HPTN 083 − A Phase 2b/3 Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/ Emtricitabine (TDF/FTC), For Pre−Exposure Prophylaxis in HIV−Uninfected Cisgender Men and Transgender Women who have Sex with Men
LIVE Open Report − June 15, 2021
Visit Cutoff Date: June 15, 2021
Table O1 − Screening Summary by Region

	Overall	US	Latin America	Asia	Africa
Screened	6449	2445	2843	918	243
Enrolled					
Yes	4570/6449 (70.9%)	1701/2445 (69.6%)	1965/2843 (69.1%)	752/918 (81.9%)	152/243 (62.6%)
No	1879/6449 (29.1%)	744/2445 (30.4%)	878/2843 (30.9%)	166/918 (18.1%)	91/243 (37.4%)
Reason Not Enrolled [1]					
Did not meet behavior risk category	146/1879 (7.8%)	65/744 (8.7%)	60/878 (6.8%)	5/166 (3.0%)	16/91 (17.6%)
Intravenous drug use in last 90 days	14/1879 (0.7%)	11/744 (1.5%)	0/878 (0.0%)	3/166 (1.8%)	0/91 (0.0%)
Reactive or positive HIV test result	238/1879 (12.7%)	38/744 (5.1%)	159/878 (18.1%)	33/166 (19.9%)	8/91 (8.8%)
Abnormal liver or kidney function tests	136/1879 (7.2%)	22/744 (3.0%)	96/878 (10.9%)	17/166 (10.2%)	1/91 (1.1%)
Other lab abnormality	46/1879 (2.4%)	24/744 (3.2%)	8/878 (0.9%)	13/166 (7.8%)	1/91 (1.1%)
Hepatitis B or C positive	87/1879 (4.6%)	32/744 (4.3%)	31/878 (3.5%)	21/166 (12.7%)	3/91 (3.3%)
Unwilling to adhere to study procedures	424/1879 (22.6%)	244/744 (32.8%)	150/878 (17.1%)	28/166 (16.9%)	2/91 (2.2%)
Co−enrollment in another HIV interventional research study	29/1879 (1.5%)	26/744 (3.5%)	0/878 (0.0%)	2/166 (1.2%)	1/91 (1.1%)
Past or current participation in HIV vaccine trial	5/1879 (0.3%)	5/744 (0.7%)	0/878 (0.0%)	0/166 (0.0%)	0/91 (0.0%)
Clinically significant cardiovascular disease	76/1879 (4.0%)	33/744 (4.4%)	27/878 (3.1%)	12/166 (7.2%)	4/91 (4.4%)
Underlying skin disease or currently active skin disorder	10/1879 (0.5%)	4/744 (0.5%)	5/878 (0.6%)	1/166 (0.6%)	0/91 (0.0%)
Dermatological condition interfering with injection site reactions	8/1879 (0.4%)	4/744 (0.5%)	3/878 (0.3%)	1/166 (0.6%)	0/91 (0.0%)
Current/chronic history of liver disease or known hepatic/biliary abnormalities	9/1879 (0.5%)	9/744 (1.2%)	0/878 (0.0%)	0/166 (0.0%)	0/91 (0.0%)
Coagulopathy which would contraindicate IM injection	2/1879 (0.1%)	2/744 (0.3%)	0/878 (0.0%)	0/166 (0.0%)	0/91 (0.0%)
Active or planned use of prohibited medications	12/1879 (0.6%)	9/744 (1.2%)	3/878 (0.3%)	0/166 (0.0%)	0/91 (0.0%)
Has a history of seizure disorder	44/1879 (2.3%)	22/744 (3.0%)	13/878 (1.5%)	4/166 (2.4%)	5/91 (5.5%)
Has surgically−placed buttock implants	2/1879 (0.1%)	2/744 (0.3%)	0/878 (0.0%)	0/166 (0.0%)	0/91 (0.0%)
Opinion of the study investigator	352/1879 (18.7%)	170/744 (22.8%)	150/878 (17.1%)	15/166 (9.0%)	17/91 (18.7%)
Allergy to product components	3/1879 (0.2%)	2/744 (0.3%)	1/878 (0.1%)	0/166 (0.0%)	0/91 (0.0%)
Screening not completed prior to window closing	276/1879 (14.7%)	30/744 (4.0%)	196/878 (22.3%)	17/166 (10.2%)	33/91 (36.3%)
Missing reason for not enrolled	0/1879 (0.0%)	0/744 (0.0%)	0/878 (0.0%)	0/166 (0.0%)	0/91 (0.0%)

[1] Participants could have multiple reasons for not being enrolled.

Source: SCHARP (Surabhi) − /trials/hptn/p083/analysis/atlas/code/open/t_screening_summary_byregion.sas, SAS Version 9.4 (15JUN2021,9:22)

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Atlas Open Report − June 15, 2021
Visit Cutoff Date: June 15, 2021
Table 1A − Screening Summary by Site − Region: US

