

HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women
Atlas Open Report – March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 3 – Progression to Step 2 by Site

	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 ¹	3224	91	66	113	111	223
Participants who have been enrolled for at least 6 weeks, received at least one injection, discontinued, or terminated during Step 1 ²	3211	90	66	113	109	223
Progressed to Step 2	3057/3211 (95.2%)	80/90 (88.9%)	64/66 (97.0%)	112/113 (99.1%)	105/109 (96.3%)	218/223 (97.8%)
Progression Status Pending	6/3211 (0.2%)	0/90 (0.0%)	1/66 (1.5%)	0/113 (0.0%)	0/109 (0.0%)	0/223 (0.0%)
Did Not Progress to Step 2	148/3211 (4.6%)	10/90 (11.1%)	1/66 (1.5%)	1/113 (0.9%)	4/109 (3.7%)	5/223 (2.2%)
Permanently discontinued from study product	14/3211 (0.4%)	4/90 (4.4%)	0/66 (0.0%)	0/113 (0.0%)	0/109 (0.0%)	1/223 (0.4%)
Terminated from the study	82/3211 (2.6%)	1/90 (1.1%)	1/66 (1.5%)	1/113 (0.9%)	1/109 (0.9%)	2/223 (0.9%)
Permanently discontinued from study product first and then terminated from study	52/3211 (1.6%)	5/90 (5.6%)	0/66 (0.0%)	0/113 (0.0%)	3/109 (2.8%)	2/223 (0.9%)

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	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	South Africa: Kwa Zulu Natal: Verulam CRS	South Africa: Soweto: Soweto HPTN CRS
Total Participants Enrolled ¹	223	159	206	170	151	176
Participants who have been enrolled for at least 6 weeks, received at least one injection, discontinued, or terminated during Step 1 ²	222	158	205	170	150	176
Progressed to Step 2	210/222 (94.6%)	141/158 (89.2%)	196/205 (95.6%)	162/170 (95.3%)	140/150 (93.3%)	169/176 (96.0%)
Progression Status Pending	0/222 (0.0%)	0/158 (0.0%)	1/205 (0.5%)	0/170 (0.0%)	1/150 (0.7%)	0/176 (0.0%)
Did Not Progress to Step 2	12/222 (5.4%)	17/158 (10.8%)	8/205 (3.9%)	8/170 (4.7%)	9/150 (6.0%)	7/176 (4.0%)
Permanently discontinued from study product	0/222 (0.0%)	0/158 (0.0%)	0/205 (0.0%)	1/170 (0.6%)	0/150 (0.0%)	0/176 (0.0%)
Terminated from the study	8/222 (3.6%)	15/158 (9.5%)	6/205 (2.9%)	4/170 (2.4%)	3/150 (2.0%)	4/176 (2.3%)
Permanently discontinued from study product first and then terminated from study	4/222 (1.8%)	2/158 (1.3%)	2/205 (1.0%)	3/170 (1.8%)	6/150 (4.0%)	3/176 (1.7%)

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	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 ¹	160	182	210	204	160	166
Participants who have been enrolled for at least 6 weeks, received at least one injection, discontinued, or terminated during Step 1 ²	159	182	210	202	159	166
Progressed to Step 2	150/159 (94.3%)	175/182 (96.2%)	192/210 (91.4%)	190/202 (94.1%)	152/159 (95.6%)	160/166 (96.4%)
Progression Status Pending	0/159 (0.0%)	0/182 (0.0%)	2/210 (1.0%)	0/202 (0.0%)	0/159 (0.0%)	1/166 (0.6%)
Did Not Progress to Step 2	9/159 (5.7%)	7/182 (3.8%)	16/210 (7.6%)	12/202 (5.9%)	7/159 (4.4%)	5/166 (3.0%)
Permanently discontinued from study product	0/159 (0.0%)	0/182 (0.0%)	3/210 (1.4%)	2/202 (1.0%)	0/159 (0.0%)	2/166 (1.2%)
Terminated from the study	1/159 (0.6%)	4/182 (2.2%)	12/210 (5.7%)	5/202 (2.5%)	7/159 (4.4%)	1/166 (0.6%)
Permanently discontinued from study product first and then terminated from study	8/159 (5.0%)	3/182 (1.6%)	1/210 (0.5%)	5/202 (2.5%)	0/159 (0.0%)	2/166 (1.2%)

