

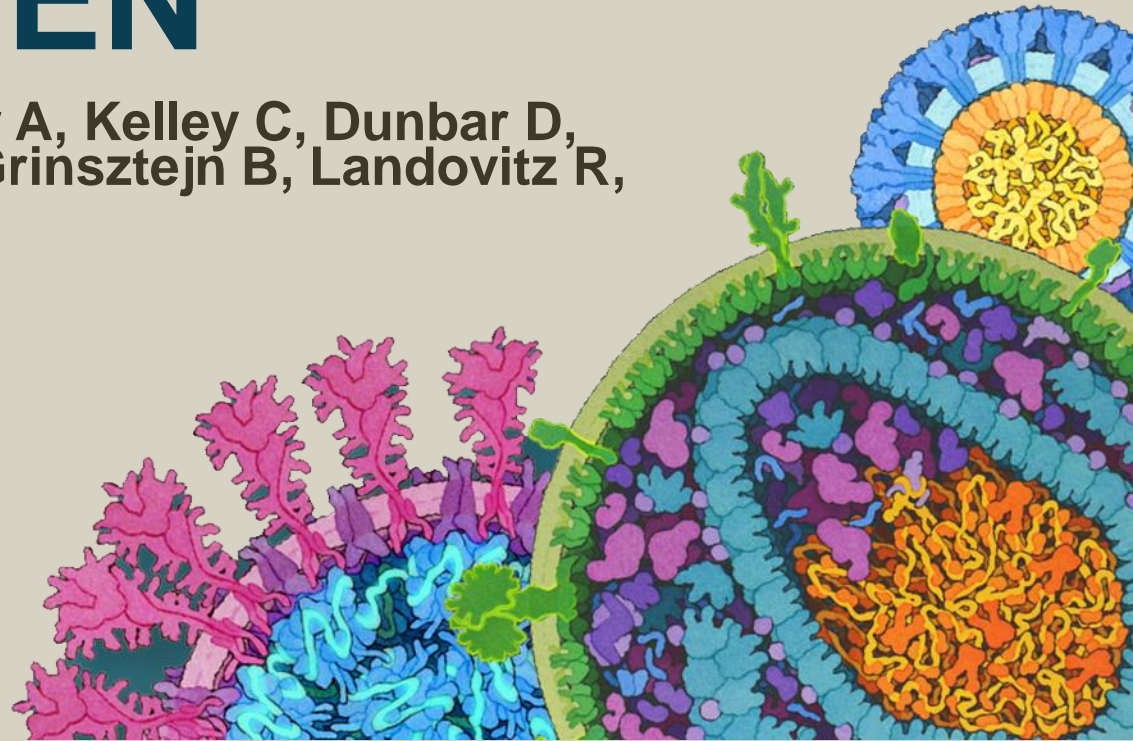
# CABOTEGRAVIR FOR HIV PrEP IN US BLACK MEN AND TRANSGENDER WOMEN WHO HAVE SEX WITH MEN

Scott H, Hanscom B, Hutchinson C, Lucas J, Guar A, Kelley C, Dunbar D, Richardson P, Rooney J, Rinehart A, Adeyeye A, Grinsztejn B, Landovitz R, Fields S, and the HPTN 083 Study Team

