

# Sexually Transmitted Infections in the DISCOVER HIV PrEP Trial



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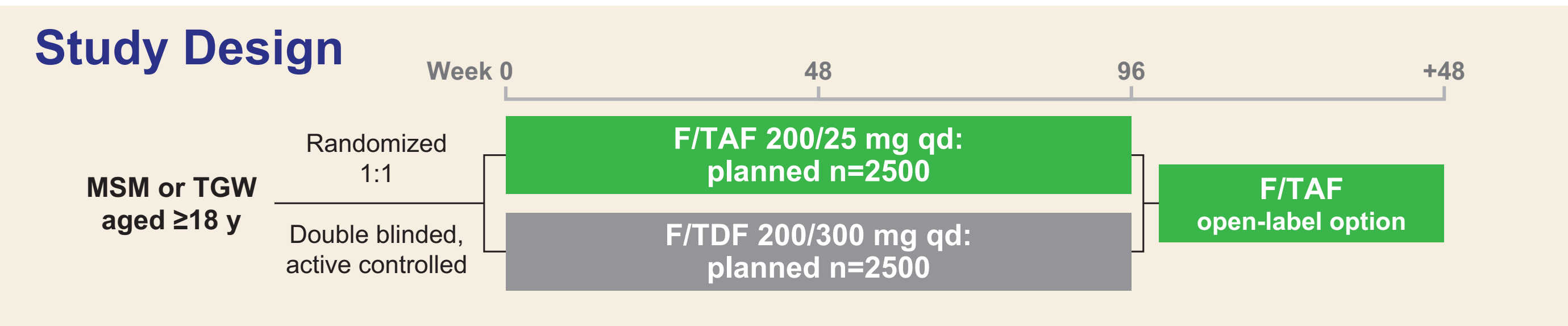
## Introduction

- DISCOVER (ClinicalTrials.gov NCT02842086) is an ongoing, randomized, controlled trial comparing emtricitabine/tenofovir alafenamide (F/TAF) with emtricitabine/tenofovir disoproxil fumarate (F/TDF) for pre-exposure prophylaxis (PrEP) in men who have sex with men (MSM) and transgender women (TGW)
- The burden of sexually transmitted infections (STIs) is high worldwide<sup>1</sup>
  - Some MSM and TGW face a disproportionately high burden of STIs, which may increase the risk of acquiring HIV<sup>2</sup>
  - Rectal gonorrhea incidence is directly correlated with HIV infection and has been proposed as a predictor of HIV incidence<sup>3</sup>
- Most clinical studies of PrEP have reported stable or decreasing STI rates during follow-up<sup>4</sup>

