR recipients in business and development strategies for their medical innovations. Shawna is also a medical device engineer with patents pending on emergency medicine and orthopedic technologies. These technologies have received national innovation awards and been featured in a special exhibition at the Smithsonian. She has both a Master’s Degree in Biomedical Innovation and Development and Bachelor of Science in Biomedical Engineering from Georgia Institute of Technology.

Moka Lantum, M.D. – MicroClinic Technologies

Dr. Lantum is a serial entrepreneur with 20-year experience in health care management in resource-limited settings, and with specific expertise in m-Health and e-Health in the Africa health setting. As managing director and founder of MicroClinic Technologies, he carried out extensive market research in public and private clinics to establish the optimal user experience for mobile electronic medical records systems in Africa. This led to the development of a) ZiDi™, the first enterprise health management system to be adopted by a Ministry of Health in Kenya, and subsequently, b) iSikCure™, the first mobile information exchange platform in Africa, for which we now seek funding to scale. He has grown ZiDi™ to become the leading EMR solution in Kenya, with a turnover of $650,000 in 2016, through partnerships with the MoH, counties, private provider networks, CSR partners (GSK Health Innovation Award, Pfizer Foundation, and strategic partners including Huawei Technologies, Philips East Africa, and other stakeholders in Every Woman Every Childconsortium). Through ZiDi™, he has built relationships with providers and owners of hospitals in over 12 counties in Kenya and a database with over 1,000 health providers and 600,000 patients.

Prior to founding MicroClinic Technologies, Dr. Lantum played multiple executive roles in a Fortune 500 manufacturing company and was director of business process improvement for a $6 billion New York-based health insurance company in the USA.

Dr. Lantum obtained his Doctor of Medicine training at Faculty of Medicine and Biomedical Sciences, University of Yaoundé, Cameroon; a Diploma in Nutrition and International Child Health, from Uppsala University, Uppsala, Sweden; a Doctorate in Pharmacology, from the University of Rochester, Rochester, New York. He is a graduate of the Masters in Health Care Management at the Harvard School of Public Health. He is a frequent featured guest speaker on social entrepreneurship. Dr. Lantum is the recipient of numerous international awards, including the 2014 Sankalp Award, the 2013 and 2015 GSK-Save the Children Healthcare Innovation Award, and was runner-up for the 2014 IFC/Financials Times Sustainable Business Award. He was nominated a 2016 100 Top Global Thinker by the Foreign Policy Magazine.
TIFFANI BAILEY LASH, PH.D. – NATIONAL INSTITUTES OF HEALTH

Dr. Tiffani Bailey Lash serves as a Program Director/Health Scientist Administrator at the National Institutes of Health. She manages the research portfolios for Point of Care Technologies, Microfluidic and Bioanalytical Systems, and Connected Health 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 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 a 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.

EDWARD LIVINGSTON, M.D. – THE JOURNAL OF THE AMERICAN MEDICAL ASSN.

Edward H. Livingston, M.D., F.A.C.S., A.G.A.F., has served as Deputy Editor for Clinical Content of JAMA, The Journal of the American Medical Association since July 1, 2012. Before that, he was a Contributing Editor at JAMA for 3 years.

Born and raised in Los Angeles, Dr. Livingston received his Medical Degree from UCLA. He completed a General Surgery Residency at UCLA and served as the Administrative Chief Resident for Surgery in 1992. After Residency, he remained on the faculty at UCLA eventually serving as Assistant Dean of the Medical School and Surgical Service Line Director for the VA Greater Los Angeles Health Care System. He also founded the UCLA bariatric surgery program.

In 2003, he moved to Dallas to become the Professor and Chairman of GI and Endocrine Surgery at the University Of Texas Southwestern School Of Medicine. During this time period, Dr. Livingston headed the VA’s national effort in bariatric surgery quality improvement. He was appointed as a Professor of Biomedical Engineering in 2007 at the University of Texas Arlington. Dr. Livingston became Chairman of the Graduate Program in Biomedical Engineering at UTSW in 2010.

