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
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Table 1A – OLE Enrollment Summary by Original Randomized Study Arm

	Overall	TDF/FTC	Cabotegravir
Total enrollment in the primary study	**4566**	**2284**	**2282**
Joined the OLE	2658/4566 (58.2%)	1303/2284 (57.0%)	1355/2282 (59.4%)
Terminated from the study	1908/4566 (41.8%)	981/2284 (43.0%)	927/2282 (40.6%)
Not joined the OLE and termination pending	0/4566 (0.0%)	0/2284 (0.0%)	0/2282 (0.0%)
Not eligible for OLE [1]	**348**	**185**	**163**
Joined the OLE	0/348 (0.0%)	0/185 (0.0%)	0/163 (0.0%)
Terminated from the study	348/348 (100.0%)	185/185 (100.0%)	163/163 (100.0%)
Not joined the OLE and termination pending	0/348 (0.0%)	0/185 (0.0%)	0/163 (0.0%)
Potentially eligible for OLE	**4218**	**2099**	**2119**
Completed product choice CRF and joined the OLE	**2658/4218 (63.0%)**	**1303/2099 (62.1%)**	**1355/2119 (63.9%)**
Completed product choice CRF and declined the OLE	**982/4218 (23.3%)**	**502/2099 (23.9%)**	**480/2119 (22.7%)**
Missing	1/982 (0.1%)	1/502 (0.2%)	0/480 (0.0%)
Study participation too burdensome	38/982 (3.9%)	25/502 (5.0%)	13/480 (2.7%)
Already accessed TDF/FTC through another mechanism	18/982 (1.8%)	11/502 (2.2%)	7/480 (1.5%)
Prefer to take TAF/FTC	8/982 (0.8%)	4/502 (0.8%)	4/480 (0.8%)
Relocating to area where study is not offered	75/982 (7.6%)	39/502 (7.8%)	36/480 (7.5%)
Prefer not to answer	4/982 (0.4%)	2/502 (0.4%)	2/480 (0.4%)
Prefers TDF/FTC but not eligible for study–provided TDF/FTC	32/982 (3.3%)	26/502 (5.2%)	6/480 (1.3%)
Other [2]	806/982 (82.1%)	394/502 (78.5%)	412/480 (85.8%)
Don´t have product choice CRF and terminated	**578/4218 (13.7%)**	**294/2099 (14.0%)**	**284/2119 (13.4%)**
Not joined the OLE and termination pending	**0/4218 (0.0%)**	**0/2099 (0.0%)**	**0/2119 (0.0%)**

[1] Participants are potentially eligible for OLE if: site is approved for protocol v4/v5/v6, not HIV infected, not terminated prior to May 14, 2020, and not permanently discontinued study products prior to May 14, 2020 due to safety reasons (i.e. reactive HIV test, clinical or lab AE, ISR, CMC recommendation, Hepatitis B infections).
[2] See listing 1 for details regarding the reasons of 'other, specify'.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_enrl_byarm.sas, SAS Version 9.4 (04MAR2026,6:05)

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Table 1B – OLE Enrollment Summary by Region

	Overall	US	Latin America	Asia	Africa
Total enrollment in the primary study	**4566**	**1698**	**1964**	**752**	**152**
Joined the OLE	2658/4566 (58.2%)	822/1698 (48.4%)	1221/1964 (62.2%)	528/752 (70.2%)	87/152 (57.2%)
Terminated from the study	1908/4566 (41.8%)	876/1698 (51.6%)	743/1964 (37.8%)	224/752 (29.8%)	65/152 (42.8%)
Not joined the OLE and termination pending	0/4566 (0.0%)	0/1698 (0.0%)	0/1964 (0.0%)	0/752 (0.0%)	0/152 (0.0%)
Not eligible for OLE [1]	**348**	**170**	**146**	**17**	**15**
Joined the OLE	0/348 (0.0%)	0/170 (0.0%)	0/146 (0.0%)	0/17 (0.0%)	0/15 (0.0%)
Terminated from the study	348/348 (100.0%)	170/170 (100.0%)	146/146 (100.0%)	17/17 (100.0%)	15/15 (100.0%)
Not joined the OLE and termination pending	0/348 (0.0%)	0/170 (0.0%)	0/146 (0.0%)	0/17 (0.0%)	0/15 (0.0%)
Potentially eligible for OLE	**4218**	**1528**	**1818**	**735**	**137**
Completed product choice CRF and joined the OLE	**2658/4218 (63.0%)**	**822/1528 (53.8%)**	**1221/1818 (67.2%)**	**528/735 (71.8%)**	**87/137 (63.5%)**
Completed product choice CRF and declined the OLE	**982/4218 (23.3%)**	**460/1528 (30.1%)**	**332/1818 (18.3%)**	**155/735 (21.1%)**	**35/137 (25.5%)**
Missing	1/982 (0.1%)	0/460 (0.0%)	1/332 (0.3%)	0/155 (0.0%)	0/35 (0.0%)
Study participation too burdensome	38/982 (3.9%)	22/460 (4.8%)	5/332 (1.5%)	11/155 (7.1%)	0/35 (0.0%)
Already accessed TDF/FTC through another mechanism	18/982 (1.8%)	15/460 (3.3%)	3/332 (0.9%)	0/155 (0.0%)	0/35 (0.0%)
Prefer to take TAF/FTC	8/982 (0.8%)	7/460 (1.5%)	1/332 (0.3%)	0/155 (0.0%)	0/35 (0.0%)
Relocating to area where study is not offered	75/982 (7.6%)	43/460 (9.3%)	20/332 (6.0%)	12/155 (7.7%)	0/35 (0.0%)
Prefer not to answer	4/982 (0.4%)	2/460 (0.4%)	1/332 (0.3%)	1/155 (0.6%)	0/35 (0.0%)
Prefers TDF/FTC but not eligible for study–provided TDF/FTC	32/982 (3.3%)	7/460 (1.5%)	12/332 (3.6%)	13/155 (8.4%)	0/35 (0.0%)
Other [2]	806/982 (82.1%)	364/460 (79.1%)	289/332 (87.0%)	118/155 (76.1%)	35/35 (100.0%)
Don´t have product choice CRF and terminated	**578/4218 (13.7%)**	**246/1528 (16.1%)**	**265/1818 (14.6%)**	**52/735 (7.1%)**	**15/137 (10.9%)**
Not joined the OLE and termination pending	**0/4218 (0.0%)**	**0/1528 (0.0%)**	**0/1818 (0.0%)**	**0/735 (0.0%)**	**0/137 (0.0%)**

[1] Participants are potentially eligible for OLE if: site is approved for protocol v4/v5/v6, not HIV infected, not terminated prior to May 14, 2020, and not permanently discontinued study products prior to May 14, 2020 due to safety reasons (i.e. reactive HIV test, clinical or lab AE, ISR, CMC recommendation, Hepatitis B infections).
[2] See listing 1 for details regarding the reasons of 'other, specify'.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_enrl_byregion.sas, SAS Version 9.4 (04MAR2026,6:06)

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Table 1Ci – OLE Enrollment Summary by Site: US

	Overall	Baltimore	Los Angeles – UCLA Care	Chapel Hill	Atlanta
Total enrollment in the primary study	**1698**	**26**	**65**	**68**	**35**
Joined the OLE	822/1698 (48.4%)	6/26 (23.1%)	42/65 (64.6%)	35/68 (51.5%)	9/35 (25.7%)
Terminated from the study	876/1698 (51.6%)	20/26 (76.9%)	23/65 (35.4%)	33/68 (48.5%)	26/35 (74.3%)
Not joined the OLE and termination pending	0/1698 (0.0%)	0/26 (0.0%)	0/65 (0.0%)	0/68 (0.0%)	0/35 (0.0%)
Date site activated Protocol v4.0/v5.0/v6.0		12JUL2021	23APR2021	06MAY2021	07JUN2021
Date of first participant acceptance in the OLE [1]		24MAY2021	26APR2021	13MAY2021	03JUN2021
Not eligible for OLE [2]	**170**	**5**	**1**	**4**	**8**
Joined the OLE	0/170 (0.0%)	0/5 (0.0%)	0/1 (0.0%)	0/4 (0.0%)	0/8 (0.0%)
Terminated from the study	170/170 (100.0%)	5/5 (100.0%)	1/1 (100.0%)	4/4 (100.0%)	8/8 (100.0%)
Not joined the OLE and termination pending	0/170 (0.0%)	0/5 (0.0%)	0/1 (0.0%)	0/4 (0.0%)	0/8 (0.0%)
Potentially eligible for OLE	**1528**	**21**	**64**	**64**	**27**
Completed product choice CRF and joined the OLE	**822/1528 (53.8%)**	**6/21 (28.6%)**	**42/64 (65.6%)**	**35/64 (54.7%)**	**9/27 (33.3%)**
Completed product choice CRF and declined the OLE	**460/1528 (30.1%)**	**10/21 (47.6%)**	**10/64 (15.6%)**	**19/64 (29.7%)**	**6/27 (22.2%)**
Missing	0/460 (0.0%)	0/10 (0.0%)	0/10 (0.0%)	0/19 (0.0%)	0/6 (0.0%)
Study participation too burdensome	22/460 (4.8%)	0/10 (0.0%)	0/10 (0.0%)	0/19 (0.0%)	1/6 (16.7%)
Already accessed TDF/FTC through another mechanism	15/460 (3.3%)	0/10 (0.0%)	0/10 (0.0%)	1/19 (5.3%)	1/6 (16.7%)
Prefer to take TAF/FTC	7/460 (1.5%)	0/10 (0.0%)	0/10 (0.0%)	1/19 (5.3%)	0/6 (0.0%)
Relocating to area where study is not offered	43/460 (9.3%)	0/10 (0.0%)	1/10 (10.0%)	3/19 (15.8%)	0/6 (0.0%)
Prefer not to answer	2/460 (0.4%)	0/10 (0.0%)	0/10 (0.0%)	0/19 (0.0%)	0/6 (0.0%)
Prefers TDF/FTC but not eligible for study–provided TDF/FTC	7/460 (1.5%)	0/10 (0.0%)	0/10 (0.0%)	0/19 (0.0%)	1/6 (16.7%)
Other [3]	364/460 (79.1%)	10/10 (100.0%)	9/10 (90.0%)	14/19 (73.7%)	3/6 (50.0%)
Don´t have product choice CRF and terminated	**246/1528 (16.1%)**	**5/21 (23.8%)**	**12/64 (18.8%)**	**10/64 (15.6%)**	**12/27 (44.4%)**
Not joined the OLE and termination pending	**0/1528 (0.0%)**	**0/21 (0.0%)**	**0/64 (0.0%)**	**0/64 (0.0%)**	**0/27 (0.0%)**

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[2] Participants are potentially eligible for OLE if: site is approved for protocol v4/v5/v6, not HIV infected, not terminated prior to May 14, 2020, and not permanently discontinued study products prior to May 14, 2020 due to safety reasons (i.e. reactive HIV test, clinical or lab AE, ISR, CMC recommendation, Hepatitis B infections).
[3] See listing 1 for details regarding the reasons of 'other, specify'.

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Table 1Ci – OLE Enrollment Summary by Site: US

	New York – Weill Cornell Chelsea	Bronx	Harlem	San Francisco	Chicago – WISH
Total enrollment in the primary study	**65**	**66**	**58**	**26**	**73**
Joined the OLE	28/65 (43.1%)	29/66 (43.9%)	32/58 (55.2%)	19/26 (73.1%)	29/73 (39.7%)
Terminated from the study	37/65 (56.9%)	37/66 (56.1%)	26/58 (44.8%)	7/26 (26.9%)	44/73 (60.3%)
Not joined the OLE and termination pending	0/65 (0.0%)	0/66 (0.0%)	0/58 (0.0%)	0/26 (0.0%)	0/73 (0.0%)
Date site activated Protocol v4.0/v5.0/v6.0	19MAY2021	25MAY2021	04MAY2021	25MAY2021	09JUN2021
Date of first participant acceptance in the OLE [1]	20MAY2021	26MAY2021	10MAY2021	21MAY2021	18MAY2021
Not eligible for OLE [2]	**10**	**9**	**2**	**3**	**7**
Joined the OLE	0/10 (0.0%)	0/9 (0.0%)	0/2 (0.0%)	0/3 (0.0%)	0/7 (0.0%)
Terminated from the study	10/10 (100.0%)	9/9 (100.0%)	2/2 (100.0%)	3/3 (100.0%)	7/7 (100.0%)
Not joined the OLE and termination pending	0/10 (0.0%)	0/9 (0.0%)	0/2 (0.0%)	0/3 (0.0%)	0/7 (0.0%)
Potentially eligible for OLE	**55**	**57**	**56**	**23**	**66**
Completed product choice CRF and joined the OLE	**28/55 (50.9%)**	**29/57 (50.9%)**	**32/56 (57.1%)**	**19/23 (82.6%)**	**29/66 (43.9%)**
Completed product choice CRF and declined the OLE	**17/55 (30.9%)**	**26/57 (45.6%)**	**19/56 (33.9%)**	**1/23 (4.3%)**	**21/66 (31.8%)**
Missing	0/17 (0.0%)	0/26 (0.0%)	0/19 (0.0%)	0/1 (0.0%)	0/21 (0.0%)
Study participation too burdensome	0/17 (0.0%)	3/26 (11.5%)	1/19 (5.3%)	0/1 (0.0%)	1/21 (4.8%)
Already accessed TDF/FTC through another mechanism	1/17 (5.9%)	0/26 (0.0%)	0/19 (0.0%)	0/1 (0.0%)	0/21 (0.0%)
Prefer to take TAF/FTC	0/17 (0.0%)	0/26 (0.0%)	0/19 (0.0%)	0/1 (0.0%)	0/21 (0.0%)
Relocating to area where study is not offered	1/17 (5.9%)	1/26 (3.8%)	0/19 (0.0%)	0/1 (0.0%)	2/21 (9.5%)
Prefer not to answer	0/17 (0.0%)	0/26 (0.0%)	0/19 (0.0%)	0/1 (0.0%)	1/21 (4.8%)
Prefers TDF/FTC but not eligible for study–provided TDF/FTC	0/17 (0.0%)	2/26 (7.7%)	0/19 (0.0%)	0/1 (0.0%)	0/21 (0.0%)
Other [3]	15/17 (88.2%)	20/26 (76.9%)	18/19 (94.7%)	1/1 (100.0%)	17/21 (81.0%)
Don´t have product choice CRF and terminated	**10/55 (18.2%)**	**2/57 (3.5%)**	**5/56 (8.9%)**	**3/23 (13.0%)**	**16/66 (24.2%)**
Not joined the OLE and termination pending	**0/55 (0.0%)**	**0/57 (0.0%)**	**0/56 (0.0%)**	**0/23 (0.0%)**	**0/66 (0.0%)**

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Table 1Ci – OLE Enrollment Summary by Site: US

	Decatur	Los Angeles – UCLA Vine	Washington, DC	Boston	Newark
Total enrollment in the primary study	**86**	**70**	**61**	**81**	**66**
Joined the OLE	42/86 (48.8%)	34/70 (48.6%)	37/61 (60.7%)	42/81 (51.9%)	39/66 (59.1%)
Terminated from the study	44/86 (51.2%)	36/70 (51.4%)	24/61 (39.3%)	39/81 (48.1%)	27/66 (40.9%)
Not joined the OLE and termination pending	0/86 (0.0%)	0/70 (0.0%)	0/61 (0.0%)	0/81 (0.0%)	0/66 (0.0%)
Date site activated Protocol v4.0/v5.0/v6.0	02APR2021	24MAY2021	17MAY2021	10MAY2021	29APR2021
Date of first participant acceptance in the OLE [1]	02APR2021	25MAY2021	07MAY2021	14MAY2021	30APR2021
Not eligible for OLE [2]	**7**	**12**	**5**	**10**	**2**
Joined the OLE	0/7 (0.0%)	0/12 (0.0%)	0/5 (0.0%)	0/10 (0.0%)	0/2 (0.0%)
Terminated from the study	7/7 (100.0%)	12/12 (100.0%)	5/5 (100.0%)	10/10 (100.0%)	2/2 (100.0%)
Not joined the OLE and termination pending	0/7 (0.0%)	0/12 (0.0%)	0/5 (0.0%)	0/10 (0.0%)	0/2 (0.0%)
Potentially eligible for OLE	**79**	**58**	**56**	**71**	**64**
Completed product choice CRF and joined the OLE	**42/79 (53.2%)**	**34/58 (58.6%)**	**37/56 (66.1%)**	**42/71 (59.2%)**	**39/64 (60.9%)**
Completed product choice CRF and declined the OLE	**32/79 (40.5%)**	**4/58 (6.9%)**	**10/56 (17.9%)**	**19/71 (26.8%)**	**19/64 (29.7%)**
Missing	0/32 (0.0%)	0/4 (0.0%)	0/10 (0.0%)	0/19 (0.0%)	0/19 (0.0%)
Study participation too burdensome	0/32 (0.0%)	1/4 (25.0%)	1/10 (10.0%)	0/19 (0.0%)	4/19 (21.1%)
Already accessed TDF/FTC through another mechanism	1/32 (3.1%)	1/4 (25.0%)	1/10 (10.0%)	1/19 (5.3%)	0/19 (0.0%)
Prefer to take TAF/FTC	0/32 (0.0%)	0/4 (0.0%)	0/10 (0.0%)	0/19 (0.0%)	0/19 (0.0%)
Relocating to area where study is not offered	2/32 (6.3%)	0/4 (0.0%)	1/10 (10.0%)	3/19 (15.8%)	5/19 (26.3%)
Prefer not to answer	0/32 (0.0%)	0/4 (0.0%)	0/10 (0.0%)	0/19 (0.0%)	0/19 (0.0%)
Prefers TDF/FTC but not eligible for study–provided TDF/FTC	0/32 (0.0%)	0/4 (0.0%)	1/10 (10.0%)	0/19 (0.0%)	2/19 (10.5%)
Other [3]	29/32 (90.6%)	2/4 (50.0%)	6/10 (60.0%)	15/19 (78.9%)	8/19 (42.1%)
Don´t have product choice CRF and terminated	**5/79 (6.3%)**	**20/58 (34.5%)**	**9/56 (16.1%)**	**10/71 (14.1%)**	**6/64 (9.4%)**
Not joined the OLE and termination pending	**0/79 (0.0%)**	**0/58 (0.0%)**	**0/56 (0.0%)**	**0/71 (0.0%)**	**0/64 (0.0%)**

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[2] Participants are potentially eligible for OLE if: site is approved for protocol v4/v5/v6, not HIV infected, not terminated prior to May 14, 2020, and not permanently discontinued study products prior to May 14, 2020 due to safety reasons (i.e. reactive HIV test, clinical or lab AE, ISR, CMC recommendation, Hepatitis B infections).
[3] See listing 1 for details regarding the reasons of 'other, specify'.

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Table 1Ci – OLE Enrollment Summary by Site: US

	Birmingham	New York – Blood Center	Chicago – AYAR	Aurora	Cincinnati
Total enrollment in the primary study	**62**	**67**	**69**	**63**	**79**
Joined the OLE	34/62 (54.8%)	26/67 (38.8%)	39/69 (56.5%)	25/63 (39.7%)	33/79 (41.8%)
Terminated from the study	28/62 (45.2%)	41/67 (61.2%)	30/69 (43.5%)	38/63 (60.3%)	46/79 (58.2%)
Not joined the OLE and termination pending	0/62 (0.0%)	0/67 (0.0%)	0/69 (0.0%)	0/63 (0.0%)	0/79 (0.0%)
Date site activated Protocol v4.0/v5.0/v6.0	09JUL2021	12APR2021	06APR2021	07MAY2021	19APR2021
Date of first participant acceptance in the OLE [1]	03JUN2021	15APR2021	06APR2021	07MAY2021	20APR2021
Not eligible for OLE [2]	**3**	**10**	**7**	**6**	**10**
Joined the OLE	0/3 (0.0%)	0/10 (0.0%)	0/7 (0.0%)	0/6 (0.0%)	0/10 (0.0%)
Terminated from the study	3/3 (100.0%)	10/10 (100.0%)	7/7 (100.0%)	6/6 (100.0%)	10/10 (100.0%)
Not joined the OLE and termination pending	0/3 (0.0%)	0/10 (0.0%)	0/7 (0.0%)	0/6 (0.0%)	0/10 (0.0%)
Potentially eligible for OLE	**59**	**57**	**62**	**57**	**69**
Completed product choice CRF and joined the OLE	**34/59 (57.6%)**	**26/57 (45.6%)**	**39/62 (62.9%)**	**25/57 (43.9%)**	**33/69 (47.8%)**
Completed product choice CRF and declined the OLE	**12/59 (20.3%)**	**12/57 (21.1%)**	**6/62 (9.7%)**	**29/57 (50.9%)**	**23/69 (33.3%)**
Missing	0/12 (0.0%)	0/12 (0.0%)	0/6 (0.0%)	0/29 (0.0%)	0/23 (0.0%)
Study participation too burdensome	0/12 (0.0%)	1/12 (8.3%)	0/6 (0.0%)	2/29 (6.9%)	0/23 (0.0%)
Already accessed TDF/FTC through another mechanism	2/12 (16.7%)	0/12 (0.0%)	0/6 (0.0%)	0/29 (0.0%)	0/23 (0.0%)
Prefer to take TAF/FTC	1/12 (8.3%)	0/12 (0.0%)	0/6 (0.0%)	1/29 (3.4%)	0/23 (0.0%)
Relocating to area where study is not offered	0/12 (0.0%)	2/12 (16.7%)	0/6 (0.0%)	7/29 (24.1%)	2/23 (8.7%)
Prefer not to answer	0/12 (0.0%)	0/12 (0.0%)	0/6 (0.0%)	0/29 (0.0%)	0/23 (0.0%)
Prefers TDF/FTC but not eligible for study–provided TDF/FTC	0/12 (0.0%)	0/12 (0.0%)	0/6 (0.0%)	0/29 (0.0%)	0/23 (0.0%)
Other [3]	9/12 (75.0%)	9/12 (75.0%)	6/6 (100.0%)	19/29 (65.5%)	21/23 (91.3%)
Don´t have product choice CRF and terminated	**13/59 (22.0%)**	**19/57 (33.3%)**	**17/62 (27.4%)**	**3/57 (5.3%)**	**13/69 (18.8%)**
Not joined the OLE and termination pending	**0/59 (0.0%)**	**0/57 (0.0%)**	**0/62 (0.0%)**	**0/57 (0.0%)**	**0/69 (0.0%)**

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[2] Participants are potentially eligible for OLE if: site is approved for protocol v4/v5/v6, not HIV infected, not terminated prior to May 14, 2020, and not permanently discontinued study products prior to May 14, 2020 due to safety reasons (i.e. reactive HIV test, clinical or lab AE, ISR, CMC recommendation, Hepatitis B infections).
[3] See listing 1 for details regarding the reasons of 'other, specify'.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_enrl_bysite.sas, SAS Version 9.4 (04MAR2026,6:06)

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Table 1Ci – OLE Enrollment Summary by Site: US

	Greensboro	Houston	New Orleans	Columbus	Memphis
Total enrollment in the primary study	**58**	**60**	**53**	**55**	**93**
Joined the OLE	25/58 (43.1%)	34/60 (56.7%)	24/53 (45.3%)	22/55 (40.0%)	49/93 (52.7%)
Terminated from the study	33/58 (56.9%)	26/60 (43.3%)	29/53 (54.7%)	33/55 (60.0%)	44/93 (47.3%)
Not joined the OLE and termination pending	0/58 (0.0%)	0/60 (0.0%)	0/53 (0.0%)	0/55 (0.0%)	0/93 (0.0%)
Date site activated Protocol v4.0/v5.0/v6.0	24MAY2021	18JUN2021	28JUN2021	30APR2021	07APR2021
Date of first participant acceptance in the OLE [1]	27MAY2021	21JUN2021	09JUN2021	05MAY2021	08APR2021
Not eligible for OLE [2]	**8**	**3**	**4**	**0**	**9**
Joined the OLE	0/8 (0.0%)	0/3 (0.0%)	0/4 (0.0%)	0/0 (–%)	0/9 (0.0%)
Terminated from the study	8/8 (100.0%)	3/3 (100.0%)	4/4 (100.0%)	0/0 (–%)	9/9 (100.0%)
Not joined the OLE and termination pending	0/8 (0.0%)	0/3 (0.0%)	0/4 (0.0%)	0/0 (–%)	0/9 (0.0%)
Potentially eligible for OLE	**50**	**57**	**49**	**55**	**84**
Completed product choice CRF and joined the OLE	**25/50 (50.0%)**	**34/57 (59.6%)**	**24/49 (49.0%)**	**22/55 (40.0%)**	**49/84 (58.3%)**
Completed product choice CRF and declined the OLE	**22/50 (44.0%)**	**11/57 (19.3%)**	**19/49 (38.8%)**	**22/55 (40.0%)**	**25/84 (29.8%)**
Missing	0/22 (0.0%)	0/11 (0.0%)	0/19 (0.0%)	0/22 (0.0%)	0/25 (0.0%)
Study participation too burdensome	2/22 (9.1%)	0/11 (0.0%)	1/19 (5.3%)	0/22 (0.0%)	0/25 (0.0%)
Already accessed TDF/FTC through another mechanism	0/22 (0.0%)	0/11 (0.0%)	1/19 (5.3%)	0/22 (0.0%)	2/25 (8.0%)
Prefer to take TAF/FTC	0/22 (0.0%)	0/11 (0.0%)	0/19 (0.0%)	3/22 (13.6%)	0/25 (0.0%)
Relocating to area where study is not offered	2/22 (9.1%)	1/11 (9.1%)	2/19 (10.5%)	0/22 (0.0%)	0/25 (0.0%)
Prefer not to answer	0/22 (0.0%)	0/11 (0.0%)	0/19 (0.0%)	0/22 (0.0%)	0/25 (0.0%)
Prefers TDF/FTC but not eligible for study–provided TDF/FTC	0/22 (0.0%)	0/11 (0.0%)	0/19 (0.0%)	0/22 (0.0%)	0/25 (0.0%)
Other [3]	18/22 (81.8%)	10/11 (90.9%)	15/19 (78.9%)	19/22 (86.4%)	23/25 (92.0%)
Don´t have product choice CRF and terminated	**3/50 (6.0%)**	**12/57 (21.1%)**	**6/49 (12.2%)**	**11/55 (20.0%)**	**10/84 (11.9%)**
Not joined the OLE and termination pending	**0/50 (0.0%)**	**0/57 (0.0%)**	**0/49 (0.0%)**	**0/55 (0.0%)**	**0/84 (0.0%)**

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[3] See listing 1 for details regarding the reasons of 'other, specify'.

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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
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Table 1Ci – OLE Enrollment Summary by Site: US

	St. Louis	Philadelphia	Oakland
Total enrollment in the primary study	**65**	**88**	**40**
Joined the OLE	20/65 (30.8%)	47/88 (53.4%)	21/40 (52.5%)
Terminated from the study	45/65 (69.2%)	41/88 (46.6%)	19/40 (47.5%)
Not joined the OLE and termination pending	0/65 (0.0%)	0/88 (0.0%)	0/40 (0.0%)
Date site activated Protocol v4.0/v5.0/v6.0	09APR2021	07MAY2021	26APR2021
Date of first participant acceptance in the OLE [1]	12APR2021	04MAY2021	27APR2021
Not eligible for OLE [2]	**5**	**9**	**11**
Joined the OLE	0/5 (0.0%)	0/9 (0.0%)	0/11 (0.0%)
Terminated from the study	5/5 (100.0%)	9/9 (100.0%)	11/11 (100.0%)
Not joined the OLE and termination pending	0/5 (0.0%)	0/9 (0.0%)	0/11 (0.0%)
Potentially eligible for OLE	**60**	**79**	**29**
Completed product choice CRF and joined the OLE	**20/60 (33.3%)**	**47/79 (59.5%)**	**21/29 (72.4%)**
Completed product choice CRF and declined the OLE	**36/60 (60.0%)**	**23/79 (29.1%)**	**7/29 (24.1%)**
Missing	0/36 (0.0%)	0/23 (0.0%)	0/7 (0.0%)
Study participation too burdensome	1/36 (2.8%)	3/23 (13.0%)	0/7 (0.0%)
Already accessed TDF/FTC through another mechanism	0/36 (0.0%)	2/23 (8.7%)	1/7 (14.3%)
Prefer to take TAF/FTC	0/36 (0.0%)	1/23 (4.3%)	0/7 (0.0%)
Relocating to area where study is not offered	1/36 (2.8%)	6/23 (26.1%)	1/7 (14.3%)
Prefer not to answer	0/36 (0.0%)	0/23 (0.0%)	1/7 (14.3%)
Prefers TDF/FTC but not eligible for study–provided TDF/FTC	1/36 (2.8%)	0/23 (0.0%)	0/7 (0.0%)
Other [3]	33/36 (91.7%)	11/23 (47.8%)	4/7 (57.1%)
Don´t have product choice CRF and terminated	**4/60 (6.7%)**	**9/79 (11.4%)**	**1/29 (3.4%)**
Not joined the OLE and termination pending	**0/60 (0.0%)**	**0/79 (0.0%)**	**0/29 (0.0%)**

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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
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Table 1Cii – OLE Enrollment Summary by Site: Latin America

	Overall	Lima – Barranco	Lima – San Miguel	Rio de Janeiro
Total enrollment in the primary study	**1964**	**176**	**150**	**240**
Joined the OLE	1221/1964 (62.2%)	74/176 (42.0%)	62/150 (41.3%)	192/240 (80.0%)
Terminated from the study	743/1964 (37.8%)	102/176 (58.0%)	88/150 (58.7%)	48/240 (20.0%)
Not joined the OLE and termination pending	0/1964 (0.0%)	0/176 (0.0%)	0/150 (0.0%)	0/240 (0.0%)
Date site activated Protocol v4.0/v5.0/v6.0		17APR2023	18APR2023	27JUL2021
Date of first participant acceptance in the OLE [1]		21APR2023	26APR2023	28JUL2021
Not eligible for OLE [2]	**146**	**20**	**27**	**4**
Joined the OLE	0/146 (0.0%)	0/20 (0.0%)	0/27 (0.0%)	0/4 (0.0%)
Terminated from the study	146/146 (100.0%)	20/20 (100.0%)	27/27 (100.0%)	4/4 (100.0%)
Not joined the OLE and termination pending	0/146 (0.0%)	0/20 (0.0%)	0/27 (0.0%)	0/4 (0.0%)
Potentially eligible for OLE	**1818**	**156**	**123**	**236**
Completed product choice CRF and joined the OLE	**1221/1818 (67.2%)**	**74/156 (47.4%)**	**62/123 (50.4%)**	**192/236 (81.4%)**
Completed product choice CRF and declined the OLE	**332/1818 (18.3%)**	**26/156 (16.7%)**	**34/123 (27.6%)**	**42/236 (17.8%)**
Missing	1/332 (0.3%)	1/26 (3.8%)	0/34 (0.0%)	0/42 (0.0%)
Study participation too burdensome	5/332 (1.5%)	0/26 (0.0%)	0/34 (0.0%)	0/42 (0.0%)
Already accessed TDF/FTC through another mechanism	3/332 (0.9%)	0/26 (0.0%)	0/34 (0.0%)	0/42 (0.0%)
Prefer to take TAF/FTC	1/332 (0.3%)	0/26 (0.0%)	0/34 (0.0%)	0/42 (0.0%)
Relocating to area where study is not offered	20/332 (6.0%)	0/26 (0.0%)	1/34 (2.9%)	5/42 (11.9%)
Prefer not to answer	1/332 (0.3%)	0/26 (0.0%)	0/34 (0.0%)	0/42 (0.0%)
Prefers TDF/FTC but not eligible for study–provided TDF/FTC	12/332 (3.6%)	0/26 (0.0%)	2/34 (5.9%)	3/42 (7.1%)
Other [3]	289/332 (87.0%)	25/26 (96.2%)	31/34 (91.2%)	34/42 (81.0%)
Don´t have product choice CRF and terminated	**265/1818 (14.6%)**	**56/156 (35.9%)**	**27/123 (22.0%)**	**2/236 (0.8%)**
Not joined the OLE and termination pending	**0/1818 (0.0%)**	**0/156 (0.0%)**	**0/123 (0.0%)**	**0/236 (0.0%)**

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[3] See listing 1 for details regarding the reasons of 'other, specify'.

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Table 1Cii – OLE Enrollment Summary by Site: Latin America

	Porto Alegre	Iquitos	Lima – Via Libre	Sao Paulo – DST–AIDS
Total enrollment in the primary study	**215**	**177**	**176**	**155**
Joined the OLE	164/215 (76.3%)	74/177 (41.8%)	92/176 (52.3%)	116/155 (74.8%)
Terminated from the study	51/215 (23.7%)	103/177 (58.2%)	84/176 (47.7%)	39/155 (25.2%)
Not joined the OLE and termination pending	0/215 (0.0%)	0/177 (0.0%)	0/176 (0.0%)	0/155 (0.0%)
Date site activated Protocol v4.0/v5.0/v6.0	27AUG2021	18APR2023	18APR2023	28JUL2021
Date of first participant acceptance in the OLE [1]	30AUG2021	24APR2023	26APR2023	29JUL2021
Not eligible for OLE [2]	**5**	**11**	**20**	**23**
Joined the OLE	0/5 (0.0%)	0/11 (0.0%)	0/20 (0.0%)	0/23 (0.0%)
Terminated from the study	5/5 (100.0%)	11/11 (100.0%)	20/20 (100.0%)	23/23 (100.0%)
Not joined the OLE and termination pending	0/5 (0.0%)	0/11 (0.0%)	0/20 (0.0%)	0/23 (0.0%)
Potentially eligible for OLE	**210**	**166**	**156**	**132**
Completed product choice CRF and joined the OLE	**164/210 (78.1%)**	**74/166 (44.6%)**	**92/156 (59.0%)**	**116/132 (87.9%)**
Completed product choice CRF and declined the OLE	**22/210 (10.5%)**	**61/166 (36.7%)**	**28/156 (17.9%)**	**7/132 (5.3%)**
Missing	0/22 (0.0%)	0/61 (0.0%)	0/28 (0.0%)	0/7 (0.0%)
Study participation too burdensome	0/22 (0.0%)	0/61 (0.0%)	0/28 (0.0%)	1/7 (14.3%)
Already accessed TDF/FTC through another mechanism	1/22 (4.5%)	0/61 (0.0%)	0/28 (0.0%)	0/7 (0.0%)
Prefer to take TAF/FTC	0/22 (0.0%)	0/61 (0.0%)	0/28 (0.0%)	0/7 (0.0%)
Relocating to area where study is not offered	1/22 (4.5%)	3/61 (4.9%)	1/28 (3.6%)	1/7 (14.3%)
Prefer not to answer	0/22 (0.0%)	0/61 (0.0%)	0/28 (0.0%)	0/7 (0.0%)
Prefers TDF/FTC but not eligible for study–provided TDF/FTC	0/22 (0.0%)	0/61 (0.0%)	0/28 (0.0%)	0/7 (0.0%)
Other [3]	20/22 (90.9%)	58/61 (95.1%)	27/28 (96.4%)	5/7 (71.4%)
Don´t have product choice CRF and terminated	**24/210 (11.4%)**	**31/166 (18.7%)**	**36/156 (23.1%)**	**9/132 (6.8%)**
Not joined the OLE and termination pending	**0/210 (0.0%)**	**0/166 (0.0%)**	**0/156 (0.0%)**	**0/132 (0.0%)**

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Table 1Cii – OLE Enrollment Summary by Site: Latin America

	Lima – CITBM	Buenos Aires – Fundacion Huesped	Buenos Aires – Hospital JM Ramos Mejia	Sao Paulo – IC–HCFMUSP
Total enrollment in the primary study	**152**	**199**	**138**	**186**
Joined the OLE	52/152 (34.2%)	151/199 (75.9%)	109/138 (79.0%)	135/186 (72.6%)
Terminated from the study	100/152 (65.8%)	48/199 (24.1%)	29/138 (21.0%)	51/186 (27.4%)
Not joined the OLE and termination pending	0/152 (0.0%)	0/199 (0.0%)	0/138 (0.0%)	0/186 (0.0%)
Date site activated Protocol v4.0/v5.0/v6.0	20APR2023	02JUL2021	21OCT2021	17NOV2021
Date of first participant acceptance in the OLE [1]	24APR2023	05JUL2021	14OCT2021	23AUG2021
Not eligible for OLE [2]	**24**	**6**	**3**	**3**
Joined the OLE	0/24 (0.0%)	0/6 (0.0%)	0/3 (0.0%)	0/3 (0.0%)
Terminated from the study	24/24 (100.0%)	6/6 (100.0%)	3/3 (100.0%)	3/3 (100.0%)
Not joined the OLE and termination pending	0/24 (0.0%)	0/6 (0.0%)	0/3 (0.0%)	0/3 (0.0%)
Potentially eligible for OLE	**128**	**193**	**135**	**183**
Completed product choice CRF and joined the OLE	**52/128 (40.6%)**	**151/193 (78.2%)**	**109/135 (80.7%)**	**135/183 (73.8%)**
Completed product choice CRF and declined the OLE	**13/128 (10.2%)**	**33/193 (17.1%)**	**20/135 (14.8%)**	**46/183 (25.1%)**
Missing	0/13 (0.0%)	0/33 (0.0%)	0/20 (0.0%)	0/46 (0.0%)
Study participation too burdensome	3/13 (23.1%)	0/33 (0.0%)	0/20 (0.0%)	1/46 (2.2%)
Already accessed TDF/FTC through another mechanism	0/13 (0.0%)	1/33 (3.0%)	0/20 (0.0%)	1/46 (2.2%)
Prefer to take TAF/FTC	0/13 (0.0%)	1/33 (3.0%)	0/20 (0.0%)	0/46 (0.0%)
Relocating to area where study is not offered	0/13 (0.0%)	0/33 (0.0%)	4/20 (20.0%)	4/46 (8.7%)
Prefer not to answer	1/13 (7.7%)	0/33 (0.0%)	0/20 (0.0%)	0/46 (0.0%)
Prefers TDF/FTC but not eligible for study–provided TDF/FTC	1/13 (7.7%)	2/33 (6.1%)	2/20 (10.0%)	2/46 (4.3%)
Other [3]	8/13 (61.5%)	29/33 (87.9%)	14/20 (70.0%)	38/46 (82.6%)
Don´t have product choice CRF and terminated	**63/128 (49.2%)**	**9/193 (4.7%)**	**6/135 (4.4%)**	**2/183 (1.1%)**
Not joined the OLE and termination pending	**0/128 (0.0%)**	**0/193 (0.0%)**	**0/135 (0.0%)**	**0/183 (0.0%)**

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Table 1Ciii – OLE Enrollment Summary by Site: Asia

	Overall	Chiang Mai	Bangkok – Silom Clinic	Bangkok – Thai Red Cross	Hanoi
Total enrollment in the primary study	**752**	**140**	**203**	**210**	**199**
Joined the OLE	528/752 (70.2%)	90/140 (64.3%)	150/203 (73.9%)	145/210 (69.0%)	143/199 (71.9%)
Terminated from the study	224/752 (29.8%)	50/140 (35.7%)	53/203 (26.1%)	65/210 (31.0%)	56/199 (28.1%)
Not joined the OLE and termination pending	0/752 (0.0%)	0/140 (0.0%)	0/203 (0.0%)	0/210 (0.0%)	0/199 (0.0%)
Date site activated Protocol v4.0/v5.0/v6.0		14DEC2021	21OCT2022	03AUG2021	27AUG2021
Date of first participant acceptance in the OLE [1]		17DEC2021	25OCT2022	10AUG2021	30AUG2021
Not eligible for OLE [2]	**17**	**8**	**5**	**1**	**3**
Joined the OLE	0/17 (0.0%)	0/8 (0.0%)	0/5 (0.0%)	0/1 (0.0%)	0/3 (0.0%)
Terminated from the study	17/17 (100.0%)	8/8 (100.0%)	5/5 (100.0%)	1/1 (100.0%)	3/3 (100.0%)
Not joined the OLE and termination pending	0/17 (0.0%)	0/8 (0.0%)	0/5 (0.0%)	0/1 (0.0%)	0/3 (0.0%)
Potentially eligible for OLE	**735**	**132**	**198**	**209**	**196**
Completed product choice CRF and joined the OLE	**528/735 (71.8%)**	**90/132 (68.2%)**	**150/198 (75.8%)**	**145/209 (69.4%)**	**143/196 (73.0%)**
Completed product choice CRF and declined the OLE	**155/735 (21.1%)**	**23/132 (17.4%)**	**38/198 (19.2%)**	**54/209 (25.8%)**	**40/196 (20.4%)**
Missing	0/155 (0.0%)	0/23 (0.0%)	0/38 (0.0%)	0/54 (0.0%)	0/40 (0.0%)
Study participation too burdensome	11/155 (7.1%)	6/23 (26.1%)	1/38 (2.6%)	4/54 (7.4%)	0/40 (0.0%)
Already accessed TDF/FTC through another mechanism	0/155 (0.0%)	0/23 (0.0%)	0/38 (0.0%)	0/54 (0.0%)	0/40 (0.0%)
Prefer to take TAF/FTC	0/155 (0.0%)	0/23 (0.0%)	0/38 (0.0%)	0/54 (0.0%)	0/40 (0.0%)
Relocating to area where study is not offered	12/155 (7.7%)	5/23 (21.7%)	3/38 (7.9%)	2/54 (3.7%)	2/40 (5.0%)
Prefer not to answer	1/155 (0.6%)	0/23 (0.0%)	0/38 (0.0%)	1/54 (1.9%)	0/40 (0.0%)
Prefers TDF/FTC but not eligible for study–provided TDF/FTC	13/155 (8.4%)	6/23 (26.1%)	7/38 (18.4%)	0/54 (0.0%)	0/40 (0.0%)
Other [3]	118/155 (76.1%)	6/23 (26.1%)	27/38 (71.1%)	47/54 (87.0%)	38/40 (95.0%)
Don´t have product choice CRF and terminated	**52/735 (7.1%)**	**19/132 (14.4%)**	**10/198 (5.1%)**	**10/209 (4.8%)**	**13/196 (6.6%)**
Not joined the OLE and termination pending	**0/735 (0.0%)**	**0/132 (0.0%)**	**0/198 (0.0%)**	**0/209 (0.0%)**	**0/196 (0.0%)**

[1] Some participants appear to have been offered participation in the OLE prior to site activation. These participants had previously transferred to sites that are active under protocol v4/v5/v6, but per standard practice are reported under their enrolling site.
[2] Participants are potentially eligible for OLE if: site is approved for protocol v4/v5/v6, not HIV infected, not terminated prior to May 14, 2020, and not permanently discontinued study products prior to May 14, 2020 due to safety reasons (i.e. reactive HIV test, clinical or lab AE, ISR, CMC recommendation, Hepatitis B infections).
[3] See listing 1 for details regarding the reasons of 'other, specify'.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_enrl_bysite.sas, SAS Version 9.4 (04MAR2026,6:06)

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
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Table 1Civ – OLE Enrollment Summary by Site: Africa

	Overall	Cape Town
Total enrollment in the primary study	**152**	**152**
Joined the OLE	87/152 (57.2%)	87/152 (57.2%)
Terminated from the study	65/152 (42.8%)	65/152 (42.8%)
Not joined the OLE and termination pending	0/152 (0.0%)	0/152 (0.0%)
Date site activated Protocol v4.0/v5.0/v6.0		26AUG2021
Date of first participant acceptance in the OLE [1]		27AUG2021
Not eligible for OLE [2]	**15**	**15**
Joined the OLE	0/15 (0.0%)	0/15 (0.0%)
Terminated from the study	15/15 (100.0%)	15/15 (100.0%)
Not joined the OLE and termination pending	0/15 (0.0%)	0/15 (0.0%)
Potentially eligible for OLE	**137**	**137**
Completed product choice CRF and joined the OLE	**87/137 (63.5%)**	**87/137 (63.5%)**
Completed product choice CRF and declined the OLE	**35/137 (25.5%)**	**35/137 (25.5%)**
Missing	0/35 (0.0%)	0/35 (0.0%)
Study participation too burdensome	0/35 (0.0%)	0/35 (0.0%)
Already accessed TDF/FTC through another mechanism	0/35 (0.0%)	0/35 (0.0%)
Prefer to take TAF/FTC	0/35 (0.0%)	0/35 (0.0%)
Relocating to area where study is not offered	0/35 (0.0%)	0/35 (0.0%)
Prefer not to answer	0/35 (0.0%)	0/35 (0.0%)
Prefers TDF/FTC but not eligible for study–provided TDF/FTC	0/35 (0.0%)	0/35 (0.0%)
Other [3]	35/35 (100.0%)	35/35 (100.0%)
Don´t have product choice CRF and terminated	**15/137 (10.9%)**	**15/137 (10.9%)**
Not joined the OLE and termination pending	**0/137 (0.0%)**	**0/137 (0.0%)**

[1] Some participants appear to have been offered participation in the OLE prior to site activation. These participants had previously transferred to sites that are active under protocol v4/v5/v6, but per standard practice are reported under their enrolling site.
[2] Participants are potentially eligible for OLE if: site is approved for protocol v4/v5/v6, not HIV infected, not terminated prior to May 14, 2020, and not permanently discontinued study products prior to May 14, 2020 due to safety reasons (i.e. reactive HIV test, clinical or lab AE, ISR, CMC recommendation, Hepatitis B infections).
[3] See listing 1 for details regarding the reasons of 'other, specify'.

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Listing 1 – Listing of 'Other' Reasons of Not Joining the OLE

# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
1	US	Atlanta	709824645	Other	History of Grade 4 AEs; PI decision after CMC input
2	US	Atlanta	709891622	Other	Refused participation
3	US	Atlanta	709434749	Other	participant has been MIA over 1 year, and is over 3 years since enrollment. Participant is LTFU
4	US	Aurora	846372937	Other	Focusing on other health conditions at this time.
5	US	Aurora	846741185	Other	Investigator decision, participant showed persistently elevated LFTs
6	US	Aurora	846694875	Other	LTFU
7	US	Aurora	846134389	Other	Lost to follow up
8	US	Aurora	846150638	Other	Lost to follow up
9	US	Aurora	846179799	Other	Lost to follow up
10	US	Aurora	846201529	Other	Lost to follow up
11	US	Aurora	846369051	Other	Lost to follow up
12	US	Aurora	846414056	Other	Lost to follow up
13	US	Aurora	846449103	Other	Lost to follow up
14	US	Aurora	846461109	Other	Lost to follow up
15	US	Aurora	846488661	Other	Lost to follow up
16	US	Aurora	846573514	Other	Lost to follow up
17	US	Aurora	846796782	Other	Lost to follow up
18	US	Aurora	846831125	Other	Lost to follow up
19	US	Aurora	846944642	Other	Lost to follow up
20	US	Aurora	846614212	Other	Participant does not want to receive PrEP at this time
21	US	Aurora	846315219	Other	Participant is not eligible due to indeterminate HIV testing
22	US	Aurora	846593112	Other	Participant no longer at high risk of HIV, does not want to take PrEP
23	US	Baltimore	700494717	Other	LTFU
24	US	Baltimore	700544318	Other	LTFU
25	US	Baltimore	700555558	Other	LTFU
26	US	Baltimore	700792874	Other	LTFU
27	US	Baltimore	700807982	Other	LTFU
28	US	Baltimore	700827395	Other	LTFU
29	US	Baltimore	700832384	Other	LTFU
30	US	Baltimore	700969738	Other	LTFU
31	US	Baltimore	700969760	Other	LTFU
32	US	Baltimore	700866488	Other	Lost to follow–up
33	US	Birmingham	821400116	Other	LOST TO FOLLOW UP
34	US	Birmingham	821818199	Other	LOST TO FOLLOW–UP
35	US	Birmingham	821618332	Other	LTFU
36	US	Birmingham	821915504	Other	PPT LOST TO FOLLOW–UP

[1] This listing is sorted by region, site, 'other specify' text, and PTID.

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# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
37	US	Birmingham	821699245	Other	PREFER TAKING PILLS
38	US	Birmingham	821124510	Other	Participant is ineligible due to increased LFTs.
39	US	Birmingham	821830033	Other	Ppt is Lost to follow–up.
40	US	Birmingham	821952830	Other	Ppt is lost to follow–up
41	US	Birmingham	821102244	Other	ltfu
42	US	Boston	819223845	Other	LTFU
43	US	Boston	819360885	Other	LTFU
44	US	Boston	819367558	Other	LTFU
45	US	Boston	819369798	Other	LTFU
46	US	Boston	819507020	Other	LTFU
47	US	Boston	819549927	Other	LTFU
48	US	Boston	819552664	Other	LTFU
49	US	Boston	819781009	Other	LTFU
50	US	Boston	819794175	Other	LTFU
51	US	Boston	819842077	Other	LTFU
52	US	Boston	819851088	Other	LTFU
53	US	Boston	819865335	Other	LTFU
54	US	Boston	819185804	Other	Truvada works for me, I can access through PCP and I might not be at this location from much longer.
55	US	Boston	819365474	Other	lost to follow up
56	US	Boston	819901258	Other	withdrew consent due to lengthy travel to site
57	US	Bronx	734262664	Other	Participant lost in follow up
58	US	Bronx	734263855	Other	Participant lost in follow up
59	US	Bronx	734329488	Other	Participant lost in follow up
60	US	Bronx	734435957	Other	Participant lost in follow up
61	US	Bronx	734457560	Other	Participant lost in follow up
62	US	Bronx	734561128	Other	Participant lost in follow up
63	US	Bronx	734573938	Other	Participant lost in follow up
64	US	Bronx	734601217	Other	Participant lost in follow up
65	US	Bronx	734837506	Other	Participant lost in follow up
66	US	Bronx	734932026	Other	Participant was not eligible because study product was permanently discontinued in 11/19 due to Grade 4 AST& ALT
67	US	Bronx	734467607	Other	Participant with difficulties attending visits, he was lost in follow up visit regularly
68	US	Bronx	734276571	Other	Participant with more than 3 years of enrollment and lost in follow up; last seen 2/20/2020
69	US	Bronx	734562376	Other	ineligible
70	US	Bronx	734599504	Other	ineligible
71	US	Bronx	734945793	Other	ineligible

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Listing 1 – Listing of 'Other' Reasons of Not Joining the OLE

# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
72	US	Bronx	734431367	Other	ineligible to participate due to permanent product hold per CMC guidance
73	US	Bronx	734227260	Other	lost to follow up
74	US	Bronx	734640105	Other	lost to follow up
75	US	Bronx	734426190	Other	ppt was incarcerated
76	US	Bronx	734741165	Other	seroconverted, lost to follow up
77	US	Chapel Hill	706241346	Other	Did not like injections because they sometime hurt and he does not want to switch back to CAB.
78	US	Chapel Hill	706889533	Other	He is regularly donating plasma and not having sex. No need for PrEP and unable to be on experimental medication
79	US	Chapel Hill	706248714	Other	LTFU; contact attempts made with no follow–through by participant
80	US	Chapel Hill	706451903	Other	LTFU; participant moved out of state and has been lost to follow up for greater than 6 months
81	US	Chapel Hill	706463388	Other	LTFU; participant relocated and never signed consent at new site, lost to follow up
82	US	Chapel Hill	706470503	Other	Participant lost to follow up
83	US	Chapel Hill	706456323	Other	confirmed that he was not currently interested in being on PrEP as he was in a long–term committed (mutually monogamous) relationship
84	US	Chapel Hill	706503928	Other	other health priorities
85	US	Chapel Hill	706374842	Other	participant is lost to follow–up
86	US	Chapel Hill	706616993	Other	participant is lost to follow–up
87	US	Chapel Hill	706361048	Other	participant lost to follow up for greater than 6 months
88	US	Chapel Hill	706590848	Other	participant lost to follow up for greater than 6 months
89	US	Chapel Hill	706681687	Other	participant lost to follow–up
90	US	Chapel Hill	706103592	Other	site staff attempted to contact ppt about version 4.0 with no response, ppt LTF longer than 6 months
91	US	Chicago – AYAR	844226026	Other	LTFU
92	US	Chicago – AYAR	844622885	Other	LTFU
93	US	Chicago – AYAR	844774986	Other	LTFU
94	US	Chicago – AYAR	844360760	Other	LTFU since 2019
95	US	Chicago – AYAR	844907775	Other	Not moving forward due to prohibited medication. Pt can access Truvada through student health center at USC.
96	US	Chicago – AYAR	844474307	Other	n/a – ppt had completed seroconverter schedule prior to unblinding
97	US	Chicago – WISH	780193650	Other	LTFU
98	US	Chicago – WISH	780234491	Other	LTFU
99	US	Chicago – WISH	780367116	Other	LTFU
100	US	Chicago – WISH	780474973	Other	LTFU
101	US	Chicago – WISH	780555655	Other	LTFU

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# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
102	US	Chicago – WISH	780619743	Other	LTFU
103	US	Chicago – WISH	780722711	Other	LTFU
104	US	Chicago – WISH	780862068	Other	LTFU
105	US	Chicago – WISH	780879597	Other	LTFU
106	US	Chicago – WISH	780898066	Other	LTFU
107	US	Chicago – WISH	780926939	Other	LTFU
108	US	Chicago – WISH	780983373	Other	New daily schedule will not allow him to complete visits
109	US	Chicago – WISH	780179908	Other	No longer interested in participating
110	US	Chicago – WISH	780393842	Other	Participant refused without stating reason for termination
111	US	Chicago – WISH	780469054	Other	Stated he was no longer interested in study
112	US	Chicago – WISH	780761435	Other	Subject stated he was withdrawing for "personal reasons"
113	US	Chicago – WISH	780256569	Other	participant refused further participation without stating reason for termination
114	US	Cincinnati	847202609	Other	Does not wish to go on new version of protocol
115	US	Cincinnati	847378078	Other	LTFU
116	US	Cincinnati	847552916	Other	Lost to follow up
117	US	Cincinnati	847405800	Other	Participant decided to not proceed with the next phase of the study.
118	US	Cincinnati	847730737	Other	Participant does not wish to proceed on the protocol.
119	US	Cincinnati	847463261	Other	Participant refused further participation
120	US	Cincinnati	847728881	Other	Participant refused further participation
121	US	Cincinnati	847845429	Other	Participant refused further participation
122	US	Cincinnati	847660630	Other	Participant refused further particpation
123	US	Cincinnati	847684029	Other	Patient chose to come off study
124	US	Cincinnati	847176501	Other	Patient getting prescription from PCP for PREP
125	US	Cincinnati	847110854	Other	Patient refused further participation
126	US	Cincinnati	847665344	Other	Pt. LTFU
127	US	Cincinnati	847552215	Other	Pt. has been in jail and no contact has been made.
128	US	Cincinnati	847495603	Other	Pt. lost to follow up.
129	US	Cincinnati	847893444	Other	Pt. lost to follow–up
130	US	Cincinnati	847929517	Other	Pt. lost to follow–up
131	US	Cincinnati	847527471	Other	Pt. refused further participation
132	US	Cincinnati	847308777	Other	Pt. stopped meds due to prohibited med–could not continue on Version 4
133	US	Cincinnati	847126834	Other	loss to follow up
134	US	Cincinnati	847102279	Other	unable to reach patient, lost to follow up
135	US	Columbus	856407252	Other	LFTU
136	US	Columbus	856144172	Other	LTFU
137	US	Columbus	856176251	Other	LTFU

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Listing 1 – Listing of 'Other' Reasons of Not Joining the OLE

# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
138	US	Columbus	856255466	Other	LTFU
139	US	Columbus	856272375	Other	LTFU
140	US	Columbus	856297215	Other	LTFU
141	US	Columbus	856426179	Other	LTFU
142	US	Columbus	856458017	Other	LTFU
143	US	Columbus	856553919	Other	LTFU
144	US	Columbus	856559472	Other	LTFU
145	US	Columbus	856637736	Other	LTFU
146	US	Columbus	856650718	Other	LTFU
147	US	Columbus	856700555	Other	LTFU
148	US	Columbus	856798096	Other	LTFU
149	US	Columbus	856989635	Other	LTFU
150	US	Columbus	856995287	Other	LTFU
151	US	Columbus	856996402	Other	LTFU
152	US	Columbus	856512117	Other	Participant discontinued study medication . Does not want to continue study visits
153	US	Columbus	856541594	Other	Participant lost to follow up
154	US	Decatur	787103593	Other	Conflict with his work schedule and participant is out of window to continue with V4 , according with Lo # 3 (six months period)
155	US	Decatur	787380604	Other	Does not think he needs PrEP at the moment due to a committed relationship and does not want to start a new drug.
156	US	Decatur	787162515	Other	LTFU
157	US	Decatur	787322939	Other	LTFU
158	US	Decatur	787343738	Other	LTFU
159	US	Decatur	787383461	Other	LTFU
160	US	Decatur	787460260	Other	LTFU
161	US	Decatur	787803061	Other	LTFU
162	US	Decatur	787827011	Other	LTFU
163	US	Decatur	787864629	Other	LTFU
164	US	Decatur	787365333	Other	LTFU, not interested in CAB at last visit
165	US	Decatur	787113588	Other	LTFU>6 months
166	US	Decatur	787307317	Other	SAE made him ineligible
167	US	Decatur	787286948	Other	lost to follow up
168	US	Decatur	787159369	Other	ltfu
169	US	Decatur	787170589	Other	ltfu
170	US	Decatur	787240117	Other	ltfu
171	US	Decatur	787262918	Other	ltfu
172	US	Decatur	787444697	Other	ltfu
173	US	Decatur	787449477	Other	ltfu

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# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
174	US	Decatur	787464789	Other	ltfu
175	US	Decatur	787545826	Other	ltfu
176	US	Decatur	787626670	Other	ltfu
177	US	Decatur	787692578	Other	ltfu
178	US	Decatur	787764996	Other	ltfu
179	US	Decatur	787771850	Other	ltfu
180	US	Decatur	787785647	Other	ltfu
181	US	Decatur	787803072	Other	ltfu
182	US	Decatur	787383210	Other	not a candidate for CAB.
183	US	Greensboro	851543975	Other	LTFU, unable to contact after multiple attempts
184	US	Greensboro	851843574	Other	LTFU, unable to contact after several attempts. Terminated from study
185	US	Greensboro	851296091	Other	Participant LTFU
186	US	Greensboro	851158432	Other	Refused further participation
187	US	Greensboro	851272718	Other	Refused further participation
188	US	Greensboro	851837574	Other	Relocating to an area where study is not offered
189	US	Greensboro	851862263	Other	participant refused further participation
190	US	Greensboro	851328790	Other	participant refused further participation
191	US	Greensboro	851630206	Other	participant refused further participation
192	US	Greensboro	851648384	Other	participant refused further participation
193	US	Greensboro	851703642	Other	participant refused further participation
194	US	Greensboro	851728609	Other	participant refused further participation
195	US	Greensboro	851807867	Other	participant refused further participation
196	US	Greensboro	851870444	Other	participant refused further participation
197	US	Greensboro	851897011	Other	participant refused further participation
198	US	Greensboro	851899954	Other	participant refused further participation
199	US	Greensboro	851927426	Other	participant refused further participation
200	US	Greensboro	851948896	Other	participant refused further participation
201	US	Harlem	745893437	Other	Had liver discontinuation event
202	US	Harlem	745147156	Other	LTFU
203	US	Harlem	745165783	Other	LTFU
204	US	Harlem	745200909	Other	LTFU
205	US	Harlem	745248904	Other	LTFU
206	US	Harlem	745262175	Other	LTFU
207	US	Harlem	745458619	Other	LTFU
208	US	Harlem	745633565	Other	LTFU
209	US	Harlem	745717062	Other	LTFU
210	US	Harlem	745901707	Other	Seroconversion to HIV positive, CMC states not eligible for V4

[1] This listing is sorted by region, site, 'other specify' text, and PTID.

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# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
211	US	Harlem	745116084	Other	loss to follow up
212	US	Harlem	745210748	Other	loss to follow up
213	US	Harlem	745299234	Other	loss to follow up
214	US	Harlem	745469329	Other	loss to follow up
215	US	Harlem	745634394	Other	loss to follow up
216	US	Harlem	745652890	Other	loss to follow up
217	US	Harlem	745902542	Other	loss to follow up
218	US	Harlem	745909549	Other	loss to follow up
219	US	Houston	853190719	Other	LTFU
220	US	Houston	853197242	Other	LTFU
221	US	Houston	853548640	Other	LTFU
222	US	Houston	853166192	Other	Lost to follow up
223	US	Houston	853288447	Other	Lost to follow up
224	US	Houston	853864838	Other	Lost to follow up
225	US	Houston	853282588	Other	Participant refused further participation
226	US	Houston	853683633	Other	Participant refused further participation
227	US	Houston	853947797	Other	Participant refused further participation
228	US	Houston	853209223	Other	Unable to contact participant, participant LTFU
229	US	Los Angeles – UCLA Care	701188684	Other	LTFU–Site unable to contact participant
230	US	Los Angeles – UCLA Care	701414078	Other	LTFU–site no longer in contact with participant
231	US	Los Angeles – UCLA Care	701365188	Other	LTFU–site unable to reach participant
232	US	Los Angeles – UCLA Care	701330358	Other	LTFU–unable to contact participant
233	US	Los Angeles – UCLA Care	701700746	Other	LTFU–unable to contact participant
234	US	Los Angeles – UCLA Care	701639060	Other	LTFU–unable to schedule participant
235	US	Los Angeles – UCLA Care	701135812	Other	Not eligible for OLE due to multiple AEs
236	US	Los Angeles – UCLA Care	701316110	Other	lab abnormalities with CMC guidance
237	US	Los Angeles – UCLA Care	701879406	Other	participant withdrew from the study
238	US	Los Angeles – UCLA Vine	800320851	Other	In monogamous relationship and no longer taking PrEP
239	US	Los Angeles – UCLA Vine	800781851	Other	Moved away, and no contact for over a year.
240	US	Memphis	857183702	Other	LTFU
241	US	Memphis	857214972	Other	LTFU
242	US	Memphis	857264062	Other	LTFU
243	US	Memphis	857290311	Other	LTFU
244	US	Memphis	857376618	Other	LTFU
245	US	Memphis	857403020	Other	LTFU
246	US	Memphis	857433029	Other	LTFU
247	US	Memphis	857520423	Other	LTFU
248	US	Memphis	857531978	Other	LTFU

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# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
249	US	Memphis	857533664	Other	LTFU
250	US	Memphis	857784262	Other	LTFU
251	US	Memphis	857784330	Other	LTFU
252	US	Memphis	857812170	Other	LTFU
253	US	Memphis	857818975	Other	LTFU
254	US	Memphis	857836127	Other	LTFU
255	US	Memphis	857956211	Other	LTFU
256	US	Memphis	857968063	Other	LTFU
257	US	Memphis	857980959	Other	LTFU
258	US	Memphis	857996866	Other	LTFU
259	US	Memphis	857286516	Other	ppt LTFU
260	US	Memphis	857467965	Other	ppt refused further participation
261	US	Memphis	857102042	Other	ppt refuses further participation
262	US	Memphis	857551428	Other	unknown
263	US	New Orleans	855648650	Other	Investigator decision, after LTFU contact with participant for over a year.
264	US	New Orleans	855248450	Other	Investigator decision, after prolonged loss of contact. LTFU
265	US	New Orleans	855436485	Other	Lost contact for over a year.
266	US	New Orleans	855528046	Other	Lost follow up
267	US	New Orleans	855231671	Other	Lost to contact, after he did not follow through with transfer.
268	US	New Orleans	855239818	Other	Lost to follow–up, greater than 6 months.
269	US	New Orleans	855907917	Other	Lost to follow–up, greater than 6 months.
270	US	New Orleans	855285964	Other	Not eligible for OLE – On permanent product hold from Step 3.
271	US	New Orleans	855491645	Other	Over 6 months with no contact LTFU, after V 4.0 released
272	US	New Orleans	855893350	Other	Participant was LTFU. Not able to contact.
273	US	New Orleans	855807080	Other	Participant was on permanent product hold, and had been transitioned to annual visits. He completed yearly visit #2 in January, 2021.
274	US	New Orleans	855414175	Other	Personal choice not to continue. May start a vaccine research study
275	US	New Orleans	855716785	Other	Study drug discontinued in Step 2
276	US	New Orleans	855994776	Other	Wants to wait for more data on CAB
277	US	New Orleans	855103036	Other	participant MIA–Participant LTFU
278	US	New York – Blood Center	825225390	Other	LTFU
279	US	New York – Blood Center	825600676	Other	Lost to follow up
280	US	New York – Blood Center	825601219	Other	Lost to follow up
281	US	New York – Blood Center	825778248	Other	Lost to follow up

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# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
282	US	New York – Blood Center	825737002	Other	Subject had been lost to follow up for a long time. Per investigator decision, they were officially terminated at site on 12 October 2021.
283	US	New York – Blood Center	825968778	Other	Subject is lost to follow up.
284	US	New York – Blood Center	825423584	Other	Subject is not interested in continuing in the study because they are on prep.
285	US	New York – Blood Center	825127604	Other	Subject was unreachable and terminated as lost to follow up.
286	US	New York – Blood Center	825639331	Other	lost to follow up
287	US	New York – Weill Cornell Chelsea	712139645	Other	LOST TO FOLLOW UP
288	US	New York – Weill Cornell Chelsea	712205225	Other	Participant incarcerated in 2018
289	US	New York – Weill Cornell Chelsea	712131213	Other	Participant lost to follow up
290	US	New York – Weill Cornell Chelsea	712298897	Other	lost to follow up
291	US	New York – Weill Cornell Chelsea	712598165	Other	lost to follow up
292	US	New York – Weill Cornell Chelsea	712673048	Other	lost to follow up
293	US	New York – Weill Cornell Chelsea	712676272	Other	lost to follow up
294	US	New York – Weill Cornell Chelsea	712720979	Other	lost to follow up
295	US	New York – Weill Cornell Chelsea	712122445	Other	lost to follow up
296	US	New York – Weill Cornell Chelsea	712142444	Other	lost to follow up
297	US	New York – Weill Cornell Chelsea	712360481	Other	lost to follow up
298	US	New York – Weill Cornell Chelsea	712642818	Other	lost to follow up
299	US	New York – Weill Cornell Chelsea	712915957	Other	lost to follow up
300	US	New York – Weill Cornell Chelsea	712163271	Other	participant interested in receiving meds at local clinic
301	US	New York – Weill Cornell Chelsea	712940540	Other	participant lost to follow up
302	US	Newark	820243126	Other	Doesn't want study product. Just wants to get tested for HIV.
303	US	Newark	820783513	Other	Has trouble making appointment. Trouble communicating with staff due to phone insecurities. May not want to participate, but hasn't said.
304	US	Newark	820570918	Other	LTFU
305	US	Newark	820777370	Other	LTFU
306	US	Newark	820920907	Other	LTFU–Site unable to contact participant.
307	US	Newark	820310010	Other	LTFU: cannot reach participant
308	US	Newark	820179207	Other	Medical history of NSTEMI, on contraindicated meds currently, and moved to new location.
309	US	Newark	820661981	Other	Partner did not want him to do study.
310	US	Oakland	864749516	Other	Patient lost to follow up.
311	US	Oakland	864627546	Other	lost to follow up
312	US	Oakland	864682100	Other	per P4 – not eligible for Step 4 / 5
313	US	Oakland	864902221	Other	ppt not eligible
314	US	Philadelphia	863152485	Other	LTFU

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# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
315	US	Philadelphia	863182942	Other	LTFU
316	US	Philadelphia	863215117	Other	LTFU
317	US	Philadelphia	863251121	Other	LTFU
318	US	Philadelphia	863291171	Other	LTFU
319	US	Philadelphia	863575653	Other	LTFU
320	US	Philadelphia	863620658	Other	LTFU
321	US	Philadelphia	863799372	Other	LTFU
322	US	Philadelphia	863935471	Other	LTFU
323	US	Philadelphia	863207610	Other	Lost to follow–up, greater than 6 months.
324	US	Philadelphia	863175885	Other	unable to contact. Lost to Follow–Up
325	US	San Francisco	764962238	Other	Lost to follow–up. Had completed Step 3.
326	US	St. Louis	861911609	Other	LOST TO FOLLOW UP
327	US	St. Louis	861480768	Other	LTFU
328	US	St. Louis	861735847	Other	ineligible due to HBV infection
329	US	St. Louis	861107654	Other	lost to follow up
330	US	St. Louis	861156390	Other	lost to follow up
331	US	St. Louis	861164375	Other	lost to follow up
332	US	St. Louis	861189684	Other	lost to follow up
333	US	St. Louis	861192131	Other	lost to follow up
334	US	St. Louis	861260452	Other	lost to follow up
335	US	St. Louis	861267183	Other	lost to follow up
336	US	St. Louis	861310170	Other	lost to follow up
337	US	St. Louis	861368571	Other	lost to follow up
338	US	St. Louis	861389753	Other	lost to follow up
339	US	St. Louis	861439675	Other	lost to follow up
340	US	St. Louis	861516738	Other	lost to follow up
341	US	St. Louis	861519656	Other	lost to follow up
342	US	St. Louis	861556190	Other	lost to follow up
343	US	St. Louis	861605934	Other	lost to follow up
344	US	St. Louis	861624549	Other	lost to follow up
345	US	St. Louis	861637971	Other	lost to follow up
346	US	St. Louis	861656476	Other	lost to follow up
347	US	St. Louis	861708760	Other	lost to follow up
348	US	St. Louis	861727025	Other	lost to follow up
349	US	St. Louis	861805226	Other	lost to follow up
350	US	St. Louis	861908404	Other	lost to follow up
351	US	St. Louis	861943969	Other	lost to follow up
352	US	St. Louis	861968603	Other	lost to follow up

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# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
353	US	St. Louis	861260606	Other	participant withdrawn from study @ week 6
354	US	St. Louis	861677179	Other	study product–related AE
355	US	St. Louis	861382566	Other	unable to contact – LTFU
356	US	St. Louis	861546232	Other	unable to contact – LTFU
357	US	St. Louis	861786889	Other	unable to contact – LTFU
358	US	St. Louis	861231427	Other	withdrew consent
359	US	Washington, DC	801112226	Other	Lost to follow–up
360	US	Washington, DC	801172114	Other	Lost to follow–up
361	US	Washington, DC	801439021	Other	Lost to follow–up
362	US	Washington, DC	801622693	Other	Not interested in taking PrEP
363	US	Washington, DC	801203848	Other	Participant is not interested in continuing on CAB due to injection site pain.
364	US	Washington, DC	801387909	Other	Pt declines to continue due to injection site reactions.
365	Latin America	Buenos Aires – Fundacion Huesped	850253190	Other	1 year since lost to follow up
366	Latin America	Buenos Aires – Fundacion Huesped	850113341	Other	LTFU. More than six months has passed since the version 4 of the protocol was implemented, so the volunteer is not longer elegible
367	Latin America	Buenos Aires – Fundacion Huesped	850183761	Other	LTFU. More than six months has passed since the version 4 of the protocol was implemented, so the volunteer is not longer elegible
368	Latin America	Buenos Aires – Fundacion Huesped	850957989	Other	LTFU. More than six months passed from protocol 4.0 implementation
369	Latin America	Buenos Aires – Fundacion Huesped	850624474	Other	LTFU. Not elegible. More than six months passed from open label extension implementation
370	Latin America	Buenos Aires – Fundacion Huesped	850199975	Other	LTFU. Participant did not pass to OLE instance due to loss of tracking
371	Latin America	Buenos Aires – Fundacion Huesped	850484084	Other	Lost to Follow up
372	Latin America	Buenos Aires – Fundacion Huesped	850569306	Other	Lost to follow up
373	Latin America	Buenos Aires – Fundacion Huesped	850738547	Other	Participant lost to follow–up during the year 2021, it is decided to close his participation in the study.
374	Latin America	Buenos Aires – Fundacion Huesped	850117780	Other	The participant cannot enter version 4.0 of the protocol because he presented transaminases Grade 4 during acute HCV infection. The CMC was consulted
375	Latin America	Buenos Aires – Fundacion Huesped	850402042	Other	The participant did not make the Product Choice – OLE as it does not tolerate injections.
376	Latin America	Buenos Aires – Fundacion Huesped	850821692	Other	The patient was murdered on 10 May 2021, in the context of a femicide (trying to help a friend)
377	Latin America	Buenos Aires – Fundacion Huesped	850687301	Other	had an adverse event (increased triglycerides) and did not like how that event was handled
378	Latin America	Buenos Aires – Fundacion Huesped	850834266	Other	is not considered at risk of acquiring hiv
379	Latin America	Buenos Aires – Fundacion Huesped	850361834	Other	lost to follow up
380	Latin America	Buenos Aires – Fundacion Huesped	850389730	Other	lost to follow up
381	Latin America	Buenos Aires – Fundacion Huesped	850476060	Other	participant refused further participation

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# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
382	Latin America	Buenos Aires – Fundacion Huesped	850177915	Other	participant refused further participation
383	Latin America	Buenos Aires – Fundacion Huesped	850343698	Other	participant refused further participation
384	Latin America	Buenos Aires – Fundacion Huesped	850473652	Other	participant refused further participation
385	Latin America	Buenos Aires – Fundacion Huesped	850615656	Other	participant refused further participation
386	Latin America	Buenos Aires – Fundacion Huesped	850725126	Other	participant refused further participation
387	Latin America	Buenos Aires – Fundacion Huesped	850834009	Other	participant refused further participation
388	Latin America	Buenos Aires – Fundacion Huesped	850834433	Other	participant refused further participation
389	Latin America	Buenos Aires – Fundacion Huesped	850838985	Other	participant refused further participation
390	Latin America	Buenos Aires – Fundacion Huesped	850872206	Other	participant refused further participation
391	Latin America	Buenos Aires – Fundacion Huesped	850883332	Other	participant refused further participation
392	Latin America	Buenos Aires – Fundacion Huesped	850897796	Other	participant refused further participation
393	Latin America	Buenos Aires – Fundacion Huesped	850963681	Other	participant refused further participation
394	Latin America	Buenos Aires – Hospital JM Ramos Mejia	852876173	Other	Lost follow up
395	Latin America	Buenos Aires – Hospital JM Ramos Mejia	852144372	Other	Lost of follow up
396	Latin America	Buenos Aires – Hospital JM Ramos Mejia	852355934	Other	Lost of follow up
397	Latin America	Buenos Aires – Hospital JM Ramos Mejia	852906350	Other	Lost of follow up
398	Latin America	Buenos Aires – Hospital JM Ramos Mejia	852125621	Other	Lost to follow up
399	Latin America	Buenos Aires – Hospital JM Ramos Mejia	852360218	Other	Lost to follow up
400	Latin America	Buenos Aires – Hospital JM Ramos Mejia	852522561	Other	Lost to follow up
401	Latin America	Buenos Aires – Hospital JM Ramos Mejia	852569207	Other	Lost to follow up
402	Latin America	Buenos Aires – Hospital JM Ramos Mejia	852771045	Other	Lost to follow up
403	Latin America	Buenos Aires – Hospital JM Ramos Mejia	852977576	Other	Lost to follow up
404	Latin America	Buenos Aires – Hospital JM Ramos Mejia	852612910	Other	Participant decided to terminate his participation on the study
405	Latin America	Buenos Aires – Hospital JM Ramos Mejia	852938187	Other	Participant was in the cabotegravir arm, then went on a trip a year ago and start taking PREP on the trip. Participant come back to site and is considered not eligible for the OLE phase.
406	Latin America	Buenos Aires – Hospital JM Ramos Mejia	852331610	Other	lost to follow up
407	Latin America	Buenos Aires – Hospital JM Ramos Mejia	852659762	Other	lost to follow up
408	Latin America	Iquitos	732102017	Other	Lost to Follow up (LTFU)
409	Latin America	Iquitos	732237472	Other	Not permitted to participate in V5 due to study product discontinuation for AE.
410	Latin America	Iquitos	732237532	Other	Participant didn´t transfer to Step 2
411	Latin America	Iquitos	732280567	Other	Participant lost to follow up (LTFU)
412	Latin America	Iquitos	732327986	Other	Participant lost to follow up (LTFU)
413	Latin America	Iquitos	732329929	Other	Participant lost to follow up (LTFU)
414	Latin America	Iquitos	732335444	Other	Participant lost to follow up (LTFU)
415	Latin America	Iquitos	732336066	Other	Participant lost to follow up (LTFU)
416	Latin America	Iquitos	732372015	Other	Participant lost to follow up (LTFU)
417	Latin America	Iquitos	732393846	Other	Participant lost to follow up (LTFU)

