Data Management and Analysis Report
Study 'Sample Vivax Study'

Automated report generated
by WWARN

June 21, 2012

Vivax Report

Mapper V. 416/484

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Introduction

WWARN would like to thank you, your collaborators and colleagues, for contributing data on 3/3/2012 from the study entitled, *Sample Vivax Study* , to the WWARN project. Combining data across countries and time will be the only way to track effectively the emergence and spread of antimalarial drug resistance, leading to improved health policy and effective malaria control and containment measures.

WWARN has curated and transformed your submitted dataset(s) to a standard, defined format. Key variables, required for analysis of the data, have been derived according to a series of procedures, details of which are available in the WWARN Clinical data management and statistical analysis plan (DM-SAP). This important document available at www.wwarn.org/research/clinical/methodology is referred to throughout this report.

The purpose of this report is to describe the study and patient data that have been derived from your data set and used for analyses and to summarize the results. The results presented here may differ from your results due to different inclusion and exclusion criteria and methods of analysis. We would be happy to discuss any variances with you.

1 Study design, description of datasets and key variables

1.1 Study design

This study was conducted in [Asia]. This study started on 2012-06-01 and ended on 2012-12-31.

In the submitted dataset(s), 335 patients were treated with AS3+AQ and DHA+PQP with a follow-up period of 42 days. 168 patients were allocated AS3+AQ and 167 patients were allocated DHA+PQP .

1.2 Imported Variables

WWARN follows a standard procedure for importing variables from submitted datasets. The following imported variables are used to define drug efficacy outcomes:

- days post treatment
- parasitemia and gametocytemia by species
- patient temperature
- baseline characteristics (e.g. age, weight and gender.)

From datasets 'AMT Clin-WWARN.sav' , 'AMT Drug-WWARN.sav' , 'AMT Merged Efficacy Data-WWARN.sav' , 'AMT Pct-WWARN.sav' and'AMT PK-WWARN.sav' a total of 102 variables, listed in Annex D, were imported into the WWARN data repository. A complete description of the audit trail is available in Annex E and Annex F.

1.3 Excluded Variables

We did not import 98 variables from your dataset (see Annex G for a complete list). These variables are not currently required for WWARN statistical analysis.

2 Quality Control

WWARN conducts systematic audits on submitted datasets using standard procedures (see WWARN DM-SAP at www.wwarn.org/research/clinical/methodology). These audits provide a detailed profile of the data used in the WWARN analyses.

2.1 Data Consistency

Data are checked for inconsistencies or unexpected results that may otherwise influence baseline characteristics, efficacy results or other types of analysis. The detailed list of variables audited for inconsistencies can be found in Annex B. The comment: ("AutoCorrect ⇒ Missing Value") means that if this value is not being corrected by the donor of the dataset, our systems will transform it into a missing value.

Annex H lists all identified data inconsistencies, with the date of the event, patient identification number and additional explanations of identified anomalies. Table 1 summarizes the occurrence and frequency of inconsistencies identified in the submitted dataset.

Table 1: Summary of Data Inconsistencies

Type of result	*N*
Low temperature ($< 34\ ^\circ$ C)	2

2.2 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 methodology used for allocating efficacy outcomes is described in the Data Management and Statistical Analysis Plan. A complete list of these study deviations and the WWARN definitions can be found in annex C.

The table below summarizes the occurrence and frequency of study deviations identified in the submitted dataset.

Table 2: Summary of Study Deviations

Study Deviation	*N*
Excessive amount of days without BS ($\geq$ 18 days)	17
Lost to Follow-Up (before 42 days)	63
Mixed Infection during follow-up	4
No Plasmodiums (any species) on D0	4
No Vivax on D0	188

The full list of study deviations can be found in Annex I with the date of event, patient identification number and additional explanations of the identified deviation.

2.3 Data Description

A review of missing data and unexpected results is required to identify potential biases that may affect the study results. Table 3 documents the proportion of such situations from the submitted study. The frequencies of some of those situations are described in sections 2.1 and 2.2 and will eventually be listed in Annex 'Unexpected Results' and Annex 'Deviations'. Annex 'Data Desriptions' eventually lists those remaining situations that were not described. The table below specifies where to find the details.

If some of these data are retrievable (e.g. from other source files or study documents), then these can be submitted as revised data using the table provided at the end of this report.

Table 3: List of Study Descriptions

Description
4.78% (16/335) *patients* exceeding 18 days between Blood Smears ⇒ §2.2/*AnnexI*
1.07 % (24/2250) *follow-up visits* without blood smears results ⇒ *AnnexJ*
0.00 % (0/335) *patients* with age > 90 years ⇒ §2.1/*AnnexI*
0.00 % (0/2583) *parasitaemia* > 500000 / μL ⇒ §2.1
0.00 % (0/335) *patients* with unexpected weight for age ⇒ §2.1
0.00 % (0/335) *patients* without gender ⇒ §2.1
0.08 % (2/2566) *temperatures* exceeding expected results (> 42 or < 34 ° C) ⇒ §2.1
56.12 % (188/335)*patients* with eligibility deviation ⇒ §2.2/*AnnexI*

3 Outputs

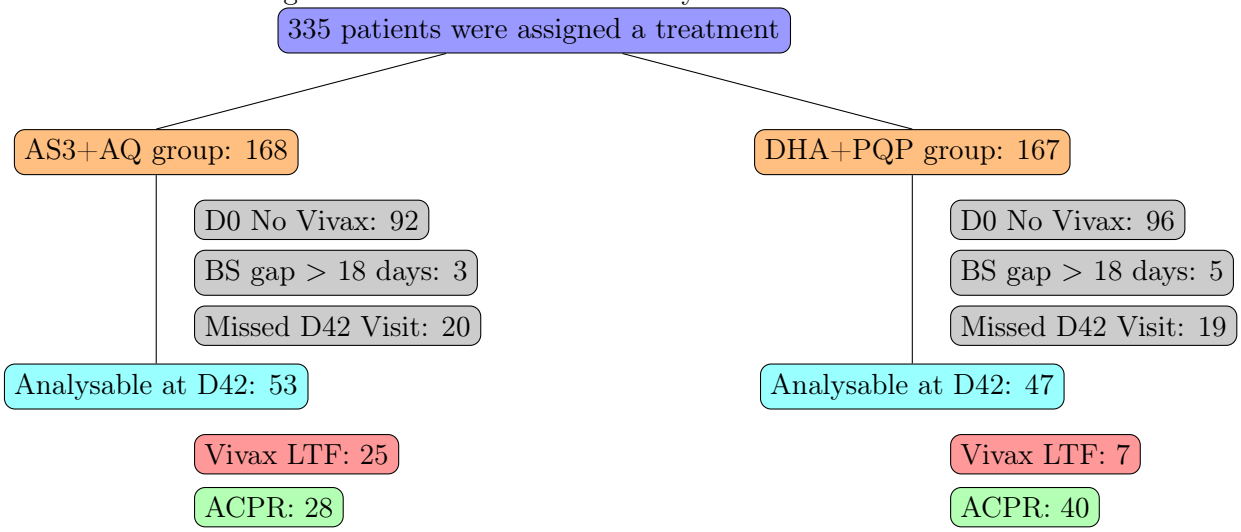
The following outputs have been produced from the submitted data using the WWARN standard analysis procedures (see WWARN DM-SAP at www.wwarn.org/research/clinical/methodology). Please note that our automated analysis establishes the studies' last day of follow-up as the most common last day found among study participants. The results are displayed in two formats - exactly as received without any data correction, and also after automatic data correction.

In the latter case, all data inconsistencies (identified in Annex H) have been transformed to missing values. After reviewing these alternative outputs, you may leave your data set as received on or resubmit revised data according to the procedure in Annex A. Once we have received your approval we will present the results on WWARN explorer with automatic data correction.

3.1 Trial Profile

The trial profile summarizes participant flow, with numbers of randomization assignment, treatment group, and outcomes for each randomized group.

Figure 1: Trial Profile of the study with corrected data



3.2 Baseline Characteristics

The baseline characteristic tables below summarise key features of the trial population in the submitted dataset(s).

3.2.1 Without Automatic Data Correction

Table 4: Baseline Characteristics without data correction

	AS3+AQ (n=168)	DHA+PQP (n=167)
Median Age (IQR)	$14.0 years (21.5)$	$17.0 years (23.0)$
Gender (% Male)	56.50%	59.80%
Fever* (%)	30.30%	33.50%
Median weight (IQR)	$43.1 kg (36.0)$	$46.4 kg (35.8)$
Geom. Mean P.*falc* (IQR)	$4187/\mu L (7837)$	$4928/\mu L (9600)$
Geom. Mean P.*vivax* (IQR)	$1743/\mu L (1650)$	$986/\mu L (690)$
Proportion $\geq$ 100,000 para/μL	0.60%	0.60%
Gametocyte Carriage	10.10%	10.70%
Mean Hb (SD)	$10.80 g/dL (2.60)$	$11.10 g/dL (2.60)$

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

3.2.2 With Automatic Data Correction

Table 5: Baseline Characteristics with data correction

	AS3+AQ (n=168)	DHA+PQP (n=167)
Median Age (IQR)	$14.0 years (21.5)$	$17.0 years (23.0)$
Gender (% Male)	56.50%	59.80%
Fever* (%)	30.30%	33.50%
Median weight (IQR)	$43.1 kg (36.0)$	$46.4 kg (35.8)$
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Gametocyte Carriage	10.10%	10.70%
Mean Hb (SD)	$10.80 g/dL (2.60)$	$11.10 g/dL (2.60)$

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

3.3 Treatment Outcome

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 . The parasitaemia clearance were as follows:

- For 'AS3+AQ':
  - 13.41 % (22/ 164) on Day1
  - 0.61 % (1/ 163) on Day2
  - 0.00 % (0/ 163) on Day3

- For 'DHA+PQP':
  - 17.83 % (28/ 157) on Day1
  - 0.64 % (1/ 156) on Day2
  - 0.62 % (1/ 162) on Day3

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 (WHO Methods for surveillance of antimalarial drug efficacy, 2009)

3.3.1 At D28

Table 6: Outcome table, PCR-unadjusted and with data correction at day 28

	AS3+AQ (n=168)	DHA+PQP (n=167)
ACPR	46	50
BS gap > 18 days	3	4
D0 No Vivax	92	96
Missed D28 Visit	15	14
Vivax LTF	12	3

3.3.2 At D42

Table 7: Outcome table, PCR-unadjusted and with data correction at day 42

	AS3+AQ (n=168)	DHA+PQP (n=167)
ACPR	28	40
BS gap > 18 days	3	5
D0 No Vivax	92	96
Missed D42 Visit	20	19
Vivax LTF	25	7

3.4 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.

