

HPTN 074 - Integrated treatment and prevention for people who inject drugs: A vanguard study for a network-based randomized HIV prevention trial comparing an integrated intervention including supported antiretroviral therapy to the standard of care

Report October 29, 2018

Visit Cutoff Date: October 28, 2018

Table A - Accrual Summary by Site

Index

Site	Activation Date	First Enrollment Date	Last Enrollment Date¹	Duration of Accrual² (weeks)	Enrollment Target	Total Enrolled	Average Enrolled per Week	Percent Enrolled
Indonesia CRS	15JUN2015	27JUL2015	08JUN2016	45.4	167	121	2.7	72.5%
Ukraine CRS	11MAY2015	09JUN2015	10JUN2016	52.6	167	188	3.6	112.6%
Vietnam CRS	04FEB2015	21APR2015	26MAY2016	57.4	167	195	3.4	116.8%
Overall	04FEB2015	21APR2015	10JUN2016	59.6	501	504	8.5	100.6%

¹Date of most recent enrollment as of October 28, 2018.

²Duration of accrual based on first enrollment date.

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Table A - Accrual Summary by Site

Partner

Site	Activation Date	First Enrollment Date	Last Enrollment Date¹	Duration of Accrual² (weeks)	Enrollment Target	Total Enrolled	Average Enrolled per Week	Percent Enrolled
Indonesia CRS	15JUN2015	27JUL2015	23DEC2016	73.7	250	183	2.5	73.2%
Ukraine CRS	11MAY2015	09JUN2015	28DEC2016	81.3	250	321	3.9	128.4%
Vietnam CRS	04FEB2015	21APR2015	05OCT2016	76.3	250	306	4.0	122.4%
Overall	04FEB2015	21APR2015	28DEC2016	88.3	750	810	9.2	108.0%

¹Date of most recent enrollment as of October 28, 2018.

²Duration of accrual based on first enrollment date.

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Table - Accrual Summary and Accrual by Calendar Month and Site

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	Overall	Indonesia CRS	Ukraine CRS	Vietnam CRS
Activation Date	04FEB2015	15JUN2015	11MAY2015	04FEB2015
First Enrollment Date	21APR2015	27JUL2015	09JUN2015	21APR2015
Summary				
Total Enrolled	504	121	188	195
Enrollment Target	501	167	167	167
Percent Enrolled	100.6%	72.5%	112.6%	116.8%
Accrual				
Calendar Month of Accrual				
APR2015	4 (4)	- (-)	- (-)	4 (4)
MAY2015	12 (16)	- (-)	- (-)	12 (16)
JUN2015	58 (74)	- (-)	25 (25)	33 (49)
JUL2015	57 (131)	3 (3)	31 (56)	23 (72)
AUG2015	34 (165)	10 (13)	6 (62)	18 (90)
SEP2015	39 (204)	22 (35)	4 (66)	13 (103)
OCT2015	46 (250)	13 (48)	11 (77)	22 (125)
NOV2015	46 (296)	9 (57)	18 (95)	19 (144)
DEC2015	44 (340)	8 (65)	19 (114)	17 (161)
JAN2016	30 (370)	9 (74)	9 (123)	12 (173)
FEB2016	35 (405)	8 (82)	20 (143)	7 (180)
MAR2016	35 (440)	11 (93)	22 (165)	2 (182)
APR2016	32 (472)	19 (112)	7 (172)	6 (188)
MAY2016	23 (495)	7 (119)	9 (181)	7 (195)
JUN2016	9 (504)	2 (121)	7 (188)	0 (195)
Average Enrolled per Month	33.6	10.1	14.5	13.0

