

A really (really) rapid overview of the HPTN 083 results

# Long-acting injectable CAB vs. daily oral TDF/FTC for PrEP among MSM and TGW

Raphael J. Landovitz, MD, MSc

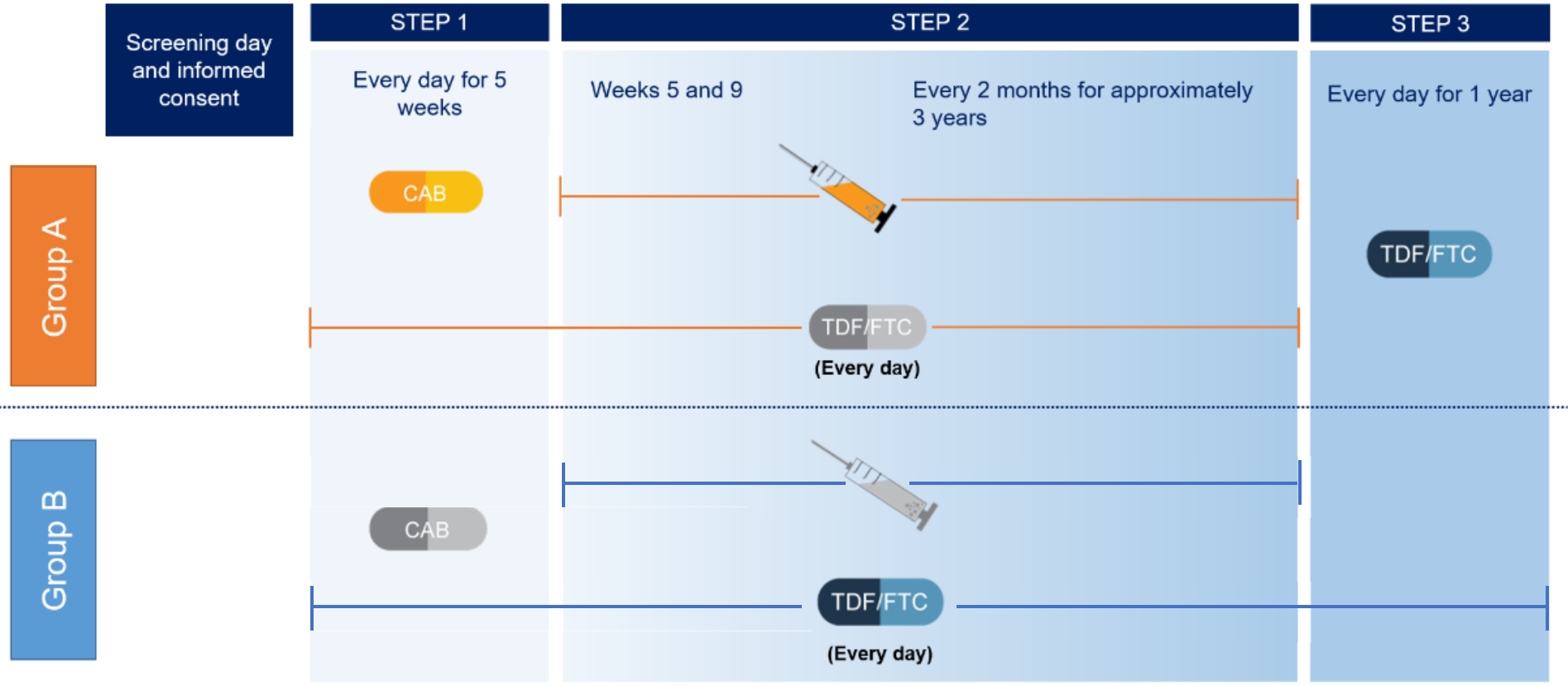
University of California, Los Angeles

