

# Results from HPTN 083 and 084

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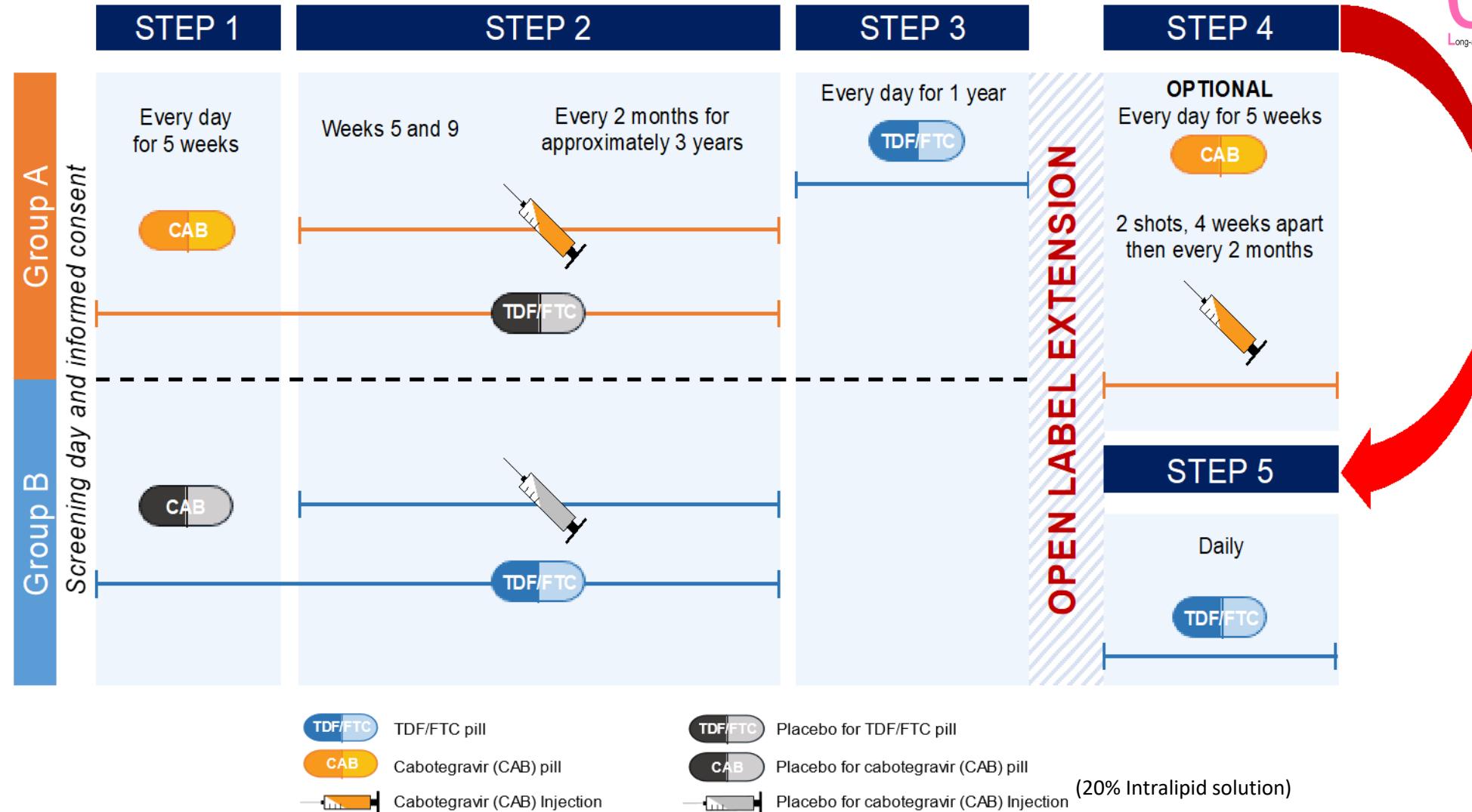
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# HPTN 083 Study Design



