**STUDY SITE QUESTIONNAIRE**

**1. Client Details – *As per general SSQ***

Name, contact details, Institution Details, as per PG’s document.

Interaction: Interrogate WARN / Uploading Data

**2. Preliminary Page**

2.1 What Modular Data is Available?  Clinical  In vitro  Molecular  PK

Any one upload would be for data derived from the same patient /study. NB More than one module can be ticked.

2.2 Was the study conducted at more than one site:  Yes  No

How many locations?

Definition site:

Appendix per site

For each location:

Location1: Country (pull down menu)

Sublocation:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (free text) Link to site data App I

Internal Study Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**3. Study Protocol**

**3.1 Clinical**

***NB a load of Information will be gathered from the database itself and tagged to the study (ie not need to ask).***

Eg Dates of enrolment and finished, Number of patients enrolled, frequency of observations. etc

Efficacy data available (eg para, gam, hct)

**3.1.1 General**

Was this study registered : Yes / No

Which Register: clinical trials.gov etc

Protocol URL or Register: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Has data been published? If so Reference.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

When can data be put on web?(embargo period)?

**3.1.2 Inclusion / Exclusion Criteria**

Age: Min – Max

Parasitaemia: Min to Max

Species Infection:  Pf  Pv  Pm  Po  Pk

Exclude if Prior Antimalarial Treatment: Y/N

If Y then: Prior treatment based on history  or drug test

If by history then over what period of time: \_\_\_\_\_\_weeks

**3.1.3 Treatments**

How many treatment regimens?

Regimen 1 :\_*AL6*\_\_\_\_\_\_\_\_ Supervised: Full/Partial/ None Link for detailed information AppII

Regimen 2 :\_*Mfq+As3*\_\_\_ Supervised: Full/Partial/ None

Regimen 3 :\_\_\_\_\_\_\_\_\_\_\_ Supervised: Full/Partial/ None

Allocation (if >1 treatment regimen): Randomised (proportion) / QuasiRandomised

Blinding: Open Label / Single / Double

**3.1.4 Follow Up**

Maximum Duration of follow up: \_\_\_\_\_

Fever Measurement: Ax / Oral / Rectal / Tympanic

Haemoglobin recording: Hb  / Hct

If Hb: QBC / Haemaccue / Other

**3.1.5 Microscopy**

Thick Film:  Thin Film:

Parasite Density calculation: *Pulled Down Menu describe methodology ? select from list of possibilities ?*

**Gametocytes** Density calculation: *Pulled Down Menu*

Species Confirmed by PCR: *Pulled Down Menu*

**Quality Control**: Internal: *Pulled Down Options*

External: *Pulled Down Options*

**3.1.6 Genotyping for Recrud vs Reinfection**

Was it done: Y/N

How Many Markers:

How Many Markers:  MSP1  MSP2  Glurp  Microsatellites If Yes how many \_\_\_\_\_

( which lab ? )

Other Markers: Y/N If Yes which:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Method of discrimination: Agarose Gel  If Y then Visual  or Computerised

Cap Electrophoresis

Other  If Yes what\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Analytical Protocol: ***Drop down menu*** (eg WHO, MMV…)

Mixed Alleles: recrudescence / Reinfection / Other

Recrudescence defined as: Old alleles only  Old and new alleles mixed

Reinfection defined as: New alleles only  Old and new alleles mixed

**3.2-3.4 Molecular / In Vitro /PK Information**

**APPENDIX I Site Site** *To be filled by Donator*

One per site

|  |  |  |  |
| --- | --- | --- | --- |
| **Country:** |  |  |  |
| **City or Village** |  | Lat:\_\_\_\_\_\_\_\_\_ | Longit:\_\_\_\_\_\_\_\_\_ |
| **Catchment Area** | Urban  Rural Periurban  Displaced persons/refugees  Other, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **Assessment of transmission intensity** | | | |
| **Annual Parasitological Incidence** | Unknown  Estimated API :  in \_\_\_\_\_\_\_\_\_\_(Year) | | |
| **Parasite prevalence (age)** | Unknown  Estimated prevalence: in\_\_\_\_\_\_\_\_\_\_(Year) | | |
| **Annual EIR** | Unknown  Estimated EIR:  in \_\_\_\_\_\_\_\_\_\_(Year) | | |
| **Epidemiological Publications** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **Is transmission seasonal?** | NO  YES, specify months: | | |
| **Other Available Data:** | Prevelance  Entomology  Host Polymorphisms | | |

**APPENDIX II Treatment Regimens**

3.1.3 DETAILS FOR EACH REGIMEN AVAILABLE (hidden but can click to retrieve set protocols)

NB level of detail for PK will be critical

How Many Drugs  (a single drug or co-formulation)

Drug 1: AL Formulation: Tablet / Dispersal

Manufacturer:\_\_\_\_\_\_\_\_\_\_\_\_Batch number: \_\_\_\_\_\_\_\_\_\_ Expiry date:\_\_\_\_\_\_\_\_\_\_

Storage of Medication: Room Temperature / Fridge

Number of Doses: \_\_\_\_\_\_ Number of Days of treatment: \_\_\_\_\_\_

Dosing by Age or Weight:\_\_\_\_\_\_ Attach regimen details:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Day 0 | Day 1 | Day 2 | Day3 | Day4 | … |
| Dose1 |  |  |  |  |  |  |
| Dose2 |  |  |  |  |  |  |
| Dose3 |  |  |  |  |  |  |

Level supervision: Yes  No

If Yes: All Doses  Partial

If Partial: Explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Special instructions: With food intake etc

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ eg major deviations from norm

Drug 2: DHP Formulation: Tablet / Dispersal

Manufacturer:\_\_\_\_\_\_\_\_\_\_\_\_Batch number: \_\_\_\_\_\_\_\_\_\_ Expiry date:\_\_\_\_\_\_\_\_\_\_

…