

HPTN 077 - A Phase IIa Safety, Tolerability and Acceptability Study of an Investigational Injectable HIV Integrase Inhibitor, GSK1265744, for PrEP in HIV Uninfected Men and Women
Report November 16, 2018
Visit Cutoff Date: November 15, 2018
Table B - Accrual Summary by Site

Overall

Site	Activation Date	First Enrollment Date	Last Enrollment Date¹	Duration of Accrual² (weeks)	Enrollment Target	Total Enrolled	Average Enrolled per Week	Percent Enrolled
UNC AIDS CRS	13FEB2015	29DEC2015	25MAY2016	21.3	11	14	0.7	127.3%
UCLA CRS	09FEB2015	14JAN2016	10MAY2016	16.9	11	6	0.4	54.5%
San Francisco	11FEB2015	17FEB2016	27MAY2016	14.4	11	13	0.9	118.2%
GWU CRS	17MAR2015	21DEC2015	10MAY2016	20.3	11	10	0.5	90.9%
Soweto CTU	16JUL2015	09FEB2016	10MAY2016	13.1	11	10	0.8	90.9%
Vulindlela CRS	18JUN2015	04APR2016	26APR2016	3.3	11	2	0.6	18.2%
Lilongwe UNC	26AUG2015	01APR2016	17MAY2016	6.7	11	17	2.5	154.5%
Rio de Janeiro	05JUN2015	18DEC2015	25MAY2016	22.9	11	18	0.8	163.6%
Overall	09FEB2015	18DEC2015	27MAY2016	23.1	88	90	3.9	102.3%

¹Date of most recent enrollment as of November 15, 2018.

²Duration of accrual based on first enrollment date.

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Female

Site	Activation Date	First Enrollment Date	Last Enrollment Date¹	Duration of Accrual² (weeks)	Enrollment Target	Total Enrolled	Average Enrolled per Week	Percent Enrolled
UNC AIDS CRS	13FEB2015	29DEC2015	25MAY2016	21.3	7	11	0.5	157.1%
UCLA CRS	09FEB2015	14JAN2016	05MAY2016	16.1	7	2	0.1	28.6%
San Francisco	11FEB2015	17FEB2016	27MAY2016	14.4	7	8	0.6	114.3%
GWU CRS	17MAR2015	21DEC2015	10MAY2016	20.3	7	4	0.2	57.1%
Soweto CTU	16JUL2015	09FEB2016	10MAY2016	13.1	7	6	0.5	85.7%
Vulindlela CRS	18JUN2015	04APR2016	26APR2016	3.3	7	2	0.6	28.6%
Lilongwe UNC	26AUG2015	04APR2016	17MAY2016	6.3	7	15	2.4	214.3%
Rio de Janeiro	05JUN2015	18DEC2015	25MAY2016	22.9	7	13	0.6	185.7%
Overall	09FEB2015	18DEC2015	27MAY2016	23.1	56	61	2.6	108.9%

¹Date of most recent enrollment as of November 15, 2018.

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Male

Site	Activation Date	First Enrollment Date	Last Enrollment Date ¹	Duration of Accrual ² (weeks)	Enrollment Target	Total Enrolled	Average Enrolled per Week	Percent Enrolled
UNC AIDS CRS	13FEB2015	11FEB2016	29APR2016	11.3	4	3	0.3	75.0%
UCLA CRS	09FEB2015	14JAN2016	10MAY2016	16.9	4	4	0.2	100.0%
San Francisco	11FEB2015	17MAR2016	09MAY2016	7.7	4	5	0.6	125.0%
GWU CRS	17MAR2015	19JAN2016	06MAY2016	15.6	4	6	0.4	150.0%
Soweto CTU	16JUL2015	03MAR2016	31MAR2016	4.1	4	4	1.0	100.0%
Vulindlela CRS	18JUN2015	-	-	-	4	-	-	-
Lilongwe UNC	26AUG2015	01APR2016	19APR2016	2.7	4	2	0.7	50.0%
Rio de Janeiro	05JUN2015	14JAN2016	05MAY2016	16.1	4	5	0.3	125.0%
Overall	09FEB2015	14JAN2016	10MAY2016	16.9	32	29	1.7	90.6%

¹Date of most recent enrollment as of November 15, 2018.

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

Overall

	Overall	UNC AIDS CRS Site ID 257	UCLA CRS Site ID 258	San Francisco Site ID 259	GWU CRS Site ID 260	Soweto CTU Site ID 261	Vulindlela CRS Site ID 262	Lilongwe UNC Site ID 263	Rio de Janeiro Site ID 264
Activation Date	09FEB2015	13FEB2015	09FEB2015	11FEB2015	17MAR2015	16JUL2015	18JUN2015	26AUG2015	05JUN2015
First Enrollment Date	18DEC2015	29DEC2015	14JAN2016	17FEB2016	21DEC2015	09FEB2016	04APR2016	01APR2016	18DEC2015
Summary									
Total Enrolled	90	14	6	13	10	10	2	17	18
Enrollment Target	88	11	11	11	11	11	11	11	11
Percent Enrolled	102.3%	127.3%	54.5%	118.2%	90.9%	90.9%	18.2%	154.5%	163.6%
Accrual									
Calendar Month of Accrual									
DEC2015	4 (4)	1 (1)	- (-)	- (-)	1 (1)	- (-)	- (-)	- (-)	2 (2)
JAN2016	12 (16)	2 (3)	2 (2)	- (-)	2 (3)	- (-)	- (-)	- (-)	6 (8)
FEB2016	10 (26)	2 (5)	1 (3)	2 (2)	1 (4)	3 (3)	- (-)	- (-)	1 (9)
MAR2016	12 (38)	1 (6)	0 (3)	3 (5)	3 (7)	5 (8)	- (-)	- (-)	0 (9)
APR2016	30 (68)	5 (11)	1 (4)	5 (10)	0 (7)	0 (8)	2 (2)	12 (12)	5 (14)
MAY2016	22 (90)	3 (14)	2 (6)	3 (13)	3 (10)	2 (10)	0 (2)	5 (17)	4 (18)
Average Enrolled per Month	15.0	2.3	1.2	3.3	1.7	2.5	1.0	8.5	3.0