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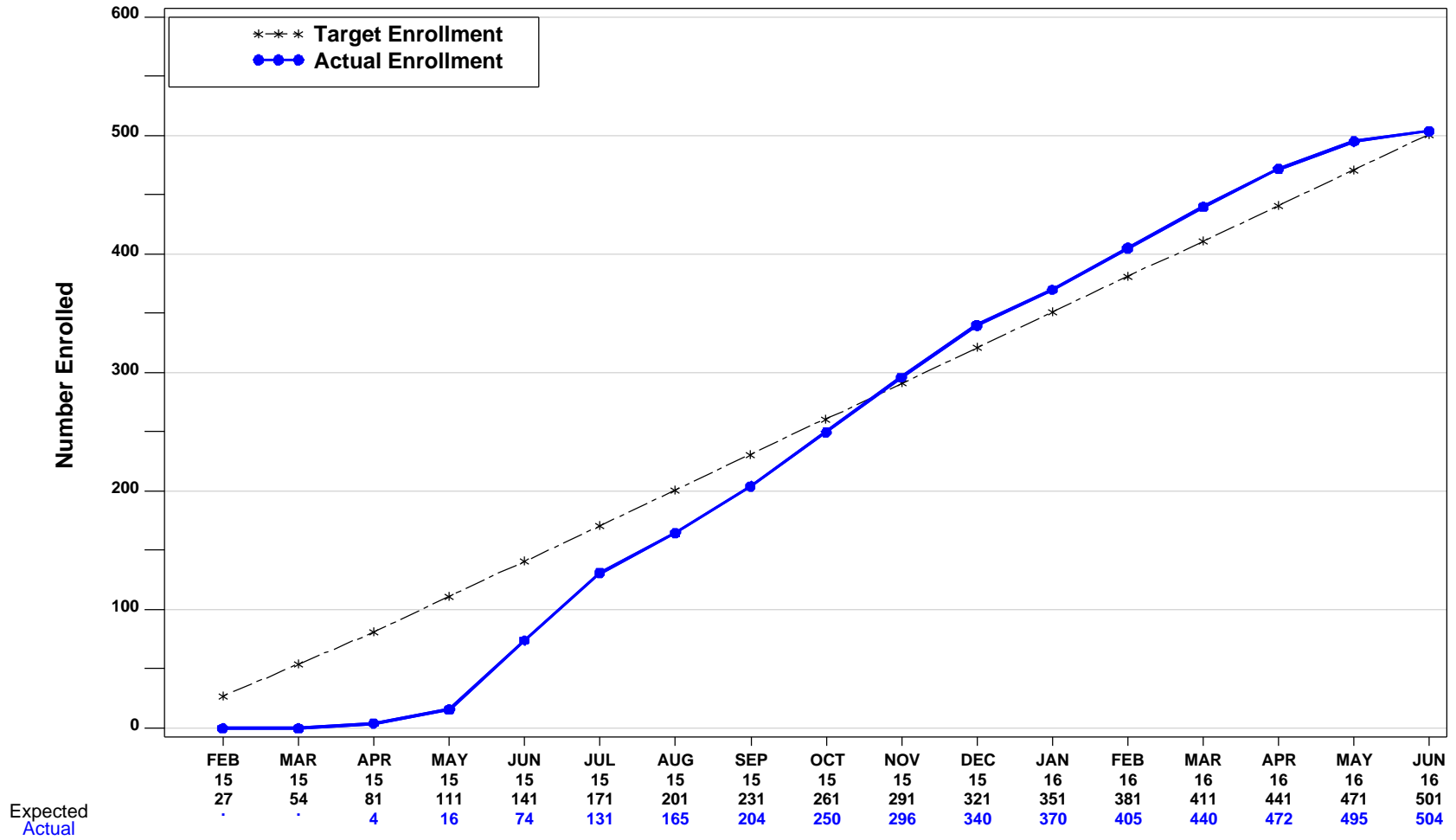
Table - Accrual Summary and Accrual by Calendar Month and Site

