2020 CONFERENCE PROGRAMS

POCT TECHNOLOGIES AND STRATEGY

- Enabling Point-of-Care Diagnostics
- Point-of-Care Technologies

POCT AND INFECTIOUS DISEASE

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

LIQUID BIOPSY/ EARLY DETECTION

- Enabling Technologies for Liquid Biopsy
- Early Detection of Disease

COMPANION DX AND IO BIOMARKERS

- Drug-Diagnostics Co-Development & Companion Dx
- Immuno-Oncology Biomarkers and Diagnostics

BUSINESS

- Coverage and Reimbursement
- Commercialization

NGS ADVANCES

- NGS Advances and Multimodality Assays

Organized by Cambridge Healthtech Institute

Advancing Diagnostics Together

12th Annual

Next Generation VIRTUAL Dx

INTERACTIVE GLOBAL SUMMIT

AUGUST 25-27, 2020 NextGenerationDx.com

Register Early for Maximum Savings!

FOCUS ON COVID-19 The Diagnostics Community Takes on the Pandemic

PLENARY KEYNOTE

Ultrasensitive SARS-CoV-2 Protein Assays for Precision Clinical Decisions

David R. Walt, PhD, Harvard University

PLENARY PANEL DISCUSSION

Lessons Learned for Diagnostic Testing During the COVID-19 Pandemic

Moderator: Susan Hsiao, MD, PhD, Columbia University Medical Center

Co-organized with AMP Association for Molecular Pathology

PANEL DISCUSSION

COVID-19 Survey of Labs from the Association for Molecular Pathology: Recommendations for a Better Pandemic Response

Moderator: Jordan S. Laser, MD, Northwell Health

Co-organized with AMP Association for Molecular Pathology

Fireside Chat with the FDA: Innovation in Diagnostics

Sara Brenner, MD, MPH, U.S. Food & Drug Administration

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#NGDx20 NextGenerationDX.com

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Next Generation Dx VIRTUAL
INTERACTIVE GLOBAL SUMMIT

2020 CONFERENCE PROGRAMS

Welcome

Next Generation Dx VIRTUAL INTERACTIVE GLOBAL SUMMIT

#NGDx20

Rapid diagnostics tests are advancing to help manage the current pandemic and decentralized testing holds tremendous promise for how we might manage emerging pathogens and future outbreaks. Non-invasive testing, immunotherapy biomarkers and companion diagnostics are vital tools for the pharma and biotech industries, and the implementation of these tests require successful reimbursement and commercialization strategies to ensure the safety and viability of essential therapies.

For more than a decade, 800 industry professionals have considered the **Next Generation Dx Summit** a nexus for key decision and policy-makers, academic and industry leaders to learn the latest technologies, assays, sample prep and detection methods, analysis and machine learning approaches that drive innovation. In-depth discussion of regulatory and reimbursement solutions will be featured that are critical to the implementation of value-based care and rapid response to pandemic testing.

Conference At-A-Glance

STREAM	August 25 - 26 | Tuesday - Wednesday AM | **PART A CONFERENCES**	August 26 - 27 | Wednesday PM - Thursday | **PART B CONFERENCES**
POCT TECHNOLOGIES AND STRATEGY	Enabling Point-of-Care Diagnostics	Point-of-Care Technologies
POCT AND INFECTIOUS DISEASE	Enabling Point-of-Care Diagnostics (SHARED PROGRAMS)	Advanced Diagnostics for Infectious Disease
LIQUID BIOPSY/EARLY DETECTION	Enabling Technologies for Liquid Biopsy	Early Detection of Disease
COMPANION DX AND IO BIOMARKERS	Drug-Diagnostics Co-Development & Companion Dx	Immuno-Oncology Biomarkers and Diagnostics
BUSINESS	Coverage and Reimbursement	Commercialization of Diagnostic Tests
NGS ADVANCES		NGS Advances and Multimodality Assays

Plenary Keynote Session

Wednesday, August 26 | 11:10-12:55pm

Next Generation VIRTUAL Dx INTERACTIVE GLOBAL SUMMIT

11:10 Organizer's Opening Remarks

Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech

11:15 Ultrasensitive SARS-CoV-2 Protein Assays for Precision Clinical Decisions

David Walt, PhD, Hansjörg Wyss Professor, Biologically Inspired Engineering, Harvard Medical School; Professor, Department of Pathology, Brigham and Women's Hospital; Core Faculty, Wyss Institute for Bioinspired Engineering, Harvard University, HHMI Professor

We have developed ultrasensitive single molecule assays for multiple relevant SAR-CoV-2 proteins that can detect both active virus and prior infection. The assays have been tested in thousands of individuals, including patients and healthcare workers and exhibit exceptional sensitivity and specificity. Additionally, we have followed these protein concentrations over time during the course of disease in many patients and can predict outcomes based on the dynamics of the protein responses.

"The value per minute per day was just off the charts."

VP Marketing, Click Diagnostics

Co-Organized by

AMP Association for Molecular Pathology

11:40 pm PANEL DISCUSSION: What Technologies Will Shape Precision Medicine in 2020?

Moderator: Susan Hsiao, MD, PhD, Assistant Professor, Pathology and Cell Biology, Columbia University Medical Center

Panelists: Alex Greninger, MD, PhD, MS, MPhil, Assistant Professor, Lab Medicine, University of Washington

Jordan S. Laser, MD, Medical Director, Department of Pathology and Laboratory Medicine; LIJMC Associate Medical Director, Core Laboratories; Sr. Director, Division of Cytogenetics and Molecular Pathology; Director, Division of Near Patient Testing, Northwell Health

David Walt, PhD, Hansjörg Wyss Professor, Biologically Inspired Engineering, Harvard Medical School; Professor, Department of Pathology, Brigham and Women's Hospital; Core Faculty, Wyss Institute for Bioinspired Engineering, Harvard University, HHMI Professor

What is the clinical impact of some of the following technologies and what are the current bottlenecks and challenges that need to be surmounted? Examples of each will be given:

- Supply chain challenges
- Navigating and validating multiple platforms
- Reimbursement
- Value of distributed testing
- Value of tests available: PCR vs. antigen vs. serology
- Developing sustainable testing protocols

12:15 Plenary Keynote Introduction

ClearView Healthcare Partners

Charles Mathews, Principal, ClearView Healthcare Partners

12:30-12:55 Fireside Chat

Moderator: Charles Mathews, Principal, ClearView Healthcare Partners

Sara Brenner, MD, MPH, Associate Director for Medical Affairs; CMO, In Vitro Diagnostics, Office of In Vitro Diagnostics & Radiological Health (OIR), Office of Product Evaluation & Quality (OPEQ), Center for Devices & Radiological Health (CDRH), U.S. Food & Drug Administration

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Jon Stroup
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781-972-5483
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- Post event, CHI will provide full contact information for your specific session
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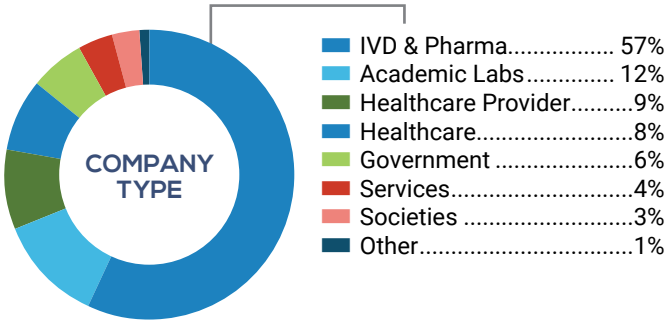
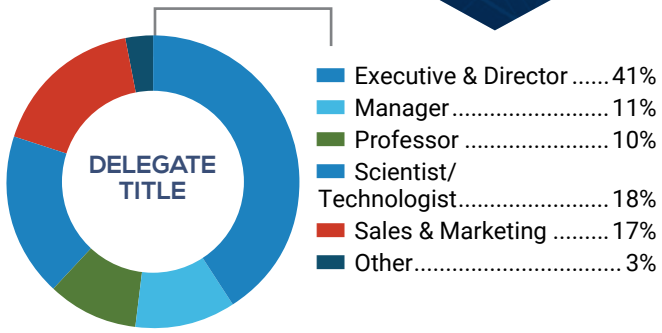
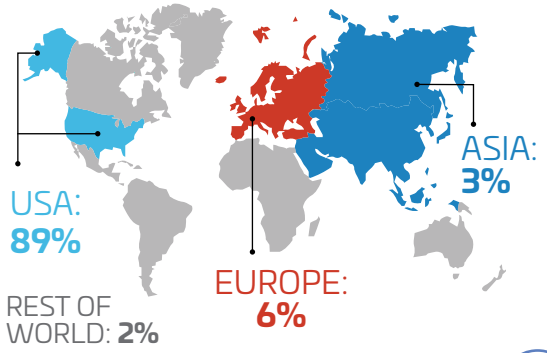




ATTENDEES BY GEOGRAPHIC LOCATION



DOWNLOAD EXHIBITOR PROSPECTUS

POCT Technologies and Strategy Stream

CONFERENCE STREAMS

- POCT TECHNOLOGIES AND STRATEGY
- POCT AND INFECTIOUS DISEASE
- LIQUID BIOPSY/EARLY DETECTION
- COMPANION DX AND IO BIOMARKERS
- BUSINESS
- NGS ADVANCES

2020 POCT TECHNOLOGIES AND STRATEGY CONFERENCES

AUGUST 25-26

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

AUGUST 26-27

AGENDA **Point-of-Care Technologies**

REGISTER EARLY & SAVE!

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CHI'S 14TH ANNUAL | **AUGUST 25-26, 2020**

Enabling Point-of-Care Diagnostics

IMPLEMENTATION AND BUSINESS STRATEGIES

TUESDAY, AUGUST 25

REDUCING ERRORS AT THE POINT-OF-CARE

9:00 am Chairperson's Remarks

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

9:05 Real-World Issues Encountered with POCT

Valerie L Ng, MD, PhD, Chair of Laboratory Medicine & Pathology, and Director of Transfusion Services, Clinical Laboratories, Alameda Health System

Caregivers expect point-of-care testing (POCT) to be fast and accurate. This talk will present real-world vignettes of POCT, highlighting the impact of non-laboratory test personnel, patient care time pressures, and less than orderly environments on POCT devices, their performance, and quality of test results. Suggestions for improved POCT design based on these known real-world pitfalls will be presented.

9:25 Challenges and Practical Solutions in Implementing Point-of-Care Testing

Joe Wiencek, PhD, Assistant Professor, Department of Pathology; Medical Director, Point-of-Care Testing; Associate Medical Director, Clinical Chemistry; Co-Director, Clinical Chemistry Fellowship, University of Virginia School of Medicine

Point-of-care testing (POCT) is universal in modern healthcare. New and innovative technologies permit diagnostic tests to leave the confines of the centralized laboratory and migrate to the site of patient care. Unfortunately, the excitement of this technology is often lost due to an assortment of practical obstacles. Many of these challenges will be discussed and practical solutions will be offered.

9:45 Presentation to be Announced

Bryan Bothwell

10:10 Risk Management for Point-of-Care Testing

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

As point-of-care tests migrate out of the laboratory, devices are subject to environmental extremes and operator variation that can impact patient results. Errors with can come from a number of sources, including the instrument, operator, reagent, and environment. This presentation discusses common sources of POCT error, describe how manufacturers are engineering products to prevent errors, and will identify ways that institutions can design their quality control programs to minimize error.

10:30 Coffee Break - View our Virtual Exhibit Hall

REDUCING ERRORS AT THE POINT-OF-CARE

10:45 Chairperson's Remarks

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

10:50 Let's Talk about Quality Control & Individualized Quality Control Plans

Jelani Sanaa, MS, MLS(ASCP)CM, SBBCM, SHCM, Clinical Lab Scientist, Centers for Medicare and Medicaid Services (CMS); Centers for Clinical Standards and Quality (CCSQ); Quality, Safety and Oversight Group (QSOG), Division of Clinical Laboratory Improvement and Quality (DCLIQ), US Department of Health & Human Services

IQCP provides laboratories with flexibility in customizing quality control (QC) policies and procedures for non-waived testing, based on the test systems in use and the unique aspects of each laboratory. IQCP is voluntary. Laboratories can achieve compliance by following manufacturer's guidelines and all CLIA QC regulations as written. If those guidelines are less stringent than CLIA, or if the manufacturer does not provide guidelines, the laboratory must implement an IQCP.

11:10 Failsafes: The Last Frontier towards CLIA Waiver

Corinne Fantz, PhD, Director, Scientific Affairs, Roche

Test operators in the CLIA-waived environment often have limited laboratory experience. Instruments used in these areas should be equipped with failsafes to prevent the instrument from delivering bad test results. Failsafes can block the release of test results when there is operator error, humidity/temperature failures, or interfering substances. This presentation reviews common failsafes and highlights new design opportunities for manufacturers preparing for CLIA waiver.

11:30 Session Wrap-Up

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

Panelists:

Corinne Fantz, PhD, Director, Scientific Affairs, Roche

Bryan Bothwell

Joe Wiencek, PhD, Assistant Professor, Department of Pathology; Medical Director, Point-of-Care Testing; Associate Medical Director, Clinical Chemistry; Co-Director, Clinical Chemistry Fellowship, University of Virginia School of Medicine

Valerie L Ng, MD, PhD, Chair of Laboratory Medicine & Pathology, and Director of Transfusion Services, Clinical Laboratories, Alameda Health System

12:15 pm Lunch Break - View our Virtual Exhibit Hall

PREPARING FOR THE NEXT WAVE OF POC DIAGNOSTICS: OVERCOMING CHALLENGES WITH CONSUMER TESTING

12:40 Chairperson's Remarks

Lawrence Worden, Founder, Principal, IVD Logix

12:45 Overcoming Regulatory Challenges for Home-Use Tests

Elliot Cowan, PhD, Principal, Partners in Diagnostics LLC

Home-use tests can increase access to testing, safeguard privacy, empower individuals to take control of their healthcare decisions, and protect public health. However, these benefits come with significant risks and challenges, including how to demonstrate that the benefits outweigh the risks, how to address the need for infectious disease reporting, and post-market surveillance. This talk will describe how regulators deal with such issues to bring home-use tests to market.

1:05 Innovative Approaches to At-Home Collection for STI Testing

Charlotte Gaydos, MS, MPH, DrPH, Professor, Infectious Diseases, Johns Hopkins University

The iwantthekit (IWTK) program offers internet-requested kits for home collection for screening of common STI. Other programs exist. We will discuss innovation programs and acceptability for home collection, and we will review published programs. Many

ENABLING POINT-OF-CARE DIAGNOSTICS, continued

studies reported use of and willingness to use home collection when available. There was willingness to pay an average of $10-30. User satisfaction was high for home collection.

1:25 Professional Concerns with At-Home Testing

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

Currently at-home testing is available in many formats. Though many arguments support the use of consumer OTC self-testing, there are still some concerns from a quality assurance perspective from the medical technologist who currently oversee point-of-care testing in the healthcare setting. In this session, we will discuss some of those concerns from the point of care coordinator's point of view.

1:45 Live Q&A: Session Wrap-Up

Moderator: Lawrence Worden, Founder, Principal, IVD Logix

Panelists:

Elliot Cowan, PhD, Principal, Partners in Diagnostics LLC

Charlotte Gaydos, MS, MPH, DrPH, Professor, Infectious Diseases, Johns Hopkins University

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

2:10 Refresh Break - View our Virtual Exhibit Hall

3:30 Happy Hour - View our Virtual Exhibit Hall

4:00 Close of Day

WEDNESDAY, AUGUST 26

DEPLOYING POINT-OF-CARE TESTING TO MANAGE DISEASE OUTBREAKS

9:00 am Chairperson's Remarks

Gerald Kost, MD, PhD, MS, FAACC, Director, Point-of-Care Testing Center for Teaching and Research (POCT•CTR), University of California, Davis

9:05 Point-of-Care COVID-19 Diagnostics: Understanding Metrics and Creating Guidelines

Gerald Kost, MD, PhD, MS, FAACC, Director, Point-of-Care Testing Center for Teaching and Research (POCT•CTR), University of California, Davis

Increasingly, we observe the adverse personal, societal, economic, and cultural impact of outbreaks, antimicrobial resistance, and disasters. Nations are not prepared! POC strategies can mitigate risk, reduce harm, and improve crisis standards of care. Global solutions integrate national POCT policy and guidelines, and distribute financial burden and reasonable business models.

9:25 Point-of-Care Molecular Diagnostics for Disease Outbreak Settings: The Path to the Future

Rachel Spurbeck, PhD, Principal Research Scientist, Health Outcomes and Biotechnology Solutions, Battelle Memorial Institute

Rapid, accurate, and affordable point-of-care (POC) diagnostics are key to detecting and mitigating the impact of disease outbreaks, particularly for emerging pathogens. Molecular approaches offer speed, sensitivity, and specificity, but can introduce complexity and expense, making it difficult to achieve a POC diagnostic suitable for use outside a clinical setting. This talk reviews molecular diagnostics and examines the path to deployable POC diagnostics for outbreak settings, including challenges undertaken today.

