ADVANCING DIAGNOSTICS TOGETHER

REGISTER EARLY FOR MAXIMUM SAVINGS

16th ANNUAL Next Generation Dx SUMMIT

AUGUST 19-21, 2024
WASHINGTON, D.C. & VIRTUAL
CAPITAL HILTON

Conference Programs

POCT AND INFECTIOUS DISEASE
- Enabling Point-of-Care Diagnostics
- Advanced Diagnostics for Infectious Disease

COMPANION DX AND REIMBURSEMENT
- Advancing Novel Frameworks for Companion Diagnostics
- Emerging Trends in Coverage and Reimbursement for Advanced Diagnostics

LIQUID BIOPSY AND EARLY DETECTION
- Liquid Biopsy for Disease Management
- Early Cancer Surveillance

DECENTRALIZED TESTING
- Enabling Point-of-Care Diagnostics
- Decentralized POC Testing

POC SPECIAL FORUMS
- POC Product Strategies, Market Access, and Implementation
- Point-of-Care Histology
- Regulatory Strategies for POC Diagnostics

PLENARY KEYNOTE

COURTNEY H. LIAS, PHD,
Acting Director, OHT7: Office of *in vitro* Diagnostic Devices, United States Food and Drug Administration (FDA)

Premier Sponsor Co-Dx

Organized by Cambridge HEALTHTECH Institute

NextGenerationDx.com #NGDx

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- Regulatory Strategies for POC Diagnostics

"I was able to get a big-picture outlook at the technologies and challenges in the diagnostics world! The networking opportunities were fantastic."

Senior Product Training Specialist, Millipore Sigma

About the Event

Cambridge Healthtech Institute is proud to present the 16th Annual Next Generation Dx Summit which will take place at the Capital Hilton in Washington, D.C., on August 19-21, 2024. The Next Generation Dx Summit is the nexus for international thought leaders to discuss diagnostic advancement and technology innovation. This year's event provides a valuable window on the state-of-the-art forecasting and future trends in point-of-care and decentralized testing, infectious disease, liquid biopsy, multi-cancer early detection, reimbursement, regulation, and companion diagnostics to improve the standard of care in medicine. This must-attend Summit offers incomparable networking and complete coverage of the most timely and important topics for the industry.

BENEFITS OF ATTENDING INCLUDE:

- **Form partnerships** with major global players in the evolving areas of diagnostics as well as emerging product innovators
- **Gain** a comprehensive, up-to-date view of diagnostics, including the latest point-of-care, rapid, decentralized, and pharmacy-based diagnostic tests
- **Gather** important industry announcements
- **Hear** late-breaking news on the latest trends in regulation and reimbursement
- **Review** innovative products, platforms, and technologies in the exhibit hall and poster session
- **Network** with peers in industry, government, clinical and research institutions

CONFERENCE AT-A-GLANCE >

STREAMS	MONDAY, AUGUST 19 & TUESDAY AM, AUGUST 20	TUESDAY PM, AUGUST 20 & WEDNESDAY, AUGUST 21
POCT AND INFECTIOUS DISEASE	Enabling Point-of-Care Diagnostics	Advanced Diagnostics for Infectious Disease
COMPANION DX/ REIMBURSEMENT	Advancing Novel Frameworks for Companion Diagnostics	Emerging Trends in Coverage and Reimbursement for Advanced Diagnostics
LIQUID BIOPSY AND EARLY DETECTION	Liquid Biopsy for Disease Management	Early Cancer Surveillance
DECENTRALIZED TESTING	Enabling Point-of-Care Diagnostics	Decentralized POC Testing

	AUGUST 19, 2024, 8:25 AM – 12:15 PM	AUGUST 19, 2024, 1:30 – 5:15 PM	AUGUST 20, 2024, 8:25 – 10:30 AM
POC SPECIAL FORUMS	POC Product Strategies, Market Access and Implementation	Point-of-Care Histology	Regulatory Strategies for POC Diagnostics

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Next Generation Dx SUMMIT

SPONSORSHIP & EXHIBIT OPPORTUNITIES

PODIUM PRESENTATIONS

— Available within Main Agenda!

Showcase your solutions to a guaranteed, targeted audience through a 15- or 30-minute presentation during a specific program, breakfast, lunch, or a pre-conference workshop. Package includes exhibit space, on-site branding, and access to cooperative marketing efforts by CII. Lunches are delivered to attendees who are already seated in the main session room. Presentations will sell out quickly! Sign on early to secure your talk.

INVITATION-ONLY VIP DINNER/HOSPITALITY SUITE

Select specific delegates from the pre-registration list to attend a private function at an upscale restaurant or a reception at the hotel. From extending the invitations, to venue suggestions, CII will deliver your prospects and help you make the most of this invaluable opportunity.

ONE-TO-ONE MEETINGS

CII will set up 6-8 in-person meetings during the conference, based on your selections from the advance registration list. Our staff will handle invites, confirmations, and reminders, and walk the guest over to the meeting area. This package also includes a meeting space at the venue, complimentary main-conference registrations, branding, an 8'x10' exhibit space, and more.

EXHIBIT

Exhibitors will enjoy facilitated networking opportunities with qualified delegates, making it the perfect platform to launch a new product, collect feedback, and generate new leads. Exhibit space sells out quickly, so reserve yours today!

Additional branding and promotional opportunities are available, including:

» Conference Tote Bags
» Literature Distribution (Tote Bag Insert or Chair Drop)
» Badge Lanyards
» Conference Materials Advertisement
» Digital Monitors and More…

FOR MORE INFORMATION, PLEASE CONTACT:

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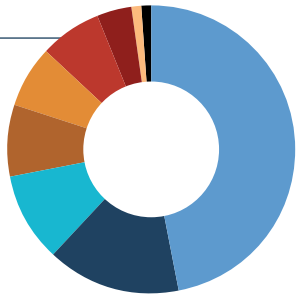
Sr. Business Development Manager
Cambridge Healthtech Institute
(+1) 781-247-1824
kfitzgerald@cambridgeinnovationinstitute.com

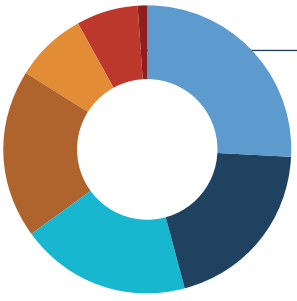
2023 ATTENDEE DEMOGRAPHICS

COMPANY TYPE



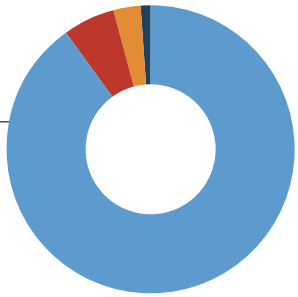
- Biotech 47%
- Healthcare..... 15%
- Services..... 10%
- Academic 8%
- Government 7%
- Pharma.....7%
- Societies 4%
- Financial.....1%
- Press 1%

DELEGATE TITLE

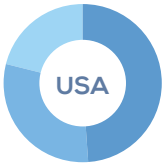


- Executive.....26%
- Director.....20%
- Scientist/Technologist....19%
- Sales & Marketing 19%
- Manager.....8%
- Professor 7%
- Assistant.....1%

GEOGRAPHIC LOCATION



- USA.....90%
- Europe 6%
- Asia.....3%
- Rest of World 1%



- East Coast.....49%
- West Coast 30%
- Midwest 21%

2024 **PLENARY KEYNOTE** SESSION

TUESDAY, AUGUST 20

11:30 am - 12:00 pm

COURTNEY H. LIAS, PHD,

Acting Director, OHT7: Office of *in vitro* Diagnostic Devices, United States Food and Drug Administration (FDA)

PLENARY **FIRESIDE CHAT**

B. MELINA CIMLER, PHD,
CEO & Founder, PandiaDx LLC

LAURIE MENSER,
CEO, Association for Molecular Pathology

STEFAN BURDE, PHD,
Director, Global Strategic Business Development, IVD, TÜV SÜD

GIRISH PUTCHA, MD, PHD,
Principal, Precision Medicine & Diagnostics LLC

TUESDAY, AUGUST 20

12:10 - 1:10 pm

PLENARY FIRESIDE CHAT: Laboratory-Developed Tests: Proposed Rule, Reclassification Activities, Potential Impact and Path Forward

Moderator: B. Melina Cimler, PhD, CEO & Founder, PandiaDx

Laboratory-developed tests (LDTs) are an important part of healthcare. The FDA released a proposed rule September 29th, 2023 that seeks to amend the FDA's regulations to make explicit that IVDs are devices under the Federal FD&C Act, including when the manufacturer of the IVD is a laboratory. FDA is proposing a policy under which the FDA intends to provide greater oversight of LDTs, through a phaseout of its general enforcement discretion approach to LDTs.

This panel brings together stakeholders to:

- Discuss elements of the proposed rule including classification of IVDs
- Impact on various stakeholders and expected activities
- CMS vs FDA roles as to oversight of laboratory tests
- Regulation of LDTs under the IVDR

Panelists:

Lauren S. Menser, CEO, Association for Molecular Pathology

Stefan Burde, PhD, Director, Global Strategic Business Development, IVD, TÜV SÜD

Girish Putcha, MD, PhD, Principal, Precision Medicine & Diagnostics LLC

POCT AND INFECTIOUS DISEASE STREAM

"NextGenDx Summit continues to impress. I appreciate the mix of science and commercial nature of the presentations as well as the incredible networking opportunities. For me, it hits that sweet spot of education and connection."

JORDAN S. LASER, MD, Chief Laboratory Officer, Everly Health

The **Point-of-Care and Infectious Disease stream** at the Next Generation Dx Summit focuses on the latest science and novel technologies to improve clinical outcomes by providing rapid results across a wide range of applications. State-of-the-art devices and testing methods will be highlighted along with strategies that continue to move diagnostics out into the market and to the consumer. This stream will examine how research institutions and diagnostic companies are applying new science and technology in developing next-generation POC and infectious disease tests and devices.

AUGUST 19-20:

Enabling Point-of-Care Diagnostics

AGENDA

AUGUST 20-21:

Advanced Diagnostics for Infectious Disease

AGENDA

ENABLING POINT-OF-CARE DIAGNOSTICS

Expediting Rapid Testing for at-Home, Clinical Lab, and Pharmacy Settings

POCT AND INFECTIOUS DISEASE

MONDAY, AUGUST 19

7:15 am Registration Open and Morning Coffee

8:20 Organizer's Welcome Remarks

INTEGRATION OF CGM FOR PATIENT CARE

8:25 Chairperson's Remarks

James Nichols, PhD, DABCC, FADLM, Professor of Pathology, Microbiology, and Immunology; Medical Director, Clinical Chemistry and POCT, Vanderbilt University School of Medicine

8:30 KEYNOTE PRESENTATION: Performance Metrics for Continuous Glucose Monitors

James Nichols, PhD, DABCC, FADLM, Professor of Pathology, Microbiology, and Immunology; Medical Director, Clinical Chemistry and POCT, Vanderbilt University School of Medicine

CGM systems are medical devices that measure glucose in the interstitial fluid just under the skin. This presentation will discuss how CGM is utilized in patient care and management of diabetes. The CLSI guideline, POCT05: Performance Metrics for Continuous Interstitial Glucose, will be discussed including how CGM data should be assessed for accuracy and CGM systems should be operated for quality performance. Challenges with interfacing CGM data will be highlighted.

9:00 Continuous Glucose Monitoring in the Hospital Setting

Guillermo Umpierrez, MD, CDCES, FACE, MACP, Professor of Medicine, Emory University School of Medicine

Recent observational and randomized controlled studies in the hospital setting have reported acceptable accuracy and a greater ability to detect hypoglycemia of intermittently scanned and real-time CGM when compared with capillary POC testing. RCTs have also reported on the safety and efficacy of real-time CGM in guiding daily insulin adjustment in hospitalized patients with Type 1 and Type 2 diabetes. CGM provides information about glucose concentration and direction.

9:30 Presentation to be Announced

9:45 Method to Observe Bubble Removal in MDx Panels to Help Down-Select, Sort, or Optimize Vent Materials during Development

Tyler Hinkle, Head of R&D Life Science Venting, Gore

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

10:45 CGM Data Integration into the Electronic Health Record

Juan Espinoza, MD, Chief Research Informatics Officer, Stanley Manne Children's Research Institute, Ann & Robert H. Lurie Children's Hospital of Chicago; Director, Consortium for Technology & Innovation in Pediatrics (CTIP); Associate Director, Center for Biomedical Informatics and Data Science, Northwestern University Feinberg School of Medicine

Continuous glucose monitors (CGMs) are an important technology for improving glycemic outcomes in diabetes. However, in most care settings, CGM data is siloed in manufacturer-specific data platforms and is not integrated with the electronic health record (EHR). The state of CGM-EHR integration has advanced rapidly, but new policies, technologies, and funding mechanisms will need to be put in place to ensure broad access to and implementation of CGM-EHR integrations.

11:15 FEATURED PRESENTATION: Intelligent Diagnostics Fusion: The Synergy of Generative AI and POCT

Bernard Gouget, PhD, Chair, IFCC Committee on Mobile Health and Bioengineering in Laboratory Medicine (C-MHBLM)

The presentation explores the synergy between smart point-of-care testing (POCT) technologies and Generative AI. By leveraging these tools, novel models for collaborative and integrated care systems emerge, revolutionizing healthcare delivery. This interdisciplinary approach promises to enhance diagnostic accuracy, streamline processes, and optimize patient outcomes. By embracing innovation at the intersection of healthcare and technology, this approach aims to redefine standards in healthcare delivery and prioritize patient-centered care.

11:45 Presentation to be Announced

12:15 pm Luncheon Presentation to be Announced

The Co-Dx PCR platform is a new real-time PCR testing technology for at-home and point-of-care use, with a portable PCR instrument that operates via a smartphone interface to enable affordable PCR testing, powered by Patented Co-Dx Co-Primers PCR technology.

12:45 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Session Break

THE ROCKY ROAD TO POCT SUCCESS: OBTAINING REGULATORY CLEARANCE AND APPROPRIATE CLIA LEVEL

1:30 Chairperson's Remarks

Lawrence Worden, Founder, Principal, IVD Logix

1:35 Business as Unusual: The Impact of the Pandemic on the FDA's Regulation of IVDs

Elliot Cowan, PhD, Principal, Partners in Diagnostics LLC

The COVID pandemic demanded that the FDA respond in ways that, arguably, it had not done previously, This was especially the case for *in vitro* diagnostics. That extraordinary effort left in its wake a legacy of positives and negatives for the FDA's regulation of IVDs. This talk will highlight what the industry can expect from the agency going forward, both the good and the challenging.

