



# Progress Report

2016

---

## INTRODUCTION

Since its founding, PMC has organized all stakeholders in personalized medicine to support the science, policy and business of the field through a diverse group of educational and advocacy activities. As a result, personalized medicine and PMC have grown in import and impact.

While maintaining leadership in education and advocacy as referenced below, PMC expanded its influence in 2016 by assuming responsibility for the Personalized Medicine Conference at Harvard Medical School, which has allowed the organization to broadcast its agenda to an exceptionally broad and sophisticated group of leaders in health care.

## EDUCATION

- 1. PMC defined the science, business and policy challenges facing the field by organizing the 12<sup>th</sup> Annual State of Personalized Medicine Luncheon Address, delivered by Stephen J. Ubl, President, CEO, PhRMA.**
  - 150+ people attended the event
  - As a result of the conversation, news stories in outlets including *Politico* and *Bloomberg* highlighted the personalized medicine implications of topics like Medicare's proposed Part B demonstration and the Institute for Clinical and Economic Review's value assessments
- 2. PMC organized a comprehensive discussion of the science, business and policy challenges facing the field at the 12<sup>th</sup> Annual Personalized Medicine Conference.**
  - 400+ people attended the event, which had broad media coverage
  - Speakers included C-suite executives, members of the media and leading investors
  - Four government officials shared their thoughts on the coming year as attendees considered the landscape for personalized medicine in a new era
  - Six payers on the program revealed a new interest in and commitment to personalized medicine
- 3. PMC directed ongoing discussions about personalized medicine by defining developments in the field.**
  - The Coalition's analysis of FDA's 2015 personalized medicine approvals was widely cited by several publications, including *GenomeWeb*

- An essay in *The Journal of Precision Medicine* titled “Towards Targeted Therapeutics: The Pharmaceutical Industry and Personalized Medicine” by Edward Abrahams and Stephen Eck documented the industry’s commitment to personalized medicine
- Eight regularly occurring essays by PMC authors in *Personalized Medicine in Oncology* highlighted and analyzed the most significant challenges facing the field
- “The Impact of Alternative Payment Models on Oncology Innovation and Patient Care” in *Clinical Cancer Research*, co-authored by PMC and the other co-conveners of the Turning the Tide Against Cancer Initiative, drew attention to the personalized medicine implications of alternative payment models
- An essay titled “Patient and Provider Readiness for Personalized Medicine,” based in part on PMC-commissioned research, published in *Personalized Medicine in Oncology* by PMC’s Amy M. Miller, Ph.D., and a team of member authors, discussed the landscape for personalized medicine education
- Two editions of PMC’s newsletter, *Personalized Medicine in Brief*, as well as regular email updates reviewed the latest developments in the field and summarized relevant news coverage

**4. PMC discussed developments in both science and public policy with its members during five policy committee meetings.**

- These meetings featured leaders from FDA, the White House and member organizations as well as panels on coding and value assessment
- The meetings set the agenda for the personalized medicine community, regularly bringing together more than 100 of the field’s leaders

**5. PMC proposed ideas on how personalized medicine might be advanced through participation in member and non-member events.**

- PMC co-organized and co-hosted with the Biotechnology Innovation Organization (BIO) the *BIO/PMC Track on Personalized Medicine and Diagnostics* at the 2016 BIO International Convention
  - The event included two networking receptions and seven sessions
- PMC increased its international presence through keynote, moderator and panel speaking engagements held in the United States, Germany, Spain and Canada

**6. PMC continued to grow the reach of its digital communication tools.**

- 18 blogs published by PMC staff members and external thought leaders on *Education & Advocacy*
  - Blogs were cited by outlets including *Medscape* and *The Gray Sheet*
- 100%+ increase in @permedcoalition followers (now totaling 600+)

**7. PMC spearheaded a comprehensive effort to understand the best practices to integrate personalized medicine into health care.**

- Convened the Health Care Working Group to produce guidelines for implementing personalized medicine in a manuscript titled “Strategies for Integrating Personalized Medicine into Health Care Practice,” which has been accepted for publication in *Personalized Medicine*
- Conducted interviews with key personnel at health care systems nationwide to inform a forthcoming case studies report

**8. PMC helped keep personalized medicine on the health care agenda by securing 125+ media mentions.**

- PMC's efforts shaped the arc for many media stories, including some published in *The Boston Globe*, *Bloomberg*, *STAT News* and *GenomeWeb*

## ADVOCACY

**9. PMC promoted public policies that encourage investment in personalized approaches to care via meetings with and letters to White House staffers.**

- Discussed the future of the field with staffers and other stakeholders during White House events on personalized medicine, including the Precision Medicine Initiative Summit and the "Frontiers Conference" in Pittsburgh
- Submitted comments to Vice President Joe Biden in response to the Cancer Moonshot Task Force's request for information from the personalized medicine community
- Regularly provided comments on the importance of innovation in personalized medicine to media outlets including *Politico* and *STAT News*

**10. PMC promoted regulatory reforms to accelerate the development of personalized medicine products by convening stakeholders to agree on various policy positions.**

- Developed PMC's position on regulating next-generation sequencing by publishing public comments on the FDA's draft guidance documents for oversight of next-generation sequencing and the use of public human genetic variant databases to support clinical validity
- Contributed to the development of a clear and efficient regulatory pathway for companion and complementary diagnostic products by publishing public comments on the codevelopment of laboratory-developed tests
- Led an effort to forge a consensus framework for regulating laboratory-developed tests in coordination with the American Medical Association, which led to FDA acknowledging principles for regulation and asking PMC for venues to engage the community

**11. PMC defined how personalized medicine can be enhanced through reimbursement policies.**

- Engaged CMS in support of policies that encourage coverage and payment of personalized medicine by publishing public comments on its Medicare Part B Drug Payment Model and its preliminary gapfill determinations for multianalyte assays with algorithmic analyses and genomic sequencing
- Contributed to the national dialog on value assessment frameworks by inviting an Institute for Clinical and Economic Review (ICER) representative to a PMC policy committee meeting and engaging press outlets including *STAT News* and *GenomeWeb*
- Successfully negotiated for changes to ICER's process by submitting comments on ICER's Value Assessment Framework and Non-Small Cell Lung Cancer Scoping Document
- Leveraged the 12<sup>th</sup> Annual Personalized Medicine Conference to establish relationships with private payers, including Harvard Pilgrim HealthCare, Blue Cross Blue Shield and Humana

## SPONSORED INITIATIVE

This year, the Coalition also funded and launched the "Clinical and Economic Value of Next-Generation Sequencing" research project.

### **The Clinical and Economic Value of Next-Generation Sequencing: A Research Project**

The Clinical and Economic Value of Next-Generation Sequencing (NGS) research project will examine the value of NGS technologies to both patients and the health system. Partner organization(s) will provide funding and expertise to help develop an impactful, evidence-based research program. In 2016, PMC formed an advisory committee, contracted a health economist as lead researcher and secured 100% of its preliminary sponsorship goal.

## **SPONSORSHIP OPPORTUNITY**

The Coalition also positioned itself to launch the Personalized Medicine Education Initiative in 2017.

### **The Personalized Medicine Education Initiative**

Through the Education Initiative, PMC will develop a carefully curated, leading personalized medicine resource that can be updated in real time. Partner organizations will provide funding and/or expertise in selecting and developing appropriate content for online publication. In 2016, the Coalition published a proof of concept on its website, formed content partnerships with the Mayo Clinic, Boehringer Ingelheim and NextGxDx, and raised initial sponsorship revenue from Boehringer Ingelheim.