

HPTN 106 Enrollment Report
Report Date - Sunday 24MAY2026
Data Cutoff Date - Sunday 24MAY2026 ¹
Table O2 - Accrual Summary by Site

Site	Activation Date	First Enrollment Date	Last Enrollment Date ²	Duration of Accrual ³ (weeks)	Enrollment Target	Total Participants Enrolled	Average Enrolled per Week	Percentage Enrolled
Total	25SEP2024	29OCT2024	15JAN2026	81.7	150	150	1.8	100.0%
Baltimore	23JAN2025	26FEB2025	14JAN2026	64.6	19	19	0.3	100.0%
Los Angeles - Care Center	09OCT2024	17DEC2024	29DEC2025	74.7	19	13	0.2	68.4%
Pittsburgh - U of Pitt	25SEP2024	29OCT2024	11DEC2025	81.7	19	17	0.2	89.5%
Chapel Hill	27NOV2024	06JAN2025	17DEC2025	71.9	19	28	0.4	147.4%
Cornell Clinical Research	07MAR2025	12JUN2025	15JAN2026	49.4	19	8	0.2	42.1%
Atlanta - Hope Clinic	09OCT2024	20NOV2024	30OCT2025	78.6	19	22	0.3	115.8%
Boston - Fenway	22NOV2024	06JAN2025	07JAN2026	71.9	19	27	0.4	142.1%
Birmingham	12NOV2024	22JAN2025	08JAN2026	69.6	19	16	0.2	84.2%

² Date of most recent enrollment. Enrollment is defined as indicated in randomization form.

³ Duration of Accrual in weeks based on first enrollment date through data cutoff date.

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Table O3 - Accrual Summary and Accrual by Calendar Month and Site

	Total	Baltimore	Los Angeles - Care Center	Pittsburgh - U of Pitt	Chapel Hill	Cornell Clinical Research	Atlanta - Hope Clinic	Boston - Fenway	Birmingham
Activation Date	25SEP2024	23JAN2025	09OCT2024	25SEP2024	27NOV2024	07MAR2025	09OCT2024	22NOV2024	12NOV2024
First Enrollment Date	29OCT2024	26FEB2025	17DEC2024	29OCT2024	06JAN2025	12JUN2025	20NOV2024	06JAN2025	22JAN2025
Last Enrollment Date	15JAN2026	14JAN2026	29DEC2025	11DEC2025	17DEC2025	15JAN2026	30OCT2025	07JAN2026	08JAN2026
Total Participants Enrolled	150	19	13	17	28	8	22	27	16
Enrollment Target	150	19	19	19	19	19	19	19	19
Percentage Enrolled	100.0%	100.0%	68.4%	89.5%	147.4%	42.1%	115.8%	142.1%	84.2%
Months of Active Enrollment ²	18.8	14.9	17.2	18.8	16.6	11.4	18.1	16.6	16.1
Average Enrolled per Month ³	8	1.3	0.8	0.9	1.7	0.7	1.2	1.6	1
	Total	Baltimore	Los Angeles - Care Center	Pittsburgh - U of Pitt	Chapel Hill	Cornell Clinical Research	Atlanta - Hope Clinic	Boston - Fenway	Birmingham
Enrollment (Accrual) by Calendar Month ⁴									
SEP2024	0 (0)	- (-)	- (-)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)
OCT2024	1 (1)	- (-)	0 (0)	1 (1)	- (-)	- (-)	0 (0)	- (-)	- (-)
NOV2024	4 (5)	- (-)	0 (0)	2 (3)	0 (0)	- (-)	2 (2)	0 (0)	0 (0)
DEC2024	3 (8)	- (-)	1 (1)	0 (3)	0 (0)	- (-)	2 (4)	0 (0)	0 (0)

² Duration of Accrual in months based on first enrollment date through data cutoff date. Months may be fractional due to enrollment start date and data cutoff date.

³ Total enrolled divided by months of active enrollment.

⁴ Enrollment by month is shown and followed by Accrual (cumulative enrollment).