2:05 Clinical Study Strategies for POCT Technologies in a Post-Pandemic World

Joen T. Johansen, President & CEO, MDC Associates LLC

Speed-to-market and controlling costs are critical factors for manufacturers assessing their clinical study strategies. Study design and execution needs to ensure all FDA requirements are met while at the same time limiting over-enrollment and longer study timelines that inevitably increase costs to sponsors. We will present strategies that support fast and efficient study design for a range of POCT devices.

2:35 Centering Your End User: Roadmap to Defining and Testing POCT Usability Requirements

Aarti Swaminathan, Manager, Human Factors/User Research, TE IVD Solutions

Your end user influences product performance, from market research through clinical trials. Ensuring that you design for these end users, their use environments, capabilities, and biases is vital to product success. Capturing requirements early and iteratively reaffirming them with testing is critical to this goal. This presentation will talk about how to identify end users, generate relevant requirements, and execute necessary usability testing that brings confidence to all stakeholders.

3:05 Refreshment Break in the Exhibit Hall with Poster Viewing

3:45 PANEL DISCUSSION: The Rocky Road to POCT Success: Obtaining Regulatory Clearance and Appropriate CLIA Level

Moderator: Lawrence Worden, Founder, Principal, IVD Logix

Panelists:

Elliot Cowan, PhD, Principal, Partners in Diagnostics LLC

Joen T. Johansen, President & CEO, MDC Associates LLC

Aarti Swaminathan, Manager, Human Factors/User Research, TE IVD Solutions

4:45 Increasing Access to Point-of-Care Diagnostics through Innovative Advances in Molecular Reagents for Assay Development meridian BIOSCIENCE

Lina Gasiunaite, Team Leader, R&D, Meridian Bioscience

Despite gaining traction in diagnostics, molecular Point-of-Care (POC) tests face challenges related to accessibility, stability, and ease of workflow. This session explores innovative molecular reagents that enable direct detection without the need for extraction and offer ambient temperature stability, advancing key diagnostic technologies like qPCR and isothermal methods for use at the point-of-care.

5:15 Welcome Reception in the Exhibit Hall with Poster Viewing

6:30 Close of Day

TUESDAY, AUGUST 20

7:15 am Registration Open

7:30 Interactive Discussions with Continental Breakfast

Interactive discussions provide an opportunity to discuss a focused topic with peers from around the world in an open, collegial setting. Select from the list of topics available and join the moderated discussion to share ideas, gain insights, establish collaborations or commiserate about persistent challenges. Please visit the interactive discussions page on the conference website for a complete listing of topics and descriptions.

IN-PERSON ONLY BREAKOUT: How to Successfully Partner with DDDI and BARDA

Christopher J. Knickerbocker, Contracting Officer Representative, United States Department of Health and Human Services

Kristy Stoudt, PhD, Biologist and Project Officer, Biomedical Advanced Research and Development Authority (BARDA)

- Preliminary inquiries and interactions
- Funding mechanisms
- BAA solicitation process (Stage I – III)
- Key questions before starting a submission/advice for submitters.

FUTURE TRENDS IN POCT

8:25 Co-Chairperson's Remarks

Norman Moore, PhD, Volwiler Senior Associate Research Fellow, Director, Infectious Diseases, Scientific Affairs, Abbott

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

8:30 Future Diagnostics Needs at the Point-of-Care

Norman Moore, PhD, Volwiler Senior Associate Research Fellow, Director, Infectious Diseases, Scientific Affairs, Abbott

The trend toward increased point-of-care testing was accelerated due to the COVID-19 pandemic. Patients now expect high-quality results with far greater convenience. Point-of-care testing must give the appropriate results in a timely fashion while also being easy enough to be performed by people with different trainings.

8:45 Embracing the Evolution of Diagnostic Testing for Public Health Outbreaks and Emergencies

Reynolds M. Salerno, PhD, Director, Lab Systems & CSELS, Center for Disease Control & Prevention

The COVID-19 pandemic brought about significant shifts in the diagnostic testing landscape as it pertains to public health outbreaks and emergencies. We witnessed the rapid expansion of both point-of-care testing and self-testing that empowered patients and providers as never before. These advances will continue to impact future public health threats, and we must embrace the role of private sector clinical diagnostics in future public health responses.

9:00 Pronounced Impacts of PAMA on Point-of-Care Testing

Nicholas Halzack, MPH, Director, Health Policy, Roche Diagnostics

The way that Medicare laboratory reimbursement is currently set under PAMA results in uniquely challenging dynamics for point-of-care tests. Understanding how PAMA impacts the Medicare Clinical Laboratory Fee Schedule and how point-of-care testing fits into that system has implications for legislative, regulatory, and coding reform.

9:15 Family Story

Michele Slafkosky, Executive Director, Families Fighting Flu

Families Fighting Flu will share a personal story on how serious the flu can be and the importance of taking symptoms seriously and seeing a healthcare provider for accurate testing to receive appropriate treatment.

9:30 PANEL DISCUSSION: Future Trends in POCT

Moderator: Deborah R. Godes, Vice President, McDermott+Consulting LLC

Panelists:

Nicholas Halzack, MPH, Director, Health Policy, Roche Diagnostics

Reynolds M. Salerno, PhD, Director, Lab Systems & CSELS, Center for Disease Control & Prevention

Michele Slafkosky, Executive Director, Families Fighting Flu

10:00 Seek Labs Proudly Introduces the SeekIt Platform, a Groundbreaking Advancement in POC Diagnostics seek LABS

Jared Bauer, CEO, Seek Labs

Seek Labs proudly introduces the SeekIt Platform, a groundbreaking advancement in POC diagnostics. The SeekIt Platform represents a paradigm shift in the industry; Seek Labs has innovated an easy-to-use, laboratory-quality molecular diagnostic system specifically designed for POC settings. Join us as we unveil this transformative technology and discuss the importance of innovating solutions that empower patients.

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

ENABLING POINT-OF-CARE DIAGNOSTICS

Expediting Rapid Testing for at-Home, Clinical Lab, and Pharmacy Settings

PLENARY SESSION

11:30 PLENARY KEYNOTE PRESENTATION: Talk Title to be Announced

Courtney H. Lias, PhD, Acting Director, OHT7: Office of in vitro Diagnostic Devices, United States Food and Drug Administration (FDA)

12:00 pm Plenary Fireside Chat Introduction (Sponsorship Opportunity Available)

12:10 PLENARY FIRESIDE CHAT: Laboratory-Developed Tests: Proposed Rule, Reclassification Activities, Potential Impact, and Path Forward




Moderator: B. Melina Cimler, PhD, CEO & Founder, PandiaDx LLC

Laboratory-developed tests (LDTs) are an important part of healthcare. The FDA released a proposed rule on September 29, 2023, that seeks to amend the FDA's regulations to make explicit that IVDs are devices under the Federal FD&C Act, including when the manufacturer of the IVD is a laboratory.

Panelists:

Stefan Burde, PhD, Director, Global Strategic Business Development, TÜV SÜD America, Inc.

Laurie Menser, CEO, Association for Molecular Pathology

Girish Putcha, MD, PhD, Principal & Founder, Precision Medicine & Diagnostics

1:10 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

2:10 Close of Enabling Point-of-Care Diagnostics Conference

TUESDAY, AUGUST 20

10:30 am Registration Open

PLENARY SESSION

11:30 PLENARY KEYNOTE PRESENTATION: Talk Title to be Announced

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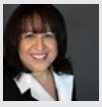


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Girish Putcha, MD, PhD, Principal & Founder, Precision Medicine & Diagnostics

1:10 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

2:25 Organizer's Welcome Remarks

HOST RESPONSE TESTING FOR INFECTIOUS DISEASES

2:30 Chairperson's Remarks

Timothy Sweeney, MD, PhD, Co-Founder & CEO, Inflammatix, Inc.

2:35 Bacterial vs.Viral Tests: How Do We Implement Appropriate Use of an Appropriate Use Tool?

Tanya Gottlieb, PhD, Vice President, Scientific Affairs, MeMed

Highly accurate and rapid, host-based tools for differentiating between bacterial and viral infection have great potential to support appropriate antibiotic use, reduce clinical uncertainty and care variance, and improve operational efficiencies. The challenge is to identify best practices for implementation to ensure these added value dimensions are realized in real-world settings. This talk will consider the interplay of clinical workflows and target patient populations in clinical evidence approaches.

3:05 Host-Response Testing in Suspected Acute Infections and Sepsis

Timothy Sweeney, MD, PhD, Co-Founder & CEO, Inflammatix, Inc.

The diagnosis and prognosis of patients with suspected acute infection and suspected sepsis remains a clinical challenge. Novel tests offer the potential to improve patient and health system outcomes. We will discuss how these new technologies work and how they might be clinically applied.

3:35 FebriDx Point-of-Care Test: Detection of Host Immune Response to Bacterial Respiratory Infections

Annie Bell, Senior Director & Head, Medical Affairs, Lumos Diagnostics

This presentation will focus on FebriDx, a novel technology designed to detect and rule out bacterial acute respiratory infection at the point-of-care. FebriDx uses two host response biomarkers to aid clinicians in balancing their need to rapidly detect and treat bacterial infection while also contributing to antimicrobial stewardship efforts by accurately ruling out bacterial infection and avoiding the prescription of unnecessary antibiotics. This presentation will review the science behind tests.

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing

USING INNOVATIVE SPECIMEN TYPES/SAMPLING FOR DIAGNOSIS OF INFECTIOUS DISEASES

4:45 Non-Invasive Screening for Tuberculosis: Applying the Lessons of COVID-19 to the World's Worst Pathogen

Gerard A. Cangelosi, PhD, Professor, Environmental & Occupational Health Sciences, University of Washington

Tuberculosis case finding is hampered by the need to collect sputum. We have found that most pulmonary tuberculosis cases can instead be identified by testing tongue swab samples, which are easy to collect from any person in any setting. In the same way that non-invasive nasal swabbing replaced nasopharyngeal swabbing and enabled mass screening for COVID-19, tongue swabbing could enable entirely new strategies for tuberculosis diagnosis, screening, and control.

5:15 Rapid Screening via Smartphone for TB

Thomas R. Hawn, MD, PhD, Professor, Allergy and Infectious Diseases, University of Washington

We used a machine learning classifier to develop TBScreen, a cough-based respiratory disease diagnostic screening assay which discriminates between TB and non-TB-related passive coughs. We trained and evaluated a dataset of 33K coughs with a ResNet18-based classifier. Passive cough spectral features distinguished TB and non-TB groups. TBScreen can be deployed on a smartphone and identifies cough features associated with bacterial burden and disease severity.

5:45 Sponsored Presentation *(Opportunity Available)*

6:15 Close of Day

WEDNESDAY, AUGUST 21

7:15 am Registration Open

7:30 Interactive Discussions with Continental Breakfast

Interactive discussions provide an opportunity to discuss a focused topic with peers from around the world in an open, collegial setting. Select from the list of topics available and join the moderated discussion to share ideas, gain insights, establish collaborations or commiserate about persistent challenges. Please visit the interactive discussions page on the conference website for a complete listing of topics and descriptions.

IN-PERSON ONLY BREAKOUT: How to Successfully Partner with DDDI and BARDA

Christopher J. Knickerbocker, Contracting Officer Representative, United States Department of Health and Human Services

Kristy Stoudt, PhD, Biologist and Project Officer, Biomedical Advanced Research and Development Authority (BARDA)

- Preliminary inquiries and interactions
- Funding Mechanisms
- BAA Solicitation Process (Stage I – III)
- Key questions before starting a submission/Advice for Submitters

USE OF NEXT-GENERATION SEQUENCING FOR INFECTIOUS DISEASE DIAGNOSIS

8:25 Chairperson's Remarks

Jennifer Dien Bard, PhD, D(ABMM), Director, Microbiology and Virology, Children's Hospital Los Angeles; Professor, Pathology and Laboratory Medicine, Keck School of Medicine, University of Southern California

8:30 Options, Obstacles, and Opportunities for Send-Out NGS Tests and in-House Development for Clinical Microbiology

David C. Gaston, MD, PhD, Assistant Professor, Department of Pathology, Microbiology, and Immunology, Medical Director, Molecular Infectious Diseases Laboratory (MIDL), Vanderbilt University Medical Center

NGS-based diagnostics for infectious diseases are advancing from pioneering studies to practice implementation. This talk will provide an overview of currently available assays from reference laboratories, as well as perspectives on independent assay development. Topics will include best-use practices to optimize value, the importance of collaborative diagnostic stewardship, and a focus on data quality for patient safety.

9:00 Next-Generation Sequencing for Infectious Diseases: Applications, Breakthroughs, and Challenges

Kyle Rodino, PhD, D(ABMM), Assistant Professor, Pathology and Laboratory Medicine, Perelman School of Medicine, University of Pennsylvania; Assistant Director, Clinical Microbiology Laboratory; Director, Rittenhouse Molecular Laboratory, Hospital of the University of Pennsylvania

Next-generation sequencing (NGS) has found multiple applications in infectious diseases diagnostics, including infection prevention, pathogen detection, and antimicrobial resistance prediction. While great advancement has been made in these areas, we must identify and address remaining challenges to move infectious diseases NGS into routine practice.

9:30 A Tech-Driven and Community-Based Approach to Recruiting and Executing Effective Infectious Disease Diagnostics Studies

LindusHealth

Meri Beckwith, Co-Founder, Lindus Health Ltd.

Valentina Milanova, Founder & CPO, Daye Ltd.

Infectious disease diagnostic trials face unique challenges differing from other areas of clinical research. This session explores innovative strategies for faster, cost-effective market entry while ensuring high-quality evidence. We'll discuss decentralized recruitment, including digital marketing and local care integration, plus tactics like home-based pre-screening and sample collection. Highlighting a case study with Daye, we unveil methods making studies more efficient and patient-centric.

9:45 Sponsored Presentation *(Opportunity Available)*

10:00 Networking Coffee Break

10:30 Interpreting Infectious Next-Generation Sequencing: The Medical Microbiologist's Role

Cristina Costales, MD, Assistant Director, Clinical Microbiology and Virology, Department of Pathology and Laboratory Medicine, Children's Hospital Los Angeles

As new applications of infectious NGS testing are being implemented in both clinical and commercial laboratories, the medical microbiologist plays a key role in assay interpretation and communication of results. Here we will utilize several case-based examples of the challenges in NGS result reporting and suggestions for best practice.

11:00 Prediction of Antimicrobial Susceptibility Using Sequencing Approaches

Rebecca Yee, PhD, D(ABMM), Chief of Microbiology and Assistant Professor, Department of Pathology, George Washington University

Next-generation sequencing methods allow for comprehensive detection of antimicrobial resistance genes. Here, we will discuss the current NGS technologies and approaches to study antimicrobial resistance and predict antimicrobial susceptibility.

