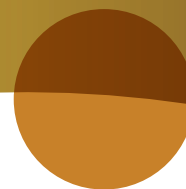


EQUITABLE BREAKTHROUGHS IN MEDICINE DEVELOPMENT™



The Challenge

As we look at the development of new medicines, it is essential to take meaningful action to help ensure that underserved communities, who have historically faced barriers to participating in the development of health care advances, are given the opportunity to be included every step of the way.

Enhancing clinical trial diversity is a highly complex challenge driven by systemic barriers to participation and issues of mistrust.

Systemic barriers, including not being asked to participate, limited awareness and understanding of clinical trials, limited access to trial sites and lack of sustainable support for many community-based sites, limited investigators who reflect the diversity of the population, and financial and time burdens placed on patients, can all impact diversity in clinical research.

Issues of mistrust also abound, caused by experiences with medical bias, mistrust of the health care industry, and historical mistreatment of patients, including the U.S. Public Health Service Syphilis Study at Tuskegee. Such historical mistreatment led to major changes in how clinical trials are conducted to protect the rights, safety, and welfare of participants in clinical trials.

Equitable Breakthroughs in Medicine Development will help underrepresented patients be more involved in the research and development of potential life-saving medical treatments.

Over the course of 18 months, this effort seeks to connect diverse communities, patients, providers, health partners, community organizations and academic institutions, along with the support of the pharmaceutical industry, **to pilot a network of sustainable, connected, community-based trial sites.**

Led by Yale School of Medicine, Morehouse School of Medicine, the Research Centers in Minority Institutions Coordinating Center at Morehouse School of Medicine, and Vanderbilt University Medical Center and funded with a grant from PhRMA, this effort has four primary goals:

- Show proof of concept for a comprehensive, collaborative network of sustainable, connected, community-based sites supporting clinical trial diversity in underserved communities.
- Partner with trusted messengers and community leaders to raise education, awareness and support for clinical trial participation.
- Provide the resources and technical support for local sites to be successful, sustainable, and thrive.
- Build training opportunities and mentorship for investigators and staff.

Additional partners will be announced in coming weeks and months.

Changing the Paradigm

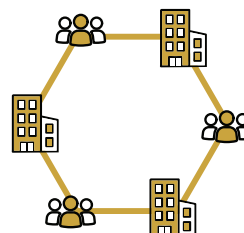

Disparate sites at varying levels of readiness / community connectiveness



Create an Infrastructure that Provides...

- ✓ A network
- ✓ Communications
- ✓ Community relationships
- ✓ Ongoing site training
- ✓ Sustainable support
- ✓ Standardized platforms / metrics

A sustainable community-based infrastructure supporting multiple touchpoints / sites dedicated to CT diversity



We Owe It to Patients to Work Towards Solutions

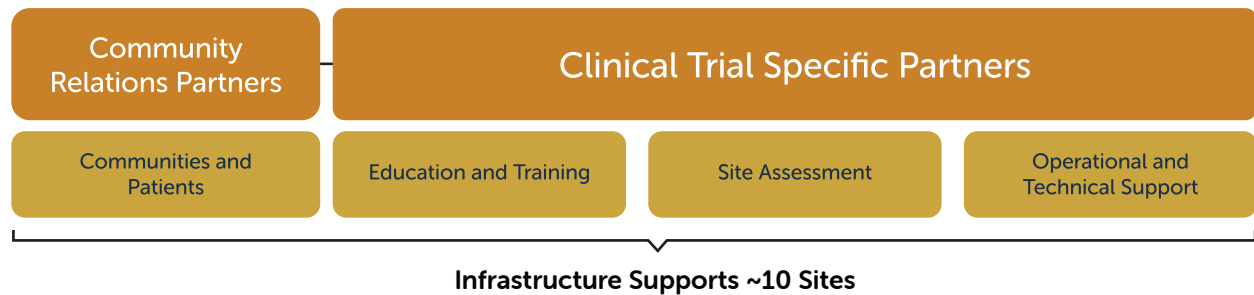
Diverse clinical trials provide researchers more information about the patient experience with a potential new medicine, potentially highlighting different responses to the medicine, and helping to further inform the safety and effectiveness profile of that medicine for patients.

It is also an issue of fairness. People who may want to participate in a clinical trial should have information about how to do so and be able to more easily access the trial. Right now, many people, particularly from communities of color and rural communities, may not be asked to participate or may not have easy access, effectively depriving them of the choice.

The Partnership

- 1 **WHO:** Industry, Academia, Community Organizations, Health Systems
- 2 **WHAT:** A broad partnership aiming to show proof of concept to enhance clinical trial diversity via connected, community rooted clinical trial sites in underserved areas.
- 3 **WHEN:** Partnership announced in July 2022, with an initial 18 month **Learning Phase** to refine the proof of concept
- 4 **WHERE:** Partners from across the United States with an initial trial site focus in the Southeast and Southwest

Structure of 18 Month Learning Phase



Getting to This Point

Yale School of Medicine, Morehouse School of Medicine, the Research Centers in Minority Institutions Coordinating Center at Morehouse School of Medicine, and Vanderbilt University Medical Center have worked tirelessly on this issue for many years, and are true leaders in their respective fields.

PhRMA recognizes this leadership and expertise. Over the past two years, PhRMA has led discussions with thousands of patients, advocacy groups, health care providers, and leaders from the clinical trial, health equity, and racial justice communities as they have united the pharmaceutical industry and stakeholders on this effort to show proof of concept for a sustainable, community-based infrastructure supporting underserved patients and local clinical trial sites.

We understand communities of color may have cautious optimism about clinical trials. Our hope is that the partnership provides a comprehensive proof of concept for this unique approach and will bring lasting change.

Follow our progress at PhRMA.org/equity.

