

Advancing Diagnostics Together

17th Annual

Next Generation 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

Premier Sponsor



seek LABS

NextGenerationDx.com



#NGDx

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“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 Programs

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POCT and Infectious Disease

[Enabling Point-of-Care Diagnostics](#)

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Companion Dx/Reimbursement

[Coverage and Reimbursement for Advanced Diagnostics](#)

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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



2025 SPONSORS

PREMIER SPONSOR



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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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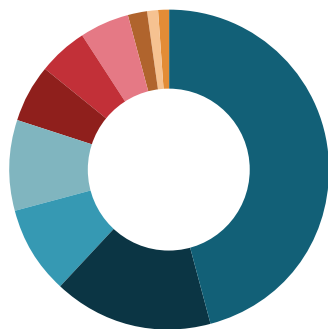
COMPANIES L-Z

KATELIN FITZGERALD

Senior, Business Development Manager
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2024 ATTENDEE DEMOGRAPHICS



COMPANY TYPE

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

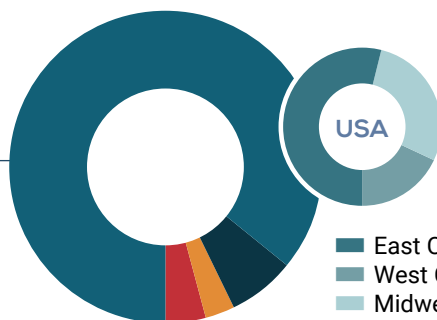


DELEGATE TITLE

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

GEOGRAPHIC LOCATION

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



East Coast	49%
West Coast	30%
Midwest	21%





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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Jennifer R. Leib, Founder, Innovation Policy Solutions LLC

John William Musick, Patient Advocate, End the Legacy

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

12:15 pm Keynote Panel Introduction (Opportunity Available)

12:20 pm PLENARY PANEL DISCUSSION:

From AI to LDTs: Top Lab Advocacy Topics



PANEL MODERATOR:

Susan Van Meter, President, American Clinical Laboratory Association

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- 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

William Ferreira, R&D Team Leader, Life Science

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

Phonetik 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.

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.





Enabling Point-of-Care Diagnostics

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

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.

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

- Strep testing guidelines
- Managing the increase of STIs
- Patient access to medical care
- Workforce considerations

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



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

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



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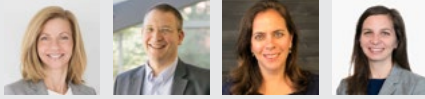


Enabling Point-of-Care Diagnostics

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

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

Rachel Stauffer, Principal, McDermottPlus Consulting LLC

1:05 Session Break

LUNCHEON PRESENTATION

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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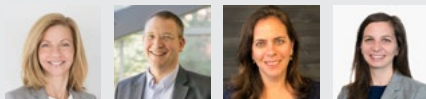
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Rachel Stauffer, Principal, McDermottPlus Consulting LLC

1:05 Session Break**2:25 Organizer's Welcome Remarks****RAPID BACTERIAL DETECTION AND RESISTANCE/SUSCEPTIBILITY TESTING****2:30 Chairperson's Remarks**

Robin M. Patel, MD, D(ABMM), FIDSA, FACP, F(AAM), FRCPC, 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****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





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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

Christine C. Ginocchio, PhD, MT(ASCP), Retired Professor of Medicine, Zucker School of Medicine; CMO and CSO, VedaBio

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 Refreshment 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

MULTI-MODAL 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.

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





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 MoIDx 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 Talk Title to be Announced

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

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

3:45 PANEL DISCUSSION: Creating Alignment in How Utilization-Management Practices Impact Access to Care

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

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.

