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 − Accrual Summary by Site

Site [1, 5, 6]	Activation Date	First Enrollment Date	Last Enrollment Date [2]	Duration of Accrual [3] (weeks)	Enrollment Target [4]	Total Enrolled	Average Enrolled per Week	Percentage Enrolled
Overall	07NOV2017	27NOV2017	04NOV2020	153.4	3200	3224	21.0	100.8%
South Africa: Johannesburg: Ward 21	07NOV2017	04DEC2017	04NOV2020	152.4	201	206	1.4	102.5%
South Africa: Soweto: Soweto HPTN CRS	**09NOV2017**	**27NOV2017**	**14OCT2020**	**150.4**	**172**	**176**	**1.2**	**102.3%**
Botswana: Gaborone: Gaborone CRS	14DEC2017	05FEB2018	22OCT2019	89.3	91	91	1.0	100.0%
Zimbabwe: Chitungwiza: Zengeza CRS	12JAN2018	12FEB2018	17OCT2019	87.6	162	162	1.8	100.0%
Zimbabwe: Chitungwiza: St.Mary's CRS	12JAN2018	15FEB2018	09OCT2019	86	166	166	1.9	100.0%
Zimbabwe: Harare: Parirenyatwa CRS	12JAN2018	19FEB2018	24OCT2019	87.6	153	153	1.7	100.0%
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	**31AUG2018**	**25SEP2018**	**09OCT2020**	**106.6**	**160**	**159**	**1.5**	**99.4%**
South Africa: Botha's Hill: Botha's Hill CRS	**05SEP2018**	**25SEP2018**	**02OCT2020**	**105.6**	**221**	**223**	**2.1**	**100.9%**
Uganda: Kampala: MU−JHU Research Collaboration CRS	07SEP2018	20SEP2018	10MAR2020	76.9	204	204	2.7	100.0%
South Africa: Kwa Zulu Natal: Isipingo CRS	**07SEP2018**	**25SEP2018**	**12OCT2020**	**107**	**163**	**170**	**1.6**	**104.3%**
South Africa: Kwa Zulu Natal: Verulam CRS	**07SEP2018**	**28SEP2018**	**27OCT2020**	**108.7**	**145**	**151**	**1.4**	**104.1%**
Zimbabwe: Chitungwiza: Seke South CRS	07SEP2018	31OCT2018	21OCT2019	50.9	160	160	3.1	100.0%
Zimbabwe: Harare: Spilhaus CRS	07SEP2018	31OCT2018	24OCT2019	51.3	138	138	2.7	100.0%
Uganda: Kampala: Baylor−Uganda CRS	21SEP2018	03OCT2018	10MAR2020	75	210	210	2.8	100.0%
South Africa: Cape Town: Emavundleni CRS	10OCT2018	30OCT2018	03SEP2020	96.4	223	223	2.3	100.0%
Kenya: Kisumu: Kisumu CRS	17OCT2018	06NOV2018	29MAY2019	29.3	66	66	2.3	100.0%
Uganda: Entebbe: UVRI−IAVI	30OCT2018	12NOV2018	10FEB2020	65.1	182	182	2.8	100.0%
Malawi: Blantyre: Blantyre CRS	08NOV2018	20NOV2018	23OCT2019	48.3	113	113	2.3	100.0%
Malawi: Lilongwe: Malawi CRS	08NOV2018	23NOV2018	24OCT2019	48	111	111	2.3	100.0%
Swaziland: Siteki: Swaziland Prevention Center	21NOV2018	04DEC2018	07OCT2020	96.3	159	160	1.7	100.6%

[1] Enrollment was temporarily paused for the sites that have been activated before May 26th, 2018. Ward 21 & Soweto CRS were on an enrollment pause from May 26th, 2018 through July 16th, 2018. Gaborone CRS was on an enrollment pause from May 26th, 2018 through August 21st, 2018. Zengeza CRS was on an enrollment pause from May 26th, 2018 through August 20th, 2018. Parirenyatwa CRS & St.Mary's CRS were on an enrollment pause from May 26th, 2018 through August 23rd, 2018.
[2] Date of most recent enrollment as of June 22, 2021.
[3] Duration of accrual is based on first enrollment date.
[4] Overall enrollment target is for all the sites. Overall enrollment target indicates the protocol target and is not necessarily equal to the sum of individual site targets.
[5] Bolded sitenames indicate ongoing enrollment as of June 22, 2021.
[6] For sites that have capped enrollment, per PI's recommendation, the enrollment target has been adjusted to be the same as the total enrolled.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_accrual_summary.sas, SAS Version 9.4 (22JUN2021,9:15)

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 2 − Accrual Summary by Calendar Month and 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	South Africa: Cape Town: Emavundleni CRS
Activation Date	07NOV2017	14DEC2017	17OCT2018	08NOV2018	08NOV2018	05SEP2018	10OCT2018
First Enrollment Date	27NOV2017	05FEB2018	06NOV2018	20NOV2018	23NOV2018	25SEP2018	30OCT2018
Last Enrollment Date [1]	04NOV2020	22OCT2019	29MAY2019	23OCT2019	24OCT2019	02OCT2020	03SEP2020
Total Enrolled	3224	91	66	113	111	223	223
Enrollment Target	3200	91	66	113	111	221	223
Percent Enrolled	100.8%	100.0%	100.0%	100.0%	100.0%	100.9%	100.0%
Months of Active Enrollment [2]	32.2	26.8	23.7	20.7	21.4	23.3	22.3
Average Enrolled per Month [3]	100.1	3.4	2.8	5.5	5.2	9.6	10.0
Accrual by Calendar Month [4]							
NOV2017	3 (3)	− (−)	− (−)	− (−)	− (−)	− (−)	− (−)
DEC2017	5 (8)	− (−)	− (−)	− (−)	− (−)	− (−)	− (−)
JAN2018	9 (17)	− (−)	− (−)	− (−)	− (−)	− (−)	− (−)
FEB2018	44 (61)	4 (4)	− (−)	− (−)	− (−)	− (−)	− (−)
MAR2018	44 (105)	3 (7)	− (−)	− (−)	− (−)	− (−)	− (−)
APR2018	31 (136)	1 (8)	− (−)	− (−)	− (−)	− (−)	− (−)
MAY2018	15 (151)	4 (12)	− (−)	− (−)	− (−)	− (−)	− (−)
JUN2018	− (151)	− (12)	− (−)	− (−)	− (−)	− (−)	− (−)
JUL2018	13 (164)	− (12)	− (−)	− (−)	− (−)	− (−)	− (−)
AUG2018	17 (181)	0 (12)	− (−)	− (−)	− (−)	− (−)	− (−)
SEP2018	39 (220)	2 (14)	− (−)	− (−)	− (−)	2 (2)	− (−)
OCT2018	110 (330)	7 (21)	− (−)	− (−)	− (−)	21 (23)	1 (1)
NOV2018	177 (507)	9 (30)	12 (12)	5 (5)	3 (3)	5 (28)	7 (8)
DEC2018	76 (583)	2 (32)	4 (16)	2 (7)	3 (6)	1 (29)	5 (13)
JAN2019	134 (717)	3 (35)	3 (19)	2 (9)	0 (6)	13 (42)	10 (23)
FEB2019	227 (944)	10 (45)	13 (32)	7 (16)	16 (22)	13 (55)	19 (42)
MAR2019	207 (1151)	6 (51)	13 (45)	12 (28)	6 (28)	9 (64)	25 (67)
APR2019	191 (1342)	6 (57)	13 (58)	17 (45)	9 (37)	6 (70)	16 (83)
MAY2019	193 (1535)	3 (60)	8 (66)	13 (58)	12 (49)	12 (82)	10 (93)
JUN2019	168 (1703)	13 (73)	0 (66)	12 (70)	13 (62)	17 (99)	11 (104)
JUL2019	228 (1931)	3 (76)	0 (66)	13 (83)	12 (74)	9 (108)	23 (127)
AUG2019	201 (2132)	8 (84)	0 (66)	13 (96)	11 (85)	16 (124)	13 (140)

[1] Date of most recent enrollment as of June 22, 2021.
[2] Months from first enrollment through completing enrollment target, plus months with enrollment over target. First and last months may be fractional due to enrollment start date and data cutoff date.
[3] Total enrolled divided by months of active enrollment.
[4] A dash (−) in the enrollment column indicates a month not in active enrollment period [2], so no enrollment is expected.
Source: SCHARP (Surabhi) − /trials/hptn/p084/analysis/atlas/code/open/t_accrual_calmonth.sas, SAS Version 9.4 (22JUN2021,9:15)

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 2 − Accrual Summary by Calendar Month and 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	South Africa: Cape Town: Emavundleni CRS
SEP2019	208 (2340)	0 (84)	0 (66)	7 (103)	16 (101)	14 (138)	5 (145)
OCT2019	298 (2638)	7 (91)	0 (66)	10 (113)	10 (111)	15 (153)	16 (161)
NOV2019	67 (2705)	0 (91)	0 (66)	0 (113)	0 (111)	3 (156)	5 (166)
DEC2019	30 (2735)	0 (91)	0 (66)	0 (113)	0 (111)	0 (156)	2 (168)
JAN2020	111 (2846)	0 (91)	0 (66)	0 (113)	0 (111)	8 (164)	9 (177)
FEB2020	114 (2960)	0 (91)	0 (66)	0 (113)	0 (111)	20 (184)	19 (196)
MAR2020	72 (3032)	0 (91)	0 (66)	0 (113)	0 (111)	10 (194)	6 (202)
APR2020	0 (3032)	0 (91)	0 (66)	0 (113)	0 (111)	0 (194)	0 (202)
MAY2020	0 (3032)	0 (91)	0 (66)	0 (113)	0 (111)	0 (194)	0 (202)
JUN2020	0 (3032)	0 (91)	0 (66)	0 (113)	0 (111)	0 (194)	0 (202)
JUL2020	30 (3062)	0 (91)	0 (66)	0 (113)	0 (111)	8 (202)	4 (206)
AUG2020	54 (3116)	0 (91)	0 (66)	0 (113)	0 (111)	9 (211)	14 (220)
SEP2020	84 (3200)	0 (91)	0 (66)	0 (113)	0 (111)	10 (221)	3 (223)
OCT2020	23 (3223)	0 (91)	0 (66)	0 (113)	0 (111)	2 (223)	0 (223)
NOV2020	1 (3224)	0 (91)	0 (66)	0 (113)	0 (111)	− (223)	0 (223)

[1] Date of most recent enrollment as of June 22, 2021.
[2] Months from first enrollment through completing enrollment target, plus months with enrollment over target. First and last months may be fractional due to enrollment start date and data cutoff date.
[3] Total enrolled divided by months of active enrollment.
[4] A dash (−) in the enrollment column indicates a month not in active enrollment period [2], so no enrollment is expected.
Source: SCHARP (Surabhi) − /trials/hptn/p084/analysis/atlas/code/open/t_accrual_calmonth.sas, SAS Version 9.4 (22JUN2021,9:15)

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 2 − Accrual Summary by Calendar Month and Site

	South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	South Africa: Johannessburg: Ward 21	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	Uganda: Entebbe: UVRI−IAVI
Activation Date	31AUG2018	07NOV2017	07SEP2018	07SEP2018	09NOV2017	21NOV2018	30OCT2018
First Enrollment Date	25SEP2018	04DEC2017	25SEP2018	28SEP2018	27NOV2017	04DEC2018	12NOV2018
Last Enrollment Date [1]	09OCT2020	04NOV2020	12OCT2020	27OCT2020	14OCT2020	07OCT2020	10FEB2020
Total Enrolled	159	206	170	151	176	160	182
Enrollment Target	160	201	163	145	172	159	182
Percent Enrolled	99.4%	102.5%	104.3%	104.1%	102.3%	100.6%	100.0%
Months of Active Enrollment [2]	26.2	32.2	23.2	24.0	31.9	20.3	17.6
Average Enrolled per Month [3]	6.1	6.4	7.3	6.3	5.5	7.9	10.3
Accrual by Calendar Month [4]							
NOV2017	− (−)	− (−)	− (−)	− (−)	3 (3)	− (−)	− (−)
DEC2017	− (−)	4 (4)	− (−)	− (−)	1 (4)	− (−)	− (−)
JAN2018	− (−)	2 (6)	− (−)	− (−)	7 (11)	− (−)	− (−)
FEB2018	− (−)	11 (17)	− (−)	− (−)	15 (26)	− (−)	− (−)
MAR2018	− (−)	11 (28)	− (−)	− (−)	6 (32)	− (−)	− (−)
APR2018	− (−)	4 (32)	− (−)	− (−)	1 (33)	− (−)	− (−)
MAY2018	− (−)	0 (32)	− (−)	− (−)	0 (33)	− (−)	− (−)
JUN2018	− (−)	− (32)	− (−)	− (−)	− (33)	− (−)	− (−)
JUL2018	− (−)	7 (39)	− (−)	− (−)	6 (39)	− (−)	− (−)
AUG2018	− (−)	9 (48)	− (−)	− (−)	8 (47)	− (−)	− (−)
SEP2018	2 (2)	9 (57)	4 (4)	1 (1)	5 (52)	− (−)	− (−)
OCT2018	5 (7)	10 (67)	3 (7)	12 (13)	8 (60)	− (−)	− (−)
NOV2018	7 (14)	7 (74)	0 (7)	3 (16)	10 (70)	− (−)	15 (15)
DEC2018	2 (16)	6 (80)	0 (7)	0 (16)	5 (75)	5 (5)	5 (20)
JAN2019	1 (17)	10 (90)	4 (11)	3 (19)	10 (85)	6 (11)	10 (30)
FEB2019	12 (29)	8 (98)	6 (17)	9 (28)	16 (101)	0 (11)	3 (33)
MAR2019	9 (38)	5 (103)	2 (19)	6 (34)	0 (101)	3 (14)	7 (40)
APR2019	8 (46)	8 (111)	2 (21)	3 (37)	13 (114)	7 (21)	8 (48)
MAY2019	16 (62)	12 (123)	5 (26)	0 (37)	2 (116)	12 (33)	10 (58)
JUN2019	3 (65)	5 (128)	4 (30)	6 (43)	5 (121)	4 (37)	11 (69)
JUL2019	8 (73)	7 (135)	11 (41)	12 (55)	14 (135)	25 (62)	10 (79)

[1] Date of most recent enrollment as of June 22, 2021.
[2] Months from first enrollment through completing enrollment target, plus months with enrollment over target. First and last months may be fractional due to enrollment start date and data cutoff date.
[3] Total enrolled divided by months of active enrollment.
[4] A dash (−) in the enrollment column indicates a month not in active enrollment period [2], so no enrollment is expected.
Source: SCHARP (Surabhi) − /trials/hptn/p084/analysis/atlas/code/open/t_accrual_calmonth.sas, SAS Version 9.4 (22JUN2021,9:15)

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 2 − Accrual Summary by Calendar Month and Site

	South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	South Africa: Johannessburg: Ward 21	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	Uganda: Entebbe: UVRI−IAVI
AUG2019	10 (83)	7 (142)	29 (70)	10 (65)	7 (142)	24 (86)	12 (91)
SEP2019	9 (92)	9 (151)	18 (88)	11 (76)	5 (147)	15 (101)	15 (106)
OCT2019	19 (111)	7 (158)	23 (111)	17 (93)	7 (154)	22 (123)	22 (128)
NOV2019	0 (111)	2 (160)	0 (111)	5 (98)	2 (156)	3 (126)	7 (135)
DEC2019	0 (111)	0 (160)	0 (111)	0 (98)	3 (159)	2 (128)	7 (142)
JAN2020	0 (111)	0 (160)	8 (119)	5 (103)	2 (161)	9 (137)	32 (174)
FEB2020	17 (128)	4 (164)	6 (125)	8 (111)	1 (162)	11 (148)	8 (182)
MAR2020	13 (141)	12 (176)	8 (133)	9 (120)	0 (162)	0 (148)	0 (182)
APR2020	0 (141)	0 (176)	0 (133)	0 (120)	0 (162)	0 (148)	0 (182)
MAY2020	0 (141)	0 (176)	0 (133)	0 (120)	0 (162)	0 (148)	0 (182)
JUN2020	0 (141)	0 (176)	0 (133)	0 (120)	0 (162)	0 (148)	0 (182)
JUL2020	0 (141)	2 (178)	6 (139)	8 (128)	0 (162)	2 (150)	0 (182)
AUG2020	2 (143)	10 (188)	2 (141)	8 (136)	0 (162)	9 (159)	0 (182)
SEP2020	15 (158)	11 (199)	26 (167)	9 (145)	10 (172)	0 (159)	0 (182)
OCT2020	1 (159)	6 (205)	3 (170)	6 (151)	4 (176)	1 (160)	0 (182)
NOV2020	0 (159)	1 (206)	− (170)	− (151)	− (176)	− (160)	0 (182)

[1] Date of most recent enrollment as of June 22, 2021.
[2] Months from first enrollment through completing enrollment target, plus months with enrollment over target. First and last months may be fractional due to enrollment start date and data cutoff date.
[3] Total enrolled divided by months of active enrollment.
[4] A dash (−) in the enrollment column indicates a month not in active enrollment period [2], so no enrollment is expected.
Source: SCHARP (Surabhi) − /trials/hptn/p084/analysis/atlas/code/open/t_accrual_calmonth.sas, SAS Version 9.4 (22JUN2021,9:15)

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 2 − Accrual Summary by Calendar Month and Site

	Uganda: Kampala: Baylor−Uganda CRS	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	Zimbabwe: Harare: Spilhaus CRS
Activation Date	21SEP2018	07SEP2018	07SEP2018	12JAN2018	12JAN2018	12JAN2018	07SEP2018
First Enrollment Date	03OCT2018	20SEP2018	31OCT2018	15FEB2018	12FEB2018	19FEB2018	31OCT2018
Last Enrollment Date [1]	10MAR2020	10MAR2020	21OCT2019	09OCT2019	17OCT2019	24OCT2019	24OCT2019
Total Enrolled	210	204	160	166	162	153	138
Enrollment Target	210	204	160	166	162	153	138
Percent Enrolled	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Months of Active Enrollment [2]	19.6	20.0	20.8	20.8	24.4	27.6	22.2
Average Enrolled per Month [3]	10.7	10.2	7.7	8.0	6.6	5.5	6.2
Accrual by Calendar Month [4]							
NOV2017	− (−)	− (−)	− (−)	− (−)	− (−)	− (−)	− (−)
DEC2017	− (−)	− (−)	− (−)	− (−)	− (−)	− (−)	− (−)
JAN2018	− (−)	− (−)	− (−)	− (−)	− (−)	− (−)	− (−)
FEB2018	− (−)	− (−)	− (−)	4 (4)	6 (6)	4 (4)	− (−)
MAR2018	− (−)	− (−)	− (−)	6 (10)	9 (15)	9 (13)	− (−)
APR2018	− (−)	− (−)	− (−)	15 (25)	1 (16)	9 (22)	− (−)
MAY2018	− (−)	− (−)	− (−)	4 (29)	4 (20)	3 (25)	− (−)
JUN2018	− (−)	− (−)	− (−)	− (29)	− (20)	− (25)	− (−)
JUL2018	− (−)	− (−)	− (−)	− (29)	− (20)	− (25)	− (−)
AUG2018	− (−)	− (−)	− (−)	0 (29)	0 (20)	0 (25)	− (−)
SEP2018	− (−)	4 (4)	− (−)	0 (29)	10 (30)	0 (25)	− (−)
OCT2018	19 (19)	10 (14)	1 (1)	0 (29)	8 (38)	2 (27)	3 (3)
NOV2018	4 (23)	24 (38)	6 (7)	15 (44)	13 (51)	15 (42)	17 (20)
DEC2018	4 (27)	1 (39)	4 (11)	1 (45)	14 (65)	7 (49)	5 (25)
JAN2019	14 (41)	3 (42)	7 (18)	4 (49)	12 (77)	10 (59)	9 (34)
FEB2019	17 (58)	8 (50)	15 (33)	20 (69)	12 (89)	15 (74)	8 (42)
MAR2019	21 (79)	13 (63)	17 (50)	19 (88)	16 (105)	10 (84)	8 (50)
APR2019	11 (90)	7 (70)	11 (61)	13 (101)	7 (112)	16 (100)	10 (60)
MAY2019	11 (101)	7 (77)	14 (75)	8 (109)	9 (121)	15 (115)	14 (74)
JUN2019	16 (117)	14 (91)	3 (78)	1 (110)	8 (129)	9 (124)	13 (87)
JUL2019	12 (129)	3 (94)	16 (94)	21 (131)	11 (140)	7 (131)	11 (98)
AUG2019	7 (136)	6 (100)	4 (98)	6 (137)	5 (145)	9 (140)	4 (102)

[1] Date of most recent enrollment as of June 22, 2021.
[2] Months from first enrollment through completing enrollment target, plus months with enrollment over target. First and last months may be fractional due to enrollment start date and data cutoff date.
[3] Total enrolled divided by months of active enrollment.
[4] A dash (−) in the enrollment column indicates a month not in active enrollment period [2], so no enrollment is expected.
Source: SCHARP (Surabhi) − /trials/hptn/p084/analysis/atlas/code/open/t_accrual_calmonth.sas, SAS Version 9.4 (22JUN2021,9:15)

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 2 − Accrual Summary by Calendar Month and Site

	Uganda: Kampala: Baylor−Uganda CRS	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	Zimbabwe: Harare: Spilhaus CRS
SEP2019	8 (144)	5 (105)	21 (119)	15 (152)	11 (156)	9 (149)	15 (117)
OCT2019	12 (156)	25 (130)	41 (160)	14 (166)	6 (162)	4 (153)	21 (138)
NOV2019	8 (164)	32 (162)	0 (160)	0 (166)	0 (162)	0 (153)	0 (138)
DEC2019	3 (167)	13 (175)	0 (160)	0 (166)	0 (162)	0 (153)	0 (138)
JAN2020	26 (193)	12 (187)	0 (160)	0 (166)	0 (162)	0 (153)	0 (138)
FEB2020	8 (201)	12 (199)	0 (160)	0 (166)	0 (162)	0 (153)	0 (138)
MAR2020	9 (210)	5 (204)	0 (160)	0 (166)	0 (162)	0 (153)	0 (138)
APR2020	0 (210)	0 (204)	0 (160)	0 (166)	0 (162)	0 (153)	0 (138)
MAY2020	0 (210)	0 (204)	0 (160)	0 (166)	0 (162)	0 (153)	0 (138)
JUN2020	0 (210)	0 (204)	0 (160)	0 (166)	0 (162)	0 (153)	0 (138)
JUL2020	0 (210)	0 (204)	0 (160)	0 (166)	0 (162)	0 (153)	0 (138)
AUG2020	0 (210)	0 (204)	0 (160)	0 (166)	0 (162)	0 (153)	0 (138)
SEP2020	0 (210)	0 (204)	0 (160)	0 (166)	0 (162)	0 (153)	0 (138)
OCT2020	0 (210)	0 (204)	0 (160)	0 (166)	0 (162)	0 (153)	0 (138)
NOV2020	0 (210)	0 (204)	0 (160)	0 (166)	0 (162)	0 (153)	0 (138)

[1] Date of most recent enrollment as of June 22, 2021.
[2] Months from first enrollment through completing enrollment target, plus months with enrollment over target. First and last months may be fractional due to enrollment start date and data cutoff date.
[3] Total enrolled divided by months of active enrollment.
[4] A dash (−) in the enrollment column indicates a month not in active enrollment period [2], so no enrollment is expected.
Source: SCHARP (Surabhi) − /trials/hptn/p084/analysis/atlas/code/open/t_accrual_calmonth.sas, SAS Version 9.4 (22JUN2021,9:15)

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%)

[1] Inappropriately enrolled participants are excluded.
[2] Participants who did not progress to Step 2 due to HIV infection are not included.

Source: SCHARP (Ting) − /trials/hptn/p084/analysis/atlas/code/open/t_prog2step2_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

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

	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%)

[1] Inappropriately enrolled participants are excluded.
[2] Participants who did not progress to Step 2 due to HIV infection are not included.

Source: SCHARP (Ting) − /trials/hptn/p084/analysis/atlas/code/open/t_prog2step2_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

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

	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%)

[1] Inappropriately enrolled participants are excluded.
[2] Participants who did not progress to Step 2 due to HIV infection are not included.

Source: SCHARP (Ting) − /trials/hptn/p084/analysis/atlas/code/open/t_prog2step2_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

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

	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%)

[1] Inappropriately enrolled participants are excluded.
[2] Participants who did not progress to Step 2 due to HIV infection are not included.

Source: SCHARP (Ting) − /trials/hptn/p084/analysis/atlas/code/open/t_prog2step2_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Listing 1 − Participants Pending Progression to Step 2 : Enrolled 6 Weeks or More[1]

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_prog2step2.sas, SAS Version 9.4 (05MAR2024,19:50)

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_prog2step2.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Listing 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 Particpat 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 Partcipant did not enter step 2
	818302699	TERMINATED	10OCT2019	1608	2	−		01AUG2022	Other, specify Participant did not enter step 2

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_prog2step2.sas, SAS Version 9.4 (05MAR2024,19:50)

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_prog2step2.sas, SAS Version 9.4 (05MAR2024,19:50)

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_prog2step2.sas, SAS Version 9.4 (05MAR2024,19:50)

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_prog2step2.sas, SAS Version 9.4 (05MAR2024,19:50)

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_prog2step2.sas, SAS Version 9.4 (05MAR2024,19:50)

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_prog2step2.sas, SAS Version 9.4 (05MAR2024,19:50)

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_prog2step2.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 4 − Permanent Discontinuation of Study Product during Steps 1 and 2 by Site

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

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_pdisc_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 4 − Permanent Discontinuation of Study Product during Steps 1 and 2 by Site

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

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_pdisc_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 4 − Permanent Discontinuation of Study Product during Steps 1 and 2 by Site

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

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_pdisc_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 4 − Permanent Discontinuation of Study Product during Steps 1 and 2 by Site

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

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_pdisc_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 4 − Permanent Discontinuation of Study Product during Steps 1 and 2 by Site

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

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_pdisc_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 4 − Permanent Discontinuation of Study Product during Steps 1 and 2 by Site

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

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_pdisc_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 4 − Permanent Discontinuation of Study Product during Steps 1 and 2 by Site

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

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_pdisc_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Listing 3 − All Participants who Permanently Discontinued Study Product during Steps 1 and 2[1]

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_pdisc_all.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Listing 3 − All Participants who Permanently Discontinued Study Product during Steps 1 and 2[1]

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_pdisc_all.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Listing 3 − All Participants who Permanently Discontinued Study Product during Steps 1 and 2[1]

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_pdisc_all.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Listing 3 − All Participants who Permanently Discontinued Study Product during Steps 1 and 2[1]

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_pdisc_all.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Listing 3 − All Participants who Permanently Discontinued Study Product during Steps 1 and 2[1]

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_pdisc_all.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Listing 3 − All Participants who Permanently Discontinued Study Product during Steps 1 and 2[1]

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_pdisc_all.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Listing 3 − All Participants who Permanently Discontinued Study Product during Steps 1 and 2[1]

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_pdisc_all.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Listing 3 − All Participants who Permanently Discontinued Study Product during Steps 1 and 2[1]

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_pdisc_all.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Listing 3 − All Participants who Permanently Discontinued Study Product during Steps 1 and 2[1]

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_pdisc_all.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Listing 3 − All Participants who Permanently Discontinued Study Product during Steps 1 and 2[1]

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

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_pdisc_all.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Listing 3 − All Participants who Permanently Discontinued Study Product during Steps 1 and 2[1]

Site	Subject ID	Permanent Discontinuation Date	Permanent Discontinuation Visit	Step in which Permanently Discontinued	Reason for Permanent Discontinuation	Other Reasons
	771662562	04DEC2018	Interim Visit 2.1	Step 1	Participant request − other reason	Fear of side effects
	771937626	15APR2019	Interim Visit 4.2	Step 1	Participant request − unwilling or unable to comply with required study procedures	

[1] Inappropriately enrolled participants are excluded.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/l_pdisc_all.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
SMC Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 5 − Baseline Demographics 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
Age (years)						
18−25	1849/3224 (57%)	31/91 (34%)	20/66 (30%)	33/113 (29%)	82/111 (74%)	143/223 (64%)
26−35	1102/3224 (34%)	45/91 (49%)	40/66 (61%)	42/113 (37%)	29/111 (26%)	76/223 (34%)
36−45	273/3224 (8%)	15/91 (16%)	6/66 (9%)	38/113 (34%)	0/111 (0%)	4/223 (2%)
Missing	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Mean (SD)	26.0 (5.8)	28.9 (6.4)	28.4 (5.1)	31.2 (7.1)	23.3 (3.6)	24.8 (4.4)
Median	25.0	28.0	29.0	31.0	23.0	24.0
Min, Max	18, 45	18, 43	20, 44	18, 43	18, 33	18, 41
Voice Risk Score at Screening						
0	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
1	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
2	21/3224 (1%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
3	332/3224 (10%)	21/91 (23%)	24/66 (36%)	61/113 (54%)	8/111 (7%)	9/223 (4%)
4	319/3224 (10%)	11/91 (12%)	7/66 (11%)	6/113 (5%)	13/111 (12%)	24/223 (11%)
5	731/3224 (23%)	25/91 (27%)	16/66 (24%)	30/113 (27%)	28/111 (25%)	52/223 (23%)
6	714/3224 (22%)	13/91 (14%)	10/66 (15%)	6/113 (5%)	16/111 (14%)	58/223 (26%)
7	594/3224 (18%)	9/91 (10%)	9/66 (14%)	4/113 (4%)	27/111 (24%)	62/223 (28%)
8	513/3224 (16%)	12/91 (13%)	0/66 (0%)	6/113 (5%)	19/111 (17%)	18/223 (8%)
9	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Missing	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Median (Q1,Q3)	6.0 (5,7)	5.0 (4,6)	5.0 (3,6)	3.0 (3,5)	6.0 (5,7)	6.0 (5,7)
Race/Ethnicity						
African	160/3224 (5%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Asian	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Black	1979/3224 (61%)	91/91 (100%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	220/223 (99%)
Chewa	47/3224 (1%)	0/91 (0%)	0/66 (0%)	3/113 (3%)	44/111 (40%)	0/223 (0%)
Chinese, Indian or other Asian	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Colored/Mixed	10/3224 (<1%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Indian	5/3224 (<1%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	2/223 (1%)
Kalenjin	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Kamba	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_demog_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
SMC Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 5 − Baseline Demographics 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
Kikuyu	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Kisii	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Lomwe	63/3224 (2%)	0/91 (0%)	0/66 (0%)	44/113 (39%)	19/111 (17%)	0/223 (0%)
Luhya	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Luo	4/3224 (<1%)	0/91 (0%)	4/66 (6%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Ndebele	9/3224 (<1%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Ngoni	60/3224 (2%)	0/91 (0%)	0/66 (0%)	33/113 (29%)	27/111 (24%)	0/223 (0%)
Originating from Europe, the Middle East or North Africa	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Other African Tribe	6/3224 (<1%)	0/91 (0%)	0/66 (0%)	1/113 (1%)	1/111 (1%)	0/223 (0%)
Shona	761/3224 (24%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Tumbuka	9/3224 (<1%)	0/91 (0%)	0/66 (0%)	6/113 (5%)	3/111 (3%)	0/223 (0%)
White	1/3224 (<1%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	1/223 (<1%)
Yao	25/3224 (1%)	0/91 (0%)	0/66 (0%)	13/113 (12%)	12/111 (11%)	0/223 (0%)
Other	85/3224 (3%)	0/91 (0%)	62/66 (94%)	13/113 (12%)	5/111 (5%)	0/223 (0%)
Missing	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Marital Status						
Married/Civil Union/Legal Partnership	343/3224 (11%)	5/91 (5%)	30/66 (45%)	53/113 (47%)	27/111 (24%)	5/223 (2%)
Living with Primary or Main Partner	224/3224 (7%)	21/91 (23%)	4/66 (6%)	25/113 (22%)	3/111 (3%)	11/223 (5%)
Have Primary or Main Partner, Not Living Together	1729/3224 (54%)	30/91 (33%)	10/66 (15%)	22/113 (19%)	18/111 (16%)	206/223 (92%)
Single/Divorced/Widowed	919/3224 (29%)	35/91 (38%)	22/66 (33%)	13/113 (12%)	63/111 (57%)	1/223 (<1%)
Other	9/3224 (<1%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Missing	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Employment status						
Full−time Employment	456/3224 (14%)	37/91 (41%)	4/66 (6%)	13/113 (12%)	4/111 (4%)	3/223 (1%)
Part−time Employment	422/3224 (13%)	9/91 (10%)	5/66 (8%)	22/113 (19%)	3/111 (3%)	11/223 (5%)
Not Employed	2346/3224 (73%)	45/91 (49%)	57/66 (86%)	78/113 (69%)	104/111 (94%)	209/223 (94%)
Missing	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Highest Education						
No Schooling	32/3224 (1%)	0/91 (0%)	0/66 (0%)	2/113 (2%)	0/111 (0%)	0/223 (0%)
Primary School	506/3224 (16%)	2/91 (2%)	33/66 (50%)	52/113 (46%)	49/111 (44%)	2/223 (1%)
Secondary School	2336/3224 (72%)	68/91 (75%)	28/66 (42%)	58/113 (51%)	62/111 (56%)	214/223 (96%)
Technical Training	89/3224 (3%)	7/91 (8%)	1/66 (2%)	0/113 (0%)	0/111 (0%)	2/223 (1%)
College/University or Higher	261/3224 (8%)	14/91 (15%)	4/66 (6%)	1/113 (1%)	0/111 (0%)	5/223 (2%)
Missing	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_demog_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
SMC Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 5 − Baseline Demographics 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
BMI(Kg/m^2)						
Low − 18.5: Underweight	116/3224 (4%)	6/91 (7%)	1/66 (2%)	2/113 (2%)	5/111 (5%)	7/223 (3%)
18.6 − 24.9: Normal	1328/3224 (41%)	40/91 (44%)	39/66 (59%)	56/113 (50%)	70/111 (63%)	76/223 (34%)
25.0 − 29.9: Overweight	885/3224 (27%)	21/91 (23%)	17/66 (26%)	31/113 (27%)	20/111 (18%)	48/223 (22%)
30.0 − High: Obese	895/3224 (28%)	24/91 (26%)	9/66 (14%)	24/113 (21%)	16/111 (14%)	92/223 (41%)
Missing	0/3224 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_demog_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

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

	South Africa: Cape Town: Emavundleni CRS	South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	South Africa: Johannessburg: 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
Age (years)						
18−25	198/223 (89%)	125/159 (79%)	146/206 (71%)	123/170 (72%)	88/151 (58%)	114/176 (65%)
26−35	21/223 (9%)	30/159 (19%)	52/206 (25%)	36/170 (21%)	51/151 (34%)	53/176 (30%)
36−45	4/223 (2%)	4/159 (3%)	8/206 (4%)	11/170 (6%)	12/151 (8%)	9/176 (5%)
Missing	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Mean (SD)	22.1 (3.9)	23.2 (4.5)	24.1 (4.7)	24.4 (4.8)	26.0 (6.0)	24.9 (5.2)
Median	21.0	22.0	23.0	23.0	25.0	24.0
Min, Max	18, 43	18, 44	18, 42	18, 42	18, 44	18, 43
Voice Risk Score at Screening						
0	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
1	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
2	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	2/151 (1%)	0/176 (0%)
3	6/223 (3%)	11/159 (7%)	6/206 (3%)	3/170 (2%)	10/151 (7%)	16/176 (9%)
4	3/223 (1%)	5/159 (3%)	25/206 (12%)	4/170 (2%)	14/151 (9%)	20/176 (11%)
5	32/223 (14%)	24/159 (15%)	44/206 (21%)	34/170 (20%)	35/151 (23%)	47/176 (27%)
6	35/223 (16%)	29/159 (18%)	54/206 (26%)	42/170 (25%)	37/151 (25%)	32/176 (18%)
7	61/223 (27%)	40/159 (25%)	49/206 (24%)	59/170 (35%)	30/151 (20%)	34/176 (19%)
8	86/223 (39%)	50/159 (31%)	28/206 (14%)	28/170 (16%)	23/151 (15%)	27/176 (15%)
9	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Missing	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Median (Q1,Q3)	7.0 (6,8)	7.0 (5,8)	6.0 (5,7)	7.0 (6,7)	6.0 (5,7)	6.0 (5,7)
Race/Ethnicity						
African	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Asian	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Black	223/223 (100%)	149/159 (94%)	206/206 (100%)	170/170 (100%)	149/151 (99%)	175/176 (99%)
Chewa	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Chinese, Indian or other Asian	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Colored/Mixed	0/223 (0%)	9/159 (6%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	1/176 (1%)
Indian	0/223 (0%)	1/159 (1%)	0/206 (0%)	0/170 (0%)	2/151 (1%)	0/176 (0%)
Kalenjin	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_demog_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

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

	South Africa: Cape Town: Emavundleni CRS	South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	South Africa: Johannessburg: Ward 21	South Africa: Kwa Zulu Natal: Isipingo CRS	South Africa: Kwa Zulu Natal: Verulam CRS	South Africa: Soweto: Soweto HPTN CRS
Kamba	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Kikuyu	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Kisii	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Lomwe	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Luhya	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Luo	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Ndebele	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Ngoni	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Originating from Europe, the Middle East or North Africa	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Other African Tribe	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Shona	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Tumbuka	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
White	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Yao	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Other	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Missing	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Marital Status						
Married/Civil Union/Legal Partnership	1/223 (<1%)	6/159 (4%)	1/206 (<1%)	1/170 (1%)	3/151 (2%)	1/176 (1%)
Living with Primary or Main Partner	4/223 (2%)	6/159 (4%)	13/206 (6%)	3/170 (2%)	14/151 (9%)	9/176 (5%)
Have Primary or Main Partner, Not Living Together	184/223 (83%)	110/159 (69%)	185/206 (90%)	154/170 (91%)	118/151 (78%)	131/176 (74%)
Single/Divorced/Widowed	34/223 (15%)	37/159 (23%)	7/206 (3%)	11/170 (6%)	16/151 (11%)	34/176 (19%)
Other	0/223 (0%)	0/159 (0%)	0/206 (0%)	1/170 (1%)	0/151 (0%)	1/176 (1%)
Missing	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Employment status						
Full−time Employment	4/223 (2%)	8/159 (5%)	14/206 (7%)	4/170 (2%)	9/151 (6%)	13/176 (7%)
Part−time Employment	7/223 (3%)	11/159 (7%)	26/206 (13%)	5/170 (3%)	19/151 (13%)	9/176 (5%)
Not Employed	212/223 (95%)	140/159 (88%)	166/206 (81%)	161/170 (95%)	123/151 (81%)	154/176 (88%)
Missing	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Highest Education						
No Schooling	1/223 (<1%)	1/159 (1%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Primary School	0/223 (0%)	1/159 (1%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
Secondary School	187/223 (84%)	124/159 (78%)	140/206 (68%)	142/170 (84%)	121/151 (80%)	136/176 (77%)
Technical Training	7/223 (3%)	7/159 (4%)	12/206 (6%)	9/170 (5%)	16/151 (11%)	3/176 (2%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_demog_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