9:45 Live Q&A: Session Wrap-Up

Moderator: Gerald Kost, MD, PhD, MS, FAACC, Director, Point-of-Care Testing Center for Teaching and Research (POCT•CTR), University of California, Davis

Panelists:

Rachel Spurbeck, PhD, Principal Research Scientist, Health Outcomes and Biotechnology Solutions, Battelle Memorial Institute

10:30 Coffee Break - View our Virtual Exhibit Hall

10:40 Problem Solving Discussions - View our Virtual Exhibit Hall

BREAKOUT 2: Risk Management for Point-of-Care Testing

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

BREAKOUT 3: Work Smarter, Not Harder: Tips to Make Your POCT Life Easier

Joe Wiencek, PhD, Assistant Professor, Department of Pathology; Medical Director, Point-of-Care Testing; Associate Medical Director, Clinical Chemistry; Co-Director, Clinical Chemistry Fellowship, University of Virginia School of Medicine

BREAKOUT 4: Reimbursement Issues with COVID-19 Testing

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

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

PLENARY KEYNOTE SESSION

11:10 Organizer's Opening Remarks

Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

11:15 KEYNOTE PRESENTATION: Ultrasensitive SARS-CoV-2 Protein Assays for Precision Clinical Decisions

David Walt, PhD, HHMI Professor; Hansjörg Wyss Professor of Biologically Inspired Engineering, Harvard Medical School; Professor of Pathology, Department of Pathology-Brigham and Women's Hospital; Core Faculty, Wyss Institute for Bioinspired Engineering, Harvard University

We have developed ultrasensitive single molecule assays for multiple relevant SAR-CoV-2 proteins that can detect both active virus and prior infection. The assays have been tested in thousands of individuals, including patients and healthcare workers and exhibit exceptional sensitivity and specificity. Additionally, we have followed these protein concentrations over time during the course of disease in many patients and can predict outcomes based on the dynamics of the protein responses.

11:40 Lessons Learned for Diagnostic Testing During the COVID-19 Pandemic

Moderator: Susan Hsiao, MD, PhD, Assistant Professor, Pathology and Cell Biology, Columbia University Medical Center

- Supply chain challenges
- Navigating and validating multiple platforms
- Reimbursement
- Value of distributed testing
- Value of tests available: PCR vs. antigen vs. serology
- Developing sustainable testing protocols

Panelists:

Alex Greninger, MD, PhD, MS, MPhil, Assistant Professor, Lab Medicine, University of Washington

Jordan S. Laser, MD, Medical Director, Department of Pathology and Laboratory Medicine; LIJMC; Associate Medical Director, Core Laboratories; Director, Division of Near Patient Testing, Northwell Health; Associate Professor, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell

David Walt, PhD, HHMI Professor; Hansjörg Wyss Professor of Biologically Inspired Engineering, Harvard Medical School; Professor of Pathology, Department of Pathology-Brigham and Women's Hospital; Core Faculty, Wyss Institute for Bioinspired Engineering, Harvard University

ENABLING POINT-OF-CARE DIAGNOSTICS, continued

12:15 pm Keynote Introduction

Charles Mathews, Principal, ClearView Healthcare Partners

12:30 Panel Discussion : Fireside Chat

Moderator: Charles Mathews, Principal, ClearView Healthcare Partners

Panelists:

Sara Brenner, MD, MPH, Associate Director for Medical Affairs; CMO, In Vitro Diagnostics, Office of In Vitro Diagnostics & Radiological Health (OIR), Office of Product Evaluation & Quality (OPEQ), Center for Devices & Radiological Health (CDRH), U.S. Food & Drug Administration

12:55 Lunch Break - View our Virtual Exhibit Hall

1:00 The Critical Role of Antigens and Antibodies in SARS-CoV-2 Serological Test Development

Joe Jiang, Product Manager, Product Development, ACROBiosystems

High-quality recombinant SARS-CoV-2 antigens and antibodies are key reagents in the development of SARS-CoV-2 serological test kits. ACROBiosystems has developed a series of SARS-CoV-2 antigen and antibody products that can be used in serological tests.

1:25 Close of Enabling Point-of-Care Diagnostics Conference

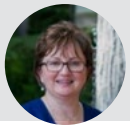
CHI'S 2ND ANNUAL | **AUGUST 26-27, 2020**

Point-of-Care Technologies

EXPLORING MICROFLUIDICS, SENSORS & DIGITAL TOOLS

WEDNESDAY, AUGUST 26

PLENARY KEYNOTE SESSION



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Moderator: Susan Hsiao, MD, PhD, Assistant Professor, Pathology and Cell Biology, Columbia University Medical Center

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Panelists:

Alex Greninger, MD, PhD, MS, MPhil, Assistant Professor, Lab Medicine, University of Washington

Jordan S. Laser, MD, Medical Director, Department of Pathology and Laboratory Medicine; LIJMC; Associate Medical Director, Core Laboratories; Director, Division of Near Patient Testing, Northwell Health; Associate Professor, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell

David Walt, PhD, HHMI Professor; Hansjörg Wyss Professor of Biologically Inspired Engineering, Harvard Medical School; Professor of Pathology, Department of Pathology-Brigham and Women's Hospital; Core Faculty, Wyss Institute for Bioinspired Engineering, Harvard University

12:15 pm Keynote Introduction ClearView Healthcare Partners

Charles Mathews, Principal, ClearView Healthcare Partners

12:30 Fireside Chat

Moderator: Charles Mathews, Principal, ClearView Healthcare Partners

Panelists:

Sara Brenner, MD, MPH, Associate Director for Medical Affairs; CMO, In Vitro Diagnostics, Office of In Vitro Diagnostics & Radiological Health (OIR), Office of Product Evaluation & Quality (OPEQ), Center for Devices & Radiological Health (CDRH), U.S. Food & Drug Administration

12:55 Lunch Break - View our Virtual Exhibit Hall

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Joe Jiang, Product Manager, Product Development, ACROBiosystems

High-quality recombinant SARS-CoV-2 antigens and antibodies are key reagents in the development of SARS-CoV-2 serological test kits. ACROBiosystems has developed a series of SARS-CoV-2 antigen and antibody products that can be used in serological tests.

INNOVATING THE NEXT GENERATION OF POC

1:30 The Next Generation of Continuous Diagnostic Sensors: A Case Study on the Breakthroughs for Sweat Biosensing

Jason Heikenfeld, PhD, Associate Vice President, Operations, Office of Innovation; Professor and Director, Novel Device Laboratory, University of Cincinnati

Continuous biosensing promises to bring the lab into a wearable format that measures anything from cardiac health to pre-symptomatic viral detection. The reality of this promise is that success continues to be limited to glucose monitoring or conventional, decades-old optical or electrical non-specific measures. We present the real challenges the field faces, along with first-ever breakthroughs that have resulted in non-invasive wearables that can provide continuous blood-correlated chemical data.

1:50 Developing Next-Generation Diagnostics to Meet Clinical Needs

Ping Wang, PhD, DABCC, Chief, Clinical Chemistry; Director, Core Laboratory Hospital, University of Pennsylvania

The field of POC technologies has witnessed strong growth. Only when combined with appropriate strategies for clinical needs assessment, validation and implementation, these technologies may significantly impact care delivery and associated outcomes and costs. I will discuss clinical needs, validation and implementation strategies for novel POC technologies from two perspectives: as a practicing clinical laboratory director and as a technology researcher and developer.

2:10 Session Break - View Our Virtual Exhibit Hall

2:35 Live Q&A: Session Wrap-Up

Moderator: Shawn Mulvaney, PhD, Section Head, Surface Nanoscience and Sensor Technology Section, Chemistry, U.S. Naval Research Laboratory

Panelists:

Ping Wang, PhD, DABCC, Chief, Clinical Chemistry; Director, Core Laboratory Hospital, University of Pennsylvania

Jason Heikenfeld, PhD, Associate Vice President, Operations, Office of Innovation; Professor and Director, Novel Device Laboratory, University of Cincinnati

2:55 Refresh Break - View our Virtual Exhibit Hall

POINT-OF-CARE TECHNOLOGIES, continued

FEATURED SESSION: NUCLEIC ACID DETECTION

3:35 KEYNOTE PRESENTATION: Engineering Biology for Diagnostic Solutions

William Blake, PhD, CTO, Sherlock Biosciences

SHERLOCK is a method for single molecule detection of nucleic acid targets by amplifying genetic sequences and programming a CRISPR molecule to detect the presence of a genetic signature. When it finds those signatures, the CRISPR enzyme is activated and releases a signal. It can be adapted to work on a paper strip test, laboratory equipment, or to provide an electrochemical readout that can be read with a mobile phone.

3:55 Instrument-Free Paper-Based POC Pathogen Diagnostics for the Clinic and the Home

Paul Yager, PhD, Professor, Department of Bioengineering, University of Washington

Instruments ranging from the venerable GeneXpert to ones just coming on the market allow fairly rapid NAAT pathogen detection, but they are based on disposable cartridges and a permanent (and relatively expensive) instrument. Our lab has been developing instrument-free disposable NAAT devices that retain the advantages of the instrumented systems, but free the user from the need for purchasing a permanent instrument (and the upfront cost that incurs).

4:15 Live Q&A: Session Wrap-Up

Moderator: Shawn Mulvaney, PhD, Section Head, Surface Nanoscience and Sensor Technology Section, Chemistry, U.S. Naval Research Laboratory

Panelists:

William Blake, PhD, CTO, Sherlock Biosciences

Paul Yager, PhD, Professor, Department of Bioengineering, University of Washington

4:35 Happy Hour - View our Virtual Exhibit Hall

5:10 Close of Day

THURSDAY, AUGUST 27

REDEFINING POC IN THE DIGITAL ERA

9:05 am Fast, Accurate, and Actionable: How Digital Tools in Femtech Unlock a $50 Billion Market

Danielle Bradnan, MS, Research Associate, Digital Health and Wellness, Lux Research

Current diagnostic paradigms often leave women's health as a secondary or niche consideration, leading to considerable struggles in terms of getting a rapid, accurate, and actionable diagnosis. However, with the advent of digital tools such as apps, wearables, and AI, healthcare startups are rapidly developing solutions to close the gap between symptoms and diagnosis. In this talk, we will explore the current solution landscape and highlight opportunities.

9:25 Advancing Care with Digital Therapeutics

Sharief Taraman, MD, CMO, Cognoa; Division Chief, CHOC Children's Hospital

Early intervention of autism is proven to impact a child's lifelong outcomes, but today's system misses the critical window when treatment has its greatest impact. This session explains how a clinically validated, AI-powered prescription diagnostic, designed for use by pediatricians, can streamline and scale early diagnosis and fast-track access to care. Audiences will understand how digital therapeutics can enable equitable health outcomes for children with behavioral health conditions.

9:45 Live Q&A: Session Wrap Up

Moderator: Sharief Taraman, MD, CMO, Cognoa; Division Chief, CHOC Children's Hospital

Panelists:

Danielle Bradnan, MS, Research Associate, Digital Health and Wellness, Lux Research

10:05 Coffee Break - View Our Virtual Exhibit Hall

10:15 Problem Solving Discussions - View Our Virtual Exhibit Hall

BREAKOUT 10: How AI-Based Devices can Better Inform Clinical Decision-Making

Sharief Taraman, MD, CMO, Cognoa; Division Chief, CHOC Children's Hospital

IMPROVING POC

10:45 Chairperson's Remarks

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

10:50 Novel Techniques for POC Disease Monitoring Utilizing Programmable Molecular Velcro

Kaylyn Oshaben, PhD, Synthetic Biology Specialist, Altratech Limited

Altratech is interested in moving disease monitoring to the point-of-care and beyond. Common barriers to implementing point-of-care or home nucleic acid disease monitoring systems revolve around sample prep, reagent storage and user expertise. To overcome some of these barriers, we are developing new techniques that utilize peptide nucleic acids (PNA) as both enrichment and capture agents that simplify sample prep, reagents and detection technology.

11:10 Application of Intelligent Quality Management at Point-of-Care

Sohrab Mansouri, PhD, Staff Scientist, Advance Development, Instrumentation Laboratory

This presentation describes an integrated QC method based on identifying error patterns for a given measurement system and devising a method for rapid detection and targeted corrective action with no user involvement.

11:30 Session Break

11:40 Live Q&A: Session Wrap Up

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

Panelists:

Sohrab Mansouri, PhD, Staff Scientist, Advance Development, Instrumentation Laboratory

Kaylyn Oshaben, PhD, Synthetic Biology Specialist, Altratech Limited

12:00 pm Lunch Break - View our Virtual Exhibit Hall

CASE STUDIES

12:30 eRAPID Technology – A Universal Multiplexed Electrochemical Sensor Platform Repurposed to Detect COVID-19 Antibodies

Pawan Jolly, PhD, Senior Scientist, Wyss Institute, Harvard University

eRapid is proprietary electrical sensor technology, enabling the detection of small chemicals and large biomolecules in complex fluid samples without requiring sample preparation. During the current pandemic, eRapid technology has been repurposed to develop a rapid multi-antigen platform for the detection of IgG, IgM, and IgA. The platform has been tested with nearly 80 samples and has shown high sensitivity and selectivity.

POINT-OF-CARE TECHNOLOGIES, continued

12:50 CASE STUDY: Federal Resources for Early-Stage Diagnostic Start-Up

Tiffani Lash, PhD, Program Director, National Institutes of Health

I will discuss the federal resources for early-stage companies that fall into the research portfolios of biosensors, platform technologies, and mHealth programs at NIH. NIBIB Point-of-Care Technologies Research Network will be explained, consisting of three centers charged with developing point-of-care diagnostic technologies through collaborative efforts that merge scientific and technological capabilities with clinical need.

1:10 Panel Discussion: Commercializing Point-of-Care Tests – Translating Early-Stage Innovation

Moderator: Richard Chasen Spero, PhD, CEO, Redbud Labs, Inc.

- Current status on bringing your technology to market
- Key considerations for developing an early translational roadmap
- Funding opportunities and business plan requirements
- How do you develop your go-to-market strategy?
- Attracting early strategic partners
- What role are KOLs and/or institutions playing as you bring your technology to market?

Panelists:

Pawan Jolly, PhD, Senior Scientist, Wyss Institute, Harvard University

Tiffani Lash, PhD, Program Director, National Institutes of Health

1:20 Close of Summit

POCT and Infectious Disease Stream

CONFERENCE STREAMS

- POCT TECHNOLOGIES AND STRATEGY
- POCT AND INFECTIOUS DISEASE
- LIQUID BIOPSY/EARLY DETECTION
- COMPANION DX AND IO BIOMARKERS
- BUSINESS
- NGS ADVANCES

2020 POCT AND INFECTIOUS DISEASE CONFERENCES

AUGUST 25-26

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

AUGUST 26-27

AGENDA **Advanced Diagnostics for Infectious Disease**

Enabling Point-of-Care Diagnostics

IMPLEMENTATION AND BUSINESS STRATEGIES

TUESDAY, AUGUST 25

REDUCING ERRORS AT THE POINT-OF-CARE

9:00 am Chairperson's Remarks

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

9:05 Real-World Issues Encountered with POCT

Valerie L Ng, MD, PhD, Chair of Laboratory Medicine & Pathology, and Director of Transfusion Services, Clinical Laboratories, Alameda Health System

Caregivers expect point-of-care testing (POCT) to be fast and accurate. This talk will present real-world vignettes of POCT, highlighting the impact of non-laboratory test personnel, patient care time pressures, and less than orderly environments on POCT devices, their performance, and quality of test results. Suggestions for improved POCT design based on these known real-world pitfalls will be presented.

9:25 Challenges and Practical Solutions in Implementing Point-of-Care Testing

Joe Wiencek, PhD, Assistant Professor, Department of Pathology; Medical Director, Point-of-Care Testing; Associate Medical Director, Clinical Chemistry; Co-Director, Clinical Chemistry Fellowship, University of Virginia School of Medicine

Point-of-care testing (POCT) is universal in modern healthcare. New and innovative technologies permit diagnostic tests to leave the confines of the centralized laboratory and migrate to the site of patient care. Unfortunately, the excitement of this technology is often lost due to an assortment of practical obstacles. Many of these challenges will be discussed and practical solutions will be offered.

9:45 Presentation to be Announced

Bryan Bothwell

10:10 Risk Management for Point-of-Care Testing

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

As point-of-care tests migrate out of the laboratory, devices are subject to environmental extremes and operator variation that can impact patient results. Errors with can come from a number of sources, including the instrument, operator, reagent, and environment. This presentation discusses common sources of POCT error, describe how manufacturers are engineering products to prevent errors, and will identify ways that institutions can design their quality control programs to minimize error.

