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# A STRATEGIC PLAN FOR ADVANCING PERSONALIZED MEDICINE IN 2023

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An Overview of Initiatives in Education,  
Advocacy, and Evidence Development

## 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, 20 years later, 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 number of personalized drugs with biomarker strategies on their labels in the United States has grown from five in 2008 to more than 300 today, 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 2023*. With reference to the initiatives PMC will complete with the support of its more than 225 members as well as those 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

## PART I: EDUCATION

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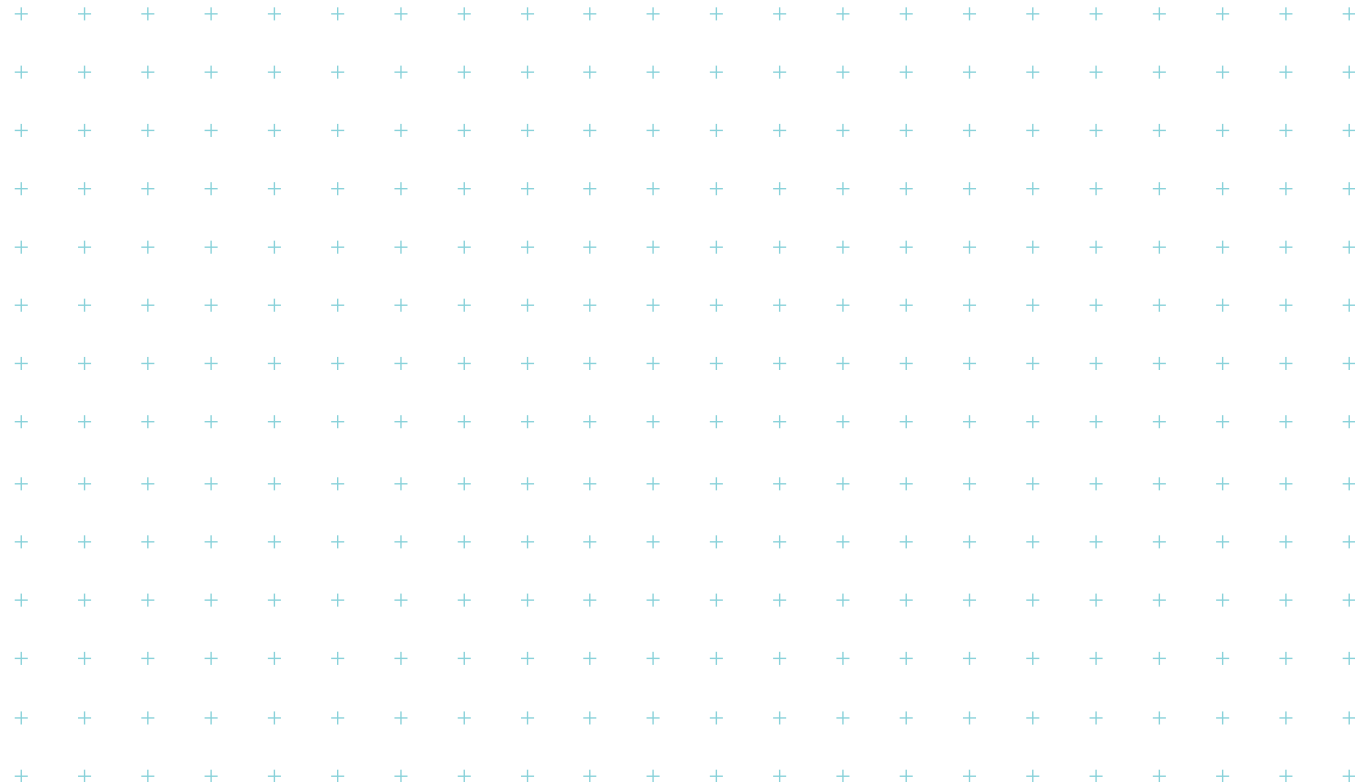


## PART I

# Education

In 2023, PMC will explore the evolving value proposition of personalized medicine across multiple disease states. Member-facing communications will help decision-makers track and tackle key challenges facing personalized medicine. Patient-facing educational initiatives will prompt more point-of-care conversations about molecularly targeted treatments and the ways in which various medical interventions may alter patients' lives.