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

	South Africa: Cape Town: Emavundleni CRS	South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	South Africa: Johannessburg: Ward 21	South Africa: Kwa Zulu Natal: Isipingo CRS	South Africa: Kwa Zulu Natal: Verulam CRS	South Africa: Soweto: Soweto HPTN CRS
College/University or Higher	28/223 (13%)	26/159 (16%)	54/206 (26%)	19/170 (11%)	14/151 (9%)	37/176 (21%)
Missing	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)
BMI(Kg/m^2)						
Low − 18.5: Underweight	10/223 (4%)	6/159 (4%)	7/206 (3%)	4/170 (2%)	2/151 (1%)	9/176 (5%)
18.6 − 24.9: Normal	71/223 (32%)	54/159 (34%)	68/206 (33%)	65/170 (38%)	48/151 (32%)	53/176 (30%)
25.0 − 29.9: Overweight	51/223 (23%)	51/159 (32%)	62/206 (30%)	38/170 (22%)	32/151 (21%)	49/176 (28%)
30.0 − High: Obese	91/223 (41%)	48/159 (30%)	69/206 (33%)	63/170 (37%)	69/151 (46%)	65/176 (37%)
Missing	0/223 (0%)	0/159 (0%)	0/206 (0%)	0/170 (0%)	0/151 (0%)	0/176 (0%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_demog_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

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

	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
Age (years)						
18−25	99/160 (62%)	121/182 (66%)	93/210 (44%)	92/204 (45%)	81/160 (51%)	81/166 (49%)
26−35	54/160 (34%)	44/182 (24%)	90/210 (43%)	87/204 (43%)	77/160 (48%)	73/166 (44%)
36−45	7/160 (4%)	17/182 (9%)	27/210 (13%)	25/204 (12%)	2/160 (1%)	12/166 (7%)
Missing	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Mean (SD)	25.2 (4.9)	25.8 (6.0)	27.9 (6.3)	27.1 (5.8)	25.6 (3.7)	26.8 (5.2)
Median	24.0	24.0	27.0	27.0	25.0	26.0
Min, Max	18, 43	18, 44	18, 44	18, 44	18, 36	19, 42
Voice Risk Score at Screening						
0	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
1	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
2	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
3	19/160 (12%)	10/182 (5%)	3/210 (1%)	15/204 (7%)	3/160 (2%)	8/166 (5%)
4	22/160 (14%)	21/182 (12%)	15/210 (7%)	18/204 (9%)	18/160 (11%)	12/166 (7%)
5	33/160 (21%)	25/182 (14%)	52/210 (25%)	47/204 (23%)	48/160 (30%)	40/166 (24%)
6	32/160 (20%)	54/182 (30%)	76/210 (36%)	58/204 (28%)	47/160 (29%)	48/166 (29%)
7	28/160 (18%)	27/182 (15%)	25/210 (12%)	28/204 (14%)	28/160 (18%)	25/166 (15%)
8	26/160 (16%)	45/182 (25%)	39/210 (19%)	38/204 (19%)	16/160 (10%)	33/166 (20%)
9	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Missing	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Median (Q1,Q3)	6.0 (4,7)	6.0 (5,7)	6.0 (5,7)	6.0 (5,7)	6.0 (5,7)	6.0 (5,7)
Race/Ethnicity						
African	160/160 (100%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Asian	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Black	0/160 (0%)	182/182 (100%)	210/210 (100%)	204/204 (100%)	0/160 (0%)	0/166 (0%)
Chewa	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Chinese, Indian or other Asian	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Colored/Mixed	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Indian	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Kalenjin	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Kamba	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_demog_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

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

	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
Kikuyu	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Kisii	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Lomwe	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Luhya	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Luo	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Ndebele	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	1/160 (1%)	1/166 (1%)
Ngoni	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Originating from Europe, the Middle East or North Africa	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Other African Tribe	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Shona	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	159/160 (99%)	164/166 (99%)
Tumbuka	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
White	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Yao	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Other	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	1/166 (1%)
Missing	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Marital Status						
Married/Civil Union/Legal Partnership	16/160 (10%)	13/182 (7%)	1/210 (<1%)	11/204 (5%)	2/160 (1%)	4/166 (2%)
Living with Primary or Main Partner	9/160 (6%)	36/182 (20%)	6/210 (3%)	21/204 (10%)	1/160 (1%)	9/166 (5%)
Have Primary or Main Partner, Not Living Together	131/160 (82%)	78/182 (43%)	99/210 (47%)	39/204 (19%)	92/160 (58%)	63/166 (38%)
Single/Divorced/Widowed	3/160 (2%)	54/182 (30%)	104/210 (50%)	133/204 (65%)	65/160 (41%)	90/166 (54%)
Other	1/160 (1%)	1/182 (1%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Missing	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Employment status						
Full−time Employment	22/160 (14%)	128/182 (70%)	111/210 (53%)	59/204 (29%)	0/160 (0%)	3/166 (2%)
Part−time Employment	17/160 (11%)	9/182 (5%)	94/210 (45%)	61/204 (30%)	4/160 (3%)	24/166 (14%)
Not Employed	121/160 (76%)	45/182 (25%)	5/210 (2%)	84/204 (41%)	156/160 (98%)	139/166 (84%)
Missing	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Highest Education						
No Schooling	0/160 (0%)	13/182 (7%)	10/210 (5%)	5/204 (2%)	0/160 (0%)	0/166 (0%)
Primary School	9/160 (6%)	91/182 (50%)	97/210 (46%)	96/204 (47%)	17/160 (11%)	20/166 (12%)
Secondary School	92/160 (58%)	71/182 (39%)	97/210 (46%)	99/204 (49%)	141/160 (88%)	145/166 (87%)
Technical Training	10/160 (6%)	5/182 (3%)	3/210 (1%)	2/204 (1%)	2/160 (1%)	1/166 (1%)
College/University or Higher	49/160 (31%)	2/182 (1%)	3/210 (1%)	2/204 (1%)	0/160 (0%)	0/166 (0%)
Missing	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_demog_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

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

	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
BMI(Kg/m^2)						
Low − 18.5: Underweight	5/160 (3%)	3/182 (2%)	3/210 (1%)	6/204 (3%)	9/160 (6%)	6/166 (4%)
18.6 − 24.9: Normal	69/160 (43%)	72/182 (40%)	94/210 (45%)	97/204 (48%)	76/160 (48%)	67/166 (40%)
25.0 − 29.9: Overweight	48/160 (30%)	63/182 (35%)	69/210 (33%)	56/204 (27%)	55/160 (34%)	51/166 (31%)
30.0 − High: Obese	38/160 (24%)	44/182 (24%)	44/210 (21%)	45/204 (22%)	20/160 (13%)	42/166 (25%)
Missing	0/160 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_demog_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

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

	Zimbabwe: Chitungwiza: Zengeza CRS	Zimbabwe: Harare: Parirenyatwa CRS	Zimbabwe: Harare: Spilhaus CRS
Total Participants Enrolled [1]	162	153	138
Age (years)			
18−25	61/162 (38%)	41/153 (27%)	77/138 (56%)
26−35	90/162 (56%)	72/153 (47%)	40/138 (29%)
36−45	11/162 (7%)	40/153 (26%)	21/138 (15%)
Missing	0/162 (0%)	0/153 (0%)	0/138 (0%)
Mean (SD)	27.7 (5.3)	30.9 (6.5)	27.4 (6.6)
Median	27.0	31.0	25.0
Min, Max	18, 41	19, 45	18, 43
Voice Risk Score at Screening			
0	0/162 (0%)	0/153 (0%)	0/138 (0%)
1	0/162 (0%)	0/153 (0%)	0/138 (0%)
2	0/162 (0%)	0/153 (0%)	19/138 (14%)
3	24/162 (15%)	60/153 (39%)	15/138 (11%)
4	29/162 (18%)	26/153 (17%)	26/138 (19%)
5	50/162 (31%)	42/153 (27%)	27/138 (20%)
6	33/162 (20%)	14/153 (9%)	20/138 (14%)
7	19/162 (12%)	8/153 (5%)	22/138 (16%)
8	7/162 (4%)	3/153 (2%)	9/138 (7%)
9	0/162 (0%)	0/153 (0%)	0/138 (0%)
Missing	0/162 (0%)	0/153 (0%)	0/138 (0%)
Median (Q1,Q3)	5.0 (4,6)	4.0 (3,5)	5.0 (4,6)
Race/Ethnicity			
African	0/162 (0%)	0/153 (0%)	0/138 (0%)
Asian	0/162 (0%)	0/153 (0%)	0/138 (0%)
Black	0/162 (0%)	0/153 (0%)	0/138 (0%)
Chewa	0/162 (0%)	0/153 (0%)	0/138 (0%)
Chinese, Indian or other Asian	0/162 (0%)	0/153 (0%)	0/138 (0%)
Colored/Mixed	0/162 (0%)	0/153 (0%)	0/138 (0%)
Indian	0/162 (0%)	0/153 (0%)	0/138 (0%)
Kalenjin	0/162 (0%)	0/153 (0%)	0/138 (0%)
Kamba	0/162 (0%)	0/153 (0%)	0/138 (0%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_demog_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

Table 5 − Baseline Demographics by Site

	Zimbabwe: Chitungwiza: Zengeza CRS	Zimbabwe: Harare: Parirenyatwa CRS	Zimbabwe: Harare: Spilhaus CRS
Kikuyu	0/162 (0%)	0/153 (0%)	0/138 (0%)
Kisii	0/162 (0%)	0/153 (0%)	0/138 (0%)
Lomwe	0/162 (0%)	0/153 (0%)	0/138 (0%)
Luhya	0/162 (0%)	0/153 (0%)	0/138 (0%)
Luo	0/162 (0%)	0/153 (0%)	0/138 (0%)
Ndebele	5/162 (3%)	1/153 (1%)	1/138 (1%)
Ngoni	0/162 (0%)	0/153 (0%)	0/138 (0%)
Originating from Europe, the Middle East or North Africa	0/162 (0%)	0/153 (0%)	0/138 (0%)
Other African Tribe	2/162 (1%)	1/153 (1%)	1/138 (1%)
Shona	151/162 (93%)	151/153 (99%)	136/138 (99%)
Tumbuka	0/162 (0%)	0/153 (0%)	0/138 (0%)
White	0/162 (0%)	0/153 (0%)	0/138 (0%)
Yao	0/162 (0%)	0/153 (0%)	0/138 (0%)
Other	4/162 (2%)	0/153 (0%)	0/138 (0%)
Missing	0/162 (0%)	0/153 (0%)	0/138 (0%)
Marital Status			
Married/Civil Union/Legal Partnership	43/162 (27%)	70/153 (46%)	50/138 (36%)
Living with Primary or Main Partner	1/162 (1%)	15/153 (10%)	13/138 (9%)
Have Primary or Main Partner, Not Living Together	7/162 (4%)	34/153 (22%)	18/138 (13%)
Single/Divorced/Widowed	111/162 (69%)	29/153 (19%)	57/138 (41%)
Other	0/162 (0%)	5/153 (3%)	0/138 (0%)
Missing	0/162 (0%)	0/153 (0%)	0/138 (0%)
Employment status			
Full−time Employment	6/162 (4%)	6/153 (4%)	8/138 (6%)
Part−time Employment	36/162 (22%)	15/153 (10%)	35/138 (25%)
Not Employed	120/162 (74%)	132/153 (86%)	95/138 (69%)
Missing	0/162 (0%)	0/153 (0%)	0/138 (0%)
Highest Education			
No Schooling	0/162 (0%)	0/153 (0%)	0/138 (0%)
Primary School	6/162 (4%)	18/153 (12%)	13/138 (9%)
Secondary School	153/162 (94%)	134/153 (88%)	124/138 (90%)
Technical Training	1/162 (1%)	1/153 (1%)	0/138 (0%)
College/University or Higher	2/162 (1%)	0/153 (0%)	1/138 (1%)
Missing	0/162 (0%)	0/153 (0%)	0/138 (0%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_demog_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

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

	Zimbabwe: Chitungwiza: Zengeza CRS	Zimbabwe: Harare: Parirenyatwa CRS	Zimbabwe: Harare: Spilhaus CRS
BMI(Kg/m^2)			
Low − 18.5: Underweight	10/162 (6%)	4/153 (3%)	11/138 (8%)
18.6 − 24.9: Normal	82/162 (51%)	58/153 (38%)	73/138 (53%)
25.0 − 29.9: Overweight	43/162 (27%)	46/153 (30%)	34/138 (25%)
30.0 − High: Obese	27/162 (17%)	45/153 (29%)	20/138 (14%)
Missing	0/162 (0%)	0/153 (0%)	0/138 (0%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_demog_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 6 − Baseline Sex Behavior 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 completed CASI at baseline[2]	3211	91	66	113	111	223
During the past month the participant had:						
a primary partner						
Missing	2/3211 (<1%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Yes	2559/3211 (80%)	74/91 (81%)	55/66 (83%)	109/113 (96%)	82/111 (74%)	185/223 (83%)
No	598/3211 (19%)	14/91 (15%)	10/66 (15%)	4/113 (4%)	29/111 (26%)	25/223 (11%)
Prefer not to answer	52/3211 (2%)	3/91 (3%)	1/66 (2%)	0/113 (0%)	0/111 (0%)	13/223 (6%)
a primary partner who is reported to be HIV positive or unknown						
Missing	2/3211 (<1%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Yes	1100/3211 (34%)	44/91 (48%)	30/66 (45%)	32/113 (28%)	46/111 (41%)	93/223 (42%)
No	2018/3211 (63%)	43/91 (47%)	35/66 (53%)	81/113 (72%)	64/111 (58%)	107/223 (48%)
Prefer not to answer	91/3211 (3%)	4/91 (4%)	1/66 (2%)	0/113 (0%)	1/111 (1%)	23/223 (10%)
transactional sex with a man						
Missing	2/3211 (<1%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Yes	1313/3211 (41%)	22/91 (24%)	40/66 (61%)	9/113 (8%)	62/111 (56%)	22/223 (10%)
No	1845/3211 (57%)	67/91 (74%)	26/66 (39%)	104/113 (92%)	48/111 (43%)	184/223 (83%)
Prefer not to answer	51/3211 (2%)	2/91 (2%)	0/66 (0%)	0/113 (0%)	1/111 (1%)	17/223 (8%)
# male sex partners						
Missing	2/3211 (<1%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Don't Know	0/3211 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Prefer not to answer	278/3211 (9%)	15/91 (16%)	14/66 (21%)	0/113 (0%)	7/111 (6%)	55/223 (25%)
0	82/3211 (3%)	4/91 (4%)	2/66 (3%)	2/113 (2%)	0/111 (0%)	5/223 (2%)
1	1094/3211 (34%)	32/91 (35%)	15/66 (23%)	98/113 (87%)	29/111 (26%)	52/223 (23%)
2−3	969/3211 (30%)	36/91 (40%)	20/66 (30%)	7/113 (6%)	50/111 (45%)	108/223 (48%)
4+	786/3211 (24%)	4/91 (4%)	15/66 (23%)	6/113 (5%)	25/111 (23%)	3/223 (1%)
# male sex partners who are reported to be HIV positive						
Missing	2/3211 (<1%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Don't Know	643/3211 (20%)	13/91 (14%)	7/66 (11%)	16/113 (14%)	39/111 (35%)	11/223 (5%)
Prefer not to answer	622/3211 (19%)	26/91 (29%)	32/66 (48%)	2/113 (2%)	20/111 (18%)	104/223 (47%)
0	1568/3211 (49%)	26/91 (29%)	20/66 (30%)	80/113 (71%)	45/111 (41%)	68/223 (30%)
1	270/3211 (8%)	24/91 (26%)	4/66 (6%)	14/113 (12%)	5/111 (5%)	32/223 (14%)
2+	106/3211 (3%)	2/91 (2%)	3/66 (5%)	1/113 (1%)	2/111 (2%)	8/223 (4%)

[1] Inappropriately enrolled participants are excluded.
[2] Incomplete CASI at baseline means the file was lost and cannot be recovered.
Source: SCHARP (Gordon) − /trials/hptn/p084/analysis/atlas/code/open/t_blsexbh_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 6 − Baseline Sex Behavior 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
During the past month the participant had:						
# episodes of vaginal sex (median (Q1, Q3))	7 (4,15)	5 (3,11)	6 (4,14)	8 (4,12)	5 (3,10)	3 (2,6)
# episodes of vaginal sex without condom (median (Q1, Q3))	3 (1,6)	2 (0,4)	3 (1,6)	5 (2,10)	3 (1,6)	2 (1,3)
# episodes of vaginal sex without condom, with HIV+ or unknown partner						
Missing	2/3211 (<1%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Don't Know	426/3211 (13%)	5/91 (5%)	13/66 (20%)	2/113 (2%)	10/111 (9%)	21/223 (9%)
Prefer not to answer	615/3211 (19%)	32/91 (35%)	25/66 (38%)	1/113 (1%)	19/111 (17%)	112/223 (50%)
0	1414/3211 (44%)	39/91 (43%)	15/66 (23%)	93/113 (82%)	34/111 (31%)	42/223 (19%)
1	223/3211 (7%)	5/91 (5%)	5/66 (8%)	2/113 (2%)	12/111 (11%)	23/223 (10%)
2+	531/3211 (17%)	10/91 (11%)	8/66 (12%)	15/113 (13%)	36/111 (32%)	25/223 (11%)
# episodes of anal sex						
Missing	2/3211 (<1%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Don't Know	0/3211 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Prefer not to answer	264/3211 (8%)	14/91 (15%)	18/66 (27%)	0/113 (0%)	7/111 (6%)	73/223 (33%)
0	2760/3211 (86%)	74/91 (81%)	39/66 (59%)	111/113 (98%)	99/111 (89%)	127/223 (57%)
1	62/3211 (2%)	1/91 (1%)	4/66 (6%)	0/113 (0%)	2/111 (2%)	10/223 (4%)
2+	123/3211 (4%)	2/91 (2%)	5/66 (8%)	2/113 (2%)	3/111 (3%)	13/223 (6%)
# episodes of anal sex without condom						
Missing	2/3211 (<1%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Don't Know	0/3211 (0%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Prefer not to answer	276/3211 (9%)	15/91 (16%)	18/66 (27%)	0/113 (0%)	7/111 (6%)	77/223 (35%)
0	2789/3211 (87%)	74/91 (81%)	40/66 (61%)	113/113 (100%)	100/111 (90%)	129/223 (58%)
1	56/3211 (2%)	1/91 (1%)	3/66 (5%)	0/113 (0%)	1/111 (1%)	10/223 (4%)
2+	88/3211 (3%)	1/91 (1%)	5/66 (8%)	0/113 (0%)	3/111 (3%)	7/223 (3%)
# episodes of anal sex without condom, with HIV+ or unknown partner						
Missing	2/3211 (<1%)	0/91 (0%)	0/66 (0%)	0/113 (0%)	0/111 (0%)	0/223 (0%)
Don't Know	23/3211 (1%)	0/91 (0%)	1/66 (2%)	0/113 (0%)	0/111 (0%)	3/223 (1%)
Prefer not to answer	293/3211 (9%)	15/91 (16%)	20/66 (30%)	0/113 (0%)	8/111 (7%)	78/223 (35%)
0	2822/3211 (88%)	75/91 (82%)	42/66 (64%)	113/113 (100%)	100/111 (90%)	132/223 (59%)
1	36/3211 (1%)	1/91 (1%)	0/66 (0%)	0/113 (0%)	1/111 (1%)	7/223 (3%)
2+	35/3211 (1%)	0/91 (0%)	3/66 (5%)	0/113 (0%)	2/111 (2%)	3/223 (1%)

[1] Inappropriately enrolled participants are excluded.
[2] Incomplete CASI at baseline means the file was lost and cannot be recovered.
Source: SCHARP (Gordon) − /trials/hptn/p084/analysis/atlas/code/open/t_blsexbh_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 6 − Baseline Sex Behavior by Site

	South Africa: Cape Town: Emavundleni CRS	South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	South Africa: Johannessburg: 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 completed CASI at baseline[2]	223	150	206	169	150	176
During the past month the participant had:						
a primary partner						
Missing	0/223 (0%)	1/150 (1%)	0/206 (0%)	0/169 (0%)	0/150 (0%)	0/176 (0%)
Yes	195/223 (87%)	114/150 (76%)	189/206 (92%)	162/169 (96%)	146/150 (97%)	152/176 (86%)
No	21/223 (9%)	26/150 (17%)	13/206 (6%)	6/169 (4%)	4/150 (3%)	20/176 (11%)
Prefer not to answer	7/223 (3%)	9/150 (6%)	4/206 (2%)	1/169 (1%)	0/150 (0%)	4/176 (2%)
a primary partner who is reported to be HIV positive or unknown						
Missing	0/223 (0%)	1/150 (1%)	0/206 (0%)	0/169 (0%)	0/150 (0%)	0/176 (0%)
Yes	62/223 (28%)	44/150 (29%)	66/206 (32%)	73/169 (43%)	31/150 (21%)	66/176 (38%)
No	153/223 (69%)	95/150 (63%)	136/206 (66%)	95/169 (56%)	119/150 (79%)	102/176 (58%)
Prefer not to answer	8/223 (4%)	10/150 (7%)	4/206 (2%)	1/169 (1%)	0/150 (0%)	8/176 (5%)
transactional sex with a man						
Missing	0/223 (0%)	1/150 (1%)	0/206 (0%)	0/169 (0%)	0/150 (0%)	0/176 (0%)
Yes	23/223 (10%)	13/150 (9%)	43/206 (21%)	4/169 (2%)	2/150 (1%)	82/176 (47%)
No	200/223 (90%)	135/150 (90%)	161/206 (78%)	164/169 (97%)	147/150 (98%)	89/176 (51%)
Prefer not to answer	0/223 (0%)	1/150 (1%)	2/206 (1%)	1/169 (1%)	1/150 (1%)	5/176 (3%)
# male sex partners						
Missing	0/223 (0%)	1/150 (1%)	0/206 (0%)	0/169 (0%)	0/150 (0%)	0/176 (0%)
Don't Know	0/223 (0%)	0/150 (0%)	0/206 (0%)	0/169 (0%)	0/150 (0%)	0/176 (0%)
Prefer not to answer	14/223 (6%)	15/150 (10%)	6/206 (3%)	2/169 (1%)	1/150 (1%)	10/176 (6%)
0	8/223 (4%)	8/150 (5%)	4/206 (2%)	4/169 (2%)	1/150 (1%)	1/176 (1%)
1	128/223 (57%)	102/150 (68%)	80/206 (39%)	103/169 (61%)	118/150 (79%)	21/176 (12%)
2−3	71/223 (32%)	21/150 (14%)	106/206 (51%)	58/169 (34%)	29/150 (19%)	86/176 (49%)
4+	2/223 (1%)	3/150 (2%)	10/206 (5%)	2/169 (1%)	1/150 (1%)	58/176 (33%)
# male sex partners who are reported to be HIV positive						
Missing	0/223 (0%)	1/150 (1%)	0/206 (0%)	0/169 (0%)	0/150 (0%)	0/176 (0%)
Don't Know	28/223 (13%)	18/150 (12%)	28/206 (14%)	49/169 (29%)	12/150 (8%)	28/176 (16%)
Prefer not to answer	31/223 (14%)	32/150 (21%)	38/206 (18%)	6/169 (4%)	4/150 (3%)	35/176 (20%)
0	142/223 (64%)	84/150 (56%)	120/206 (58%)	108/169 (64%)	131/150 (87%)	93/176 (53%)
1	18/223 (8%)	11/150 (7%)	13/206 (6%)	5/169 (3%)	2/150 (1%)	9/176 (5%)
2+	4/223 (2%)	4/150 (3%)	7/206 (3%)	1/169 (1%)	1/150 (1%)	11/176 (6%)

[1] Inappropriately enrolled participants are excluded.
[2] Incomplete CASI at baseline means the file was lost and cannot be recovered.
Source: SCHARP (Gordon) − /trials/hptn/p084/analysis/atlas/code/open/t_blsexbh_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 6 − Baseline Sex Behavior by Site

	South Africa: Cape Town: Emavundleni CRS	South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	South Africa: Johannessburg: Ward 21	South Africa: Kwa Zulu Natal: Isipingo CRS	South Africa: Kwa Zulu Natal: Verulam CRS	South Africa: Soweto: Soweto HPTN CRS
During the past month the participant had:						
# episodes of vaginal sex (median (Q1, Q3))	5 (3,8)	4 (3,5)	8 (5,12)	4 (2,6)	4 (3,7)	8 (5,13)
# episodes of vaginal sex without condom (median (Q1, Q3))	2 (1,3)	2 (1,3)	3 (1,6)	2 (0,4)	2 (0,4)	4 (2,8)
# episodes of vaginal sex without condom, with HIV+ or unknown partner						
Missing	0/223 (0%)	1/150 (1%)	0/206 (0%)	0/169 (0%)	0/150 (0%)	0/176 (0%)
Don't Know	20/223 (9%)	10/150 (7%)	40/206 (19%)	9/169 (5%)	5/150 (3%)	43/176 (24%)
Prefer not to answer	38/223 (17%)	50/150 (33%)	50/206 (24%)	3/169 (2%)	5/150 (3%)	39/176 (22%)
0	134/223 (60%)	72/150 (48%)	79/206 (38%)	108/169 (64%)	120/150 (80%)	58/176 (33%)
1	15/223 (7%)	9/150 (6%)	19/206 (9%)	15/169 (9%)	7/150 (5%)	14/176 (8%)
2+	16/223 (7%)	8/150 (5%)	18/206 (9%)	34/169 (20%)	13/150 (9%)	22/176 (13%)
# episodes of anal sex						
Missing	0/223 (0%)	1/150 (1%)	0/206 (0%)	0/169 (0%)	0/150 (0%)	0/176 (0%)
Don't Know	0/223 (0%)	0/150 (0%)	0/206 (0%)	0/169 (0%)	0/150 (0%)	0/176 (0%)
Prefer not to answer	12/223 (5%)	17/150 (11%)	14/206 (7%)	1/169 (1%)	3/150 (2%)	15/176 (9%)
0	201/223 (90%)	127/150 (85%)	168/206 (82%)	162/169 (96%)	147/150 (98%)	138/176 (78%)
1	5/223 (2%)	4/150 (3%)	10/206 (5%)	1/169 (1%)	0/150 (0%)	11/176 (6%)
2+	5/223 (2%)	1/150 (1%)	14/206 (7%)	5/169 (3%)	0/150 (0%)	12/176 (7%)
# episodes of anal sex without condom						
Missing	0/223 (0%)	1/150 (1%)	0/206 (0%)	0/169 (0%)	0/150 (0%)	0/176 (0%)
Don't Know	0/223 (0%)	0/150 (0%)	0/206 (0%)	0/169 (0%)	0/150 (0%)	0/176 (0%)
Prefer not to answer	12/223 (5%)	17/150 (11%)	14/206 (7%)	1/169 (1%)	3/150 (2%)	16/176 (9%)
0	205/223 (92%)	127/150 (85%)	175/206 (85%)	163/169 (96%)	147/150 (98%)	142/176 (81%)
1	4/223 (2%)	4/150 (3%)	9/206 (4%)	2/169 (1%)	0/150 (0%)	8/176 (5%)
2+	2/223 (1%)	1/150 (1%)	8/206 (4%)	3/169 (2%)	0/150 (0%)	10/176 (6%)
# episodes of anal sex without condom, with HIV+ or unknown partner						
Missing	0/223 (0%)	1/150 (1%)	0/206 (0%)	0/169 (0%)	0/150 (0%)	0/176 (0%)
Don't Know	1/223 (<1%)	0/150 (0%)	4/206 (2%)	1/169 (1%)	0/150 (0%)	1/176 (1%)
Prefer not to answer	13/223 (6%)	18/150 (12%)	16/206 (8%)	1/169 (1%)	3/150 (2%)	19/176 (11%)
0	205/223 (92%)	129/150 (86%)	182/206 (88%)	165/169 (98%)	147/150 (98%)	148/176 (84%)
1	3/223 (1%)	1/150 (1%)	3/206 (1%)	2/169 (1%)	0/150 (0%)	6/176 (3%)
2+	1/223 (<1%)	1/150 (1%)	1/206 (<1%)	0/169 (0%)	0/150 (0%)	2/176 (1%)

[1] Inappropriately enrolled participants are excluded.
[2] Incomplete CASI at baseline means the file was lost and cannot be recovered.
Source: SCHARP (Gordon) − /trials/hptn/p084/analysis/atlas/code/open/t_blsexbh_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 6 − Baseline Sex Behavior by Site

	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 completed CASI at baseline[2]	159	182	210	204	160	166
During the past month the participant had:						
a primary partner						
Missing	0/159 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Yes	149/159 (94%)	144/182 (79%)	83/210 (40%)	133/204 (65%)	107/160 (67%)	109/166 (66%)
No	8/159 (5%)	38/182 (21%)	126/210 (60%)	71/204 (35%)	51/160 (32%)	55/166 (33%)
Prefer not to answer	2/159 (1%)	0/182 (0%)	1/210 (<1%)	0/204 (0%)	2/160 (1%)	2/166 (1%)
a primary partner who is reported to be HIV positive or unknown						
Missing	0/159 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Yes	49/159 (31%)	71/182 (39%)	35/210 (17%)	60/204 (29%)	53/160 (33%)	54/166 (33%)
No	102/159 (64%)	111/182 (61%)	174/210 (83%)	142/204 (70%)	104/160 (65%)	107/166 (64%)
Prefer not to answer	8/159 (5%)	0/182 (0%)	1/210 (<1%)	2/204 (1%)	3/160 (2%)	5/166 (3%)
transactional sex with a man						
Missing	0/159 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Yes	11/159 (7%)	122/182 (67%)	198/210 (94%)	159/204 (78%)	130/160 (81%)	136/166 (82%)
No	145/159 (91%)	59/182 (32%)	10/210 (5%)	42/204 (21%)	29/160 (18%)	27/166 (16%)
Prefer not to answer	3/159 (2%)	1/182 (1%)	2/210 (1%)	3/204 (1%)	1/160 (1%)	3/166 (2%)
# male sex partners						
Missing	0/159 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Don't Know	0/159 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Prefer not to answer	21/159 (13%)	2/182 (1%)	14/210 (7%)	8/204 (4%)	25/160 (16%)	29/166 (17%)
0	3/159 (2%)	2/182 (1%)	8/210 (4%)	3/204 (1%)	4/160 (3%)	5/166 (3%)
1	106/159 (67%)	30/182 (16%)	0/210 (0%)	15/204 (7%)	4/160 (3%)	13/166 (8%)
2−3	29/159 (18%)	96/182 (53%)	8/210 (4%)	67/204 (33%)	29/160 (18%)	30/166 (18%)
4+	0/159 (0%)	52/182 (29%)	180/210 (86%)	111/204 (54%)	98/160 (61%)	89/166 (54%)
# male sex partners who are reported to be HIV positive						
Missing	0/159 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Don't Know	19/159 (12%)	48/182 (26%)	101/210 (48%)	64/204 (31%)	51/160 (32%)	17/166 (10%)
Prefer not to answer	34/159 (21%)	10/182 (5%)	20/210 (10%)	26/204 (13%)	53/160 (33%)	54/166 (33%)
0	93/159 (58%)	95/182 (52%)	63/210 (30%)	86/204 (42%)	43/160 (27%)	63/166 (38%)
1	12/159 (8%)	17/182 (9%)	16/210 (8%)	16/204 (8%)	7/160 (4%)	24/166 (14%)
2+	1/159 (1%)	12/182 (7%)	10/210 (5%)	12/204 (6%)	6/160 (4%)	8/166 (5%)

[1] Inappropriately enrolled participants are excluded.
[2] Incomplete CASI at baseline means the file was lost and cannot be recovered.
Source: SCHARP (Gordon) − /trials/hptn/p084/analysis/atlas/code/open/t_blsexbh_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 6 − Baseline Sex Behavior by Site

	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
During the past month the participant had:						
# episodes of vaginal sex (median (Q1, Q3))	4 (2,5)	7 (4,15)	15 (6,30)	10 (4,21)	20 (12,40)	17 (8,30)
# episodes of vaginal sex without condom (median (Q1, Q3))	1 (0,3)	4 (2,6)	1 (0,4)	3 (1,8)	6 (3,10)	3 (1,6)
# episodes of vaginal sex without condom, with HIV+ or unknown partner						
Missing	0/159 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Don't Know	6/159 (4%)	45/182 (25%)	16/210 (8%)	46/204 (23%)	38/160 (24%)	32/166 (19%)
Prefer not to answer	31/159 (19%)	8/182 (4%)	11/210 (5%)	20/204 (10%)	36/160 (23%)	39/166 (23%)
0	103/159 (65%)	62/182 (34%)	133/210 (63%)	73/204 (36%)	27/160 (17%)	51/166 (31%)
1	11/159 (7%)	14/182 (8%)	14/210 (7%)	16/204 (8%)	9/160 (6%)	11/166 (7%)
2+	8/159 (5%)	53/182 (29%)	36/210 (17%)	49/204 (24%)	50/160 (31%)	33/166 (20%)
# episodes of anal sex						
Missing	0/159 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Don't Know	0/159 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Prefer not to answer	11/159 (7%)	5/182 (3%)	6/210 (3%)	8/204 (4%)	10/160 (6%)	14/166 (8%)
0	147/159 (92%)	164/182 (90%)	193/210 (92%)	188/204 (92%)	142/160 (89%)	135/166 (81%)
1	1/159 (1%)	0/182 (0%)	0/210 (0%)	2/204 (1%)	3/160 (2%)	2/166 (1%)
2+	0/159 (0%)	13/182 (7%)	11/210 (5%)	6/204 (3%)	5/160 (3%)	15/166 (9%)
# episodes of anal sex without condom						
Missing	0/159 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Don't Know	0/159 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Prefer not to answer	11/159 (7%)	5/182 (3%)	6/210 (3%)	8/204 (4%)	10/160 (6%)	18/166 (11%)
0	147/159 (92%)	164/182 (90%)	194/210 (92%)	189/204 (93%)	143/160 (89%)	135/166 (81%)
1	1/159 (1%)	0/182 (0%)	1/210 (<1%)	3/204 (1%)	3/160 (2%)	3/166 (2%)
2+	0/159 (0%)	13/182 (7%)	9/210 (4%)	4/204 (2%)	4/160 (3%)	10/166 (6%)
# episodes of anal sex without condom, with HIV+ or unknown partner						
Missing	0/159 (0%)	0/182 (0%)	0/210 (0%)	0/204 (0%)	0/160 (0%)	0/166 (0%)
Don't Know	0/159 (0%)	5/182 (3%)	1/210 (<1%)	2/204 (1%)	1/160 (1%)	2/166 (1%)
Prefer not to answer	11/159 (7%)	6/182 (3%)	7/210 (3%)	9/204 (4%)	12/160 (8%)	18/166 (11%)
0	148/159 (93%)	165/182 (91%)	197/210 (94%)	189/204 (93%)	143/160 (89%)	137/166 (83%)
1	0/159 (0%)	0/182 (0%)	1/210 (<1%)	3/204 (1%)	2/160 (1%)	3/166 (2%)
2+	0/159 (0%)	6/182 (3%)	4/210 (2%)	1/204 (<1%)	2/160 (1%)	6/166 (4%)

[1] Inappropriately enrolled participants are excluded.
[2] Incomplete CASI at baseline means the file was lost and cannot be recovered.
Source: SCHARP (Gordon) − /trials/hptn/p084/analysis/atlas/code/open/t_blsexbh_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 6 − Baseline Sex Behavior by Site

	Zimbabwe: Chitungwiza: Zengeza CRS	Zimbabwe: Harare: Parirenyatwa CRS	Zimbabwe: Harare: Spilhaus CRS
Total Participants Enrolled[1]	162	153	138
Participants who completed CASI at baseline[2]	162	152	138
During the past month the participant had:			
a primary partner			
Missing	1/162 (1%)	0/152 (0%)	0/138 (0%)
Yes	129/162 (80%)	124/152 (82%)	118/138 (86%)
No	29/162 (18%)	28/152 (18%)	20/138 (14%)
Prefer not to answer	3/162 (2%)	0/152 (0%)	0/138 (0%)
a primary partner who is reported to be HIV positive or unknown			
Missing	1/162 (1%)	0/152 (0%)	0/138 (0%)
Yes	70/162 (43%)	63/152 (41%)	58/138 (42%)
No	84/162 (52%)	86/152 (57%)	78/138 (57%)
Prefer not to answer	7/162 (4%)	3/152 (2%)	2/138 (1%)
transactional sex with a man			
Missing	1/162 (1%)	0/152 (0%)	0/138 (0%)
Yes	121/162 (75%)	71/152 (47%)	43/138 (31%)
No	37/162 (23%)	79/152 (52%)	92/138 (67%)
Prefer not to answer	3/162 (2%)	2/152 (1%)	3/138 (2%)
# male sex partners			
Missing	1/162 (1%)	0/152 (0%)	0/138 (0%)
Don’t Know	0/162 (0%)	0/152 (0%)	0/138 (0%)
Prefer not to answer	16/162 (10%)	10/152 (7%)	14/138 (10%)
0	6/162 (4%)	9/152 (6%)	3/138 (2%)
1	12/162 (7%)	73/152 (48%)	63/138 (46%)
2−3	66/162 (41%)	22/152 (14%)	30/138 (22%)
4+	61/162 (38%)	38/152 (25%)	28/138 (20%)
# male sex partners who are reported to be HIV positive			
Missing	1/162 (1%)	0/152 (0%)	0/138 (0%)
Don’t Know	29/162 (18%)	37/152 (24%)	28/138 (20%)
Prefer not to answer	47/162 (29%)	22/152 (14%)	26/138 (19%)
0	62/162 (38%)	77/152 (51%)	69/138 (50%)
1	17/162 (10%)	13/152 (9%)	11/138 (8%)
2+	6/162 (4%)	3/152 (2%)	4/138 (3%)

[1] Inappropriately enrolled participants are excluded.
[2] Incomplete CASI at baseline means the file was lost and cannot be recovered.
Source: SCHARP (Gordon) − /trials/hptn/p084/analysis/atlas/code/open/t_blsexbh_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

Table 6 − Baseline Sex Behavior by Site

	Zimbabwe: Chitungwiza: Zengeza CRS	Zimbabwe: Harare: Parirenyatwa CRS	Zimbabwe: Harare: Spilhaus CRS
During the past month the participant had:			
# episodes of vaginal sex (median (Q1, Q3))	15 (7,21)	14 (8,20)	10 (5,20)
# episodes of vaginal sex without condom (median (Q1, Q3))	5 (2,10)	4 (1,10)	4 (2,10)
# episodes of vaginal sex without condom, with HIV+ or unknown partner			
Missing	1/162 (1%)	0/152 (0%)	0/138 (0%)
Don’t Know	32/162 (20%)	16/152 (11%)	17/138 (12%)
Prefer not to answer	48/162 (30%)	20/152 (13%)	28/138 (20%)
0	33/162 (20%)	78/152 (51%)	60/138 (43%)
1	10/162 (6%)	8/152 (5%)	4/138 (3%)
2+	38/162 (23%)	30/152 (20%)	29/138 (21%)
# episodes of anal sex			
Missing	1/162 (1%)	0/152 (0%)	0/138 (0%)
Don’t Know	0/162 (0%)	0/152 (0%)	0/138 (0%)
Prefer not to answer	17/162 (10%)	4/152 (3%)	15/138 (11%)
0	139/162 (86%)	144/152 (95%)	115/138 (83%)
1	1/162 (1%)	1/152 (1%)	4/138 (3%)
2+	4/162 (2%)	3/152 (2%)	4/138 (3%)
# episodes of anal sex without condom			
Missing	1/162 (1%)	0/152 (0%)	0/138 (0%)
Don’t Know	0/162 (0%)	0/152 (0%)	0/138 (0%)
Prefer not to answer	17/162 (10%)	4/152 (3%)	17/138 (12%)
0	140/162 (86%)	146/152 (96%)	116/138 (84%)
1	1/162 (1%)	1/152 (1%)	1/138 (1%)
2+	3/162 (2%)	1/152 (1%)	4/138 (3%)
# episodes of anal sex without condom, with HIV+ or unknown partner			
Missing	1/162 (1%)	0/152 (0%)	0/138 (0%)
Don’t Know	1/162 (1%)	0/152 (0%)	0/138 (0%)
Prefer not to answer	18/162 (11%)	4/152 (3%)	17/138 (12%)
0	140/162 (86%)	146/152 (96%)	119/138 (86%)
1	1/162 (1%)	1/152 (1%)	1/138 (1%)
2+	1/162 (1%)	1/152 (1%)	1/138 (1%)

[1] Inappropriately enrolled participants are excluded.
[2] Incomplete CASI at baseline means the file was lost and cannot be recovered.
Source: SCHARP (Gordon) − /trials/hptn/p084/analysis/atlas/code/open/t_blsexbh_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 7 − Baseline Prevalence of STIs 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
Number of Participants Enrolled[1]	3224	91	66	113	111	223
Number of Participants Tested for Syphilis[2]	3219/3224 (100%)	91/91 (100%)	66/66 (100%)	113/113 (100%)	111/111 (100%)	223/223 (100%)
Number of Participants Tested Positive for Syphilis[3]	107	1	0	11	4	2
Prevalence of Syphilis[4]	107/3219 (3%)	1/91 (1%)	0/66 (0%)	11/113 (10%)	4/111 (4%)	2/223 (1%)
Number of Participants Tested for Gonorrhea[2]	3193/3224 (99%)	91/91 (100%)	66/66 (100%)	113/113 (100%)	110/111 (99%)	223/223 (100%)
Number of Participants Tested Positive for Gonorrhea[3]	210	5	1	7	9	10
Prevalence of Gonorrhea[4]	210/3193 (7%)	5/91 (5%)	1/66 (2%)	7/113 (6%)	9/110 (8%)	10/223 (4%)
Number of Participants Tested for Chlamydia[2]	3193/3224 (99%)	91/91 (100%)	66/66 (100%)	113/113 (100%)	110/111 (99%)	223/223 (100%)
Number of Participants Tested Positive for Chlamydia[3]	604	22	10	6	17	50
Prevalence of Chlamydia[4]	604/3193 (19%)	22/91 (24%)	10/66 (15%)	6/113 (5%)	17/110 (15%)	50/223 (22%)
Number of Participants Tested for Trichomonas[2]	3134/3224 (97%)	91/91 (100%)	58/66 (88%)	110/113 (97%)	111/111 (100%)	220/223 (99%)
Number of Participants Tested Positive for Trichomonas[3]	270	0	0	15	11	8
Prevalence of Trichomonas[4]	270/3134 (9%)	0/91 (0%)	0/58 (0%)	15/110 (14%)	11/111 (10%)	8/220 (4%)

[1] Inappropriately enrolled participants are excluded.
[2] Being tested is defined as having a specimen collected for testing purpose.
[3] Syphilis is positive if either Treponemal or non−Treponemal test showed positive results; Gonorrhea/Chlamydia is positive if either urine or vaginal sample tested positive ; Trichomonas is positive if either rapid test or wet prep tested positive.
[4] Prevalence is calculated as the number of participants with positive results among the number of participants completed the test.

