Updated 4.30.2019

Therapeutic Efficacy Survey QA/QC Checklist (participant)

Instructionsa

Participant ID#:

Name of site: Principal investigator of site:

Checklist conducted by: Date(s) of visit (MM/DD/YY): / /

1. **Study Forms**

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| --- | --- | --- | --- |
|  | **Yes** | **No** | **Comments** |
| 1) All study forms are present in the participant’s folder. *See protocol for specified required forms including consent/assent forms, screening forms, Day 0 enrollment, days of follow-up, and final classification form.* |  |  |  |
| 2) The screening form indicates that the participant meets all study entry criteria according to the study protocol for inclusion and exclusion. |  |  |  |
| 3) Consent/Assent forms are completed |  |  |  |
| a) Consent/assent form included in folder |  |  |  |
| 1. Consent/assent form signed and dated by participant |  |  |  |
| 1. Consent/assent form signed and dated by staff |  |  |  |
| 1. Participant’s copy is not attached to first copy |  |  |  |
| 4) Enrollment form and follow-up day forms are completed. *Note that microscopy is not conducted on Day 1 and an antimalarial is given on Days 0-2.* |  |  |  |
| 5) The participant’s unique identification number is on all study forms. |  |  |  |
| 6) Follow-up dates in study forms are correct and correspond to standard follow-up days (see protocol for follow-up schedule) |  |  |  |
| 7) Dosage of medication, including weight and use of second dose in case of vomiting after taking medication, is documented and correct (*Day 0, Day 1, Day 2*). *Consult dosing chart and verify which drug presentations are used to determine if # of pills is correct.* |  |  |  |

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| 8a) Parasitemia levels are recorded on enrollment and follow-up day forms (*Day 0, Day 2, Day 3, Day 7, Day 14,*  *Day 21, Day 28 [Day 35 and 42 if applicable]* or until most recent scheduled day if follow-up is ongoing*)*.  8b) Patients are withdrawn from the study if Day 2 parasitemia levels are greater than Day 0 or if Day 3 parasitemia levels are greater than 25% of Day 0 according to WHO Guidelines. |  |  |  |
| 9) The decision to continue follow-up or to complete the Final Classification Form is correct (*Day 1, Day 2, Day 3, Day 7, Day 14, Day 21, Day 28 [Day 35 and 42 if applicable]* or until most recent scheduled day if follow-up is ongoing). Early Treatment Failure if any of the following criteria are met:   * danger signs or severe malaria on day 1, 2 or 3 in the presence of parasitaemia * parasitaemia on day 2 higher than on day 0, irrespective of axillary temperature * parasitaemia on day 3 with axillary temperature ≥ 37.5 ºC * parasitaemia on day 3 ≥ 25% of count on day 0   Late Treatment Failure if any of the following criteria are met:  *Late Clinical Failure*   * danger signs or severe malaria in the presence of parasitaemia on any day between day 4 and day 28 (or day 42) in patients who did not previously meet any of the criteria of early treatment failure * presence of parasitaemia on any day between day 4 and day 28 (or day 42) with axillary temperature ≥ 37.5ºC (or history of fever depending on inclusion criteria) in patients who did not previously meet any of the criteria of early treatment failure   *Late Parasitological Failure*   * presence of parasitaemia on any day between day 7 and day 28 (or day 42) and axillary temperature <   37.5 ºC in patients who did not previously meet any of the criteria of early treatment failure or late clinical failure  Adequate Clinical and Parasitological Response:   * absence of parasitaemia on day 28 (or day 42), irrespective of axillary temperature, in patients who did not previously meet any of the criteria of treatment failure listed above |  |  |  |

1. **Laboratory**

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| --- | --- | --- | --- |
|  | **Yes** | **No** | **Comments** |
| **Filter papers** |  |  |  |
| 1) The participant’s unique identification number, date, and follow-up day are clearly labeled on all filter papers. |
| 2) Filter papers were collected for the participant on designated days or until most recent scheduled day of follow up if still ongoing. |  |  |  |
| 3) Blood is captured in the center of the printed circles in the filter papers, reaching as much saturation within the circle as possible. |  |  |  |
| 4) Filter papers are stored in individual plastic bags (one filter paper/bag) with desiccant, and organized by day of visit or by patient. |  |  |  |
| 5) Date written on individual filter papers matches date in corresponding clinical forms. |  |  |  |
| **Blood slides** |  |  |  |
| 6) The participant’s unique identification number, date and follow-up day are labeled on all smear slides. |
| 7) Slides were prepared and labeled with day for the participant on Day 0, Day 2, Day 3, Day 7, Day 14, Day 21, and Day 28 [Day 35 and 42 where applicable] or until most recent scheduled day if follow-up is ongoing. |  |  |  |
| 8) Thick and thin (when appropriate) blood smears are prepared on each follow-up day as per WHO Guidelines. *Note that the thin smear is often omitted because it is mainly relevant for sites with >1 Plasmodium species.* |  |  |  |