

Recruitment of Disproportionately Affected Populations in the PURPOSE 5 Study Evaluating Lenacapavir for PrEP in France and the UK

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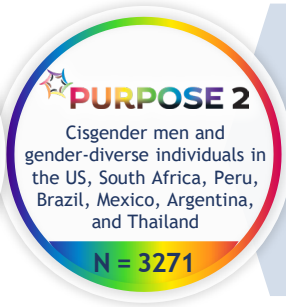
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Presenter Disclosures

- Jean-Michel Molina has received consulting fees and active grants from Gilead Sciences, Inc., Merck, and ViiV Healthcare
- Gilead Sciences, Inc. funded the study and designed the study with input from the PIs and G-CAGs. The PIs and study staff gathered data; Gilead Sciences, Inc. monitored conduct of the trial, received the data, and performed analyses
- Medical writing support was provided by Emma Davies, PhD (Aspire Scientific Ltd, UK), and was funded by Gilead Sciences, Inc.



Lenacapavir Was Safe and Efficacious for PrEP in a Broad and Diverse Phase 3 Program



- PURPOSE 1 and PURPOSE 2 were Phase 3 pivotal studies that demonstrated that LEN for PrEP is safe and effective in men, women, and gender-diverse populations,^{1,2} leading to the approval in the US and EU
 - European countries were not included in these studies



- Ongoing Phase 2 study in France and the UK investigating the persistence, safety, PK, and acceptability of twice-yearly SC LEN for HIV prevention among people not currently benefiting from PrEP
- We selected France and the UK because of the high PrEP use in those countries and the inequities that exist between PrEP availability and uptake^{3,4}

The aim of PURPOSE 5 is to investigate annual persistence, defined as consistent adherence over 1 year, in populations disproportionately affected by HIV in France and the UK

LEN, lenacapavir; PK, pharmacokinetics; PrEP, pre-exposure prophylaxis; SC, subcutaneous.

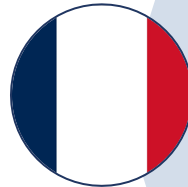
1. Bekker L-G, et al. *N Engl J Med*. 2024;391:1179-92. 2. Kelley CF, et al. *N Engl J Med*. 2025;392:1261-76. 3. British Association for Sexual Health and HIV/British HIV Association.

<https://bhiva.org/wp-content/uploads/2025/07/2025-PrEP-guidelines.pdf> (accessed Sept. 5, 2025). 4. EACS. 2025. <https://eacs.sanfordguide.com/eacs-part1/art/eacs-pre-exposure-prophylaxis> (accessed Sept. 5, 2025).

Despite Widespread Availability of PrEP, Not Everyone Is Benefiting



- The number of new HIV diagnoses first diagnosed in England has remained relatively stable since 2019¹
- However, HIV continues to disproportionately affect ethnic minority groups, particularly people of Black heritage, transgender individuals, migrants, cisgender women, and sex workers, and inequities still exist in PrEP uptake¹⁻⁴

