

15TH ANNUAL
**PERSONALIZED MEDICINE
CONFERENCE**

The Paradigm Evolves

November 13–14, 2019

JOSEPH B. MARTIN CONFERENCE CENTER • HARVARD MEDICAL SCHOOL
77 AVENUE LOUIS PASTEUR, BOSTON, MA 02115

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President's Message

Dear Colleague:

The personalized medicine paradigm is evolving to address some of the most pressing issues facing health systems around the world.

Encouraged by ongoing genetic discoveries that the biopharmaceutical industry is translating into personalized treatments with unparalleled benefits for patients and society, scientists have begun to explore how groundbreaking molecular diagnostics augmented by artificial intelligence, advanced data analytics, and digital health applications can empower both physicians and patients with information about how an expanded set of biological characteristics – including those found in the proteome and microbiome – may influence their health and their responses to various therapies.

But these scientific developments are difficult to integrate into health systems, many of which are still more accustomed to one-size-fits-all medicine.

Personalized tests and treatments that leverage insights about the molecular make-up of each patient to guide earlier prevention strategies and longer-lasting interventions pose unprecedented regulatory, reimbursement, and clinical adoption questions to decision-makers in the public and private sectors, who are under increasing pressure to deliver more value to patients and help curb rising health care costs.

Thank you for joining us at *The 15th Annual Personalized Medicine Conference: The Paradigm Evolves* as we explore these challenges and consider solutions that can pave the way for a new era of personalized medicine that benefits patients and health systems.

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. By combining the data from those molecular diagnostic tests with an individual's medical history, circumstances and values, health care providers can develop targeted prevention and treatment plans.



Overview · Part I

November 13, 2019

8:00 am Registration and Breakfast

8:50 am Opening Remarks

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

8:55 am Welcoming Remarks

Raju Kucherlapati, Ph.D., Paul C. Cabot
Professor of Genetics, Harvard Medical School

9:00 am The Era of the ‘Living Drug:’
A Keynote Conversation With Dr. Carl June,
Pioneer of CAR T-cell Therapy

During this opening keynote session, the University of Pennsylvania’s Carl June, M.D., the discoverer of the chimeric antigen receptor (CAR) T-cell therapies that are unlocking a new era of personalized cancer care, will join Immatics US Chief Medical Officer Stephen L. Eck, M.D., Ph.D., for a wide-ranging conversation about the future of personalized medicine, touching on issues including but not limited to access and affordability, regulation and manufacturing, and cell-based therapies beyond cancer.

MODERATOR | **Stephen L. Eck**, M.D., Ph.D.,
Chief Medical Officer, Immatics US

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

9:45 am Transformative Technologies: Previewing
the Value Proposition and Outlook for
Disruptive Tools Designed to Enable
Personalized Medicine

Emerging personalized medicine technologies may help facilitate earlier interventions that eliminate the need for expensive treatment of advanced diseases that have devastating consequences for patients. They can also help target treatments to only those patients who will benefit. But the success of these technologies depends on whether they can be integrated into a health system that has historically focused on treating diseases after symptoms have intensified, usually based on the assumption that every patient taking a given medication will respond to the treatment in a similar way.

During this session, Section 32 Managing Partner Dr. Michael J. Pellini will moderate a discussion between industry representatives and a payer about the value proposition and outlook for disruptive technologies that are designed to support more informed disease prevention and treatment plans. The conversation will focus on how developments in areas including but not limited to artificial intelligence, data analytics, genomic sequencing, liquid biopsies, and proteomics may impact the prevention, diagnosis, and treatment of diseases including cancer, cardiovascular diseases, and diabetes.

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

Steven Kafka, Ph.D., Partner, Third Rock
Ventures; Executive Chairman, Thrive Earlier
Detection

Nancy Mendelsohn, M.D., Chief Medical Officer,
Special Needs Initiative, UnitedHealth Group

Eric E. Schadt, Ph.D., CEO, Sema4

Roy Smythe, M.D., CEO, SomaLogic

10:45 am Networking Break**11:15 am Introducing Developing Diagnostics – Opportunities and Challenges in Personalized Medicine: A Two-Part Discussion**

Diagnostic test developers are working to make personalized medicine possible by giving physicians tools that help them select the optimal treatment for every patient. Doing so requires that they navigate a complex business and policy landscape while being mindful of the day-to-day needs of payers and health care providers.

In this context, Mr. Mark P. Stevenson, Executive Vice President, Chief Operating Officer, Thermo Fisher Scientific, will take 10 minutes to introduce a two-part discussion titled “Developing Diagnostics – Opportunities and Challenges in Personalized Medicine.”

INTRODUCTION | Mark P. Stevenson, Executive Vice President, Chief Operating Officer, Thermo Fisher Scientific

*Discussion Part 1***11:25 am Developing Diagnostics – From Concept to the Clinic: Perspectives on the Landscape for Developing and Integrating Personalized Medicine Diagnostics into Health Systems**

To kick off the “Developing Diagnostics” discussion, Moffitt Cancer Center’s DeBartolo Family Personalized Medicine Institute Medical Director Dr. Howard McLeod will moderate a conversation among leaders from the clinical, diagnostics, IT, and pharmaceutical communities about the landscape for developing and integrating personalized medicine diagnostics into health systems.

MODERATOR | Howard McLeod, Pharm.D., Medical Director, DeBartolo Family Personalized Medicine Institute at Moffitt Cancer Center

Assaf Halevy, Founder, CEO, 2bPrecise

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

Peter Maag, Ph.D., CEO, CareDx

Hakan Sakul, Ph.D., Vice President, Head of Diagnostics, Worldwide R & D and Medical, Pfizer

Kenna R. Mills Shaw, Ph.D., Executive Director, MD Anderson Institute for Personalized Cancer Therapy

Discussion Part 2

12:10 pm **Developing Diagnostics – The Role of Research: A Closer Look at Efforts to Encourage the Clinical Adoption of Personalized Medicine Diagnostics by Studying the Clinical and Economic Utility of Genomic Sequencing**

During the second portion of the “Developing Diagnostics” session, a health care provider, a health economist, an industry leader, and a payer representative will join moderator and Personalized Medicine Coalition Senior Vice President for Science Policy Dr. Daryl Pritchard to examine the impact of emerging research on the clinical and economic utility of genomic sequencing for patients with diseases including but not limited to cancer and suspected rare diseases.

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

Roy J. Gandolfi, M.D., Medical Director, SelectHealth

Lincoln Nadauld, M.D., Ph.D., Chief, Precision Health, Intermountain Healthcare

Peter J. Neumann, Sc.D., Director, Center for the Evaluation of Value and Risk in Health at the Institute for Clinical Research and Health Policy Studies, Tufts Medical Center

Ammar Qadan, Vice President, Global Head of Market Access, Illumina

12:55 pm **Seated Luncheon**

2:10 pm **Overcoming Opioids: Considering the Potential of Personalized Medicine to Address the Opioid Crisis in the US**

Emerging technologies present new opportunities to study the genetic, biological, and environmental factors that drive public health crises, with an eye toward developing personalized medicine health care strategies that can mitigate their devastating consequences.

During this session, Dr. Alissa M. Resch, Chief Scientific Officer, Coriell Institute for Medical Research, will explore the significance of Coriell’s ongoing effort to inform interventions that may help prevent opioid addiction by identifying with more precision which patients are most likely to develop dependency on this class of drugs.

SPEAKER | **Alissa M. Resch**, Ph.D., Chief Scientific Officer, Coriell Institute for Medical Research

2:30 pm **Assessing Progress Toward the Clinical Integration of Personalized Medicine: A Landscape Analysis**

Case studies and anecdotal reports suggest that leading academic medical centers and pioneering community health systems have begun to integrate personalized medicine approaches into their clinical work streams. The extent to which health care providers more generally have begun to adopt personalized medicine strategies that go beyond the ordering of genetic sequencing, however, remains unclear.

During this session, Mr. Gary Gustavsen, Partner, Managing Director, Health Advances, will share preliminary findings from a PMC-commissioned survey that examined the landscape for the clinical integration of personalized medicine in the U.S. based on a multi-factorial definition of the field. Survey respondents included a geographically diverse set of academic medical centers and community health systems.

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

SPEAKER | **Gary Gustavsen**, Partner, Managing Director, Health Advances

2:50 pm **The 15th Annual Leadership in Personalized Medicine Award**

PRESENTER | **Kimberly Popovits**, Chairman of the Board, CEO, President, Genomic Health

AWARDEE | **Steven Shak**, M.D., Chief Scientific Officer, Genomic Health

3:20 pm **Networking Break**

4:00 pm **Wellness in the Workplace: Understanding the Opportunities and Challenges Associated With Genetic Testing Programs for Healthy Patients**

Reasoning that genetic testing may encourage healthy lifestyles by providing information about an employee’s relative risk of developing various diseases, employers seeking to improve patients’ lives and mitigate downstream health care costs have begun to sponsor genetic testing for healthy employees by partnering with various genetic testing companies, some of which sell the tests directly to consumers.

This session, moderated by Quest Diagnostics Chief Medical Officer Dr. Jay G. Wohlgemuth, who is responsible for overseeing health care benefits for Quest’s employees, will spotlight two such genetic testing partnerships and explore the relevant issues. The panel discussion will focus on the significance of information generated from genetic testing, the differences between various genetic testing business models, and the privacy risks associated with the collection of genetic data.

MODERATOR | **Jay G. Wohlgemuth**, M.D., Chief Medical Officer, Senior Vice President, Quest Diagnostics

Jane Cheshire Gilbert, C.P.A., Director, Retiree Health Care, Teachers’ Retirement System of Kentucky

Karen E. Knudsen, M.B.A., Ph.D., Executive Vice President, Oncology Services, Jefferson Health; Enterprise Director, Sidney Kimmel Cancer Center at Thomas Jefferson University

Othman Laraki, CEO, Color Genomics

Scott Megill, President, CEO, Coriell Life Sciences

5:00 pm **Preparing Policies: A Keynote Address on the Policy Landscape for Personalized Medicine by Dr. Scott Gottlieb, Resident Fellow, American Enterprise Institute**

During this keynote address, former U.S. Food and Drug Administration (FDA) commissioner Dr. Scott Gottlieb will share his thoughts on the evolving policy landscape for personalized medicine.

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

SPEAKER | **Scott Gottlieb**, M.D., Resident Fellow, American Enterprise Institute

5:45 pm **Closing Remarks**

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

6:00 pm **Welcome Reception at the Isabella Stewart Gardner Museum**

Overview · Part II

November 14, 2019

8:00 am Registration and Breakfast

8:50 am Opening Remarks

Stephen L. Eck, M.D., Ph.D., Chief Medical Officer, Immatics US

8:55 am Welcoming Remarks

Joseph B. Martin, M.D., Ph.D., Dean Emeritus, Harvard Medical School

9:00 am Going Global: Learning From Governmental Efforts to Advance Personalized Medicine Around the World

Global leaders are working to accelerate an era of personalized medicine around the world by encouraging innovation, modernizing policies, and reforming health systems to speed the clinical adoption of personalized medicine products and services.

During this panel discussion, four governmental representatives will share their visions for the future of personalized medicine and elaborate on their efforts to accelerate progress in the field.

MODERATOR | Antonio L. Andreu, M.D., Ph.D., Scientific Director, EATRIS (European Infrastructure for Translational Medicine)

Wadha Al Muftah, M.D., Ph.D., Manager, Clinical Initiatives, Qatar Genome Program

Noella Bigirimana, Strategic Advisor, Rwanda Biomedical Center, Ministry of Health, Government of Rwanda; Government Fellow, World Economic Forum

Erja Heikkinen, Ph.D., Deputy Director, General Ministry of Education and Culture, Finland

Raquel Yotti, M.D., Ph.D., General Director, Instituto de Salud Carlos III (Spain)

10:00 am Networking Break

10:15 am Innovation in the Era of Personalized Medicine: A Keynote Conversation With Dr. Paul Stoffels, Chief Scientific Officer, Johnson & Johnson

During this fireside chat with *CNBC* Reporter Ms. Meg Tirrell, Johnson & Johnson Chief Scientific Officer Dr. Paul Stoffels will help frame the second half of the conference by sharing the pharmaceutical industry's perspective on the emerging issues in health care, touching on topics including costs, prices, and access.

