

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	18MAR2015	15SEP2015	26.0	13	28	1.1	215.4%
UCLA CRS	09FEB2015	23FEB2015	21AUG2015	25.7	13	12	0.5	92.3%
San Francisco	11FEB2015	30APR2015	09SEP2015	19.0	14	10	0.5	71.4%
GWU CRS	17MAR2015	30APR2015	28AUG2015	17.3	14	13	0.8	92.9%
Soweto CTU	16JUL2015	24AUG2015	16SEP2015	3.4	13	8	2.4	61.5%
Vulindlela CRS	18JUN2015	06JUL2015	25AUG2015	7.3	13	22	3.0	169.2%
Lilongwe UNC	26AUG2015	07SEP2015	07SEP2015	0.1	13	1	10.0	7.7%
Rio de Janeiro	05JUN2015	03JUL2015	03SEP2015	9.0	13	16	1.8	123.1%
Overall	09FEB2015	23FEB2015	16SEP2015	29.4	106	110	3.7	103.8%

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	23MAR2015	15SEP2015	25.3	8	20	0.8	250.0%
UCLA CRS	09FEB2015	23FEB2015	20AUG2015	25.6	8	3	0.1	37.5%
San Francisco	11FEB2015	30APR2015	31JUL2015	13.3	9	4	0.3	44.4%
GWU CRS	17MAR2015	30APR2015	14AUG2015	15.3	8	5	0.3	62.5%
Soweto CTU	16JUL2015	24AUG2015	16SEP2015	3.4	8	7	2.1	87.5%
Vulindlela CRS	18JUN2015	06JUL2015	25AUG2015	7.3	8	22	3.0	275.0%
Lilongwe UNC	26AUG2015	-	-	-	8	-	-	-
Rio de Janeiro	05JUN2015	03JUL2015	03SEP2015	9.0	8	11	1.2	137.5%
Overall	09FEB2015	23FEB2015	16SEP2015	29.4	65	72	2.4	110.8%

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Male

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	18MAR2015	28AUG2015	23.4	6	8	0.3	133.3%
UCLA CRS	09FEB2015	27FEB2015	21AUG2015	25.1	6	9	0.4	150.0%
San Francisco	11FEB2015	30APR2015	09SEP2015	19.0	6	6	0.3	100.0%
GWU CRS	17MAR2015	07MAY2015	28AUG2015	16.3	6	8	0.5	133.3%
Soweto CTU	16JUL2015	10SEP2015	10SEP2015	0.1	6	1	10.0	16.7%
Vulindlela CRS	18JUN2015	-	-	-	5	-	-	-
Lilongwe UNC	26AUG2015	07SEP2015	07SEP2015	0.1	5	1	10.0	20.0%
Rio de Janeiro	05JUN2015	08JUL2015	28AUG2015	7.4	5	5	0.7	100.0%
Overall	09FEB2015	27FEB2015	10SEP2015	28.0	45	38	1.4	84.4%

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	23FEB2015	18MAR2015	23FEB2015	30APR2015	30APR2015	24AUG2015	06JUL2015	07SEP2015	03JUL2015
Summary									
Total Enrolled	110	28	12	10	13	8	22	1	16
Enrollment Target	106	13	13	14	14	13	13	13	13
Percent Enrolled	103.8%	215.4%	92.3%	71.4%	92.9%	61.5%	169.2%	7.7%	123.1%
Accrual									
Calendar Month of Accrual									
FEB2015	2 (2)	- (-)	2 (2)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
MAR2015	7 (9)	5 (5)	2 (4)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
APR2015	11 (20)	6 (11)	2 (6)	2 (2)	1 (1)	- (-)	- (-)	- (-)	- (-)
MAY2015	6 (26)	1 (12)	2 (8)	1 (3)	2 (3)	- (-)	- (-)	- (-)	- (-)
JUN2015	8 (34)	3 (15)	1 (9)	1 (4)	3 (6)	- (-)	- (-)	- (-)	- (-)
JUL2015	27 (61)	7 (22)	0 (9)	4 (8)	3 (9)	- (-)	8 (8)	- (-)	5 (5)
AUG2015	34 (95)	5 (27)	3 (12)	1 (9)	4 (13)	1 (1)	14 (22)	- (-)	6 (11)
SEP2015	15 (110)	1 (28)	0 (12)	1 (10)	0 (13)	7 (8)	0 (22)	1 (1)	5 (16)
Average Enrolled per Month	13.8	4.0	1.5	1.7	2.2	4.0	7.3	1.0	5.3

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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	Rio de Janeiro Site ID 264
Activation Date	09FEB2015	13FEB2015	09FEB2015	11FEB2015	17MAR2015	16JUL2015	18JUN2015	05JUN2015
First Enrollment Date	23FEB2015	23MAR2015	23FEB2015	30APR2015	30APR2015	24AUG2015	06JUL2015	03JUL2015
Summary								
Total Enrolled	72	20	3	4	5	7	22	11
Enrollment Target	65	8	8	9	8	8	8	8
Percent Enrolled	110.8%	250.0%	37.5%	44.4%	62.5%	87.5%	275.0%	137.5%
Accrual								
Calendar Month of Accrual								
FEB2015	1 (1)	- (-)	1 (1)	- (-)	- (-)	- (-)	- (-)	- (-)
MAR2015	3 (4)	3 (3)	0 (1)	- (-)	- (-)	- (-)	- (-)	- (-)
APR2015	7 (11)	5 (8)	0 (1)	1 (1)	1 (1)	- (-)	- (-)	- (-)
MAY2015	1 (12)	1 (9)	0 (1)	0 (1)	0 (1)	- (-)	- (-)	- (-)
JUN2015	5 (17)	3 (12)	1 (2)	0 (1)	1 (2)	- (-)	- (-)	- (-)
JUL2015	19 (36)	5 (17)	0 (2)	3 (4)	0 (2)	- (-)	8 (8)	3 (3)
AUG2015	24 (60)	2 (19)	1 (3)	0 (4)	3 (5)	1 (1)	14 (22)	3 (6)
SEP2015	12 (72)	1 (20)	0 (3)	0 (4)	0 (5)	6 (7)	0 (22)	5 (11)
Average Enrolled per Month	9.0	2.9	0.4	0.7	0.8	3.5	7.3	3.7

