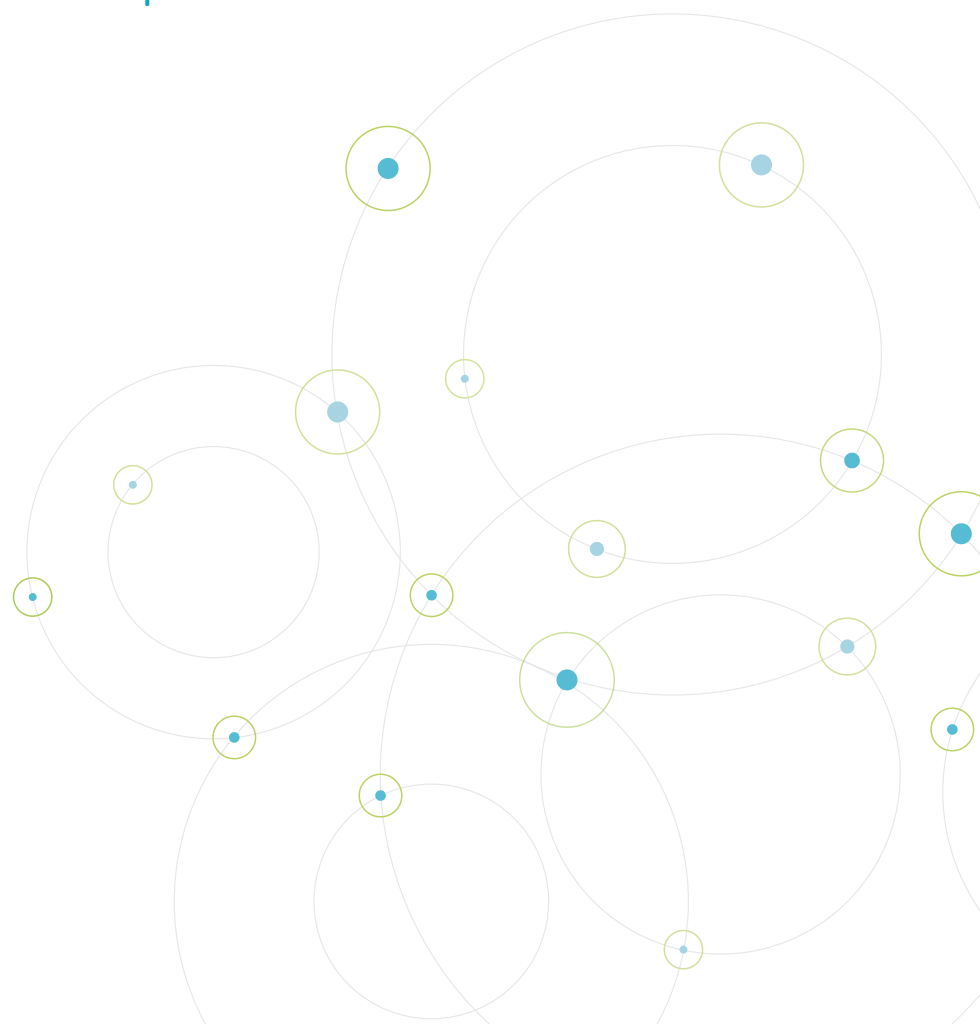

A STRATEGIC PLAN FOR ADVANCING PERSONALIZED MEDICINE IN 2024

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An Overview of Planned Educational,
Advocacy, and Clinical Uptake Initiatives



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 health systems.

President and Chairperson's Letter

Dear Colleague:

Assuming that a new paradigm in medicine that links therapies to diagnostics would not emerge just because the science and new technologies suggest it should, some 20 institutions launched the Personalized Medicine Coalition in 2003. Then, as now, PMC contended that public policies and medical practices condition the pace at which personalized medicine yields better outcomes for patients and more efficiency for health systems — and that we could be doing better at effecting needed changes to those policies and practices to ensure that the promise of personalized medicine is realized.

Today's health care landscape demands continued attention to the intervening variables that stand between the science and the patient. Although the numbers of molecular tests and personalized therapies have grown exponentially since 2003 to include more than 140,000 diagnostic offerings and more than 300 drugs, PMC has demonstrated that public policy challenges, clinical adoption obstacles, and skepticism about the anticipated benefits of personalized medicine continue to make it difficult for health systems around the world to capitalize on the groundbreaking scientific and technological developments that make personalized medicine possible.

We are pleased in this context to present PMC's *Strategic Plan for Advancing Personalized Medicine in 2024*. With reference to the educational and advocacy activities PMC will complete with the support of its more than 225 members as well as a new clinical uptake initiative that we could undertake with additional sponsorship dollars, the three-part plan outlined here proposes a roadmap to a brighter future based on targeting the right health care interventions to the right patients at the right times.