10:30 Coffee Break - View our Virtual Exhibit Hall

REDUCING ERRORS AT THE POINT-OF-CARE

10:45 Chairperson's Remarks

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

10:50 Let's Talk about Quality Control & Individualized Quality Control Plans

Jelani Sanaa, MS, MLS(ASCP)^{CM}, SBB^{CM}, SH^{CM}, Clinical Lab Scientist, Centers for Medicare and Medicaid Services (CMS); Centers for Clinical Standards and Quality (CCSQ); Quality, Safety and Oversight Group (QSOG), Division of Clinical Laboratory Improvement and Quality (DCLIQ), US Department of Health & Human Services

IQCP provides laboratories with flexibility in customizing quality control (QC) policies and procedures for non-waived testing, based on the test systems in use and the unique aspects of each laboratory. IQCP is voluntary. Laboratories can achieve compliance by following manufacturer's guidelines and all CLIA QC regulations as written. If those guidelines are less stringent than CLIA, or if the manufacturer does not provide guidelines, the laboratory must implement an IQCP.

11:10 Failsafes: The Last Frontier towards CLIA Waiver

Corinne Fantz, PhD, Director, Scientific Affairs, Roche

Test operators in the CLIA-waived environment often have limited laboratory experience. Instruments used in these areas should be equipped with failsafes to prevent the instrument from delivering bad test results. Failsafes can block the release of test results when there is operator error, humidity/temperature failures, or interfering substances. This presentation reviews common failsafes and highlights new design opportunities for manufacturers preparing for CLIA waiver.

11:30 Session Wrap-Up

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

Panelists:

Corinne Fantz, PhD, Director, Scientific Affairs, Roche

Bryan Bothwell

Joe Wiencek, PhD, Assistant Professor, Department of Pathology; Medical Director, Point-of-Care Testing; Associate Medical Director, Clinical Chemistry; Co-Director, Clinical Chemistry Fellowship, University of Virginia School of Medicine

Valerie L Ng, MD, PhD, Chair of Laboratory Medicine & Pathology, and Director of Transfusion Services, Clinical Laboratories, Alameda Health System

12:15 pm Lunch Break - View our Virtual Exhibit Hall

PREPARING FOR THE NEXT WAVE OF POC DIAGNOSTICS: OVERCOMING CHALLENGES WITH CONSUMER TESTING

12:40 Chairperson's Remarks

Lawrence Worden, Founder, Principal, IVD Logix

12:45 Overcoming Regulatory Challenges for Home-Use Tests

Elliot Cowan, PhD, Principal, Partners in Diagnostics LLC

Home-use tests can increase access to testing, safeguard privacy, empower individuals to take control of their healthcare decisions, and protect public health. However, these benefits come with significant risks and challenges, including how to demonstrate that the benefits outweigh the risks, how to address the need for infectious disease reporting, and post-market surveillance. This talk will describe how regulators deal with such issues to bring home-use tests to market.

1:05 Innovative Approaches to At-Home Collection for STI Testing

Charlotte Gaydos, MS, MPH, DrPH, Professor, Infectious Diseases, Johns Hopkins University

The iwantthekit (IWTK) program offers internet-requested kits for home collection for screening of common STI. Other programs exist. We will discuss innovation programs and acceptability for home collection, and we will review published programs. Many

ENABLING POINT-OF-CARE DIAGNOSTICS, continued

studies reported use of and willingness to use home collection when available. There was willingness to pay an average of $10-30. User satisfaction was high for home collection.

1:25 Professional Concerns with At-Home Testing

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

Currently at-home testing is available in many formats. Though many arguments support the use of consumer OTC self-testing, there are still some concerns from a quality assurance perspective from the medical technologist who currently oversee point-of-care testing in the healthcare setting. In this session, we will discuss some of those concerns from the point of care coordinator's point of view.

1:45 Live Q&A: Session Wrap-Up

Moderator: Lawrence Worden, Founder, Principal, IVD Logix

Panelists:

Elliot Cowan, PhD, Principal, Partners in Diagnostics LLC

Charlotte Gaydos, MS, MPH, DrPH, Professor, Infectious Diseases, Johns Hopkins University

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

2:10 Refresh Break - View our Virtual Exhibit Hall

3:30 Happy Hour - View our Virtual Exhibit Hall

4:00 Close of Day

WEDNESDAY, AUGUST 26

DEPLOYING POINT-OF-CARE TESTING TO MANAGE DISEASE OUTBREAKS

9:00 am Chairperson's Remarks

Gerald Kost, MD, PhD, MS, FAACC, Director, Point-of-Care Testing Center for Teaching and Research (POCT•CTR), University of California, Davis

9:05 Point-of-Care COVID-19 Diagnostics: Understanding Metrics and Creating Guidelines

Gerald Kost, MD, PhD, MS, FAACC, Director, Point-of-Care Testing Center for Teaching and Research (POCT•CTR), University of California, Davis

Increasingly, we observe the adverse personal, societal, economic, and cultural impact of outbreaks, antimicrobial resistance, and disasters. Nations are not prepared! POC strategies can mitigate risk, reduce harm, and improve crisis standards of care. Global solutions integrate national POCT policy and guidelines, and distribute financial burden and reasonable business models.

9:25 Point-of-Care Molecular Diagnostics for Disease Outbreak Settings: The Path to the Future

Rachel Spurbeck, PhD, Principal Research Scientist, Health Outcomes and Biotechnology Solutions, Battelle Memorial Institute

Rapid, accurate, and affordable point-of-care (POC) diagnostics are key to detecting and mitigating the impact of disease outbreaks, particularly for emerging pathogens. Molecular approaches offer speed, sensitivity, and specificity, but can introduce complexity and expense, making it difficult to achieve a POC diagnostic suitable for use outside a clinical setting. This talk reviews molecular diagnostics and examines the path to deployable POC diagnostics for outbreak settings, including challenges undertaken today.

9:45 Live Q&A: Session Wrap-Up

Moderator: Gerald Kost, MD, PhD, MS, FAACC, Director, Point-of-Care Testing Center for Teaching and Research (POCT•CTR), University of California, Davis

Panelists:

Rachel Spurbeck, PhD, Principal Research Scientist, Health Outcomes and Biotechnology Solutions, Battelle Memorial Institute

10:30 Coffee Break - View our Virtual Exhibit Hall

10:40 Problem Solving Discussions - View our Virtual Exhibit Hall

BREAKOUT 2: Risk Management for Point-of-Care Testing

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

BREAKOUT 3: Work Smarter, Not Harder: Tips to Make Your POCT Life Easier

Joe Wiencek, PhD, Assistant Professor, Department of Pathology; Medical Director, Point-of-Care Testing; Associate Medical Director, Clinical Chemistry; Co-Director, Clinical Chemistry Fellowship, University of Virginia School of Medicine

BREAKOUT 4: Reimbursement Issues with COVID-19 Testing

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

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

PLENARY KEYNOTE SESSION

11:10 Organizer's Opening Remarks

Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

11:15 KEYNOTE PRESENTATION: Ultrasensitive SARS-CoV-2 Protein Assays for Precision Clinical Decisions

David Walt, PhD, HHMI Professor; Hansjörg Wyss Professor of Biologically Inspired Engineering, Harvard Medical School; Professor of Pathology, Department of Pathology-Brigham and Women's Hospital; Core Faculty, Wyss Institute for Bioinspired Engineering, Harvard University

We have developed ultrasensitive single molecule assays for multiple relevant SAR-CoV-2 proteins that can detect both active virus and prior infection. The assays have been tested in thousands of individuals, including patients and healthcare workers and exhibit exceptional sensitivity and specificity. Additionally, we have followed these protein concentrations over time during the course of disease in many patients and can predict outcomes based on the dynamics of the protein responses.

11:40 Lessons Learned for Diagnostic Testing During the COVID-19 Pandemic

Moderator: Susan Hsiao, MD, PhD, Assistant Professor, Pathology and Cell Biology, Columbia University Medical Center

- Supply chain challenges
- Navigating and validating multiple platforms
- Reimbursement
- Value of distributed testing
- Value of tests available: PCR vs. antigen vs. serology
- Developing sustainable testing protocols

Panelists:

Alex Greninger, MD, PhD, MS, MPhil, Assistant Professor, Lab Medicine, University of Washington

Jordan S. Laser, MD, Medical Director, Department of Pathology and Laboratory Medicine; LIJMC; Associate Medical Director, Core Laboratories; Director, Division of Near Patient Testing, Northwell Health; Associate Professor, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell

David Walt, PhD, HHMI Professor; Hansjörg Wyss Professor of Biologically Inspired Engineering, Harvard Medical School; Professor of Pathology, Department of Pathology-Brigham and Women's Hospital; Core Faculty, Wyss Institute for Bioinspired Engineering, Harvard University

ENABLING POINT-OF-CARE DIAGNOSTICS, continued

12:15 pm Keynote Introduction

Charles Mathews, Principal, ClearView Healthcare Partners

12:30 Panel Discussion : Fireside Chat

Moderator: Charles Mathews, Principal, ClearView Healthcare Partners

Panelists:

Sara Brenner, MD, MPH, Associate Director for Medical Affairs; CMO, In Vitro Diagnostics, Office of In Vitro Diagnostics & Radiological Health (OIR), Office of Product Evaluation & Quality (OPEQ), Center for Devices & Radiological Health (CDRH), U.S. Food & Drug Administration

12:55 Lunch Break - View our Virtual Exhibit Hall

1:00 The Critical Role of Antigens and Antibodies in SARS-CoV-2 Serological Test Development

Joe Jiang, Product Manager, Product Development, ACROBiosystems

High-quality recombinant SARS-CoV-2 antigens and antibodies are key reagents in the development of SARS-CoV-2 serological test kits. ACROBiosystems has developed a series of SARS-CoV-2 antigen and antibody products that can be used in serological tests.

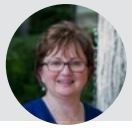
1:25 Close of Enabling Point-of-Care Diagnostics Conference

Advanced Diagnostics for Infectious Disease

IMPROVING CLINICAL OUTCOMES THROUGH NOVEL TECHNOLOGY AND MOLECULAR TESTING

WEDNESDAY, AUGUST 26

PLENARY KEYNOTE SESSION



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11:40 Panel Discussion : Lessons Learned for Diagnostic Testing During the COVID-19 Pandemic

Moderator: Susan Hsiao, MD, PhD, Assistant Professor, Pathology and Cell Biology, Columbia University Medical Center

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- Value of distributed testing
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- Developing sustainable testing protocols

Panelists:

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Jordan S. Laser, MD, Medical Director, Department of Pathology and Laboratory Medicine; LIJMC; Associate Medical Director, Core Laboratories; Director, Division of Near Patient Testing, Northwell Health; Associate Professor, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell

David Walt, PhD, HHMI Professor; Hansjörg Wyss Professor of Biologically Inspired Engineering, Harvard Medical School; Professor of Pathology, Department of Pathology-Brigham and Women's Hospital; Core Faculty, Wyss Institute for Bioinspired Engineering, Harvard University

12:15 pm Keynote Introduction ClearView Healthcare Partners

Charles Mathews, Principal, ClearView Healthcare Partners

12:30 Fireside Chat

Moderator: Charles Mathews, Principal, ClearView Healthcare Partners

Panelists:

Sara Brenner, MD, MPH, Associate Director for Medical Affairs; CMO, In Vitro Diagnostics, Office of In Vitro Diagnostics & Radiological Health (OIR), Office of Product Evaluation & Quality (OPEQ), Center for Devices & Radiological Health (CDRH), U.S. Food & Drug Administration

12:55 Lunch Break - View our Virtual Exhibit Hall

1:00 The Critical Role of Antigens and Antibodies in SARS-CoV-2 Serological Test Development Acro Biosystems

Joe Jiang, Product Manager, Product Development, ACROBiosystems

High-quality recombinant SARS-CoV-2 antigens and antibodies are key reagents in the development of SARS-CoV-2 serological test kits. ACROBiosystems has developed a series of SARS-CoV-2 antigen and antibody products that can be used in serological tests.

DEVELOPING AND SHOWING CLINICAL IMPACT OF RAPID DIAGNOSTICS

1:30 Clinical Impact of Rapid Molecular Blood Culture Test at a Tertiary Cancer Care Center

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

Sepsis remains a significant cause of morbidity and mortality in hospitalized patients. Cancer patients and other immunocompromised hosts are particularly at increased risk of sepsis. Novel molecular methods for rapid diagnosis directly from blood samples are now available for identification of pathogens and select resistance markers. This presentation will review the clinical impact of rapid molecular tests on patient outcomes at a tertiary cancer care center.

1:50 DOD's Pursuit of Pre-Symptomatic Non-Invasive Diagnostics

Edward Argenta, Science & Technology Mgr, Biological & Chemical Technologies, Defense Threat Reduction Agcy

The Department of Defense, Chemical and Biological Technologies Department is managing a disruptive portfolio developing algorithms utilizing artificial intelligence approaches to deliver warning of an acute exposure to a pathogen or toxic chemical prior to overt signs and symptoms using non-invasive biomarkers. The portfolio has shown successes in both animal and human exposure studies, and will continue to pursue advancing the research to provide early identification of exposure.

2:10 Presentation to be Announced Seegene

Glen Hansen, MD

2:35 Panel Discussion: The Challenges in Testing for COVID-19 and How do we Learn for the Next Pandemic

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

- Supply shortages
- Regulatory changes
- Surveillance networks
- FDA-cleared products vs labs developing their own tests
- What is the role of NGS-based assays in mass surveillance
- Extraction challenges
- Test performance, what can we learn?

Panelists:

Norman Moore, PhD, Director, Scientific Affairs, Abbott

ADVANCED DIAGNOSTICS FOR INFECTIOUS DISEASE, continued

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

Matthew Binnicker, PhD, Consultant, Division of Clinical Microbiology, Department of Laboratory Medicine and Pathology; Vice Chair of Supply Chain Management, Department of Laboratory Medicine and Pathology; Vice Chair of Practice, Department of Laboratory Medicine/ Pathology, Mayo Clinic; Chair, ASM's Professional Development Subcommittee

Emily Crawford, PhD, Scientist II, Infectious Disease Initiative, Chan Zuckerberg Biohub

Glen Hansen, MD

2:55 Refresh Break - View our Virtual Exhibit Hall

DIAGNOSTIC STEWARDSHIP

3:10 Chairperson's Remarks

Joseph Campos, PhD, D(ABMM), F(AAM), Director, Microbiology Laboratory, Infectious Disease Molecular Diagnostics Laboratory, Laboratory Informatics, Children's National Medical Center; Strategic Alliances Liaison and Former Secretary, ASM

3:15 Diagnostic Stewardship: Because You Can't Do Everything for Everyone All the Time

Christopher Doern, PhD, D(ABMM), Associate Director, Microbiology, Virginia Commonwealth University Medical Center, Medical College of Virginia Campus; Co-Chair, ASM's Clinical Micro Open

3:35 The Role of Diagnostic Stewardship in Improving Patient Care and Reducing Overall Healthcare Costs

Matthew Binnicker, PhD, Consultant, Division of Clinical Microbiology, Department of Laboratory Medicine and Pathology; Vice Chair of Supply Chain Management, Department of Laboratory Medicine and Pathology; Vice Chair of Practice, Department of Laboratory Medicine/ Pathology, Mayo Clinic; Chair, ASM's Professional Development Subcommittee

Healthcare is transitioning from a fee-for-service model to focus on value-based care. As a key component of patient care and the value-based equation, clinical laboratories will need to be an active participant in the development of diagnostic stewardship programs. This presentation will provide an overview of establishing an effective diagnostic stewardship program. Specific case scenarios will be reviewed to demonstrate how diagnostic stewardship can lead to increased efficiency.

3:55 A Laboratory Medicine Best Practices Systematic Review and Meta-Analysis for the Laboratory Diagnosis of *C. difficile*

Colleen Kraft, MD, Associate Chief Medical Officer, Associate Professor, Pathology/Laboratory Medicine, Medicine/Division of Infectious Diseases, Emory University Hospital; Chair, ASM's Evidence-Based Laboratory Medicine Practice Guidelines

4:15 LIVE Q&A: Session Wrap-Up

Moderator: Joseph Campos, PhD, D(ABMM), F(AAM), Director, Microbiology Laboratory, Infectious Disease Molecular Diagnostics Laboratory, Laboratory Informatics, Children's National Medical Center; Strategic Alliances Liaison and Former Secretary, ASM

Panelists:

Matthew Binnicker, PhD, Consultant, Division of Clinical Microbiology, Department of Laboratory Medicine and Pathology; Vice Chair of Supply Chain Management, Department of Laboratory Medicine and Pathology; Vice Chair of Practice, Department of Laboratory Medicine/ Pathology, Mayo Clinic; Chair, ASM's Professional Development Subcommittee

Christopher Doern, PhD, D(ABMM), Associate Director, Microbiology, Virginia Commonwealth University Medical Center, Medical College of Virginia Campus; Co-Chair, ASM's Clinical Micro Open

Colleen Kraft, MD, Associate Chief Medical Officer, Associate Professor, Pathology/Laboratory Medicine, Medicine/Division of Infectious Diseases, Emory University Hospital; Chair, ASM's Evidence-Based Laboratory Medicine Practice Guidelines

4:35 Happy Hour - View our Virtual Exhibit Hall

5:10 Close of Day

THURSDAY, AUGUST 27

MULTIPLEX PANELS

9:00 am Chairperson's Remarks

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

9:05 Comparison: Nanopore Sequencing and Microarray Resequencing for Multiplex Pathogen Identification

Robert Duncan, PhD, Principal Investigator, Office of Blood Research and Review, Center for Biologics Evaluation and Research (CBER), FDA

GeneChip Resequencing microarrays have been advanced for infectious disease agent detection and identification from Ebola to Zika. Next-generation sequencing with the highly mobile and cost-effective nanopore sequencing device is challenging the supremacy of the microarray in rapid point-of-need pathogen detection. This talk will present results from application of these two platforms for pathogen detection and compare their performance.