	Overall	Baltimore	Los Angeles − UCLA Care	Chapel Hill	Atlanta
Screened	**2445**	**28**	**78**	**86**	**79**
Enrolled					
Yes	1701/2445 (69.6%)	26/28 (92.9%)	65/78 (83.3%)	69/86 (80.2%)	35/79 (44.3%)
No	744/2445 (30.4%)	2/28 (7.1%)	13/78 (16.7%)	17/86 (19.8%)	44/79 (55.7%)
Reason Not Enrolled[1]					
Did not meet behavior risk category	64/744 (8.6%)	0/2 (0.0%)	2/13 (15.4%)	2/17 (11.8%)	5/44 (11.4%)
Intravenous drug use in last 90 days	11/744 (1.5%)	0/2 (0.0%)	1/13 (7.7%)	1/17 (5.9%)	0/44 (0.0%)
Reactive or positive HIV test result	38/744 (5.1%)	0/2 (0.0%)	0/13 (0.0%)	0/17 (0.0%)	4/44 (9.1%)
Abnormal liver or kidney function tests	22/744 (3.0%)	0/2 (0.0%)	1/13 (7.7%)	1/17 (5.9%)	1/44 (2.3%)
Other lab abnormality	22/744 (3.0%)	0/2 (0.0%)	1/13 (7.7%)	0/17 (0.0%)	2/44 (4.5%)
Hepatitis B or C positive	32/744 (4.3%)	0/2 (0.0%)	0/13 (0.0%)	0/17 (0.0%)	1/44 (2.3%)
Unwilling to adhere to study procedures	242/744 (32.5%)	1/2 (50.0%)	2/13 (15.4%)	6/17 (35.3%)	8/44 (18.2%)
Co−enrollment in another HIV interventional research study	26/744 (3.5%)	0/2 (0.0%)	0/13 (0.0%)	0/17 (0.0%)	2/44 (4.5%)
Past or current participation in HIV vaccine trial	5/744 (0.7%)	0/2 (0.0%)	0/13 (0.0%)	0/17 (0.0%)	0/44 (0.0%)
Clinically significant cardiovascular disease	33/744 (4.4%)	1/2 (50.0%)	2/13 (15.4%)	1/17 (5.9%)	2/44 (4.5%)
Underlying skin disease or currently active skin disorder	4/744 (0.5%)	0/2 (0.0%)	0/13 (0.0%)	0/17 (0.0%)	1/44 (2.3%)
Dermatological condition interfering with injection site reactions	4/744 (0.5%)	0/2 (0.0%)	0/13 (0.0%)	0/17 (0.0%)	0/44 (0.0%)
Current/chronic history of liver disease or known hepatic/biliary abnormalities	8/744 (1.1%)	0/2 (0.0%)	3/13 (23.1%)	0/17 (0.0%)	0/44 (0.0%)
Coagulopathy which would contraindicate IM injection	2/744 (0.3%)	0/2 (0.0%)	0/13 (0.0%)	0/17 (0.0%)	1/44 (2.3%)
Active or planned use of prohibited medications	8/744 (1.1%)	0/2 (0.0%)	0/13 (0.0%)	0/17 (0.0%)	0/44 (0.0%)
Has a history of seizure disorder	22/744 (3.0%)	0/2 (0.0%)	1/13 (7.7%)	1/17 (5.9%)	1/44 (2.3%)
Has surgically−placed buttock implants	2/744 (0.3%)	0/2 (0.0%)	0/13 (0.0%)	0/17 (0.0%)	0/44 (0.0%)
Opinion of the study investigator	168/744 (22.6%)	0/2 (0.0%)	0/13 (0.0%)	4/17 (23.5%)	10/44 (22.7%)
Allergy to product components	2/744 (0.3%)	0/2 (0.0%)	0/13 (0.0%)	0/17 (0.0%)	0/44 (0.0%)
Screening not completed prior to window closing	29/744 (3.9%)	0/2 (0.0%)	0/13 (0.0%)	1/17 (5.9%)	6/44 (13.6%)
Missing reason for not enrolled	0/744 (0.0%)	0/2 (0.0%)	0/13 (0.0%)	0/17 (0.0%)	0/44 (0.0%)

[1] Participants could have multiple reasons for not being enrolled.

Source: SCHARP (Anusha) − /trials/hptn/p083/analysis/atlas/code/open/t_screening_summary_bysite_atlas.sas, SAS Version 9.4 (15JUN2021,9:22)

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Atlas Open Report − June 15, 2021
Visit Cutoff Date: June 15, 2021
Table 1A − Screening Summary by Site − Region: US

	New York − Weill Cornell Chelsea	Bronx	Harlem	San Francisco	Chicago − WISH
Screened	**75**	**135**	**94**	**58**	**114**
Enrolled					
Yes	65/75 (86.7%)	66/135 (48.9%)	58/94 (61.7%)	26/58 (44.8%)	73/114 (64.0%)
No	10/75 (13.3%)	69/135 (51.1%)	36/94 (38.3%)	32/58 (55.2%)	41/114 (36.0%)
Reason Not Enrolled[1]					
Did not meet behavior risk category	0/10 (0.0%)	0/69 (0.0%)	5/36 (13.9%)	2/32 (6.3%)	10/41 (24.4%)
Intravenous drug use in last 90 days	0/10 (0.0%)	1/69 (1.4%)	2/36 (5.6%)	0/32 (0.0%)	1/41 (2.4%)
Reactive or positive HIV test result	1/10 (10.0%)	0/69 (0.0%)	0/36 (0.0%)	0/32 (0.0%)	6/41 (14.6%)
Abnormal liver or kidney function tests	0/10 (0.0%)	1/69 (1.4%)	2/36 (5.6%)	1/32 (3.1%)	2/41 (4.9%)
Other lab abnormality	0/10 (0.0%)	0/69 (0.0%)	0/36 (0.0%)	0/32 (0.0%)	1/41 (2.4%)
Hepatitis B or C positive	1/10 (10.0%)	2/69 (2.9%)	1/36 (2.8%)	0/32 (0.0%)	2/41 (4.9%)
Unwilling to adhere to study procedures	1/10 (10.0%)	17/69 (24.6%)	7/36 (19.4%)	17/32 (53.1%)	3/41 (7.3%)
Co−enrollment in another HIV interventional research study	4/10 (40.0%)	5/69 (7.2%)	4/36 (11.1%)	0/32 (0.0%)	0/41 (0.0%)
Past or current participation in HIV vaccine trial	0/10 (0.0%)	0/69 (0.0%)	1/36 (2.8%)	0/32 (0.0%)	1/41 (2.4%)
Clinically significant cardiovascular disease	0/10 (0.0%)	1/69 (1.4%)	0/36 (0.0%)	0/32 (0.0%)	2/41 (4.9%)
Underlying skin disease or currently active skin disorder	0/10 (0.0%)	1/69 (1.4%)	0/36 (0.0%)	0/32 (0.0%)	0/41 (0.0%)
Dermatological condition interfering with injection site reactions	0/10 (0.0%)	0/69 (0.0%)	1/36 (2.8%)	0/32 (0.0%)	1/41 (2.4%)
Current/chronic history of liver disease or known hepatic/biliary abnormalities	0/10 (0.0%)	1/69 (1.4%)	0/36 (0.0%)	0/32 (0.0%)	2/41 (4.9%)
Coagulopathy which would contraindicate IM injection	0/10 (0.0%)	0/69 (0.0%)	0/36 (0.0%)	0/32 (0.0%)	0/41 (0.0%)
Active or planned use of prohibited medications	0/10 (0.0%)	1/69 (1.4%)	0/36 (0.0%)	1/32 (3.1%)	1/41 (2.4%)
Has a history of seizure disorder	1/10 (10.0%)	0/69 (0.0%)	2/36 (5.6%)	1/32 (3.1%)	1/41 (2.4%)
Has surgically−placed buttock implants	0/10 (0.0%)	0/69 (0.0%)	0/36 (0.0%)	0/32 (0.0%)	0/41 (0.0%)
Opinion of the study investigator	1/10 (10.0%)	36/69 (52.2%)	10/36 (27.8%)	10/32 (31.3%)	4/41 (9.8%)
Allergy to product components	0/10 (0.0%)	0/69 (0.0%)	1/36 (2.8%)	0/32 (0.0%)	0/41 (0.0%)
Screening not completed prior to window closing	1/10 (10.0%)	3/69 (4.3%)	0/36 (0.0%)	0/32 (0.0%)	4/41 (9.8%)
Missing reason for not enrolled	0/10 (0.0%)	0/69 (0.0%)	0/36 (0.0%)	0/32 (0.0%)	0/41 (0.0%)