MODERATOR | Meg Tirrell, Reporter, *CNBC*

Paul Stoffels, M.D., Vice Chairman, Executive Committee, Chief Scientific Officer, Johnson & Johnson

10:45 am **Prospecting the Pipeline: Exploring the Implications of a Biopharmaceutical Pipeline Dominated by Personalized Treatments**

As researchers develop an enhanced understanding of the molecular causes that underpin various diseases, many biopharmaceutical companies have begun to develop therapies that are targeted to patient subgroups and even personalized to individual patients. In oncology, for example, there are reportedly more than 900 personalized “immunotherapy” treatments being tested in the clinic, with more than 1,000 in preclinical development. The challenging scientific questions and systemic implications associated with these new therapies do not always fit neatly into existing regulatory, payment, and care delivery frameworks.

During this session, CNBC Reporter Ms. Meg Tirrell will moderate a panel discussion that explores the scientific, regulatory, reimbursement, and other systemic issues associated with future gene editing treatments, gene therapies, immunotherapies, and targeted therapies. The panelists, who include industry representatives, a researcher, and an academic leader, will also consider a new approach to immunotherapy for cancer patients in which a unique product is developed for every patient treated.

MODERATOR | **Meg Tirrell**, Reporter, CNBC

Donald L. Siegel, Ph.D., M.D., Director, Division of Transfusion Medicine & Therapeutic Pathology, Director, Clinical Cell & Vaccine Production Facility, University of Pennsylvania’s Perelman School of Medicine

Harpreet Singh, Ph.D., CEO, Immatix

Paul Stoffels, M.D., Vice Chairman, Executive Committee, Chief Scientific Officer, Johnson & Johnson

Alex Vadas, Ph.D., Managing Director, Partner, LEK Consulting

11:45 am **Bag Lunch**

12:45 pm **Balancing Business and Social Objectives to Advance Personalized Medicine: A Case Study of the Dementia Discovery Fund**

This interactive case study discussion will explore how and why a group of government agencies, nonprofit organizations, and pharmaceutical companies came together to support the Dementia Discovery Fund, focusing on whether a disease-specific venture that seeks to create meaningful new medicines in part by capitalizing on the evolving science underpinning personalized medicine can successfully balance social and business objectives.

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

SPEAKER | **Kate Bingham**, M.B.A., Managing Partner, SV Health Investors

1:45 pm **Toward a Shared Value Proposition in Health Care: Pursuing Value-Based Solutions in Research, Regulation, Reimbursement, and Clinical Adoption**

To advance the principles of personalized medicine, the field's proponents will need to align representatives from multiple sectors of the health system on a shared value proposition that recognizes the importance of addressing the shortcomings of one-size-fits-all medicine.

During this session, M2Gen Executive Chairman Dr. William S. Dalton will convene a commercial payer, an industry representative, a patient, and a value assessment framework developer to explore research, regulatory, clinical adoption, and especially reimbursement solutions that will, in the interest of patients, advance the principles of personalized medicine.

MODERATOR | **William S. Dalton**, Ph.D., M.D., Executive Chairman, M2Gen

Bonnie J. Addario, Co-Founder, Chair, GO₂ Foundation for Lung Cancer

Sarah K. Emond, M.P.P., Executive Vice President, Chief Operating Officer, Institute for Clinical and Economic Review

Anne-Marie Martin, Ph.D., Senior Vice President, Global Head of Precision Medicine, Novartis Pharmaceuticals Corporation

Michael Sherman, M.D., Chief Medical Officer, Senior Vice President, Harvard Pilgrim Health Care

2:45 pm **Closing Remarks**

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

PART I

DIAGNOSING, DIFFERENT



November 13, 2019

JOSEPH B. MARTIN CONFERENCE CENTER • HARVARD MEDICAL SCHOOL, BOSTON, MA 02115

The Era of the ‘Living Drug’

A Keynote Conversation With Dr. Carl June, Pioneer of CAR T-cell Therapy

Following the U.S. Food and Drug Administration (FDA)’s approval in August of 2017 of the first chimeric antigen receptor (CAR) T-cell therapy, which was underpinned by the pioneering research of Carl June, M.D., Richard W. Vague Professor in Immunotherapy, University of Pennsylvania, Dr. June described the treatment for acute lymphoblastic leukemia (ALL), called Kymriah (tisagenlecleucel), as the first “living drug.”

Recognizing that the therapy has given physicians the unprecedented opportunity to prescribe a treatment comprised of genetically modified versions of a patient’s own immune cells that are primed to seek the CD19 proteins expressed by many ALL cells and attack those cells accordingly, Dr. June predicted that the approval was only the beginning of a new era of personalized medicine characterized by treatments that home in on molecular characteristics present in patients with various diseases.

His assessment is proving prescient.

A recent study suggests, for example, that the pharmaceutical industry is developing nearly 300 similar gene- and cell-based therapies, which are characterized by their ability to introduce genetic material into patients’ cells to address the biological causes of various diseases, facilitating long-term treatment responses.

But as Dr. June also says, developing these powerful personalized medicine products, which sometimes incur higher up-front costs than daily pills since they are manufactured specifically for each patient at external locations, poses unprecedented regulatory, scientific, and reimbursement challenges to policymakers and providers. Representatives from every sector of the health system, he notes, must work together in coming years so that patients and health systems can reap the unprecedented benefits of these groundbreaking new treatment approaches.

“It is important that the research, medical, and pharmaceutical communities collaborate to maintain momentum in personalized medicine so that we are able to deliver cutting-edge care and clinical trial opportunities to all patients,” Dr. June said.

During “The Era of the ‘Living Drug:’ A Keynote Conversation With Dr. Carl June, Pioneer of CAR T-cell Therapy,” Dr. June will join his former colleague at the University of Pennsylvania, Stephen L. Eck, M.D., Ph.D., now the Chief Medical Officer of Immatics US, for a conversation about the future of personalized medicine, dealing with scientific, affordability, accessibility, regulatory, and reimbursement challenges.

Participants



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

Chief Medical Officer, Immatics US
Moderator

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 Immatics US, which develops novel immune therapies for cancer patients. He is Chairman of the Board of the Personalized Medicine Coalition. He also serves on the Boards of Directors of Luminex Corporation and Circulogene, which develop and market medical diagnostics. He also serves on the Board of Trustees of the Keck Graduate Institute and on the Board of Directors of the Central Pennsylvania Clinic, which serves patients with rare genetic disorders.

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
Keynote Speaker

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.

Transformative Technologies

Previewing the Value Proposition and Outlook for Disruptive Tools Designed to Enable Personalized Medicine

Since its inception in 2004, the Personalized Medicine Coalition has contended in its annual *Personalized Medicine Report*, then called *The Case for Personalized Medicine*, that timely insights about the dynamic molecular characteristics that underpin various diseases and determine how a patient responds to treatment will someday give us the ability to detect the onset of disease at its earliest stages; pre-empt the progression of disease; and target treatments to only those patients who will benefit from them.

We are on the cusp of this new era, which promises improved outcomes for patients and a more efficient health system.

Guided by ongoing discoveries about what genes, proteins, and physiological biomarkers can tell us about a person's health and likely responses to various therapies, industry pioneers are developing groundbreaking diagnostics augmented by artificial intelligence and advanced data analytics in hopes of facilitating more impactful and timely interventions that eliminate the need for expensive treatment of advanced diseases. In some cases, these technologies may even deliver independent treatment recommendations based on their own evolving understanding of the associations between biomarkers and diseases, even if the biological processes underlying those associations are unknown.

This extraordinary new vision for the future of medicine, however, is emerging within health systems around the world that are still largely accustomed to translating knowledge about human biology into preferred treatment protocols based on what has been proven to work for the highest percentage of all patients with a given disease — as opposed to analyzing the specific biological characteristics of each individual so that physicians can base health care decisions on data from small subsets of similar patients.

“Transformative Technologies: Previewing the Value Proposition and Outlook for Disruptive Tools Designed to Enable Personalized Medicine” will convene three industry visionaries and a payer to consider these and related issues.

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 of 2017.

He currently serves as a member of the Board of Directors for Tango Therapeutics, Singular Genomics, Adaptive Biotechnologies, Octave Health, Vineti, the Personalized Medicine Coalition, 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 in 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.



Steven Kafka, Ph.D.

Partner, Third Rock Ventures; Executive Chairman, Thrive Earlier Detection

Panelist

Steve Kafka is a Partner at Third Rock Ventures, where he brings more than 20 years of operating experience in building therapeutics and molecular diagnostic companies dedicated to transformational patient impact. At Third Rock, Steve was the founding CEO of Thrive Earlier Detection, where he currently serves as Executive Chairman. Thrive is focused on incorporating earlier cancer detection into routine medical care to extend and save lives.

Prior to his time at Third Rock, Steve served as President and Chief Operating Officer at Foundation Medicine, which was sold to Roche in 2018. Outside of professional pursuits, Steve loves exploring mountains on skis, in hiking boots, and in a rock-climbing harness.



Nancy Mendelsohn, M.D.

Chief Medical Officer, Special Needs Initiative, UnitedHealth Group

Panelist

Dr. Mendelsohn is a senior physician-scientist and health care leader with an international reputation as a clinical geneticist and researcher. Dr. Mendelsohn's current role as Chief Medical Officer of the Special Needs Initiative at UnitedHealthcare encompasses clinical strategy, leadership, and execution in support of UnitedHealth Group's Special Needs Initiative. Dr. Mendelsohn's accountabilities include efforts to guide and support UHG's strategic priorities related to genomic medicine.

Dr. Mendelsohn has also recently served as Chief of Specialty Pediatrics at Children's Minnesota. She has 25 years as a board-certified medical geneticist, and is a national leader in the clinical genetics community. Dr. Mendelsohn received an undergraduate degree in molecular biology from Indiana University and an M.D. from the University of Missouri in 1987. From 1987 to 1992, she completed a residency in pediatrics and a fellowship in medical genetics at Washington University Children's Hospital in St. Louis.



Eric E. Schadt, Ph.D.

CEO, Sema4

Panelist

Eric Schadt, Ph.D., is Founder and CEO of Sema4, a patient-centered predictive health company built on the idea that more information, deeper analysis, and increased engagement will improve the diagnosis, treatment, and prevention of disease. Dr. Schadt also serves as the Dean for Precision Medicine and Mount Sinai Professor in Predictive Health and Computational Biology at the Icahn School of Medicine at Mount Sinai. He was previously Founding Director of the Icahn Institute for Genomics and Multiscale Biology, and Professor and Chair of the Department of Genetics and Genomic Sciences.

Dr. Schadt is an expert on constructing predictive models of disease that link molecular biology to physiology to enable clinical medicine. Over the past 20 years, he has built groups and companies (at Merck, Rosetta, Sage Bionetworks, Pacific Biosciences, Icahn Institute, and now Sema4) to elucidate the complexity of human diseases. He has published more than 350 peer-reviewed papers in leading scientific journals and contributed to discoveries relating to the genetic basis of common human diseases such as diabetes, obesity, and Alzheimer's disease. Now, with the innovative Sema4 Health Intelligence Platform, Dr. Schadt is using advanced network analysis to build better models of human health and deliver personalized insights for patients.



Roy Smythe, M.D.

CEO, SomaLogic

Panelist

Roy Smythe, M.D., joined SomaLogic in November of 2018 as CEO. Originally trained as a thoracic surgeon and physician-scientist, Dr. Smythe subsequently gained highly diverse experience and expertise across many areas of cutting-edge health care, technology, and translational medicine.

Dr. Smythe came to SomaLogic from Royal Philips, where he served as Chief Medical Officer for Strategy and Partnerships. Before joining Philips, he served as Chief

Medical Officer at Valence Health, a Chicago-based health care company. He held the same title previously at AVIA, a health care technology accelerator.

A highly sought-after lecturer and the author of more than 300 papers, abstracts, and essays in academic, literary, and humanities publications, Dr. Smythe is also currently a member in more than 20 national learned societies.

