The stark disparities in maternal health outcomes in the United States reveal how our healthcare 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 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 PRETERM BIRTH CRISIS IN THE UNITED STATES

- 2nd largest contributor to infant death
- 4th highest rate of preterm birth worldwide
- 10.1% of births
- Unequal burden on communities of color

### 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.

#### ORIGINAL TRIAL (MEIS)\(^{iv}\)
- Women recruited from U.S. academic medical centers and had high-baseline risk for PTB
- 59% Non-Hispanic Black
- 25% Hispanic
- 7% Asian
- 3% Other
- 2% Asian

#### CONFIRMATORY TRIAL (PROLONG)\(^{v}\)
- Most women (>75%) recruited from outside the U.S. and had lower baseline risk for PTB
- 88% Non-Hispanic White
- 25% Non-Hispanic Black
- 14% Hispanic
- 1% Asian
- 1% Other
- 2% Asian

### 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.

- Wearables
- Electronic Health Records
- Claims & Billing Activities
- Patient Generated Data

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\(^{i}\) 2020 March of Dimes Report Card.  
\(^{ii}\) 2021 March of Dimes Report Card.  
\(^{v}\) Survey of women’s health, obstetric, and neonatal nurses, July 2021.