	Partner			
	Overall	Indonesia CRS	Ukraine CRS	Vietnam CRS
Activation Date	04FEB2015	15JUN2015	11MAY2015	04FEB2015
First Enrollment Date	21APR2015	27JUL2015	09JUN2015	21APR2015
Summary				
Total Enrolled	810	183	321	306
Enrollment Target	750	250	250	250
Percent Enrolled	108.0%	73.2%	128.4%	122.4%
Accrual				
Calendar Month of Accrual				
APR2015	4 (4)	- (-)	- (-)	4 (4)
MAY2015	15 (19)	- (-)	- (-)	15 (19)
JUN2015	67 (86)	- (-)	29 (29)	38 (57)
JUL2015	96 (182)	3 (3)	48 (77)	45 (102)
AUG2015	56 (238)	10 (13)	9 (86)	37 (139)
SEP2015	46 (284)	22 (35)	5 (91)	19 (158)
OCT2015	63 (347)	14 (49)	22 (113)	27 (185)
NOV2015	76 (423)	10 (59)	32 (145)	34 (219)
DEC2015	69 (492)	12 (71)	36 (181)	21 (240)
JAN2016	37 (529)	14 (85)	11 (192)	12 (252)
FEB2016	55 (584)	15 (100)	33 (225)	7 (259)
MAR2016	64 (648)	23 (123)	33 (258)	8 (267)
APR2016	55 (703)	26 (149)	13 (271)	16 (283)
MAY2016	45 (748)	14 (163)	18 (289)	13 (296)
JUN2016	13 (761)	5 (168)	8 (297)	0 (296)
JUL2016	14 (775)	7 (175)	4 (301)	3 (299)
AUG2016	5 (780)	3 (178)	1 (302)	1 (300)
SEP2016	7 (787)	0 (178)	2 (304)	5 (305)
OCT2016	9 (796)	4 (182)	4 (308)	1 (306)
NOV2016	6 (802)	0 (182)	6 (314)	0 (306)
DEC2016	8 (810)	1 (183)	7 (321)	0 (306)
Average Enrolled per Month	38.6	10.2	16.9	14.6

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Data as of 28OCT2018

Figure 1A. Cumulative Enrollment - All Sites

Total Enrolled: 504 Enrollment Target: 501 Enrollment Needed: 0



Source: SCHARP (whiteau) - /trials/hptn/p074/reporting/progress/code/g_accrual.sas, SAS Version 9.4 (29OCT2018,1:19)