Developing Diagnostics – From Concept to the Clinic

Perspectives on the Landscape for Developing and Integrating Personalized Medicine Diagnostics into Health Systems

In a post published in January on the Personalized Medicine Coalition’s blog, *Education & Advocacy*, Brad Power, a patient who was diagnosed with lymphoma in July of 2018, describes the myriad challenges he faced as he worked with his doctor to finally gain access to genomic sequencing at an institution that has earned a reputation for leading the way in personalized medicine. Power submits that if his experience is representative – and his conversations with other patients suggest that it is – then the pace at which patients are gaining access to personalized medicine diagnostics is “excruciatingly slow.”

This is not for a lack of scientific breakthroughs.

Moffitt Cancer Center’s Dr. Howard McLeod notes, for example, that the Clinical Pharmacogenetics Implementation Consortium (CPIC)’s medical guidelines now include a robust list of drug-gene interactions that can help inform personalized health care strategies.

Scientists have made progress in translating the decreasing costs of genomic sequencing into diagnostics that can help inform care for many patients, including those with cancers, organ transplants, and suspected rare diseases.

And diagnostics industry leaders, alone and in combination with partners from the biopharmaceutical and IT sectors, are invested in leveraging advanced data analytics, artificial intelligence, and new insights about the proteome and microbiome to guide more valuable prevention and treatment strategies.

But in their quest to develop and integrate diagnostic tests into health systems that are still biased toward basing medical decisions exclusively on assumptions about what works for the “average” patient, these leaders are challenged to overcome business, policy, and practical obstacles, many of which stem from differing perspectives among payers, policymakers, and providers about the clinical and economic utility of personalized medicine.

“Developing Diagnostics – From Concept to the Clinic” will convene a multi-stakeholder panel of leaders to address these challenges and explore possible solutions.

Participants

Howard McLeod, Pharm.D.

Medical Director, DeBartolo Family Personalized Medicine Institute, Moffitt Cancer Center

Moderator

Dr. Howard McLeod is Medical Director of the DeBartolo Family Personalized Medicine Institute at the Moffitt Cancer Center. He is Chair of the Department of Individualized Cancer Medicine and a state of Florida Endowed Chair in Cancer Research. He is also a Senior Member of the Division of Population Sciences and a Professor at the University of South Florida. Dr. McLeod is chair of the external scientific panel for the National Human Genome Research Institute’s eMERGE program, a recent member of FDA’s Committee on Clinical Pharmacology, and a member of the National Institutes of Health’s Human Genome Advisory Council.

Since 2002, Dr. McLeod has been Vice Chair for Pharmacogenomics for the National Cancer Institute’s clinical trials group, overseeing the largest oncology pharmacogenomics portfolio in the world. Dr. McLeod is also a 1000 Talent Scholar of China and a Professor at Central South University in Changsha, China. He has published more than 530 peer-reviewed papers on pharmacogenomics, applied therapeutics, and clinical pharmacology, and continues to work to advance individualized medicine.



Assaf Halevy

Founder, CEO, 2bPrecise

Panelist

Assaf Halevy is the Founder and CEO of 2bPrecise LLC, leading an international team dedicated to bridging the “final mile” between the science of genomics and making genomic data useful at the point of care. He served previously at Allscripts as Senior Vice President of Products and Business Development, following the company’s acquisition of Israel-based dbMotion in 2013. An initial inventor and Co-Founder of dbMotion, Halevy helped

develop the leading clinical integration and population health management platforms in the industry today.

With 13 patents pending in the areas of actionable clinical integration, interoperability, and precision medicine, Halevy leverages his industry expertise by evaluating strategic alliances and partnerships for U.S. and international markets.





Kris Joshi, Ph.D.

Executive Vice President, President,
Network Solutions, Change Healthcare

Panelist

Kris Joshi is Executive Vice President and President, Network Solutions, for Change Healthcare. He initially joined Change Healthcare as Executive Vice President, Products, in December of 2013. Prior to that, Dr. 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, Dr. Joshi served in senior strategy roles in IBM’s Global Sales and Distribution organization. Prior to that, Dr. Joshi was with McKinsey and Company, where he served *Fortune* 500 clients on strategy issues.

Dr. Joshi holds a bachelor’s degree in mathematics from Caltech and a Ph.D. in physics from MIT.



Peter Maag, Ph.D.

CEO, 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.



Hakan Sakul, Ph.D.

Vice President, Head of Diagnostics,
Worldwide R & D and Medical, Pfizer

Panelist

Dr. Sakul leads Pfizer’s company-wide diagnostics efforts. He worked in the biotechnology industry in the human genetics and statistical genetics fields early in his career before moving to Parke-Davis Pharmaceuticals to direct human genetics, statistical genetics, and pharmacogenetics programs. Following the merger of Parke-Davis with Pfizer, he has held positions of increasing responsibility, including Director/Site Head for Clinical Pharmacogenomics; Senior Director in Molecular Profiling and in Translational Oncology; and, most recently, Executive Director of Diagnostics.

Dr. Sakul interacted closely with Pfizer’s executive leadership team and Board of Directors to define and implement Pfizer’s current companion diagnostics strategy. One of his most significant professional accomplishments was to lead Pfizer’s flagship companion diagnostics program for Xalkori (crizotinib), resulting in simultaneous FDA approvals of the drug/diagnostic combination in 2011. He has established partnerships with several diagnostics companies on behalf of Pfizer.



Kenna R. Mills Shaw, Ph.D.

Executive Director, MD Anderson Institute
for Personalized Cancer Therapy

Panelist

Dr. Shaw is Executive Director of the Sheikh Khalifa Bin Zayed Al Nahyan Institute for Personalized Cancer Therapy at MD Anderson. She joined The University of Texas MD Anderson Cancer Center in 2013, bringing an extensive background in science leadership and education. Prior to joining MD Anderson, Dr. Shaw spent four years with The Cancer Genome Atlas, a flagship project of the National Cancer Institute focused on accelerating understanding of the molecular basis of cancer. Dr. Shaw earned undergraduate degrees in Spanish and biology at the College of William and Mary, and completed her doctoral degree in cell and developmental biology at Harvard University.

Developing Diagnostics – The Role of Research

A Closer Look at Efforts to Encourage the Clinical Adoption of Personalized Medicine Diagnostics by Studying the Clinical and Economic Utility of Genomic Sequencing

Summarizing the results of a study that examined efforts to integrate personalized medicine into clinical work streams, a team of researchers led by PMC Senior Vice President for Science Policy Dr. Daryl Pritchard noted in a peer-reviewed paper published in *Personalized Medicine* in January of 2017 that although “many stakeholders believe that personalized medicine can provide benefits to patients and the health care system,” payers and providers are often “reluctant to change policies and practices without convincing evidence of clinical and economic value.”

As Dr. Lincoln Nadauld, Chief, Precision Health, Intermountain Healthcare, is quick to remind us, patients are counting on the proponents of personalized medicine to accelerate the pace at which promising personalized medicine strategies are adopted by health care providers by addressing this ongoing evidence development challenge.

“I personally have grown tired of young patients showing up in our centers with advanced diseases when we possibly could have known about it, and perhaps prevented it, through personalized medicine approaches,” Dr. Nadauld said.

“Developing Diagnostics – The Role of Research” will examine the progress of evidence development efforts spearheaded by PMC, Intermountain Healthcare, and others.

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 clinical adoption of personalized medicine; 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.



Roy J. Gandolfi, M.D.

Medical Director, SelectHealth

Panelist

Dr. Gandolfi is a Medical Director at SelectHealth, a not-for-profit health plan serving more than 900,000 members in Utah, Idaho, and Nevada. SelectHealth and Intermountain Healthcare form a not-for-profit health system committed to helping people live the healthiest lives possible. Dr. Gandolfi's responsibilities include developing and implementing medical policies. Dr. Gandolfi is deeply involved in genomic utilization and has established a medical oncology quality project that promotes pathway compliance and genetic evaluation.

Dr. Gandolfi received his undergraduate and M.D. degrees from the University of Michigan. He is a practicing internist in a large multi-specialty clinic in Salt Lake City. He is also an Adjunct Associate Professor of Medicine at the University of Utah School of Medicine.



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

Chief, Precision Health, Intermountain Healthcare

Panelist

Lincoln Nadauld, M.D., Ph.D., is the Chief of Precision Health 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.



Peter J. Neumann, Sc.D.

Director, Center for the Evaluation of Value and Risk in Health at the Institute for Clinical Research and Health Policy Studies, Tufts Medical Center

Panelist

Peter J. Neumann, Sc.D., is Director of the Center for the Evaluation of Value and Risk in Health at the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center, where he is also a Professor of Medicine at Tufts University School of Medicine. He is the Founder and Director of the Cost-Effectiveness Registry, a comprehensive database of cost-effectiveness analyses in health care. Dr. Neumann has written widely on the role of clinical and economic evidence in pharmaceutical decision-making and on regulatory and reimbursement issues in health care.

He is the author of *Using Cost-Effectiveness Analysis to Improve Health Care* and Co-Editor of *Cost-Effectiveness in Health and Medicine, 2nd Edition*.



Ammar Qadan

Vice President, Global Head of Market Access, Illumina

Panelist

Ammar Qadan is currently and since November 2016 the Vice President and Global Market Access Lead at Illumina, a company whose mission is “to improve human health by unlocking the power of the genome.”

Throughout his career, Ammar has been distinguished as a passionate, innovative, patient-focused biotechnology leader who has worked in different health care industries, multiple global geographies, and multiple disease areas/products in different life-cycle stages. Ammar has also worked in

different corporate functions ranging from commercial to clinical development.

While at Illumina, Ammar built the market access function; designed and executed the first value-based contract in next-generation sequencing; and collaborated with the Blue Cross Blue Shield Association on a national program to study genomic testing utilization trends. Before joining Illumina, Ammar was the Vice President and Global Product Team Lead at Halozyne Therapeutics, a biotechnology company focused on oncology development.

Overcoming Opioids

Considering the Potential of Personalized Medicine to Address the Opioid Crisis in the US

“The idea that a developed, wealthy nation like ours has declining life expectancy just doesn’t seem right.”

So said Dr. Robert Anderson, Chief of Mortality Statistics for the U.S. Centers for Disease Control and Prevention, in November of 2018 after a new CDC report revealed that drug overdoses fueled by a surge in opioid dependence had reduced life expectancy in the U.S. for three years in a row.

The alarming numbers speak for themselves.

In part because physicians have no reliable way to assess which patients will become addicted to opioids and therefore become more likely to overdose and experiment with increasingly prevalent illegal types of them after their prescriptions run out, fatal opioid overdoses have increased by more than 500 percent in the last three decades, from less than 10,000 in 1990 to 68,557 last year.

Enter the Camden Opioid Research Initiative.

Financed by a \$3 million grant from the state of New Jersey, the Coriell Institute for Medical Research is conducting a study to identify the genetic, biological, and environmental factors that may influence which patients become addicted to these commonly prescribed pain medications. If successful, the initiative may inform personalized health care strategies that can alleviate the burden of the opioid addiction crisis in New Jersey and around the country.

During “Overcoming Opioids: Considering the Potential of Personalized Medicine to Address the Opioid Crisis in the US,” Dr. Alissa M. Resch, Chief Scientific Officer, Coriell Institute for Medical Research, will provide an update on the progress of the study.

Participants



Alissa M. Resch, Ph.D.

Chief Scientific Officer, Coriell Institute for Medical Research

Speaker

Alissa M. Resch, Ph.D., is the Chief Scientific Officer at Coriell. Alissa provides oversight and guidance for all repository contracts and grants and, in this role, oversees the project management teams to ensure all project deliverables are met or exceeded.

Alissa is also Principal Investigator of the National Human Genome Research Institute Sample Repository, a diverse

collection of cell lines and DNA that have contributed to several landmark initiatives, including the International HapMap and 1000 Genomes projects. Alissa executes the deliverables of this federally funded grant, manages sample distribution to a scientific community investigating genetic variation in human populations, and actively pursues the expansion and quality assurance goals of the repository.

Assessing Progress Toward the Clinical Integration of Personalized Medicine

A Landscape Analysis

“It’s one thing to talk about personalized medicine,” Dr. Howard McLeod, Medical Director of Moffitt Cancer Center’s DeBartolo Family Personalized Medicine Institute, said at *The 13th Annual Personalized Medicine Conference: From Concept to the Clinic*.

