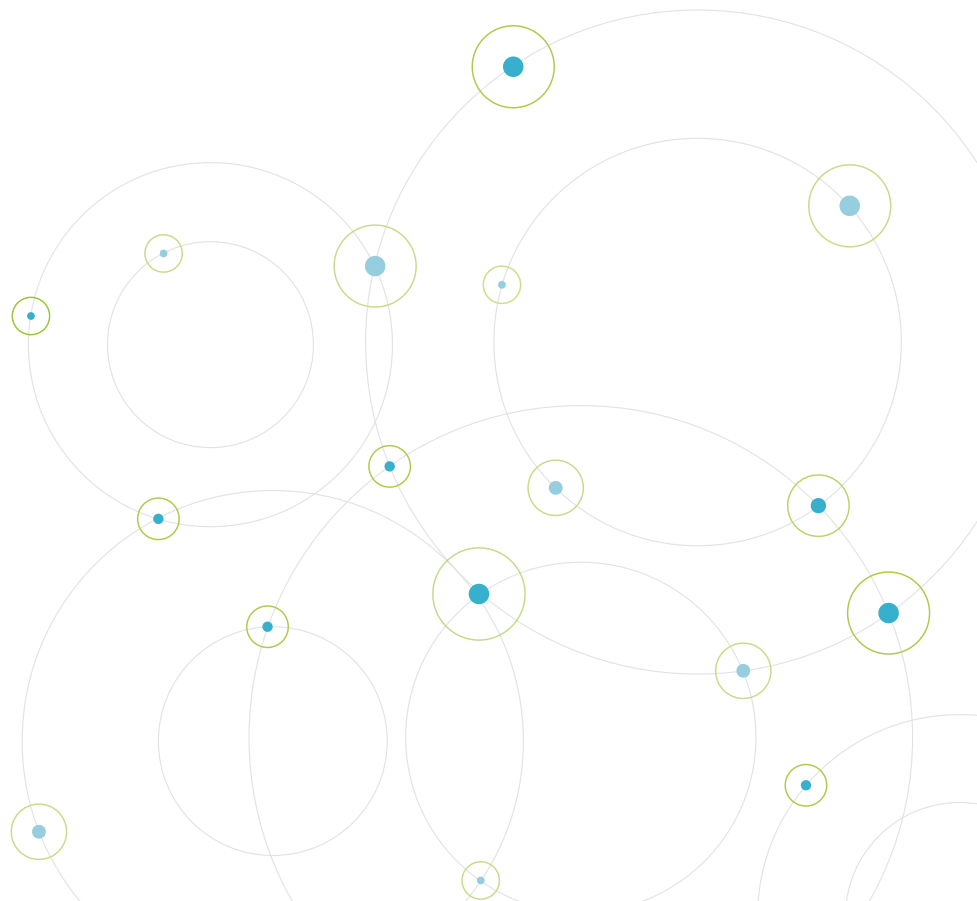

EXPANDING THE FRONTIERS OF PERSONALIZED MEDICINE

Through Education, Advocacy and
Evidence Development

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A STRATEGIC PLAN FOR ADVANCING THE FIELD IN 2021



MISSION

The Personalized Medicine Coalition, 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.

President's Letter

Dear Colleague:

In November 2004, some 20 institutions launched the Personalized Medicine Coalition based on the assumption that a new paradigm in medicine – one that links therapies to diagnostics – would not happen just because the science suggests it should. Then, as now, the Coalition's supporters contended that the intervening variables related to public policies and medical practices would condition the pace at which personalized medicine delivers on its promise of better patient outcomes and more efficient health systems.

As we examine the landscape for personalized medicine in 2021, this assumption resonates with increasing clarity. Although the number of personalized drugs with biomarker strategies on their labels in the United States has grown from five in 2008 to 286 today, complicated policy challenges and clinical adoption obstacles continue to make it difficult for health care systems around the world to capitalize on groundbreaking science and technology that point to a new era in the history of medicine that for the first time promises to put the individual at the center of care. In fact, amidst the tumult of COVID-19 and a turbulent political landscape, most Americans have never heard the words “personalized medicine.”

It is in this context that I am pleased to present *Expanding the Frontiers of Personalized Medicine Through Education, Advocacy and Evidence Development: A Strategic Plan for Advancing the Field in 2021*. With reference to the initiatives PMC will complete with the support of its more than 210 members, as well as those that we could undertake with additional sponsorship dollars, this three-part plan outlines our proposed roadmap to the brighter future we can build for patients and health systems with a continued focus on targeting the right treatments to the right patients at the right time.

