

IM Cabotegravir vs. TDF-FTC for PrEP in Cisgender Women  
**HPTN 084**

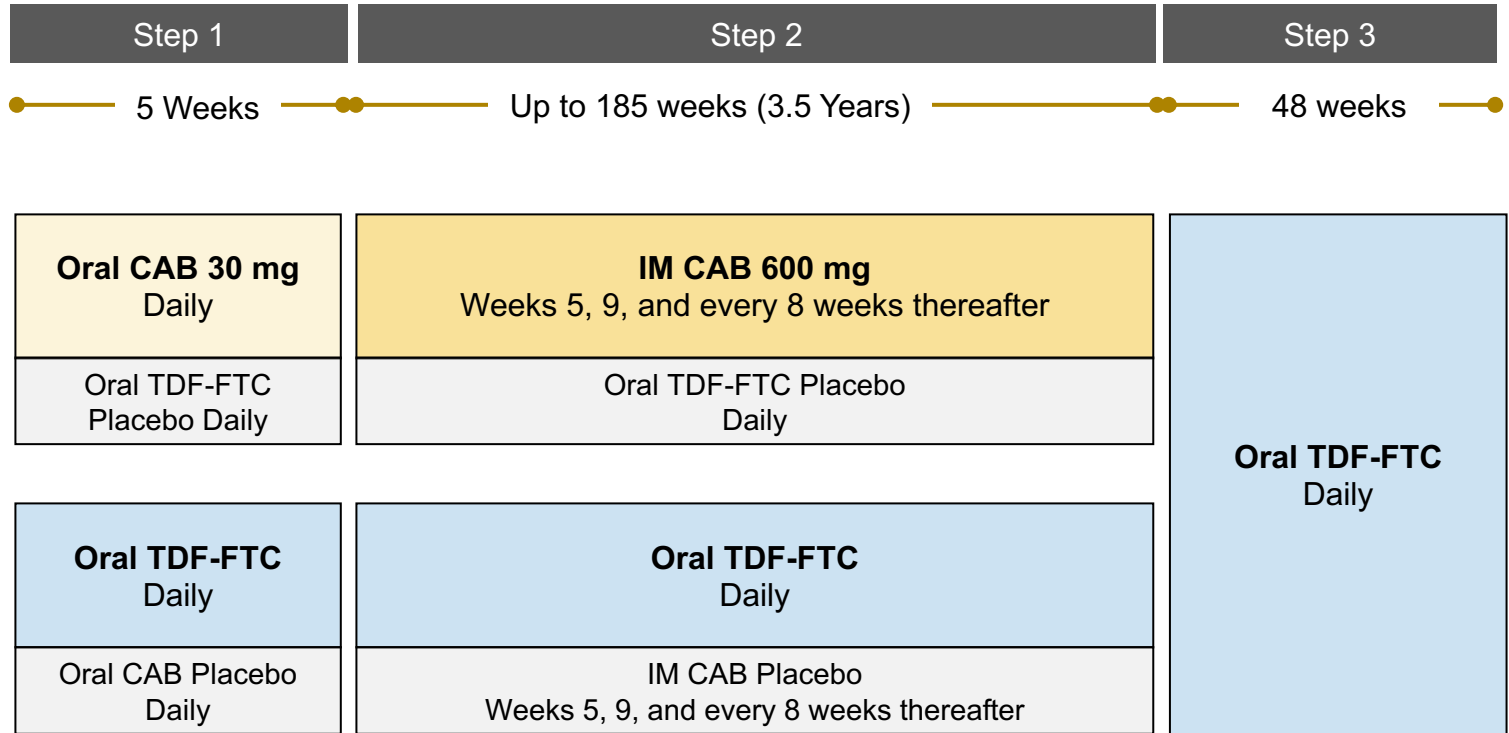
# IM Cabotegravir versus TDF-FTC for PrEP in Cisgender Women

## HPTN 084: Study Design

- **Background:** Phase 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 cisgender women (assigned female sex at birth)
- **Setting**
  - 20 sites in 7 countries in Sub-Saharan Africa
- **Inclusion Criteria**
  - Cisgender women (assigned female sex at birth) 18-45 years of age
  - Sexually active (e.g vaginal sex on  $\geq 2$  separate days in the 30 days prior to screening)
  - HBsAg-negative and willing to receive hepatitis B vaccination
  - HCV antibody negative
  - No contraindications to gluteal injections
  - Creatinine clearance of greater than or equal to 60 mL/min
  - ALT  $< 2$  x upper limit of normal (ULN) and total bilirubin  $\leq 2.5$  x ULN
  - Excluded if pregnant or breastfeeding

