

**HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women**  
**Atlas Open Report – March 5, 2024**  
**Visit Cutoff Date: March 5, 2024**

**Table 4 – Permanent Discontinuation of Study Product during Steps 1 and 2 by Site**

	<b>Overall</b>	<b>Botswana: Gaborone: Gaborone CRS</b>	<b>Kenya: Kisumu: Kisumu CRS</b>
Total Participants Enrolled <sup>1</sup>	3224	91	66
Participants who Permanently Discontinued Study Product during Steps 1 and 2	227/3224 (7.0%)	28/91 (30.8%)	10/66 (15.2%)
Participants who Permanently Discontinued Study Product during Step 1	67/3224 (2.1%)	9/91 (9.9%)	0/66 (0.0%)
Reported use of prohibited concomitant medication	0/67 (0.0%)	0/9 (0.0%)	0/0 (-%)
Participant is currently using or planning to use PrEP or PEP (other than study product)	1/67 (1.5%)	0/9 (0.0%)	0/0 (-%)
Clinical AE (protocol mandated)	8/67 (11.9%)	3/9 (33.3%)	0/0 (-%)
Laboratory AE (protocol mandated)	8/67 (11.9%)	0/9 (0.0%)	0/0 (-%)
Low oral adherence – Step 1	10/67 (14.9%)	2/9 (22.2%)	0/0 (-%)
CMC recommendation based on a clinical event	3/67 (4.5%)	0/9 (0.0%)	0/0 (-%)
CMC recommendation based on a laboratory value	2/67 (3.0%)	0/9 (0.0%)	0/0 (-%)
CMC recommendation based on a psychosocial concern	0/67 (0.0%)	0/9 (0.0%)	0/0 (-%)
Other clinical reason	2/67 (3.0%)	0/9 (0.0%)	0/0 (-%)
Hepatitis B infection	1/67 (1.5%)	0/9 (0.0%)	0/0 (-%)
Positive pregnancy test result	1/67 (1.5%)	0/9 (0.0%)	0/0 (-%)
Participant request – unwilling or unable to comply with required study procedures	12/67 (17.9%)	2/9 (22.2%)	0/0 (-%)
Participant request – other reason	13/67 (19.4%)	2/9 (22.2%)	0/0 (-%)
Other	5/67 (7.5%)	0/9 (0.0%)	0/0 (-%)
Participant refused long acting contraception	1/67 (1.5%)	0/9 (0.0%)	0/0 (-%)
Participants who Permanently Discontinued Study Product during Step 2	160/3224 (5.0%)	19/91 (20.9%)	10/66 (15.2%)
Reported use of prohibited concomitant medication	0/160 (0.0%)	0/19 (0.0%)	0/10 (0.0%)
Participant is currently using or planning to use PrEP or PEP (other than study product)	0/160 (0.0%)	0/19 (0.0%)	0/10 (0.0%)
Clinical AE (protocol mandated)	7/160 (4.4%)	1/19 (5.3%)	0/10 (0.0%)
Laboratory AE (protocol mandated)	30/160 (18.8%)	0/19 (0.0%)	1/10 (10.0%)
Injection site reaction	0/160 (0.0%)	0/19 (0.0%)	0/10 (0.0%)
CMC recommendation based on a clinical event	2/160 (1.3%)	0/19 (0.0%)	0/10 (0.0%)
CMC recommendation based on a laboratory value	5/160 (3.1%)	0/19 (0.0%)	0/10 (0.0%)
CMC recommendation based on a psychosocial concern	0/160 (0.0%)	0/19 (0.0%)	0/10 (0.0%)
Other clinical reason	0/160 (0.0%)	0/19 (0.0%)	0/10 (0.0%)
Hepatitis B infection	1/160 (0.6%)	0/19 (0.0%)	0/10 (0.0%)
Positive pregnancy test result	13/160 (8.1%)	1/19 (5.3%)	0/10 (0.0%)
Participant request – injection intolerance	2/160 (1.3%)	0/19 (0.0%)	0/10 (0.0%)
Participant request – unwilling or unable to comply with required study procedures	26/160 (16.3%)	7/19 (36.8%)	1/10 (10.0%)
Participant request – other reason	9/160 (5.6%)	3/19 (15.8%)	0/10 (0.0%)
Other	17/160 (10.6%)	2/19 (10.5%)	1/10 (10.0%)
Participant refused long acting contraception	48/160 (30.0%)	5/19 (26.3%)	7/10 (70.0%)

<sup>1</sup> Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) – /trials/hptn/p084/analysis/atlas/code/open/t\_pdisc\_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

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**Visit Cutoff Date: March 5, 2024**

**Table 4 – Permanent Discontinuation of Study Product during Steps 1 and 2 by Site**

	<b>Malawi: Blantyre: Blantyre CRS</b>	<b>Malawi: Lilongwe: Malawi CRS</b>	<b>South Africa: Botha's Hill: Botha's Hill CRS</b>
Total Participants Enrolled <sup>1</sup>	113	111	223
Participants who Permanently Discontinued Study Product during Steps 1 and 2	2/113 (1.8%)	12/111 (10.8%)	11/223 (4.9%)
Participants who Permanently Discontinued Study Product during Step 1	0/113 (0.0%)	3/111 (2.7%)	3/223 (1.3%)
Reported use of prohibited concomitant medication	0/0 (–%)	0/3 (0.0%)	0/3 (0.0%)
Participant is currently using or planning to use PrEP or PEP (other than study product)	0/0 (–%)	0/3 (0.0%)	0/3 (0.0%)
Clinical AE (protocol mandated)	0/0 (–%)	0/3 (0.0%)	0/3 (0.0%)
Laboratory AE (protocol mandated)	0/0 (–%)	0/3 (0.0%)	0/3 (0.0%)
Low oral adherence – Step 1	0/0 (–%)	0/3 (0.0%)	0/3 (0.0%)
CMC recommendation based on a clinical event	0/0 (–%)	0/3 (0.0%)	0/3 (0.0%)
CMC recommendation based on a laboratory value	0/0 (–%)	0/3 (0.0%)	1/3 (33.3%)
CMC recommendation based on a psychosocial concern	0/0 (–%)	0/3 (0.0%)	0/3 (0.0%)
Other clinical reason	0/0 (–%)	0/3 (0.0%)	0/3 (0.0%)
Hepatitis B infection	0/0 (–%)	0/3 (0.0%)	0/3 (0.0%)
Positive pregnancy test result	0/0 (–%)	0/3 (0.0%)	0/3 (0.0%)
Participant request – unwilling or unable to comply with required study procedures	0/0 (–%)	2/3 (66.7%)	2/3 (66.7%)
Participant request – other reason	0/0 (–%)	0/3 (0.0%)	0/3 (0.0%)
Other	0/0 (–%)	1/3 (33.3%)	0/3 (0.0%)
Participant refused long acting contraception	0/0 (–%)	0/3 (0.0%)	0/3 (0.0%)
Participants who Permanently Discontinued Study Product during Step 2	2/113 (1.8%)	9/111 (8.1%)	8/223 (3.6%)
Reported use of prohibited concomitant medication	0/2 (0.0%)	0/9 (0.0%)	0/8 (0.0%)
Participant is currently using or planning to use PrEP or PEP (other than study product)	0/2 (0.0%)	0/9 (0.0%)	0/8 (0.0%)
Clinical AE (protocol mandated)	0/2 (0.0%)	0/9 (0.0%)	0/8 (0.0%)
Laboratory AE (protocol mandated)	0/2 (0.0%)	0/9 (0.0%)	0/8 (0.0%)
Injection site reaction	0/2 (0.0%)	0/9 (0.0%)	0/8 (0.0%)
CMC recommendation based on a clinical event	0/2 (0.0%)	1/9 (11.1%)	0/8 (0.0%)
CMC recommendation based on a laboratory value	0/2 (0.0%)	1/9 (11.1%)	1/8 (12.5%)
CMC recommendation based on a psychosocial concern	0/2 (0.0%)	0/9 (0.0%)	0/8 (0.0%)
Other clinical reason	0/2 (0.0%)	0/9 (0.0%)	0/8 (0.0%)
Hepatitis B infection	0/2 (0.0%)	0/9 (0.0%)	0/8 (0.0%)
Positive pregnancy test result	0/2 (0.0%)	1/9 (11.1%)	0/8 (0.0%)
Participant request – injection intolerance	0/2 (0.0%)	0/9 (0.0%)	1/8 (12.5%)
Participant request – unwilling or unable to comply with required study procedures	0/2 (0.0%)	0/9 (0.0%)	1/8 (12.5%)
Participant request – other reason	0/2 (0.0%)	0/9 (0.0%)	1/8 (12.5%)
Other	1/2 (50.0%)	2/9 (22.2%)	0/8 (0.0%)
Participant refused long acting contraception	1/2 (50.0%)	4/9 (44.4%)	4/8 (50.0%)