[1] Participants could have multiple reasons for not being enrolled.

Source: SCHARP (Anusha) − /trials/hptn/p083/analysis/atlas/code/open/t_screening_summary_bysite_atlas.sas, SAS Version 9.4 (15JUN2021,9:22)

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Atlas Open Report − June 15, 2021
Visit Cutoff Date: June 15, 2021
Table 1A − Screening Summary by Site − Region: US

	Decatur	Los Angeles − UCLA Vine	Washington, DC	Boston	Newark
Screened	**112**	**128**	**93**	**109**	**121**
Enrolled					
Yes	86/112 (76.8%)	70/128 (54.7%)	61/93 (65.6%)	81/109 (74.3%)	67/121 (55.4%)
No	26/112 (23.2%)	58/128 (45.3%)	32/93 (34.4%)	28/109 (25.7%)	54/121 (44.6%)
Reason Not Enrolled[1]					
Did not meet behavior risk category	0/26 (0.0%)	6/58 (10.3%)	6/32 (18.8%)	0/28 (0.0%)	5/54 (9.3%)
Intravenous drug use in last 90 days	0/26 (0.0%)	3/58 (5.2%)	0/32 (0.0%)	0/28 (0.0%)	0/54 (0.0%)
Reactive or positive HIV test result	0/26 (0.0%)	1/58 (1.7%)	0/32 (0.0%)	3/28 (10.7%)	5/54 (9.3%)
Abnormal liver or kidney function tests	0/26 (0.0%)	2/58 (3.4%)	1/32 (3.1%)	2/28 (7.1%)	1/54 (1.9%)
Other lab abnormality	4/26 (15.4%)	1/58 (1.7%)	0/32 (0.0%)	3/28 (10.7%)	3/54 (5.6%)
Hepatitis B or C positive	0/26 (0.0%)	3/58 (5.2%)	1/32 (3.1%)	2/28 (7.1%)	1/54 (1.9%)
Unwilling to adhere to study procedures	6/26 (23.1%)	11/58 (19.0%)	18/32 (56.3%)	12/28 (42.9%)	24/54 (44.4%)
Co−enrollment in another HIV interventional research study	0/26 (0.0%)	0/58 (0.0%)	0/32 (0.0%)	0/28 (0.0%)	1/54 (1.9%)
Past or current participation in HIV vaccine trial	0/26 (0.0%)	0/58 (0.0%)	0/32 (0.0%)	3/28 (10.7%)	0/54 (0.0%)
Clinically significant cardiovascular disease	1/26 (3.8%)	12/58 (20.7%)	1/32 (3.1%)	0/28 (0.0%)	1/54 (1.9%)
Underlying skin disease or currently active skin disorder	1/26 (3.8%)	0/58 (0.0%)	0/32 (0.0%)	0/28 (0.0%)	1/54 (1.9%)
Dermatological condition interfering with injection site reactions	0/26 (0.0%)	1/58 (1.7%)	1/32 (3.1%)	0/28 (0.0%)	0/54 (0.0%)
Current/chronic history of liver disease or known hepatic/biliary abnormalities	0/26 (0.0%)	0/58 (0.0%)	0/32 (0.0%)	1/28 (3.6%)	0/54 (0.0%)
Coagulopathy which would contraindicate IM injection	0/26 (0.0%)	1/58 (1.7%)	0/32 (0.0%)	0/28 (0.0%)	0/54 (0.0%)
Active or planned use of prohibited medications	0/26 (0.0%)	0/58 (0.0%)	2/32 (6.3%)	0/28 (0.0%)	1/54 (1.9%)
Has a history of seizure disorder	0/26 (0.0%)	4/58 (6.9%)	0/32 (0.0%)	1/28 (3.6%)	0/54 (0.0%)
Has surgically−placed buttock implants	0/26 (0.0%)	2/58 (3.4%)	0/32 (0.0%)	0/28 (0.0%)	0/54 (0.0%)
Opinion of the study investigator	13/26 (50.0%)	11/58 (19.0%)	1/32 (3.1%)	1/28 (3.6%)	10/54 (18.5%)
Allergy to product components	0/26 (0.0%)	0/58 (0.0%)	1/32 (3.1%)	0/28 (0.0%)	0/54 (0.0%)
Screening not completed prior to window closing	1/26 (3.8%)	0/58 (0.0%)	0/32 (0.0%)	0/28 (0.0%)	1/54 (1.9%)
Missing reason for not enrolled	0/26 (0.0%)	0/58 (0.0%)	0/32 (0.0%)	0/28 (0.0%)	0/54 (0.0%)

[1] Participants could have multiple reasons for not being enrolled.