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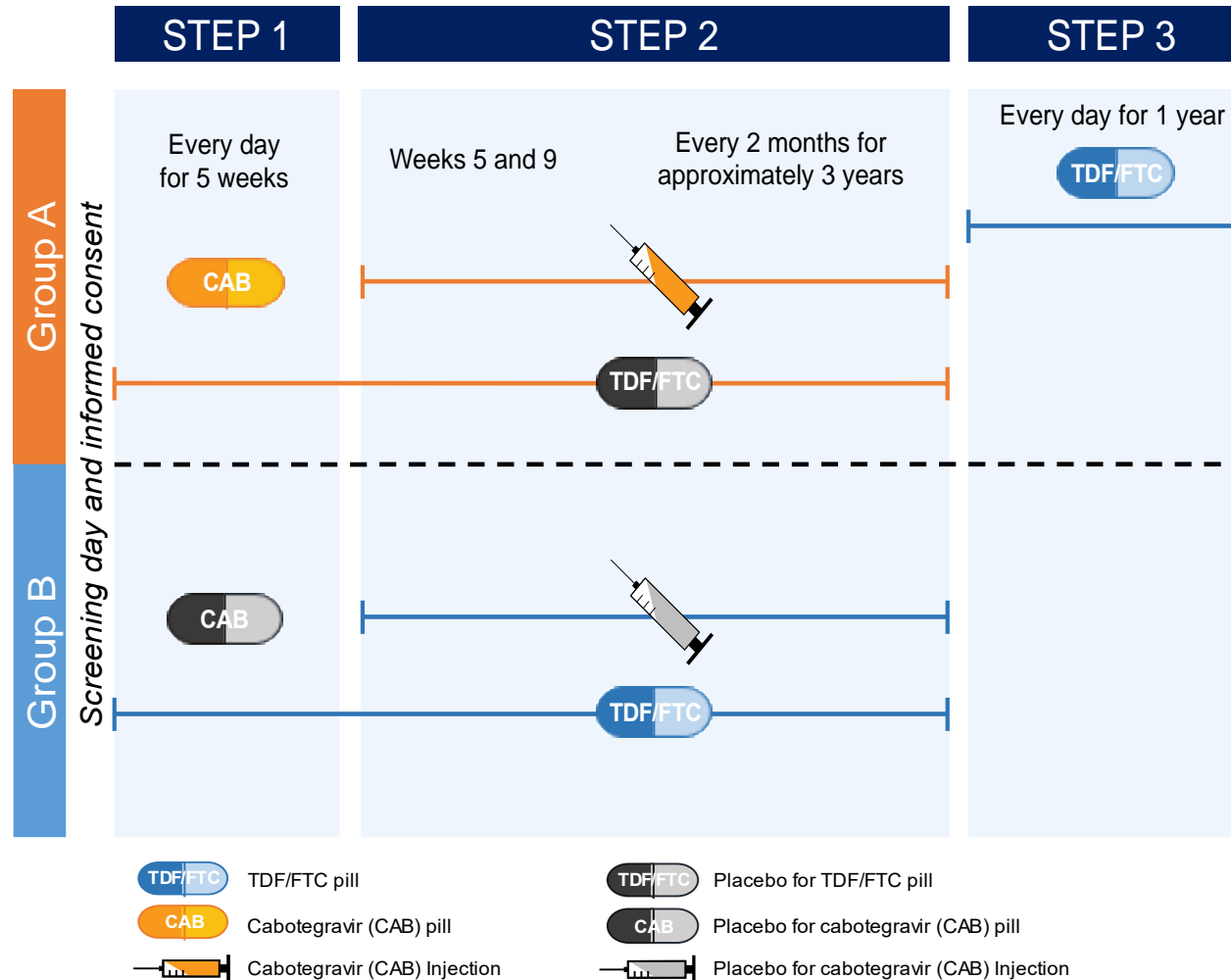
*Disclosure:* None



## Background

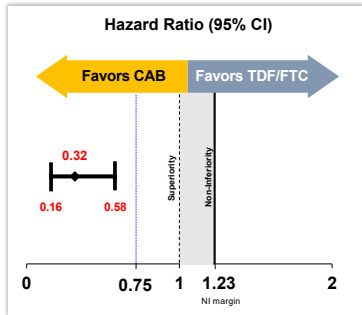
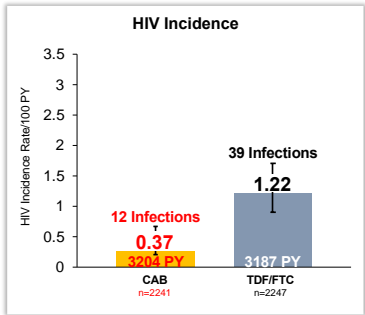
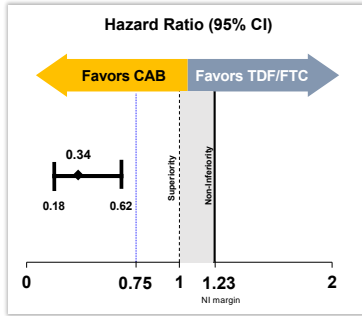
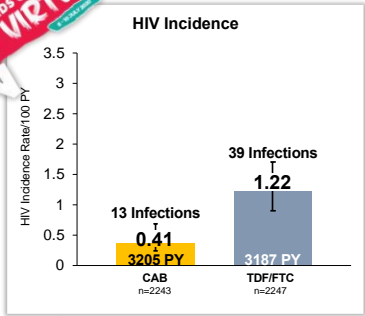
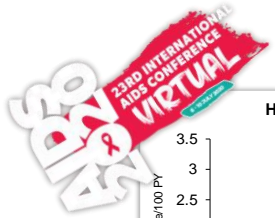
- Black men who have sex with men (MSM) and transgender women (TGW) who have sex with men are disproportionately impacted by HIV in the US.<sup>1</sup>
- HPTN 083 is an ongoing Phase 2b/3 randomized controlled trial of increased-risk, HIV-uninfected MSM + TGW at 43 sites in 7 countries<sup>2</sup>
  - HPTN 083 and HPTN 084 demonstrated that long-acting injectable Cabotegravir (CAB-LA) is superior to daily oral TDF/FTC for HIV PrEP across populations and regions<sup>2, 3</sup>
- In the US, 49.7% of HPTN 083 enrollment is Black/African American and HIV prevention efficacy among Black MSM and TGW was a pre-specified sub-group analysis.