Source: SCHARP (Ting) − /trials/hptn/p084/analysis/atlas/code/open/t_baseline_sti_prevalence_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 7 − Baseline Prevalence of STIs by Site

	South Africa: Cape Town: Emavundleni CRS	South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	South Africa: Johannessburg: Ward 21	South Africa: Kwa Zulu Natal: Isipingo CRS	South Africa: Kwa Zulu Natal: Verulam CRS	South Africa: Soweto: Soweto HPTN CRS
Number of Participants Enrolled[1]	223	159	206	170	151	176
Number of Participants Tested for Syphilis[2]	223/223 (100%)	159/159 (100%)	206/206 (100%)	170/170 (100%)	147/151 (97%)	176/176 (100%)
Number of Participants Tested Positive for Syphilis[3]	5	4	0	4	5	2
Prevalence of Syphilis[4]	5/223 (2%)	4/159 (3%)	0/206 (0%)	4/170 (2%)	5/147 (3%)	2/176 (1%)
Number of Participants Tested for Gonorrhea[2]	222/223 (100%)	159/159 (100%)	206/206 (100%)	167/170 (98%)	135/151 (89%)	176/176 (100%)
Number of Participants Tested Positive for Gonorrhea[3]	35	23	10	7	5	8
Prevalence of Gonorrhea[4]	35/222 (16%)	23/159 (14%)	10/206 (5%)	7/167 (4%)	5/135 (4%)	8/176 (5%)
Number of Participants Tested for Chlamydia[2]	222/223 (100%)	159/159 (100%)	206/206 (100%)	167/170 (98%)	135/151 (89%)	176/176 (100%)
Number of Participants Tested Positive for Chlamydia[3]	73	52	47	26	26	45
Prevalence of Chlamydia[4]	73/222 (33%)	52/159 (33%)	47/206 (23%)	26/167 (16%)	26/135 (19%)	45/176 (26%)
Number of Participants Tested for Trichomonas[2]	223/223 (100%)	159/159 (100%)	206/206 (100%)	166/170 (98%)	134/151 (89%)	176/176 (100%)
Number of Participants Tested Positive for Trichomonas[3]	15	13	7	7	6	10
Prevalence of Trichomonas[4]	15/223 (7%)	13/159 (8%)	7/206 (3%)	7/166 (4%)	6/134 (4%)	10/176 (6%)

[1] Inappropriately enrolled participants are excluded.
[2] Being tested is defined as having a specimen collected for testing purpose.
[3] Syphilis is positive if either Treponemal or non−Treponemal test showed positive results; Gonorrhea/Chlamydia is positive if either urine or vaginal sample tested positive ; Trichomonas is positive if either rapid test or wet prep tested positive.
[4] Prevalence is calculated as the number of participants with positive results among the number of participants completed the test.

Source: SCHARP (Ting) − /trials/hptn/p084/analysis/atlas/code/open/t_baseline_sti_prevalence_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 7 − Baseline Prevalence of STIs by Site

	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
Number of Participants Enrolled[1]	160	182	210	204	160	166
Number of Participants Tested for Syphilis[2]	160/160 (100%)	182/182 (100%)	209/210 (100%)	204/204 (100%)	160/160 (100%)	166/166 (100%)
Number of Participants Tested Positive for Syphilis[3]	6	6	16	10	8	9
Prevalence of Syphilis[4]	6/160 (4%)	6/182 (3%)	16/209 (8%)	10/204 (5%)	8/160 (5%)	9/166 (5%)
Number of Participants Tested for Gonorrhea[2]	150/160 (94%)	182/182 (100%)	210/210 (100%)	204/204 (100%)	160/160 (100%)	166/166 (100%)
Number of Participants Tested Positive for Gonorrhea[3]	8	18	8	10	9	11
Prevalence of Gonorrhea[4]	8/150 (5%)	18/182 (10%)	8/210 (4%)	10/204 (5%)	9/160 (6%)	11/166 (7%)
Number of Participants Tested for Chlamydia[2]	150/160 (94%)	182/182 (100%)	210/210 (100%)	204/204 (100%)	160/160 (100%)	166/166 (100%)
Number of Participants Tested Positive for Chlamydia[3]	25	35	22	32	39	23
Prevalence of Chlamydia[4]	25/150 (17%)	35/182 (19%)	22/210 (10%)	32/204 (16%)	39/160 (24%)	23/166 (14%)
Number of Participants Tested for Trichomonas[2]	153/160 (96%)	165/182 (91%)	189/210 (90%)	202/204 (99%)	160/160 (100%)	164/166 (99%)
Number of Participants Tested Positive for Trichomonas[3]	10	22	11	17	34	18
Prevalence of Trichomonas[4]	10/153 (7%)	22/165 (13%)	11/189 (6%)	17/202 (8%)	34/160 (21%)	18/164 (11%)

[1] Inappropriately enrolled participants are excluded.
[2] Being tested is defined as having a specimen collected for testing purpose.
[3] Syphilis is positive if either Treponemal or non−Treponemal test showed positive results; Gonorrhea/Chlamydia is positive if either urine or vaginal sample tested positive ; Trichomonas is positive if either rapid test or wet prep tested positive.
[4] Prevalence is calculated as the number of participants with positive results among the number of participants completed the test.

Source: SCHARP (Ting) − /trials/hptn/p084/analysis/atlas/code/open/t_baseline_sti_prevalence_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

Table 7 − Baseline Prevalence of STIs by Site

	Zimbabwe: Chitungwiza: Zengeza CRS	Zimbabwe: Harare: Parirenyatwa CRS	Zimbabwe: Harare: Spilhaus CRS
Number of Participants Enrolled[1]	162	153	138
Number of Participants Tested for Syphilis[2]	162/162 (100%)	153/153 (100%)	138/138 (100%)
Number of Participants Tested Positive for Syphilis[3]	6	4	4
Prevalence of Syphilis[4]	6/162 (4%)	4/153 (3%)	4/138 (3%)
Number of Participants Tested for Gonorrhea[2]	162/162 (100%)	153/153 (100%)	138/138 (100%)
Number of Participants Tested Positive for Gonorrhea[3]	10	6	10
Prevalence of Gonorrhea[4]	10/162 (6%)	6/153 (4%)	10/138 (7%)
Number of Participants Tested for Chlamydia[2]	162/162 (100%)	153/153 (100%)	138/138 (100%)
Number of Participants Tested Positive for Chlamydia[3]	23	13	18
Prevalence of Chlamydia[4]	23/162 (14%)	13/153 (8%)	18/138 (13%)
Number of Participants Tested for Trichomonas[2]	162/162 (100%)	147/153 (96%)	138/138 (100%)
Number of Participants Tested Positive for Trichomonas[3]	30	15	21
Prevalence of Trichomonas[4]	30/162 (19%)	15/147 (10%)	21/138 (15%)

[1] Inappropriately enrolled participants are excluded.
[2] Being tested is defined as having a specimen collected for testing purpose.
[3] Syphilis is positive if either Treponemal or non−Treponemal test showed positive results; Gonorrhea/Chlamydia is positive if either urine or vaginal sample tested positive ; Trichomonas is positive if either rapid test or wet prep tested positive.
[4] Prevalence is calculated as the number of participants with positive results among the number of participants completed the test.

Source: SCHARP (Ting) − /trials/hptn/p084/analysis/atlas/code/open/t_baseline_sti_prevalence_bysite.sas, SAS Version 9.4 (05MAR2024,19:50)

HPTN 084 − A Phase 3 Double Blind Safety and Efficacy Study of Long−Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre−Exposure Prophylaxis in HIV−Uninfected Women
Atlas Open Report − March 5, 2024
Visit Cutoff Date: March 5, 2024
Table 8 − Retention [2] by Visit and 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	South Africa: Cape Town: Emavundleni CRS
Total Participants Enrolled [1]	3224	91	66	113	111	223	223
Step 1							
Week 2	3068/3212 (95.5%)	85/91 (93.4%)	65/66 (98.5%)	108/113 (95.6%)	107/109 (98.2%)	218/222 (98.2%)	214/223 (96.0%)
Week 4	3137/3197 (98.1%)	84/87 (96.6%)	65/66 (98.5%)	112/113 (99.1%)	108/109 (99.1%)	222/222 (100.0%)	216/222 (97.3%)
Step 2							
Participants entering Step 2 [3]	3058/3063 (99.8%)	80/80 (100.0%)	64/65 (98.5%)	112/112 (100.0%)	105/105 (100.0%)	218/218 (100.0%)	210/210 (100.0%)
Week 6 Safety Visit	2933/3063 (95.8%)	76/80 (95.0%)	63/65 (96.9%)	112/112 (100.0%)	104/105 (99.0%)	208/218 (95.4%)	196/210 (93.3%)
Week 9 (Injection #2)	2935/3061 (95.9%)	76/80 (95.0%)	55/65 (84.6%)	112/112 (100.0%)	101/104 (97.1%)	195/218 (89.4%)	204/210 (97.1%)
Week 13 Safety Visit	2797/3053 (91.6%)	71/79 (89.9%)	58/65 (89.2%)	108/111 (97.3%)	99/104 (95.2%)	204/217 (94.0%)	181/210 (86.2%)
Week 17 (Injection #3)	2872/3047 (94.3%)	73/78 (93.6%)	48/64 (75.0%)	109/111 (98.2%)	97/103 (94.2%)	210/217 (96.8%)	196/210 (93.3%)
Week 21 Safety Visit	2764/3037 (91.0%)	73/77 (94.8%)	59/64 (92.2%)	107/111 (96.4%)	94/103 (91.3%)	201/216 (93.1%)	189/210 (90.0%)
Week 25 (Injection #4)	2836/3029 (93.6%)	73/76 (96.1%)	62/64 (96.9%)	108/111 (97.3%)	93/103 (90.3%)	205/216 (94.9%)	198/209 (94.7%)
Week 33 (Injection #5)	2796/3013 (92.8%)	72/76 (94.7%)	60/64 (93.8%)	107/111 (96.4%)	95/103 (92.2%)	197/214 (92.1%)	196/208 (94.2%)
Week 41 (Injection #6)	2606/2996 (87.0%)	67/76 (88.2%)	60/64 (93.8%)	99/111 (89.2%)	86/101 (85.1%)	185/214 (86.4%)	186/207 (89.9%)
Week 42 Safety Visit	2496/2977 (83.8%)	66/75 (88.0%)	61/64 (95.3%)	62/111 (55.9%)	86/98 (87.8%)	184/209 (88.0%)	151/207 (72.9%)
Week 49 (Injection #7)	2695/2970 (90.7%)	72/74 (97.3%)	60/64 (93.8%)	103/111 (92.8%)	89/98 (90.8%)	185/209 (88.5%)	182/207 (87.9%)
Week 57 (Injection #8)	2642/2955 (89.4%)	69/72 (95.8%)	60/64 (93.8%)	98/109 (89.9%)	84/97 (86.6%)	182/206 (88.3%)	180/207 (87.0%)
Week 65 (Injection #9)	2594/2942 (88.2%)	68/71 (95.8%)	62/64 (96.9%)	97/108 (89.8%)	80/97 (82.5%)	186/204 (91.2%)	182/206 (88.3%)
Week 73 (Injection #10)	2505/2920 (85.8%)	66/70 (94.3%)	61/63 (96.8%)	94/108 (87.0%)	76/95 (80.0%)	187/202 (92.6%)	179/204 (87.7%)
Week 81 (Injection #11)	2436/2909 (83.7%)	65/69 (94.2%)	60/63 (95.2%)	91/108 (84.3%)	74/95 (77.9%)	188/197 (95.4%)	166/204 (81.4%)
Week 89 (Injection #12)	2281/2885 (79.1%)	66/68 (97.1%)	58/61 (95.1%)	87/107 (81.3%)	71/93 (76.3%)	171/193 (88.6%)	150/203 (73.9%)
Week 97 (Injection #13)	2197/2867 (76.6%)	64/66 (97.0%)	57/61 (93.4%)	86/106 (81.1%)	67/91 (73.6%)	160/192 (83.3%)	146/203 (71.9%)
Week 105 (Injection #14)	2129/2845 (74.8%)	61/65 (93.8%)	54/59 (91.5%)	85/105 (81.0%)	60/90 (66.7%)	160/192 (83.3%)	143/200 (71.5%)
Week 113 (Injection #15)	1962/2769 (70.9%)	61/63 (96.8%)	53/59 (89.8%)	84/105 (80.0%)	60/87 (69.0%)	143/187 (76.5%)	121/197 (61.4%)
Week 121 (Injection #16)	1834/2649 (69.2%)	59/62 (95.2%)	52/57 (91.2%)	83/104 (79.8%)	54/86 (62.8%)	125/165 (75.8%)	117/179 (65.4%)
Week 129 (Injection #17)	1630/2629 (62.0%)	52/61 (85.2%)	53/57 (93.0%)	76/103 (73.8%)	45/86 (52.3%)	115/165 (69.7%)	98/177 (55.4%)
Week 137 (Injection #18)	1379/2585 (53.3%)	41/61 (67.2%)	52/56 (92.9%)	75/103 (72.8%)	30/85 (35.3%)	96/163 (58.9%)	82/174 (47.1%)
Week 145 (Injection #19)	1114/2441 (45.6%)	33/60 (55.0%)	47/56 (83.9%)	71/103 (68.9%)	19/84 (22.6%)	74/137 (54.0%)	65/155 (41.9%)
Week 153 (Injection #20)	866/2290 (37.8%)	24/60 (40.0%)	32/55 (58.2%)	59/102 (57.8%)	13/83 (15.7%)	55/125 (44.0%)	43/144 (29.9%)
Week 161 (Injection #21)	640/2036 (31.4%)	20/55 (36.4%)	15/55 (27.3%)	47/97 (48.5%)	5/77 (6.5%)	43/112 (38.4%)	19/133 (14.3%)
Week 169 (Injection #22)	434/1689 (25.7%)	15/48 (31.3%)	8/55 (14.5%)	28/80 (35.0%)	1/56 (1.8%)	28/90 (31.1%)	9/120 (7.5%)

[1] Inappropriately enrolled participants are excluded.
[2] Retention at a visit is defined as the number (and %) of participants who completed the visit divided by the number of participants who are expected (visit window has closed), plus any participants who have completed the visit prior to their window closure. The denominator includes participants who are alive, HIV uninfected and have not permanently discontinued study product at the time of the visit.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_retention.sas, SAS Version 9.4 (05MAR2024,19:59)

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 8 − Retention [2] by Visit and Site

	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	Swaziland: Siteki: Swaziland Prevention Center	Uganda: Entebbe: UVRI−IAVI
Total Participants Enrolled [1]	159	206	170	151	176	160	182
Step 1							
Week 2	118/158 (74.7%)	203/205 (99.0%)	164/168 (97.6%)	138/151 (91.4%)	170/173 (98.3%)	151/160 (94.4%)	176/182 (96.7%)
Week 4	149/157 (94.9%)	199/203 (98.0%)	167/168 (99.4%)	144/150 (96.0%)	171/173 (98.8%)	158/160 (98.8%)	178/181 (98.3%)
Step 2							
Participants entering Step 2 [3]	141/141 (100.0%)	197/197 (100.0%)	162/162 (100.0%)	140/141 (99.3%)	169/169 (100.0%)	150/150 (100.0%)	175/175 (100.0%)
Week 6 Safety Visit	98/141 (69.5%)	193/197 (98.0%)	155/162 (95.7%)	131/141 (92.9%)	168/169 (99.4%)	148/150 (98.7%)	173/175 (98.9%)
Week 9 (Injection #2)	126/141 (89.4%)	191/197 (97.0%)	153/162 (94.4%)	132/141 (93.6%)	166/169 (98.2%)	149/150 (99.3%)	168/174 (96.6%)
Week 13 Safety Visit	84/139 (60.4%)	190/196 (96.9%)	151/162 (93.2%)	134/141 (95.0%)	162/169 (95.9%)	146/150 (97.3%)	139/173 (80.3%)
Week 17 (Injection #3)	119/139 (85.6%)	190/195 (97.4%)	157/161 (97.5%)	131/141 (92.9%)	165/169 (97.6%)	147/150 (98.0%)	167/173 (96.5%)
Week 21 Safety Visit	81/139 (58.3%)	186/194 (95.9%)	155/160 (96.9%)	127/140 (90.7%)	165/169 (97.6%)	143/149 (96.0%)	147/173 (85.0%)
Week 25 (Injection #4)	122/139 (87.8%)	182/191 (95.3%)	148/160 (92.5%)	129/140 (92.1%)	167/168 (99.4%)	140/149 (94.0%)	161/172 (93.6%)
Week 33 (Injection #5)	119/138 (86.2%)	174/188 (92.6%)	140/160 (87.5%)	131/139 (94.2%)	163/167 (97.6%)	138/147 (93.9%)	157/171 (91.8%)
Week 41 (Injection #6)	99/138 (71.7%)	164/187 (87.7%)	133/159 (83.6%)	116/139 (83.5%)	159/163 (97.5%)	134/146 (91.8%)	138/169 (81.7%)
Week 42 Safety Visit	52/137 (38.0%)	166/186 (89.2%)	153/159 (96.2%)	125/139 (89.9%)	124/162 (76.5%)	132/146 (90.4%)	136/169 (80.5%)
Week 49 (Injection #7)	108/137 (78.8%)	165/184 (89.7%)	154/158 (97.5%)	134/139 (96.4%)	158/162 (97.5%)	137/146 (93.8%)	149/169 (88.2%)
Week 57 (Injection #8)	109/136 (80.1%)	162/183 (88.5%)	146/156 (93.6%)	132/139 (95.0%)	155/162 (95.7%)	131/146 (89.7%)	150/168 (89.3%)
Week 65 (Injection #9)	103/136 (75.7%)	155/183 (84.7%)	148/156 (94.9%)	129/139 (92.8%)	152/162 (93.8%)	132/146 (90.4%)	138/166 (83.1%)
Week 73 (Injection #10)	100/134 (74.6%)	138/182 (75.8%)	149/154 (96.8%)	125/139 (89.9%)	147/162 (90.7%)	128/144 (88.9%)	127/165 (77.0%)
Week 81 (Injection #11)	91/133 (68.4%)	134/181 (74.0%)	146/153 (95.4%)	129/139 (92.8%)	137/162 (84.6%)	125/144 (86.8%)	121/165 (73.3%)
Week 89 (Injection #12)	81/133 (60.9%)	128/180 (71.1%)	121/151 (80.1%)	116/139 (83.5%)	133/161 (82.6%)	113/143 (79.0%)	105/162 (64.8%)
Week 97 (Injection #13)	83/133 (62.4%)	122/179 (68.2%)	113/151 (74.8%)	103/139 (74.1%)	130/158 (82.3%)	113/142 (79.6%)	101/161 (62.7%)
Week 105 (Injection #14)	86/132 (65.2%)	117/179 (65.4%)	111/150 (74.0%)	96/137 (70.1%)	127/157 (80.9%)	107/138 (77.5%)	98/161 (60.9%)
Week 113 (Injection #15)	61/124 (49.2%)	117/168 (69.6%)	105/136 (77.2%)	91/128 (71.1%)	124/145 (85.5%)	89/134 (66.4%)	85/160 (53.1%)
Week 121 (Injection #16)	55/118 (46.6%)	105/153 (68.6%)	95/116 (81.9%)	83/110 (75.5%)	122/142 (85.9%)	84/125 (67.2%)	71/158 (44.9%)
Week 129 (Injection #17)	51/113 (45.1%)	94/153 (61.4%)	92/114 (80.7%)	72/108 (66.7%)	106/141 (75.2%)	71/124 (57.3%)	56/158 (35.4%)
Week 137 (Injection #18)	40/109 (36.7%)	77/150 (51.3%)	71/111 (64.0%)	59/99 (59.6%)	98/139 (70.5%)	50/122 (41.0%)	37/158 (23.4%)
Week 145 (Injection #19)	30/88 (34.1%)	65/138 (47.1%)	33/103 (32.0%)	45/92 (48.9%)	92/138 (66.7%)	19/114 (16.7%)	34/149 (22.8%)
Week 153 (Injection #20)	22/80 (27.5%)	58/135 (43.0%)	19/93 (20.4%)	28/85 (32.9%)	77/135 (57.0%)	11/96 (11.5%)	28/121 (23.1%)
Week 161 (Injection #21)	14/72 (19.4%)	46/125 (36.8%)	16/79 (20.3%)	24/68 (35.3%)	56/120 (46.7%)	7/79 (8.9%)	21/100 (21.0%)
Week 169 (Injection #22)	10/61 (16.4%)	37/111 (33.3%)	13/47 (27.7%)	16/53 (30.2%)	50/109 (45.9%)	1/63 (1.6%)	16/76 (21.1%)

[1] Inappropriately enrolled participants are excluded.
[2] Retention at a visit is defined as the number (and %) of participants who completed the visit divided by the number of participants who are expected (visit window has closed), plus any participants who have completed the visit prior to their window closure. The denominator includes participants who are alive, HIV uninfected and have not permanently discontinued study product at the time of the visit.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_retention.sas, SAS Version 9.4 (05MAR2024,19:59)

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 8 − Retention [2] by Visit and Site

	Uganda: Kampala: Baylor−Uganda CRS	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	Zimbabwe: Harare: Spilhaus CRS
Total Participants Enrolled [1]	210	204	160	166	162	153	138
Step 1							
Week 2	201/210 (95.7%)	198/204 (97.1%)	153/160 (95.6%)	157/166 (94.6%)	162/162 (100.0%)	145/153 (94.8%)	135/136 (99.3%)
Week 4	202/209 (96.7%)	198/202 (98.0%)	153/160 (95.6%)	166/166 (100.0%)	160/162 (98.8%)	150/152 (98.7%)	135/135 (100.0%)
Step 2							
Participants entering Step 2 [3]	192/194 (99.0%)	190/190 (100.0%)	152/152 (100.0%)	160/161 (99.4%)	159/159 (100.0%)	148/148 (100.0%)	134/134 (100.0%)
Week 6 Safety Visit	188/194 (96.9%)	184/190 (96.8%)	151/152 (99.3%)	155/161 (96.3%)	159/159 (100.0%)	137/148 (92.6%)	134/134 (100.0%)
Week 9 (Injection #2)	184/194 (94.8%)	185/190 (97.4%)	147/152 (96.7%)	153/161 (95.0%)	158/159 (99.4%)	147/148 (99.3%)	133/134 (99.3%)
Week 13 Safety Visit	178/194 (91.8%)	172/190 (90.5%)	142/152 (93.4%)	147/160 (91.9%)	154/159 (96.9%)	146/148 (98.6%)	131/134 (97.8%)
Week 17 (Injection #3)	174/194 (89.7%)	172/189 (91.0%)	144/152 (94.7%)	148/160 (92.5%)	152/159 (95.6%)	143/148 (96.6%)	130/134 (97.0%)
Week 21 Safety Visit	166/194 (85.6%)	162/187 (86.6%)	141/152 (92.8%)	144/159 (90.6%)	149/158 (94.3%)	145/148 (98.0%)	130/134 (97.0%)
Week 25 (Injection #4)	167/194 (86.1%)	175/187 (93.6%)	139/152 (91.4%)	146/159 (91.8%)	149/158 (94.3%)	144/148 (97.3%)	128/133 (96.2%)
Week 33 (Injection #5)	160/193 (82.9%)	179/186 (96.2%)	140/152 (92.1%)	150/159 (94.3%)	147/158 (93.0%)	144/147 (98.0%)	127/132 (96.2%)
Week 41 (Injection #6)	140/193 (72.5%)	159/185 (85.9%)	136/152 (89.5%)	133/157 (84.7%)	144/157 (91.7%)	140/146 (95.9%)	128/132 (97.0%)
Week 42 Safety Visit	148/192 (77.1%)	161/183 (88.0%)	135/150 (90.0%)	142/155 (91.6%)	145/157 (92.4%)	140/146 (95.9%)	127/132 (96.2%)
Week 49 (Injection #7)	150/191 (78.5%)	165/182 (90.7%)	136/149 (91.3%)	139/155 (89.7%)	144/157 (91.7%)	138/146 (94.5%)	127/132 (96.2%)
Week 57 (Injection #8)	144/191 (75.4%)	161/181 (89.0%)	134/149 (89.9%)	142/155 (91.6%)	138/156 (88.5%)	139/146 (95.2%)	126/132 (95.5%)
Week 65 (Injection #9)	141/191 (73.8%)	164/178 (92.1%)	127/147 (86.4%)	133/154 (86.4%)	136/156 (87.2%)	134/146 (91.8%)	127/132 (96.2%)
Week 73 (Injection #10)	136/191 (71.2%)	157/175 (89.7%)	115/145 (79.3%)	133/153 (86.9%)	134/156 (85.9%)	129/146 (88.4%)	124/132 (93.9%)
Week 81 (Injection #11)	131/191 (68.6%)	147/174 (84.5%)	114/144 (79.2%)	129/153 (84.3%)	132/156 (84.6%)	131/146 (89.7%)	125/132 (94.7%)
Week 89 (Injection #12)	130/191 (68.1%)	145/173 (83.8%)	108/144 (75.0%)	125/153 (81.7%)	130/156 (83.3%)	124/142 (87.3%)	119/132 (90.2%)
Week 97 (Injection #13)	125/191 (65.4%)	139/170 (81.8%)	106/144 (73.6%)	124/153 (81.0%)	126/154 (81.8%)	117/141 (83.0%)	115/132 (87.1%)
Week 105 (Injection #14)	123/191 (64.4%)	135/169 (79.9%)	104/144 (72.2%)	120/152 (78.9%)	121/153 (79.1%)	106/140 (75.7%)	115/131 (87.8%)
Week 113 (Injection #15)	109/190 (57.4%)	119/169 (70.4%)	99/145 (68.3%)	111/149 (74.5%)	120/152 (78.9%)	103/140 (73.6%)	107/131 (81.7%)
Week 121 (Injection #16)	98/190 (51.6%)	106/168 (63.1%)	91/144 (63.2%)	106/149 (71.1%)	118/152 (77.6%)	104/140 (74.3%)	106/131 (80.9%)
Week 129 (Injection #17)	79/188 (42.0%)	69/166 (41.6%)	80/143 (55.9%)	104/149 (69.8%)	113/152 (74.3%)	101/140 (72.1%)	103/131 (78.6%)
Week 137 (Injection #18)	67/182 (36.8%)	56/160 (35.0%)	68/142 (47.9%)	92/149 (61.7%)	102/151 (67.5%)	96/140 (68.6%)	90/131 (68.7%)
Week 145 (Injection #19)	56/168 (33.3%)	51/145 (35.2%)	51/142 (35.9%)	74/149 (49.7%)	94/150 (62.7%)	85/139 (61.2%)	76/131 (58.0%)
Week 153 (Injection #20)	49/145 (33.8%)	37/128 (28.9%)	35/139 (25.2%)	61/149 (40.9%)	80/147 (54.4%)	79/139 (56.8%)	56/129 (43.4%)
Week 161 (Injection #21)	30/125 (24.0%)	29/85 (34.1%)	28/121 (23.1%)	51/144 (35.4%)	66/144 (45.8%)	61/133 (45.9%)	42/112 (37.5%)
Week 169 (Injection #22)	17/99 (17.2%)	20/73 (27.4%)	14/82 (17.1%)	32/119 (26.9%)	50/131 (38.2%)	43/123 (35.0%)	26/93 (28.0%)

[1] Inappropriately enrolled participants are excluded.
[2] Retention at a visit is defined as the number (and %) of participants who completed the visit divided by the number of participants who are expected (visit window has closed), plus any participants who have completed the visit prior to their window closure. The denominator includes participants who are alive, HIV uninfected and have not permanently discontinued study product at the time of the visit.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_retention.sas, SAS Version 9.4 (05MAR2024,19:59)

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 8 − Retention [2] by Visit and 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	South Africa: Cape Town: Emavundleni CRS
Week 177 (Injection #23)	266/1338 (19.9%)	9/40 (22.5%)	0/55 (0.0%)	9/61 (14.8%)	0/38 (0.0%)	20/74 (27.0%)	0/86 (0.0%)
Week 185 (Injection #24)	145/1058 (13.7%)	7/32 (21.9%)	0/47 (0.0%)	6/33 (18.2%)	0/24 (0.0%)	4/55 (7.3%)	0/70 (0.0%)
Number of All Visits Completed	64047/81525 (78.6%)	1748/2052 (85.2%)	1504/1827 (82.3%)	2535/3092 (82.0%)	2003/2709 (73.9%)	4569/5469 (83.5%)	4219/5605 (75.3%)

[1] Inappropriately enrolled participants are excluded.
[2] Retention at a visit is defined as the number (and %) of participants who completed the visit divided by the number of participants who are expected (visit window has closed), plus any participants who have completed the visit prior to their window closure. The denominator includes participants who are alive, HIV uninfected and have not permanently discontinued study product at the time of the visit.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_retention.sas, SAS Version 9.4 (05MAR2024,19:59)

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 8 − Retention [2] by Visit and Site

	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	Swaziland: Siteki: Swaziland Prevention Center	Uganda: Entebbe: UVRI−IAVI
Week 177 (Injection #23)	5/43 (11.6%)	24/101 (23.8%)	6/21 (28.6%)	9/34 (26.5%)	39/96 (40.6%)	0/32 (0.0%)	8/57 (14.0%)
Week 185 (Injection #24)	0/32 (0.0%)	15/89 (16.9%)	6/17 (35.3%)	8/29 (27.6%)	32/94 (34.0%)	0/16 (0.0%)	0/40 (0.0%)
Number of All Visits Completed	2357/3621 (65.1%)	3994/5110 (78.2%)	3382/4009 (84.4%)	2977/3619 (82.3%)	3884/4565 (85.1%)	3054/3861 (79.1%)	3260/4581 (71.2%)

[1] Inappropriately enrolled participants are excluded.
[2] Retention at a visit is defined as the number (and %) of participants who completed the visit divided by the number of participants who are expected (visit window has closed), plus any participants who have completed the visit prior to their window closure. The denominator includes participants who are alive, HIV uninfected and have not permanently discontinued study product at the time of the visit.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_retention.sas, SAS Version 9.4 (05MAR2024,19:59)

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 8 − Retention [2] by Visit and Site

	Uganda: Kampala: Baylor−Uganda CRS	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	Zimbabwe: Harare: Spilhaus CRS
Week 177 (Injection #23)	11/84 (13.1%)	13/63 (20.6%)	6/62 (9.7%)	22/93 (23.7%)	40/115 (34.8%)	30/106 (28.3%)	15/77 (19.5%)
Week 185 (Injection #24)	0/66 (0.0%)	1/44 (2.3%)	2/49 (4.1%)	18/79 (22.8%)	26/102 (25.5%)	20/84 (23.8%)	0/56 (0.0%)
Number of All Visits Completed	3696/5320 (69.5%)	3849/4886 (78.8%)	3151/4173 (75.5%)	3517/4481 (78.5%)	3708/4547 (81.5%)	3469/4217 (82.3%)	3171/3781 (83.9%)

[1] Inappropriately enrolled participants are excluded.
[2] Retention at a visit is defined as the number (and %) of participants who completed the visit divided by the number of participants who are expected (visit window has closed), plus any participants who have completed the visit prior to their window closure. The denominator includes participants who are alive, HIV uninfected and have not permanently discontinued study product at the time of the visit.

Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_retention.sas, SAS Version 9.4 (05MAR2024,19:59)

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 9A − Baseline Contraceptive Use 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	South Africa: Cape Town: Emavundleni CRS
Total Participants Enrolled[1]	3224	91	66	113	111	223	223
Number of Participants with Contraception	3223	91	66	113	111	223	223
Number of Participants Missing Contraception Data	1	0	0	0	0	0	0
Oral contraceptive pills	37/3223 (1.1%)	6/91 (6.6%)	0/66 (0.0%)	0/113 (0.0%)	0/111 (0.0%)	0/223 (0.0%)	0/223 (0.0%)
Intrauterine device (IUD) (hormonal)	11/3223 (0.3%)	0/91 (0.0%)	0/66 (0.0%)	0/113 (0.0%)	1/111 (0.9%)	0/223 (0.0%)	0/223 (0.0%)
Intrauterine device (IUD) (non−hormonal)	131/3223 (4.1%)	3/91 (3.3%)	0/66 (0.0%)	1/113 (0.9%)	0/111 (0.0%)	2/223 (0.9%)	2/223 (0.9%)
Injectable − DMPA	1661/3223 (51.5%)	42/91 (46.2%)	33/66 (50.0%)	65/113 (57.5%)	65/111 (58.6%)	182/223 (81.6%)	124/223 (55.6%)
Injectable − NET−EN	343/3223 (10.6%)	0/91 (0.0%)	0/66 (0.0%)	0/113 (0.0%)	0/111 (0.0%)	31/223 (13.9%)	50/223 (22.4%)
Injectable − Sayana Press/Lunelle/Cyclofem	5/3223 (0.2%)	0/91 (0.0%)	0/66 (0.0%)	0/113 (0.0%)	0/111 (0.0%)	0/223 (0.0%)	0/223 (0.0%)
Injectable − Other	0/3223 (0.0%)	0/91 (0.0%)	0/66 (0.0%)	0/113 (0.0%)	0/111 (0.0%)	0/223 (0.0%)	0/223 (0.0%)
Contraceptive Patch	0/3223 (0.0%)	0/91 (0.0%)	0/66 (0.0%)	0/113 (0.0%)	0/111 (0.0%)	0/223 (0.0%)	0/223 (0.0%)
Contraceptive vaginal ring	0/3223 (0.0%)	0/91 (0.0%)	0/66 (0.0%)	0/113 (0.0%)	0/111 (0.0%)	0/223 (0.0%)	0/223 (0.0%)
Implants	1011/3223 (31.4%)	40/91 (44.0%)	33/66 (50.0%)	30/113 (26.5%)	45/111 (40.5%)	8/223 (3.6%)	46/223 (20.6%)
Emergency contraception	0/3223 (0.0%)	0/91 (0.0%)	0/66 (0.0%)	0/113 (0.0%)	0/111 (0.0%)	0/223 (0.0%)	0/223 (0.0%)
Other	0/3223 (0.0%)	0/91 (0.0%)	0/66 (0.0%)	0/113 (0.0%)	0/111 (0.0%)	0/223 (0.0%)	0/223 (0.0%)
Sterilization	24/3223 (0.7%)	0/91 (0.0%)	0/66 (0.0%)	17/113 (15.0%)	0/111 (0.0%)	0/223 (0.0%)	1/223 (0.4%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Gordon) − /trials/hptn/p084/analysis/atlas/code/open/t_contrac_bysite.sas, SAS Version 9.4 (05MAR2024,19:51)

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 9A − Baseline Contraceptive Use by Site

	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	Swaziland: Siteki: Swaziland Prevention Center	Uganda: Entebbe: UVRI−IAVI
Total Participants Enrolled[1]	159	206	170	151	176	160	182
Number of Participants with Contraception	159	206	170	151	176	159	182
Number of Participants Missing Contraception Data	0	0	0	0	0	1	0
Oral contraceptive pills	0/159 (0.0%)	9/206 (4.4%)	0/170 (0.0%)	0/151 (0.0%)	5/176 (2.8%)	0/159 (0.0%)	0/182 (0.0%)
Intrauterine device (IUD) (hormonal)	0/159 (0.0%)	0/206 (0.0%)	1/170 (0.6%)	3/151 (2.0%)	0/176 (0.0%)	0/159 (0.0%)	0/182 (0.0%)
Intrauterine device (IUD) (non−hormonal)	4/159 (2.5%)	6/206 (2.9%)	1/170 (0.6%)	5/151 (3.3%)	0/176 (0.0%)	25/159 (15.7%)	2/182 (1.1%)
Injectable − DMPA	87/159 (54.7%)	86/206 (41.7%)	102/170 (60.0%)	86/151 (57.0%)	87/176 (49.4%)	77/159 (48.4%)	100/182 (54.9%)
Injectable − NET−EN	41/159 (25.8%)	66/206 (32.0%)	40/170 (23.5%)	29/151 (19.2%)	73/176 (41.5%)	6/159 (3.8%)	0/182 (0.0%)
Injectable − Sayana Press/Lunelle/Cyclofem	0/159 (0.0%)	0/206 (0.0%)	0/170 (0.0%)	0/151 (0.0%)	0/176 (0.0%)	0/159 (0.0%)	0/182 (0.0%)
Injectable − Other	0/159 (0.0%)	0/206 (0.0%)	0/170 (0.0%)	0/151 (0.0%)	0/176 (0.0%)	0/159 (0.0%)	0/182 (0.0%)
Contraceptive Patch	0/159 (0.0%)	0/206 (0.0%)	0/170 (0.0%)	0/151 (0.0%)	0/176 (0.0%)	0/159 (0.0%)	0/182 (0.0%)
Contraceptive vaginal ring	0/159 (0.0%)	0/206 (0.0%)	0/170 (0.0%)	0/151 (0.0%)	0/176 (0.0%)	0/159 (0.0%)	0/182 (0.0%)
Implants	27/159 (17.0%)	39/206 (18.9%)	26/170 (15.3%)	27/151 (17.9%)	10/176 (5.7%)	51/159 (32.1%)	78/182 (42.9%)
Emergency contraception	0/159 (0.0%)	0/206 (0.0%)	0/170 (0.0%)	0/151 (0.0%)	0/176 (0.0%)	0/159 (0.0%)	0/182 (0.0%)
Other	0/159 (0.0%)	0/206 (0.0%)	0/170 (0.0%)	0/151 (0.0%)	0/176 (0.0%)	0/159 (0.0%)	0/182 (0.0%)
Sterilization	0/159 (0.0%)	0/206 (0.0%)	0/170 (0.0%)	1/151 (0.7%)	1/176 (0.6%)	0/159 (0.0%)	2/182 (1.1%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Gordon) − /trials/hptn/p084/analysis/atlas/code/open/t_contrac_bysite.sas, SAS Version 9.4 (05MAR2024,19:51)

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 9A − Baseline Contraceptive Use by Site

	Uganda: Kampala: Baylor−Uganda CRS	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	Zimbabwe: Harare: Spilhaus CRS
Total Participants Enrolled[1]	210	204	160	166	162	153	138
Number of Participants with Contraception	210	204	160	166	162	153	138
Number of Participants Missing Contraception Data	0	0	0	0	0	0	0
Oral contraceptive pills	0/210 (0.0%)	0/204 (0.0%)	0/160 (0.0%)	11/166 (6.6%)	1/162 (0.6%)	5/153 (3.3%)	0/138 (0.0%)
Intrauterine device (IUD) (hormonal)	3/210 (1.4%)	0/204 (0.0%)	0/160 (0.0%)	1/166 (0.6%)	1/162 (0.6%)	1/153 (0.7%)	0/138 (0.0%)
Intrauterine device (IUD) (non−hormonal)	8/210 (3.8%)	25/204 (12.3%)	2/160 (1.3%)	7/166 (4.2%)	9/162 (5.6%)	8/153 (5.2%)	21/138 (15.2%)
Injectable − DMPA	119/210 (56.7%)	80/204 (39.2%)	74/160 (46.3%)	77/166 (46.4%)	84/162 (51.9%)	67/153 (43.8%)	24/138 (17.4%)
Injectable − NET−EN	0/210 (0.0%)	0/204 (0.0%)	7/160 (4.4%)	0/166 (0.0%)	0/162 (0.0%)	0/153 (0.0%)	0/138 (0.0%)
Injectable − Sayana Press/Lunelle/Cyclofem	4/210 (1.9%)	1/204 (0.5%)	0/160 (0.0%)	0/166 (0.0%)	0/162 (0.0%)	0/153 (0.0%)	0/138 (0.0%)
Injectable − Other	0/210 (0.0%)	0/204 (0.0%)	0/160 (0.0%)	0/166 (0.0%)	0/162 (0.0%)	0/153 (0.0%)	0/138 (0.0%)
Contraceptive Patch	0/210 (0.0%)	0/204 (0.0%)	0/160 (0.0%)	0/166 (0.0%)	0/162 (0.0%)	0/153 (0.0%)	0/138 (0.0%)
Contraceptive vaginal ring	0/210 (0.0%)	0/204 (0.0%)	0/160 (0.0%)	0/166 (0.0%)	0/162 (0.0%)	0/153 (0.0%)	0/138 (0.0%)
Implants	76/210 (36.2%)	98/204 (48.0%)	77/160 (48.1%)	69/166 (41.6%)	67/162 (41.4%)	71/153 (46.4%)	93/138 (67.4%)
Emergency contraception	0/210 (0.0%)	0/204 (0.0%)	0/160 (0.0%)	0/166 (0.0%)	0/162 (0.0%)	0/153 (0.0%)	0/138 (0.0%)
Other	0/210 (0.0%)	0/204 (0.0%)	0/160 (0.0%)	0/166 (0.0%)	0/162 (0.0%)	0/153 (0.0%)	0/138 (0.0%)
Sterilization	0/210 (0.0%)	0/204 (0.0%)	0/160 (0.0%)	1/166 (0.6%)	0/162 (0.0%)	1/153 (0.7%)	0/138 (0.0%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Gordon) − /trials/hptn/p084/analysis/atlas/code/open/t_contrac_bysite.sas, SAS Version 9.4 (05MAR2024,19:51)

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 9B − Most Recent Contraceptive Use 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	South Africa: Cape Town: Emavundleni CRS
Total Participants Enrolled[1]	3224	91	66	113	111	223	223
Number of Participants Terminated	1189	29	10	47	52	86	128
Number of Participants Missing Contraception Data	0						
Number of Participants with Contraception and not Terminated	2035	62	56	66	59	137	95
Oral contraceptive pills	273/2033 (13.4%)	8/62 (12.9%)	4/56 (7.1%)	0/66 (0.0%)	16/59 (27.1%)	10/137 (7.3%)	11/94 (11.7%)
Intrauterine device (IUD) (hormonal)	16/2033 (0.8%)	0/62 (0.0%)	1/56 (1.8%)	0/66 (0.0%)	0/59 (0.0%)	0/137 (0.0%)	0/94 (0.0%)
Intrauterine device (IUD) (non−hormonal)	99/2033 (4.9%)	8/62 (12.9%)	1/56 (1.8%)	1/66 (1.5%)	0/59 (0.0%)	1/137 (0.7%)	2/94 (2.1%)
Injectable − DMPA	998/2033 (49.1%)	28/62 (45.2%)	28/56 (50.0%)	34/66 (51.5%)	4/59 (6.8%)	107/137 (78.1%)	39/94 (41.5%)
Injectable − NET−EN	238/2033 (11.7%)	0/62 (0.0%)	0/56 (0.0%)	0/66 (0.0%)	0/59 (0.0%)	18/137 (13.1%)	34/94 (36.2%)
Injectable − Sayana Press/Lunelle/Cyclofem	47/2033 (2.3%)	0/62 (0.0%)	0/56 (0.0%)	3/66 (4.5%)	32/59 (54.2%)	0/137 (0.0%)	0/94 (0.0%)
Injectable − Other	0/2033 (0.0%)	0/62 (0.0%)	0/56 (0.0%)	0/66 (0.0%)	0/59 (0.0%)	0/137 (0.0%)	0/94 (0.0%)
Contraceptive Patch	0/2033 (0.0%)	0/62 (0.0%)	0/56 (0.0%)	0/66 (0.0%)	0/59 (0.0%)	0/137 (0.0%)	0/94 (0.0%)
Contraceptive vaginal ring	0/2033 (0.0%)	0/62 (0.0%)	0/56 (0.0%)	0/66 (0.0%)	0/59 (0.0%)	0/137 (0.0%)	0/94 (0.0%)
Implants	339/2033 (16.7%)	18/62 (29.0%)	22/56 (39.3%)	13/66 (19.7%)	7/59 (11.9%)	1/137 (0.7%)	7/94 (7.4%)
Emergency contraception	2/2033 (0.1%)	0/62 (0.0%)	0/56 (0.0%)	0/66 (0.0%)	0/59 (0.0%)	0/137 (0.0%)	0/94 (0.0%)
Other	0/2033 (0.0%)	0/62 (0.0%)	0/56 (0.0%)	0/66 (0.0%)	0/59 (0.0%)	0/137 (0.0%)	0/94 (0.0%)
Sterilization	21/2033 (1.0%)	0/62 (0.0%)	0/56 (0.0%)	15/66 (22.7%)	0/59 (0.0%)	0/137 (0.0%)	1/94 (1.1%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Gordon) − /trials/hptn/p084/analysis/atlas/code/open/t_contrac_bysite.sas, SAS Version 9.4 (05MAR2024,19:51)

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 9B − Most Recent Contraceptive Use by Site

	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	Swaziland: Siteki: Swaziland Prevention Center	Uganda: Entebbe: UVRI−IAVI
Total Participants Enrolled[1]	159	206	170	151	176	160	182
Number of Participants Terminated	64	78	47	71	58	53	92
Number of Participants Missing Contraception Data							
Number of Participants with Contraception and not Terminated	95	128	123	80	118	107	90
Oral contraceptive pills	3/95 (3.2%)	18/128 (14.1%)	2/123 (1.6%)	3/80 (3.8%)	23/118 (19.5%)	2/107 (1.9%)	0/90 (0.0%)
Intrauterine device (IUD) (hormonal)	1/95 (1.1%)	3/128 (2.3%)	1/123 (0.8%)	1/80 (1.3%)	0/118 (0.0%)	2/107 (1.9%)	0/90 (0.0%)
Intrauterine device (IUD) (non−hormonal)	3/95 (3.2%)	4/128 (3.1%)	1/123 (0.8%)	2/80 (2.5%)	2/118 (1.7%)	19/107 (17.8%)	2/90 (2.2%)
Injectable − DMPA	54/95 (56.8%)	37/128 (28.9%)	86/123 (69.9%)	53/80 (66.3%)	18/118 (15.3%)	54/107 (50.5%)	55/90 (61.1%)
Injectable − NET−EN	23/95 (24.2%)	38/128 (29.7%)	15/123 (12.2%)	13/80 (16.3%)	71/118 (60.2%)	9/107 (8.4%)	0/90 (0.0%)
Injectable − Sayana Press/Lunelle/Cyclofem	0/95 (0.0%)	0/128 (0.0%)	0/123 (0.0%)	0/80 (0.0%)	0/118 (0.0%)	0/107 (0.0%)	5/90 (5.6%)
Injectable − Other	0/95 (0.0%)	0/128 (0.0%)	0/123 (0.0%)	0/80 (0.0%)	0/118 (0.0%)	0/107 (0.0%)	0/90 (0.0%)
Contraceptive Patch	0/95 (0.0%)	0/128 (0.0%)	0/123 (0.0%)	0/80 (0.0%)	0/118 (0.0%)	0/107 (0.0%)	0/90 (0.0%)
Contraceptive vaginal ring	0/95 (0.0%)	0/128 (0.0%)	0/123 (0.0%)	0/80 (0.0%)	0/118 (0.0%)	0/107 (0.0%)	0/90 (0.0%)
Implants	11/95 (11.6%)	27/128 (21.1%)	18/123 (14.6%)	8/80 (10.0%)	3/118 (2.5%)	21/107 (19.6%)	26/90 (28.9%)
Emergency contraception	0/95 (0.0%)	1/128 (0.8%)	0/123 (0.0%)	0/80 (0.0%)	0/118 (0.0%)	0/107 (0.0%)	0/90 (0.0%)
Other	0/95 (0.0%)	0/128 (0.0%)	0/123 (0.0%)	0/80 (0.0%)	0/118 (0.0%)	0/107 (0.0%)	0/90 (0.0%)
Sterilization	0/95 (0.0%)	0/128 (0.0%)	0/123 (0.0%)	0/80 (0.0%)	1/118 (0.8%)	0/107 (0.0%)	2/90 (2.2%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Gordon) − /trials/hptn/p084/analysis/atlas/code/open/t_contrac_bysite.sas, SAS Version 9.4 (05MAR2024,19:51)

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 9B − Most Recent Contraceptive Use by Site

	Uganda: Kampala: Baylor−Uganda CRS	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	Zimbabwe: Harare: Spilhaus CRS
Total Participants Enrolled[1]	210	204	160	166	162	153	138
Number of Participants Terminated	97	82	41	45	44	51	14
Number of Participants Missing Contraception Data							
Number of Participants with Contraception and not Terminated	113	122	119	121	118	102	124
Oral contraceptive pills	0/112 (0.0%)	0/122 (0.0%)	42/119 (35.3%)	43/121 (35.5%)	29/118 (24.6%)	37/102 (36.3%)	22/124 (17.7%)
Intrauterine device (IUD) (hormonal)	0/112 (0.0%)	1/122 (0.8%)	0/119 (0.0%)	2/121 (1.7%)	2/118 (1.7%)	0/102 (0.0%)	2/124 (1.6%)
Intrauterine device (IUD) (non−hormonal)	7/112 (6.3%)	20/122 (16.4%)	0/119 (0.0%)	4/121 (3.3%)	11/118 (9.3%)	2/102 (2.0%)	9/124 (7.3%)
Injectable − DMPA	83/112 (74.1%)	51/122 (41.8%)	57/119 (47.9%)	57/121 (47.1%)	50/118 (42.4%)	42/102 (41.2%)	61/124 (49.2%)
Injectable − NET−EN	0/112 (0.0%)	0/122 (0.0%)	10/119 (8.4%)	0/121 (0.0%)	0/118 (0.0%)	0/102 (0.0%)	7/124 (5.6%)
Injectable − Sayana Press/Lunelle/Cyclofem	0/112 (0.0%)	7/122 (5.7%)	0/119 (0.0%)	0/121 (0.0%)	0/118 (0.0%)	0/102 (0.0%)	0/124 (0.0%)
Injectable − Other	0/112 (0.0%)	0/122 (0.0%)	0/119 (0.0%)	0/121 (0.0%)	0/118 (0.0%)	0/102 (0.0%)	0/124 (0.0%)
Contraceptive Patch	0/112 (0.0%)	0/122 (0.0%)	0/119 (0.0%)	0/121 (0.0%)	0/118 (0.0%)	0/102 (0.0%)	0/124 (0.0%)
Contraceptive vaginal ring	0/112 (0.0%)	0/122 (0.0%)	0/119 (0.0%)	0/121 (0.0%)	0/118 (0.0%)	0/102 (0.0%)	0/124 (0.0%)
Implants	21/112 (18.8%)	43/122 (35.2%)	10/119 (8.4%)	14/121 (11.6%)	26/118 (22.0%)	20/102 (19.6%)	23/124 (18.5%)
Emergency contraception	1/112 (0.9%)	0/122 (0.0%)	0/119 (0.0%)	0/121 (0.0%)	0/118 (0.0%)	0/102 (0.0%)	0/124 (0.0%)
Other	0/112 (0.0%)	0/122 (0.0%)	0/119 (0.0%)	0/121 (0.0%)	0/118 (0.0%)	0/102 (0.0%)	0/124 (0.0%)
Sterilization	0/112 (0.0%)	0/122 (0.0%)	0/119 (0.0%)	1/121 (0.8%)	0/118 (0.0%)	1/102 (1.0%)	0/124 (0.0%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Gordon) − /trials/hptn/p084/analysis/atlas/code/open/t_contrac_bysite.sas, SAS Version 9.4 (05MAR2024,19:51)

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 10 − Baseline Contraceptive Use by Site for Contraception Sub−study

	Overall	South Africa: Kwa Zulu Natal: Verulam CRS	South Africa: Cape Town: Emavundleni CRS	South Africa: Botha's Hill: Botha's Hill CRS	South Africa: Soweto: Soweto HPTN CRS
Total Participants in the Substudy[1]	190	27	23	22	14
Number of Participants with Contraception	190	27	23	22	14
Number of Participants Missing Contraception Data	0				
Oral contraceptive pills	2/190 (1.1%)	0/27 (0.0%)	0/23 (0.0%)	0/22 (0.0%)	0/14 (0.0%)
Intrauterine device (IUD) (hormonal)	0/190 (0.0%)	0/27 (0.0%)	0/23 (0.0%)	0/22 (0.0%)	0/14 (0.0%)
Intrauterine device (IUD) (non−hormonal)	0/190 (0.0%)	0/27 (0.0%)	0/23 (0.0%)	0/22 (0.0%)	0/14 (0.0%)
Injectable − DMPA	87/190 (45.8%)	17/27 (63.0%)	8/23 (34.8%)	14/22 (63.6%)	3/14 (21.4%)
Injectable − NET−EN	68/190 (35.8%)	4/27 (14.8%)	13/23 (56.5%)	5/22 (22.7%)	10/14 (71.4%)
Injectable − Sayana Press/Lunelle/Cyclofem	0/190 (0.0%)	0/27 (0.0%)	0/23 (0.0%)	0/22 (0.0%)	0/14 (0.0%)
Injectable − Other	0/190 (0.0%)	0/27 (0.0%)	0/23 (0.0%)	0/22 (0.0%)	0/14 (0.0%)
Contraceptive Patch	0/190 (0.0%)	0/27 (0.0%)	0/23 (0.0%)	0/22 (0.0%)	0/14 (0.0%)
Contraceptive vaginal ring	0/190 (0.0%)	0/27 (0.0%)	0/23 (0.0%)	0/22 (0.0%)	0/14 (0.0%)
Implants	33/190 (17.4%)	6/27 (22.2%)	2/23 (8.7%)	3/22 (13.6%)	1/14 (7.1%)
Emergency contraception	0/190 (0.0%)	0/27 (0.0%)	0/23 (0.0%)	0/22 (0.0%)	0/14 (0.0%)
Other	0/190 (0.0%)	0/27 (0.0%)	0/23 (0.0%)	0/22 (0.0%)	0/14 (0.0%)
Sterilization	0/190 (0.0%)	0/27 (0.0%)	0/23 (0.0%)	0/22 (0.0%)	0/14 (0.0%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Gordon) − /trials/hptn/p084/analysis/atlas/code/open/t_contrac_substudy_monitor.sas, SAS Version 9.4 (05MAR2024,19:52)

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 10 − Baseline Contraceptive Use by Site for Contraception Sub−study

	South Africa: Kwa Zulu Natal: Isipingo CRS	South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	South Africa: Johannessburg: Ward 21
Total Participants in the Substudy[1]	27	34	43
Number of Participants with Contraception	27	34	43
Number of Participants Missing Contraception Data			
Oral contraceptive pills	0/27 (0.0%)	0/34 (0.0%)	2/43 (4.7%)
Intrauterine device (IUD) (hormonal)	0/27 (0.0%)	0/34 (0.0%)	0/43 (0.0%)
Intrauterine device (IUD) (non−hormonal)	0/27 (0.0%)	0/34 (0.0%)	0/43 (0.0%)
Injectable − DMPA	13/27 (48.1%)	22/34 (64.7%)	10/43 (23.3%)
Injectable − NET−EN	9/27 (33.3%)	9/34 (26.5%)	18/43 (41.9%)
Injectable − Sayana Press/Lunelle/Cyclofem	0/27 (0.0%)	0/34 (0.0%)	0/43 (0.0%)
Injectable − Other	0/27 (0.0%)	0/34 (0.0%)	0/43 (0.0%)
Contraceptive Patch	0/27 (0.0%)	0/34 (0.0%)	0/43 (0.0%)
Contraceptive vaginal ring	0/27 (0.0%)	0/34 (0.0%)	0/43 (0.0%)
Implants	5/27 (18.5%)	3/34 (8.8%)	13/43 (30.2%)
Emergency contraception	0/27 (0.0%)	0/34 (0.0%)	0/43 (0.0%)
Other	0/27 (0.0%)	0/34 (0.0%)	0/43 (0.0%)
Sterilization	0/27 (0.0%)	0/34 (0.0%)	0/43 (0.0%)

[1] Inappropriately enrolled participants are excluded.
Source: SCHARP (Gordon) − /trials/hptn/p084/analysis/atlas/code/open/t_contrac_substudy_monitor.sas, SAS Version 9.4 (05MAR2024,19:52)

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 O11A − Pregnancy Incidence 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
Number of Pregnancies [2]	261	8	11	7	13	3
Person−Years	7526.0	227.2	177.0	285.9	228.9	524.1
Incidence Rate of All Pregnancy [3]	3.5	3.5	6.2	2.4	5.7	0.6
95% CI for the Incidence Rate [4]	[3.1, 3.9]	[1.5, 6.9]	[3.1, 11.1]	[1.0, 5.0]	[3.0, 9.7]	[0.1, 1.7]
Number of Confirmed Pregnancies [5]	194	5	7	5	9	2
Person−Years	7526.0	227.2	177.0	285.9	228.9	524.1
Incidence Rate of Confirmed Pregnancy [3]	2.6	2.2	4	1.7	3.9	0.4
95% CI for the Incidence Rate [4]	[2.2, 3.0]	[0.7, 5.1]	[1.6, 8.1]	[0.6, 4.1]	[1.8, 7.5]	[0.0, 1.4]

[1] Inappropriately enrolled participants are excluded.
[2] Includes all pregnancies identified through pregnancy testing regardless duration of pregnancy.
[3] Incidence rate is reported as the number of new pregnancies per 100 person−years.
[4] The 95% CI for incidence rate is calculated using the exact Poisson method.
[5] Includes pregnancies identified through pregnancy testing and lasted for longer than four weeks.

Source: SCHARP (Amber) − /trials/hptn/p084/analysis/atlas/code/open/t_pregnancy_incidence_bysite.sas, SAS Version 9.4 (05MAR2024,19:59)

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 O11A − Pregnancy Incidence by Site

	South Africa: Cape Town: Emavundleni CRS	South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	South Africa: Johannessburg: 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
Number of Pregnancies [2]	4	4	9	4	2	2
Person−Years	482.1	291.8	476.0	376.5	349.3	456.8
Incidence Rate of All Pregnancy [3]	0.8	1.4	1.9	1.1	0.6	0.4
95% CI for the Incidence Rate [4]	[0.2, 2.1]	[0.4, 3.5]	[0.9, 3.6]	[0.3, 2.7]	[0.1, 2.1]	[0.1, 1.6]
Number of Confirmed Pregnancies [5]	3	3	6	1	2	1
Person−Years	482.1	291.8	476.0	376.5	349.3	456.8
Incidence Rate of Confirmed Pregnancy [3]	0.6	1	1.3	0.3	0.6	0.2
95% CI for the Incidence Rate [4]	[0.1, 1.8]	[0.2, 3.0]	[0.5, 2.7]	[0.0, 1.5]	[0.1, 2.1]	[0.0, 1.2]

[1] Inappropriately enrolled participants are excluded.
[2] Includes all pregnancies identified through pregnancy testing regardless duration of pregnancy.
[3] Incidence rate is reported as the number of new pregnancies per 100 person−years.
[4] The 95% CI for incidence rate is calculated using the exact Poisson method.
[5] Includes pregnancies identified through pregnancy testing and lasted for longer than four weeks.

Source: SCHARP (Amber) − /trials/hptn/p084/analysis/atlas/code/open/t_pregnancy_incidence_bysite.sas, SAS Version 9.4 (05MAR2024,19:59)

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 O11A − Pregnancy Incidence by Site

	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
Number of Pregnancies [2]	3	24	23	27	26	27
Person−Years	341.3	388.4	441.8	447.4	372.6	434.5
Incidence Rate of All Pregnancy [3]	0.9	6.2	5.2	6	7	6.2
95% CI for the Incidence Rate [4]	[0.2, 2.6]	[4.0, 9.2]	[3.3, 7.8]	[4.0, 8.8]	[4.6, 10.2]	[4.1, 9.0]
Number of Confirmed Pregnancies [5]	2	18	17	19	24	23
Person−Years	341.3	388.4	441.8	447.4	372.6	434.5
Incidence Rate of Confirmed Pregnancy [3]	0.6	4.6	3.8	4.2	6.4	5.3
95% CI for the Incidence Rate [4]	[0.1, 2.1]	[2.7, 7.3]	[2.2, 6.2]	[2.6, 6.6]	[4.1, 9.6]	[3.4, 7.9]

[1] Inappropriately enrolled participants are excluded.
[2] Includes all pregnancies identified through pregnancy testing regardless duration of pregnancy.
[3] Incidence rate is reported as the number of new pregnancies per 100 person−years.
[4] The 95% CI for incidence rate is calculated using the exact Poisson method.
[5] Includes pregnancies identified through pregnancy testing and lasted for longer than four weeks.

Source: SCHARP (Amber) − /trials/hptn/p084/analysis/atlas/code/open/t_pregnancy_incidence_bysite.sas, SAS Version 9.4 (05MAR2024,19:59)

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 O11A − Pregnancy Incidence by Site

	Zimbabwe: Chitungwiza: Zengeza CRS	Zimbabwe: Harare: Parirenyatwa CRS	Zimbabwe: Harare: Spilhaus CRS
Total Participants Enrolled [1]	162	153	138
Number of Pregnancies [2]	19	15	30
Person−Years	445.2	418.0	361.5
Incidence Rate of All Pregnancy [3]	4.3	3.6	8.3
95% CI for the Incidence Rate [4]	[2.6, 6.7]	[2.0, 5.9]	[5.6, 11.8]
Number of Confirmed Pregnancies [5]	13	12	22
Person−Years	445.2	418.0	361.5
Incidence Rate of Confirmed Pregnancy [3]	2.9	2.9	6.1
95% CI for the Incidence Rate [4]	[1.6, 5.0]	[1.5, 5.0]	[3.8, 9.2]

[1] Inappropriately enrolled participants are excluded.
[2] Includes all pregnancies identified through pregnancy testing regardless duration of pregnancy.
[3] Incidence rate is reported as the number of new pregnancies per 100 person−years.
[4] The 95% CI for incidence rate is calculated using the exact Poisson method.
[5] Includes pregnancies identified through pregnancy testing and lasted for longer than four weeks.

Source: SCHARP (Amber) − /trials/hptn/p084/analysis/atlas/code/open/t_pregnancy_incidence_bysite.sas, SAS Version 9.4 (05MAR2024,19:59)

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 O11B − Pregnancy Incidence in OLE

	Overall
Total Participants Enrolled in OLE	2472
Number of Reported Pregnancies [1]	421
Person−Years	3225
Incidence Rate of All Pregnancies [2]	13.05
95% CI for Incidence Rate [3]	[11.84, 14.36]
Number of Confirmed Pregnancies	403
Person−Years	3225
Incidence Rate of Confirmed Pregnancies [2]	12.49
95% CI for Incidence Rate [3]	[11.30, 13.78]

[1] Includes all pregnancies reported after OLE initiation.
[2] Incidence rate is reported as the number of new pregnancies per 100 person−years.
[3] The 95% CI for incidence rate is calculated using the exact Poisson method.

Source: SCHARP (Amber) − /trials/hptn/p084/analysis/atlas/code/open/t_ole_pregnancy_incidence.sas, SAS Version 9.4 (05MAR2024,19:59)

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 12 − Cumulative Pregnancy Outcomes by CAB Status

	Overall	CAB Arm in Blinded Trial	TDF/FTC Arm in Blinded Trial, but CAB Exposure Prior or During Pregnancy in OLE	TDF/FTC Arm in Blinded Trial, and No CAB Exposure Prior or During Pregnancy in OLE
Number of Participants with Positive Pregnancy Test	638	327	155	156
Number of Reported Pregnancies	731	371	185	175
Pending Confirmation	8/731 (1.1%)	3/371 (0.8%)	2/185 (1.1%)	3/175 (1.7%)
No Obtainable Outcomes [1]	0/8 (0.0%)	0/3 (0.0%)	0/2 (0.0%)	0/3 (0.0%)
Not Confirmed or Ended Prior to Confirmation [2]	74/731 (10.1%)	39/371 (10.5%)	6/185 (3.2%)	29/175 (16.6%)
Pending Outcome [3]	1/74 (1.4%)	0/39 (0.0%)	0/6 (0.0%)	1/29 (3.4%)
Number with Obtainable Outcomes [4]	73/74 (98.6%)	39/39 (100.0%)	6/6 (100.0%)	28/29 (96.6%)
Spontaneous Abortion (<20 Weeks)	47/73 (64.4%)	25/39 (64.1%)	4/6 (66.7%)	18/28 (64.3%)
Ectopic Pregnancy	5/73 (6.8%)	2/39 (5.1%)	0/6 (0.0%)	3/28 (10.7%)
Therapeutic/Elective Abortion	21/73 (28.8%)	12/39 (30.8%)	2/6 (33.3%)	7/28 (25.0%)
Other	0/73 (0.0%)	0/39 (0.0%)	0/6 (0.0%)	0/28 (0.0%)
No Obtainable Outcomes [5]	0/74 (0.0%)	0/39 (0.0%)	0/6 (0.0%)	0/29 (0.0%)
Confirmed Pregnancies	649/731 (88.8%)	329/371 (88.7%)	177/185 (95.7%)	143/175 (81.7%)
Pending Outcome [6]	129/649 (19.9%)	76/329 (23.1%)	44/177 (24.9%)	9/143 (6.3%)
Confirmed Pregnancies with Obtainable Outcomes	519/649 (80.0%)	252/329 (76.6%)	133/177 (75.1%)	134/143 (93.7%)
Number of Obtainable Outcomes [4]	529	255	135	139
Full Term Delivery (>=37 Weeks)	368/529 (69.6%)	176/255 (69.0%)	79/135 (58.5%)	113/139 (81.3%)
Preterm Delivery (<37 Weeks)	31/529 (5.9%)	16/255 (6.3%)	8/135 (5.9%)	7/139 (5.0%)
Stillbirth/Intrauterine Fetal Demise (>=20 Weeks)	15/529 (2.8%)	7/255 (2.7%)	2/135 (1.5%)	6/139 (4.3%)
Spontaneous Abortion (<20 Weeks)	79/529 (14.9%)	43/255 (16.9%)	28/135 (20.7%)	8/139 (5.8%)
Ectopic Pregnancy	5/529 (0.9%)	0/255 (0.0%)	4/135 (3.0%)	1/139 (0.7%)
Therapeutic/Elective Abortion	28/529 (5.3%)	12/255 (4.7%)	12/135 (8.9%)	4/139 (2.9%)
Other	3/529 (0.6%)	1/255 (0.4%)	2/135 (1.5%)	0/139 (0.0%)
No Obtainable Outcomes [7]	1/649 (0.2%)	1/329 (0.3%)	0/177 (0.0%)	0/143 (0.0%)

[1] Cases with a single positive pregnancy test and no additional information about the pregnancy ("No" in response to "Did this pregnancy have an obtainable outcome?" on the Pregnancy Outcome Log).
[2] Includes a) cases where the confirmatory pregnancy test was negative, and b) cases with a pregnancy outcome log indicating a loss (with gestational age <20 weeks) prior to confirmation.
[3] Cases with an initial positive pregnancy test followed by a negative pregnancy test at the confirmation visit, but no Pregnancy Outcome Log completed yet.
[4] The number of outcomes will be higher than the number of pregnancies when there are multiple births. As of the cutoff date, one Confirmed Pregnancy is missing all the required information on the Pregnancy Outcome Log. This is a data issue. So, Confirmed Pregnancies with Obtainable Outcome row of the table displays a count of 208 instead of 209.
[5] Cases with an initial positive pregnancy test followed by a negative pregnancy test at the confirmation visit, but no additional information about the pregnancy ("No" in response to "Did this pregnancy have an obtainable outcome?" on the Pregnancy Outcome Log).
[6] Confirmed pregnancies with no Pregnancy Outcome Log completed yet (the majority of these pregnancies are ongoing).
[7] Confirmed pregnancies with no available information regarding the pregnancy outcome ("No" in response to "Did this pregnancy have an obtainable outcome?" on the Pregnancy Outcome Log).
[8] The denominator is the sum of known outcomes for those that ended prior to confirmation and those with confirmed pregnancies.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_pregout_bycab.sas, SAS Version 9.4 (05MAR2024,19:59)

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 12 − Cumulative Pregnancy Outcomes by CAB Status

	Overall	CAB Arm in Blinded Trial	TDF/FTC Arm in Blinded Trial, but CAB Exposure Prior or During Pregnancy in OLE	TDF/FTC Arm in Blinded Trial, and No CAB Exposure Prior or During Pregnancy in OLE
Congenital Anomalies [8]				
Yes	8/602 (1.3%)	3/294 (1.0%)	3/141 (2.1%)	2/167 (1.2%)
No	415/602 (68.9%)	198/294 (67.3%)	84/141 (59.6%)	133/167 (79.6%)
Unknown	173/602 (28.7%)	90/294 (30.6%)	51/141 (36.2%)	32/167 (19.2%)
Missing	6/602 (1.0%)	3/294 (1.0%)	3/141 (2.1%)	0/167 (0.0%)

[1] Cases with a single positive pregnancy test and no additional information about the pregnancy ("No" in response to "Did this pregnancy have an obtainable outcome?" on the Pregnancy Outcome Log).
[2] Includes a) cases where the confirmatory pregnancy test was negative, and b) cases with a pregnancy outcome log indicating a loss (with gestational age <20 weeks) prior to confirmation.
[3] Cases with an initial positive pregnancy test followed by a negative pregnancy test at the confirmation visit, but no Pregnancy Outcome Log completed yet.
[4] The number of outcomes will be higher than the number of pregnancies when there are multiple births. As of the cutoff date, one Confirmed Pregnancy is missing all the required information on the Pregnancy Outcome Log. This is a data issue. So, Confirmed Pregnancies with Obtainable Outcome row of the table displays a count of 208 instead of 209.
[5] Cases with an initial positive pregnancy test followed by a negative pregnancy test at the confirmation visit, but no additional information about the pregnancy ("No" in response to "Did this pregnancy have an obtainable outcome?" on the Pregnancy Outcome Log).
[6] Confirmed pregnancies with no Pregnancy Outcome Log completed yet (the majority of these pregnancies are ongoing).
[7] Confirmed pregnancies with no available information regarding the pregnancy outcome ("No" in response to "Did this pregnancy have an obtainable outcome?" on the Pregnancy Outcome Log).
[8] The denominator is the sum of known outcomes for those that ended prior to confirmation and those with confirmed pregnancies.
Source: SCHARP (Anusha) − /trials/hptn/p084/analysis/atlas/code/open/t_pregout_bycab.sas, SAS Version 9.4 (05MAR2024,19:59)