Source: SCHARP (Anusha) − /trials/hptn/p083/analysis/atlas/code/open/t_screening_summary_bysite_atlas.sas, SAS Version 9.4 (15JUN2021,9:22)

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Atlas Open Report − June 15, 2021
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Table 1A − Screening Summary by Site − Region: US

	Birmingham	New York − Blood Center	Chicago − AYAR	Aurora	Cincinnati
Screened	**89**	**129**	**74**	**69**	**95**
Enrolled					
Yes	62/89 (69.7%)	68/129 (52.7%)	69/74 (93.2%)	63/69 (91.3%)	79/95 (83.2%)
No	27/89 (30.3%)	61/129 (47.3%)	5/74 (6.8%)	6/69 (8.7%)	16/95 (16.8%)
Reason Not Enrolled[1]					
Did not meet behavior risk category	2/27 (7.4%)	1/61 (1.6%)	1/5 (20.0%)	0/6 (0.0%)	1/16 (6.3%)
Intravenous drug use in last 90 days	0/27 (0.0%)	0/61 (0.0%)	0/5 (0.0%)	0/6 (0.0%)	1/16 (6.3%)
Reactive or positive HIV test result	2/27 (7.4%)	0/61 (0.0%)	0/5 (0.0%)	0/6 (0.0%)	0/16 (0.0%)
Abnormal liver or kidney function tests	1/27 (3.7%)	0/61 (0.0%)	0/5 (0.0%)	0/6 (0.0%)	0/16 (0.0%)
Other lab abnormality	0/27 (0.0%)	1/61 (1.6%)	0/5 (0.0%)	0/6 (0.0%)	0/16 (0.0%)
Hepatitis B or C positive	4/27 (14.8%)	1/61 (1.6%)	0/5 (0.0%)	2/6 (33.3%)	2/16 (12.5%)
Unwilling to adhere to study procedures	6/27 (22.2%)	39/61 (63.9%)	3/5 (60.0%)	1/6 (16.7%)	9/16 (56.3%)
Co−enrollment in another HIV interventional research study	1/27 (3.7%)	9/61 (14.8%)	0/5 (0.0%)	0/6 (0.0%)	0/16 (0.0%)
Past or current participation in HIV vaccine trial	0/27 (0.0%)	0/61 (0.0%)	0/5 (0.0%)	0/6 (0.0%)	0/16 (0.0%)
Clinically significant cardiovascular disease	3/27 (11.1%)	0/61 (0.0%)	0/5 (0.0%)	0/6 (0.0%)	0/16 (0.0%)
Underlying skin disease or currently active skin disorder	0/27 (0.0%)	0/61 (0.0%)	0/5 (0.0%)	0/6 (0.0%)	0/16 (0.0%)
Dermatological condition interfering with injection site reactions	0/27 (0.0%)	0/61 (0.0%)	0/5 (0.0%)	0/6 (0.0%)	0/16 (0.0%)
Current/chronic history of liver disease or known hepatic/biliary abnormalities	0/27 (0.0%)	0/61 (0.0%)	0/5 (0.0%)	0/6 (0.0%)	0/16 (0.0%)
Coagulopathy which would contraindicate IM injection	0/27 (0.0%)	0/61 (0.0%)	0/5 (0.0%)	0/6 (0.0%)	0/16 (0.0%)
Active or planned use of prohibited medications	0/27 (0.0%)	0/61 (0.0%)	0/5 (0.0%)	0/6 (0.0%)	0/16 (0.0%)
Has a history of seizure disorder	1/27 (3.7%)	0/61 (0.0%)	1/5 (20.0%)	1/6 (16.7%)	0/16 (0.0%)
Has surgically−placed buttock implants	0/27 (0.0%)	0/61 (0.0%)	0/5 (0.0%)	0/6 (0.0%)	0/16 (0.0%)
Opinion of the study investigator	7/27 (25.9%)	5/61 (8.2%)	0/5 (0.0%)	2/6 (33.3%)	1/16 (6.3%)
Allergy to product components	0/27 (0.0%)	0/61 (0.0%)	0/5 (0.0%)	0/6 (0.0%)	0/16 (0.0%)
Screening not completed prior to window closing	0/27 (0.0%)	5/61 (8.2%)	0/5 (0.0%)	0/6 (0.0%)	2/16 (12.5%)
Missing reason for not enrolled	0/27 (0.0%)	0/61 (0.0%)	0/5 (0.0%)	0/6 (0.0%)	0/16 (0.0%)

[1] Participants could have multiple reasons for not being enrolled.

Source: SCHARP (Anusha) − /trials/hptn/p083/analysis/atlas/code/open/t_screening_summary_bysite_atlas.sas, SAS Version 9.4 (15JUN2021,9:22)

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Table 1A − Screening Summary by Site − Region: US