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	Zimbabwe: Chitungwiza: Zengeza CRS	Zimbabwe: Harare: Parirenyatwa CRS	Zimbabwe: Harare: Spilhaus CRS
Total Participants Enrolled ¹	162	153	138
Participants who have been enrolled for at least 6 weeks, received at least one injection, discontinued, or terminated during Step 1 ²	162	153	136
Progressed to Step 2	159/162 (98.1%)	148/153 (96.7%)	134/136 (98.5%)
Progression Status Pending	0/162 (0.0%)	0/153 (0.0%)	0/136 (0.0%)
Did Not Progress to Step 2	3/162 (1.9%)	5/153 (3.3%)	2/136 (1.5%)
Permanently discontinued from study product	1/162 (0.6%)	0/153 (0.0%)	0/136 (0.0%)
Terminated from the study	2/162 (1.2%)	4/153 (2.6%)	0/136 (0.0%)
Permanently discontinued from study product first and then terminated from study	0/162 (0.0%)	1/153 (0.7%)	2/136 (1.5%)

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Listing 1 – Participants Pending Progression to Step 2 : Enrolled 6 Weeks or More¹

Site	Subject ID	Enrolled Date	Days from Enrollment	Last Completed Visit Number	Last Completed Visit Date	Days from Last Completed Visit
Kenya: Kisumu: Kisumu CRS	792230082	31JAN2019	1860	112	12JAN2022	783
South Africa: Johannesburg: Ward 21	837239918	12MAR2020	1454	15	07DEC2021	819
South Africa: Kwa Zulu Natal: Verulam CRS	548329059	13MAR2019	1819	113	26APR2022	679
Uganda: Kampala: Baylor-Uganda CRS	872151178	03JAN2020	1523	4	31JAN2020	1495
	872691565	21JAN2020	1505	51	01MAR2022	735
Zimbabwe: Chitungwiza: St.Mary's CRS	762913971	15JUL2019	1695	4	14AUG2019	1665

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Listing 2 – Participants Who Did Not Progress to Step 2 by Site