3.4.1 PCR Unadjusted without Automatic Data Inconsistency Correction

Figure 2: Kaplan Meier curve, PCR-unadjusted and without data correction

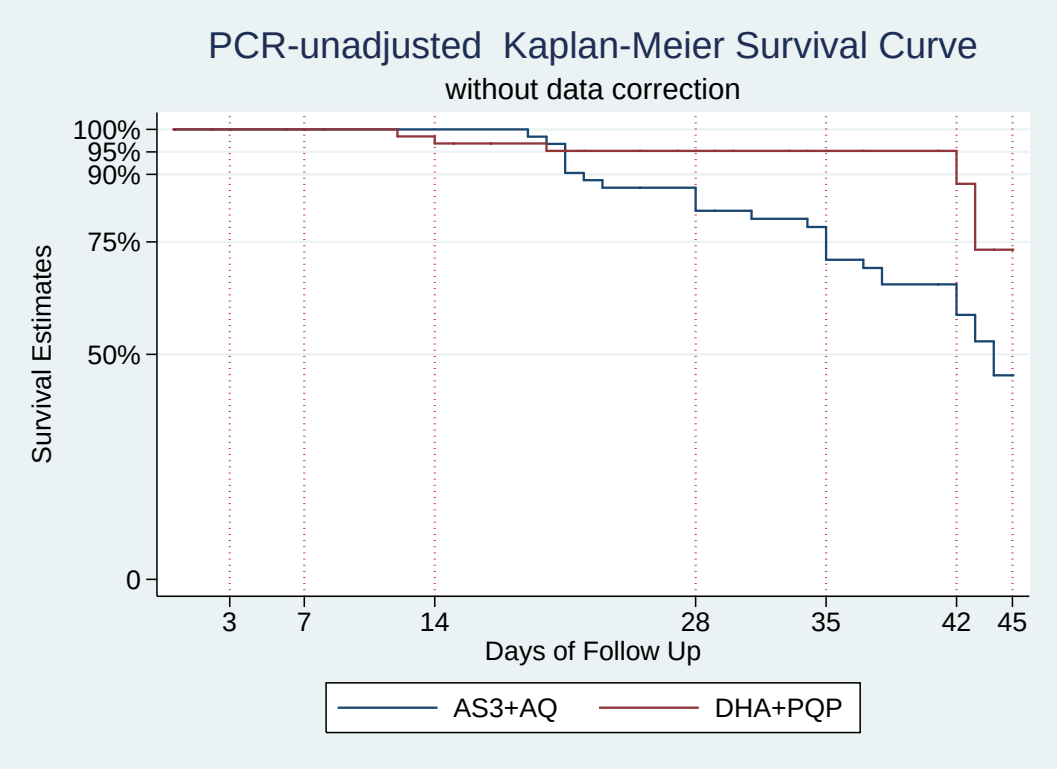

Table 8: PCR unadjusted outcomes without data correction

Day	Population	Fail	Censored	Estimate	95% CI
AS3+AQ (N=168)					
Day2	76	0	7	1	(.-.)
Day3	69	0	1	1	(.-.)
Day6	68	0	1	1	(.-.)
Day7	67	0	3	1	(.-.)
Day8	64	0	1	1	(.-.)
Day12	63	0	1	1	(.-.)
Day19	62	1	0	0.984	(0.891-0.998)
Day20	61	1	0	0.968	(0.877-0.992)
Day21	60	4	0	0.903	(0.797-0.955)
Day22	56	1	2	0.887	(0.778-0.945)
Day23	53	1	0	0.870	(0.757-0.933)
Day25	52	0	1	0.870	(0.757-0.933)
Day28	51	3	1	**0.819**	(0.697-0.896)
Day29	47	0	1	0.819	(0.697-0.896)
Day31	46	1	1	0.801	(0.676-0.882)
Day34	44	1	0	0.783	(0.655-0.868)
Day35	43	4	0	0.710	(0.575-0.809)
Day37	39	1	0	0.692	(0.556-0.794)

Day38	38	2	0	0.656	(0.518-0.763)
Day41	36	0	7	0.656	(0.518-0.763)
Day42	29	3	16	**0.588**	(0.444-0.706)
Day43	10	1	2	0.529	(0.358-0.674)
Day44	7	1	2	0.454	(0.256-0.632)
Day45	4	0	1	0.454	(0.256-0.632)
Day46	3	0	1	0.454	(0.256-0.632)
Day47	2	0	2	0.454	(0.256-0.632)
DHA+PQP (N=167)					
Day2	69	0	1	1	(.-.)
Day3	68	0	1	1	(.-.)
Day7	67	0	3	1	(.-.)
Day12	64	1	0	0.984	(0.894-0.998)
Day14	63	1	1	0.969	(0.881-0.992)
Day15	61	0	1	0.969	(0.881-0.992)
Day17	60	0	1	0.969	(0.881-0.992)
Day20	59	1	0	0.952	(0.859-0.984)
Day21	58	0	3	0.952	(0.859-0.984)
Day22	55	0	1	0.952	(0.859-0.984)
Day25	54	0	1	0.952	(0.859-0.984)
Day27	53	0	1	0.952	(0.859-0.984)
Day28	52	0	1	**0.952**	(0.859-0.984)
Day29	51	0	1	0.952	(0.859-0.984)
Day30	50	0	1	0.952	(0.859-0.984)
Day33	49	0	1	0.952	(0.859-0.984)
Day34	48	0	1	0.952	(0.859-0.984)
Day35	47	0	2	0.952	(0.859-0.984)
Day37	45	0	1	0.952	(0.859-0.984)
Day41	44	0	5	0.952	(0.859-0.984)
Day42	39	3	30	**0.879**	(0.746-0.945)
Day43	6	1	2	0.733	(0.356-0.910)
Day44	3	0	2	0.733	(0.356-0.910)
Day45	1	0	1	0.733	(0.356-0.910)

3.4.2 PCR Unadjusted with Automatic Data Inconsistency Correction

Figure 3: Kaplan Meier curve, PCR-unadjusted and with data correction

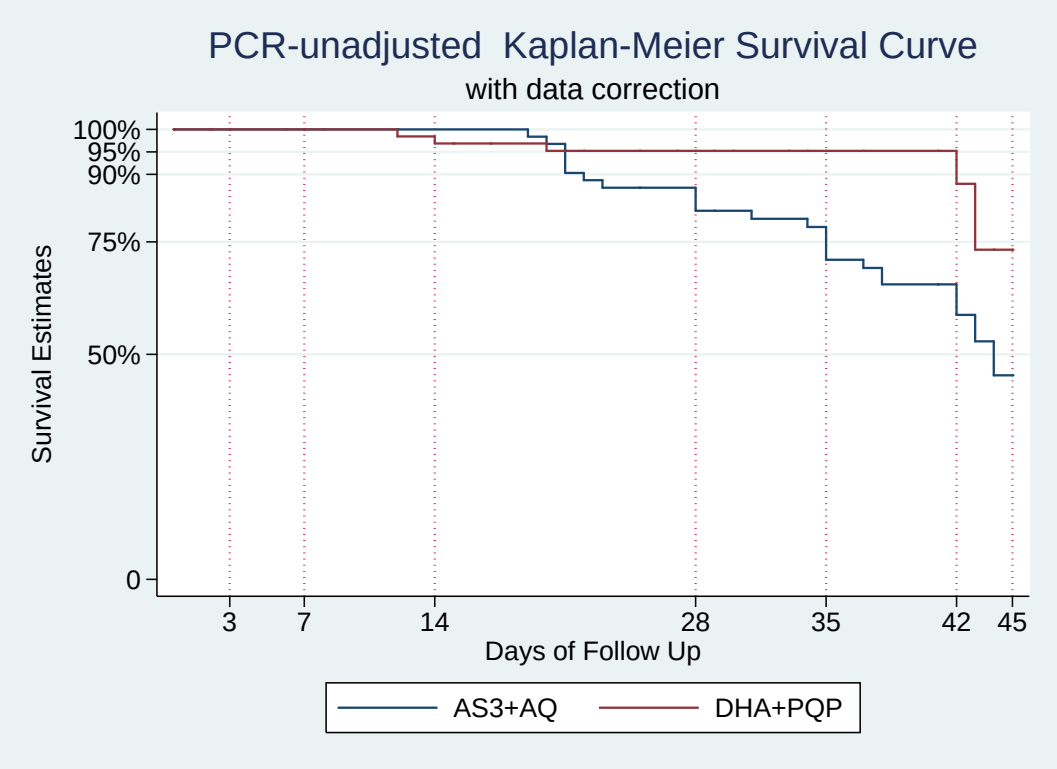

Table 9: PCR unadjusted outcomes with data correction

Day	Population	Fail	Censored	Estimate	95% CI
AS3+AQ (N=168)					
Day2	76	0	7	1	(.-.)
Day3	69	0	1	1	(.-.)
Day6	68	0	1	1	(.-.)
Day7	67	0	3	1	(.-.)
Day8	64	0	1	1	(.-.)
Day12	63	0	1	1	(.-.)
Day19	62	1	0	0.984	(0.891-0.998)
Day20	61	1	0	0.968	(0.877-0.992)
Day21	60	4	0	0.903	(0.797-0.955)
Day22	56	1	2	0.887	(0.778-0.945)
Day23	53	1	0	0.870	(0.757-0.933)
Day25	52	0	1	0.870	(0.757-0.933)
Day28	51	3	1	**0.819**	(0.697-0.896)
Day29	47	0	1	0.819	(0.697-0.896)
Day31	46	1	1	0.801	(0.676-0.882)
Day34	44	1	0	0.783	(0.655-0.868)
Day35	43	4	0	0.710	(0.575-0.809)
Day37	39	1	0	0.692	(0.556-0.794)

Day38	38	2	0	0.656	(0.518-0.763)
Day41	36	0	7	0.656	(0.518-0.763)
Day42	29	3	16	**0.588**	(0.444-0.706)
Day43	10	1	2	0.529	(0.358-0.674)
Day44	7	1	2	0.454	(0.256-0.632)
Day45	4	0	1	0.454	(0.256-0.632)
Day46	3	0	1	0.454	(0.256-0.632)
Day47	2	0	2	0.454	(0.256-0.632)
DHA+PQP (N=167)					
Day2	69	0	1	1	(.-.)
Day3	68	0	1	1	(.-.)
Day7	67	0	3	1	(.-.)
Day12	64	1	0	0.984	(0.894-0.998)
Day14	63	1	1	0.969	(0.881-0.992)
Day15	61	0	1	0.969	(0.881-0.992)
Day17	60	0	1	0.969	(0.881-0.992)
Day20	59	1	0	0.952	(0.859-0.984)
Day21	58	0	3	0.952	(0.859-0.984)
Day22	55	0	1	0.952	(0.859-0.984)
Day25	54	0	1	0.952	(0.859-0.984)
Day27	53	0	1	0.952	(0.859-0.984)
Day28	52	0	1	**0.952**	(0.859-0.984)
Day29	51	0	1	0.952	(0.859-0.984)
Day30	50	0	1	0.952	(0.859-0.984)
Day33	49	0	1	0.952	(0.859-0.984)
Day34	48	0	1	0.952	(0.859-0.984)
Day35	47	0	2	0.952	(0.859-0.984)
Day37	45	0	1	0.952	(0.859-0.984)
Day41	44	0	5	0.952	(0.859-0.984)
Day42	39	3	30	**0.879**	(0.746-0.945)
Day43	6	1	2	0.733	(0.356-0.910)
Day44	3	0	2	0.733	(0.356-0.910)
Day45	1	0	1	0.733	(0.356-0.910)

4 Conclusion

The following conclusions are at Day 42. Using WWARN analytical methods the Kaplan-Meier survival estimates are 58.8% (95% CI (44.4-70.6)) in the AS3+AQ group (N=168), 87.9% (95% CI (74.6-94.5)) in the DHA+PQP group (N=167).