9:20 Syndromic Testing for Meningitis/Encephalitis: Saga of the Love-Hate Relationship

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

As part of the Multiplex Panel session, this talk will focus on multiplex testing for the laboratory diagnosis of meningitis and encephalitis as compared to standard-of-care testing. The potential benefits and limitations of panel testing for meningitis and encephalitis compared to standard-of-care testing will be discussed. The potential approaches to maximize testing yield will also be discussed.

9:35 The Biofire Pneumonia Panel: Does It Relate to Microbiological and Clinical Variables?

Kenneth Rand, MD, Medical Director, Clinical Microbiology Laboratory; Professor, Pathology and Medicine, University of Florida

The BioFire FilmArray Pneumonia Panel (PP) detects 15 common bacterial pathogens, 3 atypical pneumonia bacteria, 8 viruses, and 7 antimicrobial resistance markers by multiplex PCR. Results of our 396-patient study suggest PP detects more bacterial isolates than conventional microbiology, and the copy number correlates with outcome variables Results reported in a 3-4 h timeframe after a BAL could potentially improve both antibiotic choice and de-escalation in critically ill intubated patients.

9:50 Panel Discussion : Advancing Multiplex Panels for Clinical Diagnostics

Moderator: Esther Babady, PhD, Medical Director, Clinical Microbiology Service, Memorial Sloan Kettering Cancer Center

- Comparison of multiplex platforms
- Reimbursement considerations
- Proving clinical utility of multiplex diagnostic tests

Panelists:

Robert Duncan, PhD, Principal Investigator, Office of Blood Research and Review, Center for Biologics Evaluation and Research (CBER), FDA

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

Kenneth Rand, MD, Medical Director, Clinical Microbiology Laboratory; Professor, Pathology and Medicine, University of Florida

10:05 Coffee Break - View Our Virtual Exhibit Hall

ADVANCED DIAGNOSTICS FOR INFECTIOUS DISEASE, continued

10:15 Problem Solving Discussions - View our Virtual Exhibit Hall

BREAKOUT 9: Getting a Foot in the SBIR Grant Rat Race

Robert Duncan, PhD, Principal Investigator, Office of Blood Research and Review, Center for Biologics Evaluation and Research (CBER), FDA

BREAKOUT 8: Clinical Metagenomic Sequencing

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

CONSIDERATIONS FOR AMR DIAGNOSTICS

10:45 Reimbursement Challenges under PAMA for New Tests

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

This talk will focus on the reimbursement challenges under PAMA for the more commonly performed diagnostic tests. The talk will focus primarily on coding and payment issues, and will provide policy updates.

11:00 Don't Take That Antibiotic! You Might Get...Fat? The Science of the Microbiome

Norman Moore, PhD, Director, Scientific Affairs, Abbott

Even though the global threat of antibiotic-resistant microorganisms is significant, many patients demand antibiotics and doctors are far too willing to provide them. This talk shows that the relationship between us and our bacteria is more important than previously thought. Disrupting that balance can cause a host of medical issues.

11:20 Evaluation of Microbial Cell-Free DNA as an Alternative to Invasive Diagnostic Testing in Immunocompromised Patients

Tim Blauwkamp, CSO, Karius

Karius microbial cell-free DNA sequencing from plasma (mcfDNA-Seq) is emerging as an alternative to invasive diagnostic tests for species-level identification of pathogens. We will present consolidated results from several clinical studies to address key questions on how to use this new technology to improve patient outcomes and lower diagnostic testing costs in immunocompromised patients with suspected invasive infection.

11:45 Development of High Quality Antigens and Antibodies for Infectious Disease IVD Tests

Jiahui Yang, PhD, R&D Director, R&D, Sino Biological Inc

Antigens and antibodies are key components for serological diagnosis kits. Sino Biological used mammalian cells for antigen production to ensure proper biological activity. Antibodies against viral proteins were generated by multiple platforms, including hybridoma, phage display and B cell cloning, to achieve high sensitivity and specificity.

12:00 pm Lunch Break - View our Virtual Exhibit Hall

NEXT GENERATION AND CLINICAL METAGENOMIC SEQUENCING

12:15 Chairperson's Remarks

Norman Moore, PhD, Director, Scientific Affairs, Abbott

12:20 FLASH: A Next-Generation CRISPR Diagnostic for Multiplexed Detection of Antimicrobial Resistance Sequences

Emily Crawford, PhD, Scientist II, Infectious Disease Initiative, Chan Zuckerberg Biohub

12:40 Clinical Metagenomic Sequencing and Human Host Response: Changing the Diagnostic Paradigm?

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

Metagenomic next-generation sequencing (mNGS) is a transformative technology for infectious disease diagnosis as it enables detection of nearly all pathogens – viruses, bacteria, fungi, and parasites – in a single assay. Here we will discuss the integration of multiple approaches to enhance the clinical utility of body fluid mNGS, including nanopore sequencing, CRISPR-Cas12-based pathogen detection, complementary host response analyses, and simultaneous diagnosis of cancer.

1:00 Metagenomic Next-Generation Sequencing to Detect & Predict Antimicrobial Resistance

Patricia Simner, PhD, D(ABMM), Associate Professor, Pathology; Director, Bacteriology, Division of Medical Microbiology, The Johns Hopkins University School of Medicine

Initial efforts for applying metagenomic next-generation sequencing (mNGS) for infectious disease diagnostics have focused on pathogen detection. However, we can also gain information on antimicrobial resistance markers, virulence factors or even host biomarkers associated with different disease states. In this presentation, we will discuss the challenges of using mNGS for detection of antimicrobial resistance genes to predict phenotypes and discuss the current status of mNGS for detection of antimicrobial resistance.

1:20 LIVE Q&A: Session Wrap-Up

Moderator: Norman Moore, PhD, Director, Scientific Affairs, Abbott

Panelists:

Emily Crawford, PhD, Scientist II, Infectious Disease Initiative, Chan Zuckerberg Biohub

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

Patricia Simner, PhD, D(ABMM), Associate Professor, Pathology; Director, Bacteriology, Division of Medical Microbiology, The Johns Hopkins University School of Medicine

Robert Schlaberg, MD, PhD, MPH, Co-Founder, Chief Medical Officer, Medical & Scientific Affairs, IDbyDNA

1:35 Close of Summit

Liquid Biopsy/ Early Detection Stream

CONFERENCE STREAMS

- POCT TECHNOLOGIES AND STRATEGY
- POCT AND INFECTIOUS DISEASE
- LIQUID BIOPSY/EARLY DETECTION
- COMPANION DX AND IO BIOMARKERS
- BUSINESS
- NGS ADVANCES

2020 LIQUID BIOPSY/EARLY DETECTION CONFERENCES

AUGUST 25-26

AGENDA **Enabling Technologies for Liquid Biopsy**

AUGUST 26-27

AGENDA **Early Detection of Disease**

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Enabling Technologies for Liquid Biopsy

ADVANCING TECHNOLOGIES FOR CLINICAL UTILITIES

TUESDAY, AUGUST 25

EXOSOMES AND CIRCULATING TUMOR CELLS IN CANCER LIQUID BIOPSY

9:00 am Chairperson's Remarks

Hakho Lee, Center for Systems Biology, Massachusetts General Hospital

9:05 The Wide World of Liquid Biopsy Biomarker Platforms for Cancer Screening

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

There is currently intense interest in developing liquid biopsy applications for cancer screening with a multitude of platforms being implemented to this effect. The contribution and merits of biomarkers types for lung cancer screening will be presented.

9:25 Clinical Platform for Molecular Analyses of Extracellular Vesicles

Hakho Lee, Center for Systems Biology, Massachusetts General Hospital

This presentation will discuss our key advances towards clinical analyses of extracellular vesicles (EVs): i) development of a high-throughput assay strategy, HiMEX (high-throughput magneto-electrochemical exosome), and ii) assessment of EVs as potent biomarkers for cancer management.

9:45 Circulating Tumor Cells: Importance of their phenotypic and molecular characterization at the single cell level

MENARINI silicon biosystems

Catherine Alix-Panabières, PhD, Head of the Human Rare Circulating Cells Laboratory (LCCRH), Montpellier University Hospital, University Institute of Clinical Research (IURC)

Merkel cell carcinoma (MCC) is a rare and highly metastatic skin malignancy. We compared circulating tumor cell (CTC) detection and characterization in blood samples using the FDA-cleared CellSearch® System and the RosetteSep -DEPArray workflow, to enrich, detect and isolate single CTCs.

In a separate prospective clinical trial, the clinicopathological correlations and prognostic value of PD-L1(+)-CTCs in metastatic breast cancer (MBC) patients were evaluated correlate to survival in MBC.

10:10 LIVE Q&A: Session Wrap-Up

Moderator: Hakho Lee, Center for Systems Biology, Massachusetts General Hospital

Panelists:

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

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10:30 Coffee Break - View our Virtual Exhibit Hall

EXOSOMES AND CIRCULATING TUMOR CELLS IN CANCER LIQUID BIOPSY

10:45 Chairperson's Remarks

Hakho Lee, Center for Systems Biology, Massachusetts General Hospital

10:50 Chasing the Exosome Dream: Developing an Exosome-Based Platform for the Screening and Monitoring of Lung Cancer

Lydia Sohn, PhD, Chancellor's Professor, Mechanical Engineering, University of California, Berkeley

Although the standard of care for non-small cell lung cancer includes surgery and many options for therapeutics, the response is highly variable and patient specific. Detecting early-stage recurrence would allow clinicians to adapt or change therapy within a curative window, greatly improving outcomes and mortality rates. We are developing a sensitive, simple-to-use, platform based on exogenous labeling that could detect tumor-derived extracellular vesicles in blood and saliva for patient monitoring.

11:10 High-Throughput Label-Free Isolation of Heterogeneous Circulating Tumor Cells and CTC Clusters from Non-Small-Cell Lung Cancer Patients

Sunitha Nagrath, PhD, Associate Professor, Chemical Engineering; Co-Director, Single Cell Analysis Core, Rogel Cancer Center BioInterfaces Institute, University of Michigan

We applied an inertial microfluidic Labyrinth device for highthroughput, biomarker-independent, size-based isolation of CTCs/CTC clusters from patients with metastatic non-small-cell lung cancer (NSCLC). The Labyrinth device recovered heterogeneous CTCs in 100% and CTC clusters in 96% of patients with metastatic NSCLC. The majority of recovered CTCs/clusters were EpCAM, suggesting that these would have been missed using traditional antibody-based capture methods.

11:30 LIVE Q&A: Session Wrap-Up

Moderator: Hakho Lee, Center for Systems Biology, Massachusetts General Hospital

Panelists:

Lydia Sohn, PhD, Chancellor's Professor, Mechanical Engineering, University of California, Berkeley

Sunitha Nagrath, PhD, Associate Professor, Chemical Engineering; Co-Director, Single Cell Analysis Core, Rogel Cancer Center BioInterfaces Institute, University of Michigan

12:15 pm Lunch Break - View our Virtual Exhibit Hall

ADVANCES IN DETECTING CELL-FREE DNA

12:40 Chairperson's Remarks

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

12:45 FNIH Biomarkers Consortium Development of Quality Control Materials for ctDNA Assays

Dana Connors, MSc, PMP, Senior Scientific Project Manager, Cancer, Foundation for the National Institutes of Health (NIH)

ctDNA shows promise for cancer patient management but there's a need for standardization. A public private partnership was initiated through the Biomarkers Consortium at the FNIH to address this unmet need. This presentation describes how a pre-competitive alliance came together to better understand the need and acceptable performance characteristics of quality control materials, and provide updates on the intended use and outcomes of the FNIH ctDNA Quality Control Materials project.

1:05 New Technologies for Low-Cost and Efficient Targeted Re-Sequencing for Liquid Biopsy Applications

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

As the potential of liquid biopsies for prognostic, predictive or early cancer detection applications grows, so does the demand for technical advances to accompany the burgeoning range of applications. We present new developments that enable targeted re-sequencing for liquid biopsy applications at a fraction of the current cost, while retaining or increasing sensitivity and specificity. Examples for detecting low-level mutations in circulating DNA will be presented.

ENABLING TECHNOLOGIES FOR LIQUID BIOPSY, continued

1:25 Liquid Biopsy Quantification using 6-color Multiplexing for Cancer Panels

Kimberley Gutierrez, Senior Field Application Scientist, Stilla Technologies

The quantification of cell-free DNA is important in order to diagnose and interpret a therapeutic response. Digital PCR is known to have increased sensitivity and higher precision over qPCR. The increased sensitivity afforded by dPCR can better identify low levels of circulating cell-free DNA from liquid biopsy samples. Stilla has expanded the multiplexing of the Naica system with 6-color dPCR. 6-color dPCR combined with liquid biopsy samples allows for maximum information output from precious samples.

2:10 Refresh Break - View our Virtual Exhibit Hall

ADVANCES IN DETECTING CELL-FREE DNA

2:25 Chairperson's Remarks

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

2:30 Targeted Digital Sequencing of Circulating Tumor DNA for Minimal Residual Disease Detection and Treatment Monitoring

Bradon McDonald, PhD, Computational Scientist, Murtaza Lab, Translational Genomics Research Institute

Longitudinal analysis of circulating tumor DNA has shown promise for monitoring treatment response. However, most current methods lack adequate sensitivity for residual disease detection during or after treatment completion in patients with nonmetastatic cancer. To address this, we have developed targeted digital sequencing (TARDIS) for multiplexed analysis of patient-specific cancer mutations. I'll share TARDIS benchmarking results and plasma sample analysis from early-stage breast cancer patients treated with neoadjuvant therapy.

2:50 Exploiting ctDNA Biology and Personalized Sequencing for Sensitive Detection of Low Burden Disease

Christopher Smith, PhD, Research Associate, CRUK Cambridge Institute, University of Cambridge

Cell-free tumor derived DNA (ctDNA) analysis offers the potential for minimally invasive detection of early stage disease as well as minimal residual disease after treatment. However, the utility of ctDNA is currently limited when the tumor burden is low. Here, I will describe novel approaches that leverage knowledge of ctDNA biology and personalized sequencing for sensitive detection even in these challenging settings.

3:10 LIVE Q&A: Session Wrap-Up

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

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Christopher Smith, PhD, Research Associate, CRUK Cambridge Institute, University of Cambridge

Kimberley Gutierrez, Senior Field Application Scientist, Stilla Technologies

3:30 Happy Hour - View our Virtual Exhibit Hall

4:00 Close of Day

WEDNESDAY, AUGUST 26

EMERGING TECHNOLOGIES FOR EARLY DETECTION AND RECURRENCE

9:00 am Chairperson's Remarks

Lynn Sorbara, PhD, Program Director, Cancer Biomarkers Research Group, National Cancer Institute (NCI), NIH

9:05 Detection of Exosomal Protein and MicroRNA-Combined Biomarkers via Exo-PROS Assay for Cancer Early Detection

Yun (Sunny) Wu, PhD, Associate Professor, Biomedical Engineering, University at Buffalo, The State University of New York

Exosomal proteins and microRNAs are promising biomarkers for cancer liquid biopsy. We've developed an exosome protein microRNA one stop (Exo-PROS) liquid biopsy assay, which enables one-stop capture of tumor-derived exosomes (TEX) and sensitive quantitation of TEX surface proteins and intra-vesicular microRNAs on a single device. The Exo-PROS assay has shown superior sensing performance than ELISA and qRT-PCR. The potential application of Exo-PROS assay has been demonstrated in lung cancer early detection.

9:25 Direct Kinetic Fingerprinting and Digital Counting of Single Cancer Biomarker Molecules in Human Biofluids and Single Cells

Nils Walter, PhD, Francis S. Collins Collegiate Professor of Chemistry, Biophysics & Biological Chemistry; Founding Director, Single Molecule Analysis in Real-Time (SMART) Center; Founding Co-Director of the Center for RNA Biomedicine, University of Michigan

The sensitive and accurate quantification of specific cancer biomarkers plays important roles in medical diagnostics and research. We've developed a kinetic fingerprinting approach with dynamically binding probes for direct, digital, hyper-accurate detection and counting of diverse single-biomarker molecules in complex biofluids, including blood serum, urine and *in situ*, with femtomolar to attomolar limits of detection (LODs). We're currently working to commercialize our technology, termed SiMREPS (single-molecule recognition through equilibrium Poisson sampling).

9:45 Third-Generation Liquid Biopsy: A Comprehensive Characterization of Circulating Analytes for Patient-Centered Cancer Research

Peter Kuhn, PhD, Director, USC Michelson CSI-Cancer; Dean's Professor of Biological Sciences; Professor of Biological Sciences, Medicine, Biomedical Engineering, and Aerospace and Mechanical Engineering, University of Southern California

There is significant interest in determining the extent that non-invasive liquid biopsies reflect the gold standard solid biopsy. We have established an approach for measuring patient-specific circulating and solid cell concordance by introducing tumor touch preparations to the high-definition single-cell analysis workflow for high-resolution cytomorphometric characterization. Patient-specific level of concordance can readily be measured to establish the utility of circulating cells as biomarkers and define biosignatures for liquid biopsy assays.

