31st International

Precision Med TRI-CON

March 26-28, 2024 | Hilton San Diego Bayfront San Diego, CA

Over 30 Years of Connecting the Precision Medicine Community

2024 Conference Programs

March 26-27

- AI in Precision Medicine
- Implementing Precision Medicine
- At-Home & Point-of-Care Diagnostics
- Liquid Biopsy
- Spatial Biology

March 27-28

- Artificial Intelligence in Diagnostics
- Diagnostics Market Access
- Infectious Disease Diagnostics
- Multi-Cancer Early Detection
- Single-Cell Multiomics

Final Days to Register!

Featured Speakers

Eric Topol
Founder, Scripps Research Translational Institute

Mara Aspinall
Partner, Illumina Ventures

Kari Stefansson
CEO, deCODE genetics

Atul Butte
Chief Data Scientist, University of California Health

Jean-Francois Martini
Diagnostics Lead, Oncology, Pfizer

Jonathan Carlson
Managing Director, Microsoft Health Futures

Jeffrey Venstrom
CMO, GRAIL

Anthony Sireci
Senior Vice President, Diagnostics Development, Loxo Oncology, Eli Lilly

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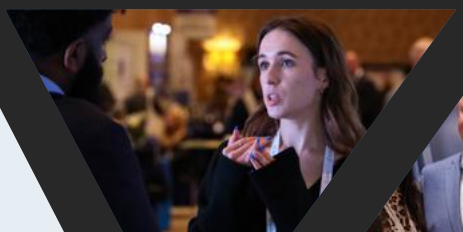
- Single-Cell Multiomics

> TRI-CON 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*

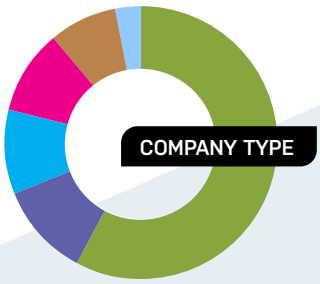
Over 30 Years of Connecting the Precision Medicine Community

For three decades, the Precision Med TRI-CON has served as the leading international meeting place for the diagnostics and precision medicine community. Join thousands of international thought leaders to discuss the latest research, technologies, innovation, and business models in implementing precision medicine, biomarkers and companion diagnostics, genomic medicine, and precision health; innovation and market access strategies for at-home diagnostics, point-of-care testing, and molecular diagnostics for infectious diseases; liquid biopsy and advanced diagnostics for precision oncology, including multi-cancer early detection and minimal residual disease testing. Emerging implications of faster and cheaper sequencing, AI and digital tools, and spatial biology and single-cell multiomics in advancing precision medicine will be covered in 2024. Join us in sunny San Diego for the in-person networking and visionary and thought-provoking keynote discussions you've come to expect from the TRI-CON!

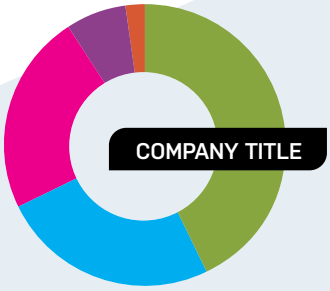


2023

Attendee Demographics



58% Biotech/Commercial
11% Academic
10% Healthcare
10% Services/Societies
8% Pharma
3% Other



43% Executive
25% Sales & Marketing
23% Scientist
7% Manager
2% Other

Sponsorship & Exhibit Opportunities

Exhibitors will have an opportunity to enjoy in-person and virtual facilitated networking opportunities with qualified delegates, making it the perfect platform to launch a new product, collect feedback, and generate new leads from around the world.

How Sponsoring/Exhibiting Promotes & Benefits Your Business:

- Generate qualified leads consisting of actual decision-makers from within your focus area
- Network with senior-level professionals and generate leads during dedicated exhibit hall hours, lunches, etc.
- Promote your company's participation in the Event Materials—including contact information and 50-word description
- Increase your brand awareness and drive traffic to your website through our various marketing campaigns
- Increase dedicated networking time in the exhibit hall

Podium Presentations

Available within Main Agenda!

Showcase your solutions to a guaranteed, targeted audience through a 15- or 30-minute presentation during a specific conference program, breakfast, or lunch. Package includes exhibit space, onsite branding, and access to cooperative marketing efforts by CHI. For the luncheon option, lunches are delivered to attendees already seated in the main session room. Presentations do sell out early.

One-on-One Meetings

Work with us to identify your target prospects and we will schedule meetings for you. Think of us as your inside sales team with all your hottest leads in close reach. Opportunities sold on a very limited basis.

Exhibit Hall Networking Reception Sponsorship

Your company will be recognized as the exclusive sponsor of either the Welcome Reception on day 1 or the Networking Reception on day 3 to be held in the Exhibit Hall. Use this lively social occasion to launch a new product or solution and drive delegates to your exhibit booth.

Invitation-Only Dinner/Hospitality Suite

Sponsors will select their top prospects from the conference preregistration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations, conduct follow-up, and confirm attendees. The evening will be customized to meet with your specific objectives.

Additional sponsorship & branding opportunities include:

- Wall of Fame (Meter Boards)
- Meter Boards
- Lanyards
- Foot Trails—NEW
- Keynote Chair Drop
- Tote Bag Exclusive Sponsorship
- Water Bottles
- Conference Track Notebooks
- Tote Bag Insert
- Chair Drop in Session Room

How will CHI ensure that delegates visit the exhibit hall?

- Welcome receptions
- Themed functions
- Refreshment breaks
- Exhibit Hall Booth Crawl
- Raffles and more

For additional information, please contact:

Katelin Fitzgerald
Sr. Manager, Business Development
781-247-1824
kfitzgerald@cambridgeinnovationinstitute.com

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March 26-27, 2024

Plenary Keynote Program

TUESDAY, MARCH 26

PLENARY KEYNOTE SESSION: CONVERGENCE OF ARTIFICIAL INTELLIGENCE AND GENOMICS

8:00 Chairperson's Remarks
Kevin Davies, PhD, Executive Editor, The CRISPR Journal; Author, Editing Humanity: The CRISPR Revolution and the New Era of Genome Editing

8:05 Sponsored Presentation *(Opportunity Available)*

8:15 The Genomics/AI Revolution: A Fireside Chat with Kari Stefansson


Kevin Davies, PhD, Executive Editor, The CRISPR Journal; Author, Editing Humanity: The CRISPR Revolution and the New Era of Genome Editing
Kari Stefansson, MD, PhD, CEO, deCODE genetics
Kari Stefansson built deCODE Genetics in Iceland into a groundbreaking organization that fueled major advances in uncovering the genomic basis of genetic diseases and cancers. Over the past decade, deCODE has provided the genomics engine to spur Amgen's drug development and clinical programs. In this plenary fireside chat, Stefansson shares insights about deCODE's journey, the future of genomic medicine, and the myriad applications of AI in genomic and biopharma research.

8:45 PANEL DISCUSSION: AI and Genomics Come Together





Moderator: Kevin Davies, PhD, Executive Editor, The CRISPR Journal; Author, Editing Humanity: The CRISPR Revolution and the New Era of Genome Editing
Artificial intelligence (AI) promises to enable the analysis of trillions of genomic, molecular, clinical, and epidemiological data points, offering unprecedented insights into health and disease, the development of drugs and diagnostics, and empowering precision medicine. Our distinguished panel will review the opportunities, challenges, and innovations in applying emerging AI tools to biological data, and their potential to revolutionize drug development, diagnostics, and precision medicine.
Panelists:
Kari Stefansson, MD, PhD, CEO, deCODE genetics
Atul Butte, PhD, Chan & Zuckerberg Distinguished Professor & Director, University of California, San Francisco
George Vacek, PhD, MBA, Global Head, Genomics Alliances, NVIDIA
Jonathan M. Carlson, PhD, Managing Director, Microsoft Health Futures

PLENARY KEYNOTE SESSION: ARTIFICIAL INTELLIGENCE FOR PRECISION MEDICINE

4:10 Chairperson's Remarks
Mara G. Aspinall, Partner, Illumina Ventures; Professor of Practice, Arizona State University; Editor, Sensitive & Specific: The Testing Newsletter

4:15 FIRESIDE CHAT: Artificial Intelligence Innovation for Precision Medicine


Mara G. Aspinall, Partner, Illumina Ventures; Professor of Practice, Arizona State University; Editor, Sensitive & Specific: The Testing Newsletter
Eric Topol, MD, Founder and Director, Scripps Research Translational Institute; Executive Vice President and Professor, Scripps Research
A visionary at the intersection of medicine and technology, Dr. Eric Topol articulates the big picture for radical improvement in healthcare through personalized and data-driven medicine. Eric published three books, over 1,200 peer-reviewed publications, and provides his reasoned perspective on medical AI on social media. We will discuss his views on the current state of precision medicine and artificial intelligence, including generative AI in medicine, diagnostics, and clinical trials.

4:45 PLENARY KEYNOTE PANEL DISCUSSION: AI in Precision Medicine: Innovation and Growth Opportunities



Moderator: Mara G. Aspinall, Partner, Illumina Ventures; Professor of Practice, Arizona State University; Editor, Sensitive & Specific: The Testing Newsletter
The convergence of artificial intelligence (AI) and precision medicine promises to revolutionize health care. Generative AI, machine learning, and sophisticated computational power promise to enable clinical decision support and diagnostics, support drug development, and optimize personalized medicine.
Panelists:
Eric Topol, MD, Founder and Director, Scripps Research Translational Institute; Executive Vice President and Professor, Scripps Research
Michael J. Alkire, President and CEO, Premier, Inc.

WEDNESDAY, MARCH 27

PLENARY KEYNOTE SESSION: THE STATE OF INNOVATION IN DIAGNOSTIC TESTING FOR PERSONALIZED MEDICINE

8:00 Chairperson's Remarks
Edward Abrahams, PhD, President, Personalized Medicine Coalition

8:05 Sponsored Presentation *(Opportunity Available)*

8:15 PANEL DISCUSSION: The State of Innovation in Diagnostic Testing for Personalized Medicine





Moderator: Edward Abrahams, PhD, President, Personalized Medicine Coalition
Integrating diagnostics into clinical care faces numerous challenges, including regulatory, reimbursement, and clinical adoption among others, before the promise of personalized medicine can be realized. This panel, with support from the Personalized Medicine Coalition, will consider these barriers and propose solutions to overcome them.
Panelists:
Peter Bach, MD, CMO, Delfi Diagnostics
Christopher Conn, PhD, Global Director, Clinical Biomarkers & Diagnostics, Diagnostics Strategy Lead, Amgen
Jeffrey Venstrom, MD, CMO, GRAIL
Helmy Eltoukhy, PhD, Co-CEO, Guardant Health

2024 Featured Speakers

Precision Med TRI-CON

Eric Topol
Founder, Scripps Research Translational Institute

Mara Aspinall
Partner, Illumina Ventures

Kari Stefansson
CEO, deCODE genetics

Atul Butte
Chief Data Scientist, University of California Health

Anthony Sireci
Senior Vice President, Diagnostics Development, Loxo Oncology, Eli Lilly

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

Jeffrey Venstrom
CMO, GRAIL

Razelle Kurzrock
CMO, Worldwide Innovative Network for Personalized Cancer Therapy

Jonathan Carlson
Managing Director, Microsoft Health Futures

Sonya Makhni
Medical Director, Mayo Clinic Platform

Ezra Cohen
CMO, Oncology, Tempus Labs

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

Jean-Francois Martini
Diagnostics Lead, Oncology, Pfizer

Lourdes Barrera
Executive Director, Precision Medicine, Merck

Christopher Hartshorn
Chief, Digital & Mobile Technologies, NCATS

Jai Pandey
Head, Global Device Regulatory IVD/CDx, Sanofi

George Vacek
Global Head, Genomics Alliances, NVIDIA

Larry Kessler
Co-Chair, MCED Consortium

Peter Bach
CMO, Delfi Diagnostics

Hoi-Ying Elsie Yu
Laboratory Director, Point-of-Care Testing, Geisinger Health

Jonathan Beer
Senior Director, Diagnostic Science, Bristol Myers Squibb

Edward Abrahams
President, Personalized Medicine Coalition

Jennifer Quigley
Senior Director, Precision Diagnostics, Novartis

Scott Penberthy
Managing Director, Applied AI, Google Cloud

Sudhir Srivastava
Chief, Cancer Biomarkers Research, NCI

TUESDAY, MARCH 26

7:00 am Registration and Morning Coffee

PLENARY KEYNOTE SESSION: CONVERGENCE OF ARTIFICIAL INTELLIGENCE AND GENOMICS

8:00 Chairperson's Remarks
Kevin Davies, PhD, Executive Editor, The CRISPR Journal; Author, Editing Humanity: The CRISPR Revolution and the New Era of Genome Editing

8:05 Plenary Keynote Introduction
Keynote Introduction
Damian Verdnik, PhD, Director, Diagnostics, Dx PMO, Invetech

8:15 FIRESIDE CHAT: Convergence of Artificial Intelligence and Precision Oncology


Kevin Davies, PhD, Executive Editor, The CRISPR Journal; Author, Editing Humanity: The CRISPR Revolution and the New Era of Genome Editing
Douglas Flora, MD, Executive Medical Director, Oncology Services, St. Elizabeth Healthcare; Editor-in-Chief, AI in Precision Oncology Journal
Artificial Intelligence (AI) is exhibiting immense power to transform the practice of science and medicine, from genome analysis and drug discovery to health data and the practice of medicine. Nowhere is this more evident than in the field of oncology. Dr. Flora will share his AI epiphany and offer real-world examples of how AI is already changing the practice of medicine—at his organization (St. Elizabeth Healthcare) and beyond.

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Panelists:
Kari Stefansson, MD, PhD, CEO, deCODE genetics
Atul Butte, MD, PhD, Distinguished Professor and Institute Director, University of California
Pankaj Vats, PhD, Senior Bioinformatics/Genomics Scientist, NVIDIA
Jonathan M. Carlson, PhD, Managing Director, Microsoft Health Futures

9:30 Refreshment Break

AI FOR DISCOVERY AND DEVELOPMENT OF PRECISION THERAPIES

9:45 Chairperson's Remarks
Geoff McCleary, Vice President, Global Connected Health, Capgemini

9:50 Precisely Practicing Medicine from 700 Trillion Points of Data
Atul Butte, MD, PhD, Distinguished Professor and Institute Director, University of California
There is an urgent need to take what we have learned in our new data-driven era of medicine and use it to create a new system of precision medicine, delivering the best, safest, cost-effective preventative or therapeutic intervention at the right time, for the right patients. We build and apply tools that convert trillions of points of molecular, clinical, and epidemiological data into diagnostics, therapeutics, and new insights into disease.