	Greensboro	Houston	New Orleans	Columbus	Memphis
Screened	**66**	**79**	**70**	**72**	**108**
Enrolled					
Yes	58/66 (87.9%)	60/79 (75.9%)	53/70 (75.7%)	55/72 (76.4%)	93/108 (86.1%)
No	8/66 (12.1%)	19/79 (24.1%)	17/70 (24.3%)	17/72 (23.6%)	15/108 (13.9%)
Reason Not Enrolled[1]					
Did not meet behavior risk category	0/8 (0.0%)	1/19 (5.3%)	1/17 (5.9%)	3/17 (17.6%)	1/15 (6.7%)
Intravenous drug use in last 90 days	0/8 (0.0%)	0/19 (0.0%)	0/17 (0.0%)	0/17 (0.0%)	0/15 (0.0%)
Reactive or positive HIV test result	1/8 (12.5%)	1/19 (5.3%)	8/17 (47.1%)	1/17 (5.9%)	2/15 (13.3%)
Abnormal liver or kidney function tests	0/8 (0.0%)	2/19 (10.5%)	0/17 (0.0%)	0/17 (0.0%)	0/15 (0.0%)
Other lab abnormality	1/8 (12.5%)	1/19 (5.3%)	0/17 (0.0%)	1/17 (5.9%)	1/15 (6.7%)
Hepatitis B or C positive	2/8 (25.0%)	0/19 (0.0%)	0/17 (0.0%)	0/17 (0.0%)	0/15 (0.0%)
Unwilling to adhere to study procedures	4/8 (50.0%)	10/19 (52.6%)	4/17 (23.5%)	10/17 (58.8%)	8/15 (53.3%)
Co−enrollment in another HIV interventional research study	0/8 (0.0%)	0/19 (0.0%)	0/17 (0.0%)	0/17 (0.0%)	0/15 (0.0%)
Past or current participation in HIV vaccine trial	0/8 (0.0%)	0/19 (0.0%)	0/17 (0.0%)	0/17 (0.0%)	0/15 (0.0%)
Clinically significant cardiovascular disease	0/8 (0.0%)	1/19 (5.3%)	0/17 (0.0%)	1/17 (5.9%)	0/15 (0.0%)
Underlying skin disease or currently active skin disorder	0/8 (0.0%)	0/19 (0.0%)	0/17 (0.0%)	0/17 (0.0%)	0/15 (0.0%)
Dermatological condition interfering with injection site reactions	0/8 (0.0%)	0/19 (0.0%)	0/17 (0.0%)	0/17 (0.0%)	0/15 (0.0%)
Current/chronic history of liver disease or known hepatic/biliary abnormalities	0/8 (0.0%)	0/19 (0.0%)	0/17 (0.0%)	1/17 (5.9%)	0/15 (0.0%)
Coagulopathy which would contraindicate IM injection	0/8 (0.0%)	0/19 (0.0%)	0/17 (0.0%)	0/17 (0.0%)	0/15 (0.0%)
Active or planned use of prohibited medications	0/8 (0.0%)	1/19 (5.3%)	0/17 (0.0%)	0/17 (0.0%)	0/15 (0.0%)
Has a history of seizure disorder	0/8 (0.0%)	1/19 (5.3%)	0/17 (0.0%)	0/17 (0.0%)	0/15 (0.0%)
Has surgically−placed buttock implants	0/8 (0.0%)	0/19 (0.0%)	0/17 (0.0%)	0/17 (0.0%)	0/15 (0.0%)
Opinion of the study investigator	0/8 (0.0%)	1/19 (5.3%)	2/17 (11.8%)	0/17 (0.0%)	0/15 (0.0%)
Allergy to product components	0/8 (0.0%)	0/19 (0.0%)	0/17 (0.0%)	0/17 (0.0%)	0/15 (0.0%)
Screening not completed prior to window closing	0/8 (0.0%)	0/19 (0.0%)	2/17 (11.8%)	0/17 (0.0%)	3/15 (20.0%)
Missing reason for not enrolled	0/8 (0.0%)	0/19 (0.0%)	0/17 (0.0%)	0/17 (0.0%)	0/15 (0.0%)

[1] Participants could have multiple reasons for not being enrolled.

Source: SCHARP (Anusha) − /trials/hptn/p083/analysis/atlas/code/open/t_screening_summary_bysite_atlas.sas, SAS Version 9.4 (15JUN2021,9:22)

HPTN 083 − A Phase 2b/3 Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/ Emtricitabine (TDF/FTC), For Pre−Exposure Prophylaxis in HIV−Uninfected Cisgender Men and Transgender Women who have Sex with Men
Atlas Open Report − June 15, 2021
Visit Cutoff Date: June 15, 2021
Table 1A − Screening Summary by Site − Region: US

	St. Louis	Philadelphia	Oakland
Screened	**90**	**149**	**45**
Enrolled			
Yes	65/90 (72.2%)	88/149 (59.1%)	40/45 (88.9%)
No	25/90 (27.8%)	61/149 (40.9%)	5/45 (11.1%)
Reason Not Enrolled[1]			
Did not meet behavior risk category	5/25 (20.0%)	5/61 (8.2%)	0/5 (0.0%)
Intravenous drug use in last 90 days	0/25 (0.0%)	1/61 (1.6%)	0/5 (0.0%)
Reactive or positive HIV test result	1/25 (4.0%)	2/61 (3.3%)	0/5 (0.0%)
Abnormal liver or kidney function tests	1/25 (4.0%)	3/61 (4.9%)	0/5 (0.0%)
Other lab abnormality	0/25 (0.0%)	2/61 (3.3%)	0/5 (0.0%)
Hepatitis B or C positive	3/25 (12.0%)	1/61 (1.6%)	3/5 (60.0%)
Unwilling to adhere to study procedures	5/25 (20.0%)	9/61 (14.8%)	1/5 (20.0%)
Co−enrollment in another HIV interventional research study	0/25 (0.0%)	0/61 (0.0%)	0/5 (0.0%)
Past or current participation in HIV vaccine trial	0/25 (0.0%)	0/61 (0.0%)	0/5 (0.0%)
Clinically significant cardiovascular disease	2/25 (8.0%)	1/61 (1.6%)	1/5 (20.0%)
Underlying skin disease or currently active skin disorder	0/25 (0.0%)	0/61 (0.0%)	0/5 (0.0%)
Dermatological condition interfering with injection site reactions	0/25 (0.0%)	0/61 (0.0%)	0/5 (0.0%)
Current/chronic history of liver disease or known hepatic/biliary abnormalities	0/25 (0.0%)	0/61 (0.0%)	0/5 (0.0%)
Coagulopathy which would contraindicate IM injection	0/25 (0.0%)	0/61 (0.0%)	0/5 (0.0%)
Active or planned use of prohibited medications	1/25 (4.0%)	0/61 (0.0%)	0/5 (0.0%)
Has a history of seizure disorder	3/25 (12.0%)	2/61 (3.3%)	0/5 (0.0%)
Has surgically−placed buttock implants	0/25 (0.0%)	0/61 (0.0%)	0/5 (0.0%)
Opinion of the study investigator	4/25 (16.0%)	35/61 (57.4%)	0/5 (0.0%)
Allergy to product components	0/25 (0.0%)	0/61 (0.0%)	0/5 (0.0%)
Screening not completed prior to window closing	0/25 (0.0%)	0/61 (0.0%)	0/5 (0.0%)
Missing reason for not enrolled	0/25 (0.0%)	0/61 (0.0%)	0/5 (0.0%)

[1] Participants could have multiple reasons for not being enrolled.