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## HPTN 084: Study Design



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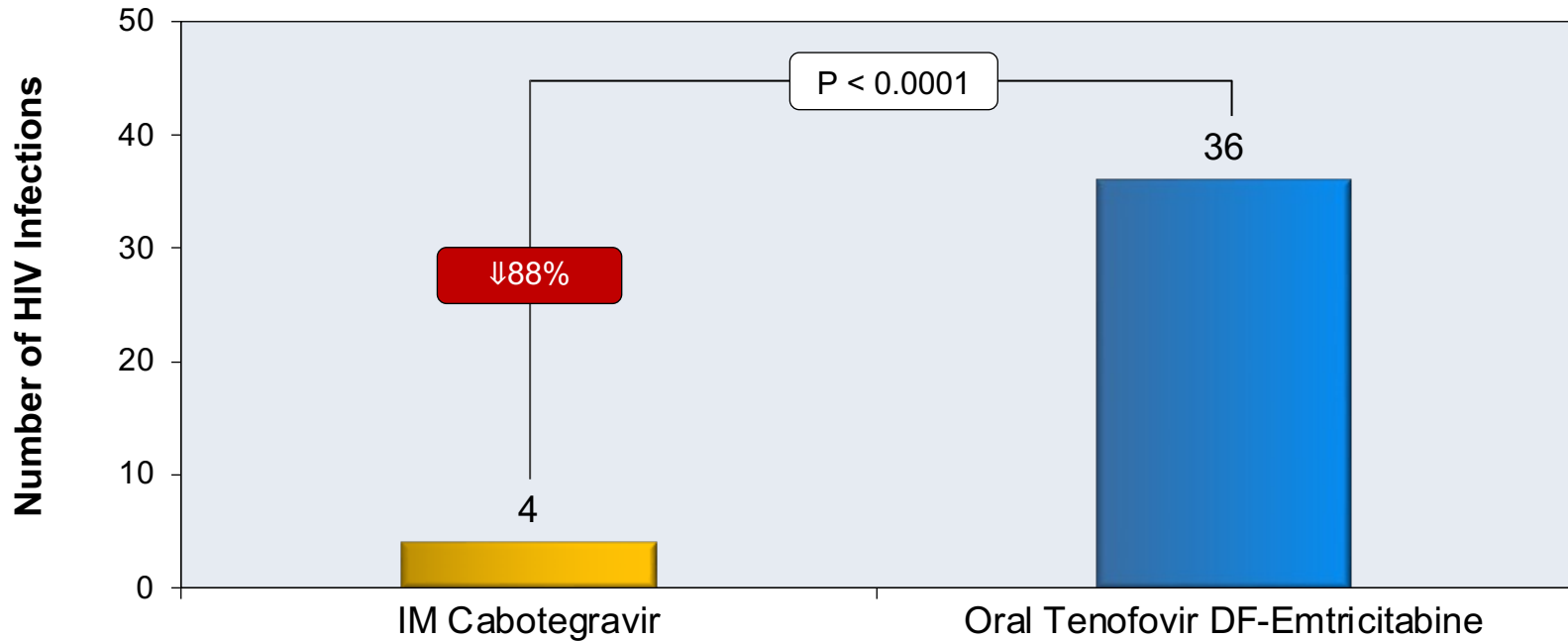
## HPTN 084: Baseline Characteristics

<b>HPTN 084: Selected Baseline Characteristics</b>		
<b>Baseline Characteristics</b>	<b>Cabotegravir (n = 1,614)</b>	<b>TDF-FTC (n = 1,610)</b>
Median age, years	25	25
Age <25 years, n (%)	814 (50.4%)	816 (50.7%)
Black/African race, n (%)	1,569 (97.2%)	1,554 (96.5%)
Sexual activity in past month (reported)		
>2 sex partners, n (%)	878/1,609 (54.5%)	877/1,609 (54.8%)
Transactional sex, n (%)	658/1,609 (40.9%)	655/1,600 (40.9%)
Partner HIV(+) or unknown, n (%)	542/1,609 (33.7%)	558/1,600 (34.9%)
Anal sex, n (%)	90/1,609 (5.6%)	95/1,600 (5.9%)

Source: Delany-Moretlwe S, et al. Lancet. 2022;399:1779-89.