Dr. Livingston has had peer review funding and has published in excess of 150 peer reviewed papers as well as numerous other scientific writings. He has also served on numerous local and national committees and is a past president of the Association of VA Surgeons. He continues to serve as a Professor of Surgery at UTSW.
MICHAEL LAUER, M.D. – NATIONAL INSTITUTES OF HEALTH

Michael Lauer, M.D., is the Deputy Director for Extramural Research at the National Institutes of Health (NIH). He received education at Rensselaer Polytechnic Institute, Albany Medical College, Massachusetts General Hospital, Boston’s Beth Israel Hospital, Harvard School of Public Health, and the NHLBI’s Framingham Heart Study. A board-certified cardiologist, he spent 14 years at Cleveland Clinic as Professor of Medicine, Epidemiology, and Biostatistics. From 2007 to 2015 he served as a Division Director at the National Heart, Lung, and Blood Institute (NHLBI). He has received numerous awards including the NIH Equal Employment Opportunity Award of the Year and the Arthur S. Flemming Award for Exceptional Federal Service.

ANAND K. IYER, PH.D. – WELLDOC INC.

Anand is a respected global digital health leader—most known for his insights on and experience with technology, strategy and regulatory policy. Anand has been instrumental in WellDoc’s success and the development of BlueStar®, the first FDA-cleared mobile prescription therapy for adults with type 2 diabetes. Since joining WellDoc in 2008, he has held core leadership positions that included Chief Data Science Officer, President and Chief Operations Officer. In 2013, Anand was named “Maryland Healthcare Innovator of the Year” in the field of mobile health.

Prior to joining WellDoc, Anand was already an established thought leader in the field. He had served as the Director of PRTM’s wireless practice, where helped companies take advantage of disruptive technologies, business models and process models offered by and enabled by advanced wireless communications.

Anand was the founder and immediate-past president of the In-Building Wireless Alliance, and teaches advanced wireless courses to senior officers in the US Department of Defense at the Institute for Defense and Business. Prior to joining PRTM, Anand was a member of the scientific staff at Bell Northern Research and Nortel Networks. He holds an MS and a PhD in electrical and computer engineering, and an MBA from Carnegie Mellon University. He also holds a BS in electrical and computer engineering from Carleton University.
TIM MCCARTHY – TELEMEDICINE AND ADVANCED TECHNOLOGY RESEARCH CENTER

Tim McCarthy joined TATRC’s “Command Team” after serving 26 years in the Army Medical Department (AMEDD) in a variety of assignments as a Healthcare Administrator which led to functional and technical innovation. He also spent 11 years with Electronic Data Systems (EDS) and Hewlett Packard (HP) working in the technology industry, providing strategic information technology support to the Army Medical Department, Recruiting Command, and Army Knowledge Online (AKO). Before joining TATRC, Mr. McCarthy spent 6 + years working for the Defense Center of Excellence (DCoE) for PH and TBI, as Deputy in the Primary Care Behavioral Health Directorate, providing program development and IT support for case and risk management tracking, as well as program evaluation. While on active duty, Mr. McCarthy’s focus was on human resources, operations, leadership development and executive skills, training technology, distance learning, IM/IT training and knowledge management. He retired from the AMEDD as the Chief of the Leadership and Instructional Innovations Branch, where among other things, he was responsible for the creation of the AMEDD’s IM/IT training program, the Joint Medical Executive Skills Institute, and helped to inspire the creation of AKO.

He also taught in the Army/Baylor University Master’s program in Healthcare Administration. Working for EDS and HP, Mr. McCarthy led the efforts to bring a knowledge management focus to the IT community and created “Recruiting Central”, an initial virtual community Recruiting Command. He served as the on-site Program Manager providing key technology support and strategy for the development of AKO. For the Army Surgeon General, he was responsible for the creation of many virtual medical communities in AKO, as well as several other technology projects. During his time at the Primary Care Behavioral Health Directorate, DCoE, he was responsible for central development of an automated patient tracking/case-management system, and provided program development, implementation support, the development and collection of metrics and a flat-file database capability for program evaluation for all DoD Services. Mr. McCarthy currently serves as the Deputy Director for TATRC working in conjunction with the Director, Chief Scientist, Executive Officer as well as all Lab Managers, to provide insight to the advancement of technology supporting the MHS.

