Screening Summary by Site
Number Screened: 220
Report Date: 2026-05-24

Screening Outcome by Site

	All Sites	Baltimore	Los Angeles - Care Center	Pittsburgh - U of Pitt	Chapel Hill
Eligible and enrolled	150(68.2%)	19(8.6%)	13(5.9%)	17(7.7%)	28(12.7%)
Eligible/Not enrolled	16(7.3%)	3(1.4%)	1(0.5%)	3(1.4%)	3(1.4%)
Ineligible	54(24.5%)	3(1.4%)	5(2.3%)	3(1.4%)	11(5.0%)
Incomplete Screening	-	-	-	-	-

The denominator is the number of screened participants (220)

Screening Summary by Site
Number Screened: 220
Report Date: 2026-05-24

Screening Outcome by Site

	All Sites	Cornell Clinical Research	Atlanta - Hope Clinic	Boston - Fenway	Birmingham
Eligible and enrolled	150(68.2%)	8(3.6%)	22(10.0%)	27(12.3%)	16(7.3%)
Eligible/Not enrolled	16(7.3%)	-	1(0.5%)	1(0.5%)	4(1.8%)
Ineligible	54(24.5%)	11(5.0%)	9(4.1%)	8(3.6%)	4(1.8%)
Incomplete Screening	-	-	-	-	-

The denominator is the number of screened participants (220)

Screening Summary by Site
Number Screened: 220
Report Date: 2026-05-24

Screen Failure Reasons by Site

	All Sites	Baltimore	Los Angeles - Care Center	Pittsburgh - U of Pitt	Chapel Hill
Was not assigned male sex at birth	-	-	-	-	-
Wasn't at least 18 years of age or older	-	-	-	-	-
Wasn't willing and able to provide informed consent	1(1.4%)	-	-	-	1(1.4%)
Wasn't able to read at a level required for the study components	-	-	-	-	-
Doesn't have access to device and the internet for completion of study procedures	-	-	-	-	-
Doesn't understand or agree to local STI reporting requirements	-	-	-	-	-
Does not have a history of consensual RAI at least five times in their lifetime and at least once in the prior 3 months	1(1.4%)	1(1.4%)	-	-	-
Has not received or self-administered an enema or rectal douche more than half the time prior to engaging in RAI in the past year	2(2.7%)	-	-	-	-
Is not willing and able to use condoms for all sexual intercourse for the duration of participation	-	-	-	-	-
Does not agree to not participate in other research studies as outlined in the protocol	-	-	-	-	-
Is not willing and able to provide adequate locator information	-	-	-	-	-

The denominator is the number of reasons (74) reported for ineligible participants (70)

Screening Summary by Site
Number Screened: 220
Report Date: 2026-05-24

Screen Failure Reasons by Site

	All Sites	Baltimore	Los Angeles - Care Center	Pittsburgh - U of Pitt	Chapel Hill
Does not agree to not engage in receptive or insertive sexual activity with another study participant	2(2.7%)	-	-	-	2(2.7%)
Is not available to return for all study visits and within any site's catchment area	5(6.8%)	1(1.4%)	1(1.4%)	-	-
A reactive/positive HIV test at screening or at least one reactive/positive test result at enrollment	3(4.1%)	-	-	1(1.4%)	1(1.4%)
A history of active hepatitis B virus infection, as documented by positive HBV surface antigen at screening	-	-	-	-	-
Co-enrollment in any other interventional research study that may interfere with this study	-	-	-	-	-
Grade 2 or above laboratory abnormality at baseline	12(16.2%)	-	2(2.7%)	-	5(6.8%)
Significant colorectal symptom(s) as determined by medical history or by participant self-report	5(6.8%)	-	-	-	1(1.4%)
Symptoms and/or clinical or laboratory diagnosis of active rectal or reproductive tract infection requiring treatment	12(16.2%)	-	1(1.4%)	1(1.4%)	2(2.7%)
History of an underlying clinically significant cardiac arrhythmia or renal disease	-	-	-	-	-

The denominator is the number of reasons (74) reported for ineligible participants (70)

Screening Summary by Site
Number Screened: 220
Report Date: 2026-05-24

Screen Failure Reasons by Site

	All Sites	Baltimore	Los Angeles - Care Center	Pittsburgh - U of Pitt	Chapel Hill
History of severe or recent cardiac or pulmonary event	-	-	-	-	-
History of significant gastrointestinal bleeding	-	-	-	-	-
Use of F/TDF or use of F/TAF as HIV PrEP within 8 weeks prior to screening visit or anticipated use throughout study participation	3(4.1%)	-	-	-	-
Use of injectable PrEP within 8 weeks prior to the screening visit or anticipated use throughout study participation	-	-	-	-	-
Use of protocol exclusionary medication or product	4(5.4%)	-	-	-	2(2.7%)
Known allergic reaction to TFV or other components of the test articles	-	-	-	-	-
Current known partners with HIV, unless with sustained viral suppression on antiretroviral treatment	-	-	-	-	-
History of recurrent urticaria	1(1.4%)	-	-	-	1(1.4%)
Symptoms suggestive of acute HIV infection	-	-	-	-	-
Individual changed their mind	8(10.8%)	3(4.1%)	-	1(1.4%)	1(1.4%)
Unable to contact/no show	3(4.1%)	-	-	2(2.7%)	1(1.4%)
Investigator decision	12(16.2%)	2(2.7%)	2(2.7%)	1(1.4%)	-