Sincerely yours,



Edward Abrahams, Ph.D.
President



Lincoln Nadauld, Ph.D.
Board Chair

OVERVIEW

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PART I

Education

PMC's communications explore the evolving value proposition of personalized medicine across multiple disease states. Its messages help scientists, business leaders, and policymakers track and tackle key challenges facing personalized medicine. Its patient-facing educational initiatives prompt more point-of-care conversations about molecularly targeted treatments and the ways in which various medical interventions may alter patients' lives.

These activities are designed to provide a foundation of awareness and understanding that will help make policymakers, physicians, and patients more receptive to the revised public policies and medical practices necessary to advance the frontiers of the field.

For Scientists, Business Leaders, and Policymakers

Made Possible by 2024 Membership Dues, 2024 Conference Sponsorships, and 2022/2023 Research Grants

PMC's educational programs for scientists, business leaders, and policymakers are designed to explore personalized medicine's evolving value proposition across multiple disease states. The programs also define the opportunities and challenges facing the field. In 2024, PMC's educational initiatives will include:

- + *A State of Personalized Medicine* Address at the National Press Club in Washington, DC (an annual guest speaker series)
- + *Addressing Disparities in Research Informing Personalized Medicine* (a community-developed blueprint for engaging underserved communities in biomedical research)
- + *Improvements in Clinical Care Associated With Personalized Medicine* (a study of the quality of care that the leading adopters of personalized medicine are able to deliver)
- + *Payer Policies on Personalized Medicine* (an overview of the coverage landscape for the tests and treatments underpinning the field)
- + *Personalized Medicine at FDA: The Scope & Significance of Progress in 2023* (an annual research report)
- + *Personalized Medicine Today* (a monthly e-newsletter)
- + *The 18th Annual Personalized Medicine Conference* (November 12–13, 2024, at Harvard Medical School)
- + *Understanding Personalized Medicine and Its Significance: A Series of Briefings Co-Hosted with the Congressional Personalized Medicine Caucus*

For Patients

Made Possible by 2024 Membership Dues

In keeping with its mission to promote the understanding and adoption of personalized medicine, the Personalized Medicine Coalition maintains three websites containing more than 100 pages of educational content. Much of this content is designed to empower patients to advocate for health care tailored to their biological characteristics, circumstances, and values. Through a partnership with Mediaplanet, PMC also contributes editorial content to advertorial inserts published in outlets including the *USA Today* and the *Toronto Star*. PMC's patient-facing educational resources include:

- + *Personalized Medicine 101* (an educational overview hosted on personalizedmedicinecoalition.org)
- + *More Than a Number: Better Health Begins With You* (a digital engagement platform hosted on mtan.org)
- + *Moving Beyond Population Averages: A Patient-Centered Research Agenda Advancing Personalized Medicine*
- + *What to Know About Personalized Medicine* (an annual campaign distributed to *USA Today* readers in select metropolitan markets across the country)
- + *A Consumer's Guide to Genetic Health Testing*



PART II

Advocacy

PMC shapes and advocates for public policies that pave the way for more tailored prevention and treatment plans. PMC's advocacy efforts are focused on addressing emerging questions about how and when to regulate, pay for, and integrate the innovative diagnostics and treatments underpinning personalized medicine into health systems whose capacities are already stretched by efforts to develop and equitably deploy one-size-fits-all medical interventions.

Informing Lawmakers' and Federal Policymakers' Decision-making

Made Possible by 2024 Membership Dues

To help facilitate the development and adoption of personalized medicine tests and therapies, PMC advocates for continued investments in biomedical research as well as modernized regulatory, coverage, and payment policies that support access to personalized medicine. In 2024, the Coalition's advocacy efforts will leverage the Coalition's growing body of research supporting personalized medicine's implementation and the strong relationships PMC has built on and off Capitol Hill focusing on:

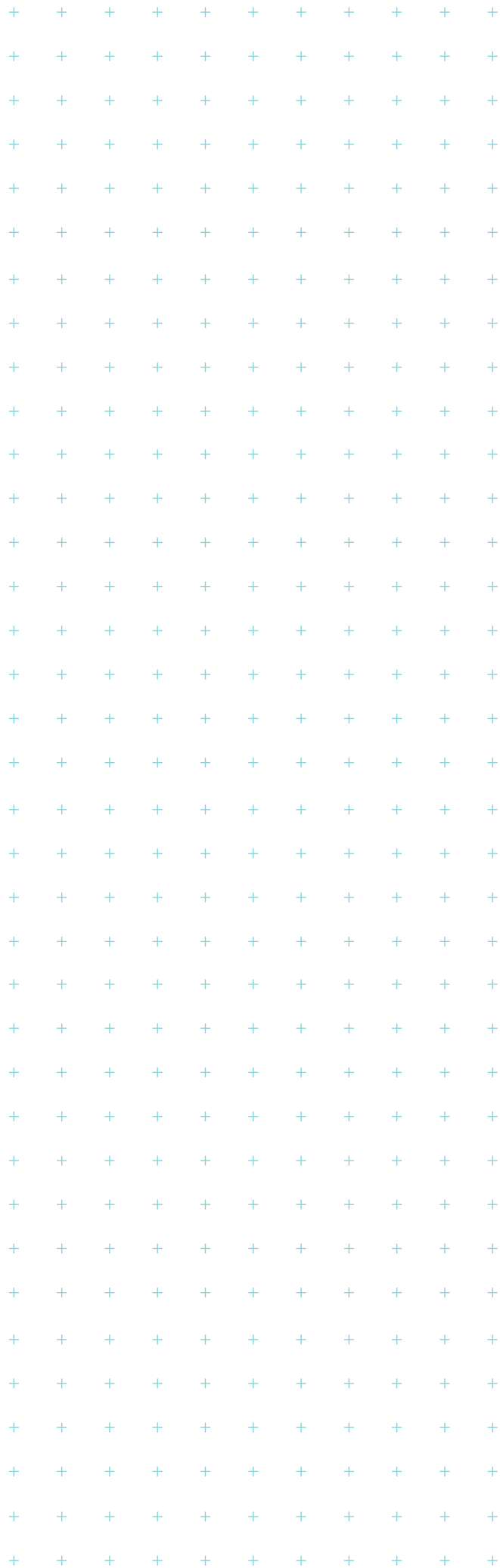
- + **Guiding an Agenda for the Congressional Personalized Medicine Caucus:** After inspiring the launch of a Congressional Personalized Medicine Caucus through its advocacy on Capitol Hill in 2020, PMC continues to play a leading role in shaping a legislative agenda for the caucus, growing the caucus' membership, and using the caucus to educate Members of Congress about key issues facing personalized medicine. PMC will also take advantage of opportunities to brief caucuses focused on care delivery about ways that their members can embrace the adoption of personalized medicine, including how public policies can encourage physician utilization of personalized medicine strategies that promise to improve outcomes and reduce costs.
- + **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 actively advocates for increases to NIH and FDA's budgets. The Coalition also advocates for activities that broadly advance personalized medicine supported through the newly created Advanced Research Projects Agency for Health (ARPA-H) and the Biden administration's Cancer Moonshot program.
- + **Modernizing Regulatory Policies:** By approving and clearing personalized medicine products and services, FDA unlocks patient access to many of the tests and treatments that facilitate personalized health care. In 2024, PMC will continue to educate the Coalition's members and policymakers about the need for legislation to improve the regulatory landscape for personalized medicine and preserve functional pathways to market. PMC plans to continue monitoring policies, emerging guidance for stakeholders, and major initiatives, as well as develop priorities for the upcoming cycle of FDA user fee reauthorizations. The Coalition will weigh in as appropriate to protect innovation and preserve patients' confidence in medicine.

+ **Shaping 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 designed to facilitate enhanced screening and earlier disease detection, more precise disease diagnosis, and improved treatment. In 2024, PMC will continue to work with Congress and the Centers for Medicare and Medicaid Services to advance strategies that document the value of personalized medicine to support arrangements that promise better outcomes and more efficient health systems.

+ **Improving 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, particularly if they are used by government to implement drug pricing reforms. In 2024, PMC will continue to highlight that VAFs and health technology assessments do not currently account for the value of personalized medicine; explain the impact of such methodologies on innovation and patient access; and identify areas for improvement.





PART III

Clinical Uptake

Despite the extraordinary pace of scientific and technological progress in personalized medicine, PMC's research has found that the molecular tests and treatments underpinning the field rarely reach patients in clinical settings. In 2024, PMC is seeking supplemental sponsorship funding to develop and publish a new Roadmap for Addressing Clinical Practice Gaps in Personalized Medicine. The Coalition's network of partners, including key administrators and clinicians, would use the roadmap to spearhead reforms designed to bring the benefits of personalized medicine to more patients.

