Statistical Analysis Plan Part 4

Study ID: 217711

Official Study Title: A phase 4, randomized, open-label, three-arm study to evaluate implementation strategies for the delivery of CAB for HIV Preexposure Prophylaxis (PrEP) across clinical settings for adult (≥18 years) Black cis-and transgender women without HIV infection living in the United States Ending the Epidemic (EHE) territories.

Document Date: 08 Sep 2025

As the source document, the Statistical Analysis Plan, exceeds the maximum permitted file size, the SAP has been split into 4 separate documents.

7.12.002. Frequencies of Perception of the Sexual Health Assessment and Study Engagement among Patient Study Participants by Clinic Type (All Participants at Month 12/13)

	All Participants	Women's Health	Primary Care	HIV Specialist	Other
	(N=X)	(N=XX)	(N=XX)	(N=XX)	(N=XX)
Have you experienced any difficulties that impacted your ability to participate in the EBONI study?					
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I don't know	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX
What difficulties have impacted your participation in the EBONI study?[5]					
No child care	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Inability to take time off work	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Concerns about lost pay	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No extended clinic hours (e.g., weekend or open later)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Transportation to or from clinic	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Distrust in research	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Lack of awareness of PrEP	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Lack of awareness of APRETUDE	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Belief APRETUDE is for men	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Belief PrEP is for men	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Do not think HIV is concern for them	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Stigma with PrEP	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Lack of insurance to take PrEP	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Concerns about side effects	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Time commitment involved in study participation	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX

[1]This item follows a skip logic pattern. Only participants who report 'yes' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[2]Participants are allowed to select more than one response.
[3]This item follows a skip logic pattern. Only participants who report 'yes' to their provider discussing results of the assessment with them are required to provide a response (n=XX).
[4]This item follows a skip logic pattern. Only participants who report 'no' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[5]This item follows a skip logic pattern. Only participants who report 'yes' to experiencing difficulties that impacted their ability to participate in the study are required to provide a response (n=XX).

7.12.003. Frequencies of Perception of the Sexual Health Assessment and Study Engagement among Patient Study Participants by Region (All Participants at Month 12/13)

	All Participants	Northeast	South	West	Midwest
	(N=XX)	(N=XX)	(N=XX)	(N=XX)	(N=XX)
Did you complete a Sexual Health Assessment from your provider or clinic/practice in the last 12 months? (ECI only)					
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I don't know	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX
Did your provider or another person at the clinic/practice discuss the results of the assessment with you? (ECI only)[1]					
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I don't know	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX
Who discussed the results of the assessment with you? (ECI only)[2,3]					
My healthcare provider/doctor	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
A nurse	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
A social worker	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
A peer educator	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I don't know	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX

[1]This item follows a skip logic pattern. Only participants who report 'yes' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[2]Participants are allowed to select more than one response.
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[5]This item follows a skip logic pattern. Only participants who report 'yes' to experiencing difficulties that impacted their ability to participate in the study are required to provide a response (n=XX).

7.12.003. Frequencies of Perception of the Sexual Health Assessment and Study Engagement among Patient Study Participants by Region (All Participants at Month 12/13)

	All Participants	Northeast	South	West	Midwest
	(N=XX)	(N=XX)	(N=XX)	(N=XX)	(N=XX)
How helpful was discussing the results with your provider or another person at the clinic/practice? (ECI only)[1]					
Very helpful	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Somewhat helpful	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
A little helpful	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Not at all helpful	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX
Rate your experience with the Sexual Health Assessment (ECI only)					
It was difficult to take the assessment on my digital device[1]					
Completely disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Neither agree nor disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Completely agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX
The assessment is quick to complete[1]					
Completely disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Neither agree nor disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Completely agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX

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[5]This item follows a skip logic pattern. Only participants who report 'yes' to experiencing difficulties that impacted their ability to participate in the study are required to provide a response (n=XX).

7.12.003. Frequencies of Perception of the Sexual Health Assessment and Study Engagement among Patient Study Participants by Region (All Participants at Month 12/13)

	All Participants	Northeast	South	West	Midwest
	(N=XX)	(N=XX)	(N=XX)	(N=XX)	(N=XX)
I like that my doctor sent the assessment before my appointment[1]					
Completely disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Neither agree nor disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Completely agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX
I was concerned about the privacy of my answers[1]					
Completely disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Neither agree nor disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Completely agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX
I like that my doctor is assessing my sexual health and whether PrEP is right for me[1]					
Completely disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Neither agree nor disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Completely agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX

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[3]This item follows a skip logic pattern. Only participants who report 'yes' to their provider discussing results of the assessment with them are required to provide a response (n=XX).
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[5]This item follows a skip logic pattern. Only participants who report 'yes' to experiencing difficulties that impacted their ability to participate in the study are required to provide a response (n=XX).

7.12.003. Frequencies of Perception of the Sexual Health Assessment and Study Engagement among Patient Study Participants by Region (All Participants at Month 12/13)

	All Participants	Northeast	South	West	Midwest
	(N=XX)	(N=XX)	(N=XX)	(N=XX)	(N=XX)
The assessment asked the right questions to help my doctor and me determine whether if PrEP is right for me[1]					
Completely disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Neither agree nor disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Completely agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX
The assessment made me feel uncomfortable[1]					
Completely disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Neither agree nor disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Completely agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX
The assessment asked too many private questions[1]					
Completely disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Neither agree nor disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Completely agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX

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[5]This item follows a skip logic pattern. Only participants who report 'yes' to experiencing difficulties that impacted their ability to participate in the study are required to provide a response (n=XX).

7.12.003. Frequencies of Perception of the Sexual Health Assessment and Study Engagement among Patient Study Participants by Region (All Participants at Month 12/13)

	All Participants	Northeast	South	West	Midwest
	(N=XX)	(N=XX)	(N=XX)	(N=XX)	(N=XX)
Why did you not complete the assessment (ECI only)[2,4]					
I did not receive a Sexual Health Assessment from my provider or clinic/practice	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I forgot	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I did not know how to complete it	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
The link my doctor sent did not work	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I didn't have the time	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
The assessment took too long to complete	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
The assessment included too many personal questions	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
The assessment made me feel uncomfortable	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I was concerned about the privacy of my answers	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I did not want to share sexual health information with my doctor or clinic	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I did not understand why my doctor or clinic was asking me to complete the assessment	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I don't know	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX

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7.12.003. Frequencies of Perception of the Sexual Health Assessment and Study Engagement among Patient Study Participants by Region (All Participants at Month 12/13)

	All Participants	Northeast	South	West	Midwest
	(N=XX)	(N=XX)	(N=XX)	(N=XX)	(N=XX)
Thinking back to when you first learned about the EBONI study, what was the most helpful in letting you know about APRETUDE and the study?[2]					
Provision of educational materials	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
During consultation with your provider	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Through peer educators	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Posters in the clinic/practice	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Flyers in the clinic/practice	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Mentions on the clinic/practice's website	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Mentions on social media	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Social media campaign - SheIsMe (on Instagram, Facebook, Youtube)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
The EBONI study website (ebonistudyinfo.com)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Outreach events done by the clinic	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Outreach events by ViiV (e.g., Risk to Reasons events)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Radio ads about the study	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Internet ads about the study	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Ads in pharmacies (such as Walgreens)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Referrals from community organizations	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Referrals from other providers or health centers	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
The study's SHE Ambassadors	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Word of mouth	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX

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7.12.003. Frequencies of Perception of the Sexual Health Assessment and Study Engagement among Patient Study Participants by Region (All Participants at Month 12/13)

	All Participants	Northeast	South	West	Midwest
	(N=XX)	(N=XX)	(N=XX)	(N=XX)	(N=XX)
Have you experienced any difficulties that impacted your ability to participate in the EBONI study?					
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I don't know	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX
What difficulties have impacted your participation in the EBONI study?[5]					
No child care	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Inability to take time off work	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Concerns about lost pay	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No extended clinic hours (e.g., weekend or open later)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Transportation to or from clinic	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Distrust in research	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Lack of awareness of PrEP	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Lack of awareness of APRETUDE	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Belief APRETUDE is for men	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Belief PrEP is for men	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Do not think HIV is concern for them	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Stigma with PrEP	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Lack of insurance to take PrEP	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Concerns about side effects	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Time commitment involved in study participation	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX	XX

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[2]Participants are allowed to select more than one response.
[3]This item follows a skip logic pattern. Only participants who report 'yes' to their provider discussing results of the assessment with them are required to provide a response (n=XX).
[4]This item follows a skip logic pattern. Only participants who report 'no' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[5]This item follows a skip logic pattern. Only participants who report 'yes' to experiencing difficulties that impacted their ability to participate in the study are required to provide a response (n=XX).

7.12.004. Frequencies of Perception of the Sexual Health Assessment and Study Engagement among Patient Study Participants by Gender (All Participants at Month 12/13)

	All Participants	Cisgender	Transgender
	(N=XX)	(N=XX)	(N=XX)
Did you complete a Sexual Health Assessment from your provider or clinic/practice in the last 12 months? (ECI only)			
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I don't know	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX
Did your provider or another person at the clinic/practice discuss the results of the assessment with you? (ECI only)[1]			
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I don't know	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX
Who discussed the results of the assessment with you? (ECI only)[2,3]			
My healthcare provider/doctor	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
A nurse	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
A social worker	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
A peer educator	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I don't know	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX

[1]This item follows a skip logic pattern. Only participants who report 'yes' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[2]Participants are allowed to select more than one response.
[3]This item follows a skip logic pattern. Only participants who report 'yes' to their provider discussing results of the assessment with them are required to provide a response (n=XX).
[4]This item follows a skip logic pattern. Only participants who report 'no' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[5]This item follows a skip logic pattern. Only participants who report 'yes' to experiencing difficulties that impacted their ability to participate in the study are required to provide a response (n=XX).

7.12.004. Frequencies of Perception of the Sexual Health Assessment and Study Engagement among Patient Study Participants by Gender (All Participants at Month 12/13)

	All Participants	Cisgender	Transgender
	(N=XX)	(N=XX)	(N=XX)
How helpful was discussing the results with your provider or another person at the clinic/practice? (ECI only)[1]			
Very helpful	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Somewhat helpful	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
A little helpful	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Not at all helpful	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX
Rate your experience with the Sexual Health Assessment (ECI only)			
It was difficult to take the assessment on my digital device[1]			
Completely disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Neither agree nor disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Completely agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX
The assessment is quick to complete[1]			
Completely disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Neither agree nor disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Completely agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX

[1]This item follows a skip logic pattern. Only participants who report 'yes' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[2]Participants are allowed to select more than one response.
[3]This item follows a skip logic pattern. Only participants who report 'yes' to their provider discussing results of the assessment with them are required to provide a response (n=XX).
[4]This item follows a skip logic pattern. Only participants who report 'no' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[5]This item follows a skip logic pattern. Only participants who report 'yes' to experiencing difficulties that impacted their ability to participate in the study are required to provide a response (n=XX).

7.12.004. Frequencies of Perception of the Sexual Health Assessment and Study Engagement among Patient Study Participants by Gender (All Participants at Month 12/13)

	All Participants	Cisgender	Transgender
	(N=XX)	(N=XX)	(N=XX)
I like that my doctor sent the assessment before my appointment[1]			
Completely disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Neither agree nor disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Completely agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX
I was concerned about the privacy of my answers[1]			
Completely disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Neither agree nor disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Completely agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX
I like that my doctor is assessing my sexual health and whether PrEP is right for me[1]			
Completely disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Neither agree nor disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Completely agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX

[1]This item follows a skip logic pattern. Only participants who report 'yes' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[2]Participants are allowed to select more than one response.
[3]This item follows a skip logic pattern. Only participants who report 'yes' to their provider discussing results of the assessment with them are required to provide a response (n=XX).
[4]This item follows a skip logic pattern. Only participants who report 'no' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[5]This item follows a skip logic pattern. Only participants who report 'yes' to experiencing difficulties that impacted their ability to participate in the study are required to provide a response (n=XX).