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Table O3 - Accrual Summary and Accrual by Calendar Month and Site

	Total	Baltimore	Los Angeles - Care Center	Pittsburgh - U of Pitt	Chapel Hill	Cornell Clinical Research	Atlanta - Hope Clinic	Boston - Fenway	Birmingham
Enrollment (Accrual) by Calendar Month ⁴									
JAN2025	14 (22)	0 (0)	0 (1)	0 (3)	4 (4)	- (-)	5 (9)	4 (4)	1 (1)
FEB2025	12 (34)	1 (1)	0 (1)	3 (6)	3 (7)	- (-)	1 (10)	1 (5)	3 (4)
MAR2025	16 (50)	2 (3)	2 (3)	2 (8)	0 (7)	0 (0)	4 (14)	3 (8)	3 (7)
APR2025	14 (64)	4 (7)	0 (3)	0 (8)	2 (9)	0 (0)	2 (16)	5 (13)	1 (8)
MAY2025	10 (74)	0 (7)	2 (5)	2 (10)	2 (11)	0 (0)	1 (17)	3 (16)	0 (8)
JUN2025	13 (87)	2 (9)	0 (5)	0 (10)	5 (16)	1 (1)	2 (19)	2 (18)	1 (9)
JUL2025	10 (97)	0 (9)	3 (8)	2 (12)	3 (19)	0 (1)	1 (20)	1 (19)	0 (9)
AUG2025	8 (105)	0 (9)	1 (9)	1 (13)	1 (20)	3 (4)	0 (20)	1 (20)	1 (10)
SEP2025	9 (114)	2 (11)	1 (10)	0 (13)	2 (22)	1 (5)	1 (21)	2 (22)	0 (10)
OCT2025	17 (131)	4 (15)	1 (11)	3 (16)	3 (25)	0 (5)	1 (22)	1 (23)	4 (14)
NOV2025	8 (139)	2 (17)	1 (12)	0 (16)	2 (27)	1 (6)	0 (22)	2 (25)	0 (14)
DEC2025	6 (145)	1 (18)	1 (13)	1 (17)	1 (28)	0 (6)	0 (22)	1 (26)	1 (15)
JAN2026	5 (150)	1 (19)	0 (13)	0 (17)	0 (28)	2 (8)	0 (22)	1 (27)	1 (16)
FEB2026	0 (150)	0 (19)	0 (13)	0 (17)	0 (28)	0 (8)	0 (22)	0 (27)	0 (16)
MAR2026	0 (150)	0 (19)	0 (13)	0 (17)	0 (28)	0 (8)	0 (22)	0 (27)	0 (16)
APR2026	0 (150)	0 (19)	0 (13)	0 (17)	0 (28)	0 (8)	0 (22)	0 (27)	0 (16)
MAY2026	0 (150)	0 (19)	0 (13)	0 (17)	0 (28)	0 (8)	0 (22)	0 (27)	0 (16)

² Duration of Accrual in months based on first enrollment date through data cutoff date. Months may be fractional due to enrollment start date and data cutoff date.

³ Total enrolled divided by months of active enrollment.

⁴ Enrollment by month is shown and followed by Accrual (cumulative enrollment).

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Table O2.1 - Accrual Summary by Site: Main study only

Site	Activation Date	First Enrollment Date	Last Enrollment Date ²	Duration of Accrual ³ (weeks)	Enrollment Target	Total Participants Enrolled	Average Enrolled per Week	Percentage Enrolled
Total	25SEP2024	13NOV2024	15JAN2026	79.6	122	122	1.5	100.0%
Baltimore	23JAN2025	27MAR2025	14JAN2026	60.4	-	13	0.2	10.7%
Los Angeles - Care Center	09OCT2024	17DEC2024	29DEC2025	74.7	-	13	0.2	10.7%
Pittsburgh - U of Pitt	25SEP2024	13NOV2024	11DEC2025	79.6	-	9	0.1	7.4%
Chapel Hill	27NOV2024	06JAN2025	17DEC2025	71.9	-	28	0.4	23.0%
Cornell Clinical Research	07MAR2025	12JUN2025	15JAN2026	49.4	-	8	0.2	6.6%
Atlanta - Hope Clinic	09OCT2024	20NOV2024	30OCT2025	78.6	-	15	0.2	12.3%
Boston - Fenway	22NOV2024	06JAN2025	07JAN2026	71.9	-	27	0.4	22.1%
Birmingham	12NOV2024	22JAN2025	08JAN2026	69.6	-	9	0.1	7.4%

² Date of most recent enrollment. Enrollment is defined as indicated in randomization form.

