

Investigator Initiated Clinical Trials (IICTs): call for proposals 2020

1. Aim and scope

The programme for Investigator Initiated Clinical Trials (IICTs) of the Swiss National Science Foundation (SNSF) offers targeted support for clinical studies that are of value to the patients and address important unmet medical and societal needs. These studies are designed and conducted according to the highest international standards.

Clinical trials are defined in the Federal Act on Research involving Human Beings (Human Research Act, HRA)* and regulated by the Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance, ClinO)**.

IICT 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, sometimes international collaborations, and are not in the industry focus.

Excluded from support under the IICT programme are:

- Non-randomised and uncontrolled studies
- Pilot studies, proof of concept studies
- Studies with safety endpoints only
- Observational studies
- Preclinical studies
- Studies conducted for directly commercial purposes

* Clinical trial means a research project in which persons are prospectively assigned to a health-related intervention** in order to investigate its effects on health or on the structure and function of the human body. **Source:** Art. 3 letter l HRA

** Health-related intervention means a preventive, diagnostic, therapeutic, palliative or rehabilitative measure investigated in a clinical trial. **Source:** Article 2 letter a ClinO

2. Key information about the call

2.1 Deadlines

The deadlines for the call 2020 are:

- Submission of letters of intent via *mySNF* on **26 May 2020 until 5 p.m.** Swiss local time (for details see: 5.3 Formal requirements, item a)
- Submission of full proposals via *mySNF* on **2 November 2020 until 5 p.m.** Swiss local time.

2.2 Duration of evaluation

The evaluation procedure usually takes seven months as of the submission of the full proposal.

3. Legal framework

The call for the IICT 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 Regulations on project funding, the Funding Regulations of the SNSF and its Implementation Regulations apply.

4. Programme-specific requirements

4.1 Setting

IICT studies should generally involve more than two centres. In special cases, studies may involve only one or two centres, provided the applicants can show that the trial cannot be carried out successfully as a multicentric project.

The trials must be initiated in Switzerland and coordinated by a Swiss group. No funding shall be awarded for clinical trials for which patients are already being recruited.

4.2 Duration of funding

The funding period is limited to 60 months, including a potential preparation phase (e.g. to finalise the study protocol, obtain the authorisations needed to conduct the project, organise data collection and register the study) of max. 12 months. Each study must define at least one endpoint or interim analysis within the 60-month funding period.

4.3 Supplementary grant

Applicants wishing to address endpoints beyond the 60-month funding period can apply for a supplementary grant for a maximum of 24 months. Such applications are evaluated based on the criteria defined in Section 7.2. The applicants must contact the Administrative Offices 1.5 years before the end of the grant at the latest. There is no legal entitlement to receive a supplementary grant.

4.4 Cost-neutral extension

The SNSF may, at the grantee's request, cost-neutrally extend the grant by a maximum of 24 months if the reasons why the initial grant duration is insufficient were neither foreseeable nor avertable. The extension must be requested before the end of the funding period.

4.5 Patient and public involvement

In the research plan, applicants must document their efforts and plans to actively involve patients, members of their family, carers, the public or respective organisations in the design and delivery of the project. If no patient or public involvement was or will be possible, the reasons need to be outlined in the research plan.

4.6 Recruiting centres

Recruiting centres must confirm their participation in writing. These confirmations (letters of commitment) form part of the application to be submitted via the *mySNF* portal and must contain the items described in *mySNF*. The letters of commitment must be written in English.

4.7 Recruiting subjects abroad

Subjects must be recruited primarily in Switzerland (see also 6.1.). It is permissible to include subjects at foreign centres should this be necessary for reaching the sample size, provided the legal requirements are met.

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

5.1 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 as well as Arts. 4 and 5 of the Project Funding Regulations, 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 trial involving various experts and institutions in a multicentric setting;

The research group consists of a maximum of 5 people. 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 PI of the clinical trial.

5.2 Project partners

Project partners are researchers who contribute to a research project through cooperation without being responsible for the project. In a clinical research context, project partners may be, for instance, researchers who contribute to the inclusion of patients in recruiting centres. They must be designated as such in the application. Within the scope of their contributions, such as analyses etc., project partners benefit from the SNSF grant. However, they do not count as (remunerated) employees of the project and are not among those responsible for the project as a whole. They may not refer to the support received from the SNSF as a grant they have themselves acquired.

5.3 Formal requirements

- a. Applicants must submit a letter of intent via *mySNF* by 5 p.m. Swiss local time on 26 May 2020. The letter of intent template is available on the SNSF website and the *mySNF* platform. Full proposals for which no letter of intent was submitted in good time cannot be considered for evaluation. The letter of intent enables the SNSF to organise the forthcoming evaluation process and to provide preliminary, non-binding feedback on the formal eligibility of the applicants. The letters of intent do not serve as a pre-selection criterion.
- b. Full proposals must be submitted via the *mySNF* portal by 5 p.m. Swiss local time on 2 November 2020. They must be submitted in accordance with the requirements issued by the SNSF and must contain all the necessary data and documents.
- c. The research group submits a joint research plan. It is mandatory to use the IICT proposal template 2020. The template is available on the SNSF website and on the *mySNF* platform. The IICT proposal must not exceed a maximum of 25 pages (excluding bibliography). No annexes are permissible.
- d. Applicants may submit only one application per IICT call.
- e. Researchers may not participate as grantees in more than one IICT project during the same funding period. However, they may contribute to multiple projects as project partners;
- f. Applications as well as all supporting documentation must be in English.
- g. In all other respects, the formal requirements for the submission of applications apply, in particular those stipulated in the Funding Regulations and its Implementation Regulations.

