

HPTN 076 - Phase II Safety and Acceptability of an Investigational Injectable Product, TMC278 LA, for Pre Exposure Prophylaxis (PrEP)
Report January 17, 2018
Visit Cutoff Date: January 16, 2018
Table A - Accrual Summary by Site

Site	Activation Date	First Enrollment Date	Last Enrollment Date¹	Duration of Accrual² (weeks)	Enrollment Target	Total Enrolled	Average Enrolled per Week	Percent Enrolled
Bronx CRS	30MAR2015	20APR2015	14SEP2015	21.1	18	19	0.9	105.6%
New Jersey CRS	06MAR2015	13APR2015	11SEP2015	21.7	18	17	0.8	94.4%
Emavundleni CRS	24MAR2015	13MAY2015	14SEP2015	17.9	48	48	2.7	100.0%
Spilhaus CRS	23MAR2015	27APR2015	11SEP2015	19.7	48	52	2.6	108.3%
Overall	06MAR2015	13APR2015	14SEP2015	22.1	132	136	6.2	103.0%

¹Date of most recent enrollment as of January 16, 2018.

²Duration of accrual based on first enrollment date.

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

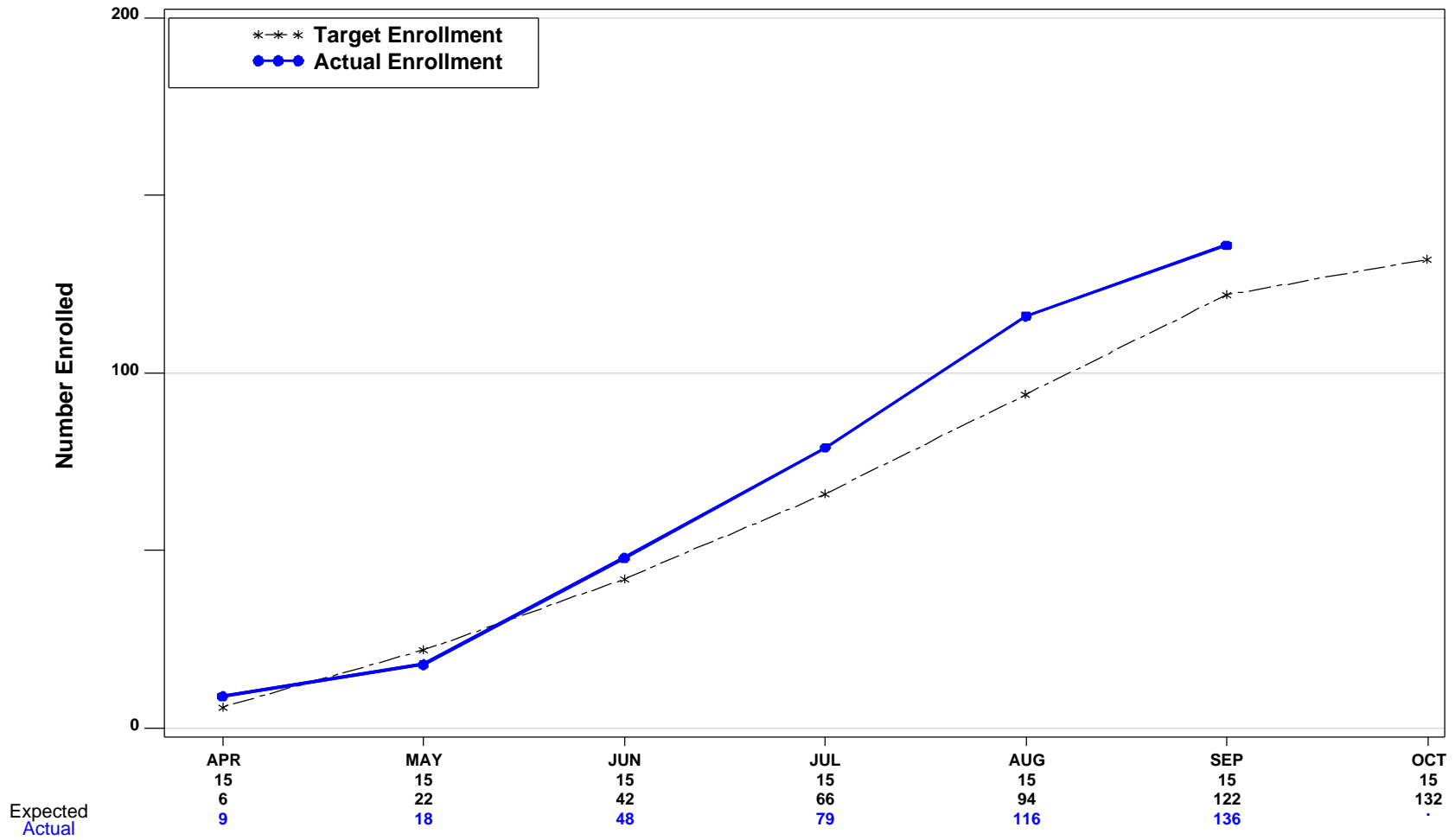
Overall

