2019 CONFERENCE PROGRAMS

POCT & INFECTIOUS DISEASE

- Point-of-Care Diagnostics
- Technologies at the Point-of-Care
- Molecular Diagnostics for Infectious Disease

LIQUID BIOPSY

- Technologies for Circulating Biomarkers
- Application of Circulating Biomarkers

IMMUNO-ONCOLOGY

- Biomarkers for Cancer Immunotherapy
- Companion Diagnostics in Immuno-Oncology

BUSINESS

- Coverage & Reimbursement
- Commercialization of Diagnostic Tests

COMPANION DIAGNOSTICS

- Companion Diagnostics
- Companion Diagnostics in Immuno-Oncology

DIGITAL PATHOLOGY AND AI

- Applications of Digital Pathology

Training SEMINARS

By Cambridge Healthtech Institute

- Clinical NGS Laboratory
- Introduction to Liquid Biopsy for Cancer
- Introduction to Image Analysis and Deep Learning for Digital Pathology

POC SPECIAL FORUMS

- POC for Veterinary Applications
- POC Product Strategies
- POC in the Pharmacy

Organized by Cambridge Healthtech Institute

11th Annual

Next Generation Dx SUMMIT

AUGUST 20–22, 2019
WASHINGTON, DC
Grand Hyatt Washington

800+ Diagnostics Professionals

58% of Attendees from IVD & Pharma

60+ Industry Leading Sponsors & Exhibitors

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Advancing Diagnostics Together

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2019 CONFERENCE PROGRAMS

Welcome to Next Generation Dx Summit

Diagnostics is a vital market sector that links new, innovative precision medicine to patients and ensures their viability and safety. Rapid diagnostics is becoming more important to the industry every day and methods to predict response to innovative therapies, including immunotherapy, are integral to their success.

More than 800 industry professionals attend the **Next Generation Dx Summit** in Washington, DC. The event is a nexus for key decision makers, bringing together industry leaders with academic and clinical researchers to learn the latest technologies, assays, detection methods and machine learning approaches that are driving breakthroughs. Regulatory and reimbursement solutions will be featured that are critical to implementation of value-based care.

Conference At-A-Glance

#NGDx19

STREAM	M	T	August 20 - 21 | Tuesday - Wednesday AM | **PART A CONFERENCES**	W	August 21 - 22 | Wednesday PM - Thursday | **PART B CONFERENCES**
POCT & INFECTIOUS DISEASE			Enabling Point-of-Care Diagnostics		Emerging Technologies at the Point-of-Care
POC SPECIAL FORUMS			Expanding Dx Portfolio for Veterinary Applications - AUG. 20 AM Point-of-Care Product Strategies - AUG. 20 PM Point-of-Care in the Pharmacy - AUG. 21 AM		Molecular Diagnostics for Infectious Disease
LIQUID BIOPSY			Enabling Technologies for Circulating Biomarkers		Clinical Application of Circulating Biomarkers
IMMUNO-ONCOLOGY			Emerging Technologies & Biomarkers for Cancer Immunotherapy		Companion Diagnostics & Clinical Biomarkers in Immuno-Oncology
BUSINESS			Coverage & Reimbursement for Advanced Diagnostics		Commercialization of Diagnostic Tests
COMPANION DIAGNOSTICS			Companion Diagnostics: Strategy & Partnerships		Companion Diagnostics & Clinical Biomarkers in Immuno-Oncology
DIGITAL PATHOLOGY AND AI			Applications of Digital Pathology		
Training SEMINARS	TS		Introduction to Liquid Biopsy for Cancer		Introduction to Image Analysis & Deep Learning for Digital Pathology Your NGS Lab: Relevant Issues from Test Development to Commercialization
SHORT COURSES	**PRECONFERENCE SHORT COURSES** August 19 Monday				**DINNER SHORT COURSES** August 21 Wednesday PM

11:30-11:40AM

Chairperson's Remarks
Charles Mathews, Principal, ClearView Healthcare Partners

Sponsored by
ClearView Healthcare Partners

11:40AM-12:10PM

PLENARY KEYNOTE PRESENTATION

FDA Updates: Now and Looking to the Future

Katherine Donigan, PhD, Acting Director of Personalized Medicine, Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health, U.S. Food and Drug Administration

Introduction and background of the new Office Director of OIR and updates on precision medicine and other initiatives at the FDA.

12:10-1:05PM

Co-Organized with
PMC Personalized Medicine Coalition
Celebrating 10 Years

PLENARY KEYNOTE DISCUSSION

Proposals and Solutions for Diagnostic Reform Including Oversight of Laboratory Developed Tests (LDTs)

Moderator:
Cynthia A. Bens, Senior Vice President, Public Policy, Personalized Medicine Coalition

- How are stakeholders influencing congressional activity on the Verifying Accurate Leading-edge IVCT Development (VALID) Act?
- How will the VALID Act change the current oversight landscape for diagnostics, including LDTs?
- How are policymakers addressing the role of CMS and CLIA in the VALID Act?
- How will increased regulatory and oversight activities at the FDA affect the diagnostics industry?
- What impact will changes in diagnostics regulation and oversight have on patient care?

Panelists:
Julie Khani, MPA, President, American Clinical Laboratory Association (ACLA)

Donald E. Horton, Jr., Senior Vice President, Global Government Relations & Public Policy, Laboratory Corporation of America Holdings

Susan Van Meter, Executive Director, AdvaMedDx

Tara Burke, PhD, Senior Director, Public Policy & Advocacy, Association for Molecular Pathology (AMP)

Laura Lasiter, PhD, Science Policy Analyst, Friends of Cancer Research

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Next Generation DX SUMMIT

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– Available within Main Agenda!

Showcase your solutions to a guaranteed, targeted audience through a 15- or 30-minute presentation during a specific conference program. Package includes exhibit space, on-site branding, and access to cooperative marketing efforts by CHI. For the luncheon option, lunches are delivered to attendees who are already seated in the main session room.

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- Program Guide Advertisement

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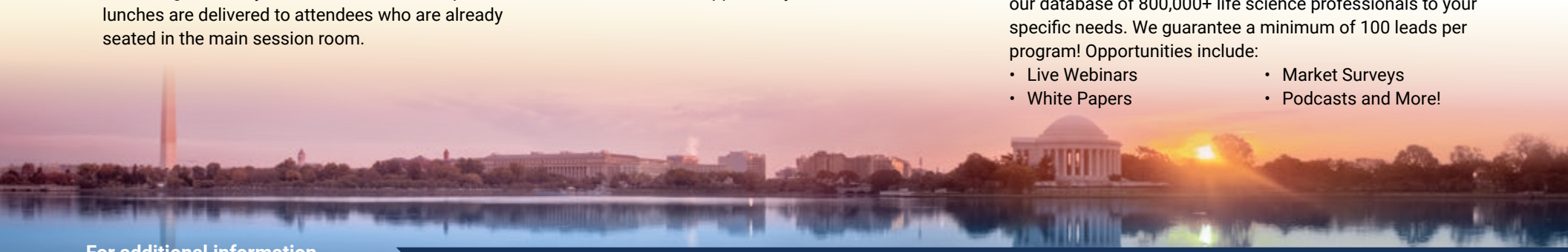

For additional information regarding sponsorship and exhibit opportunities, please contact:

COMPANIES A-K
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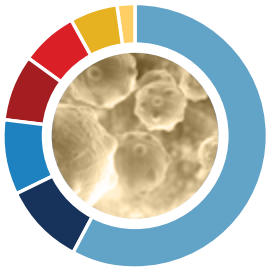
781-972-5483 | **jstroup@cambridgeinnovationinstitute.com**

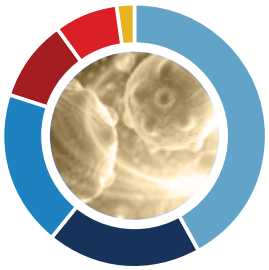
COMPANIES L-Z
Ashley Harvey | Business Development Manager
781-247-6292 | **aharvey@cambridgeinnovationinstitute.com**

2018 Attendee Demographics



COMPANY TYPE

IVD & Pharma	58%
Academic Labs	10%
Hospital Labs	9%
Payers & Insurers	8%
Government	7%
Services & Societies	6%
Other	2%



DELEGATE TITLE

C-Suite & Director	42%
Sales & Marketing	19%
Scientist/Technologist	19%
Manager	10%
Professor	8%
Other	2%

ATTENDEES BY GEOGRAPHIC LOCATION

REST OF WORLD: **2%**

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DOWNLOAD EXHIBITOR PROSPECTUS

Short Courses

MONDAY, AUGUST 19

MORNING, 9:00 AM–12:00 PM

SC1: Technologies, Applications and Commercialization of POC Dx

Holger Becker, PhD, Founder & CSO, microfluidic ChipShop GmbH

This short course will provide an overview on the technological aspects of POC system developments. It will introduce current technologies such as microfluidics, sensors, paper- and smartphone-based approaches and discuss their trends and limitations. The course will discuss a variety of POC systems in different stages of their development, from early stage to established diagnostic systems in the clinical routine. Market aspects of POC systems as well as practical examples of commercialization for molecular diagnostic, immunological and clinical tests will be presented.

SC3: Emerging Applications of ctDNA

John Simmons, PhD, Vice President, Translational Medicine, Personal Genome Diagnostics

This short course will cover cutting edge applications and clinical trials that use ctDNA for monitoring, minimal residual disease, and plasma tumor mutation burden. The background basics, the technologies, the clinical evidence out there so far, and the highlights of the prospective designs that are underway will be discussed.

AFTERNOON, 2:00–5:00 PM

SC4: Digital Pathology from A to Z for Beginners

Matthew G. Hanna, MD, Clinical Instructor, Breast and Informatics, Department of Pathology, Memorial Sloan Kettering Cancer Center

Digital pathology is a disruptive technology in the laboratory workflow. It has tremendous potential to change the way pathologists, researchers, and other personnel interact with pathology data. It is an exciting era of potentially practice-changing technology. Although digital pathology comes with significant promise, there are still numerous obstacles that stand in the way of becoming the next standard of care. Aside from clinical practice, digital pathology can be leveraged in the research and education arms of the medical community. This course will cover the nuts and bolts for all related topics in digital pathology for those who are just wondering what all the hype is about, to those who want a little more depth in their understanding of what digital pathology can and will do in the medical community.

SC6: Liquid Biopsies based on Extracellular Vesicles: Prospects, Challenges, and Opportunities

Joshua T. Smith, PhD, Research Staff Member and Silicon Development Team Leader, Translational Systems Biology and Nanobiotechnology, IBM T. J. Watson Research Center

Extracellular vesicles (EVs) exhibit a number of properties that make them attractive as a rich source of biomarkers for disease diagnosis, treatment monitoring, and therapeutics, including their abundance in a wide breadth of bodily fluids, nucleic acid and protein content, and protective lipid membrane that preserves this cargo from degradation. This course reviews key discoveries in EV research, describes current efforts to exploit their properties to capture market value, and takes a look at exploratory and emerging technologies aimed at accelerating their study and use. Existing gaps in understanding along with current efforts to address these unknowns will also be elucidated.

WEDNESDAY, AUGUST 21

DINNER, 6:45–9:15 PM

SC8: Generating Evidence and Creating a Winning Dossier for Regulatory and Reimbursement Needs

John Sninsky, PhD, Consultant, Translational Sciences
Melina Cimler, PhD, CEO & Founder, PandiaDx
Shivang Doshi, Director, Boston Healthcare Associates, Inc.
Mark Hiatt, MD, Vice President, Guardant Health

Managing the clinical narrative for your diagnostic test requires careful evaluation of the evidentiary requirements of stakeholders. Using those evidentiary requirements to determine your clinical and economic study designs is the cornerstone of effective product development.

SC9: Microfluidics and Lab-on-a-Chip Devices for POCT: Technologies and Commercialization

Chris Myatt, Founder & CEO, MBio Diagnostics, Inc.
Kris Buchanan, CEO and Founder, Phase Three Product Development
Richard Spero, PhD, Co-founder, CEO, Redbud Labs
Evan F Cromwell, President & CEO, Protein Fluidics

This short course will provide an overview of microfluidic techniques, including valved and valve-less devices, pumped systems, and capillary flow approaches. Practical examples will keep the discussion grounded in the realization of commercializable devices. We will discuss engineering approaches to enhance the advantages and minimize the challenges. Throughout, the science will be linked to the commercial case for these devices, including a full discussion of a recent success story of a centrifugal microfluidic molecular assay system.

SC10: Development of Novel Diagnostics for Antimicrobial Resistance

Charles L Fromer, Diagnostics Team Leader, Diagnostics and Detection Division, Chemical and Biological Technologies Department Research and Development Directorate, Defense Threat Reduction Agency

Diane L. Dutt, PhD, PMP, Science and Technology Manager, Diagnostics and Detection Division, Defense Threat Reduction Agency

Stephen C. Francesconi, PhD, Diagnostics and Detection Division, Defense Threat Reduction Agency

The U.S. Department of Defense (DoD) is keenly focused on developing novel field-forward medical diagnostic systems to guide physician decision-making during patient treatment, thereby improving patient outcomes and speeding return to service. As a primary step, the Defense Threat Reduction Agency (DTRA) is developing assays to discriminate between bacterial-based and viral infections. Secondly, DTRA is exploring the genetic content of Select Agents to identify the resistance potential, regulation and distribution of AMR genes and cassettes among bacteria genera, species and within clades. Thirdly, DTRA is developing multiplexed lateral flow assays as a rapid, low-cost diagnostic for field-forward applications. And lastly, DTRA is assessing agent sensitivity to antimicrobial agents through the development of Food & Drug Administration (FDA) 510K-cleared benchtop and hand-held platforms that can identify both the infectious bacterial species and its antibiotic sensitivity profile, going from sample to answer within 2 hours. It is through the use of these diagnostic devices that caregivers will speed triage and improve treatment of wounded warfighters.

TUESDAY, AUGUST 20 AND WEDNESDAY, AUGUST 21

DAY 1: 8:30 AM–6:00 PM | DAY 2: 8:30 AM–12:35 PM

TS10A: Introduction to Liquid Biopsy for Cancer

This 1.5-day lecture-based interactive seminar will provide an introduction to the biology and science of liquid biopsies for improving cancer detection and treatment. It will provide an in-depth look into the clinical application, utility and validation of liquid biopsy assays with a focus on how to choose the right assay for your goals. It will present a variety of liquid biopsy techniques and go into the pros and cons of each. Overall, this seminar will provide attendees with a comprehensive tool-kit to overcome their liquid biopsy challenges.

Instructor:
Stuart S. Martin, PhD, Professor, Physiology, Marlene and Stewart Greenebaum NCI Comprehensive Cancer Center, University of Maryland School of Medicine

WEDNESDAY, AUGUST 21 AND THURSDAY, AUGUST 22

DAY 1: 2:05 PM–6:30 PM | DAY 2: 8:30 AM–4:20 PM

TS8B: Your NGS Lab: Relevant Issues from Test Development to Commercialization

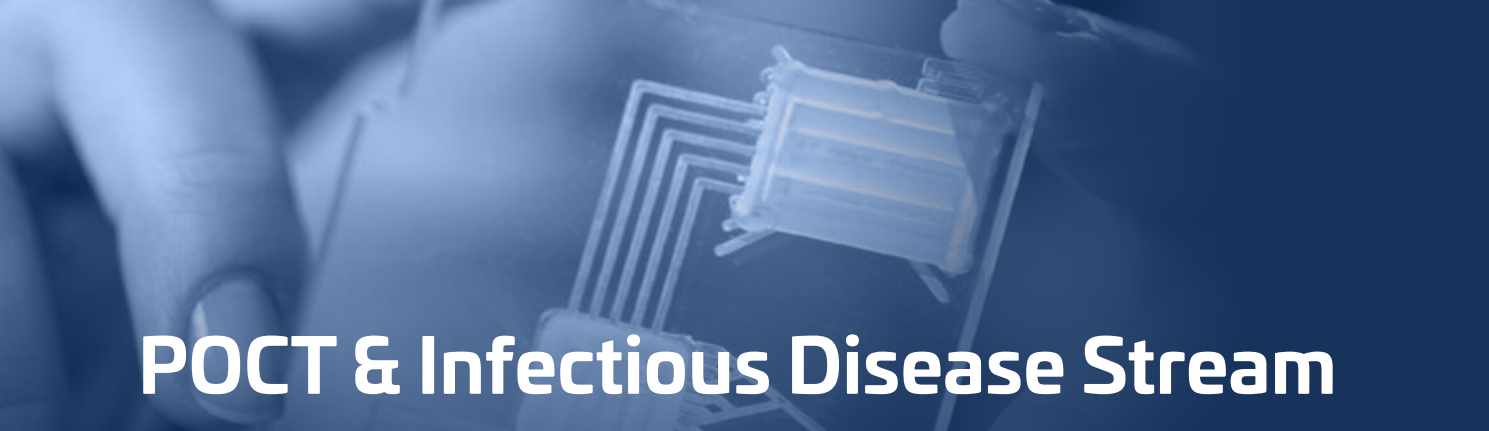
Nearly 10 years after the first publication of next-generation sequencing, this paradigm-shifting technology has progressively migrated into the clinical diagnostic space. A diversity of clinical diagnostic assays is now routinely performed on a variety of NGS platforms, spanning from single gene to multi-gene sequencing, to genome wide analyses for the detection of germline and somatic mutations. For clinical laboratories with NGS experience, and especially for those just starting to use the technology, designing and operationalizing robust NGS assays remains a challenge. This training seminar will review principles and diagnostic approaches for NGS assays as applied to molecular oncology and inherited disorders, platforms and instruments, as well as laboratory accreditation and proficiency testing specific to NGS.

Instructors:
Robert Young, CGMBS, MS Bioinformatics, Owner, Principal Consultant, Lab Insights, LLC
Shawn Clairmont, MBA, COO, Co-Founder, BRIDGenomics, LLC
Naomi Thomson, BRIDGenomics, LLC
Eden Hutchinson, BRIDGenomics, LLC
Shawn Clairmont, MBA, COO, Co-Founder, BRIDGenomics, LLC

Each CHI Training Seminar offers 1.5 Days of instruction with start and stop times for each day shown above and on the Event-at-a-Glance published in the onsite Program & Event Guide. Training Seminars will include morning and afternoon refreshment breaks, as applicable, and lunch will be provided to all registered attendees on the full day of the class.

Each person registered specifically for the training seminar will be provided with a hard copy handbook for the seminar in which they are registered. A limited number of additional handbooks will be available for other delegates who wish to attend the seminar, but after these have been distributed no additional books will be available.

Though CHI encourages track hopping between conference programs, we ask that Training Seminars not be disturbed once they have begun. In the interest of maintaining the highest quality learning environment for Training Seminar attendees, and because Seminars are conducted differently than conference programming, we ask that attendees commit to attending the entire program, and NOT engaging in track hopping, as to not disturb the hands-on style instruction being offered to the other participants.



POCT & Infectious Disease Stream

The Point-of-Care Testing and Infectious Disease stream focuses on the latest technologies and applications of POCT and rapid diagnostics for emerging and existing diseases. State-of-the-art devices and testing methods will be highlighted along with strategies to move diagnostics to the clinic and through reimbursement hurdles. Innovation at the point-of-care including IoT and wearables will be featured.

2019 POCT & INFECTIOUS DISEASE CONFERENCES

AUGUST 20-21

AGENDA **Enabling Point-of-Care Diagnostics**

AUGUST 21-22

AGENDA **Emerging Technologies at the Point-of-Care**

AUGUST 21-22

AGENDA **Molecular Diagnostics for Infectious Disease**

CONFERENCE STREAMS

- POCT & INFECTIOUS DISEASE
- LIQUID BIOPSY
- IMMUNO-ONCOLOGY
- BUSINESS
- COMPANION DIAGNOSTICS
- DIGITAL PATHOLOGY AND AI
- POC SPECIAL FORUMS

Enabling Point-of-Care Diagnostics

DELIVERING RAPID RESULTS TO IMPROVE OUTCOMES

RECOMMENDED SHORT COURSE*

SC1: Technologies, Applications and Commercialization of POC Dx

**Separate registration required, click here for details*

TUESDAY, AUGUST 20

7:30 am Registration and Morning Coffee

APPLICATIONS OF RAPID LABORATORY DIAGNOSTICS

8:30 Chairperson's Opening Remarks

James H. Nichols, PhD, DABCC, FACB, Professor of Pathology, Microbiology and Immunology & Medical Director, Clinical Chemistry and Point-of-Care Testing, Vanderbilt University School of Medicine

8:40 Opportunities for POCT in Modern Healthcare

James H. Nichols, PhD, DABCC, FACB, Professor of Pathology, Microbiology and Immunology & Medical Director, Clinical Chemistry and Point-of-Care Testing, Vanderbilt University School of Medicine

Point-of-care testing is laboratory testing performed close to the site of patient care. With the advantage of rapid turnaround time and device portability, POCT is finding new applications as healthcare expands into the community. This presentation will explore the variety of ways that POCT is being deployed and finding new avenues for delivering faster testing for improved patient management.

9:10 Environmental Effects on Point-of-Care Testing: Challenges in Mobile and Austere Settings

Nam Tran, PhD, Associate Clinical Professor, Clinical Chemistry, Special Chemistry, Toxicology, POCT and SARC Sections, Department of Pathology and Laboratory Medicine, University of California, Davis

Environmental factors such as temperature, humidity, and altitude can impact the analytical performance of point-of-care (POC) devices. Operation of POC devices outside of established specifications may result in erroneous results. Temperature and humidity have been shown to alter the performance of certain glucose meter test strips. Point-of-care testing operators need to be aware of device limitations in mobile and austere testing. Field-robust POC devices are needed for these unique settings.

9:40 Artificial Intelligence and Point-of-Care Diagnostics

Joel Saltz, MD, PhD, Chair and Professor Department of Biomedical Informatics, Vice President, Clinical Informatics Stony Brook Medicine, Cherith Endowed Chair, Stony Brook University

We are employing deep learning methods synthesize patient laboratory, medication and coding information to generate nuanced clinical phenotype information. The models are trained with a combination of very large de-identified multi-institution patient datasets and smaller institution-specific datasets. The current use of these methods is to provide support for our health system's clinically integrated network and diabetes management efforts. We will discuss prospects of adapting these models to optimize point-of-care test frequency as well as to optimize point-of-care diagnostics quality control.

10:10 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 Options and Importance of Connectivity and Informatics in POC Testing

Bill Marquardt, C(ASCP), MBA, CSSBB, Vice President, Lab Intelligence, McKesson Laboratory Solutions

As point-of-care testing becomes more prevalent and more tests become available, connectivity will become increasingly important to ensure quality of results (and as a result, overall quality of patient care) but to ensure costs are contained with reimbursements being maximized. This talk will identify solutions to connectivity challenges and uncover both the obvious and hidden costs associated with remaining unconnected as well as the potential impact to patient care.

11:30 PANEL DISCUSSION

12:00 pm Optimized Lyophilization: Providing Options for You, Your Products, and Your Molecular Diagnostics Customers

Sponsored by BIOLYPH

Timothy Pearcy, Managing Director, BIOLYPH LLC

Lyophilization is the highest quality form of preservation, and LyoSpheres™ maximize the benefits of lyophilization. Enjoy room temperature stability, storage, and transport, more robust performance, greatly increased shelf life, superior ease of use, limitless reagent cocktails, instant rehydration, and device flexibility for your MDx, POCT, NGS and liquid biopsy products.

12:15 Breaking Through the Sample Prep Bottleneck

Sponsored by Redbud Labs

Richard Spero, PhD, CEO, Redbud Labs, Inc

Sample prep is the performance-limiting bottleneck in virtually all next-generation point-of-care diagnostics. We present an open sample-prep platform that delivers ultra-fast sample prep with benchtop quality in a cartridge-ready format.

