

# Addressing Disparities In Research Informing Personalized Medicine

Recommendations from Underserved Communities

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A RESEARCH REPORT



# Table of Contents

Introduction	1
<b>PART I – Background</b>	<b>2</b>
<b>PART II – Introducing Underserved Community Recommendations</b>	<b>4</b>
Research Methodology	4
Community Recommendations	8
<b>PART III – Implementation Framework</b>	<b>29</b>
Policy, Structure, and Behavior	29
Conclusion	31
Link to Digital Appendices	32
References	33

# Introduction

Physicians have long recognized that basing healthcare decisions on one-size-fits-all assumptions risks overlooking the needs of biologically and culturally unique patient populations. With its emphasis on tailoring care more closely to the biological characteristics, circumstances, and values shaping each patient's disease trajectory and experiences with the health system, personalized medicine is designed to shift healthcare toward more targeted prevention and treatment strategies that can make healthcare more efficient, effective, and equitable for everyone.

The success of the personalized approach depends on an inclusive biomedical research environment that fosters a trusting relationship between researchers studying the potential of new technologies and treatments and underserved patients who may benefit from the use of tests and therapies in clinical settings. But the current clinical research system has historically underrepresented racial and ethnic minorities, older adults, women, LGBTQIA+ populations\*, persons with disabilities, and socioeconomically disadvantaged communities. Systemic disparities and barriers for these underrepresented biomedical research (UBR) communities persist even in disease areas characterized by elevated incidence and mortality counts among understudied patient populations. This circumstance undercuts the promise of personalized medicine and significantly limits the potential for achieving better health outcomes through targeted medical interventions.

The following report reviews recent public and private sector efforts to promote diversity and inclusivity in biomedical research, introduces underserved communities' perspectives and recommendations for addressing research participation barriers, and considers implementation strategies that could pave the way toward better, more targeted healthcare for underserved patients and their families.

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\*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 (NAEM). *Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups* (2022)

## PART I

# Background

Over the last two decades, less than half of trials reported race and ethnicity data.<sup>1</sup> For those trials that did report race and ethnicity, 85 percent of clinical trial participants were White with European ancestry.<sup>2,3,4</sup> In genome-wide association studies, less than two percent of study subjects are of African or Hispanic/Latin American ancestries.<sup>5</sup> Similar disparities have existed related to gender, age, disability, and social and economic factors.<sup>4</sup>

In 1993, the *National Institutes of Health (NIH) Revitalization Act* was signed into law, requiring the inclusion of women and minorities in federal clinical research.<sup>6</sup> Five years later, the U.S. Food and Drug Administration (FDA) issued the demographic rule in the *Code of Regulations for Applications for FDA Approval to Market a New Drug*.<sup>7</sup> The demographic rule ensured that clinical trial participants' gender, age, and race information is included in the New Drug Approval (NDA) process. In April 2022, nearly 20 years later, FDA published draft guidance titled *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials*,<sup>8</sup> which provides sponsors of medical products with nonbinding recommendations for improving diversity enrollment in their clinical trials. FDA suggests that sponsors should submit diversity plans for engaging with underrepresented communities. Despite these federal policies, participation of diverse populations within clinical trials remains low.

Personalized medicine research, which relies upon recognizing variability between patients, suffers from this lack of diversity among participants in clinical trials. For example, according to a *JAMA* study reporting the proportion of race representation in trials supporting targeted oncology drug approvals, expected representation based on population prevalence is significantly off for major racial and ethnic groups.<sup>9</sup> Black and Hispanic participants were significantly underrepresented (only 22 and 44 percent, respectively, of the expected proportion of patients within the full cohort) and Asian participants were overrepresented (438 percent of the expected proportion of patients). This imbalance is particularly concerning considering that Black and Hispanic populations have a larger burden of incidence of certain cancers.<sup>10</sup> With these known diversity gaps in clinical trial participation, a recent study published in *Health Affairs* quantitatively demonstrated how the risk of underrepresented samples could lead to biases and false associations regarding the under-studied populations, a significant concern for personalized medicine.<sup>11</sup> A [patient-centered research agenda](#) for advancing personalized medicine, published by PMC in 2020, identified the

active engagement of underrepresented populations in personalized medicine research as one opportunity to help ensure personalized medicine treatment strategies better align with diverse patient needs.<sup>12</sup> Underrepresented populations can include racial and ethnic minorities, older adults, women, LGBTQIA+ populations, persons with disabilities, and socioeconomically disadvantaged people.

In 2017, the U.S. Department of Health and Human Services (HHS) released a report identifying the “five primary social and economic constructs that can influence cancer outcomes and research participation.”<sup>13</sup> These include economic stability, education, neighborhood and environment, health and healthcare, and social and community context. The report has led to a rise in patient engagement strategies that attempt to build constructive partnerships between researchers and underrepresented communities.

The NIH *All of Us* Research Program (*All of Us*) provides an example of a government program determined to improve diversity within research cohorts. Launched in 2015, the goal of *All of Us* is to enroll one million or more participants in the program to study improved healthcare through large-scale data collection.

Community organizations have also taken steps to advance diversity in personalized medicine research. For example, the Institute for eHealth Equity has launched pilot programs across three cities in the United States and partnered with faith-based organizations in the area to try to increase patient utilization of health information technology.<sup>14</sup> Community engagement can extend across industry, such as through public-private partnerships affiliated with the [DiME Project](#) at the Digital Medicine Society, which is working to optimize patient care and health outcomes for all communities.<sup>15</sup> The Health Equity Initiative recently released a report highlighting the importance of aligning healthcare technologies and services with the needs of diverse patient populations.<sup>16</sup> The Multi-Regional Clinical Trials (MRCT) Center at Brigham and Women’s Hospital and Harvard University has focused on innovative and practical measures to increase diverse and inclusive representation in the clinical research enterprise, including publication of a diversity guidance document, tool kits, and other resources that address personalized medicine research.<sup>17,18</sup>

## PART II

# Introducing Underserved Community Recommendations

## Research Methodology

To help guide public and private sector institutions working to promote inclusive biomedical research, PMC engaged a cohort of individuals from UBR communities to develop key engagement recommendations. The research and recommendation development process involved a literature review, discussions with UBR community leaders who served on the study's Health Equity Task Force (HETF), and an HETF member-administered survey of people within various UBR communities. The process involved a thorough examination of the barriers that lead to and continue to perpetuate racial, ethnic, demographic, and socioeconomic inequalities in research. The resulting recommendations reflect the perspectives and needs of communities that have traditionally been underrepresented in personalized medicine research.

### RECOMMENDATION DEVELOPMENT APPROACH

The following activities took place beginning in May of 2022 and ending in January of 2023.