10:20 Harnessing Human Genetics with AI
Kari Stefansson, MD, PhD, CEO, deCODE genetics

10:50 Artificial Intelligence in Therapeutic Discovery, Development, and Delivery: From Multimodal Analysis to Individualized Treatments
Sean Khozin, MD, MPH, CEO, CEO Roundtable on Cancer and Project Data Sphere | Founder, Phyusion | Research Affiliate, MIT
AI is catalyzing rational drug discovery and design using multimodal data and playing a pivotal role in optimizing Phase 1 trial designs. AI-powered approaches are also reshaping clinical development programs through methods such as covariate adjustments and complex biomarkers. The intersection of AI at the point-of-care underscores its capacity to enable personalized treatments via data-driven insights delivered as clinical decision support tools.

11:20 Enjoy Lunch on Your Own

12:55 pm Session Break

INTEGRATING ARTIFICIAL INTELLIGENCE INTO PRECISION MEDICINE

1:10 Chairperson's Remarks
Chris M. Hartshorn, PhD, Chief, Digital & Mobile Technologies Section—CTSA Program, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH)

1:15 Challenges to Precision X (Health, Medicine, Oncology, Nutrition, etc.): The Need for AI/ML to Become Transformational & the NIH Approach
Chris M. Hartshorn, PhD, Chief, Digital & Mobile Technologies Section—CTSA Program, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH)
A recent topic of much discussion has been the use of AI/ML for healthcare application; its use for biomedical research is not novel, though its clinical use has increased substantially of late—and simultaneously, understanding of its current limitations. The talk will focus on the challenges of bringing AI/ML to its 'big data' analytical endpoint for the totality of medical evidence, and the NIH funding landscape aiming to address these.

1:45 Integration of AI-Accelerated Solutions in Healthcare to Transform Precision Medicine
Pankaj Vats, PhD, Senior Bioinformatics/Genomics Scientist, NVIDIA
AI-driven platforms are significantly advancing the field of precision medicine, enabling rapid genetic diagnosis, accelerating genomic analysis, and leading the way in drug discovery. Case studies highlight the transformative impact of these technologies such as Nanopore genome sequencing for rapid genetic diagnosis in critical care; GPU-Accelerated analysis of population-scale genomic datasets, and generative AI for small-molecule drug discovery.

2:15 Unlocking the Future: Implementing Precision Medicine with the Power of AI

Partha Das, MD, Global Medical Director, Precision Medicine & Pipeline, Janssen Oncology

The presentation will explore the transformative potential of AI in healthcare. It begins by defining precision medicine and highlighting its promises, including improved outcomes and cost savings. The challenges in implementing precision medicine are discussed, leading to the introduction of AI as a solution. The presentation showcases AI applications across genomics, drug development, diagnostics, and more, with case studies demonstrating its impact.

2:45 AI Unlocks the Clinical Utility of Spatialomics

Robert Cook, PhD, Senior Vice President, Research & Development, Castle Biosciences

Spatialomics provides a rich data set to interrogate multiple pathways of disease in parallel. Using Artificial Intelligence to interpret these pathways has the potential to unlock new understanding with profound abilities to improve patient management. This talk will explore how this synergy of AI and spatialomics has been used and validated in Barrett's esophagus to predict a patient's future risk of progression to esophageal adenocarcinoma.

3:00 Session Break

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

PLENARY KEYNOTE SESSION: ARTIFICIAL INTELLIGENCE FOR PRECISION MEDICINE

4:10 Chairperson's Remarks

Mara G. Aspinall, Partner, Illumina Ventures; Professor of Practice, Arizona State University; Editor, Sensitive & Specific: The Testing Newsletter

4:15 FIRESIDE CHAT: Artificial Intelligence Innovation for Precision Medicine


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Michael Pellini, MD, General Partner, S32
Charity Williams, Partner, Cooley LLP

5:30 Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

6:30 Close of Day

WEDNESDAY, MARCH 27

7:30 am Registration and Morning Coffee

PLENARY KEYNOTE SESSION: THE STATE OF INNOVATION IN DIAGNOSTIC TESTING FOR PERSONALIZED MEDICINE

8:00 Chairperson's Remarks

Edward Abrahams, PhD, President, Personalized Medicine Coalition

8:05 Plenary Keynote Introduction

Paul Beresford, Vice President and General Manager, CDx, Agilent Technologies

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Jeffrey Venstrom, MD, CMO, GRAIL
Justin Odegaard, MD, PhD, Vice President, Clinical Development, Guardant Health
Paul Beresford, Vice President and General Manager, CDx, Agilent Technologies

9:00 Transition to Sessions

ARTIFICIAL INTELLIGENCE IN PRECISION ONCOLOGY

9:05 Chairperson's Remarks
Douglas Flora, MD, Executive Medical Director, Oncology Services, St. Elizabeth Healthcare; Editor-in-Chief, AI in Precision Oncology Journal

9:10 AI in Medicine—Is the Promise Real?
Douglas Flora, MD, Executive Medical Director, Oncology Services, St. Elizabeth Healthcare; Editor-in-Chief, AI in Precision Oncology Journal
Dr. Flora will delve into the fascinating world of Artificial Intelligence (AI) in Medicine. Attendees will gain valuable insights into the current applications and future possibilities of AI in the medical field. The talk will serve as a primer for clinicians, industry experts, and researchers who are eager to understand whether the hype surrounding AI in Medicine is justified or merely an illusion.

10:10 Informed, Data-Driven Patient Care in Oncology
Ezra Cohen, MD, CMO, Oncology, Tempus Labs, Inc.
A decade ago, somatic genome sequencing disrupted oncologic management paradigms by informing personalization of therapy. Presently, the combination of multiomic, pathologic, radiographic, and clinical data is further revolutionizing oncology by shifting from personalized to truly individualized care. This lecture will discuss some technologies being developed to improve treatment decisions and patient outcomes.

10:40 Coffee Break in the Exhibit Hall with Poster Viewing biodesix

11:25 The Rise of Phenomics
Scott Penberthy, PhD, Managing Director, Applied AI, Google Cloud
Phenomics is a new, AI-driven approach to oncology and health care pioneered by Dr. Leroy Hood, a pioneer of genomics, next-generation sequencing, and the human genome project. We'll discuss how phenomics combines data from nanoscale, next-generation sequencing reads to the daily steps on a Fitbit to diagnose, debug, and repair our bodies in often dramatic ways—today.

11:55 PANEL DISCUSSION: Navigating the AI Revolution in Precision Oncology
Moderator: Sanjay Juneja, MD, Hematologist & Medical Oncologist, Mary Bird Perkins Cancer Center
The discovered value of precision and molecular therapy, both on a tumor level as well as that relating to germline polymorphisms, has made the research and discovery of clinically relevant biomarkers explode. In a field already starved for physicians to fulfill our country's unmet cancer needs, how can AI immediately alleviate the growing concerns of health inequity as it relates to democratizing optimal care?

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Douglas Flora, MD, Executive Medical Director, Oncology Services, St. Elizabeth Healthcare; Editor-in-Chief, AI in Precision Oncology Journal
Ezra Cohen, MD, CMO, Oncology, Tempus Labs, Inc.
Scott Penberthy, PhD, Managing Director, Applied AI, Google Cloud
Sean Khozin, MD, MPH, CEO, CEO Roundtable on Cancer and Project Data Sphere | Founder, Phyusion | Research Affiliate, MIT

12:55 pm Session Break

1:00 Enjoy Lunch on Your Own

1:30 Refreshment Break in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

2:00 Close of Artificial Intelligence in Precision Medicine Conference

TUESDAY, MARCH 26

7:00 am Registration and Morning Coffee

PLENARY KEYNOTE SESSION: CONVERGENCE OF ARTIFICIAL INTELLIGENCE AND GENOMICS

8:00 Chairperson's Remarks
Kevin Davies, PhD, Executive Editor, The CRISPR Journal; Author, Editing Humanity: The CRISPR Revolution and the New Era of Genome Editing

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Atul Butte, MD, PhD, Distinguished Professor and Institute Director, University of California
Pankaj Vats, PhD, Senior Bioinformatics/Genomics Scientist, NVIDIA
Jonathan M. Carlson, PhD, Managing Director, Microsoft Health Futures

9:30 Refreshment Break

COMPANION DIAGNOSTICS IMPLEMENTATION AND CLINICAL ADOPTION

9:45 Chairperson's Remarks
Hakan Sakul, PhD, Owner and President, Precision Dx Strategies, Inc.

9:50 Regulatory Considerations for Companion Diagnostic Devices
Jai Pandey, PhD, Head, Global Device Regulatory IVD/CDx and Digital Health, Sanofi
Companion diagnostic devices play a crucial role in personalized medicine by helping healthcare professionals identify the most appropriate treatment for a patient based on their genetic, molecular, or other specific characteristics. Due to the unique nature of these devices, there are several regulatory considerations that must be taken into account to ensure their safety and effectiveness. These considerations include regulatory authorities, classification, clinical and analytical validation, and labeling.

10:20 PANEL DISCUSSION: What's Holding Back CDx from Wider Global Clinical Adoption?
Moderator: Hakan Sakul, PhD, Owner and President, Precision Dx Strategies, Inc.
Despite the availability of CDx testing for many precision medicine drugs, several barriers remain to their global adoption including value-based reimbursement and changing regulatory landscape (especially US-FDA, China, and EU-IVDR regulations). These and other factors hindering effective commercialization of CDx tests and global patient access will be discussed.
Panelists:
Andrea L. Stevens, PhD, Senior Director, Global Precision Medicine Access Strategy, Janssen Pharmaceuticals, Inc.
Jennifer Quigley, Senior Director, Global Precision Diagnostics, Novartis
Jai Pandey, PhD, Head, Global Device Regulatory IVD/CDx and Digital Health, Sanofi
Jennifer Faikish, Global Head, Commercial Biomarkers and Diagnostics, Amgen

11:20 Novel genomic strategies for diagnostic development in hereditary diseases
Huw Ricketts, QIAGEN,, Translational Science & Precision Diagnostics, QIAGEN
William Lee, Senior Vice President, Chief Science Officer, Research & Development, Helix, Inc.
Precision diagnostics has long been adopted within the treatment of cancer patients but adoption in non-oncology diseases has been slow. QIAGEN and Helix have formed a partnership to address the growing need of genetic characterization of patients prior to treatment with precision medicines. The partnership aims to a develop globally accessible whole exome sequencing IVD solution. QIAGEN and Helix will describe the need for standardized WES assays for non-oncology diseases.

11:50 Session Break

11:55 LUNCHEON PRESENTATION: Using Advanced Molecular Diagnostics to Improve Risk-Aligned Patient Care and Patient Outcomes
Matthew Goldberg, M.D., Senior Vice President, Medical, Castle Biosciences
Precision medicine tools are useful when grounded in addressing unmet clinical needs and applied by clinicians to inform patient management decisions. Advanced molecular diagnostics are being used in dermatology to improve the care of skin cancer patients based on the gene expression profile of their tumor. This talk will explore how using these tests are aiding in diagnostic accuracy, enhanced risk stratification and risk-aligned treatment pathways that can improve patient outcomes.

12:25 pm Session Break

IMPLEMENTING PRECISION ONCOLOGY

1:10 Chairperson's Remarks
Daryl Pritchard, PhD, Senior Vice President, Science Policy, Personalized Medicine Coalition

1:15 The Futures of Genomics in Cancer Care: Choose Your Adventure
Damon Hostin, Lead, Health System Market Access, Illumina, Inc.
The forces that have historically driven genomic testing in precision oncology are changing, and a new set of challenges and opportunities are presenting themselves. The healthcare and the industry ecosystem have been forced to evolve, with access and clinical quality in the balance. Technology is ever expanding with promise but needs to navigate both new and familiar challenges. This talk will approach these dynamics from a strategic perspective.

1:45 Implementing Precision Oncology: Addressing Clinical Practice Challenges
Anthony N. Sireci, MD, Senior Vice President, Clinical Biomarkers & Diagnostics Division, Loxo@Lilly
Despite the availability of many high-value precision oncology therapies, cancer patients who are eligible do not receive appropriate testing and/or targeted treatments due to clinical practice gaps related to diagnostic testing and the delivery of appropriate biomarker-indicated therapies. Modernized healthcare delivery policies and streamlined clinical practices are needed to address practice challenges and optimize precision oncology implementation.

2:15 PANEL DISCUSSION: Implementing Precision Oncology: Addressing Clinical Practice Challenges
Moderator: Daryl Pritchard, PhD, Senior Vice President, Science Policy, Personalized Medicine Coalition
Clinical practice gaps related to diagnostic testing and the delivery of appropriate biomarker-indicated therapies are hampering the delivery of precision oncology. Panelists will discuss the impact of these practice gaps on clinical care and propose modernized healthcare delivery policies and streamlined clinical practices that can lead to more efficient precision oncology implementation.
Panelists:
Adrian Lee, PhD, Professor, Pharmacology & Chemical Biology, University of Pittsburgh
Anthony N. Sireci, MD, Senior Vice President, Clinical Biomarkers & Diagnostics Division, Loxo@Lilly
Noah Zimmerman, PhD, Vice President, Translational Science, Tempus

2:45 Beyond sequencing: CytoProfiling on AVITI24 Element Biosciences
Isaku Tanida, PhD, Associate Director, Product Management, Element Biosciences
In this session I will present the capabilities and potential of AVITI24, the newest innovation from Element Biosciences that advances its core Avidity Base Chemistry for CytoProfiling applications. Using AVITI24 I will show you how with one technician and 45 minutes hands on time, you can combine multiplexed, multi-omic, phosphoproteomic, and morphological studies with dose response and time dependence parameters to deliver analyzed results within 24 hours.

