

HPTN 083 – A Phase 2b/3 Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/ Emtricitabine (TDF/FTC), For Pre-Exposure Prophylaxis in HIV-Uninfected Cisgender Men and Transgender Women who have Sex with Men
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Visit Cutoff Date: June 15, 2021
Table O2 – Accrual Summary by Region

Region	Activation Date	First Enrollment Date	Last Enrollment Date ¹	Duration of Accrual ² (Weeks)	Enrollment Target ³	Total Enrolled	Average Enrolled per Week	Percentage Enrolled
US	05DEC2016	19DEC2016	21FEB2019	113.6	1690	1701	15	100.7%
Latin America	02NOV2017	16NOV2017	16MAR2020	186.9	2213	1965	10.5	88.8%
Asia	10AUG2017	07SEP2017	21FEB2020	196.9	808	752	3.8	93.1%
Africa	16AUG2017	12SEP2017	16MAR2020	196.1	225	152	0.8	67.6%
Overall	05DEC2016	19DEC2016	16MAR2020	234.3	5000	4570	19.5	91.4%

¹ Date of most recent enrollment as of June 15, 2021.

² Duration of accrual based on first enrollment date.

³ Overall enrollment target indicates the protocol target and is not necessarily equal to the sum of individual site targets.

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Table O2A – Accrual Summary by Site – Region: US

Site ⁴	Activation Date	First Enrollment Date	Last Enrollment Date ¹	Duration of Accrual ² (Weeks)	Enrollment Target ³	Total Enrolled	Average Enrolled per Week	Percentage Enrolled
Los Angeles – UCLA Care	05DEC2016	19DEC2016	07FEB2019	111.6	65	65	0.6	100.0%
Chicago – AYAR	08DEC2016	19DEC2016	04SEP2018	89.3	65	69	0.8	106.2%
Harlem	21DEC2016	10FEB2017	14FEB2019	105	65	58	0.6	89.2%
Chapel Hill	04JAN2017	24JAN2017	22JAN2019	104.1	65	69	0.7	106.2%
New York – Blood Center	06JAN2017	24FEB2017	25JAN2019	100.1	65	68	0.7	104.6%
St. Louis	10JAN2017	06FEB2017	16OCT2017	36.1	65	65	1.8	100.0%
Memphis	12JAN2017	27JAN2017	11FEB2019	106.6	65	93	0.9	143.1%
Greensboro	18JAN2017	02FEB2017	20DEC2018	98.1	65	58	0.6	89.2%
Birmingham	24JAN2017	17FEB2017	04FEB2019	102.6	65	62	0.6	95.4%
Washington, DC	25JAN2017	07MAR2017	10JAN2019	96.4	65	61	0.6	93.8%
Philadelphia	31JAN2017	07MAR2017	31JAN2019	99.4	65	88	0.9	135.4%
San Francisco	08FEB2017	03APR2017	14MAR2018	49.4	25	26	0.5	104.0%
Cincinnati	09FEB2017	07MAR2017	05FEB2019	100.1	65	79	0.8	121.5%
New York – Weill Cornell Chelsea	21FEB2017	09MAR2017	22JAN2019	97.9	65	65	0.7	100.0%
Newark	21FEB2017	26APR2017	30JAN2019	92.1	65	67	0.7	103.1%
Aurora	22FEB2017	10MAR2017	24JAN2019	98	65	63	0.6	96.9%
Baltimore	09MAR2017	23MAY2017	19DEC2018	82.3	65	26	0.3	40.0%
Los Angeles – UCLA Vine	21MAR2017	20JUN2017	17DEC2018	78	65	70	0.9	107.7%
Bronx	22MAR2017	02JUN2017	28JAN2019	86.6	65	66	0.8	101.5%
Houston	22MAR2017	26MAY2017	17JAN2019	86	65	60	0.7	92.3%
New Orleans	07APR2017	17MAY2017	13FEB2019	91.1	65	53	0.6	81.5%
Atlanta	21APR2017	07AUG2017	25JAN2019	76.7	65	35	0.5	53.8%
Oakland	21APR2017	05SEP2017	27DEC2018	68.4	40	40	0.6	100.0%
Columbus	24APR2017	05MAY2017	31DEC2018	86.6	65	55	0.6	84.6%
Boston	08MAY2017	25MAY2017	07FEB2019	89.1	65	81	0.9	124.6%
Chicago – WISH	08JUN2017	22JUN2017	21FEB2019	87.1	65	73	0.8	112.3%
Decatur	27MAY2021	14MAR2017	28JAN2019	98	65	86	0.9	132.3%
Overall	05DEC2016	19DEC2016	21FEB2019	113.6	1690	1701	15	100.7%

¹ Date of most recent enrollment as of June 15, 2021.

² Duration of accrual based on first enrollment date.

³ Overall enrollment target is for all the sites including those that are not yet activated.

⁴ No sites were actively enrolling as of June 15, 2021. Enrollment period for the US Region ended on 21FEB2019.

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Table O2B – Accrual Summary by Site – Region: Latin America

Site ⁴	Activation Date	First Enrollment Date	Last Enrollment Date ¹	Duration of Accrual ² (Weeks)	Enrollment Target ³	Total Enrolled	Average Enrolled per Week	Percentage Enrolled
Rio de Janeiro	02NOV2017	16NOV2017	16MAR2020	121.7	247	240	2	97.2%
Buenos Aires – Fundacion Huesped	07MAR2018	21MAR2018	13MAR2020	103.4	277	199	1.9	71.8%
Lima – Barranco	12APR2018	26APR2018	22AUG2019	69.1	177	177	2.6	100.0%
Lima – San Miguel	12APR2018	04MAY2018	03OCT2019	74	150	150	2	100.0%
Iquitos	12APR2018	25APR2018	04JUN2019	58	227	177	3.1	78.0%
Lima – CITBM	12APR2018	04MAY2018	15OCT2019	75.7	150	152	2	101.3%
Lima – Via Libre	13APR2018	26APR2018	04OCT2019	75.3	277	176	2.3	63.5%
Porto Alegre	23APR2018	27APR2018	18OCT2019	77.1	177	215	2.8	121.5%
Buenos Aires – Hospital JM Ramos Mejia	13JUN2018	02JUL2018	24OCT2019	68.6	177	138	2	78.0%
Sao Paulo – IC–HCFMUSP	01AUG2018	17AUG2018	03OCT2019	59	177	186	3.2	105.1%
Sao Paulo – DST–AIDS	11MAR2019	29MAR2019	25OCT2019	30.1	177	155	5.1	87.6%
Overall	02NOV2017	16NOV2017	16MAR2020	186.9	2213	1965	10.5	88.8%

¹ Date of most recent enrollment as of June 15, 2021.

² Duration of accrual based on first enrollment date.

³ Overall enrollment target is for all the sites including those that are not yet activated.

