
Understanding and Delivering the Clinical and Economic Benefits of Personalized Medicine

A Research Program Focused on Evaluating Progress in Health
Care, Assessing Clinical and Economic Value, and Examining
Clinical Integration Strategies

President/Chairman's Letter

Dear Colleague:

Personalized medicine — linking therapies to molecular diagnostic tests to ensure that the right treatments are targeted to the right patients — is still more aspiration than reality.

Although we have made enormous progress in developing a new scientific appreciation of human heterogeneity, as evidenced by the rise in the number of personalized treatments on the market from five in 2008 to over 250 today, significant obstacles remain.

In brief, we need more evidence that personalized medicine works — that it can improve clinical outcomes while making health care more efficient and therefore less costly. We also need to understand the opportunities and challenges shaping the pace of our progress toward integrating personalized medicine into clinical work streams.

This three-part research program, titled *Understanding and Delivering the Clinical and Economic Benefits of Personalized Medicine*, is designed to facilitate progress on each of these fronts. The projects presented in these pages focus on evaluating technological progress in personalized medicine, assessing its clinical and economic value, and examining clinical integration efforts. We have made considerable progress in advancing many of these studies, but others are not fully funded.

We therefore request your thoughtful consideration of these initiatives as we call on organizations from multiple sectors of the health care ecosystem to provide support, in addition to membership dues, for the Personalized Medicine Coalition's expanding research portfolio.

Sincerely yours,



Edward Abrahams
President



Jay G. Wohlgemuth, M.D.
Chairman, Board of Directors

Program Overview

AS OF NOVEMBER 2020

EVALUATING PROGRESS IN HEALTH CARE

STUDY 1	Understanding Genomic Testing Utilization and Coverage in the US (Published)	5
STUDY 2	Pharmacogenomics in Clinical Guidelines and at FDA (Not Fully Funded)	7

ASSESSING CLINICAL AND ECONOMIC VALUE

STUDY 3	The Cost-Effectiveness of Next-Generation Sequencing (NGS)-Based Diagnostic Tests for Cancer Patients (Published)	10
STUDY 4	Evaluating the Clinical and Economic Value of Sequencing-Based Diagnostic Tests for Patients With Rare and Undiagnosed Diseases (In Progress)	13
STUDY 5	Improvements in Clinical Care Associated With Personalized Medicine (Not Fully Funded)	16

EXAMINING CLINICAL INTEGRATION STRATEGIES

STUDY 6	The Integration of Personalized Medicine into US Health Systems: A Landscape Analysis (In Progress)	20
STUDY 7	Defining the Clinical Utility of Genomic Testing in Cancer Care (In Progress)	22
STUDY 8	Addressing Practice Gaps in the Implementation of Personalized Medicine in Cancer Care (Not Fully Funded)	25

STUDIES 1-2

Evaluating Progress in Health Care

The first two studies included in this research program are designed to outline the trends and opportunities associated with personalized medicine. Focusing on genomic testing and pharmacogenetics, the studies will give payers and providers more clarity as they consider the merits of testing for their patients. By advancing a more comprehensive understanding of the utilization of genomic testing as related to coverage and highlighting the circumstances in which current clinical guidelines and U.S. Food and Drug Administration-approved drug labels support the use of pharmacogenomic strategies, the studies promise to inform stakeholders as they look to advance the use of personalized medicine.

STUDY 1 (Published)

Understanding Genomic Testing Utilization and Coverage in the US

BACKGROUND

Personalized medicine rests partly on the assumption that genomic testing can aid in treatment management decisions, yielding both clinical utility and economic value. Genomic testing has the potential to improve clinical care by providing important information that can speed diagnosis, inform treatment decisions, and improve the efficiency of health care delivery in several areas, such as prenatal screening, oncology, and rare and undiagnosed disease. However, genomic testing technologies are relatively new, and providers face several barriers to the adoption of policies and procedures that will lead to widespread access of genomic testing in clinical practice. A better understanding of the utilization of genomic testing across the U.S. health system and how it relates to patient access will provide insight into genomic testing implementation trends and barriers.