10:05 Live Q&A: Session Wrap-Up

Moderator: Lynn Sorbara, PhD, Program Director, Cancer Biomarkers Research Group, National Cancer Institute (NCI), NIH

Panelists:

Yun (Sunny) Wu, PhD, Associate Professor, Biomedical Engineering, University at Buffalo, The State University of New York

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Nils Walter, PhD, Francis S. Collins Collegiate Professor of Chemistry, Biophysics & Biological Chemistry; Founding Director, Single Molecule Analysis in Real-Time (SMART) Center; Founding Co-Director of the Center for RNA Biomedicine, University of Michigan

10:30 Coffee Break - View Our Virtual Exhibit Hall

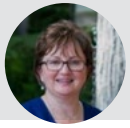
ENABLING TECHNOLOGIES FOR LIQUID BIOPSY, continued

10:40 Problem Solving Discussions - View our Virtual Exhibit Hall

BREAKOUT 1: Extracellular Vesicles (EV) are Heterogenous, but Would Single EV Analysis be Helpful for Making Clinical Decisions?

Lydia Sohn, PhD, Chancellor's Professor, Mechanical Engineering, University of California, Berkeley

PLENARY KEYNOTE SESSION



11:10 Organizer's Opening Remarks

Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

11:15 KEYNOTE PRESENTATION: Ultrasensitive SARS-CoV-2 Protein Assays for Precision Clinical Decisions

David Walt, PhD, HHMI Professor; Hansjörg Wyss Professor of Biologically Inspired Engineering, Harvard Medical School; Professor of Pathology, Department of Pathology-Brigham and Women's Hospital; Core Faculty, Wyss Institute for Bioinspired Engineering, Harvard University

We have developed ultrasensitive single molecule assays for multiple relevant SAR-CoV-2 proteins that can detect both active virus and prior infection. The assays have been tested in thousands of individuals, including patients and healthcare workers and exhibit exceptional sensitivity and specificity. Additionally, we have followed these protein concentrations over time during the course of disease in many patients and can predict outcomes based on the dynamics of the protein responses.

11:40 Panel Discussion : Lessons Learned for Diagnostic Testing During the COVID-19 Pandemic

Moderator: Susan Hsiao, MD, PhD, Assistant Professor, Pathology and Cell Biology, Columbia University Medical Center

- Supply chain challenges
- Navigating and validating multiple platforms
- Reimbursement
- Value of distributed testing
- Value of tests available: PCR vs. antigen vs. serology
- Developing sustainable testing protocols

Panelists:

Alex Greninger, MD, PhD, MS, MPhil, Assistant Professor, Lab Medicine, University of Washington

Jordan S. Laser, MD, Medical Director, Department of Pathology and Laboratory Medicine; LIJMC; Associate Medical Director, Core Laboratories; Director, Division of Near Patient Testing, Northwell Health; Associate Professor, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell

David Walt, PhD, HHMI Professor; Hansjörg Wyss Professor of Biologically Inspired Engineering, Harvard Medical School; Professor of Pathology, Department of Pathology-Brigham and Women's Hospital; Core Faculty, Wyss Institute for Bioinspired Engineering, Harvard University

12:15 pm Keynote Introduction CLEARVIEW Healthcare Partners

Charles Mathews, Principal, ClearView Healthcare Partners

12:30 Fireside Chat

Moderator: Charles Mathews, Principal, ClearView Healthcare Partners

Panelists:

Sara Brenner, MD, MPH, Associate Director for Medical Affairs; CMO, In Vitro Diagnostics, Office of In Vitro Diagnostics & Radiological Health (OIR), Office of Product Evaluation & Quality (OPEQ), Center for Devices & Radiological Health (CDRH), U.S. Food & Drug Administration

12:55 Lunch Break - View our Virtual Exhibit Hall

1:25 Close of Enabling Technologies for Liquid Biopsy Conference

Early Detection of Disease

ASSESSING OPPORTUNITY AND OVERCOMING CHALLENGES

WEDNESDAY, AUGUST 26

PLENARY KEYNOTE SESSION

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12:55 Lunch Break - View our Virtual Exhibit Hall

OVERVIEW

1:25 Chairperson's Remarks

John Sninsky, PhD, Independent Consultant, Translational Medicine and Science

1:30 Overcoming the Challenges to Realize the Opportunities of Early Disease Detection

John Sninsky, PhD, Independent Consultant, Translational Medicine and Science

Diagnosis early in the natural history of disease promises to lead to improved health management. However, over-diagnosis needs to be avoided. Valuable lessons learned from cancer will be instructive for other chronic diseases. The integration of Information from multiple disparate biological compartments to generate informative probabilistic models will be paramount. How the healthcare system determines applicable evidence level and rewards value with reimbursement will be critical.

1:50 JAMA Users' Guides to the Medical Literature: How to Read Articles That Use Machine Learning

Yun Liu, PhD, Senior Research Scientist, Google Health

Many recent clinical diagnostic tools have been developed using machine learning and must be evaluated using a 3-step process of deriving, validating, and establishing the clinical effectiveness of the tool. Several key considerations are appropriate machine learning methods used for the type and size of data, proper tuning of prespecified settings (called hyperparameters) on a dataset independent of the final validation set, and a rigorous reference standard.

DATA AND ECONOMIC ANALYSIS

2:10 Technology Valuation in the Era of Value-Based Incentives for Physician Services

John Hornberger, MD, MS, FACP, Senior Clinical Reseacher/Adjunct Clinical Professor of Medicine, Acumen LLC/Stanford University

The U.S. has the highest per capita healthcare costs, with substantial financial and clinical variability due to over- and under-use of mispriced technologies ("moral hazard"). Physician-led professional societies are creating/owning quality metrics for assessing performance. Under MACRA, performance also is assessed based on costs for an episode of care. To succeed under these new incentives, physicians will need risk-based algorithms assessing technology quality and costs; representative examples to be presented.

2:35 Live Q&A: Session Wrap-Up

Moderator: John Sninsky, PhD, Independent Consultant, Translational Medicine and Science

Panelists:

John Hornberger, MD, MS, FACP, Senior Clinical Reseacher/Adjunct Clinical Professor of Medicine, Acumen LLC/Stanford University

Yun Liu, PhD, Senior Research Scientist, Google Health

2:55 Refresh Break - View our Virtual Exhibit Hall

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EARLY DETECTION OF DISEASE, continued

REIMBURSEMENT

3:15 Medicare: Adapting Prevention Policy for a New Molecular Era

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

Medicare has historically been far behind the curve in providing coverage for preventive services, especially novel diagnostic tests. Medicare's approach is so slow, it risks actually discouraging investing because of the long and slow policy pipeline. We will discuss the pros and cons of the status quo, best practices, and case studies for coping with the status quo, and the outlook for new policy that would better encourage much-needed innovations.

3:35 Lessons Learned and Challenges of Reimbursement for Early Detection of Disease

Paul Gerrard, MD, Vice President, McDermott+ Consulting

3:55 LIVE Q&A: Session Wrap-Up

Moderator: John Sninsky, PhD, Independent Consultant, Translational Medicine and Science

Panelists:

Paul Gerrard, MD, Vice President, McDermott+ Consulting

John Hornberger, MD, MS, FACP, Senior Clinical Reseacher/Adjunct Clinical Professor of Medicine, Acumen LLC/Stanford University

Yun Liu, PhD, Senior Research Scientist, Google Health

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

4:35 Happy Hour - View our Virtual Exhibit Hall

5:10 Close of Day

THURSDAY, AUGUST 27

OPPORTUNITIES AND CHALLENGES OF EARLY DIAGNOSIS OF DISEASE

9:00 am Chairperson's Remarks

John Sninsky, PhD, Independent Consultant, Translational Medicine and Science

9:05 KEYNOTE PRESENTATION: Overdiagnosis and Premature Treatment Challenge of Early Disease Detection

Laura Esserman, MD, MBA, Professor, Surgery, University of California San Francisco Medical Center

9:25 Multi-Modal Approaches to Early Disease Detection and Population-Based Screening

Drew Watson, MBA, PhD, Senior Vice President, Biostatistics and Clinical Development, CellMax Life

For many diseases, population screening is essential to improving patient survival. Despite the promise of blood-based "liquid biopsies," progress has been limited necessitating new multi-omics approaches incorporating multiple technologies. We discuss new approaches to biomarker discovery, algorithm development, and clinical validation using mechanistic, statistical, and machine learning approaches for handling of multi-omics data. We further discuss the need to improve clinical decision support systems to facilitate clinical decision making.

9:45 Multi-Cancer Detection and Localization Using a Methylation-Based cfDNA Assay

Arash Jamshidi, PhD, Vice President, Bioinformatics and Data Science, GRAIL, Inc.

GRAIL is a healthcare company whose mission is to detect cancer early, when it can be cured. GRAIL is focused on alleviating the global burden of cancer by developing pioneering technology to detect and identify multiple deadly cancers early. The company is using the power of next-generation sequencing, population-scale clinical studies, and state-of-the-art computer science and data science to develop its multi-cancer early detection blood test.

10:05 Coffee Break - View Our Virtual Exhibit Hall

10:15 Problem Solving Discussions - View our Virtual Exhibit Hall

BREAKOUT 12: Comprehensive Approach to Early Detection of Disease

John Sninsky, PhD, Independent Consultant, Translational Medicine and Science

BREAKOUT 11: Blood-Based Biomarkers in Oncology

Katie Streicher, PhD, Associate Director, Translational Medicine, Research and Early Development, Oncology R&D, AstraZeneca

Jonathan Baden, MS, Senior Director, Pharmacodiagnostic, Bristol-Myers Squibb

OPPORTUNITIES AND CHALLENGES OF EARLY DIAGNOSIS OF DISEASE (CONT.)

10:45 Chairperson's Remarks

John Sninsky, PhD, Independent Consultant, Translational Medicine and Science

10:50 Opportunity for Pre-Competitive Multi-Stakeholder Collaboration for NAFLD Detection and Intervention

Veronica Miller, PhD, Executive Director, Forum for Collaborative Research

Non-alcoholic fatty liver disease (NAFLD) affects approximately 25% of adults and 10% of children in the U.S. and is associated with obesity, type 2 diabetes mellitus, dyslipidemia and hypertension. Early diagnosis of the higher risk individuals is paramount. Representation and active engagement of scientific experts from all stakeholder groups in a non-competitive environment increases clarity and standardization while decreasing uncertainty. Lessons learned will be summarized.

11:10 Breast Cancer Overdiagnosis and the Precancer Problem

Alexander Borowsky, PhD, Associate Professor, Pathology and Laboratory Medicine, University of California, Davis

Breast cancer screening by mammography, which began in the U.S. about 40 years ago, has led to significant increases in the incidence of early-stage breast cancers, including ductal carcinoma *in situ* (DCIS), also called precancer or stage 0 disease. However, the expected reciprocal decrease in subsequent late-stage breast cancers was not found. It is now clear that some screen-detected breast "cancers" are indolent lesions without significant malignant potential.

11:30 Live Q&A: Opportunities and Challenges of Early Diagnosis of Disease

Moderator: John Sninsky, PhD, Independent Consultant, Translational Medicine and Science

Panelists:

Alexander Borowsky, PhD, Associate Professor, Pathology and Laboratory Medicine, University of California, Davis

Veronica Miller, PhD, Executive Director, Forum for Collaborative Research

11:50 Lunch Break - View our Virtual Exhibit Hall

EARLY DETECTION OF DISEASE, continued

EARLY DETECTION OF CANCER AND BEYOND

12:15 pm Chairperson's Remarks

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

12:20 Saliva Liquid Biopsy

David TW Wong, DMD, DMSc, Associate Dean of Research, Felix & Mildred Yip Endowed Distinguished Professor, UCLA School of Dentistry

We produce ~600ml of saliva per day that harbors multiple omics constituents that can be harnessed non-invasively for personalized, precision medicine, making it ideal for liquid biopsy applications. Yet, PCR-based technologies cannot detect ctDNA in saliva, whereas an emerging liquid biopsy platform "Electric Field Induced Release and Measurement (EFIRM)" detects ctDNA from NSCLC patients with actionable mutations in plasma and saliva with 95%+ concordance with tissue/biopsy-based genotyping, including early stage lesions.

12:40 Plasma-Based Liquid Biopsies for Early Detection of Cancer

Nickolas Papadopoulos, PhD, Professor, Oncology and Pathology, Director of Translational Genetics, Ludwig Center for Cancer Genetics & Therapeutics, Sidney Kimmel Comprehensive Cancer Center, The Johns Hopkins Institutions

Early detection of cancer has the potential to significantly reduce cancer deaths. Liquid biopsies provide an opportunity to develop tests for the detection of multiple-types of cancer in a single test. We will discuss the opportunities and the challenges of developing and utilizing such test.

1:00 Leveraging Novel Exosome Nanosensors for Earlier Pancreatic Cancer Detection

Cesar Martin Castro, MD, Director, Cancer Program, MGH Center for Systems Biology, Massachusetts General Hospital/Harvard Medical School

Exosomes reflect promising cancer biomarkers due to their abundance in biofluids, protein, and RNA contents reflecting parental cells, and stability in circulation. Pancreatic ductal adenocarcinomas (PDAC) represent highly lethal cancers often presenting at advanced stages. Integrating exosomes into monitoring programs for PDAC could improve clinical outcomes. This talk will discuss novel nanosensors we developed to analyze exosomes in blood and recent translational strategies to position them into clinical workflows.

1:20 Live Q&A: Session Wrap-Up

Moderator: Abhijit A. Patel, MD, PhD, Associate Professor, Yale University School of Medicine

Panelists:

David TW Wong, DMD, DMSc, Associate Dean of Research, Felix & Mildred Yip Endowed Distinguished Professor, UCLA School of Dentistry

Nickolas Papadopoulos, PhD, Professor, Oncology and Pathology, Director of Translational Genetics, Ludwig Center for Cancer Genetics & Therapeutics, Sidney Kimmel Comprehensive Cancer Center, The Johns Hopkins Institutions

Cesar Martin Castro, MD, Director, Cancer Program, MGH Center for Systems Biology, Massachusetts General Hospital/Harvard Medical School

1:40 Close of Summit

Companion DX & IO Biomarkers Stream

CONFERENCE STREAMS

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2020 COMPANION DX & IO BIOMARKERS CONFERENCES

AUGUST 25-26

AGENDA **Drug-Diagnostics Co-Development & Companion Dx**

AUGUST 26-27

AGENDA **Immuno-Oncology Biomarkers and Diagnostics**

Drug-Diagnostics Co-Development & Companion Dx

INNOVATIVE STRATEGIES AND BUSINESS MODELS IN CDX AND PRECISION MEDICINE

TUESDAY, AUGUST 25

NOVEL INTEGRATED APPROACHES

9:05 am Leveraging Gene Expression Subgroups to Enrich Patient Population

Neeraj Adya, PhD, Head, Diagnostics, Genmab

Precision medicine is transforming treatment paradigms using complex biomarkers in the interpretation of clinical data. Biomarkers, such as TMB and GEP that can identify immune status of a tumor as well as the tumor's microenvironment, may help optimize treatment decisions, individually or in combination. New technological innovations offer the capability to further develop this field. Potential considerations in approving an IVD for complex biomarkers will be discussed.

9:25 Fully Integrated Drug-Diagnostics Co-Development – A New Approach to Targeting Cancers with High Copy Number Amplification

Jason Christiansen, PhD, CTO, Boundless Bio, Inc.

Oncogene amplified tumors have poor prognosis and have been a problematic target for therapeutics. However, the recent elucidation of extrachromosomal DNA (ecDNA) as a mechanism for supporting gene amplified tumors and tumor heterogeneity has provided insight on previous therapeutic failures and new avenues for potential treatment. Using an integrated approach that focuses on improved methods for patient identification coupled with comprehensive target identification strategies, new therapeutic avenues can be explored.

9:45 The Importance of Shaping the Precision Medicine Ecosystem

Kara O'Brien, Senior Director, Global Precision Medicine Strategy, Novartis Oncology

With the growth in on-market targeted therapies & strong precision medicine oncology pipelines the importance of shaping the associated ecosystem is increasing in importance.

10:10 Expanding the Value of Liquid Biopsy Across the Continuum of Drug Development GUARDANT

Mark Landers, Vice President BioPharma Business Development, Guardant Health

As precision medicine continues to evolve, so does the role of liquid biopsy. At Guardant Health, we work with our pharma partners to provide value from biomarker discover, to companion diagnostic development through commercial launch.

10:30 Coffee Break - View Our Virtual Exhibit Hall

NAVIGATING POLICIES & MARKETS, AND PARTNERING WITH PATIENTS

10:45 From Proof-of-Concept to Market Approvals: Regulatory Insights into Drug and Diagnostic Co-Development Programs in Oncology

Eunice Lee, PhD, Executive Director, Global Regulatory Affairs, Merck & Co, Inc.

