Connecting the Precision Medicine Community

29th International

Molecular & Precision Med TRI-CON

February 21-23, 2022
Hilton San Diego Bayfront
San Diego, CA

ATTEND
IN-PERSON & VIRTUALLY
FLEXIBLE REGISTRATION

Conference Programs

February 21-22

- Precision Health
- At Home & Point-of-Care Diagnostics
- Circulating Tumor Cells and Liquid Biopsy
- Spatial Biology & Single-Cell Analysis

February 22-23

- Diagnostics Innovation and Market Access
- Infectious Disease Diagnostics
- Precision Oncology
- Clinical Biomarkers & Companion Diagnostics

Featured & Keynote Speakers

Sir Mark Caulfield
CEO, Barts Life Sciences

Ruth March
SVP & Head, Precision Medicine, AstraZeneca

Steven Schachter
RADx Chief; Professor Harvard Medical School

Jessica L. Mega
Co-Founder & CSO, Verily

Lisa Suennen
Lead, Digital & Technology Group, Manatt Ventures

Robert C. Green
Director, G2P Program, Brigham and Women's Hospital

Esther Babady
Head, Clinical Microbiology, Memorial Sloan Kettering Cancer Center

Jeffrey Venstrom
Chief Medical Partner Cross Portfolio, Genentech

Megan Mahoney
Chief of Staff, Stanford Health Care

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Register Today

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- Clinical Biomarkers & Companion Diagnostics

> "The TRICON has most diverse group of attendees compared to any other conference with bench researchers to bedside practitioners."
>
> *Head of Innovation, Droice Labs*

TRI-CON 2022

Driving Innovation and Collaboration in Diagnostics and Precision Medicine

Over the past 28 years, the Tri-Conference has served as the leading international meeting place for the precision medicine community. As the world faces the challenges from the pandemic recovery, Cambridge Healthtech Institute once again takes the leadership role of bringing together the life science community at the TRI-CON 2022. Join thousands of international thought leaders —in-person and/or virtually— to discuss the latest research and technologies in precision medicine and precision health; innovation in point-of-care and molecular diagnostics and market access strategies; advanced diagnostics for COVID-19 and other infectious diseases; precision oncology diagnostics and therapeutics; liquid biopsy and minimal residual disease testing; biomarkers and companion diagnostics; and new technologies for spatial multi-omic analysis. Come to sunny San Diego for the in-person networking you've come to expect from the Tri-Conference; or join us virtually from the comfort of your home or office for online networking, the cutting-edge scientific program, and convenient on-demand viewing.

Our Best Shot — CHI's Mandatory COVID-19 Vaccination Policy

To ensure maximum safety, CHI has instituted a mandatory COVID-19 vaccination policy for all in-person participants across all our events. We feel it is our community duty to ensure CHI events are part of the COVID-19 solution to reopening safely. We are confident the scientific community, which developed the vaccine, will rally behind us on this first-of-its-kind policy. Read More

Our Code of Conduct

All in-person attendees must agree to CHI's Code of Conduct

Distinguished Speakers

Featured Presentations

February 22, 8:00 am

View Agenda

Big Data, Health and COVID-19

Michael Snyder, Chair, Department of Genetics, Stanford University

Precision Health

February 21, 1:35 pm

View Agenda

The CRISPR Platform for Diagnostics

Janice Chen, Co-Founder & CTO, Mammoth Biosciences

At Home & Point-of-Care Diagnostics

February 21, 8:00 am

View Agenda

Liquid Biopsies: A New Frontier

Razelle Kurzrock, Chair, Clinical Trials, Worldwide Innovative Network (WIN) for Personalized **Cancer Therapy**

Circulating Tumor Cells and Liquid Biopsy

February 21, 8:00 am

View Agenda

Using Spatial Approaches to Understand the Molecular Pathology of Alzheimer's Disease

Simon Gregory, Director, Molecular Genomics Core, Duke Molecular Physiology Institute

Spatial Biology & Single-Cell Analysis

February 22, 3:30 pm

View Agenda

Investing in Precision Medicine Diagnostics

Tom Miller, Founder and Managing Partner, GreyBird Ventures

Diagnostics Innovation and Market Access

February 22, 4:00 pm

View Agenda

SARS-CoV-2 Molecular Testing: From LDT to Variants Testing at a Cancer Hospital

Esther Babady, Head, Clinical Microbiology, Memorial Sloan Kettering Cancer Center

Infectious Disease Diagnostics

February 23, 10:25 am

View Agenda

Improving Precision Medicine by Studying Bladder Cancer with Single-Cell Omics

Dan Theodorescu, Director, Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai

Precision Oncology

February 22, 3:30 pm

View Agenda

Global Implementation of Companion Diagnostic Solutions: A Changing Landscape

Marielena Mata, Senior Director and Diagnostic Lead, Oncology Programs, Pfizer

Clinical Biomarkers & Companion Diagnostics

All times PST (Pacific Standard Time)

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Featured & Keynote Speakers

Molecular & Precision Med TRI-CON

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RADx Chief; Professor
Harvard Medical School

Lisa Suennen
Lead, Digital & Technology Group, Manatt Ventures

Sir Mark Caulfield
CEO, Barts Life Sciences

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Jeffrey Venstrom
Chief Medical Partner Cross Portfolio, Genentech

Simon Gregory
Director, Molecular Genomics Core
Duke Molecular Physiology Institute

Ruth March
Senior Vice President & Head, Precision Medicine, AstraZeneca

Howard I. Scher
Head, Biomarker Development, Memorial Sloan Kettering Cancer Center

Mara Aspinall
Managing Director, BlueStone Venture Partners

Tom Miller
Founder, Managing Partner
GreyBird Ventures

Lara Jehi
Chief Research Information Officer, Cleveland Clinic

Vincent Mikol
Head, Translational Sciences
Sanofi

Megan Mahoney
Chief of Staff, Stanford Health Care

Michael Snyder
Director, Genomics & Personalized Medicine
Stanford University

Esther Babady
Head, Clinical Microbiology, Memorial Sloan Kettering Cancer Center

Jürgen Scheuenpflug
Global Head, Biomarkers and Companion Diagnostics
Merck

Edward Abrahams
President
Personalized Medicine Coalition

Dan Theodorescu
Director, Cedars-Sinai Cancer Center

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Chair, Worldwide Innovative Network (WIN) for Personalized Cancer Therapy

Nathan D. Price
CSO, Thorne HealthTech

Shirin Khambata Ford
Global Head, Companion Diagnostics
Daiichi Sankyo

Adam Dakin
Partner, Healthtech, Dreamit Ventures

Pia Davidsson
Head, Experimental Medicine
AstraZeneca

John Quackenbush
Chair, Biostatistics, Harvard

Molecular & Precision Med TRI-CON

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Comprehensive sponsorship packages allow you to achieve your objectives before, during, and long after the event. Signing on earlier will allow you to maximize exposure to hard-to-reach decision-makers.

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Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations and deliver prospects, helping you to make the most out of this invaluable opportunity.

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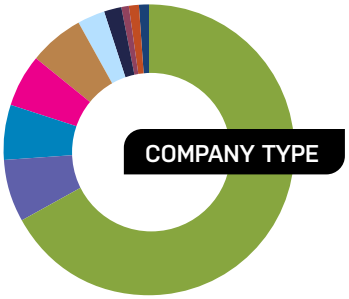
For additional information regarding sponsorship and exhibit opportunities, please contact:

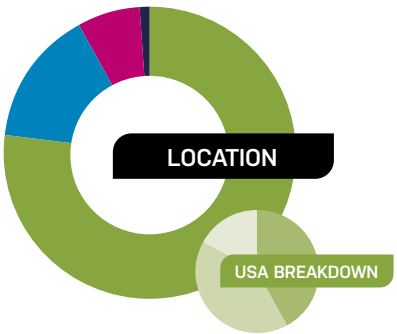
Jon Stroup
Senior Manager, Business Development
781-972-5483 jstroup@healthtech.com

2021

Attendee Demographics



67% Biotech & Pharma
7% Academic
6% Services
6% Healthcare
6% Healthcare Provider
3% Government
2% CRO
1% Financial
1% Press
1% Societies



77% USA
15% Europe
7% Asia
1% Rest of World

42% West Coast
41% East Coast
17% Midwest

37% Executive + Director
22% Sales & Marketing
21% Scientist/Technologist
11% Manager
6% Professor
2% Assistant

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Plenary Keynote Program

Hear from Precision Medicine Thought Leaders!

MONDAY, FEBRUARY 21

PLENARY KEYNOTE SESSION

PRECISION HEALTH: GENOMICS AND BEYOND

4:15 pm Chairperson's Remarks

Robert C. Green, MD, MPH, Professor and Director of G2P Program, Mass General Brigham, Broad Institute, Ariadne Labs and Harvard Medical School

4:20 Keynote Introduction

Stephen Williams, PhD, Chief Medical Officer, SomaLogic

Reliable outcomes prediction enables increased power in clinical trials and improved allocation of resources in clinical practice. The new discipline of using highly multiplexed measurements, machine learning and mixed study populations can lead to robust and generalized predictors of catastrophic and near-term risks. Key examples using SomaScan® proteomics for cardiovascular events, heart failure mortality and loss of kidney function will be shown.

4:30 Universal Newborn Sequencing and the Path to Preventive Genomics

Robert C. Green, MD, MPH, Professor and Director of G2P Program, Mass General Brigham, Broad Institute, Ariadne Labs and Harvard Medical School

> The TRI-CON is an industry-shaping event! Bringing together top researchers and business professionals to revolutionize global health!
>
> *Research Associate, Sysmex Corp.*

5:00 Transforming Genomic Healthcare in the United Kingdom

Sir Mark Caulfield, PhD, Professor & Director, Clinical Pharmacology, The William Harvey Research Institute, Queen Mary University of London; CEO, Barts Life Sciences

5:30 Precision Health: Closing the Information and Decision Gaps

Jessica L. Mega, MD, MPH, Co-Founder and Chief Medical & Scientific Officer, Verily; Adjunct Professor, Stanford University School of Medicine

6:00 Panel Discussion: Precision Health: Convergence of Genomics, Digital MedTech and Healthcare

Precision Health promises a much-needed shift from "sick-care" to "healthcare." Driven by innovations in genomics, medtech, and AI, precision health strategies can focus on prediction, prevention, and early detection for individualized health and wellness. The panel will discuss how genomics and digital health technologies can advance community-wide genetic screening and early disease detection, patient monitoring and preventative health strategies, personalized lifestyle and wellness approaches, and precision health equity.





Moderator:

Robert C. Green, MD, MPH, Professor and Director of G2P Program, Mass General Brigham, Broad Institute, Ariadne Labs and Harvard Medical School

Panelists:

Sir Mark Caulfield, PhD, Professor & Director, Clinical Pharmacology, The William Harvey Research Institute, Queen Mary University of London; CEO, Barts Life Sciences

Jessica L. Mega, MD, MPH, Co-Founder and Chief Medical & Scientific Officer, Verily; Adjunct Professor, Stanford University School of Medicine

Lara Jehi, MD, Chief Research Information Officer, Professor, Neurology, Cleveland Clinic

Megan Mahoney, MD, Clinical Professor, Primary Care & Population Health, Stanford University

6:30 Welcome Reception in the Exhibit Hall with Poster Viewing

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TUESDAY, FEBRUARY 22

PLENARY KEYNOTE SESSION

INNOVATION IN PRECISION MEDICINE: FROM DIAGNOSTICS TO DIGITAL HEALTH

1:00 pm Chairperson's Remarks
Lisa M. Suennen, Lead/Senior Managing Director, Digital & Technology Group, Manatt Phelps & Phillips LLP

1:05 Plenary Keynote Introduction *(Opportunity Available)*

1:15 Innovating Diagnostics to End a Pandemic: The RADx Tech Experience
Steven Schachter, MD, Professor, Neurology, Harvard Medical School; Chief Academic Officer and RADx Chief, CIMIT

1:45 Panel Discussion: Investing in Precision Medicine: Trends in Diagnostics, HealthTech and Digital Health

Precision Medicine is driven by the innovation continuum spanning genomics and diagnostics, MedTech and HealthTech, AI and Digital Health. The panel will explore investment opportunities and growth trends in the post-pandemic era, as well as the impact of precision medicine innovation on improving health outcomes and patient experience, managing healthcare costs, and advancing health equity.

Moderator:
Lisa M. Suennen, Lead/Senior Managing Director, Digital & Technology Group, Manatt Phelps & Phillips LLP
Panelists:
Tom Miller, Founder & Managing Partner, GreyBird Ventures, LLC
Mara Aspinall, Managing Director, BlueStone Venture Partners, LLC
Jenny Rooke, PhD, Managing Director, Genoa Ventures
Taha Jangda, Partner, HealthX Ventures
Michele Colucci, Co-Founder & Managing Partner, DigitalDx Ventures

WEDNESDAY, FEBRUARY 23

PLENARY KEYNOTE SESSION

PRECISION MEDICINE AT BIG PHARMA

7:55 am Chairperson's Remarks
Edward Abrahams, PhD, President, Personalized Medicine Coalition

8:00 Plenary Keynote Introduction *(Opportunity Available)*

8:10 Personalized Healthcare in Big Pharma: A Perspective
Jeffrey Venstrom, MD, Chief Medical Partner, Cross Portfolio, Genentech

8:40 Increasing Access to Precision Medicine – The Next Generation of Companion Diagnostics
Ruth E. March, PhD, Senior Vice President & Head, Precision Medicine & Biosamples, AstraZeneca

9:10 Panel Discussion: Implementing Precision Medicine at Big Pharma

Over the past decade, precision medicine promised to impact drug development by targeting the right medicine to the right patient. The panel of pharma thought leaders will discuss strategies to implement precision medicine in the drug discovery and development pipeline, including biomarker and companion diagnostic development, patient stratification, precision oncology advances, and emerging molecular tools for disease characterization.

Moderator:
Edward Abrahams, PhD, President, Personalized Medicine Coalition
Panelists:
Jeffrey Venstrom, MD, Chief Medical Partner, Cross Portfolio, Genentech
Maria C. M. Orr, PhD, Head, Precision Medicine, Biopharmaceuticals, AstraZeneca
Lourdes Barrera, PhD, Executive Director, Global Medical Affairs, Merck
Marielena Mata, PhD, Senior Director and Diagnostic Lead, Oncology Program, Pfizer
Shirin Khambata Ford, PhD, Global Head, Companion Diagnostics Daiichi Sankyo
Christopher Conn, PhD, Director, Companion Diagnostics, AbbVie
Andrea L. Stevens, PhD, Director, Companion Diagnostics Market Access, Global Precision Medicine Commercial Strategy, Janssen Pharmaceuticals, Inc.

MONDAY, FEBRUARY 21

7:00 am Registration Open and Morning Coffee (Indigo West Foyer AB)

ROOM LOCATION: Indigo 202 A

GENOMICS AND MOLECULAR PHENOTYPING FOR PRECISION HEALTH

7:55 Chairperson's Remarks
Erica F. Sanford Kobayashi, MD, Assistant Professor, Rady Children's Hospital San Diego

8:00 Precision Health Equity
Megan Mahoney, MD, Clinical Professor, Primary Care & Population Health, Stanford University
There is an unprecedented opportunity for healthcare to harness the power of new streams of patient monitoring and genetic data to tailor chronic disease management and cancer prevention for the unique patient in front of us. Precision health can be more effective, more responsive, and treats the whole person based on their unique factors.

