



Prevention with PURPOSE



# Global Racial, Ethnic, and Gender Diversity Among Participants Enrolled in the PURPOSE 2 Trial of Lenacapavir for Pre-Exposure Prophylaxis

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# Disclosures

- Jorge Gallardo-Cartagena has received honoraria from ViiV Healthcare and MSD (speaker)
- Gilead Sciences, Inc., funded the study and designed the study with input from the PIs and G-CAG. The PIs and study staff gathered data; Gilead Sciences, Inc., monitored conduct of the trial, received the data, and performed analyses. The PURPOSE 2 Study Team all vouch for the data and analysis
- Graphical and copyediting support was provided by Aimee Sherlock, MSc, of Aspire Scientific (Bollington, UK), and Amy Watkins, PhD, of Ashfield MedComms (Macclesfield, UK), an Inizio company, and was funded by Gilead Sciences, Inc.



# Summary

## What is your main question?

- How can we ensure that historically underrepresented populations are purposefully included in PrEP efficacy trials?

## What did you find?

- Over 3000 people were enrolled in PURPOSE 2 from seven countries across four continents
- PURPOSE 2 enrolled a diverse population of cisgender gay, bisexual, and other men; transgender women; transgender men; and gender nonbinary individuals who have sex with partners assigned male at birth
  - Among enrolled people, 67% were non-White, 63% were of Hispanic/Latine ethnicity, and 22% were gender diverse
- PURPOSE 2 is the first HIV prevention trial to intentionally include transgender men and gender nonbinary individuals

## Why is it important?

- The inclusion of a broad and diverse participant population is important for understanding the efficacy of lenacapavir for all populations including communities disproportionately affected by HIV-1 and for increasing PrEP use among those who have not yet benefited from current PrEP options

# HIV Prevention Research Must Include Communities That Are Most Affected by HIV-1



Disparities in new HIV-1 diagnoses and PrEP uptake persist globally<sup>1-3</sup> and are magnified in low- and middle-income countries and the Global South<sup>3</sup>



People of color and gender-diverse people experience disproportionate HIV-1 acquisition and are historically underrepresented in PrEP clinical trials<sup>3-5</sup>



Here, we describe the global racial, ethnic, and gender diversity among participants enrolled in the PURPOSE 2 trial

# The PURPOSE Program



## PURPOSE 2

Global Phase 3 trial<sup>a</sup> investigating the efficacy and safety of twice-yearly injectable **LEN** for HIV prevention among **cisgender gay, bisexual, and other men; transgender women; transgender men; and gender nonbinary individuals** who have condomless receptive anal sex with partners assigned male at birth


PURPOSE 1 NCT identifier: NCT04994509; PURPOSE 2: NCT04925752; PURPOSE 3: NCT06101329; PURPOSE 4: NCT06101342. PURPOSE studies available at: <https://www.purposestudies.com/> (accessed September 25, 2024).

Access statement: <https://www.gilead.com/company/company-statements/2024/updated-statement-on-access-planning-in-high-incidence-resource-limited-countries-for-lenacapavir-for-hiv-prevention> (accessed October 4, 2024); <https://www.gilead.com/news/news-details/2024/gilead-signs-royalty-free-voluntary-licensing-agreements-with-six-generic-manufacturers-to-increase-access-to-lenacapavir-for-hiv-prevention-in-high-incidence-resource-limited-countries> (accessed October 4, 2024). <sup>a</sup>PURPOSE 2 study initiation: June 28, 2021.

CGBMSM, cisgender gay and bisexual men who have sex with men; GNB, gender nonbinary individuals; FR, France; F/TDF, emtricitabine/tenofovir disoproxil fumarate; LEN, lenacapavir; NCT, National Clinical Trial; PWID, people who inject drugs; TGM, transgender men; TGW, transgender women; UK, United Kingdom; US, United States. 1. Bekker L-G, et al. N Engl J Med. 2024;391:1179-92.