⁴ Rio de Janeiro, Buenos Aires – Fundacion Huesped, Iquitos and Lima – Via Libre were the only sites actively enrolling as of June 15, 2021.

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Table O2C – Accrual Summary by Site – Region: Asia

Site ⁴	Activation Date	First Enrollment Date	Last Enrollment Date ¹	Duration of Accrual ² (Weeks)	Enrollment Target ³	Total Enrolled	Average Enrolled per Week	Percentage Enrolled
Chiang Mai	10AUG2017	07SEP2017	01MAY2019	86	177	140	1.6	79.1%
Bangkok – Thai Red Cross	29AUG2017	12SEP2017	21FEB2020	127.6	227	210	1.6	92.5%
Bangkok – Silom Clinic	27NOV2017	07DEC2017	17MAY2019	75.3	177	203	2.7	114.7%
Hanoi	14DEC2017	03JAN2018	05NOV2019	96	227	199	2.1	87.7%
Overall	10AUG2017	07SEP2017	21FEB2020	196.9	808	752	3.8	93.1%

¹ Date of most recent enrollment as of June 15, 2021.

² Duration of accrual based on first enrollment date.

³ Overall enrollment target is for all the sites including those that are not yet activated.

⁴ Bangkok – Thai Red Cross and Hanoi were the only sites actively enrolling as of June 15, 2021.

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Table O2D – Accrual Summary by Site – Region: Africa

Site ⁴	Activation Date	First Enrollment Date	Last Enrollment Date ¹	Duration of Accrual ² (Weeks)	Enrollment Target ³	Total Enrolled	Average Enrolled per Week	Percentage Enrolled
Cape Town	16AUG2017	12SEP2017	16MAR2020	131	225	152	1.2	67.6%
Overall	16AUG2017	12SEP2017	16MAR2020	196.1	225	152	0.8	67.6%

¹ Date of most recent enrollment as of June 15, 2021.

² Duration of accrual based on first enrollment date.

³ Overall enrollment target is for all the sites including those that are not yet activated.

⁴ Cape Town was actively enrolling as of June 15, 2021.

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Table O3 – Accrual Summary and Accrual by Calendar Month and Region

	Overall	US	Latin America	Asia	Africa
Activation Date	05DEC2016	05DEC2016	02NOV2017	10AUG2017	16AUG2017
First Enrollment Date	19DEC2016	19DEC2016	16NOV2017	07SEP2017	12SEP2017
Total Enrolled	4570	1701	1965	752	152
Enrollment Target ¹	5000	1690	2213	808	225
Percent Enrolled	91.4%	100.7%	88.8%	93.1%	67.6%
Months of Active Enrollment ²	53.6	26.4	42.7	45	44.8
Average Enrolled per Month ³	85.3	64.4	46.0	16.7	3.4
Accrual by Calendar Month ⁴					
DEC2016	5 (5)	5 (5)	- (-)	- (-)	- (-)
JAN2017	7 (12)	7 (12)	- (-)	- (-)	- (-)
FEB2017	39 (51)	39 (51)	- (-)	- (-)	- (-)
MAR2017	66 (117)	66 (117)	- (-)	- (-)	- (-)
APR2017	41 (158)	41 (158)	- (-)	- (-)	- (-)
MAY2017	59 (217)	59 (217)	- (-)	- (-)	- (-)
JUN2017	85 (302)	85 (302)	- (-)	- (-)	- (-)
JUL2017	105 (407)	105 (407)	- (-)	- (-)	- (-)
AUG2017	95 (502)	95 (502)	- (-)	- (-)	- (-)
SEP2017	114 (616)	90 (592)	- (-)	22 (22)	2 (2)
OCT2017	96 (712)	90 (682)	- (-)	4 (26)	2 (4)
NOV2017	131 (843)	89 (771)	8 (8)	26 (52)	8 (12)
DEC2017	100 (943)	57 (828)	14 (22)	24 (76)	5 (17)
JAN2018	106 (1049)	78 (906)	4 (26)	24 (100)	0 (17)
FEB2018	121 (1170)	75 (981)	4 (30)	38 (138)	4 (21)
MAR2018	128 (1298)	83 (1064)	8 (38)	31 (169)	6 (27)
APR2018	165 (1463)	79 (1143)	38 (76)	29 (198)	19 (46)
MAY2018	245 (1708)	71 (1214)	103 (179)	61 (259)	10 (56)
JUN2018	205 (1913)	74 (1288)	75 (254)	47 (306)	9 (65)
JUL2018	175 (2088)	65 (1353)	59 (313)	40 (346)	11 (76)
AUG2018	207 (2295)	73 (1426)	95 (408)	33 (379)	6 (82)
SEP2018	175 (2470)	48 (1474)	81 (489)	37 (416)	9 (91)
OCT2018	299 (2769)	62 (1536)	175 (664)	51 (467)	11 (102)
NOV2018	226 (2995)	54 (1590)	125 (789)	39 (506)	8 (110)

¹ Overall enrollment target is the protocol target. This is not necessarily equal to the sum of region targets, which are the sum of site targets which may be adjusted over time to meet the protocol target.

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/p083/analysis/atlas/code/open/t_accrual_calmonth.sas, SAS Version 9.4 (15JUN2021,9:22)

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Table O3 – Accrual Summary and Accrual by Calendar Month and Region

	Overall	US	Latin America	Asia	Africa
DEC2018	137 (3132)	43 (1633)	66 (855)	23 (529)	5 (115)
JAN2019	173 (3305)	52 (1685)	67 (922)	54 (583)	0 (115)
FEB2019	194 (3499)	16 (1701)	127 (1049)	45 (628)	6 (121)
MAR2019	118 (3617)	– (1701)	68 (1117)	45 (673)	5 (126)
APR2019	163 (3780)	– (1701)	117 (1234)	40 (713)	6 (132)
MAY2019	146 (3926)	– (1701)	139 (1373)	2 (715)	5 (137)
JUN2019	115 (4041)	– (1701)	108 (1481)	0 (715)	7 (144)
JUL2019	131 (4172)	– (1701)	129 (1610)	0 (715)	2 (146)
AUG2019	146 (4318)	– (1701)	133 (1743)	13 (728)	0 (146)
SEP2019	122 (4440)	– (1701)	114 (1857)	8 (736)	0 (146)
OCT2019	94 (4534)	– (1701)	91 (1948)	3 (739)	0 (146)
NOV2019	1 (4535)	– (1701)	0 (1948)	1 (740)	0 (146)
DEC2019	0 (4535)	– (1701)	0 (1948)	0 (740)	0 (146)
JAN2020	0 (4535)	– (1701)	0 (1948)	0 (740)	0 (146)
FEB2020	15 (4550)	– (1701)	3 (1951)	12 (752)	0 (146)
MAR2020	20 (4570)	– (1701)	14 (1965)	0 (752)	6 (152)

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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 period², so no enrollment is expected.