∴∴∴ HPTN ANNUAL ∴∴∴  
∴∴∴ MEETING 2021 ∴∴∴∴∴



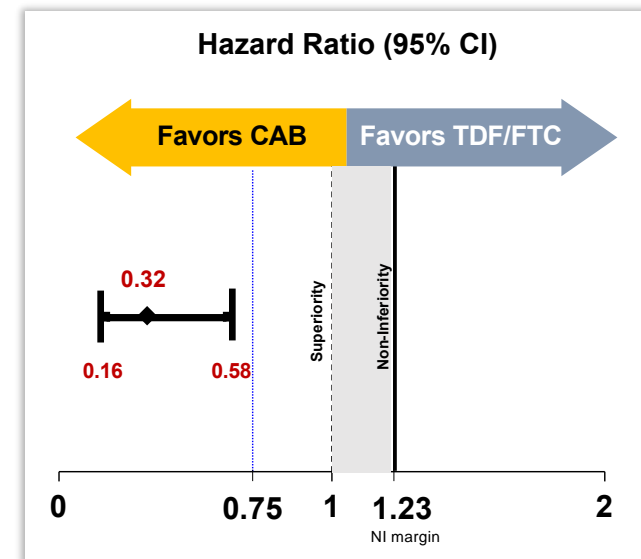
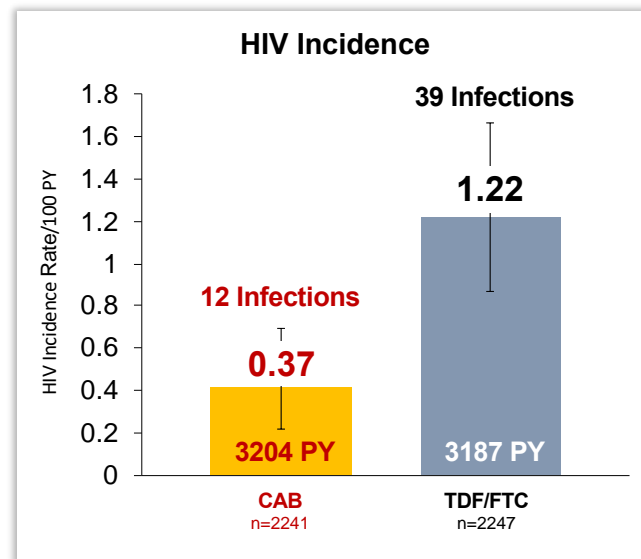
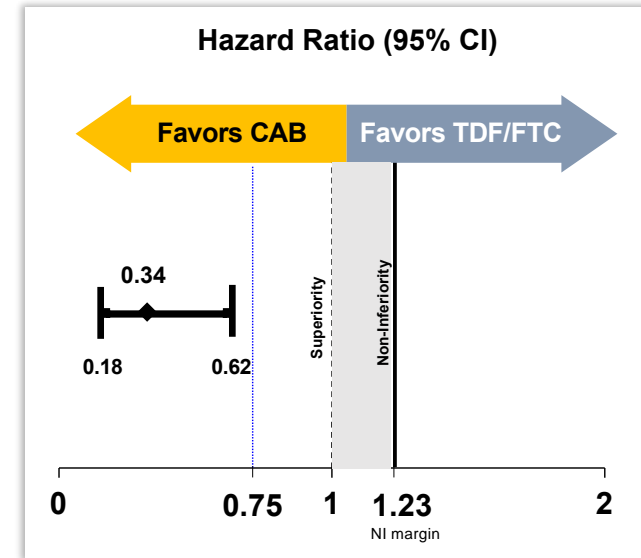
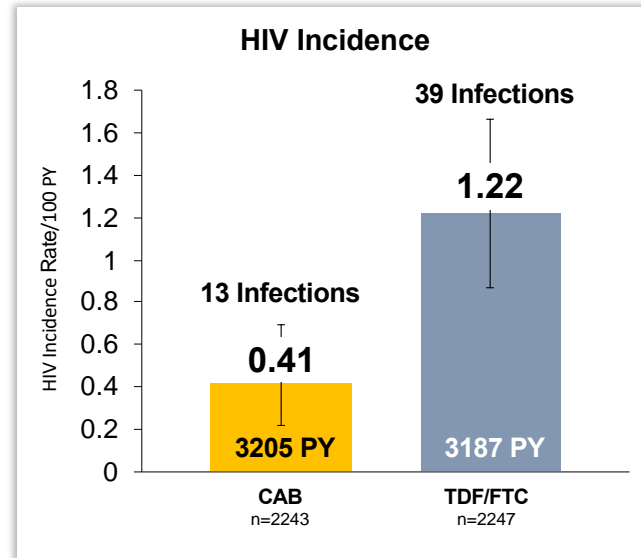
HPTN  
HIV Prevention  
Trials Network