OBJECTIVE

This study will examine the patterns of utilization of genomic sequencing for noninvasive prenatal testing, tumor diagnosis, and rare and undiagnosed disease in the U.S. Utilization will likely be related to a patient's distance to testing facilities, insurance coverage, and social/environmental impacts on access to testing. The results of this study's analysis will be included in a report whose purpose will be to provide key personalized medicine stakeholders, including providers, pharmaceutical and diagnostic manufacturers, payers, patients, and lawmakers with insight into genomic testing implementation and barriers so as to inform efforts to integrate and deliver personalized medicine to all patients who can benefit.

PROJECT OUTLINE

Using a U.S. clinical genetic testing market database cross-referenced to claims data, the project will involve examination of current utilization patterns of genomic sequencing-based testing as related to access factors, including coverage, distance to genomic testing facility, and social and patient-level determinants of health care.

PMC, Illumina, Concert Genetics, and the Blue Cross Blue Shield Association will work together to coordinate data collection, analysis, and development of reports.

Results of the study will be published in three separate documents:

1. A two-page analysis preview;
2. A PMC white paper detailing the findings; and
3. A manuscript focusing on implications to the integration of personalized medicine in health care to be published in a peer-reviewed journal.

The report and manuscript will be disseminated through a robust communications plan to increase awareness and become a resource for health care decision-makers.

STUDY 2 (Not Fully Funded)

Pharmacogenomics in Clinical Guidelines and at FDA

BACKGROUND

Pharmacogenomics (PGx) can play an important role in identifying responders and non-responders to medications, avoiding adverse events, and optimizing drug dosing. The use of diagnostic tests to detect PGx gene-drug interactions is a cornerstone of personalized medicine, providing a way to guide treatment and prevention strategies based on individual patient characteristics. Despite varying levels of evidence supporting the clinical utility of many PGx markers, only a select few are recommended for use in informing clinical decisions. Because of this variability in supporting evidence, PGx clinical practice guidelines formulated by panels of experts have a significant impact on the pace at which providers integrate new PGx tests and other novel technologies into their clinical work streams.

A better understanding of the current status of PGx gene-drug association inclusion in the clinical practice guidelines developed by major guideline development bodies will help clarify the extent to which personalized medicine technologies have been integrated into clinical care. An examination of biomarkers included in guidelines can also highlight areas where clinical evidence of utility is being developed but where widely recognized biomarker-based prevention and treatment strategies have not yet been included in clinical guidelines or within drug labels. This, in turn, can inform further efforts to advance personalized medicine implementation.

OBJECTIVES

PMC will catalogue the PGx-based gene-drug associations that are included in current guidelines for different health conditions and compare this to PGx associations included in drug labels. The results will be included in a report whose purpose will be to provide key personalized medicine stakeholders, including product developers, clinical laboratories, health care providers, payers, patients and policymakers with information about what PGx strategies are commonly used in practice and what strategies may require additional evidence development or provider outreach and education efforts.

PROJECT OUTLINE

The project will involve a comprehensive examination of the current clinical practice guidelines for PGx published by major guideline development organizations, including but not limited to those published by CPIC, and subsequent cataloging of included gene-drug interactions.

The clinical guideline PGx catalogue will be compared directly to PGx information listed in FDA's *Table of Biomarkers in Drug Labeling* and through a direct review of existing drug labels.

Drug-gene interactions for which there is inconsistency between inclusion in FDA labeling and clinical guidelines will be highlighted.

The results will be published in a white paper detailing the findings and policy implications.

PMC will engage with guideline development organizations and FDA to have them advise the research strategy and review results.

