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| **A. GENERAL STUDY INFORMATION** |
| **Study title:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Protocol and version number:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Principal Investigator:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Country of study:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Target sample size:** \_\_\_ (*P. falciparum*) \_\_\_ (*P. vivax*) |
| **Ethical approval:** [ ]  Yes [ ]  No [ ]  Initiated |
| If Yes, provide ethical approval ID number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Clinical trial registry:** [ ]  Yes [ ]  No [ ]  Initiated |
| If Yes, provide clinical trial registry ID number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Study dates:** mmm-yyyy to mmm-yyyy |
| **Sponsor:** Ministry of Health, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Site Monitor name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  | [ ]  Internal [ ]  External |
| If Site Monitor is External:  |
| [ ]  Sponsor staff member/consultant or [ ]  WHO staff member/consultant  |
| Please provide affiliation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **STUDY SITES** |
| **Site Name** | **Drug** | **Hospital** | **Community-based** | **Health centre** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |

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| Comments (if needed):  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **B. SITE SPECIFIC INFORMATION** |
| **Site name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  | **Was the site visited?** [ ]  Yes [ ]  No |
| If Yes, indicate date of visit: dd-mmm-yyyy |
| **Name of site focal person:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **1. SITE STAFF** |
| **Name** | **Qualifications** | **Role** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| **2. TRAINING** - Indicate whether the staff have received training on: | **Yes** | **No** | **N/A** |
| **1** | Protocol requirements: target population and sample size, inclusion and exclusion criteria, definition of severe malaria, follow-up procedure, classification of outcome | [ ]  | [ ]  | [ ]  |
| **2** | Ethical requirements and confidentiality | [ ]  | [ ]  | [ ]  |
| **3** | Clinical assessment: physical examination, temperature, weight, height | [ ]  | [ ]  | [ ]  |
| **4** | Test medicine and rescue medicines: dosage and administration | [ ]  | [ ]  | [ ]  |
| **5** | Test medicine and rescue medicines: handling and storage | [ ]  | [ ]  | [ ]  |
| **6** | List of medications that should not be used during the study period  | [ ]  | [ ]  | [ ]  |
| **7** | Completing the screening form, case report forms, logbooks | [ ]  | [ ]  | [ ]  |
| **8** | Microscopy procedures | [ ]  | [ ]  | [ ]  |
| **9** | Other laboratory procedures (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  | [ ]  |
| **10** | Collection, handling and storage of blood slides | [ ]  | [ ]  | [ ]  |
| **11** | Collection, handling and storage of biological samples | [ ]  | [ ]  | [ ]  |
| **12** | Data entry procedures and analysis | [ ]  | [ ]  | [ ]  |
| **13** | Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |

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| **3. SITE FACILITIES** – Indicate whether or not the following facilities exist at the site: | **Yes** | **No** | **N/A** |
| **1** | Clinical examination room |[ ] [ ] [ ]
| **2** | General laboratory | [ ]  | [ ]  | [ ]  |
| **3** | Molecular biology laboratory | [ ]  | [ ]  | [ ]  |
| **4** | Pharmacy or medical store  | [ ]  | [ ]  | [ ]  |
|  | If no pharmacy or medical store available, describe handling and storage of medicines: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |
| **5** | Office space for data management |[ ] [ ] [ ]
| **6** | Is transportation available for patient follow-up? |[ ] [ ] [ ]
|  | [ ] Public transportation |  |  |  |
|  | [ ] Private car |  |  |  |
|  | [ ] Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |

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| **4. STUDY DOCUMENTS** –Are the following essential study documents available at the study site? | **Yes** | **No** | **N/A** |
| **1** | Approved protocol and amendments, if any | [ ]  | [ ]  | [ ]  |
| **2** | Approved informed consent and assent forms | [ ]  | [ ]  | [ ]  |
| **3** | Approved translation of informed consent and assent forms | [ ]  | [ ]  | [ ]  |
| **4** | Letters of approval from ethical committees | [ ]  | [ ]  | [ ]  |
| **5** | Screening forms/screening logbook | [ ]  | [ ]  | [ ]  |
| **6** | Case report forms/enrolment logbook | [ ]  | [ ]  | [ ]  |
| **7** | Serious adverse event forms | [ ]  | [ ]  | [ ]  |
| **8** | Laboratory register | [ ]  | [ ]  | [ ]  |
| **9** | Drug inventory log/registry/form | [ ]  | [ ]  | [ ]  |
| **10** | Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |

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| **5. RESOURCES, MATERIAL AND SUPPLIES** **(CLINICAL)** – Are facilities, material and supplies for clinical assessments available and in good working order? | **Yes** | **No** | **N/A** |
| **1** | Clinical examination room (space, cleanliness) | [ ]  | [ ]  | [ ]  |
| **2** | Stethoscopes | [ ]  | [ ]  | [ ]  |
| **3** | Scale for children (calibrated) | [ ]  | [ ]  | [ ]  |
| **4** | Scale for adults (calibrated) | [ ]  | [ ]  | [ ]  |
| **5** | Thermometers (mercury or digital) and battery if electronic thermometer (calibrated) | [ ]  | [ ]  | [ ]  |
| **6** | Medicines for the study including rescue treatment (see 6. Drug inventory) | [ ]  | [ ]  | [ ]  |
| **7** | Syringes 2 ml, 5 ml and needles | [ ]  | [ ]  | [ ]  |
| **8** | Sphygmomanometer (blood pressure monitor) | [ ]  | [ ]  | [ ]  |
| **9** | Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |

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| **6. Drug inventory** |
|  |  | **Formulation** | **Expiry date** | **Adequate quantity** | **Storage<30°C** |
|  | **Antimalarials** |  |  | **Yes** | **No** | **Yes** | **No** |
| **1** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
| **2** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
| **3** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
|  | **Antipyretics** |  |  |  |  |  |  |
| **4** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
| **5** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
| **6** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
|  | **Rescue treatment** |  |  |  |  |  |  |
| **7** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
| **8** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
|  | **Other medications** |  |  |  |  |  |  |
| **9** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |
| **10** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | mmm-yy | [ ]  | [ ]  | [ ]  | [ ]  |

| **7. Resources, material and supplies (laboratory)** – Are facilities, material and supplies for laboratory assessments available and in good working order? | **Yes** | **No** | **N/A** |
| --- | --- | --- | --- |
| **1** | Laboratory facility room (electrical power, sink and running water) | [ ]  | [ ]  | [ ]  |
| **2** | Work bench and stool/chair | [ ]  | [ ]  | [ ]  |
| **3** | Microscopes and eye pieces | [ ]  | [ ]  | [ ]  |
| **4** | Spare microscope light bulbs | [ ]  | [ ]  | [ ]  |
| **5** | Slides | [ ]  | [ ]  | [ ]  |
| **6** | Permanent glass pen or pencils for frosted-edge slides | [ ]  | [ ]  | [ ]  |
| **7** | Slide storage boxes (vertical or horizontal) | [ ]  | [ ]  | [ ]  |
| **8** | Immersion oil  | [ ]  | [ ]  | [ ]  |
| **9** | Lancets | [ ]  | [ ]  | [ ]  |
| **10** | Laboratory timer | [ ]  | [ ]  | [ ]  |
| **11** | Consumables (alcohol, swabs, cotton wool) | [ ]  | [ ]  | [ ]  |
| **12** | Biosafety (rubber gloves, protective clothes, sharp disposal box) | [ ]  | [ ]  | [ ]  |
| **13** | Hand tally counters (at least 2) | [ ]  | [ ]  | [ ]  |
| **14** | Giemsa | [ ]  | [ ]  | [ ]  |
| **15** | Distilled water and buffer solution/tablets | [ ]  | [ ]  | [ ]  |
| **16** | pH meter | [ ]  | [ ]  | [ ]  |
| **17** | Methanol | [ ]  | [ ]  | [ ]  |
| **18** | Drying rack | [ ]  | [ ]  | [ ]  |
| **19** | Measuring cylinders 10 ml and 500 ml | [ ]  | [ ]  | [ ]  |
| **20** | Funnel | [ ]  | [ ]  | [ ]  |
| **21** | Staining jar Coplin or horizontal | [ ]  | [ ]  | [ ]  |
| **22** | Pipettes and pipettes fillers | [ ]  | [ ]  | [ ]  |
| **23** | Bottles and bottle screw-caps 500 ml | [ ]  | [ ]  | [ ]  |
| **24** | Forceps | [ ]  | [ ]  | [ ]  |
| **25** | Dropping bottle | [ ]  | [ ]  | [ ]  |
| **26** | Glass rod | [ ]  | [ ]  | [ ]  |
| **27** | Filter paper for PCR | [ ]  | [ ]  | [ ]  |
| **28** | Plastic bags, desiccant and labels | [ ]  | [ ]  | [ ]  |
| **29** | Absorbent tissue to clean the slides | [ ]  | [ ]  | [ ]  |
| **30** | Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |

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| **C. STUDY SPECIFIC INFORMATION** |
| **8. ETHICS** | **Yes** | **No** | **N/A** |
| **1** | Were there any changes to the protocol? | [ ]  | [ ]  | [ ]  |
| **2** | If yes, have the changes been approved by the Institutional Review Board? | [ ]  | [ ]  | [ ]  |
| **3** | Is informed consent always obtained prior to enrolment?  | [ ]  | [ ]  | [ ]  |
| **4** | Is the informed consent form always signed or thumb-printed, and dated by each subject? | [ ]  | [ ]  | [ ]  |
| **5** | Is the informed assent form, used for minor participants over 12 years of age, always signed or thumb-printed, and dated, where applicable? | [ ]  | [ ]  | [ ]  |
| **6** | Is the informed consent form for illiterate subjects always signed or thumb-printed, and dated, by an impartial witness? | [ ]  | [ ]  | [ ]  |
| **7** | Is consent obtained for pregnancy testing, when applicable? | [ ]  | [ ]  | [ ]  |

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| **9. PATIENT RECRUITMENT AND FOLLOW-UP** |
| Date of recruitment of the first patient: dd-mmm-yyyy |
|  | ***P. falciparum*** | ***P. vivax* (if applicable)** |
| **1** | Number of patients screened (total) | \_\_\_ | \_\_\_ |
| **2** | Number of patients enrolled (treated) | \_\_\_ | \_\_\_ |
| **3** | Number of patients that completed last scheduled visit | \_\_\_ | \_\_\_ |
| **4** | Number of patients lost to follow-up | \_\_\_ | \_\_\_ |
| **5** | Number of patients withdrawn (other than lost to follow-up) | \_\_\_ | \_\_\_ |
| **6** | Target sample size | \_\_\_ | \_\_\_ |
| **7** | Is it likely that the target sample size will be achieved? | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| **8** | Was the screening log checked to review the reasons for non-inclusion? | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |

| **10. PROTOCOL COMPLIANCE AND CASE RECORD FORM (CRF)**  | **Yes** | **No** | **N/A** |
| --- | --- | --- | --- |
| **1** | Are all CRFs complete and available? | [ ]  | [ ]  | [ ]  |
| **2** | Are the CRFs checked against source documents (screening log book, enrolment log book, laboratory register)? | [ ]  | [ ]  | [ ]  |
| **3** | Are the patients’ ID numbers and the visit dates correctly recorded? | [ ]  | [ ]  | [ ]  |
| **4** | Are there any protocol violations (i.e. erroneous inclusion, use of drug with antimalarial activity, missed visits, infection with another species)? | [ ]  | [ ]  | [ ]  |
| **5** | If yes, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |
| **6** | Is the date of birth (or age) always recorded? | [ ]  | [ ]  | [ ]  |
| **7** | Are the parasite densities at enrolment within the range of the inclusion criteria set in the protocol? | [ ]  | [ ]  | [ ]  |
| **8** | Are pregnancy tests performed at enrolment (where applicable)? | [ ]  | [ ]  | [ ]  |
| **9** | Do the study visit dates occur in accordance with the visit calendar? | [ ]  | [ ]  | [ ]  |
| **10** | Are the values for body temperature within the appropriate range (>36°C and <42°C)?  | [ ]  | [ ]  | [ ]  |
| **11** | Is the temperature value recorded to one decimal point? | [ ]  | [ ]  | [ ]  |
| **12** | Are the study drug doses administered according to the dosing chart? | [ ]  | [ ]  | [ ]  |
| **13** | Are all doses administered under supervision? | [ ]  | [ ]  | [ ]  |
| **14** | Are blood smears and blood spots for filter papers collected according to protocol?  | [ ]  | [ ]  | [ ]  |
| **15** | Are all blood smears and filter paper samples correctly labelled? | [ ]  | [ ]  | [ ]  |
| **16** | Do the dates in the CRFs match the corresponding dates on the blood smears and filter papers?  | [ ]  | [ ]  | [ ]  |
| **17** | Are adverse events captured and recorded? | [ ]  | [ ]  | [ ]  |
| **18** | Is the use of concomitant medications captured and recorded? | [ ]  | [ ]  | [ ]  |
| **19** | Were there any severe adverse events (SAE)? | [ ]  | [ ]  | [ ]  |
| **20** | If yes, was the SAE form completed (Appendix 8)? | [ ]  | [ ]  | [ ]  |
| **21** | If yes, was the sponsor/WHO/pharmaceutical company notified? | [ ]  | [ ]  | [ ]  |
| **22** | Are the outcome classifications adequate clinical and parasitological response, early treatment failure, late clinical failure and late parasitological failure) accurate for each patient? | [ ]  | [ ]  | [ ]  |
| **23** | In case of treatment failure, is the correct rescue medication (and appropriate dose) given according to protocol? | [ ]  | [ ]  | [ ]  |
| **24** | Are patients withdrawn according to protocol? | [ ]  | [ ]  | [ ]  |
| **25** | Are the reasons for withdrawal provided in the CRF? | [ ]  | [ ]  | [ ]  |
| **26** | Is the drug dispensing log/registry, or any other form of drug inventory record, up to date and accurate? | [ ]  | [ ]  | [ ]  |
| **27** | How many CRFs were checked during this visit? \_\_\_\_  |  |  |  |
| **28** | What percentage of the total patients enrolled does this represent? \_\_\_\_% |  |  |  |
| **29** | Was this a random sample? | [ ]  | [ ]  | [ ]  |
| **30** | Are all of the errors in the CRFs identified, recorded and corrected? | [ ]  | [ ]  | [ ]  |
| **31** | Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |

| **11. LABORATORY AND MICROSCOPY** | **Yes** | **No** | **N/A** |
| --- | --- | --- | --- |
| **1** | Is Giemsa solution correctly prepared daily? | [ ]  | [ ]  | [ ]  |
| **2** | Is the quality of blood smear staining acceptable? | [ ]  | [ ]  | [ ]  |
| **3** | Are slides kept in a slide box and stored properly? | [ ]  | [ ]  | [ ]  |
| **4** | Are any blood smears missing for any patient? | [ ]  | [ ]  | [ ]  |
| **5** | Are parasites counted as per protocol? | [ ]  | [ ]  | [ ]  |
| **6** | Is there a separate microscopy logbook for microscopist 1 and 2? | [ ]  | [ ]  | [ ]  |
| **7** | Are the final parasite counts an average of the 1st and 2nd reading? | [ ]  | [ ]  | [ ]  |
| **8** | Are blood smears read and quality controlled in accordance with the protocol (1st and 2nd readings and 3rd if needed)? | [ ]  | [ ]  | [ ]  |
| **9** | Do the parasite counts from the log/registry match the values in the CRF? | [ ]  | [ ]  | [ ]  |
| **10** | Is there an adequate supply of high quality filter-paper? | [ ]  | [ ]  | [ ]  |
| **11** | Are filter-papers properly stored, protected from light, humidity and extreme temperatures? | [ ]  | [ ]  | [ ]  |
| **12** | Are biosafety procedures followed for blood sampling? | [ ]  | [ ]  | [ ]  |
| **13** | Is the site performing any optional assessments (haematology, urine screen, G6PD, drug blood concentration sampling)? | [ ]  | [ ]  | [ ]  |
| **14** | If yes, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |
| **15** | Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |

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| **12. DATA ENTRY** | **Yes** | **No** | **N/A** |
| **1** | Is the WHO data entry excel sheet for TES being used? | [ ]  | [ ]  | [ ]  |
| **2** | Is the CRF data entered by two different individuals?  | [ ]  | [ ]  | [ ]  |
| **3** | Are data entry errors identified? | [ ]  | [ ]  | [ ]  |

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| **D. CONCLUSIONS** |
| **13. COMMENTS** –In particular please comment on items from shaded or “N/A” check boxes. Please include the item number. |
| **Item** | **Comment** |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
| **14. ACTION ITEMS** |
| **Item** | **Action required** | **Person responsible** | **Due date** |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |

| **15. FOLLOW-UP ITEMS FROM LAST VISIT (IF APPLICABLE)**  |
| --- |
| **Date of last visit:** dd-mmm-yyyy |
| **Item** | **Action required** | **Person responsible** | **Due date** |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |

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| --- | --- | --- |
|   |  | dd-mmm-yy |
| **Name of monitor** | **Signature** | **Date** |