

Approaches to Optimise Recruitment of Historically Under-represented Black and Hispanic LatinX MSM, Transgender, and Gender Non-binary Individuals Into the Lenacapavir for PrEP (PURPOSE 2) Trial



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Introduction

- Despite being disproportionately affected by HIV, specific populations have been historically under-represented in HIV prevention trials:
 - Black and Hispanic/LatinX gay, bisexual, and other men who have sex with men (MSM)¹⁻³
 - Transgender women and men (TGW and TGM, respectively)⁴⁻⁸
 - Gender non-binary individuals (GNB)
- Studies of pre-exposure prophylaxis (PrEP), a highly effective intervention for reducing HIV incidence, should include these individuals and doing so would promote generalisability of the findings
- PURPOSE 2 (GS-US-528-9023; NCT04925752) is a Phase 3 trial to evaluate the efficacy and safety of lenacapavir (LEN) in preventing HIV infection in these populations

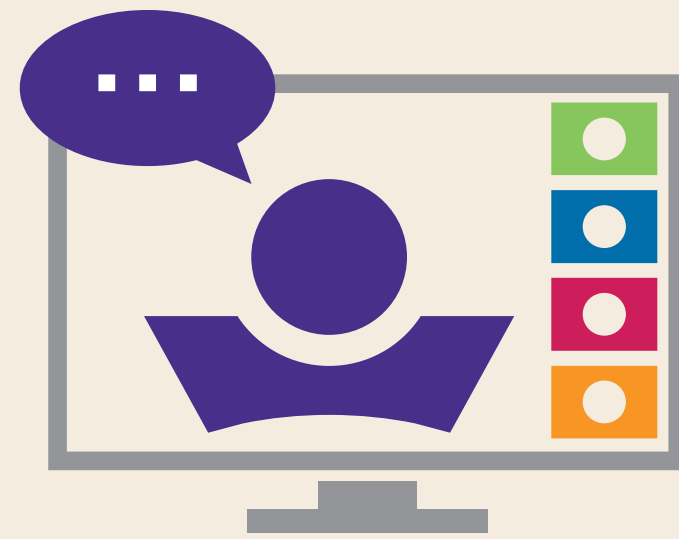
Fostering Diversity and Inclusivity

Diversify Sites and Set Recruitment Goals



- Choosing sites with experience in community engagement with historically under-represented populations, and robust relationships with community groups
- Diversifying study staff so that they are representative of the people we are trying to engage
- Set study-wide and site-specific recruitment goals:
 - US sites: race, ethnicity, and gender goals
 - Peru, Brazil, and South Africa: gender goals
- Monitor recruitment demographics in real time

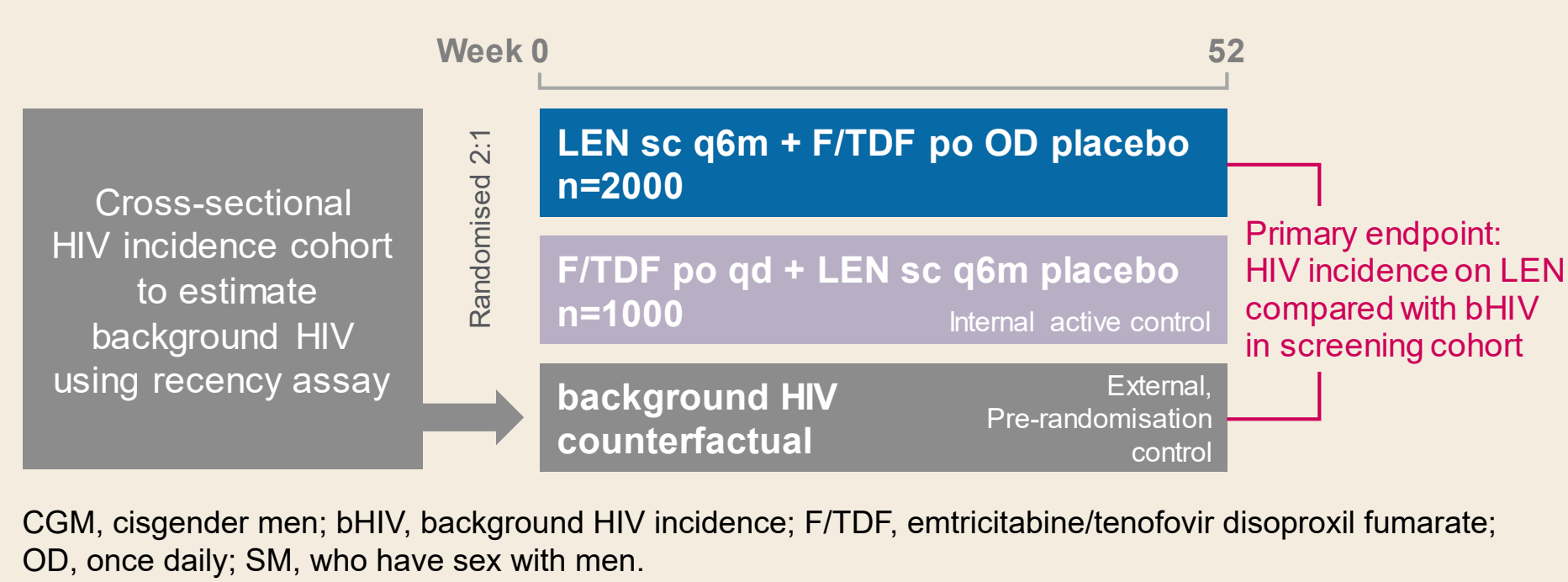
Improve Cross-cultural Humility and Competence on the Study Team With Sites and External Partners/Vendors