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418	Latin America	Iquitos	732430787	Other	Participant lost to follow up (LTFU)
419	Latin America	Iquitos	732430811	Other	Participant lost to follow up (LTFU)
420	Latin America	Iquitos	732435189	Other	Participant lost to follow up (LTFU)
421	Latin America	Iquitos	732449666	Other	Participant lost to follow up (LTFU)
422	Latin America	Iquitos	732456599	Other	Participant lost to follow up (LTFU)
423	Latin America	Iquitos	732511403	Other	Participant lost to follow up (LTFU)
424	Latin America	Iquitos	732534947	Other	Participant lost to follow up (LTFU)
425	Latin America	Iquitos	732648679	Other	Participant lost to follow up (LTFU)
426	Latin America	Iquitos	732650429	Other	Participant lost to follow up (LTFU)
427	Latin America	Iquitos	732663589	Other	Participant lost to follow up (LTFU)
428	Latin America	Iquitos	732668674	Other	Participant lost to follow up (LTFU)
429	Latin America	Iquitos	732689910	Other	Participant lost to follow up (LTFU)
430	Latin America	Iquitos	732696737	Other	Participant lost to follow up (LTFU)
431	Latin America	Iquitos	732707333	Other	Participant lost to follow up (LTFU)
432	Latin America	Iquitos	732720601	Other	Participant lost to follow up (LTFU)
433	Latin America	Iquitos	732727261	Other	Participant lost to follow up (LTFU)
434	Latin America	Iquitos	732104621	Other	Participant lost to follow up (LTFU)
435	Latin America	Iquitos	732116410	Other	Participant lost to follow up (LTFU)
436	Latin America	Iquitos	732192385	Other	Participant lost to follow up (LTFU)
437	Latin America	Iquitos	732212865	Other	Participant lost to follow up (LTFU)
438	Latin America	Iquitos	732349674	Other	Participant lost to follow up (LTFU)
439	Latin America	Iquitos	732358105	Other	Participant lost to follow up (LTFU)
440	Latin America	Iquitos	732429768	Other	Participant lost to follow up (LTFU)
441	Latin America	Iquitos	732539751	Other	Participant lost to follow up (LTFU)
442	Latin America	Iquitos	732568844	Other	Participant lost to follow up (LTFU)
443	Latin America	Iquitos	732592030	Other	Participant lost to follow up (LTFU)
444	Latin America	Iquitos	732595879	Other	Participant lost to follow up (LTFU)
445	Latin America	Iquitos	732639709	Other	Participant lost to follow up (LTFU)
446	Latin America	Iquitos	732645093	Other	Participant lost to follow up (LTFU)
447	Latin America	Iquitos	732753126	Other	Participant lost to follow up (LTFU)
448	Latin America	Iquitos	732769047	Other	Participant lost to follow up (LTFU)
449	Latin America	Iquitos	732779072	Other	Participant lost to follow up (LTFU)
450	Latin America	Iquitos	732781683	Other	Participant lost to follow up (LTFU)
451	Latin America	Iquitos	732791000	Other	Participant lost to follow up (LTFU)
452	Latin America	Iquitos	732814608	Other	Participant lost to follow up (LTFU)
453	Latin America	Iquitos	732817826	Other	Participant lost to follow up (LTFU)
454	Latin America	Iquitos	732822630	Other	Participant lost to follow up (LTFU)
455	Latin America	Iquitos	732838176	Other	Participant lost to follow up (LTFU)

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# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
456	Latin America	Iquitos	732842827	Other	Participant lost to follow up (LTFU)
457	Latin America	Iquitos	732853341	Other	Participant lost to follow up (LTFU)
458	Latin America	Iquitos	732897154	Other	Participant lost to follow up (LTFU)
459	Latin America	Iquitos	732897909	Other	Participant lost to follow up (LTFU)
460	Latin America	Iquitos	732908324	Other	Participant lost to follow up (LTFU)
461	Latin America	Iquitos	732959954	Other	Participant lost to follow up (LTFU)
462	Latin America	Iquitos	732973700	Other	Participant lost to follow up (LTFU)
463	Latin America	Iquitos	732992370	Other	Participant lost to follow up (LTFU)
464	Latin America	Iquitos	732998988	Other	Participant lost to follow up (LTFU)
465	Latin America	Iquitos	732999583	Other	Participant lost to follow up (LTFU)
466	Latin America	Lima – Barranco	714918466	Other	ALT grade 3
467	Latin America	Lima – Barranco	714741595	Other	Antecedent of ALT G3
468	Latin America	Lima – Barranco	714670336	Other	Buttock aumentation procedures
469	Latin America	Lima – Barranco	714213443	Other	LTFU
470	Latin America	Lima – Barranco	714242966	Other	LTFU
471	Latin America	Lima – Barranco	714307126	Other	LTFU
472	Latin America	Lima – Barranco	714329173	Other	LTFU
473	Latin America	Lima – Barranco	714352576	Other	LTFU
474	Latin America	Lima – Barranco	714388076	Other	LTFU
475	Latin America	Lima – Barranco	714454459	Other	LTFU
476	Latin America	Lima – Barranco	714708248	Other	LTFU
477	Latin America	Lima – Barranco	714729834	Other	LTFU
478	Latin America	Lima – Barranco	714801886	Other	LTFU
479	Latin America	Lima – Barranco	714907513	Other	LTFU
480	Latin America	Lima – Barranco	714278573	Other	Lost to follow up
481	Latin America	Lima – Barranco	714373134	Other	Lost to follow up
482	Latin America	Lima – Barranco	714374634	Other	Lost to follow up
483	Latin America	Lima – Barranco	714669374	Other	Lost to follow up
484	Latin America	Lima – Barranco	714673152	Other	Lost to follow up
485	Latin America	Lima – Barranco	714785155	Other	Lost to follow up
486	Latin America	Lima – Barranco	714891446	Other	Persistent ALT grade 2
487	Latin America	Lima – Barranco	714141564	Other	antecedent of ALT G3
488	Latin America	Lima – Barranco	714687092	Other	not elegible for study for ALT grade 2 persistent
489	Latin America	Lima – Barranco	714847292	Other	not interested on ole
490	Latin America	Lima – Barranco	714274803	Other	ppt does not wish to participate in the OLE
491	Latin America	Lima – CITBM	848348125	Other	LTFU
492	Latin America	Lima – CITBM	848669179	Other	LTFU.
493	Latin America	Lima – CITBM	848555346	Other	Not eligible for CAB LA due to buttock fillers

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# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
494	Latin America	Lima – CITBM	848640146	Other	Participant lost to follow up (LTFU)
495	Latin America	Lima – CITBM	848992590	Other	Participant not eligible due to HIV infection
496	Latin America	Lima – CITBM	848523453	Other	participant not interested
497	Latin America	Lima – CITBM	848914922	Other	participant not interested in version 5
498	Latin America	Lima – CITBM	848732905	Other	participant refused further participation
499	Latin America	Lima – San Miguel	715354002	Other	Implants in both buttocks
500	Latin America	Lima – San Miguel	715272894	Other	Implants in the buttocks region
501	Latin America	Lima – San Miguel	715319429	Other	Participant is lost in follow–up
502	Latin America	Lima – San Miguel	715966107	Other	Participant is lost in follow–up
503	Latin America	Lima – San Miguel	715469785	Other	Participant is lost in follow–up
504	Latin America	Lima – San Miguel	715598884	Other	Participant is lost in the follow up
505	Latin America	Lima – San Miguel	715743222	Other	Participant is lost in the follow–up
506	Latin America	Lima – San Miguel	715875869	Other	Participant is lost in the follow–up
507	Latin America	Lima – San Miguel	715936735	Other	Participant is lost in the follow–up
508	Latin America	Lima – San Miguel	715209851	Other	Participant is not eligible for OLE due to an adverse event related to oral cabotegravir
509	Latin America	Lima – San Miguel	715395879	Other	Participant is not eligible for V5 by G4 lipase.
510	Latin America	Lima – San Miguel	715517678	Other	Participant lost to follow up (LTFU)
511	Latin America	Lima – San Miguel	715698923	Other	Participant withdrew consent by job reasons
512	Latin America	Lima – San Miguel	715147497	Other	The participant does not have time to attend the appointments for work reasons
513	Latin America	Lima – San Miguel	715805704	Other	The participant underwent a lipotransfer and was told by his private physician that he could not use injectables in the gluteal area for a period of 6 months to 1 year.
514	Latin America	Lima – San Miguel	715355731	Other	Withdraw informed consent due to work and personal reasons.
515	Latin America	Lima – San Miguel	715330321	Other	Withdraws consent for study reasons
516	Latin America	Lima – San Miguel	715817710	Other	Withdraws informed consent because He is out of town for work.
517	Latin America	Lima – San Miguel	715859555	Other	Withdraws informed consent due to work reasons.
518	Latin America	Lima – San Miguel	715795817	Other	Withdraws informed consent due work reasons.
519	Latin America	Lima – San Miguel	715409256	Other	adverse event related to injectable CAB
520	Latin America	Lima – San Miguel	715230498	Other	participant is lost in the follow–up
521	Latin America	Lima – San Miguel	715542228	Other	participant is lost in the follow–up
522	Latin America	Lima – San Miguel	715548106	Other	participant is lost in the follow–up
523	Latin America	Lima – San Miguel	715670854	Other	participant is lost in the follow–up
524	Latin America	Lima – San Miguel	715676787	Other	participant is lost in the follow–up
525	Latin America	Lima – San Miguel	715841698	Other	participant is lost in the follow–up
526	Latin America	Lima – San Miguel	715955794	Other	participant is lost in the follow–up
527	Latin America	Lima – San Miguel	715717285	Other	participant is not eligible for Adverse Event
528	Latin America	Lima – San Miguel	715605209	Other	withdraws his consent because he moved to another city

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# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
529	Latin America	Lima – San Miguel	715868010	Other	withdraws his consent because he moved to another city
530	Latin America	Lima – Via Libre	831636357	Other	ALT GRADE 4 BACKGROUND
531	Latin America	Lima – Via Libre	831478125	Other	HISTORY OF ALT GRADE 4
532	Latin America	Lima – Via Libre	831224091	Other	LFTU
533	Latin America	Lima – Via Libre	831143393	Other	LFTU
534	Latin America	Lima – Via Libre	831224408	Other	LFTU
535	Latin America	Lima – Via Libre	831294387	Other	LFTU
536	Latin America	Lima – Via Libre	831309827	Other	LFTU
537	Latin America	Lima – Via Libre	831548877	Other	LFTU
538	Latin America	Lima – Via Libre	831569871	Other	LFTU
539	Latin America	Lima – Via Libre	831643433	Other	LFTU
540	Latin America	Lima – Via Libre	831771318	Other	LFTU
541	Latin America	Lima – Via Libre	831793295	Other	LFTU
542	Latin America	Lima – Via Libre	831834643	Other	LFTU
543	Latin America	Lima – Via Libre	831856613	Other	LFTU
544	Latin America	Lima – Via Libre	831885485	Other	LFTU
545	Latin America	Lima – Via Libre	831906833	Other	LFTU
546	Latin America	Lima – Via Libre	831973630	Other	LFTU
547	Latin America	Lima – Via Libre	831570415	Other	LTFU
548	Latin America	Lima – Via Libre	831732447	Other	Partgicipant is not able to take part in OLE, because subjetc will travel abroad (Uruguay)
549	Latin America	Lima – Via Libre	831519775	Other	Participant cannot go to the site because it is outside the city of Lima.
550	Latin America	Lima – Via Libre	831715815	Other	Participant cannot go to the site for his work.
551	Latin America	Lima – Via Libre	831111431	Other	Participant is not eligible for this version 5.0
552	Latin America	Lima – Via Libre	831546741	Other	Participant is not eligible for version 5.0
553	Latin America	Lima – Via Libre	831865519	Other	Participant is not eligible for version 5.0
554	Latin America	Lima – Via Libre	831936764	Other	Participant lost to follow–up
555	Latin America	Lima – Via Libre	831446163	Other	not suitable for version 5.0
556	Latin America	Lima – Via Libre	831484766	Other	participant refused further participation
557	Latin America	Porto Alegre	722927174	Other	ALT INCREASED, GRADE 3
558	Latin America	Porto Alegre	722737345	Other	AST INCREASED, GRADE 2
559	Latin America	Porto Alegre	722276451	Other	Due to AE.
560	Latin America	Porto Alegre	722127302	Other	participant refused further participation
561	Latin America	Porto Alegre	722156075	Other	participant refused further participation
562	Latin America	Porto Alegre	722179103	Other	participant refused further participation
563	Latin America	Porto Alegre	722222547	Other	participant refused further participation
564	Latin America	Porto Alegre	722231508	Other	participant refused further participation

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# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
565	Latin America	Porto Alegre	722240244	Other	participant refused further participation
566	Latin America	Porto Alegre	722409777	Other	participant refused further participation
567	Latin America	Porto Alegre	722532317	Other	participant refused further participation
568	Latin America	Porto Alegre	722688701	Other	participant refused further participation
569	Latin America	Porto Alegre	722708852	Other	participant refused further participation
570	Latin America	Porto Alegre	722751252	Other	participant refused further participation
571	Latin America	Porto Alegre	722819657	Other	participant refused further participation
572	Latin America	Porto Alegre	722937339	Other	participant refused further participation
573	Latin America	Porto Alegre	722944278	Other	participant refused further participation
574	Latin America	Porto Alegre	722959472	Other	participant refused further participation
575	Latin America	Porto Alegre	722842791	Other	participant refused visit.
576	Latin America	Porto Alegre	722181116	Other	previous serious adverse event
577	Latin America	Rio de Janeiro	721694886	Other	Despite the desire of using the injection in order to prevent forgetting to take pills daily, the participant is ineligible for safety reasons – Hepatic Toxicity.
578	Latin America	Rio de Janeiro	721866760	Other	Does not want to take any sort of PrEP
579	Latin America	Rio de Janeiro	721919389	Other	Ineligibility criteria for Cabotegravir: Liver toxicity.
580	Latin America	Rio de Janeiro	721457690	Other	Ineligibility criteria to Cabotegravir: Clinical AE
581	Latin America	Rio de Janeiro	721282766	Other	Ineligibility criteria to Cabotegravir: Clinical AE –Liver Steatosis and Liver Fibrosis.
582	Latin America	Rio de Janeiro	721534736	Other	Ineligibility criteria to Cabotegravir: LAB AE
583	Latin America	Rio de Janeiro	721139256	Other	Ineligibility criteria to Cabotegravir: Liver toxicity.
584	Latin America	Rio de Janeiro	721805804	Other	Ineligibility criteria to Cabotegravir: Liver toxicity.
585	Latin America	Rio de Janeiro	721344504	Other	Lost of follow up. Positive HIV result.
586	Latin America	Rio de Janeiro	721281006	Other	Lost to follow up.
587	Latin America	Rio de Janeiro	721142923	Other	Lost to follow up.
588	Latin America	Rio de Janeiro	721160382	Other	Lost to follow up.
589	Latin America	Rio de Janeiro	721236831	Other	Lost to follow up.
590	Latin America	Rio de Janeiro	721496409	Other	Lost to follow up.
591	Latin America	Rio de Janeiro	721521545	Other	Lost to follow up.
592	Latin America	Rio de Janeiro	721541728	Other	Lost to follow up.
593	Latin America	Rio de Janeiro	721594821	Other	Lost to follow up.
594	Latin America	Rio de Janeiro	721685768	Other	Lost to follow up.
595	Latin America	Rio de Janeiro	721771355	Other	Lost to follow up.
596	Latin America	Rio de Janeiro	721807859	Other	Lost to follow up.
597	Latin America	Rio de Janeiro	721819032	Other	Lost to follow up.
598	Latin America	Rio de Janeiro	721968332	Other	Lost to follow up.

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# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
599	Latin America	Rio de Janeiro	721492323	Other	Not elegible – The participant returned to the site for a study visit beyond six months after the Version 4.0 implementation date. LTFU.
600	Latin America	Rio de Janeiro	721574937	Other	Not elegible – The participant returned to the site for a study visit beyond six months after the Version 4.0 implementation date. LTFU.
601	Latin America	Rio de Janeiro	721297848	Other	Not elegible. The participant returned to the site beyond six months from the date Version 4.0 implementation. LTFU.
602	Latin America	Rio de Janeiro	721205029	Other	Not elegible.The participant returned to the site beyond six months from the date of Version 4.0 implementation. LTFU.
603	Latin America	Rio de Janeiro	721245958	Other	Not elegible.The participant returned to the site beyond six months from the date of Version 4.0 implementation. LTFU.
604	Latin America	Rio de Janeiro	721701650	Other	Not elegible.The participant returned to the site beyond six months from the date of Version 4.0 implementation. LTFU.
605	Latin America	Rio de Janeiro	721978639	Other	Not elegible.The participant returned to the site beyond six months from the date of Version 4.0 implementation. LTFU.
606	Latin America	Rio de Janeiro	721832013	Other	Not elegible.The participant returned to the site for a study visit beyond six months from the date of Version 4.0 implementation. LTFU.
607	Latin America	Rio de Janeiro	721238075	Other	The participant returned to the site after six months from the Version 4.0 implementation date. So, ineligible. LTFU.
608	Latin America	Rio de Janeiro	721570013	Other	The participant returned to the site after six months from the Version 4.0 implementation date. LTFU.
609	Latin America	Rio de Janeiro	721424274	Other	The participant returned to the site after six months from the Version 4.0 implementation date. LTFU.
610	Latin America	Rio de Janeiro	721504803	Other	The participant returned to the site after six months from the Version 4.0 implementation date. LTFU.
611	Latin America	Sao Paulo – DST–AIDS	845422597	Other	LTFU
612	Latin America	Sao Paulo – DST–AIDS	845909293	Other	Participant refused further participation.
613	Latin America	Sao Paulo – DST–AIDS	845139497	Other	Seroconverter. Stopped the study before the protocol version 4.0
614	Latin America	Sao Paulo – DST–AIDS	845576791	Other	Since 24–Mar–2020 participant permanently discontinued study medication due to Laboratory AE (protocol mandated).
615	Latin America	Sao Paulo – DST–AIDS	845618548	Other	participant withdraw consent.
616	Latin America	Sao Paulo – IC–HCFMUSP	860401591	Other	ALT elevation G3
617	Latin America	Sao Paulo – IC–HCFMUSP	860479938	Other	Due to ALT G3
618	Latin America	Sao Paulo – IC–HCFMUSP	860416201	Other	Hepatite C
619	Latin America	Sao Paulo – IC–HCFMUSP	860764688	Other	Hepatitis B
620	Latin America	Sao Paulo – IC–HCFMUSP	860288359	Other	Hepatitis C
621	Latin America	Sao Paulo – IC–HCFMUSP	860844055	Other	Hepatitis C
622	Latin America	Sao Paulo – IC–HCFMUSP	860761278	Other	Hepatitis c
623	Latin America	Sao Paulo – IC–HCFMUSP	860286090	Other	Ineligibility criteria to Cabotegravir: Clinical AE
624	Latin America	Sao Paulo – IC–HCFMUSP	860259836	Other	Injection stie reaction

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# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
625	Latin America	Sao Paulo – IC–HCFMUSP	860507434	Other	Lost follow up
626	Latin America	Sao Paulo – IC–HCFMUSP	860767740	Other	Lost follow up
627	Latin America	Sao Paulo – IC–HCFMUSP	860107330	Other	Lost follow up
628	Latin America	Sao Paulo – IC–HCFMUSP	860142013	Other	Lost follow up
629	Latin America	Sao Paulo – IC–HCFMUSP	860180244	Other	Lost follow up
630	Latin America	Sao Paulo – IC–HCFMUSP	860252238	Other	Lost follow up
631	Latin America	Sao Paulo – IC–HCFMUSP	860255446	Other	Lost follow up
632	Latin America	Sao Paulo – IC–HCFMUSP	860308292	Other	Lost follow up
633	Latin America	Sao Paulo – IC–HCFMUSP	860319802	Other	Lost follow up
634	Latin America	Sao Paulo – IC–HCFMUSP	860664218	Other	Lost follow up
635	Latin America	Sao Paulo – IC–HCFMUSP	860806454	Other	Lost follow up
636	Latin America	Sao Paulo – IC–HCFMUSP	860851064	Other	Lost follow up
637	Latin America	Sao Paulo – IC–HCFMUSP	860980589	Other	Lost follow up
638	Latin America	Sao Paulo – IC–HCFMUSP	860792119	Other	Lost follow–up
639	Latin America	Sao Paulo – IC–HCFMUSP	860912134	Other	Lost follow–up
640	Latin America	Sao Paulo – IC–HCFMUSP	860516070	Other	Lost of follow up
641	Latin America	Sao Paulo – IC–HCFMUSP	860313675	Other	Lost to follow up
642	Latin America	Sao Paulo – IC–HCFMUSP	860447208	Other	Lost to follow up
643	Latin America	Sao Paulo – IC–HCFMUSP	860917836	Other	Lost to follow up
644	Latin America	Sao Paulo – IC–HCFMUSP	860924868	Other	Lost to follow up
645	Latin America	Sao Paulo – IC–HCFMUSP	860775664	Other	Not elegible for stage migration
646	Latin America	Sao Paulo – IC–HCFMUSP	860335916	Other	Participant did not attend within 6 months from version 4 implementation and also due to ALT grade 3.
647	Latin America	Sao Paulo – IC–HCFMUSP	860215450	Other	Prior request to discontinue the study product due to ISR
648	Latin America	Sao Paulo – IC–HCFMUSP	860775759	Other	Prior request to discontinue the study product due to ISR
649	Latin America	Sao Paulo – IC–HCFMUSP	860416799	Other	Transition to step 3 due ISR
650	Latin America	Sao Paulo – IC–HCFMUSP	860586557	Other	lost to follow up
651	Latin America	Sao Paulo – IC–HCFMUSP	860767068	Other	lost to follow up
652	Latin America	Sao Paulo – IC–HCFMUSP	860634914	Other	lost to follow–up
653	Latin America	Sao Paulo – IC–HCFMUSP	860486623	Other	prior request to discontinue the study product due to ISR
654	Asia	Bangkok – Silom Clinic	813578766	Other	Participant is busy at work and participant refuses to come to in–person re–consent or remote re–consent and refuses to get any further information about the study
655	Asia	Bangkok – Silom Clinic	813340517	Other	CMC was not allowed to join the 083 OLE due to prior AEs requiring study discontinuation.
656	Asia	Bangkok – Silom Clinic	813622710	Other	CMC was not allowed to join the 083 OLE due to prior G3 ALT.
657	Asia	Bangkok – Silom Clinic	813998856	Other	HIV–infected participant

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# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
658	Asia	Bangkok – Silom Clinic	813657866	Other	He moved to work in his hometown (Chiang Rai Province), and he refuses to come to in–person re–consent or remote re–consent and refuses to get any further information about the study.
659	Asia	Bangkok – Silom Clinic	813844195	Other	He moved to work in his hometown (Suphan Buri Province), and he refuses to come to in–person re–consent or remote re–consent and refuses to get any further information about the study.
660	Asia	Bangkok – Silom Clinic	813180230	Other	He was still working in his hometown so he cannot visit to SCC. Participant refuses to come to in–person re–consent or remote re–consent and refuses to get any further information about the study.
661	Asia	Bangkok – Silom Clinic	813950556	Other	Participant busy with his work so he cannot visit to SCC and participant refuses to come to in–person re–consent or remote re–consent and refuses to get any further information about the study.
662	Asia	Bangkok – Silom Clinic	813468517	Other	Participant did not report any history of liver disease at enrollment, so this is considered a "participant driven" deviation, and this is still technically an enrollment violation.
663	Asia	Bangkok – Silom Clinic	813606907	Other	Participant refused due to having low risk sexual behavior
664	Asia	Bangkok – Silom Clinic	813828970	Other	Participant refuses to come to in–person re–consent or remote re–consent and refuses to get any further information about the study
665	Asia	Bangkok – Silom Clinic	813881703	Other	Participant refuses to come to in–person re–consent or remote re–consent and refuses to get any further information about the study
666	Asia	Bangkok – Silom Clinic	813946000	Other	Participant refuses to come to in–person re–consent or remote re–consent and refuses to get any further information about the study
667	Asia	Bangkok – Silom Clinic	813752955	Other	Participant was busy with her work so she cannot visit to SCC and participant refuses to come to in–person re–consent or remote re–consent and refuses to get any further information about the study.
668	Asia	Bangkok – Silom Clinic	813547784	Other	Participant was busy with his work and not available to return for study follow up visit
669	Asia	Bangkok – Silom Clinic	813659119	Other	Participant was busy with his work and not available to return for study follow up visit.
670	Asia	Bangkok – Silom Clinic	813139636	Other	Participant was busy with his work so he cannot visit to SCC. Participant refuses to come to in–person re–consent or remote re–consent and refuses to get any further information about the study.
671	Asia	Bangkok – Silom Clinic	813784420	Other	Participant wasn't allowed to go on CAB–LA in the OLE due to liver–related discontinuation event.
672	Asia	Bangkok – Silom Clinic	813124029	Other	She moved to study and work in Australia, and she refuses to come to in–person re–consent or remote re–consent and refuses to get any further information about the study.
673	Asia	Bangkok – Silom Clinic	813705857	Other	She still lives in Uttaradit and still busy with her work. Participant refuses to come to in–person re–consent or remote re–consent and refuses to get any further information about the study.

[1] This listing is sorted by region, site, 'other specify' text, and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_enrl.sas, SAS Version 9.4 (04MAR2026,6:06)

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
OLE Open Report – March 4, 2026
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Listing 1 – Listing of 'Other' Reasons of Not Joining the OLE

# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
674	Asia	Bangkok – Silom Clinic	813224847	Other	She was busy with her work so she cannot visit to SCC. Participant refuses to come to in–person re–consent or remote re–consent and refuses to get any further information about the study.
675	Asia	Bangkok – Silom Clinic	813242333	Other	She was busy with her work so she cannot visit to SCC. Participant refuses to come to in–person re–consent or remote re–consent and refuses to get any further information about the study.
676	Asia	Bangkok – Silom Clinic	813422178	Other	She was busy with her work so she cannot visit to SCC. Participant refuses to come to in–person re–consent or remote re–consent and refuses to get any further information about the study.
677	Asia	Bangkok – Silom Clinic	813294816	Other	The participant moved to live in Spain and refused to come to in–person re–consent or re–mote re–consent and refused to get any further information about the study.
678	Asia	Bangkok – Silom Clinic	813125500	Other	The participant was terminated because she moved to work in Oman, and she refuses to come to in–person re–consent or remote re–consent and refuses to get any further information about the study.
679	Asia	Bangkok – Silom Clinic	813709010	Other	unable to contact participant.
680	Asia	Bangkok – Silom Clinic	813794895	Other	unable to contact participant.
681	Asia	Bangkok – Thai Red Cross	858425459	Other	AST & ALT grade 3 due to Acute HAV infection
682	Asia	Bangkok – Thai Red Cross	858152625	Other	LTFU
683	Asia	Bangkok – Thai Red Cross	858894999	Other	LTFU
684	Asia	Bangkok – Thai Red Cross	858114511	Other	LTFU
685	Asia	Bangkok – Thai Red Cross	858128976	Other	LTFU
686	Asia	Bangkok – Thai Red Cross	858132888	Other	LTFU
687	Asia	Bangkok – Thai Red Cross	858139804	Other	LTFU
688	Asia	Bangkok – Thai Red Cross	858167003	Other	LTFU
689	Asia	Bangkok – Thai Red Cross	858192915	Other	LTFU
690	Asia	Bangkok – Thai Red Cross	858238098	Other	LTFU
691	Asia	Bangkok – Thai Red Cross	858280250	Other	LTFU
692	Asia	Bangkok – Thai Red Cross	858306434	Other	LTFU
693	Asia	Bangkok – Thai Red Cross	858322541	Other	LTFU
694	Asia	Bangkok – Thai Red Cross	858370642	Other	LTFU
695	Asia	Bangkok – Thai Red Cross	858397259	Other	LTFU
696	Asia	Bangkok – Thai Red Cross	858408393	Other	LTFU
697	Asia	Bangkok – Thai Red Cross	858446505	Other	LTFU
698	Asia	Bangkok – Thai Red Cross	858450476	Other	LTFU
699	Asia	Bangkok – Thai Red Cross	858482957	Other	LTFU
700	Asia	Bangkok – Thai Red Cross	858489954	Other	LTFU
701	Asia	Bangkok – Thai Red Cross	858490291	Other	LTFU

[1] This listing is sorted by region, site, 'other specify' text, and PTID.

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Listing 1 – Listing of 'Other' Reasons of Not Joining the OLE

# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
702	Asia	Bangkok – Thai Red Cross	858533377	Other	LTFU
703	Asia	Bangkok – Thai Red Cross	858544532	Other	LTFU
704	Asia	Bangkok – Thai Red Cross	858551546	Other	LTFU
705	Asia	Bangkok – Thai Red Cross	858555591	Other	LTFU
706	Asia	Bangkok – Thai Red Cross	858567521	Other	LTFU
707	Asia	Bangkok – Thai Red Cross	858581703	Other	LTFU
708	Asia	Bangkok – Thai Red Cross	858585632	Other	LTFU
709	Asia	Bangkok – Thai Red Cross	858601207	Other	LTFU
710	Asia	Bangkok – Thai Red Cross	858665617	Other	LTFU
711	Asia	Bangkok – Thai Red Cross	858686304	Other	LTFU
712	Asia	Bangkok – Thai Red Cross	858770692	Other	LTFU
713	Asia	Bangkok – Thai Red Cross	858826883	Other	LTFU
714	Asia	Bangkok – Thai Red Cross	858845152	Other	LTFU
715	Asia	Bangkok – Thai Red Cross	858850851	Other	LTFU
716	Asia	Bangkok – Thai Red Cross	858930670	Other	LTFU
717	Asia	Bangkok – Thai Red Cross	858934619	Other	LTFU
718	Asia	Bangkok – Thai Red Cross	858938206	Other	LTFU
719	Asia	Bangkok – Thai Red Cross	858950962	Other	LTFU
720	Asia	Bangkok – Thai Red Cross	858964214	Other	LTFU
721	Asia	Bangkok – Thai Red Cross	858992492	Other	LTFU
722	Asia	Bangkok – Thai Red Cross	858994871	Other	LTFU
723	Asia	Bangkok – Thai Red Cross	858867054	Other	Not eligible for OLE due to AE elevated ALT
724	Asia	Bangkok – Thai Red Cross	858484118	Other	Not eligible for OLE due to AE elevated ALT SP related
725	Asia	Bangkok – Thai Red Cross	858973767	Other	Not eligible for OLE due to AE elevated ALT SP related
726	Asia	Bangkok – Thai Red Cross	858278331	Other	Not eligible for OLE due to AE status Epilepticus related to stress
727	Asia	Bangkok – Thai Red Cross	858989797	Other	Participant concerned about side effect of study medication, participant not come to clinic every visit.
728	Asia	Chiang Mai	791515328	Other	Beyond six months from date of version 4.0 implementation (ppt was ineligible because they were LTFU)
729	Asia	Chiang Mai	791672337	Other	Lost to follow up more than 6 months.
730	Asia	Chiang Mai	791779835	Other	beyond six months from date of version 4.0 implementation(ppt was ineligible because they were LTFU)
731	Asia	Chiang Mai	791495884	Other	beyond six months from date of version 4.0 implementation(ppt was ineligible because they were LTFU)
732	Asia	Chiang Mai	791797466	Other	beyond six months from date of version 4.0 implementation(ppt was ineligible because they were LTFU)
733	Asia	Chiang Mai	791613454	Other	participant incarcerated
734	Asia	Hanoi	862698946	Other	Due to Drug side effects
735	Asia	Hanoi	862256581	Other	Participant does not want to use drug

[1] This listing is sorted by region, site, 'other specify' text, and PTID.

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Listing 1 – Listing of 'Other' Reasons of Not Joining the OLE

# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
736	Asia	Hanoi	862565583	Other	Participant got Hepatitis B virus, so he does not eligible to participate in the study.
737	Asia	Hanoi	862210066	Other	The participant did not want to participate further in the study
738	Asia	Hanoi	862408226	Other	The participant did not want to participate further in the study
739	Asia	Hanoi	862691858	Other	The participant did not want to participate further in the study
740	Asia	Hanoi	862830019	Other	The participant did not want to participate further in the study
741	Asia	Hanoi	862124348	Other	The participant did not want to participate in the study
742	Asia	Hanoi	862234012	Other	The participant did not want to participate in the study
743	Asia	Hanoi	862381804	Other	The participant did not want to participate in the study
744	Asia	Hanoi	862388390	Other	The participant did not want to participate in the study
745	Asia	Hanoi	862452134	Other	The participant did not want to participate in the study
746	Asia	Hanoi	862468589	Other	The participant did not want to participate in the study
747	Asia	Hanoi	862584301	Other	The participant did not want to participate in the study
748	Asia	Hanoi	862637142	Other	The participant did not want to participate in the study
749	Asia	Hanoi	862910520	Other	The participant did not want to participate in the study
750	Asia	Hanoi	862582733	Other	The participant died
751	Asia	Hanoi	862890566	Other	The participant goes to jail
752	Asia	Hanoi	862219171	Other	The participant has concerned about the effects of study product on health
753	Asia	Hanoi	862296163	Other	The participant is not eligible to move to OLE due to AE#12 Increased ALT
754	Asia	Hanoi	862181271	Other	The participant refused further participation
755	Asia	Hanoi	862281155	Other	The participant refused further participation
756	Asia	Hanoi	862306531	Other	The participant refused further participation
757	Asia	Hanoi	862576707	Other	The participant refused further participation
758	Asia	Hanoi	862612748	Other	The participant refused further participation
759	Asia	Hanoi	862131141	Other	The participant refused to participate in the study
760	Asia	Hanoi	862209992	Other	The participant refused to participate in the study
761	Asia	Hanoi	862386725	Other	The participant refused to participate in the study
762	Asia	Hanoi	862404318	Other	The participant refused to participate in the study
763	Asia	Hanoi	862411525	Other	The participant refused to participate in the study
764	Asia	Hanoi	862458875	Other	The participant refused to participate in the study
765	Asia	Hanoi	862855885	Other	The participant refused to participate in the study
766	Asia	Hanoi	862484541	Other	The paticipant does not want to use CAB
767	Asia	Hanoi	862183310	Other	The paticipant does not want to use study product
768	Asia	Hanoi	862325761	Other	The paticipant does not want to use study product
769	Asia	Hanoi	862780582	Other	The paticipant does not want to use study product
770	Asia	Hanoi	862220760	Other	The paticipant does not want to use study product.

[1] This listing is sorted by region, site, 'other specify' text, and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_enrl.sas, SAS Version 9.4 (04MAR2026,6:06)

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
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Listing 1 – Listing of 'Other' Reasons of Not Joining the OLE

# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
771	Asia	Hanoi	862755882	Other	The paticipant does not want to use study product.
772	Africa	Cape Town	816219263	Other	LTFU
773	Africa	Cape Town	816444054	Other	LTFU
774	Africa	Cape Town	816111182	Other	LTFU more than 6 months
775	Africa	Cape Town	816112303	Other	LTFU more than 6 months
776	Africa	Cape Town	816119482	Other	LTFU more than 6 months
777	Africa	Cape Town	816150389	Other	LTFU more than 6 months
778	Africa	Cape Town	816167268	Other	LTFU more than 6 months
779	Africa	Cape Town	816182705	Other	LTFU more than 6 months
780	Africa	Cape Town	816289847	Other	LTFU more than 6 months
781	Africa	Cape Town	816433926	Other	LTFU more than 6 months
782	Africa	Cape Town	816467162	Other	LTFU more than 6 months
783	Africa	Cape Town	816482825	Other	LTFU more than 6 months
784	Africa	Cape Town	816556648	Other	LTFU more than 6 months
785	Africa	Cape Town	816610565	Other	LTFU more than 6 months
786	Africa	Cape Town	816660563	Other	LTFU more than 6 months
787	Africa	Cape Town	816677377	Other	LTFU more than 6 months
788	Africa	Cape Town	816700330	Other	LTFU more than 6 months
789	Africa	Cape Town	816711926	Other	LTFU more than 6 months
790	Africa	Cape Town	816727711	Other	LTFU more than 6 months
791	Africa	Cape Town	816744606	Other	LTFU more than 6 months
792	Africa	Cape Town	816782752	Other	LTFU more than 6 months
793	Africa	Cape Town	816834849	Other	LTFU more than 6 months
794	Africa	Cape Town	816846206	Other	LTFU more than 6 months
795	Africa	Cape Town	816870658	Other	LTFU more than 6 months
796	Africa	Cape Town	816898366	Other	LTFU more than 6 months
797	Africa	Cape Town	816910281	Other	LTFU more than 6 months
798	Africa	Cape Town	816922218	Other	LTFU more than 6 months
799	Africa	Cape Town	816940158	Other	LTFU more than 6 months
800	Africa	Cape Town	816806813	Other	PArticipant transitioned early to Step 3 due to needle phobia. Ineligible for OLE
801	Africa	Cape Town	816327179	Other	Participant will not continue on version 4 of the Protocol
802	Africa	Cape Town	816783046	Other	Participant will not continue on version 4 of the Protocol
803	Africa	Cape Town	816839199	Other	Participants completed the study in 2019. The study product Hold was initiated on 15 Jun 2018 due to abnormal lab results. Therefore, He was not eligible to go to the next Phase.
804	Africa	Cape Town	816731099	Other	Ppt completed study and was LTFU and not contactable

[1] This listing is sorted by region, site, 'other specify' text, and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_enrl.sas, SAS Version 9.4 (04MAR2026,6:06)

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
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Listing 1 – Listing of 'Other' Reasons of Not Joining the OLE

# [1]	Region	Site	Participant ID	Reason not moving to OLE	Other, Specify
805	Africa	Cape Town	816626807	Other	Ppt ineligible for OLE
806	Africa	Cape Town	816351063	Other	scheduled exit visit/end of study and did not wish to continue

[1] This listing is sorted by region, site, 'other specify' text, and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_enrl.sas, SAS Version 9.4 (04MAR2026,6:06)

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

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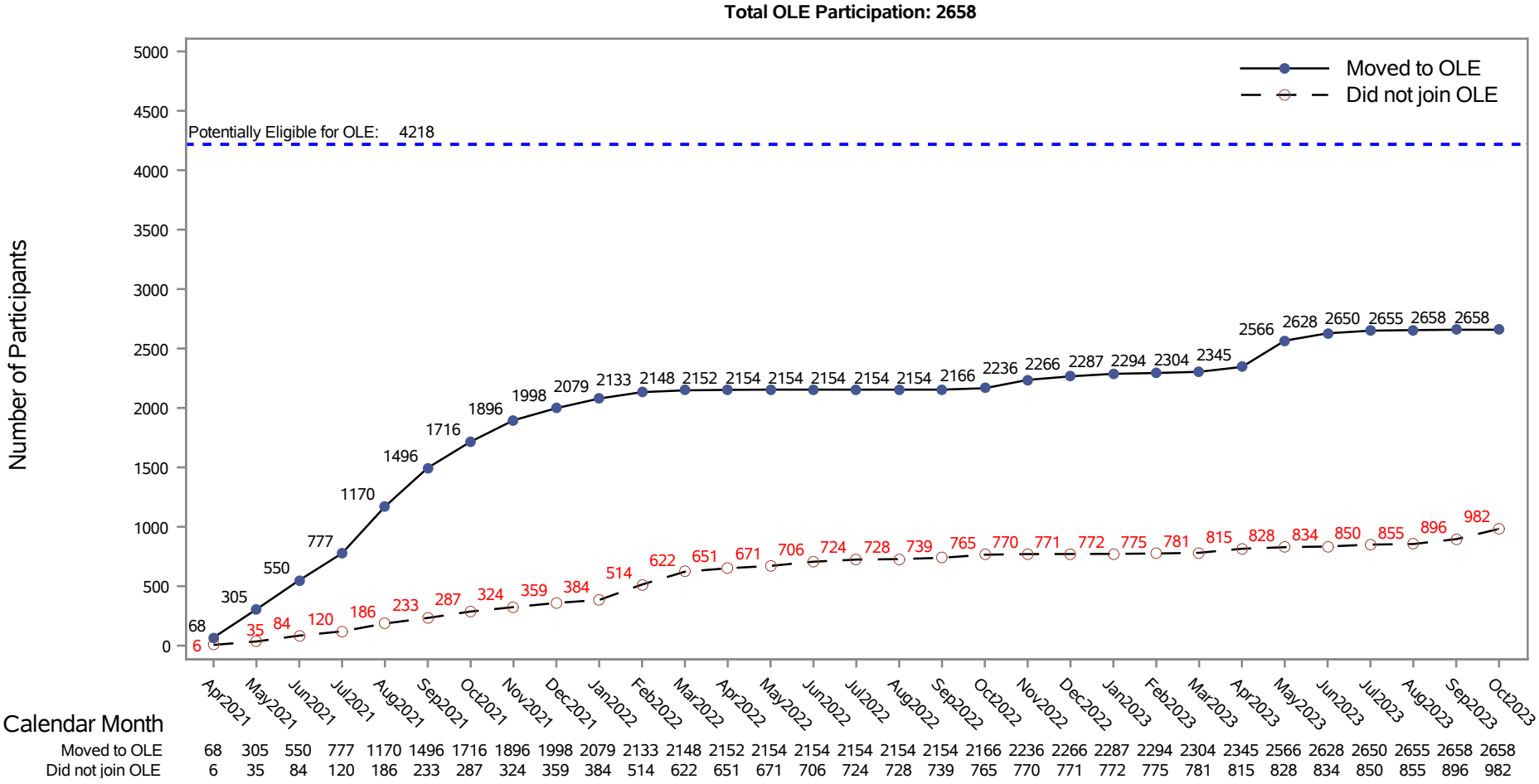
Figure 1 - Cumulative Participation in OLE - All Sites



	Apr2021	May2021	Jun2021	Jul2021	Aug2021	Sep2021	Oct2021	Nov2021	Dec2021	Jan2022	Feb2022	Mar2022	Apr2022	May2022	Jun2022	Jul2022	Aug2022	Sep2022	Oct2022	Nov2022	Dec2022	Jan2023	Feb2023	Mar2023	Apr2023	May2023	Jun2023	Jul2023	Aug2023	Sep2023	Oct2023
Moved to OLE	68	305	550	777	1170	1496	1716	1896	1998	2079	2133	2148	2152	2154	2154	2154	2154	2154	2166	2236	2266	2287	2294	2304	2345	2566	2628	2650	2655	2658	2658
Did not join OLE	6	35	84	120	186	233	287	324	359	384	514	622	651	671	706	724	728	739	765	770	771	772	775	781	815	828	834	850	855	896	982

'Potentially eligible for OLE' includes participants at sites that are active under protocol version 4.0, and excludes participants who are HIV infected or were terminated from the trial prior to May 14, 2020

Source: SCHARP (Carolyn) - /trials/hptn/p083/analysis/live/code/ole/g_ole_accrual.sas, SAS Version 9.4 (04MAR2026,6:06)

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

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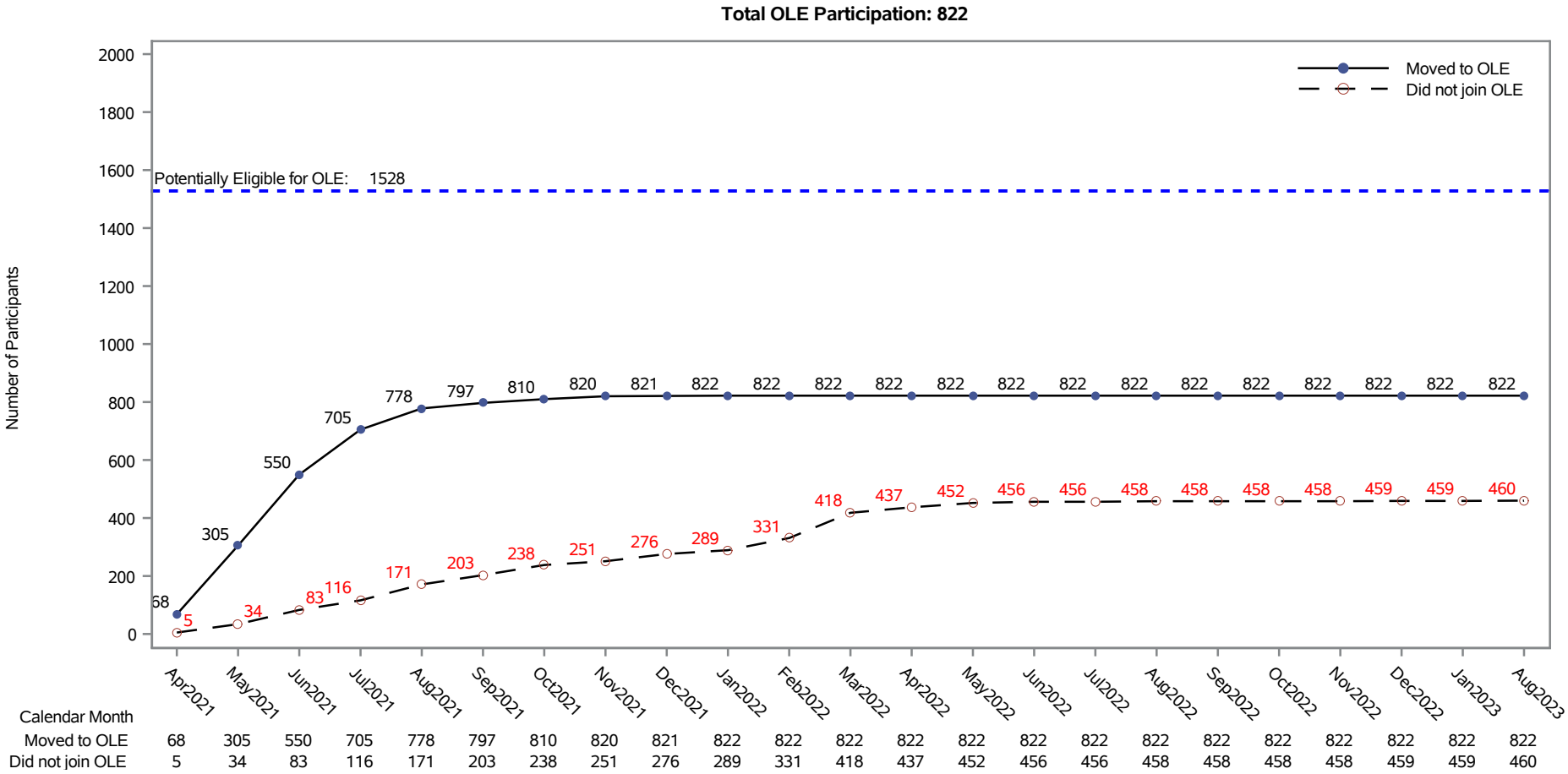
Figure 2 - Cumulative Participation in OLE by Region

Figure 2a. - US



Calendar Month	Apr2021	May2021	Jun2021	Jul2021	Aug2021	Sep2021	Oct2021	Nov2021	Dec2021	Jan2022	Feb2022	Mar2022	Apr2022	May2022	Jun2022	Jul2022	Aug2022	Sep2022	Oct2022	Nov2022	Dec2022	Jan2023	Aug2023
Moved to OLE	68	305	550	705	778	797	810	820	821	822	822	822	822	822	822	822	822	822	822	822	822	822	822
Did not join OLE	5	34	83	116	171	203	238	251	276	289	331	418	437	452	456	456	458	458	458	458	459	459	460

'Potentially eligible for OLE' includes participants at sites that are active under protocol version 4.0, and excludes participants who are HIV infected or were terminated from the trial prior to May 14, 2020

Source: SCHARP (Carolyn) - /trials/hptn/p083/analysis/live/code/ole/g_ole_accrual.sas, SAS Version 9.4 (04MAR2026,6:06)

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

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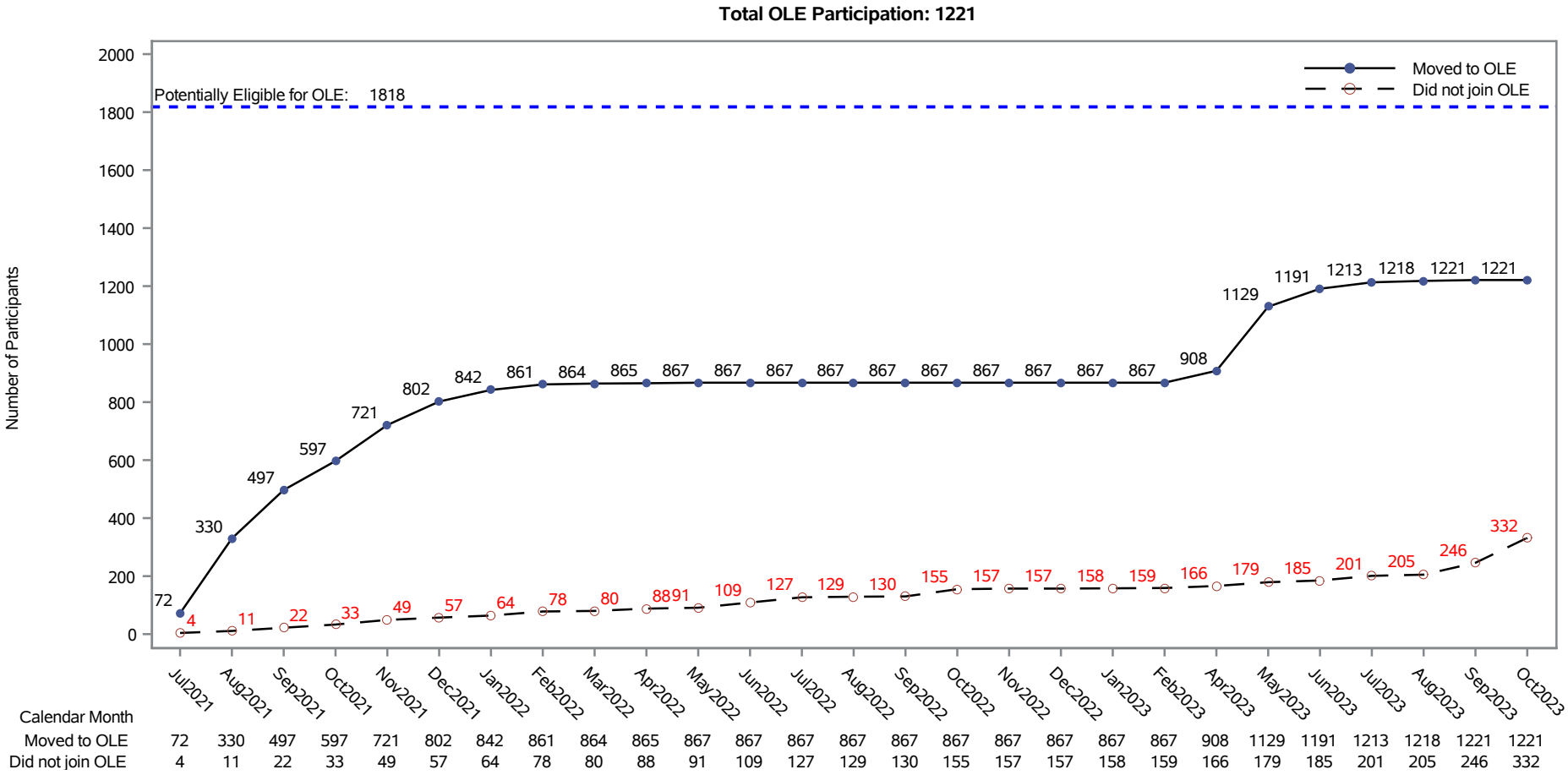
Figure 2 - Cumulative Participation in OLE by Region

Figure 2b. - Latin America



Calendar Month	Jul2021	Aug2021	Sep2021	Oct2021	Nov2021	Dec2021	Jan2022	Feb2022	Mar2022	Apr2022	May2022	Jun2022	Jul2022	Aug2022	Sep2022	Oct2022	Nov2022	Dec2022	Jan2023	Feb2023	Apr2023	May2023	Jun2023	Jul2023	Aug2023	Sep2023	Oct2023
Moved to OLE	72	330	497	597	721	802	842	861	864	865	867	867	867	867	867	867	867	867	867	867	908	1129	1191	1213	1218	1221	1221
Did not join OLE	4	11	22	33	49	57	64	78	80	88	91	109	127	129	130	155	157	157	158	159	166	179	185	201	205	246	332

'Potentially eligible for OLE' includes participants at sites that are active under protocol version 4.0, and excludes participants who are HIV infected or were terminated from the trial prior to May 14, 2020

Source: SCHARP (Carolyn) - /trials/hptn/p083/analysis/live/code/ole/g_ole_accrual.sas, SAS Version 9.4 (04MAR2026,6:06)

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

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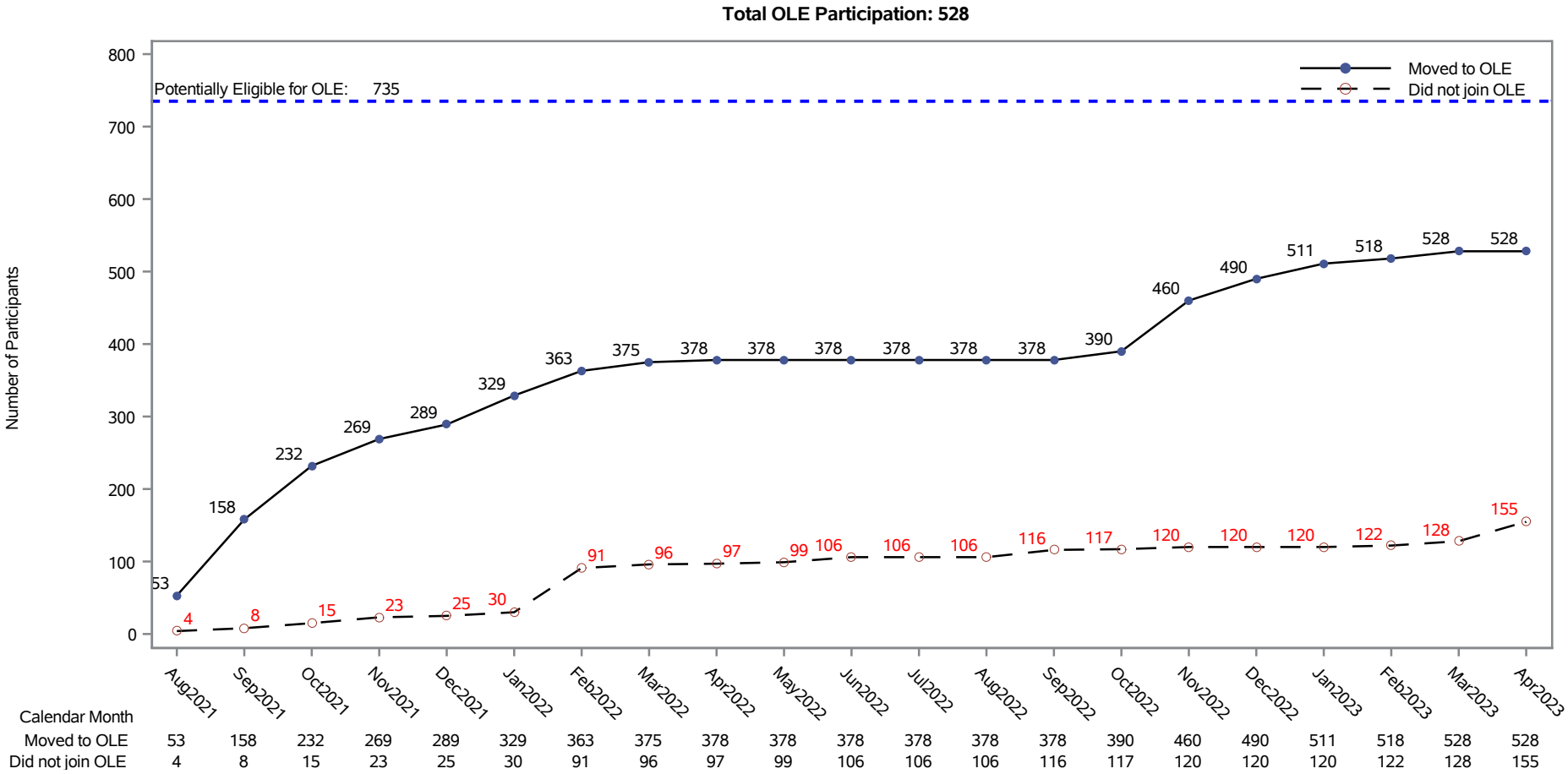
Figure 2 - Cumulative Participation in OLE by Region

Figure 2c. - Asia



Calendar Month	Aug2021	Sep2021	Oct2021	Nov2021	Dec2021	Jan2022	Feb2022	Mar2022	Apr2022	May2022	Jun2022	Jul2022	Aug2022	Sep2022	Oct2022	Nov2022	Dec2022	Jan2023	Feb2023	Mar2023	Apr2023
Moved to OLE	53	158	232	269	289	329	363	375	378	378	378	378	378	378	390	460	490	511	518	528	528
Did not join OLE	4	8	15	23	25	30	91	96	97	99	106	106	106	116	117	120	120	120	122	128	155

'Potentially eligible for OLE' includes participants at sites that are active under protocol version 4.0, and excludes participants who are HIV infected or were terminated from the trial prior to May 14, 2020

Source: SCHARP (Carolyn) - /trials/hptn/p083/analysis/live/code/ole/g_ole_accrual.sas, SAS Version 9.4 (04MAR2026,6:06)

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

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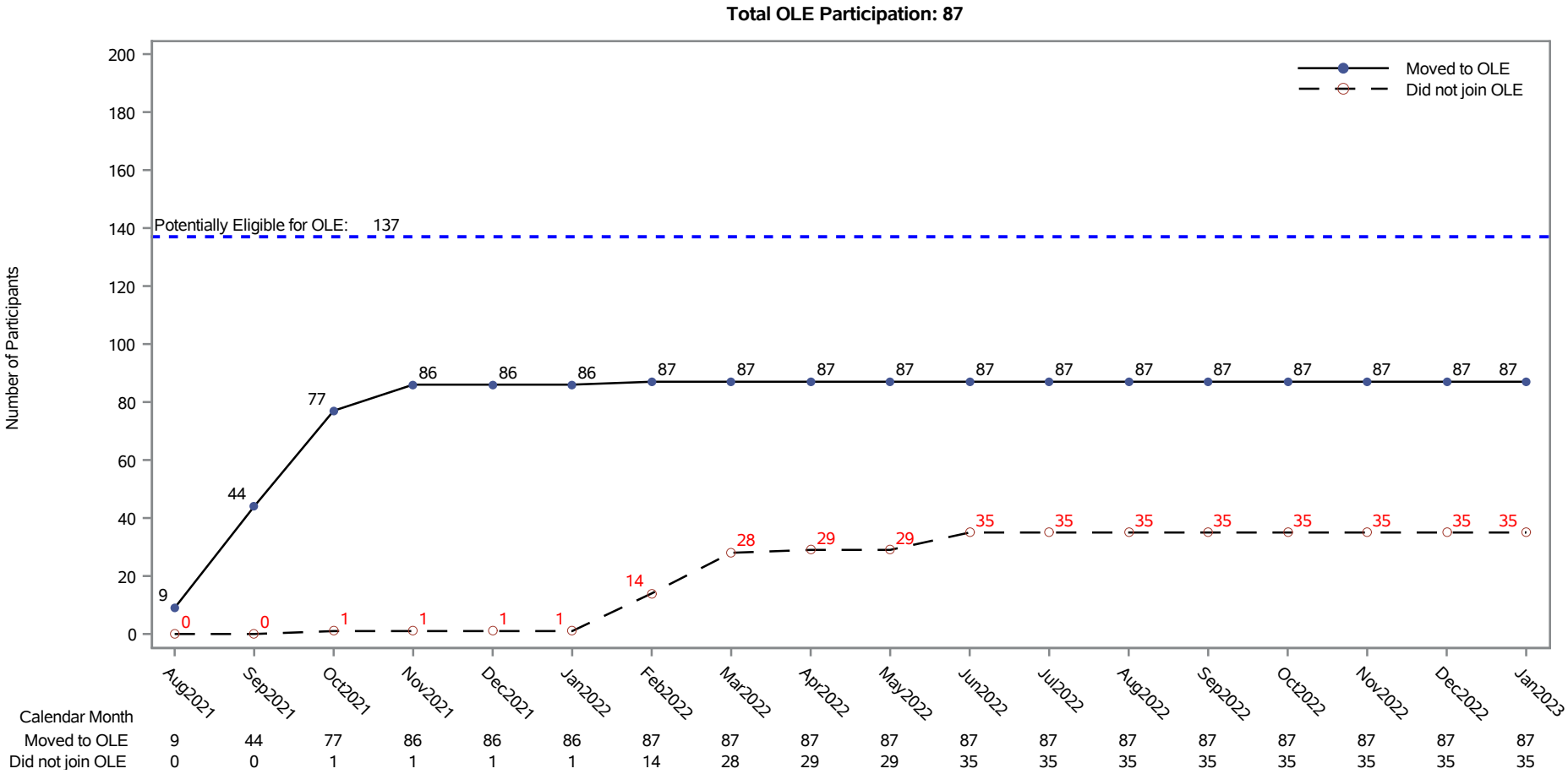
Figure 2 - Cumulative Participation in OLE by Region

Figure 2d. - Africa



Calendar Month	Aug2021	Sep2021	Oct2021	Nov2021	Dec2021	Jan2022	Feb2022	Mar2022	Apr2022	May2022	Jun2022	Jul2022	Aug2022	Sep2022	Oct2022	Nov2022	Dec2022	Jan2023
Moved to OLE	9	44	77	86	86	86	87	87	87	87	87	87	87	87	87	87	87	87
Did not join OLE	0	0	1	1	1	1	14	28	29	29	35	35	35	35	35	35	35	35

'Potentially eligible for OLE' includes participants at sites that are active under protocol version 4.0, and excludes participants who are HIV infected or were terminated from the trial prior to May 14, 2020

Source: SCHARP (Carolyn) - /trials/hptn/p083/analysis/live/code/ole/g_ole_accrual.sas, SAS Version 9.4 (04MAR2026,6:06)

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
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Table 2A – OLE Regimen Choice versus Original Randomized Study Arm by Region

	Overall	US	Latin America	Asia	Africa
Total participants who joined the OLE	2658	822	1221	528	87
Originally in TDF/FTC	1303/2658 (49.0%)	396/822 (48.2%)	607/1221 (49.7%)	258/528 (48.9%)	42/87 (48.3%)
Originally in Cabotegravir	1355/2658 (51.0%)	426/822 (51.8%)	614/1221 (50.3%)	270/528 (51.1%)	45/87 (51.7%)
Regimen choices of those originally in TDF/FTC					
TDF/FTC	84/1303 (6.4%)	20/396 (5.1%)	46/607 (7.6%)	13/258 (5.0%)	5/42 (11.9%)
Oral CAB (Step 4a)	434/1303 (33.3%)	140/396 (35.4%)	83/607 (13.7%)	196/258 (76.0%)	15/42 (35.7%)
Loading Dose CAB–LA (Step 4b)	766/1303 (58.8%)	228/396 (57.6%)	472/607 (77.8%)	47/258 (18.2%)	19/42 (45.2%)
Standard Dose CAB–LA (Step 4c)	0/1303 (0.0%)	0/396 (0.0%)	0/607 (0.0%)	0/258 (0.0%)	0/42 (0.0%)
Continuing on seroconverter follow–up schedule	10/1303 (0.8%)	5/396 (1.3%)	3/607 (0.5%)	1/258 (0.4%)	1/42 (2.4%)
Completing 48–week TDF/FTC schedule	9/1303 (0.7%)	3/396 (0.8%)	3/607 (0.5%)	1/258 (0.4%)	2/42 (4.8%)
Missing	0/1303 (0.0%)	0/396 (0.0%)	0/607 (0.0%)	0/258 (0.0%)	0/42 (0.0%)
Regimen choices of those originally in Cabotegravir					
TDF/FTC	23/1355 (1.7%)	13/426 (3.1%)	7/614 (1.1%)	2/270 (0.7%)	1/45 (2.2%)
Oral CAB (Step 4a) [1]	5/1355 (0.4%)	4/426 (0.9%)	1/614 (0.2%)	0/270 (0.0%)	0/45 (0.0%)
Loading Dose CAB–LA (Step 4b)	751/1355 (55.4%)	278/426 (65.3%)	271/614 (44.1%)	186/270 (68.9%)	16/45 (35.6%)
Standard Dose CAB–LA (Step 4c)	539/1355 (39.8%)	120/426 (28.2%)	322/614 (52.4%)	72/270 (26.7%)	25/45 (55.6%)
Continuing on seroconverter follow–up schedule	10/1355 (0.7%)	6/426 (1.4%)	2/614 (0.3%)	2/270 (0.7%)	0/45 (0.0%)
Completing 48–week TDF/FTC schedule	27/1355 (2.0%)	5/426 (1.2%)	11/614 (1.8%)	8/270 (3.0%)	3/45 (6.7%)
Missing	0/1355 (0.0%)	0/426 (0.0%)	0/614 (0.0%)	0/270 (0.0%)	0/45 (0.0%)

[1] These are protocol deviations for participants originally in CAB arm and chose the Oral CAB regimen.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_regm_choice.sas, SAS Version 9.4 (04MAR2026,6:06)

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Table 2Bi – OLE Regimen Choice versus Original Randomized Study Arm by Site: US

	Overall	Atlanta	Aurora	Baltimore	Birmingham	Boston	Bronx
Total participants who joined the OLE	822	9	25	6	34	42	29
Originally in TDF/FTC	396/822 (48.2%)	4/9 (44.4%)	12/25 (48.0%)	4/6 (66.7%)	17/34 (50.0%)	18/42 (42.9%)	15/29 (51.7%)
Originally in Cabotegravir	426/822 (51.8%)	5/9 (55.6%)	13/25 (52.0%)	2/6 (33.3%)	17/34 (50.0%)	24/42 (57.1%)	14/29 (48.3%)
Regimen choices of those originally in TDF/FTC							
TDF/FTC	20/396 (5.1%)	0/4 (0.0%)	0/12 (0.0%)	0/4 (0.0%)	1/17 (5.9%)	0/18 (0.0%)	3/15 (20.0%)
Oral CAB (Step 4a)	140/396 (35.4%)	1/4 (25.0%)	1/12 (8.3%)	3/4 (75.0%)	16/17 (94.1%)	5/18 (27.8%)	3/15 (20.0%)
Loading Dose CAB–LA (Step 4b)	228/396 (57.6%)	3/4 (75.0%)	10/12 (83.3%)	1/4 (25.0%)	0/17 (0.0%)	13/18 (72.2%)	9/15 (60.0%)
Standard Dose CAB–LA (Step 4c)	0/396 (0.0%)	0/4 (0.0%)	0/12 (0.0%)	0/4 (0.0%)	0/17 (0.0%)	0/18 (0.0%)	0/15 (0.0%)
Continuing on seroconverter follow–up schedule	5/396 (1.3%)	0/4 (0.0%)	1/12 (8.3%)	0/4 (0.0%)	0/17 (0.0%)	0/18 (0.0%)	0/15 (0.0%)
Completing 48–week TDF/FTC schedule	3/396 (0.8%)	0/4 (0.0%)	0/12 (0.0%)	0/4 (0.0%)	0/17 (0.0%)	0/18 (0.0%)	0/15 (0.0%)
Missing	0/396 (0.0%)	0/4 (0.0%)	0/12 (0.0%)	0/4 (0.0%)	0/17 (0.0%)	0/18 (0.0%)	0/15 (0.0%)
Regimen choices of those originally in Cabotegravir							
TDF/FTC	13/426 (3.1%)	0/5 (0.0%)	0/13 (0.0%)	0/2 (0.0%)	1/17 (5.9%)	2/24 (8.3%)	3/14 (21.4%)
Oral CAB (Step 4a) [1]	4/426 (0.9%)	0/5 (0.0%)	0/13 (0.0%)	0/2 (0.0%)	0/17 (0.0%)	0/24 (0.0%)	1/14 (7.1%)
Loading Dose CAB–LA (Step 4b)	278/426 (65.3%)	3/5 (60.0%)	9/13 (69.2%)	2/2 (100.0%)	14/17 (82.4%)	17/24 (70.8%)	3/14 (21.4%)
Standard Dose CAB–LA (Step 4c)	120/426 (28.2%)	2/5 (40.0%)	4/13 (30.8%)	0/2 (0.0%)	2/17 (11.8%)	5/24 (20.8%)	7/14 (50.0%)
Continuing on seroconverter follow–up schedule	6/426 (1.4%)	0/5 (0.0%)	0/13 (0.0%)	0/2 (0.0%)	0/17 (0.0%)	0/24 (0.0%)	0/14 (0.0%)
Completing 48–week TDF/FTC schedule	5/426 (1.2%)	0/5 (0.0%)	0/13 (0.0%)	0/2 (0.0%)	0/17 (0.0%)	0/24 (0.0%)	0/14 (0.0%)
Missing	0/426 (0.0%)	0/5 (0.0%)	0/13 (0.0%)	0/2 (0.0%)	0/17 (0.0%)	0/24 (0.0%)	0/14 (0.0%)

[1] These are protocol deviations for participants originally in CAB arm and chose the Oral CAB regimen.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_regm_choice.sas, SAS Version 9.4 (04MAR2026,6:06)

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Table 2Bi – OLE Regimen Choice versus Original Randomized Study Arm by Site: US

	Chapel Hill	Chicago – AYAR	Chicago – WISH	Cincinnati	Columbus	Decatur	Greensboro
Total participants who joined the OLE	35	39	29	33	22	42	25
Originally in TDF/FTC	18/35 (51.4%)	16/39 (41.0%)	14/29 (48.3%)	16/33 (48.5%)	16/22 (72.7%)	18/42 (42.9%)	8/25 (32.0%)
Originally in Cabotegravir	17/35 (48.6%)	23/39 (59.0%)	15/29 (51.7%)	17/33 (51.5%)	6/22 (27.3%)	24/42 (57.1%)	17/25 (68.0%)
Regimen choices of those originally in TDF/FTC							
TDF/FTC	0/18 (0.0%)	0/16 (0.0%)	0/14 (0.0%)	1/16 (6.3%)	0/16 (0.0%)	2/18 (11.1%)	0/8 (0.0%)
Oral CAB (Step 4a)	9/18 (50.0%)	1/16 (6.3%)	1/14 (7.1%)	12/16 (75.0%)	8/16 (50.0%)	6/18 (33.3%)	1/8 (12.5%)
Loading Dose CAB–LA (Step 4b)	9/18 (50.0%)	14/16 (87.5%)	13/14 (92.9%)	3/16 (18.8%)	8/16 (50.0%)	9/18 (50.0%)	7/8 (87.5%)
Standard Dose CAB–LA (Step 4c)	0/18 (0.0%)	0/16 (0.0%)	0/14 (0.0%)	0/16 (0.0%)	0/16 (0.0%)	0/18 (0.0%)	0/8 (0.0%)
Continuing on seroconverter follow–up schedule	0/18 (0.0%)	1/16 (6.3%)	0/14 (0.0%)	0/16 (0.0%)	0/16 (0.0%)	1/18 (5.6%)	0/8 (0.0%)
Completing 48–week TDF/FTC schedule	0/18 (0.0%)	0/16 (0.0%)	0/14 (0.0%)	0/16 (0.0%)	0/16 (0.0%)	0/18 (0.0%)	0/8 (0.0%)
Missing	0/18 (0.0%)	0/16 (0.0%)	0/14 (0.0%)	0/16 (0.0%)	0/16 (0.0%)	0/18 (0.0%)	0/8 (0.0%)
Regimen choices of those originally in Cabotegravir							
TDF/FTC	0/17 (0.0%)	0/23 (0.0%)	1/15 (6.7%)	0/17 (0.0%)	0/6 (0.0%)	0/24 (0.0%)	1/17 (5.9%)
Oral CAB (Step 4a) [1]	1/17 (5.9%)	0/23 (0.0%)	0/15 (0.0%)	0/17 (0.0%)	0/6 (0.0%)	0/24 (0.0%)	0/17 (0.0%)
Loading Dose CAB–LA (Step 4b)	12/17 (70.6%)	17/23 (73.9%)	13/15 (86.7%)	11/17 (64.7%)	5/6 (83.3%)	13/24 (54.2%)	10/17 (58.8%)
Standard Dose CAB–LA (Step 4c)	3/17 (17.6%)	6/23 (26.1%)	1/15 (6.7%)	6/17 (35.3%)	1/6 (16.7%)	9/24 (37.5%)	5/17 (29.4%)
Continuing on seroconverter follow–up schedule	0/17 (0.0%)	0/23 (0.0%)	0/15 (0.0%)	0/17 (0.0%)	0/6 (0.0%)	2/24 (8.3%)	1/17 (5.9%)
Completing 48–week TDF/FTC schedule	1/17 (5.9%)	0/23 (0.0%)	0/15 (0.0%)	0/17 (0.0%)	0/6 (0.0%)	0/24 (0.0%)	0/17 (0.0%)
Missing	0/17 (0.0%)	0/23 (0.0%)	0/15 (0.0%)	0/17 (0.0%)	0/6 (0.0%)	0/24 (0.0%)	0/17 (0.0%)

[1] These are protocol deviations for participants originally in CAB arm and chose the Oral CAB regimen.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_regm_choice.sas, SAS Version 9.4 (04MAR2026,6:06)

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Table 2Bi – OLE Regimen Choice versus Original Randomized Study Arm by Site: US