Site	Subject	Study Status	Enrollment Date	Days from Enrollment	Coded Classification	End of Treatment Date	End of Treatment Reason	Termination Date	Termination Reason
Botswana: Gaborone: Gaborone CRS	723342457	ONGOING	07FEB2019	1853	1	21FEB2019	Participant request – other reason Pressure from family and boyfriend to stop medication	–	
	723380157	ONGOING	24JAN2019	1867	1	13FEB2019	Participant request – other reason Participant wants to stop taking oral study product due to side effects	–	
	723815986	ONGOING	03DEC2018	1919	1	22FEB2019	Low oral adherence – Step 1	–	
	723975273	ONGOING	15NOV2018	1937	1	05MAR2020	Low oral adherence – Step 1	–	
	723622049	TERMINATED	20NOV2018	1932	2	–		05AUG2022	Unable to contact participant
	723342980	TERMINATED	08APR2019	1793	3	14JUN2019	Participant request – unwilling or unable to comply with required study procedures	21JUN2022	Participant refused further participation, specify Did not want to state reason
	723470718	TERMINATED	08MAY2018	2128	3	19JUN2018	Clinical AE (protocol mandated)	19AUG2022	Unable to contact participant
	723506359	TERMINATED	28FEB2018	2197	3	21MAR2018	Clinical AE (protocol mandated)	17MAY2022	Participant refused further participation, specify History of night disturbances whilst she was taking CAB
723540103	TERMINATED	24JAN2019	1867	3	28FEB2019	Participant request – unwilling or unable to comply with required study procedures	27JUL2022	Participant refused further participation, specify No longer interested in taking part in the study	
723749271	TERMINATED	24APR2019	1777	3	28MAY2019	Clinical AE (protocol mandated)	01MAR2022	Participant refused further participation, specify She was not open to discuss her reasons	
Kenya: Kisumu: Kisumu CRS	792563355	TERMINATED	18MAR2019	1814	2	–		17OCT2022	Unable to contact participant
Malawi: Blantyre: Blantyre CRS	760517555	TERMINATED	26FEB2019	1834	2	–		31OCT2022	Participant refused further participation, specify Refused further participation
Malawi: Lilongwe: Malawi CRS	720544024	TERMINATED	14MAR2019	1818	2	–		09AUG2022	Unable to contact participant
	720230185	TERMINATED	05DEC2018	1917	3	18MAR2019	Participant request – unwilling or unable to comply with required study procedures	14JUL2022	Participant relocated, no follow-up planned
	720929757	TERMINATED	01AUG2019	1678	3	27JUL2020	Other The participant was lost to follow up since enrollment and CMC recommended that we transition her to annual HIV testing.	30AUG2022	Unable to contact participant
	720950061	TERMINATED	17SEP2019	1631	3	21OCT2019	Participant request – unwilling or unable to comply with required study procedures	31MAY2023	Scheduled exit visit/end of study
South Africa: Botha's Hill: Botha's Hill CRS	789487180	ONGOING	25JAN2019	1866	1	28FEB2019	Participant request – unwilling or unable to comply with required study procedures	–	
	789167406	TERMINATED	07FEB2020	1488	2	–		09NOV2022	Participant refused further participation, specify Participant noted she is busy at work and cannot comply with study visits

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Listing 2 – Participants Who Did Not Progress to Step 2 by Site

Site	Subject	Study Status	Enrollment Date	Days from Enrollment	Coded Classification	End of Treatment Date	End of Treatment Reason	Termination Date	Termination Reason
	789378863	TERMINATED	14SEP2020	1268	2	-		25OCT2021	Participant refused further participation, specify Ppt did a course and then got a job and her employer would not give her time off to come. She said she was no longer interested in the study and please not to contact her.
	789154604	TERMINATED	17OCT2019	1601	3	22NOV2019	CMC recommendation based on a laboratory value	25AUG2022	Participant relocated, no follow-up planned
	789891977	TERMINATED	20FEB2019	1840	3	05JUN2019	Participant request – unwilling or unable to comply with required study procedures	30JUN2022	Participant refused further participation, specify Participant noted that due to work constraints and only being free on Sundays she does not have time to come to the site for her visits
South Africa: Cape Town: Emavundleni CRS	779171637	TERMINATED	07FEB2020	1488	2	-		09SEP2022	Participant relocated, no follow-up planned
	779559875	TERMINATED	31OCT2019	1587	2	-		09SEP2022	Unable to contact participant
	779588788	TERMINATED	21JUN2019	1719	2	-		09SEP2022	Participant refused further participation, specify Participant refused study participation
	779707820	TERMINATED	31JAN2020	1495	2	-		09SEP2022	Participant relocated, no follow-up planned
	779758571	TERMINATED	21NOV2019	1566	2	-		09SEP2022	Participant relocated, no follow-up planned
	779872421	TERMINATED	10APR2019	1791	2	-		07NOV2022	Participant refused further participation, specify Participant not interested in study participation
	779961474	TERMINATED	27JUN2019	1713	2	-		07NOV2022	Participant refused further participation, specify Study participation becoming to bothersome to participant
	779999116	TERMINATED	11AUG2020	1302	2	-		07NOV2022	Participant relocated, no follow-up planned
	779351275	TERMINATED	23APR2019	1778	3	27MAY2019	Laboratory AE (protocol mandated)	18AUG2022	Other, specify Product discontinued due to Grade 2 raised ALT. Not eligible for OLE.
	779364536	TERMINATED	01AUG2019	1678	3	15AUG2019	Clinical AE (protocol mandated)	09SEP2022	Participant relocated, no follow-up planned
	779745781	TERMINATED	16APR2019	1785	3	20MAY2019	Laboratory AE (protocol mandated)	01JUL2022	Unable to contact participant
	779983061	TERMINATED	14MAR2019	1818	3	16APR2019	Laboratory AE (protocol mandated)	15SEP2023	Participant relocated, no follow-up planned
South Africa: Cape Town: Stellenbosch University (DTTC-SU) CRS	818127334	TERMINATED	09OCT2019	1609	2	-		06SEP2022	Other, specify Participant did not enter step 2
	818209025	TERMINATED	25JUN2019	1715	2	-		01AUG2022	Other, specify Participant did not enter step 2
	818222364	TERMINATED	23AUG2019	1656	2	-		01AUG2022	Other, specify Participant did not enter step 2
	818270497	TERMINATED	21OCT2019	1597	2	-		06SEP2022	Other, specify Participant did not enter step 2
	818294533	TERMINATED	27FEB2019	1833	2	-		27MAR2019	Participant refused further participation, specify participant unwilling to continue using oral study product
	818294883	TERMINATED	03FEB2020	1492	2	-		06SEP2022	Other, specify Participant did not enter step 2
	818302699	TERMINATED	10OCT2019	1608	2	-		01AUG2022	Other, specify Participant did not enter step 2