Source: SCHARP (Anusha) − /trials/hptn/p083/analysis/atlas/code/open/t_screening_summary_bysite_atlas.sas, SAS Version 9.4 (15JUN2021,9:22)

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Atlas Open Report − June 15, 2021
Visit Cutoff Date: June 15, 2021
Table 1B − Screening Summary by Site − Region: Latin America

	Overall	Lima − Barranco	Lima − San Miguel	Rio de Janeiro
Screened	**2843**	**295**	**291**	**308**
Enrolled				
Yes	1965/2843 (69.1%)	177/295 (60.0%)	150/291 (51.5%)	240/308 (77.9%)
No	878/2843 (30.9%)	118/295 (40.0%)	141/291 (48.5%)	68/308 (22.1%)
Reason Not Enrolled[1]				
Did not meet behavior risk category	57/878 (6.5%)	12/118 (10.2%)	15/141 (10.6%)	2/68 (2.9%)
Intravenous drug use in last 90 days	0/878 (0.0%)	0/118 (0.0%)	0/141 (0.0%)	0/68 (0.0%)
Reactive or positive HIV test result	157/878 (17.9%)	29/118 (24.6%)	40/141 (28.4%)	1/68 (1.5%)
Abnormal liver or kidney function tests	90/878 (10.3%)	8/118 (6.8%)	15/141 (10.6%)	1/68 (1.5%)
Other lab abnormality	8/878 (0.9%)	1/118 (0.8%)	0/141 (0.0%)	1/68 (1.5%)
Hepatitis B or C positive	30/878 (3.4%)	3/118 (2.5%)	5/141 (3.5%)	1/68 (1.5%)
Unwilling to adhere to study procedures	150/878 (17.1%)	4/118 (3.4%)	13/141 (9.2%)	7/68 (10.3%)
Co−enrollment in another HIV interventional research study	0/878 (0.0%)	0/118 (0.0%)	0/141 (0.0%)	0/68 (0.0%)
Past or current participation in HIV vaccine trial	0/878 (0.0%)	0/118 (0.0%)	0/141 (0.0%)	0/68 (0.0%)
Clinically significant cardiovascular disease	25/878 (2.8%)	2/118 (1.7%)	10/141 (7.1%)	0/68 (0.0%)
Underlying skin disease or currently active skin disorder	5/878 (0.6%)	1/118 (0.8%)	0/141 (0.0%)	0/68 (0.0%)
Dermatological condition interfering with injection site reactions	3/878 (0.3%)	0/118 (0.0%)	0/141 (0.0%)	2/68 (2.9%)
Current/chronic history of liver disease or known hepatic/biliary abnormalities	0/878 (0.0%)	0/118 (0.0%)	0/141 (0.0%)	0/68 (0.0%)
Coagulopathy which would contraindicate IM injection	0/878 (0.0%)	0/118 (0.0%)	0/141 (0.0%)	0/68 (0.0%)
Active or planned use of prohibited medications	3/878 (0.3%)	0/118 (0.0%)	0/141 (0.0%)	0/68 (0.0%)
Has a history of seizure disorder	12/878 (1.4%)	1/118 (0.8%)	0/141 (0.0%)	0/68 (0.0%)
Has surgically−placed buttock implants	0/878 (0.0%)	0/118 (0.0%)	0/141 (0.0%)	0/68 (0.0%)
Opinion of the study investigator	145/878 (16.5%)	4/118 (3.4%)	10/141 (7.1%)	52/68 (76.5%)
Allergy to product components	1/878 (0.1%)	0/118 (0.0%)	0/141 (0.0%)	0/68 (0.0%)
Screening not completed prior to window closing	192/878 (21.9%)	53/118 (44.9%)	33/141 (23.4%)	1/68 (1.5%)
Missing reason for not enrolled	0/878 (0.0%)	0/118 (0.0%)	0/141 (0.0%)	0/68 (0.0%)

[1] Participants could have multiple reasons for not being enrolled.

Source: SCHARP (Anusha) − /trials/hptn/p083/analysis/atlas/code/open/t_screening_summary_bysite_atlas.sas, SAS Version 9.4 (15JUN2021,9:22)

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Atlas Open Report − June 15, 2021
Visit Cutoff Date: June 15, 2021
Table 1B − Screening Summary by Site − Region: Latin America

	Porto Alegre	Iquitos	Lima − Via Libre	Sao Paulo − DST−AIDS
Screened	**241**	**353**	**300**	**192**
Enrolled				
Yes	215/241 (89.2%)	177/353 (50.1%)	176/300 (58.7%)	155/192 (80.7%)
No	26/241 (10.8%)	176/353 (49.9%)	124/300 (41.3%)	37/192 (19.3%)
Reason Not Enrolled[1]				
Did not meet behavior risk category	6/26 (23.1%)	9/176 (5.1%)	9/124 (7.3%)	1/37 (2.7%)
Intravenous drug use in last 90 days	0/26 (0.0%)	0/176 (0.0%)	0/124 (0.0%)	0/37 (0.0%)
Reactive or positive HIV test result	2/26 (7.7%)	33/176 (18.8%)	6/124 (4.8%)	8/37 (21.6%)
Abnormal liver or kidney function tests	1/26 (3.8%)	22/176 (12.5%)	20/124 (16.1%)	3/37 (8.1%)
Other lab abnormality	0/26 (0.0%)	0/176 (0.0%)	2/124 (1.6%)	1/37 (2.7%)
Hepatitis B or C positive	0/26 (0.0%)	4/176 (2.3%)	5/124 (4.0%)	3/37 (8.1%)
Unwilling to adhere to study procedures	7/26 (26.9%)	52/176 (29.5%)	8/124 (6.5%)	16/37 (43.2%)
Co−enrollment in another HIV interventional research study	0/26 (0.0%)	0/176 (0.0%)	0/124 (0.0%)	0/37 (0.0%)
Past or current participation in HIV vaccine trial	0/26 (0.0%)	0/176 (0.0%)	0/124 (0.0%)	0/37 (0.0%)
Clinically significant cardiovascular disease	1/26 (3.8%)	0/176 (0.0%)	8/124 (6.5%)	0/37 (0.0%)
Underlying skin disease or currently active skin disorder	0/26 (0.0%)	0/176 (0.0%)	2/124 (1.6%)	0/37 (0.0%)
Dermatological condition interfering with injection site reactions	0/26 (0.0%)	0/176 (0.0%)	1/124 (0.8%)	0/37 (0.0%)
Current/chronic history of liver disease or known hepatic/biliary abnormalities	0/26 (0.0%)	0/176 (0.0%)	0/124 (0.0%)	0/37 (0.0%)
Coagulopathy which would contraindicate IM injection	0/26 (0.0%)	0/176 (0.0%)	0/124 (0.0%)	0/37 (0.0%)
Active or planned use of prohibited medications	1/26 (3.8%)	0/176 (0.0%)	0/124 (0.0%)	0/37 (0.0%)
Has a history of seizure disorder	6/26 (23.1%)	1/176 (0.6%)	1/124 (0.8%)	0/37 (0.0%)
Has surgically−placed buttock implants	0/26 (0.0%)	0/176 (0.0%)	0/124 (0.0%)	0/37 (0.0%)
Opinion of the study investigator	1/26 (3.8%)	37/176 (21.0%)	26/124 (21.0%)	1/37 (2.7%)
Allergy to product components	0/26 (0.0%)	0/176 (0.0%)	0/124 (0.0%)	0/37 (0.0%)
Screening not completed prior to window closing	1/26 (3.8%)	18/176 (10.2%)	36/124 (29.0%)	4/37 (10.8%)
Missing reason for not enrolled	0/26 (0.0%)	0/176 (0.0%)	0/124 (0.0%)	0/37 (0.0%)