Tim holds a M.A. in College Student Personnel and Counselling/Higher Education from Bowling Green State University in Ohio and a B.S. in Biology/Education from SUNY at Geneseo.

MATTHEW McMAHON, PH.D. – NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Dr. McMahon leads the Office of Translational Alliances and Coordination to enable the development and commercialization of research discoveries funded by the Heart, Lung, and Blood Institute. His office manages NHLBI’s $100 million/year Small Business Program and a national network of six proof-of-concept centers that support the translation of academic discoveries into product development projects. He recently served as the NIH representative on the National Evaluation System for health Technology (NEST) planning board and the associated registry task force. Dr. McMahon previously created and led the National Eye Institute’s Office of Translational Research to advance ophthalmic technologies through public-private partnerships with the pharmaceutical and biotechnology industries. His previous experience includes service as the principal scientist for the bionic eye company Second Sight Medical Products and as a staff member on the Senate and House of Representatives committees responsible for science, technology, and innovation policy.
Dr. George Mensah is a clinician-scientist who currently serves as the Director of the Center for Translation Research and Implementation Science (CTRIS). He also serves as a senior advisor in the Office of the Director at the National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health (NIH). In these roles, Dr. Mensah leads a trans-NHLBI effort to advance late-stage translational research and implementation science at NHLBI. Dr. Mensah’s primary focus is the application of late-stage translational research and implementation science approaches to address gaps in the prevention and treatment of heart, lung, and blood diseases and the elimination of related health inequities. His goal is to maximize the population health impact of advances made in fundamental discovery science and pre-clinical or early-stage translational research. Dr. Mensah is an honors graduate of Harvard University. He obtained his medical degree from Washington University and trained in internal medicine and the subspecialty of cardiovascular diseases at Cornell. His professional experience includes more than 20 years of public service between the U.S. Department of Veterans Affairs (VA), the Centers for Disease Control and Prevention (CDC), and the NIH. He has had management experience as a chief of cardiology; head of a clinical care department; and a past member of the Board of Governors of the American College of Cardiology as Governor for Public Health. In addition to his public service at CDC, Dr. Mensah had 15 years of experience in direct patient care, teaching, and research at Cornell, Vanderbilt, and the Medical College of Georgia. He was a professor with tenure at MCG and is currently a Visiting Full Professor at the University of Cape Town, South Africa. He holds a merit of proficiency from the American Society of Echocardiography and has been designated a hypertension specialist by the American Society of Hypertension. He has been admitted to fellowships in several medical societies in Africa, Europe and the US. He maintains active collaboration with several international groups to advance research on the global burden of diseases, injuries, and risk factors.

Amit Mistry is a Senior Scientist in NIH’s Fogarty International Center where he advises on science policy issues and leads multi-disciplinary projects on critical global health challenges. Previously, Amit served as a program manager in USAID’s Global Development Lab and USAID’s Bureau for Food Security. Amit has also served as a Congressional Fellow for health, education, and science policy and worked as a high school science teacher with Teach for America. Amit earned a bachelor’s degree in chemical engineering in 2000 and a doctorate in bioengineering in 2007, both from Rice University.
Wendy J. Nilsen, Ph.D. – National Science Foundation

Wendy Nilsen, Ph.D. is a Program Director for the Smart and Connected Health Program in the Directorate for Computer & Information Science & Engineering at the National Science Foundation. Her work focuses on the intersection of technology and health. This includes a wide range of methods for data collection, advanced analytics and the creation of effective cyber-human systems. Her interests span the areas of sensing, analytics, cyber-physical systems, information systems, big data and robotics. More specifically, her efforts include: serving as co-chair of the Health Information Technology Research and Development working group of the Networking and Information Technology Research and Development Program; the lead for the NSF/NIH Smart and Connected Health announcement; convening workshops to address methodology in mobile technology research; serving on numerous federal technology initiatives; and, leading training institutes. Previously, Wendy was at the National Institutes of Health.