	Harlem	Houston	Los Angeles – UCLA Care	Los Angeles – UCLA Vine	Memphis	New Orleans	New York – Blood Center
Total participants who joined the OLE	32	34	42	34	49	24	26
Originally in TDF/FTC	16/32 (50.0%)	13/34 (38.2%)	23/42 (54.8%)	16/34 (47.1%)	22/49 (44.9%)	12/24 (50.0%)	13/26 (50.0%)
Originally in Cabotegravir	16/32 (50.0%)	21/34 (61.8%)	19/42 (45.2%)	18/34 (52.9%)	27/49 (55.1%)	12/24 (50.0%)	13/26 (50.0%)
Regimen choices of those originally in TDF/FTC							
TDF/FTC	2/16 (12.5%)	0/13 (0.0%)	1/23 (4.3%)	1/16 (6.3%)	0/22 (0.0%)	0/12 (0.0%)	3/13 (23.1%)
Oral CAB (Step 4a)	11/16 (68.8%)	12/13 (92.3%)	4/23 (17.4%)	15/16 (93.8%)	7/22 (31.8%)	2/12 (16.7%)	8/13 (61.5%)
Loading Dose CAB–LA (Step 4b)	3/16 (18.8%)	0/13 (0.0%)	18/23 (78.3%)	0/16 (0.0%)	13/22 (59.1%)	10/12 (83.3%)	2/13 (15.4%)
Standard Dose CAB–LA (Step 4c)	0/16 (0.0%)	0/13 (0.0%)	0/23 (0.0%)	0/16 (0.0%)	0/22 (0.0%)	0/12 (0.0%)	0/13 (0.0%)
Continuing on seroconverter follow–up schedule	0/16 (0.0%)	0/13 (0.0%)	0/23 (0.0%)	0/16 (0.0%)	2/22 (9.1%)	0/12 (0.0%)	0/13 (0.0%)
Completing 48–week TDF/FTC schedule	0/16 (0.0%)	1/13 (7.7%)	0/23 (0.0%)	0/16 (0.0%)	0/22 (0.0%)	0/12 (0.0%)	0/13 (0.0%)
Missing	0/16 (0.0%)	0/13 (0.0%)	0/23 (0.0%)	0/16 (0.0%)	0/22 (0.0%)	0/12 (0.0%)	0/13 (0.0%)
Regimen choices of those originally in Cabotegravir							
TDF/FTC	0/16 (0.0%)	0/21 (0.0%)	1/19 (5.3%)	0/18 (0.0%)	0/27 (0.0%)	0/12 (0.0%)	1/13 (7.7%)
Oral CAB (Step 4a) [1]	0/16 (0.0%)	0/21 (0.0%)	0/19 (0.0%)	0/18 (0.0%)	0/27 (0.0%)	0/12 (0.0%)	2/13 (15.4%)
Loading Dose CAB–LA (Step 4b)	8/16 (50.0%)	12/21 (57.1%)	12/19 (63.2%)	12/18 (66.7%)	20/27 (74.1%)	9/12 (75.0%)	6/13 (46.2%)
Standard Dose CAB–LA (Step 4c)	8/16 (50.0%)	8/21 (38.1%)	6/19 (31.6%)	6/18 (33.3%)	5/27 (18.5%)	2/12 (16.7%)	4/13 (30.8%)
Continuing on seroconverter follow–up schedule	0/16 (0.0%)	0/21 (0.0%)	0/19 (0.0%)	0/18 (0.0%)	2/27 (7.4%)	1/12 (8.3%)	0/13 (0.0%)
Completing 48–week TDF/FTC schedule	0/16 (0.0%)	1/21 (4.8%)	0/19 (0.0%)	0/18 (0.0%)	0/27 (0.0%)	0/12 (0.0%)	0/13 (0.0%)
Missing	0/16 (0.0%)	0/21 (0.0%)	0/19 (0.0%)	0/18 (0.0%)	0/27 (0.0%)	0/12 (0.0%)	0/13 (0.0%)

[1] These are protocol deviations for participants originally in CAB arm and chose the Oral CAB regimen.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_regm_choice.sas, SAS Version 9.4 (04MAR2026,6:06)

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Table 2Bi – OLE Regimen Choice versus Original Randomized Study Arm by Site: US

	New York – Weill Cornell Chelsea	Newark	Oakland	Philadelphia	San Francisco	St. Louis	Washington, DC
Total participants who joined the OLE	28	39	21	47	19	20	37
Originally in TDF/FTC	16/28 (57.1%)	19/39 (48.7%)	13/21 (61.9%)	22/47 (46.8%)	10/19 (52.6%)	10/20 (50.0%)	15/37 (40.5%)
Originally in Cabotegravir	12/28 (42.9%)	20/39 (51.3%)	8/21 (38.1%)	25/47 (53.2%)	9/19 (47.4%)	10/20 (50.0%)	22/37 (59.5%)
Regimen choices of those originally in TDF/FTC							
TDF/FTC	3/16 (18.8%)	2/19 (10.5%)	0/13 (0.0%)	0/22 (0.0%)	0/10 (0.0%)	0/10 (0.0%)	1/15 (6.7%)
Oral CAB (Step 4a)	1/16 (6.3%)	5/19 (26.3%)	2/13 (15.4%)	0/22 (0.0%)	2/10 (20.0%)	1/10 (10.0%)	3/15 (20.0%)
Loading Dose CAB–LA (Step 4b)	12/16 (75.0%)	11/19 (57.9%)	10/13 (76.9%)	22/22 (100.0%)	8/10 (80.0%)	9/10 (90.0%)	11/15 (73.3%)
Standard Dose CAB–LA (Step 4c)	0/16 (0.0%)	0/19 (0.0%)	0/13 (0.0%)	0/22 (0.0%)	0/10 (0.0%)	0/10 (0.0%)	0/15 (0.0%)
Continuing on seroconverter follow–up schedule	0/16 (0.0%)	0/19 (0.0%)	0/13 (0.0%)	0/22 (0.0%)	0/10 (0.0%)	0/10 (0.0%)	0/15 (0.0%)
Completing 48–week TDF/FTC schedule	0/16 (0.0%)	1/19 (5.3%)	1/13 (7.7%)	0/22 (0.0%)	0/10 (0.0%)	0/10 (0.0%)	0/15 (0.0%)
Missing	0/16 (0.0%)	0/19 (0.0%)	0/13 (0.0%)	0/22 (0.0%)	0/10 (0.0%)	0/10 (0.0%)	0/15 (0.0%)
Regimen choices of those originally in Cabotegravir							
TDF/FTC	0/12 (0.0%)	0/20 (0.0%)	0/8 (0.0%)	0/25 (0.0%)	1/9 (11.1%)	0/10 (0.0%)	2/22 (9.1%)
Oral CAB (Step 4a) [1]	0/12 (0.0%)	0/20 (0.0%)	0/8 (0.0%)	0/25 (0.0%)	0/9 (0.0%)	0/10 (0.0%)	0/22 (0.0%)
Loading Dose CAB–LA (Step 4b)	9/12 (75.0%)	12/20 (60.0%)	6/8 (75.0%)	10/25 (40.0%)	8/9 (88.9%)	10/10 (100.0%)	15/22 (68.2%)
Standard Dose CAB–LA (Step 4c)	3/12 (25.0%)	8/20 (40.0%)	2/8 (25.0%)	12/25 (48.0%)	0/9 (0.0%)	0/10 (0.0%)	5/22 (22.7%)
Continuing on seroconverter follow–up schedule	0/12 (0.0%)	0/20 (0.0%)	0/8 (0.0%)	0/25 (0.0%)	0/9 (0.0%)	0/10 (0.0%)	0/22 (0.0%)
Completing 48–week TDF/FTC schedule	0/12 (0.0%)	0/20 (0.0%)	0/8 (0.0%)	3/25 (12.0%)	0/9 (0.0%)	0/10 (0.0%)	0/22 (0.0%)
Missing	0/12 (0.0%)	0/20 (0.0%)	0/8 (0.0%)	0/25 (0.0%)	0/9 (0.0%)	0/10 (0.0%)	0/22 (0.0%)

[1] These are protocol deviations for participants originally in CAB arm and chose the Oral CAB regimen.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_regm_choice.sas, SAS Version 9.4 (04MAR2026,6:06)

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Table 2Bii – OLE Regimen Choice versus Original Randomized Study Arm by Site: Latin America

	Overall	Buenos Aires – Fundacion Huesped	Buenos Aires – Hospital JM Ramos Mejia	Iquitos	Lima – Barranco	Lima – CITBM
Total participants who joined the OLE	1221	151	109	74	74	52
Originally in TDF/FTC	607/1221 (49.7%)	68/151 (45.0%)	57/109 (52.3%)	36/74 (48.6%)	35/74 (47.3%)	24/52 (46.2%)
Originally in Cabotegravir	614/1221 (50.3%)	83/151 (55.0%)	52/109 (47.7%)	38/74 (51.4%)	39/74 (52.7%)	28/52 (53.8%)
Regimen choices of those originally in TDF/FTC						
TDF/FTC	46/607 (7.6%)	9/68 (13.2%)	13/57 (22.8%)	0/36 (0.0%)	0/35 (0.0%)	0/24 (0.0%)
Oral CAB (Step 4a)	83/607 (13.7%)	10/68 (14.7%)	0/57 (0.0%)	0/36 (0.0%)	2/35 (5.7%)	7/24 (29.2%)
Loading Dose CAB–LA (Step 4b)	472/607 (77.8%)	49/68 (72.1%)	44/57 (77.2%)	36/36 (100.0%)	33/35 (94.3%)	17/24 (70.8%)
Standard Dose CAB–LA (Step 4c)	0/607 (0.0%)	0/68 (0.0%)	0/57 (0.0%)	0/36 (0.0%)	0/35 (0.0%)	0/24 (0.0%)
Continuing on seroconverter follow–up schedule	3/607 (0.5%)	0/68 (0.0%)	0/57 (0.0%)	0/36 (0.0%)	0/35 (0.0%)	0/24 (0.0%)
Completing 48–week TDF/FTC schedule	3/607 (0.5%)	0/68 (0.0%)	0/57 (0.0%)	0/36 (0.0%)	0/35 (0.0%)	0/24 (0.0%)
Missing	0/607 (0.0%)	0/68 (0.0%)	0/57 (0.0%)	0/36 (0.0%)	0/35 (0.0%)	0/24 (0.0%)
Regimen choices of those originally in Cabotegravir						
TDF/FTC	7/614 (1.1%)	2/83 (2.4%)	0/52 (0.0%)	0/38 (0.0%)	0/39 (0.0%)	0/28 (0.0%)
Oral CAB (Step 4a) [1]	1/614 (0.2%)	1/83 (1.2%)	0/52 (0.0%)	0/38 (0.0%)	0/39 (0.0%)	0/28 (0.0%)
Loading Dose CAB–LA (Step 4b)	271/614 (44.1%)	19/83 (22.9%)	3/52 (5.8%)	38/38 (100.0%)	39/39 (100.0%)	28/28 (100.0%)
Standard Dose CAB–LA (Step 4c)	322/614 (52.4%)	61/83 (73.5%)	46/52 (88.5%)	0/38 (0.0%)	0/39 (0.0%)	0/28 (0.0%)
Continuing on seroconverter follow–up schedule	2/614 (0.3%)	0/83 (0.0%)	0/52 (0.0%)	0/38 (0.0%)	0/39 (0.0%)	0/28 (0.0%)
Completing 48–week TDF/FTC schedule	11/614 (1.8%)	0/83 (0.0%)	3/52 (5.8%)	0/38 (0.0%)	0/39 (0.0%)	0/28 (0.0%)
Missing	0/614 (0.0%)	0/83 (0.0%)	0/52 (0.0%)	0/38 (0.0%)	0/39 (0.0%)	0/28 (0.0%)

[1] These are protocol deviations for participants originally in CAB arm and chose the Oral CAB regimen.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_regm_choice.sas, SAS Version 9.4 (04MAR2026,6:06)

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Table 2Bii – OLE Regimen Choice versus Original Randomized Study Arm by Site: Latin America

	Lima – San Miguel	Lima – Via Libre	Porto Alegre	Rio de Janeiro	Sao Paulo – DST–AIDS	Sao Paulo – IC–HCFMUSP
Total participants who joined the OLE	62	92	164	192	116	135
Originally in TDF/FTC	28/62 (45.2%)	51/92 (55.4%)	84/164 (51.2%)	98/192 (51.0%)	60/116 (51.7%)	66/135 (48.9%)
Originally in Cabotegravir	34/62 (54.8%)	41/92 (44.6%)	80/164 (48.8%)	94/192 (49.0%)	56/116 (48.3%)	69/135 (51.1%)
Regimen choices of those originally in TDF/FTC						
TDF/FTC	0/28 (0.0%)	0/51 (0.0%)	3/84 (3.6%)	4/98 (4.1%)	15/60 (25.0%)	2/66 (3.0%)
Oral CAB (Step 4a)	15/28 (53.6%)	5/51 (9.8%)	0/84 (0.0%)	0/98 (0.0%)	40/60 (66.7%)	4/66 (6.1%)
Loading Dose CAB–LA (Step 4b)	13/28 (46.4%)	46/51 (90.2%)	80/84 (95.2%)	91/98 (92.9%)	4/60 (6.7%)	59/66 (89.4%)
Standard Dose CAB–LA (Step 4c)	0/28 (0.0%)	0/51 (0.0%)	0/84 (0.0%)	0/98 (0.0%)	0/60 (0.0%)	0/66 (0.0%)
Continuing on seroconverter follow–up schedule	0/28 (0.0%)	0/51 (0.0%)	0/84 (0.0%)	3/98 (3.1%)	0/60 (0.0%)	0/66 (0.0%)
Completing 48–week TDF/FTC schedule	0/28 (0.0%)	0/51 (0.0%)	1/84 (1.2%)	0/98 (0.0%)	1/60 (1.7%)	1/66 (1.5%)
Missing	0/28 (0.0%)	0/51 (0.0%)	0/84 (0.0%)	0/98 (0.0%)	0/60 (0.0%)	0/66 (0.0%)
Regimen choices of those originally in Cabotegravir						
TDF/FTC	0/34 (0.0%)	0/41 (0.0%)	1/80 (1.3%)	1/94 (1.1%)	3/56 (5.4%)	0/69 (0.0%)
Oral CAB (Step 4a) [1]	0/34 (0.0%)	0/41 (0.0%)	0/80 (0.0%)	0/94 (0.0%)	0/56 (0.0%)	0/69 (0.0%)
Loading Dose CAB–LA (Step 4b)	34/34 (100.0%)	39/41 (95.1%)	24/80 (30.0%)	37/94 (39.4%)	0/56 (0.0%)	10/69 (14.5%)
Standard Dose CAB–LA (Step 4c)	0/34 (0.0%)	0/41 (0.0%)	54/80 (67.5%)	55/94 (58.5%)	50/56 (89.3%)	56/69 (81.2%)
Continuing on seroconverter follow–up schedule	0/34 (0.0%)	1/41 (2.4%)	0/80 (0.0%)	0/94 (0.0%)	1/56 (1.8%)	0/69 (0.0%)
Completing 48–week TDF/FTC schedule	0/34 (0.0%)	1/41 (2.4%)	1/80 (1.3%)	1/94 (1.1%)	2/56 (3.6%)	3/69 (4.3%)
Missing	0/34 (0.0%)	0/41 (0.0%)	0/80 (0.0%)	0/94 (0.0%)	0/56 (0.0%)	0/69 (0.0%)

[1] These are protocol deviations for participants originally in CAB arm and chose the Oral CAB regimen.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_regm_choice.sas, SAS Version 9.4 (04MAR2026,6:06)

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Table 2Biii – OLE Regimen Choice versus Original Randomized Study Arm by Site: Asia

	Overall	Bangkok – Silom Clinic	Bangkok – Thai Red Cross	Chiang Mai	Hanoi
Total participants who joined the OLE	528	150	145	90	143
Originally in TDF/FTC	258/528 (48.9%)	79/150 (52.7%)	70/145 (48.3%)	43/90 (47.8%)	66/143 (46.2%)
Originally in Cabotegravir	270/528 (51.1%)	71/150 (47.3%)	75/145 (51.7%)	47/90 (52.2%)	77/143 (53.8%)
Regimen choices of those originally in TDF/FTC					
TDF/FTC	13/258 (5.0%)	0/79 (0.0%)	4/70 (5.7%)	1/43 (2.3%)	8/66 (12.1%)
Oral CAB (Step 4a)	196/258 (76.0%)	79/79 (100.0%)	18/70 (25.7%)	41/43 (95.3%)	58/66 (87.9%)
Loading Dose CAB–LA (Step 4b)	47/258 (18.2%)	0/79 (0.0%)	47/70 (67.1%)	0/43 (0.0%)	0/66 (0.0%)
Standard Dose CAB–LA (Step 4c)	0/258 (0.0%)	0/79 (0.0%)	0/70 (0.0%)	0/43 (0.0%)	0/66 (0.0%)
Continuing on seroconverter follow–up schedule	1/258 (0.4%)	0/79 (0.0%)	1/70 (1.4%)	0/43 (0.0%)	0/66 (0.0%)
Completing 48–week TDF/FTC schedule	1/258 (0.4%)	0/79 (0.0%)	0/70 (0.0%)	1/43 (2.3%)	0/66 (0.0%)
Missing	0/258 (0.0%)	0/79 (0.0%)	0/70 (0.0%)	0/43 (0.0%)	0/66 (0.0%)
Regimen choices of those originally in Cabotegravir					
TDF/FTC	2/270 (0.7%)	0/71 (0.0%)	2/75 (2.7%)	0/47 (0.0%)	0/77 (0.0%)
Oral CAB (Step 4a)	0/270 (0.0%)	0/71 (0.0%)	0/75 (0.0%)	0/47 (0.0%)	0/77 (0.0%)
Loading Dose CAB–LA (Step 4b)	186/270 (68.9%)	71/71 (100.0%)	39/75 (52.0%)	33/47 (70.2%)	43/77 (55.8%)
Standard Dose CAB–LA (Step 4c)	72/270 (26.7%)	0/71 (0.0%)	33/75 (44.0%)	10/47 (21.3%)	29/77 (37.7%)
Continuing on seroconverter follow–up schedule	2/270 (0.7%)	0/71 (0.0%)	0/75 (0.0%)	0/47 (0.0%)	2/77 (2.6%)
Completing 48–week TDF/FTC schedule	8/270 (3.0%)	0/71 (0.0%)	1/75 (1.3%)	4/47 (8.5%)	3/77 (3.9%)
Missing	0/270 (0.0%)	0/71 (0.0%)	0/75 (0.0%)	0/47 (0.0%)	0/77 (0.0%)

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_regm_choice.sas, SAS Version 9.4 (04MAR2026,6:06)

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Table 2Biv – OLE Regimen Choice versus Original Randomized Study Arm by Site: Africa

	Overall	Cape Town
Total participants who joined the OLE	87	87
Originally in TDF/FTC	42/87 (48.3%)	42/87 (48.3%)
Originally in Cabotegravir	45/87 (51.7%)	45/87 (51.7%)
Regimen choices of those originally in TDF/FTC		
TDF/FTC	5/42 (11.9%)	5/42 (11.9%)
Oral CAB (Step 4a)	15/42 (35.7%)	15/42 (35.7%)
Loading Dose CAB–LA (Step 4b)	19/42 (45.2%)	19/42 (45.2%)
Standard Dose CAB–LA (Step 4c)	0/42 (0.0%)	0/42 (0.0%)
Continuing on seroconverter follow–up schedule	1/42 (2.4%)	1/42 (2.4%)
Completing 48–week TDF/FTC schedule	2/42 (4.8%)	2/42 (4.8%)
Missing	0/42 (0.0%)	0/42 (0.0%)
Regimen choices of those originally in Cabotegravir		
TDF/FTC	1/45 (2.2%)	1/45 (2.2%)
Oral CAB (Step 4a)	0/45 (0.0%)	0/45 (0.0%)
Loading Dose CAB–LA (Step 4b)	16/45 (35.6%)	16/45 (35.6%)
Standard Dose CAB–LA (Step 4c)	25/45 (55.6%)	25/45 (55.6%)
Continuing on seroconverter follow–up schedule	0/45 (0.0%)	0/45 (0.0%)
Completing 48–week TDF/FTC schedule	3/45 (6.7%)	3/45 (6.7%)
Missing	0/45 (0.0%)	0/45 (0.0%)

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_regm_choice.sas, SAS Version 9.4 (04MAR2026,6:06)

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Table 3 – Reasons of OLE Regimen Choice

	Overall	US	Latin America	Asia	Africa
Total participants joined the OLE and their regimen choices	2658	822	1221	528	87
TDF/FTC	107/2658 (4.0%)	33/822 (4.0%)	53/1221 (4.3%)	15/528 (2.8%)	6/87 (6.9%)
Cabotegravir	2495/2658 (93.9%)	770/822 (93.7%)	1149/1221 (94.1%)	501/528 (94.9%)	75/87 (86.2%)
Continuing Seroconverter Schedule	20/2658 (0.8%)	11/822 (1.3%)	5/1221 (0.4%)	3/528 (0.6%)	1/87 (1.1%)
Continuing Step 3 TDF/FTC Schedule	36/2658 (1.4%)	8/822 (1.0%)	14/1221 (1.1%)	9/528 (1.7%)	5/87 (5.7%)
Reasons for choosing Cabotegravir regimen in OLE					
Missing	0/2495 (0.0%)	0/770 (0.0%)	0/1149 (0.0%)	0/501 (0.0%)	0/75 (0.0%)
Prefer injections and/or Don´t like pills	1762/2495 (70.6%)	530/770 (68.8%)	783/1149 (68.1%)	405/501 (80.8%)	44/75 (58.7%)
CAB was shown to be superior to Truvada for HIV prevention	432/2495 (17.3%)	109/770 (14.2%)	241/1149 (21.0%)	78/501 (15.6%)	4/75 (5.3%)
Want to avoid potential side effects of Truvada	63/2495 (2.5%)	31/770 (4.0%)	20/1149 (1.7%)	10/501 (2.0%)	2/75 (2.7%)
Other	238/2495 (9.5%)	100/770 (13.0%)	105/1149 (9.1%)	8/501 (1.6%)	25/75 (33.3%)
Reasons for choosing TDF/FTC regimen in OLE					
Missing	0/107 (0.0%)	0/33 (0.0%)	0/53 (0.0%)	0/15 (0.0%)	0/6 (0.0%)
Don´t like injections and/or prefer pills	50/107 (46.7%)	14/33 (42.4%)	22/53 (41.5%)	12/15 (80.0%)	2/6 (33.3%)
The potential side effects of Truvada are better understood than those of Cabotegravir	5/107 (4.7%)	3/33 (9.1%)	0/53 (0.0%)	1/15 (6.7%)	1/6 (16.7%)
Concerned about resistance if injectable PrEP fails	8/107 (7.5%)	4/33 (12.1%)	4/53 (7.5%)	0/15 (0.0%)	0/6 (0.0%)
Other	44/107 (41.1%)	12/33 (36.4%)	27/53 (50.9%)	2/15 (13.3%)	3/6 (50.0%)

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_regm_choice_reason.sas, SAS Version 9.4 (04MAR2026,6:06)

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Listing 2 – Listing of 'Other' Reasons of OLE Regimen Choice

# [1]	OLE Regimen Choice	Region	Participant ID	Original Randomized Arm	Reason for choosing this regimen	Other, Specify
1	TDF/FTC	US	847242549	TDF/FTC	OTHER	DID NOT WANT TO TAKE A CHANCE ON HAVING A REACTION TO A NEW DRUG
2	TDF/FTC	US	821340505	Cabotegravir	OTHER	DUE TO TRAVELING AND SCHEDULING CONFLICTS, HE WILL NOT BE ABOUT TO RECEIVE HIS INJECTIONS WITHIN WINDOW AT THIS TIME. IT WILL BE SAFER TO KEEP HIM ON TRUVADA
3	TDF/FTC	US	734456740	Cabotegravir	OTHER	GETTING COVID VACCINE TODAY AND UNDECIDED RE RESUMING INJECTIONS
4	TDF/FTC	US	801588090	Cabotegravir	OTHER	HE WANTS TO DISCONTINUE CAB AND SWITCH TO STEP 5 IN ORDER TO "PHASE OUT" OF THE STUDY.
5	TDF/FTC	US	745570651	TDF/FTC	OTHER	IS USED TO TRUVADA
6	TDF/FTC	US	820414268	TDF/FTC	OTHER	JUST FEEL MORE COMFORTABLE RIGHT NOW [WITH THE PILL]. THE SHOT DOES SOUND GOOD. I WILL TRY IT DOWN THE LINE.
7	TDF/FTC	US	851808362	Cabotegravir	OTHER	MOVING OUT OF STATE IN THE FUTURE AND EASIER TO STAY ON ORAL MEDS IF STUDY UNAVAILABLE ELSEWHERE
8	TDF/FTC	US	819699810	Cabotegravir	OTHER	PAIN OF INJECTION SITE REACTIONS
9	TDF/FTC	US	819665708	Cabotegravir	OTHER	PARTICIPANT IS NOT SURE ABOUT TAKING PREP LONG–TERM.
10	TDF/FTC	US	701853923	Cabotegravir	OTHER	PREFERENCE
11	TDF/FTC	US	734467815	TDF/FTC	OTHER	STUDY SCHEDULE, UNABLE TO COME IN EVERY 1–2 MONTHS
12	TDF/FTC	US	780471823	Cabotegravir	OTHER	THIS VISIT WAS STARTED AND SOME PROCEDURES DONE BEFORE IT WAS REALIZED THAT PPT HAD PASSED THE 3–YEAR CAP. PPT DID NOT WANT TO TAKE CAB, SO HE CHOSE TO TERMINATE FROM THE STUDY.
13	TDF/FTC	Latin America	850682504	TDF/FTC	OTHER	ALL 3 ARE CORRECT
14	TDF/FTC	Latin America	845856233	Cabotegravir	OTHER	ASSESS TOLERABILITY AND ADHERENCE
15	TDF/FTC	Latin America	721693309	TDF/FTC	OTHER	DO NOT WANT TO CHANGE PREP MEDICATION
16	TDF/FTC	Latin America	721760147	TDF/FTC	OTHER	DO NOT WANT TO CHANGE PREP MEDICATION
17	TDF/FTC	Latin America	850604016	TDF/FTC	OTHER	DO NOT WANT TO HAVE LONG–RELEASE DRUGS
18	TDF/FTC	Latin America	721185282	TDF/FTC	OTHER	DON'T WANT TO CHANGE MEDICATION
19	TDF/FTC	Latin America	845494026	TDF/FTC	OTHER	FEEL SAFE AND ADAPTED WITH TDF/FTC
20	TDF/FTC	Latin America	845513246	TDF/FTC	OTHER	FEELS COMFORTABLE USING TRUVADA AND FEELS UNSAFE IN CHANGING
21	TDF/FTC	Latin America	845702543	TDF/FTC	OTHER	IMPOSSIBILITY OF FREQUENT IN–PERSON VISITS AT THE MOMENT
22	TDF/FTC	Latin America	722551933	Cabotegravir	OTHER	INJECTION SITE PAIN
23	TDF/FTC	Latin America	850193645	TDF/FTC	OTHER	OPTION A AND OTHER: A GLUTEAL PROSTHESIS WILL BE PLACED
24	TDF/FTC	Latin America	722519276	TDF/FTC	OTHER	PARTICIPANT ADAPTED TO ORAL MEDICATION AND HAS DIFFICULTY MOVING
25	TDF/FTC	Latin America	845407201	TDF/FTC	OTHER	PARTICIPANT BELIEVES THAT INJECTION WAS CAUSING WEIGHT GAIN.
26	TDF/FTC	Latin America	845483640	TDF/FTC	OTHER	PARTICIPANT DECIDED TO SWITCH TO CABOTEGRAVIR ARM BUT, DUE THE USE OF CARBAMAZEPINE BY THE PARTICIPANT IT WAS MAINTAINED IN THE TDF/FTC ARM.
27	TDF/FTC	Latin America	845374286	TDF/FTC	OTHER	PARTICIPANT PREFERS TRUVADA
28	TDF/FTC	Latin America	845631679	Cabotegravir	OTHER	PARTICIPANT REPORTED A LOT OF PAIN AT THE INJECTION SITE
29	TDF/FTC	Latin America	845791578	TDF/FTC	OTHER	PERIODICITY OF STUDY VISITS
30	TDF/FTC	Latin America	845293445	TDF/FTC	OTHER	PREFER TO CONTINUE USING WHAT IS ALREADY KNOWN

[1] This listing is sorted by OLE regimen choice, region, 'other specify' text, and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_regm_choice_reason.sas, SAS Version 9.4 (04MAR2026,6:06)

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# [1]	OLE Regimen Choice	Region	Participant ID	Original Randomized Arm	Reason for choosing this regimen	Other, Specify
31	TDF/FTC	Latin America	850259464	TDF/FTC	OTHER	PREFER TO CONTINUE WITH TABLETS BECAUSE HAS TO PERFORM SURGERY AND DOESEN'T WANT TO PERFORM INJECTIONS
32	TDF/FTC	Latin America	845743536	TDF/FTC	OTHER	SURVEY PREFERS TO COME TO THE CENTER AT LONGER INTERVALS OF TIME
33	TDF/FTC	Latin America	722613161	TDF/FTC	OTHER	THE PARTICIPANT LIVES IN ANOTHER CITY AND HAS DIFFICULTY ATTENDING VISITS.
34	TDF/FTC	Latin America	852384249	TDF/FTC	OTHER	THE PARTICIPANT WAS DISCONTINUED FROM SP DUE AN ADVERSE EVENT, AND HE WOULD BE FOLLOWED IN STEP 5 OFF STUDY PRODUCT BY CMC RECOMMENDATION
35	TDF/FTC	Latin America	722451434	TDF/FTC	OTHER	THE PARTICIPANT WILL TRAVEL AND WILL NOT BE AVAILABLE FOR A NEW CAB DOSE
36	TDF/FTC	Latin America	845510631	Cabotegravir	OTHER	THE SURVEY HAD SEVERE PAIN AT THE INJECTION SITE
37	TDF/FTC	Latin America	852884602	TDF/FTC	OTHER	THE TABLETS IS COMFORT, SINCE IT HAS NO PROBLEM WITH ADHERENCE ALL DAYS.
38	TDF/FTC	Latin America	850480459	Cabotegravir	OTHER	WANTS TO SPEND LESS TIME IN THE STUDY
39	TDF/FTC	Latin America	721792122	Cabotegravir	OTHER	WOULD LIKE TO TRY ORAL PREP FOR A LONGER PERIOD
40	TDF/FTC	Asia	791772502	TDF/FTC	OTHER	ENTER TO STEP 5 OFF STUDY PRODUCT BY PROTOCOL TEAM CONSULTATION
41	TDF/FTC	Asia	858136149	TDF/FTC	OTHER	PARTICIPANT PLAN TO HAVE BUTTOCK FILLER
42	TDF/FTC	Africa	816800690	TDF/FTC	OTHER	CAB IS CONTRAINDICATED TO USE WITH TB TREATMENT
43	TDF/FTC	Africa	816387927	TDF/FTC	OTHER	PILLS ARE CONVENIENT
44	TDF/FTC	Africa	816822220	TDF/FTC	OTHER	USED TO PILLS. DIFFICULT TO CHANGE TO SOMETHING BODY DOES NOT KNOW
45	CABOTEGRAVIR	US	857371968	TDF/FTC	OTHER	"BETTER FOR MY LIFESTYLE"
46	CABOTEGRAVIR	US	745730236	Cabotegravir	OTHER	"FELT LIKE IT WAS WORKING MORE"
47	CABOTEGRAVIR	US	706205694	Cabotegravir	OTHER	"IT'S EASIER FOR ME BECAUSE THE PILLS ARE HARDER TO REMEMBER TO TAKE. ONCE I HAVE MY INJECTION, I DON'T NEED TO WORRY."
48	CABOTEGRAVIR	US	706972830	TDF/FTC	OTHER	"IT'S MORE CONVENIENT TO HAVE AN INJECTION AND LESS RISK OF FORGETTING TO TAKE A PILL"
49	CABOTEGRAVIR	US	857476607	TDF/FTC	OTHER	"MORE CONVENIENT"
50	CABOTEGRAVIR	US	706354290	TDF/FTC	OTHER	"SOMETIMES I FORGET TO TAKE THE PILL AND I WANT TO AVOID LONG–TERM SIDE EFFECTS OF TRUVADA."
51	CABOTEGRAVIR	US	857196270	Cabotegravir	OTHER	"THE CONVENIENCE"
52	CABOTEGRAVIR	US	857800186	TDF/FTC	OTHER	"WANT TO SEE HOW CAB GOES AND WANT TO CONTINUE ON STUDY"
53	CABOTEGRAVIR	US	706888948	Cabotegravir	OTHER	"WITH A SHOT, I DON'T HAVE TO WORRY ABOUT IT IN THE MORNINGS."
54	CABOTEGRAVIR	US	701485102	TDF/FTC	OTHER	ALL OF THE ABOVE
55	CABOTEGRAVIR	US	819485476	Cabotegravir	OTHER	ALL OF THE ABOVE PER PARTICIPANT
56	CABOTEGRAVIR	US	801558429	Cabotegravir	OTHER	CAB OPTION OUTWEIGHS TRUVADA
57	CABOTEGRAVIR	US	847487026	TDF/FTC	OTHER	CAN BE USED DISCREETLY & DOES NOT INTERRUPT SEX
58	CABOTEGRAVIR	US	825856687	TDF/FTC	OTHER	CAN BE USED DISCREETLY, TDF MAKES PPT NAUSEOUS WHEN TAKEN PRIOR TO MEALS
59	CABOTEGRAVIR	US	800900346	Cabotegravir	OTHER	CONTINUING TAKING THE MEDICATION THAT HE'S USE TO.
60	CABOTEGRAVIR	US	734509628	Cabotegravir	OTHER	CONVENIENCE

[1] This listing is sorted by OLE regimen choice, region, 'other specify' text, and PTID.

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# [1]	OLE Regimen Choice	Region	Participant ID	Original Randomized Arm	Reason for choosing this regimen	Other, Specify
61	CABOTEGRAVIR	US	819228700	TDF/FTC	OTHER	CONVENIENCE
62	CABOTEGRAVIR	US	861582169	TDF/FTC	OTHER	CONVENIENCE
63	CABOTEGRAVIR	US	706834894	Cabotegravir	OTHER	CONVENIENCE "ONE AND DONE".
64	CABOTEGRAVIR	US	706225589	TDF/FTC	OTHER	CONVENIENCE OF "PERIODIC TREATMENT" VS. DAILY PILLS
65	CABOTEGRAVIR	US	863238875	Cabotegravir	OTHER	CONVENIENT
66	CABOTEGRAVIR	US	801211968	Cabotegravir	OTHER	EAGER TO EXPLORE ALTERNATIVE METHOD OF HIV PREVENTION
67	CABOTEGRAVIR	US	851263340	Cabotegravir	OTHER	EASE OF INJECTIONS, DOESN'T HAVE TO WORRY ABOUT TAKING A PILL EVERYDAY
68	CABOTEGRAVIR	US	706461759	TDF/FTC	OTHER	EASE OF USE AND CAB WAS SHOWN TO BE SUPERIOR.
69	CABOTEGRAVIR	US	706824431	TDF/FTC	OTHER	EASE OF USE; LESS CHANCE OF GETTING OFF TRACK WITH PREP IF YOU MISS A DOSE.
70	CABOTEGRAVIR	US	844531547	Cabotegravir	OTHER	EASIER
71	CABOTEGRAVIR	US	745668261	TDF/FTC	OTHER	EASIER TO MANAGE
72	CABOTEGRAVIR	US	847592738	Cabotegravir	OTHER	EASIER TO REMEMBER
73	CABOTEGRAVIR	US	847840114	TDF/FTC	OTHER	EASIER TO REMEMBER THAN PILLS
74	CABOTEGRAVIR	US	857592758	TDF/FTC	OTHER	EASIER TO USE
75	CABOTEGRAVIR	US	857752322	Cabotegravir	OTHER	EASIER TO USE
76	CABOTEGRAVIR	US	847107374	TDF/FTC	OTHER	EASIER TO USE THAN OTHER METHODS
77	CABOTEGRAVIR	US	825895389	TDF/FTC	OTHER	FREE AND DOES NOT WANT TO PAY FOR PREP
78	CABOTEGRAVIR	US	856780503	Cabotegravir	OTHER	HARD TO REMEMBER TO TAKE PILLS
79	CABOTEGRAVIR	US	706730302	Cabotegravir	OTHER	HAS BEEN ON CAB THROUGHOUT STUDY. PREFERS NO PILLS
80	CABOTEGRAVIR	US	820520520	Cabotegravir	OTHER	I DON'T HAVE TO TAKE IT EVERY DAY. [JUST] EVERY 8 WEEKS. I'D RATHER DO THAT THAN TAKE A PILL EVERY DAY.
81	CABOTEGRAVIR	US	819944363	TDF/FTC	OTHER	I JUST WANT TO TRY IT!
82	CABOTEGRAVIR	US	745957991	TDF/FTC	OTHER	I PREFER INJECTION BECAUSE I FORGET TO TAKE PILLS SOME DAYS
83	CABOTEGRAVIR	US	856134391	TDF/FTC	OTHER	INJECTIONS ARE EASIER, AND REMEMBERING TOO TAKE PILLS IS CHALLENGING.
84	CABOTEGRAVIR	US	706827658	TDF/FTC	OTHER	INJECTIONS WOULD BE MORE CONVENIENT AND LAST FOR A LONGER TIME. PARTICIPANT ALSO LIKES TO BE ON A STUDY.
85	CABOTEGRAVIR	US	800616917	Cabotegravir	OTHER	INTERESTED IN CONTINUING CAB FOR RESEARCH PURPOSES.
86	CABOTEGRAVIR	US	800938032	TDF/FTC	OTHER	INTERESTED IN CONTINUING PARTICIPATING IN RESEARCH.
87	CABOTEGRAVIR	US	706541177	TDF/FTC	OTHER	INTERESTED IN TRYING "THE NEWEST THING" AND DON'T HAVE TO WORRY ABOUT TAKING A PILL.
88	CABOTEGRAVIR	US	819806161	Cabotegravir	OTHER	IT IS MORE CONVENIENT AND SUPERIOR.
89	CABOTEGRAVIR	US	820265163	Cabotegravir	OTHER	IT PAYS MORE MONEY.
90	CABOTEGRAVIR	US	801189048	Cabotegravir	OTHER	IT'S USEFUL TO BE PART OF THE CONTINUED STUDY IN THE LIFE OF CAB, AND KNOWING THAT CAB WILL BE APPROVED FOR PREP IS IMPORTANT TO HIM.
91	CABOTEGRAVIR	US	820260551	TDF/FTC	OTHER	JUST WANTED TO TRY IT
92	CABOTEGRAVIR	US	745673514	Cabotegravir	OTHER	LIKES THAT IT IS EVERY 2 MONTHS

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93	CABOTEGRAVIR	US	800478531	TDF/FTC	OTHER	LIKES THE IDEA OF AN INJECTABLE FORM OF PREP.
94	CABOTEGRAVIR	US	701472167	TDF/FTC	OTHER	LOOKING TO CONTINUE TO RECEIVE FREE PROTECTION
95	CABOTEGRAVIR	US	709629097	Cabotegravir	OTHER	MORE CONVENIENT
96	CABOTEGRAVIR	US	825234165	Cabotegravir	OTHER	MORE CONVENIENT
97	CABOTEGRAVIR	US	844874387	Cabotegravir	OTHER	MORE CONVENIENT
98	CABOTEGRAVIR	US	856184712	Cabotegravir	OTHER	MORE VISITS. MORE PATIENT STIPENDS.
99	CABOTEGRAVIR	US	800641217	Cabotegravir	OTHER	NO ADVERSE REACTION TO CAB AND WANTS TO CONTRIBUTE TO RESEARCH.
100	CABOTEGRAVIR	US	844608621	TDF/FTC	OTHER	ONLY WAY TO CONTINUE IN STUDY
101	CABOTEGRAVIR	US	706968440	Cabotegravir	OTHER	PARTICIPANT "JUST FEELS MORE SAFE, GIVES HIM PEACE OF MIND"
102	CABOTEGRAVIR	US	820569431	Cabotegravir	OTHER	PARTICIPANT DECIDED THAT AT THIS TIME CAB IS NOT A PRIORITY AFTER SIGNING CONSENT AND PERFORMING SURVEYS. PARTICIPANT DECLINED CAB INJECTION AND DECLINED TO COMPLETE STEP 5 PARTICIPATION.
103	CABOTEGRAVIR	US	861338840	Cabotegravir	OTHER	PARTICIPANT DID NOT SPECIFY.
104	CABOTEGRAVIR	US	745263928	Cabotegravir	OTHER	PARTICIPANT HAS BEEN ON CAB AND DOES NOT WANT TO CHANGE
105	CABOTEGRAVIR	US	701819536	Cabotegravir	OTHER	PARTICIPANT REPORTED, ALL OF THE ABOVE
106	CABOTEGRAVIR	US	780721003	TDF/FTC	OTHER	PARTICIPANT STATES HE PREFERS INJECTIONS INSTEAD OF PILLS, AND HE KNOWS FOR SURE HE WILL RECEIVE A PROTECTIVE REGIMEN.
107	CABOTEGRAVIR	US	800735942	TDF/FTC	OTHER	PARTICIPANT WANTS TO TRY CAB FOR CONVENIENCE OF NOT TAKING ORAL MEDICATION EVERYDAY.
108	CABOTEGRAVIR	US	864970202	TDF/FTC	OTHER	PRE–CAUTION
109	CABOTEGRAVIR	US	701828151	Cabotegravir	OTHER	PREFER INJECTION AND CAB WAS SHOWN TO BE SUPERIOR THAN TRUVADA
110	CABOTEGRAVIR	US	701935684	Cabotegravir	OTHER	PREFER INJECTION AND/OR DON'T LIKE PILLS AND CAB WAS SHOWN TO BE SUPERIOR TO TRUVADA FOR HIV PREVENTION
111	CABOTEGRAVIR	US	800549760	Cabotegravir	OTHER	PREFERS CONVENIENCE OF CAB INJECTIONS.
112	CABOTEGRAVIR	US	800988201	Cabotegravir	OTHER	PREFERS CONVENIENCE OF INJECTION.
113	CABOTEGRAVIR	US	800754886	TDF/FTC	OTHER	PREFERS INJECTION TO DAILY PILLS.
114	CABOTEGRAVIR	US	745956834	TDF/FTC	OTHER	PREFERS LESS FREQUENCY TO TAKE IT
115	CABOTEGRAVIR	US	801615869	TDF/FTC	OTHER	PREFERS NOT TO TAKE A DAILY MEDICATION
116	CABOTEGRAVIR	US	847842061	TDF/FTC	OTHER	PREFERS PILLS OVER INJECTIONS
117	CABOTEGRAVIR	US	800544517	Cabotegravir	OTHER	PT PREFERS CAB INJECTIONS DUE TO GI SIDE EFFECTS OF TRUVADA.
118	CABOTEGRAVIR	US	800378616	Cabotegravir	OTHER	PT REPORTED THAT HE IS HAVING UNPROTECTED RELATIONS AND WANTS TO PROTECT HIMSELF.
119	CABOTEGRAVIR	US	800675425	TDF/FTC	OTHER	PT WANTS TO TRY CAB AND CONTRIBUTE TO SCIENCE.
120	CABOTEGRAVIR	US	844914467	TDF/FTC	OTHER	PT WOULD LIKE TO TRY CAB AND FEELS COMFORTABLE HE CAN SWITCH BACK TO TRUVADA IF HE FEELS ANY AES.
121	CABOTEGRAVIR	US	800824099	TDF/FTC	OTHER	PT WOULD LIKE TO TRY INJECTABLE CAB.
122	CABOTEGRAVIR	US	706701709	TDF/FTC	OTHER	SCIENCE IS THE PRIMARY REASON AS WELL AS HELPING OUT THE COMMUNITY. CAB ALSO HAS A HIGHER EFFICACY.
123	CABOTEGRAVIR	US	825917775	Cabotegravir	OTHER	SHOT IS MORE CONVENIENT

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124	CABOTEGRAVIR	US	844663509	Cabotegravir	OTHER	SHOT WORK FOR LONGER
125	CABOTEGRAVIR	US	800134115	Cabotegravir	OTHER	STUDY INTEREST
126	CABOTEGRAVIR	US	825269981	TDF/FTC	OTHER	SUBJECT PREFERRED CAB INJECTIONS BUT RECEIVED BUTTOCK IMPLANTS, SO 4A WAS CHOSEN.
127	CABOTEGRAVIR	US	856248581	TDF/FTC	OTHER	THINKS IT WILL BE EASIER
128	CABOTEGRAVIR	US	734239407	TDF/FTC	OTHER	TO BE ABLE TO REMAIN IN THE STUDY
129	CABOTEGRAVIR	US	820300409	Cabotegravir	OTHER	TO SUPPORT THE STUDY
130	CABOTEGRAVIR	US	734651607	Cabotegravir	OTHER	TOOK CAB PILLS IN STEP 1
131	CABOTEGRAVIR	US	844306257	TDF/FTC	OTHER	TRY SOMETHING NEW
132	CABOTEGRAVIR	US	856371058	Cabotegravir	OTHER	WANT TO STAY IN THE STUDY LONGER
133	CABOTEGRAVIR	US	819424060	TDF/FTC	OTHER	WANT TO TRY A DIFFERENT OPTION INCLUDING USING INJECTION.
134	CABOTEGRAVIR	US	855579399	TDF/FTC	OTHER	WANTS MORE INFORMATION ABOUT CAB LA BEFORE STARTING.
135	CABOTEGRAVIR	US	825968343	Cabotegravir	OTHER	WANTS TO ASSIST THE STUDY IN COLLECTING ADDITIONAL DATA BY USING CAB
136	CABOTEGRAVIR	US	800244865	TDF/FTC	OTHER	WANTS TO BE INFORMED ABOUT CAB FOR EDUCATIONAL EVENTS.
137	CABOTEGRAVIR	US	819352785	TDF/FTC	OTHER	WANTS TO CONTINUE IN THE STUDY
138	CABOTEGRAVIR	US	706134280	TDF/FTC	OTHER	WANTS TO CONTRIBUTE TO RESEARCH OF CAB WHILST SIMULTANEOUSLY RECEIVING PREP
139	CABOTEGRAVIR	US	819132619	Cabotegravir	OTHER	WANTS TO STAY IN THE STUDY BECAUSE IT HELPS HIM TAKE CARE OF HIS HEALTH.
140	CABOTEGRAVIR	US	706744143	TDF/FTC	OTHER	WANTS TO TAKE ADVANTAGE OF NEW ADVANCES IN MEDICINE AND ADHERENCE WILL BE EASIER
141	CABOTEGRAVIR	US	800242661	TDF/FTC	OTHER	WANTS TO TRY IM PREP.
142	CABOTEGRAVIR	US	847768019	TDF/FTC	OTHER	WASHOUT PERIOD OF DRUG
143	CABOTEGRAVIR	US	864437018	TDF/FTC	OTHER	WORKED TO GET CAB
144	CABOTEGRAVIR	US	800299428	TDF/FTC	OTHER	WOULD LIKE TO TRY IM PREP.
145	CABOTEGRAVIR	Latin America	721268992	Cabotegravir	OTHER	AFRAID OF FORGETTING TO TAKE DAILY PILLS. DIFFICULTY IN JOINING DUE TO FORGETFULNESS.
146	CABOTEGRAVIR	Latin America	721303134	Cabotegravir	OTHER	AFRAID OF FORGETTING TO TAKE PILLS.
147	CABOTEGRAVIR	Latin America	721912766	Cabotegravir	OTHER	AFRAID OF FORGETTING TO TAKE PILLS.
148	CABOTEGRAVIR	Latin America	721996836	Cabotegravir	OTHER	AFRAID OF FORGETTING TO TAKE PILLS.
149	CABOTEGRAVIR	Latin America	850192532	Cabotegravir	OTHER	ALL 3 OPTIONS ARE CORRECT
150	CABOTEGRAVIR	Latin America	850200873	Cabotegravir	OTHER	ALL 3 OPTIONS ARE CORRECT
151	CABOTEGRAVIR	Latin America	850288158	TDF/FTC	OTHER	ALL 3 OPTIONS ARE CORRECT
152	CABOTEGRAVIR	Latin America	850911919	Cabotegravir	OTHER	ALL 3 OPTIONS ARE CORRECT
153	CABOTEGRAVIR	Latin America	850667261	Cabotegravir	OTHER	ALL ARE CORRECT
154	CABOTEGRAVIR	Latin America	850524111	Cabotegravir	OTHER	ALL THE OPTIONS ARE CORRECT
155	CABOTEGRAVIR	Latin America	850574331	Cabotegravir	OTHER	ALL THREE ARE CORRECT
156	CABOTEGRAVIR	Latin America	850280871	Cabotegravir	OTHER	BE ABLE TO CONTINUE IN THE STUDY

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157	CABOTEGRAVIR	Latin America	850432434	TDF/FTC	OTHER	BECAUSE WANT'S TO CONTINUE IN THE STUDY
158	CABOTEGRAVIR	Latin America	850291960	TDF/FTC	OTHER	CAB WAS SHOWN TO BE SUPERIOR TO TRUVADA FOR HIV PREVENTION AND DUE TO ADHERENCE PROBLEMS WITH TDF / FTC
159	CABOTEGRAVIR	Latin America	850642822	TDF/FTC	OTHER	CAB WAS SHOWN TO BE SUPERIOR TO TRUVADA FOR HIV PREVENTION AND THE CONVENIENCE OF NOT TAKING PILLS ON A DAILY BASIS
160	CABOTEGRAVIR	Latin America	845169675	TDF/FTC	OTHER	CONVENIENCE
161	CABOTEGRAVIR	Latin America	850116889	TDF/FTC	OTHER	DECIDE TO CONTINUE RECEIVING PREP
162	CABOTEGRAVIR	Latin America	721577792	TDF/FTC	OTHER	DOES NOT FEEL COMFORTABLE WITH THE NEED TO TAKE PILLS DAILY.
163	CABOTEGRAVIR	Latin America	721423857	Cabotegravir	OTHER	DUE TO THE PRACTICALITY OF THE INJECTION.
164	CABOTEGRAVIR	Latin America	845357708	Cabotegravir	OTHER	EASY TO USE EVERY TWO MONTHS
165	CABOTEGRAVIR	Latin America	721420103	Cabotegravir	OTHER	FEAR OF FORGETTING TO TAKE THE TABLET DAILY.
166	CABOTEGRAVIR	Latin America	721532752	TDF/FTC	OTHER	FEEL SAFER AND MORE PROTECTED ONCE YOU FORGET TO TAKE A PILL.
167	CABOTEGRAVIR	Latin America	721385538	TDF/FTC	OTHER	FEELS SAFER WITH THE INJECTION. BECAUSE SOMETIMES FORGET TO TAKE THE PILLS.
168	CABOTEGRAVIR	Latin America	850279089	TDF/FTC	OTHER	FOR STAYING LONGER IN THE STUDY
169	CABOTEGRAVIR	Latin America	722432986	TDF/FTC	OTHER	HE THINKS THAT HAVING DECIDED TO BE A RESEARCH PARTICIPANT IN HPTN083, HE THINKS IT MAKES SENSE TO USE THE STUDY DRUG.
170	CABOTEGRAVIR	Latin America	722483051	TDF/FTC	OTHER	HE WANTS TO STAY IN THE STUDY LONGER.
171	CABOTEGRAVIR	Latin America	721951038	TDF/FTC	OTHER	HE WOULD LIKE TO CONTINUE HIS FOLLOW–UP THROUGH THE PROTOCOL.
172	CABOTEGRAVIR	Latin America	721436987	Cabotegravir	OTHER	INJECTION IS A MORE ANONYMOUS OPTION AND AVOIDS FORGETTING TAKING PILLS.
173	CABOTEGRAVIR	Latin America	721128379	Cabotegravir	OTHER	INJECTION IS MORE PRACTICAL.
174	CABOTEGRAVIR	Latin America	721307805	TDF/FTC	OTHER	INJECTION IS MORE PRACTICAL.
175	CABOTEGRAVIR	Latin America	721335790	TDF/FTC	OTHER	INJECTION IS MORE PRACTICAL.
176	CABOTEGRAVIR	Latin America	721440891	Cabotegravir	OTHER	INJECTION IS MORE PRACTICAL.
177	CABOTEGRAVIR	Latin America	721690783	Cabotegravir	OTHER	INJECTION IS MORE PRACTICAL.
178	CABOTEGRAVIR	Latin America	721842035	Cabotegravir	OTHER	INJECTION IS MORE PRACTICAL.
179	CABOTEGRAVIR	Latin America	721942648	TDF/FTC	OTHER	INJECTION IS MORE PRACTICAL.
180	CABOTEGRAVIR	Latin America	721218380	TDF/FTC	OTHER	INJECTION IS MORE PRACTICAL. FEAR OF FORGETTING THE PILLS.
181	CABOTEGRAVIR	Latin America	721523784	Cabotegravir	OTHER	INJECTION IS MORE PRACTICAL. FEAR OF FORGETTING TO TAKE PILLS DAILY.
182	CABOTEGRAVIR	Latin America	721993879	Cabotegravir	OTHER	INJECTION IS MORE PRACTICAL. IT'S AN EASIER METHOD.
183	CABOTEGRAVIR	Latin America	860287442	TDF/FTC	OTHER	INJECTION PRACTICALITY AND SAFETY.
184	CABOTEGRAVIR	Latin America	721155533	TDF/FTC	OTHER	INJECTION PRACTICALITY AND SAFETY. AFRAID OF FORGETTING TO TAKE THE PILLS.
185	CABOTEGRAVIR	Latin America	721139724	Cabotegravir	OTHER	INJECTION PRACTICALITY.
186	CABOTEGRAVIR	Latin America	721163535	Cabotegravir	OTHER	INJECTION PRACTICALITY.
187	CABOTEGRAVIR	Latin America	721327547	TDF/FTC	OTHER	INJECTION PRACTICALITY.
188	CABOTEGRAVIR	Latin America	721503329	TDF/FTC	OTHER	INJECTION PRACTICALITY.
189	CABOTEGRAVIR	Latin America	721580675	Cabotegravir	OTHER	INJECTION PRACTICALITY.

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190	CABOTEGRAVIR	Latin America	721945780	TDF/FTC	OTHER	INJECTION PRACTICALITY. AFRAID OF MISSING A DOSE OF THE TABLET.
191	CABOTEGRAVIR	Latin America	721616367	TDF/FTC	OTHER	INJECTION PRACTICALITY. FEAR OF FORGETTING TO TAKE THE PILL.
192	CABOTEGRAVIR	Latin America	845486728	Cabotegravir	OTHER	IT WILL BE EASIER TO MAINTAIN ADHERENCE AND REGULARITY
193	CABOTEGRAVIR	Latin America	721590526	TDF/FTC	OTHER	NO OBLIGATION TO TAKE PILLS DAILY. FEAR OF FORGETTING.
194	CABOTEGRAVIR	Latin America	721926235	TDF/FTC	OTHER	NOT BEING COMMITTED TO TAKING PILLS DAILY.
195	CABOTEGRAVIR	Latin America	721435677	Cabotegravir	OTHER	NOT RESPONSIBLE FOR TAKING HIS DAILY PILLS.
196	CABOTEGRAVIR	Latin America	850145702	TDF/FTC	OTHER	ON 15 JUL 2021 SHE SELECTED TDF/FTC DUE TO A PLANNED TRIP, BUT ON 10 MAR 2022 SHE CHANGED TO CAB REGIMEN DUE TO RECENT HIV EXPOSURE.
197	CABOTEGRAVIR	Latin America	850509787	TDF/FTC	OTHER	OPTION 1 AND 2
198	CABOTEGRAVIR	Latin America	850526130	TDF/FTC	OTHER	OPTION 1 AND 2
199	CABOTEGRAVIR	Latin America	850305508	Cabotegravir	OTHER	OPTION A AND B
200	CABOTEGRAVIR	Latin America	850535683	Cabotegravir	OTHER	OPTION A AND B
201	CABOTEGRAVIR	Latin America	850536065	Cabotegravir	OTHER	OPTION A AND B
202	CABOTEGRAVIR	Latin America	850577366	TDF/FTC	OTHER	OPTION A AND B
203	CABOTEGRAVIR	Latin America	850709378	Cabotegravir	OTHER	OPTION A AND B
204	CABOTEGRAVIR	Latin America	850729780	TDF/FTC	OTHER	OPTION A AND B
205	CABOTEGRAVIR	Latin America	850621821	Cabotegravir	OTHER	OPTION A AND B ARE CORRECT
206	CABOTEGRAVIR	Latin America	850602972	Cabotegravir	OTHER	OPTION A AND POOR ADHERENCE TO PILLS
207	CABOTEGRAVIR	Latin America	850130547	Cabotegravir	OTHER	OPTION A,C AND THE TDF / FTC GIVES HIM INSOMNIA
208	CABOTEGRAVIR	Latin America	850120154	TDF/FTC	OTHER	OPTION B AND EXTEND THE DURATION OF THE STUDY
209	CABOTEGRAVIR	Latin America	850344803	Cabotegravir	OTHER	OPTION B AND STAY LONGER IN THE PROTOCOL
210	CABOTEGRAVIR	Latin America	850357033	Cabotegravir	OTHER	OPTIONS 1 AND 2
211	CABOTEGRAVIR	Latin America	850182915	Cabotegravir	OTHER	OPTIONS A AND B
212	CABOTEGRAVIR	Latin America	850346073	Cabotegravir	OTHER	OPTIONS A AND B
213	CABOTEGRAVIR	Latin America	850405660	Cabotegravir	OTHER	OPTIONS A AND B
214	CABOTEGRAVIR	Latin America	850677725	TDF/FTC	OTHER	OPTIONS B AND C
215	CABOTEGRAVIR	Latin America	831576129	TDF/FTC	OTHER	PARTICIPANT CANNOT CHOOSE TO INITIATE TDF/FTC
216	CABOTEGRAVIR	Latin America	721513548	TDF/FTC	OTHER	PARTICIPANT WANT TO TRY OTHER KIND OF PREP
217	CABOTEGRAVIR	Latin America	721167798	TDF/FTC	OTHER	PRACTICALITY
218	CABOTEGRAVIR	Latin America	721567435	TDF/FTC	OTHER	PRACTICALITY
219	CABOTEGRAVIR	Latin America	721310134	Cabotegravir	OTHER	PRACTICALITY
220	CABOTEGRAVIR	Latin America	721518635	Cabotegravir	OTHER	PRACTICALITY
221	CABOTEGRAVIR	Latin America	721576127	Cabotegravir	OTHER	PRACTICALITY
222	CABOTEGRAVIR	Latin America	721646111	TDF/FTC	OTHER	PRACTICALITY
223	CABOTEGRAVIR	Latin America	721673235	Cabotegravir	OTHER	PRACTICALITY
224	CABOTEGRAVIR	Latin America	721697901	Cabotegravir	OTHER	PRACTICALITY
225	CABOTEGRAVIR	Latin America	721925522	TDF/FTC	OTHER	PRACTICALITY

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Listing 2 – Listing of 'Other' Reasons of OLE Regimen Choice

# [1]	OLE Regimen Choice	Region	Participant ID	Original Randomized Arm	Reason for choosing this regimen	Other, Specify
226	CABOTEGRAVIR	Latin America	721277393	Cabotegravir	OTHER	PREFER INJECTION DUE TO PRACTICALITY.
227	CABOTEGRAVIR	Latin America	831404470	Cabotegravir	OTHER	PREFER INJECTION OVER PILLS
228	CABOTEGRAVIR	Latin America	831174589	TDF/FTC	OTHER	PREFER INJECTIONS BECAUSE IS EASY
229	CABOTEGRAVIR	Latin America	831116269	TDF/FTC	OTHER	PREFER INJECTIONS TO PILLS
230	CABOTEGRAVIR	Latin America	721310476	Cabotegravir	OTHER	RISK OF FORGET DOSES WHEN TAKING PILLS.
231	CABOTEGRAVIR	Latin America	845866569	TDF/FTC	OTHER	THE AMOUNT OF DAILY PILLS HE USES IS LARGE, THAN HE INTENDS TO REDUCE IT.
232	CABOTEGRAVIR	Latin America	721843428	Cabotegravir	OTHER	THE EASE OF INJECTION.
233	CABOTEGRAVIR	Latin America	722126194	TDF/FTC	OTHER	THE PARTICIPANT WANTS TO STAY LONGER IN THE STUDY. THE USE OF TRUVADA WOULD SHORTEN YOUR TIME IN THE CENTER.
234	CABOTEGRAVIR	Latin America	845490721	TDF/FTC	OTHER	THE PARTICIPANT WOULD LIKE TO TRY CABOTEGRAVIR.
235	CABOTEGRAVIR	Latin America	721179649	Cabotegravir	OTHER	THE PRACTICALITY AND EASE OF INJECTION. AFRAID OF FORGETTING TO TAKE YOUR TABLET DAILY.
236	CABOTEGRAVIR	Latin America	721654443	Cabotegravir	OTHER	THE PRACTICALITY AND EASE OF INJECTION. AFRAID OF FORGETTING TO TAKE YOUR TABLET DAILY.
237	CABOTEGRAVIR	Latin America	721262461	TDF/FTC	OTHER	THE PRACTICALITY OF THE INJECTION.
238	CABOTEGRAVIR	Latin America	721690174	TDF/FTC	OTHER	TO AVOID FORGETTING TO TAKE THE PILLS
239	CABOTEGRAVIR	Latin America	721836334	TDF/FTC	OTHER	TO AVOID FORGETTING TO TAKE THE PILLS
240	CABOTEGRAVIR	Latin America	850291247	TDF/FTC	OTHER	TO CONTINUE LONGER IN THE STUDY
241	CABOTEGRAVIR	Latin America	721236439	TDF/FTC	OTHER	TO CONTINUE MONITORING AND CONTRIBUTING TO THE STUDY AND BECAUSE OF THE PRACTICALITY OF THE INJECTION.
242	CABOTEGRAVIR	Latin America	850485424	TDF/FTC	OTHER	TO STAY LONGER IN THE STUDY
243	CABOTEGRAVIR	Latin America	722236847	TDF/FTC	OTHER	TRUVADA TREATMENT IS SHORTER
244	CABOTEGRAVIR	Latin America	850667487	TDF/FTC	OTHER	WANT TO STAY LONGER IN THE STUDIO
245	CABOTEGRAVIR	Latin America	850768878	TDF/FTC	OTHER	WANT TO STAY LONGER IN THE STUDY
246	CABOTEGRAVIR	Latin America	850393105	TDF/FTC	OTHER	WANTS TO CONTINUE IN THE STUDY RECEIVING PREP
247	CABOTEGRAVIR	Latin America	860673521	TDF/FTC	OTHER	WANTS TO KNOW WHAT IT'S LIKE TO USE CABOTEGRAVIR
248	CABOTEGRAVIR	Latin America	850849246	TDF/FTC	OTHER	WANT'S TO CONTINUE IN THE STUDY AND PROLONG THE USE OF PREP
249	CABOTEGRAVIR	Latin America	721310312	TDF/FTC	OTHER	WOULD LIKE TO TRY OTHER CHOICE OF USING PREP
250	CABOTEGRAVIR	Asia	862645155	TDF/FTC	OTHER	EASIER TO MEDICATION ADHERENCE THAN ORAL MEDICINE
251	CABOTEGRAVIR	Asia	862903707	TDF/FTC	OTHER	EASY TO ADHERENCE, NOT AFRAID OF FORGETTING TO TAKE MEDICINE
252	CABOTEGRAVIR	Asia	862160842	Cabotegravir	OTHER	EASY TO MEDICATION ADHERENCE AS RECOMMENDED
253	CABOTEGRAVIR	Asia	862176953	TDF/FTC	OTHER	EASY TO MEDICATION ADHERENCE AS RECOMMENDED
254	CABOTEGRAVIR	Asia	862292860	Cabotegravir	OTHER	EASY TO MEDICATION ADHERENCE AS RECOMMENDED
255	CABOTEGRAVIR	Asia	862657813	Cabotegravir	OTHER	EASY TO MEDICATION ADHERENCE, EASY TO KEEP SECRET FROM OTHERS.
256	CABOTEGRAVIR	Asia	862368334	TDF/FTC	OTHER	MORE CONVENIENT IN MEDICATION ADHERENCE AS RECOMMENDED
257	CABOTEGRAVIR	Asia	862145647	TDF/FTC	OTHER	THE PATICIPANT IS AFRAID OF FORGETTING TO TAKE ORAL MEDICINE
258	CABOTEGRAVIR	Africa	816277715	TDF/FTC	OTHER	ADHERENCE EASIER

[1] This listing is sorted by OLE regimen choice, region, 'other specify' text, and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_regm_choice_reason.sas, SAS Version 9.4 (04MAR2026,6:06)

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
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# [1]	OLE Regimen Choice	Region	Participant ID	Original Randomized Arm	Reason for choosing this regimen	Other, Specify
259	CABOTEGRAVIR	Africa	816499646	Cabotegravir	OTHER	ADHERENCE EASIER
260	CABOTEGRAVIR	Africa	816751666	TDF/FTC	OTHER	ADHERENCE EASY
261	CABOTEGRAVIR	Africa	816295785	Cabotegravir	OTHER	ADHERENCE FITS INTO HIS LIFESTYLE MORE EASILY
262	CABOTEGRAVIR	Africa	816949873	Cabotegravir	OTHER	CAB IS EASIER
263	CABOTEGRAVIR	Africa	816100559	TDF/FTC	OTHER	CAN FORGET PILLS
264	CABOTEGRAVIR	Africa	816115972	TDF/FTC	OTHER	COUSIN THROWING PILLS AWAY
265	CABOTEGRAVIR	Africa	816657549	TDF/FTC	OTHER	DIFFICULT TO TAKE TABLETS. HAS TO HIDE IT FROM WIFE
266	CABOTEGRAVIR	Africa	816770541	Cabotegravir	OTHER	DOCTOR DID NOT ASK
267	CABOTEGRAVIR	Africa	816521398	Cabotegravir	OTHER	EASIER
268	CABOTEGRAVIR	Africa	816680115	Cabotegravir	OTHER	EASIER
269	CABOTEGRAVIR	Africa	816640972	TDF/FTC	OTHER	EASIER WITH INJECTIONS
270	CABOTEGRAVIR	Africa	816312214	Cabotegravir	OTHER	EASY
271	CABOTEGRAVIR	Africa	816456558	Cabotegravir	OTHER	EASY ADHERENCE. NO SIDE EFFECTS
272	CABOTEGRAVIR	Africa	816605160	Cabotegravir	OTHER	FORGET PILLS
273	CABOTEGRAVIR	Africa	816248332	TDF/FTC	OTHER	INJECTION MORE CONVENIENT. CAN FORGET PILLS
274	CABOTEGRAVIR	Africa	816287866	TDF/FTC	OTHER	MORE CONVENIENT
275	CABOTEGRAVIR	Africa	816626014	Cabotegravir	OTHER	MUCH EASIER THAN TABS
276	CABOTEGRAVIR	Africa	816664910	TDF/FTC	OTHER	NOT GOOD AT TAKING PILLS
277	CABOTEGRAVIR	Africa	816837388	TDF/FTC	OTHER	PARTNER SOMETIMES DIFFICULT ABOUT ORAL PREP
278	CABOTEGRAVIR	Africa	816617512	TDF/FTC	OTHER	PILLS – FORGETFUL
279	CABOTEGRAVIR	Africa	816292797	Cabotegravir	OTHER	PILLS CAN BE FORGOTTEN
280	CABOTEGRAVIR	Africa	816660127	TDF/FTC	OTHER	STAYING IN THE STUDY FOR LENGTHY PURPOSES
281	CABOTEGRAVIR	Africa	816566103	Cabotegravir	OTHER	STAYS LONG IN THE BODY. NO NEED TO TAKE PILLS
282	CABOTEGRAVIR	Africa	816789949	TDF/FTC	OTHER	WANTS TO TRY CAB

[1] This listing is sorted by OLE regimen choice, region, 'other specify' text, and PTID.

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Table 4A – Demographics by OLE Enrollment Status

	Overall	Enrolled in the OLE	Did not join the OLE and terminated	OLE status pending
Total Participants Enrolled in the Primary Phase	4566	2658	1908	0
Age (years)				
18–19	376/4566 (8.2%)	202/2658 (7.6%)	174/1908 (9.1%)	0/0 (–%)
20–24	1468/4566 (32.2%)	790/2658 (29.7%)	678/1908 (35.5%)	0/0 (–%)
25–29	1236/4566 (27.1%)	731/2658 (27.5%)	505/1908 (26.5%)	0/0 (–%)
30–39	1048/4566 (23.0%)	647/2658 (24.3%)	401/1908 (21.0%)	0/0 (–%)
40–49	315/4566 (6.9%)	219/2658 (8.2%)	96/1908 (5.0%)	0/0 (–%)
50–59	110/4566 (2.4%)	66/2658 (2.5%)	44/1908 (2.3%)	0/0 (–%)
60+	13/4566 (0.3%)	3/2658 (0.1%)	10/1908 (0.5%)	0/0 (–%)
Missing	0/4566 (0.0%)	0/2658 (0.0%)	0/1908 (0.0%)	0/0 (–%)
Mean (SD)	28 (8.2)	29 (8.2)	27 (8.1)	
Median (Q1,Q3)	26 (22,32)	27 (23,33)	25 (22,31)	
Min, Max	18, 69	18, 61	18, 69	
Cohort				
MSM	3992/4566 (87.4%)	2322/2658 (87.4%)	1670/1908 (87.5%)	0/0 (–%)
TGW [1]	570/4566 (12.5%)	333/2658 (12.5%)	237/1908 (12.4%)	0/0 (–%)
Prefer not to answer	4/4566 (0.1%)	3/2658 (0.1%)	1/1908 (0.1%)	0/0 (–%)
Missing	0/4566 (0.0%)	0/2658 (0.0%)	0/1908 (0.0%)	0/0 (–%)
Ethnicity (Latino or Hispanic) [2]				
Yes	2109/3662 (57.6%)	1243/2043 (60.8%)	866/1619 (53.5%)	0/0 (–%)
No	1552/3662 (42.4%)	800/2043 (39.2%)	752/1619 (46.4%)	0/0 (–%)
Missing	1/3662 (<0.1%)	0/2043 (0.0%)	1/1619 (0.1%)	0/0 (–%)
Black [3]				
Black or African American or Mixed Race, Including Black/AA	845/1698 (49.8%)	430/822 (52.3%)	415/876 (47.4%)	0/0 (–%)
Black or African American	805/845 (95.3%)	410/430 (95.3%)	395/415 (95.2%)	0/0 (–%)
Mixed Race, Including Black/AA	40/845 (4.7%)	20/430 (4.7%)	20/415 (4.8%)	0/0 (–%)

[1] TGW cohort includes participants who self–identify as female, transgender female, gender queer, gender variant, gender non–conforming, or gender fluid.
[2] US and Latin American only.
[3] US only.
[4] US and Latin American only.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_demo_byenr.sas, SAS Version 9.4 (04MAR2026,6:06)

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Table 4A – Demographics by OLE Enrollment Status

	Overall	Enrolled in the OLE	Did not join the OLE and terminated	OLE status pending
Marital Status				
Married/Civil Union/Legal Partnership	177/4566 (3.9%)	96/2658 (3.6%)	81/1908 (4.2%)	0/0 (–%)
Living with Primary or Main Partner	292/4566 (6.4%)	179/2658 (6.7%)	113/1908 (5.9%)	0/0 (–%)
Have Primary or Main Partner, Not Living Together	335/4566 (7.3%)	211/2658 (7.9%)	124/1908 (6.5%)	0/0 (–%)
Single/Divorced/Widowed	3751/4566 (82.2%)	2165/2658 (81.5%)	1586/1908 (83.1%)	0/0 (–%)
Other	11/4566 (0.2%)	7/2658 (0.3%)	4/1908 (0.2%)	0/0 (–%)
Missing	0/4566 (0.0%)	0/2658 (0.0%)	0/1908 (0.0%)	0/0 (–%)
SexPro Score [4]				
<=16	3122/3662 (85.3%)	1728/2043 (84.6%)	1394/1619 (86.1%)	0/0 (–%)
>16	540/3662 (14.7%)	315/2043 (15.4%)	225/1619 (13.9%)	0/0 (–%)
Missing	0/3662 (0.0%)	0/2043 (0.0%)	0/1619 (0.0%)	0/0 (–%)
Employment Status				
Full–time Employment	2332/4566 (51.1%)	1402/2658 (52.7%)	930/1908 (48.7%)	0/0 (–%)
Part–time Employment	1014/4566 (22.2%)	587/2658 (22.1%)	427/1908 (22.4%)	0/0 (–%)
Not Employed	1220/4566 (26.7%)	669/2658 (25.2%)	551/1908 (28.9%)	0/0 (–%)
Missing	0/4566 (0.0%)	0/2658 (0.0%)	0/1908 (0.0%)	0/0 (–%)
Education				
No Schooling	8/4566 (0.2%)	4/2658 (0.2%)	4/1908 (0.2%)	0/0 (–%)
Primary School	70/4566 (1.5%)	38/2658 (1.4%)	32/1908 (1.7%)	0/0 (–%)
Secondary School	1012/4566 (22.2%)	544/2658 (20.5%)	468/1908 (24.5%)	0/0 (–%)
Technical Training	375/4566 (8.2%)	201/2658 (7.6%)	174/1908 (9.1%)	0/0 (–%)
College/University or Higher	3101/4566 (67.9%)	1871/2658 (70.4%)	1230/1908 (64.5%)	0/0 (–%)
Missing	0/4566 (0.0%)	0/2658 (0.0%)	0/1908 (0.0%)	0/0 (–%)

[1] TGW cohort includes participants who self–identify as female, transgender female, gender queer, gender variant, gender non–conforming, or gender fluid.
[2] US and Latin American only.
[3] US only.
[4] US and Latin American only.