7.12.004. Frequencies of Perception of the Sexual Health Assessment and Study Engagement among Patient Study Participants by Gender (All Participants at Month 12/13)

	All Participants	Cisgender	Transgender
	(N=XX)	(N=XX)	(N=XX)
The assessment asked the right questions to help my doctor and me determine whether if PrEP is right for me[1]			
Completely disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Neither agree nor disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Completely agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX
The assessment made me feel uncomfortable[1]			
Completely disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Neither agree nor disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Completely agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX
The assessment asked too many private questions[1]			
Completely disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Neither agree nor disagree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Completely agree	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX

[1]This item follows a skip logic pattern. Only participants who report 'yes' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[2]Participants are allowed to select more than one response.
[3]This item follows a skip logic pattern. Only participants who report 'yes' to their provider discussing results of the assessment with them are required to provide a response (n=XX).
[4]This item follows a skip logic pattern. Only participants who report 'no' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[5]This item follows a skip logic pattern. Only participants who report 'yes' to experiencing difficulties that impacted their ability to participate in the study are required to provide a response (n=XX).

7.12.004. Frequencies of Perception of the Sexual Health Assessment and Study Engagement among Patient Study Participants by Gender (All Participants at Month 12/13)

	All Participants	Cisgender	Transgender
	(N=XX)	(N=XX)	(N=XX)
Why did you not complete the assessment (ECI only)[2,4]			
I did not receive a Sexual Health Assessment from my provider or clinic/practice	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I forgot	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I did not know how to complete it	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
The link my doctor sent did not work	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I didn't have the time	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
The assessment took too long to complete	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
The assessment included too many personal questions	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
The assessment made me feel uncomfortable	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I was concerned about the privacy of my answers	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I did not want to share sexual health information with my doctor or clinic	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I did not understand why my doctor or clinic was asking me to complete the assessment	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I don't know	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX

[1]This item follows a skip logic pattern. Only participants who report 'yes' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[2]Participants are allowed to select more than one response.
[3]This item follows a skip logic pattern. Only participants who report 'yes' to their provider discussing results of the assessment with them are required to provide a response (n=XX).
[4]This item follows a skip logic pattern. Only participants who report 'no' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[5]This item follows a skip logic pattern. Only participants who report 'yes' to experiencing difficulties that impacted their ability to participate in the study are required to provide a response (n=XX).

7.12.004. Frequencies of Perception of the Sexual Health Assessment and Study Engagement among Patient Study Participants by Gender (All Participants at Month 12/13)

	All Participants	Cisgender	Transgender
	(N=XX)	(N=XX)	(N=XX)
Thinking back to when you first learned about the EBONI study, what was the most helpful in letting you know about APRETUDE and the study?[2]			
Provision of educational materials	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
During consultation with your provider	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Through peer educators	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Posters in the clinic/practice	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Flyers in the clinic/practice	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Mentions on the clinic/practice's website	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Mentions on social media	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Social media campaign - SheIsMe (on Instagram, Facebook, Youtube)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
The EBONI study website (ebonistudyinfo.com)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Outreach events done by the clinic	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Outreach events by ViiV (e.g., Risk to Reasons events)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Radio ads about the study	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Internet ads about the study	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Ads in pharmacies (such as Walgreens)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Referrals from community organizations	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Referrals from other providers or health centers	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
The study's SHE Ambassadors	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Word of mouth	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX

[1]This item follows a skip logic pattern. Only participants who report 'yes' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[2]Participants are allowed to select more than one response.
[3]This item follows a skip logic pattern. Only participants who report 'yes' to their provider discussing results of the assessment with them are required to provide a response (n=XX).
[4]This item follows a skip logic pattern. Only participants who report 'no' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[5]This item follows a skip logic pattern. Only participants who report 'yes' to experiencing difficulties that impacted their ability to participate in the study are required to provide a response (n=XX).

7.12.004. Frequencies of Perception of the Sexual Health Assessment and Study Engagement among Patient Study Participants by Gender (All Participants at Month 12/13)

	All Participants	Cisgender	Transgender
	(N=XX)	(N=XX)	(N=XX)
Have you experienced any difficulties that impacted your ability to participate in the EBONI study?			
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I don't know	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX
What difficulties have impacted your participation in the EBONI study?[5]			
No child care	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Inability to take time off work	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Concerns about lost pay	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No extended clinic hours (e.g., weekend or open later)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Transportation to or from clinic	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Distrust in research	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Lack of awareness of PrEP	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Lack of awareness of APRETUDE	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Belief APRETUDE is for men	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Belief PrEP is for men	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Do not think HIV is concern for them	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Stigma with PrEP	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Lack of insurance to take PrEP	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Concerns about side effects	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Time commitment involved in study participation	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX

[1]This item follows a skip logic pattern. Only participants who report 'yes' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[2]Participants are allowed to select more than one response.
[3]This item follows a skip logic pattern. Only participants who report 'yes' to their provider discussing results of the assessment with them are required to provide a response (n=XX).
[4]This item follows a skip logic pattern. Only participants who report 'no' to having completed a Sexual Health Assessment in the last 12 months are required to provide a response (n=XX).
[5]This item follows a skip logic pattern. Only participants who report 'yes' to experiencing difficulties that impacted their ability to participate in the study are required to provide a response (n=XX).

7.13.001. Treatment Effects on Primary and Secondary Outcomes at Month 12/13

Intervention Arm							EI vs. SI		ECI vs. SI	
Outcomes	**Enhanced Implementation (EI)**		**Enhanced Collaborative Implementation (ECI)**		**Standard Implementation (SI)**		**Adjusted Mean Difference* (95% CI)**	***P* value**	**Adjusted Mean Difference* (95% CI)**	***P* value**
	n	**Adjusted Mean (SE)**	**n**	**Adjusted Mean (SE)**	**n**	**Adjusted Mean (SE)**				
Secondary										
APRETUDE IAM	XX	XX.X (XX.XX)	XX	XX.X (XX.XX)	XX	XX.X (XX.XX)	XX.X (XX.X, XX.X)	X.XXX	XX.X (XX.X, XX.X)	X.XXX
APRETUDE AIM	XX	XX.X (XX.XX)	XX	XX.X (XX.XX)	XX	XX.X (XX.XX)	XX.X (XX.X, XX.X)	X.XXX	XX.X (XX.X, XX.X)	X.XXX
APRETUDE FIM	XX	XX.X (XX.XX)	XX	XX.X (XX.XX)	XX	XX.X (XX.XX)	XX.X (XX.X, XX.X)	X.XXX	XX.X (XX.X, XX.X)	X.XXX
Change from Baseline to Month 12/13										
APRETUDE IAM	XX	XX.X (XX.XX)	XX	XX.X (XX.XX)	XX	XX.X (XX.XX)	XX.X (XX.X, XX.X)	X.XXX	XX.X (XX.X, XX.X)	X.XXX
APRETUDE AIM	XX	XX.X (XX.XX)	XX	XX.X (XX.XX)	XX	XX.X (XX.XX)	XX.X (XX.X, XX.X)	X.XXX	XX.X (XX.X, XX.X)	X.XXX
APRETUDE FIM	XX	XX.X (XX.XX)	XX	XX.X (XX.XX)	XX	XX.X (XX.XX)	XX.X (XX.X, XX.X)	X.XXX	XX.X (XX.X, XX.X)	X.XXX

AIM= Acceptability of Intervention Measure; FIM= Feasibility Intervention Measure; IAM= Intervention Appropriateness Measure
*Adjusted mean differences, 95% CI, and *P* values considering clustering of participants within study sites and correlation within sites using a linear mixed-effect model. No correction for multiple comparisons has been made.

7.14.001. Demographic Characteristics, Sexual Behaviors, and History of PrEP Use among Patient Study Participants by Study Arm (Participants at both Month 4/5 and Month 12/13)

	All Participants	SI strategy	EI strategy	ECI strategy
	(N=XX)	(N=XX)	(N=XX)	(N=XX)
Gender				
Cisgender female	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Transgender woman	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX
Age				
Mean	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX
Median (Q1, Q3)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Min-Max	XX - XX	XX - XX	XX - XX	XX - XX
Missing	XX	XX	XX	XX
Race				
Pacific Islander	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Asian	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Black or African American	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Mixed race	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Native American	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
White	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX

[1]Participants allowed to select more than one response.
[2]Responses are among the n=XX participants who responded Yes to having had sex in the last 6 months
[3]Responses are among the n=XX participants who described the HIV status of their sexual partner(s) as not having HIV/AIDS or unknown
[4]Responses are among the n=XX participants who described having at least one partner within the last 6 months living with HIV/AIDS
Note: N=XX PSPs have been excluded due to ineligible M4/5 data. N=XX PSPs did not complete a M4/5 assessment.

7.14.001. Demographic Characteristics, Sexual Behaviors, and History of PrEP Use among Patient Study Participants by Study Arm (Participants at both Month 4/5 and Month 12/13)

	All Participants	SI strategy	EI strategy	ECI strategy
	(N=XX)	(N=XX)	(N=XX)	(N=XX)
Ethnicity				
Hispanic/Latinx	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Non-Hispanic/Latinx	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX
How would you describe your current sexual orientation?				
Heterosexual or straight	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Lesbian or gay	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Bisexual	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Asexual	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Pansexual and/or questioning	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Same gender loving	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Queer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX

[1]Participants allowed to select more than one response.
[2]Responses are among the n=XX participants who responded Yes to having had sex in the last 6 months
[3]Responses are among the n=XX participants who described the HIV status of their sexual partner(s) as not having HIV/AIDS or unknown
[4]Responses are among the n=XX participants who described having at least one partner within the last 6 months living with HIV/AIDS
Note: N=XX PSPs have been excluded due to ineligible M4/5 data. N=XX PSPs did not complete a M4/5 assessment.

7.14.001. Demographic Characteristics, Sexual Behaviors, and History of PrEP Use among Patient Study Participants by Study Arm (Participants at both Month 4/5 and Month 12/13)

	All Participants	SI strategy	EI strategy	ECI strategy
	(N=XX)	(N=XX)	(N=XX)	(N=XX)
Which of the following best describes your current relationship status?				
Single, never married	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Single, widowed	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Single, separated or divorced	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Dating but not living with a partner	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Dating but living with a partner	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Domestic partnership/civil union	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Married	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX
What best describes your current employment status?[1]				
Employed for wages full-time (1 employer)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Employed for wages full-time (2 or more employers)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Employed for wages part-time (1 employer)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Employed for wages part-time (2 or more employers)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Self-employed	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
A homemaker	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Student	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Retired	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Not employed	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Unable to work (disabled)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX

[1]Participants allowed to select more than one response.
[2]Responses are among the n=XX participants who responded Yes to having had sex in the last 6 months
[3]Responses are among the n=XX participants who described the HIV status of their sexual partner(s) as not having HIV/AIDS or unknown
[4]Responses are among the n=XX participants who described having at least one partner within the last 6 months living with HIV/AIDS
Note: N=XX PSPs have been excluded due to ineligible M4/5 data. N=XX PSPs did not complete a M4/5 assessment.

7.14.001. Demographic Characteristics, Sexual Behaviors, and History of PrEP Use among Patient Study Participants by Study Arm (Participants at both Month 4/5 and Month 12/13)

	All Participants	SI strategy	EI strategy	ECI strategy
	(N=XX)	(N=XX)	(N=XX)	(N=XX)
What type of medical insurance do you currently have?				
Private insurance	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Private insurance I purchased through an exchange (e.g., Obamacare, Affordable Care Act)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
My parent's insurance	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
My partner's/spouse's insurance	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Federal insurance (e.g., VA, TRICARE)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Medicare or Medicaid	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Some other health care plan	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I don't have any health insurance currently	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX

[1]Participants allowed to select more than one response.
[2]Responses are among the n=XX participants who responded Yes to having had sex in the last 6 months
[3]Responses are among the n=XX participants who described the HIV status of their sexual partner(s) as not having HIV/AIDS or unknown
[4]Responses are among the n=XX participants who described having at least one partner within the last 6 months living with HIV/AIDS
Note: N=XX PSPs have been excluded due to ineligible M4/5 data. N=XX PSPs did not complete a M4/5 assessment.

7.14.001. Demographic Characteristics, Sexual Behaviors, and History of PrEP Use among Patient Study Participants by Study Arm (Participants at both Month 4/5 and Month 12/13)

	All Participants	SI strategy	EI strategy	ECI strategy
	(N=XX)	(N=XX)	(N=XX)	(N=XX)
Have you had sex in the last 6 months?				
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX
How would you describe your sexual behavior in the last 6 months?[1,2]				
I have had vaginal sex (penis in vagina) with only 1 partner	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I have had vaginal sex (penis in vagina) with more than 1 partner	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I have had anal sex (penis in butt) with only 1 partner	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I have had anal sex (penis in butt) with more than 1 partner	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I have had oral sex (mouth, tongue or lips on vagina, penis, or butt) with only 1 partner	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I have had oral sex (mouth, tongue or lips on vagina, penis, or butt) with more than 1 partner	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX

[1]Participants allowed to select more than one response.
[2]Responses are among the n=XX participants who responded Yes to having had sex in the last 6 months
[3]Responses are among the n=XX participants who described the HIV status of their sexual partner(s) as not having HIV/AIDS or unknown
[4]Responses are among the n=XX participants who described having at least one partner within the last 6 months living with HIV/AIDS
Note: N=XX PSPs have been excluded due to ineligible M4/5 data. N=XX PSPs did not complete a M4/5 assessment.