# HPTN 083 Study Design

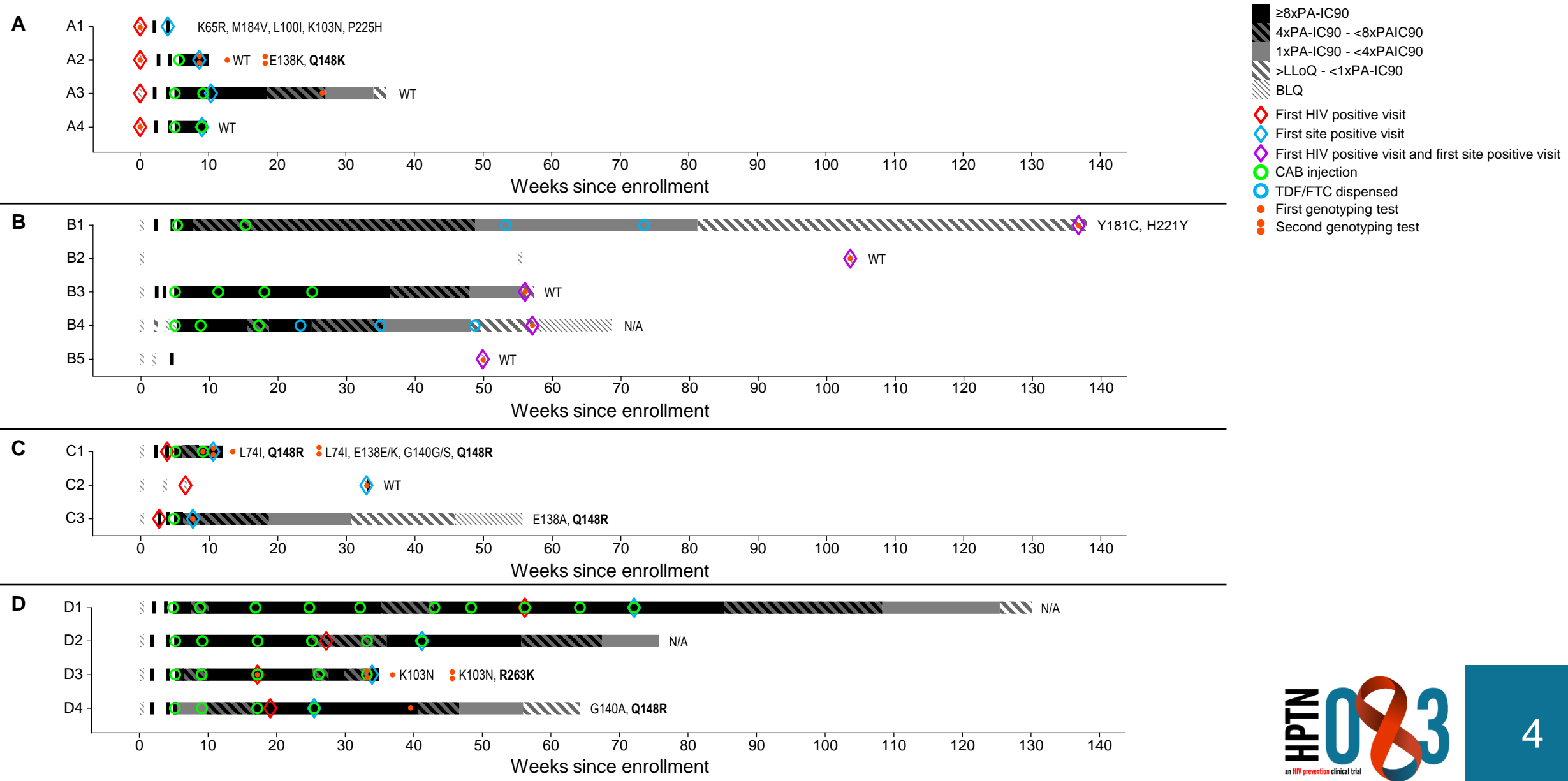


TDF/FTC pill    
 Cabotegravir (CAB) injection    
 Placebo for TDF/FTC pill    
 Placebo for cabotegravir (CAB) injection  
 Cabotegravir (CAB) pill    
 Placebo for cabotegravir (CAB) pill