- Trainings on good participatory practice (GPP), gender inclusivity, and anti-racism:
 - Introduction to PrEP and GPP
 - “Improving Cultural Humility and Competence in Research for Transgender and Gender Diverse Individuals”
 - “Identifying and Addressing Racism in Clinical Trials”

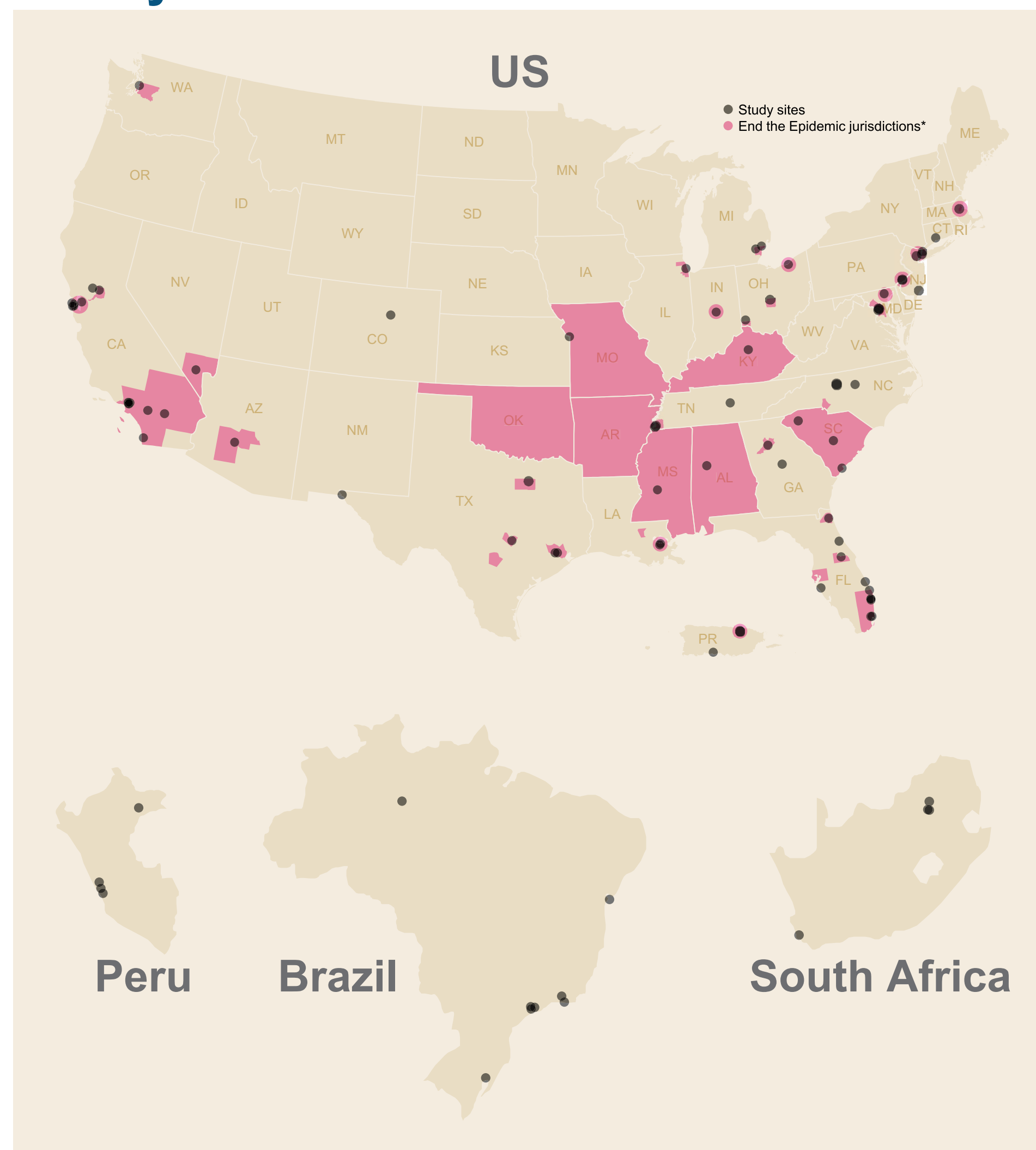
PURPOSE 2 Study Design

CGM, TGW, TGM, and GNB SM: N=3000

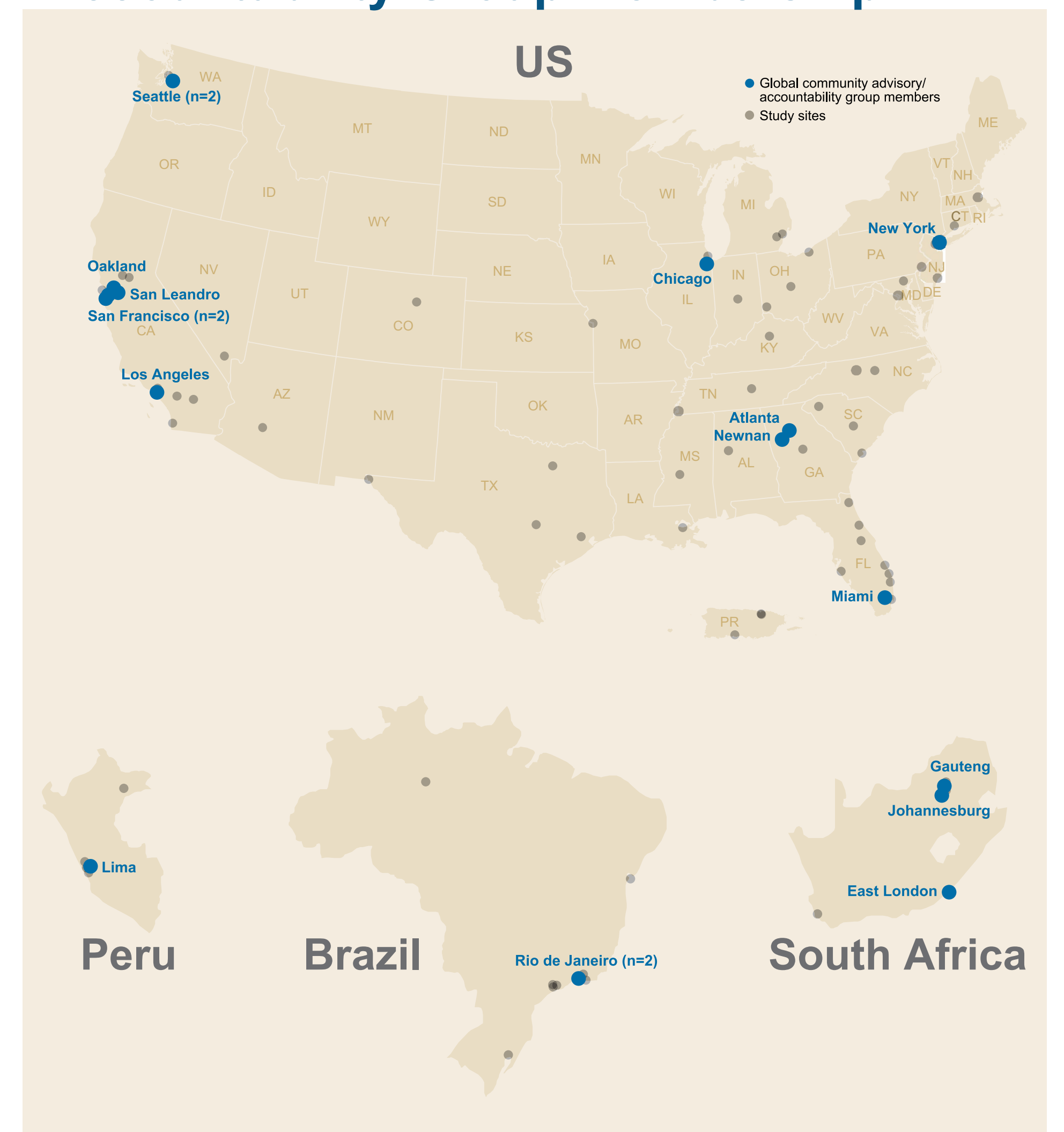


- Sites in the US, Peru, Brazil, and South Africa with high HIV incidence (>3.5/100 person-years)
- Multifactorial approach to address historic underrepresentation:
 - Literature review to assess successful evidence-based approaches for increasing enrollment of Black and Hispanic/LatinX MSM, TG, and GNB individuals
 - Engagement with community and patient advocates, as well as key stakeholders, to solicit feedback prior to protocol development
 - Formation of a trial-specific global community advisory/accountability group to review and advise on diversity, equity, and inclusion efforts