7.14.001. Demographic Characteristics, Sexual Behaviors, and History of PrEP Use among Patient Study Participants by Study Arm (Participants at both Month 4/5 and Month 12/13)

	All Participants	SI strategy	EI strategy	ECI strategy
	(N=XX)	(N=XX)	(N=XX)	(N=XX)
How often did you/your partner use a condom when you had sex in the last 6 months?[2]				
All of the time	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Most of the time	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Some of the time	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
A little of the time	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
None of the time	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX
Did you/your partner use a condom the last time you had sex?[2]				
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I don't remember	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX
In the past 6 months, how would you describe the HIV status of your sexual partner(s)[2]				
I know that none of my sexual partner(s) in the past 6 months have HIV/AIDS	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I know that at least one sexual partner from the past 6 months is living with HIV/AIDS	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I do not know my sexual partners' HIV status	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX

[1]Participants allowed to select more than one response.
[2]Responses are among the n=XX participants who responded Yes to having had sex in the last 6 months
[3]Responses are among the n=XX participants who described the HIV status of their sexual partner(s) as not having HIV/AIDS or unknown
[4]Responses are among the n=XX participants who described having at least one partner within the last 6 months living with HIV/AIDS
Note: N=XX PSPs have been excluded due to ineligible M4/5 data. N=XX PSPs did not complete a M4/5 assessment.

7.14.001. Demographic Characteristics, Sexual Behaviors, and History of PrEP Use among Patient Study Participants by Study Arm (Participants at both Month 4/5 and Month 12/13)

	All Participants	SI strategy	EI strategy	ECI strategy
	(N=XX)	(N=XX)	(N=XX)	(N=XX)
As far as you know, were any of your partner(s) from the past 6 months taking PrEP, to prevent HIV infection?[3]				
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I don't know	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX
You mentioned that you had at least one partner in the last 6 months who is living with HIV/AIDS. As far as you know, were any of your partners taking HIV medications (antiretrovirals) to treat their HIV infection?[4]				
Yes, my partner(s) was/were taking HIV medications	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Yes, my partner(s) was/were taking HIV medications and was/were undetectable, meaning HIV tests are not finding the virus	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No, my partner(s) was/were not taking HIV medications	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I do not know whether my partner(s) was/were taking HIV medications	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX
In the last 6 months, have you experienced any incidents of sexual violence, physical abuse, or any other type of trauma from a partner?				
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX

[1]Participants allowed to select more than one response.
[2]Responses are among the n=XX participants who responded Yes to having had sex in the last 6 months
[3]Responses are among the n=XX participants who described the HIV status of their sexual partner(s) as not having HIV/AIDS or unknown
[4]Responses are among the n=XX participants who described having at least one partner within the last 6 months living with HIV/AIDS
Note: N=XX PSPs have been excluded due to ineligible M4/5 data. N=XX PSPs did not complete a M4/5 assessment.

7.14.001. Demographic Characteristics, Sexual Behaviors, and History of PrEP Use among Patient Study Participants by Study Arm (Participants at both Month 4/5 and Month 12/13)

	All Participants	SI strategy	EI strategy	ECI strategy
	(N=XX)	(N=XX)	(N=XX)	(N=XX)
In the last 6 months, have you exchanged things like money or drugs for sex with a sexual partner?[2]				
Yes, I gave a sexual partner things like drugs or money for sex	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Yes, a sexual partner gave me things like drugs or money for sex	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No, I have not exchanged things like drugs or money for sex	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX	XX

[1]Participants allowed to select more than one response.
[2]Responses are among the n=XX participants who responded Yes to having had sex in the last 6 months
[3]Responses are among the n=XX participants who described the HIV status of their sexual partner(s) as not having HIV/AIDS or unknown
[4]Responses are among the n=XX participants who described having at least one partner within the last 6 months living with HIV/AIDS
Note: N=XX PSPs have been excluded due to ineligible M4/5 data. N=XX PSPs did not complete a M4/5 assessment.

7.14.002. Demographic Characteristics, Sexual Behaviors, and History of PrEP Use among Patient Study Participants by Gender (Participants at both M4/5 and Month 12/13)

	All Participants	Cisgender	Transgender
	(N=XX)	(N=XX)	(N=XX)
Age			
Mean	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX
Median (Q1, Q3)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Min-Max	XX - XX	XX - XX	XX - XX
Missing	XX	XX	XX
Race			
Pacific Islander	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Asian	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Black or African American	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Mixed race	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Native American	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
White	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX

[1]Participants allowed to select more than one response.
[2]Responses are among the n=XX participants who responded Yes to having had sex in the last 6 months
[3]Responses are among the n=XX participants who described the HIV status of their sexual partner(s) as not having HIV/AIDS or unknown in the last 6 months
[4]Responses are among the n=XX participants who described having at least one partner within the last 6 months living with HIV/AIDS
Note: N=XX PSPs have been excluded due to ineligible M4/5 data. N=XX PSPs did not complete a M4/5 assessment.

7.14.002. Demographic Characteristics, Sexual Behaviors, and History of PrEP Use among Patient Study Participants by Gender (Participants at both M4/5 and Month 12/13)

	All Participants	Cisgender	Transgender
	(N=XX)	(N=XX)	(N=XX)
Ethnicity			
Hispanic/Latinx	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Non-Hispanic/Latinx	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX
How would you describe your current sexual orientation?			
Heterosexual or straight	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Lesbian or gay	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Bisexual	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Asexual	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Pansexual and/or questioning	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Same gender loving	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Queer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX

[1]Participants allowed to select more than one response.
[2]Responses are among the n=XX participants who responded Yes to having had sex in the last 6 months
[3]Responses are among the n=XX participants who described the HIV status of their sexual partner(s) as not having HIV/AIDS or unknown in the last 6 months
[4]Responses are among the n=XX participants who described having at least one partner within the last 6 months living with HIV/AIDS
Note: N=XX PSPs have been excluded due to ineligible M4/5 data. N=XX PSPs did not complete a M4/5 assessment.

7.14.002. Demographic Characteristics, Sexual Behaviors, and History of PrEP Use among Patient Study Participants by Gender (Participants at both M4/5 and Month 12/13)

	All Participants	Cisgender	Transgender
	(N=XX)	(N=XX)	(N=XX)
Which of the following best describes your current relationship status?			
Single, never married	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Single, widowed	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Single, separated or divorced	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Dating but not living with a partner	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Dating but living with a partner	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Domestic partnership/civil union	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Married	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX
What best describes your current employment status?[1]			
Employed for wages full-time (1 employer)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Employed for wages full-time (2 or more employers)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Employed for wages part-time (1 employer)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Employed for wages part-time (2 or more employers)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Self-employed	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
A homemaker	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Student	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Retired	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Not employed	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Unable to work (disabled)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX

[1]Participants allowed to select more than one response.
[2]Responses are among the n=XX participants who responded Yes to having had sex in the last 6 months
[3]Responses are among the n=XX participants who described the HIV status of their sexual partner(s) as not having HIV/AIDS or unknown in the last 6 months
[4]Responses are among the n=XX participants who described having at least one partner within the last 6 months living with HIV/AIDS
Note: N=XX PSPs have been excluded due to ineligible M4/5 data. N=XX PSPs did not complete a M4/5 assessment.

7.14.002. Demographic Characteristics, Sexual Behaviors, and History of PrEP Use among Patient Study Participants by Gender (Participants at both M4/5 and Month 12/13)

	All Participants	Cisgender	Transgender
	(N=XX)	(N=XX)	(N=XX)
What type of medical insurance do you currently have?			
Private insurance	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Private insurance I purchased through an exchange (e.g., Obamacare, Affordable Care Act)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
My parent's insurance	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
My partner's/spouse's insurance	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Federal insurance (e.g., VA, TRICARE)	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Medicare or Medicaid	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Some other health care plan	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I don't have any health insurance currently	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX

[1]Participants allowed to select more than one response.
[2]Responses are among the n=XX participants who responded Yes to having had sex in the last 6 months
[3]Responses are among the n=XX participants who described the HIV status of their sexual partner(s) as not having HIV/AIDS or unknown in the last 6 months
[4]Responses are among the n=XX participants who described having at least one partner within the last 6 months living with HIV/AIDS
Note: N=XX PSPs have been excluded due to ineligible M4/5 data. N=XX PSPs did not complete a M4/5 assessment.

7.14.002. Demographic Characteristics, Sexual Behaviors, and History of PrEP Use among Patient Study Participants by Gender (Participants at both M4/5 and Month 12/13)

	All Participants	Cisgender	Transgender
	(N=XX)	(N=XX)	(N=XX)
Have you had sex in the last 6 months?			
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX
How would you describe your sexual behavior in the last 6 months?[1,2]			
I have had vaginal sex (penis in vagina) with only 1 partner	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I have had vaginal sex (penis in vagina) with more than 1 partner	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I have had anal sex (penis in butt) with only 1 partner	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I have had anal sex (penis in butt) with more than 1 partner	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I have had oral sex (mouth, tongue or lips on vagina, penis, or butt) with only 1 partner	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I have had oral sex (mouth, tongue or lips on vagina, penis, or butt) with more than 1 partner	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Other	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX

[1]Participants allowed to select more than one response.
[2]Responses are among the n=XX participants who responded Yes to having had sex in the last 6 months
[3]Responses are among the n=XX participants who described the HIV status of their sexual partner(s) as not having HIV/AIDS or unknown in the last 6 months
[4]Responses are among the n=XX participants who described having at least one partner within the last 6 months living with HIV/AIDS
Note: N=XX PSPs have been excluded due to ineligible M4/5 data. N=XX PSPs did not complete a M4/5 assessment.

7.14.002. Demographic Characteristics, Sexual Behaviors, and History of PrEP Use among Patient Study Participants by Gender (Participants at both M4/5 and Month 12/13)

	All Participants	Cisgender	Transgender
	(N=XX)	(N=XX)	(N=XX)
How often did you/your partner use a condom when you had sex in the last 6 months?[2]			
All of the time	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Most of the time	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Some of the time	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
A little of the time	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
None of the time	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX
Did you/your partner use a condom the last time you had sex?[2]			
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I don’t remember	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX
In the past 6 months, how would you describe the HIV status of your sexual partner(s)[2]			
I know that none of my sexual partner(s) in the past 6 months have HIV/AIDS	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I know that at least one sexual partner from the past 6 months is living with HIV/AIDS	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I do not know my sexual partners’ HIV status	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX

[1]Participants allowed to select more than one response.
[2]Responses are among the n=XX participants who responded Yes to having had sex in the last 6 months
[3]Responses are among the n=XX participants who described the HIV status of their sexual partner(s) as not having HIV/AIDS or unknown in the last 6 months
[4]Responses are among the n=XX participants who described having at least one partner within the last 6 months living with HIV/AIDS
Note: N=XX PSPs have been excluded due to ineligible M4/5 data. N=XX PSPs did not complete a M4/5 assessment.

7.14.002. Demographic Characteristics, Sexual Behaviors, and History of PrEP Use among Patient Study Participants by Gender (Participants at both M4/5 and Month 12/13)

	All Participants	Cisgender	Transgender
	(N=XX)	(N=XX)	(N=XX)
As far as you know, were any of your partner(s) from the past 6 months taking PrEP, to prevent HIV infection?[3]			
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I don't know	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX
You mentioned that you had at least one partner in the last 6 months who is living with HIV/AIDS. As far as you know, were any of your partners taking HIV medications (antiretrovirals) to treat their HIV infection?[4]			
Yes, my partner(s) was/were taking HIV medications	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Yes, my partner(s) was/were taking HIV medications and was/were undetectable, meaning HIV tests are not finding the virus	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No, my partner(s) was/were not taking HIV medications	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I do not know whether my partner(s) was/were taking HIV medications	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX
In the last 6 months, have you experienced any incidents of sexual violence, physical abuse, or any other type of trauma from a partner?			
No	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Yes	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX

[1]Participants allowed to select more than one response.
[2]Responses are among the n=XX participants who responded Yes to having had sex in the last 6 months
[3]Responses are among the n=XX participants who described the HIV status of their sexual partner(s) as not having HIV/AIDS or unknown in the last 6 months
[4]Responses are among the n=XX participants who described having at least one partner within the last 6 months living with HIV/AIDS
Note: N=XX PSPs have been excluded due to ineligible M4/5 data. N=XX PSPs did not complete a M4/5 assessment.