11:30 Alternates to Metagenomic Testing that Can Be Explored for Fungal Disease

Esther Babady, PhD, D(ABMM), FIDSA, FAAM, Chief, Clinical Microbiology Service, Memorial Sloan Kettering Cancer Center

Invasive Fungal Diseases are a significant cause of mortality and morbidity, especially in immunocompromised patients population. Metagenomics is being explored as an emerging method for the diagnosis of invasive fungal diseases but is still not widely available, costly and its performance characteristic remains to be established. This talk will discuss available molecular diagnostic methods currently more readily available, cost-effective and may be used to improve the diagnosis of fungal diseases

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* or Enjoy Lunch on Your Own

1:00 Session Break

DIAGNOSTIC STEWARDSHIP

1:10 Chairperson's Remarks

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

1:15 KEYNOTE PRESENTATION: Diagnostic Stewardship: Current and Future Tools

Gary W. Procop, MD, CEO, Professor of Pathology, American Board of Pathology

The impact of a variety of tools that may be used to optimize diagnostic stewardship will be reviewed. The potential future benefits of the use of artificial intelligence and machine learning in this space will be considered. Evidence will be presented that diagnostic stewardship efforts can improve healthcare delivery and patient satisfaction, while decreasing healthcare costs.

1:45 Strategic Synergy: Elevating Diagnostic Stewardship through Health System Leadership

Allison Chambliss, PhD, DABCC, FADLM, Associate Clinical Professor, Department of Pathology & Laboratory Medicine, University of California, Los Angeles

I will describe UCLA Health's laboratory stewardship program and governance structure as an example of how to get started with effective laboratory stewardship for a large health system. I will discuss our program's initial successes, including establishing oversight and data monitoring for referral lab (send-out) testing and inpatient genetic testing.

2:15 First, Do No Harm: Challenges in Stewarding and Interpreting Plasma mNGS from a Lab Perspective

Hannah Wang, MD, D(ABMM), Assistant Professor of Pathology, Cleveland Clinic, Lerner College of Medicine; Medical Director, Molecular Microbiology & Virology Laboratories, Robert J. Tomsich Department of Pathology and Laboratory Medicine, Diagnostics Institute, Cleveland Clinic

Increasingly complex and expensive sequencing-based tests for the diagnosis of infectious diseases are becoming more commonly used. They can be extremely helpful in some instances, and highly misleading or wasteful in others. The literature is variable and influenced by publication bias. This case-based presentation highlights challenges in stewardship and interpretation of plasma metagenomic sequencing from a laboratory perspective.

2:45 POINT/COUNTERPOINT DEBATE: Diagnostic Stewardship and Metagenomics: Does It Do More Harm than Good?

Co-Moderators:

Jennifer Dien Bard, PhD, D(ABMM), Director, Microbiology and Virology, Children's Hospital Los Angeles; Professor, Pathology and Laboratory Medicine, Keck School of Medicine, University of Southern California

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

The panel will explore the use cases of metagenomics for the diagnosis of infectious diseases, the cost and reimbursement environment for metagenomics, and the complexities of metagenomic result interpretation.

Panelists:

Blake W. Buchan, PhD, Associate Professor, Pathology, Medical College of Wisconsin

Christopher Doern, PhD, D(ABMM), Director of Microbiology, Associate Professor of Pathology, Virginia Commonwealth University Health System/Medical College of Virginia

3:45 Close of Summit

COMPANION DX AND REIMBURSEMENT STREAM

"I was struck by the diversity of the attendees that enabled well-rounded discussion on early detection in terms of technology, performance, regulatory as well as clinician and patient experience."

Gulfem Guler, PhD, Director, Translational Research, Bluestar Genomics

The **Companion Diagnostics and Reimbursement stream** at the Next Generation Dx Summit will focus on the future of diagnostic development through a complementary set of lenses, including global and domestic regulations, partnerships and commercialization, and coverage and reimbursement. As diagnostics become increasingly varied and personalized—and regulations continue to evolve—it is imperative to facilitate collaboration. The conference stream will bring together major players from industry, regulators, payers, and labs to tackle emerging challenges, collaborate on workstreams, and ultimately determine what companion and advanced diagnostics will look like going forward.

AUGUST 19-20:

Advancing Novel Frameworks for Companion Diagnostics

AGENDA

AUGUST 20-21:

Emerging Trends in Coverage and Reimbursement for Advanced Diagnostics

AGENDA

ADVANCING NOVEL FRAMEWORKS FOR COMPANION DIAGNOSTICS

Collaborating on the Future of Drug-Diagnostic Co-Development

MONDAY, AUGUST 19

7:15 am Registration Open and Morning Coffee

8:20 Organizer's Welcome Remarks

FDA's CDx OCE PILOT PROGRAM

8:25 Chairperson's Remarks

Dun Liang, PhD, Executive Director, Regulatory Affairs, Companion Diagnostics, Loxo@Lilly

8:30 Oncology CDx Regulation: Implications of the OCE Dx Pilot Program in Drug Development

Dun Liang, PhD, Executive Director, Regulatory Affairs, Companion Diagnostics, Loxo@Lilly

This informative presentation will offer an oncology-centric discussion of current US companion diagnostic (CDx) regulation with focus on FDA Pilot Program for Oncology Drug Products Used with Certain *In Vitro* Diagnostic Tests and relevant FDA CDx/Dx regulatory guidance. Attendees will benefit from discussion of the pilot, including potential challenges in implementation, comparison to current CDx regulation, and the implications of a changing US CDx regulatory landscape to oncology drug development.

9:00 PANEL DISCUSSION: FDA/OCE Oncology Drug Products Used with Certain *in vitro* Diagnostic Tests Pilot Program: Opportunities, Challenges, and Implications

Moderator: Sarah K. Martin, MS, PhD, Senior Director, Global Regulatory Policy, Eli Lilly and Company

The session will conclude with an expert, multi-stakeholder panel discussion that will feature regulatory, industry, academic medical center laboratory, and patient perspectives. The panelists will explore benefits of the voluntary FDA/OCE Oncology Drug Products Used with Certain *in vitro* Diagnostic Tests Pilot Program, define potential challenges associated with implementation, and propose solutions to advance the program.

Panelists:

Shannon A. Bennett, MS, Director, Regulatory Affairs, Mayo Clinic & Foundation

Tod Guidry, PhD, Associate Director, Regulatory and Diagnostics Policy, LUNGevity Foundation

Dun Liang, PhD, Executive Director, Regulatory Affairs, Companion Diagnostics, Loxo@Lilly

Lakshman Ramamurthy, PhD, Vice President Regulatory Affairs, GRAIL

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

PREPARING FOR FDA's LDT PROPOSED RULE

10:45 Impact of FDA Changes to the Regulation of LDTs and IVDs on Companion Diagnostics and Drug Trials

Kate A. Simon, PhD, Senior Director, Global Regulatory Strategy IVD, Bayer

FDA published a proposed rule in October 2023 to more clearly assert their authority to regulate Laboratory Developed Tests (LDTs). FDA also recently announced their intention to down-classify most *in vitro* diagnostic (IVD) tests that are currently Class III. This talk will provide a summary of the key aspects of these FDA proposals and will also cover the potential impact(s) to companion diagnostics and drug clinical trials.

11:15 FDA Regulation of LDTs—The Laboratory Perspective

Shannon A. Bennett, MS, Director, Regulatory Affairs, Mayo Clinic & Foundation

Laboratory-developed tests (LDTs) have been subject to FDA enforcement discretion for decades, but in the last ten years, the Agency has expressed a desire for greater oversight. Guidance documents and attempts at legislation have failed, so in the Spring of 2024, FDA released regulations placing LDTs into the medical device regulatory framework. This change will dramatically change the diagnostic testing landscape, particularly for clinical laboratories that develop LDTs.

11:45 Sponsored Presentation *(Opportunity Available)*

12:15 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Session Break

THE FUTURE OF CDx FOR NON-ONCOLOGY INDICATIONS

1:30 Chairperson's Remarks

Jai Pandey, PhD, Head, Global Device Regulatory IVD/CDx and Digital Health, Sanofi

1:35 Regulatory Considerations for Companion Diagnostic Devices beyond Oncology

Jai Pandey, PhD, Head, Global Device Regulatory IVD/CDx and Digital Health, Sanofi

Companion diagnostic devices play a crucial role in personalized medicine by helping healthcare professionals identify the most appropriate treatment for a patient based on their genetic, molecular, or other specific characteristics. Due to the unique nature of these devices, there are several regulatory considerations that must be taken into account to ensure their safety and effectiveness. These considerations include regulatory authorities, classification, clinical and analytical validation, and labeling.

2:05 Expanding Companion Diagnostics beyond Oncology: A Regulatory Perspective

Vihanga Pahalawatta, PhD, Director, Regulatory Affairs Device and Combination Products, AbbVie, Inc.

Most companion diagnostics (CDx) support therapeutic endeavors in oncology. Additional disease areas in which CDx has the potential to improve the likelihood of success for drugs in development include immunology, neuroscience, and rare/orphan diseases. Despite the potential for expanded use of CDx, regulatory hurdles pose a key challenge. The current regulatory paradigm may need to evolve for further expansion of the utility of CDx in disease areas other than oncology.

2:35 Presentation to be Announced

3:05 Refreshment Break in the Exhibit Hall with Poster Viewing

PHARMA-DIAGNOSTIC CO-DEVELOPMENT

3:45 Drug and Diagnostic Co-Development and Regulatory Pathways

B. Melina Cimler, PhD, CEO & Founder, PandiaDx LLC

Drug and diagnostic co-development has accelerated the availability of novel therapeutics. This session will focus on key regulatory changes and potential impact on bringing companion diagnostics to market. Lessons learned from partnerships between pharma and diagnostic stakeholders and future trends will be shared.

4:15 A Framework for Simultaneously Validating Multiple Companion Diagnostic Assays in a Global Clinical Trial

Songbai Wang, MD, MSPH, Head, Precision Informatics, Oncology Precision Medicine and Diagnostics, Johnson & Johnson

We have developed a novel framework based on advanced analytic methods to simultaneously validate all candidate companion diagnostic tests without increasing the size of clinical trials and samples. We conclude this novel strategy is preferred over the existing methods (such as noninferiority external

concordance, attenuation factor, and missing data imputation) from the perspective of data totality and benefit-risk principle.

4:45 Sponsored Presentation *(Opportunity Available)*

5:15 Welcome Reception in the Exhibit Hall with Poster Viewing

6:30 Close of Day

TUESDAY, AUGUST 20

7:15 am Registration Open

7:30 Interactive Discussions with Continental Breakfast

Interactive discussions provide an opportunity to discuss a focused topic with peers from around the world in an open, collegial setting. Select from the list of topics available and join the moderated discussion to share ideas, gain insights, establish collaborations or commiserate about persistent challenges. Please visit the interactive discussions page on the conference website for a complete listing of topics and descriptions.

GLOBAL REGULATORY LANDSCAPE

8:25 Chairperson's Remarks

Albine K. Martin, PhD, Executive-in-Residence, BioHealth Innovation; Entrepreneur-in-Residence, Johns Hopkins University

8:30 Navigating Companion Diagnostic Co-Development in an Evolving Global Regulatory Environment

Grace Lee, Associate Vice President, CDx Global Regulatory Affairs, Agilent Technologies, Inc.

The global regulatory landscape for companion diagnostics has evolved, including in markets such as the EU, the UK, Australia, and China. Co-development planning should consider ex-US regulatory strategy early to mitigate costly barriers to entry or delays in global testing. This presentation will review how companion diagnostics are regulated in different regions and best practices for coordinating activities between diagnostic companies, Pharma partners, and regulators.

9:00 Advancing Novel Frameworks for Companion Diagnostics in Europe

Rolf Thermann, PhD, Section Manager, IVD and Companion Diagnostics Lead, TUEV Rheinland AG

With the implementation of the new EU regulation on *in vitro* diagnostics (IVDR) in May 2022, notified bodies will be required to perform a conformity assessment for companion diagnostics (CDx). As part of the conformity assessment of a CDx, the notified body consults the European Medicines Agency on a scientific opinion on the suitability of the CDx with the concerned medicinal product(s), which will be discussed.

9:30 PANEL DISCUSSION: Putting the Pieces Together: Bringing Companion Diagnostics through Development to Market

Moderator: Albine K. Martin, PhD, Executive-in-Residence, BioHealth Innovation; Entrepreneur-in-Residence, Johns Hopkins University

This panel discussion will bring together key perspectives on companion diagnostic development and success in the market. The discussion will look at how technology selection, regulatory factors, development strategy, and clinical outcomes all impact CDx advancement in established and emerging indications.

10:00 Sponsored Presentation *(Opportunity Available)*

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

PLENARY SESSION

11:30 PLENARY KEYNOTE PRESENTATION: Talk Title to be Announced

Courtney H. Lias, PhD, Acting Director, OHT7: Office of in vitro Diagnostic Devices, United States Food and Drug Administration (FDA)

12:00 pm Plenary Fireside Chat Introduction (Sponsorship Opportunity Available)

12:10 PLENARY FIRESIDE CHAT: Laboratory-Developed Tests: Proposed Rule, Reclassification Activities, Potential Impact, and Path Forward




Moderator: B. Melina Cimler, PhD, CEO & Founder, PandiaDx LLC

Laboratory-developed tests (LDTs) are an important part of healthcare. The FDA released a proposed rule on September 29, 2023, that seeks to amend the FDA's regulations to make explicit that IVDs are devices under the Federal FD&C Act, including when the manufacturer of the IVD is a laboratory.

Panelists:

Stefan Burde, PhD, Director, Global Strategic Business Development, TÜV SÜD America, Inc.

Laurie Menser, CEO, Association for Molecular Pathology

Girish Putcha, MD, PhD, Principal & Founder, Precision Medicine & Diagnostics

1:10 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

2:10 Close of Advancing Novel Frameworks for Companion Diagnostics Conference

EMERGING TRENDS IN COVERAGE AND REIMBURSEMENT FOR ADVANCED DIAGNOSTICS

Assessing and Anticipating the Future of Diagnostic Reimbursement

TUESDAY, AUGUST 20

10:30 am Registration Open

PLENARY SESSION

11:30 PLENARY KEYNOTE PRESENTATION: Talk Title to be Announced

Courtney H. Lias, PhD, Acting Director, OHT7: Office of in vitro Diagnostic Devices, United States Food and Drug Administration (FDA)

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Girish Putcha, MD, PhD, Principal & Founder, Precision Medicine & Diagnostics

1:10 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

2:25 Organizer's Welcome Remarks

GROWTH IN MEDICARE ADVANTAGE AND ROLE OF PRIOR AUTHORIZATION

2:30 Chairperson's Remarks

Sarah Thibault-Sennett, PhD, Senior Director, Reimbursement Policy, American Clinical Lab Association

2:35 KEYNOTE PRESENTATION: Labs and Utilization Management Procedures: Why Don't Positive Coverage Policies Result in Real-World Reimbursement?