Lucila Ohno-Machado, M.D., Ph.D. – University of California, San Diego

Lucila Ohno-Machado, MD, MBA, PhD received her medical degree from the University of São Paulo and her doctoral degree in medical information sciences and computer science from Stanford. She is Associate Dean for Informatics and Technology, and the founding chair of the Health System Department of Biomedical Informatics at UCSD, where she leads a group of faculty with diverse backgrounds in medicine, nursing, informatics, and computer science. Prior to her current position, she was faculty at Brigham and Women’s Hospital, Harvard Medical School and at the MIT Division of Health Sciences and Technology. Dr. Ohno-Machado is an elected fellow of the American College of Medical Informatics, the American Institute for Medical and Biological Engineering, and the American Society for Clinical Investigation. She serves as editor-in-chief for the Journal of the American Medical Informatics Association since 2011. She directs the patient-centered Scalable National Network for Effectiveness Research funded by PCORI (and previously AHRQ), a clinical data research network with over 24 million patients and 14 health systems, as well as the NIH/BD2K-funded Data Discovery Index Consortium. She was one of the founders of UC-Research eXchange, a clinical data research network that connected the data warehouses of the five University of California medical centers. She was the director of the NIH-funded National Center for Biomedical Computing iDASH (integrating Data for Analysis, ‘anonymization,’ and Sharing) based at UCSD with collaborators in multiple institutions. iDASH funded collaborations involving study of consent for data and biospecimen sharing in underserved and under-represented populations.
Dr. Pearlman received his BSEE from the Georgia Institute of Technology. His graduate work took place at Yale University where he earned an MS, MPhil, and PhD, all in Electrical Engineering. He has conducted research in the Georgia Tech Biomedical Engineering Department, Georgia Tech Research Institute, Yale Medical School, and University Medical Center Utrecht. His focus was biomedical image analysis, with emphasis on development, evaluation, and application of pathology-driven/clinically-applicable computer aided diagnosis and treatment planning techniques with additional focus on low-cost modalities. After years in basic and translational research, Dr. Pearlman transitioned to the fields of science policy and diplomacy, obtaining a prestigious AAAS Science and Technology Policy Fellowship. He is currently a Program Director and the Lead for Global Health Technology at the United States National Cancer Institute’s Center for Global Health, where he coordinates global cancer research funding opportunities and engages in cancer control planning activities in low- and middle-income countries around the world.

Dr. Pollock is the Associate Medical Director of the Infectious Diseases Diagnostic Laboratory at Boston Children’s Hospital and a faculty member of the Division of Infectious Diseases at Beth Israel Deaconess Medical Center (BIDMC) in Boston. She is jointly appointed in the Departments of Medicine and Pathology at Harvard Medical School. She completed her MD/PhD at the University of California, San Francisco; her medical residency at Brigham and Women’s Hospital in Boston; and her infectious diseases/clinical microbiology fellowships at BIDMC.

Dr. Pollock has an active research program focused on the development and evaluation of novel diagnostics for infectious diseases and related applications. Her diagnostics research has spanned a range of diseases including C. difficile infection, active and latent tuberculosis, influenza, Lyme disease, and Ebola virus disease (EVD), and has involved many different technologies, ranging from simple paper-based lateral flow and microfluidic platforms to novel automated platforms for protein and nucleic acid detection. Her experience in the point-of-care (POC) diagnostics space includes development and evaluation of a paper-based POC fingerstick transaminase test, field evaluation of a POC rapid diagnostic test for EVD during the 2014-16 outbreak in Sierra Leone, and recent development of a novel device for collection and dispensation of fingerstick blood to enable POC testing.
Laura Povlich is a Program Officer in the Division of International Training and Research at the Fogarty International Center, part of the National Institutes of Health, where she was previously an American Association for the Advancement of Science (AAAS) Science & Technology Policy Fellow. Dr. Povlich administers a portfolio of grants that covers a range of research, research training, and research education projects related to global health technology, with a significant focus on information and communication technology. Additionally, she works with U.S. and international researchers to identify gaps in the global health technology landscape and develops funding opportunity announcements to address these gaps. Prior to working at Fogarty, Dr. Povlich was the 2011-2012 Materials Research Society/Optical Society Congressional Science and Engineering Fellow in the Office of Congressman Sander Levin.

