Swiss National Science Foundation

Investigator Initiated Clinical Trials (IICTs): Call for proposals 2023

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 and regulated by the Ordinance on Clinical Trials with the exception of Clinical Trials of Medical Devices (Clinical Trials Ordinance, ClinO)* and the Ordinance on Clinical Trials with Medical Devices (ClinO-MD). The IICT programme goes beyond the scope of SNSF project funding in terms of its research questions, comprehensive nature, duration, complexity and costs. The trials generally require a multicentric setting, sometimes international collaborations, and are not in the industry focus.

Included are randomised controlled trials (RCTs) such as:

- Treatment trials
- Prevention trials
- Screening trials
- Diagnostic trials
- Quality of life trials
- Adaptive trials (i.e. platform trials)
- Repurposing trials
- Replication trials with significant knowledge gain***

Excluded from support under the IICT programme are:

- Studies conducted for directly commercial purposes
- Non-randomised and uncontrolled studies
- Pilot studies
- Proof of concept studies (phase I and IIa)
- Studies with safety endpoints only
- Observational studies
- Preclinical studies

* 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. 2 letter a ClinO
**Health-related intervention means a preventive, diagnostic, therapeutic, palliative or rehabilitative measure investigated in a clinical trial. Source: Art. 2 letter b ClinO
***i.e. different setting, greater sample size, more relevant endpoint

2 Key information about the call

2.1 Deadlines

The deadlines for the call 2023 are:

- Submission of letters of intent via *my*SNF by **26 May 2023**, **5 p.m.** Swiss local time
- If applicable, submission of PPI Preparatory Grant applications via *my*SNF by **26 May 2023**, **5 p.m.** Swiss local time
- Submission of full proposals via *my*SNF by **1 November 2023, 5 p.m.** Swiss local time.

2.2 Duration of evaluation

The evaluation procedure usually takes eight 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 details of the application process, awarding of grants, 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 should generally involve more than two centres. In special cases, studies may involve only one or two centres, provided the applicant(s) 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.

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-months 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.

4.4 Cost-neutral extension

The SNSF may, at the grantee's request, cost-neutrally extend the grant if the initial grant duration is insufficient for achieving the study goals.

4.5 Patient and public involvement (PPI)

In the research plan, applicants must document their efforts and plans to actively involve patients, members of their family, carers, the public or the relevant patient organisations across the entire lifecycle of the project (from the design of the study to its management and conduct, data analysis, dissemination of results and final evaluation)[1].

4.6 Preparatory grant for PPI representatives during the development of the application

Together with the submission of the letter of intent, a preparatory grant for patient engagement during the development of the application (PPI preparatory grant) of up to CHF 5000 can be requested. This grant aims to support activities during which PPI representatives can provide input for the development of the grant application/protocol. The budget must be outlined in a patient engagement plan and can include compensation of the PPI representatives for the time spent on providing input, as well as reimbursement of travel costs and expenses for accommodation and meals. In addition, the costs associated with the organisation of meetings for PPI activities can be charged to this grant.
After checking the formal requirements, the SNSF Administrative Offices directly award these preparatory grants.

4.7 Recruiting centres

Recruiting centres must confirm their participation in writing. These confirmations (letters of commitment) are of central importance for assessing the feasibility of the study and must include the items described in *my*SNF. The letters of commitment must be written in English.

4.8 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.

4.9 Clinical trial unit involvement

The involvement of a clinical trial unit (CTU) is highly recommended. You are advised to contact your local CTU[2] as early as possible. If a CTU is involved, a letter of support describing its involvement must be submitted together with the letter of intent as well as the full proposal.

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[1] For more information, please refer the SCTO webpage https://www.scto.ch/en/patient-and-public-involvement.html
[2] For more information on your local CTU, please visit https://www.scto.ch/en/clinical-trial-units.html

