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| image001  Visit: <http://www.wwarn.org/working-together/malaria-standards-CDISC> |
| TEMPLATE:  Annotated Case Record Form (CRF) for use in clinical trials in patients with uncomplicated malaria (phase II/III) |
|  |
| **V2.0 09th, APRIL, 2018** |

The WorldWide Antimalarial Resistance Network (WWARN) would like to acknowledge the following groups for their participation and contribution to the development of the [CDISC malaria data standard](https://www.cdisc.org/standards/therapeutic-areas/malaria): Bill & Melinda Gates Foundation, Clinical Data Interchange Standards Consortium (CDISC), Critical Path Institute (C-PATH), United States Food and Drug Administration (FDA), pharmaceutical companies (including Glaxo SmithKline, Novartis, Sanofi, Takeda, Shin Poong, Sigma-Tau, Merck), the World Health Organization (Global Malaria Programme and Special Programme for Research & Training in Tropical Diseases, TDR), academic researchers (from University of Cape Town, Oxford University, Menzies School of Health Research, Mahidol University and Liverpool School of Tropical Medicine), and product development partnerships (notably the Medicines for Malaria Venture) active in antimalarial drug development.

To download the [Therapeutic Area User Guide (TAUG)-malaria](https://www.cdisc.org/standards/therapeutic-areas/malaria), visit the [CDISC website](https://www.cdisc.org/).

**INSTRUCTION & CONTENTS PAGE**

This Case Record Form template is intended as a guide and may be tailored to collect the data required by the clinical research protocol to answer the specific research question being addressed. It is intended for participants who meet the enrolment criteria as specified in the protocol and excludes severe malaria disease; Clinical Data Acquisition Standards Harmonization (CDASH) annotations are included in blue; Standard Data Tabulation Module (SDTM) in red. Trial sites can select which modules to include in their CRF based on protocol requirements; modules included in the following CRF are below:

|  |  |
| --- | --- |
|  | **DATA MODULE** |
| **DAY 0/VISIT 1[[1]](#footnote-1)** | Eligibility assessment |
| Demographics |
| Pregnancy status |
| Household characteristics |
| HIV status[[2]](#footnote-2) |
| Malaria symptoms[[3]](#footnote-3) and general medical/surgical history[[4]](#footnote-4) |
| Previous medication |
| **VISIT 1 & FOLLOW-UP DAYS[[5]](#footnote-5) [[6]](#footnote-6)** | Vital signs |
| Physical examination |
| Malaria diagnostic test and microscopy |
| Study drug administration |
| Laboratory results |
| Adverse events, serious adverse events and adverse events of special interest |
| Concomitant medications |
| **DISPOSITION** | Efficacy assessment (includes clinical and parasitological response) |
| OR Reason for non-completion of study |

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| **APPENDIX A** | Molecular genotyping (Recrudescence vs Re-infection of *P[[7]](#footnote-7). falciparum*) |
| **APPENDIX B** | Molecular genotyping (Homologous or Heterologous recurrence of *P. vivax*) |
| **APPENDIX C** | Pharmacokinetic sampling |
| **APPENDIX D** | Glucose-6-phosphate dehydrogenase (G6PD) |
| **APPENDIX E** | Cytochrome P459 (CYP) 2D6 genotyping |
| **APPENDIX F** | Electrocardiogram (ECG) |
| **APPENDIX G** | Meal record |
| **FOLLOW-UP ASSESSMENTS** | Clinical events  **ALL OTHER DATA MODULES CAN BE REPEATED AS PER PROTOCOL** |

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| VISIT 1 | VISIT DATE[[8]](#footnote-8) [[9]](#footnote-9) | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **VISDAT** | | VISIT TIME[[10]](#footnote-10) | | |\_\_|\_\_|:|\_\_|\_\_| **VISTIM** | | |
| ELIGIBILITY ASSESSMENT [[11]](#footnote-11) | | | | | | | | | |
| Inclusion CriteriaIETEST (IECAT= INCLUSION) | | **Criterion Description**  **[Adapt as per protocol]** | | | | | | **Yes** | **No** |
| **IEORRES** | |
| IN001 | | [Protocol specified species] uncomplicated malaria[[12]](#footnote-12) | | | | | | **€** | **€**[[13]](#footnote-13) |
| IN002 | | Asexual parasitemia between (xxxx) and (xxxxxx)/µL | | | | | | **€** | **€** |
| IN003 | | A history of fever in the past 24 hours, or measured temperature greater than e.g. 38°C (tympanic) OR 37.5°C (axillary) | | | | | | **€** | **€** |
| IN004 | | Subject between the ages of (xx) and (xxx) | | | | | | **€** | **€** |
| IN005 | | Subject’s weight between (xxx) kg and (xxx) kg | | | | | | **€** | **€** |
| Exclusion Criteria **IETEST (IECAT=EXCLUSION)** | | **Criterion Description**  **[Adapt as per protocol[[14]](#footnote-14)]** | | | | | | **Yes** | **No** |
| **IEORRES** | |
| EX001 | | Signs of severe malaria (see foot-note[[15]](#endnote-1)) | | | | | | **€** | **€** |
| EX002 | | Antimalarial taken within the last (xx) days[[16]](#footnote-15) | | | | | | **€** | **€** |
| EX003 | | Administration of RTSS vaccine or any investigational malaria vaccine | | | | | | **€** | **€** |
| EX004 | | History of allergy to study drug/s (antimalarial treatment) | | | | | | **€** | **€** |
| **Assessment of eligibility at VISIT 1** | | | | | | | | **Yes** | **No** |
| **Did the subject meet all eligibility criteria? IEYN** | | | | | | | | **€** | **€** |
| **If no, specify criteria not met IETESTCD** | | | |  | | | | | |
| **Date and time informed consent given**  **DSDECOD=INFORMED CONSENT** | | | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **DSSTDAT RFICDTC[[17]](#footnote-16)** | | **|\_\_|\_\_|:|\_\_|\_\_|**  **DSSTTIM RFICDTIM** | | | |

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| If applicable, to which group is participant randomised? **ARM** | | |  |
| **Investigator statement: I have reviewed the data recorded in this CRF and confirm that the data are accurate and complete[[18]](#footnote-17)** | | | |
| **Investigator name** | **Investigator signature** | **Date CRF confirmed** | **Time CRF confirmed** |
|  |  | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **|\_\_|\_\_|:|\_\_|\_\_|** |

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| VISIT 1 | | | | | | |
| **DEMOGRAPHICS** **DM** | | | | | | |
| **What is the subject’s date of birth?[[19]](#footnote-18)**  **BRTHDAT BRTHDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| | | | | | |
| **OR, if BRTHDAT unknown,**  **what is the subject’s age?[[20]](#footnote-19)** | |\_\_|\_\_| years AGEU  **AGE** | | | |\_\_|\_\_| months AGEU  AGE | | |
| **What is the sex of the subject?**  **SEX** | **€** Male | **€** Female | **€** Other | **If other, specify**  **SEXOTH** |  | |
| **What is the race of the subject?**  **CRACE[[21]](#footnote-20) RACE** | **€** Black | **€** White | **€** Coloured | **€** Indian | **€** Asian | **€** Other |
| **If other, specify**  **RACEOTH** |  | | | | | |

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| **PREGNANCY STATUS[[22]](#footnote-21) RP** | | | | | | | | | |
| **Is the subject pregnant?**  **RPTEST=Pregnant During the Study**  **RPTESTCD=PREGST** | **€** Yes | **€** No | | **€** UNK[[23]](#footnote-22) | **€** NA[[24]](#footnote-23) | | **If yes, date of last menstrual period (LMP) RPTEST= Last Menstrual Period Start Date**  **RPTESTCD=LMPSTDTC** | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **RPORRES where RPTEST=Last Menstrual Period Start Date** |
| **RPORRES where RPTEST = Pregnant During the Study** | | | | | |  | | |
| **If pregnant, estimate gestational age**  **RPTEST=Estimated Gestational Age**  **RPTESTCD=EGESTAGE** | **|\_\_|\_\_|**  **RPORRES where RPTEST=Estimated Gestational Age** | | | | | | **Weeks**  **RPORRESU where RPTEST=Estimated Gestational Age** | | |
| **Gestational age determined by**  **RPMETHOD where RPTESTCD=EGESTAGE** | **€** Fundal ht[[25]](#footnote-24) | | **€** LMP[[26]](#footnote-25) | | | **€** Ultrasound | | **€** Other | **If other, specify**  **RPMETHOTH** |
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| **HOUSEHOLD CHARACTERISTICS ER EROCCUR** | | |
| **Has the Malaria Control Program performed Indoor Residual Insecticide Spraying (IRS) of your home in the last 12 months? ERTERM= Indoor residual insecticide spraying; EREVLINT=-P12M** | **€** Yes | **€** No |
| **Did you sleep under an insecticide treated bed-net last night? ERTERM=Sleep under an insecticide treated bed-net; EREVINTX=LAST NIGHT** | **€** Yes | **€** No |