Sarah Thibault-Sennett, PhD, Senior Director, Reimbursement Policy, American Clinical Lab Association

The US payer landscape is incredibly diverse with public and private payers in addition to laboratory benefit managers who use constantly evolving prior authorization and other utilization management procedures. This session will explore the challenges for labs to successfully navigate these various utilization management procedures and highlight current advocacy activities to respond to these issues.

3:05 Case Study in Addressing Root Cause Access Issues for Exome and Genome Sequencing in Pediatric Rare Disease

Stacey Brown, Market Access Lead, Optum Genomics

This session will review at least one case study, involving implementation across several healthcare ecosystem stakeholders (payer, provider, industry), aimed at addressing various issues associated with the commercial clinical adoption of exome and genome sequencing in pediatric rare disease.

3:35 Talk Title to be Announced

Lon Castle, MD, Associate CMO, Precision Medicine, EviCore

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing

PRICE SETTING AND VALUATION FOR NOVEL DIAGNOSTICS

4:45 Impact of CMS Rate-Setting on Access for Novel Tests

Nicholas Halzack, MPH, Director, Health Policy, Roche Diagnostics

The process by which CMS establishes reimbursement rates for new codes appearing on the Medicare Clinical Laboratory Fee Schedule can be opaque and unpredictable, resulting in significant uncertainty for novel technologies entering the market. This presentation will discuss the crosswalk and gap-fill processes, their impact on private payers and PAMA implementation, and potential policy solutions to improve them.

5:15 PANEL DISCUSSION: Pricing and Valuation of Novel Diagnostic Tests

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

In the US, novel diagnostics must first become anchor-priced by Medicare. The process involves Medicare accepting or rejecting a "crosswalk" amount or pushing the novel assay into the gap-fill process. This panel will discuss this process and seeks to address improvements in the process. What is the value of a diagnostic? Is there a way to make the process more transparent? Is there a role for value-based pricing?

Panelists:

Gabriel Bien-Willner, MD, PhD, Medical Director, MolDx, Palmetto GBA

Hannah Mamuszka, Co-Founder & CEO, Alva10

5:45 Sponsored Presentation *(Opportunity Available)*

6:15 Close of Day

WEDNESDAY, AUGUST 21

7:15 am Registration Open

7:30 Interactive Discussions with Continental Breakfast

Interactive discussions provide an opportunity to discuss a focused topic with peers from around the world in an open, collegial setting. Select from the list of topics available and join the moderated discussion to share ideas, gain insights, establish collaborations or commiserate about persistent challenges. Please visit the interactive discussions page on the conference website for a complete listing of topics and descriptions.

NATIONAL UPDATES ON MEDICARE AND MOLDx

8:25 Chairperson's Remarks

Megan Anderson Brooks, PhD, President, Innovation Policy Solutions LLC

8:30 What's New at CMS: Rapid Changes for Advanced Diagnostics

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

2024 is a busy year at CMS. New approaches to coverage are proposed (Transitional Coverage for Emerging Technologies). New rules are being tested to improve the often nightmarish swamp of getting Medicare

Advantage coverage and payments. Stakeholders continue to debate the dysfunctional 14-day rule that delays critical genomic tests for cancer patients. CMS struggles to handle AI testing ("indirect IDTFs" vs. procedure "bundling"). We'll update on all this and more.

9:00 Demystifying Molecular Diagnostics Coverage and Reimbursement in Medicare: MolDX

Gabriel Bien-Willner, MD, PhD, Medical Director, MolDx, Palmetto GBA

This talk will review the concepts and processes for molecular diagnostics payor controls. The discussion will include a description of 1) differentiating Medicare and private payors; 2) the difficulties of claims processing in molecular diagnostics; 3) DEX registry; 4) technical assessments; 5) how to approach Medicare for reimbursement; 6) policy-writing procedures for Medicare; 7) how payors consider evidence.

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Networking Coffee Break

TRENDS IN TESTING LEGISLATION

10:30 Congressional Action on Laboratory Test Pricing, Coverage, and Reimbursement: Trends and Outlook

Megan Anderson Brooks, PhD, President, Innovation Policy Solutions LLC

Despite the election year polarization, Congress is taking action that impacts laboratory test reimbursement—from conducting oversight to introducing legislation related to prior authorization, pricing, coverage, and more. This presentation will explore trends in Congress' approach to resolving barriers to reimbursement, as well as provide insights into what legislation is likely to advance and successful strategies for engaging policymakers to increase support for continued innovation in diagnostics.

11:00 Bringing the Promise of Precision Medicine to Patients Everywhere: State Legislative Solutions to Expand Access to Biomarker Testing

Hilary Gee Goeckner, MSW, Director, State and Local Campaigns, Access to Care, American Cancer Society Cancer Action Network (ACS CAN)

Biomarker testing is revolutionizing the treatment of cancer and other conditions but these advances are not benefiting all patients equally. Insurance coverage for biomarker testing is not keeping pace with the science, contributing to disparities in which patients can get the testing they need. ACS CAN and partners have worked to pass legislation in 16 states (and counting) to align coverage of biomarker testing with the latest evidence.

11:30 Navigating the Biomarker Testing State Legislative Landscape: Opportunities and Challenges for Clinical Laboratories

Chris Johnson, JD, Director, Government Affairs, Myriad Genetics

In recent years, state legislators have introduced dozens of measures requiring health insurers to cover a diverse array of biomarker tests. This surge in legislative activity reflects policymakers' commitment to enhancing access to biomarker testing. However, it also signifies a significant shift in market dynamics, presenting implementation challenges for affected stakeholders. Join us as we explore the evolving landscape of coverage and patient access within this dynamic field of medicine.

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:00 Session Break

CODING FOR NOVEL DIAGNOSTICS

1:10 Chairperson's Remarks

Tara Burke, PhD, Vice President, Payment and Healthcare Delivery Policy, AdvaMed

1:15 The Future of Coding for Genomics: AMA CPT Update

Zach Hochstetler, Director, CPT Editorial & Regulatory Services, American Medical Association

CPT codes to describe genomic tests have changed rapidly over the past few years. The CPT Editorial Panel, in response to consistent feedback to enhance the clarity of important areas of genomics, has created several workgroups to address these issues. Learn how over the past year several new coding paradigms have been approved by the CPT Panel to ameliorate issues in coding for genomic tests.

1:45 A Practical Understanding of Proprietary Laboratory Analysis (PLA) Codes and What to Consider When Requesting a PLA Code

Lee H. Hilborne, MD, Professor, Pathology & Lab Medicine, University of California Los Angeles

Proprietary Laboratory Analysis (PLA) codes, within the CPT codeset, began in 2018. Codes were driven by the Protecting Access to Medicare Act PAMA legislation requiring a solution to report clinical laboratory diagnostic tests more specifically for ADLTs, but also for CDLTs. This program discusses practical considerations when considering and requesting a PLA code for a unique test and then issues for assuring reimbursement once a code is recognized.

2:15 Improving Health Outcomes While Reducing Costs: Case Studies with Advanced Diagnostic Laboratory Tests (ADLTs)

Derek Maetzold, Founder, President, CEO, Castle Biosciences, Inc.

ADLTs represent innovative tests that "provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests." Since ADLTs are the first tests to address unmet clinical needs, a core question is if the evidence shows that (a) clinicians change their treatment pathways and (b) that these changes improve outcomes and reduce overall healthcare costs. Case studies will be presented.

2:45 PANEL DISCUSSION: Considerations for Bringing Novel Test Codes through the Price Setting Process

Moderator: Deborah R. Godes, Vice President, McDermott+Consulting LLC

This discussion will cover how labs can best participate in the price setting process and what CMS looks for in the codes and information submitted. Laboratories and diagnostic manufacturers will learn how better to navigate the clinical lab fee schedule and how stakeholders work together. Additionally, the talk will reflect on the lessons learned and key insights gleaned from the agency.

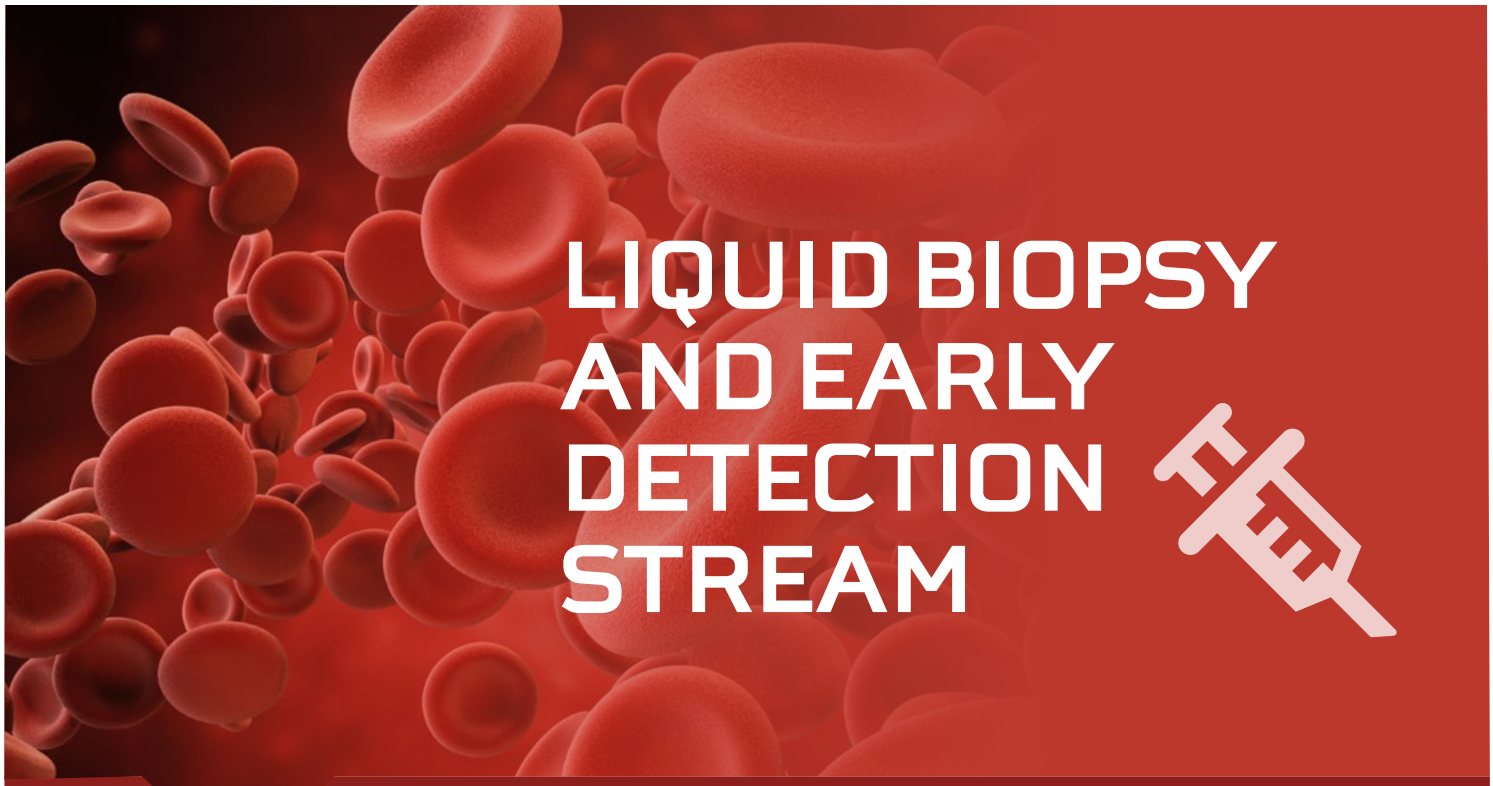
Panelists:

Tara Burke, PhD, Vice President, Payment and Healthcare Delivery Policy, AdvaMed

Joan Kegerize, JD, Vice President, Reimbursement & Scientific Affairs, American Clinical Laboratory Association

Samantha Pettersen, MPH, Senior Policy Analyst, Policy and Advocacy, Association for Molecular Pathology

3:15 Close of Summit



LIQUID BIOPSY AND EARLY DETECTION STREAM

"The Next Generation Dx Summit brings together experts in laboratory diagnostics to discuss advances in technology and how testing can be applied to care for patients. It's an excellent forum to share best practices and learn about cutting edge technology that has the potential to transform healthcare."

MATTHEW BINNICKER, PHD, Consultant, Division of Clinical Microbiology; Vice Chair of Practice, Department of Laboratory Medicine and Pathology, Mayo Clinic

While analysis of tissue biopsies has long been the gold standard for disease monitoring and characterization, the invasive nature of this approach limits its frequency and small tissue samples may make the biological material unrepresentative in some cases. These are some of the reasons that liquid biopsies have attracted considerable interest and development. Technical issues include the selection of different biomarker classes, methods for improving sensitivity and specificity, as well as clinical validation of specific applications. The Liquid Biopsy program focuses on a range of indications, with particular emphasis on oncology patients who have already been diagnosed. Tumor profiling for treatment selection and testing for cancer recurrence are key applications being developed. Early Cancer Surveillance focuses on a single, more challenging indication of early screening for cancer, where the genetics, or even the presence of cancer, is not known. While multi-cancer early detection (MCED) has the potential to significantly alter the course of cancer diagnostics, significant hurdles, both technical and otherwise, need to be overcome for commercial success.

AUGUST 19-20:

Liquid Biopsy for Disease Management

AGENDA

AUGUST 20-21:

Early Cancer Surveillance

AGENDA

MONDAY, AUGUST 19

7:15 am Registration Open and Morning Coffee

8:20 Organizer's Welcome Remarks

DISEASE BIOMARKERS FOR LIQUID BIOPSY: WHAT IS NEEDED FOR CLINICAL TRANSLATION?

8:25 Co-Chairperson's Remarks

Lokesh Agrawal, PhD, Program Director, Biorepositories & Biospecimen Research, NIH NCI

Chris Karlovich, PhD, Associate Director, Molecular Characterization Laboratory, Frederick National Laboratory for Cancer Research

8:30 KEYNOTE PRESENTATION: Role of Biospecimen Science in Understanding Clinical Biomarkers and Biobanking

Lokesh Agrawal, PhD, Program Director, Biorepositories & Biospecimen Research, NIH NCI

Biospecimens are the essential starting materials for the biomarker assays that enable precision medicine and preanalytical factors can directly influence molecular results from assays conducted for basic research, biomarker discovery, and biomarker validation, and can also influence the development of clinical assays. This talk will focus on role of biospecimen science in understanding clinical biomarkers and cover briefly.

