



Addressing Disparities in Research Informing Personalized Medicine

Executive Summary

Personalized medicine offers significant promise to improve health outcomes through the delivery of more individualized care and targeted therapies. The success of the personalized approach, however, depends on the inclusive representation of patients with diverse characteristics and health needs in research studies about the clinical applications of emerging treatments and technologies. The current clinical research ecosystem has historically underrepresented racial and ethnic minorities, older adults, women, LGBTQIA+ populations¹, persons with disabilities, and socioeconomically disadvantaged communities. For these underrepresented biomedical research (UBR) communities, systemic disparities and research participation barriers persist even in disease

areas characterized by elevated incidence and mortality counts among understudied patient populations. This significantly limits the potential for better health outcomes.

To better understand and develop strategies to address personalized medicine research disparities, the perspectives of stakeholders representing underrepresented communities must be considered. Here, we describe eight actionable recommendations, developed through a wide-ranging community-engagement process, that can help address barriers in two priority areas that have historically limited diversity and inclusion in personalized medicine research.

¹ LGBTQIA+ is used as an inclusive term for the various gender identities and sexual orientations, including lesbian, gay, bisexual, transgender, questioning, queer, intersex, asexual, and pansexual, as defined by the National Academies of Science, Engineering, and Medicine (NASEM)'s report titled *Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups* (2022).

Objectives

The following eight recommendations are designed to achieve two priority objectives, as follows:

- 1 **Empowering** community engagement in research; and
- 2 **Expanding** the intentional collection and use of inclusive health data (see Table 1 below).

Table 1: Recommendations to Address Disparities in Research Informing Personalized Medicine

EMPOWER COMMUNITY ENGAGEMENT IN RESEARCH	
Recommendation	Expected Impact
1 Provide resources for community-based organization (CBO) programs to enhance research participation.	CBOs are trusted entities among many UBR communities. Thoughtful investment and capacity building for CBOs can help build lasting pathways for community participation in research and make it easier to recruit diverse participants.
2 Empower and provide necessary support to CBOs to deliver training in research competency to their communities and to deliver diversity and cultural competency training to researchers.	When a CBO is given the responsibility to represent a UBR community in the context of research and is directly consulted on educating researchers, it sends a clear message about the needs of the community being a priority for personalized medicine research.
3 Increase funding for Federally Qualified Rural Health Centers (FQHCs), Urban Indian Health programs, and rural health clinics.	Increased investment in FQHCs and rural health programs, where clinicians have longstanding relationships and trust with community members, can allow for studies to be designed in ways that benefit the community of interest.
4 Require a Community Impact Board (CIB) to provide consultation within Institutional Review Board (IRB) deliberations, and include two community representatives on an IRB.	Empowering CIBs within IRBs will allow for potential cultural or ethical concerns to be addressed early, and can help limit bias and avoid informational gaps that can render the results less externally valid for UBR communities.
5 Foster the recruitment of investigators from diverse backgrounds to conduct personalized medicine research through research sponsor-based initiatives.	Research teams that include leaders with diverse community backgrounds and experiences will be vital to recruiting diverse research participants and assuring development of personalized medicine technologies that are inclusive of patients with a range of health circumstances and experiences.

Table 1: Cont.

IMPROVE THE COLLECTION & USE OF INCLUSIVE HEALTH DATA	
Recommendation	Expected Impact
6 Examine and highlight gaps in existing real-world data (RWD) sources, and intentionally collect UBR community data to fill those gaps.	Intentional collection and curation of RWD on patients from UBR communities will help ensure inclusive representation of all patient populations in newly collected and existing evidence used in personalized medicine implementation and outcomes research.
7 Modify and improve systems to capture and share data on social determinants of health (SDOH) in electronic health records (EHRs).	Availability of standardized SDOH information collected in EHRs can enrich personalized medicine research by ensuring that the unique circumstances of UBR participants are accounted for.
8 Develop and provide resources for community programs designed to ensure that research information is collected, used, and shared responsibly.	Community transparency regarding the empowerment of research participants to make decisions regarding the collection and use of their own research data will help alleviate community perceptions on the potential for data misuse and build community trust in the personalized medicine research enterprise.



