

# Long-acting injectable CAB for HIV prevention in cisgender women

Sinéad Delany-Moretlwe, MBBCh PhD

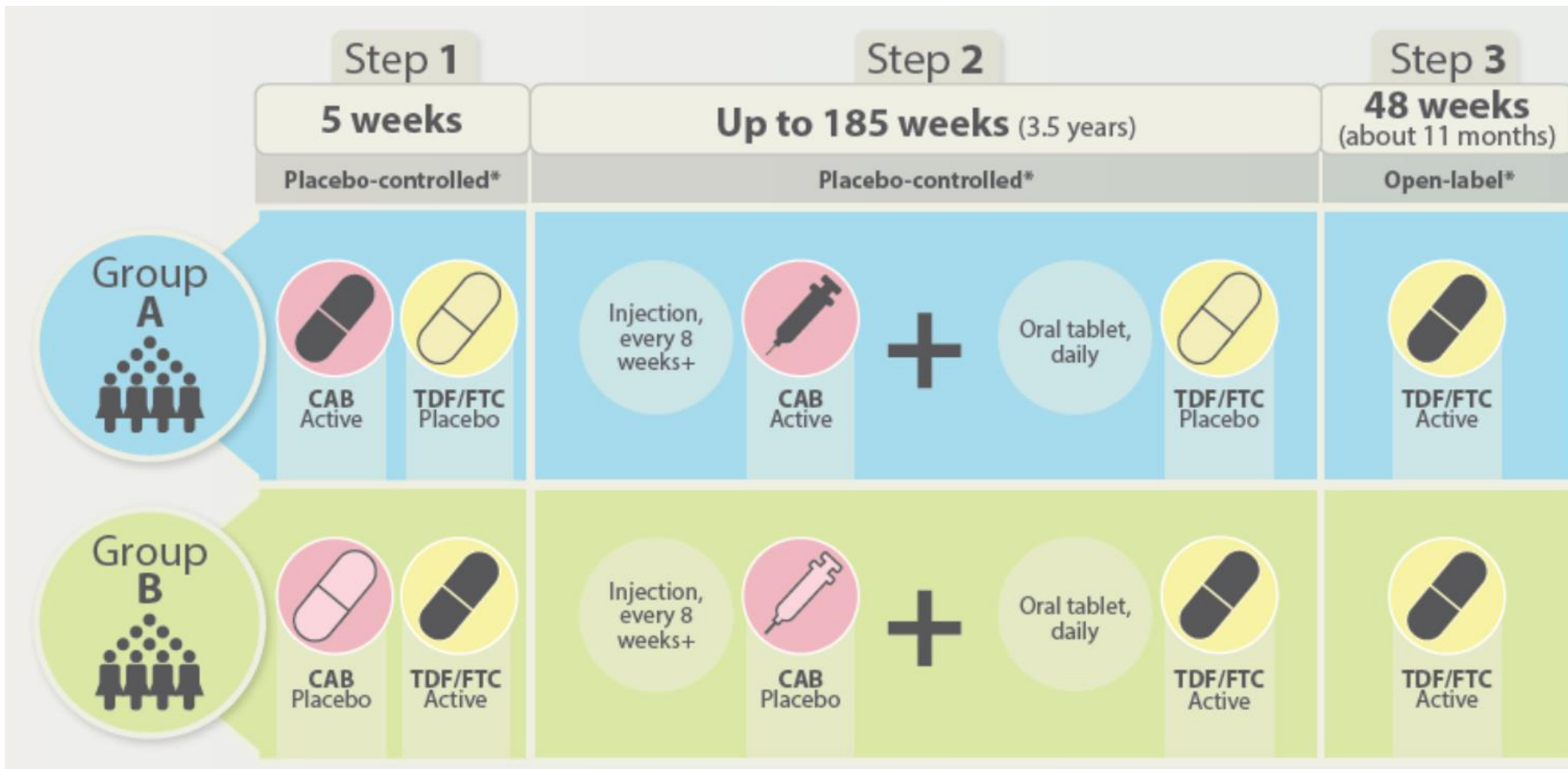
University of the Witwatersrand, Johannesburg, South Africa

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HPTN  
HIV Prevention  
Trials Network