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

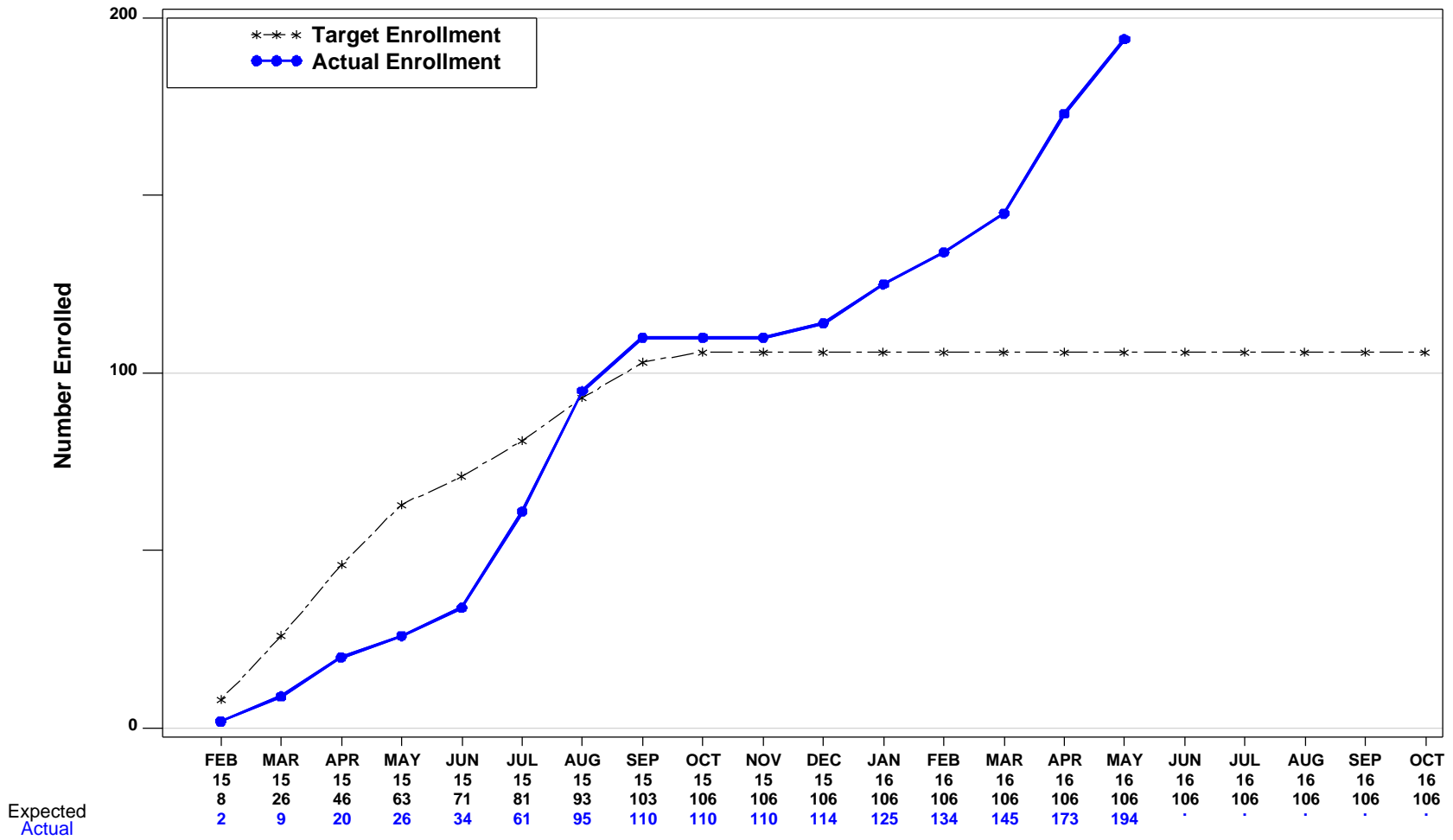
Male

	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	27FEB2015	18MAR2015	27FEB2015	30APR2015	07MAY2015	10SEP2015	07SEP2015	08JUL2015
Summary								
Total Enrolled	38	8	9	6	8	1	1	5
Enrollment Target	45	6	6	6	6	6	5	5
Percent Enrolled	84.4%	133.3%	150.0%	100.0%	133.3%	16.7%	20.0%	100.0%
Accrual								
Calendar Month of Accrual								
FEB2015	1 (1)	- (-)	1 (1)	- (-)	- (-)	- (-)	- (-)	- (-)
MAR2015	4 (5)	2 (2)	2 (3)	- (-)	- (-)	- (-)	- (-)	- (-)
APR2015	4 (9)	1 (3)	2 (5)	1 (1)	- (-)	- (-)	- (-)	- (-)
MAY2015	5 (14)	0 (3)	2 (7)	1 (2)	2 (2)	- (-)	- (-)	- (-)
JUN2015	3 (17)	0 (3)	0 (7)	1 (3)	2 (4)	- (-)	- (-)	- (-)
JUL2015	8 (25)	2 (5)	0 (7)	1 (4)	3 (7)	- (-)	- (-)	2 (2)
AUG2015	10 (35)	3 (8)	2 (9)	1 (5)	1 (8)	- (-)	- (-)	3 (5)
SEP2015	3 (38)	0 (8)	0 (9)	1 (6)	0 (8)	1 (1)	1 (1)	0 (5)
Average Enrolled per Month	4.8	1.1	1.1	1.0	1.6	1.0	1.0	1.7