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Table 4B – Demographics by OLE Regimen Choice

	Overall [1]	TDF/FTC	Cabotegravir
Total Participants Joined the OLE	2658	107	2495
Age (years)			
18–19	202/2658 (7.6%)	7/107 (6.5%)	188/2495 (7.5%)
20–24	790/2658 (29.7%)	30/107 (28.0%)	744/2495 (29.8%)
25–29	731/2658 (27.5%)	32/107 (29.9%)	678/2495 (27.2%)
30–39	647/2658 (24.3%)	28/107 (26.2%)	610/2495 (24.4%)
40–49	219/2658 (8.2%)	8/107 (7.5%)	208/2495 (8.3%)
50–59	66/2658 (2.5%)	2/107 (1.9%)	64/2495 (2.6%)
60+	3/2658 (0.1%)	0/107 (0.0%)	3/2495 (0.1%)
Missing	0/2658 (0.0%)	0/107 (0.0%)	0/2495 (0.0%)
Mean (SD)	29 (8.2)	29 (7.4)	29 (8.2)
Median (Q1,Q3)	27 (23,33)	27 (23,32)	27 (23,33)
Min, Max	18, 61	18, 52	18, 61
Cohort			
MSM	2322/2658 (87.4%)	95/107 (88.8%)	2179/2495 (87.3%)
TGW [2]	333/2658 (12.5%)	12/107 (11.2%)	313/2495 (12.5%)
Prefer not to answer	3/2658 (0.1%)	0/107 (0.0%)	3/2495 (0.1%)
Missing	0/2658 (0.0%)	0/107 (0.0%)	0/2495 (0.0%)
Ethnicity (Latino or Hispanic) [3]			
Yes	1243/2043 (60.8%)	52/86 (60.5%)	1169/1919 (60.9%)
No	800/2043 (39.2%)	34/86 (39.5%)	750/1919 (39.1%)
Missing	0/2043 (0.0%)	0/86 (0.0%)	0/1919 (0.0%)
Black [4]			
Black or African American or Mixed Race, Including Black/AA	430/822 (52.3%)	21/33 (63.6%)	397/770 (51.6%)
Black or African American	410/430 (95.3%)	19/21 (90.5%)	379/397 (95.5%)
Mixed Race, Including Black/AA	20/430 (4.7%)	2/21 (9.5%)	18/397 (4.5%)

[1] Includes all participants enrolled in all the OLE regimen: CAB, TDF/FTC, seroconverter schedule and open label Truvada schedule.
[2] TGW cohort includes participants who self–identify as female, transgender female, gender queer, gender variant, gender non–conforming, or gender fluid.
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[4] US only.
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	Overall [1]	TDF/FTC	Cabotegravir
Marital Status			
Married/Civil Union/Legal Partnership	96/2658 (3.6%)	3/107 (2.8%)	93/2495 (3.7%)
Living with Primary or Main Partner	179/2658 (6.7%)	5/107 (4.7%)	169/2495 (6.8%)
Have Primary or Main Partner, Not Living Together	211/2658 (7.9%)	12/107 (11.2%)	189/2495 (7.6%)
Single/Divorced/Widowed	2165/2658 (81.5%)	86/107 (80.4%)	2038/2495 (81.7%)
Other	7/2658 (0.3%)	1/107 (0.9%)	6/2495 (0.2%)
Missing	0/2658 (0.0%)	0/107 (0.0%)	0/2495 (0.0%)
SexPro Score [5]			
<=16	1728/2043 (84.6%)	77/86 (89.5%)	1616/1919 (84.2%)
>16	315/2043 (15.4%)	9/86 (10.5%)	303/1919 (15.8%)
Missing	0/2043 (0.0%)	0/86 (0.0%)	0/1919 (0.0%)
Employment Status			
Full–time Employment	1402/2658 (52.7%)	59/107 (55.1%)	1319/2495 (52.9%)
Part–time Employment	587/2658 (22.1%)	19/107 (17.8%)	551/2495 (22.1%)
Not Employed	669/2658 (25.2%)	29/107 (27.1%)	625/2495 (25.1%)
Missing	0/2658 (0.0%)	0/107 (0.0%)	0/2495 (0.0%)
Education			
No Schooling	4/2658 (0.2%)	0/107 (0.0%)	4/2495 (0.2%)
Primary School	38/2658 (1.4%)	3/107 (2.8%)	34/2495 (1.4%)
Secondary School	544/2658 (20.5%)	18/107 (16.8%)	516/2495 (20.7%)
Technical Training	201/2658 (7.6%)	6/107 (5.6%)	194/2495 (7.8%)
College/University or Higher	1871/2658 (70.4%)	80/107 (74.8%)	1747/2495 (70.0%)
Missing	0/2658 (0.0%)	0/107 (0.0%)	0/2495 (0.0%)

[1] Includes all participants enrolled in all the OLE regimen: CAB, TDF/FTC, seroconverter schedule and open label Truvada schedule.
[2] TGW cohort includes participants who self–identify as female, transgender female, gender queer, gender variant, gender non–conforming, or gender fluid.
[3] US and Latin American only.
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Listing 3 – Listing of 'Other' Reasons of Terminated Early from OLE

# [1]	Participant ID	Region	Site	Reason for Terminated Early from OLE	Other, Specify
1	709467239	US	Atlanta	Other	Participant is lost to follow up.
2	846695208	US	Aurora	Other	Participant did not return after his week 64 visit. We have been unable to reach after multiple attempts. Participant taken off study effective 11/10/22 as that was our last contact with him.
3	821340505	US	Birmingham	Other	Ineligible under Version 4 of the Protocol, Letter of Amendment No. 3, and lost to follow–up.
4	821866535	US	Birmingham	Other	Participant lost to follow up.
5	821319416	US	Birmingham	Other	lost to follow up
6	819613462	US	Boston	Other	Deemed lost to follow up
7	819517422	US	Boston	Other	Lost to follow–up (LTFU)
8	819633614	US	Boston	Other	Terminated per protocol as they have reached one year past their last injection.
9	819381070	US	Boston	Other	Withdraw due to scheduling difficulties and decreased access to study site.
10	734239407	US	Bronx	Other	Lost in follow up
11	734468385	US	Bronx	Other	Lost in follow up
12	734509628	US	Bronx	Other	Lost in follow up
13	706445145	US	Chapel Hill	Other	participant lost to follow up
14	706946565	US	Chapel Hill	Other	participant lost to follow up greater than 6 months
15	706225589	US	Chapel Hill	Other	participant required to take concomitant medication that is prohibited with CAB–LA
16	844423588	US	Chicago – AYAR	Other	Truvada – Oral PrEP from PCP started on 2/27/23. Truvada listed on Con Med Log
17	844755585	US	Chicago – AYAR	Other	lost to follow up
18	844991499	US	Chicago – AYAR	Other	lost to follow up
19	844531547	US	Chicago – AYAR	Other	participant decided to begin dosing with oral PrEP medication
20	844745267	US	Chicago – AYAR	Other	participant decided to take oral PrEP medication
21	844874712	US	Chicago – AYAR	Other	participant has decided to take oral PrEP medication
22	844962624	US	Chicago – AYAR	Other	ppt began taking oral PrEP medication
23	844295776	US	Chicago – AYAR	Other	site closing – scheduled end of study
24	844826565	US	Chicago – AYAR	Other	site closing – scheduled end of study
25	844841589	US	Chicago – AYAR	Other	site closing – scheduled end of study
26	844622919	US	Chicago – AYAR	Other	site closing, scheduled end of study
27	844677244	US	Chicago – AYAR	Other	site closing, scheduled end of study
28	844786915	US	Chicago – AYAR	Other	site closing, scheduled end of study
29	844966596	US	Chicago – AYAR	Other	site closing, scheduled end of study
30	847415360	US	Cincinnati	Other	Linkage to local Descovy
31	847628074	US	Cincinnati	Other	Linkage to local Descovy
32	847768019	US	Cincinnati	Other	Linkage to local Truvada
33	847733042	US	Cincinnati	Other	Patient lost to follow–up

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# [1]	Participant ID	Region	Site	Reason for Terminated Early from OLE	Other, Specify
34	847361315	US	Cincinnati	Other	Unable to reach patient, took patient off study
35	856247585	US	Columbus	Other	LTFU
36	856337406	US	Columbus	Other	Lost To Follow Up
37	856407357	US	Columbus	Other	Lost to follow up
38	787295026	US	Decatur	Other	LTFU
39	787402240	US	Decatur	Other	LTFU
40	787457317	US	Decatur	Other	LTFU
41	787800867	US	Decatur	Other	LTFU
42	787964164	US	Decatur	Other	LTFU
43	787857173	US	Decatur	Other	LTFU since interim visit at 74.1. Able to reach participant on 4/17 and he reported wanted to end study participation with plans to receive PrEP with outside provider.
44	787552289	US	Decatur	Other	SAE
45	787184260	US	Decatur	Other	ltfu
46	787557857	US	Decatur	Other	ltfu
47	787703224	US	Decatur	Other	ltfu
48	851364256	US	Greensboro	Other	Lost to follow up
49	745345862	US	Harlem	Other	Lost to follow up
50	745393656	US	Harlem	Other	Lost to follow up
51	745828114	US	Harlem	Other	Unable to contact participant. Terminating per guidance from study team.
52	745367090	US	Harlem	Other	lost to follow up
53	853918032	US	Houston	Other	Participant lost to follow up
54	853926180	US	Houston	Other	Participant lost to follow up
55	701207061	US	Los Angeles – UCLA Care	Other	Participant LTFU–site unable to contact participant
56	701853923	US	Los Angeles – UCLA Care	Other	Participant LTFU–site unable to reach participant
57	701828151	US	Los Angeles – UCLA Care	Other	Participant relocated, new site not able to contact participant
58	701953786	US	Los Angeles – UCLA Care	Other	coenrolled in a separate study, per protocol and CMC guidelines, participant transitioned off study
59	701272680	US	Los Angeles – UCLA Care	Other	participant lost to follow up for 6 months
60	701526017	US	Los Angeles – UCLA Care	Other	participant non responsive
61	800134115	US	Los Angeles – UCLA Vine	Other	Ppt could not be contacted and was dropped as lost to follow up
62	857152902	US	Memphis	Other	LTFU
63	857226316	US	Memphis	Other	LTFU
64	857409368	US	Memphis	Other	LTFU
65	857476607	US	Memphis	Other	LTFU
66	857592758	US	Memphis	Other	LTFU
67	857610956	US	Memphis	Other	LTFU
68	857720191	US	Memphis	Other	LTFU

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69	857926927	US	Memphis	Other	LTFU
70	857963638	US	Memphis	Other	LTFU
71	857371968	US	Memphis	Other	Lost contact with participant. He had started on oral PrEP with outside PCP.
72	857846737	US	Memphis	Other	PPT removed from study before actually receiving shot from local provider
73	857196270	US	Memphis	Other	participant inadvertantly discharged before receiving Apretude injection at community provider
74	857561731	US	Memphis	Other	participant inadvertantly discharged before receiving Apretude injection at community provider
75	857800186	US	Memphis	Other	ppt no longer wants to recieve CAB injections – wishes to switch to oral PREP
76	855479050	US	New Orleans	Other	Lost to follow up
77	855564696	US	New Orleans	Other	Lost to follow–up
78	855566125	US	New Orleans	Other	Lost to follow–up.
79	855107774	US	New Orleans	Other	Participant has been lost to contact for > 6 months
80	855612233	US	New Orleans	Other	Participant relocated, was to transfer sites, then lost to contact.
81	855168673	US	New Orleans	Other	Subject LTFU
82	855662120	US	New Orleans	Other	Subject LTFU
83	855640700	US	New Orleans	Other	Subject statesin a monogamous relationship and feels that she doesn't need the injection because the risk factor is low.Will discuss with her primary care physician.
84	825941553	US	New York – Blood Center	Other	Lost to follow up
85	825940787	US	New York – Blood Center	Other	Participant reported medical history of seizures, making him ineligible for the study
86	825844201	US	New York – Blood Center	Other	Participant transitioning out of the study and decided to not continue CAB at this time.
87	825579229	US	New York – Blood Center	Other	Ppt is self–transitioning out the study to oral TDF/FTC
88	825364853	US	New York – Blood Center	Other	Ppt is transitioning out of the study and will not continue Prep post study
89	825213807	US	New York – Blood Center	Other	Repeated failure to attend study visits with staff or continue contact.
90	825182853	US	New York – Blood Center	Other	Subject decided to self–transition to oral TDF/FTC
91	825856687	US	New York – Blood Center	Other	Subject reported having a seizure Jan 2020. CMC said that they are not eligible to continue on in the study.
92	825269981	US	New York – Blood Center	Other	Unable to continue in new amendment due to their buttock implant
93	712493145	US	New York – Weill Cornell Chelsea	Other	recurrent injection site reactions
94	820260551	US	Newark	Other	LTFU. Multiple attempts to contact participant. No answer.
95	820519816	US	Newark	Other	Linkage to local descovy. Still not able to get CAB. Feels it'is too far a commute with work schedule.
96	864216259	US	Oakland	Other	Lost to follow up
97	864425628	US	Oakland	Other	Lost to follow–up
98	864437018	US	Oakland	Other	Participant did not return after his week 72 Visits. We tried to contact and schedule several times, and we were unable to bring him back in.

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# [1]	Participant ID	Region	Site	Reason for Terminated Early from OLE	Other, Specify
99	863222437	US	Philadelphia	Other	After multiple attempts to contact and reschedule the participant, he has not returned any messages; lost to follow–up
100	863320542	US	Philadelphia	Other	Participant has been traveling out of the area over the year and has not returned any contact attempts. Lost to follow–up
101	863238875	US	Philadelphia	Other	ltfu for >6 months
102	764398624	US	San Francisco	Other	Unable to reach participant for exit visit
103	861236061	US	St. Louis	Other	LTFU – unable to contact
104	861736122	US	St. Louis	Other	lost to follow up
105	861866251	US	St. Louis	Other	lost to follow up
106	861930223	US	St. Louis	Other	lost to follow up
107	801627443	US	Washington, DC	Other	Grade 3 ALT, per CMC guidance
108	801189799	US	Washington, DC	Other	Participant decided to pursue enrollment in another biomedical intervention study in early December 2022.
109	850114825	Latin America	Buenos Aires – Fundacion Huesped	Other	LTFU. More than 6 months between subjetcs last visit implementation of protocol version 4.0
110	850911981	Latin America	Buenos Aires – Fundacion Huesped	Other	LTFU. More than 6 months between subjetcs last visit implementation of protocol version 4.0
111	850291960	Latin America	Buenos Aires – Fundacion Huesped	Other	Living abroad
112	850346073	Latin America	Buenos Aires – Fundacion Huesped	Other	Living abroad
113	850595324	Latin America	Buenos Aires – Fundacion Huesped	Other	Living abroad
114	850812088	Latin America	Buenos Aires – Fundacion Huesped	Other	Living abroad
115	850272000	Latin America	Buenos Aires – Fundacion Huesped	Other	Lost to follow up
116	850460724	Latin America	Buenos Aires – Fundacion Huesped	Other	Lost to follow up
117	850807613	Latin America	Buenos Aires – Fundacion Huesped	Other	Lost to follow up
118	850493053	Latin America	Buenos Aires – Fundacion Huesped	Other	More than six months between subject's last visit, implementation of protocol 4.0
119	850332716	Latin America	Buenos Aires – Fundacion Huesped	Other	The participant does not feel at risk to continue PrEP
120	850206806	Latin America	Buenos Aires – Fundacion Huesped	Other	The ppt was referred to local PrEP services. He cannot receive TDF/FTC through the study.
121	850893633	Latin America	Buenos Aires – Fundacion Huesped	Other	for loss to follow–up
122	850480459	Latin America	Buenos Aires – Fundacion Huesped	Other	lost to follow up
123	850509929	Latin America	Buenos Aires – Fundacion Huesped	Other	neurologist indicated to suspend CAB–LA injection
124	852509661	Latin America	Buenos Aires – Hospital JM Ramos Mejia	Other	Lost to follow up
125	852301788	Latin America	Buenos Aires – Hospital JM Ramos Mejia	Other	The participant cannot continue due to work–related reasons.
126	732936198	Latin America	Iquitos	Other	
127	732224847	Latin America	Iquitos	Other	Participant is in the city of Lima for work reasons
128	732111818	Latin America	Iquitos	Other	Unable contact to participant. Lost to follow up
129	732855394	Latin America	Iquitos	Other	ViiV Follow–up study activation
130	714417508	Latin America	Lima – Barranco	Other	HIV diagnosis

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# [1]	Participant ID	Region	Site	Reason for Terminated Early from OLE	Other, Specify
131	714725509	Latin America	Lima – Barranco	Other	Participant is not eligible for the study
132	714528388	Latin America	Lima – Barranco	Other	Participant is not eligible to continue in the study
133	714667726	Latin America	Lima – Barranco	Other	Participant is not eligible to continue in the study
134	714117331	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
135	714146130	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
136	714148039	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
137	714178883	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
138	714181819	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
139	714189019	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
140	714210755	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
141	714221601	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
142	714224250	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
143	714260397	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
144	714277948	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
145	714289279	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
146	714292225	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
147	714297218	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
148	714314556	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
149	714336265	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
150	714347660	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
151	714355583	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
152	714395526	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
153	714399821	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
154	714432308	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
155	714435155	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
156	714447053	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
157	714451452	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
158	714483758	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
159	714486024	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
160	714486128	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
161	714491583	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
162	714520631	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
163	714526468	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
164	714536171	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
165	714566682	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
166	714570190	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
167	714596340	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation

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# [1]	Participant ID	Region	Site	Reason for Terminated Early from OLE	Other, Specify
168	714623394	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
169	714633595	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
170	714658594	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
171	714678738	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
172	714681267	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
173	714708613	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
174	714709162	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
175	714711013	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
176	714716561	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
177	714748763	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
178	714769833	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
179	714818030	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
180	714823001	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
181	714845739	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
182	714852786	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
183	714855897	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
184	714870539	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
185	714881934	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
186	714884650	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
187	714901503	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
188	714931870	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
189	714969450	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
190	714973338	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
191	714995804	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
192	714999073	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation
193	714776195	Latin America	Lima – Barranco	Other	ViiV Follow–up study activation and participant could not come to appointed visit due to travel issues
194	848871338	Latin America	Lima – CITBM	Other	
195	715839819	Latin America	Lima – San Miguel	Other	Lost to follow up
196	715665091	Latin America	Lima – San Miguel	Other	Lost to follow–up
197	715676505	Latin America	Lima – San Miguel	Other	lost to follow up
198	831131691	Latin America	Lima – Via Libre	Other	
199	831298109	Latin America	Lima – Via Libre	Other	
200	831406491	Latin America	Lima – Via Libre	Other	
201	831745315	Latin America	Lima – Via Libre	Other	
202	831116269	Latin America	Lima – Via Libre	Other	unable to schedule appointment(s) within allowable window
203	722903028	Latin America	Porto Alegre	Other	Lost follow up

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# [1]	Participant ID	Region	Site	Reason for Terminated Early from OLE	Other, Specify
204	722658944	Latin America	Porto Alegre	Other	Lost to Follow–up
205	722824415	Latin America	Porto Alegre	Other	Lost to Follow–up
206	721120090	Latin America	Rio de Janeiro	Other	Adverse Event (Event of importance for HPTN083) – CMC´s guidance.
207	721267446	Latin America	Rio de Janeiro	Other	Adverse Event.
208	721167798	Latin America	Rio de Janeiro	Other	Diagnosis of HIV Infection
209	721942648	Latin America	Rio de Janeiro	Other	Diagnosis of HIV Infection.
210	721979436	Latin America	Rio de Janeiro	Other	HIV Infection.
211	721420103	Latin America	Rio de Janeiro	Other	Liver toxicity. Per CMC guidance: Permanent interruption of the SP.
212	721210028	Latin America	Rio de Janeiro	Other	Liver toxicity. Per Protocol: Permanent interruption of the SP.
213	721230784	Latin America	Rio de Janeiro	Other	Lost to follow up.
214	721268992	Latin America	Rio de Janeiro	Other	Lost to follow up.
215	721436987	Latin America	Rio de Janeiro	Other	Lost to follow up.
216	721484621	Latin America	Rio de Janeiro	Other	Lost to follow up.
217	721553176	Latin America	Rio de Janeiro	Other	Lost to follow up.
218	721679746	Latin America	Rio de Janeiro	Other	Lost to follow up.
219	721690174	Latin America	Rio de Janeiro	Other	Lost to follow up.
220	721746230	Latin America	Rio de Janeiro	Other	Lost to follow up.
221	721841671	Latin America	Rio de Janeiro	Other	Lost to follow up.
222	721261760	Latin America	Rio de Janeiro	Other	Lost to follow–up.
223	721332504	Latin America	Rio de Janeiro	Other	Lost to follow–up.
224	721337818	Latin America	Rio de Janeiro	Other	Lost to follow–up.
225	721495979	Latin America	Rio de Janeiro	Other	Lost to follow–up.
226	721590526	Latin America	Rio de Janeiro	Other	Lost to follow–up.
227	721623318	Latin America	Rio de Janeiro	Other	Lost to follow–up.
228	721659154	Latin America	Rio de Janeiro	Other	Lost to follow–up.
229	721693309	Latin America	Rio de Janeiro	Other	Participant completed more than 3 years of Inclusion and wishes to remain in TDF/FTC.
230	721907736	Latin America	Rio de Janeiro	Other	Participant completed more than 3 years of Inclusion and wishes to remain in TDF/FTC.
231	721697901	Latin America	Rio de Janeiro	Other	Participant termination visit as per CMC instructions.
232	721366033	Latin America	Rio de Janeiro	Other	The participant completed 1 year after the last injection.
233	721540461	Latin America	Rio de Janeiro	Other	The participant is beyond 3 years from enrollment and wishes to remain on TDF/FTC.
234	721185282	Latin America	Rio de Janeiro	Other	The participant is beyond 3 years from enrollment and wishes to remain on TDF/FTC.
235	721760147	Latin America	Rio de Janeiro	Other	The participant is beyond 3 years from enrollment and wishes to remain on TDF/FTC.

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236	721126496	Latin America	Rio de Janeiro	Other	Use of Precautionary and Prohibited Medication (Carbamazepine). The participant has the intention to stay on Carbamazepine and not plan to restart CAB–LA.
237	721127156	Latin America	Rio de Janeiro	Other	Use of industrial liquid silicone on the buttocks.
238	845371011	Latin America	Sao Paulo – DST–AIDS	Other	HIV Seroconverter
239	845767840	Latin America	Sao Paulo – DST–AIDS	Other	Participant not eligible to transition to OLE.
240	845726128	Latin America	Sao Paulo – DST–AIDS	Other	laboratory changes according to study protocol
241	845977825	Latin America	Sao Paulo – DST–AIDS	Other	participant decided to take oral medication for personal reasons.
242	860310380	Latin America	Sao Paulo – IC–HCFMUSP	Other	Due to ALT grade 3
243	860121943	Latin America	Sao Paulo – IC–HCFMUSP	Other	HIV seroconvertion
244	860376901	Latin America	Sao Paulo – IC–HCFMUSP	Other	Hepatitis C
245	860603943	Latin America	Sao Paulo – IC–HCFMUSP	Other	Loss of follow up
246	860669114	Latin America	Sao Paulo – IC–HCFMUSP	Other	Loss of follow–up
247	860929337	Latin America	Sao Paulo – IC–HCFMUSP	Other	Lost of follow up
248	860662039	Latin America	Sao Paulo – IC–HCFMUSP	Other	Lost to follow up
249	860287442	Latin America	Sao Paulo – IC–HCFMUSP	Other	Lost to follow up.
250	860548404	Latin America	Sao Paulo – IC–HCFMUSP	Other	due to neurologic sequelae participant is enable to resume participation on study.
251	860794668	Latin America	Sao Paulo – IC–HCFMUSP	Other	lost to follow up
252	813350501	Asia	Bangkok – Silom Clinic	Other	
253	813473771	Asia	Bangkok – Silom Clinic	Other	
254	813521084	Asia	Bangkok – Silom Clinic	Other	
255	813545740	Asia	Bangkok – Silom Clinic	Other	
256	813896707	Asia	Bangkok – Silom Clinic	Other	
257	813561793	Asia	Bangkok – Silom Clinic	Other	HIV–infected
258	813512645	Asia	Bangkok – Silom Clinic	Other	LTFU
259	813827179	Asia	Bangkok – Silom Clinic	Other	LTFU
260	813827873	Asia	Bangkok – Silom Clinic	Other	LTFU
261	813891814	Asia	Bangkok – Silom Clinic	Other	LTFU
262	813330727	Asia	Bangkok – Silom Clinic	Other	Lost to follow up
263	813640475	Asia	Bangkok – Silom Clinic	Other	No longer want to receive CAB injection in ViiV protocol.
264	813696230	Asia	Bangkok – Silom Clinic	Other	No longer want to receive CAB injection in ViiV protocol.
265	813949423	Asia	Bangkok – Silom Clinic	Other	No longer want to receive CAB injection in ViiV protocol.
266	813324790	Asia	Bangkok – Silom Clinic	Other	Participant completed screening in the rollover study on 27 Jun 2024 then participant could not be contacted.
267	813630363	Asia	Bangkok – Silom Clinic	Other	Participant no longer want to receive injection in ViiV protocol
268	813229937	Asia	Bangkok – Silom Clinic	Other	Participant no longer want to receive injection in ViiV protocol
269	813442334	Asia	Bangkok – Silom Clinic	Other	Participant no longer want to receive injection in ViiV protocol

[1] This listing is sorted by region, site, 'other specify' text, and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_disposition.sas, SAS Version 9.4 (04MAR2026,6:06)

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# [1]	Participant ID	Region	Site	Reason for Terminated Early from OLE	Other, Specify
270	813570343	Asia	Bangkok – Silom Clinic	Other	Participant no longer want to receive injection in ViiV protocol
271	813630335	Asia	Bangkok – Silom Clinic	Other	Participant no longer want to receive injection in ViiV protocol
272	813697120	Asia	Bangkok – Silom Clinic	Other	Participant no longer want to receive injection in ViiV protocol
273	813813462	Asia	Bangkok – Silom Clinic	Other	Participant no longer want to receive injection in ViiV protocol
274	813256847	Asia	Bangkok – Silom Clinic	Other	Participant wish to continue on CAB from OLE but changed his mind to get oral TDF/FTC
275	813937096	Asia	Bangkok – Silom Clinic	Other	Participant wish to continue on CAB from OLE but changed his mind to get oral TDF/FTC
276	813987409	Asia	Bangkok – Silom Clinic	Other	Participant wish to continue on CAB from OLE but changed his mind to get oral TDF/FTC
277	813260171	Asia	Bangkok – Silom Clinic	Other	Participant wished to continue on CAB from OLE but participant did not show up at IHRI site and could not further contact to participant
278	813323964	Asia	Bangkok – Silom Clinic	Other	Participant wished to continue on CAB from OLE but participant did not show up at IHRI site and could not further contact to participant
279	813690062	Asia	Bangkok – Silom Clinic	Other	Participant wished to continue on CAB from OLE but participant did not show up at IHRI site and could not further contact to participant
280	813969430	Asia	Bangkok – Silom Clinic	Other	Participant wished to continue on CAB from OLE but participant did not show up at IHRI site and could not further contact to participant
281	813113183	Asia	Bangkok – Silom Clinic	Other	Participant wishes to continue on CAB from OLE but participant relocated abroad
282	813251955	Asia	Bangkok – Silom Clinic	Other	Participant wishes to continue on CAB from OLE but participant relocated abroad
283	813402991	Asia	Bangkok – Silom Clinic	Other	Participant wishes to continue on CAB from OLE but participant relocated abroad
284	813827723	Asia	Bangkok – Silom Clinic	Other	The participant had HCV infected and Permanently discontinuation study product.
285	813183083	Asia	Bangkok – Silom Clinic	Other	The participant no longer wants to receive injection in ViiV protocol.
286	813530917	Asia	Bangkok – Silom Clinic	Other	The participant no longer wants to receive injection in ViiV protocol.
287	813751704	Asia	Bangkok – Silom Clinic	Other	The participant no longer wants to receive injection in ViiV protocol.
288	813842556	Asia	Bangkok – Silom Clinic	Other	The participant no longer wants to receive injection in ViiV protocol.
289	813241100	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol
290	813623217	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol
291	813719893	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol
292	813736383	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol
293	813806804	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol
294	813108721	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
295	813119356	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
296	813127581	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
297	813161785	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
298	813172112	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.

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# [1]	Participant ID	Region	Site	Reason for Terminated Early from OLE	Other, Specify
299	813175437	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
300	813177844	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
301	813193086	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
302	813215964	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
303	813226950	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
304	813232504	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
305	813239176	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
306	813241009	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
307	813248547	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
308	813284854	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
309	813299547	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
310	813300063	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
311	813310759	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
312	813339695	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
313	813352851	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
314	813358018	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
315	813362499	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
316	813379038	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
317	813395232	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
318	813395266	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
319	813415741	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
320	813453605	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
321	813454923	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
322	813472096	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
323	813475011	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
324	813475753	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
325	813487940	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
326	813492594	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
327	813499243	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
328	813529997	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
329	813542109	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
330	813543154	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
331	813547792	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
332	813552041	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
333	813561262	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
334	813561935	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
335	813562131	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.

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# [1]	Participant ID	Region	Site	Reason for Terminated Early from OLE	Other, Specify
336	813576460	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
337	813577958	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
338	813589516	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
339	813592970	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
340	813617497	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
341	813640522	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
342	813643961	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
343	813647207	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
344	813651547	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
345	813668593	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
346	813687745	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
347	813689515	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
348	813736041	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
349	813770459	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
350	813776165	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
351	813780941	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
352	813794520	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
353	813798584	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
354	813809662	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
355	813820974	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
356	813835055	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
357	813835378	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
358	813839509	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
359	813860196	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
360	813865292	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
361	813890132	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
362	813894817	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
363	813903784	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
364	813917899	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
365	813927474	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
366	813933862	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
367	813935345	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
368	813946408	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
369	813947455	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
370	813963777	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
371	813972609	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.

[1] This listing is sorted by region, site, 'other specify' text, and PTID.

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# [1]	Participant ID	Region	Site	Reason for Terminated Early from OLE	Other, Specify
372	813977069	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
373	813977778	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
374	813982499	Asia	Bangkok – Silom Clinic	Other	Transitioned to ViiV protocol.
375	813887754	Asia	Bangkok – Silom Clinic	Other	Unable to schedule appointment(s) within allowable window until 31 Mar 2024
376	813610682	Asia	Bangkok – Silom Clinic	Other	transitioned to ViiV protocol
377	813156635	Asia	Bangkok – Silom Clinic	Other	transitioned to ViiV protocol.
378	813237254	Asia	Bangkok – Silom Clinic	Other	transitioned to ViiV protocol.
379	813362285	Asia	Bangkok – Silom Clinic	Other	transitioned to ViiV protocol.
380	813452135	Asia	Bangkok – Silom Clinic	Other	transitioned to ViiV protocol.
381	813528151	Asia	Bangkok – Silom Clinic	Other	transitioned to ViiV protocol.
382	813591633	Asia	Bangkok – Silom Clinic	Other	transitioned to ViiV protocol.
383	813635935	Asia	Bangkok – Silom Clinic	Other	transitioned to ViiV protocol.
384	813684278	Asia	Bangkok – Silom Clinic	Other	transitioned to ViiV protocol.
385	813829031	Asia	Bangkok – Silom Clinic	Other	transitioned to ViiV protocol.
386	813889623	Asia	Bangkok – Silom Clinic	Other	transitioned to ViiV protocol.
387	813890690	Asia	Bangkok – Silom Clinic	Other	transitioned to ViiV protocol.
388	813944934	Asia	Bangkok – Silom Clinic	Other	transitioned to ViiV protocol.
389	813289557	Asia	Bangkok – Silom Clinic	Other	unable to schedule appointment(s) within allowable window until 31 Mar 2024
390	858195675	Asia	Bangkok – Thai Red Cross	Other	LTFU for more than 6 months
391	858176822	Asia	Bangkok – Thai Red Cross	Other	Loss to follow up > 6 months
392	858463940	Asia	Bangkok – Thai Red Cross	Other	Loss to follow up > 6 months
393	858657725	Asia	Bangkok – Thai Red Cross	Other	Loss to follow up >6 months
394	858716830	Asia	Bangkok – Thai Red Cross	Other	Loss to follow up >6 months
395	858538374	Asia	Bangkok – Thai Red Cross	Other	Loss to follow up more than 6 months
396	858757889	Asia	Bangkok – Thai Red Cross	Other	Loss to follow up more than 6 months
397	858192339	Asia	Bangkok – Thai Red Cross	Other	Lost to follow up
398	858266359	Asia	Bangkok – Thai Red Cross	Other	Lost to follow up
399	858362093	Asia	Bangkok – Thai Red Cross	Other	Lost to follow up
400	858510979	Asia	Bangkok – Thai Red Cross	Other	Lost to follow up
401	858904435	Asia	Bangkok – Thai Red Cross	Other	Lost to follow up
402	858787081	Asia	Bangkok – Thai Red Cross	Other	loss to follow more than 6 months
403	858179311	Asia	Bangkok – Thai Red Cross	Other	loss to follow up more than 6 months
404	858434264	Asia	Bangkok – Thai Red Cross	Other	loss to follow up more than 6 months
405	858776352	Asia	Bangkok – Thai Red Cross	Other	loss to follow up more than 6 months
406	858830443	Asia	Bangkok – Thai Red Cross	Other	loss to follow up more than 6 months
407	858984327	Asia	Bangkok – Thai Red Cross	Other	loss to follow up more than 6 months

[1] This listing is sorted by region, site, 'other specify' text, and PTID.

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# [1]	Participant ID	Region	Site	Reason for Terminated Early from OLE	Other, Specify
408	858817384	Asia	Bangkok – Thai Red Cross	Other	lost to follow up more than 6 months
409	862404066	Asia	Hanoi	Other	Lost to follow–up. The participant was unable to come to the visit before the HPTN 083 study in Vietnam ends.
410	862891986	Asia	Hanoi	Other	Lost to follow–up. The participant was unable to come to the visit before the HPTN 083 study in Vietnam ends.
411	862616105	Asia	Hanoi	Other	The participant is going to serve in the military and request to stop participating in the study.
412	862957453	Asia	Hanoi	Other	The participant is serving in the military
413	862643240	Asia	Hanoi	Other	The participant lost to follow–up more than 6 months since the first missed visit.
414	862798418	Asia	Hanoi	Other	The participant lost to follow–up more than 6 months since the first missed visit.
415	862540775	Asia	Hanoi	Other	The participant lost to follow–up more than 6 months since the last missed visit
416	816128730	Africa	Cape Town	Other	LTFU
417	816195435	Africa	Cape Town	Other	LTFU
418	816398625	Africa	Cape Town	Other	LTFU
419	816800690	Africa	Cape Town	Other	LTFU
420	816991241	Africa	Cape Town	Other	LTFU
421	816566103	Africa	Cape Town	Other	Lost to follow
422	816287866	Africa	Cape Town	Other	Lost to follow up
423	816312214	Africa	Cape Town	Other	Lost to follow up
424	816690645	Africa	Cape Town	Other	Lost to follow up
425	816422782	Africa	Cape Town	Other	Unable to attend his visits for more than 6 months

[1] This listing is sorted by region, site, 'other specify' text, and PTID.

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Table 6 – Step 3 and Step 5 Visit Completion by Region

	Overall	US	Latin America	Asia	Africa
Total Participants Enrolled [1]	4566	1698	1964	752	152
Number of participants who have had at least one CAB injection [2]	3326/4566 (72.8%)	1137/1698 (67.0%)	1481/1964 (75.4%)	608/752 (80.9%)	100/152 (65.8%)
Number of participants who moved to open label TDF/FTC [3]	1647/3326 (49.5%)	655/1137 (57.6%)	630/1481 (42.5%)	336/608 (55.3%)	26/100 (26.0%)
Completed week 12 visit [4]	1445/1647 (87.7%)	571/655 (87.2%)	539/630 (85.6%)	310/336 (92.3%)	25/26 (96.2%)
Completed week 24 visit [4]	1208/1647 (73.3%)	474/655 (72.4%)	467/630 (74.1%)	254/336 (75.6%)	13/26 (50.0%)
Completed week 36 visit [4]	950/1647 (57.7%)	348/655 (53.1%)	396/630 (62.9%)	197/336 (58.6%)	9/26 (34.6%)
Completed week 48 visit [4]	602/1647 (36.6%)	211/655 (32.2%)	326/630 (51.7%)	61/336 (18.2%)	4/26 (15.4%)

[1] Inappropriately enrolled participants and participants with invalid ID due to duplicate screening or enrollment are excluded.
[2] Including participants who received at least one CAB LA injection any time during the study.
[3] Including participants who moved to open label TDF/FTC during either the primary study, the unblinded phase, or the OLE.
[4] The denominator is number of participants who moved to open label TDF/FTC, without considering the expected visit windows, study termination, and seroconversion.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_step3n5_byregion.sas, SAS Version 9.4 (04MAR2026,6:07)

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Table 7A – Visit Completion by Visit by OLE Regimen Choice

	Overall [1]	TDF/FTC	Oral CAB – Step 4a	Loading Dose CAB–LA – Step 4b	Standard Dose CAB–LA – Step 4c
Participants Enrolled in OLE [2]	2658	107	439	1517	539
Step 4a					
Day 0	452/2658 (17.0%)	12/107 (11.2%)	439/439 (100.0%)	0/1517 (0.0%)	0/539 (0.0%)
Week 4	436/447 (97.5%)	11/12 (91.7%)	424/434 (97.7%)	0/0 (–%)	0/0 (–%)
Step 4b					
Day 0	1968/2658 (74.0%)	36/107 (33.6%)	413/439 (94.1%)	1514/1517 (99.8%)	0/539 (0.0%)
Step 4c [3]					
Day 0	2437/2658 (91.7%)	36/107 (33.6%)	406/439 (92.5%)	1451/1517 (95.6%)	539/539 (100.0%)
Week 8	2364/2476 (95.5%)	33/36 (91.7%)	390/421 (92.6%)	1415/1479 (95.7%)	521/535 (97.4%)
Week 16	2318/2454 (94.5%)	31/33 (93.9%)	388/415 (93.5%)	1379/1469 (93.9%)	515/532 (96.8%)
Week 24	2283/2436 (93.7%)	31/33 (93.9%)	382/411 (92.9%)	1357/1457 (93.1%)	508/530 (95.8%)
Week 32	2244/2408 (93.2%)	30/33 (90.9%)	374/402 (93.0%)	1332/1439 (92.6%)	503/529 (95.1%)
Week 40	2214/2376 (93.2%)	30/33 (90.9%)	371/393 (94.4%)	1317/1421 (92.7%)	491/524 (93.7%)
Week 48	2187/2341 (93.4%)	30/32 (93.8%)	364/385 (94.5%)	1306/1398 (93.4%)	483/521 (92.7%)
Step 6					
Week 56	2065/2065 (100.0%)	29/29 (100.0%)	340/340 (100.0%)	1232/1232 (100.0%)	460/460 (100.0%)
Week 64	1944/2054 (94.6%)	28/29 (96.6%)	319/338 (94.4%)	1156/1223 (94.5%)	438/460 (95.2%)
Week 72	1795/1961 (91.5%)	27/28 (96.4%)	264/316 (83.5%)	1076/1161 (92.7%)	425/452 (94.0%)
Week 80	1517/1717 (88.4%)	24/27 (88.9%)	224/262 (85.5%)	852/974 (87.5%)	414/451 (91.8%)
Week 88	1406/1550 (90.7%)	24/26 (92.3%)	215/232 (92.7%)	759/848 (89.5%)	405/441 (91.8%)
Week 96	1346/1479 (91.0%)	24/26 (92.3%)	210/220 (95.5%)	709/797 (89.0%)	400/433 (92.4%)
Step 7					
Week 104	1030/1030 (100.0%)	16/16 (100.0%)	149/149 (100.0%)	518/518 (100.0%)	344/344 (100.0%)
Week 112	948/1018 (93.1%)	13/13 (100.0%)	126/148 (85.1%)	480/512 (93.8%)	327/342 (95.6%)
Week 120	856/956 (89.5%)	9/10 (90.0%)	101/120 (84.2%)	431/488 (88.3%)	314/337 (93.2%)
Week 128	771/892 (86.4%)	4/6 (66.7%)	95/104 (91.3%)	376/449 (83.7%)	296/332 (89.2%)
Week 136	646/800 (80.8%)	1/2 (50.0%)	80/92 (87.0%)	311/391 (79.5%)	254/314 (80.9%)
Week 144	475/652 (72.9%)	1/2 (50.0%)	63/72 (87.5%)	226/303 (74.6%)	185/274 (67.5%)
Week 152	328/434 (75.6%)	0/1 (0.0%)	47/54 (87.0%)	145/197 (73.6%)	136/181 (75.1%)
Week 160	241/300 (80.3%)	0/0 (–%)	21/24 (87.5%)	120/149 (80.5%)	100/127 (78.7%)
Week 168	132/171 (77.2%)	0/0 (–%)	2/2 (100.0%)	73/93 (78.5%)	57/76 (75.0%)
Week 176	22/49 (44.9%)	0/0 (–%)	1/1 (100.0%)	10/24 (41.7%)	11/24 (45.8%)
Week 184	0/5 (0.0%)	0/0 (–%)	0/0 (–%)	0/2 (0.0%)	0/3 (0.0%)
Week 192	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)

[1] Include all participants participating in OLE phase (CAB, TDF/FTC, seroconverter schedule and open label Truvada schedule).
[2] Visit Completion is defined as the number (and %) of participants who completed the visit among the participants who are expected according to the protocol schedule, plus any participants who have completed the visit even though their visit window has not yet closed. "Expected according to the protocol schedule" refers to all participants who are active (Alive, HIV uninfected, have not permanently discontinued randomized study product, and not terminated from study) at the time of the visit and the visit window has closed.
[3] Participants can directly go to later visits without attending Day 0.
[4] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

Source: SCHARP (Rajee) – /trials/hptn/p083/analysis/live/code/ole/t_ole_vcomp_byregm.sas, SAS Version 9.4 (04MAR2026,6:07)

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
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Table 7A – Visit Completion by Visit by OLE Regimen Choice

	Overall [1]	TDF/FTC	Oral CAB – Step 4a	Loading Dose CAB–LA – Step 4b	Standard Dose CAB–LA – Step 4c
Step 5 [4]					
Participants entering Step 5	271/2658 (10.2%)	107/107 (100.0%)	26/439 (5.9%)	74/1517 (4.9%)	62/539 (11.5%)
Week 12	157/273 (57.5%)	76/103 (73.8%)	22/27 (81.5%)	38/73 (52.1%)	14/63 (22.2%)
Week 24	131/242 (54.1%)	55/82 (67.1%)	21/25 (84.0%)	33/70 (47.1%)	11/52 (21.2%)
Week 36	111/210 (52.9%)	42/62 (67.7%)	19/24 (79.2%)	21/57 (36.8%)	12/50 (24.0%)
Week 48	86/170 (50.6%)	23/42 (54.8%)	16/19 (84.2%)	18/43 (41.9%)	7/44 (15.9%)
Week 60	3/73 (4.1%)	1/19 (5.3%)	0/2 (0.0%)	0/16 (0.0%)	0/34 (0.0%)
Week 72	4/53 (7.5%)	2/12 (16.7%)	0/2 (0.0%)	0/9 (0.0%)	0/28 (0.0%)
Week 84	2/46 (4.3%)	0/8 (0.0%)	0/1 (0.0%)	0/8 (0.0%)	0/27 (0.0%)
Week 96	1/39 (2.6%)	0/7 (0.0%)	0/0 (–%)	0/7 (0.0%)	0/24 (0.0%)
Step 5b					
Day 0	1/2658 (<0.1%)	0/107 (0.0%)	1/439 (0.2%)	0/1517 (0.0%)	0/539 (0.0%)
Week 12	1/1 (100.0%)	0/0 (–%)	1/1 (100.0%)	0/0 (–%)	0/0 (–%)
Week 24	1/1 (100.0%)	0/0 (–%)	1/1 (100.0%)	0/0 (–%)	0/0 (–%)
Week 36	1/1 (100.0%)	0/0 (–%)	1/1 (100.0%)	0/0 (–%)	0/0 (–%)
Week 48	1/1 (100.0%)	0/0 (–%)	1/1 (100.0%)	0/0 (–%)	0/0 (–%)

[1] Include all participants participating in OLE phase (CAB, TDF/FTC, seroconverter schedule and open label Truvada schedule).
[2] Visit Completion is defined as the number (and %) of participants who completed the visit among the participants who are expected according to the protocol schedule, plus any participants who have completed the visit even though their visit window has not yet closed. "Expected according to the protocol schedule" refers to all participants who are active (Alive, HIV uninfected, have not permanently discontinued randomized study product, and not terminated from study) at the time of the visit and the visit window has closed.
[3] Participants can directly go to later visits without attending Day 0.
[4] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

Source: SCHARP (Rajee) – /trials/hptn/p083/analysis/live/code/ole/t_ole_vcomp_byregm.sas, SAS Version 9.4 (04MAR2026,6:07)

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Table 7B – Visit Completion by Visit by Region

	Overall	US	Latin America	Asia	Africa
Participants Enrolled in OLE [1]	2658	822	1221	528	87
Step 4a					
Day 0	452/2658 (17.0%)	148/822 (18.0%)	88/1221 (7.2%)	199/528 (37.7%)	17/87 (19.5%)
Week 4	436/447 (97.5%)	142/147 (96.6%)	85/87 (97.7%)	193/196 (98.5%)	16/17 (94.1%)
Step 4b					
Day 0	1968/2658 (74.0%)	647/822 (78.7%)	843/1221 (69.0%)	426/528 (80.7%)	52/87 (59.8%)
Step 4c [2]					
Day 0	2437/2658 (91.7%)	741/822 (90.1%)	1134/1221 (92.9%)	487/528 (92.2%)	75/87 (86.2%)
Week 8	2364/2476 (95.5%)	720/751 (95.9%)	1091/1147 (95.1%)	479/500 (95.8%)	74/78 (94.9%)
Week 16	2318/2454 (94.5%)	702/743 (94.5%)	1068/1136 (94.0%)	476/497 (95.8%)	72/78 (92.3%)
Week 24	2283/2436 (93.7%)	690/734 (94.0%)	1055/1127 (93.6%)	468/497 (94.2%)	70/78 (89.7%)
Week 32	2244/2408 (93.2%)	677/719 (94.2%)	1036/1120 (92.5%)	461/491 (93.9%)	70/78 (89.7%)
Week 40	2214/2376 (93.2%)	666/704 (94.6%)	1017/1107 (91.9%)	462/487 (94.9%)	69/78 (88.5%)
Week 48	2187/2341 (93.4%)	645/689 (93.6%)	1016/1091 (93.1%)	459/484 (94.8%)	67/77 (87.0%)
Step 6					
Week 56	2065/2065 (100.0%)	532/532 (100.0%)	1016/1016 (100.0%)	452/452 (100.0%)	65/65 (100.0%)
Week 64	1944/2054 (94.6%)	494/527 (93.7%)	959/1010 (95.0%)	427/452 (94.5%)	64/65 (98.5%)
Week 72	1795/1961 (91.5%)	450/496 (90.7%)	913/967 (94.4%)	368/433 (85.0%)	64/65 (98.5%)
Week 80	1517/1717 (88.4%)	403/472 (85.4%)	736/798 (92.2%)	317/382 (83.0%)	61/65 (93.8%)
Week 88	1406/1550 (90.7%)	364/432 (84.3%)	672/725 (92.7%)	309/329 (93.9%)	61/64 (95.3%)
Week 96	1346/1479 (91.0%)	308/387 (79.6%)	670/707 (94.8%)	307/321 (95.6%)	61/64 (95.3%)
Step 7					
Week 104	1030/1030 (100.0%)	0/0 (–%)	671/671 (100.0%)	298/298 (100.0%)	61/61 (100.0%)
Week 112	948/1018 (93.1%)	0/0 (–%)	630/660 (95.5%)	257/297 (86.5%)	61/61 (100.0%)
Week 120	856/956 (89.5%)	0/0 (–%)	603/648 (93.1%)	196/249 (78.7%)	57/59 (96.6%)
Week 128	771/892 (86.4%)	0/0 (–%)	571/631 (90.5%)	146/204 (71.6%)	54/57 (94.7%)
Week 136	646/800 (80.8%)	0/0 (–%)	503/592 (85.0%)	108/168 (64.3%)	35/40 (87.5%)
Week 144	475/652 (72.9%)	0/0 (–%)	373/509 (73.3%)	92/128 (71.9%)	10/15 (66.7%)
Week 152	328/434 (75.6%)	0/0 (–%)	249/339 (73.5%)	79/93 (84.9%)	0/2 (0.0%)
Week 160	241/300 (80.3%)	0/0 (–%)	180/227 (79.3%)	61/73 (83.6%)	0/0 (–%)
Week 168	132/171 (77.2%)	0/0 (–%)	111/149 (74.5%)	21/22 (95.5%)	0/0 (–%)
Week 176	22/49 (44.9%)	0/0 (–%)	21/48 (43.8%)	1/1 (100.0%)	0/0 (–%)
Week 184	0/5 (0.0%)	0/0 (–%)	0/5 (0.0%)	0/0 (–%)	0/0 (–%)
Week 192	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Step 5 [3]					
Participants entering Step 5	271/2658 (10.2%)	112/822 (13.6%)	128/1221 (10.5%)	25/528 (4.7%)	6/87 (6.9%)

[1] "Visit Completion" is defined as the number (and %) of participants who completed the visit among the participants who are expected according to the protocol schedule, plus any participants who have completed the visit even though their visit window has not yet closed. "Expected according to the protocol schedule" refers to all participants who are active (Alive, HIV uninfected, have not permanently discontinued randomized study product, and not terminated from study) at the time of the visit and the visit window has closed.
[2] Participants can directly go to later visits without attending Day 0.
[3] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

Source: SCHARP (Rajee) – /trials/hptn/p083/analysis/live/code/ole/t_ole_vcomp_byregion.sas, SAS Version 9.4 (04MAR2026,6:07)

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Table 7B – Visit Completion by Visit by Region

	Overall	US	Latin America	Asia	Africa
Week 12	157/273 (57.5%)	48/106 (45.3%)	79/131 (60.3%)	23/28 (82.1%)	7/8 (87.5%)
Week 24	131/242 (54.1%)	38/88 (43.2%)	70/123 (56.9%)	17/23 (73.9%)	6/8 (75.0%)
Week 36	111/210 (52.9%)	35/73 (47.9%)	56/109 (51.4%)	16/21 (76.2%)	4/7 (57.1%)
Week 48	86/170 (50.6%)	24/53 (45.3%)	49/96 (51.0%)	11/16 (68.8%)	2/5 (40.0%)
Week 60	3/73 (4.1%)	0/11 (0.0%)	2/53 (3.8%)	0/4 (0.0%)	1/5 (20.0%)
Week 72	4/53 (7.5%)	0/6 (0.0%)	3/40 (7.5%)	0/3 (0.0%)	1/4 (25.0%)
Week 84	2/46 (4.3%)	0/4 (0.0%)	2/37 (5.4%)	0/1 (0.0%)	0/4 (0.0%)
Week 96	1/39 (2.6%)	0/2 (0.0%)	1/33 (3.0%)	0/0 (–%)	0/4 (0.0%)
Step 5b					
Day 0	1/2658 (<0.1%)	1/822 (0.1%)	0/1221 (0.0%)	0/528 (0.0%)	0/87 (0.0%)
Week 12	1/1 (100.0%)	1/1 (100.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 24	1/1 (100.0%)	1/1 (100.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 36	1/1 (100.0%)	1/1 (100.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 48	1/1 (100.0%)	1/1 (100.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)

[1] "Visit Completion" is defined as the number (and %) of participants who completed the visit among the participants who are expected according to the protocol schedule, plus any participants who have completed the visit even though their visit window has not yet closed. "Expected according to the protocol schedule" refers to all participants who are active (Alive, HIV uninfected, have not permanently discontinued randomized study product, and not terminated from study) at the time of the visit and the visit window has closed.
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Table 7Ci – Visit Completion by Visit by Site: US

	Overall	Baltimore	Los Angeles – UCLA Care	Chapel Hill	Atlanta	New York – Weill Cornell Chelsea
Participants Enrolled in OLE [1]	822	6	42	35	9	28
Step 4a						
Day 0	148/822 (18.0%)	3/6 (50.0%)	4/42 (9.5%)	10/35 (28.6%)	1/9 (11.1%)	1/28 (3.6%)
Week 4	142/147 (96.6%)	3/3 (100.0%)	4/4 (100.0%)	10/10 (100.0%)	1/1 (100.0%)	1/1 (100.0%)
Step 4b						
Day 0	647/822 (78.7%)	6/6 (100.0%)	34/42 (81.0%)	31/35 (88.6%)	7/9 (77.8%)	25/28 (89.3%)
Step 4c [2]						
Day 0	741/822 (90.1%)	6/6 (100.0%)	40/42 (95.2%)	34/35 (97.1%)	8/9 (88.9%)	27/28 (96.4%)
Week 8	720/751 (95.9%)	5/6 (83.3%)	37/39 (94.9%)	33/34 (97.1%)	7/8 (87.5%)	26/27 (96.3%)
Week 16	702/743 (94.5%)	5/5 (100.0%)	35/39 (89.7%)	33/33 (100.0%)	7/8 (87.5%)	24/26 (92.3%)
Week 24	690/734 (94.0%)	5/5 (100.0%)	36/38 (94.7%)	33/33 (100.0%)	7/7 (100.0%)	24/25 (96.0%)
Week 32	677/719 (94.2%)	5/5 (100.0%)	34/37 (91.9%)	32/33 (97.0%)	6/7 (85.7%)	23/24 (95.8%)
Week 40	666/704 (94.6%)	5/5 (100.0%)	33/37 (89.2%)	32/32 (100.0%)	5/6 (83.3%)	23/23 (100.0%)
Week 48	645/689 (93.6%)	5/5 (100.0%)	33/36 (91.7%)	32/32 (100.0%)	5/6 (83.3%)	22/22 (100.0%)
Step 6						
Week 56	532/532 (100.0%)	4/4 (100.0%)	31/31 (100.0%)	30/30 (100.0%)	4/4 (100.0%)	21/21 (100.0%)
Week 64	494/527 (93.7%)	3/4 (75.0%)	29/30 (96.7%)	30/30 (100.0%)	4/4 (100.0%)	21/21 (100.0%)
Week 72	450/496 (90.7%)	3/3 (100.0%)	26/29 (89.7%)	28/29 (96.6%)	4/4 (100.0%)	21/21 (100.0%)
Week 80	403/472 (85.4%)	3/3 (100.0%)	24/25 (96.0%)	25/29 (86.2%)	4/4 (100.0%)	21/21 (100.0%)
Week 88	364/432 (84.3%)	3/3 (100.0%)	22/25 (88.0%)	22/26 (84.6%)	4/4 (100.0%)	21/21 (100.0%)
Week 96	308/387 (79.6%)	3/3 (100.0%)	22/23 (95.7%)	17/22 (77.3%)	4/4 (100.0%)	21/21 (100.0%)
Step 5 [3]						
Participants entering Step 5	112/822 (13.6%)	0/6 (0.0%)	4/42 (9.5%)	15/35 (42.9%)	0/9 (0.0%)	3/28 (10.7%)
Week 12	48/106 (45.3%)	0/0 (–%)	2/3 (66.7%)	2/15 (13.3%)	0/0 (–%)	1/3 (33.3%)
Week 24	38/88 (43.2%)	0/0 (–%)	1/3 (33.3%)	3/15 (20.0%)	0/0 (–%)	1/1 (100.0%)
Week 36	35/73 (47.9%)	0/0 (–%)	2/3 (66.7%)	3/15 (20.0%)	0/0 (–%)	0/1 (0.0%)
Week 48	24/53 (45.3%)	0/0 (–%)	1/2 (50.0%)	3/14 (21.4%)	0/0 (–%)	0/0 (–%)
Week 60	0/11 (0.0%)	0/0 (–%)	0/0 (–%)	0/2 (0.0%)	0/0 (–%)	0/0 (–%)
Week 72	0/6 (0.0%)	0/0 (–%)	0/0 (–%)	0/1 (0.0%)	0/0 (–%)	0/0 (–%)
Week 84	0/4 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 96	0/2 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Step 5b						
Day 0	1/822 (0.1%)	0/6 (0.0%)	0/42 (0.0%)	0/35 (0.0%)	0/9 (0.0%)	0/28 (0.0%)
Week 12	1/1 (100.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 24	1/1 (100.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)

[1] "Visit Completion" is defined as the number (and %) of participants who completed the visit among the participants who are expected according to the protocol schedule, plus any participants who have completed the visit even though their visit window has not yet closed. "Expected according to the protocol schedule" refers to all participants who are active (Alive, HIV uninfected, have not permanently discontinued randomized study product, and not terminated from study) at the time of the visit and the visit window has closed.
[2] Participants can directly go to later visits without attending Day 0.
[3] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

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Table 7Ci – Visit Completion by Visit by Site: US

	Bronx	Harlem	San Francisco	Chicago – WISH	Decatur	Los Angeles – UCLA Vine
Participants Enrolled in OLE [1]	29	32	19	29	42	34
Step 4a						
Day 0	5/29 (17.2%)	11/32 (34.4%)	2/19 (10.5%)	1/29 (3.4%)	6/42 (14.3%)	15/34 (44.1%)
Week 4	5/5 (100.0%)	11/11 (100.0%)	2/2 (100.0%)	1/1 (100.0%)	6/6 (100.0%)	15/15 (100.0%)
Step 4b						
Day 0	18/29 (62.1%)	22/32 (68.8%)	18/19 (94.7%)	27/29 (93.1%)	28/42 (66.7%)	25/34 (73.5%)
Step 4c [2]						
Day 0	23/29 (79.3%)	29/32 (90.6%)	18/19 (94.7%)	27/29 (93.1%)	37/42 (88.1%)	30/34 (88.2%)
Week 8	23/25 (92.0%)	27/30 (90.0%)	18/18 (100.0%)	26/27 (96.3%)	37/37 (100.0%)	30/30 (100.0%)
Week 16	22/25 (88.0%)	27/29 (93.1%)	18/18 (100.0%)	26/27 (96.3%)	36/37 (97.3%)	30/30 (100.0%)
Week 24	22/25 (88.0%)	27/29 (93.1%)	18/18 (100.0%)	25/27 (92.6%)	34/37 (91.9%)	30/30 (100.0%)
Week 32	22/25 (88.0%)	26/29 (89.7%)	18/18 (100.0%)	21/26 (80.8%)	34/35 (97.1%)	28/30 (93.3%)
Week 40	21/25 (84.0%)	25/28 (89.3%)	18/18 (100.0%)	21/24 (87.5%)	34/35 (97.1%)	29/30 (96.7%)
Week 48	22/24 (91.7%)	25/28 (89.3%)	18/18 (100.0%)	19/23 (82.6%)	32/35 (91.4%)	28/30 (93.3%)
Step 6						
Week 56	21/21 (100.0%)	25/25 (100.0%)	17/17 (100.0%)	19/19 (100.0%)	30/30 (100.0%)	28/28 (100.0%)
Week 64	21/21 (100.0%)	23/25 (92.0%)	16/17 (94.1%)	19/19 (100.0%)	27/29 (93.1%)	27/28 (96.4%)
Week 72	21/21 (100.0%)	20/25 (80.0%)	16/17 (94.1%)	17/19 (89.5%)	27/29 (93.1%)	27/28 (96.4%)
Week 80	21/21 (100.0%)	17/24 (70.8%)	16/17 (94.1%)	15/19 (78.9%)	24/28 (85.7%)	26/28 (92.9%)
Week 88	20/21 (95.2%)	18/24 (75.0%)	16/17 (94.1%)	17/19 (89.5%)	21/28 (75.0%)	26/27 (96.3%)
Week 96	20/21 (95.2%)	20/23 (87.0%)	11/16 (68.8%)	17/18 (94.4%)	21/28 (75.0%)	26/27 (96.3%)
Step 5 [3]						
Participants entering Step 5	7/29 (24.1%)	5/32 (15.6%)	1/19 (5.3%)	2/29 (6.9%)	10/42 (23.8%)	1/34 (2.9%)
Week 12	6/7 (85.7%)	2/4 (50.0%)	0/1 (0.0%)	1/1 (100.0%)	2/10 (20.0%)	0/0 (–%)
Week 24	4/6 (66.7%)	1/4 (25.0%)	0/1 (0.0%)	1/1 (100.0%)	2/2 (100.0%)	0/0 (–%)
Week 36	4/4 (100.0%)	2/4 (50.0%)	0/1 (0.0%)	0/0 (–%)	2/2 (100.0%)	0/0 (–%)
Week 48	2/3 (66.7%)	0/3 (0.0%)	0/1 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 60	0/1 (0.0%)	0/2 (0.0%)	0/1 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 72	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 84	0/0 (–%)	0/1 (0.0%)	0/1 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 96	0/0 (–%)	0/1 (0.0%)	0/1 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Step 5b						
Day 0	0/29 (0.0%)	0/32 (0.0%)	0/19 (0.0%)	0/29 (0.0%)	0/42 (0.0%)	0/34 (0.0%)
Week 12	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 24	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)

[1] "Visit Completion" is defined as the number (and %) of participants who completed the visit among the participants who are expected according to the protocol schedule, plus any participants who have completed the visit even though their visit window has not yet closed. "Expected according to the protocol schedule" refers to all participants who are active (Alive, HIV uninfected, have not permanently discontinued randomized study product, and not terminated from study) at the time of the visit and the visit window has closed.
[2] Participants can directly go to later visits without attending Day 0.
[3] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

Source: SCHARP (Rajee) – /trials/hptn/p083/analysis/live/code/ole/t_ole_vcomp_bysite.sas, SAS Version 9.4 (04MAR2026,6:08)

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Table 7Ci – Visit Completion by Visit by Site: US

	Washington, DC	Boston	Newark	Birmingham	New York – Blood Center	Chicago – AYAR
Participants Enrolled in OLE [1]	37	42	39	34	26	39
Step 4a						
Day 0	3/37 (8.1%)	5/42 (11.9%)	5/39 (12.8%)	16/34 (47.1%)	12/26 (46.2%)	1/39 (2.6%)
Week 4	3/3 (100.0%)	5/5 (100.0%)	5/5 (100.0%)	15/16 (93.8%)	11/11 (100.0%)	1/1 (100.0%)
Step 4b						
Day 0	30/37 (81.1%)	35/42 (83.3%)	28/39 (71.8%)	29/34 (85.3%)	16/26 (61.5%)	32/39 (82.1%)
Step 4c [2]						
Day 0	34/37 (91.9%)	37/42 (88.1%)	35/39 (89.7%)	30/34 (88.2%)	20/26 (76.9%)	36/39 (92.3%)
Week 8	32/34 (94.1%)	36/39 (92.3%)	34/35 (97.1%)	30/31 (96.8%)	20/20 (100.0%)	35/36 (97.2%)
Week 16	32/33 (97.0%)	34/39 (87.2%)	34/35 (97.1%)	30/31 (96.8%)	20/20 (100.0%)	34/35 (97.1%)
Week 24	31/33 (93.9%)	34/39 (87.2%)	33/35 (94.3%)	28/29 (96.6%)	20/20 (100.0%)	34/34 (100.0%)
Week 32	32/33 (97.0%)	34/38 (89.5%)	32/34 (94.1%)	28/29 (96.6%)	20/20 (100.0%)	33/33 (100.0%)
Week 40	31/32 (96.9%)	34/37 (91.9%)	31/32 (96.9%)	28/28 (100.0%)	20/20 (100.0%)	33/33 (100.0%)
Week 48	29/31 (93.5%)	32/35 (91.4%)	31/32 (96.9%)	28/28 (100.0%)	18/20 (90.0%)	32/33 (97.0%)
Step 6						
Week 56	20/20 (100.0%)	30/30 (100.0%)	30/30 (100.0%)	28/28 (100.0%)	17/17 (100.0%)	31/31 (100.0%)
Week 64	15/20 (75.0%)	27/30 (90.0%)	29/29 (100.0%)	28/28 (100.0%)	17/17 (100.0%)	30/31 (96.8%)
Week 72	12/14 (85.7%)	23/29 (79.3%)	27/28 (96.4%)	26/28 (92.9%)	16/16 (100.0%)	30/30 (100.0%)
Week 80	7/12 (58.3%)	10/25 (40.0%)	27/28 (96.4%)	26/26 (100.0%)	13/16 (81.3%)	30/30 (100.0%)
Week 88	6/8 (75.0%)	5/18 (27.8%)	24/25 (96.0%)	22/25 (88.0%)	10/14 (71.4%)	27/30 (90.0%)
Week 96	4/6 (66.7%)	3/6 (50.0%)	17/22 (77.3%)	18/23 (78.3%)	3/10 (30.0%)	7/28 (25.0%)
Step 5 [3]						
Participants entering Step 5	7/37 (18.9%)	6/42 (14.3%)	7/39 (17.9%)	3/34 (8.8%)	6/26 (23.1%)	3/39 (7.7%)
Week 12	6/7 (85.7%)	4/6 (66.7%)	1/6 (16.7%)	1/3 (33.3%)	4/6 (66.7%)	2/3 (66.7%)
Week 24	5/7 (71.4%)	4/5 (80.0%)	2/5 (40.0%)	0/3 (0.0%)	1/4 (25.0%)	2/2 (100.0%)
Week 36	5/6 (83.3%)	4/5 (80.0%)	0/3 (0.0%)	0/2 (0.0%)	1/3 (33.3%)	1/2 (50.0%)
Week 48	4/4 (100.0%)	2/2 (100.0%)	1/4 (25.0%)	0/2 (0.0%)	1/2 (50.0%)	1/2 (50.0%)
Week 60	0/0 (–%)	0/0 (–%)	0/1 (0.0%)	0/1 (0.0%)	0/0 (–%)	0/1 (0.0%)
Week 72	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/1 (0.0%)	0/0 (–%)	0/1 (0.0%)
Week 84	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/1 (0.0%)	0/0 (–%)	0/1 (0.0%)
Week 96	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Step 5b						
Day 0	0/37 (0.0%)	0/42 (0.0%)	0/39 (0.0%)	1/34 (2.9%)	0/26 (0.0%)	0/39 (0.0%)
Week 12	0/0 (–%)	0/0 (–%)	0/0 (–%)	1/1 (100.0%)	0/0 (–%)	0/0 (–%)
Week 24	0/0 (–%)	0/0 (–%)	0/0 (–%)	1/1 (100.0%)	0/0 (–%)	0/0 (–%)

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[2] Participants can directly go to later visits without attending Day 0.
[3] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

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Table 7Ci – Visit Completion by Visit by Site: US

	Aurora	Cincinnati	Greensboro	Houston	New Orleans	Columbus
Participants Enrolled in OLE [1]	25	33	25	34	24	22
Step 4a						
Day 0	1/25 (4.0%)	12/33 (36.4%)	1/25 (4.0%)	13/34 (38.2%)	2/24 (8.3%)	8/22 (36.4%)
Week 4	1/1 (100.0%)	10/12 (83.3%)	1/1 (100.0%)	13/13 (100.0%)	1/2 (50.0%)	8/8 (100.0%)
Step 4b						
Day 0	20/25 (80.0%)	24/33 (72.7%)	18/25 (72.0%)	24/34 (70.6%)	20/24 (83.3%)	20/22 (90.9%)
Step 4c [2]						
Day 0	23/25 (92.0%)	29/33 (87.9%)	22/25 (88.0%)	32/34 (94.1%)	21/24 (87.5%)	19/22 (86.4%)
Week 8	21/22 (95.5%)	28/30 (93.3%)	22/23 (95.7%)	32/33 (97.0%)	21/22 (95.5%)	19/20 (95.0%)
Week 16	20/22 (90.9%)	25/29 (86.2%)	21/23 (91.3%)	31/33 (93.9%)	21/22 (95.5%)	19/20 (95.0%)
Week 24	20/21 (95.2%)	23/28 (82.1%)	21/22 (95.5%)	31/33 (93.9%)	19/22 (86.4%)	18/20 (90.0%)
Week 32	21/21 (100.0%)	25/27 (92.6%)	20/22 (90.9%)	31/32 (96.9%)	21/22 (95.5%)	17/19 (89.5%)
Week 40	20/21 (95.2%)	24/26 (92.3%)	20/21 (95.2%)	30/32 (93.8%)	21/22 (95.5%)	17/18 (94.4%)
Week 48	20/21 (95.2%)	24/24 (100.0%)	20/21 (95.2%)	28/31 (90.3%)	19/22 (86.4%)	17/18 (94.4%)
Step 6						
Week 56	17/17 (100.0%)	13/13 (100.0%)	5/5 (100.0%)	0/0 (–%)	1/1 (100.0%)	14/14 (100.0%)
Week 64	16/16 (100.0%)	8/12 (66.7%)	4/5 (80.0%)	0/0 (–%)	0/1 (0.0%)	13/14 (92.9%)
Week 72	10/11 (90.9%)	7/8 (87.5%)	3/4 (75.0%)	0/0 (–%)	0/0 (–%)	11/13 (84.6%)
Week 80	9/11 (81.8%)	7/7 (100.0%)	1/3 (33.3%)	0/0 (–%)	0/0 (–%)	11/11 (100.0%)
Week 88	7/7 (100.0%)	5/6 (83.3%)	1/1 (100.0%)	0/0 (–%)	0/0 (–%)	11/11 (100.0%)
Week 96	7/7 (100.0%)	4/5 (80.0%)	1/1 (100.0%)	0/0 (–%)	0/0 (–%)	8/11 (72.7%)
Step 5 [3]						
Participants entering Step 5	3/25 (12.0%)	3/33 (9.1%)	5/25 (20.0%)	1/34 (2.9%)	0/24 (0.0%)	0/22 (0.0%)
Week 12	3/3 (100.0%)	3/3 (100.0%)	2/5 (40.0%)	1/1 (100.0%)	0/0 (–%)	0/0 (–%)
Week 24	2/2 (100.0%)	3/3 (100.0%)	1/5 (20.0%)	1/2 (50.0%)	0/0 (–%)	0/0 (–%)
Week 36	2/2 (100.0%)	2/2 (100.0%)	1/3 (33.3%)	1/1 (100.0%)	0/0 (–%)	0/0 (–%)
Week 48	1/2 (50.0%)	2/2 (100.0%)	1/2 (50.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 60	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 72	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 84	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 96	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Step 5b						
Day 0	0/25 (0.0%)	0/33 (0.0%)	0/25 (0.0%)	0/34 (0.0%)	0/24 (0.0%)	0/22 (0.0%)
Week 12	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 24	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)

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[2] Participants can directly go to later visits without attending Day 0.
[3] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

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Table 7Ci – Visit Completion by Visit by Site: US

	Memphis	St. Louis	Philadelphia	Oakland
Participants Enrolled in OLE [1]	49	20	47	21
Step 4a				
Day 0	7/49 (14.3%)	1/20 (5.0%)	0/47 (0.0%)	2/21 (9.5%)
Week 4	7/7 (100.0%)	0/1 (0.0%)	0/0 (–%)	2/2 (100.0%)
Step 4b				
Day 0	40/49 (81.6%)	20/20 (100.0%)	32/47 (68.1%)	18/21 (85.7%)
Step 4c [2]				
Day 0	43/49 (87.8%)	19/20 (95.0%)	43/47 (91.5%)	19/21 (90.5%)
Week 8	41/44 (93.2%)	18/19 (94.7%)	43/43 (100.0%)	19/19 (100.0%)
Week 16	39/44 (88.6%)	18/18 (100.0%)	43/43 (100.0%)	18/19 (94.7%)
Week 24	39/44 (88.6%)	18/18 (100.0%)	42/43 (97.7%)	18/19 (94.7%)
Week 32	37/41 (90.2%)	18/18 (100.0%)	41/43 (95.3%)	18/18 (100.0%)
Week 40	36/40 (90.0%)	17/18 (94.4%)	41/43 (95.3%)	17/18 (94.4%)
Week 48	34/38 (89.5%)	14/15 (93.3%)	41/43 (95.3%)	17/18 (94.4%)
Step 6				
Week 56	30/30 (100.0%)	10/10 (100.0%)	39/39 (100.0%)	17/17 (100.0%)
Week 64	21/30 (70.0%)	10/10 (100.0%)	39/39 (100.0%)	17/17 (100.0%)
Week 72	11/25 (44.0%)	9/9 (100.0%)	39/39 (100.0%)	16/17 (94.1%)
Week 80	6/21 (28.6%)	9/9 (100.0%)	37/39 (94.9%)	14/15 (93.3%)
Week 88	2/12 (16.7%)	8/8 (100.0%)	35/37 (94.6%)	11/15 (73.3%)
Week 96	1/4 (25.0%)	7/8 (87.5%)	35/36 (97.2%)	11/14 (78.6%)
Step 5 [3]				
Participants entering Step 5	14/49 (28.6%)	2/20 (10.0%)	3/47 (6.4%)	1/21 (4.8%)
Week 12	2/13 (15.4%)	2/2 (100.0%)	0/3 (0.0%)	1/1 (100.0%)
Week 24	2/12 (16.7%)	2/2 (100.0%)	0/2 (0.0%)	0/1 (0.0%)
Week 36	1/8 (12.5%)	2/2 (100.0%)	2/4 (50.0%)	0/0 (–%)
Week 48	1/2 (50.0%)	1/2 (50.0%)	3/4 (75.0%)	0/0 (–%)
Week 60	0/2 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 72	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 84	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 96	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Step 5b				
Day 0	0/49 (0.0%)	0/20 (0.0%)	0/47 (0.0%)	0/21 (0.0%)
Week 12	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 24	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)

[1] "Visit Completion" is defined as the number (and %) of participants who completed the visit among the participants who are expected according to the protocol schedule, plus any participants who have completed the visit even though their visit window has not yet closed. "Expected according to the protocol schedule" refers to all participants who are active (Alive, HIV uninfected, have not permanently discontinued randomized study product, and not terminated from study) at the time of the visit and the visit window has closed.
[2] Participants can directly go to later visits without attending Day 0.
[3] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

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Table 7Ci – Visit Completion by Visit by Site: US

	Overall	Baltimore	Los Angeles – UCLA Care	Chapel Hill	Atlanta	New York – Weill Cornell Chelsea
Week 36	1/1 (100.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 48	1/1 (100.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)

[1] "Visit Completion" is defined as the number (and %) of participants who completed the visit among the participants who are expected according to the protocol schedule, plus any participants who have completed the visit even though their visit window has not yet closed. "Expected according to the protocol schedule" refers to all participants who are active (Alive, HIV uninfected, have not permanently discontinued randomized study product, and not terminated from study) at the time of the visit and the visit window has closed.
[2] Participants can directly go to later visits without attending Day 0.
[3] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

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Table 7Ci – Visit Completion by Visit by Site: US

	Bronx	Harlem	San Francisco	Chicago – WISH	Decatur	Los Angeles – UCLA Vine
Week 36	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 48	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)

[1] "Visit Completion" is defined as the number (and %) of participants who completed the visit among the participants who are expected according to the protocol schedule, plus any participants who have completed the visit even though their visit window has not yet closed. "Expected according to the protocol schedule" refers to all participants who are active (Alive, HIV uninfected, have not permanently discontinued randomized study product, and not terminated from study) at the time of the visit and the visit window has closed.
[2] Participants can directly go to later visits without attending Day 0.
[3] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

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Table 7Ci – Visit Completion by Visit by Site: US

	Washington, DC	Boston	Newark	Birmingham	New York – Blood Center	Chicago – AYAR
Week 36	0/0 (–%)	0/0 (–%)	0/0 (–%)	1/1 (100.0%)	0/0 (–%)	0/0 (–%)
Week 48	0/0 (–%)	0/0 (–%)	0/0 (–%)	1/1 (100.0%)	0/0 (–%)	0/0 (–%)

[1] "Visit Completion" is defined as the number (and %) of participants who completed the visit among the participants who are expected according to the protocol schedule, plus any participants who have completed the visit even though their visit window has not yet closed. "Expected according to the protocol schedule" refers to all participants who are active (Alive, HIV uninfected, have not permanently discontinued randomized study product, and not terminated from study) at the time of the visit and the visit window has closed.
[2] Participants can directly go to later visits without attending Day 0.
[3] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

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Table 7Ci – Visit Completion by Visit by Site: US

	Aurora	Cincinnati	Greensboro	Houston	New Orleans	Columbus
Week 36	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 48	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)

[1] "Visit Completion" is defined as the number (and %) of participants who completed the visit among the participants who are expected according to the protocol schedule, plus any participants who have completed the visit even though their visit window has not yet closed. "Expected according to the protocol schedule" refers to all participants who are active (Alive, HIV uninfected, have not permanently discontinued randomized study product, and not terminated from study) at the time of the visit and the visit window has closed.
[2] Participants can directly go to later visits without attending Day 0.
[3] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

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Table 7Ci – Visit Completion by Visit by Site: US

	Memphis	St. Louis	Philadelphia	Oakland
Week 36	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 48	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)

[1] "Visit Completion" is defined as the number (and %) of participants who completed the visit among the participants who are expected according to the protocol schedule, plus any participants who have completed the visit even though their visit window has not yet closed. "Expected according to the protocol schedule" refers to all participants who are active (Alive, HIV uninfected, have not permanently discontinued randomized study product, and not terminated from study) at the time of the visit and the visit window has closed.
[2] Participants can directly go to later visits without attending Day 0.
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Table 7Cii – Visit Completion by Visit by Site: Latin America