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

PLENARY KEYNOTE SESSION: ARTIFICIAL INTELLIGENCE FOR PRECISION MEDICINE

4:10 Chairperson's Remarks
Mara G. Aspinall, Partner, Illumina Ventures; Professor of Practice, Arizona State University; Editor, Sensitive & Specific: The Testing Newsletter

4:15 FIRESIDE CHAT: Artificial Intelligence Innovation for Precision Medicine


Mara G. Aspinall, Partner, Illumina Ventures; Professor of Practice, Arizona State University; Editor, Sensitive & Specific: The Testing Newsletter
Eric Topol, MD, Founder and Director, Scripps Research Translational Institute; Executive Vice President and Professor, Scripps Research
A visionary at the intersection of medicine and technology, Dr. Eric Topol articulates the big picture for radical improvement in healthcare through personalized and data-driven medicine. Eric published three books, over 1,200 peer-reviewed publications, and provides his reasoned perspective on medical AI on social media. We will discuss his views on the current state of precision medicine and artificial intelligence, including generative AI in medicine, diagnostics, and clinical trials.

4:45 PLENARY KEYNOTE PANEL DISCUSSION: AI in Precision Medicine: Innovation and Growth Opportunities




Moderator: Mara G. Aspinall, Partner, Illumina Ventures; Professor of Practice, Arizona State University; Editor, Sensitive & Specific: The Testing Newsletter
The convergence of artificial intelligence (AI) and precision medicine promises to revolutionize health care. Generative AI, machine learning, and sophisticated computational power promise to enable clinical decision support and diagnostics, support drug development, and optimize personalized medicine.
Panelists:
Chris M. Hartshorn, PhD, Chief, Digital & Mobile Technologies Section—CTSA Program, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH)
Michael Pellini, MD, General Partner, S32
Charity Williams, Partner, Cooley LLP

5:30 Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

6:30 Close of Day

WEDNESDAY, MARCH 27

7:30 am Registration and Morning Coffee

PLENARY KEYNOTE SESSION: THE STATE OF INNOVATION IN DIAGNOSTIC TESTING FOR PERSONALIZED MEDICINE

8:00 Chairperson's Remarks
Edward Abrahams, PhD, President, Personalized Medicine Coalition

8:05 Plenary Keynote Introduction
Paul Beresford, Vice President and General Manager, CDx, Agilent Technologies

8:15 PANEL DISCUSSION: The State of Innovation in Diagnostic Testing for Personalized Medicine





Moderator: Edward Abrahams, PhD, President, Personalized Medicine Coalition
Integrating diagnostics into clinical care faces numerous challenges, including regulatory, reimbursement, and clinical adoption among others, before the promise of personalized medicine can be realized. This panel, with support from the Personalized Medicine Coalition, will consider these barriers and propose solutions to overcome them.
Panelists:
Peter Bach, MD, CMO, Delfi Diagnostics
Christopher Conn, PhD, Global Director, Clinical Biomarkers & Diagnostics, Diagnostics Strategy Lead, Amgen
Jeffrey Venstrom, MD, CMO, GRAIL
Justin Odegaard, MD, PhD, Vice President, Clinical Development, Guardant Health
Paul Beresford, Vice President and General Manager, CDx, Agilent Technologies

9:00 Transition to Sessions

LABORATORY STEWARDSHIP FOR GENETIC TESTING

9:05 Chairperson's Remarks
Michael Astion, MD, PhD, Regional Medical Director & Professor, Laboratory Medicine and Pathology, Seattle Children's Hospital and the University of Washington

9:10 Medical Necessity Policies for Lab Tests: Challenges for Patients, Labs, Physicians, and Insurers
Michael Astion, MD, PhD, Regional Medical Director & Professor, Laboratory Medicine and Pathology, Seattle Children's Hospital and the University of Washington
Dr. Astion will share background and challenges associated with medical necessity policies for laboratory tests. These policies are foundational to the laboratory payment system in the US. Problems with medical necessity policies affect patients, labs, physicians, and insurers. The talk emphasizes: 1) methods for achieving alignment and collaboration among patients, labs, and payers; and 2) ideas for decreasing problems in policy that fall disproportionately on the most seriously ill patients.

9:40 Value Frameworks for Multi-Cancer Genetic Testing: A New Paradigm for Oncology Practice
Julie Wiedower, Director, Medical Affairs, Managed Care, Guardant Health
While technology assessment and coverage-decision frameworks used by insurance providers provide structure to a sea of heterogeneous evidence, stakeholders often cite the existing approaches as lacking elements specific to precision medicine. Following a conceptual analysis and literature review, a new value framework is proposed with a scoring system to enable a comprehensive evaluation of all evidence pertaining to multi-cancer genetic testing for hereditary and somatic evaluation, and potentially early detection.

10:10 Leveraging Technology to Identify the Right Patients for Genetic Testing
Molly McGinniss, Senior Director, Population Genomics and Precision Medicine, Genome Medical
Physicians face many challenges in accurately and efficiently ordering genetic tests, leading to inappropriate ordering practices. A critical first step in ensuring successful laboratory utilization practices is appropriately identifying patients who meet guideline criteria for genetic testing. Digital health tools with point-of-care testing offer scalable approaches to hereditary risk assessment. This session will explore the usability, yield, and other implementation outcomes specific to deployment in a variety of clinical settings.

10:40 Coffee Break in the Exhibit Hall with Poster Viewing

11:25 PANEL DISCUSSION: Laboratory Stewardship for Genetic Testing: Is It Possible to Increase Access to Testing, Collaborate with Insurers, *and* Get Paid?
Moderator: Michael Astion, MD, PhD, Regional Medical Director & Professor, Laboratory Medicine and Pathology, Seattle Children's Hospital and the University of Washington
Labs want to get paid for genetic testing. Insurers want to block waste. Patients want medically necessary tests without gigantic out-of-pocket expenses. Can an alignment be reached? This session examines the lab test payment system, looking for solutions in coding, administration, and medical necessity policies to achieve alignment. The session will be of interest to payers, labs, and test developers who are involved in genetic testing.
Panelists:
Julie Wiedower, Director, Medical Affairs, Managed Care, Guardant Health
Molly McGinniss, Senior Director, Population Genomics and Precision Medicine, Genome Medical
Ashley Arthur, Head of Market Access, GeneDx

11:55 Enjoy Lunch on Your Own

1:30 pm Refreshment Break in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

2:00 Close of Implementing Precision Medicine Conference

TUESDAY, MARCH 26

7:00 am Registration and Morning Coffee

PLENARY KEYNOTE SESSION: CONVERGENCE OF ARTIFICIAL INTELLIGENCE AND GENOMICS

8:00 Chairperson's Remarks
Kevin Davies, PhD, Executive Editor, The CRISPR Journal; Author, Editing Humanity: The CRISPR Revolution and the New Era of Genome Editing

8:05 Plenary Keynote Introduction
Keynote Introduction
Damian Verdnik, PhD, Director, Diagnostics, Dx PMO, Invetech

8:15 FIRESIDE CHAT: Convergence of Artificial Intelligence and Precision Oncology


Kevin Davies, PhD, Executive Editor, The CRISPR Journal; Author, Editing Humanity: The CRISPR Revolution and the New Era of Genome Editing
Douglas Flora, MD, Executive Medical Director, Oncology Services, St. Elizabeth Healthcare; Editor-in-Chief, AI in Precision Oncology Journal
Artificial Intelligence (AI) is exhibiting immense power to transform the practice of science and medicine, from genome analysis and drug discovery to health data and the practice of medicine. Nowhere is this more evident than in the field of oncology. Dr. Flora will share his AI epiphany and offer real-world examples of how AI is already changing the practice of medicine—at his organization (St. Elizabeth Healthcare) and beyond.

8:45 PANEL DISCUSSION: AI and Genomics Come Together





Moderator: Kevin Davies, PhD, Executive Editor, The CRISPR Journal; Author, Editing Humanity: The CRISPR Revolution and the New Era of Genome Editing
Artificial intelligence (AI) promises to enable the analysis of trillions of genomic, molecular, clinical, and epidemiological data points, offering unprecedented insights into health and disease, the development of drugs and diagnostics, and empowering precision medicine. Our distinguished panel will review the opportunities, challenges, and innovations in applying emerging AI tools to biological data, and their potential to revolutionize drug development, diagnostics, and precision medicine.
Panelists:
Kari Stefansson, MD, PhD, CEO, deCODE genetics
Atul Butte, MD, PhD, Distinguished Professor and Institute Director, University of California
Pankaj Vats, PhD, Senior Bioinformatics/Genomics Scientist, NVIDIA
Jonathan M. Carlson, PhD, Managing Director, Microsoft Health Futures

9:30 Refreshment Break

ADVANCES IN AT-HOME DIAGNOSTICS AND DIRECT-ACCESS TESTING

9:45 Chairperson's Remarks
Hoi-Ying Elsie Yu, PhD, System and Core Laboratory Director, Chemistry, Toxicology and Point-of-Care Testing, Geisinger Health System

9:50 Home Testing for Infectious Diseases and Chronic Disease Monitoring
Paul Yager, PhD, Professor, Department of Bioengineering, University of Washington
Having demonstrated a low-cost paper-based multiplexed system for home-based detection of bacterial and viral pathogen DNA or RNA, we are developing an equally user-friendly system to measure proteins and small molecules with ELISA-like precision and sensitivity. The immunoassay at home (IA@H) will be a home-based system for measuring the concentrations of multiple-protein and small-molecule biomarkers to extend health, monitor the progression of inflammatory diseases, and guide their treatment.

10:20 Improving Healthcare Delivery and Patient Engagement with Direct Access Tests
Hoi-Ying Elsie Yu, PhD, System and Core Laboratory Director, Chemistry, Toxicology and Point-of-Care Testing, Geisinger Health System
Traditionally, all clinical tests must be ordered by physicians. Direct Access Testing (DAT) is, however, done without prior physician authorization. Direct-to-consumer testing can take the form of at-home point-of-care testing, at-home sample collection, or traditional phlebotomy/laboratory testing at a clinical laboratory. In this presentation, we will discuss how DAT in the proper setting can drive healthcare delivery, promote health literacy, and simplify patients' lives.

10:50 Removing Barriers with in-Home Kidney Health Screening
Lesley Northrop, PhD, Chief Diagnostic Officer, Everly Health
Chronic kidney disease (CKD) affects 1 in 7 US adults, and over 90% with the disease are asymptomatic. Early screening and detection of kidney disease are associated with lower lifetime costs and better health outcomes in patients, often with other health conditions such as diabetes and high blood pressure. Allowing at-home testing to detect and monitor CKD markers allows healthcare gap closure in patients in care deserts.

11:20 Scalable Solutions for Antibody Development and Manufacturing
Jennifer McClure, Global Portfolio Manager, Custom Antibodies, MilliporeSigma, Diagnostics and Regulated Materials, MilliporeSigma
Sean Roenspie, Senior Scientist, Custom Antibodies Lead, MilliporeSigma, Diagnostics and Regulated Materials, MilliporeSigma
Increases in research and diagnostic immunoassay volumes coupled with pressure on global supply systems has highlighted the need for sustainable and robust means of producing critical antibodies. At MilliporeSigma, our antibody manufacturing capabilities enable us to provide complete support for custom antibody development and large-scale diagnostic manufacturing by using our custom antibody generation platform that utilizes recombinant technology and large-scale manufacturing optimization.

11:50 Session Break

11:55 LUNCHEON PRESENTATION: Accelerating Patient-Centered Diagnostics by Bringing Innovative Molecular Technologies to Point-of-Care Testing
Thomas Fouqueau, PhD, R&D Team leader, R&D, Meridian Bioscience
The COVID-19 pandemic has reinforced the importance of rapid and accurate diagnosis for disease management. Whether it's infectious diseases, cancer, or other health hazards, the patient's journey is guided by diagnostics from early detection and diagnosis to treatment, monitoring, and prevention. In

this session, you will learn how Meridian's innovative molecular diagnostic technologies such as qPCR and isothermal, are enabling the transition of diagnostic tests from clinical labs to near-patient testing.

12:25 pm LUNCHEON PRESENTATION: A Digital Bridge to Breakthrough: Scaling Diagnostic Innovations for the Modern Era

Care Evolution™

Apurv Soni, MD, PhD, Assistant Professor of Medicine, Director of Digital Medicine, Digital Medicine, UMass Chan Medical School

Thejas Suvarna, Director of Product, MyDataHelps, CareEvolution

This case-study on RADx initiatives introduces a digital, siteless protocol for COVID rapid at-home antigen testing that highlights significant fiscal and operational efficiencies. Realizing over $110 million in cost reductions, this model leverages technology as a digital bridge - paving the way to accelerate the path to FDA approval. We discuss the potential of digital models in real-world settings offering a scalable blueprint for diagnostic innovations.

12:55 Session Break

ADVANCES IN AT-HOME DIAGNOSTICS AND DIRECT-ACCESS TESTING (CONT.)

1:10 Chairperson's Remarks

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

1:15 Remote Specimen Collection and at-Home Testing Strategies: Where Do We Go from Here?

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

The SARS-CoV-2 pandemic impacted healthcare delivery systems and accelerated alternative delivery strategies. Remote specimen collection with samples sent to a central laboratory as well as at-home testing options have shifted the paradigm in the patient journey. The goal of this talk is exploring how laboratory medicine is pivoting to meet the needs of alternative delivery strategies for diagnostics, and the impact on the central laboratory.

1:45 At-Home Blood Microsampling: Innovations, Opportunities, and Challenges

Gregory Sommer, PhD, Scientific Discipline Director, Alternative Sample Collection, Labcorp

At-home, self-collection of capillary blood samples opens new opportunities to improve accessibility and compliance across many diagnostic fronts. This talk will provide an overview of new technologies and products enabling at-home specimen collection, describe recent validation efforts comparing capillary specimen accuracy versus gold-standard venous draws, and discuss the challenges facing widespread adoption of at-home microsampling solutions.

2:15 PANEL DISCUSSION: Direct Access Testing—What Can Be Done to Realize Its Full Potential?

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

Pregnancy and COVID tests are probably the two most widely used at-home tests. Limited tests for different clinical indications and at-home blood collection devices are among the top reasons that restricted their widespread use. From a clinical perspective, the subpar test accuracy and (sometimes) misleading marketing claims are concerns. In this panel discussion, different stakeholders will share their perspectives on where they see the market is going for at-home testing.