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	818365327	TERMINATED	15AUG2019	1664	2	–		01AUG2022	Other, specify Participant did not enter step 2
	818365525	TERMINATED	25AUG2020	1288	2	–		01AUG2022	Other, specify Participant did not enter step 2
	818439943	TERMINATED	28FEB2019	1832	2	–		06SEP2022	Other, specify Participant did not enter step 2
	818546457	TERMINATED	25APR2019	1776	2	–		01AUG2022	Other, specify Participant did not enter step 2
	818805514	TERMINATED	19MAR2019	1813	2	–		06SEP2022	Unable to contact participant
	818969400	TERMINATED	11SEP2019	1637	2	–		01AUG2022	Other, specify Participant did nit enter 2
	818971551	TERMINATED	06JUN2019	1734	2	–		01AUG2022	Other, specify Participant did not enter step 2
	818979851	TERMINATED	09OCT2020	1243	2	–		01AUG2022	Other, specify Participant did not enter step 2
	818909846	TERMINATED	12APR2019	1789	3	31JUL2019	Low oral adherence – Step 1	06SEP2022	Other, specify Participant did not enter step 2
	818915874	TERMINATED	16MAY2019	1755	3	25MAY2019	Participant is currently using or planning to use PrEP or PEP (other than study product)	01AUG2022	Other, specify Partiicipant did not enter step 2
South Africa: Johannesburg: Ward 21	837151624	TERMINATED	06DEC2018	1916	2	–		28JAN2019	Participant refused further participation, specify Participant returned to site on 28 Jan 2019 to return her study product. She stated that she has lost interest in the study and withdrew her consent
	837265551	TERMINATED	12OCT2020	1240	2	–		02NOV2020	Participant refused further participation, specify Withdrew consent
	837324285	TERMINATED	07OCT2020	1245	2	–		10AUG2022	Participant refused further participation, specify no time for visits, requested not to be called again.
	837451444	TERMINATED	04MAR2020	1462	2	–		01MAR2021	Participant refused further participation, specify telephonically notified site that she does not want to continue with study and informed site not to make further contact with her.
	837551494	TERMINATED	09MAR2018	2188	2	–		13JUL2018	Participant refused further participation, specify She wishes to withdraw from the study for family reasons. She will be relocating to another province to care for her grandmother
	837910733	TERMINATED	12OCT2020	1240	2	–		30OCT2020	Participant refused further participation, specify Telephonically withdrew consent
	837511965	TERMINATED	23JUL2018	2052	3	22AUG2018	Laboratory AE (protocol mandated)	17AUG2022	Scheduled exit visit/end of study
	837568646	TERMINATED	18FEB2019	1842	3	27FEB2019	Other clinical reason Pre-existing ALT Grade 3	16AUG2022	Scheduled exit visit/end of study
South Africa: Kwa Zulu Natal: Isipingo CRS	803684408	ONGOING	05MAR2020	1461	1	06MAY2020	Low oral adherence – Step 1	–	
	803390097	TERMINATED	21MAY2019	1750	2	–		10JUL2019	Participant refused further participation, specify participant has withdrawn consent for hepatitis B and future study product administrations
	803629969	TERMINATED	17SEP2020	1265	2	–		16OCT2020	Participant relocated, no follow-up planned

