Advancing Diagnostics Together

17th Annual Next Generation Dx Summit

AUGUST 18-20, 2025
WASHINGTON, D.C.
CAPITAL HILTON & VIRTUAL

REGISTER EARLY
FOR MAXIMUM SAVINGS

PLENARY SESSION

PLENARY PANEL DISCUSSION:

Genetic Discrimination:
Impact of Genetic Test Results on Access to Life, Long-Term Care, and Disability Insurance

Panel Moderator:
LAURA GELLER
National Investigative Producer, CBS

Panelists:
JENNIFER R. LEIB
Founder, Innovation Policy Solutions LLC

JOHN WILLIAM MUSICK
Patient Advocate, End the Legacy

JESSICA LYNN ROBERTS, JD
Professor of Law, Artificial Intelligence, Machine Learning and Data Science, Emory Law

LISA SCHLAGER
Vice President, Public Policy, FORCE Facing Our Risk of Cancer Empowered

PLENARY PANEL DISCUSSION:

From AI to LDTs: Top Lab Advocacy Topics

Panel Moderator:
SUSAN VAN METER
President, American Clinical Laboratory Association

Panelists:
JONATHAN R. GENZEN, PHD
CMO, ARUP Labs

LAUREN R. SILVIS, PHD
Senior Vice President, External Affairs, Tempus, Inc.

RACHEL STAUFFER
Principal, McDermottPlus Consulting LLC

CONFERENCE PROGRAMS

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

COMPANION DX/ REIMBURSEMENT
- Coverage and Reimbursement for Advanced Diagnostics
- Clinical Biomarkers and Companion Diagnostics

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

"Discover the latest expert insights and trends in health innovation and cutting-edge technologies."

Bernard Gouget, IFCC Committee Chair, IFCC- Intl Federation of Clinical Chemistry

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CONFERENCE FEATURES

Conference Programs

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- Enabling Point-of-Care Diagnostics
- Advanced Diagnostics for Infectious Disease

Companion Dx/Reimbursement

- Coverage and Reimbursement for Advanced Diagnostics
- Clinical Biomarkers and Companion Diagnostics

Liquid Biopsy and Early Detection

- Early Cancer Surveillance
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17th Annual Next Generation Dx Summit

AUGUST 18-20, 2025 | WASHINGTON, D.C. + VIRTUAL

About the Event

Cambridge Healthtech Institute is proud to present the 17th Annual Next Generation Dx Summit which will take place at the Capital Hilton in Washington, D.C. on August 18-20, 2025. 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 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 and emerging product innovators in the evolving areas of diagnostics**
- **Gain a comprehensive, up-to-date view of diagnostics, including the latest point-of-care, rapid, decentralized, and pharmacy-based diagnostic tests**
- **Stay up-to-date on important industry announcements**
- **Review innovative products, platforms, and technologies in the exhibit hall and poster session**
- **Network with peers in industry, government, clinical and research institutions**

CONFERENCE PROGRAMS AT-A-GLANCE

	MONDAY, AUGUST 18 & TUESDAY AM, AUGUST 19	TUESDAY PM, AUGUST 19 & WEDNESDAY, AUGUST 20
POCT AND INFECTIOUS DISEASE	Enabling Point-of-Care Diagnostics	Advanced Diagnostics for Infectious Disease
COMPANION DX/ REIMBURSEMENT	Coverage and Reimbursement for Advanced Diagnostics	Clinical Biomarkers and Companion Diagnostics
LIQUID BIOPSY AND EARLY DETECTION	Early Cancer Surveillance	Liquid Biopsy for Disease Management

Next Generation Dx Summit

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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, onsite 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 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 **SOLD**
» Conference Materials Advertisement
» Digital Monitors and More…

FOR MORE INFORMATION, PLEASE CONTACT:

COMPANIES A-K

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COMPANIES L-Z

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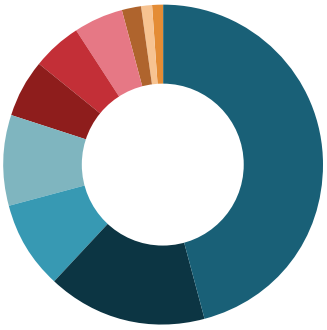
2024 ATTENDEE DEMOGRAPHICS

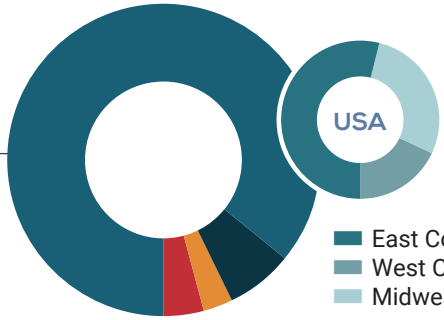


COMPANY TYPE

- Biotech 46%
- Healthcare..... 16%
- Academic 9%
- Services..... 9%
- Government 6%
- Pharma..... 5%
- Societies 5%
- CRO..... 2%
- Financial..... 1%
- Press 1%

GEOGRAPHIC LOCATION

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



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

DELEGATE TITLE

- Executive.....29%
- Director.....23%
- Sales & Marketing 15%
- Scientist/Technologist....13%
- Manager.....9%
- Professor 8%
- Assistant.....3%

2025 **PLENARY** SESSION

TUESDAY, AUGUST 19, 2025

11:30 Introduction to GINA and the Current Landscape

Jessica Lynn Roberts, JD, Professor of Law, Artificial Intelligence, Machine Learning and Data Science, Emory Law

11:40 am PLENARY PANEL DISCUSSION:

Genetic Discrimination: Impact of Genetic Test Results on Access to Life, Long-Term Care, and Disability Insurance

MODERATOR:
Laura Geller, National Investigative Producer, CBS

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John William Musick, Patient Advocate, End the Legacy
Lisa Schlager, Vice President, Public Policy, FORCE Facing Our Risk of Cancer Empowered

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From AI to LDTs: Top Lab Advocacy Topics

PANEL MODERATOR:
Susan Van Meter, President, American Clinical Laboratory Association

- Reimbursement issues to be covered will include improving coding policy for new and existing codes, bringing rationality to Medicare payment through PAMA reform, and cutting through aggressive payer prior-authorization practices and other barriers to care and payment
- Regulatory issues will delve into the latest for LDTs from the administration, courts, and Congress



PANELISTS:
Jonathan R. Genzen, PhD, CMO, ARUP Labs
Lauren R. Silvis, PhD, Senior Vice President, External Affairs, Tempus, Inc.
Rachel Stauffer, Principal, McDermottPlus Consulting LLC

1:05 pm Session Break

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

"The conference excelled in networking opportunities and provided insights into key issues currently impacting the lab diagnostics sector. The downtown D.C. location facilitated the organization of networking events, benefiting from the city's walkability and vibrant atmosphere."

Chad Miles, Director Reimbursement Management, Quadax Inc.

POCT AND INFECTIOUS DISEASE STREAM

"One of the best networking events in Diagnostics."

Joen Johansen, President, MDC Associates, Inc.

The **Point-of-Care and Infectious Disease stream** at 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 18-19:

Enabling Point-of-Care Diagnostics

AGENDA

AUGUST 19-20:

Advanced Diagnostics for Infectious Disease

AGENDA

Enabling Point-of-Care Diagnostics

EXPEDITING RAPID TESTING FOR AT-HOME, CLINICAL LAB, AND PHARMACY SETTINGS

MONDAY, AUGUST 18

7:15 am Registration Open and Morning Coffee

8:20 Organizer's Welcome Remarks

HOT TOPICS IN POCT

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: Guidelines for Using AI/ML in Point-of-Care Testing: Generative and Non-Generative AI Capabilities & Limitations

Hooman H. Rashidi, MD, FCAP, Associate Dean of AI in Medicine, University of Pittsburgh; SOM Professor & Endowed Chair, Lombardi-Shinozuka Experimental Pathology Research Executive Vice Chair, Computational Pathology; Executive Director, CPACE AI Center

In this talk, we explore guidelines for AI/ML in point-of-care testing along with some AI/ML basics. We examine generative and non-generative AI capabilities, highlighting opportunities, constraints, and ethical considerations. Attendees will learn how to harness these technologies responsibly, while also becoming aware of their key limitations that will ultimately help improve diagnostic accuracy, streamline workflows, and ensure patient safety.

9:00 CMS CLIA Interpretation Changes to Technical Consultant and Impact on POCT Training and Competency

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

In this session, we will discuss the final updates to the CMS CLIA 88 regulations that went into effect on December 26, 2024. We'll focus on those that are specific to Technical Consultants and their role in training and in performing competency assessment for non-laboratorian testing personnel.

9:30 Empowering Molecular Point-of-Care Diagnostics with Timesaving, Cost-Effective, and Ambient-Stable Chemistries

meridian BIOSCIENCE

William Ferreira, R&D Team Leader, Meridian Bioscience

Point-of-care diagnostics are transforming healthcare, though challenges remain in their development due to component stabilization and cost. In this talk, we will examine how established POC technologies—such as qPCR and isothermal amplification—and emerging methods like next-generation sequencing can be adapted to create fast, ambient-stable assays. These advances help overcome logistical and financial hurdles and promote wider distribution of tests to patients.

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

10:45 Integrating Patient-Generated Health Data from Mobile Devices into Electronic Health Records: Best Practice Recommendations by the IFCC Committee on Mobile Health and Bioengineering in Laboratory Medicine (C-MHBLM)

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

An increasing number of wearable medical devices are being used for personal monitoring and professional healthcare purposes. Mobile health devices collect a variety of biometric and health data but do not routinely connect to a patient's electronic health record for access by a patient's healthcare team. The IFCC Committee on Mobile Health and Bioengineering in Laboratory Medicine developed consensus recommendations when interfacing mobile health devices to an EHR.