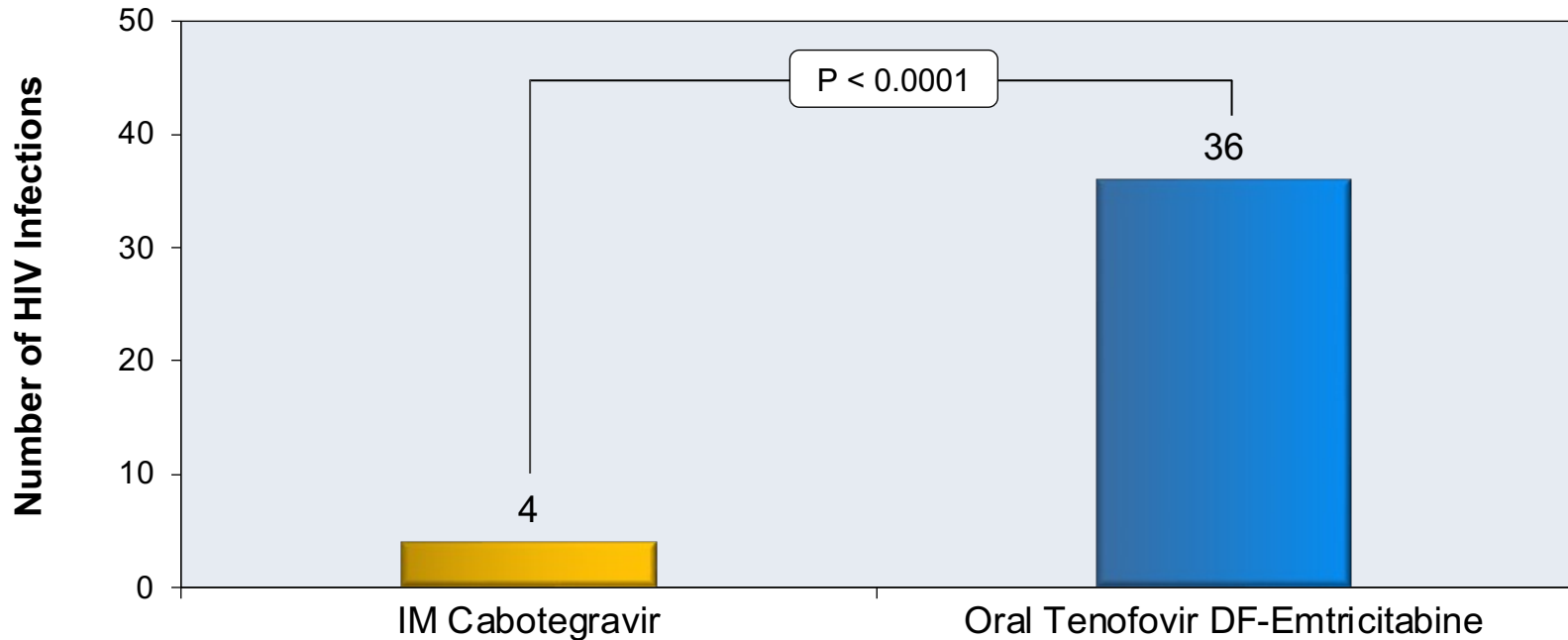
# IM Cabotegravir versus TDF-FTC for PrEP in Cisgender Women HPTN 084: Results