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:00 Cookie & Refreshment Break in the Exhibit Hall with Poster Viewing

INFECTIOUS DISEASE MANAGEMENT WITH POCT

1:30 Chairperson's Remarks

William Clarke, PhD, MBA, DABCC, Professor of Pathology, Johns Hopkins University School of Medicine

1:35 Nanopore Sequencing for Viral Diagnostics in POC Settings

Charles Chiu, MD, PhD, Professor, Departments of Laboratory Medicine and Medicine, Division of Infectious Diseases; Director, UCSF-Abbott Viral Diagnostics and Discovery Center; Associate Director, UCSF Clinical Microbiology Laboratory, UCSF School of Medicine

Nanopore sequencing is a paradigm-shifting technology enabling real-time and comprehensive analysis of clinical samples for potential pathogens and interrogation of the host response by RNA sequencing (RNA-Seq). We will discuss current and future applications of nanopore sequencing for diagnosis for viral infections in low-resource and POC settings.

2:05 Ensuring the Quality of Infectious Disease Point-of-Care Testing in the Urgent Care

Omai Garner, PhD, D(ABMM), Assistant Clinical Professor, Section Chief, Clinical Microbiology; Director, Point of Care Testing, UCLA Department of Pathology and Laboratory Medicine

This talk will focus on strategies and challenges in performing point-of-care tests for infectious disease in the urgent care setting. We will explore some of the most common challenges that disrupt quality in the near patient testing environment. We will also discuss test validation, work flow analysis, and other key indicators of success for point-of-care tests.

ENABLING POINT-OF-CARE DIAGNOSTICS, continued

2:35 Respiratory Pathogen Detection by NGS, Removing Barriers for Routine Application

Robert Schlaberg, MD, MPH, Assistant Professor of Pathology, University of Utah; Medical Director, ARUP Laboratories; Co-Founder and CMO, IDbyDNA, Inc.

Universal pathogen detection tests using NGS-based metagenomics are being adopted by a growing number of diagnostic laboratories. Removing remaining barriers for adoption of this technology early in the diagnostic work-up will maximize the utility and diagnostic yield. This presentation will summarize efforts to standardize and expedite workflows and outline a path towards potential POC solutions in the future.

3:05 A Multiplexed Platform for Point of Care Precision Medicine and Clinical Trial Enrichment

Sponsored by m·bio DIAGNOSTICS

Chris Myatt, Founder, CEO, MBio Diagnostics

Heterogeneity of septic shock is a major challenge. For clinical trials, it is unclear which patients will benefit from new treatment approaches. A robust risk stratification tool has been developed to aid decision-making in the context of pediatric sepsis. A 5-protein biomarker adaptation of the PERSEVERE risk stratification panel has been developed on the MBio point-of-care platform. The panel has been run on banked clinical samples, and comparisons with the original Luminex-based assay are underway.

3:20 Introduction to Cyclo Olefin Polymer in Life Science Application

Sponsored by ZEON

Larry Atupem, Senior Business Development Specialist, Zeon Specialty Materials

ZEON manufactures ZEONEX® and ZEONOR® Cyclo Olefin Polymer; an ultra-pure, inert, optically clear low-fluorescence polymer used for the construction of consumables used NGS and molecular diagnostics. The unique inherent properties ZEONEX® and ZEONOR® Cyclo Olefin Polymer (COP) allow engineers to expand their device and detection capabilities when constructing a fully integrated consumable versus using more traditional polymers.

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

MICROFLUIDICS ENABLED POINT-OF-CARE TESTING

4:25 Chairperson's Remarks

Holger Becker, PhD, Founder & CSO, microfluidic ChipShop GmbH

4:30 An Update on the Status of CD Fluidics for Advanced Diagnostics

Marc Madou, PhD, Chancellor's Professor, Biomedical Engineering, University of California, Irvine

Nucleic-acid (NA) based diagnostics hold much potential, especially for the more rapid and accurate diagnosis of infectious diseases. However, nucleic acid diagnostics are still impractical to implement in many settings, requiring, to name a few, large and expensive labs with sophisticated equipment, a well-trained staff, and many hours of labor. As a part of the shift towards de-centralized and low-cost healthcare, microfluidic platforms aim to move nucleic-acid based diagnostics out of the laboratory and to the point-of-care (POC). This talk focuses on the research, design, and development of centrifugal microfluidic platforms as tools for nucleic acid analysis and diagnostics. In particular, novel microfluidic systems are presented towards sample-to-answer *in vitro* diagnostic applications, to make nucleic acid diagnostics a reality by overcoming many of the current hurdles. Finally an overview of CD-based commercial products is given highlighting where the field is moving to.

5:00 Accurate Diagnosis to Sepsis Using Microfluidic Assays

Daniel Irimia, MD, PhD, Associate Professor, Surgery, Massachusetts General Hospital

Neutrophils, the first white blood cells to respond to infections, are key for understanding sepsis. However, neutrophils have short lives and new tools are required to study them as soon as blood is drawn. We have recently designed novel microfluidic assays that advance our understanding of how neutrophils regulate their numbers at sites of infections, swarm around microbes, and return to circulation.

We are leveraging these findings to design POC assays for sepsis diagnosis and monitoring.

5:30 Mobilizing Diagnostics - Overcoming the Challenges in Testing Outside the Laboratory

Sponsored by BBI Solutions

Nick Davala, MBA, Business Development Manager, BBI Solutions

Novarum Dx technology brings the benefit of mobile to diagnostics wherever they are deployed, ensuring patient's access care and surveillance organizations have access to real-time statistics on disease spread. We will discuss the benefits and demonstrate the use of a smartphone to guide users through the test workflow for a point of care test, including test timings and visual cues, before using our patented image capture software to record and analyze the test result.

6:00 Wine & Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing

Sponsored by PILLAR BIOSCIENCES

7:00 Close of Day

WEDNESDAY, AUGUST 21

7:15 am Registration

7:30 Problem Solving Breakout Discussions with Continental Breakfast *(See website for details)*

EXPLOITING A NEW DIAGNOSTIC LANDSCAPE – THE EPIGENOME

8:20 Chairperson's Remarks

Eric Van Gieson, PhD, Program Manager, Defense Advanced Research Projects Agency (DARPA)

8:30 Blood Epigenetic Signatures to Predict Infection and Environmental Exposures

Stuart Sealfon, MD, Glickenhaus Family Professor of Neurology, Icahn School of Medicine at Mount Sinai

Infection and environmental exposures may lead to persistent epigenetic changes in blood cells. Under the DARPA Epigenetic CHaracterization and Observation (ECHO) program, we are studying the use of bulk and single cell blood epigenetic assays and machine learning approaches to predict exposure to infectious agents, specific chemicals and other perturbations, with the goal of developing a new diagnostic approach and device.

8:50 Next Generation Epigenetic POC Diagnostics

Joshua LaBaer, MD, PhD, Executive Director, The Biodesign Institute, Arizona State University

Epigenetic chromatin modifications (ECM) are heritable changes to the genome and the molecules that package it, which can alter the accessibility of DNA to regulatory proteins. Epigenetic changes can be rapid or slow, and once established, they are stable, potentially heritable and have the potential to modify gene expression. Environmental factors like chemicals, explosives, pathogens and radioactivity can alter epigenetic regulatory features such as DNA methylation, histone modifications and microRNA expression. Exposures to different amounts, duration and types of these agents are linked to different epigenetic modifications. With funding from DARPA, we are part of a program to develop an epigenetics signature-based point-of-care (POC) test to identify exposures to weapons of mass destruction (WMD). WMD could be biological, radiological, chemical or explosive in nature and

ENABLING POINT-OF-CARE DIAGNOSTICS, continued

the epigenetic signatures could come directly from either DNA or proteins associated with DNA. DARPA's Epigenetic CHaracterization and Observation (ECHO) program will build a man-portable device that examines an individual's epigenetic changes to reveal a detailed history of exposure to WMD or their precursors. Our multidisciplinary Diagnostic EPigenetics of Infectious agents and Chemical Toxicity (DEPICT) program, will apply a comprehensive approach: a) identify both transient and long-lasting epigenetic changes by ChIPmen-Seq in blood, b) develop a microfluidic on-site sample processing cards to enrich signature specific changes, and c) develop a POC next generation sequencing (NGS) platform to reveal WMD exposure types and time-line. We believe, in addition to providing rapid diagnosis for troops who are exposed WMD agents, offering timely information for effective medical countermeasures, the same technology has the potential to provide a "one-size-fits-all" diagnostic tool for both chronic and infectious diseases at large.

9:10 Single-Cell Analysis for Forensic Epigenetics (SAFE)

Joseph R. Ecker, PhD, Professor and Salk International Council Chair in Genetics, Howard Hughes Medical Institute Investigator, The Salk Institute for Biological Studies

The goal of this research is to define temporal changes in the features of an individual's epigenome to determine their history of environmental exposures. In SAFE, we are applying state-of-the-art single-cell epigenomic analyses of blood samples to identify signatures of exposure. Biomarker discovery from single nuclei avoids losing strong epigenetic signals from rare cells in the dynamic epigenetic background noise, allowing identification of low-abundance features that can be correlated with exposure.

9:30 A New Nanopore Approach to Rapid Readout of DNA Epigenetic Modifications

Bharath Takulapalli, PhD, Founder & CEO, INanoBio, Inc.

Information encoded in the epigenome is linear from one end to the other, encoded in epigenetic markers on DNA, nucleosomal histones and the DNA sequence. The simplest way to read this linear information chain is to probe it at a single point along the chain using nanopore technology, from end to end. INanoBio is developing an advanced nanopore-transistor device for rapid readout the epigenome, at the point of need.

9:50 Q&A

10:00 The Future of Near Patient Testing

Sponsored by Qorvo Biotechnologies

Bryan Bothwell, Director, Strategy and Business Development, Qorvo Biotechnologies, LLC

Qorvo Biotechnologies biosensor platform creates a paradigm shift in point of need testing. Bulk acoustic wave detection arrays combined with microfluidics and electronics integration enables centralized lab results at the true point of need- breaking technological barriers limiting ubiquitous deployment.

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:30 Plenary Keynote Session

Please click here for details

1:05 pm Luncheon Presentation ***(Sponsorship Opportunity Available)*** **or Enjoy Lunch on Your Own**

1:35 Close of Enabling Point-of-Care Diagnostics

RECOMMENDED SHORT COURSE*

SC9: Microfluidics and Lab-on-a-Chip Devices for POCT: Technologies and Commercialization

**Separate registration required, click here for details*

Emerging Technologies at the Point-of-Care

ENABLING CLINICIANS WITH CUTTING EDGE TECHNOLOGY TO IMPROVE PATIENT HEALTH OUTCOMES AT THE POINT-OF-CARE

WEDNESDAY, AUGUST 21

10:30 am Registration

11:30 Plenary Keynote Session
Please click here for details

1:05 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:35 Ice Cream & Cookie Break in the Exhibit Hall with Poster Viewing

KEYNOTE PANEL SESSION:

WHAT MAKES EMERGING TECHNOLOGY ATTRACTIVE?

2:05 Chairperson's Opening Remarks
David Deetz, Co-Founder, CTO, Ativa Med

2:10 KEYNOTE PANEL DISCUSSION: What Makes Emerging Technology Attractive?
Moderator: David Deetz, Co-Founder, CTO, Ativa Med
Panelists: Manish Deshpande, PhD, Vice President, R&D, Point of Care BU, Siemens Healthcare
Prasad V. A Pamidi, PhD, Director, Sensor Development, R&D, Instrumentation Laboratory, A Werfen Company
Matt Bates, Head of R&D, Abbott
Nina Menezes, Head, Marketing Innovation, Abbott

- Analysis of the latest trends in lab testing
- Identification of hot new tests and the value they create
- Creating new uses for established tests by adding in new tech

3:40 Sponsored Presentation *(Opportunity Available)*

4:10 Refreshment Break in the Exhibit Hall with Poster Viewing

ADVANCING POINT-OF-CARE WITH CONNECTIVITY

4:55 Chairperson's Remarks
Matt Quinn, MBA, Senior Advisor, Health Technology, HRSA

5:00 Advancing Use of Innovative Health Technologies in the Safety Net
Matt Quinn, MBA, Senior Advisor, Health Technology, HRSA
The Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services, is the primary federal agency for improving healthcare to people who are geographically isolated, economically or medically vulnerable. This session will describe how HRSA advances the use of health technologies to achieve its mission of improving health and achieving health equity through access to quality services, a skilled health workforce and innovative programs.

5:30 Smart and Connected Molecular Diagnostics at the Point-of-Care
Changchun Liu, Associate Professor, Biomedical Engineering Department, University of Connecticut, UConn Health
Smartphones have a growing and pervasive influence on our daily life. Especially, with the rapid development of microfluidics technology, the incorporation of microfluidics technology with smartphone-based detection technology will create a new paradigm shift towards affordable, smart and connected health monitoring. In this talk, I will introduce our synergistically enhanced colorimetric molecular detection method, molecular diagnostic chips, smart connected systems and their applications in early cancer screening (e.g., HPV-associated cancer) and infectious disease detection (e.g., Zika virus, HIV virus) at the point-of-care.

6:00 Q-POC – Molecular Diagnostics Point-of-Care 2.0
Jonathan O'Halloran, CSO, QuantuMDx Group Ltd
QuantuMDx has developed a novel, low-cost sample to answer molecular diagnostics device aimed at both low and high resource settings. The device performs both qPCR and end-point PCR followed by a microarray, all within a single ultra-low-cost disposable. The company's first assay is an HPV assay, due for launch in 2020, that individually genotypes 13 high-risk sub-types of the virus, directly from a swab sample in under 30 minutes.

6:30 Close of Day

6:30 Dinner Short Course Registration

6:45 - 9:15 pm RECOMMENDED DINNER SHORT COURSE*

SC9: Microfluidics and Lab-on-a-Chip Devices for POCT: Technologies and Commercialization
**Separate registration required, click here for details*

THURSDAY, AUGUST 22

7:15 am Registration

7:30 Problem Solving Breakout Discussions with Continental Breakfast *(See website for details)*

VALIDATING NEW POCT TECHNOLOGIES

8:25 Chairperson's Remarks
Jonathan O'Halloran, CSO, QuantuMDx Group Ltd

8:30 Clinical Needs, Validation and Implementation Strategies for Novel Point-of-Care Technologies
Ping Wang, PhD, DABCC, Chief, Clinical Chemistry, Director, Core Laboratory Hospital of University of Pennsylvania
The field of point-of-care technologies has witnessed strong growth, as evidenced by new clinical or consumer products, or research and development directions. Only when combined with appropriate strategies for clinical needs assessment, validation and implementation, these technologies may significantly impact care delivery and associated outcomes and costs. In this presentation, I will discuss clinical needs, validation and implementation strategies for novel point-of-care technologies from two perspectives: as a practicing clinical laboratory director, and as a technology researcher and developer.

9:00 Diagnostic Workstation: A New Approach to Diagnosing Primary-Care Patients Enables New Processes
David Deetz, Founder, CTO, Ativa Med
Ativa's Diagnostic Workstation integrates a synergistic array of breakthrough diagnostic and AI technologies that has the potential to disrupt the current process of primary care because it facilitates:

- Much faster diagnoses - It permits healthcare personnel to run the major blood/urine panels immediately themselves, which enables the provider to diagnose a patient within moments, rather than hours or days
- Improved diagnoses – Its cloud-based AI enables protocol-driven test selection and provides meaningful interpretation to improve diagnoses
- Expanded ability to detect serious diseases in primary care

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

EMERGING TECHNOLOGIES AT THE POINT-OF-CARE, continued

LATERAL FLOW IMMUNOASSAYS AND PAPER DIAGNOSTICS

11:00 Chairperson's Remarks

Karl Poterack, MD, Medical Director, Applied Clinical Informatics, Mayo Clinic

11:05 Catalytic Nanoparticles as Labels in Lateral Flow Immunoassays

Shawn Mulvaney, PhD, Section Head, Surface Nanoscience and Sensor Technology Section, Chemistry, US Naval Research Laboratory

Lateral-flow immunoassays (LFIs of LFIAs) are widely used point-of-care technology. Visually-read, LFIAs typically use colloidal gold or colored latex as the reporter elements for the antibody-antigen binding event. Due to their visual extinction coefficients, the intensity of these labels are limited which ultimately limits the sensitivity of the assay. We have substituted specially-prepared, colloidal palladium for the traditional labels and use it as a chemical catalyst to produce an easily-observable, stable, blue dye that localizes at the capture line. Importantly, the catalyst is heat stable, functions at room temperature, under physical conditions, and results in up to a 500-fold increase in sensitivity with only five additional minutes of development.

11:35 Paper Devices for Medical Self-testing at Home: Opportunities and Challenges

Dionysios Christodouleas, PhD, Assistant Professor, Department of Chemistry, University of Massachusetts Lowell

Diagnostic devices for home use should operate with minimal user involvement, be able to analyze untreated samples, and have low cost. Paper devices are inexpensive and, if they are designed carefully, could be capable of analyzing untreated samples and be fully integrated. In this presentation, I will discuss examples of paper devices that allow biochemical testing without user involvement and point toward areas of future research in paper diagnostics to address current challenges

12:05 pm Paper-Based Surface-Enhanced Raman Scattering Lateral Flow Strips for Point-of-Care Applications

Nianqiang (Nick) Wu, Professor, Mechanical and Aerospace Engineering, West Virginia University

This presentation will present our effort to develop plasmonic nanostructures for amplifying surface-enhanced Raman scattering (SERS) signals. It will also show how to incorporate SERS sensors into paper-based lateral flow strips (PLFS) as point-of-care tools. The PLFS is composed of the on-chip sample pretreatment, flow control and detection components. Moreover, this talk will demonstrate measurement of the traumatic brain injury (TBI) protein biomarkers in clinical samples by the SERS-based PLFS.

12:35 Sponsored Presentation *(Opportunity Available)*

1:05 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:35 Dessert Break in the Exhibit Hall with Poster Viewing

DEALING WITH WEARABLE AND IMAGING DATA

2:15 Chairperson's Remarks

Wilbur A. Lam, MD, PhD, Associate Professor, Wallace H. Coulter Department of Biomedical Engineering and Department of Pediatrics, Aflac Cancer and Blood Disorders Center of Children's Healthcare of Atlanta, Georgia Institute of Technology and Emory University School of Medicine

2:20 Wearable Monitors in Health Care: Signal or Noise?

Karl Poterack, MD, Medical Director, Applied Clinical Informatics, Mayo Clinic

Widely used wearable devices like activity trackers and smart watches continuously measure physiologic data during everyday activities. Utilizing this data requires a paradigm shift for health care, since traditionally this data was only collected during patients' healthcare visits. This presentation will cover the types of data that can be collected, the associated technical challenges, as well as the system changes required in order to be able to utilize this data to improve care and outcomes.

2:50 Development of a Smartphone App for Non-Invasive Detection of Anemia Using Only Patient-Sourced Photos

Wilbur A. Lam, MD, PhD, Associate Professor, Wallace H. Coulter Department of Biomedical Engineering and Department of Pediatrics, Aflac Cancer and Blood Disorders Center of Children's Healthcare of Atlanta, Georgia Institute of Technology and Emory University School of Medicine

We introduce a paradigm of non-invasive, on-demand diagnostics for hematologic diseases using only a smartphone app and photos. We initially targeted anemia, characterized by low blood hemoglobin levels, which afflicts >2 billion people. Our app estimates hemoglobin levels by analyzing color and metadata of fingernail smartphone photos and screens for anemia (hemoglobin levels <12.5 g/dL) with a 97% sensitivity (n = 100 subjects). Moreover, with personalized calibration, this system achieves an accuracy of ±0.92 g/dL compared to gold standard hemoglobin levels (n = 16 subjects), empowering chronic anemia patients to serially monitor their hemoglobin levels instantaneously and non-invasively.

FUTURE ASPECTS OF CLINICAL DX - WEARABLES AND BEYOND

3:20 Fully Integrated Wearable Impedance Cytometry Platform On Flexible Circuit Board With Online Smartphone Readout

Mehdi Javanmard, PhD, Assistant Professor of Electrical and Computer Engineering School of Engineering Rutgers, The State University of New Jersey

We present a wearable microfluidic impedance cytometer implemented on a flexible circuit wristband with on-line smartphone readout for portable biomarker counting and analysis. The platform contains a standard polydimethylsiloxane (PDMS) microfluidic channel integrated on a wristband, and the circuitry on the wristband is composed of a custom analog lock-in amplification system, a microcontroller with an 8-bit analog-to-digital converter (ADC), and a Bluetooth module wirelessly paired with a smartphone.

3:50 Future Trends in POC Diagnostics

Jim Sackrison, Consultant

This talk will discuss the future trends in POC diagnostics and where the field may be in the next 5, 10, 20 years.

4:20 End of Summit

Molecular Diagnostics for Infectious Disease

IMPROVING CLINICAL OUTCOMES THROUGH MOLECULAR TESTING

WEDNESDAY, AUGUST 21

10:30 am Registration

11:30 Plenary Keynote Session
Please click here for details

1:05 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:35 Ice Cream & Cookie Break in the Exhibit Hall with Poster Viewing

ANTIMICROBIAL SUSCEPTIBILITY TESTING

2:05 Chairperson's Opening Remarks
Amy J. Mathers, MD, D(ABMM), Medical Director, Antimicrobial Stewardship & Associate Director, Clinical Microbiology, Infectious Diseases & International Health University of Virginia School of Medicine

2:10 Managing Current and Future Hurdles in Implementing Novel Microbiology Diagnostics for Improved Antimicrobial Stewardship
Amy J. Mathers, MD, D(ABMM), Medical Director, Antimicrobial Stewardship & Associate Director, Clinical Microbiology, Infectious Diseases & International Health University of Virginia School of Medicine

With several novel and emerging technologies entering the clinical microbiology field to assist with decreasing the time to identification and antimicrobial susceptibility testing it can be challenging to navigate the potential application and barriers for each one. This session will explore some of the technical hurdles found in the clinical microbiology laboratory as well as some of the deployment challenges with getting results to expedite changes in patient care.

2:40 How Inkjet Printing Can Defeat Multi-Drug Resistant Superbugs
James E. Kirby, MD, D(ABMM), Director, Clinical Microbiology Laboratory, Beth Israel Deaconess Medical Center; Program Director, Medical Microbiology Fellowships, Beth Israel Deaconess Medical Center; Associate Professor of Pathology, Harvard Medical School

Emerging antimicrobial resistance has led to a critical need to identify antibiotics that are active against infections as quickly as possible. Dr. Kirby will discuss the MAST (microscopy-based antimicrobial susceptibility testing) platform, which makes use of inkjet printing, advanced microscopy, and machine learning technologies to determine the susceptibility of pathogens to any antimicrobial at will in under 4 hours, thereby addressing the antimicrobial testing gap.

3:10 Phenotypic Antibiotic Susceptibility Testing: From Monte-Carlo to the Bedside
Christopher Doern, PhD, D(ABMM), Associate Director, Microbiology, Virginia Commonwealth University Medical Center, Medical College of Virginia Campus

This talk will provide an in depth discussion of phenotypic AST methods and the various ways in which they are used. We will cover the role of AST in breakpoint development as well as the role in predicting individual patient outcomes. Along the way we'll highlight the strengths and weaknesses of phenotypic assessment of antimicrobial susceptibility.

3:40 Sample-to-Result MDx in Less Than 15 Minutes
Sponsored by KMC Systems
Sally McFall, PhD, Director of Research of the Center for Innovation in Global Health Technologies, Biomedical Engineering, Northwestern University

Point-of-care molecular diagnostics for infectious diseases are used to guide treatment decisions and improve outcomes. Minute Molecular Diagnostics, M2Dx, has developed fast sample prep and PCR technologies that enable sample-to-result turnaround times of less than 15 minutes. Functionality will be demonstrated with influenza and chlamydia assays.