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Data as of 28OCT2018

Figure 1B. Indonesia CRS

Total Enrolled: 121 Enrollment Target: 167 Enrollment Needed: 46

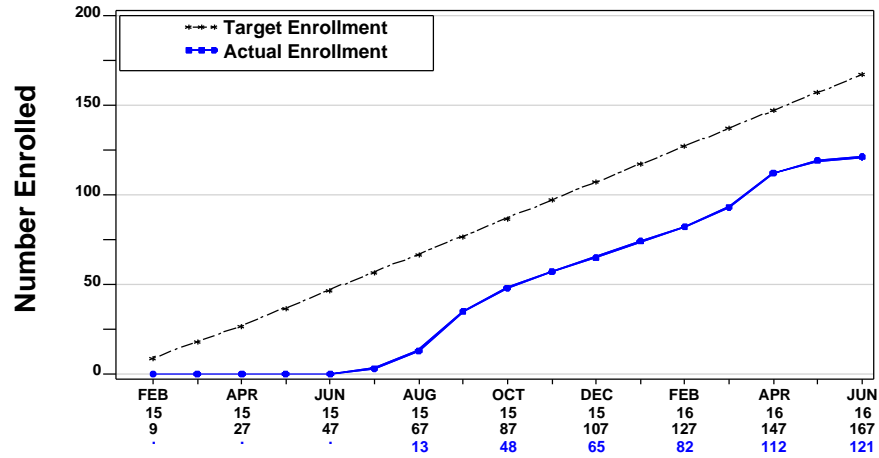


Figure 1C. Ukraine CRS

Total Enrolled: 188 Enrollment Target: 167 Enrollment Needed: 0

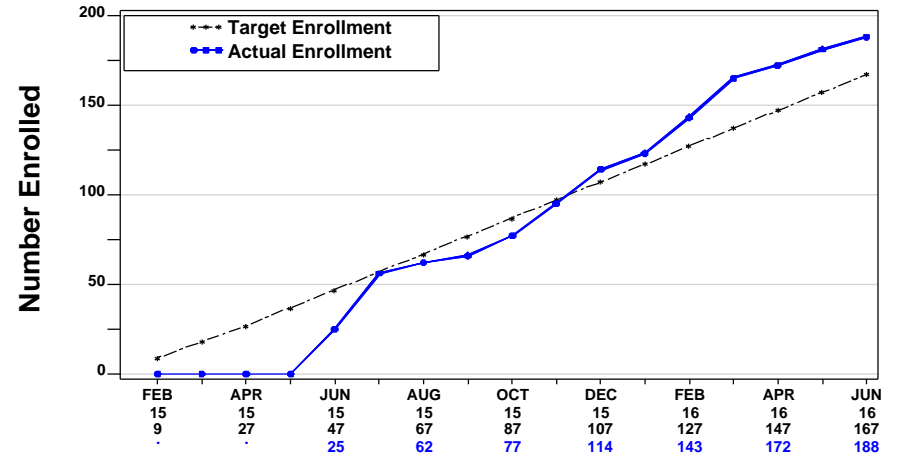
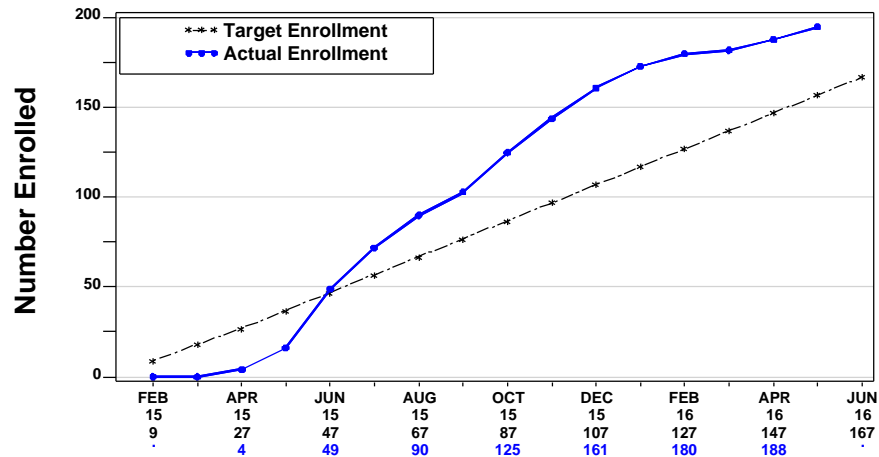