7.14.002. Demographic Characteristics, Sexual Behaviors, and History of PrEP Use among Patient Study Participants by Gender (Participants at both M4/5 and Month 12/13)

	All Participants	Cisgender	Transgender
	(N=XX)	(N=XX)	(N=XX)
In the last 6 months, have you exchanged things like money or drugs for sex with a sexual partner?[2]			
Yes, I gave a sexual partner things like drugs or money for sex	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Yes, a sexual partner gave me things like drugs or money for sex	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
No, I have not exchanged things like drugs or money for sex	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
I prefer not to answer	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Missing	XX	XX	XX

[1]Participants allowed to select more than one response.
[2]Responses are among the n=XX participants who responded Yes to having had sex in the last 6 months
[3]Responses are among the n=XX participants who described the HIV status of their sexual partner(s) as not having HIV/AIDS or unknown in the last 6 months
[4]Responses are among the n=XX participants who described having at least one partner within the last 6 months living with HIV/AIDS
Note: N=XX PSPs have been excluded due to ineligible M4/5 data. N=XX PSPs did not complete a M4/5 assessment.

7.15.001. Descriptive Analyses of Average Appropriateness, Acceptability, and Feasibility of APRETUDE among Patient Study Participants (Participants at both Month 4/5 and Month 12/13)

Average Appropriateness of APRETUDE (IAM)										
Strategy	**Visit**	**N**	**Mean**	**SD**	**Median**	**Q1**	**Q3**	**Min**	**Max**	**Missing**
All participants	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
SI	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
EI	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
ECI	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Gender	**Visit**	**N**	**Mean**	**SD**	**Median**	**Q1**	**Q3**	**Min**	**Max**	**Missing**
All participants	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Cisgender	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Transgender	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX

Average Appropriateness of APRETUDE (IAM)										
Clinic Type	**Visit**	**N**	**Mean**	**SD**	**Median**	**Q1**	**Q3**	**Min**	**Max**	**Missing**
All participants	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Women's Health	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Primary Care	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
HIV Specialist	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Other	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Region	**Visit**	**N**	**Mean**	**SD**	**Median**	**Q1**	**Q3**	**Min**	**Max**	**Missing**
All participants	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Northeast	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
South	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX

Average Appropriateness of APRETUDE (IAM)										
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
West	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Midwest	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX

Note: N=XX PSPs have been excluded due to ineligible interim data (PSP interim assessment data submitted outside required assessment window). N=XX PSPs did not complete an interim assessment.
Note: IAM/AIM/FIM use the following 5-point scale: 1=Completely disagree, 2=Disagree, 3=Neither agree nor disagree, 4=Agree, 5=Completely agree. Average scores are calculated considering only non-missing responses.

7.15.001. Descriptive Analyses of Average Appropriateness, Acceptability, and Feasibility of APRETUDE among Patient Study Participants (Participants at both Month 4/5 and Month 12/13)

Average Acceptability of APRETUDE (AIM)										
Strategy	**Visit**	**N**	**Mean**	**SD**	**Median**	**Q1**	**Q3**	**Min**	**Max**	**Missing**
All participants	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
SI	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
EI	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
ECI	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Gender	**Visit**	**N**	**Mean**	**SD**	**Median**	**Q1**	**Q3**	**Min**	**Max**	**Missing**
All participants	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Cisgender	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Transgender	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX

Average Acceptability of APRETUDE (AIM)										
Clinic Type	**Visit**	**N**	**Mean**	**SD**	**Median**	**Q1**	**Q3**	**Min**	**Max**	**Missing**
All participants	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Women's Health	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Primary Care	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
HIV Specialist	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Other	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Region	**Visit**	**N**	**Mean**	**SD**	**Median**	**Q1**	**Q3**	**Min**	**Max**	**Missing**
All participants	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Northeast	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
South	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX

Average Acceptability of APRETUDE (AIM)										
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
West	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Midwest	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX

Note: N=XX PSPs have been excluded due to ineligible interim data (PSP interim assessment data submitted outside required assessment window). N=XX PSPs did not complete an interim assessment.
Note: IAM/AIM/FIM use the following 5-point scale: 1=Completely disagree, 2=Disagree, 3=Neither agree nor disagree, 4=Agree, 5=Completely agree. Average scores are calculated considering only non-missing responses.

7.15.001. Descriptive Analyses of Average Appropriateness, Acceptability, and Feasibility of APRETUDE among Patient Study Participants (Participants at both Month 4/5 and Month 12/13)

Average Feasibility of APRETUDE (FIM)										
Strategy	**Visit**	**N**	**Mean**	**SD**	**Median**	**Q1**	**Q3**	**Min**	**Max**	**Missing**
All participants	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
SI	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
EI	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
ECI	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Gender	**Visit**	**N**	**Mean**	**SD**	**Median**	**Q1**	**Q3**	**Min**	**Max**	**Missing**
All participants	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Cisgender	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Transgender	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX

Average Feasibility of APRETUDE (FIM)										
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Clinic Type	**Visit**	**N**	**Mean**	**SD**	**Median**	**Q1**	**Q3**	**Min**	**Max**	**Missing**
All participants	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Women's Health	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Primary Care	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
HIV Specialist	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Other	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Region	**Visit**	**N**	**Mean**	**SD**	**Median**	**Q1**	**Q3**	**Min**	**Max**	**Missing**
All participants	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Northeast	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
South	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX

Average Feasibility of APRETUDE (FIM)										
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
West	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
Midwest	Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Month 12/13	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX
	Change from Month 4/5	XX	XX.X	XX.XX	XX.X	XX.X	XX.X	XX	XX	XX

Note: N=XX PSPs have been excluded due to ineligible interim data (PSP interim assessment data submitted outside required assessment window). N=XX PSPs did not complete an interim assessment.
Note: IAM/AIM/FIM use the following 5-point scale: 1=Completely disagree, 2=Disagree, 3=Neither agree nor disagree, 4=Agree, 5=Completely agree. Average scores are calculated considering only non-missing responses.

7.16.001. eCOA Compliance for Staff Study Participant Questionnaire Data

	All Participants (N=XX)	SI Strategy (N=XX)	EI Strategy (N=XX)	ECI Strategy (N=XX)
Study-level compliance				
Number of complete questionnaires[1]	XX	XX	XX	XX
Expected number of complete questionnaires[2]	XX	XX	XX	XX
Percentage compliance	XX.X%	XX.X%	XX.X%	XX.X%
Endpoint-level compliance				
Number of complete AIMs (APRETUDE)[3]	XX	XX	XX	XX
Expected number of complete AIMs (APRETUDE)[4]	XX	XX	XX	XX
Percentage compliance	XX.X%	XX.X%	XX.X%	XX.X%

[1]Accepting the dynamic questionnaire structuring, a complete questionnaire is one with no unexpected missing information.
[2]The expected number of completed questionnaires considers all questionnaires expected to have been completed prior to participant completion or withdrawal.
[3]A complete AIM is one where all 4 AIM (APRETUDE) questions at Month 12/13 have completed information.
[4]The expected number of completed AIMs (APRETUDE) considers all Month 12/13 AIMs (APRETUDE) expected to have been completed prior to participant completion or withdrawal.

7.16.002. eCOA Compliance for Patient Study Participant Questionnaire Data

	All Participants (N=XX)	SI Strategy (N=XX)	EI Strategy (N=XX)	ECI Strategy (N=XX)
Study-level compliance				
Number of complete questionnaires[1]	XX	XX	XX	XX
Expected number of complete questionnaires[2]	XX	XX	XX	XX
Percentage compliance	XX.X%	XX.X%	XX.X%	XX.X%

[1]Accepting the dynamic questionnaire structuring, a complete questionnaire is one with no unexpected missing information.
[2]The expected number of completed questionnaires considers all questionnaires expected to have been completed prior to participant completion or withdrawal.

Statistical Analysis Plan for Interventional Studies

SAP Version Number: v1.0
SAP Date: 08-Sept-2025

Sponsor Name: ViiV Healthcare

Protocol Number: 217711
Protocol Title: A phase 4, randomized, open-label, three-arm study to evaluate implementation strategies for the delivery of CAB for HIV Pre-exposure Prophylaxis (PrEP) across clinical settings for adult (≥18 years) Black cis-and transgender women without HIV infection living in the United States Ending the Epidemic (EHE) territories

Protocol Version and Date: Amendment 1.0, 23-Dec-2023

Syneos Health Project Code: 7032342

Author: PPD, Senior Biostatistician

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Revision History

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I confirm that I have reviewed this document and agree with the content.

Approvals

Syneos Health Approval

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1. Glossary of Abbreviations

Abbreviation	Description
AE	Adverse Event
ATC	Anatomical Therapeutic Chemical
CAB	Cabotegravir
CDC	Centers for Disease Control and Prevention
CVA	Cerebrovascular Accident
D	Dose Number
DTI	Direct to Injection
eCRF	Electronic Case Report Form
EHE	Ending the Epidemic
ECI	Enhanced Collaborative Implementation
EI	Enhance Implementation
IAM	Intervention Appropriateness Measure
ICF	Informed Consent Form
IM	Intramuscular
MedDRA	Medical Dictionary for Regulatory Activities
OLI	Oral Lead-in
PrEP	Pre-exposure Prophylaxis
PSP	Patient Study Participant
PT	Preferred Term
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SI	Standard Implementation
SOC	System Organ Class
SSP	Staff Study Participants
STI	Sexually Transmitted Infection
TDF	Tenofovir disoproxil fumarate
TGW	Transgender women
TIA	Transient Ischemic Attack

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Abbreviation	Description
TFL	Table, Figure and Listing
WHO	World Health Organization

2. Purpose

The purpose of this statistical analysis plan (SAP) is to ensure that the data listings, summary tables and figures which will be produced, and the statistical methodologies which will be used, are complete and appropriate to allow valid conclusions regarding the study objectives for the clinical analysis.

2.1. Responsibilities

Syneos Health will perform the statistical analyses and is responsible for the production and quality control of all tables, figures and listings related to the clinical portion of the study.

2.2. Timings of Analyses

The analysis of safety and efficacy for clinical data is planned after all subjects complete the final study visit or terminate early from the study. Clinical data may be included in the interim analyses.

One or more interim analysis will be conducted to provide early evaluation of the implantation science primary and key secondary objectives. The timing of the interim(s) will be based in when a sufficient number of staff study participants (SSPs) and/or patient study participants (PSPs) surveys and interviews have been completed.

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3. Study Objectives

3.1. Primary Objective

The primary objective is to evaluate the appropriateness of APRETUDE as assessed by SSPs, comparing the Enhanced Implementation (EI) to the Standard Implementation (SI) arm and the Enhanced Collaborative Implementation arm (ECI) compared to the SI arm.