an HIV prevention clinical trial



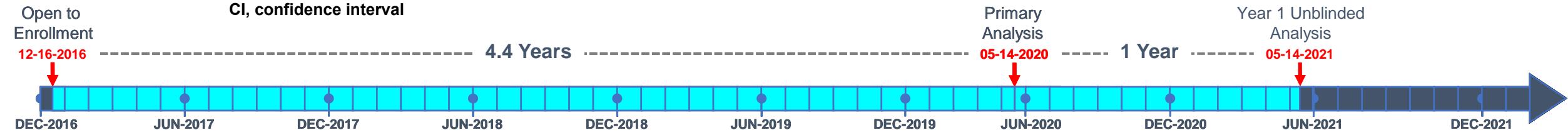
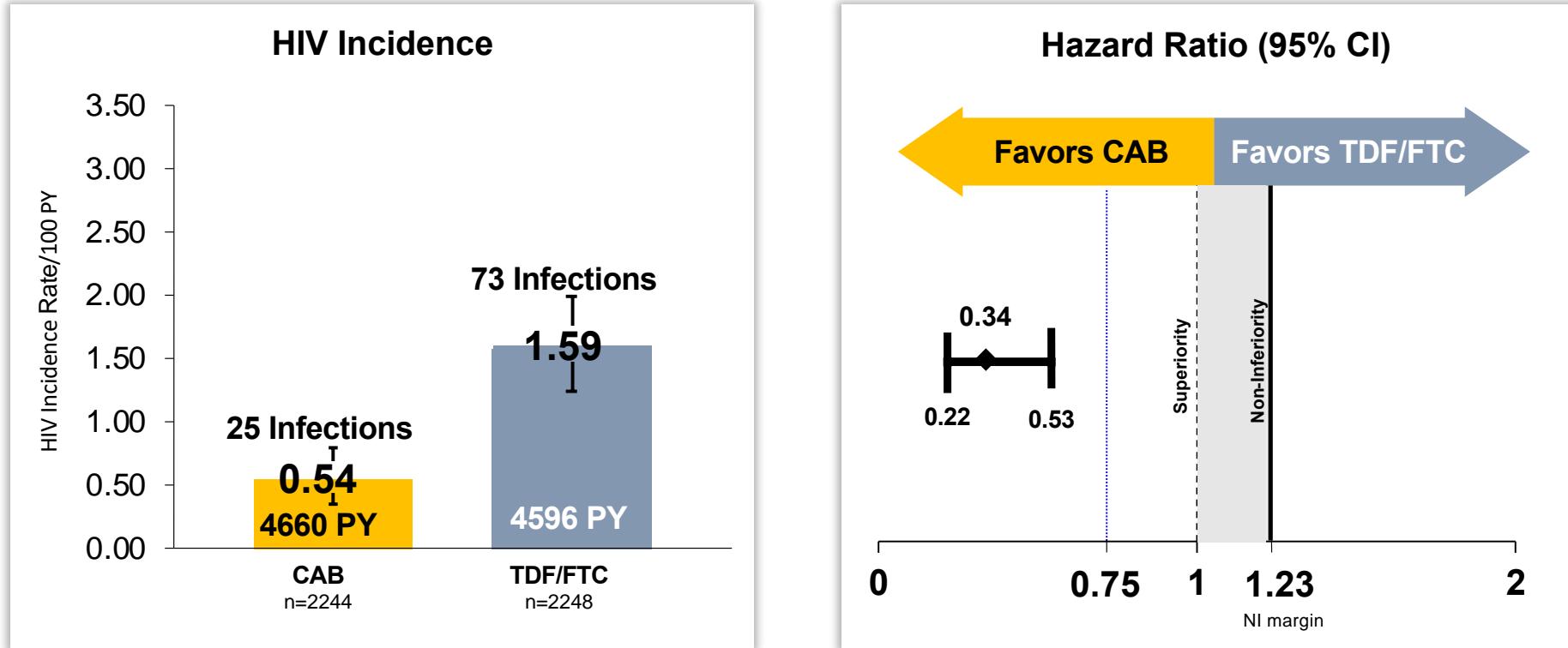
# EFFICACY

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# HPTN 083 HIV Incidence: CAB vs. TDF/FTC