STUDIES 3-5

Assessing Clinical and Economic Value

Projects three through five are designed to assess the clinical and economic value of personalized medicine in clinical care. By examining the clinical and economic benefits of personalized medicine for patients with cancers and suspected rare diseases and by relating overall improvements in clinical care to the implementation of personalized medicine, these studies will advance peer-reviewed evidence necessary to help payers and providers make decisions about the circumstances in which they should adopt policies and programs that provide access to the tests and treatments underpinning personalized medicine.

STUDY 3 (Published)

The Cost-Effectiveness of NGS-Based Diagnostic Tests for Cancer Patients

BACKGROUND

Introducing new technologies in health care, especially ones that propose to transform medical practice, can be a daunting exercise because, as Machiavelli explained, most people “do not believe in anything new until they have actual experience of it.”

While the rapid decrease in the cost of next-generation sequencing (NGS) has opened up new opportunities to analyze cancer tumors to determine what therapies may be most effective, most payers and providers have had too little experience with the proposed new approach to take the lead in the introduction of a new paradigm that links the choice of therapy to the information that can be derived from sophisticated molecular diagnostics.

Without evidence that it works both for patients in better clinical outcomes and for the health systems that employ it in lower systemic costs, “medicine’s next step,” as former President Barack Obama has called it, will come much more slowly than we would like.

OBJECTIVES

With a planning grant of \$150,000 from Quest Diagnostics, PMC organized a steering committee to develop a proposal that would demonstrate the clinical and economic value of NGS-based diagnostic testing in cancer care. The proposal outlines research that will evaluate the value, both clinical and economic, of solid tumor NGS-based diagnostic testing to guide targeted therapies. Developed by Scott Ramsey, M.D., Ph.D., at the Fred Hutchinson Cancer Research Center, it will lead to peer-reviewed publications whose purpose is to provide evidence for developers, payers, and providers that NGS-based diagnostic testing is both clinically useful and economically efficient. As the research proposal states, “The primary hypothesis of this study is that, based on current evidence, multiplex NGS testing can be cost-effective from a payer perspective, when compared to the current standard in diagnostic testing (i.e., no testing or selected mutation testing).”

RESEARCH OUTLINE

The project will be broken into two phases. The first phase, to be completed in 6–9 months, will consist of the development of a value model validated with existing real-world data on NGS-based testing in non-small cell lung cancer, given the growing importance of targeted therapies in this cancer type.

The second phase, to be completed in 18 months, will include an expansion of the value assessment in other major carcinomas for which mutational analysis is prevalent, such as colorectal cancer and/or melanoma, and will also involve a value of information analysis and the identification of factors that significantly impact the cost-effectiveness of NGS-based diagnostic testing.

The project will aim to assess the value of tumor mutation profiling in general, rather than compare technology platforms.

A project advisory committee will be formed to guide the project, review progress at various milestones, and to ensure the use of appropriate and up-to-date data.

Research will utilize existing data sets and/or ongoing studies to the extent possible, supplemented with data from health systems and medical records.

In the first phase of the study, PMC will coordinate a meeting with the research team, advisory committee members, and other partners, to determine what data sets should be explored for use in the study and how we will gain access to these data sets.

A payer advisory committee will also be formed to provide guidance so the project results will be useful in informing the coverage and payment process.

Results of the study will be published in a peer-reviewed journal and disseminated through a robust communications plan to increase awareness and become a resource for decision-makers in government, industry, and health care.

CONCLUSION

Many organizations within the personalized medicine community have called for assessments of the value of NGS-based diagnostic testing. This project is PMC's answer to that call.

STUDY 4 (In Progress)

Evaluating the Clinical and Economic Value of Sequencing-Based Diagnostics for Patients With Rare and Undiagnosed Diseases

BACKGROUND

For patients with rare and undiagnosed diseases, genomic sequencing — determining a patient’s entire unique DNA makeup — may be an extremely valuable tool for discovering the genetic alterations that contribute to disease development, as well as for influencing treatment decision-making. Patients with rare and undiagnosed diseases are most often children who may have already undergone single-gene testing but still have not received a definitive diagnosis. They are sometimes referred to as “diagnostic odyssey” cases, as a child and family can bounce around various medical centers for years while numerous diagnostic procedures are performed and health care costs are accrued. All the while, the disease goes undiagnosed.