# Good Participatory Practice to Optimize Enrollment





# Voice of the People: PURPOSE 2 G-CAG and Other Stakeholders

Establish Global Community Advisory Group (G-CAG) with robust representation of persons of color and transgender populations

Choose PIs and sites with experience in gender-affirming care and strong community relationships

Site PI and staff representative of participant population

Set specific enrollment goals to improve inclusion

Support cross-cultural humility and competence on study teams

Assess intimate partner violence and social harms and provide counseling and social work support for participants

Evaluate gender-affirming hormones and PrEP drug interactions

# **PURPOSE 2**: Intentional Inclusion of Transgender Populations

Transgender Women bear a disproportionate burden of HIV globally  
Missing or limited data exist for transgender men and gender nonbinary people<sup>1-6</sup>

## Global HIV prevalence in TGW: ~19%<sup>4-6</sup>



**“As a transmasculine person who has sex with cis men...my identity... is historically and consistently overlooked by the HIV establishment.”**

—Max Appenroth, Cologne



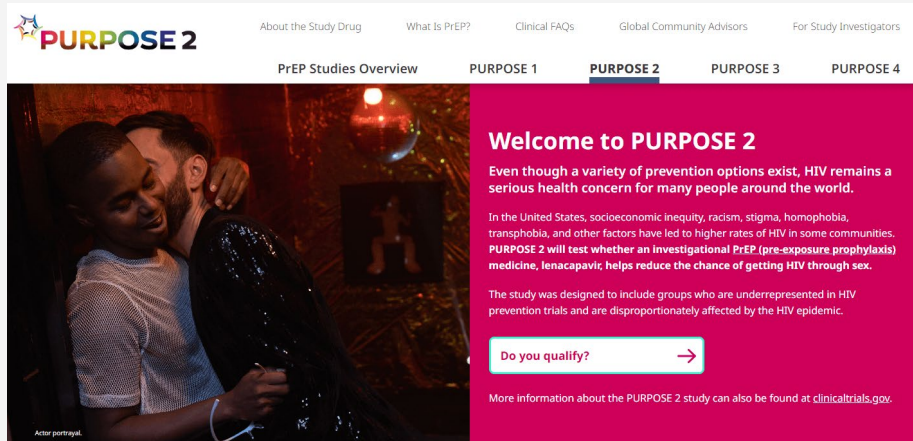
Read ***No Data No More***,  
a manifesto for the priorities of trans and  
gender-diverse people in #HIVprevention R&D.  
[avac.org/no-data-no-more](https://avac.org/no-data-no-more)

**PURPOSE 2** strived to enroll a significant number of TGW, and in response to the Transgender Manifesto was the first PrEP trial to include TGM and GNB

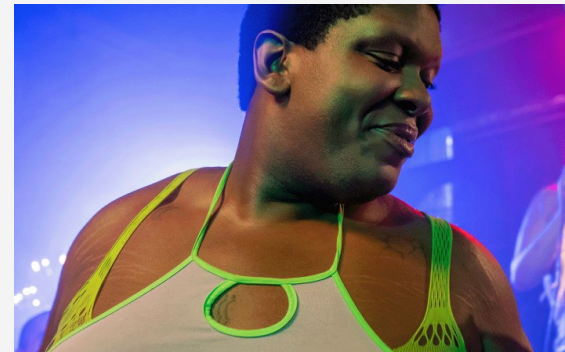
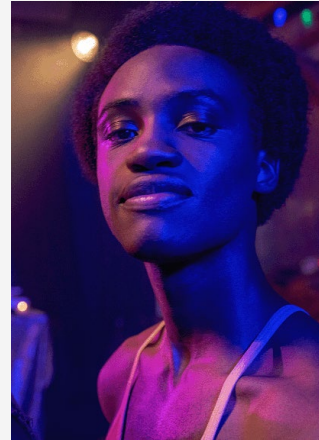
GNB, gender nonbinary individuals; PrEP, pre-exposure prophylaxis; R&D, research and development; TGM, transgender men; TGW, transgender women; US, United States. 1. Becasen JS, et al. *Am J Public Health*. 2019;109:e1-8. 2. Reisner SL, et al. *J Int AIDS Soc*. 2019;22:e25391. 3. CDC. <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-special-report-number-27.pdf> (accessed October 1, 2024). 4. Straube T. <https://www.poz.com/article/hiv-prevention-manifesto-transgender-genderdiverse-people> (accessed October 1, 2024). 5. Baral SD, et al. *Lancet Infect Dis*. 2013;13:213-22. 6. Stutterheim SE, et al. *PLoS One*. 2021;16:e0260063. 7. van Griensven F, et al. *J Int AIDS Soc*. 2021;24:e25683. 8. Arantxa Colchero M, et al. *Salud Publica Mex*. 2015;57(suppl. 2):s99-106. 9. Silva-Santisteban A, et al. *AIDS Behav*. 2012;16:872-81. 10. Sullivan PS, et al. *J Int AIDS Soc*. 2020;23(suppl. 6):e25591. 11. Ministerio de Salud y Desarrollo Social. *Boletín sobre el VIH, sida e ITS en la Argentina*. N° 34. Buenos Aires, Argentina; 2017. 12. Grinsztejn B, et al. *Lancet HIV*. 2017;4:e169-76.



