

HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women
Atlas OLE Report – May 24, 2026
Visit Cutoff Date: May 24, 2026
Table 1B – OLE Enrollment Summary by Site ¹

	Overall	South Africa: Kwa Zulu Natal: Verulam CRS	Malawi: Lilongwe: Malawi CRS	Botswana: Gaborone: Gaborone CRS
Total Participants Enrolled in the main study	3224	151	114	91
Potentially eligible for OLE ²	3032/3224 (94.0%)	143/151 (94.7%)	100/114 (87.7%)	87/91 (95.6%)
Joined the OLE	2472/3032 (81.5%)	119/143 (83.2%)	75/100 (75.0%)	71/87 (81.6%)
Did not join the OLE	560/3032 (18.5%)	24/143 (16.8%)	25/100 (25.0%)	16/87 (18.4%)
1	39/560 (7.0%)	5/24 (20.8%)	0/25 (0.0%)	6/16 (37.5%)
3	33/560 (5.9%)	3/24 (12.5%)	1/25 (4.0%)	0/16 (0.0%)
4	18/560 (3.2%)	3/24 (12.5%)	0/25 (0.0%)	1/16 (6.3%)
5	6/560 (1.1%)	0/24 (0.0%)	0/25 (0.0%)	6/16 (37.5%)
6	78/560 (13.9%)	6/24 (25.0%)	14/25 (56.0%)	0/16 (0.0%)
99	44/560 (7.9%)	5/24 (20.8%)	1/25 (4.0%)	1/16 (6.3%)
.	342/560 (61.1%)	2/24 (8.3%)	9/25 (36.0%)	2/16 (12.5%)

¹ OLE enrollment sites are used.

²Only includes participants at sites that are active under protocol version 3.0. Excludes participants who are HIV infected or permanently discontinued study products due to safety reasons (reactive HIV test, clinical or lab AE, ISR, CMC recommendation, Hepatitis B infections) or were terminated from the study prior to or on the start date of the OLE at the site.

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	Uganda: Kampala: MU-JHU Research Collaboration CRS	Zimbabwe: Chitungwiza: Seke South CRS	Malawi: Blantyre: Blantyre CRS	Zimbabwe: Chitungwiza: St.Mary's CRS
Total Participants Enrolled in the main study	204	160	110	166
Potentially eligible for OLE ²	194/204 (95.1%)	151/160 (94.4%)	107/110 (97.3%)	162/166 (97.6%)
Joined the OLE	149/194 (76.8%)	125/151 (82.8%)	82/107 (76.6%)	135/162 (83.3%)
Did not join the OLE	45/194 (23.2%)	26/151 (17.2%)	25/107 (23.4%)	27/162 (16.7%)
1	0/45 (0.0%)	0/26 (0.0%)	7/25 (28.0%)	0/27 (0.0%)
3	0/45 (0.0%)	0/26 (0.0%)	6/25 (24.0%)	1/27 (3.7%)
4	0/45 (0.0%)	0/26 (0.0%)	0/25 (0.0%)	2/27 (7.4%)
5	0/45 (0.0%)	0/26 (0.0%)	0/25 (0.0%)	0/27 (0.0%)
6	1/45 (2.2%)	0/26 (0.0%)	5/25 (20.0%)	23/27 (85.2%)
99	0/45 (0.0%)	0/26 (0.0%)	3/25 (12.0%)	1/27 (3.7%)
.	44/45 (97.8%)	26/26 (100.0%)	4/25 (16.0%)	0/27 (0.0%)

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	Zimbabwe: Harare: Parirenyatwa CRS	Zimbabwe: Harare: Spilhaus CRS	Zimbabwe: Chitungwiza: Zengeza CRS	South Africa: Cape Town: Emavundleni CRS
Total Participants Enrolled in the main study	153	133	161	227
Potentially eligible for OLE ²	146/153 (95.4%)	131/133 (98.5%)	159/161 (98.8%)	219/227 (96.5%)
Joined the OLE	121/146 (82.9%)	123/131 (93.9%)	130/159 (81.8%)	170/219 (77.6%)
Did not join the OLE	25/146 (17.1%)	8/131 (6.1%)	29/159 (18.2%)	49/219 (22.4%)
1	0/25 (0.0%)	2/8 (25.0%)	0/29 (0.0%)	12/49 (24.5%)
3	0/25 (0.0%)	4/8 (50.0%)	0/29 (0.0%)	15/49 (30.6%)
4	0/25 (0.0%)	0/8 (0.0%)	0/29 (0.0%)	8/49 (16.3%)
5	0/25 (0.0%)	0/8 (0.0%)	0/29 (0.0%)	0/49 (0.0%)
6	0/25 (0.0%)	0/8 (0.0%)	1/29 (3.4%)	3/49 (6.1%)
99	0/25 (0.0%)	2/8 (25.0%)	4/29 (13.8%)	11/49 (22.4%)
.	25/25 (100.0%)	0/8 (0.0%)	24/29 (82.8%)	0/49 (0.0%)