Methodology

The five-step process for developing the above recommendations involved a multi-faceted approach incorporating review of available literature, insights from community leaders and experts working to address challenges to equitable research participation, and input from individuals within or working with UBR communities (see Figure 1 on the following page).

Key to this community-engagement approach was the formation of an iterative engagement with a Health Equity Task Force (HETF) comprising 25 research, data management, and community leaders who are part of or are working directly with underrepresented communities (see link to Digital Appendix A at the end of this document). Members of the HETF shared insights into factors leading to disparities in health data used in the research and development of personalized medicine technologies (steps three and four shown in Figure 1). Through the Community Network Input process, 63 respondents from

within HETF member networks identified priority recommendations, rated their impact and feasibility on a scale of 1-5, and suggested refinements (step four shown in Figure 1). (See also link to Digital Appendix C at the end of this document).

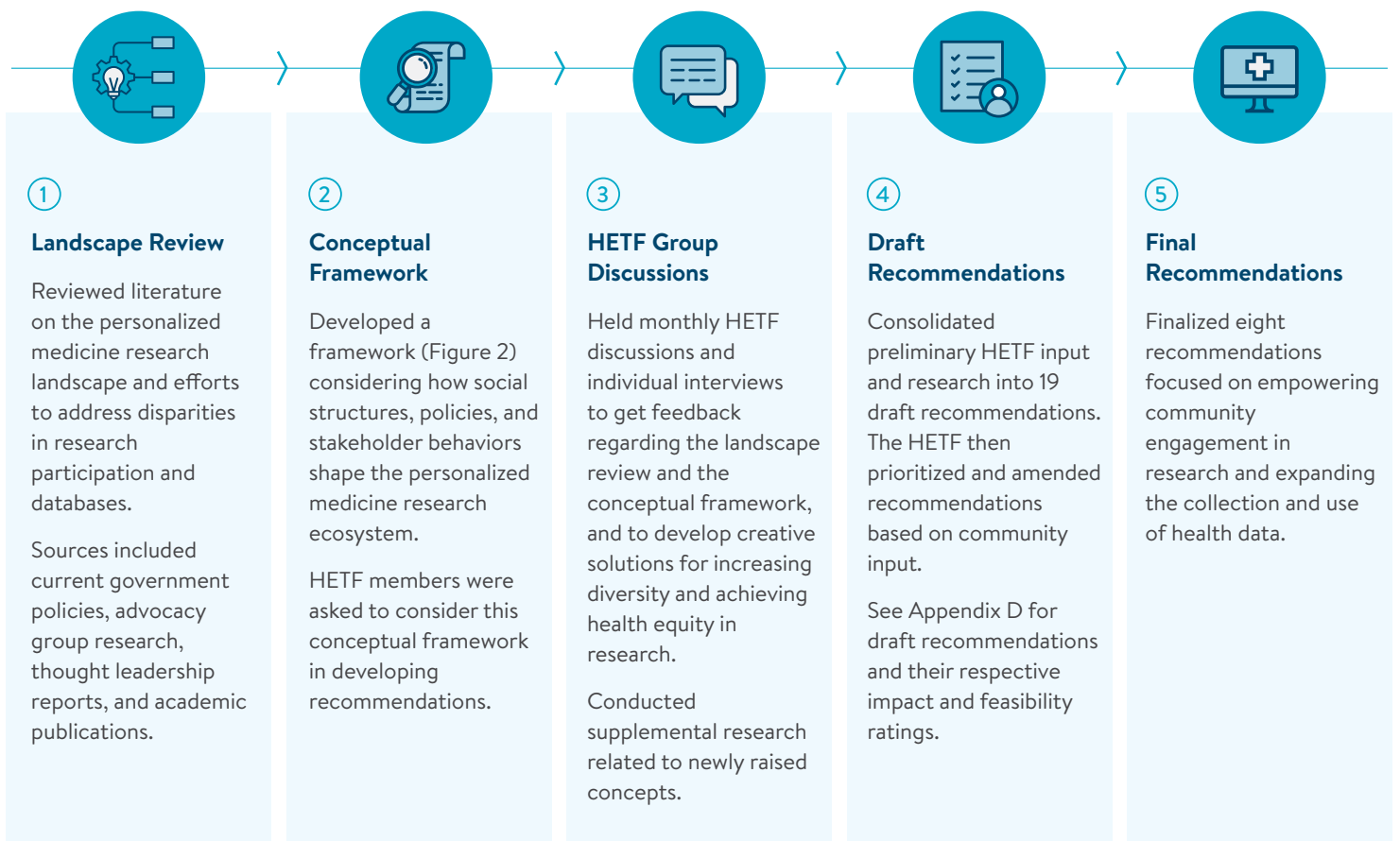
A conceptual framework that captures the interplay between policies, social structures, and stakeholders' behaviors that shape the personalized medicine research ecosystem was also developed based on the initial landscape review. HETF members were encouraged to consider how these domains interconnect to drive accountability in advancing health equity (see Figure 2 on page six of this document).

