

IM Cabotegravir versus TDF-FTC for HIV PrEP for MSM and TGW  
**HPTN 083**

# IM Cabotegravir versus TDF-FTC for HIV PrEP for MSM and TGW

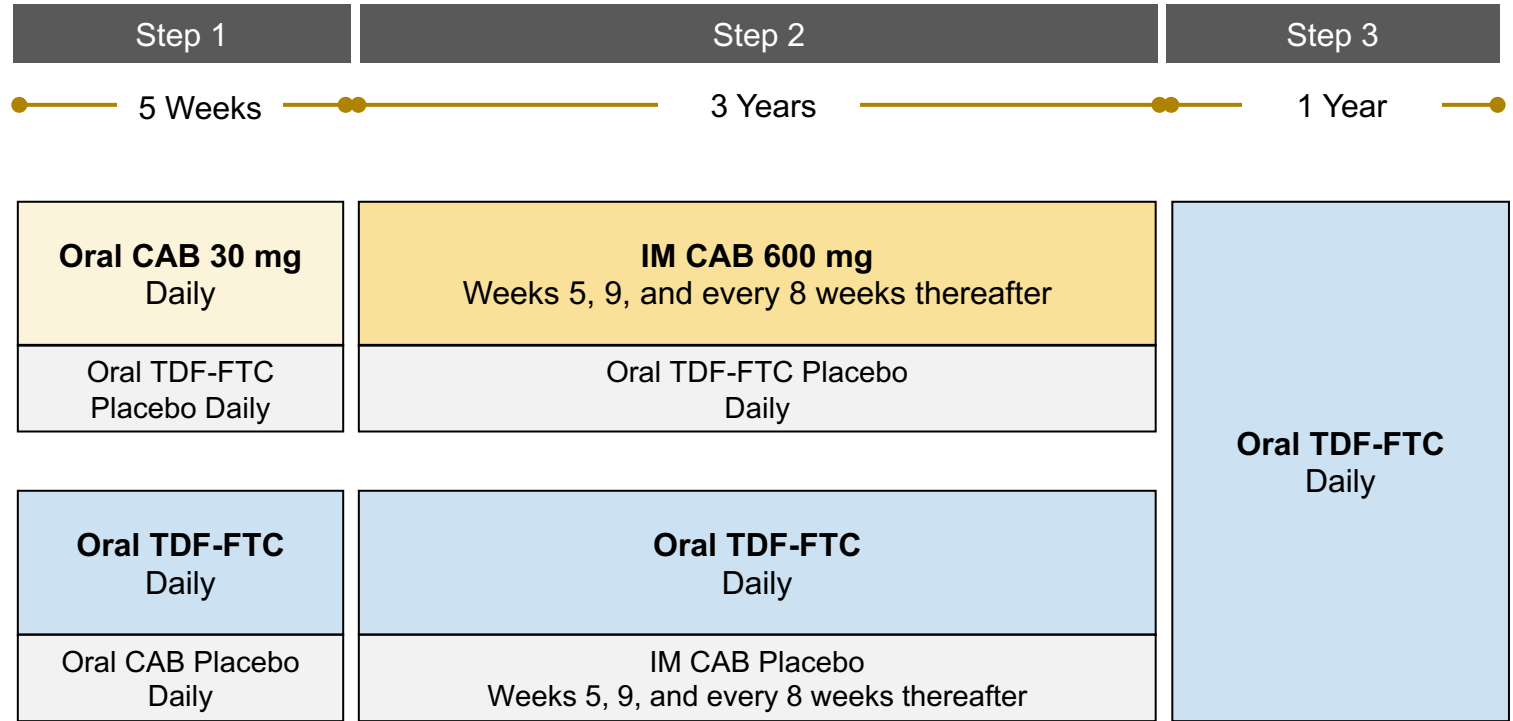
## HPTN 083: Study Design

- **Background:** Phase 2b/3, double-blind, randomized, multinational trial to assess efficacy of long-acting IM cabotegravir (CAB) compared to daily oral tenofovir DF-emtricitabine (TDF-FTC) for HIV PrEP for men who have sex with men (MSM) and transgender women
- **Setting**
  - 43 global sites
- **Inclusion Criteria**
  - Adult ( $\geq 18$  years) cisgender MSM and transgender women who have sex with men
  - Substantial HIV risk\*
  - Negative HIV serologic test at enrollment and negative HIV RNA  $\leq 14$  days before trial entry
  - Generally good health and CrCl 60 mL/min
  - HBsAg negative and HCV antibody negative
  - No contraindications to gluteal injections
  - No injection drug use within 90 days of trial entry