## Objective

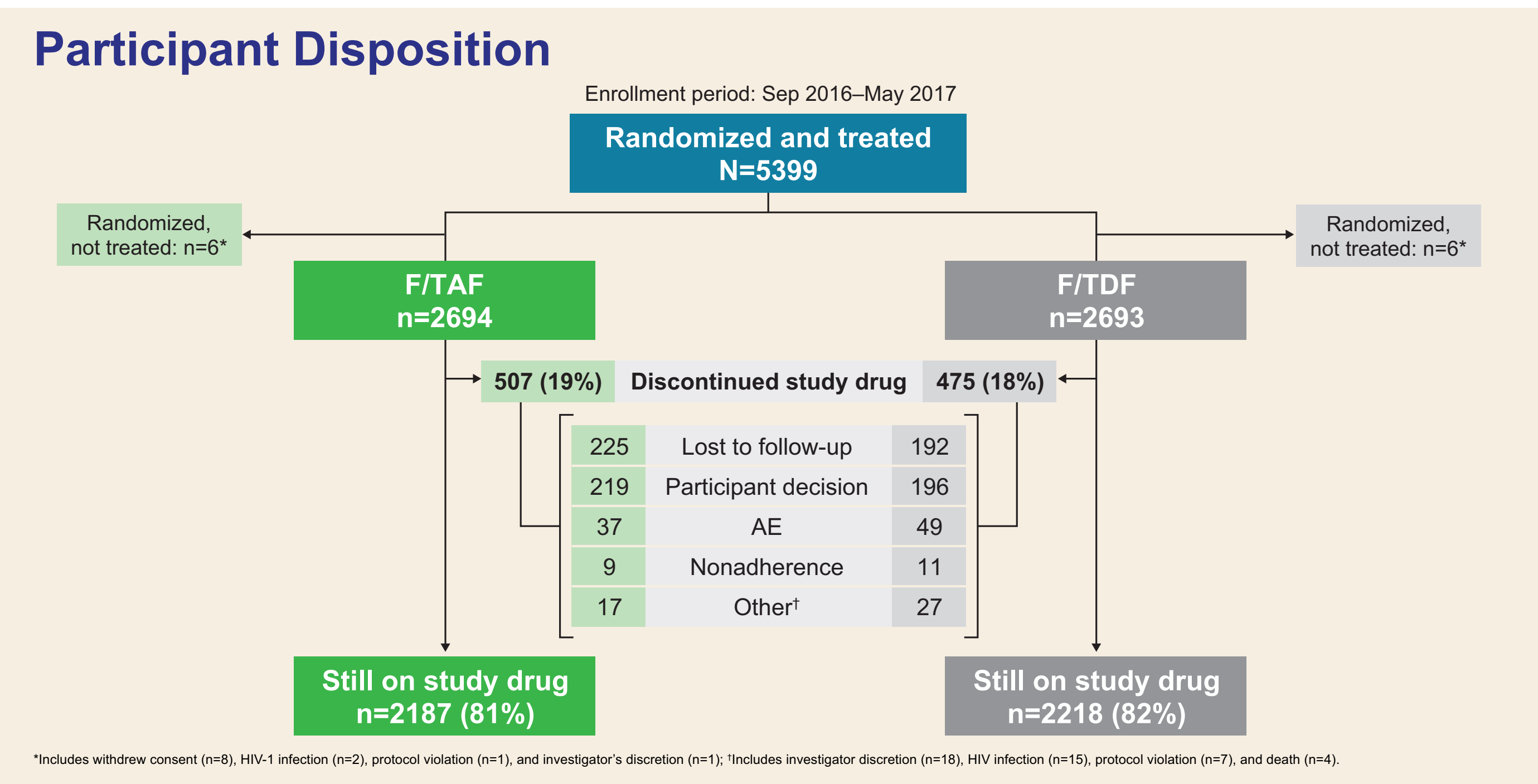
- To report STI outcomes in DISCOVER through 96 wk of follow-up

## Methods



- Eligibility: high sexual risk of HIV
  - 2+ episodes of condomless anal sex in past 12 wk or rectal gonorrhea/chlamydia or syphilis in past 24 wk
  - HIV and hepatitis B virus negative, and estimated glomerular filtration rate (Cockcroft-Gault equation) ≥60 mL/min
  - Prior use of PrEP allowed
- Study conducted in Europe and North America in cities/sites with high HIV incidence
- STI assessments were performed at screening and each postbaseline visit
  - Gonorrhea and chlamydia rates were assessed by central laboratory testing (nucleic acid amplification) and investigator-reported adverse events (AEs)
  - Gonorrhea and chlamydia testing was performed from 3 anatomic sites: rectum, oropharynx, and urethra (urine)
  - Syphilis testing was performed by local laboratories in accordance with local guidelines