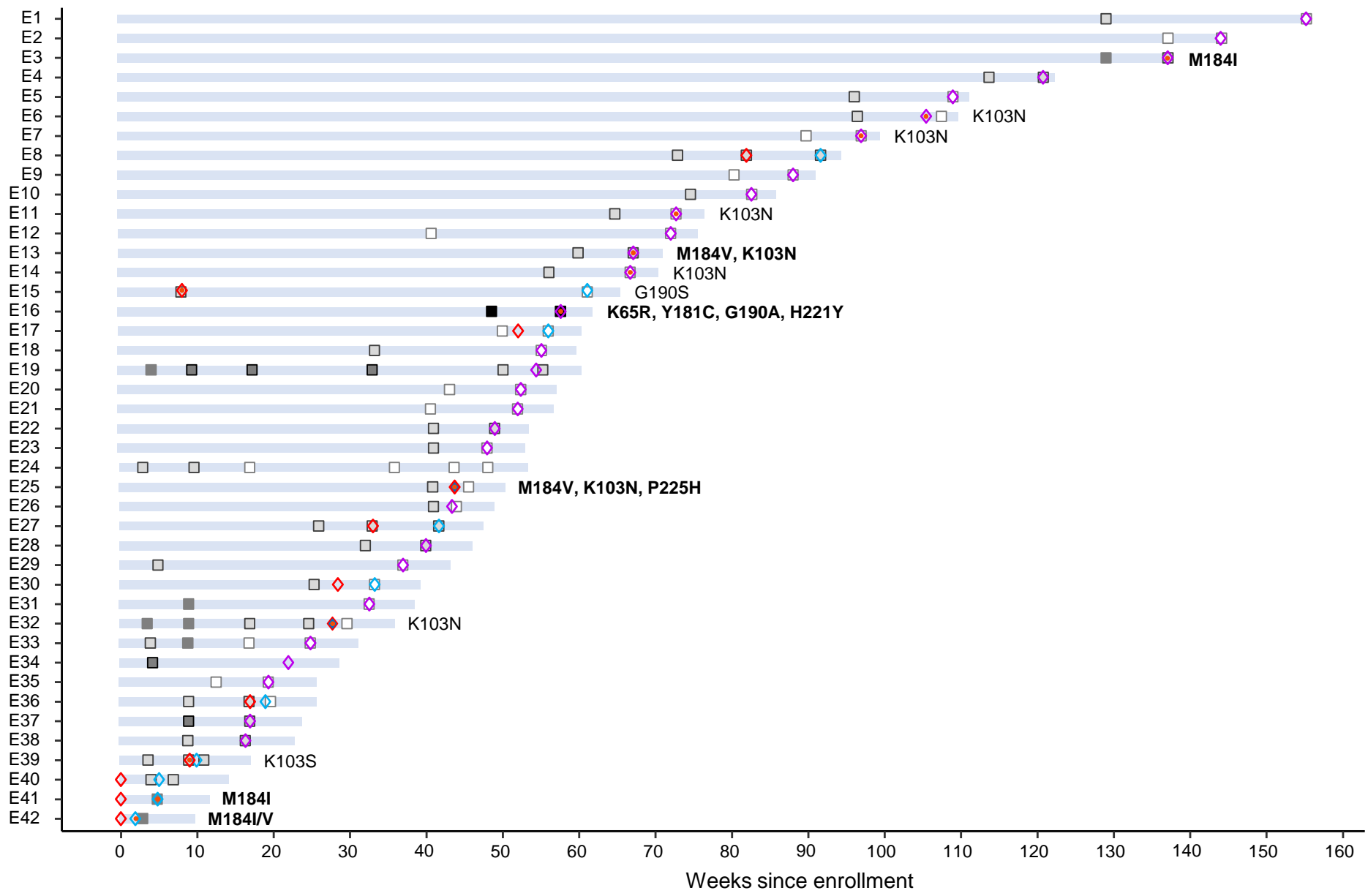
# HIV Incidence: CAB vs. TDF/FTC



# Cabotegravir Arm



# TDF/FTC Arm



- TFV-DP  $\geq 1250$  fmol/punch
- TFV-DP  $\geq 700$  -  $< 1250$  fmol/punch
- TFV-DP  $\geq 350$  -  $< 700$  fmol/punch
- TFV-DP  $> \text{LLOQ}$  -  $< 350$  fmol/punch
- TFV-DP BLQ
- First HIV positive visit
- First site positive visit
- First HIV positive visit and first site positive visit
- HIV genotyping test

# Conclusions

- Both agents highly effective for HIV prevention
- The PrEP regimen containing CAB-LA was superior to a daily oral regimen of TDF/FTC in HPTN 083 and HPTN 084
- CAB-LA was generally well tolerated despite injection site reactions
- **1/4**, **0/5**, **2/3**, and **2/4 Acute (Prevalent)**, **Distant from CAB**, **Oral-lead-in**, and **On-time injection** participants developed INSTI resistance
  - Tail phase seroconversion did not result in INSTI resistance
  - Breakthrough at high and expected CAB concentrations resulted in INSTI resistance
- CAB is the first long-acting injectable agent to demonstrate robust HIV prevention efficacy