Panelists:

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

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

Gregory Sommer, PhD, Scientific Discipline Director, Alternative Sample Collection, Labcorp

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

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

PLENARY KEYNOTE SESSION: ARTIFICIAL INTELLIGENCE FOR PRECISION MEDICINE

4:10 Chairperson's Remarks

Mara G. Aspinall, Partner, Illumina Ventures; Professor of Practice, Arizona State University; Editor, Sensitive & Specific: The Testing Newsletter

4:15 FIRESIDE CHAT: Artificial Intelligence Innovation for Precision Medicine


Mara G. Aspinall, Partner, Illumina Ventures; Professor of Practice, Arizona State University; Editor, Sensitive & Specific: The Testing Newsletter

Eric Topol, MD, Founder and Director, Scripps Research Translational Institute; Executive Vice President and Professor, Scripps Research

A visionary at the intersection of medicine and technology, Dr. Eric Topol articulates the big picture for radical improvement in healthcare through personalized and data-driven medicine. Eric published three books, over 1,200 peer-reviewed publications, and provides his reasoned perspective on medical AI on social media. We will discuss his views on the current state of precision medicine and artificial intelligence, including generative AI in medicine, diagnostics, and clinical trials.

4:45 PLENARY KEYNOTE PANEL DISCUSSION: AI in Precision Medicine: Innovation and Growth Opportunities




Moderator: Mara G. Aspinall, Partner, Illumina Ventures; Professor of Practice, Arizona State University; Editor, Sensitive & Specific: The Testing Newsletter

The convergence of artificial intelligence (AI) and precision medicine promises to revolutionize health care. Generative AI, machine learning, and sophisticated computational power promise to enable clinical decision support and diagnostics, support drug development, and optimize personalized medicine.

Panelists:

Chris M. Hartshorn, PhD, Chief, Digital & Mobile Technologies Section—CTSA Program, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH)

Michael Pellini, MD, General Partner, S32

Charity Williams, Partner, Cooley LLP

5:30 Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

6:30 Close of Day

WEDNESDAY, MARCH 27

7:30 am Registration and Morning Coffee

PLENARY KEYNOTE SESSION: THE STATE OF INNOVATION IN DIAGNOSTIC TESTING FOR PERSONALIZED MEDICINE

8:00 Chairperson's Remarks
Edward Abrahams, PhD, President, Personalized Medicine Coalition

8:05 Plenary Keynote Introduction
Paul Beresford, Vice President and General Manager, CDx, Agilent Technologies

8:15 PANEL DISCUSSION: The State of Innovation in Diagnostic Testing for Personalized Medicine





Moderator: Edward Abrahams, PhD, President, Personalized Medicine Coalition
Integrating diagnostics into clinical care faces numerous challenges, including regulatory, reimbursement, and clinical adoption among others, before the promise of personalized medicine can be realized. This panel, with support from the Personalized Medicine Coalition, will consider these barriers and propose solutions to overcome them.
Panelists:
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Christopher Conn, PhD, Global Director, Clinical Biomarkers & Diagnostics, Diagnostics Strategy Lead, Amgen
Jeffrey Venstrom, MD, CMO, GRAIL
Justin Odegaard, MD, PhD, Vice President, Clinical Development, Guardant Health
Paul Beresford, Vice President and General Manager, CDx, Agilent Technologies

9:00 Transition to Sessions

MOBILE HEALTH, AI, AND DIGITAL TECHNOLOGIES FOR POINT-OF-CARE TESTING

9:05 Chairperson's Remarks
James Nichols, PhD, DABCC, FADLM, Professor of Pathology, Microbiology, and Immunology; Medical Director, Clinical Chemistry and POCT, Vanderbilt University School of Medicine

9:10 Advances in Mobile and Digital Technologies for Point-of-Care Diagnostics
James Nichols, PhD, DABCC, FADLM, Professor of Pathology, Microbiology, and Immunology; Medical Director, Clinical Chemistry and POCT, Vanderbilt University School of Medicine
Mobile health is revolutionizing healthcare, providing patients with access to critical services, personal data tracking, and doctors, regardless of their location. As the number of health applications for smartphones, wearables, tablets, and other digital technologies grows, more people will use them to take control of their own health. This session will explore mobile health technologies and how digital health is transforming the future of laboratory medicine.

9:40 The Role of Artificial Intelligence and Machine Learning for Laboratory and POCT Applications
Nam K. Tran, PhD, Professor, Pathology and Laboratory Medicine, University of California, Davis
Artificial intelligence (AI) and machine learning (ML) are poised to change not only our daily lives but also revolutionize the practice of medicine. Machine learning in particular has shown great promise in identifying testing errors, pattern recognition for image analysis, and analyzing complex datasets to predict disease. This presentation provides an overview of emerging areas where AI/ML can be used for laboratory and point-of-care testing.

10:10 Sponsored Presentation *(Opportunity Available)*

10:40 Coffee Break in the Exhibit Hall with Poster Viewing

DEVELOPMENT AND VALIDATION OF POCT AND AT-HOME DIAGNOSTICS AT THE NIH

11:25 RADically Speeding the Development and Validation of POC and Home-Based Diagnostics at the NIH: Lessons Learned and Future Directions
C. Taylor Gilliland, PhD, Senior Advisor for Innovation Programs, Office of the Director, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health
The National Institute of Biomedical Imaging and Bioengineering (NIBIB), through its Rapid Acceleration of Diagnostics Technology (RADx Tech) Program, helped lead the country through the COVID-19 pandemic by accelerating POC and home-based diagnostic development and catalyzing the fundamental shift towards the acceptance and widespread use of self-testing. The RADx Tech program represents a new paradigm by which NIBIB, in partnership with others, can drive innovation in medical technology R&D.

11:55 PANEL DISCUSSION: Accelerating HIV Viral-Load Diagnostics: A Case Study of Government, Industry, and Academia Collaboration
Moderator: C. Taylor Gilliland, PhD, Senior Advisor for Innovation Programs, Office of the Director, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health
The National Institutes of Health has partnered with the Point-of-Care Technology Research Network (POCTRN) and launched a nationwide program to accelerate the prototyping and validation of innovative HIV VL testing platforms that are designed for POC use and that fill unmet national and global needs. This session will demonstrate how a collaboration among government, industry, and academia is driving diagnostic technology development.
Panelists:
Shawn Mulvaney, PhD, Health Science Administrator, Bioanalytical Sensors Portfolio, National Institute of Biomedical Imaging and Bioengineering
Rainer Ng, PhD, Head, Technology Development, Baebies, Inc.
Stuart C. Ray, MD, Professor of Medicine (Infectious Diseases) and Oncology, Vice Chair of Medicine for Data Integrity and Analytics, Johns Hopkins University School of Medicine

12:25 pm Enjoy Lunch on Your Own

1:30 Refreshment Break in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

2:00 Close of At-Home & Point-of-Care Diagnostics Conference

TUESDAY, MARCH 26

7:00 am Registration and Morning Coffee

PLENARY KEYNOTE SESSION: CONVERGENCE OF ARTIFICIAL INTELLIGENCE AND GENOMICS

8:00 Chairperson's Remarks
Kevin Davies, PhD, Executive Editor, The CRISPR Journal; Author, Editing Humanity: The CRISPR Revolution and the New Era of Genome Editing

8:05 Plenary Keynote Introduction
Keynote Introduction
Damian Verdnik, PhD, Director, Diagnostics, Dx PMO, Invetech

8:15 FIRESIDE CHAT: Convergence of Artificial Intelligence and Precision Oncology


Kevin Davies, PhD, Executive Editor, The CRISPR Journal; Author, Editing Humanity: The CRISPR Revolution and the New Era of Genome Editing
Douglas Flora, MD, Executive Medical Director, Oncology Services, St. Elizabeth Healthcare; Editor-in-Chief, AI in Precision Oncology Journal
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8:45 PANEL DISCUSSION: AI and Genomics Come Together





Moderator: Kevin Davies, PhD, Executive Editor, The CRISPR Journal; Author, Editing Humanity: The CRISPR Revolution and the New Era of Genome Editing
Artificial intelligence (AI) promises to enable the analysis of trillions of genomic, molecular, clinical, and epidemiological data points, offering unprecedented insights into health and disease, the development of drugs and diagnostics, and empowering precision medicine. Our distinguished panel will review the opportunities, challenges, and innovations in applying emerging AI tools to biological data, and their potential to revolutionize drug development, diagnostics, and precision medicine.
Panelists:
Kari Stefansson, MD, PhD, CEO, deCODE genetics
Atul Butte, MD, PhD, Distinguished Professor and Institute Director, University of California
Pankaj Vats, PhD, Senior Bioinformatics/Genomics Scientist, NVIDIA
Jonathan M. Carlson, PhD, Managing Director, Microsoft Health Futures

9:30 Refreshment Break

LIQUID BIOPSY DIAGNOSTICS: CLINICAL UTILITY AND ADOPTION

9:45 Chairperson's Remarks
Jonathan Beer, Senior Director, Diagnostic Sciences, Bristol Myers Squibb

9:50 Clinical Utility and Population Health Potential for Liquid Biopsy Early Cancer Detection
Peter Bach, MD, CMO, Delfi Diagnostics

10:20 An Industry/Academic Collaboration Framework Focused on Novel Diagnostic Test Development in Oncology
Gary Pestano, PhD, Chief Development Officer, Biodesix, Inc.
Howard I. Scher, MD, Head of Biomarker Development Program, Member and Attending Physician, Department of Medicine, Memorial Sloan Kettering Cancer Center
The development and commercialization of diagnostic tests in today's environment can be challenging and complex. This case study will examine a framework for productive collaboration between a major academic center and a leading diagnostic test developer, with the aim of illustrating how to progress discoveries through a compliant product development test process, including clinical validation and reimbursement studies and into the clinical, commercial testing arena.

10:50 PANEL DISCUSSION: Clinical Adoption of Liquid Biopsy Diagnostics
Moderator: Jonathan Beer, Senior Director, Diagnostic Sciences, Bristol Myers Squibb
The expert panel will review challenges and opportunities in clinical adoption of liquid biopsy diagnostics, including development, validation, and commercialization.
Panelists:
Nicholas C. Dracopoli, PhD, CSO, Delfi Diagnostics
Howard I. Scher, MD, Head of Biomarker Development Program, Member and Attending Physician, Department of Medicine, Memorial Sloan Kettering Cancer Center
Gary Pestano, PhD, Chief Development Officer, Biodesix, Inc.

11:20 Transforming Disease Detection: The Crucial Role of Biobanking & Diversity in Liquid Biopsy Research
Courtney Noah, PhD, Vice President, Scientific Affairs, BioIVT
Liquid biopsy research is revolutionizing the way we detect, diagnose, and treat diseases. Relevant specimens are essential for R&D programs, but the complexity and cost associated with procuring samples can be daunting. Collection conditions influence analytical variability, with validation of molecular biomarkers requiring access to heterogeneous cohorts of both disease and control donors. Standardized collection protocols and a diverse donor base allow more accurate models.

11:50 Session Break

11:55 LUNCHEON PRESENTATION: Analyte Stabilization Chemistry: Another Lever for Increasing Sensitivity and Enabling Multimodality
Surya Viswanathan, General Manager, PhD, Global Marketing, PreAnalytiX
Christian Neander, Scientist, PhD, R&D, PreAnalytiX
Liquid biopsy has shown promise in various aspects of oncological research, including cancer screening, monitoring and detection. Currently, much attention is placed on circulating cell-free DNA as a primary target. By exploring additional analytes using a multimodal approach, complementary

insights can be gained from a single blood specimen. The method used for specimen collection and stabilization can influence the ability to unlock these insights.

12:25 pm Session Break

MINIMAL RESIDUAL DISEASE

1:10 Chairperson's Remarks
Peter Bach, MD, CMO, Delfi Diagnostics

1:15 An Update from the FNIH Biomarkers Consortium MRD in AML Project and Future Directions for Liquid Biopsy Standards
Dana Connors, MSc, PMP, Director, Cancer Research Partnerships, Foundation for the National Institutes of Health
The FNIH Biomarkers Consortium initiated a public-private partnership (PPP) to assess new methods of evaluating MRD and response to AML. The project has established a library of reagents for assay development and an assay network for testing new technologies. This presentation will describe steps to support MRD as a validated surrogate endpoint in AML as well as efforts to evaluate MRD in other indications through the FNIH BC.

1:45 PANEL DISCUSSION: Molecular Residual Disease in Clinical Care and Drug Development
Moderator: Peter Bach, MD, CMO, Delfi Diagnostics
ctDNA-based minimal residual disease (or molecular residual disease, MRD) has potential in patient management and supporting drug development programs. The expert panel will discuss challenges in integrating MRD in clinical care, including validation, implementation, and standardization of MRD assays, as well as utility of MRD testing as prognostic biomarkers and early surrogate endpoints in drug development.
Panelists:
Jean-Francois Martini, PhD, Diagnostics & Translational Lead, Global Product Development – Oncology and Rare Diseases, Pfizer Inc.
Dana Connors, MSc, PMP, Director, Cancer Research Partnerships, Foundation for the National Institutes of Health
Christopher Conn, PhD, Global Director, Clinical Biomarkers & Diagnostics, Diagnostics Strategy Lead, Amgen
Rajiv Raja, PhD, Executive Director, Translational Research and Innovation, Precision Medicine, Oncology R&D, GSK

2:45 Talk Title to be Announced
DefineMBC™
David Bourdon, Director of Assay Development, Epic Sciences

3:00 Epigenomic Tools for Early Cancer Detection and Therapy Response
ClearNote HEALTH
Gulfem Guler, Senior Director, Translational Research, ClearNote Health
Epigenomic states underpin cellular identity and disease phenotypes, which can be leveraged for cancer detection and monitoring in liquid biopsies. 5-hydroxymethylated cytosine (5hmC) is an epigenetic modification that is enriched over active genes and regulatory regions such as promoters and enhancers. 5hmC analysis of cell-free DNA provides powerful insights into disease biology from a single blood draw, with applications ranging from cancer early detection to cancer treatment response and monitoring.