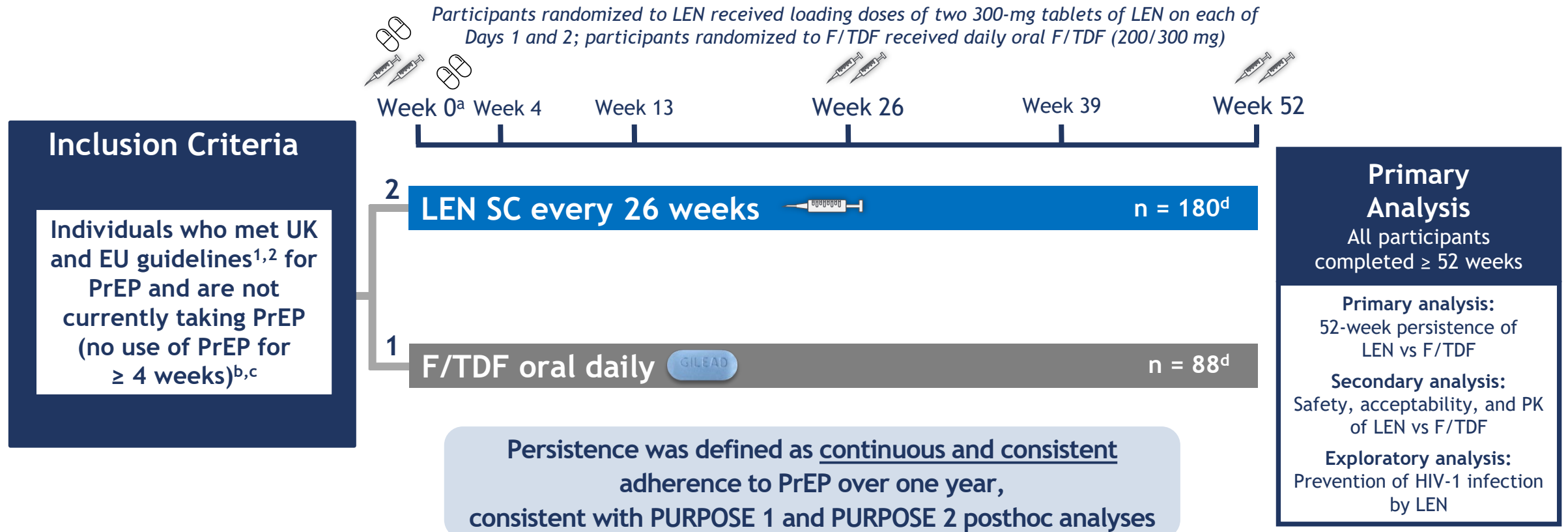


- In France, although the number of new HIV diagnoses has decreased, this reduction has primarily been in men born in France who have sex with men⁵⁻⁸
- Non-adherence and early PrEP discontinuation are common, resulting in lower real-world HIV risk reduction than observed in clinical trials^{6,8-10}

We sought to enroll a majority of participants from disproportionally affected populations, including cisgender women,^{1,3,11} men from minoritized ethnic groups who have sex with men,^{1,11} transgender people,^{4,11-14} and sex workers^{4,11}

PURPOSE 5 Is Evaluating Persistence on Twice-Yearly LEN vs Daily Oral F/TDF for PrEP in France and the UK