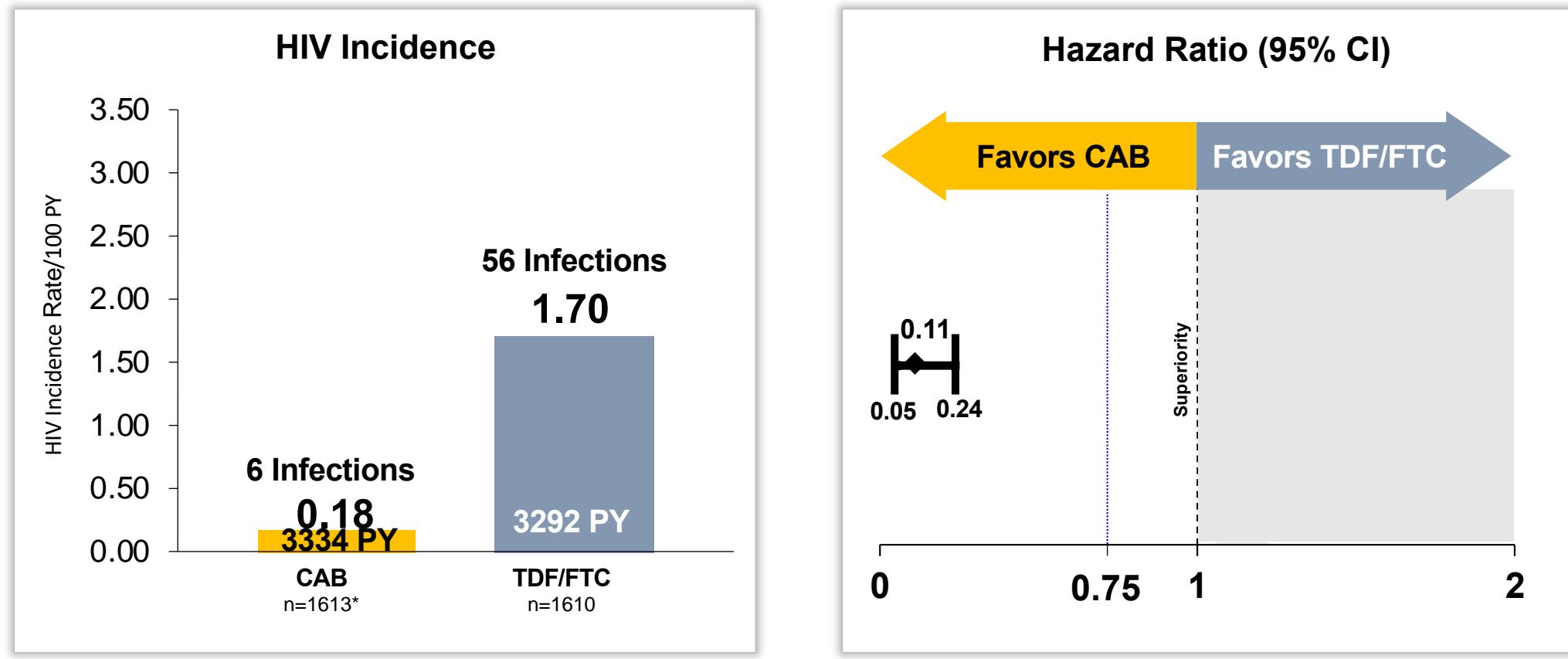
Combined blinded and unblinded period, through May 2021



# HPTN 084 HIV Incidence: CAB vs. TDF/FTC



Combined blinded and unblinded period, through Dec 2021



CI, confidence interval

\*Excludes 1 baseline infection from the blinded period

# The Bottom Line: Efficacy

Long-acting cabotegravir is very effective at preventing HIV in MSM, TGW, and cisgender women

- 66% reduction in HIV infection when compared to MSM and TGW who were offered TDF/FTC
- 89% reduction in HIV infection when compared to cisgender women who were offered TDF/FTC

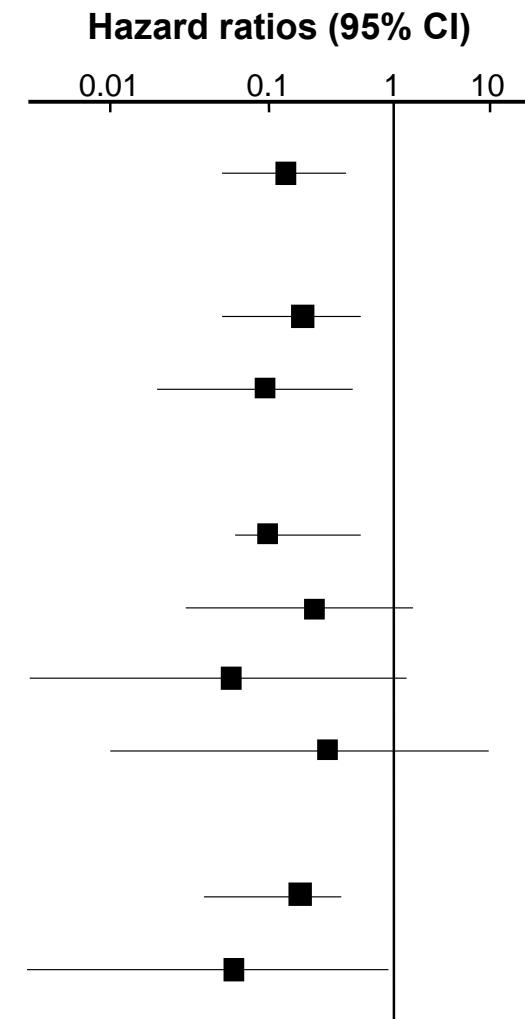
# HPTN 083 HIV Incidence by Subgroup CAB vs. TDF/FTC



