

Extract from the Announcement

by the German Federal Ministry of Education and Research (BMBF)

Full text in German see <http://www.bmbf.de/foerderungen/6527.php>

## **“Innovation in the Development of Medicines”**

**Funding will be granted to a limited number of industry-led collaborative projects** with high innovation potential for new methods in the development of medicines. It is intended to develop new methods and processes which will allow predictions concerning the effectiveness of medicines and their toxicity in humans **at as early a stage as possible** during the development process and **with a high degree of reliability**. Such methods and procedures may be associated with the development of new classes of substances or may be provided as a service by companies which are not themselves active in the development of medicines.

The collaborations should consist of clinical and theoretical working groups from university, non-university and industrial research institutions at regional and supra-regional level and should pool the necessary expertise and available resources. The collaborations should be focused thematically and as a rule consist of 3 to 5 working groups.

**Individual projects which do not belong to a collaborative project will not be considered for funding.**

Collaborative projects may apply for funding for work in the field of applied basic research and preclinical research dealing *inter alia* with the following topics:

- ***In vitro* test systems**

A promising approach here is the development of new complex *in vitro* models, such as, for example, organotypical culture systems, mixed cell culture systems or tissue chips. Of essential importance is a validation of tissue culture models using relevant animal models or human primary tissue samples. There is also a tremendous need for the development of *in vitro* models which can help to better understand the long-term effects of candidate agents.

- **Pathophysiologically relevant animal models**

There continues to be a need for animal models which relate more closely to the human pathophysiology. It is striking that the available animal models in those areas of diseases with a very high failure rate in the development of medicines (oncology and diseases of the central nervous system) say little about human pathophysiology. Molecular biological techniques for the genetic manipulation of the genome (transgenic or knock-out animals or transient gene inactivation using RNAi techniques) offer new approaches to obtaining better models.

- **In vivo imaging**

The use of innovative imaging procedures, *inter alia* in conjunction with new biomarkers, enables non-invasive long-term tests on organotypical culture systems or relevant animal models which can lead in the longer term to the development of a medicine based on imaging techniques.

- **Modelling methods**

Systems-biological and bioinformatical approaches can also be used in order to be better able to depict the complexity of an organism. Models to predict efficacy and/or toxic side-effects (pathway analyses) can be developed on the basis of a detailed knowledge of the gene expression and protein profiles of certain cell types or the metabolic changes in tissues. Validation using experimental data is always important to improve in silico models.

Research work in the following areas will not be considered for funding:

- Tests which can be categorized as pure basic research
- Clinical studies
- Studies on the development of new forms of administration
- Tests to establish and validate biomarkers.

A collaborative project must pursue an original research approach with a high development risk which cannot be considered as either pure basic research or market-oriented research and development.

Collaborative projects must involve at least one commercial company. The partners must appoint a project coordinator who should preferably be based at the industrial company involved.

Prior to submitting their applications, applicants will have already investigated the situation with regard to patents for the procedure described and will provide details of their findings. The applicant must safeguard results which need protection appropriately.

The partners should be willing to cooperate on an international basis where this is wise. International partners may therefore also be involved in collaborative projects in order to avoid the unnecessary duplication of developments and to involve all the necessary competences. In such cases, the international partner must prove that it is receiving its own national funding for its part of the project.

Partners in a collaborative project should determine their cooperation in a cooperation agreement. The cooperation agreement should contain a clause to the effect that companies will pay the usual market rate for those parts of the invention or patent which are based on the work of a research institution.

The funding procedure is two-tiered.

Initially there are two deadlines for submitting project descriptions. Informal project descriptions for the first round of selection can be submitted to the project management organization from now until **19 January 2007** at the latest and for the second round of selection by **21 January 2009** at the latest.