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
South Africa: Kwa Zulu Natal: Verulam CRS	548116336	11SEP2020	Y	08DEC2023	V117.0 − Step 6−CAB LA − Week 64 (1)	08DEC2023	11AUG2022	Y		Confirmed	−		
South Africa: Kwa Zulu Natal: Verulam CRS	548187126	04NOV2019	Y	07MAR2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	07MAR2023	20JUN2022	Y		Confirmed	06JUL2023	Premature Term Live Birth (< 37 Weeks)	admitted for pre−eclampsia 12 jun 2023. emergency c−section done 06 jul 2023 (31 weeks). baby was born alive, and died in nicu on 19 jul 2023
South Africa: Kwa Zulu Natal: Verulam CRS	548369817	21FEB2019		28JUN2023	V70.0 − Step 4c−TDF/ FTC − Week 48 (1)	28JUN2023	27JUL2022	Y		Confirmed	−		
South Africa: Kwa Zulu Natal: Verulam CRS	548655284	17SEP2019		09JAN2023	V67.0 − Step 4c−TDF/ FTC − Week 24 (1)	09JAN2023	25JUL2022	Y		Confirmed	−		
South Africa: Kwa Zulu Natal: Verulam CRS	548655284	17SEP2019		16OCT2023	V71.0 − Step 5−TDF/ FTC − Day 0 (1)	16OCT2023	25JUL2022	Y		Ended Prior To Confirmation	19JAN2023	Spontaneous Abortion (< 20 Weeks)	spontaneous abortion at 8 weeks gestation
South Africa: Kwa Zulu Natal: Verulam CRS	548758104	05NOV2019		04APR2023	V69.0 − Step 4c−TDF/ FTC − Week 40 (1)	04APR2023	03JUN2022	Y		Confirmed	02NOV2023	Full Term Live Birth (>= 37 Weeks)	
South Africa: Kwa Zulu Natal: Verulam CRS	548826465	04SEP2019	Y	15FEB2024	V71.0 − Step 5−TDF/ FTC − Day 0 (1)	15FEB2024	07JUL2022	Y		Confirmed	−		
South Africa: Kwa Zulu Natal: Verulam CRS	548847524	03APR2019	Y	11MAY2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	11MAY2023	30JUN2022	Y		Confirmed	26NOV2023	Full Term Live Birth (>= 37 Weeks)	baby was delivered vaginally, no complications reported.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
South Africa: Kwa Zulu Natal: Verulam CRS	548848032	08OCT2019		26JAN2023	V68.0 − Step 4c−TDF/ FTC − Week 32 (1)	26JAN2023	26MAY2022	Y		Confirmed	13MAY2023	Stillbirth/ Intrauterine Fetal Demise (>= 20 Weeks)	participant had stillbirth >20 weeks, which she reported on 19oct2023. the outcome occurred in hospital on 13may2023. no other information available.
South Africa: Kwa Zulu Natal: Verulam CRS	548848032	08OCT2019		26OCT2023		19OCT2023	26MAY2022	Y		Pending Confirmation	−		
South Africa: Kwa Zulu Natal: Verulam CRS	548867819	23JUL2019	Y	12DEC2023	V118.0 − Step 6−CAB LA − Week 72 (1)	12DEC2023	26JUL2022	Y		Confirmed	−		
Malawi: Lilongwe: Malawi CRS	720105795	31JUL2019	Y	09AUG2022	V76.0 − Step 4d − Week 0 Pregnanc y 1	09AUG2022	05APR2022	Y		Confirmed	04MAR2023	Full Term Live Birth (>= 37 Weeks)	participant had an uneventful labour and delivered a live 2555g male infant
Malawi: Lilongwe: Malawi CRS	720131129	04SEP2019	Y	01MAR2022	V203 − Open Label Truvada Week 24 (1)	01MAR2022	24FEB2022	Y		Confirmed	23JUL2022	Full Term Live Birth (>= 37 Weeks)	participant progressed to a live full term female infant on 23 jul 22. birth weight 3.1 kilograms and is breastfeedin g.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Malawi: Lilongwe: Malawi CRS	720172586	12APR2019	Y	05JUL2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	05JUL2022	04APR2022	Y		Confirmed	16JUL2022	Therapeutic/ Elective Abortion	on 16 july 2022 the participant ingested some unknown pills and experienced per vaginal bleeding with tissue for 10 days. an ultrasound on 01 sep 2022 confirmed she had a complete abortion.
Malawi: Lilongwe: Malawi CRS	720172586	12APR2019	Y	12DEC2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	12DEC2023	04APR2022	Y		Confirmed	−		
Malawi: Lilongwe: Malawi CRS	720196739	31JUL2019	Y	07DEC2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	07DEC2022	11APR2022	Y		Confirmed	24JUL2023	Full Term Live Birth (>= 37 Weeks)	participant progressed to a spontaneous vertex delivery of a live full term female infant on 24 jul 23. apgar scole 9/10 then 10/10. no complications noted.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Malawi: Lilongwe: Malawi CRS	720261814	06JUN2019	Y	13JUL2022	V76.0 − Step 4d − Week 0 Pregnancy 1	13JUL2022	21APR2022	Y		Confirmed	22NOV2022	Premature Term Live Birth (< 37 Weeks)	induction of labor was done because of lethal congenital anomalies. she progessed to a vertex delivery of a female infant. apgar score 2/10 then 3/10 baby was taken to nursery.
Malawi: Lilongwe: Malawi CRS	720376833	18APR2019	Y	19JAN2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	19JAN2023	07MAR2022	Y		Confirmed	09AUG2023	Full Term Live Birth (>= 37 Weeks)	participant had prolonged labour with non reassuring ctg. she had an emergency c−section, an extraction of a live full term female infant was done.
Malawi: Lilongwe: Malawi CRS	720433707	27AUG2019	Y	15FEB2024	V121.0 − Step 4c−CAB LA − Week 96 (1)	15FEB2024	15FEB2022	Y		Pending Confirmation	−		
Malawi: Lilongwe: Malawi CRS	720469117	19AUG2019	Y	25JAN2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	25JAN2023	23FEB2022	Y		Confirmed	24AUG2023	Full Term Live Birth (>= 37 Weeks)	the participant progressed into labor and delivered a full term infant on 24 august 2023 via spontaneous vaginal delivery with no complications.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Malawi: Lilongwe: Malawi CRS	720478035	20MAY2019	Y	15SEP2021	V24.0 Week 121 − S2 (1)	15SEP2021	04MAR2022			Confirmed	17APR2022	Full Term Live Birth (>= 37 Weeks)	the participant had an uneventful labour and proceeded to deliver a live infant female
Malawi: Lilongwe: Malawi CRS	720535096	26SEP2019	Y	06JUN2022	V65.0 − Step 4c−TDF/ FTC − Week 8 (1)	06JUN2022	01MAR2022	Y		Confirmed	−		
Malawi: Lilongwe: Malawi CRS	720554712	30JUL2019		04JAN2023	V69.0 − Step 4c−TDF/ FTC − Week 40 (1)	04JAN2023	29MAR2022	Y		Confirmed	16AUG2023	Full Term Live Birth (>= 37 Weeks)	the participant started labour and delivered on 16 august 2023 via svd. it was an uneventful delivery.
Malawi: Lilongwe: Malawi CRS	720594005	12JUN2019	Y	07SEP2023	V118.0 − Step 6−CAB LA − Week 72 (1)	07SEP2023	31MAR2022	Y		Confirmed	−		
Malawi: Lilongwe: Malawi CRS	720660808	27JUN2019	Y	18MAY2022	V56.0 − Step 4b − Day 0 (1)	18MAY2022	18MAY2022			Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Malawi: Lilongwe: Malawi CRS	720709274	18DEC2018		19OCT2022	V68.0 − Step 4c−TDF/ FTC − Week 32 (1)	19OCT2022	02MAR2022	Y		Confirmed	05MAY2023	Stillbirth/ Intrauterine Fetal Demise (>= 20 Weeks)	the intrauterine fetal death was confirmed on ultrasound scan however participant was reluctant to receive medical attention until she was full term. she believed she could still feel fetal movements.
Malawi: Lilongwe: Malawi CRS	720713962	28NOV2018	Y	19DEC2023	V121.0 − Step 4c−CAB LA − Week 96 (1)	03JAN2024	09MAR2022	Y		Confirmed	−		
Malawi: Lilongwe: Malawi CRS	720815354	05FEB2019	Y	11MAY2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	11MAY2022	16FEB2022	Y		Confirmed	13DEC2022	Full Term Live Birth (>= 37 Weeks)	membrane sweep was done then spontaneous vertex delivery
Malawi: Lilongwe: Malawi CRS	720825170	23OCT2019		03AUG2022	V67.0 − Step 4c−TDF/ FTC − Week 24 (1)	03AUG2022	16FEB2022	Y		Confirmed	10FEB2023	Full Term Live Birth (>= 37 Weeks)	participant had uneventful labour and delivered a live 3000g male infant

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Malawi: Lilongwe: Malawi CRS	720845087	08FEB2019		25APR2022	V64.0 − Step 4c−TDF/ FTC − Week 0 (1)	25APR2022	25APR2022			Confirmed	21MAY2022	Therapeutic/ Elective Abortion	participant took some drugs for an abortion on 20−21 may 2022. she started bleeding on 21 may 2022. she went to hospital on 03 jun 2022 where she was treated. she had a complete induced abortion.
Malawi: Lilongwe: Malawi CRS	720858728	17SEP2019	Y	21SEP2023	V118.0 − Step 6−CAB LA − Week 72 (1)	21SEP2023	21MAR2022	Y		Confirmed	05OCT2023	Spontaneous Abortion (< 20 Weeks)	she experienced per vaginal bleeding on 04 october 2023 and reported to the hospital on 05 october where she was assessed and diagnosed with an incomplete miscarriage.
Malawi: Lilongwe: Malawi CRS	720888514	25FEB2019	Y	08JAN2024	V120.0 − Step 4c−CAB LA − Week 88 (1)	08JAN2024	07MAR2022	Y		Confirmed	−		
Malawi: Lilongwe: Malawi CRS	720901779	20FEB2019		04JUL2022	V64.0 − Step 4c−TDF/ FTC − Week 0 (1)	04JUL2022	04JUL2022			Confirmed	11JUL2022	Full Term Live Birth (>= 37 Weeks)	the participant had an uneventful labour and successfully delivered a live male infant

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Malawi: Lilongwe: Malawi CRS	720912502	10SEP2019	Y	13JUL2023	V118.0 − Step 6−CAB LA − Week 72 (1)	13JUL2023	10MAR2022	Y		Confirmed	24DEC2023	Premature Term Live Birth (< 37 Weeks)	
Malawi: Lilongwe: Malawi CRS	720915042	05SEP2019	Y	04JAN2022	V204 − Open Label Truvada Week 36 (1)	04JAN2022	07MAR2022			Confirmed	18JUN2022	Full Term Live Birth (>= 37 Weeks)	participant had uneventful labour and delivered a live 2900g female infant
Malawi: Lilongwe: Malawi CRS	720971503	21AUG2019	Y	31AUG2022	V76.0 − Step 4d − Week 0 Pregnancy 1	31AUG2022	11APR2022	Y		Confirmed	25APR2023	Full Term Live Birth (>= 37 Weeks)	
Malawi: Lilongwe: Malawi CRS	720997827	10JUL2019	Y	06SEP2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	06SEP2023	28FEB2022	Y		Confirmed	−		
Botswana: Gaborone: Gaborone CRS	723132141	21AUG2019	Y	19SEP2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	19SEP2022	15FEB2022	Y		Confirmed	10MAY2023	Full Term Live Birth (>= 37 Weeks)	hospital delivery, baby noted to have polydactyly and respiratory distress, resuscitated immediately after delivery but stabilized on the same day. admission into the neonatal unit was not indicated.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Botswana: Gaborone: Gaborone CRS	723190883	13MAY2019	Y	10OCT2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	10OCT2022	04MAR2022	Y		Confirmed	11OCT2022	Spontaneous Abortion (< 20 Weeks)	participant with positive pregnancy test result and history of vaginal bleeding. confirmed complete miscarriage on pelvic ultrasound
Botswana: Gaborone: Gaborone CRS	723190883	13MAY2019	Y	20FEB2024	V121.0 − Step 4c−CAB LA − Week 96 (1)	20FEB2024	04MAR2022	Y		Confirmed	−		
Botswana: Gaborone: Gaborone CRS	723244317	26FEB2019	Y	21JUL2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	21JUL2022	03MAR2022	Y		Confirmed	19MAR2023	Full Term Live Birth (>= 37 Weeks)	delivered at the hospital, svd with no complications
Botswana: Gaborone: Gaborone CRS	723271858	23OCT2018	Y	01NOV2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	01NOV2023	14MAR2022	Y		Confirmed	21NOV2023	Spontaneous Abortion (< 20 Weeks)	participant noted to have an anembryonic gestational sac on ultrasound scan done at local hospital indicating a missed miscarriage and subsequently had an evacuation done

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Botswana: Gaborone: Gaborone CRS	723368062	24JAN2019	Y	17NOV2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	17NOV2022	05MAY2022	Y		Confirmed	25NOV2022	Spontaneous Abortion (< 20 Weeks)	participant with positive pregnancy test results. denied history of amenorrhea . pelvic ultrasound was unremarkable. serum b−hcg performed on 22 nov 2022 and 24 nov 2022 and noted to be declining
Botswana: Gaborone: Gaborone CRS	723397886	29NOV2018	Y	15MAR2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	15MAR2023	21FEB2022	Y		Confirmed	15NOV2023	Full Term Live Birth (>= 37 Weeks)	participant had spontaneous vaginal delivery at term at a local clinic
Botswana: Gaborone: Gaborone CRS	723497556	02MAR2018	Y	07DEC2023	V120.0 − Step 4c−CAB LA − Week 88 (1)	07DEC2023	15FEB2022	Y		Confirmed	12JAN2024	Spontaneous Abortion (< 20 Weeks)	participant reported she had vaginal bleeding, ultrasound scan performed noted incomplete miscarriage and evacuation was subsequently performed at a local hospital

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Botswana: Gaborone: Gaborone CRS	723566105	21AUG2019		09FEB2023	V70.0 − Step 4c−TDF/ FTC − Week 48 (1)	09FEB2023	15FEB2022	Y		Confirmed	08MAR2023	Spontaneous Abortion (< 20 Weeks)	participant noted to have positive pregnancy test result at visit 70.0 and unremarkable ultrasound findings. noted to have declining serum b−hcg levels
Botswana: Gaborone: Gaborone CRS	723646763	29MAR2019	Y	27JUN2023	V117.0 − Step 6−CAB LA − Week 64 (1)	27JUN2023	14MAR2022	Y		Confirmed	08DEC2023	Stillbirth/ Intrauterine Fetal Demise (>= 20 Weeks)	history of gestational hypertension in previous pregnancies. initiated on methyldopa on 6 nov 2023. delivered a stillborn baby post ultrasound confirming intrauterine fetal death
Botswana: Gaborone: Gaborone CRS	723656537	05JUL2019	Y	02FEB2023	V69.0 − Step 4c−TDF/ FTC − Week 40 (1)	02FEB2023	14APR2022	Y		Confirmed	22MAR2023	Spontaneous Abortion (< 20 Weeks)	participant with history of positive pregnancy test result with history of vaginal bleeding. subsequent pregnancy test performed on 22 mar 2023 noted to be negative consistent with miscarriage

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Botswana: Gaborone: Gaborone CRS	723772671	26MAR2019	Y	12JUL2023	V118.0 − Step 6−CAB LA − Week 72 (1)	12JUL2023	14FEB2022	Y		Confirmed	11JAN2024	Premature Term Live Birth (< 37 Weeks)	participant went into pre−term labor and progressed to delivering a live baby.
Botswana: Gaborone: Gaborone CRS	723804644	26FEB2019	Y	05SEP2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	05SEP2022	19APR2022	Y		Confirmed	16FEB2023	Premature Term Live Birth (< 37 Weeks)	participant hospitalized on 15 feb 2023 for elevated blood pressure readings. induction of labour performed and participant subsequentl y delivered a live baby boy on 16 feb 2023
Botswana: Gaborone: Gaborone CRS	723822035	27NOV2018	Y	19OCT2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	19OCT2022	05JUL2022	Y		Confirmed	11MAY2023	Full Term Live Birth (>= 37 Weeks)	hospital delivery through c/s for fetal bradycardia. baby admitted in nnu for meconium aspiration syndrome
Botswana: Gaborone: Gaborone CRS	723975273	15NOV2018	Y	15FEB2023	V60.0 − Step 4c−CAB LA − Week 24 (1)	15FEB2023	14JUL2022	Y		Confirmed	09MAR2023	Spontaneous Abortion (< 20 Weeks)	participant reported lower abdominal pain and vaginal bleeding on. ultrasound performed noted intrauterine mass, no fetal parts. mva performed noted retained products of conception

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Botswana: Gaborone: Gaborone CRS	723992050	22OCT2018	Y	01MAR2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	01MAR2023	11MAR2022	Y		Confirmed	07OCT2023	Full Term Live Birth (>= 37 Weeks)	
Uganda: Kampala: MU−JHU Research Collaboration CRS	753187947	19JUN2019	Y	29AUG2023	V117.0 − Step 6−CAB LA − Week 64 (1)	29AUG2023	25MAY2022	Y		Confirmed	−		
Uganda: Kampala: MU−JHU Research Collaboration CRS	753219505	21OCT2019	Y	03AUG2022	V76.0 − Step 4d − Week 0 Pregnancy 1	03AUG2022	13APR2022	Y		Confirmed	11NOV2022	Spontaneous Abortion (< 20 Weeks)	had expulsion of fetal products on the 11 nov 2022.
Uganda: Kampala: MU−JHU Research Collaboration CRS	753227548	13DEC2019	Y	30SEP2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	30SEP2022	10JUN2022	Y		Confirmed	30NOV2022	Therapeutic/ Elective Abortion	participant terminated the pregnancy and does not want to divulge the details
Uganda: Kampala: MU−JHU Research Collaboration CRS	753227548	13DEC2019	Y	01MAR2024	V120.0 − Step 4c−CAB LA − Week 88 (1)	01MAR2024	10JUN2022	Y		Ended Prior To Confirmation	16FEB2024	Therapeutic/ Elective Abortion	she took some herbs from a traditional healer and had vaginal bleeding same day with some clots and the bleeding stopped after 2 days
Uganda: Kampala: MU−JHU Research Collaboration CRS	753244890	15NOV2018		18JAN2023	V69.0 − Step 4c−TDF/ FTC − Week 40 (1)	18JAN2023	13APR2022	Y		Confirmed	30AUG2023	Full Term Live Birth (>= 37 Weeks)	baby was delivered by spontaneous vaginal delivery at kawaala health center at 10 50pm on 30 aug 23. no complications reported

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Kampala: MU−JHU Research Collaboration CRS	753309095	25OCT2019	Y	20JUL2023	V117.0 − Step 6−CAB LA − Week 64 (1)	20JUL2023	28APR2022	Y		Confirmed	27FEB2024	Full Term Live Birth (>= 37 Weeks)	a live baby boy was delivered by spontaneous vaginal delivery weighing 3.2kg
Uganda: Kampala: MU−JHU Research Collaboration CRS	753337561	08NOV2019	Y	27NOV2023	V118.0 − Step 6−CAB LA − Week 72 (1)	27NOV2023	12MAY2022	Y		Confirmed	−		
Uganda: Kampala: MU−JHU Research Collaboration CRS	753349972	19FEB2019	Y	22JAN2024	V119.0 − Step 4c−CAB LA − Week 80 (1)	22JAN2024	13JUN2022	Y		Confirmed	−		
Uganda: Kampala: MU−JHU Research Collaboration CRS	753358920	01NOV2019	Y	13JUL2023	V117.0 − Step 6−CAB LA − Week 64 (1)	13JUL2023	22APR2022	Y		Confirmed	14AUG2023	Spontaneous Abortion (< 20 Weeks)	participant was diagnosed with a missed abortion and was managed with manual vaccum aspiration at kawempe regional referral hospital. she is steady and well
Uganda: Kampala: MU−JHU Research Collaboration CRS	753378585	12NOV2019	Y	26JUL2022	V76.0 − Step 4d − Week 0 Pregnancy 1	26JUL2022	27MAY2022	Y		Confirmed	04APR2023	Full Term Live Birth (>= 37 Weeks)	delivered baby girl via svd in kawempe hospital .mother and baby are both fine.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Kampala: MU−JHU Research Collaboration CRS	753381430	10FEB2020	Y	14FEB2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	14FEB2023	12APR2022	Y		Confirmed	17SEP2023	Full Term Live Birth (>= 37 Weeks)	after ten hours of active labour, partcipant developed pv bleeding with foetal bradycardia. labor progressed and later a baby was delivered by svd at 19:16hours
Uganda: Kampala: MU−JHU Research Collaboration CRS	753406172	20MAY2019	Y	09NOV2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	09NOV2023	27APR2022	Y		Confirmed	06FEB2024	Full Term Live Birth (>= 37 Weeks)	participant had c/section done due to big baby from kawempe national referral hospital on 06 feb 2024
Uganda: Kampala: MU−JHU Research Collaboration CRS	753437273	18NOV2019	Y	16MAY2022	V64.0 − Step 4c−TDF/ FTC − Week 0 (1)	16MAY2022	16MAY2022			Confirmed	14JUN2022	Spontaneous Abortion (< 20 Weeks)	participant had a missed abortion
Uganda: Kampala: MU−JHU Research Collaboration CRS	753437273	18NOV2019	Y	28NOV2022	V57.0 − Step 4c−CAB LA − Week 0 (1)	28NOV2022	16MAY2022	Y		Confirmed	25JUL2023	Full Term Live Birth (>= 37 Weeks)	participant delivered a live baby girl on the 25 jul 23 at life link hospital. both mothe and baby are well

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Kampala: MU−JHU Research Collaboration CRS	753465231	16NOV2018	Y	16NOV2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	16NOV2022	04MAY2022	Y		Confirmed	05JUL2023	Full Term Live Birth (>= 37 Weeks)	mother delivered baby by spontaneous vaginal delivery in komamboga health centre, no intrapartum and postpartum complications reported. both mother and baby stable
Uganda: Kampala: MU−JHU Research Collaboration CRS	753474024	12NOV2019	Y	17NOV2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	17NOV2022	05MAY2022	Y		Confirmed	16JAN2023	Therapeutic/ Elective Abortion	participant started inducing abortion on 16 dec 2022 and by 16 jan 23 the abortion had been completed and she had no complaints.
Uganda: Kampala: MU−JHU Research Collaboration CRS	753505795	15NOV2018	Y	27JUN2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	27JUN2023	30JUN2022	Y		Confirmed	22SEP2023	Spontaneous Abortion (< 20 Weeks)	participant suffered an incomplete abortion at 16 weeks of amenorrhea which started out as abdominal crumping followed by caginal bleeding on the 20 sep 23 morning.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Kampala: MU−JHU Research Collaboration CRS	753529755	15OCT2019	Y	01MAR2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	01MAR2023	30MAY2022	Y		Confirmed	08OCT2023	Full Term Live Birth (>= 37 Weeks)	participant delivered on 08 oct 23 by spontaneous vaginal delivery to a live baby boy at home assisted by health worker near by home.
Uganda: Kampala: MU−JHU Research Collaboration CRS	753571198	04NOV2019	Y	06NOV2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	06NOV2023	25APR2022	Y		Confirmed	−		
Uganda: Kampala: MU−JHU Research Collaboration CRS	753601059	21OCT2019		04JUL2022	V65.0 − Step 4c−TDF/FTC − Week 8 (1)	04JUL2022	06MAY2022	Y		Confirmed	02FEB2023	Full Term Live Birth (>= 37 Weeks)	mother delivered twins by caesearean section in hospital. the twins are doing well. no postpartum complications reported
Uganda: Kampala: MU−JHU Research Collaboration CRS	753601059	21OCT2019		04JUL2022	V65.0 − Step 4c−TDF/FTC − Week 8 (1)	04JUL2022	06MAY2022	Y		Confirmed	02FEB2023	Full Term Live Birth (>= 37 Weeks)	mother delivered twins by caesearean section in hospital. the twins are doing well. no postpartum complications reported
Uganda: Kampala: MU−JHU Research Collaboration CRS	753609016	31OCT2019	Y	07OCT2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	07OCT2022	22APR2022	Y		Confirmed	12MAY2023	Full Term Live Birth (>= 37 Weeks)	deliverd by spontaneous vaginal delivery at 14 44hrs and no episiotomy given during delivery and no post partum bleeding recorded.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Kampala: MU−JHU Research Collaboration CRS	753627736	09MAR2020	Y	11OCT2022	V66.0 − Step 4c−TDF/ FTC − Week 16 (1)	11OCT2022	21JUN2022	Y		Confirmed	04JUN2023	Full Term Live Birth (>= 37 Weeks)	delivered baby boy on 04 jun 2023 from roswell hospital. other and baby are all in good condition.
Uganda: Kampala: MU−JHU Research Collaboration CRS	753658629	17DEC2019	Y	01NOV2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	01NOV2023	20APR2022	Y		Confirmed	09NOV2023	Therapeutic/ Elective Abortion	she went to the clinic and was given sublingual misoprostol and she aborted the same da
Uganda: Kampala: MU−JHU Research Collaboration CRS	753686922	19FEB2019	Y	02JAN2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	02JAN2023	16MAY2022	Y		Confirmed	24JUL2023	Full Term Live Birth (>= 37 Weeks)	a live baby boy delivered by spontaneous vaginal delivery at a weight of 3.56kg scoring 8 at 1 minute and 10 at 5 minutes. no intrapartum andpost partum complications were reported
Uganda: Kampala: MU−JHU Research Collaboration CRS	753693496	01NOV2019	Y	10OCT2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	10OCT2022	25APR2022	Y		Confirmed	17DEC2022	Spontaneous Abortion (< 20 Weeks)	participant had a miscarriage on 17th december 2022(started out as abdominal cramps followed by intense per vaginal bleeding progressing to a miscarriage in one day).

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Kampala: MU−JHU Research Collaboration CRS	753693496	01NOV2019	Y	17JUL2023	V117.0 − Step 6−CAB LA − Week 64 (1)	17JUL2023	25APR2022	Y		Confirmed	10FEB2024	Full Term Live Birth (>= 37 Weeks)	a live baby boy weighing 3.3 kgs was delivered by spontaneous vaginal delivery on 10 feb 2024 with no complications encountered.
Uganda: Kampala: MU−JHU Research Collaboration CRS	753727488	26MAR2019	Y	28OCT2022	V55.0 − Step 4a − Day 0 (1)	28OCT2022	08JUL2022	Y		Confirmed	01JUL2023	Full Term Live Birth (>= 37 Weeks)	mother delivered baby by spontaneous vaginal delivery and no intrapartum and postpartum complications reported, both mother and baby are stable
Uganda: Kampala: MU−JHU Research Collaboration CRS	753753395	07NOV2018	Y	06OCT2022	V67.0 − Step 4c−TDF/FTC − Week 24 (1)	06OCT2022	21APR2022	Y		Confirmed	30APR2023	Full Term Live Birth (>= 37 Weeks)	mother deliverd baby by spontaneous vaginal delivery in hospital, no delivery complications reported and both mother and baby were well and stable
Uganda: Kampala: MU−JHU Research Collaboration CRS	753759000	16NOV2018	Y	18NOV2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	18NOV2022	08JUN2022	Y		Confirmed	30NOV2022	Spontaneous Abortion (< 20 Weeks)	this was a spontaneous abortion < 20 weeks

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Kampala: MU−JHU Research Collaboration CRS	753766940	30APR2019	Y	09AUG2022	V76.0 − Step 4d − Week 0 Pregnancy 1	09AUG2022	08JUN2022	Y		Confirmed	06APR2023	Full Term Live Birth (>= 37 Weeks)	she delivered a female baby by standard vadinal delivery around midnight on 06 apr 2023.no complications during delivery or the early postpartum period.
Uganda: Kampala: MU−JHU Research Collaboration CRS	753781022	23OCT2019		24JAN2022	V203 − Open Label Truvada Week 24 (1)	24JAN2022	20APR2022			Confirmed	24JUL2022	Full Term Live Birth (>= 37 Weeks)	baby was delivered by spontaneous vaginal delivery
Uganda: Kampala: MU−JHU Research Collaboration CRS	753781022	23OCT2019		22FEB2023	V69.0 − Step 4c−TDF/FTC − Week 40 (1)	22FEB2023	20APR2022	Y		Confirmed	−		
Uganda: Kampala: MU−JHU Research Collaboration CRS	753784840	07MAR2019		20JUL2022	V64.0 − Step 4c−TDF/FTC − Week 0 (1)	20JUL2022	20JUL2022			Confirmed	18NOV2022	Full Term Live Birth (>= 37 Weeks)	it was a normal delivery
Uganda: Kampala: MU−JHU Research Collaboration CRS	753785729	09MAR2020	Y	10NOV2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	10NOV2022	26MAY2022	Y		Confirmed	02MAY2023	Full Term Live Birth (>= 37 Weeks)	mother delivered live baby boy weighing 2.7kgs by spontaneous vaginal delivery in a hospital. both baby and mother are fine. no delivery complications reported

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Kampala: MU−JHU Research Collaboration CRS	753847262	16NOV2018	Y	20OCT2023	V118.0 − Step 6−CAB LA − Week 72 (1)	20OCT2023	02JUN2022	Y		Confirmed	−		
Uganda: Kampala: MU−JHU Research Collaboration CRS	753861001	19FEB2020	Y	18AUG2022	V76.0 − Step 4d − Week 0 Pregnancy 1	18AUG2022	19APR2022	Y		Confirmed	04APR2023	Full Term Live Birth (>= 37 Weeks)	mother delivered baby by spontaneous vaginal delivery and no intrapartum and post partum complications reported. both mother and baby are stable
Uganda: Kampala: MU−JHU Research Collaboration CRS	753864926	11FEB2020	Y	03JAN2023	V67.0 − Step 4c−TDF/FTC − Week 24 (1)	03JAN2023	19JUL2022	Y		Confirmed	21FEB2023	Spontaneous Abortion (< 20 Weeks)	on the night of 18 feb 2023, she noticed heavy per vaginal bleeding and she rushed to kawempe regional referral hospital where a scan that was done on arrival was suggestive of a blighted ovum at 6w4d

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Kampala: MU−JHU Research Collaboration CRS	753878816	06NOV2019	Y	23JUN2022	V76.0 − Step 4d − Week 0 Pregnancy 1	23JUN2022	27APR2022	Y		Confirmed	21FEB2023	Full Term Live Birth (>= 37 Weeks)	she reports she delivered a baby boy on 21 feb 2022 from sda health center iii in kireka .she delivered by svd.reports had no delivery complications and was discharged on 22 feb 2022.
Uganda: Kampala: MU−JHU Research Collaboration CRS	753898469	01NOV2018	Y	10AUG2023	V117.0 − Step 6−CAB LA − Week 64 (1)	10AUG2023	19MAY2022	Y		Confirmed	−		
Uganda: Kampala: MU−JHU Research Collaboration CRS	753917968	23MAY2019	Y	19SEP2023	V118.0 − Step 6−CAB LA − Week 72 (1)	19SEP2023	03MAY2022	Y		Confirmed	20SEP2023	Therapeutic/ Elective Abortion	she went to a clinic and was given 4 tablets of misoprostol to swallow and later she aborted the same day
Uganda: Kampala: MU−JHU Research Collaboration CRS	753940384	22FEB2019	Y	12AUG2021	V25.0 Week 129 − S2 (1)	12AUG2021	21APR2022			Confirmed	06MAY2022	Full Term Live Birth (>= 37 Weeks)	hospital delivery to live male baby that cried immediately .
Uganda: Kampala: MU−JHU Research Collaboration CRS	753995022	28FEB2019		23MAY2022	V64.0 − Step 4c−TDF/ FTC − Week 0 (1)	23MAY2022	23MAY2022			Confirmed	26MAY2022	Therapeutic/ Elective Abortion	participant reported to have induced the abortion using unspecified sublingual tablets obtained from a nearby clinic.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: Seke South CRS	754108189	09APR2019	Y	12DEC2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	12DEC2022	07JUN2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: Seke South CRS	754130387	01OCT2019	Y	04AUG2022	V56.0 − Step 4b − Day 0 (1)	04AUG2022	04AUG2022			Confirmed	13MAR2023	Full Term Live Birth (>= 37 Weeks)	participant delivered by standard vaginal delivery and had an episiotomy done. she was prescribed antibiotics and sitz baths.
Zimbabwe: Chitungwiza: Seke South CRS	754140349	07MAR2019	Y	26SEP2022	V76.0 − Step 4d − Week 0 Pregnancy 1	26SEP2022	01AUG2022	Y		Confirmed	05MAY2023	Full Term Live Birth (>= 37 Weeks)	participant had a standard unassisted vaginal delivery at her local health center
Zimbabwe: Chitungwiza: Seke South CRS	754151572	05SEP2019		09FEB2022	V202 − Open Label Truvada Week 12 (1)	09FEB2022	27JUL2022			Confirmed	05SEP2022	Full Term Live Birth (>= 37 Weeks)	she did not present at the local clinic where she had booked to deliver when she went into labor and delivered at home. she presented at her local clinic 3 days later. baby was not weighed.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: Seke South CRS	754225938	20MAY2019	Y	02FEB2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	02FEB2023	07JUL2022	Y		Confirmed	15SEP2023	Full Term Live Birth (>= 37 Weeks)	she was referred from local clinic to the hospital for meconium−stained liquor. she then delivered by standard vaginal delivery and had antibiotics prescribed.
Zimbabwe: Chitungwiza: Seke South CRS	754251914	01APR2019	Y	24APR2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	24APR2023	07JUL2022	Y		Confirmed	22DEC2023	Full Term Live Birth (>= 37 Weeks)	no complicatio ns reported in both mom and infant.
Zimbabwe: Chitungwiza: Seke South CRS	754386759	05MAR2019	Y	18AUG2022	V56.0 − Step 4b − Day 0 (1)	18AUG2022	18AUG2022			Confirmed	13MAR2023	Full Term Live Birth (>= 37 Weeks)	caesarian section was done for fetal distress.
Zimbabwe: Chitungwiza: Seke South CRS	754387401	01AUG2019	Y	15FEB2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	15FEB2023	09JUN2022	Y		Confirmed	03OCT2023	Full Term Live Birth (>= 37 Weeks)	baby was delivered at local clinic. no maternal or infant complicatio ns were reported.
Zimbabwe: Chitungwiza: Seke South CRS	754388987	11APR2019	Y	08JUN2022	V56.0 − Step 4b − Day 0 (1)	08JUN2022	08JUN2022			Confirmed	24JAN2023	Full Term Live Birth (>= 37 Weeks)	she delivered by standard vaginal delivery but passed thick meconium stained liquor for which both mom and baby were treated.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: Seke South CRS	754423776	31JAN2019	Y	06APR2022	V203 − Open Label Truvada Week 24 (1)	06APR2022	23JUN2022			Confirmed	11NOV2022	Full Term Live Birth (>= 37 Weeks)	standard vaginal delivery labor duration lasted 2 hours and 55 minutes.
Zimbabwe: Chitungwiza: Seke South CRS	754427832	12SEP2019	Y	02OCT2023	V116.0 − Step 6−CAB LA − Week 56 (1)	02OCT2023	25JUL2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: Seke South CRS	754440908	25JUL2019	Y	07DEC2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	07DEC2022	06JUL2022	Y		Confirmed	16DEC2022	Spontaneous Abortion (< 20 Weeks)	participant had an uncomplicated spontaneous abortion at home and did not seek medical attention. an ultrasound scan done on 06 jan 23 showed no retained products of conception.
Zimbabwe: Chitungwiza: Seke South CRS	754440908	25JUL2019	Y	11JAN2024	V118.0 − Step 6−CAB LA − Week 72 (1)	11JAN2024	06JUL2022	Y		Ended Prior To Confirmation	28DEC2023	Spontaneous Abortion (< 20 Weeks)	she had a spontaneous miscarriage on 28 dec 23 and had rpocs . she was given misoprostol orally on 02 jan 24 and repeat uss showed rpocs on 15 jan 24.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: Seke South CRS	754452785	31JUL2019	Y	05DEC2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	05DEC2022	28JUL2022	Y		Confirmed	06JUL2023	Full Term Live Birth (>= 37 Weeks)	participant delivered a full−term girl and sustained perineal lacerations. there were no infant or maternal complicatio ns.
Zimbabwe: Chitungwiza: Seke South CRS	754458612	22JAN2019	Y	15MAR2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	15MAR2023	15JUN2022	Y		Confirmed	01NOV2023	Full Term Live Birth (>= 37 Weeks)	participant delivered at home and was assisted by a traditional birth attendant.
Zimbabwe: Chitungwiza: Seke South CRS	754471087	09JUL2019	Y	19JUN2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	19JUN2023	22JUN2022	Y		Confirmed	06FEB2024	Full Term Live Birth (>= 37 Weeks)	this was a post−dates delivery. no complicatio ns reported in both mom and infant except perineal lacerations in mom.
Zimbabwe: Chitungwiza: Seke South CRS	754481374	19FEB2019	Y	11JAN2023	V60.0 − Step 4c−CAB LA − Week 24 (1)	11JAN2023	23JUN2022	Y		Confirmed	30AUG2023	Full Term Live Birth (>= 37 Weeks)	no maternal or infant complicatio ns were reported.
Zimbabwe: Chitungwiza: Seke South CRS	754514746	20FEB2019	Y	27NOV2023	V118.0 − Step 6−CAB LA − Week 72 (1)	27NOV2023	30JUN2022	Y		Confirmed	12DEC2023	Spontaneous Abortion (< 20 Weeks)	she had a incomplete miscarriage. date of miscarriage isn't known but uss scan done on 12 dec 23 showed no fetal pole. repeat uss on 23 jan 24 showed incomplete miscarriage.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: Seke South CRS	754544202	01AUG2019	Y	15MAY2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	15MAY2023	15AUG2022	Y		Confirmed	24NOV2023	Full Term Live Birth (>= 37 Weeks)	participant delivered at home and only registered the birth on 27 nov 23.
Zimbabwe: Chitungwiza: Seke South CRS	754545184	14OCT2019	Y	15FEB2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	15FEB2023	02JUN2022	Y		Confirmed	15OCT2023	Full Term Live Birth (>= 37 Weeks)	normal vaginal delivery of a boy who was exposed to syphilis and whose mother was hospitalised for substance−induced psychosis.
Zimbabwe: Chitungwiza: Seke South CRS	754577766	08OCT2019	Y	03FEB2022	V203 − Open Label Truvada Week 24 (1)	03FEB2022	21JUL2022			Confirmed	24SEP2022	Full Term Live Birth (>= 37 Weeks)	participant had a standard vaginal delivery
Zimbabwe: Chitungwiza: Seke South CRS	754623726	30APR2019	Y	06MAR2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	06MAR2023	30MAY2022	Y		Confirmed	13OCT2023	Full Term Live Birth (>= 37 Weeks)	she delivered a full term live baby girl. there were no maternal nor fetal complicatio ns.
Zimbabwe: Chitungwiza: Seke South CRS	754689125	11SEP2019	Y	09NOV2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	09NOV2022	23JUN2022	Y		Confirmed	31DEC2022	Spontaneous Abortion (< 20 Weeks)	non viable pregnancy was picked on ultrasound scan. she was not bleeding and cervical os was closed. participant declined both medical and surgical evacuation of retained products.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: Seke South CRS	754689125	11SEP2019	Y	05DEC2023	V118.0 − Step 6−CAB LA − Week 72 (1)	05DEC2023	23JUN2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: Seke South CRS	754689864	10OCT2019	Y	27JUL2022	V76.0 − Step 4d − Week 0 Pregnanc y 1	27JUL2022	01JUN2022	Y		Confirmed	16OCT2022	Spontaneous Abortion (< 20 Weeks)	participant had a spontaneou s abortion at home and did not immediately seek medical attention.
Zimbabwe: Chitungwiza: Seke South CRS	754693177	02JUL2019	Y	08DEC2023	V118.0 − Step 6−CAB LA − Week 72 (1)	08DEC2023	16JUN2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: Seke South CRS	754710179	09OCT2019	Y	03MAY2022	V202 − Open Label Truvada Week 12 (1)	03MAY2022	08JUN2022			Confirmed	26DEC2022	Full Term Live Birth (>= 37 Weeks)	this was a normal standard vaginal delivery with no complicatio ns reported in both baby and mom. however, the mother did not know her lnmp and uss showed edd of 26 nov 22. she delivered on 26 dec 22.
Zimbabwe: Chitungwiza: Seke South CRS	754724887	12SEP2019	Y	30MAY2022	V55.0 − Step 4a − Day 0 (1)	30MAY2022	30MAY2022			Confirmed	09DEC2022	Full Term Live Birth (>= 37 Weeks)	standard vaginal delivery
Zimbabwe: Chitungwiza: Seke South CRS	754798852	03JUL2019	Y	12DEC2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	12DEC2022	10JUN2022	Y		Confirmed	31JUL2023	Full Term Live Birth (>= 37 Weeks)	