	Overall	Bronx CRS Site ID 253	New Jersey CRS Site ID 254	Emavundleni CRS Site ID 255	Spilhaus CRS Site ID 256
Activation Date	06MAR2015	30MAR2015	06MAR2015	24MAR2015	23MAR2015
First Enrollment Date	13APR2015	20APR2015	13APR2015	13MAY2015	27APR2015
Summary					
Total Enrolled	136	19	17	48	52
Enrollment Target	132	18	18	48	48
Percent Enrolled	103.0%	105.6%	94.4%	100.0%	108.3%
Accrual					
Calendar Month of Accrual					
APR2015	9 (9)	2 (2)	3 (3)	- (-)	4 (4)
MAY2015	9 (18)	2 (4)	1 (4)	2 (2)	4 (8)
JUN2015	30 (48)	5 (9)	2 (6)	16 (18)	7 (15)
JUL2015	31 (79)	3 (12)	3 (9)	10 (28)	15 (30)
AUG2015	37 (116)	5 (17)	3 (12)	11 (39)	18 (48)
SEP2015	20 (136)	2 (19)	5 (17)	9 (48)	4 (52)
Average Enrolled per Month	22.7	3.2	2.8	9.6	8.7

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Figure 1A. Cumulative Enrollment - All Sites

Total Enrolled: 136 Enrollment Target: 132 Enrollment Needed: 0



Source: SCHARP (whiteau) - /trials/hptn/p076/reporting/progress/code/g_accrual.sas, SAS Version 9.4 (17JAN2018,12:48)