Figure 1D. Vietnam CRS

Total Enrolled: 195 Enrollment Target: 167 Enrollment Needed: 0

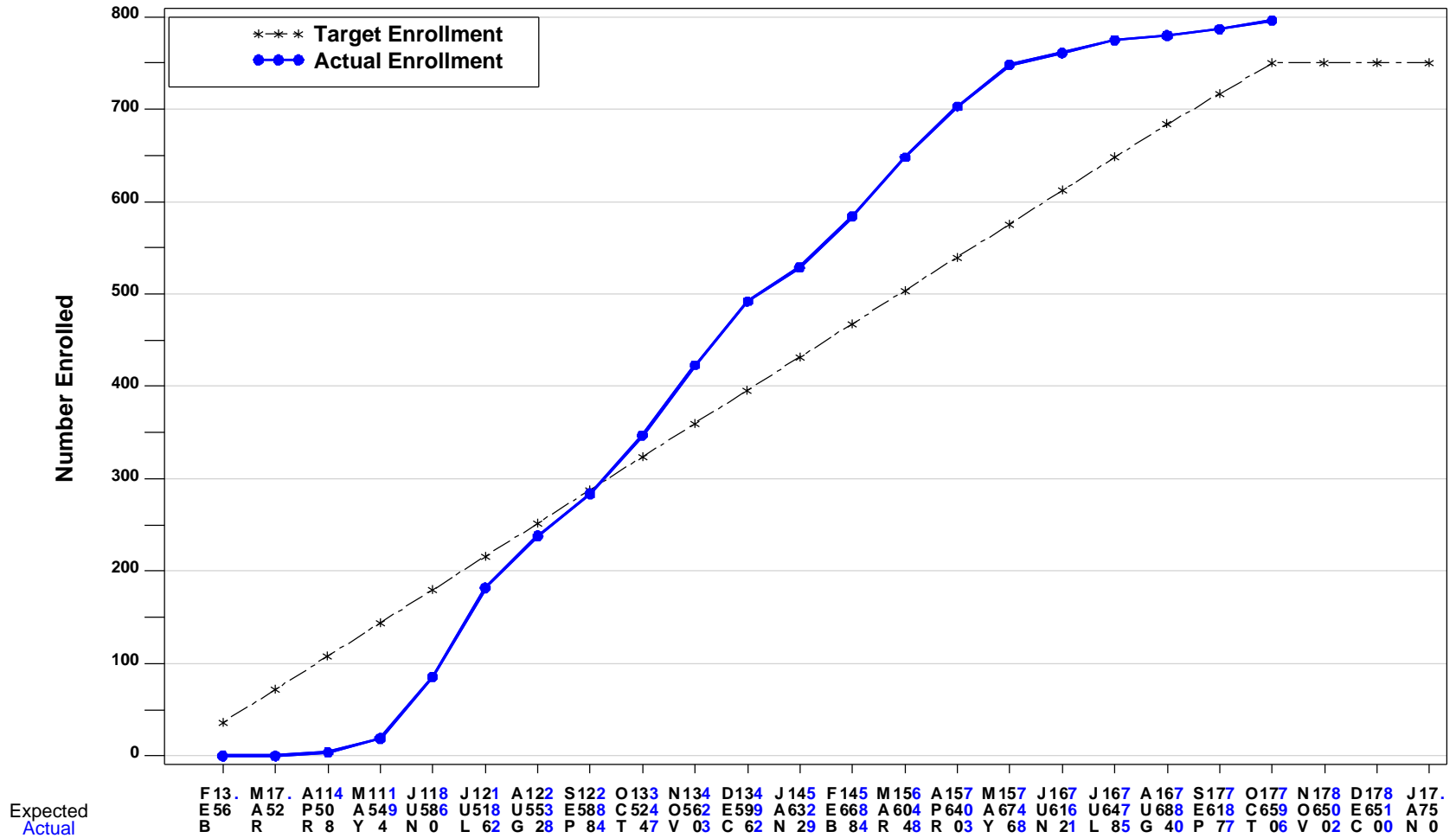


Source: SCHARP (whiteau) - /trials/hptn/p074/reporting/progress/code/g_accrual.sas, SAS Version 9.4 (29OCT2018,1:19)

Partner
Data as of 28OCT2018

Figure 2A. Cumulative Enrollment - All Sites

Total Enrolled: 810 Enrollment Target: 750 Enrollment Needed: 0



Source: SCHARP (whiteau) - /trials/hptn/p074/reporting/progress/code/g_accrual.sas, SAS Version 9.4 (29OCT2018,1:19)