- ① **Conducted** a literature review of the personalized medicine research landscape related to diversity and equity insights and ideas.
- ② **Developed** a conceptual framework.
- ③ **Organized** an interdisciplinary racially, culturally, and perspective-diverse Health Equity Task Force (HETF).
- ④ **Conducted** in-depth one-on-one interviews with HETF members using an open-ended discussion guide to structure conversation.
  - Drafted preliminary recommendations.
- ⑤ **Facilitated** diverse community feedback through the community networks of HETF members.
  - Developed priority recommendations.

## 1. Conducting a Literature Review

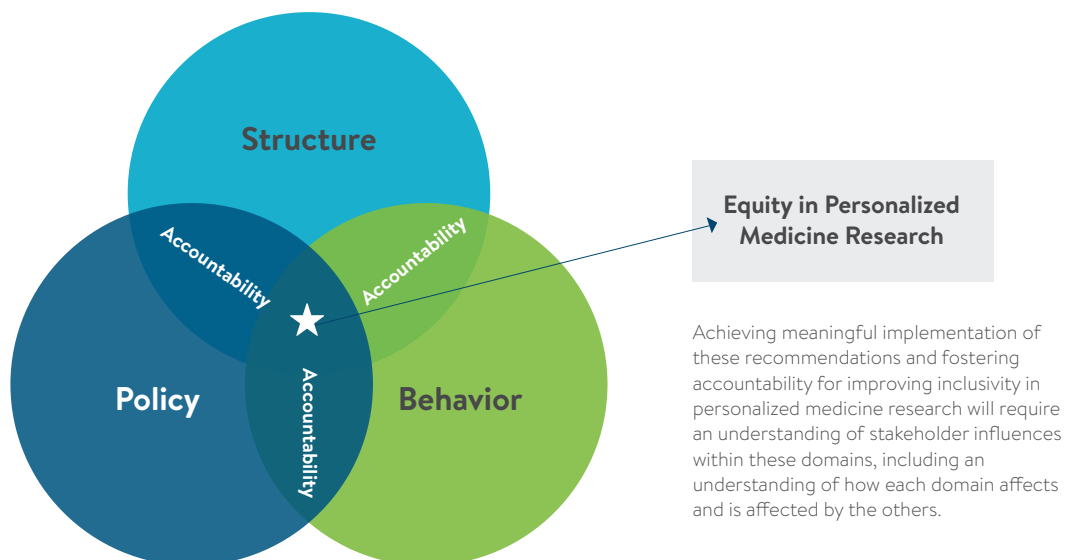
A thorough review of available literature related to the personalized medicine research landscape and efforts to address research participation and database disparities served as a foundation for community discussions from which recommendations were developed. Sources of information included a combination of current government policies, advocacy group research, thought leadership reports, and academic literature. The review was later augmented to support concepts raised during HETF meetings, focus groups, and one-on-one discussions with Task Force members. The initial review of the personalized medicine landscape and body of knowledge was conducted between May and July of 2022, with the goals of understanding the current status of equity in personalized medicine research and clinical trials and identifying best practices.

## 2. Developing a Conceptual Framework

The literature review provided a basis for building a framework that considers complex domains throughout the personalized medicine research ecosystem, including research infrastructure, policies, and the behaviors of various research stakeholders. Recommendations aimed at addressing barriers that have led to disparities in personalized medicine research were developed with consideration of these domains and how they are interconnected. Community leaders were asked to consider this conceptual framework when developing recommendations.

The conceptual framework was developed to illustrate how stakeholders within these groups influence complex personalized medicine research system domains of policy, infrastructure, and behaviors.

**Figure 1:** Conceptual Framework: Personalized Medicine Research System Domains Related to Research Data Equity



### 3. Organizing a Health Equity Task Force

The HETF consists of 25 research, data management, and community leaders who are part of or are working directly with UBR communities (Appendix A). The Task Force was assembled to help elucidate the factors that lead to disparities in health data used in the research and development of personalized medicine technologies. Its members were asked to consider the conceptual framework to help develop and refine recommendations to address disparities and improve inclusiveness.

Perspectives included academia, clinical research, industry, government, provider groups and healthcare organizations, patient advocacy institutions, UBR advocacy groups, and community/faith-based organizations. To ensure diversity and balance across the HETF, the following criteria were applied to identify potential members:

Members must...

- Represent a key stakeholder impacted or engaged in personalized medicine research.
- Understand and bring a perspective across the broad definition of diversity.
- Have an established network to engage for community input and feedback.
- Align to the mission and goals of personalized medicine research.

Once identified and accepted, the HETF members were offered honorariums for their time and commitment to a set of core responsibilities. The HETF was engaged in monthly group meetings, break-out focus groups, one-on-one discussions, and individual community outreach.

### 4. Conducting Expert Interviews/Developing Preliminary Recommendations

Drawing on insights gained from landscape research and initial HETF group discussions, 21 one-on-one discussions with HETF members were conducted. An open-ended discussion guide was used to balance discussion cohesion and flexibility (Appendix B). The discussion guide and questions were designed to encourage candid, in-depth conversations in which thoughtful and creative solutions for increasing diversity and achieving health equity could be explored. These topics were brought forward for additional HETF group discussions and supplementary concurrent research.

Utilization of the open-ended discussion guide was unique to each HETF member based on the member's specific areas of expertise. Certain questions were explored more deeply for some HETF members as appropriate to their backgrounds. Not all questions in the discussion guide were asked or addressed by each Task Force member; rather, as conversations naturally developed, potential questions and areas of inquiry not listed were explored.

From the literature review and discussions with HETF members, a set of 19 draft recommendations related to empowering community engagement and improving the collection and use of health data were developed to be considered for prioritization through the community feedback phase. These topics were brought forward for additional discussion by the full HETF group during subsequent HETF meetings and supplementary concurrent research. The HETF, in turn, provided reactions to the preliminary recommendations as well as guidance on collecting broader community feedback.



## 5. Soliciting Community Network Input/Developing Priority Recommendations

The HETF circulated the draft recommendations within their respective communities and engaged with at least three community members each to seek feedback on the draft recommendations and to refine and prioritize them based on perceived impact and feasibility. A total of 63 responses were recorded. A breakdown of community members' stakeholder groups and professions is shown in Appendix C. Each respondent rated each recommendation on a scale of 1–5 for their perceived potential for impact and feasibility of implementation, and then were asked to prioritize three recommendations for actionability. For the full set of draft recommendations with their respective impact and feasibility ratings, please see Appendix D.

The engagement of community members was left to the discretion of HETF members; however, supporting materials (email templates, FAQs sheets, and a PowerPoint) were provided to help facilitate conversations and feedback.

The preliminary recommendations were vetted, amended, and refined. The eight recommendations that received the most buy-in from community members and the highest perceived feasibility and impact ratings were selected for inclusion in the final recommendations.