3.2. Secondary Objective(s)

Secondary objectives include:

- To evaluate the appropriateness of APRETUDE by SSPs in the EI compared to SI and the ECI compared to the SI
- To evaluate PSPs perception of the appropriateness of APRETUDE in participants enrolled in EI compared to SI and ECI compared to SI over time
- To evaluate adoption of APRETUDE across clinical settings
- To evaluate feasibility and utility of EI tools and strategies compared to SI and ECI compared to SI for APRETUDE
- To evaluate fidelity to injection and dosing window across traditional and non-traditional settings
- To evaluate SSP's and PSP's perceptions, barriers, and facilitators to implementation
- To evaluate feasibility and acceptability of APRETUDE by SSP and PSP
- To evaluate the use of oral CAB as oral lead-in by participants and providers
- To evaluate switch from oral PrEP to APRETUDE

3.3. Tertiary Objective(s)

CCI

[redacted]

4. Study Details/Design

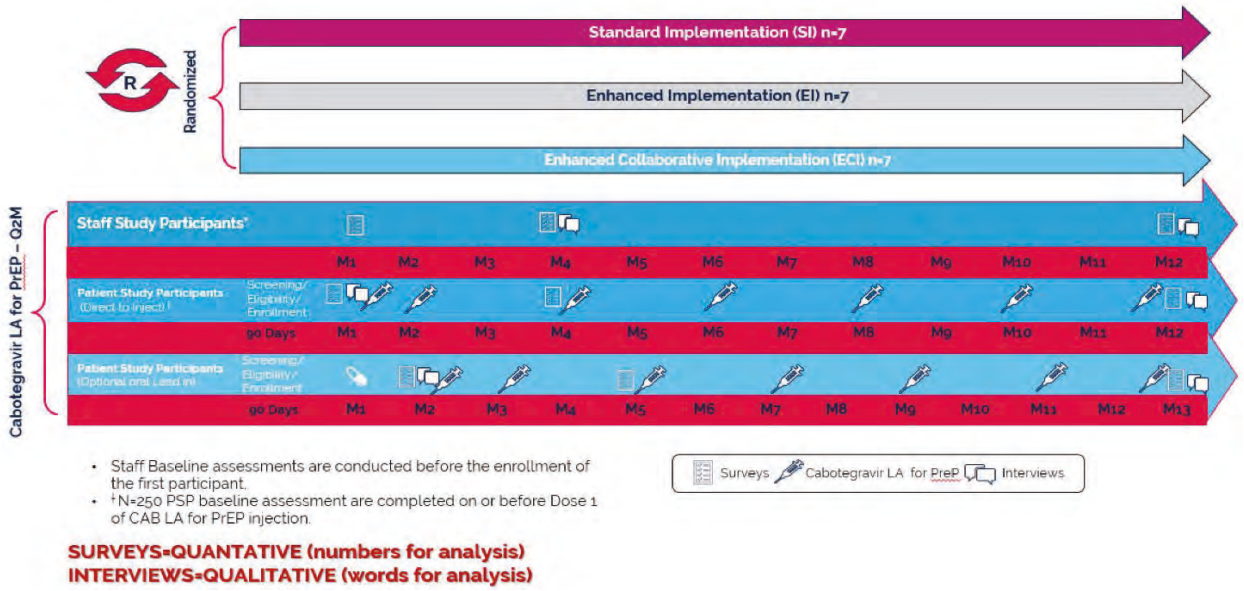
4.1. Brief Description

This study is being conducted following FDA approval and commercial availability of CAB PrEP in the U.S. Approximately 21 clinics located in EHE jurisdictions will be randomized 1:1:1 across the three implementation conditions. Randomization will occur at the level of clinical study sites. Sites will be stratified by clinic type, e.g., women's health, general primary care, trans health. The study team will enroll the staff (approximately 35 per arm) at the study site (who will be enrolled as "Staff Study Participants" (SSPs). Approximately 130 to 160 adult Black cis-and-transgender women who recently tested negative for HIV at the clinical sites will be enrolled by their PrEP provider across the 21 clinical sites. Clinics withdrawing from study participation may be replaced. Replacement sites will be assigned to the implementation arm of the site being replaced to promote the overall balance in the number of completing sites per implementation arm

Clinics randomized to SI will have access to the standard toolkits for providers and patients that will be available for APRETUDE to use as needed. Clinics randomized to EI will receive enhanced toolkits for providers and patients, a patient-provider assessment to be completed with patients during clinical visits, and a robust provider education on HIV and PrEP. Clinics randomized to ECI will receive enhanced toolkits for providers and patients, a patient-provider assessment to be completed by patients prior to clinical visits, and robust patient and provider education on HIV and PrEP. No study participants will be blinded, and all will be aware of the intervention conditions.

Implementation science methodology using both quantitative and qualitative measures will be used to assess whether EI and ECI as opposed to SI results in higher perceptions of appropriateness of CAB PrEP for Black cisgender women and transgender women (TGW). The study will also evaluate adoption, feasibility, fidelity to, and acceptability of the implementation strategies and CAB PrEP; and identify barriers and facilitators to implementation. The implementation outcomes will be assessed from the perspectives of individuals receiving CAB PrEP who are enrolled as "Patient Study Participants" (PSPs) and the SSPs (see below for definitions of participants). Clinical data will be collected from PSPs to monitor safety and efficacy.

Figure 1: Study Design Schematic



4.2. Subject Selection

4.2.1. Inclusion Criteria for PSPs

Age

1. Participant must be ≥18 years of age, at the time of signing the informed consent.

Type of Participant and Disease Characteristics

2. HIV negative at screening. Type of HIV-1 test is per standard of care. NOTE: A negative HIV-1 test must be documented ≤7 days prior to the initiation of CAB PrEP. If the participant was confirmed to be HIV negative >7 days prior to initiation of CAB PrEP, repeat the HIV-1 test and reconfirm that the participant is HIV negative.

3. No prior history of receiving oral CAB or CAB LA injections (Note: prior or active use of non-CAB PrEP (TDF/FTC or TAF/FTC) at screening is allowed).

4. PrEP provider deems CAB PrEP use to be appropriate per the applicable CAB PrEP prescribing information prior to enrollment in the study.

Sex

5. Female at birth or self-identified Transgender Female.

Race

6. Self-identified as African American/Black

Informed Consent

7. Capable of giving signed informed consent, which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in the protocol.

4.2.2. Exclusion Criteria for PSPs

Medical Conditions

1. HIV indeterminate or positive test result during screening.

Prior/Concurrent Clinical Study Experience

2. A participant of concurrent interventional clinical or implementation science study at any time during the study

Other Exclusions

3. Cis-gender or Transgender male

4. As dictated in the Prescribing Information in consultation with the prescriber.

5. Enrolled in the study as a SSP, is part of clinical care for PSPs or otherwise engage in the research study.

4.2.3. Inclusion Criteria for SSPs

An SSP will be eligible for inclusion in this study if:

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1. They are site employees responsible for administrative (for administrative SSPs)/ or clinical (for clinical SSPs) aspects of implementing and administering CAB PrEP at the site.

2. Has the required qualifications according to their role and delegated the appropriate responsibilities by the investigator.

3. Be able to understand and comply with protocol requirements, instructions, and restrictions.

4. Understand the long-term commitment to the study, have adequate resource to complete assessments for the duration of the study at the point of enrollment.

4.2.4. Exclusion Criteria for SSPs

An SSP will be ineligible for inclusion in this study if:

1. Engaged or planned engagement in an implementation science study with similar population on long-acting PrEP injectables at any time during the study. SSP does not have adequate resource to complete study assessments.

2. Enrolled in the study as a PSP.

4.3. Determination of Sample Size

4.3.1. Sample Size for Staff Study Participants *(SSPs)*

The primary endpoint is the SSPs mean Intervention Appropriateness Measure (IAM) score at M12 when comparing Enhanced Implementation to Standard Implementation or Enhanced Collaborative Implementation to Standard Implementation.

Approximately 21 sites will be randomly assigned to one of three arms, each with its own suite of study implementation strategies. Each arm will have approximately five SSPs per site, hence there will be approximately 105 evaluable SSPs with approximately 35 SSPs in each implementation strategy arm. Results from previous CAB LA treatment study CUSTOMIZE (209493) have shown that the estimated mean score of IAM for SSPs was 4.61 with standard deviation of 0.5 at M12(DTI)/ M13(OLI). Assuming standard deviation of 0.5, with approximately 7 clinics randomized to each implementation arm and approximately 5 SSPs per site this design has 80% power to detect a difference of 0.34 in the mean score of IAM at M12(DTI)/ M13(OLI) using a two-sided test with an alpha level of 0.05 (Figure 2).

4.3.2. Sample Size *for* Patient Study Participants *(*PSPs*)*

Key secondary endpoint is the PSPs IAM score at M12(DTI)/ M13(OLI) when comparing Enhanced Implementation to Standard Implementation or Enhanced Collaborative Implementation to Standard Implementation. Approximately 34 evaluable PSPs at M12(DTI)/ M13(OLI) in each implementation strategy group (approximately 102 in total), produces 80% power at the 0.05 significance level to detect a difference in mean IAM score of 0.34, 0.41 and 0.48 for SD of 0.5, 0.6 and 0.7, respectively. Assuming 20% drop out rate, around 43 participants must be randomized to each implementation strategy to achieve at least 80% power.

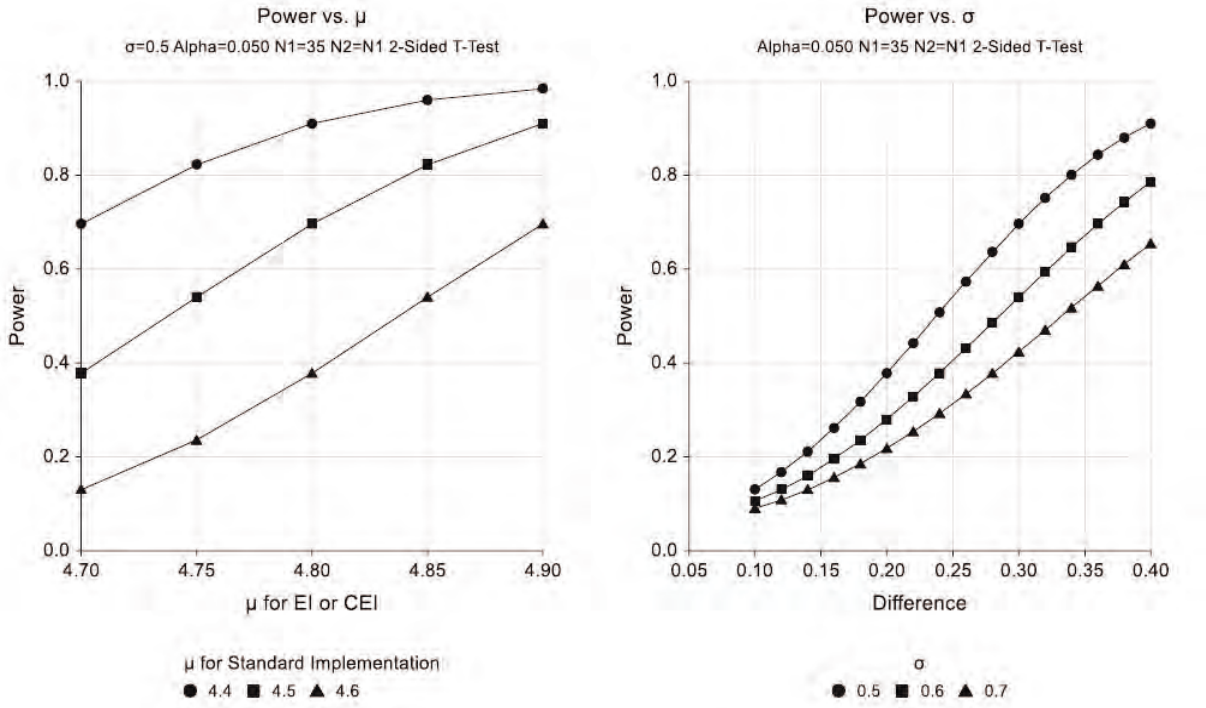
4.3.3. Sample Size Sensitivity

There is no previous implementation science study conducted with APRETUDE hence to demonstrate the sensitivity of the sample size calculation for the primary endpoint of this study, the following figure

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presents the power under different circumstances in terms of the mean (Figure 2a) or standard deviation (Figure 2b), when calculated with a sample size of 35 SSPs per implementation strategy.

Figure 2: Sample Size Sensitivity



a. Power of this study under the assumption of fixed SD of 0.5.

b. Power of this study under different mean difference and SD assumptions.

Power can be further investigated based on standardized effect size d. When comparing the enhanced implementation and standard implementation, d can be defined as the ratio of difference of mean IAM scores between two arms to the standard deviation. Table 1 provides various assumptions of the mean difference, standard deviation, and the relationship to the power. With 35 SSPs per arm, the study will have >=80% power to detect a difference if the effect size is >0.67. Same comparison applies when comparing collaborative enhanced implementation and standard implementation.

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Table 1: Power to test difference in IAM between two implementation strategies

Difference in mean at M12	Standard deviation	Effect Size d	Power
0.1	0.5	0.2	0.13
0.1	0.3	0.33	0.28
0.2	0.5	0.4	0.38
0.3	0.7	0.43	0.43
0.4	0.7	0.57	0.65
0.3	0.5	0.6	0.70
0.2	0.3	0.67	0.79
0.4	0.5	0.8	0.91

4.4. Assignment and Blinding

This study is open label. Sites will be stratified by clinic type, e.g., women's health, general primary care, trans health. All sites are randomized before the investigator meeting.

4.5. Administration of Study Medication

Cisgender and transgender women who are HIV negative prior to initiation of CAB PrEP who have either not previously received PrEP (i.e., PrEP naïve) or that are current or prior users of oral PrEP (e.g., Truvada, Descovy, generic TDF/TFC) or who meet eligibility for PrEP initiation are allowed in the study.

Administration of CAB PrEP will be in accordance with the prescribing information in the US. PSPs will either receive or not receive optional oral lead-in (OLI) of CAB PrEP prior to their first APRETUDE IM injection based on participant or PrEP provider preference, which will be recorded in the eCRF. PSPs who receive optional OLI should receive oral CAB tablets for PrEP for approximately 1 month (at least 28 days) prior to their first injection of APRETUDE.