# Acknowledgments

## Sponsor

- U.S. National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Mental Health (NIMH), National Institute on Drug Abuse (NIDA), and the National Institute of Child Health and Human Development (NICHD) all components of the U.S. National Institutes of Health (NIH)
- Additional funding from ViiV Healthcare

## HIV Prevention Trials Network (HPTN)

- Laboratory Center (Johns Hopkins University)
- Statistical Center for HIV/AIDS Research and Prevention (SCHARP), Fred Hutchinson Cancer Research Center
- Leadership and Operations Center, FHI 360
- HPTN Leadership

## Pharmaceutical Support

- ViiV Healthcare
- Gilead Sciences, Inc.

## HPTN 083 Study Team

## Community Program Managers Community Educators & Recruiters, CAB Members

## Our 43 Sites in 7 countries

## ...and our Study Participants!

# Acknowledgments

- Overall support for the HIV Prevention Trials Network (HPTN) is provided by the National Institute of Allergy and Infectious Diseases (NIAID), Office of the Director (OD), National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) under Award Numbers UM1AI068619-15 (HPTN Leadership and Operations Center), UM1AI068617-15 (HPTN Statistical and Data Management Center), and UM1AI068613-15 (HPTN Laboratory Center).
- The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.



**HPTN**   
**ANNUAL**   
**MEETING**  
2021 