	Overall	Lima – Barranco	Lima – San Miguel	Rio de Janeiro	Porto Alegre
Participants Enrolled in OLE [1]	1221	74	62	192	164
Step 4a					
Day 0	88/1221 (7.2%)	2/74 (2.7%)	15/62 (24.2%)	0/192 (0.0%)	0/164 (0.0%)
Week 4	85/87 (97.7%)	2/2 (100.0%)	15/15 (100.0%)	0/0 (–%)	0/0 (–%)
Step 4b					
Day 0	843/1221 (69.0%)	74/74 (100.0%)	61/62 (98.4%)	129/192 (67.2%)	106/164 (64.6%)
Step 4c [2]					
Day 0	1134/1221 (92.9%)	68/74 (91.9%)	59/62 (95.2%)	181/192 (94.3%)	158/164 (96.3%)
Week 8	1091/1147 (95.1%)	66/73 (90.4%)	55/59 (93.2%)	179/183 (97.8%)	152/158 (96.2%)
Week 16	1068/1136 (94.0%)	61/73 (83.6%)	54/58 (93.1%)	178/183 (97.3%)	149/155 (96.1%)
Week 24	1055/1127 (93.6%)	58/71 (81.7%)	54/56 (96.4%)	176/183 (96.2%)	148/152 (97.4%)
Week 32	1036/1120 (92.5%)	49/70 (70.0%)	52/55 (94.5%)	176/182 (96.7%)	146/152 (96.1%)
Week 40	1017/1107 (91.9%)	53/67 (79.1%)	50/55 (90.9%)	173/181 (95.6%)	141/151 (93.4%)
Week 48	1016/1091 (93.1%)	62/62 (100.0%)	49/55 (89.1%)	171/180 (95.0%)	140/150 (93.3%)
Step 6					
Week 56	1016/1016 (100.0%)	62/62 (100.0%)	47/47 (100.0%)	171/171 (100.0%)	140/140 (100.0%)
Week 64	959/1010 (95.0%)	59/61 (96.7%)	44/44 (100.0%)	159/171 (93.0%)	134/140 (95.7%)
Week 72	913/967 (94.4%)	41/46 (89.1%)	29/33 (87.9%)	163/170 (95.9%)	130/138 (94.2%)
Week 80	736/798 (92.2%)	5/12 (41.7%)	13/14 (92.9%)	159/169 (94.1%)	131/138 (94.9%)
Week 88	672/725 (92.7%)	0/1 (0.0%)	1/2 (50.0%)	158/168 (94.0%)	129/138 (93.5%)
Week 96	670/707 (94.8%)	0/0 (–%)	0/0 (–%)	163/168 (97.0%)	126/136 (92.6%)
Step 7					
Week 104	671/671 (100.0%)	0/0 (–%)	0/0 (–%)	161/161 (100.0%)	134/134 (100.0%)
Week 112	630/660 (95.5%)	0/0 (–%)	0/0 (–%)	157/160 (98.1%)	116/129 (89.9%)
Week 120	603/648 (93.1%)	0/0 (–%)	0/0 (–%)	153/160 (95.6%)	111/124 (89.5%)
Week 128	571/631 (90.5%)	0/0 (–%)	0/0 (–%)	151/159 (95.0%)	105/121 (86.8%)
Week 136	503/592 (85.0%)	0/0 (–%)	0/0 (–%)	151/157 (96.2%)	84/108 (77.8%)
Week 144	373/509 (73.3%)	0/0 (–%)	0/0 (–%)	150/153 (98.0%)	45/88 (51.1%)
Week 152	249/339 (73.5%)	0/0 (–%)	0/0 (–%)	143/150 (95.3%)	17/56 (30.4%)
Week 160	180/227 (79.3%)	0/0 (–%)	0/0 (–%)	138/146 (94.5%)	8/16 (50.0%)
Week 168	111/149 (74.5%)	0/0 (–%)	0/0 (–%)	106/125 (84.8%)	1/3 (33.3%)
Week 176	21/48 (43.8%)	0/0 (–%)	0/0 (–%)	21/47 (44.7%)	0/0 (–%)
Week 184	0/5 (0.0%)	0/0 (–%)	0/0 (–%)	0/5 (0.0%)	0/0 (–%)
Week 192	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)

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[2] Participants can directly go to later visits without attending Day 0.
[3] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

Source: SCHARP (Rajee) – /trials/hptn/p083/analysis/live/code/ole/t_ole_vcomp_bysite.sas, SAS Version 9.4 (04MAR2026,6:08)

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Table 7Cii – Visit Completion by Visit by Site: Latin America

	Iquitos	Lima – Via Libre	Sao Paulo – DST–AIDS	Sao Paulo – DST–AIDS	Lima – CITBM
Participants Enrolled in OLE [1]	74	92	116	116	52
Step 4a					
Day 0	0/74 (0.0%)	5/92 (5.4%)	44/116 (37.9%)	44/116 (37.9%)	7/52 (13.5%)
Week 4	0/0 (–%)	5/5 (100.0%)	42/44 (95.5%)	42/44 (95.5%)	6/6 (100.0%)
Step 4b					
Day 0	74/74 (100.0%)	89/92 (96.7%)	53/116 (45.7%)	53/116 (45.7%)	51/52 (98.1%)
Step 4c [2]					
Day 0	70/74 (94.6%)	85/92 (92.4%)	103/116 (88.8%)	103/116 (88.8%)	46/52 (88.5%)
Week 8	65/71 (91.5%)	83/86 (96.5%)	100/102 (98.0%)	100/102 (98.0%)	42/48 (87.5%)
Week 16	59/71 (83.1%)	79/86 (91.9%)	100/101 (99.0%)	100/101 (99.0%)	40/46 (87.0%)
Week 24	64/71 (90.1%)	80/86 (93.0%)	99/100 (99.0%)	99/100 (99.0%)	37/46 (80.4%)
Week 32	66/70 (94.3%)	79/86 (91.9%)	97/100 (97.0%)	97/100 (97.0%)	40/46 (87.0%)
Week 40	64/68 (94.1%)	79/85 (92.9%)	93/98 (94.9%)	93/98 (94.9%)	39/46 (84.8%)
Week 48	62/68 (91.2%)	76/83 (91.6%)	94/97 (96.9%)	94/97 (96.9%)	39/44 (88.6%)
Step 6					
Week 56	65/65 (100.0%)	77/77 (100.0%)	94/94 (100.0%)	94/94 (100.0%)	41/41 (100.0%)
Week 64	59/65 (90.8%)	74/75 (98.7%)	89/94 (94.7%)	89/94 (94.7%)	33/41 (80.5%)
Week 72	63/65 (96.9%)	64/65 (98.5%)	88/93 (94.6%)	88/93 (94.6%)	32/38 (84.2%)
Week 80	25/27 (92.6%)	0/0 (–%)	88/91 (96.7%)	88/91 (96.7%)	20/30 (66.7%)
Week 88	0/1 (0.0%)	0/0 (–%)	87/90 (96.7%)	87/90 (96.7%)	3/10 (30.0%)
Week 96	0/0 (–%)	0/0 (–%)	87/88 (98.9%)	87/88 (98.9%)	0/0 (–%)
Step 7					
Week 104	0/0 (–%)	0/0 (–%)	87/87 (100.0%)	87/87 (100.0%)	0/0 (–%)
Week 112	0/0 (–%)	0/0 (–%)	85/85 (100.0%)	85/85 (100.0%)	0/0 (–%)
Week 120	0/0 (–%)	0/0 (–%)	82/83 (98.8%)	82/83 (98.8%)	0/0 (–%)
Week 128	0/0 (–%)	0/0 (–%)	78/79 (98.7%)	78/79 (98.7%)	0/0 (–%)
Week 136	0/0 (–%)	0/0 (–%)	73/74 (98.6%)	73/74 (98.6%)	0/0 (–%)
Week 144	0/0 (–%)	0/0 (–%)	69/73 (94.5%)	69/73 (94.5%)	0/0 (–%)
Week 152	0/0 (–%)	0/0 (–%)	58/61 (95.1%)	58/61 (95.1%)	0/0 (–%)
Week 160	0/0 (–%)	0/0 (–%)	31/36 (86.1%)	31/36 (86.1%)	0/0 (–%)
Week 168	0/0 (–%)	0/0 (–%)	2/4 (50.0%)	2/4 (50.0%)	0/0 (–%)
Week 176	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 184	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 192	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)

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[2] Participants can directly go to later visits without attending Day 0.
[3] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

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Table 7Cii – Visit Completion by Visit by Site: Latin America

	Buenos Aires – Fundacion Huesped	Buenos Aires – Hospital JM Ramos Mejia	Sao Paulo – IC–HCFMUSP
Participants Enrolled in OLE [1]	151	109	135
Step 4a			
Day 0	11/151 (7.3%)	0/109 (0.0%)	4/135 (3.0%)
Week 4	11/11 (100.0%)	0/0 (–%)	4/4 (100.0%)
Step 4b			
Day 0	80/151 (53.0%)	53/109 (48.6%)	73/135 (54.1%)
Step 4c [2]			
Day 0	139/151 (92.1%)	97/109 (89.0%)	128/135 (94.8%)
Week 8	134/141 (95.0%)	94/98 (95.9%)	121/128 (94.5%)
Week 16	133/140 (95.0%)	93/97 (95.9%)	122/126 (96.8%)
Week 24	133/139 (95.7%)	92/97 (94.8%)	114/126 (90.5%)
Week 32	132/137 (96.4%)	91/97 (93.8%)	108/125 (86.4%)
Week 40	130/136 (95.6%)	91/95 (95.8%)	104/125 (83.2%)
Week 48	126/134 (94.0%)	91/95 (95.8%)	106/123 (86.2%)
Step 6			
Week 56	118/118 (100.0%)	90/90 (100.0%)	111/111 (100.0%)
Week 64	117/118 (99.2%)	90/90 (100.0%)	101/111 (91.0%)
Week 72	116/118 (98.3%)	90/90 (100.0%)	97/111 (87.4%)
Week 80	115/117 (98.3%)	85/89 (95.5%)	95/111 (85.6%)
Week 88	115/116 (99.1%)	84/89 (94.4%)	95/110 (86.4%)
Week 96	114/116 (98.3%)	81/89 (91.0%)	99/110 (90.0%)
Step 7			
Week 104	109/109 (100.0%)	75/75 (100.0%)	105/105 (100.0%)
Week 112	105/107 (98.1%)	71/74 (95.9%)	96/105 (91.4%)
Week 120	100/104 (96.2%)	63/72 (87.5%)	94/105 (89.5%)
Week 128	95/100 (95.0%)	48/68 (70.6%)	94/104 (90.4%)
Week 136	76/90 (84.4%)	28/61 (45.9%)	91/102 (89.2%)
Week 144	38/63 (60.3%)	2/43 (4.7%)	69/89 (77.5%)
Week 152	1/4 (25.0%)	0/30 (0.0%)	30/38 (78.9%)
Week 160	1/1 (100.0%)	0/24 (0.0%)	2/4 (50.0%)
Week 168	0/0 (–%)	0/15 (0.0%)	2/2 (100.0%)
Week 176	0/0 (–%)	0/1 (0.0%)	0/0 (–%)
Week 184	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 192	0/0 (–%)	0/0 (–%)	0/0 (–%)

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Table 7Cii – Visit Completion by Visit by Site: Latin America

	Overall	Lima – Barranco	Lima – San Miguel	Rio de Janeiro	Porto Alegre
Step 5 [3]					
Participants entering Step 5	128/1221 (10.5%)	6/74 (8.1%)	2/62 (3.2%)	8/192 (4.2%)	9/164 (5.5%)
Week 12	79/131 (60.3%)	6/6 (100.0%)	0/2 (0.0%)	8/8 (100.0%)	7/9 (77.8%)
Week 24	70/123 (56.9%)	5/6 (83.3%)	0/2 (0.0%)	7/7 (100.0%)	5/7 (71.4%)
Week 36	56/109 (51.4%)	0/4 (0.0%)	0/2 (0.0%)	6/7 (85.7%)	6/6 (100.0%)
Week 48	49/96 (51.0%)	0/0 (–%)	0/1 (0.0%)	6/6 (100.0%)	5/7 (71.4%)
Week 60	2/53 (3.8%)	0/0 (–%)	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)
Week 72	3/40 (7.5%)	0/0 (–%)	0/0 (–%)	1/1 (100.0%)	0/2 (0.0%)
Week 84	2/37 (5.4%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/2 (0.0%)
Week 96	1/33 (3.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/1 (0.0%)

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Table 7Cii – Visit Completion by Visit by Site: Latin America

	Iquitos	Lima – Via Libre	Sao Paulo – DST–AIDS	Sao Paulo – DST–AIDS	Lima – CITBM
Step 5 [3]					
Participants entering Step 5	0/74 (0.0%)	1/92 (1.1%)	23/116 (19.8%)	23/116 (19.8%)	1/52 (1.9%)
Week 12	0/0 (–%)	0/1 (0.0%)	21/23 (91.3%)	21/23 (91.3%)	3/3 (100.0%)
Week 24	0/0 (–%)	1/1 (100.0%)	20/24 (83.3%)	20/24 (83.3%)	1/2 (50.0%)
Week 36	0/0 (–%)	0/1 (0.0%)	19/22 (86.4%)	19/22 (86.4%)	0/1 (0.0%)
Week 48	0/0 (–%)	0/0 (–%)	13/20 (65.0%)	13/20 (65.0%)	0/0 (–%)
Week 60	0/0 (–%)	0/0 (–%)	2/6 (33.3%)	2/6 (33.3%)	0/0 (–%)
Week 72	0/0 (–%)	0/0 (–%)	2/4 (50.0%)	2/4 (50.0%)	0/0 (–%)
Week 84	0/0 (–%)	0/0 (–%)	2/4 (50.0%)	2/4 (50.0%)	0/0 (–%)
Week 96	0/0 (–%)	0/0 (–%)	1/3 (33.3%)	1/3 (33.3%)	0/0 (–%)

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Table 7Cii – Visit Completion by Visit by Site: Latin America

	Buenos Aires – Fundacion Huesped	Buenos Aires – Hospital JM Ramos Mejia	Sao Paulo – IC–HCFMUSP
Step 5 [3]			
Participants entering Step 5	52/151 (34.4%)	17/109 (15.6%)	9/135 (6.7%)
Week 12	16/53 (30.2%)	11/17 (64.7%)	7/9 (77.8%)
Week 24	16/51 (31.4%)	9/14 (64.3%)	6/9 (66.7%)
Week 36	15/50 (30.0%)	4/8 (50.0%)	6/8 (75.0%)
Week 48	14/48 (29.2%)	4/6 (66.7%)	7/8 (87.5%)
Week 60	0/37 (0.0%)	0/2 (0.0%)	0/4 (0.0%)
Week 72	0/30 (0.0%)	0/1 (0.0%)	0/2 (0.0%)
Week 84	0/29 (0.0%)	0/1 (0.0%)	0/1 (0.0%)
Week 96	0/28 (0.0%)	0/1 (0.0%)	0/0 (–%)

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[3] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

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Table 7Ciii – Visit Completion by Visit by Site: Asia

	Overall	Chiang Mai	Bangkok – Silom Clinic	Bangkok – Thai Red Cross	Hanoi
Participants Enrolled in OLE [1]	528	90	150	145	143
Step 4a					
Day 0	199/528 (37.7%)	41/90 (45.6%)	79/150 (52.7%)	18/145 (12.4%)	61/143 (42.7%)
Week 4	193/196 (98.5%)	40/40 (100.0%)	77/77 (100.0%)	17/18 (94.4%)	59/61 (96.7%)
Step 4b					
Day 0	426/528 (80.7%)	74/90 (82.2%)	146/150 (97.3%)	103/145 (71.0%)	103/143 (72.0%)
Step 4c [2]					
Day 0	487/528 (92.2%)	82/90 (91.1%)	141/150 (94.0%)	134/145 (92.4%)	130/143 (90.9%)
Week 8	479/500 (95.8%)	81/85 (95.3%)	138/143 (96.5%)	132/138 (95.7%)	128/134 (95.5%)
Week 16	476/497 (95.8%)	81/85 (95.3%)	138/141 (97.9%)	132/138 (95.7%)	125/133 (94.0%)
Week 24	468/497 (94.2%)	82/85 (96.5%)	136/141 (96.5%)	127/138 (92.0%)	123/133 (92.5%)
Week 32	461/491 (93.9%)	80/84 (95.2%)	134/139 (96.4%)	126/137 (92.0%)	121/131 (92.4%)
Week 40	462/487 (94.9%)	80/83 (96.4%)	133/137 (97.1%)	128/137 (93.4%)	121/130 (93.1%)
Week 48	459/484 (94.8%)	80/82 (97.6%)	129/136 (94.9%)	130/136 (95.6%)	120/130 (92.3%)
Step 6					
Week 56	452/452 (100.0%)	80/80 (100.0%)	126/126 (100.0%)	127/127 (100.0%)	119/119 (100.0%)
Week 64	427/452 (94.5%)	80/80 (100.0%)	107/126 (84.9%)	124/127 (97.6%)	116/119 (97.5%)
Week 72	368/433 (85.0%)	80/80 (100.0%)	54/107 (50.5%)	119/127 (93.7%)	115/119 (96.6%)
Week 80	317/382 (83.0%)	80/80 (100.0%)	5/58 (8.6%)	118/126 (93.7%)	114/118 (96.6%)
Week 88	309/329 (93.9%)	80/80 (100.0%)	0/5 (0.0%)	115/127 (90.6%)	114/117 (97.4%)
Week 96	307/321 (95.6%)	78/80 (97.5%)	0/0 (–%)	115/126 (91.3%)	114/115 (99.1%)
Step 7					
Week 104	298/298 (100.0%)	72/72 (100.0%)	0/0 (–%)	114/114 (100.0%)	112/112 (100.0%)
Week 112	257/297 (86.5%)	47/71 (66.2%)	0/0 (–%)	99/114 (86.8%)	111/112 (99.1%)
Week 120	196/249 (78.7%)	12/38 (31.6%)	0/0 (–%)	79/100 (79.0%)	105/111 (94.6%)
Week 128	146/204 (71.6%)	0/9 (0.0%)	0/0 (–%)	46/85 (54.1%)	100/110 (90.9%)
Week 136	108/168 (64.3%)	0/0 (–%)	0/0 (–%)	11/65 (16.9%)	97/103 (94.2%)
Week 144	92/128 (71.9%)	0/0 (–%)	0/0 (–%)	0/30 (0.0%)	92/98 (93.9%)
Week 152	79/93 (84.9%)	0/0 (–%)	0/0 (–%)	0/4 (0.0%)	79/89 (88.8%)
Week 160	61/73 (83.6%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	61/73 (83.6%)
Week 168	21/22 (95.5%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	21/22 (95.5%)
Week 176	1/1 (100.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	1/1 (100.0%)
Week 184	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Week 192	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)
Step 5 [3]					

[1] "Visit Completion" is defined as the number (and %) of participants who completed the visit among the participants who are expected according to the protocol schedule, plus any participants who have completed the visit even though their visit window has not yet closed. "Expected according to the protocol schedule" refers to all participants who are active (Alive, HIV uninfected, have not permanently discontinued randomized study product, and not terminated from study) at the time of the visit and the visit window has closed.
[2] Participants can directly go to later visits without attending Day 0.
[3] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

Source: SCHARP (Rajee) – /trials/hptn/p083/analysis/live/code/ole/t_ole_vcomp_bysite.sas, SAS Version 9.4 (04MAR2026,6:08)

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Table 7Ciii – Visit Completion by Visit by Site: Asia

	Overall	Chiang Mai	Bangkok – Silom Clinic	Bangkok – Thai Red Cross	Hanoi
Participants entering Step 5	25/528 (4.7%)	2/90 (2.2%)	7/150 (4.7%)	7/145 (4.8%)	9/143 (6.3%)
Week 12	23/28 (82.1%)	2/2 (100.0%)	6/7 (85.7%)	7/8 (87.5%)	8/11 (72.7%)
Week 24	17/23 (73.9%)	3/3 (100.0%)	5/7 (71.4%)	4/6 (66.7%)	5/7 (71.4%)
Week 36	16/21 (76.2%)	5/5 (100.0%)	4/6 (66.7%)	3/5 (60.0%)	4/5 (80.0%)
Week 48	11/16 (68.8%)	5/5 (100.0%)	3/5 (60.0%)	1/3 (33.3%)	2/3 (66.7%)
Week 60	0/4 (0.0%)	0/0 (–%)	0/1 (0.0%)	0/2 (0.0%)	0/1 (0.0%)
Week 72	0/3 (0.0%)	0/0 (–%)	0/0 (–%)	0/2 (0.0%)	0/1 (0.0%)
Week 84	0/1 (0.0%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/1 (0.0%)

[1] "Visit Completion" is defined as the number (and %) of participants who completed the visit among the participants who are expected according to the protocol schedule, plus any participants who have completed the visit even though their visit window has not yet closed. "Expected according to the protocol schedule" refers to all participants who are active (Alive, HIV uninfected, have not permanently discontinued randomized study product, and not terminated from study) at the time of the visit and the visit window has closed.
[2] Participants can directly go to later visits without attending Day 0.
[3] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

Source: SCHARP (Rajee) – /trials/hptn/p083/analysis/live/code/ole/t_ole_vcomp_bysite.sas, SAS Version 9.4 (04MAR2026,6:08)

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Table 7Civ – Visit Completion by Visit by Site: Africa

	Overall	Cape Town
Participants Enrolled in OLE [1]	87	87
Step 4a		
Day 0	17/87 (19.5%)	17/87 (19.5%)
Week 4	16/17 (94.1%)	16/17 (94.1%)
Step 4b		
Day 0	52/87 (59.8%)	52/87 (59.8%)
Step 4c [2]		
Day 0	75/87 (86.2%)	75/87 (86.2%)
Week 8	74/78 (94.9%)	74/78 (94.9%)
Week 16	72/78 (92.3%)	72/78 (92.3%)
Week 24	70/78 (89.7%)	70/78 (89.7%)
Week 32	70/78 (89.7%)	70/78 (89.7%)
Week 40	69/78 (88.5%)	69/78 (88.5%)
Week 48	67/77 (87.0%)	67/77 (87.0%)
Step 6		
Week 56	65/65 (100.0%)	65/65 (100.0%)
Week 64	64/65 (98.5%)	64/65 (98.5%)
Week 72	64/65 (98.5%)	64/65 (98.5%)
Week 80	61/65 (93.8%)	61/65 (93.8%)
Week 88	61/64 (95.3%)	61/64 (95.3%)
Week 96	61/64 (95.3%)	61/64 (95.3%)
Step 7		
Week 104	61/61 (100.0%)	61/61 (100.0%)
Week 112	61/61 (100.0%)	61/61 (100.0%)
Week 120	57/59 (96.6%)	57/59 (96.6%)
Week 128	54/57 (94.7%)	54/57 (94.7%)
Week 136	35/40 (87.5%)	35/40 (87.5%)
Week 144	10/15 (66.7%)	10/15 (66.7%)
Week 152	0/2 (0.0%)	0/2 (0.0%)
Week 160	0/0 (–%)	0/0 (–%)
Week 168	0/0 (–%)	0/0 (–%)
Week 176	0/0 (–%)	0/0 (–%)
Week 184	0/0 (–%)	0/0 (–%)
Week 192	0/0 (–%)	0/0 (–%)
Step 5 [3]		
Participants entering Step 5	6/87 (6.9%)	6/87 (6.9%)

[1] "Visit Completion" is defined as the number (and %) of participants who completed the visit among the participants who are expected according to the protocol schedule, plus any participants who have completed the visit even though their visit window has not yet closed. "Expected according to the protocol schedule" refers to all participants who are active (Alive, HIV uninfected, have not permanently discontinued randomized study product, and not terminated from study) at the time of the visit and the visit window has closed.
[2] Participants can directly go to later visits without attending Day 0.
[3] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

Source: SCHARP (Rajee) – /trials/hptn/p083/analysis/live/code/ole/t_ole_vcomp_bysite.sas, SAS Version 9.4 (04MAR2026,6:08)

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Table 7Civ – Visit Completion by Visit by Site: Africa

	Overall	Cape Town
Week 12	7/8 (87.5%)	7/8 (87.5%)
Week 24	6/8 (75.0%)	6/8 (75.0%)
Week 36	4/7 (57.1%)	4/7 (57.1%)
Week 48	2/5 (40.0%)	2/5 (40.0%)
Week 60	1/5 (20.0%)	1/5 (20.0%)
Week 72	1/4 (25.0%)	1/4 (25.0%)
Week 84	0/4 (0.0%)	0/4 (0.0%)
Week 96	0/4 (0.0%)	0/4 (0.0%)

[1] "Visit Completion" is defined as the number (and %) of participants who completed the visit among the participants who are expected according to the protocol schedule, plus any participants who have completed the visit even though their visit window has not yet closed. "Expected according to the protocol schedule" refers to all participants who are active (Alive, HIV uninfected, have not permanently discontinued randomized study product, and not terminated from study) at the time of the visit and the visit window has closed.
[2] Participants can directly go to later visits without attending Day 0.
[3] Some participants completed open–label TDF/FTC visits in Step 3 prior to the OLE; these visits are not expected in Step 5.

Source: SCHARP (Rajee) – /trials/hptn/p083/analysis/live/code/ole/t_ole_vcomp_bysite.sas, SAS Version 9.4 (04MAR2026,6:08)

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Table 8A – Retention by OLE Regimen Choice [1]

	Overall [2]	TDF/FTC	Cabotegravir
Total participants enrolled	2658	107	2495
Month 6	2432/2586 (94.0%)	64/78 (82.1%)	2361/2486 (95.0%)
Month 12	2230/2507 (89.0%)	35/56 (62.5%)	2189/2434 (89.9%)
Month 18	1656/2236 (74.1%)	30/56 (53.6%)	1623/2165 (75.0%)
Month 24	1101/1900 (57.9%)	23/51 (45.1%)	1075/1834 (58.6%)
Month 30	898/1720 (52.2%)	18/48 (37.5%)	879/1660 (53.0%)
Month 36	248/984 (25.2%)	4/34 (11.8%)	244/938 (26.0%)

[1] Retention is the proportion of participants who remain in follow–up at least as long as the nominal visit time (every 6 months) since they joined the OLE. Participants are expected at month 6 (or 12, 18... etc) if they have been enrolled in study at least 9 (or 15, 21... etc) months respectively, i.e. three months longer than the retention period. Participants are counted as retained if they completed any type of visit at or beyond the nominal visit time.
[2] Include all participants participating in OLE phase (CAB, TDF/FTC, seroconverter schedule and open label Truvada schedule).

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_ret_bychoice.sas, SAS Version 9.4 (04MAR2026,6:08)

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Table 8B – Retention by Region [1]

	Overall	US	Latin America	Asia	Africa
Total participants enrolled	2658	822	1221	528	87
Month 6	2432/2586 (94.0%)	730/796 (91.7%)	1138/1194 (95.3%)	490/512 (95.7%)	74/84 (88.1%)
Month 12	2230/2507 (89.0%)	622/752 (82.7%)	1069/1167 (91.6%)	470/506 (92.9%)	69/82 (84.1%)
Month 18	1656/2236 (74.1%)	461/711 (64.8%)	786/938 (83.8%)	345/505 (68.3%)	64/82 (78.0%)
Month 24	1101/1900 (57.9%)	34/401 (8.5%)	694/920 (75.4%)	311/497 (62.6%)	62/82 (75.6%)
Month 30	898/1720 (52.2%)	1/374 (0.3%)	651/878 (74.1%)	195/397 (49.1%)	51/71 (71.8%)
Month 36	248/984 (25.2%)	1/374 (0.3%)	191/383 (49.9%)	55/202 (27.2%)	1/25 (4.0%)

[1] Retention is the proportion of participants who remain in follow–up at least as long as the nominal visit time (every 6 months) since they joined the OLE. Participants are expected at month 6 (or 12, 18... etc) if they have been enrolled in study at least 9 (or 15, 21... etc) months respectively, i.e. three months longer than the retention period. Participants are counted as retained if they completed any type of visit at or beyond the nominal visit time.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_ret_byregion.sas, SAS Version 9.4 (04MAR2026,6:08)

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Table 8Ci – Retention by Site: US [1]

	Overall	Baltimore	Atlanta	Bronx	Boston	Birmingham	Aurora
Total participants enrolled	822	6	9	29	42	34	25
Month 6	730/796 (91.7%)	5/6 (83.3%)	8/9 (88.9%)	25/27 (92.6%)	38/40 (95.0%)	29/34 (85.3%)	23/24 (95.8%)
Month 12	622/752 (82.7%)	5/6 (83.3%)	5/8 (62.5%)	22/25 (88.0%)	33/39 (84.6%)	29/34 (85.3%)	20/21 (95.2%)
Month 18	461/711 (64.8%)	3/5 (60.0%)	4/8 (50.0%)	21/25 (84.0%)	12/23 (52.2%)	28/34 (82.4%)	9/13 (69.2%)
Month 24	34/401 (8.5%)	0/2 (0.0%)	0/4 (0.0%)	4/8 (50.0%)	0/9 (0.0%)	1/16 (6.3%)	0/5 (0.0%)
Month 30	1/374 (0.3%)	0/2 (0.0%)	0/4 (0.0%)	0/4 (0.0%)	0/9 (0.0%)	0/15 (0.0%)	0/5 (0.0%)
Month 36	7/374 (1.9%)	0/2 (0.0%)	0/4 (0.0%)	0/4 (0.0%)	0/9 (0.0%)	0/15 (0.0%)	0/5 (0.0%)

[1] Retention is the proportion of participants who remain in follow–up at least as long as the nominal visit time (every 6 months) since they joined the OLE. Participants are expected at month 6 (or 12, 18... etc) if they have been enrolled in study at least 9 (or 15, 21... etc) months respectively, i.e. three months longer than the retention period. Participants are counted as retained if they completed any type of visit at or beyond the nominal visit time.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_ret_bysite.sas, SAS Version 9.4 (04MAR2026,6:09)

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Table 8Ci – Retention by Site: US [1]

	Chapel Hill	Chicago – WISH	Decatur	Chicago – AYAR	Cincinnati	Greensboro	Columbus
Total participants enrolled	35	29	42	39	33	25	22
Month 6	34/34 (100.0%)	25/29 (86.2%)	35/38 (92.1%)	35/38 (92.1%)	28/32 (87.5%)	23/24 (95.8%)	19/22 (86.4%)
Month 12	33/34 (97.1%)	20/29 (69.0%)	31/36 (86.1%)	32/38 (84.2%)	26/30 (86.7%)	12/22 (54.5%)	16/21 (76.2%)
Month 18	31/33 (93.9%)	19/29 (65.5%)	25/34 (73.5%)	30/37 (81.1%)	8/27 (29.6%)	3/22 (13.6%)	11/21 (52.4%)
Month 24	1/16 (6.3%)	0/12 (0.0%)	1/13 (7.7%)	1/35 (2.9%)	3/24 (12.5%)	0/21 (0.0%)	0/13 (0.0%)
Month 30	0/15 (0.0%)	0/12 (0.0%)	0/12 (0.0%)	0/35 (0.0%)	1/23 (4.3%)	0/21 (0.0%)	0/13 (0.0%)
Month 36	0/15 (0.0%)	0/12 (0.0%)	0/12 (0.0%)	1/35 (2.9%)	2/23 (8.7%)	0/21 (0.0%)	0/13 (0.0%)

[1] Retention is the proportion of participants who remain in follow–up at least as long as the nominal visit time (every 6 months) since they joined the OLE. Participants are expected at month 6 (or 12, 18... etc) if they have been enrolled in study at least 9 (or 15, 21... etc) months respectively, i.e. three months longer than the retention period. Participants are counted as retained if they completed any type of visit at or beyond the nominal visit time.

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Table 8Ci – Retention by Site: US [1]

	Los Angeles – UCLA Care	Harlem	Los Angeles – UCLA Vine	New York – Blood Center	Houston	New Orleans	Memphis
Total participants enrolled	42	32	34	26	34	24	49
Month 6	39/42 (92.9%)	27/30 (90.0%)	30/33 (90.9%)	20/25 (80.0%)	31/33 (93.9%)	21/23 (91.3%)	42/47 (89.4%)
Month 12	33/42 (78.6%)	26/30 (86.7%)	29/33 (87.9%)	20/25 (80.0%)	6/9 (66.7%)	18/23 (78.3%)	36/46 (78.3%)
Month 18	26/41 (63.4%)	23/30 (76.7%)	27/33 (81.8%)	18/25 (72.0%)	0/5 (0.0%)	4/22 (18.2%)	19/45 (42.2%)
Month 24	0/18 (0.0%)	7/16 (43.8%)	3/9 (33.3%)	3/21 (14.3%)	0/5 (0.0%)	0/22 (0.0%)	0/42 (0.0%)
Month 30	0/18 (0.0%)	0/10 (0.0%)	0/6 (0.0%)	0/21 (0.0%)	0/5 (0.0%)	0/22 (0.0%)	0/42 (0.0%)
Month 36	0/18 (0.0%)	1/10 (10.0%)	0/6 (0.0%)	3/21 (14.3%)	0/5 (0.0%)	0/22 (0.0%)	0/42 (0.0%)

[1] Retention is the proportion of participants who remain in follow–up at least as long as the nominal visit time (every 6 months) since they joined the OLE. Participants are expected at month 6 (or 12, 18... etc) if they have been enrolled in study at least 9 (or 15, 21... etc) months respectively, i.e. three months longer than the retention period. Participants are counted as retained if they completed any type of visit at or beyond the nominal visit time.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_ret_bysite.sas, SAS Version 9.4 (04MAR2026,6:09)

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Table 8Ci – Retention by Site: US [1]

	New York – Weill Cornell Chelsea	San Francisco	Washington, DC	Newark	St. Louis	Philadelphia	Oakland
Total participants enrolled	28	19	37	39	20	47	21
Month 6	26/28 (92.9%)	18/18 (100.0%)	35/37 (94.6%)	34/38 (89.5%)	20/20 (100.0%)	42/44 (95.5%)	18/21 (85.7%)
Month 12	22/27 (81.5%)	17/18 (94.4%)	28/34 (82.4%)	33/38 (86.8%)	13/19 (68.4%)	40/44 (90.9%)	17/21 (81.0%)
Month 18	21/27 (77.8%)	16/18 (88.9%)	11/33 (33.3%)	29/37 (78.4%)	9/19 (47.4%)	39/44 (88.6%)	15/21 (71.4%)
Month 24	0/6 (0.0%)	1/6 (16.7%)	1/29 (3.4%)	3/13 (23.1%)	0/12 (0.0%)	1/10 (10.0%)	4/14 (28.6%)
Month 30	0/6 (0.0%)	0/5 (0.0%)	0/28 (0.0%)	0/10 (0.0%)	0/12 (0.0%)	0/9 (0.0%)	0/10 (0.0%)
Month 36	0/6 (0.0%)	0/5 (0.0%)	0/28 (0.0%)	0/10 (0.0%)	0/12 (0.0%)	0/9 (0.0%)	0/10 (0.0%)

[1] Retention is the proportion of participants who remain in follow–up at least as long as the nominal visit time (every 6 months) since they joined the OLE. Participants are expected at month 6 (or 12, 18... etc) if they have been enrolled in study at least 9 (or 15, 21... etc) months respectively, i.e. three months longer than the retention period. Participants are counted as retained if they completed any type of visit at or beyond the nominal visit time.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_ret_bysite.sas, SAS Version 9.4 (04MAR2026,6:09)

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Table 8Cii – Retention by Site: Latin America [1]

	Overall	Lima – Barranco	Lima – San Miguel	Iquitos	Lima – CITBM	Buenos Aires – Fundacion Huesped	Buenos Aires – Hospital JM Ramos Mejia
Total participants enrolled	1221	74	62	74	52	151	109
Month 6	1138/1194 (95.3%)	68/74 (91.9%)	56/62 (90.3%)	67/69 (97.1%)	47/50 (94.0%)	145/151 (96.0%)	97/100 (97.0%)
Month 12	1069/1167 (91.6%)	63/74 (85.1%)	51/61 (83.6%)	65/68 (95.6%)	42/47 (89.4%)	133/144 (92.4%)	96/98 (98.0%)
Month 18	786/938 (83.8%)	53/72 (73.6%)	1/13 (7.7%)	1/5 (20.0%)	7/15 (46.7%)	120/139 (86.3%)	91/98 (92.9%)
Month 24	694/920 (75.4%)	1/72 (1.4%)	0/12 (0.0%)	0/5 (0.0%)	0/8 (0.0%)	115/137 (83.9%)	85/96 (88.5%)
Month 30	651/878 (74.1%)	1/59 (1.7%)	0/9 (0.0%)	0/4 (0.0%)	0/7 (0.0%)	100/126 (79.4%)	75/96 (78.1%)
Month 36	267/383 (69.7%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	0/0 (–%)	9/31 (29.0%)	40/51 (78.4%)

[1] Retention is the proportion of participants who remain in follow–up at least as long as the nominal visit time (every 6 months) since they joined the OLE. Participants are expected at month 6 (or 12, 18... etc) if they have been enrolled in study at least 9 (or 15, 21... etc) months respectively, i.e. three months longer than the retention period. Participants are counted as retained if they completed any type of visit at or beyond the nominal visit time.

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Table 8Cii – Retention by Site: Latin America [1]

	Rio de Janeiro	Porto Alegre	Lima – Via Libre	Sao Paulo – DST–AIDS	Sao Paulo – IC–HCFMUSP
Total participants enrolled	192	164	92	116	135
Month 6	185/189 (97.9%)	154/163 (94.5%)	84/91 (92.3%)	110/115 (95.7%)	125/130 (96.2%)
Month 12	177/188 (94.1%)	147/162 (90.7%)	79/90 (87.8%)	99/106 (93.4%)	117/129 (90.7%)
Month 18	168/188 (89.4%)	137/161 (85.1%)	2/15 (13.3%)	94/104 (90.4%)	112/128 (87.5%)
Month 24	162/187 (86.6%)	133/160 (83.1%)	2/15 (13.3%)	89/102 (87.3%)	107/126 (84.9%)
Month 30	158/187 (84.5%)	126/159 (79.2%)	2/8 (25.0%)	87/101 (86.1%)	102/122 (83.6%)
Month 36	141/166 (84.9%)	47/74 (63.5%)	0/0 (–%)	23/36 (63.9%)	7/25 (28.0%)

[1] Retention is the proportion of participants who remain in follow–up at least as long as the nominal visit time (every 6 months) since they joined the OLE. Participants are expected at month 6 (or 12, 18... etc) if they have been enrolled in study at least 9 (or 15, 21... etc) months respectively, i.e. three months longer than the retention period. Participants are counted as retained if they completed any type of visit at or beyond the nominal visit time.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_ret_bysite.sas, SAS Version 9.4 (04MAR2026,6:09)

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Table 8Ciii – Retention by Site: Asia [1]

	Overall	Chiang Mai	Bangkok – Silom Clinic	Bangkok – Thai Red Cross	Hanoi
Total participants enrolled	528	90	150	145	143
Month 6	490/512 (95.7%)	82/85 (96.5%)	145/150 (96.7%)	136/141 (96.5%)	127/136 (93.4%)
Month 12	470/506 (92.9%)	80/84 (95.2%)	136/147 (92.5%)	130/140 (92.9%)	124/135 (91.9%)
Month 18	345/505 (68.3%)	80/84 (95.2%)	22/147 (15.0%)	125/139 (89.9%)	118/135 (87.4%)
Month 24	311/497 (62.6%)	73/78 (93.6%)	2/147 (1.4%)	121/139 (87.1%)	115/133 (86.5%)
Month 30	195/397 (49.1%)	0/4 (0.0%)	2/147 (1.4%)	84/113 (74.3%)	109/133 (82.0%)
Month 36	80/202 (39.6%)	0/4 (0.0%)	0/82 (0.0%)	14/32 (43.8%)	66/84 (78.6%)

[1] Retention is the proportion of participants who remain in follow–up at least as long as the nominal visit time (every 6 months) since they joined the OLE. Participants are expected at month 6 (or 12, 18... etc) if they have been enrolled in study at least 9 (or 15, 21... etc) months respectively, i.e. three months longer than the retention period. Participants are counted as retained if they completed any type of visit at or beyond the nominal visit time.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_ret_bysite.sas, SAS Version 9.4 (04MAR2026,6:09)

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Table 8Civ – Retention by Site: Africa [1]

	Overall	Cape Town
Total participants enrolled	87	87
Month 6	74/84 (88.1%)	74/84 (88.1%)
Month 12	69/82 (84.1%)	69/82 (84.1%)
Month 18	64/82 (78.0%)	64/82 (78.0%)
Month 24	62/82 (75.6%)	62/82 (75.6%)
Month 30	51/71 (71.8%)	51/71 (71.8%)
Month 36	6/25 (24.0%)	6/25 (24.0%)

[1] Retention is the proportion of participants who remain in follow–up at least as long as the nominal visit time (every 6 months) since they joined the OLE. Participants are expected at month 6 (or 12, 18... etc) if they have been enrolled in study at least 9 (or 15, 21... etc) months respectively, i.e. three months longer than the retention period. Participants are counted as retained if they completed any type of visit at or beyond the nominal visit time.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_ret_bysite.sas, SAS Version 9.4 (04MAR2026,6:09)

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Table 9 – Permanent Discontinuation of OLE Study Product by Regimen Choice

	Overall	TDF/FTC	Cabotegravir
Total Participants Enrolled in the OLE	2658	107	2495
Participants Permanently Discontinued from Study Product during the OLE (all steps combined) [1, 2]	243/2658 (9.14%)	35/107 (32.72%)	208/2495 (8.34%)
One or more reactive HIV test results or acute HIV infection suspected	40/243 (16.46%)	0/35 (0.00%)	40/208 (19.24%)
Reported use of prohibited concomitant medication	4/243 (1.64%)	0/35 (0.00%)	4/208 (1.92%)
Participant is currently using or planning to use PrEP or PEP	9/243 (3.70%)	1/35 (2.86%)	8/208 (3.84%)
Low oral adherence	1/243 (0.42%)	0/35 (0.00%)	1/208 (0.48%)
Clinical AE (protocol mandated)	15/243 (6.18%)	0/35 (0.00%)	15/208 (7.22%)
Laboratory AE (protocol mandated)	22/243 (9.06%)	1/35 (2.86%)	21/208 (10.10%)
Injection site reaction	4/243 (1.64%)	1/35 (2.86%)	3/208 (1.44%)
CMC recommendation based on a clinical event	2/243 (0.82%)	0/35 (0.00%)	2/208 (0.96%)
CMC recommendation based on a laboratory value	6/243 (2.46%)	0/35 (0.00%)	6/208 (2.88%)
CMC recommendation based on a psychosocial concern	0/243 (0.00%)	0/35 (0.00%)	0/208 (0.00%)
Other clinical reason	16/243 (6.58%)	0/35 (0.00%)	16/208 (7.70%)
Participant request for injection intolerance (AE or ISR not protocol mandated)	25/243 (10.28%)	0/35 (0.00%)	25/208 (12.02%)
Participant request – participant is unwilling or unable to comply with required study procedures	37/243 (15.22%)	1/35 (2.86%)	36/208 (17.30%)
Other participant request	62/243 (25.52%)	31/35 (88.58%)	31/208 (14.90%)
Participants Permanently Discontinued from TDF/FTC during Step 5	52/2658 (1.96%)	33/107 (30.84%)	19/2495 (0.76%)
One or more reactive HIV test results or acute HIV infection suspected	1/52 (1.92%)	0/33 (0.00%)	1/19 (5.26%)
Reported use of prohibited concomitant medication	0/52 (0.00%)	0/33 (0.00%)	0/19 (0.00%)
Participant is currently using or planning to use PrEP or PEP	1/52 (1.92%)	1/33 (3.04%)	0/19 (0.00%)
Low oral adherence	0/52 (0.00%)	0/33 (0.00%)	0/19 (0.00%)
Clinical AE (protocol mandated)	0/52 (0.00%)	0/33 (0.00%)	0/19 (0.00%)
Laboratory AE (protocol mandated)	1/52 (1.92%)	0/33 (0.00%)	1/19 (5.26%)
Injection site reaction	0/52 (0.00%)	0/33 (0.00%)	0/19 (0.00%)
CMC recommendation based on a clinical event	0/52 (0.00%)	0/33 (0.00%)	0/19 (0.00%)
CMC recommendation based on a laboratory value	2/52 (3.84%)	0/33 (0.00%)	2/19 (10.52%)
CMC recommendation based on a psychosocial concern	0/52 (0.00%)	0/33 (0.00%)	0/19 (0.00%)
Other clinical reason	10/52 (19.24%)	0/33 (0.00%)	10/19 (52.64%)
Participant request for injection intolerance (AE or ISR not protocol mandated)	0/52 (0.00%)	0/33 (0.00%)	0/19 (0.00%)
Participant request – participant is unwilling or unable to comply with required study procedures	2/52 (3.84%)	1/33 (3.04%)	1/19 (5.26%)
Other participant request	35/52 (67.30%)	31/33 (93.94%)	4/19 (21.06%)
Participants Permanently Discontinued from Oral CAB during Step 4a	10/2658 (0.38%)	0/107 (0.00%)	10/2495 (0.40%)
One or more reactive HIV test results or acute HIV infection suspected	3/10 (30.00%)	0/0 (–%)	3/10 (30.00%)
Reported use of prohibited concomitant medication	0/10 (0.00%)	0/0 (–%)	0/10 (0.00%)
Participant is currently using or planning to use PrEP or PEP	0/10 (0.00%)	0/0 (–%)	0/10 (0.00%)

[1] Excludes participants who are missing information about initial OLE regimen choice or who entered the OLE in the seroconverter follow–up schedule and hence were not taking study PrEP products.
[2] Participants who completed Step 3 (Open label TDF/FTC) during the OLE did not have the option to select CAB are not included in this table (n=36).

Source: SCHARP (Rajee) – /trials/hptn/p083/analysis/live/code/ole/t_ole_pdisc_byregm.sas, SAS Version 9.4 (04MAR2026,6:09)

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	Overall	TDF/FTC	Cabotegravir
Low oral adherence	0/10 (0.00%)	0/0 (–%)	0/10 (0.00%)
Clinical AE (protocol mandated)	1/10 (10.00%)	0/0 (–%)	1/10 (10.00%)
Laboratory AE (protocol mandated)	2/10 (20.00%)	0/0 (–%)	2/10 (20.00%)
Injection site reaction	0/10 (0.00%)	0/0 (–%)	0/10 (0.00%)
CMC recommendation based on a clinical event	0/10 (0.00%)	0/0 (–%)	0/10 (0.00%)
CMC recommendation based on a laboratory value	0/10 (0.00%)	0/0 (–%)	0/10 (0.00%)
CMC recommendation based on a psychosocial concern	0/10 (0.00%)	0/0 (–%)	0/10 (0.00%)
Other clinical reason	1/10 (10.00%)	0/0 (–%)	1/10 (10.00%)
Participant request for injection intolerance (AE or ISR not protocol mandated)	0/10 (0.00%)	0/0 (–%)	0/10 (0.00%)
Participant request – participant is unwilling or unable to comply with required study procedures	2/10 (20.00%)	0/0 (–%)	2/10 (20.00%)
Other participant request	1/10 (10.00%)	0/0 (–%)	1/10 (10.00%)
Participants Permanently Discontinued from CAB–LA injection during Step 4b	26/2658 (0.98%)	0/107 (0.00%)	26/2495 (1.04%)
One or more reactive HIV test results or acute HIV infection suspected	17/26 (65.38%)	0/0 (–%)	17/26 (65.38%)
Reported use of prohibited concomitant medication	0/26 (0.00%)	0/0 (–%)	0/26 (0.00%)
Participant is currently using or planning to use PrEP or PEP	0/26 (0.00%)	0/0 (–%)	0/26 (0.00%)
Low oral adherence	0/26 (0.00%)	0/0 (–%)	0/26 (0.00%)
Clinical AE (protocol mandated)	0/26 (0.00%)	0/0 (–%)	0/26 (0.00%)
Laboratory AE (protocol mandated)	3/26 (11.54%)	0/0 (–%)	3/26 (11.54%)
Injection site reaction	0/26 (0.00%)	0/0 (–%)	0/26 (0.00%)
CMC recommendation based on a clinical event	1/26 (3.84%)	0/0 (–%)	1/26 (3.84%)
CMC recommendation based on a laboratory value	2/26 (7.70%)	0/0 (–%)	2/26 (7.70%)
CMC recommendation based on a psychosocial concern	0/26 (0.00%)	0/0 (–%)	0/26 (0.00%)
Other clinical reason	1/26 (3.84%)	0/0 (–%)	1/26 (3.84%)
Participant request for injection intolerance (AE or ISR not protocol mandated)	2/26 (7.70%)	0/0 (–%)	2/26 (7.70%)
Participant request – participant is unwilling or unable to comply with required study procedures	0/26 (0.00%)	0/0 (–%)	0/26 (0.00%)
Other participant request	0/26 (0.00%)	0/0 (–%)	0/26 (0.00%)
Participants Permanently Discontinued from CAB–LA injection during Step 4c	102/2658 (3.84%)	2/107 (1.86%)	100/2495 (4.00%)
One or more reactive HIV test results or acute HIV infection suspected	11/102 (10.78%)	0/2 (0.00%)	11/100 (11.00%)
Reported use of prohibited concomitant medication	1/102 (0.98%)	0/2 (0.00%)	1/100 (1.00%)
Participant is currently using or planning to use PrEP or PEP	3/102 (2.94%)	0/2 (0.00%)	3/100 (3.00%)
Low oral adherence	1/102 (0.98%)	0/2 (0.00%)	1/100 (1.00%)
Clinical AE (protocol mandated)	8/102 (7.84%)	0/2 (0.00%)	8/100 (8.00%)
Laboratory AE (protocol mandated)	11/102 (10.78%)	1/2 (50.00%)	10/100 (10.00%)
Injection site reaction	3/102 (2.94%)	1/2 (50.00%)	2/100 (2.00%)
CMC recommendation based on a clinical event	1/102 (0.98%)	0/2 (0.00%)	1/100 (1.00%)
CMC recommendation based on a laboratory value	1/102 (0.98%)	0/2 (0.00%)	1/100 (1.00%)

[1] Excludes participants who are missing information about initial OLE regimen choice or who entered the OLE in the seroconverter follow–up schedule and hence were not taking study PrEP products.
[2] Participants who completed Step 3 (Open label TDF/FTC) during the OLE did not have the option to select CAB are not included in this table (n=36).

Source: SCHARP (Rajee) – /trials/hptn/p083/analysis/live/code/ole/t_ole_pdisc_byregm.sas, SAS Version 9.4 (04MAR2026,6:09)

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	Overall	TDF/FTC	Cabotegravir
CMC recommendation based on a psychosocial concern	0/102 (0.00%)	0/2 (0.00%)	0/100 (0.00%)
Other clinical reason	2/102 (1.96%)	0/2 (0.00%)	2/100 (2.00%)
Participant request for injection intolerance (AE or ISR not protocol mandated)	23/102 (22.54%)	0/2 (0.00%)	23/100 (23.00%)
Participant request – participant is unwilling or unable to comply with required study procedures	21/102 (20.58%)	0/2 (0.00%)	21/100 (21.00%)
Other participant request	16/102 (15.68%)	0/2 (0.00%)	16/100 (16.00%)
Participants Permanently Discontinued from CAB–LA injection during Step 6	26/2658 (0.98%)	0/107 (0.00%)	26/2495 (1.04%)
One or more reactive HIV test results or acute HIV infection suspected	2/26 (7.70%)	0/0 (–%)	2/26 (7.70%)
Reported use of prohibited concomitant medication	3/26 (11.54%)	0/0 (–%)	3/26 (11.54%)
Participant is currently using or planning to use PrEP or PEP	5/26 (19.24%)	0/0 (–%)	5/26 (19.24%)
Low oral adherence	0/26 (0.00%)	0/0 (–%)	0/26 (0.00%)
Clinical AE (protocol mandated)	4/26 (15.38%)	0/0 (–%)	4/26 (15.38%)
Laboratory AE (protocol mandated)	3/26 (11.54%)	0/0 (–%)	3/26 (11.54%)
Injection site reaction	1/26 (3.84%)	0/0 (–%)	1/26 (3.84%)
CMC recommendation based on a clinical event	0/26 (0.00%)	0/0 (–%)	0/26 (0.00%)
CMC recommendation based on a laboratory value	0/26 (0.00%)	0/0 (–%)	0/26 (0.00%)
CMC recommendation based on a psychosocial concern	0/26 (0.00%)	0/0 (–%)	0/26 (0.00%)
Other clinical reason	2/26 (7.70%)	0/0 (–%)	2/26 (7.70%)
Participant request for injection intolerance (AE or ISR not protocol mandated)	0/26 (0.00%)	0/0 (–%)	0/26 (0.00%)
Participant request – participant is unwilling or unable to comply with required study procedures	5/26 (19.24%)	0/0 (–%)	5/26 (19.24%)
Other participant request	1/26 (3.84%)	0/0 (–%)	1/26 (3.84%)
Participants Permanently Discontinued from CAB–LA injection during Step 7	27/2658 (1.02%)	0/107 (0.00%)	27/2495 (1.08%)
One or more reactive HIV test results or acute HIV infection suspected	6/27 (22.22%)	0/0 (–%)	6/27 (22.22%)
Reported use of prohibited concomitant medication	0/27 (0.00%)	0/0 (–%)	0/27 (0.00%)
Participant is currently using or planning to use PrEP or PEP	0/27 (0.00%)	0/0 (–%)	0/27 (0.00%)
Low oral adherence	0/27 (0.00%)	0/0 (–%)	0/27 (0.00%)
Clinical AE (protocol mandated)	2/27 (7.40%)	0/0 (–%)	2/27 (7.40%)
Laboratory AE (protocol mandated)	2/27 (7.40%)	0/0 (–%)	2/27 (7.40%)
Injection site reaction	0/27 (0.00%)	0/0 (–%)	0/27 (0.00%)
CMC recommendation based on a clinical event	0/27 (0.00%)	0/0 (–%)	0/27 (0.00%)
CMC recommendation based on a laboratory value	1/27 (3.70%)	0/0 (–%)	1/27 (3.70%)
CMC recommendation based on a psychosocial concern	0/27 (0.00%)	0/0 (–%)	0/27 (0.00%)
Other clinical reason	0/27 (0.00%)	0/0 (–%)	0/27 (0.00%)
Participant request for injection intolerance (AE or ISR not protocol mandated)	0/27 (0.00%)	0/0 (–%)	0/27 (0.00%)
Participant request – participant is unwilling or unable to comply with required study procedures	7/27 (25.92%)	0/0 (–%)	7/27 (25.92%)
Other participant request	9/27 (33.34%)	0/0 (–%)	9/27 (33.34%)

[1] Excludes participants who are missing information about initial OLE regimen choice or who entered the OLE in the seroconverter follow–up schedule and hence were not taking study PrEP products.
[2] Participants who completed Step 3 (Open label TDF/FTC) during the OLE did not have the option to select CAB are not included in this table (n=36).

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Listing 4 – Listing of 'Other' Reasons for Permanent Study Product Discontinuation in the OLE [1, 2]

# [3]	Participant ID	Initial OLE Regimen Choice	Region	Site	Study Product Permanently Discontinued (CAB or TDF/FTC)	Permanent Discontinuation Date	Permanent Discontinuation Visit	Reason for Permanent Discontinuation	Other Reasons
1	712235582	TDF/FTC	US	New York – Weill Cornell Chelsea	TDF/FTC	16SEP2021:00:00:00.000	V102.0 – Step 5 – Week 12	Other participant request	participant requested to move on to step 4
2	712360182	TDF/FTC	US	New York – Weill Cornell Chelsea	TDF/FTC	22FEB2022:00:00:00.000	V103.0 – Step 5 – Week 24	Other participant request	Want to avoid potential side effects to Truvada
3	712841676	TDF/FTC	US	New York – Weill Cornell Chelsea	TDF/FTC	07SEP2021:00:00:00.000	V102.0 – Step 5 – Week 12	Other participant request	participant interested in cab injections
4	721792122	TDF/FTC	Latin America	Rio de Janeiro	TDF/FTC	18APR2022:00:00:00.000	V104.0 – Step 5 – Week 36	Other participant request	Participant request. Moving to a new step.
5	722451434	TDF/FTC	Latin America	Porto Alegre	TDF/FTC	12JAN2022:00:00:00.000	V101.0 – Step 5 – Day 0	Other participant request	Participant temporarily used TRUVADA while awaiting visit date to start CABOTEGRAVIR.
6	722519276	TDF/FTC	Latin America	Porto Alegre	TDF/FTC	19JAN2022:00:00:00.000	V101.0 – Step 5 – Day 0	Other participant request	Participant requests to start using CABOTEGRAVIR
7	734456740	TDF/FTC	US	Bronx	TDF/FTC	04OCT2021:00:00:00.000	V102.0 – Step 5 – Week 12	Other participant request	Participant wanted to switch to CAB
8	734876129	TDF/FTC	US	Bronx	TDF/FTC	13JAN2022:00:00:00.000	V103.0 – Step 5 – Week 24	Other participant request	ppt request to switch to CAB injections
9	801648228	TDF/FTC	US	Washington, DC	TDF/FTC	17NOV2021:00:00:00.000	V103.0 – Step 5 – Week 24	Other participant request	Participant wanted to switch to CAB
10	820414268	TDF/FTC	US	Newark	TDF/FTC	09JUL2021:00:00:00.000	V102.0 – Step 5 – Week 12	Other participant request	Wanted to try CAB. Felt more comfortable after giving it some thought.
11	825141428	TDF/FTC	US	New York – Blood Center	TDF/FTC	29NOV2021:00:00:00.000	V103.0 – Step 5 – Week 24	Other participant request	Participant would like to switch to Cabotegravir
12	825182853	TDF/FTC	US	New York – Blood Center	TDF/FTC	14OCT2021:00:00:00.000	Interim Visit 102.1	Other participant request	Participant decided to move to oral Cab
13	845513246	TDF/FTC	Latin America	Sao Paulo – DST–AIDS	TDF/FTC	07JUL2022:00:00:00.000	V105.0 – Step 5 – Week 48	Other participant request	participant is moving to a new step (Step 4a)
14	845631679	TDF/FTC	Latin America	Sao Paulo – DST–AIDS	TDF/FTC	23AUG2022:00:00:00.000	V105.0 – Step 5 – Week 48	Other participant request	due to work routine
15	845702543	TDF/FTC	Latin America	Sao Paulo – DST–AIDS	TDF/FTC	28APR2022:00:00:00.000	V103.0 – Step 5 – Week 24	Other participant request	participant switched regimens
16	845743536	TDF/FTC	Latin America	Sao Paulo – DST–AIDS	TDF/FTC	30JUN2022:00:00:00.000	V105.0 – Step 5 – Week 48	Other participant request	Participant wanted to evaluate his adaptation with new way of PreP

[1] Excludes participants who are missing information about initial OLE regimen choice or who entered the OLE in the seroconverter follow–up schedule and hence were not taking study PrEP products.
[2] Participants who completed Step 3 (Open label TDF/FTC) during the OLE did not have the option to select CAB are not included in this table (n=36).
[3] This listing is sorted by Step, OLE regimen choice, discontinuation reason and PTID.

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Listing 4 – Listing of 'Other' Reasons for Permanent Study Product Discontinuation in the OLE [1, 2]

# [3]	Participant ID	Initial OLE Regimen Choice	Region	Site	Study Product Permanently Discontinued (CAB or TDF/FTC)	Permanent Discontinuation Date	Permanent Discontinuation Visit	Reason for Permanent Discontinuation	Other Reasons
17	845745885	TDF/FTC	Latin America	Sao Paulo – DST–AIDS	TDF/FTC	13JUN2022:00:00:00.000	V104.0 – Step 5 – Week 36	Other participant request	Participant would like to evaluate his adaptation to the investigational injectable product.
18	845791578	TDF/FTC	Latin America	Sao Paulo – DST–AIDS	TDF/FTC	08JUL2022:00:00:00.000	V105.0 – Step 5 – Week 48	Other participant request	participant chose to switch regimen
19	845822508	TDF/FTC	Latin America	Sao Paulo – DST–AIDS	TDF/FTC	05MAY2022:00:00:00.000	V103.0 – Step 5 – Week 24	Other participant request	participant wants to try injectable study drug
20	850193645	TDF/FTC	Latin America	Buenos Aires – Fundacion Huesped	TDF/FTC	20OCT2022:00:00:00.000	Interim Visit 105.1	Other participant request	Participant decided to stop taking the medication due abdominal pain
21	850682504	TDF/FTC	Latin America	Buenos Aires – Fundacion Huesped	TDF/FTC	12MAY2022:00:00:00.000	V103.0 – Step 5 – Week 24	Other participant request	Volunteer requests to continue CAB because they are not consistently compliant with TDF/FCT intake and do not feel protected.
22	850893633	TDF/FTC	Latin America	Buenos Aires – Fundacion Huesped	TDF/FTC	23NOV2021:00:00:00.000	V101.0 – Step 5 – Day 0	Other participant request	Participant regrets having chosen STEP 5 refers not to want to take more pills.
23	852285887	TDF/FTC	Latin America	Buenos Aires – Hospital JM Ramos Mejia	TDF/FTC	14FEB2022:00:00:00.000	V102.0 – Step 5 – Week 12	Other participant request	The participant was moved to a new step
24	852304154	TDF/FTC	Latin America	Buenos Aires – Hospital JM Ramos Mejia	TDF/FTC	21APR2022:00:00:00.000	V103.0 – Step 5 – Week 24	Other participant request	the participant is moving to another country and will not be continuing with the study
25	852546200	TDF/FTC	Latin America	Buenos Aires – Hospital JM Ramos Mejia	TDF/FTC	17AUG2022:00:00:00.000	V103.0 – Step 5 – Week 24	Other participant request	The participant chose to move to a new step
26	852687374	TDF/FTC	Latin America	Buenos Aires – Hospital JM Ramos Mejia	TDF/FTC	12APR2022:00:00:00.000	V103.0 – Step 5 – Week 24	Other participant request	The participant chose to move to a new step
27	852957824	TDF/FTC	Latin America	Buenos Aires – Hospital JM Ramos Mejia	TDF/FTC	30JUN2022:00:00:00.000	V104.0 – Step 5 – Week 36	Other participant request	Participant decided to move to other step
28	858269803	TDF/FTC	Asia	Bangkok – Thai Red Cross	TDF/FTC	13DEC2021:00:00:00.000	V102.0 – Step 5 – Week 12	Other participant request	Change regimen

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[2] Participants who completed Step 3 (Open label TDF/FTC) during the OLE did not have the option to select CAB are not included in this table (n=36).
[3] This listing is sorted by Step, OLE regimen choice, discontinuation reason and PTID.

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OLE Open Report – March 4, 2026
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Listing 4 – Listing of 'Other' Reasons for Permanent Study Product Discontinuation in the OLE [1, 2]

# [3]	Participant ID	Initial OLE Regimen Choice	Region	Site	Study Product Permanently Discontinued (CAB or TDF/FTC)	Permanent Discontinuation Date	Permanent Discontinuation Visit	Reason for Permanent Discontinuation	Other Reasons
29	862131096	TDF/FTC	Asia	Hanoi	TDF/FTC	11FEB2022:00:00:00.000	V103.0 – Step 5 – Week 24	Other participant request	Participant decided to change his regimen into Cab
30	862291239	TDF/FTC	Asia	Hanoi	TDF/FTC	11JAN2022:00:00:00.000	V102.0 – Step 5 – Week 12	Other participant request	Participant decided to change his regimen into Cab
31	862550286	TDF/FTC	Asia	Hanoi	TDF/FTC	05JAN2022:00:00:00.000	V102.0 – Step 5 – Week 12	Other participant request	Participant decided to change his regimen into Cab
32	787368680	Cabotegravir	US	Decatur	TDF/FTC	23JUN2022:00:00:00.000	V101.0 – Step 5 – Day 0	Other clinical reason	switch back to CABLA
33	787489949	Cabotegravir	US	Decatur	TDF/FTC	28JUN2022:00:00:00.000	V101.0 – Step 5 – Day 0	Other clinical reason	switched back to CABLA
34	787738775	Cabotegravir	US	Decatur	TDF/FTC	28JUN2022:00:00:00.000	V101.0 – Step 5 – Day 0	Other clinical reason	Switched back to CAB LA on step 6
35	787794626	Cabotegravir	US	Decatur	TDF/FTC	14JUL2022:00:00:00.000	V101.0 – Step 5 – Day 0	Other clinical reason	Switched back to CAB LA
36	787887821	Cabotegravir	US	Decatur	TDF/FTC	24JUN2022:00:00:00.000	V101.0 – Step 5 – Day 0	Other clinical reason	moved to step 6 on open label CAB
37	787894920	Cabotegravir	US	Decatur	TDF/FTC	12JUL2022:00:00:00.000	V101.0 – Step 5 – Day 0	Other clinical reason	Switching back to CAB LA
38	787914125	Cabotegravir	US	Decatur	TDF/FTC	06JUL2022:00:00:00.000	V101.0 – Step 5 – Day 0	Other clinical reason	Switched back to CAB LA
39	844663509	Cabotegravir	US	Chicago – AYAR	TDF/FTC	09JUN2022:00:00:00.000	V101.0 – Step 5 – Day 0	Other clinical reason	Subject resumed CABLA in Step 6
40	857828344	Cabotegravir	US	Memphis	TDF/FTC	24JUN2022:00:00:00.000	V101.0 – Step 5 – Day 0	Other clinical reason	V5.0 of the protocol was approved and the participant moved to CAB–LA.
41	863238875	Cabotegravir	US	Philadelphia	TDF/FTC	01SEP2022:00:00:00.000	V101.0 – Step 5 – Day 0	Other clinical reason	Switch to V5 protocol
42	787992640	Cabotegravir	US	Decatur	TDF/FTC	21JUN2022:00:00:00.000	V101.0 – Step 5 – Day 0	Other participant request	Switched to step 6
43	850781300	Cabotegravir	Latin America	Buenos Aires – Fundacion Huesped	TDF/FTC	12MAY2023:00:00:00.000	V104.0 – Step 5 – Week 36	Other participant request	Decreased risk, has a stable partner.
44	852182663	Cabotegravir	Latin America	Buenos Aires – Hospital JM Ramos Mejia	TDF/FTC	17AUG2022:00:00:00.000	V103.0 – Step 5 – Week 24	Other participant request	Participant wants to resume CAB–LA injection
45	860170861	Cabotegravir	Latin America	Sao Paulo – IC–HCFMUSP	TDF/FTC	18NOV2022:00:00:00.000	Interim Visit 102.1	Other participant request	Ppt finished chemo and now wishes to resume his CAB injections
46	825940787	Cabotegravir	US	New York – Blood Center	Oral CAB	24MAY2021:00:00:00.000	V61.0 – Step 4a – Day 0	Other clinical reason	Subject reported a history of seizures

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[2] Participants who completed Step 3 (Open label TDF/FTC) during the OLE did not have the option to select CAB are not included in this table (n=36).
[3] This listing is sorted by Step, OLE regimen choice, discontinuation reason and PTID.

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# [3]	Participant ID	Initial OLE Regimen Choice	Region	Site	Study Product Permanently Discontinued (CAB or TDF/FTC)	Permanent Discontinuation Date	Permanent Discontinuation Visit	Reason for Permanent Discontinuation	Other Reasons
47	800299428	Cabotegravir	US	Los Angeles – UCLA Vine	Oral CAB	16AUG2021:00:00:00.000	V62.0 – Step 4a – Week 4	Other participant request	Participant decision to discontinue IP
48	845866569	Cabotegravir	Latin America	Sao Paulo – DST–AIDS	CAB–LA injection	15SEP2021:00:00:00.000	V63.0 – Step 4b – Day 0	Other clinical reason	potential interaction of cabotegravir with the volunteer's medical history
49	722984334	Cabotegravir	Latin America	Porto Alegre	CAB–LA injection	03SEP2021:00:00:00.000	V64.0 – Step 4c – Day 0	Other clinical reason	Participant with liposuction and fat graft in buttocks.
50	860548404	Cabotegravir	Latin America	Sao Paulo – IC–HCFMUSP	CAB–LA injection	11FEB2022:00:00:00.000	Interim Visit 64.1	Other clinical reason	Stroke
51	706699693	Cabotegravir	US	Chapel Hill	CAB–LA injection	13JUN2022:00:00:00.000	V68.0 – Step 4c – Week 32	Other participant request	participant elected to discontinue dosing of CAB LA and move to Step 5 due to concern about his weight gain, is attributing it to Cabotegravir
52	801211968	Cabotegravir	US	Washington, DC	CAB–LA injection	14JUN2022:00:00:00.000	V69.0 – Step 4c – Week 40	Other participant request	Participant prefers TDF/FTC but wanted to finish Step 4 before switching to Step 5. Transitioned to Step 5 in consultation with protocol team.
53	816782848	Cabotegravir	Africa	Cape Town	CAB–LA injection	31AUG2022:00:00:00.000	V70.0 – Step 4c – Week 48	Other participant request	Participant relocated
54	819548441	Cabotegravir	US	Boston	CAB–LA injection	28FEB2022:00:00:00.000	V67.0 – Step 4c – Week 24	Other participant request	Participant decided to switch back to oral Truvada as attributed symptoms (AE#47) and discomfort (ISR #5 & #6)to Cabotegravir.
55	821883488	Cabotegravir	US	Birmingham	CAB–LA injection	27JUN2022:00:00:00.000	V67.0 – Step 4c – Week 24	Other participant request	Participant Request
56	825917775	Cabotegravir	US	New York – Blood Center	CAB–LA injection	07SEP2022:00:00:00.000	Interim Visit 69.1	Other participant request	PPT opted to move to Step 5
57	844914467	Cabotegravir	US	Chicago – AYAR	CAB–LA injection	17FEB2022:00:00:00.000	V67.0 – Step 4c – Week 24	Other participant request	Pt reported that he would no longer like to receive CAB injections.

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[3] This listing is sorted by Step, OLE regimen choice, discontinuation reason and PTID.

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# [3]	Participant ID	Initial OLE Regimen Choice	Region	Site	Study Product Permanently Discontinued (CAB or TDF/FTC)	Permanent Discontinuation Date	Permanent Discontinuation Visit	Reason for Permanent Discontinuation	Other Reasons
58	845126475	Cabotegravir	Latin America	Sao Paulo – DST–AIDS	CAB–LA injection	11OCT2022:00:00:00.000	V69.0 – Step 4c – Week 40	Other participant request	feels more adapted to the oral product
59	845415297	Cabotegravir	Latin America	Sao Paulo – DST–AIDS	CAB–LA injection	02MAY2022:00:00:00.000	V68.0 – Step 4c – Week 32	Other participant request	insomnia and change in sexual practices
60	846163532	Cabotegravir	US	Aurora	CAB–LA injection	12JUL2022:00:00:00.000	Interim Visit 70.1	Other participant request	No perceived HIV risk due to relationship status
61	850179449	Cabotegravir	Latin America	Buenos Aires – Fundacion Huesped	CAB–LA injection	14DEC2021:00:00:00.000	V64.0 – Step 4c – Day 0	Other participant request	Volunteer decides to switch to TDF/FTC due to pain associated with CAB injection.
62	850427445	Cabotegravir	Latin America	Buenos Aires – Fundacion Huesped	CAB–LA injection	11JAN2022:00:00:00.000	V66.0 – Step 4c – Week 16	Other participant request	The participant chose to continue with Cabotegravir and performed Step 4c until the week 8 visit, however, in November 2021 silicones were injected, so she was transferred to the TDF/FTC branch.
63	850460724	Cabotegravir	Latin America	Buenos Aires – Fundacion Huesped	CAB–LA injection	04JAN2022:00:00:00.000	Interim Visit 64.1	Other participant request	Since the participant was going on a trip on 14Jan2022, he preferred to switch to the TDF/FTC branch
64	850956455	Cabotegravir	Latin America	Buenos Aires – Fundacion Huesped	CAB–LA injection	21APR2022:00:00:00.000	V67.0 – Step 4c – Week 24	Other participant request	The participant returned to take TDF/FTC due to discomfort at the application site
65	852410443	Cabotegravir	Latin America	Buenos Aires – Hospital JM Ramos Mejia	CAB–LA injection	08FEB2022:00:00:00.000	V65.0 – Step 4c – Week 8	Other participant request	The participant chose to move to a new step
66	858989060	Cabotegravir	Asia	Bangkok – Thai Red Cross	CAB–LA injection	26JUL2022:00:00:00.000	V69.0 – Step 4c – Week 40	Other participant request	Refused the injection and wanted to withdraw form the study
67	706354290	Cabotegravir	US	Chapel Hill	CAB–LA injection	15MAY2023:00:00:00.000	Interim Visit 72.1	Other clinical reason	Clinical AE, per IoR judgement
68	850509929	Cabotegravir	Latin America	Buenos Aires – Fundacion Huesped	CAB–LA injection	16MAR2023:00:00:00.000	Interim Visit 72.1	Other clinical reason	neurologist indicated to suspend CAB–LA injection for the moment
69	847881283	Cabotegravir	US	Cincinnati	CAB–LA injection	20DEC2022:00:00:00.000	V73.0 – Step 6 – Week 72	Other participant request	Started on Apretude though SOC

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[2] Participants who completed Step 3 (Open label TDF/FTC) during the OLE did not have the option to select CAB are not included in this table (n=36).
[3] This listing is sorted by Step, OLE regimen choice, discontinuation reason and PTID.

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# [3]	Participant ID	Initial OLE Regimen Choice	Region	Site	Study Product Permanently Discontinued (CAB or TDF/FTC)	Permanent Discontinuation Date	Permanent Discontinuation Visit	Reason for Permanent Discontinuation	Other Reasons
70	722756029	Cabotegravir	Latin America	Porto Alegre	CAB–LA injection	01JUL2024:00:00:00.000	V131.0 – Step 7 – Week 104	Other participant request	Participant withdrew from study
71	722861908	Cabotegravir	Latin America	Porto Alegre	CAB–LA injection	01JUL2024:00:00:00.000	V131.0 – Step 7 – Week 104	Other participant request	Participant withdrew from study
72	722991164	Cabotegravir	Latin America	Porto Alegre	CAB–LA injection	23FEB2024:00:00:00.000	V132.0 – Step 7 – Week 112	Other participant request	Participant is in a stable relationship and does not see himself as risking exposure to HIV
73	845324834	Cabotegravir	Latin America	Sao Paulo – DST–AIDS	CAB–LA injection	24OCT2024:00:00:00.000	V136.0 – Step 7 – Week 144	Other participant request	participant refused further participation
74	845382210	Cabotegravir	Latin America	Sao Paulo – DST–AIDS	CAB–LA injection	11OCT2024:00:00:00.000	V138.0 – Step 7 – Week 160	Other participant request	Participant no longer wants to receive PREP, for this reason he decides to leave the study.
75	845555635	Cabotegravir	Latin America	Sao Paulo – DST–AIDS	CAB–LA injection	09SEP2024:00:00:00.000	Interim Visit 137.1	Other participant request	participant changed country and is no longer able to continue in the study
76	845857033	Cabotegravir	Latin America	Sao Paulo – DST–AIDS	CAB–LA injection	05JUL2024:00:00:00.000	Interim Visit 135.1	Other participant request	participant moved to another country
77	845895953	Cabotegravir	Latin America	Sao Paulo – DST–AIDS	CAB–LA injection	08AUG2024:00:00:00.000	V137.0 – Step 7 – Week 152	Other participant request	participant decided to withdraw consent
78	845977825	Cabotegravir	Latin America	Sao Paulo – DST–AIDS	CAB–LA injection	04OCT2024:00:00:00.000	V136.0 – Step 7 – Week 144	Other participant request	participant decided to take oral medication for personal reasons

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[2] Participants who completed Step 3 (Open label TDF/FTC) during the OLE did not have the option to select CAB are not included in this table (n=36).
[3] This listing is sorted by Step, OLE regimen choice, discontinuation reason and PTID.