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| **HIV STATUS[[27]](#footnote-26) LB** | | | **Was HIV status collected for this study? LBYN** | **€ Yes** | | **€ No** |
| **HIV status at enrolment**  **LBORRES where LBTESTCD=HIV** | **€** Positive  **€** Negative  **€** Unknown | | **How was HIV status at enrolment determined?**  **LBMETH** | **€** Self-report[[28]](#footnote-27)  **€** HIV laboratory test[[29]](#footnote-28) | | |
| **If HIV positive, date of last CD4 count**  **LBDTC where LBTESTCD= CD4** | **CD4 abs.**  **LBORRES where LBTESTCD=CD4 and LBORRESU=/uL** | **CD4 % LBORRES where LBTESTCD=CD4 and LBORRESU=%** | **If HIV positive, date of last viral load**  **LBDTC where LBTESTCD=RNA and LBCAT=VIRAL LOAD and NHOID=HUMAN IMMUNODEFICIENCY VIRUS** | **Viral load result**  **LBORRES where LBTESTCD**  **=HIVVL** | **Viral load units**  **LBORRESU where LBTESTCD**  **=HIVVL** | |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** |  | % | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** |  | cells/mm3 | |
| **€** UNK[[30]](#footnote-29) | **€** UNK | **€** UNK | | |

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| *Malaria symptoms at enrolment may be collected in different ways, the study protocol will guide the method of determining these and which symptoms are of interest; if a check list-type of symptoms enquiry is used the symptoms can be pre-specified as shown below. An alternative way to collect this information could be a log-type approach, where each symptom is recorded with a start and stop date and time, if the symptom reoccurs, an additional line on the log is added. Examples of these are included below - choose the one most appropriate for your study: Malaria symptoms reported after treatment start are recorded as clinical events, see follow-up assessments.* | | | | | | | | | | | | | | |
| VISIT 1 | | | | | | | | | | | | | | |
| MALARIA SYMPTOMS[[31]](#footnote-30) ON MEDICAL HISTORY (MH) | | | | | | | | | | | | | | |
| **Did the subject have any of the following symptoms[[32]](#footnote-31) within the last (xx) days? MHYN[[33]](#footnote-32) The variable EVLINT is used to represent “within the last “xx” days”** | | | | | | | | | | **Yes** € | | **No** € | | |
| **Symptom**  **MHTERM** | **Yes** | **No** | | **Not done**  **MHSTAT** | **Reason not done**  **MHREASND** | **Start date MHSTDAT MHSTDTC**  **Start time****[[34]](#footnote-33) MHSTTIM** | **End date MHENDAT MHENDTC**  **End time**33 **MHENTIM** | **Or ongoing**  **MHONGO**  **MHENRTPT/MHENRF** | **Greatest severity MHSEV**  **(highest intensity)** | | | | | |
| **MHOCCUR** | | | **DD-MMM-YYYY** | HH:MM |  |  | | | | | |
| Fever | **€** | | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Mild | | **€** Moderate | | **€** Severe | |
| Chills | **€** | | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Mild | | **€** Moderate | | **€** Severe | |
| Malaise[[35]](#footnote-34) | **€** | | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Mild | | **€** Moderate | | **€** Severe | |
| Fatigue[[36]](#footnote-35) | **€** | | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Mild | | **€** Moderate | | **€** Severe | |

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| Muscle pain | **€** | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Joint pain | **€** | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Headache | **€** | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Irritability[[37]](#footnote-36) | **€** | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Nausea | **€** | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Vomiting | **€** | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Diarrhea | **€** | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Abdominal pain | **€** | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Loss of appetite | **€** | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Shortness of breath | **€** | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Dizziness | **€** | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Other symptom | € | € | € |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **|\_\_|\_\_|:|\_\_|\_\_|** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Mild | **€** Moderate | **€** Severe |
| If yes, other symptom describe **MHTERMOTH** | | | | |  | | | | | |

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| VISIT 1 | | | | | | | | | | |
| MEDICAL HISTORY – MALARIA SYMPTOMS LOG[[38]](#footnote-37) MHCAT = MALARIA SYMPTOMS | | | | | | | | | | |
| **List all protocol specified symptoms that occurred within the last (xx)[[39]](#footnote-38) days MHYN[[40]](#footnote-39) The variable EVLINT is used to represent “within the last “xx” days”** | | | | | | | | **€** **Yes[[41]](#footnote-40)** | | **€** **No** |
| **Symptom[[42]](#footnote-41)**  **MHTERM** | **Start date**  **MHSTDAT MHSTDTC** | **Start time**  **MHSTTIM** | **End date**  **MHENDAT MHENDTC** | **End time**  **MHSTTIM** | **Ongoing**  **MHONGO**  **MHENRTPT/**  **MHENRF** | **Greatest severity (highest intensity) MHSEV** | | | | |
|  | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **|\_\_|\_\_|:|\_\_|\_\_|** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| | **|\_\_|\_\_|:|\_\_|\_\_|** | **€** Yes | **€** Mild | **€** Moderate | | **€** Severe | |
|  | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **|\_\_|\_\_|:|\_\_|\_\_|** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| | **|\_\_|\_\_|:|\_\_|\_\_|** | **€** Yes | **€** Mild | **€** Moderate | | **€** Severe | |
|  | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **|\_\_|\_\_|:|\_\_|\_\_|** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| | **|\_\_|\_\_|:|\_\_|\_\_|** | **€** Yes | **€** Mild | **€** Moderate | | **€** Severe | |

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| VISIT 1 | | | | |
| GENERAL MEDICAL HISTORY **MHCAT** | | | | |
| **Has the subject experienced any past and/or concomitant disease within the last (xx) days/years[[43]](#footnote-42)?** **The variable EVLINT is used to represent “within the last “xx” days”**  **MHYN****[[44]](#footnote-43)** | | | **Yes €** | **No €** |
| **What is the term for the medical history condition/event?**  **MHTERM** | **Start date****[[45]](#footnote-44)**  **MHSTDAT MHSTDTC** | **End date**  **MHENDAT MHENDTC** | **Is the medical condition/event still ongoing?**  **MHONGO**  **MHENRTPT/MHENRF** | |
|  | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **€** | |
|  | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **€** | |
|  | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **€** | |
|  | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **€** | |
|  | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **€** | |
|  | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **€** | |

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| VISIT 1 | | |
| SURGICAL HISTORY PR | | |
| **Has the subject had any past surgeries? PRYN****[[46]](#footnote-45)** | **Yes €** | **No €** |
| **Name of past surgery PRTRT** | **Procedure/surgery date PRSTDAT PRSTDTC** | |
|  | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | |
|  | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | |
|  | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | |
|  | | |
| PREVIOUS MEDICATION CMCAT=PRIOR | | |
| **Were any medications taken within the last (xx) days[[47]](#footnote-46)?**  **The variable EVLINT is used to represent “within the last “xx” days”**  **CMYN**45 | **Yes €** | **No €** |
| *If yes, record on the concomitant medications page (record full trade or generic names)* | |

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| VISIT 1 | | | | | |
| **VITAL SIGNS VS** | | Were vital signs performed?VSPERF[[48]](#footnote-47) | | Yes € | No € |
| **Vital sign measurements[[49]](#footnote-48) VSTEST** | **Results**  **VSORRES** | **Units[[50]](#footnote-49)**  **VSORRESU** | **Not done**  **VSSTAT** | **Reason not done**  **VSREASND** | |
| Temperature[[51]](#footnote-50)  **TEMP\_VSTEST** | **|\_\_|\_\_|.|\_\_|**  **TEMP\_VSORRES** | **°C TEMP\_VSORRESU** | **€** **TEMP\_VSSTAT** | **TEMP\_VSREASND** | |
| Systolic blood pressure **SYSBP\_VSTEST** | **|\_\_|\_\_|\_\_|**  **SYSBP\_VSORRES** | **mmHg SYSBP\_VSORRESU** | **€ SYSBP\_VSSTAT** | **SYSBP\_VSREASND** | |
| Diastolic blood pressure **DIABP\_VSTEST** | **|\_\_|\_\_|\_\_|**  **DIABP\_VSORRES** | **mmHg DIABP\_VSORRESU** | **€ DIAPB\_VSSTAT** | **DIABP\_VSREASND** | |
| Pulse  **PULSE\_VSTEST** | **|\_\_|\_\_|\_\_|**  **PULSE\_VSORRES** | **beats/minute PULSE\_VSORRESU** | **€ PULSE\_VSSTAT** | **PULSE\_VSREASND** | |
| Respiratory rate  **RESP\_VSTEST** | **|\_\_|\_\_|**  **RESP\_VSORRES** | **breaths/minute RESP\_VSORRESU** | **€ RESP\_VSSTAT** | **RESP\_VSREASND** | |
| Weight  **WEIGHT\_VSTEST** | **|\_\_|\_\_|\_\_|.|\_\_|**  **WEIGHT\_VSORRES** | **kg WEIGHT\_VSORRESU** | **€ WEIGHT\_VSSTAT** | **WEIGHT\_VSREASND** | |
| Height  **HEIGHT\_VSTEST** | **|\_\_|\_\_|\_\_|.|\_\_|**  **HEIGHT\_VSORRES** | **cm HEIGHT\_VSORRESU** | **€ HEIGHT\_VSSTAT** | **HEIGHT\_VSREASND** | |
| Mid upper arm circumference  **MUAC\_VSTEST** | **|\_\_|\_\_|.|\_\_|**  **MUAC\_VSORRES** | **cm MUAC\_VSORRESU** | **€ MUAC\_VSSTAT** | **MUAC\_VSREASND** | |