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Appendix – Table O1A – Accrual Summary and Accrual by Calendar Month and Site – Region : US

	Overall	Atlanta	Aurora	Baltimore	Birmingham	Boston	Bronx
Activation Date	05DEC2016	21APR2017	22FEB2017	09MAR2017	24JAN2017	08MAY2017	22MAR2017
First Enrollment Date	19DEC2016	07AUG2017	10MAR2017	23MAY2017	17FEB2017	25MAY2017	02JUN2017
Total Enrolled	1701	35	63	26	62	81	66
Enrollment Target ¹	1690	65	65	65	65	65	65
Percent Enrolled	100.7%	53.8%	96.9%	40.0%	95.4%	124.6%	101.5%
Months of Active Enrollment ²	26.4	18.8	23.7	21.3	24.4	21.2	20.9
Average Enrolled per Month ³	64.4	1.9	2.7	1.2	2.5	3.8	3.2
Accrual by Calendar Month ⁴							
DEC2016	5 (5)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
JAN2017	7 (12)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
FEB2017	39 (51)	- (-)	- (-)	- (-)	1 (1)	- (-)	- (-)
MAR2017	66 (117)	- (-)	1 (1)	- (-)	3 (4)	- (-)	- (-)
APR2017	41 (158)	- (-)	4 (5)	- (-)	1 (5)	- (-)	- (-)
MAY2017	59 (217)	- (-)	2 (7)	2 (2)	2 (7)	2 (2)	- (-)
JUN2017	85 (302)	- (-)	3 (10)	1 (3)	1 (8)	8 (10)	4 (4)
JUL2017	105 (407)	- (-)	3 (13)	2 (5)	3 (11)	3 (13)	1 (5)
AUG2017	95 (502)	1 (1)	1 (14)	1 (6)	5 (16)	8 (21)	2 (7)
SEP2017	90 (592)	1 (2)	3 (17)	1 (7)	4 (20)	12 (33)	3 (10)
OCT2017	90 (682)	0 (2)	2 (19)	0 (7)	3 (23)	10 (43)	2 (12)
NOV2017	89 (771)	3 (5)	3 (22)	1 (8)	3 (26)	8 (51)	3 (15)
DEC2017	57 (828)	2 (7)	3 (25)	2 (10)	1 (27)	3 (54)	0 (15)
JAN2018	78 (906)	1 (8)	5 (30)	0 (10)	2 (29)	4 (58)	2 (17)
FEB2018	75 (981)	1 (9)	5 (35)	1 (11)	5 (34)	7 (65)	0 (17)
MAR2018	83 (1064)	1 (10)	3 (38)	1 (12)	7 (41)	- (65)	6 (23)
APR2018	79 (1143)	3 (13)	4 (42)	0 (12)	1 (42)	- (65)	7 (30)
MAY2018	71 (1214)	3 (16)	2 (44)	1 (13)	3 (45)	2 (67)	3 (33)
JUN2018	74 (1288)	1 (17)	3 (47)	2 (15)	2 (47)	2 (69)	6 (39)
JUL2018	65 (1353)	1 (18)	5 (52)	1 (16)	5 (52)	5 (74)	4 (43)
AUG2018	73 (1426)	1 (19)	2 (54)	2 (18)	2 (54)	2 (76)	5 (48)
SEP2018	48 (1474)	1 (20)	0 (54)	3 (21)	0 (54)	- (76)	3 (51)
OCT2018	62 (1536)	5 (25)	3 (57)	2 (23)	1 (55)	- (76)	3 (54)
NOV2018	54 (1590)	2 (27)	1 (58)	2 (25)	2 (57)	3 (79)	2 (56)

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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.

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Appendix – Table O1A – Accrual Summary and Accrual by Calendar Month and Site – Region : US

	Overall	Atlanta	Aurora	Baltimore	Birmingham	Boston	Bronx
DEC2018	43 (1633)	2 (29)	2 (60)	1 (26)	0 (57)	1 (80)	3 (59)
JAN2019	52 (1685)	6 (35)	3 (63)	0 (26)	4 (61)	– (80)	7 (66)
FEB2019	16 (1701)	0 (35)	0 (63)	0 (26)	1 (62)	1 (81)	– (66)
MAR2019	– (1701)	– (35)	– (63)	– (26)	– (62)	– (81)	– (66)
APR2019	– (1701)	– (35)	– (63)	– (26)	– (62)	– (81)	– (66)
MAY2019	– (1701)	– (35)	– (63)	– (26)	– (62)	– (81)	– (66)
JUN2019	– (1701)	– (35)	– (63)	– (26)	– (62)	– (81)	– (66)
JUL2019	– (1701)	– (35)	– (63)	– (26)	– (62)	– (81)	– (66)
AUG2019	– (1701)	– (35)	– (63)	– (26)	– (62)	– (81)	– (66)
SEP2019	– (1701)	– (35)	– (63)	– (26)	– (62)	– (81)	– (66)
OCT2019	– (1701)	– (35)	– (63)	– (26)	– (62)	– (81)	– (66)
NOV2019	– (1701)	– (35)	– (63)	– (26)	– (62)	– (81)	– (66)
DEC2019	– (1701)	– (35)	– (63)	– (26)	– (62)	– (81)	– (66)
JAN2020	– (1701)	– (35)	– (63)	– (26)	– (62)	– (81)	– (66)
FEB2020	– (1701)	– (35)	– (63)	– (26)	– (62)	– (81)	– (66)
MAR2020	– (1701)	– (35)	– (63)	– (26)	– (62)	– (81)	– (66)

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³ Total enrolled divided by months of active enrollment.

⁴ A dash (–) in the enrollment column indicates a month not in active enrollment period², so no enrollment is expected.

