Clinical Analysis Report For Study 'Sample Study'

Automated report generated by WWARN

May 9, 2014

Falciparum

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1 Executive Summary

This is an automatic report generated using WWARN standardised methods. The individual patient data received were first curated and then analysed according to the WWARN Clinical Module Data Management and Statistical Analysis Plan (DMSAP)[1]. The results generated by WWARN may be different to your own results due to different methods of analysis.

In your study conducted in Kampala Uganda between 01 Nov 2004 and 31 Dec 2008, 1,409 patients with uncomplicated Falciparum malaria were treated using AL , AQ+SP and AS3+AQ with a follow-up period of 28 days. 579 patients were allocated AL, 396 patients were allocated AQ+SP and 434 patients were allocated AS3+AQ .

Treatment outcomes were classified in line with the World Health Organization (WHO) methodology. In brief, Kaplan-Meier survival analyses were used to calculate the survival estimates for each treatment at a given time during follow-up. Confidence intervals for these point estimates were calculated based on the asymptotic variance of the log-log transformed survival function. PCR unadjusted and adjusted analyses were performed. In the unadjusted analysis the following were regarded as failures; early treatment failures (ETFs), all recurrences of P.Falciparum parasitaemia after day 4 or persisting parasitaemia up to day 7. The same rules were applied in the PCR adjusted analysis (if PCR data is available) except patients who develop a PCR-confirmed new infection of Falciparum were censored at the time of parasite reappearance.

The study included 1,409 patients enrolled, treated and followed for 28 days. The *unadjusted* Kaplan-Meier survival estimates are 95.4% (95% CI (93.6-97.2) in the AL group (N=579), 85% (95% CI (81.2-88.7) in the AQ+SP group (N=396) and 93% (95% CI (90.4-95.5) in the AS3+AQ group (N=434). The *adjusted* Kaplan-Meier survival estimates are 99.8% (95% CI (99.4-100) in the AL group (N=579), 90.9% (95% CI (87.9-93.9) in the AQ+SP group (N=396) and 98.7% (95% CI (97.6-99.8) in the AS3+AQ group (N=434).

[1]The DM-SAP is available at `http://www.wwarn.org/sites/default/files/ClinicalDMSAP.pdf`

2 Abbreviations

ACPR	Adequate clinical and parasitological response
DMSAP	Data management and statistical analysis plan
ETF	Early treatment failure
Hb	Haemoglobin (g/dL)
Ht	Haematocrit (%)
IQR	Interquartile range
LTF	Late treatment failure

3 Introduction

The spread of resistance to antimalarial drugs is a major threat to control and elimination of the disease in endemic countries.

Although most clinical efficacy studies follow the design laid out in the World Health Organisation (WHO) guidelines[2], some studies modify the design to address local logistical or specific research agendas. WWARN has established a comprehensive clinical database from which standardised estimates of antimalarial efficacy can be derived and monitored over time from diverse geographical and endemic regions. The application of this approach to the management of deviations and heterogeneous datasets minimises the intrinsic biases of the original study design.

This report summarizes the results obtained from a clinical study from Kampala Uganda so that the results can be easily compared to other studies from different areas, using different protocols and over time.

[2]The guidelines are available at `http://www.wwarn.org/sites/default/files/ClinicalDMSAP.pdf`

4 Methods

The process of data assimilation and automated reporting are documented in full in the Clinical Module DMSAP[1].

4.1 Data Cleaning

Data were checked for inconsistencies, unexpected and missing values that may influence baseline characteristics or efficacy results. The detailed list of variable audited for inconsistencies can be found in Data Management Report. The Data Managment Report lists all identified data inconsistencies, with the date of the event, patient identification number and additional explanations of identified anomalies.

4.2 Kaplan Meier Survival Analysis

The efficacy assessment was done by modified intention to treat (mITT) and was derived from Kaplan Meier estimates. The proportion of patients free of clinical malaria over the follow-up period is represented in the survival analysis and summary tables. The WHO recommends the Kaplan Meier method for deriving estimates of clinical drug efficacy. In the PCR adjusted results, recurrent infections are only regarded as treatment failures when the infection has been confirmed to be a recrudescence based on PCR analysis (see WHO methods and techniques for clinical trials on antimalarial drug efficacy, 2008). In this method, new infections are censored on the day of recurrence. When PCR results are unavailable all recurrent P. falciparum infections are censored on the day of recurrence.

5 Results

5.1 Data Inconsistencies

Table 1 summarises the occurrence and frequency of inconsistencies identified in the submitted dataset.

Table 1: Summary of Data Inconsistencies

Description
0.43% (6/1409) *patients* exceeding 18 days between Blood Smears
3.06% (3/98) *recurrent parasitaemia* without PCR
2.10% (177/8421) *follow-up visits* without blood smears results
0.00% (0/1409) *patients* with age $>$ 90 years
0.00% (0/1409) *patients* with unexpected weight for age
0.00% (0/1409) *patients* without gender
0.00% (0/8367) *temperatures* exceeding expected results ($>$ 42 or $<$ 34 $^\circ$ C)
2.20% (31/1409) *patients* with eligibility deviation

5.2 Study Deviations

WWARN has compiled a list of deviations from the study protocol that may affect efficacy outcomes. The same definitions are applied to all study datasets to ensure comparability of results between studies. The full list of deviations occurring in this study can be found in the Daata Management Report with the date of event, patient identification number and additional explanations of the identified deviation. Table 2 summarises the occurrence and frequency of enrolment deviations and Table 3 summarises the occurrence and frequency of more general study deviations identified in the submitted dataset.