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

PLENARY KEYNOTE SESSION: ARTIFICIAL INTELLIGENCE FOR PRECISION MEDICINE

4:10 Chairperson's Remarks
Mara G. Aspinall, Partner, Illumina Ventures; Professor of Practice, Arizona State University; Editor, Sensitive & Specific: The Testing Newsletter

4:15 FIRESIDE CHAT: Artificial Intelligence Innovation for Precision Medicine


Mara G. Aspinall, Partner, Illumina Ventures; Professor of Practice, Arizona State University; Editor, Sensitive & Specific: The Testing Newsletter
Eric Topol, MD, Founder and Director, Scripps Research Translational Institute; Executive Vice President and Professor, Scripps Research
A visionary at the intersection of medicine and technology, Dr. Eric Topol articulates the big picture for radical improvement in healthcare through personalized and data-driven medicine. Eric published three books, over 1,200 peer-reviewed publications, and provides his reasoned perspective on medical AI on social media. We will discuss his views on the current state of precision medicine and artificial intelligence, including generative AI in medicine, diagnostics, and clinical trials.

4:45 PLENARY KEYNOTE PANEL DISCUSSION: AI in Precision Medicine: Innovation and Growth Opportunities




Moderator: Mara G. Aspinall, Partner, Illumina Ventures; Professor of Practice, Arizona State University; Editor, Sensitive & Specific: The Testing Newsletter
The convergence of artificial intelligence (AI) and precision medicine promises to revolutionize health care. Generative AI, machine learning, and sophisticated computational power promise to enable clinical decision support and diagnostics, support drug development, and optimize personalized medicine.
Panelists:
Chris M. Hartshorn, PhD, Chief, Digital & Mobile Technologies Section—CTSA Program, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH)
Michael Pellini, MD, General Partner, S32
Charity Williams, Partner, Cooley LLP

5:30 Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

6:30 Close of Day

WEDNESDAY, MARCH 27

7:30 am Registration and Morning Coffee

PLENARY KEYNOTE SESSION: THE STATE OF INNOVATION IN DIAGNOSTIC TESTING FOR PERSONALIZED MEDICINE

8:00 Chairperson's Remarks
Edward Abrahams, PhD, President, Personalized Medicine Coalition

8:05 Plenary Keynote Introduction
Paul Beresford, Vice President and General Manager, CDx, Agilent Technologies

8:15 PANEL DISCUSSION: The State of Innovation in Diagnostic Testing for Personalized Medicine





Moderator: Edward Abrahams, PhD, President, Personalized Medicine Coalition
Integrating diagnostics into clinical care faces numerous challenges, including regulatory, reimbursement, and clinical adoption among others, before the promise of personalized medicine can be realized. This panel, with support from the Personalized Medicine Coalition, will consider these barriers and propose solutions to overcome them.
Panelists:
Peter Bach, MD, CMO, Delfi Diagnostics
Christopher Conn, PhD, Global Director, Clinical Biomarkers & Diagnostics, Diagnostics Strategy Lead, Amgen
Jeffrey Venstrom, MD, CMO, GRAIL
Justin Odegaard, MD, PhD, Vice President, Clinical Development, Guardant Health
Paul Beresford, Vice President and General Manager, CDx, Agilent Technologies

9:00 Transition to Sessions

LIQUID BIOPSY BIOMARKERS FOR PATIENT SELECTION AND TREATMENT MONITORING

9:05 Chairperson's Remarks
Dave S. B. Hoon, PhD, Director, Translational Molecular Medicine and Genome Sequencing, Saint John's Cancer Institute

9:10 Adoption of Liquid Biopsy in Precision Oncology
Jonathan Beer, Senior Director, Diagnostic Sciences, Bristol Myers Squibb
Successful implementation of Precision Oncology requires accurate and timely biomarker data to inform patient treatment strategies. Liquid biopsy testing has many intrinsic advantages over tissue-based testing. The FDA has approved 5 plasma CDx assays for treatment selection. New applications, such as ECD and MRD, are in development with the body of clinical evidence and reimbursement, which will lead to greater adoption of liquid biopsies.

9:40 Liquid and Tissue Biopsies in the Precision Oncology Era
Razelle Kurzrock, MD, Professor, Medicine, Associate Director, Clinical Research, Linda T. and John A. Mellowes Endowed Chair of Precision Oncology, Medical College of Wisconsin; CMO, Worldwide Innovative Network (WIN) for Personalized Cancer Therapy
Both liquid and tissue biopsies are exploitable for molecular profiling that enables a precision oncology strategy. Liquid biopsies are mainly "blood" biopsies, but other fluids—ascites, pleural fluid, and cerebrospinal fluid—can also be sampled. Both tissue and liquid biopsies yield DNA for next-generation sequencing. Liquid biopsies can also be interrogated in other ways as well, examining also circulating tumor cells (CTCs) for DNA, RNA, protein, and functional assays.

10:10 Cell-Free DNA Fragmentation Profiling for Monitoring Therapeutic Response in Metastatic Colorectal Cancer
Nicholas C. Dracopoli, PhD, CSO, Delfi Diagnostics
Cell-free circulating tumor DNA (ctDNA) assays have been adopted to monitor therapeutic response in both early- and late-stage cancer. However, tests currently available require deep-targeted sequencing to detect cancer-specific mutations at low mutant allele frequency (MAF) levels in the circulation. Recently, we developed a tumor-agnostic approach called DELFI Tumor Fraction (DELFI-TF), a Bayesian probabilistic model designed to predict plasma tumor fractions based on genome-wide fragmentation-related features.

10:40 Coffee Break in the Exhibit Hall with Poster Viewing

11:25 cfDNA ILF2 Amplication Utility in Monitoring Melanoma Patients Receiving Checkpoint Inhibitor Immunotherapy
Dave S. B. Hoon, PhD, Director, Translational Molecular Medicine and Genome Sequencing, Saint John's Cancer Institute
Checkpoint inhibitor immunotherapy(CII) has provided significant benefits in improving outcomes of metastatic cutaneous melanoma patients. One of the major problems to date is early identification of treatment responses. We applied a unique ddPCR assay to monitor ILF2 amplification as a cfDNA biomarker to monitor melanoma patients before, during, and post treatment in AJCC stage III/IV patients. The assay can identify real-time status of patients disease status and responses.

11:55 PANEL DISCUSSION: Liquid Biopsy Biomarkers for Patient Selection and Treatment Monitoring
Moderator: Dave S. B. Hoon, PhD, Director, Translational Molecular Medicine and Genome Sequencing, Saint John's Cancer Institute
Panelists:
Dana Connors, MSc, PMP, Director, Cancer Research Partnerships, Foundation for the National Institutes of Health
Nicholas C. Dracopoli, PhD, CSO, Delfi Diagnostics
Razelle Kurzrock, MD, Professor, Medicine, Associate Director, Clinical Research, Linda T. and John A. Mellowes Endowed Chair of Precision Oncology, Medical College of Wisconsin; CMO, Worldwide Innovative Network (WIN) for Personalized Cancer Therapy
Jonathan Beer, Senior Director, Diagnostic Sciences, Bristol Myers Squibb

12:55 pm Session Break

1:00 LUNCHEON PRESENTATION: Unlocking access to MSK-ACCESS®: A decentralized approach to innovative liquid biopsy technology
Chloe Ryder, PhD, Liquid Biopsy Clinical Application Product Manager, SOPHiA GENETICS
A. Rose Brannon, PhD, Director of Clinical Bioinformatics, Memorial Sloan Kettering Cancer Center (MSK)
SOPHiA GENETICS is collaborating with MSK to decentralize MSK-ACCESS® for liquid biopsy. By combining MSK's clinical expertise in cancer genomics and the predictive algorithms of the SOPHiA DDM™ Platform, we aim to expand access to precision cancer analysis capabilities worldwide. Join our expert speakers to gain insights into the clinical utility of liquid biopsy at MSK and explore the analytical performance data of MSK-ACCESS® powered with SOPHiA DDM™ - a decentralized application

1:30 Refreshment Break in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

2:00 Close of Liquid Biopsy Conference

TUESDAY, MARCH 26

7:00 am Registration and Morning Coffee

PLENARY KEYNOTE SESSION: CONVERGENCE OF ARTIFICIAL INTELLIGENCE AND GENOMICS

8:00 Chairperson's Remarks
Kevin Davies, PhD, Executive Editor, The CRISPR Journal; Author, Editing Humanity: The CRISPR Revolution and the New Era of Genome Editing

8:05 Plenary Keynote Introduction
Keynote Introduction
Damian Verdnik, PhD, Director, Diagnostics, Dx PMO, Invetech

8:15 FIRESIDE CHAT: Convergence of Artificial Intelligence and Precision Oncology


Kevin Davies, PhD, Executive Editor, The CRISPR Journal; Author, Editing Humanity: The CRISPR Revolution and the New Era of Genome Editing
Douglas Flora, MD, Executive Medical Director, Oncology Services, St. Elizabeth Healthcare; Editor-in-Chief, AI in Precision Oncology Journal
Artificial Intelligence (AI) is exhibiting immense power to transform the practice of science and medicine, from genome analysis and drug discovery to health data and the practice of medicine. Nowhere is this more evident than in the field of oncology. Dr. Flora will share his AI epiphany and offer real-world examples of how AI is already changing the practice of medicine—at his organization (St. Elizabeth Healthcare) and beyond.

8:45 PANEL DISCUSSION: AI and Genomics Come Together





Moderator: Kevin Davies, PhD, Executive Editor, The CRISPR Journal; Author, Editing Humanity: The CRISPR Revolution and the New Era of Genome Editing
Artificial intelligence (AI) promises to enable the analysis of trillions of genomic, molecular, clinical, and epidemiological data points, offering unprecedented insights into health and disease, the development of drugs and diagnostics, and empowering precision medicine. Our distinguished panel will review the opportunities, challenges, and innovations in applying emerging AI tools to biological data, and their potential to revolutionize drug development, diagnostics, and precision medicine.
Panelists:
Kari Stefansson, MD, PhD, CEO, deCODE genetics
Atul Butte, MD, PhD, Distinguished Professor and Institute Director, University of California
Pankaj Vats, PhD, Senior Bioinformatics/Genomics Scientist, NVIDIA
Jonathan M. Carlson, PhD, Managing Director, Microsoft Health Futures

9:30 Refreshment Break

ADVANCES IN SPATIAL TRANSCRIPTOMICS

9:45 Chairperson's Remarks
Evan T. Keller, DVM, PhD, Professor of Urology and Pathology, School of Medicine, University of Michigan; Director, Single Cell Spatial Analysis Program

9:50 The Changing Spatial Landscape of Subcellular Omics in Single Cells
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
The spatial localization of cells not only impacts cellular associations with other cells but also single cell subcellular organelle localization, interactions, and function. New data highlighting the complexities of multiple organelle coordinated responses to spatial localization will be discussed.

10:20 Beyond Spatial Transcriptomics: Multiomics and Temporal Dynamics
William L. Hwang, MD, PhD, Assistant Professor, Radiation Oncology, Harvard Medical School
Cancer cells can attain different cellular states—driven by specific transcription factors and associated gene regulatory networks which modulate the tumor microenvironment and engage specific multicellular interactions. In this study, we developed novel experimental and analysis methods to integrate high-resolution, high-plex spatial proteotranscriptomics with live-phase holotomography to comprehensively dissect the cell-intrinsic and -extrinsic mechanisms of deleterious immune remodeling and therapeutic resistance in pancreatic cancer.

10:50 Spatial Analysis of Urological Cancers
Evan T. Keller, DVM, PhD, Professor of Urology and Pathology, School of Medicine, University of Michigan; Director, Single Cell Spatial Analysis Program
The recent explosion of high-plex methods to evaluate biomolecules in a spatial context allows for identifying novel relationships and interactions between tumor cells and their microenvironment. This presentation will describe the use of these methods, to (1) determine biomarkers in prostate cancer biopsies to improve tumor grading; and (2) delineate a mechanism through which renal clear cell carcinoma progresses to a renal sarcomatoid cancer subtype.

11:20 In-situ Sequencing: Enabling Spatial Biology at Scale
Eli Glezer, CSO & Founder, Singular Genomics
In-situ multiomics is revolutionizing research in oncology, immunology and neurobiology. However, speed and throughput are major bottlenecks for these critical studies. Here, we present data from a novel in-situ sequencing system, with sub-micron resolution and ultra-high throughput capacity, employing rapid 4-color SBS chemistry to profile RNA transcripts and proteins in FFPE tissue. The system also generates virtual H&E images, producing multi-modal spatial images of 40 cm^2 of tissue in <24 hours.

11:50 Session Break

11:55 Enjoy Lunch on Your Own

12:55 pm Session Break

SPATIAL ANALYSIS OF THE TUMOR MICROENVIRONMENT

1:10 Chairperson's Remarks
Anil K. Sood, PhD, Professor and Vice Chair for Translational Research, Departments of Gynecologic Oncology and Reproductive Medicine; Co-Director, Center for RNA Interference and Non-Coding RNA, MD Anderson Cancer Center

1:15 The Cancer Atlas: A High-Resolution Subcellular View of Solid Malignancies
Colles Price, PhD, Principal Scientist, Takeda
To advance our ability to treat cancer patients requires knowledge about critical spatial architecture, including how cancer cells are organized and how they interact with each other and their environment. We present the Cancer Atlas. This atlas was used to discover complex relationships between cell types and their neighborhood within the tumor microenvironment. We explore these atlases to identify novel fundamental biology and potential cancer targets across multiple solid malignancies.

1:45 Spatially Resolved Biomarkers in Hodgkin's Lymphoma
Alexander Xu, PhD, Instructor, Biomedical Sciences, Cedars Sinai Medical Center
Using highly multiplexed protein measurements, single-cell spatial analysis of the Hodgkin's Lymphoma tumor microenvironment reveals cell phenotypes and spatial arrangements in the tissue that are prognostic. We find that aggregation-dependent ligand receptor expression is a promising biomarker of patient survival, and it does not rely on an expression threshold. We demonstrate a biomarker discovery pipeline, and use it to translate a complex biomarker to multiplex immunofluorescence.

