

## Investigator Initiated Clinical Trials (IICTs): call for proposals 2017

### 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 novel or existing treatments on topics that are not in the industry focus and therefore insufficiently researched. 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. 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 2017 call for proposals

Researchers wishing to participate need to inform the SNSF by **1 September 2017** (for details see: formal requirements, item c). The deadline for the submission of applications is **1 November 2017**.

### **3. Background**

Since 2015, the IICT programme offers targeted support for independent, comprehensive clinical studies with the aim of meeting 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, sometimes, international collaboration. There is one call each year, up to and including 2020.

The first two calls have attracted considerable attention from the clinical research community. The SNSF received 75 and 35 proposals, respectively, from a broad field of medical disciplines. All 16 proposals rated as outstanding and excellent received funding. Key success factors included high clinical relevance, convincing hypotheses, adequate study design and sample size/power calculation, appropriate methodology and primary endpoints as well as the project leaders' expertise and experience in conducting randomised, controlled trials. 108 recruiting sites are participating in the funded studies. All Swiss university hospitals as well as 13 cantonal hospitals and other Swiss institutions and 20 hospitals outside Switzerland are involved. The investigators plan to recruit 7180 patients in total. The projects have a duration of 3 – 5 years. First results are expected in 2019.

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 more closely into line with the needs of young physicians, creating the Swiss Biobanking Platform SBP and introducing the special programme IICT, the SNSF has, since 2004, contributed significantly to the establishment and enhancement of clinical research in Switzerland in line with international standards.

### **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 awarding 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. The studies must be initiated in Switzerland. The programme does not support ongoing trials that are already recruiting patients.

Data collection and quality must be in line with international standards. It is advisable to involve a Clinical Trial Unit or equivalent at an early stage when developing the study.

## **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, Arts. 4 and 5 of the Regulations on Project Funding and if they form a research group pursuant to Art. 12 of the Funding Regulations.

The members of the research group must have an excellent scientific track record and the ability to lead a clinical study involving various experts and institutions in a multicentric setting;

The research group consists of a maximum of 5 persons. The members of the research group have clearly defined roles and responsibilities 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 themselves have 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](mailto:iict@snf.ch) by 1 September 2017. The letter of intent contains a brief outline of the project. A template for the letter of intent can be downloaded from the SNSF website. Proposals for which no letter of intent was submitted in good time cannot be considered for evaluation. The letters enable the SNSF to organise the forthcoming evaluation process. There is no pre-selection of proposals based on the letters of intent;
- 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 contribute as project partners to additional projects;
- f. Applications must be submitted to the SNSF electronically via the mySNF portal by 1 November 2017;
- 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 General Implementation Regulations for the Funding Regulations (section 2, Eligible costs) and Article 8 of the Regulations on Project Funding apply. IICT funding grants may be used to cover the following costs:

- a. the salaries of scientific and technical staff in research projects within the scope of the salary ranges and rates prescribed by the SNSF;
- b. material costs that are directly related to the research work, namely material of enduring value, expendable items, medicines, placebo, reagents, fees for the obtainment of official authorisations, travel costs or third-party charges;
- c. direct costs incurred through the use of research infrastructure linked to the research work;
- d. direct costs incurred at Clinical Trial Units or equivalent, in particular costs in connection with study set-up, monitoring, data collection and analysis;
- e. costs and fees of scientific open access e-publications produced within the scope of the funded research;
- f. costs for the organisation of conferences and workshops in connection with the funded research;

The costs must be applied for and quantified in the proposal.

The SNSF may award global budgets and approve transfers between the individual cost categories during the funding period.

Costs for further projects resulting from the study are not covered by the IICT grant. The funding of such further projects may be applied for separately under project funding.

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 corresponding rates of the Swiss Clinical Trial Organisation apply.

## **7.2 Donations from commercially oriented institutions**

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

- a. applicants are able to prove to the SNSF that the principles of research freedom, research independence and freedom to publish will be upheld;
- b. sponsors and owners of commercially oriented institutions may not derive any pecuniary benefit from the funded research work.

## **8. Evaluation and evaluation criteria**

An international panel of experts who are experienced clinical study leaders, will appraise proposals that meet the personal and formal requirements and that are not manifestly inadequate.

Additionally, at least three external reviews, i.e. two reviews by clinical experts in the field of the research proposal and one review by a biostatistician, must be obtained for each application, unless an insufficient number of responses to requests for review were received. 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 National Research Council will make funding decisions and submit them to the Presiding Board of the National 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 methodological approach;
- e. Feasibility of the project (incl. the financial planning, the organisation and management of the study and the patient recruitment plan);
- 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 Ordinance on Clinical Trials in Human Research (SR 810.301).

## **9.4 Use of data**

A Data Management Plan must be submitted along with the IICT proposal. The data collected with the aid of an SNSF grant must also be made available to other researchers for further research. In principle, the Funding Regulations (Article 47) and General Implementation Regulations for the Funding Regulations (Article 2.13) apply hereto.

## **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 as well as a financial report;
- b. every 6 months after the start of the study period, a report on the pre-defined milestones;
- c. every 12 months after the start of the study period, a financial report;
- d. a final report on conclusion of the project;
- e. a final financial 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. Prior to taking such measures, the SNSF will communicate the decision in the form of a ruling after conducting a hearing with those concerned.