## Community Recommendations

### OVERVIEW

The eight priority recommendations fell into two primary categories: 1) Community Empowerment and 2) Intentional Collection and Use of Inclusive Health Data. The set of actionable recommendations within these two priority categories are meant to provide personalized medicine research stakeholders, including policymakers, research sponsors, research institution leaders, research teams, community organizations, and research participants, with prioritized strategies to counteract inequities in personalized medicine research.

Every stakeholder is influenced by independent but interconnected domains of structures, policies, and behaviors (See Figure 1). An action that affects one domain, for example enactment of a new policy, will have implications for the other domains, for example updated structures or incentivized stakeholder behaviors. An understanding of the interplay of each of these domains on each recommendation and sub-recommendation are important in realizing their potential impact in helping to address disparities in personalized medicine research and in determining strategies for their implementation.

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

EMPOWER COMMUNITY ENGAGEMENT IN RESEARCH	
1	Provide resources for community-based organization (CBO) programs to enhance research participation.
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.
3	Increase funding for Federally Qualified Rural Health Centers (FQHCs), Urban Indian Health programs, and rural health clinics.
4	Require a Community Impact Board (CIB) to provide consultation within Institutional Review Board (IRB) deliberations, and include two community representatives on an IRB.
5	Foster the recruitment of investigators from diverse backgrounds to conduct personalized medicine research through research sponsor-based initiatives.

Table 1: Cont.

### IMPROVE THE COLLECTION & USE OF INCLUSIVE HEALTH DATA

- ⑥ Examine and highlight gaps in existing real-world data (RWD) sources, and intentionally collect UBR community data to fill those gaps.

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- ⑦ Modify and improve systems to capture and share data on social determinants of health (SDOH) in electronic health records (EHRs).

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- ⑧ Develop and provide resources for community programs designed to ensure that research information is collected, used, and shared responsibly.

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### A CLOSER LOOK: EMPOWERING COMMUNITY ENGAGEMENT IN RESEARCH

The HETF indicated that the top priority for addressing personalized medicine research disparities should be empowering UBR communities throughout the research enterprise by assuring an appropriate and significant role for UBR representatives in planning and conducting research, recruiting participants, and making decisions related to collecting, handling, and sharing data. This will not only improve community interest and influence on personalized medicine research but will also lead to a necessary and appropriate level of community authority within the research agenda. Structural and policy initiatives to build the necessary partnerships linking empowered UBR communities with personalized medicine researchers can drive key stakeholder behaviors, especially related to scientific and social engagement competencies and capacities.

The following pages describe in detail each of the five community engagement recommendations, including a justification for inclusion as well as implementation and accountability considerations.

#### RECOMMENDATION 1

Provide resources (funding, training, partnership building, and other development and sustainability support) for community-based organizations (CBOs) to enhance research participation.

*“CBOs are heavily involved in advocating for their communities’ health and should receive support to help increase research in the community.”* – HETF Member

## **Justification**

Biomedical research is typically conducted in urban areas with well-funded academic medical centers, which tend to have fairly homogenous populations that skew both wealthy and White. Partnerships with CBOs can effectively reach more diverse and less centralized populations. However, these types of partnerships have historically been overly transactional, with researchers utilizing CBO resources and connections but having limited investment in the CBO beyond the scope of the research project.<sup>20</sup> There has been a tendency for biomedical researchers to only interact with CBOs when participation is needed for a study, which can limit the strength of these researcher/CBO relationships and lead to breakdowns in trust.<sup>21</sup> More thoughtful investment and capacity building for CBOs can help build longer lasting community participation and easier research study recruitment.<sup>22,23</sup>

Personalized medicine carries a unique message about delivering better care to patients based on their individual traits and circumstances. This message has significant potential to resonate with CBOs and their community members and has been well-received by underserved patient communities in the past.<sup>24</sup> Thus, it should be highlighted by CBOs to drive participation in personalized medicine research studies. Investing in CBO capacity includes ensuring the organization can access wraparound services such as translation and transportation that support their educational, recruitment, and coordination efforts. Providing capacity for wraparound services to these CBOs will allow potential UBR participants to make informed decisions and improve their capability to participate.<sup>22</sup> It will also make CBOs and potential participants more likely to invest their time and energy, making recruitment easier.<sup>23</sup> Finally, as shared by UBR participants in the HETF, building robust, long-lasting relationships with their communities has significant potential to directly impact the perceived trustworthiness of research institutions within UBR communities. Maintaining long-lasting relationships provides the foundation for building trustworthiness and will be key to sustaining improvements in representativeness.

CBOs can engage their respective communities through several avenues, which include educating potential research participants in that community, often referred to as community-based clinical trial education (CBTE), or the coordination and recruitment of participants for decentralized community-led research, often referred to as community-based participatory research (CBPR). CBTE conducted by a CBO focused on the importance of participation in clinical research can significantly increase the understanding of clinical research programs and practices in traditionally difficult-to-reach populations.<sup>25</sup> CBPR, likewise, has been shown to increase broader community participation connected to larger academic research hubs.<sup>26</sup> Personalized medicine technologies manufacturers can also develop CBPR. For example, Eli Lilly and Company has a partnership with the Network for Excellence in Health Innovation (NEHI) to form a community focused research organization (CFRO) aimed at promoting diversity in clinical trial participation.<sup>27</sup> By enlisting CFROs as equitable research partners, this strategy can help foster empowerment and capacity building within the community directly.<sup>28</sup>

## Implementation and Accountability Considerations

CBO leaders may be concerned about the lack of bidirectional communication and resource sharing of traditional clinical research processes. For personalized medicine research to elicit the robust community response desired for more representative cohorts, research studies must be designed to mutually benefit both the research team and the community that the CBO represents.<sup>20</sup>

Providing resources for CBO programs focused on enhancing diversity in biomedical research will require community engagement, capacity building, and grant allocation, and will have to take into account technology access and long-term sustainability. Programs should optimize contributions of community-based healthcare professionals such as community health workers and provide accessibility services (language translation, transportation) to study participants. Programs that involve developing and implementing educational opportunities that enhance community member personalized medicine literacy may be positioned for greater success. Research participant feedback loops should be created to help evaluate programs.

For investment in CBO capacity to become more ingrained in the personalized medicine research ecosystem, a coalition of like-minded institutions and CBO networks may be necessary. Resource allocation will need to be led by federal and private research institutions that are committed to improving research data diversity along with underrepresented community organizations that advocate for equitable healthcare. It will be important to also identify clear measurement tools and metrics to quantify impact. To ensure shared vision and goals, trusted community partners should be empowered to lead discussions and gather feedback about equity in personalized medicine research.