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: Seke South CRS	754822026	09OCT2019	Y	14DEC2023	V118.0 − Step 6−CAB LA − Week 72 (1)	14DEC2023	13JUL2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: Seke South CRS	754863833	19SEP2019	Y	26FEB2024	V119.0 − Step 4c−CAB LA − Week 80 (1)	26FEB2024	04JUL2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: Seke South CRS	754880675	31JAN2019	Y	22JAN2024	V119.0 − Step 4c−CAB LA − Week 80 (1)	22JAN2024	30JUN2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: Seke South CRS	754905721	27FEB2019	Y	17AUG2022	V56.0 − Step 4b − Day 0 (1)	17AUG2022	17AUG2022			Confirmed	−		
Zimbabwe: Chitungwiza: Seke South CRS	754906674	07OCT2019	Y	12DEC2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	12DEC2022	08JUN2022	Y		Confirmed	04JUN2023	Premature Term Live Birth (< 37 Weeks)	caesarian section was done for abnormal dopplers
Zimbabwe: Chitungwiza: Seke South CRS	754921154	30JUL2019	Y	25JUL2022	V56.0 − Step 4b − Day 0 (1)	25JUL2022	25JUL2022			Confirmed	27FEB2023	Full Term Live Birth (>= 37 Weeks)	normal vaginal delivery with no infant or maternal complicatio ns.
Malawi: Blantyre: Blantyre CRS	760312658	16APR2019	Y	27FEB2024	V119.0 − Step 4c−CAB LA − Week 80 (1)	27FEB2024	06SEP2022	Y		Confirmed	−		
Malawi: Blantyre: Blantyre CRS	760369980	01MAR2019	Y	22SEP2022	V56.0 − Step 4b − Day 0 (1)	22SEP2022	22SEP2022			Confirmed	03JUN2023	Full Term Live Birth (>= 37 Weeks)	normal spontaneou s vaginal delivery
Malawi: Blantyre: Blantyre CRS	760383696	22MAR2019	Y	11JAN2022	V205 − Open Label Truvada Week 48 (1)	11JAN2022	29JUL2022			Confirmed	07AUG2022	Full Term Live Birth (>= 37 Weeks)	normal spontaneou s vaginal delivery

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Malawi: Blantyre: Blantyre CRS	760435612	04JUL2019	Y	04SEP2023	V116.0 − Step 6−CAB LA − Week 56 (1)	04SEP2023	04AUG2022	Y		Confirmed	−		
Malawi: Lilongwe: Malawi CRS	760485693	16MAY2019	Y	08SEP2022	V76.0 − Step 4d − Week 0 Pregnanc y 1	08SEP2022	24FEB2022	Y		Confirmed	12APR2023	Full Term Live Birth (>= 37 Weeks)	participant underwent induction of labour and delivered a live 3400g female infant
Malawi: Blantyre: Blantyre CRS	760534405	02AUG2019	Y	03AUG2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	03AUG2023	05SEP2022	Y		Confirmed	−		
Malawi: Blantyre: Blantyre CRS	760541244	06JUN2019	Y	23NOV2023	V117.0 − Step 6−CAB LA − Week 64 (1)	23NOV2023	01SEP2022	Y		Confirmed	−		
Malawi: Blantyre: Blantyre CRS	760738802	17OCT2019		08MAY2023	V69.0 − Step 4c−TDF/ FTC − Week 40 (1)	08MAY2023	01AUG2022	Y		Confirmed	05JUN2023	Spontaneous Abortion (< 20 Weeks)	had positive pregnancy at visit 69.0.then scanning report on 05 june shows missed abortion.
Malawi: Blantyre: Blantyre CRS	760811063	31JAN2019	Y	23AUG2022	V56.0 − Step 4b − Day 0 (1)	23AUG2022	23AUG2022			Confirmed	20APR2023	Full Term Live Birth (>= 37 Weeks)	spontaneou s vaginal delivery
Malawi: Blantyre: Blantyre CRS	760877692	20AUG2019	Y	28OCT2022	V57.0 − Step 4c−CAB LA − Week 0 (1)	28OCT2022	04AUG2022	Y		Confirmed	07JUL2023	Full Term Live Birth (>= 37 Weeks)	participant had one previous c−section scar
Malawi: Blantyre: Blantyre CRS	760899011	05JUN2019	Y	09MAY2023	V60.0 − Step 4c−CAB LA − Week 24 (1)	09MAY2023	01SEP2022	Y		Confirmed	21NOV2023	Full Term Live Birth (>= 37 Weeks)	spontaneou s vaginal delivery

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: St.Mary's CRS	762129566	11SEP2019	Y	05JUN2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	05JUN2023	21JUN2022	Y		Confirmed	04AUG2023	Spontaneous Abortion (< 20 Weeks)	reported that she had an incomplete abortion on 04 aug 2023
Zimbabwe: Chitungwiza: St.Mary's CRS	762129566	11SEP2019	Y	22FEB2024	V120.0 − Step 4c−CAB LA − Week 88 (1)	22FEB2024	21JUN2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: St.Mary's CRS	762138551	25JUL2019	Y	24JAN2024	V118.0 − Step 6−CAB LA − Week 72 (1)	24JAN2024	13JUL2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: St.Mary's CRS	762157246	16MAY2018		12DEC2022	V67.0 − Step 4c−TDF/ FTC − Week 24 (1)	12DEC2022	13JUN2022	Y		Confirmed	18JUL2023	Full Term Live Birth (>= 37 Weeks)	participant delivered twin girls at hospital on 18 jul 2023
Zimbabwe: Chitungwiza: St.Mary's CRS	762157246	16MAY2018		12DEC2022	V67.0 − Step 4c−TDF/ FTC − Week 24 (1)	12DEC2022	13JUN2022	Y		Confirmed	18JUL2023	Full Term Live Birth (>= 37 Weeks)	participant delivered twin girls at the hospital on 18 jul 2023
Zimbabwe: Chitungwiza: St.Mary's CRS	762164599	03JUL2019	Y	28FEB2022	V203 − Open Label Truvada Week 24 (1)	28FEB2022	01JUN2022			Confirmed	12SEP2022	Premature Term Live Birth (< 37 Weeks)	delivered a live baby boy by nvd on 12 sep 2022.
Zimbabwe: Chitungwiza: St.Mary's CRS	762189636	14AUG2019	Y	06APR2022	V26.0 Week 137 − S2 (1)	06APR2022	06JUN2022			Confirmed	04DEC2022	Full Term Live Birth (>= 37 Weeks)	delivered by nvd a live female infant on 04 dec 2022 at 02:50
Zimbabwe: Chitungwiza: St.Mary's CRS	762209232	02OCT2019	Y	02NOV2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	02NOV2022	23MAY2022	Y		Confirmed	21MAY2023	Full Term Live Birth (>= 37 Weeks)	participant delivered a live baby boy on 21 may 2023.
Zimbabwe: Chitungwiza: St.Mary's CRS	762237846	15JUL2019	Y	14JUL2022	V56.0 − Step 4b − Day 0 (1)	14JUL2022	14JUL2022			Confirmed	22JAN2023	Full Term Live Birth (>= 37 Weeks)	a normal vertex delivery of a live female baby

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: St.Mary's CRS	762252275	21JAN2019	Y	27JUN2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	27JUN2023	01JUN2022	Y		Ended Prior To Confirmation	12JUN2023	Spontaneous Abortion (< 20 Weeks)	participant had a miscarriage on 12 jul 2023.
Zimbabwe: Chitungwiza: St.Mary's CRS	762296531	17SEP2019	Y	14FEB2023	V60.0 − Step 4c−CAB LA − Week 24 (1)	14FEB2023	20JUL2022	Y		Confirmed	05SEP2023	Full Term Live Birth (>= 37 Weeks)	mother delivered a live male infant
Zimbabwe: Chitungwiza: St.Mary's CRS	762302241	05MAR2019	Y	19JUL2022	V55.0 − Step 4a − Day 0 (1)	19JUL2022	19JUL2022			Confirmed	−		
Zimbabwe: Chitungwiza: St.Mary's CRS	762343689	01OCT2019	Y	10JAN2023	V67.0 − Step 4c−TDF/ FTC − Week 24 (1)	10JAN2023	20JUL2022	Y		Confirmed	24JUL2023	Full Term Live Birth (>= 37 Weeks)	delivered a live male infant by nvd
Zimbabwe: Chitungwiza: St.Mary's CRS	762346373	02SEP2019	Y	02NOV2023	V118.0 − Step 6−CAB LA − Week 72 (1)	02NOV2023	13JUN2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: St.Mary's CRS	762377362	20AUG2019	Y	29DEC2022	V71.0 − Step 5−TDF/ FTC − Day 0 (1)	29DEC2022	01JUN2022	Y		Confirmed	23MAR2023	Full Term Live Birth (>= 37 Weeks)	participant delivered a live baby girl girl through normal vertex delivery
Zimbabwe: Chitungwiza: St.Mary's CRS	762399574	16JUL2019	Y	12DEC2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	12DEC2022	19JUL2022	Y		Confirmed	01FEB2023	Therapeutic/ Elective Abortion	pregnancy medically terminated on 01 feb 2023
Zimbabwe: Chitungwiza: St.Mary's CRS	762410382	22JUL2019	Y	07JUN2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	07JUN2023	30JUN2022	Y		Confirmed	23JAN2024	Full Term Live Birth (>= 37 Weeks)	participant delivered a live female infant at 38 weeks on 23 jan 2024
Zimbabwe: Chitungwiza: St.Mary's CRS	762416801	21JAN2019	Y	17MAY2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	17MAY2023	14JUN2022	Y		Confirmed	02JAN2024	Full Term Live Birth (>= 37 Weeks)	participant delivered a live male infant at 38/40 by nvd

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: St.Mary's CRS	762442183	05AUG2019	Y	20JUL2022	V55.0 − Step 4a − Day 0 (1)	20JUL2022	20JUL2022			Confirmed	27JUL2022	Spontaneous Abortion (< 20 Weeks)	participant had an abortion on 27 jul 2022
Zimbabwe: Chitungwiza: St.Mary's CRS	762442183	05AUG2019	Y	22NOV2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	22NOV2022	20JUL2022	Y		Confirmed	17JUL2023	Full Term Live Birth (>= 37 Weeks)	participant delivered a live baby girl on 17 jul 2023
Zimbabwe: Chitungwiza: St.Mary's CRS	762443022	15MAY2019	Y	10MAY2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	10MAY2023	15JUN2022	Y		Confirmed	10JAN2024	Full Term Live Birth (>= 37 Weeks)	
Zimbabwe: Chitungwiza: St.Mary's CRS	762454307	29JUL2019	Y	19JUL2023	V116.0 − Step 6−CAB LA − Week 56 (1)	19JUL2023	13JUN2022	Y		Confirmed	10FEB2024	Full Term Live Birth (>= 37 Weeks)	live female infant delivered by nvd
Zimbabwe: Chitungwiza: St.Mary's CRS	762514984	07MAR2019	Y	21SEP2022	V65.0 − Step 4c−TDF/ FTC − Week 8 (1)	21SEP2022	25JUL2022	Y		Confirmed	14MAY2023	Full Term Live Birth (>= 37 Weeks)	participant delivered a live baby girl by cesarean section on 14 may 2023
Zimbabwe: Chitungwiza: St.Mary's CRS	762517230	07MAR2019	Y	03AUG2022	V76.0 − Step 4d − Week 0 Pregnancy 1	03AUG2022	16MAY2022	Y		Confirmed	26FEB2023	Full Term Live Birth (>= 37 Weeks)	participant delivered live baby girl on 26 feb 2023
Zimbabwe: Chitungwiza: St.Mary's CRS	762569038	02OCT2019	Y	28FEB2023	V58.0 − Step 4c−CAB LA − Week 8 (1)	28FEB2023	18MAY2022	Y		Confirmed	10OCT2023	Full Term Live Birth (>= 37 Weeks)	delivered a live female infant

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: St.Mary's CRS	762573613	09JUL2019	Y	04JAN2023	V60.0 − Step 4c−CAB LA − Week 24 (1)	04JAN2023	08JUN2022	Y		Confirmed	13JAN2023	Spontaneous Abortion (< 20 Weeks)	participant experienced pv bleeding with clots since 13 jan 2023 had an ultrasound scan on 19 jan 2023 which shows non gravida uterus
Zimbabwe: Chitungwiza: St.Mary's CRS	762584856	21NOV2018	Y	24JAN2024	V119.0 − Step 4c−CAB LA − Week 80 (1)	24JAN2024	08JUN2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: St.Mary's CRS	762652051	14MAR2018	Y	27JUL2022	V56.0 − Step 4b − Day 0 (1)	27JUL2022	27JUL2022			Confirmed	21JAN2023	Full Term Live Birth (>= 37 Weeks)	participant delivered a live male infant on 21 jan 2023
Zimbabwe: Chitungwiza: St.Mary's CRS	762668573	27FEB2018	Y	30MAY2023	V59.0 − Step 4c−CAB LA − Week 16 (1)	30MAY2023	11AUG2022	Y		Confirmed	24OCT2023	Premature Term Live Birth (< 37 Weeks)	delivered a preterm baby by caesarean section for 2 previous caesarean on 24 oct 2023
Zimbabwe: Chitungwiza: St.Mary's CRS	762691138	21MAR2018	Y	28FEB2023	V58.0 − Step 4c−CAB LA − Week 8 (1)	28FEB2023	24MAY2022	Y		Confirmed	04OCT2023	Full Term Live Birth (>= 37 Weeks)	
Zimbabwe: Chitungwiza: St.Mary's CRS	762692167	25FEB2019	Y	01JUN2022	V56.0 − Step 4b − Day 0 (1)	01JUN2022	01JUN2022			Confirmed	02JAN2023	Full Term Live Birth (>= 37 Weeks)	participant delivered a live female infant on 02 jan 2023
Zimbabwe: Chitungwiza: St.Mary's CRS	762692167	25FEB2019	Y	17JAN2024	V119.0 − Step 4c−CAB LA − Week 80 (1)	17JAN2024	01JUN2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: St.Mary's CRS	762728922	11SEP2019	Y	22NOV2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	22NOV2022	14JUL2022	Y		Confirmed	16JUL2023	Full Term Live Birth (>= 37 Weeks)	
Zimbabwe: Chitungwiza: St.Mary's CRS	762742834	08MAR2019	Y	06DEC2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	06DEC2023	02JUN2022	Y		Confirmed	13DEC2023	Spontaneous Abortion (< 20 Weeks)	participant bled from 10 dec 2023 to 13 dec 2023 at4 weeks gestation
Zimbabwe: Chitungwiza: St.Mary's CRS	762803664	24JUL2019	Y	15MAR2022	V202 − Open Label Truvada Week 12 (1)	15MAR2022	13JUN2022			Confirmed	14SEP2022	Full Term Live Birth (>= 37 Weeks)	it was a spontaneou s normal vaginal delivery
Zimbabwe: Chitungwiza: St.Mary's CRS	762810818	08MAR2019	Y	02SEP2022	V76.0 − Step 4d − Week 0 Pregnanc y 1	02SEP2022	02JUN2022	Y		Confirmed	18NOV2022	Spontaneous Abortion (< 20 Weeks)	participant had a miscarriage on 18 nov 2022 and did not seek any medical attention
Zimbabwe: Chitungwiza: St.Mary's CRS	762810818	08MAR2019	Y	17JAN2024	V119.0 − Step 4c−CAB LA − Week 80 (1)	17JAN2024	02JUN2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: St.Mary's CRS	762836271	02MAY2018	Y	30MAR2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	30MAR2023	23MAY2022	Y		Confirmed	22OCT2023	Full Term Live Birth (>= 37 Weeks)	live female infant delivered by nvd
Zimbabwe: Chitungwiza: St.Mary's CRS	762846613	22NOV2018	Y	26APR2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	26APR2023	08JUN2022	Y		Confirmed	04NOV2023	Premature Term Live Birth (< 37 Weeks)	
Zimbabwe: Chitungwiza: St.Mary's CRS	762846613	22NOV2018	Y	26APR2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	26APR2023	08JUN2022	Y		Confirmed	04NOV2023	Premature Term Live Birth (< 37 Weeks)	

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: St.Mary's CRS	762856938	09OCT2019	Y	11OCT2023	V60.0 − Step 4c−CAB LA − Week 24 (1)	11OCT2023	06JUL2022	Y		Confirmed	11OCT2023	Spontaneous Abortion (< 20 Weeks)	c/o bleeding from un sep 2023, miscarriage confirmed by uss
Zimbabwe: Chitungwiza: St.Mary's CRS	762933734	08JUL2019	Y	12JUL2023	V116.0 − Step 6−CAB LA − Week 56 (1)	12JUL2023	15JUN2022	Y		Confirmed	08NOV2023	Premature Term Live Birth (< 37 Weeks)	the participant reports that she experienced mild lower abdominal pain and backache whilst at home. she then went on to deliver a live male infant. the birth was assisted by a non skilled attendant.
Zimbabwe: Chitungwiza: St.Mary's CRS	762949037	25APR2018	Y	06DEC2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	06DEC2023	19JUL2022	Y		Confirmed	09DEC2023	Therapeutic/ Elective Abortion	
Zimbabwe: Chitungwiza: St.Mary's CRS	762964603	24SEP2019	Y	13SEP2022	V65.0 − Step 4c−TDF/ FTC − Week 8 (1)	13SEP2022	20JUL2022	Y		Confirmed	28NOV2022	Stillbirth/ Intrauterine Fetal Demise (>= 20 Weeks)	she experienced pv bleeding on 28 nov 22 and expelled fetal material at a local clinic.and had a still birth'
Zimbabwe: Chitungwiza: St.Mary's CRS	762978768	30SEP2019	Y	18JAN2024	V119.0 − Step 4c−CAB LA − Week 80 (1)	18JAN2024	02JUN2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Harare: Parirenyatwa CRS	770129737	22OCT2019	Y	15MAR2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	15MAR2023	07JUL2022	Y		Confirmed	28SEP2023	Full Term Live Birth (>= 37 Weeks)	normal vaginal delivery at term
Zimbabwe: Harare: Parirenyatwa CRS	770130605	05AUG2019	Y	24JAN2023	V60.0 − Step 4c−CAB LA − Week 24 (1)	24JAN2023	14JUL2022	Y		Ended Prior To Confirmation	11JAN2023	Ectopic Pregnancy	participant had right salpingectomy for ectopic pregnancy on 11 jan 2023.
Zimbabwe: Harare: Parirenyatwa CRS	770162407	19FEB2018	Y	26OCT2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	26OCT2022	03AUG2022	Y		Confirmed	03MAY2023	Full Term Live Birth (>= 37 Weeks)	c−section for breech presentation .
Zimbabwe: Harare: Parirenyatwa CRS	770214653	24APR2019	Y	16NOV2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	16NOV2022	01JUN2022	Y		Confirmed	30NOV2022	Spontaneous Abortion (< 20 Weeks)	participant had an ultrasound scan at 11 weeks 4 days gestation which showed failure of pregnancy progression
Zimbabwe: Harare: Parirenyatwa CRS	770214653	24APR2019	Y	12FEB2024	V120.0 − Step 4c−CAB LA − Week 88 (1)	12FEB2024	01JUN2022	Y		Confirmed	−		
Zimbabwe: Harare: Parirenyatwa CRS	770249117	09SEP2019	Y	07AUG2023	V60.0 − Step 4c−CAB LA − Week 24 (1)	07AUG2023	22JUN2022	Y		Confirmed	14AUG2023	Spontaneous Abortion (< 20 Weeks)	participant had a menstrual bleed from 14 aug 2023 to 19 aug 2023
Zimbabwe: Harare: Parirenyatwa CRS	770249117	09SEP2019	Y	08NOV2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	08NOV2023	22JUN2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Harare: Parirenyatwa CRS	770249820	15AUG2019	Y	04JUL2023	V116.0 − Step 6−CAB LA − Week 56 (1)	04JUL2023	31MAY2022	Y		Confirmed	04SEP2023	Spontaneous Abortion (< 20 Weeks)	the participant has a first trimester ultrasound scan which showed that she was no longer pregnant. she then gave history of passing brownish discharge for three days at the end of august 2023
Zimbabwe: Harare: Parirenyatwa CRS	770249820	15AUG2019	Y	02OCT2023	V118.0 − Step 6−CAB LA − Week 72 (1)	02OCT2023	31MAY2022	Y		Confirmed	−		
Zimbabwe: Harare: Parirenyatwa CRS	770355563	30MAY2019	Y	31MAY2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	31MAY2023	30JUN2022	Y		Confirmed	06JUN2023	Spontaneous Abortion (< 20 Weeks)	following a confirmed pregnancy test. no fetus seen on initial and repeat ultrasound scan.
Zimbabwe: Harare: Parirenyatwa CRS	770397053	22JUL2019	Y	21SEP2022	V57.0 − Step 4c−CAB LA − Week 0 (1)	21SEP2022	24AUG2022	Y		Confirmed	14MAY2023	Full Term Live Birth (>= 37 Weeks)	participant had an uncomplicated labour and proceeded to have a normal vaginal delivery.
Zimbabwe: Harare: Parirenyatwa CRS	770403219	28MAR2019		23AUG2022	V64.0 − Step 4c−TDF/FTC − Week 0 (1)	23AUG2022	23AUG2022			Confirmed	04NOV2022	Full Term Live Birth (>= 37 Weeks)	participant had uncomplicated labour and proceeded to a normal vaginal delivery.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Harare: Parirenyatwa CRS	770531572	20AUG2019	Y	14DEC2023	V117.0 − Step 6−CAB LA − Week 64 (1)	14DEC2023	25AUG2022	Y		Confirmed	−		
Zimbabwe: Harare: Parirenyatwa CRS	770555730	19JUN2019	Y	14FEB2024	V120.0 − Step 4c−CAB LA − Week 88 (1)	14FEB2024	07JUN2022	Y		Confirmed	−		
Zimbabwe: Harare: Parirenyatwa CRS	770602943	10APR2019	Y	20NOV2023	V118.0 − Step 6−CAB LA − Week 72 (1)	20NOV2023	06JUL2022	Y		Confirmed	−		
Zimbabwe: Harare: Parirenyatwa CRS	770705139	14FEB2019	Y	25JAN2024	V118.0 − Step 6−CAB LA − Week 72 (1)	25JAN2024	11AUG2022	Y		Confirmed	−		
Zimbabwe: Harare: Parirenyatwa CRS	770753977	06FEB2019	Y	06DEC2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	06DEC2022	12JUL2022	Y		Confirmed	08JUN2023	Full Term Live Birth (>= 37 Weeks)	participant had normal vaginal delivery at term with no obstetric complicatio ns.
Zimbabwe: Harare: Parirenyatwa CRS	770880542	25JAN2019	Y	21MAR2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	21MAR2023	14JUN2022	Y		Confirmed	16OCT2023	Full Term Live Birth (>= 37 Weeks)	had an uneventful normal vaginal delivery of a female live infant at a local clinic.
Zimbabwe: Harare: Parirenyatwa CRS	770935233	21MAR2019	Y	31AUG2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	31AUG2022	07JUL2022	Y		Confirmed	25MAR2023	Full Term Live Birth (>= 37 Weeks)	participant had an uncomplicat ed labour and proceeded to have a normal vaginal delivery

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Harare: Parirenyatwa CRS	770955071	06JUN2019	Y	16AUG2022	V65.0 − Step 4c−TDF/ FTC − Week 8 (1)	16AUG2022	21JUN2022	Y		Confirmed	26MAR2023	Full Term Live Birth (>= 37 Weeks)	uneventful normal vaginal delivery
Zimbabwe: Harare: Parirenyatwa CRS	770981966	21OCT2019	Y	10OCT2022	V57.0 − Step 4c−CAB LA − Week 0 (1)	10OCT2022	10AUG2022	Y		Confirmed	08JUN2023	Full Term Live Birth (>= 37 Weeks)	delivered by caesarean section due to post dates and one previous caesarean section
Zimbabwe: Harare: Spilhaus CRS	771145100	25FEB2019	Y	08MAY2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	08MAY2023	23MAY2022	Y		Confirmed	23NOV2023	Full Term Live Birth (>= 37 Weeks)	standard vaginal delivery at a health facility
Zimbabwe: Harare: Spilhaus CRS	771168969	01NOV2018	Y	15JUN2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	15JUN2023	02JUN2022	Y		Confirmed	03FEB2024	Full Term Live Birth (>= 37 Weeks)	participant had a standard vaginal delivery at a health facility
Zimbabwe: Harare: Spilhaus CRS	771169771	08OCT2019	Y	29SEP2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	29SEP2022	12JUL2022	Y		Confirmed	28MAY2023	Full Term Live Birth (>= 37 Weeks)	participant had a normal vaginal delivery at local clinic.
Zimbabwe: Harare: Spilhaus CRS	771211215	15APR2019	Y	29AUG2023	V117.0 − Step 6−CAB LA − Week 64 (1)	29AUG2023	31MAY2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Harare: Spilhaus CRS	771213424	09MAY2019	Y	22JUN2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	22JUN2023	26JUL2022	Y		Confirmed	08OCT2023	Stillbirth/ Intrauterine Fetal Demise (>= 20 Weeks)	participant started experiencing per vaginal bleeding on the 8th of october 2023 which culminated in intrauterine fetal demise and delivery at 23 weeks gestation
Zimbabwe: Harare: Spilhaus CRS	771302882	23MAY2019	Y	17OCT2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	17OCT2022	22JUN2022	Y		Confirmed	05JUN2023	Full Term Live Birth (>= 37 Weeks)	participant had a normal vaginal delivery at local clinic.
Zimbabwe: Harare: Spilhaus CRS	771348000	06DEC2018	Y	05APR2022	V203 − Open Label Truvada Week 24 (1)	05APR2022	13JUL2022			Confirmed	02DEC2022	Full Term Live Birth (>= 37 Weeks)	participant had a normal vaginal delivery at local clinic on 02dec22
Zimbabwe: Harare: Spilhaus CRS	771353888	08OCT2019	Y	25JUL2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	25JUL2023	21JUL2022	Y		Confirmed	−		
Zimbabwe: Harare: Spilhaus CRS	771359757	16OCT2019	Y	18OCT2022	V56.0 − Step 4b − Day 0 (1)	18OCT2022	30MAY2022	Y		Confirmed	01DEC2022	Spontaneous Abortion (< 20 Weeks)	an ultrasound done on 01 dec 22 showed no sonographic evidence of pregnancy. she did not experience any symptoms.
Zimbabwe: Harare: Spilhaus CRS	771359757	16OCT2019	Y	27JUN2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	27JUN2023	30MAY2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Harare: Spilhaus CRS	771378864	25JUL2019	Y	22JUN2022	V57.0 − Step 4c−CAB LA − Week 0 (1)	22JUN2022	22JUN2022			Confirmed	15FEB2023	Full Term Live Birth (>= 37 Weeks)	participant had a c−section done for 1 previous c−section at harare hospital
Zimbabwe: Harare: Spilhaus CRS	771395505	24JUL2019	Y	10JAN2023	V60.0 − Step 4c−CAB LA − Week 24 (1)	10JAN2023	15JUL2022	Y		Confirmed	11AUG2023	Full Term Live Birth (>= 37 Weeks)	participant had a standard vaginal delivery. duration of labour was 7 hours
Zimbabwe: Harare: Spilhaus CRS	771426649	15NOV2018	Y	12SEP2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	12SEP2023	07JUN2022	Y		Confirmed	19SEP2023	Therapeutic/ Elective Abortion	abortion was self−induced by use of an unnamed sublingual pill on 19 sep 23. s he then took oral amoxycillin and metronidazole for a week to prevent infection. no complications reported
Zimbabwe: Harare: Spilhaus CRS	771429498	21OCT2019	Y	14FEB2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	14FEB2023	06JUN2022	Y		Confirmed	03SEP2023	Premature Term Live Birth (< 37 Weeks)	participant had pre−term vaginal delivery at a hospital
Zimbabwe: Harare: Spilhaus CRS	771429498	21OCT2019	Y	14FEB2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	14FEB2023	06JUN2022	Y		Confirmed	03SEP2023	Premature Term Live Birth (< 37 Weeks)	participant had preterm delivery at a hospital.
Zimbabwe: Harare: Spilhaus CRS	771430809	17JAN2019	Y	24JAN2024	V119.0 − Step 4c−CAB LA − Week 80 (1)	24JAN2024	07JUN2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Harare: Spilhaus CRS	771453608	05SEP2019	Y	02JAN2024	V119.0 − Step 4c−CAB LA − Week 80 (1)	02JAN2024	14JUN2022	Y		Confirmed	−		
Zimbabwe: Harare: Spilhaus CRS	771491157	09SEP2019	Y	03AUG2022	V57.0 − Step 4c−CAB LA − Week 0 (1)	03AUG2022	11JUL2022	Y		Confirmed	31MAR2023	Full Term Live Birth (>= 37 Weeks)	participant had a normal vaginal delivery at local hospital
Zimbabwe: Harare: Spilhaus CRS	771534304	25JUN2019		11JAN2022	V204 − Open Label Truvada Week 36 (1)	11JAN2022	29JUN2022			Confirmed	04AUG2022	Full Term Live Birth (>= 37 Weeks)	participant had a normal vaginal delivery at local clinic
Zimbabwe: Harare: Spilhaus CRS	771545025	14OCT2019	Y	21NOV2023	V118.0 − Step 6−CAB LA − Week 72 (1)	21NOV2023	07JUN2022	Y		Confirmed	11JAN2024	Spontaneous Abortion (< 20 Weeks)	participant experienced per vaginal bleeding from 20 nov 23 to 03 dec 23. ultrasound scan done on 01 dec 23 showed intrauterine pregnancy and a scan done on 11 jan 24 showed non−gravid uterus.
Zimbabwe: Harare: Spilhaus CRS	771610240	18FEB2019	Y	16NOV2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	16NOV2022	15JUL2022	Y		Confirmed	03JUL2023	Full Term Live Birth (>= 37 Weeks)	had a standard vaginal delivery at her local clinic

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Harare: Spilhaus CRS	771634170	18OCT2019	Y	28AUG2023	V117.0 − Step 6−CAB LA − Week 64 (1)	28AUG2023	30MAY2022	Y		Confirmed	04SEP2023	Spontaneous Abortion (< 20 Weeks)	initial ultrasound done on 04 sep 23 showed non−gravid uterus. repeat scan was done on 02 oct 23 and showed a non−gravid uterus. participant experienced bleeding from 02 sep 23.
Zimbabwe: Harare: Spilhaus CRS	771660330	23APR2019	Y	29JAN2024	V120.0 − Step 4c−CAB LA − Week 88 (1)	29JAN2024	23MAY2022	Y		Confirmed	−		
Zimbabwe: Harare: Spilhaus CRS	771675982	23APR2019	Y	19APR2022	V202 − Open Label Truvada Week 12 (1)	19APR2022	08JUN2022			Confirmed	11DEC2022	Full Term Live Birth (>= 37 Weeks)	participant had a normal vaginal delivery at a local clinic
Zimbabwe: Harare: Spilhaus CRS	771699787	24OCT2019	Y	10OCT2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	10OCT2022	20JUN2022	Y		Confirmed	05MAY2023	Full Term Live Birth (>= 37 Weeks)	participant had a normal vaginal delivery at local hospital
Zimbabwe: Harare: Spilhaus CRS	771724445	30MAY2019	Y	17JAN2022	V26.0 Week 137 − S2 (1)	17JAN2022	16JUN2022			Confirmed	23AUG2022	Full Term Live Birth (>= 37 Weeks)	participant had a normal vaginal delivery at local clinic
Zimbabwe: Harare: Spilhaus CRS	771743385	14JAN2019	Y	22MAY2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	22MAY2023	25JUL2022	Y		Confirmed	19JUN2023	Spontaneous Abortion (< 20 Weeks)	participant has vaginal bleeding and subsequent spontaneous abortion

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Harare: Spilhaus CRS	771825218	08MAY2019	Y	07AUG2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	07AUG2023	03AUG2022	Y		Confirmed	03FEB2024	Full Term Live Birth (>= 37 Weeks)	
Zimbabwe: Harare: Spilhaus CRS	771840403	04SEP2019	Y	23MAR2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	23MAR2023	14JUN2022	Y		Confirmed	08OCT2023	Full Term Live Birth (>= 37 Weeks)	participant went into spontaneous labor at 41 weeks and 5 days by dates. she had a standard vaginal delivery.
Zimbabwe: Harare: Spilhaus CRS	771855650	11SEP2019	Y	13OCT2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	13OCT2022	22JUN2022	Y		Confirmed	10NOV2022	Spontaneous Abortion (< 20 Weeks)	participant had an ultrasound scan on 10nov22 and no pregnancy was noted
Zimbabwe: Harare: Spilhaus CRS	771855650	11SEP2019	Y	02FEB2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	02FEB2023	22JUN2022	Y		Confirmed	18AUG2023	Full Term Live Birth (>= 37 Weeks)	participant had a normal vaginal delivery at local clinic
Zimbabwe: Harare: Spilhaus CRS	771886502	16MAY2019	Y	31JAN2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	31JAN2023	15JUN2022	Y		Confirmed	06AUG2023	Full Term Live Birth (>= 37 Weeks)	participant had a normal vaginal delivery at local clinic

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Harare: Spilhaus CRS	771952514	22OCT2019	Y	13MAR2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	13MAR2023	24MAY2022	Y		Confirmed	29MAY2023	Spontaneous Abortion (< 20 Weeks)	participant had grade 2 per vaginal bleeding from 29may23, associated with grade 1 backache and grade 1 lower abdominal pain . uss showed a non−gravid uterus and retained products of conception.
Zimbabwe: Harare: Spilhaus CRS	771974001	03JUL2019	Y	04APR2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	04APR2023	08JUN2022	Y		Confirmed	07NOV2023	Full Term Live Birth (>= 37 Weeks)	participant had a standard vaginal delivery
Zimbabwe: Chitungwiza: Zengeza CRS	774229208	26FEB2019	Y	07JUN2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	07JUN2023	07JUN2022	Y		Confirmed	04FEB2023	Full Term Live Birth (>= 37 Weeks)	participant had a lower segment caesarean section done
Zimbabwe: Chitungwiza: Zengeza CRS	774232801	15OCT2019	Y	24NOV2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	24NOV2022	09JUN2022	Y		Confirmed	19MAY2023	Premature Term Live Birth (< 37 Weeks)	preterm delivery at 34 weeks and 1 day with birth weight of 1900grams
Zimbabwe: Chitungwiza: Zengeza CRS	774232801	15OCT2019	Y	24NOV2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	24NOV2022	09JUN2022	Y		Confirmed	19MAY2023	Premature Term Live Birth (< 37 Weeks)	participant went into preterm labour and had standard vaginal delivery of twin pregnancy at 34 weeks and 1 day

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: Zengeza CRS	774291401	12NOV2018	Y	23FEB2023	V60.0 − Step 4c−CAB LA − Week 24 (1)	23FEB2023	21JUL2022	Y		Confirmed	23OCT2023	Full Term Live Birth (>= 37 Weeks)	
Zimbabwe: Chitungwiza: Zengeza CRS	774313675	28MAY2019	Y	13DEC2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	13DEC2022	05JUL2022	Y		Confirmed	13JUL2023	Full Term Live Birth (>= 37 Weeks)	
Zimbabwe: Chitungwiza: Zengeza CRS	774335634	04SEP2019	Y	21NOV2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	21NOV2022	07JUN2022	Y		Confirmed	30MAY2023	Full Term Live Birth (>= 37 Weeks)	participant had a normal vaginal delivery to a live, healthy girl infant with no complicatio ns.
Zimbabwe: Chitungwiza: Zengeza CRS	774336973	27MAR2019	Y	06OCT2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	06OCT2022	14JUL2022	Y		Confirmed	24FEB2023	Stillbirth/ Intrauterine Fetal Demise (>= 20 Weeks)	participant was referred to a tertiary hospital for manageme nt of grade 2 gestational hypertensio n where she was diagnosed of intrauterine fetal demise with a with subsequent macerated still birth

