16TH ANNUAL

PERSONALIZED MEDICINE CONFERENCE

From an Enterprise to an Era

May 19–20, 2022

RITZ-CARLTON LAGUNA NIGUEL
ONE RITZ CARLTON DRIVE, DANA POINT, CA 92629

PERSONALIZED
MEDICINE
CONFERENCE

Contents

President's Message

Dear Colleague:

On behalf of the Personalized Medicine Coalition (PMC), I am pleased to present the program book for the *16th Annual Personalized Medicine Conference*.

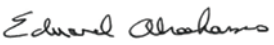
In addition to introducing our conference discussions, this book is designed to tell the story of personalized medicine in 2022. Following the emergence of a pandemic virus that has a unique impact on each infected patient, it invites us to rediscover the significance of personalized medicine's emphasis on tailoring prevention and treatment strategies to each patient's biological characteristics, circumstances, and values. With attention to the original promises of personalized medicine and lessons learned during the pandemic, each of the book's 16 narrative essays considers an issue we plan to cover during the conference.

As shown in the program book, over the course of two days of conference programming on May 19 and 20 separated by a Welcome Reception sponsored by Intermountain Precision Genomics on the Ritz-Carlton's Dana Point Lawn, we will convene eight panel discussions focused on the most pressing opportunities and challenges facing the field in science, business, and policy.

Keynote speakers include Verily's Amy Abernethy, the University of Pennsylvania's Carl June, the U.S. Food and Drug Administration's Janet Woodcock, Amgen's Jean-Charles Soria, Exact Sciences CEO Kevin Conroy, and Kite CEO Christi Shaw, each of whom will deliver important statements about the landscape and outlook for personalized medicine in the post-pandemic world.

On behalf of myself and my colleagues at PMC, welcome to our 2022 exploration of personalized medicine: *From an Enterprise to an Era*.

Sincerely yours,



Edward Abrahams, Ph.D.
President
Personalized Medicine Coalition

Personalized medicine is an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients.

Overview · Part I

May 19, 2022

7:30 am **Registration and Breakfast**

8:30 am **Opening Remarks**

Edward Abrahams, Ph.D., President, Personalized Medicine Coalition

8:35 am **Personalized Medicine, Pandemic, and the Future of Cell-Based Cancer Therapies: A Keynote Fireside Chat With Kite CEO Christi Shaw**

Following the approval of Kite's first chimeric antigen receptor (CAR) T-cell therapy in 2017, the company set its sights on delivering these highly personalized treatments to every patient who can benefit. Then COVID-19 upended the landscape for delivering cancer care. During this wide-ranging keynote fireside chat, Kite CEO Christi Shaw will reflect on the company's journey thus far and share her perspectives on the future of personalized medicine and cancer care.

MODERATOR | **Clifton Leaf**, Global Fellow, Ellison Institute for Transformative Medicine

KEYNOTE SPEAKER | **Christi Shaw**, CEO, Kite, a Gilead Company

9:15 am **Personalized Medicine in the Post-Pandemic Era: A Panel Discussion About Lessons Learned From the Emergence of COVID-19**

The devastating effects of COVID-19 exposed the shortcomings of the modern biomedical enterprise. But the pandemic also demonstrated medicine's ability to move further, faster. During this panel discussion, a cross-sector group of thought leaders will convene to consider what the lessons learned from the pandemic may mean for the future of personalized medicine.

MODERATOR | **Jay G. Wohlgemuth**, M.D., Chief Medical Officer, Senior Vice President, Research and Development, Medical, Population Health, Quest Diagnostics

Alex J. Carlisle, Ph.D., Founder, Chairman, CEO, National Alliance Against Disparities in Patient Health

Kris Joshi, Ph.D., Executive Vice President, President, Network Solutions, Change Healthcare

Lauren Silvis, Senior Vice President of External Affairs, Tempus

10:00 am **Networking Break**

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THIRD ROCK VENTURES

10:15 am **Personalized Medicine Outside of Oncology: A Panel Discussion on Opportunities and Challenges**

Molecular diagnostics, more sophisticated approaches to analyzing health care data, and molecularly guided treatments for non-oncologic indications are expanding the frontiers of personalized medicine outside of oncology. But progress remains uneven across disease states. During this panel discussion, leaders in the field will join us to explore the opportunities and challenges for personalized medicine in multiple disease states.

MODERATOR | **Elizabeth O'Day**, Ph.D., CEO, Founder, Olaris

William Hagstrom, Founder, CEO, Octave Bioscience

Dan M. Roden, M.D., Senior Vice President for Personalized Medicine, Vanderbilt University Medical Center

Catherine Sanders, Ph.D., Vice President, Research and Business Development, Adaptive Biotechnologies

10:55 am **The Priorities of Patients: A Presentation and Panel Discussion About Patient-Centered Research Principles for the Era of Personalized Medicine**

In the era of personalized medicine, health care researchers are aligning their work more closely with patients' values, circumstances, and preferences. After two years of discussions convened by the Personalized Medicine Coalition, patients will join us during this presentation and panel discussion to share principles and recommendations for conducting patient-centered personalized medicine research.

MODERATOR | **Lori Frank**, Ph.D., Senior Vice President, Research, Policy, and Programs, The New York Academy of Medicine; Medical, Scientific, and Memory Screening Advisory Board Member, Alzheimer's Foundation of America

J. Michael Graglia, Co-Founder, Managing Director, SynGAP Research Fund

Laura Holmes Haddad, Writer/Patient Advocate

Richard Knight, President, American Association of Kidney Patients

11:40 am **Presentation of *The 16th Annual Award for Leadership in Personalized Medicine***

The *Annual Award for Leadership in Personalized Medicine* recognizes an individual whose contributions in science, business, and policy have helped advance the frontiers of the field. This year's award goes to Carl June, M.D., Richard W. Vague Professor in Immunotherapy, University of Pennsylvania. By paving the way for cancer treatments that use a patient's own immune cells to combat cancer, Dr. June's scientific discoveries have saved the lives of hundreds of patients and brought new hope to thousands.

PRESENTER | **Stephen L. Eck**, M.D., Ph.D., Senior Vice President, Clinical Development, Chief Medical Officer, MacroGenics

AWARDEE | **Carl June**, M.D., Richard W. Vague Professor in Immunotherapy, University of Pennsylvania

12:10 pm **Lunch Buffet in the Monarch Courtyard and Pool**

1:00 pm **Beyond the Barriers: A Keynote Address on Realizing the Promise of Personalized Medicine**

As the CEO of a diagnostics company focused on enabling "earlier, smarter answers across the cancer journey," Kevin Conroy has broad-based ambitions for personalized medicine to transform cancer care. But realizing the promise of personalized medicine has been fraught with challenges since the human genome was first mapped in 2003. During this keynote address, Conroy will outline his vision for the future of the field.

INTRODUCTION | **Michael J. Pellini**, M.D., Managing Partner, Section 32

KEYNOTE SPEAKER | **Kevin Conroy**, CEO, President, Chairman of the Board, Exact Sciences

1:45 pm **Developing Diagnostics: A Panel Discussion About the Outlook for Diagnostic Tools Underpinning Personalized Medicine**

The diagnostics underpinning personalized medicine promise to improve health care by facilitating interventions at earlier stages of disease and targeting treatments to those who will benefit. The road to clinical adoption, however, is fraught with challenges. During this panel discussion, industry representatives will convene to discuss the outlook for transformative diagnostic tools designed to upend one-size-fits-all medicine.

MODERATOR | **Tom Miller**, Founder, Managing Partner, GreyBird Ventures

Okan Ekinci, M.D., Senior Vice President, Global Head of Marketing and Innovation, Roche Diagnostics Information Solutions

Megan P. Hall, Ph.D., Vice President, Medical Affairs, GRAIL

Peter Maag, Ph.D., Board Member, CareDx

Robert L. Nussbaum, M.D., Chief Medical Officer, Invitae

2:30 pm **Networking Break**

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3:00 pm The State of Pharmacogenomics: A Panel Discussion About the Future of Pharmacogenetic Testing and Personalized Medicine

By providing information about how certain genes may affect a patient's response to a drug, pharmacogenetic testing can inform personalized treatment strategies. But differing perspectives regarding the strength of the evidence supporting certain gene-drug interactions have slowed the pace at which clinicians are utilizing pharmacogenetic testing in clinical settings. During this panel discussion, a cross-sector group of thought leaders will convene to discuss the future of pharmacogenetic testing and personalized medicine.

MODERATOR | **Howard McLeod**, Pharm.D., Executive Clinical Director, Precision Health, Intermountain Healthcare

Kelly Caudle, Ph.D., Pharm.D., Principal Investigator and Director, Clinical Pharmacogenetics Implementation Consortium, St. Jude Children's Research Hospital

Jami Elliott, Director, Global Business Development, Thermo Fisher Scientific

Don Rule, CEO, Founder, Translational Software

Jeffrey A. Shaman, Ph.D., Chief Science Officer, Coriell Life Sciences

3:45 pm Reflections on Reimbursement: A Panel Discussion Spotlighting Payers' Perspectives on Personalized Medicine

Payers have historically directed their resources toward medical interventions that will deliver immediate value to patients. But increased spending on personalized medicine may improve clinical and economic results over time. In this context, some payers have found innovative ways to cover groundbreaking personalized prevention and treatment strategies with extraordinary but understudied potential benefits. During this panel discussion, three payer representatives will share their perspectives on the evolving landscape for coverage and payment in personalized medicine.

MODERATOR | **Michael J. Pellini**, M.D., Managing Partner, Section 32

Jill Hagenkord, M.D., Chief Medical Officer, Optum Genomics

Thomas C. Hawes, M.D., Partner, Sandbox Industries; Member, BlueCross BlueShield Fund Management Team

Michael Sherman, M.D., Executive Vice President, Chief Medical Officer, Point32Health

4:30 pm **Amgen and the 'Undruggable' Cancer Target: A Keynote Address on the Future of Personalized Medicine and the Pharmaceutical Industry**

In December of 2016, *The Wall Street Journal* lamented cancer-associated genetic mutations in the KRAS gene as "undruggable" targets. Less than five years later, Amgen won approval from the U.S. Food and Drug Administration for LUMAKRAS (sotorasib), a targeted therapy for certain lung cancer patients whose tumors express KRASG12C mutations. The historic approval underlines how personalized medicine is redefining the boundaries of medicine. But the road to commercialization presents many obstacles. During this closing keynote address, Amgen Senior Vice President for Research and Development Jean-Charles Soria will envision the future of personalized medicine and the pharmaceutical industry with attention to the scientific, business, and policy challenges associated with developing and commercializing targeted therapeutics.

INTRODUCTION | **Randy Burkholder**, Vice President, Policy and Research, PhRMA

KEYNOTE SPEAKER | **Jean-Charles Soria**, M.D., Ph.D., Senior Vice President, Research and Development, Amgen

5:00 pm **Welcome Reception on the Dana Point Lawn**

Sponsored by

Intermountain Precision Genomics

Overview · Part II

May 20, 2022

7:30 am **Registration and Breakfast**

8:30 am **Opening Remarks**

Jay G. Wohlgemuth, M.D., Chief Medical Officer, Senior Vice President, Research and Development, Medical, Population Health, Quest Diagnostics

8:35 am **Public Policies and Personalized Medicine: Outlining a Vision for the Future of Personalized Medicine at FDA**

In 2007, when Janet Woodcock began a 13-year stint as the Director of the U.S. Food and Drug Administration's Center for Drug Evaluation and Research, there were less than five personalized medicines on the market. Today, there are more than 300. During this wide-ranging keynote address, the winner of the *First Annual Award for Leadership in Personalized Medicine* will join us to reflect on the progress and future of the field as she continues a tenure of public service spanning three decades and counting.