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Overall Cohort1
 Data as of 15NOV2018

Figure 1A. Cumulative Enrollment - All Sites

Total Enrolled: 194 Enrollment Target: 106 Enrollment Needed: 0



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

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Overall Cohort1
 Data as of 15NOV2018

Figure 1B. UNC AIDS CRS

Total Enrolled: 40 Enrollment Target: 13 Enrollment Needed: 0

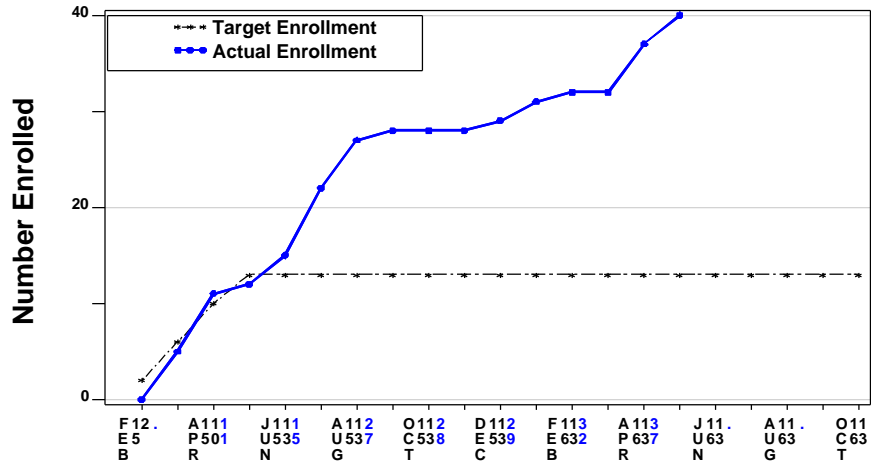


Figure 1C. UCLA CRS

Total Enrolled: 18 Enrollment Target: 13 Enrollment Needed: 0

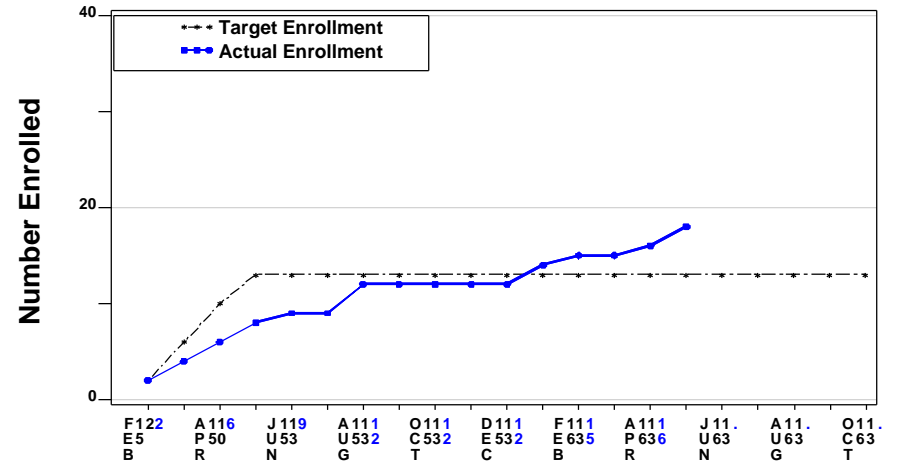


Figure 1D. San Francisco

Total Enrolled: 23 Enrollment Target: 14 Enrollment Needed: 0

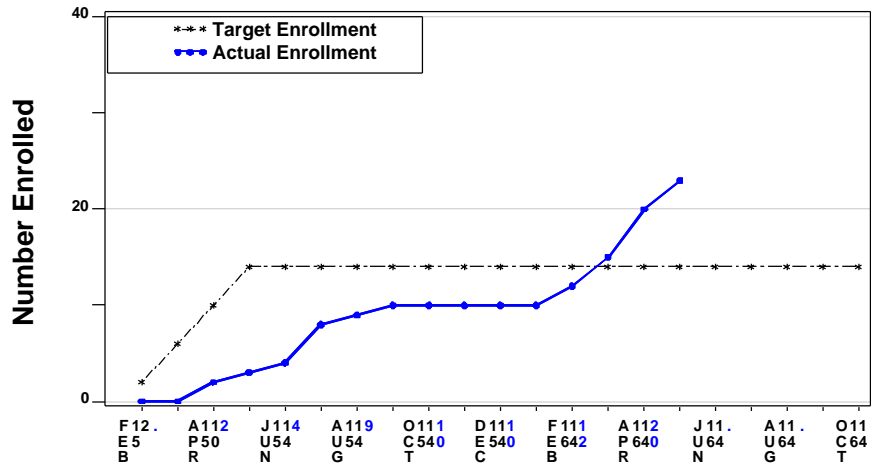
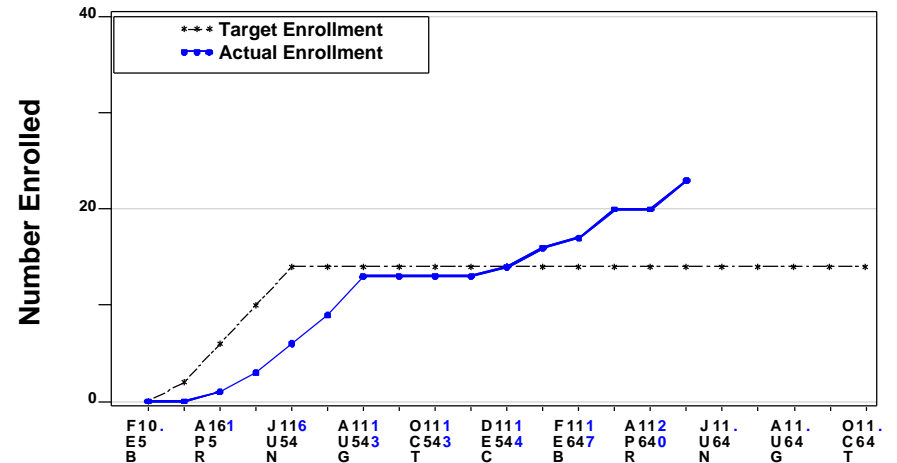