As they go through their diagnostic odysseys, these patients’ diseases progress and they lose time during which they could potentially receive effective therapies or be enrolled in a clinical trial.

OBJECTIVE

PMC organized a project planning committee to develop a request for proposals for a study that would demonstrate the clinical and economic value of sequencing for rare and undiagnosed diseases. A research proposal developed by Peter Neumann, Sc.D., at the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center was selected. The study will address the primary hypothesis as stated in the proposal: “Genomic sequencing testing can speed diagnosis and initiation of appropriate care and can be cost-effective when performed early on in clinical course.”

Interested partners will be included on a project steering committee that will help guide the project, review progress at various milestones, and ensure the use of appropriate and up-to-date data. The study will lead to a peer-reviewed publication whose purpose will be to provide evidence for sequencing platform developers, payers, and providers that sequencing-based diagnostic testing is both clinically useful and economically efficient when applied to the right patient population.

RESEARCH OUTLINE

The project, to be completed in 6–9 months, will involve the development of a clinical and economic value model validated with existing real-world data from institutions that are regularly sequencing patients (and in some cases, the child and both parents) with diseases of unknown etiology.

The project may also involve a value of information analysis and the identification of factors that significantly impact the cost-effectiveness of sequencing-based diagnostic testing.

Research will utilize existing data sets and/or ongoing studies to the extent possible – supplemented by the collection of data from health system and medical records.

As the convener of the study, PMC will coordinate a meeting with the research team, steering committee members and other partners to determine what data sets should be explored for use in the study and how we will gain access to these data sets.

The project's aim is to assess the value of sequencing rare and undiagnosed disease patients in general. The study will not compare technology platforms.

A payer and employer advisory committee to include health insurers, large employers, and employer benefits management groups will also be formed to provide guidance, especially related to cost/benefit assumptions utilized in the value model, so the project results will incorporate the perspectives of these key stakeholders, increasing the likelihood that the results will be useful in informing the coverage and reimbursement process. Results of the study will be published in a peer-reviewed journal and disseminated through a robust communications plan to increase awareness and become a resource for decision-makers in government, industry and health care.

CONCLUSION

Many organizations within the personalized medicine community have called for evidence demonstrating the value of genomic sequencing in rare and undiagnosed disease. This project is PMC's answer to that call.

STUDY 5 (Not Fully Funded)

Improvements in Clinical Care Associated With Personalized Medicine

BACKGROUND

Integrating personalized medicine into health care delivery systems requires a shift from traditional “one-size-fits-all” practices to a more efficient approach based on understanding and addressing individual patient characteristics and circumstances, therefore requiring an investment in workforce and financial resources associated with new technologies, policies, practices and education. As providers consider integrating personalized medicine approaches into their health care delivery systems, they increasingly want evidence showing that the implementation of personalized medicine improves clinical care.

To gain a better understanding of the current landscape of personalized medicine integration, PMC coordinated a study to capture a holistic picture of the complete range of personalized medicine implementation strategies and technologies being undertaken at a representative sample of health care delivery institutions across the United States. Based on a quantitative framework that assesses progress toward personalized medicine integration at the institutional level with consideration of multiple clinical areas, institutions were assigned scores between one (minimal personalized medicine integration) and five (expansive and systematic integration). The findings show that U.S. health care organizations are widely distributed in terms of integration across clinical areas, but most are at level two or level three.

Level four and level five institutions stand out as pioneers in personalized medicine but are still not common. While many of these institutions are thought of as outstanding health systems, there is a need for evidence linking the personalized medicine approach to improved clinical care. A better understanding of the level of integration of personalized medicine associated with improved health care delivery and clinical outcomes may help justify the adoption of policy changes and investments associated with its implementation.