INTRODUCTION | **Cynthia A. Bens**, Senior Vice President, Public Policy, Personalized Medicine Coalition

KEYNOTE SPEAKER | **Janet Woodcock**, M.D., Principal Deputy Commissioner, U.S. Food and Drug Administration

9:15 am **Breakthroughs at Blueprint Medicines: A Case Study Led by Harvard Business School's Richard Hamermesh**

By developing a unique library of compounds to target the kinase tree, Blueprint Medicines has been able to identify and develop new molecules and get them approved almost twice as fast as is typical. The result has been a robust pipeline and commercialization opportunities. Balancing all of these efforts was already challenging. The emergence of COVID-19 made it more so. Led by Harvard Business School's Richard Hamermesh, this interactive case study discussion will consider the potential impact of Blueprint's approach on the future of drug discovery and personalized medicine as well as the challenges that the pandemic posed.

LEADER | **Richard Hamermesh**, D.B.A., Co-Faculty Chair, Harvard Business School Kraft Precision Medicine Accelerator

GUEST SPEAKER | **Kate Haviland**, President, CEO, Blueprint Medicines

10:00 am **Networking Break**

Sponsored by

SANFORD HEALTH

10:15 am **Closing the 'Practice Gap' in Personalized Cancer Care: Research Findings From Diaceutics and the Personalized Medicine Coalition**

Recent research has revealed a "practice gap" in personalized cancer care whereby patients whose tumors test positive for key biomarkers never receive the corresponding targeted treatments that could have helped them. During this presentation, a Diaceutics executive will present the findings from a Personalized Medicine Coalition study that explores the factors contributing to this practice gap.

INTRODUCTION | **Daryl Pritchard**, Ph.D., Senior Vice President, Science Policy, Personalized Medicine Coalition

SPEAKER | **Susanne Munksted**, Chief Precision Officer, Diaceutics

10:30 am **Providing Personalized Medicine: Reflections From Representatives of Differently Structured Health Care Systems**

In demonstrating that the vast majority of health care institutions are taking steps to integrate personalized medicine into clinical care, research findings published in the *Journal of Personalized Medicine* in March of 2021 underline the field's evolution from a promising concept to a practical reality. But the Personalized Medicine Coalition study also spotlighted considerable opportunities to further optimize personalized medicine integration. This panel discussion will feature reflections on delivering personalized medicine from representatives of a clinical integration partner institution, an academic medical center that manages research and clinical care programs, an integrated health care delivery system that combines reimbursement and care delivery functions, and a community health care system that focuses predominantly on the delivery of care.

MODERATOR | **Daryl Pritchard**, Ph.D., Senior Vice President, Science Policy, Personalized Medicine Coalition

Lisa Alderson, Co-Founder, CEO, Genome Medical

Burns C. Blaxall, Ph.D., Director, Precision Medicine, The Christ Hospital Health Network

Lincoln Nadauld, M.D., Ph.D., Vice President, Chief of Precision Health and Academics, Intermountain Healthcare

Apostolia M. Tsimberidou, M.D., Ph.D., Professor, The University of Texas MD Anderson Cancer Center

11:15 am **Precision Partnership: A Fireside Chat With Leaders From GNS Healthcare and the Multiple Myeloma Research Foundation**

Artificial intelligence presents unprecedented opportunities to develop better predictive models for individual patients facing difficult decisions about the future of their care. But progress depends on pairing computational capacity with the right datasets. During this fireside chat, leaders from GNS Healthcare and the Multiple Myeloma Research Foundation (MMRF) will discuss the significance of their cross-sector collaboration to develop patient-specific models of disease progression and drug response using the data from MMRF's CoMMpass Study.

MODERATOR | **Mark P. Stevenson**, Board Member, Personalized Medicine Coalition

Michael Andreini, President, CEO, Multiple Myeloma Research Foundation

Colin Hill, Chairman, CEO, Co-Founder, GNS Healthcare

11:45 am **Envisioning the Future of Data-Driven Personalized Medicine: A Keynote Address by Verily's Amy Abernethy**

As a pioneering leader in personalized medicine with a broad-based platform for advancing Alphabet Inc.'s ambitions in health care, Amy Abernethy sees tremendous opportunities on the horizon for patients and personalized medicine. During this closing keynote address, the former Principal Deputy Commissioner of the U.S. Food and Drug Administration will outline her data-driven vision for the future of the field.

INTRODUCTION | **Edward Abrahams**, Ph.D., President, Personalized Medicine Coalition

KEYNOTE SPEAKER | **Amy P. Abernethy**, M.D., Ph.D., President, Clinical Studies Platforms, Verily

12:15 pm **Closing Remarks**

Edward Abrahams, Ph.D., President, Personalized Medicine Coalition

12:20 pm **Lunch Buffet in the Monarch Courtyard and Pool**

PART I

ASSESSING AN EVOLVING SCIENTIFIC, BUSINESS, AND POLICY LANDSCAPE

May 19, 2022
The Ritz-Carlton Ballroom

RITZ-CARLTON LAGUNA NIGUEL • ONE RITZ CARLTON DRIVE, DANA POINT, CA 92629

Personalized Medicine, Pandemic, and the Future of Cell-Based Cancer Therapies

A Keynote Fireside Chat With Kite CEO Christi Shaw

With the approval of the first chimeric antigen receptor (CAR) T-cell therapies in 2017, the U.S. Food and Drug Administration added a paradigm-shifting opportunity to a personalized medicine landscape previously dominated by targeted therapies in cancer care. By affirming the safety and efficacy of therapies designed to genetically re-engineer a patient's own immune cells to combat cancer, the new approvals signaled that the latest scientific and technological breakthroughs had not only given researchers and clinicians the ability to develop targeted treatments based on certain biological characteristics. They also provided a chance to make long-lasting changes to patients' cells, perhaps forever altering how they behave.

But then, as now, CAR T-cell therapies faced a daunting road to clinical adoption. In the expensive and time-consuming process of producing a tailor-made CAR T-cell therapy for each patient by removing immune cells, shipping them to external locations for genetic engineering and preservation, and shipping them back to the patient for re-infusion, skeptics saw insurmountable logistical and reimbursement challenges.

Christi Shaw saw opportunities for patients.

In August of 2019, three years after leaving her position as the President of Novartis Pharmaceuticals Corporation to spend a year caring for a sister navigating a multiple myeloma diagnosis, Shaw accepted a position as the CEO of Kite, a Gilead Company, whose CAR T-cell therapies are FDA-approved for patients with certain blood and lymphatic cancers. Soon afterward, the COVID-19 pandemic upended the landscape for delivering cancer care. Lockdowns delayed diagnoses. Travel restrictions disrupted flight schedules. Supply chains became longer.

Yet, by the Summer of 2020, Kite's revenues had increased 25 percent as compared to the Fall of 2019. By this time, Kite had just opened a new manufacturing facility in Europe with the potential to treat 4,000 more patients globally each year. Despite industry-wide challenges caused by the onset of the pandemic, Kite continued to deliver patients' T-cells without disruption and never failed a single patient as a result of the pandemic. Kite's revenues continued to grow in 2021.

During her opening keynote interview with former *Fortune* Editor-in-Chief and critically acclaimed author Clifton Leaf, Shaw will reflect on what Kite's journey thus far might mean for the future of gene and cell-based therapies, many of which have progressed in fits and starts in recent years as their extraordinary potential intersects with the realities of science, business, and policy. By envisioning the future of personalized medicine and cell-based therapy, the session promises to help set the stage for our exploration of personalized medicine: "From an Enterprise to an Era."

Participants

Clifton Leaf

Global Fellow, Ellison Institute for Transformative Medicine

Moderator

Clifton Leaf is a Global Fellow at the Ellison Institute for Transformative Medicine and an Adjunct Professor of Journalism at Columbia University's Graduate School of Journalism. Previously (until June 2021) he was the 19th Editor-in-Chief of *FORTUNE*, where he directed the editorial content and strategy across all of *FORTUNE*'s platforms, shepherding this venerable publication through its 90th anniversary and beyond. During his nearly four-and-a-half-year tenure as Editor-in-Chief, *FORTUNE* was honored with more than 70 top journalism prizes, earned high acclaim for its print magazine redesign, substantially expanded its digital offerings, audience, and virtual events, and built a formidable premium subscription business.

Mr. Leaf is also the author of the critically acclaimed book, *The Truth in Small Doses: Why We're Losing the War on Cancer – and How to Win It*, which was named by *Newsweek* as one of "The Best Books About Cancer."

Christi Shaw

CEO, Kite, a Gilead Company

Keynote Speaker

Christi Shaw serves as Chief Executive Officer of Kite, Gilead's cell therapy company. Based in Santa Monica, California, Christi and her team at Kite are pursuing the ambitious goal of curing cancer as an industry leader in CAR T-cell therapy. In her role, Christi is responsible for Kite's end-to-end, global cell therapy business. She is driven by values, integrity and a deep connection to people living with cancer and those who love them. Her leadership has spanned a broad range of therapeutic areas, including oncology, immunology, Alzheimer's disease, and medical devices. She has been responsible for overseeing the full lifecycle of product portfolios, from discovery and development to commercialization and manufacturing.

Before joining Kite, Christi held senior executive positions at Eli Lilly & Co. and Novartis Corp. Christi currently serves on the boards of directors of Avantor and the Healthcare Businesswomen's Association (HBA). She is also on the executive committee and the board of directors of the Biotechnology Innovation Organization (BIO).

Personalized Medicine in the Post-Pandemic Era

A Panel Discussion About Lessons Learned From the Emergence of COVID-19

"The lessons learned from the emergence of this new virus will undoubtedly shape discussions about the future of health care in America and around the globe for years to come."

These words, excerpted from a digital dispatch sent to members of the Personalized Medicine Coalition at the height of the pandemic lockdowns on April 2, 2020, have born themselves out over the past two years. Examples abound of pandemic developments that have reshaped the calculus for the future of health care and personalized medicine.

For one, the pandemic's tragically uneven consequences have spotlighted health disparities across diverse patient populations. Finding strategies for increasing diversity among participants in health care studies has emerged as a priority for personalized medicine, which depends on inclusive research to inform medical interventions that affect patient populations differently.

In addition, the rapid collection of data about the new virus has reminded us of our emerging opportunities to use data to make personalized prevention and treatment recommendations. Doing so helps ensure that scarce health care resources are allocated to those who need them most.

The pharmaceutical industry's success in quickly developing COVID-19 vaccines has put added pressure on the biomedical enterprise to move further, faster.