2:15 Unraveling Ovarian Cancer Complexity with Spatial Analyses
Anil K. Sood, PhD, Professor and Vice Chair for Translational Research, Departments of Gynecologic Oncology and Reproductive Medicine; Co-Director, Center for RNA Interference and Non-Coding RNA, MD Anderson Cancer Center

2:45 Spatial Biology Market Growth and Trends
Miguel Edwards, PhD, Partner, DeciBio Consulting

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

PLENARY KEYNOTE SESSION: ARTIFICIAL INTELLIGENCE FOR PRECISION MEDICINE

4:10 Chairperson's Remarks
Mara G. Aspinall, Partner, Illumina Ventures; Professor of Practice, Arizona State University; Editor, Sensitive & Specific: The Testing Newsletter

4:15 FIRESIDE CHAT: Artificial Intelligence Innovation for Precision Medicine


Mara G. Aspinall, Partner, Illumina Ventures; Professor of Practice, Arizona State University; Editor, Sensitive & Specific: The Testing Newsletter
Eric Topol, MD, Founder and Director, Scripps Research Translational Institute; Executive Vice President and Professor, Scripps Research
A visionary at the intersection of medicine and technology, Dr. Eric Topol articulates the big picture for radical improvement in healthcare through personalized and data-driven medicine. Eric published three books, over 1,200 peer-reviewed publications, and provides his reasoned perspective on medical AI on social media. We will discuss his views on the current state of precision medicine and artificial intelligence, including generative AI in medicine, diagnostics, and clinical trials.

4:45 PLENARY KEYNOTE PANEL DISCUSSION: AI in Precision Medicine: Innovation and Growth Opportunities




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Michael Pellini, MD, General Partner, S32
Charity Williams, Partner, Cooley LLP

5:30 Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

6:30 Close of Day

WEDNESDAY, MARCH 27

7:30 am Registration and Morning Coffee

PLENARY KEYNOTE SESSION: THE STATE OF INNOVATION IN DIAGNOSTIC TESTING FOR PERSONALIZED MEDICINE

8:00 Chairperson's Remarks
Edward Abrahams, PhD, President, Personalized Medicine Coalition

8:05 Plenary Keynote Introduction
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8:15 PANEL DISCUSSION: The State of Innovation in Diagnostic Testing for Personalized Medicine





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Jeffrey Venstrom, MD, CMO, GRAIL
Justin Odegaard, MD, PhD, Vice President, Clinical Development, Guardant Health
Paul Beresford, Vice President and General Manager, CDx, Agilent Technologies

9:00 Transition to Sessions

SPATIAL PROFILING TO STUDY DISEASE BIOLOGY

9:05 Chairperson's Remarks
Lauri Diehl, PhD, Executive Director, Research Pathology, Gilead Sciences

9:10 Spatial Epigenome Transcriptome Co-Profiling of Mammalian Tissues
Yanxiang Deng, PhD, Assistant Professor, Pathology & Lab Medicine, University of Pennsylvania
We present spatially resolved joint profiling of the epigenome and transcriptome by cosequencing chromatin accessibility and gene expression, or histone modifications and gene expression on the same tissue section. These were applied to mouse brains, to map how epigenetic mechanisms control transcriptional phenotype and cell dynamics in tissue. Linking epigenome to transcriptome allows the uncovering of new insights in spatial epigenetic priming, differentiation, and gene regulation within the tissue architecture.

9:40 Bento and SPACEseq: Computational and Experimental Methods for Spatial Subcellular RNA Biology
Eugene Yeo, PhD, MBA, Professor, Cellular and Molecular Medicine, University of California, San Diego; Founding Member, Institute for Genomic Medicine
Emerging genomic technologies that measure spatial information about RNA molecules promise to shed light on cell biology and function. Most analytical techniques have primarily concentrated on spatial relationships at the multicellular and cellular scale without fully tapping into single-molecule spatial information. To address this gap, my lab introduces Bento, a toolkit designed for discerning spatial relationships at the subcellular scale. Bento incorporates a suite of statistical and machine learning methods.

10:10 Spatial Transcriptomics of Crohn's Disease Recurrence
Niels Vande Casteele, PharmD, PhD, President, AcelaBio
Review AcelaBio validated GCP/GcLP compliant end-to-end 10X Visium spatial transcriptomics workflow from sample processing to bioinformatics analysis
Case Study: Discuss how formalin fixed paraffin embedded mucosal tissue biopsies were analyzed and spatial transcriptomics data were used to investigate disease recurrence in IBD patients

10:25 Session Break

10:40 Coffee Break in the Exhibit Hall with Poster Viewing

11:25 The Challenges and Opportunities of Multi-Modal Technologies in Early Discovery
Sangeetha Mahadevan, PhD, Senior Research Scientist, Gilead Sciences
This presentation will cover the challenges and opportunities of designing and implementing spatial transcriptomics projects. I will also touch on the ways in which we are thinking about integration of high-plex protein analysis or other tissue based staining modalities into our analytical workflows. The talk will be broad, but I hope to be able to share examples from oncology and inflammation therapeutic areas.

11:55 Single-Cell and Spatial-Omics: Challenges in Global Representation
Jasmine Plummer, PhD, Associate Member, Developmental Neurobiology, St Jude Children's Research Hospital
Single-cell and spatial-omics bring new insights into cell biology and cellular basis of disease. Dr. Plummer will discuss how major advances in next-generation sequencing and imaging-based approaches are now leading a revolution in how these methods are being used in tissue. She will discuss current technologies, opportunities, and challenges they present in utilization, implementation, and continued use in a global environment.

12:25 pm Enjoy Lunch on Your Own

1:30 Refreshment Break in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

2:00 Close of Spatial Biology Conference

WEDNESDAY, MARCH 27

2:00 pm Registration Open

ARTIFICIAL INTELLIGENCE IN PRECISION ONCOLOGY

2:00 Chairperson's Remarks
Douglas Flora, MD, Executive Medical Director, Oncology Services, St. Elizabeth Healthcare; Editor-in-Chief, AI in Precision Oncology Journal
John Mattison, MD, UCSD Scholar in Residence, Responsible AI and Advanced Technologies, Chief Medical Information Officer, Arsenal Capital Partners

2:35 Digital Twins and Optimal Treatment Development
Eric Stahlberg, PhD, Director, Cancer Data Science Initiatives, Cancer Research Technology Program, Frederick National Laboratory for Cancer Research, Rockville, Maryland, USA
The recent advances in AI have accelerated interest in the use of digital twins and virtual models in medicine. The presentation will provide an overview of biomedical digital twins and how AI is impacting the development of precision medicine digital twins. The presentation will provide a glimpse into the future where diagnostics, virtual models, and AI algorithms converge to provide new avenues for optimal treatment in precision medicine.

3:05 Transforming Oncology through AI: A New Frontier in Business Intelligence
Olalekan Ajayi, PharmD, MBA, COO, Highlands Oncology Group

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

4:15 PANEL DISCUSSION: Innovation in AI for Precision Oncology: Commercialization and Implementation Strategies
Moderator: John Mattison, MD, UCSD Scholar in Residence, Responsible AI and Advanced Technologies, Chief Medical Information Officer, Arsenal Capital Partners
Application of AI in oncology has the potential to revolutionize cancer care, from early detection to precision medicine. The expert panel will discuss emerging opportunities for investment, innovation, and commercialization of AI-enabled technologies and solutions for precision oncology.
Panelists:
Oscar Puig, PhD, Vice President, Translational Medicine & Diagnostics, Nucleai
Ben Glass, Vice President, Product & Translational Research, PathAI
Arturo Loaiza-Bonilla, MD, Co-Founder & CMO, Massive Bio, Inc.

5:15 Close of Day

THURSDAY, MARCH 28

8:00 am Morning Coffee

ARTIFICIAL INTELLIGENCE IN CLINICAL DECISION SUPPORT AND DIAGNOSTICS

8:30 Chairperson's Remarks
Stephen T. C. Wong, PhD, Chair & Professor, Houston Methodist Hospital and Weill Cornell Medical College

8:35 Delivering AI Solutions Effectively and Responsibly
Sonya Makhni, MD, Medical Director, Mayo Clinic Platform
Once an AI model is developed, it is only a fraction of the way to impacting outcomes. The model must seamlessly integrate into a complex and nuanced health care system, where heterogeneous clinical workflows can challenge the success of any given AI model. Innovators, clinicians, and health systems must learn how to safely deploy solutions. In order to accomplish this, a novel approach must be developed and applied in practice.

9:05 Deep Reinforcement Learning for Cost-Effective Medical Diagnosis
Yuan Luo, PhD, Chief AI Officer & Associate Professor, Northwestern University Feinberg School of Medicine
We apply reinforcement learning (RL) to optimize sequential lab test panel selection for cost-effective and accurate diagnosis in cases where clinical data is imbalanced. We introduce a reward-shaping approach to find Pareto-optimal policies for budget-constrained score maximization. Our model achieves state-of-the-art diagnosis accuracy with substantial cost savings (up to 85% reduction) across various clinical tasks.

9:35 Augmenting AI-Powered Clinician Decision Support Tools for Severe Infection through Dynamic Coupling of Wearables and Electronic Medical Record Models Enhanced with Federated Learning Models
Imanuel Lerman, MD, MSc, Professor, Electrical and Computer Engineering, Anesthesiology, University of California, San Diego
Our group is developing an AI-powered clinician decision health care platform comprised of real-time ingestion of EHR data features aggregated in a federated learning architecture. Federated learning models dynamically couple to an AI-enabled wearable sensor that indicates early-stage infection (12 hours prior to standard-of-care). The dynamically coupled model will notify the clinician of critical change in patient infectious status allowing for expedited lifesaving therapeutics.

10:05 Coffee Break in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

ARTIFICIAL INTELLIGENCE IN CLINICAL DECISION SUPPORT AND DIAGNOSTICS (CONT.)

10:50 Chairperson's Remarks
Stephen T. C. Wong, PhD, Chair & Professor, Houston Methodist Hospital and Weill Cornell Medical College

10:55 Cognitive Automation to Improve Precision and Improve Clinical Care: Use Case Studies in Stroke Management
Stephen T. C. Wong, PhD, Chair & Professor, Houston Methodist Hospital and Weill Cornell Medical College
Can we leverage Artificial Intelligence (AI) to address clinical tasks that involve interpreting multimodal patient data and clinicians' cognitive capabilities—or even beat the clinicians' performance? We describe novel AI tools developed at Houston Methodist Hospital that address clinical challenges in triage, diagnosis, and treatment of stroke in emergency rooms and beyond.

11:25 Enjoy Lunch on Your Own

1:00 pm Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing

ENABLING DIGITAL PATHOLOGY WITH ARTIFICIAL INTELLIGENCE

1:40 Chairperson's Remarks
Jithesh Veetil, PhD, Senior Program Director, Digital Health & Technology, Medical Device Innovation Consortium

1:45 Advancing the AI in Diagnostics and Healthcare: Role of the Public-Private Partnership Model
Jithesh Veetil, PhD, Senior Program Director, Digital Health & Technology, Medical Device Innovation Consortium
Novel technologies including AI promise to revolutionize healthcare, from earlier diagnosis to better treatments and improved clinical care. Some of the perpetual concerns are the scarcity of data and the uncertainty in the regulatory frameworks. In addition, many of the stakeholders in the fast-moving space are working in silos. This presentation will highlight a few concrete examples of how public-private partnerships such as MDIC are bringing together stakeholders.

2:15 PANEL DISCUSSION: Unlocking the Potential of Digital Pathology and Artificial Intelligence (AI) through Regulatory Science
Moderator: Jithesh Veetil, PhD, Senior Program Director, Digital Health & Technology, Medical Device Innovation Consortium
Industry and regulatory leaders will discuss advances in digital pathology and AI as well as progress and hurdles in the quest to broadly implement digital pathology and AI/machine learning. The impact of recent regulatory and legislative developments in digital pathology and AI tools in diagnostics will be highlighted as well as the work of the Pathology Innovation Collaborative Community, a regulatory science initiative that aims to facilitate innovations in pathology.
Panelists:
Maryellen de Mars, PhD, Program Director, Clinical Diagnostics, Medical Device Innovation Consortium
Jochen Lennerz, MD, PhD, CSO, BostonGene
Keith Wharton, Jr, MD, PhD, Global Medical Affairs Leader - Pathology, Roche Diagnostics Solutions

3:15 Close of Conference

WEDNESDAY, MARCH 27

2:00 pm Registration Open

PARTNERING STRATEGIES FOR EVIDENCE GENERATION

2:00 Chairperson Remarks
Lon Castle, MD, Associate CMO, Precision Medicine, EviCore

2:05 FIRESIDE CHAT: An Innovative Partnering Model to Generate Evidence and Increase Access to Molecular Medicine
Moderator: Stacey Brown, Market Access Lead, Optum Genomics
During this session, we will discuss: 1) Cepheid's innovative partnership with Optum to holistically uncover payer insights, generate evidence, and demonstrate the value of molecular diagnostics; 2) the results of a large, claims-based clinical utility study demonstrating the impact of point-of-care respiratory PCR diagnostics; and 3) the implementation of a robust value story and integrated evidence strategy to improve access to Cepheid's point-of-care diagnostics.
Panelists:
Stacey DaCosta Byfield, PhD, MPH, Vice President, Genomic Health Economics and Outcomes Research, Optum Genomics
Anne Beaubrun, PhD, Vice President, Global Health Economics & Outcomes Research, Cepheid

2:35 FIRESIDE CHAT: Genomics-Era Market Access at Illumina: New Models, Partnerships, and Lessons Learned
Moderator: Bruce Quinn, MD, PhD, Principal, Bruce Quinn Associates, LLC
Illumina operates globally across numerous applications and channels to impact care (e.g., hospitals, testing labs) with a history of innovation. As genomic tests continue to enter standard-of-care, partnerships are needed to amplify the impact of evidence, guidelines, and regulatory to progress patient access. In this moderated case study, leaders will share the 8-year evolution of the market access form/function, strategic pillars, innovative partnerships, and lessons learned.
Panelists:
Brock Schroeder, PhD, Vice President, Market Access, Illumina, Inc.
John L. Fox, MD, Senior Medical Director for the Americas, Illumina, Inc.
Damon Hostin, Lead, Health System Market Access, Illumina, Inc.

