NOVEMBER 15 - 17, 2016
JOSEPH B. MARTIN CONFERENCE CENTER
HARVARD MEDICAL SCHOOL

Innovative Leaders, Finding Solutions

"What we need is a national conversation of experts," Mark Levin, Partner, Third Rock Ventures, once told the audience at the Annual Personalized Medicine Conference. "Across the industry, across government, the best people in this country to come together to tell us how to maximize value for patients. That is the big challenge in our future."

The 12th Annual Personalized Medicine Conference responds to Levin's call to action with a concentrated focus on generating solutions to the field's challenges. It will showcase what is new, offer insights into the issues, and provide partnership and networking opportunities for attendees. But most importantly, it will examine the unique contributions that researchers, investors, industry representatives, policy experts, payers, health care providers and patients can make at each stage in the development of personalized medicine products and services to forge a path through the field's barriers.

The conference program, which is organized around those stages, will go beyond defining personalized medicine's challenges by, for example:

- Exploring the latest trends in research and development
- Analyzing the issues facing the diagnostic industry
- Finding commonalities in multiple definitions of "value" in health care
- Providing examples of the kinds of evidence appropriate for coverage and payment
- Examining the best practices for integrating personalized medicine into clinical settings
- Debating the circumstances that warrant the sharing of data for research

We are pleased to present the entire conference program here, which covers these and many other topics.

Sincerely yours,

Edward Abrahams, Ph.D.
President
Personalized Medicine Coalition

William S. Dalton, Ph.D., M.D.
Board Chair
Personalized Medicine Coalition

PROGRAM

DAY 1 — NOVEMBER 15, 2016

5:30 p.m. - 8:30 p.m. — Opening Reception
Hotel Commonwealth, 500 Commonwealth Avenue, Boston, MA

DAY 2 — NOVEMBER 16, 2016

7:00 a.m. Registration and Continental Breakfast
Joseph B. Martin Conference Center at Harvard Medical School
77 Avenue Louis Pasteur, Boston, MA

8:00 a.m. Opening Remarks
Edward Abrahams, Ph.D., President, Personalized Medicine Coalition

8:05 a.m. *The Personalized Medicine Report*
William S. Dalton, Ph.D., M.D., CEO, M2Gen, Chairman, Personalized Medicine Coalition

8:15 a.m. Keynote Speaker
Greg Simon, Executive Director, Cancer Moonshot Task Force

8:45 a.m. Pioneering Precision: Charting a Course for Cutting-Edge Innovations
Many scientists believe innovations in personalized medicine are poised to yield major breakthroughs in coming years, but not all members of the health care system are clear on which research topics have the most potential. The participants in this panel will identify the most encouraging scientific directions for personalized medicine and point to the most promising topics for future research.

Moderator: Stephen Eck, M.D., Ph.D., Vice President, Oncology Medical Sciences, Astellas Pharma Global Development

David Altshuler, M.D., Ph.D., Executive Vice President, Global Research and Chief Scientific Officer, Vertex

Paul Bolno, M.D., M.B.A., President and Chief Executive Officer, WAVE Life Sciences

Barbara Weber, M.D., Interim Chief Medical Officer, Neon Therapeutics

9:45 a.m. Networking Break

10:15 a.m. Money Talks: The Future of Investment in Personalized Medicine

Innovation requires investment. During this discussion, a panel of diverse investors will illuminate the most promising business opportunities for advancing personalized medicine, focusing on both macro and micro environments while also discussing the barriers to investment and potential solutions for removing them.

Moderator: Edward Winnick, Editor in Chief, *GenomeWeb*

Alexis Borisy, Partner, Third Rock Ventures

Vamil Divan, M.D., M.B.A., Senior Research Analyst, Credit Suisse

Ryan Lindquist, Director, Investment Banking, Leerink Partners

11:15 a.m. You + 999,999: How a 1 Million-Person Cohort Can Pave the Way for Personalized Care

Eric Dishman, Director, Precision Medicine Initiative Cohort Program, National Institutes of Health

12:00 p.m. Luncheon

1:15 p.m. "Precision Trials Challenge" Award

A question-and-answer session with the winner and runners up of Harvard Business School's "Precision Trials Challenge," hosted by the Kraft Precision Medicine Accelerator.