8:30 Ultra-Rapid Whole Genome Sequencing in Critically Ill Children: Where We're at, Where We're Going, and How We Get There
Erica F. Sanford Kobayashi, MD, Assistant Professor, Rady Children's Hospital San Diego
There are currently more than 6,700 known single-locus disorders. Using phenotype-driven ultra-rapid whole genome sequencing (urWGS), it is possible to diagnose genetic disorders in as little as 13.5 hours, facilitating changes in clinical management from empiric therapy to disease-specific treatment and improving patient outcomes. urWGS diagnostic and clinical utility are well-established in neonatal and pediatric intensive care units, and next steps include scalability and widespread dissemination.

9:00 Population Genetic Screening: The Impact of the Sanford Chip Program
Kurt D. Christensen, PhD, Assistant Professor, Population Medicine, Harvard Pilgrim Health Care Institute
In 2018, Sanford Health began offering its primary care patients the Sanford Chip, a genetic test that provides pharmacogenomic profiling and optional screening for medically actionable predispositions. This talk summarizes data about the impact of the Sanford Chip program on healthcare providers and patients. Findings that will be discussed include the effectiveness of mandatory provider education efforts, the frequency of informative genetic findings, and early results about patient outcomes.

9:30 Session Break

INTERACTIVE DISCUSSIONS

9:45 Interactive Discussions (In-person only)
Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. For in-person events, the facilitator will lead from the front of the room while attendees remain seated to promote social distancing. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussion page on the conference website for a complete listing of topics and descriptions.

GENOMICS AND MOLECULAR PHENOTYPING FOR PRECISION HEALTH (CONT.)

10:15 Scientific Wellness and Deep Phenotyping to Enhance Human Health
Nathan D. Price, PhD, CSO, Thorne HealthTech
An increasing focus on wellness and prevention is key to dealing with chronic diseases that drive most health costs today. Enabling predictive and preventive approaches requires the generation of dense data on healthy people to quantify wellness states and to observe the earliest transitions to disease. I will discuss how such 'deep phenotyping' data is used to drive biological discovery and improve health.

10:45 High-Tech, High-Touch – Accelerating Population-Scale Genomics with Technology and Comprehensive Genomic Services
Erica Ramos, Vice President, Population Genomics, Genome Medical
Genomic medicine promises to help people understand and manage their health with individualized and actionable insights. An increasing number of health systems, biopharma companies, and others seek to build the programs needed to deliver on this promise, whether centered in research, clinical care or both. True end-to-end development, technology-enabled solutions, and scalable genetic services are required to deliver the right care to the right patient at the right time.

11:15 A Gene Expression Discovery Platform for Large-Scale Studies of Chronic Diseases
Guru Banavar, PhD, CTO & Head of Discovery AI, Viome Life Sciences
The interaction between the microbiome and the human host holds the key to the triggers and progression of many chronic diseases. By analyzing large host-microbiome gene expression datasets obtained from blood, stool, and saliva samples, we have discovered biomarkers and therapeutic targets for multiple chronic diseases and cancer, and translated them into clinical applications. We invite collaborators to leverage our platform to discover insights at this frontier of systems biology.

11:45 Enjoy Lunch on Your Own

1:20 pm Session Break

INNOVATION AND GROWTH OPPORTUNITIES IN PRECISION HEALTH

1:30 Chairperson's Remarks
Taha Jangda, Partner, HealthX Ventures

1:35 Precision Medicine Minefields - An Investor's Perspective
Adam Dakin, Partner, HealthTech, Dreamit Ventures

2:05 2022 Healthcare Investments and Exits Report
Milo Bissin, Director, Life Sciences and Healthcare, Silicon Valley Bank
What's driving innovation in healthcare? SVB provides unique insight into the ecosystem with its industry-leading reports featuring proprietary analysis and targeted outlooks informed by our deep relationships with top healthcare entrepreneurs and investors. Twice a year we publish deep-dive analysis of fundraising, investment and exit activity of private, venture-backed biopharma, healthtech, diagnostics/tools and device companies to help companies and investors achieve their goals.

2:35 Precision Medicine: New Categories and Implementation
Taha Jangda, Partner, HealthX Ventures
For the adoption of technologies to become tangible and real, we need to continue to evaluate them with great scientific vigor. Join the conversation to take a deep dive into the promise of precision medicine and how it can be best used in practice.

3:05 A Patient-Centric Model for Delivering Precision Oncology Care to All
Brian Leyland-Jones, MBBS, PhD, Dr., Parthen
Parthen offers precision oncology services to patients, their caregivers, and Primary Clinical Care Team. Using a patient-centered globally connected digital health platform, Parthen offers guidance on molecular testing, patient advocacy/navigation services and medication acquisition specialists to best support cancer patients and their families.

3:35 Session Break

KEYNOTE LOCATION: Indigo A

PLENARY KEYNOTE SESSION: PRECISION HEALTH: GENOMICS AND BEYOND

4:15 Chairperson's Remarks
Robert C. Green, MD, MPH, Professor and Director of Genomes2People Research, Mass General Brigham, Broad Institute, Ariadne Labs and Harvard Medical School

4:20 Keynote Introduction: Predicting Clinical Outcomes in Three Easy Steps
Stephen Williams, MD, PhD, CMO, SomaLogic
Reliable outcomes prediction enables increased power in clinical trials and improved allocation of resources in clinical practice. The new discipline of using highly multiplexed measurements, machine learning and mixed study populations can lead to robust and generalized predictors of catastrophic and near-term risks. Key examples using SomaScan® proteomics for cardiovascular events, heart failure mortality and loss of kidney function will be shown.

4:30 KEYNOTE PRESENTATION: Universal Newborn Sequencing and the Path to Preventive Genomics
Robert C. Green, MD, MPH, Professor and Director of Genomes2People Research, Mass General Brigham, Broad Institute, Ariadne Labs and Harvard Medical School
Twenty years after the completion of the Human Genome Project, population-scale genomic screening is being implemented. We recently completed the first randomized trial of comprehensive genome sequencing in healthy newborns (the NIH funded BabySeq Project). We present data from this and other studies to suggest that universal newborn sequencing may soon provide a platform for the lifelong use of genomics in risk stratification, disease mitigation and expanding longevity.

5:00 KEYNOTE PRESENTATION: Transforming Genomic Healthcare in the United Kingdom
Sir Mark Caulfield, PhD, Professor & Director, Clinical Pharmacology, The William Harvey Research Institute, Queen Mary University of London; CEO, Barts Life Sciences
The 100,000 Genomes Project focused on rare disease, cancer, and infection and demonstrated the potential of whole genomes to uplift diagnoses by 25% in rare disease, have a clinical utility for 25% of cancer patients, and discover 15 novel gene loci for severe COVID-19. Exploring of pharmacogenomics reveals many of us have genetic variants which if paired with a drug may cause harm.

5:30 KEYNOTE PRESENTATION: Precision Health: Closing the Information and Decision Gaps
Jessica L. Mega, MD, MPH, Co-Founder and Chief Medical & Scientific Officer, Verily; Adjunct Professor, Stanford University School of Medicine

6:00 Panel Discussion: Precision Health: Convergence of Genomics, Digital MedTech and Healthcare
Moderator: Robert C. Green, MD, MPH, Professor and Director of Genomes2People Research, Mass General Brigham, Broad Institute, Ariadne Labs and Harvard Medical School
Precision health promises a much-needed shift from "sick-care" to "healthcare." Driven by innovations in genomics, medtech, and AI, precision health strategies can focus on prediction, prevention, and early detection for individualized health and wellness. The panel will discuss how genomics and digital health technologies can advance community-wide genetic screening and early disease detection, patient monitoring and preventative health strategies, personalized lifestyle and wellness approaches, and precision health equity.
Panelists:
Sir Mark Caulfield, PhD, Professor & Director, Clinical Pharmacology, The William Harvey Research Institute, Queen Mary University of London; CEO, Barts Life Sciences
Jessica L. Mega, MD, MPH, Co-Founder and Chief Medical & Scientific Officer, Verily; Adjunct Professor, Stanford University School of Medicine
Lara Jehi, MD, Chief Research Information Officer, Professor, Neurology, Cleveland Clinic
Megan Mahoney, MD, Clinical Professor, Primary Care & Population Health, Stanford University

6:30 Welcome Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Day

TUESDAY, FEBRUARY 22

7:30 am Registration Open and Morning Coffee

ROOM LOCATION: Indigo 202 A

BIG DATA, AI AND DIGITAL MEDICINE AS DRIVERS OF PRECISION HEALTH

7:55 Chairperson's Remarks

Jay Pandit, MD, Director, Digital Medicine, Scripps Research Translational Institute; Adjunct Professor, Scripps Research; Assistant Professor, Division of Cardiology, Northwestern University Feinberg School of Medicine

8:00 Big Data, Health, and COVID-19

Michael Snyder, PhD, Stanford W. Ascherman Professor & Chair, Department of Genetics; Director, Center for Genomics & Personalized Medicine, Stanford University

Recent technological advances as well as longitudinal monitoring not only have the potential to improve the treatment of disease (precision medicine) but also empower people to stay healthy (precision health). We have been using advanced multiomics technologies as well as wearables for monitoring health in 109 individuals for up to 11 years and made numerous major health discoveries covering cardiovascular disease, oncology, metabolic health and infectious disease.

8:30 Accelerating Precision Medicine at a Health-System Level

Lara Jehi, MD, Chief Research Information Officer, Professor, Neurology, Cleveland Clinic

Accelerating precision medicine at a Health System level is the holy grail for patients and healthcare professionals alike. Several technical, regulatory, and cultural hurdles currently complicate the largescale implementation of data-driven individualized healthcare decisions and precision medicine approaches. This talk will review a vision for "learning from a million patients to better care for the one" through scalable biobanking and research information solutions in the Cleveland Clinic Health System.

9:00 Universal AI-based Whole Genome Sequencing Solution for Genetic Screening and Diagnosis

Jeanette McCarthy, MPH, PhD, Vice President, Precision Medicine, Fabric Genomics

Diagnostic sequencing for rare disease using whole genome is becoming a routine part of care for critically ill newborns as well as children with undiagnosed diseases, enabled by Fabric Genomics GEM AI technology. This technology is now being leveraged for identifying disease-causing variants among ostensibly healthy individuals in the screening setting. Potential applications, including genome-wide newborn screening, carrier testing and adult hereditary risk profiling, will be discussed.

9:30 Coffee Break in the Exhibit Hall with Poster Viewing

10:10 The Future of Health Data and Precision Medicine

Ardy Arianpour, CEO & Co-Founder, Seqster

High fidelity, high-quality Real World Data can be obtained by placing the patient at the center, breaking down data silos to obtain comprehensive, longitudinal health data. Such data is critical for Precision Medicine as well as for clinical studies leading to the discovery of novel cures. Health Data is Medicine.

10:40 Person-Generated Health Data (PGHD): Applications in Research, Healthcare, and Public Health

Luca Foschini, PhD, Co-Founder & Chief Data Scientist, Evidation Health Inc.

Dr. Foschini will give examples of applications of Person-Generated Health Data (PGHD) across therapeutic areas, including post-op monitoring, screening for cognitive impairment, and COVID-19 detection and quantification. Finally, Dr. Foschini will discuss lessons learned in translating PGHD research into benefit for the individuals, and how good analytic performance is a necessary but not at all sufficient condition to engender the trust that clinical investigators, doctors, regulators, and ultimately individuals seek.

11:10 Democratizing Digital Trials: The First Step in Personalizing the Practice of Digital Medicine

Jay Pandit, MD, Director, Digital Medicine, Scripps Research Translational Institute; Adjunct Professor, Scripps Research; Assistant Professor, Division of Cardiology, Northwestern University Feinberg School of Medicine

In an era of smart devices and sensors, we now have the ability to finally understand our patient's physiology beyond the snapshots we get in the clinic. However, many clinical studies continues to rely on the bottleneck of referrals through clinic visits. In this talk we will discuss the major digital clinical studies, the promises and challenges of digital clinical trials and some future directions.

11:40 Session Break

11:50 Enjoy Lunch on Your Own

12:20 pm Refreshment Break in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)

1:00 Close of Precision Health Conference

MONDAY, FEBRUARY 21

7:00 am Registration Open and Morning Coffee (Indigo West Foyer AB)

ROOM LOCATION: Indigo A

ADVANCES IN AT-HOME AND POINT-OF-USE TESTING

7:55 Chairperson's Remarks

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

8:00 Personalized POCT: Opportunities and Risks of At-Home Diagnostics

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

Patients are more engaged in their health. POCT allows patients access to laboratory testing in the privacy of their homes, but patients may not understand test limitations and misinterpret results. This presentation will review the advantages and limitations of home testing, explore the ways that patients are accessing POCT, and provide opportunities for new models of POCT delivery that can ensure quality of test results as well as professional interpretation.

8:30 At-Home Point-of-Care Testing: How Clinical Laboratory Professionals Can Assist

Hoi-Ying Elsie Yu, PhD, System and Core Laboratory Director, Chemistry, Toxicology and Point-of-Care Testing, Geisinger Health System

In recent years, there has been an expansion of at-home testing well beyond just pregnancy or glucose meter tests – for example, "23 and Me," "Ancestry.com," and COVID tests. Many of these tests are cheaper and more convenient than testing at a licensed clinical laboratory. In this presentation, the roles of clinical laboratory professionals are being redefined to promote public health safety and improve patient care management using at-home tests.

9:00 "That's What I Want…": Exploring Pandemic-Era Voice of the Customer (VoC) Trends in Community Pharmacy

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

The COVID-19 pandemic has accelerated the pace at which point-of-care (POC) testing is being adopted in the community pharmacy setting. Increasing numbers of community pharmacies are interested in developing their POC test and treat programs, including large pharmacy chains, as the US increasingly looks to this setting as a public health destination. After two years of the pandemic, the question is not if community pharmacy will adopt, but how.

9:30 Session Break

INTERACTIVE DISCUSSIONS

9:45 Interactive Discussions (In-person only)

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

AT-HOME AND POINT-OF-USE TESTING: COVID-19 AND BEYOND

10:15 Home COVID-19 Testing: Strategies for Measurements that Are Fit for Purpose

Robert H. Christenson, PhD, Director, Clinical Chemistry Labs & Professor, Pathology & Medical & Research Technology, University of Maryland, Baltimore

Home COVID-19 testing is beneficial to public health by improving testing and treatment access, easing overcrowding at healthcare venues, and reducing risk of transmission. Effective home testing devices must fit the intended purpose with facile specimen collection with straightforward instructions for use and interpretation aimed at comprehension and performance by non-technical individuals with limited literate skills. This session will specify and discuss characteristics for successful home use in diverse communities.

10:45 Development of a Home Testing System for Respiratory Pathogens Infections and Other Medical Conditions

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

We have been developing two-dimensional porous networks for ultra-low-cost point-of-care disease detection and management; readout is by optical imaging. The COVID-19 pandemic and the restriction of people to their homes has opened up new markets for a full range of rapid home testing. We are now developing rapid multiplexed nucleic acid testing a home for a panel of respiratory pathogens under support of WRF and the Emergent Ventures fund.

11:15 The Comprehensive COVID-19 Test

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

Non-invasive diagnostics are urgently needed to address supply-chain and logistical deficiencies in the current COVID-19 testing environment. We developed quantitative multiplex assays that can assess SARS-CoV-2 gRNA (N2 and NL) (LOD: 6.25 copy number per reaction), Antigen (N) (3.5 TCID50), and Antibody (IgG RBD) (LOD: 30pg/ml) non-invasively in a sample of saliva with performance that surpasses current EUA assays, with TAT in 1.5 hours, deployable at the population level.