³ Duration of Accrual in weeks based on first enrollment date through data cutoff date.

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Table O3.1 - Accrual Summary and Accrual by Calendar Month and Site: Main study only

	Total	Baltimore	Los Angeles - Care Center	Pittsburgh - U of Pitt	Chapel Hill	Cornell Clinical Research	Atlanta - Hope Clinic	Boston - Fenway	Birmingham
Duration of Accrual (days)	557	423	523	557	503	346	550	503	487
Duration of Accrual (weeks)	79.6	60.4	74.7	79.6	71.9	49.4	78.6	71.9	69.6
Duration of Accrual (whole months)	18	14	17	18	16	11	18	16	16
Days from calculated end of month to today	11	-3	7	11	18	12	4	18	2
Days in This Month	31	31	31	31	31	31	31	31	31
Days as Percent of This Month	0.4	-0.1	0.2	0.4	0.6	0.4	0.1	0.6	0.1
Average Enrolled per Week	1.5	0.2	0.2	0.1	0.4	0.2	0.2	0.4	0.1
Activation Date	25SEP2024	23JAN2025	09OCT2024	25SEP2024	27NOV2024	07MAR2025	09OCT2024	22NOV2024	12NOV2024
First Enrollment Date	13NOV2024	27MAR2025	17DEC2024	13NOV2024	06JAN2025	12JUN2025	20NOV2024	06JAN2025	22JAN2025
Last Enrollment Date	15JAN2026	14JAN2026	29DEC2025	11DEC2025	17DEC2025	15JAN2026	30OCT2025	07JAN2026	08JAN2026
Total Participants Enrolled	122	13	13	9	28	8	15	27	9
Enrollment Target	122	-	-	-	-	-	-	-	-
Percentage Enrolled	100.0%	10.7%	10.7%	7.4%	23.0%	6.6%	12.3%	22.1%	7.4%
Months of Active Enrollment ²	18.4	13.9	17.2	18.4	16.6	11.4	18.1	16.6	16.1
Average Enrolled per Month ³	6.6	0.9	0.8	0.5	1.7	0.7	0.8	1.6	0.6

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Table O3.1 - Accrual Summary and Accrual by Calendar Month and Site: Main study only

