



Strategic Plan

2017

INTRODUCTION

For the last dozen years, PMC has worked to create a friendlier landscape for investment in and adoption of personalized medicine. Personalized medicines now account for a significant component of all new drugs that enter the market each year. Hospital systems now label themselves as “personalized medicine centers” and investments in many areas of personalized medicine have never been greater. Maintaining progress in a changing environment, however, requires a sustained effort. To ensure that past momentum is maintained, PMC has outlined a comprehensive strategic plan for the coming year that runs along the entire spectrum of health care from research and development to the delivery of personalized medicine products.

The change of administration in Washington provides an important opportunity to educate new policymakers on the role that personalized medicine plays in health care.

2017 OBJECTIVES

Guided by an analysis of the personalized medicine landscape and the PMC board-identified priorities in education and advocacy, PMC has 10 objectives for 2017.

EDUCATION

- 1. PMC will define the science, business and policy challenges facing the field by organizing the 13th Annual State of Personalized Medicine Luncheon Address:**
 - The event will feature a keynote address by a leader in science, policy and/or business who will share a vision for the future of the field
 - 150+ attend annually
 - Past keynote speakers include PhRMA President & CEO Stephen J. Ubl, U.S. Congressman Michael C. Burgess, M.D., and CMS Deputy Administrator for Innovation and Quality Patrick Conway, M.D.
- 2. PMC will organize comprehensive discussions of the science, business and policy challenges facing the field at the 13th Annual Personalized Medicine Conference. The event will:**
 - Attract leading speakers and a sophisticated audience
 - Be considered a “must-attend” for those interested in personalized medicine
 - Include premier networking events
- 3. PMC will contribute thought leadership and help define the field by:**
 - Publishing a summary and analysis of the 12th Annual Personalized Medicine Conference
 - Publishing an analysis of FDA’s 2016 personalized medicine approvals

- Publishing a retitled and rebranded version of PMC’s signature document, *The Personalized Medicine Report*
 - Publishing an annual report to update the community on progress in the field and PMC’s efforts to facilitate that progress
 - Publishing, on PMC’s website, updated appendices that list personalized medicine therapeutic products and diagnostic tests
 - Publishing a white paper about how value-assessment programs could and should reflect the rapidly evolving science and clinical practice of personalized medicine
 - Writing and producing PMC’s publications, including the bi-annual newsletter, *Personalized Medicine in Brief*, and the monthly *Member Update*
 - Publishing a monthly column, “The Last Word,” in *Personalized Medicine in Oncology*
 - Writing, inviting and publishing timely thought leadership pieces that call attention to issues facing the field and opportunities to address them on PMC’s blog *Education & Advocacy*
- 4. PMC will review developments in both science and public policy with its members during a series of policy committee meetings.**
- Meetings will feature key policymakers in personalized medicine. 2016 speakers included FDA Deputy Office Director, Personalized Medicine and Molecular Diagnostics Elizabeth Mansfield, Ph.D., ICER Director, Health Economics Rick Chapman, Ph.D., and White House Project Manager, Precision Medicine Initiative Stephanie Devaney, Ph.D.
 - These meetings will help drive PMC’s 2017 advocacy agenda
- 5. PMC will offer thoughts on how personalized medicine might be advanced through participation in member and non-member events.**
- PMC will co-organize and co-host with the Biotechnology Innovation Organization (BIO) the *BIO/PMC Track on Personalized Medicine and Diagnostics* at the BIO International Convention
 - PMC will organize a seminar on the science, business and policy issues underpinning personalized medicine at the Tri-Molecular Conference on Personalized Medicine in San Francisco
 - PMC will partner with the American Association of Cancer Research and Feinstein Kean Healthcare through the Turning The Tide Against Cancer Initiative to produce a national conference educating new policymakers on the state of personalized cancer care
- 6. PMC will keep personalized medicine on the health care agenda by securing regular media mentions.**
- PMC will continue to pitch personalized medicine stories and provide interviews, quotes and background materials to trade and mainstream press
- 7. PMC will spearhead comprehensive efforts to understand the best practices for integrating personalized medicine into health care by:**
- Publishing the results of its Health Care Working Group’s efforts to outline solutions for integrating personalized medicine into health care systems
 - Demonstrating how personalized medicine can be integrated into practice by publishing a series of case studies on the topic
 - Presenting key themes from PMC’s work on the topic at relevant conferences and meetings

ADVOCACY

- 8. PMC will promote public policies that encourage investment in personalized approaches to care by:**
- Educating a new administration and Congress on the state of personalized medicine and the implications that policies can have on the field
 - Encouraging Congressional leaders to ensure that pharmaceutical and medical device legislation encourages innovation and investment in personalized medicine as well as creates value for patients and the health care system

9. PMC will promote regulatory reforms that accelerate the development of personalized medicine products by:

- Helping to develop a clear and efficient regulatory pathway for companion and complementary diagnostic products and a new regulatory process based on curated databases for next-generation sequencing products

10. PMC will define how personalized medicine can be enhanced through reimbursement policies by:

- Engaging CMS to support policies that encourage coverage and payment of personalized medicine technologies and approaches
- Working with private payers to advance policies supportive of personalized medicine
- Advocating for the consideration and inclusion of personalized medicine principles in value assessment frameworks

SPECIAL INITIATIVES

PMC has also identified four projects that could be undertaken with additional resources. They include:

- 1. The Clinical and Economic Value of Next-Generation Sequencing: A Research Project (funded)**
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. In consultation with payers to ensure the significance of the findings, partner organization(s) will provide funding and expertise to help develop an impactful, evidence-based research program.
- 2. The Personalized Medicine Education Initiative (funding pending)**
Through its Education Initiative, PMC plans to build a platform of digital communication tools through which it can advance strategic communications efforts in partnership with its members. The tools, which will include a standalone website, branded slide decks and shareable infographics, will permit PMC to become the go-to source for raising awareness of personalized medicine.
- 3. *Advancing Access to Personalized Medicine: A Comparative Assessment of International Regulatory, Reimbursement and Health Technology Systems* (funding pending)**
The white paper titled *Advancing Access to Personalized Medicine: A Comparative Assessment of International Regulatory, Reimbursement and Health Technology Systems* will establish a ranking system to facilitate the understanding of how regulation, reimbursement and technology assessment policies impact the adoption of personalized medicine around the world.
- 4. Evidence for Coverage and Payment of Personalized Medicine Diagnostics (funding pending)**
By convening an expert working group of payers, diagnostic company representatives, patients and providers, PMC will seek to define and agree on the types and levels of evidence that are reasonably necessary for coverage and adequate payment of personalized medicine diagnostics.