\*Condomless receptive anal intercourse; >5 sex partners, stimulant use, rectal/urethral STI or syphilis  $\leq 6$  months; SexPro Score <16 (U.S. only)

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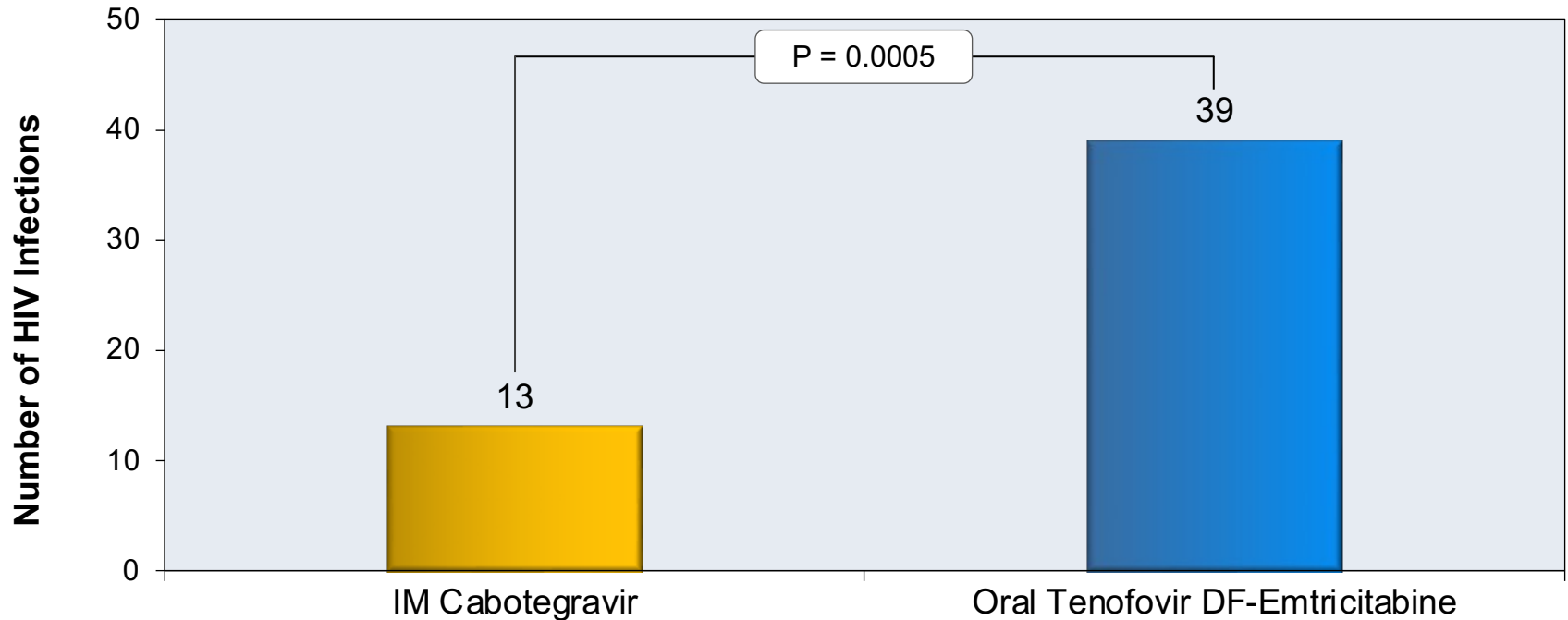
## HPTN 083: Study Population