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| PHYSICAL EXAMINATION[[52]](#footnote-51) PE | Was a physical examination performed? PEPERF[[53]](#footnote-52) | | Yes € | No € |
| **Body system examined PETEST** | **Results** | **Not done** | **Reason not examined** | |
| **PEORRES** | **PESTAT** | **PEREASND** | |
| General appearance[[54]](#footnote-53)  **GEN\_PETEST** | **€** Normal **€** Abnormal  **GEN\_PEORRES** | **€ GEN\_PESTAT** | **GEN\_PEREASND** | |
| HEENT[[55]](#footnote-54)  **HEENT\_PETEST** | **€** Normal **€** Abnormal  **HEENT\_PEORRES** | **€ HEENT\_PESTAT** | **HEENT\_PEREASND** | |
| Gastrointestinal  **GI\_PETEST** | **€** Normal **€** Abnormal  **GI\_PEORRES** | **€ GI\_PESTAT** | **GI\_PEREASND** | |
| Joints  **JOINT\_PETEST** | **€** Normal **€** Abnormal  **JOINT\_PEORRES** | **€ JOINT\_PESTAT** | **JOINT\_PEREASND** | |
| Skin  **SKIN\_PETEST** | **€** Normal **€** Abnormal  **SKIN\_PEORRES** | **€ SKIN\_PESTAT** | **SKIN\_PEREASND** | |
| Respiratory  **RESP\_PETEST** | **€** Normal **€** Abnormal  **RESP\_PEORRES** | **€ RESP\_PESTAT** | **RESP\_PEREASND** | |
| Cardiovascular  **CV\_PETEST** | **€** Normal **€** Abnormal  **CV\_PEORRES** | **€ CV\_PESTAT** | **CV\_PEREASND** | |
| Neurological  **NEURO\_PETEST** | **€** Normal  **€** Abnormal  **NEURO\_PEORRES** | **€ NEURO\_PESTAT** | **NEURO\_PEREASND** | |

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| VISIT 1 | | | | | | | |
| MALARIA DIAGNOSTIC TEST LB | | | | | | | |
| Was malaria RDT performed?MBPERFYN[[56]](#footnote-55) | **€** Yes **€** No **€** NA**[[57]](#footnote-56)** | | **Date**  **MBDAT MBDTC** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **Time**  **MBTIM MBDTC** | | **|\_\_|\_\_|:|\_\_|\_\_|** |
| **Test type**  **MBTESTCD/MBTEST** | **Lot number**  **DIVAL when DIPARM=Lot** | **Trade name**  **DIVAL when DIPARM=Trade Name** | **Result**  **MBORRES** | | **Not done**  **MBSTAT** | **Reason not done**  **MBREASND** | |
| **€** Pf **€** Pf+Pan **€** Pan **€** Other  If other, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **MBTESTOTH** |  |  | **€** Positive **€** Negative **€** Invalid | | **€** |  | |

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| **MICROSCOPY MBCAT = MALARIA MICROSCOPY**  **REPEAT AS PER PROTOCOL** | | | | | | | | | |
| **Collection date and time**  **MBDAT MBDTC** | **Reader number[[58]](#footnote-57)**  **MBEVALID** | **Slide quality**  **SDQUAL** | **Smear type**  **MBMETHOD** | **Parasite type[[59]](#footnote-58) [[60]](#footnote-59)**  **MBTESTCD/**  **TEST** | **Parasite count[[61]](#footnote-60) MBORRES** | **Parasite count units[[62]](#footnote-61)**  **MBORRESU** | | | **Malaria species[[63]](#footnote-62)**  **MBTESTCD/TEST** |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **|\_\_|\_\_|:|\_\_|\_\_| MBTIM MBDTC** |  | **€** Good  **€** Poor  **€** Missing | **€** Thick smear  **€** Thin smear | **€** Asexual  **€** Sexual | **|\_\_|\_\_|\_\_|\_\_|** | **€** /\_\_\_\_\_WBC | **€** /\_\_\_\_\_HPF | **€** /\_\_\_\_\_RBC | **€**Pf **€**Pv **€**Po  **€**Pm **€**Pk |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **|\_\_|\_\_|:|\_\_|\_\_| MBTIM MBDTC** |  | **€** Good  **€** Poor  **€** Missing | **€** Thick smear  **€** Thin smear | **€** Asexual  **€** Sexual | **|\_\_|\_\_|\_\_|\_\_|** | **€** /\_\_\_\_\_WBC | **€** /\_\_\_\_\_HPF | **€** /\_\_\_\_\_RBC | **€**Pf **€**Pv **€**Po  **€**Pm **€**Pk |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **|\_\_|\_\_|:|\_\_|\_\_| MBTIM MBDTC** |  | **€** Good  **€** Poor  **€** Missing | **€** Thick smear  **€** Thin smear | **€** Asexual  **€** Sexual | **|\_\_|\_\_|\_\_|\_\_|** | **€** /\_\_\_\_\_WBC | **€** /\_\_\_\_\_HPF | **€** /\_\_\_\_\_RBC | **€**Pf **€**Pv **€**Po  **€**Pm **€**Pk |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **|\_\_|\_\_|:|\_\_|\_\_| MBTIM MBDTC** |  | **€** Good  **€** Poor  **€** Missing | **€** Thick smear  **€** Thin smear | **€** Asexual  **€** Sexual | **|\_\_|\_\_|\_\_|\_\_|** | **€** /\_\_\_\_\_WBC | **€** /\_\_\_\_\_HPF | **€** /\_\_\_\_\_RBC | **€**Pf **€**Pv **€**Po  **€**Pm **€**Pk |

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| **STUDY DRUG ADMINISTRATION**[[64]](#footnote-63) [[65]](#footnote-64) EC | | | | | | | | | |
| **Scheduled dose number** | **Treatment name**  **ECTRT** | **Number of tablets[[66]](#footnote-65) ECDOSE where ECDOSU = TABLETS** | **Date of dose ECSTDAT ECSTDTC**  **Time of dose ECSTTIM ECSTDTC** | **OR**  **Missed dose ECOCCUR** | **Administration observed**  **DOTIND**  **SUPPEC.QVAL** | **Given with fat/food[[67]](#footnote-66)**  **FAORRES where**  **FATEST=TAKEN WITH FOOD** | **Did the subject vomit within (xx) minutes of the dose[[68]](#footnote-67)**  **FAORRES where FAOBJ = VOMITING, FACAT = POST-DOSE VOMITING; When vomiting occurs, an AE record is created where AEPRESP=Y and AETERM=VOMITING** | **Time of vomit**  **AESTDAT**  **AESTDTC** | **Dose/Re-treatment**  **RDIND**  **SUPPEC.QVAL** |
|  |  | **|\_\_|.|\_\_|** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Yes  **€** No | **€** Yes  **€** No | **€** Yes  **€** No | **|\_\_|\_\_|:|\_\_|\_\_|** | **€** Dose  **€** Redose |
|  |  | **|\_\_|.|\_\_|** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Yes  **€** No | **€** Yes  **€** No | **€** Yes  **€** No | **|\_\_|\_\_|:|\_\_|\_\_|** | **€** Dose  **€** Redose |
|  |  | **|\_\_|.|\_\_|** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Yes  **€** No | **€** Yes  **€** No | **€** Yes  **€** No | **|\_\_|\_\_|:|\_\_|\_\_|** | **€** Dose  **€** Redose |
|  |  | **|\_\_|.|\_\_|** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Yes  **€** No | **€** Yes  **€** No | **€** Yes  **€** No | **|\_\_|\_\_|:|\_\_|\_\_|** | **€** Dose  **€** Redose |
|  |  | **|\_\_|.|\_\_|** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** | **€** Yes  **€** No | **€** Yes  **€** No | **€** Yes  **€** No | **|\_\_|\_\_|:|\_\_|\_\_|** | **€** Dose  **€** Redose |