Open-Label Randomized Phase

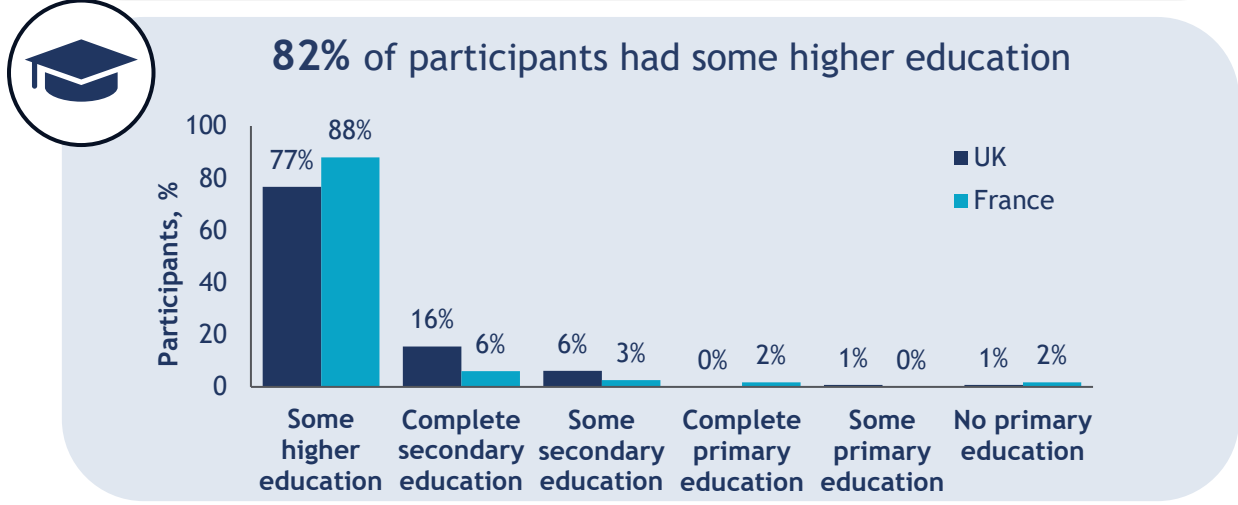
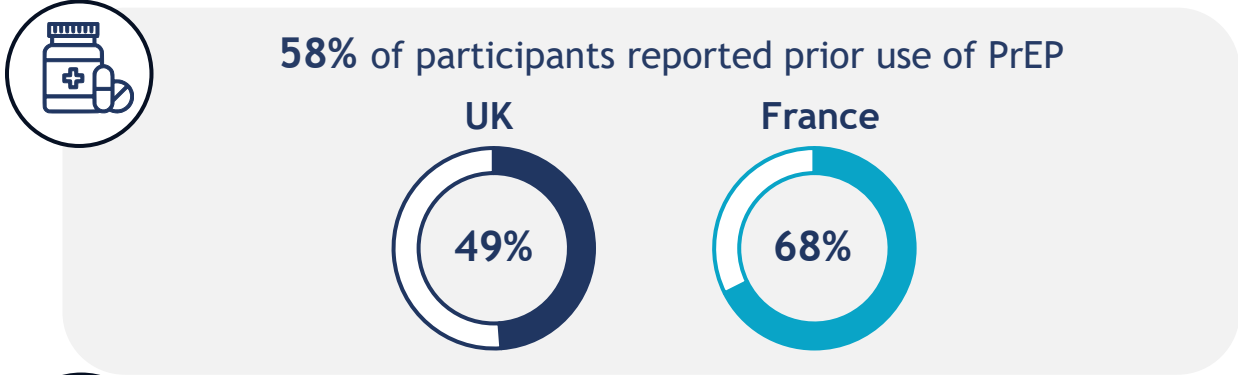
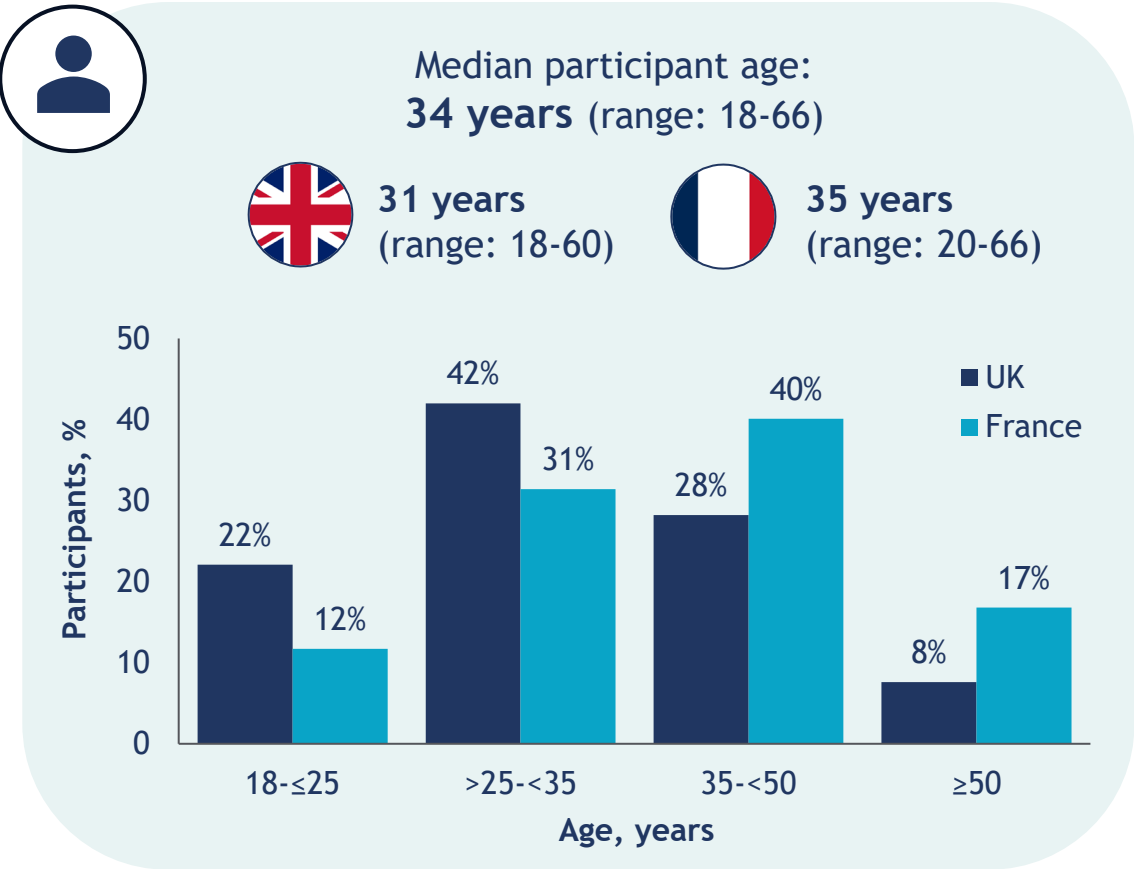


ClinicalTrials.gov: NCT06513312

^aOn Days 1 and 2, all participants receiving LEN received a pharmacologic loading dose of 600 mg oral LEN. ^b ≥ 18 years of age, HIV-negative test, eGFR ≥ 60 mL/min. ^cHIV-negative status was confirmed by a local rapid HIV-1/2 antibody (Ab)/antigen (Ag) test, central HIV-1/2 Ab/Ag, and HIV-RNA NAAT at screening and on Day 1. ^dn numbers represent completed enrollment. F/TDF, emtricitabine/tenofovir disoproxil fumarate; LEN, lenacapavir; NAAT, nucleic acid amplification testing; PK, pharmacokinetics; PrEP, pre-exposure prophylaxis; SC, subcutaneous.