# HPTN 084 HIV Incidence by Subgroup CAB vs. TDF/FTC



Subgroup	CAB Events/PY (IR%)	TDF/FTC Events/PY (IR%)	HR (95%CI)
<b>Overall</b>	4/1956 (0·20%)	36/1942 (1·85%)	0·12 (0·05–0·31)
<b>Age</b>			
<25 years	3/866 (0·35%)	20/851 (2·34%)	0·17 (0·05–0·54)
≥25 years	1/1090 (0·09%)	16/1091 (1·47%)	0·09 (0·02–0·49)
<b>Contraceptive Method</b>			
DMPA	3/1009 (0·30%)	21/1000 (2·10%)	0·16 (0·05–0·53)
NET-EN	1/175 (0·57%)	6/182 (3·30%)	0·22 (0·03–1·48)
Implant	0	8/607 (1·32%)	0·06 (0·00–1·16)
Other	0	1/152 (0·66%)	0·32 (0·01–9·89)
<b>BMI</b>			
≤30 kg/m <sup>2</sup>	4/1389 (0·29%)	27/1447 (1·87%)	0·16 (0·06–0·45)
>30 kg/m <sup>2</sup>	0	9/495 (1·82%)	0·05 (0·00–0·96)



# The Bottom Line: Efficacy in specific populations

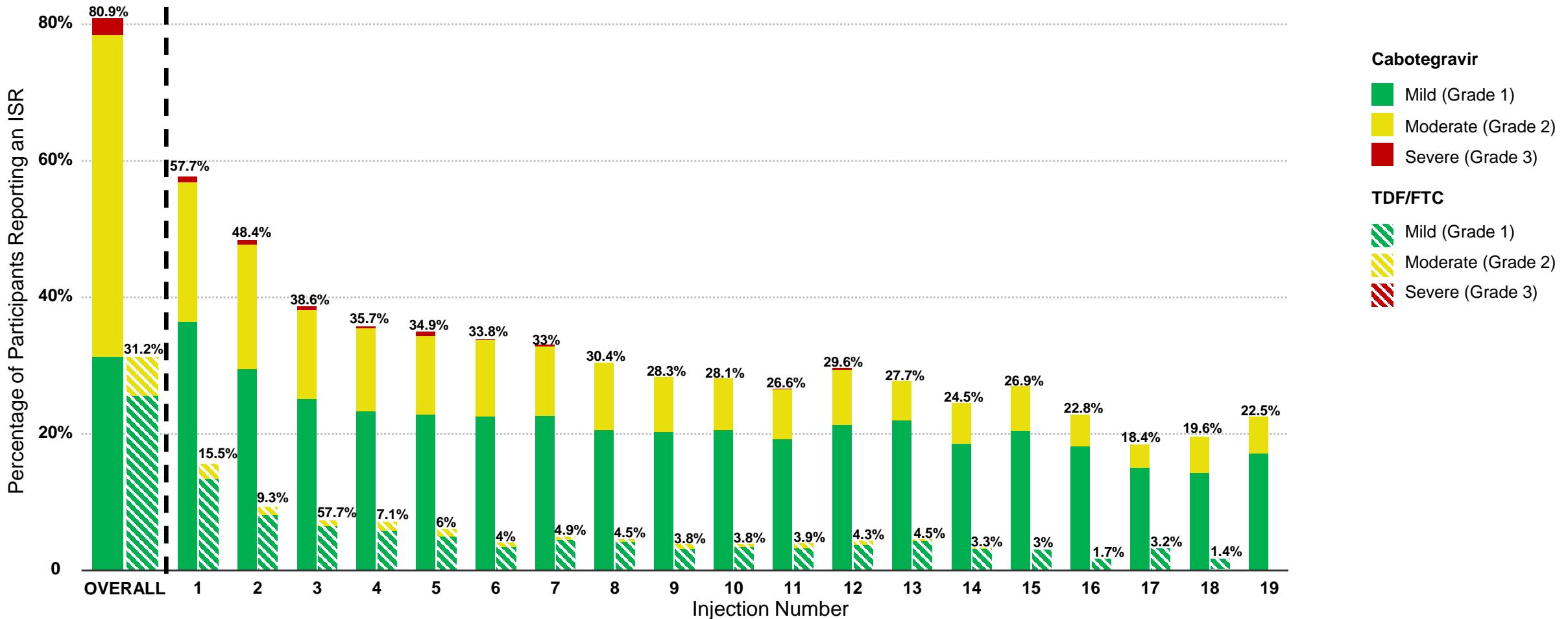
**Long-acting cabotegravir is also very effective at preventing HIV in:**

