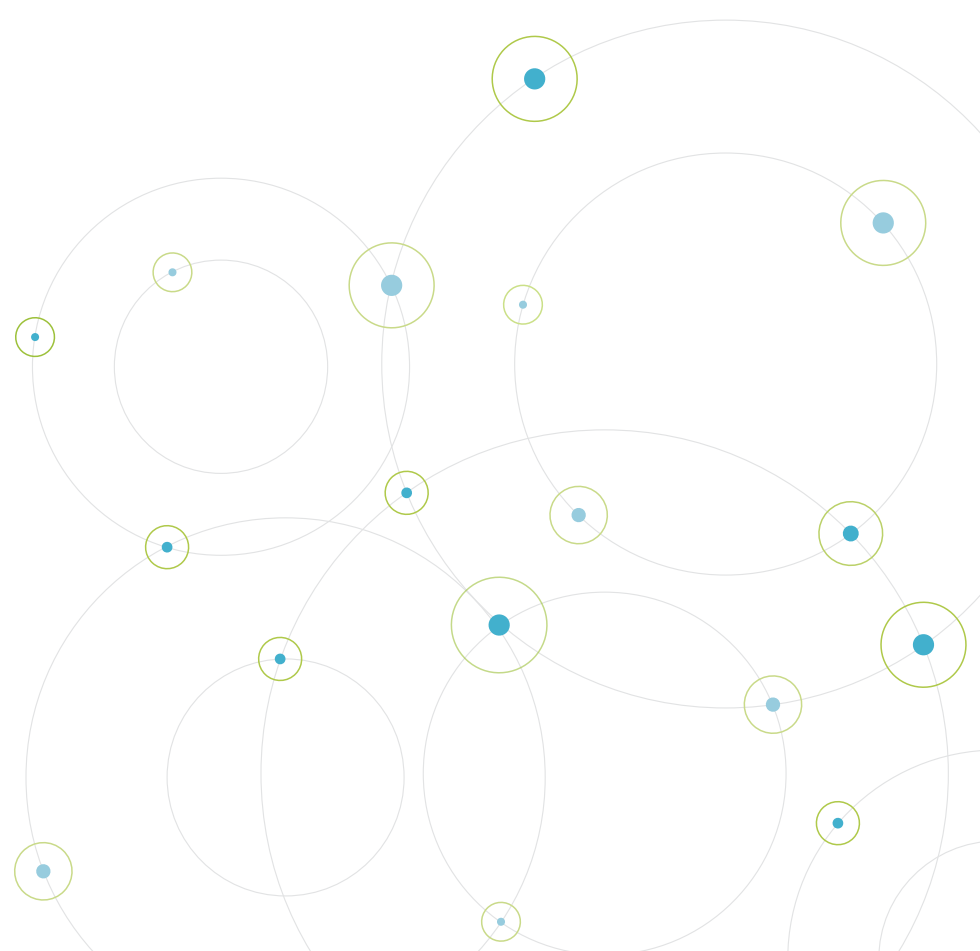

A STRATEGIC PLAN FOR ADVANCING PERSONALIZED MEDICINE IN 2022

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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'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, PMC's supporters contended that public policies and medical practices would condition the pace at which personalized medicine yields better outcomes for patients and more efficiency for health systems.

Today's health care landscape begs for 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, 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. The pandemic's tragically uneven consequences spotlight missed opportunities to tailor prevention and treatment strategies to subpopulations of patients with careful attention to their biology, circumstances, and values.

I am pleased to present in this context PMC's *Strategic Plan for Advancing Personalized Medicine in 2022*. With reference to the initiatives PMC will complete with the support of its more than 220 members as well as those that we could undertake with additional sponsorship dollars, this three-part plan outlines our proposed roadmap to building a brighter future based on targeting the right health care interventions to the right patients at the right time.

Sincerely yours,



Edward Abrahams
President

OVERVIEW

PART I: EDUCATION

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2. More Than a Number: Empowering Patients to Advocate for Health Care Tailored to Their Biology, Circumstances, and Values (page 6)