1. British Association for Sexual Health and HIV/British HIV Association. 2025. <https://bhiva.org/wp-content/uploads/2025/07/2025-PrEP-guidelines.pdf> (accessed Sept. 5, 2025). 2. EACS. 2025. <https://eacs.sanfordguide.com/eacs-part1/art/eacs-pre-exposure-prophylaxis> (accessed Sept. 5, 2025). 3. Mayer KH, et al. *Lancet*. 2020;396:239-54.

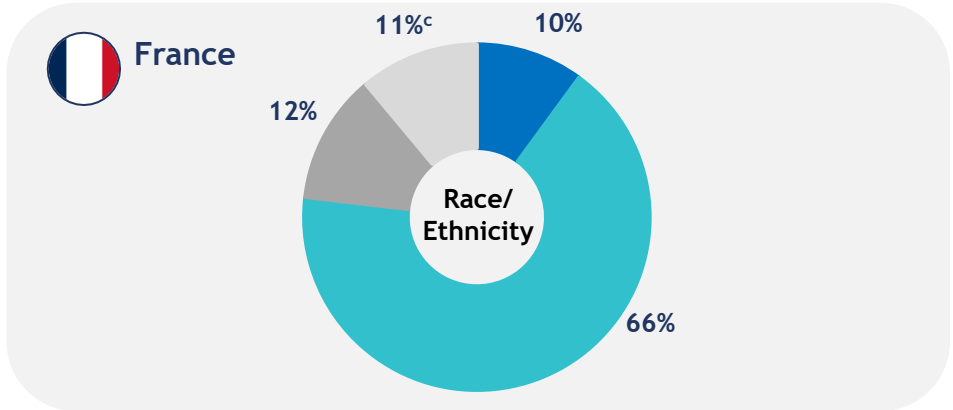
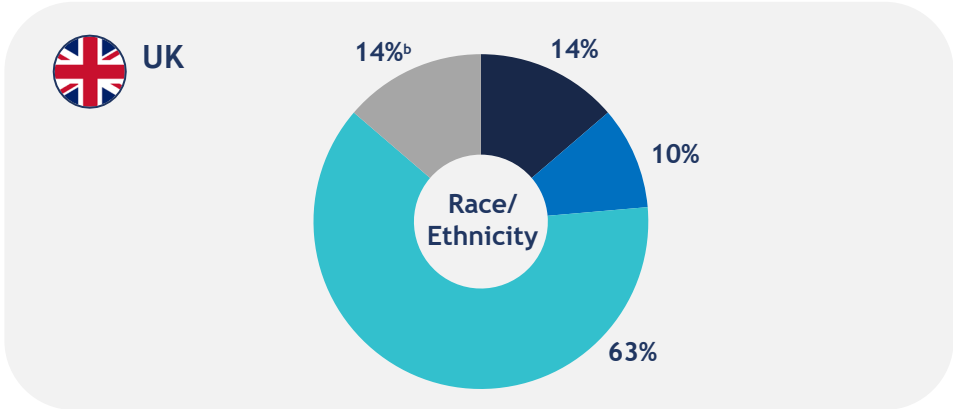
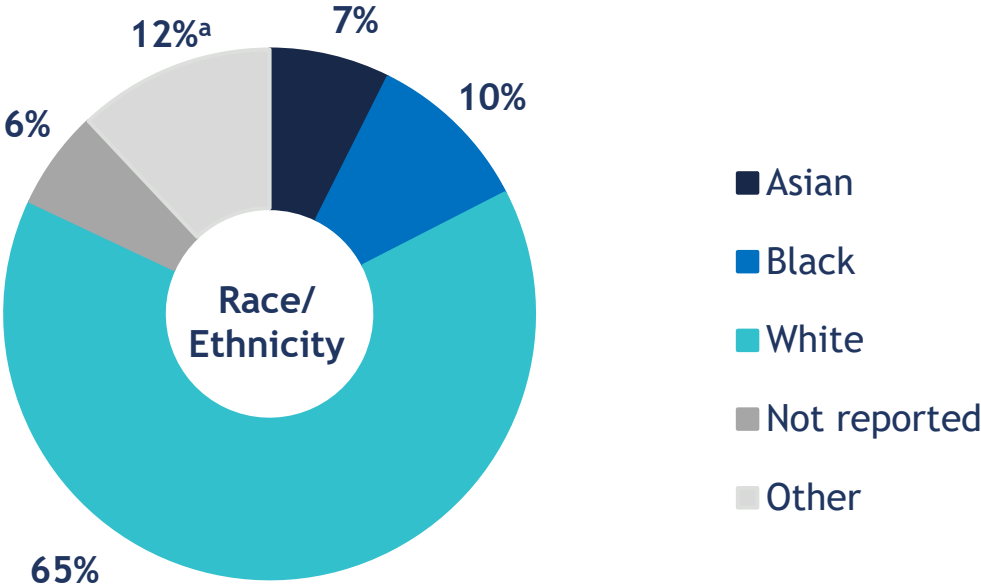
Participants' Age, Highest Education Level, and Prior PrEP Use