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Appendix – Table O1A – Accrual Summary and Accrual by Calendar Month and Site – Region : US

	Chapel Hill	Chicago – AYAR	Chicago – WISH	Cincinnati	Columbus	Decatur	Greensboro
Activation Date	04JAN2017	08DEC2016	08JUN2017	09FEB2017	24APR2017	27MAY2021	18JAN2017
First Enrollment Date	24JAN2017	19DEC2016	22JUN2017	07MAR2017	05MAY2017	14MAR2017	02FEB2017
Total Enrolled	69	69	73	79	55	86	58
Enrollment Target ¹	65	65	65	65	65	65	65
Percent Enrolled	106.2%	106.2%	112.3%	121.5%	84.6%	132.3%	89.2%
Months of Active Enrollment ²	25.2	26.4	20.3	23.8	21.8	23.5	24.9
Average Enrolled per Month ³	2.7	2.6	3.6	3.3	2.5	3.7	2.3
Accrual by Calendar Month ⁴							
DEC2016	– (–)	2 (2)	– (–)	– (–)	– (–)	– (–)	– (–)
JAN2017	3 (3)	2 (4)	– (–)	– (–)	– (–)	– (–)	– (–)
FEB2017	3 (6)	3 (7)	– (–)	– (–)	– (–)	– (–)	7 (7)
MAR2017	4 (10)	3 (10)	– (–)	6 (6)	– (–)	2 (2)	6 (13)
APR2017	4 (14)	3 (13)	– (–)	5 (11)	– (–)	2 (4)	2 (15)
MAY2017	1 (15)	3 (16)	– (–)	5 (16)	2 (2)	3 (7)	3 (18)
JUN2017	0 (15)	8 (24)	5 (5)	7 (23)	3 (5)	1 (8)	3 (21)
JUL2017	4 (19)	13 (37)	8 (13)	4 (27)	4 (9)	6 (14)	2 (23)
AUG2017	3 (22)	1 (38)	3 (16)	1 (28)	3 (12)	7 (21)	3 (26)
SEP2017	5 (27)	1 (39)	3 (19)	2 (30)	3 (15)	5 (26)	2 (28)
OCT2017	2 (29)	5 (44)	2 (21)	3 (33)	2 (17)	4 (30)	3 (31)
NOV2017	2 (31)	3 (47)	4 (25)	3 (36)	3 (20)	3 (33)	5 (36)
DEC2017	3 (34)	2 (49)	1 (26)	3 (39)	2 (22)	3 (36)	0 (36)
JAN2018	7 (41)	4 (53)	2 (28)	5 (44)	5 (27)	5 (41)	0 (36)
FEB2018	3 (44)	4 (57)	1 (29)	4 (48)	2 (29)	1 (42)	1 (37)
MAR2018	4 (48)	2 (59)	2 (31)	3 (51)	6 (35)	7 (49)	4 (41)
APR2018	2 (50)	2 (61)	7 (38)	1 (52)	7 (42)	5 (54)	2 (43)
MAY2018	2 (52)	2 (63)	5 (43)	2 (54)	2 (44)	5 (59)	4 (47)
JUN2018	5 (57)	2 (65)	4 (47)	4 (58)	1 (45)	3 (62)	1 (48)
JUL2018	2 (59)	2 (67)	1 (48)	2 (60)	1 (46)	5 (67)	3 (51)
AUG2018	3 (62)	1 (68)	6 (54)	3 (63)	3 (49)	2 (69)	3 (54)
SEP2018	2 (64)	1 (69)	5 (59)	5 (68)	2 (51)	2 (71)	0 (54)
OCT2018	2 (66)	– (69)	6 (65)	3 (71)	2 (53)	5 (76)	2 (56)
NOV2018	1 (67)	– (69)	2 (67)	3 (74)	0 (53)	3 (79)	1 (57)

¹ Overall enrollment target is the protocol target. This is not necessarily equal to the sum of region targets, which are the sum of site targets which may be adjusted over time to meet the protocol target.

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/p083/analysis/atlas/code/open/t_accrual_calmonth.sas, SAS Version 9.4 (15JUN2021,9:22)

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Appendix – Table O1A – Accrual Summary and Accrual by Calendar Month and Site – Region : US

	Chapel Hill	Chicago – AYAR	Chicago – WISH	Cincinnati	Columbus	Decatur	Greensboro
DEC2018	1 (68)	– (69)	1 (68)	4 (78)	2 (55)	2 (81)	1 (58)
JAN2019	1 (69)	– (69)	3 (71)	– (78)	0 (55)	5 (86)	0 (58)
FEB2019	– (69)	– (69)	2 (73)	1 (79)	0 (55)	– (86)	0 (58)
MAR2019	– (69)	– (69)	– (73)	– (79)	– (55)	– (86)	– (58)
APR2019	– (69)	– (69)	– (73)	– (79)	– (55)	– (86)	– (58)
MAY2019	– (69)	– (69)	– (73)	– (79)	– (55)	– (86)	– (58)
JUN2019	– (69)	– (69)	– (73)	– (79)	– (55)	– (86)	– (58)
JUL2019	– (69)	– (69)	– (73)	– (79)	– (55)	– (86)	– (58)
AUG2019	– (69)	– (69)	– (73)	– (79)	– (55)	– (86)	– (58)
SEP2019	– (69)	– (69)	– (73)	– (79)	– (55)	– (86)	– (58)
OCT2019	– (69)	– (69)	– (73)	– (79)	– (55)	– (86)	– (58)
NOV2019	– (69)	– (69)	– (73)	– (79)	– (55)	– (86)	– (58)
DEC2019	– (69)	– (69)	– (73)	– (79)	– (55)	– (86)	– (58)
JAN2020	– (69)	– (69)	– (73)	– (79)	– (55)	– (86)	– (58)
FEB2020	– (69)	– (69)	– (73)	– (79)	– (55)	– (86)	– (58)
MAR2020	– (69)	– (69)	– (73)	– (79)	– (55)	– (86)	– (58)

¹ Overall enrollment target is the protocol target. This is not necessarily equal to the sum of region targets, which are the sum of site targets which may be adjusted over time to meet the protocol target.

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/p083/analysis/atlas/code/open/t_accrual_calmonth.sas, SAS Version 9.4 (15JUN2021,9:22)

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Appendix – Table O1A – Accrual Summary and Accrual by Calendar Month and Site – Region : US