# **PURPOSE 2** Inclusive and Representative Website

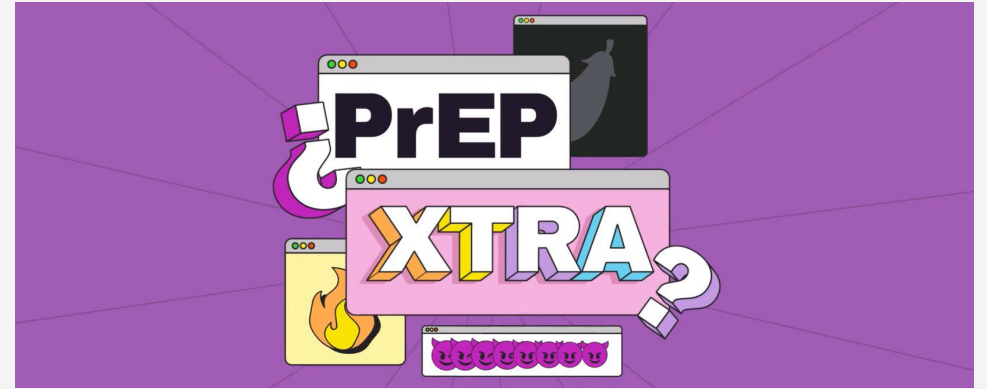
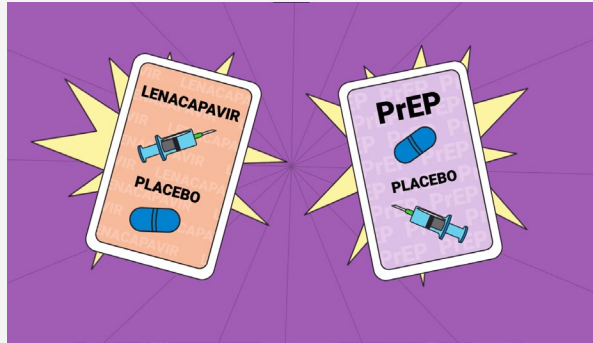


The screenshot shows the website's navigation menu with links for 'About the Study Drug', 'What Is PrEP?', 'Clinical FAQs', 'Global Community Advisors', and 'For Study Investigators'. Below the menu, there are tabs for 'PrEP Studies Overview', 'PURPOSE 1', 'PURPOSE 2' (which is selected), 'PURPOSE 3', and 'PURPOSE 4'. The main content area features a pink background with the heading 'Welcome to PURPOSE 2' and a paragraph explaining the study's focus on HIV prevention. A 'Do you qualify?' button with a right-pointing arrow is visible, along with a link to 'clinicaltrials.gov'.



<https://www.purposestudies.com>

# Tailoring Recruitment to the Local Context Online and in Real Life



**DO YOU WANT TO STICK OR SWALLOW YOUR PREP?**

We're looking for cisgender men, trans women, trans men, and non-binary folks to test an investigational long-acting injectable PrEP compared to a daily PrEP pill.

You may be eligible to participate if you're:  
• 18 years or older & HIV Negative,  
• currently having receptive anal sex,  
• and a cisgender man, trans woman, trans man or non-binary.