Overall, 42% participants had not previously accessed PrEP

Distribution of Participants by Ethnic Group, Overall and by Country

29% of participants are in a minoritized ethnic group

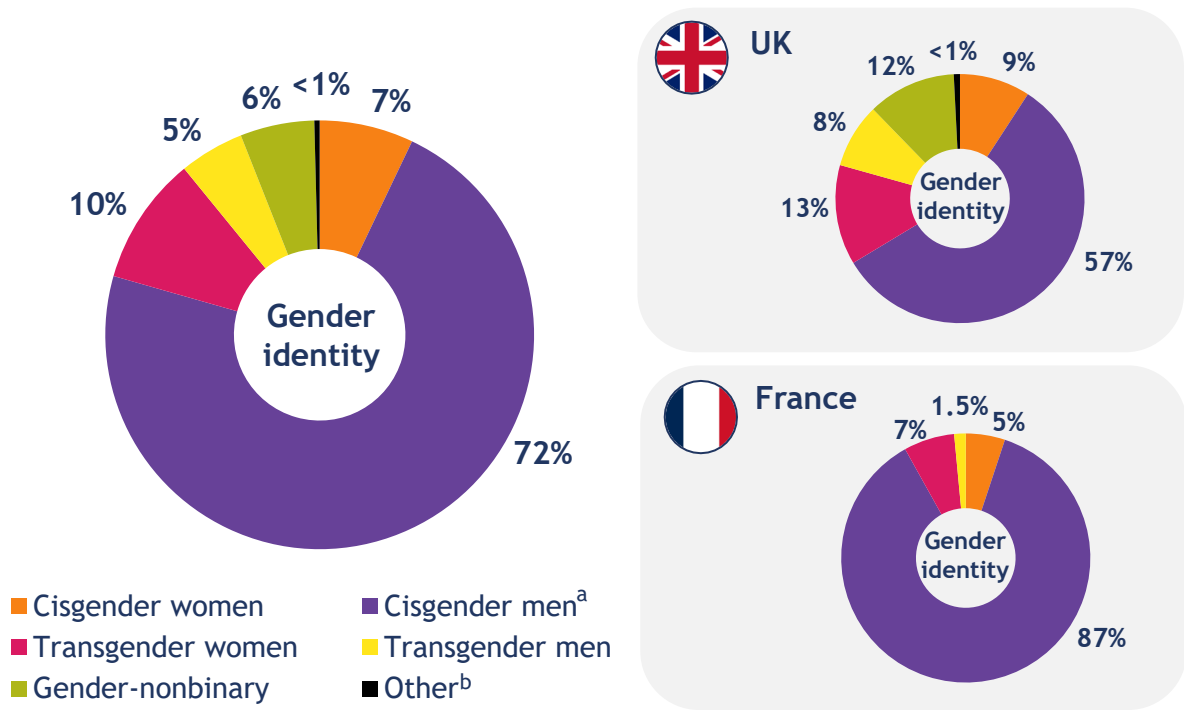


Overall, 29% of participants in PURPOSE 5 identify as a minoritized ethnic group

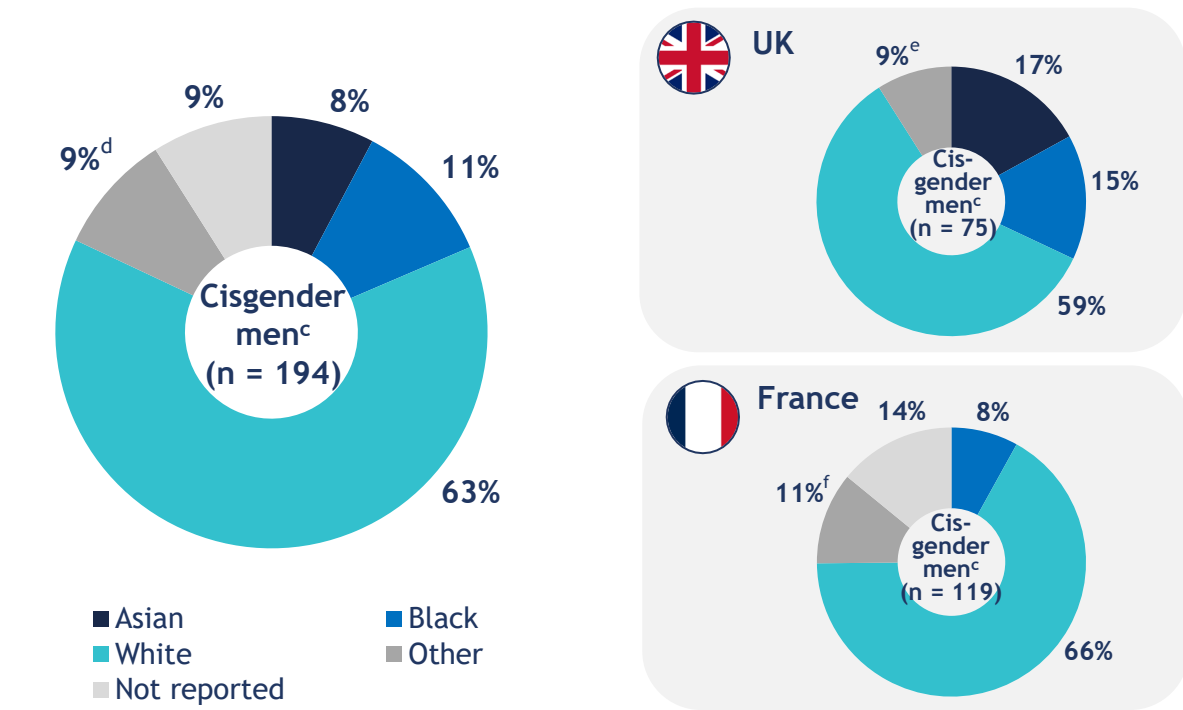
7 Some percentages do not sum to 100% due to rounding. ^aIncludes Other (n = 29), American Indian or Alaska Native (n = 