NIH's *All of Us* program employs a CBPR approach based on a community engagement partner network to recruit one million participants in a longitudinal personalized medicine research program. *All of Us* has invested in relationships with CBOs to conduct research within the community. This framework can serve as an example for any research funding institution wishing to undertake a similar approach.<sup>29</sup> *All of Us* is centered on institutional buy-in regarding the benefits of community-driven research, with CBO funding and capacity building becoming part of the regular grants administration process and with bidirectional resource and information sharing at the heart of its operations.

## RECOMMENDATION 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 personalized medicine researchers.

*“CBOs recruit, educate, and enroll in-house so everything is happening within the community. We try to educate community members about research as much as possible.”* — CBO leader

### Justification

Cultural competency, accessibility, and diversity, equity, and inclusion (DEI) training for researchers is part of NIH research guidelines<sup>30</sup> under the agency’s Office of Equity, Diversity, and Inclusion. However, the value of current DEI training efforts for researchers and medical professionals is not clear to all those who might participate in them.<sup>31</sup> While there have been indications of some positive effects from accounting for diversity in research studies, questions exist about a lack of lasting influence and reliance on delivery mediums that may not adequately address the concerns and realities of UBR populations.<sup>31,32</sup> Consultants that are brought in to conduct diversity, cultural competency, and accessibility training for researchers often lack direct expertise in, or connection to, diverse populations. While both guidelines and best practices are helpful, they do not provide robust education on ethical and cultural humility.<sup>33</sup> Research studies would likely benefit from another approach to DEI and cultural competency training.

CBOs are likely in a better position to provide training. CBOs are a part of UBR communities, bringing a direct perspective to community considerations and a greater likelihood of perceived trust of the represented community. Many CBOs already are engaged in community-academic partnerships. The most effective strategies implemented to reach UBR communities center around displaying respect, displaying a caring attitude, and sharing information with the community.<sup>34</sup> CBO-led DEI and cultural competency training can be effective and help foster greater UBR community involvement when CBOs are treated as valued partners and educators.<sup>35</sup> Additionally, when a CBO is charged with representing 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 that research institution.

## Implementation and Accountability Considerations

Funding CBOs for the purpose of cultural competency, accessibility, and DEI training can build bridges in these communities where investigators are interested in building long-standing relationships. However, competency training and the development of trust have not always been bidirectional. CBOs sometimes describe community-academic partnerships as negative due to researchers having limited interest in attaining information about community considerations and in sharing information and grant resources towards community engagement.<sup>20</sup> This can lead to negative viewpoints towards researchers on the part of CBOs and to breakdowns in trust. It will therefore be imperative to assure bidirectional interest in being involved in education, research design, human subject protection, and program evaluation.<sup>36</sup>

An example of implementing CBO-led DEI, accessibility, and cultural competence training in the personalized medicine ecosystem is a CBPR program run by the University of Arkansas for Medical Sciences (UAMS).<sup>37</sup> This pilot program involved a community-informed needs assessment followed by a two-year training series. Community healthcare workers and research leaders reported high levels of change in community knowledge, cultural competency, and understanding.<sup>38</sup> This led to research policy changes at an organizational level.

While the UAMS example lays out a structure for CBO-driven training, policies and community behavior considerations will also need to be considered. Consistent inclusion of CBO-led training as part of standard operating procedures will require grant funds to be set aside for these purposes. It will be vital to develop a consistent funding stream with allocation targets set through federal and private sponsor policy that will provide the resources for personalized medicine research to include a CBO tie-in and built-in diversity training. A move toward compensating community health workers and engaging them in CBO cultural competency training would also benefit programs. CBO training programs would be perceived as more credible and are likely to be more sustainable with consistent and sustainable funding and reimbursement models that support community healthcare worker involvement.

The broad adoption of CBO-led training will also require community and research team recognition of the value of community-driven diversity, cultural competency, and accessibility training. While policies can mandate adherence at an individual organization/institution level, to be adopted more broadly, professional and trade associations with strong ties to research institutions must also participate in a change of culture through coalition building and building evidence regarding the efficacy of this approach. Cultural change will require advocacy and awareness efforts throughout the personalized medicine and DEI communities. With policies in place, and with cultural evolution through increased awareness and issue advocacy, CBOs will become empowered to take a leadership role in agenda/curriculum setting, staffing, and implementation.

### RECOMMENDATION 3

Increase funding for Federally Qualified Health Centers (FQHCs), rural health clinics, and urban Indian health programs (UIHPs).

*“FQHCs have the ability to unlock the power of personalized medicine research, especially in diseases/conditions that disproportionately impact people of color and the underserved. FQHC data infrastructures regarding race/ethnicity/gender data collection are significantly more robust than many private or larger public systems (e.g., Medicare).”* – HETF Member

#### Justification

FQHCs, rural health clinics, and UIHPs serve diverse communities often consisting of UBR populations. Additionally, their clinicians have long-standing relationships and trust with community members. These organizations provide direct access to diverse patient populations and have a track record of improving UBR representation within research studies.<sup>39</sup> Similar to the dynamic between CBOs and the communities they serve, strong trust can lead to better recruitment and retention rates when paired with greater ease of access to participation and return of results information.<sup>40</sup>

However, these institutions are often overlooked for clinical research studies due to capacity or resource limitations. Systemic challenges for these institutions to participate in personalized medicine research studies include limited investigator bandwidth to lead multiple studies, lack of access to staffing and equipment needed to both conduct the study and serve their communities, and hesitancy to pursue research grants due to competition from highly resourced academic institutions.<sup>41</sup> These challenges often translate into investigators only being able to take on one study at a time while balancing other responsibilities and resources to best serve their communities. This minimizes their ability to conduct meaningful research within the community, despite significant benefits and the potential to improve personalized medicine research. With greater resources, FQHCs, rural health clinics, and UIHPs could bolster their research participation capacities.



## Implementation and Accountability Considerations

To achieve FQHC funding that will advance health equity, several changes in biomedical research funding policy will be helpful, including, first, dedicated funding for community-based research. This funding should be separate from traditional academic research grants and should prioritize projects that engage with and benefit underrepresented communities. Second, community engagement and partnership grants will play a role. These FQHC grants can facilitate collaboration, capacity-building, and trust-building between researchers and the communities they aim to serve. Third is incentives for inclusive research practices. This can include providing additional funding or recognition for projects that actively involve underrepresented populations. Finally, inclusivity in peer review can also move the needle. This will help ensure that peer-review panels include diverse perspectives, including members of underrepresented communities, to evaluate research proposals fairly and prioritize community engagement.