	Total	Baltimore	Los Angeles - Care Center	Pittsburgh - U of Pitt	Chapel Hill	Cornell Clinical Research	Atlanta - Hope Clinic	Boston - Fenway	Birmingham
Enrollment (Accrual) by Calendar Month ⁴									
SEP2024	0 (0)	- (-)	- (-)	0 (0)	- (-)	- (-)	- (-)	- (-)	- (-)
OCT2024	0 (0)	- (-)	0 (0)	0 (0)	- (-)	- (-)	0 (0)	- (-)	- (-)
NOV2024	3 (3)	- (-)	0 (0)	1 (1)	0 (0)	- (-)	2 (2)	0 (0)	0 (0)
DEC2024	2 (5)	- (-)	1 (1)	0 (1)	0 (0)	- (-)	1 (3)	0 (0)	0 (0)
JAN2025	13 (18)	0 (0)	0 (1)	0 (1)	4 (4)	- (-)	4 (7)	4 (4)	1 (1)
FEB2025	8 (26)	0 (0)	0 (1)	1 (2)	3 (7)	- (-)	1 (8)	1 (5)	2 (3)
MAR2025	11 (37)	1 (1)	2 (3)	1 (3)	0 (7)	0 (0)	3 (11)	3 (8)	1 (4)
APR2025	10 (47)	3 (4)	0 (3)	0 (3)	2 (9)	0 (0)	0 (11)	5 (13)	0 (4)
MAY2025	7 (54)	0 (4)	2 (5)	0 (3)	2 (11)	0 (0)	0 (11)	3 (16)	0 (4)
JUN2025	12 (66)	2 (6)	0 (5)	0 (3)	5 (16)	1 (1)	1 (12)	2 (18)	1 (5)
JUL2025	10 (76)	0 (6)	3 (8)	2 (5)	3 (19)	0 (1)	1 (13)	1 (19)	0 (5)
AUG2025	6 (82)	0 (6)	1 (9)	0 (5)	1 (20)	3 (4)	0 (13)	1 (20)	0 (5)
SEP2025	8 (90)	1 (7)	1 (10)	0 (5)	2 (22)	1 (5)	1 (14)	2 (22)	0 (5)
OCT2025	13 (103)	2 (9)	1 (11)	3 (8)	3 (25)	0 (5)	1 (15)	1 (23)	2 (7)
NOV2025	8 (111)	2 (11)	1 (12)	0 (8)	2 (27)	1 (6)	0 (15)	2 (25)	0 (7)
DEC2025	6 (117)	1 (12)	1 (13)	1 (9)	1 (28)	0 (6)	0 (15)	1 (26)	1 (8)
JAN2026	5 (122)	1 (13)	0 (13)	0 (9)	0 (28)	2 (8)	0 (15)	1 (27)	1 (9)

² Duration of Accrual in months based on first enrollment date through data cutoff date. Months may be fractional due to enrollment start date and data cutoff date.

³ Total enrolled divided by months of active enrollment.

⁴ Enrollment by month is shown and followed by Accrual (cumulative enrollment).

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Table O3.1 - Accrual Summary and Accrual by Calendar Month and Site: Main study only

	Total	Baltimore	Los Angeles - Care Center	Pittsburgh - U of Pitt	Chapel Hill	Cornell Clinical Research	Atlanta - Hope Clinic	Boston - Fenway	Birmingham
Enrollment (Accrual) by Calendar Month ⁴									
FEB2026	0 (122)	0 (13)	0 (13)	0 (9)	0 (28)	0 (8)	0 (15)	0 (27)	0 (9)
MAR2026	0 (122)	0 (13)	0 (13)	0 (9)	0 (28)	0 (8)	0 (15)	0 (27)	0 (9)
APR2026	0 (122)	0 (13)	0 (13)	0 (9)	0 (28)	0 (8)	0 (15)	0 (27)	0 (9)
MAY2026	0 (122)	0 (13)	0 (13)	0 (9)	0 (28)	0 (8)	0 (15)	0 (27)	0 (9)

² Duration of Accrual in months based on first enrollment date through data cutoff date. 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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Table O2.2 - Accrual Summary by Site: Day 1 substudy

Site	Activation Date	First Enrollment Date	Last Enrollment Date ²	Duration of Accrual ³ (weeks)	Enrollment Target	Total Participants Enrolled	Average Enrolled per Week	Percentage Enrolled
Total	25SEP2024	29OCT2024	23MAY2025	81.7	7	7	0.1	100.0%
Baltimore	23JAN2025	-	-	-	-	-	-	-
Pittsburgh - U of Pitt	25SEP2024	29OCT2024	23MAY2025	81.7	-	7	0.1	100.0%
Atlanta - Hope Clinic	09OCT2024	-	-	-	-	-	-	-
Birmingham	12NOV2024	-	-	-	-	-	-	-

² Date of most recent enrollment. Enrollment is defined as indicated in randomization form.

³ Duration of Accrual in weeks based on first enrollment date through data cutoff date.