Figure 1E. GWU CRS

Total Enrolled: 23 Enrollment Target: 14 Enrollment Needed: 0



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

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Overall Cohort1
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Figure 1F. Soweto CTU

Total Enrolled: 18 Enrollment Target: 13 Enrollment Needed: 0

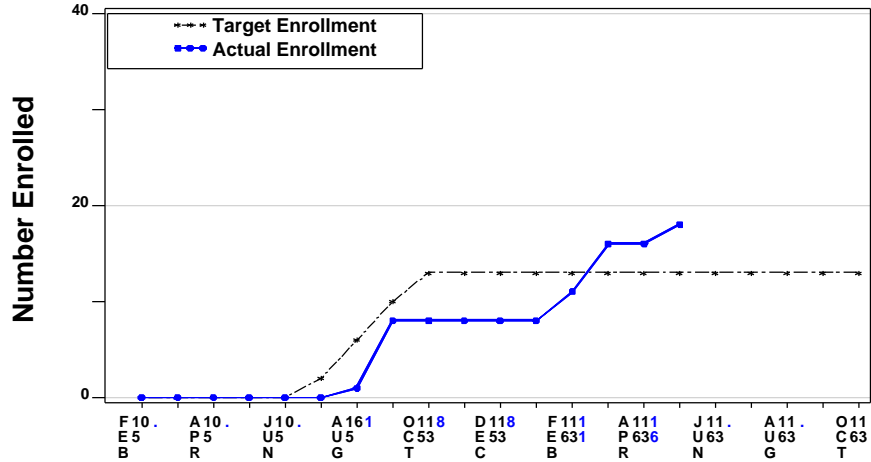


Figure 1G. Vulindlela CRS

Total Enrolled: 24 Enrollment Target: 13 Enrollment Needed: 0

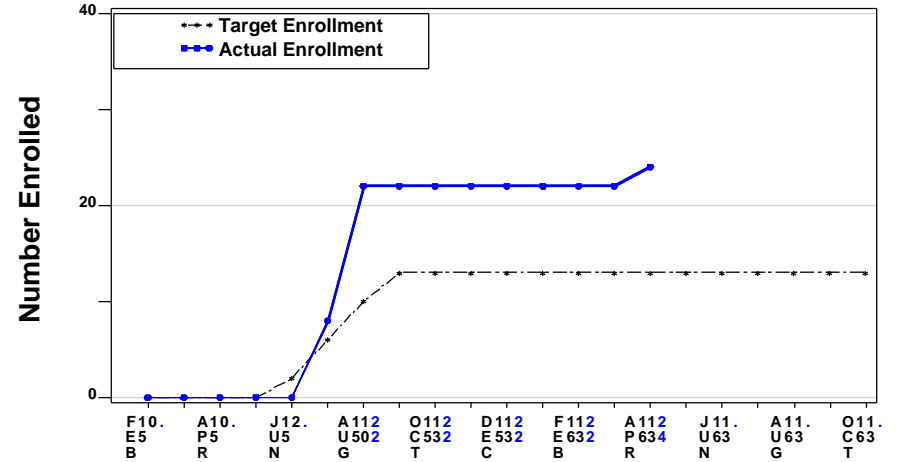


Figure 1H. Lilongwe UNC

Total Enrolled: 15 Enrollment Target: 13 Enrollment Needed: 0

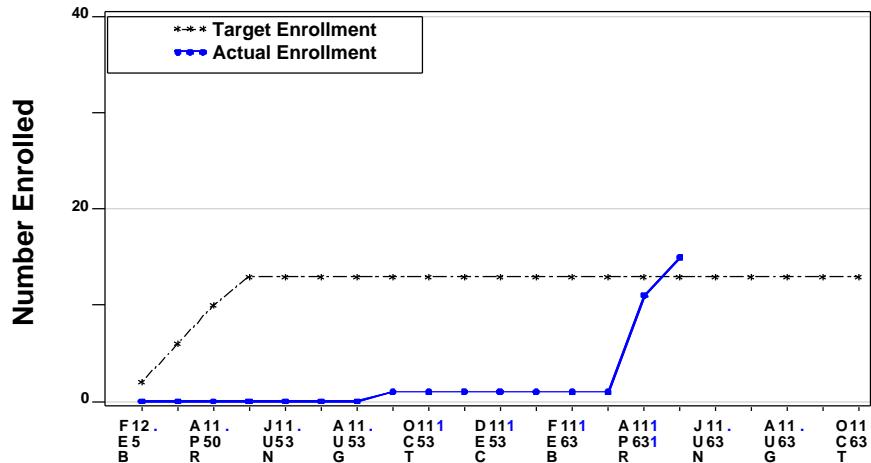
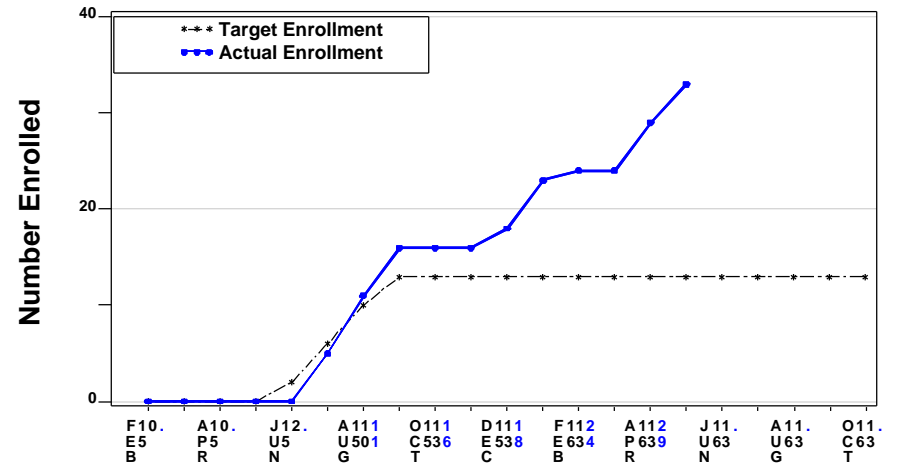