“It’s another to have your health system invest in it.”

With these comments, Dr. McLeod reminded us that the remarkable pace of scientific and technological progress in personalized medicine will have limited value for patients if health care providers do not align their clinical practices with the principles of the field.

And we’re not sure if they are doing so.

Anecdotal reports and case studies suggest that leading academic medical centers and pioneering community health care systems have begun to utilize genetic sequencing to improve care for cancer patients, but the field lacks definitive data from a more representative set of institutions. And the data that are available say little about the efforts of health care providers to go beyond genetics in pursuit of personalized health care that is guided by a more comprehensive understanding of each individual’s biological characteristics, circumstances, and values.

In this context, Gary Gustavsen, Partner, Managing Director, Health Advances, will join us during “Assessing Progress Toward the Clinical Integration of Personalized Medicine: A Landscape Analysis” to share the preliminary findings from a PMC-commissioned survey that examines the personalized medicine integration efforts of a geographically diverse set of academic medical centers and community health care systems in the U.S.

By assessing the prevalence and characteristics of personalized medicine programs as they progress through five stages of increasing sophistication, the study will define the landscape for clinical adoption of personalized medicine based on a multi-factorial definition of the field. It will also establish benchmarks that providers can use to assess their own implementation efforts.

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 clinical adoption of personalized medicine; 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.



Gary Gustavsen

Partner, Managing Director, Health Advances
Speaker

Gary joined Health Advances in 2005 and leads the firm's personalized medicine practice.

A noted writer and workshop leader in the field of companion diagnostics and personalized medicine, his work focuses on commercialization strategy, indication prioritization, pricing and reimbursement strategy, system economics, and business development opportunities for both diagnostic and therapeutic clients.

Prior to joining Health Advances, Gary was a researcher at Brookhaven National Lab evaluating a proprietary line of synthetic growth factors. Gary also worked in the Cell & Tissue Technologies group at Becton Dickinson; the Exploratory Cancer Research group at OSI Pharmaceuticals; and, most recently, the Corporate Strategy group at Millennium Pharmaceuticals. Gary received his B.S.E. degree in biomedical engineering from Duke University and his M.S. degree in biomedical engineering from Stony Brook University.

The 15th Annual Leadership in Personalized Medicine Award

In recognition of visionary scientific research underpinning two flagship personalized medicine products – a therapy and a diagnostic – that have revolutionized cancer care, the Personalized Medicine Coalition will present the *15th Annual Leadership in Personalized Medicine Award* to Dr. Steven Shak, Co-Founder, Chief Scientific Officer, Genomic Health.

Dr. Shak demonstrated his talent for groundbreaking scientific discoveries soon after he earned his M.D. from New York University. After beginning his career as an assistant professor at NYU, Dr. Shak discovered and cloned the human DNase I gene during the first half of his 14-year tenure at Genentech. This discovery provided the foundation for Genentech's development of dornase alfa (Pulmozyme), the first treatment for cystic fibrosis. The therapy helped extend the life expectancy of cystic fibrosis patients significantly.

Dr. Shak turned his attention to personalized medicine while leading development of Genentech's trastuzumab (Herceptin), a targeted therapy that is designed to inhibit the function of genes over-expressed by breast cancer cells. Dr. Shak spearheaded the first regulatory approval of a personalized medicine in the U.S. by shepherding trastuzumab through FDA on the heels of rigorous clinical trials in 1998, five years before scientists spurred the development of additional personalized therapies by finishing the first complete sequence of a human genome.

Trastuzumab is now standard of care for breast cancer patients whose tumors over-express HER2 genes.

Following his tenure at Genentech, Dr. Shak co-founded Genomic Health, where he led the development of the Oncotype IQ® portfolio of diagnostic tests and services, which analyzes the genomic characteristics of cancer cells to predict how aggressively the cancer might spread, thereby sparing patients and the health system from unnecessary side effects and costs. The tests, which were among the first to demonstrate that personalized medicine can improve patient care and make health systems more efficient, have already been used to guide treatment decision-making for more than 1 million cancer patients and have saved health care systems more than \$5 billion.

Following the release of long-term study results last year, the American Society of Clinical Oncology (ASCO) has published new guidelines that support the use of Oncotype testing based on its ability to identify which node-negative, early-stage breast cancer patients can safely avoid chemotherapy treatment.

“Steve is truly a pioneer in personalized medicine who continues to blaze new frontiers,” said Kim Popovits, Chairman of the Board, CEO, President, Genomic Health. “He constantly challenges all of us to innovate so that we continue to answer the most critical clinical and scientific questions.”

Participants

Kimberly Popovits

Chairman of the Board, CEO, President, Genomic Health

Presenter

Committed to changing the paradigm of cancer care, Kim Popovits has led Genomic Health in revolutionizing the treatment of cancer through genomic-based diagnostic tests for breast, colon, and prostate cancers that address the over-treatment and optimal treatment of early-stage cancer, one of the greatest issues in health care today.

Kim has served as Genomic Health's Chairman of the Board since 2012, and CEO and President since 2009. She was President and Chief Operating Officer since joining the company in 2002. Prior to joining Genomic Health, Kim served as Senior Vice President, Marketing and Sales, at Genentech.



Steven Shak, M.D.

Chief Scientific Officer, Genomic Health

Awardee

Dedicated to optimizing cancer treatment outcomes and bringing the patient voice into product development, Steven Shak, M.D., has served as Co-Founder, Chief Scientific Officer, of Genomic Health since 2012 and was Chief Medical Officer from 2000 to 2013.

Under Steve's leadership, Genomic Health used innovative molecular diagnostic methods and rigorous clinical studies to develop the Oncotype DX® breast cancer and colon cancer assays and has maintained an 80 percent product development success rate.

Steve has been a leader in personalized medicine for more than two decades. Prior to co-founding Genomic Health in 2000, Steve served for 14 years in various roles in discovery research and medical affairs at Genentech Inc., a biotechnology company dedicated to using human genetic information to discover, develop, manufacture, and commercialize medicines to treat patients with serious or life-threatening medical conditions.



Wellness in the Workplace

Understanding the Opportunities and Challenges Associated With Genetic Testing Programs for Healthy Patients

Since the first complete sequencing of a human genome in 2003, proponents of personalized medicine have envisioned a future in which healthy patients collaborate with medical professionals to identify screening protocols and lifestyle choices that will help them live healthier lives.

That vision has not gone unchallenged, especially as progress has been elusive.

But the field's advocates remain confident that certain genetic mutations will prove to be relatively strong predictors of future medical circumstances. Health systems, they contend, will be able to justify investments in genetic sequencing tests because patients and physicians can and will act on test results to mitigate the clinical and economic consequences of diseases that would otherwise keep people from working and enjoying time with friends and family.

For most of the field's history, this was a hypothetical argument.

Not anymore.

Following years of research and technical advancements that have driven down the costs associated with genetic testing, pioneering employers around the country have begun to cover the costs of genetic testing for their employees in pursuit of healthier and more productive work forces. Along the way, they are tackling complex questions about the medical significance of genetic testing; the differences among various genetic testing business models; and the privacy risks associated with the collection and storage of sensitive genetic data that are subject to an important set of legal and ethical safeguards.

Moderated by Quest Diagnostics Chief Medical Officer Dr. Jay G. Wohlgemuth, "Wellness in the Workplace: Understanding the Opportunities and Challenges Associated With Genetic Testing Programs for Healthy Patients" will explore the experiences of genetic testing partnerships between Jefferson Health/Color Genomics and the Teachers' Retirement System of Kentucky/Coriell Life Sciences.

Participants



Jay G. Wohlgemuth, M.D.

Chief Medical Officer, Senior Vice President,
Quest Diagnostics

Moderator

Dr. Wohlgemuth oversees R & D, medical, employee health, and employer health and wellness for Quest Diagnostics and is a member of the senior management team. Prior to joining Quest Diagnostics, Dr. Wohlgemuth held the position of Director of Clinical Diagnostics, Immunology, Tissue Growth and Repair, at Genentech. He was Co-Founder and Chief Medical Officer for the molecular diagnostics company XDx, for which he was awarded Technology Pioneer 2005 at the World Economic Forum in Davos. Jay obtained his undergraduate degree in biology at Harvard College and received his medical degree from Stanford, where he also served a fellowship in cardiovascular medicine. He is on the Board of Directors of the Personalized Medicine Coalition, Q2 Solutions, and Diagnostic Labs of Oklahoma, and serves as trustee of the Anne and Henry Zarrow Foundation, a charitable foundation focused on supporting the delivery of health care and social services.



Jane Cheshire Gilbert, C.P.A.

Director, Retiree Health Care, Teachers'
Retirement System of Kentucky

Panelist

Jane Gilbert is the Director of Retiree Health Care for the Teachers' Retirement System of the State of Kentucky and has served TRS retirees since April 2002. She manages two retiree health plans covering 48,000 retirees. She also serves as a leader in the areas of health insurance cost-containment, project management, risk management, and federal health care solutions.

Ms. Gilbert served in management and directorship positions for a Louisville Kentucky law firm and cost-containment company, The Rawlings Company, from 1989 through 2002. Prior to serving at The Rawlings Company, she worked as an accountant for a national CPA firm.



Karen E. Knudsen, M.B.A., Ph.D.

Executive Vice President, Oncology Services, Jefferson Health; Enterprise Director, Sidney Kimmel Cancer Center at Thomas Jefferson University

Panelist

Karen E. Knudsen, Ph.D., is Executive Vice President of Oncology Services and Enterprise Director of the Sidney Kimmel Cancer Center at Jefferson, one of only 70 National Cancer Institute-designated centers. Dr. Knudsen oversees cancer research and cancer patient care across Jefferson Health, and the center is consistently ranked as one of the top centers for cancer care in the nation.

Dr. Knudsen also serves as Chair of the Department of Cancer Biology at the Thomas Jefferson University, and holds joint appointments in the departments of Urology, Medical Oncology, and Radiation Oncology. Dr. Knudsen's expertise is in developing new means to treat advanced prostate cancer and discovering genetic alterations that contribute to disease progression. Dr. Knudsen is active in the field, serving as Editor-in-Chief of *Molecular Cancer Research* and as President-Elect of the Association of American Cancer Institutes. She holds leadership roles in national organizations including the American Society of Clinical Oncology, and serves on the National Cancer Institute's Board of Scientific Advisors.



Othman Laraki

CEO, Color Genomics

Panelist

Othman Laraki is Co-Founder and CEO of Color. He spent several years at Google, where he worked on Google's performance infrastructure and client-side software, including the Google Chrome browser. Following Google, he co-founded MixerLabs, which was acquired by Twitter in 2009. At Twitter, Othman was the Vice President of Product, helping create the company's first revenue products and grow the user base from 50 to 200 million users. Othman holds degrees in computer science and management from Stanford University and MIT. Othman is a long-time investor and advisor to leading companies such as Pinterest, AngelList, Slack, Instacart, and others.



Scott Megill

President, CEO, Coriell Life Sciences

Panelist

As Founder and CEO of Coriell Life Sciences, Mr. Megill led the formation and successful market launch of CLS as the commercial arm of the Coriell Institute for Medical Research, where he previously served as Chief Information Officer. Under his stewardship, CLS has attained a market leading position in molecular diagnostic interpretation and reporting. The company's products provide clinical decision support for physicians and pharmacists in the areas of medication management, women's health, infectious disease, and more.

Prior to Coriell, Mr. Megill was with the Rohm and Haas/Dow Chemical Corporation, where he led Enterprise Technology Development and Architecture. There, he spearheaded the implementation of many global-scale, multi-year business technology initiatives, including the Digital Rights and Identity Management program. He also led the cross-company team responsible for integrating all aspects of the technology infrastructure leading up to the \$15 billion acquisition of Rohm and Haas. Mr. Megill also spent five years with Willis Towers Watson.

Preparing Policies

A Keynote Address on the Policy Landscape for Personalized Medicine by Dr. Scott Gottlieb, Resident Fellow, American Enterprise Institute

On May 10, 2019, former U.S. Food and Drug Administration (FDA) commissioner Dr. Scott Gottlieb stood before an eager audience at the National Press Club to reflect on a historic tenure at FDA during which he oversaw the approval of record numbers of groundbreaking personalized treatments and spearheaded a series of regulatory precedents that are designed to help speed the commercialization of the diagnostic tools necessary to guide those therapies to the right patients.