6. Eligible costs/financing

6.1 Eligible costs

All costs mentioned in the General Implementation Regulations (Clause 2 Eligible costs) and in Art. 8 of the Project Funding Regulations may be charged to the IICT grant. They include:

- a. the salaries of scientific and technical staff in research projects according to 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, active drug substances and inactive control formulations, 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, particularly costs in connection with setting up the study, patient recruitment, project management, monitoring and data collection and analysis;
- e. costs for organising conferences and workshops in connection with the funded research;
- f. costs for national and international cooperation and networking activities carried out in connection with the funded research.

In the application, the costs must be set out in detail according to cost type and attributed to the applicant or project partner that will receive this part of the budget.

Patient recruitment costs at clinical trial centres abroad may be charged to the grant. In justified cases, payments to such centres can exceed 20% of the grant if the conditions defined in Sections 4.1 and 4.6 are fulfilled.

6.2 Contributions and donations from third parties

Contributions towards financing the project as well as donations (e.g. supply of drugs or medical products at reduced rates or free of charge) from third parties are permissible if:

- a. applicants confirm that the relevant third parties are not the sponsors of the trial as defined in the Ordinance on Clinical Trials in Human Research (Source: *Article 2 letter c ClinO*);
- b. applicants provide proof that the principles of research freedom, research independence and freedom to publish will be upheld;
- c. applicants confirm that the data collected in the research project belongs to the applicants or to their employers;
- d. the type and amount of the contribution or donation is declared;
- e. they do not derive any direct pecuniary benefit from the SNSF-funded research work;
- f. the applicant confirms the contribution or donation in writing when submitting the full proposal.

7. Evaluation and evaluation criteria

7.1 Evaluation process

Proposals that meet the personal and formal requirements and that are not manifestly inadequate will be evaluated by an international panel which includes experts and members of the public.

At least two external reviews must be obtained per proposal.

Based on the anonymised reviews, the applicants may draw up a rebuttal to resolve any misunderstandings or to propose potential solutions for specific criticisms. Simply disputing experts' comments or competences to defend one's application is not acceptable. On submission of the full proposal, the SNSF informs the applicants of the two-week time window available to provide the rebuttal which will be available to the evaluators.

A steering board composed of members of the National Research Council supports the evaluation process in an advisory role.

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.

7.2 Evaluation criteria

The main criteria considered in the evaluation are:

- a. Originality, clinical relevance, scientific value and topicality of the study;
- b. Suitability of methodological approach and feasibility of the project (incl. the patient recruitment plan, the organisation and management of the study and the financial planning);
- c. Documentation of patient and public involvement;
- d. Applicants' scientific track record and expertise in relation to the project, particularly with regard to multicentric clinical studies.

In addition, the following criterion is relevant to the evaluation of a supplementary grant applications (see Section 4.3.):

- e. Achievement of pre-defined milestones and favourable interim analysis

8. Grant management/rights and obligations of grantees

8.1 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 once the grant has been awarded. Before any further instalments can be paid, the scientific report on the predefined milestones (see section 8.4 on Reporting) will need to be approved by the SNSF.

8.2 Compliance with national and international regulations and clinical research guidelines

Grantees must ensure that the study is conducted in accordance with the study protocol and that it takes into account the Helsinki Declaration, the ICH-GCP Guidelines and the applicable statutory and regulatory provisions.

In the event of collaboration with a project partner 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 sponsor of the trial as defined in the Ordinance on Clinical Trials in Human Research (Source: *Article 2 letter c ClinO*).

8.3 Providing open access to research data (open research data)

All clinical trials funded under the IICT programme must be registered and trial protocols made publicly accessible before the first participant receives an intervention. After completion of the study, appropriately anonymised datasets must be made available for further analysis wherever possible.

A data management plan (DMP) is an integral part of the IICT research proposal. It is entered directly in *mySNF*. Applicants are expected to submit a DMP that is understandable, suits their project and meets the standards set by their research community. At this stage, the DMP is considered a draft and is not included in the scientific evaluation. The definitive DMP needs to be submitted by the end of the project at the latest.

Costs of providing open access to research data (Open Research Data) are chargeable to the IICT grant pursuant to the General implementation regulations for the Funding Regulations, Clause 2.13.

8.4 Reporting

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

- a. every 6 months, a scientific report on the pre-defined milestones;
- b. every 12 months, a financial report;
- c. a final scientific report upon conclusion of the project;
- d. a final financial report upon conclusion of the project;
- e. a DMP in accordance with SNSF requirements by the end of the project at the latest.

8.5 Discontinuation of the grant

The SNSF may discontinue the grant for significant reasons, particularly if the defined milestones are not reached, the stated aims for the trial can no longer be achieved within the remaining time or the formal requirements no longer met. The SNSF conducts a hearing with those concerned before issuing its decision in the form of a ruling.