Figure 1I. Rio de Janeiro

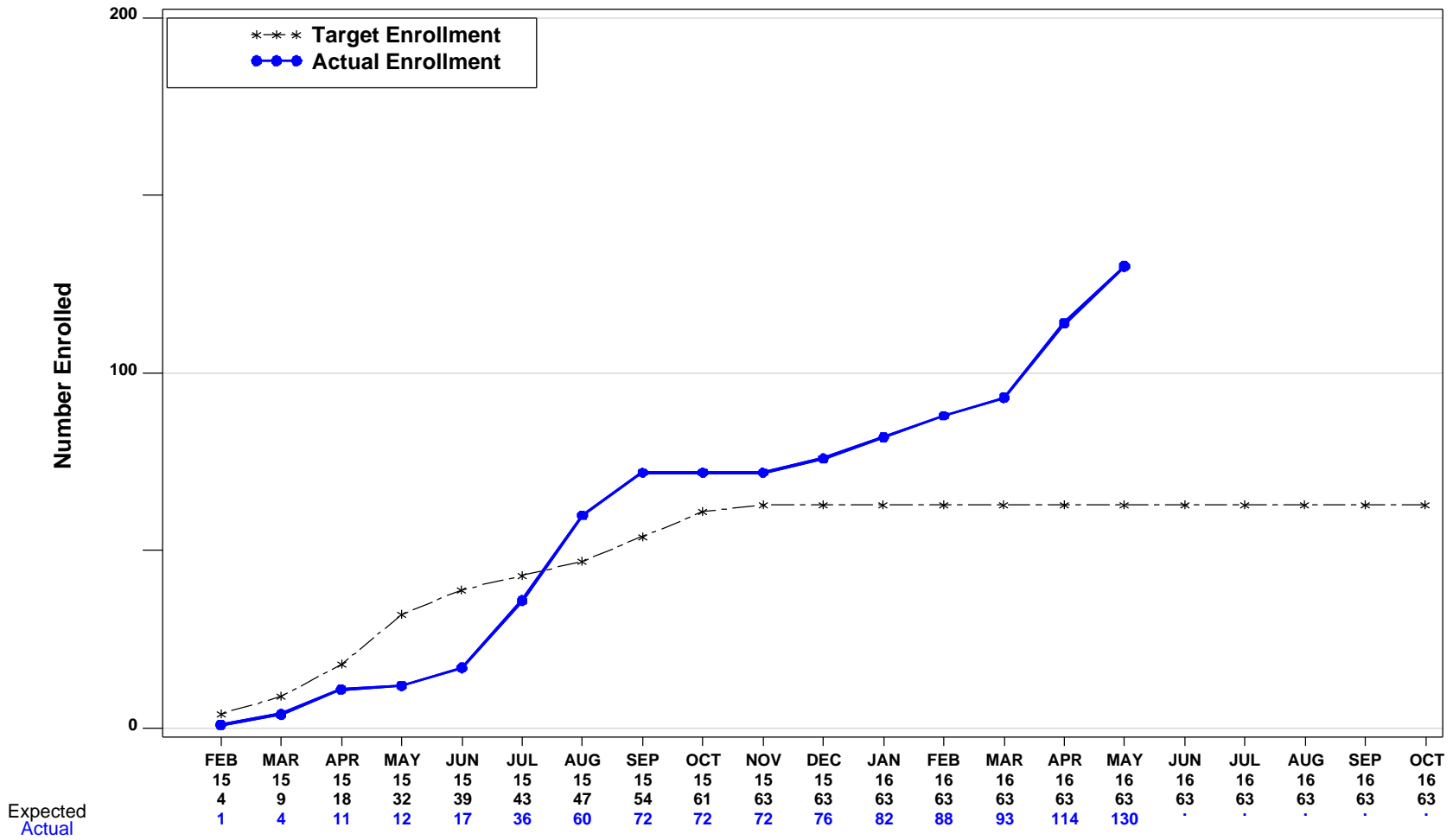
Total Enrolled: 33 Enrollment Target: 13 Enrollment Needed: 0



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: 130 Enrollment Target: 63 Enrollment Needed: 0



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: 13 Enrollment Target: 8 Enrollment Needed: 0