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

Female

	Overall	UNC AIDS CRS Site ID 257	UCLA CRS Site ID 258	San Francisco Site ID 259	GWU CRS Site ID 260	Soweto CTU Site ID 261	Vulindlela CRS Site ID 262	Lilongwe UNC Site ID 263	Rio de Janeiro Site ID 264
Activation Date	09FEB2015	13FEB2015	09FEB2015	11FEB2015	17MAR2015	16JUL2015	18JUN2015	26AUG2015	05JUN2015
First Enrollment Date	18DEC2015	29DEC2015	14JAN2016	17FEB2016	21DEC2015	09FEB2016	04APR2016	04APR2016	18DEC2015
Summary									
Total Enrolled	61	11	2	8	4	6	2	15	13
Enrollment Target	56	7	7	7	7	7	7	7	7
Percent Enrolled	108.9%	157.1%	28.6%	114.3%	57.1%	85.7%	28.6%	214.3%	185.7%
Accrual									
Calendar Month of Accrual									
DEC2015	4 (4)	1 (1)	- (-)	- (-)	1 (1)	- (-)	- (-)	- (-)	2 (2)
JAN2016	6 (10)	2 (3)	1 (1)	- (-)	0 (1)	- (-)	- (-)	- (-)	3 (5)
FEB2016	6 (16)	0 (3)	0 (1)	2 (2)	0 (1)	3 (3)	- (-)	- (-)	1 (6)
MAR2016	6 (22)	1 (4)	0 (1)	2 (4)	2 (3)	1 (4)	- (-)	- (-)	0 (6)
APR2016	22 (44)	4 (8)	0 (1)	2 (6)	0 (3)	0 (4)	2 (2)	10 (10)	4 (10)
MAY2016	17 (61)	3 (11)	1 (2)	2 (8)	1 (4)	2 (6)	0 (2)	5 (15)	3 (13)
Average Enrolled per Month	10.2	1.8	0.4	2.0	0.7	1.5	1.0	7.5	2.2

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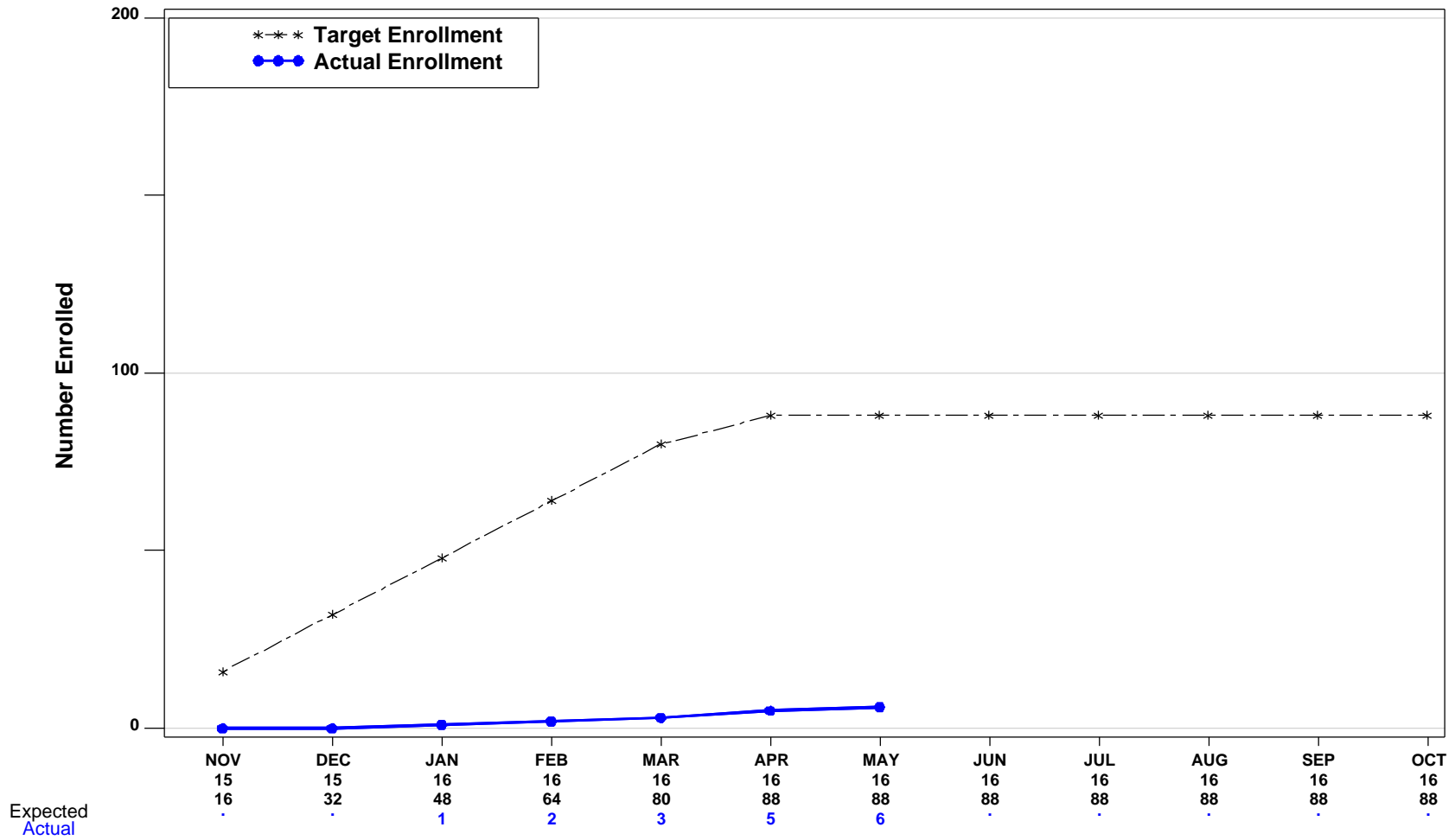
Table B - Accrual Summary and Accrual by Calendar Month and Site

Male

	Overall	UNC AIDS CRS Site ID 257	UCLA CRS Site ID 258	San Francisco Site ID 259	GWU CRS Site ID 260	Soweto CTU Site ID 261	Lilongwe UNC Site ID 263	Rio de Janeiro Site ID 264
Activation Date	09FEB2015	13FEB2015	09FEB2015	11FEB2015	17MAR2015	16JUL2015	26AUG2015	05JUN2015
First Enrollment Date	14JAN2016	11FEB2016	14JAN2016	17MAR2016	19JAN2016	03MAR2016	01APR2016	14JAN2016
Summary								
Total Enrolled	29	3	4	5	6	4	2	5
Enrollment Target	32	4	4	4	4	4	4	4
Percent Enrolled	90.6%	75.0%	100.0%	125.0%	150.0%	100.0%	50.0%	125.0%
Accrual								
Calendar Month of Accrual								
JAN2016	6 (6)	- (-)	1 (1)	- (-)	2 (2)	- (-)	- (-)	3 (3)
FEB2016	4 (10)	2 (2)	1 (2)	- (-)	1 (3)	- (-)	- (-)	0 (3)
MAR2016	6 (16)	0 (2)	0 (2)	1 (1)	1 (4)	4 (4)	- (-)	0 (3)
APR2016	8 (24)	1 (3)	1 (3)	3 (4)	0 (4)	0 (4)	2 (2)	1 (4)
MAY2016	5 (29)	0 (3)	1 (4)	1 (5)	2 (6)	0 (4)	0 (2)	1 (5)
Average Enrolled per Month	5.8	0.8	0.8	1.7	1.2	1.3	1.0	1.0

Figure 1A. Cumulative Enrollment - All Sites

Total Enrolled: 6 Enrollment Target: 88 Enrollment Needed: 82



Source: SCHARP (whiteau) - /trials/hptn/p077/reporting/progress/code/g_accrual.sas, SAS Version 9.4 (16NOV2018,3:20)