If some of these missing data are retrievable or deviations correctable, then these can be submitted as revised data using the table provided at the end of this report.

Table 2: Summary of Enrolment Study Deviations

Study Deviation	*N*
D0 ($>$ 250000 Plasm. $/\mu L$)	30
No Falciparum on D0	2
No Plasmodiums (any species) on D0	1
Low Haemoglobin	0
Low Haematocrit	0
LT 10 Patients in treatment arm	0

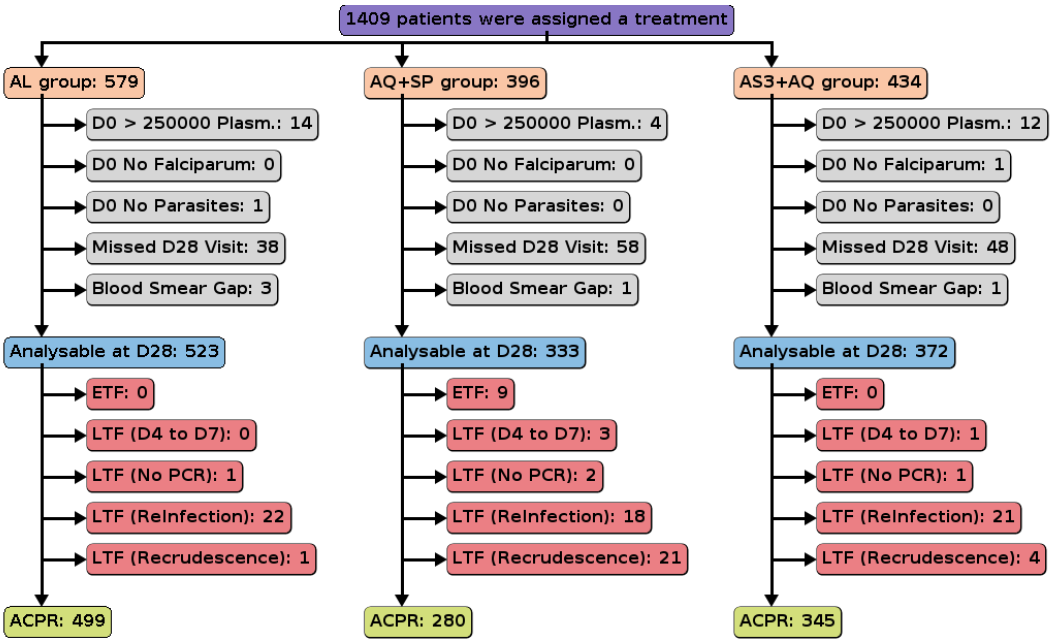
Table 3: Summary of Other Study Deviations

Study Deviation	*N*
Lost to Follow-Up (before 28 days)	144
Non-Pf MonoInfection	0
More than 18 days without blood smear	5

5.3 Trial Profile

The trial profile summarises participant flow, with numbers of assignment, treatment group, and outcomes for each randomised group.

Figure 1: Trial Profile of the study



5.4 Baseline Characteristics

The baseline characteristic table 4 below summarises key features of the trial population in the submitted dataset(s).

Table 4: Baseline Characteristics

	AL (n=579)	AQ+SP (n=396)	AS3+AQ (n=434)
Median Age (years)	6.8	7.1	6.1
Median Age IQR (years)	4.8 → 9.4	4.9 → 8.9	4.3 → 8.3
Gender (Male)	0.00%	0.00%	0.00%
Fever*	100.00%	100.00%	100.00%
Median weight (Kg)	-	-	-
Median weight IQR (Kg)	- → −	- → −	- → −
Geom. Mean P.*falc*	0	12242	11407
Geom. Mean P.*falc* IQR	3040 → 54720	3290 → 58640	2840 → 59000
Proportion P.*falc* $\geq$ 100,000	14.34%	12.12%	15.90%
Gametocyte Carriage	0.00%	0.00%	0.00%
Mean Hb (SD)	11.60 g/dL (1.34)	11.78 g/dL (1.32)	11.63 g/dL (1.39)

*Fever defined as temperature $\geq$ 37.5°C

5.5 Treatment Outcomes

5.5.1 Early Parasitological Response

The parasite clearance rate measures the percentage of remaining parasites at Day1, Day2 and Day3. Missing parasitaemia were considered negative if they were negative earlier and the table only includes results where parasitaemia counts were available. The parasitaemia clearance results were as follows:

Table 5: Early Parasite Clearance

Treatment	Day 1	Day 2	Day 3
AL	50.00% (3/6)	1.58% (9/570)	0.17% (1/575)
AQ+SP	100.00% (2/2)	43.77% (172/393)	6.20% (24/387)
AS3+AQ	0.00% (0/1)	2.33% (10/429)	0.00% (0/431)

5.5.2 Late Parasitological Response

The following treatment outcomes were classified on the basis of an assessment of the parasitological and clinical outcome of antimalarial treatment according to the latest WHO guidelines 2.