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	South Africa: Botha's Hill: Botha's Hill CRS	Kenya: Kisumu: Kisumu CRS	South Africa: Soweto: Soweto HPTN CRS	South Africa: Kwa Zulu Natal: Isipingo CRS
Total Participants Enrolled in the main study	223	66	175	170
Potentially eligible for OLE ²	189/223 (84.8%)	65/66 (98.5%)	155/175 (88.6%)	151/170 (88.8%)
Joined the OLE	180/189 (95.2%)	63/65 (96.9%)	133/155 (85.8%)	141/151 (93.4%)
Did not join the OLE	9/189 (4.8%)	2/65 (3.1%)	22/155 (14.2%)	10/151 (6.6%)
1	0/9 (0.0%)	0/2 (0.0%)	0/22 (0.0%)	0/10 (0.0%)
3	1/9 (11.1%)	0/2 (0.0%)	0/22 (0.0%)	0/10 (0.0%)
4	0/9 (0.0%)	0/2 (0.0%)	0/22 (0.0%)	0/10 (0.0%)
5	0/9 (0.0%)	0/2 (0.0%)	0/22 (0.0%)	0/10 (0.0%)
6	0/9 (0.0%)	0/2 (0.0%)	0/22 (0.0%)	0/10 (0.0%)
99	0/9 (0.0%)	0/2 (0.0%)	0/22 (0.0%)	3/10 (30.0%)
.	8/9 (88.9%)	2/2 (100.0%)	22/22 (100.0%)	7/10 (70.0%)

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Table 1B – OLE Enrollment Summary by Site ¹

	South Africa: Cape Town: Stellenbosch University (DTTC-SU) CRS	South Africa: Johannesburg: Ward 21	Swaziland: Siteki: Swaziland Prevention Center	Uganda: Kampala: Baylor-Uganda CRS
Total Participants Enrolled in the main study	158	211	159	210
Potentially eligible for OLE ²	148/158 (93.7%)	186/211 (88.2%)	157/159 (98.7%)	205/210 (97.6%)
Joined the OLE	99/148 (66.9%)	165/186 (88.7%)	121/157 (77.1%)	146/205 (71.2%)
Did not join the OLE	49/148 (33.1%)	21/186 (11.3%)	36/157 (22.9%)	59/205 (28.8%)
1	0/49 (0.0%)	1/21 (4.8%)	6/36 (16.7%)	0/59 (0.0%)
3	0/49 (0.0%)	0/21 (0.0%)	0/36 (0.0%)	0/59 (0.0%)
4	0/49 (0.0%)	0/21 (0.0%)	3/36 (8.3%)	0/59 (0.0%)
5	0/49 (0.0%)	0/21 (0.0%)	0/36 (0.0%)	0/59 (0.0%)
6	0/49 (0.0%)	1/21 (4.8%)	0/36 (0.0%)	0/59 (0.0%)
99	0/49 (0.0%)	0/21 (0.0%)	3/36 (8.3%)	1/59 (1.7%)
.	49/49 (100.0%)	19/21 (90.5%)	24/36 (66.7%)	58/59 (98.3%)

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	Uganda: Entebbe: UVRI-IAVI
Total Participants Enrolled in the main study	182
Potentially eligible for OLE ²	177/182 (97.3%)
Joined the OLE	124/177 (70.1%)
Did not join the OLE	53/177 (29.9%)
1	0/53 (0.0%)
3	2/53 (3.8%)
4	1/53 (1.9%)
5	0/53 (0.0%)
6	24/53 (45.3%)
99	9/53 (17.0%)
.	17/53 (32.1%)

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Table 3B – Visit Completion by Visit and Site ¹