1), and Native Hawaiian or Pacific Islander (n = 1). ^bIncludes Other (n = 18). ^cIncludes Other (n = 11), Asian (n = 2), American Indian or Alaska Native (n = 1), and Native Hawaiian or Pacific Islander (n = 1).

Distribution of Participants by Gender Identity, Overall, and by Country

21% of participants are transgender men, transgender women, or gender-nonbinary



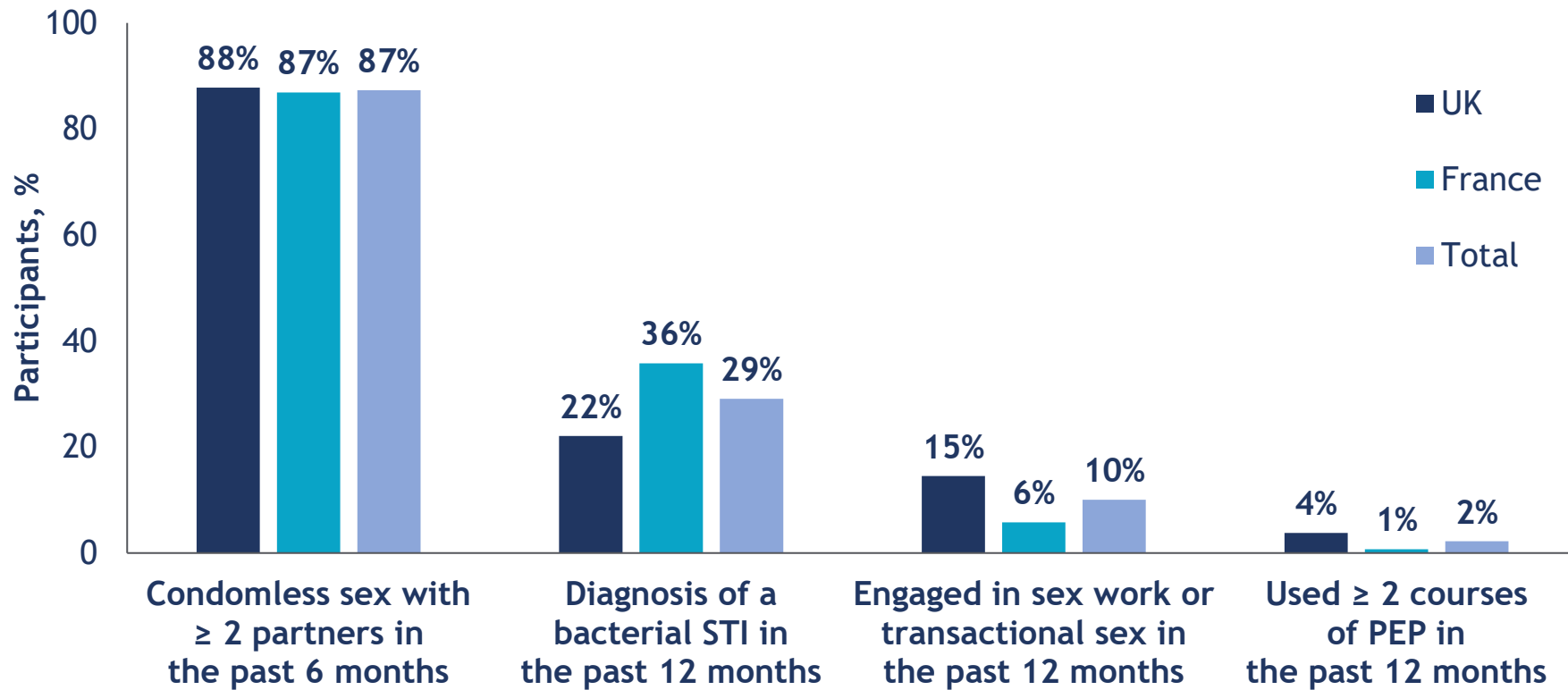
28% of cisgender men identify as a minoritized ethnic group