11:45 The Future of Point-of-Care Testing: COVID-19 and Beyond

qorvo BIOTECHNOLOGIES

Bryan Bothwell, Senior Director of Strategy and Business Development, Qorvo Biotechnologies

COVID-19 has stressed worldwide demand for POC testing. Companies have had to innovate and develop at a rapid pace to meet pandemic demands. This presentation will discuss how Qorvo Biotechnologies has developed a breakthrough platform to address todays COVID-19 testing needs, and highlight what that differentiation means clinically. It will also show what investments have done to position for future success beyond COVID.

12:15 pm Session Break

12:20 LUNCHEON PRESENTATION: Co-Diagnostics New Eikon PCR Platform
Dwight Egan, CEO, Co-Diagnostics, Inc.
Co-Diagnostics New Eikon Platform provides inexpensive, fast, and accurate PCR Results for At-Home and Point-of-Care Testing.

12:50 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:20 Session Break

EMERGING TECHNOLOGIES FOR RAPID DETECTION AT THE POINT-OF-CARE

1:30 Chairperson's Remarks
Hoi-Ying Elsie Yu, PhD, System and Core Laboratory Director, Chemistry, Toxicology and Point-of-Care Testing, Geisinger Health System

1:35 Next-Generation CRISPR Products
Janice Chen, PhD, Co-Founder & CTO, Mammoth Biosciences
The programmable nature of sequence-specific targeting by CRISPR-Cas nucleases has revolutionized a wide range of genomic applications and is now emerging as a new method for nucleic acid detection. This talk will touch on the therapeutics capabilities of Mammoth's CRISPR platform, and then focus on current efforts and future potential for CRISPR-based detection and its impact across a continuum of diagnostic applications, particularly as it relates to the COVID-19 pandemic.

2:05 LAMP & Isothermal Nucleic Acid Amplification: Ready for Prime Time?
Robert Meagher, PhD, Staff Scientist, Biotechnology & Bioengineering, Sandia National Labs
The COVID-19 pandemic brought new popularity and a new user base for isothermal nucleic acid amplifications, especially LAMP. We will survey recent developments in the field such as widespread adoption of closed-tube endpoint monitoring. We will identify knowledge gaps in the fundamental understanding of isothermal amplification methods, and we will discuss some of our own group's research efforts toward making LAMP more robust and ready to adopt for future emergencies.

2:35 Instrument-Free Molecular Diagnostic Test of SARS-CoV-2 at the Point-of-Care
Changchun Liu, PhD, Associate Professor, Biomedical Engineering, University of Connecticut, Farmington
Rapid and early detection of the novel coronavirus SARS-CoV-2, the causative agent of the COVID-19, plays a crucial role in reducing transmission of the virus and facilitating early intervention and treatment. In this talk, I will present our All-In-One Dual CRISPR-Cas12a (AIOD-CRISPR) technology for SARS-CoV-2 testing. I will introduce our low-cost diagnostic devices and detection platforms, enabling simple, affordable, instrument-free molecular diagnostics of SARS-CoV-2 at the point of care.

3:05 Towards rapid and scalable antimicrobial susceptibility testing
Ryan McGuinness, Global Head, In Vitro Technologies/Commercial GM, Triple Ring Technologies

3:20 Sponsored Presentation *(Opportunity Available)*

3:35 Session Break

KEYNOTE LOCATION: Indigo A

PLENARY KEYNOTE SESSION: PRECISION HEALTH: GENOMICS AND BEYOND

4:15 Chairperson's Remarks
Robert C. Green, MD, MPH, Professor and Director of Genomes2People Research, Mass General Brigham, Broad Institute, Ariadne Labs and Harvard Medical School

4:20 Keynote Introduction: Predicting Clinical Outcomes in Three Easy Steps
Stephen Williams, MD, PhD, CMO, SomaLogic
Reliable outcomes prediction enables increased power in clinical trials and improved allocation of resources in clinical practice. The new discipline of using highly multiplexed measurements, machine learning and mixed study populations can lead to robust and generalized predictors of catastrophic and near-term risks. Key examples using SomaScan® proteomics for cardiovascular events, heart failure mortality and loss of kidney function will be shown.

4:30 KEYNOTE PRESENTATION: Universal Newborn Sequencing and the Path to Preventive Genomics
Robert C. Green, MD, MPH, Professor and Director of Genomes2People Research, Mass General Brigham, Broad Institute, Ariadne Labs and Harvard Medical School
Twenty years after the completion of the Human Genome Project, population-scale genomic screening is being implemented. We recently completed the first randomized trial of comprehensive genome sequencing in healthy newborns (the NIH funded BabySeq Project). We present data from this and other studies to suggest that universal newborn sequencing may soon provide a platform for the lifelong use of genomics in risk stratification, disease mitigation and expanding longevity.

5:00 KEYNOTE PRESENTATION: Transforming Genomic Healthcare in the United Kingdom
Sir Mark Caulfield, PhD, Professor & Director, Clinical Pharmacology, The William Harvey Research Institute, Queen Mary University of London; CEO, Barts Life Sciences

The 100,000 Genomes Project focused on rare disease, cancer, and infection and demonstrated the potential of whole genomes to uplift diagnoses by 25% in rare disease, have a clinical utility for 25% of cancer patients, and discover 15 novel gene loci for severe COVID-19. Exploring of pharmacogenomics reveals many of us have genetic variants which if paired with a drug may cause harm.

5:30 KEYNOTE PRESENTATION: Precision Health: Closing the Information and Decision Gaps
Jessica L. Mega, MD, MPH, Co-Founder and Chief Medical & Scientific Officer, Verily; Adjunct Professor, Stanford University School of Medicine

6:00 Panel Discussion: Precision Health: Convergence of Genomics, Digital MedTech and Healthcare
Moderator: Robert C. Green, MD, MPH, Professor and Director of Genomes2People Research, Mass General Brigham, Broad Institute, Ariadne Labs and Harvard Medical School
Precision health promises a much-needed shift from "sick-care" to "healthcare." Driven by innovations in genomics, medtech, and AI, precision health strategies can focus on prediction, prevention, and early detection for individualized health and wellness. The panel will discuss how genomics and digital health technologies can advance community-wide genetic screening and early disease detection, patient monitoring and preventative health strategies, personalized lifestyle and wellness approaches, and precision health equity.
Panelists:
Sir Mark Caulfield, PhD, Professor & Director, Clinical Pharmacology, The William Harvey Research Institute, Queen Mary University of London; CEO, Barts Life Sciences
Jessica L. Mega, MD, MPH, Co-Founder and Chief Medical & Scientific Officer, Verily; Adjunct Professor, Stanford University School of Medicine
Lara Jehi, MD, Chief Research Information Officer, Professor, Neurology, Cleveland Clinic
Megan Mahoney, MD, Clinical Professor, Primary Care & Population Health, Stanford University

6:30 Welcome Reception in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)

7:30 Close of Day

TUESDAY, FEBRUARY 22

7:30 am Registration Open and Morning Coffee (Indigo West Foyer AB)

ROOM LOCATION: Indigo A

INFECTIOUS DISEASE POINT-OF-CARE TESTING: LESSONS FROM THE PANDEMIC

7:55 Chairperson's Remarks
Larissa May, MD, MSPH, MSHS, Professor, Emergency Medicine; Director, ED Antibiotic Stewardship; Medical Director, Learning Health System Hub, UC Davis Health

8:00 Point-of-Care Testing for COVID-19: Opportunities and Challenges
Julie Shaw, PhD, Clinical Biochemist & Director for POCT, EORLA, Ottawa Hospital
Point-of-care rapid molecular and antigen detection tests for COVID-19 were developed quickly during the second wave of the pandemic. Here, I will discuss our experiences with quickly verifying and validating the performance of these tests, while also developing and supporting quality assurance programs suitable for testing in non-traditional environments, performed by diverse groups of individuals.

8:30 Point-of-Care Diagnostics in the Emergency Department: Current Use and Future Directions
Larissa May, MD, MSPH, MSHS, Professor, Emergency Medicine; Director, ED Antibiotic Stewardship; Medical Director, Learning Health System Hub, UC Davis Health
This presentation will highlight current and emerging trends in rapid and point-of-care diagnostic testing for infectious diseases. Gaps in current diagnostics for infectious diseases and future directions for research and development will be discussed using specific use cases. This presentation will cover diagnostics for respiratory infections, emerging diagnostics for sepsis, and diagnostic needs for urinary tract symptoms. Point-of-care testing for SARS-CoV-2 will be included.

9:00 Latest Advances in MDx Chemistries to Accelerate Assay Development
Florent Chang-Pi-Hin, Ph.D., Vice President, Research and Development Life Science, Meridian Bioscience
Direct amplification in molecular assays is desired due to its speed, ease of use, and avoidance of extraction reagents. However, clinical specimens contain a wide range of inhibitors that can hinder both the accuracy and sensitivity of an assay. In this session, you will learn about Meridian's latest technologies which are the newest solution for overcoming PCR inhibition and provide a fast-track method for developing room-temperature stable assays for POC applications.

9:30 Coffee Break in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)

10:10 Wows and Woes of Molecular Testing for COVID
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
Laboratory detection of SARS-CoV-2 using nucleic acid amplification technologies is considered the gold standard with maximum sensitivity and specificity compared to other testing modalities. Innovation and development of SARS-CoV-2 molecular assays were high throughout the pandemic, offering much successes. Yet there are challenges that are important to recognize including inclusivity of testing and lingering detection. This session will explore these successes of molecular testing but also the challenges.

10:40 Community-Based Testing for Respiratory Pathogens
Michael E. Klepser, PharmD, FCCP, FIDP, Professor, Ferris State University College of Pharmacy
COVID-19 demonstrated the value of offering CLIA-waived point-of-care tests in non-traditional settings. Additionally, the need to promote frequent, sequential testing with rapid receipt of results opened the door for new models for home-based testing. As we move forward, the value of

such testing strategies for pathogens other than SARS-CoV-2 have been recognized. This presentation will examine future of community/home-based testing for various respiratory pathogens.

11:10 Does Outsourcing Point-of-Care Diagnostics Design, Development, and Manufacturing Make Sense? A Breakeven Analysis

James Downs, Global Business Development, Schott Minifab

If one thing is clear as we roll into 2022, it is that IVD point of care medical diagnostics have taken on new importance in global healthcare. However, designing, developing and manufacturing these complex lab-on-a-chip systems in a rapid and commercially viable manner remains challenging. This presentation will examine these challenges and explore which key decision-making factors are important when considering an in-house effort vs outsourcing to a partner.

11:25 Sponsored Presentation *(Opportunity Available)*

11:40 Session Break

11:50 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:20 pm Refreshment Break in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)

1:00 Close of At-Home & Point-of-Care Diagnostics Conference

> "The Tri-Conference captured the key topics of the moment combined with a very diverse set of attendees."
>
> *CCO, OmniSeq*

MONDAY, FEBRUARY 21

7:00 am Registration Open and Morning Coffee (Indigo West Foyer AB)

ROOM LOCATION: Indigo 202 B

LIQUID BIOPSY FOR EARLY DETECTION AND PATIENT SCREENING

7:55 Chairperson's Remarks
Dave S.B. Hoon, PhD, Director, Translational Molecular Medicine and Genome Sequencing, Saint John's Cancer Institute

8:00 Liquid Biopsy – From Discovery to Clinical Implementation
Klaus Pantel, PhD, Professor, Medicine & Director & Chairman, Institute of Tumor Biology, University Hospital Hamburg, Eppendorf
The molecular analysis of circulating tumor cells and cell-free tumor DNA in blood can provide clinically relevant information as "liquid biopsy," which provides information on tumor biology, early detection of cancer, identification of cancer patients at risk to develop relapse, and monitoring tumor evolution, therapeutic targets or mechanisms of resistance. Technical standardization and clinical validation of liquid biopsy assays are essential and currently performed by the Cancer-ID/European Liquid Biopsy Society.

8:30 Large Cancer Fingerprint Screening for Detection of Minimal Residual Disease
Viktor A. Adalsteinsson, PhD, Associate Director, Gerstner Center for Cancer Diagnostics, Broad Institute of MIT and Harvard
Liquid biopsies could enable cancer treatment response monitoring including the detection of minimal residual disease. I will describe our team's efforts to increase the sensitivity of liquid biopsies to detect low parts-per-million levels of circulating tumor DNA from blood. My talk will include new genomic technologies as well as their application to small clinical studies.

9:00 Genome-Wide cfDNA Fragmentation in Patients with Cancer
Nicholas C. Dracopoli, PhD, CSO, Delfi Diagnostics
Cell-free DNA (cfDNA) consists of small nucleic acid fragments entering the bloodstream during apoptosis or necrosis. cfDNA fragmentation patterns detected by low-coverage whole genome sequencing can be used to detect the presence of circulating tumor DNA (ctDNA) in a background of cfDNA mostly derived from hematologic cells. This presentation will describe the development of a blood-based, whole-genome, next-generation sequencing (NGS) test to detect early stages of cancer.

9:30 Session Break

INTERACTIVE DISCUSSIONS

9:45 Interactive Discussions (In-person only)
Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. For in-person events, the facilitator will lead from the front of the room while attendees remain seated to promote social distancing. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussion page on the conference website for a complete listing of topics and descriptions.

LIQUID BIOPSY FOR TUMOR MOLECULAR CHARACTERIZATION

10:15 Comprehensive Cancer Profiling with a Next-Generation Liquid Biopsy
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
Liquid biopsy offers the ability to assess a cancer patient's tumor without a costly and invasive tissue biopsy. The Comprehensive Cancer Profiling with a Next-Generation Liquid Biopsy combines CTC analysis, single-cell genomics, and ctDNA sequencing to empower the characterization of the tumor. This talk will present the capabilities to clinical and translational research and how the next-generation liquid biopsy approach promises to revolutionize the development of future diagnostics.

10:45 Clinical Considerations for ctDNA across the Continuum of Cancer
Minetta C. Liu, MD, Professor & Research Chair, Oncology & Consultant, Lab Medicine & Pathology, Mayo Clinic & Foundation
Real-time identification of tumor-specific molecular alterations is the essence of precision oncology. Technologic advances allow for the detection of mutations, rearrangements, insertions/deletions, copy number alterations, and methylation patterns from peripheral blood DNA with increasing sensitivity. These "liquid biopsies" offer a less invasive, potentially more cost-effective tool to assess prognosis, treatment response, early diagnosis of recurrence, and multicancer early detection. Solutions to promote rapid translation into clinical practice are needed.

11:15 Multiplex Gene Expression Profiling of Circulating Tumor Cells Identifies Treatment-Resistant Prostate Cancer
Joshua M. Lang, MD, Associate Professor, Hematology & Oncology, University of Wisconsin, Madison

11:45 New Enzymatic Tool for Nucleic Acid Applications
Brandon Young, Chief Science Officer, simplSEQ, Inc.
Enzymatic tailing of nucleic acids can revolutionize standard molecular biology tools. Dramatic improvements in the areas of isolation, purification, and sample preparation will lead to further advances in multi-omics analyses.

