

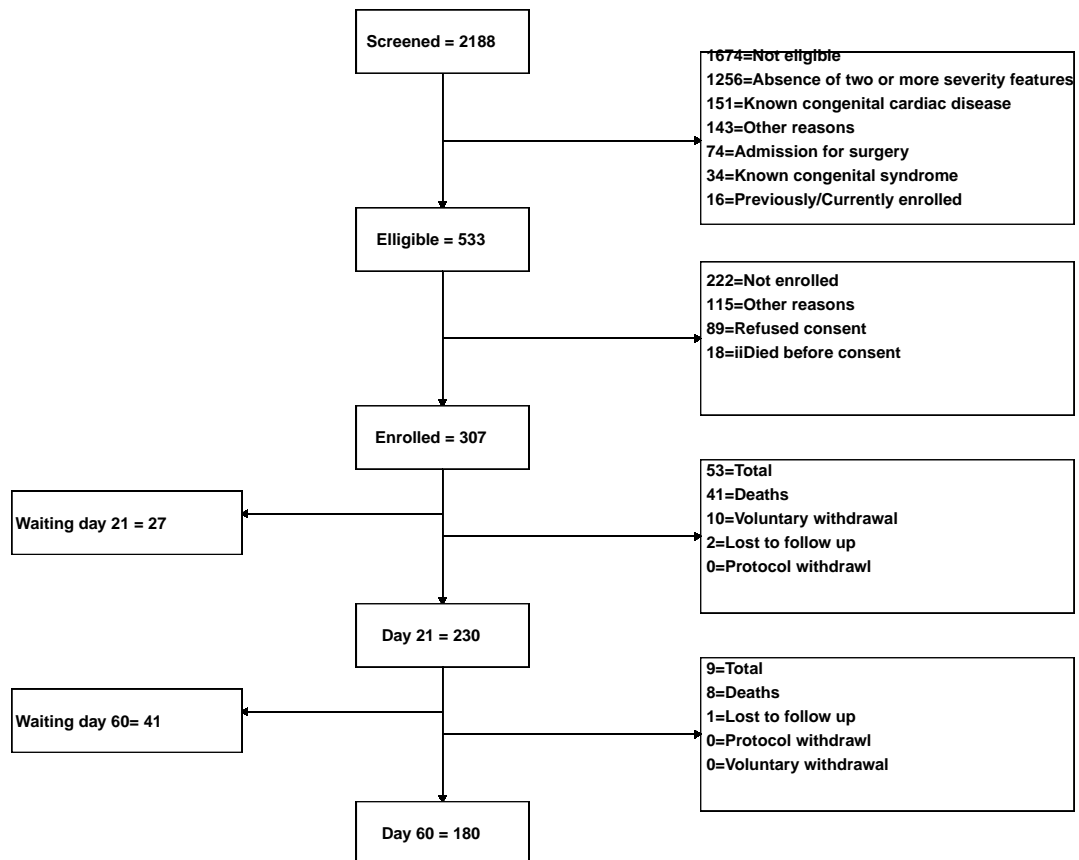
PBSAM Report as of Wed, 06-Jul-2022

CHAIN Data Team

2022-07-12

Screening Report

Study Flow Diagram



Screening Data split by site

variable	Blantyre	Kilifi	Kampala	Dhaka	All
Screened	430	268	487	1003	2188
Eligible (%)	145(33.7)	125(46.6)	153(31.4)	110(11)	533(24.4)
Enrolled (%)	102(70.3)	72(57.6)	48(31.4)	85(77.3)	307(57.6)

Reasons given for the not enrolled

field_label	Blantyre	Kilifi	Kampala	Dhaka	Total
Died before consent	2	6	9	1	18
Enrolled to other studies	0	4	0	1	5
Missed consent	2	0	0	0	2
Other Reasons	14	32	56	6	108
Refused consent	27	13	32	17	89
Total	45	55	97	25	222