Presenter:

Robert Huckman, Ph.D., Albert J. Weatherhead III Professor of Business Administration, Harvard Business School; Faculty Co-Chair, Harvard Business School Health Care Initiative

Winner:

MatchMiner

Team Lead:

Ethan Cerami, Ph.D.
Director, Knowledge Systems Group
Department of Biostatistics and Computational Biology
Dana-Farber Cancer Institute

Runners Up:

No Patients Left Behind

Team Lead:

Gavin MacBeath, Ph.D.
Co-Founder and Senior Vice President
Merrimack Pharmaceuticals

iCare for Cancer Patients

Team Lead:

Christopher R. Cogle, M.D.
Associate Professor of Medicine
University of Florida

1:45 p.m. Keynote Speaker

Reforming Clinical Trials: How Alternative Trial Designs May Reshape Regulatory Review

Traditional clinical trial designs are often too cumbersome and expensive to study the efficacy of personalized medicine products and services in sub-populations of patients. Yet there is no consensus on which methods have the most promise to speed trials and lower costs. The participants in this panel will discuss which of the latest progressive designs are best suited to demonstrate the efficacy of personalized medicine based on past successes and proposed reforms.

Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, U.S. FDA

2:15 p.m. Keynote Speaker

Peer M. Schatz, CEO, Qiagen

2:45 p.m. Networking Break

3:15 p.m. Diagnostics Debate: Regulatory and Reimbursement Hurdles for Personalized Medicine Diagnostics

Nowhere are the regulatory and reimbursement challenges facing personalized medicine more evident than in the diagnostics industry, where the routes to market are often hampered by a lack of clarity regarding the possible changes to the regulatory pathway for laboratory-developed tests, ambiguity regarding the kinds of evidence that justify payment, and the need for large marketing budgets to sell low-cost procedures, all of which impede the development of sophisticated diagnostics with the power to transform medicine. During this panel discussion, representatives from a diverse range of diagnostics companies and a payer will identify the most promising strategies to alter the landscape to encourage the investment in personalized medicine diagnostic products, including the roles of other stakeholders such as the pharmaceutical industry and integrated health systems.

Moderator: Ronnie Andrews, Founder and Principal, The Bethesda Group

Suzanne Belinson Ph.D., M.P.H., Executive Director, Center for Clinical Effectiveness, Blue Cross Blue Shield Association

Brad Gray, CEO, NanoString

L. Patrick James, M.D., Chief Clinical Officer, Health Plans and Policy, Medical Affairs, Quest

Michael J. Pellini, M.D., CEO, Foundation Medicine Inc.

4:30 p.m. Visions of Value: Evaluating Evidence for Personalized Medicine

The fact that payers, providers, patients, industry representatives and regulators all define value differently makes it difficult for personalized medicine's champions to contribute to and communicate about the body of evidence supporting the field. Participants in this panel discussion will bring the personalized medicine community closer to an accepted definition of value by identifying common elements in multiple stakeholders' understanding of the concept.

Moderator: Susan Dentzer, President and CEO, Network for Excellence in Health Innovation

Peter B. Bach, M.D., M.A.P.P., Director, Center for Health Policy and Outcomes, Memorial Sloan Kettering Cancer Center

Donna Cryer, J.D., President and CEO, Global Liver Institute

Lori Reilly, J.D., Executive Vice President, Policy & Research, PhRMA

Michael Sherman, M.D., M.B.A., M.S. SVP, Chief Medical Officer, Harvard Pilgrim HealthCare

5:30 p.m. Elements Café Cocktail Reception

DAY 3 — NOVEMBER 17, 2016

7:00 a.m. Registration and Continental Breakfast

8:00 a.m. Opening Remarks
Edward Abrahams, Ph.D., President, Personalized Medicine Coalition

8:15 a.m. Fireside Chat
Moderator: Meg Tirrell, Reporter, CNBC
Daniel O'Day, COO, Pharmaceuticals Division, Roche

8:45 a.m. Coverage is King: Identifying the Evidence That Leads to Reimbursement
Many innovators in personalized medicine are unclear on the kinds of evidence that inform the coverage and payment decisions of payers. That lack of clarity can have negative financial consequences for personalized medicine companies with products and services that are on the market but not paid for. During this panel, payer representatives will help define the reimbursement landscape for the field by providing examples of the evidence they consider appropriate for coverage and payment.