11:00 FDA Perspective: Regulatory Framework for Co-Development of Companion and Complementary Diagnostics with Therapeutic Products

Reena Philip, PhD, Director, Division of Molecular Genetics and Pathology, CDRH, FDA

Precision medicine uses approved CDx tests to select patients to receive the right drug, at the right dose, and at the right time. Addressing regulations for drug and companion diagnostics has challenges running the gamut, from global clinical trial enrollment, to co-approval, to post-market commitments.

11:20 CDER Perspective on Drug-Diagnostics Co-Development: Leading Industry Partnerships by Example

Julie Schneider, PhD, Associate Director for Research Strategy and Partnerships, Oncology Center of Excellence, FDA

11:40 Global CDx Commercialization Dynamics CLEARVIEW Healthcare Partners

Charles Mathews, Principal, ClearView Healthcare Partners

Successful commercialization of Rx/Dx combinations requires alignment between pharma and Dx players in a number of key areas. In this session, we will review a framework to organize market development, test execution dynamics, quality, market access, partnering best practices. We will also discuss innovative Dx life-cycle management concepts.

11:55 Navigating Policies and Markets

Christine Vietz, PhD, Senior Vice President, Product Development, Foundation Medicine Inc.

This presentation will share the Foundation Medicine perspective and case studies in oncology and other therapeutic areas.

12:15 pm Lunch Break - View Our Virtual Exhibit Hall

HARNESSING POLICIES AND PARTNERING WITH PATIENTS (CONT.)

12:45 Best Practices and Study Design Options for Incorporating Biomarker Strategies to Expedite Drug and Diagnostic Development

Jennifer Shen, PhD, Director, Regulatory Affairs, ORIC Pharmaceuticals

By delineating the development strategies that led to recent oncology therapeutic and diagnostic approvals, common patterns in study designs and development approaches can be identified. Building on these successful co-development examples, this presentation aims to discuss when and how to incorporate a biomarker strategy into a clinical trial to expedite drug development, and to consider best practices for co-development of a companion or complementary diagnostic.

1:05 Opportunities for Optimizing Co-Development of Drugs and Diagnostics

Mark Stewart, PhD, Vice President, Science Policy, Friends of Cancer Research

Molecular diagnostic tests are being used with increasing frequency, especially in oncology. Opportunities and strategies to help guide clinical trials for drug-diagnostic co-development are necessary to align patient and regulatory needs in the era of breakthrough drugs and complex biomarkers.

1:25 LIVE Q&A: Session Wrap-Up

Moderator: Eunice Lee, PhD, Executive Director, Global Regulatory Affairs, Merck & Co, Inc.

Panelists:

Reena Philip, PhD, Director, Division of Molecular Genetics and Pathology, CDRH, FDA

Charles Mathews, Principal, ClearView Healthcare Partners

Julie Schneider, PhD, Associate Director for Research Strategy and Partnerships, Oncology Center of Excellence, FDA

Christine Vietz, PhD, Senior Vice President, Product Development, Foundation Medicine Inc.

Jennifer Shen, PhD, Director, Regulatory Affairs, ORIC Pharmaceuticals

Mark Stewart, PhD, Vice President, Science Policy, Friends of Cancer Research

2:10 Refresh Break - View our Virtual Exhibit Hall

DRUG-DIAGNOSTICS CO-DEVELOPMENT & COMPANION DX, continued

PRECISION MEDICINE BEYOND ONCOLOGY: FDA & PHARMA PERSPECTIVE

2:30 RWD in Precision Medicine and Companion Diagnostics: FDA's Perspective

Wendy Rubinstein, MD, PhD, Director, Personalized Medicine, Center for Devices and Radiological Health, FDA

This presentation will address real world data considerations and how RWD can be utilized for regulatory purposes.

2:50 Panel Discussion: Companion Diagnostics and Precision Medicine beyond Oncology

Moderator: Renee Yura, PhD, Director & Lead, Diagnostics, Pfizer Inc

Panelists:

Wendy Rubinstein, MD, PhD, Director, Personalized Medicine, Center for Devices and Radiological Health, FDA

Mark Curran, PhD, Vice President, Companion Diagnostics, Immunology Therapeutic Area, Janssen R&D LLC

Jason Christiansen, PhD, CTO, Boundless Bio, Inc.

Neeraj Adya, PhD, Head, Diagnostics, Genmab

3:30 Happy Hour - View Our Virtual Exhibit Hall

4:00 Close of Day

WEDNESDAY, AUGUST 26

ACHIEVING REIMBURSEMENT SUCCESS IN THE ERA OF PRECISION MEDICINE

9:00 am Chairperson's Remarks

Joseph Ferrara, President & CEO, Boston Healthcare

9:05 The Reimbursement Outlook for Liquid Biopsy: Liquid Gold or Fool's Gold?

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

Liquid biopsy represents a revolution in cancer care, precipitating seismic paradigm shifts: (1) from tissue- to liquid-diagnosis; (2) from single- to multi-gene panels; (3) from tumor-specific to tumor-agnostic diagnosis and treatment; and (4) from late-stage detection to screening. The acceptance (and consequential reimbursement) of liquid biopsy will depend upon these pivotal transitions in thought and technology.

9:25 Activating Precision Medicine: Overcoming Barriers to Companion Diagnostic Testing

Joseph Ferrara, President & CEO, Boston Healthcare

The testing paradigm in precision oncology is growing increasingly complex, including multi-gene, multi-modality approaches. Add to this the considerations of clinical, policy, and funding stakeholders and geographic variability in test access, and routine companion diagnostic testing becomes a goal that often takes too long to reach. The talk outlines typical barriers encountered, and some key planning and mitigation approaches that biopharmaceutical and diagnostics companies can take to meet key commercial implementation challenges in precision medicine.

9:50 NGS-Based Companion Diagnostic Access

Maude Champagne, Associate Director, Market Access Strategy, Illumina

Access and reimbursement are key factors in a successful diagnostic product go-to-market strategy. For a companion diagnostic, the complexity increases based on the pharmaceutical partner(s)' drug access timeline, regulatory considerations, and fast changing or opaque in-country diagnostic access framework. This session will outline some key considerations in building a roadmap for CDx access.

10:10 Panel Discussion : Joining Forces to Achieve Co-Commercialization Success for Drugs and Diagnostics

Moderator: Joseph Ferrara, President & CEO, Boston Healthcare

- Aligning commercialization activities and timelines
- Understanding global commercial dynamics and complexity
- Best practices in establishing partnerships: Cross-industry, payers, distributors, etc.
- Stakeholder engagement and value communication

Panelists:

Kara O'Brien, Senior Director, Global Precision Medicine Strategy, Novartis Oncology

Maude Champagne, Associate Director, Market Access Strategy, Illumina

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

10:30 Coffee Break - View Our Virtual Exhibit Hall

10:40 Problem Solving Discussions and Coffee Break - View Our Virtual Exhibit Hall

BREAKOUT 6: Disruptive Technologies and Approaches for Companion Diagnostics and Clinical Biomarkers

Neeraj Adya, PhD, Head, Diagnostics, Genmab

PLENARY KEYNOTE SESSION

11:10 Organizer's Opening Remarks

Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

11:15 KEYNOTE PRESENTATION: Ultrasensitive SARS-CoV-2 Protein Assays for Precision Clinical Decisions

David Walt, PhD, HHMI Professor; Hansjörg Wyss Professor of Biologically Inspired Engineering, Harvard Medical School; Professor of Pathology, Department of Pathology-Brigham and Women's Hospital; Core Faculty, Wyss Institute for Bioinspired Engineering, Harvard University

We have developed ultrasensitive single molecule assays for multiple relevant SAR-CoV-2 proteins that can detect both active virus and prior infection. The assays have been tested in thousands of individuals, including patients and healthcare workers and exhibit exceptional sensitivity and specificity. Additionally, we have followed these protein concentrations over time during the course of disease in many patients and can predict outcomes based on the dynamics of the protein responses.

11:40 Panel Discussion : Lessons Learned for Diagnostic Testing During the COVID-19 Pandemic

Moderator: Susan Hsiao, MD, PhD, Assistant Professor, Pathology and Cell Biology, Columbia University Medical Center

- Supply chain challenges
- Navigating and validating multiple platforms
- Reimbursement
- Value of distributed testing
- Value of tests available: PCR vs. antigen vs. serology
- Developing sustainable testing protocols

Panelists:

Alex Greninger, MD, PhD, MS, MPhil, Assistant Professor, Lab Medicine, University of Washington

Jordan S. Laser, MD, Medical Director, Department of Pathology and Laboratory Medicine; LIJMC; Associate Medical Director, Core Laboratories; Director, Division of Near Patient Testing, Northwell Health; Associate Professor, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell

DRUG-DIAGNOSTICS CO-DEVELOPMENT & COMPANION DX, continued

David Walt, PhD, HHMI Professor; Hansjörg Wyss Professor of Biologically Inspired Engineering, Harvard Medical School; Professor of Pathology, Department of Pathology-Brigham and Women's Hospital; Core Faculty, Wyss Institute for Bioinspired Engineering, Harvard University

Alex Greninger, MD, PhD, MS, MPhil, Assistant Professor, Lab Medicine, University of Washington

12:15 pm Keynote Introduction ClearView Healthcare Partners

Charles Mathews, Principal, ClearView Healthcare Partners

12:30 Panel Discussion : Fireside Chat

Moderator: Charles Mathews, Principal, ClearView Healthcare Partners

Panelists:

Sara Brenner, MD, MPH, Associate Director for Medical Affairs; CMO, In Vitro Diagnostics, Office of In Vitro Diagnostics & Radiological Health (OIR), Office of Product Evaluation & Quality (OPEQ), Center for Devices & Radiological Health (CDRH), U.S. Food & Drug Administration

12:55 Lunch Break - View Our Virtual Exhibit Hall

1:25 Close of Drug Diagnostics Co-Development and Companion Dx Conference

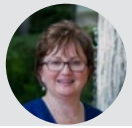
CHI'S 6TH ANNUAL | **AUGUST 26-27, 2020**

Immuno-Oncology Biomarkers and Diagnostics

PREDICTING AND MONITORING RESPONSE TO CANCER IMMUNOTHERAPY

WEDNESDAY, AUGUST 26

PLENARY KEYNOTE SESSION



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Charles Mathews, Principal, ClearView Healthcare Partners

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Moderator: Charles Mathews, Principal, ClearView Healthcare Partners

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Sara Brenner, MD, MPH, Associate Director for Medical Affairs; CMO, In Vitro Diagnostics, Office of In Vitro Diagnostics & Radiological Health (OIR), Office of Product Evaluation & Quality (OPEQ), Center for Devices & Radiological Health (CDRH), U.S. Food & Drug Administration

12:45 Lunch Break - View our Virtual Exhibit Hall

BIOMARKERS TO GUIDE COMBINATION CANCER TRIALS

1:30 Biomarkers in the Era of Immuno-Oncology: Update on Keytruda and Combinations

Andrea Webber, PhD, Assistant Head, Clinical Biomarkers, Translational Oncology, Merck & Co., Inc.

This talk will discuss the evolving landscape of biomarkers in the field of immuno-oncology, on immunohistochemistry and genomic approaches, for both immune-checkpoint single-agent treatments and combination therapies.

1:50 Blood-Based Biomarkers for Drug Discovery and Patient Selection in Immuno-Oncology

Katie Streicher, PhD, Associate Director, Translational Medicine, Research and Early Development, Oncology R&D, AstraZeneca

The presentation will present the opportunities and challenges in developing impactful biomarker strategies for early clinical development of new immuno-oncology drugs. We will focus on the design of fit-for-purpose entry into human clinical trials, proof or disproof of mechanism of action and optimal biological dose finding.

2:10 Highly Multiplexed Liquid and Tissue Biopsy: Introducing the RareCyte Orion Platform RARECYTE

Tad George, PhD, Sr. VP, Biology R&D, RARECYTE, INC

We will share advancements in multi-biomarker CTC analysis and introduce the Orion spatial biology platform for multiplex tissue analysis. Orion's single day workflow for 21-channel whole-slide imaging enables immuno-oncology and infectious disease applications. In addition, multi-biomarker CTC assays with high accuracy and precision suitable for multi-center trials will be reviewed.

2:23 Personalizing Immunotherapy for Each Cancer Patient

Matthew Davis, PhD, Associate Director, Molecular Biology and Sequencing, Gritstone Oncology

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

2:40 Panel Discussion: Session Wrap-Up

Moderator: Andrea Webber, PhD, Assistant Head, Clinical Biomarkers, Translational Oncology, Merck & Co., Inc.

Panelists:

Katie Streicher, PhD, Associate Director, Translational Medicine, Research and Early Development, Oncology R&D, AstraZeneca

Matthew Davis, PhD, Associate Director, Molecular Biology and Sequencing, Gritstone Oncology

Tad George, PhD, Sr. VP, Biology R&D, RARECYTE, INC

2:55 Refresh Break – View Our Virtual Exhibit Hall

IMMUNO-ONCOLOGY BIOMARKERS AND DIAGNOSTICS, continued

PREDICTIVE BIOMARKERS OF RESPONSE AND PROGRESSION

3:15 Predictive Biomarkers for Immunotherapy in Lung Cancer: Current Status and Future Perspectives

Fred Hirsch, MD, PhD, Executive Director, Center for Thoracic Oncology, Tisch Cancer Center; Professor, Medicine and Pathology, Icahn School of Medicine, Mount Sinai NY

It might be time to look into the role of "combined" biomarkers or assays for the most optimal selection of patients who benefit from immunotherapy. The current role of PD-L1 and TMB as predictive biomarkers will be discussed as well as potential new biomarkers for immunotherapy, such as genomic classifiers and the role of the microbiome for immunotherapy of lung cancer.

3:35 Measurable ('Minimal') Residual Disease (MRD) in Acute Myeloid Leukemia (AML)

Roland B. Walter, MD, PhD, MS, Associate Professor, Clinical Research Division, Fred Hutchinson Cancer Research Center

Over the last decades, several assays that detect immunophenotypic or genetic/molecular abnormalities of AML cells have been developed to quantify MRD in AML. While methodologies continue to evolve, existing data indicate MRD test results are useful for the refinement of prognosis/risk-stratification. Interest increases in using information from MRD tests for therapeutic decision-making as well as a surrogate endpoint for drug testing/approval, but well-controlled data supporting these uses are currently lacking.

3:55 Comparison of Gene Expression Profiling Platforms: Translataility of Tumor Inflammation Gene Signatures

Nancy Zhang, PhD, Associate Director, Pharmacodiagnostics, Bristol-Myers Squibb

A CD8 gene expression signature, developed using pathology-assisted digital immunohistochemistry and machine-learning approach to access inflammation in the tumor microenviroment, was associated with response to nivolumab in a post-hoc analysis of patients with urothelial carcinoma from CheckMate 275. A comparison study demonstrates platform-independent consistency when assessing GEP-derived tumor inflammation signatures and the feasibility of utilizion gene expression signatures across GEP platforms.

4:15 LIVE Q&A: Session Wrap-Up

Moderator: Nancy Zhang, PhD, Associate Director, Pharmacodiagnostics, Bristol-Myers Squibb

Panelists:

Fred Hirsch, MD, PhD, Executive Director, Center for Thoracic Oncology, Tisch Cancer Center; Professor, Medicine and Pathology, Icahn School of Medicine, Mount Sinai NY

Roland B. Walter, MD, PhD, MS, Associate Professor, Clinical Research Division, Fred Hutchinson Cancer Research Center

4:35 Happy Hour - View Our Virtual Exhibit Hall

5:10 Close of Day

THURSDAY, AUGUST 27

CHALLENGES OF EARLY CANCER DETECTION

9:00 am Chairperson to be Announced

Chairperson to be Announced

9:05 KEYNOTE PRESENTATION: Overdiagnosis and Premature Treatment Challenge of Early Disease Detection

Laura Esserman, MD, MBA, Professor, Surgery, University of California San Francisco Medical Center

9:25 Multi-Modal Approaches to Early Disease Detection and Population-Based Screening

Drew Watson, MBA, PhD, Senior Vice President, Biostatistics and Clinical Development, CellMax Life

For many diseases, population screening is essential to improving patient survival. Despite the promise of blood-based "liquid biopsies," progress has been limited necessitating new multi-omics approaches incorporating multiple technologies. We discuss new approaches to biomarker discovery, algorithm development, and clinical validation using mechanistic, statistical, and machine learning approaches for handling of multi-omics data. We further discuss the need to improve clinical decision support systems to facilitate clinical decision making.

9:45 Multi-Cancer Detection and Localization Using a Methylation-Based cfDNA Assay

Arash Jamshidi, PhD, Vice President, Bioinformatics and Data Science, GRAIL, Inc.

GRAIL is a healthcare company whose mission is to detect cancer early, when it can be cured. GRAIL is focused on alleviating the global burden of cancer by developing pioneering technology to detect and identify multiple deadly cancers early. The company is using the power of next-generation sequencing, population-scale clinical studies, and state-of-the-art computer science and data science to develop its multi-cancer early detection blood test.