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

4:15 PANEL DISCUSSION: The Taylor Swift Effect
Moderator: Lon Castle, MD, Associate CMO, Precision Medicine, EviCore
New tests can provide great value to payers—particularly when the test addresses a specific area of interest. It's just like the NFL embracing the association with Taylor Swift. She provides access to an untapped demographic. But is it possible for a lab to whet a payer's interest without the support of Taylor Swift? Our panel will discuss what their organizations look for when developing pilots and value-based contracts.
Panelists:
Michael Astion, MD, PhD, Regional Medical Director & Professor, Laboratory Medicine and Pathology, Seattle Children's Hospital and the University of Washington
John L. Fox, MD, Senior Medical Director for the Americas, Illumina, Inc.
Anne Beaubrun, PhD, Vice President, Global Health Economics & Outcomes Research, Cepheid
Stacey Brown, Market Access Lead, Optum Genomics

5:15 Close of Day

THURSDAY, MARCH 28

8:00 am Morning Coffee

STRATEGIES TO ACCELERATE NEXT-GENERATION DIAGNOSTICS

8:30 Chairperson Remarks
Bruce Quinn, MD, PhD, Principal, Bruce Quinn Associates, LLC

8:35 Dos and Don'ts: From Product Concept to Widespread Adoption
Jill Hagenkord, MD, CMO, Optum Genomics
Navigating the fractured US healthcare system can be challenging but there is a basic recipe that test developers can use to plan their market access strategy. We will review evidentiary milestones and discuss some dos and don'ts for engaging stakeholders and refining your go-to-market strategy.

9:05 Achieving Market Access: How Can Labs Meet Evolving Requirements for Reimbursement?
Sarah Thibault-Sennett, PhD, Senior Director, Reimbursement Policy, American Clinical Lab Association
The US payer landscape is incredibly diverse, requiring laboratories to develop relationships with multiple public and private payers, in addition to laboratory benefit managers and other evidentiary review organizations, to assure reimbursement for their services. This session will explore the challenges of developing and maintaining unique claim submission processes to meet these requirements and discuss activities taken by stakeholders to respond to these issues.
Lauren Feldman, Vice President and Head, Value, Access, and Pricing, ADVI

10:05 Coffee Break in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

STRATEGIES TO ACCELERATE NEXT-GENERATION DIAGNOSTICS (CONT.)

10:50 Chairperson Remarks
Bruce Quinn, MD, PhD, Principal, Bruce Quinn Associates, LLC

10:55 Time from FDA Authorization to Medicare Coverage for Novel Technologies
Sandra Waugh Ruggles, PhD, Director, Policy Research, Stanford Byers Center for Biodesign; President, Summit Rock Strategy
Hundreds of new medical products are authorized by the FDA each year. New coding, coverage, and payment must be established for physicians and patients to reliably access a subset of novel technologies. Sandra will discuss an analysis of timelines from FDA authorization to Medicare coverage for 64 novel devices and diagnostics where coverage was achieved by 28 (44%) within a median of 5.7 years.

11:25 PANEL DISCUSSION: Understanding How Industry and Payors See Each Other
Moderator: Bruce Quinn, MD, PhD, Principal, Bruce Quinn Associates, LLC
It seems like industry and payors are often at odds. Hear the latest data on claims, denials, and appeals, and how they evolve. Learn about the new field of academic studies of payor behavior—how they make decisions, how diverse they are, how long it should take. Understand better how commercial payors and Medicare differ.

Panelists:
Clarisa Blattner, Senior Director, Revenue and Payor Optimization, XiFin, Inc.
Jim Almas, MD, Vice President and National Medical Director, Clinical Effectiveness, LabCorp
Jill Hagenkord, MD, CMO, Optum Genomics
Sandra Waugh Ruggles, PhD, Director, Policy Research, Stanford Byers Center for Biodesign; President, Summit Rock Strategy
Samantha Freeze, Director, Market Access Precision Medicine, ADVI Health

12:25 pm **Enjoy Lunch on Your Own**

1:00 **Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing**

REIMBURSEMENT STRATEGIES FOR ADVANCED DIAGNOSTICS

1:40 **Chairperson's Remarks**
Bruce Quinn, MD, PhD, Principal, Bruce Quinn Associates, LLC

1:45 **Medicare: Understanding Its Priorities for 2024**
Bruce Quinn, MD, PhD, Principal, Bruce Quinn Associates, LLC
Medicare is a big factor for most lab tests, and its mix of national and local coverage policies is confusing. A proposal for Transitional Coverage for Emerging Technology is under review, for FDA-approved tests, while FDA's proposal to regulate all lab-developed tests would be chaotic for the ADLT pricing method. Meanwhile, Medicare struggles to price new genomic sequencing codes and the MolDx program expands to private payers.

2:15 **Demystifying Molecular Diagnostics Coverage and Reimbursement in Medicare: MolDx**
Gabriel Bien-Willner, MD, PhD, Medical Director, MolDx, Palmetto GBA
This presentation will review the underlying principles of molecular diagnostic payor controls, including the DEX registry and technical assessments, as well as policy writing for the MolDX program.

2:45 **Impact of CMS Rate-Setting on Access for Novel Tests**
Nicholas Halzack, MPH, Director, Health Policy, Roche Diagnostics
The process by which CMS establishes reimbursement rates for new codes appearing on the Medicare Clinical Laboratory Fee Schedule can be opaque and unpredictable, resulting in significant uncertainty for novel technologies entering the market. This presentation will discuss the crosswalk and gapfill processes, their impact on private payers and PAMA implementation, and potential policy solutions to improve them.

3:15 **Close of Conference**

WEDNESDAY, MARCH 27

2:00 pm Registration Open

CLINICAL UTILITY OF METAGENOMIC NEXT-GENERATION SEQUENCING FOR DIAGNOSIS OF INFECTIOUS DISEASE

2:00 Chairperson's Remarks

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

2:05 Clinical Metagenomic Sequencing for Rapid Diagnosis of Infections

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

Clinical metagenomic next-generation sequencing (mNGS) is an emerging approach for broad-based diagnosis of infections, whether caused by bacteria, viruses, fungi, or parasites. Here we will discuss recent improvements in turnaround time, performance, and bioinformatics that make these tests more accessible to clinical and public health laboratories. We will also discuss how machine learning-based host response analysis by human RNA sequencing can be leveraged to aid in the diagnosis of infections.

2:35 Diagnosis of Invasive Fungal Infections by Microbial Metagenomics Sequencing

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

In high-risk oncology patients, invasive fungal infections (IFI) remain a major cause of morbidity and mortality. This is due, in part, to challenges associated with IFI diagnosis, which currently relies on a combination of risk stratification, limited laboratory methods and imaging studies. In this talk, the current data on the potential of microbial metagenomics sequencing to improve IFI diagnosis will be reviewed, including remaining gaps and future opportunities.

3:05 Clinical Integration of Microbial Whole-Genome Sequencing

Shaun Yang, PhD, Associate Clinical Professor, Director, Molecular Microbiology and Pathogen Genomics Laboratory, University of California, Los Angeles

The clinical and diagnostic utility of microbial whole-genome sequencing (WGS) is vast. It includes speciation/classification of microorganisms, virulence genotyping, antimicrobial resistance (AMR) prediction, emerging pathogen and AMR mechanism surveillance, and outbreak investigation. This talk will describe the real-world implementation of microbial WGS testing and its integration into routine patient care and infection prevention practice at a large academic medical center.

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

(Sponsorship Opportunity Available)

4:15 PANEL DISCUSSION: Clinical Metagenomic Sequencing: Where Does It Fit in the Diagnostic Algorithm?

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

This session will provide expert recommendations and best practices regarding the use of metagenomic next-generation sequencing (mNGS) testing in clinical practice. Speakers will discuss potential clinical indications for mNGS, considering patient selection criteria, diagnostic yield, timing for test ordering, assay turnaround time, cost, as well as test and sample availability. We will also review diagnostic and antimicrobial stewardship considerations related to mNGS.

Panelists:

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

Brad Perkins, MD, CMO, Karius, Inc.

Shaun Yang, PhD, Associate Clinical Professor, Director, Molecular Microbiology and Pathogen Genomics Laboratory, University of California, Los Angeles

Steve Miller, MD, PhD, CMO, Delve Bio

5:15 Close of Day

THURSDAY, MARCH 28

8:00 am Morning Coffee

MOLECULAR SYNDROMIC PANELS FOR RESPIRATORY PATHOGEN TESTING

8:30 Chairperson's Remarks

Gregory J. Berry, PhD, Associate Professor, Pathology & Cell Biology, Columbia University Vagelos College of Physicians and Surgeons

8:35 The Shifting Landscape of Respiratory Pathogen Testing

Gregory J. Berry, PhD, Associate Professor, Pathology & Cell Biology, Columbia University Vagelos College of Physicians and Surgeons

There are many different options available for respiratory testing, ranging from detecting a single pathogen to multiplex testing for numerous pathogens simultaneously. The choice of what pathogens to test for involves many different factors, such as the target patient population, testing setting, and what viruses are circulating at the time of testing. These factors can also dramatically change in certain circumstances, such as during the SARS-CoV-2 pandemic.

9:05 PANEL DISCUSSION: Multiplex Testing for Respiratory Pathogens—What Is the Right Fit?

Moderator: Gregory J. Berry, PhD, Associate Professor, Pathology & Cell Biology, Columbia University Vagelos College of Physicians and Surgeons

There are many different molecular options for respiratory pathogen testing, ranging from detecting one to numerous pathogens simultaneously. While having many options is advantageous, the decision of which test or tests to choose can be daunting and is driven by many different variables such as the healthcare setting, patient population, and even the time of year. We plan on interactively discussing these variables and how to assess them.

Panelists:

Alex Greninger, MD, PhD, Assistant Professor, Laboratory Medicine, University of Washington

Larissa May, MD, MSPH, MBA, Professor, Emergency Medicine; Director, Emergency Medicine Innovation and External Partnerships; Assistant Clinical Ventures Officer, UC Davis Health

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

10:05 Coffee Break in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

HOST RESPONSE-BASED DIAGNOSTICS FOR INFECTIOUS DISEASE

10:50 Chairperson's Remarks
Christopher W. Woods, MD, MPH, Professor, Medicine, Global Health & Pathology, Duke University

10:55 Controlled Human Infection Models in Biomarker Development for Precision Medicine
Christopher W. Woods, MD, MPH, Professor, Medicine, Global Health & Pathology, Duke University
Controlled human challenge models are ideal study designs for monitoring host:pathogen interactions for colonization and mild to moderate symptomatic infections. Active models include a diversity of respiratory viruses, dengue, norovirus, a variety of bacterial gastrointestinal and genitourinary pathogens, and malaria. Precise inoculation times and serial sampling, often under quarantine, allow for dense timepoints supporting more precise kinetics of physiological and molecular responses.

11:25 The Host Response in Acute Infections and Sepsis: Potential Challenges and Benefits
Timothy Sweeney, PhD, Co-Founder & CEO, Inflammatix, Inc.
Host-response technologies offer the promise for rapid assessments (diagnostic and prognostic) of patients with suspected acute infection and sepsis. However, improving outcomes depends on test design, performance, and implementation. We will discuss practical challenges and solutions in improving patient outcomes in this challenging patient segment.

11:55 Enjoy Lunch on Your Own

1:00 pm Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing

DIAGNOSTIC STEWARDSHIP: RIGHT TEST TO THE RIGHT PATIENT AT THE RIGHT TIME

1:40 Chairperson's Remarks
Michael E. Klepser, PharmD, FCCP, FIDP, Professor, Ferris State University College of Pharmacy

1:45 Diagnostic Stewardship and Implementation of New Tests for Infectious Diseases in the Emergency Department
Larissa May, MD, MSPH, MBA, Professor, Emergency Medicine; Director, Emergency Medicine Innovation and External Partnerships; Assistant Clinical Ventures Officer, UC Davis Health
This session will highlight the importance of diagnostic test stewardship in parallel with antibiotic stewardship to provide value to diagnostic testing for infectious diseases in the emergency department (ED) setting. Opportunities and challenges with implementation of new ID diagnostic tests in the ED will be illustrated with use cases.

2:15 Diagnostic Stewardship in Ambulatory Care and Community Pharmacy Settings
Michael E. Klepser, PharmD, FCCP, FIDP, Professor, Ferris State University College of Pharmacy
Inappropriate use of laboratory tests to guide management of individuals can lead to suboptimal patient outcomes and inappropriate use of antibiotics. Data suggests diagnostic tests, when ordered judiciously, can decrease time to receipt of appropriate antibiotics and decrease unwarranted use of antibiotics. However, indiscriminate use tests may result in excess costs and overuse of antibiotics, owing to reaction to false positive results.

2:45 Point-of-Care Diagnostic Stewardship
Ester Stein, Director, Corporate Reimbursement, Government Affairs, Abbott Laboratories
John Warren, Owner and Principal Consultant, Gettysburg Healthcare Consulting, LLC
Consumers demand convenience and have grown accustomed to getting rapid testing in pharmacies and other nontraditional healthcare settings. During the pandemic, public health officials ensured that patients were tested quickly, with rapid access to treatment. Post-pandemic, payers have started to roll back some of these flexibilities. We will discuss the role of sound government policy in appropriately balancing access to, and innovation in point-of-care diagnostics.

3:15 Close of Conference

WEDNESDAY, MARCH 27

2:00 pm Registration Open

EVIDENCE GENERATION AND MARKET ACCESS FOR MULTI-CANCER EARLY DETECTION

2:00 Chairperson's Remarks
Larry Kessler, ScD, Professor, Health Systems and Population Health, University of Washington; Deputy Chair, MCED Consortium

2:05 The Promise and Early Experience with MCED
Jeffrey Venstrom, MD, CMO, GRAIL
Unscreened cancers account for ~70% of US cancer deaths; however, early diagnosis is transformative, with up to an 89% survival rate, depending on the disease and stage. Multi-cancer early detection (MCED) tests are a new simple blood-based solution to screen for multiple cancers, like Galleri, which screens for more than 50 cancer signals—shifting from screening for individual cancers to screening individuals for cancer as a whole.

2:35 Using RWE to Learn about the Clinical Utility and Impact of Multi-Cancer Early Detection Tests
Larry Kessler, ScD, Professor, Health Systems and Population Health, University of Washington; Deputy Chair, MCED Consortium
Recent research shows the potential to detect multiple cancers early with a single blood test. The evidence standard for screening tests has been long-term randomized controlled trials with a survival endpoint, but these are challenging to conduct. The use of "real-world evidence" as part an alternative evaluation approach holds promise. We describe a set of recommended data elements that will address key questions in the evaluation of MCED tests.