OBJECTIVE

This project will examine the effect of integrating personalized medicine approaches in driving improved clinical care and systemic efficiency. The extent to which a health care delivery institution has integrated personalized medicine will be based on integration scores as determined through PMC's *Integration of Personalized Medicine in U.S. Health Systems* landscape analysis. Improvements in clinical care and systemic efficiency will be considered as part of a matrix of elements contributing to the increased delivery of high-quality health care practices and services that can improve clinical outcomes and/or provide greater access to relatively higher value care, and will include both quantitative and qualitative measures.

The results will be included in a report whose purpose will be to provide key personalized medicine stakeholders — including providers, payers, clinical guideline developers, pharmaceutical and diagnostic manufacturers, patients and policymakers — with evidence of the value of integrating personalized medicine into clinical practice. This, in turn, can help inform efforts to address the most critical outstanding integration challenges.

PROJECT OUTLINE

The project, to be completed in 12 months, will involve the development of an evidence-based framework linking personalized medicine integration scores with improved clinical care, along with subsequent analysis that will help demonstrate the current value of personalized medicine integration.

A project steering committee composed of partner members of PMC's Health Care Working Group will guide the development of the value framework with the inclusion of appropriate evidence; track progress at various milestones; and ensure that results are meaningful to key audiences.

The analysis will include examination of a representative sample of U.S. health care delivery institutions including academic health centers; urban, suburban, and rural community hospital systems; and integrated payer/provider systems.

A payer advisory committee will also be formed to provide guidance especially related to assumptions about improved clinical care utilized in the value framework. The advisory committee will help ensure that the project results incorporate the perspectives of these key stakeholders, increasing the likelihood that the results will be useful in informing coverage and reimbursement processes.

Results of the study will be published in a peer-reviewed journal and become a resource for decision-makers in health care delivery, industry, and government.

CONCLUSION

The personalized medicine community needs an evidence-based analysis linking the implementation of personalized medicine to improved clinical care to help advance personalized medicine integration efforts and to make clear to health care decision-makers that they should develop policies and practices that drive personalized medicine. *Improvements in Clinical Care Associated With Personalized Medicine* is designed to address this need.

STUDIES 6–8

Examining Clinical Integration Strategies

The final three projects are designed to better understand the trends and challenges that health care providers face when integrating the principles of personalized medicine into their clinical work streams and uncover strategies to overcome implementation challenges. The studies are focused on surveying a representative sample of providers in the United States to determine the extent to which personalized medicine has been integrated into the U.S. health care system as well as developing strategies to ensure that cancer patients benefit from targeted therapies. The results of the studies will help accelerate progress by focusing clinical integration efforts on the most pressing systemic obstacles.

STUDY 6 (In Progress)

The Integration of Personalized Medicine into U.S. Health Systems: A Landscape Analysis

BACKGROUND

Providers are increasingly working to integrate personalized medicine into their health care delivery systems. Led by several pioneering institutions, academic health centers and community hospital systems across the U.S. are adopting strategies and processes to overcome clinical implementation challenges. By examining the experiences of these personalized medicine programs, the broader health care community is developing a better understanding of how to integrate personalized medicine into clinical practice. It is not clear, however, what impact the move toward personalized medicine within these pioneering institutions has had so far on the health care system in general. A better understanding of the current landscape for implementation within the U.S. health care delivery system will help clarify the extent to which personalized medicine has penetrated health care and help identify remaining needs. This, in turn, will inform efforts to address the most critical outstanding integration challenges.

OBJECTIVE

This project will examine varying perspectives and practices in order to capture a holistic picture of the clinical adoption of personalized medicine strategies and technologies within the U.S. health care system by querying provider institutions about baseline community, institutional, and service delivery details as well as practice patterns and viewpoints related to personalized medicine and its utilization. This, in turn, can help inform efforts to address the most critical outstanding integration challenges. The landscape analysis will include a representative sample of U.S. health care delivery institutions and could include both quantitative and qualitative results to ensure that a U.S. health system-wide picture of the integration of personalized medicine is captured.