Overall, 21% participants identify as gender diverse and 7% are cisgender women. 28% of the cisgender men in PURPOSE 5 identify as a minoritized ethnic group

8 Some percentages do not sum to 100% due to rounding. ^aWho have sex with partners assigned male at birth. ^bIncludes 1 participant assigned male at birth. ^cData are percentage of participants in each ethnic group. ^dIncludes Other (n = 17) and Native Hawaiian or Pacific Islander (n = 1). ^eIncludes Other (n = 7). ^fIncludes Other (n = 10), Asian (n = 2), and Native Hawaiian or Pacific Islander (n = 1).

Screened Participants Were at Increased Likelihood of HIV Acquisition



STIs at baseline:

13% of participants had gonorrhea, chlamydia, or *Trichomonas vaginalis*

2% of participants had syphilis

Approximately 50% of participants in PURPOSE 5 were representative of disproportionately affected groups

Retention to Date Is Very High

Study progress:



of participants have reached the Week 13 visit



of participants have reached the Week 26 visit

Retention:



of participants remain in the study as of Oct. 8, 2025

Retention in PURPOSE 5 is high to date

Conclusions



- In the PURPOSE 5 study of twice-yearly SC LEN for PrEP in France and the UK, ~50% of participants represent disproportionately affected populations not currently benefiting from PrEP
- Inclusion of a broad and diverse population is important for understanding the benefit of LEN for PrEP for all populations, including communities disproportionately affected by HIV
- Primary data are expected in mid 2026

PURPOSE 5 enrollment demonstrates the feasibility of reaching underserved populations with LEN for PrEP



PURPOSE 5 Acknowledgments

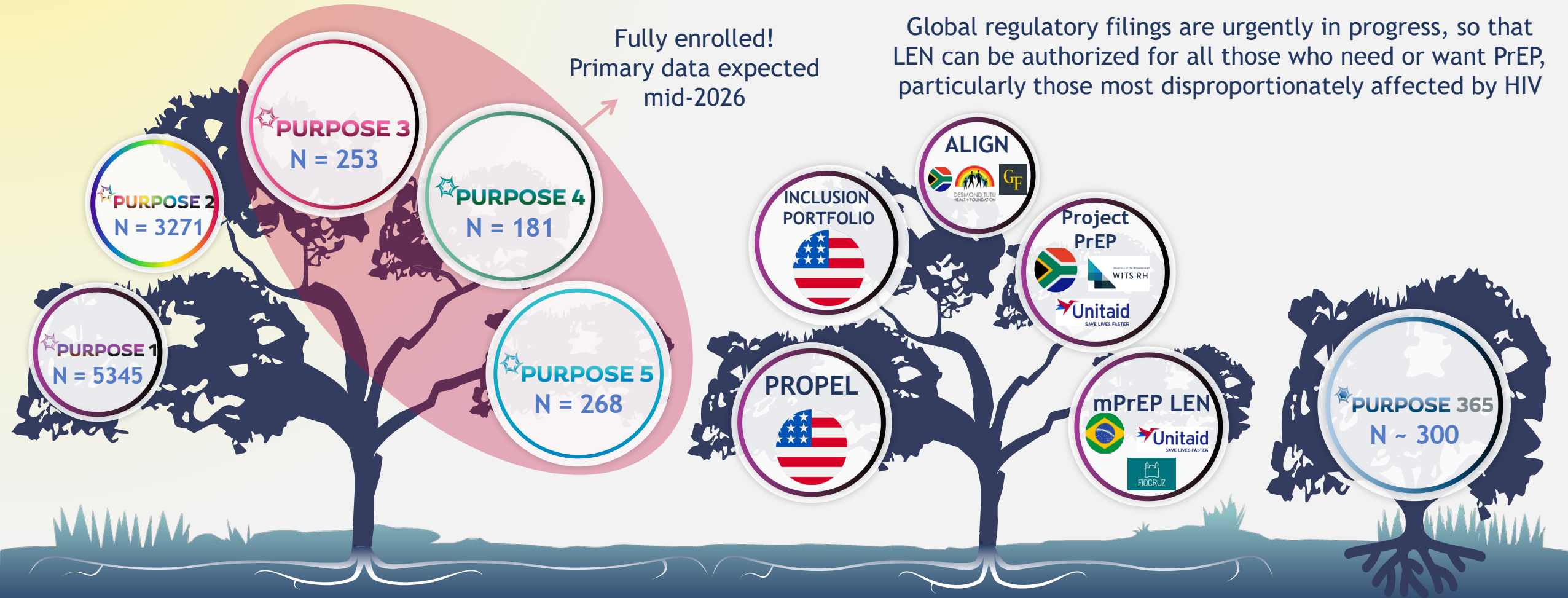
We extend our gratitude to the PURPOSE study participants and their communities, local community advisors, the site staff and investigators, and all the members of the PURPOSE 5 study team for their insights and support