Sincerely yours,



Edward Abrahams
President

OVERVIEW

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PART I

Education

As global leaders adapt to shifting political landscapes and seek to mitigate COVID-19's impact in 2021, it is imperative that they understand the importance of considering how their choices may affect the pace of progress in personalized medicine. With most consumers still unaware of what personalized medicine is and why it matters, patient-facing educational efforts are also needed to prompt more point-of-care conversations about molecularly targeted treatments and the ways in which various medical interventions can alter patients' lives.

The Coalition's educational activities will address both of these challenges in 2021.

Personalized Medicine 101: A Package of Programs Designed to Educate Decision-Makers About the Significance of Personalized Medicine

Supported by PMC Membership Dues and Sponsorships for the *Annual Personalized Medicine Conference*

PMC's flagship package of educational programs, titled *Personalized Medicine 101*, will help decision-makers track and tackle key challenges facing personalized medicine. In 2021, PMC will leverage its traditional and social media presence as well as its mailing list of 8,000+ leaders in the public and private sectors to maximize the impact of the following educational initiatives:

- + *The State of Personalized Medicine in 2021: A Virtual Seminar Exploring the Landscape for the Field*
- + *Personalized Medicine at FDA: The Scope & Significance of Progress in 2020* (an annual research report)
- + *Personalized Medicine 101* (a one-page overview of the field)
- + *Understanding Personalized Medicine and Its Significance: A Series of Educational Briefings Co-hosted by PMC and the Congressional Personalized Medicine Caucus*
- + *Personalized Medicine Today* (a monthly e-newsletter)
- + *Personalized Medicine in Brief* (a bi-annual print/PDF landscape analysis)
- + *The 16th Annual Personalized Medicine Conference at Harvard Medical School*

More Than a Number: A Patient-Focused Educational Campaign About Personalized Medicine and Its Benefits

A Supplemental Sponsorship Opportunity

To prompt patients to ask their physicians about the extent to which various prevention and treatment plans are tailored to their biological characteristics, circumstances, and values, PMC will partner with Genome Creative, a communications firm dedicated exclusively to supporting efforts to raise awareness about personalized medicine, to develop and promote a series of patient-facing educational tools about personalized medicine across a wide range of traditional and social media channels. The *More Than a Number* initiative will feature a patient-friendly website with downloadable resources including:

- + *More Than a Number: Better Health Begins With You* (an educational infographic)
- + *A Consumer's Guide to Genetic Health Testing*
- + *Moving Beyond Population Averages: A Patient-Centered Research Agenda Advancing Personalized Medicine*

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PART II

Advocacy

In recent years, the continued advancement of personalized medicine has raised new questions about how and when to regulate, pay for, and integrate the innovative diagnostics and treatments underpinning the field into health systems whose capacity is already stretched by efforts to develop and equitably deploy one-size-fits-all medical interventions. To overcome these challenges, proponents for personalized medicine must shape and advocate for policies that will help pave the way for more tailored prevention and treatment plans in 2021.

PMC will lead the way in this area.

Policies and Personalized Medicine: A Series of Advocacy Priorities Designed to Cultivate a Friendlier Landscape for Advancing the Field

Supported by PMC Membership Dues

To help facilitate the development of personalized medicine tests and therapies, PMC will advocate for continued investments in biomedical research as well as modernized regulatory, coverage, and payment policies that support access to personalized medicine. In 2021, the Coalition's advocacy efforts will focus on:

- + **Guiding an Agenda for the Congressional Personalized Medicine Caucus:** After inspiring the launch of a Congressional Personalized Medicine Caucus through its advocacy on Capitol Hill last year, PMC will continue to play a leading role in shaping an agenda for the caucus and growing the caucus' membership in 2021.
- + **Increasing Funding for Critical Federal Health Agencies:** Investments in scientific research conducted by the National Institutes of Health (NIH) drive many of the discoveries that underpin personalized prevention and treatment strategies. The U.S. Food and Drug Administration (FDA) serves as the gateway for many personalized medicine products entering the market. Through congressional testimonies, public statements, and meetings with members of Congress, PMC will actively advocate for increases to NIH and FDA's budgets for FY 2022. PMC will also call for

resources to support activities at FDA to advance personalized medicine in the context of the Prescription Drug and Medical Device User Fee program reauthorizations.