In light of a health care landscape that may be forever changed, Jay G. Wohlgemuth, M.D., Chief Medical Officer, Senior Vice President, Population Health, Quest Diagnostics, will moderate this panel discussion titled "Personalized Medicine in the Post-Pandemic Era." The session will feature perspectives from National Alliance Against Disparities in Patient Health CEO Alex J. Carlisle, Change Healthcare Executive Vice President Kris Joshi, and Tempus Senior Vice President for External Affairs Lauren Silvis, who served as an adviser to the Biden Administration as it sought to develop and deploy COVID-19 vaccines with maximum impact.

Participants

Jay G. Wohlgemuth, M.D.

Chief Medical Officer, Senior Vice President, Research and Development, Medical, Population Health, Quest Diagnostics

Moderator

Jay G. Wohlgemuth, M.D., is Chief Medical Officer and Senior Vice President, Research and Development, Medical, and Population Health, for Quest Diagnostics. He is based at the Quest Diagnostics Nichols Institute in San Juan Capistrano, California.

Dr. Wohlgemuth has many years of experience in medical diagnostics and research and development. He rejoined Quest in 2016 from HealthTap, a health information start-up, where he served as Senior Vice President and Chief Healthcare Officer. Prior to that, he was Senior Vice President, Research and Development, Medical, and Chief Scientific Officer with Quest. Dr. Wohlgemuth originally joined Quest in 2009 from Genentech, where he was Director, Clinical Diagnostics, Immunology, Tissue Growth and Repair, and Global Development Team Leader for ocrulizumab. He serves on the board of directors of the Personalized Medicine Coalition.

Alex J. Carlisle, Ph.D.

Founder, Chairman, CEO, National Alliance Against Disparities in Patient Health

Panelist

Dr. Alex Carlisle holds a doctorate in biochemistry and molecular biology from Howard University and has spent the past 17 years developing and applying translational and clinical research approaches in the areas of molecular oncology and neuroscience. Dr. Carlisle received his post-doctoral training at the U.S. National Institutes of Health, where he served at the National Cancer Institute as a leading member of the Cancer Genome Anatomy Project, and at the National Institute for Neurological Disorders and Stroke.

Kris Joshi, Ph.D.

Executive Vice President, President, Network Solutions, Change Healthcare

Panelist

Mr. Joshi is Executive Vice President and President, Network Solutions, for Change Healthcare. He initially joined Change Healthcare as Executive Vice President, Products, in December 2013. Prior to that, Mr. Joshi was Global Vice President for Health Care Product Strategy for the Health Sciences Global Business Unit of the Oracle Corporation. He helped launch the health sciences business unit and successfully led two acquisitions for Oracle in the life sciences space. Before joining Oracle, Mr. Joshi served in senior strategy roles in IBM's Global Sales and Distribution organization. Prior to that, Mr. Joshi was with McKinsey and Company, where he served Fortune 500 clients on strategy issues.

Lauren Silvis

Senior Vice President of External Affairs, Tempus

Panelist

Lauren Silvis serves as Senior Vice President of External Affairs at Tempus, overseeing regulatory, public policy, and government affairs. Silvis most recently served as the Chief of Staff of the U.S. Food and Drug Administration. Prior to that role, she was the Deputy Center Director for Policy in FDA's Center for Devices and Radiological Health. At the FDA, she advanced policies on clinical testing, precision medicine, and digital health. Silvis was also a partner at Sidley Austin LLP, focusing on FDA regulation of pharmaceuticals and medical devices. She graduated from Duke University and earned her law degree from Georgetown University Law Center.

Personalized Medicine Outside of Oncology

A Panel Discussion on Opportunities and Challenges

In 1998, the U.S. Food and Drug Administration's approval of Herceptin (trastuzumab), a drug that binds to protein receptors on cancerous cells to block tumor growth among breast cancer patients whose diseases over-express the HER2 protein, ignited the public's imagination with visions of a new era of personalized medicine in oncology. In the years that followed, researchers made cancer a focal point of personalized medicine, spurring the development of more than 90 biomarker-based cancer therapies on the market today.

Now the field is gaining momentum in other disease states.

In the latest edition of *Personalized Medicine at FDA: The Scope & Significance of Progress in 2021*, the Personalized Medicine Coalition shows that more than half of the personalized medicines FDA approved in 2021 are indicated for rare, common, or infectious diseases. The report shows industry leaders extending the benefits of personalized medicine to millions of additional patients across multiple disease states.

During this session, Octave Bioscience CEO William Hagstrom, Vanderbilt University Medical Center Senior Vice President for Personalized Medicine Dan M. Roden, M.D., and Adaptive Biotechnologies Vice President for Research and Development Catherine Sanders, Ph.D., will join moderator and PMC Board Member Elizabeth O'Day, Ph.D., who also serves as CEO of Olaris, to explore the evolving contours of personalized medicine beyond oncology.

Dr. Sanders will reflect on the opportunities and challenges for personalized medicine as it relates to infectious diseases. Mr. Hagstrom will discuss his focus on advancing personalized medicine to benefit patients with central nervous system disorders. And Dr. Roden, a cardiologist, will explain how personalized medicine approaches can inform the treatment of cardiovascular diseases.

Participants

Elizabeth O'Day, Ph.D.

CEO, Founder, Olaris

Moderator

Elizabeth O'Day, M.Phil., Ph.D., is the CEO and Founder of Olaris, Inc., a precision medicine company that uses a pioneering metabolomics platform and proprietary machine learning algorithms to fundamentally improve how disease is diagnosed and treated. Olaris identifies "biomarkers of response" (BoR) to stratify patients into optimal treatment groups, increasing survival rates, decreasing adverse events, and reducing unnecessary health care costs.

Outside of Olaris, Dr. O'Day plays an incredibly active role in partnering with government leaders and global organizations in advancing the field of precision medicine around the world. Dr. O'Day was invited to attend the first United States of Women Summit convened by the White House in 2016 and was selected to participate in then-Vice President Joe Biden's Cancer Moonshot Summit to discuss collaborative ways "to end cancer as we know it."

William Hagstrom

Founder, CEO, Octave Bioscience

Panelist

William Hagstrom has over 30 years of start-up experience in a broad range of medical specialties integrating new science, technology, and data analytics to improve patient outcomes. Prior to founding Octave Bioscience, he was CEO of Crescendo Bioscience, which created novel measurement tools and software in rheumatology. Previously, he was President of Alpha BioPartners, a strategic consulting firm focused on launching new life sciences companies, where he created the business plan for Crescendo and co-founded Altheus Therapeutics and Biolytx Pharmaceuticals.

Prior to that, he was the initial CEO of Selexys Pharmaceuticals and interim CEO of Inoveon in ophthalmology. In the 1990s, Bill was Chairman and CEO of UroCor, a urology specialty diagnostics company that he scaled from start-up through IPO. Earlier, he was Vice President of Baxter International's $1 billion Scientific Products Division and held management positions at American Hospital Supply and Becton Dickinson.

Dan M. Roden, M.D.

Senior Vice President for Personalized Medicine, Vanderbilt University Medical Center

Panelist

Dan Roden was born and raised in Montreal and received his medical degree and training in internal medicine from McGill University. He then went to Vanderbilt, where he trained in clinical pharmacology and cardiology, and has been a faculty member there since. His initial career focus — that he has maintained — was studies of the clinical, genetic, cellular, and molecular basis of arrhythmia susceptibility and variability responses to arrhythmia therapies.

Over the last 10 years, Dr. Roden has led Vanderbilt's broader efforts in pharmacogenomics discovery and implementation. He is principal investigator for the Vanderbilt sites of the National Institutes of Health's Pharmacogenomics Research Network (PGRN) and the National Human Genome Research Institute's Electronic Medical Records and Genomics (eMERGE) Network. He directs the Vanderbilt DNA databank BioVU, a discovery resource that as of Spring 2014 included more than 175,000 samples linked to de-identified electronic medical records.

Catherine Sanders, Ph.D.

Vice President, Research and Business Development, Adaptive Biotechnologies

Panelist

Catherine Sanders, Ph.D., M.S., is Vice President, Research and Business Development at Adaptive Biotechnologies, a commercial-stage biotech company that aims to translate the genetics of the adaptive immune system into clinical products to diagnose and treat disease. With more than 10 years at the company and vast expertise in the field of immunosequencing, Catherine is responsible for establishing partnerships with pharmaceutical companies and collaborations with key opinion leaders in oncology, hematology, transplantation, infectious disease, and autoimmunity to drive therapeutic development.

Catherine began her career as a post-doctoral fellow at the HudsonAlpha Institute for Biotechnology analyzing immune repertoire changes in cancer, autoimmune disease, and infectious disease. She received a Ph.D. in immunopathology and an M.S. in pathology from the University of Mississippi Medical Center in Jackson, where she focused on TLR, chemokine receptor, and cytokine expression in HIV-infected T lymphocyte subsets. Catherine also holds a B.S. degree in Medical Technology from Mississippi State University and received her board certification from Vanderbilt University Medical Center.

The Priorities of Patients

A Presentation and Panel Discussion About Patient-Centered Research Principles for the Era of Personalized Medicine

In a press release announcing the launch of the Personalized Medicine Coalition's *Patient-Centered Research Agenda Advancing Personalized Medicine* on August 21, 2020, PMC Board Member Lori Frank, Ph.D., who also serves as a Medical, Scientific, and Memory Screening Advisory Board Member at the Alzheimer's Foundation of America, reflected on what it will take to advance a new era of personalized medicine. To put the patient at the center of health care decision-making, Dr. Frank said, we must "align future research in personalized medicine with the perspectives of the patients who will be most affected by new developments in this rapidly evolving field." Engaging patients in all aspects of health care decision-making, she notes, is the only way to ensure that systemic changes are calibrated to patients' biological characteristics, circumstances, and values.

Especially in the wake of a devastating pandemic that has had tragically uneven consequences across patient populations, Dr. Frank's remarks are worth bearing in mind. As we become increasingly dependent on a diverse, equitable, and inclusive biomedical research enterprise to generate reliable evidence to inform health care interventions that affect subsets of heterogeneous patient populations differently, we must ensure that health care studies are positioned to meaningfully improve the experiences of the patients they are designed to serve.

In this context, Dr. Frank will moderate "The Priorities of Patients: A Presentation and Panel Discussion About Patient-Centered Research Principles for the Era of Personalized Medicine." After two years of discussions convened by PMC, three patients will join us during this session to present and discuss the findings of the Coalition's work on its patient-centered research agenda, which outlines principles and recommendations for conducting patient-centered personalized medicine research.

Participants

Lori Frank, Ph.D.

Senior Vice President, Research, Policy, and Programs, The New York Academy of Medicine; Medical, Scientific, and Memory Screening Advisory Board Member, Alzheimer's Foundation of America

Moderator

Lori Frank is currently president of the International Society for Quality of Life Research, and she serves on the board of the Personalized Medicine Coalition and the Alzheimer's Foundation of America's Medical, Scientific, and Memory Screening Advisory Board. She completed her Health and Aging Policy Fellowship through the American Political Science Association Congressional Fellowship Program with a placement at the National Institutes of Health.

Frank founded and served as program director of the Evaluation and Analysis Program at the Patient-Centered Outcomes Research Institute (PCORI), establishing a research program to examine stakeholder engagement, along with survey research and portfolio analysis functions. Prior to joining PCORI, she served as executive director and senior research leader, Center for Health Outcomes Research, with MEDTAP International/United BioSource Corporation, where she managed the scientific and financial performance of the Center, overseeing international operations.