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	803886564	TERMINATED	03MAR2020	1463	2	–		10JUN2020	Participant refused further participation, specify relocation; family refuses that participant participates further
	803940587	TERMINATED	10SEP2019	1638	2	–		29OCT2020	Participant refused further participation, specify participant was on annual visit schedule but decided o terminate from the study as she is working full-time
	803431091	TERMINATED	08AUG2019	1671	3	30SEP2019	CMC recommendation based on a clinical event	19OCT2020	Participant refused further participation, specify no longer interested–consent withdrawn
	803521888	TERMINATED	08SEP2020	1274	3	16SEP2020	Other As per CMC: Enrollment error due to discordant results	17SEP2020	Other, specify discordant results. CMC recommendation
	803688417	TERMINATED	04MAR2020	1462	3	13JUL2020	Laboratory AE (protocol mandated)	02AUG2022	Other, specify ineligible for protocol version 3.0
South Africa: Kwa Zulu Natal: Verulam CRS	548275960	TERMINATED	05JUL2019	1705	2	–		08NOV2022	Participant relocated, no follow-up planned
	548394794	TERMINATED	17OCT2019	1601	2	–		08NOV2022	Scheduled exit visit/end of study
	548925013	TERMINATED	16SEP2020	1266	2	–		09NOV2022	Unable to contact participant
	548285996	TERMINATED	30JUL2020	1314	3	07SEP2020	Low oral adherence – Step 1	09NOV2022	Scheduled exit visit/end of study
	548400644	TERMINATED	14JUN2019	1726	3	09JUL2019	Clinical AE (protocol mandated)	06JUL2021	Unable to contact participant
	548571548	TERMINATED	22FEB2019	1838	3	05APR2019	Clinical AE (protocol mandated)	18SEP2023	Unable to contact participant
	548661676	TERMINATED	27FEB2020	1468	3	12MAY2020	CMC recommendation based on a clinical event	01SEP2023	Other, specify Ppt did not enrol into OLE
	548669070	TERMINATED	20FEB2019	1840	3	09APR2019	Laboratory AE (protocol mandated)	20JUN2022	Participant refused further participation, specify Participant refused further participation.
	548808291	TERMINATED	24FEB2020	1471	3	21APR2020	Low oral adherence – Step 1	08NOV2022	Scheduled exit visit/end of study
South Africa: Soweto: Soweto HPTN CRS	802177864	TERMINATED	06DEC2019	1551	2	–		14JUL2022	Participant refused further participation, specify Participant never returned to start Step 2.
	802406425	TERMINATED	12NOV2018	1940	2	–		22JUL2022	Unable to contact participant
	802998655	TERMINATED	30MAY2019	1741	2	–		22JUL2022	Participant refused further participation, specify Participant did not return for further visits. She then relocated to another province.
	802998931	TERMINATED	05DEC2018	1917	2	–		22JUL2022	Unable to contact participant
	802409667	TERMINATED	27NOV2017	2290	3	06DEC2017	Participant request – other reason Related to social harm	06DEC2017	Participant refused further participation, specify Partner requested participant stop further participation in the study. Social impact completed.
	802558106	TERMINATED	05AUG2019	1674	3	06AUG2019	Clinical AE (protocol mandated)	07AUG2019	Investigator decision, specify Participant terminated due to adverse event experienced. Relatedness to study product could not be confirmed. Investigator's decision to terminate.
	802990522	TERMINATED	16SEP2020	1266	3	17SEP2020	CMC recommendation based on a laboratory value	14JUL2022	Investigator decision, specify Participant had a grade 3 ALT at enrolment.