	Overall	Botswana: Gaborone: Gaborone CRS	Kenya: Kisumu: Kisumu CRS	Malawi: Blantyre: Blantyre CRS	Malawi: Lilongwe: Malawi CRS	South Africa: Botha's Hill: Botha's Hill CRS
Total Participants Enrolled in OLE ²	2472	71	63	82	75	180
Step 4a – Oral CAB						
Day 0	211	2	11	7	3	9
Step 4b – Loading Dose CAB-LA						
Day 0/ Week 4	1081	44	31	33	33	52
Step 4c – Standard Dose CAB-LA or TDF/FTC ³						
Day 0	2387	71	61	80	70	176
Week 8	2285/2439 (93.7%)	70/70 (100.0%)	61/62 (98.4%)	79/82 (96.3%)	68/72 (94.4%)	179/179 (100.0%)
Week 16	2219/2435 (91.1%)	68/70 (97.1%)	58/61 (95.1%)	77/81 (95.1%)	64/71 (90.1%)	178/179 (99.4%)
Week 24	2160/2430 (88.9%)	65/70 (92.9%)	58/61 (95.1%)	76/81 (93.8%)	62/71 (87.3%)	174/179 (97.2%)
Week 32	2121/2422 (87.6%)	64/69 (92.8%)	57/62 (91.9%)	74/81 (91.4%)	63/71 (88.7%)	173/178 (97.2%)
Week 40	2099/2412 (87.0%)	64/68 (94.1%)	56/62 (90.3%)	74/81 (91.4%)	60/71 (84.5%)	170/177 (96.0%)
Week 48	2051/2407 (85.2%)	61/68 (89.7%)	57/62 (91.9%)	76/81 (93.8%)	58/71 (81.7%)	167/175 (95.4%)
Step 5 – TDF/FTC ³						
Day 0	72	2	0	1	6	6
Week 12	60/78 (76.9%)	3/3 (100.0%)	1/1 (100.0%)	1/1 (100.0%)	5/6 (83.3%)	6/7 (85.7%)
Week 24	56/76 (73.7%)	3/3 (100.0%)	1/1 (100.0%)	1/1 (100.0%)	5/5 (100.0%)	5/6 (83.3%)
Week 36	56/67 (83.6%)	3/3 (100.0%)	1/1 (100.0%)	1/1 (100.0%)	4/5 (80.0%)	6/7 (85.7%)
Week 48	54/64 (84.4%)	3/3 (100.0%)	1/1 (100.0%)	1/1 (100.0%)	5/5 (100.0%)	4/7 (57.1%)
Step 6 – CAB ³						
First Start Date	10FEB2023	21MAR2023	04APR2023	28AUG2023	04MAY2023	05JUN2023
Week 56	1622/1622 (100.0%)	52/52 (100.0%)	46/46 (100.0%)	58/58 (100.0%)	38/38 (100.0%)	123/123 (100.0%)
Week 64	1645/1701 (96.7%)	54/54 (100.0%)	45/47 (95.7%)	56/58 (96.6%)	48/51 (94.1%)	124/124 (100.0%)
Week 72	1643/1712 (96.0%)	52/53 (98.1%)	48/48 (100.0%)	56/59 (94.9%)	49/51 (96.1%)	123/124 (99.2%)
Week 80	1610/1714 (93.9%)	50/53 (94.3%)	47/49 (95.9%)	56/59 (94.9%)	47/50 (94.0%)	121/124 (97.6%)
Week 88	1568/1712 (91.6%)	51/53 (96.2%)	46/49 (93.9%)	57/60 (95.0%)	42/46 (91.3%)	120/124 (96.8%)
Week 96	1562/1728 (90.4%)	54/55 (98.2%)	46/50 (92.0%)	58/61 (95.1%)	42/47 (89.4%)	118/123 (95.9%)
Week 104	1500/1722 (87.1%)	52/55 (94.5%)	46/51 (90.2%)	59/62 (95.2%)	44/50 (88.0%)	112/123 (91.1%)
Week 112	1462/1710 (85.5%)	53/56 (94.6%)	48/51 (94.1%)	59/62 (95.2%)	44/52 (84.6%)	88/122 (72.1%)
Week 120	0/1246 (0.0%)	0/49 (0.0%)	0/43 (0.0%)	0/58 (0.0%)	0/43 (0.0%)	0/15 (0.0%)
Week 128	0/1092 (0.0%)	0/35 (0.0%)	0/7 (0.0%)	0/53 (0.0%)	0/43 (0.0%)	0/76 (0.0%)
Week 136	0/583 (0.0%)	0/0 (–%)	0/0 (–%)	0/42 (0.0%)	0/38 (0.0%)	0/0 (–%)
Week 144	0/265 (0.0%)	0/0 (–%)	0/0 (–%)	0/10 (0.0%)	0/35 (0.0%)	0/0 (–%)

¹ Participants are grouped under the site where they enrolled into the OLE.

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 prior to the site started OLE, 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 day 0.

⁴ Date the first participant is expected to need an injection that falls outside the current OLE2 schedule.

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	Overall	Botswana: Gaborone: Gaborone CRS	Kenya: Kisumu: Kisumu CRS	Malawi: Blantyre: Blantyre CRS	Malawi: Lilongwe: Malawi CRS	South Africa: Botha's Hill: Botha's Hill CRS
Week 152	0/134 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/36 (0.0%)	0/0 (-%)
Week 160	0/56 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/27 (0.0%)	0/0 (-%)
130	0/9 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/4 (0.0%)	0/0 (-%)
First Post-OLE2 Visit Date ⁴	12JAN2024	20FEB2024	05MAR2024	29JUL2024	04APR2024	06MAY2024

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Table 3B – Visit Completion by Visit and Site ¹