The recommendation development process resulted in the selection and refinement of eight final recommendations that underrepresented communities believe are important to operationalize for the improvement of diversity and inclusion in personalized medicine research.

Figure 1: A Five-Step Process for Developing Community Recommendations to Improve Diversity and Inclusion in Personalized Medicine Research

Health Equity Task Force (HETF) (n=25)

Assembled 25 research, data management, and community leaders who are part of or are working directly with underrepresented communities (Appendix A) to help elucidate the factors that lead to disparities in personalized medicine research data, and to help develop and refine recommendations to address these disparities and improve inclusiveness. HETF members engaged their respective communities in developing, prioritizing, and refining recommendations.



HETF Individual Interviews (n=21)

Conducted 21 candid, in-depth interviews with HETF members using an open-ended discussion guide (Appendix B).

Community Network Input (n=63)

HETF members engaged members from their communities to provide input on draft recommendations. 63 respondents identified three priority recommendations, rated their impact and feasibility on a scale of 1-5, and suggested refinements. See Appendix C for a breakdown of respondents by stakeholder group.

Anticipated Impact

Empowering UBR communities in the personalized medicine research enterprise, including in decision-making related to the collection, use, and sharing of health data, will increase research engagement and help establish community influence and authority.

This includes building partnerships between empowered UBR communities and personalized medicine research programs that will improve scientific and social engagement competencies and capacities. The recommendations for new academic and clinical research ecosystem policies that give UBR communities an important stakeholder role in planning and conducting research have significant potential to raise the perceived trustworthiness of research institutions.

Expanding the collection and use of diverse and inclusive health data for personalized medicine clinical and implementation research will help ensure that the understanding of the benefits, risks, and access challenges for personalized medicine products and services reflects the views of all patients, including those traditionally underrepresented in health research data. Understanding gaps in existing data sources and consistently collecting information from UBR communities when building new data sources, including on social determinants of health, will allow researchers to account for existing inequities, ensure that newly acquired data is inclusive, and avoid drawing conclusions that may be biased or flawed based on incomplete data sets.



Implementation

These recommendations are meant to provide personalized medicine research stakeholders, including policymakers, research sponsors, research institution leaders, research teams, community organizations, health database organizations, and research participants with strategies to address disparities in personalized medicine research data. Each of these stakeholders influence complex and interconnected personalized medicine research system domains of policies, structure, and behaviors. Achieving meaningful implementation of these recommendations and fostering accountability for improving inclusivity in personalized medicine research will require an understanding of stakeholder influences within these domains, including an understanding of how each domain affects and is affected by the others.

