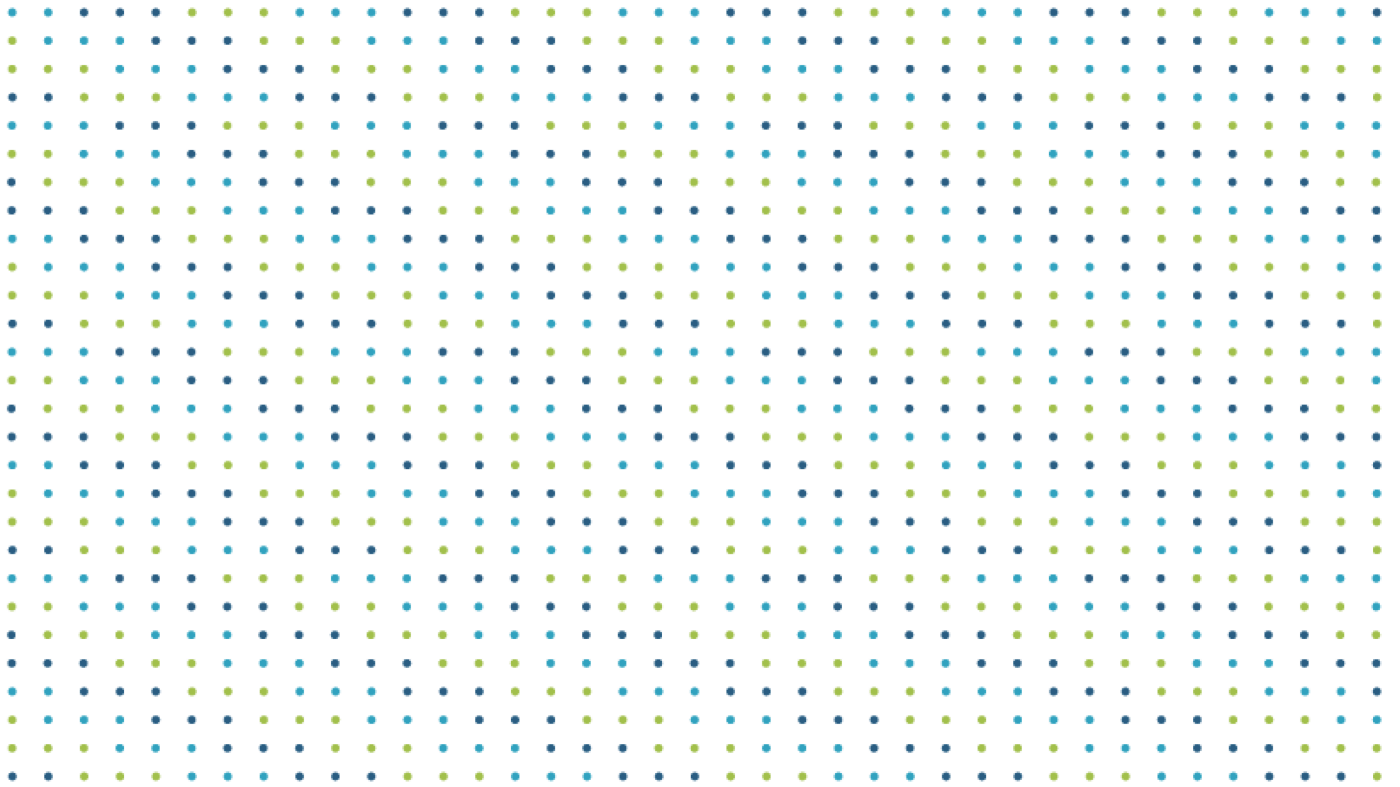




CONFERENCE PROGRAM

From Concept to the Clinic

November 14 – 16, 2017

Joseph B. Martin Conference Center, Harvard Medical School
77 Avenue Louis Pasteur, Boston, MA 02115

13TH ANNUAL

○ ○ ○ **PERSONALIZED**
● ● ● **MEDICINE**
● ● ● **CONFERENCE**

President and Chairman's Message

Dear Colleague:

“The standard of care is just not good enough,” Michael Pellini, M.D., Chairman, Board of Directors, Foundation Medicine, told the audience at the 12th Annual Personalized Medicine Conference. It is time, Pellini said, to think about the space differently.

