

Approaches to optimize recruitment of historically underrepresented Black and Hispanic/LatinX MSM, transgender, and gender non-binary individuals into the lenacapavir for PrEP (PURPOSE 2) trial

Paul W⁵, Cespedes M¹, Blumenthal J², Hodge T³, Elliott A⁴, Demidont A.C⁴, Watson C.C⁴, Carter C⁴, Kintu A⁴, Das M⁴, Baeten J⁴, Ogbuagu O⁶

¹Icahn School of Medicine at Mount Sinai, New York, NY, ²UC San Diego, La Jolla, CA, ³Washington Health Institute, Washington, DC, ⁴Gilead Sciences, Inc., Foster City, CA, ⁵Gilead Sciences Ltd Pty Melbourne AUS, ⁶Yale School of Medicine, New Haven, CT

Background: Black, Hispanic/Latinx gay and other men who have sex with men (MSM), transgender women (TGW), transgender men (TGM), and gender-nonbinary individuals (GNB) have been historically underrepresented in HIV prevention trials despite being disproportionately affected by the disease. Therefore, studies of pre-exposure prophylaxis (PrEP), a highly effective intervention for reducing HIV incidence, should include these individuals, doing so would promote generalizability of the findings.

Methods: PURPOSE 2 (GS-US-528-9023) will evaluate a twice-yearly long-acting subcutaneous, first in class capsid inhibitor, lenacapavir, for PrEP in MSM, TGW, TGM, and GNB in the US, Brazil, Peru, and South Africa. The study team adopted a multifactorial approach to address historic underrepresentation. This included a literature review to assess successful evidence-based approaches for increasing enrolment of Black and Hispanic/ LatinX MSM, TG, and GNB individuals. We engaged with community and patient advocates as well as key stakeholders to solicit feedback prior to protocol development.

Results: We established a trial-specific Global Community Advisory Group and implemented their recommendations for site selection, investigator and staff diversity, and strong linkage with community-based organizations. We recruited new community-based research sites and principal investigators (PIs) to mirror historically underrepresented populations and emphasized mentorship of junior sub-Is by seasoned PIs to support enrolment and retention. We developed required trainings for all study and site staff on good participatory practices for PrEP, anti-racism and transgender cultural humility. We established recruitment goals of 50% Black and 20% Hispanic/LatinX MSM in the US, and 20% TGW study-wide. Our strategy to ensure achievement of these overall goals involves nuanced site-specific recruitment goals considering site capacity, local demographics, and HIV incidence data. We will review metrics weekly during enrolment and make any necessary adjustments.

Conclusions: Using novel approaches, we have carefully chosen with whom, where, and how we will collaborate to increase the diversity, equity, and inclusion in the PURPOSE 2 trial.

Acknowledgement of Funding: This study was funded by Gilead Sciences.

Disclosure of Interest: Wayne Paull is an employee of Gilead Sciences.