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Figure 1B. Bronx CRS

Total Enrolled: 19 Enrollment Target: 18 Enrollment Needed: 0

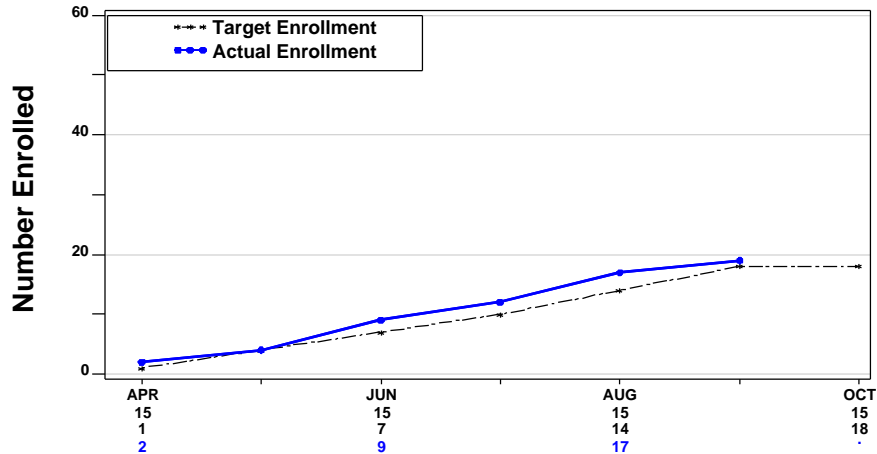


Figure 1C. New Jersey CRS

Total Enrolled: 17 Enrollment Target: 18 Enrollment Needed: 1

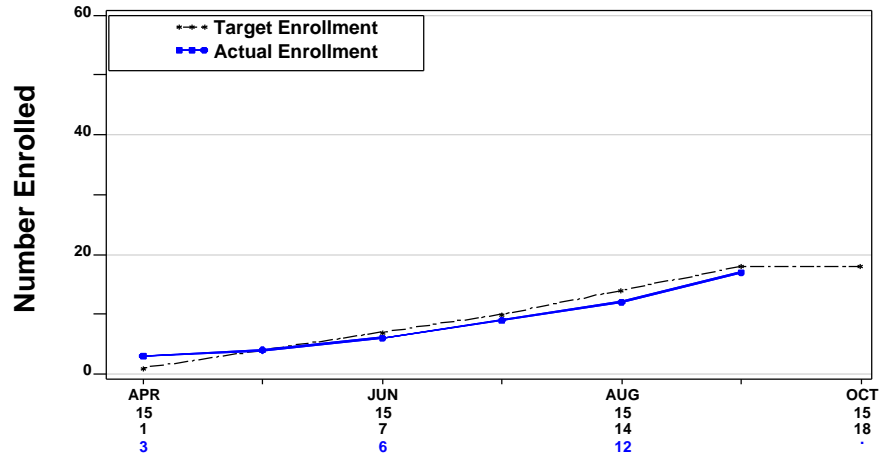


Figure 1D. Emavundleni CRS

Total Enrolled: 48 Enrollment Target: 48 Enrollment Needed: 0

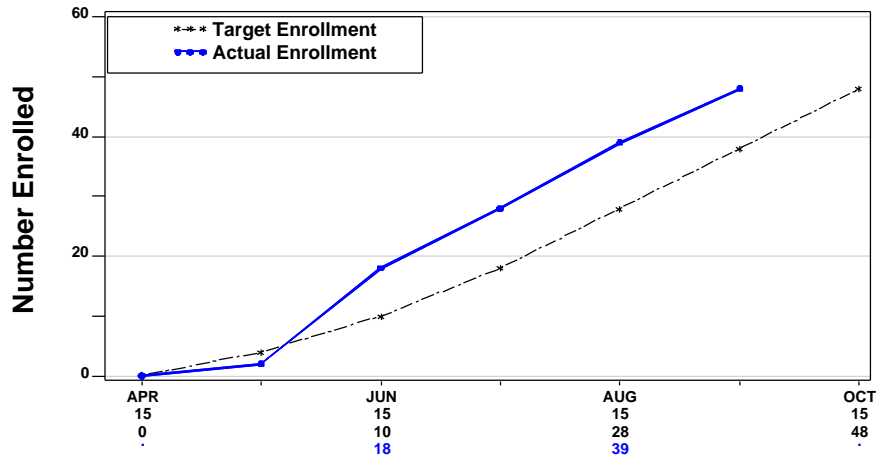
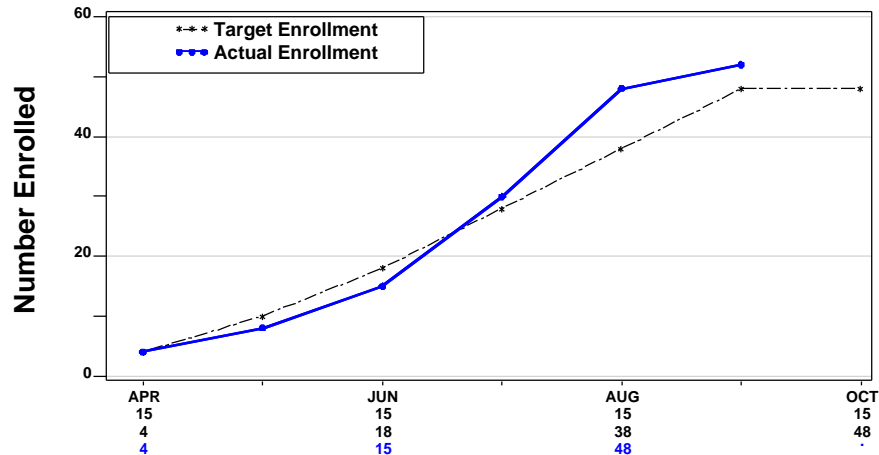


Figure 1E. Spilhaus CRS

Total Enrolled: 52 Enrollment Target: 48 Enrollment Needed: 0



Source: SCHARP (whiteau) - /trials/hptn/p076/reporting/progress/code/g_accrual.sas, SAS Version 9.4 (17JAN2018,12:48)