<sup>1</sup> Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) – /trials/hptn/p084/analysis/atlas/code/open/t\_pdisc\_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

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**Atlas Open Report – March 5, 2024**  
**Visit Cutoff Date: March 5, 2024**

**Table 4 – Permanent Discontinuation of Study Product during Steps 1 and 2 by Site**

	<b>South Africa: Cape Town: Emavundleni CRS</b>	<b>South Africa: Cape Town: Stellenbosch University (DTTC-SU) CRS</b>	<b>South Africa: Johannesburg: Ward 21</b>
Total Participants Enrolled <sup>1</sup>	223	159	206
Participants who Permanently Discontinued Study Product during Steps 1 and 2	8/223 (3.6%)	7/159 (4.4%)	13/206 (6.3%)
Participants who Permanently Discontinued Study Product during Step 1	4/223 (1.8%)	2/159 (1.3%)	2/206 (1.0%)
Reported use of prohibited concomitant medication	0/4 (0.0%)	0/2 (0.0%)	0/2 (0.0%)
Participant is currently using or planning to use PrEP or PEP (other than study product)	0/4 (0.0%)	1/2 (50.0%)	0/2 (0.0%)
Clinical AE (protocol mandated)	1/4 (25.0%)	0/2 (0.0%)	0/2 (0.0%)
Laboratory AE (protocol mandated)	3/4 (75.0%)	0/2 (0.0%)	1/2 (50.0%)
Low oral adherence – Step 1	0/4 (0.0%)	1/2 (50.0%)	0/2 (0.0%)
CMC recommendation based on a clinical event	0/4 (0.0%)	0/2 (0.0%)	0/2 (0.0%)
CMC recommendation based on a laboratory value	0/4 (0.0%)	0/2 (0.0%)	0/2 (0.0%)
CMC recommendation based on a psychosocial concern	0/4 (0.0%)	0/2 (0.0%)	0/2 (0.0%)
Other clinical reason	0/4 (0.0%)	0/2 (0.0%)	1/2 (50.0%)
Hepatitis B infection	0/4 (0.0%)	0/2 (0.0%)	0/2 (0.0%)
Positive pregnancy test result	0/4 (0.0%)	0/2 (0.0%)	0/2 (0.0%)
Participant request – unwilling or unable to comply with required study procedures	0/4 (0.0%)	0/2 (0.0%)	0/2 (0.0%)
Participant request – other reason	0/4 (0.0%)	0/2 (0.0%)	0/2 (0.0%)
Other	0/4 (0.0%)	0/2 (0.0%)	0/2 (0.0%)
Participant refused long acting contraception	0/4 (0.0%)	0/2 (0.0%)	0/2 (0.0%)
Participants who Permanently Discontinued Study Product during Step 2	4/223 (1.8%)	5/159 (3.1%)	11/206 (5.3%)
Reported use of prohibited concomitant medication	0/4 (0.0%)	0/5 (0.0%)	0/11 (0.0%)
Participant is currently using or planning to use PrEP or PEP (other than study product)	0/4 (0.0%)	0/5 (0.0%)	0/11 (0.0%)
Clinical AE (protocol mandated)	1/4 (25.0%)	1/5 (20.0%)	0/11 (0.0%)
Laboratory AE (protocol mandated)	1/4 (25.0%)	3/5 (60.0%)	6/11 (54.5%)
Injection site reaction	0/4 (0.0%)	0/5 (0.0%)	0/11 (0.0%)
CMC recommendation based on a clinical event	0/4 (0.0%)	0/5 (0.0%)	0/11 (0.0%)
CMC recommendation based on a laboratory value	0/4 (0.0%)	0/5 (0.0%)	0/11 (0.0%)
CMC recommendation based on a psychosocial concern	0/4 (0.0%)	0/5 (0.0%)	0/11 (0.0%)
Other clinical reason	0/4 (0.0%)	0/5 (0.0%)	0/11 (0.0%)
Hepatitis B infection	0/4 (0.0%)	0/5 (0.0%)	0/11 (0.0%)
Positive pregnancy test result	0/4 (0.0%)	0/5 (0.0%)	0/11 (0.0%)
Participant request – injection intolerance	0/4 (0.0%)	0/5 (0.0%)	0/11 (0.0%)
Participant request – unwilling or unable to comply with required study procedures	0/4 (0.0%)	0/5 (0.0%)	2/11 (18.2%)
Participant request – other reason	0/4 (0.0%)	0/5 (0.0%)	0/11 (0.0%)
Other	0/4 (0.0%)	0/5 (0.0%)	1/11 (9.1%)
Participant refused long acting contraception	2/4 (50.0%)	1/5 (20.0%)	2/11 (18.2%)

<sup>1</sup> Inappropriately enrolled participants are excluded.

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**Atlas Open Report – March 5, 2024**  
**Visit Cutoff Date: March 5, 2024**