8:50 Impact of Preanalytics in cfDNA Biomarker Development and Cancer Detection

Rena Xian, MD, FCAP, Assistant Professor, Pathology and Oncology, Johns Hopkins Medical Institutions

As cfDNA markers for cancer detection and monitoring become more accessible, there is a growing need to standardize preanalytical variables to ensure accurate and generalizable results. This talk will review the current recommendations for specimen collection, handling and processing, and will highlight efforts to enhance the sensitivity and specificity of tumor cfDNA detection.

9:10 Enabling Access to Genomic Profiling through Decentralized Liquid Biopsy Solution PGDx elio Plasma Focus Dx

Kenneth Valkenburg, PhD, Director of Research & Development, Labcorp Oncology

Liquid biopsy next-generation sequencing (NGS) assays help guide treatment selection in cancer patients, particularly when tumor tissue is unavailable or during disease progression. Extensive analytical validation of the targeted 33-gene assay PGDx elio plasma focus Dx assay has shown that detection of cancer-associated variants in circulating tumor DNA (ctDNA) is highly specific, sensitive, reproducible, and accurate. Distribution of this kitted assay, including automated machine-learning software, can inform precision oncology decision-making.

9:30 Liquid Biopsies in Support of NCI Precision Medicine Initiatives

Chris Karlovich, PhD, Associate Director, Molecular Characterization Laboratory, Frederick National Laboratory for Cancer Research

I will present our experience testing ctDNA from the plasma of ~4200 patients from NCI-MATCH, the largest precision medicine initiative ever conducted. Most patients had rare or uncommon tumors and were screened for the trial but did not enroll to treatment. Patients enrolled to 3 treatment arms have also had ctDNA tested, including one arm that enrolled patients with mismatch repair deficiency by tumor IHC.

9:50 Aggregate Analyses to Assess ctDNA Associations with Long-Term Outcomes

Hillary Andrews, PhD, Director, Regulatory and Research Partnerships, Friends of Cancer Research

Friends of Cancer Research (Friends) has an ongoing collaboration to assess associations between change in ctDNA levels and long-term outcomes in aggregate patient-level datasets. The data analyzed to date have focused on aNSCLC with different treatment modalities and the results intend to provide consensus around how ctDNA can be used to inform treatment decisions, support drug development, and inform regulatory decision-making.

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

ZEON

10:45 Talk Title to be Announced

Daniel Stetson, PhD, Principal Scientist, AstraZeneca Pharmaceuticals

11:05 PANEL DISCUSSION: What Is Needed for Clinical Translation?

Co-Moderators:

Lokesh Agrawal, PhD, Program Director, Biorepositories & Biospecimen Research, NIH NCI

Chris Karlovich, PhD, Associate Director, Molecular Characterization Laboratory, Frederick National Laboratory for Cancer Research

Panelists:

Hillary Andrews, PhD, Director, Regulatory and Research Partnerships, Friends of Cancer Research

Daniel Stetson, PhD, Principal Scientist, AstraZeneca Pharmaceuticals

Kenneth Valkenburg, PhD, Director of Research & Development, Labcorp Oncology

Rena Xian, MD, FCAP, Assistant Professor, Pathology and Oncology, Johns Hopkins Medical Institutions

11:45 Sponsored Presentation *(Opportunity Available)*

12:15 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Session Break

DISEASE MANAGEMENT USING LIQUID BIOPSIES

1:30 Chairperson's Remarks

Steven A. Soper, PhD, Professor & Director, CBM2 Precision Medicine, Chemistry & Mechanical Engineering, University of Kansas, Lawrence

1:35 Lineage-Specific Extracellular Vesicle-Associated Protein Biomarkers for the Diagnosis and Early Detection of High-Grade Serous Ovarian Cancer

Andrew K. Godwin, PhD, Professor and Division Director, Genomic Diagnostics; Deputy Director, KU Cancer Center; Founding Director, Kansas Institute for Precision Medicine; Chancellors Distinguished Chair in Biomedical Sciences Endowed Professor, Department of Pathology and Laboratory Medicine, University of Kansas Medical Center

Non-invasive, highly specific blood-based tests for pre-symptomatic screening of women at increased risk for developing high-grade serous ovarian cancer (HGSOC) are crucial to reducing its mortality. Since this deadliest form typically arises from the fallopian tubes (FT), our biomarker search focused on proteins found on the surface of extracellular vesicles released by both FT and tumor tissue explants. These lineage-associated exo-biomarkers can detect HGSOC with high specificity and sensitivity.

2:05 Exosomal mRNA for the Diagnosis of Acute Ischemic Stroke

Alison Baird, MB, BS, FRACP, PhD, MPH, Professor of Neurology and Physiology/ Pharmacology, SUNY Downstate Health Sciences University

Stroke is a leading cause of death and adult disability worldwide, and finding new tools for expediting stroke diagnosis is a critical and unmet need. I am working with my colleagues at the University of Kansas to develop an

integrated, innovative technology to permit the measurement of ribonucleic acid expression data in near-real-time to help diagnose ischemic and hemorrhagic stroke, using circulating extracellular vesicles in plasma.

2:35 Glia at the Crossroads of NeuroHIV and Aging: Blaming the Messengers

Shilpa J. Buch, PhD, Professor, Pharmacology & Experimental Neuroscience, University of Nebraska, Omaha

The talk will cover the role of glial EVs in propagating neuroinflammation and senescence to other brain cells in the context of HIV proteins and opiates. Specifically, the role of shuttled micro RNAs in mediating recipient cell reprogramming will be discussed, and how it relates to cognitive impairment in the host. How such an approach can be tapped into for biomarker discovery will also be touched upon.

3:05 Refreshment Break in the Exhibit Hall with Poster Viewing

3:45 Microfluidic Tools for the Analysis of Liquid Biopsy Markers for Viral Infections

Steven A. Soper, PhD, Professor & Director, CBM2 Precision Medicine, Chemistry & Mechanical Engineering, University of Kansas, Lawrence

We developed a microfluidic chip consisting of 1.5M micropillars decorated with affinity agents to select viral particles (VPs) from saliva, including SARS-CoV-2 and Respiratory Syncytial Virus from saliva. In this presentation, we discuss technology that can accept saliva samples and search for VPs and then count the selected VPs using a label-free approach; nano-Coulter Counter chip (nCC). The assay could be completed in ~20 minutes with full process automation.

4:15 Machine Perception Liquid Biopsy Captures a Biomarker-Agnostic Disease Fingerprint

Daniel A. Heller, PhD, Head, Cancer Nanomedicine Laboratory; Member, Molecular Pharmacology Program, Sloan Kettering Institute, Memorial Sloan Kettering Cancer Center; Professor, Weill Cornell Graduate School of Medical Sciences, Weill Cornell Medicine

Serum biomarkers are often insufficiently sensitive or specific to facilitate disease screening or diagnostic testing. In many cancers, biomarkers fail to detect early-stage disease or to substantially impact mortality rates. We developed a perception-based sensing method that captures a biomarker-agnostic 'disease fingerprint' of disease from serum. The method uses large data sets of molecular binding interactions, to an array of moderately-selective nanosensors, used to train machine learning algorithms.

4:45 Sponsored Presentation *(Opportunity Available)*

5:15 Welcome Reception in the Exhibit Hall with Poster Viewing

6:30 Close of Day

TUESDAY, AUGUST 20

7:15 am Registration Open

7:30 Interactive Discussions with Continental Breakfast

Interactive discussions provide an opportunity to discuss a focused topic with peers from around the world in an open, collegial setting. Select from the list of topics available and join the moderated discussion to share ideas, gain insights, establish collaborations or commiserate about persistent challenges. Please visit the interactive discussions page on the conference website for a complete listing of topics and descriptions.

IN-PERSON ONLY BREAKOUT: Funding and Commercialization Resources for Cancer Technologies

Linda K. Zane, PhD, Program Director, SBIR Development Center, National Cancer Institute

- NIH-wide SBIR and STTR
- Funding opportunities
- Application tips
- Assistance and initiatives for awardees and applicants

IN-PERSON ONLY BREAKOUT: IN-PERSON ONLY BREAKOUT: How to Successfully Partner with DDDI and BARDA

Christopher J. Knickerbocker, Contracting Officer Representative, United States Department of Health and Human Services

Kristy Stoudt, PhD, Biologist and Project Officer, Biomedical Advanced Research and Development Authority (BARDA)

- Preliminary inquiries and interactions
- Funding mechanisms
- BAA solicitation process (Stage I – III)
- Key questions before starting a submission/advice for submitters

TUNING PRECISION MEDICINE FOR PATIENT'S DISEASE

7:55 Chairperson's Remarks

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

8:00 Priming Agents Boost the Sensitivity of Liquid Biopsies by Inhibiting Cell-Free DNA Clearance

Shervin Tabrizi, MD, Radiation Oncologist, Massachusetts General Hospital

Liquid biopsies using circulating tumor DNA (ctDNA) enable early detection and monitoring of cancer. But their sensitivity is limited by the intrinsic scarcity of ctDNA in blood. Despite technical improvements in the accuracy of sequencing technology, the biological limitation of ctDNA scarcity remains a major barrier to clinical use of liquid biopsies. To address this problem, we have developed novel "priming agents" that are administered 1-2 hours before blood draw.

8:30 Rapid Microfluidic Analysis of Metastatic Phenotypes

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

9:00 Pro-Metastatic Effects of Chemotherapy on Tumor Microenvironment in Breast Cancer

Maja H. Oktay, PhD, Professor of Pathology, L.G. Koss Division of Cytology, Montefiore Einstein Comprehensive Cancer Center

The talk will describe advances in the development of biomarkers for cancer cell dissemination that can be obtained from fixed tissue and by MRI in real-time. It will also address the effect of chemotherapy on these biomarkers as well as the observed racial disparity in pro-metastatic tumor microenvironment, potentially related to treatment. Finally, the use of these biomarkers for tailoring neoadjuvant chemotherapy will be explored.

9:30 Microfluidic Digital DNA Methylation Analysis for Highly Sensitive and Affordable Cancer Detection

Jeff Tza-Huei Wang, PhD, Louis M. Sardella Professor, Whiting School of Engineering; Professor, Departments of Mechanical Engineering, Biomedical Engineering, Materials Science & Engineering, Oncology, and Medicine; Professor, Institute for NanoBioTechnology, Johns Hopkins University

The advancement in DNA methylation-based cancer diagnostics and screening is impeded by the unavailability of cost-effective, easily accessible technologies capable of performing comprehensive assessments of methylation biomarker panels. Current methods also lack the necessary high sensitivity and CpG-site specificity for early detection of tumor-derived cfDNA, crucial in cancer diagnostics. To address these issues, we developed a multiplexed digital high-resolution melt (dHRM) technology.

10:00 Sponsored Presentation *(Opportunity Available)*

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

PLENARY SESSION

11:30 PLENARY KEYNOTE PRESENTATION: Talk Title to be Announced

Courtney H. Lias, PhD, Acting Director, OHT7: Office of in vitro Diagnostic Devices, United States Food and Drug Administration (FDA)

12:00 pm Plenary Fireside Chat Introduction (Sponsorship Opportunity Available)

12:10 PLENARY FIRESIDE CHAT: Laboratory-Developed Tests: Proposed Rule, Reclassification Activities, Potential Impact, and Path Forward




Moderator: B. Melina Cimler, PhD, CEO & Founder, PandiaDx LLC

Laboratory-developed tests (LDTs) are an important part of healthcare. The FDA released a proposed rule on September 29, 2023, that seeks to amend the FDA's regulations to make explicit that IVDs are devices under the Federal FD&C Act, including when the manufacturer of the IVD is a laboratory.

Panelists:

Stefan Burde, PhD, Director, Global Strategic Business Development, TÜV SÜD America, Inc.

Laurie Menser, CEO, Association for Molecular Pathology

Girish Putcha, MD, PhD, Principal & Founder, Precision Medicine & Diagnostics

1:10 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

2:10 Close of Liquid Biopsy for Disease Management Conference

TUESDAY, AUGUST 20

10:30 am Registration Open

PLENARY SESSION

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1:10 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

2:25 Organizer's Welcome Remarks

OVERVIEW AND STRATEGIES

2:30 Chairperson's Remarks

Christos Patriotis, PhD, Program Director, Cancer Biomarkers Research Group, NIH NCI

2:35 Biomarkers for Cancer Risk Asssessment

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

Single- or multi-cancer detection tests require high specificity when applied to the general population which in general reduces sensitivity and detecting cancer at an early stage. Identifying an individual's cancer risk based on subject characteristics and their biomarker profile allows tailoring screening according to risk. Personalized risk assessment also provides an opportunity for preventive intervention.

3:05 KEYNOTE PRESENTATION: Early Detection and Screening for Cancer in the Era of Multi-Cancer Detection Tests: Opportunities, Evidence Gaps, and Risks

Christos Patriotis, PhD, Program Director, Cancer Biomarkers Research Group, NIH NCI

In this presentation, I will discuss the rationale and promise of Multi-Cancer Detection (MCD) screening tests and key technologies employed in their development. I'll overview the landscape of MCD tests and discuss possible outcomes, and potential benefits and harms of MCD screening. I will summarize efforts in assessing clinical utility of MCD screening tests and NCI's plans in this space—the Cancer Screening Research Network and the Vanguard Study.

3:35 Cancer Screening Legislative Landscape and Patient Perspectives: How Do MCED Tests Fit In

Jody Hoyos, MHA, CEO, Prevent Cancer Foundation
Caitlin Kubler, MS, Senior Director, Policy and Advocacy, Prevent Cancer Foundation

There is growing support for legislation to improve access to innovative cancer screenings among Medicare beneficiaries to increase early detection of more cancer cases. Advocacy organizations are committed to ensuring patient needs and preferences inform the development, planning, and implementation of novel innovations like multi-cancer early detection tests. As these tests emerge into an already complex cancer screening landscape, there is a need to discuss access, acceptance, affordability, and accountability.

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing

4:45 MCED Barriers: Results from a Quantitative Multi-Stakeholder Survey

Gary Gustavsen, PhD, Partner & Managing Director, Health Advances
Elissa Quinn, Medical Director, Cancer Screening & Early Detection, AstraZeneca

AstraZeneca recently partnered with Health Advances to launch a multi-stakeholder survey designed to quantitatively assess the barriers to MCED adoption. Survey responses from clinicians, payers, and patients highlight key stakeholder specific barriers that are critical to understand if widespread adoption is to be a reality. The implications of this research will be put into the context of the broader market to facilitate continued discussion of solutions throughout the conference.

