

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 – June 22, 2021
Visit Cutoff Date: June 22, 2021
Table 1 – Screening Summary by Site

	Overall	Botswana: Gaborone: Gaborone CRS	Kenya: Kisumu: Kisumu CRS	Malawi: Blantyre: Blantyre CRS	Malawi: Lilongwe: Malawi CRS
Total Participants Screened	4880	144	93	134	154
Enrolled	3224/4880 (66.1%)	91/144 (63.2%)	66/93 (71.0%)	113/134 (84.3%)	111/154 (72.1%)
Eligible, Not Yet Enrolled	0/4880 (0.0%)	0/144 (0.0%)	0/93 (0.0%)	0/134 (0.0%)	0/154 (0.0%)
Not Enrolled	1656/4880 (33.9%)	53/144 (36.8%)	27/93 (29.0%)	21/134 (15.7%)	43/154 (27.9%)
Not eligible	1120/1656 (67.6%)	28/53 (52.8%)	25/27 (92.6%)	14/21 (66.7%)	26/43 (60.5%)
Participant declined to receive study product	2/1656 (0.1%)	0/53 (0.0%)	0/27 (0.0%)	0/21 (0.0%)	0/43 (0.0%)
Participant changed her mind	52/1656 (3.1%)	10/53 (18.9%)	0/27 (0.0%)	1/21 (4.8%)	4/43 (9.3%)
Unable to contact participant/no show	262/1656 (15.8%)	6/53 (11.3%)	1/27 (3.7%)	4/21 (19.0%)	6/43 (14.0%)
Other	220/1656 (13.3%)	9/53 (17.0%)	1/27 (3.7%)	2/21 (9.5%)	7/43 (16.3%)
Missing reason not enrolled ¹	0/1656 (0.0%)	0/53 (0.0%)	0/27 (0.0%)	0/21 (0.0%)	0/43 (0.0%)
Ineligible ² participants who failed to meet one or more of the inclusion criteria					
Not born female	0/1120 (0.0%)	0/28 (0.0%)	0/25 (0.0%)	0/14 (0.0%)	0/26 (0.0%)
Not 18–45 years at the time of screening	2/1120 (0.2%)	0/28 (0.0%)	0/25 (0.0%)	0/14 (0.0%)	1/26 (3.8%)
Not willing and able to provide informed consent	2/1120 (0.2%)	0/28 (0.0%)	0/25 (0.0%)	0/14 (0.0%)	0/26 (0.0%)
Not willing and able to undergo all required study procedures	105/1120 (9.4%)	1/28 (3.6%)	6/25 (24.0%)	0/14 (0.0%)	4/26 (15.4%)
Reactive HIV test results at Screening or Enrollment	206/1120 (18.4%)	0/28 (0.0%)	8/25 (32.0%)	1/14 (7.1%)	2/26 (7.7%)
Not sexually active	31/1120 (2.8%)	0/28 (0.0%)	2/25 (8.0%)	0/14 (0.0%)	0/26 (0.0%)
Score not > 2 using a modified VOICE risk score	75/1120 (6.7%)	2/28 (7.1%)	3/25 (12.0%)	1/14 (7.1%)	0/26 (0.0%)
Plans to re-locate or travel away from the site for > 8 consecutive weeks during study participation	39/1120 (3.5%)	0/28 (0.0%)	1/25 (4.0%)	0/14 (0.0%)	1/26 (3.8%)
Creatinine clearance not > 60 mL/min	3/1120 (0.3%)	0/28 (0.0%)	0/25 (0.0%)	1/14 (7.1%)	0/26 (0.0%)
HBsAg not negative or does not accept vaccination	53/1120 (4.7%)	1/28 (3.6%)	3/25 (12.0%)	4/14 (28.6%)	5/26 (19.2%)
Liver function values not ALT < 2x ULN or Tbili < 2.5 x ULN	16/1120 (1.4%)	0/28 (0.0%)	0/25 (0.0%)	0/14 (0.0%)	1/26 (3.8%)
Not HCV antibody negative	39/1120 (3.5%)	0/28 (0.0%)	2/25 (8.0%)	1/14 (7.1%)	3/26 (11.5%)
Pregnant	109/1120 (9.7%)	3/28 (10.7%)	0/25 (0.0%)	2/14 (14.3%)	4/26 (15.4%)
Of reproductive potential, but not willing to use a reliable form of contraception during the study	48/1120 (4.3%)	2/28 (7.1%)	1/25 (4.0%)	0/14 (0.0%)	3/26 (11.5%)
Medical condition that, in the opinion of the IoR, would interfere with the conduct of the study	301/1120 (26.9%)	16/28 (57.1%)	0/25 (0.0%)	3/14 (21.4%)	1/26 (3.8%)
Alcohol or substance use that, in the opinion of the IoR, would interfere with the conduct of the study	15/1120 (1.3%)	1/28 (3.6%)	0/25 (0.0%)	0/14 (0.0%)	0/26 (0.0%)

¹ This number includes participants where the enrollment status was missing at the time of data freeze.