**Table 4 – Permanent Discontinuation of Study Product during Steps 1 and 2 by Site**

	<b>South Africa: Kwa Zulu Natal: Isipingo CRS</b>	<b>South Africa: Kwa Zulu Natal: Verulam CRS</b>	<b>South Africa: Soweto: Soweto HPTN CRS</b>
Total Participants Enrolled <sup>1</sup>	170	151	176
Participants who Permanently Discontinued Study Product during Steps 1 and 2	8/170 (4.7%)	7/151 (4.6%)	12/176 (6.8%)
Participants who Permanently Discontinued Study Product during Step 1	4/170 (2.4%)	6/151 (4.0%)	3/176 (1.7%)
Reported use of prohibited concomitant medication	0/4 (0.0%)	0/6 (0.0%)	0/3 (0.0%)
Participant is currently using or planning to use PrEP or PEP (other than study product)	0/4 (0.0%)	0/6 (0.0%)	0/3 (0.0%)
Clinical AE (protocol mandated)	0/4 (0.0%)	2/6 (33.3%)	1/3 (33.3%)
Laboratory AE (protocol mandated)	1/4 (25.0%)	1/6 (16.7%)	0/3 (0.0%)
Low oral adherence – Step 1	1/4 (25.0%)	2/6 (33.3%)	0/3 (0.0%)
CMC recommendation based on a clinical event	1/4 (25.0%)	1/6 (16.7%)	0/3 (0.0%)
CMC recommendation based on a laboratory value	0/4 (0.0%)	0/6 (0.0%)	1/3 (33.3%)
CMC recommendation based on a psychosocial concern	0/4 (0.0%)	0/6 (0.0%)	0/3 (0.0%)
Other clinical reason	0/4 (0.0%)	0/6 (0.0%)	0/3 (0.0%)
Hepatitis B infection	0/4 (0.0%)	0/6 (0.0%)	0/3 (0.0%)
Positive pregnancy test result	0/4 (0.0%)	0/6 (0.0%)	0/3 (0.0%)
Participant request – unwilling or unable to comply with required study procedures	0/4 (0.0%)	0/6 (0.0%)	0/3 (0.0%)
Participant request – other reason	0/4 (0.0%)	0/6 (0.0%)	1/3 (33.3%)
Other	1/4 (25.0%)	0/6 (0.0%)	0/3 (0.0%)
Participant refused long acting contraception	0/4 (0.0%)	0/6 (0.0%)	0/3 (0.0%)
Participants who Permanently Discontinued Study Product during Step 2	4/170 (2.4%)	1/151 (0.7%)	9/176 (5.1%)
Reported use of prohibited concomitant medication	0/4 (0.0%)	0/1 (0.0%)	0/9 (0.0%)
Participant is currently using or planning to use PrEP or PEP (other than study product)	0/4 (0.0%)	0/1 (0.0%)	0/9 (0.0%)
Clinical AE (protocol mandated)	1/4 (25.0%)	0/1 (0.0%)	1/9 (11.1%)
Laboratory AE (protocol mandated)	1/4 (25.0%)	0/1 (0.0%)	3/9 (33.3%)
Injection site reaction	0/4 (0.0%)	0/1 (0.0%)	0/9 (0.0%)
CMC recommendation based on a clinical event	0/4 (0.0%)	0/1 (0.0%)	0/9 (0.0%)
CMC recommendation based on a laboratory value	0/4 (0.0%)	0/1 (0.0%)	0/9 (0.0%)
CMC recommendation based on a psychosocial concern	0/4 (0.0%)	0/1 (0.0%)	0/9 (0.0%)
Other clinical reason	0/4 (0.0%)	0/1 (0.0%)	0/9 (0.0%)
Hepatitis B infection	0/4 (0.0%)	1/1 (100.0%)	0/9 (0.0%)
Positive pregnancy test result	0/4 (0.0%)	0/1 (0.0%)	0/9 (0.0%)
Participant request – injection intolerance	0/4 (0.0%)	0/1 (0.0%)	0/9 (0.0%)
Participant request – unwilling or unable to comply with required study procedures	2/4 (50.0%)	0/1 (0.0%)	2/9 (22.2%)
Participant request – other reason	0/4 (0.0%)	0/1 (0.0%)	1/9 (11.1%)
Other	0/4 (0.0%)	0/1 (0.0%)	1/9 (11.1%)
Participant refused long acting contraception	0/4 (0.0%)	0/1 (0.0%)	1/9 (11.1%)

<sup>1</sup> Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) – /trials/hptn/p084/analysis/atlas/code/open/t\_pdisc\_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

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**Atlas Open Report – March 5, 2024**  
**Visit Cutoff Date: March 5, 2024**

**Table 4 – Permanent Discontinuation of Study Product during Steps 1 and 2 by Site**

	<b>Swaziland: Siteki: Swaziland Prevention Center</b>	<b>Uganda: Entebbe: UVRI-IAVI</b>	<b>Uganda: Kampala: Baylor-Uganda CRS</b>
Total Participants Enrolled <sup>1</sup>	160	182	210
Participants who Permanently Discontinued Study Product during Steps 1 and 2	21/160 (13.1%)	16/182 (8.8%)	5/210 (2.4%)
Participants who Permanently Discontinued Study Product during Step 1	9/160 (5.6%)	3/182 (1.6%)	4/210 (1.9%)
Reported use of prohibited concomitant medication	0/9 (0.0%)	0/3 (0.0%)	0/4 (0.0%)
Participant is currently using or planning to use PrEP or PEP (other than study product)	0/9 (0.0%)	0/3 (0.0%)	0/4 (0.0%)
Clinical AE (protocol mandated)	0/9 (0.0%)	1/3 (33.3%)	0/4 (0.0%)
Laboratory AE (protocol mandated)	0/9 (0.0%)	1/3 (33.3%)	0/4 (0.0%)
Low oral adherence – Step 1	0/9 (0.0%)	1/3 (33.3%)	2/4 (50.0%)
CMC recommendation based on a clinical event	0/9 (0.0%)	0/3 (0.0%)	0/4 (0.0%)
CMC recommendation based on a laboratory value	0/9 (0.0%)	0/3 (0.0%)	0/4 (0.0%)
CMC recommendation based on a psychosocial concern	0/9 (0.0%)	0/3 (0.0%)	0/4 (0.0%)
Other clinical reason	1/9 (11.1%)	0/3 (0.0%)	0/4 (0.0%)
Hepatitis B infection	0/9 (0.0%)	0/3 (0.0%)	1/4 (25.0%)
Positive pregnancy test result	0/9 (0.0%)	0/3 (0.0%)	0/4 (0.0%)
Participant request – unwilling or unable to comply with required study procedures	0/9 (0.0%)	0/3 (0.0%)	1/4 (25.0%)
Participant request – other reason	7/9 (77.8%)	0/3 (0.0%)	0/4 (0.0%)
Other	1/9 (11.1%)	0/3 (0.0%)	0/4 (0.0%)
Participant refused long acting contraception	0/9 (0.0%)	0/3 (0.0%)	0/4 (0.0%)
Participants who Permanently Discontinued Study Product during Step 2	12/160 (7.5%)	13/182 (7.1%)	1/210 (0.5%)
Reported use of prohibited concomitant medication	0/12 (0.0%)	0/13 (0.0%)	0/1 (0.0%)
Participant is currently using or planning to use PrEP or PEP (other than study product)	0/12 (0.0%)	0/13 (0.0%)	0/1 (0.0%)
Clinical AE (protocol mandated)	0/12 (0.0%)	0/13 (0.0%)	0/1 (0.0%)
Laboratory AE (protocol mandated)	2/12 (16.7%)	5/13 (38.5%)	0/1 (0.0%)
Injection site reaction	0/12 (0.0%)	0/13 (0.0%)	0/1 (0.0%)
CMC recommendation based on a clinical event	0/12 (0.0%)	0/13 (0.0%)	0/1 (0.0%)
CMC recommendation based on a laboratory value	0/12 (0.0%)	0/13 (0.0%)	0/1 (0.0%)
CMC recommendation based on a psychosocial concern	0/12 (0.0%)	0/13 (0.0%)	0/1 (0.0%)
Other clinical reason	0/12 (0.0%)	0/13 (0.0%)	0/1 (0.0%)
Hepatitis B infection	0/12 (0.0%)	0/13 (0.0%)	0/1 (0.0%)
Positive pregnancy test result	0/12 (0.0%)	1/13 (7.7%)	0/1 (0.0%)
Participant request – injection intolerance	1/12 (8.3%)	0/13 (0.0%)	0/1 (0.0%)
Participant request – unwilling or unable to comply with required study procedures	4/12 (33.3%)	1/13 (7.7%)	0/1 (0.0%)
Participant request – other reason	1/12 (8.3%)	1/13 (7.7%)	0/1 (0.0%)
Other	0/12 (0.0%)	1/13 (7.7%)	0/1 (0.0%)
Participant refused long acting contraception	4/12 (33.3%)	4/13 (30.8%)	1/1 (100.0%)

