

APPENDIX A

Proposed Amendments to form CDC 54.1 (Malaria Case Surveillance Report)

As a part of the monitoring of the new treatment drug for use in the U.S., Artemether/lumefantrine, these questions have been added or updated to comply with the FDA protocol.

***Changes are in **Bold font**

| Current Form (Field Names) | Current Value Set | Proposed Form (Field Names) | Proposed Value Set | Justification |
|--|---|--|--|---|
| PART I | | | | |
| NEW FIELD | | Height | ___ ft. and ___ in. | available |
| NEW FIELD | | Weight | ___ lbs/kg (circle units) | available |
| Therapy for this attack (check all that apply) | Chloroquine, Tetracycline, Doxycycline, Mefloquine, Exchange transfusion, Unknown, Primaquine, Quinine, Quinidine, Clindamycin, Atovaquone/proguanil, Artesunate, Other (specify) | Therapy for this attack (check all that apply) | Chloroquine, Tetracycline, Doxycycline, Mefloquine, Exchange transfusion, Unknown, Primaquine, Quinine, Quinidine, Clindamycin, Atovaquone/proguanil, Artesunate, Artemether/lumefantrine , Other (specify) | Updated value set to capture the drug Artemether/lumefantrine available for treatment |

NOTE: The expectation for PART II is that CDC staff will be completing this section, therefore the PRA change worksheet will not change (no additional Cost/Burden hours are added). States are allowed to complete section if desired, however are not obligated.

PART II

NEW FIELD

Please list all prescription and over the counter medicines the patient had taken during the 2 weeks before starting their treatment for malaria.

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| NEW FIELD | Please list all prescription and over the counter medicines the patient had taken during the 4 weeks after starting their treatment for malaria. | |
| NEW FIELD | Was the medicine for malaria treatment taken as prescribed? | No, doses missed/Yes, no doses missed/Unknown |
| NEW FIELD | Did all signs or symptoms of malaria resolve without any additional malaria treatment within 7 days after treatment start? | No/Yes/Unknown |
| NEW FIELD | If yes, did the patient experience a recurrence of signs or symptoms of malaria during the 4 weeks after starting malaria treatment? | No/Yes/Unknown |
| NEW FIELD | Did the patient experience any adverse events within 4 weeks after receiving the malaria treatment? | No/Yes/Unknown |
| NEW FIELD | (If Yes): Event description | Relationship to treatment suspected*/Time to onset since treatment start/Fatal?/Life-threatening?/Other seriousness? ** |

* Suspected means that a causal relationship between the treatment and an adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out.

** A *serious* adverse event is defined as an event which is fatal or life-threatening, results in persistent or significant disability/incapacity, constitutes a congenital anomaly/birth defect, is medically significant (i.e., jeopardizes the patient or may require medical or surgical intervention), or requires inpatient hospitalization or prolongation of existing hospitalization