12:15 pm Session Break

12:20 LUNCHEON PRESENTATION: An Integrated BioView-CapioCyte Platform for Effective Capture of Circulating Tumor Cells

Seungpyo Hong, Professor of Pharmaceutical Sciences, Pharmaceutical Sciences and Biomedical Engineering, Capio

Introducing a biomimetic approach utilizing cell rolling and adhesion characteristics combined with nanotechnology to enable clinically significant detection and post-capture analysis of circulating tumor cells (CTCs). Join us as we present the integrated BioView-CapioCyte platform featuring a fully automated and standardized CTC enrichment tool with labeling and detection functions for clinical practice

12:50 LUNCHEON PRESENTATION: Liquid Biopsy and Oncocatch

Min-Seob Lee, PhD, CEO, EDGC

An overall information session on the current development of Liquid Biopsy and EDGC's LB service 'Oncocatch'

1:20 Session Break

LIQUID BIOPSY BIOMARKERS FOR DRUG DEVELOPMENT

1:30 Chairperson's Remarks

Dave S.B. Hoon, PhD, Director, Translational Molecular Medicine and Genome Sequencing, Saint John's Cancer Institute

1:35 Metastasis-Initiator Circulating Tumor Cells: One of the Keys to Understand the Biology of the Metastatic Cascade

Catherine Alix-Panabières, PhD, Associate Professor and Director, Laboratory of Rare Human Circulating Cells (LCCRH), University Medical Center of Montpellier, France

The emergence of immunotherapy in oncology requires the validation and adoption of robust, sensitive and specific predictive and prognostic biomarkers for daily practice. The use of liquid biopsy could provide an important complementary or alternative added value to PD-L1 detection in tissue biopsy. In my talk, I discuss how liquid biopsy could be used in the field of immuno-oncology to predict response or relapse for patients undergoing immune-checkpoint inhibitor therapy.

2:05 Analytes in Liquid Biopsies as Oncologic Biomarkers for Early Detection and Drug Development

Gary J. Kelloff, MD, Special Advisor, Cancer Imaging Program, National Cancer Institute, NIH

Liquid biopsies are sources of response biomarkers to measure drug efficacy and monitor patient treatment (including detection of emerging resistance and MRD). Continually developing/improving technologies include CTCs, ctDNA, exosomes, epigenetics, nucleic acid fragments, and micro-RNAs. Analytical validation of the assays is essential and access to large datasets with clinical outcomes and analytics will determine future use. Liquid biopsy-based multi-cancer early detection assays are a recent promising development.

2:35 1q21 Region Amplification as a Prognostic cfDNA Plasma Biomarker for Melanoma Patients on Immune Checkpoint Inhibitor Therapy

Dave S.B. Hoon, PhD, Director, Translational Molecular Medicine and Genome Sequencing, Saint John's Cancer Institute

1q21.3 amplification frequently occurs in metastatic melanoma. We determined the utility of 1q21.3 amplification detection of cfDNA to monitor inhibitor checkpoint immunotherapy (ICI) response in metastatic melanoma patients. CfDNA 1q21.3 amplification was analyzed in plasma by multiplex ddPCR from 50 patients receiving ICI. CfDNA from patients who had progressive disease had a higher frequency of 1q21.3 amplification. The specific genes in the 1q21.3 region represent prognostic biomarkers in melanoma patients.

3:05 MRE-Seq-Based Cancer Screening by Deep Learning Analysis of cfDNA Methylation Pattern

Hyukjung Kwon, PhD, Director, AI Big Data, EDGC

The methylation pattern of plasma circulating-tumor DNA(ctDNA) is the most plentiful indicator of cancer types. The underlying pattern of cancer genomes is global hypomethylation at the intergenic region. This presentation will describe various methods for cfDNA methylation patterns analysis. In particular, we would like to share the results of applying MRE(Methylation-sensitive Restriction Enzyme)-seq, enriching and analyzing the de-methylated regions of cfDNA, and the possibility of using it for multi-cancer early detection.

3:20 Challenges in Validating a Diagnostic cfDNA NGS Assay

Florian Battke, PhD, Director of Development, CeGaT GmbH

In recent years, analyses starting from formalin-fixed or fresh frozen tumor tissue samples were complemented by analyses starting from cell-free DNA extracted from patient blood plasma obtained in "liquid biopsies", requiring validation with a well-defined control standard. In this talk we will cover the difficulties labs face when trying to establish such standards on their own, share our experience with a publicly available standard, present validation results and discuss some caveats.

3:35 Session Break

KEYNOTE LOCATION: Indigo A

PLENARY KEYNOTE SESSION: PRECISION HEALTH: GENOMICS AND BEYOND

4:15 Chairperson's Remarks

Robert C. Green, MD, MPH, Professor and Director of Genomes2People Research, Mass General Brigham, Broad Institute, Ariadne Labs and Harvard Medical School

4:20 Keynote Introduction: Predicting Clinical Outcomes in Three Easy Steps

Stephen Williams, MD, PhD, CMO, SomaLogic

Reliable outcomes prediction enables increased power in clinical trials and improved allocation of resources in clinical practice. The new discipline of using highly multiplexed measurements, machine learning and mixed study populations can lead to robust and generalized predictors of catastrophic and near-term risks. Key examples using SomaScan® proteomics for cardiovascular events, heart failure mortality and loss of kidney function will be shown.

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5:30 KEYNOTE PRESENTATION: Precision Health: Closing the Information and Decision Gaps

Jessica L. Mega, MD, MPH, Co-Founder and Chief Medical & Scientific Officer, Verily; Adjunct Professor, Stanford University School of Medicine

6:00 Panel Discussion: Precision Health: Convergence of Genomics, Digital MedTech and Healthcare

Moderator: Robert C. Green, MD, MPH, Professor and Director of Genomes2People Research, Mass General Brigham, Broad Institute, Ariadne Labs and Harvard Medical School

Precision health promises a much-needed shift from "sick-care" to "healthcare." Driven by innovations in genomics, medtech, and AI, precision health strategies can focus on prediction, prevention, and early detection for individualized health and wellness. The panel will discuss how genomics and digital health technologies can advance community-wide genetic screening and early disease detection, patient monitoring and preventative health strategies, personalized lifestyle and wellness approaches, and precision health equity.

Panelists:

Sir Mark Caulfield, PhD, Professor & Director, Clinical Pharmacology, The William Harvey Research Institute, Queen Mary University of London; CEO, Barts Life Sciences

Jessica L. Mega, MD, MPH, Co-Founder and Chief Medical & Scientific Officer, Verily; Adjunct Professor, Stanford University School of Medicine

Lara Jehi, MD, Chief Research Information Officer, Professor, Neurology, Cleveland Clinic

Megan Mahoney, MD, Clinical Professor, Primary Care & Population Health, Stanford University

6:30 Welcome Reception in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)

7:30 Close of Day

TUESDAY, FEBRUARY 22

7:30 am Registration Open and Morning Coffee (Indigo West Foyer AB)

ROOM LOCATION: Indigo 202 B

LIQUID BIOPSY BIOMARKER DISCOVERY AND ASSAY DEVELOPMENT

7:55 Chairperson's Remarks

John Nolan, PhD, Professor, The Scintillon Institute

8:00 Single Vesicle Analysis of EV Heterogeneity: A Window on Tumor Heterogeneity

John Nolan, PhD, Professor, The Scintillon Institute

Extracellular vesicles (EVs) released by tumor cells carry molecular cargo from their cells of origin, making them attractive targets for liquid biopsy development. However, EVs are small and heterogeneous, making them difficult to measure reliably. High-resolution single vesicle flow cytometry (vFC) can directly count, size, and measure the cargo of individual EVs, enabling the identification of EV sub-types that can be targeted as part of liquid biopsy development.

8:30 BloodPAC Consortium: Defining Liquid Biopsy Standards to Accelerate Development, Approval & Accessibility

Lauren Leiman, Executive Director, BloodPAC

BloodPAC is a public-private consortium developing standards and best practice while operating a data commons to support the liquid biopsy community. Over 50 members collaboratively work to accelerate the development, validation and clinical use of liquid biopsy assays to better inform medical decisions and improve cancer patient care and outcomes. Let's discuss how BloodPAC enables sharing of information between stakeholders in public, industry, academia and regulatory agencies to accelerate progress.

9:00 Circulating Tumor Cell Transcriptomics as Biopsy Surrogates in Metastatic Breast Cancer

ANGLE

Julie E. Lang, M.D., FACS, Chief of Breast Surgery, Co-Leader of the Breast Cancer Program, Division of Breast Services, General Surgery, Cancer Biology, Cleveland Clinic, Lerner Research Institute

9:30 Coffee Break in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)

10:10 Liquid Biopsies: A New Frontier

Razelle Kurzrock, MD, CMO, Chair, Clinical Trials Committee, Worldwide Innovative Network (WIN) for Personalized Cancer Therapy

Gene/immune-directed therapies are most effective in cancer subgroups harboring their cognate target. Critical advances in molecular testing involve liquid biopsies, wherein circulating tumor DNA (ctDNA)/circulating tumor cells (CTCs) are analyzed. Liquid biopsies are generally blood based,

but can derive from ascites, cerebrospinal fluid, etc. A small tube of blood is exploitable for early cancer diagnosis, identifying molecular abnormalities in shed DNA from multiple metastases, and for monitoring post-treatment changes.

10:40 Novel Technologies for Mutation Enrichment and Biomarker Identification in Liquid Biopsies

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 that enable the ever-increasing range of applications. We present new technologies allowing highly parallel, PCR-free elimination of wild-type alleles, boosting the ability of all downstream detection methods for detecting point mutations in liquid biopsies and clinical samples. Developments boosting the detection of microsatellite mutations will also be described.

11:10 Protease Biomarkers for Liquid Biopsy Companion Diagnostics

Michael J. Heller, PhD, Professor Emeritus/Recall, University of California, San Diego

11:40 Session Break

11:50 LUNCHEON PRESENTATION: A Novel CSF Assay to Help Diagnose, Manage, and Follow Response to Therapy in Patients with Leptomeningeal Metastasis

Biocept

Michael Dugan, MD, Senior Vice President, CMO & Medical Director, Biocept, Inc.

CNSide™ by Biocept, Inc. is a novel diagnostic assay using enhanced CSF tumor cell recovery, cell labeling, and digital imagery to provide a more accurate, quantitative tumor cell count and molecular characterization of these cells (such as HER2 amplification in breast cancer) to better manage patients with brain metastasis. Microfluidic cell capture, immunochemistry, FISH, PCR, and NGS of cell-free DNA can be combined. Dr. Dugan will feature several case studies illustrating how the assay has helped manage patients suffering from leptomeningeal disease (LM).

12:20 pm Refreshment Break in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)

1:00 Close of Circulating Tumor Cells and Liquid Biopsy Conference

MONDAY, FEBRUARY 21

7:00 am Registration Open and Morning Coffee (Indigo West Foyer AB)

ROOM LOCATION: Indigo 206

SPATIAL ANALYSIS FOR PRECISION MEDICINE AND DISEASE BIOLOGY

7:55 Chairperson's Remarks

Daniel T. Chiu, PhD, A. Bruce Montgomery Professor of Chemistry; Endowed Professor in Analytical Chemistry; Professor of Bioengineering, University of Washington

8:00 Using Spatial Approaches to Understand the Molecular Pathology of Alzheimer's Disease

Simon Gregory, PhD, Professor, Neurology and Vice Chair of Research, Duke University; Director, Molecular Genomics Core, Duke Molecular Physiology Institute

Differences in Alzheimer's disease (AD) susceptibility are observed between brain regions as they accumulate disease related pathology. We have used spatial transcriptome and *in situ* sequencing to characterize amyloid plaque-related and grey matter expression changes from multiple tissues from a single AD individual. Our spatial approach is providing insight into the mechanisms of AD development and may guide future therapeutic strategies aimed at preventing disease progression.

8:30 Multiplex Immunohistochemistry/Immunofluorescence Techniques in the Era of Cancer Immunotherapy

Edwin R. Parra Cuentas, PhD, Assistant Professor, Translational Molecular Pathology, MD Anderson Cancer Center

As the field of cancer immunotherapy advances and new therapeutics are developed, there has been much emphasis on understanding tumor-specific aspects of a patient's individualized disease, and subsequently targeting specific biomarkers. Multiplexed imaging platforms to simultaneously detect multiple markers in a single cell resolution in the same tissue section emerged in the last years as powerful tools to immuno-profiling several tumor tissues and cell-cell interactions which suggest improved diagnostic benefit.

9:00 Multi-Scale Spatial Multi-Omics Profiling for Precision Medicine

Ahmet Coskun, PhD, Assistant Professor, Biomedical Engineering, Georgia Institute of Technology

The spatial organization of cells and subcellular variations in tissues can be considered as a quantitative metric in determining the health and disease. Single-cell analyses of molecular profiles dissect spatial heterogeneity of distinct cell types. In this talk, I will introduce multiplex imaging modalities (genomics, proteomics, and metabolomics) to quantify up to a hundred markers at macromolecular resolution in single cells for immuno-engineering, precision oncology, and regenerative medicine applications.

9:30 Session Break

INTERACTIVE DISCUSSIONS

9:45 Interactive Discussions (In-person only)

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

SINGLE-CELL MULTI-OMIC PROFILING

10:15 Building Single-Cell Proteomics Platforms for Therapeutic Discovery

Christopher M. Rose, PhD, Scientist, Microchemistry & Proteomics & Lipidomics, Genentech, Inc.

Single-cell proteomics (SCP) is undergoing a revolution due to the increased sensitivity of mass spectrometers and the increased level of sample multiplexing. Here, we describe the characterization of quantitative accuracy within current SCP analyses and describe novel data acquisition methods aimed at improving the quality and depth of SCP analyses. Lastly, we describing how these methods are utilized to better understand therapeutically relevant pathways within research and early development.

10:45 Talk Title to be Announced

D. Lansing Taylor, PhD, Distinguished Professor and Allegheny Foundation Professor of Computational & Systems Biology; Director, University of Pittsburgh Drug Discovery Institute

11:15 Microscopy-Based Functional Single-Cell Profiling

Miao-Ping Chien, PhD, Principal Investigator, Oncode Institute, Molecular Genetics, Erasmus University

Our lab developed microscopy-based functional single-cell sequencing (FUNseq) and analysis technologies, which can be applied to subtype heterogeneous populations of cells and link tumorigenic phenotypes to causative genotypes. FUNseq can be combined with single-cell genome, transcriptome, and proteome profiling. FUNseq has been exploited to identify driving pathways related to aggressive migration in different (patient-derived) tumors and to profile subpopulations of cancer cells displaying chromosomal instability or abnormal DNA damage response.

11:45 Advancements in Single-Cell and Spatial Solutions from 10x Genomics

10x GENOMICS

Jason Kim, Senior Science & Technology Advisor, 10x Genomics

10x Genomics Chromium Single Cell products enable molecular profiling with multiomic capabilities in hundreds of thousands of single cells, and our Visium Spatial products provide a comprehensive understanding of the relationships between cellular function, phenotype, and location in intact tissue sections. Join us to learn how you can uncover molecular insights, dissect cell-type differences, detect novel cell subtypes and biomarkers, define gene regulatory interactions, and decipher spatiotemporal gene expression patterns.

12:15 pm Session Break

12:20 LUNCHEON PRESENTATION: Comprehensive Analysis of IO Markers in TME of Solid Tumor Samples Using GeoMx DSP and MultiOmyx Immunofluorescence

Lakshmi Chandramohan, PhD (ABMM), Principal Scientist, Associate Director, Molecular Assay Services, Pharma Services, NeoGenomics Laboratories

We applied a multi-faceted, highly multiplexed tissue analysis approach to quantitate and characterize spatial arrangement of key IO protein markers in a solid tumor cohort using GeoMx™ DSP and MultiOmyx™ Immunofluorescence. Direct correlation was observed for eight out of 10 IO markers between DSP counts and MultiOmyx positive cell densities. This study showed that integrated analysis by both technologies provides a comprehensive understanding of the immune landscape in oncology FFPE tissues.