Nonprofit organizations, advocacy groups, researchers, and community organizations can play a crucial role in raising awareness and advocating for funding policy by engaging with policymakers at the federal, state, and institutional levels to promote needed changes. Federal and private sponsors should work closely with experts, stakeholders, and advocacy groups to design and revise funding initiatives, ensure necessary allocation, and establish clear criteria for grant eligibility and evaluation that prioritize community engagement and diversity. FQHCs and individual researchers will be responsible for adapting their research practices to align with the new programs. The federal and private sponsors should establish metrics and benchmarks to assess the impact on research diversity. Regular evaluations and reports should be published to track progress, and all stakeholders should be committed to continuous improvement and adaptation based on the evolving needs of underrepresented communities and the research landscape.

## RECOMMENDATION 4

Require a Community Impact Board (CIB) to provide consultation within Institutional Review Board (IRB) deliberations, and include two community representatives on an IRB.

*“Developing Community Impact Boards [early in the process] is imperative to ensuring personalized medicine research is mutually beneficial for the patient community and health systems.”* – Community member

### Justification

Funding agencies and researchers have increasingly recognized the vital role of community advisory boards (CABs) in CBPR programs.<sup>42</sup> CABs have helped build and formalize the community-academic relationship, often providing community groups with an opportunity to voice their needs and concerns regarding a study. However, CAB engagement is usually limited to a single consult either early or late in the research project.<sup>43</sup> CABs provide useful input regarding research projects, however there is a dearth of potential community advisors with adequate health literacy education. Therefore, improved training programs are needed. Additionally, it would be helpful to develop guidelines that help ensure CAB members’ participation is productive in yielding community-related suggestions and context for researchers.<sup>44</sup>

IRBs are intended as the safety net for ethics, data integrity, and other considerations that may impact a personalized medicine research study. These boards are usually composed of academic/industry insiders who may not understand how the proposed study would affect the community of interest.<sup>45</sup> Empowering communities with representatives in IRBs will allow for potential ethical or cultural 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.<sup>46</sup> Ensuring that CABs participate in IRBs will allow for strong consideration of DEI issues, community engagement, and a stronger emphasis on cultural integrity in research design.<sup>47</sup>

By requiring CAB consultation in all aspects of study design and implementation, protocol development, and program assessment, CABs will be empowered as a partner in research. Renaming these advisory boards as Community Impact Boards (CIBs) emphasizes their direct impact as they are provided with more responsibility to hold researchers accountable. Including at least two CIB representatives on an IRB gives UBR communities a key stakeholder role in the research study and will ensure that a community perspective on ethical and data integrity is considered during the research/study protocol review and approval process.

## Implementation and Accountability Considerations

Creating impactful CIBs requires a commitment to community influence throughout the research community, probably requiring broad IRB policy change that would be considered across all biomedical research studies.

Researchers, IRBs, and CBOs should work together to establish CIBs within IRBs. This includes defining the CIB's structure, membership, roles, and responsibilities, including how CIB representatives are selected. The research institution would be responsible for providing training and capacity-building opportunities for CIB members. This may include training in research ethics, the research process, and relevant regulations, as well as broader health literacy education. Once established, CIBs should hold regular meetings during which they provide input, feedback, and advice on research proposals and protocols as requested from the IRB. Additionally, CIBs should participate as key members in all IRB meetings related to projects being conducted within their communities. Researchers and IRBs should be transparent about the existence and contributions of the CIB. This includes reporting on the impact of community engagement on research outcomes in order to increase transparency and improve trust within underrepresented communities. Creating a DEI body within research institutions may help manage the potential for resource-heavy requirements by CIBs, especially where there are limited numbers of qualified participants.<sup>48</sup> The research institution's DEI body can assess the institution's unique research mission and goals and help manage the necessary resources and engagements.

IRBs and researchers bear significant accountability for creating and maintaining CIBs and ensuring that their contributions are considered. However, the broader research community, including funding agencies, research institutions, and community organizations, also plays a role in supporting and overseeing CIBs to ensure their effectiveness in promoting ethical and inclusive biomedical research. Implementing structural changes to IRB composition for biomedical research and development subject to federal regulatory oversight may bring additional challenges. FDA can and should provide guidance regarding its inclusivity goals.

## RECOMMENDATION 5

Provide resources to foster the recruitment of investigators from diverse backgrounds to lead personalized medicine research studies in underrepresented communities through sponsor-based initiatives.

*“As we work toward increasing the diversity of populations in studies, we should also increase the diversity of the biomedical research workforce. A more diverse workforce in culture, ancestry, beliefs, scientific backgrounds, and methodological approaches brings increased understanding, innovation, trust, and cultural sensitivity; is more likely to pursue questions relevant to different audiences; and ultimately delivers better research.”* – Joshua C. Denny and Francis S. Collins, NIH All of Us Research Program

### Justification

When it comes to biomedical research leadership, there has been systemic underrepresentation of Black people, Indigenous peoples, people of color (BIPOC), LGBTQIA+ persons, and disabled researchers.<sup>49</sup> A career in clinical research requires extensive resources, training, and capacity to dedicate the necessary time at an individual level. Due to cultural factors and the nature of clinical research work, the clinical research career pipeline has historically favored students of European and Asian descent. Furthermore, scientists from many parts of the world, and from disadvantaged groups, have yet to be as engaged in the fields of genetics and genomics, on which much of personalized medicine research is built.<sup>50</sup>

The personalized medicine research pipeline, like the clinical research pipeline more broadly, is rooted in systems that disadvantage students and professionals from lower resource socioeconomic groups and those that do not have a strong existing biomedical research foundation. Structural barriers persist, such as reliance on standardized testing, costs associated with obtaining necessary degrees, and a lack of peer mentorship.<sup>51</sup>

Historically Black colleges and universities (HBCUs), Hispanic-serving institutions (HSIs), and minority-serving institutions (MSIs) have traditionally provided disadvantaged BIPOC students interested in STEM careers with research training opportunities. Many HBCUs have become highly regarded research institutions.<sup>52</sup> However, similar institutions and programs have not traditionally been available for LGBTQIA+ or disabled students interested in research careers. Additionally, MSIs face challenges breaking into the research grant process dominated by elite research institutions, thus providing fewer research opportunities for UBR students and young professionals.

In recent years, several initiatives have attempted to address these academic pipeline and workforce disparities, generally at the federal or state level. However, institutional-level change has remained elusive.<sup>53,54</sup>

Increased diversity within research teams can provide greater diversity of thought and experience to personalized medicine research design, including community outreach approaches. The benefit of increased diversity can be realized through inclusion of members from different UBR communities on research teams; however, individual team members can often fall into several underrepresented community categories at once, allowing for a better understanding of the intersectionality of community issues. Intersectional underrepresented community understanding brought on by diverse research teams will bring the greatest benefit to personalized medicine's promise to provide targeted therapies for a range of conditions for patients with a wide array of characteristics and experiences.