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	Overall	Botswana: Gaborone: Gaborone CRS	Kenya: Kisumu: Kisumu CRS	Malawi: Blantyre: Blantyre CRS	Malawi: Lilongwe: Malawi CRS
Ineligible ² participants who met one or more of the exclusion criteria					
One or more reactive HIV test results at Screening or Enrollment	206/1120 (18.4%)	0/28 (0.0%)	8/25 (32.0%)	1/14 (7.1%)	2/26 (7.7%)
Pregnant or currently breastfeeding, or intends to become pregnant and/or breastfeed during the study	168/1120 (15.0%)	4/28 (14.3%)	1/25 (4.0%)	3/14 (21.4%)	5/26 (19.2%)
Co-enrollment in any other HIV interventional research study	1/1120 (0.1%)	0/28 (0.0%)	0/25 (0.0%)	0/14 (0.0%)	0/26 (0.0%)
Current or past enrollment in an HIV vaccine trial or broadly neutralizing antibody trial	2/1120 (0.2%)	0/28 (0.0%)	0/25 (0.0%)	0/14 (0.0%)	0/26 (0.0%)
Current or chronic history of liver disease or known hepatic or biliary abnormalities	27/1120 (2.4%)	0/28 (0.0%)	0/25 (0.0%)	1/14 (7.1%)	0/26 (0.0%)
History of seizure disorder	20/1120 (1.8%)	0/28 (0.0%)	0/25 (0.0%)	3/14 (21.4%)	1/26 (3.8%)
Clinically significant cardiovascular disease	52/1120 (4.6%)	0/28 (0.0%)	0/25 (0.0%)	0/14 (0.0%)	0/26 (0.0%)
Inflammatory skin conditions that compromise the safety of IM injections, per the IoR	10/1120 (0.9%)	0/28 (0.0%)	0/25 (0.0%)	0/14 (0.0%)	0/26 (0.0%)
Has a tattoo or other dermatological condition overlying the buttock region	1/1120 (0.1%)	0/28 (0.0%)	0/25 (0.0%)	0/14 (0.0%)	0/26 (0.0%)
Coagulopathy which would contraindicate IM injection	4/1120 (0.4%)	0/28 (0.0%)	0/25 (0.0%)	0/14 (0.0%)	0/26 (0.0%)
Active or planned use of prohibited medications	7/1120 (0.6%)	0/28 (0.0%)	0/25 (0.0%)	0/14 (0.0%)	0/26 (0.0%)
Known or suspected allergy to study product components (active or placebo)	27/1120 (2.4%)	0/28 (0.0%)	0/25 (0.0%)	0/14 (0.0%)	0/26 (0.0%)

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	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
Total Participants Screened	320	346	284	268
Enrolled	223/320 (69.7%)	223/346 (64.5%)	159/284 (56.0%)	206/268 (76.9%)
Eligible, Not Yet Enrolled	0/320 (0.0%)	0/346 (0.0%)	0/284 (0.0%)	0/268 (0.0%)
Not Enrolled	97/320 (30.3%)	123/346 (35.5%)	125/284 (44.0%)	62/268 (23.1%)
Not eligible	62/97 (63.9%)	50/123 (40.7%)	58/125 (46.4%)	44/62 (71.0%)
Participant declined to receive study product	0/97 (0.0%)	0/123 (0.0%)	0/125 (0.0%)	0/62 (0.0%)
Participant changed her mind	7/97 (7.2%)	1/123 (0.8%)	6/125 (4.8%)	1/62 (1.6%)
Unable to contact participant/no show	10/97 (10.3%)	31/123 (25.2%)	45/125 (36.0%)	10/62 (16.1%)
Other	18/97 (18.6%)	41/123 (33.3%)	16/125 (12.8%)	7/62 (11.3%)
Missing reason not enrolled ¹	0/97 (0.0%)	0/123 (0.0%)	0/125 (0.0%)	0/62 (0.0%)
Ineligible ² participants who failed to meet one or more of the inclusion criteria				
Not born female	0/62 (0.0%)	0/50 (0.0%)	0/58 (0.0%)	0/44 (0.0%)
Not 18–45 years at the time of screening	0/62 (0.0%)	0/50 (0.0%)	0/58 (0.0%)	0/44 (0.0%)
Not willing and able to provide informed consent	0/62 (0.0%)	0/50 (0.0%)	0/58 (0.0%)	0/44 (0.0%)
Not willing and able to undergo all required study procedures	10/62 (16.1%)	2/50 (4.0%)	5/58 (8.6%)	4/44 (9.1%)
Reactive HIV test results at Screening or Enrollment	15/62 (24.2%)	8/50 (16.0%)	15/58 (25.9%)	8/44 (18.2%)
Not sexually active	0/62 (0.0%)	6/50 (12.0%)	3/58 (5.2%)	4/44 (9.1%)
Score not > 2 using a modified VOICE risk score	5/62 (8.1%)	7/50 (14.0%)	12/58 (20.7%)	4/44 (9.1%)
Plans to re-locate or travel away from the site for > 8 consecutive weeks during study participation	3/62 (4.8%)	1/50 (2.0%)	2/58 (3.4%)	0/44 (0.0%)
Creatinine clearance not > 60 mL/min	0/62 (0.0%)	0/50 (0.0%)	0/58 (0.0%)	0/44 (0.0%)
HBsAg not negative or does not accept vaccination	5/62 (8.1%)	1/50 (2.0%)	0/58 (0.0%)	3/44 (6.8%)
Liver function values not ALT < 2x ULN or Tbili < 2.5 x ULN	1/62 (1.6%)	1/50 (2.0%)	0/58 (0.0%)	1/44 (2.3%)
Not HCV antibody negative	3/62 (4.8%)	3/50 (6.0%)	1/58 (1.7%)	4/44 (9.1%)
Pregnant	2/62 (3.2%)	4/50 (8.0%)	1/58 (1.7%)	3/44 (6.8%)
Of reproductive potential, but not willing to use a reliable form of contraception during the study	2/62 (3.2%)	0/50 (0.0%)	4/58 (6.9%)	1/44 (2.3%)
Medical condition that, in the opinion of the IoR, would interfere with the conduct of the study	11/62 (17.7%)	1/50 (2.0%)	8/58 (13.8%)	11/44 (25.0%)
Alcohol or substance use that, in the opinion of the IoR, would interfere with the conduct of the study	1/62 (1.6%)	0/50 (0.0%)	1/58 (1.7%)	1/44 (2.3%)