- Young individuals
- Black individuals
- Transgender women
- Individuals from various regions of the world
- Individuals using various contraceptive methods
- Individuals with higher BMIs

# SAFETY

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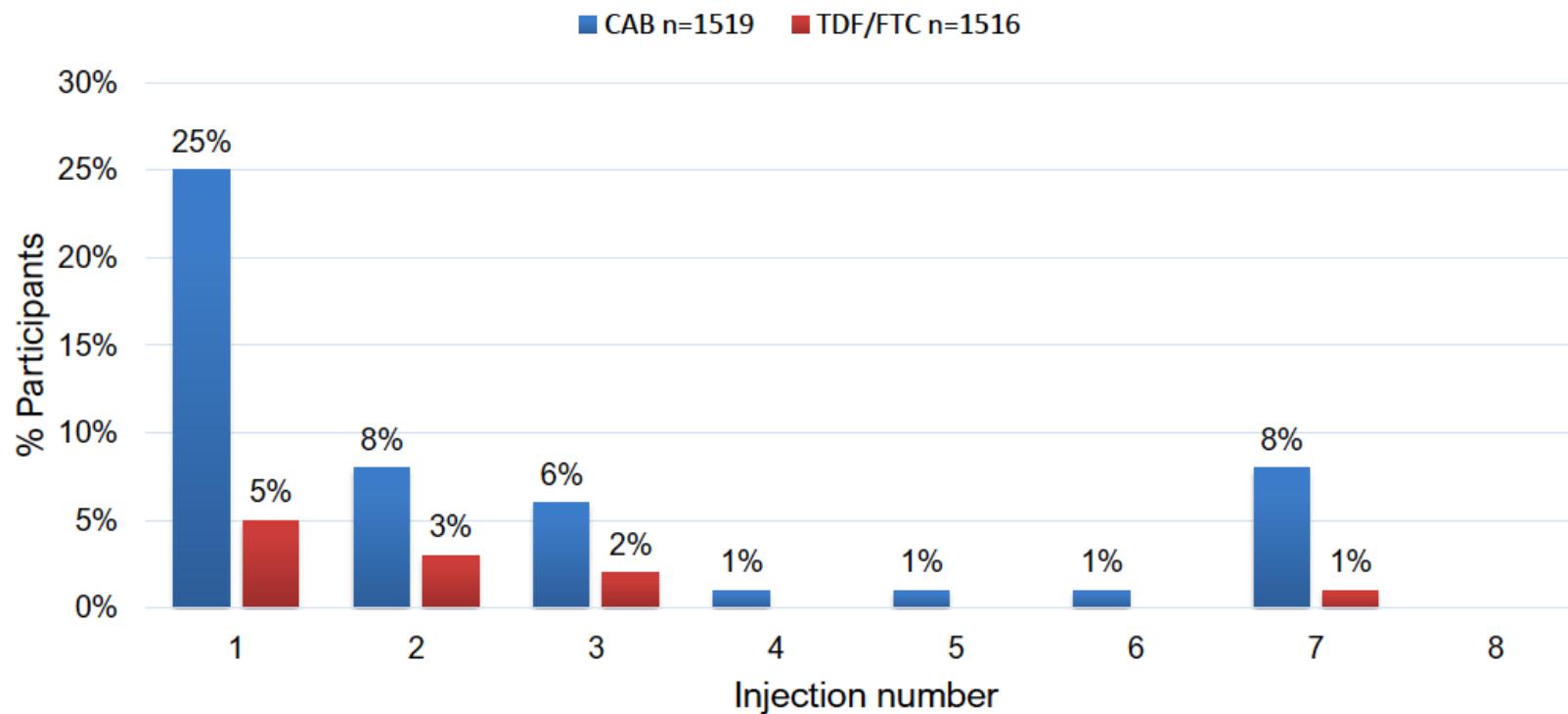
# HPTN 083: Injection Site Reactions