These efforts are designed to provide a foundation of awareness and understanding that will make constituents and health care decision-makers more receptive to the revised public policies and scientific practices necessary to advance the frontiers of the field.



## Personalized Medicine 101: Exploring the Field's Evolution With Attention to Opportunities, Challenges, and the Importance of Evidence Generation

### 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 draw on the evidence emerging from its research portfolio to explore personalized medicine's evolving value proposition across multiple disease states. The program will also define the opportunities and challenges facing the field more broadly. Ongoing initiatives include:

- + *Personalized Medicine: An Evolving Value Proposition* (a series of virtual seminars focused on evidence development in personalized medicine)
- + *The State of Personalized Medicine Address* at the National Press Club in Washington, DC, May 24, 2023 (an annual guest speaker series)
- + *The 17<sup>th</sup> Annual Personalized Medicine Conference: Reflections and Visions 20 Years After the Human Genome Project* (Nov. 30 – Dec. 1, 2023, at the Ritz-Carlton Laguna Niguel)
- + *Personalized Medicine at FDA: The Scope & Significance of Progress in 2022* (an annual research report)
- + *Understanding Personalized Medicine and Its Significance: A Series of Briefings Co-Hosted with the Congressional Personalized Medicine Caucus*
- + *Personalized Medicine Today* (a monthly e-newsletter)

## More Than a Number: Empowering Patients to Advocate for Health Care Tailored to Their Biology, Circumstances, and Values

### A Supplemental Sponsorship Opportunity

As a digital engagement platform, PMC's *More Than a Number* initiative empowers patients to advocate for health care tailored to their biological characteristics, circumstances, and values. Through a partnership with *Mediaplanet*, articles cross-posted on the *MTAN* website have reached millions of patients as part of advertorial inserts in the *USA Today* and the *Toronto Star*. In 2023, *MTAN*'s campaigns will continue to educate patients about the multiple dimensions of personalized medicine through articles and patient stories about prevention, diagnosis, and treatment opportunities. The platform references resources and initiatives including:

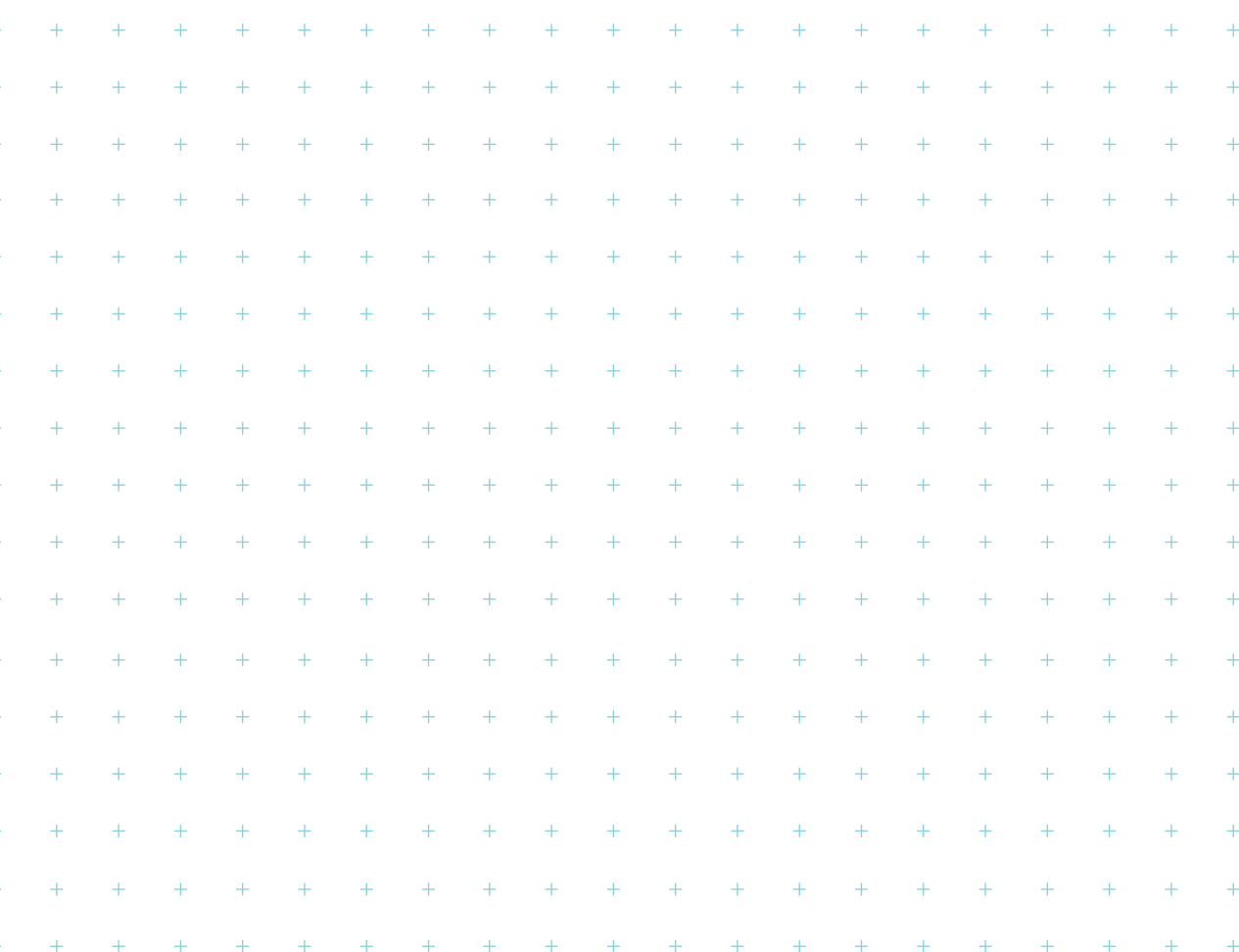
- + *More Than a Number: Better Health Begins With You* (an educational infographic)
- + *A Consumer's Guide to Genetic Health Testing*
- + *Moving Beyond Population Averages: A Patient-Centered Research Agenda Advancing Personalized Medicine*
- + *What to Know About Personalized Medicine: A Series of Collaborative Virtual Discussions Designed to Educate Patients About the Opportunities in Personalized Medicine Across Multiple Disease States*
- + *The Personalized Medicine and the Patient Summit*, November 15, 2022



## PART II

# Advocacy

PMC shapes and advocates for public policies that pave the way for more tailored prevention and treatment plans. In 2023, PMC's advocacy efforts will continue to address emerging questions about how and when to regulate, pay for, and integrate the innovative diagnostics and treatments underpinning personalized medicine into health systems whose capacity is already stretched by efforts to develop and equitably deploy one-size-fits-all medical interventions.