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: Zengeza CRS	774356961	30APR2018	Y	24JUL2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	24JUL2023	27JUN2022	Y		Confirmed	31AUG2023	Spontaneous Abortion (< 20 Weeks)	participant reported she had vaginal bleeding, low back pain and lower abdominal pain a week after her visit on 24 jul 23. uss done on 06 sep 2023 revealed incomplete miscarriage for erpoc.
Zimbabwe: Chitungwiza: Zengeza CRS	774358445	01MAR2018	Y	06NOV2023	V118.0 − Step 6−CAB LA − Week 72 (1)	06NOV2023	24MAY2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: Zengeza CRS	774369432	28MAR2018		28NOV2022	V67.0 − Step 4c−TDF/ FTC − Week 24 (1)	28NOV2022	21JUN2022	Y		Ended Prior To Confirmation	07NOV2022	Spontaneous Abortion (< 20 Weeks)	had a spontaneous miscarriage on 07 nov 2022 and was managed at a local health facility.
Zimbabwe: Chitungwiza: Zengeza CRS	774414379	12SEP2019	Y	24JUL2023	V116.0 − Step 6−CAB LA − Week 56 (1)	24JUL2023	16JUN2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: Zengeza CRS	774419797	25MAR2019	Y	18AUG2022	V57.0 − Step 4c−CAB LA − Week 0 (1)	18AUG2022	20JUL2022	Y		Confirmed	10APR2023	Full Term Live Birth (>= 37 Weeks)	participant had a normal vaginal delivery to a live boy infant with no delivery challenges.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: Zengeza CRS	774421331	27SEP2018	Y	13APR2022	V205 − Open Label Truvada Week 48 (1)	13APR2022	20JUN2022			Confirmed	22JUN2022	Spontaneous Abortion (< 20 Weeks)	participant disclosed that she had a spontaneous miscarriage at home at ega 14 weeks 2 days.
Zimbabwe: Chitungwiza: Zengeza CRS	774421331	27SEP2018	Y	24APR2023	Interim Visit − OLE 79.8	24APR2023	20JUN2022	Y		Confirmed	15NOV2023	Full Term Live Birth (>= 37 Weeks)	participant delivered a healthy boy infant through a lower segment caesarean section with no complications.
Zimbabwe: Chitungwiza: Zengeza CRS	774474144	18JUL2019	Y	10MAY2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	10MAY2023	21JUN2022	Y		Confirmed	28DEC2023	Full Term Live Birth (>= 37 Weeks)	participant had an emergency lscs to a live girl infant with low birth weight after suffering from intrauterine growth restriction.
Zimbabwe: Chitungwiza: Zengeza CRS	774516096	21JAN2019	Y	20JUL2022	V56.0 − Step 4b − Day 0 (1)	20JUL2022	20JUL2022			Confirmed	14OCT2022	Full Term Live Birth (>= 37 Weeks)	had a normal vaginal delivery at a local health facility with no complications.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: Zengeza CRS	774529393	15MAY2018	Y	12DEC2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	12DEC2022	13JUN2022	Y		Confirmed	13JAN2023	Other	per uss, the participant was diagnosed of an unembryonic pregnancy/ blighted ovum after which she miscarried.
Zimbabwe: Chitungwiza: Zengeza CRS	774565054	23JAN2019	Y	13SEP2023	V117.0 − Step 6−CAB LA − Week 64 (1)	13SEP2023	22JUN2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: Zengeza CRS	774626164	02OCT2018		24JAN2022	V202 − Open Label Truvada Week 12 (1)	24JAN2022	13JUL2022			Confirmed	13SEP2022	Full Term Live Birth (>= 37 Weeks)	participant had a home delivery through normal vaginal delivery to a live girl infant who reportedly cried t birth . no delivery complications reported nor noted.
Zimbabwe: Chitungwiza: Zengeza CRS	774631603	13MAY2019	Y	14NOV2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	14NOV2022	20JUL2022	Y		Confirmed	03JUL2023	Full Term Live Birth (>= 37 Weeks)	partticipant delivered through an uncomplicated caesarean section.
Zimbabwe: Chitungwiza: Zengeza CRS	774670422	27JUN2019	Y	26OCT2023	Interim Visit − OLE 117.1	26OCT2023	06JUN2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: Zengeza CRS	774702670	01OCT2018	Y	04APR2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	04APR2023	02JUN2022	Y		Confirmed	26APR2023	Spontaneous Abortion (< 20 Weeks)	participant was diagnosed of intrauterine fetal demise at ega 8 weeks 4 days, through an obstetric ultrasound scan done on 26 apr 2023.
Zimbabwe: Chitungwiza: Zengeza CRS	774734310	24SEP2018	Y	21NOV2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	21NOV2022	06JUN2022	Y		Confirmed	08FEB2023	Spontaneous Abortion (< 20 Weeks)	participant was diagnosed of an anembryonic gestational sac per ultrasonography.
Zimbabwe: Chitungwiza: Zengeza CRS	774764437	23JAN2019	Y	22JUN2022	V56.0 − Step 4b − Day 0 (1)	22JUN2022	22JUN2022			Confirmed	27NOV2022	Full Term Live Birth (>= 37 Weeks)	participant had a standard uncomplicated vaginal delivery
Zimbabwe: Chitungwiza: Zengeza CRS	774788291	13SEP2018	Y	27FEB2024	V119.0 − Step 4c−CAB LA − Week 80 (1)	27FEB2024	20JUL2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: Zengeza CRS	774800987	17JUN2019	Y	17NOV2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	17NOV2022	31MAY2022	Y		Confirmed	13JUN2023	Full Term Live Birth (>= 37 Weeks)	participant had a normal vaginal delivery to a live healthy girl infant with no complications

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: Zengeza CRS	774801731	09APR2019	Y	20SEP2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	20SEP2022	30MAY2022	Y		Confirmed	08MAY2023	Full Term Live Birth (>= 37 Weeks)	participant had a normal vaginal delivery to a live boy infant with no obstetric complications.
Zimbabwe: Chitungwiza: Zengeza CRS	774812285	20MAR2018	Y	05DEC2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	05DEC2022	26MAY2022	Y		Confirmed	24JUL2023	Full Term Live Birth (>= 37 Weeks)	
Zimbabwe: Chitungwiza: Zengeza CRS	774878578	25SEP2019	Y	19JAN2023	V60.0 − Step 4c−CAB LA − Week 24 (1)	19JAN2023	13JUL2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: Zengeza CRS	774878578	25SEP2019	Y	28JUN2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	28JUN2023	13JUL2022	Y		Confirmed	21FEB2024	Full Term Live Birth (>= 37 Weeks)	
Zimbabwe: Chitungwiza: Zengeza CRS	774919591	14NOV2018	Y	23FEB2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	23FEB2023	09JUN2022	Y		Confirmed	20OCT2023	Full Term Live Birth (>= 37 Weeks)	had a normal vaginal delivery to a healthy boy infant.
Zimbabwe: Chitungwiza: Zengeza CRS	774941857	25JUN2019	Y	05DEC2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	05DEC2023	31MAY2022	Y		Confirmed	−		
Zimbabwe: Chitungwiza: Zengeza CRS	774971267	05DEC2018	Y	28SEP2023	V74.0 − Step 5−TDF/FTC − Week 36 (1)	28SEP2023	19JUL2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Zimbabwe: Chitungwiza: Zengeza CRS	774983867	27MAR2018	Y	12JAN2023	V60.0 − Step 4c−CAB LA − Week 24 (1)	12JAN2023	16JUN2022	Y		Confirmed	28JAN2023	Spontaneous Abortion (< 20 Weeks)	participant had a spontaneous miscarriage in january 2023. no further management undertaken.
Zimbabwe: Chitungwiza: Zengeza CRS	774983867	27MAR2018	Y	19APR2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	19APR2023	16JUN2022	Y		Confirmed	21NOV2023	Full Term Live Birth (>= 37 Weeks)	participant had a c−section done on 21 nov 2023 with no complications.
Zimbabwe: Chitungwiza: Zengeza CRS	774989707	15OCT2019	Y	24NOV2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	24NOV2022	09JUN2022	Y		Confirmed	16MAY2023	Other	an ultrasound scan done on 09 mar 23 showed a non−gravid uterus. a follow−up scan done on 16 may 23 showed molar pregnancy. she was admitted and suction and curettage done on 23 may 23.
Zimbabwe: Chitungwiza: Zengeza CRS	774996623	22JUL2019	Y	09MAY2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	09MAY2023	05JUL2022	Y		Confirmed	04JAN2024	Full Term Live Birth (>= 37 Weeks)	participant had a normal vaginal delivery of a live female infant

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
South Africa: Cape Town: Emavundleni CRS	779248407	16NOV2018	Y	15JUN2023	V116.0 − Step 6−CAB LA − Week 56 (1)	15JUN2023	12APR2022	Y		Confirmed	26JAN2024	Premature Term Live Birth (< 37 Weeks)	participant went into labour at 36weeks 1 day and had normal vaginal delivery at guguletu midwife obstetric unit
South Africa: Cape Town: Emavundleni CRS	779363099	10MAY2019	Y	11JAN2024	V120.0 − Step 4c−CAB LA − Week 88 (1)	11JAN2024	05MAY2022	Y		Confirmed	12JAN2024	Therapeutic/ Elective Abortion	
South Africa: Cape Town: Emavundleni CRS	779453467	09APR2019	Y	31AUG2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	31AUG2023	15MAR2022	Y		Confirmed	−		
South Africa: Cape Town: Emavundleni CRS	779577757	24JAN2019	Y	08SEP2023	V118.0 − Step 6−CAB LA − Week 72 (1)	08SEP2023	05APR2022	Y		Confirmed	−		
South Africa: Cape Town: Emavundleni CRS	779629144	03MAY2019		19APR2022	V64.0 − Step 4c−TDF/ FTC − Week 0 (1)	19APR2022	19APR2022			Ended Prior To Confirmation	23APR2022	Ectopic Pregnancy	had an ectopic pregnancy with salpingectomy.
South Africa: Cape Town: Emavundleni CRS	779807740	20JUN2019		14APR2022	V64.0 − Step 4c−TDF/ FTC − Week 0 (1)	14APR2022	14APR2022			Ended Prior To Confirmation	18APR2022	Spontaneous Abortion (< 20 Weeks)	participant had complete miscarriage.
South Africa: Cape Town: Emavundleni CRS	779919200	10DEC2019		01DEC2022	V68.0 − Step 4c−TDF/ FTC − Week 32 (1)	01DEC2022	09APR2022	Y		Confirmed	−		
South Africa: Cape Town: Emavundleni CRS	779948233	18APR2019	Y	18APR2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	18APR2023	22MAR2022	Y		Confirmed	07NOV2023	Full Term Live Birth (>= 37 Weeks)	planned c−section because of previous c−section

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
South Africa: Cape Town: Emavundleni CRS	779955411	17JAN2020		05JAN2023	V69.0 − Step 4c−TDF/ FTC − Week 40 (1)	01NOV2022	22MAR2022	Y		Confirmed	−		
South Africa: Botha's Hill: Botha's Hill CRS	789286635	04OCT2018		25OCT2022	V67.0 − Step 4c−TDF/ FTC − Week 24 (1)	25OCT2022	10MAY2022	Y		Confirmed	−		
South Africa: Botha's Hill: Botha's Hill CRS	789472370	26OCT2018		09JAN2023	V67.0 − Step 4c−TDF/ FTC − Week 24 (1)	09JAN2023	19JUL2022	Y		Confirmed	17AUG2023	Full Term Live Birth (>= 37 Weeks)	ppt delivered term baby by caesarean section for preeclampsia. baby is well
South Africa: Botha's Hill: Botha's Hill CRS	789555359	31JUL2020	Y	15FEB2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	15FEB2023	11MAY2022	Y		Confirmed	−		
South Africa: Botha's Hill: Botha's Hill CRS	789555359	31JUL2020	Y	07JUN2023	V116.0 − Step 6−CAB LA − Week 56 (1)	07JUN2023	11MAY2022	Y		Confirmed	07JAN2024	Full Term Live Birth (>= 37 Weeks)	ppt delivered a normal baby boy −3.5kg by c/s . mother and baby are well.
South Africa: Botha's Hill: Botha's Hill CRS	789582677	24OCT2018	Y	04OCT2023	V118.0 − Step 6−CAB LA − Week 72 (1)	04OCT2023	12MAY2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
South Africa: Botha's Hill: Botha's Hill CRS	789587048	07JUN2019		21OCT2022	V66.0 − Step 4c−TDF/FTC − Week 16 (1)	21OCT2022	29JUN2022	Y		Confirmed	28OCT2022	Spontaneous Abortion (< 20 Weeks)	started with lower abdominal pain then bleeding went to hospital, ultrasound confirmed incomplete abortion, she refused removal of products and requested to go home
South Africa: Botha's Hill: Botha's Hill CRS	789587048	07JUN2019		10FEB2023	V68.0 − Step 4c−TDF/FTC − Week 32 (1)	10FEB2023	29JUN2022	Y		Confirmed	22SEP2023	Full Term Live Birth (>= 37 Weeks)	delivered by normal vaginal delivery− a normal baby girl
South Africa: Botha's Hill: Botha's Hill CRS	789670319	26SEP2019	Y	03APR2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	03APR2023	16MAY2022	Y		Confirmed	−		
South Africa: Botha's Hill: Botha's Hill CRS	789787801	22MAY2019	Y	15FEB2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	15FEB2023	28APR2022	Y		Confirmed	−		
South Africa: Botha's Hill: Botha's Hill CRS	789799056	26OCT2018	Y	08AUG2023	V117.0 − Step 6−CAB LA − Week 64 (1)	08AUG2023	13MAY2022	Y		Confirmed	−		
South Africa: Botha's Hill: Botha's Hill CRS	789844996	01MAR2019		16MAY2023	V70.0 − Step 4c−TDF/FTC − Week 48 (1)	16MAY2023	14JUN2022	Y		Confirmed	−		
South Africa: Botha's Hill: Botha's Hill CRS	789885268	26SEP2019	Y	10MAR2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	10MAR2023	06MAY2022	Y		Confirmed	23NOV2023	Full Term Live Birth (>= 37 Weeks)	ppt delieved a healthy male baby at term

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
South Africa: Botha's Hill: Botha's Hill CRS	789893462	28AUG2020		28OCT2022	V67.0 − Step 4c−TDF/ FTC − Week 24 (1)	28OCT2022	13MAY2022	Y		Confirmed	07MAY2023	Full Term Live Birth (>= 37 Weeks)	ppt delivered normally a healthy baby boy on the 7th of may without complicatio ns−birth weight 3.2kg. mom and baby discharged same day
South Africa: Botha's Hill: Botha's Hill CRS	789914443	15MAR2019	Y	27FEB2024	V121.0 − Step 4c−CAB LA − Week 96 (1)	27FEB2024	22APR2022	Y		Confirmed	−		
South Africa: Botha's Hill: Botha's Hill CRS	789984674	23OCT2019	Y	01AUG2023	V116.0 − Step 6−CAB LA − Week 56 (1)	01AUG2023	07JUN2022	Y		Confirmed	−		
Kenya: Kisumu: Kisumu CRS	792108380	15APR2019	Y	07SEP2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	07SEP2022	21MAR2022	Y		Confirmed	08APR2023	Full Term Live Birth (>= 37 Weeks)	mother experienced prolonged labor, this necessitate d a decision on going in for caeserian section. mother had a safe delivery process.
Kenya: Kisumu: Kisumu CRS	792252373	15FEB2019	Y	14AUG2023	V118.0 − Step 6−CAB LA − Week 72 (1)	14AUG2023	23MAR2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Kenya: Kisumu: Kisumu CRS	792292932	23JAN2019	Y	16FEB2022	V202 − Open Label Truvada Week 12 (1)	16FEB2022	16MAR2022			Confirmed	17SEP2022	Full Term Live Birth (>= 37 Weeks)	participant had a normal vaginal delivery at ahero county hospital at 4.00 am on 17sep22, mother and baby had no complicatio ns and were discharged home in general good health.
Kenya: Kisumu: Kisumu CRS	792300699	14MAR2019	Y	11OCT2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	11OCT2022	19APR2022	Y		Confirmed	05APR2023	Full Term Live Birth (>= 37 Weeks)	mother had a safe vaginal standard delivery. both mother and baby are in great health
Kenya: Kisumu: Kisumu CRS	792343368	11APR2019	Y	04APR2023	V116.0 − Step 6−CAB LA − Week 56 (1)	04APR2023	02MAR2022	Y		Confirmed	27APR2023	Spontaneous Abortion (< 20 Weeks)	participant had a first trimester uncomplicat ed miscarriage on 27 apr 2023.
Kenya: Kisumu: Kisumu CRS	792358548	04APR2019	Y	13JAN2023	V69.0 − Step 4c−TDF/ FTC − Week 40 (1)	13JAN2023	04APR2022	Y		Confirmed	25FEB2023	Spontaneous Abortion (< 20 Weeks)	participant experienced spontaneou s vaginal bleeding on 25th feb 2023 then went to a local clinic where a manual vacuum aspiration was conducted, completing the abortion and stopping pv bleeding.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Kenya: Kisumu: Kisumu CRS	792367184	01APR2019	Y	06DEC2023	V120.0 − Step 4c−CAB LA − Week 88 (1)	06DEC2023	01MAR2022	Y		Confirmed	−		
Kenya: Kisumu: Kisumu CRS	792367807	28FEB2019		08SEP2021	Interim Visit 203.1	08SEP2021	01MAR2022			Confirmed	19APR2022	Full Term Live Birth (>= 37 Weeks)	she had a safe delivery. there were no complicatio ns at delivery or post delivery and participant was discharged from hospital on 20 apr 2022.
Kenya: Kisumu: Kisumu CRS	792440609	22FEB2019	Y	31MAY2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	31MAY2022	04APR2022	Y		Confirmed	28DEC2022	Full Term Live Birth (>= 37 Weeks)	participant walked to the jootrh maternity unit on 28 dec 2022, got admitted and delivered on the same day.
Kenya: Kisumu: Kisumu CRS	792446262	18DEC2018	Y	21NOV2023	V120.0 − Step 4c−CAB LA − Week 88 (1)	21NOV2023	15MAR2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Kenya: Kisumu: Kisumu CRS	792483575	16APR2019	Y	07DEC2021	V204 − Open Label Truvada Week 36 (1)	07DEC2021	08MAR2022			Confirmed	07AUG2022	Full Term Live Birth (>= 37 Weeks)	participant had a normal vaginal delivery to a healthy infant at 1.00 am on 7th aug 2022, no delivery complications, mother and baby were discharged in good general health.
Kenya: Kisumu: Kisumu CRS	792672220	15MAR2019	Y	13JUL2022	V76.0 − Step 4d − Week 0 Pregnancy 1	13JUL2022	22FEB2022	Y		Confirmed	11OCT2022	Spontaneous Abortion (< 20 Weeks)	participant reports experiencing moderate pv bleeding that began on 09sep2022 and stopped on 12sep2022, it did not seek intervention.
Kenya: Kisumu: Kisumu CRS	792672220	15MAR2019	Y	30JAN2024	V75.0 − Step 5−TDF/FTC − Week 48 (1)	30JAN2024	22FEB2022	Y		Confirmed	−		
Kenya: Kisumu: Kisumu CRS	792752970	27MAR2019	Y	13JUN2023	V117.0 − Step 6−CAB LA − Week 64 (1)	13JUN2023	02MAR2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Kenya: Kisumu: Kisumu CRS	792865080	11APR2019	Y	19DEC2022	V61.0 − Step 4c−CAB LA − Week 32 (1)	19DEC2022	21MAR2022	Y		Confirmed	07JUL2023	Full Term Live Birth (>= 37 Weeks)	delivered on 07jul2023 at 10.00 pm via emergency caesarian section due to prolonged labor and one previous scar (myomectomy). gave birth to live female infant weighing 2950 grams, both in good health
Kenya: Kisumu: Kisumu CRS	792898439	11APR2019	Y	01NOV2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	01NOV2023	21MAR2022	Y		Confirmed	−		
South Africa: Soweto: Soweto HPTN CRS	802138494	08NOV2018	Y	05APR2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	05APR2023	07APR2022	Y		Pending Confirmation	−		
South Africa: Soweto: Soweto HPTN CRS	802490043	06NOV2018	Y	28FEB2024	V121.0 − Step 4c−CAB LA − Week 96 (1)	28FEB2024	29MAR2022	Y		Confirmed	−		
South Africa: Soweto: Soweto HPTN CRS	802604147	30SEP2020	Y	14DEC2023	V76.0 − Step 4d − Week 0 Pregnancy 1	14DEC2023	18MAR2022	Y		Confirmed	−		
South Africa: Soweto: Soweto HPTN CRS	802653992	26JUL2018	Y	12DEC2023	V120.0 − Step 4c−CAB LA − Week 88 (1)	12DEC2023	07APR2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
South Africa: Soweto: Soweto HPTN CRS	802787902	15JAN2020	Y	21MAR2023		14MAR2023	18MAR2022	Y		Ended Prior To Confirmation	01FEB2023	Spontaneous Abortion (< 20 Weeks)	participant found out on 19 jan 2023 that she was pregnant. vaginal bleeding started on 30 jan 2023. complete miscarriage diagnosed on 01 feb 2023.
South Africa: Soweto: Soweto HPTN CRS	802787902	15JAN2020	Y	07JUL2023	V76.0 − Step 4d − Week 0 Pregnancy 1	07JUL2023	18MAR2022	Y		Confirmed	16JAN2024	Full Term Live Birth (>= 37 Weeks)	
South Africa: Soweto: Soweto HPTN CRS	802809243	28NOV2017	Y	20OCT2023	Interim Visit − OLE 119.1	20OCT2023	17MAR2022	Y		Confirmed	−		
South Africa: Soweto: Soweto HPTN CRS	802810960	29JAN2018		05AUG2022	Interim Visit − OLE 65.1	05AUG2022	20APR2022	Y		Ended Prior To Confirmation	07AUG2022	Ectopic Pregnancy	presented to clinic with lower abdominal pain, dizziness, vomiting. pregnancy test positive. referred to hospital on 06 aug 2022. diagnosed with a ruptured ectopic pregnancy.
South Africa: Soweto: Soweto HPTN CRS	802850042	26JUL2018	Y	26JUL2023	V117.0 − Step 6−CAB LA − Week 64 (1)	26JUL2023	06APR2022	Y		Confirmed	07AUG2023	Therapeutic/ Elective Abortion	pregnancy was unwanted. participant opted to terminate the pregnancy.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
South Africa: Soweto: Soweto HPTN CRS	802941551	30OCT2019	Y	24JAN2024	V76.0 − Step 4d − Week 0 Pregnancy 1	24JAN2024	20APR2022	Y		Confirmed	−		
South Africa: Soweto: Soweto HPTN CRS	802956232	18JAN2018	Y	11MAY2023	V116.0 − Step 6−CAB LA − Week 56 (1)	11MAY2023	18MAR2022	Y		Confirmed	15MAY2023	Ectopic Pregnancy	participant had a positive pregnancy test on 11 may 23. on 14 may 23 she had severe abdominal pain. ectopic pregnancy diagnosed on ultrasound. take to theater for a salpingectomy.
South Africa: Soweto: Soweto HPTN CRS	802981090	29OCT2019	Y	28NOV2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	28NOV2023	22APR2022	Y		Confirmed	−		
South Africa: Kwa Zulu Natal: Isipingo CRS	803212226	21AUG2019	Y	02NOV2023	V116.0 − Step 6−CAB LA − Week 56 (1)	02NOV2023	02JUN2022	Y		Confirmed	−		
South Africa: Kwa Zulu Natal: Isipingo CRS	803319904	17SEP2019		19APR2023	V70.0 − Step 4c−TDF/FTC − Week 48 (1)	19APR2023	17MAY2022	Y		Confirmed	20NOV2023	Full Term Live Birth (>= 37 Weeks)	delivery was uneventful.
South Africa: Kwa Zulu Natal: Isipingo CRS	803347695	02SEP2019	Y	10NOV2023	V118.0 − Step 6−CAB LA − Week 72 (1)	10NOV2023	24JUN2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
South Africa: Kwa Zulu Natal: Isipingo CRS	803467995	31JUL2019	Y	26OCT2023	V117.0 − Step 6−CAB LA − Week 64 (1)	26OCT2023	02AUG2022	Y		Confirmed	−		
South Africa: Kwa Zulu Natal: Isipingo CRS	803821428	15OCT2019	Y	10OCT2023	V117.0 − Step 6−CAB LA − Week 64 (1)	10OCT2023	31MAY2022	Y		Confirmed	−		
South Africa: Kwa Zulu Natal: Isipingo CRS	803821958	20FEB2020		26MAY2023	V70.0 − Step 4c−TDF/ FTC − Week 48 (1)	26MAY2023	24JUN2022	Y		Confirmed	25JAN2024	Full Term Live Birth (>= 37 Weeks)	labour progressed well with no complicatio ns.
South Africa: Kwa Zulu Natal: Isipingo CRS	803889736	18OCT2019		17APR2023	V70.0 − Step 4c−TDF/ FTC − Week 48 (1)	17APR2023	06JUN2022	Y		Pending Confirmation	−		
South Africa: Kwa Zulu Natal: Isipingo CRS	803918477	14AUG2019	Y	20JUN2023	V116.0 − Step 6−CAB LA − Week 56 (1)	20JUN2023	24MAY2022	Y		Confirmed	−		
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818113259	04DEC2018	Y	03APR2023	V76.0 − Step 4d − Week 0 Pregnanc y 1	03APR2023	25JUL2022	Y		Confirmed	21NOV2023	Full Term Live Birth (>= 37 Weeks)	emergency c−section due to non− reasuring fetalstatus
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818163867	14MAY2019	Y	24JUL2023	V116.0 − Step 6−CAB LA − Week 56 (1)	24JUL2023	26APR2022	Y		Confirmed	−		
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818186006	23MAY2019		14MAR2023	V69.0 − Step 4c−TDF/ FTC − Week 40 (1)	14MAR2023	23MAY2022	Y		Confirmed	24SEP2023	Full Term Live Birth (>= 37 Weeks)	required an episiotomy ,but not obutructed labour
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818210397	03FEB2020	Y	13FEB2024	V76.0 − Step 4d − Week 0 Pregnanc y 1	13FEB2024	08APR2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818235766	01JUL2019	Y	07DEC2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	07DEC2023	11APR2022	Y		Confirmed	−		
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818248597	31MAY2019	Y	28MAR2023	V76.0 − Step 4d − Week 0 Pregnancy 1	28MAR2023	17MAY2022	Y		Confirmed	17OCT2023	Full Term Live Birth (>= 37 Weeks)	spontaneous onset of labour, uncomplecated vaginal delivery
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818302757	04JUL2019	Y	04OCT2023	V76.0 − Step 4d − Week 0 Pregnancy 1	04OCT2023	04MAY2022	Y		Confirmed	−		
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818321100	25OCT2019	Y	16MAY2023	V76.0 − Step 4d − Week 0 Pregnancy 1	16MAY2023	19MAY2022	Y		Confirmed	04JAN2024	Full Term Live Birth (>= 37 Weeks)	normal vaginal delivery
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818375185	19AUG2019	Y	15NOV2022	V67.0 − Step 4c−TDF/FTC − Week 24 (1)	15NOV2022	02JUN2022	Y		Confirmed	29JUN2023	Full Term Live Birth (>= 37 Weeks)	labour induced with ballon catheter ,episiotomy cut
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818440166	04OCT2018	Y	23NOV2022	V76.0 − Step 4d − Week 0 Pregnancy 1	23NOV2022	09MAY2022	Y		Confirmed	21JUN2023	Full Term Live Birth (>= 37 Weeks)	normal vaginal delivery in hospital
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818445689	19MAR2019	Y	14SEP2022	V76.0 − Step 4d − Week 0 Pregnancy 1	14SEP2022	04MAY2022	Y		Confirmed	23APR2023	Full Term Live Birth (>= 37 Weeks)	c−section planned due to previous c−section. child was due on 1 may 2023.
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818500945	04MAR2020	Y	05FEB2024	V119.0 − Step 4c−CAB LA − Week 80 (1)	05FEB2024	28JUN2022	Y		Confirmed	10FEB2024	Spontaneous Abortion (< 20 Weeks)	spontaneous onset of vaginal bleeding at home

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818502641	05FEB2019	Y	12JUN2023	V116.0 − Step 6−CAB LA − Week 56 (1)	12JUN2023	03MAY2022	Y		Confirmed	−		
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818555881	30SEP2019	Y	31JAN2024	V76.0 − Step 4d − Week 0 Pregnanc y 1	31JAN2024	20MAY2022	Y		Confirmed	−		
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818631926	11MAR2020	Y	27NOV2023	V76.0 − Step 4d − Week 0 Pregnanc y 1	27NOV2023	16MAY2022	Y		Confirmed	−		
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818655195	21SEP2020	Y	24OCT2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	24OCT2023	12APR2022	Y		Confirmed	01NOV2023	Therapeutic/ Elective Abortion	self−administered doses taken at home for elective abortion.
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818810633	08OCT2018		04JAN2022	V30.0 Week 169 − S2 (1)	04JAN2022	21JUN2022			Confirmed	26AUG2022	Full Term Live Birth (>= 37 Weeks)	uncompleca ted vaginal delivery
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818842449	18FEB2020	Y	12APR2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	12APR2023	11MAY2022	Y		Confirmed	31OCT2023	Full Term Live Birth (>= 37 Weeks)	emergency c−section due to non−reassuring cardiotocogr aph
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818878790	31JUL2019	Y	16MAY2023	V76.0 − Step 4d − Week 0 Pregnanc y 1	16MAY2023	18MAY2022	Y		Confirmed	09JAN2024	Full Term Live Birth (>= 37 Weeks)	elective c−section uncomplicat ed
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818892015	13AUG2019	Y	06MAR2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	06MAR2023	02JUN2022	Y		Ended Prior To Confirmation	16FEB2023	Therapeutic/ Elective Abortion	underwent medical termination, product of conception passed at home

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818908277	26SEP2019	Y	19APR2023	V76.0 − Step 4d − Week 0 Pregnancy 1	19APR2023	13APR2022	Y		Confirmed	17OCT2023	Full Term Live Birth (>= 37 Weeks)	spontaneous onset of labour , uncomplecated vaginal delivery
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818955643	04SEP2020	Y	15AUG2023	V76.0 − Step 4d − Week 0 Pregnancy 1	15AUG2023	12APR2022	Y		Confirmed	24FEB2024	Full Term Live Birth (>= 37 Weeks)	uncomplecated labour and delivery
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818977261	10SEP2020	Y	25NOV2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	05DEC2022	31MAY2022	Y		Confirmed	04AUG2023	Full Term Live Birth (>= 37 Weeks)	
South Africa: Johannesburg: Ward 21	837118410	30JUL2018	Y	23AUG2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	23AUG2022	03FEB2022	Y		Ended Prior To Confirmation	19AUG2022	Spontaneous Abortion (< 20 Weeks)	had heavy vaginal bleeding from 29 jul 22 to 19 aug 22. ultrasound was performed on 30 aug 22, uterus empty. complete miscarriage.
South Africa: Johannesburg: Ward 21	837151671	20FEB2018	Y	19DEC2023	V121.0 − Step 4c−CAB LA − Week 96 (1)	19DEC2023	03FEB2022	Y		Confirmed	−		
South Africa: Johannesburg: Ward 21	837233206	02MAR2020	Y	30MAR2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	30MAR2023	22JUL2022	Y		Confirmed	03APR2023	Therapeutic/ Elective Abortion	participant did a termination of pregnancy at local clinic, manual vacuum aspiration was done.
South Africa: Johannesburg: Ward 21	837316121	27JUN2019	Y	21JUL2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	21JUL2022	12FEB2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
South Africa: Johannesburg: Ward 21	837401438	25OCT2018	Y	12AUG2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	12AUG2022	01FEB2022	Y		Confirmed	02MAR2023	Full Term Live Birth (>= 37 Weeks)	participant gave birth at the hospital to a baby girl via natural vaginal delivery at 39 weeks 3 days.
South Africa: Johannesburg: Ward 21	837418847	21SEP2020	Y	01DEC2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	01DEC2022	25APR2022	Y		Confirmed	28DEC2022	Spontaneous Abortion (< 20 Weeks)	first trimester miscarriage
South Africa: Johannesburg: Ward 21	837418847	21SEP2020	Y	25APR2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	25APR2023	25APR2022	Y		Confirmed	05DEC2023	Full Term Live Birth (>= 37 Weeks)	the participant delivered a female infant via normal vaginal delivery on 05 dec 23. an episiotomy was done during the delivery process and sutures were placed.
South Africa: Johannesburg: Ward 21	837434423	04DEC2018	Y	13APR2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	13APR2023	13APR2022	Y		Confirmed	10NOV2023	Full Term Live Birth (>= 37 Weeks)	the participant went to zola chc on 09 nov 23 when she started experiencing labour pains. she was transferred to chris hani baragwanath hospital due to prolonged second stage of labour. this was the

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
South Africa: Johannesburg: Ward 21	837520326	01MAR2018	Y	24OCT2022	V57.0 − Step 4c−CAB LA − Week 0 (1)	24OCT2022	23MAR2022	Y		Confirmed	17JUN2023	Full Term Live Birth (>= 37 Weeks)	baby boy born via nvd at 38 weeks 6 days gestation.
South Africa: Johannesburg: Ward 21	837527479	18SEP2018		24FEB2022	V64.0 − Step 4c−TDF/ FTC − Week 0 (1)	24FEB2022	24FEB2022			Confirmed	21SEP2022	Premature Term Live Birth (< 37 Weeks)	c−section at 35 weeks gestation for previous c−section x1
South Africa: Johannesburg: Ward 21	837558548	28AUG2019	Y	15AUG2023	V118.0 − Step 6−CAB LA − Week 72 (1)	15AUG2023	08MAR2022	Y		Confirmed	−		
South Africa: Johannesburg: Ward 21	837593905	24OCT2018	Y	30AUG2023	V118.0 − Step 6−CAB LA − Week 72 (1)	30AUG2023	08FEB2022	Y		Confirmed	12FEB2024	Full Term Live Birth (>= 37 Weeks)	delivered a healthy male infant via nvd, nil complicatio ns.
South Africa: Johannesburg: Ward 21	837630835	05DEC2018	Y	02AUG2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	02AUG2022	16MAR2022	Y		Confirmed	10OCT2022	Therapeutic/ Elective Abortion	elective medical abortion at 17 weeks 5 days gestation.
South Africa: Johannesburg: Ward 21	837688250	04MAR2020	Y	18JAN2023	V60.0 − Step 4c−CAB LA − Week 24 (1)	18JAN2023	21JUN2022	Y		Ended Prior To Confirmation	09JAN2023	Therapeutic/ Elective Abortion	elective abortion at 10 weeks gestation.
South Africa: Johannesburg: Ward 21	837695646	07NOV2018	Y	25OCT2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	25OCT2022	20JUL2022	Y		Confirmed	06NOV2022	Therapeutic/ Elective Abortion	elective abortion on 06 nov 22.
South Africa: Johannesburg: Ward 21	837744201	23MAY2019	Y	27NOV2023	V120.0 − Step 4c−CAB LA − Week 88 (1)	27NOV2023	03FEB2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
South Africa: Johannesburg: Ward 21	837768119	05DEC2018	Y	06FEB2023	V76.0 − Step 4d − Week 0 Pregnancy 1	06FEB2023	05APR2022	Y		Confirmed	25MAY2023	Stillbirth/ Intrauterine Fetal Demise (>= 20 Weeks)	delivered at 42 weeks 2 days. emergency c−section done due to fetal bradycardia with impending fetal distress
South Africa: Johannesburg: Ward 21	837782113	09FEB2018	Y	11AUG2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	11AUG2022	17FEB2022	Y		Confirmed	−		
South Africa: Johannesburg: Ward 21	837817108	28JAN2019	Y	23JAN2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	23JAN2023	26JAN2022	Y		Confirmed	19SEP2023	Full Term Live Birth (>= 37 Weeks)	the participant delivered on 19 sep 23 at hillbrow chc. the participant does not have her discharge summary on site, however the road to health book notes that the participant had prolonged second sta
South Africa: Johannesburg: Ward 21	837881196	04SEP2019		13MAY2022	V64.0 − Step 4c−TDF/ FTC − Week 0 (1)	13MAY2022	13MAY2022			Confirmed	23NOV2022	Full Term Live Birth (>= 37 Weeks)	c−section at 41+ weeks for previous c−section x1 and post dates

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
South Africa: Johannesburg: Ward 21	837883809	26FEB2020	Y	12OCT2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	12OCT2022	21JUN2022	Y		Confirmed	09JAN2023	Therapeutic/ Elective Abortion	participant did a termination of pregnancy through a private facility which was done medically only. manual vacuum aspiration was not performed.
South Africa: Johannesburg: Ward 21	837929481	27MAY2019	Y	16AUG2023	V117.0 − Step 6−CAB LA − Week 64 (1)	16AUG2023	29MAR2022	Y		Confirmed	06SEP2023	Therapeutic/ Elective Abortion	requested a termination at clinic on 06 sep 23.
South Africa: Johannesburg: Ward 21	837969169	13MAR2018	Y	12APR2023	V117.0 − Step 6−CAB LA − Week 64 (1)	12APR2023	01FEB2022	Y		Confirmed	14DEC2023	Full Term Live Birth (>= 37 Weeks)	the participant presented to bertha gxowa hospital when she started experiencin g labour pains on 14 dec 23. an emergency c−section was done on the same day. she was told that the indication for the c−