<sup>1</sup> Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) – /trials/hptn/p084/analysis/atlas/code/open/t\_pdisc\_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

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**Atlas Open Report – March 5, 2024**  
**Visit Cutoff Date: March 5, 2024**

**Table 4 – Permanent Discontinuation of Study Product during Steps 1 and 2 by Site**

	<b>Uganda: Kampala: MU-JHU Research Collaboration CRS</b>	<b>Zimbabwe: Chitungwiza: Seke South CRS</b>	<b>Zimbabwe: Chitungwiza: St.Mary's CRS</b>
Total Participants Enrolled <sup>1</sup>	204	160	166
Participants who Permanently Discontinued Study Product during Steps 1 and 2	30/204 (14.7%)	6/160 (3.8%)	11/166 (6.6%)
Participants who Permanently Discontinued Study Product during Step 1	7/204 (3.4%)	0/160 (0.0%)	4/166 (2.4%)
Reported use of prohibited concomitant medication	0/7 (0.0%)	0/0 (-%)	0/4 (0.0%)
Participant is currently using or planning to use PrEP or PEP (other than study product)	0/7 (0.0%)	0/0 (-%)	0/4 (0.0%)
Clinical AE (protocol mandated)	0/7 (0.0%)	0/0 (-%)	0/4 (0.0%)
Laboratory AE (protocol mandated)	1/7 (14.3%)	0/0 (-%)	0/4 (0.0%)
Low oral adherence – Step 1	0/7 (0.0%)	0/0 (-%)	1/4 (25.0%)
CMC recommendation based on a clinical event	0/7 (0.0%)	0/0 (-%)	1/4 (25.0%)
CMC recommendation based on a laboratory value	0/7 (0.0%)	0/0 (-%)	0/4 (0.0%)
CMC recommendation based on a psychosocial concern	0/7 (0.0%)	0/0 (-%)	0/4 (0.0%)
Other clinical reason	0/7 (0.0%)	0/0 (-%)	0/4 (0.0%)
Hepatitis B infection	0/7 (0.0%)	0/0 (-%)	0/4 (0.0%)
Positive pregnancy test result	1/7 (14.3%)	0/0 (-%)	0/4 (0.0%)
Participant request – unwilling or unable to comply with required study procedures	3/7 (42.9%)	0/0 (-%)	0/4 (0.0%)
Participant request – other reason	1/7 (14.3%)	0/0 (-%)	1/4 (25.0%)
Other	1/7 (14.3%)	0/0 (-%)	1/4 (25.0%)
Participant refused long acting contraception	0/7 (0.0%)	0/0 (-%)	0/4 (0.0%)
Participants who Permanently Discontinued Study Product during Step 2	23/204 (11.3%)	6/160 (3.8%)	7/166 (4.2%)
Reported use of prohibited concomitant medication	0/23 (0.0%)	0/6 (0.0%)	0/7 (0.0%)
Participant is currently using or planning to use PrEP or PEP (other than study product)	0/23 (0.0%)	0/6 (0.0%)	0/7 (0.0%)
Clinical AE (protocol mandated)	0/23 (0.0%)	1/6 (16.7%)	0/7 (0.0%)
Laboratory AE (protocol mandated)	2/23 (8.7%)	3/6 (50.0%)	1/7 (14.3%)
Injection site reaction	0/23 (0.0%)	0/6 (0.0%)	0/7 (0.0%)
CMC recommendation based on a clinical event	0/23 (0.0%)	0/6 (0.0%)	1/7 (14.3%)
CMC recommendation based on a laboratory value	2/23 (8.7%)	1/6 (16.7%)	0/7 (0.0%)
CMC recommendation based on a psychosocial concern	0/23 (0.0%)	0/6 (0.0%)	0/7 (0.0%)
Other clinical reason	0/23 (0.0%)	0/6 (0.0%)	0/7 (0.0%)
Hepatitis B infection	0/23 (0.0%)	0/6 (0.0%)	0/7 (0.0%)
Positive pregnancy test result	7/23 (30.4%)	0/6 (0.0%)	1/7 (14.3%)
Participant request – injection intolerance	0/23 (0.0%)	0/6 (0.0%)	0/7 (0.0%)
Participant request – unwilling or unable to comply with required study procedures	3/23 (13.0%)	0/6 (0.0%)	0/7 (0.0%)
Participant request – other reason	1/23 (4.3%)	0/6 (0.0%)	0/7 (0.0%)
Other	2/23 (8.7%)	0/6 (0.0%)	1/7 (14.3%)
Participant refused long acting contraception	6/23 (26.1%)	1/6 (16.7%)	3/7 (42.9%)

<sup>1</sup> Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) – /trials/hptn/p084/analysis/atlas/code/open/t\_pdisc\_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

**HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women**  
**Atlas Open Report – March 5, 2024**  
**Visit Cutoff Date: March 5, 2024**

**Table 4 – Permanent Discontinuation of Study Product during Steps 1 and 2 by Site**

	<b>Zimbabwe: Chitungwiza: Zengeza CRS</b>	<b>Zimbabwe: Harare: Parirenyatwa CRS</b>	<b>Zimbabwe: Harare: Spiilhaus CRS</b>
Total Participants Enrolled <sup>1</sup>	162	153	138
Participants who Permanently Discontinued Study Product during Steps 1 and 2	4/162 (2.5%)	13/153 (8.5%)	3/138 (2.2%)
Participants who Permanently Discontinued Study Product during Step 1	1/162 (0.6%)	1/153 (0.7%)	2/138 (1.4%)
Reported use of prohibited concomitant medication	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)
Participant is currently using or planning to use PrEP or PEP (other than study product)	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)
Clinical AE (protocol mandated)	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)
Laboratory AE (protocol mandated)	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)
Low oral adherence – Step 1	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)
CMC recommendation based on a clinical event	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)
CMC recommendation based on a laboratory value	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)
CMC recommendation based on a psychosocial concern	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)
Other clinical reason	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)
Hepatitis B infection	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)
Positive pregnancy test result	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)
Participant request – unwilling or unable to comply with required study procedures	1/1 (100.0%)	0/1 (0.0%)	1/2 (50.0%)
Participant request – other reason	0/1 (0.0%)	0/1 (0.0%)	1/2 (50.0%)
Other	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)
Participant refused long acting contraception	0/1 (0.0%)	1/1 (100.0%)	0/2 (0.0%)
Participants who Permanently Discontinued Study Product during Step 2	3/162 (1.9%)	12/153 (7.8%)	1/138 (0.7%)
Reported use of prohibited concomitant medication	0/3 (0.0%)	0/12 (0.0%)	0/1 (0.0%)
Participant is currently using or planning to use PrEP or PEP (other than study product)	0/3 (0.0%)	0/12 (0.0%)	0/1 (0.0%)
Clinical AE (protocol mandated)	1/3 (33.3%)	0/12 (0.0%)	0/1 (0.0%)
Laboratory AE (protocol mandated)	0/3 (0.0%)	2/12 (16.7%)	0/1 (0.0%)
Injection site reaction	0/3 (0.0%)	0/12 (0.0%)	0/1 (0.0%)
CMC recommendation based on a clinical event	0/3 (0.0%)	0/12 (0.0%)	0/1 (0.0%)
CMC recommendation based on a laboratory value	0/3 (0.0%)	0/12 (0.0%)	0/1 (0.0%)
CMC recommendation based on a psychosocial concern	0/3 (0.0%)	0/12 (0.0%)	0/1 (0.0%)
Other clinical reason	0/3 (0.0%)	0/12 (0.0%)	0/1 (0.0%)
Hepatitis B infection	0/3 (0.0%)	0/12 (0.0%)	0/1 (0.0%)
Positive pregnancy test result	0/3 (0.0%)	1/12 (8.3%)	1/1 (100.0%)
Participant request – injection intolerance	0/3 (0.0%)	0/12 (0.0%)	0/1 (0.0%)
Participant request – unwilling or unable to comply with required study procedures	0/3 (0.0%)	3/12 (25.0%)	0/1 (0.0%)
Participant request – other reason	0/3 (0.0%)	1/12 (8.3%)	0/1 (0.0%)
Other	1/3 (33.3%)	4/12 (33.3%)	0/1 (0.0%)
Participant refused long acting contraception	1/3 (33.3%)	1/12 (8.3%)	0/1 (0.0%)