	Harlem	Houston	Los Angeles – UCLA Care	Los Angeles – UCLA Vine	Memphis	New Orleans	New York – Blood Center
Activation Date	21DEC2016	22MAR2017	05DEC2016	21MAR2017	12JAN2017	07APR2017	06JAN2017
First Enrollment Date	10FEB2017	26MAY2017	19DEC2016	20JUN2017	27JAN2017	17MAY2017	24FEB2017
Total Enrolled	58	60	65	70	93	53	68
Enrollment Target ¹	65	65	65	65	65	65	65
Percent Enrolled	89.2%	92.3%	100.0%	107.7%	143.1%	81.5%	104.6%
Months of Active Enrollment ²	24.6	21.2	26.4	20.3	25.1	21.5	24.1
Average Enrolled per Month ³	2.4	2.8	2.5	3.4	3.7	2.5	2.8
Accrual by Calendar Month ⁴							
DEC2016	- (-)	- (-)	3 (3)	- (-)	- (-)	- (-)	- (-)
JAN2017	- (-)	- (-)	1 (4)	- (-)	1 (1)	- (-)	- (-)
FEB2017	2 (2)	- (-)	3 (7)	- (-)	12 (13)	- (-)	1 (1)
MAR2017	1 (3)	- (-)	4 (11)	- (-)	11 (24)	- (-)	4 (5)
APR2017	1 (4)	- (-)	4 (15)	- (-)	2 (26)	- (-)	0 (5)
MAY2017	0 (4)	1 (1)	3 (18)	- (-)	4 (30)	4 (4)	2 (7)
JUN2017	2 (6)	2 (3)	2 (20)	6 (6)	5 (35)	2 (6)	3 (10)
JUL2017	2 (8)	3 (6)	1 (21)	3 (9)	4 (39)	1 (7)	3 (13)
AUG2017	2 (10)	1 (7)	5 (26)	6 (15)	10 (49)	3 (10)	5 (18)
SEP2017	3 (13)	4 (11)	4 (30)	1 (16)	4 (53)	2 (12)	2 (20)
OCT2017	0 (13)	8 (19)	3 (33)	6 (22)	4 (57)	2 (14)	2 (22)
NOV2017	3 (16)	1 (20)	2 (35)	3 (25)	7 (64)	3 (17)	4 (26)
DEC2017	1 (17)	1 (21)	4 (39)	6 (31)	0 (64)	3 (20)	1 (27)
JAN2018	0 (17)	1 (22)	3 (42)	4 (35)	3 (67)	2 (22)	1 (28)
FEB2018	2 (19)	7 (29)	3 (45)	4 (39)	4 (71)	0 (22)	5 (33)
MAR2018	5 (24)	2 (31)	2 (47)	2 (41)	2 (73)	2 (24)	7 (40)
APR2018	2 (26)	3 (34)	2 (49)	5 (46)	2 (75)	3 (27)	4 (44)
MAY2018	2 (28)	7 (41)	0 (49)	3 (49)	4 (79)	1 (28)	2 (46)
JUN2018	5 (33)	3 (44)	4 (53)	4 (53)	2 (81)	3 (31)	1 (47)
JUL2018	3 (36)	4 (48)	2 (55)	3 (56)	1 (82)	3 (34)	6 (53)
AUG2018	3 (39)	1 (49)	1 (56)	6 (62)	2 (84)	4 (38)	5 (58)
SEP2018	2 (41)	2 (51)	1 (57)	3 (65)	1 (85)	4 (42)	2 (60)
OCT2018	2 (43)	3 (54)	1 (58)	1 (66)	- (85)	2 (44)	4 (64)

¹ Overall enrollment target is the protocol target. This is not necessarily equal to the sum of region targets, which are the sum of site targets which may be adjusted over time to meet the protocol target.

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/p083/analysis/atlas/code/open/t_accrual_calmonth.sas, SAS Version 9.4 (15JUN2021,9:22)

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Appendix – Table O1A – Accrual Summary and Accrual by Calendar Month and Site – Region : US

	Harlem	Houston	Los Angeles – UCLA Care	Los Angeles – UCLA Vine	Memphis	New Orleans	New York – Blood Center
NOV2018	4 (47)	2 (56)	3 (61)	2 (68)	– (85)	2 (46)	2 (66)
DEC2018	1 (48)	1 (57)	2 (63)	2 (70)	2 (87)	3 (49)	1 (67)
JAN2019	4 (52)	3 (60)	1 (64)	– (70)	4 (91)	2 (51)	1 (68)
FEB2019	6 (58)	0 (60)	1 (65)	– (70)	2 (93)	2 (53)	– (68)
MAR2019	– (58)	– (60)	– (65)	– (70)	– (93)	– (53)	– (68)
APR2019	– (58)	– (60)	– (65)	– (70)	– (93)	– (53)	– (68)
MAY2019	– (58)	– (60)	– (65)	– (70)	– (93)	– (53)	– (68)
JUN2019	– (58)	– (60)	– (65)	– (70)	– (93)	– (53)	– (68)
JUL2019	– (58)	– (60)	– (65)	– (70)	– (93)	– (53)	– (68)
AUG2019	– (58)	– (60)	– (65)	– (70)	– (93)	– (53)	– (68)
SEP2019	– (58)	– (60)	– (65)	– (70)	– (93)	– (53)	– (68)
OCT2019	– (58)	– (60)	– (65)	– (70)	– (93)	– (53)	– (68)
NOV2019	– (58)	– (60)	– (65)	– (70)	– (93)	– (53)	– (68)
DEC2019	– (58)	– (60)	– (65)	– (70)	– (93)	– (53)	– (68)
JAN2020	– (58)	– (60)	– (65)	– (70)	– (93)	– (53)	– (68)
FEB2020	– (58)	– (60)	– (65)	– (70)	– (93)	– (53)	– (68)
MAR2020	– (58)	– (60)	– (65)	– (70)	– (93)	– (53)	– (68)

¹ Overall enrollment target is the protocol target. This is not necessarily equal to the sum of region targets, which are the sum of site targets which may be adjusted over time to meet the protocol target.

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 period², so no enrollment is expected.

Source: SCHARP (Surabhi) – /trials/hptn/p083/analysis/atlas/code/open/t_accrual_calmonth.sas, SAS Version 9.4 (15JUN2021,9:22)

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Appendix – Table O1A – Accrual Summary and Accrual by Calendar Month and Site – Region : US

	New York – Weill Cornell Chelsea	Newark	Oakland	Philadelphia	San Francisco	St. Louis	Washington, DC
Activation Date	21FEB2017	21FEB2017	21APR2017	31JAN2017	08FEB2017	10JAN2017	25JAN2017
First Enrollment Date	09MAR2017	26APR2017	05SEP2017	07MAR2017	03APR2017	06FEB2017	07MAR2017
Total Enrolled	65	67	40	88	26	65	61
Enrollment Target ¹	65	65	40	65	25	65	65
Percent Enrolled	100.0%	103.1%	100.0%	135.4%	104.0%	100.0%	93.8%
Months of Active Enrollment ²	23.7	21.2	17.8	23.8	22.8	24.8	23.8
Average Enrolled per Month ³	2.7	3.2	2.2	3.7	1.1	2.6	2.6
Accrual by Calendar Month ⁴							
DEC2016	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
JAN2017	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
FEB2017	- (-)	- (-)	- (-)	- (-)	- (-)	7 (7)	- (-)
MAR2017	1 (1)	- (-)	- (-)	5 (5)	- (-)	12 (19)	3 (3)
APR2017	1 (2)	1 (1)	- (-)	2 (7)	3 (3)	1 (20)	5 (8)
MAY2017	2 (4)	0 (1)	- (-)	2 (9)	0 (3)	12 (32)	4 (12)
JUN2017	4 (8)	1 (2)	- (-)	2 (11)	3 (6)	6 (38)	3 (15)
JUL2017	6 (14)	1 (3)	- (-)	11 (22)	3 (9)	12 (50)	2 (17)
AUG2017	3 (17)	4 (7)	- (-)	7 (29)	1 (10)	7 (57)	2 (19)
SEP2017	4 (21)	5 (12)	7 (7)	3 (32)	3 (13)	3 (60)	0 (19)
OCT2017	3 (24)	3 (15)	6 (13)	5 (37)	2 (15)	5 (65)	3 (22)
NOV2017	6 (30)	2 (17)	1 (14)	7 (44)	2 (17)	- (65)	4 (26)
DEC2017	1 (31)	1 (18)	3 (17)	6 (50)	3 (20)	- (65)	2 (28)
JAN2018	5 (36)	5 (23)	3 (20)	1 (51)	4 (24)	- (65)	4 (32)
FEB2018	3 (39)	1 (24)	5 (25)	3 (54)	1 (25)	- (65)	2 (34)
MAR2018	2 (41)	4 (28)	2 (27)	0 (54)	1 (26)	- (65)	6 (40)
APR2018	2 (43)	6 (34)	5 (32)	2 (56)	- (26)	- (65)	2 (42)
MAY2018	3 (46)	5 (39)	1 (33)	3 (59)	- (26)	- (65)	4 (46)
JUN2018	2 (48)	3 (42)	0 (33)	8 (67)	- (26)	- (65)	3 (49)
JUL2018	0 (48)	5 (47)	0 (33)	1 (68)	- (26)	- (65)	0 (49)
AUG2018	1 (49)	8 (55)	1 (34)	3 (71)	- (26)	- (65)	3 (52)
SEP2018	3 (52)	2 (57)	1 (35)	1 (72)	- (26)	- (65)	2 (54)
OCT2018	4 (56)	4 (61)	2 (37)	3 (75)	- (26)	- (65)	2 (56)