Appendices

A Data Query Procedures

The above list will be made available to you as a an Excel spreadsheet with more details in order to enable corrections if you wish. There will also be an added column to enable corrections. The spreadsheet is composed of the following variables:

1. sid: This is the Study ID that WWARN uses to identify your study.
2. psid: This is the patient's study ID from your dataset.
3. date: This is the date on which the event took place
4. flagDT: This the flag code that we use internally to identify the type of inconsistency. It is essential for us to reintegrate your correction automatically in the dataset, without human involvement in order to minimise handling errors.
5. flgDTtxt: This variable explains in more details the cause of the inconsistency, with the source dataset result in parenthesis.
6. flgcommentDT: This variable explains how your data will be managed in case you cannot correct it and if you approve so. We will present you the results of the Baseline Characteristics, the Kaplan Meier estimates and curves as well as the WHO ACPR tables using:
   - the non modified dataset
   - the dataset in the listed transformations were done automatically
7. flagtypeDT: this variable corresponds to the incosisteny group summarised above.
8. Correction: This blank column is for your usage. Please add the corrected results in the following column using the information from the corresponding observation.

B Data Consistency Criteria

Table 10: List of WWARN data checks

Flag Number	*Data Check*
1	Temperature >42° C (AutoCorrect ⇒ $MissingValue$)
2	Temperature <34° C (AutoCorrect ⇒ $MissingValue$)
3	Weight contradicts age (W⇒ $MissingValue$)
4	PCR+ but no BS+ (PCR⇒ $MissingValue$)
5	Parasitaemia contradicts Binary (B⇒ $MissingValue$)
6	No Treatment
7	No Gender
8	Recudescence but no Pf recurrence (PCR⇒ $MissingValue$)
9	Age >90years (AutoCorrect ⇒ $MissingValue$)
10	Hb >25g/dL (AutoCorrect ⇒ $MissingValue$)
11	Ht >50% (AutoCorrect ⇒ $MissingValue$)
12	Parasitaemia >500000/μ L (AutoCorrect ⇒ $MissingValue$)

C Deviation Criteria

Table 11: List of WWARN deviations

Situation	*Adjusted*	*Unadjusted*
No Parasites at inclusion	Excluded	Excluded
Hyperparasitaemia ($> 250000/\mu$ L)	Excluded	Excluded
D0 Hb$<$ 5g/dL	Excluded	Excluded
D0 Ht$<$ 15%	Excluded	Excluded
BS gap$>$ 18days	Censored	Censored
Lost to follow Up	Censored	Censored
Vivax ETF	Fail	Fail
Vivax LTF	N/A	Fail

D Imported Variables

Variable	*Source Label*	*WWARN Label*
code		Patient Identifier
date0	admissi...	Date of inclusion
age		Age in years
sex		Gender
weight		Weight
treatw		Treatment in words
mal1m	how man...	Malaria episodes in the last month
lastday	last da...	Last day of follow up
outcome		Outcome
genotype		Genotype
dvomas1	vom d1 as	Vomitted day 1 artesunate
dvomaq1	vom d1 aq	Vomitted day 1 amodiaquine
dvomdhp1	vom d1 dhp	Vomitted day 1 DHA + PIP
dvomas2	vom d2 as	Vomitted day 2 artesunate
dvomaq2	vom d2 as	Vomitted day 2 amodiaquine
dvomdhp2	vom d3 dhp	Vomitted day 3 DHA + PIP
dvomas3	vom d3 as	Vomitted day 3 AS
dvomaq3	vom d3 aq	Vomitted day 3 AQ
dvomdhp3	vom d3 dhp	Vomitted day 2 DHA + PIP
hb0		Hemoglobin on day 0
wcc0		White blood cell count
pfpct0		Pfalciparum parasitemia day 0
pvpct0		Pvivax parasitemia day 0
gampfpct0		Falciparum gametocytes day 0
gampvpct0		Vivax gametocytes day 0
temp0	temp day0	Temperature on day 0
fv0	hx of f...	History of fever day 0
vom0	vom on ...	Vomitted on day 0
diar0	diar day0	Diarrhea on day 0
sp0	splenom...	Splenomegaly day 0
pfpct1		Pfalciparum parasitemia day 1
pvpct1		Pvivax parasitemia day 1
gampfpct1		Falciparum gametocytes day 1
gampvpct1		Vivax gametocytes day 1
temp1		Temperature day 1
fv1		History of fever day 1
vom1		Vomitted on day 1
diar1		Diarrhea on day 1
pfpct2		Pfalciparum parasitemia day 2
pvpct2		Pvivax parasitemia day 2
gampfpct2		Falciparum gametocytes day 2
gampvpct2		Vivax gametocytes day 2
temp2		Temperature day 2
fv2		History of fever day 2
vom2		Vomitted on day 2

diar2		Diarrhea on day 2
pfpct3		Pfalciparum parasitemia day 3
pvpct3		Pvivax parasitemia day 3
gampfpct3		Falciparum gametocytes day 3
gampvpct3		Vivax gametocytes day 3
temp3		Temperature day 3
fv3		History of fever day 3
vom3		Vomitted on day 3
diar3		Diarrhea on day 3
pfpct4		Pfalciparum parasitemia day 4
pvpct4		Pvivax parasitemia day 4
gampfpct4		Falciparum gametocytes day 4
gampvpct4		Vivax gametocytes day 3
temp4		Temperature day 4
fv4		History of fever day 4
vom4		Vomitted on day 4
diar4		Diarrhea on day 4
pfpct5		Pfalciparum parasitemia day 5
pvpct5		Pvivax parasitemia day 5
gampfpct5		Falciparum gametocytes day 5
gampvpct5		Vivax gametocytes day 3
temp5		Temperature day 5
fv5		History of fever day 5
vom5		Vomitted on day 5
diar5		Diarrhea on day 5
pfpct6		Pfalciparum parasitemia day 5
pvpct6		Pvivax parasitemia day 5
gampfpct6		Falciparum gametocytes day 6
gampvpct6		Vivax gametocytes day 6
temp6		Temperature day 6
fv6		History of fever day 6
vom6		Vomitted on day 6
diar6		Diarrhea on day 5
hbf	hb at f...	Hemoglobin at failure
pfpctf		Pfalciparum at failure
pvpctf		Pvivax at failure
gampfpctf		Falciparum gametocytes at failure
gampvpctf		Vivax gametocytes at failure
lvf	hepatom...	Hepatomegaly at failure
spf	spleen ...	Splenomegaly at failure
date-obs		
firstdrug	which d...	First drug
firstdose	how muc...	First drug dose
seconddrug		Second drug
seconddose		Second drug dose
thirddrug		Third drug
thirddose		
day-event	day of ...	Day of follow up visit
temp	tempera...	Temperature

liver	hepatomeg	Hepatomegaly
spleen	splenomeg	Splenomegaly
hb	haemagl...	Haemaglobin
wcc	wcc ...	White blood cell count
pfpct		Pfalciparum parasiteamia
pvpct		Pvivax parasitemia
gampfpct		Pfalciparum gametocytes
gampvpct		Pvivax gametocytes

E Audit trail of imported variables

age: in the source dataset 'age' is a Continuous variable. It was not labeled. Out of 340 completed observations there were 73 unique values. The range of this variable is [1.0-60.0] with a mean of 18.1. This variable was renamed following the WWARN format: name = 'ageyears'; label = 'Age in years'; type = Numeric.

sex: in the source dataset 'sex' is a String variable. It was not labeled. Out of 340 completed observations there were 2 unique values. This variable was renamed following the WWARN format: name = 'gender'; label = 'Gender'; type = String.

weight: in the source dataset 'weight' is a Continuous variable. It was not labeled. Out of 337 completed observations there were 125 unique values. The range of this variable is [6.6-85.0] with a mean of 38.5. This variable was renamed following the WWARN format: name = 'weight'; label = 'Weight in kilograms'; type = Numeric.

treatw: in the source dataset 'treatw' is a String variable. It was not labeled. Out of 340 completed observations there were 2 unique values. This variable was renamed following the WWARN format: name = 'treat'; label = 'Investigational Product'; type = String. The categories of the source variable were recoded into WWARN categories. The specific transformations are listed in Annex F.

mal1m: in the source dataset 'mal1m' is a Continuous variable. Its label is 'how man...'. Out of 340 completed observations there were 3 unique values. This variable was renamed following the WWARN format: name = 'hadmlrbfore'; label = 'Had malaria in the last 28 days?'; type = 0=NO / 1=Yes. This variable was transformed as follows: 1/max=1.

lastday: in the source dataset 'lastday' is a Continuous variable. Its label is 'last da...'. Out of 1842 completed observations there were 39 unique values. This variable was renamed following the WWARN format: name = 'lastdayfup'; label = 'Last day of follow-up of the patient'; type = Numeric.

outcome: in the source dataset 'outcome' is a Continuous variable. It was not labeled. Out of 340 completed observations there were 11 unique values. This variable was renamed following the WWARN format: name = 'outcome'; label = 'Outcome (WWARN)'; type = String. The categories of the source variable were recoded into WWARN categories. The specific transformations are listed in Annex F.

genotype: in the source dataset 'genotype' is a Continuous variable. It was not labeled. Out of 340 completed observations there were 5 unique values. This variable was renamed following the WWARN format: name = 'pcr'; label = 'PCR results'; type = String. The categories of the source variable were recoded into WWARN categories. The specific transformations are listed in Annex F.

dvomas1: in the source dataset 'dvomas1' is a Continuous variable. Its label is 'vom d1 as'. Out of 170 completed observations there was 1 unique value. This variable was renamed following the WWARN format: name = 'drug1vomm1'; label = 'Vomitted Drug 1 on first daily dose'; type = 0=NO / 1=Yes.