3:55 Real-Time Phenotypic Antibiotic Susceptibility Testing (AST) at the Point of Care
Sponsored by stratec
Johan Elf, PhD, Stratec

Astrego's disruptive technology makes it possible to capture individual bacterial cells from complex samples on a microfluidic chip and measure their growth rates in real-time. Each channel can be loaded with antibiotic concentrations of choice and the effect on growth rate can be measured real time and almost immediately. Results may be expected within 20 minutes as the effects of antibiotics on growth rates of rods and cocci is immediate. This enables the fastest possible Antibiotic Susceptibility Test (AST), independent of McFarland concentration.

4:10 Refreshment Break in the Exhibit Hall with Poster Viewing

REIMBURSEMENT OF MOLECULAR TESTS

Co-Organized with AMP

4:55 Chairperson's Remarks
Jennifer Dien Bard, PhD, D(ABMM), Director, Microbiology and Virology, Children's Hospital Los Angeles; Associate Professor, Pathology and Laboratory Medicine, Keck School of Medicine, University of Southern California (AMP Infectious Diseases Subdivision Representative to the Program Committee; AMP Member)

5:00 Reimbursement Challenges in Developing Molecular Tests
Susan Butler-Wu, PhD, D(ABMM), Associate Professor of Clinical Pathology, Keck School of Medicine, University of Southern California, Director of Clinical Microbiology, LAC+USC Medical Center (AMP Economics Affairs Committee Member; AMP Member)

5:25 From Palmetto to PAMA: Recent Changes in Reimbursement for Infectious Diseases Diagnostics
Kimberly Hanson, MD, MHS, Director, Transplant Infectious Diseases and Immunocompromised Host Service, Director, Medical Microbiology Fellowship Program, Section Head, Clinical Microbiology, University of Utah, ARUP Laboratories (AMP Member)

On January 1, 2019 outpatient clinical laboratory tests received the second of three expected 10% reimbursement cuts under the Protecting Access to Medicare Act (PAMA). In addition, Medicare contractor Palmetto GBA issued local coverage determinations (LCDs) that limited coverage for syndromic multiplexed molecular infectious diseases tests. This session will describe recent reimbursement changes under the Centers for Medicare and Medicaid Services (CMS) and discuss the potential impact on clinical laboratories.

5:50 Reimbursement Woes from the Perspective of a Laboratorian
Jennifer Dien Bard, PhD, D(ABMM), Director, Microbiology and Virology, Children's Hospital Los Angeles; Associate Professor, Pathology and Laboratory Medicine, Keck School of Medicine, University of Southern California (AMP Infectious Diseases Subdivision Representative to the Program Committee; AMP Member)

Paradoxal to the vast array of innovative molecular diagnostic tests becoming available, securing reimbursement for such tests is becoming increasingly difficult. The ability to prove clinical utility is paramount in order to justify coverage and requires collaborative efforts between multiple disciplines, including diagnostic companies, clinical laboratories and providers. Failure to secure coverage directly impacts the clinical laboratories' ability to implement novel

MOLECULAR DIAGNOSTICS FOR INFECTIOUS DISEASE continued

diagnostic tests. This presentation will discuss the challenges that laboratories face in balancing implementation of molecular tests to conform to best practices versus reimbursement woes.

6:10 An Update on Coverage and Reimbursement from AMP's Economic Affairs Committee
Samuel K. Caughron, MD, FCAP, Director, MAWD Molecular Lab, MAWD Pathology Group (AMP Economic Affairs Committee Chair and Representative to the AMP 2018 Board of Directors; AMP Member)

6:30 Close of Day

6:30 Dinner Short Course Registration

6:45 - 9:15 pm RECOMMENDED DINNER SHORT COURSE*
SC10: Development of Novel Diagnostics for Antimicrobial Resistance
**Separate registration required, click here for details*

THURSDAY, AUGUST 22

7:15 am Registration

7:30 Problem Solving Breakout Discussions with Continental Breakfast *(See website for details)*

DEVELOPING AND IMPLEMENTING NEW TECHNOLOGY

8:25 Chairperson's Remarks
Kfir Oved, PhD, CTO, MeMed, Israel

8:30 Diagnostic Stewardship and Implementation of New Tests for Infectious Diseases in the Emergency Department
Larissa May, MD, MSPH, MSHS, Director, Emergency Department, Outpatient Antibiotic Stewardship, University of California Davis
This presentation will highlight the importance of diagnostic stewardship in parallel with antibiotic stewardship and opportunities and challenges with implementation of new infectious disease diagnostic tests in the ED and other acute episodic care settings.

9:00 Viral Load Testing for CMV: The Quagmire Continues
Christopher Polage, MD, MAS, Medical Director, Duke University Health Systems Clinical Microbiology Laboratory; Associate Processor, Duke University Medical Center
Variability in cytomegalovirus (CMV) viral load results between laboratories and assays remains a barrier to standardizing treatment protocols and defining disease despite efforts to harmonize tests. Differences in assay design may be part of the problem.

9:30 Sensitive Sequencing Approaches for Metagenomics, Infectious Disease and Forensic Applications *Sponsored by* DISCOVERY LIFE SCIENCES
Shawn Levy, PhD, CSO, Genomics, Discovery Life Sciences

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

AI-BASED INFECTIOUS DISEASE DIAGNOSTICS

11:00 Chairperson's Remarks
James Courtney Fackler, MD, Director, Pediatric Critical Care Medicine, Associate Professor of Anesthesiology and Critical Medicine, Johns Hopkins Medicine

11:05 Harnessing the Host Response for Real Time Infectious Disease Diagnosis
Ephraim L. Tsalik, MD, MHS, PhD, Associate Professor, Medicine, Duke University School of Medicine; Founder, Predigen, Inc.
For more than a decade, Duke, and now Predigen, have been at the forefront of capturing the molecular response to exogenous perturbations to develop diagnostic and predictive signatures for disease. Infectious disease pathogens induce robust and specific host responses that can be assayed using RNA and proteomic technologies. Using machine learning and advanced analytics we have pioneered the discovery of highly specific signatures and have translated them into clinically relevant assays. Our strategy is to develop rapid diagnostic tests for use in hospital, clinic, and home.

11:35 CO-PRESENTATION: Burn Sepsis and Acute Kidney Injury: Unique Population and the Promise of Artificial Intelligence
Hooman H. Rashidi, MD, FASCP, Professor and Vice Chair, GME, Director of Residency Program; Director, Flow Cytometry & Immunology, Department of Pathology and Laboratory Medicine, University of California, Davis School of Medicine
Nam Tran, PhD, Associate Clinical Professor, Clinical Chemistry, Special Chemistry, Toxicology, Point-of-Care Testing, SARC Sections, Pathology and Laboratory Medicine, University of California, Davis
Burn patients are at high risk for sepsis. Acute kidney injury (AKI) is common in burn sepsis patients. Early recognition of AKI is impeded by the poor performance biomarkers such as urine output and creatinine. Artificial intelligence (AI) could be used to augment the performance of current biomarkers of AKI. Our study evaluates the clinical utility of AI in detecting sepsis vs. non-sepsis related AKI in severely burned patients.

12:05 pm Integrating Artificial Intelligence Technologies into Clinical Care for Infectious Disease
James Courtney Fackler, MD, Director, Pediatric Critical Care Medicine, Associate Professor of Anesthesiology and Critical Medicine, Johns Hopkins Medicine
AI techniques (e.g., deep learning) are finding patterns in data that humans can not routinely see. The opportunity for improved health care value is early diagnosis and intervention. The key, however, to delivering this value will be optimizing and managing the symbiosis between the AI machines and the expert clinician.

12:35 The Key™ to Making an Impact: Accurate, Actionable, and Fast Host Response-based Diagnostics *Sponsored by* MeMed
Kfir Oved, PhD, CTO, MeMed
Antibiotic overuse drives AMR. Accurately differentiating bacterial from viral infection is essential to improve antibiotic stewardship. For this, we developed and validated a pioneering test (MeMedBV™) that integrates levels of three host-proteins into a score with >90% accuracy in differentiating bacterial from viral infections. We also developed a novel POC platform (MeMedKey™) that runs BV™ in 15 minutes. BV™ on Key™, a rapid and actionable diagnostic, enables physicians to better manage patients while combating AMR.

1:05 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:35 Dessert Break in the Exhibit Hall with Poster Viewing

NGS AND CLINICAL METAGENOMIC SEQUENCING

2:15 Chairperson's Remarks
Heike Sichtig, PhD, Principal Investigator and Team Lead, Microbiology Devices, Center for Devices (CDRH), FDA

2:20 Clinical Metagenomic Sequencing – New Technologies and Advances in the Near Future
Charles Chiu, MD, PhD, Professor, Laboratory Medicine and Medicine/Infectious Diseases, Director, UCSF-Abbott Viral Diagnostics and Discovery Center, Associate Director, UCSF Clinical Microbiology Laboratory, UCSF School of Medicine
Metagenomic next-generation sequencing (mNGS) is a potentially game-changing technology for infectious disease diagnosis as it enables detection of nearly all pathogens in a single assay. This approach has been made feasible by the rapid advances in sequencing technology, bioinformatics analysis, and reference databases. In this talk I will discuss how we overcome challenges in development and validation of an mNGS-based assay in a CLIA laboratory regulatory environment. I will discuss efforts to expand clinical mNGS validation and testing to new body fluids, as well as new transformative technologies including CRISPR-Cas and spiked primer enrichment strategies, and machine learning-based identification of host biomarkers.

MOLECULAR DIAGNOSTICS FOR INFECTIOUS DISEASE continued

2:40 Clinical Utility of Next-Generation Sequencing for Infectious Disease Diagnosis

Esther Babady, PhD, Director, Clinical Microbiology Operations, Memorial Sloan Kettering Cancer Center

The use of next generation sequencing (NGS) for infectious disease diagnosis has recently become a reality. Although not widely available in most laboratories, a few studies have highlighted the impact and potential utility of NGS in patient care. However, the optimal approach to implementing this powerful method for optimal impact remains unclear. This presentation will review the current state of NGS for the diagnosis and management of infectious diseases and discuss options for implementation that could maximize its clinical utility.

3:00 The Challenges and Opportunities of In-House NGS in Clinical Microbiology versus the Reference Lab Model

Nathan Ledeboer, PhD, Professor and Vice Chair, Pathology and Medical Director, Medical College of Wisconsin

Clinical labs are increasingly considering the use of NGS for detection of infectious diseases, a technique that has largely been confined to select reference labs and public health labs. This session will focus on the challenges and opportunities for a hospital based laboratory in implementing NGS for detection of infectious diseases.

3:20 PANEL DISCUSSION: Commercialization and Validation of NGS Diagnostics

Moderator: Heike Sichtig, PhD, Principal Investigator and Team Lead, Microbiology Devices, Center for Devices (CDRH), FDA

Panelists: Charles Chiu, MD, PhD, Professor, Laboratory Medicine and Medicine/Infectious Diseases, Director, UCSF-Abbott Viral Diagnostics and Discovery Center, Associate Director, UCSF Clinical Microbiology Laboratory, UCSF School of Medicine

Kimberly Hanson, MD, MHS, Director, Transplant Infectious Diseases and Immunocompromised Host Service, Director, Medical Microbiology Fellowship Program, Section Head, Clinical Microbiology, University of Utah, ARUP Laboratories

- FDA submission guidelines and submission strategies
- Comparative methods
- Lab validation vs point-of-care
- Strategies around regulation and commercialization

4:20 End of Summit

POC Special Forums

The Point-of-Care Special Forums offer extended coverage into emerging topics of point-of-care and *in vitro* diagnostics. Special Forums offer a mix of formal lectures, interactive panel discussions, and fireside chats with key opinion leaders to help attendees maximize their involvement in the forum. These immersive half-day events aim to unite point-of-care professionals interested in new market opportunities and technologies.

2019 POC SPECIAL FORUMS

AUGUST 20

AGENDA **Expanding Dx Portfolio for Veterinary Applications**

AUGUST 20

AGENDA **Point-of-Care Product Strategies**

AUGUST 21

AGENDA **Point-of-Care in the Pharmacy**

CONFERENCE STREAMS

- POCT & INFECTIOUS DISEASE
- LIQUID BIOPSY
- IMMUNO-ONCOLOGY
- BUSINESS
- COMPANION DIAGNOSTICS
- DIGITAL PATHOLOGY AND AI
- POC SPECIAL FORUMS

CAMBRIDGE HEALTHTECH'S INAUGURAL | **AUGUST 20, 2019 8:30 AM – 1:00 PM**

Expanding Dx Portfolio for Veterinary Applications

REPURPOSING DIAGNOSTICS FROM HUMANS TO ALL SPECIES OF ANIMALS

Each Special Forum offers half-day of instruction with start and stop times for each day shown above. Special Forums will include morning and afternoon refreshment breaks, as applicable. You can register for individual Special Forums or all three Special Forums (best value). CHI encourages track hopping between conference programs. Based upon your package selection, we do allow you to move between conferences occurring on the same dates.

TUESDAY, AUGUST 20

7:30 am Registration and Morning Coffee

CURRENT TRENDS IN VETERINARY DX SPACE

8:30 Chairperson's Opening Remarks

Chris Myatt, Founder & CEO, MBio Diagnostics, Inc.

8:40 Case Study: Why Go into Vet DX?

Chris Myatt, Founder & CEO, MBio Diagnostics, Inc.

I will discuss the benefits and challenges of designing, manufactoring, and testing human and animal microfluidic diagnostics platforms.

9:10 INTERACTIVE PANEL DISCUSSION: Identifying Current Trends and Opportunities in Veterinary Diagnostics

Moderator: Chris Myatt, Founder & CEO, MBio Diagnostics, Inc.

Panelists: Stephane Shu Kin So, PhD, MBA, CLP, Associate Director, Research Alliances, External Innovation, Zoetis

Chand Khanna, DVM, PhD, DACVIM (Onc), DACVP (Hon), CSO, Ethos Veterinary Health, President, Ethos Discovery

Anne Avery, PhD, VMD, Associate Professor of Immunology, Director of the Clinical Immunology Laboratory Colorado Statue University

Brian Cassell, DVM, Chief Strategy Officer, Ethos Veterinary Health

This panel will discuss the trends in precision medicine for companion and livestock animals, the veterinary reference lab landscape and how to deliver advanced veterinary diagnostics.

10:10 Coffee Break in the Exhibit Hall with Poster Viewing

FOCUS ON COMPANION ANIMALS

10:55 Chairperson's Remarks

Chand Khanna, DVM, PhD, DACVIM (Onc), DACVP (Hon), Chief Science Officer, Ethos Veterinary Health, President, Ethos Discovery

11:00 Exploiting Quorum Sensing to Identify Bacterial Infections

Edgar D. Goluch, PhD, Founder & CEO, QSM Diagnostics, Inc.

Real-time measurement of molecules secreted by bacterial cells provides important insights about the species that are present in a sample as well as what the cells are doing. My research for the last nine years has focused on studying quorum sensing molecules and other metabolites made by Pseudomonas aeruginosa in various samples and environments. We use low-cost sensors that allow us to measure the amounts and production rates of these chemicals, which are secreted by all species of bacterial cells, in real time at physiologically relevant concentrations. This talk will describe our findings and introduce you to the platform technology that we are developing at QSM Diagnostics for immediate identification and continuous monitoring of bacteria causing urinary tract infections in animals and humans.

11:30 INTERACTIVE PANEL DISCUSSION: Bridging the Gap between Clinical Vets and Diagnostics Companies

Moderator: Chand Khanna, DVM, PhD, DACVIM (Onc), DACVP (Hon), CSO, Ethos Veterinary Health, President, Ethos Discovery

Panelists: Jan Suchodolski, PhD, AGAF, DACVM, Associate Professor, Gastrointestinal Laboratory, Texas A&M University

Samuel Stewart, DVM, DACVECC, Ethos Veterinary Health

12:30 pm End of Expanding Dx Portfolio for Veterinary Applications

1:00 Cookie & Refreshment Break in the Exhibit Hall with Poster Viewing

RECOMMENDED SHORT COURSE*

SC9: Microfluidics and Lab-on-a-Chip Devices for POCT: Technologies and Commercialization

**Separate registration required, click here for details*

CAMBRIDGE HEALTHTECH'S INAUGURAL | **AUGUST 20, 2019 1:30 – 6:00 PM**

Point-of-Care Product Strategies

UNDERSTANDING POINT-OF-CARE TESTING MARKETS TO LAUNCH SUCCESSFUL PRODUCTS

Each Special Forum offers half-day of instruction with start and stop times for each day shown above. Special Forums will include morning and afternoon refreshment breaks, as applicable. You can register for individual Special Forums or all three Special Forums (best value). CHI encourages track hopping between conference programs. Based upon your package selection, we do allow you to move between conferences occurring on the same dates.

TUESDAY, AUGUST 20, 2019

1:00 pm Registration

1:30 Chairperson's Opening Remarks
Lawrence J. Worden, Founder, Principal, IVD Logix

1:35 OPENING KEYNOTE PRESENTATION: How Disruptive Could Disruptive Technology Be?
Gregory J. Tsongalis, PhD, HCLD, CC, Professor, Pathology, Director, Laboratory for Clinical Genomics and Advanced Technology (CGAT), Pathology and Laboratory Medicine, Dartmouth Hitchcock Health System, The Audrey and Theodor Geisel School of Medicine at Dartmouth

The world of diagnostic laboratory medicine has and continues to evolve at a rapid pace. Numerous drivers are responsible for this change but none more so than the so-called disruptive technologies. Here we discuss this trend.

OPPORTUNTIES IN THE CURRENT MARKET

2:00 Point-of-Care: Overview of Global Market Size, Growth, and Future Outlook
Mark Hughes, MBA, Vice President, Enterprise Analysis Corporation

2:15 Trends and Countertrends in Point-of-Care Diagnostics
Lucy Hattingh, MBA, Principal, Lucy Hattingh Consulting

2:30 POCT Future in China- Reasons for Optimism and Cautions
Nathaniel Whitney, President, Whitney Research

2:45 PANEL DISCUSSION with Session Speakers

- Opportunities and strategies for implantation across different
- markets including hospital, clinic, resource-limited setting,
- pharmacy, home
- Determining the how, when, and why of point-of-care in the market
- Global market size, growth, and trend analysis
- Understanding emerging and reemerging markets
- Predicting the future of point-of-care markets

3:00 Battle Studies: How Successful Companies Commercialize Innovative Rapid Diagnostic Technologies
Ryan Schmidt, Vice President of Sales & Marketing, Click Diagnostics

There is a tremendous need and opportunity to democratize diagnostic technologies so that they can empower more personalized care in a more efficient manner. During this session we will discuss case studies that will illuminate what happens when you "cut the cord" and how to navigate the competitive pressures to drive adoption.

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

4:25 PANEL DISCUSSION: Current Status – Future Promise, Clinical Perspectives on POC Implementation
Moderator: Lawrence J. Worden, Founder, Principal, IVD Logix
Panelists: Jeanne Mumford, MT(ASCP), Pathology Manager I, Point of Care Testing, Johns Hopkins Medicine; President, KEYPOCC
Joseph Campos, PhD, D(ABMM), F(AAM), Director, Microbiology Laboratory, Infectious Disease Molecular Diagnostics Laboratory, Laboratory Informatics, Children's National Medical Center
Robert H. Christenson, PhD, Professor, Pathology; Professor Medical and Research Technology, University of Maryland School of Medicine

- Where have you been able to successfully implement point-of-care in your institution?
- Where have there been failures?
- What are the challenges and opportunities presented by new point-of-care diagnostics?
- Lessons learned and best practices
- What are you looking for in a POC diagnostic?
- Future perspectives, what are some of the unmet needs and emerging technologies?

5:10 PANEL DISCUSSION: Reimbursement and Pricing Considerations
Moderator: Marc R. Jones, Chief Operating Officer & CFO, Binx Health
Panelists: Victoria Pratt, PhD, FACMG, Director, Pharmacogenomics and Molecular Genetics Laboratories, Medical and Molecular Genetics, Indiana University School of Medicine; President, Association of Molecular Pathology
Mark Girardi, Vice President, Boston Healthcare Associates

- Reimbursement models in point-of-care testing
- Balancing value and price in test development
- Working with reimbursement and regulatory agencies
- Reimbursement planning throughout the product development process.

6:00 End of Point-of-Care Product Strategies

6:00 Wine & Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing

Sponsored by PILLAR BIOSCIENCES

7:00 Close of Day

RECOMMENDED SHORT COURSE*
SC8: Generating Evidence and Creating a Winning Dossier for Regulatory and Reimbursement Needs
**Separate registration required, click here for details*

CAMBRIDGE HEALTHTECH'S 4TH ANNUAL | **AUGUST 21, 2019 8:25 AM – 12:35 PM**

Point-of-Care in the Pharmacy

STRATEGIES AND EFFECTIVE BUSINESS MODELS TO ENABLE POINT-OF-CARE IN THE PHARMACY

Each Special Forum offers half-day of instruction with start and stop times for each day shown above. Special Forums will include morning and afternoon refreshment breaks, as applicable. You can register for individual Special Forums or all three Special Forums (best value). CHI encourages track hopping between conference programs. Based upon your package selection, we do allow you to move between conferences occurring on the same dates.

WEDNESDAY, AUGUST 21, 2019

7:15 am Registration and Morning Coffee

8:25 FIRESIDE CHAT: Decision Making Process for Point-of-Care Implementation

Host: Kenneth Burton, MBA, Senior Manager, Strategic Growth and Operations, Minute Clinic, CVS Health

Participant: Alexander Sbordone, JD, OTR/L, Senior Advisor, Operations, MinuteClinic, CVS Health

- Ideation of new testing – Where do opportunities come from
- Key considerations when evaluating opportunities. We will discuss ROI, financial and operational considerations
- Maintaining a successful program. We will discuss the benefits of strategic relationships, understanding the payer landscape and what is on the horizon with emerging technology.

9:00 PANEL DISCUSSION: Considerations in the Community Pharmacy

Moderator: Donald Klepser, PhD, MBA, Associate Professor and Vice Chair, Pharmacy Practice, University of Nebraska Medical Center

Panelists: Jamie Bennett, PharmD, Clinical Services Leader, Fruth Pharmacy

Hamilton Borden, PharmD, Pharmacy Consultant, MTM Coordinator, Blount Discount Pharmacy; Blount Discount Pharmacy Residency Program Director

Keith Yon, PharmD, Pharmacist, Rx Clinic Pharmacy

- Case studies of successful business models
- Challenges and barriers to point-of-care implementation
- Working with different players including practitioners and regulatory agencies
- Impact of the pharmacy on the local community

9:55 FIRESIDE CHAT: Strategies to Advance Patient Care through Collaborative Practice Agreements and CLIA-Waivers

Host: Benjamin M. Bluml, RPh, Senior Vice President, Research and Innovation, American Pharmacists Association Foundation

Participant: Marialice S. Bennett, RPh, Professor Emeritus, The Ohio State University, College of Pharmacy

- Consensus principles for effective Collaborative Practice Agreement (CPA) partnerships
- Multi-center practice-based research experiences and results with point-of-care (POC) testing
- Successful community pharmacy-based POC implementations with CLIA waivers
- Review of the IMPACT innovative technology and process of care integrations produce

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:30 PANEL DISCUSSION: Strategic Implementation in the Retail Pharmacy Setting

Moderator: Michael Klepser, PharmD, FCCP, Professor, Pharmacy Practice, Ferris State University College of Pharmacy

Panelists: Mary Miller, PharmD, Manager, Clinical and Pharmacy Services, Rite Aid Corporation

Kenneth Burton, MBA, Senior Manager, Strategic Growth and Operations, Minute Clinic, CVS Health

- Challenges and barriers in implementing point-of-care
- Establishing payment models and provider-pharmacist relationships
- What are you looking for in a manufacturing partner?
- What technologies are you looking forward to seeing?