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Ineligible ² participants who met one or more of the exclusion criteria				
One or more reactive HIV test results at Screening or Enrollment	15/62 (24.2%)	8/50 (16.0%)	15/58 (25.9%)	8/44 (18.2%)
Pregnant or currently breastfeeding, or intends to become pregnant and/or breastfeed during the study	2/62 (3.2%)	16/50 (32.0%)	4/58 (6.9%)	3/44 (6.8%)
Co-enrollment in any other HIV interventional research study	0/62 (0.0%)	0/50 (0.0%)	0/58 (0.0%)	0/44 (0.0%)
Current or past enrollment in an HIV vaccine trial or broadly neutralizing antibody trial	0/62 (0.0%)	1/50 (2.0%)	0/58 (0.0%)	0/44 (0.0%)
Current or chronic history of liver disease or known hepatic or biliary abnormalities	1/62 (1.6%)	0/50 (0.0%)	0/58 (0.0%)	0/44 (0.0%)
History of seizure disorder	1/62 (1.6%)	0/50 (0.0%)	2/58 (3.4%)	0/44 (0.0%)
Clinically significant cardiovascular disease	1/62 (1.6%)	3/50 (6.0%)	0/58 (0.0%)	0/44 (0.0%)
Inflammatory skin conditions that compromise the safety of IM injections, per the IoR	0/62 (0.0%)	0/50 (0.0%)	0/58 (0.0%)	0/44 (0.0%)
Has a tattoo or other dermatological condition overlying the buttock region	0/62 (0.0%)	0/50 (0.0%)	0/58 (0.0%)	0/44 (0.0%)
Coagulopathy which would contraindicate IM injection	0/62 (0.0%)	1/50 (2.0%)	0/58 (0.0%)	0/44 (0.0%)
Active or planned use of prohibited medications	1/62 (1.6%)	0/50 (0.0%)	1/58 (1.7%)	0/44 (0.0%)
Known or suspected allergy to study product components (active or placebo)	1/62 (1.6%)	0/50 (0.0%)	0/58 (0.0%)	0/44 (0.0%)

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	South Africa: Kwa Zulu Natal: Isipingo CRS	South Africa: Kwa Zulu Natal: Verulam CRS	South Africa: Soweto: Soweto HPTN CRS	Swaziland: Siteki: Swaziland Prevention Center
Total Participants Screened	274	283	220	352
Enrolled	170/274 (62.0%)	151/283 (53.4%)	176/220 (80.0%)	160/352 (45.5%)
Eligible, Not Yet Enrolled	0/274 (0.0%)	0/283 (0.0%)	0/220 (0.0%)	0/352 (0.0%)
Not Enrolled	104/274 (38.0%)	132/283 (46.6%)	44/220 (20.0%)	192/352 (54.5%)
Not eligible	81/104 (77.9%)	101/132 (76.5%)	28/44 (63.6%)	137/192 (71.4%)
Participant declined to receive study product	0/104 (0.0%)	0/132 (0.0%)	0/44 (0.0%)	0/192 (0.0%)
Participant changed her mind	2/104 (1.9%)	2/132 (1.5%)	2/44 (4.5%)	1/192 (0.5%)
Unable to contact participant/no show	7/104 (6.7%)	8/132 (6.1%)	9/44 (20.5%)	36/192 (18.8%)
Other	14/104 (13.5%)	21/132 (15.9%)	5/44 (11.4%)	18/192 (9.4%)
Missing reason not enrolled ¹	0/104 (0.0%)	0/132 (0.0%)	0/44 (0.0%)	0/192 (0.0%)
Ineligible ² participants who failed to meet one or more of the inclusion criteria				
Not born female	0/81 (0.0%)	0/101 (0.0%)	0/28 (0.0%)	0/137 (0.0%)
Not 18–45 years at the time of screening	0/81 (0.0%)	0/101 (0.0%)	1/28 (3.6%)	0/137 (0.0%)
Not willing and able to provide informed consent	0/81 (0.0%)	0/101 (0.0%)	0/28 (0.0%)	0/137 (0.0%)
Not willing and able to undergo all required study procedures	9/81 (11.1%)	6/101 (5.9%)	1/28 (3.6%)	13/137 (9.5%)
Reactive HIV test results at Screening or Enrollment	22/81 (27.2%)	18/101 (17.8%)	5/28 (17.9%)	31/137 (22.6%)
Not sexually active	1/81 (1.2%)	0/101 (0.0%)	4/28 (14.3%)	3/137 (2.2%)
Score not > 2 using a modified VOICE risk score	1/81 (1.2%)	0/101 (0.0%)	6/28 (21.4%)	5/137 (3.6%)
Plans to re-locate or travel away from the site for > 8 consecutive weeks during study participation	0/81 (0.0%)	4/101 (4.0%)	0/28 (0.0%)	0/137 (0.0%)
Creatinine clearance not > 60 mL/min	0/81 (0.0%)	0/101 (0.0%)	0/28 (0.0%)	0/137 (0.0%)
HBsAg not negative or does not accept vaccination	1/81 (1.2%)	4/101 (4.0%)	1/28 (3.6%)	2/137 (1.5%)
Liver function values not ALT < 2x ULN or Tbili < 2.5 x ULN	0/81 (0.0%)	1/101 (1.0%)	0/28 (0.0%)	2/137 (1.5%)
Not HCV antibody negative	1/81 (1.2%)	2/101 (2.0%)	1/28 (3.6%)	5/137 (3.6%)
Pregnant	1/81 (1.2%)	4/101 (4.0%)	4/28 (14.3%)	13/137 (9.5%)
Of reproductive potential, but not willing to use a reliable form of contraception during the study	4/81 (4.9%)	5/101 (5.0%)	1/28 (3.6%)	8/137 (5.8%)
Medical condition that, in the opinion of the IoR, would interfere with the conduct of the study	31/81 (38.3%)	49/101 (48.5%)	5/28 (17.9%)	63/137 (46.0%)
Alcohol or substance use that, in the opinion of the IoR, would interfere with the conduct of the study	3/81 (3.7%)	2/101 (2.0%)	0/28 (0.0%)	1/137 (0.7%)