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| VISIT 1 | | | | | | |
| LABORATORY RESULTS[[69]](#footnote-68) | | | | | | |
| **HEMATOLOGY LBCAT=HEMATOLOGY SPEC TYPE = BLOOD** | | | | | | |
| **Were hematology samples** **taken**  **LBPERFYN[[70]](#footnote-69)** | **€ Yes** | **€ No** | **€ NA[[71]](#footnote-70)** | **Date and time of sample** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| LBDAT LBDTC** | |
| **|\_\_|\_\_|:|\_\_|\_\_| LBTIM LBDTC** | |
| **Hematology test name**  **LBTEST** | **Results**  **LBORRES** | | | **Units[[72]](#footnote-71)**  **LBORRESU** | **Not done**  **LBSTAT** | **Reason not done**  **LBREASND** |
| Hemoglobin | **|\_\_|\_\_|.|\_\_|**  **HGB\_LBORRES** | | | Hb (g/dL) **HGB\_LBORRESU** | **€** |  |
| Hematocrit | **|\_\_|\_\_|.|\_\_|**  **HCT\_LBORRES** | | | Haematocrit (%)  **HCT\_LBORRESU** | **€** |  |
| White cell count | **|\_\_|\_\_|\_\_|.|\_\_|**  **WBC\_LBORRES** | | | WBC (109/L)  **WBC\_LBORRESU** | **€** |  |
| Neutrophils | **|\_\_|\_\_|.|\_\_|**  **NEUT\_LBORRES** | | | Neutrophils (109/L)  **NEUT\_LBORRESU** | **€** |  |
| Basophils | **|\_\_|\_\_|.|\_\_| BASO\_LBORRES** | | | Basophils (109/L)  **BASO\_LBORRESU** | **€** |  |
| Lymphocytes | **|\_\_|\_\_|.|\_\_|**  **LYM\_LBORRES** | | | Lymphocytes (109/L)  **LYM\_LBORRESU** | **€** |  |
| Monocytes | **|\_\_|\_\_|.|\_\_|**  **MONO\_LBORRES** | | | Monocytes (109/L)  **MONO\_LBORRESU** | **€** |  |
| Eosinophils | **|\_\_|\_\_|.|\_\_| EOS\_LBORRES** | | | Eosinophils (109/L)  **EOS\_LBORRESU** | **€** |  |
| Reticulocytes | **|\_\_|\_\_|.|\_\_| RETI\_LBORRES** | | | Reticulocytes (109/L)  **RETI\_LBORRESU** | **€** |  |
| Platelets | **|\_\_|\_\_|\_\_|\_\_|**  **PLAT\_LBORRES** | | | Platelets (109/L)  **PLAT\_LBORRESU** | **€** |  |

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| **BIOCHEMISTRY LBCAT=BIOCHEMISTRY** | | | | |
| **Were biochemistry samples taken?LBPERFYN[[73]](#footnote-72)** | **€** Yes **€** No **€** NA**[[74]](#footnote-73)** | **Date and time of sample** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **LBDAT LBDTC** | |
| **|\_\_|\_\_|:|\_\_|\_\_|** **LBTIM LBDTC** | |
| **Biochemistry test name**  **LBTEST** | **Results**  **LBORRES** | **Units[[75]](#footnote-74)**  **LBORRESU** | **Not done**  **LBSTAT** | **Reason not done**  **LBREASND** |
| AST | **|\_\_|\_\_|\_\_|\_\_|**  **AST\_LBORRES** | AST (IU/L)  **AST\_LBORRESU** | **€** |  |
| ALT | **|\_\_|\_\_|\_\_|\_\_|**  **ALT\_LBORRES** | ALT (IU/L)  **ALT\_LBORRESU** | **€** |  |
| Total Bilirubin | **|\_\_|\_\_|\_\_|.|\_\_|**  **BILI\_LBORRES** | Total bilirubin (µmol/L )  **BILI\_ORRESU** | **€** |  |
| Direct (conjugated) bilirubin | **|\_\_|\_\_|\_\_|.|\_\_|**  **BILDIR\_LBORRES** | Conjugated bilirubin (µmol/L ) **BILDIR\_ORRESU** | **€** |  |
| Haptoglobin | **|\_\_|\_\_|\_\_|.|\_\_|**  **HAPTOG\_LBORRES** | Haptoglobin (g/L)  **HAPTOG\_ORRESU** | **€** |  |
| Glucose | **|\_\_|\_\_|.|\_\_|**  **GLUC\_LBORRES** | Glucose (mmol/L) **GLUC\_ORRESU** | **€** |  |
| LDH | **|\_\_|\_\_|\_\_|\_\_|.|\_\_|**  **LDH\_LBORRES** | LDH (IU/L)  **LDH\_ORRESU** | **€** |  |
| Creatinine | **|\_\_|\_\_|\_\_|\_\_|**  **CREAT\_LBORRES** | Creatinine (µmol/L)  **CREAT\_LBORRESU** | **€** |  |
| Urea | **|\_\_|\_\_|\_\_|.|\_\_|**  **UREA\_LBORRES** | Urea (mmol/L)  **UREA\_LBORRESU** | **€** |  |
| Bicarbonate | **|\_\_|\_\_|\_\_|**  **BICARB\_LBORRES** | Bicarbonate (mmol/L)  **BICARB\_LBORRESU** | **€** |  |
| Lactic acid | **|\_\_|\_\_|.|\_\_|**  **LACTICAC\_LBORRES** | Lactic acid (mmol/L)  **LACTICAC\_LBORRESU** | **€** |  |
| Potassium | **|\_\_|.|\_\_|**  **K\_LBORRES** | Potassium (mmol/L)  **K\_LBORRESU** | **€** |  |
| Sodium | **|\_\_|\_\_|\_\_|**  **NA\_LBORRES** | Sodium (mmol/L)  **NA\_LBORRESU** | **€** |  |

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| **URINALYSIS LBCAT=URINALYSIS SPEC TYPE = URINE** | | | | | |
| **Was a sample taken for urinalysis?**  **LBPERFYN [[76]](#footnote-75)** | **€** Yes **€** No **€** NA**[[77]](#footnote-76)** | **Date and time of sample** | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| LBDAT LBDTC** | |
| **|\_\_|\_\_|:|\_\_|\_\_|** **LBTIM LBDTC** | |
| **Urinalysis test name**  **LBTEST** | **Method**  **LBMETH** | **Results**  **LBORRES** | **Units**  **LBORRESU** | **Not done**  **LBSTAT** | **Reason not done**  **LBREASND** |
| Hemoglobinuria | **€** Hillmen colour chart | **€** Scale 1 – 10  **HB\_LBORRES** |  | **€** |  |
| **€** Dipstix | **HB\_LBORRES** |  | **€** |  |
| **€** Microscopy | **HB\_LBORRES** |  | **€** |  |
| Bilirubinuria | **€** Dipstix | **BILI\_LBORRES** |  | **€** |  |

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| **PREGNANCY LBCAT=PREGNANCY** | | | | |
| Was a sample taken for pregnancy  testing? **LBPREFYN [[78]](#footnote-77)** | **€** Yes **€** No **€** NA76 | **Date and time of sample** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| LBDAT LBDTC** | |
| **|\_\_|\_\_|:|\_\_|\_\_|** **LBTIM LBDTC** | |
| **Pregnancy test name**  **LBTEST** | **Results**  **LBORRES** | **Method**  **LBMETH** | **Not done**  **LBSTAT** | **Reason not done**  **LBREASND** |
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| ADVERSE EVENTS (AE)*(make multiple copies of this page if necessary)* | | | | | | | | | | | | | | |
| **Any AEs?**  **AEYN [[79]](#footnote-78)** | **€** Yes | | **€** No | | **What is the AE term?**  **AETERM** | | | |  | | | **AE number**  **AESPID** | |  |
| **Start date/time** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **AESTDAT AESTDTC** | | | | | **End date/time** | | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **AEENDAT AEENDTC** | | | **Ongoing? AEONGO**  **MHENRTPT/MHENRF** | | |
| **|\_\_|\_\_|:|\_\_|\_\_|**  **AESTTIM AESTDTC** | | | | | **|\_\_|\_\_|:|\_\_|\_\_|**  **AEENTIM AEENDTC** | | | **€** | | |
| **Toxicity grade**  **AETOXGRV** | | **€** Mild  **AETOXGRV4\_1** | | | **€** Moderate  **AETOXGRV4\_2** | | **€** Severe  **AETOXGRV4\_3** | | **€** Life threatening[[80]](#footnote-79)  **AETOXGRV4\_4** | **€** Fatal7979  **AETOXGRV4\_5** | |  | | |
| **Outcome**  **AEOUT** | | **€** Recovered/  Resolved | | | **€** Recovering**/**  Resolving with sequelae | | **€** Recovering/  Resolving | | **€** Not recovered/  Not resolved | **€** Fatal | | **€** Unknown | | |
| **Relationship to study treatment AEREL** | | **€** Not related | | | **€** Unlikely related | | **€** Possibly related | | **€** Probably related | **€** Definitely related | | **If AE related to study treatment, specify IP[[81]](#footnote-80)** | | |
|  | | |
| **Action taken with study treatment AEACN** | | **€** Drug withdrawn | | | **€** Dose reduced | | **€** Dose not changed | | **€** Unknown | **€** NA | | **€** Other | **If other, specify**  **AEACNOTH** | |
|  | |
| **Other action taken[[82]](#footnote-81)**  **AEACNOTH** | | **€** Yes | | **€** No | **Describe other action taken** | | | |  | | | | | |
| **Is the AE serious**  **AESER** | | **€** Yes[[83]](#footnote-82) | | **€** No | **Is this a special interest AE? AESI** | **€** Yes | | **€** No | **Was the AE expected? AEEXP** | | **€** Yes | **€** No | | |
| **Give short description of the AE** | |  | | | | | | | | | | | | |