12:35 pm End of Point-of-Care in the Pharmacy

RECOMMENDED DINNER SHORT COURSE*

SC10: Development of Novel Diagnostics for Antimicrobial Resistance

**Separate registration required, click here for details*

Liquid Biopsy Stream

Technologies in the liquid biopsy field are maturing rapidly and are on track to revolutionize the management of patients in many clinical applications. The Liquid Biopsy stream at the Next Generation Dx Summit gathers technology developers, clinicians and other experts in circulating biomarkers to validate and uncover promising emerging technologies for liquid biopsy applications that make use of diverse biomarker types such as CTCs, cfDNA, RNA, exosomes and platelets. We will investigate the medical evidence needed to establish clinical utility of these novel diagnostic approaches.

2019 LIQUID BIOPSY CONFERENCES

AUGUST 20-21

AGENDA **Enabling Technologies for Circulating Biomarkers**

AUGUST 21-22

AGENDA **Clinical Application of Circulating Biomarkers**

CONFERENCE STREAMS

- POCT & INFECTIOUS DISEASE
- LIQUID BIOPSY
- IMMUNO-ONCOLOGY
- BUSINESS
- COMPANION DIAGNOSTICS
- DIGITAL PATHOLOGY AND AI
- POC SPECIAL FORUMS

Enabling Technologies for Circulating Biomarkers

ADVANCING TECHNOLOGIES FOR CLINICAL UTILITIES

RECOMMENDED SHORT COURSE*

SC3: Emerging Applications of ctDNA

SC6: Liquid Biopsies Based on Extracellular Vesicles: Prospects, Challenges, and Opportunities

**Separate registration required, click here for details*

TUESDAY, AUGUST 20

7:30 am Registration and Morning Coffee

THE ERA OF MARKER COMBINATIONS

8:30 Chairperson's Opening Remarks

G. Mike Makrigiorgos, PhD, Professor of Radiation Oncology, Dana Farber Cancer Institute and Harvard Medical School

8:40 KEYNOTE PRESENTATION: Precision Medicine Using Liquid Biopsies: A New Paradigm for Managing Cancer Diseases

Steven A. Soper, PhD, Chemistry, Mechanical Engineering, BioEngineering, KUMC Cancer Center University of Kansas, Lawrence; Director, NIH Biotechnology Resource Center of BioModular Multi-Scale Systems for Precision Medicine

We are generating innovative microfluidic tools for selecting circulating markers from whole blood and determining the presence/absence of disease-specific molecular signatures secured from the liquid biopsy markers to guide therapy for a patient. The microfluidics can process whole blood (≥1 mL) and search for CTCs, cfDNA, or exosomes and make them available for downstream molecular processing. I will talk extensively about our exosome isolation chip, and its use in several clinical examples and securing molecular information from the affinity-selected exosomes. The exosome chip consists of 1.4 million pillars that contain surface-immobilized antibodies directed against antigens from cancer cells that are epithelial based (EpCAM) and those with a mesenchymal phenotype (fibrobast activation protein alpha, FAPα). The chip is operated by a robotic workstation and can perform 32 isolation assays per day per machine in a fully automated fashion.

9:10 Opportunities and Challenges for Liquid Biopsies in the Fight Against Cancer

Lynn R. Sorbara, PhD, Program Director, Cancer Biomarker Research Group, National Cancer Institute

This presentation will address the need for better focus on the clinical decision making support being enabled by liquid biopsy-based assays in the context of new enabling technologies that are shaping the landscape of possibilities. The persistent need for standards development in this field to qualify new assays are a critical components for that, and as promising as ctDNA is we know we can't throw out consideration of CTCs.

9:40 Multi-Parametric Liquid Biopsy Analysis in Metastatic Prostate Cancer

Amir Goldkorn, MD, Associate Professor of Medicine, Co-Leader, Translational & Clinical Science Program; Director, Circulating Tumor Cell Research Core, USC Norris Comprehensive Cancer Center & Keck School of Medicine; Chair, Prostate Cancer Organ Site Translational Medicine, SWOG

Multiparametric liquid biopsy profiles were successfully generated for each patient and time point, demonstrating the feasibility of this approach and highlighting shared as well as unique cancer-relevant alterations. With further refinement and validation in large cohorts, multiparametric liquid biopsies can optimally integrate disparate but clinically informative data sets and maximize their utility for molecularly directed, real-time patient management.

10:10 Coffee Break in the Exhibit Hall with Poster Viewing

10:55 Chairperson's Remarks

G. Mike Makrigiorgos, PhD, Professor of Radiation Oncology, Dana Farber Cancer Institute and Harvard Medical School

11:00 Multi-Omic Liquid Biopsy Platform

Sam Hanash, MD, PhD, Director, Red & Charline McCombs Institute; Evelyn & Sol Rubenstein Distinguished Chair, Cancer Prevention; Professor, Clinical Cancer Prevention-Research, Translational Molecular Pathology, University of Texas MD Anderson Cancer Center

Multiple technologies are currently being explored for liquid biopsy applications beyond genomics, including proteomics, metabolomics, immunomics and extra-cellular vesicles. The individual and combined contributions of these approaches will be presented.

11:30 Analysis of Therapeutically-Relevant Markers in Circulating Tumor Cells

Shana O. Kelley, PhD, Professor, Leslie Dan Faculty of Pharmacy, Faculty of Medicine, Biochemistry, University of Toronto

12:00 pm An Open Platform for CTC Analysis: Identification, Phenotypic Characterization and Molecular Analysis

Sponsored by RARECYTE

Arturo Ramirez, Director, Oncology R&D, RareCyte, Inc.

This talk will highlight the unique benefits of the RareCyte platform for CTC characterization. It will present the method to transfer nucleated cells from whole blood to slides as well as immunofluorescence staining to identify CTCs and phenotypically characterize clinically relevant biomarkers. Clinical studies were performed comparing our platform to CellSearch® and single CTCs were isolated for next generation sequencing to obtain molecular information about the tumor via liquid biopsy.

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:00 Cookie & Refreshment Break in the Exhibit Hall with Poster Viewing

DETECTION AND ANALYSIS OF CTCs AND OTHER TUMOR-ASSOCIATED CELLS

1:30 Chairperson's Remarks

Steven A. Soper, PhD, Chemistry, Mechanical Engineering, BioEngineering, KUMC Cancer Center University of Kansas, Lawrence; Director, NIH Biotechnology Resource Center of BioModular Multi-Scale Systems for Precision Medicine

1:35 Targeting CTC Cytoskeletal Alterations to Reduce Metastasis

Stuart Martin, PhD, Professor, Greenebaum Comprehensive Cancer Center, University of Maryland School of Medicine

2:05 Isolation of Circulating Tumor Cells in Non-Small-Cell-Lung-Cancer Patients Using a Multi-Flow Microfluidic Channel

Ian Papautsky, PhD, Professor, Bioengineering; Co-Director, NSF Center for Advanced Design & Manufacturing of Integrated Microfluidics (CADMIM) Bioengineering, University of Illinois at Chicago

Our device is constructed and configured based on the phenomenal effect of size-dependent inertial migration. The recovery rate of >93% has been achieved using spiked cancer cells at clinically relevant concentrations (10 cells per 5 mL and above). We have also successfully detected CTCs from 6 out of 8 non-small-cell-lung-cancer (NSCLC) patients, while none for 5 healthy control subjects. With these results, we envision our approach is a promising alternative for reliable CTC capture, and thus for facilitating the progress of extracting information from CTCs to personalize treatment strategies for solid tumor patients.

2:35 Detection and Analysis of Circulating Epithelial Cells in Liquid Biopsies from Patients with Liver Disease

Irun Bhan, MD, Clinical Instructor, Harvard Medical School, Transplant Hepatologist, Division of Gastroenterology, Massachusetts General Hospital

In this work, we used the iChip platform to detect CECs in patients with CLD but without HCC and to phenotypically discriminate between CECs in patients with and without HCC.

ENABLING TECHNOLOGIES FOR CIRCULATING BIOMARKERS, continued

3:05 Sponsored Presentation *(Opportunity Available)*

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

ADVANCES IN CIRCULATING NUCLEIC-ACID TECHNOLOGIES

4:25 Chairperson's Remarks

G. Mike Makrigiorgos, PhD, Professor of Radiation Oncology, Dana Farber Cancer Institute and Harvard Medical School

4:30 Novel Digital PCR and Mutation Enrichment Technologies for the Analysis of Clinically Relevant DNA Alterations in Liquid Biopsies

G. Mike Makrigiorgos, PhD, Professor of Radiation Oncology, Dana Farber Cancer Institute and Harvard Medical School

With the increasing interest in treatment assessment using liquid biopsy and circulating DNA, sensitive and multiplexed detection of tumor-derived alterations in blood are desirable. We provide novel forms of digital PCR, as well as mutation enrichment-based real time PCR methods that (a) enable several orders of magnitude improvement of detecting mutations or microsatellite instability than currently possible; (b) are highly multiplex-able; (c) reduce cost of analysis. Application in circulating DNA from clinical cancer samples will be presented.

5:00 Phospho-sRNA-seq Enables Plasma mRNA/lncRNA Transcriptome Profiling as a Liquid Biopsy Approach

Ryan M. Spengler, PhD, Postdoctoral Fellow, Muneesh Tewari Laboratory, Hematology/Oncology, University of Michigan

We present a modified RNA-seq methodology, called phospho-sRNA-seq, which, when combined with a stringent computational pipeline, allows enhanced profiling of extracellular mRNA and lncRNAs in blood plasma. We find that signal comes from transcript fragments that are detected across individuals, and demonstrate dynamic expression patterns consistent with physiological changes in patients. Together, our methods increase access to extracellular transcriptome signatures, providing additional avenues to uncover RNA biomarkers in liquid biopsies.

5:30 Digital Counting of Target cfRNA and cfDNA with NanoString nCounter® Technology

Sponsored by nanoString TECHNOLOGIES

Adam Abdool, Senior Product Manager, Life Sciences, NanoString

Liquid (versus tissue) biopsy offers advantages for early disease diagnosis, progression monitoring and evaluation of therapeutic interventions because sample collection is rapid, easy, minimally invasive, and repeatable. However, detection has been difficult due to low abundance of target molecules, leading to complex workflows with highly variable signal detection. We'll demonstrate utilizing nCounter technology for liquid biopsy applications (Research Use Only), including mutation detection of ctDNA & RNA profiling, and fusion detection of cfRNA.

6:00 Wine & Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing

Sponsored by PILLAR BIOSCIENCES

7:00 Close of Day

WEDNESDAY, AUGUST 21

7:15 am Registration

7:30 Problem Solving Breakout Discussions with Continental Breakfast (See website for details)

EXOSOME PROFILING AND ANALYSIS

8:25 Chairperson's Remarks

Hyungsoon Im, PhD, Assistant Professor of Radiology, Massachusetts General Hospital, Radiology, Massachusetts General Hospital

8:30 Ultrasensitive Detection of Circulating Exosomes with a 3D-Nanopatterned Microfluidic Chip

Yong Zeng, PhD, Associate Professor and Docking Faculty Scholar, Chemistry, KU Cancer Center, University of Kansas

Here, we show that a microfluidic chip designed with self-assembled three-dimensional herringbone nanopatterns can detect low levels of tumour-associated exosomes in plasma (10 exosomes µl−1, or approximately 200 vesicles per 20 µl of spiked sample) that would otherwise be undetectable by standard microfluidic systems for biosensing. The nanopatterns promote microscale mass transfer, increase surface area and probe density to enhance the efficiency and speed of exosome binding, and permit drainage of the boundary fluid to reduce near-surface hydrodynamic resistance, thus promoting particle–surface interactions for exosome binding.

9:00 AC Electrokinetic Chip Device for Rapid Isolation and Integrated Analysis of Exosome and cf-DNA Biomarkers from Cancer Patient Blood Samples

Michael J. Heller, PhD, Distinguished Scientist, Knight Cancer Institute at Oregon Health & Science University (OHSU), Center for Cancer Early Detection and Research (CEDAR); Professor Emeritus, Bioengineering and Nanoengineering, University of California San Diego

New multi-omic approaches for different biomarkers is becoming a viable strategy for liquid biopsy diagnostics and early cancer detection. Electrokinetic sample to answer ACE chip devices were used for the rapid isolation of exosomes, extracellular vesicles (EVs) and cell free (cf) DNA/RNA from cancer patient plasma samples. Subsequent fluorescent detection of cf-DNA levels, immunostaining for specific exosome/EV protein biomarkers and ddPCR/sequencing analysis for point mutations were all carried out.

9:20 Nanoplasmonic Exosome (nPLEX) Technology for Circulating Tumor Exosome Profiling

Hyungsoon Im, PhD, Assistant Professor of Radiology, Massachusetts General Hospital, Radiology, Massachusetts General Hospital

Exosomes have emerged as promising circulating biomarkers for diagnosis and prognosis of various cancer types. This presentation will discuss a recent progress of nPLEX (nano-plasmonic exosome) technology that we developed for sensitive detection and molecular profiling of circulating exosomes for ovarian and pancreatic cancers.

9:40 High Precision Isolation and Analysis of Exosomes

Daniel T. Chiu, PhD, A. Bruce Montgomery Professor, Chemistry and Bioengineering, University of Washington, Seattle

Here, we show that a microfluidic chip designed with self-assembled three-dimensional herringbone nanopatterns can detect low levels of tumour-associated exosomes in plasma (10 exosomes µl−1, or approximately 200 vesicles per 20 µl of spiked sample) that would otherwise be undetectable by standard microfluidic systems for biosensing. The nanopatterns promote microscale mass transfer, increase surface area and probe density to enhance the efficiency and speed of exosome binding, and permit drainage of the boundary fluid to reduce near-surface hydrodynamic resistance, thus promoting particle–surface interactions for exosome binding.

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:30 Plenary Keynote Session

Please click here for details

1:05 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:35 End of Enabling Technologies for Circulating Biomarkers

Clinical Application of Circulating Biomarkers

FROM DISCOVERY TO A CLINICALLY ROBUST TEST

WEDNESDAY, AUGUST 21

10:30 am Registration

11:30 Plenary Keynote Session
Please click here for details

1:05 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:35 Ice Cream & Cookie Break in the Exhibit Hall with Poster Viewing

CLINICAL APPLICATIONS OF METHYLATED DNA

2:05 Chairperson's Opening Remarks
Scott Kopetz, MD, PhD, FACP, Associate Professor, Gastrointestinal Medical Oncology, University of Texas MD Anderson Cancer Center

2:10 Genomic Location of DNA Methylation Biomarker Development
James G. Herman, MD, Hematology/Oncology, Professor of Medicine, UPMC Endowed Chair for Lung Cancer Research; Co-Director, Lung Cancer Program, University of Pittsburgh
DNA methylation alterations in cancer are promising targets for the development of diagnostic, prognostic, and predictive biomarkers. Ultrasensitive methods for detection can improve early cancer detection. However, effective development of DNA methylation-based biomarkers is often limited by suboptimal assay design, which includes consideration of genomic location. We will examine the importance of genomic location in DNA methylation biomarker development for uses in cancer, and discuss particular issues related to circulating tumor DNA.

2:40 Applications of Mutation-Agnostic Detection of Circulating Tumor DNA Using Methylation Profiling
Filip Janku, MD, PhD, Associate Professor, Department of Investigational Cancer Therapeutics, The University of Texas MD Anderson Cancer Center
Detection of circulating tumor DNA can be used for molecular diagnostics, assessment of efficacy of cancer therapy and detection of minimal residual disease. Most currently used approaches utilize detection of well-defined molecular alterations such as hot spot mutations, which can limit applicability especially in patients without clinically detectable disease. Unlike detection of hot spot mutations, methylation profiling can identify tumor DNA irrespective of underlying mutation profile. Integrating methylation profiling into detection of circulating tumor DNA can increase sensitivity and help to transition molecular testing of circulating tumor DNA from metastatic cancers to early stages.

3:10 A DREAM Come True – Assessing Heterogeneous Methylation with Digital Microfluidics for Enhanced Detection of Rare Tumor DNA
Thomas R. Pisanic II, PhD, Research Scientist, Johns Hopkins Institute for NanoBioTechnology, Johns Hopkins University
Aberrant DNA methylation is commonly heralded as a promising cancer biomarker; however, its inherently stochastic nature often leads to variable methylation patterns that can complicate the use of methylation biomarkers for clinical diagnostics. Here we demonstrate how incorporation of our novel assay strategy termed DREAMing into a digital microfluidic platform allows for facile assessment of intermolecular methylation heterogeneity and enhances diagnostic performance in challenging samples such as liquid biopsies.

3:40 Drop-off Assay Using Crystal™ Digital PCR for the Detection and Quantification of EGFR Mutations in Circulating cfDNA
Sponsored by STILLA
Romain Parillaud, PhD, Application Specialist, Stilla Technologies
Using Crystal™ Digital PCR, a 3-color multiplex drop-off assay was developed to detect NRAS, KRAS, and EGFR mutations in circulating cell-free DNA samples of non-small cell lung cancer patients. Furthermore, a unique 6-color target multiplexing drop-off assay was validated to monitor the most prevalent EGFR mutations in the patient samples.

4:10 Refreshment Break in the Exhibit Hall with Poster Viewing

DISEASE MONITORING

4:55 Chairperson's Remarks
Scott Kopetz, MD, PhD, FACP, Associate Professor, Gastrointestinal Medical Oncology, University of Texas MD Anderson Cancer Center

5:00 CSF Tumor DNA for the Detection and Monitoring of Central Nervous System Cancers
Chetan Bettegowda, MD, PhD, Jennison and Novak's Families Chair, Departments of Neurosurgery and Oncology, Johns Hopkins University School of Medicine
There are no existing biomarkers for the diagnosis and monitoring of nearly all central nervous system tumors. Circulating biomarkers for CNS tumors are present in diminished levels compared to those in the cerebrospinal fluid. CSF-tDNA has been shown to be elevated in a myriad of CNS neoplasms. This talk will discuss the application of CSF-tDNA for the detection and monitoring of tumors involving the central nervous system.

5:30 Development of a Translational Pipeline for EV-Based Liquid Biopsies
Jennifer C. Jones, MD, PhD, Investigator, Laboratory of Pathology; Head, Translational Nanobiology Section, Center for Cancer Research, NCI, NIH
Tumor cells, immune cells, and irradiated tissues release large quantities of biologically active (and distinct) nanoscale extracellular vesicles (e.g., exosomes and microparticles). Dr. Jones is developing improved methods to characterize, sort, and perform functional studies of nanoparticles, and has established a translational EV analysis pipeline, with instrumentation for preparation, analysis, counting, and cytometric study of extracellular vesicles.

6:00 Beyond Histology: Using Circulating Tumor DNA to Augment Clinical Trial Patient Selection
Yelena Y. Janjigian, MD, Chief, Gastrointestinal Oncology Service, Memorial Sloan Kettering Cancer Center
My talk will cover application of cfDNA technology in clinic, specifically innovation in clinical trial design and patient selection. We will review trials in progress and cover challenges in interpretation of cfDNA results, contribution of clonal hematopoiesis and tumor heterogeneity to discordant results.

6:30 Close of Day

6:30 Dinner Short Course Registration*
**Separate registration required, click here for details*

THURSDAY, AUGUST 22

7:15 am Registration

7:30 Problem Solving Breakout Discussions with Continental Breakfast *(See website for details)*

KEYNOTE SESSION

8:25 Chairperson's Remarks
Abhijit Patel, MD, PhD, Associate Professor, Yale University School of Medicine

8:30 Perspectives of Liquid Biopsies in Genomics-Driven Oncology
Michael R. Speicher, MD, Professor and Chairman, Institute of Human Genetics, Diagnostic and Research Center for Molecular BioMedicine, Medical University of Graz
Genome-driven oncology may have enormous potential to change the clinical management of patients with cancer. To this end, liquid biopsies, i.e. components of tumors, which ar

CLINICAL APPLICATION OF CIRCULATING BIOMARKERS, continued

shed into the circulation, such as circulating tumor DNA (ctDNA) or circulating tumor cells (CTCs), are increasingly being used for monitoring tumor genomes and to identify predictive biomarkers. Current and future perspectives of liquid biopsies and their impact on genomics-driven oncology will be presented.

9:15 Development of NGS ctDNA Assays for Oncology Translational and Clinical Research

Brian Dougherty, PhD, MBA, Executive Director, Translational Science, Oncology IMED, AstraZeneca

AstraZeneca has been investigating the use of ctDNA testing for patient selection, drug resistance emergence, and patient monitoring. Additional studies have extended studies into exosomal DNA and transcriptome sequencing. I will also present a recently published orthogonal bench-marking study of commercial ctDNA assays that determined most tumor-plasma discordance is due to assay technical performance, not tumor heterogeneity or clonal hematopoiesis.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

CLINICAL TRIAL PROGRESS AND GUIDING TREATMENT DECISIONS

11:00 Chairperson's Remarks

Abhijit Patel, MD, PhD, Associate Professor, Yale University School of Medicine

11:05 Value of ctDNA in Monitoring and Guiding Therapy in Advanced Cancer

Christine Parseghian, MD, Assistant Professor, Gastrointestinal Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center

Advances in ctDNA analyses allow reliable detection and quantification of tumor mutations in real-time. Dynamic changes in ctDNA levels provides a highly specific noninvasive tool for early assessment (up to 16 weeks prior to radiographic change) of treatment response. This allows early selection of patients likely to respond and helps avoid toxicities. We propose ctDNA as a tool to refine monitoring and management of metastatic cancers in clinics and clinical trials.

11:35 Blood-Based Assays for Monitoring of Treatment Response in Glioma Patients

Leonora Balaj, PhD, Instructor of Neurosurgery, Massachusetts General Hospital

We performed longitudinal whole-transcriptome profiling of serum exosomes from patients suffering from recurrent glioblastoma (GBM) enrolled in a clinical trial to assess response to Dacomitinib, a second-generation irreversible EGFR tyrosine kinase inhibitor. All patients had failed standard of care therapy and had tumors amplified for EGFR. They underwent daily oral administration of Dacomitinib and blood serum samples were collected immediately prior to first treatment and monthly thereafter. Deep sequencing of exosomal RNA (exRNA), derived from just 2 ml of patient serum, revealed robust signatures of treatment response, as defined by >6-month progression-free survival. Non-responders were found to have significantly elevated levels of a number of transcripts including colony stimulating factor 1 (CSF1), which regulates the proliferation, differentiation, and survival of macrophages and microglia. We further identified robust signatures of treatment response in post-treatment serum samples, including the suppression of DNA methyltransferase 3 alpha (DNMT3a), an important player in DNA methyl transfer for de-novo methylation, as well as Adenosine A2B receptor (ADORA2B), a member of the G protein-coupled receptor superfamily which is overexpressed in a variety of cancers and has been shown to play a role in tumor progression via increased angiogenesis and metastasis. Furthermore, we identified general decreases in oncogene abundance following Dacomitinib treatment, including tumor protein p53 (TP53) and Ovo like transcriptional repressor 1 (OVOL1), a zinc finger containing transcription factor, shown to be a critical inducer of epithelial-tomesenchymal transition in cancer. Finally, in comparison to healthy control serum we find hundreds of transcripts exhibiting differential abundance in pre-treatment GBM patients that may serve as general non-invasive biomarkers for this devastating disease. This study is unique because it represents the first longitudinal profiling of the exosomal transcriptome in a cohort of genomically selected GBM patients. These findings are a tantalizing step toward exosome-based biomarkers for the detection of GBM, as well as patient stratification and monitoring.

12:05 pm Redefining Adjuvant Therapy in the Era of Circulating Biomarkers

Jamie E. Chaft, MD, Medical Oncologist, Memorial Sloan Kettering Cancer Center

Solid tumors have long been defined by TNM staging, providing risk of disease recurrence and death. Stage and other clinical features are used to prescribe adjuvant therapy. This system over treats many and misses some who may benefit. Logical trial designs using circulating biomarkers will lead to smaller trials with greater impact per intervention studied, moving towards an era of precision cancer care in the curative setting.