Participation includes receiving injections of an investigational PrEP medicine, taking a daily pill, & giving blood for lab tests and HIV/STI testing.

For their time and travel, eligible participants can receive up to \$175 per visit.

415-355-4345  
HELPFI@HIV.VA

**Do it because...**

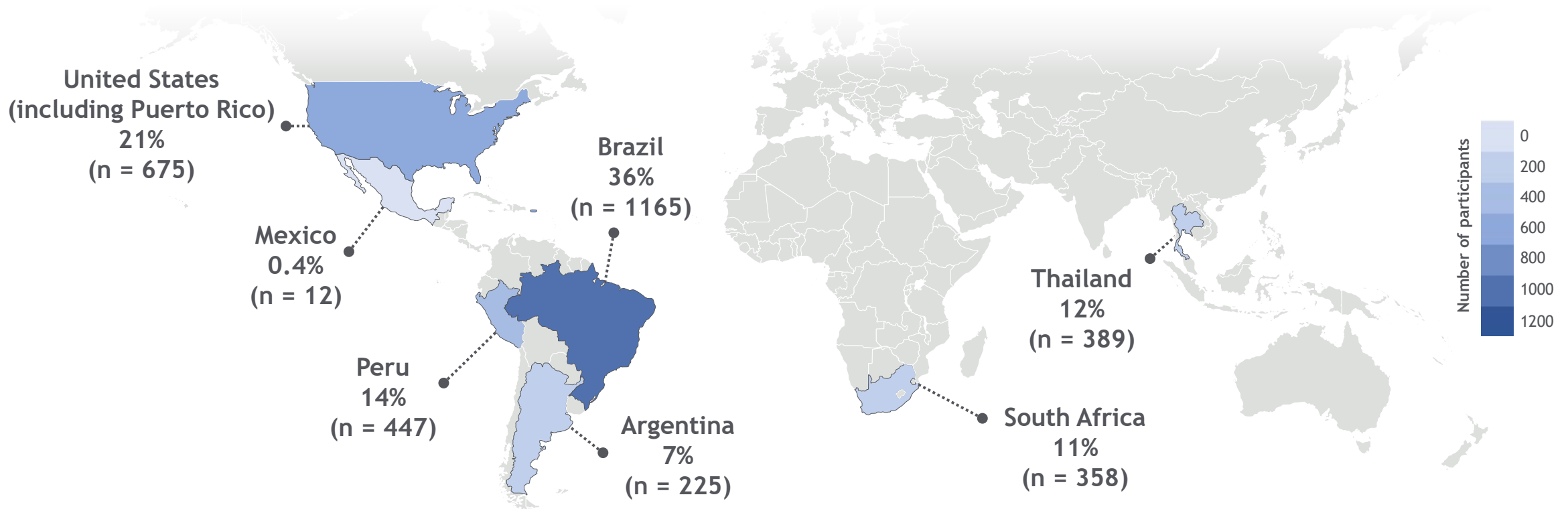
Representation in HIV prevention matters.

**Make yourself seen. >**  
Learn about a clinical trial.

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GS-US-XXX-XXXX 10/22  
For illustrative purposes only.



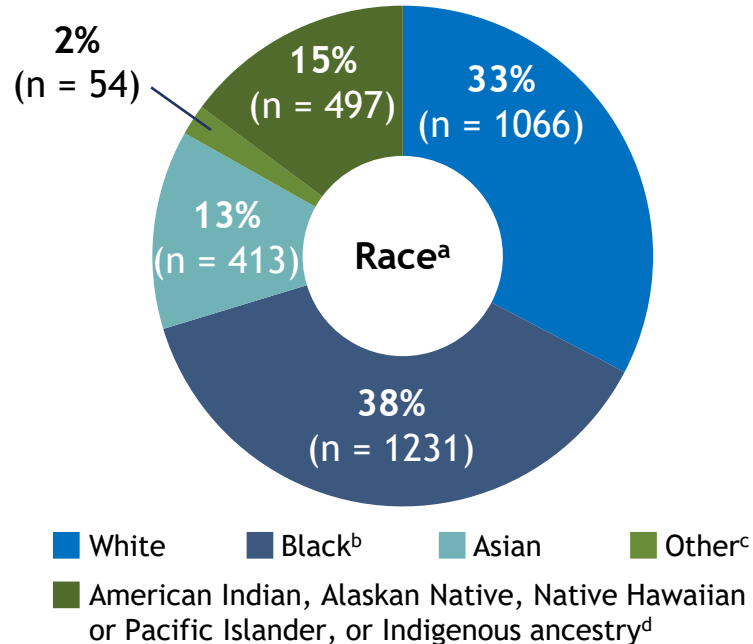
# Geographic Distribution of Participants in the PURPOSE 2 Trial