## Public Policies and Personalized Medicine: Cultivating a Friendlier Policy Landscape for Advancing the Field

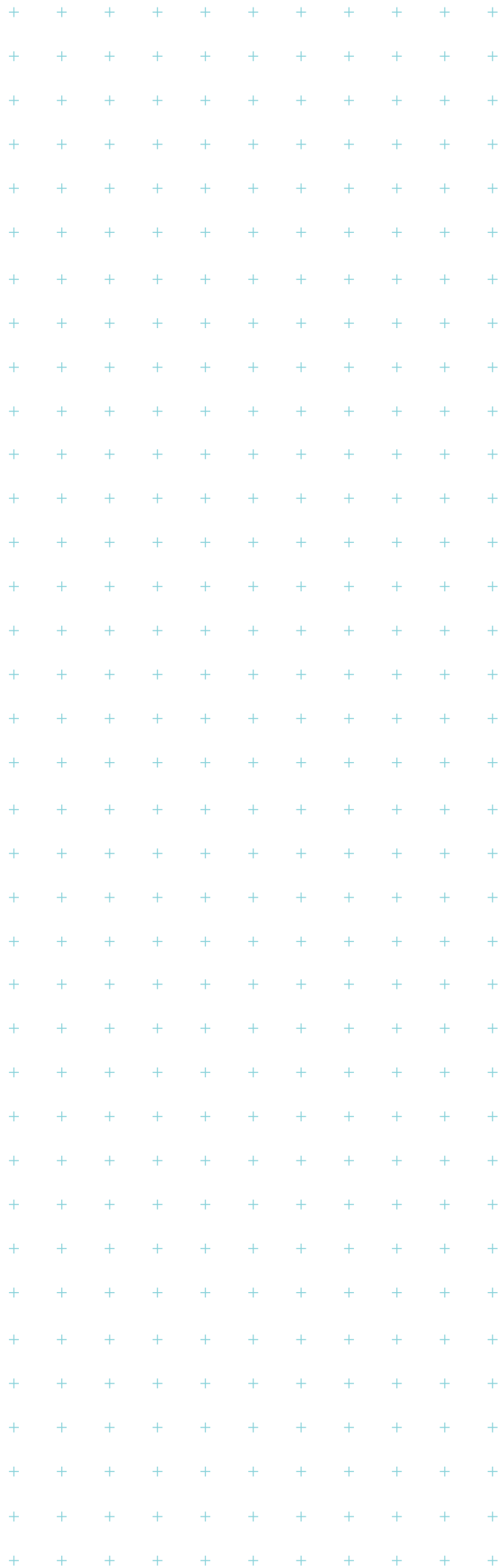
### Supported by PMC Membership Dues

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 2023, the Coalition's advocacy efforts will leverage the Coalition's growing body of research supporting personalized medicine's implementation, 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 will continue 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 in 2023. 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 to improve patient outcomes and reduce costs to the United States health care system.
- + **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 2024. The Coalition will advocate for activities that broadly advance personalized medicine supported through the newly created Advanced Research Projects Agency for Health (ARPA-H) and the re-launched 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 2023, 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, including those resulting from the 2022 reauthorization of the FDA's user fee programs. The Coalition will weigh in as appropriate to protect innovation and preserve patients' confidence in medicine.



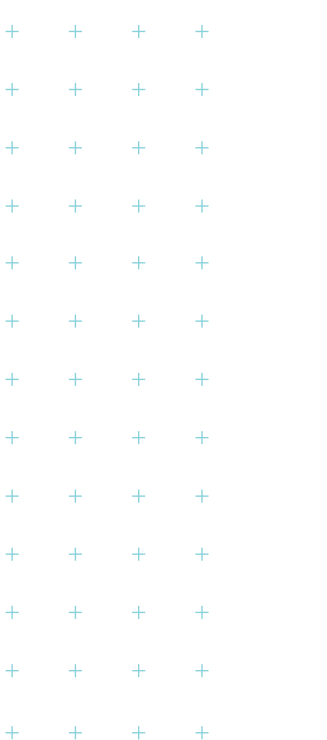
- + Shaping Coverage and Payment Policies:**  
To ensure that patients have access to personalized medicine, PMC advocates for flexible coverage policies and adequate payment rates for existing technologies and novel personalized medicine products and services designed to facilitate enhanced screening and earlier disease detection, more precise disease diagnosis, and improved treatment. In 2023, 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 2023, 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

# Evidence Development



Despite the extraordinary pace of scientific and 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 remain hesitant to utilize the tests and treatments that underpin the field.

In 2023, PMC's research portfolio will continue to focus on generating evidence to support the clinical adoption of personalized medicine.



## Understanding and Delivering the Clinical and Economic Benefits of Personalized Medicine: An Evidence Development Program

### Three Supplemental Sponsorship Opportunities

Titled *Understanding and Delivering the Clinical and Economic Benefits of Personalized Medicine*, PMC's evidence development portfolio includes programs and initiatives that will help establish the foundation of personalized medicine by building and communicating a greater understanding of associated technologies and health care strategies and informing policy decision-making. Continued advancement of the field requires policy development as well as implementation and access strategies with a focus in three increasingly important areas:

- + Evaluating progress in personalized medicine that can inform further advancement of the field;
- + Assessing the clinical and economic value of personalized medicine; and
- + Examining personalized medicine research and clinical integration strategies.