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Table 10 – Protocol Deviations by OLE Regimen Choice

	Overall	TDF/FTC	Cabotegravir
Number of Protocol Deviations and Enrollment Violations for OLE [1]	180	17	163
Inappropriate enrollment	0/180 (0.0%)	0/17 (0.0%)	0/163 (0.0%)
Failure to follow trial randomization or blinding procedures	0/180 (0.0%)	0/17 (0.0%)	0/163 (0.0%)
Study product management deviation	8/180 (4.4%)	1/17 (5.9%)	7/163 (4.3%)
Study product dispensing error	7/180 (3.9%)	3/17 (17.6%)	4/163 (2.5%)
Conduct of non–protocol procedure	10/180 (5.6%)	2/17 (11.8%)	8/163 (4.9%)
Breach of confidentiality	1/180 (0.6%)	0/17 (0.0%)	1/163 (0.6%)
Physical assessment deviation	0/180 (0.0%)	0/17 (0.0%)	0/163 (0.0%)
Lab assessment deviation	84/180 (46.7%)	8/17 (47.1%)	76/163 (46.6%)
Use of non–IRB/EC–approved materials	0/180 (0.0%)	0/17 (0.0%)	0/163 (0.0%)
Informed assent/consent process deviation	23/180 (12.8%)	0/17 (0.0%)	23/163 (14.1%)
Other	47/180 (26.1%)	3/17 (17.6%)	44/163 (27.0%)

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_deviation.sas, SAS Version 9.4 (04MAR2026,6:09)

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Listing 5 – Listing of Protocol Deviations [1]

# [2]	OLE Regimen Choice	Original Arm	Region	Participant ID	Site Awareness Date	Deviation Date	Reported to IRB/EC	Reported to DAIDS	Type of Deviation	Description of Deviation	Steps taken to address Deviation	Steps taken to prevent future occurrences of the Deviation
1	TDF/FTC	TDF/FTC	US	800155268	13JUL2021	16JUN2021	Yes	No	Study product management deviation	Participant was dispensed 3 bottles of oral Truvada at visit 101.1. Because this was participant's last visit, he should not have been given study product.	Plan to address the deviation will be to adhere to study protocol and procedures.	To prevent future occurrences will make sure all staff is properly trained and will follow up with CMC for any confusion regarding protocol.
2	TDF/FTC	TDF/FTC	Latin America	852495757	02JUN2022	13JAN2022	Yes	No	Study product dispensing error	the participant realized day 0 step 5 visit on january, 13 of 2022. That visit was previus day of 3 years aniversary of TRUVADA, and it was dispenced 3 bottles of TRUVADA by mistake. On April 7, 2022 the participant came to the site and return SP. The date of last oral study product was april 6, 2022	this desviation was registered in the medical chart. The participant had already finished his participation on the study and had return medication on april 7, 2022.	Staff is retrained on the importance of knowing the protocol and its steps. An internal meeting was held in which it was verified that the 3 year term begins at visit week 0, thus counting the calendar year. A review of the medical records of all the participants in this branch is also carried out to verify that they are within this period.
3	TDF/FTC	TDF/FTC	Latin America	852825902	20JAN2022	24NOV2021	Yes	No	Study product dispensing error	According to the protocol, the duration of the participants who have the assigned TRUVADA arm should not exceed 3 years. However, during the visit on November 24, 2021, medication was dispensed by mistake, when the study exit visit should have been made.	Upon detecting the error, several attempts were made to communicate with the patient, finally the study doctor was able to communicate and make an appointment to carry out the end of the study on 22Apr22.	Staff is retrained on the importance of knowing the protocol and its steps. An internal meeting was held in which it was verified that the 3 year term begins at visit week 0, thus counting the calendar year. A review of the medical records of all the participants in this branch is also carried out to verify that they are within this period.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

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Listing 5 – Listing of Protocol Deviations [1]

# [2]	OLE Regimen Choice	Original Arm	Region	Participant ID	Site Awareness Date	Deviation Date	Reported to IRB/EC	Reported to DAIDS	Type of Deviation	Description of Deviation	Steps taken to address Deviation	Steps taken to prevent future occurrences of the Deviation
4	TDF/FTC	TDF/FTC	Latin America	852884602	02JUN2022	24NOV2021	Yes	No	Study product dispensing error	acording to protocol the participant with TRUVADA arm shouldnt taken the SP for more than three consecutive years. But this participant return the bottles on the termination visit realized on april 20, 2022. On this visit the participant report the date of last oral study product was on april 19, 2022. But he should stop taking medication on april 10, 2022 (three years aniversary of TRUVADA).	this desviation was registered in the medical chart. The participant had already finished his participation on the study and had return medication on april 20, 2022.	Staff is retrained on the importance of knowing the protocol and its steps. An internal meeting was held in which it was verified that the 3 year term begins at visit week 0, thus counting the calendar year. A review of the medical records of all the participants in this branch is also carried out to verify that they are within this period.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

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Listing 5 – Listing of Protocol Deviations [1]

# [2]	OLE Regimen Choice	Original Arm	Region	Participant ID	Site Awareness Date	Deviation Date	Reported to IRB/EC	Reported to DAIDS	Type of Deviation	Description of Deviation	Steps taken to address Deviation	Steps taken to prevent future occurrences of the Deviation
5	TDF/FTC	Cabotegravir	US	780471823	14JUL2021	14JUL2021	Yes	No	Conduct of non–protocol procedure	Visit 101 was started in error and was stopped part–way thru when staff realized they had misread participant´s enrollment date. During the visit it was realized that the participant had already exceeded the 3 year cap of enrollment in the study and was not eligible for Step 5. Participant refused step 4 because he did not want to take CAB LA and terminated from the study. Before it was realized that participant was ineligible for step 5, participant signed ICF v3.0 for protocol v4.0, completed the CASI survey, SMSQ survey, elected to have an HIV rapid test, but refused all other blood work testing.	¯ A Prompt report to notify IRB. ¯ This protocol deviation form created and stapled to corresponding Visit form, in participant´s chart. ¯ eCRF protocol deviation form will be created for this event. ¯ Event will be reported to HPTN 083 PD Alias	Staff will be more careful to check eligibility of all incoming participants, prior to study entry to into new protocol.
6	TDF/FTC	TDF/FTC	Latin America	845483640	28MAR2022	28MAR2022	Yes	No	Conduct of non–protocol procedure	Participant performed visit 4a Day O on 18 Nov 2021 and he didn't complete the step 4a and he didn't receive his first injection within 8 weeks of starting Day 0 of Step 4a. Participant didn't rescheduled the 4a W4 visit despite the several contacts attempts performed by the site staff.	The participant was contacted by study staff several times on different communication platforms.	Not applicable

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Listing 5 – Listing of Protocol Deviations [1]

# [2]	OLE Regimen Choice	Original Arm	Region	Participant ID	Site Awareness Date	Deviation Date	Reported to IRB/EC	Reported to DAIDS	Type of Deviation	Description of Deviation	Steps taken to address Deviation	Steps taken to prevent future occurrences of the Deviation
7	TDF/FTC	TDF/FTC	US	825141428	09SEP2021	27APR2021	Yes	No	Lab assessment deviation	On 27 Apr 2021, an HIV rapid test was conducted for the subject during their PA4 screening visit. Plasma was not stored on this date. HIV testing was also done on request on 22 Jun 2021, 22 Jul 2021, and 06 Aug 2021. Plasma had not been stored during those visits as well.	Site staff have been made aware that plasma will be stored any time HIV testing is done.	Site staff have been made aware that plasma will be stored any time HIV testing is done.
8	TDF/FTC	TDF/FTC	US	825141428	05AUG2022	16JUN2022	Yes	No	Lab assessment deviation	HIV 4th generation antibody/antigen test result is unavailable for Visit 66 conducted on 16 Jun 2022, because of an identification discrepancy between the requisition and specimen per the Quest local lab. Site staff contacted Quest diagnostics in order to provide the specimen information; however, the test could not be conducted on Quest´s end.	The New York Blood Center IRB will be notified of this protocol event. Participant 825141428 will be rescheduled for HIV testing as an interim visit before their next injection visit.	Staff have been reminded to double check requisition orders and participant identification number in order to verify that the correct lab tests are ordered for the correct participant.
9	TDF/FTC	TDF/FTC	US	825141428	10AUG2022	09AUG2022	Yes	No	Lab assessment deviation	Subject was brought in for repeat HIV testing on 09 Aug 2022 because we were missing results for their HIV 4th generation test. During the visit, specimens were collected for HIV testing; however, plasma storage was not completed.	The New York Blood Center IRB will be notified of this protocol event. Relevant staff have been notified the event.	Trainings have been held before regarding the storage of specimen each time it is collected for HIV testing. Another training was held for relevant staff on 10 Aug 2022 and staff were reminded to ensure that plasma storage is conducted at each visit where HIV testing is done.

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10	TDF/FTC	TDF/FTC	Latin America	721185282	26OCT2021	10AUG2021	Yes	No	Lab assessment deviation	Urinalysis testing (Protein and glucose) and Rectal Swab GC/CT testing were not done at D0/Step 5 visit because them had been missed in the visit checklist.	D0/Step 5 visit checklist was updated to include Urinalysis testing (Protein and glucose) and Rectal Swab GC/CT testing. Those collections have been done during the next study visit. The LOC team was informed about the deviation on 26–oct–2021. On the same date all visit checklists were reviewed by the coordenation and the lab team and the IRB was informed on 27–oct–2021.	Coordenation and the lab team were re–trained on the study procedures.
11	TDF/FTC	TDF/FTC	Latin America	721693309	26OCT2021	31AUG2021	Yes	No	Lab assessment deviation	Urinalysis testing (Protein and glucose) and Rectal Swab GC/CT testing were not done at D0/Step 5 visit because them had been missed in the visit checklist.	D0/Step 5 visit checklist was updated to include Urinalysis testing (Protein and glucose) and Rectal Swab GC/CT testing. Those collections have been done during the next study visit. The LOC team was informed about the deviation on 26–oct–2021. On the same date all visit checklists were reviewed by the coordenation and the lab team and the IRB was informed on 27–oct–2021.	Coordenation and the lab team were re–trained on the study procedures.

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Listing 5 – Listing of Protocol Deviations [1]

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12	TDF/FTC	TDF/FTC	Latin America	721760147	26OCT2021	16AUG2021	Yes	No	Lab assessment deviation	Urinalysis testing (Protein and glucose) and Rectal Swab GC/CT testing were not done at D0/Step 5 visit because them had been missed in the visit checklist.	D0/Step 5 visit checklist was updated to include Urinalysis testing (Protein and glucose) and Rectal Swab GC/CT testing. Those collections have been done during the next study visit. The LOC team was informed about the deviation on 26–oct–2021. On the same date all visit checklists were reviewed by the coordenation and the lab team and the IRB was informed on 27–oct–2021.	Coordenation and the lab team were re–trained on the study procedures.
13	TDF/FTC	Cabotegravir	Latin America	721792122	26OCT2021	03AUG2021	Yes	No	Lab assessment deviation	Urinalysis testing (Protein and glucose) and Rectal Swab GC/CT testing were not done at D0/Step 5 visit because them had been missed in the visit checklist.	0/Step 5 visit checklist was updated to include Urinalysis testing (Protein and glucose) and Rectal Swab GC/CT testing. Those collections have been done during the next study visit. The LOC team was informed about the deviation on 26–oct–2021. On the same date all visit checklists were reviewed by the coordenation and the lab team and the IRB was informed on 27–oct–2021.	Coordenation and the lab team were re–trained on the study procedures.

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14	TDF/FTC	TDF/FTC	Latin America	721907736	26OCT2021	02AUG2021	Yes	No	Lab assessment deviation	Urinalysis testing (Protein and glucose) and Rectal Swab GC/CT testing were not done at D0/Step 5 visit because them had been missed in the visit checklist.	D0/Step 5 visit checklist was updated to include Urinalysis testing (Protein and glucose) and Rectal Swab GC/CT testing. Those collections have been done during the next study visit. The LOC team was informed about the deviation on 26–oct–2021. On the same date all visit checklists were reviewed by the coordenation and the lab team and the IRB was informed on 27–oct–2021.	Coordenation and the lab team were re–trained on the study procedures.
15	TDF/FTC	Cabotegravir	US	819665708	07SEP2021	07SEP2021	No	No	Other	Study product was dispensed at last visit. The participant completed v102.0 on 7–sep–21,this was also his end of the study visit as his 3 years post enrollment ended on 6–Nov–20 and the 1–year mark since the last CAB injection was 8–sep–21. Although the study product was dispensed within the 1–year mark we were told by CMC that the study product cannot be dispensed at participant's last visit.	Clarified with CMC. Study staff have been made aware of the procedure for those participants in step 5 of the OLE phase. Participant returned the study product on 22–sep–21	Clarified with CMC. Study staff have been made aware of the procedure for those participants in step 5 of the OLE phase. Participant returned the study product on 22–sep–21

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
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16	TDF/FTC	TDF/FTC	US	825182853	17MAY2021	21APR2021	Yes	No	Other	Step 5 day 0– CASI was not done.	Staff are instructed to review procedures outlined on the visit checklists. A overview of the protocol deviations found and a training of the steps and procedures under the new amendment was conducted at a staff meeting on 26 May 2021.	Staff will be required to complete all protocol amendment trainings and demonstrate knowledge of steps involved in the new amendment. Hands on training will continue to be given to staff members by site coordinator and PI.
17	TDF/FTC	TDF/FTC	Latin America	852884602	10MAY2022	20APR2022	Yes	No	Other	by mistake it was regisetred 70.7 kg as weigth in the source document of visit week 24 step 5, but the participant not decreased 10 kg.	The data of weight cannot be recovered. The desviation was documented on the source documents.	Nurce staff retrained of the importance of correct data documentation in the source document.

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18	Cabotegravir	Cabotegravir	US	706235209	21DEC2021	24AUG2021	Yes	No	Study product management deviation	St4a–day0, v61, 8/24/21 & St4a–wk4, v62, 9/16/21–––Pt assigned to active CAB injections during step 2. Last CAB IM on 11/19/19. Early 2020 we went into COVID lock down and the patient then received oral Truvada in step 3 for which he completed this therapy out to 48 weeks. We received approval to implement protocol version 4 on 7/12/21. The patient elected to continue to step 4 on August 24, 2021. Given his extended time off Cabotegravir, IOR decided to repeat his oral CAB lead–in (v61 and v62) for subject safety concerns. He then went on to re–start injections. We elected to do this out of an abundance of caution.	Continue to correctly follow protocol	Retrained staff – Clarified internally that this is not allowed.
19	Cabotegravir	Cabotegravir	US	734640164	16DEC2021	08JUN2021	Yes	No	Study product management deviation	Participant was originally randomized to cabotegravir so he was not elegible for Step 4A. He requested to enter version 4 of the protocol with Step 4A. He should have begun with step 4B	Review protocol	Review protocol and QC tool

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20	Cabotegravir	TDF/FTC	US	819548441	16JUL2021	16JUL2021	No	No	Study product management deviation	Participant was given study product in visit 62.0 without collecting blood samples (due to lack of venous access). The study product was given because the participant had misplaced the one bottle of unopened study product he had.	Participant was scheduled for an interim visit on 20–Jul–21 to perform the blood draw. Protocol deviation was documented and noted in visit note.	Not Applicable

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21	Cabotegravir	Cabotegravir	US	825727481	16DEC2021	20APR2021	Yes	No	Study product management deviation	Participant 825727481 was originally randomized to the cabotegravir arm. For Protocol Amendment 4, with offer of continuing on cabotegravir for those randomized originally to the cabotegravir arm, they were incorrectly started on Visit 61–Step 4a Day 0 (oral cabotegravir), based on participant preference for oral cabotegravir, on 20 April 2021 instead of going into Step 4b (loading phase of injectable cabotegravir).	The site has held several trainings to review HPTN 083 Amendment 4 before implementing and after implementing Amendment 4, including trainings led by the site PI and site coordinator and protocol–wide trainings by the HPTN 083 protocol team. Staff have been led through the different steps of Amendment 4 at multiple meetings, including which participants should be offered to go into oral cabotegravir Step 4a and which participants should be offered to go directly into Steps 4b and 4c. The IRB will be notified of this protocol event.	The site has held several trainings to review HPTN 083 Amendment 4 before implementing and after implementing Amendment 4, including trainings led by the site PI and site coordinator and protocol–wide trainings by the HPTN 083 protocol team. Staff have been led through the different steps of Amendment 4 at multiple meetings, including which participants should be offered to go into oral cabotegravir Step 4a and which participants should be offered to go directly into Steps 4b and 4c. Slides with diagrams of steps have been provided to staff to facilitate visualization of steps based on which arm the participants were originally randomized into and which arm the participants were in prior to consenting to Protocol Amendment 4.

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22	Cabotegravir	Cabotegravir	US	825917775	16DEC2021	29JUN2021	Yes	No	Study product management deviation	Participant 825917775 was originally randomized to the cabotegravir arm. For Protocol Amendment 4, with offer of continuing on cabotegravir for those randomized originally to the cabotegravir arm, they were incorrectly started on Visit 61–Step 4a Day 0 (oral cabotegravir) based on participant preference for oral cabotegravir, on 29 June 2021 instead of going into Step 4b (loading phase of injectable cabotegravir).	The site has held several trainings to review HPTN 083 Amendment 4 before implementing and after implementing Amendment 4, including trainings led by the site PI and site coordinator and protocol–wide trainings by the HPTN 083 protocol team. Staff have been led through the different steps of Amendment 4 at multiple meetings, including which participants should be offered to go into oral cabotegravir Step 4a and which participants should be offered to go directly into Steps 4b and 4c. The IRB will be notified of this protocol event.	The site has held several trainings to review HPTN 083 Amendment 4 before implementing and after implementing Amendment 4, including trainings led by the site PI and site coordinator and protocol–wide trainings by the HPTN 083 protocol team. Staff have been led through the different steps of Amendment 4 at multiple meetings, including which participants should be offered to go into oral cabotegravir Step 4a and which participants should be offered to go directly into Steps 4b and 4c. Slides with diagrams of steps have been provided to staff to facilitate visualization of steps based on which arm the participants were originally randomized into and which arm the participants were in prior to consenting to Protocol Amendment 4.

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23	Cabotegravir	TDF/FTC	Latin America	714995804	17AUG2023	03JUL2023	Yes	Yes	Study product management deviation	33 years old participant enrolled in HPTN083 study on 03MAY18. The participant entered to the OLE version on 23MAY23 and received his first dose of Cabotegravir LA. During his 64.0 visit (22JUN23) he did not reported any complication or concomitant medication. During his 64.1 visit he reported that he had been taking Pregabaline 75mg + Carbamazepine 200 mg from 03JUL23 until 10JUL23 as indicated by his neurologist due to Trigeminal neuralgia diagnosis. On 10JUL23 he went to his neurologist for a reevaluation and he physician changed the medication for Gabapentine 300mg + Carbamazepine 200 mg for one month. However, the participant reported that he had taken the medications until 24JUL23.	– The Sponsor was notified. – It is communicated to the Ethics Committee. – The INS will be notified.	– Clinical staff will continue to remind participants about prohibited medications.

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24	Cabotegravir	Cabotegravir	Latin America	850924523	16DEC2021	02SEP2021	Yes	No	Study product management deviation	The patient was enrolled on April 5, 2018. During step 2 the blind was opened according to protocol. Ppte. was randomized to CAB, so he completed step 2 with CAB LA until week 153. Then he was moved to step 3 with Truvada as per protocol until week 12. Under version 4.0 the patient chose CAB for the OLE, and he was moved to Step 4 A instead of step 4B . It was an interpretation error of the algorithm. So far we have not found another participant with this same situation We consider a deviation from the procedures required by the study.	Upon receiving the alert from the SHARP team , the internal QA team reviewed the medical history , confirmed that the procedures were not followed as per protocol , notified the sponsor and IRB as deviation. Other action taken the status of all the participants who did step 4A in relation to their assigned arm was checked, it was verified that there was no other error.	All the participants of our site have already made the transition to the OLE extension, therefore we wouldn't be on time to do a retraining of the new version.
25	Cabotegravir	TDF/FTC	US	861586356	20JUL2021	20JUL2021	No	No	Study product dispensing error	Participant given OLE cabotegravir injection at visit 62 instead of having them come in for first injection at visit 63.	Protocol, SSP, and decision tree reviewed by site staff for clarification.	Site is aware after study material reviewal that participants must be scheduled for visit 63 after visit 62 to receive injection.

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26	Cabotegravir	TDF/FTC	Latin America	722616370	10APR2025	12MAR2025	Yes	No	Study product dispensing error	During the visit, the participant reported experiencing an Acute Myocardial Infarction (AMI), which the Investigator initially assessed as a Grade 3 adverse event and allowed the participant to continue receiving the study medication. Following the report of the event to DAIDS, the RSC requested that the severity grade be updated to Grade 4. According to the study protocol, any Grade 4 event requires temporary discontinuation of the study product and consultation with the CMC.	Not applicable, as the error occurred during the final study visit and the participant had already received the study medication.	Review the DAIDS table for severity classification and evaluate the conduct to be taken in relation to the study procedures.

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[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_deviation.sas, SAS Version 9.4 (04MAR2026,6:09)

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Listing 5 – Listing of Protocol Deviations [1]

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27	Cabotegravir	TDF/FTC	Latin America	845848931	16MAR2022	21JAN2022	Yes	No	Study product dispensing error	Participant performed visit Step 4c Week 16 (V66.0) on 21–Jan–2022 and samples related to visit were collected. However, the lab result of HIV viral load issued by FMUSP lab was ˆInvalid, there was no amplification of the internal reaction control˜. The participant, by an error of site staff, performed the visit Step 4c Week 24 (V67.0) on 11–Mar–2022 before a new collection was performed.	This information was submitted to HPTN LC, CMC and EC. The HPTN LC authorized the use of the plasma storaged sample collected on 21–Jan–2022 to perform the HIV viral load in the FMUSP, the result of HIV RNA PCR from this sample was Below the lower detection limit. The HIV rapid test, HIV serology and HIV RNA PCR performed on 11 Mar 2022 were non reactive/negative.	The site decided to implement preventive additional controls. The additional controls implemented to prevent any invalid or not performed lab results includes: implementation of a results tracking sheet that is completed by the person responsible for printing lab reports, review of test results by the study coordinator prior to the next study visit, updated the study visit template (source document) with inclusion of a question if all HIV testing algorithm tests have been performed.
28	Cabotegravir	Cabotegravir	Latin America	860709513	29NOV2023	23AUG2023	Yes	No	Study product dispensing error	On 23Aug2023, the physician prescribed TDF/FTC and the pharmacist dispensed bottles of step 5 TDF/FTC in V105/W48 (the participant's last visit).	Participant attended V105.1, 29Nov2023, to return the bottles.	Team reorientation.

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29	Cabotegravir	Cabotegravir	US	745312240	16JUN2021	20MAY2021	Yes	No	Conduct of non–protocol procedure	PTID 745–31224–0 was originally assigned to the active CAB LA arm. Her last CAB LA injection under Version 3 was 12MAR20. As documented via clinical notes & emails, a product hold/discontinuation was initiated on 13JUL20, V42.1 as per participant´s request, & the participant was advanced to Step 3, daily oral TDF/FTC. The participant was seen at the site on 20MAY21 & having completed the informed consent process for V4 of the study protocol, indicated her desire to re–start CAB LA injections. Upon review of participant´s records, no outstanding or concerning AE findings were identified. She received a CAB LA injection at the CRS following normal procedures. In oral review of the participant visit it was noted that a Brazilian butt lift (BBL: injected buttock implants/fillers) on 05OCT20 was documented in the participant´s chart. The CRS staff	1.IoR and site leader informed of incident. 2. CRS notified the CMC and HPTN 083 protocol deviation team. . The local IRB was informed. 4. Participant was informed that BBL excludes her from continuing with CAB LA injections and will be transitioned to Step 5 with TDF/FTC. . CMC advised that a protocol deviation be documented in participant´s record, to report this deviation to our local IRB and the 083 PD alias, and to complete the PD eCRF. CMC also advised that the participant should be transitioned to Step 5 with TDF/FTC.	1. Clinicians reviewed inclusion and exclusion criteria for HPTN 083. . Inclusion and exclusion criteria to be reviewed whenever an informed consent or informed consent addendum is to be signed. . Retrospective QA performed of all previous version 4 visits to ensure this is not a systematic issue at the site. Documented in charts via CAB LA eligibility criteria checklist.

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										confirmed that BBL is an exclusion criterion for CAB LA under the study protocol & prepared this description of the protocol deviation.		

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30	Cabotegravir	Cabotegravir	US	780959417	28SEP2021	15SEP2021	Yes	No	Conduct of non–protocol procedure	There was a disruption to the HIV testing algorithm for Participant 780–9594–1–7. Subject came in for a scheduled study visit (Step 4c–visit 65–week 8) on 15 Sep 2021. As per protocol, labs were drawn for HIV. However, Quest Diagnostics Laboratories would not run HIV testing due to a discrepancy between the lab requisition and the specimen labels on the blood samples. Participant has two last names. Staff mistakenly used his first last name on the requisition and his second last name on the specimen labels. Participant is being asked to return to our clinic for re–testing so that he may continue his scheduled CAB LA study visits without interruption	¯ IRB notified via prompt report ¯ 083PD Alias notified ¯ eCRF protocol deviation data entered for participant. ¯ PD form created and stapled to corresponding lab in participant´s chart ¯ Copy of PD filed in Regulatory. ¯ Participant was called to return to the clinic for repeat HIV testing to avoid interruption to participant´s study schedule.	¯ Going forward, for this participant, staff will include both last names on participant's lab requisition and specimen labels.
31	Cabotegravir	TDF/FTC	US	825308274	17MAY2021	21APR2021	Yes	No	Conduct of non–protocol procedure	Combined Step 3 week 48 and 4a day 0 visit. Extra labs were drawn which were not part of 4a day 0 protocol, however Quest lost some of the labs drawn on this day.	Staff are instructed to review procedures outlined on the visit checklists. A overview of the protocol deviations found and a training of the steps and procedures under the new amendment was conducted at a staff meeting on 26 May 2021.	Staff will be required to complete all protocol amendment trainings and demonstrate knowledge of steps involved in the new amendment. Hands on training will continue to be given to staff members by site coordinator and PI.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
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32	Cabotegravir	Cabotegravir	US	825727481	17MAY2021	20APR2021	Yes	No	Conduct of non–protocol procedure	During Step 4a Day 0, SMSQs was administered instead of SMSQ:OLE. Ppt was unable to be contacted to fill out the correct version, so responses were entered as N/A.	Staff are instructed to review procedures outlined on the visit checklists. A overview of the protocol deviations found and a training of the steps and procedures under the new amendment was conducted at a staff meeting on 26 May 2021.	Staff will be required to complete all protocol amendment trainings and demonstrate knowledge of steps involved in the new amendment. Hands on training will continue to be given to staff members by site coordinator and PI.
33	Cabotegravir	TDF/FTC	US	825771945	17MAY2021	15APR2021	Yes	No	Conduct of non–protocol procedure	Visit 41 (under amendment 3) was conducted even though site was IRB approved for amendment 4 and the subject had signed the consent form for the new amendment.	Staff are instructed to review procedures outlined on the visit checklists. A overview of the protocol deviations found and a training of the steps and procedures under the new amendment was conducted at a staff meeting on 26 May 2021.	Staff will be required to complete all protocol amendment trainings and demonstrate knowledge of steps involved in the new amendment. Hands on training will continue to be given to staff members by site coordinator and PI.
34	Cabotegravir	Cabotegravir	US	825949294	17MAY2021	19APR2021	Yes	No	Conduct of non–protocol procedure	Interviewer administered baseline and SMSQ had originally been administered during 4c day 0. Correct OLE versions were then administered over the phone. CASI was submitted for the wrong visit.	Staff are instructed to review procedures outlined on the visit checklists. A overview of the protocol deviations found and a training of the steps and procedures under the new amendment was conducted at a staff meeting on 26 May 2021.	Staff will be required to complete all protocol amendment trainings and demonstrate knowledge of steps involved in the new amendment. Hands on training will continue to be given to staff members by site coordinator and PI.

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35	Cabotegravir	TDF/FTC	Latin America	831406491	19MAY2023	19MAY2023	Yes	No	Conduct of non–protocol procedure	The participant presented an adverse event of elevated ALT grade 2 and after controls at the center, without improvement, the CMC indicated to discontinue the study product and complete step 3 without the study product. At his last visit, he presented elevated ALT grade 2 and obesity. The participant was invited to continue to the protocol extension. He accepted and came to the center on 19MAY2023, was reconsented and chose step 4b (v63.0). The procedures of the first part of the visit and the sampling of this visit were performed. In the pre–assessment, before the application of the study product, the fact that the participant did not receive the study product several visits ago is highlighted and the CMC is consulted, at that moment, if the participant is eligible, receiving the answer that he is not eligible. The research product was not applied.	Notify IBC and report to NIH in next quarterly report.	Review of all medical records prior to summoning the participant to their visits and assess whether they are eligible to participate in HPTN 083 Amendment 5.0 and consult with the CMC if there is any doubt.

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36	Cabotegravir	Cabotegravir	Asia	858865711	14NOV2022	20SEP2022	Yes	No	Conduct of non–protocol procedure	The participant PTID 858865711. TGW, 31 years old, enrolled in HPTN083 on 28 May 2018. Her last visit with HPTN083 was a Step 4C Week 48 on 30 AUG 2022. We learned from history taking that the participant had been enrolled in a new clinical trial on Bexsero vaccination for Gonorrheal infection prophylaxis on 20 Sep 2022. The first Bexsero vaccine dose was given to her on 20 Sep 2022, and a second shot was scheduled for 15 Nov 2022. â â â â â â Following the retrieval of the participant's information, we informed the participant of the possibility of terminating her participation in the HPTN083 study. To continue receiving long–acting cabotegravir from the HPTN083 study, the participant is willing to stop receiving the Bexsero vaccine. 14 Nov 2022, the Investigator consulted the CMC on this issue. 9 Nov 2022, the CMC suggested to report the co–enrollment as a protocol deviation. the participant is	1. Study staff has reported the event to the protocol team for further management. 2. Plan to submit the protocol deviation to the local IRB as soon as possible. . As a preventative measure against future detection failures, the study team will emphasize protocol procedures in the future.	Root course analysis. In this case, the participant was not aware of the restriction on co–enrollment, which influenced her decision to take part in another study. To prevent future failure of detection. As a preventative measure, the study team will emphasize the study protocol, reminding participants to refrain from co–enrolling in another study while participating in HPTN083.

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										eligible to remain in the study.		

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37	Cabotegravir	Cabotegravir	US	745345862	24MAR2022	22MAR2022	Yes	No	Breach of confidentiality	On March 22, 2022, a prescription for participant 745–34586–2 was lost on route to the CU research pharmacy for a medication pickup. Prescription was lost on the A train from the site on 125th street to the CU research pharmacy on 168th street. The prescription only contained the name of the study participant, it did not include the participant identifier (PTID). The site leadership became aware of the lost prescription on March 24, 2022.	–PI, Site Coordinator, Regulatory Coordinator, and CU Pharmacy were made aware on March 24, 2022. –The study protocol team and DAIDS program officer have been notified. –Site communicated with the CU Research Pharmacy to ensure that all needed prescriptions were received. –CU IRB will be notified. –CUIMC Chief Privacy Officer will be notified. –Protocol PD alias will be notified –DAIDS OCSO PO will be notified	The site reviewed the courier procedures and updated it as follows: –The Study Product Transfer SOP and Courier SOP has been updated. –The Handling Confidential Participant Information/Sensitive Data Storage SOP has been updated to include a section regarding the process of handling a breach in confidentiality. –Prescription will be kept inside of the courier bag after the initial check until the courier´s arrival at the pharmacy. –Before the courier leaves, both another staff member and the courier will double check to ensure that the prescription is secured in the courier bag. –We created a checklist for the courier and secondary staff member to initial and date. –The courier will leave the courier bag locked and unopened for the duration of the trip to ensure that the prescriptions stay inside the bag. –All staff involved in the courier process have attended a training with site leadership on these revised procedures; training

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												sign–in sheet is attached in Appendix 1
38	Cabotegravir	TDF/FTC	US	700156559	20JUL2022	19AUG2021	Yes	No	Lab assessment deviation	4a, Day 0–HIV testing algorithm not followed – HIV RNA not done	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

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39	Cabotegravir	TDF/FTC	US	700156559	20JUL2022	16SEP2021	Yes	No	Lab assessment deviation	4a, wk 4–HIV testing algorithm not followed – HIV RNA not done	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
40	Cabotegravir	TDF/FTC	US	700156559	20JUL2022	28SEP2021	Yes	No	Lab assessment deviation	4b, day 0–HIV testing algorithm not followed – HIV RNA not done	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

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41	Cabotegravir	TDF/FTC	US	700156559	20JUL2022	03NOV2021	Yes	No	Lab assessment deviation	4c, day 0 – HIV testing algorithm not followed – HIV RNA not done	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
42	Cabotegravir	TDF/FTC	US	700156559	20JUL2022	16FEB2022	Yes	No	Lab assessment deviation	4c, wk 8 – HIV testing algorithm not followed – HIV RNA not done	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

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43	Cabotegravir	TDF/FTC	US	700156559	20JUL2022	31MAR2022	Yes	No	Lab assessment deviation	4c, wk 16–HIV testing algorithm not followed – HIV RNA not done	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
44	Cabotegravir	TDF/FTC	US	700156559	20JUL2022	11MAY2022	Yes	No	Lab assessment deviation	4c, wk 24–HIV testing algorithm not followed – HIV RNA not done	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_deviation.sas, SAS Version 9.4 (04MAR2026,6:09)

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
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Listing 5 – Listing of Protocol Deviations [1]

# [2]	OLE Regimen Choice	Original Arm	Region	Participant ID	Site Awareness Date	Deviation Date	Reported to IRB/EC	Reported to DAIDS	Type of Deviation	Description of Deviation	Steps taken to address Deviation	Steps taken to prevent future occurrences of the Deviation
45	Cabotegravir	Cabotegravir	US	700212778	20JUL2022	25AUG2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4b Day 0	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
46	Cabotegravir	Cabotegravir	US	700212778	20JUL2022	14SEP2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Day 0	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

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47	Cabotegravir	Cabotegravir	US	700212778	20JUL2022	10NOV2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Week 8	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
48	Cabotegravir	Cabotegravir	US	700212778	20JUL2022	11JAN2022	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Week 16	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_deviation.sas, SAS Version 9.4 (04MAR2026,6:09)

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49	Cabotegravir	Cabotegravir	US	700212778	20JUL2022	09MAR2022	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Week 24	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
50	Cabotegravir	Cabotegravir	US	700212778	20JUL2022	19APR2022	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Week 32	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

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Listing 5 – Listing of Protocol Deviations [1]

# [2]	OLE Regimen Choice	Original Arm	Region	Participant ID	Site Awareness Date	Deviation Date	Reported to IRB/EC	Reported to DAIDS	Type of Deviation	Description of Deviation	Steps taken to address Deviation	Steps taken to prevent future occurrences of the Deviation
51	Cabotegravir	TDF/FTC	US	700424129	20JUL2022	27JUL2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4a Day 0.	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
52	Cabotegravir	TDF/FTC	US	700424129	20JUL2022	27AUG2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4a Week 4.	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

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53	Cabotegravir	TDF/FTC	US	700424129	20JUL2022	17SEP2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4b Day 0.	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
54	Cabotegravir	TDF/FTC	US	700424129	20JUL2022	22OCT2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Day 0	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

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# [2]	OLE Regimen Choice	Original Arm	Region	Participant ID	Site Awareness Date	Deviation Date	Reported to IRB/EC	Reported to DAIDS	Type of Deviation	Description of Deviation	Steps taken to address Deviation	Steps taken to prevent future occurrences of the Deviation
55	Cabotegravir	TDF/FTC	US	700614541	20JUL2022	03AUG2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4a Day 0.	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
56	Cabotegravir	TDF/FTC	US	700614541	20JUL2022	31AUG2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4a Week 4	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

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[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

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Listing 5 – Listing of Protocol Deviations [1]

# [2]	OLE Regimen Choice	Original Arm	Region	Participant ID	Site Awareness Date	Deviation Date	Reported to IRB/EC	Reported to DAIDS	Type of Deviation	Description of Deviation	Steps taken to address Deviation	Steps taken to prevent future occurrences of the Deviation
57	Cabotegravir	TDF/FTC	US	700614541	20JUL2022	08SEP2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit step 4b Day 0.	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
58	Cabotegravir	TDF/FTC	US	700614541	20JUL2022	20OCT2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Day 0.	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

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59	Cabotegravir	TDF/FTC	US	700614541	20JUL2022	15DEC2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Week 8.	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
60	Cabotegravir	TDF/FTC	US	700614541	20JUL2022	16FEB2022	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Week 16	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
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61	Cabotegravir	TDF/FTC	US	700614541	20JUL2022	03MAY2022	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Week 24.	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
62	Cabotegravir	Cabotegravir	US	700633703	20JUL2022	28SEP2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4b Day 0	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

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63	Cabotegravir	Cabotegravir	US	700633703	20JUL2022	28OCT2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Day 0	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
64	Cabotegravir	Cabotegravir	US	700633703	20JUL2022	14DEC2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Week 8	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
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65	Cabotegravir	Cabotegravir	US	700633703	20JUL2022	08FEB2022	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Week 16.	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
66	Cabotegravir	Cabotegravir	US	700633703	20JUL2022	06APR2022	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Week 24	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
67	Cabotegravir	Cabotegravir	US	701694685	15JUL2021	14JUL2021	No	No	Lab assessment deviation	Additional blood collection completed	Review SOE according to the study visit	Review SOE and verify study visit blood collection at each scheduled visit

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68	Cabotegravir	Cabotegravir	US	706235209	20JUL2022	24AUG2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4a Day 0	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
69	Cabotegravir	Cabotegravir	US	706235209	20JUL2022	17SEP2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4a Week 4	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

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70	Cabotegravir	Cabotegravir	US	706235209	20JUL2022	30SEP2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4b Day 0	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
71	Cabotegravir	Cabotegravir	US	706235209	20JUL2022	04NOV2021	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Day 0	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

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[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

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Listing 5 – Listing of Protocol Deviations [1]

# [2]	OLE Regimen Choice	Original Arm	Region	Participant ID	Site Awareness Date	Deviation Date	Reported to IRB/EC	Reported to DAIDS	Type of Deviation	Description of Deviation	Steps taken to address Deviation	Steps taken to prevent future occurrences of the Deviation
72	Cabotegravir	Cabotegravir	US	706235209	20JUL2022	13JAN2022	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Week 8	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
73	Cabotegravir	Cabotegravir	US	706235209	20JUL2022	03MAR2022	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Week 16	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

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74	Cabotegravir	Cabotegravir	US	706235209	20JUL2022	29APR2022	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Week 24	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
75	Cabotegravir	TDF/FTC	US	712324274	20JUL2022	11JAN2022	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4a Day 0.	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

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76	Cabotegravir	TDF/FTC	US	712324274	20JUL2022	15FEB2022	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4a Week 4.	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
77	Cabotegravir	TDF/FTC	US	712324274	20JUL2022	01MAR2022	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4b Day 0	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

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Listing 5 – Listing of Protocol Deviations [1]

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78	Cabotegravir	TDF/FTC	US	712324274	20JUL2022	08APR2022	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Day 0	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
79	Cabotegravir	TDF/FTC	US	712324274	20JUL2022	03JUN2022	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Week 8	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.
80	Cabotegravir	Cabotegravir	US	745828114	10AUG2023	07AUG2023	No	No	Lab assessment deviation	Rectal Specimen not sufficient for result	Collect at next study visit	review specimen collection procedure with a participant

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81	Cabotegravir	Cabotegravir	US	780457812	14JUL2021	07JUL2021	Yes	No	Lab assessment deviation	Participant 780–4578–1–2 came in for study visit (Step 4b–Visit 63–Day 0) on 07 July 2021. As per protocol, labs were drawn for HIV testing. Blood was collected and picked up by courier to be analyzed at Quest Diagnostics Laboratories. However, upon arriving at QUEST Diagnostic laboratories, sample was not kept frozen before analyzing. As a result, sample was not used for testing because it had exceeded its viability.	¯ IRB notified via prompt report ¯ 083PD Alias notified ¯ eCRF protocol deviation data entered for participant. ¯ PD form created and stapled to corresponding lab in participant´s chart ¯ Copy of PD filed in Regulatory. ¯ Participant was called to return to the clinic on 22 July 2021 for repeat labs ¯ HIV/PCR results obtained without interruption to participant´s study schedule	¯ Deviation to HIV testing algorithm was brought about by an error committed by Quest Diagnostic Laboratories. Unable to put actions in place to prevent future re–occurrence.

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Listing 5 – Listing of Protocol Deviations [1]

# [2]	OLE Regimen Choice	Original Arm	Region	Participant ID	Site Awareness Date	Deviation Date	Reported to IRB/EC	Reported to DAIDS	Type of Deviation	Description of Deviation	Steps taken to address Deviation	Steps taken to prevent future occurrences of the Deviation
82	Cabotegravir	Cabotegravir	US	780495545	13MAR2023	07MAR2023	Yes	No	Lab assessment deviation	Disruption to the HIV testing algorithm for Participant 780–4955–4–5. Subject came in for a scheduled study visit (Step 6 – Visit 75 – Week 88) on 07 Mar 2023. As per protocol, labs were drawn for HIV. HIV rapid was non–reactive, Cab Injection was given. The rest of the blood samples were sent out to Quest Diagnostics for testing. However, Quest informed me by phone that they lost the frozen sample for PCR testing. All other visit labs were perfomred except for the viral load.	Participant is due to return for an Interim OLE Visit (Visit 75.1) for repeat testing. An HIV rapid, HIV 4th generation, and PCR will be drawn and evaluated before his next scheduled CAB injection visit.	As this was an error on the part of Quest Diagnostics, there is no action that can be taken to prevent future occurrences.
83	Cabotegravir	TDF/FTC	US	801552092	20JUL2022	17MAY2022	Yes	No	Lab assessment deviation	HIV testing algorithm not followed – HIV RNA not done at visit Step 4c Week 48.	We are contacting the lab and study team to see if HIV RNA should be run retroactively from stored plasma for these participants. If HIV RNA cannot be run retroactively, then we are considering contacting participants to return for an interim visit to check this test (if the protocol team agrees).	Lab orders updated to include HIV RNA test. Reviewed with leadership and staff at staff meeting.

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Listing 5 – Listing of Protocol Deviations [1]

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84	Cabotegravir	Cabotegravir	US	819132619	13SEP2022	31AUG2022	Yes	No	Lab assessment deviation	Site sent a sample to local lab for HIV RNA testing at visit 71.0 on 15Aug22 per protocol. Staff contacted local lab on 24Aug22 because the test had not yet resulted. Local lab informed site that they were processing the sample and did not note any issues. On 31Aug22, local lab informed site that the test could not be performed because "deterioration occurred during specimen handling."	Participant was contacted to schedule a repeat blood draw for HIV RNA testing before the next injection visit. He was not available until 12Sep22. A sample was collected on that date and sent to the local lab.	We will continue to implement our weekly inventory of lab reports expected from visits that occurred during the previous week, which helped us identify this missing lab report in real–time. We are attempting to determine what caused the issue at the local lab.
85	Cabotegravir	TDF/FTC	US	819352785	30DEC2021	17DEC2021	No	No	Lab assessment deviation	Quest did not perform HIV RNA testing for V 67.0 claiming not suitable specimen.	Participant unable to come for a redraw as he is diagnosed with COVID–19, therefore, one of the stored frozen aliquot from V 67.0 was sent to Quest to perform the HIV RNA testing (checked with CMC).	Our site has started sending frozen samples rather than room temp as it is ideal considering the current delays.
86	Cabotegravir	Cabotegravir	US	819484119	22NOV2021	09NOV2021	No	No	Lab assessment deviation	Quest reported that HIV RNA testing was not done for V66.0 due to inadequate sample. Participant was unable to come for a re draw within window (window for V 66 ended on 29–Nov–21).	Followed up with Quest to clarify on the issue. A re–draw was done out of window on 10–Dec–21 to perform the missed HIV RNA testing.	Staff retrained on adequate sample requirements.
87	Cabotegravir	Cabotegravir	US	819517422	12OCT2021	01OCT2021	No	No	Lab assessment deviation	HIV RNA not done by Quest lab on V65.0 as "Quantity not sufficient (on collected sample)".	Interim visit 65.1 done to collect pending HIV RNA per protocol	Clarified with Quest and staff retrained.
88	Cabotegravir	TDF/FTC	US	819633614	02DEC2021	19NOV2021	No	No	Lab assessment deviation	HIV RNA not done by Quest lab on V102.0 as "sample was not suitable".	Interim visit 102.1 done to re–draw and collect pending HIV RNA per protocol.	Clarified with Quest lab and staff retrained.

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89	Cabotegravir	TDF/FTC	US	819836492	22DEC2021	08DEC2021	No	No	Lab assessment deviation	HIV RNA not done by Quest lab on V66.0 as "sample was not suitable" per reference lab (Quest lab).	Interim visit 66.1 done to re–draw and to collect pending HIV RNA per protocol.	Clarified with Quest and staff retrained
90	Cabotegravir	Cabotegravir	US	819933386	27DEC2021	16DEC2021	No	No	Lab assessment deviation	HIV RNA not done by Quest lab on V66.0 as "Quantity not sufficient (on collected sample)".	Interim visit 66.1 done to collect pending HIV RNA per protocol.	Clarified with Quest and staff retrained.
91	Cabotegravir	Cabotegravir	US	819996833	27DEC2021	11DEC2021	No	No	Lab assessment deviation	Quest did not perform HIV RNA testing for V 67.0 claiming not suitable specimen.	Participant unable to come for a redraw as he does not live in Boston area, therefore, one of the stored frozen aliquot from V 67.0 was sent to Quest on 1/4/22 to perform the HIV RNA testing. LDMS updated with sample condition codes.	Our site has started sending frozen samples rather than room temp as it is ideal considering the current delays.
92	Cabotegravir	Cabotegravir	US	821581225	22MAR2022	15MAR2022	Yes	No	Lab assessment deviation	All appropriate labs were drawn for visit 67. UAB Molecular Diagnostics was contacted yesterday due to delay in result for HIV Quant. Lab tech said there was a problem with the COBAS 6800 Analyzer & after running the sample with no success, there was no longer sufficient volume to run again. Lab error was attributed to "New Techs" learning there.	Ppt was contacted & can come later today for redraw of HIV Quant–Storage.	Communication w/ Molecular Diagnostics to see if additional blood needs to be drawn in order to ensure a result occurs. Awaiting their response. They did ensure that new staff is now up to speed on instrument & we shouldn't have anymore delays nor anticipate future problems.

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93	Cabotegravir	Cabotegravir	US	825364853	05AUG2022	22JUL2022	Yes	No	Lab assessment deviation	HIV viral load PCR result is unavailable for Visit 70 conducted on 22 Jul 2022, because the quantity of specimen submitted to the local lab was not sufficient, according to the lab, to verify result.	The New York Blood Center IRB will be notified of this protocol event. Participant 825364853 will be rescheduled for HIV testing as an interim visit before their next injection visit.	Site staff have been informed of this protocol event and have been reminded to ensure a sufficient amount of blood specimen is collected for lab testing (e.g., by filling the tube as much as possible to the top or when the vacuum stops)
94	Cabotegravir	Cabotegravir	US	825949294	05OCT2021	01SEP2021	Yes	No	Lab assessment deviation	Specimen collection storage was not done when the subject came in for a HIV testing re–draw.	Protocol deviation will be submitted at next continuing review.	Staff have been informed that Specimen collection storage is to be done anytime HIV testing is done.
95	Cabotegravir	TDF/FTC	US	844914467	08NOV2022	08NOV2022	No	No	Lab assessment deviation	Specimen collected, laboratory did not process, specimen not stored.	Participant is the only participant in Step 5, highlight DBS on paperwork to avoid future errors. Noted in CRF and chart.	Participant is the only participant in Step 5, highlight DBS on paperwork to avoid future errors. Noted in CRF and chart.
96	Cabotegravir	TDF/FTC	US	846926364	21DEC2022	12DEC2022	No	No	Lab assessment deviation	On 10/12/22, a Week 72 visit was accidentally completed instead of a Week 64, including all Week 72 labs. On 12/12/22, a Week 80 visit was completed, which should have been a Week 72, and Week 72 labs were missed at this visit.	Patient´s next visit, in February of 2023, will be conducted as a Week 80 Visit to place the participant back on the correct timeline for Step 6 Visits. Staff will document the labs needed for Week 72 as missed, and report the Protocol Deviation in Mediata as well as to the sponsor team.	Study staff will confirm Visit Code in Medidata and Visit Tracker prior to visit. Staff will double check EPIC notes reflect the accurate visit, and that proper documentation of Visits are recorded in both Medidata, and EPIC.
97	Cabotegravir	TDF/FTC	US	847768019	13OCT2021	27SEP2021	Yes	No	Lab assessment deviation	A dried blood spot was not created for the Step 4, week 0 visit as required by the protocol.	Review requisition to ensure proper labs are documented as collected and stored. If requisition does not indicate visit, will contact study coordinator to confirm which visit is to be processed	Review of lab manual before processing specimens to ensure correct processing procedures. Review requisition to ensure proper labs are documented as collected and stored.

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98	Cabotegravir	Cabotegravir	US	851789301	21JUN2022	21JUN2022	No	No	Lab assessment deviation	HIV RNA obtained at visit on 16Jun2022. Lab but lab did not process lab	Had participant return for repeat HIVRNA on 22Jun2022	Continue to work with and follow up with processing lab
99	Cabotegravir	Cabotegravir	US	853334809	31AUG2021	31AUG2021	Yes	No	Lab assessment deviation	A FOURTH GENERATION HIV TESTING WAS ACCIDENTALLY NOT REQUESTED AT THE STEP4C WEEK 8 VISIT ON 08/31/2021.	1. AN ORAQUICK AND HIV VIRAL LOAD TESTS WERE PERFORMED AT STEP4C WEEK 8 VISIT ON 8/31/2021. BOTH TESTS WERE NEGATIVE. 2. AN ORAQUICK TEST, 4TH GENERATION HIV AND HIV VIRAL LOAD TESTS WERE PERFORMED AT THE FOLLOWING VISIT, STEP4C WEEK16, ON 10/28/2021. ALL OF THEM WERE NEGATIVE.	. LABORATORY REQUISITION FORMS WERE PRE–FILLED WITH THE LABORATORY ASSESSMENTS REQUIRED FOR EACH VISIT. . QA/QC CONTROL WAS REINFORCED.
100	Cabotegravir	Cabotegravir	US	853663039	31AUG2021	30AUG2021	Yes	No	Lab assessment deviation	A FOURTH GENERATION HIV TESTING WAS ACCIDENTALLY NOT REQUESTED AT THE STEP4C WEEK 8 VISIT ON 08/30/2021.	1. AN ORAQUICK AND HIV VIRAL LOAD TESTS WERE PERFORMED AT STEP4C WEEK 8 VISIT ON 8/30/2021. BOTH TESTS WERE NEGATIVE. 2. AN ORAQUICK TEST, 4TH GENERATION HIV AND HIV VIRAL LOAD TESTS WERE PERFORMED AT THE FOLLOWING VISIT, STEP4C WEEK16, ON 10/26/2021. ALL OF THEM WERE NEGATIVE.	1. LABORATORY REQUISITION FORMS WERE PRE–FILLED WITH THE LABORATORY ASSESSMENTS REQUIRED FOR EACH VISIT. . QA/QC CONTROL WAS REINFORCED.

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Listing 5 – Listing of Protocol Deviations [1]

# [2]	OLE Regimen Choice	Original Arm	Region	Participant ID	Site Awareness Date	Deviation Date	Reported to IRB/EC	Reported to DAIDS	Type of Deviation	Description of Deviation	Steps taken to address Deviation	Steps taken to prevent future occurrences of the Deviation
101	Cabotegravir	Cabotegravir	US	863184169	28JUN2022	06JUN2022	No	No	Lab assessment deviation	Local laboratory erroneously did not complete HIV RNA PCR testing on specimens sent at visit 70.0.	Site staff attempted to bring participant back in to recollect specimen but participant´s schedule did not allow for this.	Site will continue keeping an eye on labs requested to note whether lab has completed required testing. Site will attempt to bring participants back in for any required testing.
102	Cabotegravir	Cabotegravir	US	863301068	08SEP2022	08SEP2022	No	No	Lab assessment deviation	HIV RNA PCR testing was not completed on 9/8/2022 for v72.0 due to insufficient blood volume collected.	Site brought participant back in on 9/16/2022 to complete the testing for clinical purposes.	Site will make all attempts to obtain appropriate blood volume to complete required testing.
103	Cabotegravir	Cabotegravir	US	863301068	24APR2023	19APR2023	No	No	Lab assessment deviation	Local laboratory erroneously did not complete HIV RNA PCR testing on specimens sent at visit 76.0 (final visit).	Clinic called lab to attempt to rectify the situation but lab was unable to comply. Ppt brought back in to complete testing at final interim visit.	Site to reach out to local laboratory again to clarify situation and prevent future occurrences.
104	Cabotegravir	TDF/FTC	US	863387751	22NOV2021	19NOV2021	No	No	Lab assessment deviation	Plasma storage was not completed at an interim visit where HIV testing was performed.	Deviation filed. No further action taken.	Staff retrained on HIV testing algorithm.
105	Cabotegravir	TDF/FTC	US	863389868	24APR2023	19APR2023	No	No	Lab assessment deviation	Local laboratory erroneously did not complete HIV RNA PCR testing on specimens sent at visit 74.0.	Clinic called lab to attempt to rectify the situation but lab was unable to comply. Ppt brought back in to complete testing at interim visit.	Site to reach out to local laboratory to clarify situation and prevent future occurrences.
106	Cabotegravir	TDF/FTC	US	863426684	17MAR2023	15MAR2023	No	No	Lab assessment deviation	Quantity of specimen submitted for HIV RNA PCR testing was insufficient to verify results so local lab did not release results to site.	Site is attempting to bring the participant back in to complete this testing.	Site will always attempt to obtain enough quantity of specimens to complete all required testing.

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[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_deviation.sas, SAS Version 9.4 (04MAR2026,6:09)

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107	Cabotegravir	Cabotegravir	US	863514631	09AUG2022	21MAY2021	No	No	Lab assessment deviation	Specimens for HIV RNA PCR testing were collected on 5/21/2021 but testing was erroneously not completed.	Site brought participant back in on 6/8/2021 to recollect specimens to complete HIV RNA PCR testing.	Site staff does not control local laboratory procedures but will continue to bring participants back into clinic to complete this testing if it is not completed at the initial visit.
108	Cabotegravir	Cabotegravir	US	863528933	21SEP2022	31AUG2022	No	No	Lab assessment deviation	Specimens for HIV RNA PCR testing were collected on 8/31/2022 for v72.0 but testing was erroneously not completed.	Site contacted local laboratory to complete testing but lab failed to complete requested tests.	Site will monitor and make sure that requested testing is being performed.
109	Cabotegravir	TDF/FTC	Latin America	721743237	26OCT2021	07OCT2021	Yes	No	Lab assessment deviation	Urinalysis testing (Protein and glucose) and Rectal Swab GC/CT testing were not done at D0/Step 5 visit because them had been missed in the visit checklist.	D0/Step 5 visit checklist was updated to include Urinalysis testing (Protein and glucose) and Rectal Swab GC/CT testing. Those collections have been done during the next study visit. The LOC team was informed about the deviation on 26–oct–2021. On the same date all visit checklists were reviewed by the coordenation and the lab team and the IRB was informed on 27–oct–2021.	Coordenation and the lab team were re–trained on the study procedures.

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110	Cabotegravir	TDF/FTC	Latin America	845531707	27FEB2024	24JAN2024	Yes	No	Lab assessment deviation	Participant PTID 845531707 performed the visit for Week 96 – Step 6 (Vst76.0) on 01/24/2024. However, due to an error by the site's staff, the laboratory requisition and collection tubes were filled with the identification of another participant (PTID 845446202). Because of this error, the visit for Week 96 – Step 6 (Vst76.0) performed on 01/24/2024 was recorded in the LDMS as belonging to participant 845446202.	The site's staff has verified, and PTID 845446202 did not attend the site on 01/24/2024. Therefore, we have ruled out the possibility of sample exchange between participants. After guidance of HPTN LC the participant will recollect all the samples related to Week 96 ˇ Step 6 (Vst 76.0). The storage samples (PL2) will be destroyed and a note about this deviation will be registered in LDMS. NTF will be done to confirm removal of the lab test results from the participant notes and RAVE.	The clinic (nurses) and laboratory teams will undergo retraining regarding the correct procedures of the study. The clinic (nurses) and lab staff must have 2 people checking laboratory requisitions and specimen collection labeling. Clinic staff should be verifying the participants name, ID, birthdate etc before collecting the sample, labeling the tubes and completing the lab requisitions. Lab staff should be verifying that PTID/visit/collection date matches between: primary collection tubes, processing tubes, aliquots, lab specimen processing forms and lab requisitions/medical order.
111	Cabotegravir	Cabotegravir	Latin America	860607760	19JUN2023	19JUN2023	Yes	No	Lab assessment deviation	Ppt came for visit and received study medication without the HIV serology and viral load the previous visit being evaluated by the physician. Therefore, the evaluation process for all HIV testing was not performed as described per protocol and section 11 of the SSP manual	The HIV tests were printed and evaluated by the doctor and all the results were negative	Team retraining

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112	Cabotegravir	Cabotegravir	Africa	816585446	29NOV2023	29NOV2023	Yes	No	Lab assessment deviation	Oversight and misunderstanding between staff as participant had an interim visit for wk 88 but in error Site conducted wk 96 and bloods were not taken in error	DCF sent to BARC to change the results form from wk88 to wk 96	The Study Coordinator should conduct a Quality Control on the Study Procedures before participant leaves the Site
113	Cabotegravir	Cabotegravir	Africa	816623892	18JAN2024	03MAY2022	Yes	No	Lab assessment deviation	Hep–C Ab was done with week–24 laboratory procedures in error by the nurse who saw the participant at this visit.	The nursing team was retrained to take note of the laboratory instruction reminders and tick the appropriate boxes when requesting tests.	Continue to do a peer QC including the laboratory requisition forms to reduce errors of this nature going forward.
114	Cabotegravir	TDF/FTC	US	764220221	11AUG2022	10FEB2022	Yes	No	Informed assent/consent process deviation	Lab drawn prior to patient signing ICF amendmnet.	Monitor made site staff aware and retrained staff.	Instruct patient to arrive 15 minutes early to complete ICF before lab collection.
115	Cabotegravir	TDF/FTC	US	764220221	11AUG2022	07JUL2022	Yes	No	Informed assent/consent process deviation	Lab drawn before patient signing ICF amendment.	Monitor made staff aware and retrained staff.	Instruct patient to arrive 15 minutes early to complete ICF before lab collection.

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116	Cabotegravir	TDF/FTC	US	764339301	13JUL2021	03JUN2021	Yes	No	Informed assent/consent process deviation	Ppt seen for interim visit on 6/3/21 to consent to V4. ICF 14May21 was implemented on 6/2/21, but ppt signed previous V4 ICF 05Apr21. Ppt seen for V63 on 6/17/21 and received a study product injection, but the staff seeing the visit did not realize the ppt had not signed the latest ICF. At V64 on 7/13/21, after completing the blood draw, rapid HIV test, and CASI, the staff conducting the visit realized the ppt needed to consent to 14May21. Consent obtained mid–visit. Consent implementation steps: . Train staff on new ICF . Place ICF in front of binder 3. Add important reminder to reconsent at next visit. In this case, the ICF/important reminder was not added to the binder. The previous ICF was still there so staff consented ppt to that version on 6/3/21. The staff person did not check that the correct version of the consent was used. At V63 and V64 staff did not check the ppt consent folder to	Ppt signed the 14May21 consent during visit 64 on 7/13/21 and was informed of the minor differences between the addendums which did not affect the ppt's safety or the procedures done at V63 and V64. The PI, study coordinator, protocol team and IRB were informed of the consent violation. We conducted an audit of all active HPTN 083 ppts to make sure the most current version of the ICF addendum was signed or had been added to the binder to be signed at their next visit (if not seen since the implementation date). No additional violations were identified.	We are not sure why the original error in consent implementation happened, since the staff person who was responsible for updating the study binders is no longer at our site. In the past our process has been effective at ensuring ppts sign the most current ICF at the first visit after implementation. In response to this violation we are implementing the following updates: 1. After the ICFs and Important Reminder are added to the study binders, a 2nd staff person will double check to make sure all active ppt charts are updated. . Staff have been retrained on checking the consent folder BEFORE every visit and making sure the most recent ICF has been signed. To facilitate review, the consent folder will be put into each binder when prepping charts for the next day's visits. . We have posted a reference list of current ICFs and implementation dates above the shelves where that day's study binders are kept.

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										verify presence of most recent consent.		

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117	Cabotegravir	Cabotegravir	US	780959417	24FEB2022	22OCT2021	Yes	No	Informed assent/consent process deviation	On 22 OCT 2021, Subject 780–9594–1–7 was seen at our clinic to have previous labs redrawn (Interim Visit OLE – 65.1). While at our clinic subject was not re–consented with the most up–to–date consent form. This amounts to a protocol deviation. Subject was re–consented upon his next study visit.	¯ IRB notified via prompt report ¯ 083PD Alias notified ¯ eCRF protocol deviation data entered for participant. ¯ PD form created and stapled to corresponding ICF ¯ Copy of PD filed in Regulatory. ¯ Participant was re–consented upon his following visit (Visit 66 on 16–Nov–2021)	¯ Staff understands the importance of providing the most up–to–date version of the consent form to subjects at every visit. ¯ Newly released ICFs are printed out, filed and flagged, inside each participant chart, at front of all paperwork. This cues the staff that subject needs to sign a new ICF at next appointment

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118	Cabotegravir	Cabotegravir	US	825234165	14DEC2023	27JUL2023	Yes	No	Informed assent/consent process deviation	On 20 Jun 2023, ICF V. 6.0, NYBC IRB stamp expired. Per NYBC policy, the ˆconsent form is only valid if it carries the IRB approval stamp with current datesˆ. On 20 Jun 2023, the study staff requested the NYBC IRB restamp the Version 6.0 of the ICF with an updated expiration date (to extend beyond 20 Jun 2023) and revise the Continuing Review IRB Approval Letter. The NYBC IRB´s Human Subjects Protection Senior Manager (IRB administrator) was away from 16 Jun 2023 to 03 Jul 2023 and no other IRB staff was able to stamp the consent form with the new expiration date. The NYBC IRB informed the study team that Informed consent Version 6.0 would be stamped upon the return of the NYBC IRB administrator on 03 Jul 2023; however, a new stamped consent form with extended expiration date was not provided to the site staff after that date. As to not miss critical CAB inj, scheduled visits were kept, and this study participant signed the	The HPTN 083 protocol team will be notified of this Protocol Event. The affected participants will be contacted by study site staff so they are aware of the protocol event and that they can ask any questions. No direct harm to participants is anticipated from the protocol event. The NYBC IRB has been notified previously about this consent form stamp issue. The study has been closed for review with the NYBC IRB, but a copy of the protocol event form will be sent to the NYBC IRB.	Site staff will continue to closely check the expiration dates of consent form versions and continue to communicate closely with the IRB to ensure the consent versions have active expiration dates. The NYBC IRB has been notified previously about this consent form stamp issue, and is exploring ways to ensure multiple IRB staff have stamping capabilities.

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										expired V.6 ICF on 27JUL23.		
119	Cabotegravir	TDF/FTC	US	825269981	25AUG2022	03JUN2021	Yes	No	Informed assent/consent process deviation	Subject 825269981 was screened for Protocol Amendment 4 on 03 Jun 2021. During this visit they signed the informed consent form for the new amendment, and we collected their medical history and vital signs. They were determined to be ineligible for the new amendment with transition to injectable cabotegravir because they had previously received buttock implants (exclusion criterion for receiving injectable cabotegravir).	Since the subject was ineligible for Protocol Amendment 4 with transition to injectable cabotegravir, they completed a termination visit instead of initiating Step 4a. The New York Blood Center IRB will be notified of this protocol event.	Relevant staff were made aware of this protocol event. Eligibility criteria for future amendments will be thoroughly reviewed to prevent consenting of participants who do not fully meet the eligibility criteria for the new protocol amendment/consent.

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120	Cabotegravir	TDF/FTC	US	825579229	26OCT2022	27MAY2021	Yes	No	Informed assent/consent process deviation	Participant signed the PA4 ICF after blood had been drawn for the visit.	Site has held several trainings regarding the ICF process. IRB will be notified of the protocol event.	System will be implemented to notify and check in with them so they are aware of any new consents to be reviewed.

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121	Cabotegravir	Cabotegravir	US	825589931	14DEC2023	27JUL2023	Yes	No	Informed assent/consent process deviation	On 20 Jun 2023, ICF V. 6.0, NYBC IRB stamp expired. Per NYBC policy, the ˆconsent form is only valid if it carries the IRB approval stamp with current datesˆ. On 20 Jun 2023, the study staff requested the NYBC IRB restamp the Version 6.0 of the ICF with an updated expiration date (to extend beyond 20 Jun 2023) and revise the Continuing Review IRB Approval Letter. The NYBC IRB´s Human Subjects Protection Senior Manager (IRB administrator) was away from 16 Jun 2023 to 03 Jul 2023 and no other IRB staff was able to stamp the consent form with the new expiration date. The NYBC IRB informed the study team that Informed consent Version 6.0 would be stamped upon the return of the NYBC IRB administrator on 03 Jul 2023; however, a new stamped consent form with extended expiration date was not provided to the site staff after that date. As to not miss critical CAB inj, scheduled visits were kept, and this study participant signed the	The HPTN 083 protocol team will be notified of this Protocol Event. The affected participants will be contacted by study site staff so they are aware of the protocol event and that they can ask any questions. No direct harm to participants is anticipated from the protocol event. The NYBC IRB has been notified previously about this consent form stamp issue. The study has been closed for review with the NYBC IRB, but a copy of the protocol event form will be sent to the NYBC IRB.	Site staff will continue to closely check the expiration dates of consent form versions and continue to communicate closely with the IRB to ensure the consent versions have active expiration dates. The NYBC IRB has been notified previously about this consent form stamp issue, and is exploring ways to ensure multiple IRB staff have stamping capabilities.

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										expired V.6 ICF on 24JUL23.		

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122	Cabotegravir	TDF/FTC	US	825595469	14DEC2023	07AUG2023	Yes	No	Informed assent/consent process deviation	On 20 Jun 2023, ICF V. 6.0, NYBC IRB stamp expired. Per NYBC policy, the ˆconsent form is only valid if it carries the IRB approval stamp with current datesˆ. On 20 Jun 2023, the study staff requested the NYBC IRB restamp the Version 6.0 of the ICF with an updated expiration date (to extend beyond 20 Jun 2023) and revise the Continuing Review IRB Approval Letter. The NYBC IRB´s Human Subjects Protection Senior Manager (IRB administrator) was away from 16 Jun 2023 to 03 Jul 2023 and no other IRB staff was able to stamp the consent form with the new expiration date. The NYBC IRB informed the study team that Informed consent Version 6.0 would be stamped upon the return of the NYBC IRB administrator on 03 Jul 2023; however, a new stamped consent form with extended expiration date was not provided to the site staff after that date. As to not miss critical CAB inj, scheduled visits were kept, and this study participant signed the	The HPTN 083 protocol team will be notified of this Protocol Event. The affected participants will be contacted by study site staff so they are aware of the protocol event and that they can ask any questions. No direct harm to participants is anticipated from the protocol event. The NYBC IRB has been notified previously about this consent form stamp issue. The study has been closed for review with the NYBC IRB, but a copy of the protocol event form will be sent to the NYBC IRB.	Site staff will continue to closely check the expiration dates of consent form versions and continue to communicate closely with the IRB to ensure the consent versions have active expiration dates. The NYBC IRB has been notified previously about this consent form stamp issue, and is exploring ways to ensure multiple IRB staff have stamping capabilities.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_deviation.sas, SAS Version 9.4 (04MAR2026,6:09)

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										expired V.6 ICF on 07AUG23.		

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123	Cabotegravir	Cabotegravir	US	825820900	14DEC2023	23JUN2023	Yes	No	Informed assent/consent process deviation	On 20 Jun 2023, ICF V. 6.0, NYBC IRB stamp expired. Per NYBC policy, the ˆconsent form is only valid if it carries the IRB approval stamp with current datesˆ. On 20 Jun 2023, the study staff requested the NYBC IRB restamp the Version 6.0 of the ICF with an updated expiration date (to extend beyond 20 Jun 2023) and revise the Continuing Review IRB Approval Letter. The NYBC IRB´s Human Subjects Protection Senior Manager (IRB administrator) was away from 16 Jun 2023 to 03 Jul 2023 and no other IRB staff was able to stamp the consent form with the new expiration date. The NYBC IRB informed the study team that Informed consent Version 6.0 would be stamped upon the return of the NYBC IRB administrator on 03 Jul 2023; however, a new stamped consent form with extended expiration date was not provided to the site staff after that date. As to not miss critical CAB inj, scheduled visits were kept, and this study participant signed the	The HPTN 083 protocol team will be notified of this Protocol Event. The affected participants will be contacted by study site staff so they are aware of the protocol event and that they can ask any questions. No direct harm to participants is anticipated from the protocol event. The NYBC IRB has been notified previously about this consent form stamp issue. The study has been closed for review with the NYBC IRB, but a copy of the protocol event form will be sent to the NYBC IRB.	Site staff will continue to closely check the expiration dates of consent form versions and continue to communicate closely with the IRB to ensure the consent versions have active expiration dates. The NYBC IRB has been notified previously about this consent form stamp issue, and is exploring ways to ensure multiple IRB staff have stamping capabilities.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
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										expired V.6 ICF on 23JUN23.		
124	Cabotegravir	Cabotegravir	US	853926180	18AUG2022	24FEB2022	Yes	No	Informed assent/consent process deviation	During the external monitoring visit on 08/18/2022, it was found that the version 4 LoA3 ICF was signed on 02/24/22; however, both the participant and the study coordinator incorrectly dated the document as 10/24/2022. The ICF process documentation form and research visit source documentation were properly dated at 2/24/2022. The dating error did not affect the participant´s safety.	1. The participant will correct the ICF on the next study visit. 2. The deviation was reported to the IRB and the protocol sponsor on 08/24/22.	1. All site staff will be re–trained on QA/QC control to adequately review informed consent documentation. 1. Study team re–training on the Protocol SSP and site CQMP will be done at the HART team weekly meeting on 08/31/2022.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

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125	Cabotegravir	TDF/FTC	US	856200087	11JUL2022	28JUN2022	Yes	No	Informed assent/consent process deviation	The participant signed a consent form for Version 5.0 on 6/28/2022 before proceeding with their Step 4C Week 48 visit with the intention of completing this visit, but not continuing to Step 6. Due to a misunderstanding of team guidance and consent language, the coordinator´s consent discussion with the participant led to the participant initialing the wrong option stating ˆI do not agree to take part in this portion of the study, but I do agree to the procedures listed in the table for not continuing in this part of the study." This selection should have led to completion of study termination procedures outlined in the consent. However, the Week 48 visit was still completed. Instead, the participant should have initialed the option: ˆI am currently in Step 4c and taking IM CAB. I voluntarily agree to continue to take part in this portion of the study˜ which would have consented the participant to Version 5 and allow the Week 48 visit to proceed with a	Per the team´s guidance, the participant will be brought back into the clinic to re–consent and initial the correct option stated above. The participant will be terminated from the study after this point to complete the participant's wishes of not continuing to Step 6. This deviation is being reported to HPTN and the site´s local IRB.	The local study team met on 7/13/2022 to ensure all study coordinators are clear on the team´s guidance and consent language. Study coordinators will discuss the consent options and the subsequent study procedures that follow each option with participants moving forward. Any future participant that expresses wishes to terminate from the study after completing their Step 4c Week 48 visit and not proceed to Step 6 will be instructed to initial the option stating "I am currently in Step_____ and taking_____. I voluntarily agree to continue to take part in this portion of the study." This will ensure that they consent to Version 5 and can proceed with the Week 48 visit before study termination.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
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										subsequent study termination.		
126	Cabotegravir	Cabotegravir	US	864170443	11AUG2022	17JUL2021	Yes	No	Informed assent/consent process deviation	Lab drawn prior to patient signing ICF amendment.	Monitor discovered during the visit, made aware and retrained onsite staff.	Instruct patient to arrive 15 minutes early to complete ICF before lab collection.

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127	Cabotegravir	TDF/FTC	US	864289502	01MAR2023	03JUN2021	Yes	No	Informed assent/consent process deviation	Lab drawn prior to signing consent	When the deviation discovered, CRC reported to site admin and PI. Advise participants to arrive 15 minutes early to finsih the consent process before getting the blood draw in order to get the injection within the 2 hour window frame.	CRC reviewed SOP on lab draw and ICF process. Admin will conduct audit when new ICF becomes available to ensure staff follows protocol.
128	Cabotegravir	Cabotegravir	US	864537581	11AUG2022	13JAN2022	Yes	No	Informed assent/consent process deviation	Lab drawn prior to reconsenting process	Notified site admin and PI. Reviewed SOP on lab work and ICF.	Advise participants to arrive 15 minutes early to sign the consent priro to lab work in order to receive injection within 2 hour window frame.
129	Cabotegravir	TDF/FTC	US	864537857	27OCT2022	07JUN2021	Yes	No	Informed assent/consent process deviation	Lab drawn prior to patient signing ICF amendment.	Monitor discovered during the visit, made aware to staff and retrained staff. IRB notified.	Instruct patient to arrive 15 minutes early to complete ICF before lab collection.
130	Cabotegravir	TDF/FTC	US	864800299	27OCT2022	29JUL2021	Yes	No	Informed assent/consent process deviation	Patient got lab drawn before signing ICF amendment.	The error was discovered by monitor. Staff made aware and retrained. SHIRB notified.	Instruct patient to arrive 15 minutes early to sign ICF before blood collection.
131	Cabotegravir	Cabotegravir	US	864894076	11AUG2022	31JAN2022	Yes	No	Informed assent/consent process deviation	Lab draw prior to reconsenting process.	During a monitor onsite visit. site staff made aware and retrained.	Patient instructed to arrive 15 minutes early to reconsenting before lab collection.
132	Cabotegravir	Cabotegravir	US	864894076	11AUG2022	15JUN2022	Yes	No	Informed assent/consent process deviation	Lab drawn prior to patient signing ICF amendment.	Monitor made staff aware of the issue and retrained staff.	Instruct patient to arrive 15 minutes early to complete ICF before lab collection.

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133	Cabotegravir	Cabotegravir	Latin America	860166064	08AUG2022	08AUG2022	Yes	No	Informed assent/consent process deviation	The ppt came for for V66 on 08Aug2022 and informed conset for version 4.0 Loa#3 was not done	ICF process for version 4.0Loa#3 was done on an interim visit on 15Sep2022	Team reorientation
134	Cabotegravir	Cabotegravir	Latin America	860548404	14DEC2021	14DEC2021	Yes	No	Informed assent/consent process deviation	The ppt signed the informed consent for version 4.0 LoA#1 on 14Dec2021, but he didn't initial the page 11 of 11.	The ppt had a cerevral hemorrahgic stoke with sequelae, for this reason he can't come to our site and make this corretion.	Team reorientation.
135	Cabotegravir	TDF/FTC	Latin America	860732204	08DEC2023	08DEC2023	Yes	No	Informed assent/consent process deviation	THE PPT ARRIVED FOR V76 ON DECEMBER 8,2023,AND ADDENDUM TO INFORMED CONSENT FOR VERSION 3.0 ON MARCH10,2020, ADAPTED TO OUR CENTER ON AUGUST 3,2023 WAS NOT OBTAINED BEFORE PERFORMING THE PROCEDURES SPECIFIED BY THE PROTOCOL	THE CONSENT PROCESS FOR THE ADDENDUM TO INFORMED CONSENT TO VERSION 3.0 OF MARCH 10,2020 ADAPTED TO OUR CENTER ON AUGUST 3, 2023 WAS CARRIED OUT ON THE SAME DAY (DECEMBER 8,2023)	TEAM REORIENTATION
136	Cabotegravir	Cabotegravir	Latin America	860995774	23AUG2022	23AUG2022	Yes	No	Informed assent/consent process deviation	The ppt came for V67 on 23Aug2022, and informed consent for version 4.0 LoA#3 was not obtained prior to performing protocol–specified procedures	ICF process for version 4.0 LoA#3 was done on the same day (23Aug2022)	Team reorientation

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137	Cabotegravir	Cabotegravir	US	700212778	15MAY2024	01MAY2024	No	No	Other	Stored specimens were accidentally destroyed. They were erroneously stored in a box for another study. When that study's specimens were approved to be destroyed, the specimens were not reviewed before destruction.	None as destruction already occurred.	Specimens will not be destroyed before scanning them into the database, generate reports that will be emailed to the study leadership for review and approval. This was a derivation of the JHBR protocol, which will be enforced, and staff was reeducated.
138	Cabotegravir	TDF/FTC	US	701953786	27OCT2022	27OCT2022	Yes	No	Other	participant coenrolled in a hypertension study	Per CMC recommendation. Transition participant off study.	Site will continue to remind participants that coenrollment is not allowed.