Moderator: Amy M. Miller, Ph.D., Executive Vice President, Personalized Medicine Coalition

Kristine Bordenave, M.D., Lead Medical Director, Humana

Matthew Fontana, M.D., Vice President and Chief Medical Officer, Pharmacy, Health Care Service Corporation

Elaine Jeter, M.D., MolDx Medical Director, Palmetto GBA

9:45 a.m. Networking Break

10:15 a.m. HBS Case Presentation
Leader: Richard Hamermesh, D.B.A., Senior Fellow and Former MBA Class of 1961, Professor of Management Practice, Harvard Business School

DNA-editing technologies have been hailed as revolutionary with the possibility to edit out mutations that cause disease. Yet the CRISPR-Cas system is currently locked in a legal dispute between two great research institutions involving, as one journalist put it, "who own molecular biology." The CRISPR technology in short raises the broader issue of whether these new techniques should be privately owned or placed in the public domain. The technology also raises serious ethical issues. The case study will serve as the point of departure for our discussion of these issues.

11:15 a.m. Keynote Speaker
Introduction: William Chin, M.D., Chief Medical Officer, Executive Vice President, PhRMA
Keynote: Victor Dzau, M.D., President, National Academy of Medicine

11:45 a.m. Bag Lunch

12:45 p.m. Personalizing Care: Strategies for Integrating Personalized Medicine into Health Care

Personalized medicine lacks sufficient literature on how health care providers can integrate personalized medicine into clinical care, which makes it difficult for providers to take advantage of the growing number of personalized medicine products and services now available to them. During this session, panelists who have spearheaded integration efforts will share the strategies they found most useful for speeding the pace of personalized medicine's adoption in clinical settings.

Moderator: Howard McLeod, Pharm.D., Medical Director, DeBartolo Family Personalized Medicine Institute, Moffitt Cancer Center

Amy Abernethy, M.D., Ph.D., Chief Medical Officer, Chief Scientific Officer, Senior Vice President, Oncology, Flatiron Health

Dax Kurbegov, M.D., Physician Vice President, National Oncology Service Line, Catholic Health Initiatives

Lincoln Nadauld, M.D., Ph.D., Executive Director of Precision Genomics, Intermountain Healthcare

Peter H. O'Donnell, M.D., Assistant Professor of Medicine and Associate Director for Clinical Implementation, Center for Personalized Therapeutics, The University of Chicago

1:45 p.m. Leadership in Personalized Medicine Award

Presenter: William S. Dalton, Ph.D., M.D., CEO, M2Gen, Chairman, Personalized Medicine Coalition
Recipient: Raju Kucherlapati, Ph.D., Paul C. Cabot Professor of Genetics, Harvard Medical School

2:15 p.m. Networking Break

2:45 p.m. The Data Dilemma: Fulfilling Expectations of Big Data in the Future of Personalized Medicine

There is consensus that the massive amounts of genomic, clinical, claims and other types of data could yield important insights for research and clinical care. But for years, obstacles around technical standards, interoperability, privacy and confidentiality, data security, and consent have been held up as daunting challenges that inevitably slowed progress. During this discussion, a panel of academic and industry experts will discuss their respective organizations' strategies to obtain and analyze the data, including what has worked and what has not; the programs and processes that have led to the most productive data usage; examples of important knowledge that has been derived from data analysis; and the infrastructure they believe is needed to achieve fulfillment of the potential of big data in personalized medicine nationwide.

Moderator: Marcia A. Kean, M.B.A., Chairman, Strategic Initiatives, Feinstein Kean Healthcare

Paul Bleicher, M.D., Ph.D., CEO, OptumLabs

Kathy Giusti, J.D., Founder, Multiple Myeloma Research Foundation, and Multiple Myeloma Research Consortium

Kris Joshi, Ph.D., Executive Vice President, Products, Change Healthcare

Christophe G. Lambert, Ph.D., Associate Professor, Center for Global Health, Division of Translational Informatics, Department of Internal Medicine, University of New Mexico

Adam Margolin, Ph.D., Director, Computational Biology, Oregon Health & Science University School of Medicine

3:45 p.m. Keynote Speaker: “Medicine and the Targeted Marketing Problem”
Anthony Philippakis, M.D., Ph.D., Chief Data Officer, Broad Institute and Partner, GV

4:30 p.m. Closing Remarks
Edward Abrahams, Ph.D., President, Personalized Medicine Coalition

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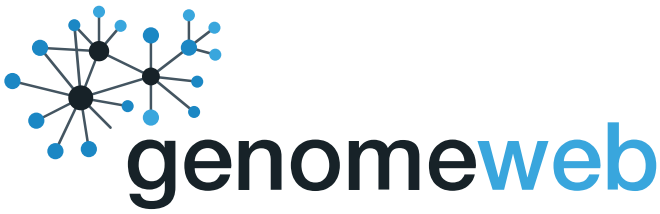
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