Figure 1B. UNC AIDS CRS

Total Enrolled: 2 Enrollment Target: 11 Enrollment Needed: 9

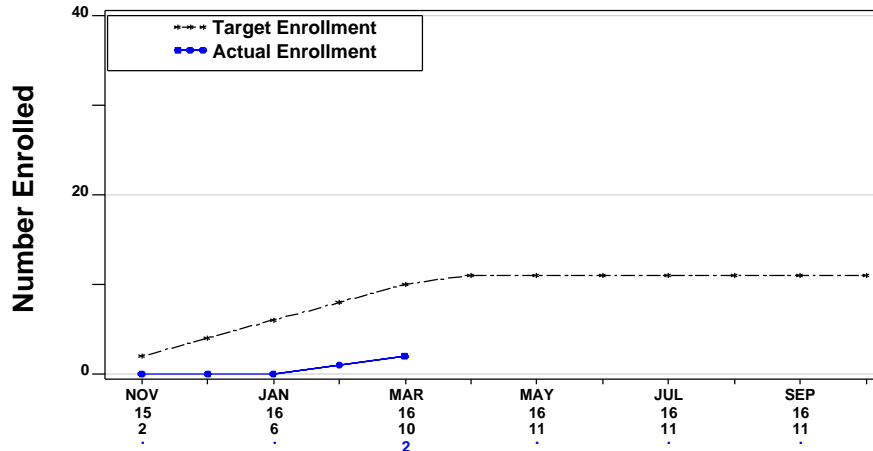


Figure 1C. UCLA CRS

Total Enrolled: 0 Enrollment Target: 11 Enrollment Needed: 11

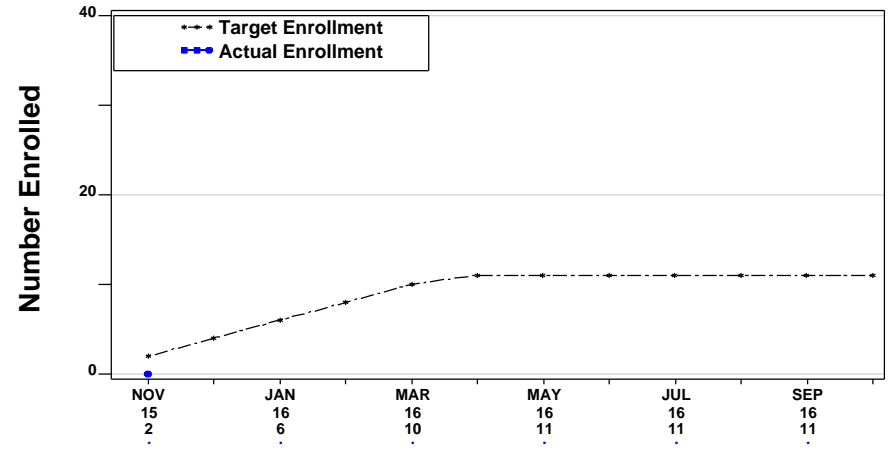


Figure 1D. San Francisco

Total Enrolled: 0 Enrollment Target: 11 Enrollment Needed: 11

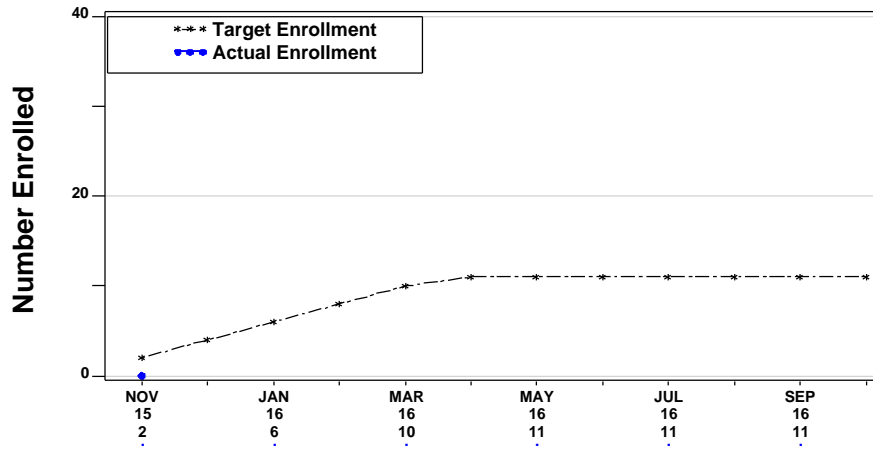


Figure 1E. GWU CRS

Total Enrolled: 0 Enrollment Target: 11 Enrollment Needed: 11

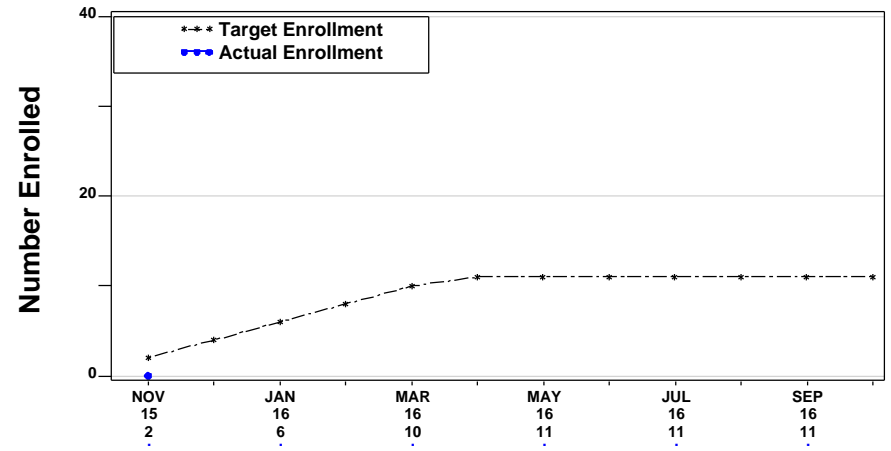


Figure 1F. Soweto CTU