Table 6: Outcome table at day 28

Outcome	AL (n = 523)	AQ+SP (n = 333)	AS3+AQ (n = 372)
ACPR	499	280	345
ETF	0	9	0
LTF (D4 to D7)	0	3	1
LTF (No PCR)	1	2	1
LTF (Reinfection)	22	18	21
LTF (Recrudescence)	1	21	4

5.6 Kaplan Meier Curves and Lifetables

Cure rates are described by Kaplan Meier estimates where the y-axis represents cumulative risk of recurrent parasitemia calculated by survival analysis. The WHO recommends the Kaplan Meier method for deriving estimates of clinical drug efficacy (WHO Methods for surveillance of antimalarial drug efficacy, 2009, pg. 7.). In the PCR adjusted results recurrent infections are only regarded as treatment failures when the infection has been confirmed to be a recrudescence based on PCR result (see WHO methods and techniques for clinical trials on antimalarial drug efficacy: genotyping to identify parasite populations). In this method new infections are censored on the day of recurrence. When PCR results are unavailable recurrent P. falciparum infections are censored.

The life tables presented below each survival curve summarize the survival analysis results.

5.6.1 PCR Adjusted

Figure 2: Kaplan Meier curve, PCR-Adjusted

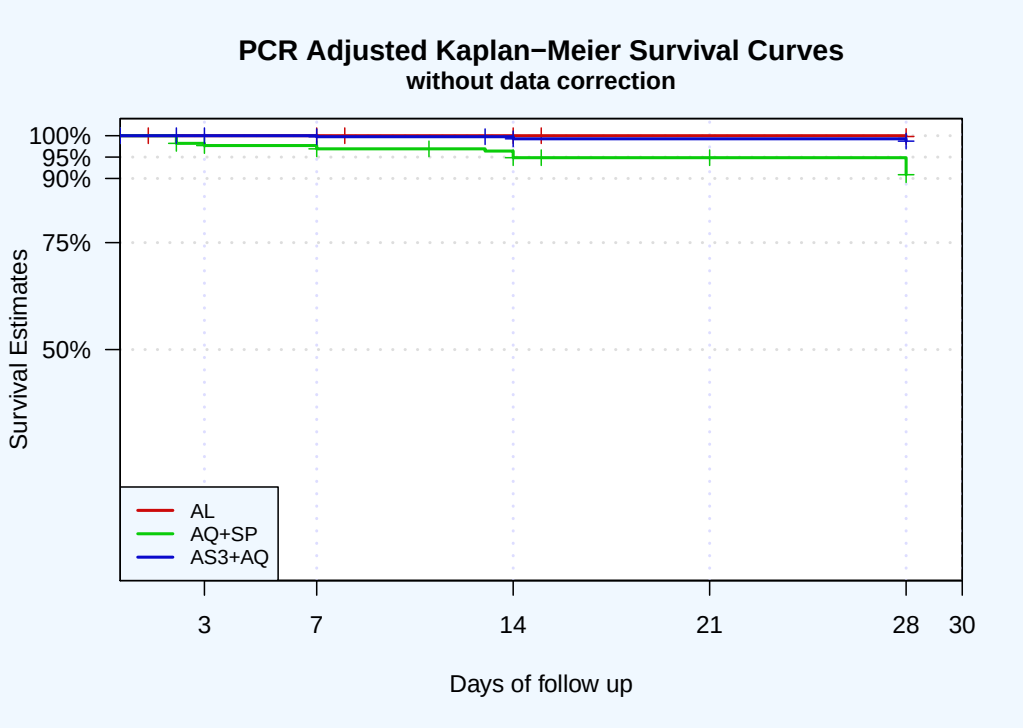


Table 7: PCR Adjusted outcomes

Day	Population	Fail	Censored	Estimate	95% CI
AL (N=579)					
Day0	579	0	18	**1**	(1-1)
Day1	561	0	1	1	(1-1)
Day7	560	0	7	1	(1-1)
Day8	553	0	2	1	(1-1)
Day14	551	0	28	**1**	(1-1)
Day15	523	0	1	1	(1-1)
Day28	522	1	521	**0.998**	(0.994-1)
AQ+SP (N=396)					
Day0	396	0	5	**1**	(1-1)
Day2	391	7	1	0.982	(0.969-0.995)
Day3	383	2	1	0.977	(0.962-0.992)
Day7	380	3	1	0.969	(0.952-0.986)
Day11	376	0	1	0.969	(0.952-0.986)
Day13	375	2	0	0.964	(0.946-0.983)
Day14	373	6	54	**0.949**	(0.927-0.971)
Day15	313	0	2	0.949	(0.927-0.971)
Day21	311	0	1	0.949	(0.927-0.971)
Day28	310	13	297	**0.909**	(0.879-0.939)
AS3+AQ (N=434)					
Day0	434	0	16	**1**	(1-1)
Day2	418	0	1	1	(1-1)
Day3	417	0	1	1	(1-1)
Day7	416	1	3	0.998	(0.993-1)
Day13	412	0	1	0.998	(0.993-1)
Day14	411	2	46	**0.993**	(0.985-1)
Day28	363	2	361	**0.987**	(0.976-0.998)

