European Medicines Agency

London, 23 September 2009
Doc. Ref. EMEA/585460/2009

The European Medicines Agency's participation in Innovative Medicines Initiative (IMI) Research projects

Background information on the IMI:
The IMI is a Public-Private Partnership (PPP) involving the pharmaceutical industry represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Commission.

Operationally, IMI is a Joint Technology Initiative (JTI), introduced within the scope of the Seventh Framework Programme (FP7). Research activities are to be performed through collaborative projects involving both industry and non-industry partners, following open calls and peer review. Non-profit organisations and SME's are also eligible for Community support. All research is pre-competitive, enabling different companies to collaborate, and to share expertise among themselves and with non-industry partners. The IMI Research Agenda (http://www.imi.europa.eu/sra_en.html) describes the research bottlenecks in the drug development process and identifies four strategic pillars: Predictivity of safety evaluation, Predictivity of efficacy evaluation, Knowledge management and Education and Training. With these topics, IMI aims to accelerate the discovery and development of new medicines in the field of cancer, inflammatory and infectious disease.

The second call for research proposals will be launched by the joint IMI undertaking in October 2009 (http://imi.europa.eu/calls-02_en.html).

The European Medicines Agency's potential contribution to IMI projects:
All IMI activities are expected to foster drug-development and to bring drugs to market faster. It is therefore anticipated that many IMI-sponsored research projects will comprise at least some regulatory aspects, and that the European Medicines Agency may be asked by applicant consortia wishing to submit an expression of interest, to participate in their project.

The European Medicines Agency's position regarding participation in IMI consortia:
The agency fully supports the overall goals of IMI, recognising its benefits for public health. We may therefore be willing and able to participate in select projects, contingent upon a number of considerations. These include:

- *Considerations of resources:* Participation in an IMI project may be labour intensive and we need to be conscious of its internal resource constraints.
- *Potential for conflicts of interest (CoI):* Since IMI projects will be designed to, *inter alia*, develop methodologies to be applied to drug development (e.g. biomarkers, novel approaches to analysis of clinical trials, etc), it is probable that some of these novel methodologies will, at a later stage, become part of a marketing authorisation dossier or a scientific advice procedure for e.g. biomarker qualification that will be assessed by the European Medicines Agency's Scientific Committees and Working Parties. This may create a situation of potential CoI.
- *Relevance of our contribution to the consortium:* We recognise that participation of (a) regulatory agency(ies) is critical for some but not all IMI call topics and consortia.

How to contact The European Medicines Agency about IMI projects:
Applicant consortia wishing to submit an expression of interest for one of the IMI call topics and considering inviting the European Medicines Agency to be a participant in their consortium are invited to submit their request to: Hans-Georg.Eichler@emea.europa.eu **at the latest two weeks before the official deadline for submission of expressions of interest to IMI JU**.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Consortia should kindly indicate in their request the following information:

- Call topic (Topic Code)
- List of members of public consortium and consortium leader
- Pre final research proposal
- Expected contribution from The European Medicines Agency (including an estimate of anticipated workload)

The European Medicines Agency will make every attempt to communicate its decision to participate or not participate in the applicant consortium at the earliest possible time. In taking its decision, we will carefully consider the criteria described above (resources, potential for CoI, relevance).

Please feel free to contact us at the email address provided above if you have any questions.