Study Sites

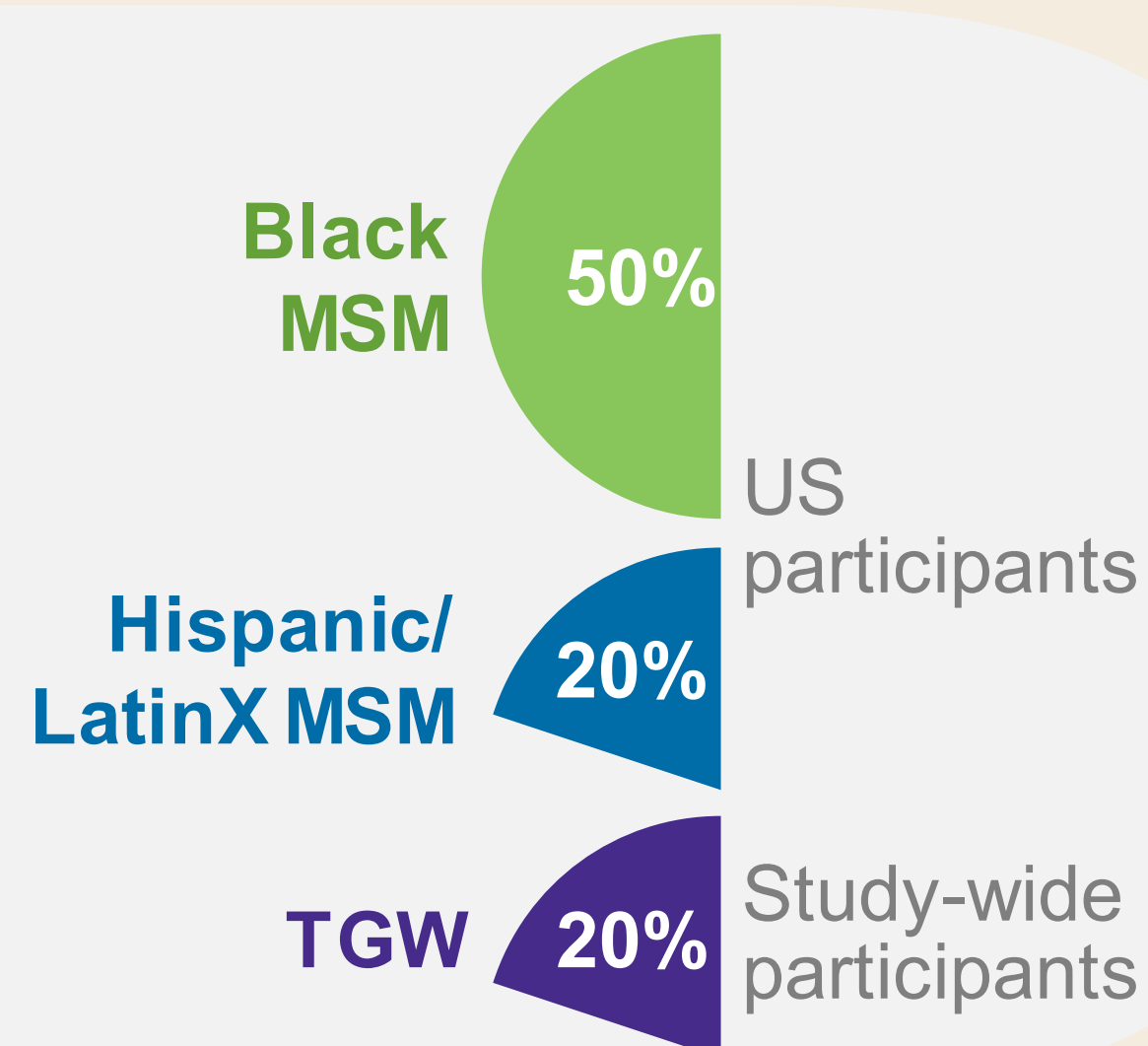


Global Community Advisory/Accountability Group Membership

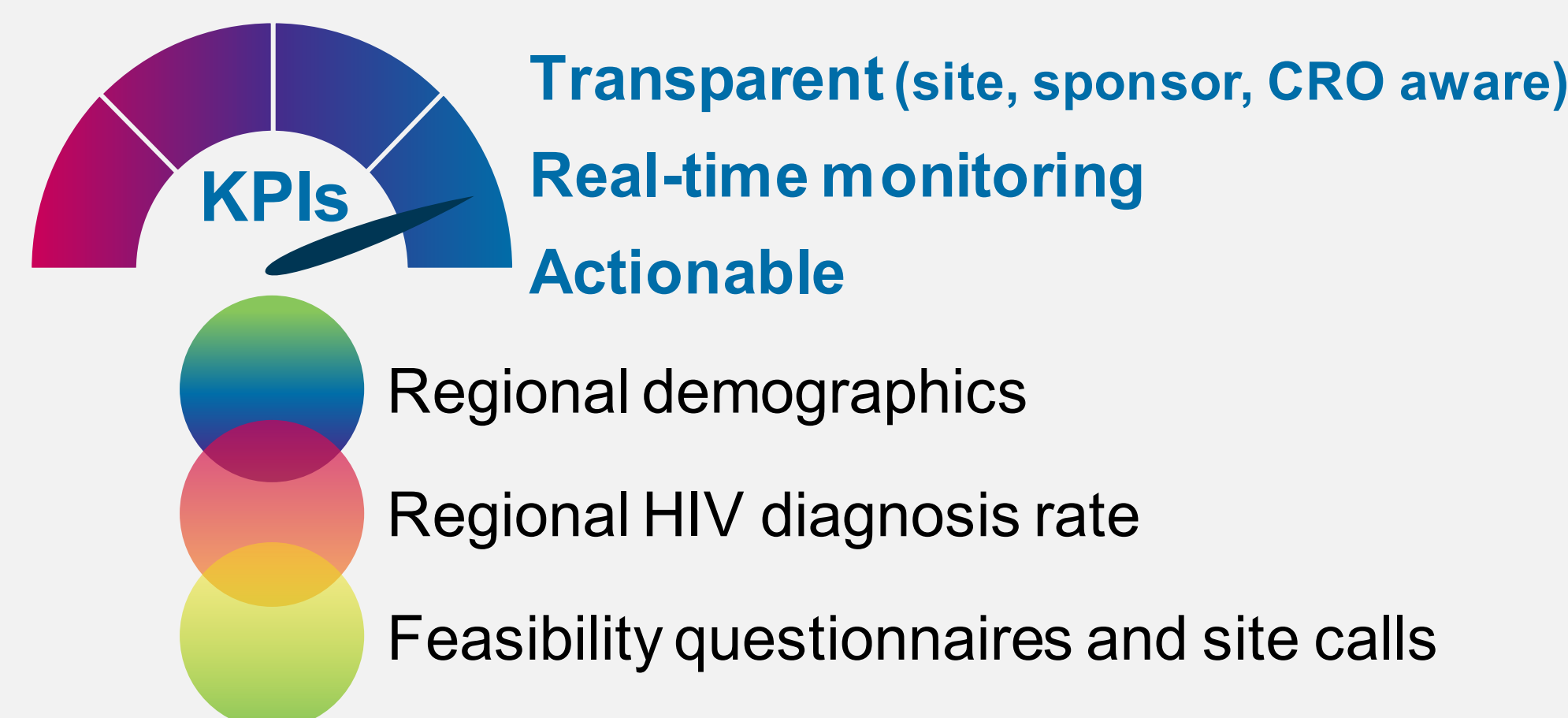


Specific Recruitment Goals to Ensure Diversity and Inclusion

Overall Recruitment Goals



Site-Specific US Recruitment Plans



- Study-wide recruitment goals: race and gender based in US, and gender based in Peru, Brazil, and South Africa
- For example, 50% Black MSM recruitment goal in US recommended by HPTN Black Caucus¹⁰

- Nuanced site-specific recruitment goals considering site capacity, local census demographics, and CDC data on rate of new HIV diagnoses among MSM¹¹
- Weekly metrics review during enrollment to make necessary adjustments to achieve overall recruitment goals

Conclusions:

- Using novel and intentional approaches, we have carefully chosen with whom, where, and how we work to increase the diversity, equity, and inclusion in the PURPOSE 2 trial

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Acknowledgments: We extend our thanks to the participants, their families, all participating investigators and staff, and the global community advisory/accountability group members. This study was funded by Gilead Sciences, Inc.