If a PSP plans to miss the injections by more than 7 days from a scheduled APRETUDE injection, then in consultation with the PrEP provider, CAB tablets for PrEP may be taken daily until the PSP restarts IM injections as per the US prescribing information for CAB PrEP and within the study's time period. For oral PrEP duration greater than two months, the decision to use other recommended oral PrEP regimens (Saag, 2020) in this clinical setting will be made by the PrEP provider. Dosing of oral PrEP regimen used in such cases of missed APRETUDE injections will be recorded in the eCRF. ViiV is not supplying APRETUDE to the participants in this study. However, oral APRETUDE is provided through commercial means and will be consistent for the study in the event of oral bridging.

The total study duration for PSPs is approximately 12 months from the time of enrollment and receipt of the first administration of APRETUDE IM injections. A participant is considered to have completed the study if he/she has finished all Month 12 assessments and receive their last injections of APRETUDE.

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4.6. Study Procedures and Flowchart

Table 2 below contains the schedule of activities for direct to injection. Questionnaires and Interviews are not included as they are not part of this SAP.

Table 2: Schedule of Activities – Direct to Injection

Procedure[1]	Screening/ Enrollment[2]	Treatment Period[4] Month (M)/Dose (D)												E.D.[5]	Notes
		M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12		
	Up to 90 days	D1[3] Visit	D2 Visit		D3 Visit		D4 Visit		D5 Visit		D6 Visit		D7 Visit		
1. The timing and number of planned study assessments, specifically interviews with SSPs and PSPs, may be altered during the study based on newly available data. Brief interviews may be held at other times based on learnings during implementation. 2. Benefits verification should be performed at the start of the screening period, which may be extended up to 90 days to allow for this confirmation. Screening/eligibility procedures (excluding informed consent) should not be performed prior to receiving this confirmation. Additionally, in line with USPI, all patient participants require proof of a negative HIV test, dated within the 7 days prior to PrEP initiation, regardless of any prior negative results. During screening/enrollment, the following will be completed for PSPs: 1) Informed consent form (ICF), 2) Benefits verification, as required, 3) Confirm Inclusion and Exclusion criteria, 4) Demography, 5) Medical History, including history of HCV infection, and current medical conditions, 6) required labs per clinical local standard of care. Screening/enrollment can occur on the same date as the first APRETUDE injection as long as a negative HIV test is documented within 7 days prior to initiation of APRETUDE. 3. Dose 1(D1) is defined as the date of first APRETUDE injection. The following sequence of events must be followed for participants at the D1 visit: 1) complete questionnaires and assessments prior to or at the visit, and 2) Receive first intramuscular (IM) injections at the visit. 4. The treatment period is based on 12 calendar months. The last APRETUDE injection is to occur at the last study visit. 5. E.D. = early discontinuation/withdrawal: This visit should only be conducted if the participant discontinues from the study prior to completing the Study at Month 12, and the discontinuation/withdrawal reason should be recorded. For SSPs, this visit will only occur if the SSP withdraws and remains in the role for which they were enrolled and no replacement is possible.															
Clinical and Other Assessments															
Informed consent	X														Written informed consent must be obtained from each potentially eligible participant by site personnel prior to the initiation of any M1 procedures
Inclusion and exclusion criteria	X														Inclusion/ exclusion criteria will be fully implemented during screening.

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Procedure[1]	Screening/ Enrollment[2]	Treatment Period[4] Month (M)/Dose (D)												E.D.[5]	Notes
		M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12		
	Up to 90 days	D1[3] Visit	D2 Visit		D3 Visit		D4 Visit		D5 Visit		D6 Visit		D7 Visit		
Benefits verification, as needed[2]	X														
Demography	X														
Medical History	X														
Current Medical Conditions	X														
Laboratory assessments	X Needed at BL, M4 and end of study, can be just HIV test and STI testing	Lab assessments, including HIV testing and STI clinical diagnoses (defined for this study as syphilis (any stage), gonorrhea, chlamydia, or trichomonas) at Screening and during study duration should be performed using local laboratories and should be in accordance with CDC PrEP clinical management guidelines and the USPI or per clinical local standard of care. All lab reports must be stored in the participants source documentation at the clinical sites with only the protocol-specified test results to be reported in the eCRF*. For PSPs with incident HIV-1 infections, all available HIV-1 test results (HIV Test Result (positive, negative, and indeterminate), HIV Test Type (HIV-1 Antibody/Antigen test and HIV-1 RNA)) conducted by the site as standard of care and, if applicable and available, the start date of ART and ART regimen (by category) used will be reported in the eCRF,												X	*All performed HIV test results (regardless of result, including positive, negative, or indeterminate) and HIV test type will be reported in the eCRF. For other laboratory tests, only abnormal laboratory results associated with AEs leading to study discontinuation, as well as any clinical diagnosis (made by PrEP provider) of STIs will be reported in the eCRF.
Study Treatment: Participants who are started on oral CAB PrEP as optional oral lead-in will receive their first dose of oral CAB on M1. Participants who are started on APRETUDE injections (direct to injection) will receive their first dose of APRETUDE injection on Day 1. All injections will be administered according to the Cabotegravir LA PrEP USPI.															

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Cabotegravir LA PrEP IM Initiation injection		X													The recommended initiation injection doses of APRETUDE in individuals is a single 600 mg (3 mL) intramuscular injection of APRETUDE given 1 month apart for 2 consecutive months. Individuals should be given the second APRETUDE initiation injection up to 7 days before or after the date the individual is scheduled to receive the injections. If the second initiation injection is not administered 1 month after the first initiation injection within the (+/-) 7 days window, it must be given ≤ 2months (60days) from the treatment target injection schedule. If it is administered greater than 60 days, restart with 600 mg (3 mL) gluteal intramuscular injection of APRETUDE, followed by a second 600 mg (3 mL) initiation injection dose, 1

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Procedure[1]	Screening/ Enrollment[2]	Treatment Period[4] Month (M)/Dose (D)												E.D.[5]	Notes
		M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12		
	Up to 90 days	D1[3] Visit	D2 Visit		D3 Visit		D4 Visit		D5 Visit		D6 Visit		D7 Visit		
															month later. Then continue to follow the every 2-month injection dosing schedule thereafter.
Cabotegravir LA PrEP IM Maintenance injections			X		X		X		X		X		X		IM dosing is expected to occur on the same date of the month as determined by Dose 1 – Treatment Target Date. Dosing window is (* or -) a 7-day window, as per the USPI.
Concomitant medication review	X	←==========→												X	Record in CRF if contraindicated medications, concomitant medications with a potential for a drug-drug interaction (DDI) per the CAB tablet for PrEP or APRETUDE USPI
Adverse Event (AE) Review		X	←==========→											X	Only drug related AEs and AEs leading to CAB PrEP discontinuation will be collected in the eCRF.
Serious AEs (SAEs)	X	←==========→												X	All SAEs regardless of relatedness will be collected in the eCRF.

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Procedure[1]	Screening/ Enrollment[2]	Treatment Period[4] Month (M)/Dose (D)												E.D.[5]	Notes
		M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12		
	Up to 90 days	D1[3] Visit	D2 Visit		D3 Visit		D4 Visit		D5 Visit		D6 Visit		D7 Visit		
Pregnancy Status	X	←==========→												X	Ask person of childbearing potential at each visit if they are pregnant and ask for the date of their LMP.

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Table 3 below contains the schedule of activities for optional oral lead in. Questionnaires and Interviews are not included as they are not part of this SAP.

Table 3: Schedule of Activities – Optional Oral Lead In

Procedure[1]	Screening/ Eligibility/ Enrollment[2]	Treatment Period[4] Months (M) & Dose (D)													E.D.[5]	Notes
	Up to 90 days	M1 (At least 28 days)	M2[3]	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13		
		OLI	D1 visit	D2 visit		D3 visit		D4 visit		D5 visit		D6 visit		D7 visit		
1. The timing and number of planned study assessments, specifically interviews with SSPs and PSPs, may be altered during the study based on newly available data. Brief interviews may be held at other times based on learnings during implementation. 2. Benefits verification should be performed at the start of the screening period, which may be extended up to 90 days to allow for this confirmation. Screening/eligibility procedures (except informed consent) should not be performed prior to receiving this confirmation. Additionally, in line with USPI, all patient participants require proof of a negative HIV test, dated within the 7 days prior to PrEP initiation, regardless of any prior negative results. During screening/enrollment, the following will be completed for PSPs: 1) Informed consent form (ICF), 2) Benefits verification, as required, 3) Confirm Inclusion and Exclusion criteria, 4) Demography, 5) Medical History, including history of hepatits C infection, and current medical conditions, 6) required labs per clinical local standard of care. Screening/enrollment can occur on the same date as the start of OLI as long as a negative HIV test is documented within 7 days prior to initiation of CAB PrEP. 3. Dose 1(D1) is defined as the date of first APRETUDE injection. The following sequence of events must be followed for participants at the D1 visit: 1) completion of surveys and assessments prior to or at the visit, and 2) Receipt of first intramuscular (IM) injections at the visit. The last APRETUDE injection is to occur at the last study visit. 4. The treatment period is based on 12 calendar months. The last APRETUDE injection is to occur at the last study visit. 5. E.D. = early discontinuation/withdrawal: This visit should only be conducted if the participant discontinues from the study prior to completing the Study at Month 13, and the discontinuation/withdrawal reason should be recorded.															
Clinical and Other Assessments																
Informed consent	X															Written informed consent must be obtained from each potentially eligible PSP by site personnel prior to the initiation of any M1 procedures.
Inclusion and exclusion criteria	X															Inclusion/ exclusion criteria will be assessed during screening.

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Procedure[1]	Screening/ Eligibility/ Enrollment[2]	Treatment Period[4] Months (M) & Dose (D)													E.D.[5]	Notes
	Up to 90 days	M1 (At least 28 days)	M2[3]	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13		
		OLI	D1 visit	D2 visit		D3 visit		D4 visit		D5 visit		D6 visit		D7 visit		
Benefits verification, as needed	X															
Demography	X															
Laboratory Assessments	X	Lab assessments, including HIV testing and STI clinical diagnoses (defined for this study as syphilis (any stage), gonorrhea, chlamydia, or trichomonas) at Screening and during PrEP should be performed using local laboratories and should be in accordance with CDC PrEP clinical management guidelines and the USPI or per clinical local standard of care. All lab reports must be stored in the participants source documentation at the clinical sites with only the protocol-specified test results to be reported in the eCRF*. For PSPs with incident HIV-1 infections, all available HIV-1 test results (HIV Test Result (positive, negative and indeterminate), HIV Test Type (HIV-1 Antibody/Antigen test and HIV-1 RNA) conducted by the site as standard of care and, if applicable and available, the start date of ART and ART regimen (by category) used will be reported in the eCRF,													X	*All performed HIV test results (negative or positive) and HIV test type will be reported in the eCRF. For other laboratory tests, only abnormal laboratory results associated with AEs leading to study discontinuation, as wel as any clinical diagnosis (made by PrEP provider) of STIs will be reported in the eCRF.
Study Treatment: Participants who are started on oral Cabotegravir PrEP as optional oral lead in will receive their first dose of oral CAB in Day 1. Participants who are started on APRETUDE injections (direct to inject) will receive their first dose of APRETUDE injection in Day 1. All injections will be administered according to the APRETUDE USPI																
CAB tablets for PrEP		X														

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APRETUDE IM Initiation injection			X													For PSPs receiving optional OLI, 1st injection occurs following completion of OLI and the final oral doses of OLI should be taken on the same day when injections with APRETUDE are started. The recommended initiation injection doses of APRETUDE in individuals is a single 600 mg (3 mL) intramuscular injection of APRETUDE given 1 month apart for 2 consecutive months. Individuals should be given the second APRETUDE initiation injection up to 7 days before or after the date the individual is scheduled to receive the injections. If the second initiation injection is not administered 1 month after the first initiation injection within the (+/-) 7 days window, it must be given ≤ 2months (60days) from the treatment target injection schedule. If it is administered greater than 60 days, restart with 600 mg

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Procedure[1]	Screening/ Eligibility/ Enrollment[2]	Treatment Period[4] Months (M) & Dose (D)													E.D.[5]	Notes
	Up to 90 days	M1 (At least 28 days)	M2[3]	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13		
		OLI	D1 visit	D2 visit		D3 visit		D4 visit		D5 visit		D6 visit		D7 visit		
																(3 mL) gluteal intramuscular injection of APRETUDE, followed by a second 600 mg (3 mL) initiation injection dose, 1 month later. Then continue to follow the every 2-month injection dosing schedule thereafter.
APRETUDE IM Maintenance injection				X		X		X		X		X		X		IM dosing is expected to occur on the same date of the month as determined by Dose 1 – Treatment Target date. Dosing window is (+ or -) 7-day window as per the USPI.
Concomitant medication review	X	←==========→													X	Record in CRF if; contraindicated medications, concomitant medications with a potential for drug-drug interactions per the CAB tablet for PrEP or APRETUDE USPI.
Medical History	X															

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Procedure[1]	Screening/ Eligibility/ Enrollment[2]	Treatment Period[4] Months (M) & Dose (D)												E.D.[5]	Notes
	Up to 90 days	M1 (At least 28 days)	M2[3]	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	
		OLI	D1 visit	D2 visit		D3 visit		D4 visit		D5 visit		D6 visit		D7 visit	
Adverse Event (AE) Review		X	←==========→												X	Only drug related AEs and AEs leading to CAB PrEP discontinuation will be collected in the eCRF.
Serious AEs (SAEs)		X	←==========→												X	All SAEs regardless of relatedness will be collected in the eCRF.
Pregnancy status	X	←==========→													X	Ask person of childbearing potential at each visit if they are pregnant and ask for the date of their LMP.