[1] Participants could have multiple reasons for not being enrolled.

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Atlas Open Report − June 15, 2021
Visit Cutoff Date: June 15, 2021
Table 1B − Screening Summary by Site − Region: Latin America

	Lima − CITBM	Buenos Aires − Fundacion Huesped	Buenos Aires − Hospital JM Ramos Mejia	Sao Paulo − IC−HCFMUSP
Screened	**252**	**233**	**154**	**224**
Enrolled				
Yes	152/252 (60.3%)	199/233 (85.4%)	138/154 (89.6%)	186/224 (83.0%)
No	100/252 (39.7%)	34/233 (14.6%)	16/154 (10.4%)	38/224 (17.0%)
Reason Not Enrolled[1]				
Did not meet behavior risk category	2/100 (2.0%)	0/34 (0.0%)	0/16 (0.0%)	1/38 (2.6%)
Intravenous drug use in last 90 days	0/100 (0.0%)	0/34 (0.0%)	0/16 (0.0%)	0/38 (0.0%)
Reactive or positive HIV test result	28/100 (28.0%)	4/34 (11.8%)	5/16 (31.3%)	1/38 (2.6%)
Abnormal liver or kidney function tests	12/100 (12.0%)	1/34 (2.9%)	0/16 (0.0%)	7/38 (18.4%)
Other lab abnormality	2/100 (2.0%)	0/34 (0.0%)	1/16 (6.3%)	0/38 (0.0%)
Hepatitis B or C positive	2/100 (2.0%)	2/34 (5.9%)	3/16 (18.8%)	2/38 (5.3%)
Unwilling to adhere to study procedures	14/100 (14.0%)	7/34 (20.6%)	2/16 (12.5%)	20/38 (52.6%)
Co−enrollment in another HIV interventional research study	0/100 (0.0%)	0/34 (0.0%)	0/16 (0.0%)	0/38 (0.0%)
Past or current participation in HIV vaccine trial	0/100 (0.0%)	0/34 (0.0%)	0/16 (0.0%)	0/38 (0.0%)
Clinically significant cardiovascular disease	0/100 (0.0%)	1/34 (2.9%)	0/16 (0.0%)	3/38 (7.9%)
Underlying skin disease or currently active skin disorder	1/100 (1.0%)	1/34 (2.9%)	0/16 (0.0%)	0/38 (0.0%)
Dermatological condition interfering with injection site reactions	0/100 (0.0%)	0/34 (0.0%)	0/16 (0.0%)	0/38 (0.0%)
Current/chronic history of liver disease or known hepatic/biliary abnormalities	0/100 (0.0%)	0/34 (0.0%)	0/16 (0.0%)	0/38 (0.0%)
Coagulopathy which would contraindicate IM injection	0/100 (0.0%)	0/34 (0.0%)	0/16 (0.0%)	0/38 (0.0%)
Active or planned use of prohibited medications	0/100 (0.0%)	0/34 (0.0%)	1/16 (6.3%)	1/38 (2.6%)
Has a history of seizure disorder	2/100 (2.0%)	1/34 (2.9%)	0/16 (0.0%)	0/38 (0.0%)
Has surgically−placed buttock implants	0/100 (0.0%)	0/34 (0.0%)	0/16 (0.0%)	0/38 (0.0%)
Opinion of the study investigator	12/100 (12.0%)	1/34 (2.9%)	0/16 (0.0%)	1/38 (2.6%)
Allergy to product components	0/100 (0.0%)	0/34 (0.0%)	0/16 (0.0%)	1/38 (2.6%)
Screening not completed prior to window closing	25/100 (25.0%)	16/34 (47.1%)	4/16 (25.0%)	1/38 (2.6%)
Missing reason for not enrolled	0/100 (0.0%)	0/34 (0.0%)	0/16 (0.0%)	0/38 (0.0%)

[1] Participants could have multiple reasons for not being enrolled.

Source: SCHARP (Anusha) − /trials/hptn/p083/analysis/atlas/code/open/t_screening_summary_bysite_atlas.sas, SAS Version 9.4 (15JUN2021,9:22)

HPTN 083 − A Phase 2b/3 Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/ Emtricitabine (TDF/FTC), For Pre−Exposure Prophylaxis in HIV−Uninfected Cisgender Men and Transgender Women who have Sex with Men
Atlas Open Report − June 15, 2021
Visit Cutoff Date: June 15, 2021
Table 1C − Screening Summary by Site − Region: Asia