Screening report 2022-06-30, 2022-07-06

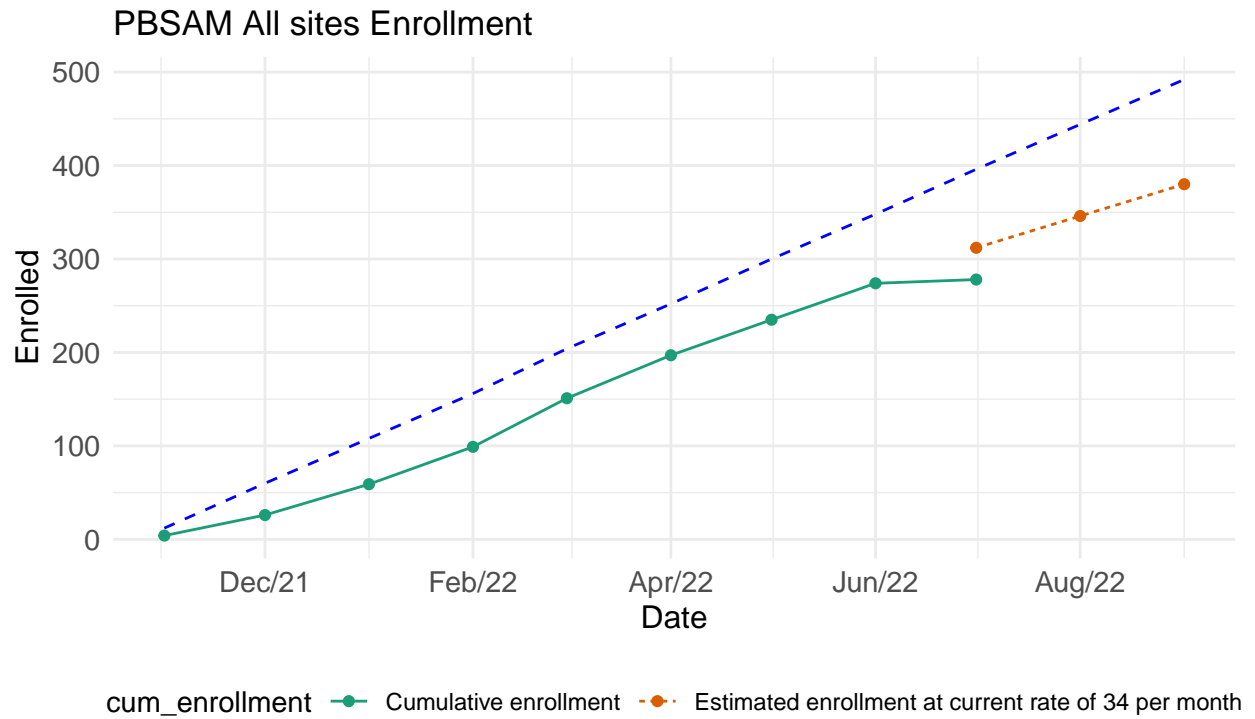
- *Screened value is for those within age range*

field_label	Blantyre	Kilifi	Kampala	Dhaka	Total
Screened	5	8	20	33	66
Eligible	2	6	5	1	14
Enrolled	2	4	1	0	7

Enrolled Report

Cumulative Enrollment

- Blue line curve is the expected curve if each site enrolled 4 per week/36 per month all sites
- Current enrollment rate is 34 per month
- Participants enrolled before all arms of investigation products were received have been omitted



Monthly enrollments

month_year	Kilifi	Kampala	Blantyre	Dhaka	All sites
2021-11	NA	NA	4	NA	4
2021-12	10	NA	7	5	22
2022-01	8	5	8	12	33
2022-02	11	7	12	10	40
2022-03	7	12	17	16	52
2022-04	10	8	6	22	46
2022-05	11	5	8	14	38
2022-06	11	13	9	6	39
2022-07	2	1	1	NA	4
Total	70	51	72	85	278

Expected enrolments per week if we set to complete by Thu, 11-Aug-2022

- *Number of weeks to Thu, 11-Aug-2022 are 4.29*
- Participants enrolled before all arms of investigation products were received have been omitted

Site	First enrolment date	Enrolled	Number remaining	Average weekly enrolments	Expected completion date
Kilifi	2021-12-11	70	0	2	NA
Kampala	2022-01-11	51	0	2	NA
Blantyre	2021-11-22	72	0	2	NA
Dhaka	2021-12-13	85	0	3	NA