Cabotegravir, n	2117	2117	2037	1938	1872	1761	1620	1464	1360	1200	1034	877	744	604	465	372	298	234	168	111
TDF/FTC, n	2081	2081	2014	1940	1869	1760	1606	1463	1355	1193	1037	903	760	596	482	370	288	220	146	89



## Any ISR, by injection number and arm



- 21% participants had any ISR
  - 32% CAB vs 9% TDF/FTC
- 4% participants had Grade 2+ ISR
  - 7% CAB vs 1% TDF/FTC
- Zero discontinuations d/t ISRs

## The Bottom Line: Efficacy in specific populations

- Long-acting cabotegravir was safe and well tolerated
- The most common side effect was injection site reaction (ISR)
  - The majority were mild to moderate in severity
  - Reports of ISRs decreased over time
  - Very few ISRs led to the discontinuation of cabotegravir



- Data are still being collected on the safety of cabotegravir during pregnancy and breastfeeding
- To date, data does not suggest there are any safety concerns

# FAILURES

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## HIV Testing Challenges

## CAB-LA suppresses viral replication and delays Ab production

- Rapid tests and Ag/Ab assays often fail to detect infection
- Supplemental Ab tests may be negative/indeterminate for many months
- HIV RNA levels often remain low or undetectable for long periods

**Delayed detection  
of HIV infection**

- Delayed ART initiation
- Emergence of INSTI resistance



## HPTN 083

### Breakthrough infections:

- Very rare, but unexplained
- Total of 6 cases of breakthrough despite on-time injections
- **INSTI resistance:** all 6 cases