Total Enrolled: 0 Enrollment Target: 11 Enrollment Needed: 11

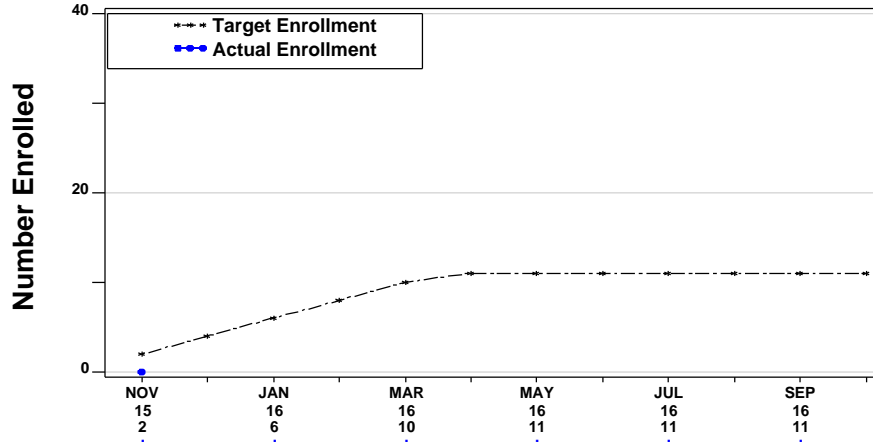


Figure 1G. Vulindlela CRS

Total Enrolled: 0 Enrollment Target: 11 Enrollment Needed: 11

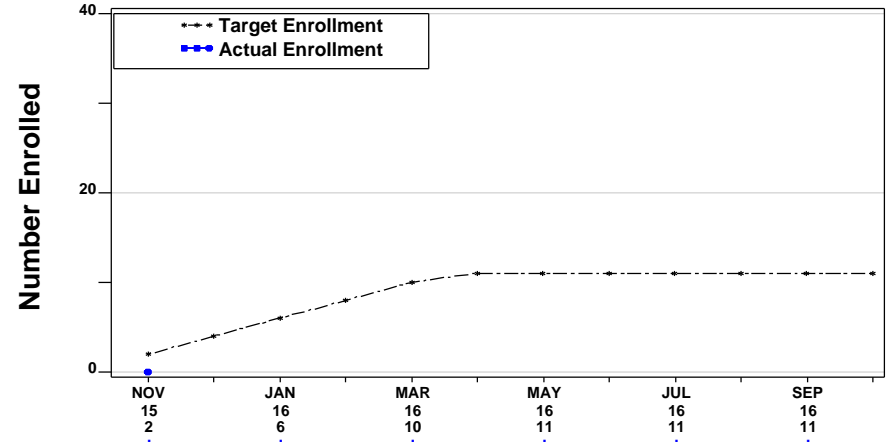


Figure 1H. Lilongwe UNC

Total Enrolled: 3 Enrollment Target: 11 Enrollment Needed: 8

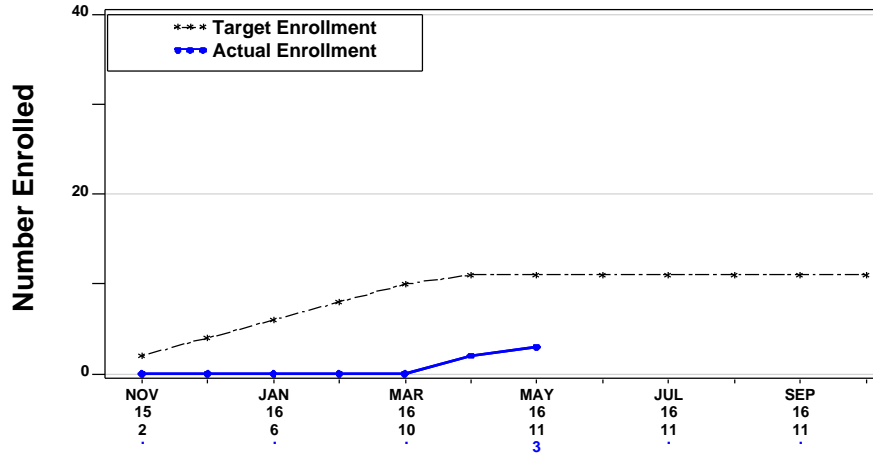
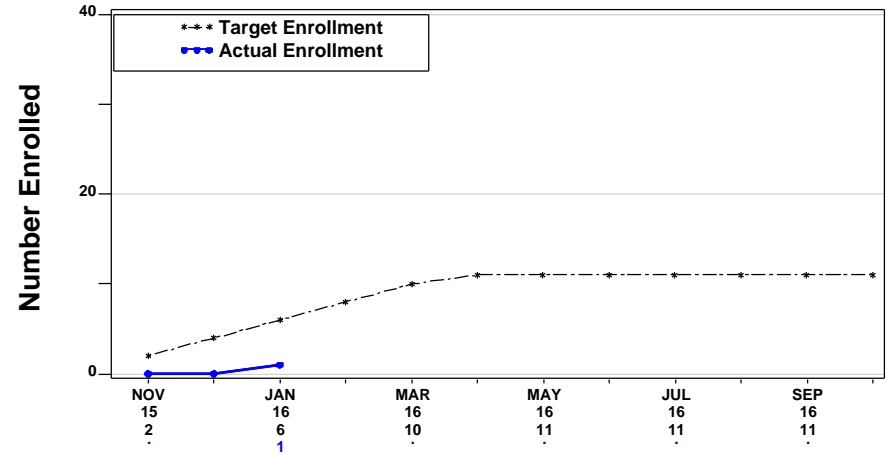


Figure 1I. Rio de Janeiro

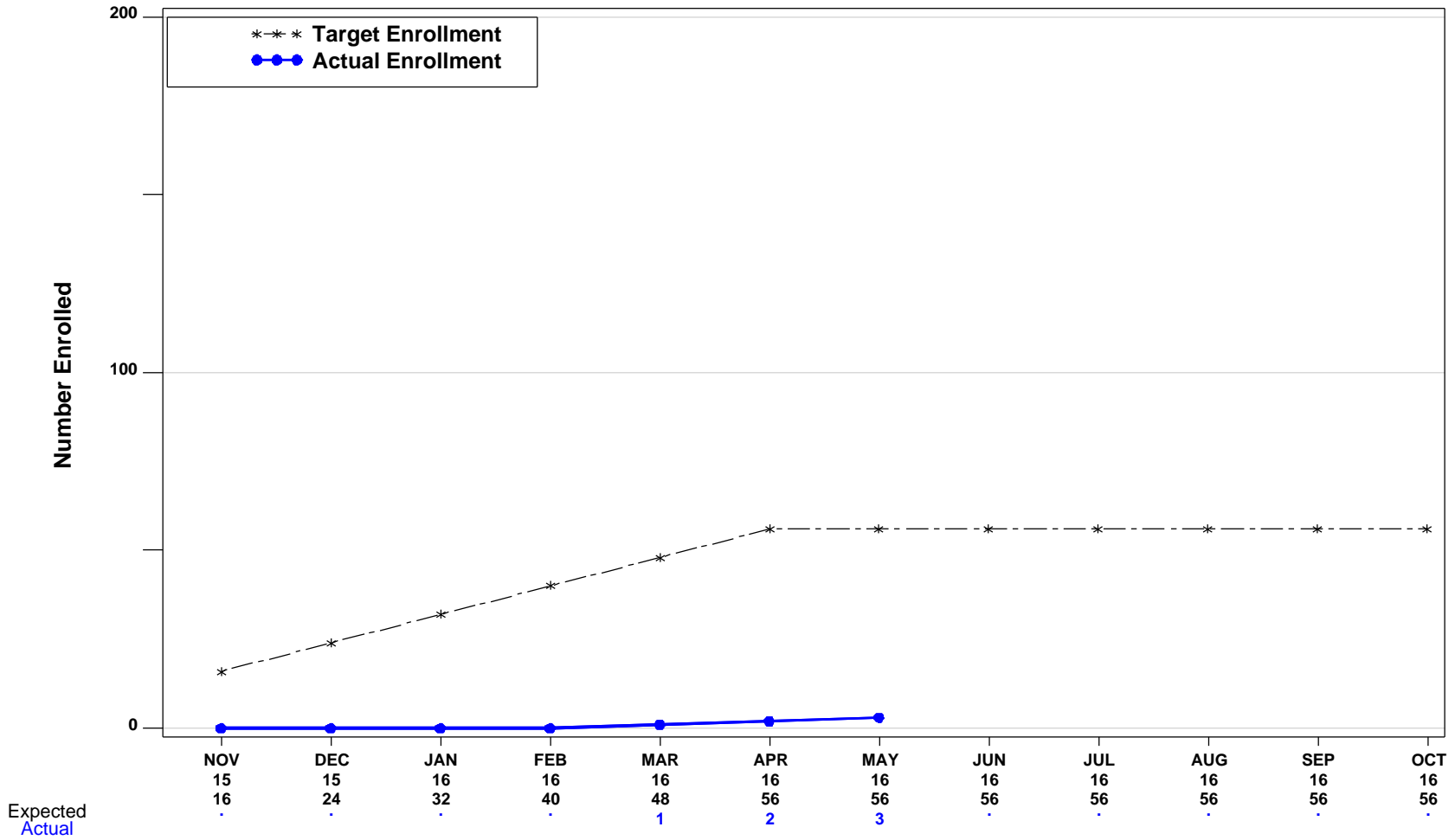
Total Enrolled: 1 Enrollment Target: 11 Enrollment Needed: 10