Partner
Data as of 28OCT2018

Figure 2B. Indonesia CRS

Total Enrolled: 183 Enrollment Target: 250 Enrollment Needed: 67

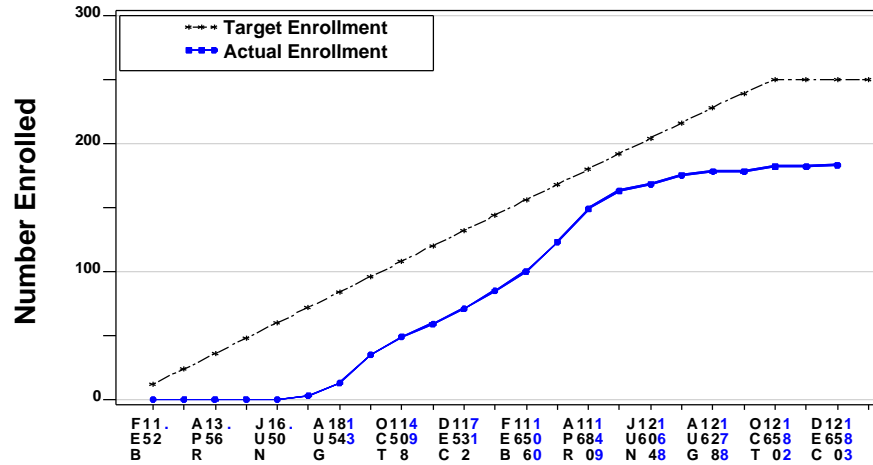


Figure 2C. Ukraine CRS

Total Enrolled: 321 Enrollment Target: 250 Enrollment Needed: 0

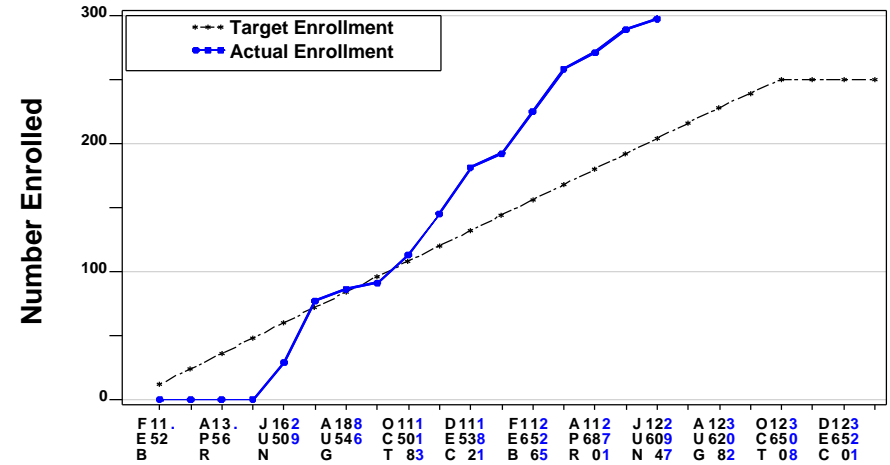
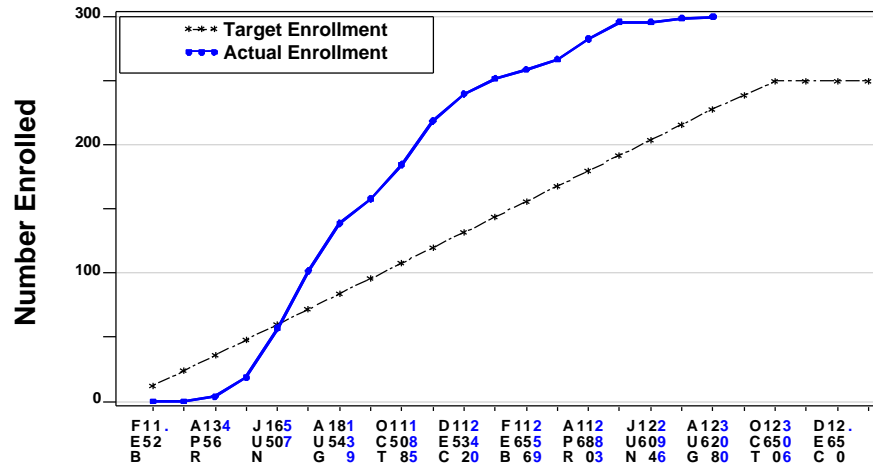


Figure 2D. Vietnam CRS

Total Enrolled: 306 Enrollment Target: 250 Enrollment Needed: 0



Source: SCHARP (whiteau) - /trials/hptn/p074/reporting/progress/code/g_accrual.sas, SAS Version 9.4 (29OCT2018,1:19)