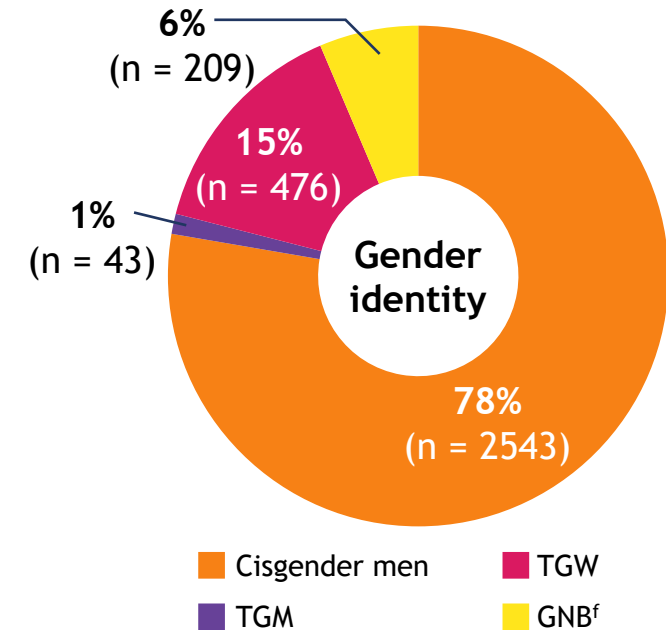
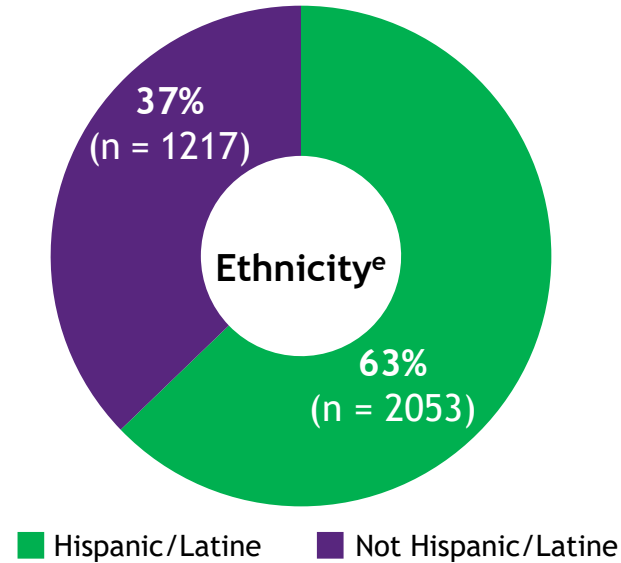
A total of 3271 participants<sup>a</sup> from seven countries across the United States (including Puerto Rico), Latin America, South Africa, and Asia were randomized