5.6.2 PCR Unadjusted

Figure 3: Kaplan Meier curve, PCR-Unadjusted

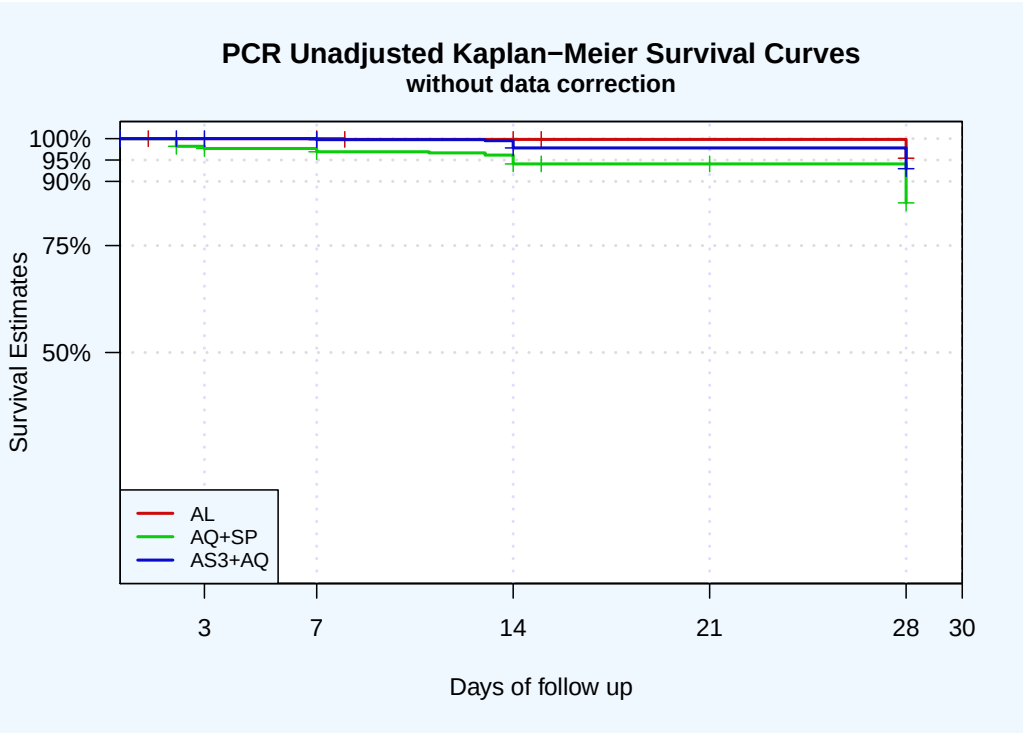


Table 8: PCR Unadjusted outcomes

Day	Population	Fail	Censored	Estimate	95% CI
AL (N=579)					
Day0	579	0	18	**1**	(1-1)
Day1	561	0	1	1	(1-1)
Day7	560	0	7	1	(1-1)
Day8	553	1	1	0.998	(0.995-1)
Day14	551	0	28	**0.998**	(0.995-1)
Day15	523	0	1	0.998	(0.995-1)
Day28	522	23	499	**0.954**	(0.936-0.972)
AQ+SP (N=396)					
Day0	396	0	5	**1**	(1-1)
Day2	391	7	1	0.982	(0.969-0.995)
Day3	383	2	1	0.977	(0.962-0.992)
Day7	380	3	1	0.969	(0.952-0.986)
Day11	376	1	0	0.967	(0.949-0.984)
Day13	375	2	0	0.962	(0.942-0.981)
Day14	373	8	52	**0.941**	(0.917-0.964)
Day15	313	0	2	0.941	(0.917-0.964)
Day21	311	0	1	0.941	(0.917-0.964)
Day28	310	30	280	**0.85**	(0.812-0.887)
AS3+AQ (N=434)					
Day0	434	0	16	**1**	(1-1)
Day2	418	0	1	1	(1-1)
Day3	417	0	1	1	(1-1)
Day7	416	1	3	0.998	(0.993-1)
Day13	412	1	0	0.995	(0.989-1)
Day14	411	7	41	**0.978**	(0.964-0.992)
Day28	363	18	345	**0.93**	(0.904-0.955)

6 Conclusion

The following conclusions are at Day 28. Using WWARN analytical methods the *unadjusted* Kaplan-Meier survival estimates are 95.4% (95% CI (93.6-97.2) in the AL group (N=579), 85% (95% CI (81.2-88.7) in the AQ+SP group (N=396) and 93% (95% CI (90.4-95.5) in the AS3+AQ group (N=434). The *adjusted* Kaplan-Meier survival estimates are 99.8% (95% CI (99.4-100) in the AL group (N=579), 90.9% (95% CI (87.9-93.9) in the AQ+SP group (N=396) and 98.7% (95% CI (97.6-99.8) in the AS3+AQ group (N=434).

7 Curator's Notes

No curator notes supplied

8 References

1. Clinical Module: Data Management and Statistical Analysis Plan; WWARN, 2011. Available from: https://www.wwarn.org/sites/default/files/ClinicalDMSAP.pdf.