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Swaziland: Siteki: Swaziland Prevention Center	871448182	TERMINATED	07AUG2019	1672	2	-		28JUL2022	Unable to contact participant
	871378054	TERMINATED	19SEP2019	1629	3	26JUN2020	Participant request – other reason Participant not willing to receive injection	30MAY2023	Scheduled exit visit/end of study
	871385831	TERMINATED	11OCT2019	1607	3	30JUN2020	Participant request – other reason Participant not willing to use oral PREP	06APR2022	Participant refused further participation, specify Not willing to resume study product
	871454855	TERMINATED	02OCT2019	1616	3	29OCT2019	Participant request – other reason Participant changed her mind about study participation	28JUN2022	Unable to contact participant
	871676777	TERMINATED	15JAN2019	1876	3	22FEB2019	Other clinical reason Pre-existing Psychosis	28JUL2022	Investigator decision, specify lost to follow-up for more than 2 years. Unable to contact participant
	871690373	TERMINATED	05FEB2020	1490	3	24JUN2020	Participant request – other reason Participant no longer interested in oral Prep	28JUL2022	Unable to contact participant
	871857274	TERMINATED	20DEC2018	1902	3	17JAN2019	Participant request – other reason Grade 1 Adverse events	23JUN2022	Scheduled exit visit/end of study
	871857671	TERMINATED	15JAN2019	1876	3	06MAR2019	Other Participant request due to mild adverse events	25MAY2022	Participant refused further participation, specify She was on the annual schedule and would not like to continue. as she is concerned that the previous Macopapular rash might occur.
871948673	TERMINATED	08OCT2019	1610	3	29OCT2019	Participant request – other reason No longer interested in PREP	25MAY2022	Other, specify participant would only like to do annual testing. After CMC consultation there no provision for annual testing	
Uganda: Entebbe: UVRI-IAVI	873240731	TERMINATED	07FEB2020	1488	2	-		15OCT2022	Unable to contact participant
	873390709	TERMINATED	09JAN2020	1517	2	-		03OCT2022	Unable to contact participant
	873570761	TERMINATED	17JAN2019	1874	2	-		30SEP2022	Participant relocated, no follow-up planned
	873735409	TERMINATED	30JAN2019	1861	2	-		24OCT2022	Unable to contact participant
	873178696	TERMINATED	23OCT2019	1595	3	25NOV2019	Low oral adherence – Step 1	28OCT2022	Unable to contact participant
	873221389	TERMINATED	30JAN2020	1496	3	20FEB2020	Clinical AE (protocol mandated)	28OCT2022	Unable to contact participant
	873381392	TERMINATED	21JAN2019	1870	3	20FEB2019	Laboratory AE (protocol mandated)	03OCT2022	Scheduled exit visit/end of study
Uganda: Kampala: Baylor-Uganda CRS	872185400	ONGOING	07JUN2019	1733	1	18JUL2019	Participant request – unwilling or unable to comply with required study procedures	-	
	872954161	ONGOING	05OCT2018	1978	1	26FEB2019	Low oral adherence – Step 1	-	
	872961531	ONGOING	16OCT2018	1967	1	22NOV2018	Low oral adherence – Step 1	-	
	872173157	TERMINATED	24JAN2019	1867	2	-		11MAR2019	Participant refused further participation, specify Participant is no longer interested in the study
	872238056	TERMINATED	05MAR2019	1827	2	-		11AUG2022	Unable to contact participant