12:50 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:20 Session Break

ASSAY DEVELOPMENT FOR SPATIAL MULTI-OMIC ANALYSIS

1:30 Chairperson's Remarks

Jason Kim, Senior Science & Technology Advisor, 10x Genomics

1:35 Single-Cell Spatial Analysis of Single-Stranded DNA Using Light-Assisted *in situ* DNA Synthesized

James Eberwine, PhD, Elmer Holmes Bobst Professor, Systems Pharmacology and Translational Therapeutics; Co-Director, Penn Program in Single Cell Biology; Co-Director, Penn Center for Subcellular Biology, University of Pennsylvania Perelman School of Medicine

Genomic DNA transitions between single-stranded and double-stranded states during transcription, DNA repair and replication. This interconversion is critical to the maintenance of cellular homeostasis and plasticity. To assess the single-stranded DNA chromatin landscape at the level of a single cell, we have developed spatially light-activated CHEX-seq (CHromatin EXposed) that utilizes our *in situ* transcription technology, for identifying the non-B-form single-stranded open chromatin *in situ* in individual, formalin-fixed cells.

2:05 New Fluorescent Reagents to Enable Spatial Biology

Daniel T. Chiu, PhD, A. Bruce Montgomery Professor of Chemistry; Endowed Professor in Analytical Chemistry; Professor of Bioengineering, University of Washington

Fluorescence-based techniques have become an indispensable tool kit in both basic cellular studies and *in vitro* diagnostics. However, the intrinsic limitations of conventional dyes, such as short Stoke's shift and low absorptivity, have posed difficulties for advancing highly multiplexed assays. We have developed a new class of fluorescent probes called Pdots, and this talk will highlight their development to enable high multiplex single-cell analysis and spatial biology.

2:35 AI-Enabled, Label-Free Single-Cell Spatial Biology Technologies with Image-Guided FACS

Yuhwa Lo, PhD, Professor, Electrical & Computer Engineering, University of California, San Diego

We will discuss the application of image-guided single-cell sorter to recognize and isolate cell types and intracellular cellular features. Image-guided sorter can generate a large amount of cell images with high resolution and throughput. Applying artificial intelligence with CNN, we show that rich information can be obtained to produce insight in cell types, behaviors, and health. The ability to isolate cells for verification helps the semi-supervised deep-learning system improve performance.

3:05 Precise Spatial Multiplexing for Quantitative Single-Cell Immune Profiling with ChipCytometry

Thomas Campbell, PhD, Product Manager, Canopy Biosciences - A Bruker Company

Understanding the spatial distribution of immune cell populations is critical in advancing our understanding of cancer. Here we present the analysis of tissue samples using ChipCytometry, which combines iterative immuno-fluorescent staining with high-dynamic range imaging to facilitate quantitative phenotyping with single-cell resolution. Standard FCS files are generated from multichannel images, enabling quantification of dozens of protein biomarkers and accurate identification of cellular phenotypes via flow cytometry-like gating.

3:20 Sponsored Presentation *(Opportunity Available)*

3:35 Session Break

KEYNOTE LOCATION: Indigo A

PLENARY KEYNOTE SESSION: PRECISION HEALTH: GENOMICS AND BEYOND

4:15 Chairperson's Remarks

Robert C. Green, MD, MPH, Professor and Director of Genomes2People Research, Mass General Brigham, Broad Institute, Ariadne Labs and Harvard Medical School

4:20 Keynote Introduction: Predicting Clinical Outcomes in Three Easy Steps

Stephen Williams, MD, PhD, CMO, SomaLogic

Reliable outcomes prediction enables increased power in clinical trials and improved allocation of resources in clinical practice. The new discipline of using highly multiplexed measurements, machine learning and mixed study populations can lead to robust and generalized predictors of catastrophic and near-term risks. Key examples using SomaScan® proteomics for cardiovascular events, heart failure mortality and loss of kidney function will be shown.

4:30 KEYNOTE PRESENTATION: Universal Newborn Sequencing and the Path to Preventive Genomics

Robert C. Green, MD, MPH, Professor and Director of Genomes2People Research, Mass General Brigham, Broad Institute, Ariadne Labs and Harvard Medical School

Twenty years after the completion of the Human Genome Project, population-scale genomic screening is being implemented. We recently completed the first randomized trial of comprehensive genome sequencing in healthy newborns (the NIH funded BabySeq Project). We present data from this and other studies to suggest that

universal newborn sequencing may soon provide a platform for the lifelong use of genomics in risk stratification, disease mitigation and expanding longevity.

5:00 KEYNOTE PRESENTATION: Transforming Genomic Healthcare in the United Kingdom
Sir Mark Caulfield, PhD, Professor & Director, Clinical Pharmacology, The William Harvey Research Institute, Queen Mary University of London; CEO, Barts Life Sciences
The 100,000 Genomes Project focused on rare disease, cancer, and infection and demonstrated the potential of whole genomes to uplift diagnoses by 25% in rare disease, have a clinical utility for 25% of cancer patients, and discover 15 novel gene loci for severe COVID-19. Exploring of pharmacogenomics reveals many of us have genetic variants which if paired with a drug may cause harm.

5:30 KEYNOTE PRESENTATION: Precision Health: Closing the Information and Decision Gaps
Jessica L. Mega, MD, MPH, Co-Founder and Chief Medical & Scientific Officer, Verily; Adjunct Professor, Stanford University School of Medicine

6:00 Panel Discussion: Precision Health: Convergence of Genomics, Digital MedTech and Healthcare
Moderator: Robert C. Green, MD, MPH, Professor and Director of Genomes2People Research, Mass General Brigham, Broad Institute, Ariadne Labs and Harvard Medical School
Precision health promises a much-needed shift from "sick-care" to "healthcare." Driven by innovations in genomics, medtech, and AI, precision health strategies can focus on prediction, prevention, and early detection for individualized health and wellness. The panel will discuss how genomics and digital health technologies can advance community-wide genetic screening and early disease detection, patient monitoring and preventative health strategies, personalized lifestyle and wellness approaches, and precision health equity.
Panelists:
Sir Mark Caulfield, PhD, Professor & Director, Clinical Pharmacology, The William Harvey Research Institute, Queen Mary University of London; CEO, Barts Life Sciences
Jessica L. Mega, MD, MPH, Co-Founder and Chief Medical & Scientific Officer, Verily; Adjunct Professor, Stanford University School of Medicine
Lara Jehi, MD, Chief Research Information Officer, Professor, Neurology, Cleveland Clinic
Megan Mahoney, MD, Clinical Professor, Primary Care & Population Health, Stanford University

6:30 Welcome Reception in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)

7:30 Close of Day

TUESDAY, FEBRUARY 22

7:30 am Registration Open and Morning Coffee (Indigo West Foyer AB)

ROOM LOCATION: Indigo 206

ADVANCES IN SPATIAL TRANSCRIPTOMICS

8:00 Single-Cell and Spatial Genomics for Next-Generation Neuropathology
Evan Macosko, PhD, Assistant Professor, Psychiatry, Stanley Center for Psychiatric Research, Broad Institute
For decades, neuropathological tissue analysis has been hypothesis-driven: genes or pathways are nominated by experimental models, and then tested in human samples. However, single cell and spatial genomics technologies enable much more detailed characterization of tissue, allowing us to build disease hypotheses directly from the human tissue itself. In this talk I will describe our technology development in single-cell (Drop-seq) and spatial genomics (Slide-seq) and our application to Parkinson's disease.

8:30 Comprehensive Integration of Single-Cell and Spatial Transcriptomic for Mapping Human Tissue Architecture
Omer Bayraktar, PhD, Group Leader, Wellcome Sanger Institute
Spatial transcriptomic technologies promise to resolve cellular wiring diagrams of tissues in health and disease, but comprehensive mapping of cell types *in situ* remains a challenge. We present cell2location, a principled Bayesian model that can resolve fine-grained cell types in spatial transcriptomic data and create comprehensive cellular maps of diverse tissues. We comprehensively assess cell2location in three different tissues and consistently demonstrate improved mapping of fine-grained cell types.

9:00 The Implications of Single-Cell Transcriptomics at Unprecedented Scale
Charlie Roco, PhD, CTO, Parse Biosciences
Single-cell experiments are rapidly evolving to embrace scale following the introduction of a commercial solution that enables up to 1 million cells at a time. Cohorts and replicates simplified for cost or assay compatibility are being pursued ambitiously. This rapid expansion has highlighted opportunities for more effective single-cell research at scale. This session explores historical considerations and highlights effective strategies to embrace this newfound power.

9:30 Coffee Break in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)

10:10 Next-Generation Tools for Spatial Genomics
Fei Chen, PhD, Assistant Professor, Stem Cell & Regenerative Biology, Broad Institute
The precise spatial localization of molecular signals within tissues richly informs the mechanisms of tissue formation and function. Here, we'll introduce Slide-seq, a technology which enables transcriptome-wide measurements with near-single cell spatial resolution. We'll describe recent experimental and computational advances to enable Slide-seq in biological contexts in biological contexts where high detection sensitivity is important. More broadly, we'll discuss the promise and challenges of spatial transcriptomics for tissue genomics.

10:40 Integrating Single-Cell and Spatial Transcriptomics for In-Depth Patient Tissue Interrogation
Ioannis Vlachos, PhD, Assistant Professor & Co-Director, Bioinformatics, Cancer Research Institute, Beth Israel Deaconess Medical Center
Spatial technologies have started to revolutionize our ability to deeply interrogate tissue and capture layers of information which were not previously possible. During this talk I will provide an overview of our

efforts to seamlessly integrate spatial transcriptomics with single nucleus sequencing to capture cellular and transcriptional alterations observed in human pathologies, with an emphasis on an extensive collaborative project focusing on COVID-19 phenotypes.

11:10 Sponsored Presentation *(Opportunity Available)*

11:40 Session Break

11:50 Luncheon Presentation *(Sponsorship Opportunity Available)*
or Enjoy Lunch on Your Own

12:20 pm Refreshment Break in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)

1:00 Close of Spatial Biology & Single-Cell Analysis Conference

> "I learned by example what our start-up diagnostic company needs to be doing differently to be successful while also getting ideas for new products."
>
> *Associate Professor, University of Illinois at Chicago*

TUESDAY, FEBRUARY 22

KEYNOTE LOCATION: Indigo A

PLENARY KEYNOTE SESSION: INNOVATION IN PRECISION MEDICINE: FROM DIAGNOSTICS TO DIGITAL HEALTH

1:00 pm Chairperson's Remarks
Lisa M. Suennen, Lead/Senior Managing Director, Digital & Technology Group, Manatt Phelps & Phillips LLP

1:05 From Open-Source PCR Assay to National SalivaDirect™ Diagnostics Network: Delivering Equitable, Accessible Testing Solutions for the Pandemic and Beyond
Anne Wyllie, PhD, SalivaDirect Principal Investigator, Research Scientist, Epidemiology of Microbial Diseases, Yale School of Public Health

1:15 KEYNOTE PRESENTATION: Innovating Diagnostics to End a Pandemic: The RADx Tech Experience
Steven Schachter, MD, Professor, Neurology, Harvard Medical School; Chief Academic Officer and RADx Chief, CIMIT
Rapid Acceleration of Diagnostics (RADx) Tech is an NIH-funded program to accelerate development, validation, and commercialization of innovative point-of-care and home-based tests, as well as improvements to clinical laboratory tests, that can directly detect the virus that causes COVID-19 and its variants. The program generated 27 FDA Emergency Use Authorizations for COVID-19 diagnostic tests, including the first over-the-counter test for use at home without prescription, and produced 500 million tests.

1:45 KEYNOTE PRESENTATION: Innovative Tests for COVID-19, Future Pandemics, and Potential use in Non-Pandemic Test Development
Timothy Stenzel, MD, PhD, Director, Office of in vitro Diagnostics and Radiological Health, FDA

2:15 Panel Discussion: Investing in Precision Medicine: Trends in Diagnostics, HealthTech and Digital Health
Moderator: Lisa M. Suennen, Lead/Senior Managing Director, Digital & Technology Group, Manatt Phelps & Phillips LLP
Precision medicine is driven by the innovation continuum spanning genomics and diagnostics, MedTech and HealthTech, AI and digital health. The panel will explore investment opportunities and growth trends in the post-pandemic era, as well as the impact of precision medicine innovation on improving health outcomes and patient experience, managing healthcare costs, and advancing health equity.
Panelists:
Tom Miller, Founder & Managing Partner, GreyBird Ventures, LLC
Mara G. Aspinall, Managing Director, BlueStone Venture Partners, LLC
Jenny Rooke, PhD, Managing Director, Genoa Ventures
Taha Jangda, Partner, HealthX Ventures
Michele Colucci, Founder & Managing Partner, DigitalDx Ventures

2:45 Refreshment Break in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)

ROOM LOCATION: Indigo 202 A

INNOVATION AND INVESTMENT OPPORTUNITIES IN DIAGNOSTICS AND PRECISION MEDICINE

3:25 Chairperson's Remarks
Michele Colucci, Founder & Managing Partner, DigitalDx Ventures

3:30 Investing in Precision Medicine Diagnostics
Tom Miller, Founder & Managing Partner, GreyBird Ventures, LLC
GreyBird Ventures has an exclusive investment focus on precision diagnostics. We have reviewed over 1500 diagnostic start-up firms investing in fewer than one for every 150 that we review. We will present an overview of this experience, our thoughts about how we (and others) make diagnostic investment decisions, some advice for firms seeking funding, and present a few "Grand Challenges" in diagnostics that would automatically warrant careful consideration.

4:00 COVID-19 Diagnostics: The Key to the Beginning, Middle & End of the Global Pandemic
Mara G. Aspinall, Managing Director, BlueStone Venture Partners, LLC
Diagnostics have never been more important or visible as they are today amid the COVID-19 pandemic. Mara will discuss how COVID diagnostics developed and how they are and should be used to fight the virus through timely diagnosis and monitoring – as well as introduce you to the largest database of COVID tests worldwide, TestingCommons.com, which she created with the team at Arizona State University and The Rockefeller Foundation.

4:30 Diagnostics Innovation for Point-of-Care Settings
Bryan Bothwell, Senior Director of Strategy and Business Development, Qorvo Biotechnologies
The pandemic highlighted historical gaps in diagnostics infrastructure. Significant private and government resources have been activated, and Qorvo Biotechnologies has developed Point-of-Care diagnostics capability based on orthogonal technology to address todays testing needs. This presentation focuses on product technological innovation, the government partnerships that have established volume market access, and how this positions the platform for future testing success beyond COVID-19.

4:45 From Biobank to CDx: Smoothing the Path to Validation
David Parker, Senior Vice President, Diagnostics Solutions, Precision for Medicine
Often, assay validation requires additional mutated or wild type samples to supplement reserved tissue from trial subjects. In response, Precision has embarked on a large-scale initiative to sequence curated samples from our massive tissue archive, Project P.O.S.I. – the Precision Oncology Sequencing Initiative. In this talk we will discuss how CDx development programs can be accelerated by overcoming the barriers of exhausted or insufficient clinical trial material with pre-characterized disease-specific specimens.

5:00 Tech-Nostics: An Industry in Transition
Michele Colucci, Founder & Managing Partner, DigitalDx Ventures

Technology has changed the way we diagnose and treat illness. A doctor used to diagnose using a stick and small flashlight. Doctors had an incredibly small amount of information. Today they have way too much. Diagnostics has evolved into Tech-nostics. We are innovating at the intersection of science, chemistry and technology. This tectonic shift is forever changing the way we think about, and approach, the science of medicine.