| <b>HPTN 083: Selected Baseline Demographics</b> |                             |                                    |                               |
|-------------------------------------------------|-----------------------------|------------------------------------|-------------------------------|
| <b>Characteristic</b>                           | <b>Total</b><br>(n = 4,566) | <b>Cabotegravir</b><br>(n = 2,282) | <b>TDF-FTC</b><br>(n = 2,284) |
| Cisgender MSM, n (%)                            | 3,992 (87.4)                | 2,013 (88.2)                       | 1,979 (86.6)                  |
| Transgender women, n (%)                        | 570 (12.5)                  | 266 (11.7)                         | 304 (13.3)                    |
| Median age (IQR), years, n (%)                  | 26 (22-32)                  | 26 (22-32)                         | 26 (22-32)                    |
| Black race, United States, n (%)                | 845 (49.8)                  | 411 (48.4)                         | 434 (51.1)                    |
| Geographic region, n (%)                        |                             |                                    |                               |
| United States, n (%)                            | 1,698 (37.2)                | 849 (37.2)                         | 849 (37.2)                    |
| Latin America, n (%)                            | 1,964 (43.0)                | 980 (42.9)                         | 984 (43.2)                    |
| Asia, n (%)                                     | 752 (16.5)                  | 375 (16.5)                         | 377 (16.5)                    |
| Africa, n (%)                                   | 152 (3.3)                   | 78 (3.4)                           | 74 (3.2)                      |

\*Abbreviations: MSM = men who have sex with men; IQR = interquartile range

# IM Cabotegravir versus TDF-FTC for HIV PrEP for MSM and TGW HPTN 083: Results

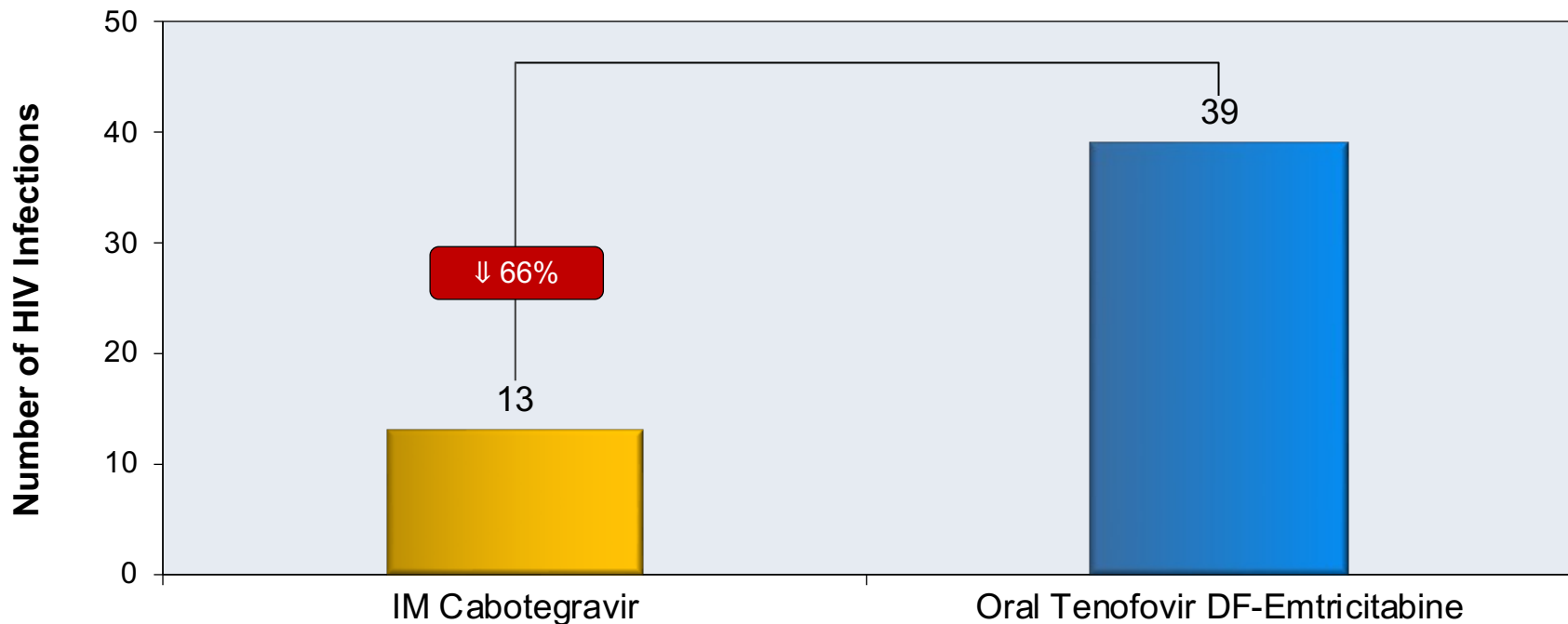
Number of HIV Infections (After Enrollment)



Source: Landovitz RJ, et al. N Engl J Med. 2021;385:595-608.