Study Events Summary

- Participants enrolled before all arms of investigation products were received have been omitted

site	Enrolled	Discharged	Day 21	Day 60	Lost to follow up	Deaths	Voluntary withdrawal
Kilifi	70	61	52	38	0	10	1
Kampala	51	31	33	24	1	10	1
Blantyre	72	53	43	35	2	12	7
Dhaka	85	81	76	61	0	10	0
Total	278	226	204	158	3	42	9

Participants enrolled before all arms of investigation products were received

site	Enrolled	Discharged	Day 21	Day 60	Deaths	Voluntary withdrawal
Blantyre	29	25	24	20	8	1
Total	29	25	24	20	8	1

Demographic Summary

- Participants enrolled before all arms of investigation products were received have been omitted

variable	Kilifi	Kampala	Blantyre	Dhaka	Overall
	(N=70)	(N=51)	(N=72)	(N=85)	(N=278)
Sex					
Male	39 (55.7%)	26 (51.0%)	45 (62.5%)	44 (51.8%)	154 (55.4%)
Female	31 (44.3%)	25 (49.0%)	27 (37.5%)	41 (48.2%)	124 (44.6%)
Weight					
Mean (SD)	5.34 (2.02)	5.51 (1.61)	5.90 (1.53)	4.37 (1.04)	5.22 (1.66)
Median [Min, Max]	4.97 [2.24, 12.0]	5.65 [2.67, 11.2]	5.70 [2.24, 10.0]	4.20 [2.50, 7.10]	5.01 [2.24, 12.0]
Missing	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	1 (0.4%)
Age Adm(months)					
Mean (SD)	15.6 (13.4)	12.9 (8.20)	18.6 (9.79)	6.63 (4.86)	13.2 (10.5)
Median [Min, Max]	10.6 [2.20, 55.6]	11.0 [-0.526, 40.4]	16.4 [2.27, 50.6]	4.66 [2.10, 22.6]	10.2 [-0.526, 55.6]
Muac					
Mean (SD)	10.3 (1.49)	10.2 (1.37)	10.5 (1.00)	10.1 (0.825)	10.3 (1.17)
Median [Min, Max]	10.5 [7.05, 14.6]	10.4 [7.40, 17.3]	10.5 [8.25, 14.5]	10.3 [8.15, 12.1]	10.4 [7.05, 17.3]
Missing	0 (0%)	0 (0%)	2 (2.8%)	0 (0%)	2 (0.7%)
Height					
Mean (SD)	65.3 (10.9)	65.8 (7.75)	69.9 (8.90)	58.9 (6.32)	64.5 (9.49)
Median [Min, Max]	65.3 [46.6, 89.6]	65.4 [48.5, 83.5]	68.6 [46.1, 89.0]	57.8 [47.2, 78.2]	64.0 [46.1, 89.6]
Missing	3 (4.3%)	2 (3.9%)	4 (5.6%)	0 (0%)	9 (3.2%)
HIV					
Negative	18 (25.7%)	40 (78.4%)	65 (90.3%)	84 (98.8%)	207 (74.5%)
Untested	46 (65.7%)	0 (0%)	1 (1.4%)	0 (0%)	47 (16.9%)
Infected	6 (8.6%)	11 (21.6%)	6 (8.3%)	1 (1.2%)	24 (8.6%)

Medication Usage

Bottle 1

site	study_med	sample_size	Not returned	Partly used	Used completely
Kilifi	Enzyme/Placebo	52	5(9.6%)	39(75%)	7(13.5%)
Kilifi	Urso/Placebo	52	4(7.7%)	34(65.4%)	13(25%)
Kampala	Enzyme/Placebo	35	NA	30(85.7%)	1(2.9%)
Kampala	Urso/Placebo	35	NA	20(57.1%)	9(25.7%)
Blantyre	Enzyme/Placebo	43	6(14%)	27(62.8%)	6(14%)
Blantyre	Urso/Placebo	43	9(20.9%)	15(34.9%)	14(32.6%)
Dhaka	Enzyme/Placebo	76	4(5.3%)	70(92.1%)	2(2.6%)
Dhaka	Urso/Placebo	76	4(5.3%)	60(78.9%)	10(13.2%)