¹ Overall enrollment target is the protocol target. This is not necessarily equal to the sum of region targets, which are the sum of site targets which may be adjusted over time to meet the protocol target.

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.

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Appendix – Table O1A – Accrual Summary and Accrual by Calendar Month and Site – Region : US

	New York – Weill Cornell Chelsea	Newark	Oakland	Philadelphia	San Francisco	St. Louis	Washington, DC
NOV2018	3 (59)	2 (63)	0 (37)	9 (84)	- (26)	- (65)	3 (59)
DEC2018	3 (62)	2 (65)	3 (40)	2 (86)	- (26)	- (65)	1 (60)
JAN2019	3 (65)	2 (67)	- (40)	2 (88)	- (26)	- (65)	1 (61)
FEB2019	- (65)	- (67)	- (40)	- (88)	- (26)	- (65)	0 (61)
MAR2019	- (65)	- (67)	- (40)	- (88)	- (26)	- (65)	- (61)
APR2019	- (65)	- (67)	- (40)	- (88)	- (26)	- (65)	- (61)
MAY2019	- (65)	- (67)	- (40)	- (88)	- (26)	- (65)	- (61)
JUN2019	- (65)	- (67)	- (40)	- (88)	- (26)	- (65)	- (61)
JUL2019	- (65)	- (67)	- (40)	- (88)	- (26)	- (65)	- (61)
AUG2019	- (65)	- (67)	- (40)	- (88)	- (26)	- (65)	- (61)
SEP2019	- (65)	- (67)	- (40)	- (88)	- (26)	- (65)	- (61)
OCT2019	- (65)	- (67)	- (40)	- (88)	- (26)	- (65)	- (61)
NOV2019	- (65)	- (67)	- (40)	- (88)	- (26)	- (65)	- (61)
DEC2019	- (65)	- (67)	- (40)	- (88)	- (26)	- (65)	- (61)
JAN2020	- (65)	- (67)	- (40)	- (88)	- (26)	- (65)	- (61)
FEB2020	- (65)	- (67)	- (40)	- (88)	- (26)	- (65)	- (61)
MAR2020	- (65)	- (67)	- (40)	- (88)	- (26)	- (65)	- (61)

¹ Overall enrollment target is the protocol target. This is not necessarily equal to the sum of region targets, which are the sum of site targets which may be adjusted over time to meet the protocol target.

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.

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Appendix – Table O1B – Accrual Summary and Accrual by Calendar Month and Site – Region : Latin America

	Overall	Buenos Aires – Fundacion Huesped	Buenos Aires – Hospital JM Ramos Mejia	Iquitos	Lima – Barranco	Lima – CITBM
Activation Date	02NOV2017	07MAR2018	13JUN2018	12APR2018	12APR2018	12APR2018
First Enrollment Date	16NOV2017	21MAR2018	02JUL2018	25APR2018	26APR2018	04MAY2018
Total Enrolled	1965	199	138	177	177	152
Enrollment Target ¹	2213	277	177	227	177	150
Percent Enrolled	88.8%	71.8%	78.0%	78.0%	100.0%	101.3%
Months of Active Enrollment ²	42.7	38.5	35.1	37.4	37.3	37.1
Average Enrolled per Month ³	46.0	5.2	3.9	4.7	4.7	4.1
Accrual by Calendar Month ⁴						
NOV2017	8 (8)	- (-)	- (-)	- (-)	- (-)	- (-)
DEC2017	14 (22)	- (-)	- (-)	- (-)	- (-)	- (-)
JAN2018	4 (26)	- (-)	- (-)	- (-)	- (-)	- (-)
FEB2018	4 (30)	- (-)	- (-)	- (-)	- (-)	- (-)
MAR2018	8 (38)	1 (1)	- (-)	- (-)	- (-)	- (-)
APR2018	38 (76)	15 (16)	- (-)	4 (4)	2 (2)	- (-)
MAY2018	103 (179)	11 (27)	- (-)	34 (38)	7 (9)	9 (9)
JUN2018	75 (254)	8 (35)	- (-)	6 (44)	6 (15)	10 (19)
JUL2018	59 (313)	0 (35)	6 (6)	0 (44)	5 (20)	9 (28)
AUG2018	95 (408)	0 (35)	4 (10)	0 (44)	14 (34)	5 (33)
SEP2018	81 (489)	4 (39)	1 (11)	0 (44)	11 (45)	0 (33)
OCT2018	175 (664)	20 (59)	16 (27)	37 (81)	19 (64)	0 (33)
NOV2018	125 (789)	6 (65)	11 (38)	35 (116)	15 (79)	0 (33)
DEC2018	66 (855)	3 (68)	3 (41)	2 (118)	15 (94)	0 (33)
JAN2019	67 (922)	2 (70)	6 (47)	7 (125)	13 (107)	0 (33)
FEB2019	127 (1049)	20 (90)	10 (57)	31 (156)	11 (118)	0 (33)
MAR2019	68 (1117)	31 (121)	12 (69)	0 (156)	0 (118)	0 (33)
APR2019	117 (1234)	4 (125)	12 (81)	0 (156)	14 (132)	0 (33)
MAY2019	139 (1373)	14 (139)	13 (94)	13 (169)	20 (152)	31 (64)
JUN2019	108 (1481)	18 (157)	12 (106)	8 (177)	14 (166)	12 (76)
JUL2019	129 (1610)	14 (171)	5 (111)	0 (177)	7 (173)	11 (87)
AUG2019	133 (1743)	9 (180)	7 (118)	0 (177)	4 (177)	24 (111)

¹ Overall enrollment target is the protocol target. This is not necessarily equal to the sum of region targets, which are the sum of site targets which may be adjusted over time to meet the protocol target.