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Listing 2 – Participants Who Did Not Progress to Step 2 by Site

Site	Subject	Study Status	Enrollment Date	Days from Enrollment	Coded Classification	End of Treatment Date	End of Treatment Reason	Termination Date	Termination Reason
	872294851	TERMINATED	04MAR2019	1828	2	–		11AUG2022	Unable to contact participant
	872313868	TERMINATED	05MAR2020	1461	2	–		17AUG2022	Unable to contact participant
	872339887	TERMINATED	11OCT2018	1972	2	–		03AUG2023	Scheduled exit visit/end of study
	872408417	TERMINATED	03OCT2018	1980	2	–		09NOV2018	Participant relocated, no follow-up planned
	872434046	TERMINATED	15OCT2019	1603	2	–		17AUG2022	Unable to contact participant
	872728875	TERMINATED	11FEB2019	1849	2	–		06NOV2023	Scheduled exit visit/end of study
	872804489	TERMINATED	18OCT2018	1965	2	–		17AUG2022	Unable to contact participant
	872822160	TERMINATED	10OCT2019	1608	2	–		17AUG2022	Unable to contact participant
	872942139	TERMINATED	14OCT2019	1604	2	–		17AUG2022	Unable to contact participant
	872996925	TERMINATED	03JUL2019	1707	2	–		07AUG2022	Unable to contact participant
	872856831	TERMINATED	15OCT2018	1968	3	30OCT2018	Hepatitis B infection	25JUL2022	Other, specify Inappropriate enrollment due to Hep B infection
Uganda: Kampala: MU-JHU Research Collaboration CRS	753469002	ONGOING	22JAN2020	1504	1	19MAR2020	Participant request – unwilling or unable to comply with required study procedures	–	
	753505795	ONGOING	15NOV2018	1937	1	20DEC2018	Other CMC recommendation following drug dispensing error	–	
	753366598	TERMINATED	30NOV2018	1922	2	–		02NOV2022	Unable to contact participant
	753406504	TERMINATED	19NOV2018	1933	2	–		04AUG2022	Unable to contact participant
	753574020	TERMINATED	24OCT2018	1959	2	–		10JAN2019	Participant refused further participation, specify participant has been promising to come but doesnot come.When visited on 10 Jan 19 she ran away from study staff.She was last seen in clinic at enrolment
	753578759	TERMINATED	06DEC2018	1916	2	–		29JUL2022	Unable to contact participant
	753866583	TERMINATED	19FEB2020	1476	2	–		29JUL2022	Unable to contact participant
	753439311	TERMINATED	24APR2019	1777	3	27MAY2019	Participant request – other reason Participant opted for annual HIV schedule	09AUG2022	Participant refused further participation, specify She travelled abroad for work
	753521639	TERMINATED	17MAY2019	1754	3	17JUN2019	Laboratory AE (protocol mandated)	12JUL2022	Investigator decision, specify Participant ineligible for OLE
	753590038	TERMINATED	08NOV2018	1944	3	09JAN2019	Positive pregnancy test result	08AUG2022	Unable to contact participant
	753835997	TERMINATED	15NOV2018	1937	3	08APR2019	Participant request – unwilling or unable to comply with required study procedures	29JUL2022	Unable to contact participant
	753975068	TERMINATED	05DEC2019	1552	3	09JAN2020	Participant request – unwilling or unable to comply with required study procedures	01AUG2022	Unable to contact participant
Zimbabwe: Chitungwiza: Seke South CRS	754190389	TERMINATED	12JUN2019	1728	2	–		28JUL2022	Unable to contact participant