dvomaq1: in the source dataset 'dvomaq1' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. Its label is 'vom d1 aq'. Out of 170 completed observations there were 2 unique values. This variable was renamed following the WWARN format: name = 'drug2vomm1'; label = 'Vomitted Drug 2 on first daily dose'; type = 0=NO / 1=Yes.

dvomdhp1: in the source dataset 'dvomdhp1' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. Its label is 'vom d1 dhp'. Out of 170 completed observations there were 2 unique values. This variable was renamed following the WWARN format: name = 'drug3vomm1'; label = 'Vomitted Drug 3 on first daily dose'; type = 0=NO / 1=Yes.

dvomas2: in the source dataset 'dvomas2' is a Continuous variable. Its label is 'vom d2 as'. Out of 168 completed observations there was 1 unique value. This variable was renamed following the WWARN format: name = 'drug1vomm2'; label = 'Vomitted Drug 1 on second daily dose'; type = 0=NO / 1=Yes.

dvomaq2: in the source dataset 'dvomaq2' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. Its label is 'vom d2 as'. Out of 168 completed observations there were 2 unique values. This variable was renamed following the WWARN format: name = 'drug2vomm2'; label = 'Vomitted Drug 2 on second daily dose'; type = 0=NO / 1=Yes.

dvomdhp2: in the source dataset 'dvomdhp2' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. Its label is 'vom d3 dhp'. Out of 166 completed observations there were 2 unique values. This variable was renamed following the WWARN format: name = 'drug3vomm2'; label = 'Vomitted Drug 3 on second daily dose'; type = 0=NO / 1=Yes.

dvomas3: in the source dataset 'dvomas3' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. Its label is 'vom d3 as'. Out of 163 completed observations there were 2 unique values. This variable was renamed following the WWARN format: name = 'drug1vomm3'; label = 'Vomitted Drug 1 on third daily dose'; type = 0=NO / 1=Yes.

dvomaq3: in the source dataset 'dvomaq3' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. Its label is 'vom d3 aq'. Out of 163 completed observations there were 2 unique values. This variable was renamed following the WWARN format: name = 'drug2vomm3'; label = 'Vomitted Drug 2 on third daily dose'; type = 0=NO / 1=Yes.

dvomdhp3: in the source dataset 'dvomdhp3' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. Its label is 'vom d3 dhp'. Out of 164 completed observations there were 2 unique values. This variable was renamed following the WWARN format: name = 'drug3vomm3'; label = 'Vomitted Drug 3 on third daily dose'; type = 0=NO / 1=Yes.

hb0: in the source dataset 'hb0' is a Continuous variable. It was not labeled. Out of 338 completed observations there were 106 unique values. The range of this variable is [4.9-19.4] with a mean of 10.9. This variable contains data on the day of the event (in this case Day 0) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'hb'; label = 'Hemoglobin'; type = Numeric.

wcc0: in the source dataset 'wcc0' is a Continuous variable. It was not labeled. Out of 340 completed observations there were 73 unique values. The range of this variable is [1.7-99.9] with a mean of 51.1. This variable contains data on the day of the event (in this case Day 0) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'wbc'; label = 'Amount of WBC in G/L'; type = Numeric.

pfpct0: in the source dataset 'pfpct0' is a Continuous variable. It was not labeled. Out of 340 completed observations there were 198 unique values. This variable contains data on the day of the event (in this case Day 0) which was used to generate the date of event. After transposition,

this variable was renamed following the WWARN format: name = 'pfmicl'; label = 'Asexual form of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

pvpct0: in the source dataset 'pvpct0' is a Continuous variable. It was not labeled. Out of 339 completed observations there were 126 unique values. This variable contains data on the day of the event (in this case Day 0) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'pvmicl'; label = 'Asexual form of P. vivax count in parasites per microlitre of blood'; type = Numeric.

gampfpct0: in the source dataset 'gampfpct0' is a Continuous variable. It was not labeled. Out of 340 completed observations there were 30 unique values. This variable contains data on the day of the event (in this case Day 0) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gfmicl'; label = 'Gametocytes of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

gampvpct0: in the source dataset 'gampvpct0' is a Continuous variable. It was not labeled. Out of 340 completed observations there were 68 unique values. This variable contains data on the day of the event (in this case Day 0) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gvmicl'; label = 'Gametocytes of P. vivax count in parasites per microlitre of blood'; type = Numeric.

temp0: in the source dataset 'temp0' is a Continuous variable. Its label is 'temp day0'. Out of 340 completed observations there were 52 unique values. The range of this variable is [35.0-40.2] with a mean of 37.1. This variable contains data on the day of the event (in this case Day 0) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'temp'; label = 'Body temperature'; type = Numeric.

fv0: in the source dataset 'fv0' is a Continuous variable. Its label is 'hx of f...'. Out of 340 completed observations there was 1 unique value. This variable contains data on the day of the event (in this case Day 0) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'feverhist'; label = 'History of fever within 24h'; type = 0=NO / 1=Yes.

vom0: in the source dataset 'vom0' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. Its label is 'vom on ...'. Out of 340 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 0) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'vomit'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

diar0: in the source dataset 'diar0' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. Its label is 'diar day0'. Out of 340 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 0) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'spleen'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

sp0: in the source dataset 'sp0' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. Its label is 'splenom...'. Out of 340 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 0) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'liver'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

pfpct1: in the source dataset 'pfpct1' is a Continuous variable. It was not labeled. Out of 326 completed observations there were 26 unique values. This variable contains data on the day of the event (in this case Day 1) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'pfmicl'; label = 'Asexual form of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

pvpct1: in the source dataset 'pvpct1' is a Continuous variable. It was not labeled. Out of 326 completed observations there were 4 unique values. This variable contains data on the day of the event (in this case Day 1) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'pvmicl'; label = 'Asexual form of P. vivax count in parasites per microlitre of blood'; type = Numeric.

gampfpct1: in the source dataset 'gampfpct1' is a Continuous variable. It was not labeled. Out of 326 completed observations there were 7 unique values. This variable contains data on the day of the event (in this case Day 1) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gfmicl'; label = 'Gametocytes of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

gampvpct1: in the source dataset 'gampvpct1' is a Continuous variable. It was not labeled. Out of 326 completed observations there were 3 unique values. This variable contains data on the day of the event (in this case Day 1) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gvmicl'; label = 'Gametocytes of P. vivax count in parasites per microlitre of blood'; type = Numeric.

temp1: in the source dataset 'temp1' is a Continuous variable. It was not labeled. Out of 321 completed observations there were 32 unique values. The range of this variable is [33.2-37.9] with a mean of 36.0. This variable contains data on the day of the event (in this case Day 1) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'temp'; label = 'Body temperature'; type = Numeric.

fv1: in the source dataset 'fv1' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. It was not labeled. Out of 324 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 1) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'feverhist'; label = 'History of fever within 24h'; type = 0=NO / 1=Yes.

vom1: in the source dataset 'vom1' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. It was not labeled. Out of 324 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 1) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'vomit'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

diar1: in the source dataset 'diar1' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. It was not labeled. Out of 324 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 1) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'diarrhea'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

pfpct2: in the source dataset 'pfpct2' is a Continuous variable. It was not labeled. Out of 295 completed observations there were 3 unique values. This variable contains data on the day of

the event (in this case Day 2) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'pfmicl'; label = 'Asexual form of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

pvpct2: in the source dataset 'pvpct2' is a Continuous variable. It was not labeled. Out of 295 completed observations there was 1 unique value. This variable contains data on the day of the event (in this case Day 2) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'pvmicl'; label = 'Asexual form of P. vivax count in parasites per microlitre of blood'; type = Numeric.

gampfpct2: in the source dataset 'gampfpct2' is a Continuous variable. It was not labeled. Out of 295 completed observations there were 9 unique values. This variable contains data on the day of the event (in this case Day 2) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gfmicl'; label = 'Gametocytes of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

gampvpct2: in the source dataset 'gampvpct2' is a Continuous variable. It was not labeled. Out of 295 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 2) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gvmicl'; label = 'Gametocytes of P. vivax count in parasites per microlitre of blood'; type = Numeric.

temp2: in the source dataset 'temp2' is a Continuous variable. It was not labeled. Out of 296 completed observations there were 29 unique values. The range of this variable is [33.8-37.8] with a mean of 35.8. This variable contains data on the day of the event (in this case Day 2) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'temp'; label = 'Body temperature'; type = Numeric.

fv2: in the source dataset 'fv2' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. It was not labeled. Out of 297 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 2) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'feverhist'; label = 'History of fever within 24h'; type = 0=NO / 1=Yes.

vom2: in the source dataset 'vom2' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. It was not labeled. Out of 297 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 2) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'vomit'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

diar2: in the source dataset 'diar2' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. It was not labeled. Out of 297 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 2) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'diarrhea'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

pfpct3: in the source dataset 'pfpct3' is a Continuous variable. It was not labeled. Out of 46 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 3) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'pfmicl'; label = 'Asexual

form of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

pvpct3: in the source dataset 'pvpct3' is a Continuous variable. It was not labeled. Out of 46 completed observations there was 1 unique value. This variable contains data on the day of the event (in this case Day 3) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'pvmicl'; label = 'Asexual form of P. vivax count in parasites per microlitre of blood'; type = Numeric.

gampfpct3: in the source dataset 'gampfpct3' is a Continuous variable. It was not labeled. Out of 46 completed observations there were 3 unique values. This variable contains data on the day of the event (in this case Day 3) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gfmicl'; label = 'Gametocytes of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

gampvpct3: in the source dataset 'gampvpct3' is a Continuous variable. It was not labeled. Out of 46 completed observations there was 1 unique value. This variable contains data on the day of the event (in this case Day 3) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gvmicl'; label = 'Gametocytes of P. vivax count in parasites per microlitre of blood'; type = Numeric.

temp3: in the source dataset 'temp3' is a Continuous variable. It was not labeled. Out of 46 completed observations there were 18 unique values. The range of this variable is [35.0-36.9] with a mean of 35.9. This variable contains data on the day of the event (in this case Day 3) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'temp'; label = 'Body temperature'; type = Numeric.

fv3: in the source dataset 'fv3' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. It was not labeled. Out of 47 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 3) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'feverhist'; label = 'History of fever within 24h'; type = 0=NO / 1=Yes.

vom3: in the source dataset 'vom3' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. It was not labeled. Out of 47 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 3) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'vomit'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

diar3: in the source dataset 'diar3' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. It was not labeled. Out of 47 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 3) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'diarrhea'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

pfpct4: in the source dataset 'pfpct4' is a Continuous variable. It was not labeled. Out of 13 completed observations there was 1 unique value. This variable contains data on the day of the event (in this case Day 4) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'pfmicl'; label = 'Asexual form of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

pvpct4: in the source dataset 'pvpct4' is a Continuous variable. It was not labeled. Out of 13 completed observations there was 1 unique value. This variable contains data on the day of the event (in this case Day 4) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'pvmicl'; label = 'Asexual form of P. vivax count in parasites per microlitre of blood'; type = Numeric.