# HPTN 084 Study Design



Outcome:  
HIV incidence

HIV, pregnancy testing and safety assessments at each product administration visit; additional post injection safety visits  
Real-world adherence counselling support aligned with national guidelines

# Primary outcome: HIV incidence

**40 infections over 3892 person-years**  
**Pooled HIV incidence 1.03 (0.73, 1.4) per 100 person-years**

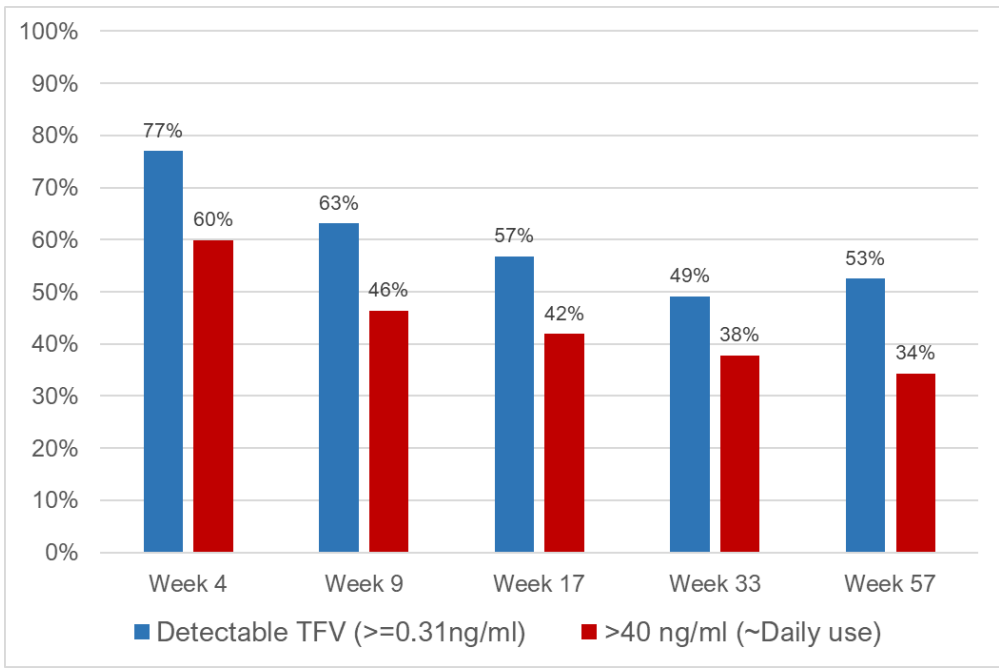
	CAB	TDF/FTC
HIV infections	4	36
Person-years	1,953	1,939
HIV incidence (95% CI)	0.2 (0.06, 0.52)	1.86 (1.3, 2.57)

*Wald test z statistic – 4.20, efficacy stopping bound (z scale) – 3.61*



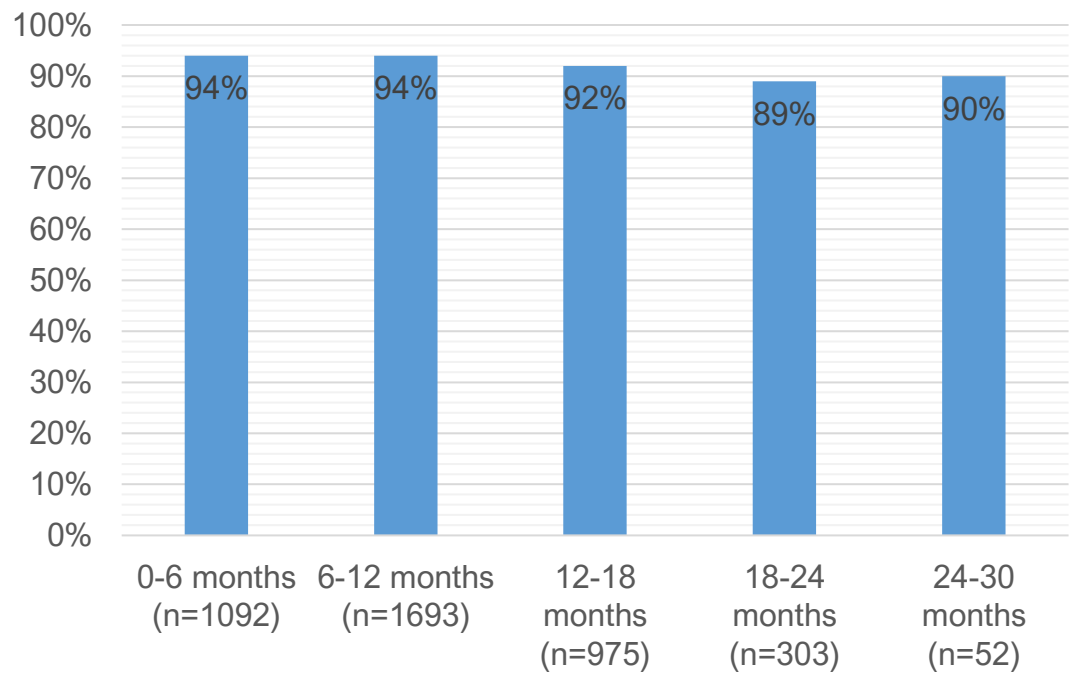
# CAB LA likely conferred an adherence advantage