11:15 How FDA's Microfluidic Devices Program Is Developing Tools to Overcome Barriers in Next-Generation Diagnostic Devices

Suvajyoti Guha, PhD, Mechanical Engineer, Applied Mechanics, FDA CDRH

The talk will first introduce FDA/Center for Device and Radiological Health's Microfluidic Devices Program. Then it will discuss what barriers to medical device development have been identified in the microfluidic device space. Lastly, it will share the regulatory science tools that are being developed to overcome the barriers to innovation.

11:45 Sponsored Presentation *(Opportunity Available)*

12:15 pm Lateral Flow 2.0: The Evolution and the Future of Lateral Flow Diagnostics

ABINGDON HEALTH

Chris Yates, President & CCO, Abingdon Health plc

The COVID-19 pandemic catapulted lateral flow diagnostics into the global spotlight, demonstrating both its strengths and limitations in real-world crisis applications. This presentation examines how the industry has evolved in response to the lessons from COVID, highlighting technological advancements that have expanded sensitivity, usability, sustainability and digital integration. Drawing on Abingdon Health's expertise and market intelligence, we'll explore emerging applications beyond infectious disease and into areas such as oncology, cardiology, and personalized medicine. Join us for an insightful look at how lateral flow technology is positioned to address tomorrow's diagnostic challenges with greater precision, accessibility, and clinical utility.

THE VARIOUS MEANINGS OF POCT

1:30 Chairperson's Remarks

Lawrence Worden, Founder, Principal, IVD Logix

1:35 Mobile Services for Precision Medicine

Aaron BenComo, MD, CMO, Phonetik

Phronetik is pioneering mobile diagnostic labs—delivering onsite genomic testing and real-time data analysis to underserved and rural communities, bridging healthcare gaps and advancing precision medicine. Utilizing proprietary technologies including iHarmony-Seq for rapid sequencing and iConcordia for secure data integration, these units enhance clinical trial diversity, accelerate diagnostics, and enable timely interventions. This model transforms healthcare access, strengthens public health response, and drives equitable, community-centered solutions in precision medicine.

2:05 Lab-in-a-Box Diagnostics—Access, Convenience, and Knowledge for Doctors and Patients

Robert Lacroix, Executive Director, LTC LLC Healthcare Diagnostics & Life Science

Lab-in-a-Box (LIAB)—diagnostics designed to provide access, convenience, and knowledge to both doctors and patients in just 60 minutes. No send-outs for commonly order tests, no additional blood draw visit, optimized sample utilization; plus the doctor is paid for the tests and reviews the results with the patient during the visit. And, the patient leaves knowing what's next!

2:35 The Potential Contribution of Biometric Monitoring Wearables to POC Diagnostics

Frank Criscione, PhD, Manager, BroadBranch Advisors

Wearable devices measuring biometrics have the opportunity to support caregivers with more representative baselines and supplement time point-based diagnostics through the wealth of personalized, real-time data they generate. How manufacturers navigate the challenges of generating clinically relevant and reproducible data while supporting caregivers with the analytical tools necessary to process and manage this information will dictate the future position of wearables as a supplement to clinical diagnostics.

Enabling Point-of-Care Diagnostics

EXPEDITING RAPID TESTING FOR AT-HOME, CLINICAL LAB, AND PHARMACY SETTINGS

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

3:45 At-Home Testing vs. at-Home Specimen Collection

Elizabeth M. Marlowe, PhD, D(ABMM), Executive Scientific Director, Head, R&D Infectious Diseases & Immunology, Quest Diagnostics

Remote specimen collection with samples sent to a central laboratory "Home to Lab" as well as at-home testing options have shifted the paradigm in the patient journey. The goal of this talk is explore what is needed to support the changing paradigm and reduce barriers for diagnostic testing.
Objectives:
- Discuss test-at-home vs. home-to-lab
- Examine hurdles to alternative strategies
- Highlight key points of consideration

4:15 PANEL DISCUSSION: The Various Meanings of POCT

Moderator: Bruce Carlson, Publisher, Eye on IVD LLC

Panelists:

Aaron BenComo, MD, CMO, Phonetik

Frank Criscione, PhD, Manager, BroadBranch Advisors

Robert Lacroix, Executive Director, LTC LLC Healthcare Diagnostics & Life Science

Elizabeth M. Marlowe, PhD, D(ABMM), Executive Scientific Director, Head, R&D Infectious Diseases & Immunology, Quest Diagnostics

4:45 Sponsored Presentation *(Opportunity Available)*

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

6:15 Close of Day

TUESDAY, AUGUST 19

7:15 am Registration Open

7:30 Interactive Discussions with Continental Breakfast

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: Best Practice Recommendations by the IFCC Committee on Mobile Health and Bioengineering in Laboratory Medicine

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

- Identify common types of personal health devices
- Describe the data collected by health devices
- Recognize the advantages of interfacing personal health data with a patient's electronic medical record
- Debate the challenges of connecting health devices to an EMR

BREAKOUT DISCUSSION: Integrating AI and Machine Learning into IVD Products

Giles Sanders, DPhil, Head, Diagnostics, TTP plc

Lawrence Worden, Founder, Principal, IVD Logix

Even beyond the hype, we are seeing a technological shift enabled by AI and ML disrupting professions and whole industries. *In vitro* diagnostics will also see changes from the broader upheavals that AI will bring. Already, imaging has been enjoying a quieter revolution; Machine Learning (ML) models equal pathologists at interpreting patient scans. This open breakout discussion looks to consider how AI may impact us in POCDX in the future.

HOT BUTTON ISSUES IN POCT

8:25 Chairperson's Remarks

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

8:30 Point-of-Care Tests: How Good Is Good Enough?

Sheldon M. Campbell, MD, PhD, Professor, Department of Laboratory Medicine, Yale University

COVID overturned the way we think about testing for infections; moving patient expectations from "I'll call my doctor and they'll tell me if I'm sick enough to come in and get looked at" to "I've got this test in my bathroom, let's see what's wrong." But different tests perform differently, and an understanding of test performance is essential to using these tests to improve patient care and safety.

9:00 Diagnostic Stewardship: The Right Test for the Right Patient at the Right Time

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

Diagnostic stewardship is about offering the right test to the right patient so there can be the best medical impact. The appropriate test can vary depending on symptoms, the patient, and what is circulating. This lecture will cover preanalytical and postanalytical considerations for respiratory testing in relation to guidelines.

9:30 PANEL DISCUSSION: Hot Button Issues in POCT

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

- Patient access to medical care
- Respiratory testing environment
- Managing the increase of STIs

Panelists:
Sheldon M. Campbell, MD, PhD, Professor, Department of Laboratory Medicine, Yale University
Norman Moore, PhD, Volwiler Senior Associate Research Fellow, Director, Infectious Diseases, Scientific Affairs, Abbott Laboratories
Michael W. Ryan, PhD, Partner, McDermott Will & Emery LLP

10:00 Faster, Smarter, Stronger: Enhancing SeekIt for Real-World Impact

seek LABS

Jared Bauer, CEO, Seek Labs

Seek Labs SeekIt is revolutionizing point-of-care diagnostics with SeekIt, a rapid, accurate, and accessible testing solutions. In this talk, Jared Bauer will explore the latest advancements in SeekIt's technology, focusing on how we've made it faster, smarter, and stronger to meet the demands of real-world healthcare settings. From optimizing assay performance to integrating cutting-edge data analytics, we are continuously refining SeekIt to improve user experience, enhance reliability, and expand its impact across diverse environments. Join us as we dive into the breakthroughs that are shaping the future of SeekIt and, ultimately, transforming how diagnostics are delivered where and when they're needed most.

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

PLENARY SESSION

11:30 Introduction to GINA and the Current Landscape

Jessica Lynn Roberts, JD, Professor of Law, Artificial Intelligence, Machine Learning and Data Science, Emory Law

This session will provide a brief introduction to the federal Genetic Information Nondiscrimination Act (GINA) and its protections. It will also discuss recent legal developments in the areas of genetic privacy and genetic discrimination.

Enabling Point-of-Care Diagnostics

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12:15 pm Keynote Panel Introduction (Opportunity Available)

12:20 PLENARY PANEL DISCUSSION: From AI to LDTs: Top Lab Advocacy Topics

Co-Organized with ACLA
AMERICAN CLINICAL LABORATORY ASSOCIATION




Moderator: Joyce Gresko, Partner, Legal, Alston & Bird LLP

• Reimbursement issues to be covered will include improving coding policy for new and existing codes, bringing rationality to Medicare payment through PAMA reform, and cutting through aggressive payer prior-authorization practices and other barriers to care and payment
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Rachel Stauffer, Principal, McDermottPlus Consulting LLC

1:05 Session Break

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

1:40 Close of Enabling POC Diagnostics Conference

Advanced Diagnostics for Infectious Disease

IMPROVING CLINICAL OUTCOMES THROUGH NOVEL TECHNOLOGIES AND MOLECULAR TESTING

TUESDAY, AUGUST 19

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Rachel Stauffer, Principal, McDermottPlus Consulting LLC

1:05 Session Break

2:25 Organizer's Welcome Remarks

RAPID BACTERIAL DETECTION AND RESISTANCE/ SUSCEPTIBILITY TESTING

2:30 Chairperson's Remarks

Robin Patel, MD, D(ABMM), FIDSA, FACP, F(AAM), Elizabeth P. and Robert E. Allen Professor of Individualized Medicine; Director, Infectious Diseases Research Laboratory; Professor of Medicine and Microbiology, Co-Director, Bacteriology Laboratory; Vice Chair of Education, Department of Laboratory Medicine and Pathology, Mayo Clinic

2:35 Impact and Outcomes of Rapid Molecular Detection and Resistance Testing

Michael J. Loeffelholz, PhD, D(ABMM), Vice President, Scientific Affairs, Cepheid

The fight against emerging antimicrobial resistance relies in large part on the use of rapid and accurate detection methods. Molecular methods are inherently able to provide fast and accurate results but may come at greater cost-per-test compared to traditional methods. It is therefore incumbent upon those who promote the use of molecular methods to demonstrate their ability to improve patient outcomes and provide downstream economic savings.