Implementing Precision Oncology Initiative: A Roadmap for Addressing Clinical Practice Gaps and Streamlining the Delivery of Personalized Medicine

A Supplemental Sponsorship Opportunity

BACKGROUND

The findings of a PMC/Diaceutics analysis published in 2022 highlight the impact of clinical practice gaps that are impeding the delivery of personalized medicine. The study, which PMC published in *JCO Precision Oncology* as a special report titled “Impact of Clinical Practice Gaps on the Implementation of Personalized Medicine in Advanced Non–Small-Cell Lung Cancer,” shows that due to the complexities involved in biomarker testing and genetically based prescribing, personalized medicines reached only 36 percent of potentially eligible advanced non-small cell lung cancer (aNSCLC) patients, an indication where more than 70 percent of patients have actionable mutations. Although these findings are made in aNSCLC, they likely reflect similar gaps in all biomarker testing-driven indications, indicating a need for strategies to improve implementation across personalized medicine.

PROPOSED PROGRAM

To help catalyze clinical and operational practice and policy reforms, PMC is seeking supplemental sponsorship funding for an implementation roadmap that establishes and promotes best practices and policies for implementing precision oncology. The Coalition has a two-part plan for developing and implementing such a roadmap, as follows:

1. **Developing a roadmap to streamline the delivery of precision oncology.** Development of the roadmap, to be completed in six to nine months, will involve alignment with the relevant stakeholders needed to effect change in order to improve the delivery of precision oncology, including clinical workforces, provider groups, clinical guideline developers, payers, patients, and technology developers.
2. **Improving precision oncology care through a demonstration project.** Upon completion of the roadmap, an interested health care provider will be recruited for a demonstration project, to be completed in 12 months, designed to bring expert consultation to examine the impact of clinical practice gaps at the institution and use the implementation roadmap to directly advise on the needed programmatic and practice reforms to streamline the delivery of precision oncology.

CONTACT INFORMATION

Interested funders who want to learn more about the Coalition’s proposal for an *Implementing Precision Oncology* program can contact Kayla Smith at ksmith@personalizedmedicinecoalition.org.

PMC Membership

JANUARY 2024

CLINICAL LABORATORY TESTING SERVICES

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Laboratory Corporation of America (Labcorp)
Quest Diagnostics
SmartLabs

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Agendia NV
Agilent Technologies
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Circulogene
Cofactor Genomics
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Exai Bio
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Adaptive Biotechnologies
Alexion Pharmaceuticals
Day One Bio
Denovo Biopharma
Elevation Oncology, Inc.
Freenome
Helix

ImmunoGen
Jazz Pharmaceuticals
Kyverna Therapeutics
Merus
OneOme
Rapafusyn Pharmaceuticals

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Point32Health

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American Clinical Laboratory Association
Biocom California
National Society of Genetic Counselors
PhRMA

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Action
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Nucleai
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Pfizer, Inc.
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PATIENT ADVOCACY GROUPS

Accelerated Cure Project for Multiple Sclerosis
AiArthritis
Alliance for Aging Research
Alzheimer's Foundation of America
American Association of Kidney Patients (AAKP)
American Cancer Society Cancer Action Network (ACS-CAN)
Bulgarian Association for Personalized Medicine
Cancer Treatment Options & Management Inc. (CTOAM)
Colorectal Cancer Alliance
Emily's Entourage
EveryLife Foundation for Rare Disease
Friends of Cancer Research
Glioblastoma Foundation
Global Liver Institute
GO2 for Lung Cancer
International Cancer Advocacy Network
KRAS Kickers
LUNGevery Foundation
Multiple Myeloma Research Foundation
National Alliance Against Disparities in Patient Health
National Alliance for Hispanic Health
National Health Council
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 Hospital Albert Einstein
 iCAN – Digital Precision Cancer Medicine at University of Helsinki
 Intermountain Healthcare
 King Faisal Specialist Hospital and Research Centre

MaineHealth Accountable Care Organization
 Manchester University School of Pharmacy
 Marshfield Clinic
 Mayo Clinic
 MD Anderson – Institute for Personalized Cancer Therapy
 Moffitt Cancer Center
 Morehouse School of Medicine
 National Pharmaceutical Council
 Nicklaus Children’s Hospital Research Institute
 North Carolina Biotechnology Center (NCBIO)
 NorthShore University
 Parkview Health
 Qatar Biobank
 Sanford Imagenetics, Sanford Health
 Teachers’ Retirement System of Kentucky
 The Christ Hospital
 The Jackson Laboratory
 Translational Genomics Research Institute (Tgen)
 UC Davis Mouse Biology Program
 University of Alabama, Birmingham
 University of California, San Francisco (UCSF)
 University of Chicago
 University of Pennsylvania Health System
 University of Pittsburgh Medical Center (UPMC)
 University of South Florida Morsani College of Medicine

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