This document is confidential.

5. Endpoints

Endpoints for the analysis of the clinical data provided in this SAP are listed below for each objective provided earlier. All other endpoints and analyses are provided in separate SAPs implementation science quantitative and qualitative data analyses, which may also include clinical data.

Objective: To evaluate fidelity to injection and dosing window across traditional and non-traditional settings

Endpoint:

- Proportion of injections occurring within target window from target date (±7 days of target date) through M13 across all arms
- Proportion of PSPs completing target number of injections through M13 and by patient subgroups

Objective: To evaluate the use of oral CAB as oral lead-in by participants and providers

Endpoint:

- Proportion of PSPs that have oral lead-in before CAB injection

Objective: To evaluate use of oral coverage for planned and unplanned missed visits

Endpoint:

- Proportion of PSPs who have been prescribed oral CAB vs. non-CAB PrEP after initial CAB LA injection (for missing appointments vs. any other reason)
- Summary of the number of times oral CAB (vs. non-CAB PrEP) has been prescribed after initial CAB LA injection for participants
- Summary of duration of oral CAB (vs. non-CAB PrEP) after initiation of CAB LA injections

Objective: To evaluate the HIV diagnostic test used as primary HIV test for APRETUDE initiation and during PrEP monitoring

Endpoint:

- Summary of which types of HIV tests that are used prior to LA initiation and through M13
- Summary of timepoints at which HIV tests are being performed
- Summary of HIV test results whenever performed

Objective: To evaluate the incidence of HIV and sexually transmitted infections (STIs) at clinical sites

Endpoint:

- Proportion of PSP clinic visits with positive diagnosis of at least one HIV and/or STI (syphilis, gonorrhea, chlamydia, and trichomonas) at study start through M13
- The type of HIV test completed at each visit (only if done by provider)
- The result of the HIV test completed

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Objective: To evaluate safety and effectiveness of APRETUDE

Endpoint:

- Incidence of CAB non-Serious Adverse drug-related reactions, (limited to Grade 3 or 4, to exclude ISR)
- Proportion of PSPs who discontinue treatment due to AEs over time
- All SAEs
- Proportion and number of PSPs with pregnancy reported during the study
- Proportion and number of PSPs that are identified with incident HIV infection

Objective: To evaluate discontinuation of APRETUDE among participants

Endpoint:

- Proportion of PSPs who discontinue CAB LA not due to AEs during the study and by:
    - Enhanced Implementation vs. Standard Implementation
    - Enhanced Collaborative Implementation vs. Standard Implementation

This document is confidential.

6. Analysis Sets

6.1. Screened Set

The Screened Set will include all PSPs screened. Unless specified otherwise, this set will be used for subject listings and for summaries of subject disposition.

6.2. Safety Set

The Safety Set will include all PSPs who were administered at least one dose of study medication. The safety set will be used for all summaries except subject disposition.

6.3. Staff Study Set

The Staff Study Set will include all Staff Study Participants (SSPs) who are involved in administrative and clinical aspects of offering and administering PrEP to PSPs and participate in the staff study assessments. This population will be used for all summaries involving staff study participants.

6.4. Study Site Set

The Study Site Set will include all Study sites with at least one PSP who was administered at least one dose of study medication. This population will be used for all summaries involving study sites.

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7. General Aspects for Statistical Analysis

7.1. General Methods

- Unless otherwise specified, summaries will be presented for SI, EI, ECI, and overall. Where stated summaries will be provided by clinic type (e.g., women's health, general primary care, trans health) or by APRETUDE initiation method (DTI vs. OLI).

- Continuous variables will be summarized using the number of observations (n), mean, standard deviation (SD), median, minimum, and maximum. Categorical variables will be summarized using number of observations (n), frequency and percentages. Where stated, a 95% confidence interval (CI) will be provided for means and proportions.

- All relevant subject data will be included in listings. All subjects entered into the database will be included in subject data listings

7.2. Key Definitions

The date of first dose of study medication is defined as the date the first APRETUDE injection is received.

Baseline is defined as the last observed value prior to first APRETUDE injection or first oral dose of CAB PrEP tablets, whichever occurred first.

7.3. Missing Data

Partial start and end dates for concomitant medications will be imputed to determine if the medication is prior or concomitant.

Concomitant Medications

For the partial start date of medication:

- If the year is present and the month and day are missing, then the month and day will be set to January 1.
- If the year and day are present and the month is missing, then the month will be set to January.
- If the year and month are present and the day is missing, then the day will be set to the 1st day of month.
- If the imputed start date of medication is after the non-imputed end date of medication, then the start date will be set to the end date of medication.

For the partial end date of medication:

- If the year is present and the month and day are missing, then the month and day will be set to December 31.
- If the year and day are present and the month is missing, then the month will be set to December. If the year and month are present and the day is missing, then the day will be set to the last day of the month.
- If the year and day are present and the month is missing, then treat it as if the day is also missing. Set the month and day to be December 31.

For completely missing start or end dates, no imputation will be done. Available information will be used to determine if the medication is prior or concomitant. If unable to determine if a mediation is prior or concomitant or both, the medication will be counted as both prior and concomitant.

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7.4. Visit Window

The potential unscheduled visits and the regular clinic visits for the participants with direct to injection and optional oral lead-in will be mapped to the analysis visits based on the following visit window. The visit window refers to Day 1 as the day of receiving the first APRETUDE injection.

Direct to Injection			
Analysis Visit	Target Day	Visit Window - Start Day	Visit Window - End Day
SCREENING		90 days before the first injection	the day right before the first injection
MONTH 1	1	1	14
MONTH 2	30	15	44
MONTH 3	60	45	74
MONTH 4	90	75	104
MONTH 5	120	105	134
MONTH 6	150	135	164
MONTH 7	180	165	194
MONTH 8	210	195	224
MONTH 9	240	225	254
MONTH 10	270	255	284
MONTH 11	300	285	314
MONTH 12	330	315	345
Out of Planned Study Duration		>345	

Optional Oral-Lead in			
Analysis Visit	Target Day	Visit Window - Start Day	Visit Window – End Day
SCREENING		90 days before the first injection	the day right before the first oral dose

MONTH 1		first oral dose day	the day right before the first injection
MONTH 2	1	1	14
MONTH 3	30	15	44
MONTH 4	60	45	74
MONTH 5	90	75	104
MONTH 6	120	105	134
MONTH 7	150	135	164
MONTH 8	180	165	194
MONTH 9	210	195	224
MONTH 10	240	225	254
MONTH 11	270	255	284
MONTH 12	300	285	314
MONTH 13	330	315	345
Out of Planned Study Duration		>345	

The below injection visit window (Day 1 as the day of receiving the first APRETUDE injection) will be used to determine if participants injection falls within the protocol defined +/- 7 day window.

Direct to Injection				
Dose	Visit	Target day	Visit Window - Start Day	Visit Window - End Day
Dose 1	Month 1	1		
Dose 2	Month 2	30	23	37
Dose 3	Month 4	90	83	97
Dose 4	Month 6	150	143	157
Dose 5	Month 8	210	203	217
Dose 6	Month 10	270	263	277
Dose 7	Month 12	330	323	337

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Optional Oral-Lead in				
Dose	Visit	Target day	Visit Window - Start Day	Visit Window - EndDay
Dose 1	Month 2	1		
Dose 2	Month 3	30	23	37
Dose 3	Month 5	90	83	97
Dose 4	Month 7	150	143	157
Dose 5	Month 9	210	203	217
Dose 6	Month 11	270	263	277
Dose 7	Month 13	330	323	337

The below injection visit window (using previous injection date) will be used to determine if participants injection falls within the in-practice defined +/- 7 day window.

Direct to Injection				
Dose	Visit	Target Day	Visit Window - Start Day	Visit Window – End Day
Dose 1	Month 1	1		
Dose 2	Month 2	30	23	37
Dose 3	Month 4	Dose 3 Target Day	Dose 3 Target Day - 7	Dose 3 Target Day + 7
Dose 4	Month 6	Dose 4 Target Day	Dose 4 Target Day - 7	Dose 4 Target Day + 7
Dose 5	Month 8	Dose 5 Target Day	Dose 5 Target Day - 7	Dose 5 Target Day + 7
Dose 6	Month 10	Dose 6 Target Day	Dose 6 Target Day - 7	Dose 6 Target Day + 7
Dose 7	Month 12	Dose 7 Target Day	Dose 7 Target Day - 7	Dose 6 Target Day + 7

Dose x Target Day= Dose (x -1) injection date - first APRETUDE injection date +1 + 60* days

*In case of oral bridging and restart of APRETUDE injection, add 30 days instead of 60 days for restart injection.

Optional Oral-Lead in				
Dose	Visit	Target Day	Visit Window - Start Day	Visit Window - End Day
Dose 1	Month 2	1		

Dose 2	Month 3	30	23	37
Dose 3	Month 5	Dose 3 Target Day	Dose 3 Target Day - 7	Dose 3 Target Day + 7
Dose 4	Month 7	Dose 4 Target Day	Dose 4 Target Day - 7	Dose 4 Target Day + 7
Dose 5	Month 9	Dose 5 Target Day	Dose 5 Target Day - 7	Dose 5 Target Day + 7
Dose 6	Month 11	Dose 6 Target Day	Dose 6 Target Day - 7	Dose 6 Target Day + 7
Dose 7	Month 13	Dose 7 Target Day	Dose 7 Target Day - 7	Dose 6 Target Day + 7

Dose x Target Day= Dose (x -1) injection date - first APRETUDE injection date +1 + 60* days

*In case of oral bridging and restart of APRETUDE injection, add 30 days instead of 60 days (about 2 months) for restart injection.

8. Demographic, Other Baseline Characteristics and Medication

8.1. Disposition and Withdrawals

The disposition table will summarize the number and percentage of PSPs screened and reason for screen failure, enrolled, completed and discontinued the study, together with the reasons for discontinuation. The disposition table will also include the number of PSPs who completed and discontinued treatment, together with the reasons for discontinuation. Summaries will be provided by study arms (SI, EI, ECI), and clinic type (e.g., women's health, general primary care, trans health). A listing will be provided with study populations, completed study and reasons for discontinuation, and completed treatment and reasons for discontinuation.

The proportion of PSPs who discontinue APRETUDE not due to AEs during the study will be provided by study arms, and clinic type (e.g., women's health, general primary care, trans health).

8.2. Protocol Deviations

Important (equivalent to Major) protocol deviations by participants will be summarized for the Safety Set by study arm and clinic characteristics. A listing will be provided for all protocol deviations (important and minor) for the Safety Set.

8.3. Demographic and Baseline Characteristics

The demographics data that will be summarized includes age, sex, sex reported at birth, self-identified gender, child-bearing potential, and ethnicity. Age will be computed based on the year of birth and the year of informed consent, where age=(year of informed consent-year of birth). Summaries will be provided by study arms (SI, EI, ECI) and clinic type (e.g., women's health, general primary care, trans health). Demographic and baseline characteristics will be listed.

8.4. Medical History and Concomitant Diseases

Family history of cardiovascular risk factors will be summarized by study arms and the all medical history data will only be listed.

8.5. Medication

8.5.1. Prior Medication

Prior medications includes any medication taken before the date of first dose of study medication (either direct to inject or oral lead in). Medications including antiretroviral therapy will be listed by study arms.