Bottle 2

site	study_med	sample_size	Not returned	Partly used	Returned as unused	Used completely
Kilifi	Urso/Placebo	19	1(5.3%)	11(57.9%)	2(10.5%)	3(15.8%)
Kampala	Urso/Placebo	8	NA	7(87.5%)	NA	NA
Blantyre	Urso/Placebo	19	2(10.5%)	13(68.4%)	1(5.3%)	1(5.3%)
Dhaka	Urso/Placebo	6	1(16.7%)	5(83.3%)	NA	NA

SAE

- Participants enrolled before all arms of investigation products were received have been omitted

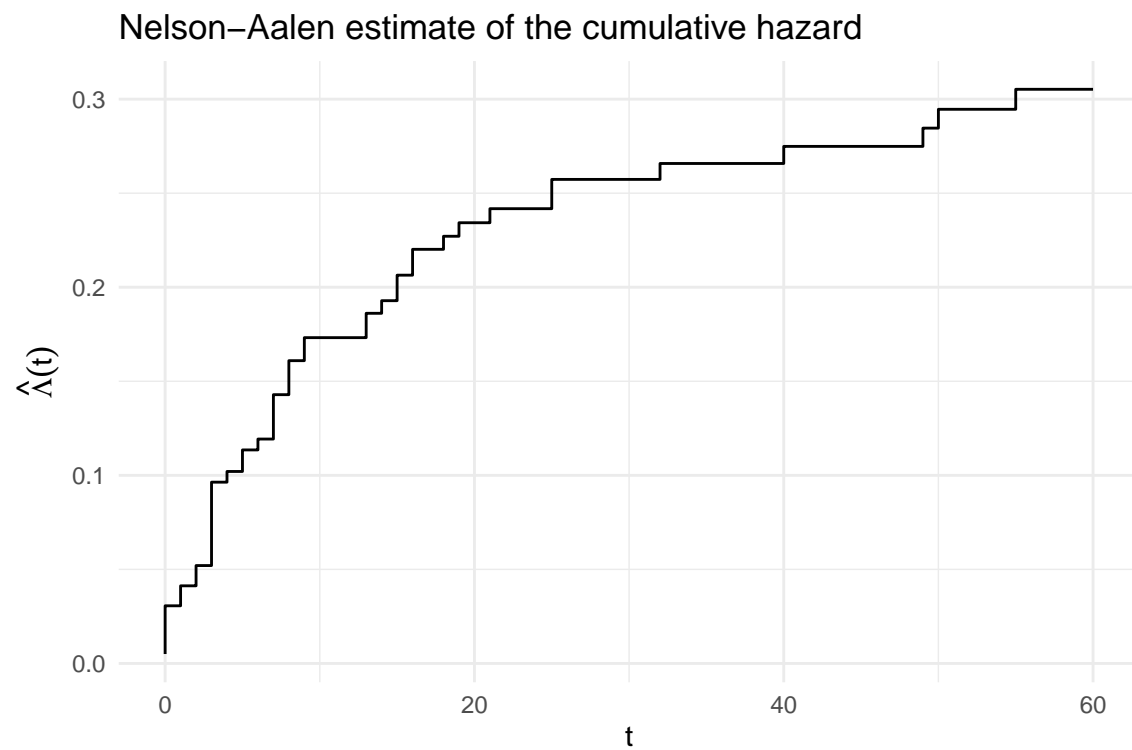
Participants with at least 1 sae

site	SAEs	Enrolled	%
Kilifi	23	70	32.9
Kampala	16	51	31.4
Blantyre	19	72	26.4
Dhaka	26	85	30.6
All Sites	84	278	30.2