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| SERIOUS ADVERSE EVENTS – REPEAT AS REQUIRED | | | |
| **SAE Classification** | **€** Fatal[[84]](#footnote-83) **AESDTH**  **€** Life threatening **AESLIFE**  **€** Requires or prolongs hospitalization **AESHOSP**  **€** Results in permanent or significant disability/incapacity **AESDISAB**  **€** Congenital anomaly/birth defect **AESCONG**  **€** Medically significant **AESMIE**  Describe medically significant condition: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **If hospitalization/ prolonged hospitalization give admission date**  **HOSTDAT where HOTERM = HOSPITALIZATION** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** |
| **If hospitalization/prolonged hospitalization give discharge date**  **HOENDAT where HOTERM = HOSPITALIZATION** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** |
| **Give short description of the SAE** |  | | |

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| CONCOMITANT MEDICATION [[85]](#footnote-84) CM | | | | | | | | | | | |
| **Was any medication given?**  **CMYN** [[86]](#footnote-85) | | | **€** Yes[[87]](#footnote-86) **€** No | | | | | | | | |
| **Medication**  **CMTRT** | **Total daily dose**  **CMDOSTOT** | **Taken prior to study?**  **CMPRIOR** | **Units**  **CMDOSU** | | **Route of administration[[88]](#footnote-87)**  **CMROUTE** | | | **Start date CMSTDAT CMSTDTC**  **Start time CMTIM CMSTDTC** | **End date CMENDAT CMENDTC**  **End time CMENTIM CMENDTC** | | **Indication**  **CMINDC** |
|  |  | **€** Yes | **€** mg | **€** mL | **€** PO | **€** IV | **€** IM | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | |  |
| **|\_\_|\_\_|:|\_\_|\_\_|** | **|\_\_|\_\_|:|\_\_|\_\_|** | |
| **€** No | **€** tsp | **€** TABLET | **€** SC | **€** TOP | **€** PR |  | **Ongoing? CMONGO CMENRTPT/CMENRF** | **€** |
|  |  | **€** Yes | **€** mg | **€** mL | **€** PO | **€** IV | **€** IM | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | |  |
| **|\_\_|\_\_|:|\_\_|\_\_|** | **|\_\_|\_\_|:|\_\_|\_\_|** | |
| **€** No | **€** tsp | **€** TABLET | **€** SC | **€** TOP | **€** PR |  | **Ongoing? CMONGO CMENRTPT/CMENRF** | **€** |

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| **DISPOSITION EVENT** **DSCAT** | |
| **What was the date of completion/discontinuation?**  **DSSTDAT DSSTDTC** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** |
| **What was the subject’s status?** | **€** Completed study (indicate efficacy assessment below) **DSTERM** |
| **€** Early treatment failure (day 1-3) **RSORRES when RSTEST = Overall Response**  **€** Late clinical failure before day 7 (day 4-6) **RSORRES when RSTEST = Overall Response**  **€** Late clinical failure or late parasitological failure on or after day 7 **RSORRES when RSTEST = Overall Response**  **€** Adequate clinical and parasitological response[[89]](#footnote-88) [[90]](#footnote-89) **RSORRES when RSTEST = Overall Response** |
| **€** Did not complete study (indicate primary reason below) **DSTERM** |
| **€** Screen Failure **RSORRES when RSTEST = Overall Response** |
| **€** Adverse event/serious adverse event (non-fatal) **RSORRES when RSTEST = Overall Response** |
| **€** Death (not malaria-related) **RSORRES when RSTEST = Overall Response** |
| **€** Lost to follow-up **RSORRES when RSTEST = Overall Response** |
| **€** Withdrawal by investigator **RSORRES when RSTEST = Overall Response** |
| **€** Study terminated by sponsor **RSORRES when RSTEST = Overall Response** |
| **€** Withdrawal by subject/guardian **RSORRES when RSTEST = Overall Response** |
| **€** Other (specify below) **RSORRES when RSTEST = Overall Response** |
| **Comment** |  |

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| **APPENDIX A** | | | | | | | | | | |
| **MOLECULAR GENOTYPING = PFCAT FOR *P.* *falciparum* (NHOID=PLASMODIUM FALCIPARUM)**[[91]](#footnote-90) | | | | | | | | | | |
| **Was molecular genotyping for *P. falciparum* performed (Y/N) PFPERF [[92]](#footnote-91)** | | | | | | | | **€ Yes** | **€ No** | **€ NA[[93]](#footnote-92)** |
| **Study day**  **PFDY** | **Date of sample** **PFDAT PFDTC** | MSP 1  **PFGENRI** | | MSP 2  **PFGENRI** | | GLURP[[94]](#footnote-93)  **PFGENRI** | **Other loci specify** | | **Not done**  **PFSTAT** | **Reason not done**  **PFREASND** |
| Family[[95]](#footnote-94)  **PFTEST=Allelic family** | Bp[[96]](#footnote-95)  **PFTEST= Amplicon size** | Family  **PFTEST=Allelic family** | Bp  **PFTEST= Amplicon size** | Bp  **PFTEST= Amplicon size** | Marker name  **PFGENRI** | Bp  **PFTEST= Amplicon size** |  |  |
| **Visit1**  **(Pre-dose)** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **€** K1  **KI\_PFORRES** | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** FC27  **FC27\_PFORRES** | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** |  | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | € |  |
| **€** MAD20  **MAD20\_PFORRES** | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** IC/3D7  **IC/3D7\_PFORRES** | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** |  |  | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | € |  |
| **€** RO33  **RO33\_PFORRES** | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** |  | |  |  | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | € |  |
| **Day of recurrence** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **€** K1  **KI\_PFORRES** | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** FC27  **FC27\_PFORRES** | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** |  |  | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | € |  |
| **€** MAD20  **MAD20\_PFORRES** | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** IC/3D7  **IC/3D7\_PFORRES** | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** |  |  | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | € |  |
| **€** RO33  **RO33\_PFORRES** | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** |  | |  |  | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | € |  |
| **Final assessment**  **PFORRES where PFTEST = Interpretation** | | **€** RECRUDESCENCE | | | **€** REINFECTION | | **€** NOT KNOWN **[[97]](#footnote-96)** | |

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| **APPENDIX B** | | | | | | | | | | |
| **MOLECULAR GENOTYPING = PFCAT FOR *P.* *vivax* (NHOID=PLASMODIUM VIVAX )[[98]](#footnote-97), [[99]](#footnote-98)** **PFGENTYP = MICROSATELLITE** | | | | | | | | | | |
| **Was molecular genotyping for *P. vivax* performed (Y/N) PFPERF[[100]](#footnote-99)** | | | | | | | | **€ Yes** | **€ No** | **€ NA[[101]](#footnote-100)** |
| **Study day**  **PFDY** | Date of sample **PFDAT PFDTC** | MSP 1  **PFGENRI** | | **Other surface proteins** | | **Microsatellites**  **PFEGNTYP** | | **Not done**  **PFSTAT** | **Reason not done**  **PFREASND** | |
| Domain  **PFGENSR** | Bp[[102]](#footnote-101)  **PFTEST= Amplicon size** | Marker gene name  **PFGENRI** | Bp  **PFORRES** | Marker name  **PFGENRI** | Bp  **PFORRES** |
| **Visit1**  **(Pre-dose)** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **€** F1 | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** MSP3a | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** MS16 | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** |  | |
| **€** F3 | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** MSP4 | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** Pv3.27 | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** |  | |
|  |  | **€** MSP5 | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** Pv1.501 | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** |  | |
| **Day of recurrence/ relapse** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **€** F1 | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** MSP3a | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** MS16 | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** |  | |
| **€** F3 | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** MSP4 | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** Pv3.27 | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** |  | |
|  |  | **€** MSP5 | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** Pv1.501 | **\_\_\_\_\_\_\_\_\_\_**  **PFORRES** | **€** |  | |

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| **APPENDIX C** | | | | | | | |
| PHARMACOKINETIC (PK) SAMPLING[[103]](#footnote-102) PC | | | **Was PK sampling performed?**  **PCYN**[[104]](#footnote-103) | | **€ Yes** | **€ No** | **€ NA[[105]](#footnote-104)** |
| **Collection date**  **PCDAT PCDTC** | **Collection time PCTIM PCDTC** | **Time-point[[106]](#footnote-105)**  **PCTPT** | **Lab identifier**[[107]](#footnote-106) **PCREFID** | **Sample type**  **PCSPEC** | **Sample condition**  **PCSPCCND** | **Not done**  **PCSTAT** | **Reason not done**  **PCREASND** |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **|\_\_|\_\_|:|\_\_|\_\_|** | **PREDOSE** | **S01** | **€** Capillary plasma  **€** Venous plasma |  | **€** |  |
| **€** Whole blood [[108]](#footnote-107)  **€** Venous blood  **€** Capillary blood | **€** Dried  **€** Dried  **€** Dried |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **|\_\_|\_\_|:|\_\_|\_\_|** | **D1H6** | **S02** | **€** Capillary plasma  **€** Venous plasma |  | **€** |  |
| **€** Whole blood [[109]](#footnote-108)  **€** Venous blood  **€** Capillary blood | **€** Dried  **€** Dried  **€** Dried |