# IM Cabotegravir versus TDF-FTC for HIV PrEP for MSM and TGW HPTN 083: Results

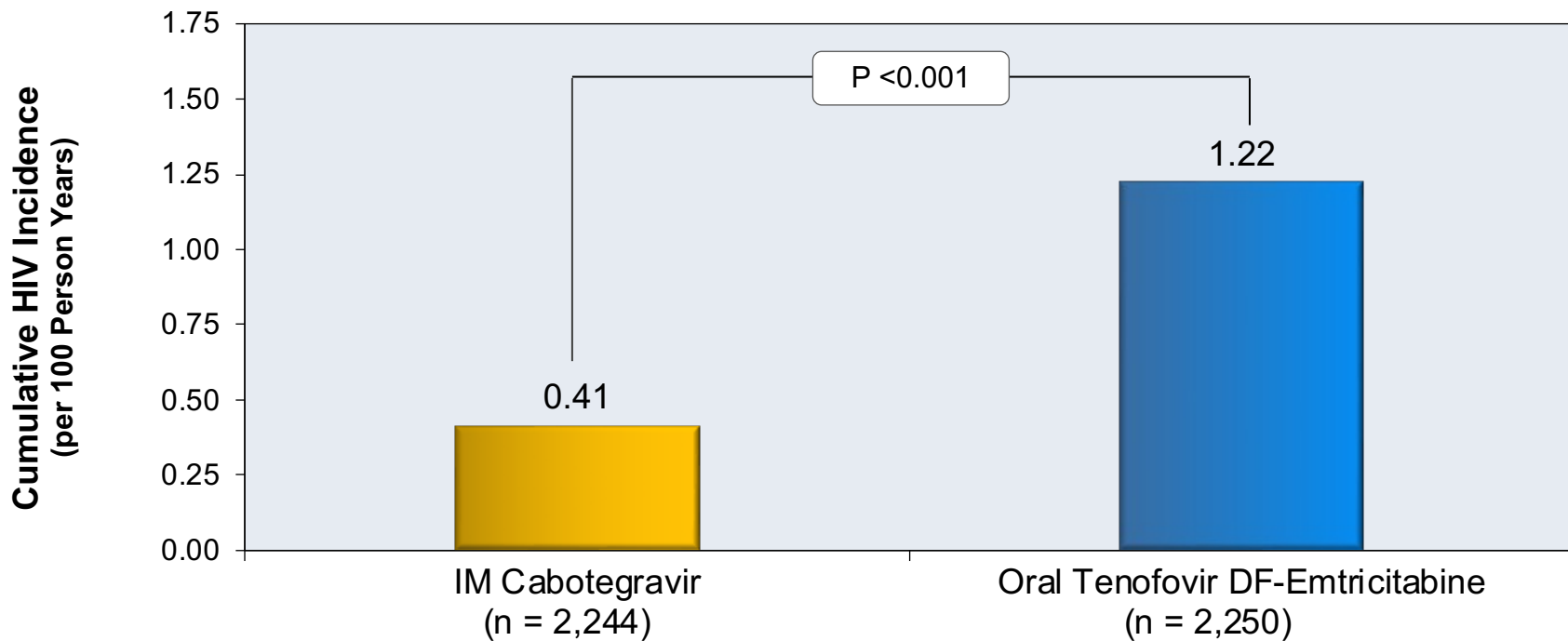
Risk Reduction in HIV Infections (After Enrollment)



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## HPTN 083: Results

### Cumulative HIV Incidence (After Enrollment)



# IM Cabotegravir versus TDF-FTC for HIV PrEP for MSM and TGW

## HPTN 083: Results

- **When did incident HIV infections occur in CAB arm?**
  - 3 during oral lead-in
  - 5 after “prolonged hiatus” from IM CAB
  - 5 during continuous CAB administration
- **Were drug levels adequate in TDF-FTC arm?**
  - Random sample of 372 participants:
    - 87% detectable plasma tenofovir level
    - 75% levels correlated with high-level protection
    - ≈70% levels suggestive of >4 doses/week (by dried blood spot)