5:15 Real-World Experiences with Liquid Biopsy-Based Early Cancer Detection Testing: Perspectives from Early Adopters and Sideline Observers

Andrew P. Aijian, PhD, Partner, DeciBio Consulting LLC

Early cancer detection is a nascent market: pre-FDA approval, pre-guideline recommendations, and largely, pre-reimbursement. We conducted a survey of clinicians who have ordered such, probing their experience and satisfaction and expectations. We also surveyed non-adopters, to understand what might drive adoption. This presentation aims to shed light on the opportunities and challenges ahead for what has potential to be a disruptive clinical paradigm.

5:45 PANEL DISCUSSION: Scenarios for the Future of MCEDs: Access, Reimbursement, Costs, Follow-Up, and Stage Shifting

Moderator: Sudhir Srivastava, PhD, Chief, Cancer Biomarkers Research Group, NIH NCI

The outlook for Multi-Cancer Early Detection looks very promising, but there are considerable questions and scenarios as to how the landscape may evolve in the coming years. This panel will comment of perspectives related to access, reimbursement, health economics, investment, options for follow-up

and the realistic potential for stage-shifting, as well as other issues raised by the audience.

Panelists:

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

Mark Massaro, Managing Director & Senior Equity Research Analyst, BTIG LLC

Christos Patriotis, PhD, Program Director, Cancer Biomarkers Research Group, NIH NCI

6:15 Close of Day

WEDNESDAY, AUGUST 21

7:15 am Registration Open

7:30 Interactive Discussions with Continental Breakfast

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IMPROVED SINGLE CANCER DETECTION

8:25 Chairperson's Remarks

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

8:30 Early Detection of Ovarian Cancer in a Large Prospective Screening Cohort Using a Novel Blood-Based Assay Measuring Tumor-Derived Extracellular Vesicles

Dawn Mattoon, PhD, CEO, Mercy BioAnalytics

We are developing low-cost blood tests for the early detection of cancer based on measuring highly abundant tumor-associated extracellular vesicles. Data from a large clinical study demonstrating detection of early-stage ovarian cancer with high sensitivity and specificity in samples from asymptomatic post-menopausal women up to three years before clinical symptoms. This represents a significant improvement and suggests the test may be suitable for use in population screening for postmenopausal women.

9:00 Clinical Results of Uptake and Sensitivity of CRC Testing

Craig Eagle, PhD, CMO, Guardant Health

The results of our ECLIPSE study, highlighting Shield's ability to detect colorectal cancer will be presented. The Shield test has been used by over 20,000 individuals, with over 90% completion rate among patients prescribed the test. These findings suggest that Shield's sensitivity in detecting CRC, coupled with high real-world adherence, could enhance the detection of earlier-stage CRC cases. The clinical implications of these results will also be discussed.

9:30 ColoSense: Multitarget Stool RNA Test for Colorectal Cancer Screening

Erica Barnell, PhD, CMO, Geneoscopy LLC

CRC-PREVENT was a large pivotal prospective trial which evaluated the sensitivity and specificity of the mt-sRNA test compared with olonoscopy and served as clinical validation for the pre-market approval application. Sensitivity results of the test will be presented. We are developing additional tests that can improve early detection for subjects at higher risk for developing CRC, and we have ongoing clinical trials in IBD, FAP, and other predisposing diseases.

10:00 Circulating T Cell Receptor Repertoire Analysis Improves Cancer Early Detection SERUM DETECT

Roman Yelensky, PhD, Founder and CEO, Serum Detect, Inc.

Serum Detect is a cancer diagnostics company focused on advancing new technologies for the early detection of cancer from routine liquid biopsy samples. We present a novel approach for discovery and use of lung cancer associated circulating TCR repertoire functional units (RFUs), which are computationally derived sets of TCRs with similar sequences that may recognize shared tumor antigens. A TCR RFU-based machine learning model for cancer prediction detected nearly 50% of Stage I lung cancers at a specificity of 80%. The TCR RFU model also achieved an approximately 20%-point gain in sensitivity for Stage I cancer when added to plasma ctDNA and lung cancer-related protein biomarkers, highlighting the complementary nature of the approach.

10:15 Networking Coffee Break

MULTIOMIC MCEDs

10:30 Answering Common Questions about MCED Testing

Tomasz Beer, MD, CMO, Multi-Cancer Early Detection, Exact Sciences

The Multi-Cancer Early Detection field is still in its beginning stages, and it shows great promise as a fundamentally novel approach to help markedly expand our ability to detect multiple cancers through routine screening. Like most disruptive technologies, MCED tests are prompting questions from patients, providers, regulators, and payers. This session will address shared questions about MCED testing, provide insights from recent research, and discuss a roadmap to future answers.

11:00 Harnessing Extracellular Vesicle-Derived Multiomic Signatures for Solid Tumor Management

HsianRong Tseng, PhD, Professor, Department of Molecular & Medical Pharmacology, David Geffen School of Medicine, UCLA

Recent advancements have ushered in the era of "liquid biopsy," a minimally invasive alternative to traditional tissue pathology. Our research team is at the forefront of this revolution, having developed innovative technologies to isolate tumor-derived extracellular vesicles (EVs). Our approach facilitates multi-omic analysis, providing rich molecular signatures, which demonstrate significant promise for the early detection and monitoring of various solid tumors, heralding a new paradigm in cancer diagnostics and management.

11:30 Leveraging Multiomics and Machine Learning towards a Stepwise Approach to Multi-Cancer Screening

Jimmy ChengHo Lin, PhD, CSO, Freenome, Inc.

Early cancer discovery is challenging due to heterogeneity of different cancers. In order to tackle this problem, Freenome has built a multiomics platform that looks for signals across a broad range of biomarker classes. In order to train and build the best models we incorporate machine learning, aligned with a step-wise investigation of cancers that can most benefit patients, starting with colorectal cancer and advanced adenoma.

12:00 pm LUNCHEON PRESENTATION I: The Evolution of a Multi-Biomarker Class Approach to Multi-Cancer Early Detection Testing EXACT SCIENCES

Tomasz Beer, MD, CMO, Multi-Cancer Early Detection, Exact Sciences Corp.

Early cancer detection can help save lives, yet cancer remains a leading cause of death. Multi-cancer Early Detection (MCED) tests are designed to help expand the range of cancers that can be detected by screening, bridging gaps that exist in today's screening paradigm. A multi-biomarker class approach to MCED test design shows promise for earlier cancer detection. We will provide insights on our evolving approach to designing an MCED test and share data from the recent ASCEND 2 study.

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

1:00 Session Break

SEQUENCE-BASED MCEDs

1:10 Chairperson's Remarks

Sudhir Srivastava, PhD, Chief, Cancer Biomarkers Research Group, NIH NCI

1:15 Multi-Cancer Early Detection Technology: A New Front in the War on Cancer

Megan P. Hall, PhD, Vice President, Medical Affairs, GRAIL LLC

Blood-based MCED tests expand detection to include the ~70% of cancers that are missed by current screening and that result in >600,000 cancer deaths yearly in the US. MCED testing holds promise to improve screening efficiency and reduce cancer deaths. Several studies demonstrate that MCED tests have the ability to detect a broad spectrum of potentially lethal cancers, to predict cancer type, and to do so with very high specificity.

1:45 Strategies and Approaches for Improved Early Cancer Detection Assays and Data Generation

Alexey Aleshin, MD, General Manager, Oncology and Early Cancer Detection; CMO, Natera, Inc.

2:15 Prospective Case-Control Study of Novel Blood-Based Cancer Detection

May Orfali, MD, CMO, Harbinger Health

First Interim Performance data from Cancer Origin Epigenetics—Harbinger Health study in early multi-cancer screening results are critical in defining the path forward for early cancer detection with robust biology and clinical profile. Here we will be presenting our first interim data for assay development phase and path forward towards validation.

2:45 Cancer Treatment Outcome Monitoring Using a cfDNA Fragmentation Assay

Nicholas C. Dracopoli, PhD, CSO, Delfi Diagnostics

Monitoring disease progression in cancer patients receiving immune checkpoint inhibitors is challenging because there are no reliable biomarkers of clinical response. Current next-generation sequencing cfDNA assays are costly and have limited sensitivity for cases with low tumor burden. Here, we demonstrate the utility of DELFI Tumor Fraction (DELFI-TF), a tumor- and mutation-independent cfDNA fragmentome approach to monitor treatment response in patients with metastatic non-small cell lung cancer (mNSCLC).

3:15 Close of Summit

DECENTRALIZED TESTING STREAM

"Excellent meeting that offers interesting and innovative presentations and discussions from clinical experts and industry partners."

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

The **Decentralized Testing** stream focuses on pharmacy, home-based testing, and beyond—to see the introduction of new tests to market and new avenues for testing to improve access and outcomes. This stream will tackle issues such as reporting, standards, integration of devices, reimbursement, regulation of emerging devices, and more. Don't miss this exciting forum to network with industry leaders and learn the latest updates.

AUGUST 19-20:

Enabling Point-of-Care Diagnostics

AGENDA

AUGUST 20-21:

Decentralized POC Testing

AGENDA

ENABLING POINT-OF-CARE DIAGNOSTICS

Expediting Rapid Testing for at-Home, Clinical Lab, and Pharmacy Settings

DECENTRALIZED TESTING

MONDAY, AUGUST 19

7:15 am Registration Open and Morning Coffee

8:20 Organizer's Welcome Remarks

INTEGRATION OF CGM FOR PATIENT CARE

8:25 Chairperson's Remarks

James Nichols, PhD, DABCC, FADLM, Professor of Pathology, Microbiology, and Immunology; Medical Director, Clinical Chemistry and POCT, Vanderbilt University School of Medicine

8:30 KEYNOTE PRESENTATION: Performance Metrics for Continuous Glucose Monitors

James Nichols, PhD, DABCC, FADLM, Professor of Pathology, Microbiology, and Immunology; Medical Director, Clinical Chemistry and POCT, Vanderbilt University School of Medicine

CGM systems are medical devices that measure glucose in the interstitial fluid just under the skin. This presentation will discuss how CGM is utilized in patient care and management of diabetes. The CLSI guideline, POCT05: Performance Metrics for Continuous Interstitial Glucose, will be discussed including how CGM data should be assessed for accuracy and CGM systems should be operated for quality performance. Challenges with interfacing CGM data will be highlighted.

9:00 Continuous Glucose Monitoring in the Hospital Setting

Guillermo Umpierrez, MD, CDCES, FACE, MACP, Professor of Medicine, Emory University School of Medicine

Recent observational and randomized controlled studies in the hospital setting have reported acceptable accuracy and a greater ability to detect hypoglycemia of intermittently scanned and real-time CGM when compared with capillary POC testing. RCTs have also reported on the safety and efficacy of real-time CGM in guiding daily insulin adjustment in hospitalized patients with Type 1 and Type 2 diabetes. CGM provides information about glucose concentration and direction.

9:30 Presentation to be Announced

9:45 Method to Observe Bubble Removal in MDx Panels to Help Down-Select, Sort, or Optimize Vent Materials during Development

Tyler Hinkle, Head of R&D Life Science Venting, Gore

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

10:45 CGM Data Integration into the Electronic Health Record

Juan Espinoza, MD, Chief Research Informatics Officer, Stanley Manne Children's Research Institute, Ann & Robert H. Lurie Children's Hospital of Chicago; Director, Consortium for Technology & Innovation in Pediatrics (CTIP); Associate Director, Center for Biomedical Informatics and Data Science, Northwestern University Feinberg School of Medicine

Continuous glucose monitors (CGMs) are an important technology for improving glycemic outcomes in diabetes. However, in most care settings, CGM data is siloed in manufacturer-specific data platforms and is not integrated with the electronic health record (EHR). The state of CGM-EHR integration has advanced rapidly, but new policies, technologies, and funding mechanisms will need to be put in place to ensure broad access to and implementation of CGM-EHR integrations.

11:15 FEATURED PRESENTATION: Intelligent Diagnostics Fusion: The Synergy of Generative AI and POCT

Bernard Gouget, PhD, Chair, IFCC Committee on Mobile Health and Bioengineering in Laboratory Medicine (C-MHBLM)

The presentation explores the synergy between smart point-of-care testing (POCT) technologies and Generative AI. By leveraging these tools, novel models for collaborative and integrated care systems emerge, revolutionizing healthcare delivery. This interdisciplinary approach promises to enhance diagnostic accuracy, streamline processes, and optimize patient outcomes. By embracing innovation at the intersection of healthcare and technology, this approach aims to redefine standards in healthcare delivery and prioritize patient-centered care.

11:45 Presentation to be Announced

12:15 pm Luncheon Presentation to be Announced

The Co-Dx PCR platform is a new real-time PCR testing technology for at-home and point-of-care use, with a portable PCR instrument that operates via a smartphone interface to enable affordable PCR testing, powered by Patented Co-Dx Co-Primers PCR technology.

12:45 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Session Break

THE ROCKY ROAD TO POCT SUCCESS: OBTAINING REGULATORY CLEARANCE AND APPROPRIATE CLIA LEVEL

1:30 Chairperson's Remarks

Lawrence Worden, Founder, Principal, IVD Logix

1:35 Business as Unusual: The Impact of the Pandemic on the FDA's Regulation of IVDs

Elliot Cowan, PhD, Principal, Partners in Diagnostics LLC

The COVID pandemic demanded that the FDA respond in ways that, arguably, it had not done previously, This was especially the case for *in vitro* diagnostics. That extraordinary effort left in its wake a legacy of positives and negatives for the FDA's regulation of IVDs. This talk will highlight what the industry can expect from the agency going forward, both the good and the challenging.

2:05 Clinical Study Strategies for POCT Technologies in a Post-Pandemic World

Joen T. Johansen, President & CEO, MDC Associates LLC

Speed-to-market and controlling costs are critical factors for manufacturers assessing their clinical study strategies. Study design and execution needs to ensure all FDA requirements are met while at the same time limiting over-enrollment and longer study timelines that inevitably increase costs to sponsors. We will present strategies that support fast and efficient study design for a range of POCT devices.

2:35 Centering Your End User: Roadmap to Defining and Testing POCT Usability Requirements

Aarti Swaminathan, Manager, Human Factors/User Research, TE IVD Solutions

Your end user influences product performance, from market research through clinical trials. Ensuring that you design for these end users, their use environments, capabilities, and biases is vital to product success. Capturing requirements early and iteratively reaffirming them with testing is critical to this goal. This presentation will talk about how to identify end users, generate relevant requirements, and execute necessary usability testing that brings confidence to all stakeholders.

