**Template Quality Assurance Plan for Clinical Research Studies**

**Purpose**

All research studies on human subjects should have a level of quality and ethical standard assurance built into their operations to ensure that that the rights and well-being of human subjects are protected and that the data are reliable.

ICH GCP (1) applies to all research on human subjects and states that the appropriate extent and nature of monitoring should be determined for each study based on considerations such as the objective, purpose, design, complexity, blinding, size and endpoints of the study. This document applies those considerations to the WHO protocol for surveillance of the therapeutic efficacy of antimalarial medicines (2) with the aim of enabling sites to design and implement a pragmatic and effective quality assurance plan for their antimalarial drug surveillance studies.

An important element of assuring data quality is comparing the entries in the database with the original source of the data (e.g. laboratory results). This procedure is known as Source Data Verification (SDV). The process of quality assurance should be straightforward and pragmatic and easily built into a research team’s operations. Contracting an external monitoring contract organisation is not normal or warranted for these studies, yet there is a need for ensuring that data and ethical standards are met. A good in-house or reciprocal (with other sites in a network) scheme can be put in place and carry this task out perfectly well. Irrespective of who it is that is tasked with carrying out this important role, they should be considered positively as part standard research practice with objectives of guiding and supporting the study. This is not audit, policing, but helpful and constructive. It is the responsibility of the Investigator for the study and appropriate staff team members to ensure high standards of data collection and Source Data Verification are maintained at all times. Here we present a guideline and template tool to put a simple system in place for this.

This template guides the investigator in preparing and operationalising a quality assurance plan. Therefore, whether an external sponsor is responsible, or the investigator is putting in place their own quality assurance procedure we recommend this document is used to ensure a simple, pragmatic process that is specially designed for this type of study to ensure valid data and ethical practices.

**Scope**

This document is designed specifically for investigators running all types of clinical studies to guide the development of an operational tool to confirm quality and ethical standards within their studies. Therefore, this is a pragmatic approach that could be adapted for all non-interventional clinical research studies.

**How to use this document**

The following steps are written to guide a study team in planning how to assure that high ethical and data standards are met for their antimalarial surveillance study. The person designated to prepare this plan should use the headings in the contents provided below and insert text within each section, replacing the guidance text in brackets and italics.

1. **Study details** *(study name, location, investigator, number of subjects)*
2. **Procedure**

**Name of person(s) or organisation that will be performing the quality assurance:**

*(It is quite acceptable for a member of the study team to be assigned the task of study quality assurance manager (QAM). However, it is typically a role given to someone separate from the study team which has advantages as this brings independence, perhaps someone working for another study team at the same centre? An external sponsor may have contracted this out to a CRO, or have their own QAM. If the study is being run within a network, it might be advantageous for a reciprocal monitoring scheme to be established. Whoever is conducting this study it is advisable for the investigator and their study team to write this plan so that it is highly specific and appropriate for their study and circumstances.*

**Details of timing of quality assurance activities**

*(This should begin as soon as possible after the study begins and the timing of this should be agreed between the investigator and the quality assurance manager and detailed here. Then subsequent ‘visits’ should also be planned and detailed here. This will be a pragmatic decision based on whether it is someone internal or external. The volume of work will be dictated by the frequency and time needed for these ‘visits’ it will depend on the number of participants and how quickly they are enrolled. An initial plan can be put in place based on estimated recruitments times and this can be adjusted if needed as the study progresses. For the first 30 participants 100% SDV checking is recommended for all visits. For the remaining participants it is recommends that 25% of the data points are checked against the source date. Here details of which data points for which visits will be checked and how they will be selected should be described.)*

**Preparation needed by study staff prior to a quality assurance visit**

*(To confirm data is valid and correct it is necessary to cross check against the original record. This is called the source data. So to confirm a patient attended a clinic, for example, the clinic records can be checked. To ensure a correct blood sample or PCR result is as is recorded on the database the original lab record sheet should be cross referenced. Where possible, all study documents, forms and data bases should be up to date prior to a QAM visit. Not every single data point needs to be verified, as explained below. However, the documents and information needed should be thought about and detailed here so they can be ready for this validation process. Informed consent forms are an important component. A room or quiet desk should be booked for the use during the visit. The study team should be aware of the planned visits and be able to make available the necessary time and assistance)*

**Details of the Quality Assurance Visits**

*(On the day of the visit the Lead Investigator or other nominated team member(s) must be available to show the quality assurance manager to their allocated space or room and ascertain that they have everything they need (as above). The Principal Investigator should also be available on the day of the visit. It is preferable that the Principal Investigator is available for at least a proportion of each visit. Detail here what people and departments should be visited. This should include checking storage of the study medication and drug accountability. For anti-malarial surveillance studies the laboratory data is key, so the laboratory should be visited at appropriate intervals to observe PCR and microscopy procedures, these visits should be detailed here. Appropriate arrangements should be made in advance with the appropriate people. If the healthcare facility where the study is being conducted does not have a system for patient notes, clinic diary, drug accountability then simply source data form should be designed and provided. For PCR and blood-slide reading quality standards procedures should be followed and compliance to these should be observed. These might be local standards or others (3). All this should be simply and concisely described here. Below is a table to guide each visit, this has been written specifically for a malaria drug surveillance study, using the WHO example protocol (2) it can however be amended as consider appropriate and pragmatic for each study following an assessment of risk and complexity of the study. For each visit the QAM should complete a visit form as attached as appendix one)*

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| **Data point or Activity** | **Location/Source/People** | **100% Validation / Notes** |
| Inclusion/exclusion Criteria;   * *From the protocol* * …. | Clinic/patients notes  Laboratory records  Other *(detail)* | 100% of all participants |
| Informed consent provided | Signed Consent forms | 100% of all participants |
| Blood test results  PCR results | Laboratory records | 100% of first 30 participants then 25% randomly selection of following? *Decide what is appropriate* |
| Serious adverse events  Protocol violations  Loss to follow up  Withdrawals | Laboratory records, clinic records | 100% validation checks. |
| Intervention administration and accountability – if applicable? | Patient notes  Drug accountability records | 100% of first 30 participants then 20% randomly selection of following |
| Participant attendance | Clinic Diary/patient notes | 100% of first 30 participants then 20% randomly selection of following |

**Abbreviations**

PI – Principal Investigator

QAM – Quality assurance manager

International Conference for Harmonisation – ICH

Good Clinical Practice - GCP

CRO – Contract Research Organisation

Source Document Verification -SDV

**References**

1. <http://whqlibdoc.who.int/publications/2009/9789241597531_eng.pdf>
2. <http://www.ich.org/LOB/media/MEDIA482.pdf>