

**Information required for submission of Letter of Interest (LOI) to Medicines for Malaria
Venture's 10th Call for Proposals for
Malaria Drug Discovery, Development and Clinical Capacity Building Projects**

Deadline for receipt in MMV office: 12 noon (CET) March 15th, 2012

Please read the instructions carefully. Submissions should be completed on 3 pages of A4. MMV will only receive submissions electronically; please see the accompanying templates and contact details at the end of this document.

There are two stages to the process of seeking funding of a project through the Medicines for Malaria Venture.

The first stage is a concise 3 page LOI outlining the project using the guidelines and templates provided. These letters will be competitively assessed by MMV and MMV's Expert Scientific Advisory Committee (ESAC). A short-list of projects will then be invited for the submission of a more detailed proposal, which will be presented and discussed at the MMV offices in Geneva, in a face-to-face meeting (later in 2012) with MMV and MMV ESAC. Experience has shown that MMV funding is highly competitive and it is in your interest to present all relevant data as completely and as concisely as possible. Some guidelines on this are provided below.

Please note: If you have several approaches or potential projects that you wish to propose for funding, then each approach should be submitted as a separate project application. Also remember to state in your application that you are submitting a drug discovery, drug development or clinical capacity building application.

Please remember when preparing the application that MMV and the MMV ESAC are already familiar with the key issues of malaria, malaria chemotherapy and the need for antimalarial drugs. So please focus on key information and data. Your proposal should restrict itself to details placed in the context of drug discovery and development or capacity building.

MMV has identified four basic categories of indications for antimalarial treatment:

- (a) The hits-to-lead stage for new families of molecules specifically addressing the key priorities of the malaria eradication agenda: transmission blocking and prevention of *P. vivax* relapse.
- (b) Proposals for chemical series with the potential for *P. falciparum* chemoprevention or blood stage efficacy as a result of long-half lives are encouraged, though the project should already have initial confirmation of *in vivo* oral blood stage activity. Early target validation falls outside of our mandate.
- (c) In the clinical arena, new chemical entities.

- (d) Applications regarding capacity building to develop new sites for first-in-patient testing of these new molecules, including both blood stage, transmission blocking and *P. vivax* anti-relapse capabilities.

The prime area of interest for MMV is for agents that fall into the first category of affordable treatment for non-severe malaria in children, pregnant women and adults as we currently see this as the area of greatest medical need. Our ultimate goal is to be able to develop treatments that are completed with a single dose (certainly no more than once a day dosing for three days) so as to ensure patient compliance, have a low cost of goods and which are likely to have activity against artemisinin-resistant strains.

The following information will assist you in preparing a focused application.

The 1st page of your application should outline:

- Type of application: Discovery or Development or Capacity Building
- Project title
- Contact details of Principal Investigator, and partners with areas of responsibility of within the project and a succinct description of their professional expertise and contribution to the team.
- Overall goals of the project and the Target Product Profile focus
- Proposal Phase – to clarify the position of the proposal within the drug development continuum (delete as appropriate)

The 2nd page of your application should include:

- Scientific basis for the project and justification vs. the call for proposals criteria e.g.
 - ⇒ Biology rationale
 - ⇒ Chemistry rationale
 - ⇒ Evidence of site capacity to run a clinical trial (if relevant)
 - ⇒ Comparative advantages of approach (and compounds) over existing drugs and other approaches
- Project status:
 - Give a clear account what has been achieved to date giving the latest full data and information.
 - ⇒ Identify where the project is in relation to its goals and include any key results
 - ⇒ Include pharmacokinetic and safety data when available
 - ⇒ Clearly state activities of any lead compounds
 - (a) *in vitro* against enzyme / molecular target e.g., IC₅₀ / Ki
 - (b) in culture against parasite strains e.g. EC₅₀ along with mammalian cytotoxicity data;
 - (c) in animal models e.g., ED₅₀, indicating route of application and precise model.
 - ⇒ Chemical structures of lead compounds should be provided along with medicinal chemistry comments; as with all other information these will be treated confidentially.

The 3rd page of your application should include:

- Highlight the critical issues and explain the mitigation strategy

- ⇒ Give a summary of the medicinal chemistry plan specifically focusing on how the critical issues will be solved whilst maintaining the attractive properties
- ⇒ Identify gaps in knowledge or a bottleneck that need to be addressed to validate the biological approach, compound or clinical site
- ⇒ Give specific timed milestones for the progression of the project towards the final goal
- ⇒ Outline project approach and methodologies to be used
- Likely resource requirements and how these would be allocated to: project partners, consumables, etc.
 - ⇒ Include budget for year 1.
 - ⇒ Costs may be approximate at this stage.
 - ⇒ Please note that MMV has a zero indirect cost policy.
- Maximum 3 literature references if any.

If accepted, the project will be integrated into the MMV portfolio as soon as a legal agreement is reached between MMV and the relevant parties. As part of the MMV portfolio, we will strive to aid movement of the project toward drug development and registration for fast access to the markets in developing countries.

SUBMISSION CONTACT DETAILS:

Deadline for receipt in MMV office: 12 noon CET March 15th, 2012

Send your 3 page letter of interest, electronically to: proposals@mmv.org