5:30 **Close of Day**

WEDNESDAY, FEBRUARY 23

7:30 am **Registration Open and Morning Coffee (Indigo West Foyer AB)**

KEYNOTE LOCATION: Indigo A

PLENARY KEYNOTE SESSION: PRECISION MEDICINE AT BIG PHARMA

8:05 **Chairperson's Remarks**
Edward Abrahams, PhD, President, Personalized Medicine Coalition

8:10 KEYNOTE PRESENTATION: **Personalized Healthcare in Big Pharma: A 2022 Perspective**
Jeffrey Venstrom, MD, Chief Medical Partner, US Medical Affairs, Genentech
Realizing the promises of PHC can deliver improved outcomes for patients at a lower cost to them and to society. At Genentech, we believe the key to rapidly deploying personalized solutions and delivering optimal outcomes for patients faster is through strategic partnerships from a range of different sectors and disciplines across the healthcare system, collaborating and innovating together.

8:40 KEYNOTE PRESENTATION: **Increasing Access to Precision Medicine – The Next-Generation of Companion Diagnostics**
Ruth E. March, PhD, Senior Vice President & Head, Precision Medicine & Biosamples, AstraZeneca
Precision medicine uses diagnostic tests to match the right drugs to patients most likely to respond. As science advances through the use of advanced analytics, artificial intelligence and integrated sources of biomarker data, we need a new generation of diagnostic tests. Following the patient journey in different treatment settings offers opportunities to all patients to be able to gain access to appropriate diagnostic solutions.

9:10 **Panel Discussion: Implementing Precision Medicine at Big Pharma**
Moderator: Edward Abrahams, PhD, President, Personalized Medicine Coalition
Over the past decade, precision medicine promised to impact drug development by targeting the right medicine to the right patient. The panel of pharma thought leaders will discuss strategies to implement precision medicine in the drug discovery and development pipeline, including biomarker and companion diagnostic development, patient stratification, precision oncology advances, and emerging molecular tools for disease characterization.
Panelists:
Jeffrey Venstrom, MD, Chief Medical Partner, US Medical Affairs, Genentech
Maria C. M. Orr, PhD, FRSB, Head of Precision Medicine, Biopharmaceuticals, AstraZeneca
Marielena Mata, PhD, Senior Director and Diagnostic Lead, Oncology Program, Pfizer Inc.
Christopher Conn, PhD, Director, Companion Diagnostics, AbbVie
Andrea L. Stevens, PhD, Director, Precision Medicine Access Strategy, Janssen Pharmaceuticals, Inc.

9:40 **Coffee Break in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)**

ROOM LOCATION: Indigo 202 A

REIMBURSEMENT AND EVIDENCE GENERATION STRATEGIES

10:20 **Chairperson's Remarks**
Bruce Quinn, MD, PhD, Principal, Bruce Quinn Associates, LLC

10:25 **Demystifying Molecular Diagnostics Coverage and Reimbursement in Medicare**
Gabriel Bien-Willner, MD, PhD, Medical Director, MolDx, Palmetto GBA
MolDX is a program operated by PalmettoGBA to set molecular diagnostics policy and payor controls in 28 states. This talk will cover the scope and philosophy of the program, as well as provide instruction to providers on how to approach payors seeking coverage and reimbursement.

10:55 **Medicare Local and National Coverage: How It's Shaping the Genomics Industry**
Bruce Quinn, MD, PhD, Principal, Bruce Quinn Associates, LLC
Medicare remains one of the largest payors for molecular diagnostics, with over $1.5B in payments in CY2019. Both national and local decisions are coming out at a rapid pace, and the Medicare agency is so large it impacts both investment and development. Recent decisions reshape germline testing, cancer tissue testing, and preventive testing. Understand what areas are "pre-covered" and how your test can qualify.

11:25 **Commercial Test Coverage: Unlocking the Door**
Lon Castle, MD, CMO, Molecular Genetics & Personalized Medicine, eviCore healthcare
Only one hurdle remains: Commercial payer coverage. But the door is locked (and dead-bolted). Getting through seems impossible–but it's not. All you need are the right keys. Fortunately, you can make them yourself. But they'll only work if you adhere to certain specifications. In this session, we'll talk about those specifications, how to make the keys you need, and what to expect on the other side of the door.

11:55 **Sponsored Presentation** *(Opportunity Available)*

12:25 pm **Session Break**

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

1:30 Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing (Indigo BFGCDH)

MARKET ACCESS IN THE POST-PANDEMIC ERA

2:00 Chairperson's Remarks

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

2:05 Market Access in the Post-Pandemic Era: Leveraging Innovative Approaches to Drive Access

Brock Schroeder, PhD, Senior Director, Global Market Access Strategy & Health Economic Outcomes Research, Illumina, Inc.

Traditional market access – with a primary focus on coverage, coding, and reimbursement – is evolving. The COVID-19 pandemic has accelerated these changes and has created new challenges and opportunities. Innovative approaches, focusing on partnership and high-quality evidence generation, can help accelerate access.

2:35 The COVID Effect: How Relationships Have Changed

Suzanne Belinson, PhD, Vice President, Commercial Markets, Tempus, Inc.

Market access is a business of relationships. It is a business driven by market knowledge and how that market knowledge can be translated and communicated to industry stakeholders. The global pandemic has shifted the way we do business. This session will focus on redefining market access to align with our new realities.

3:05 The Future of Clinical Diagnostics after the COVID-19 Disruption

David Cavanaugh, Founding Partner, DeciBio Consulting LLC

COVID-19 significantly disrupted the diagnostics industry as manufacturers raced to develop and manufacture millions of SARS-CoV-2 tests, testing laboratories struggled to source enough SARS-CoV-2 tests, governments and payers spent tens of billions of dollars on testing, investors entered to capitalize on this windfall and clinicians managed many of their patients remotely. We will examine this unprecedented moment in the history of diagnostics and how our world has changed.

INTERACTIVE DISCUSSIONS

3:35 Interactive Discussions (In-person only)

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4:05 Session Break

TECHNOLOGY INNOVATION IN NEXT-GENERATION DIAGNOSTICS

4:15 Engineering Biology for Diagnostic Solutions

William Blake, PhD, CTO, Sherlock Biosciences

Sherlock Biosciences is engineering biology to develop products that enable people to access answers and have more control over their health decisions. In this talk, we will discuss how Sherlock is harnessing proprietary CRISPR and synthetic biology tools, together with deep learning, to solve a range of diagnostic challenges in environments ranging from clinical labs to low resources areas, including the home.

4:45 Autonomous AI and Health Equity

Michael D. Abramoff, MD, PhD, Founder & Executive Chairman, Digital Diagnostics

Autonomous AI allows for immediate point-of-care diagnosis which can increase access, address health disparities, and lower costs. But to address health equity with AI it's important to start with an ethical framework then address liability, standard of care, (FDA) regulation, CPT coding, reimbursement, and HEDIS/MIPS quality measurements. Autonomous AI can have a positive impact in healthcare, but it must be done the right way.

5:15 Wearable Electrochemical Sensors for Healthcare, Wellness, and Nutrition Applications

Joseph Wang, PhD, Distinguished Professor & Chair, Nanoengineering, University of California, San Diego

This presentation will discuss recent developments in the field of wearable electrochemical sensors integrated directly on the epidermis, under the skin, or within the mouth for various non-invasive and minimally invasive biomedical monitoring applications. Particular attention will be given to non-invasive monitoring of metabolites and electrolytes using flexible electrochemical sensors, to multiplexed microneedle sensor arrays, along with related materials, energy, and integration considerations.

5:45 Close of Conference

TUESDAY, FEBRUARY 22

KEYNOTE LOCATION: Indigo A

PLENARY KEYNOTE SESSION: INNOVATION IN PRECISION MEDICINE: FROM DIAGNOSTICS TO DIGITAL HEALTH

1:00 pm Chairperson's Remarks
Lisa M. Suennen, Lead/Senior Managing Director, Digital & Technology Group, Manatt Phelps & Phillips LLP

1:05 From Open-Source PCR Assay to National SalivaDirect™ Diagnostics Network: Delivering Equitable, Accessible Testing Solutions for the Pandemic and Beyond
Anne Wyllie, PhD, SalivaDirect Principal Investigator, Research Scientist, Epidemiology of Microbial Diseases, Yale School of Public Health

1:15 KEYNOTE PRESENTATION: Innovating Diagnostics to End a Pandemic: The RADx Tech Experience
Steven Schachter, MD, Professor, Neurology, Harvard Medical School; Chief Academic Officer and RADx Chief, CIMIT
Rapid Acceleration of Diagnostics (RADx) Tech is an NIH-funded program to accelerate development, validation, and commercialization of innovative point-of-care and home-based tests, as well as improvements to clinical laboratory tests, that can directly detect the virus that causes COVID-19 and its variants. The program generated 27 FDA Emergency Use Authorizations for COVID-19 diagnostic tests, including the first over-the-counter test for use at home without prescription, and produced 500 million tests.

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

2:15 Panel Discussion: Investing in Precision Medicine: Trends in Diagnostics, HealthTech and Digital Health
Moderator: Lisa M. Suennen, Lead/Senior Managing Director, Digital & Technology Group, Manatt Phelps & Phillips LLP
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Panelists:
Tom Miller, Founder & Managing Partner, GreyBird Ventures, LLC
Mara G. Aspinall, Managing Director, BlueStone Venture Partners, LLC
Jenny Rooke, PhD, Managing Director, Genoa Ventures
Taha Jangda, Partner, HealthX Ventures
Michele Colucci, Founder & Managing Partner, DigitalDx Ventures

2:45 Refreshment Break in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)

ROOM LOCATION: Indigo A

UPDATE ON MOLECULAR DIAGNOSTICS FOR COVID-19

3:30 SARS-CoV-2 Testing: The University of Washington Medical Center Experience
Alex Greninger, MD, PhD, MS, MPhil, Assistant Professor, Laboratory Medicine, University of Washington
This talk will cover the rapidly evolving area of SARS-CoV-2 diagnostics from 2020-2022, highlighting recent trends, as well as our experience with central lab and distributed testing.

4:00 SARS-CoV-2 Molecular Testing: From LDT to Variants Testing at a Cancer Hospital
Esther Babady, PhD, D(ABMM), FIDSA, Section Head, Clinical Microbiology Service, Memorial Sloan Kettering Cancer Center
This presentation will discuss the evolution of molecular diagnostics for SARS-CoV-2 testing at a cancer hospital from the beginning of the pandemic to current state including development and implementation of laboratory-developed tests to SARS-CoV-2 variant testing.

4:30 Crucial Applications of Single-Cell Gene Expression and Immune Profiling for Infectious Disease Research
Cliff Ramsdell, Science & Technology Advisor, 10x Genomics
The ongoing coronavirus (COVID-19) outbreak has taken thousands of lives, and the number of infections is growing daily. In this webinar we will discuss the utility of single cell technologies to advance infectious disease research, highlighting how the scientific community can respond to such events.

4:45 Breath-Based, Fast PCR Test for SARS-CoV-2
Erik Crawford, Strategic Partnerships Manager, imec
Imec has developed a SARS-CoV-2 test that combines an 'easy' breath sample and a sensitive PCR analysis on chip (<15min). The silicon chip at the core combines efficient aerosol collection and low impedance to air flow so a sample can be collected with a 1-minute breath. This platform demonstrated in SARS-CoV-2 will unlock the potential of breath specimens for diagnostics, novel biomarkers, and research in pandemic management and in other indications.

5:00 COVID-19 and Beyond: Navigating Testing in a Dynamic Respiratory Environment
Gregory J. Berry, PhD, Associate Professor, Pathology & Cell Biology, Columbia University Vagelos College of Physicians and Surgeons
As the COVID-19 pandemic has progressed and common respiratory infections have re-emerged, the need to simultaneously test for multiple pathogens is more apparent than ever. This is compounded by the fact that there is no way to definitively diagnose COVID-19 versus other common respiratory illnesses based on clinical symptomology. The aim of this presentation will be to review SARS-CoV-2 and COVID-19 clinical symptomology in relation to other common respiratory viruses.

5:30 Use Case Scenarios for the Selection of Molecular Methods for Point-of-Care Testing: How the SARS-CoV-2 Pandemic Taught Us New Best Practices
Jeanne Mumford, MT(ASCP), Manager, Point-of-Care Testing, Johns Hopkins Hospital

We will review several use case scenarios that cover inpatient, outpatient, and employee testing locations. We will outline each of the testing options that were available, what factors affected the decision process, and how to narrow down the best test for each. Selecting molecular point-of-care tests in the last 20 months was sometimes strongly dependent on the global supply chain and manufacturing limitations and learning how to overcome those challenges.

6:00 The "New Normal" in COVID-19 Testing

Mark J. Lee, PhD, Assistant Professor & Assistant Director, DUHS Clinical Microbiology Labs, Duke University

From the first SARS-CoV-2 assays to genotyping, the demand for testing has put considerable burden on clinical laboratories. Laboratories are faced with juggling pre-op screening, symptomatic and asymptomatic testing, viral load estimation, and more recently, genotyping to meet the demands of the "New Normal" in COVID-19 testing. This juggling act hinges on diagnostic stewardship, regulatory compliance, logistics, and various technical constraints.

6:30 Close of Day

WEDNESDAY, FEBRUARY 23

7:30 am Registration Open and Morning Coffee (Indigo West Foyer AB)

KEYNOTE LOCATION: Indigo A

PLENARY KEYNOTE SESSION: PRECISION MEDICINE AT BIG PHARMA

8:05 Chairperson's Remarks

Edward Abrahams, PhD, President, Personalized Medicine Coalition

8:10 KEYNOTE PRESENTATION: Personalized Healthcare in Big Pharma: A 2022 Perspective

Jeffrey Venstrom, MD, Chief Medical Partner, US Medical Affairs, Genentech

Realizing the promises of PHC can deliver improved outcomes for patients at a lower cost to them and to society. At Genentech, we believe the key to rapidly deploying personalized solutions and delivering optimal outcomes for patients faster is through strategic partnerships from a range of different sectors and disciplines across the healthcare system, collaborating and innovating together.

8:40 KEYNOTE PRESENTATION: Increasing Access to Precision Medicine – The Next-Generation of Companion Diagnostics

Ruth E. March, PhD, Senior Vice President & Head, Precision Medicine & Biosamples, AstraZeneca

Precision medicine uses diagnostic tests to match the right drugs to patients most likely to respond. As science advances through the use of advanced analytics, artificial intelligence and integrated sources of biomarker data, we need a new generation of diagnostic tests. Following the patient journey in different treatment settings offers opportunities to all patients to be able to gain access to appropriate diagnostic solutions.

9:10 Panel Discussion: Implementing Precision Medicine at Big Pharma

Moderator: Edward Abrahams, PhD, President, Personalized Medicine Coalition

Over the past decade, precision medicine promised to impact drug development by targeting the right medicine to the right patient. The panel of pharma thought leaders will discuss strategies to implement precision medicine in the drug discovery and development pipeline, including biomarker and companion diagnostic development, patient stratification, precision oncology advances, and emerging molecular tools for disease characterization.

Panelists:
Jeffrey Venstrom, MD, Chief Medical Partner, US Medical Affairs, Genentech
Maria C. M. Orr, PhD, FRSB, Head of Precision Medicine, Biopharmaceuticals, AstraZeneca
Marielena Mata, PhD, Senior Director and Diagnostic Lead, Oncology Program, Pfizer Inc.
Christopher Conn, PhD, Director, Companion Diagnostics, AbbVie
Andrea L. Stevens, PhD, Director, Precision Medicine Access Strategy, Janssen Pharmaceuticals, Inc.