10:05 Coffee Break - View Our Virtual Exhibit Hall

10:15 Problem Solving Discussions - View Our Virtual Exhibit Hall

BREAKOUT 11: Blood-Based Biomarkers in Oncology

Katie Streicher, PhD, Associate Director, Translational Medicine, Research and Early Development, Oncology R&D, AstraZeneca

Jonathan Baden, MS, Senior Director, Pharmacodiagnostic, Bristol-Myers Squibb

BLOOD-BASED BIOMARKERS AND IMMUNO-PROFILING

10:50 Blood-Based Biomarkers in Immuno-Oncology

Jonathan Baden, MS, Senior Director, Pharmacodiagnostic, Bristol-Myers Squibb

Blood is accessible with minimally invasive and cost-effective methods, so it has always been considered an attractive source of biomarkers. With rapid technological advancements, circulating tumor DNA (ctDNA), in particular, has become an invaluable diagnostic material with multiple potential applications across the disease continuum. Here, we review the recent findings on ctDNA to aid in patient selection and disease monitoring from an immuno-oncology perspective, and we discuss potential future directions.

11:10 Changing the Light by Mass to Resolve the Immune-Profiling of Tumor Tissue and Tumor-Associated Immune Cells

Alejandro Francisco-Cruz, MD, PhD, Postdoctoral Reasearcher, Translational Molecular Pathology, The University of Texas MD Anderson Cancer Center

Next-generation IHC analyzes around thirty-nine markers at a time followed by two-dimensional image analysis of signals from metal-isotope conjugated antibodies revealing the multi-epitope cell composition within the tumor microenvironment.

11:30 Panel Discussion: LIVE Q&A: Session Wrap-Up

Moderator: Jonathan Baden, MS, Senior Director, Pharmacodiagnostic, Bristol-Myers Squibb

Panelists:

Alejandro Francisco-Cruz, MD, PhD, Postdoctoral Reasearcher, Translational Molecular Pathology, The University of Texas MD Anderson Cancer Center

11:50 Lunch Break - View Our Virtual Exhibit Hall

IMMUNO-ONCOLOGY BIOMARKERS AND DIAGNOSTICS, continued

LIQUID BIOPSY FOR EARLY CANCER DETECTION

12:15 pm Chairperson's Remarks

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

12:20 Saliva Liquid Biopsy

David TW Wong, DMD, DMSc, Associate Dean of Research, Felix & Mildred Yip Endowed Distinguished Professor, UCLA School of Dentistry

We produce ~600ml of saliva per day that harbors multiple omics constituents that can be harnessed non-invasively for personalized, precision medicine, making it ideal for liquid biopsy applications. Yet, PCR-based technologies cannot detect ctDNA in saliva, whereas an emerging liquid biopsy platform "Electric Field Induced Release and Measurement (EFIRM)" detects ctDNA from NSCLC patients with actionable mutations in plasma and saliva with 95%+ concordance with tissue/biopsy-based genotyping, including early stage lesions.

12:40 Plasma-Based Liquid Biopsies for Early Detection of Cancer

Nickolas Papadopoulos, PhD, Professor, Oncology and Pathology, Director of Translational Genetics, Ludwig Center for Cancer Genetics & Therapeutics, Sidney Kimmel Comprehensive Cancer Center, The Johns Hopkins Institutions

Early detection of cancer has the potential to significantly reduce cancer deaths. Liquid biopsies provide an opportunity to develop tests for the detection of multiple-types of cancer in a single test. We will discuss the opportunities and the challenges of developing and utilizing such test.

1:00 Leveraging Novel Exosome Nanosensors for Earlier Pancreatic Cancer Detection

Cesar Martin Castro, MD, Director, Cancer Program, MGH Center for Systems Biology, Massachusetts General Hospital/Harvard Medical School

Exosomes reflect promising cancer biomarkers due to their abundance in biofluids, protein, and RNA contents reflecting parental cells, and stability in circulation. Pancreatic ductal adenocarcinomas (PDAC) represent highly lethal cancers often presenting at advanced stages. Integrating exosomes into monitoring programs for PDAC could improve clinical outcomes. This talk will discuss novel nanosensors we developed to analyze exosomes in blood and recent translational strategies to position them into clinical workflows.

1:30 Close of Summit

Business Stream

CONFERENCE STREAMS

- POCT TECHNOLOGIES AND STRATEGY
- POCT AND INFECTIOUS DISEASE
- LIQUID BIOPSY/EARLY DETECTION
- COMPANION DX AND IO BIOMARKERS
- BUSINESS
- NGS ADVANCES

2020 BUSINESS CONFERENCES

AUGUST 25-26

AGENDA **Coverage and Reimbursement for Advanced Diagnostics**

AUGUST 26-27

AGENDA **Commercialization of Diagnostic Tests**

Coverage and Reimbursement for Advanced Diagnostics

LATEST DEVELOPMENTS IN THE DX REIMBURSEMENT LANDSCAPE

TUESDAY, AUGUST 25

COVID LESSONS LEARNED & OTHER HOT BUTTONS

9:05 am FEATURED PRESENTATION: Coding for The Frontlines: Establishing CPT® Codes for Novel Coronavirus (SARS-CoV-2) Tests

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

The American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel during a roughly one-month period between March and April 2020 twice enacted their rarely used expedited approval process to develop new codes for reporting novel coronavirus tests. In this session, the secretary of the CPT Editorial Panel will discuss adapting the code development process, and how the code additions streamline a data-driven response to the COVID-19 pandemic.

9:25 Panel Discussion: Hot Button Issues in Dx Reimbursement

Moderator: Danielle Scelfo, Vice President of Market Access and Health Policy, Care Dx

10:30 Coffee Break - View Our Virtual Exhibit Hall

CMS UPDATE

10:50 Demystifying Molecular Diagnostics Coverage and Reimbursement in Medicare: MolDx

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

This presentation will provide an overview of how the MolDx program works and makes coverage determinations for Medicare, as well as the process providers will need to follow when seeking coverage.

11:10 How MolDx and CMS Make Coverage Decisions

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

Innovative diagnostics labs depend on coverage decisions, especially from Medicare. But how are they really made? Understand how CMS drafts and finalizes national decisions (NCDs), and successful and unsuccessful approaches to public comment.

11:30 Live Q&A: Session Wrap-Up

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

Panelists:

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

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

11:50 Session Break

12:15 pm Lunch Break - View Our Virtual Exhibit Hall

MAKING REIMBURSEMENT A STRATEGIC PRIORITY

12:45 CO-PRESENTATION: Making Reimbursement a Strategic Priority

Shaun O'Neil, MBA, Chief Commercial Officer, PAVmed Inc. and Lucid Diagnostics

John F. Warren, Owner, Gettysburg Healthcare Consultants

The diagnostics industry has continued to evolve at a breakneck pace. Payer reimbursement models are advancing as well. Hear from two industry experts about how payers, particularly Medicare, are changing the way that diagnostics are paid for, and learn why developers need to incorporate a sound reimbursement strategy into their product commercialization plans.

1:25 Navigating the Reimbursement Landscape in the Era of Precision Medicine BOSTON HEALTHCARE ASSOCIATES

Shivang Doshi, Executive Director, Boston Healthcare

The increasing complexity of cancer care and accelerated approvals of targeted and immuno-oncology therapies has shifted CDx testing from a one test-one drug approach to a next-generation sequencing (NGS)-based multi-gene approach. Despite recent improvements, coverage and reimbursement remains fragmented and challenging for NGS testing.

1:50 Live Q&A: Session Wrap-Up

Moderator: John F. Warren, Owner, Gettysburg Healthcare Consultants

Panelists:

Shaun O'Neil, MBA, Chief Commercial Officer, PAVmed Inc. and Lucid Diagnostics

Shivang Doshi, Executive Director, Boston Healthcare

2:10 Refresh Break - View Our Virtual Exhibit Hall

STRATEGIES TO SATISFY EVIDENTIARY REQUIREMENTS

2:25 Chairperson's Remarks

Hannah Mamuszka, Founder & CEO, Alva10

2:30 Launching New Tests: Setting Up for Success by Assuring Coverage and Reimbursement

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

2:50 Co-Presentation: Partnering to Rethink Real-World Data Development: Why Payers and Diagnostics Companies Should Come Together Early in Commercial Planning

Matthew Tucker, Director, Enterprise Strategy and Innovation, Highmark Health

Hannah Mamuszka, Founder & CEO, Alva10

3:10 Live Q&A: Session Wrap-Up

Moderator: Hannah Mamuszka, Founder & CEO, Alva10

Panelists:

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

Matthew Tucker, Director, Enterprise Strategy and Innovation, Highmark Health

3:30 Happy Hour - View Our Virtual Exhibit Hall

4:00 Close of Day

WEDNESDAY, AUGUST 26

ACHIEVING REIMBURSEMENT SUCCESS IN THE ERA OF PRECISION MEDICINE

9:00 am Chairperson's Remarks

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COVERAGE AND REIMBURSEMENT FOR ADVANCED DIAGNOSTICS, continued

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

10:30 Coffee Break - View Our Virtual Exhibit Hall

10:40 Problem Solving Discussions - View Our Virtual Exhibit Hall

BREAKOUT 4: Reimbursement Issues with COVID-19 Testing

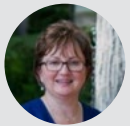
Ester Stein, Director, Corporate Reimbursement, Government Affairs, Abbott Laboratories

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

BREAKOUT 5: Working with CMS Contractors

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

PLENARY KEYNOTE SESSION



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12:15 pm Keynote Introduction

Charles Mathews, Principal, ClearView Healthcare Partners

12:30 Fireside Chat

Moderator: Charles Mathews, Principal, ClearView Healthcare Partners

Panelists:

Sara Brenner, MD, MPH, Associate Director for Medical Affairs; CMO, In Vitro Diagnostics, Office of In Vitro Diagnostics & Radiological Health (OIR), Office of Product Evaluation & Quality (OPEQ), Center for Devices & Radiological Health (CDRH), U.S. Food & Drug Administration

12:55 Lunch Break - View Our Virtual Exhibit Hall

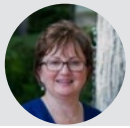
1:25 Close of Coverage and Reimbursement for Advanced Diagnostics Conference

Commercialization of Diagnostic Tests

SUCCESSFUL STRATEGIES AND PARTNERSHIPS

WEDNESDAY, AUGUST 26

PLENARY KEYNOTE SESSION



11:10 am Organizer's Opening Remarks

Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

11:15 KEYNOTE PRESENTATION: Ultrasensitive SARS-CoV-2 Protein Assays for Precision Clinical Decisions

David Walt, PhD, HHMI Professor; Hansjörg Wyss Professor of Biologically Inspired Engineering, Harvard Medical School; Professor of Pathology, Department of Pathology-Brigham and Women's Hospital; Core Faculty, Wyss Institute for Bioinspired Engineering, Harvard University

We have developed ultrasensitive single molecule assays for multiple relevant SAR-CoV-2 proteins that can detect both active virus and prior infection. The assays have been tested in thousands of individuals, including patients and healthcare workers and exhibit exceptional sensitivity and specificity. Additionally, we have followed these protein concentrations over time during the course of disease in many patients and can predict outcomes based on the dynamics of the protein responses.

11:40 Panel Discussion : Lessons Learned for Diagnostic Testing During the COVID-19 Pandemic

Moderator: Susan Hsiao, MD, PhD, Assistant Professor, Pathology and Cell Biology, Columbia University Medical Center

- Supply chain challenges
- Navigating and validating multiple platforms
- Reimbursement
- Value of distributed testing
- Value of tests available: PCR vs. antigen vs. serology
- Developing sustainable testing protocols

Panelists:

Alex Greninger, MD, PhD, MS, MPhil, Assistant Professor, Lab Medicine, University of Washington

Jordan S. Laser, MD, Medical Director, Department of Pathology and Laboratory Medicine; LIJMC; Associate Medical Director, Core Laboratories; Director, Division of Near Patient Testing, Northwell Health; Associate Professor, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell

David Walt, PhD, HHMI Professor; Hansjörg Wyss Professor of Biologically Inspired Engineering, Harvard Medical School; Professor of Pathology, Department of Pathology-Brigham and Women's Hospital; Core Faculty, Wyss Institute for Bioinspired Engineering, Harvard University

12:15 pm Keynote Introduction CLEARVIEW Healthcare Partners

Charles Mathews, Principal, ClearView Healthcare Partners

12:30 Fireside Chat

Moderator: Charles Mathews, Principal, ClearView Healthcare Partners

Panelists:

Sara Brenner, MD, MPH, Associate Director for Medical Affairs; CMO, In Vitro Diagnostics, Office of In Vitro Diagnostics & Radiological Health (OIR), Office of Product Evaluation & Quality (OPEQ), Center for Devices & Radiological Health (CDRH), U.S. Food & Drug Administration

12:55 Lunch Break - View Our Virtual Exhibit Hall

NEW BUSINESS MODELS AND PARTNERSHIPS

1:25 Chairperson's Remarks

Charles Mathews, Principal, ClearView Healthcare Partners

1:30 Partnering to Drive Patient Impact and Growth at Exact Sciences

David Harding, Senior Vice President, Strategy and Business Development, Exact Sciences

Exact Sciences has made 3 crucial moves to accelerate impact and drive growth: (1) Entered into a partnership with Pfizer to drive patient and physician awareness of Cologuard and increase adoption; (2) Forged a partnership with Epic to improve order management of Cologuard and to allow seamless ordering within EHR systems; (3) Acquired Genomic Health to expand into new areas of cancer patient care. These serve patients throughout their journey.

1:50 Models and Partnerships for Bringing Genomics to Routine Health Care

Huntington Willard, PhD, CSO & Senior Vice President, Medical Affairs, Genome Medical, Inc.

Our goal at Genome Medical is to facilitate genomic testing and downstream care for those whose clinical findings, family history, or interest in finding out their risk of actionable genetic disease indicates a need for genetic care. We establish key partnerships – with testing laboratories, employers, health systems, and treatment centers – that optimize access across a range of value-based products in both primary care and specialty care pathways.

2:10 Commercialization of an IVD in a Changing Global Environment MilliporeSigma

Erin Lahti, Marketing Manager, Dx Manufacturing & OEM, MilliporeSigma

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

2:35 Refresh Break - View Our Virtual Exhibit Hall

3:05 Live Q&A: New Business Models and Partnerships

Moderator: Charles Mathews, Principal, ClearView Healthcare Partners

- Incorporating the consumer/patient into diagnostics
- Potential value-added services that diagnostic players can provide
- Innovative partnering models

Panelists:

David Harding, Senior Vice President, Strategy and Business Development, Exact Sciences

Huntington Willard, PhD, CSO & Senior Vice President, Medical Affairs, Genome Medical, Inc.

Erin Lahti, Marketing Manager, Dx Manufacturing & OEM, MilliporeSigma

3:35 pm Session Break

3:45 Live Q&A: Investment Landscape and Opportunity for Diagnostic Tests

Moderator: Roger D. Klein, MD, JD, CMO, OmniSeq

- How to best frame value proposition

COMMERCIALIZATION OF DIAGNOSTIC TESTS, continued

- Investors' portfolios in diagnostics space
- The shift in Dx test investment and where this is going

Panelists:

Mark Jelley, Managing Director, OrbiMed Advisors, LLC

Tom Miller, Founder & Managing Partner, GreyBird Ventures, LLC

William Harman, Senior Advisor, Special Limited Partner, VCFA Group

4:35 Happy Hour - View Our Virtual Exhibit Hall

5:10 Close of Day

THURSDAY, AUGUST 27

HOW ONCOLOGISTS CHOOSE AND EVALUATE DIAGNOSTIC TESTS

9:05 am How Oncologists Choose and Evaluate Diagnostic Tests

Moderator: Paul Gerrard, MD, Vice President, McDermott+ Consulting

- Academic versus community hospitals' requirements for diagnostics
- Resources, processes, and outcomes
- Reimbursement and regulations

Panelists:

Kashyap Patel, MD, CEO & Medical Oncologist, Hematology, Oncology & Internal Medicine, Carolina Blood and Cancer Care Associates

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

10:05 Coffee Break - View Our Virtual Exhibit Hall

10:15 Problem Solving Discussions - View Our Virtual Exhibit Hall

SUCCESSFUL COMMERCIALIZATION STRATEGIES AND MARKET LAUNCH

10:50 Launching Dx Tests Successfully: Is Product Performance and Regulatory Approval Sufficient?

Charudutt Shah, Director of Marketing (EMEA), BioMérieux

Launching innovative diagnostics tests has never been so challenging. You did all the right things – followed your customer's voice, developed the product to meet performance requirements, conducted clinical validations, and obtained regulatory approvals. Yet, this is not sufficient to be successful in the marketplace. In fact, these are the prerequisites. This talk covers several factors that drive successful commercialization and market access efforts required to make successful product launches.

11:00 Foundation Medicine's Strategy for Commercializing Liquid Biopsy Tests

Tesh Khullar, CCO, Foundation Medicine Inc.

