



AFRICAN MALARIA NETWORK TRUST

Tanzania Commission for Science and Technology Building
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AMANET Call for European Candidate Malaria Vaccines Ready for Clinical Development in Africa

Background

The mission of AMANET is to promote capacity strengthening and networking of malaria R&D in Africa. Presently, the focus is on the development of candidate malaria vaccines which meet relevant requirements and are ready for evaluation in malaria-endemic areas at phase I and II clinical trials. This is complimented with capacity strengthening and site development activities for strategically preparing African research centres to undertake the clinical evaluation of potential candidate vaccines according to ICH-GCP guidelines. The role of AMANET in malaria R&D is based on the need to shorten the time and investment between discovery of potential interventions and their deployment. Recognising the lack of mechanisms outside pharmaceutical industry for developing malaria vaccines, the European Commission's EuropeAid Co-operation (AIDCO) has made funds available to AMANET to enable this as well as build its own capacity for undertaking the responsibility of the sponsor of clinical trials under international guidelines and standards.

This call is inviting European scientists or institutions who are interested in collaborating with AMANET and have malaria vaccine candidates which are ready for clinical evaluation in Africa.

What AMANET is offering

1. Not-for-profit investment in farther clinical development of candidate malaria vaccines
2. Role of sponsor for phase I and II vaccine trials within Africa
3. Funding of phase I and II malaria vaccines clinical trials in African malaria-endemic countries
4. Clinical evaluation centres prepared for malaria vaccine trials
5. Efficient, flexible and transparent decision-making mechanisms
6. Partnership in vaccine development including possibility to out-source relevant specialised activities.

Who can apply?

European scientists and institutions that hold patents over malaria vaccine candidate molecules which meet the profile for endemic country evaluation are invited. The restriction to European products is a requirement from the funding authority.

Vaccine candidate profile

The following are important considerations for the vaccine to be acceptable to this call:

1. Documentation to demonstrate ownership of the molecule by the applying institution or scientist
2. Proven and convincing vaccine development rationale as evidenced in published preclinical studies
3. Completion of adequate preclinical and toxicological evaluation in at least two animal models
4. Demonstrated safety in humans in a phase Ia trial
5. Certification of current Good Manufacturing Practice (cGMP) for all the clinical lots used in the early development of the product
6. Acceptable batch release protocol/certificate for the clinical lots
7. Feasibility of vaccine production up-scaling under cGMP conditions
8. Provision of up-to-date Investigator's Brochure (IB) and sufficient information for European regulatory registration of the product
9. Provision of all information necessary for developing a comprehensive clinical development plan
10. Agreement to make vaccine readily accessible at affordable cost in Africa should it eventually become licensed
11. Willingness to work with other collaborators such as EDTCP

How to apply

Interested persons/institutions should submit a letter of interest highlighting the above requirements and curriculum vitae of the involved key scientists.

All applications must be directed to:

The Managing Trustee,
African Malaria Network Trust (AMANET),
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