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| **APPENDIX D** | | | | | | | | | |
| **G6PD**  **LBTEST = Glucose-6-Phosphate\_Dehydrogenase[[110]](#footnote-109)**  **LB** | **Was a sample for G6PD testing taken? LBPERF[[111]](#footnote-110)** | | | | | | **€** Yes | **€** No | **€** NA[[112]](#footnote-111) |
| **Collection date**  **Collection time** | **Test category**  **LBMTHCAT** | **Test type**  **DIVAL where DIPARM=Device type** | **Trade name**  **DIVAL when DIPARM=Trade Name** | **Sample type**  **LBSPEC** | **Sample condition**  **LBSPCCND** | **Result**  **LBORRES** | **Units**  **LBORRESU** | **Not done**  **LBSTAT** | **Reason not done**  **LBREASND** |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **LBDAT LBDTC**  **|\_\_|\_\_|:|\_\_|\_\_|**  **LBTIM LBDTC** | **€** Qualitative | **€** Fluorescence spot test  **€** RDT  **€** Other |  | **€** Whole blood | **€** Dried | **€** Normal  **€** Deficient  **€** Invalid |  | **€** |  |
| Other specify |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** Quantitative | **€** Spectrophotometry  **€** Biosensor  **€** WST 8/1 assay  **€** Other |  | **€** Whole blood | **€** Dried | **|\_\_||\_\_|.|\_\_||\_\_|** | Per gram hemoglobin | **€** |  |
| Other specify |

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| **APPENDIX E** | | | | | | | |
| **CYP 2D6 GENOTYPING**[[113]](#footnote-112)  **PFCAT=GENETIC VARIATION PFSCAT=GENOTYPE**  **PF** | | | **Was CYP 2D6 Genotyping performed**?  **PFPERF** [[114]](#footnote-113) | | **€ Yes** | **€ No** | **€ NA[[115]](#footnote-114)** |
| **Test type**  **PFTEST** | **Gene location**  **PFGENLOC** | **Date of sample**  **PFDAT PFDTC** | **Sample type**  **PFSPEC** | **Sample condition**  **PFSPCCND** | **Not done**  **PFSTAT** | **Reason not done**  **PFREASND** | |
| Genotype | CYP 2D6 | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| | **€** Whole blood | **€** Dried | **€** |  | |

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| **APPENDIX F** | | | | | | | | |
| **ECG RECORDING** | | **Was the ECG recorded?**  **EGPERF [[116]](#footnote-115)** | | | **€ Yes** | | **€ No** | **€ NA[[117]](#footnote-116)** |
| **Date of ECG EGDAT EGDTC**  **Time of ECG EGTIM EGDTC** | **Method**  **EGMETHOD** | **Position**  **EGPOS** | | | **Not done**  **EGSTAT** | **Reason not done**  **EGREASND** | | |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | **€** 12 Lead standard  **12-LEAD STANDARD** | **€** Sitting **SITTING**  **€** Standing **STANDING**  **€** Supine **SUPINE** | | | **€** |  | | |
| **|\_\_|\_\_|:|\_\_|\_\_|** |
| **ECG TEST RESULTS** | | | | | | | | |
| **ECG test name**  **EGTEST** | **Results**  **EGORRES** | | **Units[[118]](#footnote-117)**  **EGORRESU** | **Not done**  **EGSTAT** | | **Reason not done**  **EGREASND** | | |
| **RR-interval** | **|\_\_|\_\_|\_\_|\_\_| RRMEAN\_EGORRES** | | MSEC | **€** | |  | | |
| **PR-interval** | **|\_\_|\_\_|\_\_| PRMEAN\_EGORRES** | | MSEC | **€** | |  | | |
| **QT-interval[[119]](#footnote-118)** | **|\_\_|\_\_|\_\_| QTMEAN\_EGORRES** | | MSEC | **€** | |  | | |
| **QRS-duration** | **|\_\_|\_\_|\_\_| QRSDUR\_EGORRES** | | MSEC | **€** | |  | | |

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| **APPENDIX G** | | | | | | | |
| **MEAL RECORD[[120]](#footnote-119)**  **ML** | **Was detailed meal record information collected**?  **MLPERF** [[121]](#footnote-120) | | | | **€ Yes** | **€ No** | **€ NA[[122]](#footnote-121)** |
| **Date of meal**  **MLDAT MLDTC** | **Start time**  **MLSTTIM**  **MLSTDTC** | **End time**  **MLENTIM**  **MLENDTC** | **Meal type**  **MLTRT** | **Amount consumed MLDOSTXT** | **Amount of fat (gms) FAORRES where FATEST = Amount of Fat and FAORRESU = g** | **Not done**  **MLSTAT** | **Reason not done**  **MLREASND** |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| | **|\_\_|\_\_|:|\_\_|\_\_|** | **|\_\_|\_\_|:|\_\_|\_\_|** | **€** Breakfast  **€** Lunch  **€** Dinner  **€** Snack | **€** Entire meal  **€** Three quarters to almost everything  **€** Half to three quarters  **€** Less than half |  | **€** |  |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| | **|\_\_|\_\_|:|\_\_|\_\_|** | **|\_\_|\_\_|:|\_\_|\_\_|** | **€** Breakfast  **€** Lunch  **€** Dinner  **€** Snack | **€** Entire meal  **€** Three quarters to almost everything  **€** Half to three quarters  **€** Less than half |  | **€** |  |

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| FOLLOW-UP ASSESSMENTS (AS PER PROTOCOL) | | | | | | | | | | |
| *Malaria symptoms at enrolment may be collected in different ways, the study protocol will guide the method of determining these and which symptoms are of interest; if a check list-type of symptoms enquiry is used the symptoms can be pre-specified as shown below. An alternative way to collect this information could be a log-type approach, where each symptom is recorded with a start and stop date and time, if the symptoms reoccur, an additional line on the log is added. Examples of these are included below (choose the one most appropriate for your study:* | | | | | | | | | | |
| VISIT 2 | | | | | | | | | | |
| MALARIA SYMPTOMS[[123]](#footnote-122) CLINICAL EVENTS (CECAT) | | | | | | | | | | |
| **Did the subject have any of the following symptoms[[124]](#footnote-123) since the last visit? CEYN[[125]](#footnote-124)** | | | | | | | **€ Yes** | | **€ No** | |
| **Symptom**  **CETERM** | **Yes** | **No** | **Not done**  **CESTAT** | **Reason not done**  **CEREASND** | **Start date CESTDAT CESTDTC**  **Start time[[126]](#footnote-125) CESTTIM CESTDTC** | **End date CEENDAT CEENDTC**  **End time**33 **CEENTIM CEENDTC** | **Greatest severity (highest intensity)**  **CESEV** | | | |
| **CEOCCUR** | | **DD-MMM-YYYY** | HH:MM |
| Fever | **€** | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **|\_\_|\_\_|:|\_\_|\_\_|** | **€** Mild | **€** Moderate | | **€** Severe |
| Chills | **€** | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | **€** Mild | **€** Moderate | | **€** Severe |
| Malaise[[127]](#footnote-126) | **€** | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | **€** Mild | **€** Moderate | | **€** Severe |
| Fatigue[[128]](#footnote-127) | **€** | **€** | **€** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | **€** Mild | **€** Moderate | | **€** Severe |

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| Muscle pain | **€** | | **€** | **€** |  | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | | **€** Mild | | **€** Moderate | | **€** Severe |
| Joint pain | **€** | | **€** | **€** |  | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | | **€** Mild | | **€** Moderate | | **€** Severe |
| Headache | **€** | | **€** | **€** |  | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | | **€** Mild | | **€** Moderate | | **€** Severe |
| Irritability[[129]](#footnote-128) | **€** | | **€** | **€** |  | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | | **€** Mild | | **€** Moderate | | **€** Severe |
| Nausea | **€** | | **€** | **€** |  | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | | **€** Mild | | **€** Moderate | | **€** Severe |
| Vomiting | **€** | | **€** | **€** |  | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | | **€** Mild | | **€** Moderate | | **€** Severe |
| Diarrhea | **€** | | **€** | **€** |  | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | | **€** Mild | | **€** Moderate | | **€** Severe |
| Abdominal pain | **€** | | **€** | **€** |  | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | | **€** Mild | | **€** Moderate | | **€** Severe |
| Loss of appetite | **€** | | **€** | **€** |  | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | | **€** Mild | | **€** Moderate | | **€** Severe |
| Shortness of breath | **€** | | **€** | **€** |  | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | | **€** Mild | | **€** Moderate | | **€** Severe |
| Dizziness | **€** | | **€** | **€** |  | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | | **€** Mild | | **€** Moderate | | **€** Severe |
| Other | **€** | | **€** | **€** |  | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  |\_\_|\_\_|:|\_\_|\_\_| | | | **€** Mild | | **€** Moderate | | **€** Severe |
| If yes, other symptom describe **MHTERMOTH** | | | | |  | | | | | | | | | | | |
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| DAY 1/VISIT 2… | | | | | | | | | | | | | | | | | | |
| CLINICAL EVENTS – MALARIA SYMPTOMS LOG[[130]](#footnote-129) CECAT = MALARIA SYMPTOMS | | | | | | | | | | | | | | | | | | |
| **Did the subject have any of the following symptoms since the last visit[[131]](#footnote-130) days? CEYN[[132]](#footnote-131)** | | | | | | | | | | | | | | **€ Yes[[133]](#footnote-132)** | | **€ No** | | |
| **Symptom[[134]](#footnote-133)**  **CETERM** | | | **Start date**  **CESTDAT CESTDTC** | | | | **Start time**  **CESTTIM CESTDTC** | | **End date**  **CEENDAT CEENDTC** | | **End time**  **CESTTIM CEENDTC** | **Greatest severity (highest intensity) CESEV** | | | | | | |
|  | | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | | | | **|\_\_|\_\_|:|\_\_|\_\_|** | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| | | **|\_\_|\_\_|:|\_\_|\_\_|** | **€** Mild | | **€** Moderate | | **€** Severe | | |
|  | | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | | | | **|\_\_|\_\_|:|\_\_|\_\_|** | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| | | **|\_\_|\_\_|:|\_\_|\_\_|** | **€** Mild | | **€** Moderate | | **€** Severe | | |
|  | | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** | | | | **|\_\_|\_\_|:|\_\_|\_\_|** | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| | | **|\_\_|\_\_|:|\_\_|\_\_|** | **€** Mild | | **€** Moderate | | **€** Severe | | |

