Swiss National Science Foundation

Investigator Initiated Clinical Trials (IICT): Evaluation form for panel members

All panel members (clinical, statistical/methodological, PPI) have access to all application documents and are asked the same questions following the evaluation criteria defined in the call document.

1 Preliminary comments

General comments & declaration

Here you have the option to enter general comments.

Declaration concerning conflicts of interest

☑ I have no conflicts of interests or have declared any conflicts of interest below

By checking the box, you confirm that your assessment has not been affected by any conflict of interests or that you have declared any potential conflicts of interests by inserting a comment.

***Potential conflicts** of interests can be deemed to exist if a referee/co-referee*

- *is a mentioned project partner;*
- *has jointly published with the applicants in the last five years;*
- *professionally depends on or competes with the applicants, or has done so until recently or will do so in the foreseeable future;*
- *has close personal ties with the applicants (partnership, family ties, friendship);*
- *is otherwise biased.*

The members of the IICT Panel are obliged to declare all potential conflicts of interests.

2 Outline of the proposed study

In this part, please outline the proposed project very briefly. You should provide information on the subject, problem and approach/methods of the project, as outlined in the application.

3 Reviews

Please indicate whether the reviews are useful, partly useful or not useful. The summary of each review can be very short. A list of the key arguments is sufficient. Please mostly focus on clinical and statistical reviews as this is where your expertise lies (for PPI review, “useful” and n/a is fine).

Reviewer	Suggested by	Rating	Usefulness and consideration	Comments on usefulness
	Administrative Offices			
	Administrative Offices			

Reviewer	Summary of the main points

4 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)*.
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 through IICT programme are:

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

* Clinical trial means a research project involving individuals that prospectively assigns them to undergo one or more interventions** in order to study the effects thereof on health or on the structure and function of the human body. Source: Art. 2 letter a ClinO

**Intervention means any measure to which the participant is subjected and whose effects on this person are to be investigated. Source: Art. 2 letter b ClinO

Please comment on the fulfilment of the above listed criteria, specifically considering the exclusions of certain types of trials.

Should the trial not fulfil the scope of IICT, please contact the office (iict@snf.ch) prior to the continuation of this evaluation.

5 Assessment of the applicants

Applicants' scientific track record and expertise in relation to the project, particularly with regard to multicentric clinical studies

The **scientific qualifications of each applicant**, in particular the **track record** and the **expertise to carry out the research project,** have to be assessed on the basis of the following documents: CV(s). The SNSF has introduced a standardized CV format in October 2022. Consult the fact sheet to learn more about the format and its use in the evaluation.

The SNSF requires from reviewers and referees to consider the scientific qualifications of applicants based on their entire research output (including, when applicable, datasets, software, prototypes, etc.), in addition to research publications. In this context, **the scientific quality and relevance of a paper is deemed much more important than publication metrics.** The scientific quality and relevance of selected research outputs may be assessed directly by the sources provided by each applicant in the section "Major achievements" of the CV.

In general, the evaluation has to be done against the background of the scientific discipline and the academic age of each applicant.

Indicate whether and to what extent the research group (group of applicants) has the scientific and methodological expertise needed to carry out the proposed study successfully. Specifically assess whether the team as a whole has the expertise to carry out this particular prospective, randomized, interventional, multicentric clinical trial.

Specific strengths * (4000 characters (max.))	-
Specific weaknesses * (4000 characters (max.))	-
Comments (8000 characters (max.))	-

Use 5 (Strong in several relevant aspects. Some clearly identified weaknesses.) as a starting point and develop arguments to justify grading the application as 5, higher, or lower respectively.

Rating

	9	Strong in all relevant aspects. No or negligible weaknesses.
	8	
	7	Strong in most relevant aspects. Few clearly identified weaknesses.
	6	
	5	Strong in several relevant aspects. Some clearly identified weaknesses.
	4	
	3	Some strengths in relevant aspects. Several clearly identified weaknesses.
	2	
	1	Few or no strengths in relevant aspects. Many serious weaknesses.

6 Assessment of the proposed study

6.1 Clinical relevance, originality, scientific value and topicality of the study

Please assess in this part the clinical relevance, originality, scientific quality and topicality of the study

Please indicate whether and to what extent the:
• study addresses an unmet medical need

• topic, research questions and hypotheses of the planned study are relevant to the discipline and beyond
• proposed research question has already been addressed by other researchers
• approach offers unexpected or novel combinations of familiar aspects
• proposed study increases knowledge within the medical field and potentially beyond the medical field (broader impact)
• proposed study has the potential to change or confirm medical guidelines and whether the results can be transferred to clinical practice
• trial is internationally competitive

Specific strengths * (4000 characters (max.))	-
Specific weaknesses * (4000 characters (max.))	-
Comments (8000 characters (max.))	-

Use 5 (Strong in several relevant aspects. Some clearly identified weaknesses.) as a starting point and develop arguments to justify grading the application as 5, higher, or lower respectively.

Rating

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	4	
	3	Some strengths in relevant aspects. Several clearly identified weaknesses.
	2	
	1	Few or no strengths in relevant aspects. Many serious weaknesses.