3:05 Refreshment Break in the Exhibit Hall with Poster Viewing

3:45 PANEL DISCUSSION: The Rocky Road to POCT Success: Obtaining Regulatory Clearance and Appropriate CLIA Level

Moderator: Lawrence Worden, Founder, Principal, IVD Logix

Panelists:

Elliot Cowan, PhD, Principal, Partners in Diagnostics LLC

Joen T. Johansen, President & CEO, MDC Associates LLC

Aarti Swaminathan, Manager, Human Factors/User Research, TE IVD Solutions

4:45 Increasing Access to Point-of-Care Diagnostics through Innovative Advances in Molecular Reagents for Assay Development

Lina Gasiunaite, Team Leader, R&D, Meridian Bioscience

Despite gaining traction in diagnostics, molecular Point-of-Care (POC) tests face challenges related to accessibility, stability, and ease of workflow. This session explores innovative molecular reagents that enable direct detection without the need for extraction and offer ambient temperature stability, advancing key diagnostic technologies like qPCR and isothermal methods for use at the point-of-care.

5:15 Welcome Reception in the Exhibit Hall with Poster Viewing

6:30 Close of Day

TUESDAY, AUGUST 20

7:15 am Registration Open

7:30 Interactive Discussions with Continental Breakfast

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Christopher J. Knickerbocker, Contracting Officer Representative, United States Department of Health and Human Services

Kristy Stoudt, PhD, Biologist and Project Officer, Biomedical Advanced Research and Development Authority (BARDA)

- Preliminary inquiries and interactions
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- Key questions before starting a submission/advice for submitters.

FUTURE TRENDS IN POCT

8:25 Co-Chairperson's Remarks

Norman Moore, PhD, Volwiler Senior Associate Research Fellow; Director Infectious Diseases, Scientific Affairs, Abbott

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

8:30 Future Diagnostics Needs at the Point-of-Care

Norman Moore, PhD, Volwiler Senior Associate Research Fellow; Director Infectious Diseases, Scientific Affairs, Abbott

The trend toward increased point-of-care testing was accelerated due to the COVID-19 pandemic. Patients now expect high-quality results with far greater convenience. Point-of-care testing must give the appropriate results in a timely fashion while also being easy enough to be performed by people with different trainings.

8:45 Embracing the Evolution of Diagnostic Testing for Public Health Outbreaks and Emergencies

Reynolds M. Salerno, PhD, Director, Lab Systems & CSELS, Center for Disease Control & Prevention

The COVID-19 pandemic brought about significant shifts in the diagnostic testing landscape as it pertains to public health outbreaks and emergencies. We witnessed the rapid expansion of both point-of-care testing and self-testing that empowered patients and providers as never before. These advances will continue to impact future public health threats, and we must embrace the role of private sector clinical diagnostics in future public health responses.

9:00 Pronounced Impacts of PAMA on Point-of-Care Testing

Nicholas Halzack, MPH, Director, Health Policy, Roche Diagnostics

The way that Medicare laboratory reimbursement is currently set under PAMA results in uniquely challenging dynamics for point-of-care tests. Understanding how PAMA impacts the Medicare Clinical Laboratory Fee Schedule and how point-of-care testing fits into that system has implications for legislative, regulatory, and coding reform.

9:15 Family Story

Michele Slafkosky, Executive Director, Families Fighting Flu

Families Fighting Flu will share a personal story on how serious the flu can be and the importance of taking symptoms seriously and seeing a healthcare provider for accurate testing to receive appropriate treatment.

9:30 PANEL DISCUSSION: Future Trends in POCT

Moderator: Deborah R. Godes, Vice President, McDermott+Consulting LLC

Panelists:

Nicholas Halzack, MPH, Director, Health Policy, Roche Diagnostics

Reynolds M. Salerno, PhD, Director, Lab Systems & CSELS, Center for Disease Control & Prevention

Michele Slafkosky, Executive Director, Families Fighting Flu

10:00 Seek Labs Proudly Introduces the SeekIt Platform, a Groundbreaking Advancement in POC Diagnostics

Jared Bauer, CEO, Seek Labs

Seek Labs proudly introduces the SeekIt Platform, a groundbreaking advancement in POC diagnostics. The SeekIt Platform represents a paradigm shift in the industry; Seek Labs has innovated an easy-to-use, laboratory-quality molecular diagnostic system specifically designed for POC settings. Join us as we unveil this transformative technology and discuss the importance of innovating solutions that empower patients.

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

PLENARY SESSION

11:30 PLENARY KEYNOTE PRESENTATION: Talk Title to be Announced

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Girish Putcha, MD, PhD, Principal & Founder, Precision Medicine & Diagnostics

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2:10 Close of Enabling Point-of-Care Diagnostics Conference

TUESDAY, AUGUST 20

10:30 am Registration Open

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11:30 PLENARY KEYNOTE PRESENTATION: Talk Title to be Announced

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12:10 PLENARY FIRESIDE CHAT: Laboratory-Developed Tests: Proposed Rule, Reclassification Activities, Potential Impact, and Path Forward




Moderator: B. Melina Cimler, PhD, CEO & Founder, PandiaDx LLC

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Panelists:
Stefan Burde, PhD, Director, Global Strategic Business Development, TÜV SÜD America, Inc.
Laurie Menser, CEO, Association for Molecular Pathology
Girish Putcha, MD, PhD, Principal & Founder, Precision Medicine & Diagnostics

1:10 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

2:25 Organizer's Welcome Remarks

NOVEL TECHNOLOGIES FOR DECENTRALIZED POINT-OF-CARE TESTING

2:30 Chairperson's Remarks

2:35 Point-of-Care Smartphone-Enabled Fluorescence Microscopy Setup for Diagnostic Applications

Umer Hassan, PhD, Assistant Professor, Electrical & Computer Engineering, Rutgers University

Dr. Hassan's lab has developed a 3D-printed, portable, smartphone-enabled fluorescence microscopy setup for point-of-care diagnostic applications. This hand-held setup can be easily used to image cells of interest or other micro-nano particles used in different biological assays.The validation of the device with clinical samples will be shown in the talk. The setup is user-friendly and can be easily adaptable to different diagnostic applications.

3:05 A Novel Point-of-Care Diagnostics Platform to Revolutionize Antibiotic Prescription Practices

Giulia Pilla, PhD, Clinical Lead, Nostics

Nostics is developing a point-of-care diagnostics platform integrating photonics, nanotechnology, and machine learning, to detect and identify pathogens at species-level within minutes. With our first application DUTI, we target the identification of bacteria causing urinary tract infections from urine samples during the first patient visit, enabling more effective antibiotic treatments. The platform can be expanded to other pathogens (e.g., fungi) and sample types (e.g., blood cultures), revolutionizing infectious disease testing.

3:35 Talk Title to be Announced

Andrew Miller, Founder, CEO, NAT Diagnostics

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing

4:45 KEYNOTE PRESENTATION: Point-of-Care Diagnostics for Global Health

David Erickson, PhD, SC Thomas Sze Director, Professor, Director, PORTENT Center for Point-of-Care Technologies for Nutrition, Infection, and Cancer in Global Health, Mechanical, and Aerospace Engineering, Cornell University

I will discuss our recent work on the development of point-of-care diagnostic technologies for the differential diagnosis of nutritional deficiencies, febrile illnesses, quantification of antibiotic resistance, and some virus-causing cancers. Several approaches will be demonstrated and justified by the availability of infrastructure in their anticipated setting of use. In addition, I will discuss our efforts to for deployment and commercialization.

5:15 Developing Cost-Effective, Rapid-Response Diagnostics for Snakebite Envenomation in Decentralized Healthcare Settings

Jonas Jürgensen, MSc, Co-Founder, CEO, VenomAid

Snakebite envenoming, one of the world's most neglected diseases, causes significant morbidity and mortality annually. Diagnosis largely relies on patient history and symptomatic assessment, with the availability of diagnostic tests varying globally. Timely diagnosis and treatment are warranted, emphasizing the need for novel, rapid, and affordable diagnostics to improve outcomes in both established and decentralized healthcare settings. This could enhance patient outcomes and reduce costs in resource-scarce healthcare institutions worldwide.

5:45 Sponsored Presentation *(Opportunity Available)*

6:15 Close of Day

WEDNESDAY, AUGUST 21

7:15 am Registration Open

7:30 Interactive Discussions with Continental Breakfast

Interactive discussions provide an opportunity to discuss a focused topic with peers from around the world in an open, collegial setting. Select from the list of topics available and join the moderated discussion to share ideas, gain insights, establish collaborations or commiserate about persistent challenges. Please visit the interactive discussions page on the conference website for a complete listing of topics and descriptions.

IN-PERSON ONLY BREAKOUT: How to Successfully Partner with DDDI and BARDA

Christopher J. Knickerbocker, Contracting Officer Representative, United States Department of Health and Human Services

Kristy Stoudt, PhD, Biologist and Project Officer, Biomedical Advanced Research and Development Authority (BARDA)

- Preliminary inquiries and interactions
- Funding mechanisms
- BAA solicitation process (Stage I – III)
- Key questions before starting a submission/advice for submitters

SUSTAINABLE AND SCALABLE DECENTRALIZED TESTING MODELS

8:25 Chairperson's Remarks

Donald G. Klepser, PhD, MBA, Professor and Senior Associate Dean for Academic Affairs, College of Pharmacy, University of Nebraska Medical Center

8:30 Reimbursement Models That Support Sustainable and Scalable Point-of-Care Testing Services in Non-Traditional Settings

Donald G. Klepser, PhD, MBA, Professor and Senior Associate Dean for Academic Affairs, College of Pharmacy, University of Nebraska Medical Center

With recent legislative changes, many regulatory barriers to providing point-of-care testing services in pharmacies and other non-traditional settings have been removed. Reimbursement for services in these settings remains the largest barrier to wide-scale adoption and sustainability. In this session, current and potential reimbursement models for non-traditional settings will be presented along with the role diagnostic manufacturers can play in supporting reimbursement efforts.

9:00 Transforming Colorectal Cancer Screening: A Collaborative, Novel Approach to Patient-Direct Cologuard Testing

Tom Draney, MHA, Associate Director, Customer Experience, Exact Sciences

Kate Sowerwine, MD, CMO, Recuro Health

Explore the success story of our innovative collaboration, where Recuro Health's virtual care delivery seamlessly integrates with Exact Sciences, bringing large-scale colorectal cancer screening and care to patients nationwide within the comfort of their homes. Our talk will highlight the program's practical value, the rich data generated, and its notable success so far for Exact Sciences.

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Networking Coffee Break

10:30 Operationalizing a Service and Expanding the Scope of the Community Pharmacist

Brian Strong, PharmD, Director, New Services Development, Walgreens Co.

As patient needs evolved throughout the pandemic, Walgreens stepped up to uncover and address the challenges and root issues that continue to impact community health. From parking lot testing sites to over 7000 testing locations, learn how Walgreens operationalized testing, assessment, and treatment services to not only offer alternatives to traditional channels but also allow our pharmacists to provide services to and help bridge care gaps.

11:00 PANEL DISCUSSION: Pushing Past the Tipping Point: Scalability of Pharmacy-Based Testing Models

Moderator: Michael E. Klepser, PharmD, FCCP, FIDP, Professor, Ferris State University College of Pharmacy

During this session, panelists will: discuss the current state of community-based POCT services, provide prospective about the types of POCT and services that have been successful, identify historical barriers that have begun to fall, discuss what needs to happen to allow for testing services to continue to grow and expand, and suggest future tests and services that may be viable in this space.

Panelists:

Brian Strong, PharmD, Director, New Services Development, Walgreens Co.

John Warren, Owner and Principal Consultant, Gettysburg Healthcare Consulting, LLC

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:00 Session Break

THE ROLE OF POCT AT THE PHARMACY LEVEL

1:10 Chairperson's Remarks

Kenneth C. Hohmeier, PharmD, Associate Professor, Director of Community Affairs, PGY-1 Community-Based Pharmacy Residency Program, The University of Tennessee Health Science Center

1:15 Nationwide Study of Influenza POCT in U.S. Community Pharmacies

Kenneth C. Hohmeier, PharmD, Associate Professor, Director of Community Affairs, PGY-1 Community-Based Pharmacy Residency Program, The University of Tennessee Health Science Center

Community pharmacists remain one of the most accessible healthcare providers in the U.S., with 9 in 10 Americans living within five miles of a pharmacy. Post-pandemic, there continues a shift in the perception of the role of the pharmacist as it relates to acute infectious disease treatment. However, there is sparse literature on pharmacist POCT service impact. This session will shed light on the topic with insights from a nationwide study.

1:45 Supporting CLIA-Waived POCT in Community Pharmacies

Michael E. Klepser, PharmD, FCCP, FIDP, Professor, Ferris State University College of Pharmacy

Integrating CLIA-waived POCT into the work flow of a pharmacy is critical to the success of a testing service. Means to track scheduling, clinical notes, and other data are essential for such programs. Additionally, understanding and tracking compliance with state-level legislative requirements for disease reporting, record keeping, and training of personnel is vital.

2:15 Empowering Pharmacists—Point-of-Care Testing for Enhancing Patient Care

Adam S. Chesler, PharmD, MBA, Senior Vice President, Pharmacy Integration and Strategic Alliances, VillageMD

This presentation aims to empower pharmacists and technicians in point-of-care testing (POCT) for improved patient care. Attendees will gain insights into the pivotal role that pharmacists and technicians can play in POCT, explore the process and workflow of pharmacy-conducted POCT, and discover how these practices can elevate value-based care.

2:45 How Point-of-Care Testing Can Fight Antibiotic Resistance—Antimicrobial Stewardship and the CHARM Project

Benjamin Pontefract, PharmD, BCPS, Director of Research, CHARM; Assistant Professor, College of Pharmacy, Ferris State University

Point-of-care testing (POCT) provides unprecedented amounts information to outpatient healthcare practitioners. If used correctly, these tests can help reduce inappropriate antibiotic use by a substantial amount. In this talk, we will discuss how the appropriate use of POCTs can fuel antimicrobial stewardship efforts. We will also discuss the Collaboration to Harmonize AntiMicrobial Registry Measures (CHARM) project and how tracking antibiotic use is essentially to monitoring antimicrobial stewardship efforts.

