



RECOGNIZING THE POTENTIAL FOR REAL-WORLD EVIDENCE IN MATERNAL HEALTH

The stark disparities in maternal health outcomes in the United States reveal how our health care system is failing Women of Color. Too often, diverse communities are underrepresented in clinical studies for treatments addressing maternal morbidity and mortality. Preterm birth and its disproportionate impact on women of color provide a key example of why we need representative research and Real-World Evidence on treatment efficacy across populations.

THE PRETERM BIRTH CRISIS IN THE UNITED STATES

- 2nd largest contributor to infant death
- 6th highest rate of preterm birth worldwide
- 10.1% of births
- Unequal burden on communities of color

The preterm birth rate among Black women in the U.S. is **51%** higher than the rate among all other women



THE NEED FOR MORE RESEARCH ACROSS DIVERSE POPULATIONS

A survey conducted in 2021 among women's health, obstetric, and neonatal nurses^v found that:

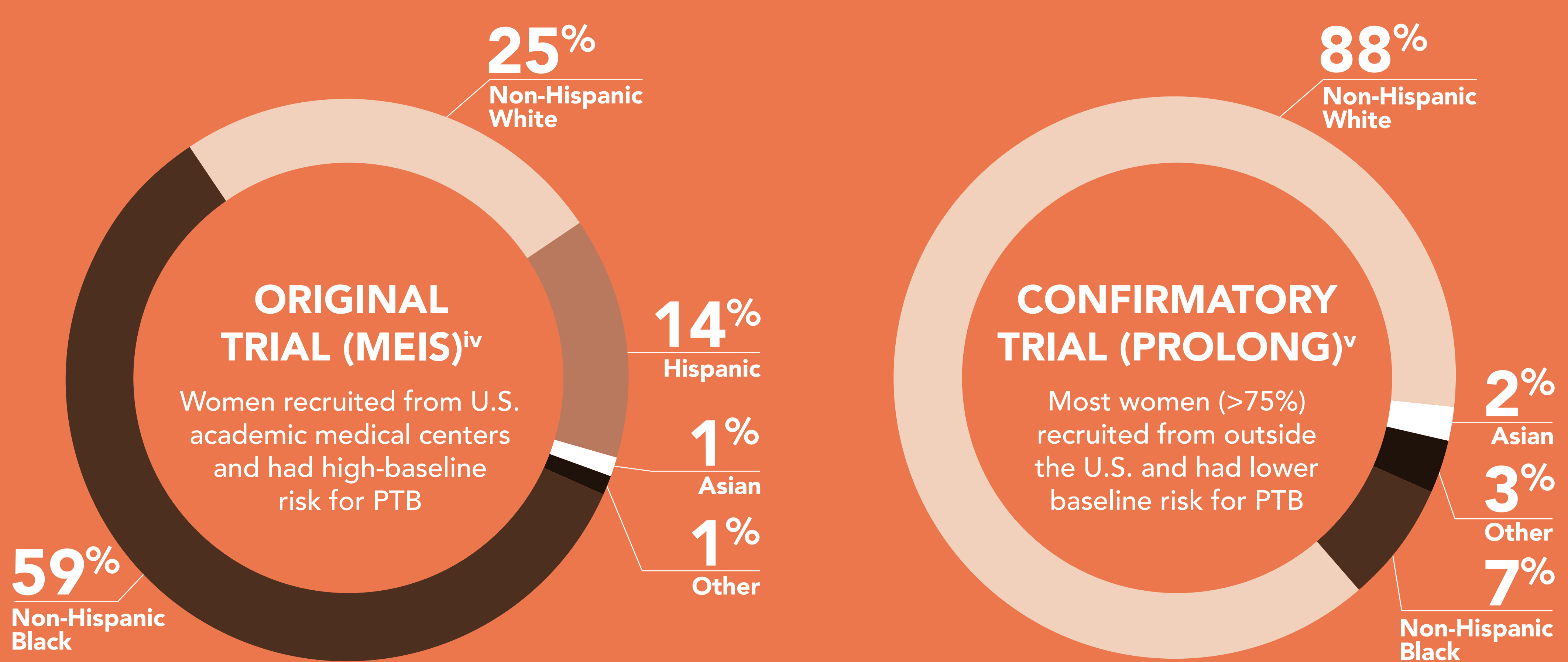
>70% believe patients at risk of preterm birth **would be at a disadvantage if 17P were removed** from market

8/10 believe that having approved **treatments** to prevent preterm birth **AND** conducting more **research** on effectiveness across diverse populations are important



UNDERSTANDING TREATMENT EFFICACY IN DIVERSE POPULATIONS: 17P

The only FDA-approved treatment to prevent spontaneous, recurrent preterm birth—17P—was recommended for withdrawal based on conflicting efficacy results from two clinical trials with vastly different patient populations, one inclusive of women in the U.S. most vulnerable to preterm birth and one not. The Preterm Birth Prevention Alliance believes that to achieve birth equity, we must gain a better understanding of who can benefit most from treatments like 17P before decisions are made.



THE VALUE OF REAL-WORLD EVIDENCE

Real-world evidence (RWE) can help drive a better understanding of how a drug or intervention will work in diverse patient communities by **examining performance in the context of multiple variables.**



ⁱ 2020 March of Dimes Report Card.
ⁱⁱ 2021 March of Dimes Report Card.
ⁱⁱⁱ Meis, et al. Prevention of Recurrent Preterm Delivery by 17 Alpha-Hydroxyprogesterone Caproate. N Engl J Med 2003;348:2379-2385.
^{iv} Blackwell, et al. 17-OHPC to Prevent Recurrent Preterm Birth in Singleton Gestations (PROLONG Study): A Multicenter, International, Randomized Double-Blind Trial. Am J Perinatol 2020;37(2):127-136.
^v Survey of women's health, obstetric and neonatal nurses, July 2021.