SWISS NATIONAL SCIENCE FOUNDATION

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To: Clinical Researchers

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Pre-announcement

In 2015 and 2016, the Swiss National Science Foundation is for the first time issuing a call for proposals aimed at supporting independent Investigator Initiated Clinical Trials (IICT).

The SNSF is assigning a maximum budget of CHF 10 million to each call and is expecting to support at least 4-5 studies per call. Subsequent calls as of 2017 will be conditional on the funds available for this programme pursuant to the ERI Dispatch.

The call 2015 will be issued on 12 August 2015. Researchers wishing to participate need to inform the SNSF with a letter of intent by 26 August 2015. The deadline for submission of applications is 15 October 2015. Proposals must be submitted via mySNF. Proposal forms will very closely adhere to the spirit check list for clinical trial protocols (http://www.spirit-statement.org/).

Please find below some key information on the scope of the call and the participation requirements. For more detailed information you may contact the programme coordinator Dr Raphael Banz (raphael.banz@snf.ch) as of 30 June 2015.

We very much look forward to an active participation in the IICT calls 2015 and 2016, and to contributing to a highly competitive clinical trials research environment in Switzerland.

Yours sincerely

Prof Urs Frey
President, Biology and Medicine division, SNSF

Dr Aysim Yilmaz
Head, Biology and Medicine division, SNSF

Aims and scope of the call

- The call concerns prospective, randomised, interventional, multicentric studies of new or existing treatments. Support will be given to studies that are not in the industry focus and whose topics are as yet under-researched (e.g. rare diseases, paediatric diseases, therapy combinations, dosage reduction studies and rehabilitation measures). The studies are clinically relevant and of public interest.
- Studies conducted for directly commercial purposes are not eligible for funding.
- Observation studies, explorative studies, translational studies, experimental studies on healthy subjects, pathophysiological studies of patients, diagnosis studies and prognosis studies will not be supported. Such studies are eligible to apply for SNSF project funding. Also excluded is technology development for new treatments.

Programme-specific requirements

- The studies need to be conducted in a multicentric setting, generally involving at least 2 centres.
- Data collection and quality assurance of the collected data must be in line with international standards; an academic institution such as a Clinical Trial Unit supervises and supports these processes.
- Applicants must be employed at higher education institutions or at research institutions outside the higher education sector in Switzerland that are eligible for SNSF funding.
- The funding period is limited to 60 months. It is divided into a preparation phase of no more than 12 months (finalising the study protocol, obtaining the authorisations needed to conduct the project, organising data collection, registering the study, etc.) and a study phase of no more than 48 months. The study phase starts with the recruitment of subjects and ends once the data has been fully analysed.
- Subjects should be recruited primarily in Switzerland. It is permissible to include subjects at foreign centres should this be necessary for reaching the sample size, provided the legal requirements are met.

Personal requirements

- Natural persons are eligible to submit applications if they meet the general eligibility requirements for the submission of applications pursuant to Articles 8 and 13 of the Funding Regulations and if they form a research group pursuant to Article 14 of the Funding Regulations.
- The members of the research group:
  a. have an excellent scientific track record of many years and the ability to lead a clinical study involving various experts and institutions in a multicentric setting;
  b. are employed at least for the duration of the project at a research institution eligible for SNSF funding or have been given assurance of such employment in writing;
- The members of the research group appoint an applicant employed in Switzerland as the applicant responsible for correspondence with the SNSF ("responsible applicant" pursuant to Art. 14 para 3 of the Funding Regulations); this person is generally the leader of the clinical study.

Formal requirements

- The applications must be submitted in accordance with the requirements issued by the SNSF and must contain all the necessary data and documents.
- The applicants must submit a joint research plan in which they describe in detail the proposed project, the allocation of funding, the collaboration between those involved in the project and the envisaged milestones, particularly the subject matter and the date on which they plan to complete the preparation phase.
- Applicants must announce their intention to submit a proposal to the SNSF by sending a letter of intent to the e-mail address iict@snf.ch by Wednesday, 26 August 2015. The letter of intent should contain a brief outline of the project (one A4 page). On the basis of this brief description, the SNSF will select external experts in view of the forthcoming evaluation.
- The applications must be submitted to the SNSF electronically via the mySNF portal by 15 October 2015.
- Applications must be written in English, as must all supporting documentation.
- Applicants may submit only one proposal per IICT call and may participate in only one project within the scope of this funding scheme.
- In all other respects, any further formal requirements for the submission of applications apply, in particular those of the Funding Regulations and its Implementation Regulations.

Project partners

In contrast to the members of the research group, project partners are researchers who make a partial contribution to the project without being responsible for it individually. They do not count as (remunerated) employees of the project and are not among those responsible for the project as a whole. They must be designated accordingly in the application. They may not refer to the support received from the SNSF as a grant they have acquired themselves. In a clinical research context, project partners may be, for instance, researchers who contribute to the inclusion of patients in recruiting centres but are not involved in the design or analysis of the study.

Donations from industry

In principle, donations from commercially oriented enterprises (e.g. supply of drugs/medical products at reduced rates or free of charge) are permissible if:

a. the donor cannot influence the research work in any way;
b. the publication and copyrights are not restricted;
c. the donations are not compensated monetarily or by any other means.

Evaluation and assessment criteria

- Proposals that meet the personal and formal requirements and that are not manifestly inadequate will be appraised in collaboration with an international panel of experts who are experienced clinical study leaders.
- At least two external reviews must generally be obtained for each application.
- Steering Board composed of members of the National Research Council will support the evaluation process in an advisory role. The Steering Board may consult persons involved in public health care.
- Based on the recommendations of the international panel, the Biology and Medicine division of the Research Council will make funding decisions and submit them to the Presiding Board of the Research Council for endorsement.

The main criteria considered in the scientific evaluation are:

a. Clinical relevance, scientific quality and topicality of the study;
b. Public importance of the study and its significance for clinical research in Switzerland;
c. Originality of research objectives;
d. Suitability of methodical approach;
e. Feasibility of the project (incl. the financial planning as well as organisation and management of the study);
f. Scientific track record of the applicants;
g. Applicants' expertise in relation to the project, particularly with regard to multicentric clinical studies.

Compliance with national and international regulations and clinical research guidelines

- Grantees must ensure that the study is conducted in accordance with the study protocol, the Helsinki Declaration, the ICH-GCP Guidelines and the applicable statutory and regulatory provisions.
- If a grantee collaborates with partners abroad, the above-mentioned requirements must be met also for the research work carried out abroad for as long as the project lasts.
- The SNSF is not regarded as the organisation initiating research within the meaning of the Human Research Act or as sponsor pursuant to the recognised guidelines on good clinical practice.

Use of data

- The data collected in clinical trials must be made available in anonymised form to other researchers for secondary research. This needs to be clearly stated in the study protocol and in the patient consent form. The data collected must be integrated into recognised data pools in accordance with the rules of the SNSF.
- Any patient samples must correspond to the quality standards of the Swiss Biobanking Platform and must be included in its inventory.