<sup>1</sup> Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) – /trials/hptn/p084/analysis/atlas/code/open/t\_pdisc\_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

**HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women**  
**Atlas Open Report – March 5, 2024**  
**Visit Cutoff Date: March 5, 2024**

**Listing 3 – All Participants who Permanently Discontinued Study Product during Steps 1 and 2<sup>1</sup>**

Site	Subject ID	Permanent Discontinuation Date	Permanent Discontinuation Visit	Step in which Permanently Discontinued	Reason for Permanent Discontinuation	Other Reasons
Botswana: Gaborone: Gaborone CRS	723157397	03FEB2020	V14.0 – Step 2 Week 42	Step 2	Positive pregnancy test result	
	723212769	08MAY2020	V16.0 – Step 2 Week 57	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	723244317	05OCT2020	V201 – Open Label Truvada	Step 2	Participant refused long acting contraception	
	723271858	18MAY2021	V26.0 – Step 2 Week 137	Step 2	Participant refused long acting contraception	
	723279163	08AUG2022	Interim Visit 23.2	Step 2	Other	Participant terminated from the study as the participant was not coming for study visits and site was unable to contact participant
	723285712	28JAN2020	V15.0 – Step 2 Week 49	Step 2	Clinical AE (protocol mandated)	
	723342457	21FEB2019	V3.0 – Step 1 Week 2	Step 1	Participant request – other reason	Pressure from family and boyfriend to stop medication
	723342980	14JUN2019	V4.0 – Step 1 Week 4	Step 1	Participant request – unwilling or unable to comply with required study procedures	
	723367394	26APR2021	V21.0 – Step 2 Week 97	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	723368062	16JUN2021	V24.0 – Step 2 Week 121	Step 2	Other	Wants to start preparing for child bearing
	723380157	13FEB2019	V3.0 – Step 1 Week 2	Step 1	Participant request – other reason	Participant wants to stop taking oral study product due to side effects
	723445412	18DEC2020	V20.0 – Step 2 Week 89	Step 2	Participant refused long acting contraception	
	723470718	19JUN2018	Interim Visit 4.1	Step 1	Clinical AE (protocol mandated)	
	723506359	21MAR2018	Interim Visit 3.1	Step 1	Clinical AE (protocol mandated)	
	723530395	10JUN2021	V22.0 – Step 2 Week 105	Step 2	Participant request – other reason	Family pressure to stop
	723540103	28FEB2019	V4.0 – Step 1 Week 4	Step 1	Participant request – unwilling or unable to comply with required study procedures	
	723574060	06JUL2020	V201 – Open Label Truvada	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	723614286	12JUL2018	V9.0 – Step 2 Week 17	Step 2	Participant refused long acting contraception	
	723656537	10MAR2021	V20.0 – Step 2 Week 89	Step 2	Participant refused long acting contraception	
	723658283	08APR2020	V13.0 – Step 2 Week 41	Step 2	Participant request – other reason	not willing to take study product

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**HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women**  
**Atlas Open Report – March 5, 2024**  
**Visit Cutoff Date: March 5, 2024**

**Listing 3 – All Participants who Permanently Discontinued Study Product during Steps 1 and 2<sup>1</sup>**

Site	Subject ID	Permanent Discontinuation Date	Permanent Discontinuation Visit	Step in which Permanently Discontinued	Reason for Permanent Discontinuation	Other Reasons
	723698508	19FEB2020	V10.0 – Step 2 Week 21	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	723716077	16FEB2022	V29.0 – Step 2 Week 161	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	723749271	28MAY2019	Interim Visit 4.1	Step 1	Clinical AE (protocol mandated)	
	723758815	19DEC2019	V15.0 – Step 2 Week 49	Step 2	Participant request – other reason	wants to stop due to work commitments
	723782890	10SEP2019	V8.0 – Step 2 Week 13	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	723815986	22FEB2019	V4.0 – Step 1 Week 4	Step 1	Low oral adherence – Step 1	
	723822035	04MAR2020	V17.0 – Step 2 Week 65	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	723975273	05MAR2020	Interim Visit 4.1	Step 1	Low oral adherence – Step 1	
Kenya: Kisumu: Kisumu CRS	792292932	17NOV2021	V27.0 – Step 2 Week 145	Step 2	Participant refused long acting contraception	
	792358548	25MAY2021	V23.0 – Step 2 Week 113	Step 2	Other	Participant intends to stop using Long acting Contraception (Implant) following pressure from partner to conceive.
	792367184	14SEP2021	V25.0 – Step 2 Week 129	Step 2	Participant refused long acting contraception	
	792367807	03FEB2021	V21.0 – Step 2 Week 97	Step 2	Participant refused long acting contraception	
	792457385	25AUG2020	V17.0 – Step 2 Week 65	Step 2	Laboratory AE (protocol mandated)	
	792483575	16MAR2021	V21.0 – Step 2 Week 97	Step 2	Participant refused long acting contraception	
	792545683	18MAR2019	V8.0 – Step 2 Week 13	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	792764810	12OCT2020	V19.0 – Step 2 Week 81	Step 2	Participant refused long acting contraception	
	792865080	16JUN2021	V23.0 – Step 2 Week 113	Step 2	Participant refused long acting contraception	
Malawi: Blantyre: Blantyre CRS	760383696	27JAN2021	V21.0 – Step 2 Week 97	Step 2	Other	want to get pregnant
	760824202	25JUN2021	V23.0 – Step 2 Week 113	Step 2	Participant refused long acting contraception	
Malawi: Lilongwe: Malawi CRS	720131129	05AUG2021	V21.0 – Step 2 Week 97	Step 2	CMC recommendation based on a clinical event	

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**HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women**  
**Atlas Open Report – March 5, 2024**  
**Visit Cutoff Date: March 5, 2024**