### **Implementation and Accountability Considerations**

While improving diversity in the research workforce will bring clear benefits to addressing disparities in personalized medicine research, it may also be the most challenging strategy to pursue. It is a complex and ongoing process, requiring commitment, resources, and a sustained effort to address systemic biases and disparities within the field.

To improve diversity in the personalized medicine research workforce, a long-term, multi-faceted, and comprehensive approach is necessary. It begins with implementing DEI initiatives that promote a culture of inclusivity, respect, and belonging within research institutions and organizations. This includes providing training on unconscious bias, fostering mentorship and sponsorship programs, and creating safe spaces for open dialogue on diversity issues. Research institutions must also actively seek and recruit individuals from underrepresented groups for biomedical research teams. This can be achieved through targeted outreach, partnerships with organizations that support underrepresented communities, and the use of diverse search committees. Furthermore, it may be necessary to support pipeline development programs that engage underrepresented groups in science and research at early stages of their education. This could include mentorship, internships, and educational outreach programs to encourage students to pursue careers in biomedical research.

Intentional partnership with MSIs can help to create an education-to-career pipeline. Public and private sponsors can help provide resources to develop long-standing relationships with MSIs through internship/fellowship programs. NIH can be used as a case study in intentional collaboration with MSIs to improve the career pipeline for young and early-career UBR community researchers through the Minority Student Research Symposium. It is held annually in partnership with the *All of Us* Researcher's Convention and brings together established, early-career, and student researchers from UBR backgrounds for knowledge sharing and mentorship opportunities.<sup>55</sup>

Specific funding and grant opportunities could include the allocation of resources to fund research projects led by UBR researchers and encouragement of diversity in grant review panels. This can be done through targeted grant programs with diversity requirements in grant applications. Efforts to recruit the most qualified underrepresented researchers to apply for leadership positions within research institutions, funding agencies, and professional organizations should be carried out. Requirements for investigators to lead a minimum number of research studies should be waived to create a more level playing field for clinicians in community settings to lead research studies.

Structurally, flexible work policies should be implemented to help accommodate researchers with different life circumstances, such as caregiving responsibilities or disabilities, to ensure they can participate in the workforce. Finally, reasonable accommodation and support for researchers with disabilities must be provided, ensuring they have equal access to research opportunities.

Improving diversity in the biomedical research workforce is a collective responsibility that involves various stakeholders. While there is not a single entity solely accountable, key contributions will be needed from research institutions and organizations, government research funding agencies, academic and professional societies, individual researchers, community advocates, and, most importantly, a diverse set of potential students.

## A CLOSER LOOK: INTENTIONAL COLLECTION & USE OF INCLUSIVE HEALTH DATA

HETF members also prioritized expanding the collection and use of appropriately diverse and inclusive real-world evidence (RWE) in health data sources used for personalized medicine research to help ensure that the processes of clearance and approval of new health services and products and their subsequent implementation into clinical practice accurately represent all patients, including those whose experiences are traditionally underrepresented in health research data. This includes a focus on understanding gaps in existing data sources and on intentional collection and curation of data on race/ethnicity, age, sex, LGBTQIA+ status, disability, and social determinants of health (SDOH) to ensure equitable representation of all patient populations within new and existing data sources.

The following pages explain the justification for including each of the three data collection and utilization recommendations. They also explore implementation and accountability considerations for each.

### RECOMMENDATION 6

Examine and highlight gaps in existing real-world data (RWD) sources, and intentionally collect UBR community data to fill those gaps.

#### Justification

RWD refers to information collected from actual patient experiences, clinical settings, and healthcare systems. These data are typically used for personalized medicine research to study disease patterns, treatment outcomes, and the effectiveness of healthcare interventions. RWD include information stored in electronic health records (EHRs), claims data, patient registries, pharmacy records, and other sources, providing valuable insights into patient experiences and outcomes related to healthcare practice in clinical settings rather than in controlled research trials. Researchers use these data to improve healthcare, inform medical decision-making, and assess the safety and comparative efficacy of treatments in real-world populations.<sup>56</sup>

Gaps in RWD, particularly concerning underrepresented communities, can hinder the progress of personalized medicine for these populations. For example, clinical data are essential for understanding how genetic and environmental factors impact health. However, underrepresented communities often have limited access to healthcare. Data available may therefore be incomplete or less comprehensive,<sup>57,58</sup> thus making it unavailable or inaccessible when designing personalized medicine implementation strategies. Furthermore, many underrepresented communities face higher rates of specific health conditions,

such as diabetes, heart disease, or certain types of cancer. These disparities are often not adequately reflected in existing data, making it challenging to develop personalized prevention and treatment plans tailored to the unique health risks of these communities.

Many of the genetic databases used in personalized medicine research have limited diversity and are predominantly representative of individuals of European ancestry.<sup>59</sup> Additionally, they typically lack social classifications related to LGBTQIA+ or disability status. This can lead to a poor understanding of any genetic variations in underrepresented communities, potentially resulting in inadvertent biases in data analyses, artificial intelligence, and machine learning. Intentional collection and curation of RWD on patients from UBR communities, including standardized SDOH data, will help ensure inclusive representation of all patient populations within newly collected data and can help fill gaps in existing data sources.

Advances in the digital world have opened the door to greater use of EHRs to expand the scope of RWD. However, EHR data are often missing, pieced together, inconsistently recorded by various practitioners, and not interoperable between providers.<sup>60,61</sup>

Recognizing and addressing data gaps in underrepresented communities demonstrates a commitment to ethical research and medical practice. It helps ensure that all individuals, regardless of their background, benefit from advances in healthcare. Highlighting data gaps can drive policymakers to allocate resources for targeted healthcare initiatives and interventions in underrepresented communities. Inclusivity in data collection provides evidence to support these policy decisions.

### Implementation and Accountability Considerations

Accounting for existing data gaps and intentionally collecting data from underrepresented communities in biomedical research may be challenging. Difficulties gaining access to these communities is a primary cause of data disparities, especially in cases where healthcare resources are scarce.<sup>59</sup> Researchers must navigate several ethical considerations when working with underrepresented communities, including respecting cultural norms, obtaining informed consent, and ensuring data privacy and security. Additional funding for data collection may also be necessary, and data will need to be curated for quality and accuracy. Even with intentional collection efforts, biases may still exist in the data due to factors such as sampling bias, non-response bias, or selection bias. Therefore, careful data analysis and interpretation by data experts in consultation with community leaders may be necessary. Overcoming these challenges requires a multifaceted approach, including community engagement, adequate resources, culturally sensitive approaches, and data collaborations.

The complex nature of the examination of current databases and intentional collection of data requires coordinated action across the health and social services sectors. Researchers and healthcare providers should be trained in cultural competence to communicate



effectively and respectfully with diverse populations. Informed consent will be crucial to ensure that participants fully understand the research objectives, potential risks and benefits, and have the right to withdraw at any time.