2. WHO. 2009. Methods for surveillance of antimalarial drug efficacy. Geneva: World Health Organization.

3. Methods and techniques for clinical trials on antimalarial drug efficacy; Genotyping to identify parasite populations, WHO, 2008
http://www.who.int/malaria/publications/atoz/9789241596305/en/index.html

Appendices

A Efficacy endpoints

Day 28

Day 28 - Treatment:AL - D0 No Parasites
PatientID (listing 1 observations):
56317594
Day 28 - Treatment:AL - D0 >250000/μL Plasm.
PatientID (listing 14 observations):
2116534, 2117337, 6017191, 16816633, 19916927, 26116775, 41816694, 45417359, 46117170, 50516512, 50817411, 59417208, 63617680, 69717728
Day 28 - Treatment:AL - BSGap >18
PatientID (listing 3 observations):
29717207, 50717483, 58116968
Day 28 - Treatment:AL - LTF (No PCR)
PatientID (listing 1 observations):
41417309
Day 28 - Treatment:AL - LTF (ReInfection)
PatientID (listing 22 observations):
2116602, 2116890, 2116921, 2117003, 2117080, 2117114, 2117305, 2117444, 6017681, 6617493, 16216784, 21617504, 31917144, 35316771, 41217236, 41816933, 47316601, 50817237, 50817271, 50817850, 56916690, 59417180
Day 28 - Treatment:AL - LTF (Recrudescence)
PatientID (listing 1 observations):
1316937
Day 28 - Treatment:AL - Missed D28 visit
PatientID (listing 38 observations):
2116631, 2117147, 2416460, 2617626, 2716446, 6017646, 6617557, 16217856, 17216551, 17417055, 19016653, 20616914, 32116815, 39317666, 39717544, 43517714, 50517494, 50517519, 50517874, 50817646, 50817742, 53716702, 57316931, 57317196, 58516530, 59416601, 59416625, 59516608, 59616575, 59917651, 60717646, 61317002, 63417201, 66417496, 66417870, 68217679, 71717678, 74917415
Day 28 - Treatment:AL - ACPR
PatientID (listing 499 observations):
316390, 1017581, 1117691, 1217680, 1316426, 1316464, 1316499, 1316578, 1316667, 1316739, 1316810, 1316968, 1317023, 1317149, 1317196, 1317235, 1317358, 1317682, 2016397, 2016433, 2016629, 2016934, 2016989, 2017445, 2116562, 2116659, 2116700, 2116733, 2116773, 2116817, 2116853, 2116962, 2117038, 2117179, 2117217, 2117260, 2117389, 2117502, 2117536, 2117590, 2117730, 2117852, 2416402, 2416922, 2417309, 2417603, 2417679, 2417807, 2417879, 2516507, 2516563, 2516684, 2516978, 2517110, 2716472, 2816463, 4517716, 4616446, 4617549, 5117217, 5216580, 5216989, 5217167, 5316423, 5317488, 5817300, 6016553, 6016798, 6017008, 6017487, 6516400, 6516453, 6516615, 6516652, 6516747, 6516784, 6516956, 6617410, 7116596, 7116707, 7116784, 7116897, 8016722, 8017175, 8116440, 8317001, 8317439, 9616584, 9616804, 9617210, 11617234, 11617306, 11617499, 11617556, 11617673, 11617813, 11816462, 11817559, 12217170, 12316563, 12316824, 12616908, 12617500, 13516932, 13817187, 13916461, 13917200, 13917239, 14417718, 15216575, 15216622, 15216935, 15217170, 15217430, 15217538, 15316896, 15416426,