LEGISLATION AND ADVOCACY IN BIOMARKER TESTING

8:25 Chairperson's Remarks





Emerging Trends in Coverage and Reimbursement for Advanced Diagnostics

ASSESSING POLICY IMPACTS AND BUILDING A ROADMAP FOR THE FUTURE

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)

Kim Linthicum, Principal, Todd Strategy Group

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

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



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 Session Break

LUNCHEON PRESENTATION

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





Clinical Biomarkers and Companion Diagnostics

COLLABORATING TO DRIVE PRECISION MEDICINE FORWARD

TUESDAY, AUGUST 19

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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 Considerations for Implementing Early-Stage Trials in China

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

China plays a pivotal role in MRCTs for global drug development. Successfully conducting early-stage trials in China requires navigating a unique regulatory landscape. Biomarker-driven trials and CDx development face additional regulatory scrutiny such as HGRAC approvals for genetic resource use, as well as operational challenges such as site selection, investigator expertise, and patient recruitment. Navigating these challenges effectively ensures regulatory compliance and trial success in China's evolving clinical landscape.

3:35 Presentation to be Announced

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

COMPANION DIAGNOSTIC DEVELOPMENT

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.

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.





Clinical Biomarkers and Companion Diagnostics

COLLABORATING TO DRIVE PRECISION MEDICINE FORWARD

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 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 Refreshment Break

NEXT-GENERATION BIOMARKERS FOR NEXT-GENERATION DIAGNOSTICS

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 Diagnostics Development, 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.

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





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 Sequencing of Epigenetic Biomarkers in Screening for Ovarian, Pancreatic, and MCED

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

9:30 Update on Guardant Health MCED Development Programs

Craig Eagle, PhD, CMO, Guardant Health

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 Updated Data from GRAIL MCED Screening Studies

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

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

Stacey Brown, Market Access Lead, 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

IMPLEMENTING EARLY CANCER SCREENING (CONT.)

3:45 Clinical Trial Design for the Vanguard Study

Speaker to be Announced

The Vanguard Trail is a pilot study that will enroll up to 24,000 patients to evaluate and feasibility and performance of two different MCED assays, from Guardant Health and ClearNote. Details of the clinical trial design, challenges for the study, and questions to be addressed by the prospective trial will be discussed. Results from this trial are expected to inform a larger trial to achieve the goals of stage shifting and reduction in mortality.

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

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

6:15 Close of Day





Early Cancer Surveillance

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

TUESDAY, AUGUST 19**7:15 am Registration Open****7:30 Interactive Discussions with Continental Breakfast**

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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

Phillip 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.

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 Precancer Detection via RNA Liquid Biopsy Technology

Daniel H. Kim, PhD, Assistant Professor, Biomolecular Engineering Genomics Institute, 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.

9:45 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.

10:00 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 proprietary 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.

10:15 Presentation to be Announced**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

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



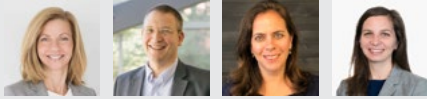


Early Cancer Surveillance

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

12:15 pm Keynote Panel Introduction (*Opportunity Available*)

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



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 Session Break

LUNCHEON PRESENTATION

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

1:40 Close of Early Cancer Surveillance Conference





Liquid Biopsy for Disease Management

ADVANCES IN LIQUID BIOPSIES FOR CANCER PATIENTS: ADVANTAGES AND CHALLENGES

TUESDAY, AUGUST 19

PLENARY SESSION

11:30 Introduction to GINA and the Current Landscape

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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

Jake Chabon, PhD, Co-Founder & CEO, 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****WEDNESDAY, AUGUST 20****7:15 am Registration Open**



Liquid Biopsy for Disease Management

ADVANCES IN LIQUID BIOPSIES FOR CANCER PATIENTS: ADVANTAGES AND CHALLENGES

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.

IMPROVING LIQUID BIOPSIES

8:25 Chairperson's Remarks

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

Panieh Terraf, 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-Wilner, 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 will be provided. The presentation will also focus on existing liquid biopsy policy and coding strategies.

9:30 Sponsored Presentation (Opportunity Available)

10:00 Networking Refreshment 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, CEO and 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.

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, 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



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