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Table O3.2 - Accrual Summary and Accrual by Calendar Month and Site: Day 1 substudy

	Total	Baltimore	Pittsburgh - U of Pitt	Atlanta - Hope Clinic	Birmingham
Activation Date	25SEP2024	23JAN2025	25SEP2024	09OCT2024	12NOV2024
First Enrollment Date	29OCT2024	-	29OCT2024	-	-
Last Enrollment Date	23MAY2025	-	23MAY2025	-	-
Total Participants Enrolled	7	-	7	-	-
Enrollment Target	7	-	-	-	-
Percentage Enrolled	100.0%	-	100.0%	-	-
Months of Active Enrollment ²	18.8	-	18.8	-	-
Average Enrolled per Month ³	0.4	-	0.4	-	-
	Total	Baltimore	Pittsburgh - U of Pitt	Atlanta - Hope Clinic	Birmingham
Enrollment (Accrual) by Calendar Month ⁴					
SEP2024	0 (0)	- (-)	0 (0)	- (-)	- (-)
OCT2024	1 (1)	- (-)	1 (1)	0 (0)	- (-)
NOV2024	1 (2)	- (-)	1 (2)	0 (0)	0 (0)
DEC2024	0 (2)	- (-)	0 (2)	0 (0)	0 (0)
JAN2025	0 (2)	0 (0)	0 (2)	0 (0)	0 (0)

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Table O3.2 - Accrual Summary and Accrual by Calendar Month and Site: Day 1 substudy

Enrollment (Accrual) by Calendar Month ⁴	Total	Baltimore	Pittsburgh - U of Pitt	Atlanta - Hope Clinic	Birmingham
FEB2025	2 (4)	0 (0)	2 (4)	0 (0)	0 (0)
MAR2025	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)
APR2025	0 (5)	0 (0)	0 (5)	0 (0)	0 (0)
MAY2025	2 (7)	0 (0)	2 (7)	0 (0)	0 (0)
JUN2025	0 (7)	0 (0)	0 (7)	0 (0)	0 (0)
JUL2025	0 (7)	0 (0)	0 (7)	0 (0)	0 (0)
AUG2025	0 (7)	0 (0)	0 (7)	0 (0)	0 (0)
SEP2025	0 (7)	0 (0)	0 (7)	0 (0)	0 (0)
OCT2025	0 (7)	0 (0)	0 (7)	0 (0)	0 (0)
NOV2025	0 (7)	0 (0)	0 (7)	0 (0)	0 (0)
DEC2025	0 (7)	0 (0)	0 (7)	0 (0)	0 (0)
JAN2026	0 (7)	0 (0)	0 (7)	0 (0)	0 (0)
FEB2026	0 (7)	0 (0)	0 (7)	0 (0)	0 (0)
MAR2026	0 (7)	0 (0)	0 (7)	0 (0)	0 (0)
APR2026	0 (7)	0 (0)	0 (7)	0 (0)	0 (0)
MAY2026	0 (7)	0 (0)	0 (7)	0 (0)	0 (0)

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³ Total enrolled divided by months of active enrollment.

⁴ Enrollment by month is shown and followed by Accrual (cumulative enrollment).

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Table O2.3 - Accrual Summary by Site: Day 2 substudy

Site	Activation Date	First Enrollment Date	Last Enrollment Date ²	Duration of Accrual ³ (weeks)	Enrollment Target	Total Participants Enrolled	Average Enrolled per Week	Percentage Enrolled
Total	25SEP2024	02DEC2024	23APR2025	76.9	7	7	0.1	100.0%
Baltimore	23JAN2025	26FEB2025	25MAR2025	64.6	-	2	0	28.6%
Pittsburgh - U of Pitt	25SEP2024	-	-	-	-	-	-	-
Atlanta - Hope Clinic	09OCT2024	02DEC2024	23APR2025	76.9	-	4	0.1	57.1%
Birmingham	12NOV2024	18APR2025	18APR2025	57.3	-	1	0	14.3%

² Date of most recent enrollment. Enrollment is defined as indicated in randomization form.

³ Duration of Accrual in weeks based on first enrollment date through data cutoff date.