J. Michael Graglia

Co-Founder, Managing Director, SynGAP Research Fund

Panelist

Mike comes from a career in public policy, international development, and strategy. Previous roles have included establishing a new program at New America, a DC think tank, Budget & Planning at both the Gates Foundation & Emerson Collective, health care consulting at BCG, developing world university support for the World Bank Group, managing a refugee program for the International Catholic Migration Commission in Zimbabwe, and teaching math in Peace Corps Namibia.

Graglia has an M.B.A. from Columbia University, where he was a Bronfman Fellow, and an M.A. in Southeast Asian studies from Johns Hopkins School of Advanced International Studies, where his studies were supported by the Paul & Daisy Soros Fellowship for New Americans. He studied mathematics at Gonzaga University.

Laura Holmes Haddad

Writer/Patient Advocate

Panelist

Laura Holmes Haddad is a writer, patient advocate, and speaker from Massachusetts. A former cookbook editor and food writer, Laura's career focus shifted when she was diagnosed with stage IV inflammatory breast cancer at the age of 37. After completing three years of precision medicine-based treatment — including a Phase 1a clinical trial — Laura speaks to a wide range of audiences about cancer-related topics. Her speaking engagements have included panels and keynotes to various stakeholders, including patients, providers, payers, and legislators. She shares her insights on topics such as clinical trials; financial side effects; hereditary cancer and genetic testing; and parenting with cancer. Her advocacy work is rooted in health care policy reform for access to comprehensive cancer care.

Laura has contributed articles related to cancer and health to numerous publications and has been a guest on numerous radio shows and podcasts to discuss cancer issues. She is also the author of *This is Cancer: Everything You Need to Know, from the Waiting Room to the Bedroom*, where she writes frankly about the patient experience and shares practical tips and resources for getting through a cancer diagnosis.

Richard Knight

President, American Association of Kidney Patients

Panelist

Richard Knight received his M.B.A. from the University of Virginia Darden School of Business and his B.A. from Hampton University. He is a results-oriented business strategist with diverse experience in the public and private sectors in finance, accounting, business development, health care, and nonprofits. Entrepreneurial experience includes starting and running several ventures. Currently, he is a business strategist, providing patient engagement consulting for health care organizations and businesses developing tools designed to leverage patient input and preferences in their care plans and quality measures. He serves as an adjunct professor at Bowie State University (BSU) and is a founding member of BSU's College of Business Advisory Council.

Mr. Knight is a health care professional and a former hemodialysis patient. He received a kidney transplant approximately 14 years ago. He is President of the American Association of Kidney Patients, which is the oldest and largest independent kidney patient organization in the United States.

Presentation of the *Award for Leadership in Personalized Medicine*

For most of the last two decades, proponents of personalized medicine have focused on tailoring prevention and treatment plans to the biology of each patient. Although the field's early advocates foresaw the development of increasingly powerful ways to align health care strategies with each patient's molecular characteristics, it was assumed that our ability to fundamentally alter those molecular characteristics would remain largely unchanged.

Carl June's research has upended this assumption.

Working out of his laboratory at the University of Pennsylvania, the winner of the Personalized Medicine Coalition's *16th Annual Award for Leadership in Personalized Medicine* has saved the lives of hundreds of cancer patients and brought new hope to thousands by showing that a patient's own immune cells can be genetically modified to seek and attack cancer cells. His discoveries have already informed the development of two such approaches to chimeric antigen receptor (CAR) T-cell therapy, which is perhaps the closest the world has ever come to a cure for cancer.

Carl June will join us during this session to accept PMC's award for contributions in science, business, and policy that have helped advance the frontiers of personalized medicine. Following an introduction by Stephen L. Eck, Senior Vice President for Clinical Development and Chief Medical Officer of MacroGenics, Carl June's keynote remarks promise to help define the expanding scientific boundaries of personalized medicine.

Participants

Stephen L. Eck, M.D., Ph.D.

Senior Vice President, Clinical Development, Chief Medical Officer, MacroGenics

Presenter

Stephen L. Eck, M.D., Ph.D., is a hematologist/oncologist with extensive experience in the development of pharmaceuticals and their companion diagnostics. He is currently Chief Medical Officer of MacroGenics. He also serves on the boards of directors of Luminex Corporation and Circulogene, which develop and market medical diagnostics.

Previously, Dr. Eck has held a variety of industry leadership positions at Aravive Biologics, Astellas Pharma, Lilly, and Pfizer. He has also served on the faculty of the University of Michigan School of Medicine and the University of Pennsylvania School of Medicine. He holds a B.S. degree from Kalamazoo College, an M.D. degree from the University of Mississippi, and a Ph.D. from Harvard University.

Carl June, M.D.

Richard W. Vague Professor in Immunotherapy, University of Pennsylvania

Awardee

Carl June is the Richard W. Vague Professor in Immunotherapy in the Department of Pathology and Laboratory Medicine at the University of Pennsylvania. He is also the Director of the Center for Cellular Immunotherapies at the Perelman School of Medicine and the Director of the Parker Institute for Cancer Immunotherapy. He is a graduate of the Naval Academy in Annapolis and Baylor College of Medicine in Houston, 1979. He had graduate training in immunology and malaria with Dr. Paul-Henri Lambert at the World Health Organization, Geneva, Switzerland, from 1978–1979, and post-doctoral training in transplantation biology with E. Donnell Thomas and John Hansen at the Fred Hutchinson Cancer Research Center in Seattle from 1983–1986. He is board-certified in internal medicine and medical oncology.

Beyond the Barriers

A Keynote Address on Realizing the Promise of Personalized Medicine

Since the completion of the Human Genome Project in 2003, proponents of personalized medicine have envisioned a new era in which we have the capacity to detect the onset of disease at its earliest stages, pre-empt the progression of disease, and increase the efficiency of health care systems by targeting treatments to only those who will benefit.

We have made tremendous progress.

There are now more than 75,000 genetic testing products and 286 personalized medicines on the market. Genetically guided personalized medicine has brought new hope to patients with certain cancers and rare diseases. In the future, if liquid biopsies prove capable of improving downstream patient outcomes, they promise to shift the cancer care landscape toward prevention and early detection, upending a paradigm long focused on the treatment of late-stage diseases.

Translating breakthroughs in personalized medicine into improved clinical care, however, has proven challenging. A recent study shows, for example, that between one-third and one-fourth of non-small cell lung cancer patients with actionable mutations detected by genomic testing do not receive the genetically targeted therapies that could improve their health. Many others never receive genomic testing at all. The most skeptical observers speculate that personalized medicine has taken us as far as it can. But its proponents maintain that if we can overcome the clinical integration barriers, the field has only just begun to deliver on its promise of a more effective and efficient health care system.

Thus, the stage is set for Exact Sciences CEO Kevin Conroy, who has a broad-based vision for developing and integrating genetic testing and liquid biopsies into the health care system. During this wide-ranging keynote address, Conroy will outline his thoughts on the future of the field with reference to challenges and solutions in science, business, and policy.

Participants

Michael J. Pellini, M.D.

Managing Partner, Section 32

Introduction

Dr. Pellini is Managing Partner of Section 32, a venture fund that invests in companies and inventors that are changing the way humans use technology and the way technology betters humanity. Previously, he served as CEO of Foundation Medicine from May 2011 until he transitioned to Chairman in February 2017.

He currently serves as a member of the boards of directors for Tango Therapeutics, Singular Genomics, Adaptive Biotechnologies, and the Mission Hospital Foundation. As a physician with more than 20 years of executive experience with companies at the forefront of clinical diagnostics and genomics, Dr. Pellini brings a breadth of understanding in personalized medicine, with a particular interest and focus on defeating cancer. Dr. Pellini is a member of the President's Leadership Council at Thomas Jefferson University and Jefferson Health, as well as the Advisory Board for Mission Hospital's Cancer Institute (Providence/St. Joseph Health).

Kevin Conroy

CEO, President, Chairman of the Board, Exact Sciences

Keynote Speaker

Kevin Conroy is the Chief Executive Officer, President, and Chairman of the Board of Exact Sciences. He became CEO 11 years ago and he has been part of a team that transformed Exact Sciences into one of the world's premier cancer diagnostics companies with more than 4,500 employees.

Mr. Conroy has led Exact Sciences through the development, clinical trial, regulatory approval, and commercialization of its noninvasive colorectal cancer screening test, Cologuard®. This culminated with Cologuard becoming the first medical device or diagnostic to receive simultaneous FDA approval and national Medicare coverage. Since 2014, millions of Americans have used Cologuard to screen for colorectal cancer, the second leading cause of cancer death in the United States.

In 2019, Exact Sciences' acquisition of Genomic Health united two of the industry's strongest brands, Cologuard and Oncotype DX®, and established the company's position as a global leader in advanced cancer diagnostics. The company is working to improve screening, early detection, and treatment guidance throughout the cancer continuum.

Developing Diagnostics

A Panel Discussion About the Outlook for Diagnostic Tools Underpinning Personalized Medicine

Game-changing early detection. Less invasive wellness monitoring. Enhanced clinical decision support. In the era of personalized medicine, biomarker-based diagnostics are captivating the public imagination.

The road to clinical adoption, however, is fraught with challenges. Industry leaders have sometimes had difficulty convincing payers to cover the costs of genetically based diagnostics, with variable reimbursement policies contributing to inconsistent testing utilization patterns across the United States. Clinicians are still adjusting to the norms of personalized medicine. For some, our enhanced capacity for assessing disease risk has also raised questions about how to avoid an "all-encompassing kingdom of the ill." These factors complicate the landscape for investing in innovative diagnostics underpinning personalized medicine. But the potential of such products to improve patient care is undeniable.

Tom Miller, Founder, Managing Partner, GreyBird Ventures, will moderate this panel discussion about the outlook for transformative diagnostic tools designed to upend one-size-fits-all medicine with tremendous potential benefits for both patients and health systems. Participating panelists include Okan Ekinci, M.D., Senior Vice President, Global Head of Marketing and Innovation, Roche Diagnostics Information Solutions; Megan P. Hall, Ph.D., Vice President, Medical Affairs, GRAIL; Peter Maag, Ph.D., Board Member, CareDx; and Robert L. Nussbaum, M.D., Chief Medical Officer, Invitae.

Participants

Tom Miller

Founder, Managing Partner, GreyBird Ventures

Moderator

After earning a graduate degree from the Harvard/MIT Health Sciences and Technology program, Tom joined Siemens, where he ran the global MRI business. He has also served as the CEO of the global medical operations of Carl Zeiss, the CEO of Analogic Corporation, and Chairman and CEO of LightLab Imaging, a start-up he helped to establish and sell. Tom re-joined Siemens in 2002, serving as a member of the Global Operating Board and Division CEO of Siemens Healthcare with 26,000 employees in over 130 countries. In 2013, Tom started GreyBird Ventures, an investment firm focused on technologies for precision medicine diagnosis. Tom is a speaker on health care technology at conferences around the world and serves as a director on the boards of five medical technology companies.

Okan Ekinci, M.D.