3:05 *Mycoplasma pneumoniae* Detection and Antibiotic Resistance Prediction

Tanner Rothstein, MS, Senior Developer, Department of Laboratory Medicine and Pathology, Clinical Microbiology, Translation Research, Innovation, and Test Development, Mayo Clinic

Mycoplasma pneumoniae is a significant respiratory pathogen, and emerging macrolide (azithromycin) resistance poses a clinical challenge. This presentation will discuss the epidemiology of *M. pneumoniae* and the mechanisms of macrolide resistance. Current diagnostic methods will be reviewed, including use of real-time PCR for genotypic prediction of macrolide resistance and its role in directing antimicrobial therapy.

3:35 Addressing a Super Threat: Untreatable Gonorrhea

Jeffrey D. Klausner, MD, Clinical Professor, Preventive Medicine, University of Southern California

Gonorrhea is becoming increasingly resistant to antibiotic therapy. Novel diagnostics that include markers for resistance can help guide therapy and facilitate treatment diversification. We will discuss the state-of-the art in resistance-guided therapy including FDA trials and assays in development.

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

4:45 POINT-COUNTERPOINT DEBATE: Will AI Replace Most Conventional Microbiology Testing in 10 Years?

Moderator: Susan Butler-Wu, PhD, D(ABMM), SM(ASCP), Associate Professor of Clinical Pathology, Keck School of Medicine of USC; Director, Clinical Microbiology Laboratory, LAC+USC Medical Center

Panelists:

Steven D. Dallas, PhD, D(ABMM), Department of Pathology and Laboratory Medicine, UT Health San Antonio

Khosrow R. Shotorbani, MBA, MT (ASCP), President, Executive Director, Project Santa Fe Foundation; Founder, CEO, Lab 2.0 Strategic Services, LLC

5:45 Sponsored Presentation *(Opportunity Available)*

6:15 Close of Day

Advanced Diagnostics for Infectious Disease

IMPROVING CLINICAL OUTCOMES THROUGH NOVEL TECHNOLOGIES AND MOLECULAR TESTING

WEDNESDAY, AUGUST 20

7:15 am Registration Open

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BREAKOUT DISCUSSION: The Role of CRISPR Technology in the Future of Clinical Diagnostics

Gregory Brett Robb, PhD, Senior Scientific Director & Head, CRISPR Science, VedaBio, Inc.

Nucleic acid-based testing offers high sensitivity and specificity for the diagnosis of infectious diseases, applicable in both Laboratory and Point-of-Care settings. Innovative diagnostics continue to emerge including the use of CRISPR-based technologies. The developing power of CRISPR/Cas systems for current and future applications will be reviewed. Advantages and challenges to be discussed include sample preparation, enzyme characteristics, selection of target and guide sequences, amplification versus amplification-free applications for clinical diagnostics.

BREAKOUT DISCUSSION: What Future Syndromic Panels Are Needed in the Clinical Laboratory?

Niaz Banaei, MD, Professor, Pathology and Medicine; Medical Director, Stanford Health Care Clinical Microbiology Laboratory; Director, Stanford Clinical Microbiology Fellowship; Associate Program Director, Stanford Clinical Pathology Residency Training, Stanford University School of Medicine

- Met needs for syndromic panels
- Unmet needs for syndromic panels
- Challenges for industry to develop future syndromic panels
- Regulatory changes for future syndromic pane

FUTURE CLINICAL MICROBIOLOGY DIAGNOSTICS

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 What Future Syndromic Panels Are Needed in the Clinical Laboratory?

Niaz Banaei, MD, Professor, Pathology and Medicine; Medical Director, Stanford Health Care Clinical Microbiology Laboratory; Director, Stanford Clinical Microbiology Fellowship; Associate Program Director, Stanford Clinical Pathology Residency Training, Stanford University School of Medicine

Syndromic panels have advanced healthcare delivery and efficiency. However, there is a need for novel syndromic panels to further advance medicine. This presentation will discuss novel syndromic panels including the role of fungal panels used to non-invasively diagnose patients with invasive fungal disease.

9:00 The Role of CRISPR Technology in the Future of Clinical Diagnostics

Gregory Brett Robb, PhD, Senior Scientific Director & Head, CRISPR Science, VedaBio, Inc.

Nucleic acid-based testing offers high sensitivity and specificity for the diagnosis of a variety of diseases by Laboratories and now efficiently in Point-of Care settings. Innovative technologies continue to emerge including the use of CRISPR-based diagnostics. The developing power of CRISPR/Cas systems for these applications will be reviewed.

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Networking Coffee Break

10:30 Artificial Intelligence Applications in Clinical Microbiology

Thomas Durant, MD, Resident, Pathology & Lab Medicine, Yale University

As digitization and automation advance in microbiology, opportunities for the integration of artificial intelligence (AI) and machine learning (ML) are expanding. This session will provide an overview of machine learning concepts and commonly used terminology, equipping attendees with the foundational technological literacy needed to navigate this evolving field. Additionally, it will explore both established and emerging AI/ML-enabled technologies and devices relevant to clinical microbiology, along with future considerations for laboratory professionals.

11:00 From Disk to Desktop: Novel Approaches to Improve Antimicrobial Susceptibility Testing

Lucas J. Osborn, PhD, D(ABMM), Director of Microbiology, Keck Medical Center of USC; Assistant Professor, Clinical Pathology, Keck School of Medicine, USC

Antimicrobial susceptibility testing (AST) remains a cornerstone of infectious disease management, yet prolonged turnaround times of conventional AST methods can delay optimal treatment. This talk will explore novel strategies to accelerate AST, from low-cost enhancements that integrate into existing workflows within the laboratory, to cutting-edge next-generation sequencing-based methods. By adopting these innovations, laboratories may enhance diagnostic efficiency, which could help reduce time to optimal treatment and potentially improve patient outcomes.

11:30 Utility of AI in PCR QC Monitoring

Meghan W. Starolis, MS, PhD, HCLD(ABB), Senior Science Director, Infectious Disease, Quest Diagnostics

In this session, artificial intelligence (AI) will be defined and its current applications in the routine and molecular microbiology laboratory will be discussed. The use of software as a service (Saas) programs for use in PCR data analysis will be demonstrated with data presented from workflow studies. Future areas of opportunity for the use of AI, such as diagnostic stewardship and clinical decision support, will also be highlighted.

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

MULTIMODAL TESTING

1:10 Chairperson's Remarks

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

1:15 Testing Needs from the Point-of-Care, Can Multimodal Testing Move the Needle in the ED?

Chadd Kraus, DO, DrPH, CPE, FACEP, Vice Chair, Research, Department of Emergency and Hospital Medicine, Lehigh Valley Health Network

Multimodal diagnostic testing platforms offer the potential for rapid, high-sensitivity results that are necessary in emergency departments (EDs) and other acute care settings. Emergency physicians, clinical care teams, and their patients rely on diagnostic tests that are accessible, sensitive, cost-effective, and can be integrated efficiently into existing workflows to provide information that informs decisions for initiating time-sensitive interventions and for clinical disposition such as hospitalization and care linkages.

Advanced Diagnostics for Infectious Disease

IMPROVING CLINICAL OUTCOMES THROUGH NOVEL TECHNOLOGIES AND MOLECULAR TESTING

1:45 Multimodal Detection System to Streamline Healthcare Delivery

Vasu Nadella, CEO, Vital Biosciences

Timely and accurate diagnostics are vital for receiving effective care, yet traditional lab testing often introduces delays in the process. This session will delve into how breakthroughs in biochemistry, robotics, and microfluidics are revolutionizing diagnostics, enabling faster, decentralized testing without sacrificing accuracy. This talk will share new insights on how rapid blood analysis is transforming clinical decision-making, improving patient outcomes, and streamlining healthcare delivery.

2:15 How Multimodal Technology Reduces Healthcare Costs

Tej Patel, CEO, Fluxergy LLC

This talk will cover how an innovative manufacturing and platform lowers cost and enables affordable, decentralized testing in urgent cares, community health centers, free-standing emergency departments, and community hospitals. The result? Lower costs, better access, and improved patient outcomes.

2:45 Expanding beyond Molecular Syndromic Testing: Catalyzing the Shift to Multifunctional Syndromic Testing with Digital Microfluidics

Vamsee K. Pamula, PhD, Founder & President, Baebies, Inc.

Patients requiring rapid diagnosis often need molecular, chemistry, immunoassay, and coagulation testing, yet current platforms rely on multiple single-function instruments. Digital microfluidics (DMF) enables multifunctional syndromic testing, integrating all major modalities on a single system. We demonstrate example applications in sepsis, trauma, and hepatitis. Multifunctional testing improves efficiency, reduces delays, and maximizes diagnostic yield. Data on DMF assays across modalities will highlight its potential as a comprehensive near-patient diagnostic platform.

3:15 Close of Summit

COMPANION DX AND REIMBURSEMENT STREAM

"Great speakers and an opportunity to network across different disciplines."

Tanya M Gottlieb, VP Scientific Affairs, MeMed

The **Companion Diagnostics and Reimbursement** stream at the Next Generation Dx Summit will focus on the future of diagnostic development through complementary sets 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 18-19:

Emerging Trends in Coverage and Reimbursement for Advanced Diagnostics

AGENDA

AUGUST 19-20:

Clinical Biomarkers and Companion Diagnostics

AGENDA

CHI'S 13TH ANNUAL | AUGUST 18-19, 2025

Emerging Trends in Coverage and Reimbursement for Advanced Diagnostics

ASSESSING POLICY IMPACTS AND BUILDING A ROADMAP FOR THE FUTURE

MONDAY, AUGUST 18

7:15 am Registration Open and Morning Coffee

8:20 Organizer's Welcome Remarks

CODING AND RATE SETTING FOR ADVANCED DIAGNOSTICS

8:25 Chairperson's Remarks

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

8:30 Critical Updates to Lab CPT Codes

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

The evolving landscape of coverage and reimbursement for advanced diagnostics is shaped by recent trends in CPT coding. This session will explore how the CPT code set is adapting to market needs and addressing reporting for innovation. Attendees will gain insights into key developments in coding, influencing access, and payment for next-generation diagnostic services.