12:35 Sponsored Presentation *(Opportunity Available)*

1:05 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:35 Dessert Break in the Exhibit Hall with Poster Viewing

EARLY DETECTION

2:15 Chairperson's Remarks

Luis A. Diaz, MD, Head, Solid Tumor Oncology, Memorial Sloan Kettering Cancer Center, Conference Chairman

2:20 Therapy Monitoring and Early Detection via ctDNA: Progress and Challenges

Abhijit Patel, MD, PhD, Associate Professor, Yale University School of Medicine

Our group has developed NGS-based methods that use molecular and computational error suppression techniques to enable ultrasensitive detection of ctDNA based on genomic and epigenomic features. This presentation will describe our work in the areas of therapeutic response assessment and early cancer detection.

2:50 Sensitive Tumour Detection and Classification Using Plasma Cell-Free DNA Methylomes

Scott V. Bratman, MD, PhD, Radiation Oncologist, Radiation Medicine Program; Scientist, Princess Margaret Cancer Centre, University Health Network; Assistant Professor, Depts of Radiation Oncology and Medical Biophysics, University of Toronto

Sequencing of somatic mutations in plasma cell-free DNA (cfDNA) may have low sensitivity among early-stage cancer patients given the limited availability of recurrent mutations. In contrast, DNA methylation patterns, which are tissue and cancer-type specific, are not similarly constrained. Here, we demonstrate the performance of genome-wide methylome analysis of plasma cfDNA for cancer detection and classification across an extensive collection of plasma samples from multiple tumor types.

3:20 Somatic Mutations and HPV as a Biomarker for Head and Neck Squamous Cell Carcinoma

Nishant Agrawal, MD, Professor of Surgery, Director of Head and Neck Surgery Oncology, University of Chicago

Head and neck squamous cell carcinoma (HNSCC) is the 6th most common cancer worldwide. HNSCC develops in the oral cavity, pharynx, and larynx and is associated with tobacco exposure, alcohol abuse, and infection with oncogenic viruses. Despite global advances in cancer care, HNSCC often presents with advanced disease and is associated with poor 5-year survival of ~50%. Conventional analysis of tissue through cytopathology or histopathology are the mainstay of diagnosis. Furthermore, there are no useful biomarkers for disease diagnosis or surveillance. With recent advances, tumor and HPV DNA for HNSCC diagnosis, monitoring, and surveillance, is emerging as a biomarker in HNSCC. In HNSCC, analysis of tumor DNA has the potential to enhance tumor profiling, aid in determining patient prognosis, and guide treatment decisions.

3:50 Why Is It So Hard to Develop Molecular Markers for Cancer Screening? Lessons from CRC Screening

David F. Ransohoff, MD, Professor, Medicine and Epidemiology, University of North Carolina, Chapel Hill

Developing molecular markers – like a blood test – for cancer screening has been a 'holy grail' in cancer research since the 1970s, when initial results for carcinoembryonic antigen (CEA) showed nearly 100% sensitivity and specificity for colon cancer, only to be followed by disappointing results in later research. Lessons from past failures and from to-date modest successes can illustrate the challenges in this field and how to address them.

4:20 End of Summit

Immuno-Oncology Stream

Recent advances in cancer immunotherapy have generated excitement across all fields of oncology, and the pressure to discover and validate robust and predictive immuno-oncology biomarkers for patient selection is at all-time high. Many diagnostic and pharmaceutical companies are working hand in hand to deliver biomarker support for clinical trials and patient care. Genomic biomarkers, cell-based biomarkers, and biomarkers of tumor microenvironment have the potential to guide cancer immunotherapy and improve patient outcomes. Some of these biomarkers are being promoted to companion and complementary tests, which brings about unique regulatory, reimbursement and logistical challenges. Technical and scientific advances as well as business considerations with biomarkers and companion diagnostics for cancer immunotherapy will be discussed at the Immuno-Oncology Stream by major stakeholders including biomarker experts from the biopharmaceutical industry, IVD companies and the laboratory medicine community.

2019 IMMUNO-ONCOLOGY CONFERENCES

AUGUST 20-21

AGENDA **Emerging Technologies and Biomarkers for Cancer Immunotherapy**

AUGUST 21-22

AGENDA **Companion Diagnostics and Clinical Biomarkers in Immuno-Oncology**

CONFERENCE STREAMS

- POCT & INFECTIOUS DISEASE
- LIQUID BIOPSY
- IMMUNO-ONCOLOGY
- BUSINESS
- COMPANION DIAGNOSTICS
- DIGITAL PATHOLOGY AND AI
- POC SPECIAL FORUMS

Emerging Technologies and Biomarkers for Cancer Immunotherapy

NEXT GENERATION OF IMMUNO-ONCOLOGY BIOMARKERS

RECOMMENDED SHORT COURSES*
SC3: Emerging Applications of ctDNA
SC5: Tumor Mutation Burden
**Separate registration required, click here for details*

TUESDAY, AUGUST 20

7:30 am Registration and Morning Coffee

UTILIZING CUTTING EDGE TECHNOLOGIES IN IO

8:30 Chairperson's Opening Remarks
Omar Laterza, PhD, DABCC, Executive Director, Molecular Biomarkers and Diagnostics, Merck & Co., Inc.

8:40 Biomarkers in Early Clinical Development of Immuno-Oncology Drugs
Omar Laterza, PhD, DABCC, Executive Director, Molecular Biomarkers and Diagnostics, Merck & Co., Inc.

Biomarkers play a critical role in the early clinical development of novel Immuno-Oncology compounds, including in the assessment of target engagement, pharmacodynamic response, verification of the hypothesized mechanism of action, identification of safety signals and getting an early read into potential predictive biomarkers. This information is important in decision making in dose selection, prioritization of assets, acceleration of programs and go/no-go decisions. In this session, case studies of how biomarkers are used in decision making for early Immuno-Oncology programs will be presented, including considerations for the analytical validation of biomarker assays.

9:10 Highly Multiplex Quantification of Immunomodulatory Proteins in Blood and the Tumor Microenvironment
Amanda Paulovich, MD, PhD, Full Member & Aven Foundation Endowed Chair, Clinical Research Division, Fred Hutchinson Cancer Research Center; Professor, Division of Oncology, Department of Medicine at the University of Washington School of Medicine

Novel assays are being developed to quantify ~100 immunomodulatory proteins. Assay targets were selected by key stakeholders in the immuno-oncology space. All assays will be based on monoclonal antibodies incorporated into the NextGen immuno-multiple reaction monitoring platform. This next generation protein quantification platform is a highly attractive complement to current immunoassay platforms given its high specificity, quantitative precision, and ability to quantify large panels of proteins in a multiplex manner.

9:40 CO-PRESENTATION: Single-Cell Imaging Technologies and Transcriptomic Approaches to Guide the Development of Tumor Immunotherapies
Andrea Pomerantz, investigator III, Microscopy and Biophotonics (MiBs), Analytical Sciences and Imaging, Novartis Institutes for Biomedical Research, Inc.
Tingyu Liu, PhD, Postdoctoral Scholar, Exploratory Immuno-Oncology, Novartis Institutes for BioMedical Research, Inc.

In support of the development of new immunomodulatory therapies at NIBR, we are implementing multiple single-cell analyses including microfluidic and confocal imaging assays for interrogating single immune cell / target cell interaction dynamics. To better understand the heterogeneity and functional alterations of tumor infiltrating lymphocytes, we are also performing single-cell RNA sequencing on lymphocytes extracted from primary human tumors. Collectively, these single-cell approaches provide powerful tools to investigate tumor infiltrating lymphocyte heterogeneity while helping to identify novel targets to improve tumor immunotherapy.

10:10 Coffee Break in the Exhibit Hall with Poster Viewing

DECIPHERING MECHANISMS OF RESISTANCE

10:55 Chairperson's Remarks
Robin Edwards, MD, Group Director, Pathology, Bristol-Myers Squibb

11:00 Tumor-Intrinsic Mechanisms of Resistance to Immunotherapy
Scott Ely, MD, MPH, Director, Pathology, Bristol-Myers Squibb

Mechanisms of resistance to immunotherapy may derive from factors in the tumor microenvironment or from the tumor cells themselves. Genetic mutations and copy number variants observed in the IFN-γ signaling pathway may affect antigen presentation and T-cell infiltration. STK11 loss of function is associated with cold tumors that show diminished PD-L1 expression. This presentation will focus on the key role that genetic variants in tumor cells play in thwarting the anti-tumor immune response.

11:30 Immune Heterogeneity in Pancreatic Cancer: Implications for Effective Immune Therapy
Shannon Liudahl, PhD, Postdoctoral Researcher, Cell, Developmental & Cancer Biology, Oregon Health & Science University

Multiplex immunohistochemistry (mIHC) enables unprecedented depth of *in situ* immune profiling of human tumors and is a promising tool for biomarker discovery. We have used mIHC to evaluate immune heterogeneity of 120 pancreatic ductal adenocarcinoma (PDAC) surgical specimens and revealed associations between tumor immune subtype, mutational status and patient outcomes. Tumor immune signatures determined from these data have potential to inform patient stratification and predict therapeutic response in immunotherapy trials in PDAC.

12:00 pm Reshaping Oncology Drug Development Landscape with ctDNA + ctRNA Liquid Biopsy Solutions
Sponsored by Predicine
Shidong Jia, MD, PhD, CEO, Predicine

This talk will discuss the clinical applications of Predicine's blood- and urine-based ctDNA+ctRNA liquid biopsy assays which detect a full range of genomic alterations including DNA copy number loss, RNA splicing, and RNA fusion. Case studies of how a harmonized assay is utilized to accelerate global trials will be presented.

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:00 Cookie & Refreshment Break in the Exhibit Hall with Poster Viewing

MULTIPLEXED IHC

1:30 Chairperson's Remarks
Jaime Rodriguez-Canales, MD, FEBP, Senior Pathologist, Translational Pathology Laboratory, MedImmune

1:35 Highly Consistent Multiplex Immunofluorescence Automated Method for Clinical Trials
Jaime Rodriguez-Canales, MD, FEBP, Senior Pathologist, Translational Pathology Laboratory, MedImmune

1:50 Creating High-Quality Datasets for Biomarker Discovery Using Multiplex IF/IHC
Janis Taube, MD, MSc, Director, Division of Dermatopathology, Associate Professor of Dermatology, Johns Hopkins Medicine

We have developed a microscopic imaging pipeline, based upon an astronomy prototype, that allows us to generate high-quality maps of the tumor microenvironment. These maps will provide critical insights into mechanisms of cell-extrinsic immune modulation (how cell A modulates the function of cell B via proximity or direct cell-cell contact, thus informing how cancer evades the immune system during development) and identify rational combinatorial therapeutic strategies and potential new therapeutic targets.

2:15 Validation of Melanoma Immune Profile (MIP), a Prognostic Immune Gene Prediction Score for Stage II-III Melanoma
Yvonne Saenger, MD, Department of Medicine, Division of Hematology/Oncology, Director, Melanoma Immunotherapy, Columbia University Irving Medical Center

Biomarkers are needed to stratify patients with stage II-III melanoma for clinical trials of adjuvant therapy because, while immunotherapy is protective, it also confers the risk of severe toxicity. We previously defined and validated a 53-immune gene melanomaimmune profile (MIP) predictive both of distant metastatic recurrence and of disease-specific survival (DSS). Here, we test MIP on a third independent population.

EMERGING TECHNOLOGIES AND BIOMARKERS FOR CANCER IMMUNOTHERAPY, continued

2:40 Translational Advances of Multiplexed Immunofluorescence Methods

Clifford Hoyt, Vice President, Translational and Scientific Affairs, Akoya Biosciences, Inc.

I will discuss advances in multiplexed immunofluorescence (mIF) analysis of FFPE tissue sections, including imaging capabilities, reagents for automation, panel design for accurate image analysis, and image storage infrastructure for sharing and analysis of whole slide imagery. I will also discuss a multi-institutional demonstration of analytical performance and a meta-analysis of published studies suggesting expression and spatial information together correlate better with response to immunotherapy than other biomarker approaches.

3:05 NeoGenomics Knowledgebase Provides Pathways for Patient Management

Sponsored by NEO GENOMICS

Forrest J. Holmes Blocker, PhD, Director, Scientific Affairs, NeoGenomics

NeoGenomics connects unique, patient-specific identifiers such as tumor type, DNA mutation, and molecular pathway, with targeted therapy. Which will continue to evolve and improve to incorporate new algorithms and decisions metrics to aid in specialized research, improved diagnosis, as well as offering a more personalized approach to treatment of cancers.

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

CAR T CELL BIOMARKERS UPDATE

4:25 Chairperson's Remarks

Joseph Melenhorst, PhD, Adjunct Associate Professor, Pathology & Laboratory Medicine, University of Pennsylvania

4:30 The CAR T Cell Revolution

Joseph Melenhorst, PhD, Adjunct Associate Professor, Pathology & Laboratory Medicine, University of Pennsylvania

It has been almost a decade since we started treating leukemia patients with chimeric antigen receptor (CAR)-engineered T cells. General principles of efficacy and toxicities are starting to take shape. These principles have altered the way we design trails, but also engineer CAR T cells. During my talk I will provide examples of such findings and novel, yet unpublished findings shaping this rapidly evolving field.

5:00 TCR Biomarkers in Cancer Immunotherapy Development

Elizabeth Maloney, Senior Research Associate, NGS & Molecular Biology, Gritstone Oncology

Gritstone Oncology is a cancer immunotherapy company working to help patients with the most difficult-to-treat tumors. Gritstone's process leverages our EDGE AI platform to predict neoantigens that will be presented on a patient's tumor, creating a patient-specific immunotherapy that is designed to elicit a potent anti-tumor T cell response. Our team has developed a novel protocol for identifying these neoantigen-specific T cells to enable translational studies and characterize immunotherapy response.

5:30 Digital Counting of Target cfRNA and cfDNA with NanoString nCounter® Technology

Sponsored by nanoString

Adam Abdool, Senior Product Manager, Life Sciences, NanoString

Liquid (versus tissue) biopsy offers advantages for early disease diagnosis, progression monitoring and evaluation of therapeutic interventions because sample collection is rapid, easy, minimally invasive, and repeatable. However, detection has been difficult due to low abundance of target molecules, leading to complex workflows with highly variable signal detection. We'll demonstrate utilizing nCounter technology for liquid biopsy applications (Research Use Only), including mutation detection of ctDNA & RNA profiling, and fusion detection of cfRNA.

6:00 Wine & Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing

Sponsored by PILLAR BIOSCIENCES

7:00 Close of Day

WEDNESDAY, AUGUST 21

7:15 am Registration

7:30 Problem Solving Breakout Discussions with Continental Breakfast *(See website for details)*

NOVEL APPROACHES

8:25 Chairperson's Remarks

Ana I. Robles, PhD, Program Director, Office of Cancer Clinical Proteomics Research, Center for Strategic Scientific Initiatives, National Cancer Institute, National Institutes of Health

8:30 Precision Medicine Targeting the Homologous Recombination Repair Pathway

Matthew Marton, PhD, Director, Companion Diagnostics and Genomics, Merck & Co., Inc.

The therapeutic benefit of PARP inhibition in BRCA-mutated ovarian and breast cancer is well established. Recent data suggest this therapeutic benefit may extend to patients harboring other defects in the homologous recombination repair pathway. Multiple predictive biomarkers are being studied in clinical trials. We will describe different predictive biomarker assays for response to PARP inhibition, as well as the potential routes and challenges to their development into companion diagnostic tests.

9:00 Applications of Proteomics and Proteo-Genomics for Immuno-Oncology

Ana I. Robles, PhD, Program Director, Office of Cancer Clinical Proteomics Research, Center for Strategic Scientific Initiatives, National Cancer Institute, National Institutes of Health

Successful use of immune checkpoint blockade for the treatment of patients with previously intractable advanced cancers has led to widespread enthusiasm for therapeutic approaches that are immunomodulatory, but challenges remain. Proteomics can complement genomics for the development of biomarkers that predict which patients will most likely respond to immune-based therapy, and support informatic strategies that reveal which peptides translated from mutated sequences are promising neoantigens for use in immunotherapy protocols.

9:30 A New Approach to Personalizing Cancer Therapies

Clifford Reid, MBA, PhD, CEO, Travera

Travera has developed a multi-drug companion diagnostic that uses a phenotypic biomarker to match cancer drugs to cancer patients. It uses a breakthrough measurement tool invented at MIT that weighs single cells with sub-picogram accuracy. We will enable oncologists to order a next-day test that predicts the most effective therapies for their relapsed patients. We are also exploring its use to characterize fitness of T cells used in immunotherapies.

10:00 Breakthrough DNA Methylation Technology Enables Epigenetic Diagnostic Biomarker Discovery and Clinical Applications

Sponsored by GenPro

Adam Marsh, CSO, Genome Profiling LLC

GenPro's novel DNA methylation quantification and predictive modeling provides efficient and direct utilization of these biomarkers (EpiMarkers) to assess underlying mechanisms and indications of disease phenotypes and drug responsiveness. Our technology provides sensitive tools with unparalleled statistical power to identify epigenetic changes and translate those EpiMarkers into cost-effective clinical assays.

10:15 Leveraging Real-World Data for Selection of Biomarkers with High Clinical Utility for Development of Precision CDx

Sponsored by QIAGEN

Sean Scott, VP, Business Development, QIAGEN

With so many considerations that go into translational medicine for precision oncology drugs, it is vital that the right biomarker targets and the right patient population are identified. Constructing the specific list of mutations to be used in a Companion Diagnostic assay is complex, as the success of the project depends on maximizing the proportion of patients in the trial who are sensitive to the drug, while capturing as large a number of patients as possible for the trial.

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:30 Plenary Keynote Session

Please click here for details

1:05 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:35 End of Emerging Technologies & Biomarkers for Cancer Immunotherapy conference

Companion Diagnostics and Clinical Biomarkers in Immuno-Oncology

PREDICTING AND MONITORING RESPONSE TO CANCER IMMUNOTHERAPY

WEDNESDAY, AUGUST 21

10:30 am Registration

11:30 Plenary Keynote Session
Please click here for details

1:05 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:35 Ice Cream & Cookie Break in the Exhibit Hall with Poster Viewing

BIOMARKERS IN THE CONTEXT OF IMMUNO-ONCOLOGY COMBINATIONS

2:05 Chairperson's Opening Remarks
Kenneth Emancipator, MD, DABP, Executive Medical Director, Companion Diagnostics, Translational Medicine, Merck & Co., Inc.

2:10 Biomarkers in the Context of IO Combinations
J.D. Alvarez, MD, PhD, Vice President, Oncology Diagnostics, Janssen Pharmaceutical Companies

Will current assays be combined or completely superseded? Are standard clinical biomarkers being overlooked in IO trials? What is the current utility and future potential of blood-based biomarkers? How can NGS panels data be used to improve target discovery and/or combo prioritization? These and other important issues will be addressed in this presentation. Harmonization of multiple assays for the similar biomarker(s) will be discussed as well.

2:40 TMB as a Clinical Biomarker in Combination Trials
Rajiv Raja, PhD, Director, Translational Medicine Oncology and Pharmacogenomics, AstraZeneca

3:10 PD-L1 as a Companion Diagnostic for Tumors Beyond Non-Small Cell Lung Cancer: It's the Same Thing, Only Different
Kenneth Emancipator, MD, DABP, Executive Medical Director, Companion Diagnostics, Translational Medicine, Merck & Co., Inc.

The PD-L1 companion diagnostic had a huge impact on the clinical development of pembrolizumab, making it the first immunotherapy approved as a first-line agent for non-small cell lung cancer. However, this is just the beginning of the story, not the end. Adapting the PD-L1 diagnostic to incorporate immune cell expression facilitated approval of pembrolizumab for several additional indications and may shed light on the mechanism of action of checkpoint inhibitors.

3:40 How Biospecimen Sourcing Can Impact Your R&D
Sponsored by TRANS-HIT BIO
Vanessa Tumilasci, PhD, Commercial Director, Trans-Hit Biomarkers

Biospecimen sourcing is becoming a challenge for many scientists who need to respect timelines for R&D plans as well as regulatory and ethical constraints. Are the scientists working with the samples aware of all the imperatives to obtain them; quality, respect of laws, ethics and regulations?

3:55 Sponsored Presentation *(Opportunity Available)*

4:10 Refreshment Break in the Exhibit Hall with Poster Viewing

NEW BIOMARKERS AND NOVEL CLINICAL STRATEGIES

4:55 Chairperson's Remarks
Nicholas Dracopoli, PhD, CSO, DELFI Diagnostics

5:00 Immuno-Oncology Biomarkers: What's New?
Nancy Zhang, MD, Associate Director, Pharmacodiagnostics, Bristol Myers Squibb

Precision medicine continues to transform treatment paradigms through development of new biomarkers and interpretation of clinical data. Testing for Immuno-Oncology biomarkers, such as PD-L1, and emerging ones, such as tumor mutational burden, may help optimize treatment decisions when assessed individually or in combination. The advancement of increasingly complex biomarkers also brings a need for advanced diagnostic tools. We will discuss biomarkers, their dynamic monitoring, and assessment in the evolving field of pharmacodiagnostics.

5:30 Companion Diagnostics in Immuno-Oncology
Anand Pathak, MD, PhD, MPH, Medical Officer, FDA

This session will focus on the implementation of immuno-oncology diagnostic tests in clinical trials, including understanding the regulatory implications of different approaches, validation of emerging pan-tumor CDx claims, and complementary diagnostics vs. companion diagnostics.

6:00 PANEL DISCUSSION: Companion Diagnostics in Immuno-Oncology
Moderator: Nicholas Dracopoli, PhD, CSO, DELFI Diagnostics
Panelists: Speakers of the Day

Topics to be discussed:
- Advantages and disadvantages of complex multianalyte panels versus simple single analyte Dx tests
- Issues in developing CDx tests for drugs being launched in different countries
- Tumor mutation burden (TMB) and other very large panel tests
- Advantages and disadvantages of plasma based ctDNA testing compared to tissue-based tests
- Emergence of new CDx tests for immuno-oncology drugs

6:30 Close of Day

6:30 Dinner Short Course Registration

6:45 - 9:15 pm RECOMMENDED DINNER SHORT COURSE*
SC8: Generating Evidence and Creating Winning Dossier for Regulatory and Reimbursement Needs
**Separate registration required, click here for details*

THURSDAY, AUGUST 22

7:15 am Registration

7:30 Problem Solving Breakout Discussions with Continental Breakfast *(See website for details)*

BEYOND IO

8:25 Chairperson's Remarks
Mitch Raponi, PhD, Vice President, Biomarkers & Translational Research, BeiGene

8:30 Silver Linings: Embracing the Positive and Negative in Predictive Biomarker Development
Jamie Shaw, Principal Scientist, Clinical Biomarkers and Diagnostics at EMD Serono, Inc.

Despite development of countless drugs targeting the PI3K/Akt/mTOR pathway in cancer, no biomarkers have been validated to identify patients likely to benefit from these therapies. This

COMPANION DIAGNOSTICS AND CLINICAL BIOMARKERS IN IMMUNO-ONCOLOGY, continued

presentation will review findings from the PhI trial of M2698, a p70S6K/AKT inhibitor, which suggest that tumor resistance markers could identify a patient population benefitting from treatment and illustrates how implementing a combination of positive and negative selection markers may increase robustness and predictivity.

9:00 PARPi Development in Prostate Cancer: Limitations and Opportunities for Companion Diagnostic Development

Mitch Raponi, PhD, Vice President, Biomarkers & Translational Research, BeiGene

PARP inhibitors have demonstrated clinical utility in treating metastatic prostate cancer due to enrichment of DNA repair deficiencies in a subset of these tumors. NGS testing of tumor tissue to identify patients with BRCA defects or other homologous recombination repair deficiencies has limited utility due to limited amount of tumor isolated from bone biopsies. Opportunities of developing liquid biopsy-based companion diagnostics for this disease will be discussed.