Senior Vice President, Global Head of Marketing and Innovation, Roche Diagnostics Information Solutions

Panelist

Okan is a Senior Vice President and Global Head of Marketing and Innovation for Roche Diagnostics Information Solutions, an organization focused on decision support solutions, powered by aggregated data and advanced analytics, in support of Roche's personalized health care strategy. He brings 20 years of experience in the health care sector, among which are eight years of clinical practice in cardiology. With his global team, he designs and implements novel value-centric approaches in medical and scientific affairs to support the whole lifecycle of digital health products & services, from early ideation and development through implementation and evidence generation.

Okan worked previously at Siemens Healthineers, where he was most recently Global Head of the Healthcare Consulting business, a unit developing and offering digitally enabled transformation and clinical consulting services. Prior to that, he established the Global Medical Office of Healthineers and served as its first Chief Medical Officer.

Megan P. Hall, Ph.D.

Vice President, Medical Affairs, GRAIL

Panelist

Megan P. Hall is Vice President of Medical Affairs at GRAIL, where she established and leads the Medical Affairs group supporting the development and launch of Galleri, a blood-based multi-cancer early detection test. Previously, Megan was Director of Medical Communications at Jazz Pharmaceuticals, where she led health care provider-focused publication and education strategies for the company's hematology/oncology and chronic pain portfolios. Before Jazz, Megan established a Medical Communication team at Natera to support the launch and evolution of the Panorama non-invasive prenatal test, and was an editor at the flagship open access journal, *PLOS Biology*. She also held research roles funded by the American Heart Association, the California Institute of Regenerative Medicine, the National Institutes of Health, and the Howard Hughes Research Foundation.

Megan earned a B.S. in biological sciences from the University of California at Santa Barbara and a Ph.D. in microbiology, immunology, and molecular genetics from the University of California at Los Angeles.

Peter Maag, Ph.D.

Board Member, CareDx

Panelist

Dr. Maag has over 20 years of executive management experience in the pharmaceutical and diagnostics industries. Prior to joining CareDx, Dr. Maag was President of Novartis Diagnostics based in Emeryville, California. He headed the expansion of the unit with worldwide growth in its blood screening business and established new ventures in molecular diagnostics. Dr. Maag also led one of Novartis' key affiliates as Country President, Germany, and lived in a dynamically growing and emerging market as Country President, Korea.

At Novartis' headquarters in Switzerland, he helped launch the Infectious Diseases franchise and served as the Head of Strategy for Novartis Pharmaceuticals. Prior to joining Novartis, Dr. Maag worked for six years at McKinsey and Company in New Jersey and Germany, focusing on pharmaceuticals and globalization strategies. Supporting various health care and high-tech companies in their growth efforts, he holds board and advisory positions at Phoenix, MolecularMD, and with the Personalized Medicine Coalition.

Robert L. Nussbaum, M.D.

Chief Medical Officer, Invitae

Panelist

Robert L. Nussbaum, M.D., is the Chief Medical Officer of Invitae. He is board certified in internal medicine, clinical genetics, and clinical molecular genetics, and is a Fellow of the American College of Physicians and the American College of Medical Genetics and Genomics. From 2006–2015, he was the Holly Smith Professor of Medicine at UCSF, and Chief of the Division of Genomic Medicine.

Before that, he served in the Division of Intramural Research of the National Human Genome Research Institute.

He has also served as a Professor of Human Genetics, Pediatrics, and Medicine at the University of Pennsylvania and an Associate Investigator of the Howard Hughes Medical Institute. He received an M.D. in 1975 from the Harvard-MIT Joint Program in Health Science and Technology, internal medicine training at Barnes Hospital/Washington University (1975–1978), and genetics training at Baylor College of Medicine (1978–1981).

The State of Pharmacogenomics

A Panel Discussion About the Future of Pharmacogenetic Testing and Personalized Medicine

Pharmacogenetic (PGx) tests are a cornerstone of personalized medicine. By informing physicians of potential gene-drug interactions, PGx testing helps optimize treatment selections for each patient, improving therapeutic effectiveness and reducing side effects.

But nearly two decades after the completion of the Human Genome Project, clinical adoption of PGx testing lags. Regulators and industry leaders have differing perspectives on the evidence supporting certain gene-drug interactions, and some health care players claim the available evidence "does not support the cost-effectiveness of broad-based testing." Both factors muddy the waters for health care providers already challenged to keep up with the rapidly evolving pace of progress in personalized medicine.

PGx testing advocates hope this dynamic will begin to change in the wake of watershed developments emerging from the first two quarters of 2022.

The Teachers' Retirement System of the State of Kentucky and Coriell Life Sciences, for example, have published a landmark case study showing that Coriell's PGx testing program saved the system an average of $5,176 per enrolled member. The Personalized Medicine Coalition has spotlighted the similarities and differences evident in the lists of gene-drug interactions published by the U.S. Food and Drug Administration and widely consulted clinical guidelines published by the Clinical Pharmacogenetics Implementation Consortium (CPIC). And with the bipartisan *Right Drug Dose Now Act*, the House co-chairs of the Congressional Personalized Medicine Caucus have introduced a bill designed to pave the way for more widespread utilization of PGx tests through research, educational programs, and incentives to encourage the integration of PGx information into electronic health records.

Howard McLeod, Pharm.D., Executive Clinical Director, Precision Health, Intermountain Healthcare, one of the nation's leading authorities on pharmacogenomics, will moderate this panel discussion titled "The State of Pharmacogenomics." Featuring representatives from Coriell Life Sciences, CPIC, Thermo Fisher Scientific, and Translational Software, the discussion will explore the future of PGx testing and personalized medicine with attention to issues in science, public policy, and clinical adoption.

Participants

Howard McLeod, Pharm.D.

Executive Clinical Director, Precision Health, Intermountain Healthcare

Moderator

Dr. Howard McLeod is an internationally recognized expert in precision medicine, having made novel contributions at the discovery, translation, implementation, and policy levels. He is the Medical Director for Precision Medicine at the Geriatric Oncology Consortium. Dr. McLeod chaired the NHGRI eMERGE network external scientific panel for the past decade and was a recent member of both the FDA Committee on Clinical Pharmacology and the NIH Human Genome Advisory Council. Dr. McLeod has been recognized as a Fellow of both the American Society of Clinical Oncology and the American College of Clinical Pharmacy. He has also been an active board member and/or founder for over a dozen privately held and publicly traded companies.

Kelly Caudle, Ph.D., Pharm.D.

Principal Investigator and Director, Clinical Pharmacogenetics Implementation Consortium, St. Jude Children's Research Hospital

Panelist

Kelly E. Caudle, Pharm.D., Ph.D., is the Clinical Pharmacogenetics Implementation Consortium (CPIC) Principal Investigator and Director. CPIC provides guidelines that enable the translation of genetic laboratory test results into actionable prescribing decisions for specific drugs. To date, CPIC has published 24 gene-based clinical guidelines. Dr. Caudle oversees all CPIC-related projects and the CPIC guideline development process, including the coordination of the guideline writing committees, the guideline evidence reviews, and the writing of the guideline manuscript and supplement. Furthermore, Dr. Caudle is involved in the clinical implementation of pharmacogenetics at St. Jude Children's Research Hospital.

Dr. Caudle received her Pharm.D. and Ph.D. from The University of Tennessee Health Science Center and completed an ASHP-accredited PGY2 residency at Le Bonheur Children's Hospital. She is also a board certified pharmacotherapy specialist. Dr. Caudle is currently an affiliate Assistant Professor at The University of Tennessee Health Science Center.

Jami Elliott

Director, Global Business Development, Thermo Fisher Scientific

Panelist

Jami Elliott leads clinical business strategy within Thermo Fisher Scientific's Genetic Sciences Division (GSD), where he directs new platform and test development for diagnostic segments. Jami is actively involved in CE-IVD and U.S.-IVD strategy development as well as programs focused on pharmacogenetics enabled medication therapy management, reimbursement, and regulatory strategy.

Don Rule

CEO, Founder, Translational Software

Panelist

Don founded Translational Software to accelerate the use of molecular diagnostics. Prior to this, he had a 14-year career at Microsoft, holding a variety of roles in providing Internet access to MSN, pioneering virtual private networking products, and integrating instant messaging with voice over IP networks. Don founded the BioIT Alliance from within Microsoft to accelerate collaboration in translational research.

Jeffrey A. Shaman, Ph.D.

Chief Science Officer, Coriell Life Sciences

Panelist

Jeffrey A. Shaman, Ph.D., M.S., is the Chief Science Officer at Coriell Life Sciences, where he oversees the company's research, education, and clinical programs and leads efforts focused on bridging the gap between genetic science and clinical application. Dr. Shaman brings years of experience in advising cross-functional teams together with his scholarship in genetics, pharmacology, stem cells, and clinical laboratory operations. Along with the CEO, he forges strategic partnerships with worldwide companies, laboratories, academic institutions, public/private self-insured companies, and federal, state, and regional health care and employee systems.

Dr. Shaman supports a team of scientists dedicated to precision medicine and pharmacogenomics who actively research, publish, and present findings in top-tier peer-reviewed journals. He is passionate about educating people from all backgrounds about the power of genetics and pharmacogenomic testing that is integrated with patient health history and clinical decision support to proactively promote better health.

Reflections on Reimbursement

A Panel Discussion Spotlighting Payers' Perspectives on Personalized Medicine

When the Personalized Medicine Coalition was launched in 2004, a fundamental challenge was to inspire health care leaders to invest in developing the tests and treatments necessary to target medical interventions to only those patients who will benefit.

We have made tremendous progress on this front.

There are now more than 75,000 genetic testing products and 286 personalized medicines on the market. These products and services have brought new hope to millions of patients across multiple disease states around the world. The newest innovations in personalized medicine anticipate an era in which we deploy liquid biopsy-based testing to catch cancers in early stages and gene editing to correct the root causes of rare genetic diseases.

But as we have seen with genomic sequencing, payers will be slow to adopt the updated reimbursement policies necessary to facilitate patient access to personalized medicine in the absence of evidence proving that the growing number of tools underpinning the field help health systems make better use of finite resources. Thus, an additional challenge for personalized medicine today is to understand payers' perspectives on the body of evidence underpinning the field and calibrate ongoing research efforts to address key evidence gaps.

PMC will take another step toward this goal during "Reflections on Reimbursement," which will feature conversations with representatives of three commercial payers about the evidence in support of the clinical and economic utility of personalized medicine across various disease states.

Participants

Michael J. Pellini, M.D.

Managing Partner, Section 32

Moderator

Dr. Pellini is Managing Partner of Section 32, a venture fund that invests in companies and inventors that are changing the way humans use technology and the way technology betters humanity. Previously, he served as CEO of Foundation Medicine from May 2011 until he transitioned to Chairman in February 2017.

He currently serves as a member of the boards of directors for Tango Therapeutics, Singular Genomics, Adaptive Biotechnologies, and the Mission Hospital Foundation. As a physician with more than 20 years of executive experience with companies at the forefront of clinical diagnostics and genomics, Dr. Pellini brings a breadth of understanding in personalized medicine, with a particular interest and focus on defeating cancer. Dr. Pellini is a member of the President's Leadership Council at Thomas Jefferson University and Jefferson Health, as well as the Advisory Board for Mission Hospital's Cancer Institute (Providence/St. Joseph Health).

