SCHWEIZERISCHER NATIONALFONDS
ZUR FÖRDERUNG DER WISSENSCHAFTLICHEN FORSCHUNG

www.snsf.ch
Wildhainweg 3, P.O. Box 8232, CH-3001 Berne

Biology and Medicine division

Investigator Initiated Clinical Trials (IICTs): call for proposals 2016

1. Aim and scope

The special programme for Investigator Initiated Clinical Trials (IICTs) of the Swiss National Science Foundation supports independent clinical studies. The call is limited to prospective, randomised, controlled, interventional, multicentric studies of existing treatments on topics that are not in the industry focus and therefore insufficiently researched. This may comprise rare illnesses, paediatric illnesses, therapy combinations, dosage reduction studies, surgical studies, rehabilitation measures and effectiveness studies on new diagnostic or risk-stratified treatment strategies. The studies are of high clinical relevance and public importance.

No funding will be awarded for, in particular, pilot studies, proof of concept studies, translational studies, observation studies, studies involving healthy subjects, and physiological or pathophysiological studies of patients. Also excluded are phase I and phase IIa pharmaceutical studies as well as combined studies with a phase I - or phase IIa - component. Funding for such studies can be applied for under the project funding scheme. In addition, technology development for new treatments and the development and evaluation of new diagnostic or risk-stratified procedures without a therapy component will not receive funding.

Studies conducted for directly commercial purposes will not be funded.

2. Key information about the call

2.1 Call for proposals

The SNSF has a budget of CHF 10 million for the call. This should be sufficient to fund at least four studies.

2.2 Deadlines for the 2016 call for proposals

Researchers wishing to participate need to inform the SNSF by **1 September 2016** (for details see: formal requirements, item c). The deadline for the submission of applications is **1 November 2016**.

3. Background

By setting up and expanding Clinical Trial Units at all university hospitals as well as at Kantonsspital St. Gallen, bringing them together under a new umbrella organisation, the Swiss Clinical Trial Organisation SCTO, supporting cohort and longitudinal studies, providing specific grants for young clinical researchers in translational medicine (Special Programme University Medicine SPUM), bringing its career funding schemes (MD-PhD, Ambizione SCORE, clinical SNSF professorships) more closely into line with the needs of young physicians and creating the Swiss Biobanking Platform SBP, the SNSF has, since 2004, contributed significantly to the establishment and enhancement of clinical research in Switzerland in line with international standards.

In 2015, the SNSF introduced a special programme for Investigator Initiated Clinical Trials. The programme offers targeted support for independent, comprehensive clinical studies in order to meet major scientific and societal needs. The studies go beyond the scope of project funding in terms of their research questions, comprehensive nature, duration, complexity and costs. They generally require a multicentric setting and, quite often, international collaboration. The SNSF will evaluate the study proposals in consultation with an international panel.

4. Legal framework

The call for this research programme is issued in accordance with the Funding Regulations of the SNSF (Art. 5 in conjunction with Art. 48). The call document sets out the specific requirements for the award of grants, details of the application process, and the rights and obligations of grantees. Unless the document provides otherwise, the provisions of the Funding Regulations of the SNSF and its Implementation Regulations apply.

5. Programme-specific requirements

5.1 Setting

The studies should be multicentric and should generally involve more than two centres. In justified exceptional cases, it may be possible to conduct studies involving only one or two centres.

Data collection and quality assurance must be in line with international standards; an academic institution such as a Clinical Trial Unit supervises and supports these processes.

The study must have been initiated in Switzerland. The extension of foreign studies to Switzerland will not be funded.

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.

5.2 Duration of 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.

5.3 Recruiting subjects abroad

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.

6. Personal and formal requirements for the proposals and for their submission

6.1 Personal requirements

Natural persons are eligible to submit applications if they meet the general eligibility requirements for the submission of applications pursuant to Arts. 10 and 12 of the Funding Regulations and if they form a research group pursuant to Art. 12 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 with a minimum work-time percentage of 50% 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 research group consists of a maximum of 5 persons. The members of the research group have clearly defined roles with regard to the implementation of the project as a whole.

The members of the research group appoint a corresponding applicant (Art. 12 para. 4 of the Funding Regulations); this person is generally the leader of the clinical study.