#### EVALUATING PROGRESS IN HEALTH CARE

The first arm of PMC's research portfolio aims to establish a foundational understanding of how far personalized medicine has come while informing further advancement of the field. The Coalition's past research in this area culminated in influential reports and peer-reviewed articles titled *Understanding Genomic Testing Utilization and Coverage in the United*

*States* (a white paper), "Comparison of FDA Table of Pharmacogenetic Associations and Clinical Pharmacogenetics Implementation Consortium Guidelines" (*Am J Health Syst Pharm.*, 2022), and PMC's now-annual analysis of FDA's newest personalized medicine-related approval decisions. In 2023, PMC will build on this work by launching a two-phased study on payer policies and perspectives, as follows:

- 1a. Using publicly available statements, *Payer Policies on Personalized Medicine* will analyze and evaluate the coverage, reimbursement, and utilization policies of public and private health insurance provider institutions to determine when leading payers across the globe facilitate or limit patient access to the tests and treatments underpinning personalized medicine.
- 1b. *Payer Perspectives on Personalized Medicine* will survey a sample of leaders at public and private health insurance provider institutions, pharmacy and laboratory benefits managers, and large employers to determine their perspectives on the coverage of tests and treatments underpinning personalized medicine. The survey will promote a better understanding of payer decision-making.

#### ASSESSING CLINICAL AND ECONOMIC VALUE

The second arm of PMC's research portfolio helps establish the value proposition associated with integrating personalized medicine strategies into health care. Through its previous initiatives in this area, the Coalition has developed peer-reviewed studies titled "Cost Effectiveness of Multigene Panel Sequencing for Patients With Advanced Non-Small-Cell Lung Cancer"

(*JCO Clin Cancer Inform.*, 2019) and “Cost-Effectiveness of Exome and Genome Sequencing for Children With Rare and Undiagnosed Conditions” (*Genet Med.*, 2022). In 2023, PMC will take a holistic look at the value of systemic personalized medicine integration, as follows:

2. Based on data submitted by a representative sample of health care providers in the United States, *Improvements in Clinical Care Associated With Personalized Medicine* will determine whether more holistic integration of personalized medicine — as measured by a multi-factorial assessment of clinical adoption — yields superior clinical outcomes.

#### EXAMINING CLINICAL INTEGRATION STRATEGIES

Understanding that integrating personalized medicine into clinical care presents daunting challenges for many health systems, PMC has designed the third arm of its research portfolio to provide critical information and strategies to aid in the clinical implementation of personalized medicine. The Coalition’s foundational articles and reports in this area are titled “Strategies for Integrating Personalized Medicine into Healthcare Practice” (*Per Med.*, 2017), “A Quantitative Framework for Measuring Personalized Medicine Integration into US Healthcare Delivery Organizations” (*J Pers Med.*, 2021), *Addressing Challenges in Using Health Data to Advance Personalized Medicine* (a white paper),

“Clinical Utility of Genomic Testing in Cancer Care” (*JCO Precis Oncol.*, 2022), and “Impact of Clinical Practice Gaps on the Implementation of Personalized Medicine in Advanced Non-Small-Cell Lung Cancer” (*JCO Precis Oncol.*, 2022). In 2023, PMC will focus on understanding how to address inequities in research advancing personalized medicine, as follows:

3. By outlining strategies researchers can employ to better engage more diverse patient populations, *Addressing Disparities 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.

After outlining in 2022 how inconsistent clinical practices at seven stages of the precision oncology care pathway decrease the number of patients benefitting from precision oncology (see “Impact of Clinical Practice Gaps on the Implementation of Personalized Medicine in Advanced Non-Small-Cell Lung Cancer,” *JCO Precis Oncol.*), the Coalition will also explore opportunities in 2023 to develop and employ strategies to address key clinical practice challenges, including efforts to improve access to high-value personalized treatment strategies by making a clear value proposition to payers and providers; to optimize biomarker testing processes, and to improve clinical decision support.

# PMC Membership

JANUARY 2023

## CLINICAL LABORATORY TESTING SERVICES

Avellino Labs  
Invitae  
Laboratory Corporation of America (Labcorp)  
Quest Diagnostics

## DIAGNOSTIC COMPANIES

10x Genomics  
Agendia NV  
Agilent Technologies  
Almac Diagnostics Services  
Ambry Genetics  
Biological Dynamics  
Caris Life Sciences  
Castle Biosciences  
Circulogene  
Cofactor Genomics  
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Diaceutics  
Exact Sciences  
Exai Bio  
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GeneCentric Therapeutics  
Genetic Center – Regina Maria  
GRAIL, Inc.  
Guardant Health  
Illumina  
Kiyatec  
Myriad Genetics  
NanoString Technologies  
NeoGenomics Laboratories  
NuProbe, Inc.  
Olaris Therapeutics  
Oncocyte  
Personalis  
QIAGEN, Inc.  
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Roche Diagnostics  
RxGenomix  
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Singular Genomics  
SomaLogic, Inc.  
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Adaptive Biotechnologies  
Alexion Pharmaceuticals