He began by describing “a remarkable period” of scientific opportunity in personalized medicine.

“With gene therapies, cell-based regenerative medicine, more targeted therapies, and the introduction of better tools for delivering therapies from digital health apps to artificial intelligence to next-generation sequencing, we’re living in an age of momentous progress and rapid cycles of innovation,” he said. “We have more ability to use technology to achieve sizable and secular advances in medicine than ever before.”

The rest of his address focused on solutions for addressing formidable systemic challenges, underlining the need to “finance these opportunities in a fashion that optimizes access to patients who most need them and doesn’t discourage future investment and innovation.”

Dr. Gottlieb’s attention to these downstream issues reminds us that if we want to facilitate a permanent shift away from treatment protocols based on what has been proven to work for the highest percentage of all patients with a given disease in favor of an approach that seeks to understand everything that can be learned about each patient before prescribing the therapy that can deliver the longest-lasting effect in accordance with each patient’s biology and desires, we need to align on forward-thinking policies and processes in the public and private sectors that encourage continued innovation; facilitate sustainable access to the products and services that underpin this new era of personalized health care; and prompt providers to practice medicine differently.

Dr. Gottlieb will share his thoughts on these topics and more during “Preparing Policies: A Keynote Address on the Policy Landscape for Personalized Medicine by Dr. Scott Gottlieb, Resident Fellow, American Enterprise Institute.”

Participants



Cynthia A. Bens

Senior Vice President, Public Policy,
Personalized Medicine Coalition

Introduction

Cynthia A. Bens, Senior Vice President, Public Policy, Personalized Medicine Coalition, leads the Coalition’s policy development and government relations efforts and serves as its primary liaison with Congress and federal regulators. In collaboration with PMC’s Senior Vice President, Science Policy, 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.

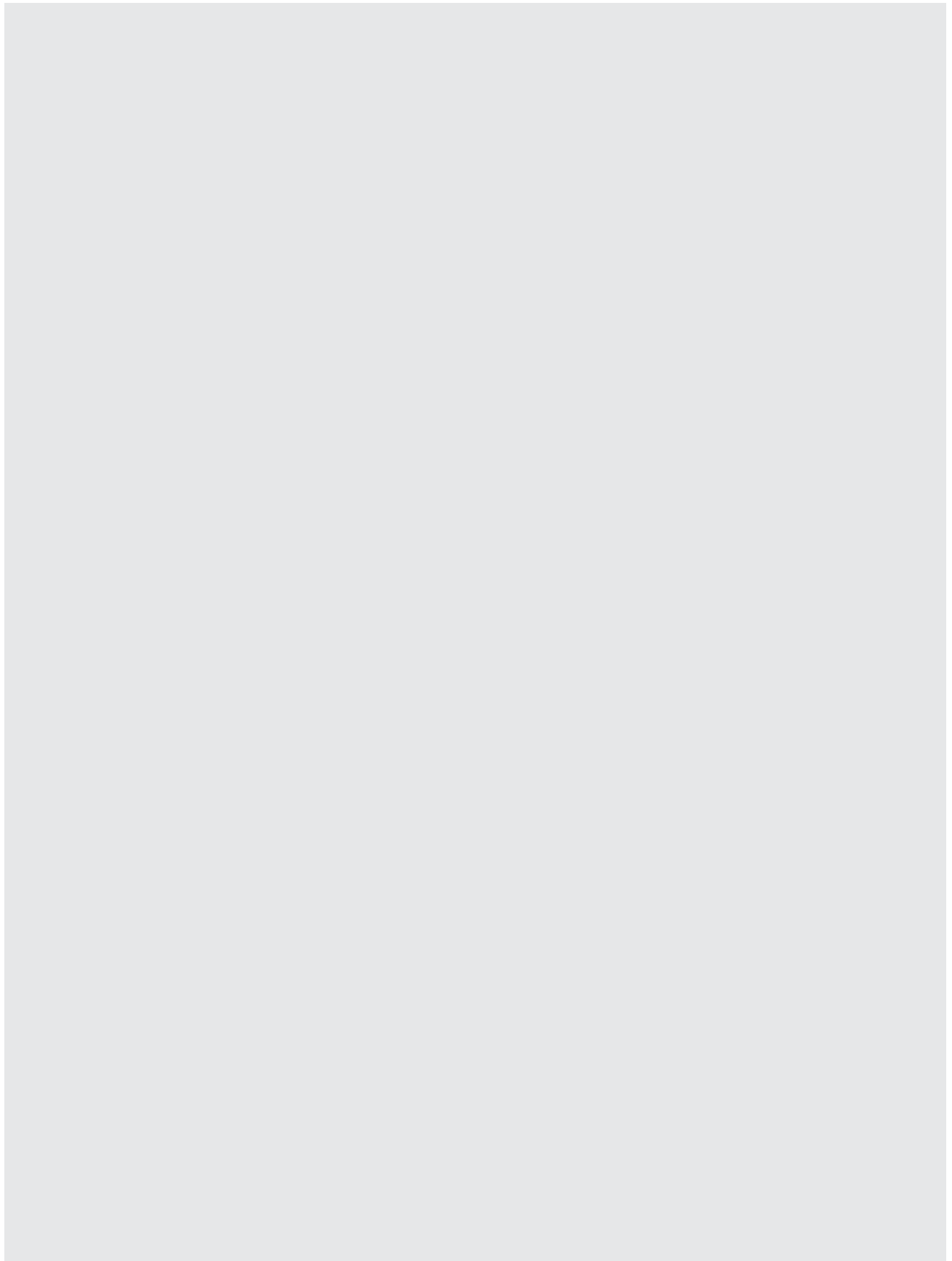


Scott Gottlieb, M.D.

Resident Fellow, American Enterprise Institute
Keynote Speaker

Scott Gottlieb, M.D., is a Resident Fellow at the American Enterprise Institute. He returned to AEI in 2019 after serving as the 23rd commissioner of FDA. At AEI, he continues his work on improving public health through entrepreneurship and medical innovation and on expanding regulatory approaches to maintain patient and physician autonomy.

At FDA, Dr. Gottlieb focused on a wide variety of issues, including drug pricing, medical product innovation, food safety, vaccination, and tobacco and vaping. He advanced new policies to address opioid addiction, working to rationalize prescribing as a way to reduce the rate of new addiction. He helped make the regulatory process for the development and review of novel drug and medical devices more efficient, including the approval of the first gene therapy-based cancer treatment. He also presided over a record number of novel drug and medical device approvals in 2017, and then broke that record in 2018.





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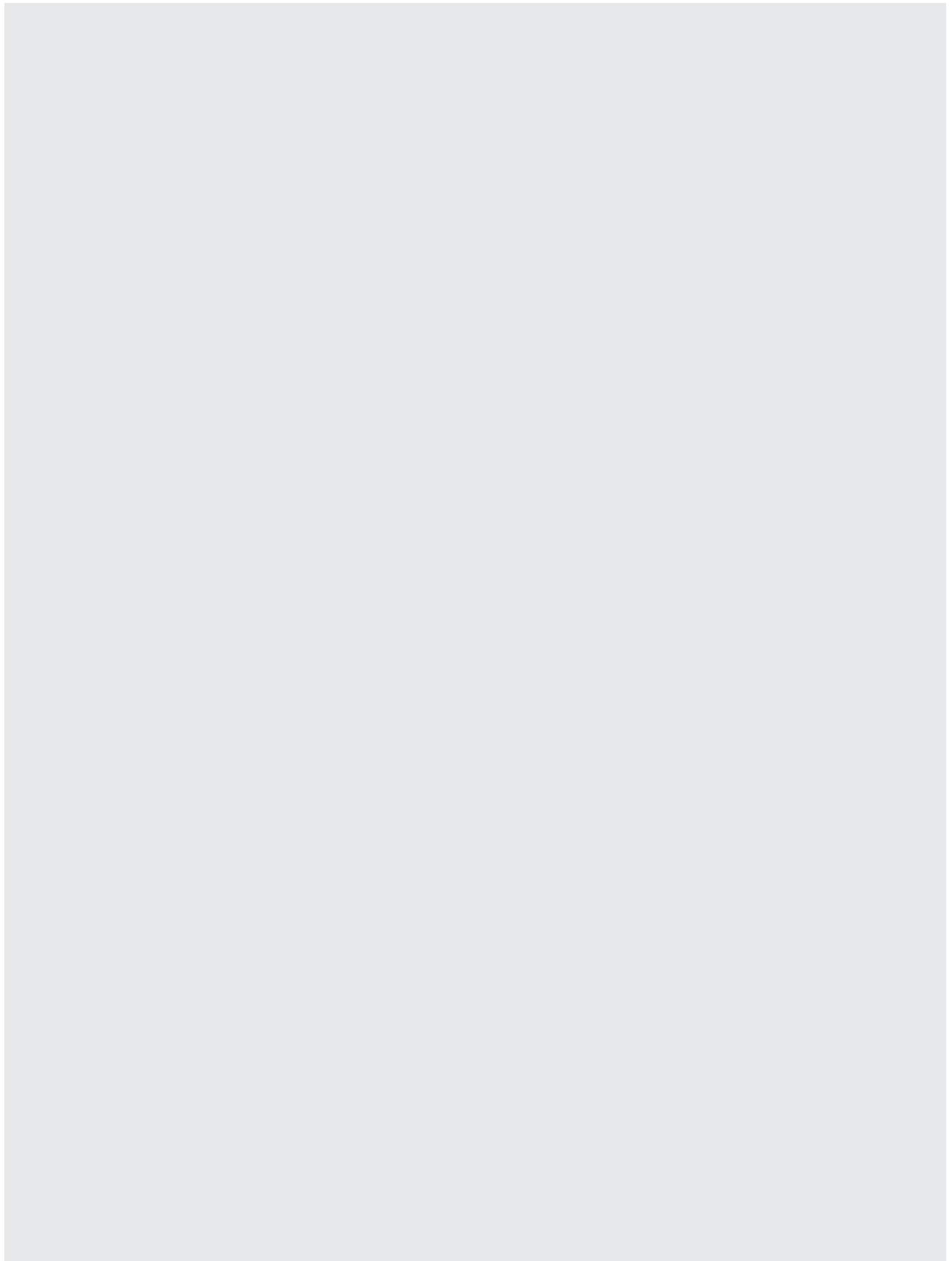
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PART II

TARGETING TREATMENT



November 14, 2019

JOSEPH B. MARTIN CONFERENCE CENTER • HARVARD MEDICAL SCHOOL, BOSTON, MA 02115

Going Global

Learning From Governmental Efforts to Advance Personalized Medicine Around the World

Writing for PMC's *Personalized Medicine in Brief* in the Spring of 2017, two representatives of the Qatar Genome Program outlined early results from the country's then six-year-old effort to gain insights about genetic predispositions to disease by collecting health data from 60,000 Qatari people. By informing Qatar's health professionals about the emerging insights from the program, leaders in Qatar and elsewhere hope to move closer to an era of personalized medicine that is guided by an enhanced understanding of the biological characteristics and environmental factors affecting each patient's health trajectory.

This has always been the goal of medicine, even if our recent scientific and technological progress has only now delivered the tools necessary to achieve it.

Reflecting on mankind's continued pursuit of the personalized medicine paradigm, Dr. Liisa-Maria Voipio-Pulkki, Director General, Chief Medical Officer, Ministry of Social Affairs and Health, Finland, notes that the field, in some ways, is just another example of the logical extensions of scientific knowledge that have characterized the history of medicine for centuries.

"This is just a revolution," she explains.

In the context of this worldwide revolution, "Going Global: Learning From Governmental Efforts to Advance Personalized Medicine Around the World" will seek to understand the circumstances under which various governmental models for advancing personalized medicine will be most successful by exploring the logic underpinning the efforts of four countries to accelerate research, update public policies, and facilitate clinical adoption.

Participants

Antonio L. Andreu, M.D., Ph.D.

