# ADVERSE EVENT

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| **Adverse Events AE No.** |\_\_|\_\_| | | | | | | |
| **1. Final Diagnosis/syndrome** (if known) | | **2. Onset Date** *(eg. 01-Jan-2013)*  |\_\_|\_\_|-|\_\_|\_\_|\_\_|- 20|\_\_|\_\_|  **3. Onset Time** *(eg.14:00)*  |\_\_|\_\_|:|\_\_|\_\_| | | | **4. End Date** *(eg. 01-Jan-2013)*  |\_\_|\_\_|-|\_\_|\_\_|\_\_|-20|\_\_|\_\_|  □ or ongoing | |
| **5. Event Description** (Signs and symptoms) | | | | | | |
| **6. Outcome**  🌕1  Recovered  🌕2  Recovered with sequelae  🌕3  Fatal  🌕4 Not recovered  🌕5  Not known | **7. Intensity**  🌕1 Mild  🌕2 Moderate  🌕3 Severe  🌕4 Potentially life-threatening | | | **8. Relationship to Study Drug** | | |
| **8a. Primaquine**  🌕1  Not related  🌕2  Possibly related  🌕3  Probably related  🌕4  Definitely related | | **8b. Chloroquine/ACT**  🌕1  Not related  🌕2  Possibly related  🌕3  Probably related  🌕4  Definitely related |
| **9. Alternative aetiology** (If 1, 2, or 3 is ticked for relationship to study drug)  🌕 Concurrent illness, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  🌕 Concomitant medication, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  🌕 Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | **10. Action taken**  🌕1  None  🌕2  Discontinue study drug  🌕3  Treatment - Medication (If ticked, fill ConMed form)  🌕4  Other treatment \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **11. Is this Adverse Event Serious?** 🌕 No 🌕 Yes, check all that apply below and complete an SAE form. | | | | | | |
| □ Results in death | | | □ Is life-threatening (subject is at immediate risk of death from the   event as it occurred), | | | |
| □ Requires subject hospitalization or prolongation of   existing hospitalization | | | □ Results in persistent or significant disability/incapacity | | | |
| □ Is a congenital anomaly/birth defect | | | □ Other medically important condition | | | |
| Completed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (initials) | | | Date |\_\_|\_\_|-|\_\_|\_\_|\_\_|-20|\_\_|\_\_|*(eg. 01-Jan-2013)* | | | |

Reviewed by:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date |\_\_|\_\_|-|\_\_|\_\_|\_\_|-20|\_\_|\_\_|