# HPTN 083 Study Design

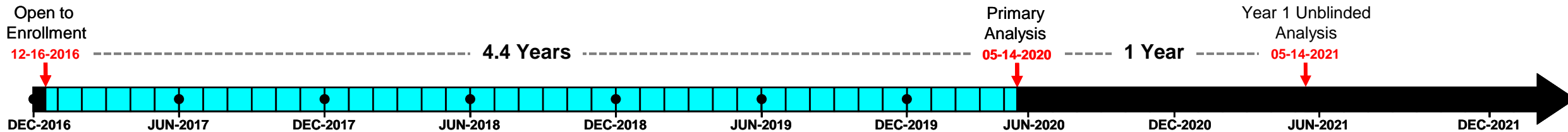
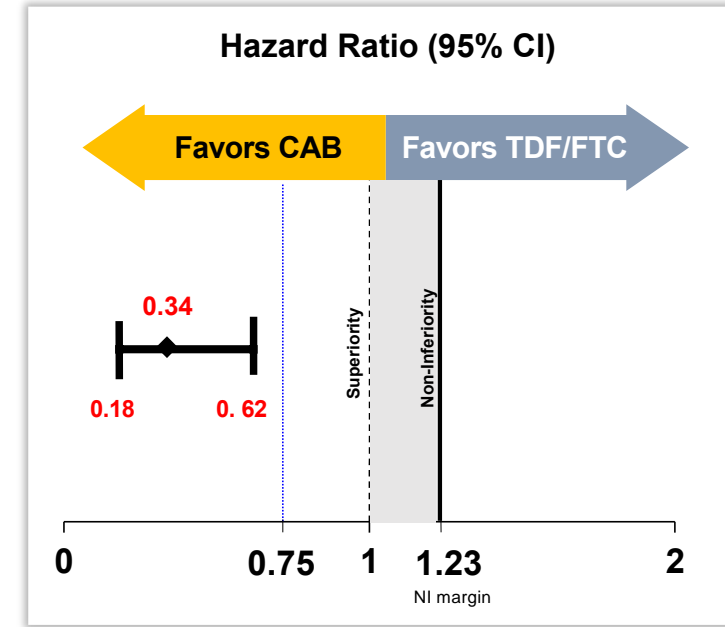
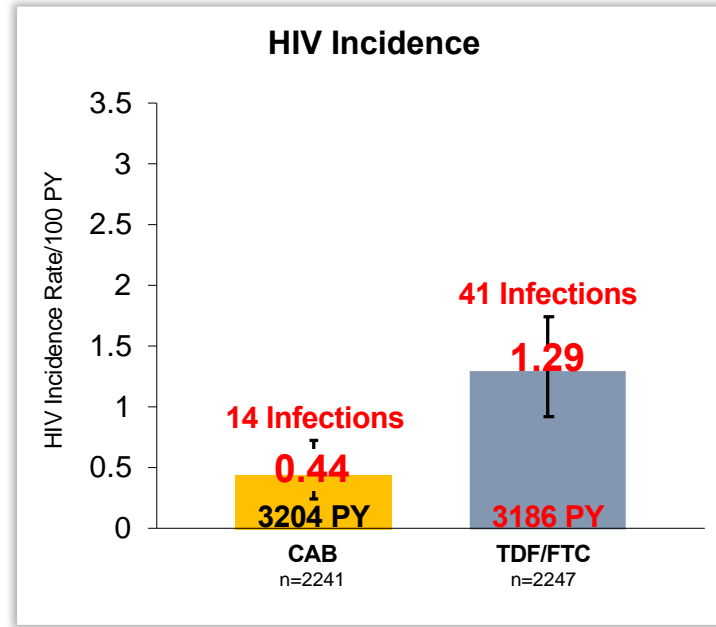