Scientific Director, EATRIS
(European Infrastructure for Translational Medicine)

Moderator

Toni is an M.D., Ph.D., who specialized in genetics and genomics of rare diseases. He has been working in the field of neuromuscular disorders from the translational perspective of the pipeline, from basic science to the development of cell and animal models and clinical research.

After working at Columbia University in New York on mitochondrial disorders from 1998 to 2001, he moved to Barcelona to create the Neuromuscular Lab at the Vall d'Hebron Research Institute, where he became Director of the Neurosciences Research Program.

He has also been extremely active in the field of policy-making and held positions as the Director of the Spanish National Institute of Health, Carlos III, creating the national program for personalized medicine. He has also been the CEO of the Bellvitge Hospital, one of the most important university hospitals in Spain, as well as the Director General for Research and Innovation at the Catalan Ministry of Health.

Toni is now the Scientific Director at EATRIS, the European Advanced Infrastructure for Translational Research.



Wadha Al Muftah, M.D., Ph.D.

Manager, Clinical Initiatives, Qatar Genome Program

Panelist

Dr. Wadha Al-Muftah is the Manager of the Clinical Initiatives at Qatar Genome Program and Instructor in Genomic Medicine (courtesy) at Weill Cornell Medicine Qatar. She holds a Ph.D. in clinical medicine research from Imperial College London in the United Kingdom and an M.D. from Arabian Gulf University in the Kingdom of Bahrain.

Dr. Al-Muftah has worked with Qatar Genome Program since late 2016, and

leads the genome interpretation project. The project is focused on establishing a computational genomics platform that provides interpretation and clinical reporting solutions and supports high-throughput panels for whole exomes and whole genomes for general wellness in phase I, pharmacogenomics in phase II, and hereditary diseases and oncology in phase III.





Noella Bigirimana

Strategic Advisor, Rwanda Biomedical Center,
Ministry of Health, Government of Rwanda;
Government Fellow, World Economic Forum

Panelist

Noella Bigirimana is a Rwanda Government Fellow at the World Economic Forum's Centre for the Fourth Industrial Revolution, where she focuses on co-designing governance protocols and policy frameworks to leverage precision medicine approaches in emerging economies.

Noella also serves as Strategic Advisor at Rwanda Biomedical Center, where she works closely with the senior management team implementing national programs. She has worked as a health policy consultant with the World Health Organization and in support of USAID-funded projects in Guinea-Conakry and Rwanda.



Erja Heikkinen, Ph.D.

Deputy Director, General Ministry of
Education and Culture, Finland

Panelist

Erja Heikkinen, Ph.D., is the Deputy Director of Finland's General Ministry of Education and Culture.

Dr. Heikkinen was conferred a Ph.D. degree (population genetics) in 1992. After post-doctoral periods at the University of Tübingen and University of California at Davis she returned to Finland in 1995 when a graduate school system was established at the national level. She was the first coordinator in the Finnish graduate schools. In 1997, Dr. Heikkinen started as a bioinformatics expert in the national supercomputing center, where she provided high performance computing counseling and ran courses in biosciences. In 2001, Dr. Heikkinen joined Tekes, the Finnish Funding Agency for Innovation. Her affiliation with the Ministry started in 2005.



Raquel Yotti, M.D., Ph.D.

General Director, Instituto de Salud Carlos III (Spain)

Panelist

Raquel Yotti is the current Director General of the Spanish Institute of Health “Carlos III,” the main public funding organization for biomedical research in Spain. She is a clinical cardiologist and an expert in cardiac imaging and inherited heart disease. Until her appointment in

September of 2018, she was the head of the Clinical Cardiology Department at the Gregorio Marañón General University Hospital and Associate Professor of the Department of Bioengineering and Aerospace Engineering at the Carlos III University in Madrid.

Innovation in the Era of Personalized Medicine

A Keynote Conversation With Dr. Paul Stoffels, Chief Scientific Officer, Johnson & Johnson

In a video posted by Johnson & Johnson in 2013, Dr. Paul Stoffels, who is now the company's Chief Scientific Officer and Vice Chairman of its Executive Committee, noted that “the threshold for innovation has continued to rise, and this has an impact on the growing cost of research and development.” Referencing the emergence of cell therapy as well as new developments in genomics, biomarkers, and companion diagnostics, Dr. Stoffels contended that the biopharmaceutical industry was positioned to “fulfill the promise of personalized medicine.”

His predictions are proving prescient.

Personalized medicines, as defined by the Personalized Medicine Coalition, have accounted for more than 20 percent of all drugs the U.S. Food and Drug Administration (FDA) approved in each of the last five years, rising to a new record of 42 percent in 2018. These new approvals include the first cell and gene therapies, which can often spare patients from otherwise fatal diseases and mitigate the expenses associated with a lifetime of ongoing symptoms and hospitalizations by eliminating disease symptoms for long periods of time with just a few prescriptions.

In so doing, these complex treatments offer unprecedented benefits to patients and society.

But they also present unprecedented business challenges to drug developers that have historically focused on selling daily maintenance medications.

Payers are more accustomed to reimbursing for daily pills, which are cheaper because they can be manufactured at scale. In contrast, cell therapies require drug developers to rely on higher list prices to recoup the costs associated with genetically re-engineering the cells of each patient treated.

And as *CNBC* noted last year in an article titled “Is Curing Patients a Sustainable Business Model?,” gene therapies, which aim to serve as “one-time cures,” cannot deliver recurring revenue to the bottom lines of pharmaceutical companies the way that daily maintenance medications can.

CNBC Reporter Meg Tirrell will moderate “Innovation in the Era of Personalized Medicine” in the context of these business challenges and society's demand for transformational treatments.

Participants



Meg Tirrell

Reporter, *CNBC*
Moderator

Meg Tirrell joined *CNBC* in April 2014 as a General Assignment Reporter focusing on biotechnology and pharmaceuticals. She appears on *CNBC*'s "Business Day" programming, contributes to *CNBC.com* and is based at the network's global headquarters in Englewood Cliffs, NJ.

Tirrell has covered development of new drugs for Alzheimer's, cancer and rare diseases, and tracked public health emergencies from Ebola to Zika. Her work has explored why fewer drugs are developed for children, chronicled the sequencing of her own genome, and followed the manufacturing of a flu shot from egg to pharmacy. In 2014, she revealed the agonizing decision-making behind "compassionate use" of unapproved drugs, and since 2016, she has reported extensively on drug pricing controversies and the impact of politics on the development of new medicines.



Paul Stoffels, M.D.

Chief Scientific Officer, Vice Chairman,
Executive Committee, Johnson & Johnson
Keynote Speaker

Paul Stoffels is a visionary leader who inspires and drives transformational innovation to bring years of life and quality of life to millions of people around the world.

Paul spearheads the Johnson & Johnson research and product pipeline by leading teams across all sectors to set the company-wide innovation agenda, discovering and developing transformational health care solutions. He is also responsible for the safety of all products of the Johnson & Johnson's global family of companies, and steers the company's global public health strategy to make innovative medicines and technologies accessible in the world's most vulnerable communities and under-resourced settings. Paul's commitment to fueling innovation and finding the best science, wherever it exists, was the driving force behind the launch of Johnson & Johnson Innovation in 2013, which he now leads to foster science and technology through strategic partnerships, licensing, and acquisitions.

Prospecting the Pipeline

Exploring the Implications of a Biopharmaceutical Pipeline Dominated by Personalized Treatments

In an article published in July that chronicles the development of chimeric antigen receptor (CAR) T-cell therapies, *Wired* magazine explains the “unthinkable” series of experiments that eventually led to the U.S. Food and Drug Administration’s approval of two revolutionary CAR T-cell therapies for certain forms of blood cancer in 2017.

Recognizing that a protein called CD19 is commonly expressed on the surfaces of certain types of cancerous cells, scientists developing CAR T-cell therapies had to refine their techniques for removing a patient’s immune cells, genetically re-engineering them, and re-injecting them back into the patient until they found a procedure that would help T-cells identify and destroy cells expressing CD19 without killing the patient.

And the science may have been the easy part.

With the latest approaches proven safe and effective, Gilead and Novartis now need to begin recouping the \$373,000 and \$475,000 costs associated with their respective CAR T-cell procedures and the resulting customized therapies from drug spending budgets that are already struggling to afford the mass production of much cheaper one-size-fits-all pills and injections.

With a new study conducted by L.E.K. Consulting and published by the Personalized Medicine Coalition showing that 55 percent of clinical trials with cancer patients in 2018 involved the identification of specific biological characteristics to guide or customize treatment protocols, some observers have begun to suggest that this new future for cancer patients is unsustainable, even if the approaches in question are able to permanently eliminate cancerous cells through just a few treatments, as CAR T-cell therapies have been shown to do for many patients.

During “Prospecting the Pipeline: Exploring the Implications of a Biopharmaceutical Pipeline Dominated by Personalized Treatments,” *CNBC* Reporter Meg Tirrell will moderate a panel discussion featuring industry representatives, a researcher, and an academic leader that explores the scientific, regulatory, reimbursement, and other systemic issues associated with future gene editing treatments, gene therapies, immunotherapies, and targeted therapies.

Participants

Meg Tirrell

Reporter, *CNBC*

Moderator

Meg Tirrell joined *CNBC* in April 2014 as a General Assignment Reporter focusing on biotechnology and pharmaceuticals. She appears on *CNBC*'s "Business Day" programming, contributes to *CNBC.com* and is based at the network's global headquarters in Englewood Cliffs, NJ.

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Donald L. Siegel, Ph.D., M.D.

Director, Division of Transfusion Medicine & Therapeutic Pathology,
Director, Clinical Cell & Vaccine Production Facility, University of
Pennsylvania's Perelman School of Medicine

Panelist

Don Siegel, Ph.D., M.D., is a Professor of Pathology & Laboratory Medicine at the University of Pennsylvania Perelman School of Medicine and Director of the Division of Transfusion Medicine & Therapeutic Pathology at the Hospital of the University of Pennsylvania. He serves as the Medical Director of the blood bank and transfusion service; the apheresis/infusion unit, the hematopoietic stem cell processing laboratory; and the cellular and vaccine production facility.

Dr. Siegel received an undergraduate degree in biophysics from Brown University, a Ph.D. in biophysics from Harvard University, and an M.D. from

the University of Pennsylvania School of Medicine. He completed a residency in clinical pathology and fellowship in transfusion medicine at the Hospital of the University of Pennsylvania and joined the faculty at the University of Pennsylvania in 1991.

Dr. Siegel has expertise in the areas of blood transfusion, antibody and cellular therapy, therapeutic apheresis, and other related areas of transfusion medicine. His basic and translational research laboratory currently focuses on the development of novel recombinant antibodies for the design of chimeric antigen receptor T-cells for cancer therapy.





Harpreet Singh, Ph.D.

CEO, Immatix

Panelist

Dr. Harpreet Singh co-founded Immatix in 2000. He now serves as CEO, overseeing the development of next-generation adoptive cell therapies. He previously served as Managing Director and Chief Scientific Officer of Immatix Biotechnologies GmbH, helping to grow the company from a start-up to an established biotechnology company. He is dedicated to translating pioneering scientific discoveries into highly innovative cancer immuno-therapeutics with clinical utility. Dr. Singh has played a leading role in raising more than \$230 million of venture capital funding over several financing rounds and \$20 million from the state of Texas CPRIT fund.

Dr. Singh is the inventor on numerous patents and patent applications and has co-authored approximately 30 publications in peer-reviewed journals including *Nature Medicine*, *Nature Biotechnology*, *Lancet Oncology*, and the *Journal of Experimental Medicine*.



Paul Stoffels, M.D.

Chief Scientific Officer, Vice Chairman,
Executive Committee, Johnson & Johnson

Panelist

Paul Stoffels is a visionary leader who inspires and drives transformational innovation to bring years of life and quality of life to millions of people around the world.

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Alex Vadas, Ph.D.

Managing Director, Partner, LEK Consulting

Panelist

Alexander Vadas is a Managing Director and Partner in L.E.K. Consulting's Biopharmaceuticals and Life Sciences practice. He joined L.E.K. in 2000 and focuses on diagnostics, research tools, and personalized medicine. Within those areas, Alexander has worked with a range

of established and emerging clients in the areas of corporate strategy, product strategy, and planning and transaction support. He received both his B.S. and Ph.D. in chemical engineering from the University of California, Los Angeles.