9:00 PLA Codes and the Clinical Lab-Fee-Schedule Rate-Setting Process

Victoria M. Pratt, PhD, Adjunct Professor, Division of Clinical Pharmacology, Indiana School of Medicine; Director, Scientific Affairs for Pharmacogenomics, Agena Bioscience

American Medical Association's Proprietary Laboratory Analyses (PLA) current procedural terminology (CPT) codes are a mechanism for novel laboratory assays to obtain a billing code specific for that assay. This session will overview the process and criteria for obtaining a PLA code as well as the Centers for Medicare and Medicaid's process for rate setting once a PLA code is obtained.

9:30 Sponsored Presentation *(Opportunity Available)*

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

10:45 Rate-Setting Process for Lab CPT Codes: What Stakeholders Need to Know

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

Hear the latest on rate-setting for laboratory CPT codes, and how to manage the pricing process. Get answers to frequently asked questions on what happens during the CMS annual rate-setting process. We'll also discuss important considerations on engagement with CMS for innovative and complex test codes.

11:15 PANEL DISCUSSION: Diagnostic Testing and Antimicrobial Resistance: Overcoming Coverage and Reimbursement Challenges

Moderator: Kristina Shultz, MPH, Associate Vice President, AdvaMedDx, AdvaMed

Antimicrobial resistance is a pervasive and critical threat. Diagnostic tests can guide clinical decision-making to ensure the appropriate use of interventions that can decelerate the spread of resistance; however, the current reimbursement model in the U.S. creates substantial barriers to bringing innovative tests to market. This panel will examine difficulties faced in attaining coverage and reimbursement for new technologies and changes needed to ensure these tests reach clinicians and patients.

Panelists:

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

11:45 Sponsored Presentation *(Opportunity Available)*

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

DRIVING ALIGNMENT IN COVERAGE AND REIMBURSEMENT

1:30 Chairperson's Remarks

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

1:35 What's New in Medicare Policy and Coverage in 2025

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

2025 is a year for rapid change in molecular test policy, from FDA's actions on lab-developed tests, to the growing impact of MolDx on commercial plans. This session highlights latest trends and changes in coding, local and national policy, and Medicare Advantage. We'll update on summer policymaking proposals from CMS, the summer new-code meetings at CMS, and help you prepare your portfolio for 2026.

2:05 Medicare Advantage and Utilization Management: What Labs Need to Know

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

As increasing numbers of beneficiaries opt for Medicare Advantage (MA) coverage, it is crucial that laboratories understand how MA plans differ from Traditional Medicare and the implications for translating coverage policies into real-world reimbursement. This session will explore the challenges that laboratories face from prior authorization and other utilization-management tactics used by MA plans and highlight current advocacy activities to respond to these challenges.

2:35 PANEL DISCUSSION: Creating Alignment in How Utilization-Management Practices Impact Access to Care

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

Congressional interest and recent Medicare policy changes are reshaping utilization management, particularly around prior authorization and and the coverage determination process. This panel will examine current policies, lab-specific challenges, and strategies to better align Medicare Advantage with Traditional Medicare. Experts will highlight insurer practices and explore opportunities to increase transparency, reduce administrative burden, and promote equitable access to care across both programs.

Panelists:

Emma Alme, PhD, Senior Director, Public Policy, Guardant Health

Brandon Leonard, Senior Director, Government Affairs, LUNGevity Foundation

Neil Patil, Health Policy Director, Senior Fellow, Medicare Policy Initiative, Center on Health Insurance Reforms, Georgetown University

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

COVERAGE AND REIMBURSEMENT STRATEGIES FOR ADVANCED DIAGNOSTICS AND PERSONALIZED MEDICINE

3:45 Developing Diagnostics that are Reimbursement-Ready: Integrating Innovation and Market Access

Marianna Polonsky, Vice President, Market Access, Business Development, and Commercial Strategy, InnoSIGN

Too often, groundbreaking diagnostics reach the market only to struggle with reimbursement and payor adoption. By integrating market access strategies and considering payer requirements early in the product development process, we can improve adoption, streamline access, and truly deliver on the promise of better patient outcomes.

Emerging Trends in Coverage and Reimbursement for Advanced Diagnostics

ASSESSING POLICY IMPACTS AND BUILDING A ROADMAP FOR THE FUTURE

4:05 From Evidence Development to Engagement: Securing Payor Coverage

Sarah Soto, Medical Policy Impact & Payor Evidence Strategy, GeneDx Inc

To secure payor coverage, it is essential to provide sufficient evidence supporting the test and to engage effectively with payors. By examining real case examples, attendees will gain a deeper understanding of the critical elements needed to develop compelling evidence for payor coverage. Additionally, the importance of fostering a collaborative mindset with payors will be discussed.

4:25 When Perception Becomes Reality: Insights from a Recent Multi-Stakeholder Survey Quantifying Barriers to NGS-Based Molecular Profiling in Metastatic Breast Cancer

Moumita Chaki, Medical Director, Breast Cancer Diagnostics, US Medical Affairs, AstraZeneca

Gary Gustavsen, PhD, Partner & Managing Director, Health Advances

Even in a well-established tumor type like metastatic breast cancer, a significant number of patients are still not receiving NGC-based molecular profiling in 2025. AstraZeneca and Health Advances will be reviewing results from a recent multi-stakeholder survey that quantifies the real and perceived barriers around market access. These learnings and resulting solutions are applicable across different indications and applications.

4:45 Sponsored Presentation *(Opportunity Available)*

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

6:15 Close of Day

TUESDAY, AUGUST 19

7:15 am Registration Open

7:30 Interactive Discussions with Continental Breakfast

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: Medicare Modernization: Adapting CMS Payment and Coverage Processes and Mechanisms for Novel, Innovative Diagnostics

Charlie Adams, Director, Global Market Access, Health Policy & Reimbursement Strategy, Beckman Coulter Inc.

LEGISLATION AND ADVOCACY IN BIOMARKER TESTING

8:25 Chairperson's Remarks

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

8:30 State Biomarker-Testing Laws: Opportunities to Maximize Impact and Support Patient Access

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

Twenty states and counting have enacted laws expanding insurance coverage of comprehensive biomarker testing across disease areas. Learn more about the impact of these laws, and how to maximize patient access to needed testing.

9:00 PANEL DISCUSSION: The Power of Patient Advocacy in Alzheimer's Biomarker Testing

Moderator: Cassie Ricci, Senior Manager, Alliance Development and Federal Government Affairs, Roche

This panel will explore the evolving landscape of Alzheimer's biomarker testing, focusing on the critical role of patient advocacy in shaping rate setting for new test codes. Experts will provide background on the reimbursement process and discuss how patient voices influence policy, access, and the future of biomarker adoption.

Panelists:

Charlie Adams, Director, Global Market Access, Health Policy & Reimbursement Strategy, Beckman Coulter Inc.

Jennifer Pollack, JD, Director, Access Policy, Alzheimer's Impact Movement

Ben Tiede, PhD, Executive Director, Global CEO Initiative on Alzheimer's Disease (CEOi)

10:00 Sponsored Presentation *(Opportunity Available)*

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

PLENARY SESSION

11:30 Introduction to GINA and the Current Landscape

Jessica Lynn Roberts, JD, Professor of Law, Artificial Intelligence, Machine Learning and Data Science, Emory Law

This session will provide a brief introduction to the federal Genetic Information Nondiscrimination Act (GINA) and its protections. It will also discuss recent legal developments in the areas of genetic privacy and genetic discrimination.

11:40 PLENARY PANEL DISCUSSION: Genetic Discrimination: Impact of Genetic Test Results on Access to Life, Long-Term Care, and Disability Insurance

Moderator: Laura Geller, National Investigative Producer, CBS

Genetic testing has become progressively more important in predicting disease risk and has facilitated the development of targeted therapies. Passed in 2008, the Genetic Information Nondiscrimination Act (GINA) prohibits genetic discrimination by health plans and employers. However, this federal law does not apply to life, long-term care, or disability insurers so it is legal to use genetic test results in these coverage or premium decisions.

Panelists:

Jennifer R. Leib, Founder, Innovation Policy Solutions LLC

John William Musick, Patient Advocate, End the Legacy

Jessica Lynn Roberts, JD, Professor of Law, Artificial Intelligence, Machine Learning and Data Science, Emory Law

Lisa Schlager, Vice President, Public Policy, FORCE Facing Our Risk of Cancer Empowered

CHI'S 13TH ANNUAL | **AUGUST 18-19, 2025**

Emerging Trends in Coverage and Reimbursement for Advanced Diagnostics

ASSESSING POLICY IMPACTS AND BUILDING A ROADMAP FOR THE FUTURE

12:15 pm Keynote Panel Introduction (Opportunity Available)

12:20 PLENARY PANEL DISCUSSION: From AI to LDTs: Top Lab Advocacy Topics

Co-Organized with ACLA
AMERICAN CLINICAL LABORATORY ASSOCIATION




Moderator: Joyce Gresko, Partner, Legal, Alston & Bird LLP

- Reimbursement issues to be covered will include improving coding policy for new and existing codes, bringing rationality to Medicare payment through PAMA reform, and cutting through aggressive payer prior-authorization practices and other barriers to care and payment
- Regulatory issues will delve into the latest for LDTs from the administration, courts, and Congress

Panelists:
Jonathan R. Genzen, PhD, CMO, ARUP Labs
Lauren R. Silvis, PhD, Senior Vice President, External Affairs, Tempus, Inc.
Rachel Stauffer, Principal, McDermottPlus Consulting LLC

1:05 Session Break

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

1:40 Close of Emerging Trends in Coverage and Reimbursement for Advanced Diagnostics Conference

CHI'S 16TH ANNUAL | AUGUST 19-20, 2025

Clinical Biomarkers and Companion Diagnostics

COLLABORATING TO DRIVE PRECISION MEDICINE FORWARD

TUESDAY, AUGUST 19

PLENARY SESSION

11:30 Introduction to GINA and the Current Landscape

Jessica Lynn Roberts, JD, Professor of Law, Artificial Intelligence, Machine Learning and Data Science, Emory Law

This session will provide a brief introduction to the federal Genetic Information Nondiscrimination Act (GINA) and its protections. It will also discuss recent legal developments in the areas of genetic privacy and genetic discrimination.