The recommendations call for change across policy, structural, and behavior-based domains. To empower UBR communities in personalized medicine research, advocates, policymakers, and other decision-makers must first advance policies that provide resources for developing and sustaining community-based participatory programs and partnerships. Policies should be designed to enhance inclusiveness in research, enact community-based authorities in IRBs, and establish research institute incentives to diversify research leadership. Health information technology stakeholders must also develop and advance policies that commit and enable stakeholders to expand the collection and use of diverse and inclusive health data by, for example, accounting for gaps in existing data

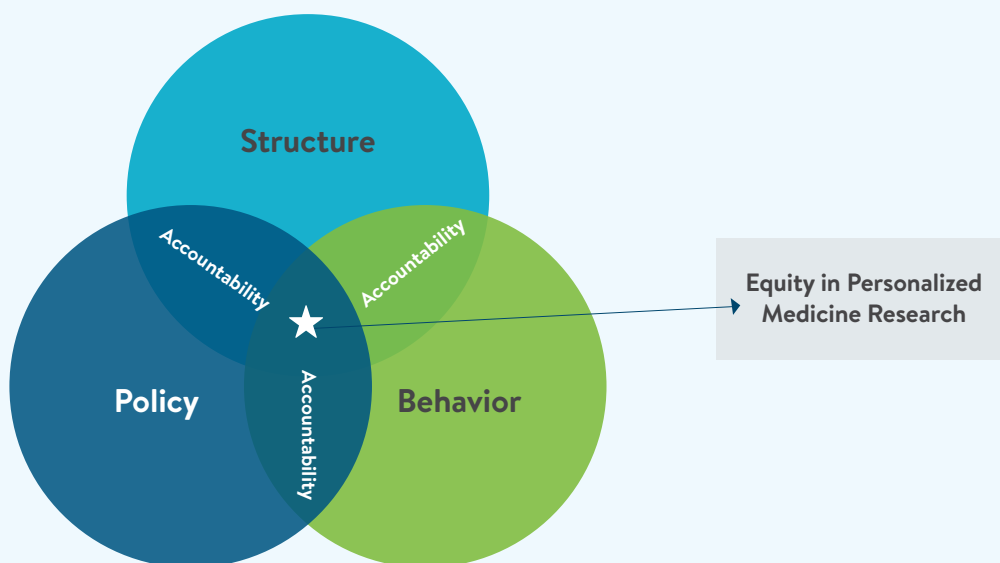
sources and intentionally collecting data from UBR communities to fill those gaps; establishing standards and systems for capturing social determinants of health in electronic health records (EHRs); and ensuring health data systems are administered with information privacy and security standards that are acceptable to UBR communities.

These public and private policies will help achieve and sustain structural changes related to real-world evidence databases, EHRs, Institutional Review Boards, research institution incentives, and programs and partnerships between community-based organizations, Federally Qualified Rural Health Centers, personalized medicine researchers, and other diversity, equity, and inclusion stakeholders whose commitments are needed to better capture the unique circumstances of UBR research participants and drive toward inclusive personalized medicine research data.

Bringing forward these policies and structural changes will require key behavioral actions, including motivated stakeholder advocacy, public-, private-, and community-level recognition of the value of inclusiveness in research, and stakeholder dedication to executing strategies that ensure research is inclusive. These policies and programs will also foster and depend upon behavioral changes related to community trust, partnership, and a willingness to be involved in personalized medicine research.

While many efforts are already underway to address disparities in health care research, these recommendations, focused on action in the interrelated domains of policy, structure, and behavior, can have a strong impact in ensuring that personalized medicine research becomes more diverse and inclusive of all patients.

Figure 2: Conceptual Framework: Personalized Medicine Research System Domains Related to Research Data Equity





About the Personalized Medicine Coalition (PMC)

The Personalized Medicine Coalition convenes over 230 organizations representing innovators, scientists, patients, providers, and payers to promote the understanding and adoption of personalized medicine concepts, services, and products to benefit patients and the health system.

Link to Digital Appendices

<https://www.personalizedmedicinecoalition.org/research/disparities-in-research/>

- Appendix A: PMC Health Equity Task Force
- Appendix B: HETF One-on-One Discussion Guide
- Appendix C: Community Network Input by Stakeholder Group
- Appendix D: Community Ratings for Draft Recommendations

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