9:30 Streamlined CDx™ - A Proven Strategy to Accelerate Drug Approvals

Sponsored by invivoscribe

Jeffrey Miller, PhD, Founder, CSO, CEO, & Chairman, Invivoscribe

Companion Diagnostics have revolutionized precision medicine as they play a pivotal role in defining the efficacy of targeted therapies. Invivoscribe's Streamlined CDx™ program has been shown to collapse development timelines, improve and accelerate selection of patient cohorts, leading to earlier submissions and accelerated FDA, EMA and PMDA approvals of new targeted therapies. Streamlined CDx™ partnership model has proven successful in approval of the first ever AML companion diagnostic – The LeukoStrat® CDx FLT3 Mutation Assay.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

CAR T CELL AND VACCINE STRATEGIES

11:00 Chairperson's Remarks

Iulian Pruteanu-Malinici, Investigator III, Lab Head, Immuno-Oncology, Novartis

11:05 Personalizing Immunotherapy for Each Cancer Patient

Roman Yelensky, MD, Executive Vice President and CTO, Sequencing and Bioinformatics, Gritstone Oncology

Gritstone Oncology is a cancer immunotherapy company working to help patients with the most difficult-to-treat tumors. Gritstone's personalized immunotherapy process leverages our EDGE AI platform to predict neoantigens that will be presented on a patient's tumor, allowing us to create a patient-specific heterologous prime-boost immunotherapy that is designed to elicit a potent anti-tumor T cell response.

11:35 Correlative and Release Test Assays for Evaluating Gene Edited Human Cell Products

Simon Lacey, PhD, Director, Translational and Correlative Studies Laboratory, Center for Cellular Immunotherapies, University of Pennsylvania

Gene editing techniques such as CRISPR/Cas9 hold potential for augmentation of CAR-T and TCR engineered cell products to be used in human clinical trials. The FDA requires additional evaluations of such gene edited and engineered cells prior to, and post infusion. This presentation will discuss the development and validation of correlative and release test assays to evaluate efficiency of transduction, gene editing and other aspects of engineered and edited cells.

12:05 pm Modeling Flow High-Dimensional Data and Biomarker Identification in a CART/Multiple Myeloma Study

Iulian Pruteanu-Malinici, Investigator III, Lab Head, Immuno-Oncology, Novartis

Here we present a Flow Cytometry based framework that, when combined with state-of-the-art bioinformatics, enables for the discovery of biomarkers that predict clinical response of CART therapeutic products.

12:35 Sponsored Presentation *(Opportunity Available)*

1:05 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:35 Dessert Break in the Exhibit Hall with Poster Viewing

COMBINATION TRIALS AND RWD

2:15 Chairperson's Remarks

Kathryn Lang, MBBS, MRCP, Vice President, Outcomes and Evidence, Guardant Health

2:20 TLR Agonist NKTR-262 Immunotherapy Combination with Bempegaldesleukin (NKTR-214) Harnessing Innate and Adaptive Immune System for the Treatment of Solid Tumors

Saul Kivimäe, PhD, Head of Pharmacology, Nektar Therapeutics

NKTR-262 is a novel TLR agonist therapeutic designed to deliver intratumoral TLR7/8 engagement and is currently evaluated in Phase 1 dose escalation study with bempegaldesleukin, a CD122-preferential IL-2 pathway agonist. NKTR-262 combination treatment with bempegaldesleukin is designed to provide a synergistic effect of localized intratumoral innate immune stimulation with systemic sustained T cell activation for comprehensive anti-tumor immune activation mimicking a natural immune response.

2:50 Integrating Clinical Research and Care in a Perpetual Trial to Continuously Learn From All Patients, on All Treatments, All the Time

Mika Newton, BSc, CEO, xCures

The explosion of molecular subtypes and oncology drugs means R&D is about to hit a wall. There are not enough patients to explore all the potential options. A Perpetual Trial provides patients and their physicians with individualized treatment options. RWD is generated longitudinally to learn what works in which patients, and coordinate treatment prioritizing the most promising therapies. This RWE is used to accelerate regulatory approvals, label expansions, and reimbursement.

3:20 How Can Real-World Data Enhance Clinical Evidence Generation?

Margaret McCusker, MD, Senior Medical Director, Flatiron Health

As the cancer treatment landscape becomes increasingly complex, biomarkers are playing a more prominent role in drug development and clinical decision support. In this setting, research-quality clinical evidence derived from cancer patients' electronic health records and paired genomic data are a valuable asset. This session will highlight examples of how clinico-genomic data can provide critical insights into the impact of biomarkers on real-world oncology practice and accelerate clinical research.

3:50 Establishing the Next Generation of Clinico-Genomic Data in Oncology and Healthcare

Kathryn Lang, MBBS, MRCP, Vice President, Outcomes and Evidence, Guardant Health

The emergence of real-world clinico-genomic data promises great value for all aspects of the healthcare system. How do organizations and individuals combine efforts to support all aspects of care and treatment?

4:20 End of Summit

Business Stream

The diagnostics industry has a critical role in medicine, especially in today's world of personalized medicine. Numerous new technologies in development stand to revolutionize the diagnostics world. Realizing this is an area that is ripe for disruption, this year's CHI Business stream at the Next Generation Dx Summit will foster development and collaboration among technology developers, pharmaceutical executives, payers and investors. Our 11th Annual Next Generation Dx Summit will bring together translational scientists, clinicians, business experts, public and private payers, regulators and investors to discuss and solve the critical challenge of market access strategies, partnering, commercialization, coverage and reimbursement for diagnostic technologies.

2019 BUSINESS CONFERENCES

AUGUST 20-21

AGENDA **Coverage and Reimbursement for Advanced Diagnostics**

AUGUST 21-22

AGENDA **Commercialization of Diagnostic Tests**

CONFERENCE STREAMS

- POCT & INFECTIOUS DISEASE
- LIQUID BIOPSY
- IMMUNO-ONCOLOGY
- BUSINESS
- COMPANION DIAGNOSTICS
- DIGITAL PATHOLOGY AND AI
- POC SPECIAL FORUMS

Coverage and Reimbursement for Advanced Diagnostics

LATEST DEVELOPMENTS IN THE DX REIMBURSEMENT LANDSCAPE

TUESDAY, AUGUST 20

7:30 am Registration and Morning Coffee

CMS, PALMETTO AND LAB BENEFIT MANAGERS

8:30 Chairperson's Opening Remarks

John Warren, Senior Director, Health Policy, McdermottPlus Consulting LLC

8:40 Updates Implementing Diagnostics Decisions at CMS

Katherine B. Szarama, PhD, Presidential Management Fellow, CMS

The Centers for Medicare & Medicaid Services (CMS) took action to advance innovative personalized medicine for Medicare patients with cancer when finalizing a National Coverage Determination (NCD) that covers diagnostic laboratory tests using Next Generation Sequencing (NGS) for patients with advanced cancer. This presentation will provide updates along the implementation timeline of the NCD and share any identified process improvement opportunities discovered by the Agency.

9:10 Moldx: Coverage, Policy, and Updates

Gabriel A. Bien-Willner, MD, PhD, Medical Director, Moldx, Palmetto Gba

This presentation will provide an overview of recent coverage decisions and the implications they may have for the future CMS decision seekers.

9:40 Working with Laboratory Benefit Managers: Tips & Best Practices

Mitchell Burken, MD, Associate Medical Director, Genetics, eviCore

Whether you're in the early stages of working with Laboratory Benefit Managers (LBMs) or have more experience, understanding how to best work with LBMs is essential for reimbursement professionals. The goal is to best attempt to achieve a mutual understanding of what evidentiary thresholds are necessary to support reimbursement for their laboratory tests. Diagnostic professionals should aim to present emerging lab testing technology in a clear, concise manner that directly makes the case for clinical utility. This is a critical lever for successful reimbursement. These and other related main points will be covered in this presentation, under the planned umbrella that outlines the particular strategy of one major LBM, eviCore Healthcare.

10:10 Coffee Break in the Exhibit Hall with Poster Viewing

10:55 Chairperson's Remarks

Bruce Quinn, MD, PhD, Principal, Bruce Quinn Associates

11:00 PANEL DISCUSSION: PAMA Update and NCDs Implementation Conundrum

While the rapid evolution of clinical genomic technologies speeds ahead, federal policies are also evolving at a rapid place, both at CMS and on the Hill. While the lab industry works to adjust to and absorb these federal changes, commercial payers often adapt and change in response to federal payment policies. This panel will provide a lively, frank, sometimes controversial, and fully up-to-date review of what's happened in 2019 so far and what to expect next.

Panelists: Bruce Quinn, MD, PhD, Principal, Bruce Quinn Associates

Brian Carey, JD, Partner, Co-Chair, Administrative Law Department, Foley Hoag LLP

Jennifer R. Leib, ScM, CGC, Founder, Innovation Policy Solutions, LLCJohn Warren, Senior Director, Health Policy, McdermottPlus Consulting LLC

12:00 pm Incorporating Market Access into the Product Development Process

Sponsored by BOSTON HEALTHCARE ASSOCIATES

Mark Girardi, Vice President, Boston Healthcare Associates Inc.

In this presentation, Mark Girardi, Vice President of Boston Healthcare, will discuss the product development process and Market Access considerations and challenges, including real-world examples to demonstrate the importance of Market Access in the business decision-making process.

12:15 How to Proactively Combat Downward Reimbursement Pressure

Sponsored by TELCOR

Patti Karabe, Account Executive, Telcor

Laboratories are feeling the negative impact from regulatory changes. With reimbursement obstacles, laboratories need to take a hard look at ways to improve profitability and offset these downward pressures. During this session, learn how other laboratories are successfully re-engineering processes to positively impact profitability and how your laboratory can benefit.

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:00 Cookie & Refreshment in the Exhibit Hall with Poster Viewing

CASE STUDIES AND OPINIONS

1:25 Chairperson's Remarks

Laura T. Housman, MPH, MBA, Head, Access, Outcomes and Population Health, Exact Sciences; Founder, Access Solutions Consulting

1:30 NCDs, LCDs, and Next-Generation Sequencing: The Commercial Lab Perspective

Jim Almas, MD, Vice President and National Medical Director for Clinical Effectiveness, LabCorp

In March 2018, CMS issued a national coverage decision on the use of next generation sequencing tests for patients with cancer. In place of coverage with evidence development, the Medicare Administrative Contractors (MACs) were allowed (under the NCD) to grant coverage for tests not covered by the NCD. The restrictions of that coverage have emerged and its effect on the operation of commercial clinical labs will be discussed.

1:50 The Quest to Win Coverage for Liquid Biopsy: From Gate Keeper to Bridge Builder

Mark D. Hiatt, MD, MBA, MS, Vice President, Medical Affairs, Guardant Health

Convincing payers of the medical necessity of a new diagnostic test can be challenging. A three-pronged approach can help with this otherwise formidable effort through enlisting support from the three "P's" of persuasion: (1) third-party review organizations, (2) positive coverage from other plans, and (3) peer-reviewed publications. These three tactics will be explored in the real-world context of actual successful advocacy for a liquid biopsy test.

2:10 Expanding Health Access to Screening Testing through Population Health

Laura T. Housman, MPH, MBA, Head, Access, Outcomes and Population Health, Exact Sciences; Founder, Access Solutions Consulting

According to the Kaiser Family Foundation, employer-sponsored health insurance plans cover more than half of the country's non-elderly population and nearly 80% offer wellness programs, yet screening testing for colorectal cancer and other diseases that benefit from early detection is underutilized. Can population health programmatic approaches make an impact to access and adoption for these organizations? How can barriers due to reimbursement challenges be overcome?

COVERAGE AND REIMBURSEMENT FOR ADVANCED DIAGNOSTICS, continued

2:30 CO-PRESENTATION: Next-Generation Diagnostics as an Information Network: Addressing Evidence Gaps Through Real-World Data Integration

Kaushal Desai, PhD, Director, Informatics & Outcomes Research, Merck & Co., Inc.

Robert Metcalf, MBA, CEO, Concert Genetics

As the US healthcare ecosystem transitions to value-based care models, advanced diagnostic technologies can only be evaluated based on evidence generated from high-quality real-world testing and outcomes data currently siloed across diverse stakeholders. This talk will review the information needs of three critical stakeholders in diagnostics-- providers that order, laboratories that render, and payers that reimburse—and discuss how point solutions can simultaneously connect the genetic health information network.

2:50 Reimbursement of POCT

Ester Stein, MBA, Director, Corporate Reimbursement, Government Affairs, Abbott Laboratories

This talk will discuss reimbursement challenges for point-of-care testing and what role point-of-care testing plays in a value-based payment system.

3:10 Wearables – RWE to Support Coverage and Reimbursement of Diagnostics

Sponsored by Analysis Group

Anita Chawla, PhD, Managing Principal, Analysis Group

Real-world evidence (RWE) is increasingly developed to support both regulatory and reimbursement decisions for new health technologies. Wearable sensors that collect RWE can help diagnostic manufacturers demonstrate the utility and value of their diagnostic tests. This presentation will review recent examples of wearable data capture to generate evidence supporting coverage and reimbursement of diagnostics, considering how wearable technology is used today, and may be used in the future.

3:40 Refreshment Break in the Exhibit Hall with Poster Viewing

HOT BUTTON ISSUES IN DX REIMBURSEMENT

4:25 Chairperson's Remarks

Patrick Terry, CEO, Gray Group Ventures

4:30 PANEL DISCUSSION: Expanded Carrier Screening: Adoption, Market Access, and Collaboration

Expanded Carrier Screening (ECS) assesses couples for 15+ serious genetic diseases for family planning and empowers them with actionable information that can improve outcomes and quality of life. A significant percentage of physicians choose ECS over traditional ethnic-specific carrier testing, but payers struggle to cover this new approach despite its endorsement by the relevant professional Colleges. This results in inequality of care across diverse patient populations. A coalition has been formed to address this issue.

Topics to be Discussed:

- Clinical utility of expanded carrier screening (ethnicity-based screening has reduced effectiveness compared with pan-ethnic approach, using NGS)
- Motivations behind the formation of an ECS coalition (Access to Expanded Carrier Screening)
- What are OB/GYNs ordering, and how does this align with current guidelines?

Moderator:
Robert Dumanois, Manager, Reimbursement Strategy, Thermo Fisher Scientific
Panelists:
Jim Goldberg, MD, Chief Medical Officer, Myriad Women's Health
Lee P. Shulman, MD, Anna Lapham Professor of Obstetrics and Gynecology, Feinberg School of Medicine, Northwestern University
Kimberly Martin, MD, Chief Clinical Advisor, Women's Health, Natera, Inc.

5:00 PANEL DISCUSSION: Hot Button Issue in Dx Reimbursement

Moderators:
Danielle Scelfo, Senior Director, Health Policy and Reimbursement, Hologic, Inc.
Ester Stein, MBA, Director, Corporate Reimbursement, Government Affairs, Abbott Laboratories
Panelists:
Jim Almas, MD, Vice President and National Medical Director for Clinical Effectiveness, LabCorp
Chandra Branham, JD, Vice President, Payment and Health Care Delivery Policy, AdvaMed
Tara Burke, PhD, Senior Director, Public Policy and Advocacy, Association for Molecular Pathology
Melina Cimler, PhD, CEO & Founder, PandiaDx
Danielle Scelfo, Senior Director, Health Policy and Reimbursement, Hologic, Inc.

6:00 Wine & Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing

Sponsored by Pillar Biosciences

7:00 Close of Day

WEDNESDAY, AUGUST 21

7:15 am Registration

7:30 Problem Solving Breakout Discussions with Continental Breakfast (See website for details)

ASSURING ACCESS TO PERSONALIZED MEDICINE: REIMBURSEMENT STRATEGIES FOR ADVANCED DIAGNOSTICS AND NOVEL THERAPIES

8:25 Chairperson's Remarks

Daryl Pritchard, PhD, Senior Vice President, Science Policy, Personalized Medicine Coalition

8:30 Influence of Genomic Tests on Decision Pathways for Reimbursement Practices for Oncological Therapeutics

Eugean Jiwanmall, MPH, MBA, Senior Research Analyst, Technology Evaluation & Medical Policy, Claim Payment Policy Department, Facilitated Health Networks, Independence Blue Cross

Achievement of optimal clinical care must be driven by multiple objective factors. Understanding and establishing the confidence in these contributing factors are essential due to their impacts on any proposed net improvement in relevant health outcomes. Development, advancement, integration, and routine clinical usage of options in oncological therapeutics are closely tied to availability, reliability, and acceptance of certain aspects of genomics. We will explore the impact of different facets of genetic testing on multiple phases of oncological therapeutics, and payment considerations based on these relationships.

8:45 Humana's Perspective on Personalized Medicine

Kristine Bordenave, MD, FACP, Corporate Medical Director, NMCARE, Healthcare Services, Humana

9:30 PANEL DISCUSSION: Funding Common Ground with Payers and Policy Makers to Advance Personalized Medicine in Oncology and Beyond

While emerging personalized medicine technologies and platforms have the potential to make drug development more economical and make health systems more efficient by targeting treatments to only those who will benefit, they are also challenging reimbursement systems accustomed to one-size-fits-all medicine. Indeed, personalized medicine has led payers to think differently about coverage and reimbursement of high-value diagnostics and novel cell-based and genetic therapies that have the potential to cure diseases with one or only a few treatments. The approval of tissue-agnostic drugs such as Keytruda and Vitrakvi, for example, will force payers to figure out policies for pan-cancer

COVERAGE AND REIMBURSEMENT FOR ADVANCED DIAGNOSTICS, continued

indications and associated genetic testing, while the approval of cellular-based CAR-T therapies and gene therapies such as Luxturna, Kymriah, and Yescarta are challenging the traditional way that high-cost therapeutics can be reimbursed.

Moderator:
Daryl Pritchard, PhD, Senior Vice President, Science Policy, Personalized Medicine Coalition

Panelists:
Kristine Bordenave, MD, FACP, Corporate Medical Director, NMCARE, Healthcare Services, Humana
Eugean Jiwanmall, MPH, MBA, Senior Research Analyst, Technology Evaluation & Medical Policy, Claim Payment Policy Department, Facilitated Health Networks, Independence Blue Cross
Katherine B. Szarama, PhD, Presidential Management Fellow, CMS
Shuvayu S. Sen, PhD, Executive Director, CORE Oncology, Merck & Co., Inc.
Stella Stergiopoulos, Associate Director, Health Economic Outcomes Research and Payer Policy, Foundation Medicine, Inc.
Robert Dumanois, Manager, Reimbursement Strategy, Thermo Fisher Scientific

Topics to be discussed:

- What are the key reimbursement challenges for advanced diagnostic tests?
- What strategies are emerging for the coverage and reimbursement of cell-based and genetic therapies?
- What evidence is necessary to demonstrate the value of personalized medicine technologies to payers and providers?
- How can practice-based evidence be developed in an environment of limited reimbursement and reduced access?

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:30 Plenary Keynote Session
*Please **click here** for details*

1:05 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:35 End of Coverage & Reimbursement for Advanced Diagnostics

Commercialization of Diagnostic Tests

CURRENT LANDSCAPE AND SUCCESSFUL STRATEGIES

WEDNESDAY, AUGUST 21

10:30 am Registration

11:30 Plenary Keynote Session
Please click here for details

1:05 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:35 Ice Cream & Cookie Break in the Exhibit Hall with Poster Viewing

REGULATION OF DX: WHERE DO WE GO FROM HERE?

2:05 Chairperson's Opening Remarks
Roger D. Klein, MD, JD, Faculty Fellow, Center for Law Science and Innovation, Sandra Day O' Connor Law School, Arizona State University; Expert, FDA & Health Working Group Federalist Society Regulatory Transparency Project

2:10 DTC/Patient Initiated Genetic Testing – Regulatory Landscape
Sheila D. Walcoff, J.D., CEO, Founder, Goldbug Strategies LLC
In the emerging area of DTC/patient initiated genetic testing, Goldbug Strategies has been the external FDA regulatory counsel for 23andMe since January 2014, when the company's founder asked Sheila to lead its regulatory compliance, FDA interactions, risk mitigation, and pre-market submission work. Goldbug Strategies helped 23andMe design, develop and implement a highly successful approach to positive FDA interactions, compliance strategies, and numerous successful *de novo* submissions. The "first-of-a-kind" device authorizations granted by FDA as a result of these efforts have helped return 23andMe to its market leadership position as the only DTC/patient initiated genetic testing service authorized by the FDA.

2:40 PANEL DISCUSSION: Regulation and Policy for Diagnostic Tests – Enhancing or Restricting the Innovation and Progress In Diagnostics?
Moderator: Roger D. Klein, MD, JD, Faculty Fellow, Center for Law Science and Innovation, Sandra Day O' Connor Law School, Arizona State University; Expert, FDA & Health Working Group Federalist Society Regulatory Transparency Project
Panelists: Alberto Gutierrez, PhD, Partner, NDA Partners
Eric Konnick, MD, MS, Assistant Professor; Associate Director, Genetics and Solid Tumors Laboratory, University of Washington
Brad Spring, VP, Regulatory Affairs & Diagnostic Systems, BD Diagnostics
Additional Panelists to be Announced

- Differences between *in vitro* diagnostic test kits and laboratory developed tests and the needs of their respective customers
- Current legislative proposals that would revamp FDA's current regulatory paradigm for regulation of *in vitro* diagnostic tests
- Potential ways to modernize to CLIA to meet perceived regulatory gaps
- FDA approaches in the face of Trump-era regulatory philosophy
- The role of Medicare and its contractors as regulators through payment pathways and processes
- Regulatory approaches to test regulation in Europe

3:40 Is Your IVD Software Prepared for the New IVD Regulations Coming in 2022
Sponsored by SoftwareCyber 510(k) When Life Depends on Software™
Nancy Knettell, Founder, Principle, SoftwareCyber510K, LLC
In vitro diagnostic (IVD) medical device Software, whether standalone or on a device, will now face a higher level of Regulatory Compliance based on the new IVD Regulations (IVDR) coming in May 2022. Any IVD Companies interested in commercializing their IVD Software will also now require FDA 510K Clearance to be able to sell their products. Learn what is required to successfully support the IVDR standard/510k regulatory requirements by ensuring IEC62304 Compliance with software.

4:10 Refreshment Break in the Exhibit Hall with Poster Viewing

FEATURED INTERACTIVE SESSION: A BUSINESS CASE STUDY ON GENOMIC HEALTH

4:55 Chairperson's Remarks
Roger D. Klein, MD, JD, Faculty Fellow, Center for Law Science and Innovation, Sandra Day O' Connor Law School, Arizona State University; Expert, FDA & Health Working Group Federalist Society Regulatory Transparency Project

5:00 Genomic Health: Launching a Paradigm Shift ... and an Innovative New Test
Joshua Krieger, PhD, Assistant Professor, Entrepreneurial Management Unit, Harvard Business School
A business case study on "Genomic Health" will be presented. This case explores the decisions the Genomic Health team had to make in defining the marketing plan, pricing, and reimbursement strategies that would give it the greatest chance of success in bringing its new product to market. This is an interactive session and the case material will be provided beforehand with a question list to be discussed during this session.

Learning Objective
To introduce market dynamics within the diagnostics segment of the medical devices industry, including issues related to traditional and emerging diagnostics business models, product development, government regulation and reimbursement; to understand of how advancements in genomics impact the traditional diagnostics market and their potential effects on payers, patients, physicians, and the larger health care system; and to introduce the constraints, opportunities, and trade-offs associated with launching an innovative product that also represents a paradigm shift within the traditional diagnostics industry.

Questions to be Discussed
1. How does Oncotype DX create value?
2. What determines the price that Genomic Health can charge for the diagnostic? Who influences the pricing decision? Ultimately, what should they charge?