11:40 PLENARY PANEL DISCUSSION: Genetic Discrimination: Impact of Genetic Test Results on Access to Life, Long-Term Care, and Disability Insurance





Moderator: Laura Geller, National Investigative Producer, CBS

Genetic testing has become progressively more important in predicting disease risk and has facilitated the development of targeted therapies. Passed in 2008, the Genetic Information Nondiscrimination Act (GINA) prohibits genetic discrimination by health plans and employers. However, this federal law does not apply to life, long-term care, or disability insurers so it is legal to use genetic test results in these coverage or premium decisions.

Panelists:

Jennifer R. Leib, Founder, Innovation Policy Solutions LLC

John William Musick, Patient Advocate, End the Legacy

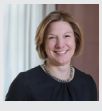
Jessica Lynn Roberts, JD, Professor of Law, Artificial Intelligence, Machine Learning and Data Science, Emory Law

Lisa Schlager, Vice President, Public Policy, FORCE Facing Our Risk of Cancer Empowered

12:15 pm Keynote Panel Introduction (Opportunity Available)

12:20 PLENARY PANEL DISCUSSION: From AI to LDTs: Top Lab Advocacy Topics

Co-Organized with ACLA AMERICAN CLINICAL LABORATORY ASSOCIATION




Moderator: Joyce Gresko, Partner, Legal, Alston & Bird LLP

- Reimbursement issues to be covered will include improving coding policy for new and existing codes, bringing rationality to Medicare payment through PAMA reform, and cutting through aggressive payer prior-authorization practices and other barriers to care and payment
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Panelists:

Jonathan R. Genzen, PhD, CMO, ARUP Labs

Lauren R. Silvis, PhD, Senior Vice President, External Affairs, Tempus, Inc.

Rachel Stauffer, Principal, McDermottPlus Consulting LLC

1:05 Session Break

2:25 Organizer's Welcome Remarks

INTEGRATION OF CLINICAL BIOMARKERS INTO EARLY-STAGE CLINICAL TRIALS

2:30 Chairperson's Remarks

Sharon Liang, MD, PhD, Executive Director, Head, Precision Medicine and Digital Health, Regulatory Innovation & Enterprise Delivery, Global Regulatory Sciences, Bristol Myers Squibb Co.

2:35 Global Considerations for Early-Stage Development in Drug Trials

Sharon Liang, MD, PhD, Executive Director, Head, Precision Medicine and Digital Health, Regulatory Innovation & Enterprise Delivery, Global Regulatory Sciences, Bristol Myers Squibb Co.

This session explores the evolving global landscape of early-stage drug trial development with a focus on biomarker strategy. Expert speakers will discuss the impact of EU IVDR's tighter regulatory framework on pharma-IVD combined trials, the uncertainty surrounding LDTs in the U.S., and challenges posed by China's NMPA regulations and geopolitical pressures.

3:05 PANEL DISCUSSION: Global Considerations for Early-Stage Development in Drug Trials

Moderator: Sharon Liang, MD, PhD, Executive Director, Head, Precision Medicine and Digital Health, Regulatory Innovation & Enterprise Delivery, Global Regulatory Sciences, Bristol Myers Squibb Co.

Panelists:

Yun-Fu Hu, RAC, ASQ CQA, President/CEO, Encore Biotech, LLC

Aaron J Schetter, PhD, Senior Director, Precision Medicine Lead, AstraZeneca

Donna M Roscoe, PhD, Senior Advisor, Precision Medicine Regulatory, Bristol Myers Squibb

COMPANION DIAGNOSTIC DEVELOPMENT

3:35 CDx Development in Partnership with Biopharma Companies: A Team Sport

Karina Kulangara, PhD, Associate Vice President, R&D, Companion Diagnostics, Agilent Technologies, Inc.

The shared goal of bringing new drugs and associated CDx to market to treat patients is the driving force of the partnership between diagnostic developers and biopharma companies. The key to a successful collaboration is teamwork, support and trust. Open and transparent communication allows for adaptation to changes in regulatory environments, and the ability to adhere to a joint strategy for bringing novel therapeutics and diagnostics to patients in need.

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

4:45 CDx Analytical Validation—Study Design and Data Analysis

Shuguang Huang, PhD, CSO, Stat4ward LLC

CDx submission requires a set of extensive analytical validation studies. Study design, data analysis plan, and acceptance criteria are often challenging decisions. Guidelines (e.g. FDA, CLSI) are indeed available. However, an appropriate interpretation is almost always case-dependent. In addition, 'surprise' situations are often encountered, but textbook suggestions are not available. This talk will provide a statistician's view on the design and analysis of CDx analytical validation studies.

5:15 Ahead of the Curve: Market-Driven Innovation in Companion Diagnostics

Shruti Mathur, Diagnostics Strategy Leader, Global Product Strategy, Genentech

This presentation aims to explore the co-creation of companion diagnostics (CDx) through early collaboration between development and business teams, emphasizing the critical role of early commercial input for future success. We will cover the entire lifecycle of CDx development, from biomarker selection to test commercialization, providing valuable insights and addressing various challenges and considerations.

Clinical Biomarkers and Companion Diagnostics

COLLABORATING TO DRIVE PRECISION MEDICINE FORWARD

5:45 Sponsored Presentation *(Opportunity Available)*

6:15 Close of Day

WEDNESDAY, AUGUST 20

7:15 am Registration Open

7:30 Interactive Discussions with Continental Breakfast

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: Have We Finally Reached a Tipping Point for Digital/Computational Pathology?

Gary Gustavsen, PhD, Partner & Managing Director, Health Advances

Liam Lee, PhD, Senior Director of Medical Diagnostics, US Lung Cancer Diagnostics Team Lead, AstraZeneca

- Novel computational biomarkers in oncology
- Pharma pipeline driving need for computational pathology
- Key stakeholders across the ecosystem

DESIGN OF LATE-STAGE CLINICAL TRIALS WITH PATIENT SELECTION AND REGULATORY CONSIDERATIONS

8:25 Chairperson's Remarks

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

8:30 Emerging Trends in Biomarker-Driven Therapies: The Future of Precision Oncology Guided by Companion Diagnostics

Mark Hiatt, MD, MBA, MS, Chief Medical Officer, RadSite

Dhruvajyoti Roy, PhD, Assistant Professor, MD Anderson Cancer Center

This session explores the rapid evolution of biomarker-driven cancer therapies and companion diagnostics (CDx). Attendees will learn about advances in next-gen sequencing, AI-enabled biomarker validation, and implementation strategies. Key challenges such as regulatory barriers and reimbursement will also be addressed. The discussion will highlight how CDx is transforming precision oncology and where diagnostics developers can lead innovation in targeted therapy selection and improved patient outcomes.

9:00 PANEL DISCUSSION: Collaborative Pathways for IVD Testing and Companion Diagnostics: A Multi-Stakeholder Approach

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

This session will cover several topics through a multi-stakeholder lens, including the evolving landscape of IVD testing and CDx; collaborative approaches among regulatory bodies, pharma, and diagnostic companies; strategies for compliance and innovation; best practices, challenges, and solutions; and improved patient outcomes and streamlined regulatory processes.

Panelists:

Lakshman Ramamurthy, PhD, Vice President, Regulatory Affairs, GRAIL

Rolf Thermann, PhD, Section Manager, IVD and Companion Diagnostics Lead, TÜV Rheinland LGA Products GmbH

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Networking Coffee Break

NEXT-GENERATION BIOMARKERS FOR NEXT-GENERATION DIAGNOSTICS

10:29 Chairperson's Remarks

Shirin Khambata Ford, PhD, Founder and Principal, Precision Medesign LLC

10:30 Circulating Tumor Cells in Medulloblastoma: A Novel Peripheral Biomarker for CNS Disease

Frank Chien, MD, Assistant Professor, Pediatrics, Hematology & Oncology, Emory University School of Medicine

Medulloblastoma is the most common pediatric brain and spine malignancy. Currently, no biomarkers are known. We detect whole tumor cells in microcirculation within peripheral blood and cerebrospinal fluid and monitoring levels throughout treatment, correlating findings with patient outcomes.

11:00 Computational Pathology to Guide Use of ADCs

Liam Lee, PhD, Senior Director of Medical Diagnostics, US Lung Cancer Diagnostics Team Lead, AstraZeneca

Explore the emerging role of computational pathology in refining predictive biomarker testing, specifically for antibody-drug conjugates (ADCs). Leveraging advancements in digital and computational pathology may significantly improve patient care by enhancing the potential for treatment response prediction. Quantitative Continuous Scoring (QCS), a state-of-the-art image analysis technique, offers an objective and precise assessment of biomarker expression at the single-cell level, identifying patients who may benefit most from ADC treatments.

11:30 Essential Insights on Genetic Testing for PARP Inhibitor Therapy in Prostate Cancer

Usha Singh, PhD, Director, Oncology Precision Medicine Diagnostics, Johnson & Johnson

This talk will highlight the insight on genetic testing for HRR for eligibility for PARP inhibitor therapy, including the efficacy data of Niraparib + Abirateron (AKEEGA) in prostate cancer patients. The main highlight is to share the advantages and disadvantages of tissue and liquid assays and show both of them are complimentary to each other.