16117340, 16117557, 16117606, 16117676, 16216541, 16216831, 16216934, 16217046, 16217177, 16217226, 16217425, 16217677, 16716411, 16716629, 16717134, 16717172, 16717259, 16717680, 16816445, 16816495, 16816696, 16816926, 16817135, 16817178, 16916493, 16916628, 17017508, 17216442, 17316418, 17316500, 17416588, 17416947, 17417015, 17417083, 17417198, 17417475, 17417794, 18116584, 19016489, 19116816, 19316738, 19316991, 19317024, 19916420, 19916982, 19917028, 19917137, 19917190, 19917414, 19917592, 20316582, 20616417, 20616595, 20616951, 20616984, 21116904, 21117621, 21417870, 21617537, 21617577, 21717185, 21817573, 22317664, 22317713, 22417664, 23016440, 23016937, 23017166, 23816454, 23816774, 23816814, 23817159, 23817212, 23916626, 23916797, 23917194, 23917299, 24616847, 24717683, 24717718, 25117275, 25117631, 26116819, 26116924, 26117099, 26117165, 26117316, 26317538, 27717570, 27917692, 28017692, 28317700, 28517573, 28717212, 28717295, 29416467, 29517312, 29617718, 29716474, 29716940, 29717126, 29916576, 29916742, 29916937, 29917141, 30716485, 30716616, 30716896, 30717179, 30817607, 31317170, 31916458, 31916946, 31917177, 32116485, 32316625, 33116956, 33117205, 33216461, 33417005, 33816928, 33816998, 34217741, 34217824, 34317765, 34317860, 34417682, 34517435, 34916557, 34916698, 34916906, 34916954, 34917198, 35316481, 35316803, 35317186, 35317672, 35916622, 35916681, 36316843, 36416607, 36516570, 36516700, 36517067, 36616613, 37716520, 37716953, 37717300, 37917495, 38517679, 38817610, 38817693, 38917698, 39016832, 39016949, 39017083, 39017153, 39017364, 39017415, 39017478, 39017545, 39017739, 39316485, 39316851, 39317344, 39317575, 39317806, 40917809, 41016926, 41016962, 41017194, 41017421, 41017876, 41217269, 41217344, 41217593, 41717674, 41816561, 41816968, 41817064, 41817300, 42117201, 42217216, 42217591, 42317580, 42416579, 42416766, 42416908, 42416964, 42517635, 42517691, 42517778, 42517814, 42616521, 42616972, 43216613, 43216765, 43217169, 43217522, 43317655, 43317703, 43317815, 43317873, 43516481, 43517224, 43517301, 43517342, 43517499, 43517663, 44716749, 45416605, 45417424, 45417811, 45617681, 45716770, 45716917, 45717166, 45717436, 45717681, 46016541, 46016627, 46016682, 46016774, 46016888, 46016938, 46016991, 46017149, 46017196, 46017255, 46017493, 46116628, 46116779, 46116915, 46116969, 46117065, 46117215, 47316679, 47916542, 47916742, 47917305, 48217224, 48617683, 50216613, 50516647, 50516883, 50516999, 50517077, 50517160, 50517356, 50517544, 50517706, 50716586, 50716670, 50716913, 50717011, 50717124, 50717179, 50717251, 50717334, 50717582, 50717635, 50717681, 50717742, 50717850, 50817306, 50817370, 50817481, 50817520, 50817556, 50817770, 51017241, 51017662, 51017698, 51017842, 51316527, 51316663, 51316922, 52317677, 52616860, 54116706, 54516556, 55316940, 55317051, 55317673, 55616675, 56316698, 56316836, 56316960, 56317210, 56416698, 56416745, 56416844, 56417514, 56916615, 56916943, 57116600, 57116720, 57116942, 57316542, 57316955, 57416737, 57416866, 57416926, 57417194, 57816633, 57817315, 58116589, 58116897, 58117016, 58516555, 58516602, 58516673, 58516915, 58616935, 58716553, 58716716, 59416653, 59416810, 59416995, 59516566, 59516630, 59516667, 59516777, 59516884, 59516939, 59517123, 59517160, 59517388, 59517448, 59616684, 59616813, 59617211, 59617464, 59717247, 59916769, 60616731, 60716628, 60716890, 60716962, 60917341, 60917394, 61317025, 61616920, 61617188, 61617598, 61717603, 61717837, 61817811, 61817866, 62116735, 62816622, 63116814, 63116923, 63117202, 63416781, 63617546, 65217299, 65617239, 65617867, 68217557, 68317667, 68317772, 68417464, 69317250, 69317671, 69717656, 70017689, 71717333, 71717869, 72617436, 72917313, 72917738, 73017264, 73017673, 74217328, 74217408, 74217486, 74817634, 74917314, 74917441, 75117720, 75117855

Day 28 - Treatment:AQ+SP - D0 >250000/μL Plasm.

PatientID (listing 4 observations):

11416927, 35216924, 41716491, 50817203

Day 28 - Treatment:AQ+SP - BSGap >18

PatientID (listing 1 observations):