- + **Modernizing Regulatory Policies:** By approving and clearing personalized medicine products and services in an efficient manner, FDA facilitates patient access to the treatments and some tests that make personalized health care possible. PMC will continue its efforts to ensure that legislation, emerging guidances for stakeholders, policies, and major initiatives preserve and improve the regulatory landscape for the field.
- + **Modernizing Coverage and Payment Policies:** To ensure that patients have access to personalized medicine, PMC advocates for flexible coverage policies and adequate payment rates for personalized medicine products and services. PMC will continue to work with Congress and the Centers for Medicare and Medicaid Services to inform strategies that can document the value of and facilitate access to personalized medicine to support arrangements that promise better outcomes and a more efficient health system.
- + **Modernizing Value Assessment Methodologies:** By influencing decisions made by patients, providers, payers, and policymakers, value assessment frameworks (VAFs) could accelerate or undermine progress in personalized medicine. PMC will continue to inform the development of VAFs and health technology assessments that account for the value of personalized medicine.



PART III

Evidence Development

Despite the extraordinary pace of technological progress in personalized medicine, payers and providers rightly demand evidence demonstrating that personalized medical interventions can be integrated into health systems in ways that deliver both clinical and economic value. Absent this evidence, they will likely remain wary of utilizing the tests and treatments underpinning the field.

In 2021, PMC's research portfolio will focus on generating evidence to support the clinical adoption of personalized medicine.

Understanding and Delivering the Clinical and Economic Benefits of Personalized Medicine: A Research Program

A Supplemental Sponsorship Opportunity

Titled *Understanding and Delivering the Clinical and Economic Benefits of Personalized Medicine*, PMC's research portfolio in 2021 will focus on evaluating the pace of progress in the field, assessing personalized medicine's clinical and economic utility, and defining the landscape for clinical adoption.

Evaluating Progress in Health Care

1. *Understanding Genomic Testing Utilization and Coverage in the US*, a workstream PMC is developing in collaboration with the Blue Cross Blue Shield Association, Concert Genetics, and Illumina, analyzes the extent to which health systems are utilizing genomic tests in various contexts related to coverage and access.
2. *Pharmacogenomics in Clinical Guidelines and at FDA* will benchmark clinical progress in personalized medicine by providing a list of the circumstances in which current clinical guidelines combined with the labels of FDA-approved therapies support the use of personalized medicine strategies that tailor care based on scientific knowledge about drug-gene interactions.

Assessing Clinical and Economic Value

3. *Evaluating the Clinical and Economic Value of Sequencing-Based Diagnostic Tests for Patients With Rare and Undiagnosed Diseases* will provide evidence for sequencing platform developers, payers, and providers about the clinical and economic utility of sequencing-based diagnostics when applied to patients with rare or undiagnosed diseases.
4. *Improvements in Clinical Care Associated With Personalized Medicine* will determine based on data submitted by a representative sample of health care providers in the United States whether more holistic integration of personalized medicine as measured by a multi-factorial assessment of clinical adoption yields superior clinical outcomes.

Examining Research and Integration Strategies

5. *The Integration of Personalized Medicine into US Health Systems: A Landscape Analysis* will explore through survey research and interviews the extent to which providers throughout the U.S. health care system are already integrating personalized medicine in clinical settings.
6. *Defining the Clinical Utility of Genomic Testing in Cancer Care* will advance a more comprehensive definition of clinical utility in cancer care that can prompt more widespread clinical adoption of genomic testing technologies by highlighting underappreciated benefits of testing.

7. *Addressing Practice Gaps in the Implementation of Personalized Medicine in Cancer Care* will examine barriers that are discouraging the clinical integration of genetic testing and the appropriate utilization of testing results in cancer care.

8. *Addressing Disparities and Improving Health Equity in Research Advancing Personalized Medicine* will help support the development of personalized medicine for racial, ethnic and socioeconomic groups that have historically been underrepresented in biomedical research by outlining strategies researchers can employ to better engage more diverse patient populations.

9. *Addressing Challenges in Using Health Data to Advance Personalized Medicine* will explain how decision-makers can catalyze new discoveries in personalized medicine by adopting policies and processes that encourage institutions to more effectively manage and share data for research purposes without jeopardizing patient privacy.



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