6:30 Close of Day

6:30 Dinner Short Course Registration

6:45 - 9:15 pm RECOMMENDED DINNER SHORT COURSE*
SC8: Generating Evidence and Creating Winning Dossier for Regulatory and Reimbursement Needs
**Separate registration required, click here for details*

COMMERCIALIZATION OF DIAGNOSTIC TESTS, continued

THURSDAY, AUGUST 22

7:15 am Registration

7:30 Problem Solving Breakout Discussions with Continental Breakfast *(See website for details)*

SUCCESSFUL COMMERCIALIZATION STRATEGIES: MARKET ACCESS AND PRODUCT LAUNCH

8:25 Chairperson's Remarks
Larry K. Wray, PhD, Wray IVD Consulting

8:30 Bringing Single-Cell Genomics to the Clinic
Charlie Silver, Co-Founder, CEO, Mission Bio

Mission Bio provides targeted single-cell DNA solutions for high-impact applications, including oncology and CRISPR validation. Our technology helps cancer centers and drug companies identify every diseased cell so they can deliver durable treatments. Our journey from university spin-out through launch and scale-up will be discussed.

8:50 Real-time *in vitro* Diagnostic Results at the Point-of-Care
Cary Gunn, PhD, Founder, CEO, Genalyte

The Maverick Detection System performs real-time detection of macromolecules in crude samples using biologically functionalized silicon photonic biosensors lithographically printed on disposable silicon chips. Test results are available in 10-30 minutes depending on the type of assay performed. Our story of how we get to where we are will be discussed.

9:10 Commercializing Guardant360, The Industry Leading Liquid Biopsy
Nnamdi Ihuegbu, PhD, Director, BioPharma Business Development, Guardant Health

Commercializing a complex diagnostic while developing a new market requires a multi-pronged and multi-year approach. Changing MD behavior requires clinical utility data, KOL endorsement, clinical guideline support, clarity around patient financial burden and reimbursement, a product that fits into practice, as well as traditional field force pull through. There are no shortcuts.

9:30 The Development and Commercialization of Companion Diagnostic (Cdx) Tests for Targeted Oncology and Immuno-Oncology Therapeutics
Lucas Dennis, PhD, Director Clinical Product Development, Foundation Medicine Inc.

Through continued innovation, Foundation Medicine is dedicated to improving outcomes for individuals living with cancer. Our approach combines genomic profiling products and data services to generate insights that can help doctors match patients to treatment options, as well as accelerates the development of new therapies. Our story will be discussed.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 PANEL DISCUSSION: Product Launch and Market Entry Approaches
Moderator: Larry K. Wray, PhD, Wray IVD Consulting
Panelists: All Speakers in the Session

- Current stand on bringing your technology to market
- How to develop your go-to-market strategy?
- What role did reimbursement play in your strategy and how did you address that?
- What were/are the major challenges incorporating your technology into healthcare and how did or are you addressing those? Are you planning on having your products incorporated into guidelines?
- How are regulatory requirements addressed as part of the marketing plan?
- What role are KOLs and/or institutions playing as you bring your technology to market?

11:50 PANEL DISCUSSION: From the Lab to the Market-Translating Early Stage Innovation and Successful Partnership Strategies
Moderator: Albine Martin, PhD, Executive in Residence, Johns Hopkin University
Panelists: Henry Ahn, Program Director, SBIR/STTR, Industrial Innovation and Partnerships, Directorate for Engineering, National Science Foundation (NSF)
Yukari C. Manabe, MD, Professor of Medicine, Infectious Diseases, Medicine, Johns Hopkins University School of Medicine

- Key considerations for developing an early translational roadmap and Angel Investment criteria
- Funding opportunities and business plan requirements
- Attracting early strategic partners

1:05 Luncheon Presentation: Commercialization of an IVD in a Changing Global Environment
Sponsored by MilliporeSigma
Lynn Stephenson, PhD, Marketing Manager, Dx Manufacturing & OEM, MilliporeSigma

Changes in international standards and regulations have created challenges and roadblocks to the commercialization of diagnostic devices. The choice of a contract manufacturing (CM) partner with the expertise to provide guidance and manufacturing capabilities is one strategy diagnostics companies can use to mitigate risk. A well-chosen CM partner can accelerate the commercialization process by anticipating potential roadblocks. In this session, we will discuss best practices and key considerations for vetting contract manufacturing partners.

1:35 Dessert Break in the Exhibit Hall with Poster Viewing

2:15 Chairperson's Remarks
Aldo Carrascoso, PhD, CEO, InterVenn

2:20 How Diagnostic Tests are Being Evaluated and Adopted at the Minute Clinic
Alexander Sbordone, JD, OTR/L, Senior Advisor, Operations, MinuteClinic, CVS Health

I will discuss the process and cycle that CVS MinuteClinic uses to evaluate new diagnostic tests. Criteria for efficiency, sensitivity, accuracy, robustness and cost will be reviewed.

2:50 Lessons Learned from Raising Capital for Diagnostic Start-Ups
Aldo Carrascoso, PhD, CEO, InterVenn

Venture capitalists have tended to shy away from diagnostics companies, whose products are not predicated on the blockbuster model of pharmaceuticals. However, several new diagnostics companies are developing products that can improve healthcare delivery. It is in the start-ups' hands to change this mindset and prove its added value to advance the standard of care. Lessons learned from raising capital for Dx start-ups will be discussed.

COMMERCIALIZATION AND VALIDATION OF NGS DIAGNOSTICS

3:20 PANEL DISCUSSION: COMMERCIALIZATION AND VALIDATION OF NGS DIAGNOSTICS
Moderator: Heike Sichtig, PhD, Principal Investigator and Team Lead, Microbiology Devices, Center for Devices (CDRH), FDA
Panelists: Charles Chiu, MD, PhD, Associate Professor, Laboratory Medicine and Medicine/Infectious Diseases, Director, UCSF-Abbott Viral Diagnostics and Discovery Center, Associate Director, UCSF Clinical Microbiology Laboratory, UCSF School of Medicine
Additional Panelists to be Announced

- FDA submission guidelines and strategies
- Comparative methods
- Lab validation
- Commercialization strategies

4:20 End of Summit

Companion Diagnostics Stream

Clinical biomarkers and companion diagnostics play pivotal roles in clinical development and market access of new therapeutics as well as deliver significant patient benefits, healthcare cost savings, and revenue opportunities. Pharmaceutical companies are embracing biomarkers as a way to decrease drug failures in the clinic by streamlining patient selection and stratification. These trends emphasize the need for open discussion between pharma and diagnostics partners to find common ground, address strategy and technology issues, and form strong mutually beneficial and sustainable partnerships. The main area of application of clinical biomarkers is oncology and immuno-oncology where treatment success is highly dependent on the choice of a specific patient population. Therefore, adoption of cancer immunotherapy requires development and implementation of robust clinical-grade biomarkers. Companion Diagnostics stream is designed to bring together major stakeholders in the field of drug-diagnostic co-development to foster winning science and business strategies.

2019 COMPANION DISGNOSTICS CONFERENCES

AUGUST 20-21

AGENDA **Companion Diagnostics: Strategy and Partnerships**

AUGUST 21-22

AGENDA **Companion Diagnostics and Clinical Biomarkers in Immuno-Oncology**

CONFERENCE STREAMS

- POCT & INFECTIOUS DISEASE
- LIQUID BIOPSY
- IMMUNO-ONCOLOGY
- BUSINESS
- COMPANION DIAGNOSTICS
- DIGITAL PATHOLOGY AND AI
- POC SPECIAL FORUMS

Companion Diagnostics: Strategy and Partnerships

WINNING STRATEGIES FOR DRUG-DIAGNOSTICS CO-DEVELOPMENT

RECOMMENDED SHORT COURSE*

SC2: Discover How Machine Learning can Complement Diagnoses Through Medical Imagery

SC5: Tumor Mutation Burden

**Separate registration required, click here for details*

TUESDAY, AUGUST 20

7:30 am Registration and Morning Coffee

KEYNOTE SESSION: STRATEGY, TECHNOLOGY, FDA

8:30 Chairperson's Opening Remarks

Jonathan Beer, MBA, Director of Disruptive Technologies, Oncology Precision Medicine, Novartis

8:40 Companion Diagnostics in the Era of Consolidation and Globalization: Multiplexed Biomarkers Across Therapeutic Areas and Around the Globe

Omar Perez, PhD, RAC, Head of Precision Medicine and Diagnostics, R&D, GSK

Although biopharmaceutical pipeline products increasingly incorporate companion diagnostics into their clinical development efforts, commercial launch plans often do not adequately address the diagnostic component. Early planning and collaboration between biopharma and diagnostic companies can better support an optimal launch.

9:00 Companion and Complementary Diagnostics: Regulatory Challenges and Opportunities

Pamela Gallagher, PhD, Scientific Reviewer, FDA

Companion diagnostics are essential for the safe and effective use of therapeutic products and promise to deliver a clearer understanding of disease development at the individual patient level. The companion diagnostics industry is rapidly progressing along with rapid advances in technology and healthcare demands leading to unique regulatory complexities. The strategies for successful codevelopment (for companion and complementary diagnostic devices) will be reviewed and the FDA regulatory review process for some approved companion diagnostic devices will be discussed.

9:20 Liquid Biopsies Enabling Precision Medicine

Jonathan Beer, MBA, Director, Disruptive Technologies, Oncology Precision Medicine, Novartis

Blood-based detection of tumor-associated variants is advantageous in the era of Precision Medicine due to the non-invasive nature of sample collection and has demonstrated effectiveness as a Companion Diagnostic assay in lung cancer. However, this sample type still has challenges to overcome before ctDNA assays reach their full potential.

9:40 How Clinical Practice is Shaping the Precision Medicine Ecosystem

Lourdes Barrera, PhD, Senior Director, Precision Medicine, Oncology Business Unit, Novartis

Pharma companies continue to build and invest in targeted therapy pipeline. New diagnostic platforms are being developed to identify the patient most likely to respond to a given treatment. There is an ever growing need to understand the precision medicine landscape thought the eyes of the practicing clinician. Geographical differences in the access to various testing modalities and reimbursement must be accounted for in clinical development programs and go-to-market strategies. This presentation will provide an overview of the considerations for the global development and life cycle management of patient diagnostic and monitoring tools.

10:00 Q&A with Speakers of the Session

10:10 Coffee Break in the Exhibit Hall with Poster Viewing

TAKING THE SHOW AROUND THE GLOBE

10:55 Chairperson's Remarks

John Lubniewski, President, CEO, HTG Molecular Diagnostics

11:00 Going Global – Setting Up a European Subsidiary

John Lubniewski, President, CEO, HTG Molecular Diagnostics

The speaker will provide a high level and lighthearted walk through the thinking behind (and the process and actual work of) setting up your first European entity. In HTG's case, we evaluated setting up in the UK, the Netherlands, Germany or France. We chose France. Buckle up.

11:30 From a Streamlined Companion Diagnostic to a Next Generation Sequencing Analysis in Acute Myeloid Leukemia: Opportunities, Challenges, and Global Considerations

Flora Berisha, Director, Companion Diagnostics, Translational Sciences, Global Oncology R&D, Daiichi-Sankyo, Inc.

Internal tandem duplications in fms-like tyrosine kinase 3 (FLT3-ITD) are common in Acute Myeloid Leukemia (AML) and confer a poor prognosis. The LeukoStrat® CDx FLT3 Mutation Assay is a PCR-based *in vitro* diagnostic test designed to detect FLT3 internal tandem duplications (ITD) mutations and tyrosine kinase domain (TKD) FLT3 mutations. Although PCR-based assays are predominantly utilized for molecular detection of mutations/translocations in AML, the field is moving toward a more rapid, robust and sensitive method. Given the importance of Minimal Residual Disease (MRD) in hematologic malignancies, particularly in AML, a standardized and highly sensitive NGS assay is needed for the detection of in FLT3-ITD mutations to enable and guide clinical and therapy decisions during the patient journey.

12:00 pm Presentation to be Announced

Sponsored by GUARDANT

12:30 Luncheon Presentation: Challenges and Strategies for Successful Global Companion Diagnostic Market Access

Sponsored by Hull Associates LLC

Stephen Hull, President, Founder, Hull Associates LLC

Companion diagnostics (CDx) have emerged as a distinct group of IVDs shaping the personalized health care spectrum. Global markets, each with distinct market access processes, evidence requirements and evaluation measures create challenges to market access, and are a key barrier to identifying patients, and subsequently accessing precision medicines for those who may benefit. The challenges of successful CDx programs will be reviewed, emphasizing strategies and activities that will facilitate optimal reimbursement and access.

1:00 Cookie & Refreshment Break in the Exhibit Hall with Poster Viewing

NEW TECHNOLOGIES AND APPLICATIONS

1:30 Chairperson's Remarks

John Sninsky, PhD, Consultant, Translational Sciences

1:35 Evolving Trends in Respiratory Infections Diagnostics and the Impact in Drug Development

Jorge Villacian, MD, Medical, Digital and Technical Solutions Leader, Janssen Pharmaceutica

Accurate and reliable diagnostics are important in assessing the etiology of acuter respiratory infections. This has great impact in drug development for viral respiratory diseases. New trends in diagnostic development include home testing. The interaction of these elements will be discussed in the presentation.

1:55 ctDNA Utility and Challenges

J. Carl Barrett, MD, Vice President, Oncology Translational Sciences, AstraZeneca

Circulating tumor DNA (ctDNA) is becoming increasingly used in clinical practice and clinical/translational research. Examples of this utility will be given for patient selection, monitoring disease response and elucidating mechanisms of resistance to targeted therapies.

TABLE OF CONTENTS

COMPANION DIAGNOSTICS: STRATEGY AND PARTNERSHIPS, continued

Despite the common use in many commercial and academic labs, issues remain with sensitivity and specificity of some assays and this will be discussed in this and other talks from our laboratories.

2:15 Design and Implementation of Rare and Orphan Disease Testing Programs

Sponsored by ClearView Healthcare Partners

Charles Mathews, Principal, ClearView Healthcare Partners

Overview of the challenges and dynamics associated with identifying patients with rare or orphan disease post FDA approval of therapy. Review of examples of different testing programs and therapy/laboratory partnerships. Discussion of test program best practices. Thoughts on future of testing and implications for therapy development

2:45 Sponsored Presentation *(Opportunity Available)*

3:15 PANEL DISCUSSION: Precision Medicine Beyond Oncology

Moderator: John Sninsky, PhD, Consultant, Translational Sciences

Panelists: Speakers of the Session

Flora Berisha, Director, Companion Diagnostics, Translational Sciences, Global Oncology R&D, Daiichi-Sankyo, Inc.

Scott Patterson, PhD, Vice President, Biomarker Sciences, Gilead Sciences, Inc.

It's been 20 years! Why so little success for a great idea (right drug, right patient, right time)? What are we doing wrong? Are health care providers outside of Oncology actually ready to implement Personalized Medicine? Where is the value for Co-Dx outside of oncology? Prediction of R? Prediction of NR? Prognosis? How good would a Co-Dx need to be to change care paradigms from requiring patients to fail "cheaper" drugs first? Is there a robust value proposition?

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

PATIENTS AND SAMPLES

4:25 Chairperson's Remarks

Carolyn Hiller, Program Director, Clinical Diagnostics Initiative, Medical Device Innovation Consortium (MDIC)

4:50 Utility of a Novel Precision Medicine Maturity Model

Sponsored by Health Advances

Gary Gustavsen, Partner, Precision Medicine, Health Advances

The Personalized Medicine Coalition, alongside several industry leaders, recently commissioned a study to assess the adoption of personalized medicine across health systems in the US. As part of this broad survey, the team developed a novel maturity model to objectively and iteratively detail the extent to which personalized medicine has been adopted. Health Advances will share this quantitative data output and suggest how it may be useful to shape future CDx tactics by pharma.

5:00 NEW: The SPOT/Dx Quality Assurance Pilot: Reference Samples for NGS Assays

Barbara Zehnbauer, PhD, FACMG, Adjunct Professor, Pathology, Emory University School of Medicine

5:20 PANEL DISCUSSION: Somatic Reference Samples for NGS Dx

Moderator: Carolyn Hiller, Program Director, Clinical Diagnostics Initiative, Medical Device Innovation Consortium (MDIC)

Panelists:

Barbara Zehnbauer, PhD, FACMG, Adjunct Professor, Pathology, Emory University School of Medicine

Timothy K. McDaniel, PhD, Senior Vice President of Emerging Opportunities, TGen

J.D. Alvarez, MD, PhD, Vice President, Oncology Diagnostics, Janssen Pharmaceutical Companies

Zivana Tezak, PhD, Associate Director for Science and Technology, Personalized Medicine Staff, Office of in vitro Diagnostic Device (IVD) Evaluation and Safety (OIR), Center for Devices and Radiological Health, FDA

Clinical oncology is being transformed by the use of next-generation sequencing (NGS) based diagnostics. NGS lays out a promise for personalized medicine in other therapeutic areas. However, lack of agreed upon, well-characterized and community-validated reference samples and data benchmarks creates a potential challenge for the efficient development of these critical tests and for understanding their results. The ultimate goal of this effort is to develop properly consented, widely shareable reference samples that can be made available to the public and scalably produced in order to enable efficient development and improve the accuracy, reliability and transparency of NGS-based oncology tests.

6:00 Wine & Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing

Sponsored by Pillar Biosciences

7:00 Close of Day

COMPANION DIAGNOSTICS: STRATEGY AND PARTNERSHIPS, continued

WEDNESDAY, AUGUST 21

7:15 am Registration

7:30 Problem Solving Breakout Discussions with Continental Breakfast *(See website for details)*

ASSURING ACCESS TO PERSONALIZED MEDICINE: REIMBURSEMENT STRATEGIES FOR ADVANCED DIAGNOSTICS AND NOVEL THERAPIES

8:25 Chairperson's Remarks

Daryl Pritchard, PhD, Senior Vice President, Science Policy, Personalized Medicine Coalition

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Eugean Jiwanmall, MPH, MBA, Senior Research Analyst, Technology Evaluation & Medical Policy, Claim Payment Policy Department, Facilitated Health Networks, Independence Blue Cross

Achievement of optimal clinical care must be driven by multiple objective factors. Understanding and establishing the confidence in these contributing factors are essential due to their impacts on any proposed net improvement in relevant health outcomes. Development, advancement, integration, and routine clinical usage of options in oncological therapeutics are closely tied to availability, reliability, and acceptance of certain aspects of genomics. We will explore the impact of different facets of genetic testing on multiple phases of oncological therapeutics, and payment considerations based on these relationships.

8:45 Humana's Perspective on Personalized Medicine

Kristine Bordenave, MD, FACP, Corporate Medical Director, NMCARE, Healthcare Services, Humana

9:00 Global Commercial and Partnership Considerations for Companion Diagnostics

Sponsored by BOSTON HEALTHCARE ASSOCIATES

Joseph Ferrara, President & CEO, Boston Healthcare Inc.

Key commercialization considerations for drug and test innovators, including balancing test access and quality, and embedding CDx global commercial considerations in pharma and diagnostic company partnerships will be highlighted.

9:30 PANEL DISCUSSION: Funding Common Ground with Payers and Policy Makers to Advance Personalized Medicine in Oncology and Beyond

While emerging personalized medicine technologies and platforms have the potential to make drug development more economical and make health systems more efficient by targeting treatments to only those who will benefit, they are also challenging reimbursement systems accustomed to one-size-fits-all medicine. Indeed, personalized medicine has led payers to think differently about coverage and reimbursement of high-value diagnostics and novel cell-based and genetic therapies that have the potential to cure diseases with one or only a few treatments. The approval of tissue-agnostic drugs such as Keytruda and Vitrakvi, for example, will force payers to figure out policies for pan-cancer indications and associated genetic testing, while the approval of cellular-based CAR-T therapies and gene therapies such as Luxturna, Kymriah, and Yescarta are challenging the traditional way that high-cost therapeutics can be reimbursed.

Moderator:

Daryl Pritchard, PhD, Senior Vice President, Science Policy, Personalized Medicine Coalition

Panelists:

Kristine Bordenave, MD, FACP, Corporate Medical Director, NMCARE, Healthcare Services, Humana

Robert Dumanois, Manager, Reimbursement Strategy, Thermo Fisher Scientific

Eugean Jiwanmall, MPH, MBA, Senior Research Analyst, Technology Evaluation & Medical Policy, Claim Payment Policy Department, Facilitated Health Networks, Independence Blue Cross

Shuvayu S. Sen, PhD, Executive Director, CORE Oncology, Merck & Co., Inc.

Stella Stergiopoulos, Associate Director, Health Economic Outcomes Research and Payer Policy, Foundation Medicine, Inc

Katherine B. Szarama, PhD, Presidential Management Fellow, CMS

Topics to be Discussed:

- What are the key reimbursement challenges for advanced diagnostic tests?
- What strategies are emerging for the coverage and reimbursement of cell-based and genetic therapies?
- What evidence is necessary to demonstrate the value of personalized medicine technologies to payers and providers?
- How can practice-based evidence be developed in an environment of limited reimbursement and reduced access?

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:30 Plenary Keynote Session

Please click here for details

1:05 pm Luncheon Presentation: CDx Development in the 21st Century: Leveraging the Clinical Genomics Community for Precision Medicine

Sponsored by SOPHiA™ SOPHIAGENETICS.COM

Adrian Willig, PhD, Associate Head of Lab, SOPHiA GENETICS

With several CE-IVD solutions developed to support clinicians in Europe, SOPHiA GENETICS is well-positioned to support pharmaceutical and biotech companies develop the next generation of targeted therapies where a CDx application is required. SOPHiA GENETICS brings expertise in solution design and validation and can deploy CDx solutions throughout its community of over 970 healthcare institutions in 81 countries. Together, we will give many patients around the globe access to new targeted therapies.

1:35 End of Companion Diagnostics: Strategy & Partnerships

Companion Diagnostics and Clinical Biomarkers in Immuno-Oncology

PREDICTING AND MONITORING RESPONSE TO CANCER IMMUNOTHERAPY

WEDNESDAY, AUGUST 21

10:30 am Registration

11:30 Plenary Keynote Session
Please click here for details

1:05 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:35 Ice Cream & Cookie Break in the Exhibit Hall with Poster Viewing

BIOMARKERS IN THE CONTEXT OF IMMUNO-ONCOLOGY COMBINATIONS

2:05 Chairperson's Opening Remarks
Kenneth Emancipator, MD, DABP, Executive Medical Director, Companion Diagnostics, Translational Medicine, Merck & Co., Inc.

2:10 Biomarkers in the Context of IO Combinations
J.D. Alvarez, MD, PhD, Vice President, Oncology Diagnostics, Janssen Pharmaceutical Companies
Will current assays be combined or completely superseded? Are standard clinical biomarkers being overlooked in IO trials? What is the current utility and future potential of blood-based biomarkers? How can NGS panels data be used to improve target discovery and/or combo prioritization? These and other important issues will be addressed in this presentation. Harmonization of multiple assays for the similar biomarker(s) will be discussed as well.

2:40 TMB as a Clinical Biomarker in Combination Trials
Rajiv Raja, PhD, Director, Translational Medicine Oncology and Pharmacogenomics, AstraZeneca

3:10 PD-L1 as a Companion Diagnostic for Tumors Beyond Non-Small Cell Lung Cancer: It's the Same Thing, Only Different
Kenneth Emancipator, MD, DABP, Executive Medical Director, Companion Diagnostics, Translational Medicine, Merck & Co., Inc.
The PD-L1 companion diagnostic had a huge impact on the clinical development of pembrolizumab, making it the first immunotherapy approved as a first-line agent for non-small cell lung cancer. However, this is just the beginning of the story, not the end. Adapting the PD-L1 diagnostic to incorporate immune cell expression facilitated approval of pembrolizumab for several additional indications and may shed light on the mechanism of action of checkpoint inhibitors.

3:40 How Biospecimen Sourcing Can Impact Your R&D
Sponsored by TRANS-HIT BIO
Vanessa Tumilasci, PhD, Commercial Director, Trans-Hit Biomarkers
Biospecimen sourcing is becoming a challenge for many scientists who need to respect timelines for R&D plans as well as regulatory and ethical constraints. Are the scientists working with the samples aware of all the imperatives to obtain them; quality, respect of laws, ethics and regulations?