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Ineligible ² participants who met one or more of the exclusion criteria				
One or more reactive HIV test results at Screening or Enrollment	22/81 (27.2%)	18/101 (17.8%)	5/28 (17.9%)	31/137 (22.6%)
Pregnant or currently breastfeeding, or intends to become pregnant and/or breastfeed during the study	2/81 (2.5%)	11/101 (10.9%)	4/28 (14.3%)	23/137 (16.8%)
Co-enrollment in any other HIV interventional research study	0/81 (0.0%)	1/101 (1.0%)	0/28 (0.0%)	0/137 (0.0%)
Current or past enrollment in an HIV vaccine trial or broadly neutralizing antibody trial	0/81 (0.0%)	0/101 (0.0%)	1/28 (3.6%)	0/137 (0.0%)
Current or chronic history of liver disease or known hepatic or biliary abnormalities	0/81 (0.0%)	2/101 (2.0%)	0/28 (0.0%)	0/137 (0.0%)
History of seizure disorder	1/81 (1.2%)	3/101 (3.0%)	3/28 (10.7%)	0/137 (0.0%)
Clinically significant cardiovascular disease	0/81 (0.0%)	4/101 (4.0%)	0/28 (0.0%)	3/137 (2.2%)
Inflammatory skin conditions that compromise the safety of IM injections, per the IoR	2/81 (2.5%)	4/101 (4.0%)	0/28 (0.0%)	0/137 (0.0%)
Has a tattoo or other dermatological condition overlying the buttock region	1/81 (1.2%)	0/101 (0.0%)	0/28 (0.0%)	0/137 (0.0%)
Coagulopathy which would contraindicate IM injection	1/81 (1.2%)	0/101 (0.0%)	0/28 (0.0%)	0/137 (0.0%)
Active or planned use of prohibited medications	3/81 (3.7%)	1/101 (1.0%)	0/28 (0.0%)	0/137 (0.0%)
Known or suspected allergy to study product components (active or placebo)	3/81 (3.7%)	1/101 (1.0%)	0/28 (0.0%)	4/137 (2.9%)

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	Uganda: Entebbe: UVRI-IAVI	Uganda: Kampala: Baylor-Uganda CRS	Uganda: Kampala: MU-JHU Research Collaboration CRS	Zimbabwe: Chitungwiza: Seke South CRS
Total Participants Screened	235	300	308	318
Enrolled	182/235 (77.4%)	210/300 (70.0%)	204/308 (66.2%)	160/318 (50.3%)
Eligible, Not Yet Enrolled	0/235 (0.0%)	0/300 (0.0%)	0/308 (0.0%)	0/318 (0.0%)
Not Enrolled	53/235 (22.6%)	90/300 (30.0%)	104/308 (33.8%)	158/318 (49.7%)
Not eligible	46/53 (86.8%)	84/90 (93.3%)	84/104 (80.8%)	107/158 (67.7%)
Participant declined to receive study product	2/53 (3.8%)	0/90 (0.0%)	0/104 (0.0%)	0/158 (0.0%)
Participant changed her mind	0/53 (0.0%)	3/90 (3.3%)	4/104 (3.8%)	4/158 (2.5%)
Unable to contact participant/no show	1/53 (1.9%)	3/90 (3.3%)	14/104 (13.5%)	46/158 (29.1%)
Other	4/53 (7.5%)	0/90 (0.0%)	2/104 (1.9%)	1/158 (0.6%)
Missing reason not enrolled ¹	0/53 (0.0%)	0/90 (0.0%)	0/104 (0.0%)	0/158 (0.0%)
Ineligible ² participants who failed to meet one or more of the inclusion criteria				
Not born female	0/46 (0.0%)	0/84 (0.0%)	0/84 (0.0%)	0/107 (0.0%)
Not 18–45 years at the time of screening	0/46 (0.0%)	0/84 (0.0%)	0/84 (0.0%)	0/107 (0.0%)
Not willing and able to provide informed consent	0/46 (0.0%)	0/84 (0.0%)	0/84 (0.0%)	0/107 (0.0%)
Not willing and able to undergo all required study procedures	3/46 (6.5%)	8/84 (9.5%)	17/84 (20.2%)	5/107 (4.7%)
Reactive HIV test results at Screening or Enrollment	11/46 (23.9%)	6/84 (7.1%)	18/84 (21.4%)	21/107 (19.6%)
Not sexually active	0/46 (0.0%)	0/84 (0.0%)	0/84 (0.0%)	7/107 (6.5%)
Score not > 2 using a modified VOICE risk score	2/46 (4.3%)	3/84 (3.6%)	12/84 (14.3%)	8/107 (7.5%)
Plans to re-locate or travel away from the site for > 8 consecutive weeks during study participation	3/46 (6.5%)	4/84 (4.8%)	10/84 (11.9%)	0/107 (0.0%)
Creatinine clearance not > 60 mL/min	0/46 (0.0%)	0/84 (0.0%)	0/84 (0.0%)	1/107 (0.9%)
HBsAg not negative or does not accept vaccination	2/46 (4.3%)	5/84 (6.0%)	4/84 (4.8%)	0/107 (0.0%)
Liver function values not ALT < 2x ULN or Tbili < 2.5 x ULN	0/46 (0.0%)	2/84 (2.4%)	1/84 (1.2%)	2/107 (1.9%)
Not HCV antibody negative	5/46 (10.9%)	3/84 (3.6%)	1/84 (1.2%)	1/107 (0.9%)
Pregnant	8/46 (17.4%)	12/84 (14.3%)	12/84 (14.3%)	17/107 (15.9%)
Of reproductive potential, but not willing to use a reliable form of contraception during the study	2/46 (4.3%)	6/84 (7.1%)	4/84 (4.8%)	2/107 (1.9%)
Medical condition that, in the opinion of the IoR, would interfere with the conduct of the study	8/46 (17.4%)	24/84 (28.6%)	0/84 (0.0%)	40/107 (37.4%)
Alcohol or substance use that, in the opinion of the IoR, would interfere with the conduct of the study	0/46 (0.0%)	3/84 (3.6%)	1/84 (1.2%)	1/107 (0.9%)