It will also be important to develop new standards as needed for collection of underrepresented community data, and to adhere to data collection standards that consider diversity and inclusivity as a priority. Many groups are developing data standards. An example involves the CodeX HL7 FHIR Accelerator driven by healthcare leaders and health information technology experts who are working together to accelerate the adoption of the HL7® Fast Healthcare Interoperability Resources (FHIR) as the standard to obtain high-quality, computable data for patient care and research.<sup>62</sup> Under the Leading Edge Acceleration Projects in Health Information Technology (LEAP in Health IT) program, the National Coordinator for Health Information Technology (ONC) funded AllianceChicago to test the establishment of FHIR standards to exchange information about SDOH in a coordinated care setting.<sup>63</sup> AllianceChicago is a Health Center Controlled Network leading health IT initiatives in the safety net setting. The institution partnered with a community health center, a community-based homeless service organization, a technology and innovation consulting firm, and NORC at the University of Chicago to leverage their expertise to break down barriers of integration and coordination of services to better address SDOH for individuals experiencing homelessness.<sup>64</sup>

These serve as examples of the collaborations that will be necessary across the healthcare sector to address RWD gaps effectively. The accountability for implementing these measures rests with many different stakeholders involved in biomedical research, including researchers, CBOs, data standardization organizations, EHR providers, healthcare information professionals, pharmacies, the pharmaceutical and biotechnology industries, data stewards and privacy experts, and funders. Digital resource divisions at several U.S. government health agencies, including at NIH, FDA, ONC, and the Centers for Medicare and Medicaid Services (CMS) can help support the coordination and connectivity of these groups by providing funding, technical resources, and infrastructure.<sup>59</sup> Collaborative efforts and a commitment to equity and inclusivity are key to successfully addressing gaps in real-world data related to underrepresented populations.

## RECOMMENDATION 7

Modify and improve systems to capture and share data on social determinants of health (SDOH) in electronic health records (EHRs).

*“Routine collection of social determinants of health in both research and clinical care in combination with more precise measures of environmental influences, habits, and genetic ancestry can provide more rational, etiology-based adjustments and yield better risk stratifications and treatments.”* – Joshua C. Denny and Francis S. Collins, NIH *All of Us* Research Program

### Justification

Personalized medicine focuses on identifying individualized treatments and improving health outcomes by taking into account genes, environments, lifestyles, and patient values. SDOH, extending to socioeconomic factors like poverty, housing, mobility, employment, and education, are critical components to contextualize the whole person’s health.<sup>65</sup>

Collecting and sharing SDOH in clinical settings has recently gained increased attention as an approach to addressing health disparities. However, multiple gaps exist in the SDOH data included in EHRs. Challenges in collection and reporting include lack of data standardization and cross-database comparability. While several community efforts have brought together expert working groups to look at potential standards, they have not been widely implemented.<sup>54</sup> Challenges remain, including data privacy concerns, data quality issues, and the need for further standardization and interoperability. Additionally, there is a need to refine and expand the use of SDOH data in healthcare systems to maximize its impact on patient care and population health outcomes.

Healthcare quality measurement organizations, like the National Quality Forum (NQF) in the U.S., are exploring the inclusion of SDOH-related quality measures in performance assessments to encourage healthcare providers to address these factors.<sup>68</sup> Additionally, health information exchange networks and organizations are working to improve data sharing and interoperability among healthcare providers. They are incorporating SDOH data into the exchange process to provide a more comprehensive patient profile for better care coordination.<sup>69</sup> CMS has introduced codes and standards to include SDOH information in EHRs. This includes capturing data related to factors like housing instability, food insecurity, and transportation challenges.<sup>70</sup>

The NIH [All of Us Research project](#) has also taken steps to collect self-reported SDOH data from its diverse cohort of participants to complement genomic and clinical data. Participants complete an SDOH survey that includes information regarding the participant's neighborhood, social life, stress, and feelings about everyday life.<sup>71</sup> This large-scale genomic data source allows researchers across a spectrum of diseases to access a database that incorporates data from social determinants, biological information, wearable devices, and clinical insights.<sup>72</sup>

Toolkits and guidance are being developed to improve the general collection and integration of SDOH data. The Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) was developed in March 2019 to serve as a guide for health centers and providers to collect social determinants data to address community health needs.<sup>73</sup> In early 2023, ONC released an SDOH Information Exchange Toolkit, which highlights various community initiatives and interoperable systems to guide SDOH planning, design, implementation, and evaluation processes and to help establish organizational, governance, and IT structures.<sup>74</sup>

A recent report from the University of Chicago and the American Health Information Management Association (AHIMA) surveyed recipients with roles in health information, data collection, and management. The report confirmed that respondents collected SDOH data via EHRs. However, the report also identified gaps in consistent and accurate usage, and called for federal agencies, including HHS, the Department of Housing and Urban Development, and the Department of Justice to coordinate partnerships across healthcare systems at the local and state levels.<sup>75</sup>

The collection and use of SDOH data is particularly important for personalized medicine data initiatives and genomics-focused research. The California Initiative to Advance Precision Medicine (CIAPM) implemented a [Data Integration Working Group](#) to help advance precision medicine in California through the intentional collection, standardization, and interoperability of SDOH data obtained in clinical settings. The group calls for establishing standards for SDOH data collection and requiring health systems to gather and regularly report SDOH, as well as cross-institutional data-sharing guidance and principles of interoperability and enhanced data collection.<sup>76</sup>

## Implementation and Accountability Considerations

While various efforts that can help to incorporate SDOH into personalized medicine research are underway, it will be important to support these efforts and to bolster them in several key areas. First, engaging with communities and individuals affected by the research is crucial. Building trust and ensuring that the research reflects the needs and priorities of these communities is a shared responsibility between researchers and community leaders. Data collection will then need to be standardized, with researchers and data experts defining SDOH data fields, and these being subject to community agreement and regulatory body codification. Efforts regarding consistent coding for SDOH data should be expanded to capture SDOH information consistently.

Policies will need to be put in place to obtain informed consent from research participants to collect SDOH data and ensure that their privacy and confidentiality are protected. SDOH data should be integrated into clinical and genomic data. So, its collection will involve ensuring compatibility and data integrity so that EHRs and databases are able to incorporate data effectively. SDOH data will need to be interoperable in order for them to be useful in personalized medicine research studies. Stakeholders, including EHR vendors, health systems, and regulatory bodies, should work on ensuring that SDOH data can be shared and used across different healthcare settings and research projects.

The responsibility for collecting SDOH data in personalized medicine research is shared among researchers, healthcare institutions, policymakers, communities, and funding agencies. Policymakers, regulatory agencies, and governmental bodies such as ONC, FDA, and CMS play a significant role in shaping the environment for SDOH data collection in personalized medicine research. They are accountable for creating the regulatory framework and standards that govern data collection and privacy. Additionally, funding agencies and research organizations must allocate resources to support the collection and analysis of SDOH data.