Guided by that premise, the 13th Annual Personalized Medicine Conference will facilitate dialogue focused on translating the concept of personalized medicine into improved clinical care. Participants will engage with thought leaders and health professionals from the front lines to explore, among other subjects, how an under-studied value proposition, information technology challenges and practical obstacles at the point of care complicate efforts to bring personalized medicine to patients — and how emerging partnership models, economic utility studies and real-world evidence may help to eliminate these impediments. The agenda includes:

- An exploration of the implications of CRISPR-Cas9 and gene therapy for medicine and humanity
- A fireside chat with a pharmaceutical industry representative on the pricing of personalized medicines
- A discussion of case studies on the economic value of personalized medicine
- Detailed clinical insights from patients, providers and payers

I hope you will join your colleagues from the industry, policy, payer, clinician and patient communities to help us chart a course for the future of personalized medicine by participating in the program, which will explore the evolution of personalized medicine “From Concept to the Clinic.”

Sincerely yours,



Edward Abrahams, Ph.D.

President

Personalized Medicine Coalition

PART I



“It’s not really ‘should we do this.’ We have to do this. We don’t get to decide what the biology of these diseases are, we just have to work with it.”

Barbara Weber, M.D.

Venture Partner, Third Rock Ventures

Following an opening cocktail reception on November 14, the personalized medicine community will begin the conference on November 15 by analyzing how the most significant trends in health care may affect the field — and vice versa. Participants will examine, among other topics, the significance of the emerging conversation on pharmaceutical pricing, the implications of CRISPR-Cas9 and gene editing technologies to the future of medicine and humanity, and the importance of ensuring that value assessment frameworks have mechanisms in place to account for the value of targeting therapies to only those patients who will benefit.

PERSONALIZED MEDICINE

FROM CONCEPT TO THE CLINIC

DAY 1 — NOVEMBER 14, 2017

5:30 p.m. – 8:30 p.m. — Opening Reception

Hotel Commonwealth, 500 Commonwealth Avenue, Boston, MA

DAY 2 — NOVEMBER 15, 2017

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

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

8:15 a.m. — *The State of Personalized Medicine*

INTRODUCTION | Steven D. Averbuch, M.D., Vice President, Oncology, Pharmacodiagnostics, Bristol-Myers Squibb

KEYNOTE | Thomas J. Lynch, Jr., M.D., Executive Vice President, Chief Scientific Officer, R & D, Bristol-Myers Squibb

8:45 a.m. — Presentation of the 13th Annual Leadership in Personalized Medicine Award

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

AWARDEE | Jay T. Flatley, Executive Chairman, Illumina

9:15 a.m. — Networking Break

DAY 2 (CONT.)

9:45 a.m. — *Progress in Partnerships: Evaluating the Impact of Emerging Models for Cross-Sector Collaboration*

Aligning the constructs of the health system with the principles of personalized medicine will require stakeholders to scale the most promising cross-sector partnership models. This series of fireside chats will examine the potential of two such models.

PART 1 | *A Model for Risk-Sharing Agreements Between Payers and the Pharmaceutical Industry*

Many payers are reluctant to assume that covering personalized medicines will help mitigate costs associated with catastrophic medical events that require hospitalization. During this fireside chat, representatives from Amgen and Harvard Pilgrim Health Care will discuss the logic and implications of their groundbreaking agreement to share the financial risks of covering a targeted medicine based on that premise. Under the terms of the agreement, Amgen agreed to cover treatment costs for patients who have a heart attack or stroke while taking its personalized therapy for familial hypercholesterolemia.

A FIRESIDE CHAT FEATURING

- **Moderator:** Meg Tirrell, Reporter, CNBC
- Joshua Ofman, M.D., M.S.H.S., Senior Vice President, Global Value, Access & Policy, Amgen Inc. (invited)
- Michael Sherman, M.D., M.B.A., M.S., Senior Vice President, Chief Medical Officer, Harvard Pilgrim Health Care

DAY 2 (CONT.)

PART 2 | *Identifying the Right Patient for the Right Therapy Using a Universal Companion Diagnostic Test*

A FIRESIDE CHAT FEATURING

- **Moderator:** Alexander Vadas, Ph.D., Managing Director, L.E.K. Consulting
- Hakan Sakul, Ph.D., Vice President, Head of Diagnostics, Genome Sciences & Technologies, Worldwide R & D, Pfizer
- Anne-Marie Martin, Ph.D., Senior Vice President, Global Head of Precision Medicine, Novartis (invited)
- Joydeep Goswami, Ph.D., President, Clinical Next-Generation Sequencing and Oncology, Thermo Fisher Scientific

10:45 a.m. — *Real-World Personalized Medicine: Examining the Role of Real-World Evidence in Personalizing Health Care*

FDA has offered a definition of real-world evidence, but the community continues to debate what is needed to fully integrate it into decision-making. This session will explore what real-world evidence is, how it is being used and what regulatory requirements are needed to realize its potential.