	South Africa: Cape Town: Emavundleni CRS	South Africa: Cape Town: Stellenbosch University (DTTC-SU) CRS	South Africa: Kwa Zulu Natal: Isipingo CRS	South Africa: Johannesburg: Ward 21	South Africa: Kwa Zulu Natal: Verulam CRS	South Africa: Soweto: Soweto HPTN CRS
Total Participants Enrolled in OLE ²	170	99	141	165	119	133
Step 4a – Oral CAB						
Day 0	10	2	0	15	6	3
Step 4b – Loading Dose CAB-LA						
Day 0/ Week 4	37	47	52	80	27	59
Step 4c – Standard Dose CAB-LA or TDF/FTC ³						
Day 0	165	98	139	163	116	130
Week 8	157/166 (94.6%)	93/98 (94.9%)	135/140 (96.4%)	154/164 (93.9%)	107/117 (91.5%)	128/131 (97.7%)
Week 16	155/166 (93.4%)	88/98 (89.8%)	133/140 (95.0%)	154/164 (93.9%)	106/117 (90.6%)	127/131 (96.9%)
Week 24	145/165 (87.9%)	88/98 (89.8%)	133/140 (95.0%)	147/163 (90.2%)	98/117 (83.8%)	129/130 (99.2%)
Week 32	142/163 (87.1%)	84/98 (85.7%)	138/140 (98.6%)	138/162 (85.2%)	103/117 (88.0%)	128/129 (99.2%)
Week 40	140/161 (87.0%)	86/98 (87.8%)	135/140 (96.4%)	144/159 (90.6%)	100/116 (86.2%)	126/128 (98.4%)
Week 48	141/159 (88.7%)	80/97 (82.5%)	137/140 (97.9%)	147/160 (91.9%)	98/116 (84.5%)	126/128 (98.4%)
Step 5 – TDF/FTC ³						
Day 0	3	2	1	5	8	1
Week 12	3/3 (100.0%)	2/2 (100.0%)	4/4 (100.0%)	5/5 (100.0%)	7/8 (87.5%)	1/1 (100.0%)
Week 24	3/3 (100.0%)	2/2 (100.0%)	5/5 (100.0%)	5/5 (100.0%)	6/8 (75.0%)	1/1 (100.0%)
Week 36	3/3 (100.0%)	3/3 (100.0%)	4/4 (100.0%)	6/6 (100.0%)	4/7 (57.1%)	1/1 (100.0%)
Week 48	3/3 (100.0%)	3/3 (100.0%)	4/4 (100.0%)	6/6 (100.0%)	2/5 (40.0%)	1/1 (100.0%)
Step 6 – CAB ³						
First Start Date	18APR2023	23MAY2023	08JUN2023	10FEB2023	26JUN2023	24MAR2023
Week 56	74/74 (100.0%)	71/71 (100.0%)	117/117 (100.0%)	119/119 (100.0%)	56/56 (100.0%)	117/117 (100.0%)
Week 64	77/82 (93.9%)	68/74 (91.9%)	113/117 (96.6%)	121/125 (96.8%)	61/61 (100.0%)	116/117 (99.1%)
Week 72	83/85 (97.6%)	69/74 (93.2%)	112/118 (94.9%)	121/126 (96.0%)	62/63 (98.4%)	114/117 (97.4%)
Week 80	79/85 (92.9%)	65/74 (87.8%)	111/118 (94.1%)	117/125 (93.6%)	59/62 (95.2%)	116/117 (99.1%)
Week 88	73/84 (86.9%)	63/73 (86.3%)	110/117 (94.0%)	115/123 (93.5%)	61/64 (95.3%)	112/117 (95.7%)
Week 96	81/85 (95.3%)	60/73 (82.2%)	111/116 (95.7%)	115/125 (92.0%)	59/63 (93.7%)	110/117 (94.0%)
Week 104	74/83 (89.2%)	60/76 (78.9%)	110/116 (94.8%)	105/122 (86.1%)	56/62 (90.3%)	106/116 (91.4%)
Week 112	75/83 (90.4%)	58/76 (76.3%)	110/116 (94.8%)	100/121 (82.6%)	44/55 (80.0%)	106/114 (93.0%)
Week 120	0/66 (0.0%)	0/60 (0.0%)	0/90 (0.0%)	0/51 (0.0%)	0/24 (0.0%)	0/104 (0.0%)
Week 128	0/50 (0.0%)	0/58 (0.0%)	0/9 (0.0%)	0/40 (0.0%)	0/10 (0.0%)	0/79 (0.0%)

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	South Africa: Cape Town: Emavundleni CRS	South Africa: Cape Town: Stellenbosch University (DTTC-SU) CRS	South Africa: Kwa Zulu Natal: Isipingo CRS	South Africa: Johannesburg: Ward 21	South Africa: Kwa Zulu Natal: Verulam CRS	South Africa: Soweto: Soweto HPTN CRS
Week 136	0/0 (-%)	0/49 (0.0%)	0/0 (-%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)
Week 144	0/0 (-%)	0/45 (0.0%)	0/0 (-%)	0/10 (0.0%)	0/0 (-%)	0/0 (-%)
Week 152	0/0 (-%)	0/8 (0.0%)	0/0 (-%)	0/18 (0.0%)	0/0 (-%)	0/0 (-%)
Week 160	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
130	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
First Post-OLE2 Visit Date ⁴	19MAR2024	23APR2024	09MAY2024	12JAN2024	27MAY2024	23FEB2024

¹ Participants are grouped under the site where they enrolled into the OLE.

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³ Participants can directly go to later visits without day 0.

⁴ Date the first participant is expected to need an injection that falls outside the current OLE2 schedule.