¹ This number includes participants where the enrollment status was missing at the time of data freeze.

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HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women
Atlas Open Report – June 22, 2021
Visit Cutoff Date: June 22, 2021
Table 1 – Screening Summary by Site

	Uganda: Entebbe: UVRI-IAVI	Uganda: Kampala: Baylor-Uganda CRS	Uganda: Kampala: MU-JHU Research Collaboration CRS	Zimbabwe: Chitungwiza: Seke South CRS
Ineligible ² participants who met one or more of the exclusion criteria				
One or more reactive HIV test results at Screening or Enrollment	11/46 (23.9%)	6/84 (7.1%)	18/84 (21.4%)	21/107 (19.6%)
Pregnant or currently breastfeeding, or intends to become pregnant and/or breastfeed during the study	9/46 (19.6%)	17/84 (20.2%)	15/84 (17.9%)	18/107 (16.8%)
Co-enrollment in any other HIV interventional research study	0/46 (0.0%)	0/84 (0.0%)	0/84 (0.0%)	0/107 (0.0%)
Current or past enrollment in an HIV vaccine trial or broadly neutralizing antibody trial	0/46 (0.0%)	0/84 (0.0%)	0/84 (0.0%)	0/107 (0.0%)
Current or chronic history of liver disease or known hepatic or biliary abnormalities	11/46 (23.9%)	0/84 (0.0%)	1/84 (1.2%)	4/107 (3.7%)
History of seizure disorder	2/46 (4.3%)	3/84 (3.6%)	0/84 (0.0%)	0/107 (0.0%)
Clinically significant cardiovascular disease	3/46 (6.5%)	2/84 (2.4%)	0/84 (0.0%)	21/107 (19.6%)
Inflammatory skin conditions that compromise the safety of IM injections, per the IoR	0/46 (0.0%)	1/84 (1.2%)	0/84 (0.0%)	2/107 (1.9%)
Has a tattoo or other dermatological condition overlying the buttock region	0/46 (0.0%)	0/84 (0.0%)	0/84 (0.0%)	0/107 (0.0%)
Coagulopathy which would contraindicate IM injection	1/46 (2.2%)	0/84 (0.0%)	0/84 (0.0%)	0/107 (0.0%)
Active or planned use of prohibited medications	0/46 (0.0%)	0/84 (0.0%)	0/84 (0.0%)	1/107 (0.9%)
Known or suspected allergy to study product components (active or placebo)	1/46 (2.2%)	2/84 (2.4%)	0/84 (0.0%)	6/107 (5.6%)

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HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women
Atlas Open Report – June 22, 2021
Visit Cutoff Date: June 22, 2021
Table 1 – Screening Summary by Site