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 in the field of the trial 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, patient representatives or 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 *my*SNF by 5 p.m. Swiss local time on 26 May 2023. The letter of intent template is available on the SNSF website and the *my*SNF platform. Full proposals for which no letter of intent was submitted in due 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. If applicable, a PPI Preparatory Grant application can be submitted together with the letter of intent by no later than 5 p.m. Swiss local time on 26 May 2023.
c. Full proposals must be submitted via the *my*SNF portal by 5 p.m. Swiss local time on 1 November 2023. They must be submitted in accordance with the requirements issued by the SNSF and must contain all the necessary data and documents.
d. The research group submits a joint research plan. Use of the IICT proposal template 2023 is mandatory. The template is available on the SNSF website and on the *my*SNF platform. The IICT proposal must not exceed a maximum of 25 pages (excluding bibliography). No annexes are permissible.
e. If the proposal is resubmitted, a separate document called “revision notes” must be uploaded with the revised proposal addressing the criticisms made of the previous version, particularly the points raised in the rejection letter. The revision notes must not exceed a maximum of 10 pages.

f. Applicants may submit only one application per IICT call.
g. Researchers may participate as grantees in two IICT projects during the same funding period if the overlap does not last for more than 2 years. In addition, they may contribute to multiple projects as project partners.
h. Applications as well as all supporting documentation must be in English.
i. 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, liability insurance premiums in connection with research on humans for centres outside Switzerland, 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.
g. Costs for PPI (Patient and Public involvement) activities, i.e. costs for involving either the patients, members of their family, carers, the public or the relevant patient organisations during the trial lifecycle, such as hourly compensation for their consulting work, meetings.

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, 4.7 and 4.8 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. the third party confirms that they are not the sponsors of the trial as defined in the Ordinance on Clinical Trials in Human Research (Source: *Article 2 letter d ClinO*);
b. the third party provides proof that the principles of research freedom, research independence and freedom to publish will be upheld;

c. the third party confirms 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. the third party does not derive any direct pecuniary benefit from the SNSF-funded research work;
f. the third party confirms the contribution or donation in writing upon submission of 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 PPI Preparatory Grant - grant management

If applicable, the PPI Preparatory Grant is paid by the SNSF in a single instalment at the request of the corresponding grantee once the grant has been awarded. The transfer of funds must be requested

during the approved funding period. No scientific report is required, but a final financial report needs to be submitted at the end of the funding period and approved by the SNSF.

8.2 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 pre-defined milestones (see section 8.4 on Reporting) will need to be approved by the SNSF.

8.3 Compliance with national and international regulations and clinical research guidelines

Grantees must ensure that the study is conducted in accordance with the study protocol and that it takes into account the Helsinki Declaration[3], the ICH-GCP Guidelines[4], 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 d ClinO*).

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

From an ethical and public health perspective, but also in view of an efficient use of research resources, it is essential that clinical trials are conducted in an open and transparent manner and that the findings are made available to the whole research community and society. As required by the Swiss regulations (Clinical Trials Ordinance, ClinO) and based on the WHO Joint statement on public disclosure of results from clinical trials[5], the SNSF expects the following requirements to be met:

- Before the first patient receives an intervention: registration in a trial registry (SNCTP Portal as well as on any WHO primary registry or on ClinicalTrials.gov)
- Within 12 months of the start of the trial: publication of the trial protocol in the registry
- During the study: update of clinical trial registry at least once per year (including safety and substantial amendments to the study protocol, end date and enrolment status)
- Within 12 months of the study's completion: publication of the summary results for non-experts in the registry regardless of whether the results of the study were positive or negative
- Within 24 months of the end of the funding period and regardless of whether the results of the study were positive or negative:
    - Publication of the results in a (specialised) journal describing design, methodology and outcome
    - Appropriately anonymised datasets made available for further analysis wherever possible.

[3] https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
[4] https://ichgcp.net/
[5] https://www.who.int/news/item/18-05-2017-joint-statement-on-registration

For easy linking of trial-related publications with clinical trial registry site records, the trial ID or registry identifier code/number is to be included in the abstract of all publications on the clinical trial concerned. Additionally, please follow the CONSORT guidelines when reporting your study (http://www.consort-statement.org/).

A data management plan (DMP) is an integral part of the IICT research proposal. It is entered directly in *my*SNF. 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.

8.5 Reporting

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

a. every 6 months, a scientific report on the pre-defined milestones (may be adapted by the SNSF depending on the nature/progress of the study);
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 definitive DMP in accordance with SNSF requirements by the end of the project at the latest.

8.6 Discontinuation of the grant

The SNSF may discontinue the grant for significant reasons, particularly if the defined milestones are not reached, the stated objectives of 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.