**FOOTNOTES**

1. Day 0 (D0) is traditionally the day the participant is enrolled in the study and the first dose of medication is administered, referred to as VISIT 1 in SDTM and in the CRF for consistency and to conform to CDISC data standards [↑](#footnote-ref-1)
2. Optional, include if specified in the study protocol [↑](#footnote-ref-2)
3. To be repeated at follow-up assessments [↑](#footnote-ref-3)
4. Include known liver disease and hepatitis status if specified in the study protocol [↑](#footnote-ref-4)
5. WHO recommended follow-up days: D0, D1, D2, D3, D7, D14, D21, D28, D35 and D42/D63; these follow-up days will be represented as visits starting at VISIT 1 [↑](#footnote-ref-5)
6. WHO recommend a minimum duration of follow-up of 28 days for antimalarial drugs with an elimination half-life of < 7 days and 42/63 days for antimalarial drugs with an elimination half-life > 7 days [↑](#footnote-ref-6)
7. *Plasmodium* [↑](#footnote-ref-7)
8. Visit date pertains to all information collected on day of enrolment / visit 1 [↑](#footnote-ref-8)
9. All dates to be recorded as DD-MMM-YYYY [↑](#footnote-ref-9)
10. All times to be recorded as 24-hour clock HH:MM [↑](#footnote-ref-10)
11. The Trial Exclusion (TI) dataset will contain all the inclusion and exclusion criteria for the trial, and will not be included in the subject-level data on inclusion and exclusion criteria. The IE domain, [refer to Section 6.3 - IE Domain] contains records only for inclusion and exclusion criteria that subjects did not meet. [↑](#footnote-ref-11)
12. Confirmed by positive blood smear [↑](#footnote-ref-12)
13. Shaded areas are **exclusion** criteria [↑](#footnote-ref-13)
14. The study protocol could specify exclusion of known severe concomitant disease [↑](#footnote-ref-14)
15. |  |  |
    | --- | --- |
    | **FEATURES OF SEVERE MALARIA** | |
    | **Clinical manifestations** | Impaired consciousness |
    | Prostration |
    | Multiple convulsions |
    | Respiratory distress (metabolic acidotic) |
    | Circulatory collapse |
    | Jaundice |
    | Hemoglobinurea |
    | Abnormal bleeding |
    | Pulmonary edema (radiological) |
    | **Laboratory findings** | Hypoglycaemia (blood glucose <2.2 mmol/l or <40 mg/dl |
    | Acidosis (plasma bicarbonate <15 mmol/l) |
    | Severe anemia (Hb < 5g/dl or haematocrit <15%) |
    | Hyperparasitemia (>4% in non-immune patients) |
    | Hyperlactatemia (venous lactic acid >5 mmol/l) |
    | Renal impairment (serum creatinine above normal range for age) |