9:40 Coffee Break in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)

ROOM LOCATION: Indigo A

EMERGING MOLECULAR DIAGNOSTICS FOR PATHOGEN DETECTION

10:20 Chairperson's Remarks

Michael J. Mina, MD, PhD, CSO, eMed

10:25 Nanopore Sequencing as an Alternative to Microarray Detection of Pathogens in Blood

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

The large number of infectious agents in blood and the continually emerging agents are a constant challenge for diagnostic and blood donor screening devices. To increase sensitivity, multiplicity and speed sample to answer, new technologies must be designed and tested. We have tested the OpenArray spatially multiplex platform, the resequencing microarray, and are now applying the Oxford Nanopore MinION next-generation sequencer to high specificity identification of pathogens in blood.

10:55 Update on COVID-19 Diagnostics

Michael J. Mina, MD, PhD, CSO, eMed

11:25 Tracking Emerging Viruses and Microbes in Sewers and Spacecraft

Christopher Mason, PhD, Associate Professor, Physiology and Biophysics; Co-Director, WorldQuant Initiative for Quantitative Prediction, Weill Cornell Medicine

The avalanche of easy-to-create genomics data has impacted almost all areas of medicine and science, from cancer patients and microbial diagnostics to molecular monitoring for astronauts in space. In this seminar, new discoveries from RNA- and DNA-sequencing across dozens of cities on Earth will be detailed, including the analysis of wastewater as a means to track SARS-CoV-2 levels, and the investigation of new species found on the International Space Station.

11:55 COVID-19 Testing: 2020 Leagues Under the Sea

Glen Hansen, PhD, Medical Director, Clinical Microbiology and Molecular Diagnostics, Hennepin County Medical Center

Laboratory diagnosis has never been more visible to patients, the public, and healthcare than it currently is. This talk focuses on contemporary lessons, and challenges in the continued diagnostic scene, including the application of diagnostics on new COVID-19 therapies, the impact of rapid PCR as a supplement to public health sequencing efforts, and the need for multiplex assays to address upcoming challenges posed by "twindemic" viruses (COVID-19 & RSV).

12:25 pm Session Break

12:30 LUNCHEON PRESENTATION: Development of Novel Molecular Diagnostics Assays

Kerry Trice, Molecular Diagnostics Application Specialist, MilliporeSigma

From molecular diagnostics based on PCR and next generation sequencing (NGS), to those incorporating CRISPR, strategies used in the design of *in vitro* diagnostic (IVD) assays increasingly take advantage of disruptive technologies at the forefront of innovation. This presentation will review unique technologies used in diagnostics testing, provide insight into case studies on the development of assays with diagnostic customers, and end with an overview of custom manufacturing capabilities at MilliporeSigma.

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:30 Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing (Indigo BFGCDH)

VARIANTS AND GENOMIC SURVEILLANCE OF SARS-CoV-2

2:00 Chairperson's Remarks

Christopher W. Woods, MD, MPH, Professor, Medicine, Global Health & Pathology, Duke University

2:05 Development of COVID Variant Agnostic and Lineage Defining Assays

Eric H. Lai, PhD, Managing Executive, Personalized Science LLC; Team Lead, RADx Initiative

In May 2020, NIH launched the Rapid Acceleration of Diagnostics (RADx) initiative to increase testing capability and to speed development of rapid and widely accessible COVID-19 testing. I will review the achievements of the RADx program related to development of variant agnostic assays and new approaches for the rapid surveillance of COVID-19 variants.

2:35 Identifying SARS-CoV-2 Mutations: A Multiplexed Microarray for Rapid COVID-19 Detection and Variant Identification

Candy M. Rivas, PhD, Principal Scientist, PathogenDx

Viral variants have emerged with resistance to the current vaccines targeting coronavirus disease 2019 (Covid-19). The increased transmissibility or virulence is hindering public health measures. Therefore, it is imperative that rapid, low-cost diagnostics are available with the ability to diagnose and identify variants. In this presentation, we describe our low-cost DNA microarray that has the ability to diagnose, identify variants present in the population, and rapidly adapt to novel mutations.

3:05 Lessons Learned from SARS-CoV-2 Sequencing Efforts in Northern New England

Joel Lefferts, PhD, HCLD, DABCC, Associate Professor of Pathology & Laboratory Medicine; Assistant Director, Clinical Genomics and Advanced Technology (CGAT), Department of Pathology and Laboratory Medicine, Geisel School of Medicine at Dartmouth, Dartmouth-Hitchcock Medical Center

SARS-CoV-2 viral genome sequencing has been a valuable tool for the clinical diagnostics, infection prevention, public health, and epidemiologic communities since the start of the pandemic. The value of SARS-CoV-2 sequencing data continues through waves of increasing and decreasing case prevalence. Viral sequencing in northern New England was helped through collaborative efforts between departments and institutions.

INTERACTIVE DISCUSSIONS

3:35 Interactive Discussions (In-person only)

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

4:05 Session Break

HOST RESPONSE DIAGNOSTICS

4:15 Point-of-Need Host Gene Expression Testing

Ephraim Tsalik, MD, MHS, PhD, Associate Professor, Medicine, Center for Applied Genomics & Precision Medicine, Duke University

Biomeme, an emerging leader in portable molecular diagnostics and infectious disease testing solutions, has developed a first-of-its-kind quantitative real-time PCR platform to measure host response tests for pre-symptomatic detection of viral infections and accurate discrimination of viral from bacterial infections at the point-of-need. This test solution will inform appropriate use of antibiotics and more generally, empower clinicians to deliver precision medicine solutions for other infectious and inflammatory diseases.

4:45 Harnessing the Host Response for Diagnosis and Prognosis of COVID-19

Micah McClain, MD, PhD, Associate Professor, Medicine, Duke University School of Medicine

The pandemic has provided a watershed moment for new diagnostics for respiratory viral infections. The vast majority of new approaches focus on pathogen detection whether at the hospital, the clinic, or in the home but have limitations. Respiratory or whole blood host response signatures using diverse analytes (mRNA, cytokines, DNA methylation) show promise for augmenting diagnostic and prognostic accuracy.

5:15 High-Precision, High-Sensitivity Molecular Diagnostics for Point-of-Use Applications

Paul W. Bohn, PhD, Arthur J. Schmitt Professor, Chemical & Biomolecular Engineering, University of Notre Dame

We describe a label-free electrochemical immunosensor for interleukin- in human cerebrospinal fluid (CSF) and serum, capable of quantitation in the range 1 pg mL-1 - 1 µg mL-1. The sensor can deliver rapid results (~ 3

min) for traumatic brain injury and potentially also address an unmet need for diagnostics for other cytokine-related illnesses, such as sepsis and COVID-19 induced cytokine storms.

5:45 Close of Conference

> TRICON is one of the most important events for us to attend and be seen at. It brings together a fantastic combination of potential clients and collaborators in one great location.
>
> *Head of Product Development, MiniFAB*

TUESDAY, FEBRUARY 22

KEYNOTE LOCATION: Indigo A

PLENARY KEYNOTE SESSION: INNOVATION IN PRECISION MEDICINE: FROM DIAGNOSTICS TO DIGITAL HEALTH

1:00 pm Chairperson's Remarks
Lisa M. Suennen, Lead/Senior Managing Director, Digital & Technology Group, Manatt Phelps & Phillips LLP

1:05 From Open-Source PCR Assay to National SalivaDirect™ Diagnostics Network: Delivering Equitable, Accessible Testing Solutions for the Pandemic and Beyond
Anne Wyllie, PhD, SalivaDirect Principal Investigator, Research Scientist, Epidemiology of Microbial Diseases, Yale School of Public Health

1:15 KEYNOTE PRESENTATION: Innovating Diagnostics to End a Pandemic: The RADx Tech Experience
Steven Schachter, MD, Professor, Neurology, Harvard Medical School; Chief Academic Officer and RADx Chief, CIMIT

Rapid Acceleration of Diagnostics (RADx) Tech is an NIH-funded program to accelerate development, validation, and commercialization of innovative point-of-care and home-based tests, as well as improvements to clinical laboratory tests, that can directly detect the virus that causes COVID-19 and its variants. The program generated 27 FDA Emergency Use Authorizations for COVID-19 diagnostic tests, including the first over-the-counter test for use at home without prescription, and produced 500 million tests.

1:45 KEYNOTE PRESENTATION: Innovative Tests for COVID-19, Future Pandemics, and Potential use in Non-Pandemic Test Development
Timothy Stenzel, MD, PhD, Director, Office of in vitro Diagnostics and Radiological Health, FDA

2:15 Panel Discussion: Investing in Precision Medicine: Trends in Diagnostics, HealthTech and Digital Health
Moderator: Lisa M. Suennen, Lead/Senior Managing Director, Digital & Technology Group, Manatt Phelps & Phillips LLP

Precision medicine is driven by the innovation continuum spanning genomics and diagnostics, MedTech and HealthTech, AI and digital health. The panel will explore investment opportunities and growth trends in the post-pandemic era, as well as the impact of precision medicine innovation on improving health outcomes and patient experience, managing healthcare costs, and advancing health equity.

Panelists:
Tom Miller, Founder & Managing Partner, GreyBird Ventures, LLC
Mara G. Aspinall, Managing Director, BlueStone Venture Partners, LLC
Jenny Rooke, PhD, Managing Director, Genoa Ventures
Taha Jangda, Partner, HealthX Ventures
Michele Colucci, Founder & Managing Partner, DigitalDx Ventures

2:45 Refreshment Break in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)

ROOM LOCATION: Indigo 206

CANCER GENOMICS TRANSFORMING DIAGNOSIS AND THERAPY

3:25 Chairperson's Remarks
Nicholas Gallerani, PhD, Senior Business Development Associate, Business Development, NuProbe

3:30 Mutation, Regulation, Risk, and Therapeutics
John Quackenbush, PhD, Chair, Biostatistics & Henry Pickering Walcott Professor, Computational Biology & Bioinformatics, Harvard T.H. Chan School of Public Health

Cancer is characterized by the accumulation of mutations that lead to uncontrolled cell growth; much of precision medicine is based on identifying causative mutations and the use of therapies that target them. Variation in disease development, progression, and response to therapies suggest that, beyond simple mutations, complex regulatory processes are at play. We will show how gene regulatory network inference can identify what truly drives disease and identify candidate therapies.

4:00 Genetic Predisposition to Childhood Solid Tumors
Jaclyn A. Biegel, PhD, Chief, Genomic Medicine & Director, Center for Personalized Medicine, Children's Hospital Los Angeles

An essential component of precision medicine in childhood cancer is to determine whether a patient has an underlying genetic predisposition to cancer. Such findings may inform selection of therapy, increase the risk for second tumors, and have implications for the family if the gene alterations are inherited. This talk will highlight current integrated molecular approaches employed to identify alterations in cancer risk genes in pediatric patients with solid tumors.

4:30 CO-PRESENTATION: Rapid Custom Development Program for Oncology Translational Research
Nicholas Gallerani, PhD, Senior Business Development Associate, Business Development, NuProbe
Deepak Thirunavukarasu, PhD, Research Scientist, Service and Partnership, NuProbe

In this presentation we will introduce blocker displacement amplification (BDA), a rare allele enrichment technology that is able to reach a limit of detection (LoD) down to 0.01% variant allele frequency by blocking out >99% of wild type molecules through PCR-based enrichment. NuProbe's BDA technology is a highly-sensitive method for both PCR and NGS-based research applications of low-frequency mutation detection.

5:00 Somatic Reference Samples (SRS) Transforming NGS by Simplifying Diagnostic Test Validation
Maryellen de Mars, PhD, SRS Technical Project Manager, Clinical Diagnostics, Medical Device Innovation Consortium

The Somatic Reference Sample initiative is a public-private partnership guiding the development of reference samples that can be used to develop and validate NGS-based oncologic tests. Ensuring that oncology patients receive accurate results is imperative; however, lack of agreed upon well-characterized, and community-validated reference samples and data benchmarks creates potential challenges for efficient development of these tests and for understanding their results. Hear an update on this transformative initiative.

5:30 **Close of Day**

WEDNESDAY, FEBRUARY 23

7:30 am **Registration Open and Morning Coffee (Indigo West Foyer AB)**

KEYNOTE LOCATION: Indigo A

PLENARY KEYNOTE SESSION: PRECISION MEDICINE AT BIG PHARMA

8:05 **Chairperson's Remarks**
Edward Abrahams, PhD, President, Personalized Medicine Coalition

8:10 KEYNOTE PRESENTATION: **Personalized Healthcare in Big Pharma: A 2022 Perspective**
Jeffrey Venstrom, MD, Chief Medical Partner, US Medical Affairs, Genentech
Realizing the promises of PHC can deliver improved outcomes for patients at a lower cost to them and to society. At Genentech, we believe the key to rapidly deploying personalized solutions and delivering optimal outcomes for patients faster is through strategic partnerships from a range of different sectors and disciplines across the healthcare system, collaborating and innovating together.

8:40 KEYNOTE PRESENTATION: **Increasing Access to Precision Medicine – The Next-Generation of Companion Diagnostics**
Ruth E. March, PhD, Senior Vice President & Head, Precision Medicine & Biosamples, AstraZeneca
Precision medicine uses diagnostic tests to match the right drugs to patients most likely to respond. As science advances through the use of advanced analytics, artificial intelligence and integrated sources of biomarker data, we need a new generation of diagnostic tests. Following the patient journey in different treatment settings offers opportunities to all patients to be able to gain access to appropriate diagnostic solutions.

9:10 **Panel Discussion: Implementing Precision Medicine at Big Pharma**
Moderator: Edward Abrahams, PhD, President, Personalized Medicine Coalition
Over the past decade, precision medicine promised to impact drug development by targeting the right medicine to the right patient. The panel of pharma thought leaders will discuss strategies to implement precision medicine in the drug discovery and development pipeline, including biomarker and companion diagnostic development, patient stratification, precision oncology advances, and emerging molecular tools for disease characterization.
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Christopher Conn, PhD, Director, Companion Diagnostics, AbbVie
Andrea L. Stevens, PhD, Director, Precision Medicine Access Strategy, Janssen Pharmaceuticals, Inc.

9:40 **Coffee Break in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)**

ROOM LOCATION: Indigo 206

TUMOR MOLECULAR CHARACTERIZATION FOR PRECISION THERAPY

10:20 **Chairperson's Remarks**
Howard I. Scher, MD, Head of Biomarker Development Program, Member and Attending Physician, Department of Medicine, Memorial Sloan Kettering Cancer Center

10:25 **Improving Precision Medicine by Studying Bladder Cancer with Single-Cell Omics**
Dan Theodorescu, MD, PhD, Professor, Surgery & Pathology & Laboratory Medicine, Cedars-Sinai Health System
Sequencing advances have revealed most genetic variants in bladder cancer yet patient response rates to therapeutics directed at such variants have been suboptimal. This is in part because of tumor heterogeneity with individual cells harboring a diverse profile of variants. This presentation will focus on recent advances in understanding tumor heterogeneity using single-cell omics in bladder cancer and highlighting the therapeutic implications of such knowledge.

10:55 **A Global, Molecular Disease Characterization Initiative (MDCI) in Oncology Clinical Trials**
Cristina H. Messina, PhD, Clinical Scientist, Oncology Clinical Development, GlaxoSmithKline
The Molecular Disease Characterization Initiative (MDCI) is an innovative study design that collects a comprehensive baseline assessment (tumor and blood) of disease and leverages data to screen against multiple trial options, across different therapeutic modalities. This study creates a platform to accelerate the availability of new therapeutic options for patients through matched investigative and precision medicine clinical trials, while building a scientific database to facilitate the investigation of biological mechanisms.