Drawing from two decades of experience working in oncology, Foundation Medicine's Chief Commercial Officer, Tesh Khullar, will discuss the importance of a patient-centered commercialization strategy. He will focus specifically on his team's efforts to expand access to precision medicine for cancer patients through the company's portfolio of comprehensive genomic profiling assays.

11:10 Current Planning and Strategy to Enter Companion Diagnostic Test Market at Guardant Health

Daniel Simon, MBA, Senior Vice President, BioPharma Business Development, Guardant Health

This presentation maps the path and discusses Guardant's approach for entering the companion diagnostic test market.

11:20 Live Q&A: Successful Commercialization Strategies and Market Launch

Moderator: Harry Glorikian, MBA, General Partner, New Ventures Funds

- Define the priority checklist for executing a successful strategy and operational plan for commercializing diagnostic tests
- Examine the process of bringing a product to market by highlighting all the key features required in today's evolving healthcare environment
- Financial resources needed to execute the project plan
- Other key factors, including market entry strategy development, regulatory, reimbursement, health economic, key opinion leader engagement, and patient advocacy considerations

Panelists:

Tesh Khullar, CCO, Foundation Medicine Inc.

Charudutt Shah, Director of Marketing (EMEA), BioMérieux

Daniel Simon, MBA, Senior Vice President, BioPharma Business Development, Guardant Health

11:50 Lunch Break - View Our Virtual Exhibit Hall

COMMERCIALIZING POINT-OF-CARE DIAGNOSTIC TESTS

12:10 pm Automated Solution for COVID-19 and Seegene Flu A/Flu B/RSV/COVID-19 Combo RT-PCR Assays

Helen Cha Roberts

12:30 eRAPID Technology – A Universal Multiplexed Electrochemical Sensor Platform Repurposed to Detect COVID-19 Antibodies

Pawan Jolly, PhD, Senior Scientist, Wyss Institute, Harvard University

eRapid is proprietary electrical sensor technology, enabling the detection of small chemicals and large biomolecules in complex fluid samples without requiring sample preparation. During the current pandemic, eRapid technology has been repurposed to develop a rapid multi-antigen platform for the detection of IgG, IgM, and IgA. The platform has been tested with nearly 80 samples and has shown high sensitivity and selectivity.

12:50 CASE STUDY: Federal Resources for Early-Stage Diagnostic Start-Up

Tiffani Lash, PhD, Program Director, National Institutes of Health

I will discuss the federal resources for early-stage companies that fall into the research portfolios of biosensors, platform technologies, and mHealth programs at NIH. NIBIB Point-of-Care Technologies Research Network will be explained, consisting of three centers charged with developing point-of-care diagnostic technologies through collaborative efforts that merge scientific and technological capabilities with clinical need.

1:10 Live Q&A: Commercializing Point-of-Care Tests – Translating Early-Stage Innovation

Moderator: Richard Chasen Spero, PhD, CEO, Redbud Labs, Inc.

- Current status on bringing your technology to market
- Key considerations for developing an early translational roadmap
- Funding opportunities and business plan requirements
- How do you develop your go-to-market strategy?
- Attracting early strategic partners
- What role are KOLs and/or institutions playing as you bring your technology to market?

Panelists:

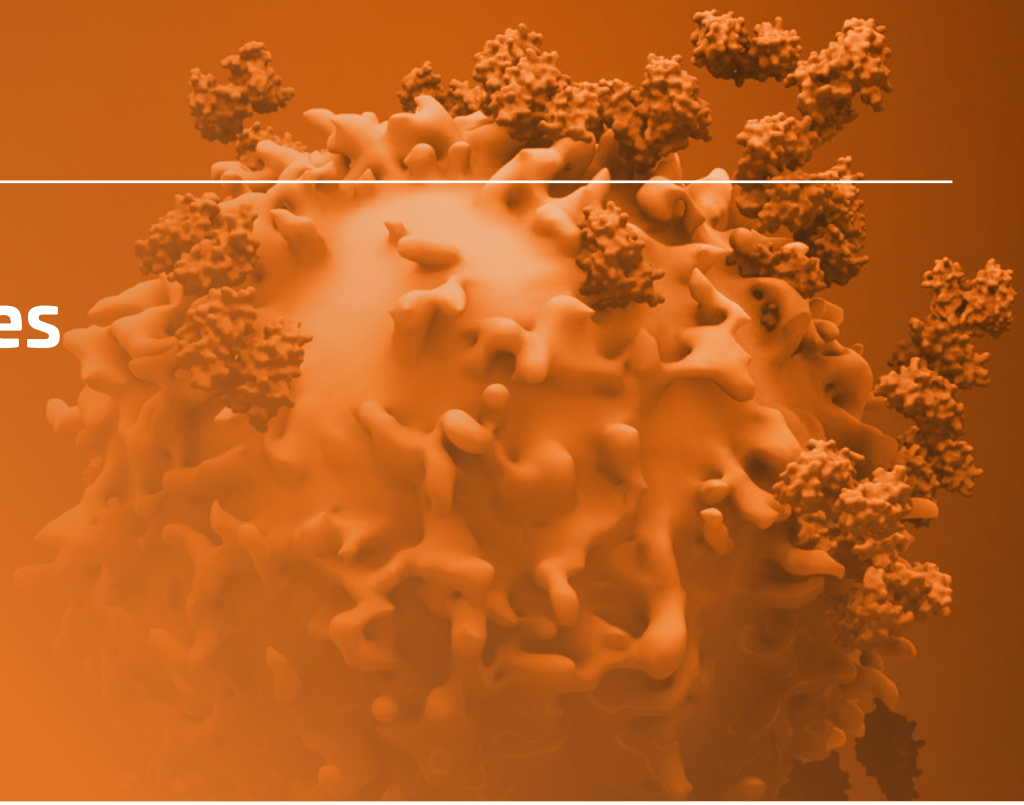
Pawan Jolly, PhD, Senior Scientist, Wyss Institute, Harvard University

Tiffani Lash, PhD, Program Director, National Institutes of Health

Helen Cha Roberts

1:30 Close of Summit

NGS Advances Stream



CONFERENCE STREAMS

- POCT TECHNOLOGIES AND STRATEGY
- POCT AND INFECTIOUS DISEASE
- LIQUID BIOPSY/EARLY DETECTION
- COMPANION DX AND IO BIOMARKERS
- BUSINESS
- NGS ADVANCES

2020 NGS ADVANCES CONFERENCE

AUGUST 26-27

AGENDA

NGS Advances and Multimodality Assays

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NGS TECHNOLOGY TRENDS AND NEW APPLICATIONS

WEDNESDAY, AUGUST 26

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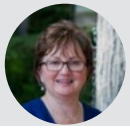

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12:55 Lunch Break - View Our Virtual Exhibit Hall

BREAKTHROUGHS AND NOVEL APPLICATIONS

1:30 The Intersection of Knowledge Informatics and Clinical NGS Platforms

Carl Morrison, MD, DVM, Senior Vice President, Pathology, Roswell Park Cancer Institute

New technologies in NGS are emerging that allow for more efficient clinical laboratory workflows. Matching knowledge informatics to the output of these new NGS technologies is essential to moving the field of clinical sequencing forward.

1:50 Cell-by-Cell: Building High-Resolution Tumor Atlases

Asaf Rotem, PhD, Associate Director, Center for Cancer Precision Medicine, Dana Farber Cancer Institute

Multicenter atlas projects greatly improve studies of tissue biology and should advance disease detection, prevention, and treatment. We aim to set joint frameworks and generate informative and accessible multi-dimensional atlases. Single-cell genomics assays combined with spatial multiplex *in situ* methods and well-annotated clinical specimens allow us to study tissue complexity at unprecedented resolution. I will demonstrate the establishment of atlas assays, frameworks, and the scientific outcomes in oncology.

2:10 The Explify Platform: Using Clinical Metagenomics to Detect Pathogens, Microorganisms and AMR IDbyDNA

Robert Schlaberg, MD, PhD, MPH, Co-Founder, Chief Medical Officer, Medical & Scientific Affairs, IDbyDNA

Infectious disease detection is of critical importance in today's pandemic-stricken world. Clinical metagenomics with next generation sequencing uniquely addresses the challenges of pathogen detection and surveillance using breakthrough technologies such as the Explify® Platform from IDbyDNA. Explify converts sequencing data to insight by applying robust bioinformatics and machine learning, and can be applied to unbiased shotgun sequencing, focused amplicon sequencing, or syndrome-based target enrichment to identify various pathogen types within a single sample.

2:35 Panel Discussion: LIVE Q&A and Session Wrap Up

Moderator: Carl Morrison, MD, DVM, Senior Vice President, Pathology, Roswell Park Cancer Institute

Panelists:

Asaf Rotem, PhD, Associate Director, Center for Cancer Precision Medicine, Dana Farber Cancer Institute

Robert Schlaberg, MD, PhD, MPH, Co-Founder, Chief Medical Officer, Medical & Scientific Affairs, IDbyDNA

2:45 Refresh Break - View Our Virtual Exhibit Hall

NGS ADVANCES AND MULTIMODALITY ASSAYS, continued

FEATURED SESSION: NUCLEIC ACID DETECTION

3:35 KEYNOTE PRESENTATION: Engineering Biology for Diagnostic Solutions

William Blake, PhD, CTO, Sherlock Biosciences

SHERLOCK is a method for single molecule detection of nucleic acid targets by amplifying genetic sequences and programming a CRISPR molecule to detect the presence of a genetic signature. When it finds those signatures, the CRISPR enzyme is activated and releases a signal. It can be adapted to work on a paper strip test, laboratory equipment, or to provide an electrochemical readout that can be read with a mobile phone.

3:55 Instrument-Free Paper-Based POC Pathogen Diagnostics for the Clinic and the Home

Paul Yager, PhD, Professor, Department of Bioengineering, University of Washington

Instruments ranging from the venerable GeneXpert to ones just coming on the market allow fairly rapid NAAT pathogen detection, but they are based on disposable cartridges and a permanent (and relatively expensive) instrument. Our lab has been developing instrument-free disposable NAAT devices that retain the advantages of the instrumented systems, but free the user from the need for purchasing a permanent instrument (and the upfront cost that incurs).

4:15 Live Q&A: Session Wrap-Up

Moderator: Shawn Mulvaney, PhD, Section Head, Surface Nanoscience and Sensor Technology Section, Chemistry, U.S. Naval Research Laboratory

Panelists:

William Blake, PhD, CTO, Sherlock Biosciences

Paul Yager, PhD, Professor, Department of Bioengineering, University of Washington

4:25 Happy Hour - View Our Virtual Exhibit Hall

5:00 Close of Day

THURSDAY, AUGUST 27

MULTIPLEX PANELS

9:00 am Chairperson's Remarks

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

9:05 Comparison: Nanopore Sequencing and Microarray Resequencing for Multiplex Pathogen Identification

Robert Duncan, PhD, Principal Investigator, Office of Blood Research and Review, Center for Biologics Evaluation and Research (CBER), FDA

GeneChip Resequencing microarrays have been advanced for infectious disease agent detection and identification from Ebola to Zika. Next-generation sequencing with the highly mobile and cost-effective nanopore sequencing device is challenging the supremacy of the microarray in rapid point-of-need pathogen detection. This talk will present results from application of these two platforms for pathogen detection and compare their performance.

9:20 Syndromic Testing for Meningitis/Encephalitis: Saga of the Love-Hate Relationship

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

As part of the Multiplex Panel session, this talk will focus on multiplex testing for the laboratory diagnosis of meningitis and encephalitis as compared to standard-of-care testing. The potential benefits and limitations of panel testing for meningitis and encephalitis compared to standard-of-care testing will be discussed. The potential approaches to maximize testing yield will also be discussed.

9:35 The Biofire Pneumonia Panel: Does It Relate to Microbiological and Clinical Variables?

Kenneth Rand, MD, Medical Director, Clinical Microbiology Laboratory; Professor, Pathology and Medicine, University of Florida

The BioFire FilmArray Pneumonia Panel (PP) detects 15 common bacterial pathogens, 3 atypical pneumonia bacteria, 8 viruses, and 7 antimicrobial resistance markers by multiplex PCR. Results of our 396-patient study suggest PP detects more bacterial isolates than conventional microbiology, and the copy number correlates with outcome variables Results reported in a 3-4 h timeframe after a BAL could potentially improve both antibiotic choice and de-escalation in critically ill intubated patients.

9:50 Panel Discussion : Advancing Multiplex Panels for Clinical Diagnostics

Moderator: Esther Babady, PhD, Medical Director, Clinical Microbiology Service, Memorial Sloan Kettering Cancer Center

- Comparison of multiplex platforms
- Reimbursement considerations
- Proving clinical utility of multiplex diagnostic tests

Panelists:

Robert Duncan, PhD, Principal Investigator, Office of Blood Research and Review, Center for Biologics Evaluation and Research (CBER), FDA

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

Kenneth Rand, MD, Medical Director, Clinical Microbiology Laboratory; Professor, Pathology and Medicine, University of Florida

10:05 Coffee Break - View Our Virtual Exhibit Hall

10:15 Problem Solving Discussions - View Our Virtual Exhibit Hall

BREAKOUT 13: Genomic Biomarkers in Oncology: Today and Tomorrow

Carl Morrison, MD, DVM, Senior Vice President, Pathology, Roswell Park Cancer Institute

OPPORTUNITIES AND CHALLENGES OF EARLY DIAGNOSIS OF DISEASE

10:45 Chairperson's Remarks

John Sninsky, PhD, Independent Consultant, Translational Medicine and Science

10:50 Opportunity for Pre-Competitive Multi-Stakeholder Collaboration for NAFLD Detection and Intervention

Veronica Miller, PhD, Executive Director, Forum for Collaborative Research

Non-alcoholic fatty liver disease (NAFLD) affects approximately 25% of adults and 10% of children in the U.S. and is associated with obesity, type 2 diabetes mellitus, dyslipidemia and hypertension. Early diagnosis of the higher risk individuals is paramount. Representation and active engagement of scientific experts from all stakeholder groups in a non-competitive environment increases clarity and standardization while decreasing uncertainty. Lessons learned will be summarized.

11:10 Breast Cancer Overdiagnosis and the Precancer Problem

Alexander Borowsky, PhD, Associate Professor, Pathology and Laboratory Medicine, University of California, Davis

Breast cancer screening by mammography, which began in the U.S. about 40 years ago, has led to significant increases in the incidence of early-stage breast cancers, including ductal carcinoma *in situ* (DCIS), also called precancer or stage 0 disease. However, the expected reciprocal decrease in subsequent late-stage breast

NGS ADVANCES AND MULTIMODALITY ASSAYS, continued

cancers was not found. It is now clear that some screen-detected breast "cancers" are indolent lesions without significant malignant potential.

11:30 Panel Discussion: Opportunities and Challenges of Early Diagnosis of Disease

Moderator: John Sninsky, PhD, Independent Consultant, Translational Medicine and Science

Panelists:

Alexander Borowsky, PhD, Associate Professor, Pathology and Laboratory Medicine, University of California, Davis

Veronica Miller, PhD, Executive Director, Forum for Collaborative Research

11:50 Lunch Break - View our Virtual Exhibit Hall

NEXT-GENERATION AND CLINICAL METAGENOMIC SEQUENCING

12:15 pm Chairperson's Remarks

Norman Moore, PhD, Director, Scientific Affairs, Abbott

12:40 Clinical Metagenomic Sequencing and Human Host Response: Changing the Diagnostic Paradigm?

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

Metagenomic next-generation sequencing (mNGS) is a transformative technology for infectious disease diagnosis as it enables detection of nearly all pathogens – viruses, bacteria, fungi, and parasites – in a single assay. Here we will discuss the integration of multiple approaches to enhance the clinical utility of body fluid mNGS, including nanopore sequencing, CRISPR-Cas12-based pathogen detection, complementary host response analyses, and simultaneous diagnosis of cancer.

12:20 FLASH: A Next-Generation CRISPR Diagnostic for Multiplexed Detection of Antimicrobial Resistance Sequences

Emily Crawford, PhD, Scientist II, Infectious Disease Initiative, Chan Zuckerberg Biohub

1:00 Metagenomic Next-Generation Sequencing to Detect & Predict Antimicrobial Resistance

Patricia Simner, PhD, D(ABMM), Associate Professor, Pathology; Director, Bacteriology, Division of Medical Microbiology, The Johns Hopkins University School of Medicine

Initial efforts for applying metagenomic next-generation sequencing (mNGS) for infectious disease diagnostics have focused on pathogen detection. However, we can also gain information on antimicrobial resistance markers, virulence factors or even host biomarkers associated with different disease states. In this presentation, we will discuss the challenges of using mNGS for detection of antimicrobial resistance genes to predict phenotypes and discuss the current status of mNGS for detection of antimicrobial resistance.

1:20 LIVE Q&A: Session Wrap-Up

Moderator: Norman Moore, PhD, Director, Scientific Affairs, Abbott

Panelists:

Emily Crawford, PhD, Scientist II, Infectious Disease Initiative, Chan Zuckerberg Biohub

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

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Robert Schlaberg, MD, PhD, MPH, Co-Founder, Chief Medical Officer, Medical & Scientific Affairs, IDbyDNA

1:35 Close of Summit

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