gampfpct4: in the source dataset 'gampfpct4' is a Continuous variable. It was not labeled. Out of 13 completed observations there was 1 unique value. This variable contains data on the day of the event (in this case Day 4) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gfmicl'; label = 'Gametocytes of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

gampvpct4: in the source dataset 'gampvpct4' is a Continuous variable. It was not labeled. Out of 13 completed observations there was 1 unique value. This variable contains data on the day of the event (in this case Day 4) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gvmicl'; label = 'Gametocytes of P. vivax count in parasites per microlitre of blood'; type = Numeric.

temp4: in the source dataset 'temp4' is a Continuous variable. It was not labeled. Out of 13 completed observations there were 9 unique values. The range of this variable is [35.2-36.5] with a mean of 35.8. This variable contains data on the day of the event (in this case Day 4) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'temp'; label = 'Body temperature'; type = Numeric.

fv4: in the source dataset 'fv4' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. It was not labeled. Out of 13 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 4) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'feverhist'; label = 'History of fever within 24h'; type = 0=NO / 1=Yes.

vom4: in the source dataset 'vom4' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. It was not labeled. Out of 13 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 4) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'vomit'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

diar4: in the source dataset 'diar4' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. It was not labeled. Out of 13 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 4) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'diarrhea'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

pfpct5: in the source dataset 'pfpct5' is a Continuous variable. It was not labeled. Out of 11 completed observations there was 1 unique value. This variable contains data on the day of the event (in this case Day 5) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'pfmicl'; label = 'Asexual form of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

pvpct5: in the source dataset 'pvpct5' is a Continuous variable. It was not labeled. Out of 11 completed observations there was 1 unique value. This variable contains data on the day of the

event (in this case Day 5) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'pvmicl'; label = 'Asexual form of P. vivax count in parasites per microlitre of blood'; type = Numeric.

gampfpct5: in the source dataset 'gampfpct5' is a Continuous variable. It was not labeled. Out of 11 completed observations there was 1 unique value. This variable contains data on the day of the event (in this case Day 5) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gfmicl'; label = 'Gametocytes of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

gampvpct5: in the source dataset 'gampvpct5' is a Continuous variable. It was not labeled. Out of 11 completed observations there was 1 unique value. This variable contains data on the day of the event (in this case Day 5) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gvmicl'; label = 'Gametocytes of P. vivax count in parasites per microlitre of blood'; type = Numeric.

temp5: in the source dataset 'temp5' is a Continuous variable. It was not labeled. Out of 10 completed observations there were 6 unique values. The range of this variable is [35.7-36.5] with a mean of 36.0. This variable contains data on the day of the event (in this case Day 5) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'temp'; label = 'Body temperature'; type = Numeric.

fv5: in the source dataset 'fv5' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. It was not labeled. Out of 10 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 5) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'feverhist'; label = 'History of fever within 24h'; type = 0=NO / 1=Yes.

vom5: in the source dataset 'vom5' is a Continuous variable. It was not labeled. Out of 10 completed observations there was 1 unique value. This variable contains data on the day of the event (in this case Day 5) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'vomit'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

diar5: in the source dataset 'diar5' is a Continuous variable. It was not labeled. Out of 10 completed observations there was 1 unique value. This variable contains data on the day of the event (in this case Day 5) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'diarrhea'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

pfpct6: in the source dataset 'pfpct6' is a Continuous variable. It was not labeled. Out of 12 completed observations there was 1 unique value. This variable contains data on the day of the event (in this case Day 6) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'pfmicl'; label = 'Asexual form of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

pvpct6: in the source dataset 'pvpct6' is a Continuous variable. It was not labeled. Out of 12 completed observations there was 1 unique value. This variable contains data on the day of the event (in this case Day 6) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'pvmicl'; label = 'Asexual form of P. vivax count in parasites per microlitre of blood'; type = Numeric.

gampfpct6: in the source dataset 'gampfpct6' is a Continuous variable. It was not labeled. Out of 12 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 6) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gfmicl'; label = 'Gametocytes of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

gampvpct6: in the source dataset 'gampvpct6' is a Continuous variable. It was not labeled. Out of 12 completed observations there was 1 unique value. This variable contains data on the day of the event (in this case Day 6) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gvmicl'; label = 'Gametocytes of P. vivax count in parasites per microlitre of blood'; type = Numeric.

temp6: in the source dataset 'temp6' is a Continuous variable. It was not labeled. Out of 13 completed observations there were 8 unique values. The range of this variable is [35.5-36.9] with a mean of 36.0. This variable contains data on the day of the event (in this case Day 6) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'temp'; label = 'Body temperature'; type = Numeric.

fv6: in the source dataset 'fv6' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. It was not labeled. Out of 13 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 6) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'feverhist'; label = 'History of fever within 24h'; type = 0=NO / 1=Yes.

vom6: in the source dataset 'vom6' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. It was not labeled. Out of 13 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 6) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'vomit'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

diar6: in the source dataset 'diar6' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. It was not labeled. Out of 13 completed observations there were 2 unique values. This variable contains data on the day of the event (in this case Day 6) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'diarrhea'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

hbf: in the source dataset 'hbf' is a Continuous variable. Its label is 'hb at f...'. Out of 36 completed observations there were 29 unique values. The range of this variable is [4.9-17.0] with a mean of 10.8. This variable contains data on the day of the event by referring to a variable (lastday) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'hb'; label = 'Hemoglobin'; type = Numeric.

pfpctf: in the source dataset 'pfpctf' is a Continuous variable. It was not labeled. Out of 68 completed observations there were 27 unique values. This variable contains data on the day of the event by referring to a variable (lastday) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'pfmicl'; label = 'Asexual form of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

pvpctf: in the source dataset 'pvpctf' is a Continuous variable. It was not labeled. Out of 68 completed observations there were 33 unique values. This variable contains data on the day of

the event by referring to a variable (lastday) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'pvmicl'; label = 'Asexual form of P. vivax count in parasites per microlitre of blood'; type = Numeric.

gampfpctf: in the source dataset 'gampfpctf' is a Continuous variable. It was not labeled. Out of 68 completed observations there were 5 unique values. This variable contains data on the day of the event by referring to a variable (lastday) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gfmicl'; label = 'Gametocytes of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

gampvpctf: in the source dataset 'gampvpctf' is a Continuous variable. It was not labeled. Out of 68 completed observations there were 13 unique values. This variable contains data on the day of the event by referring to a variable (lastday) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gvmicl'; label = 'Gametocytes of P. vivax count in parasites per microlitre of blood'; type = Numeric.

lvf: in the source dataset 'lvf' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. Its label is 'hepatom...'. Out of 65 completed observations there were 2 unique values. This variable contains data on the day of the event by referring to a variable (lastday) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'liver'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

spf: in the source dataset 'spf' is a Continuous variable. The range of this variable is [0-1] suggesting a binary variable. Its label is 'spleen ...'. Out of 65 completed observations there were 2 unique values. This variable contains data on the day of the event by referring to a variable (lastday) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'spleen'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

firstdrug: in the source dataset 'firstdrug' is a Continuous variable. Its label is 'which d...'. Out of 501 completed observations there was 1 unique value. The range of this variable is [7.0-7.0] with a mean of 7.0. This variable was renamed following the WWARN format: name = 'drug1'; label = 'Name of Drug 1'; type = String. The categories of the source variable were recoded into WWARN categories. The specific transformations are listed in Annex F.

firstdose: in the source dataset 'firstdose' is a Continuous variable. Its label is 'how muc...'. Out of 501 completed observations there were 11 unique values. The range of this variable is [0.5-5.5] with a mean of 2.9. This variable was renamed following the WWARN format: name = 'drug1tabday'; label = 'Number of Drug 1 tablets taken on this day'; type = Numeric.

seconddrug: in the source dataset 'seconddrug' is a Continuous variable. It was not labeled. Out of 501 completed observations there was 1 unique value. The range of this variable is [6.0-6.0] with a mean of 6.0. This variable was renamed following the WWARN format: name = 'drug2'; label = 'Name of Drug 2'; type = String. The categories of the source variable were recoded into WWARN categories. The specific transformations are listed in Annex F.

seconddose: in the source dataset 'seconddose' is a Continuous variable. It was not labeled. Out of 501 completed observations there were 12 unique values. The range of this variable is [0.4-4.0] with a mean of 2.5. This variable was renamed following the WWARN format: name = 'drug2tabday'; label = 'Number of Drug 2 tablets taken on this day'; type = Numeric.

thirddrug: in the source dataset 'thirddrug' is a Continuous variable. It was not labeled. Out of 500 completed observations there was 1 unique value. The range of this variable is [2.0-2.0] with a mean of 2.0. This variable was renamed following the WWARN format: name = 'drug3'; label = 'Name of Drug 3'; type = String. The categories of the source variable were recoded into WWARN categories. The specific transformations are listed in Annex F.

thirddose: in the source dataset 'thirddose' is a Continuous variable. It was not labeled. Out of 500 completed observations there were 9 unique values. The range of this variable is [0.5-5.0] with a mean of 2.2. This variable was renamed following the WWARN format: name = 'drug3tabday'; label = 'Number of Drug 3 tablets taken on this day'; type = Numeric.

temp: in the source dataset 'temp' is a Continuous variable. Its label is 'tempera...'. Out of 2604 completed observations there were 65 unique values. The range of this variable is [33.2-40.4] with a mean of 36.2. This variable contains data on the day of the event by referring to a variable (day-event) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'temp'; label = 'Body temperature'; type = Numeric.

liver: in the source dataset 'liver' is a Continuous variable. Its label is 'hepatomeg'. Out of 2612 completed observations there were 3 unique values. This variable contains data on the day of the event by referring to a variable (day-event) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'liver'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

spleen: in the source dataset 'spleen' is a Continuous variable. Its label is 'splenomeg'. Out of 2612 completed observations there were 3 unique values. This variable contains data on the day of the event by referring to a variable (day-event) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'spleen'; label = 'As diagnosed by the clinical investigator (no definition in dictionary)'; type = 0=NO / 1=Yes.

hb: in the source dataset 'hb' is a Continuous variable. Its label is 'haemagl...'. Out of 911 completed observations there were 120 unique values. The range of this variable is [4.5-19.4] with a mean of 11.0. This variable contains data on the day of the event by referring to a variable (day-event) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'hb'; label = 'Hemoglobin'; type = Numeric.

wcc: in the source dataset 'wcc' is a Continuous variable. Its label is 'wcc ...'. Out of 178 completed observations there were 72 unique values. The range of this variable is [1.7-41.4] with a mean of 5.5. This variable contains data on the day of the event by referring to a variable (day-event) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'wbc'; label = 'Amount of WBC in G/L'; type = Numeric.

pfpct: in the source dataset 'pfpct' is a Continuous variable. It was not labeled. Out of 2620 completed observations there were 229 unique values. This variable contains data on the day of the event by referring to a variable (day-event) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'pfmicl'; label = 'Asexual form of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

pvpct: in the source dataset 'pvpct' is a Continuous variable. It was not labeled. Out of 2620

completed observations there were 155 unique values. This variable contains data on the day of the event by referring to a variable (day-event) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'pvmicl'; label = 'Asexual form of P. vivax count in parasites per microlitre of blood'; type = Numeric.

gampfpct: in the source dataset 'gampfpct' is a Continuous variable. It was not labeled. Out of 2621 completed observations there were 38 unique values. This variable contains data on the day of the event by referring to a variable (day-event) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gfmicl'; label = 'Gametocytes of P. falciparum count in parasites per microlitre of blood'; type = Numeric.

gampvpct: in the source dataset 'gampvpct' is a Continuous variable. It was not labeled. Out of 2621 completed observations there were 74 unique values. This variable contains data on the day of the event by referring to a variable (day-event) which was used to generate the date of event. After transposition, this variable was renamed following the WWARN format: name = 'gvmicl'; label = 'Gametocytes of P. vivax count in parasites per microlitre of blood'; type = Numeric.