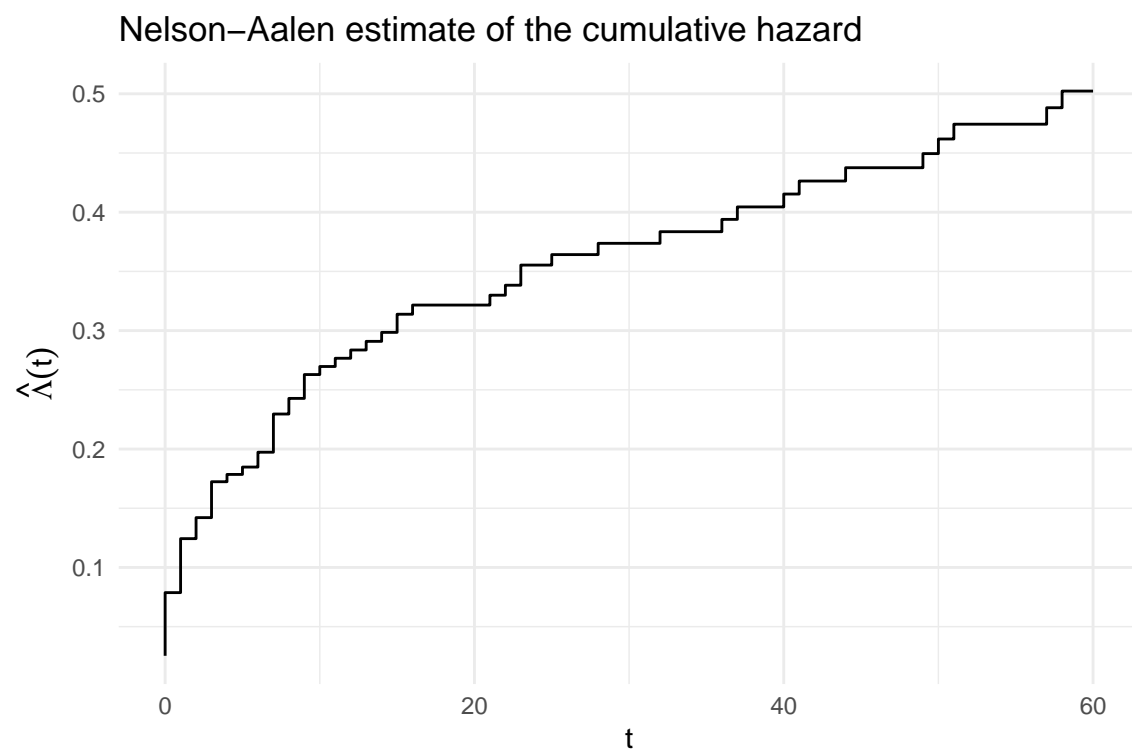
All SAE's

event_type_sae	Kilifi	Kampala	Blantyre	Dhaka	Total
Readmission to study hospital	7	2	5	13	27
Life-threatening event	4	2	NA	NA	6
Death	10	10	12	10	42
Event that prolongs hospitalisation whilst already in hospital (deterioration)	5	5	4	NA	14
Readmission to non-study hospital	1	NA	NA	NA	1
Other serious medical event where medical intervention was required e.g. new diagnosis of TB, sickle cell disease	4	4	3	11	22
Persistent or significant disability/incapacity	NA	NA	NA	1	1
Total	31	23	24	35	113

Cumulative hazard of death



Cumulative hazard of SAE



LAB & Samples

Lab Summary

time_point	aliquot	sample_size	EDTA PLASMA	RECTAL SWAB	RECTAL SWAB CULTURE	STOOL
adm	1	303	289(95.38%)	324(106.93%)	323(106.6%)	277(91.42%)
adm	2	303	285(94.06%)			260(85.81%)
adm	3	303	279(92.08%)			229(75.58%)
adm	4	303	266(87.79%)			213(70.3%)
adm	5	303	20(6.6%)			15(4.95%)
adm	6	303	20(6.6%)			15(4.95%)
adm	7	303	13(4.29%)			10(3.3%)
adm	8	303				10(3.3%)
disch	1	242		245(101.24%)	244(100.83%)	231(95.45%)
disch	2	242				229(94.63%)
disch	3	242				214(88.43%)
disch	4	242				202(83.47%)
disch	5	242				5(2.07%)
disch	6	242				5(2.07%)
disch	7	242				5(2.07%)
disch	8	242				5(2.07%)
day21	1	225	214(95.11%)	234(104%)	234(104%)	216(96%)
day21	2	225	214(95.11%)			211(93.78%)
day21	3	225	212(94.22%)			202(89.78%)
day21	4	225	206(91.56%)			193(85.78%)
day21	5	225	9(4%)			6(2.67%)
day21	6	225	9(4%)			6(2.67%)
day21	7	225	8(3.56%)			5(2.22%)
day21	8	225				4(1.78%)
day60	1	172		172(100%)	173(100.58%)	160(93.02%)
day60	2	172				154(89.53%)
day60	3	172				152(88.37%)
day60	4	172				148(86.05%)