	Overall	Chiang Mai	Bangkok − Silom Clinic	Bangkok − Thai Red Cross	Hanoi
Screened	**918**	**161**	**240**	**276**	**241**
Enrolled					
Yes	752/918 (81.9%)	140/161 (87.0%)	203/240 (84.6%)	210/276 (76.1%)	199/241 (82.6%)
No	166/918 (18.1%)	21/161 (13.0%)	37/240 (15.4%)	66/276 (23.9%)	42/241 (17.4%)
Reason Not Enrolled[1]					
Did not meet behavior risk category	5/166 (3.0%)	1/21 (4.8%)	0/37 (0.0%)	3/66 (4.5%)	1/42 (2.4%)
Intravenous drug use in last 90 days	3/166 (1.8%)	2/21 (9.5%)	0/37 (0.0%)	1/66 (1.5%)	0/42 (0.0%)
Reactive or positive HIV test result	33/166 (19.9%)	2/21 (9.5%)	12/37 (32.4%)	13/66 (19.7%)	6/42 (14.3%)
Abnormal liver or kidney function tests	17/166 (10.2%)	1/21 (4.8%)	7/37 (18.9%)	5/66 (7.6%)	4/42 (9.5%)
Other lab abnormality	10/166 (6.0%)	2/21 (9.5%)	1/37 (2.7%)	4/66 (6.1%)	3/42 (7.1%)
Hepatitis B or C positive	21/166 (12.7%)	2/21 (9.5%)	2/37 (5.4%)	11/66 (16.7%)	6/42 (14.3%)
Unwilling to adhere to study procedures	28/166 (16.9%)	5/21 (23.8%)	8/37 (21.6%)	11/66 (16.7%)	4/42 (9.5%)
Co−enrollment in another HIV interventional research study	2/166 (1.2%)	0/21 (0.0%)	2/37 (5.4%)	0/66 (0.0%)	0/42 (0.0%)
Past or current participation in HIV vaccine trial	0/166 (0.0%)	0/21 (0.0%)	0/37 (0.0%)	0/66 (0.0%)	0/42 (0.0%)
Clinically significant cardiovascular disease	12/166 (7.2%)	2/21 (9.5%)	1/37 (2.7%)	1/66 (1.5%)	8/42 (19.0%)
Underlying skin disease or currently active skin disorder	0/166 (0.0%)	0/21 (0.0%)	0/37 (0.0%)	0/66 (0.0%)	0/42 (0.0%)
Dermatological condition interfering with injection site reactions	1/166 (0.6%)	0/21 (0.0%)	1/37 (2.7%)	0/66 (0.0%)	0/42 (0.0%)
Current/chronic history of liver disease or known hepatic/biliary abnormalities	0/166 (0.0%)	0/21 (0.0%)	0/37 (0.0%)	0/66 (0.0%)	0/42 (0.0%)
Coagulopathy which would contraindicate IM injection	0/166 (0.0%)	0/21 (0.0%)	0/37 (0.0%)	0/66 (0.0%)	0/42 (0.0%)
Active or planned use of prohibited medications	0/166 (0.0%)	0/21 (0.0%)	0/37 (0.0%)	0/66 (0.0%)	0/42 (0.0%)
Has a history of seizure disorder	3/166 (1.8%)	0/21 (0.0%)	0/37 (0.0%)	0/66 (0.0%)	3/42 (7.1%)
Has surgically−placed buttock implants	0/166 (0.0%)	0/21 (0.0%)	0/37 (0.0%)	0/66 (0.0%)	0/42 (0.0%)
Opinion of the study investigator	14/166 (8.4%)	3/21 (14.3%)	3/37 (8.1%)	1/66 (1.5%)	7/42 (16.7%)
Allergy to product components	0/166 (0.0%)	0/21 (0.0%)	0/37 (0.0%)	0/66 (0.0%)	0/42 (0.0%)
Screening not completed prior to window closing	17/166 (10.2%)	1/21 (4.8%)	0/37 (0.0%)	16/66 (24.2%)	0/42 (0.0%)
Missing reason for not enrolled	0/166 (0.0%)	0/21 (0.0%)	0/37 (0.0%)	0/66 (0.0%)	0/42 (0.0%)

[1] Participants could have multiple reasons for not being enrolled.

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Atlas Open Report − June 15, 2021
Visit Cutoff Date: June 15, 2021
Table 1D − Screening Summary by Site − Region: Africa

	Overall	Cape Town
Screened	**243**	**243**
Enrolled		
Yes	152/243 (62.6%)	152/243 (62.6%)
No	91/243 (37.4%)	91/243 (37.4%)
Reason Not Enrolled[1]		
Did not meet behavior risk category	16/91 (17.6%)	16/91 (17.6%)
Intravenous drug use in last 90 days	0/91 (0.0%)	0/91 (0.0%)
Reactive or positive HIV test result	8/91 (8.8%)	8/91 (8.8%)
Abnormal liver or kidney function tests	1/91 (1.1%)	1/91 (1.1%)
Other lab abnormality	1/91 (1.1%)	1/91 (1.1%)
Hepatitis B or C positive	3/91 (3.3%)	3/91 (3.3%)
Unwilling to adhere to study procedures	2/91 (2.2%)	2/91 (2.2%)
Co−enrollment in another HIV interventional research study	1/91 (1.1%)	1/91 (1.1%)
Past or current participation in HIV vaccine trial	0/91 (0.0%)	0/91 (0.0%)
Clinically significant cardiovascular disease	4/91 (4.4%)	4/91 (4.4%)
Underlying skin disease or currently active skin disorder	0/91 (0.0%)	0/91 (0.0%)
Dermatological condition interfering with injection site reactions	0/91 (0.0%)	0/91 (0.0%)
Current/chronic history of liver disease or known hepatic/biliary abnormalities	0/91 (0.0%)	0/91 (0.0%)
Coagulopathy which would contraindicate IM injection	0/91 (0.0%)	0/91 (0.0%)
Active or planned use of prohibited medications	0/91 (0.0%)	0/91 (0.0%)
Has a history of seizure disorder	5/91 (5.5%)	5/91 (5.5%)
Has surgically−placed buttock implants	0/91 (0.0%)	0/91 (0.0%)
Opinion of the study investigator	17/91 (18.7%)	17/91 (18.7%)
Allergy to product components	0/91 (0.0%)	0/91 (0.0%)
Screening not completed prior to window closing	33/91 (36.3%)	33/91 (36.3%)
Missing reason for not enrolled	0/91 (0.0%)	0/91 (0.0%)

[1] Participants could have multiple reasons for not being enrolled.

Source: SCHARP (Anusha) − /trials/hptn/p083/analysis/atlas/code/open/t_screening_summary_bysite_atlas.sas, SAS Version 9.4 (15JUN2021,9:22)