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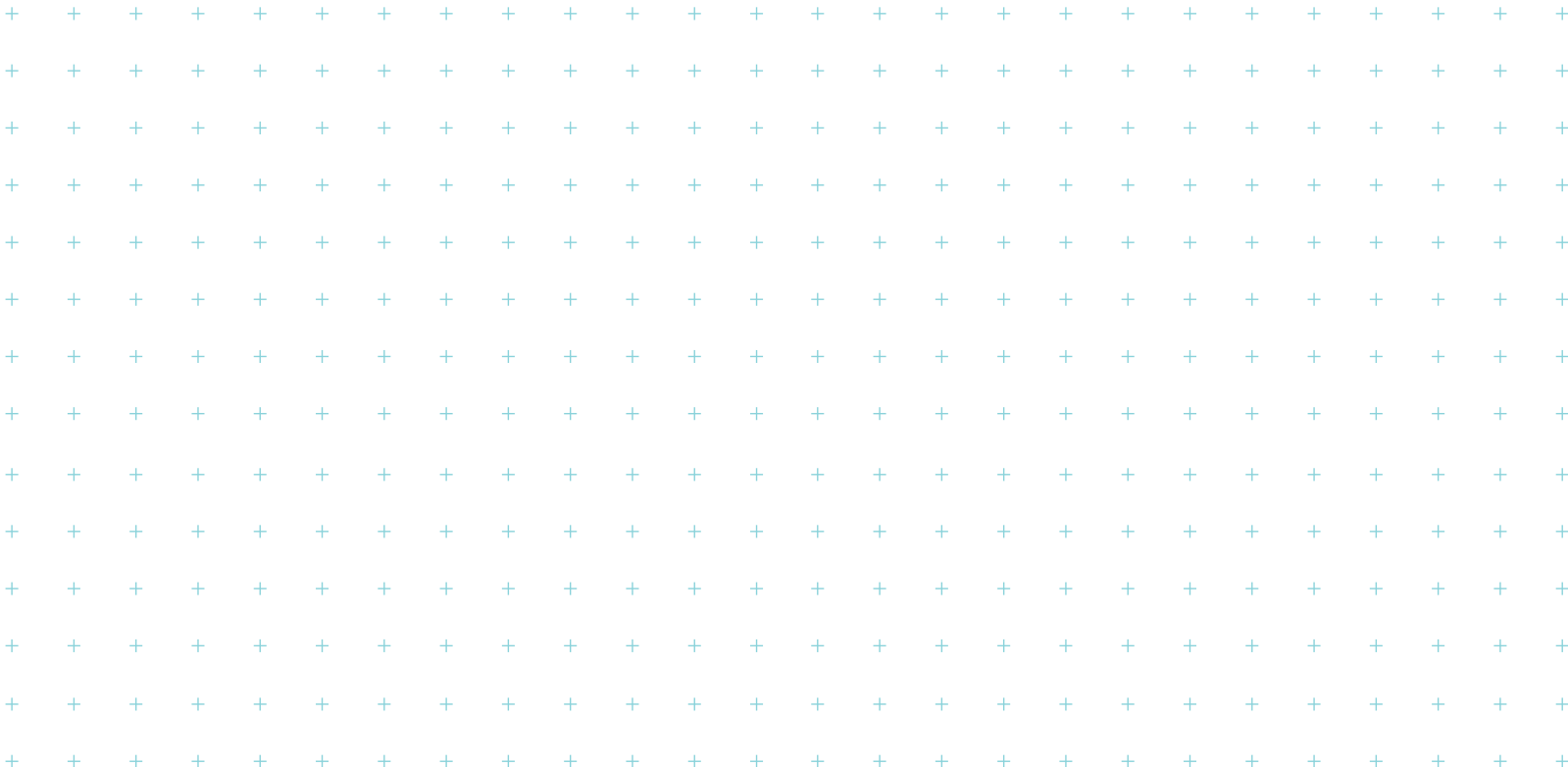


PART I

Education

In 2022, 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-driven 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 16th Annual Personalized Medicine Conference at the Ritz-Carlton Laguna Niguel*
- + *Personalized Medicine at FDA: The Scope & Significance of Progress in 2021 (An Annual Research Report)*
- + *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 landscape analysis)
- + *The 17th Annual Personalized Medicine Conference at Harvard Medical School*

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 pro bono 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 2022, *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 features resources including:

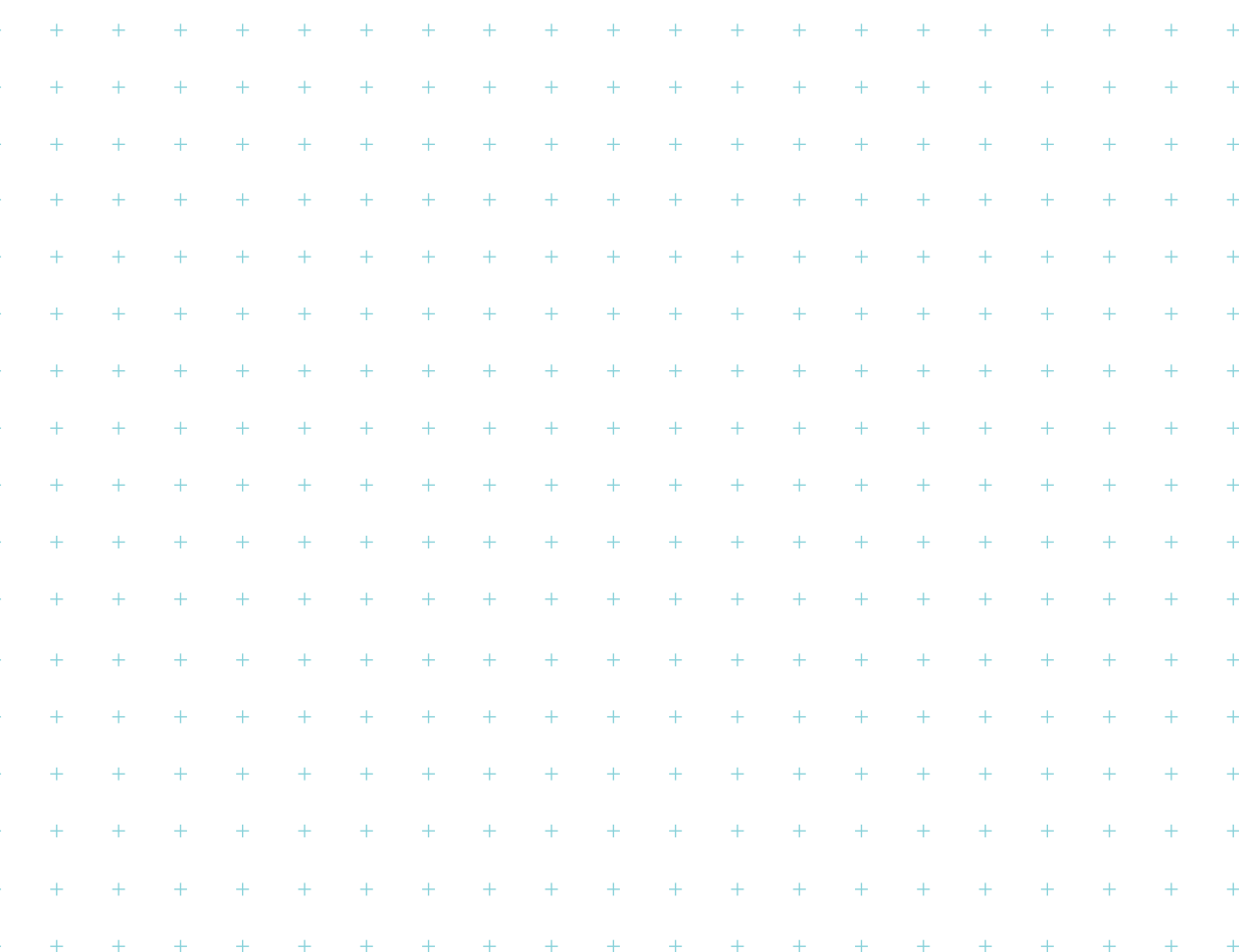
- + *More Than a Number: Better Health Begins With You* (an educational infographic)
- + *A Consumer's Guide to Genetic Health Testing*
- + *Moving Beyond Population Averages: A Patient-Centered Research Agenda Advancing Personalized Medicine*



PART II

Advocacy

PMC shapes and advocates for public policies that pave the way for more tailored prevention and treatment plans. In 2022, 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 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 2022, 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 in 2020, PMC will continue to play a leading role in shaping an agenda for the caucus and growing the caucus' membership in 2022.
- + **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 2023.
- + **Modernizing Regulatory Policies:** By approving and clearing personalized medicine products and services in an efficient manner, FDA facilitates patient access to many of the tests and treatments that make personalized health care possible. PMC will continue its efforts to ensure that legislation, emerging guidance 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 more efficient health systems.
- + **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.

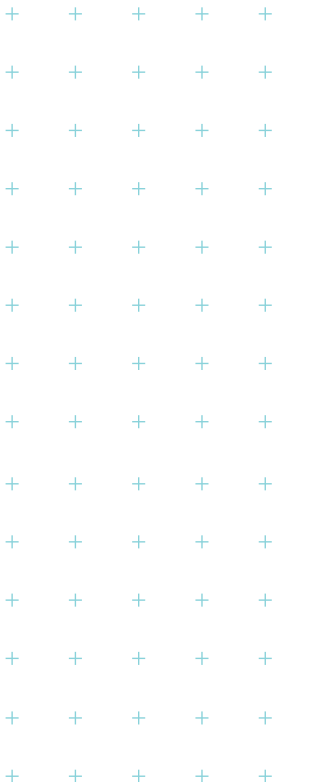


PART III

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 2022, 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: A Research Program

A Supplemental Sponsorship Opportunity

Titled *Understanding and Delivering the Clinical and Economic Benefits of Personalized Medicine*, PMC's research portfolio in 2022 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 help 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.
3. *Payer Perspectives and Policies on Personalized Medicine: A Landscape Analysis* will survey a representative sample of payer representatives to better understand payer decision-making and evaluate how coverage policies shape the development of personalized health care.