PROJECT OUTLINE

The project, to be completed in 4–6 months, will involve a short survey and/or a series of interviews of U.S. health care delivery systems and subsequent analysis that will help demonstrate the current landscape of personalized medicine integration.

PMC's health care working group will guide the project, review survey questions, track progress at various milestones, and ensure an appropriate sample of survey respondents.

Survey respondents will include a representative sample of U.S. health care delivery institutions including academic health centers; urban, suburban, and rural community hospital systems; and integrated payer/provider systems.

CONCLUSION

Many organizations within the personalized medicine community have called for an analysis of the current landscape for personalized medicine implementation in the U.S. This project is PMC's answer to that call.

STUDY 7 (In Progress)

Defining the Clinical Utility of Genomic Testing in Cancer Care

BACKGROUND

The use of advanced diagnostic tests to detect predictive and prognostic biomarkers is a cornerstone of personalized medicine, providing a way to guide treatment and prevention strategies based on individual patient characteristics. However, despite varying levels of evidence supporting the clinical utility of many biomarker-based strategies, advanced diagnostic testing is often not appropriately or effectively used in clinical practice. The consistent use of biomarker testing faces implementation challenges related to insufficient awareness and education, a lack of recognition by payers and providers of the clinical value of testing, and outdated practices, policies and processes. A firm understanding among all health care stakeholders of all the ways in which biomarker testing has clinical utility will be instrumental to overcoming implementation challenges and providing the most efficient and effective personalized health care.

Developing this expanded definition of clinical utility will require a better understanding of current provider and payer perspectives on biomarker testing along with a comprehensive examination of how testing strategies can benefit patient care. This, in turn, can inform further efforts to address challenges associated with personalized medicine implementation.

OBJECTIVES

PMC will examine current perspectives on the use of personalized medicine strategies in health care delivery and identify all of the factors that can help determine the clinical utility of multiplex genomic testing in clinical practice, such as for use in patient screening, prognosis, treatment decisions, clinical trial recruitment, and to inform potential off-label uses. Based on these findings, PMC will develop recommendations to broaden the definition of the clinical utility of multiplex genomic

testing in patient care. The recommendations will be made to key personalized medicine stakeholders, including health care providers, payers, clinical guideline developers, clinical laboratories, and patients, to help inform their policies and processes and support their educational efforts.

PROJECT OUTLINE

The project will involve examination of current perspectives on the use of multiplex genomic testing and the subsequent development of recommendations to key personalized medicine stakeholders for the inclusion of a comprehensive set of value factors within a broadened definition of clinical utility.

Phase 1: Stakeholder Roundtable Event

- a. Objectives:
 - i. Bring together health care providers and payers to identify the components of what an expanded definition of clinical utility could and should consist of
 - ii. Align on recommendations for how expanding the definition of next-generation sequencing clinical utility can be implemented in the community to enhance patient care
 - › To do this, PMC envisions the experts discussing their clinical practice (case studies), responding to pre-prepared topics/questions related to utility factors, and describing how their practical experience could inform the development of recommendations on an expanded definition of clinical utility
- b. Format:
 - i. Moderated roundtable discussion to examine case study examples and respond to pre-prepared topic points related to different elements of the clinical utility of advanced genetic tests
 - ii. Roundtable participants will discuss how recognition of clinical utility can help address practice gaps and develop recommendations on how to broaden the perception of utility and value amongst providers

- c. Who:
 - i. 10–20 experts
 - › 4 academics (representing multiple tumor types)
 - › 6 community (mix of hospital system and stand-alone practice)
 - › 2–3 payers (1–2 attached to practice also in the room – commercial, CMS)
 - › 2–3 molecular pathologists/laboratory directors
 - › Representatives from AACR (GENIE)/ASCO/NIH (All of Us and NCI Lung-MAP)
- d. Pre-meeting materials may include:
 - i. Prepared document with discussion topics, considerations, and potential suggestions for review by roundtable participants
 - ii. PowerPoint presentation for roundtable discussion
 - iii. Press release
 - iv. Blog, website and social media content
 - v. Email to membership and other identified partners