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Table O3.3 - Accrual Summary and Accrual by Calendar Month and Site: Day 2 substudy

	Total	Baltimore	Pittsburgh - U of Pitt	Atlanta - Hope Clinic	Birmingham
Activation Date	25SEP2024	23JAN2025	25SEP2024	09OCT2024	12NOV2024
First Enrollment Date	02DEC2024	26FEB2025	-	02DEC2024	18APR2025
Last Enrollment Date	23APR2025	25MAR2025	-	23APR2025	18APR2025
Total Participants Enrolled	7	2	-	4	1
Enrollment Target	7	-	-	-	-
Percentage Enrolled	100.0%	28.6%	-	57.1%	14.3%
Months of Active Enrollment ²	17.7	14.9	-	17.7	13.2
Average Enrolled per Month ³	0.4	0.1	-	0.2	0.1
	Total	Baltimore	Pittsburgh - U of Pitt	Atlanta - Hope Clinic	Birmingham
Enrollment (Accrual) by Calendar Month ⁴					
SEP2024	0 (0)	- (-)	0 (0)	- (-)	- (-)
OCT2024	0 (0)	- (-)	0 (0)	0 (0)	- (-)
NOV2024	0 (0)	- (-)	0 (0)	0 (0)	0 (0)
DEC2024	1 (1)	- (-)	0 (0)	1 (1)	0 (0)
JAN2025	0 (1)	0 (0)	0 (0)	0 (1)	0 (0)

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Table O3.3 - Accrual Summary and Accrual by Calendar Month and Site: Day 2 substudy

Enrollment (Accrual) by Calendar Month ⁴	Total	Baltimore	Pittsburgh - U of Pitt	Atlanta - Hope Clinic	Birmingham
FEB2025	1 (2)	1 (1)	0 (0)	0 (1)	0 (0)
MAR2025	2 (4)	1 (2)	0 (0)	1 (2)	0 (0)
APR2025	3 (7)	0 (2)	0 (0)	2 (4)	1 (1)
MAY2025	0 (7)	0 (2)	0 (0)	0 (4)	0 (1)
JUN2025	0 (7)	0 (2)	0 (0)	0 (4)	0 (1)
JUL2025	0 (7)	0 (2)	0 (0)	0 (4)	0 (1)
AUG2025	0 (7)	0 (2)	0 (0)	0 (4)	0 (1)
SEP2025	0 (7)	0 (2)	0 (0)	0 (4)	0 (1)
OCT2025	0 (7)	0 (2)	0 (0)	0 (4)	0 (1)
NOV2025	0 (7)	0 (2)	0 (0)	0 (4)	0 (1)
DEC2025	0 (7)	0 (2)	0 (0)	0 (4)	0 (1)
JAN2026	0 (7)	0 (2)	0 (0)	0 (4)	0 (1)
FEB2026	0 (7)	0 (2)	0 (0)	0 (4)	0 (1)
MAR2026	0 (7)	0 (2)	0 (0)	0 (4)	0 (1)
APR2026	0 (7)	0 (2)	0 (0)	0 (4)	0 (1)
MAY2026	0 (7)	0 (2)	0 (0)	0 (4)	0 (1)

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³ Total enrolled divided by months of active enrollment.

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Table O2.4 - Accrual Summary by Site: Day 4 substudy

Site	Activation Date	First Enrollment Date	Last Enrollment Date ²	Duration of Accrual ³ (weeks)	Enrollment Target	Total Participants Enrolled	Average Enrolled per Week	Percentage Enrolled
Total	25SEP2024	29JAN2025	22OCT2025	68.6	7	7	0.1	100.0%
Baltimore	23JAN2025	14OCT2025	20OCT2025	31.7	-	2	0.1	28.6%
Pittsburgh - U of Pitt	25SEP2024	13AUG2025	13AUG2025	40.6	-	1	0	14.3%
Atlanta - Hope Clinic	09OCT2024	29JAN2025	23JUN2025	68.6	-	3	0	42.9%
Birmingham	12NOV2024	22OCT2025	22OCT2025	30.6	-	1	0	14.3%

² Date of most recent enrollment. Enrollment is defined as indicated in randomization form.

³ Duration of Accrual in weeks based on first enrollment date through data cutoff date.