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

MULTI-STAKEHOLDER EFFORTS TO ADVANCE AND ACCELERATE PRECISION MEDICINE

1:10 Chairperson's Remarks

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

1:15 Biomarker Harmonization and Use of AI-Enabled Digital Pathology Tools

Jeff Allen, PhD, President and CEO, Friends of Cancer Research

Novel technologies are aiding biomarker assessment to advance precision medicine. Artificial intelligence (AI)-enable diagnostics are transforming cancer drug development and care, offering tools to improve reproducibility, accuracy, and scalability. These technologies hold significant promise for addressing challenges such as variability and inefficiencies in traditional assessments. This session will explore unique approaches to evaluate consistency in results to support new test development and utilization.

Clinical Biomarkers and Companion Diagnostics

COLLABORATING TO DRIVE PRECISION MEDICINE FORWARD

1:45 Partnering for AI-Enabled Diagnostics

Nicole St. Jean, MBA, Head, External Innovation, Precision Medicine, GSK

Partnering for AI-enabled diagnostics in an age of innovation is evolving traditional RX and DX constructs. The emergence of digital and AI-powered technologies are providing more opportunities yet creating more complexities for deal-making in the industry. This discussion includes examples of how these technologies have transformed the industry and will continue to change the status quo.

2:15 Ensuring Access and Adoption of Biomarker Testing and Targeted Treatment: A Strategic Roadmap for Implementing Precision Oncology

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

Due to challenges in the clinical delivery of molecular testing and targeted therapies, many patients do not receive the most effective personalized treatments. To help catalyze clinical and operational practice and policy reforms, here we describe an implementation roadmap that establishes and promotes best practices and policies for implementing precision oncology.

2:30 PANEL DISCUSSION: Ensuring Access and Adoption of Biomarker Testing and Targeted Treatment: A Strategic Roadmap to Improve the Implementation of Precision Oncology

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

Panelists:

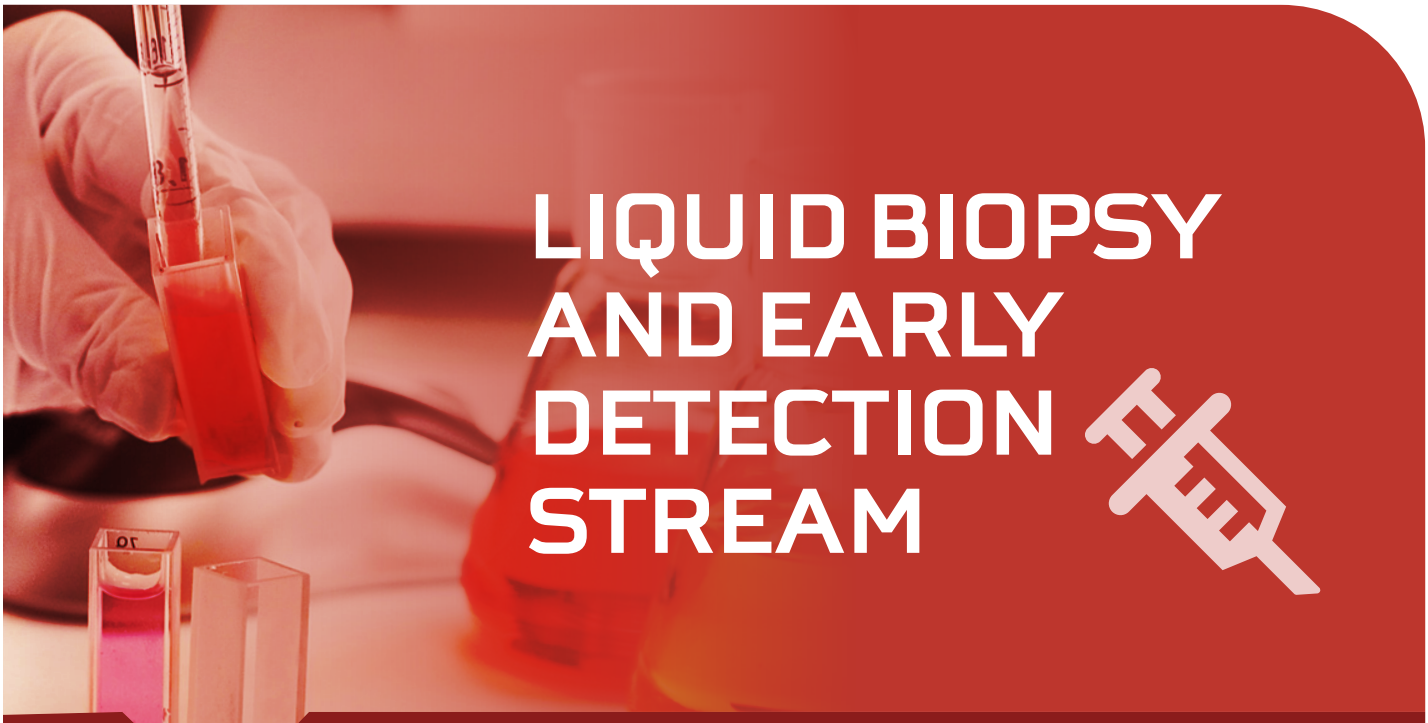
Damon Hostin, Lead, Health System Market Access, Illumina, Inc.

Jonathan Katchmore, Associate Vice President, Commercial Diagnostic Strategy, Loxo@Lilly

Ellen Matloff, President & CEO, My Gene Counsel

Eric Konnick, MD, MS, FCAP, Associate Professor, Department of Laboratory Medicine and Pathology; Associate Director, Genetics and Solid Tumors Laboratory, University of Washington

3:15 Close of Summit



LIQUID BIOPSY AND EARLY DETECTION STREAM

"The most valuable conference for the commercialization of diagnostics with excellent opportunities for one-on-one networking with industry insiders."

Evgueni Klinski, Principal Scientist, UCM Technologies Inc.

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 18-19:

Early Cancer Surveillance

AGENDA

AUGUST 19-20:

Liquid Biopsy for Disease Management

AGENDA

CHI'S 4TH ANNUAL | AUGUST 18-19, 2025

Early Cancer Surveillance

MULTI- AND SINGLE-CANCER EARLY DETECTION: VALIDATION OF IMPROVED EARLY SCREENING

MONDAY, AUGUST 18

7:15 am Registration Open and Morning Coffee

8:20 Organizer's Welcome Remarks

UPDATES ON MCED DEVELOPMENT PROGRAMS

8:25 Chairperson's Opening 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 Lessons from a Decentralized Study Design and Initial Results of an Early Cancer Detection Assay for Colorectal Cancer

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

Blood tests for colorectal cancer (CRC) screening may provide an accessible option to enhance adherence and lessen disease burden. This presentation will address the different recruitment strategies employed in the PROCEED-CRC decentralized study to enroll a diverse cohort and evaluate them in the context of historical barriers to trial access. Finally, preliminary findings from a blood-based assay for early CRC detection using samples from the PROCEED-CRC study will be presented.

9:00 Epigenomic Signals Enable Early Cancer Detection in Liquid Biopsies

Anna Bergamaschi, PhD, Vice President Product R&D, ClearNote Health

Detection of cancer using molecular methods has proven challenging due to low tumor burden associated with early-stage cancers. This presentation will showcase a new technology workflow developed by ClearNote Health that leverages epigenomics and genomics changes in circulating free-DNA to enable early detection in single cancer and multi-cancer modalities. We will provide an update on ongoing clinical strategy supporting the clinical validation and utility of single and multi-cancer tests.

9:30 Unlocking the Power of Epigenomics: Transforming Cancer Detection through Liquid Biopsy

Craig Eagle, PhD, CMO, Guardant Health

As precision oncology advances, the role of epigenomics—particularly DNA methylation analysis—is emerging as a powerful tool for improving early cancer detection. How epigenomic signatures, combined with machine learning, are enhancing the accuracy of blood-based tests across various cancer types will be presented. Insights into the latest developments in methylation-based biomarker discovery, clinical validation, and regulatory considerations, and how these breakthroughs may soon integrate into routine care will be discussed.

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

UPDATES ON MCED DEVELOPMENT PROGRAMS *(CONT.)*

10:45 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 and even within cancers from the same organ. Freenome built a multiomics discovery platform that looks for signals along the entire central dogma—DNA, methylation, RNA, protein, immunoprofiling, extracellular vesicles, circulating cells, among others. During this talk, we will discuss clinical, scientific, and computational strategies that we think are important to create the best products to benefit patients.

11:15 Clinical Development and Real-World Experience of GRAIL's Galleri

Eric Klein, MD, Distinguished Scientist, GRAIL, Inc.

GRAIL's clinical development program spanning 9 clinical trials and diverse populations, including those with occupational exposure, will be presented, including the value of a molecular Cancer Signal of Origin in guiding targeted diagnostic evaluations and highlighting real-world experience with more than 350,000 Galleri tests.

11:45 Update on MCED Development Program, Including a Prospective 25,000-Person RWE Study

Tomasz M. Beer, MD, CMO & Vice President, Multi-Cancer Early Detection, Exact Sciences

An overview of our MCED program development will be provided. Details of our 25,000-person ongoing RWE study will be described. New data on the addition of mutational analysis to our methylation and protein design backbone will also be presented.

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

IMPLEMENTING EARLY CANCER SCREENING

1:30 Chairperson's Remarks

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

1:35 Multi-Cancer Panels—From Risk Assessment to Early Detection

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

Cancer screening in the US is available for five cancers largely based on age. A Multiple Cancer Screening Test (MCaST) was developed to determine risk of harboring or developing nine cancers that represent 85% of all cancers diagnosed enhancing the prospects for preventing and detecting cancer at an early stage.

