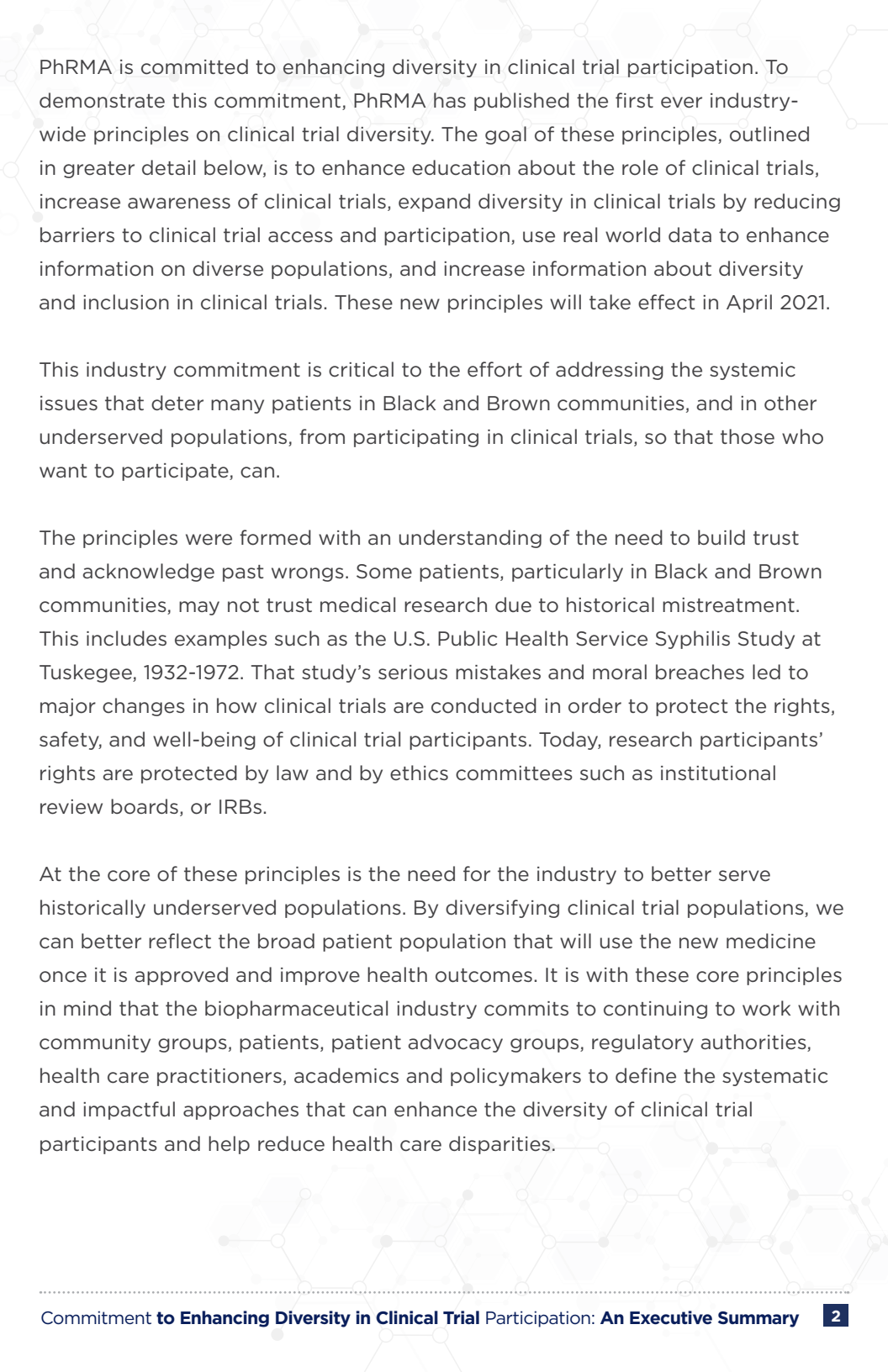




Commitment to **Enhancing Diversity**
in Clinical Trial Participation:
An Executive Summary





PhRMA is committed to enhancing diversity in clinical trial participation. To demonstrate this commitment, PhRMA has published the first ever industry-wide principles on clinical trial diversity. The goal of these principles, outlined in greater detail below, is to enhance education about the role of clinical trials, increase awareness of clinical trials, expand diversity in clinical trials by reducing barriers to clinical trial access and participation, use real world data to enhance information on diverse populations, and increase information about diversity and inclusion in clinical trials. These new principles will take effect in April 2021.

This industry commitment is critical to the effort of addressing the systemic issues that deter many patients in Black and Brown communities, and in other underserved populations, from participating in clinical trials, so that those who want to participate, can.

The principles were formed with an understanding of the need to build trust and acknowledge past wrongs. Some patients, particularly in Black and Brown communities, may not trust medical research due to historical mistreatment. This includes examples such as the U.S. Public Health Service Syphilis Study at Tuskegee, 1932-1972. That study's serious mistakes and moral breaches led to major changes in how clinical trials are conducted in order to protect the rights, safety, and well-being of clinical trial participants. Today, research participants' rights are protected by law and by ethics committees such as institutional review boards, or IRBs.

At the core of these principles is the need for the industry to better serve historically underserved populations. By diversifying clinical trial populations, we can better reflect the broad patient population that will use the new medicine once it is approved and improve health outcomes. It is with these core principles in mind that the biopharmaceutical industry commits to continuing to work with community groups, patients, patient advocacy groups, regulatory authorities, health care practitioners, academics and policymakers to define the systematic and impactful approaches that can enhance the diversity of clinical trial participants and help reduce health care disparities.

The Principles:

Enhancing education about the role of clinical trials throughout the medical community and enhancing diversity among clinical investigators. The lack of participation by historically understudied populations may result from a lack of clinical trial awareness at hospitals and clinics that treat diverse populations. To address this gap, we commit to conduct outreach to the medical professionals in underserved communities and support trial sites with comprehensive education on medical product development. We will seek to further encourage the recruitment and retention of clinical trial personnel with diverse backgrounds, including racial and ethnic backgrounds.

Increasing clinical trial awareness and participant diversity by improving individual health literacy and community outreach. Educational efforts are a key component of reaching underrepresented populations. Our outreach efforts are aimed at increasing access and reducing barriers for underrepresented and diverse populations to participate in clinical trials. We commit to conduct community outreach such as partnering with health and community advocacy groups that are working with the communities we aim to reach to increase clinical trial awareness and potential opportunities for participation.

Enhancing diversity in clinical trials depends on identifying and reducing barriers to clinical trial access and participation. To this end, we will work with patients, health care providers, and clinical trial investigators to understand barriers and identify approaches to address these barriers and enhance access to clinical trials for diverse patient populations by:

- Taking into account the needs of diverse populations in clinical trial design.
- Adopting enrollment and retention practices that enhance inclusiveness and make trial participation less burdensome for participants.
- Broadening eligibility criteria to increase diversity in enrollment when scientifically and clinically appropriate.

Using Real-World Data to Enhance Information on Diverse Populations Beyond Product Approval. During the post-approval phase, collecting clinical real-world data or evidence can be an important method of supplementing trial data, in compliance with all applicable local laws and regulations. These data can also serve as an effective and efficient means to enhancing understanding of drug effects in diverse patient populations.

Enhancing Information About Diversity and Inclusion in Clinical Trial Participation.

Lastly, to promote transparency and accountability, biopharmaceutical companies that voluntarily adopt these new principles commit to publicly sharing information about their policies and practices to increase clinical trial diversity.