Phase 2: Report/Recommendations

- a. Value data
- b. Clinical recommendations
- c. Operational recommendations
- d. Influence on guideline development bodies (such as NCCN) and payers
- e. Willingness of attendees to kick off studies at their institution
- f. Request attendees to advocate for this topic during future speaking engagements

CONCLUSION

Many organizations within the personalized medicine community have emphasized the importance of driving a better understanding of the clinical utility of genomic profiling in cancer care amongst all stakeholders, including payers and providers. This project is PMC's answer to that call.

STUDY 8 (Not Fully Funded)

Addressing Practice Gaps in the Implementation of Personalized Medicine in Cancer Care

BACKGROUND

Predictive biomarker testing to help identify patients who could benefit from targeted therapies is a cornerstone of personalized medicine in cancer care, informing treatment decisions that can lead to better patient outcomes and improve the efficiency of the health care system. Predictive biomarker testing technologies are relatively new, however, and providers face several barriers as they seek to integrate the tests into clinical work streams. For example, although more than 30 percent of patients with non-small cell lung cancer (NSCLC) have tumors that are linked to genetic driver mutations, many NSCLC patients do not receive genomic testing. Furthermore, a recent Personalized Medicine Coalition report has estimated that only 65–75 percent of NSCLC patients with an actionable mutation as determined by genomic testing actually receive targeted therapies.

A recent analysis by Diaceutics estimated that more than 30 percent of cancer patients in the U.S. never receive targeted therapies that they may have benefitted from. The practice gap between patients that are eligible for targeted therapies and those that receive them is attributed, in part, to:

1. Limited access or availability of predictive biomarker tests;
2. Sample processing constraints;
3. Test performance;
4. Challenges related to reporting and interpretation of test results;
5. Limited access to targeted therapies; and
6. Lagging awareness of the rapidly evolving field of personalized medicine.

In order to help optimize the clinical use of genomic testing in cancer care and to accelerate the clinical adoption of personalized strategies, a better understanding of the associated clinical practice gaps is necessary.

OBJECTIVE

This project will utilize the Diaceutics Global Diagnostic Index (GDI) database to examine the practice gaps associated with biomarker testing-informed personalized medicine strategies in NSCLC care. The study will draw conclusions about specific practice challenges, including those related to test access and availability, sample processing, test performance, test interpretation, and utilization of results. The study will also estimate the impact that each of these factors has on the delivery of personalized cancer care. Implementation challenges will be considered as part of a matrix of elements contributing to the overall biomarker testing practice gap. The final report will offer testing optimization recommendations.

The results will be included in a report whose purpose will be to provide key personalized medicine stakeholders, including providers, payers, clinical guideline developers, pharmaceutical and diagnostic manufacturers, and patients with insight into how biomarker testing is being implemented throughout the health care system and the impact of several potential implementation barriers. These insights can inform efforts to optimize predictive biomarker testing in clinical practice and therefore help drive the delivery of personalized medicine to all cancer patients who can benefit.

PROJECT OUTLINE

The project, to be completed in 6–9 months, will involve the development of a matrix of practice elements contributing to sub-optimal use of personalized medicine strategies in cancer care and will estimate the impact of each practice element toward the overall clinical practice gap.

Research will utilize existing data sets from the GDI database, which includes practice-level data for approximately 260,000 NSCLC patients who were diagnosed between October 2018 through September 2019, showing their testing rates, test performance, and treating habits.

A project steering committee will help guide matrix design and assure that results are meaningful to key audiences.

The project's aim is to assess the practice gaps related to biomarker testing and targeted therapy in NSCLC in general. The study will not compare technology platforms.

Based on the analysis, PMC will make clinical implementation recommendations, which will be published as a white paper alongside the results.



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.