Dr. Povlich earned a B.S.E. in Materials Science and Engineering (2006) and a Ph.D. in Macromolecular Science and Engineering (2011), both from the University of Michigan. Her research focused on the synthesis of functionalized conjugated polymers for biological sensor applications and for neural probe and prosthetic device electrode coatings.

Dr. Ramanujam is a Professor of Biomedical Engineering, Global Health and Pharmacology and directs the center for Global Women’s Health Technologies, a partnership between the Pratt School of Engineering and the Duke Global Health Institute. The center’s mission is to increase research, training and education in women’s diseases, with a focus on breast and cervical cancer. Her team is involved in three distinct activities: (1) closing the gap between screening and treatment to reduce cancer disparities through innovative diagnostic and therapeutic tools, (2) improving the efficacy of local and systemic cancer therapies and (3) perpetuating biomedical and human centered design concepts to underserved communities and underrepresented groups through student ambassadors.

Prof. Ramanujam has received several awards for her work in cancer research and technology development for women’s health. She received the TR100 Young Innovator Award from MIT in 2003, the Global Indus Technovator award from MIT in 2005 and several Era of Hope Scholar awards from the DOD. She is member of the NIH BMIT-A study section and chair elect of the DOD’s breast cancer research program (BCRP) integration panel (IP) that sets the vision of the BCRP program and plans the dissemination of over $100 M of funds for breast cancer research annually. She is co-editor of the Handbook of Biomedical Optics (publisher Taylor and Francis). Nimmi earned her PhD in Biomedical Engineering from the University of Texas, Austin in 1995 and then trained as an NIH postdoctoral fellow at the University of Pennsylvania from 1996-2000. Prior to her tenure at Duke, she was an assistant professor in the Dept. Biomedical Engineering at the University of Wisconsin, Madison from 2000-2005.
PRESENTATION ABSTRACT

Preventing Cervical Cancer through a Package of High Quality, Cost Effective Interventions

Cervical cancer prevention is based on well-established interventions including human papillomavirus (HPV) vaccination and screening followed by treatment of pre-invasive disease. In the U.S., cervical cancer incidence and mortality have decreased by 70% over the last 60 years due to screening with the Pap smear [10] and, more recently, the HPV test; however, women living in medically underserved regions experience a disproportionately high burden of cervical cancer. In the U.S. alone for example, half of cervical cancers occur in women in medically underserved communities. There has been significant effort both in the U.S. and globally to increase access to screening, and these services are often subsidized, but screen-positive women need a confirmatory test at a referral setting followed by biopsy, which, if positive, requires yet another visit for treatment. The three-visit model is required because test results at each visit are not immediate and the technologies required for confirmatory testing and treatment are not effective in communities where access to health care is fragile. We aim to prevent cervical cancer via a single visit “see and treat” model. We will talk about our efforts to prevent cancer by developing an evidence-based, transformative, single visit “see and treat” model with a package of high quality, cost-effective innovations.

KATHLEEN ROUSCHE – NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Dr. Rousche manages the NIH Centers for Accelerated Innovations (NCAI) program within the Office of Translational Alliances and Coordination (OTAC), Division of Extramural Research Activities, National Heart Lung and Blood Institute, National Institutes of Health. The NCAI program creates an academic research environment that encourages innovators to validate the commercial potential of their discoveries to more effectively transition laboratory discoveries to benefit public health. The three main goals of the network are to improve the likelihood of individual technologies transitioning from academia to the private sector, improve the efficiency and effectiveness of the processes supporting biomedical product development, and educate academic innovators about commercialization.

STEVEN SCHACHTER, M.D. – CIMIT, HARVARD MEDICAL SCHOOL

Dr. Steven Schachter attended medical school at Case Western Reserve University in Cleveland, Ohio. He completed an internship in Chapel Hill, North Carolina, a neurological residency at the Harvard Longwood Neurological Training Program, and an epilepsy fellowship at Beth Israel Hospital in Boston, Massachusetts. He is Chief Academic Officer and Program Leader of NeuroTechnology at the Consortia for Improving Medicine with Innovation & Technology (CIMIT) and a Professor of Neurology at Harvard Medical School (HMS). Dr. Schachter is Past President of the American Epilepsy Society. He is also past Chair of the Professional Advisory Board of the Epilepsy Foundation and serves on their Board of Directors. He has directed over 70 research projects involving antiepileptic therapies, and published over 200 articles and chapters. He compiled the 6-volume Brainstorms
series, which has been distributed to over 150,000 patients and families worldwide in several languages, and edited or written 30 other books on epilepsy and behavioral neurology. Dr. Schachter is the founding editor and editor-in-chief of the medical journals Epilepsy & Behavior and Epilepsy & Behavior Case Reports.