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Table 3B – Visit Completion by Visit and Site ¹

	Swaziland: Siteki: Swaziland Prevention Center	Uganda: Entebbe: UVRI-IAVI	Uganda: Kampala: Baylor-Uganda CRS	Uganda: Kampala: MU-JHU Research Collaboration CRS	Zimbabwe: Chitungwiza: Seke South CRS	Zimbabwe: Chitungwiza: St.Mary's CRS
Total Participants Enrolled in OLE ²	121	124	146	149	125	135
Step 4a – Oral CAB						
Day 0	17	4	16	20	2	35
Step 4b – Loading Dose CAB-LA						
Day 0/ Week 4	55	45	58	66	74	76
Step 4c – Standard Dose CAB-LA or TDF/FTC ³						
Day 0	113	116	138	146	114	127
Week 8	111/119 (93.3%)	103/123 (83.7%)	115/142 (81.0%)	139/147 (94.6%)	110/123 (89.4%)	118/134 (88.1%)
Week 16	108/119 (90.8%)	98/123 (79.7%)	116/142 (81.7%)	130/147 (88.4%)	105/123 (85.4%)	115/134 (85.8%)
Week 24	104/119 (87.4%)	92/123 (74.8%)	117/142 (82.4%)	125/145 (86.2%)	102/123 (82.9%)	112/134 (83.6%)
Week 32	101/118 (85.6%)	90/123 (73.2%)	115/142 (81.0%)	119/145 (82.1%)	101/123 (82.1%)	108/133 (81.2%)
Week 40	95/117 (81.2%)	89/124 (71.8%)	117/142 (82.4%)	122/145 (84.1%)	96/123 (78.0%)	108/132 (81.8%)
Week 48	75/117 (64.1%)	90/124 (72.6%)	111/142 (78.2%)	115/144 (79.9%)	94/123 (76.4%)	109/132 (82.6%)
Step 5 – TDF/FTC ³						
Day 0	4	3	14	4	3	3
Week 12	2/4 (50.0%)	3/3 (100.0%)	2/14 (14.3%)	4/4 (100.0%)	3/3 (100.0%)	3/3 (100.0%)
Week 24	1/4 (25.0%)	3/3 (100.0%)	2/14 (14.3%)	4/4 (100.0%)	2/3 (66.7%)	2/2 (100.0%)
Week 36	2/4 (50.0%)	3/3 (100.0%)	2/4 (50.0%)	4/4 (100.0%)	2/3 (66.7%)	2/2 (100.0%)
Week 48	3/4 (75.0%)	3/3 (100.0%)	2/4 (50.0%)	4/4 (100.0%)	3/3 (100.0%)	2/2 (100.0%)
Step 6 – CAB ³						
First Start Date	08MAY2023	30MAY2023	14APR2023	05MAY2023	19JUN2023	13JUN2023
Week 56	58/58 (100.0%)	59/59 (100.0%)	80/80 (100.0%)	97/97 (100.0%)	89/89 (100.0%)	92/92 (100.0%)
Week 64	71/78 (91.0%)	61/67 (91.0%)	82/85 (96.5%)	96/98 (98.0%)	88/91 (96.7%)	91/94 (96.8%)
Week 72	71/79 (89.9%)	56/63 (88.9%)	84/87 (96.6%)	91/98 (92.9%)	90/92 (97.8%)	89/95 (93.7%)
Week 80	68/78 (87.2%)	58/64 (90.6%)	83/86 (96.5%)	88/97 (90.7%)	91/97 (93.8%)	89/96 (92.7%)
Week 88	60/74 (81.1%)	55/64 (85.9%)	82/88 (93.2%)	82/97 (84.5%)	91/99 (91.9%)	84/95 (88.4%)
Week 96	58/74 (78.4%)	57/64 (89.1%)	80/88 (90.9%)	78/96 (81.3%)	90/100 (90.0%)	82/98 (83.7%)
Week 104	41/69 (59.4%)	46/61 (75.4%)	80/88 (90.9%)	70/87 (80.5%)	90/102 (88.2%)	87/102 (85.3%)
Week 112	55/69 (79.7%)	51/62 (82.3%)	80/88 (90.9%)	67/85 (78.8%)	91/105 (86.7%)	82/101 (81.2%)
Week 120	0/58 (0.0%)	0/52 (0.0%)	0/66 (0.0%)	0/57 (0.0%)	0/92 (0.0%)	0/80 (0.0%)
Week 128	0/72 (0.0%)	0/48 (0.0%)	0/74 (0.0%)	0/56 (0.0%)	0/85 (0.0%)	0/69 (0.0%)
Week 136	0/63 (0.0%)	0/37 (0.0%)	0/65 (0.0%)	0/51 (0.0%)	0/57 (0.0%)	0/46 (0.0%)
Week 144	0/46 (0.0%)	0/18 (0.0%)	0/51 (0.0%)	0/33 (0.0%)	0/0 (-)	0/2 (0.0%)

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³ Participants can directly go to later visits without day 0.

⁴ Date the first participant is expected to need an injection that falls outside the current OLE2 schedule.

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Table 3B – Visit Completion by Visit and Site ¹

	Swaziland: Siteki: Swaziland Prevention Center	Uganda: Entebbe: UVRI-IAVI	Uganda: Kampala: Baylor-Uganda CRS	Uganda: Kampala: MU-JHU Research Collaboration CRS	Zimbabwe: Chitungwiza: Seke South CRS	Zimbabwe: Chitungwiza: St.Mary's CRS
Week 152	0/42 (0.0%)	0/7 (0.0%)	0/11 (0.0%)	0/10 (0.0%)	0/0 (-%)	0/0 (-%)
Week 160	0/15 (0.0%)	0/5 (0.0%)	0/1 (0.0%)	0/7 (0.0%)	0/0 (-%)	0/0 (-%)
130	0/0 (-%)	0/1 (0.0%)	0/0 (-%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)
First Post-OLE2 Visit Date ⁴	08APR2024	30APR2024	15MAR2024	05APR2024	20MAY2024	14MAY2024

¹ Participants are grouped under the site where they enrolled into the OLE.