Number of HIV Infections: Risk Reduction



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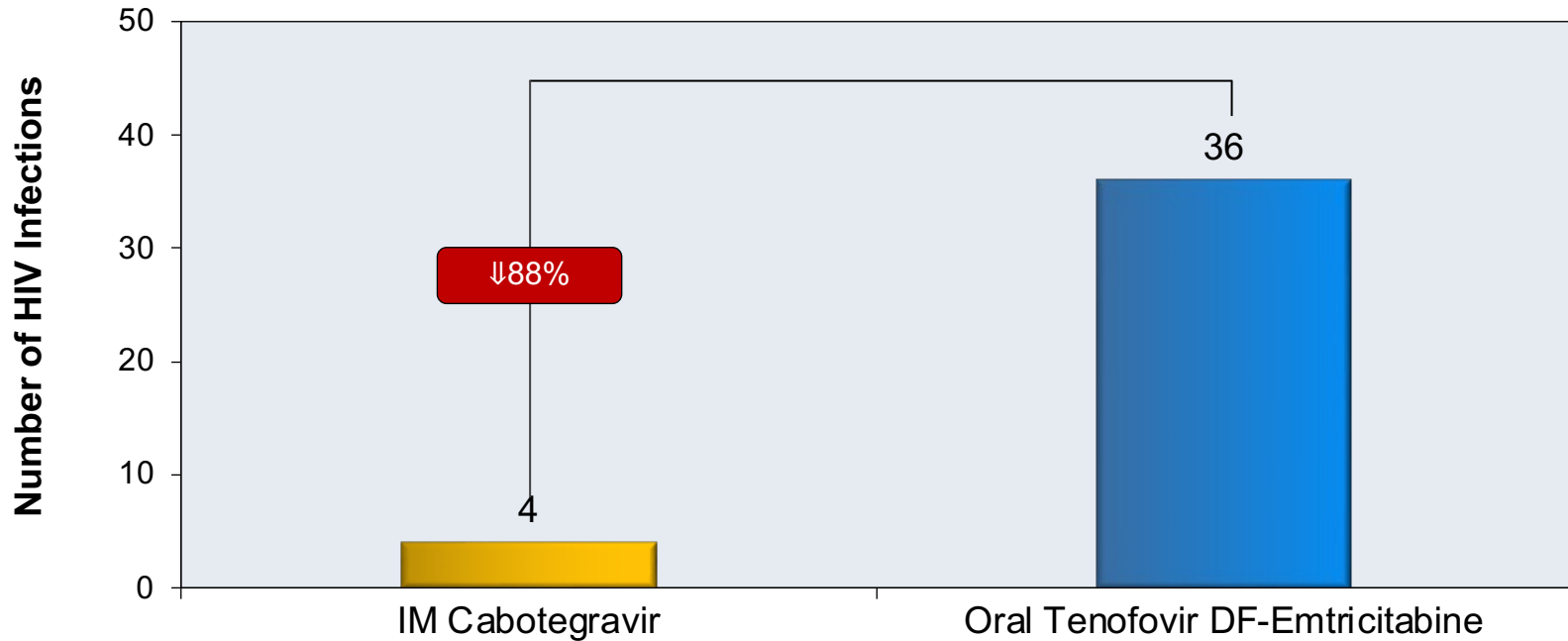
Number of HIV Infections



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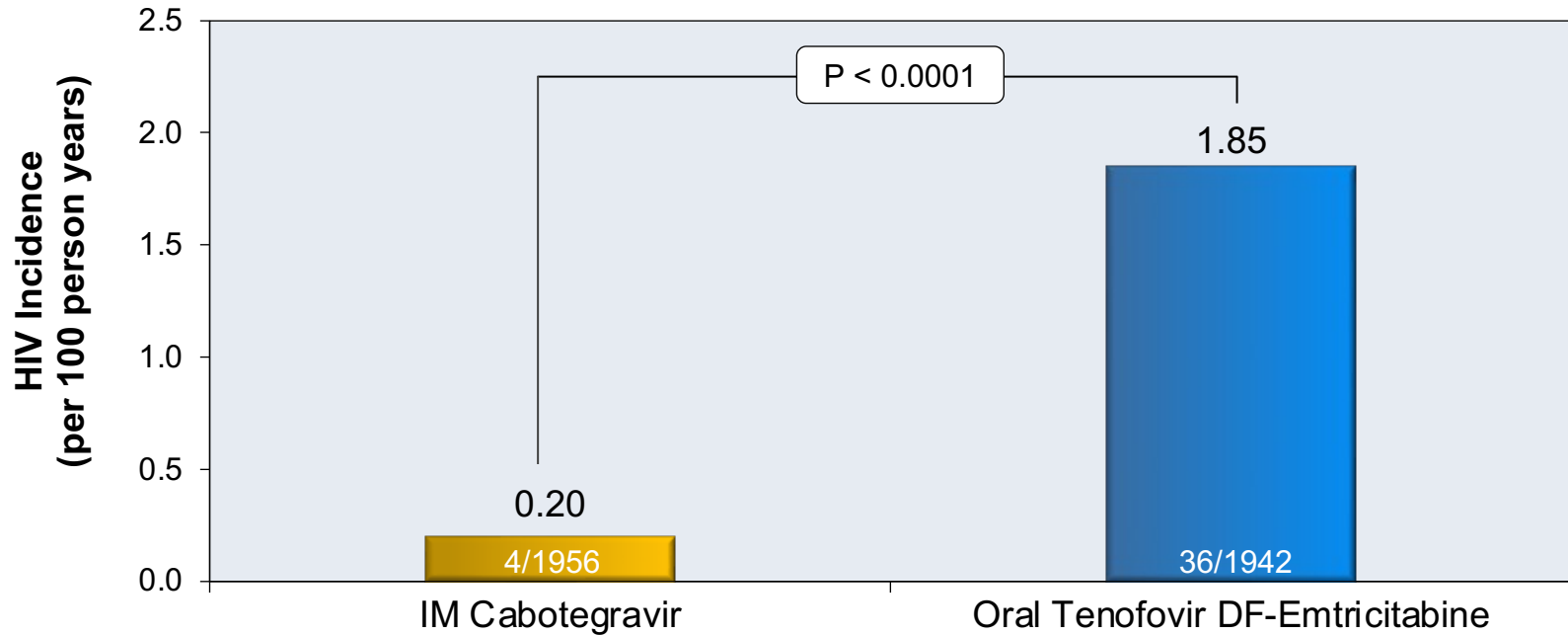
# IM Cabotegravir versus TDF-FTC for PrEP in Cisgender Women HPTN 084: Results