**Listing 3 – All Participants who Permanently Discontinued Study Product during Steps 1 and 2<sup>1</sup>**

Site	Subject ID	Permanent Discontinuation Date	Permanent Discontinuation Visit	Step in which Permanently Discontinued	Reason for Permanent Discontinuation	Other Reasons
	720184713	08FEB2021	V20.0 – Step 2 Week 89	Step 2	CMC recommendation based on a laboratory value	
	720230185	18MAR2019	V4.0 – Step 1 Week 4	Step 1	Participant request – unwilling or unable to comply with required study procedures	
	720334107	20JUL2021	V20.0 – Step 2 Week 89	Step 2	Positive pregnancy test result	
	720393123	29MAR2021	V19.0 – Step 2 Week 81	Step 2	Participant refused long acting contraception	
	720564383	04MAR2021	V22.0 – Step 2 Week 105	Step 2	Other	The participant reported that she wants to focus on personal and family activities
	720845087	17AUG2021	V201 – Open Label Truvada	Step 2	Participant refused long acting contraception	
	720901779	10OCT2019	V201 – Open Label Truvada	Step 2	Other	Participant received wrong study product at visit 12.0
	720929757	27JUL2020	V2.0 – Day 0/Enrollment	Step 1	Other	The participant was lost to follow up since enrollment and CMC recommended that we transition her to annual HIV testing.
	720950061	21OCT2019	Interim Visit 4.1	Step 1	Participant request – unwilling or unable to comply with required study procedures	
South Africa: Botha's Hill: Botha's Hill CRS	789116497	15JAN2020	V11.0 – Step 2 Week 25	Step 2	Participant refused long acting contraception	
	789154604	22NOV2019	V4.0 – Step 1 Week 4	Step 1	CMC recommendation based on a laboratory value	
	789188956	04MAR2020	V13.0 – Step 2 Week 41	Step 2	Participant request – other reason	Ppt refused to continue receiving study product. CMC was informed
	789238723	25MAY2020	V17.0 – Step 2 Week 65	Step 2	Participant refused long acting contraception	
	789487180	28FEB2019	Interim Visit 4.1	Step 1	Participant request – unwilling or unable to comply with required study procedures	
	789646839	26MAY2020	V19.0 – Step 2 Week 81	Step 2	Participant refused long acting contraception	
	789647108	08AUG2019	V10.0 – Step 2 Week 21	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	789664179	19APR2021	V11.0 – Step 2 Week 25	Step 2	CMC recommendation based on a laboratory value	
	789760760	19MAY2020	V13.0 – Step 2 Week 41	Step 2	Participant refused long acting contraception	
	789891977	05JUN2019	Interim Visit 2.1	Step 1	Participant request – unwilling or unable to comply with required study procedures	

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**HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women  
Atlas Open Report – March 5, 2024  
Visit Cutoff Date: March 5, 2024**

**Listing 3 – All Participants who Permanently Discontinued Study Product during Steps 1 and 2<sup>1</sup>**

Site	Subject ID	Permanent Discontinuation Date	Permanent Discontinuation Visit	Step in which Permanently Discontinued	Reason for Permanent Discontinuation	Other Reasons
	789944363	09FEB2021	V22.0 – Step 2 Week 105	Step 2	Participant request – injection intolerance	
South Africa: Cape Town: Emavundleni CRS	779189093	21SEP2021	Interim Visit 21.1	Step 2	Laboratory AE (protocol mandated)	
	779351275	27MAY2019	V4.0 – Step 1 Week 4	Step 1	Laboratory AE (protocol mandated)	
	779364536	15AUG2019	V3.0 – Step 1 Week 2	Step 1	Clinical AE (protocol mandated)	
	779629144	06MAY2021	V22.0 – Step 2 Week 105	Step 2	Participant refused long acting contraception	
	779745781	20MAY2019	V4.0 – Step 1 Week 4	Step 1	Laboratory AE (protocol mandated)	
	779857745	19DEC2019	V8.0 – Step 2 Week 13	Step 2	Participant refused long acting contraception	
	779904753	27MAY2019	V10.0 – Step 2 Week 21	Step 2	Clinical AE (protocol mandated)	
	779983061	16APR2019	Interim Visit 4.1	Step 1	Laboratory AE (protocol mandated)	
South Africa: Cape Town: Stellenbosch University (DTTC-SU) CRS	818260949	11JUN2020	Interim Visit 17.1	Step 2	Laboratory AE (protocol mandated)	
	818478858	26JUL2019	V7.0 – Step 2 Week 9	Step 2	Participant refused long acting contraception	
	818774069	28JUL2021	Interim Visit 23.1	Step 2	Laboratory AE (protocol mandated)	
	818803737	08JUL2020	V13.0 – Step 2 Week 41	Step 2	Laboratory AE (protocol mandated)	
	818834995	17SEP2020	Interim Visit 17.2	Step 2	Clinical AE (protocol mandated)	
	818909846	31JUL2019	V4.0 – Step 1 Week 4	Step 1	Low oral adherence – Step 1	
	818915874	25MAY2019	Interim Visit 2.1	Step 1	Participant is currently using or planning to use PrEP or PEP (other than study product)	
South Africa: Johannesburg: Ward 21	837342482	12JAN2022	Interim Visit 30.1	Step 2	Other	Terminated – Death
	837463126	12JUL2019	V11.0 – Step 2 Week 25	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	837511965	22AUG2018	Interim Visit 4.1	Step 1	Laboratory AE (protocol mandated)	
	837568646	27FEB2019	Interim Visit 2.1	Step 1	Other clinical reason	Pre-existing ALT Grade 3
	837643576	18JUN2018	Interim Visit 11.1	Step 2	Participant refused long acting contraception	

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**HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women**  
**Atlas Open Report – March 5, 2024**  
**Visit Cutoff Date: March 5, 2024**

**Listing 3 – All Participants who Permanently Discontinued Study Product during Steps 1 and 2<sup>1</sup>**

Site	Subject ID	Permanent Discontinuation Date	Permanent Discontinuation Visit	Step in which Permanently Discontinued	Reason for Permanent Discontinuation	Other Reasons
	837650737	14AUG2020	V11.0 – Step 2 Week 25	Step 2	Laboratory AE (protocol mandated)	
	837679529	02MAR2020	V13.0 – Step 2 Week 41	Step 2	Laboratory AE (protocol mandated)	
	837768119	03JUN2021	Interim Visit 25.1	Step 2	Laboratory AE (protocol mandated)	
	837806271	15JAN2019	Interim Visit 7.1	Step 2	Laboratory AE (protocol mandated)	
	837813840	05JUN2018	V11.0 – Step 2 Week 25	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	837820530	07JUL2020	V14.0 – Step 2 Week 42	Step 2	Laboratory AE (protocol mandated)	
	837859144	21JUN2018	V10.0 – Step 2 Week 21	Step 2	Participant refused long acting contraception	
	837967624	03DEC2018	Interim Visit 8.1	Step 2	Laboratory AE (protocol mandated)	
South Africa: Kwa Zulu Natal: Isipingo CRS	803218566	06MAY2021	V25.0 – Step 2 Week 129	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	803431091	30SEP2019	Interim Visit 4.1	Step 1	CMC recommendation based on a clinical event	
	803521888	16SEP2020	Interim Visit 2.1	Step 1	Other	As per CMC: Enrollment error due to discordant results
	803528872	10JUL2020	V9.0 – Step 2 Week 17	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	803651704	26JAN2022	V15.0 – Step 2 Week 49	Step 2	Clinical AE (protocol mandated)	
	803651704	26JAN2022	V15.0 – Step 2 Week 49	Step 2	Clinical AE (protocol mandated)	
	803684408	06MAY2020	Interim Visit 2.1	Step 1	Low oral adherence – Step 1	
	803688417	13JUL2020	Interim Visit 4.1	Step 1	Laboratory AE (protocol mandated)	
	803874906	12MAR2021	Interim Visit 18.1	Step 2	Laboratory AE (protocol mandated)	
South Africa: Kwa Zulu Natal: Verulam CRS	548285996	07SEP2020	V4.0 – Step 1 Week 4	Step 1	Low oral adherence – Step 1	
	548400644	09JUL2019	V4.0 – Step 1 Week 4	Step 1	Clinical AE (protocol mandated)	
	548571548	05APR2019	V4.0 – Step 1 Week 4	Step 1	Clinical AE (protocol mandated)	
	548661676	12MAY2020	Interim Visit 4.2	Step 1	CMC recommendation based on a clinical event	
	548669070	09APR2019	Interim Visit 4.2	Step 1	Laboratory AE (protocol mandated)	
	548808291	21APR2020	Interim Visit 4.1	Step 1	Low oral adherence – Step 1	