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 prior to the site started OLE, and not terminated from study) at the time of the visit and the visit window has closed.

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Table 3B – Visit Completion by Visit and Site ¹

	Zimbabwe: Chitungwiza: Zengeza CRS	Zimbabwe: Harare: Parirenyatwa CRS	Zimbabwe: Harare: Spilhaus CRS
Total Participants Enrolled in OLE ²	130	121	123
Step 4a – Oral CAB			
Day 0	18	15	16
Step 4b – Loading Dose CAB-LA			
Day 0/ Week 4	72	64	76
Step 4c – Standard Dose CAB-LA or TDF/FTC ³			
Day 0	124	120	120
Week 8	122/127 (96.1%)	118/120 (98.3%)	118/123 (95.9%)
Week 16	114/127 (89.8%)	112/119 (94.1%)	113/123 (91.9%)
Week 24	111/127 (87.4%)	111/119 (93.3%)	111/123 (90.2%)
Week 32	104/126 (82.5%)	109/119 (91.6%)	110/123 (89.4%)
Week 40	103/126 (81.7%)	108/119 (90.8%)	106/123 (86.2%)
Week 48	100/126 (79.4%)	107/119 (89.9%)	102/123 (82.9%)
Step 5 – TDF/FTC ³			
Day 0	4	1	1
Week 12	4/4 (100.0%)	1/1 (100.0%)	0/1 (0.0%)
Week 24	4/4 (100.0%)	1/1 (100.0%)	0/1 (0.0%)
Week 36	4/4 (100.0%)	1/1 (100.0%)	0/1 (0.0%)
Week 48	3/4 (75.0%)	1/1 (100.0%)	0/0 (-%)
Step 6 – CAB ³			
First Start Date	03JUN2023	20JUN2023	27JUN2023
Week 56	86/86 (100.0%)	93/93 (100.0%)	97/97 (100.0%)
Week 64	86/88 (97.7%)	92/93 (98.9%)	95/97 (97.9%)
Week 72	85/89 (95.5%)	91/93 (97.8%)	97/98 (99.0%)
Week 80	85/89 (95.5%)	87/93 (93.5%)	93/98 (94.9%)
Week 88	82/90 (91.1%)	87/95 (91.6%)	95/100 (95.0%)
Week 96	84/92 (91.3%)	86/98 (87.8%)	93/103 (90.3%)
Week 104	88/96 (91.7%)	83/97 (85.6%)	91/104 (87.5%)
Week 112	87/95 (91.6%)	75/92 (81.5%)	89/105 (84.8%)
Week 120	0/83 (0.0%)	0/75 (0.0%)	0/80 (0.0%)
Week 128	0/86 (0.0%)	0/69 (0.0%)	0/73 (0.0%)
Week 136	0/54 (0.0%)	0/37 (0.0%)	0/41 (0.0%)
Week 144	0/1 (0.0%)	0/9 (0.0%)	0/5 (0.0%)

¹ Participants are grouped under the site where they enrolled into the OLE.

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Table 3B – Visit Completion by Visit and Site ¹

	Zimbabwe: Chitungwiza: Zengeza CRS	Zimbabwe: Harare: Parirenyatwa CRS	Zimbabwe: Harare: Spilhaus CRS
Week 152	0/0 (-%)	0/1 (0.0%)	0/1 (0.0%)
Week 160	0/0 (-%)	0/0 (-%)	0/0 (-%)
130	0/0 (-%)	0/0 (-%)	0/0 (-%)
First Post-OLE2 Visit Date ⁴	04MAY2024	21MAY2024	28MAY2024

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Table 4 – Disposition Summary by Site ¹