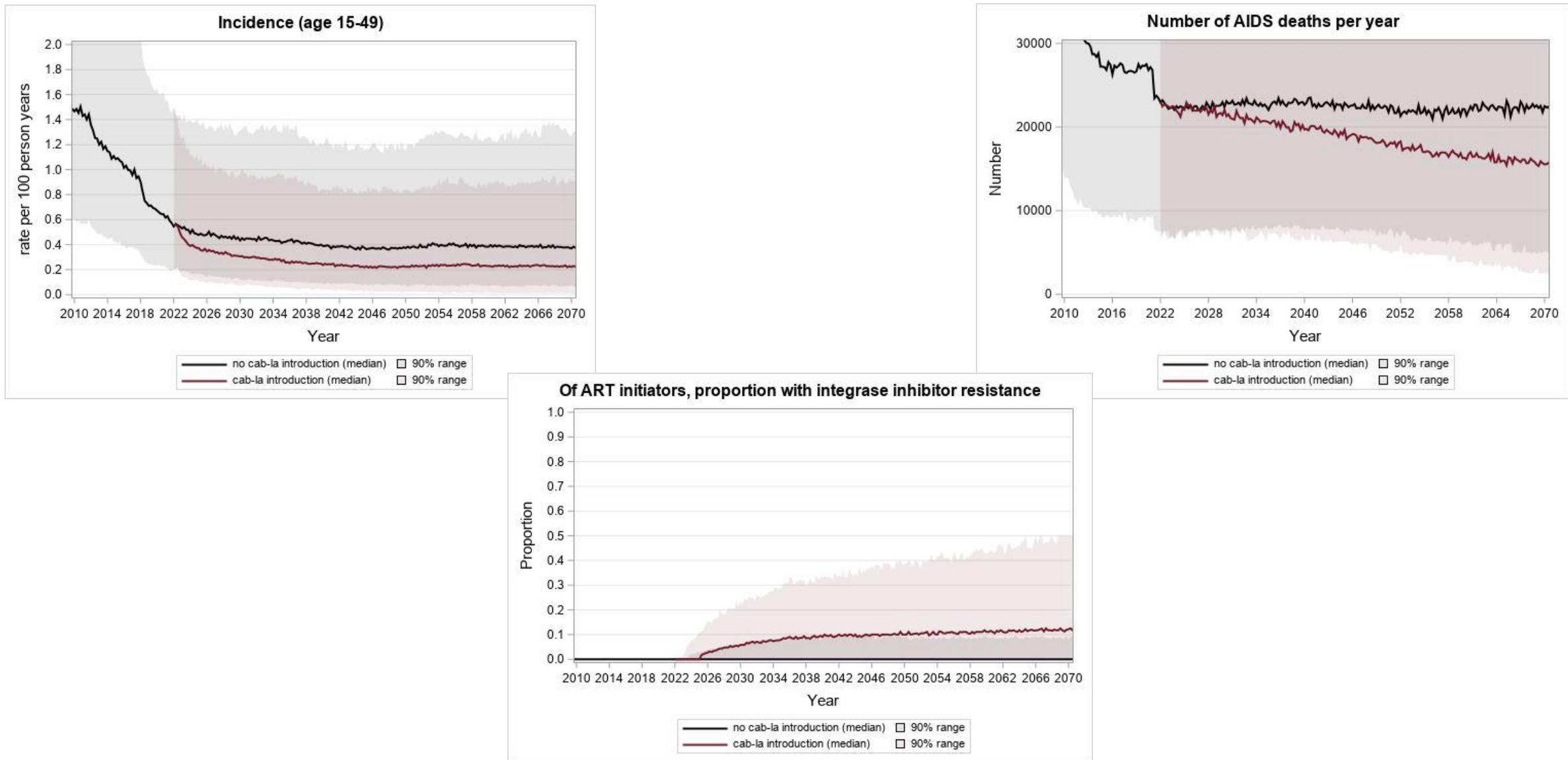
## HPTN 084

### Breakthrough infections:

- Very few infections, no true breakthrough case
- **No INSTI resistance detected**

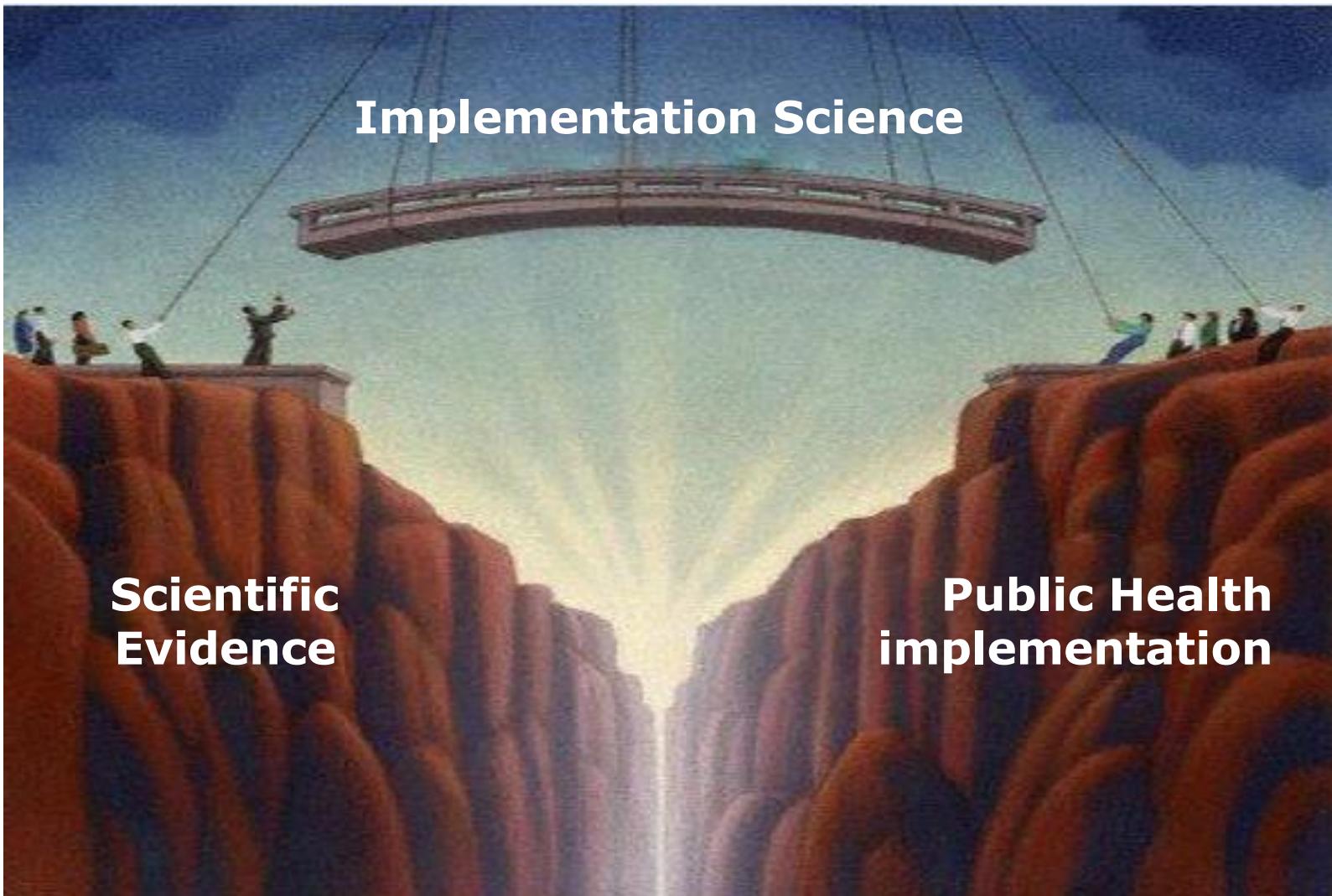
# Predicted effects of introduction of LA CAB PrEP in sub-Saharan Africa