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/p083/analysis/atlas/code/open/t_accrual_calmonth.sas, SAS Version 9.4 (15JUN2021,9:22)

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Appendix – Table O1B – Accrual Summary and Accrual by Calendar Month and Site – Region : Latin America

	Overall	Buenos Aires – Fundacion Huesped	Buenos Aires – Hospital JM Ramos Mejia	Iquitos	Lima – Barranco	Lima – CITBM
SEP2019	114 (1857)	7 (187)	10 (128)	0 (177)	- (177)	20 (131)
OCT2019	91 (1948)	0 (187)	10 (138)	0 (177)	- (177)	21 (152)
NOV2019	0 (1948)	0 (187)	0 (138)	0 (177)	- (177)	- (152)
DEC2019	0 (1948)	0 (187)	0 (138)	0 (177)	- (177)	- (152)
JAN2020	0 (1948)	0 (187)	0 (138)	0 (177)	- (177)	- (152)
FEB2020	3 (1951)	3 (190)	0 (138)	0 (177)	- (177)	- (152)
MAR2020	14 (1965)	9 (199)	0 (138)	0 (177)	- (177)	- (152)

¹ Overall enrollment target is the protocol target. This is not necessarily equal to the sum of region targets, which are the sum of site targets which may be adjusted over time to meet the protocol target.

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.

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Appendix – Table O1B – Accrual Summary and Accrual by Calendar Month and Site – Region : Latin America

	Lima – San Miguel	Lima – Via Libre	Porto Alegre	Rio de Janeiro	Sao Paulo – DST-AIDS	Sao Paulo – IC-HCFMUSP
Activation Date	12APR2018	13APR2018	23APR2018	02NOV2017	11MAR2019	01AUG2018
First Enrollment Date	04MAY2018	26APR2018	27APR2018	16NOV2017	29MAR2019	17AUG2018
Total Enrolled	150	176	215	240	155	186
Enrollment Target ¹	150	277	177	247	177	177
Percent Enrolled	100.0%	63.5%	121.5%	97.2%	87.6%	105.1%
Months of Active Enrollment ²	37.1	37.3	37.3	42.7	26.3	33.7
Average Enrolled per Month ³	4.0	4.7	5.8	5.6	5.9	5.5
Accrual by Calendar Month ⁴						
NOV2017	- (-)	- (-)	- (-)	8 (8)	- (-)	- (-)
DEC2017	- (-)	- (-)	- (-)	14 (22)	- (-)	- (-)
JAN2018	- (-)	- (-)	- (-)	4 (26)	- (-)	- (-)
FEB2018	- (-)	- (-)	- (-)	4 (30)	- (-)	- (-)
MAR2018	- (-)	- (-)	- (-)	7 (37)	- (-)	- (-)
APR2018	- (-)	3 (3)	1 (1)	13 (50)	- (-)	- (-)
MAY2018	6 (6)	20 (23)	3 (4)	13 (63)	- (-)	- (-)
JUN2018	2 (8)	8 (31)	11 (15)	24 (87)	- (-)	- (-)
JUL2018	3 (11)	2 (33)	19 (34)	15 (102)	- (-)	- (-)
AUG2018	11 (22)	7 (40)	27 (61)	19 (121)	- (-)	8 (8)
SEP2018	5 (27)	25 (65)	18 (79)	10 (131)	- (-)	7 (15)
OCT2018	14 (41)	26 (91)	21 (100)	17 (148)	- (-)	5 (20)
NOV2018	17 (58)	19 (110)	12 (112)	7 (155)	- (-)	3 (23)
DEC2018	7 (65)	4 (114)	13 (125)	12 (167)	- (-)	7 (30)
JAN2019	12 (77)	5 (119)	9 (134)	6 (173)	- (-)	7 (37)
FEB2019	3 (80)	5 (124)	10 (144)	3 (176)	- (-)	34 (71)
MAR2019	0 (80)	0 (124)	15 (159)	1 (177)	1 (1)	8 (79)
APR2019	14 (94)	24 (148)	13 (172)	11 (188)	12 (13)	13 (92)
MAY2019	8 (102)	13 (161)	7 (179)	6 (194)	6 (19)	8 (100)
JUN2019	13 (115)	5 (166)	2 (181)	7 (201)	8 (27)	9 (109)
JUL2019	13 (128)	9 (175)	5 (186)	10 (211)	40 (67)	15 (124)
AUG2019	5 (133)	0 (175)	12 (198)	12 (223)	33 (100)	27 (151)

¹ Overall enrollment target is the protocol target. This is not necessarily equal to the sum of region targets, which are the sum of site targets which may be adjusted over time to meet the protocol target.

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/p083/analysis/atlas/code/open/t_accrual_calmonth.sas, SAS Version 9.4 (15JUN2021,9:22)

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Appendix – Table O1B – Accrual Summary and Accrual by Calendar Month and Site – Region : Latin America

	Lima – San Miguel	Lima – Via Libre	Porto Alegre	Rio de Janeiro	Sao Paulo – DST-AIDS	Sao Paulo – IC-HCFMUSP
SEP2019	6 (139)	0 (175)	5 (203)	10 (233)	23 (123)	33 (184)
OCT2019	11 (150)	1 (176)	12 (215)	2 (235)	32 (155)	2 (186)
NOV2019	– (150)	0 (176)	– (215)	0 (235)	0 (155)	– (186)
DEC2019	– (150)	0 (176)	– (215)	0 (235)	0 (155)	– (186)
JAN2020	– (150)	0 (176)	– (215)	0 (235)	0 (155)	– (186)
FEB2020	– (150)	0 (176)	– (215)	0 (235)	0 (155)	– (186)
MAR2020	– (150)	0 (176)	– (215)	5 (240)	0 (155)	– (186)

¹ Overall enrollment target is the protocol target. This is not necessarily equal to the sum of region targets, which are the sum of site targets which may be adjusted over time to meet the protocol target.