Dr. Schachter is a member of the Administrative Committee (AdCom) of the IEEE Engineering in Medicine and Biology Society (EMBS) and the Clinical Editor for Journal of Translational Engineering in Health and Medicine.

Rob joined the Bill & Melinda Gates Foundation in 2011, and is currently a Program Officer in the Global Health Innovative Technology Solutions group. Currently Rob’s work is centered around developing new low-cost diagnostic concepts and developing technology platforms for host and pathogen analysis. Previously, Rob worked on the foundation’s Point-of-Care Initiative, which was aimed at creating a decentralized platform to transform diagnostics for the developing world. Prior, Rob had consulted for the foundation’s Discovery group and supported Grand Challenges Explorations (GCE)- the foundation’s innovative idea engine- among other programs. Prior to moving to Seattle, Rob supported the Department of Homeland Security’s Advanced Research Projects Agency (HSARPA), and the Defense Advanced Research Projects Agency (DARPA) in the management and technical evaluation of next-generation biodetection technologies. Rob received his M.S. in Microbiology from Virginia Tech.

Dr. Tebbs works at FDA as a lead reviewer of premarket submissions and pre-submissions for chemistry, toxicology and diabetes devices. She also reviews Investigational Device Exemption (IDE) applications for clinical studies. Dr. Tebbs received her B.S. at The University of Virginia and her Ph.D. from Yale University.
Srini Tridandapani received his MSEE and PHD degrees in electrical engineering from the University of Washington. He then served as an a tenure-track faculty member at the Iowa State University for two years before taking the bold plunge into medical school at the University of Michigan, where he received his MD and completed his residency training in Radiology. Subsequently, he earned the MS in Clinical Research and MBA from Emory University. Dr. Tridandapani is an Associate Professor of Radiology and Imaging Sciences at Emory University and Adjunct Professor of Electrical & Computer Engineering at the Georgia Institute of Technology. Dr. Tridandapani’s current research involves the development of novel gating strategies for optimizing cardiac computed tomography and innovative tools to increase patient safety in medical imaging.

Paul Yager, a native of Manhattan, received his A.B. in Biochemistry from Princeton in 1975, and a Ph.D. in Chemistry from the University of Oregon in 1980, specializing in vibrational spectroscopy of biomolecules. After an NRC Fellowship at the Naval Research Laboratory (1980-1982), he joined the NRL staff as a Research Chemist. He moved to the Center (now Department) of Bioengineering at the University of Washington as Associate Professor in 1987, advancing to Professor in 1995; he served as Chair of the department from 2007 to 2013. Initially working on both self-organizing lipid microstructure and optically based biomedical sensors, since 1992, his lab has focused primarily on development of microfluidics for the analysis of biological fluids for use in low-cost point-of-care biomedical diagnostics for the developed and developing worlds.

From 2005-2010 a team led by Yager was supported by the Bill & Melinda Gates Foundation to develop a low-cost rugged point-of-care system for pathogen identification. Since 2008, most lab activity (with several close partners) has focused on developing two-dimensional porous networks for ultra-low-cost instrument-free pathogen identification for human diagnosis. Readout is often coupled with cell phones for quantitative analysis and data transmission; this has been under support of NIH, NSF, DARPA and DTRA. He has authored >150 publications in refereed journals, and has almost 40 issued patents. Specifics are at http://faculty.washington.edu/yagerp/.
Without Bios:

Maureen Beanan, NIAID
Rao Divi, NCI
Maria Giovanni, NIAID
James Luo, Ph.D., NHLBI
Miguel Ossandon, NCI
William Riley, Ph.D., NIH
Shivkumar Sabesan, Ph.D. Google
Nina Silverberg, NIA