## Results

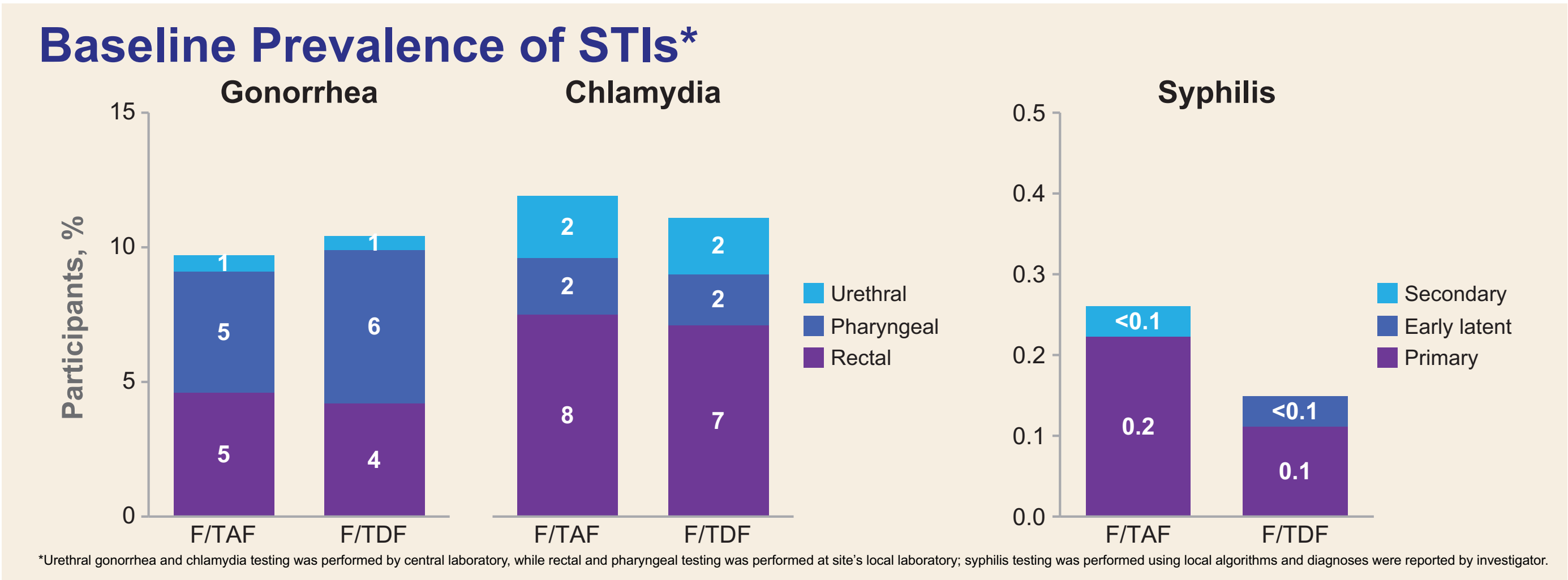


\*Includes withdrew consent (n=8), HIV-1 infection (n=2), protocol violation (n=1), and investigator's discretion (n=1); <sup>†</sup>Includes investigator discretion (n=18), HIV infection (n=15), protocol violation (n=7), and death (n=4).