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139	Cabotegravir	TDF/FTC	US	764107496	24MAY2021	21MAY2021	No	No	Other	The participant (ppt) is one of 7 ppts who signed the V 4 ICF main addendum before it received protocol registration with DAIDS PRO and activation by study LOC. On 18May21 we received a protocol registration notice for protocol Version 4.0 listing the consent as HPTN 083/Main IC/English. We received the V4 activation notice from the HPTN 083 LOC on 19May21. We consented the ppt to the addendum on 21May21 at an interim visit. No V4.0 procedures were done at the visit. At 10am the morning of 24May21, we received a second registration notice listing the consent as the HPTN 083/Main Addendum IC/English. While we did submit two consents (the V4 addendum and a more thorough consent for potential transfers), we did not realize the PRO would approve them separately. We received activation approval for V4 on 25May21. However, the implementation approval was also dated 24–May–2021.	We immediately notified the HPTN 083 protocol team on 24May21. Per communication from team, DAIDS considers this is a protocol deviation because we consented participants to a consent that was not approved by the PRO. DAIDS does not consider it a consent violation as the addendum was approved by the UCSF IRB. This event does not meet the UCSF IRB reporting requirements so will not be reported to them. Event will be documented with memo–to–file in ppt chart.	In the future, whenever multiple consent forms and/or consent addendums are submitted with DAIDS PRO registration, a list will be kept and registration will not be considered final until a registration notice is received for each consent form that was submitted.

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140	Cabotegravir	Cabotegravir	US	764434495	24MAY2021	24MAY2021	No	No	Other	The participant (ppt) is one of 7 ppts who signed the V 4 ICF main addendum before it received protocol registration with DAIDS PRO and activation by study LOC. On 18May21 we received a protocol registration notice for protocol Version 4.0 listing the consent as HPTN 083/Main IC/English. We received the V4 activation notice from the HPTN 083 LOC on 19May21. At 10am the morning of 24May21, we received a second registration notice listing the consent as the HPTN 083/Main Addendum IC/English. While we did submit two consents (the V4 addendum and a more thorough consent for potential transfers), we did not realize the PRO would approve them separately. We received activation approval for V4 on 25May21. However, the implementation approval was also dated 24May21. This ppt was scheduled for an interim visit 24May2021 afternoon. After discussion with the protocol team, we decided to consent	We immediately notified the HPTN 083 protocol team on 24May21. Per communication from team, DAIDS considers this is a protocol deviation because we consented participants to a consent that was not approved by the PRO. DAIDS does not consider it a consent violation as the addendum was approved by the UCSF IRB. This event does not meet the UCSF IRB reporting requirements so will not be reported to them. Event will be documented with memo–to–file in ppt chart.	In the future, whenever multiple consent forms and/or consent addendums are submitted with DAIDS PRO registration, a list will be kept and registration will not be considered final until a registration notice is received for each consent form that was submitted.

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										them since the addendum was now registered with PRO. No V4.0 procedures were done at the visit		

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141	Cabotegravir	TDF/FTC	US	764506542	24MAY2021	24MAY2021	No	No	Other	The participant (ppt) is one of 7 ppts who signed the V 4 ICF main addendum before it received protocol registration with DAIDS PRO and activation by study LOC. On 18May21 we received a protocol registration notice for protocol Version 4.0 listing the consent as HPTN 083/Main IC/English. We received the V4 activation notice from the HPTN 083 LOC on 19May21. At 10am the morning of 24May21, we received a second registration notice listing the consent as the HPTN 083/Main Addendum IC/English. While we did submit two consents (the V4 addendum and a more thorough consent for potential transfers), we did not realize the PRO would approve them separately. We received activation approval for V4 on 25May21. However, the implementation approval was also dated 24May21. This ppt was scheduled for an interim visit 24May2021 afternoon. After discussion with the protocol team, we decided to consent	We immediately notified the HPTN 083 protocol team on 24May21. Per communication from team, DAIDS considers this is a protocol deviation because we consented participants to a consent that was not approved by the PRO. DAIDS does not consider it a consent violation as the addendum was approved by the UCSF IRB. This event does not meet the UCSF IRB reporting requirements so will not be reported to them. Event will be documented with memo–to–file in ppt chart.	In the future, whenever multiple consent forms and/or consent addendums are submitted with DAIDS PRO registration, a list will be kept and registration will not be considered final until a registration notice is received for each consent form that was submitted.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_deviation.sas, SAS Version 9.4 (04MAR2026,6:09)

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										them since the addendum was now registered with PRO. No V4.0 procedures were done at the visit.		

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142	Cabotegravir	TDF/FTC	US	764589608	24MAY2021	21MAY2021	No	No	Other	The participant (ppt) is one of 7 ppts who signed the V 4 ICF main addendum before it received protocol registration with DAIDS PRO and activation by study LOC. On 18May21 we received a protocol registration notice for protocol Version 4.0 listing the consent as HPTN 083/Main IC/English. We received the V4 activation notice from the HPTN 083 LOC on 19May21. We consented the ppt to the addendum on 21May21 at an interim visit. No V4.0 procedures were done at the visit. At 10am the morning of 24May21, we received a second registration notice listing the consent as the HPTN 083/Main Addendum IC/English. While we did submit two consents (the V4 addendum and a more thorough consent for potential transfers), we did not realize the PRO would approve them separately. We received activation approval for V4 on 25May21. However, the implementation approval was also dated 24May21.	We immediately notified the HPTN 083 protocol team on 24May21. Per communication from team, DAIDS considers this is a protocol deviation because we consented participants to a consent that was not approved by the PRO. DAIDS does not consider it a consent violation as the addendum was approved by the UCSF IRB. This event does not meet the UCSF IRB reporting requirements so will not be reported to them. Event will be documented with memo–to–file in ppt chart.	In the future, whenever multiple consent forms and/or consent addendums are submitted with DAIDS PRO registration, a list will be kept and registration will not be considered final until a registration notice is received for each consent form that was submitted.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
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143	Cabotegravir	Cabotegravir	US	764590598	24MAY2021	21MAY2021	No	No	Other	The participant (ppt) is one of 7 ppts who signed the V 4 ICF main addendum before it received protocol registration with DAIDS PRO and activation by study LOC. On 18May21 we received a protocol registration notice for protocol Version 4.0 listing the consent as HPTN 083/Main IC/English. We received the V4 activation notice from the HPTN 083 LOC on 19May21. We consented the ppt to the addendum on 21May21 at an interim visit. No V4.0 procedures were done at the visit. At 10am the morning of 24May21, we received a second registration notice listing the consent as the HPTN 083/Main Addendum IC/English. While we did submit two consents (the V4 addendum and a more thorough consent for potential transfers), we did not realize the PRO would approve them separately. We received activation approval for V4 on 25May21. However, the implementation approval was also dated 24–May–2021.	We immediately notified the HPTN 083 protocol team on 24May21. Per communication from team, DAIDS considers this is a protocol deviation because we consented participants to a consent that was not approved by the PRO. DAIDS does not consider it a consent violation as the addendum was approved by the UCSF IRB. This event does not meet the UCSF IRB reporting requirements so will not be reported to them. Event will be documented with memo–to–file in ppt chart.	In the future, whenever multiple consent forms and/or consent addendums are submitted with DAIDS PRO registration, a list will be kept and registration will not be considered final until a registration notice is received for each consent form that was submitted.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
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144	Cabotegravir	Cabotegravir	US	764787865	24MAY2021	24MAY2021	No	No	Other	The participant (ppt) is one of 7 ppts who signed the V 4 ICF main addendum before it received protocol registration with DAIDS PRO and activation by study LOC. On 18May21 we received a protocol registration notice for protocol Version 4.0 listing the consent as HPTN 083/Main IC/English. We received the V4 activation notice from the HPTN 083 LOC on 19May21. We consented the ppt to the addendum at 8:30am 24May21 at an interim visit. No V4.0 procedures were done at the visit. At 10am the morning of 24May21, we received a second registration notice listing the consent as the HPTN 083/Main Addendum IC/English. While we did submit two consents (the V4 addendum and a more thorough consent for potential transfers), we did not realize the PRO would approve them separately. We received activation approval for V4 on 25May21. However, the implementation approval was also dated 24May21.	We immediately notified the HPTN 083 protocol team on 24May21. Per communication from team, DAIDS considers this is a protocol deviation because we consented participants to a consent that was not approved by the PRO. DAIDS does not consider it a consent violation as the addendum was approved by the UCSF IRB. This event does not meet the UCSF IRB reporting requirements so will not be reported to them. Event will be documented with memo–to–file in ppt chart.	In the future, whenever multiple consent forms and/or consent addendums are submitted with DAIDS PRO registration, a list will be kept and registration will not be considered final until a registration notice is received for each consent form that was submitted.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
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145	Cabotegravir	TDF/FTC	US	764975172	24MAY2021	21MAY2021	No	No	Other	The participant (ppt) is one of 7 ppts who signed the V 4 ICF main addendum before it received protocol registration with DAIDS PRO and activation by study LOC. On 18May21 we received a protocol registration notice for protocol Version 4.0 listing the consent as HPTN 083/Main IC/English. We received the V4 activation notice from the HPTN 083 LOC on 19May21. We consented the ppt to the addendum on 21May21 at an interim visit. No V4.0 procedures were done at the visit. At 10am the morning of 24May21, we received a second registration notice listing the consent as the HPTN 083/Main Addendum IC/English. While we did submit two consents (the V4 addendum and a more thorough consent for potential transfers), we did not realize the PRO would approve them separately. We received activation approval for V4 on 25May21. However, the implementation approval was also dated 24May21.	We immediately notified the HPTN 083 protocol team on 24May21. Per communication from team, DAIDS considers this is a protocol deviation because we consented participants to a consent that was not approved by the PRO. DAIDS does not consider it a consent violation as the addendum was approved by the UCSF IRB. This event does not meet the UCSF IRB reporting requirements so will not be reported to them. Event will be documented with memo–to–file in ppt chart.	In the future, whenever multiple consent forms and/or consent addendums are submitted with DAIDS PRO registration, a list will be kept and registration will not be considered final until a registration notice is received for each consent form that was submitted.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

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146	Cabotegravir	Cabotegravir	US	780210997	28FEB2022	28FEB2022	Yes	Yes	Other	Participant hospitalized with cardiac condition on Jan 16, 2022. While hospitalized, subject received two contraindicated medications, Heparin (on Jan 18, 2022) and Apixaban (on Jan 19, 2022). Medications were prescribed and administered by hospital staff – less than seven days post Cabotegravir injection on Jan 13, 2022. Cardiac condition is not related to HPTN 083 study procedures or study drug.	* Cabotagravir injection visits are discontinued. * Participant moved to step 5. * A prompt report to notify IRB. * 083PD Alias Notified * EAE submitted – EAE# 2022114185	Deviation to the protocol caused by the use of prohibited medications administered by an outside source (hospital staff). We are unable to place actions in place to prevent this incident from re–occurrence.
147	Cabotegravir	TDF/FTC	US	787552289	12JAN2022	17MAY2021	Yes	Yes	Other	A 33 year male enrolled on 6/12/2018 was randomized to the Truvada arm. He later transitioned to Cabotegravir under protocol version 4 on 05/17/2021. participant 787552289 received the prohibited medicine, Cellcept 500 mg daily, for 1 month in 5/2021 while he was started on Cabotegravir. He received oral CAB on 5/17/21 and transitioned to LA CAB 6/11/2021. Cellcept was discontinued 6/17/21.	Study Staff have been retrained on reporting systemically administered immunomodulators and a list of prohibited medications was reviewed.	Study Staff have been retrained on reporting systemically administered immunomodulators and a list of prohibited medications was reviewed.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

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148	Cabotegravir	Cabotegravir	US	819501376	01SEP2021	01SEP2021	No	No	Other	HIV rapid was not performed at this visit due to study staff oversight. Study product was dispensed without conducting the rapid test.	Study staff were re–trained on correct visit procedures for Step 4 visits.	Study staff were re–trained on correct visit procedures for Step 4 visits.
149	Cabotegravir	TDF/FTC	US	819548441	15AUG2022	15AUG2022	No	No	Other	Due to unsuccessful blood draw after multiple attempts by staff, we was not able to test for HIV & local labs required per protocol on V103.0; study drug was not dispensed.	Subject scheduled for re–draw on interim visit (V103.1) to get the missing labs test per protocol.	N/A
150	Cabotegravir	Cabotegravir	US	821348218	07SEP2022	19JUL2022	Yes	No	Other	Incorrect CASI survey completed. Selected "Step 3" Instead of "Step 4"	Will have ppt complete at next visit	Will verify correct CASI collection
151	Cabotegravir	Cabotegravir	US	821611502	07SEP2022	25JUL2022	Yes	No	Other	Incorrect CASI survey completed. Inadvertently selected "Step 3" instead of "Step 4".	Will have ppt complete at next visit.	Will verify correct CASI selection.
152	Cabotegravir	Cabotegravir	US	825519470	26MAY2021	22APR2021	No	No	Other	Wrong CASI questionnaire was completed during this visit.	Staff were reminded to use the correct CASI survey link.	Staff were reminded to double check the visit number on the casi survey.
153	Cabotegravir	Cabotegravir	US	825519470	17MAY2021	22APR2021	Yes	No	Other	The lot number for Step 2 week 97 was used for the Cabotegravir injection instead of the lot number for Step 4b day 0.	Staff are instructed to review procedures outlined on the visit checklists. A overview of the protocol deviations found and a training of the steps and procedures under the new amendment was conducted at a staff meeting on 26 May 2021.	Staff will be required to complete all protocol amendment trainings and demonstrate knowledge of steps involved in the new amendment. Hands on training will continue to be given to staff members by site coordinator and PI.
154	Cabotegravir	Cabotegravir	US	825727481	26MAY2021	20APR2021	No	No	Other	Correct CASI questionnaire was not completed	Staff were reminded to use the correct CASI link	Staff were reminded to double check the visit number on the questionnaire

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155	Cabotegravir	Cabotegravir	US	825844201	26MAY2021	06MAY2021	No	No	Other	Wrong CASI questionnaire was submitted.	Staff were reminded to use the correct CASI link.	Staff were reminded to double check visit number for CASI.

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156	Cabotegravir	TDF/FTC	US	825856687	09JUN2021	07JUN2021	Yes	No	Other	On 10–May–2021, participant came to the study site to review the revised informed consent form under protocol version 4 and opted for oral CAB, step 4a. He was started on oral CAB in step 4a. The participant reported to the study staff on 07–Jun–2021 that he experienced a seizure in January 2020 for the first time, resulting in hospitalization. The seizure was of unknown etiology, and the participant reported that he had not experienced another seizure since, and was not taking any medications related to the seizure. Study staff notified the HPTN 083 CMC on 07–Jun–2021 after reviewing the participant chart in more details. The CMC advised the site staff to contact the ppt to stop oral CAB now (since seizure history is an exclusion criterion for enrolling into HPTN 083). Due to the timing of the participant´s enrollment, he is ineligible to continue TDF/FTC on Step 5 and will be required	Site staff were advised to submit a protocol deviation form for the enrollment deviation. New York Blood Center IRB will be notified. Site staff had completed screening and enrollment procedures for this participant per protocol and per site guidelines, with use of a detailed medical eligibility screener which asks specifically about seizure history as well as other medical histories and review of systems. In addition, staff completed a medical history form and reviewed a detailed inclusion and exclusion criteria with the participant prior to enrolling into the study.	Site staff will continue to conduct screening and enrollment procedures per protocol, with use of a detailed medical eligibility screener which asks specifically about seizure history and other review of systems and pre–existing conditions, as well as a medical history form and inclusion/exclusion criteria checklist. If site staff believe that there is an inconsistent history from a participant during screening, staff will be advised to have the participant sign a medical records release form to obtain a more accurate medical history or request a letter from the participant´s healthcare provider prior to enrolling the participant into a study.

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										to terminate the study.		
157	Cabotegravir	TDF/FTC	US	825940787	26MAY2021	07MAY2021	No	No	Other	CASI OLE for visit 61 was not completed by participant.	Staff have been reminded to use the correct CASI link.	Staff have been reminded to double check that the correct visit number is selected when setting up the survey.

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158	Cabotegravir	TDF/FTC	Latin America	721126496	20SEP2022	08JUL2022	Yes	No	Other	Ppt driven protocol deviation. Enrollment:20–mar–2018.Last injection: 02–aug–2022(Visit 68.0).On 08–jul–2022, the ppt started Carbamazepine use (Initial dose: 200mg PO BID).Prescribed by the Neurologist for Synuvitis and motor impairments (Sequelae of a previously Brain Stroke).On 20–sep–2022, ppt came for Visit 69.0 (No SP injection) because we identified that he was using the prohibited medication on that date.The Neurologist advised progressive dose reduction of Carbamazepine (200mg of Carbamazepine dose reduction every 3 days) and switch to Gabapentin (300mg PO TID). Carbamazepine last dose: 25–sep–2022.Per CMC guidance on 27–sep–2022:Two weeks of separation between the last dose of Carbamazepine and restarting of CAB injection is indicated.According to this plan, the expected restart date of CAB would be 10–oct–2022.The ppt	Notification of protocol deviation to the official DAIDS protocol physician, to the 083PD team and to the 083 protocol team. Report form already completed. Notification of protocol deviation to our IRB. Prohibited medication progressive dose reduction until complete discontinuation – Start date: 20–sep–2022. End date: 25–sep–2022.	Based on the occurrence, the subinvestigator who performed the study visit on 02–aug–2022 was retrained on prohibited medication on 20–sep–2022. The other team members were also retrained in this matter on 23–sep–2022. So, The refreshment training for HPTN 083 team on prohibited medications was performed in order to to reiterate the list of prohibited medications and the importance of communicating this message to the study participants. Documentation of the refreshment training is available in our regulatory file. We have reinforced with the participant the list of prohibited medications and explained him that Carbamazepine affects the levels of Cabotegravir and the need of additional barrier protection.

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Listing 5 – Listing of Protocol Deviations [1]

# [2]	OLE Regimen Choice	Original Arm	Region	Participant ID	Site Awareness Date	Deviation Date	Reported to IRB/EC	Reported to DAIDS	Type of Deviation	Description of Deviation	Steps taken to address Deviation	Steps taken to prevent future occurrences of the Deviation
										was referred to local services for TDF/FTC as a bridge while awaiting CAB reiniciation. Scheduled to 30–sep–2022.		

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159	Cabotegravir	TDF/FTC	Latin America	721126496	07MAR2023	15FEB2023	Yes	No	Other	Use of Prohibited Medications, Carbamazepine and Phenytoin.Participant´s driven.The ppt reported on 07–mar–2023 that he had used Carbamazepine and Phenytoin (Carbamazepine 300mg PO TID from 15–feb–2023to22–feb–2023 and Phenytoin 100mg PO BID from 23–feb–2023to28–feb–2023) to control the symptoms related to previously brain stroke. Self–prescription.On 03–mar–2023 the participant came to the Neurologist and reported that he had felt an improvement in his symptoms when he used Carbamazepine.He expressed to the Neurologist the desire to return to the use of the medication and assume this decision even though he knew that, in this way, he could not remain on Cabotegravir.So, he restarted Carbamazepine by Neurologist guidance as described: Carbamazepine 600mg PO/day.Start date: 04–mar–2023. Ongoing.The	Notification of protocol deviation to the official DAIDS protocol physician, to the 083PD team and to the 083 protocol team. Report form already completed. Notification of protocol deviation to our IRB. On 15–mar–2023, CMC answered that they agreed with our plan to bring the participant back to the site as soon as possible in order to conduct a termination visit (The participant intends to remain on Carbamazepine) and also refer him to our local services for TDF/FTC. The SP was permanently discontinued on 16–mar–2023 and we conduct a termination visit and referred the participant to our local PrEP services for TDF/FTC.	N/A. The participant not plan to restart CAB–LA and was terminated.

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										Neurologist also prescribed Phenytoin for adequate progressive weaning, despite the medication no longer being used (Phenytoin 100mg PO QD.Start date:04–mar–2023. End date:10–mar–2023).		

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160	Cabotegravir	TDF/FTC	Latin America	721335790	14JUN2023	29MAY2023	Yes	No	Other	Use of off–study PrEP. The participant called the team on 20–apr–2023 reporting that he would travel to another state on 01–may–2023 by job and whished to use oral PrEP only during the period he would stay out (~ 3 months). When coming back, he intended to continue his participation on the study on long action injectable PrEP. So, on 26–apr–2023, he got PrEP (off–study) in order to cover him because he would miss his next visit scheduled during the period he stayed away. Previously injection visit: Week 72/Step 6 on 05–apr–2023. On 14–jun–2023, we contacted the participant by phone to record the PrEP use and he reported that he started using on 29–may–2023. End date: 08–nov–2023. Next injection visit proceeded on 09–nov–2023 (Week 96/Step 6) with his injection restart as scheduled. CMC was informed that the participant intended to use PrEP and that we intended to reffer him to a local PrEP	CMC was informed that the participant intended to use PrEP and that we intended to reffer him to a local PrEP service on 20–apr–2023. Next injection visit proceeded on 09–nov–2023 after TDF/FTC discontinuation.	Not applicable

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
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										service on 20–apr–2023.		

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161	Cabotegravir	Cabotegravir	Latin America	721435677	07NOV2023	01NOV2023	Yes	No	Other	Use of off–study PrEP. Previously injection visit: Week 104/Step 7 (Visit 131.0) on 27–sep–2023. On 01–nov–2023 he got PrEP off–study because he was going to travel to another city by job (Sex worker – High HIV risk) and would miss his next visit scheduled. He was referred to our Local PrEP Service in order to cover him during the period he stays away. On 07–nov–2023, we contacted the participant by phone to retrieve information about starting FTC/TDF by our clinical services (PrEP) and for adherence counseling. The participant reported having started the medication on 01–nov–2023. However, he reported that he did not travel and does not intend to do because he recently lost a family member, which changed his initial plans. So, we advised him to end oral PrEP use (Interrupted on 07–nov–2023) and to restart with his injection as scheduled. CMC informed on	We advised him to end oral PrEP use (Interrupted on 07–nov–2023) and to restart with his injection as scheduled. CMC informed on 01–nov–2023 and updated on 07–nov–2023. Next injection visit proceeded on 10–nov–2023 Week 112/Step 7 (Visit 132.0).	Not aplicable.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
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										01–nov–2023 and updated on 07–nov–2023. Next injection visit proceeded on 10–nov–2023 Week 112/Step 7 (Visit 132.0).		

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
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162	Cabotegravir	TDF/FTC	Latin America	721865987	21JUL2023	21JUL2023	Yes	No	Other	Use of off–study PrEP. The participant called the team on 14–jun–2023 reporting that he would travel to another state on 15–jun–2023 by job and whished to use oral PrEP only during the period he would stay out (~ 3 months). When coming back, he intended to continue his participation on the study on long action injectable PrEP. So, on14–jun–2023, he got PrEP (off–study) in order to cover him because he would miss his next visit scheduled during the period he stayed away. Previously injection visit: Week 88/Step 6 on 25–may–2023. On 21–jul–2023, we contacted the participant by phone to record the PrEP use and he reported that he started using on 21–jul–2023. End date: 23–aug–2023. Next injection visit proceeded on 24–aug–2023 (Week 96/Step 6) with his injection restart as scheduled. CMC was informed that the participant intended to use PrEP and that we intended to reffer him to a local PrEP	CMC was informed that the participant intended to use PrEP and that we intended to reffer him to a local PrEP service on 14–jun–2023.Next injection visit proceeded on 24–aug–2023 (Week 96/Step 6) after TDF/FTC discontinuation.	Not applicable.

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										service on 14–jun–2023.		

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163	Cabotegravir	Cabotegravir	Latin America	721988485	25JAN2023	19JAN2023	Yes	No	Other	Participant–driven protocol deviation.Use of prohibited medication.25 years old. Enrolled on 05–oct–18. Randomization arm:CAB–LA.Last injection on 18–nov–22 (Visit 71.0).Last study visit on 25–jan–23 (Visit 72.0.With no SP dispension/ administration).On 25–jan–23 the participant reported Rifapentine use (150mg – 06 pills PO qW).Start date: 19–jan–23 (Indication: Latent Tuberculosis Infection.Primare care service prescription). Household contact of newly TB diagnosed person (Pulmonary TB).The ppt is asymptomatic.PPD: 14mm on 19–jan–23.The SP was not administrated on 25–jan–23.On 25–jan–23, the ppt was referred to our local services for TDF/FTC as a bridge while awaiting CMC´s further guidance.On 06–feb–23 CMC guided us to circle back to them in April when the LTBI treatment course will be completed.We	CMC was informed on 25–jan–23. IRB will be informed. Cabotegravir was not administrated on 25–jan–23. On that same date, the participant was referred to our local services for TDF/FTC as a bridge while awaiting LTBI treatment course complete and CMC´s further guidance. The participant is on TDF/FTC by our local PrEP services. Start date: 25–jan–23.	We have reinforced with the participant the list of prohibited medications and explained him that Carbamazepine affects the levels of Cabotegravir and the need of additional barrier protection. This discussions with the participant are documented in our source.

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										have reinforced with the ppt the list of prohibited medications and explained him that Rifapentine affects the levels of CAB and the need of additional barrier protection.		
164	Cabotegravir	Cabotegravir	Latin America	850737107	20APR2022	02SEP2021	Yes	No	Other	Step 4c week 8 visit Was performed without the viral load result of step 4c day 0. The laboratory report was requested to Hospital Italiano de Buenos Aires on 26/APR/2022 (was sent that same date).	The deviation was reported to HPTN/DAIDS on 05/MAY/2022. Quality assurance team reviewed that all STEP 4C visits were performed with the result of the viral load of the last visit	N/A
165	Cabotegravir	TDF/FTC	Latin America	850921003	07DEC2021	07DEC2021	Yes	No	Other	By pill count, ppt adherence was higher than 100%, 24 pills could have been overtaken or lost between 20–SEP–21 and 07–DEC–21, although it remains unknown if the ppt took the 24 pills only within a month.	Adherence strategies were discussed with the ppt, focusing on overdose cases. The ppt was oriented in cases of forgetting the daily dose, or being unsure if a pill was overtaken, to not repeat the dose in the same day. In cases of doubts it was reiterated for ppt to contact the study team.	Adherence counseling was reviewed with pharmacist, counselor and physicians. A pill box was given to the ppt. The team will continue focus on adherence counseling on overdose situations.
166	Cabotegravir	Cabotegravir	Latin America	860154321	01SEP2023	01SEP2023	Yes	No	Other	No pre–test HIV counseling was done at visit 74	Not applicable	Team retraining

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167	Cabotegravir	TDF/FTC	Latin America	860190253	21JAN2022	21JAN2022	Yes	Yes	Other	By pill count, ppt adherence was higher than 100%, 03 pills could have been over taken or lost between 08Nov2021 and 21Jan2022, although it remains unknown if the ppt took the 3 pills only within a month.	NA due to transition for Step 4b.	NA due to transition for Step 4b.
168	Cabotegravir	Cabotegravir	Latin America	860280414	02APR2024	30MAR2024	Yes	No	Other	SAE of dengue hospitalization was reported only 6 days after the site team became aware of it	Team reorientation	Team reorientation
169	Cabotegravir	Cabotegravir	Latin America	860356238	09FEB2022	09FEB2022	Yes	Yes	Other	Participant moved to Paraguay to study medicine, our team and CMC decided to keep this participant on step 2. During vacation here in Brazil participant started use TDF/FTC (not prescribed by the study) on 20/dec/2019 to 01Mar/2020, he should came back to paraguay on march/2020. Our study team became aware on 9Feb22 that due to covid–19 pandemic and the borders was closed between Brazil and Paraguay, he decided to stay here Brazil, so he restarted TDF/FCT (not prescribed by the study) on un/mar/2020 to 09/feb/2022. He came back to CAB on 09/feb/2022.	Ppt came back to CAB and we reoriented not to use Prep outside the study and to contact the site previously start Prep.	Reoriented not to use Prep outside the study and to contact the site previously start Prep.

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170	Cabotegravir	Cabotegravir	Latin America	860663098	20SEP2023	05SEP2023	Yes	No	Other	Error in the registration of the sample registration on the laboratory system. syphilis sorology was registered instead of hiv	Participant will be scheduled for a new colletction	Team reorientation
171	Cabotegravir	Cabotegravir	Latin America	860709513	05JUN2023	01JUN2023	Yes	No	Other	On 29Mar2023 ppt came to visit 103/W24 and only 2 bottles of TDF/FTC were dispensed, as the expiration date of these bottles was 31May2023 and our imported truvada were still on its way. Our plan was to schedule him before the expiration date, but due to flow failure, the participant was only scheduled for 12Jun2023. He contacted our team on 03Jun2023 saying his pills ran out and we scheduled a visit for today. On 01Jun2023 and 02Jun2023 he took the pills that expired on 31May2023 eventhough we advised him not to take it after that date.	Participant was reoriented	The team will have neW training and we will create a CAPA
172	Cabotegravir	TDF/FTC	Latin America	860959330	26MAY2023	26MAY2023	Yes	No	Other	On 26May2023 ppt was in use of carbamazepine and received study product (cabotegravir)	Participant advised to contact psychiatrist to discontinue use of carbamazepine	The team receives new training

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173	Cabotegravir	Cabotegravir	Latin America	860990923	14DEC2022	11NOV2022	Yes	No	Other	Ppt collected sample for HIV serology, however, due to a laboratory failure this sample was not processed and therefore no result was available.	Ppt was scheduled for a new HIV serology test.	Laboratory will perform the sample receiving check with our sample transport team. In addition, they will reinforce with all teams about the sample receiving check.
174	Cabotegravir	Cabotegravir	Latin America	860990923	01SEP2023	01SEP2023	Yes	No	Other	Participant attended visit 74 and 75, received the study medication without the viral load from visit 73 being assessed by the physicim	The HIV tests were printed out and evaluated by the doctor	Team retraining

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175	Cabotegravir	TDF/FTC	Asia	858259217	23FEB2022	31JAN2022	Yes	No	Other	The Participant: MSM, 32 years old, the participant enrolled to HPTN083 study on 02 February 2018. The participant had Step 4a Day 0 visit on 26 October 2021. After that, he has not visited the site. As per protocol, participants who opted into Step 4a must complete Step 4b Day 0 and receive their first injection within 8 weeks of starting Day 0 of Step 4a. Subsequently, participant visit clinic on 17 Jan 2022 which is more than 8 weeks. Study team notified the CMC, CMC allowed us to conducted step4a week 4 once participant visit clinic and addressed this event as non–reportable protocol deviation. On that occasion, study team completed non–reportable protocol deviation submission to IRB, but now we have 5 participants that involved in trend of same the protocol deviation, we will update this circumstance as reportable protocol deviation for each individual PTID,	1. Study staff report the event to CMC for further management 2. Plan to submit the protocol deviation to local IRB as soon as possible.	1. Study staff will review process of participant tracking schedule with care and counseling staff. 2. Study staff will pay close attention to the Schedule of Evaluations and the allowable window for follow–up visits. . Study staff will be working hard for retention and will contact the participant to come to follow–up visit in SOE.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_deviation.sas, SAS Version 9.4 (04MAR2026,6:09)

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# [2]	OLE Regimen Choice	Original Arm	Region	Participant ID	Site Awareness Date	Deviation Date	Reported to IRB/EC	Reported to DAIDS	Type of Deviation	Description of Deviation	Steps taken to address Deviation	Steps taken to prevent future occurrences of the Deviation
										another impacted PTIDs are listed below. – 858975261 – 858280274 – 858480340 – 858724612		

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_deviation.sas, SAS Version 9.4 (04MAR2026,6:09)

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# [2]	OLE Regimen Choice	Original Arm	Region	Participant ID	Site Awareness Date	Deviation Date	Reported to IRB/EC	Reported to DAIDS	Type of Deviation	Description of Deviation	Steps taken to address Deviation	Steps taken to prevent future occurrences of the Deviation
176	Cabotegravir	TDF/FTC	Asia	858280274	23FEB2022	07DEC2021	Yes	No	Other	The Participant: TGW, 35 years old, the participant enrolled to HPTN083 study on 05 Feb 2018. The participant had conducted Step 4a Day 0 visit on 11 Oct 2021. After that, she come to follow–up Step4a week4 on 16 Nov 2021 then visited Step4b day0 for first injection under protocol version 4.0 on 20 Dec 2021 which is 10 weeks from Step4a day0. Reason for this late injection is about COVID–19 pandemic, participant could not come to follow–up visit as per protocol. As stated in protocol, participants who opted into Step 4a must complete Step 4b Day 0 and receive their first injection within 8 weeks of starting Day 0 of Step 4a. Basically, this circumstance is non–reportable protocol deviation. However, this protocol specific procedure is not followed by site staff involved 5 participants, these circumstances presented trend deviation. Thus, this event needs to report as reportable deviation, another	1. Study staff report the event to CMC for further management 2. Site will report this deviation into eCRF system . Site will report this deviation to HPTN083 protocol deviation email alias 4. Plan to submit the protocol deviation to local IRB as soon as possible	1. Study staff will review process of participant tracking schedule with care and counseling staff. 2. Study staff will pay close attention to the Schedule of Evaluations and the allowable window for follow–up visits . Study staff will be working hard for retention and will contact the participant to come to follow–up visit in SOE . Re–Training schedule as per protocol requirement follow SOE

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_deviation.sas, SAS Version 9.4 (04MAR2026,6:09)

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										impacted PTIDs are listed below. – 858975261 – 858480340 – 858724612 – 858259217		

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_deviation.sas, SAS Version 9.4 (04MAR2026,6:09)

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177	Cabotegravir	TDF/FTC	Asia	858480340	23FEB2022	07DEC2021	Yes	No	Other	The Participant: MSM, 38 years old, the participant enrolled to HPTN083 study on 08 Feb 2018. The participant had conducted Step 4a Day 0 visit on 12 Oct 2021. After that, he come to follow–up Step4a week4 on 16 Nov 2021 then visited Step4b day0 for first injection under protocol version 4.0 on 14 Dec 2021 which is 9 weeks from Step4a day0. Reason for this late injection is about COVID–19 pandemic, participant could not visit as per protocol. As stated in protocol, participants who opted into Step 4a must complete Step 4b Day 0 and receive their first injection within 8 weeks of starting Day 0 of Step 4a. Basically, this circumstance is non–reportable protocol deviation. However, this protocol specific procedure is not followed by site staff involved 5 participants, these circumstances presented trend deviation. Thus, this event needs to report as reportable deviation, another impacted PTIDs are	1. Study staff report the event to CMC for further management 2. Site will report this deviation into eCRF system . Site will report this deviation to HPTN083 protocol deviation email alias 4. Plan to submit the protocol deviation to local IRB as soon as possible	1. Study staff will review process of participant tracking schedule with care and counseling staff. 2. Study staff will pay close attention to the Schedule of Evaluations and the allowable window for follow–up visits . Study staff will be working hard for retention and will contact the participant to come to follow–up visit in SOE . Re–Training schedule as per protocol requirement follow SOE

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_deviation.sas, SAS Version 9.4 (04MAR2026,6:09)

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										listed below. – 858975261 – 858280274 – 858724612 – 858259217		

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_deviation.sas, SAS Version 9.4 (04MAR2026,6:09)

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178	Cabotegravir	TDF/FTC	Asia	858724612	23FEB2022	03NOV2021	Yes	No	Other	The Participant: MSM, 26 years old, the participant enrolled to HPTN083 study on 09 April 2018. The participant had conducted Step 4a Day 0 visit on 08 September 2021. After that, he come to follow–up Step4a week4 on 04 October 2021 then visited Step4b day0 for first injection under protocol version 4.0 on 10 November 2021 which is 9 weeks from Step4a day0. Reason for this late injection is about COVID–19 pandemic, participant could not come to follow–up visit as per protocol. As stated in protocol, participants who opted into Step 4a must complete Step 4b Day 0 and receive their first injection within 8 weeks of starting Day 0 of Step 4a. Basically, this circumstance is non–reportable protocol deviation. However, this protocol specific procedure is not followed by site staff involved 5 participants, these circumstances presented trend deviation.	1. Study staff report the event to CMC for further management 2. Site will report this deviation into eCRF system . Site will report this deviation to HPTN083 protocol deviation email alias 4. Plan to submit the protocol deviation to local IRB as soon as possible	1. Study staff will review process of participant tracking schedule with care and counseling staff. 2. Study staff will pay close attention to the Schedule of Evaluations and the allowable window for follow–up visits. . Study staff will be working hard for retention and will contact the participant to come to follow–up visit in SOE. . Re–Training schedule as per protocol requirement follow SOE.

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_deviation.sas, SAS Version 9.4 (04MAR2026,6:09)

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179	Cabotegravir	TDF/FTC	Asia	858975261	23FEB2022	13OCT2021	Yes	No	Other	Participant: TGW, 29 years old, participant enrolled in HPTN083 and started taking study product on 15 June 2018. This participant is going to have a late visit. Details are as followed: Last visit: Step 4a Day 0 on 18 AUG 2021 On January 27, 2022, we notified the CMC of the issue. CMC allowed us to conducted step4B Day 0 and record step 4a week 4 as missed visit once participant visit clinic. Basically, this circumstance is non–reportable protocol deviation. However, this protocol specific procedure is not followed by site staff involved 5 participants, these circumstances presented trend deviation. Thus, this event needs to report as reportable deviation and capture to eCRF (Medidata) for each individual PTID, another impacted PTIDs are listed below. – 858280274 – 858480340 – 858724612 – 858259217	1. Study staff report the event to CMC for further management 2. Site will report this deviation into eCRF system . Site will report this deviation to HPTN083 protocol deviation email alias 4. Plan to submit the protocol deviation to local IRB as soon as possible	1. Study staff will review process of participant tracking schedule with care and counseling staff 2. Study staff will pay close attention to the Schedule of Evaluations and the allowable window for follow–up visits . Study staff will be working hard for retention and will contact the participant to come to follow–up visit in SOE . Re–Training schedule as per protocol requirement follow SOE

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_deviation.sas, SAS Version 9.4 (04MAR2026,6:09)

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180	Cabotegravir	TDF/FTC	Africa	816115972	16NOV2022	14MAR2022	Yes	Yes	Other	Participant failed to report that he was on TB Treatment	Reported to CMC and DAIDS	Counselled Participant on reporting all Concomitant Medication use

[1] Included participants who chose CAB or TDF/FTC as the OLE regimen. Included protocol deviation reported by sites for both study participants and dummy participants which are for the purpose of reporting site level events.
[2] This listing is sorted by OLE regimen choice, deviation type, region and PTID.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/l_ole_deviation.sas, SAS Version 9.4 (04MAR2026,6:09)

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Table 11 – Adverse Experiences [1] by System Organ Class and OLE Regimen Choice, sorted by Decreasing Frequency

	Overall [2] N = 2658		TDF/FTC N = 107		Cabotegravir N = 2495	
System Organ Class	**n [3]**	**Proportion [4]**	**n**	**Proportion**	**n**	**Proportion**
Infections and infestations	1714	64.48%	58	54.21%	1641	65.77%
Investigations [5]	1188	44.70%	38	35.51%	1131	45.33%
Gastrointestinal disorders	371	13.96%	11	10.28%	356	14.27%
Injury, poisoning and procedural complications	282	10.61%	10	9.35%	269	10.78%
Psychiatric disorders	185	6.96%	5	4.67%	177	7.09%
Musculoskeletal and connective tissue disorders	175	6.58%	4	3.74%	170	6.81%
Skin and subcutaneous tissue disorders	162	6.09%	5	4.67%	157	6.29%
General disorders and administration site conditions	154	5.79%	3	2.80%	148	5.93%
Nervous system disorders	141	5.30%	5	4.67%	136	5.45%
Respiratory, thoracic and mediastinal disorders	128	4.82%	5	4.67%	122	4.89%
Metabolism and nutrition disorders	79	2.97%	3	2.80%	76	3.05%
Vascular disorders	72	2.71%	1	0.93%	70	2.81%
Renal and urinary disorders	70	2.63%	2	1.87%	67	2.69%
Reproductive system and breast disorders	62	2.33%	2	1.87%	60	2.40%
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	29	1.09%	0	–	29	1.16%
Eye disorders	28	1.05%	1	0.93%	27	1.08%
Cardiac disorders	23	0.87%	0	–	23	0.92%
Immune system disorders	18	0.68%	0	–	18	0.72%
Ear and labyrinth disorders	15	0.56%	0	–	14	0.56%
Blood and lymphatic system disorders	13	0.49%	0	–	13	0.52%
Hepatobiliary disorders	13	0.49%	0	–	13	0.52%
Endocrine disorders	5	0.19%	0	–	5	0.20%
Social circumstances	4	0.15%	0	–	4	0.16%
Congenital, familial and genetic disorders	2	0.08%	0	–	2	0.08%

[1] This table includes only those AEs which have been assigned MedDRA codes by clinical staff. Participants with OLE regimen choice missing are excluded.
[2] Includes all participants participating in OLE phase (CAB, TDF/FTC, Seroconverter Schedule and Open Label Truvada Schedule).
[3] The number of participants reporting one or more AEs within a specific system organ class.
[4] Proportion is the number of participants (n) experiencing one or more Adverse Experience in the named System Organ Class. Proportion is calculated as 100 x n divided by the number enrolled.
[5] According to the protocol, Grade 1 laboratory AEs are not to be reported unless they led to product discontinuation. The majority of Grade 1 lab AEs reported here were reported in error, and do not reflect the true number of Grade 1 lab AEs experienced in this study.

Source: SCHARP (Anusha) – /trials/hptn/p083/analysis/live/code/ole/t_ole_ae_freq_byarm.sas, SAS Version 9.4 (04MAR2026,6:09)

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Table 12 – Adverse Experiences [1] by System Organ Class/Preferred Term by OLE Regimen Choice

	Overall [2]	TDF/FTC	Cabotegravir
Number of Participants Enrolled in OLE	2658	107	2495
Number of Participants with AEs [3]	2219/2658 (83.48%)	74/107 (69.16%)	2114/2495 (84.72%)
Blood and lymphatic system disorders	**13/2658 (0.48%)**	**0/107 (0.00%)**	**13/2495 (0.52%)**
Anaemia	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Iron deficiency anaemia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Lymphadenitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Lymphadenopathy	8/2658 (0.30%)	0/107 (0.00%)	8/2495 (0.32%)
Normocytic anaemia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Cardiac disorders	**22/2658 (0.82%)**	**0/107 (0.00%)**	**22/2495 (0.88%)**
Acute myocardial infarction	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Angina pectoris	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Aortic valve stenosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Arrhythmia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Atrial fibrillation	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Bradycardia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Cardiac failure acute	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Cardiomegaly	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Coronary artery disease	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Heart valve stenosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Myocardial infarction	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Myocarditis	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Palpitations	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Tachycardia	8/2658 (0.30%)	0/107 (0.00%)	8/2495 (0.32%)
Congenital, familial and genetic disorders	**2/2658 (0.08%)**	**0/107 (0.00%)**	**2/2495 (0.08%)**
Hydrocele	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Phimosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Ear and labyrinth disorders	**12/2658 (0.46%)**	**0/107 (0.00%)**	**12/2495 (0.48%)**
Cerumen impaction	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Deafness unilateral	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Ear pain	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Eustachian tube dysfunction	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hypoacusis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Tinnitus	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Vertigo	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)

[1] This table includes only those AEs which have been assigned MedDRA codes by clinical staff. Participants with OLE regimen choice missing are excluded.
[2] Include all participants participating in OLE phase (CAB, TDF/FTC, seroconverter schedule and open label Truvada schedule).
[3] For participants reporting multiple events with the same MedDRA term, only one is counted. Percentages are calculated as the number of participants (n) reporting an event divided by the number enrolled by OLE regimen choice.
[4] According to the protocol, Grade 1 laboratory AEs are not to be reported unless they led to product discontinuation. The majority of Grade 1 lab AEs reported here were reported in error, and do not reflect the true number of Grade 1 lab AEs experienced in this study.
Source: SCHARP (Haima) – /trials/hptn/p083/analysis/live/code/ole/t_ole_ae_overall_byarm.sas, SAS Version 9.4 (04MAR2026,6:09)

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Table 12 – Adverse Experiences [1] by System Organ Class/Preferred Term by OLE Regimen Choice

	Overall [2]	TDF/FTC	Cabotegravir
Endocrine disorders	**4/2658 (0.16%)**	**0/107 (0.00%)**	**4/2495 (0.16%)**
Hypogonadism	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Hypothyroidism	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Thyroid mass	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Eye disorders	**26/2658 (0.98%)**	**1/107 (0.94%)**	**25/2495 (1.00%)**
Astigmatism	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Blepharitis	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Cataract nuclear	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Chalazion	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Conjunctival haemorrhage	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Conjunctival suffusion	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Conjunctivitis allergic	4/2658 (0.16%)	1/107 (0.94%)	3/2495 (0.12%)
Diplopia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Dry eye	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Eye irritation	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Eye pruritus	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Eye swelling	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Keratitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Lacrimal cyst	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Myopia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Pterygium	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Retinal tear	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Scleral haemorrhage	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Uveitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Vision blurred	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Visual impairment	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Gastrointestinal disorders	**332/2658 (12.50%)**	**10/107 (9.34%)**	**319/2495 (12.78%)**
Abdominal discomfort	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Abdominal pain	13/2658 (0.48%)	1/107 (0.94%)	12/2495 (0.48%)
Abdominal pain lower	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Abdominal pain upper	9/2658 (0.34%)	0/107 (0.00%)	9/2495 (0.36%)
Anal fissure	17/2658 (0.64%)	0/107 (0.00%)	17/2495 (0.68%)
Anal fistula	5/2658 (0.18%)	0/107 (0.00%)	5/2495 (0.20%)
Anal pruritus	7/2658 (0.26%)	0/107 (0.00%)	7/2495 (0.28%)
Anal rash	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)

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	Overall [2]	TDF/FTC	Cabotegravir
Anal ulcer	8/2658 (0.30%)	0/107 (0.00%)	8/2495 (0.32%)
Anogenital dysplasia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Anorectal discomfort	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Aphthous ulcer	5/2658 (0.18%)	0/107 (0.00%)	5/2495 (0.20%)
Cheilitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Chronic gastritis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Colitis	4/2658 (0.16%)	1/107 (0.94%)	3/2495 (0.12%)
Constipation	12/2658 (0.46%)	1/107 (0.94%)	11/2495 (0.44%)
Dental caries	9/2658 (0.34%)	0/107 (0.00%)	9/2495 (0.36%)
Diarrhoea	77/2658 (2.90%)	1/107 (0.94%)	75/2495 (3.00%)
Diverticulum intestinal	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Duodenitis	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Dyspepsia	13/2658 (0.48%)	0/107 (0.00%)	13/2495 (0.52%)
Dysphagia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Food poisoning	13/2658 (0.48%)	0/107 (0.00%)	13/2495 (0.52%)
Gastric polyps	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Gastric ulcer	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Gastritis	18/2658 (0.68%)	1/107 (0.94%)	17/2495 (0.68%)
Gastrooesophageal reflux disease	12/2658 (0.46%)	0/107 (0.00%)	12/2495 (0.48%)
Haematochezia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Haemorrhoids	29/2658 (1.10%)	2/107 (1.86%)	25/2495 (1.00%)
Haemorrhoids thrombosed	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Inguinal hernia	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Intestinal obstruction	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Irritable bowel syndrome	3/2658 (0.12%)	1/107 (0.94%)	2/2495 (0.08%)
Lip oedema	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Loose tooth	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Mouth ulceration	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Nausea	20/2658 (0.76%)	1/107 (0.94%)	19/2495 (0.76%)
Odynophagia	9/2658 (0.34%)	0/107 (0.00%)	9/2495 (0.36%)
Oesophagitis	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Oral pain	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Pancreatitis	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Proctalgia	8/2658 (0.30%)	1/107 (0.94%)	7/2495 (0.28%)
Proctitis	26/2658 (0.98%)	2/107 (1.86%)	24/2495 (0.96%)

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	Overall [2]	TDF/FTC	Cabotegravir
Rectal discharge	5/2658 (0.18%)	0/107 (0.00%)	5/2495 (0.20%)
Rectal haemorrhage	10/2658 (0.38%)	0/107 (0.00%)	10/2495 (0.40%)
Rectal ulcer	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Salivary hypersecretion	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Stomatitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Tongue coated	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Tongue discomfort	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Tooth impacted	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Toothache	20/2658 (0.76%)	0/107 (0.00%)	20/2495 (0.80%)
Umbilical hernia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Vomiting	7/2658 (0.26%)	1/107 (0.94%)	6/2495 (0.24%)
General disorders and administration site conditions	**150/2658 (5.64%)**	**3/107 (2.80%)**	**144/2495 (5.78%)**
Application site nodule	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Application site pain	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Asthenia	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Chest discomfort	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Chest pain	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Chills	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Cyst	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Drug withdrawal syndrome	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Facial pain	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Fatigue	20/2658 (0.76%)	1/107 (0.94%)	19/2495 (0.76%)
Granuloma	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Influenza like illness	16/2658 (0.60%)	1/107 (0.94%)	14/2495 (0.56%)
Malaise	11/2658 (0.42%)	0/107 (0.00%)	11/2495 (0.44%)
Mass	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Medical device pain	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Nodule	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Non–cardiac chest pain	6/2658 (0.22%)	0/107 (0.00%)	5/2495 (0.20%)
Oedema peripheral	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Pain	6/2658 (0.22%)	0/107 (0.00%)	6/2495 (0.24%)
Peripheral swelling	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Puncture site pain	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Pyrexia	59/2658 (2.22%)	0/107 (0.00%)	59/2495 (2.36%)
Sensation of foreign body	1/2658 (0.04%)	0/107 (0.00%)	0/2495 (0.00%)

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	Overall [2]	TDF/FTC	Cabotegravir
Swelling	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Ulcer	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Vaccination site pain	16/2658 (0.60%)	1/107 (0.94%)	15/2495 (0.60%)
Hepatobiliary disorders	**12/2658 (0.46%)**	**0/107 (0.00%)**	**12/2495 (0.48%)**
Cholecystitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Cholecystitis acute	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Cholecystitis chronic	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Cholelithiasis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Gallbladder polyp	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Hepatic steatosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hepatitis acute	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hyperbilirubinaemia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hypertransaminasaemia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Metabolic dysfunction–associated liver disease	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Immune system disorders	**17/2658 (0.64%)**	**0/107 (0.00%)**	**17/2495 (0.68%)**
Allergy to animal	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Anaphylactic reaction	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Drug hypersensitivity	6/2658 (0.22%)	0/107 (0.00%)	6/2495 (0.24%)
Hypersensitivity	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Jarisch–Herxheimer reaction	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Seasonal allergy	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Infections and infestations	**1692/2658 (63.66%)**	**57/107 (53.28%)**	**1620/2495 (64.92%)**
Abscess	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Abscess limb	5/2658 (0.18%)	0/107 (0.00%)	5/2495 (0.20%)
Abscess neck	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Abscess oral	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Acute hepatitis B	2/2658 (0.08%)	1/107 (0.94%)	1/2495 (0.04%)
Acute hepatitis C	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Acute sinusitis	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Anal abscess	12/2658 (0.46%)	1/107 (0.94%)	11/2495 (0.44%)
Anal chlamydia infection	417/2658 (15.68%)	10/107 (9.34%)	407/2495 (16.32%)
Anal fistula infection	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Anal infection	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Anorectal cellulitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Anorectal herpes	6/2658 (0.22%)	0/107 (0.00%)	6/2495 (0.24%)

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	Overall [2]	TDF/FTC	Cabotegravir
Anorectal human papilloma virus infection	10/2658 (0.38%)	0/107 (0.00%)	10/2495 (0.40%)
Anorectal infection	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Appendicitis	7/2658 (0.26%)	0/107 (0.00%)	7/2495 (0.28%)
Application site abscess	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Bacterial diarrhoea	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Bacterial urethritis	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Balanitis candida	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Body tinea	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Bronchitis	19/2658 (0.72%)	2/107 (1.86%)	17/2495 (0.68%)
Bronchopulmonary aspergillosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
COVID–19	434/2658 (16.32%)	11/107 (10.28%)	420/2495 (16.84%)
Candida infection	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Carbuncle	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Cellulitis	6/2658 (0.22%)	1/107 (0.94%)	5/2495 (0.20%)
Chlamydial infection	69/2658 (2.60%)	1/107 (0.94%)	67/2495 (2.68%)
Chronic sinusitis	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Complicated appendicitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Conjunctivitis	15/2658 (0.56%)	1/107 (0.94%)	14/2495 (0.56%)
Conjunctivitis bacterial	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Conjunctivitis viral	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Cystitis	3/2658 (0.12%)	1/107 (0.94%)	2/2495 (0.08%)
Dengue fever	9/2658 (0.34%)	0/107 (0.00%)	9/2495 (0.36%)
Dermatophytosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Dermatophytosis of nail	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Diverticulitis	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Ear infection	8/2658 (0.30%)	0/107 (0.00%)	8/2495 (0.32%)
Ear lobe infection	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Empyema	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Epididymitis	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
External ear cellulitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Eye infection syphilitic	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Febrile infection	4/2658 (0.16%)	1/107 (0.94%)	3/2495 (0.12%)
Folliculitis	13/2658 (0.48%)	0/107 (0.00%)	12/2495 (0.48%)
Folliculitis genital	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Fournier's gangrene	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)

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Fungal balanitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Fungal foot infection	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Fungal skin infection	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Furuncle	17/2658 (0.64%)	1/107 (0.94%)	16/2495 (0.64%)
Gastroenteritis	33/2658 (1.24%)	0/107 (0.00%)	32/2495 (1.28%)
Gastroenteritis bacterial	5/2658 (0.18%)	0/107 (0.00%)	5/2495 (0.20%)
Gastroenteritis viral	5/2658 (0.18%)	0/107 (0.00%)	5/2495 (0.20%)
Gastrointestinal infection	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Gastrointestinal viral infection	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Genital candidiasis	5/2658 (0.18%)	1/107 (0.94%)	4/2495 (0.16%)
Genital herpes	25/2658 (0.94%)	0/107 (0.00%)	25/2495 (1.00%)
Genital herpes simplex	18/2658 (0.68%)	0/107 (0.00%)	18/2495 (0.72%)
Genital ulcer syndrome	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Genitourinary chlamydia infection	36/2658 (1.36%)	2/107 (1.86%)	34/2495 (1.36%)
Genitourinary tract gonococcal infection	19/2658 (0.72%)	0/107 (0.00%)	19/2495 (0.76%)
Genitourinary tract infection	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Giardiasis	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Gingivitis	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Gonococcal infection	6/2658 (0.22%)	0/107 (0.00%)	6/2495 (0.24%)
Gonorrhoea	38/2658 (1.42%)	1/107 (0.94%)	37/2495 (1.48%)
Groin abscess	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Helicobacter infection	5/2658 (0.18%)	0/107 (0.00%)	5/2495 (0.20%)
Hepatitis A	7/2658 (0.26%)	0/107 (0.00%)	7/2495 (0.28%)
Hepatitis B	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hepatitis C	15/2658 (0.56%)	1/107 (0.94%)	14/2495 (0.56%)
Hepatitis E	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Herpes simplex	12/2658 (0.46%)	1/107 (0.94%)	11/2495 (0.44%)
Herpes simplex anorectal	5/2658 (0.18%)	0/107 (0.00%)	5/2495 (0.20%)
Herpes virus infection	4/2658 (0.16%)	1/107 (0.94%)	3/2495 (0.12%)
Herpes zoster	8/2658 (0.30%)	0/107 (0.00%)	8/2495 (0.32%)
Herpes zoster oticus	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hordeolum	13/2658 (0.48%)	1/107 (0.94%)	12/2495 (0.48%)
Impetigo	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Infected bite	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Influenza	54/2658 (2.04%)	1/107 (0.94%)	53/2495 (2.12%)

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Table 12 – Adverse Experiences [1] by System Organ Class/Preferred Term by OLE Regimen Choice

	Overall [2]	TDF/FTC	Cabotegravir
Labyrinthitis	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Large intestine infection	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Laryngitis	3/2658 (0.12%)	1/107 (0.94%)	2/2495 (0.08%)
Laryngopharyngitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Latent syphilis	152/2658 (5.72%)	8/107 (7.48%)	144/2495 (5.78%)
Lice infestation	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Localised infection	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Lower respiratory tract infection	4/2658 (0.16%)	0/107 (0.00%)	3/2495 (0.12%)
Lung abscess	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Lyme disease	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Lymph node tuberculosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Lymphadenitis viral	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Lymphogranuloma venereum	6/2658 (0.22%)	1/107 (0.94%)	5/2495 (0.20%)
Mastitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Molluscum contagiosum	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Monkeypox	59/2658 (2.22%)	3/107 (2.80%)	55/2495 (2.20%)
Mycoplasma genitalium infection	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Nail infection	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Nasopharyngitis	84/2658 (3.16%)	3/107 (2.80%)	81/2495 (3.24%)
Necrotising fasciitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Norovirus infection	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Oesophageal infection	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Onychomycosis	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Oral candidiasis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Oral herpes	11/2658 (0.42%)	0/107 (0.00%)	11/2495 (0.44%)
Orchitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Oropharyngeal gonococcal infection	18/2658 (0.68%)	0/107 (0.00%)	17/2495 (0.68%)
Otitis externa	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Otitis media	12/2658 (0.46%)	0/107 (0.00%)	12/2495 (0.48%)
Otitis media acute	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Overgrowth fungal	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Papilloma viral infection	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Parainfluenzae virus infection	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Parasitic gastroenteritis	3/2658 (0.12%)	1/107 (0.94%)	2/2495 (0.08%)
Paronychia	6/2658 (0.22%)	0/107 (0.00%)	6/2495 (0.24%)

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	Overall [2]	TDF/FTC	Cabotegravir
Pericoronitis	1/2658 (0.04%)	1/107 (0.94%)	0/2495 (0.00%)
Perineal abscess	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Periodontitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Perirectal abscess	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Peritonsillar abscess	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Pharyngeal chlamydia infection	8/2658 (0.30%)	0/107 (0.00%)	8/2495 (0.32%)
Pharyngitis	44/2658 (1.66%)	2/107 (1.86%)	42/2495 (1.68%)
Pharyngitis bacterial	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Pharyngitis streptococcal	17/2658 (0.64%)	0/107 (0.00%)	17/2495 (0.68%)
Pharyngotonsillitis	6/2658 (0.22%)	0/107 (0.00%)	6/2495 (0.24%)
Pneumonia	8/2658 (0.30%)	1/107 (0.94%)	7/2495 (0.28%)
Pneumonia bacterial	4/2658 (0.16%)	1/107 (0.94%)	3/2495 (0.12%)
Postoperative wound infection	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Primary syphilis	25/2658 (0.94%)	1/107 (0.94%)	23/2495 (0.92%)
Proctitis bacterial	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Proctitis chlamydial	119/2658 (4.48%)	4/107 (3.74%)	114/2495 (4.56%)
Proctitis gonococcal	429/2658 (16.14%)	6/107 (5.60%)	420/2495 (16.84%)
Pulmonary tuberculosis	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Pulpitis dental	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Pyelonephritis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Pyelonephritis acute	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Respiratory tract infection	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Respiratory tract infection viral	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Rhinitis	10/2658 (0.38%)	0/107 (0.00%)	10/2495 (0.40%)
Salmonellosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Scabies	11/2658 (0.42%)	0/107 (0.00%)	11/2495 (0.44%)
Secondary syphilis	21/2658 (0.80%)	1/107 (0.94%)	20/2495 (0.80%)
Sepsis	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Septic shock	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Sexually transmitted disease	7/2658 (0.26%)	1/107 (0.94%)	6/2495 (0.24%)
Sexually transmitted disease carrier	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Shigella infection	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Sinusitis	24/2658 (0.90%)	1/107 (0.94%)	23/2495 (0.92%)
Sinusitis bacterial	8/2658 (0.30%)	0/107 (0.00%)	8/2495 (0.32%)
Skin infection	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)

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	Overall [2]	TDF/FTC	Cabotegravir
Soft tissue infection	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Staphylococcal infection	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Subcutaneous abscess	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Syphilis	396/2658 (14.90%)	11/107 (10.28%)	381/2495 (15.28%)
Syphilis anal	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Syphilis genital	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Tinea cruris	11/2658 (0.42%)	0/107 (0.00%)	11/2495 (0.44%)
Tinea infection	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Tinea pedis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Tinea versicolour	9/2658 (0.34%)	0/107 (0.00%)	9/2495 (0.36%)
Tonsillitis	36/2658 (1.36%)	1/107 (0.94%)	35/2495 (1.40%)
Tonsillitis bacterial	11/2658 (0.42%)	0/107 (0.00%)	11/2495 (0.44%)
Tonsillitis streptococcal	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Tooth abscess	5/2658 (0.18%)	0/107 (0.00%)	5/2495 (0.20%)
Tooth infection	9/2658 (0.34%)	0/107 (0.00%)	9/2495 (0.36%)
Toxoplasmosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Upper respiratory tract infection	131/2658 (4.92%)	10/107 (9.34%)	120/2495 (4.80%)
Urethritis	93/2658 (3.50%)	4/107 (3.74%)	88/2495 (3.52%)
Urethritis chlamydial	92/2658 (3.46%)	1/107 (0.94%)	91/2495 (3.64%)
Urethritis gonococcal	77/2658 (2.90%)	2/107 (1.86%)	75/2495 (3.00%)
Urinary tract infection	21/2658 (0.80%)	1/107 (0.94%)	20/2495 (0.80%)
Varicella	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Viral diarrhoea	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Viral infection	17/2658 (0.64%)	0/107 (0.00%)	17/2495 (0.68%)
Viral pharyngitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Viral rhinitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Viral upper respiratory tract infection	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Wound infection	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Injury, poisoning and procedural complications	**271/2658 (10.20%)**	**10/107 (9.34%)**	**258/2495 (10.34%)**
Anal injury	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Animal bite	7/2658 (0.26%)	0/107 (0.00%)	7/2495 (0.28%)
Animal scratch	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Ankle fracture	3/2658 (0.12%)	1/107 (0.94%)	2/2495 (0.08%)
Arthropod bite	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Arthropod sting	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)

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	Overall [2]	TDF/FTC	Cabotegravir
Back injury	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Bone contusion	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Burns second degree	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Buttock injury	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Chemical burn of skin	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Chemical poisoning	1/2658 (0.04%)	1/107 (0.94%)	0/2495 (0.00%)
Chest injury	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Clavicle fracture	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Contusion	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Corneal abrasion	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Craniocerebral injury	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Craniofacial fracture	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Dislocation of sternum	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Epicondylitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Exposure to communicable disease	11/2658 (0.42%)	1/107 (0.94%)	10/2495 (0.40%)
Eye injury	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Face injury	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Foot fracture	7/2658 (0.26%)	0/107 (0.00%)	7/2495 (0.28%)
Foreign body in eye	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Genital injury	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hand fracture	8/2658 (0.30%)	0/107 (0.00%)	8/2495 (0.32%)
Head injury	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Human bite	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Humerus fracture	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Immunisation reaction	55/2658 (2.06%)	1/107 (0.94%)	54/2495 (2.16%)
Joint dislocation	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Joint injury	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Ligament injury	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Ligament rupture	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Ligament sprain	19/2658 (0.72%)	1/107 (0.94%)	18/2495 (0.72%)
Limb crushing injury	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Limb injury	15/2658 (0.56%)	0/107 (0.00%)	14/2495 (0.56%)
Lower limb fracture	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Meniscus injury	4/2658 (0.16%)	1/107 (0.94%)	3/2495 (0.12%)
Mouth injury	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)

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	Overall [2]	TDF/FTC	Cabotegravir
Multiple injuries	7/2658 (0.26%)	0/107 (0.00%)	7/2495 (0.28%)
Muscle injury	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Muscle strain	14/2658 (0.52%)	0/107 (0.00%)	14/2495 (0.56%)
Nail injury	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Nasal injury	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Overdose	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Pelvic fracture	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Penis injury	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Periorbital haematoma	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Periorbital haemorrhage	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Post lumbar puncture syndrome	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Post procedural complication	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Post procedural discomfort	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Post procedural erythema	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Post procedural fever	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Post procedural hypothyroidism	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Post procedural swelling	4/2658 (0.16%)	1/107 (0.94%)	3/2495 (0.12%)
Post vaccination syndrome	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Procedural headache	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Procedural pain	35/2658 (1.32%)	2/107 (1.86%)	32/2495 (1.28%)
Radius fracture	5/2658 (0.18%)	0/107 (0.00%)	5/2495 (0.20%)
Rib fracture	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Scar	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Seroma	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Skin abrasion	14/2658 (0.52%)	1/107 (0.94%)	13/2495 (0.52%)
Skin laceration	23/2658 (0.86%)	0/107 (0.00%)	22/2495 (0.88%)
Soft tissue injury	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Spinal column injury	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Spinal fracture	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Tendon injury	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Thermal burn	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Tibia fracture	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Tooth fracture	5/2658 (0.18%)	1/107 (0.94%)	4/2495 (0.16%)
Toxicity to various agents	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Traumatic pain	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)

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	Overall [2]	TDF/FTC	Cabotegravir
Upper limb fracture	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Wound	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Wrist fracture	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Investigations [4]	**1187/2658 (44.66%)**	**38/107 (35.52%)**	**1130/2495 (45.30%)**
Alanine aminotransferase increased	83/2658 (3.12%)	4/107 (3.74%)	79/2495 (3.16%)
Amylase increased	2/2658 (0.08%)	1/107 (0.94%)	1/2495 (0.04%)
Aspartate aminotransferase increased	69/2658 (2.60%)	5/107 (4.68%)	64/2495 (2.56%)
Blood albumin decreased	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Blood alkaline phosphatase increased	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Blood bilirubin increased	49/2658 (1.84%)	2/107 (1.86%)	45/2495 (1.80%)
Blood cholesterol increased	5/2658 (0.18%)	0/107 (0.00%)	5/2495 (0.20%)
Blood creatine increased	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Blood creatine phosphokinase increased	6/2658 (0.22%)	0/107 (0.00%)	6/2495 (0.24%)
Blood creatinine decreased	8/2658 (0.30%)	0/107 (0.00%)	8/2495 (0.32%)
Blood creatinine increased	245/2658 (9.22%)	6/107 (5.60%)	231/2495 (9.26%)
Blood glucose decreased	3/2658 (0.12%)	1/107 (0.94%)	2/2495 (0.08%)
Blood glucose increased	10/2658 (0.38%)	0/107 (0.00%)	10/2495 (0.40%)
Blood pressure diastolic increased	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Blood pressure increased	54/2658 (2.04%)	0/107 (0.00%)	54/2495 (2.16%)
Blood pressure systolic increased	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Blood prolactin increased	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Blood sodium increased	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Blood testosterone decreased	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Blood triglycerides increased	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Blood urine present	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Cardiac murmur	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Creatinine renal clearance decreased	956/2658 (35.96%)	28/107 (26.16%)	913/2495 (36.60%)
Creatinine renal clearance increased	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Glomerular filtration rate decreased	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Heart rate increased	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Intraocular pressure increased	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Lipase increased	5/2658 (0.18%)	1/107 (0.94%)	4/2495 (0.16%)
Low density lipoprotein increased	5/2658 (0.18%)	0/107 (0.00%)	5/2495 (0.20%)
Urine analysis abnormal	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Vitamin B12 decreased	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)

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	Overall [2]	TDF/FTC	Cabotegravir
Vitamin D decreased	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Metabolism and nutrition disorders	**71/2658 (2.68%)**	**3/107 (2.80%)**	**68/2495 (2.72%)**
Abnormal loss of weight	11/2658 (0.42%)	0/107 (0.00%)	11/2495 (0.44%)
Decreased appetite	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Dehydration	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Diabetes mellitus	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Diabetic ketoacidosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Dyslipidaemia	3/2658 (0.12%)	1/107 (0.94%)	2/2495 (0.08%)
Glucose tolerance impaired	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Gout	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hypercalcaemia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hypercholesterolaemia	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Hyperglycaemia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hyperlipidaemia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hypertriglyceridaemia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hypoglycaemia	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Hyponatraemia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Impaired fasting glucose	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Obesity	29/2658 (1.10%)	1/107 (0.94%)	28/2495 (1.12%)
Type 2 diabetes mellitus	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Vitamin D deficiency	8/2658 (0.30%)	1/107 (0.94%)	7/2495 (0.28%)
Musculoskeletal and connective tissue disorders	**150/2658 (5.64%)**	**4/107 (3.74%)**	**146/2495 (5.86%)**
Ankylosing spondylitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Arthralgia	38/2658 (1.42%)	2/107 (1.86%)	36/2495 (1.44%)
Back pain	39/2658 (1.46%)	0/107 (0.00%)	39/2495 (1.56%)
Bone pain	1/2658 (0.04%)	1/107 (0.94%)	0/2495 (0.00%)
Bursitis	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Chondromalacia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Coccydynia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Costochondritis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Diffuse idiopathic skeletal hyperostosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Exostosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Flank pain	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Groin pain	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Intervertebral disc disorder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)

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	Overall [2]	TDF/FTC	Cabotegravir
Intervertebral disc protrusion	7/2658 (0.26%)	0/107 (0.00%)	7/2495 (0.28%)
Joint range of motion decreased	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Joint swelling	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Lumbar spinal stenosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Muscle contracture	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Muscle spasms	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Muscle twitching	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Muscular weakness	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Musculoskeletal chest pain	5/2658 (0.18%)	0/107 (0.00%)	5/2495 (0.20%)
Musculoskeletal pain	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Myalgia	21/2658 (0.80%)	1/107 (0.94%)	20/2495 (0.80%)
Neck mass	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Neck pain	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Osteoarthritis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Pain in extremity	14/2658 (0.52%)	0/107 (0.00%)	14/2495 (0.56%)
Pain in jaw	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Plantar fasciitis	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Polyarthritis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Psoriatic arthropathy	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Rhabdomyolysis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Rotator cuff syndrome	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Spinal flattening	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Spinal osteoarthritis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Temporomandibular pain and dysfunction syndrome	1/2658 (0.04%)	1/107 (0.94%)	0/2495 (0.00%)
Tendonitis	7/2658 (0.26%)	0/107 (0.00%)	7/2495 (0.28%)
Tenosynovitis stenosans	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Torticollis	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Trigger finger	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**26/2658 (0.98%)**	**0/107 (0.00%)**	**26/2495 (1.04%)**
Acrochordon	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Acute myeloid leukaemia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Adenocarcinoma of colon	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Anogenital warts	10/2658 (0.38%)	0/107 (0.00%)	10/2495 (0.40%)
Basal cell carcinoma	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Lipoma	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)

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	Overall [2]	TDF/FTC	Cabotegravir
Melanocytic naevus	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Myxofibrosarcoma	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Papillary thyroid cancer	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Prostate cancer	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Pyogenic granuloma	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Seborrhoeic keratosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Skin papilloma	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Nervous system disorders	**133/2658 (5.00%)**	**5/107 (4.68%)**	**128/2495 (5.14%)**
Ageusia	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Amnesia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Balance disorder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Bell's palsy	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Burning sensation	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Carpal tunnel syndrome	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Cerebellar infarction	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Cerebrovascular accident	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Disturbance in attention	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Dizziness	7/2658 (0.26%)	0/107 (0.00%)	7/2495 (0.28%)
Epidural lipomatosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Essential tremor	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Facial paralysis	1/2658 (0.04%)	1/107 (0.94%)	0/2495 (0.00%)
Haemorrhagic stroke	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Headache	72/2658 (2.70%)	2/107 (1.86%)	70/2495 (2.80%)
Hypersomnia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hypoaesthesia	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Migraine	12/2658 (0.46%)	1/107 (0.94%)	11/2495 (0.44%)
Nerve compression	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Neuralgia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Paraesthesia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Post herpetic neuralgia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Post–traumatic headache	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Presyncope	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Radiculopathy	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Sciatica	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Seizure	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)

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Sinus headache	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Somnolence	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Syncope	7/2658 (0.26%)	1/107 (0.94%)	6/2495 (0.24%)
Tension headache	8/2658 (0.30%)	0/107 (0.00%)	8/2495 (0.32%)
Thoracic radiculopathy	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Tremor	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Trigeminal neuralgia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Psychiatric disorders	**143/2658 (5.38%)**	**3/107 (2.80%)**	**138/2495 (5.54%)**
Abnormal dreams	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Acute psychosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Affect lability	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Affective disorder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Anxiety	30/2658 (1.12%)	1/107 (0.94%)	29/2495 (1.16%)
Anxiety disorder	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Attention deficit hyperactivity disorder	9/2658 (0.34%)	0/107 (0.00%)	9/2495 (0.36%)
Bipolar disorder	2/2658 (0.08%)	1/107 (0.94%)	1/2495 (0.04%)
Borderline personality disorder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Compulsions	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Depressed mood	2/2658 (0.08%)	1/107 (0.94%)	1/2495 (0.04%)
Depression	34/2658 (1.28%)	0/107 (0.00%)	33/2495 (1.32%)
Depression suicidal	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Dissociative identity disorder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Drug abuse	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Drug dependence	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Flat affect	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Generalised anxiety disorder	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Grief reaction	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hallucinations, mixed	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Insomnia	19/2658 (0.72%)	0/107 (0.00%)	19/2495 (0.76%)
Libido decreased	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Major depression	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Mental disorder	1/2658 (0.04%)	0/107 (0.00%)	0/2495 (0.00%)
Mixed anxiety and depressive disorder	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Mood swings	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Obsessive–compulsive disorder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)

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	Overall [2]	TDF/FTC	Cabotegravir
Panic attack	6/2658 (0.22%)	0/107 (0.00%)	6/2495 (0.24%)
Panic disorder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Paranoia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Persistent depressive disorder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Personality disorder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Post–traumatic stress disorder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Psychotic disorder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Schizoaffective disorder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Schizoaffective disorder depressive type	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Schizophrenia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Self–injurious ideation	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Sleep disorder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Social anxiety disorder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Stress	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Substance abuse	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Substance use disorder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Substance–induced psychotic disorder	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Suicidal ideation	10/2658 (0.38%)	0/107 (0.00%)	10/2495 (0.40%)
Suicide attempt	10/2658 (0.38%)	0/107 (0.00%)	10/2495 (0.40%)
Renal and urinary disorders	**67/2658 (2.52%)**	**2/107 (1.86%)**	**64/2495 (2.56%)**
Acute kidney injury	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Chromaturia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Dysuria	18/2658 (0.68%)	0/107 (0.00%)	18/2495 (0.72%)
Glycosuria	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Haematuria	5/2658 (0.18%)	0/107 (0.00%)	4/2495 (0.16%)
Hydronephrosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hypertonic bladder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Nephrolithiasis	7/2658 (0.26%)	0/107 (0.00%)	7/2495 (0.28%)
Polyuria	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Proteinuria	7/2658 (0.26%)	2/107 (1.86%)	4/2495 (0.16%)
Renal colic	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Tubulointerstitial nephritis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Ureterolithiasis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Urethral discharge	20/2658 (0.76%)	0/107 (0.00%)	20/2495 (0.80%)
Urethral syndrome	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)

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	Overall [2]	TDF/FTC	Cabotegravir
Urine odour abnormal	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Reproductive system and breast disorders	**59/2658 (2.22%)**	**2/107 (1.86%)**	**57/2495 (2.28%)**
Balanoposthitis	10/2658 (0.38%)	0/107 (0.00%)	10/2495 (0.40%)
Benign prostatic hyperplasia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Breast mass	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Breast pain	1/2658 (0.04%)	1/107 (0.94%)	0/2495 (0.00%)
Erectile dysfunction	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Genital discharge	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Genital lesion	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Genital macule	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Genital ulceration	10/2658 (0.38%)	0/107 (0.00%)	10/2495 (0.40%)
Gynaecomastia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Pelvic pain	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Penile blister	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Penile dermatitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Penile discharge	5/2658 (0.18%)	1/107 (0.94%)	4/2495 (0.16%)
Penile erythema	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Penile oedema	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Penile pain	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Penis disorder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Peyronie's disease	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Prostatitis	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Scrotal dermatitis	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Scrotal ulcer	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Testicular mass	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Testicular pain	6/2658 (0.22%)	0/107 (0.00%)	6/2495 (0.24%)
Testicular torsion	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Varicocele	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Respiratory, thoracic and mediastinal disorders	**125/2658 (4.70%)**	**4/107 (3.74%)**	**120/2495 (4.80%)**
Acute respiratory distress syndrome	26/2658 (0.98%)	0/107 (0.00%)	26/2495 (1.04%)
Allergic cough	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Allergic sinusitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Alveolitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Aphonia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Asthma	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)

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	Overall [2]	TDF/FTC	Cabotegravir
Bronchospasm	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Cough	32/2658 (1.20%)	1/107 (0.94%)	30/2495 (1.20%)
Dyspnoea	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Epistaxis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hiccups	1/2658 (0.04%)	1/107 (0.94%)	0/2495 (0.00%)
Hyperventilation	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Nasal congestion	7/2658 (0.26%)	0/107 (0.00%)	7/2495 (0.28%)
Nasal polyps	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Obstructive sleep apnoea syndrome	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Organising pneumonia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Oropharyngeal pain	19/2658 (0.72%)	0/107 (0.00%)	19/2495 (0.76%)
Oropharyngeal plaque	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Paranasal sinus discomfort	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Pharyngeal swelling	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Productive cough	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Pulmonary embolism	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Rhinitis allergic	17/2658 (0.64%)	1/107 (0.94%)	16/2495 (0.64%)
Rhinorrhoea	10/2658 (0.38%)	0/107 (0.00%)	10/2495 (0.40%)
Sinus congestion	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Sinus disorder	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Sleep apnoea syndrome	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Sneezing	2/2658 (0.08%)	1/107 (0.94%)	1/2495 (0.04%)
Throat irritation	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Wheezing	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Skin and subcutaneous tissue disorders	**142/2658 (5.34%)**	**4/107 (3.74%)**	**138/2495 (5.54%)**
Acne	13/2658 (0.48%)	0/107 (0.00%)	13/2495 (0.52%)
Alopecia	10/2658 (0.38%)	2/107 (1.86%)	8/2495 (0.32%)
Androgenetic alopecia	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Blister	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Cellulite	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Chronic spontaneous urticaria	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Dermal cyst	3/2658 (0.12%)	0/107 (0.00%)	3/2495 (0.12%)
Dermatitis	12/2658 (0.46%)	0/107 (0.00%)	12/2495 (0.48%)
Dermatitis acneiform	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Dermatitis allergic	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)

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Dermatitis atopic	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Dermatitis contact	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Drug eruption	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Dry skin	1/2658 (0.04%)	1/107 (0.94%)	0/2495 (0.00%)
Dyshidrotic eczema	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Ecchymosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Eczema	8/2658 (0.30%)	1/107 (0.94%)	7/2495 (0.28%)
Erythema	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Hand dermatitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hyperhidrosis	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Ingrowing nail	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Lichen planus	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Macule	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Nail bed bleeding	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Neurodermatitis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Night sweats	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Papule	9/2658 (0.34%)	0/107 (0.00%)	9/2495 (0.36%)
Parapsoriasis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Penile ulceration	7/2658 (0.26%)	0/107 (0.00%)	7/2495 (0.28%)
Photosensitivity reaction	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Pityriasis	1/2658 (0.04%)	1/107 (0.94%)	0/2495 (0.00%)
Pityriasis rosea	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Rash	20/2658 (0.76%)	0/107 (0.00%)	20/2495 (0.80%)
Rash macular	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Rash maculo–papular	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Rash papulosquamous	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Rash pruritic	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Seborrhoeic dermatitis	4/2658 (0.16%)	0/107 (0.00%)	4/2495 (0.16%)
Skin discolouration	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Skin erosion	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Skin exfoliation	2/2658 (0.08%)	1/107 (0.94%)	1/2495 (0.04%)
Skin hyperpigmentation	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Skin lesion	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Skin mass	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Urticaria	6/2658 (0.22%)	0/107 (0.00%)	6/2495 (0.24%)

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Urticaria chronic	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Urticaria papular	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Vitiligo	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Social circumstances	**4/2658 (0.16%)**	**0/107 (0.00%)**	**4/2495 (0.16%)**
High risk sexual behaviour	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Substance use	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Victim of sexual abuse	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Vascular disorders	**69/2658 (2.60%)**	**1/107 (0.94%)**	**68/2495 (2.72%)**
Arteriosclerosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Deep vein thrombosis	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Haematoma	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Hot flush	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hypertension	57/2658 (2.14%)	1/107 (0.94%)	56/2495 (2.24%)
Hypertensive urgency	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Hypotension	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Orthostatic hypertension	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Orthostatic hypotension	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Peripheral venous disease	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)
Systolic hypertension	2/2658 (0.08%)	0/107 (0.00%)	2/2495 (0.08%)
Varicose vein	1/2658 (0.04%)	0/107 (0.00%)	1/2495 (0.04%)

[1] This table includes only those AEs which have been assigned MedDRA codes by clinical staff. Participants with OLE regimen choice missing are excluded.
[2] Include all participants participating in OLE phase (CAB, TDF/FTC, seroconverter schedule and open label Truvada schedule).
[3] For participants reporting multiple events with the same MedDRA term, only one is counted. Percentages are calculated as the number of participants (n) reporting an event divided by the number enrolled by OLE regimen choice.
[4] According to the protocol, Grade 1 laboratory AEs are not to be reported unless they led to product discontinuation. The majority of Grade 1 lab AEs reported here were reported in error, and do not reflect the true number of Grade 1 lab AEs experienced in this study.
Source: SCHARP (Haima) – /trials/hptn/p083/analysis/live/code/ole/t_ole_ae_overall_byarm.sas, SAS Version 9.4 (04MAR2026,6:09)

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
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Listing 6 – Listing of Serious Adverse Events and Expedited Adverse Events Ordered by Severity [1]

Severity Grade=Grade 5 (Death)

# [2]	Original Arm	OLE Regimen Choice	Region	Participant ID	Enrollment Date	OLE Start Date	Onset Date	Diagnosis	MedDRA Preferred Term	MedDRA low–level Term	Relationship to Study Product	Action Taken with study product	Hospitalization
1	Cabotegravir	Cabotegravir	Latin America	722990161	24APR2019	17NOV2021	21MAR2023	SEPSIS	Sepsis	Sepsis	Not Related	Not applicable	No

[1] This listing includes only those AEs which have been assigned MedDRA codes by clinical staff.
[2] This listing is sorted by descending AE severity, original randomized arm, OLE regimen choice, region, PTID and AE onset date.