	Zimbabwe: Chitungwiza: St.Mary's CRS	Zimbabwe: Chitungwiza: Zengeza CRS	Zimbabwe: Harare: Parirenyatwa CRS	Zimbabwe: Harare: Spilhaus CRS
Total Participants Screened	222	222	211	192
Enrolled	166/222 (74.8%)	162/222 (73.0%)	153/211 (72.5%)	138/192 (71.9%)
Eligible, Not Yet Enrolled	0/222 (0.0%)	0/222 (0.0%)	0/211 (0.0%)	0/192 (0.0%)
Not Enrolled	56/222 (25.2%)	60/222 (27.0%)	58/211 (27.5%)	54/192 (28.1%)
Not eligible	39/56 (69.6%)	43/60 (71.7%)	27/58 (46.6%)	36/54 (66.7%)
Participant declined to receive study product	0/56 (0.0%)	0/60 (0.0%)	0/58 (0.0%)	0/54 (0.0%)
Participant changed her mind	2/56 (3.6%)	1/60 (1.7%)	0/58 (0.0%)	1/54 (1.9%)
Unable to contact participant/no show	3/56 (5.4%)	5/60 (8.3%)	17/58 (29.3%)	0/54 (0.0%)
Other	12/56 (21.4%)	11/60 (18.3%)	14/58 (24.1%)	17/54 (31.5%)
Missing reason not enrolled ¹	0/56 (0.0%)	0/60 (0.0%)	0/58 (0.0%)	0/54 (0.0%)
Ineligible ² participants who failed to meet one or more of the inclusion criteria				
Not born female	0/39 (0.0%)	0/43 (0.0%)	0/27 (0.0%)	0/36 (0.0%)
Not 18–45 years at the time of screening	0/39 (0.0%)	0/43 (0.0%)	0/27 (0.0%)	0/36 (0.0%)
Not willing and able to provide informed consent	0/39 (0.0%)	2/43 (4.7%)	0/27 (0.0%)	0/36 (0.0%)
Not willing and able to undergo all required study procedures	5/39 (12.8%)	4/43 (9.3%)	0/27 (0.0%)	2/36 (5.6%)
Reactive HIV test results at Screening or Enrollment	2/39 (5.1%)	9/43 (20.9%)	2/27 (7.4%)	4/36 (11.1%)
Not sexually active	0/39 (0.0%)	1/43 (2.3%)	0/27 (0.0%)	0/36 (0.0%)
Score not > 2 using a modified VOICE risk score	0/39 (0.0%)	2/43 (4.7%)	1/27 (3.7%)	1/36 (2.8%)
Plans to re-locate or travel away from the site for > 8 consecutive weeks during study participation	9/39 (23.1%)	0/43 (0.0%)	0/27 (0.0%)	1/36 (2.8%)
Creatinine clearance not > 60 mL/min	0/39 (0.0%)	0/43 (0.0%)	1/27 (3.7%)	0/36 (0.0%)
HBsAg not negative or does not accept vaccination	5/39 (12.8%)	2/43 (4.7%)	3/27 (11.1%)	2/36 (5.6%)
Liver function values not ALT < 2x ULN or Tbili < 2.5 x ULN	0/39 (0.0%)	1/43 (2.3%)	1/27 (3.7%)	2/36 (5.6%)
Not HCV antibody negative	1/39 (2.6%)	2/43 (4.7%)	0/27 (0.0%)	0/36 (0.0%)
Pregnant	9/39 (23.1%)	4/43 (9.3%)	3/27 (11.1%)	3/36 (8.3%)
Of reproductive potential, but not willing to use a reliable form of contraception during the study	0/39 (0.0%)	0/43 (0.0%)	0/27 (0.0%)	3/36 (8.3%)
Medical condition that, in the opinion of the IoR, would interfere with the conduct of the study	4/39 (10.3%)	4/43 (9.3%)	15/27 (55.6%)	7/36 (19.4%)
Alcohol or substance use that, in the opinion of the IoR, would interfere with the conduct of the study	0/39 (0.0%)	0/43 (0.0%)	0/27 (0.0%)	0/36 (0.0%)

¹ This number includes participants where the enrollment status was missing at the time of data freeze.

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HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women
Atlas Open Report – June 22, 2021
Visit Cutoff Date: June 22, 2021
Table 1 – Screening Summary by Site

	Zimbabwe: Chitungwiza: St.Mary's CRS	Zimbabwe: Chitungwiza: Zengeza CRS	Zimbabwe: Harare: Parirenyatwa CRS	Zimbabwe: Harare: Spilhaus CRS
Ineligible ² participants who met one or more of the exclusion criteria				
One or more reactive HIV test results at Screening or Enrollment	2/39 (5.1%)	9/43 (20.9%)	2/27 (7.4%)	4/36 (11.1%)
Pregnant or currently breastfeeding, or intends to become pregnant and/or breastfeed during the study	8/39 (20.5%)	9/43 (20.9%)	3/27 (11.1%)	11/36 (30.6%)
Co-enrollment in any other HIV interventional research study	0/39 (0.0%)	0/43 (0.0%)	0/27 (0.0%)	0/36 (0.0%)
Current or past enrollment in an HIV vaccine trial or broadly neutralizing antibody trial	0/39 (0.0%)	0/43 (0.0%)	0/27 (0.0%)	0/36 (0.0%)
Current or chronic history of liver disease or known hepatic or biliary abnormalities	0/39 (0.0%)	6/43 (14.0%)	1/27 (3.7%)	0/36 (0.0%)
History of seizure disorder	1/39 (2.6%)	0/43 (0.0%)	0/27 (0.0%)	0/36 (0.0%)
Clinically significant cardiovascular disease	1/39 (2.6%)	4/43 (9.3%)	9/27 (33.3%)	1/36 (2.8%)
Inflammatory skin conditions that compromise the safety of IM injections, per the IoR	0/39 (0.0%)	0/43 (0.0%)	1/27 (3.7%)	0/36 (0.0%)
Has a tattoo or other dermatological condition overlying the buttock region	0/39 (0.0%)	0/43 (0.0%)	0/27 (0.0%)	0/36 (0.0%)
Coagulopathy which would contraindicate IM injection	0/39 (0.0%)	0/43 (0.0%)	1/27 (3.7%)	0/36 (0.0%)
Active or planned use of prohibited medications	0/39 (0.0%)	0/43 (0.0%)	0/27 (0.0%)	0/36 (0.0%)
Known or suspected allergy to study product components (active or placebo)	1/39 (2.6%)	3/43 (7.0%)	4/27 (14.8%)	1/36 (2.8%)

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HPTN 084 – A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women
Atlas Open Report – June 22, 2021
Visit Cutoff Date: June 22, 2021