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/p083/analysis/atlas/code/open/t_accrual_calmonth.sas, SAS Version 9.4 (15JUN2021,9:22)

HPTN 083 – A Phase 2b/3 Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/ Emtricitabine (TDF/FTC), For Pre-Exposure Prophylaxis in HIV-Uninfected Cisgender Men and Transgender Women who have Sex with Men
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Appendix – Table O1C – Accrual Summary and Accrual by Calendar Month and Site – Region : Asia

	Overall	Bangkok – Silom Clinic	Bangkok – Thai Red Cross	Chiang Mai	Hanoi
Activation Date	10AUG2017	27NOV2017	29AUG2017	10AUG2017	14DEC2017
First Enrollment Date	07SEP2017	07DEC2017	12SEP2017	07SEP2017	03JAN2018
Total Enrolled	752	203	210	140	199
Enrollment Target ¹	808	177	227	177	227
Percent Enrolled	93.1%	114.7%	92.5%	79.1%	87.7%
Months of Active Enrollment ²	45	42	44.4	45	41.1
Average Enrolled per Month ³	16.7	4.8	4.7	3.1	4.8
Accrual by Calendar Month ⁴					
AUG2017	– (–)	– (–)	– (–)	– (–)	– (–)
SEP2017	22 (22)	– (–)	17 (17)	5 (5)	– (–)
OCT2017	4 (26)	– (–)	0 (17)	4 (9)	– (–)
NOV2017	26 (52)	– (–)	17 (34)	9 (18)	– (–)
DEC2017	24 (76)	15 (15)	0 (34)	9 (27)	– (–)
JAN2018	24 (100)	10 (25)	5 (39)	2 (29)	7 (7)
FEB2018	38 (138)	11 (36)	19 (58)	5 (34)	3 (10)
MAR2018	31 (169)	15 (51)	2 (60)	3 (37)	11 (21)
APR2018	29 (198)	7 (58)	12 (72)	3 (40)	7 (28)
MAY2018	61 (259)	19 (77)	16 (88)	13 (53)	13 (41)
JUN2018	47 (306)	13 (90)	11 (99)	10 (63)	13 (54)
JUL2018	40 (346)	11 (101)	6 (105)	8 (71)	15 (69)
AUG2018	33 (379)	7 (108)	10 (115)	6 (77)	10 (79)
SEP2018	37 (416)	14 (122)	6 (121)	6 (83)	11 (90)
OCT2018	51 (467)	16 (138)	15 (136)	8 (91)	12 (102)
NOV2018	39 (506)	5 (143)	14 (150)	5 (96)	15 (117)
DEC2018	23 (529)	0 (143)	5 (155)	9 (105)	9 (126)
JAN2019	54 (583)	15 (158)	15 (170)	7 (112)	17 (143)
FEB2019	45 (628)	25 (183)	7 (177)	7 (119)	6 (149)
MAR2019	45 (673)	15 (198)	2 (179)	8 (127)	20 (169)
APR2019	40 (713)	4 (202)	11 (190)	12 (139)	13 (182)
MAY2019	2 (715)	1 (203)	0 (190)	1 (140)	0 (182)
JUN2019	0 (715)	– (203)	0 (190)	0 (140)	0 (182)

¹ Overall enrollment target is the protocol target. This is not necessarily equal to the sum of region targets, which are the sum of site targets which may be adjusted over time to meet the protocol target.

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/p083/analysis/atlas/code/open/t_accrual_calmonth.sas, SAS Version 9.4 (15JUN2021,9:22)

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Appendix – Table O1C – Accrual Summary and Accrual by Calendar Month and Site – Region : Asia

	Overall	Bangkok – Silom Clinic	Bangkok – Thai Red Cross	Chiang Mai	Hanoi
JUL2019	0 (715)	– (203)	0 (190)	0 (140)	0 (182)
AUG2019	13 (728)	– (203)	8 (198)	0 (140)	5 (187)
SEP2019	8 (736)	– (203)	0 (198)	0 (140)	8 (195)
OCT2019	3 (739)	– (203)	0 (198)	0 (140)	3 (198)
NOV2019	1 (740)	– (203)	0 (198)	0 (140)	1 (199)
DEC2019	0 (740)	– (203)	0 (198)	0 (140)	0 (199)
JAN2020	0 (740)	– (203)	0 (198)	0 (140)	0 (199)
FEB2020	12 (752)	– (203)	12 (210)	0 (140)	0 (199)
MAR2020	0 (752)	– (203)	0 (210)	0 (140)	0 (199)

¹ Overall enrollment target is the protocol target. This is not necessarily equal to the sum of region targets, which are the sum of site targets which may be adjusted over time to meet the protocol target.

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 period², so no enrollment is expected.

Source: SCHARP (Surabhi) – /trials/hptn/p083/analysis/atlas/code/open/t_accrual_calmonth.sas, SAS Version 9.4 (15JUN2021,9:22)

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Appendix – Table O1D – Accrual Summary and Accrual by Calendar Month and Site – Region : Africa

	Overall	Cape Town
Activation Date	16AUG2017	16AUG2017
First Enrollment Date	12SEP2017	12SEP2017
Total Enrolled	152	152
Enrollment Target ¹	225	225
Percent Enrolled	67.6%	67.6%
Months of Active Enrollment ²	44.8	44.8
Average Enrolled per Month ³	3.4	3.4
Accrual by Calendar Month ⁴		
AUG2017	– (–)	– (–)
SEP2017	2 (2)	2 (2)
OCT2017	2 (4)	2 (4)
NOV2017	8 (12)	8 (12)
DEC2017	5 (17)	5 (17)
JAN2018	0 (17)	0 (17)
FEB2018	4 (21)	4 (21)
MAR2018	6 (27)	6 (27)
APR2018	19 (46)	19 (46)
MAY2018	10 (56)	10 (56)
JUN2018	9 (65)	9 (65)
JUL2018	11 (76)	11 (76)
AUG2018	6 (82)	6 (82)
SEP2018	9 (91)	9 (91)
OCT2018	11 (102)	11 (102)
NOV2018	8 (110)	8 (110)
DEC2018	5 (115)	5 (115)
JAN2019	0 (115)	0 (115)
FEB2019	6 (121)	6 (121)
MAR2019	5 (126)	5 (126)
APR2019	6 (132)	6 (132)
MAY2019	5 (137)	5 (137)
JUN2019	7 (144)	7 (144)
JUL2019	2 (146)	2 (146)

¹ Overall enrollment target is the protocol target. This is not necessarily equal to the sum of region targets, which are the sum of site targets which may be adjusted over time to meet the protocol target.

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.

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Appendix – Table O1D – Accrual Summary and Accrual by Calendar Month and Site – Region : Africa

	Overall	Cape Town
AUG2019	0 (146)	0 (146)
SEP2019	0 (146)	0 (146)
OCT2019	0 (146)	0 (146)
NOV2019	0 (146)	0 (146)
DEC2019	0 (146)	0 (146)
JAN2020	0 (146)	0 (146)
FEB2020	0 (146)	0 (146)
MAR2020	6 (152)	6 (152)

¹ Overall enrollment target is the protocol target. This is not necessarily equal to the sum of region targets, which are the sum of site targets which may be adjusted over time to meet the protocol target.

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.

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