3:55 Sponsored Presentation *(Opportunity Available)*

4:10 Refreshment Break in the Exhibit Hall with Poster Viewing

NEW BIOMARKERS AND NOVEL CLINICAL STRATEGIES

4:55 Chairperson's Remarks
Nicholas Dracopoli, PhD, CSO, DELFI Diagnostics

5:00 Immuno-Oncology Biomarkers: What's New?
Nancy Zhang, MD, Associate Director, Pharmacodiagnostics, Bristol Myers Squibb
Precision medicine continues to transform treatment paradigms through development of new biomarkers and interpretation of clinical data. Testing for Immuno-Oncology biomarkers, such as PD-L1, and emerging ones, such as tumor mutational burden, may help optimize treatment decisions when assessed individually or in combination. The advancement of increasingly complex biomarkers also brings a need for advanced diagnostic tools. We will discuss biomarkers, their dynamic monitoring, and assessment in the evolving field of pharmacodiagnostics.

5:30 Companion Diagnostics in Immuno-Oncology
Anand Pathak, MD, PhD, MPH, Medical Officer, FDA
This session will focus on the implementation of immuno-oncology diagnostic tests in clinical trials, including understanding the regulatory implications of different approaches, validation of emerging pan-tumor CDx claims, and complementary diagnostics vs. companion diagnostics.

6:00 PANEL DISCUSSION: Companion Diagnostics in Immuno-Oncology
Moderator: Nicholas Dracopoli, PhD, Independent Consultant
Panelists: Speakers of the Day
Topics to be discussed:
- Advantages and disadvantages of complex multianalyte panels versus simple single analyte Dx tests
- Issues in developing CDx tests for drugs being launched in different countries
- Tumor mutation burden (TMB) and other very large panel tests
- Advantages and disadvantages of plasma based ctDNA testing compared to tissue-based tests
- Emergence of new CDx tests for immuno-oncology drugs

6:30 Close of Day

6:30 Dinner Short Course Registration

6:45 - 9:15 pm RECOMMENDED DINNER SHORT COURSE*
SC8: Generating Evidence and Creating Winning Dossier for Regulatory and Reimbursement Needs
**Separate registration required, click here for details*

THURSDAY, AUGUST 22

7:15 am Registration

7:30 Problem Solving Breakout Discussions with Continental Breakfast (See website for details)

BEYOND IO

8:25 Chairperson's Remarks
Mitch Raponi, PhD, Vice President, Biomarkers & Translational Research, BeiGene

8:30 Silver Linings: Embracing the Positive and Negative in Predictive Biomarker Development
Jamie Shaw, Principal Scientist, Clinical Biomarkers and Diagnostics at EMD Serono, Inc.
Despite development of countless drugs targeting the PI3K/Akt/

COMPANION DIAGNOSTICS AND CLINICAL BIOMARKERS IN IMMUNO-ONCOLOGY, continued

mTOR pathway in cancer, no biomarkers have been validated to identify patients likely to benefit from these therapies. This presentation will review findings from the PhI trial of M2698, a p70S6K/AKT inhibitor, which suggest that tumor resistance markers could identify a patient population benefitting from treatment and illustrates how implementing a combination of positive and negative selection markers may increase robustness and predictivity.

9:00 PARPi Development in Prostate Cancer: Limitations and Opportunities for Companion Diagnostic Development

Mitch Raponi, PhD, Vice President, Biomarkers & Translational Research, BeiGene

PARP inhibitors have demonstrated clinical utility in treating metastatic prostate cancer due to enrichment of DNA repair deficiencies in a subset of these tumors. NGS testing of tumor tissue to identify patients with BRCA defects or other homologous recombination repair deficiencies has limited utility due to limited amount of tumor isolated from bone biopsies. Opportunities of developing liquid biopsy-based companion diagnostics for this disease will be discussed.

9:30 Streamlined CDx™ - A Proven Strategy to Accelerate Drug Approvals

Sponsored by invivoscribe

Michael Vishnevetsky, PhD, Head of Global Business Development, Invivoscribe

Companion Diagnostics have revolutionized precision medicine as they play a pivotal role in defining the efficacy of targeted therapies. Invivoscribe's Streamlined CDx™ program has been shown to collapse development timelines, improve and accelerate selection of patient cohorts, leading to earlier submissions and accelerated FDA, EMA and PMDA approvals of new targeted therapies. Streamlined CDx™ partnership model has proven successful in approval of the first ever AML companion diagnostic – The LeukoStrat® CDx FLT3 Mutation Assay.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

CAR T CELL AND VACCINE STRATEGIES

11:00 Chairperson's Opening Remarks

Iulian Pruteanu-Malinici, Investigator III, Lab Head, Immuno-Oncology, Novartis

11:05 Personalizing Immunotherapy for Each Cancer Patient

Roman Yelensky, MD, Executive Vice President and CTO, Sequencing and Bioinformatics, Gritstone Oncology

Gritstone Oncology is a cancer immunotherapy company working to help patients with the most difficult-to-treat tumors. Gritstone's personalized immunotherapy process leverages our EDGE AI platform to predict neoantigens that will be presented on a patient's tumor, allowing us to create a patient-specific heterologous prime-boost immunotherapy that is designed to elicit a potent anti-tumor T cell response.

11:35 Correlative and Release Test Assays for Evaluating Gene Edited Human Cell Products

Simon Lacey, PhD, Director, Translational and Correlative Studies Laboratory, Center for Cellular Immunotherapies, University of Pennsylvania

Gene editing techniques such as CRISPR/Cas9 hold potential for augmentation of CAR-T and TCR engineered cell products to be used in human clinical trials. The FDA requires additional evaluations of such gene edited and engineered cells prior to, and post infusion. This presentation will discuss the development and validation of correlative and release test assays to evaluate efficiency of transduction, gene editing and other aspects of engineered and edited cells.

12:05 pm Modeling Flow High-Dimensional Data and Biomarker Identification in a CART/Multiple Myeloma Study

Iulian Pruteanu-Malinici, Investigator III, Lab Head, Immuno-Oncology, Novartis

Here we present a Flow Cytometry based framework that, when combined with state-of-the-art bioinformatics, enables for the discovery of biomarkers that predict clinical response of CART therapeutic products.

12:35 Sponsored Presentation *(Opportunity Available)*

1:05 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:35 Dessert Break in the Exhibit Hall with Poster Viewing

COMBINATION TRIALS AND RWD

2:15 Chairperson's Opening Remarks

Kathryn Lang, MBBS, MRCP, Vice President, Outcomes and Evidence, Guardant Health

2:20 TLR Agonist NKTR-262 Immunotherapy Combination with Bempegaldesleukin (NKTR-214) Harnessing Innate and Adaptive Immune System for the Treatment of Solid Tumors

Saul Kivimäe, PhD, Head of Pharmacology, Nektar Therapeutics

NKTR-262 is a novel TLR agonist therapeutic designed to deliver intratumoral TLR7/8 engagement and is currently evaluated in Phase 1 dose escalation study with bempegaldesleukin, a CD122-preferential IL-2 pathway agonist. NKTR-262 combination treatment with bempegaldesleukin is designed to provide a synergistic effect of localized intratumoral innate immune stimulation with systemic sustained T cell activation for comprehensive anti-tumor immune activation mimicking a natural immune response.

2:50 Integrating Clinical Research and Care in a Perpetual Trial to Continuously Learn From All Patients, on All Treatments, All the Time

Mika Newton, BSc, CEO, xCures

The explosion of molecular subtypes and oncology drugs means R&D is about to hit a wall. There are not enough patients to explore all the potential options. A Perpetual Trial provides patients and their physicians with individualized treatment options. RWD is generated longitudinally to learn what works in which patients, and coordinate treatment prioritizing the most promising therapies. This RWE is used to accelerate regulatory approvals, label expansions, and reimbursement.

3:20 How Can Real-World Data Enhance Clinical Evidence Generation?

Margaret McCusker, MD, Senior Medical Director, Flatiron Health

As the cancer treatment landscape becomes increasingly complex, biomarkers are playing a more prominent role in drug development and clinical decision support. In this setting, research-quality clinical evidence derived from cancer patients' electronic health records and paired genomic data are a valuable asset. This session will highlight examples of how clinico-genomic data can provide critical insights into the impact of biomarkers on real-world oncology practice and accelerate clinical research.

3:50 Establishing the Next Generation of Clinico-Genomic Data in Oncology and Healthcare

Kathryn Lang, MBBS, MRCP, Vice President, Outcomes and Evidence, Guardant Health

The emergence of real-world clinico-genomic data promises great value for all aspects of the healthcare system. How do organizations and individuals combine efforts to support all aspects of care and treatment?

4:20 End of Summit

Digital Pathology and AI Stream

Digital pathology and AI have the potential to improve accuracy, streamline workflows, and cut costs for both clinicians and pathologists. Both are evolving areas that are critical to advancing medicine to be able to improve access to information worldwide, and increase the speed of data interpretation, sharing and accuracy. The Digital Pathology and AI stream, part of the 11th Annual Next Generation Dx Summit, will explore this new shift to digital and data-driven methods for clinical care.

2019 DIGITAL PATHOLOGY AND AI CONFERENCES

AUGUST 20-21

AGENDA **Applications of Digital Pathology**

CONFERENCE STREAMS

- POCT & INFECTIOUS DISEASE
- LIQUID BIOPSY
- IMMUNO-ONCOLOGY
- BUSINESS
- COMPANION DIAGNOSTICS
- DIGITAL PATHOLOGY AND AI
- POC SPECIAL FORUMS

Applications of Digital Pathology

PREPARING FOR A FULLY DIGITAL WORKFLOW

RECOMMENDED SHORT COURSE*

SC2: Discover How Machine Learning Can Complement Diagnoses Through Medical Imagery

SC4: Digital Pathology from A to Z for Beginners

**Separate registration required, click here for details*

TUESDAY, AUGUST 20

7:30 am Registration and Morning Coffee

AI AND MACHINE LEARNING FOR DIGITAL PATHOLOGY

8:30 Chairperson's Opening Remarks

Liron Pantanowitz, MD, Professor, Pathology & Biomedical Informatics, University of Pittsburgh Medical Center

8:40 KEYNOTE PRESENTATION: Legal Aspects of Artificial Intelligence

Timothy Craig Allen, MD, JD, FCAP, Professor and Chair, Department of Pathology, The University of Mississippi Medical Center

Artificial intelligence promises to increase healthcare efficiencies and accuracy and reduce cost. Its development, however, has been generally outside of any regulatory environment, and little legal scholarship about it currently exists. Successful artificial intelligence regulation will require an evolving regulatory strategy that abandons traditional normative boundaries, and instead will require shared governmental and stakeholder involvement. Medical malpractice liability theory will also require careful consideration and evolution as artificial intelligence evolves.

9:10 Searching Is Intelligence: AI Solutions for Medical Imaging

Hamid Tizhoosh, PhD, Professor, Computer Science; Director, Kimia Lab, Faculty Affiliate, Vector Institute, University of Waterloo

Image search has emerged as a very promising application of artificial intelligence. We will talk about different challenges of digital pathology and what AI algorithms could offer. Whereas most papers focus on classification and segmentation, this talk will attempt to shed light on challenges and opportunities of image search for retrieving useful information from large archives of histopathology images.

9:40 Augmented Human Intelligence and Transformation of Hematopathology Workflow

Mohamed E. Salama, MD, Professor, Pathology and Laboratory Medicine, Mayo Clinic School of Medicine and Medical Director, Mayo Clinic Reference Laboratories

Hematopathologists are increasingly using digital imaging tools for a wide spectrum of practice settings. However, digital imaging associated with artificial intelligence applications for effective learning and diagnosis rendering are not yet routinely incorporated in practice. We will share our experience in utilizing digital tools and will demonstrate methods and applications of digital imaging along with augmented human intelligence to effectively improve the workflow in the practice of hematopathology. We will cover the essential elements as well as the pitfalls, advantages, challenges and opportunities in utilization of digital tools in practice.

10:10 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 KEYNOTE PRESENTATION: Rules of Engagement of Academia with Industry: Lessons for Digital Pathology Collaborations

Michael J. Becich, MD, PhD, Associate Vice-Chancellor for Informatics in the Health Sciences; Chairman and Distinguished University Professor, Department of Biomedical Informatics (DBMI), University of Pittsburgh School of Medicine

Academic Industry Partnerships (AIPs) are key to successful "innovation cycles" within academic health systems (AHCs). This keynote describes the rules of engagement for faculty innovators and AHCs to evolve "best practices" for AIPs. Keys to successful efforts involve basic/translational researchers, technology transfer and university/health systems offices of research/compliance as well as industry relations officers. Guidelines for innovators establishing AIPs and appropriate management of conflict of interest policies will be discussed.

11:30 Digital Pathology for Primary Diagnosis: FDA Regulatory Review Process

Shyam Kalavar, MPH, CT(ASCP), Senior Scientific Reviewer, Molecular Pathology and Cytology Branch, Division of Molecular Genetics and Pathology, Center for Devices and Radiological Health, Office of In Vitro Diagnostics and Radiological Health, U.S. Food and Drug Administration

FDA authorized the first digital pathology whole slide imaging system for primary diagnosis in 2017. This talk will provide a brief overview of the FDA regulatory review process for a marketing application for this type of a device and provide information about the types of studies and validation data needed to support the performance of the device. This talk will also briefly discuss regulatory perspective of issues such as interoperability and artificial intelligence as applicable to digital pathology.

12:00 pm PANEL DISCUSSION: Barriers for AI Adoption in Clinical Practice

Moderator: Liron Pantanowitz, MD, Professor, Pathology & Biomedical Informatics, University of Pittsburgh Medical Center

Panelists: Timothy Craig Allen, MD, JD, FCAP, Professor and Chair, Department of Pathology, The University of Mississippi Medical Center

Hamid Tizhoosh, PhD, Professor, Computer Science; Director, Kimia Lab, Faculty Affiliate, Vector Institute, University of Waterloo

Mohamed E. Salama, MD, Professor, Pathology and Laboratory Medicine, Mayo Clinic School of Medicine and Medical Director, Mayo Clinic Reference Laboratories

Michael J. Becich, MD, PhD, Associate Vice-Chancellor for Informatics in the Health Sciences; Chairman and Distinguished University Professor, Department of Biomedical Informatics (DBMI), University of Pittsburgh School of Medicine

12:30 Luncheon Presentation: Evolving AI to Enable the Next Generation of Digital Pathology

Sponsored by Cambridge Consultants

Joe Corrigan, Head of Technology, Medical Technology, Cambridge Consultants

The development of AI tools and their integration into diagnostics systems present an opportunity to transform digital pathology. This transformation will not be restricted to whole slide imaging and evaluation steps of digital pathology. Instead, it will impact most of its aspects - from sample collection to diagnosis. In this talk, we will use our expertise from delivering AI enabled systems on behalf of our clients and we will explore the challenges of materialising the vision for next-generation digital pathology. Moreover, we will highlight the opportunities and underline the technological advantages which will catalyse this transformation.

1:00 Cookie & Refreshment Break in the Exhibit Hall with Poster Viewing

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APPLICATIONS OF DIGITAL PATHOLOGY, continued

IMPLEMENTING TELEPATHOLOGY WORLDWIDE

1:30 Chairperson's Remarks

Liron Pantanowitz, MD, Professor, Pathology & Biomedical Informatics, University of Pittsburgh Medical Center

1:35 Implementing Telepathology Worldwide: The Cleveland Clinic Experience

Bin Yang, MD, PhD, Professor of Pathology, Co-Director of ePathology (International); Director of International Business and Collaboration, Tomsich Pathology & Laboratory Medicine Institute, Cleveland Clinic Lerner College of Medicine

Digital pathology provides an emerging role in telepathology consultations both domestically and internationally. Through innovational approaches, we have established a scanner-independent telepathology platform in our institution for eConsults to Chinese pathologists, patients and clinicians to offer guidance on diagnostic and prognostic findings to assist in therapeutic decision-making for international patients.

2:05 Challenges to Building International Digital Pathology Networks

Michael Riben, MD, Director of Informatics, MD Anderson Cancer Center

Collaborative digital pathology has been enhanced by commercial software solutions and has made tremendous progress in recent years. Many have even successfully developed connections between domestic and/or International partners. However, these implementations have been primarily point-to-point connections for the sharing of the images in isolation of pathology information or medical record information. Building a Digital pathology network for sharing both whole slide images and clinical information still faces many challenges, particularly if you wish to scale this to international partners. This talk will address the challenges that must be overcome for an international digital pathology network to be successful and highlight lessons learned along the way of planning such a network.

2:35 What You Need to Know About Performing Frozen Sections by Digital Scans

Liron Pantanowitz, MD, Professor, Pathology & Biomedical Informatics, University of Pittsburgh Medical Center

The use of telepathology for frozen sections (intraoperative consultations) has been increasing due to limited time and availability of pathologists, and the demand for increased access to pathology subspecialists in difficult cases. However, frozen sections can be difficult to handle remotely due to time constraints and artifacts. This talk will address the challenges, suitable IT solutions, practice tips and business aspects of performing remote frozen sections by telepathology.

3:05 PANEL DISCUSSION: The Business Use Case for Teleconsultation

Moderator: Mohamed E. Salama, MD, Professor, Pathology and Laboratory Medicine, Mayo Clinic School of Medicine and Medical Director, Mayo Clinic Reference Laboratories

Panelists: Bin Yang, MD, PhD, Professor of Pathology, Co-Director of ePathology (International); Director of International Business and Collaboration, Tomsich Pathology & Laboratory Medicine Institute, Cleveland Clinic Lerner College of Medicine

Michael Riben, MD, Director of Informatics, MD Anderson Cancer Center

Liron Pantanowitz, MD, Professor, Pathology & Biomedical Informatics, University of Pittsburgh Medical Center

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

APPLICATIONS IN PRIMARY DIAGNOSIS

4:25 Chairperson's Remarks

Anil Parwani, MD, PhD, MBA, Professor of Pathology and Biomedical Informatics, Vice Chair of Anatomic Pathology, Director of Pathology Informatics; Director, Digital Pathology Shared Resources, Wexner Medical Center - Department of Pathology, The Ohio State University

4:30 Implementing A Digital Pathology Workflow for Primary Diagnosis: A 2-Year Report Card

Anil Parwani, MD, PhD, MBA, Professor of Pathology and Biomedical Informatics, Vice Chair of Anatomic Pathology, Director of Pathology Informatics; Director, Digital Pathology Shared Resources, Wexner Medical Center - Department of Pathology, The Ohio State University

In recent years, whole slide imaging (WSI) has been increasingly used to digitize large numbers of slides automatically, rapidly and at high resolution. Some of the applications include education, quality assurance, clinical and image analysis. In our institution, we have validated and implemented WSI for multiple applications including primary diagnosis. This talk will address our experiences with implementing WSI for primary diagnosis and discuss technology, workflow, quality and financial opportunities.

5:00 Whitepapers of Digital Pathology from the Digital Pathology Association

Douglas Joseph Hartman, MD, Associate Professor of Pathology and Director of Pathology Informatics, University of Pittsburgh Medical Center

The first approval of a digital pathology system has begun the transition of pathology from analog to digital. This process is being led by the Digital Pathology Association. To that end, the Digital Pathology Association and its members have been publishing whitepapers on the conversion of the discipline of pathology to a digital format. This talk will review the topics presented in these recent whitepapers.

5:30 PANEL DISCUSSION: Update from the DPA – What's Next on the Horizon for Digital Pathology?

Moderator: Liron Pantanowitz, MD, Professor, Pathology & Biomedical Informatics, University of Pittsburgh Medical Center

Panelists: Anil Parwani, MD, PhD, MBA, Professor of Pathology and Biomedical Informatics, Vice Chair of Anatomic Pathology, Director of Pathology Informatics; Director, Digital Pathology Shared Resources, Wexner Medical Center - Department of Pathology, The Ohio State University

Douglas Joseph Hartman, MD, Associate Professor of Pathology and Director of Pathology Informatics, University of Pittsburgh Medical Center

6:00 Wine & Cheese Pairing Welcome Reception in the Exhibit Hall with Poster Viewing

Sponsored by PILLAR BIOSCIENCES

7:00 Close of Day

WEDNESDAY, AUGUST 21

7:15 am Registration

7:30 Problem Solving Breakout Discussions with Continental Breakfast *(See website for details)*

APPLICATIONS IN PRIMARY DIAGNOSIS (CONT.)

8:25 Chairperson's Remarks

Douglas Joseph Hartman, MD, Associate Professor of Pathology and Director of Pathology Informatics, University of Pittsburgh Medical Center

8:30 Complete Digital Pathology for Routine Histopathology Diagnosis: Three Years' Experience at Granada University Hospitals, Spain

Juan Antonio Retamero, MD, Staff Pathologist, Department of Anatomical Pathology, Hospital Campus de la Salud

Granada University Hospitals comprises two teaching and two district general hospitals integrated in the public health system in southern Spain. We report on the transition to full digital pathology for primary histopathology diagnosis and our experiences since its implementation in September 2016.

APPLICATIONS OF DIGITAL PATHOLOGY, continued

9:00 Application of AI Tools in Routine Digital Workflow: The Catania Experience

Filippo Fraggetta, MD, Head of the Pathology Department, Cannizzaro Hospital

At Cannizzaro Hospital in Catania, Italy, we use e-slides for primary diagnosis since 2017. Using a Laboratory Information System centric approach to the workflow, we integrated Artificial Intelligence tools in our routine digital workflow to facilitate automated tumor detection (in prostate and breast cancer) and detection microorganisms (Helicobacter pylori). We discuss results of this new approach as well as difficulties and solutions to the implementations of these tools.

9:30 Building the Foundation of Digital Pathology in the Diagnostic Setting: Guiding Principles and Practical Issues

Chee Leong Cheng, MBBS, FRCPath, FRCPASingapore, Senior Consultant, Anatomical Pathology; Director, Computational and Digital Pathology, Singhealth Pathology ACP; Department of Anatomical Pathology, Singapore General Hospital

Digital pathology with application of whole slide imaging (WSI) in the diagnostic setting demands the integration of WSI process into the diagnostic workflow. The key considerations include integration with laboratory information system, end-to-end accountability of specimen assets and derivatives, thorough view of electronic information flow closely correlated with the workflow, sound validation planning and execution, and continuous monitoring and sustainability by building a "digital pathology service" in the laboratory.

10:00 Integrated Specimen Management, AI Algorithms, and Companion Diagnostics: How BxLink has Transformed Our Practice

Sponsored by LUMERA light applied

Todd Randolph, MD, Digital Pathology Consultant, Medical Director, Consultant Intermountain Healthcare, Urologic Institute

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:30 Plenary Keynote Session
Please click here for details

1:05 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:35 End of Applications of Digital Pathology

RECOMMENDED SHORT COURSE*

SC7: Data-Driven Process Development in the Clinical Laboratory

**Separate registration required, click here for details*

Hotel & Travel Information

Conference Venue and Hotel:
Grand Hyatt Washington
1000 H Street, NW
Washington, DC 20001
Phone: 202-582-1234

Reservations: Go to the travel page of NextGenerationDx.com
Discounted Room Rate: $219 s/d
Discounted Cut-off Date: July 23, 2019

For additional information please go to the TRAVEL PAGE of NextGenerationDx.com.

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Please refer to Short Course list on page 7

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If you are unable to attend but would like to purchase the Next Generation Dx Summit CD for $750 (plus shipping), please visit NextGenerationDx.com. Massachusetts delivery will include sales tax.

ADDITIONAL REGISTRATION DETAILS

Each registration includes all conference sessions, posters and exhibits, food functions, and access to the conference proceedings link.

Handicapped Equal Access: In accordance with the ADA, Cambridge Healthtech Institute is pleased to arrange special accommodations for attendees with special needs. All requests for such assistance must be submitted in writing to CHI at least 30 days prior to the start of the meeting.

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