Listing 1 – Other Reasons for Not Being Enrolled by Site

Site	Other Specified Reason for Not Being Enrolled
Botswana: Gaborone: Gaborone CRS	SMC recommendation not to enroll further
	Participant could not be enrolled due to the enrolment halt.She was rescreened
	SMC decision to stop further enrollment
	Could not enrol due to the enrolment halt.Participant will be rescreened
	SMC decision to stop further enrollment
	The participant could not provide proof of contraception cover
	SMC recommendation to stop further enrollment
	participant could not enroll because of work commitments
	SMC decision to stop further enrollment
Kenya: Kisumu: Kisumu CRS	At screening, participant had complaints on most systems that appeared made up, study team felt she wouldn't make a high quality participant for the study.
Malawi: Blantyre: Blantyre CRS	Participant's 45 day screening window has elapsed
Malawi: Lilongwe: Malawi CRS	Her husband did not give consent to her study participation
	Per investigator discretion, they had a voice risk score = 3.
	participant out of screening window
	Site closed for enrollment
	out of window
	exceeded 45 day visit window
	The participant was not enrolled due to investigators discretion. she looked older than 45 years
	exceeded 45 days screening window
	exceeded 45 days screening window
South Africa: Botha's Hill: Botha's Hill CRS	Participant will not be able to attend study visits due to her work schedule.
South Africa: Botha's Hill: Botha's Hill CRS	Participant did not receive approval from her parents to participate in the study due to traditional practices.
	COVID
	COVID
	Identity number not valid
	Ppt was not able to enroll within the screening window so will rescreen
	Participant not contacted in error
	COVID
	COVID
	COVID
	Participant out of screening window due to COVID site operational limitations
	Enrolment not completed within 45 days of specimen collection
	Screening window closed
	COVID
	Currently unavailable
	COVID
COVID	
Visit window for screening process closed	

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 – June 22, 2021
Visit Cutoff Date: June 22, 2021
Listing 1 – Other Reasons for Not Being Enrolled by Site

Site	Other Specified Reason for Not Being Enrolled
South Africa: Cape Town: Emavundleni CRS	Difficult blood draw
	45 day window closed
	difficult blood draw
	Screening enrollment window closed
	45 days window closed
	45 day window closed
	Difficult blood draw
	Difficult blood draw
	Screening enrollment window closed
	Screening /enrollment window closed
	Difficult blood draw
	difficult blood draw
	Screening/enrollment window closed
	45 day window closed
	45 day window closed
	45 day window closed
	Screening window closed and have no time to be rescreened
	Screening enrollment window closed
	Screening enrollment window closed
	Screening enrollment window closed
	Screening enrollment window closed
	45 day window closed
	Enrollment completed
	45 day window closed
	45 day window closed
	Enrolment completed
	Enrollment completed
	Screening enrollment window closed
	Screening/enrollment window closed
	enrollment window closed
	Screening visit window closed
	Screening enrollment window closed
Difficult blood draw	
Screening/enrollment window closed	
unable to obtain previous medical records	
Screening/enrollment window closed	
Screening/enrollment window closed	
Participant brought her proof of sterilization late. Screening window closed 3 days later	
Difficult blood draw	

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 – June 22, 2021
Visit Cutoff Date: June 22, 2021
Listing 1 – Other Reasons for Not Being Enrolled by Site

Site	Other Specified Reason for Not Being Enrolled
	Screening/enrollment window closed
	Screening/enrollment window closed
South Africa: Cape Town: Stellenbosch University (DTTC-SU) CRS	unable to complete screening due to Covid 19
	unable to enrol due to screening and enrollment pause due to COVID19
	unable to verify participants age according to site SOP
	unable to complete screening due to covid 19
	Enrollment paused due to COVID 19
	COVID19
	unable to complete screening due to covid 19
	suicidal ideation IOR decision to exclude from study
	IOR decision
	Due to COVID 19
	unable to complete screening due to covid 19
	participant not reliable to commit to study visits
	Participant screened out because her 45 days window lapsed.
	Participant disclosed to study driver that she struggles to take pills and has to dissolve them when she is sick.
	not on contraception
	Unable to schedule enrolment visit due to COVID19
South Africa: Johannesburg: Ward 21	she will be rescreened as has bypassed 45 window due to COVID enrolment halt
	Stopped Enrolments as per Nov DSMB recommendations.
	will be rescreened at a later if still interested.
	Participant rescreened bypassed 45 days post screening blood draw.
	Unable to obtain blood for enrolment visit
	she will be rescreened as has bypassed 45 window due to COVID enrolment halt
	contraception card appeared falsified , further attempts to contact her failed
South Africa: Kwa Zulu Natal: Isipingo CRS	Difficult venepuncture
	COVID-beyond 45 days
	COVID-more than 45 days screening period
	Challenging venipuncture on multiple attempts
	screened out due to covid
	Unable to attend scheduled visits
	Screened out due to covid.
	participant withdrew consent
	Participant screened out due to covid- 16 March 2020
	Screened out due to covid - 16 march 2020
	Difficult venipuncture on multiple attempts
	Cannot come to site on allocated visit days
	difficult blood draw. blood samples not collected
	Identification on family planning card does not match identity document.