	Overall	Botswana: Gaborone: Gaborone CRS	Kenya: Kisumu: Kisumu CRS	Malawi: Blantyre: Blantyre CRS	Malawi: Lilongwe: Malawi CRS
Total participants enrolled in the blinded study	3224	91	66	110	114
Total Participants Enrolled in OLE	2472	71	63	82	75
Discontinued study product prior to termination	0/2472 (0.0%)	0/71 (0.0%)	0/63 (0.0%)	0/82 (0.0%)	0/75 (0.0%)
Terminated early in OLE	293/2472 (11.9%)	6/71 (8.5%)	2/63 (3.2%)	3/82 (3.7%)	12/75 (16.0%)
Death	2/293 (0.7%)	0/6 (0.0%)	0/2 (0.0%)	0/3 (0.0%)	0/12 (0.0%)
Participant refused further participation, specify	95/293 (32.4%)	4/6 (66.7%)	1/2 (50.0%)	0/3 (0.0%)	9/12 (75.0%)
Participant relocated, no follow-up planned	75/293 (25.6%)	2/6 (33.3%)	1/2 (50.0%)	1/3 (33.3%)	3/12 (25.0%)
Investigator decision, specify	5/293 (1.7%)	0/6 (0.0%)	0/2 (0.0%)	0/3 (0.0%)	0/12 (0.0%)
Unable to contact participant	85/293 (29.0%)	0/6 (0.0%)	0/2 (0.0%)	2/3 (66.7%)	0/12 (0.0%)
Inappropriate enrollment	0/293 (0.0%)	0/6 (0.0%)	0/2 (0.0%)	0/3 (0.0%)	0/12 (0.0%)
Early study closure	1/293 (0.3%)	0/6 (0.0%)	0/2 (0.0%)	0/3 (0.0%)	0/12 (0.0%)
HIV infection – Step 2 or later, refer to local care	10/293 (3.4%)	0/6 (0.0%)	0/2 (0.0%)	0/3 (0.0%)	0/12 (0.0%)
Other, specify	20/293 (6.8%)	0/6 (0.0%)	0/2 (0.0%)	0/3 (0.0%)	0/12 (0.0%)
Scheduled study exit / OLE complete	2179/2472 (88.1%)	65/71 (91.5%)	61/63 (96.8%)	79/82 (96.3%)	63/75 (84.0%)

¹ OLE enrollment sites are used.

² "Active follow-up" is defined as having not formally terminated from the study. Some participants in active follow-up have missed recently expected visits, but site staff are attempting to bring them back to the study.

³ Product choice detail will be included in the next reporting cycle

⁴ One participant terminated with "other" reason specified as "has other commitments".

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Table 4 – Disposition Summary by Site ¹

	South Africa: Botha's Hill: Botha's Hill CRS	South Africa: Cape Town: Emavundleni CRS	South Africa: Cape Town: Stellenbosch University (DTTC-SU) CRS	South Africa: Johannesburg: Ward 21	South Africa: Kwa Zulu Natal: Isipingo CRS
Total participants enrolled in the blinded study	223	227	158	211	170
Total Participants Enrolled in OLE	180	170	99	165	141
Discontinued study product prior to termination	0/180 (0.0%)	0/170 (0.0%)	0/99 (0.0%)	0/165 (0.0%)	0/141 (0.0%)
Terminated early in OLE	14/180 (7.8%)	37/170 (21.8%)	14/99 (14.1%)	23/165 (13.9%)	6/141 (4.3%)
Death	1/14 (7.1%)	0/37 (0.0%)	0/14 (0.0%)	0/23 (0.0%)	0/6 (0.0%)
Participant refused further participation, specify	11/14 (78.6%)	15/37 (40.5%)	4/14 (28.6%)	7/23 (30.4%)	2/6 (33.3%)
Participant relocated, no follow-up planned	0/14 (0.0%)	11/37 (29.7%)	4/14 (28.6%)	5/23 (21.7%)	1/6 (16.7%)
Investigator decision, specify	0/14 (0.0%)	0/37 (0.0%)	1/14 (7.1%)	3/23 (13.0%)	0/6 (0.0%)
Unable to contact participant	1/14 (7.1%)	10/37 (27.0%)	3/14 (21.4%)	3/23 (13.0%)	1/6 (16.7%)
Inappropriate enrollment	0/14 (0.0%)	0/37 (0.0%)	0/14 (0.0%)	0/23 (0.0%)	0/6 (0.0%)
Early study closure	0/14 (0.0%)	0/37 (0.0%)	0/14 (0.0%)	0/23 (0.0%)	0/6 (0.0%)
HIV infection – Step 2 or later, refer to local care	0/14 (0.0%)	0/37 (0.0%)	0/14 (0.0%)	0/23 (0.0%)	0/6 (0.0%)
Other, specify	1/14 (7.1%)	1/37 (2.7%)	2/14 (14.3%)	5/23 (21.7%)	2/6 (33.3%)
Scheduled study exit / OLE complete	166/180 (92.2%)	133/170 (78.2%)	85/99 (85.9%)	142/165 (86.1%)	135/141 (95.7%)

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³ Product choice detail will be included in the next reporting cycle

⁴ One participant terminated with "other" reason specified as "has other commitments".

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Table 4 – Disposition Summary by Site ¹