TDF plasma concentrations – adherence subset (n=375)



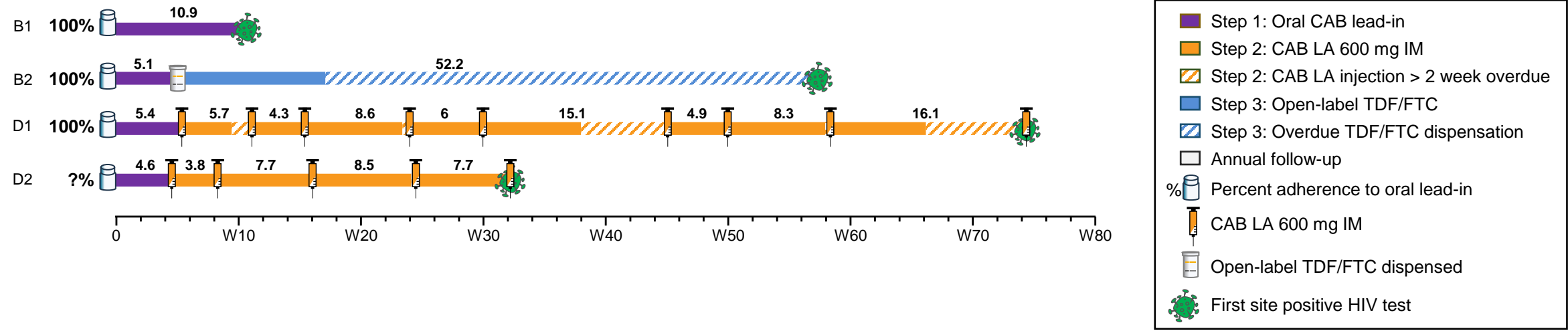
Overall,  
62% detectable TFV, 46% >40ng/ml

Injection coverage, 6-month intervals - all



Longitudinal CAB cohort data pending

# Cabotegravir - 4 incident HIV Infections



- PK and HIV virology testing currently in progress to understand infection on injection and in TDF/FTC group

# Conclusions and next steps

- Both agents highly effective in preventing HIV; overall incidence 1%
- CAB was superior to daily oral TDF/FTC in preventing HIV in cisgender women;
- Both products were safe and well tolerated; ISR CAB>TDF/FTC
- Ongoing laboratory analysis will provide insights into breakthrough infections
- Protocol amendment under development to offer open-label CAB LA
  - Includes optional oral lead in
  - Includes option to consent for active dosing through pregnancy
  - Includes HIV RNA testing as part of screening algorithm



# Acknowledgments

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- Gilead Sciences

## HIV Prevention Trials Network

- Leadership and Operations Centre, FHI360
- Laboratory Centre (Johns Hopkins)
- Statistical Center for HIV/AIDS Research and Prevention, Fred Hutchinson Cancer Research Center
- HPTN Leadership

## HPTN 084 Study team

- 20 sites in 7 countries in sub-Saharan Africa
- Community advisory boards and partners

... and our study participants!



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