MISSION

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. Believing that paradigm shifts, especially in medicine, do not happen just because the science and new technologies suggest they should, PMC supports investment in and adoption of personalized medicine by addressing barriers in areas including but not limited to regulation, reimbursement and clinical adoption.

PRIORITIES

Guided by an analysis of the personalized medicine landscape, PMC has identified 10 priorities for 2018:

1. **A Congressional Personalized Medicine Caucus**

   To establish an organizing body for the advancement of personalized medicine priorities in the U.S. Congress, PMC will lead the creation of a Congressional Personalized Medicine Caucus. The Caucus will include a bipartisan group of members interested in improving health care through personalized medicine.

2. **Ongoing Advocacy for Policies That Support the Future of Personalized Medicine: Through Interactions with U.S. Federal Agencies Including CMS and FDA**

   To ensure that policy decisions are made with the future of personalized medicine in mind, PMC will continue to liaise with officials at the Centers for Medicare and Medicaid Services and the U.S. Food and Drug Administration to support policies that will advance the field. Engagement may take the form of comment letters, meetings between PMC members and agency officials, public statements, or any other means that will advance the Coalition’s policy agenda.
3. **Public Perspectives on Personalized Medicine: A Survey of U.S. Public Opinion**

To underline the ongoing demand for education about personalized medicine’s potential, PMC has partnered with GenomeWeb to commission *Public Perspectives on Personalized Medicine*, a representative survey of Americans that assesses their awareness of personalized medicine, their reactions to value propositions based on the field’s ability to improve the quality and cost of their health care, and any concerns related to ethics, privacy and access. PMC will release the survey results in 2018 at the National Press Club in Washington, D.C.

4. **Personalized Medicine at FDA: 2017 Progress Report**

To highlight the ongoing prevalence of personalized medicine approvals at FDA, PMC will publish definitive statistics on the percentage of new drug approvals that were personalized medicines in 2017. PMC’s *Personalized Medicine at FDA: 2016 Progress Report* demonstrated that in 2016, for the third year in a row, personalized medicines accounted for more than 20 percent of the new molecular entities the agency approved.


Recognizing the need for evidence underlining the value of next-generation sequencing, PMC plans to publish peer-reviewed research showing that the technology would yield significant clinical and economic benefits if it were fully integrated into the health care system. The study will show that using next-generation sequencing test results to guide therapy selection can improve outcomes and make the health system more efficient.

6. **The Clinical Implementation and Value of Precision Medicine at Three Distinct Institutions: A Peer-Reviewed Journal Article**

To draw attention to the benefits of holistically integrating personalized medicine in clinical settings, PMC will co-author a peer-reviewed research paper in a special thematic issue of *Health Affairs* that shows how the integration of personalized treatment approaches has already led to clinical and economic benefits for three pioneering institutions. The paper will demonstrate that personalized medicine, when fully integrated into clinical care, provides benefits to both patients and the health system.

7. **An Introduction to Informational Genetic Testing: A Consumer Guide to DNA-Based Health Information Testing**

Given the renewed interest in consumer services that promise to deliver actionable information based on genetic sequencing results, PMC will update and republish its *Introduction to Informational Genetic Testing*, which serves as a resource for those who want to learn more about the value of genetic testing backed by scientific evidence.
8. **Ongoing Analysis of Trends in Personalized Medicine: Published in the *PMC Member Update* and *Personalized Medicine in Brief***

To keep members informed about the significance of 2018 news developments to the future of personalized medicine, PMC will continue to publish regular analyses of trends in the field. These analyses will include the monthly *Member Update* e-newsletter as well as the Coalition’s bi-annual print newsletter, *Personalized Medicine in Brief*, and an updated version of *The Personalized Medicine Report*.

9. **Ongoing Representation of Key Personalized Medicine Topics at Prominent Industry Conferences: Via Initiatives Including the “PMC/BIO Personalized Medicine & Diagnostics Track” at the 2018 BIO Convention and a PMC-Led Panel Discussion at the 2018 Molecular Medicine Tri-Conference**

To ensure that prominent industry conferences continue to explore key personalized medicine topics in 2018, PMC will partner with conference organizers to develop sessions that are of significance to the field. These efforts will include a collaboration with BIO on the “PMC/BIO Personalized Medicine & Diagnostics Track” at the 2018 BIO Convention in Boston and with the Cambridge Healthtech Institute on a panel discussion at the 2018 Molecular Medicine Tri-Conference in San Francisco.

10. **The 14th Annual Personalized Medicine Conference**

To examine the landscape and outlook for personalized medicine, PMC will organize the 14th Annual Personalized Medicine Conference at Harvard Medical School. The conference will explore the most significant trends in science, business and policy, and will guide the Coalition’s next steps in education and advocacy.

### SUPPLEMENTAL INITIATIVES

PMC has also identified five projects that may help enhance the Coalition’s impact in 2018.

1. **The Clinical and Economic Value of Whole Exome Sequencing in Rare and Undiagnosed Diseases: A Peer-Reviewed Journal Article**

PMC’s *Clinical and Economic Value of Whole Exome Sequencing* research study will explore the value of using whole exome sequencing to identify a cause of disease in patients with diseases of unknown etiology. The study will seek to show how whole exome sequencing can deliver benefits for patients and health systems by ending ineffective and costly “diagnostic odysseys.”
2. **The Personalized Medicine Education Collaborative**

Through its *Education Collaborative*, PMC would facilitate access to downloadable resources that underline personalized medicine’s scope and benefits. The initiative’s funders would participate in an advisory committee to drive the Collaborative’s agenda, and would have access to versions of the materials that are branded to recognize the participating organization as their official distributor.

3. **Paying for One-Time Therapies: Exploring the Landscape**

PMC’s contributions to the ongoing dialogue about paying for one-time therapies may take the form of a white paper or continued participation in ongoing collaborative initiatives to examine the most prominent reimbursement solutions being considered to pay for treatments like CAR-T therapies and gene editing applications, which promise to deliver unprecedented medical value over the course of a patient’s life.

4. **The Landscape for the Integration of Personalized Medicine into Health Care**

PMC’s analysis of the landscape for the integration of personalized medicine into health care would examine the prevalence of personalized medicine in the clinical environment by surveying hospital systems about personalized medicine program implementation, the use of personalized medicine technologies and perspectives on personalized medicine in clinical practice.

5. **Personalized Medicine Guidelines for Value Assessment Frameworks**

PMC’s *Personalized Medicine Guidelines for Value Assessment Frameworks* would identify the key considerations for personalized medicine that value frameworks should consider and describe how these considerations can and should be integrated into value framework methodologies.

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