	South Africa: Kwa Zulu Natal: Verulam CRS	South Africa: Soweto: HPTN CRS	Swaziland: Siteki: Swaziland Prevention Center	Uganda: Entebbe: UVRI-IAVI	Uganda: Kampala: Baylor-Uganda CRS
Total participants enrolled in the blinded study	151	175	159	182	210
Total Participants Enrolled in OLE	119	133	121	124	146
Discontinued study product prior to termination	0/119 (0.0%)	0/133 (0.0%)	0/121 (0.0%)	0/124 (0.0%)	0/146 (0.0%)
Terminated early in OLE	16/119 (13.4%)	11/133 (8.3%)	23/121 (19.0%)	20/124 (16.1%)	17/146 (11.6%)
Death	0/16 (0.0%)	0/11 (0.0%)	0/23 (0.0%)	1/20 (5.0%)	0/17 (0.0%)
Participant refused further participation, specify	9/16 (56.3%)	7/11 (63.6%)	2/23 (8.7%)	2/20 (10.0%)	2/17 (11.8%)
Participant relocated, no follow-up planned	1/16 (6.3%)	2/11 (18.2%)	1/23 (4.3%)	0/20 (0.0%)	13/17 (76.5%)
Investigator decision, specify	0/16 (0.0%)	0/11 (0.0%)	1/23 (4.3%)	0/20 (0.0%)	0/17 (0.0%)
Unable to contact participant	4/16 (25.0%)	0/11 (0.0%)	18/23 (78.3%)	16/20 (80.0%)	1/17 (5.9%)
Inappropriate enrollment	0/16 (0.0%)	0/11 (0.0%)	0/23 (0.0%)	0/20 (0.0%)	0/17 (0.0%)
Early study closure	0/16 (0.0%)	0/11 (0.0%)	0/23 (0.0%)	1/20 (5.0%)	0/17 (0.0%)
HIV infection – Step 2 or later, refer to local care	0/16 (0.0%)	2/11 (18.2%)	0/23 (0.0%)	0/20 (0.0%)	1/17 (5.9%)
Other, specify	2/16 (12.5%)	0/11 (0.0%)	1/23 (4.3%)	0/20 (0.0%)	0/17 (0.0%)
Scheduled study exit / OLE complete	103/119 (86.6%)	122/133 (91.7%)	98/121 (81.0%)	104/124 (83.9%)	129/146 (88.4%)

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Table 4 – Disposition Summary by Site ¹

	Uganda: Kampala: MU-JHU Research Collaboration CRS	Zimbabwe: Chitungwiza: Seke South CRS	Zimbabwe: Chitungwiza: St.Mary's CRS	Zimbabwe: Chitungwiza: Zengeza CRS	Zimbabwe: Harare: Parirenyatwa CRS
Total participants enrolled in the blinded study	204	160	166	161	153
Total Participants Enrolled in OLE	149	125	135	130	121
Discontinued study product prior to termination	0/149 (0.0%)	0/125 (0.0%)	0/135 (0.0%)	0/130 (0.0%)	0/121 (0.0%)
Terminated early in OLE	26/149 (17.4%)	13/125 (10.4%)	14/135 (10.4%)	15/130 (11.5%)	7/121 (5.8%)
Death	0/26 (0.0%)	0/13 (0.0%)	0/14 (0.0%)	0/15 (0.0%)	0/7 (0.0%)
Participant refused further participation, specify	0/26 (0.0%)	9/13 (69.2%)	4/14 (28.6%)	1/15 (6.7%)	4/7 (57.1%)
Participant relocated, no follow-up planned	0/26 (0.0%)	2/13 (15.4%)	7/14 (50.0%)	9/15 (60.0%)	3/7 (42.9%)
Investigator decision, specify	0/26 (0.0%)	0/13 (0.0%)	0/14 (0.0%)	0/15 (0.0%)	0/7 (0.0%)
Unable to contact participant	22/26 (84.6%)	2/13 (15.4%)	0/14 (0.0%)	1/15 (6.7%)	0/7 (0.0%)
Inappropriate enrollment	0/26 (0.0%)	0/13 (0.0%)	0/14 (0.0%)	0/15 (0.0%)	0/7 (0.0%)
Early study closure	0/26 (0.0%)	0/13 (0.0%)	0/14 (0.0%)	0/15 (0.0%)	0/7 (0.0%)
HIV infection – Step 2 or later, refer to local care	1/26 (3.8%)	0/13 (0.0%)	1/14 (7.1%)	4/15 (26.7%)	0/7 (0.0%)
Other, specify	3/26 (11.5%)	0/13 (0.0%)	2/14 (14.3%)	0/15 (0.0%)	0/7 (0.0%)
Scheduled study exit / OLE complete	123/149 (82.6%)	112/125 (89.6%)	121/135 (89.6%)	115/130 (88.5%)	114/121 (94.2%)

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³ Product choice detail will be included in the next reporting cycle

⁴ One participant terminated with "other" reason specified as "has other commitments".

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Table 4 – Disposition Summary by Site ¹

	Zimbabwe: Harare: Spilhaus CRS
Total participants enrolled in the blinded study	133
Total Participants Enrolled in OLE	123
Discontinued study product prior to termination	0/123 (0.0%)
Terminated early in OLE	14/123 (11.4%)
Death	0/14 (0.0%)
Participant refused further participation, specify	2/14 (14.3%)
Participant relocated, no follow-up planned	9/14 (64.3%)
Investigator decision, specify	0/14 (0.0%)
Unable to contact participant	1/14 (7.1%)
Inappropriate enrollment	0/14 (0.0%)
Early study closure	0/14 (0.0%)
HIV infection – Step 2 or later, refer to local care	1/14 (7.1%)
Other, specify	1/14 (7.1%)
Scheduled study exit / OLE complete	109/123 (88.6%)

¹ OLE enrollment sites are used.

² "Active follow-up" is defined as having not formally terminated from the study. Some participants in active follow-up have missed recently expected visits, but site staff are attempting to bring them back to the study.

³ Product choice detail will be included in the next reporting cycle

⁴ One participant terminated with "other" reason specified as "has other commitments".