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Table O3.4 - Accrual Summary and Accrual by Calendar Month and Site: Day 4 substudy

	Total	Baltimore	Pittsburgh - U of Pitt	Atlanta - Hope Clinic	Birmingham
Activation Date	25SEP2024	23JAN2025	25SEP2024	09OCT2024	12NOV2024
First Enrollment Date	29JAN2025	14OCT2025	13AUG2025	29JAN2025	22OCT2025
Last Enrollment Date	22OCT2025	20OCT2025	13AUG2025	23JUN2025	22OCT2025
Total Participants Enrolled	7	2	1	3	1
Enrollment Target	7	-	-	-	-
Percentage Enrolled	100.0%	28.6%	14.3%	42.9%	14.3%
Months of Active Enrollment ²	15.8	7.3	9.4	15.8	7.1
Average Enrolled per Month ³	0.4	0.3	0.1	0.2	0.1
	Total	Baltimore	Pittsburgh - U of Pitt	Atlanta - Hope Clinic	Birmingham
Enrollment (Accrual) by Calendar Month ⁴					
SEP2024	0 (0)	- (-)	0 (0)	- (-)	- (-)
OCT2024	0 (0)	- (-)	0 (0)	0 (0)	- (-)
NOV2024	0 (0)	- (-)	0 (0)	0 (0)	0 (0)
DEC2024	0 (0)	- (-)	0 (0)	0 (0)	0 (0)
JAN2025	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)

² Duration of Accrual in months based on first enrollment date through data cutoff date. Months may be fractional due to enrollment start date and data cutoff date.

³ Total enrolled divided by months of active enrollment.

⁴ Enrollment by month is shown and followed by Accrual (cumulative enrollment).

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Table O3.4 - Accrual Summary and Accrual by Calendar Month and Site: Day 4 substudy

Enrollment (Accrual) by Calendar Month ⁴	Total	Baltimore	Pittsburgh - U of Pitt	Atlanta - Hope Clinic	Birmingham
FEB2025	0 (1)	0 (0)	0 (0)	0 (1)	0 (0)
MAR2025	0 (1)	0 (0)	0 (0)	0 (1)	0 (0)
APR2025	0 (1)	0 (0)	0 (0)	0 (1)	0 (0)
MAY2025	1 (2)	0 (0)	0 (0)	1 (2)	0 (0)
JUN2025	1 (3)	0 (0)	0 (0)	1 (3)	0 (0)
JUL2025	0 (3)	0 (0)	0 (0)	0 (3)	0 (0)
AUG2025	1 (4)	0 (0)	1 (1)	0 (3)	0 (0)
SEP2025	0 (4)	0 (0)	0 (1)	0 (3)	0 (0)
OCT2025	3 (7)	2 (2)	0 (1)	0 (3)	1 (1)
NOV2025	0 (7)	0 (2)	0 (1)	0 (3)	0 (1)
DEC2025	0 (7)	0 (2)	0 (1)	0 (3)	0 (1)
JAN2026	0 (7)	0 (2)	0 (1)	0 (3)	0 (1)
FEB2026	0 (7)	0 (2)	0 (1)	0 (3)	0 (1)
MAR2026	0 (7)	0 (2)	0 (1)	0 (3)	0 (1)
APR2026	0 (7)	0 (2)	0 (1)	0 (3)	0 (1)
MAY2026	0 (7)	0 (2)	0 (1)	0 (3)	0 (1)

² Duration of Accrual in months based on first enrollment date through data cutoff date. Months may be fractional due to enrollment start date and data cutoff date.

³ Total enrolled divided by months of active enrollment.

⁴ Enrollment by month is shown and followed by Accrual (cumulative enrollment).