QR Code

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A Growing PURPOSE Portfolio



#preventionwithpurpose

#accesswithpurpose

PURPOSE 1: NCT04994509; PURPOSE 2: NCT04925752; PURPOSE 3: NCT06101329; PURPOSE 4: NCT06101342; PURPOSE 5: NCT06513312; PURPOSE 365: NCT07047716.

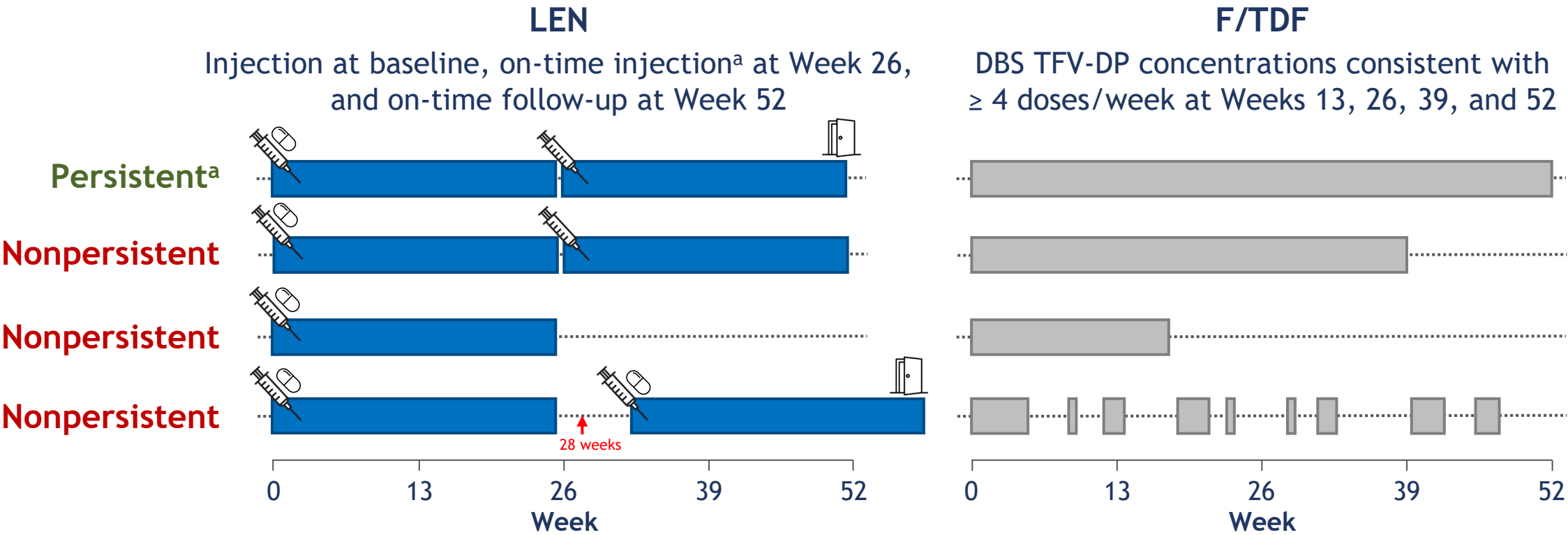
LEN, lenacapavir; PrEP, pre-exposure prophylaxis.

PURPOSE studies. <https://www.purposestudies.com> (accessed Aug. 15, 2025).

Back up

The Primary Endpoint Is 52-Week Annual Persistence

Persistence^a was defined as continuous and consistent adherence to PrEP over time



^aPersistence is calculated in the Full Analysis Set; on-time injection at Week 26 and on-time follow-up at Week 52 were defined as within 28 weeks after the last injection. The proportion of participants with persistence through Week 52 will be reported for each study group with two-sided 95% exact CIs based on the Clopper-Pearson method.
DBS, dried blood spot; F/TDF, emtricitabine/tenofovir disoproxil fumarate; LEN, lenacapavir; PrEP, pre-exposure prophylaxis; TFV-DP, tenofovir-diphosphate.