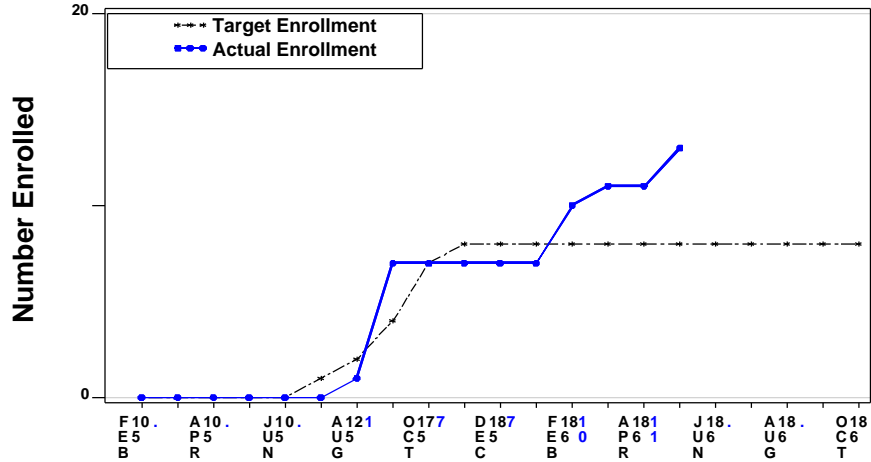


Figure 1G. Vulindlela CRS

Total Enrolled: 24 Enrollment Target: 8 Enrollment Needed: 0

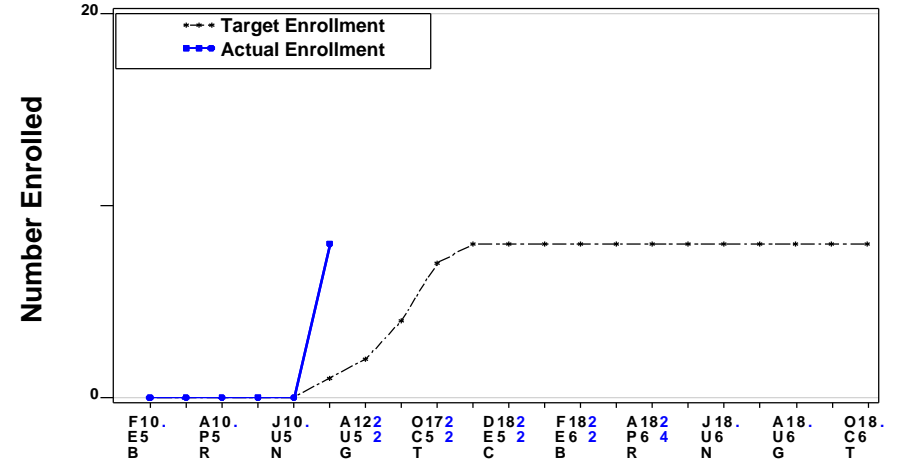


Figure 1H. Lilongwe UNC

Total Enrolled: 13 Enrollment Target: 8 Enrollment Needed: 0

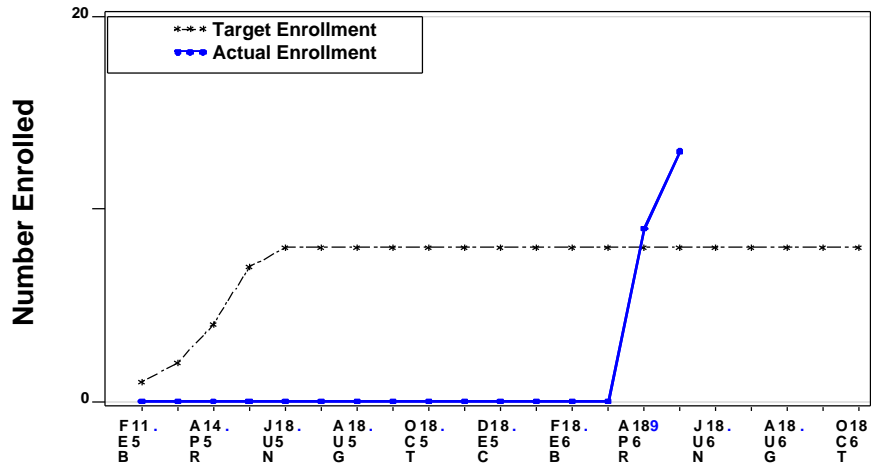


Figure 1I. Rio de Janeiro