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Table O2.5 - Accrual Summary by Site: Day 8 substudy

Site	Activation Date	First Enrollment Date	Last Enrollment Date ²	Duration of Accrual ³ (weeks)	Enrollment Target	Total Participants Enrolled	Average Enrolled per Week	Percentage Enrolled
Total	25SEP2024	18FEB2025	01OCT2025	65.7	7	7	0.1	100.0%
Baltimore	23JAN2025	07APR2025	02SEP2025	58.9	-	2	0	28.6%
Pittsburgh - U of Pitt	25SEP2024	-	-	-	-	-	-	-
Atlanta - Hope Clinic	09OCT2024	-	-	-	-	-	-	-
Birmingham	12NOV2024	18FEB2025	01OCT2025	65.7	-	5	0.1	71.4%

² Date of most recent enrollment. Enrollment is defined as indicated in randomization form.

³ Duration of Accrual in weeks based on first enrollment date through data cutoff date.

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Table O3.5 - Accrual Summary and Accrual by Calendar Month and Site: Day 8 substudy

	Total	Baltimore	Pittsburgh - U of Pitt	Atlanta - Hope Clinic	Birmingham
Activation Date	25SEP2024	23JAN2025	25SEP2024	09OCT2024	12NOV2024
First Enrollment Date	18FEB2025	07APR2025	-	-	18FEB2025
Last Enrollment Date	01OCT2025	02SEP2025	-	-	01OCT2025
Total Participants Enrolled	7	2	-	-	5
Enrollment Target	7	-	-	-	-
Percentage Enrolled	100.0%	28.6%	-	-	71.4%
Months of Active Enrollment ²	15.2	13.5	-	-	15.2
Average Enrolled per Month ³	0.5	0.1	-	-	0.3
	Total	Baltimore	Pittsburgh - U of Pitt	Atlanta - Hope Clinic	Birmingham
Enrollment (Accrual) by Calendar Month ⁴					
SEP2024	0 (0)	- (-)	0 (0)	- (-)	- (-)
OCT2024	0 (0)	- (-)	0 (0)	0 (0)	- (-)
NOV2024	0 (0)	- (-)	0 (0)	0 (0)	0 (0)
DEC2024	0 (0)	- (-)	0 (0)	0 (0)	0 (0)
JAN2025	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

² Duration of Accrual in months based on first enrollment date through data cutoff date. Months may be fractional due to enrollment start date and data cutoff date.

³ Total enrolled divided by months of active enrollment.

⁴ Enrollment by month is shown and followed by Accrual (cumulative enrollment).

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Table O3.5 - Accrual Summary and Accrual by Calendar Month and Site: Day 8 substudy

Enrollment (Accrual) by Calendar Month ⁴	Total	Baltimore	Pittsburgh - U of Pitt	Atlanta - Hope Clinic	Birmingham
FEB2025	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)
MAR2025	2 (3)	0 (0)	0 (0)	0 (0)	2 (3)
APR2025	1 (4)	1 (1)	0 (0)	0 (0)	0 (3)
MAY2025	0 (4)	0 (1)	0 (0)	0 (0)	0 (3)
JUN2025	0 (4)	0 (1)	0 (0)	0 (0)	0 (3)
JUL2025	0 (4)	0 (1)	0 (0)	0 (0)	0 (3)
AUG2025	1 (5)	0 (1)	0 (0)	0 (0)	1 (4)
SEP2025	1 (6)	1 (2)	0 (0)	0 (0)	0 (4)
OCT2025	1 (7)	0 (2)	0 (0)	0 (0)	1 (5)
NOV2025	0 (7)	0 (2)	0 (0)	0 (0)	0 (5)
DEC2025	0 (7)	0 (2)	0 (0)	0 (0)	0 (5)
JAN2026	0 (7)	0 (2)	0 (0)	0 (0)	0 (5)
FEB2026	0 (7)	0 (2)	0 (0)	0 (0)	0 (5)
MAR2026	0 (7)	0 (2)	0 (0)	0 (0)	0 (5)
APR2026	0 (7)	0 (2)	0 (0)	0 (0)	0 (5)
MAY2026	0 (7)	0 (2)	0 (0)	0 (0)	0 (5)

² Duration of Accrual in months based on first enrollment date through data cutoff date. Months may be fractional due to enrollment start date and data cutoff date.

³ Total enrolled divided by months of active enrollment.

⁴ Enrollment by month is shown and followed by Accrual (cumulative enrollment).