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 2015

1. Aim and scope

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 (IICTs). 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 will not be funded.

Observational 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.

2. Key information about the call

2.1 Call for proposals

The SNSF is assigning a maximum budget of CHF 10 million to each call. The money is to be used 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.

2.2 Deadlines for the 2015 call for proposals

Researchers wishing to participate need to inform the SNSF by **26 August 2015** (for details see: formal requirements, item c). The deadline for the submission of applications is **15 October 2015**.

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 medical researchers in translational medicine (Special Programme University Medicine SPUM), bringing its career funding schemes (MDPhD, 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.

However, there has been a lack of adequate funding opportunities for independent and comprehensive investigator initiated clinical trials (IICTs) that are not industry-funded in Switzerland up to now, even though such trials respond to an important scientific and societal need. They have not been covered by the SNSF's regular funding schemes. Because of the questions they address, their comprehensive nature, their duration, their complexity and their costs, these studies go beyond the scope of project funding. They generally require a multicentric setting and, quite often, international collaborations. A decision has therefore been made to support such studies as of 2015 through a special SNSF programme. The SNSF will evaluate the study proposals in collaboration 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. 46). 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

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

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 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.

6.2 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, particularly 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 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.
d. The applications must be submitted to the SNSF electronically via the mySNF portal by 15 October 2015.
e. Applications must be written in English, as must all supporting documentation.

f. Applicants may submit only one proposal per IICT call and may participate in only one project within the scope of this funding scheme.
g. 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.

6.3 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.

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, data collection and analysis, publications, the obtainment of official authorisations, the data safety monitoring board, 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. A flat rate per included patient applies.

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

8. 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.

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 Assessment 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 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.

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 grantee responsible for correspondence after the grant is awarded.

The second instalment is transferred if the report on reaching the first milestone is accepted.

Further payments are conditional on acceptance of the annual reports on the pre-defined milestones.

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 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.

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 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.

9.5 Reporting

Grantees are obliged to submit scientific and financial reports. In particular, after the start of the project the responsible 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 milestone defined by the SNSF;
b. every 12 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 important reasons, particularly if the defined milestones are not reached or the formal requirements are no longer met, the SNSF may discontinue the grant after conducting a hearing with those concerned.