3:15 Close of Summit

POC SPECIAL FORUMS

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

AUGUST 19, 2024
8:25 AM – 12:15 PM

Point-of-Care Product Strategies, Market Access, and Implementation

AGENDA

AUGUST 19, 2024
1:30 – 5:15 PM

Point-of-Care Histology

AGENDA

AUGUST 20, 2024
8:25 – 10:30 AM

Regulatory Strategies for Point-of-Care Diagnostics

AGENDA

SPECIAL FORUM: POINT-OF-CARE PRODUCT STRATEGIES, MARKET ACCESS, AND IMPLEMENTATION

POC SPECIAL FORUMS

MONDAY, AUGUST 19

7:15 am Registration Open and Morning Coffee

8:20 Organizer's Welcome Remarks

ASSESSING THE OPPORTUNITY AND VIABILITY OF POCT SOLUTIONS

8:25 Chairperson's Remarks

Lawrence Worden, Founder, Principal, IVD Logix

8:30 The Evolving Role of POCT Coordinators in Healthcare Systems and How IVD Manufacturers Can Support Them

Jeanne Mumford, MT(ASCP), Manager, Point-of-Care Testing, Johns Hopkins Hospital

In this session, we'll take a look back at the evolution of point-of-care testing in the last several decades and how it has shaped the role of the point-of-care coordinator. Then, we'll break down the responsibilities of the POCT coordinator and offer some insights on what tools vendor reps can develop to offer support to a POCT program.

THE PROMISE OF AI IN POCT APPLICATIONS

9:00 Intelligent Diagnostics Fusion: The Synergy of Generative AI and POCT

Bernard Gouget, PhD, Chair, IFCC Committee on Mobile Health and Bioengineering in Laboratory Medicine (C-MHBLM)

The presentation explores the synergy between smart POCT technologies and generative AI. By leveraging these tools, novel models for collaborative and integrated care systems emerge, revolutionizing healthcare delivery. This interdisciplinary approach promises to enhance diagnostic accuracy, streamline processes, and optimize patient outcomes. By embracing innovation at the intersection of healthcare and technology, this approach aims to redefine standards in healthcare delivery and prioritize patient-centered care.

9:30 How Can Women Get Better Access to Healthcare? Point-of-Care and AI Hold the Answer

Peggy Robinson, CEO, Caza Health LLC

So few women have access to OB/GYN care locally. AI diagnosis in a family practice office may hold the solution. This talk will explore the impact that self-collection and drop-off of specimens plus the potential for more point-of-care testing using artificial intelligence can have in giving women better access to healthcare.

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

EXPANDING THE ROLE OF POCT FOR ONCOLOGY

10:44 Chairperson's Remarks

Charudutt Shah, Chief Business Officer, Genomtec

10:45 Applying Current Oncology Screening Technologies in Low- and Middle-Income Countries

Lucy Hattingh, MBA, Principal, Lucy Hattingh Consulting

This talk will cover the current status of implementation of oncology screening technologies as they relate to different cancers and to countries at different income levels within the World Bank-designated group of nations who fall into the general category of low- and middle-income countries. It will also address ways in which these countries are planning to address the rising incidence of cancer as the lifestyle of their populations improves.

11:00 From High-Throughput to Point-of-Care Oncology Testing: Cutting-Edge Genotyping Chemistries

Florent Chang-Pi-Hin, PhD, Vice President, R&D Life Science, Meridian Bioscience

Advancements in PCR technology hold great promise for point-of-care oncology testing, offering rapid and accurate detection of crucial biomarkers. Meridian's unique and innovative technologies streamline workflows, enable precise allelic discrimination, and have compatibility with lyophilization, bringing oncology testing closer to the patient, enhancing its accessibility. These novel chemistries detect biomarkers directly from various samples without extraction and with exceptional sensitivity, revolutionizing genetic testing and bringing faster genotyping to point-of-care settings.

11:15 Pharmacogenetics at the Point-of-Care: Case Study

Charudutt Shah, Chief Business Officer, Genomtec

Precision medicine is exciting everyone because personalized companion diagnostics and pharmacogenetics are becoming the norm. There is an impressive list of expensive and targeted therapies being approved, and testing prior to treatment or testing prior to trial of drugs will remain an important paradigm in field of CDx. Case studies of successful pharmacogenetic technologies at point-of-care which are poised to revolutionize the field of CDx will be presented.

11:30 PANEL DISCUSSION: Expanding the Role of POCT for Oncology

Moderator: Charudutt Shah, Chief Business Officer, Genomtec

Panelists:

Florent Chang-Pi-Hin, PhD, Vice President, R&D Life Science, Meridian Bioscience

Lucy Hattingh, MBA, Principal, Lucy Hattingh Consulting

11:45 Sponsored Presentation *(Opportunity Available)*

12:15 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Close of POC Product Strategies, Market Access, and Implementation Special Forum

TUESDAY, AUGUST 20

PLENARY SESSION

11:30 PLENARY KEYNOTE PRESENTATION: Talk Title to be Announced

Courtney H. Lias, PhD, Acting Director, OHT7: Office of in vitro Diagnostic Devices, United States Food and Drug Administration (FDA)

12:00 pm Plenary Fireside Chat Introduction (Sponsorship Opportunity Available)

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Moderator: B. Melina Cimler, PhD, CEO & Founder, PandiaDx LLC

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Laurie Menser, CEO, Association for Molecular Pathology

Girish Putcha, MD, PhD, Principal & Founder, Precision Medicine & Diagnostics

1:10 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

MONDAY, AUGUST 19

1:30 pm Introduction and Overview

Richard M. Levenson, MD, Vice Chair for Strategic Technologies & Professor, Department of Pathology and Laboratory Medicine, University of California, Davis

1:35 AccessPath: A Low-Cost, Rugged System for Slide-Free Pathology Based on Computational Microscopy

Rebecca R. Richards-Kortum, PhD, Professor of Bioengineering, Malcolm Gillis University; Director, Rice 360° Institute for Global Health; Founder, Beyond Traditional Borders Undergraduate Global Health Program

AccessPath is an affordable system for immediate digital pathology of resected tumors. Tissue specimens are stained with inexpensive vital dyes and illuminated with UV excitation, localizing fluorescence emission to a thin surface layer. A custom optical phase mask and associated deep-learning algorithm jointly operate to extend depth-of-field (DOF) by >10X, resolving subcellular features in a DOF of 200 µm, allowing intact tissue specimens to be rapidly scanned without serial refocusing.

1:55 Reflectance Confocal Microscopy of Skin Cancers: Imaging Noninvasively Guides Diagnosis, Treatment, and Management

Milind Rajadhyaksha, PhD, Member of Faculty, Department of Medicine, Dermatology Service, Memorial Sloan Kettering Cancer Center

Reflectance confocal microscopy images cellular patterns and morphology in human skin and detects skin cancers with high sensitivity and specificity. Following two decades of development and clinical trials, RCM imaging of skin was granted reimbursement codes in 2016. The imaging is now being adopted and advancing into routine use for noninvasively guiding diagnosis, treatment, and management of skin cancers. This talk will present a critical overview of this field.

2:15 Light Absorption, Scattering, and Emission (LASE) Microscopy for Virtual Histology

Roger Zemp, PhD, Associate Professor, Electrical & Computer Engineering, University of Alberta

I will discuss recent developments in bringing ultraviolet absorption, scattering, and autofluorescence emission contrast into a single imaging platform. Absorption imaging is achieved using photoacoustic imaging, photoacoustic remote sensing, or negative contrast in autofluorescence imaging. Autofluorescence in multiple optical bands enable simultaneous imaging of tissue optical redox ratio for mapping metabolic activity, co-registered with virtual histology. These developments have enabled realistic virtual histology capabilities with clinically-acceptable sensitivity.

2:35 qOBM (Quantitative Oblique Back-Illumination Microscopy) for *ex* and *in vivo* Label-Free and Slide-Free Histology

Francisco (Paco) Robles, PhD, Associate Professor, Chair of Graduate Admissions and Recruiting, Wallace H. Coulter Department of Biomedical Engineering, Georgia Institute of Technology & Emory University

qOBM is a recently developed label-free optical imaging technology that enables quantitative phase imaging and 3D refractive index tomography of thick tissues. The technology achieves high contrast imaging of cellular and subcellular structures to enable real-time *ex* and *in vivo* label-free and slide-free histology. In this presentation, I will describe the working principles of qOBM and show its potential for POC histology.

2:55 Non-Destructive 3D Pathology and Analysis for Precision Treatments

Jonathan T.C. Liu, PhD, Assistant Professor, Mechanical Engineering, University of Washington

In order to catalyze a digital pathology transformation to improve clinical decisions and patient outcomes, we are developing a novel technological approach that offers significant advantages over traditional "gold-standard" histopathology in terms of accuracy and throughput. We have developed an open-top light-sheet microscopy platform for slide-free 3D pathology of large clinical specimens, enabling whole biopsies and surgical specimens to be non-destructively imaged with a similar to a flat-bed document scanner.

3:15 Refreshment Break in the Exhibit Hall with Poster Viewing

3:45 Real-Time Structured Light and Computational Microscopy for Onsite Pathology

J. Quincy Brown, PhD, Associate Professor, Department of Biomedical Engineering, Tulane University

Structured illumination microscopy (SIM) has a number of compelling applications in direct-to-digital onsite pathology, including large-area rapid 2D imaging for core biopsy and whole-resection tumor margin assessment, and rapid nondestructive cytologic imaging. Additionally, the combination of emerging concepts in computational microscopy, image analysis, and artificial intelligence may accelerate or ease translational burdens for these technologies. We will discuss these topics and more in the context of point-of-care histology for diagnosis.

4:05 FIBI (Fluorescence Imitating Brightfield Imaging): Replacing Whole-Slide Imaging with No-Slide Imaging

Farzad Fereidouni, PhD, Adjunct Assistant Professor, Pathology & Lab Medicine, University of California, Davis

FIBI (Fluorescence Imitating Brightfield Imaging) is an imaging method that generates diagnostic-grade images for the histopathological assessment of freshly excised or fixed specimens without requiring the prior preparation of a glass slide. FIBI images are created through virtual back-illumination of the stained tissue surface. These images closely resemble familiar glass-slide-based brightfield histology, making them suitable for rapid onsite evaluation (ROSE), point-of-care diagnostics, intraoperative margin assessment, and global deployment.

4:25 AI in Point-of-Care Histology: Opportunities and Obstacles

Heather D. Couture, PhD, Consultant & Researcher, Pixel Scientia Labs LLC; Individual Consultant

From expedited diagnoses to enhanced patient care, AI presents revolutionary prospects in point-of-care histology. However, challenges such as scarce labeled data and variations across devices and facilities must be addressed for robust solutions. In this talk, I'll delve into some promising uses for AI, demonstrate the primary obstacles that medical device developers should be prepared for, and propose solutions that can enable AI to transform point-of-care histology practices.

4:45 Sponsored Presentation *(Opportunity Available)*

5:15 Welcome Reception in the Exhibit Hall with Poster Viewing

6:30 Close of POC Histology Special Forum

TUESDAY, AUGUST 20

PLENARY SESSION

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1:10 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

SPECIAL FORUM: REGULATORY STRATEGIES FOR POINT-OF-CARE DIAGNOSTICS

POC SPECIAL FORUMS

TUESDAY, AUGUST 20

8:20 am Organizer's Welcome Remarks

8:25 Chairperson's Remarks

Alberto Gutierrez, PhD, Partner, NDA Partners LLC

Gail Radcliffe, PhD, President, Radcliffe Consulting, Inc.

8:30 KEYNOTE PRESENTATION: Updates on US FDA POC Test Regulations

Timothy Stenzel, MD, PhD, Former Director, Office of in vitro Diagnostics and Radiological Health, FDA

9:00 PANEL DISCUSSION: Regulatory Strategies for Point-of-Care Diagnostics: Learning from Success Stories and Avoiding Pitfalls

Moderator: Gail Radcliffe, PhD, President, Radcliffe Consulting, Inc.

- How many samples do I need for a multiplex respiratory panel clinical study?
- Multiplexing for non-respiratory tests—what is needed for clinical studies and analytical studies?
- Understanding differences between OTC and POC products for labeling and flex studies
- CLIA vs. Non-CLIA waived pathways—what is needed for waiver clinical studies?
- How do you control clinical studies in an uncontrolled environment?
- Addressing user training issues

Panelists:

Teresa Abraham, PhD, Vice President, Scientific and Technical Affairs, Sapphiros

Michaela R. Hoffmeyer, Director, Regulatory Affairs and Data Management, TE Medical Innovations

Courtney H. Lias, PhD, Acting Director, OHT7: Office of in vitro Diagnostic Devices, United States Food and Drug Administration (FDA)

Chermaen Lindberg, President, CovarsaDx Corporation

10:00 Sponsored Presentation *(Opportunity Available)*

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

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1:10 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

2:10 Close of Regulatory Strategies for Point-of-Care Dx Conference

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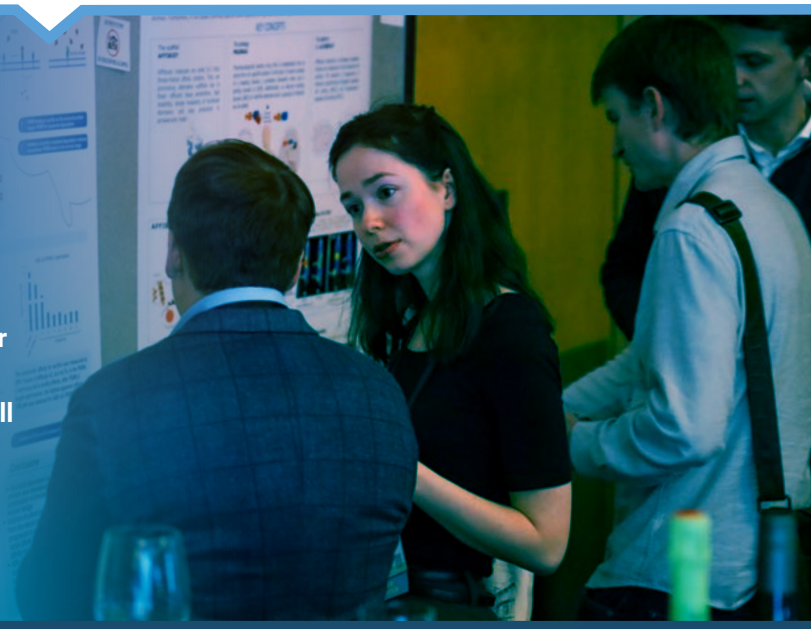

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure an onsite poster board and/or ensure your poster is included in the conference materials, your full submission must be received, and your registration paid in full by July 12, 2024.

Register and indicate that you would like to present a poster. Once your registration has been fully processed, we will send an email with a unique link and instructions for submitting your abstract and other materials.

POSTER INSTRUCTIONS AND GUIDELINES

Reasons you should present your research poster at this conference:

- Your research will be seen by our international delegation, representing leaders from top pharmaceutical, biotech, academic, and government institutions
- Discuss your research and collaborate with other attendees
- Your poster will be published in our conference materials
- Receive $50 off your registration

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