11:25 **Bringing Pharmacogenomics to the Frontlines of Oncology Care**
Mark Dunnenberger, PharmD, Director, Pharmacogenomics, NorthShore University HealthSystem
Applying pharmacogenomics to patient care in oncology has the ability to improve patient safety and disease outcomes. In this session, important drug/gene pairs will be reviewed, practical tips from live implementations will be shared, as well as real-world data pharmacogenomics data.

Attendees should gain a better understanding of the possible impact of pharmacogenomics for their patients and how to tackle some implementation challenges.

11:55 Resolve Cancer with Single-Cell & Spatial Multi-Omics

Luigi Alvarado, Market Segment Manager, Oncology, 10x Genomics

The vast complexities of cancer are characterized by heterogeneity across samples, from tumor cells and tumor microenvironments to therapeutic responses. Through innovations in single cell sequencing and spatial transcriptomics, 10x Genomics helps researchers investigate the body's response to tumors, discover tumor-associated mutations, and uncover mechanisms of acquired resistance to therapy. Join us to learn how researchers are using our single cell and spatial tools to gain a multidimensional view of cancer.

12:10 pm Sponsored Presentation *(Opportunity Available)*

12:25 Session Break

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

1:30 Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing (Indigo BFGCDH)

PRECISION ONCOLOGY AND IMMUNO-ONCOLOGY

2:00 Chairperson's Remarks

Sandip P. Patel, MD, Associate Professor, Medicine, University of California, San Diego

2:05 Lineage Plasticity in Prostate Cancer: Toward a Precision Approach to a Heterogeneous Disease

Howard I. Scher, MD, Head of Biomarker Development Program, Member and Attending Physician, Department of Medicine, Memorial Sloan Kettering Cancer Center

Prolonged androgen receptor (AR) signaling suppression in prostate cancer has led to an increase in lineage plasticity: a tumor transition from a classical, AR-positive, prostate-specific antigen (PSA) expressing adenocarcinoma to an AR-low/negative, PSA-low tumor with an undifferentiated or neuroendocrine/small cell histology. Trial entry criteria are inconsistent and underrepresent the molecular and phenotypic diversity. Our focus is liquid biopsy assays to identify actionable targets that enable a precision medicine approach.

2:35 Designing Clinical Trials for Rare Cancers: The SWOG S1609 DART Experience

Sandip P. Patel, MD, Associate Professor, Medicine, University of California, San Diego

This presentation will discuss novel biomarkers for cancer immunotherapy including host effects influencing the immune response such as the microbiome.

ROOM CHANGE: Indigo 202 B

3:05 Breakthrough Therapies Powered by Transformative Precision Medicine Approaches

Juergen Scheuenpflug, PhD, Global Head, Clinical Biomarkers & Companion Diagnostics, Merck KGaA

Transformative precision medicine approaches integrate disease root cause identification, prediction of disease dynamics, and medical interventions guided by understanding of pharmacodynamic up- and downstream effects which allows to optimize and deepen responses at individual patient level. AI/ML powered translational research generated clinically actionable insights for new targets, early interventions/ maintenance settings, and combination therapies. Digital pathology, radiomics, and advanced clinical genomics platform approaches are key enablers to develop precision oncology therapies.

INTERACTIVE DISCUSSIONS

3:35 Interactive Discussions (In-person only)

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4:05 Session Break

BIOMARKER-ENABLED PRECISION CANCER THERAPIES

4:15 Circulating Exosomes as a Liquid Biopsy Approach for Precision Cancer Therapy

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

Circulating exosomes have emerged as means for a multitude of cancer applications including early detection, tumor molecular classification, prediction of therapeutic response, and monitoring of tumor progression and regression. The informative value of circulating exosomes across several types of solid tumors will be presented that are indicative of the value of circulating exosomes as a liquid biopsy approach.

4:45 Biomarker Combinations to Guide Combinatorial Cancer Treatment

George Vasmatzis, PhD, Assistant Professor, Lab Medicine & Co-Director, Biomarker Discovery Program, Mayo Clinic & Foundation

We have developed a functional genomics engine that consists of a multi-interdisciplinary team of clinicians, pathologists and scientists, utilizing the latest comprehensive genomics tools and preclinical models dedicated to improving patient outcomes by tailoring therapy according to the compendium of alterations of the patient's cancer. Knowledge that is gained by this system leads to novel biomarkers that if validated can be translated to clinical tests in a CLIA environment.

5:15 Close of Conference

TUESDAY, FEBRUARY 22

KEYNOTE LOCATION: Indigo A

PLENARY KEYNOTE SESSION: INNOVATION IN PRECISION MEDICINE: FROM DIAGNOSTICS TO DIGITAL HEALTH

1:00 pm Chairperson's Remarks
Lisa M. Suennen, Lead/Senior Managing Director, Digital & Technology Group, Manatt Phelps & Phillips LLP

1:05 From Open-Source PCR Assay to National SalivaDirect™ Diagnostics Network: Delivering Equitable, Accessible Testing Solutions for the Pandemic and Beyond
Anne Wyllie, PhD, SalivaDirect Principal Investigator, Research Scientist, Epidemiology of Microbial Diseases, Yale School of Public Health

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Steven Schachter, MD, Professor, Neurology, Harvard Medical School; Chief Academic Officer and RADx Chief, CIMIT

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

2:15 Panel Discussion: Investing in Precision Medicine: Trends in Diagnostics, HealthTech and Digital Health
Moderator: Lisa M. Suennen, Lead/Senior Managing Director, Digital & Technology Group, Manatt Phelps & Phillips LLP

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Jenny Rooke, PhD, Managing Director, Genoa Ventures
Taha Jangda, Partner, HealthX Ventures
Michele Colucci, Founder & Managing Partner, DigitalDx Ventures

2:45 Refreshment Break in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)

ROOM LOCATION: Indigo 202 B

COMPANION DIAGNOSTICS STRATEGIES

3:25 Chairperson's Remarks
Marielena Mata, PhD, Senior Director and Diagnostic Lead, Oncology Program, Pfizer Inc.

3:30 Global Implementation of Companion Diagnostic Solutions: A Changing Landscape
Marielena Mata, PhD, Senior Director and Diagnostic Lead, Oncology Program, Pfizer Inc.

As technologies evolve and regulatory agencies throughout the world change requirements for CDx, pharma companies have to continually adjust their global CDx strategies. In this talk, we will discuss some of the recent changes, challenges and solutions.

4:00 Companion Diagnostic Strategies in Oncology Early Development
Christopher Conn, PhD, Director, Companion Diagnostics, AbbVie

Increased focus on targeted patient populations in oncology drug development has led to a rise in the requirement for fit-for-purpose assays that can select the intended patient population in early oncology programs. This creates a need to implement comprehensive strategies for CDx development early on and balance the investment approach with the biomarker complexity and probability of success. Best practices related to these challenges will be reviewed.

4:30 Realizing the Clinical Value of Ultra-Sensitive Liquid Biopsy Technology
Frederick S. Jones, PhD, Senior Director, Life Science Medical Affairs, Sysmex Inostics

Plasma-Safe-SeqS (SafeSEQ), an ultra-sensitive NGS liquid biopsy, can aid cancer drug development, treatment guidance and monitoring, in addition to post-treatment recurrence monitoring. Dr. Fred Jones discusses the clinical value of SafeSEQ by reviewing therapy de-escalation of HPV+ HNSCC patients and monitoring PIK3CA and ESR1 low-level mutations in breast cancer.

4:45 Sponsored Presentation *(Opportunity Available)*

5:00 Collaborating with a Partner to Develop a Companion Diagnostic: A Pharma Perspective from Late Phase Development
Mike Zou, PhD, Leader, Companion Diagnostics, Daiichi Sankyo, Inc.

Pharma-Diagnostic partnership has become a standard practice for most drug development programs under the Rx/Dx co-development principle. However, successful collaborations often take meticulous planning and execution with flexibility on both ends to overcome constant challenges and deliver on time with highest possible quality for the developed diagnostics. This presentation will highlight some considerations from the pharma perspective at different stages of working with a diagnostic partner.

5:30 Close of Day

WEDNESDAY, FEBRUARY 23

7:30 am Registration Open and Morning Coffee (Indigo West Foyer AB)

KEYNOTE LOCATION: Indigo A

PLENARY KEYNOTE SESSION: PRECISION MEDICINE AT BIG PHARMA

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Edward Abrahams, PhD, President, Personalized Medicine Coalition

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Ruth E. March, PhD, Senior Vice President & Head, Precision Medicine & Biosamples, AstraZeneca
Precision medicine uses diagnostic tests to match the right drugs to patients most likely to respond. As science advances through the use of advanced analytics, artificial intelligence and integrated sources of biomarker data, we need a new generation of diagnostic tests. Following the patient journey in different treatment settings offers opportunities to all patients to be able to gain access to appropriate diagnostic solutions.

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9:40 Coffee Break in the Exhibit Hall with Poster Viewing (Indigo BFGCDH)

ROOM LOCATION: Indigo 202 B

BIOMARKERS FOR DRUG DEVELOPMENT AND PRECISION MEDICINE

10:20 Chairperson's Remarks
Amanda Oran, PhD, Genomic Development Specialist, Center for Personalized Diagnostics, University of Pennsylvania

10:25 Towards the Identification of Biomarkers of NASH/NAFLD Disease Progression
Vincent Mikol, PhD, Head, Translational Sciences, Sanofi R&D
Diagnosis of disease severity is an important issue as noninvasive diagnostic biomarker is lacking. Analysis of the ABOS cohort led to the stratification of 800 patients in three distinct groups according to their liver status. A multi-omics analysis was performed from plasma/serum, miRNA sequencing from liver biopsies, RNAseq on a subset of samples from extreme phenotypes with unequivocal diagnosis. Predictive disease biomarker candidates have been identified which are being further validated.

10:55 Moving with the Crowd: Development and Validation of a Large Hybrid Capture NGS Panel Using a Shared Platform Model
Amanda Oran, PhD, Genomic Development Specialist, Center for Personalized Diagnostics, University of Pennsylvania

11:25 The Revolution of Liquid Biopsies: A Change in Perspective
Lourdes Barrera, PhD, Executive Director, Global Medical Affairs, Merck
The analysis of tumors using biomarkers in blood is already transforming treatment selection and it may have utility at almost every stage of the management of patients with cancer, but it will also bring clinical implementation challenges. Machine learning or artificial intelligence may facilitate some of these processes. We will review these and other options to understand how we could accelerate this transformation.

11:55 Sponsored Presentation *(Opportunity Available)*

12:25 pm Session Break

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

1:30 Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing (Indigo BFGCDH)

CLINICAL BIOMARKERS AND PRECISION MEDICINE: BEYOND ONCOLOGY

2:00 Chairperson's Remarks
Sam Hanash, MD, PhD, Director, Red & Charline McCombs Institute; Evelyn & Sol Rubenstein Distinguished Chair, Cancer Prevention; Professor, Clinical Cancer Prevention-Research, Translational Molecular Pathology, University of Texas MD Anderson Cancer Center

2:05 Precision Medicine Beyond Oncology
Maria C. M. Orr, PhD, FRSB, Head of Precision Medicine, Biopharmaceuticals, AstraZeneca

Over the past two decades, precision medicine has transformed the treatment of cancer by understanding disease biology and targeting treatment appropriately. Using the same approaches we can revolutionize the way that we treat other major diseases – targeting the right medicine to the right patient. In this presentation, I will outline the progress that is being made in this field and the impact that this will have on the future.

2:35 Development of Biomarkers to Assess Target Engagement in Cardiovascular, Renal and Metabolic Diseases

Pia Davidsson, PhD, Head, Biomarkers, AstraZeneca R&D

Biomarker driven decisions from preclinical research through clinical phases increase the probability of success by the ability to make accurate assessment of treatment and enable optimal clinical management of patients. When each drug discovery project enters the portfolio, a dedicated biomarker strategy is therefore developed. I will present examples on biomarker development in cardiovascular and renal diseases showing how the target engagement can change by mode-of action and modality.

3:05 Breakthrough Therapies Powered by Transformative Precision Medicine Approaches

Juergen Scheuenpflug, PhD, Global Head, Clinical Biomarkers & Companion Diagnostics, Merck KGaA

Transformative precision medicine approaches integrate disease root cause identification, prediction of disease dynamics, and medical interventions guided by understanding of pharmacodynamic up- and downstream effects which allows to optimize and deepen responses at individual patient level. AI/ML powered translational research generated clinically actionable insights for new targets, early interventions/maintenance settings, and combination therapies. Digital pathology, radiomics, and advanced clinical genomics platform approaches are key enablers to develop precision oncology therapies.

INTERACTIVE DISCUSSIONS

3:35 Interactive Discussions (In-person only)

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

4:05 Session Break

BIOMARKER-ENABLED PRECISION CANCER THERAPY

4:15 Circulating Exosomes as a Liquid Biopsy Approach for Precision Cancer Therapy

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

Circulating exosomes have emerged as means for a multitude of cancer applications including early detection, tumor molecular classification, prediction of therapeutic response, and monitoring of tumor progression and regression. The informative value of circulating exosomes across several types of solid tumors will be presented that are indicative of the value of circulating exosomes as a liquid biopsy approach.

4:45 Biomarker Combinations to Guide Combinatorial Cancer Treatment

George Vasmatzis, PhD, Assistant Professor, Lab Medicine & Co-Director, Biomarker Discovery Program, Mayo Clinic & Foundation

We have developed a functional genomics engine that consists of a multi-interdisciplinary team of clinicians, pathologists and scientists, utilizing the latest comprehensive genomics tools and preclinical models dedicated to improving patient outcomes by tailoring therapy according to the compendium of alterations of the patient's cancer. Knowledge that is gained by this system leads to novel biomarkers that if validated can be translated to clinical tests in a CLIA environment.

5:15 Close of Conference

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Conference Venue and Hotel:
Hilton San Diego Bayfront
1 Park Boulevard
San Diego, CA 92101

Discounted Room Rate: $264
Discounted Room Rate Cut-off Date: January 21, 2022

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Includes access to the entire 3-day Molecular & Precision Medicine Tri-Conference (February 21-23, 2022) – all the Conference Tracks, plus the Plenary Keynote Programs, Poster Sessions, Sponsored Talks and Exhibit Hall. In addition, post-Event, you will receive access to On-Demand Program for one year.

	Commercial	Academic, Government, Hospital-affiliated
Standard Registration and On-Site	$2,549	$1,249

CONFERENCE TRACK SELECTION

Choose one from each column. *Per your registration above, please help us arrange for appropriate capacity by indicating the Conferences you plan to spend most of your time. However, you are allowed to attend In-Person and/or Virtually and move between all of the Conference Program presentations. Track hopping is encouraged.*

Mon Feb 21, 2022 – Tue Feb 22, 2022	Tue Feb 22, 2022 – Wed Feb 23, 2022
C1A: Precision Health *-OR-*	C1B: Diagnostics Innovation and Market Access *-OR-*
C2A: At-Home & Point-of-Care Diagnostics *-OR-*	C2B: Infectious Disease Diagnostics *-OR-*
C3A: Circulating Tumor Cells and Liquid Biopsy *-OR-*	C3B: Precision Oncology *-OR-*
C4A: Spatial Biology & Single-Cell Analysis	C4B: Clinical Biomarkers & Companion Diagnostics

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** CHI reserves the right to publish your poster content in various marketing materials and products*

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

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