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**HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women**  
**Atlas Open Report – March 5, 2024**  
**Visit Cutoff Date: March 5, 2024**

**Listing 3 – All Participants who Permanently Discontinued Study Product during Steps 1 and 2<sup>1</sup>**

Site	Subject ID	Permanent Discontinuation Date	Permanent Discontinuation Visit	Step in which Permanently Discontinued	Reason for Permanent Discontinuation	Other Reasons
	548870234	07JUN2019	V201 – Open Label Truvada	Step 2	Hepatitis B infection	
South Africa: Soweto: Soweto HPTN CRS	802281600	02DEC2019	V13.0 – Step 2 Week 41	Step 2	Clinical AE (protocol mandated)	
	802309581	30AUG2018	V10.0 – Step 2 Week 21	Step 2	Participant refused long acting contraception	
	802369135	21NOV2018	V13.0 – Step 2 Week 41	Step 2	Laboratory AE (protocol mandated)	
	802409667	06DEC2017	Interim Visit 2.1	Step 1	Participant request – other reason	Related to social harm
	802460853	19SEP2019	V201 – Open Label Truvada	Step 2	Laboratory AE (protocol mandated)	
	802558106	06AUG2019	Interim Visit 2.1	Step 1	Clinical AE (protocol mandated)	
	802735879	14JAN2021	V201 – Open Label Truvada	Step 2	Participant request – other reason	Participant want to fall pregnant
	802831792	04DEC2019	V21.0 – Step 2 Week 97	Step 2	Laboratory AE (protocol mandated)	
	802923615	04FEB2021	V19.0 – Step 2 Week 81	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	802990522	17SEP2020	V2.0 – Day 0/Enrollment	Step 1	CMC recommendation based on a laboratory value	
Swaziland: Siteki: Swaziland Prevention Center	871156558	30AUG2021	V19.0 – Step 2 Week 81	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	871164875	10DEC2020	V17.0 – Step 2 Week 65	Step 2	Participant refused long acting contraception	
	871181014	23JUN2021	V21.0 – Step 2 Week 97	Step 2	Participant refused long acting contraception	
	871233515	17AUG2021	V21.0 – Step 2 Week 97	Step 2	Participant refused long acting contraception	
	871327792	29JUN2020	V12.0 – Step 2 Week 33	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	871366443	12MAY2020	V201 – Open Label Truvada	Step 2	Participant request – other reason	School commitment
	871377136	05AUG2021	V21.0 – Step 2 Week 97	Step 2	Participant refused long acting contraception	
	871378054	26JUN2020	Interim Visit 4.2	Step 1	Participant request – other reason	Participant not willing to receive injection
	871385831	30JUN2020	V4.0 – Step 1 Week 4	Step 1	Participant request – other reason	Participant not willing to use oral PREP

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**HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women**  
**Atlas Open Report – March 5, 2024**  
**Visit Cutoff Date: March 5, 2024**

**Listing 3 – All Participants who Permanently Discontinued Study Product during Steps 1 and 2<sup>1</sup>**

Site	Subject ID	Permanent Discontinuation Date	Permanent Discontinuation Visit	Step in which Permanently Discontinued	Reason for Permanent Discontinuation	Other Reasons
	871454855	29OCT2019	V4.0 – Step 1 Week 4	Step 1	Participant request – other reason	Participant changed her mind about study participation
	871676777	22FEB2019	Interim Visit 4.1	Step 1	Other clinical reason	Pre-existing Psychosis
	871690373	24JUN2020	V4.0 – Step 1 Week 4	Step 1	Participant request – other reason	Participant no longer interested in oral Prep
	871718405	26JUN2020	Interim Visit 9.2	Step 2	Laboratory AE (protocol mandated)	
	871839012	05NOV2019	V4.0 – Step 1 Week 4	Step 1	Participant request – other reason	No longer interested in PREP
	871839419	27MAR2020	Interim Visit 11.1	Step 2	Laboratory AE (protocol mandated)	
	871857274	17JAN2019	V4.0 – Step 1 Week 4	Step 1	Participant request – other reason	Grade 1 Adverse events
	871857671	06MAR2019	Interim Visit 4.2	Step 1	Other	Participant request due to mild adverse events
	871862853	25MAY2021	V21.0 – Step 2 Week 97	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	871921788	21SEP2021	V22.0 – Step 2 Week 105	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	871948673	29OCT2019	V4.0 – Step 1 Week 4	Step 1	Participant request – other reason	No longer interested in PREP
	871973317	12JUL2021	V20.0 – Step 2 Week 89	Step 2	Participant request – injection intolerance	
Uganda: Entebbe: UVRI-IAVI	873178696	25NOV2019	Interim Visit 4.1	Step 1	Low oral adherence – Step 1	
	873221389	20FEB2020	Interim Visit 3.1	Step 1	Clinical AE (protocol mandated)	
	873292244	19OCT2020	V201 – Open Label Truvada	Step 2	Participant refused long acting contraception	
	873364038	25JUL2019	Interim Visit 6.1	Step 2	Laboratory AE (protocol mandated)	
	873381392	20FEB2019	Interim Visit 4.1	Step 1	Laboratory AE (protocol mandated)	
	873422834	08JAN2021	V15.0 – Step 2 Week 49	Step 2	Positive pregnancy test result	
	873439058	07JAN2021	V16.0 – Step 2 Week 57	Step 2	Participant refused long acting contraception	
	873492201	29APR2019	V10.0 – Step 2 Week 21	Step 2	Laboratory AE (protocol mandated)	
	873497887	08SEP2021	V201 – Open Label Truvada	Step 2	Participant refused long acting contraception	
	873634014	07MAY2020	Interim Visit 12.1	Step 2	Laboratory AE (protocol mandated)	

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**HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women**  
**Atlas Open Report – March 5, 2024**  
**Visit Cutoff Date: March 5, 2024**

**Listing 3 – All Participants who Permanently Discontinued Study Product during Steps 1 and 2<sup>1</sup>**

Site	Subject ID	Permanent Discontinuation Date	Permanent Discontinuation Visit	Step in which Permanently Discontinued	Reason for Permanent Discontinuation	Other Reasons
	873640044	16MAR2021	V201 – Open Label Truvada	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	873761056	11MAY2021	V201 – Open Label Truvada	Step 2	Participant refused long acting contraception	
	873855179	10DEC2019	V7.0 – Step 2 Week 9	Step 2	Laboratory AE (protocol mandated)	
	873939292	08JUN2021	Interim Visit 19.1	Step 2	Other	Death
	873969541	05JAN2021	Interim Visit 19.1	Step 2	Laboratory AE (protocol mandated)	
Uganda: Kampala: Baylor-Uganda CRS	872185400	18JUL2019	V4.0 – Step 1 Week 4	Step 1	Participant request – unwilling or unable to comply with required study procedures	
	872326420	27MAR2019	V11.0 – Step 2 Week 25	Step 2	Participant refused long acting contraception	
	872856831	30OCT2018	V3.0 – Step 1 Week 2	Step 1	Hepatitis B infection	
	872954161	26FEB2019	Interim Visit 4.1	Step 1	Low oral adherence – Step 1	
	872961531	22NOV2018	V4.0 – Step 1 Week 4	Step 1	Low oral adherence – Step 1	
Uganda: Kampala: MU-JHU Research Collaboration CRS	753126678	15FEB2021	V22.0 – Step 2 Week 105	Step 2	Participant refused long acting contraception	
	753129279	22APR2021	V16.0 – Step 2 Week 57	Step 2	Other	Participant is breastfeeding
	753217271	07MAY2021	Interim Visit 19.1	Step 2	CMC recommendation based on a laboratory value	
	753243635	18NOV2020	V13.0 – Step 2 Week 41	Step 2	Participant refused long acting contraception	
	753290864	20MAR2019	Interim Visit 9.1	Step 2	CMC recommendation based on a laboratory value	
	753305734	07OCT2020	V16.0 – Step 2 Week 57	Step 2	Positive pregnancy test result	
	753439311	27MAY2019	V4.0 – Step 1 Week 4	Step 1	Participant request – other reason	Participant opted for annual HIV schedule
	753469002	19MAR2020	V4.0 – Step 1 Week 4	Step 1	Participant request – unwilling or unable to comply with required study procedures	
	753474774	30JUL2021	V20.0 – Step 2 Week 89	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	753505795	20DEC2018	V4.0 – Step 1 Week 4	Step 1	Other	CMC recommendation following drug dispensing error
	753521639	17JUN2019	Interim Visit 4.1	Step 1	Laboratory AE (protocol mandated)	
	753553236	21APR2021	V21.0 – Step 2 Week 97	Step 2	Positive pregnancy test result	