Investigator (NAME) Signature*(eg. 01-Jan-2013)*

# SERIOUS ADVERSE EVENTS

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| **Serious Adverse Events SAE No.** |\_\_|\_\_| | | | | | | | | | |
| **1. Report Status** 🌕 Initial report **Date of Report** |\_\_|\_\_|-|\_\_|\_\_|\_\_|-20|\_\_|\_\_| *(eg. 01-Jan-2013)*  🌕 Follow-up report **Date of Report** |\_\_|\_\_|-|\_\_|\_\_|\_\_|-20|\_\_|\_\_| *(eg. 01-Jan-2013)*  🌕 Follow-up report **Date of Report** |\_\_|\_\_|-|\_\_|\_\_|\_\_|-20|\_\_|\_\_| *(eg. 01-Jan-2013)*  🌕 Follow-up report **Date of Report** |\_\_|\_\_|-|\_\_|\_\_|\_\_|-20|\_\_|\_\_| *(eg. 01-Jan-2013)*  🌕 Final report **Date of Report** |\_\_|\_\_|-|\_\_|\_\_|\_\_|-20|\_\_|\_\_| *(eg. 01-Jan-2013)* | | | | | | | | | |
| **Subject Information** | | | | | | | | | |
| 2a. Date of Birth |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| *(eg. 01-Jan-2013)* **OR** 2b.Age |\_\_|\_\_| years |\_\_|\_\_| months  3. Gender 🌕 Male 🌕 Female  4. If the subject is female, was she pregnant at time of SAE? 🌕Yes 🌕 No 🌕 Unknown  5. G6PD 🌕 Normal 🌕 Deficient | | | | | | | | | |
| **Event Classification** | | | | | | | | | |
| **6. Serious Adverse Event** (provide key word or cause of death):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | |
| **7. Describe the serious adverse event** (include all relevant laboratory results):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | |
| **8. Onset date** |\_\_|\_\_|-|\_\_|\_\_|\_\_|-20|\_\_|\_\_| *(eg. 01-Jan-2013)* | | | | | **9. End date** |\_\_|\_\_|-|\_\_|\_\_|\_\_|-20|\_\_|\_\_| □ or ongoing  *(eg. 01-Jan-2013)* | | | | |
| **10. Primary reasons SAE is being reported:**  *(Check all that apply)* | | □ Results in death  □ Life-threatening  □ Requires inpatient hospitalization or prolongation of existing hospitalization  □ Results in persistent or significant disability/incapacity  □ Congenital anomaly or birth defect  □ Other important medical events, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | |
| **11. Relationship to Study Drug** | | **11a. Drug 1**  🌕1  Not related  🌕2  Possibly related  🌕3  Probably related  🌕4  Definitely related | | | | | **11b. Drug b**  🌕1  Not related  🌕2  Possibly related  🌕3  Probably related  🌕4  Definitely related | | |
| **11c. Alternative aetiology** (If 1, 2, or 3 is ticked for relationship to study drug)  🌕 Concurrent illness, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  🌕 Concomitant medication, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  🌕 Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | |
| **12. Intensity** 🌕 Mild 🌕 Moderate 🌕 Severe 🌕 Potentially life-threatening | | | | | | | | | |
| **13. Outcome of Event** | | 🌕 Not known  🌕 Recovered  🌕 Recovered with sequelae  🌕 Fatal, Date of death |\_\_|\_\_|-|\_\_|\_\_|\_\_|-20|\_\_|\_\_| Autopsy done? 🌕Yes 🌕 No  🌕 Not recovered**:** 🌕 Improving 🌕 Worsening 🌕 Unchanged | | | | | | | |
| **Study Drug Detail** | |  | | | | | | | |
| **14. Study drug start date**: |\_\_|\_\_|-|\_\_|\_\_|\_\_|-20|\_\_|\_\_|  *(eg. 01-Jan-2013)* | | | | | **15a. Date of last study drug taken** |\_\_|\_\_|-|\_\_|\_\_|\_\_|-20|\_\_|\_\_|  *(eg. 01-Jan-2013)*  **15b. Time of last study drug taken** |\_\_|\_\_|:|\_\_|\_\_| *(eg. 14:00)* | | | | |
| **16. Action taken to study drug:** 🌕 NA  🌕 Continue study drug  🌕 Temporarily discontinue study drug  Discontinue on |\_\_|\_\_|-|\_\_|\_\_|\_\_|-20|\_\_|\_\_| *(eg. 01-Jan-2013)*  Re-start on |\_\_|\_\_|-|\_\_|\_\_|\_\_|-20|\_\_|\_\_| *(eg. 01-Jan-2013)*  🌕 Permanently discontinue study drug  Discontinue on |\_\_|\_\_|-|\_\_|\_\_|\_\_|-20|\_\_|\_\_| *(eg. 01-Jan-2013)* | | | | | | | | | |
| **17. Was the code unblinded?** 🌕Yes 🌕 No | | | | | | | | | |
| **Therapy** | | | | | | | | | |
| **18. Medication given to treat current event** 🌕Yes (if yes, please fill in below table) 🌕 No | | | | | | | | | |
| **Medication (Generic name)** | **Dose** | | **Frequency** | **Route of administration** | | **Start Date**  *(eg. 01-Jan-2013)* | | **End Date**  *(eg. 01-Jan-2013)* | **Indication** |
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| **19. Other procedures given to treat the current event** 🌕Yes (if yes, please fill in below table) 🌕 No | | | | | | | | | |
| **20. Describe the procedures given to treat the current event:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | |

Investigator (print full name) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(eg. 01-Jan-2013)*