2:05 Early Experience of Cancer Screening in Arizona—First Responders Utilizing Liquid Biopsy

Vershalee Shukla, MD, Co-Founder, Vincere Cancer Center

Firefighters have increased risk of cancer and tend to have earlier onset than the general population. Despite advances and advantages of liquid biopsies for early detection which make them attractive screening options, these tests are still in their infancy. After performing thousands of liquid biopsy tests among firefighters and comparing results to whole-body MRI and conventional screening, these tests lacked efficacy and were associated with drawbacks, including false negatives (missed cancers).

2:35 Implementing Cancer Screening in the Self-Insured Employer Space

Laura Simmer, MD, Associate Director, Market Access, Optum Genomics

Self-funded employers are interested in innovative ways for their employee benefit programs to drive screening of cancers known to benefit from intervention when found early. Examples of screening programs sponsored by self-funded employers, as well as key learnings from developing them, will be presented.

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

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IMPLEMENTING EARLY CANCER SCREENING *(CONT.)*

3:45 Clinical Trial Design for the Vanguard Study

Wendy Rubinstein, MD, PhD, Senior Scientific Officer, Division of Cancer Prevention, National Cancer Institute

The Vanguard Study will enroll up to 24,000 people to address the feasibility of using MCD tests in future randomized controlled trials. This pilot study aims to understand how two new types of MCD tests—the Avantect MCD Test by ClearNote Health and the Shield MCD Test by Guardant Health—work as cancer screening tests for adults without cancer. Details of the clinical-trial design will be discussed.

4:15 Sponsored Presentation *(Opportunity Available)*

4:45 PANEL DISCUSSION: Challenges and Opportunities for MCEDS

Moderator: 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

What are the biggest questions still to be answered related to MCED development, and what will it take to achieve the ambitious goals of dramatically changing the paradigm for cancer screening? What level of performance may be needed, particularly for detection of early-stage cancer, where signals are more challenging? Are there different strategies for offering tests in the near-term while gaining the experience and knowledge for improving performance going forward?

Panelists:

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

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

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

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

6:15 Close of Day

TUESDAY, AUGUST 19

7:15 am Registration Open

7:30 Interactive Discussions with Continental Breakfast

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: Guidance and Considerations for Diagnostic Workups following Positive MCED Results

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

- Ways to improve comparability of MCED test performance for better matching to a patient's individualized cancer risk
- Best options for workups when cancer cannot be imaged
- The role of single-cancer tests as reflex for positive MCED results

BREAKOUT DISCUSSIONS: Funding and Commercialization Resources for Early Cancer Detection

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

- NIH-wide SBIR and STTR programs
- Funding opportunities for Early Cancer Detection
- Application tips and assistance for awardees and applicants

BREAKOUT DISCUSSIONS: Challenges with Screening Rate Data and Approaches to Improve Novel Early Cancer Screening Test Development

Gary Gustavsen, PhD, Partner & Managing Director, Health Advances

- Challenges around existing cancer screening rate data sources – inaccuracy, inaccessibility, incompleteness
- Impact of these challenges on early detection test development
- Proposed solutions and opportunities to get involved

BREAKOUT DISCUSSIONS: What is the Optimal Number of Cancers for Which an MCED Should be Trained?

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

- Trade-offs between sensitivity and specificity
- The pros and cons of broad vs. more narrow initial training
- Accounting for patient risk for more targeted screening

YOUNG COMPANY SPOTLIGHTS

8:25 Chairperson's Remarks

8:30 Multiomic Biomarker Panel for Early Detection of Bladder Cancer

Thakshila Liyanage, PhD, Founder & CEO, Early Is Good, Inc.

Bladder cancer recurs frequently (50-80%) and requires regular monitoring. The standard method, cystoscopy with cytology, is invasive and has limited sensitivity, often delaying detection and reducing patient compliance. The BCDx test is a non-invasive urine-based liquid biopsy that improves recurrence detection. Using multiomic biomarker detection, BCDx identifies molecular changes linked to cancer progression. With 99% NPV, it enables earlier detection, reduces reliance on cystoscopy, and improves patient outcomes.

8:45 Demonstrating the Power of Multiomics: A Clinical Innovation in the Early Detection of Lung Cancer

Philip Ma, PhD, CEO, PrognomiQ, Inc.

PrognomiQ is developing a blood-based test for lung cancer screening with the goal of significantly improving the rate of detection of lung cancer at the earliest stages, when potential for curative treatment is highest. Our approach is based on proteomics and multi-omics, which complement the genomics-based approaches. The fundamental technology behind the approach as well as data from current studies of our lung cancer screening test will be presented.

9:00 Integrating Lipidomics, Proteomics, and Machine Learning for Ovarian Cancer Early Detection

Abigail McElhinny, PhD, CSO, AOA, Inc.

Ovarian cancer is the fifth leading cause of cancer-related deaths among women, with most cases detected at late stages with low survival rates. We are combining lipid and protein biomarkers with machine learning to detect OC earlier in women experiencing signs and symptoms. This minimally invasive, multiomic method has the potential to improve early diagnosis and healthcare efficiency. We will discuss our approach, key findings, and its impact on early detection.

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9:15 Clinical Performance of Novel Ovarian Cancer Early Detection Tests for Population Screening and for Diagnosis of Symptomatic Disease

Dawn Mattoon, PhD, CEO, Mercy BioAnalytics

The Mercy Halo technology interrogates co-localized proteins from tumor-derived extracellular vesicles. We have demonstrated unprecedented performance in the detection of early-stage high-grade serous ovarian cancer in asymptomatic postmenopausal women, as well as exceptional accuracy in detecting ovarian cancer in women with symptoms but no definitive diagnosis. These studies suggest the test may have utility in population screening and aid in diagnosing women presenting with non-specific ovarian cancer symptoms.

9:30 Pioneering Dynamic Biopsy for Liver Cancer Surveillance

Pierre Arsène, Founder & CEO, Mursla Bio

Hepatocellular carcinoma (HCC) is a leading cause of cancer deaths, with current screening methods offering limited early detection. Mursla Bio's EvoLiver, a non-invasive blood test, leverages its Dynamic Biopsy platform to analyze organ-specific extracellular vesicles. In the MEV01 study, EvoLiver demonstrated 86% early-stage sensitivity and 88% specificity, marking a promising advance in shifting HCC detection earlier and improving outcomes.

9:45 Precancer Detection via RNA Liquid Biopsy Technology

Daniel Kim, PhD, Assistant Professor, University of California Santa Cruz

Current approaches for cancer early detection predominantly rely on circulating tumor DNA, which is present at very low levels during early-stage disease, leading to low sensitivity. Our RNA-based approach enables highly sensitive and specific detection of not only early-stage cancer but also precancerous conditions.

10:00 Combining Tumor RNA with Immune Response Biomarkers for Detection of Cancer Even at Early Stages

Jochen Kohlhaas, Founder & CEO, Hummingbird Diagnostics GmbH

Detecting cancer at early stages requires biomarkers that capture the full disease biology. By combining tumor-derived small RNAs with immune system–derived small RNAs, a more comprehensive and sensitive detection approach is achieved. Tumor-derived markers alone may miss early-stage disease, while immune system–derived small RNAs provide crucial signals of the body's response. This integrated strategy enhances accuracy and sensitivity, enabling earlier and more precise cancer detection, ultimately improving patient outcomes.

10:15 miONCO-Dx: A Novel Serum-Based Multi-Cancer Early Detection Test

Andy Shapanis, PhD, CEO, Xgenera

The development of miONCO, a blood-based multi-cancer early diagnostic test which utilizes our propriety system that involved a predictive panel of microRNAs and machine learning to detect 12 types of cancer, will be presented. Using a cohort of >20,000 patients for training/testing, miONCO can predict cancer with a sensitivity and specificity of 99% across all stages and up to 96% when predicting tumor site of origin.

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

PLENARY SESSION

11:30 Introduction to GINA and the Current Landscape

Jessica Lynn Roberts, JD, Professor of Law, Artificial Intelligence, Machine Learning and Data Science, Emory Law

This session will provide a brief introduction to the federal Genetic Information Nondiscrimination Act (GINA) and its protections. It will also discuss recent legal developments in the areas of genetic privacy and genetic discrimination.

11:40 PLENARY PANEL DISCUSSION: Genetic Discrimination: Impact of Genetic Test Results on Access to Life, Long-Term Care, and Disability Insurance





Moderator: Laura Geller, National Investigative Producer, CBS

Genetic testing has become progressively more important in predicting disease risk and has facilitated the development of targeted therapies. Passed in 2008, the Genetic Information Nondiscrimination Act (GINA) prohibits genetic discrimination by health plans and employers. However, this federal law does not apply to life, long-term care, or disability insurers so it is legal to use genetic test results in these coverage or premium decisions.

Panelists:

Jennifer R. Leib, Founder, Innovation Policy Solutions LLC

John William Musick, Patient Advocate, End the Legacy

Jessica Lynn Roberts, JD, Professor of Law, Artificial Intelligence, Machine Learning and Data Science, Emory Law

Lisa Schlager, Vice President, Public Policy, FORCE Facing Our Risk of Cancer Empowered

12:15 pm Keynote Panel Introduction (Opportunity Available)

12:20 PLENARY PANEL DISCUSSION: From AI to LDTs: Top Lab Advocacy Topics

Co-Organized with ACLA




Moderator: Joyce Gresko, Partner, Legal, Alston & Bird LLP

- Reimbursement issues to be covered will include improving coding policy for new and existing codes, bringing rationality to Medicare payment through PAMA reform, and cutting through aggressive payer prior-authorization practices and other barriers to care and payment
- Regulatory issues will delve into the latest for LDTs from the administration, courts, and Congress

Panelists:

Jonathan R. Genzen, PhD, CMO, ARUP Labs

Lauren R. Silvis, PhD, Senior Vice President, External Affairs, Tempus, Inc.

