



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



WOMEN WANT FDA-APPROVED TREATMENTS

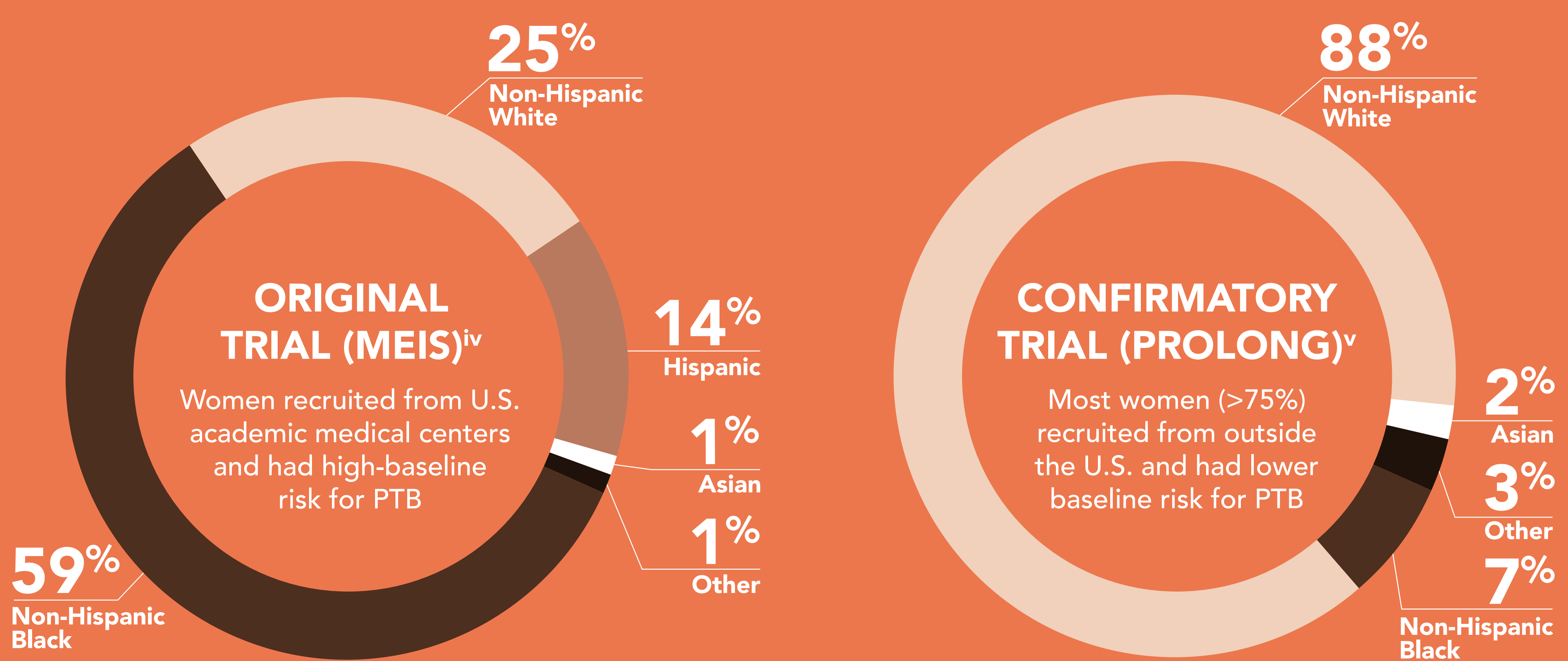
A 2021 survey of >1,000 U.S. womenⁱⁱⁱ found that:

- Only **36%** received all the information needed about preterm birth to help them make informed decisions
- **86%** believe research on treatments efficacy across diverse populations is important
- **85%** believe that having approved treatments to prevent preterm birth is 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 Survey of 1,027 U.S. women aged 35-64, August 31-September 5, 2021.
^{iv} Meis, et al. Prevention of Recurrent Preterm Delivery by 17 Alpha-Hydroxyprogesterone Caproate. N Engl J Med 2003;348:2379-2385.
^v 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.