# HIV Incidence: CAB vs TDF/FTC

Landovitz CROI 2022 Abstract #96





## Updated Primary Blinded Period



# Methods

- We will present HIV efficacy, adherence subset, and safety data among US Black MSM and TGW and Non-Black MSM and TGW.
- This pre-specified analysis is among US participants who self-identified as Black/African American or mixed race including Black.
  - This subgroup analysis includes visits in the blinded study period through May 14, 2020.
  - Overall efficacy and safety data from HPTN 083 have been previously presented for both the specified and post-hoc analysis.
- The modified intent to treat (MITT) analysis excludes inappropriately enrolled participants and those found to be HIV infected at enrollment.

# Baseline Demographics

	Overall* N=1,698	US Black N=844 (49.7%)	US Non-Black N=852 (50.2%)
MSM	1573 (92.6%)	775 (91.8%)	796 (93.4%)
TGW	125 (7.4%)	69 (8.2%)	56 (6.6%)
Age, median (IQR)	27 (24-34)	27 (23-32)	28 (24-36)
Latino or Hispanic	 303 (17.8%)	79 (9.4%)	223 (26.2%)
College Education Or Higher	 1280 (75.4%)	574 (68.0%)	704 (82.6%)
Single/Divorced/Widowed	1382 (81.4%)	708 (83.9%)	672 (78.9%)

\*Includes data on two participants with missing race and ethnicity data

# Baseline HIV Risk Factors

<b>Behavioral*</b>		<b>Overall N=1,495</b>	<b>US Black N=771</b>	<b>US Non-Black N=722</b>
Sex Partners in past month, median (IQR)		2 (1-4)	2 (1-3)	2 (1-4)
Number of receptive anal acts, median (IQR)	➔	1 (0-3)	1 (0-3)	1 (0-4)
Injected drugs in the past 6 months		18 (1.2%)	10 (1.3%)	8 (1.1%)
Any recreational drugs in the past 6 months	➔	1,006 (67.3%)	481 (62.4%)	524 (72.6%)
AUDIT –C $\geq$ 4		617 (41.3%)	250 (32.4%)	366 (50.7%)