Balancing Business and Social Objectives to Advance Personalized Medicine

A Case Study of the Dementia Discovery Fund

During last year's 14th *Annual Personalized Medicine Conference at Harvard Medical School*, Daniel O'Day, CEO, Gilead, observed that "the world is no longer prepared to accept marginally differentiated medicines."

To deliver treatments with the "transformational benefits" that patients expect, he said, pharmaceutical companies must invest in developing personalized medicines that can be guided by diagnostic tests to target the root causes of disease at a molecular level. This is risky because the success of these targeted treatment approaches will depend on the extent to which decision-makers in the public and private sectors accept these approaches as a replacement for the trusted one-size-fits-all strategies that have dominated medicine for the vast majority of human history.

The industry has historically shouldered these risks alone.

Not anymore.

In pursuit of personalized treatment approaches that patients want and need, nonprofit foundations, patient groups, and governmental institutions have begun to collaborate with industry partners to fund pharmaceutical research. In so doing, these institutions are pioneering new drug development models that are designed to better balance business and social objectives.

In this context, "Balancing Business and Social Objectives to Advance Personalized Medicine" will examine how the Dementia Discovery Fund, a venture capital fund, plans to further the economic and societal goals of its 17 supporters by creating meaningful new medicines for patients with dementia. The fund's supporters include nine nonprofit, governmental, and payer representatives such as Bill Gates, the British Department of Health and Social Care, and UnitedHealth Group; seven pharmaceutical companies including Eli Lilly, GlaxoSmithKline, Johnson & Johnson, and Pfizer; and a diagnostics company in Quest Diagnostics.

Participants

Richard Hamermesh, D.B.A.

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

Presenter

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 Bingham, M.B.A.

Managing Partner, SV Health Investors

Speaker

In her 26 years at SV, Kate’s biotechnology investments have resulted in the launch of six drugs for the treatment of patients with inflammatory and autoimmune diseases and cancer.

She is one of five managing partners serving on the firm’s Investment Committee, which manages seven venture capital funds and one public fund (with greater than \$2 billion in total assets)

for life sciences investing in the U.S. and Europe. Kate is responsible for biotechnology investments and activities in the E.U., and serves or has served on the boards of companies in the U.K., the U.S., Ireland, Sweden, and Germany.

Kate played an active role in setting up the Dementia Discovery Fund and serves on the DDF Investment Committee.



Toward a Shared Value Proposition in Health Care Pursuing Value-Based Solutions in Research, Regulation, Reimbursement, and Clinical Adoption

In 2001, before physicians had the tools necessary to identify which patients are most likely to respond to any given medication, a team of researchers published an article in *Trends in Molecular Medicine* showing that treatments for six common diseases were helping only 25–62 percent of the patients who receive them, depending on the disease in question. The authors noted that by providing information about which patients are most likely to respond to various treatment options, the emerging field of pharmacogenomics could help us overcome the scientific limitations that were perpetuating this inefficient, one-size-fits-all approach to medicine.

The implications of the study were obvious, at least to the 20 or so institutions that created the Personalized Medicine Coalition three years later.

For as long as the one-size-fits-all medical paradigm prevailed, representatives from all sectors of the health system would waste a sizeable portion of their resources on therapies that fail to alleviate patients' symptoms. Real change, it was argued, requires collaboration with other institutions, both inside and outside of one's respective sector, to advance personalized medicine. Doing so would, in turn, benefit everyone as new and better products are developed.

During the session titled “Toward a Shared Value Proposition in Health Care: Pursuing Value-Based Solutions in Research, Regulation, Reimbursement, and Clinical Adoption,” Dr. William S. Dalton, Executive Chairman, M2Gen, will introduce this concept of shared value, which was defined by Mark R. Kramer and Marc W. Pfitzer in an article published in the *Harvard Business Review* for January 2017 as re-conceiving products and markets to create new social and economic opportunities. Dr. Dalton will also engage the panelists to consider value-based research, regulatory, clinical adoption, and especially reimbursement solutions that can advance personalized medicine for the benefit of patients and health systems.

Participants



William S. Dalton, Ph.D., M.D.

Executive Chairman, M2Gen
Moderator

Dr. William (Bill) S. Dalton is Founder and Executive Chairman of M2Gen, a national biotechnology subsidiary of the Moffitt Cancer Center. He is the past president, CEO, and director of Moffitt Cancer Center, a National Cancer Institute-designated comprehensive cancer center (2002–2012).

Prior to joining Moffitt, Dr. Dalton was the Dean of the University of Arizona College of Medicine. His research interests include development of information systems to allow aggregation, organization, and sharing of patient data in real time to enhance discovery and delivery of evidence-based precision medicine. For his leadership in the area of personalized medicine, Dr. Dalton was recognized as the 2010 recipient of the Personalized Medicine Coalition's *Leadership in Personalized Medicine Award*. Dr. Dalton's basic and translational research interests focus on molecular mechanisms of drug resistance and drug discovery. He has more than 200 publications, serves on several editorial boards, and has numerous patents in the fields of drug discovery and computer/information networking.



Bonnie J. Addario

Co-Founder, Chair, GO₂ Foundation
for Lung Cancer
Panelist

Bonnie has been an activist, advocate, educator, and change agent empowering patients and giving them a strong voice in the fight against lung cancer since receiving a stage 3B diagnosis more than a decade ago. Although thrust into a role that she had never envisioned for herself, she embraced it and now considers it to be her second career and a personal calling.

Recognizing the critical need for education, empowerment, advocacy, and research to help patients and families, especially those without resources and support, Bonnie and her family founded the Bonnie J. Addario Lung Cancer Foundation in 2006, and then went on to found the Addario Lung Cancer Medical Institute with her husband, Tony Addario, in 2008. The Addario Lung Cancer Foundation merged with the Lung Cancer Alliance earlier this year to form the GO₂ Foundation for Lung Cancer.



Sarah K. Emond, M.P.P.

Executive Vice President, Chief Operating Officer,
Institute for Clinical and Economic Review

Panelist

With more than 20 years of experience in the business and policy of health care, Sarah leads the strategic operations of the Institute for Clinical and Economic Review, a leading nonprofit health policy research organization, as Executive Vice President and Chief Operating Officer. In this role, she is responsible for overseeing ICER's public programs, stakeholder engagement, and finances.

Prior to joining ICER, Sarah spent time as a communications consultant, with six years in the corporate communications and investor relations department at a commercial-stage biopharmaceutical company, and several years with a health care communications firm. Sarah began her health care career in clinical research at Beth Israel Deaconess Medical Center in Boston.



Anne-Marie Martin, Ph.D.

Senior Vice President, Global Head of Precision
Medicine, Novartis Pharmaceuticals Corporation

Panelist

As Senior Vice President, Global Head of Precision Medicine, Novartis Pharmaceuticals Corporation, Anne-Marie is responsible for the development, implementation, and execution of a precision medicine strategy to support clinical development, registration, and commercialization in Novartis Oncology. Since joining Novartis in 2016, Anne-Marie has led the development and approval of companion diagnostics in support of three clinical assets including midostaurin for Flt3 mutated AML; the first BRAF next-generation sequencing assay for tafinlar and mekinist in non-small cell lung cancer; and an ALK assay for ceritinib, also in non-small cell lung cancer. In addition, she has led the correlative science associated with all clinical assets in oncology.

Anne-Marie holds a Ph.D. in microbiology & immunology from Drexel University in Philadelphia. She has more than 19 years of experience in the health care sector. She began her career in cancer research at the University of Pennsylvania, where she received funding from the Susan G. Komen Foundation, the Leiomyosarcoma Foundation, Fibro-ossificans Progressiva Foundation and the U.S. National Institutes of Health.



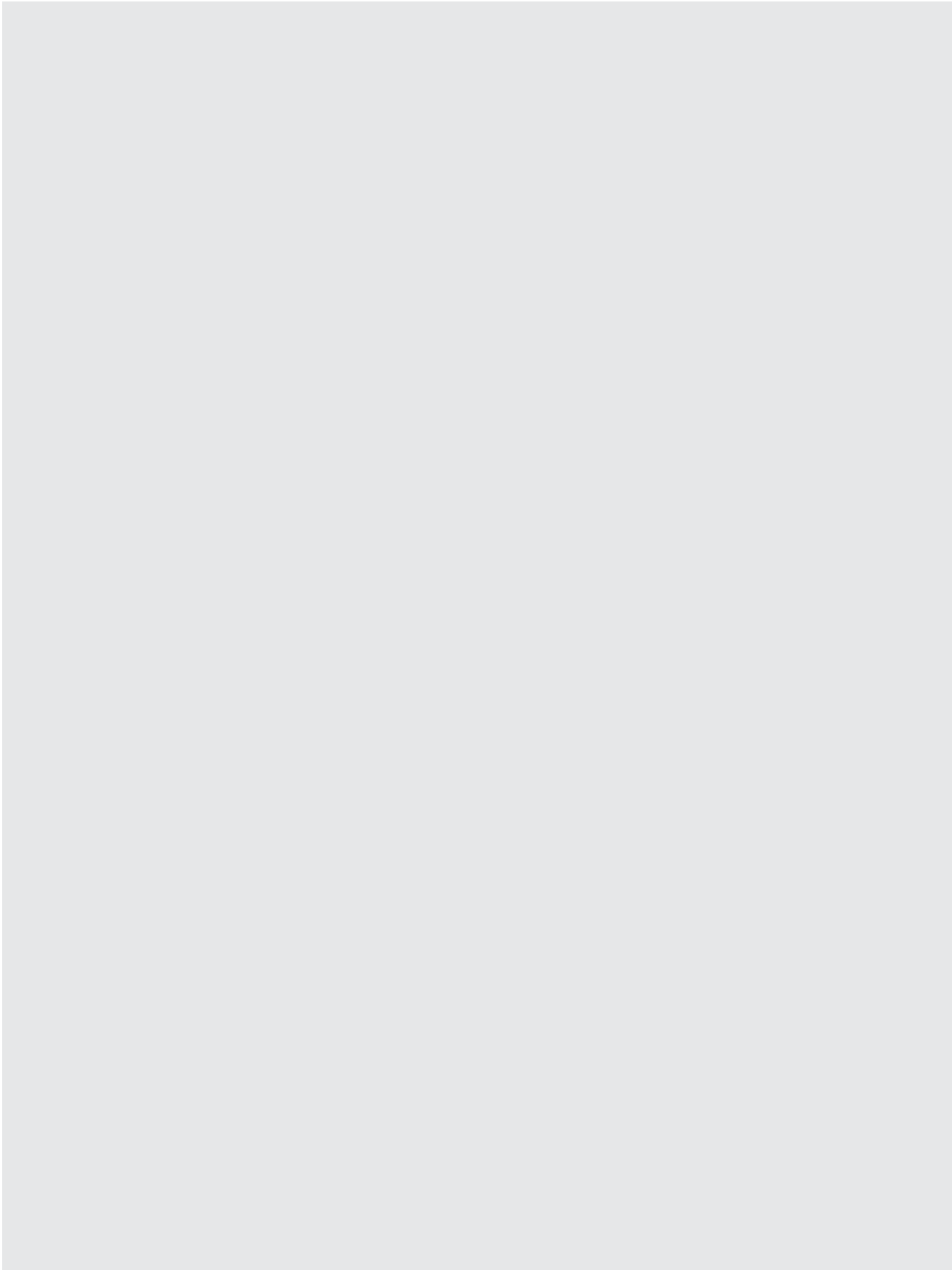
Michael Sherman, M.D.

Chief Medical Officer, Senior Vice President,
Harvard Pilgrim Health Care

Panelist

Michael Sherman serves as Chief Medical Officer and Senior Vice President for Health Services for Harvard Pilgrim Health Care. A pioneer in developing outcomes-based payment agreements with pharmaceutical companies, he recently signed the first value-based agreement for a gene therapy used to treat a form of blindness.

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. He is the current Chair for America's Health Insurance Plans' Chief Medical Officer Leadership Council, and serves on the Board of Directors for the Personalized Medicine Coalition.