F Audit trail of categorical variable recoding

Table 13: Audit trail of categorical variable recoding

S. Variable	S. Type	S. Code	S. Label	*W. String*	*W. Type*
treatw	String	N/A	Aq+As	AS3+AQ	String
treatw	String	N/A	Artekin	DHA+PQP	String
outcome	Continuous	0	acpr	ACPR	String
outcome	Continuous	3	etf, with danger signs	ETFDS	String
outcome	Continuous	5	etf, with clinical criteria	ETC	String
outcome	Continuous	10	lcf, with fever	LCFF	String
outcome	Continuous	11	lpf	LPF	String
outcome	Continuous	13	ae with change in	AE	String
outcome	Continuous	14	treatment protocol violation	PD	String
outcome	Continuous	16	lost to follow up	LFU	String
outcome	Continuous	17	other antimalarials	AMLR	String
outcome	Continuous	18	withdrawal of consent	CW	String
outcome	Continuous	21	enrolment violation	ED	String
genotype	Continuous	0	n/a	NA	String
genotype	Continuous	1	new infection	RI	String
genotype	Continuous	2	recrudescence	RC	String
genotype	Continuous	3	no results	NR	String
genotype	Continuous	4		O	String
firstdrug	Continuous	7	artesunate	AS	String
seconddrug	Continuous	6	amodiaquine	AQ	String
thirddrug	Continuous	2	artekin	DHA+PQP	String

*S. = Source, W. = WWARN

G Not Imported Variables

Variable	*Source Label*
study	
species	
fstudy	failure...
fcode	failure...
fspecies	speceis...
comments	
pulse	
rr	resp rate
numberdoses	total n...
daylastdose	day of ...
totalqhs	total d...
totalaq	total d...
totalpip	total d...
ps0	
pct0	
gampct0	
symp0	symptom...
lv0	hepatom...
pct1	
gampct1	
symp1	
pct2	
gampct2	
symp2	
pct3	
gampct3	
symp3	
pct4	
gampct4	
symp4	
pct5	
gampct5	
symp5	
pct6	
gampct6	
symp6	
psf	sp at f...
pctf	parasit...
gampctf	
sympf	symps a...
tempfgr	fever a...
anyfailure	
pfunadjusted	
pfadjusted	
pfreinfect s	

pvrecurren s	
time	time ta...
mg	
tab	tablets...
treat	
dose1	which d...
super	supervi...
dateq1	date ad...
timeq1	time ta...
doseq1	how muc...
tabq1	tablets...
superq1	supervi...
vomq1	muntah ...
vomq2	muntah ...
dated1	date ad...
timed1	time ta...
dosed1	how muc...
tabd1	tablets...
superd1	supervi...
vomd1	muntah ...
vomd2	muntah ...
doseq2	how muc...
tabq2	tablets...
dosed2	how muc...
tabd2	tablets...
otherdrug	antimal...
drug1	apa? ...
when1	kapan? ...
drug2	apa? ...
when2	kapan? ...
drug3	apa? ...
when3	kapan? ...
daycheck	
fv	hx of f...
unwell	unwell
danger	danger ...
h	headache
m	muscle ...
n	nausea
vom	vomitting
ap	abdomin...
an	anorxia
diar	diarrhoea
dz	dizzy
palp	palpita...
cough	cough
urt	urticaria
rash	rash
otherclin	

g6pd	@@@@@
ps	asxeual...
pct	
gampct	

H Unexpected Results

Patient	*Date*	*Day*	*Unexpected result*
75	27 Aug 05	D2	Temperature less than 34.0C (=33.8C)
1020	14 Jul 05	D1	Temperature less than 34.0C (=33.2C)

I Study Deviations

Patient	*Date*	*Day*	*Deviation*
1	5 Jul 05	D0	D0 Without vivax (0)
3	5 Jul 05	D0	D0 Without vivax (0)
5	7 Jul 05	D0	D0 Without vivax (0)
6	7 Jul 05	D0	D0 Without vivax (0)
7	7 Jul 05	D0	D0 Without vivax (0)
8	9 Jul 05	D0	D0 Without vivax (0)
9	9 Jul 05	D0	D0 Without vivax (0)
10	9 Jul 05	D0	D0 Without vivax (0)
15	11 Jul 05	D0	D0 Without vivax (0)
15	8 Aug 05	D28	LFU before 39 days (last BS at D28)
16	11 Jul 05	D0	D0 Without vivax (0)
16	29 Jul 05	D18	$\geq$ 18 days without BS (27 days [D19-D45])
16	26 Aug 05	D46	Mixed Infection during Follow-Up
17	11 Jul 05	D0	D0 Without vivax (0)
18	12 Jul 05	D0	D0 Without vivax (0)
20	13 Jul 05	D0	D0 Without vivax (0)
23	20 Jul 05	D7	$\geq$ 18 days without BS (26 days [D8-D33])
23	16 Aug 05	D34	LFU before 39 days (last BS at D34)
24	13 Jul 05	D0	D0 Without vivax (0)
25	15 Jul 05	D0	D0 Without vivax (0)
26	30 Jul 05	D15	LFU before 39 days (last BS at D15)
27	15 Jul 05	D0	D0 Without vivax (0)
29	15 Jul 05	D0	D0 Without vivax (0)
30	15 Jul 05	D0	D0 Without vivax (0)
33	18 Jul 05	D0	D0 Without vivax (0)
35	19 Jul 05	D0	D0 Without vivax (0)
36	20 Jul 05	D0	D0 Without vivax (0)
37	23 Jul 05	D2	LFU before 39 days (last BS at D2)
38	22 Jul 05	D0	D0 Without vivax (0)
39	22 Jul 05	D0	D0 Without vivax (0)
39	24 Jul 05	D2	LFU before 39 days (last BS at D2)
40	22 Jul 05	D0	D0 Without vivax (0)
42	23 Jul 05	D0	D0 Without vivax (0)
43	23 Jul 05	D0	D0 Without vivax (0)
44	23 Jul 05	D0	D0 Without vivax (0)
45	23 Jul 05	D0	D0 Without vivax (0)
48	25 Jul 05	D0	D0 Without vivax (0)
49	25 Jul 05	D0	D0 Without vivax (0)
49	27 Jul 05	D2	LFU before 39 days (last BS at D2)
50	16 Aug 05	D21	LFU before 39 days (last BS at D21)
52	29 Jul 05	D0	LFU before 39 days (last BS at D0)
52	29 Jul 05	D0	D0 Without Any Plasmodium
52	29 Jul 05	D0	D0 Without vivax (0)
53	29 Jul 05	D0	D0 Without vivax (0)
54	1 Aug 05	D0	D0 Without vivax (0)

55	10 Aug 05	D7	LFU before 39 days (last BS at D7)
57	3 Aug 05	D0	D0 Without vivax (0)
57	10 Aug 05	D7	LFU before 39 days (last BS at D7)
58	3 Aug 05	D0	D0 Without vivax (0)
61	5 Aug 05	D0	D0 Without vivax (0)
61	12 Aug 05	D7	LFU before 39 days (last BS at D7)
62	5 Aug 05	D0	D0 Without vivax (0)
62	5 Aug 05	D0	D0 Without Any Plasmodium
62	9 Sep 05	D35	LFU before 39 days (last BS at D35)
63	6 Aug 05	D0	D0 Without vivax (0)
64	6 Aug 05	D0	LFU before 39 days (last BS at D0)
65	8 Aug 05	D0	D0 Without vivax (0)
66	8 Aug 05	D0	D0 Without vivax (0)
67	10 Aug 05	D2	LFU before 39 days (last BS at D2)
68	8 Aug 05	D0	D0 Without vivax (0)
69	8 Aug 05	D0	D0 Without vivax (0)
70	10 Aug 05	D0	D0 Without vivax (0)
72	22 Aug 05	D0	D0 Without vivax (0)
73	23 Aug 05	D0	D0 Without vivax (0)
74	23 Aug 05	D0	D0 Without vivax (0)
77	27 Aug 05	D2	LFU before 39 days (last BS at D2)
78	25 Aug 05	D0	D0 Without vivax (0)
79	27 Aug 05	D0	D0 Without vivax (0)
79	29 Aug 05	D2	$\geq$ 18 days without BS (19 days [D3-D21])
79	18 Sep 05	D22	$\geq$ 18 days without BS (20 days [D23-D42])
80	29 Aug 05	D0	D0 Without vivax (0)
80	29 Aug 05	D0	D0 Without Any Plasmodium
80	3 Oct 05	D35	LFU before 39 days (last BS at D35)
81	29 Aug 05	D0	D0 Without vivax (0)
82	30 Aug 05	D0	D0 Without vivax (0)
83	31 Aug 05	D0	D0 Without vivax (0)
84	3 Sep 05	D0	D0 Without vivax (0)
86	5 Sep 05	D0	D0 Without vivax (0)
87	8 Sep 05	D0	D0 Without vivax (0)
88	8 Sep 05	D0	D0 Without vivax (0)
88	10 Sep 05	D2	LFU before 39 days (last BS at D2)
89	9 Sep 05	D0	D0 Without vivax (0)
90	9 Sep 05	D0	D0 Without vivax (0)
91	9 Sep 05	D0	D0 Without vivax (0)
95	17 Sep 05	D0	D0 Without vivax (0)
96	19 Sep 05	D0	D0 Without vivax (0)
99	21 Sep 05	D0	D0 Without vivax (0)
100	21 Sep 05	D0	D0 Without vivax (0)
102	26 Sep 05	D0	D0 Without vivax (0)
106	29 Sep 05	D0	D0 Without vivax (0)
107	30 Sep 05	D0	D0 Without vivax (0)
108	30 Sep 05	D0	D0 Without vivax (0)
110	3 Oct 05	D0	D0 Without vivax (0)
110	27 Oct 05	D24	LFU before 39 days (last BS at D24)