Source: SCHARP (whiteau) - /trials/hptn/p077/reporting/progress/code/g_accrual.sas, SAS Version 9.4 (16NOV2018,3:20)

Figure 1A. Cumulative Enrollment - All Sites

Total Enrolled: 3 Enrollment Target: 56 Enrollment Needed: 53



Source: SCHARP (whiteau) - /trials/hptn/p077/reporting/progress/code/g_accrual.sas, SAS Version 9.4 (16NOV2018,3:20)

Figure 1B. UNC AIDS CRS

Total Enrolled: 1 Enrollment Target: 7 Enrollment Needed: 6

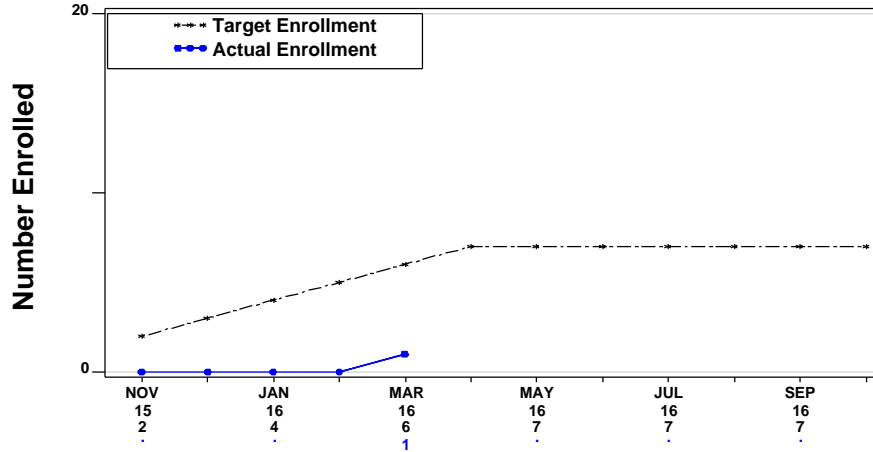


Figure 1C. UCLA CRS

Total Enrolled: 0 Enrollment Target: 7 Enrollment Needed: 7

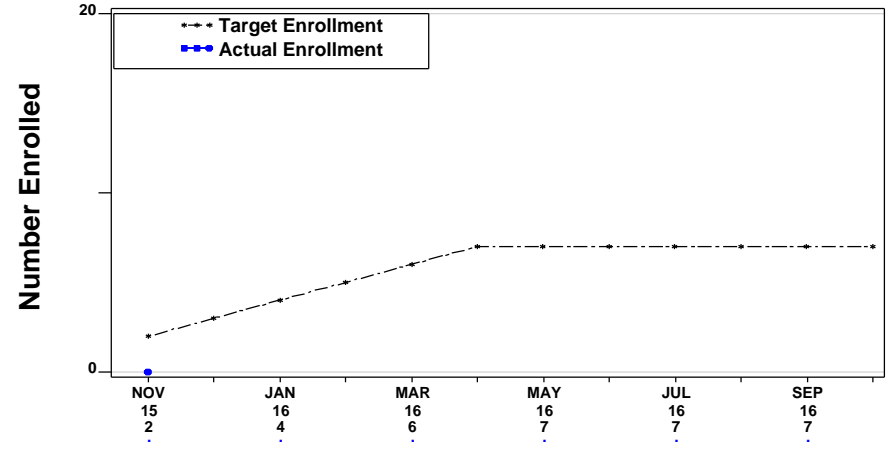


Figure 1D. San Francisco

Total Enrolled: 0 Enrollment Target: 7 Enrollment Needed: 7

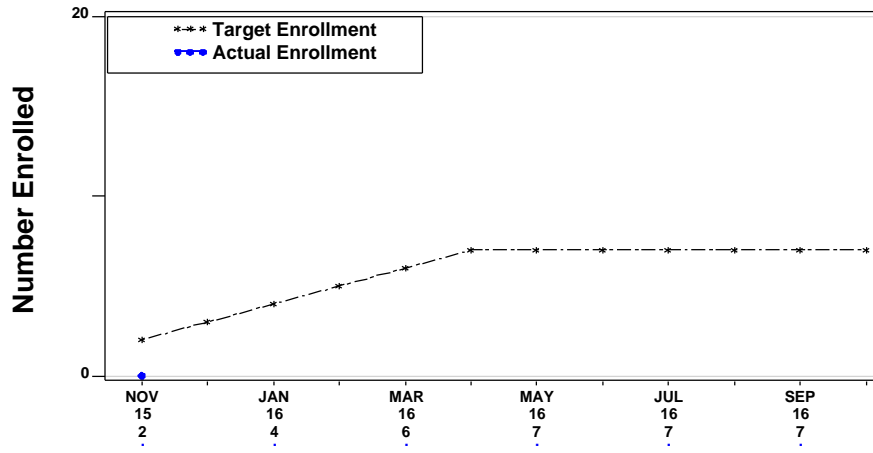
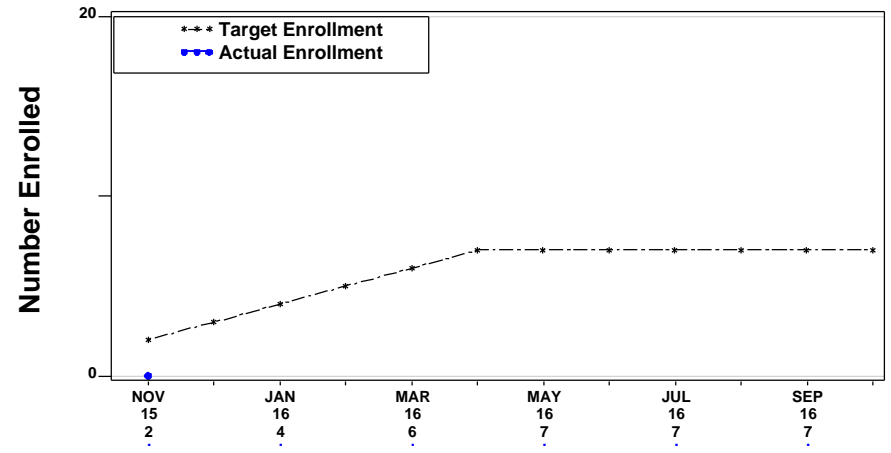