American Diagnostics and Therapeutics (ADxRx)  
Elevation Oncology, Inc.  
Freenome  
Helix  
Kyverna Therapeutics  
Macrogenics  
SmartPGX

## HEALTH INSURANCE COMPANIES

Point32Health

## INDUSTRY/TRADE ASSOCIATIONS

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

## IT/INFORMATICS COMPANIES

2bPrecise  
Aetion  
Assurance Health Data  
Change Healthcare  
Concert Genetics  
DNAnexus  
Flatiron Health  
GNS Healthcare  
Lifebit  
M2Gen  
Nucleai  
P4-ML  
Paige.ai  
PathAI  
Ruffin Health  
Syapse  
Translational Software  
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Bausch Health Companies  
Bayer  
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Blueprint Medicines

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Eli Lilly and Company  
Genentech, Inc.  
Gilead  
GlaxoSmithKline  
Johnson & Johnson  
Merck & Co.  
Novartis  
Pfizer, Inc.  
Sanofi

## 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 Association on Health and Disability (AAHD)  
American Cancer Society Cancer Action Network (ACS-CAN)  
Blue Hat Foundation  
Bulgarian Association for Personalized Medicine  
Cancer101  
Colorectal Cancer Alliance  
Emily's Entourage  
EveryLife Foundation for Rare Diseases  
Friends of Cancer Research  
Glioblastoma Foundation  
Global Liver Institute  
GO<sub>2</sub> Foundation for Lung Cancer  
HealthyWomen  
International Cancer Advocacy Network  
KRAS Kickers  
LUNgevity Foundation  
Manta Planner  
Multiple Myeloma Research Foundation  
National Alliance Against Disparities in Patient Health  
National Alliance for Hispanic Health  
National Pancreas Foundation  
National Health Council  
One Cancer Place  
Rabble Health  
Sick Cells

SynGAP Research Fund  
Team Trevor  
The Assistance Fund

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Coriell Life Sciences  
Genome Medical  
InformedDNA  
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Sema4  
Sengenics  
Tempus

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Research (AACR)  
American Medical Association (AMA)  
Arizona State University  
American Society of Health System  
Pharmacists (ASHP)  
Association for Molecular  
Pathology (AMP)  
Audubon Bioscience  
Business Finland  
Cancer Treatment Centers of  
America  
Clarified Precision Medicine  
Codex4SMEs  
College of American Pathologists  
CommonSpirit Health  
Coriell Institute for Medical Research  
Culmination Bio  
Duke Center for Research on  
Personalized Health Care  
Essentia Institute of Rural Health  
European Infrastructure for  
Translational Medicine (EATRIS)  
First Ascent Biomedical  
Genome Canada  
Gregory Hess  
Hamad Medical Corporation  
Hospital Albert Einstein  
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Medicine at University of Helsinki

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Research Centre  
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Organization  
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Marshfield Clinic  
Mayo Clinic  
MD Anderson – Institute for  
Personalized Cancer Therapy  
Mercy Health  
MITRE Corporation  
Moffitt Cancer Center  
Morehouse School of  
Medicine  
National Pharmaceutical Council  
Nicklaus Children’s Hospital Research  
Institute  
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North Carolina Biotechnology Center  
Ochsner Health System  
Qatar Biobank  
Sanford Imagenetics, Sanford Health  
Teachers’ Retirement System of  
Kentucky  
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The Jackson Laboratory  
Thomas Jefferson University  
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Institute (Tgen)  
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(UCSF)  
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Foley & Lardner, LLP  
Foley Hoag, LLP  
Genome Creative  
Goldbug Strategies, LLC  
Hanson Wade  
Health Advances, LLC  
Hogan Lovells, LLP  
Innovation Horizons  
Innovation Policy Solutions  
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KPMG  
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JANUARY 2023

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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 health systems.





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