## RECOMMENDATION 8

Develop and provide resources for community programs designed to ensure that research information is collected, used, and shared responsibly.

*“The utility of precision medicine is dependent on broad participation, and broad participation requires trust, protection of privacy, and a return of value to the participant.”* — Joshua C. Denny and Francis S. Collins, NIH All of Us Research Program

### Justification

Underserved communities may be reluctant to participate in personalized medicine research due to a combination of historical mistrust and a variety of lingering socio-cultural and economic concerns related to data protection. Concerns about ethical practices, informed consent, and the potential for exploitation in research settings can contribute to reluctance. A key strategy for advancing personalized medicine and ensuring inclusivity of underrepresented populations in research, whether through clinical trials or RWD collection, involves returning results derived from the research to study participants. However, concerns about data security and privacy are increasingly relevant in the age of digital information. Research participants may undervalue the benefits of research participation if they are worried that their data may be used for purposes they did not consent to, or that they may be mishandled, leading to unintended consequences.<sup>67</sup> Thus, existing mistrust and continued uncertainty around the potential for data misuse raises the need for clear data protection policies for which underrepresented communities are confident that their interests are accounted for.

Informed consent policies are a key part of ensuring data are handled ethically and responsibly. Informed consent allows an individual research participant to decide on how they are willing to have their data used and shared, and assumes that the consent is voluntary, the research endpoints are understood, and that adequate information about data sharing has been provided.<sup>77</sup> However, research participants often don't get a full picture about what consent entails or the end use of their health data. Therefore, many community members highlight the importance of clear and direct “meaningful consent.” Several efforts, including at CIAPM through the Equitable Consent Working Group, have the goal to develop consent protocols that are “culturally and linguistically appropriate” for research and clinical care.<sup>76</sup> Returning research results to individual participants is increasingly recognized as a strong benefit to participation; however, implementing returned results has had challenges, and providing data openly can fuel greater concern about data misuse. The MRCT Center released a set of recommendations and [toolkit documents](#) in 2017 and recently updated these materials to address logistical and ethical challenges associated with sharing clinical trials results.<sup>78,79</sup> More work is needed to ensure that data are collected, used, and shared responsibly across the healthcare system.

## Implementation and Accountability Considerations

Trust-building takes time. Building trust within underrepresented communities will require long-term engagement, collaboration with community leaders, and a commitment to addressing historical mistrust. Furthermore, data protection regulations and requirements can vary by region and country, adding complexity and potential confusion, especially in multi-site or international studies. Community data protection development programs may need to navigate complex regulatory environments, which may involve multiple oversight bodies, each with its own requirements for data protection and informed consent. Even with strong data protections in place, there may still be skepticism within underrepresented communities due to historical injustices and ongoing disparities in healthcare and research.

Developing community-based programs to ensure responsible collection, use, and sharing of biomedical research information, especially in traditionally underrepresented communities, requires a thoughtful and inclusive approach involving community engagement, capacity building, data collection policy engagement, advocacy, and resource allocation. CBOs and community leaders will need to be included from the outset as programs are designed that respect and incorporate the cultural values, languages, and preferences of the community. This includes using culturally appropriate communication channels and materials. Capacity building may involve providing training opportunities for community members to understand the research process, data protection principles, and their rights as research participants. Community members should be involved in various roles of the program, such as research assistants, educators, or advocates.

Programs will be charged with developing informed consent materials that are culturally sensitive and accessible, and that ensure that research participants fully understand the purpose of different studies, as well as the potential risks and benefits. Robust data protection measures will need to be put into place, including encryption, secure storage, and ethical data handling practices. Clear communication of these measures will help reassure participants about the security of their information. Advocates will need to engage policymakers in developing and implementing policies as part of data protection programs that create an environment supporting equitable access to research opportunities and benefits. Finally, resources will need to be allocated, such as from federal or state healthcare services programs, private foundations, community health organizations, corporate sponsors, public-private programs, or academic institutions, to help build capacity and benefit the community.

It will be important to align community program goals with the mission and priorities of potential funding sources. Building strong partnerships with local organizations, academic institutions, and community leaders can also enhance program credibility and increase the likelihood of securing support.

## PART III

# Implementation Framework

## Policy, Structure, And Behavior

These recommendations are meant to provide personalized medicine researchers and underserved communities with strategies to work together to address disparities in personalized medicine research data. Implementing changes meant to improve diversity and inclusiveness in personalized medicine research will require understanding how policies, infrastructure, and behaviors are interconnected, and how making research reforms in one domain may depend upon, and impact, changes in other domains (Figure 1).

These community engagement recommendations call for empowerment of UBR communities within personalized medicine research; sustained dedication to resource and capacity building within CBOs, rural health clinics, and FQHCs; improvements to the clinical research workforce pipeline for UBR groups; and improvements in real-world health data sources that will better capture the unique circumstances of UBR participants and lead to more inclusive outcomes in personalized medicine research.

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.

The health data recommendations involve health information technology stakeholders developing and advancing 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 SDOH in 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 RWE databases, EHRs, IRBs, research institution incentives, and programs and partnerships between CBOs, FQHCs, personalized medicine researchers, and other DEI stakeholders.

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. Ultimately, impactful policies, structural changes and community willingness to partner will lead to increased participation in personalized medicine research amongst members of underrepresented groups.

While many efforts are already underway to address disparities in healthcare 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.



# Conclusion

Personalized medicine anticipates targeted treatments based on a patient's individual characteristics and health needs, accounting for variables such as race, ethnicity, age, sex, disability, lifestyle, and socioeconomic status, as well as molecular characteristics. The success of the personalized approach therefore depends on the inclusive representation of patients with diverse characteristics and health needs in research and therapeutic development.

The recommendations described in this report were developed through a robust community engagement approach, bringing together community leaders and representatives from public, private, and nonprofit organizations that are working with or are part of communities that are underrepresented in healthcare research in the United States. These recommendations were developed by underrepresented communities to benefit underrepresented communities. The HETF identified and prioritized strategies to comprehensively address disparities in clinical trials participation and a lack of diversity in health data used in research and development as well as for the improved implementation of personalized medicine technologies.

Through recommendations designed to empower community engagement in personalized medicine research and improve the collection and use of inclusive health data, we can achieve increased diversity in personalized medicine research and equity in technological implementation. Considering reforms to policies, structures, and behaviors, and accounting for the interconnection between these considerations, will help ensure that the strategies that will be advanced through these recommendations are well-positioned to have a system-wide impact. This will ensure that the scientific breakthroughs informing personalized medicine are relevant and accessible to all patients.

# Appendices

## **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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