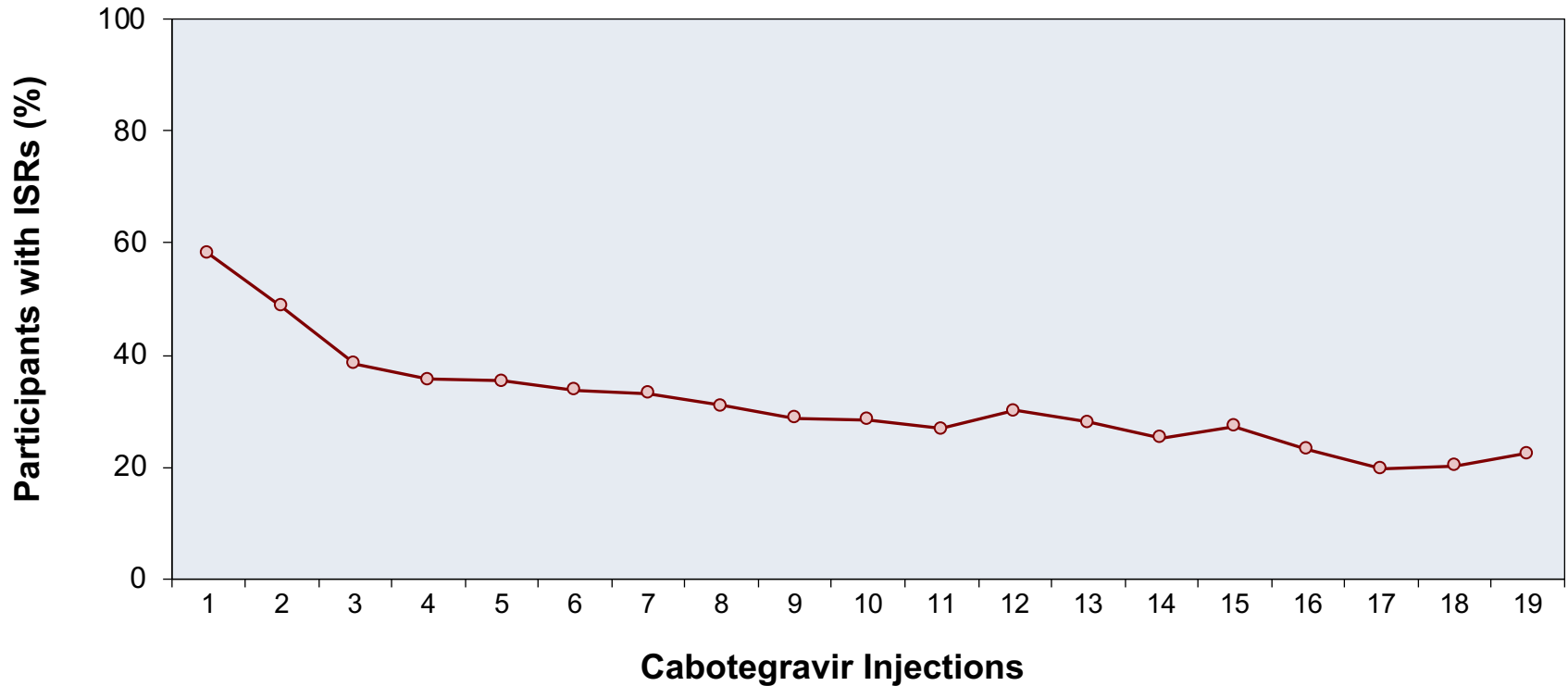
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## HPTN 083: Cabotegravir Injection Site Reactions

- **Type and Severity of Injection-Site Reactions**
  - Most common: pain and tenderness
  - 2.4% chose to discontinue study due to injection reaction
- **Onset**
  - Reactions typically began 1 day after injection
- **Duration**
  - Reactions typically lasted 3-4 days after injection