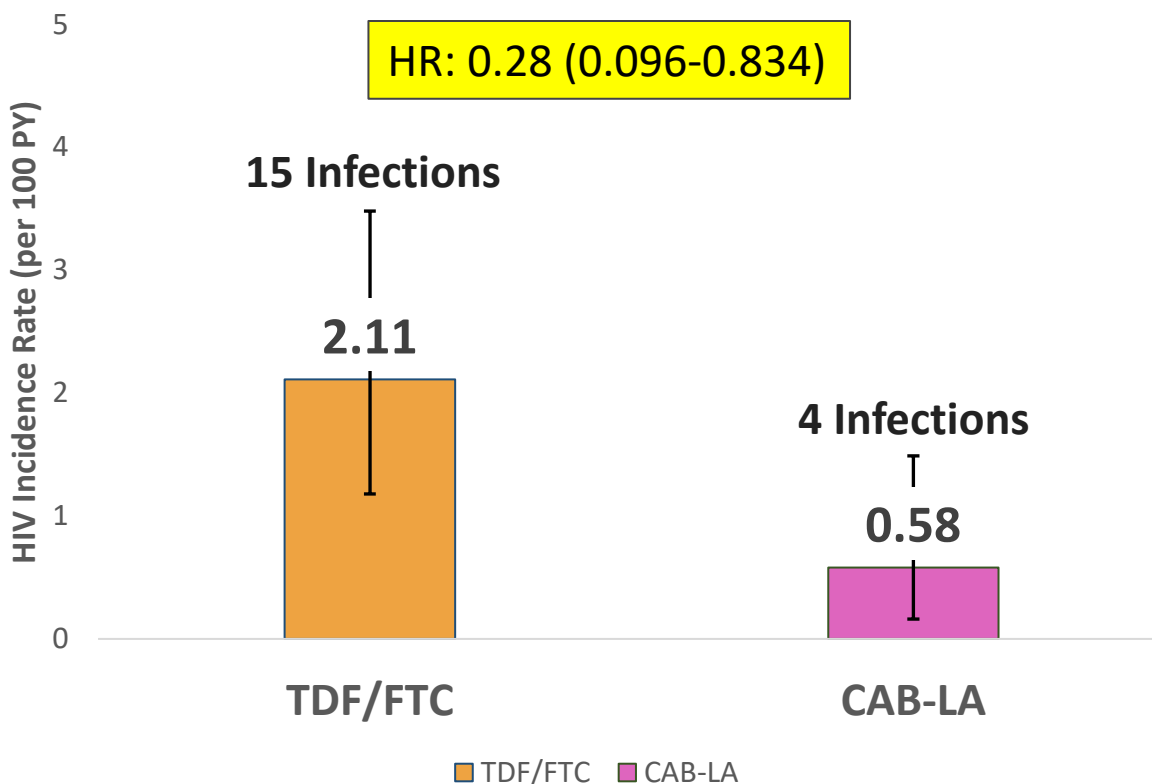
  

<b>Prevalent STIs</b>		<b>Overall N=1,698</b>	<b>US Black N=844</b>	<b>US Non-Black N=852</b>
Active Syphilis	➔	50 (3.0%)	38 (4.0%)	16 (1.9%)
Rectal Gonorrhea	➔	77 (4.6%)	48 (5.7%)	29 (3.4%)
Rectal Chlamydia		139 (8.2%)	74 (8.8%)	65 (7.7%)
Urine Gonorrhea	➔	12 (0.7%)	9 (1.1%)	3 (0.4%)
Urine Chlamydia		33 (2.0%)	19 (2.3%)	14 (1.7%)

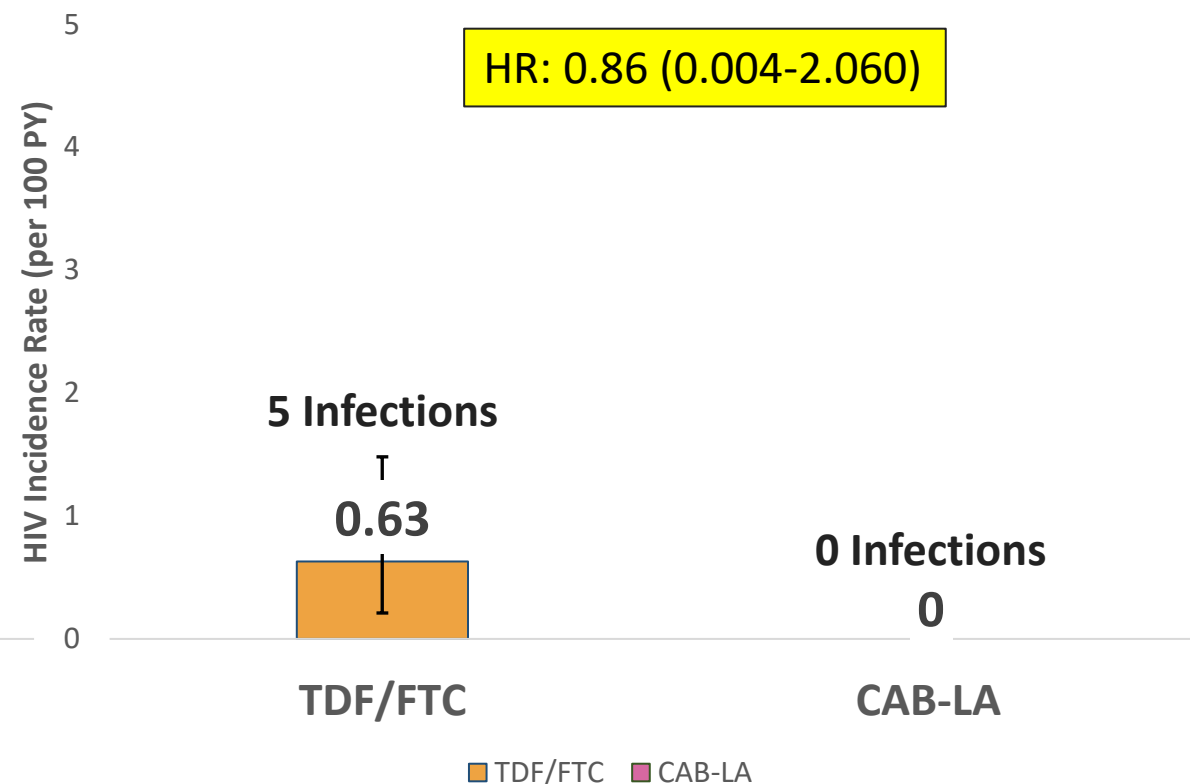
\*Behavioral data includes data from 1,495 completed baseline CASI