Figure 1E. GWU CRS

Total Enrolled: 0 Enrollment Target: 7 Enrollment Needed: 7



Source: SCHARP (whiteau) - /trials/hptn/p077/reporting/progress/code/g_accrual.sas, SAS Version 9.4 (16NOV2018,3:20)

Figure 1F. Soweto CTU

Total Enrolled: 0 Enrollment Target: 7 Enrollment Needed: 7

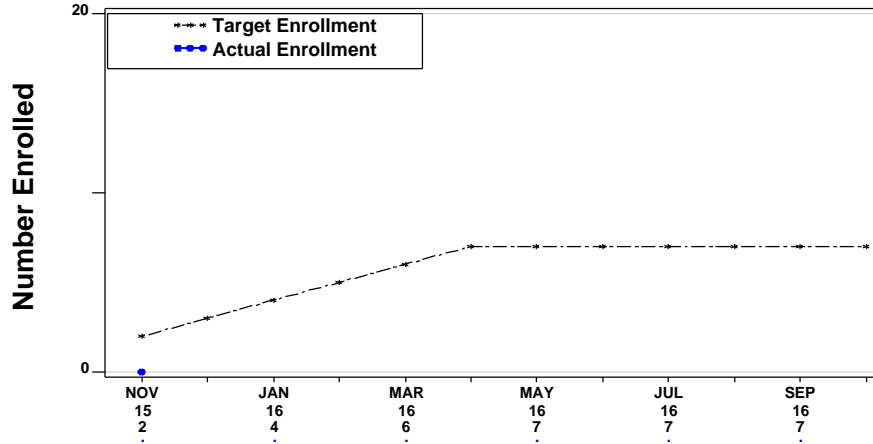


Figure 1G. Vulindlela CRS

Total Enrolled: 0 Enrollment Target: 7 Enrollment Needed: 7

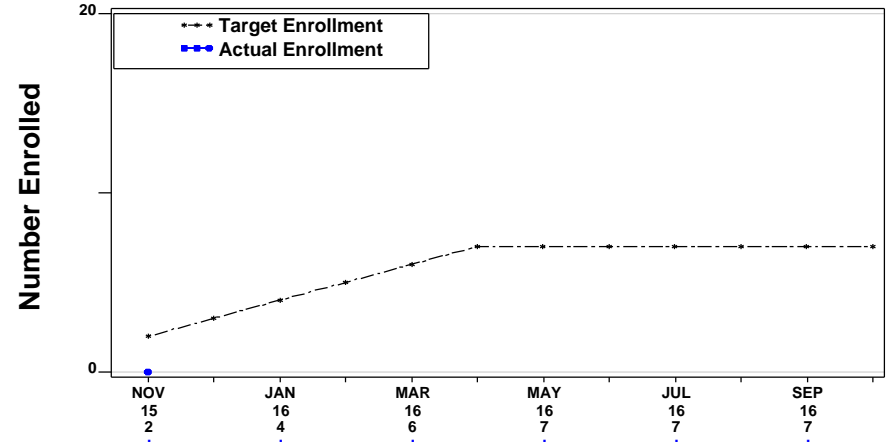


Figure 1H. Lilongwe UNC

Total Enrolled: 2 Enrollment Target: 7 Enrollment Needed: 5

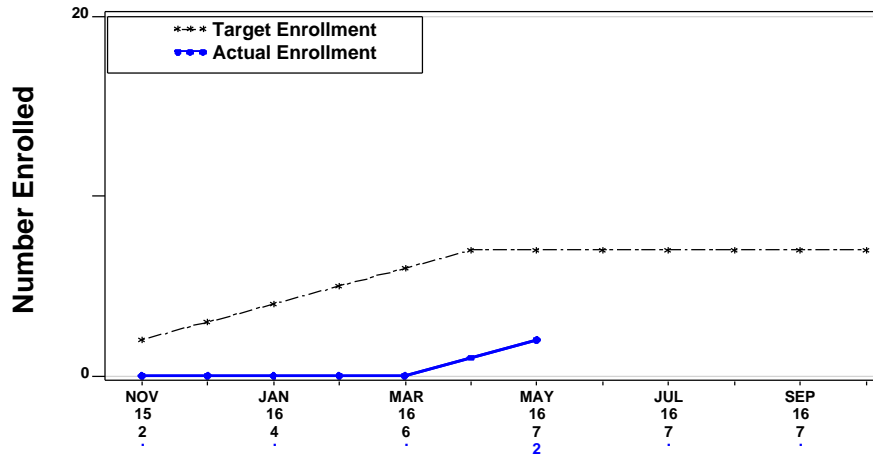
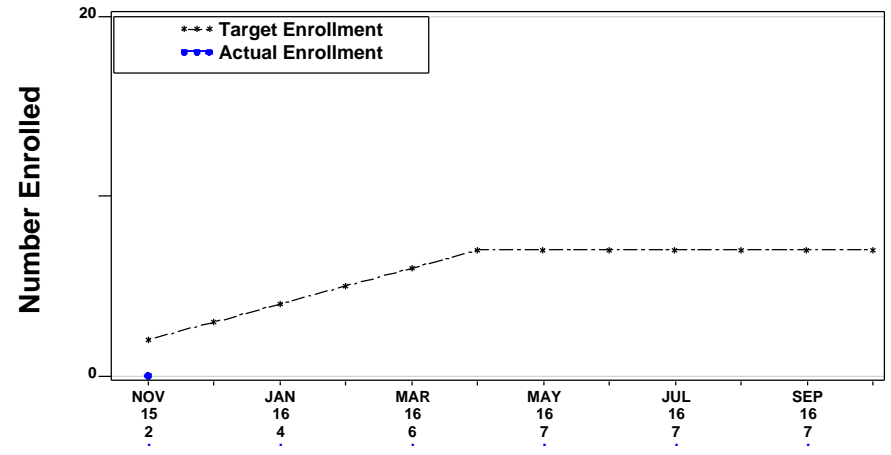