14216452

Day 28 - Treatment:AQ+SP - ETF
PatientID (listing 9 observations):
1116440, 8816798, 15916441, 17816574, 20016467, 20116588, 21616946, 41716678, 49216545
Day 28 - Treatment:AQ+SP - LTF (D4 to D7)
PatientID (listing 3 observations):
1117162, 9016804, 35816921
Day 28 - Treatment:AQ+SP - LTF (No PCR)
PatientID (listing 2 observations):
63917087, 64816975
Day 28 - Treatment:AQ+SP - LTF (ReInfection)
PatientID (listing 18 observations):
1016440, 1016940, 6316390, 10416446, 11416412, 11616749, 11616807, 28316958, 30016930, 35416935, 35416969, 35417141, 42516578, 42516695, 47116699, 49416672, 57216526, 57217183
Day 28 - Treatment:AQ+SP - LTF (Recrudescence)
PatientID (listing 21 observations):
5916620, 6616553, 6616569, 9016442, 19816464, 29616975, 34316908, 34316946, 35416626, 37117213, 39716940, 40916794, 41117164, 41217205, 41316781, 42516506, 46616830, 46916583, 46916614, 59717194, 64817197
Day 28 - Treatment:AQ+SP - Missed D28 visit
PatientID (listing 58 observations):
1016824, 1116927, 1116949, 1116974, 5816883, 7416680, 9116397, 11416444, 11616782, 11616909, 11616978, 12716975, 12717164, 19216737, 20116435, 24217180, 25117154, 28916870, 29616918, 30016946, 30016968, 30016989, 31516952, 31517172, 32016629, 34316816, 34316834, 34316857, 34316885, 35416571, 35416599, 35416909, 35616604, 35616629, 35616765, 42516479, 47116731, 47116761, 47416927, 47417151, 47616542, 48217165, 48217182, 48217202, 49316532, 49316587, 50016605, 50816669, 50817127, 50817151, 50817179, 55517012, 55517149, 60816556, 64816655, 64816910, 64816931, 64816956
Day 28 - Treatment:AQ+SP - ACPR
PatientID (listing 280 observations):
216942, 217143, 416383, 1016474, 1016614, 1016673, 1016848, 1016973, 1017127, 1017169, 1116394, 1116466, 1116552, 1116612, 1116812, 1116995, 1117122, 1117182, 1516472, 1616440, 1616592, 1616788, 2616463, 2616580, 3316469, 3416412, 3416822, 3716464, 3716569, 3716634, 3717194, 4416475, 5117044, 5816720, 5816840, 5816911, 5817182, 6316421, 6616598, 6616799, 6816449, 7416748, 8816406, 9016463, 9016532, 9016682, 9217161, 10416475, 10516397, 10816409, 11116468, 11116554, 11116787, 11116964, 11416472, 11416524, 11416619, 11516929, 11616639, 11616869, 11616932, 11617185, 12716732, 12716934, 12716998, 12717190, 13016999, 13017181, 13216503, 13217200, 13617163, 14216604, 14216814, 15516942, 15517187, 16016447, 16016696, 16416422, 16416631, 17516844, 17517218, 17616939, 19216757, 19717118, 19717148, 19816553, 19816630, 20016426, 20016570, 20016630, 20116461, 20116613, 20116657, 21516598, 21516948, 21616457, 21616596, 22216949, 22316614, 24217205, 25116565, 25116629, 25117182, 26016450, 26016790, 26016866, 26017161, 26816440, 27317194, 28317230, 28916897, 29616943, 29617007, 29617216, 30016449, 30017015, 30017139, 31416516, 31416950, 31417165, 31516463, 31516792, 31516978, 31517195, 32016649, 32017191, 34316968, 35016547, 35016688, 35016892, 35016979, 35017168, 35116683, 35216627, 35216824, 35217076, 35416469, 35416513, 35416655, 35416694, 35416803, 35416873, 35417051, 35417086, 35516568, 35516809, 35516878, 35516928, 35516971, 35616572, 35616655, 35616692, 35616793, 35616833, 35616935, 37116615, 37616827, 37616923, 37617003, 38016828, 38316749, 39116484, 39116803, 39716543, 39716597, 39716969, 39717124, 39916750, 39917188, 40116913, 40716639, 40716880, 40717088, 40717196, 40916839, 40916875, 41117195, 41216479, 41216568, 41216810, 41216926, 41316664, 41316816, 41316857, 41716954,

41717013, 41717117, 41916579, 41916790, 41916955, 42516751, 42516908, 42516964, 42517163, 45516603, 45516880, 46516830, 46517062, 46616864, 46716502, 46717065, 46916488, 46917053, 47116596, 47116784, 47416951, 47417011, 48117174, 49016756, 49216563, 49316556, 49316608, 49316650, 49416555, 49416705, 49416770, 49816555, 49816781, 49816902, 49816996, 50016532, 50016678, 50016916, 50017122, 50416509, 50416549, 50416594, 50416902, 50416945, 50817009, 51016588, 51016891, 51017190, 51416572, 52116533, 52116582, 52116646, 52116696, 52116896, 52416590, 52416864, 52416938, 53317168, 53616694, 53616856, 53816700, 54716745, 54717014, 54916573, 54917177, 55216531, 55216993, 55516894, 55516949, 55517040, 55517177, 57016557, 57016638, 57016827, 57216569, 57216752, 57216904, 57217008, 58216579, 58217181, 58816591, 58916543, 60116806, 60416885, 60816579, 60816683, 60817174, 60917161, 62316843, 62916837, 62917199, 64816547, 64816764, 64816840, 64816989

Day 28 - Treatment:AS3+AQ - D0 Without Falciparum

PatientID (listing 1 observations):

5717182

Day 28 - Treatment:AS3+AQ - D0 >250000/μL Plasm.

PatientID (listing 12 observations):

116928, 5416415, 24516902, 24816583, 24816820, 31817145, 38516939, 38916976, 43316776, 47016493, 47016540, 63517159

Day 28 - Treatment:AS3+AQ - BSGap >18

PatientID (listing 1 observations):

48316510

Day 28 - Treatment:AS3+AQ - LTF (D4 to D7)

PatientID (listing 1 observations):

14516936

Day 28 - Treatment:AS3+AQ - LTF (No PCR)

PatientID (listing 1 observations):

23716439

Day 28 - Treatment:AS3+AQ - LTF (ReInfection)

PatientID (listing 21 observations):

1117337, 1216935, 1216969, 1416419, 1417145, 1417176, 5717329, 8516537, 16616445, 24516997, 31717146, 38817087, 38916946, 39216895, 43316625, 43316884, 49516758, 59317208, 63016811, 64016912, 64016942

Day 28 - Treatment:AS3+AQ - LTF (Recrudescence)

PatientID (listing 4 observations):