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 – June 22, 2021
Visit Cutoff Date: June 22, 2021

Listing 1 – Other Reasons for Not Being Enrolled by Site

Site	Other Specified Reason for Not Being Enrolled
South Africa: Kwa Zulu Natal: Verulam CRS	enrollment was stopped due to COVID 19,ppt will be contacted when enrollment resumes
	clinician discretion difficult blood draw
	Clinical discretion :grade 01 decreased haemoglobin
	enrollment was stopped due to COVID 19,ppt will be contacted when enrollment resumes
	enrollment was stopped due to COVID 19,ppt will be contacted when enrollment resumes
	enrollment was stopped due to COVID 19,ppt will be contacted when enrollment resumes
	enrollment was stopped due to Covid 19, participant will be contacted when enrollment resume.
	enrollment stopped due to Covid 19, participant will contacted when enrollment resume
	enrollment was stopped due to COVID 19,ppt will be contacted when enrollment resumes
	difficult blood draw
	enrollment stopped due to Covid 19, participant will be contacted when enrollment resume
	enrollment stopped due to Covid19, participant will be contacted when enrollment resume.
	enrollment stopped due to Covid 19,participant will be contacted when enrollment resume
	Unable to verify participant's identity.
	enrollment was stopped due to COVID 19, ppt will be contacted when enrollment resumes
	Participant reported that she is no longer interested in study participation due to re-locating
	enrollment stopped due to Covid 19, participant will be contacted when enrollment resume
	enrollment stopped due to Covid 19, participant will be contacted when enrollment resume
	difficult venous access
	Clinical discretion applied: for decreased haemoglobin grade 02
unable to complete all screening procedures within 45 day window	
South Africa: Soweto: Soweto HPTN CRS	Investigator decision based on participant's age
	Participant did not comply with any scheduled follow up visits. Unable to reach her most times. High risk of defaulting follow up.
	Allowable window for enrollment lapsed due to study pause.
	Investigator's decision not to enroll based on questionable reliability of participant
Swaziland: Siteki: Swaziland Prevention Center	Allowable window for enrollment lapsed due to study pause. Participant will be re-screened.
	Retention issue
	Enrolment pause
	Retention issue
	Enrollment pause
	Enrolment pause
	Enrollment pause due to COVID-19
	Enrollment pause due to COVID
	Enrollment pause due to COVID-19
	Enrollment pause
	Enrollment pause
Enrollment pause	

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 – June 22, 2021
Visit Cutoff Date: June 22, 2021
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Site	Other Specified Reason for Not Being Enrolled
	Enrollment pause
	Enrollment pause
	Enrollment pause
	Enrollment pause
	Enrollment pause
	Enrollment pause
Uganda: Entebbe: UVRI-IAVI	HIV RESULTS RECEIVED ON 14TH DAY AFTER RE TESTING, PARTICIPANT HAD NOT FASTED, SPONSOR HAD PAUSED ENROLLMENTS
	PARTICIPANT DIDN NOT SHOW COMMITMENT TO STUDY PARTICIPATION
	negative family influence
	We had already enrolled the eight participants for the month of Feb as requested by HPTN 084 LOC
Uganda: Kampala: MU-JHU Research Collaboration CRS	Unable to provide adequate locator information
	Partner refused her to participate in the study
Zimbabwe: Chitungwiza: Seke South CRS	Screening 45 day window closed
Zimbabwe: Chitungwiza: St.Mary's CRS	ADMINISTRATIVE, WINDOW HAS CLOSED
	NOT ENROLLED DUE TO ADMINISTRATIVE ISSUES
	ADMINISTRATIVE, WINDOW HAS CLOSED
	ADMINISTRATIVE, WINDOW HAS CLOSED
	ADMINISTRATIVE, WINDOW CLOSED
	NOT ENROLLED DUE TO ADMINISTRATIVE ISSUES
	ADMINISTRATIVE, WINDOW CLOSED
	ADMINISTRATIVE, WINDOW HAS CLOSED
	ADMINISTRATIVE, WINDOW CLOSED
	ADMINISTRATIVE, WINDOW CLOSED
	PARTICIPANT NOT COMFORTABLE WITH BLOOD DRAWS
	PARTICIPANT'S PARTNER IS STOPPING HER FROM PARTICIPATING IN THE STUDY
Zimbabwe: Chitungwiza: Zengeza CRS	45 Day window closed due to study pause
	Screening 45 day window closed due to study pause
	Window closed due to Study Pause
	Screening 45 day window closed due to study pause
	45 Day window closed due to study pause
	Participant reported that she is now committed
	Screening 45 day window closed due to study pause
	Screening 45 day window closed due to study pause
	Due to study pause
	45 day screening window closed due to study pause
	Partner declined participant study participation.
Zimbabwe: Harare: Parirenyatwa CRS	participant not able to come to the clinic within enrollment visit window

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 – June 22, 2021
Visit Cutoff Date: June 22, 2021

Listing 1 – Other Reasons for Not Being Enrolled by Site

Site	Other Specified Reason for Not Being Enrolled
	enrollment pause
	husband refused
	enrolment pause
	Locator verification failed
	enrollment pause
	failure to comprehend study
	Enrollment pause
	Enrollment Halt
	Lab results fell out of screening window
	Failure to comprehend
	Enrollment pause
	Enrollments halted for the site
	Poor comprehension of the protocol
Zimbabwe: Harare: Spilhaus CRS	Screening to enrollment window closed
	Screening to enrollment window closed before enrolment
	Screening to enrollment visit window closed
	Screening to Enrollment window closed
	Screening to Enrollment window closed
	Screening to enrollment window closed
	protocol team stopped enrollments
	Screening to Enrollment window closed
	Partner refused to have her participate
	Screening to enrolment window closed before enrolment and enrolments have been stopped by the protocol team
	protocol team stopped enrollments
	Further Enrollments stopped by protocol team
	protocol team stopped enrollments
	Enrollments stopped by the protocol team
	screening to Enrollment window closed
	Screening to Enrollment window closed
	Screening to Enrollment window closes