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

- Sean Khozin, M.D., M.P.H., Associate Director (Acting), Oncology Center of Excellence, FDA
- Eric G. Klein, Pharm.D., Senior Director, Oncology, Global Patient Outcomes and Real World Evidence, Eli Lilly and Company
- Maria Koehler, M.D., Ph.D., Vice President, Oncology Strategy, Innovation and Collaborations, Pfizer Oncology
- Deborah Schrag, M.D., M.P.H., Chief, Division of Population Sciences, Medical Oncology, Dana-Farber Cancer Institute

12:00 p.m. — Luncheon

DAY 2 (CONT.)

1:00 p.m. — *The Designer Genome: Exploring the Implications of CRISPR-Cas9 and Gene Editing for the Future of Medicine and Humanity*

Many scientists believe the regularly interspaced short palindromic repeats (CRISPR-Cas9) genetic engineering tool and recent developments in gene therapy will dramatically alter the trajectory of medicine, but the implications of these developments for health systems around the world remain unclear. During this session, a panel of experts will discuss the status of these new technologies — and how the medical community and regulatory agencies may have to adapt to keep up with forthcoming developments.

MODERATOR | Kevin Davies, Ph.D., author, *The \$1,000 Genome*

- Katrine Bosley, CEO, Editas
- Arthur L. Caplan, Ph.D., Drs. William F. and Virginia Connolly Mitty Chair; Director, Division of Medical Ethics, New York University Langone Medical Center
- George Church, Ph.D., Professor of Genetics, Health Sciences, Technology, Harvard and MIT; Director of HMS NHGRI-Center of Excellence in Genomic Science; Director of the Personal Genome Project, Broad Institute & Wyss Harvard Institute of Biologically Inspired Engineering Harvard Medical School

2:15 p.m. — *Pricing Personalized Medicines*

The increasing pressure on industry stakeholders to alter their drug pricing practices has particular significance for personalized medicines, which must recoup research and development costs from smaller patient populations. This conversation will explore the pharmaceutical industry's strategies for facilitating patient access to these therapies.

A FIRESIDE CHAT FEATURING

- **Moderator:** Meg Tirrell, M.S.J., Reporter, CNBC
- Stephen J. Uhl, President, CEO, PhRMA

2:45 p.m. — Networking Break

DAY 2 (CONT.)

3:15 p.m. — *Precision Valuation: A Discussion of How Value Assessment Frameworks Can Account for Personalized Medicine*

Payers control access to personalized medicine, and some have begun to take an interest in findings from value assessment frameworks that are challenged to account for scientific developments in the field. In addition to exploring their potential impact on individualized care, this session will examine how value assessment frameworks can and should consider personalized medicine as part of their processes for evaluating therapeutic options.

MODERATOR | Jennifer Snow, M.P.H., Director, Health Policy, Xcenda

- Robert Dubois, M.D., Ph.D., Chief Science Officer, Executive Vice President, National Pharmaceutical Council
- Steven Pearson, M.D., M.Sc., Founder, President, Institute for Clinical and Economic Review (ICER)
- Andrea Ferris, M.B.A., President, Chairman, LUNgevity

DAY 2 (CONT.)

4:30 p.m. — *The Utility Proposition: An Analysis of Case Studies in the Economic Value of Personalized Medicine*

Although personalized medicine's proponents contend that the field can deliver economic value by helping doctors avoid prescribing costly but ineffective therapies, the field lacks literature testing that hypothesis. This session will highlight recent studies on the clinical and economic value of personalized medicine, shedding light on what we know about personalized medicine's clinical and economic utility — and what we don't.

MODERATOR | Invitation pending

- Lincoln Nadauld, M.D., Ph.D., Executive Director, Precision Medicine and Precision Genomics, Intermountain Healthcare
- Scott Ramsey, M.D., Ph.D., Director, Fred Hutchinson Institute for Cancer Outcomes Research
- David Roth, M.D., Ph.D., Director, Penn Center for Precision Medicine

5:45 p.m. — Elements Café Cocktail Reception

PART II



"[We're] not talking about something that may happen someday. [We're] talking about what's happening now."

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

The community will turn its attention to the best strategies for integrating personalized medicine in clinical settings on November 16. In addition to exploring the implications of clinical insights from representatives at pioneering health care providers around the country, participants will consider novel perspectives from patients and providers as they share their thoughts on existing and forthcoming technologies. Representatives of the Trump administration have also been invited to deliver keynote addresses on the third day of the conference.

DAY 3 — NOVEMBER 16, 2017

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

SPEAKER | Stephen L. Eck, M.D., Ph.D., President, CEO, Aravive Biologics; Chairman, Board of Directors, PMC

8:10 a.m. — *The Next Frontier: Clinical Adoption of Personalized Medicine*

Pioneering health care providers have begun to explore the business models, operational processes, IT infrastructure and educational programs that are needed to catalyze the paradigm shift toward personalized medicine. This two-part session on clinical adoption will examine the strategic and day-to-day challenges clinical organizations face as they seek to integrate personalized medicine in clinical settings — and the solutions they employ to address those challenges.