Figure 1I. Rio de Janeiro

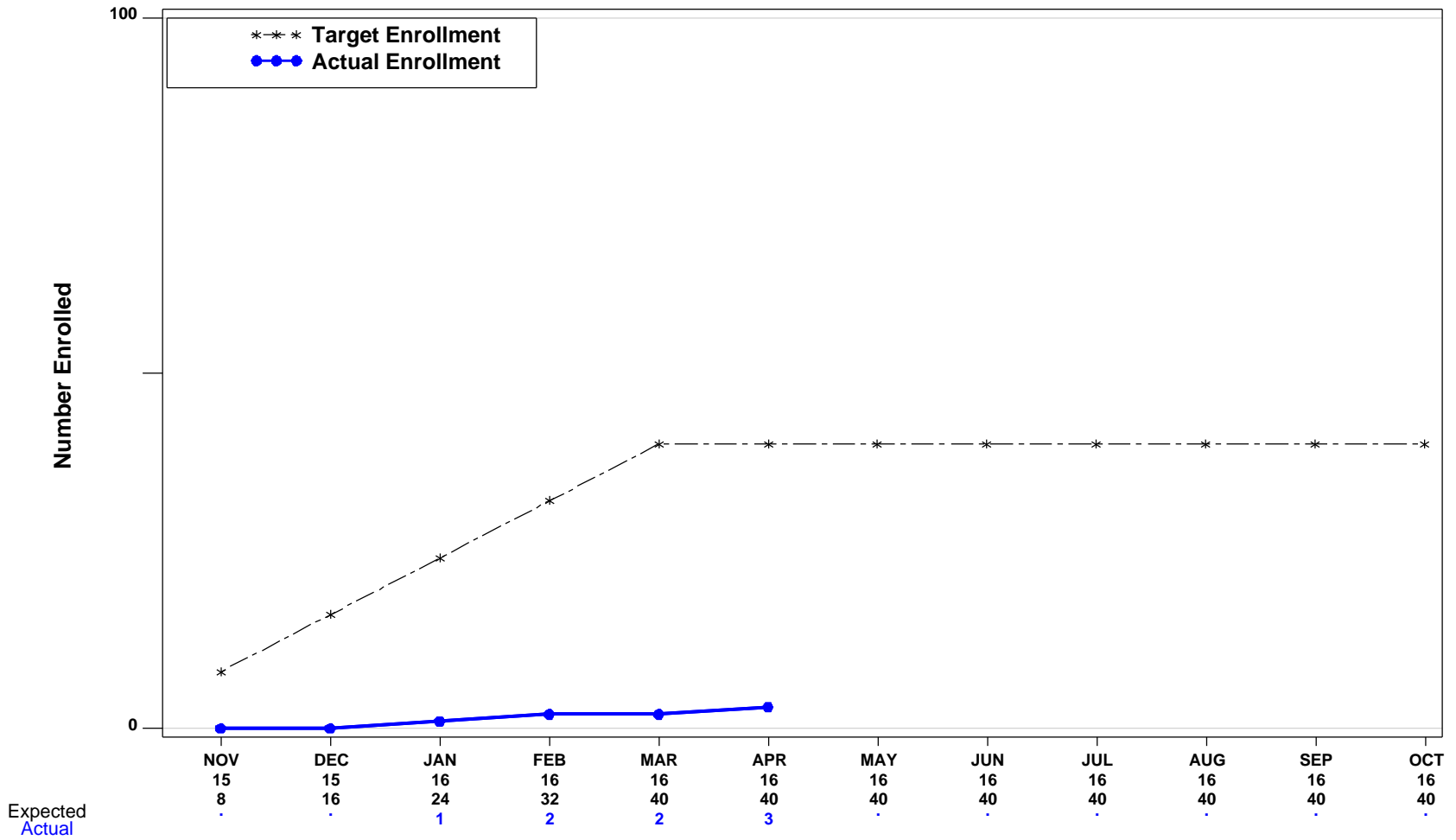
Total Enrolled: 0 Enrollment Target: 7 Enrollment Needed: 7



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Male Cohort2
 Data as of 15NOV2018

Figure 1A. Cumulative Enrollment - All Sites

Total Enrolled: 3 Enrollment Target: 40 Enrollment Needed: 37



Source: SCHARP (whiteau) - /trials/hptn/p077/reporting/progress/code/g_accrual.sas, SAS Version 9.4 (16NOV2018,3:20)