Source: SCHARP (Haima) – /trials/hptn/p083/analysis/live/code/ole/l_ole_eae.sas, SAS Version 9.4 (04MAR2026,6:09)

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
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Listing 6 – Listing of Serious Adverse Events and Expedited Adverse Events Ordered by Severity [1]

Severity Grade=Grade 4 (Potentially life–threatening)

# [2]	Original Arm	OLE Regimen Choice	Region	Participant ID	Enrollment Date	OLE Start Date	Onset Date	Diagnosis	MedDRA Preferred Term	MedDRA low–level Term	Relationship to Study Product	Action Taken with study product	Hospitalization
1	Cabotegravir	Cabotegravir	US	709467239	04MAY2018	06JUL2021	24APR2022	Severe Bicuspid Aortic Valve, Aortic Stenosis	Aortic valve stenosis	Aortic valve stenosis	Not Related	Drug interrupted	Yes
2	Cabotegravir	Cabotegravir	US	820520520	29OCT2018	14JUN2021	04JAN2022	Suicide Attempt	Suicide attempt	Suicide attempt	Not Related	Dose not changed	Yes
3	Cabotegravir	Cabotegravir	US	820520520	29OCT2018	14JUN2021	08NOV2022	Suicide Attempt	Suicide attempt	Suicide attempt	Not Related	Dose not changed	No
4	Cabotegravir	Cabotegravir	US	820546624	14AUG2017	20MAY2021	07FEB2022	NSTEMI	Acute myocardial infarction	NSTEMI	Not Related	Drug withdrawn	Yes
5	Cabotegravir	Cabotegravir	US	846728347	06NOV2017	20MAY2021	21AUG2021	Attempted suicide/self harm	Suicide attempt	Suicide attempt	Not Related	Dose not changed	Yes
6	Cabotegravir	Cabotegravir	Latin America	721139724	20JUN2018	01SEP2021	04MAY2022	Migraine	Migraine	Migraine	Not Related	Dose not changed	Yes
7	Cabotegravir	Cabotegravir	Latin America	721331991	10SEP2019	14SEP2021	03MAR2022	Suicide Attempt	Suicide attempt	Suicide attempt	Not Related	Dose not changed	No
8	Cabotegravir	Cabotegravir	Latin America	721366033	18APR2019	16AUG2021	20SEP2021	Suicide Attempts	Suicide attempt	Suicide attempt	Not Related	Not applicable	No
9	Cabotegravir	Cabotegravir	Latin America	721683301	12APR2018	09SEP2021	11SEP2022	Allergic Reaction (Acute Anaphylaxis)	Anaphylactic reaction	Acute anaphylactic reaction	Not Related	Drug interrupted	No
10	Cabotegravir	Cabotegravir	Latin America	721697901	17MAY2018	13AUG2021	01MAR2023	Acute Psychosis induced by substance (Methamphetamine)	Substance–induced psychotic disorder	Amphetamine–induced psychosis	Not Related	Drug interrupted	No
11	Cabotegravir	Cabotegravir	Latin America	721697901	17MAY2018	13AUG2021	25JAN2024	Acute Psychosis	Acute psychosis	Acute psychosis	Not Related	Drug withdrawn	No
12	Cabotegravir	Cabotegravir	Latin America	722990161	24APR2019	17NOV2021	10MAR2023	SEPSIS	Sepsis	Sepsis	Not Related	Drug withdrawn	No
13	Cabotegravir	Cabotegravir	Latin America	848871338	06MAY2019	03MAY2023	23FEB2024	Dengue	Dengue fever	Dengue	Not Related	Drug interrupted	Yes
14	Cabotegravir	Cabotegravir	Latin America	850226657	06APR2018	21JUL2021	19SEP2021	Symptomatic hyponatremia	Hyponatraemia	Hyponatremia	Not Related	Dose not changed	Yes
15	Cabotegravir	Cabotegravir	Latin America	860548404	22AUG2019	14DEC2021	04FEB2022	Cerebral Hemorrhagic Stroke	Haemorrhagic stroke	Hemorrhagic stroke	Not Related	Drug withdrawn	Yes
16	TDF/FTC	Cabotegravir	US	706354290	21MAY2018	02JUN2021	21MAY2022	suicide attempt	Suicide attempt	Suicide attempt	Not Related	Drug interrupted	Yes
17	TDF/FTC	Cabotegravir	US	706354290	21MAY2018	02JUN2021	30MAY2022	acute kidney injury	Acute kidney injury	Acute kidney injury	Not Related	Not applicable	No
18	TDF/FTC	Cabotegravir	US	706354290	21MAY2018	02JUN2021	31MAY2022	rhabdomyolysis	Rhabdomyolysis	Rhabdomyolysis	Not Related	Not applicable	No

[1] This listing includes only those AEs which have been assigned MedDRA codes by clinical staff.
[2] This listing is sorted by descending AE severity, original randomized arm, OLE regimen choice, region, PTID and AE onset date.

Source: SCHARP (Haima) – /trials/hptn/p083/analysis/live/code/ole/l_ole_eae.sas, SAS Version 9.4 (04MAR2026,6:09)

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Listing 6 – Listing of Serious Adverse Events and Expedited Adverse Events Ordered by Severity [1]

Severity Grade=Grade 4 (Potentially life–threatening)

# [2]	Original Arm	OLE Regimen Choice	Region	Participant ID	Enrollment Date	OLE Start Date	Onset Date	Diagnosis	MedDRA Preferred Term	MedDRA low–level Term	Relationship to Study Product	Action Taken with study product	Hospitalization
19	TDF/FTC	Cabotegravir	US	706354290	21MAY2018	02JUN2021	03OCT2022	suicide attempt	Suicide attempt	Suicide attempt	Not Related	Drug interrupted	Yes
20	TDF/FTC	Cabotegravir	US	706354290	21MAY2018	02JUN2021	23MAR2023	suicide attempt	Suicide attempt	Suicide attempt	Not Related	Drug withdrawn	Yes
21	TDF/FTC	Cabotegravir	US	787552289	12JUN2018	17MAY2021	04JAN2022	acute myeloid leukemia	Acute myeloid leukaemia	Acute myeloid leukemia	Not Related	Drug interrupted	Yes
22	TDF/FTC	Cabotegravir	US	787552289	12JUN2018	17MAY2021	04JAN2022	crush injury of right hand	Limb crushing injury	Crushing injury of hand(s)	Not Related	Drug withdrawn	Yes
23	TDF/FTC	Cabotegravir	US	820348389	09JUN2017	13MAY2021	09JAN2023	Suicide Attempt	Suicide attempt	Suicide attempt	Not Related	Drug interrupted	No
24	TDF/FTC	Cabotegravir	US	857373578	16AUG2017	06OCT2021	06SEP2023	low hemoglobin [Anemia]	Anaemia	Anemia	Not Related	Dose not changed	Yes
25	TDF/FTC	Cabotegravir	Latin America	721242835	15APR2019	10SEP2021	02OCT2021	Suicide Attempt	Suicide attempt	Suicide attempt	Not Related	Dose not changed	No
26	TDF/FTC	Cabotegravir	Latin America	721267446	16SEP2019	30JUL2021	29MAR2023	Suicide Attempt	Suicide attempt	Suicide attempt	Not Related	Drug withdrawn	Yes
27	TDF/FTC	Cabotegravir	Latin America	722616370	09OCT2018	01DEC2021	16DEC2024	MYOCARDIAL INFARCTION	Myocardial infarction	Myocardial infarction	Not Related	Dose not changed	Yes
28	TDF/FTC	Cabotegravir	Latin America	722946939	11JUL2018	17NOV2021	15JUN2022	SUICIDE ATTEMPT	Suicide attempt	Suicide attempt	Not Related	Dose not changed	No
29	TDF/FTC	Cabotegravir	Latin America	845642780	12JUL2019	05JAN2022	18NOV2022	polytrauma	Multiple injuries	Polytrauma	Not Related	Drug interrupted	Yes
30	TDF/FTC	Cabotegravir	Latin America	860170861	01FEB2019	30NOV2021	15JAN2022	Moderately differentiated adenocarcinoma of right colon	Adenocarcinoma of colon	Adenocarcinoma of colon	Not Related	Drug interrupted	Yes
31	TDF/FTC	Cabotegravir	Latin America	860648475	28SEP2018	26NOV2021	28JUL2022	Tonsillar abscess	Peritonsillar abscess	Tonsillar abscess	Not Related	Dose not changed	Yes
32	TDF/FTC	Cabotegravir	Asia	858242028	01FEB2018	18OCT2021	14APR2022	Septic shock	Septic shock	Septic shock	Not Related	Drug interrupted	Yes

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[2] This listing is sorted by descending AE severity, original randomized arm, OLE regimen choice, region, PTID and AE onset date.

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Listing 6 – Listing of Serious Adverse Events and Expedited Adverse Events Ordered by Severity [1]

Severity Grade=Grade 3 (Severe)

# [2]	Original Arm	OLE Regimen Choice	Region	Participant ID	Enrollment Date	OLE Start Date	Onset Date	Diagnosis	MedDRA Preferred Term	MedDRA low–level Term	Relationship to Study Product	Action Taken with study product	Hospitalization
1	Cabotegravir	TDF/FTC	Latin America	845510631	07OCT2019	25AUG2021	03AUG2022	pubic cellulitis	Cellulitis	Cellulitis	Not Related	Dose not changed	Yes
2	Cabotegravir	TDF/FTC	Latin America	845510631	07OCT2019	25AUG2021	03AUG2022	Monkeypox infection	Monkeypox	Monkeypox	Not Related	Dose not changed	Yes
3	Cabotegravir	Cabotegravir	US	706579213	05SEP2018	01JUN2021	29NOV2022	diffuse idiopathic skeletal hyperostosis (DISH)	Diffuse idiopathic skeletal hyperostosis	Diffuse idiopathic skeletal hyperostosis	Not Related	Dose not changed	No
4	Cabotegravir	Cabotegravir	US	764135244	02FEB2018	26MAY2021	12OCT2021	Perianal Abscess	Anal abscess	Perianal abscess	Not Related	Dose not changed	Yes
5	Cabotegravir	Cabotegravir	US	780210997	14NOV2017	24JUN2021	14JAN2022	Acute Decompensated Heart Failure	Cardiac failure acute	Acute decompensated heart failure	Not Related	Drug withdrawn	Yes
6	Cabotegravir	Cabotegravir	US	787997524	31OCT2017	07JUN2021	12JUL2021	noncardiac chest pain	Non–cardiac chest pain	Non–cardiac chest pain	Not Related	Dose not changed	Yes
7	Cabotegravir	Cabotegravir	US	819492344	07JUN2017	26MAY2021	27SEP2021	Pelvic Fracture	Pelvic fracture	Pelvic fracture	Not Related	Dose not changed	Yes
8	Cabotegravir	Cabotegravir	US	819514114	23JUN2017	15JUL2021	12AUG2022	Sciatica, left hip, requiring laminectomy	Sciatica	Sciatica	Not Related	Dose not changed	Yes
9	Cabotegravir	Cabotegravir	US	819514114	23JUN2017	15JUL2021	26AUG2022	Bacterial Infection (due incision from laminectomy)	Postoperative wound infection	Incision site infection	Not Related	Dose not changed	Yes
10	Cabotegravir	Cabotegravir	US	820297979	22JAN2018	13AUG2021	28FEB2022	Major Depressive Disorder	Major depression	Major depressive disorder	Not Related	Dose not changed	Yes
11	Cabotegravir	Cabotegravir	US	820297979	22JAN2018	13AUG2021	09NOV2022	COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes
12	Cabotegravir	Cabotegravir	US	820520520	29OCT2018	14JUN2021	28MAR2022	Suicidal Ideation	Suicidal ideation	Suicidal ideation	Not Related	Dose not changed	Yes
13	Cabotegravir	Cabotegravir	US	820520520	29OCT2018	14JUN2021	11NOV2022	Weight Loss abnormal	Abnormal loss of weight	Abnormal loss of weight	Not Related	Dose not changed	No
14	Cabotegravir	Cabotegravir	US	825820900	13FEB2018	21JUN2021	03SEP2021	Loss of memory	Amnesia	Loss of memory	Not Related	Dose not changed	No
15	Cabotegravir	Cabotegravir	US	825820900	13FEB2018	21JUN2021	11NOV2021	Suspected Psychosis	Psychotic disorder	Psychosis	Not Related	Dose not changed	Yes
16	Cabotegravir	Cabotegravir	US	825820900	13FEB2018	21JUN2021	11NOV2021	Suspected suicidal ideation	Suicidal ideation	Suicidal ideation	Not Related	Dose not changed	Yes
17	Cabotegravir	Cabotegravir	US	846792103	25JAN2018	07MAY2021	19AUG2021	Post–surgical swelling	Post procedural swelling	Post procedural swelling	Not Related	Dose not changed	Yes
18	Cabotegravir	Cabotegravir	US	851789301	02AUG2017	16JUN2021	23MAY2022	Sepsis	Sepsis	Sepsis	Not Related	Dose not changed	Yes

[1] This listing includes only those AEs which have been assigned MedDRA codes by clinical staff.
[2] This listing is sorted by descending AE severity, original randomized arm, OLE regimen choice, region, PTID and AE onset date.

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Listing 6 – Listing of Serious Adverse Events and Expedited Adverse Events Ordered by Severity [1]

Severity Grade=Grade 3 (Severe)

# [2]	Original Arm	OLE Regimen Choice	Region	Participant ID	Enrollment Date	OLE Start Date	Onset Date	Diagnosis	MedDRA Preferred Term	MedDRA low–level Term	Relationship to Study Product	Action Taken with study product	Hospitalization
19	Cabotegravir	Cabotegravir	US	851789301	02AUG2017	16JUN2021	23MAY2022	Shigella	Shigella infection	Shigella infection	Not Related	Dose not changed	Yes
20	Cabotegravir	Cabotegravir	US	851932517	29AUG2018	07JUN2021	30AUG2021	Cellulitis of rt leg	Cellulitis	Cellulitis of leg	Not Related	Dose not changed	Yes
21	Cabotegravir	Cabotegravir	Latin America	721163535	12JUN2018	11AUG2021	07SEP2023	Myocarditis	Myocarditis	Myocarditis	Not Related	Dose not changed	Yes
22	Cabotegravir	Cabotegravir	Latin America	721175258	26APR2018	19AUG2021	04AUG2022	Monkeypox	Monkeypox	Monkeypox	Not Related	Dose not changed	Yes
23	Cabotegravir	Cabotegravir	Latin America	721331991	10SEP2019	14SEP2021	05MAR2022	Lumbar Spine Fracture	Spinal fracture	Spinal fracture	Not Related	Dose not changed	No
24	Cabotegravir	Cabotegravir	Latin America	721366033	18APR2019	16AUG2021	19JUL2022	Seizure	Seizure	Seizure	Not Related	Drug withdrawn	No
25	Cabotegravir	Cabotegravir	Latin America	721420103	04OCT2018	09SEP2021	14JUL2024	Acute Hepatitis A	Hepatitis A	Acute hepatitis A	Not Related	Drug interrupted	Yes
26	Cabotegravir	Cabotegravir	Latin America	721440891	26JUN2018	10AUG2021	28MAR2024	Urethral Granuloma	Granuloma	Granuloma	Not Related	Dose not changed	Yes
27	Cabotegravir	Cabotegravir	Latin America	721445364	16NOV2017	06DEC2021	21DEC2023	Nasal Bone Fracture	Craniofacial fracture	Fractured nose	Not Related	Dose not changed	Yes
28	Cabotegravir	Cabotegravir	Latin America	721679746	22OCT2018	28JUL2021	22MAY2022	Traumatic Brain Injury (Left frontal hematic contusion)	Craniocerebral injury	Traumatic brain injury	Not Related	Dose not changed	Yes
29	Cabotegravir	Cabotegravir	Latin America	721803380	26NOV2018	25AUG2021	07OCT2023	Substance Abuse (Inhaled Cocaine and Alcohol)	Substance abuse	Substance abuse	Not Related	Dose not changed	Yes
30	Cabotegravir	Cabotegravir	Latin America	721811112	09APR2018	06OCT2021	06MAR2023	Bacterial Pneumonia	Pneumonia bacterial	Pneumonia bacterial	Not Related	Dose not changed	Yes
31	Cabotegravir	Cabotegravir	Latin America	721811112	09APR2018	06OCT2021	24APR2023	Right Clavicle Post–Traumatic Fracture	Clavicle fracture	Clavicle fracture	Not Related	Dose not changed	Yes
32	Cabotegravir	Cabotegravir	Latin America	721847824	22AUG2018	17AUG2021	15FEB2024	Left Perianal Abscess	Anal abscess	Perianal abscess	Not Related	Dose not changed	Yes
33	Cabotegravir	Cabotegravir	Latin America	721862030	20MAR2018	09DEC2021	28JUN2023	Anterior cruciate ligament rupture of the left knee	Ligament rupture	Anterior cruciate ligament tear	Not Related	Not applicable	Yes
34	Cabotegravir	Cabotegravir	Latin America	721895723	05SEP2018	15SEP2021	19SEP2021	Bilateral Viral Conjunctivitis	Conjunctivitis viral	Viral conjunctivitis	Not Related	Dose not changed	Yes
35	Cabotegravir	Cabotegravir	Latin America	722229502	18SEP2019	15SEP2021	26DEC2021	HEPATITIS A	Hepatitis A	Hepatitis A	Not Related	Drug withdrawn	No
36	Cabotegravir	Cabotegravir	Latin America	722576056	08OCT2018	04OCT2021	28DEC2023	PANIC DISORDER	Panic disorder	Panic disorder	Not Related	Dose not changed	Yes

[1] This listing includes only those AEs which have been assigned MedDRA codes by clinical staff.
[2] This listing is sorted by descending AE severity, original randomized arm, OLE regimen choice, region, PTID and AE onset date.

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Listing 6 – Listing of Serious Adverse Events and Expedited Adverse Events Ordered by Severity [1]

Severity Grade=Grade 3 (Severe)

# [2]	Original Arm	OLE Regimen Choice	Region	Participant ID	Enrollment Date	OLE Start Date	Onset Date	Diagnosis	MedDRA Preferred Term	MedDRA low–level Term	Relationship to Study Product	Action Taken with study product	Hospitalization
37	Cabotegravir	Cabotegravir	Latin America	722595066	19SEP2018	01SEP2021	18FEB2022	HEPATITIS A	Hepatitis A	Hepatitis A	Not Related	Drug withdrawn	Yes
38	Cabotegravir	Cabotegravir	Latin America	722614909	15JUN2018	17SEP2021	29SEP2022	CHRONIC CHOLECYSTITIS	Cholecystitis chronic	Chronic cholecystitis	Not Related	Dose not changed	Yes
39	Cabotegravir	Cabotegravir	Latin America	722648807	05NOV2018	30AUG2021	03MAY2022	Hepatitis A	Hepatitis A	Hepatitis A	Not Related	Dose not changed	Yes
40	Cabotegravir	Cabotegravir	Latin America	722712990	16AUG2018	15SEP2021	18DEC2023	HEPATITIS A, ACUTE	Hepatitis A	Acute hepatitis A	Not Related	Dose not changed	Yes
41	Cabotegravir	Cabotegravir	Latin America	722780022	22AUG2018	10SEP2021	03AUG2022	ACUTE APPENDICITIS	Appendicitis	Acute appendicitis	Not Related	Dose not changed	Yes
42	Cabotegravir	Cabotegravir	Latin America	722812461	07NOV2018	24NOV2021	16AUG2022	MONKEY POX	Monkeypox	Monkeypox	Not Related	Dose not changed	Yes
43	Cabotegravir	Cabotegravir	Latin America	831237805	16NOV2018	29MAY2023	26JUL2023	Acute cholecystitis	Cholecystitis acute	Acute cholecystitis	Not Related	Dose not changed	Yes
44	Cabotegravir	Cabotegravir	Latin America	845127792	10JUL2019	29SEP2021	28JUN2023	multiple injuries	Multiple injuries	Multiple injuries	Not Related	Dose not changed	Yes
45	Cabotegravir	Cabotegravir	Latin America	845235393	14AUG2019	20SEP2021	28FEB2022	acute gastroenterocolitis	Gastroenteritis	Gastroenterocolitis	Not Related	Dose not changed	Yes
46	Cabotegravir	Cabotegravir	Latin America	845235393	14AUG2019	20SEP2021	27NOV2022	renal colic	Renal colic	Renal colic	Not Related	Dose not changed	Yes
47	Cabotegravir	Cabotegravir	Latin America	845249763	17OCT2019	14SEP2021	31JAN2023	right meniscus tear	Meniscus injury	Meniscus tear	Not Related	Dose not changed	Yes
48	Cabotegravir	Cabotegravir	Latin America	845397099	14OCT2019	31AUG2021	16FEB2022	Ureterolithiasis	Ureterolithiasis	Ureterolithiasis	Not Related	Dose not changed	Yes
49	Cabotegravir	Cabotegravir	Latin America	845530787	18APR2019	13AUG2021	24SEP2021	left testicular torsion	Testicular torsion	Testicular torsion	Not Related	Dose not changed	Yes
50	Cabotegravir	Cabotegravir	Latin America	845629566	31JUL2019	11AUG2021	29MAY2023	fracture right elbow	Upper limb fracture	Elbow fracture	Not Related	Dose not changed	Yes
51	Cabotegravir	Cabotegravir	Latin America	845629566	31JUL2019	11AUG2021	29APR2024	post procedural complication	Post procedural complication	Post procedural complication	Not Related	Dose not changed	Yes
52	Cabotegravir	Cabotegravir	Latin America	845641694	24JUL2019	29JUL2021	01FEB2024	cholelithiasis	Cholelithiasis	Cholelithiasis	Not Related	Dose not changed	Yes
53	Cabotegravir	Cabotegravir	Latin America	850309757	02MAY2019	26AUG2021	27DEC2021	Politraumatism	Multiple injuries	Polytraumatism	Not Related	Dose not changed	Yes
54	Cabotegravir	Cabotegravir	Latin America	850656435	25APR2018	08JUL2021	18JUL2024	Problematic substance use	Substance use	Substance use	Not Related	Dose not changed	Yes
55	Cabotegravir	Cabotegravir	Latin America	850828632	12MAR2019	06JUL2021	18OCT2023	Left inguinal hernia	Inguinal hernia	Left inguinal hernia	Not Related	Dose not changed	Yes

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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
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Visit Cutoff Date: March 4, 2026
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Severity Grade=Grade 3 (Severe)

# [2]	Original Arm	OLE Regimen Choice	Region	Participant ID	Enrollment Date	OLE Start Date	Onset Date	Diagnosis	MedDRA Preferred Term	MedDRA low–level Term	Relationship to Study Product	Action Taken with study product	Hospitalization
56	Cabotegravir	Cabotegravir	Latin America	852182663	12NOV2018	20OCT2021	09NOV2021	Deep venous thrombosis	Deep vein thrombosis	Thrombosis venous deep	Not Related	Dose not changed	Yes
57	Cabotegravir	Cabotegravir	Latin America	852182663	12NOV2018	20OCT2021	06APR2022	Papillary carcinoma of the thyroid	Papillary thyroid cancer	Thyroid papillary carcinoma	Not Related	Dose not changed	No
58	Cabotegravir	Cabotegravir	Latin America	860280414	15JUL2019	30NOV2021	13OCT2023	Obesity	Obesity	Obesity	Not Related	Dose not changed	Yes
59	Cabotegravir	Cabotegravir	Latin America	860280414	15JUL2019	30NOV2021	23FEB2024	Dengue	Dengue fever	Dengue	Not Related	Dose not changed	Yes
60	Cabotegravir	Cabotegravir	Latin America	860342682	09APR2019	19JAN2022	26MAY2023	ANAL FISTULA	Anal fistula	Anal fistula	Not Related	Dose not changed	Yes
61	Cabotegravir	Cabotegravir	Latin America	860362828	15FEB2019	20DEC2021	09MAY2023	Acute apendicitis	Appendicitis	Acute appendicitis	Not Related	Dose not changed	Yes
62	Cabotegravir	Cabotegravir	Latin America	860376901	29JUL2019	07DEC2021	19JUL2023	Acute hepatitis c	Acute hepatitis C	Acute hepatitis C	Not Related	Drug withdrawn	No
63	Cabotegravir	Cabotegravir	Latin America	860474795	13SEP2019	06DEC2021	08APR2022	Left radius fracture	Radius fracture	Radius fracture	Not Related	Dose not changed	Yes
64	Cabotegravir	Cabotegravir	Latin America	860620124	10SEP2019	16FEB2022	19AUG2022	Fournier Syndrome	Fournier’s gangrene	Fournier’s gangrene	Not Related	Dose not changed	Yes
65	Cabotegravir	Cabotegravir	Asia	791798697	28DEC2017	10MAR2022	05MAY2024	Closed fracture left distal radius	Radius fracture	Distal radius fracture	Not Related	Not applicable	Yes
66	Cabotegravir	Cabotegravir	Asia	813330727	19MAR2019	21NOV2022	23DEC2022	External hemorrhoids at 6, 9 o’clock	Haemorrhoids	External hemorrhoids	Not Related	Dose not changed	Yes
67	Cabotegravir	Cabotegravir	Asia	813330727	19MAR2019	21NOV2022	23DEC2022	Chronic perianal ulcer	Anal ulcer	Perianal ulcer	Not Related	Dose not changed	Yes
68	Cabotegravir	Cabotegravir	Asia	813330727	19MAR2019	21NOV2022	10OCT2023	Chicken pox	Varicella	Chickenpox	Not Related	Dose not changed	Yes
69	Cabotegravir	Cabotegravir	Asia	813330727	19MAR2019	21NOV2022	13OCT2023	Anal fistula	Anal fistula	Anal fistula	Not Related	Dose not changed	Yes
70	Cabotegravir	Cabotegravir	Asia	813330727	19MAR2019	21NOV2022	20FEB2024	Perianal abscess	Anal abscess	Perianal abscess	Not Related	Dose not changed	Yes
71	Cabotegravir	Cabotegravir	Asia	813519735	01MAR2018	07NOV2022	29NOV2022	Acute Appendicitis	Appendicitis	Acute appendicitis	Not Related	Dose not changed	Yes
72	Cabotegravir	Cabotegravir	Asia	813617497	19JUN2018	14NOV2022	15OCT2023	Dengue Fever	Dengue fever	Dengue fever	Not Related	Dose not changed	Yes
73	Cabotegravir	Cabotegravir	Asia	813751704	14DEC2017	17NOV2022	22AUG2023	Dengue Fever	Dengue fever	Dengue fever	Not Related	Dose not changed	Yes
74	Cabotegravir	Cabotegravir	Asia	813937096	04OCT2018	15NOV2022	18JUN2023	Acute gastritis	Gastritis	Acute gastritis	Not Related	Dose not changed	Yes

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75	Cabotegravir	Cabotegravir	Asia	858183358	15SEP2017	15SEP2021	07JUL2023	Monkey Pox	Monkeypox	Monkeypox	Not Related	Dose not changed	Yes
76	Cabotegravir	Cabotegravir	Asia	858236070	05APR2018	21SEP2021	02JAN2022	Acute diarrhea	Diarrhoea	Acute diarrhea	Not Related	Dose not changed	Yes
77	Cabotegravir	Cabotegravir	Asia	858236070	05APR2018	21SEP2021	15JAN2022	COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes
78	Cabotegravir	Cabotegravir	Asia	858324446	31JAN2018	03NOV2021	26OCT2023	Gastroenteritis	Gastroenteritis	Gastroenteritis	Not Related	Dose not changed	Yes
79	Cabotegravir	Cabotegravir	Asia	858410426	13SEP2017	18AUG2021	29DEC2021	COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes
80	Cabotegravir	Cabotegravir	Asia	858475837	25JUN2018	20DEC2021	19JUL2023	Influenza A infection	Influenza	Influenza A virus infection	Not Related	Dose not changed	Yes
81	Cabotegravir	Cabotegravir	Asia	858644068	20FEB2020	17AUG2021	16APR2022	Suicidal attempt	Suicide attempt	Suicide attempt	Not Related	Dose not changed	Yes
82	Cabotegravir	Cabotegravir	Asia	858660647	20FEB2020	14SEP2021	15JUL2024	Community acqurired pneumonia	Pneumonia	Community acquired pneumonia	Not Related	Dose not changed	Yes
83	Cabotegravir	Cabotegravir	Asia	858688793	30APR2018	21SEP2021	15FEB2022	COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes
84	Cabotegravir	Cabotegravir	Asia	858797433	06NOV2017	05OCT2021	01DEC2021	COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes
85	Cabotegravir	Cabotegravir	Asia	858817702	09OCT2018	22SEP2021	06JAN2022	COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes
86	Cabotegravir	Cabotegravir	Asia	858820026	13NOV2018	06SEP2021	28FEB2022	Bronchitis due to COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes
87	Cabotegravir	Cabotegravir	Asia	858865711	05JUN2018	10AUG2021	15FEB2022	COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes
88	Cabotegravir	Cabotegravir	Asia	858929415	20JUN2018	23AUG2021	02SEP2023	Acute bronchospasm	Bronchospasm	Bronchospasm	Not Related	Dose not changed	No
89	Cabotegravir	Cabotegravir	Asia	862179964	16AUG2019	06SEP2021	22OCT2023	Dengue fever with warning signs	Dengue fever	Dengue fever	Not Related	Dose not changed	Yes
90	Cabotegravir	Cabotegravir	Asia	862292860	19DEC2018	20SEP2021	31JAN2023	Acute laryngopharyngitis	Laryngopharyngitis	Acute laryngopharyngitis	Not Related	Dose not changed	Yes
91	Cabotegravir	Cabotegravir	Asia	862712653	26FEB2019	01NOV2021	13FEB2022	Appendicitis	Appendicitis	Appendicitis	Not Related	Dose not changed	Yes
92	Cabotegravir	Cabotegravir	Asia	862730166	18JAN2019	01SEP2021	14JUN2022	Urinary tract infection	Urinary tract infection	Urinary tract infection	Not Related	Dose not changed	Yes
93	Cabotegravir	Cabotegravir	Africa	816338545	01AUG2018	21SEP2021	09SEP2023	Allergic Reaction	Hypersensitivity	Allergic reaction	Not Related	Dose not changed	Yes

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94	Cabotegravir	Cabotegravir	Africa	816605160	12MAR2020	04NOV2021	16SEP2023	Necrotizing fasciitis	Necrotising fasciitis	Necrotizing fasciitis	Not Related	Dose not changed	Yes
95	TDF/FTC	TDF/FTC	Latin America	845494026	01JUL2019	13SEP2021	25JUL2022	lymphogranuloma venereum	Lymphogranuloma venereum	Lymphogranuloma venereum	Not Related	Dose not changed	Yes
96	TDF/FTC	TDF/FTC	Latin America	845513246	02APR2019	05AUG2021	27APR2023	meniscus injury	Meniscus injury	Meniscus injury	Not Related	Dose not changed	Yes
97	TDF/FTC	TDF/FTC	Asia	858872389	22JAN2019	30AUG2021	03JAN2022	COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes
98	TDF/FTC	Cabotegravir	US	706354290	21MAY2018	02JUN2021	31AUG2022	suicidal ideation	Suicidal ideation	Suicidal ideation	Not Related	Dose not changed	Yes
99	TDF/FTC	Cabotegravir	US	745668261	12JUL2018	06JUL2021	19DEC2022	myxofibrosarcoma	Myxofibrosarcoma	Myxofibrosarcoma	Not Related	Dose not changed	Yes
100	TDF/FTC	Cabotegravir	US	745668261	12JUL2018	06JUL2021	18JAN2023	Bowel Obstruction	Intestinal obstruction	Bowel obstruction	Not Related	Dose not changed	Yes
101	TDF/FTC	Cabotegravir	US	780972494	29AUG2018	19JUL2021	26SEP2021	Torn Rotator Cuff to Left Shoulder	Rotator cuff syndrome	Rotator cuff tear	Not Related	Dose not changed	Yes
102	TDF/FTC	Cabotegravir	US	787552289	12JUN2018	17MAY2021	04JAN2022	COVID–19	COVID–19	COVID–19	Not Related	Not applicable	Yes
103	TDF/FTC	Cabotegravir	US	819586263	06DEC2017	13JUL2021	02NOV2022	Schizophrenia Exacerbation (Hospitalization)	Schizophrenia	Schizophrenia exacerbated	Not Related	Dose not changed	Yes
104	TDF/FTC	Cabotegravir	US	819946875	08SEP2017	12AUG2021	07NOV2022	Appendectomy (Appendicitis)	Appendicitis	Appendicitis	Not Related	Dose not changed	No
105	TDF/FTC	Cabotegravir	US	820348389	09JUN2017	13MAY2021	28JUN2021	Benzodiazepine Withdrawal	Drug withdrawal syndrome	Drug withdrawal syndrome	Not Related	Dose not changed	Yes
106	TDF/FTC	Cabotegravir	US	821164553	08AUG2017	16JUL2021	07JAN2023	Syphilis	Syphilis	Syphilis	Not Related	Dose not changed	Yes
107	TDF/FTC	Cabotegravir	US	846206556	11APR2018	01JUN2021	16JAN2022	Closed fracture of the left tibia/fibula	Lower limb fracture	Combined tibia–fibula fracture	Not Related	Dose not changed	Yes
108	TDF/FTC	Cabotegravir	US	847361315	30JUN2017	29APR2021	05JUN2022	Cerebellar infarction	Cerebellar infarction	Cerebellar infarction	Not Related	Dose not changed	Yes
109	TDF/FTC	Cabotegravir	US	851723629	20NOV2017	09JUL2021	25NOV2021	Lung Abscess related to BOOP	Lung abscess	Lung abscess	Not Related	Dose not changed	Yes
110	TDF/FTC	Cabotegravir	US	853154169	16APR2018	01JUL2021	01MAR2022	Ocular Syphilis	Eye infection syphilitic	Eye infection syphilitic	Not Related	Dose not changed	Yes
111	TDF/FTC	Cabotegravir	US	857406661	23MAR2017	07JUL2021	20JAN2022	acute hepatitis B infection	Acute hepatitis B	Acute hepatitis B	Not Related	Drug withdrawn	No
112	TDF/FTC	Cabotegravir	US	857476607	29JUN2018	19MAY2021	19JUN2021	Perirectal abscess	Perirectal abscess	Perirectal abscess	Not Related	Dose not changed	Yes

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113	TDF/FTC	Cabotegravir	US	857800186	18SEP2017	26APR2021	03NOV2021	acute diabetic ketoacidosis	Diabetic ketoacidosis	Diabetic ketoacidosis	Not Related	Dose not changed	Yes
114	TDF/FTC	Cabotegravir	Latin America	721120090	24MAY2018	16AUG2021	26JUL2024	Seizure	Seizure	Seizure	Not Related	Drug interrupted	No
115	TDF/FTC	Cabotegravir	Latin America	721120090	24MAY2018	16AUG2021	30JUL2024	Pulmonary Aspergillosis	Bronchopulmonary aspergillosis	Pulmonary aspergillosis	Not Related	Not applicable	Yes
116	TDF/FTC	Cabotegravir	Latin America	721242835	15APR2019	10SEP2021	13OCT2021	Exogenous Intoxication (Substance abuse)	Substance abuse	Substance abuse	Not Related	Dose not changed	Yes
117	TDF/FTC	Cabotegravir	Latin America	721267446	16SEP2019	30JUL2021	29MAR2023	Seizure	Seizure	Seizure	Not Related	Drug withdrawn	Yes
118	TDF/FTC	Cabotegravir	Latin America	721439540	16AUG2018	11AUG2021	29OCT2023	Lumbar Herniated Disc	Intervertebral disc protrusion	Lumbar disc herniation	Not Related	Dose not changed	Yes
119	TDF/FTC	Cabotegravir	Latin America	721567435	18APR2018	30AUG2021	14JUL2022	Cocaine abuse disorder	Drug abuse	Cocaine abuse	Not Related	Dose not changed	Yes
120	TDF/FTC	Cabotegravir	Latin America	721567435	18APR2018	30AUG2021	21JAN2024	Substance–induced Psychotic Disorder	Substance–induced psychotic disorder	Substance–induced psychotic disorder	Not Related	Dose not changed	Yes
121	TDF/FTC	Cabotegravir	Latin America	721824734	10APR2019	11AUG2021	10OCT2021	Acute Bacterial Suppurative Appendicitis	Appendicitis	Acute appendicitis	Not Related	Dose not changed	Yes
122	TDF/FTC	Cabotegravir	Latin America	721901172	15MAY2018	03SEP2021	23SEP2024	Nephrolithiasis	Nephrolithiasis	Nephrolithiasis	Not Related	Dose not changed	Yes
123	TDF/FTC	Cabotegravir	Latin America	722246052	13JUN2018	15SEP2021	09JAN2024	BRONCHOPNEUMONIA	Pneumonia	Bronchopneumonia	Not Related	Dose not changed	Yes
124	TDF/FTC	Cabotegravir	Latin America	722425167	03DEC2018	15SEP2021	23NOV2021	DRUG ABUSE	Drug abuse	Drug abuse	Not Related	Dose not changed	Yes
125	TDF/FTC	Cabotegravir	Latin America	722582256	17AUG2018	18OCT2021	25MAY2023	POST LUMBAR PUNCTURE HEADACHE	Post lumbar puncture syndrome	Lumbar puncture headache	Not Related	Dose not changed	Yes
126	TDF/FTC	Cabotegravir	Latin America	722726666	11JUN2019	22OCT2021	10JAN2023	HEPATITIS A	Hepatitis A	Hepatitis A	Not Related	Dose not changed	Yes
127	TDF/FTC	Cabotegravir	Latin America	722852110	07NOV2018	03NOV2021	06DEC2021	DISCAL HERNIA	Intervertebral disc protrusion	Herniated disc	Not Related	Dose not changed	Yes
128	TDF/FTC	Cabotegravir	Latin America	722852110	07NOV2018	03NOV2021	01APR2023	ATRIAL FIBRILATION	Atrial fibrillation	Atrial fibrillation	Not Related	Dose not changed	No
129	TDF/FTC	Cabotegravir	Latin America	845205655	02APR2019	22SEP2021	05DEC2023	urinary tract infection	Urinary tract infection	Urinary tract infection	Not Related	Dose not changed	Yes
130	TDF/FTC	Cabotegravir	Latin America	845292501	15OCT2019	02SEP2021	20AUG2024	inguinal abscess	Groin abscess	Inguinal abscess	Not Related	Dose not changed	Yes

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131	TDF/FTC	Cabotegravir	Latin America	845294951	13SEP2019	16AUG2021	25MAY2022	perianal cellulitis	Anorectal cellulitis	Anorectal cellulitis	Not Related	Dose not changed	Yes
132	TDF/FTC	Cabotegravir	Latin America	845294951	13SEP2019	16AUG2021	25JUN2024	perianal fistula	Anal fistula	Perianal fistula	Not Related	Dose not changed	Yes
133	TDF/FTC	Cabotegravir	Latin America	845316213	11OCT2019	01SEP2021	05MAY2022	5th finger fracture (right hand)	Hand fracture	Fractured finger	Not Related	Dose not changed	Yes
134	TDF/FTC	Cabotegravir	Latin America	845317490	30AUG2019	09SEP2021	31OCT2022	acute pyelonephritis	Pyelonephritis acute	Acute pyelonephritis	Not Related	Dose not changed	Yes
135	TDF/FTC	Cabotegravir	Latin America	845658896	20AUG2019	09SEP2021	11MAR2023	pancreatitis	Pancreatitis	Pancreatitis	Not Related	Dose not changed	Yes
136	TDF/FTC	Cabotegravir	Latin America	845658896	20AUG2019	09SEP2021	17FEB2024	left distal humerus fracture	Humerus fracture	Humerus fracture	Not Related	Dose not changed	Yes
137	TDF/FTC	Cabotegravir	Latin America	845723817	24JUN2019	08SEP2021	31JAN2023	pneumonia community (SAE)	Pneumonia	Community acquired pneumonia	Not Related	Dose not changed	Yes
138	TDF/FTC	Cabotegravir	Latin America	845723817	24JUN2019	08SEP2021	17FEB2023	right epyema	Empyema	Empyema	Not Related	Dose not changed	Yes
139	TDF/FTC	Cabotegravir	Latin America	850201402	16AUG2019	19AUG2021	24MAY2022	supraclavicular hematoma	Haematoma	Hematoma	Not Related	Dose not changed	Yes
140	TDF/FTC	Cabotegravir	Latin America	850295587	25APR2018	22SEP2021	27MAR2022	acute appendicitis	Appendicitis	Acute appendicitis	Not Related	Dose not changed	Yes
141	TDF/FTC	Cabotegravir	Latin America	850295587	25APR2018	22SEP2021	10AUG2023	Head trauma	Head injury	Head injury	Not Related	Dose not changed	Yes
142	TDF/FTC	Cabotegravir	Latin America	850425149	03APR2018	06SEP2021	16MAY2023	bronchitis	Bronchitis	Bronchitis	Not Related	Dose not changed	Yes
143	TDF/FTC	Cabotegravir	Latin America	850425149	03APR2018	06SEP2021	07APR2024	Dengue	Dengue fever	Dengue	Not Related	Dose not changed	Yes
144	TDF/FTC	Cabotegravir	Latin America	850497118	03JUN2019	05OCT2021	12APR2024	CELLULITIS OF THE RIGHT FOOT	Cellulitis	Cellulitis of foot	Not Related	Dose not changed	Yes
145	TDF/FTC	Cabotegravir	Latin America	850509929	02MAY2019	30AUG2021	04MAR2023	Stroke	Cerebrovascular accident	Stroke	Not Related	Drug interrupted	Yes
146	TDF/FTC	Cabotegravir	Latin America	850787159	01APR2019	09SEP2021	28OCT2021	complicated appendicitis	Complicated appendicitis	Complicated appendicitis	Not Related	Dose not changed	Yes
147	TDF/FTC	Cabotegravir	Latin America	860135265	14FEB2019	20DEC2021	19DEC2023	Bilateral inguinal hernia	Inguinal hernia	Bilateral inguinal hernia	Not Related	Dose not changed	Yes
148	TDF/FTC	Cabotegravir	Latin America	860486075	03JUL2019	11JAN2022	30AUG2024	SUICIDAL IDEATION	Suicidal ideation	Suicidal ideation	Not Related	Dose not changed	Yes
149	TDF/FTC	Cabotegravir	Latin America	860599643	25MAR2019	09MAR2022	10JUN2024	Left thigh infection due to dog bite	Infected bite	Infected animal bite	Not Related	Dose not changed	Yes

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[2] This listing is sorted by descending AE severity, original randomized arm, OLE regimen choice, region, PTID and AE onset date.

Source: SCHARP (Haima) – /trials/hptn/p083/analysis/live/code/ole/l_ole_eae.sas, SAS Version 9.4 (04MAR2026,6:09)

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Listing 6 – Listing of Serious Adverse Events and Expedited Adverse Events Ordered by Severity [1]

Severity Grade=Grade 3 (Severe)

# [2]	Original Arm	OLE Regimen Choice	Region	Participant ID	Enrollment Date	OLE Start Date	Onset Date	Diagnosis	MedDRA Preferred Term	MedDRA low–level Term	Relationship to Study Product	Action Taken with study product	Hospitalization
150	TDF/FTC	Cabotegravir	Latin America	860613923	25JUN2019	16DEC2021	10OCT2023	Cutaneous infection	Skin infection	Skin infection	Not Related	Dose not changed	Yes
151	TDF/FTC	Cabotegravir	Latin America	860834689	28JAN2019	09DEC2021	09JAN2024	Pneumonia	Pneumonia	Pneumonia	Not Related	Dose not changed	Yes
152	TDF/FTC	Cabotegravir	Asia	791587255	17AUG2018	06JAN2022	07JAN2022	acute bronchitis due to covid–19 infection	COVID–19	COVID–19 respiratory infection	Not Related	Dose not changed	Yes
153	TDF/FTC	Cabotegravir	Asia	791764000	02APR2019	07JAN2022	08JUL2022	Infected anal fissure	Anal infection	Anal infection	Not Related	Dose not changed	Yes
154	TDF/FTC	Cabotegravir	Asia	813241100	09NOV2018	21DEC2022	12MAR2024	Gastritis	Gastritis	Gastritis	Not Related	Dose not changed	Yes
155	TDF/FTC	Cabotegravir	Asia	813395266	01MAR2019	10NOV2022	30NOV2023	pharyngitis	Pharyngitis	Pharyngitis	Not Related	Dose not changed	Yes
156	TDF/FTC	Cabotegravir	Asia	813562131	18JAN2018	21MAR2023	08OCT2023	Bronchitis	Bronchitis	Bronchitis	Not Related	Dose not changed	Yes
157	TDF/FTC	Cabotegravir	Asia	813570343	22DEC2017	08NOV2022	16JUN2023	insignificant coronary artery disease	Coronary artery disease	Coronary artery disease	Not Related	Dose not changed	Yes
158	TDF/FTC	Cabotegravir	Asia	813708714	15DEC2017	10NOV2022	09AUG2023	Acute exudative tonsillitis	Tonsillitis	Acute tonsillitis	Not Related	Not applicable	Yes
159	TDF/FTC	Cabotegravir	Asia	813827723	01MAR2019	07FEB2023	14SEP2023	Acute hepatitis	Hepatitis acute	Hepatitis acute	Not Related	Drug withdrawn	Yes
160	TDF/FTC	Cabotegravir	Asia	813982499	06MAR2018	12DEC2022	03JUL2023	Acute gastroenteritis	Gastroenteritis	Acute gastroenteritis	Not Related	Dose not changed	Yes
161	TDF/FTC	Cabotegravir	Asia	858113640	12FEB2020	31AUG2021	04JAN2022	COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes
162	TDF/FTC	Cabotegravir	Asia	858242028	01FEB2018	18OCT2021	14APR2022	Acute gastroenteritis	Gastroenteritis	Acute gastroenteritis	Not Related	Dose not changed	Yes
163	TDF/FTC	Cabotegravir	Asia	858242028	01FEB2018	18OCT2021	14APR2022	Acute kidney injury	Acute kidney injury	Acute kidney injury	Not Related	Dose not changed	Yes
164	TDF/FTC	Cabotegravir	Asia	858259217	02FEB2018	26OCT2021	08JUL2024	acute gastroenteritis	Gastroenteritis	Acute gastroenteritis	Not Related	Dose not changed	Yes
165	TDF/FTC	Cabotegravir	Asia	858413034	13JUL2018	07SEP2021	08JAN2022	Low back pain	Back pain	Low back pain	Not Related	Dose not changed	Yes
166	TDF/FTC	Cabotegravir	Asia	858413034	13JUL2018	07SEP2021	31MAR2022	COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes
167	TDF/FTC	Cabotegravir	Asia	858523006	15SEP2017	11AUG2021	17JAN2022	COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes
168	TDF/FTC	Cabotegravir	Asia	858543369	18DEC2018	28SEP2021	22JAN2022	COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes

[1] This listing includes only those AEs which have been assigned MedDRA codes by clinical staff.
[2] This listing is sorted by descending AE severity, original randomized arm, OLE regimen choice, region, PTID and AE onset date.

Source: SCHARP (Haima) – /trials/hptn/p083/analysis/live/code/ole/l_ole_eae.sas, SAS Version 9.4 (04MAR2026,6:09)

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Listing 6 – Listing of Serious Adverse Events and Expedited Adverse Events Ordered by Severity [1]

Severity Grade=Grade 3 (Severe)

# [2]	Original Arm	OLE Regimen Choice	Region	Participant ID	Enrollment Date	OLE Start Date	Onset Date	Diagnosis	MedDRA Preferred Term	MedDRA low–level Term	Relationship to Study Product	Action Taken with study product	Hospitalization
169	TDF/FTC	Cabotegravir	Asia	858657725	27FEB2018	02FEB2022	25JUL2022	Neck muscle strain	Muscle strain	Neck strain	Not Related	Dose not changed	Yes
170	TDF/FTC	Cabotegravir	Asia	858659429	12FEB2020	31AUG2021	01JAN2022	COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes
171	TDF/FTC	Cabotegravir	Asia	858716830	21FEB2018	28SEP2021	17JAN2022	COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes
172	TDF/FTC	Cabotegravir	Asia	858770655	09APR2019	17AUG2021	04FEB2022	COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes
173	TDF/FTC	Cabotegravir	Asia	858778005	12FEB2020	31AUG2021	28JAN2022	COVID–19 infection	COVID–19	COVID–19	Not Related	Dose not changed	Yes
174	TDF/FTC	Cabotegravir	Asia	858801344	02OCT2018	27OCT2021	05SEP2023	Jarisch–Herxheimer reaction	Jarisch–Herxheimer reaction	Jarisch–Herxheimer reaction	Not Related	Dose not changed	Yes
175	TDF/FTC	Cabotegravir	Asia	858801344	02OCT2018	27OCT2021	09MAR2024	Acute Gastroenteritis	Gastroenteritis	Acute gastroenteritis	Not Related	Dose not changed	Yes
176	TDF/FTC	Cabotegravir	Asia	858812393	11MAY2018	06OCT2021	03FEB2022	COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes
177	TDF/FTC	Cabotegravir	Asia	858966492	29JAN2018	21SEP2021	05SEP2023	Gastroduodenitis	Gastritis	Gastroduodenitis	Not Related	Dose not changed	Yes
178	TDF/FTC	Cabotegravir	Asia	858989060	28JAN2019	16AUG2021	13JAN2022	COVID–19	COVID–19	COVID–19	Not Related	Dose not changed	Yes
179	TDF/FTC	Cabotegravir	Africa	816472525	03AUG2018	27AUG2021	27NOV2021	Substance induced Psychosis	Substance–induced psychotic disorder	Substance–induced psychotic disorder	Not Related	Dose not changed	Yes

[1] This listing includes only those AEs which have been assigned MedDRA codes by clinical staff.
[2] This listing is sorted by descending AE severity, original randomized arm, OLE regimen choice, region, PTID and AE onset date.

Source: SCHARP (Haima) – /trials/hptn/p083/analysis/live/code/ole/l_ole_eae.sas, SAS Version 9.4 (04MAR2026,6:09)

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Listing 6 – Listing of Serious Adverse Events and Expedited Adverse Events Ordered by Severity [1]

Severity Grade=Grade 2 (Moderate)

# [2]	Original Arm	OLE Regimen Choice	Region	Participant ID	Enrollment Date	OLE Start Date	Onset Date	Diagnosis	MedDRA Preferred Term	MedDRA low–level Term	Relationship to Study Product	Action Taken with study product	Hospitalization
1	Cabotegravir	Cabotegravir	US	819517422	18AUG2017	02JUL2021	22JUL2022	Unspecified Personality Disorder requiring hospitalization	Personality disorder	Unspecified personality disorder	Not Related	Dose not changed	Yes
2	Cabotegravir	Cabotegravir	Latin America	845235393	14AUG2019	20SEP2021	24MAY2022	bilateral inguinal hernia	Inguinal hernia	Bilateral inguinal hernia	Not Related	Dose not changed	Yes
3	Cabotegravir	Cabotegravir	Asia	858644068	20FEB2020	17AUG2021	16APR2022	Major depressive disorder	Major depression	Major depressive disorder	Not Related	Dose not changed	No
4	TDF/FTC	Cabotegravir	US	706225589	01AUG2017	19MAY2021	12SEP2022	prostatic adenocarcinoma	Prostate cancer	Adenocarcinoma of prostate	Not Related	Dose not changed	No
5	TDF/FTC	Cabotegravir	Latin America	714317365	23OCT2018	19MAY2023	13SEP2023	Increased ALT	Alanine aminotransferase increased	ALT increased	Related	Drug withdrawn	No
6	TDF/FTC	Cabotegravir	Latin America	714317365	23OCT2018	19MAY2023	13SEP2023	Increased Bilirubin	Blood bilirubin increased	Bilirubin increased	Related	Not applicable	No
7	TDF/FTC	Cabotegravir	Latin America	714725509	05JUL2018	21JUN2023	18JUL2023	HEPATITIS C	Hepatitis C	Hepatitis C	Not Related	Not applicable	No
8	TDF/FTC	Cabotegravir	Latin America	850201402	16AUG2019	19AUG2021	31JAN2022	SUPRACLAVICULAR haemathoma	Haematoma	Haematoma	Not Related	Dose not changed	Yes
9	TDF/FTC	Cabotegravir	Asia	813362499	12FEB2019	21DEC2022	07OCT2023	Monkeypox	Monkeypox	Monkeypox	Not Related	Drug interrupted	No

[1] This listing includes only those AEs which have been assigned MedDRA codes by clinical staff.
[2] This listing is sorted by descending AE severity, original randomized arm, OLE regimen choice, region, PTID and AE onset date.

Source: SCHARP (Haima) – /trials/hptn/p083/analysis/live/code/ole/l_ole_eae.sas, SAS Version 9.4 (04MAR2026,6:09)

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Table 13A – OLE Injection Site Reaction Summary by Original Randomized Study Arm

	Overall	TDF/FTC	Cabotegravir
Number of participants who have had at least one CAB injection in the OLE [1]	2494	1200	1294
Number of participants who have reported any ISR (injection site reaction)	1231/2494 (49.36%)	674/1200 (56.16%)	557/1294 (43.04%)
Number of participants who have reported any grade 2 (moderate) and above ISR	711/2494 (28.50%)	399/1200 (33.26%)	312/1294 (24.12%)
Number of participants who have reported any of the following grade 2 (moderate) and above ISRs			
Any injection site abscess	1/2494 (0.04%)	1/1200 (0.08%)	0/1294 (0.00%)
Any injection site bruising	3/2494 (0.12%)	3/1200 (0.26%)	0/1294 (0.00%)
Any injection site erythema	10/2494 (0.40%)	6/1200 (0.50%)	4/1294 (0.30%)
Any injection site hematoma	1/2494 (0.04%)	0/1200 (0.00%)	1/1294 (0.08%)
Any injection site induration	18/2494 (0.72%)	10/1200 (0.84%)	8/1294 (0.62%)
Any injection site itching	2/2494 (0.08%)	0/1200 (0.00%)	2/1294 (0.16%)
Any injection site nodule	31/2494 (1.24%)	17/1200 (1.42%)	14/1294 (1.08%)
Any injection site pain	659/2494 (26.42%)	367/1200 (30.58%)	292/1294 (22.56%)
Any injection site swelling	30/2494 (1.20%)	17/1200 (1.42%)	13/1294 (1.00%)
Any injection site tenderness	92/2494 (3.68%)	62/1200 (5.16%)	30/1294 (2.32%)
Any injection site warmth	4/2494 (0.16%)	4/1200 (0.34%)	0/1294 (0.00%)
Number of injections given in the OLE	33249	16044	17205
Number of injections where ISR reported	3444	1812	1632
Injection Site Abscess [2]			
Grade 1 (Mild)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 2 (Moderate)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 3 (Severe)	1/33249 (<0.1%)	1/16044 (<0.1%)	0/17205 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Injection Site Anesthesia [2]			
Grade 1 (Mild)	1/33249 (<0.1%)	1/16044 (<0.1%)	0/17205 (0.0%)
Grade 2 (Moderate)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 3 (Severe)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Injection Site Bruising [2]			
Grade 1 (Mild)	7/33249 (<0.1%)	5/16044 (<0.1%)	2/17205 (<0.1%)
Grade 2 (Moderate)	3/33249 (<0.1%)	3/16044 (<0.1%)	0/17205 (0.0%)
Grade 3 (Severe)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Injection Site Discoloration [2]			
Grade 1 (Mild)	3/33249 (<0.1%)	0/16044 (0.0%)	3/17205 (<0.1%)

[1] Same participant could have more than one injection site reaction.
[2] Only the maximum grade is reported here per participant per visit.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_isr_byarm.sas, SAS Version 9.4 (04MAR2026,6:09)

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Table 13A – OLE Injection Site Reaction Summary by Original Randomized Study Arm

	Overall	TDF/FTC	Cabotegravir
Grade 2 (Moderate)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 3 (Severe)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Injection Site Erythema [2]			
Grade 1 (Mild)	16/33249 (<0.1%)	12/16044 (0.1%)	4/17205 (<0.1%)
Grade 2 (Moderate)	11/33249 (<0.1%)	7/16044 (<0.1%)	4/17205 (<0.1%)
Grade 3 (Severe)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Injection Site Hematoma [2]			
Grade 1 (Mild)	4/33249 (<0.1%)	1/16044 (<0.1%)	3/17205 (<0.1%)
Grade 2 (Moderate)	1/33249 (<0.1%)	0/16044 (0.0%)	1/17205 (<0.1%)
Grade 3 (Severe)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Injection Site Induration [2]			
Grade 1 (Mild)	56/33249 (0.2%)	25/16044 (0.2%)	31/17205 (0.2%)
Grade 2 (Moderate)	18/33249 (0.1%)	10/16044 (0.1%)	8/17205 (<0.1%)
Grade 3 (Severe)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Injection Site Itching [2]			
Grade 1 (Mild)	7/33249 (<0.1%)	4/16044 (<0.1%)	3/17205 (<0.1%)
Grade 2 (Moderate)	2/33249 (<0.1%)	0/16044 (0.0%)	2/17205 (<0.1%)
Grade 3 (Severe)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Injection Site Nodule [2]			
Grade 1 (Mild)	137/33249 (0.4%)	61/16044 (0.4%)	76/17205 (0.4%)
Grade 2 (Moderate)	41/33249 (0.1%)	22/16044 (0.1%)	19/17205 (0.1%)
Grade 3 (Severe)	1/33249 (<0.1%)	1/16044 (<0.1%)	0/17205 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Injection Site Pain [2]			
Grade 1 (Mild)	1292/33249 (3.9%)	693/16044 (4.3%)	599/17205 (3.5%)
Grade 2 (Moderate)	1553/33249 (4.7%)	806/16044 (5.0%)	747/17205 (4.3%)
Grade 3 (Severe)	5/33249 (<0.1%)	3/16044 (<0.1%)	2/17205 (<0.1%)

[1] Same participant could have more than one injection site reaction.
[2] Only the maximum grade is reported here per participant per visit.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_isr_byarm.sas, SAS Version 9.4 (04MAR2026,6:09)

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Table 13A – OLE Injection Site Reaction Summary by Original Randomized Study Arm

	Overall	TDF/FTC	Cabotegravir
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Injection Site Swelling [2]			
Grade 1 (Mild)	40/33249 (0.1%)	22/16044 (0.1%)	18/17205 (0.1%)
Grade 2 (Moderate)	33/33249 (0.1%)	19/16044 (0.1%)	14/17205 (0.1%)
Grade 3 (Severe)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Injection Site Tenderness [2]			
Grade 1 (Mild)	441/33249 (1.3%)	232/16044 (1.4%)	209/17205 (1.2%)
Grade 2 (Moderate)	137/33249 (0.4%)	97/16044 (0.6%)	40/17205 (0.2%)
Grade 3 (Severe)	1/33249 (<0.1%)	1/16044 (<0.1%)	0/17205 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Injection Site Warmth [2]			
Grade 1 (Mild)	2/33249 (<0.1%)	2/16044 (<0.1%)	0/17205 (0.0%)
Grade 2 (Moderate)	4/33249 (<0.1%)	4/16044 (<0.1%)	0/17205 (0.0%)
Grade 3 (Severe)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/16044 (0.0%)	0/17205 (0.0%)

[1] Same participant could have more than one injection site reaction.
[2] Only the maximum grade is reported here per participant per visit.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_isr_byarm.sas, SAS Version 9.4 (04MAR2026,6:09)

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Table 13B – OLE Injection Site Reaction Summary by Region

	Overall	US	Latin America	Asia	Africa
Number of participants who have had at least one CAB injection in the OLE [1]	2494	765	1153	499	77
Number of participants who have reported any ISR (injection site reaction)	1231/2494 (49.36%)	269/765 (35.16%)	649/1153 (56.28%)	291/499 (58.32%)	22/77 (28.58%)
Number of participants who have reported any grade 2 (moderate) and above ISR	711/2494 (28.50%)	86/765 (11.24%)	447/1153 (38.76%)	168/499 (33.66%)	10/77 (12.98%)
Number of participants who have reported any of the following grade 2 (moderate) and above ISRs					
Any injection site abscess	1/2494 (0.04%)	0/765 (0.00%)	1/1153 (0.08%)	0/499 (0.00%)	0/77 (0.00%)
Any injection site bruising	3/2494 (0.12%)	2/765 (0.26%)	1/1153 (0.08%)	0/499 (0.00%)	0/77 (0.00%)
Any injection site erythema	10/2494 (0.40%)	2/765 (0.26%)	8/1153 (0.70%)	0/499 (0.00%)	0/77 (0.00%)
Any injection site hematoma	1/2494 (0.04%)	0/765 (0.00%)	1/1153 (0.08%)	0/499 (0.00%)	0/77 (0.00%)
Any injection site induration	18/2494 (0.72%)	3/765 (0.40%)	14/1153 (1.22%)	1/499 (0.20%)	0/77 (0.00%)
Any injection site itching	2/2494 (0.08%)	0/765 (0.00%)	2/1153 (0.18%)	0/499 (0.00%)	0/77 (0.00%)
Any injection site nodule	31/2494 (1.24%)	8/765 (1.04%)	22/1153 (1.90%)	0/499 (0.00%)	1/77 (1.30%)
Any injection site pain	659/2494 (26.42%)	61/765 (7.98%)	427/1153 (37.04%)	166/499 (33.26%)	5/77 (6.50%)
Any injection site swelling	30/2494 (1.20%)	8/765 (1.04%)	16/1153 (1.38%)	4/499 (0.80%)	2/77 (2.60%)
Any injection site tenderness	92/2494 (3.68%)	40/765 (5.22%)	37/1153 (3.20%)	7/499 (1.40%)	8/77 (10.38%)
Any injection site warmth	4/2494 (0.16%)	0/765 (0.00%)	3/1153 (0.26%)	1/499 (0.20%)	0/77 (0.00%)
Number of injections given in the OLE	33249	7963	17048	7057	1181
Number of injections where ISR reported	3444	645	1750	1003	46
Injection Site Abscess [2]					
Grade 1 (Mild)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 2 (Moderate)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 3 (Severe)	1/33249 (<0.1%)	0/7963 (0.0%)	1/17048 (<0.1%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Injection Site Anesthesia [2]					
Grade 1 (Mild)	1/33249 (<0.1%)	1/7963 (<0.1%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 2 (Moderate)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 3 (Severe)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Injection Site Bruising [2]					
Grade 1 (Mild)	7/33249 (<0.1%)	5/7963 (0.1%)	2/17048 (<0.1%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 2 (Moderate)	3/33249 (<0.1%)	2/7963 (<0.1%)	1/17048 (<0.1%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 3 (Severe)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Injection Site Discoloration [2]					
Grade 1 (Mild)	3/33249 (<0.1%)	2/7963 (<0.1%)	0/17048 (0.0%)	0/7057 (0.0%)	1/1181 (0.1%)

[1] Same participant could have more than one injection site reaction.
[2] Only the maximum grade is reported here per participant per visit.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_isr_byregion.sas, SAS Version 9.4 (04MAR2026,6:09)

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
OLE Open Report – March 4, 2026
Visit Cutoff Date: March 4, 2026
Table 13B – OLE Injection Site Reaction Summary by Region

	Overall	US	Latin America	Asia	Africa
Grade 2 (Moderate)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 3 (Severe)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Injection Site Erythema [2]					
Grade 1 (Mild)	16/33249 (<0.1%)	9/7963 (0.1%)	7/17048 (<0.1%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 2 (Moderate)	11/33249 (<0.1%)	3/7963 (<0.1%)	8/17048 (<0.1%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 3 (Severe)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Injection Site Hematoma [2]					
Grade 1 (Mild)	4/33249 (<0.1%)	0/7963 (0.0%)	4/17048 (<0.1%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 2 (Moderate)	1/33249 (<0.1%)	0/7963 (0.0%)	1/17048 (<0.1%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 3 (Severe)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Injection Site Induration [2]					
Grade 1 (Mild)	56/33249 (0.2%)	27/7963 (0.3%)	16/17048 (0.1%)	13/7057 (0.2%)	0/1181 (0.0%)
Grade 2 (Moderate)	18/33249 (0.1%)	3/7963 (<0.1%)	14/17048 (0.1%)	1/7057 (<0.1%)	0/1181 (0.0%)
Grade 3 (Severe)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Injection Site Itching [2]					
Grade 1 (Mild)	7/33249 (<0.1%)	3/7963 (<0.1%)	0/17048 (0.0%)	2/7057 (<0.1%)	2/1181 (0.2%)
Grade 2 (Moderate)	2/33249 (<0.1%)	0/7963 (0.0%)	2/17048 (<0.1%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 3 (Severe)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Injection Site Nodule [2]					
Grade 1 (Mild)	137/33249 (0.4%)	83/7963 (1.0%)	47/17048 (0.3%)	6/7057 (0.1%)	1/1181 (0.1%)
Grade 2 (Moderate)	41/33249 (0.1%)	11/7963 (0.1%)	29/17048 (0.2%)	0/7057 (0.0%)	1/1181 (0.1%)
Grade 3 (Severe)	1/33249 (<0.1%)	0/7963 (0.0%)	1/17048 (<0.1%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Injection Site Pain [2]					
Grade 1 (Mild)	1292/33249 (3.9%)	130/7963 (1.6%)	563/17048 (3.3%)	584/7057 (8.3%)	15/1181 (1.3%)
Grade 2 (Moderate)	1553/33249 (4.7%)	80/7963 (1.0%)	1073/17048 (6.3%)	393/7057 (5.6%)	7/1181 (0.6%)
Grade 3 (Severe)	5/33249 (<0.1%)	1/7963 (<0.1%)	4/17048 (<0.1%)	0/7057 (0.0%)	0/1181 (0.0%)

[1] Same participant could have more than one injection site reaction.
[2] Only the maximum grade is reported here per participant per visit.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_isr_byregion.sas, SAS Version 9.4 (04MAR2026,6:09)

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
OLE Open Report – March 4, 2026
Visit Cutoff Date: March 4, 2026
Table 13B – OLE Injection Site Reaction Summary by Region

	Overall	US	Latin America	Asia	Africa
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Injection Site Swelling [2]					
Grade 1 (Mild)	40/33249 (0.1%)	25/7963 (0.3%)	7/17048 (<0.1%)	4/7057 (0.1%)	4/1181 (0.3%)
Grade 2 (Moderate)	33/33249 (0.1%)	11/7963 (0.1%)	16/17048 (0.1%)	4/7057 (0.1%)	2/1181 (0.2%)
Grade 3 (Severe)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Injection Site Tenderness [2]					
Grade 1 (Mild)	441/33249 (1.3%)	384/7963 (4.8%)	14/17048 (0.1%)	19/7057 (0.3%)	24/1181 (2.0%)
Grade 2 (Moderate)	137/33249 (0.4%)	62/7963 (0.8%)	55/17048 (0.3%)	8/7057 (0.1%)	12/1181 (1.0%)
Grade 3 (Severe)	1/33249 (<0.1%)	1/7963 (<0.1%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Injection Site Warmth [2]					
Grade 1 (Mild)	2/33249 (<0.1%)	0/7963 (0.0%)	2/17048 (<0.1%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 2 (Moderate)	4/33249 (<0.1%)	0/7963 (0.0%)	3/17048 (<0.1%)	1/7057 (<0.1%)	0/1181 (0.0%)
Grade 3 (Severe)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 4 (Potentially life–threatening)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)
Grade 5 (Death)	0/33249 (0.0%)	0/7963 (0.0%)	0/17048 (0.0%)	0/7057 (0.0%)	0/1181 (0.0%)

[1] Same participant could have more than one injection site reaction.
[2] Only the maximum grade is reported here per participant per visit.

Source: SCHARP (Zoe) – /trials/hptn/p083/analysis/live/code/ole/t_ole_isr_byregion.sas, SAS Version 9.4 (04MAR2026,6:09)