ASSESSING CLINICAL AND ECONOMIC VALUE

4. *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.
5. *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 can yield improved clinical outcomes.

EXAMINING CLINICAL INTEGRATION STRATEGIES

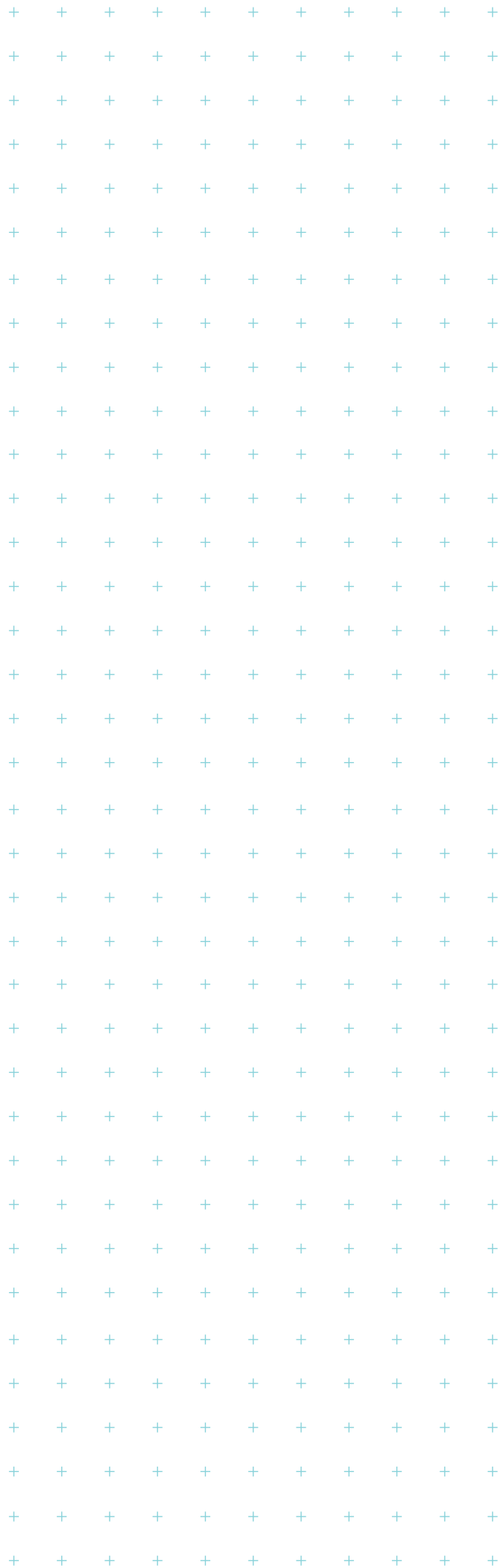
6. *Defining the Clinical Utility of Genomic*

Testing in Cancer Care will advance a more comprehensive definition of clinical utility of genomic sequencing in cancer care that can facilitate more widespread clinical adoption of genomic testing technologies by highlighting underappreciated benefits of testing.

7. *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 make it easier for researchers to collect, analyze, and share data.

8. *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.

9. *Addressing Disparities in Research Advancing Personalized Medicine* will help support the development of and access to personalized medicine for racial, ethnic, demographic, and socioeconomic groups that have historically been underrepresented in biomedical research by making recommendations to the research community and policymakers designed to ensure that research data are inclusive of diverse patient populations.



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JANUARY 2022

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AiArthritis
Alliance for Aging Research
Alport Syndrome Foundation
Alzheimer's Foundation of America
American Association of Kidney Patients (AAKP)
Blue Hat Foundation
Bulgarian Association for Personalized Medicine
Cancer101
Cancer Commons
Colorectal Cancer Alliance
CureDuchenne
Emily's Entourage
EveryLife Foundation for Rare Diseases
Fight Colorectal Cancer
Friends of Cancer Research
Global Liver Institute
GO₂ Foundation for Lung Cancer
HealthyWomen
International Cancer Advocacy Network
KRAS Kickers
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MaineHealth Accountable Care
Organization
Manchester University School of
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Marshfield Clinic
Mayo Clinic
MD Anderson – Institute for
Personalized Cancer Therapy
MITRE Corporation
Moffitt Cancer Center
Morehouse School of
Medicine
National Pharmaceutical Council
Nicklaus Children’s Hospital Research
Institute
NorthShore University HealthSystem
North Carolina Biotechnology Center
Ochsner Health System
Qatar Biobank
Sanford Imagenetics, Sanford Health
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