Number of HIV Infections: Risk Reduction



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## HIV Incidence





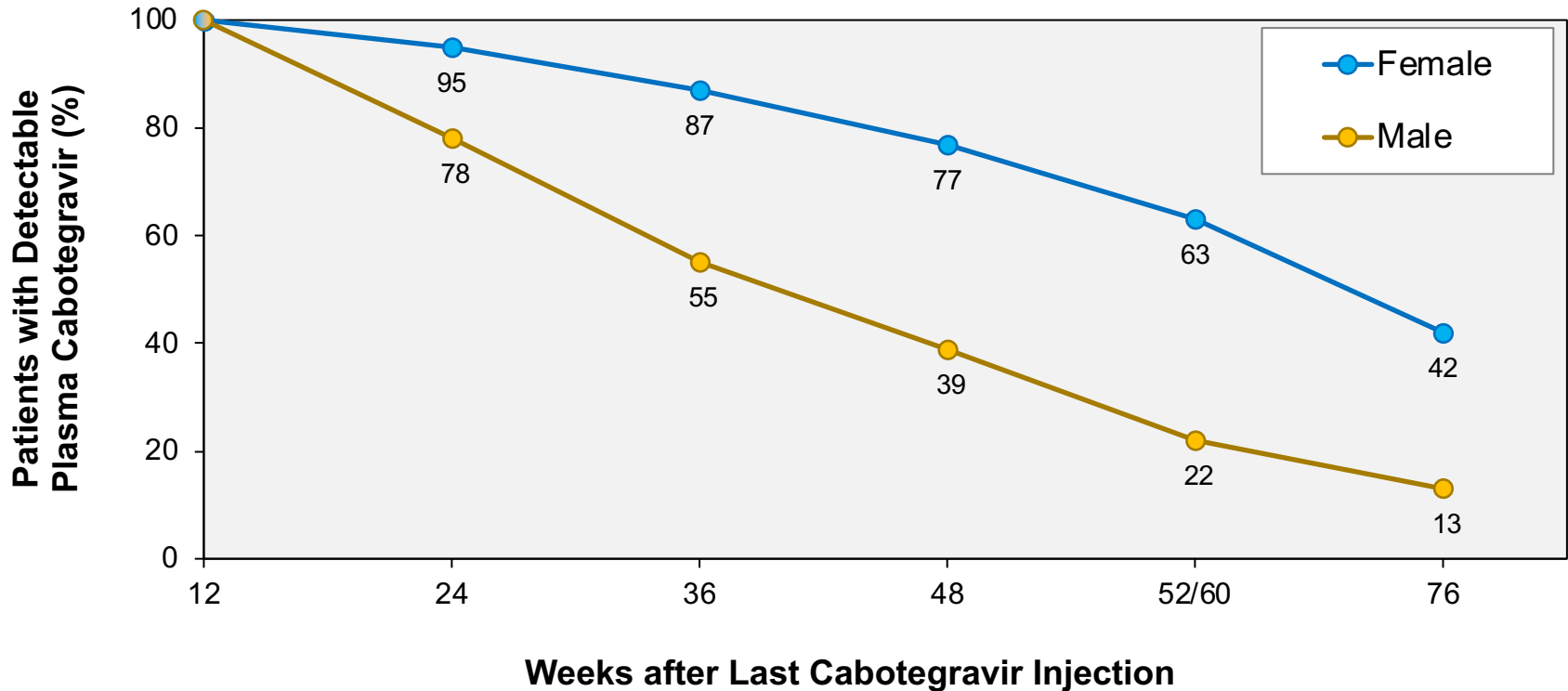
# IM Cabotegravir versus TDF-FTC for PrEP in Cisgender Women

## HPTN 084: Conclusions

**Interpretation:** Although both products for HIV prevention were generally safe, well tolerated, and effective, cabotegravir was superior to TDF-FTC in preventing HIV infection in women.

IM Cabotegravir Tail-Phase Safety, Tolerability, and Pharmacokinetics  
**HPTN 077**

# Cabotegravir Levels After Last Dose of Cabotegravir



# Acknowledgments

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