Rachel Stauffer, Principal, McDermottPlus Consulting LLC

1:05 Session Break

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

1:40 Close of Early Cancer Surveillance Conference

CHI'S 10TH ANNUAL | AUGUST 19-20, 2025

Liquid Biopsy for Disease Management

ADVANCES IN LIQUID BIOPSIES FOR CANCER PATIENTS: ADVANTAGES AND CHALLENGES

TUESDAY, AUGUST 19

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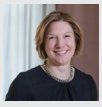
Co-Organized with ACLA AMERICAN CLINICAL LABORATORY ASSOCIATION

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1:05 Session Break

2:25 Organizer's Welcome Remarks

CLINICAL APPLICATION FOR MRD

2:30 Chairperson's Opening Remarks

Nicholas C. Dracopoli, PhD, CSO, DELFI Diagnostics

2:35 Landscape of Growing Evidence-Base for MRD Testing

Sarah Kurley, PhD, Associate Director, Evidence Planning, Molecular Diagnostics Evidence, Optum Life Sciences

Broad adoption of MRD testing is still evolving as the evidence-base grows across multiple cancer types and intended uses. Insights from clinical trials, published evidence, and medical policies give perspective on utilization and where the space is headed.

3:05 Application of Liquid Biopsies for MRD

Krupa Paranjpe, PharmD, Oncology-Global Oncology Leader-Stakeholder Engagement, Medical Affairs Strategy & Clinical Innovation, Sanofi Genzyme

Advances in cancer care include the recognition of the transformational importance of evolving endpoints such as MRD. What will it take to drive a shift toward MRD recognition and adoption? Education and awareness for all stakeholders in the ecosystem, including patients, providers, payers, and regulators is key to addressing Health System barriers in adoption of MRD as an endpoint and ensuring timely access to innovation for cancer patients.

3:35 cfDNA Fragmentation Applications to Monitor Treatment Response and Disease Progression in Patients with Advanced Cancers

Nicholas C. Dracopoli, PhD, CSO, DELFI Diagnostics

Circulating cfDNA assays for monitoring treatment response and disease progression in individuals with cancer typically rely on prior identification of tumor-specific mutations. Here, we describe a tumor-independent and mutation-independent approach (DELFI-TF) using low-coverage whole genome sequencing to determine the cfDNA tumor fraction and validate the method in independent cohorts of patients with colorectal or lung cancer.

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

CLINICAL APPLICATION FOR MRD *(CONT.)*

4:45 Tumor-Informed MRD Testing and the Road to Clinical Utility

Gina L. Costa, PhD, Vice President, Product Development, Precision Oncology, Exact Sciences Corp.

Analytical sensitivity for tumor-informed MRD detection benefits from targeting more variants and translates to improved clinical performance. NGS approaches face a trade-off between breadth of genomic regions interrogated and depth of sequencing per target. We developed a WES-informed MRD assay (targeting hundreds of variants) and a WGS-informed MAESTRO assay (targeting thousands of variants) that demonstrates striking benefits to recurrence lead times and detection of ctDNA at single-digit ppm levels.

5:15 Phased Variant Detection to Enhance the Sensitivity of MRD Detection

Jeff Gregg, Vice President, Medical Affairs, Foresight Diagnostics

This presentation will demonstrate how ultra-sensitive Minimal Residual Disease (MRD) detection technology is transforming cancer treatment decision-making and improving patient outcomes. By precisely identifying patients at high risk of relapse after first-line therapy, clinicians can initiate early intervention while disease burden is low, while confidently avoiding overtreatment in patients showing molecular clearance. This personalized approach is already being incorporated into clinical practice guidelines.

5:45 Sponsored Presentation *(Opportunity Available)*

6:15 Close of Day

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Liquid Biopsy for Disease Management

ADVANCES IN LIQUID BIOPSIES FOR CANCER PATIENTS: ADVANTAGES AND CHALLENGES

WEDNESDAY, AUGUST 20

7:15 am Registration Open

7:30 Interactive Discussions with Continental Breakfast

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BREAKOUT DISCUSSION: Funding and Commercialization Resources for Liquid Biopsy Assay Development

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

- NIH-wide SBIR and STTR programs
- Funding opportunities for Liquid Biopsy for Cancer Development
- Application tips and assistance for awardees and applicants

IMPROVING LIQUID BIOPSIES

8:25 Chairperson's Remarks

Lokesh Agrawal, PhD, Chief (Acting), Biorepositories & Biospecimen Research, NIH NCI

8:30 Standardizing ctDNA Assays: The Role of Clinical Guidelines in Driving Adoption

Panieh Terraf, PhD, FACMG, Assistant Professor, Memorial Sloan Kettering Cancer Center

As ctDNA-based assays move from research to clinical use, studies show significant variability in validation across institutions. This session will examine how clinical validation guidelines address these inconsistencies through a standardized framework, while also exploring persistent barriers and challenges as testing expands beyond specialized centers. Emphasis will be placed on the role of evidence-based standards in supporting implementation, innovation, and confidence in ctDNA-based liquid biopsy applications.

9:00 KEYNOTE PRESENTATION: Reimbursement Issues for Liquid Biopsies for Cancer

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

The differences between how CMS and Private Pays approach policy will be reviewed. A description of how MACs work, and how policies are considered with be provided. The presentation will also focus on existing liquid biopsy policy and coding strategies.

9:30 Role of Biospecimen Science and Biobanking in Understanding Liquid Biopsies in Cancer

Lokesh Agrawal, PhD, Chief (Acting), Biorepositories & Biospecimen Research, NIH NCI

10:00 Networking Coffee Break

IMPROVING LIQUID BIOPSIES *(CONT.)*

10:30 Towards the Standardization of DNA Methylation Cancer Biomarker Measurements

Hua-Jun He, PhD, Research Biologist, NIST

Aberrant DNA methylation is a promising biomarker for cancer detection. However, there is currently a lack of reliable and quantifiable methods for DNA methylation analysis. We developed both genomic and cell-free format-based reference materials (RMs) for DNA methylation measurements. I will discuss the development, characterization, and utility of these RMs through pilot interlaboratory studies, as well as the improved control assay panel, aimed at standardizing DNA methylation measurements.

11:00 cfDNA Direct from Whole Blood: A New Extraction Paradigm

Matthew S. Owens, PhD, Lead Scientist, R&D, BIOCAPTIVA Ltd.

Our innovative polymer technology transforms liquid biopsies by enabling unlimited sample collection without the need for centrifugation or chemical reagents. This breakthrough technology captures significantly higher yields of circulating cell-free DNA (cfDNA) directly from whole blood by selectively binding cfDNA while excluding unwanted contaminants. Details on performance for improving liquid biopsies and comparisons to conventional approaches will be presented.

11:30 Development of an Integrated Platform for Isolation and Analysis of CTCs, DNA, RNA, Proteins, and Other Biomarkers in a Single Instrument

Ove V. Solesvik, MSc, CEO & Co-Founder, GreinDx AS

Our GreinDisc surface is engineered with a unique periodic roughness, forming distinct and unique geometric features that induce microscale water slippage over the rotating disc. Liquid is evenly partitioned into one million microwells, generating uniform nanodroplets identical in volume and composition. Each nanodroplet undergoes selective filtration based on size and chemical affinity, directing target cells into individual microwells while channeling the remaining filtrate through a membrane for molecular biomarker analysis.

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

CLINICAL APPLICATION OF LIQUID BIOPSIES FOR TREATMENT AND DRUG DEVELOPMENT

1:10 Chairperson's Remarks

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

1:15 Update and Analysis of Results from the NCI-MATCH Study

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

Our experience testing ctDNA from the plasma of ~2300 patients with rare or uncommon cancers screened for the NCI-MATCH trial, the largest precision medicine initiative ever conducted, will be presented. We used a 523-gene targeted panel to identify tumor and CHIP-derived somatic alterations in blood and evaluated blood TMB and MSI status. CtDNA molecular profiles were also compared to targeted NGS data from matched tumor biopsies.

1:45 Liquid Biopsy beyond Genotyping

Justin Odegaard, MD, PhD, Vice President, Product Management, Guardant Health

Liquid biopsy helped democratize genomically-targeted precision oncology; however, this is only the beginning of the impact for liquid biopsy in the treatment of cancer. In this session, we will explore how Infinity, a single combined genomic-epigenomic liquid biopsy technology, unlocks molecular phenotyping as the next evolution in therapy selection, molecular disease monitoring for more precise management of early and late-stage patients alike, and patient-centric early cancer detection.

Liquid Biopsy for Disease Management

ADVANCES IN LIQUID BIOPSIES FOR CANCER PATIENTS: ADVANTAGES AND CHALLENGES

2:15 Use of ctDNA as an Early Indicator of Response to Therapy

Jeff Allen, PhD, President and CEO, Friends of Cancer Research

Circulating tumor DNA (ctDNA) holds promise as a drug development tool to measure treatment efficacy in clinical trials. The ctMoniTR Project is a multi-stakeholder partnership used to evaluate the extent to which ctDNA change correlates with treatment outcomes. Validating the use of ctDNA as an early endpoint will accelerate research by enabling rapid identification of effective new cancer therapies and ultimately allow them to reach patients faster.

2:45 Emergence of Cell Biopsies: Disruptive Forces are Reshaping the Field of Liquid Biopsies for Solid Tumors

Arshad Ahmed, MBA, Founder & CEO, Zaylan Associates

Liquid biopsy is a highly attractive market and is composed of players that provide the ability to capture and analyze circulating tumor DNA (ctDNA). The new battle however, is going to be fought on the ability to detect cancer proteins, RNA as well DNA from blood; i.e., the emergence of multiomics in liquid biopsies. A fundamental shift in pharma pipeline to protein-directed therapies is causing this change.

3:15 Close of Summit

PRESENT A POSTER and SAVE $50!

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 11, 2025.

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.

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- 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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