# HIV Incidence and Efficacy

HIV Incidence, US Black MSM and TGW



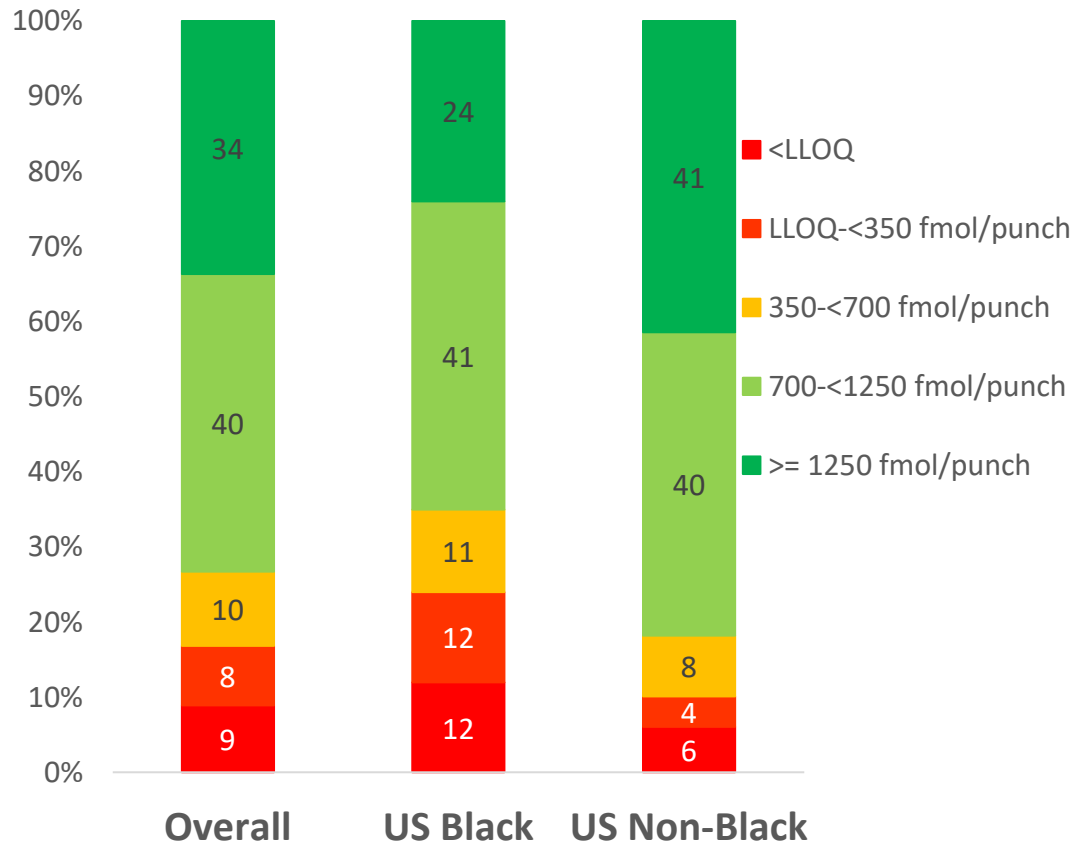
HIV Incidence, US Non-Black MSM and TGW



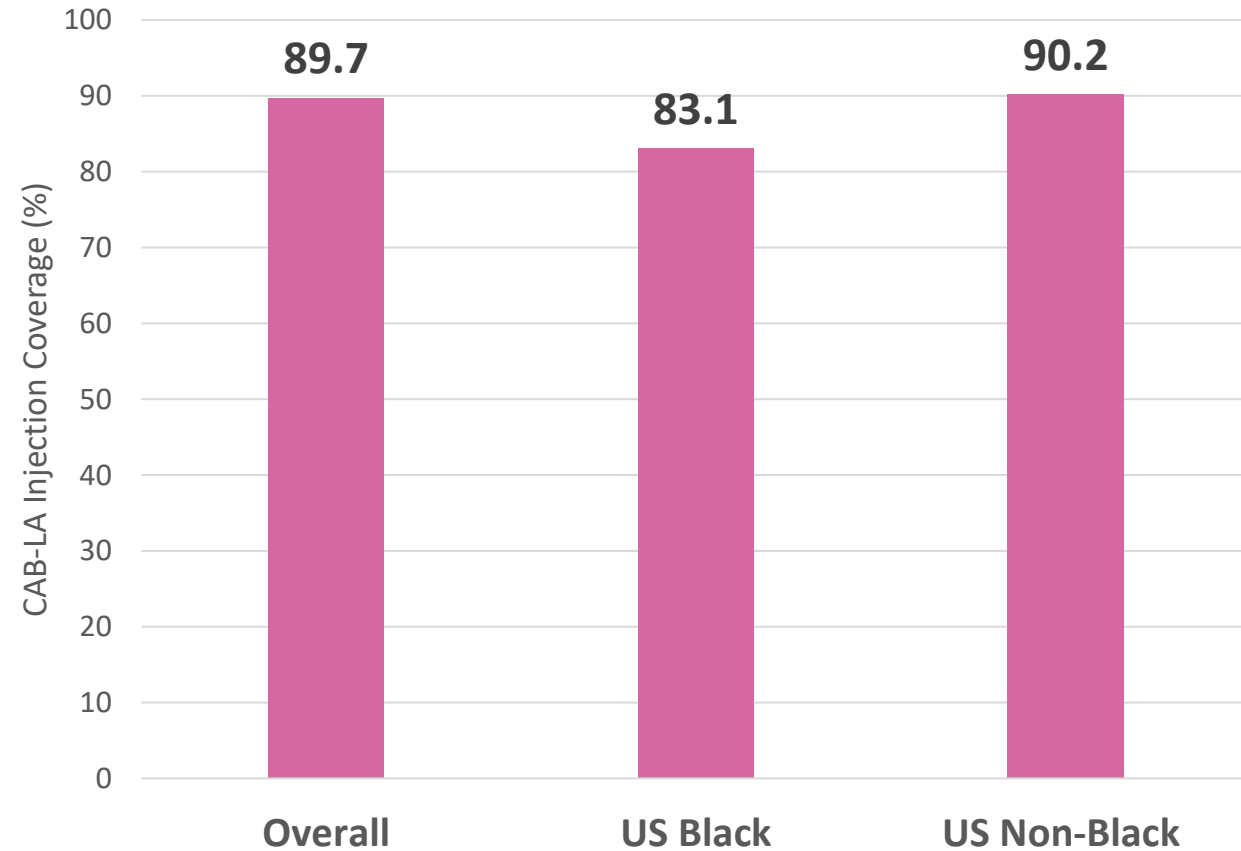


# TDF/FTC and CAB-LA Adherence

**TDF/FTC Adherence as Measured by Dried Blood Spot (DBS)**



**On-Time CAB-LA Injection Coverage**



# Injection Site Reactions

	Overall	US Black	US Non-Black
Participants with at least one injection (n)	1,523	734	788
Number of injections given	18,475	8,530	9,930
Injection Site Reactions (ISR)			
Any	927 (60.9%)	411 (56.0%)	515 (65.4%)
Grade 2 or above	334 (21.9%)	135 (18.4%)	198 (25.1%)
Grade 3 or above	34 (2.2%)	12 (1.6%)	22 (2.8%)

Overall, the most common ISR was injection site pain (17.3%) and tenderness (11.5%).

## Conclusions

- In HPTN 083, HIV incidence was higher among US Black MSM and TGW than US Non-Black MSM and TGW.
- Protective efficacy of CAB-LA vs. TDF/FTC remained high among US Black MSM and TGW.
- TDF/FTC adherence consistent with  $\geq 4$  dose/week was lower among Black MSM and TGW than non-Black MSM and TGW. CAB-LA adherence was high among both groups.
- CAB-LA is a powerful HIV prevention tool to increase access to PrEP and address continued racial disparities in HIV incidence in the US.

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## HIV Prevention Trials Network (HPTN)

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# and **OUR PARTICIPANTS!**



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