Jill Hagenkord, M.D.

Chief Medical Officer, Optum Genomics

Panelist

Jill Hagenkord, M.D., is the Chief Medical Officer of Optum Genomics. Dr. Hagenkord is a board-certified pathologist with subspecialty boards in molecular genetic pathology and an additional fellowship in pathology/oncology informatics. She specializes in the development, validation, and implementation of novel health technologies as well as coding, coverage, and reimbursement issues for novel tests.

Prior to joining Optum, she was the Chief Medical Officer of several Silicon Valley genomic companies, including Invitae and 23andMe. She began her career as the Director of Molecular Pathology and Assistant Professor of Pathology at Creighton University School of Medicine. Dr. Hagenkord is active in the College of American Pathologists, the Association for Molecular Pathology, the American College of Medical Genetics and Genomics, and the National Academy of Medicine's Genomics and Precision Health Roundtable. She lives in suburban Des Moines with her teenage sons, two dogs, and two cats.

Thomas C. Hawes, M.D.

Partner, Sandbox Industries; Member, BlueCross BlueShield Fund Management Team

Panelist

Tom serves on the boards of directors of Octave Bioscience, Perspectum, UpwardHealth, Patientco, Owl Insights, and Oncology Analytics, and is a board observer of Healthify. He was previously on the boards of InVivoLink (acquired by HCA), Nexidia (acquired by NICE), Phreesia (acquired by NYSE), Heartflow, Verata Health (acquired by Olive.Ai), and AbleTo (acquired by Optum). He was also a board observer at Thrive.

Before joining the Blue Venture Fund, Tom matched at the Yale School of Medicine for residency and completed his first year of medical training at Greenwich Hospital. During his medical training, he worked on clinical studies at the ISK Institute for Orthopedics and Sports Medicine and on outcomes research at the National Cancer Institute and NYMC's Cardiothoracic Surgery Department.

Michael Sherman, M.D.

Executive Vice President, Chief Medical Officer, Point32Health

Panelist

Dr. Michael Sherman serves as Chief Medical Officer and Executive Vice President for Point32Health, which was created in early 2021 by the merger of Harvard Pilgrim Health Care and Tufts Health Plan. He is widely recognized as a leader in partnering with precision medicine companies to develop innovative approaches to broadening access to innovative technologies while also generating real-world evidence that can drive change more broadly.

Dr. Sherman serves as chair of the Board of Managers of the Harvard Pilgrim Health Care Institute, and on the Advisory Board of the Institute for Clinical and Economic Review (ICER). He also is the current chair for AHIP's CMO Leadership Council, and serves on the board of directors for the Personalized Medicine Coalition, and on the board of advisors for the Harvard Business School Healthcare Initiative.

Amgen and the 'Undruggable' Cancer Target

A Keynote Address on the Future of Personalized Medicine and the Pharmaceutical Industry

In December of 2016, *The Wall Street Journal* noted the seemingly "undruggable" nature of mutations in the HRAS, NRAS, and KRAS genes, which show up in about a quarter of all cancers. Because the molecular surfaces of RAS proteins offer no obvious pockets to target with a drug, it once seemed that the scientific frontiers of personalized medicine would likely never extend to cancers characterized by mutated RAS genes.

Then came LUMAKRAS (sotorasib).

Approved by the U.S. Food and Drug Administration in May of 2021 for the treatment of certain lung cancer patients whose tumors express KRASG12C mutations, LUMAKRAS, a groundbreaking targeted therapy from Amgen, demonstrates how new developments in personalized medicine are redefining the boundaries of cancer care. It also underlines the pharmaceutical industry's continued focus on developing drugs for genetically defined populations of patients, which poses reimbursement challenges as the industry strives to recoup research and development costs from smaller target markets. The underutilization of genomic testing further complicates the outlook for targeted therapies.

But in light of personalized medicine's scientific potential, the pharmaceutical industry remains committed to the development of personalized treatments that can address unmet medical needs.

Thus, the stage is set for Amgen Senior Vice President for Research and Development Jean-Charles Soria's closing keynote address. During his remarks, Dr. Soria will envision the future of personalized medicine and the pharmaceutical industry with attention to the scientific, business, and policy challenges associated with developing and commercializing targeted therapeutics.

Randy Burkholder

Vice President, Policy and Research, PhRMA

Introduction

Randy Burkholder is the vice president of policy and research at PhRMA. Burkholder leads PhRMA work on policy solutions for supporting continued biopharmaceutical innovation and high-quality, patient-centered health care, including payment and delivery reform, quality measurement, appropriate use and patient adherence, evidence-based medicine and health technology assessment, value of innovation, and personalized medicine. Burkholder represents PhRMA at federal agencies and advisory bodies including the Medicare Evidence Development and Coverage Advisory Committee, the Centers for Medicare and Medicaid Services' Technical Expert Panel on Oncology, and the Federal Coordinating Council for Comparative Effectiveness Research. Burkholder also serves on the board of directors of the Personalized Medicine Coalition.

Jean-Charles Soria, M.D., Ph.D.

Senior Vice President, Research and Development, Amgen

Keynote Speaker

Jean-Charles Soria is Amgen's senior vice president of oncology within global development. Soria joined Amgen from the Institut Gustave-Roussy, where he was appointed director general by France's minister of health and solidarity.

Soria is a medical oncologist and professor of medicine at Paris-Saclay University. He holds a doctorate in molecular biology. He completed his training during a two-year appointment at the MD Anderson Cancer Center in Houston, Texas, where he was an associate professor from 2013 to 2017. He also served as the director of the Gustave-Roussy SIRIC Socrate (Integrated Cancer Research Site) from 2012 to 2017.

From 2017 to 2019, Soria held the role of senior vice president, research and development in oncology, with AstraZeneca in Gaithersburg, Maryland, where he led research teams responsible for strategy and for the development of new agents in immuno-oncology, cell therapy, and conjugated antibodies. He has authored or co-authored more than 670 articles in leading international journals and has appeared on lists of the most influential research scientists in the world.

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PART II

EXECUTING IN A NEW ERA

May 20, 2022

The Ritz-Carlton Ballroom

RITZ-CARLTON LAGUNA NIGUEL • ONE RITZ CARLTON DRIVE, DANA POINT, CA 92629

Public Policies and Personalized Medicine

Outlining a Vision for the Future of Personalized Medicine at FDA

In 2007, personalized medicine looked like an opportunity but was by no means a sure thing. Although scientific breakthroughs had spurred investment in a handful of drugs designed for use among genetically defined subpopulations of patients, industry leaders could only speculate about how those therapies and, by extension, their corresponding diagnostic products, might be received by U.S. regulators, who had historically demanded evidence from broad-based clinical trials before approving new drugs for the world's largest market. The prospects for continued progress in personalized medicine in the United States, it seemed, rested not only on the science and technology underpinning the field but also on the leadership at the U.S. Food and Drug Administration. FDA, in turn, recognized that its goal of bringing safer and more efficacious medicines to market depended on creating novel development pathways.

Fortunately for patients and for the field, Janet Woodcock, M.D., was among the pioneering leaders working for the agency at the time.

While serving as the Director of FDA's Center for Drug Evaluation and Research from 2007–2020, Dr. Woodcock spearheaded the development of key guidance documents that led to the approval of hundreds of groundbreaking targeted therapies. By the time Dr. Woodcock was asked to serve as the therapeutics lead for "Operation Warp Speed" following the emergence of the Covid-19 pandemic, the number of personalized medicines on the market had grown from five in 2005, when PMC recognized Dr. Woodcock with its first *Award for Leadership in Personalized Medicine*, to 286 in 2020. In its latest analysis of the drugs FDA approved in 2021, PMC shows that personalized medicines have accounted for more than a third of new drug approvals for four of the last five years, compared to less than 10 percent a decade ago.

During her keynote address on "Public Policies and Personalized Medicine," Dr. Woodcock, who is now serving as FDA's Principal Deputy Commissioner, will reflect on lessons learned from a 30-year career at FDA and outline the agency's vision for the future of personalized medicine.

Participants

Cynthia A. Bens

Senior Vice President, Public Policy, Personalized Medicine Coalition

Introduction

Cynthia A. Bens, Senior Vice President for Public Policy at the Personalized Medicine Coalition, leads the Coalition's policy development and government relations efforts and serves as its primary liaison with the U.S. Congress and federal regulators. In collaboration with PMC's Senior Vice President for Science Policy Daryl Pritchard, Ph.D., Bens is responsible for implementing research, regulatory, and reimbursement policy strategies that promote the understanding and adoption of personalized medicine concepts, services, and products to benefit patients and the health system.

Before joining PMC, Bens was the Vice President of Public Policy at the Alliance for Aging Research. Bens guided the Alliance's federal policy work, represented the organization in multiple national coalitions, and directed all aspects of coalitions led by the Alliance. She spent more than a decade at the Alliance advancing policies to expedite the development of interventions for neurological diseases and physical frailty; to remove access barriers for cardiovascular disease treatments; and to enhance the quality of care for older adults living with multiple chronic conditions.

Janet Woodcock, M.D.

Principal Deputy Commissioner, U.S. Food and Drug Administration

Keynote Speaker

The winner of the Personalized Medicine Coalition's first *Award for Leadership in Personalized Medicine* in 2005, Janet Woodcock is the U.S. Food and Drug Administration's Principal Deputy Commissioner. In this role, she works closely with the Commissioner of Food and Drugs to develop and implement key public health initiatives and helps oversee the agency's day-to-day functions.

She served as the Acting Commissioner of Food and Drugs from January 20, 2021, until February 17, 2022.

Dr. Woodcock began her FDA career in 1986 at the Center for Biologics Evaluation and Research (CBER). At CBER, she served as Director of the Division of Biological Investigational New Drugs and as Acting Deputy Director. She later became Director of CBER's Office of Therapeutics Research and Review, which oversaw the approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis during her tenure. In 1994, Dr. Woodcock was named Director of the FDA's Center for Drug Evaluation and Research (CDER), leading the Center's work that is the world's gold standard for drug approval and safety.

Breakthroughs at Blueprint Medicines

A Case Study Led by Harvard Business School's Richard Hamermesh

In 2011, Blueprint Medicines launched with a bet on the future of personalized medicine. Anticipating the continued advancement of scientific knowledge about the potential roles of the 518 genetically coded kinase enzymes in fueling cancer growth, the company began with a focus on identifying kinase-inhibiting compounds. Eight years after the U.S. Food and Drug Administration (FDA)'s groundbreaking approval of Gleevec (imatinib), a kinase-inhibitor that has since tripled five-year survival rates for patients with chronic myeloid leukemia to above 90 percent, Blueprint saw an opportunity to accelerate progress for patients by reversing the traditional target-to-compound drug development model.

The result has been a robust pipeline and commercialization opportunities. By developing a library of 20,000 compounds to target all branches of the "kinase tree," Blueprint has been able to cut in half the average timeline for identifying, developing, and earning regulatory approval for new molecules. Its success in earning FDA approval for Ayvakit (avapritinib) and Gavreto (pralsetinib) on extraordinarily efficient timelines has raised questions about how to manage its growth from a start-up to a full-fledged company that encompasses all aspects of drug development, from research, to clinical trials, to commercialization. Balancing all of these efforts was already challenging. The emergence of COVID-19 made it more so.