The denominator is the number of reasons (74) reported for ineligible participants (70)

Screening Summary by Site
Number Screened: 220
Report Date: 2026-05-24

Screen Failure Reasons by Site

	All Sites	Cornell Clinical Research	Atlanta - Hope Clinic	Boston - Fenway	Birmingham
Was not assigned male sex at birth	-	-	-	-	-
Wasn't at least 18 years of age or older	-	-	-	-	-
Wasn't willing and able to provide informed consent	1(1.4%)	-	-	-	-
Wasn't able to read at a level required for the study components	-	-	-	-	-
Doesn't have access to device and the internet for completion of study procedures	-	-	-	-	-
Doesn't understand or agree to local STI reporting requirements	-	-	-	-	-
Does not have a history of consensual RAI at least five times in their lifetime and at least once in the prior 3 months	1(1.4%)	-	-	-	-
Has not received or self-administered an enema or rectal douche more than half the time prior to engaging in RAI in the past year	2(2.7%)	1(1.4%)	-	1(1.4%)	-
Is not willing and able to use condoms for all sexual intercourse for the duration of participation	-	-	-	-	-
Does not agree to not participate in other research studies as outlined in the protocol	-	-	-	-	-
Is not willing and able to provide adequate locator information	-	-	-	-	-

The denominator is the number of reasons (74) reported for ineligible participants (70)

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Screen Failure Reasons by Site

	All Sites	Cornell Clinical Research	Atlanta - Hope Clinic	Boston - Fenway	Birmingham
Does not agree to not engage in receptive or insertive sexual activity with another study participant	2(2.7%)	-	-	-	-
Is not available to return for all study visits and within any site's catchment area	5(6.8%)	1(1.4%)	-	-	2(2.7%)
A reactive/positive HIV test at screening or at least one reactive/positive test result at enrollment	3(4.1%)	-	-	-	1(1.4%)
A history of active hepatitis B virus infection, as documented by positive HBV surface antigen at screening	-	-	-	-	-
Co-enrollment in any other interventional research study that may interfere with this study	-	-	-	-	-
Grade 2 or above laboratory abnormality at baseline	12(16.2%)	2(2.7%)	1(1.4%)	-	2(2.7%)
Significant colorectal symptom(s) as determined by medical history or by participant self-report	5(6.8%)	3(4.1%)	1(1.4%)	-	-
Symptoms and/or clinical or laboratory diagnosis of active rectal or reproductive tract infection requiring treatment	12(16.2%)	-	4(5.4%)	4(5.4%)	-
History of an underlying clinically significant cardiac arrhythmia or renal disease	-	-	-	-	-
History of severe or recent cardiac or pulmonary event	-	-	-	-	-

The denominator is the number of reasons (74) reported for ineligible participants (70)

Screening Summary by Site
Number Screened: 220
Report Date: 2026-05-24

Screen Failure Reasons by Site

	All Sites	Cornell Clinical Research	Atlanta - Hope Clinic	Boston - Fenway	Birmingham
History of significant gastrointestinal bleeding	-	-	-	-	-
Use of F/TDF or use of F/TAF as HIV PrEP within 8 weeks prior to screening visit or anticipated use throughout study participation	3(4.1%)	1(1.4%)	-	2(2.7%)	-
Use of injectable PrEP within 8 weeks prior to the screening visit or anticipated use throughout study participation	-	-	-	-	-
Use of protocol exclusionary medication or product	4(5.4%)	1(1.4%)	-	1(1.4%)	-
Known allergic reaction to TFV or other components of the test articles	-	-	-	-	-
Current known partners with HIV, unless with sustained viral suppression on antiretroviral treatment	-	-	-	-	-
History of recurrent urticaria	1(1.4%)	-	-	-	-
Symptoms suggestive of acute HIV infection	-	-	-	-	-
Individual changed their mind	8(10.8%)	1(1.4%)	-	1(1.4%)	1(1.4%)
Unable to contact/no show	3(4.1%)	-	-	-	-
Investigator decision	12(16.2%)	1(1.4%)	4(5.4%)	-	2(2.7%)

The denominator is the number of reasons (74) reported for ineligible participants (70)