Total Enrolled: 24 Enrollment Target: 8 Enrollment Needed: 0

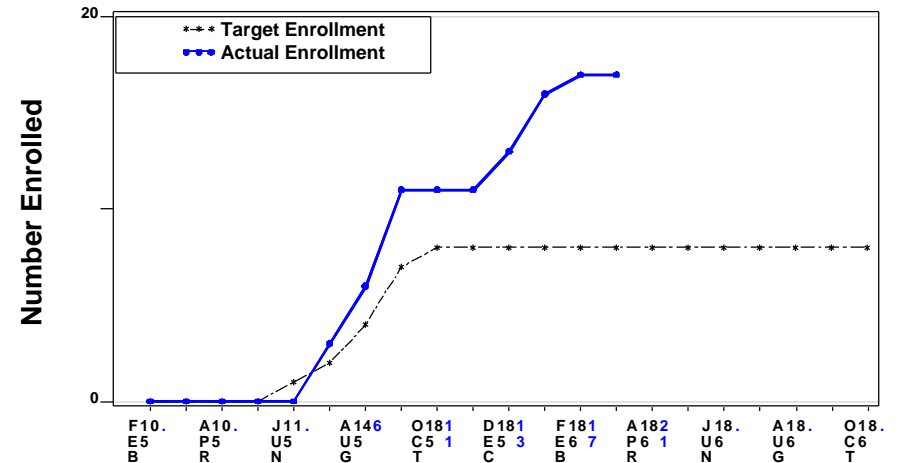
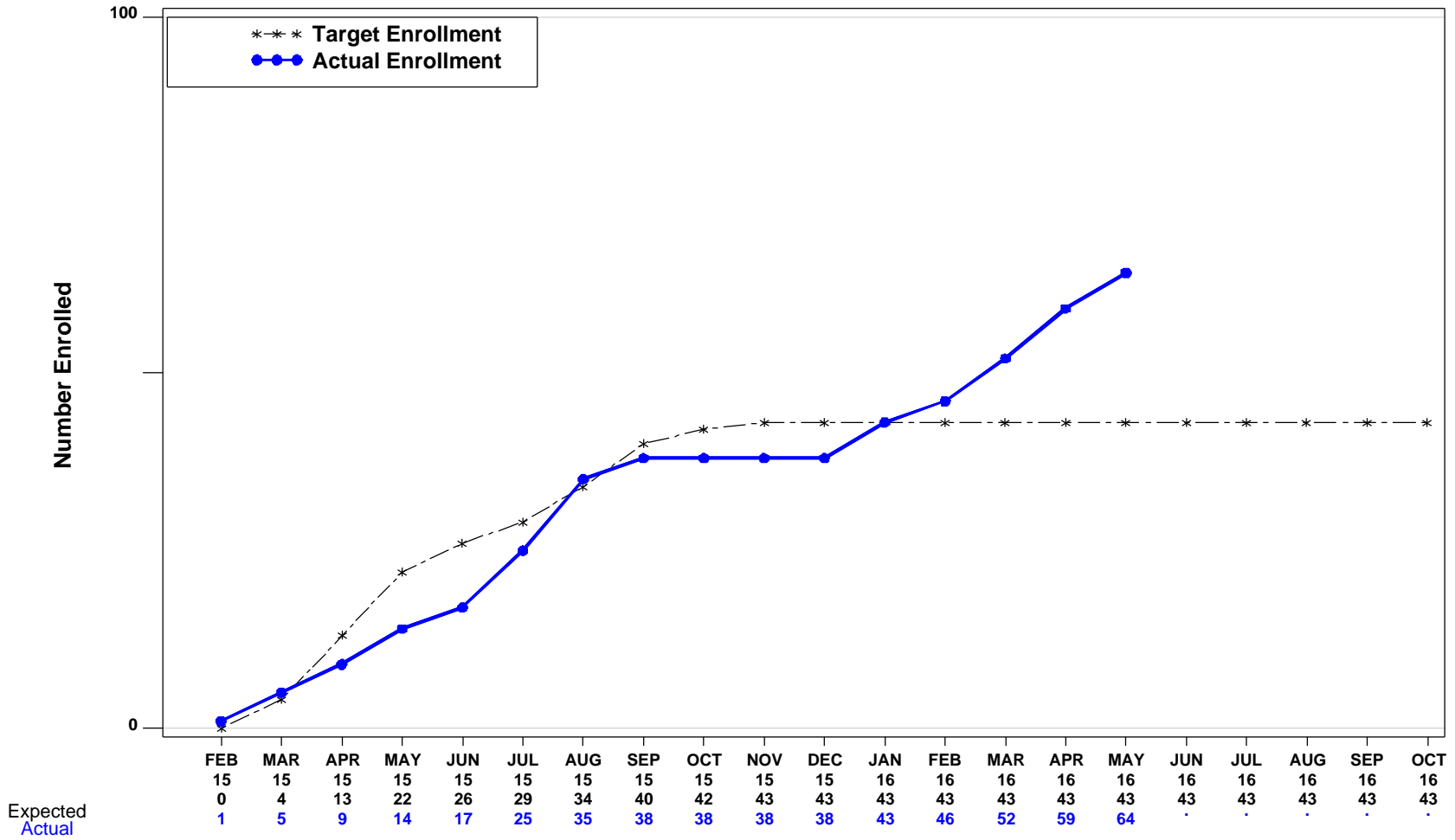


Figure 1A. Cumulative Enrollment - All Sites

Total Enrolled: 64 Enrollment Target: 43 Enrollment Needed: 0



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: 10 Enrollment Target: 6 Enrollment Needed: 0