18

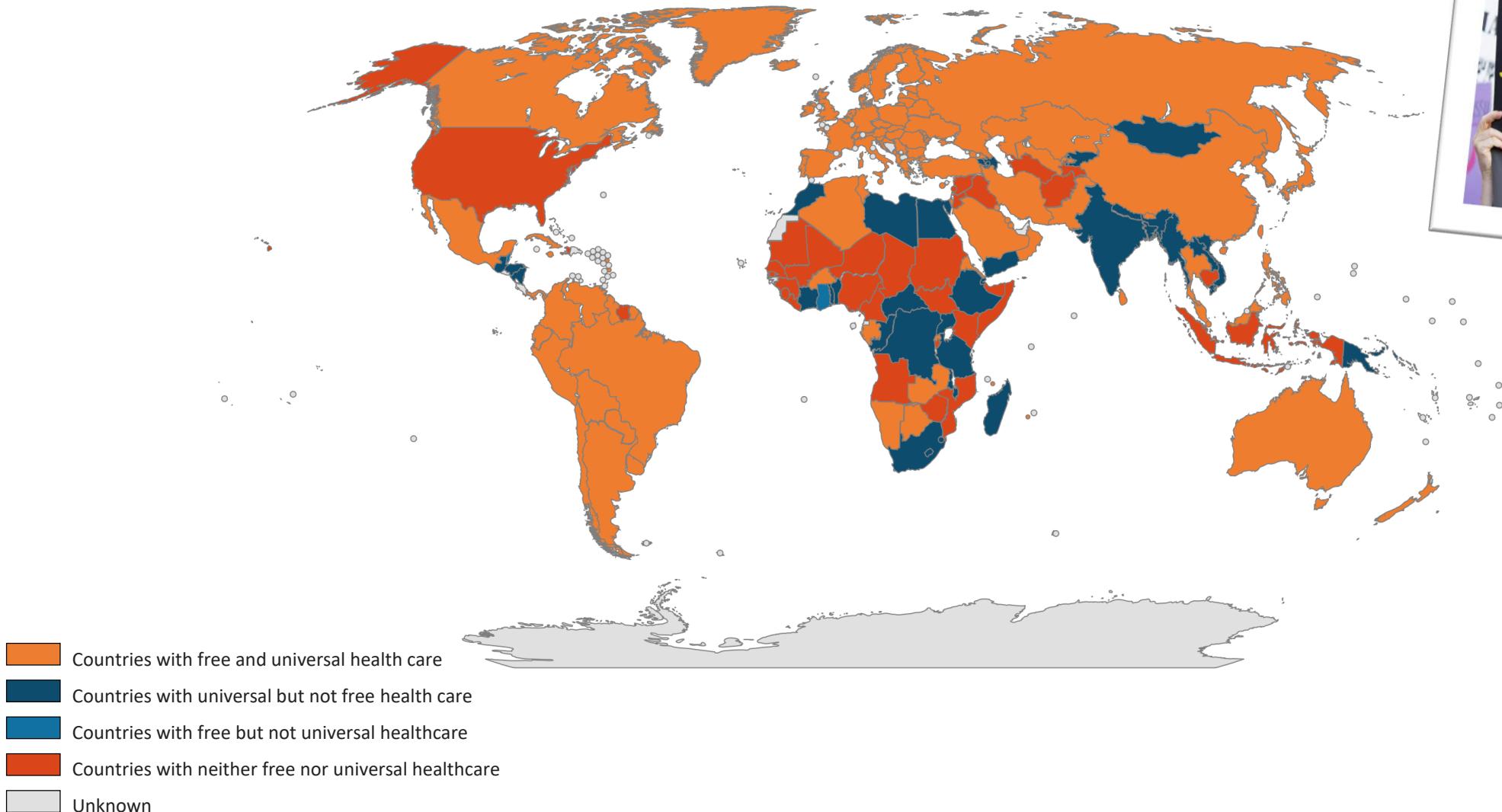


# IMPLEMENTATION

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## Countries and access to health care



# Obrigada!



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