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Swaziland: Siteki: Swaziland Prevention Center	871124857	29JAN2020	Y	05DEC2022	V61.0 − Step 4c−CAB LA − Week 32 (1)	05DEC2022	05APR2022	Y		Confirmed	14FEB2023	Ectopic Pregnancy	she was hospitalized on 14 feb 2023, had right salpingectomy and was discharged on antibiotics (metronidazole, amoxiclav) and analgesia (diclofenac and paracetamol) on 16 feb 2023.
Swaziland: Siteki: Swaziland Prevention Center	871124857	29JAN2020	Y	01AUG2023	V117.0 − Step 6−CAB LA − Week 64 (1)	01AUG2023	05APR2022	Y		Confirmed	−		
Swaziland: Siteki: Swaziland Prevention Center	871144193	28MAY2019	Y	30JAN2024	V121.0 − Step 4c−CAB LA − Week 96 (1)	30JAN2024	16MAR2022	Y		Confirmed	−		
Swaziland: Siteki: Swaziland Prevention Center	871202720	07MAR2019	Y	20FEB2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	20FEB2023	04APR2022	Y		Confirmed	04OCT2023	Full Term Live Birth (>= 37 Weeks)	
Swaziland: Siteki: Swaziland Prevention Center	871220830	04SEP2019	Y	12SEP2022	V66.0 − Step 4c−TDF/FTC − Week 16 (1)	12SEP2022	12MAY2022	Y		Confirmed	30APR2023	Full Term Live Birth (>= 37 Weeks)	breech presentation in primigravida
Swaziland: Siteki: Swaziland Prevention Center	871258126	28JUL2020		24AUG2022	V66.0 − Step 4c−TDF/FTC − Week 16 (1)	24AUG2022	27APR2022	Y		Confirmed	18APR2023	Full Term Live Birth (>= 37 Weeks)	normal live birth, male child, birth weight−2.97 kg apgar score 8/10 to 9/10. stable child with no abnomarlities noted.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Swaziland: Siteki: Swaziland Prevention Center	871267752	07AUG2019	Y	06FEB2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	06FEB2023	23MAR2022	Y		Confirmed	05SEP2023	Full Term Live Birth (>= 37 Weeks)	delivered a baby girl through normal delivery in a hospital on 05 sep 2023. no complications experienced during pregnancy and delivery. baby was admiited 06 sep 23 for jaundice
Swaziland: Siteki: Swaziland Prevention Center	871268741	27MAY2019	Y	12SEP2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	12SEP2023	15MAR2022	Y		Confirmed	−		
Swaziland: Siteki: Swaziland Prevention Center	871282175	04JUL2019	Y	04JAN2024	V120.0 − Step 4c−CAB LA − Week 88 (1)	04JAN2024	06APR2022	Y		Confirmed	−		
Swaziland: Siteki: Swaziland Prevention Center	871300860	28JUL2020	Y	04JUL2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	04JUL2023	16MAR2022	Y		Confirmed	−		
Swaziland: Siteki: Swaziland Prevention Center	871318381	30JUL2019	Y	31JAN2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	31JAN2023	23MAR2022	Y		Confirmed	31JAN2023	Spontaneous Abortion (< 20 Weeks)	participant reported severe per vaginal bleeding for 10 days before coming to site.she was treated with antibiotics iv at local hospital as an outpatient.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Swaziland: Siteki: Swaziland Prevention Center	871319341	06AUG2019	Y	17MAY2023	V117.0 − Step 6−CAB LA − Week 64 (1)	17MAY2023	10MAR2022	Y		Confirmed	03DEC2023	Full Term Live Birth (>= 37 Weeks)	delivered via normal vaginal delivery. no complications experienced
Swaziland: Siteki: Swaziland Prevention Center	871377136	10SEP2019	Y	11APR2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	11APR2023	24MAY2022	Y		Confirmed	04JAN2024	Full Term Live Birth (>= 37 Weeks)	
Swaziland: Siteki: Swaziland Prevention Center	871388192	24MAY2019	Y	27JUN2023	V117.0 − Step 6−CAB LA − Week 64 (1)	27JUN2023	10MAR2022	Y		Confirmed	06NOV2023	Full Term Live Birth (>= 37 Weeks)	participant delivered via nvd with an episiotomy in hospital. she reports that she forgot to call the study team when she went to hospital. no complications were reported.
Swaziland: Siteki: Swaziland Prevention Center	871392416	06AUG2019	Y	05JAN2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	05JAN2023	22MAR2022	Y		Confirmed	06AUG2023	Full Term Live Birth (>= 37 Weeks)	
Swaziland: Siteki: Swaziland Prevention Center	871392416	06AUG2019	Y	20FEB2024	V121.0 − Step 4c−CAB LA − Week 96 (1)	20FEB2024	22MAR2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Swaziland: Siteki: Swaziland Prevention Center	871395615	18FEB2020	Y	25OCT2022	V61.0 − Step 4c−CAB LA − Week 32 (1)	25OCT2022	14MAR2022	Y		Confirmed	27JUN2023	Full Term Live Birth (>= 37 Weeks)	participant delivered a live baby boy at 38 weeks and 4 days through a vaginal delivery. an episiotomy was done and repaired, bweight of child was 3.0 kg and no congenital abnomalities were noted.
Swaziland: Siteki: Swaziland Prevention Center	871416158	07AUG2019		16MAR2023	V70.0 − Step 4c−TDF/ FTC − Week 48 (1)	16MAR2023	24MAR2022	Y		Confirmed	20SEP2023	Full Term Live Birth (>= 37 Weeks)	delivered baby in hospital via noraml vaginal delivery. delivered 20 sep 23 and discharged from hospital on 20 sep 2023. no complications during pregnancy and delivery
Swaziland: Siteki: Swaziland Prevention Center	871418836	07NOV2019	Y	27MAR2023	V60.0 − Step 4c−CAB LA − Week 24 (1)	27MAR2023	18MAY2022	Y		Confirmed	28MAR2023	Ectopic Pregnancy	hospitalized on 28 mar 2023 due to a participant had a suspected ectopic pregnancy +/− ruptured ovarian cyst participant was done a left salpingectomy and discharged on 30 mar 2023

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Swaziland: Siteki: Swaziland Prevention Center	871477903	29MAY2019	Y	18MAY2022	V55.0 − Step 4a − Day 0 (1)	18MAY2022	17MAY2022	Y		Confirmed	02JUN2022	Spontaneous Abortion (< 20 Weeks)	participant reported that she severe per vaginal bleeding for three days prior to reporting to site. she reports she was seen at a local clinic where she was treated.
Swaziland: Siteki: Swaziland Prevention Center	871477903	29MAY2019	Y	02AUG2022		26JUL2022	17MAY2022	Y		Confirmed	02MAR2023	Full Term Live Birth (>= 37 Weeks)	the delivery was uneventful
Swaziland: Siteki: Swaziland Prevention Center	871512859	11JUN2019	Y	01FEB2023	Interim Visit − OLE 61.1	01FEB2023	22MAR2022	Y		Confirmed	22SEP2023	Full Term Live Birth (>= 37 Weeks)	the event was uneventful
Swaziland: Siteki: Swaziland Prevention Center	871631353	11JUL2019	Y	01FEB2023	V73.0 − Step 5−TDF/ FTC − Week 24 (1)	01FEB2023	25MAY2022	Y		Confirmed	12APR2023	Spontaneous Abortion (< 20 Weeks)	participant started bleeding at home un mar 2023 and she bled for approximate ly two weeks. she did not go to hoapital. visited a local clinic on 03 apr 2023 and tested negative for pregnancy
Swaziland: Siteki: Swaziland Prevention Center	871646243	16JUL2019	Y	08FEB2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	08FEB2023	03MAY2022	Y		Confirmed	20SEP2023	Full Term Live Birth (>= 37 Weeks)	

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Swaziland: Siteki: Swaziland Prevention Center	871711540	23OCT2019	Y	19JUL2022	V66.0 − Step 4c−TDF/ FTC − Week 16 (1)	19JUL2022	28MAR2022	Y		Confirmed	21MAR2023	Full Term Live Birth (>= 37 Weeks)	the delivery was un eventful
Swaziland: Siteki: Swaziland Prevention Center	871729202	13AUG2019	Y	12JUL2023	V117.0 − Step 6−CAB LA − Week 64 (1)	12JUL2023	29MAR2022	Y		Confirmed	−		
Swaziland: Siteki: Swaziland Prevention Center	871839669	03SEP2019	Y	21JUN2023	V117.0 − Step 6−CAB LA − Week 64 (1)	21JUN2023	21APR2022	Y		Confirmed	−		
Swaziland: Siteki: Swaziland Prevention Center	871859763	06AUG2019	Y	30MAY2023	V116.0 − Step 6−CAB LA − Week 56 (1)	30MAY2023	29MAR2022	Y		Confirmed	−		
Swaziland: Siteki: Swaziland Prevention Center	871914889	03APR2019	Y	07SEP2023	V117.0 − Step 6−CAB LA − Week 64 (1)	07SEP2023	18MAY2022	Y		Confirmed	07SEP2023	Spontaneous Abortion (< 20 Weeks)	
Swaziland: Siteki: Swaziland Prevention Center	871973317	14OCT2019	Y	13SEP2023	V117.0 − Step 6−CAB LA − Week 64 (1)	13SEP2023	25MAY2022	Y		Confirmed	27SEP2023	Spontaneous Abortion (< 20 Weeks)	she had heavy bleeding for five days at home.
Swaziland: Siteki: Swaziland Prevention Center	871984985	07OCT2019	Y	15JUN2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	15JUN2023	16MAY2022	Y		Confirmed	11AUG2023	Other	participant diagnosed with blighted ovum at 11 weeks gestation
Swaziland: Siteki: Swaziland Prevention Center	871989267	31OCT2019	Y	31JAN2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	31JAN2023	10MAY2022	Y		Confirmed	21SEP2023	Full Term Live Birth (>= 37 Weeks)	uneventful

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Kampala: Baylor−Uganda CRS	872105231	25MAR2019	Y	28NOV2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	28NOV2023	20APR2022	Y		Confirmed	−		
Uganda: Kampala: Baylor−Uganda CRS	872160025	04FEB2020	Y	07NOV2023		31OCT2023	08APR2022	Y		Confirmed	19AUG2023	Full Term Live Birth (>= 37 Weeks)	delivered vaginally, not assisted
Uganda: Kampala: Baylor−Uganda CRS	872185400	07JUN2019	Y	19SEP2022	V65.0 − Step 4c−TDF/ FTC − Week 8 (1)	19SEP2022	22JUL2022	Y		Confirmed	22SEP2022	Therapeutic/ Elective Abortion	it was elective abortion
Uganda: Kampala: Baylor−Uganda CRS	872185400	07JUN2019	Y	28APR2023	V69.0 − Step 4c−TDF/ FTC − Week 40 (1)	28APR2023	22JUL2022	Y		Confirmed	−		
Uganda: Kampala: Baylor−Uganda CRS	872202135	10MAR2020	Y	19MAY2022	V56.0 − Step 4b − Day 0 (1)	19MAY2022	19MAY2022			Confirmed	05DEC2022	Full Term Live Birth (>= 37 Weeks)	delivered by emergency cesaerean section. indication was fetal distress
Uganda: Kampala: Baylor−Uganda CRS	872274651	03JAN2020	Y	13DEC2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	13DEC2023	11MAY2022	Y		Confirmed	19JAN2024	Spontaneous Abortion (< 20 Weeks)	
Uganda: Kampala: Baylor−Uganda CRS	872326420	03OCT2018	Y	24AUG2022	V57.0 − Step 4c−CAB LA − Week 0 (1)	24AUG2022	25JUL2022	Y		Confirmed	27AUG2022	Therapeutic/ Elective Abortion	had elective abortion
Uganda: Kampala: Baylor−Uganda CRS	872359774	29JAN2020	Y	08DEC2021	V201 − Open Label Truvada Day 0 (1)	08DEC2021	26MAY2022			Confirmed	19JUN2022	Full Term Live Birth (>= 37 Weeks)	participant under went emergency ceasarean section due to cephalopelvic disproportion.had big baby as per medical records

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Kampala: Baylor−Uganda CRS	872365458	23MAY2019	Y	15MAR2022	V27.0 Week 145 − S2 (1)	15MAR2022	05MAY2022			Confirmed	13SEP2022	Full Term Live Birth (>= 37 Weeks)	delivered by spontaneous vaginal delivery on 13 sep 2022.no complications reported. delivered at 2105 hours
Uganda: Kampala: Baylor−Uganda CRS	872380973	05OCT2018	Y	08NOV2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	08NOV2023	28APR2022	Y		Confirmed	20DEC2023	Spontaneous Abortion (< 20 Weeks)	
Uganda: Kampala: Baylor−Uganda CRS	872381422	17FEB2020	Y	04OCT2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	04OCT2022	11APR2022	Y		Confirmed	07DEC2022	Spontaneous Abortion (< 20 Weeks)	had spontaneous abortion
Uganda: Kampala: Baylor−Uganda CRS	872381422	17FEB2020	Y	22MAY2023	V116.0 − Step 6−CAB LA − Week 56 (1)	22MAY2023	11APR2022	Y		Confirmed	−		
Uganda: Kampala: Baylor−Uganda CRS	872394892	05NOV2019	Y	18SEP2023	V118.0 − Step 6−CAB LA − Week 72 (1)	18SEP2023	29APR2022	Y		Confirmed	−		
Uganda: Kampala: Baylor−Uganda CRS	872416148	10JUN2019	Y	13JUL2022	V79.0 − Step 4d − Week 12 Pregnancy 1	13JUL2022	13JUL2022			Confirmed	24FEB2023	Full Term Live Birth (>= 37 Weeks)	delivered by spontaneous vaginal delivery. no delivery related complications. no non delivery complications also
Uganda: Kampala: Baylor−Uganda CRS	872443773	04MAR2020	Y	27JAN2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	27JAN2023	12MAY2022	Y		Confirmed	02FEB2023	Spontaneous Abortion (< 20 Weeks)	had spontaneous abortion, managed from private clinic under standard of care.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Kampala: Baylor−Uganda CRS	872449412	17OCT2018		14SEP2022	V66.0 − Step 4c−TDF/ FTC − Week 16 (1)	14SEP2022	24MAY2022	Y		Confirmed	12FEB2023	Premature Term Live Birth (< 37 Weeks)	delivered by vaginal delivery. no related complicatio ns reported
Uganda: Kampala: Baylor−Uganda CRS	872504328	04APR2019		02AUG2022	V64.0 − Step 4c−TDF/ FTC − Week 0 (1)	02AUG2022	02AUG2022			Confirmed	18MAR2023	Full Term Live Birth (>= 37 Weeks)	she delivered by vaginal delivery. no complicatio ns reported as per medical records
Uganda: Kampala: Baylor−Uganda CRS	872592440	18JAN2019	Y	26NOV2021	Interim Visit 202.1	26NOV2021	13APR2022			Confirmed	07JUL2022	Full Term Live Birth (>= 37 Weeks)	delivered by spontaneou s vaginal delivery.no delivery or non delivery related complicatio ns reported.
Uganda: Kampala: Baylor−Uganda CRS	872603448	15FEB2019	Y	20FEB2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	20FEB2023	25MAY2022	Y		Confirmed	18AUG2023	Full Term Live Birth (>= 37 Weeks)	delivered by vaginal delivery. no delivery or non delivery related complicatio ns reported
Uganda: Kampala: Baylor−Uganda CRS	872673274	05NOV2019	Y	20JUN2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	20JUN2023	23MAY2022	Y		Confirmed	25FEB2024	Full Term Live Birth (>= 37 Weeks)	delivered by vaginal delivery. no delivery or non delivery related complicatio ns noted.
Uganda: Kampala: Baylor−Uganda CRS	872679085	29JAN2020	Y	24JUN2022	V82.0 − Step 4d − Week 24 Pregnanc y 1	24JUN2022	24JUN2022			Confirmed	23SEP2022	Full Term Live Birth (>= 37 Weeks)	delivered by spontaneou s vaginal delivery.no complicatio ns reported
Uganda: Kampala: Baylor−Uganda CRS	872726004	05OCT2018		29APR2022	V64.0 − Step 4c−TDF/ FTC − Week 0 (1)	29APR2022	29APR2022			Confirmed	13NOV2022	Full Term Live Birth (>= 37 Weeks)	develivered by spontaneou s vaginal delivery.no complicatio ns

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Kampala: Baylor−Uganda CRS	872728875	11FEB2019		10NOV2022	V66.0 − Step 4c−TDF/ FTC − Week 16 (1)	10NOV2022	22JUL2022	Y		Confirmed	19JUL2023	Full Term Live Birth (>= 37 Weeks)	delivered by vaginal delivery. no delivery or non delivery related complicatio ns noted
Uganda: Kampala: Baylor−Uganda CRS	872744056	30JAN2020	Y	26JUL2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	26JUL2022	12APR2022	Y		Confirmed	05AUG2022	Spontaneous Abortion (< 20 Weeks)	had spontaneou s abortion
Uganda: Kampala: Baylor−Uganda CRS	872744056	30JAN2020	Y	13APR2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	13APR2023	12APR2022	Y		Confirmed	04DEC2023	Full Term Live Birth (>= 37 Weeks)	delivered by caesarean section due to big baby
Uganda: Kampala: Baylor−Uganda CRS	872782839	14JUN2019	Y	25MAR2022	V76.0 − Step 4d − Week 0 Pregnanc y 1	25MAR2022	25MAR2022			Confirmed	27NOV2022	Full Term Live Birth (>= 37 Weeks)	had spontaneou s vaginal delivery
Uganda: Kampala: Baylor−Uganda CRS	872827004	10JUL2019	Y	08NOV2023	V119.0 − Step 4c−CAB LA − Week 80 (1)	08NOV2023	20APR2022	Y		Confirmed	−		
Uganda: Kampala: Baylor−Uganda CRS	872873437	17FEB2020		05JAN2022	V21.0 Week 97 − S2 (1)	05JAN2022	08APR2022			Confirmed	10AUG2022	Full Term Live Birth (>= 37 Weeks)	had emergency c−section due to cephalopelv ic disproportio n
Uganda: Kampala: Baylor−Uganda CRS	872873437	17FEB2020		16JAN2023	V69.0 − Step 4c−TDF/ FTC − Week 40 (1)	16JAN2023	08APR2022	Y		Confirmed	25MAR2023	Spontaneous Abortion (< 20 Weeks)	had spontaneou s abortion
Uganda: Kampala: Baylor−Uganda CRS	872893872	15OCT2019		18JAN2023	V69.0 − Step 4c−TDF/ FTC − Week 40 (1)	18JAN2023	12APR2022	Y		Confirmed	19JUL2023	Full Term Live Birth (>= 37 Weeks)	delivered by vaginal delivery. no complicatio ns related.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Kampala: Baylor−Uganda CRS	872922787	10MAR2020	Y	19MAY2022	V56.0 − Step 4b − Day 0 (1)	19MAY2022	19MAY2022			Confirmed	02JUL2022	Spontaneous Abortion (< 20 Weeks)	she reported history of per vaginal bleeding on 01 jul 2022 and 02 jul 2022.she denied using medications prior to per vaginal bleeding.
Uganda: Kampala: Baylor−Uganda CRS	872974168	28AUG2019	Y	08JUN2022	V76.0 − Step 4d − Week 0 Pregnancy 1	08JUN2022	12APR2022	Y		Confirmed	29NOV2022	Full Term Live Birth (>= 37 Weeks)	had preterm prelabour rupture of membranes
Uganda: Kampala: Baylor−Uganda CRS	872975745	15JAN2020	Y	28MAR2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	28MAR2023	20MAY2022	Y		Confirmed	26OCT2023	Premature Term Live Birth (< 37 Weeks)	delivered by emergency caesarean section due to severe oligohydramnios
Uganda: Entebbe: UVRI−IAVI	873115205	28OCT2019	Y	03MAY2022	V56.0 − Step 4b − Day 0 (1)	03MAY2022	03MAY2022			Confirmed	14DEC2022	Full Term Live Birth (>= 37 Weeks)	pregnant participant went into labor and was taken to the clinic where she gave birth to her live baby
Uganda: Entebbe: UVRI−IAVI	873141966	22JAN2020	Y	31OCT2022	V66.0 − Step 4c−TDF/FTC − Week 16 (1)	31OCT2022	11JUL2022	Y		Confirmed	27DEC2022	Spontaneous Abortion (< 20 Weeks)	she reported to had sudden vaginal bleeding while at home that resulted into a miscarriage on 27 dec 2022.
Uganda: Entebbe: UVRI−IAVI	873141966	22JAN2020	Y	03JUL2023	V70.0 − Step 4c−TDF/FTC − Week 48 (1)	03JUL2023	11JUL2022	Y		Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Entebbe: UVRI−IAVI	873144136	27AUG2019	Y	12JUL2022	V71.0 − Step 5−TDF/ FTC − Day 0 (1)	12JUL2022	14JUN2022	Y		Confirmed	29AUG2022	Therapeutic/ Elective Abortion	participant decided to terminate the pregnancy because it was un wanted
Uganda: Entebbe: UVRI−IAVI	873178793	16SEP2019	Y	03OCT2022	Interim Visit − OLE 59.1	03OCT2022	18MAY2022	Y		Confirmed	29OCT2022	Therapeutic/ Elective Abortion	participant decided to terminate her pregnancy.
Uganda: Entebbe: UVRI−IAVI	873178793	16SEP2019	Y	10MAY2023	V63.0 − Step 4c−CAB LA − Week 48 (1)	10MAY2023	18MAY2022	Y		Ended Prior To Confirmation	29APR2023	Therapeutic/ Elective Abortion	participant was unsure of her pregnancy intentions , hence procured an abortion
Uganda: Entebbe: UVRI−IAVI	873180744	25JUN2019	Y	16OCT2023	V76.0 − Step 4d − Week 0 Pregnanc y 1	16OCT2023	13JUL2022	Y		Confirmed	14NOV2023	Full Term Live Birth (>= 37 Weeks)	participant give birth to a baby girl on her way to hospital. she has no hospital records.
Uganda: Entebbe: UVRI−IAVI	873196116	24JAN2020	Y	12JUL2022	V64.0 − Step 4c−TDF/ FTC − Week 0 (1)	12JUL2022	12JUL2022			Confirmed	29AUG2022	Spontaneous Abortion (< 20 Weeks)	participant had a miscarriage from home and did not experience any complicatio ns
Uganda: Entebbe: UVRI−IAVI	873199050	11OCT2019	Y	02FEB2022	V203 − Open Label Truvada Week 24 (1)	02FEB2022	13MAY2022			Confirmed	25SEP2022	Full Term Live Birth (>= 37 Weeks)	she gave birth to full term baby from a private clinic. she reported no post delivery complicatio ns.
Uganda: Entebbe: UVRI−IAVI	873222827	30JAN2020	Y	04NOV2021	V202 − Open Label Truvada Week 12 (1)	04NOV2021	22APR2022			Confirmed	−		

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Entebbe: UVRI−IAVI	873254657	10JAN2020	Y	11JUL2022	V64.0 − Step 4c−TDF/ FTC − Week 0 (1)	11JUL2022	11JUL2022			Confirmed	25AUG2022	Spontaneous Abortion (< 20 Weeks)	she reported to have had an abortion from home and no complicatio ns.
Uganda: Entebbe: UVRI−IAVI	873254657	10JAN2020	Y	17NOV2022	V66.0 − Step 4c−TDF/ FTC − Week 16 (1)	17NOV2022	11JUL2022	Y		Confirmed	17DEC2022	Therapeutic/ Elective Abortion	she was not willing to maintain the pregnancy hence she decided to have an abortion.
Uganda: Entebbe: UVRI−IAVI	873275923	08OCT2019		22JUL2022	V65.0 − Step 4c−TDF/ FTC − Week 8 (1)	22JUL2022	27MAY2022	Y		Confirmed	08FEB2023	Full Term Live Birth (>= 37 Weeks)	participant went into labor that resulted into child birth.
Uganda: Entebbe: UVRI−IAVI	873309790	03SEP2019	Y	29NOV2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	29NOV2022	14JUN2022	Y		Confirmed	12JUN2023	Full Term Live Birth (>= 37 Weeks)	mother gave birth on the 12jun. 2023 to a baby boy by stranded vaginal delivery. baby weighed 2.8kgs and apgar scor was 9−10.
Uganda: Entebbe: UVRI−IAVI	873329498	28NOV2018	Y	16DEC2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	16DEC2022	25MAY2022	Y		Confirmed	05AUG2023	Full Term Live Birth (>= 37 Weeks)	mother went into labor while at home and she was taken to the hospital where she gave birth to her live baby girl

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Entebbe: UVRI−IAVI	873355043	18NOV2019		19DEC2022	V68.0 − Step 4c−TDF/ FTC − Week 32 (1)	19DEC2022	09MAY2022	Y		Confirmed	22AUG2023	Full Term Live Birth (>= 37 Weeks)	mother narrates to have go to hospital as she felt labour pain, she reports to have delivered normally by standard vaginal delivery to a baby girl who weighed 3.2 kgs and cried at birth.
Uganda: Entebbe: UVRI−IAVI	873375763	16OCT2019		20SEP2022	V66.0 − Step 4c−TDF/ FTC − Week 16 (1)	20SEP2022	31MAY2022	Y		Confirmed	−		
Uganda: Entebbe: UVRI−IAVI	873395783	13JUL2019	Y	03JAN2024	V119.0 − Step 4c−CAB LA − Week 80 (1)	03JAN2024	16MAY2022	Y		Confirmed	14JAN2024	Therapeutic/ Elective Abortion	participant decided to abort the pregnancy from home on 14jan 2024. she reported no complicatio ns.
Uganda: Entebbe: UVRI−IAVI	873399748	18NOV2019		22NOV2021	V22.0 Week 105 − S2 (1)	22NOV2021	30JUN2022			Confirmed	01AUG2022	Full Term Live Birth (>= 37 Weeks)	participant came for visit 65 and reported to have given birth on 01 aug 2022. she did not come with her delivery report. however, she reported to have had a normal delivery and no complicatio ns.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Entebbe: UVRI−IAVI	873418341	09SEP2019		11APR2023	V70.0 − Step 4c−TDF/ FTC − Week 48 (1)	11APR2023	26APR2022	Y		Confirmed	08DEC2023	Full Term Live Birth (>= 37 Weeks)	participant started labor on 7th dec 2023 and she went to hospital and gave birth on 08th dec at 19:00hrs.
Uganda: Entebbe: UVRI−IAVI	873436091	31JAN2020	Y	19DEC2023	Interim Visit − OLE 118.1	19DEC2023	13JUN2022	Y		Confirmed	−		
Uganda: Entebbe: UVRI−IAVI	873497887	24JAN2019	Y	07DEC2021	V202 − Open Label Truvada Week 12 (1)	07DEC2021	27MAY2022			Confirmed	20AUG2022	Full Term Live Birth (>= 37 Weeks)	participant went into labor and was taken to the hospital were she gave birth to her baby.
Uganda: Entebbe: UVRI−IAVI	873519999	22JAN2020	Y	04OCT2022	V76.0 − Step 4d − Week 0 Pregnanc y 1	04OCT2022	17MAY2022	Y		Confirmed	29APR2023	Full Term Live Birth (>= 37 Weeks)	mother reports to have gone to the hospital (health centre 3)after having signs early labour,8hrs of arrival she gave birth to baby girl who cried on spot with 3.4kg mother narrates.
Uganda: Entebbe: UVRI−IAVI	873532175	22JAN2020	Y	03JAN2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	03JAN2023	19MAY2022	Y		Confirmed	07AUG2023	Full Term Live Birth (>= 37 Weeks)	mother went into labor and she was taken to hospital where she delivered her live baby boy

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Entebbe: UVRI−IAVI	873601281	10OCT2019	Y	13SEP2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	13SEP2022	26MAY2022	Y		Confirmed	14OCT2022	Spontaneous Abortion (< 20 Weeks)	participant felt un well and went to the clinic with bleeding per vagina, and this was diagnosed spontaneous abortion
Uganda: Entebbe: UVRI−IAVI	873601281	10OCT2019	Y	27JUL2023	V116.0 − Step 6−CAB LA − Week 56 (1)	27JUL2023	26MAY2022	Y		Confirmed	−		
Uganda: Entebbe: UVRI−IAVI	873623079	10FEB2020	Y	03OCT2022	V76.0 − Step 4d − Week 0 Pregnancy 1	03OCT2022	13JUN2022	Y		Confirmed	09JUN2023	Full Term Live Birth (>= 37 Weeks)	on the 09 jun 2023 participant had a normal stranded vaginal delivery and gave birth to a full term live baby boy she narrates no delivery complications
Uganda: Entebbe: UVRI−IAVI	873671754	22NOV2018	Y	16SEP2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	16SEP2022	30JUN2022	Y		Confirmed	20SEP2022	Spontaneous Abortion (< 20 Weeks)	participant reported to the clinic with history of abortion that happen on 20 sep 2022 while at home
Uganda: Entebbe: UVRI−IAVI	873671754	22NOV2018	Y	13FEB2024	V119.0 − Step 4c−CAB LA − Week 80 (1)	13FEB2024	30JUN2022	Y		Ended Prior To Confirmation	06FEB2024	Therapeutic/ Elective Abortion	participant reported to have procured an abortion from a nearby clinic.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Entebbe: UVRI−IAVI	873680807	09JAN2020	Y	01JUL2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	01JUL2022	05MAY2022	Y		Confirmed	27FEB2023	Full Term Live Birth (>= 37 Weeks)	mother gave birth to a full−term live baby boy with 3.2kgs and has been breastfeeding well since birth.
Uganda: Entebbe: UVRI−IAVI	873689860	31MAY2019	Y	26OCT2023	V118.0 − Step 6−CAB LA − Week 72 (1)	26OCT2023	11MAY2022	Y		Confirmed	09NOV2023	Spontaneous Abortion (< 20 Weeks)	she reported to have experienced vaginal bleeding from home that resulted into a miscarriage, she reported no complications
Uganda: Entebbe: UVRI−IAVI	873726556	24JAN2019	Y	02FEB2023	V69.0 − Step 4c−TDF/FTC − Week 40 (1)	02FEB2023	16MAY2022	Y		Confirmed	04AUG2023	Full Term Live Birth (>= 37 Weeks)	she gave birth from hospital no post delivery complications reported.
Uganda: Entebbe: UVRI−IAVI	873739127	10JAN2020	Y	08MAY2023	V62.0 − Step 4c−CAB LA − Week 40 (1)	08MAY2023	28JUN2022	Y		Confirmed	15DEC2023	Full Term Live Birth (>= 37 Weeks)	
Uganda: Entebbe: UVRI−IAVI	873748244	27AUG2019	Y	06JUL2022	V56.0 − Step 4b − Day 0 (1)	06JUL2022	06JUL2022			Confirmed	24FEB2023	Full Term Live Birth (>= 37 Weeks)	participant felt labor pains on the 24th feb 2023,she went to the maternity home where she was admitted and later gave birth to an asphyxiated baby girl with 2/10 score and baby died shortly.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Entebbe: UVRI−IAVI	873761056	14MAR2019	Y	13JUN2022	V56.0 − Step 4b − Day 0 (1)	13JUN2022	13JUN2022			Confirmed	16NOV2022	Full Term Live Birth (>= 37 Weeks)	participant had labor pains and was taken to hospital where she delivered her baby
Uganda: Entebbe: UVRI−IAVI	873798554	07FEB2020	Y	01NOV2022	V59.0 − Step 4c−CAB LA − Week 16 (1)	01NOV2022	03AUG2022	Y		Confirmed	11NOV2022	Spontaneous Abortion (< 20 Weeks)	the participant reported sudden onset of bleeding per vagina while at home. the next morning, she went to a near by clinic and it was confirmed that she had a complete abortion
Uganda: Entebbe: UVRI−IAVI	873820050	27MAY2019	Y	11JAN2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	11JAN2023	03MAY2022	Y		Confirmed	02AUG2023	Stillbirth/ Intrauterine Fetal Demise (>= 20 Weeks)	participant felt unwell associated with absence of fetal activity, she was rushed to to the hospital where she was diagnosed with iufd underwent an operation.
Uganda: Entebbe: UVRI−IAVI	873833770	23JAN2020	Y	20FEB2024	V120.0 − Step 4c−CAB LA − Week 88 (1)	20FEB2024	17MAY2022	Y		Confirmed	−		
Uganda: Entebbe: UVRI−IAVI	873851113	04NOV2019	Y	01AUG2022	V76.0 − Step 4d − Week 0 Pregnancy 1	01AUG2022	27APR2022	Y		Confirmed	31MAR2023	Full Term Live Birth (>= 37 Weeks)	mother gave birth to a full−term baby girl with no complication she reports.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Entebbe: UVRI−IAVI	873922510	13MAY2019	Y	04JAN2022	V26.0 Week 137 − S2 (1)	04JAN2022	27JUN2022			Confirmed	16AUG2022	Full Term Live Birth (>= 37 Weeks)	she delivered from a private clinic normally but baby was not assessed by pediatrician.
Uganda: Entebbe: UVRI−IAVI	873946812	02DEC2019	Y	15MAR2023	V79.0 − Step 4d − Week 12 Pregnanc y 1	15MAR2023	27APR2022	Y		Confirmed	02SEP2023	Full Term Live Birth (>= 37 Weeks)	participant has never showed up at the clinic since she gave birth, however today she has been contacted on phone. she reports to have delivered from the hospital by c−section, delivered male baby.
Uganda: Entebbe: UVRI−IAVI	873957702	16JAN2019	Y	16JAN2023	V61.0 − Step 4c−CAB LA − Week 32 (1)	16JAN2023	08JUN2022	Y		Ended Prior To Confirmation	09JAN2023	Spontaneous Abortion (< 20 Weeks)	she reports to have had a miscarriage on 9 jan 2023 from her home an ultra sound scan was done and confirmed complete spontaneou s abortion

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Enrollment Date	CAB Exposure Prior to or During Pregnancy	First Pos Test Date	First Pos Test Visit	Est Preg Start Date	OLE Start Date	OLE Pregnancy	OLE Pregnancy Sub Study	Pregnancy Status	Outcome Date	Outcome Status	Outcome Details
Uganda: Entebbe: UVRI−IAVI	873963738	05DEC2018	Y	07DEC2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	07DEC2022	25MAY2022	Y		Confirmed	13JAN2023	Ectopic Pregnancy	participant reported sharp abdominal pain for one day that was getting worse even while taking pain killers. she rushed to hospital and an abdominal ultra sound scan revealed an ectopic.
Uganda: Entebbe: UVRI−IAVI	873971330	17OCT2019	Y	13FEB2024	V118.0 − Step 6−CAB LA − Week 72 (1)	13FEB2024	11JUL2022	Y		Confirmed	−		
Uganda: Entebbe: UVRI−IAVI	873993273	02SEP2019		12AUG2022	V66.0 − Step 4c−TDF/ FTC − Week 16 (1)	12AUG2022	22APR2022	Y		Confirmed	15OCT2022	Therapeutic/ Elective Abortion	participant terminated her pregnancy
Uganda: Entebbe: UVRI−IAVI	873995123	02JUL2019	Y	22SEP2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	22SEP2022	30JUN2022	Y		Confirmed	03MAY2023	Full Term Live Birth (>= 37 Weeks)	she felt labor pains and went to the hospital where she delivered her baby.

Note: For columns where the possible value is `Y´ blanks are interpreted as `No´. For all other columns blanks are interpreted as missing.

Site	Subject	Date of First OLE Visit	Number of CAB injections received prior to pregnancy	Number of CAB injections received within 6 months prior to pregnancy	Number of CAB injections received during pregnancy	First Pos Test Date	First Pos Test Visit	Outcome Date	Outcome Status	Outcome Details	Congenital Anomaly(s)	Congenital Anomaly Description
Malawi: Lilongwe: Malawi CRS	720261814	21APR2022	13	2	3	13JUL2022	V76.0 − Step 4d − Week 0 Pregnancy 1	22NOV2022	OBTAINABLE OUTCOME	INDUCTION OF LABOR WAS DONE BECAUSE OF LETHAL CONGENITAL ANOMALIES. SHE PROGESSED TO A VERTEX DELIVERY OF A FEMALE INFANT. APGAR SCORE 2/10 THEN 3/10 BABY WAS TAKEN TO NURSERY.	YES	Central Nervous System, Spinal; Gastrointestinal; Musculoskeletal/Extremities; Genitourinary
Malawi: Lilongwe: Malawi CRS	720709274	02MAR2022	14	0	0	19OCT2022	V68.0 − Step 4c−TDF/ FTC − Week 32 (1)	05MAY2023	OBTAINABLE OUTCOME	THE INTRAUTERINE FETAL DEATH WAS CONFIRMED ON ULTRASOUND SCAN HOWEVER PARTICIPANT WAS RELUCTANT TO RECEIVE MEDICAL ATTENTION UNTIL SHE WAS FULL TERM. SHE BELIEVED SHE COULD STILL FEEL FETAL MOVEMENTS.	YES	Other: IT WAS OBSERVED THE UMBILICAL CORD WAS TIGHTLY TWISTED

Source: SCHARP (Zhuoran) − /trials/hptn/p084/analysis/atlas/code/open/l_pregnancy_conganm.sas, SAS Version 9.4 (05MAR2024,19:52)

Site	Subject	Date of First OLE Visit	Number of CAB injections received prior to pregnancy	Number of CAB injections received within 6 months prior to pregnancy	Number of CAB injections received during pregnancy	First Pos Test Date	First Pos Test Visit	Outcome Date	Outcome Status	Outcome Details	Congenital Anomaly(s)	Congenital Anomaly Description
Botswana: Gaborone: Gaborone CRS	723132141	15FEB2022	13	3	4	19SEP2022	V60.0 − Step 4c−CAB LA − Week 24 (1)	10MAY2023	OBTAINABLE OUTCOME	HOSPITAL DELIVERY, BABY NOTED TO HAVE POLYDACTYLY AND RESPIRATORY DISTRESS, RESUSCITATED IMMEDIATELY AFTER DELIVERY BUT STABILIZED ON THE SAME DAY. ADMISSION INTO THE NEONATAL UNIT WAS NOT INDICATED.	YES	Musculoskeletal/Extremities
Zimbabwe: Chitungwiza: St.Mary's CRS	762514984	25JUL2022	14	0	0	21SEP2022	V65.0 − Step 4c−TDF/ FTC − Week 8 (1)	14MAY2023	OBTAINABLE OUTCOME	PARTICIPANT DELIVERED A LIVE BABY GIRL BY CESAREAN SECTION ON 14 MAY 2023	YES	Infectious
Zimbabwe: Harare: Parirenyatwa CRS	770981966	10AUG2022	10	1	5	10OCT2022	V57.0 − Step 4c−CAB LA − Week 0 (1)	08JUN2023	OBTAINABLE OUTCOME	DELIVERED BY CAESAREAN SECTION DUE TO POST DATES AND ONE PREVIOUS CAESAREAN SECTION	YES	Other: ODONTOGENIC CYST LEFT LOWER GUM
South Africa: Cape Town: Stellenbosch University (DTTC−SU) CRS	818977261	26AUG2022	9	2	5	25NOV2022	V58.0 − Step 4c−CAB LA − Week 8 (1)	04AUG2023	OBTAINABLE OUTCOME		YES	Musculoskeletal/Extremities

Source: SCHARP (Zhuoran) − /trials/hptn/p084/analysis/atlas/code/open/l_pregnancy_conganm.sas, SAS Version 9.4 (05MAR2024,19:52)