# Global Distribution of Participants in the PURPOSE 2 Trial by Race, Ethnicity, and Gender Identity

67% of participants were non-White




22% of participants were Transgender or GNB



Some percentages do not sum to 100% due to rounding. <sup>a</sup>Data not available for n = 10. <sup>b</sup>Black included all participants who identified as Black or of Black ancestry: Black (n = 885), Black/White (n = 283), Black/Pardo (n = 22), Black/Brown (n = 20), Black/Colored (n = 11), Black/American Indian or Alaskan Native (n = 6), Black/Asian (n = 2), and Black/Native Hawaiian or Pacific Islander (n = 2). <sup>c</sup>Other included: Asian/White (n = 7), Colored (n = 6), Pardo (n = 4), White/Brown (n = 8), multiracial other (n = 16), and not multiracial other (n = 13). <sup>d</sup>American Indian, Alaskan Native, Native Hawaiian or Pacific Islander, or Indigenous ancestry included: American Indian or Alaskan Native (n = 33), Native Hawaiian or Pacific Islander (n = 3), Asian/Native Hawaiian or Pacific Islander (n=1), White/Native Hawaiian or Pacific Islander (n = 3), and White/American Indian or Alaskan Native (n = 457). <sup>e</sup>Data not available for n = 1. <sup>f</sup>GNB included n = 6 individuals who identified as Transvesti (all assigned male at birth) and n = 4 individuals who identified as an "Other" gender (all assigned male at birth). GNB, gender nonbinary individuals; PrEP, pre-exposure prophylaxis; TGM, transgender men; TGW, transgender women.

# PURPOSE 2 in Comparison With Previous PrEP Trials

PrEP trial n (%)	Non-White race	Hispanic/ Latine	Cisgender gay, bi, and other MSM	Transgender women	Transgender men	Gender nonbinary
iPrEx <sup>1</sup>	2068 (83)	1806 (72)	2470 (99)	29 (1)	0	0
IPERGAY <sup>2,a</sup>	34 (9)	-	400 (100)	0	0	0
PROUD <sup>3</sup>	99 (19)	-	543 (100)	1 (< 1)	0	0
DISCOVER <sup>4</sup>	876 (16)	1318 (24)	5313 (99)	74 (1)	0	0
HPTN 083 <sup>5,6b</sup>	3283 (72)	2110 (46)	3992 (87)	570 (13)	0	0
 PURPOSE 2 enrollment	2195 (67)	2053 (63)	2543 (78)	476 (15)	43 (1)	209 (6) <sup>c</sup>

**PURPOSE 2 is the most racially, ethnically, and gender-diverse PrEP trial to date**

Hyphens in the table denote no data were available for the corresponding baseline characteristic. <sup>a</sup>Inclusion criteria were male or transgender female sex among participants who have sex with men; however, no transgender women participants were reported. <sup>b</sup>Four (<1%) participants preferred not to provide their gender identity; data on race were not available for 20 participants. <sup>c</sup>Nonbinary included n = 6 individuals who identified as Travesti (all assigned male at birth) and n = 4 individuals who identified as an “Other” gender (all assigned male at birth). 1. Grant RM, et al. *N Engl J Med.* 2010;363:2587-99. 2. Molina JM, et al. *N Engl J Med.* 2015;373:2237-46. 3. Dolling DI, et al. *Trials.* 2016;17:163. 4. Mayer KH, et al. *Lancet.* 2020;396:239-254. 5. Landovitz RJ, personal communication. October 7, 2024. 6. Landovitz RJ, et al. *N Engl J Med.* 2021;385:595-608. MSM, men who have sex with men; PrEP, pre-exposure prophylaxis.

# Conclusions



- PURPOSE 2 is the most racially, ethnically, and gender-diverse PrEP trial to date
  - The establishment of a G-CAG and the innovative recruitment strategies implemented by the trial sites helped enroll a diverse trial population
- Inclusion of a broad and diverse participant population is important for understanding the **efficacy of LEN for all populations** including communities disproportionately affected by HIV-1 and increasing PrEP use among those who have not yet benefited from current PrEP options



# PURPOSE 2 Acknowledgments

We would like to extend our thanks to all participants and their communities, investigators and site staff, the global community advisors, and the members of the PURPOSE 2 study team for their insights and support

Graphical and copyediting support was provided by Aimee Sherlock, MSc, of Aspire Scientific (Bollington, UK), and Amy Watkins, PhD, of Ashfield MedComms (Macclesfield, UK), an Inizio company, and was funded by Gilead Sciences, Inc.

The logo for 'PURPOSE 2' features a colorful starburst icon on the left, composed of several overlapping, curved lines in shades of purple, blue, green, and yellow. To the right of the icon, the word 'PURPOSE' is written in a bold, sans-serif font with a rainbow gradient, and the number '2' is in a solid dark blue.

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