    [↑](#endnote-ref-1)
16. The study protocol will state the required exclusion duration of days for previous antimalarial treatment. Note that antimalarials with a long half-life, such as piperaquine, should not have been taken in the last 2 months [↑](#footnote-ref-15)
17. Date AND time of Informed Consent is expected in the DM and IC domains, hence the two annotations [↑](#footnote-ref-16)
18. For data management, not for inclusion in SDTM [↑](#footnote-ref-17)
19. If the actual date is unknown use 99 or 999 as a place holder for ANY day and month [↑](#footnote-ref-18)
20. Only record age if DOB unknown, if child aged less than 5 years record in months, if older than 5 years record in years [↑](#footnote-ref-19)
21. The CDASH variable CRACE (Collected Race) is used in addition to the variable RACE (Race) when more detailed race categorizations are desired (e.g., use of race designations other than those used by the FDA). For additional guidance using this variable please refer to the CDASHIG v2.0 and the SDTMIG v3.2. [↑](#footnote-ref-20)
22. If indicated [↑](#footnote-ref-21)
23. UNK = unknown [↑](#footnote-ref-22)
24. NA = not applicable [↑](#footnote-ref-23)
25. Ht = height [↑](#footnote-ref-24)
26. LMP=Last Menstrual Period [↑](#footnote-ref-25)
27. Record if indicated; if applicable please record ARVs and other concomitant medication such as co-trimoxazole in the conmeds section [↑](#footnote-ref-26)
28. If HIV status is checked “self-reported”, include in the MH domain [↑](#footnote-ref-27)
29. If HIV status is determined by laboratory test, include in the LB domain [↑](#footnote-ref-28)
30. UNK = unknown [↑](#footnote-ref-29)
31. Worsening of symptoms, or new symptom, after enrolment must be recorded as an AE in the usual manner [↑](#footnote-ref-30)
32. Medical history to include will be specified in the protocol [↑](#footnote-ref-31)
33. For data management, not for inclusion in SDTM [↑](#footnote-ref-32)
34. The requirement to collect start and end times of malaria symptoms will be defined in the study protocol, and for medical history will most probably not be known, include if relevant. [↑](#footnote-ref-33)
35. A general feeling of discomfort, illness, or lack of well-being [↑](#footnote-ref-34)
36. Unusual weakness and tiredness [↑](#footnote-ref-35)
37. Applicable to children [↑](#footnote-ref-36)
38. Worsening of symptoms must be recorded as an adverse event [↑](#footnote-ref-37)
39. Medical history to include will be specified in the protocol [↑](#footnote-ref-38)
40. For data management, not for inclusion in SDTM [↑](#footnote-ref-39)
41. If the subject presented at enrolment with or developed any malaria symptoms during the study, record each symptom on a row in the log above including the start date and time; if a symptom resolves record the end date and time. If the symptoms reoccur enter the symptom on an additional row. [↑](#footnote-ref-40)
42. Malaria symptoms might include: Fever, Chills, Muscle or Joint Pain, Headache, Irritability, Nausea, Vomiting, Diarrhoea, Abdominal pain, Loss of appetite, Shortness of breath, Dizziness ETC. [↑](#footnote-ref-41)
43. Medical history past duration will be specified in the study protocol [↑](#footnote-ref-42)
44. For data management, not for inclusion in SDTM [↑](#footnote-ref-43)
45. If the actual date is unknown use 99 or 999 as a place holder for ANY day and month [↑](#footnote-ref-44)
46. For data management, not for inclusion in SDTM [↑](#footnote-ref-45)
47. Previous medication duration will be specified in the study protocol [↑](#footnote-ref-46)
48. For data management, not for inclusion in SDTM [↑](#footnote-ref-47)
49. If vital signs are not available (such as weight and height measurements), check the “not done” box and record reason not done [↑](#footnote-ref-48)
50. The units of measure are an example, the protocol will specify which units the vital signs are to be recorded in [↑](#footnote-ref-49)
51. The method (including site) of recording temperature will be specified in the protocol [↑](#footnote-ref-50)
52. If abnormalities are found at enrolment, record as medical history at the start of the study; if new abnormalities are found on follow up days, record as adverse events (or treatment failure if signs of severe malaria) [↑](#footnote-ref-51)
53. For data management, not for inclusion in SDTM [↑](#footnote-ref-52)
54. Including JACCOL (Jaundice, Anemia, Clubbing, Cyanosis, Edema, Lymphadenophy) [↑](#footnote-ref-53)
55. Head, eyes, ears, nose and throat [↑](#footnote-ref-54)
56. For data management, not for inclusion in SDTM [↑](#footnote-ref-55)
57. NA = not applicable (not required for this study protocol) [↑](#footnote-ref-56)
58. For studies that require the slide to be read by more than one microscopist, include a separate row for the results from each reader. See [Malaria Microscopy Guidelines](http://www.wwarn.org/tools-resources/procedures/microscopy-detection-identification-and-quantification-malaria-parasites) [↑](#footnote-ref-57)
59. Complete a separate row for smears showing both asexual and sexual parasites. Adapt if additional information on the staging of the asexual parasite may be required by the study protocol; e.g. Rings, Trophozoites, Schizonts [↑](#footnote-ref-58)
60. In SDTM the malaria species and parasite type will be concatenated (linked together) and represented in MBTESTCD/TEST [↑](#footnote-ref-59)
61. Record the actual parasite count; see TAUG-malaria for additional information on then calculating parasite density. [↑](#footnote-ref-60)
62. The preferred method of calculating parasite density uses actual WBC/uL; some study protocols may specify assuming (xxx) WBC/uL; see TAUG-malaria for additional information. [↑](#footnote-ref-61)
63. In cases of mixed infections, all infecting species must be reported; however, the asexual and/or sexual parasite count need not be reported separately for each species unless specifically required in the study protocol. If species are reported separately, counts for each species must be entered on separate lines. Asexual and sexual stages from the same slide/parasite species also must be entered on separate lines. [↑](#footnote-ref-62)
64. Record each dose of study medication given; add a row for each treatment administered including if re-administration after vomiting [↑](#footnote-ref-63)
65. If study drug is interrupted due to rescue treatment, record in disposition event [↑](#footnote-ref-64)
66. The mg amount per tablet will be specified in the protocol and included in SDTM [↑](#footnote-ref-65)
67. Amount of fat to be taken with dose administration, or meal type (e.g. Fatty meal) will be specified in the protocol and included in SDTM [↑](#footnote-ref-66)
68. The time specified in the protocol which will determine if the subject should be re-dosed [↑](#footnote-ref-67)
69. The laboratory tests and units shown above are an example, use the laboratory tests and units specified in the protocol [↑](#footnote-ref-68)
70. For data management, not for inclusion in SDTM [↑](#footnote-ref-69)
71. NA = not applicable (not required for this study protocol) [↑](#footnote-ref-70)
72. The units of measure are an example, the protocol will specify which unit’s laboratory values to be recorded in [↑](#footnote-ref-71)
73. For data management, not for inclusion in SDTM [↑](#footnote-ref-72)
74. NA = not applicable (not required for this study protocol) [↑](#footnote-ref-73)
75. The units of measure are an example, the protocol will specify which unit’s laboratory values to be recorded in [↑](#footnote-ref-74)
76. For data management, not for inclusion in SDTM [↑](#footnote-ref-75)
77. NA = not applicable (not required for this study protocol) [↑](#footnote-ref-76)
78. For data management, not for inclusion in SDTM [↑](#footnote-ref-77)
79. For data management, not for inclusion in SDTM [↑](#footnote-ref-78)
80. Complete SAE CRF [↑](#footnote-ref-79)
81. IP = investigational product, specify which drug the adverse event is related to if applicable [↑](#footnote-ref-80)
82. If the AE resulted in a treatment administered, please record in the concomitant medication section [↑](#footnote-ref-81)
83. If classified as serious, please complete a SAE CRF [↑](#footnote-ref-82)
84. If SAE is fatal, date of death will be the same as end date of AE [↑](#footnote-ref-83)
85. The period for reporting concomitant medications will be specified in the protocol [↑](#footnote-ref-84)
86. List any prescription/non-prescription/traditional meds, vitamins, herbal/dietary supplements, or vaccinations given, if none were given check No for “Was any medication given?” [↑](#footnote-ref-85)
87. If concomitant medications were given, enter full trade or generic names [↑](#footnote-ref-86)
88. PO=oral; IV=intravenous; IM=intramuscular; SC=sub-cutaneous; Top=topical; PR=rectal [↑](#footnote-ref-87)
89. The study protocol will specify the duration of follow-up required for the study [↑](#footnote-ref-88)
90. See TAUG-malaria for details of PCR corrected, uncorrected [↑](#footnote-ref-89)
91. The method of genotyping, gene loci, family and results will be a direct upload as an excel/csv file from the laboratory responsible for the molecular genotyping assays [↑](#footnote-ref-90)
92. For data management, not for inclusion in SDTM [↑](#footnote-ref-91)
93. NA = not applicable (not required for this study protocol) [↑](#footnote-ref-92)
94. For GLURP, there are no families so only record base pair result [↑](#footnote-ref-93)
95. Multiple amplicons observed for the same family/marker should be recorded separated by commas. E.g. if 3 amplicons of size 250, 300, 400 bp are seen for *MSP1*-K1, enter 250, 300, 400 [↑](#footnote-ref-94)
96. Bp=base pairs (Fragment/amplification size) [↑](#footnote-ref-95)
97. Includes missing sample, failed amplification or indeterminate PCR [↑](#footnote-ref-96)
98. A range of molecular markers are used to differentiate homologous from heterologous infections, and to define the multiplicity of infection, including surface proteins (e.g. **MSP1-F3**; MSP1-F1; MSP3α; MSP4; MSP5) and microsatellites (e.g. **MS16; Pv 3.27;** Pv 1.501; Pv 3.502; MS007; MS008; MS038; MS2; MS6, with those most frequently reported highlighted in bold. Nomenclature in *P. vivax* surface proteins (e.g. MSP1-F3) describes the gene (e.g. MSP1) and sometimes the domain (e.g. F3), while nomenclature of microsatellite markers includes either a MS number (e.g. MS16) or indicates a coordinate on a given *P. vivax* gene (e.g. Pv 3.37). The selection and number of *loci* assayed depends on their baseline variability in that study population. Most requiring fragment lengths at >3 loci or all loci to be identical to define samples as homologous, which could represent either a recrudescence or relapse of that *P. vivax* infection [↑](#footnote-ref-97)
99. The method of genotyping, gene *loci*, family and results will be a direct upload as an excel/csv file from the laboratory responsible for the molecular genotyping assays [↑](#footnote-ref-98)
100. For data management, not for inclusion in SDTM [↑](#footnote-ref-99)
101. NA = not applicable (not required for this study protocol) [↑](#footnote-ref-100)
102. Bp=base pairs (Fragment/amplification size) [↑](#footnote-ref-101)
103. The analyte name, drug concentration results and units of measure will be a direct upload as an excel/csv file from the pharmacology laboratory responsible for these assays [↑](#footnote-ref-102)
104. For data management, not for inclusion in SDTM [↑](#footnote-ref-103)
105. NA = not applicable (not required for this study protocol) [↑](#footnote-ref-104)
106. The specific time-points will be documented in the protocol [↑](#footnote-ref-105)
107. Pharmacology laboratory responsible for the drug concentration assays will specify how they will link the results to the clinical data [↑](#footnote-ref-106)
108. If the blood sample, either whole blood, venous or capillary on filter paper, check sample type and dried for sample condition [↑](#footnote-ref-107)
109. If the blood sample, either whole blood, venous or capillary on filter paper, check sample type and dried for sample condition [↑](#footnote-ref-108)
110. Manufacturer, batch number and trade name will be specified in the study protocol and included in SDTM [↑](#footnote-ref-109)
111. For data management, not for inclusion in SDTM [↑](#footnote-ref-110)
112. NA = not applicable (not required for this study protocol) [↑](#footnote-ref-111)
113. The method of genotyping, gene *loci* and results will be a direct upload as an excel/csv file from the laboratory responsible for the CYP 2D6 genotype assays [↑](#footnote-ref-112)
114. For data management, not for inclusion in SDTM [↑](#footnote-ref-113)
115. NA = not applicable (not required for this study protocol) [↑](#footnote-ref-114)
116. For data management, not for inclusion in SDTM [↑](#footnote-ref-115)
117. NA = not applicable (not required for this study protocol) [↑](#footnote-ref-116)
118. The units of measure are an example, the protocol will specify which unit’s the ECG parameters are to be recorded in [↑](#footnote-ref-117)
119. The study protocol may require a calculated adjustment for the QT interval, this will be generated in the analysis, and the corrected result and method of correcting included in the ADaM dataset [↑](#footnote-ref-118)
120. Record a separate row for each meal [↑](#footnote-ref-119)
121. For data management, not for inclusion in SDTM [↑](#footnote-ref-120)
122. NA = not applicable (not required for this study protocol) [↑](#footnote-ref-121)
123. Worsening of symptoms, or new symptom, after enrolment must be recorded as an AE in the usual manner [↑](#footnote-ref-122)
124. Medical history to include will be specified in the protocol [↑](#footnote-ref-123)
125. For data management, not for inclusion in SDTM [↑](#footnote-ref-124)
126. The requirement to collect start and end times of malaria symptoms will be defined in the study protocol, and for medical history will most probably not be known, include if relevant. [↑](#footnote-ref-125)
127. A general feeling of discomfort, illness, or lack of well-being [↑](#footnote-ref-126)
128. Unusual weakness and tiredness [↑](#footnote-ref-127)
129. Applicable to children [↑](#footnote-ref-128)
130. Worsening of symptoms must be recorded as an AE [↑](#footnote-ref-129)
131. Malaria symptoms to include will be specified in the protocol [↑](#footnote-ref-130)
132. For data management, not for inclusion in SDTM [↑](#footnote-ref-131)
133. If the subject presented at enrolment with or developed any malaria symptoms during the study, record each symptom on a row in the log above including the start date and time; if a symptom resolves record the end date and time. If the symptoms reoccur enter the symptom on an additional row. [↑](#footnote-ref-132)
134. Malaria symptoms might include: Fever, Chills, Muscle or Joint Pain, Headache, Irritability, Nausea, Vomiting, Diarrhoea, Abdominal pain, Loss of appetite, Shortness of breath, Dizziness etc. [↑](#footnote-ref-133)