# IM Cabotegravir versus TDF-FTC for HIV PrEP for MSM and TGW

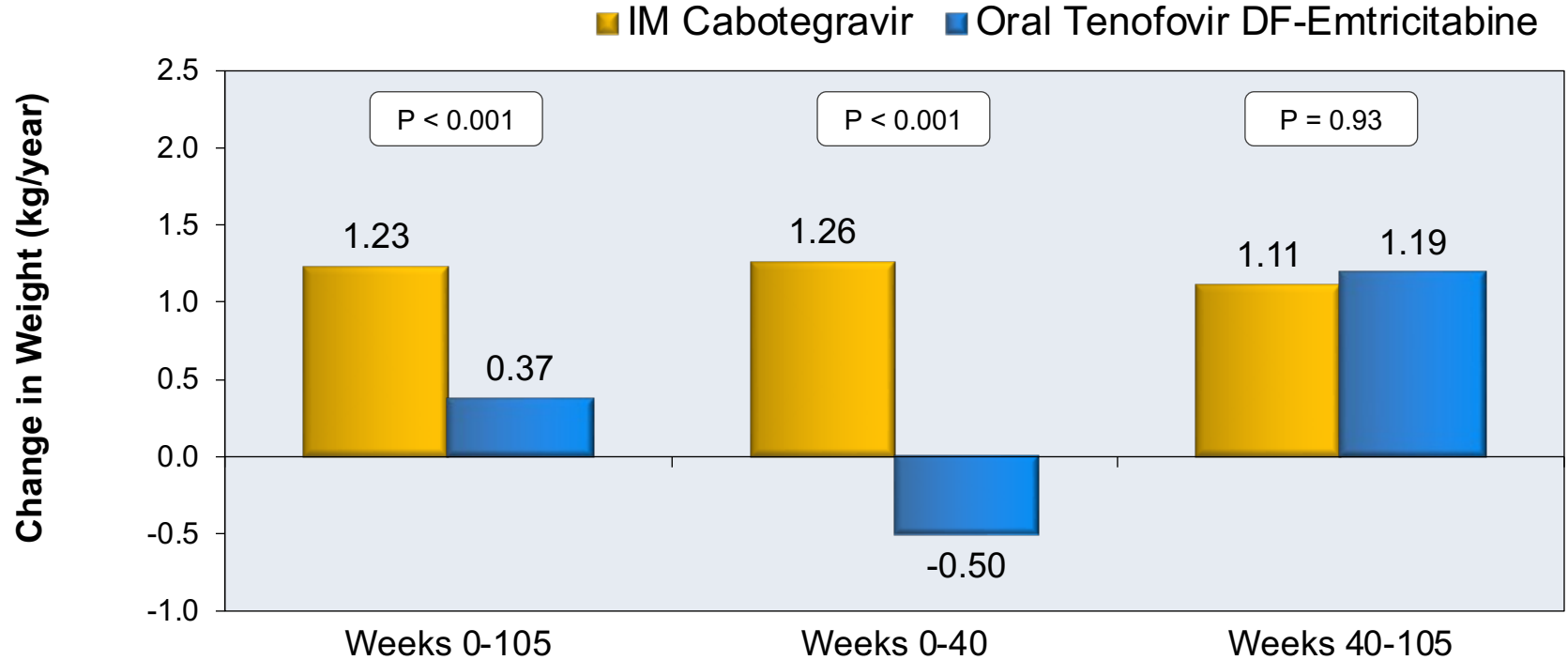
## HPTN 083: Cabotegravir Injection Site Reactions



# IM Cabotegravir versus TDF-FTC for HIV PrEP for MSM and TGW HPTN 083: Results: Resistance with Cabotegravir

- **INSTI Resistance in Cabotegravir Group**
  - 1 at baseline; 4 with incident HIV infections
  - No resistance documented after last injection during “tail phase”

# IM Cabotegravir versus TDF-FTC for HIV PrEP for MSM and TGW HPTN 083: Weight Gain



# IM Cabotegravir versus TDF-FTC for HIV PrEP for MSM and TGW HPTN 083: Conclusions

**Conclusions:** Long-acting cabotegravir was superior to daily oral Tenofovir DF–emtricitabine in preventing HIV infection among men who have sex with men and transgender women.

# Acknowledgments

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