At a tumultuous moment for a biotechnology sector whose future work will help ensure continued progress in personalized medicine, Harvard Business School's Dr. Richard Hamermesh will join us to lead this interactive case study discussion considering the potential impact of Blueprint's approach on the future of drug discovery and personalized medicine. Dr. Hamermesh will be joined by Blueprint's newly appointed CEO Kate Haviland, who will share her insights on how Blueprint is transitioning from a start-up to a full-fledged biotechnology company.

Participants

Richard Hamermesh, D.B.A.

Co-Faculty Chair, Harvard Business School Kraft Precision Medicine Accelerator

Case Study Leader

Richard Hamermesh is a Senior Fellow at the Harvard Business School, where he was formerly the MBA Class of 1961 Professor of Management Practice. Currently, Richard is the Faculty Co-Chair of the Kraft Precision Medicine Accelerator. Richard created and teaches the second-year MBA elective, Building Life Science Businesses. Previously, he was the course head for the required first-year course, The Entrepreneurial Manager.

From 1987 to 2001, Richard was a co-founder and a Managing Partner of The Center for Executive Development, an executive education and development consulting firm. Prior to this, from 1976 to 1987, he was a member of the faculty of the Harvard Business School.

Richard is also an active investor and entrepreneur, having participated as a principal, director, and investor in the founding and early stages of more than 20 organizations. He was the founding President of the Newton Schools Foundation and served on the editorial board of the *Harvard Business Review*.

Richard is the author or co-author of five books, including *New Business Ventures* and *The Entrepreneur*. His best-known book, *Fad-Free Management*, was published in 1996. He has published more than 100 case studies and numerous articles, including his recent publications "What Precision Medicine Can Learn from the NFL" and "One Obstacle to Curing Cancer: Patient Data isn't Shared."

Kate Haviland

President, CEO, Blueprint Medicines

Guest Speaker

Kate brings an impressive breadth of experience and leadership within the biopharmaceutical industry, as well as a substantial background in business development, commercial and strategic planning, and program management. Prior to becoming Blueprint Medicines' CEO, Kate served as its Chief Operating Officer and as its Chief Business Officer. Over this time, she served as the founding chair of the portfolio management team, formed and executed business development strategy, drove global capital investment plans, and played a key role in capital market financings. In addition, she worked to drive the transformative growth of the company and support its evolution into a fully integrated business by developing and providing ongoing management of critical functions, including portfolio strategy, corporate development, commercial strategy, international, technical operations, corporate affairs, and information systems.

Closing the 'Practice Gap' in Personalized Cancer Care

Research Findings From Diaceutics and the Personalized Medicine Coalition

In 2019, while reviewing data related to the use of multi-gene panel sequencing for patients with advanced non-small cell lung cancer (aNSCLC), researchers from the Personalized Medicine Coalition and the Fred Hutchinson Cancer Research Center uncovered an alarming "practice gap" in precision oncology. Although more than 70 percent of aNSCLC patients are estimated to have actionable mutations that can inform personalized treatment options, the data showed many patients do not receive genetic testing. Even among patients who do receive genetic testing, the data showed that oncologists are still prescribing one-size-fits-all treatments to as many as 40 percent of those who could have benefitted from targeted therapies. With limited access to more granular data about cancer patients' interactions with their health care providers, researchers have only been able to speculate about the reasons why many cancer patients do not benefit from personalized medicine.

This conundrum sets the stage for Susanne Munksted, Chief Precision Officer of Diaceutics, a data-driven diagnostic solutions company, to shed new light on one of the most vexing problems in personalized medicine during this special presentation titled "Closing the Practice Gap."

During her remarks, Munksted will share the results from a real-world data-based study spearheaded by Diaceutics and PMC. The study examines laboratory and claims data from more than 500,000 metastatic non-small cell lung cancer patients. By quantifying the number of patients diverted to one-size-fits-all treatment options at each stage of a seven-step precision oncology pathway beginning with biopsy referral and ending with treatment designation, the results promise to shape thinking about how to improve precision cancer care for years to come.

Participants

Daryl Pritchard, Ph.D.

Senior Vice President, Science Policy, Personalized Medicine Coalition

Introduction

Daryl Pritchard, Ph.D., is the Senior Vice President of Science Policy at the Personalized Medicine Coalition, where he leads PMC's efforts to increase awareness and understanding of personalized medicine; identify and address barriers to the adoption of personalized medicine into the health care system; and develop and promote appropriate clinical, health care infrastructure, regulatory, and payment policies.

Before coming to PMC, Dr. Pritchard served as the Director of Policy Research at the National Pharmaceutical Council. Prior to joining NPC, he served as the Director of Research Programs Advocacy and Personalized Medicine at the Biotechnology Innovation Organization.

Susanne Munksted

Chief Precision Officer, Diaceutics

Speaker

Susanne is responsible for leading the Knowledge And Insights Team of experts at Diaceutics. As the pharmaceutical business model continues to evolve toward precision medicine, there is a need to think in an integrated way about the pharmaceutical and diagnostic business models from the top-down in organizations. As Chief Precision Medicine Officer, it is Susanne's role to drive this agenda and help Diaceutics clients understand the critical relationship and dependency between testing and treatment — and ultimately build precision medicine into corporate strategies and tactical plans.

Susanne has broad commercial experience with molecular pathology, where she has led several global launches of companion diagnostic products.

Providing Personalized Medicine

Reflections From Representatives of Differently Structured Health Care Systems

In an article published in the *Journal of Personalized Medicine* on March 12, 2021, researchers from the Personalized Medicine Coalition and Health Advances summarized the results of a multi-factorial survey measuring progress toward the clinical integration of personalized medicine within a geographically diverse sample of 153 United States-based health care providers.

The results show that across an American provider network characterized by multiple care delivery models, many administrators and practitioners are working to integrate the tests and treatments underpinning personalized medicine into their clinical practices, with 83 percent of the institutions studied scoring a two or higher on the five-point scale used to examine their integration efforts. By revealing a nationwide push to implement personalized medicine in clinical settings, the findings underline personalized medicine's evolution from a promising concept introduced following the completion of the Human Genome Project in 2003 to a practical reality today.

But as provider representatives including Burns C. Blaxall of The Christ Hospital Health Network have explained, integrating personalized medicine into clinical care is, as Blaxall put it, "not a two-minute button press." The survey findings from PMC and Health Advances also showed, for example, that only 22 percent of provider institutions are maximizing the benefits of personalized medicine.

PMC will continue its efforts to accelerate the clinical integration of personalized medicine during this panel discussion titled "Providing Personalized Medicine: Reflections From Representatives of Differently Structured Health Care Systems." The session will feature reflections on the opportunities and challenges associated with the delivery of personalized medicine from representatives of a clinical integration partner institution, an academic medical center that manages research and clinical care programs, an integrated health care delivery system that combines reimbursement and care delivery functions, and a community health care system that focuses predominantly on the delivery of care.

Participants

Daryl Pritchard, Ph.D.

Senior Vice President, Science Policy, Personalized Medicine Coalition

Moderator

Daryl Pritchard, Ph.D., is the Senior Vice President of Science Policy at the Personalized Medicine Coalition, where he leads PMC's efforts to increase awareness and understanding of personalized medicine; identify and address barriers to the adoption of personalized medicine into the health care system; and develop and promote appropriate clinical, health care infrastructure, regulatory, and payment policies.

Before coming to PMC, Dr. Pritchard served as the Director of Policy Research at the National Pharmaceutical Council. Prior to joining NPC, he served as the Director of Research Programs Advocacy and Personalized Medicine at the Biotechnology Innovation Organization.

Lisa Alderson

Co-Founder, CEO, Genome Medical

Panelist

Lisa Alderson is the CEO and Co-Founder of Genome Medical, a digital health company and nationwide telegenomics medical group that is transforming the delivery of medicine by enabling access to genomic-based medicine for everyday care. Through its nationwide network of genetic specialists and efficient Genome Care Delivery technology platform, Genome Medical provides health expertise throughout the genomics journey.

Prior, Ms. Alderson served as the Chief Commercial Officer and Chief Strategy Officer of Invitae, a rapidly growing genetic information company. She was also the former CEO and President of CrossLoop, a marketplace for technical services. Prior to that, she was part of the start-up team at Genomic Health, President of Cinema Circle, and the former Manager of Strategic Planning at Walt Disney. Lisa also serves on the board of the Kidney Cancer Association. She has a track record of creating, funding, and managing high-growth ventures.

Burns C. Blaxall, Ph.D.

Director, Precision Medicine, The Christ Hospital Health Network

Panelist

Burns C. Blaxall, Ph.D., is the Director of Precision Medicine for The Christ Hospital Health Network. Dr. Blaxall received his Ph.D. in pharmacology from the University of Colorado Health Sciences Center and completed his postdoctoral fellowship at Duke University Medical Center. He has received numerous academic honors, including the Early Career Investigator Award from the American Heart Association (AHA), the Arnold "Arnie" Schwartz Award from the AHA Council on Basic Cardiovascular Sciences, and the Outstanding Achievement Award from the Founder's AHA Affiliate. He has extensive peer review service and chaired the Cardiomyopathy and Congestive Heart Failure NIH peer-review panel.

Lincoln Nadauld, M.D., Ph.D.

Vice President, Chief of Precision Health and Academics, Intermountain Healthcare

Panelist

Lincoln Nadauld, M.D., Ph.D., is Vice President and Chief of Precision Health and Academics at Intermountain Healthcare. Dr. Nadauld founded the Intermountain Precision Genomics program with a vision of finding solutions to improve health and disease through genomics and precision medicine without increasing costs. With his vision in mind, he oversees the clinical implementation of precision genomics across Intermountain's 24 hospitals and 160 physician clinics. In addition, Dr. Nadauld facilitates genomic research to better understand the human genome. Dr. Nadauld conceived of and is leading the recently announced Heredigene population study, a collaborative effort with deCODE Genetics in Iceland to collect and perform whole-genome sequencing on 500,000 participants in the Intermountain system.

Dr. Nadauld completed clinical training in medical oncology at Stanford University School of Medicine, where he also completed a postdoctoral fellowship in solid tumor genomics. He remains a visiting scholar at Stanford University, focusing on cancer genomics and personalized medicine.

Apostolia M. Tsimberidou, M.D., Ph.D.

Professor, The University of Texas MD Anderson Cancer Center

Panelist

Dr. Apostolia M. Tsimberidou is an oncologist in Houston, Texas, and is affiliated with the University of Texas MD Anderson Cancer Center. She received her medical degree from Aristotle University of Thessaloniki School of Medicine and has been in practice for more than 20 years.

Since joining the faculty at The University of Texas MD Anderson Cancer Center in 2001, Dr. Tsimberidou's clinical research has focused on the development of therapeutic strategies for advanced hematologic malignancies and solid tumors. She has served as the Principal Investigator for 20 investigator-initiated clinical trials for the treatment of patients with advanced cancer. In 2007, she designed the Initiative for Molecular Profiling and Advanced Cancer Therapy (IMPACT) trial in the Department of Investigational Cancer Therapeutics, and also developed the departmental protocol for the associated tissue bank.

