



## AFRICAN MALARIA NETWORK TRUST

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# CALL FOR APPLICATIONS

### AMANET Training Workshop for Data Safety & Monitoring Board (DSMB) Members from African Institutions

Deadline for Applications: 10<sup>th</sup> September 2007

#### **Background and rationale**

The conduct of clinical trials that fulfil GCP requires several organs to build into the process of each trial. These include clinical monitors, independent ethical committees, data safety and monitoring boards, safety monitoring boards, clinical development teams or steering committees as necessary. To be efficient each of these players in the clinical trial setting should be sufficiently experienced and trained.

The number of clinical trials going on in Africa at the present is rapidly increasing, given the amount of funding resources being made available for R&D into diseases of poverty. The development of the human resource base has not been commensurate with the increase in number of trials, resulting in an increased demand for the limited expertise available on the continent. Whereas, notable efforts have gone into capacity development to improve infrastructure, and for training in GCP, GLP, and Health Research Ethics (HRE), there has been limited training for other key support organs such as for DSMB members.

Typically, expertise to serve on DSMB is derived from individuals who are recognised for their skills in epidemiology, biostatistics, immunology, and other specialities as pertinent to a particular trial. Such competencies have usually been acquired through longstanding experience in the field, prior membership to committees, and sometimes experience in industry. This exposure cannot be adequately obtained through formal training during a university degree course. Therefore specific courses through workshops are required to equip the middle to senior level African scientists with skills to support the clinical trials, to increase the pool of available African scientists, and to provide an opportunity to develop the much needed experience. Although, the institutional activities considered for this workshop are malaria related, such a pool of expertise will likely serve other research areas in priority diseases such as HIV/AIDS and Tuberculosis.

#### **Objectives and Expected Outcomes**

**General Objective:** To contribute to capacity strengthening of the support systems for clinical research in Africa

## Specific Objectives:

1. To share experiences of DSMBs in African Institutions and from DSMB members
2. To update participants in the principles, guidelines and responsibilities of DSMB

## Highlight of topics to be covered

- Background and rationale for DSMB
- DSMB and international guidelines/regulations
- DSMB versus IDMC, DMC, DRB, ISM or ISC
- Scope of responsibilities for DSMB and study teams
- Composition and membership of DSMB and DSMB Meetings
- The place of DSMBs in the trial set-up and DSMB meetings
- Data Safety Monitoring Plan
- DSMB SOPs; DSMB review- materials, methods and procedures
- Statistical issues; Implications of Interim analysis;
- Dealing with confidentiality of trial data and conflict of interest
- Format and content of DSMB reports; information flow;
- DSMB reports and IRBs
- Group Work – Examining the integrity of a study protocol
- Group Work - Examining the safety of participants
- Group Work – Recommending conclusion of a Study

## Workshop format

*Overviews and Discussions:* Expert overviews will be presented and participants will have time for questions and discussions

*Group Work:* This will provide exercises on expected activities of DSMB and how decisions are reached

*Plenary presentations and discussions:* The plenary will convene for presentation and discussion of the outputs from group work

## Follow-up

There will be two types of post-workshop follow-up:

1. *Short term:* To create an inventory of individuals with DSMB expertise/experience within Africa”
2. *Medium to Long term:* to Facilitate the engagement of the scientists trained to serve in various DSMBs across Africa, particularly on AMANET sponsored clinical trials

## Date and venue

The workshop is intended to last three days and proposed for 8-10<sup>th</sup> October 2007, in Dar es Salaam, Tanzania.

## Who can apply?

Applications are invited from middle to senior level African scientists who are working in research institutes and Universities in Africa, and in other non- profit AMANET networked institutions. Individuals with research experience in epidemiology, clinical trials, biostatistics and those participating in or likely to be involved in malaria vaccine development are encouraged to apply. Candidates from selected centres being developed by AMANET are given preference.

**How to apply**

Interested persons should submit a complete application, which must include the following:

1. Curriculum vitae (one page maximum);
2. Summary of research and role in current research (not more than 10 lines);
3. Show how this workshop would benefit you, your institution, or the DSMB you are serving (half a page);
4. Names and addresses of two work-related referees (including their telephone numbers and email contacts), who you have requested to provide letters of recommendation, to be sent directly to the address below.

Please note that only applications meeting the above requirements will be considered.

**Applications must be received by Monday 10 September 2007 and submitted by email to the following address:**

**The Managing Trustee,**

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