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**HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women**  
**Atlas Open Report – March 5, 2024**  
**Visit Cutoff Date: March 5, 2024**

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Site	Subject ID	Permanent Discontinuation Date	Permanent Discontinuation Visit	Step in which Permanently Discontinued	Reason for Permanent Discontinuation	Other Reasons
	753592210	10FEB2021	V17.0 – Step 2 Week 65	Step 2	Participant refused long acting contraception	
	753727488	17DEC2020	V20.0 – Step 2 Week 89	Step 2	Participant refused long acting contraception	
	753813540	28AUG2020	Interim Visit 17.1	Step 2	Laboratory AE (protocol mandated)	
	753835997	08APR2019	Interim Visit 4.1	Step 1	Participant request – unwilling or unable to comply with required study procedures	
	753861001	19APR2022	V57.0 – Step 4c-CAB LA – W	Step 2	Other	switched to open label extension
	753870235	11JUL2019	Interim Visit 9.1	Step 2	Laboratory AE (protocol mandated)	
	753940384	12AUG2021	V25.0 – Step 2 Week 129	Step 2	Positive pregnancy test result	
	753956384	05MAR2020	Interim Visit 8.1	Step 2	Participant request – other reason	Participant wants to conceive and has opted to switch to open label
	753975068	09JAN2020	V4.0 – Step 1 Week 4	Step 1	Participant request – unwilling or unable to comply with required study procedures	
Zimbabwe: Chitungwiza: Seke South CRS	754175806	11MAR2020	V16.0 – Step 2 Week 57	Step 2	Participant refused long acting contraception	
	754298123	03FEB2020	Interim Visit 14.1	Step 2	Laboratory AE (protocol mandated)	
	754392001	11SEP2020	Interim Visit 18.1	Step 2	Laboratory AE (protocol mandated)	
	754435691	03JUN2020	V201 – Open Label Truvada	Step 2	CMC recommendation based on a laboratory value	
	754470074	13JAN2020	V13.0 – Step 2 Week 41	Step 2	Laboratory AE (protocol mandated)	
	754478965	06MAY2020	Interim Visit 16.2	Step 2	Clinical AE (protocol mandated)	
Zimbabwe: Chitungwiza: St.Mary's CRS	762118873	24FEB2020	Interim Visit 17.1	Step 2	Laboratory AE (protocol mandated)	
	762121766	18JUN2019	V12.0 – Step 2 Week 33	Step 2	CMC recommendation based on a clinical event	
	762136773	28MAY2020	V12.0 – Step 2 Week 33	Step 2	Participant refused long acting contraception	
	762212118	22MAY2019	V17.0 – Step 2 Week 65	Step 2	Other	RASH WHICH THE PARTICIPANT STARTED AFTER THE INITIATION OF INJECTION
	762358175	17FEB2020	V13.0 – Step 2 Week 41	Step 2	Participant refused long acting contraception	

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**HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women**  
**Atlas Open Report – March 5, 2024**  
**Visit Cutoff Date: March 5, 2024**

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Site	Subject ID	Permanent Discontinuation Date	Permanent Discontinuation Visit	Step in which Permanently Discontinued	Reason for Permanent Discontinuation	Other Reasons
	762466979	15MAR2019	V4.0 – Step 1 Week 4	Step 1	Low oral adherence – Step 1	
	762598921	18JAN2020	Interim Visit 4.1	Step 1	Other	CMC recommendations, based on participant inability to attend study visits. HIV had been confirmed to be negative
	762846646	13NOV2019	Interim Visit 4.1	Step 1	CMC recommendation based on a clinical event	
	762875775	11FEB2020	V13.0 – Step 2 Week 41	Step 2	Participant refused long acting contraception	
	762996872	24MAY2019	Interim Visit 4.1	Step 1	Participant request – other reason	REVERTED TO CHRISTIAN PRINCIPLES HENCE NO NEED FOR DRUGS
Zimbabwe: Chitungwiza: Zengeza CRS	774369039	23MAR2018	Interim Visit 4.1	Step 1	Participant request – unwilling or unable to comply with required study procedures	
	774370509	21OCT2021	V22.0 – Step 2 Week 105	Step 2	Other	Participant relocated to another city and is unwilling to continue with subsequent study procedures
	774516096	29JAN2020	Interim Visit 15.1	Step 2	Participant refused long acting contraception	
	774844473	14JAN2020	Interim Visit 9.1	Step 2	Clinical AE (protocol mandated)	
Zimbabwe: Harare: Parirenyatwa CRS	770208830	01SEP2020	V20.0 – Step 2 Week 89	Step 2	Other	perceived side effects of study drug
	770219632	09JAN2020	Interim Visit 19.1	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	770238628	25FEB2020	V12.0 – Step 2 Week 33	Step 2	Laboratory AE (protocol mandated)	
	770252695	21MAY2018	Interim Visit 4.1	Step 1	Participant refused long acting contraception	
	770355667	01JUN2022	V29.0 – Step 2 Week 161	Step 2	Other	Declined consenting to protocol v3.0
	770495187	15MAR2021	Interim Visit 19.1	Step 2	Laboratory AE (protocol mandated)	
	770542606	16AUG2018	V11.0 – Step 2 Week 25	Step 2	Participant refused long acting contraception	
	770752022	01SEP2020	V20.0 – Step 2 Week 89	Step 2	Other	perceived side effects of study drug
	770786738	20AUG2020	V21.0 – Step 2 Week 97	Step 2	Participant request – unwilling or unable to comply with required study procedures	
	770930995	22AUG2021	V20.0 – Step 2 Week 89	Step 2	Other	PARTICIPANT DISCONTINUED STUDY PARTICIPATION
Zimbabwe: Harare: Spilhaus CRS	771341868	21JUL2021	V21.0 – Step 2 Week 97	Step 2	Positive pregnancy test result	

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**Atlas Open Report – March 5, 2024**  
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<b>Site</b>	<b>Subject ID</b>	<b>Permanent Discontinuation Date</b>	<b>Permanent Discontinuation Visit</b>	<b>Step in which Permanently Discontinued</b>	<b>Reason for Permanent Discontinuation</b>	<b>Other Reasons</b>
	771662562	04DEC2018	Interim Visit 2.1	Step 1	Participant request – other reason	Fear of side effects
	771937626	15APR2019	Interim Visit 4.2	Step 1	Participant request – unwilling or unable to comply with required study procedures	

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