Figure 1B. UNC AIDS CRS

Total Enrolled: 1 Enrollment Target: 5 Enrollment Needed: 4

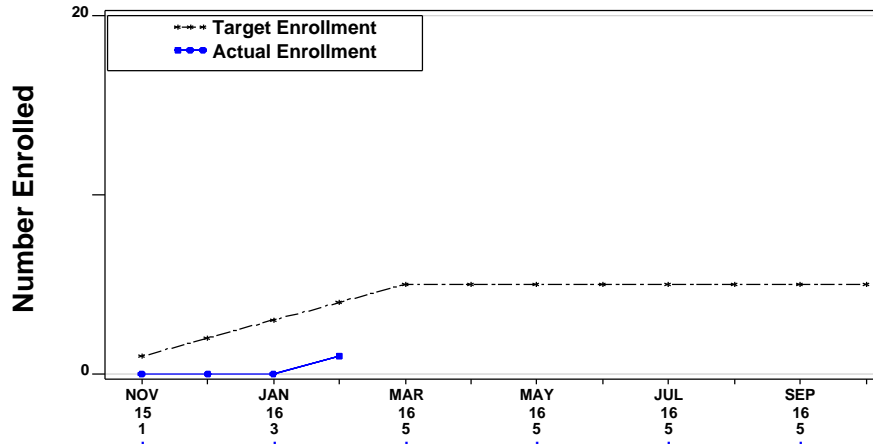


Figure 1C. UCLA CRS

Total Enrolled: 0 Enrollment Target: 5 Enrollment Needed: 5

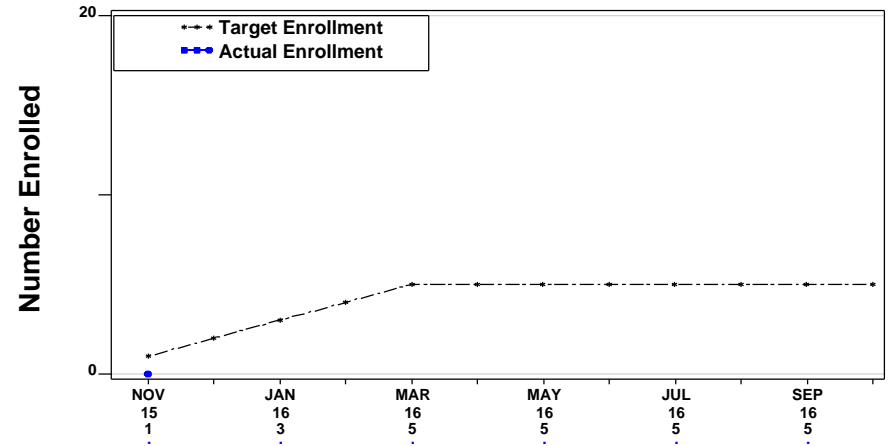


Figure 1D. San Francisco

Total Enrolled: 0 Enrollment Target: 5 Enrollment Needed: 5

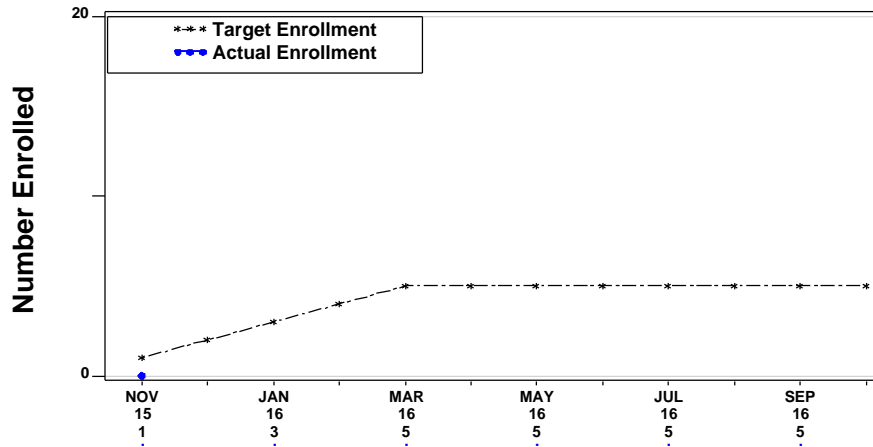
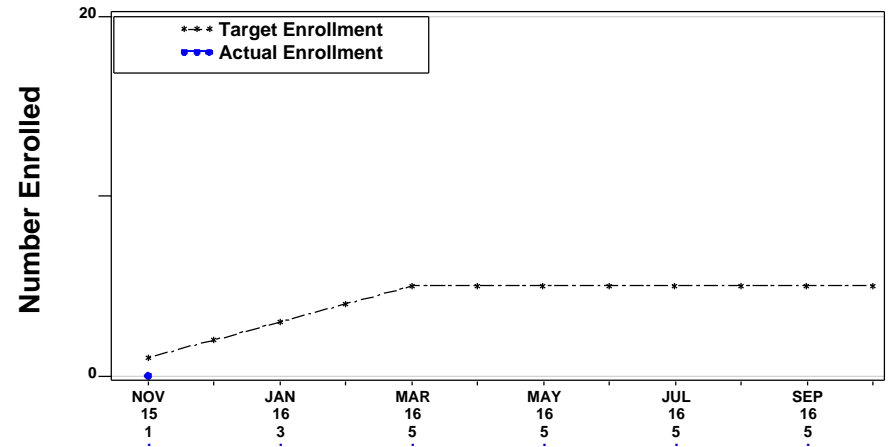


Figure 1E. GWU CRS

Total Enrolled: 0 Enrollment Target: 5 Enrollment Needed: 5



Source: SCHARP (whiteau) - /trials/hptn/p077/reporting/progress/code/g_accrual.sas, SAS Version 9.4 (16NOV2018,3:20)

Figure 1F. Soweto CTU

Total Enrolled: 0 Enrollment Target: 5 Enrollment Needed: 5

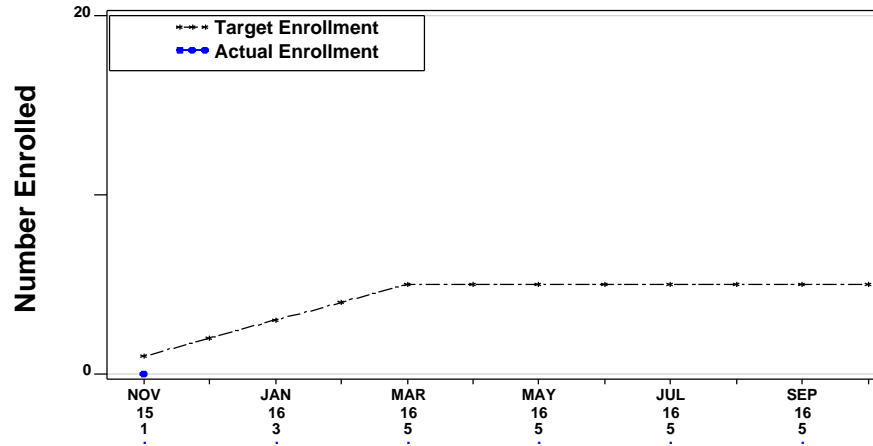


Figure 1G. Vulindlela CRS

Total Enrolled: 0 Enrollment Target: 5 Enrollment Needed: 5

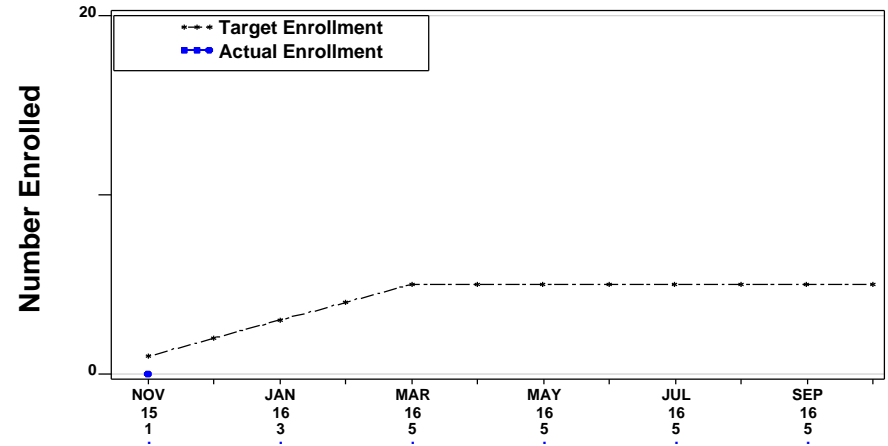


Figure 1H. Lilongwe UNC

Total Enrolled: 1 Enrollment Target: 5 Enrollment Needed: 4

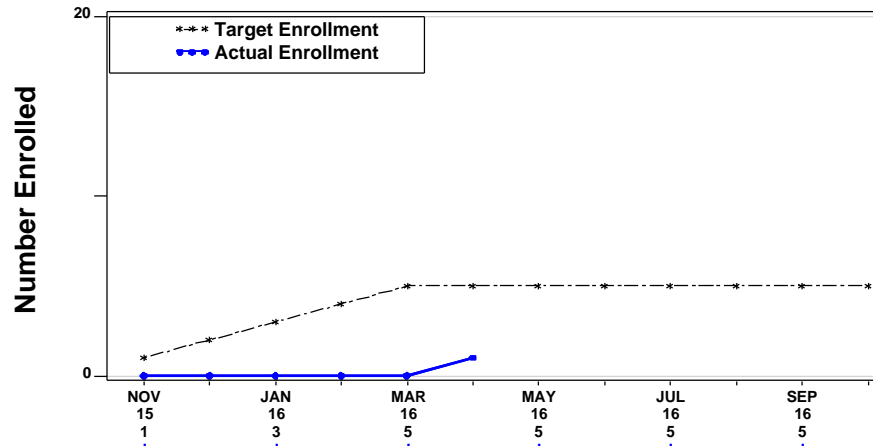


Figure 1I. Rio de Janeiro

Total Enrolled: 1 Enrollment Target: 5 Enrollment Needed: 4