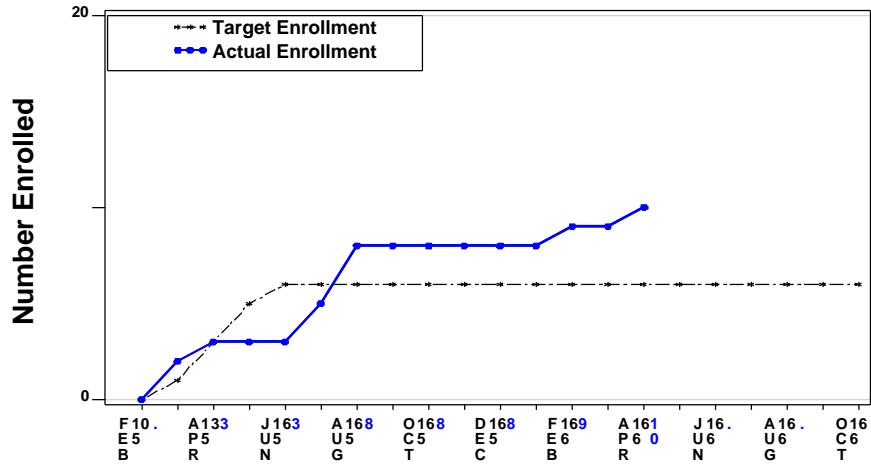


Figure 1F. Soweto CTU

Total Enrolled: 5 Enrollment Target: 6 Enrollment Needed: 1

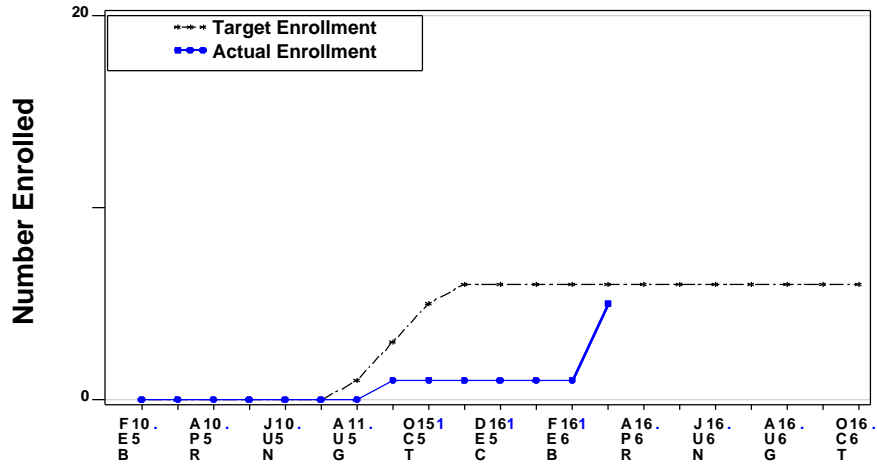


Figure 1G. Vulindlela CRS

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

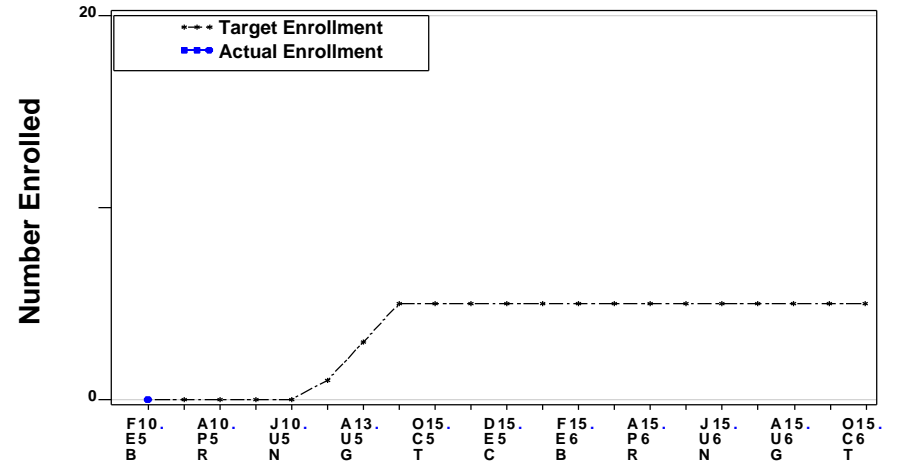


Figure 1H. Lilongwe UNC

Total Enrolled: 2 Enrollment Target: 5 Enrollment Needed: 3

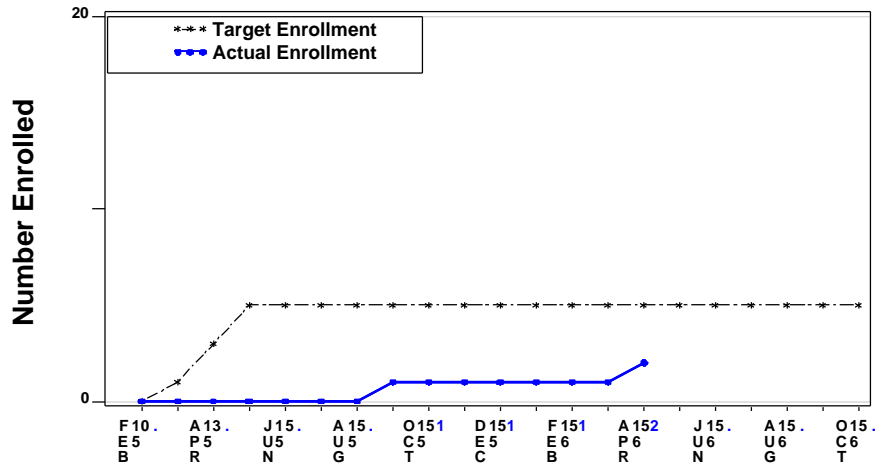
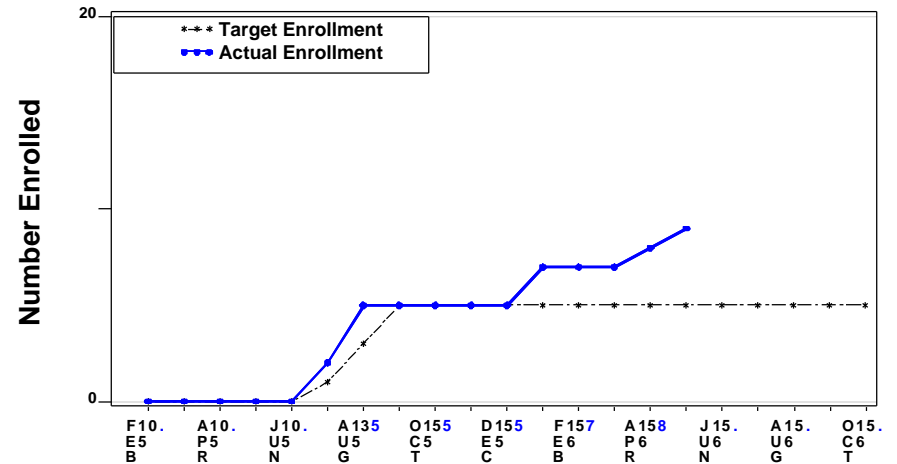


Figure 1I. Rio de Janeiro

Total Enrolled: 9 Enrollment Target: 5 Enrollment Needed: 0



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