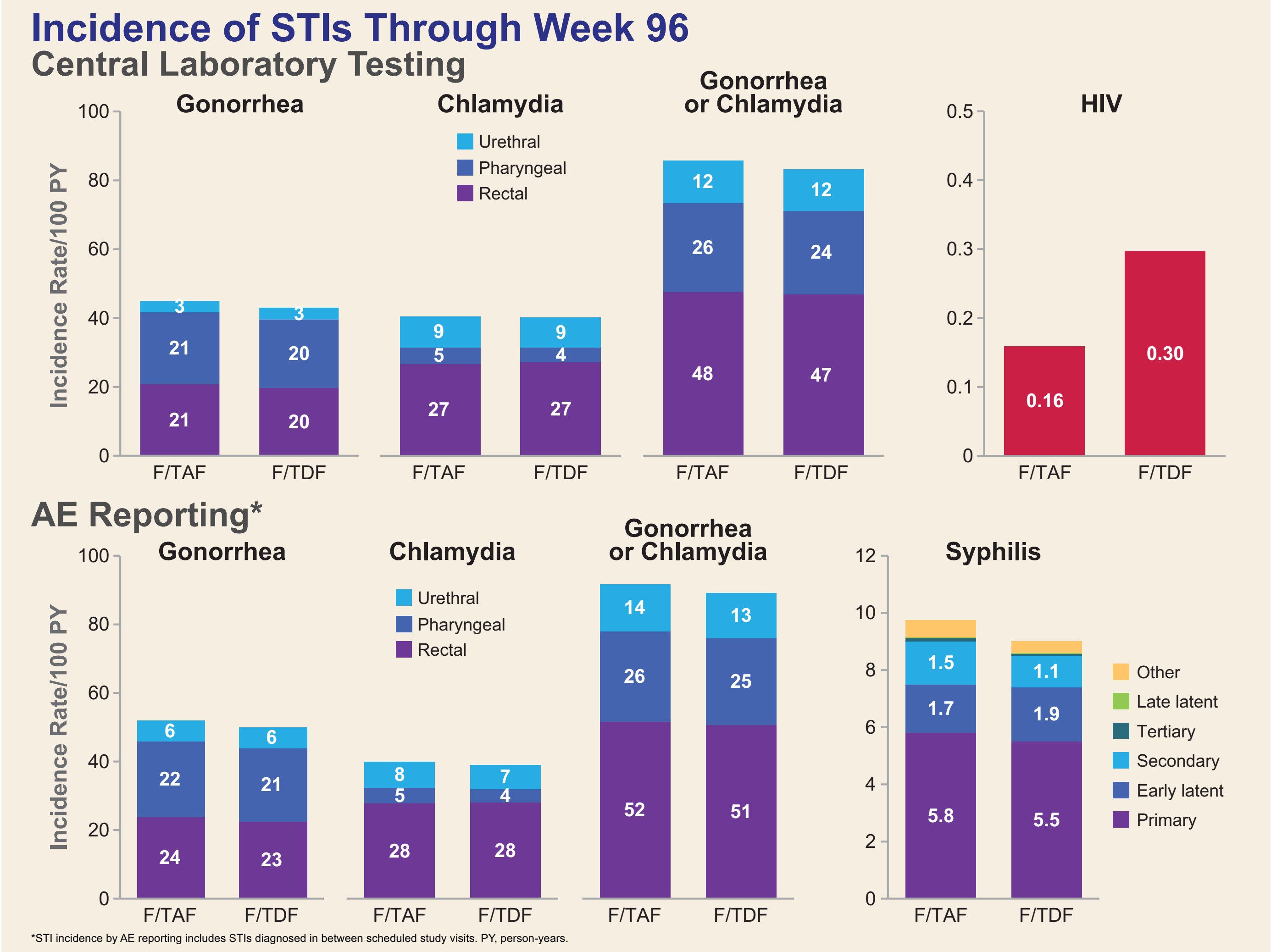
**Demographics and Baseline Characteristics**

	F/TAF n=2694	F/TDF n=2693
Median age, y (range)	34 (18–76)	34 (18–72)
Race, n (%)		
White	2264 (84)	2247 (84)
Black*	240 (9)	234 (9)
Asian	113 (4)	120 (4)
Hispanic or Latinx, n (%)	635 (24)	683 (25)
Proportion TGW, n (%) <sup>†</sup>	45 (2)	29 (1)
≥2 condomless receptive anal sex partners in past 12 wk	1616 (62)	1569 (60)
Rectal gonorrhea in past 24 wk	274 (10)	262 (10)
Rectal chlamydia in past 24 wk	342 (13)	333 (12)
Syphilis in past 24 wk	230 (9)	263 (10)
Recreational drug use in past 12 wk	1785 (67)	1786 (67)
Binge drinking <sup>‡</sup>	618 (23)	599 (22)
Taking F/TDF for PrEP at baseline	465 (17)	440 (16)

\*Includes mixed black race; <sup>†</sup>Identified by self-report; <sup>‡</sup>6 drinks on ≥1 occasion at least monthly.



- 16.1% of participants in F/TAF arm and 15.8% in F/TDF arm tested positive for gonorrhea or chlamydia at any anatomic site; a corresponding 11.3% and 10.5% tested positive for gonorrhea or chlamydia at rectum



## Conclusions

- Gonorrhea and chlamydia incidence rates were high during DISCOVER, with the rectum being the most commonly affected anatomic site
- STI prevalence remained high through 96 wk, but demonstrated a small decrease over time
- Participants who acquired HIV during DISCOVER had a higher historical rate of rectal STIs and a higher incidence rate of rectal STIs during the trial vs participants who did not acquire HIV
- In combination with participant-reported sexual behavior findings, these results suggest risk compensation did not occur in DISCOVER

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