Congratulations to the Recipients of the 2019 PMC/BIO Patient Advocacy Scholarships

Recognizing that the success of personalized medicine depends on collaboration between patients and health care providers, the Personalized Medicine Coalition partnered with the Biotechnology Innovation Organization to offer seven scholarships for patients, representatives from patient advocacy organizations, and caregivers to attend the *15th Annual Personalized Medicine Conference at Harvard Medical School*.

Each scholarship included a complimentary conference registration and a \$1,000 stipend to cover transportation and lodging. During lunch on the first day of the conference, recipients will participate in a roundtable discussion that will inform a publication that summarizes patients' expectations for this new era in health care.

2019 Recipients

Terri Booker, Co-Founder, Young Adult Sickle Cell Alliance; sickle cell disease patient

Courtney McKenzie Goble, adhesive arachnoiditis patient

Anthony Goble, caregiver

Christina Haywood, rectal cancer survivor

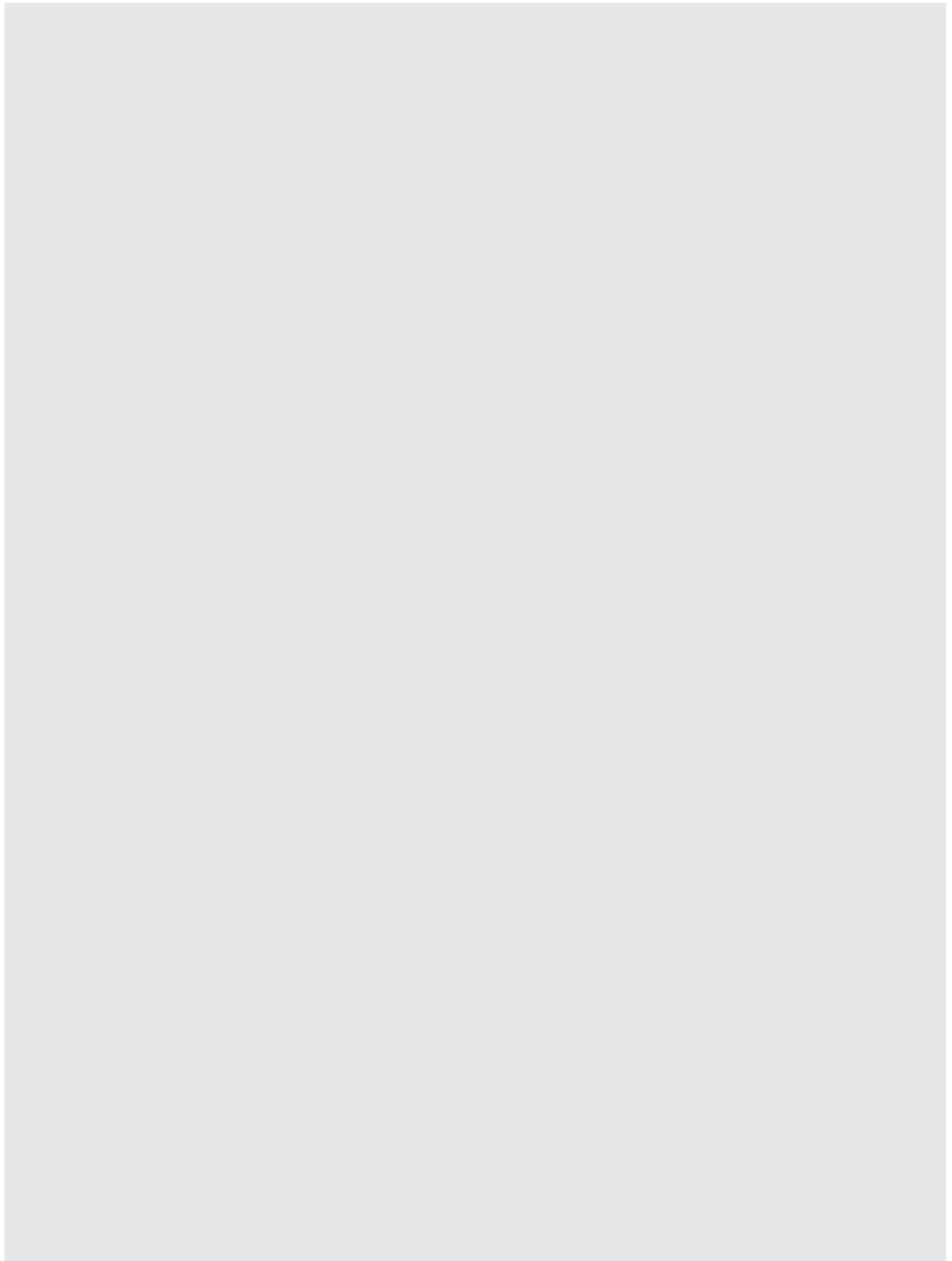
Zach Haywood, caregiver

Richard Knight, President, American Association of Kidney Patients; kidney transplant recipient

Laura Lee, caregiver

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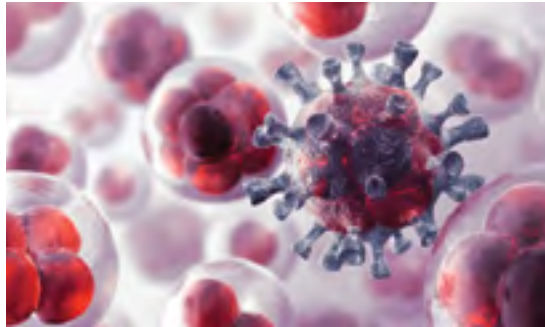
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Steven Shak, M.D.
Co-Founder,
Chief Scientific Officer,
Genomic Health

In recognition of your *Life, changing* work on behalf of cancer patients worldwide.

Congratulations Steve on receiving the 15th Annual Personalized Medicine Coalition Leadership in Personalized Medicine Award.



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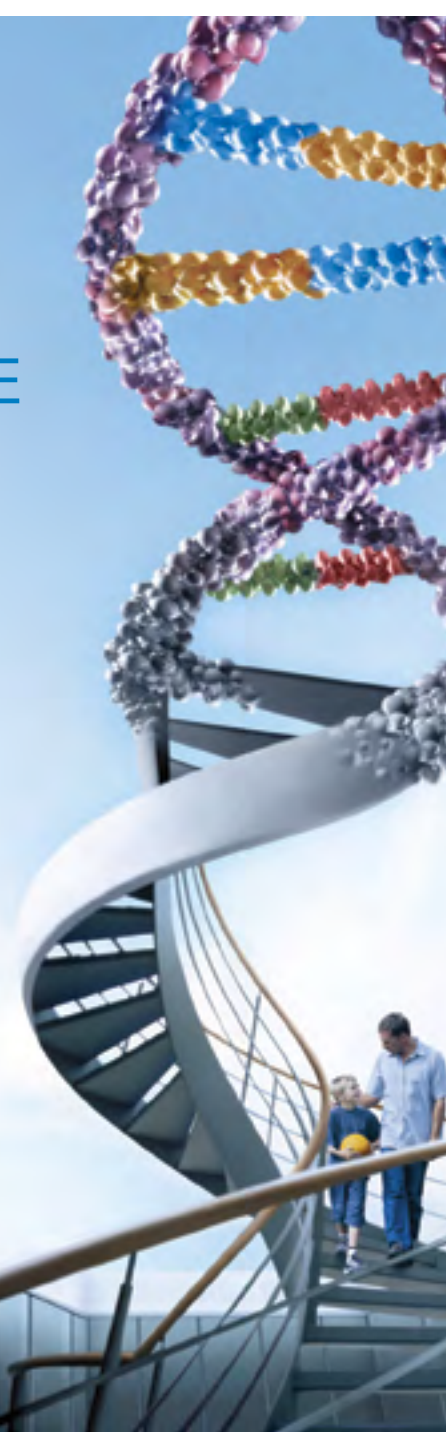


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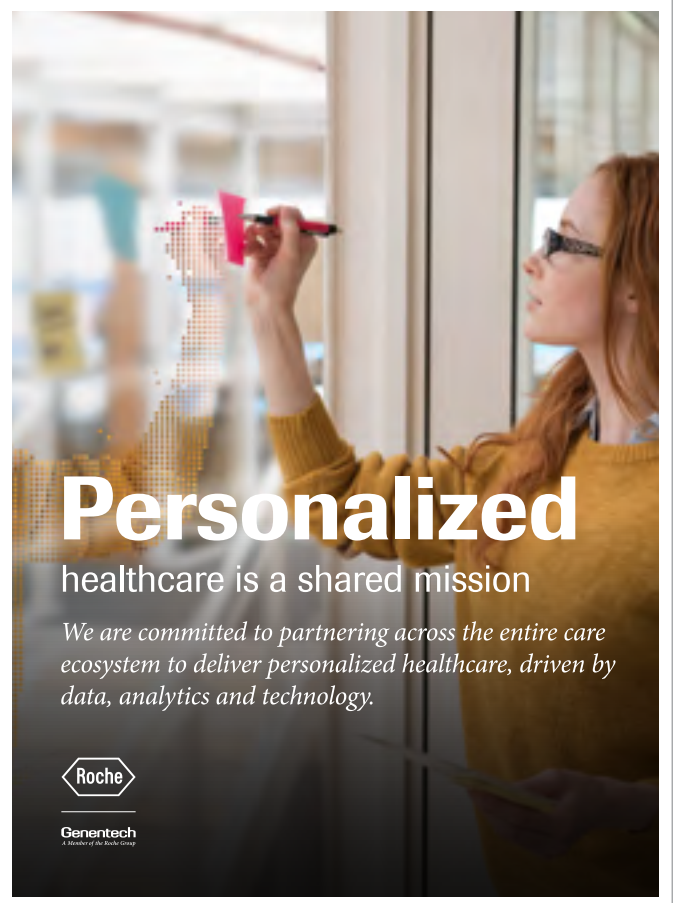
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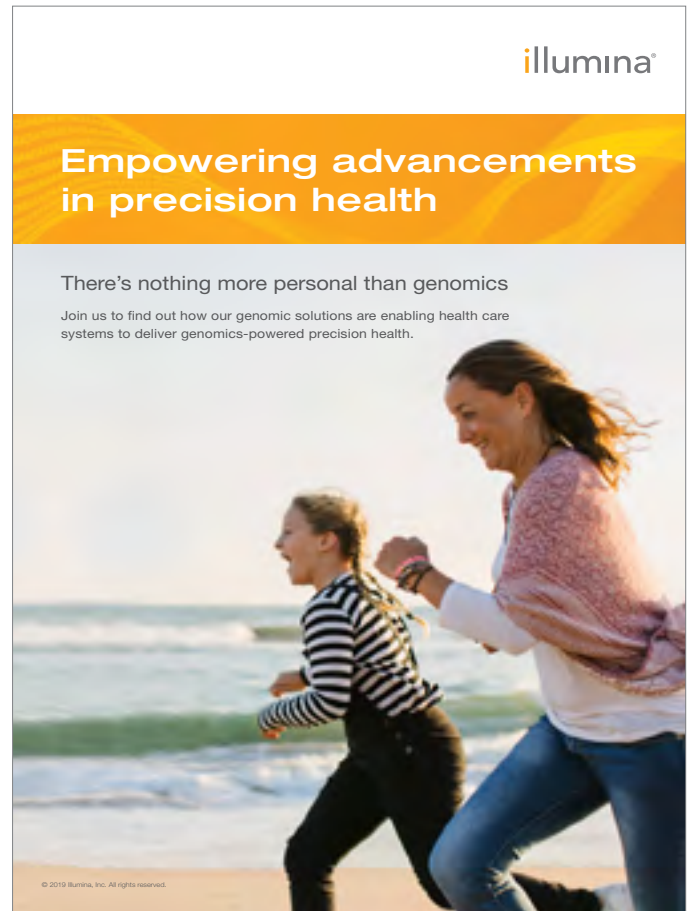
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Werner Verbiest

Strategic Partnerships and Alliances Leader, Janssen Pharmaceutical Companies of Johnson & Johnson

Jay G. Wohlgemuth, M.D.

Chief Medical Officer, Senior Vice President, Quest Diagnostics

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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 the health system.





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