

- EXCERPT -

Federal Ministry of Education and Research

Announcement

**Regulations governing the provision of funding for
"Systems medicine research consortia"
under the research and funding scheme
"e:Med – Paving the Way for Systems Medicine"**

2 May 2018

1 Aim, purpose of funding, legal basis

1.1 Aim and purpose of funding

Systems medicine uses systems-oriented approaches to understand complex physiological and pathological processes in their entirety and thus to create foundations on which to develop innovative methods for the diagnosis, treatment and prevention of diseases. The holistic approach of systems medicine transcends boundaries and goes beyond traditional views and methods in medical research and practice. A focus is on the use of sophisticated analytical or computer-based methods for studying the characteristics and behaviour of complex biological systems.

The Federal Ministry of Education and Research (BMBF) is supporting the establishment of this research field in Germany with its "e:Med – Paving the Way for Systems Medicine" research and funding scheme. A key goal is to attract outstanding researchers from the fields of biology, medicine, physics, mathematics, and computer science. Horizontal knowledge transfer will strengthen exchanges between these disciplines. This will help improve the integration of systems biology approaches, smart data analysis, mathematical modelling and computer simulation into clinical research and practice. Ultimately, this will contribute to structure building and the long-term establishment of systems-oriented medical research.

The Federal Ministry of Education and Research is developing Module I of the "e:Med – Paving the Way for Systems Medicine" research and funding scheme by announcing these funding regulations for systems medicine research consortia. The aim of the measure is to establish systems medicine research approaches in areas of diseases which are important in terms of health economics and where such approaches have not been (fully) developed yet.

Simultaneously, the BMBF is publishing regulations for funding in a further two areas: demonstrators for an individualized medicine (Module II) and junior research alliances in systems medicine (Module III).

2 Object of funding

Funding is provided for interdisciplinary research consortia including up to six partners (research groups) which focus on a clinically relevant problem and pursue a systems medicine approach in their research.

Experimental and theoretical research groups will join forces at regional or national level to ensure the necessary expertise and resources for a research consortium.

The project's direct relevance to disease is a prerequisite for funding. The consortia will study systemic molecular relations between at least two different syndromes which are important in terms of health economics. They will contribute to the identification and description of common disease mechanisms and pathways. In this context, frequent comorbidities will also be considered. The aim is to study the underlying pathological mechanisms in order to better understand the heterogeneity of diseases which were originally defined on the basis of their symptoms and morphological change. This will contribute to an improved understanding of the disease and a refined description and distinction of existing indications. The consortia will use the findings to develop systems medicine models for the identification of high-risk groups, early diagnosis of diseases and/or prediction of their progression. This will provide the basis for rational approaches to prevention and individualized causal treatments.

The studies will focus on areas of disease which reveal a certain relevance and appropriateness of systems medicine research approaches, but where such approaches have not been (fully) developed yet. Proposals for projects with a greater focus on clinical application should be submitted under the "Demonstrators for an individualized medicine" funding call.

The project should involve interdisciplinary work. The minimum requirements include participation by clinical research groups and the involvement of high-throughput research groups from basic biomedical research as well as experts in data analysis or mathematical modelling. The convincing design of a thematic focus shared by all the participating groups is an essential feature. All sub-projects must be linked to each other to create synergy and include clear milestones and time schedules.

Researchers are expected to pursue a multidimensional approach. Approval for funding requires that data is collected across several levels for the same group of test persons (e.g. including various Omics technologies, clinical data, imaging data, behavioural data, environmental impact and habits etc.) to gain a better understanding of the origin and progression of disease. New data may be collected and biomaterials generated under the planned project, but efforts should be made to use existing data and materials wherever possible.

Research approaches which involve an iterative joint process of modelling and experimenting as well as possible initial validation steps are expressly welcome. Although new approaches to methodical and technological development can be integrated into the collaboration, they must not be pursued in their own right without reference to the overall objective of the collaboration. They must contribute to the solution of the shared research problem within the overall context of the collaboration. Suitable data management strategies must be developed for the collection, archival and exchange of data.

Funding will not be provided for:

- Projects not directly related to a disease or not focusing on a clinically relevant problem,
- Study of the side effects of medical treatments,

- Exclusive *de novo* generation of large volumes of high-throughput data and the establishment of new biomaterial collections,
- Consortia whose work already covers clinical testing of the developed systems medicine interventions (such proposals may be submitted under the "Demonstrators for an individualized medicine" funding call),
- Interventional clinical trials.

The consortia need a convincing organizational strategy for the planned communication and coordination of their internal cooperation. This strategy should also include elements of internal progress review and enable the consortia to actively steer their own work.

4 Special prerequisites for funding

Funding requires that the selected research topic is clearly disease-relevant; that the planned work is of high methodical and scientific quality; that the applicants' expertise is proven by their previous work; and that the set goals have good prospects of being applied in medicine and industry.

There must be sufficient access to relevant patient and control groups and materials and/or clinical data of sufficient quality to the extent that these are needed for issues to be researched by the consortium. The equipment required for high-throughput methods must be available when the project starts.

The terms of cooperation between the partners in a collaborative project are laid down in a written cooperation agreement. Collaboration partners which are research institutions within the meaning of Article 2 (83) GBER must ensure that no indirect aid flows to companies under the collaboration. The provisions of Section 2.2 of the Commission communication concerning the Framework for State Aid for Research and Development and Innovation (OJ C 198 of 27 June 2014, p. 1) must be observed. Before a funding decision on a collaborative project is taken, the cooperation partners must prove that they have reached a basic consensus on specific criteria stipulated by the BMBF (cf. BMBF leaflet No. 0110¹).

The "e:Med – Paving the Way for Systems Medicine" research and funding scheme has a central coordination unit, the e:Med Project Committee. The e:Med Management Office provides operational support for the activities of the Project Committee. New collaborative projects must integrate into the established structures of the e:Med research and funding scheme and acknowledge the responsibilities and function of the Project Committee. Applicants must be prepared to make an active joint contribution to the objectives of the national systems medicine network envisaged by the e:Med modules. The collaborative projects which are successful in their applications and receive funding will commit themselves to participate in the measures necessary to promote visibility and quality management (surveys, workshops, etc.). Applicants are expected to be prepared to engage in secondary networking with other systems medicine research consortia and initiatives.

¹ https://foerderportal.bund.de/easy/easy_index.php?auswahl=easy_formulare; header BMBF under "Allgemeine Vordrucke und Vorlagen für Berichte".

The evaluation of the project outlines received will involve a panel of external experts and be based on the following criteria:

- Relevance of the proposal to the aims of the present call;
- Scientific and methodological quality (e.g. clearly defined research objective based on clinical needs, expected progress beyond the current state of the art);
- Level of innovation of the research approach;
- Clinical relevance and prospects for application, potential for exploitation, consistency of the utilization plan;
- Interdisciplinarity and synergy potential of the collaborative project;
- Focus on the development of systems medicine research approaches in areas of disease which are important in terms of health economics;
- Scientific and technical qualification of the applicants, relevant previous work;
- Organization and control of the collaborative project (e.g. appropriateness of the size and structure of the collaborative project, type and quality of the planned coordination, quality of the planned measures for data management and standardization in the generation and exchange of methods, samples and data, data management, networking activities, stringency of time schedule and milestone planning including interaction with the partners in the collaboration);
- Feasibility (e.g. proof of all the necessary resources, access to data and/or biomaterials, viability of the work plan).

Suitable project ideas will be selected for funding on the basis of the above criteria and evaluation. Applicants will be informed in writing of the result of the selection process.