6.2 Project partners

In contrast to the applicants, project partners are researchers who make a partial contribution to the project. They are generally responsible for individual phases or aspects of the study, but are not (remunerated) employees of the project. They do not lead the study and are not responsible for implementing the study as a whole, nor are they among those responsible for the entire project. Project partners may not refer to the support received from the SNSF as a grant they have themselves acquired. They benefit from the SNSF grant by providing services to the research project. 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. All of the project partners must be mentioned in the application.

6.3 Formal requirements

a. The applications must be submitted in accordance with the requirements issued by the SNSF and must contain all the necessary data and documents.
b. 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, incl. the subject matter and the date on which they plan to complete the preparation phase.
c. 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 1 September 2016. The letter of intent

should contain a brief outline of the project. A template for the letter of intent can be downloaded from the SNSF website. On the basis of the letter of intent, the SNSF will select external experts in view of the forthcoming evaluation.

d. Applicants may submit only one application per IICT call.

e. Researchers may not be involved as grantees in more than one IICT project during the same funding period. However, they may participate in more than one project as project partners.

f. Applications must be submitted to the SNSF electronically via the mySNF portal by 1 November 2016.

g. Applications must be written in English, as must all supporting documentation.

h. In all other respects, any further formal requirements for the submission of applications apply, in particular those stipulated in the Funding Regulations and its Implementation Regulations.

7. Eligible costs / financing

7.1 Eligible costs

In principle, the provisions for project funding also apply to IICTs. Eligible costs include:

a. salaries of scientific and technical staff employed in the project, within the scope of the salary ranges and rates defined by the SNSF;

b. expenses directly linked to the project's execution, in particular costs in connection with the set-up, recruitment and follow-up of study subjects, monitoring, data collection and analysis, publications, the obtainment of official authorisations, laboratory rules, medicines, placebo, imaging, reagents, etc.

c. travel expenses that are directly linked to the project (e.g. monitoring, investigator meetings);

d. costs and fees of scientific open access e-publications produced within the scope of the funded research;

e. costs for the organisation of conferences and workshops in connection with the funded research;

f. costs for internal coordination of the project and for collaborative and networking activities;

Costs must be quantified and their coverage requested in the proposal.

The following costs are not covered:

a. costs for further projects resulting from the study. Coverage of these costs must be applied for separately under project funding;

b. acquisition and maintenance costs of apparatuses that exceed CHF 100,000.

The requirements for the assumption of costs are set out in separate provisions issued by the SNSF. In particular, the SNSF may set upper limits for individual cost categories as well as binding rates for salaries and minimum requirements in respect of employment positions.

The SNSF may approve transfers between the individual cost categories during the funding period.

In principle, patient recruitment costs at study centres abroad may not exceed 20% of the awarded grant.

For service costs incurred in Clinical Trial Units, the rates of the Swiss Clinical Trial Organisation for internal partners apply.

7.2 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 rights and copyrights are not restricted;
c. the donations are not compensated monetarily or by any other means.

8. Evaluation and evaluation 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.

Additionally, at least two external written reviews must generally be obtained for each application.

A 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.

8.1 Evaluation criteria

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 added value for an insufficiently researched field and/or 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 the 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.

9. Payment of the grant / rights and obligations of grantees

9.1 Transfer of funds

The grants are transferred in annual instalments.

The first instalment is paid by the SNSF at the request of the corresponding grantee after the grant is awarded.

Before any further instalments can be paid, the report on the predefined milestones will need to be approved by the SNSF.

9.2 Cost-neutral extension of project duration

In justified exceptional cases, the SNSF may, at the grantee's request, cost-neutrally extend the grant by a maximum of 12 months. The extension must be requested before expiry of the funding period.

9.3 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 the duration of the grant.

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.

9.4 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 collected data must be integrated into recognised data pools in accordance with the rules of the SNSF.

Any patient samples must meet the quality standards of the Swiss Biobanking Platform and must be included in its inventory.

9.5 Reporting

Grantees are obliged to submit scientific and financial reports. In particular, after the start of the project the corresponding grantee must submit:

a. on completion of the preparation phase, i.e. after 12 months at the latest, a report on attainment of the first milestones defined by the SNSF;
b. every 6 months after the start of the grant, a report on the pre-defined milestones;
c. every 12 months after the start of the grant, a financial report;
d. a final report on conclusion of the project.

9.6 Discontinuation of the grant

For significant reasons, particularly if the defined milestones are not reached or the formal requirements no longer met, the SNSF may discontinue the grant after conducting a hearing with those concerned.