3:05 Whole Blood Stabilization for Plasma Proteins of Interest STRECK
Jing Li, R&D Scientific Manager, Research and Development, Streck
Plasma proteins are important biomarkers for the prognosis of cancer and other diseases. Preanalytical variables introduced during blood collection, storage, and processing lead to *ex vivo* platelet activation, hemolysis in the sample, and inconsistent results in plasma protein analysis. Streck's new blood collection tube ensures accurate assessment of plasma proteins of interest during whole blood storage. The isolated plasma is compatible with both immunoassays and mass spectrometry-based proteomic analysis.

3:20 Development of a Targeted DNA Methylation and Mutation Based Multi-Cancer Detection Test EPIGENDX
Collin Hudzik, PhD, Scientist, EpigenDx
Methylation and cancer mutation analyses are often not performed in tandem, despite their equal importance in cancer genetics. Here, we have developed a multiplex PCR-based targeted sequencing panel and workflow using Ion Torrent S5 Prime. The method allows for the simultaneous analysis of actionable cancer mutations and methylation markers, enabling the detection of multiple cancer types, including colon, breast, lung, brain tumors, etc., with increased sensitivity and specificity.

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

4:15 NCI's Cancer Screening Research Network (CSRN) and Multi-Cancer Detection Vanguard Pilot
Elyse LeeVan, MD, MPH, Program Officer, Cancer Screening Research Network, National Cancer Institute, National Institutes of Health
Designing a clinical trial to assess a variety of MCDs for their utility as cancer screening tools presents new challenges compared to traditional single cancer screening modalities. The CSRN program officer will provide an update on the launch of the Cancer Screening Research Network and discuss its objectives. The Network's first priority will be the Vanguard study, a pilot to assess the feasibility of a platform MCD randomized control trial.

4:45 Can We Shortcut Trials to Evaluate Multi-Cancer Tests?
Ruth Etzioni, PhD, Professor, Public Health Sciences, Fred Hutch Cancer Center

5:15 Close of Day

THURSDAY, MARCH 28

8:00 am Morning Coffee

LIQUID BIOPSY FOR CANCER SCREENING AND EARLY DETECTION

8:30 Chairperson's Remarks
Sudhir Srivastava, PhD, Chief, Cancer Biomarkers Research Group, NIH NCI

8:35 Liquid Biopsy for Cancer Early Detection: Technological Revolutions and Clinical Dilemma
Sudhir Srivastava, PhD, Chief, Cancer Biomarkers Research Group, NIH NCI
With the available screening tests, most cancers are diagnosed too late, thereby offering little hope for effective treatment. There is a burgeoning array of technologies that are allowing early detection of cancer using the latest molecular and computational tools for analyzing circulating free DNA (cfDNA), ushering in a new paradigm of multi-cancer early detection (MCED) using a pinch of blood. Blood is most suited for noninvasive detection of cancer biomarkers.

9:05 Liquid Biopsy for Single vs. Multi-Cancer Detection
Sam Hanash, MD, PhD, Director, Red & Charline McCombs Institute; Evelyn & Sol Rubenstein Distinguished Chair, Cancer Prevention; Professor, Clinical Cancer Prevention-Research, Translational Molecular Pathology, University of Texas MD Anderson Cancer Center
The field of liquid biopsy for cancer early detection has expanded considerably. Effort has proceeded under two parallel tracks, one focusing on single common cancers and another on multi-cancer detection. A wide world of biomarker testing platforms have been explored. The merits of single cancer vs. multi-cancer tests based on a single platform or a combination of platforms require assessment based on performance and cost effectiveness.

9:35 Multi-Cancer Early Detection: Evidence from the Clinical Discovery Curve
Eric Klein, MD, Distinguished Scientist, GRAIL, Inc.
Blood-based multi-cancer early detection (MCED) tests represent a new paradigm for cancer screening. Their development addresses a significant unmet need by expanding detection to include the ~70% of cancers that are missed by current screening modalities and that result in >600,000 cancer deaths yearly in the US. MCED testing holds promise to improve screening efficiency and reduce cancer deaths.

10:05 Coffee Break in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

CLINICAL VALIDATION OF MCED LIQUID BIOPSY TESTS

10:50 Chairperson's Remarks
Lauren Leiman, Executive Director, BLOODPAC Consortium

10:55 Creating Consensus on a Lexicon for Cancer Early Detection and Screening Liquid Biopsy Tests
Lauren Leiman, Executive Director, BLOODPAC Consortium
This session will provide an overview of the Blood Profiling Atlas in Cancer (BLOODPAC)'s soon-to-be-published lexicon of key terms in MCED and single-cancer early detection, created through collaborative discussion involving major assay developers, pharmaceutical companies, academic institutions, and not-for-profits working in the cancer early detection space.

11:25 PANEL DISCUSSION: Emerging Approaches to Clinical Validation of MCED Liquid Biopsy Tests
Moderator: Lauren Leiman, Executive Director, BLOODPAC Consortium
A discussion with BLOODPAC members working in the cancer early detection space exploring the challenges and best practices for clinical validation of MCED assays.
Panelists:
Kathyrn Lang, Senior Vice President, Real-World Data and Analytics, Freenome
Alexey Aleshin, MD, General Manager, Oncology and Early Cancer Detection; CMO, Natera, Inc.
Tomasz Beer, Chief Medical Officer and VP, Multi-Cancer Early Detection, Exact Sciences
Eric Klein, MD, Distinguished Scientist, GRAIL, Inc.

12:25 pm Session Break

12:30 LUNCHEON PRESENTATION: The Era of Multi-cancer Early Detection Testing: A Paradigm Shift in Cancer Screening EXACT SCIENCES
Tomasz Beer, Chief Medical Officer and VP, Multi-Cancer Early Detection, Exact Sciences
The multi-cancer early detection (MCED) field is still in its beginning stages, and it shows great promise as a fundamentally new approach to screening and detection of cancer. A rigorous approach to MCED test development that harnesses the additive sensitivity of multiple biomarker classes may help unlock the full potential of MCED testing, enabling the detection of more cancers in early stages and helping to shift the paradigm in cancer screening.

1:00 Refreshment Break in the Exhibit Hall with Last Chance Poster Viewing

POPULATION HEALTH IMPACT OF MULTI-CANCER EARLY DETECTION

1:40 Chairperson's Remarks
Eric Klein, MD, Distinguished Scientist, GRAIL, Inc.

1:45 Rethinking Risk Assessment within the Context of Multi-Cancer Early Detection
Alpa V. Patel, PhD, Director, Cancer Prevention Study, American Cancer Society
Risk assessment for cancer has typically been approached by a single cancer type at a time. This approach helps both elucidate the etiology of each cancer type and assess risk to inform screening guidelines for several common types of cancer such as breast, colon, and lung. Unlike current guidelines for different individual types of cancer, newer technologies have the potential to target detection of several cancers in a single test.

2:15 Primary Care Patient Interest in MCED Test Use for Cancer Screening
Ronald Myers, PhD, Professor, Division of Population Science, Medical Oncology, Thomas Jefferson University
Our research team surveyed 159 (32%) of 500 primary care patients identified in a large, urban health system to assess interest in multi-cancer detection (MCED) testing. 125 (79%) respondents reported high interest in having an MCED test. Interest was positively associated with the following expectations: testing would be recommended as standard-of-care, be convenient, and be effective in finding early disease (OR=11.70, 95% CI: 4.02, 34.04, $p < 0.001$).

2:45 Close of Conference

WEDNESDAY, MARCH 27

2:00 pm Registration Open

SINGLE-CELL SPATIAL BIOLOGY

2:00 Chairperson's Remarks
Stephen T. C. Wong, PhD, Chair & Professor, Houston Methodist Hospital and Weill Cornell Medical College

2:05 Medicine with Cellular Precision: High-Resolution Single-Cell and Spatial Technologies in Drug Development
Virginia Savova, PhD, Senior Director & Global Head, Single Cell Biology, Sanofi
Single-cell technologies provide a new lens for understanding diseases & dugs: 90% of Sanofi's disease targets are credentialed using single-cell genomics. Applying single-cell technologies to drug discovery increases probability of success but requires infrastructure and advanced analytics, as scaling up workflows and developing novel methods is necessary for broader impact. Spatial technology adds an important additional dimension but brings new analytical challenges, which will require even greater investment in high-throughput analytics.

2:35 Single-Cell Spatial Multiomics Analysis Unravels Cell-Cell Communication within Tumor and Brain Microenvironments
Stephen T. C. Wong, PhD, Chair & Professor, Houston Methodist Hospital and Weill Cornell Medical College
We developed a single-cell spatial imageomics pipeline with advanced analytic and modeling tools to analyze intricated cell-cell communication in heterogeneous tumor and brain microenvironments, incorporating single-cell spatial transcriptomics, proteomics, and imaging data. In this talk, we will showcase its application in studying cancer and neurological disorders, focusing on microenvironments and crosstalk pathways in ovarian cancer, brain and bone metastases, and Alzheimer's disease.

3:05 A Tale of Two Samples: Harnessing the Power of Multiomics from a Single Fresh Sample and a Single FFPE Sample
AZENTA LIFE SCIENCES
Andrea O'Hara, PhD, Strategic Technical Specialist, Azenta Life Sciences
The omics era has expanded the repertoire of approaches available for researchers and clinicians to unravel the complexity underpinning human health: NGS approaches can characterize genomes, epigenomes, transcriptomes and proteomes. Here we present two case studies, one on fresh blood draws, the other on archival FFPE tissue, using multiomics workflows to rapidly produce diverse sets of results, with a spotlight on single-cell and spatial assays. With these robust workflows, all data can be produced within days of primary sample collection using minimal inputs.

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

4:15 Single-Cell Spatial Omics Journey to Signaling and Metabolism *in Situ*
Ahmet Coskun, PhD, Assistant Professor, Biomedical Engineering, Georgia Institute of Technology
The spatial organization of cells in tissues and subcellular networks provides a quantitative metric for determining health and disease states. In this talk, I will introduce spatial omics modalities (spatial genomics, spatial proteomics, and spatial metabolomics) to decipher and model the spatio-temporal decision-making of single cells at macromolecular resolution in engineered organoids and human tissues. Automated machine learning algorithms in this single-cell big data impact biomedical practice and clinical care.

4:45 A Single-Cell Map of Dynamic Chromatin Landscapes of Immune Cells in Renal Cell Carcinoma
Nikolaos Kourtis, PhD, Scientist, Regeneron
My presentation will describe Regeneron's approach to profile the tumor microenvironment of patients with renal cancer utilizing chromatin readouts. The composition of T cell-states, regulatory dynamics, and the rewired transcriptional program of NFkB in dysfunction will be discussed.

5:15 Close of Day

THURSDAY, MARCH 28

8:00 am Morning Coffee

SINGLE-CELL MULTIOMIC PROFILING

8:30 Chairperson's Remarks
Adrian Lee, PhD, Professor, Pharmacology & Chemical Biology, University of Pittsburgh

8:35 Combined Spatial and Single-Cell Sequencing to Understand Breast Cancer
Adrian Lee, PhD, Professor, Pharmacology & Chemical Biology, University of Pittsburgh
Mixed invasive ductal and lobular carcinoma (mDLC) is a rare subtype of breast cancer displaying both ductal and lobular morphologies, posing challenges for clinical management. It remains unclear whether these distinct morphologies have distinct biology and risk of recurrence. Here we present multi-omic (spatially-resolved transcriptomic, genomic, and single-cell) profiling of collision type mDLC cases, and identify clinically significant differences between the underlying ductal and lobular tumor regions.

9:05 Harness Intercellular Heterogeneity in Cancer Treatment and Survival Prediction
Lana Garmire, PhD, Associate Professor, Computational Medicine & Bioinformatics, University of Michigan
Heterogeneity is a fundamental property of multicellular organisms. In this talk, I will describe a new drug recommendation method called ASGARD, which computationally repurposes drugs over heterogeneous cell types in the single cell RNA-Seq data. Next I will go over new discoveries on a large population cohort of single-cell imaging mass cytometry data from breast cancer patients. We reveal novel breast cancer survival subtypes with atypic prognosis outcomes.

9:35 Enabling Precision Medicine by Combining Single-Cell Multi-Omics Data and Artificial Intelligence
scailyte
Shaoline Sheppard, Senior Data Scientist, Data Science, Scailyte
Scailyte has developed a proprietary AI platform, ScaiVision, to unravel hidden secrets of complex single-cell multiomics data to extract composite biomarkers associated with different cell populations. Using a convolutional neural network, ScaiVision automatically learns molecular patterns associated with relevant clinical outcomes. These signatures can then be applied to classify new samples or to extract molecular and cellular features informing these predictions.

9:50 Session Break

10:05 Coffee Break in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

SINGLE-CELL MULTIOMIC PROFILING (CONT.)

10:50 Chairperson's Remarks
Adrian Lee, PhD, Professor, Pharmacology & Chemical Biology, University of Pittsburgh

10:55 Navigating Cancer Complexities: Unveiling Diagnostics and Therapeutic Targets via Single-Cell and Spatial Omics
Manoj Bhasin, PhD, Associate Professor, Pediatrics and Biomedical Informatics, Emory School of Medicine; Associate Professor, Biomedical Engineering and Bioinformatics, Georgia Tech
To unravel the cancer, diabetes, and cardiovascular heterogeneity and its implications for patient outcomes, we use single-cell and spatial profiling techniques. In this presentation, I will delve into our efforts to comprehensively map the heterogeneity of hematological cancers in both adult and pediatric populations. Our goal is to elucidate the intricate interplay between tumor characteristics and the tumor microenvironment, shedding light on their associations with adverse clinical outcomes.

11:25 Single-Cell Proteomics in Imaging Flow Cytometry and Cell Sorter Platforms
Yuhwa Lo, PhD, Professor, Electrical & Computer Engineering, University of California, San Diego
We investigate single-cell proteomics using 2D image-guided cell sorters and 3D imaging flow cytometers (3D-IFCs) that possess high-throughput and high-content imaging in a single system. Both systems are empowered by artificial intelligence (AI) with convolutional neural network for label-free detection of DNA damages, protein translocations, and cell fate prediction.

11:55 Close of Conference

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