Precision Partnership

A Fireside Chat With Leaders From GNS Healthcare and the Multiple Myeloma Research Foundation

With no way of anticipating the devastating global pandemic they would soon confront, the attendees filing out of the Joseph B. Martin Conference Center following the *15th Annual Personalized Medicine Conference* on November 14, 2019, focused much of their discussions on the unprecedented rate at which health systems are generating data about each patient's genome, physiology, metabolism and environment. To keep up with the pace at which researchers are producing these data, leaders from multiple sectors of the health care system noted the importance of data-sharing partnerships that give both human and artificial intelligences an opportunity to scan a wider range of health care data in pursuit of more sophisticated personalized medicine strategies.

As we continued to combat a global pandemic that caused immeasurable human suffering and delayed the diagnosis of dangerously advanced cancers, it became even more important to collaborate across sectors in order to more efficiently develop insights about how patients' bodies may respond to diseases and treatments. As M2Gen Founder and Personalized Medicine Coalition Board Member William S. Dalton, Ph.D., M.D., noted during the 2019 conference, "there is a need for multiple partners to come together to create resources that will benefit all stakeholders." This spirit of collaboration was the impetus for a promising partnership using GNS Healthcare's causal artificial intelligence platform to analyze longitudinal multi-modal patient registry data provided by the Multiple Myeloma Research Foundation (MMRF).

During "Precision Partnership: A Fireside Chat With Leaders From GNS Healthcare and the Multiple Myeloma Research Foundation," MMRF CEO Michael Andreini and GNS Healthcare CEO Colin Hill will discuss the significance of cross-sector partnerships to the future of personalized medicine.

Participants

Mark P. Stevenson

Board Member, Personalized Medicine Coalition

Moderator

Mark Stevenson served for five years as the Executive Vice President and Chief Operating Officer of Thermo Fisher Scientific, with responsibility for all of Thermo Fisher's life sciences-related businesses as well as the company's innovation and digital strategy. He joined the company as Executive Vice President and President, Life Sciences Solutions, through the acquisition of Life Technologies in 2014.

Mark previously served as President and Chief Operating Officer of Life Technologies, and President and Chief Operating Officer of Applied Biosystems prior to its merger with Invitrogen Corporation in 2008.

Mark received his M.B.A. from Henley Management School in the U.K. and his bachelor's degree in chemistry from the University of Reading, also in the U.K.

Michael Andreini

President, CEO, Multiple Myeloma Research Foundation

Panelist

Michael Andreini is the President and Chief Executive Officer of the Multiple Myeloma Research Foundation (MMRF) and the Multiple Myeloma Research Consortium (MMRC). Michael brings nearly 15 years of strategic consulting and operational experience in the life sciences industry. Prior to joining the MMRF, Michael was an Associate Principal at IQVIA in the consulting services organization, where he developed strategies for biopharmaceutical, medical device, and nonprofit organizations to drive innovation and operational excellence across a diverse set of business challenges including research, development, and launch strategy, commercial due diligence and portfolio optimization, and organizational effectiveness. Before joining IQVIA, Michael worked at Fuld & Company, a boutique consulting firm specializing in competitive intelligence and strategy.

Colin Hill

Chairman, CEO, Co-Founder, GNS Healthcare

Panelist

Colin Hill is a leading voice in health care technology and precision medicine and brings distinguished leadership experience in commercializing machine learning technologies in the biopharmaceutical and managed care industries. He co-founded GNS Healthcare, a leading AI-driven precision medicine company, in 2000 and has since served as Chairman and CEO. In 2020, the company launched Gemini, the in silico patient, a highly accurate computer model of disease.

Colin sits on the board of Biotelemetry, a leading mobile health information company, and PPD, a leading global contract research organization. He is also a founding board member of TMed (Transforming Medicine: The Elizabeth Kauffman Institute), a non-profit foundation dedicated to the advancement of personalized medicine. In 2016, he was appointed by Massachusetts Governor Charlie Baker to the Massachusetts Digital Health Council.

Envisioning the Future of Data-Driven Personalized Medicine

A Keynote Address by Verily's Amy Abernethy

During her closing remarks after the first day of PMC's *14th Annual Personalized Medicine Conference* at Harvard Medical School on November 14, 2018, Amy P. Abernethy, M.D., Ph.D., then serving as a Personalized Medicine Coalition Board Member and Chief Medical Officer of Flatiron Health, said that despite regulatory- and infrastructure-related challenges, she was excited about "where software and data and technology can take us."

Much has transpired since then.

Dr. Abernethy has finished a two-year term as the Principal Deputy Commissioner and Acting Chief Information Officer at the U.S. Food and Drug Administration. She is widely credited with modernizing FDA's information technology infrastructure and data capabilities as well as preparing the agency to use real-world data to support regulatory decision making.

The pandemic's outsized impact on historically underserved patient populations has further underlined the importance of using data to direct the right prevention and treatment strategies to the right patients at the right time.

And large technology companies have signaled an increased interest in leveraging their unrivaled computing power to support biomedical research and health care decision-making, sparking conversations about the privacy of health care data that could have major implications for the pace of progress in personalized medicine. Lawmakers from both sides of the aisle, for example, called for enhanced scrutiny of health-related data partnerships in 2019 following Google's announcement of a partnership with Ascension Health that was designed to "zero in on individual patients to suggest changes to their care."

Against this backdrop, Dr. Abernethy, who is now serving as the President for Clinical Studies Platforms at Verily, an Alphabet company, will share her views during this keynote address on the outlook for a data-driven future for personalized medicine with attention to the field's most pressing opportunities and challenges.

Participants

Edward Abrahams, Ph.D.

President, Personalized Medicine Coalition

Introduction

Edward Abrahams, Ph.D., is the President of the Personalized Medicine Coalition. Representing innovators, scientists, patients, providers and payers, PMC promotes the understanding and adoption of personalized medicine concepts, services, and products for the benefit of patients and health systems. It has grown from its original 18 founding members in 2004 to more than 200 today.

Previously, Dr. Abrahams was the Executive Director of the Pennsylvania Biotechnology Association, where he spearheaded the successful effort that led to the Commonwealth of Pennsylvania's investment of $200 million to commercialize biotechnology in the state. Earlier, he had been Assistant Vice President for Federal Relations at the University of Pennsylvania and held a senior administrative position at Brown University.

Dr. Abrahams worked for seven years for the U.S. Congress, including as a legislative assistant to Senator Lloyd Bentsen, as an economist for the Joint Economic Committee under the chairmanship of Representative Lee Hamilton, and as a AAAS Congressional Fellow for Representative Edward J. Markey.

Amy P. Abernethy, M.D., Ph.D.

President, Clinical Studies Platforms, Verily

Keynote Speaker

Amy P. Abernethy, M.D., Ph.D., is the President of Clinical Studies Platforms at Verily, an Alphabet company founded at the convergence of health care, data science and technology, where she has responsibility for the company's Baseline program and other initiatives to support a broad range of clinical trials and real-world evidence (RWE) studies.

Before joining Verily in July, Dr. Abernethy was Principal Deputy Commissioner and Acting Chief Information Officer of the U.S. Food and Drug Administration. While at FDA, she initiated critical efforts including FDA's technology and data modernization action plans and FDA's efforts to leverage real-world data and evidence to address urgent questions during the COVID-19 pandemic.

Dr. Abernethy was Chief Medical Officer and Chief Scientific Officer at Flatiron Health from 2014 to early 2019. Before joining Flatiron, Dr. Abernethy was Professor of Medicine at Duke University School of Medicine and directed the Center for Learning Health Care in the Duke Clinical Research Institute and Duke Cancer Care Research Program in the Duke Cancer Institute.

Congratulations to the Recipients of the 2022 PMC/BIO Patient Advocacy Scholarships

To help empower patients to advocate for health care tailored to their biological characteristics, circumstances, and values, the Personalized Medicine Coalition partnered with the Biotechnology Innovation Organization to offer scholarships for selected patients, representatives from patient advocacy organizations, and caregivers to attend the *16th Annual Personalized Medicine Conference*.

Each scholarship included a complimentary conference registration and a stipend to cover transportation and lodging.

2022 Recipients

Catherine Ames, National Council Representative, Autoimmune Research Empowerment Alliance

Terri Conneran, Founder, KRASKickers

Yasmeem Watson, Patient Advocate, Fight Colorectal Cancer

Tiffany Westrich-Robertson, CEO, AiArthritis

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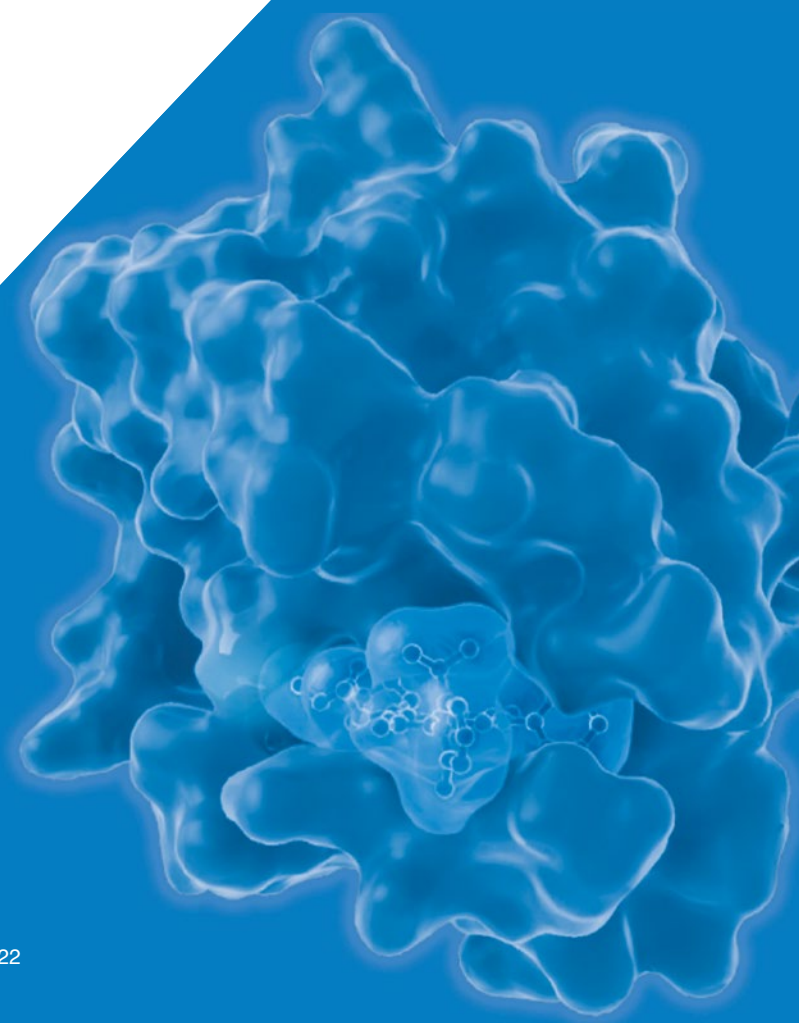

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About Us

The Personalized Medicine Coalition (PMC), representing innovators, scientists, patients, providers, and payers, promotes the understanding and adoption of personalized medicine concepts, services, and products to benefit patients and health systems.

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