SESSION CHAIR | Marcia A. Kean, M.B.A., Chairman, Strategic Initiatives, Feinstein Kean Healthcare

PART 1 | *The Case for Personalized Medicine in the Clinic: The View From the Corner Office*

Inspiring an organizational commitment to a new way of practicing medicine requires visionary leadership. This fireside chat will highlight the viewpoints and approaches of leaders who are spearheading efforts to adopt personalized medicine at clinical institutions, with an eye on the value proposition for changing existing norms and practices.

- **Moderator:** Howard McLeod, Pharm.D., Medical Director, DeBartolo Family Personalized Medicine Institute, Moffitt Cancer Center
- Ronald A. Paulus, M.D., President and CEO, Mission Health
- Jeffrey R. Balser, M.D., Ph.D., Dean of Vanderbilt University School of Medicine, President and CEO, Vanderbilt University Medical Center

DAY 3 (CONT.)

PART 2 | *Practicing Personalized Medicine: Lessons From the Front Lines*

To successfully integrate personalized medicine into a health system, administrators and clinicians must also design and implement new processes related to program infrastructure and informatics; help educate physicians and patients about the field; and inspire cultural change within the institution. During this panel discussion, a group of early adopters will share lessons learned from implementing pilot programs across the United States.

- **Moderator:** Daryl Pritchard, Ph.D., Vice President, Science Policy, Personalized Medicine Coalition
- Peter Hulick, M.D., M.M.Sc., Medical Director, Center for Personalized Medicine, NorthShore University HealthSystem
- Scott A. Beck, M.B.A., Administrator, Center for Individualized Medicine, Mayo Clinic
- Timothy Cannon, M.D., Clinical Director, Molecular Tumor Board, Inova Schar Cancer Institute
- Marc S. Williams, M.D., Director, Genomic Medicine Institute, Geisinger

10:45 a.m. — Networking Break

11:15 a.m. — Harvard Business School Case Study — *Intermountain Healthcare: Pursuing Precision Medicine*

PRESENTER | Richard Hamermesh, D.B.A., Senior Fellow, Former MBA Class of 1961, Professor of Management Practice, Harvard Business School

Intermountain has a long history of being at the forefront of health care quality improvement and the development of treatment protocols. In 2013, Intermountain Precision Genomics (IPG) was started with Dr. Lincoln Nadauld as its Executive Director. IPG focused on stage 4 cancer patients and performed three distinct functions: genomic sequencing, interpretation of sequencing results with recommendations for precision therapies, and drug acquisition and reimbursement. A paper published in February 2017 reported that in addition to having a higher quality of life, patients who received the targeted therapies had progression-free survival rates of almost twice as long as other patients. The purpose of our case discussion will be to assess these efforts, to consider their broader applicability and to review IPG's plans for the future.

DAY 3 (CONT.)

12:15 p.m. — *The Trump Administration and Personalized Medicine*

KEYNOTE | Invitation pending

12:45 p.m. — Bag Lunch

1:45 p.m. — *Personalized Medicine at FDA: An Inside Look at the Agency's Priorities for the Field*

KEYNOTE | Richard Pazdur, M.D., Director, Oncology Center of Excellence, FDA (invited)

2:15 p.m. — *The Patient Perspective on Personalized Medicine*

KEYNOTE | Bryce Olson, Global Marketing Director, Health and Life Sciences Group, Intel Corporation

2:45 p.m. — *The Direct-to-Consumer Testing Debate: Quantified Self or Over-Medicalization?*

Many observers speculate that the coming wave of direct-to-consumer genetic tests and the personalized use of wearables will change the psychology, sociology, economy and efficacy of health care. This session will examine the merits and implications of that evolving paradigm shift.

MODERATOR | Robert C. Green, M.D., M.P.H., Director, G2P Research Program, Associate Director for Research, Partners Personalized Medicine, Division of Genetics, Department of Medicine, Brigham and Women's Hospital, Broad Institute and Harvard Medical School

- Sandro Galea, M.D., Dr.P.H., Dean, Boston University School of Public Health (invited)
- Jessica Mega, M.D., M.P.H., Chief Medical Officer, Verily (invited)
- Michael Snyder, Ph.D., Stanford W. Ascherman Professor and Chair, Department of Genetics, Director, Center for Genomics and Personalized Medicine, Stanford University School of Medicine (invited)

3:30 p.m. — Closing Remarks

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

Thank You to Our Sponsors

Sponsorship opportunities for the 13th Annual Personalized Medicine Conference are available. Please contact Mary Bordini, Director, Membership & Development, at mbordini@personalizedmedicinecoalition.org for details.

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