116	5 Oct 05	D0	D0 Without vivax (0)
117	8 Oct 05	D2	LFU before 39 days (last BS at D2)
121	10 Oct 05	D2	LFU before 39 days (last BS at D2)
123	10 Oct 05	D0	D0 Without vivax (0)
124	10 Oct 05	D0	D0 Without vivax (0)
125	11 Oct 05	D0	D0 Without vivax (0)
125	18 Oct 05	D7	LFU before 39 days (last BS at D7)
126	11 Oct 05	D0	D0 Without vivax (0)
126	18 Nov 05	D38	LFU before 39 days (last BS at D38)
127	13 Oct 05	D0	D0 Without vivax (0)
128	14 Oct 05	D0	D0 Without vivax (0)
130	19 Oct 05	D0	D0 Without vivax (0)
130	21 Oct 05	D2	LFU before 39 days (last BS at D2)
132	25 Oct 05	D0	D0 Without vivax (0)
133	25 Oct 05	D0	D0 Without vivax (0)
134	25 Oct 05	D0	D0 Without vivax (0)
136	28 Oct 05	D0	D0 Without vivax (0)
1001	5 Jul 05	D0	D0 Without vivax (0)
1002	5 Jul 05	D0	D0 Without vivax (0)
1002	6 Jul 05	D1	LFU before 39 days (last BS at D1)
1003	6 Jul 05	D0	D0 Without vivax (0)
1003	9 Jul 05	D3	LFU before 39 days (last BS at D3)
1004	6 Jul 05	D0	D0 Without vivax (0)
1005	6 Jul 05	D0	D0 Without vivax (0)
1007	6 Jul 05	D0	D0 Without vivax (0)
1007	8 Jul 05	D2	LFU before 39 days (last BS at D2)
1008	7 Jul 05	D0	D0 Without vivax (0)
1009	10 Aug 05	D34	LFU before 39 days (last BS at D34)
1010	8 Jul 05	D0	D0 Without vivax (0)
1016	11 Jul 05	D0	LFU before 39 days (last BS at D0)
1017	13 Jul 05	D0	D0 Without vivax (0)
1018	11 Jul 05	D0	D0 Without vivax (0)
1020	13 Jul 05	D0	D0 Without vivax (0)
1021	13 Jul 05	D0	D0 Without vivax (0)
1021	28 Jul 05	D15	LFU before 39 days (last BS at D15)
1022	13 Jul 05	D0	D0 Without vivax (0)
1024	14 Jul 05	D0	D0 Without vivax (0)
1025	14 Jul 05	D0	D0 Without vivax (0)
1027	10 Aug 05	D25	LFU before 39 days (last BS at D25)
1028	18 Jul 05	D0	D0 Without vivax (0)
1029	18 Jul 05	D0	D0 Without vivax (0)
1030	18 Jul 05	D0	D0 Without vivax (0)
1032	19 Jul 05	D0	D0 Without vivax (0)
1033	2 Aug 05	D14	LFU before 39 days (last BS at D14)
1034	20 Jul 05	D0	D0 Without vivax (0)
1035	20 Jul 05	D0	D0 Without vivax (0)
1037	22 Jul 05	D0	D0 Without vivax (0)
1037	29 Jul 05	D7	$\geq$ 18 days without BS (21 days [D8-D28])
1037	22 Aug 05	D31	LFU before 39 days (last BS at D31)

1038	23 Jul 05	D0	D0 Without vivax (0)
1039	23 Jul 05	D0	D0 Without vivax (0)
1040	25 Jul 05	D0	D0 Without vivax (0)
1041	1 Aug 05	D7	$\geq$ 18 days without BS (20 days [D8-D27])
1046	2 Aug 05	D6	$\geq$ 18 days without BS (21 days [D7-D27])
1047	18 Aug 05	D22	$\geq$ 18 days without BS (31 days [D23-D53])
1050	29 Aug 05	D33	$\geq$ 18 days without BS (21 days [D34-D54])
1051	28 Jul 05	D0	D0 Without vivax (0)
1052	28 Jul 05	D0	D0 Without vivax (0)
1052	4 Aug 05	D7	LFU before 39 days (last BS at D7)
1053	30 Jul 05	D0	D0 Without vivax (0)
1054	30 Jul 05	D0	D0 Without vivax (0)
1054	10 Aug 05	D11	LFU before 39 days (last BS at D11)
1055	3 Aug 05	D2	LFU before 39 days (last BS at D2)
1056	1 Aug 05	D0	D0 Without vivax (0)
1058	2 Aug 05	D0	D0 Without vivax (0)
1059	29 Aug 05	D27	$\geq$ 18 days without BS (21 days [D28-D48])
1060	5 Aug 05	D2	LFU before 39 days (last BS at D2)
1062	3 Aug 05	D0	D0 Without vivax (0)
1063	4 Aug 05	D0	D0 Without vivax (0)
1063	4 Aug 05	D0	LFU before 39 days (last BS at D0)
1064	4 Aug 05	D0	D0 Without vivax (0)
1065	4 Aug 05	D0	D0 Without vivax (0)
1065	2 Sep 05	D29	$\geq$ 18 days without BS (27 days [D30-D56])
1066	4 Aug 05	D0	D0 Without vivax (0)
1067	5 Aug 05	D0	LFU before 39 days (last BS at D0)
1067	5 Aug 05	D0	D0 Without Any Plasmodium
1067	5 Aug 05	D0	D0 Without vivax (0)
1069	6 Aug 05	D0	D0 Without vivax (0)
1070	6 Aug 05	D0	D0 Without vivax (0)
1071	6 Aug 05	D0	D0 Without vivax (0)
1074	16 Aug 05	D7	$\geq$ 18 days without BS (23 days [D8-D30])
1074	9 Sep 05	D31	LFU before 39 days (last BS at D31)
1078	10 Aug 05	D0	D0 Without vivax (0)
1078	3 Sep 05	D24	LFU before 39 days (last BS at D24)
1080	11 Aug 05	D0	D0 Without vivax (0)
1081	12 Aug 05	D0	D0 Without vivax (0)
1081	15 Aug 05	D3	LFU before 39 days (last BS at D3)
1082	15 Aug 05	D0	D0 Without vivax (0)
1082	6 Sep 05	D22	LFU before 39 days (last BS at D22)
1083	15 Aug 05	D0	D0 Without vivax (0)
1083	18 Aug 05	D3	LFU before 39 days (last BS at D3)
1084	15 Aug 05	D0	D0 Without vivax (0)
1085	15 Aug 05	D0	D0 Without vivax (0)
1088	15 Aug 05	D0	D0 Without vivax (0)
1090	18 Aug 05	D0	D0 Without vivax (0)
1091	19 Aug 05	D0	D0 Without vivax (0)
1091	22 Aug 05	D3	$\geq$ 18 days without BS (31 days [D4-D34])
1091	23 Sep 05	D35	LFU before 39 days (last BS at D35)

1092	22 Aug 05	D0	D0 Without vivax (0)
1094	26 Sep 05	D35	LFU before 39 days (last BS at D35)
1095	24 Aug 05	D0	D0 Without vivax (0)
1096	14 Sep 05	D21	LFU before 39 days (last BS at D21)
1098	25 Aug 05	D0	D0 Without vivax (0)
1099	25 Aug 05	D0	D0 Without vivax (0)
1099	27 Sep 05	D33	$\geq$ 18 days without BS (19 days [D34-D52])
1100	25 Aug 05	D0	D0 Without vivax (0)
1100	5 Sep 05	D11	LFU before 39 days (last BS at D11)
1102	29 Aug 05	D0	D0 Without vivax (0)
1103	29 Aug 05	D0	D0 Without vivax (0)
1104	5 Oct 05	D37	LFU before 39 days (last BS at D37)
1105	20 Sep 05	D22	Mixed Infection during Follow-Up
1105	21 Sep 05	D23	Mixed Infection during Follow-Up
1106	5 Sep 05	D7	LFU before 39 days (last BS at D7)
1107	29 Aug 05	D0	D0 Without vivax (0)
1108	30 Aug 05	D0	D0 Without vivax (0)
1109	21 Sep 05	D21	Mixed Infection during Follow-Up
1110	31 Aug 05	D0	D0 Without vivax (0)
1113	2 Sep 05	D0	D0 Without vivax (0)
1114	2 Sep 05	D0	D0 Without vivax (0)
1117	8 Sep 05	D0	LFU before 39 days (last BS at D0)
1117	8 Sep 05	D0	D0 Without vivax (0)
1118	26 Sep 05	D17	$\geq$ 18 days without BS (19 days [D18-D36])
1120	9 Sep 05	D0	D0 Without vivax (0)
1121	10 Sep 05	D0	D0 Without vivax (0)
1121	12 Sep 05	D2	LFU before 39 days (last BS at D2)
1123	12 Sep 05	D0	D0 Without vivax (0)
1125	13 Sep 05	D0	D0 Without vivax (0)
1126	13 Sep 05	D0	D0 Without vivax (0)
1126	27 Sep 05	D14	$\geq$ 18 days without BS (23 days [D15-D37])
1129	13 Sep 05	D0	D0 Without vivax (0)
1131	15 Sep 05	D0	D0 Without vivax (0)
1137	21 Sep 05	D0	D0 Without vivax (0)
1138	21 Sep 05	D0	D0 Without vivax (0)
1138	28 Sep 05	D7	LFU before 39 days (last BS at D7)
1139	21 Sep 05	D0	D0 Without vivax (0)
1141	22 Sep 05	D0	D0 Without vivax (0)
1144	26 Sep 05	D0	D0 Without vivax (0)
1145	26 Sep 05	D0	D0 Without vivax (0)
1146	26 Sep 05	D0	D0 Without vivax (0)
1148	26 Sep 05	D0	D0 Without vivax (0)
1149	26 Sep 05	D0	D0 Without vivax (0)
1150	26 Sep 05	D0	D0 Without vivax (0)
1151	27 Oct 05	D30	LFU before 39 days (last BS at D30)
1153	27 Sep 05	D0	D0 Without vivax (0)
1154	28 Sep 05	D0	D0 Without vivax (0)
1155	5 Oct 05	D7	LFU before 39 days (last BS at D7)
1157	6 Oct 05	D8	LFU before 39 days (last BS at D8)