8.5.2. Concomitant Medication

Concomitant medication includes any medication taken on or after the date of first dose of study medication (either direct to inject or oral lead in). Medications including antiretroviral therapy will be listed by study arms.

8.6. Extent of Exposure

The proportion of injections occurring within the target window through M13 by study arms (SI, EI, ECI), clinic type (e.g., Trans Health Services, Community-Based PrEP Services, HIV Care and Prevention Services, Non-Traditional Providers of PrEP Services). Dosing is expected to occur on the same date of

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the month as determined by the injection 1. This date is defined as the target date. The dosing window for the target date is ± 7 days for injections 2 through 7. If a dose for an injection is given over more than 1 day, this will be counted as 1 injection with a date when the first part of the dose was given. If only a partial dose is given, that will be considered as an injection. If an injection is missed, the target date will be based on the date of restart for all subsequent injections. The proportion of PSPs completing target number of injections through M13 will be provided.

The proportion of PSPs that have OLI or no OLI before the APRETUDE injection will be provided. The proportion of sites that have at least one PSP with OLI versus no PSPs with OLI before the APRETUDE injection will be provided.

The proportion of PSPs who have prescribed CAB tablets for PrEP or non-CAB tablets for PrEP after initial APRETUDE injection will be provided for missing appointments vs. any other reason. The number of times CAB tablets for PrEP or non-CAB tablets for PrEP have been prescribed after initial APRETUDE injection for PSPs will be provided. The missed injection rate at each visit for PSPs on CAB tablets for PrEP after initial APRETUDE injection will be provided. This will be determined as the proportion of PSPs who missed injection at scheduled visit N+1 while receiving CAB tablets for PrEP after visit N. In the event of two APRETUDE injections with one month apart needed before the participant can resume every 2-month injection dosing schedule thereafter as per USPI, the second injection will be considered as the scheduled visit N+1 following the prior missed injection visit N. The summary of CAB tablets for PrEP and non-CAB tablets for PrEP used, including duration, after the initial injection will be provided. Summaries will be provided by study arms (SI, EI, ECI) and clinic type (e.g., women's health, general primary care, trans health).

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9. Clinical Data

9.1. Adverse Events

Adverse events and serious adverse events will be coded using Medical Dictionary for Regulatory Activities (MedDRA) version 27.0 or the latest version used at the time of the analysis. Summaries will be provided by system organ class (SOC) and preferred term (PT). For AEs, only those that are considered related to CAB PrEP or those that caused the PSP to discontinue the study are reported. For SAEs, all SAEs are reported.

Summaries will be provided for AEs related to CAB PrEP, AEs resulting in discontinuation, and SAEs by study arms (SI, EI, ECI). All reported AEs and SAEs will be listed.

9.2. Cardiovascular Events

The proportion and number of PSPs with cardiac arrhythmias, congestive heart failure, Cardiovascular accident (CVA) or stroke/Transient Ischemic Attack (TIA), deep vein thrombosis, myocardial infarction, peripheral arterial thromboembolism, pulmonary hypertension, revascularization, and valvulopathy at any time during the study will be provided by study arms (SI, EI, ECI). All cardiovascular event data will be listed.

9.3. Liver Events

The proportion and number of PSPs with a liver event, liver biopsy, or liver imaging at any time during the study will be provided by study arms (SI, EI, ECI). All liver event data will be listed.

9.4. Deaths

The proportion and number of deaths among PSPs at any time during the study will be provided by study arms (SI, EI, ECI). The primary cause of death will also be summarized, if any deaths occur. All death information will be listed.

9.5. Pregnancy

The proportion and number of PSPs with pregnancy reported at any time during the study will be summarized by study arm (SI, EI, ECI). All pregnancy data will be listed.

9.6. HIV Infections

The proportion and number of PSPs that are identified with incident HIV infection through the last on-study visit will be provided by study arms (SI, EI, ECI). All HIV tests will be listed.

The proportion of PrEP providers that choose to use an HIV-1 Antibody/Antigen test or an HIV-1 RNA (qualitative or quantitative) test as the primary HIV test will be summarized for before APRETUDE administration and by visit for each study arms (SI, EI, ECI) and clinic type (e.g., women's health, general primary care, trans health).

9.7. STI

The proportion of PSPs with a positive diagnosis of at least 1 STI (syphilis, gonorrhea, chlamydia, trichomoniasis) at study start through M13 will be summarized by study arms (SI, EI, ECI). All STI results will be listed.

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10. Interim Analyses

One or more interim analyses will be conducted to provide early evaluation of the implementation science primary and key secondary objectives. This analysis is not part of the clinical data analysis and is not described in this SAP, but clinical data may be included where it is required as part of the evaluation of implementation science objectives.

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11. Changes from Analysis Planned in Protocol

The first 18 sites were randomized and stratified by clinic type. The following clinic types were used: Trans Health Services, Community-Based PrEP Services, HIV Care and Prevention Services, and Non-Traditional Providers of PrEP services. The remaining 3 sites were randomized separately and were not stratified by clinic type.

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12. Programming Considerations

12.1. General Considerations

- One SAS program can create several outputs
- Each output will be stored in a separate file
- Output files will be delivered in rtf format
- Numbering of TFLs will follow ICH E3 guidance

12.2. Table, Figure, and Listing Format

12.2.1. General

- All Tables, Figures, and Listings (TFLs) will be produced in landscape format on American letter size, unless otherwise specified.
- All TFLs will be produced using the Courier New font, size 8 which is the smallest acceptable point size for the Regulatory Authorities
- The data displays for TFLs will have a minimum blank 1-inch margin on all 4 sides
- Headers and footers for figures will be in Courier New font, size 8 which is the smallest acceptable point size for the Regulatory Authorities
- TFLs will be in black and white (no color), unless otherwise specified
- Specialized text styles, such as bolding, italics, borders, shading, and superscripted and subscripted text, will not be used in the TFLs, unless otherwise specified. On some occasions, superscripts 1, 2, or 3 may be used (see below)
- Only standard keyboard characters will be used in the TFLs. Special characters, such as non-printable control characters, printer-specific, or font-specific characters, will not be used. Hexadecimal-derived characters will be used, where possible, if they are appropriate to help display math symbols (e.g., µ). Certain subscripts and superscripts (e.g., cm2, Cmax) will be employed on a case-by-case basis
- Mixed case will be used for all titles, footnotes, column headers, and programmer-supplied formats, as appropriate

12.2.2. Headers

- All output will have the following header at the top left of each page:
    - Protocol 217711
- Draft/Final Run <*date*>
- All output will have Page n of N at the top or bottom right corner of each page. TFLs are internally paginated in relation to the total length (i.e., the page number will appear sequentially as page n of N, where N is the total number of pages in the table)

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- The date the output was generated will appear along with the program name as a footer on each page

12.2.3. Display Titles

- Each TFL will be identified by the designation and a numeral. (i.e., Table 14.1). A decimal system (x.y) are used to identify TFLs with related contents. The title will be centered. The analysis set will be identified on the line immediately following the title and will be enclosed in parenthesis. The title and table designation will be single spaced. A solid line spanning the margins will separate the display titles from the Column headers. There will be one blank line between the last title and the solid line.

Table x.y
First Line of Title
Second Line of Title if Needed
(ITT Analysis Set)

12.2.4. Column Headers

- Column headings will be displayed immediately below the solid line described above in initial upper-case characters.
- For numeric variables, include 'unit' in column or row heading when appropriate
- Analysis set sizes will be presented for each treatment group in the column heading as (N=xx) (or in the row headings, if applicable). This is distinct from the 'n' used for the descriptive statistics representing the number of subjects in the analysis set

12.2.5. Body of the Data Display

12.2.5.1. *General Conventions*

Data in columns of a table or listing are formatted as follows:

- Alphanumeric values will be left-justified;
- Whole numbers (e.g., counts) will be right-justified; and
- Numbers containing fractional portions will be decimal aligned.

12.2.5.2. *Table Conventions*

- Units will be included where available
- For categorical parameters all categories will be presented in the table, even if n=0 for all treatment groups in a given category. For example, the frequency distribution for symptom severity would appear as:

Severity Rating	N
severe	0

moderate	8
mild	3

Where percentages are presented in these tables, zero percentages will not be presented and so counts of 0 will be presented as 0 and not as 0 (0).

- An Unknown or Missing category will be added to each parameter for which information is not available for 1 or more subjects

- Unless otherwise specified, the estimated mean and median for a set of values will be printed out to 1 more significant digit than the original values, and standard deviations will be printed out to 2 more significant digits than the original values. The minimum and maximum will report the same significant digits as the original values. For example, systolic blood pressure will be presented as follows:

N	XX
Mean	XXX.X
Std Dev	X.XX
Median	XXX.X
Minimum	XXX
Maximum	XXX

- Percentage values will be printed to one decimal place, in parentheses, one space (e.g., 7 (12.8)) or two spaces (e.g., 13 (5.4)) after the count. Unless otherwise noted, for all percentages, the number of subjects in the analysis set for the treatment group who have an observation will be the denominator. Percentages after zero counts will not be displayed and percentages equating to 100% will be presented as 100, without decimal places

- Tabular display of data for medical history, prior/concomitant medications, and all tabular displays of adverse event data will be presented by the body system, treatment class, or SOC with the highest occurrence in the active treatment group in decreasing order, assuming all terms are coded. Within the body system, drug class and SOC, medical history (by preferred term), drugs (by ATC2 code), and adverse events (by preferred term) will be displayed in decreasing order. If incidence for more than 1 term is identical, they will then be sorted alphabetically. Missing descriptive statistics or p-values which cannot be estimated will be reported as '-'

- The percentage of participants will normally be calculated as a proportion of the number of participants assessed in the study arm (or overall) for the analysis set presented. However, careful consideration is required in many instances due to the complicated nature of selecting the denominator, usually the appropriate number of subjects exposed. Details will be described in footnotes or programming notes, as necessary

- For categorical summaries (number and percentage of participants) where a participant can be included in more than one category, a footnote or programming note will be added describing whether the subject is included in the summary statistics for all relevant categories or just 1 category as well as the selection criteria

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- Where a category with a subheading (such as system organ class) has to be split over more than one page, output the subheading followed by '(cont)' at the top of each subsequent page. The overall summary statistics for the subheading should only be output on the first relevant page

12.2.5.3. *Listing Conventions*

- Listings will be sorted for presentation in order of treatment arm, subject number, visit/collection day, and visit/collection time
- Dates will be printed in SAS DATE9.format ('DD_MMM_YYYY': 01JUL2000). Missing portions of dates will be represented on subject listings as dashes (--JUL2000). Dates that are missing because they are not applicable for the subject will be output as 'N/A', unless otherwise specified
- All observed time values will be presented using a 24-hour clock HH:MM or HH:MM:SS format (e.g., 11:26:45, or 11:26). Time will only be reported if it was measured as part of the study
- Units will be included where available

12.2.6. Footnotes

- A solid line spanning the margins will separate the body of the data display from the footnotes.
- All footnotes will be left justified with single-line spacing immediately below the solid line underneath the data display
- Footnotes will always begin with 'Note:' if an informational footnote, or a, b, c, etc. if a reference footnote. Each new footnote will start on a new line, where possible
- Participant-specific footnotes are avoided, where possible
- Footnotes will be used sparingly and add value to the TFL. If more than six lines of footnotes are planned, then a cover page is strongly recommended to be used to display footnotes, and only those essential to comprehension of the data will be repeated on each page
- The last line of the footnote section will be a standard source line that indicates the name of the program used to produce the data display, the date the program was run, and the listing source (i.e., 'Program : myprogram.sas Listing source: 16.x')
- Sources and/or cross-references in footnotes will use the keyword prefix (in singular form) for each reference and will be separated by a comma when mutiple cross-references are displayed
  Example
  Listing source: Listing 16.2

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13. Quality Control

SAS programs are developed to produce output such as analysis data sets, summary tables, data listings, figures or statistical analyses. An overview of the development of programs is detailed in Syneos Health Developing Statistical Programs SOP (3907) .

Syneos Health Developing Statistical Programs SOP (3907), Conducting the Transfer of Biostatistical Deliverables SOP (3908) and the SAS Programming and Validation Plan describes the quality control procedures that are performed for all SAS programs and output. Quality control is defined here as the operational techniques and activities undertaken to verify that the SAS programs produce the output by checking for their logic, efficiency and commenting and by review of the produced output.

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14. Index of Tables

TFL shells will be provided as a separate document.

15. Index of Listings

TFL shells will be provided as a separate document.

16. Index of Figures

TFL shells will be provided as a separate document.

PPD

PPD