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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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| **C. STUDY SPECIFIC INFORMATION** |
| **2. 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** | Was informed consent always obtained prior to enrolment?  | [ ]  | [ ]  | [ ]  |
| **4** | Was the informed consent form always signed or thumb-printed, and dated by each subject? | [ ]  | [ ]  | [ ]  |
| **5** | Was the informed assent form, used for minor participants over 12 years of age, always signed or thumb-printed, and dated, where applicable? | [ ]  | [ ]  | [ ]  |
| **6** | Was the informed consent form for illiterate subjects always signed or thumb-printed, and dated, by an impartial witness? | [ ]  | [ ]  | [ ]  |
| **7** | Was consent obtained for pregnancy testing, when applicable? | [ ]  | [ ]  | [ ]  |

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| **3. PATIENT RECRUITMENT AND FOLLOW-UP**  |
| Date of recruitment of the first patient: dd-mmm-yyyy |  |  |
| Date of recruitment of the last 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** | Was the target sample size achieved? | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| **8** | Was the screening log checked to review the reasons for non-inclusion? | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |

| **4. PROTOCOL COMPLIANCE AND CASE RECORD FORM (CRF)**  | **Yes** | **No** | **N/A** |
| --- | --- | --- | --- |
| **1** | Were all CRFs complete and available? | [ ]  | [ ]  | [ ]  |
| **2** | Were the CRFs checked against source documents (screening log book, enrolment log book, laboratory register)? | [ ]  | [ ]  | [ ]  |
| **3** | Were the patients’ ID numbers and the visit dates correctly recorded? | [ ]  | [ ]  | [ ]  |
| **4** | Were 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** | Was the date of birth (or age) always recorded? | [ ]  | [ ]  | [ ]  |
| **7** | Were the parasite densities at enrolment within the range of the inclusion criteria set in the protocol? | [ ]  | [ ]  | [ ]  |
| **8** | Were pregnancy tests performed at enrolment (where applicable)? | [ ]  | [ ]  | [ ]  |
| **9** | Did the study visit dates occur in accordance with the visit calendar? | [ ]  | [ ]  | [ ]  |
| **10** | Were the values for body temperature within the appropriate range (>36°C and <42°C)?  | [ ]  | [ ]  | [ ]  |
| **11** | Was the temperature value recorded to one decimal point? | [ ]  | [ ]  | [ ]  |
| **12** | Were the study drug doses administered according to the dosing chart? | [ ]  | [ ]  | [ ]  |
| **13** | Were all doses administered under supervision? | [ ]  | [ ]  | [ ]  |
| **14** | Were blood smears and blood spots for filter papers collected according to protocol?  | [ ]  | [ ]  | [ ]  |
| **15** | Were 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** | Were adverse events captured and recorded? | [ ]  | [ ]  | [ ]  |
| **18** | Was the use of concomitant medications captured and recorded? | [ ]  | [ ]  | [ ]  |
| **19** | Were there any 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** | Were patients withdrawn according to protocol? | [ ]  | [ ]  | [ ]  |
| **25** | Were 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** | Were all of the errors in the CRFs identified, recorded and corrected? | [ ]  | [ ]  | [ ]  |
| **31** | Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |

| **5. LABORATORY AND MICROSCOPY** | **Yes** | **No** | **N/A** |
| --- | --- | --- | --- |
| **1** | Was Giemsa solution correctly prepared daily? | [ ]  | [ ]  | [ ]  |
| **2** | Was the quality of blood smear staining acceptable? | [ ]  | [ ]  | [ ]  |
| **3** | Are slides kept in a slide box and stored properly? | [ ]  | [ ]  | [ ]  |
| **4** | Were any blood smears missing for any patient? | [ ]  | [ ]  | [ ]  |
| **5** | Were parasites counted as per protocol? | [ ]  | [ ]  | [ ]  |
| **6** | Was there a separate microscopy logbook for microscopist 1 and 2? | [ ]  | [ ]  | [ ]  |
| **7** | Were the final parasite counts an average of the 1st and 2nd reading? | [ ]  | [ ]  | [ ]  |
| **8** | Were 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** | Was there an adequate supply of high quality filter-paper? | [ ]  | [ ]  | [ ]  |
| **11** | Were filter-papers properly stored, protected from light, humidity and extreme temperatures? | [ ]  | [ ]  | [ ]  |
| **12** | Were biosafety procedures followed for blood sampling and destruction of unused samples after completion of PCR analyses and QC of slides? | [ ]  | [ ]  | [ ]  |
| **13** | Did the site perform any optional assessments (haematology, urine screen, G6PD, drug blood concentration sampling)? | [ ]  | [ ]  | [ ]  |
| **14** | If yes, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |
| **15** | Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |

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| **6. DATA ENTRY** | **Yes** | **No** | **N/A** |
| **1** | Was the WHO data entry excel sheet for TES being used? | [ ]  | [ ]  | [ ]  |
| **2** | Was the CRF data entered by two different individuals?  | [ ]  | [ ]  | [ ]  |
| **3** | Were data entry errors identified? | [ ]  | [ ]  | [ ]  |
| **4** | Were data entry errors corrected using the CRF? | [ ]  | [ ]  | [ ]  |
| **5** | Were the results of PCR analysis available and entered in the database?  | [ ]  | [ ]  | [ ]  |
| **6** | Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |

| **7. REPORTING** | **Yes** | **No** | **N/A** |
| --- | --- | --- | --- |
| **1** | Were ethical committees notified of study completion and its main outcome? | [ ]  | [ ]  | [ ]  |
| **2** | Was the health authority or community of the study area informed about the study outcome?  | [ ]  | [ ]  | [ ]  |
| **3** | Was the Clinical Trial Registry updated?  | [ ]  | [ ]  | [ ]  |
| **4** | If the study was supported by WHO, have the data and report been submitted to WHO/Global Malaria Programme and/or to the WHO regional office? | [ ]  | [ ]  | [ ]  |
| **5** | Are there plans to prepare a manuscript? | [ ]  | [ ]  | [ ]  |
| **6** | Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |

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| **D. CONCLUSIONS** |
| **8. COMMENTS** –In particular please comment on items from shaded or “N/A” check boxes. Please include the item number. |
| **Item** | **Comment** |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| **9. ACTION ITEMS** |
| **Item** | **Action required** | **Person responsible** | **Due date** |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
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| **10. 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 |
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| \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | dd-mmm-yyyy |
|   |  | dd-mmm-yy |
| **Name of monitor** | **Signature** | **Date** |