1158	29 Sep 05	D0	D0 Without vivax (0)
1160	3 Oct 05	D0	D0 Without vivax (0)
1161	6 Oct 05	D3	LFU before 39 days (last BS at D3)
1162	5 Oct 05	D0	D0 Without vivax (0)
1163	5 Oct 05	D0	D0 Without vivax (0)
1164	10 Oct 05	D0	D0 Without vivax (0)
1164	31 Oct 05	D21	LFU before 39 days (last BS at D21)
1165	11 Oct 05	D0	D0 Without vivax (0)
1165	25 Oct 05	D14	$\geq$ 18 days without BS (23 days [D15-D37])
1167	12 Oct 05	D0	D0 Without vivax (0)
1168	12 Oct 05	D0	D0 Without vivax (0)
1170	15 Oct 05	D3	LFU before 39 days (last BS at D3)
1171	14 Oct 05	D0	D0 Without vivax (0)
1171	21 Oct 05	D7	LFU before 39 days (last BS at D7)
1173	15 Oct 05	D0	D0 Without vivax (0)
1173	16 Oct 05	D1	LFU before 39 days (last BS at D1)
1175	17 Oct 05	D0	D0 Without vivax (0)
1176	19 Oct 05	D2	LFU before 39 days (last BS at D2)
1177	18 Oct 05	D0	D0 Without vivax (0)
1178	18 Oct 05	D0	D0 Without vivax (0)
1180	19 Oct 05	D0	D0 Without vivax (0)
1186	20 Oct 05	D0	D0 Without vivax (0)
1187	21 Oct 05	D0	D0 Without vivax (0)
1191	25 Oct 05	D0	D0 Without vivax (0)
1193	26 Oct 05	D0	D0 Without vivax (0)
1193	25 Nov 05	D30	LFU before 39 days (last BS at D30)
1194	26 Oct 05	D0	D0 Without vivax (0)
1195	27 Oct 05	D0	D0 Without vivax (0)
1196	27 Oct 05	D0	D0 Without vivax (0)
1197	28 Oct 05	D0	D0 Without vivax (0)
1197	30 Oct 05	D2	LFU before 39 days (last BS at D2)
1198	28 Oct 05	D0	D0 Without vivax (0)
1199	31 Oct 05	D0	D0 Without vivax (0)
1200	31 Oct 05	D0	D0 Without vivax (0)
1201	31 Oct 05	D0	D0 Without vivax (0)

J Study Description

Patient	*Date*	*Day*	*Specific Study Descriptions*
63	10 Sep 05	D35	*follow-up visit* without blood smears results
67	11 Aug 05	D3	*follow-up visit* without blood smears results
80	9 Sep 05	D11	*follow-up visit* without blood smears results
135	24 Nov 05	D30	*follow-up visit* without blood smears results
1025	16 Jul 05	D2	*follow-up visit* without blood smears results
1043	28 Jul 05	D2	*follow-up visit* without blood smears results
1044	8 Aug 05	D13	*follow-up visit* without blood smears results
1045	22 Aug 05	D27	*follow-up visit* without blood smears results
1061	22 Aug 05	D19	*follow-up visit* without blood smears results
1071	10 Sep 05	D35	*follow-up visit* without blood smears results
1104	4 Oct 05	D36	*follow-up visit* without blood smears results
1104	17 Oct 05	D49	*follow-up visit* without blood smears results
1108	30 Sep 05	D31	*follow-up visit* without blood smears results
1125	10 Oct 05	D27	*follow-up visit* without blood smears results
1126	20 Oct 05	D37	*follow-up visit* without blood smears results
1128	3 Oct 05	D20	*follow-up visit* without blood smears results
1129	10 Oct 05	D27	*follow-up visit* without blood smears results
1131	12 Oct 05	D27	*follow-up visit* without blood smears results
1151	10 Oct 05	D13	*follow-up visit* without blood smears results
1153	10 Oct 05	D13	*follow-up visit* without blood smears results
1153	25 Oct 05	D28	*follow-up visit* without blood smears results
1162	7 Oct 05	D2	*follow-up visit* without blood smears results
1183	7 Nov 05	D19	*follow-up visit* without blood smears results
1194	29 Oct 05	D3	*follow-up visit* without blood smears results

K Efficacy endpoints

Day 28

Day28 - Treatment:AS3+AQ - Endpoint:ACPR

PatientID (listing 46 observations):

2 4 12 22 32 41 59 71 85 93 97 98 105 109 112 114 118 119 135 137 1006 1013 1026 1043 1044 1045 1072 1073 1089 1097 1101 1111 1112 1127 1128 1130 1135 1142 1143 1152 1156 1166 1179 1182 1189 1192

Day28 - Treatment:AS3+AQ - Endpoint:BS gap > 18 days

PatientID (listing 3 observations):

1041 1046 1074

Day28 - Treatment:AS3+AQ - Endpoint:D0 No Vivax

PatientID (listing 92 observations):

1 3 10 16 17 24 25 33 35 36 40 44 45 48 49 53 54 58 61 62 63 70 72 74 81 87 91 95 100 106 108 110 123 127 128 132 134 1002 1003 1004 1005 1010 1020 1021 1022 1024 1029 1030 1032 1037 1039 1040 1053 1058 1062 1064 1066 1067 1070 1071 1080 1083 1084 1091 1092 1095 1099 1100 1107 1113 1114 1117 1120 1121 1126 1138 1139 1141 1145 1148 1154 1158 1163 1164 1168 1171 1178 1186 1193 1194 1199 1201

Day28 - Treatment:AS3+AQ - Endpoint:Missed D28 Visit

PatientID (listing 15 observations):

13 37 55 75 77 92 117 121 1011 1055 1060 1133 1157 1161 1176

Day28 - Treatment:AS3+AQ - Endpoint:Vivax LTF

PatientID (listing 12 observations):

11 76 122 1019 1048 1086 1105 1109 1136 1169 1183 1188

Day28 - Treatment:DHA+PQP - Endpoint:ACPR

PatientID (listing 50 observations):

14 19 21 28 31 46 47 51 56 94 101 104 113 115 138 1009 1014 1015 1023 1027 1031 1036 1042 1050 1057 1061 1068 1075 1076 1077 1079 1087 1093 1094 1104 1115 1116 1119 1122 1124 1132 1134 1140 1147 1151 1159 1172 1174 1181 1184

Day28 - Treatment:DHA+PQP - Endpoint:BS gap > 18 days

PatientID (listing 4 observations):

23 1047 1059 1118

Day28 - Treatment:DHA+PQP - Endpoint:D0 No Vivax

PatientID (listing 96 observations):

5 6 7 8 9 15 18 20 27 29 30 38 39 42 43 52 57 65 66 68 69 73 78 79 80 82 83 84 86 88 89 90 96 99 102 107 116 124 125 126 130 133 136 1001 1007 1008 1017 1018 1025 1028 1034 1035 1038 1051 1052 1054 1056 1063 1065 1069 1078 1081 1082 1085 1088 1090 1098 1102 1103 1108 1110 1123 1125 1129 1131 1137 1144 1146 1149 1150 1153 1160 1162 1165 1167 1173 1175 1177 1180 1187 1191 1195 1196 1197 1198 1200

Day28 - Treatment:DHA+PQP - Endpoint:Missed D28 Visit

PatientID (listing 14 observations):

26 50 60 64 67 1012 1016 1033 1049 1096 1106 1155 1170 1202

Day28 - Treatment:DHA+PQP - Endpoint:Vivax LTF

PatientID (listing 3 observations):

120 129 131

Day 42

Day42 - Treatment:AS3+AQ - Endpoint:ACPR

PatientID (listing 28 observations):

2 4 12 22 41 59 71 93 97 98 105 119 135 137 1043 1072 1089 1101 1111 1112 1128 1130 1133 1142 1166 1182 1189 1192

Day42 - Treatment:AS3+AQ - Endpoint:BS gap > 18 days

PatientID (listing 3 observations):

1041 1046 1074

Day42 - Treatment:AS3+AQ - Endpoint:D0 No Vivax

PatientID (listing 92 observations):

1 3 10 16 17 24 25 33 35 36 40 44 45 48 49 53 54 58 61 62 63 70 72 74 81 87 91 95 100 106 108 110 123 127 128 132 134 1002 1003 1004 1005 1010 1020 1021 1022 1024 1029 1030 1032 1037 1039 1040 1053 1058 1062 1064 1066 1067 1070 1071 1080 1083 1084 1091 1092 1095 1099 1100 1107 1113 1114 1117 1120 1121 1126 1138 1139 1141 1145 1148 1154 1158 1163 1164 1168 1171 1178 1186 1193 1194 1199 1201

Day42 - Treatment:AS3+AQ - Endpoint:Missed D42 Visit

PatientID (listing 20 observations):

13 32 37 55 75 77 92 112 117 118 121 1011 1055 1060 1097 1127 1135 1157 1161 1176

Day42 - Treatment:AS3+AQ - Endpoint:Vivax LTF

PatientID (listing 25 observations):

11 76 85 109 114 122 1006 1013 1019 1026 1044 1045 1048 1073 1086 1105 1109 1136 1143 1152 1156 1169 1179 1183 1188

Day42 - Treatment:DHA+PQP - Endpoint:ACPR

PatientID (listing 40 observations):

19 21 28 31 47 51 56 60 94 101 104 113 115 138 1012 1014 1015 1023 1031 1049 1061 1068 1075 1076 1077 1079 1087 1093 1115 1116 1119 1122 1132 1134 1140 1159 1172 1174 1181 1184

Day42 - Treatment:DHA+PQP - Endpoint:BS gap > 18 days

PatientID (listing 5 observations):

23 1047 1050 1059 1118

Day42 - Treatment:DHA+PQP - Endpoint:D0 No Vivax

PatientID (listing 96 observations):

5 6 7 8 9 15 18 20 27 29 30 38 39 42 43 52 57 65 66 68 69 73 78 79 80 82 83 84 86 88 89 90 96 99 102 107 116 124 125 126 130 133 136 1001 1007 1008 1017 1018 1025 1028 1034 1035 1038 1051 1052 1054 1056 1063 1065 1069 1078 1081 1082 1085 1088 1090 1098 1102 1103 1108 1110 1123 1125 1129 1131 1137 1144 1146 1149 1150 1153 1160 1162 1165 1167 1173 1175 1177 1180 1187 1191 1195 1196 1197 1198 1200

Day42 - Treatment:DHA+PQP - Endpoint:Missed D42 Visit

PatientID (listing 19 observations):
26 46 50 64 67 1009 1016 1027 1033 1042 1094 1096 1104 1106 1147 1151 1155 1170 1202
Day42 - Treatment:DHA+PQP - Endpoint:Vivax LTF
PatientID (listing 7 observations):
14 120 129 131 1036 1057 1124