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Site	Subject	Study Status	Enrollment Date	Days from Enrollment	Coded Classification	End of Treatment Date	End of Treatment Reason	Termination Date	Termination Reason
	754259239	TERMINATED	09OCT2019	1609	2	–		28JUL2022	Participant refused further participation, specify Participant had work commitments and could not adhere to study visits
	754262704	TERMINATED	06AUG2019	1673	2	–		18AUG2022	Participant relocated, no follow-up planned
	754375553	TERMINATED	12NOV2018	1940	2	–		28JUL2022	Participant relocated, no follow-up planned
	754380421	TERMINATED	12JUN2019	1728	2	–		23AUG2022	Participant refused further participation, specify Participant notified the CRS she is no longer interested in study participation
	754405778	TERMINATED	03OCT2019	1615	2	–		28JUL2022	Investigator decision, specify Participant was not able to adhere to study visit schedules.
	754983861	TERMINATED	25JUL2019	1685	2	–		28JUL2022	Participant refused further participation, specify Participant had work commitments and was unable to adhere to study visits
Zimbabwe: Chitungwiza: St.Mary's CRS	762466979	ONGOING	20FEB2019	1840	1	15MAR2019	Low oral adherence – Step 1	–	
	762996872	ONGOING	02APR2019	1799	1	24MAY2019	Participant request – other reason REVERTED TO CHRISTIAN PRINCIPLES HENCE NO NEED FOR DRUGS	–	
	762892360	TERMINATED	13MAR2019	1819	2	–		30AUG2022	Unable to contact participant
	762598921	TERMINATED	19FEB2019	1841	3	18JAN2020	Other CMC recommendations, based on participant inability to attend study visits. HIV had been confirmed to be negative	30AUG2022	Unable to contact participant
	762846646	TERMINATED	01OCT2019	1617	3	13NOV2019	CMC recommendation based on a clinical event	27JUL2022	Investigator decision, specify A mental illness
Zimbabwe: Chitungwiza: Zengeza CRS	774369039	ONGOING	15FEB2018	2210	1	23MAR2018	Participant request – unwilling or unable to comply with required study procedures	–	
	774307700	TERMINATED	30JUL2019	1680	2	–		22JUL2022	Participant relocated, no follow-up planned
	774686264	TERMINATED	20AUG2019	1659	2	–		22JUL2022	Participant relocated, no follow-up planned
Zimbabwe: Harare: Parienyatwa CRS	770214185	TERMINATED	08NOV2018	1944	2	–		21NOV2018	Participant refused further participation, specify UNWILLING TO USE LONG-ACTING CONTRACEPTION AND NOT WILLING TO COME TO CRS FOR FURTHER COUNSELLING REGARDING CONTRACEPTION
	770438886	TERMINATED	23JAN2019	1868	2	–		20FEB2019	Participant refused further participation, specify perceived side effects of study medication
	770838216	TERMINATED	27MAY2019	1744	2	–		13NOV2019	Participant refused further participation, specify WITHDRAWAL OF CONSENT
	770945984	TERMINATED	04APR2018	2162	2	–		31OCT2022	Unable to contact participant
	770252695	TERMINATED	22MAR2018	2175	3	21MAY2018	Participant refused long acting contraception	22JUL2022	Participant refused further participation, specify Not interested any more

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Zimbabwe: Harare: Spilhaus CRS	771662562	TERMINATED	13NOV2018	1939	3	04DEC2018	Participant request – other reason Fear of side effects	29JUL2022	Participant refused further participation, specify Participant indicated that she has other commitments and cannot continue study participation
	771937626	TERMINATED	19FEB2019	1841	3	15APR2019	Participant request – unwilling or unable to comply with required study procedures	29JUL2022	Participant refused further participation, specify Participant indicated that she has personal reasons for not continuing study participation

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