4516595, 38516695, 59316651, 69717487

Day 28 - Treatment:AS3+AQ - Missed D28 visit

PatientID (listing 48 observations):

1217155, 1416450, 1417122, 5416529, 5416789, 8516453, 12816484, 12816944, 23316905, 23716792, 24416789, 24516936, 24517175, 27716892, 28517552, 31717177, 34216819, 38516713, 38516735, 38517025, 38816832, 38816854, 38817181, 38916872, 38916896, 38916924, 39217153, 41117277, 41616588, 42916574, 43316603, 43316857, 43316920, 43316943, 43316963, 44516618, 49516860, 53416930, 55416953, 58416950, 59217222, 59217247, 59316625, 64016776, 64016972, 64016997, 69017497, 69017516

Day 28 - Treatment:AS3+AQ - ACPR

PatientID (listing 345 observations):

716464, 816384, 1017232, 1117228, 1117293, 1117377, 1117452, 1216385, 1216558, 1216667, 1216706, 1216810, 1217065, 1217122, 1217182, 1217242, 1217349, 1416387, 1416478, 1416556, 1416593, 1416922, 1417242, 1417466, 1417533, 1716943, 3116916, 4516393, 4516444, 5416844, 5416977, 5417135, 5716647, 5716745, 5716896, 5717048, 5717272, 5717348, 6416464, 7016408,

7016618, 7017313, 7216950, 7616420, 7917172, 8516472, 8516568, 8516833, 10116401, 10116960, 10216534, 11016420, 11016539, 11016809, 11117258, 11316399, 11316501, 11317150, 11916463, 11917559, 12416443, 12417554, 12816512, 12816553, 12816737, 12816968, 12817080, 13017262, 13117176, 13217263, 13416471, 13417358, 14416439, 14416789, 14417397, 14417504, 14516792, 14616446, 14616549, 14616609, 14616653, 14716814, 14716922, 14717207, 14816810, 14816846, 16616468, 16616633, 16616822, 16616892, 17617549, 18516521, 18516603, 18716488, 18716604, 21016621, 21016792, 21017427, 21416952, 21517506, 21816593, 22416799, 22816455, 22816759, 22816951, 22817165, 23117164, 23316929, 23417209, 23417263, 23716819, 23717162, 24016591, 24116534, 24417169, 24516768, 24516962, 24517028, 24517088, 24517127, 24517197, 24517337, 24817172, 24917209, 25916462, 25916597, 25916705, 26216810, 26217548, 26617050, 26916440, 27116812, 27117177, 27716449, 27716920, 27716978, 27916594, 27916950, 27917169, 28516449, 29016463, 29816527, 29816614, 29817146, 30217424, 30217534, 30316474, 30316583, 30416532, 31716463, 31716587, 31717196, 31816464, 31816554, 31816624, 31817177, 32216628, 32616501, 32616595, 32616926, 32617227, 33016506, 33017205, 33316479, 34116593, 34216836, 34416479, 34416603, 35717345, 36016533, 36017544, 36716491, 36717558, 37016513, 37216488, 37216549, 37617283, 37817495, 38116567, 38116811, 38116897, 38516538, 38516759, 38516812, 38516983, 38816761, 38816923, 38817118, 38817201, 38817390, 38817435, 38817511, 38916832, 38917084, 38917182, 38917242, 38917387, 38917478, 38917545, 39216513, 39216617, 39216777, 39216924, 39217181, 39816539, 39816935, 39817065, 39817546, 40016648, 40016913, 40017144, 41516505, 41516812, 41616613, 41617198, 41617481, 41917477, 42016938, 42017006, 42017142, 42316603, 42317137, 42317202, 42317241, 42317331, 42916513, 43316565, 43316655, 43316739, 43316819, 43316984, 43317064, 43416520, 44316808, 44317169, 44417174, 44516484, 44516646, 44516843, 45617317, 45617436, 46816492, 46816534, 46816585, 46816886, 47016620, 47016960, 48316584, 48317230, 48317313, 48416921, 48417539, 48716499, 48917172, 49516679, 49516800, 49916544, 49916627, 49916902, 49917183, 50316617, 50316934, 50417556, 50616873, 51116530, 51116590, 51117187, 51117247, 51117480, 51516708, 52216536, 52216586, 52316592, 52817205, 52917105, 52917550, 53016669, 53016897, 53017560, 53216685, 53416582, 53416703, 53416949, 53417053, 53417207, 53417313, 53417554, 53517177, 54216934, 54317545, 54416587, 54616554, 55416615, 55416664, 55416846, 55416896, 55416981, 55417159, 56516583, 56516636, 56816589, 56817183, 58416973, 59216566, 59216643, 59216909, 59316540, 59316667, 59316995, 59817213, 60117414, 60817249, 61017222, 61017320, 61516718, 61516936, 61816543, 61816657, 61816939, 61817212, 61817543, 62216545, 62516694, 62616710, 62716576, 62716936, 63016842, 63016912, 63017200, 63216851, 63516779, 63816606, 64017018, 64217203, 64217281, 65117298, 65317298, 65417299, 66517223, 69617455, 69717517, 70117338, 70317311, 71117357, 74817298