6.2 Suitability of methodological approach and feasibility of the project

Please assess here the:
1) suitability of the methodological approach
2) feasibility of the project.

1) Indicate whether and to what extent the methods are appropriate and described in sufficient detail in view of the research question/s to be answered and the recommendations given in the SPIRIT Checklist. Specific points to consider:

a. Trial design

• Is the trial design adequate to answer the research question?
• Are the choice and administration of the interventions, the control(s)/comparator(s), inclusion/exclusion criteria, outcome measures, blinding methods, methods against bias appropriate?
• Is the number of assessments justified and its schedule appropriate?
• If any, are the description of the interim analysis and stopping guidelines complete?
• Is the assignment of patients to the interventions (randomisation) adequate and feasible? Is the randomisation stratified for important prognostic factors? Is the number of strata acceptable?

b. Hypothesis

• Is the hypothesis of the trial precise enough and in line with the trial design?
• Is the assumption about the efficacy of the comparators substantiated?

c. Statistics

• Are the proposed statistical methods appropriate?
• Is the sample size calculation correct and its underlying assumptions well justified?

2) Assess the feasibility of the proposed trial. Specific points to consider can be whether and to what extent the:

a. Financial planning

• targets/milestones set out in the application can be reached in the given time and with the available and requested personnel and financial resources
• number of persons to be employed is justified

b. Study organisation and management

• interventions are feasible; trial drugs or medicinal products are available; training and quality measures for complex interventions and complex outcome assessments are adequate
• trial coordination is convincing; advisory bodies are adequately defined; data management system / monitoring system is planned to guarantee high quality data

c. Patient recruitment

• recruitment rates are feasible; enrolment, potential drop-out rates and compliance of patients are adequately assessed
• If applicable, inclusion of recruiting centres outside Switzerland is justified

Specific strengths * (4000 characters (max.))	-
Specific weaknesses * (4000 characters (max.))	-
Comments (8000 characters (max.))	-

Use 5 (Strong in several relevant aspects. Some clearly identified weaknesses.) as a starting point and develop arguments to justify grading the application as 5, higher, or lower respectively.

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	1	Few or no strengths in relevant aspects. Many serious weaknesses.

6.3 Documentation of patient and public involvement

This part refers to the information given by the applicants in section 21 of the proposal form.

Please indicate whether and to what extent:

• Patients, next of kin, caretakers, the general public or respective organizations were involved in the conception and planning of the trial.
• Patients or their family are planned to be involved during the trial period.
• patient involvement is reflected in the proposal and how it affected the study protocol.

Specific strengths * (4000 characters (max.))	-
Specific weaknesses * (4000 characters (max.))	-
Comments (8000 characters (max.))	-

Use 5 (Strong in several relevant aspects. Some clearly identified weaknesses.) as a starting point and develop arguments to justify grading the application as 5, higher, or lower respectively.

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7 Overall assessment

Please provide a rating on the following scale for your overall assessment of the proposal, considering the strengths and weaknesses in the criteria-based assessment. Use 5 (Strong in several relevant aspects. Some clearly identified weaknesses.) as a starting point and develop arguments to justify grading the application as 5, higher, or lower respectively.

Rating

	9	Strong in all relevant aspects. No or negligible weaknesses.
	8	
	7	Strong in most relevant aspects. Few clearly identified weaknesses.
	6	
	5	Strong in several relevant aspects. Some clearly identified weaknesses.
	4	
	3	Some strengths in relevant aspects. Several clearly identified weaknesses.
	2	
	1	Few or no strengths in relevant aspects. Many serious weaknesses.

Please summarise the main reasons for your overall assessment by listing the **strengths** and **weaknesses** of the proposal.

This statement is the most important part of your recommendation, as it makes the reasoning behind your assessment transparent, it prepares the panel for the decision-making, and it provides the administrative office with the necessary information for the further processing of the proposal. A summary of your statement will be forwarded to the applicant(s), especially in the case of negative funding decisions.

Main reasons for your overall assessment * (8000 characters (max.))	-

8 Funding conditions

Please make a funding proposition for the planned project (e.g. funding level as requested, financial cut either in form of a global cut, or by cutbacks for certain budget items or an entire project part). The SNSF generally awards a total budget for approved research projects. In case of financial cuts, justify by one ore more of the following reasons:

- the requested amount is disproportionately high;
- a specific part of the project is not relevant and can be cut;
- some items in the budget are not eligible cost items;
- reduced budget due to applicants having been awarded grants with overlapping funding periods/scientific topics;
- based on the scientific quality of the application.

Comment on financing

Duration:

Please make a recommendation with regard to the duration of the proposed project. If your application differs strongly from the request submitted by the applicants, explain why. In general, the funding periods should be left unchanged unless strong justification is provided and should never be shortened purely as a means of reducing funding.

Requested duration
Proposed project duration (num. of months) *
Reasons

Conditions:

An application becomes subject to specific conditions/reservations if its assessment reveals minor problems with regard to the research plan, necessary infrastructure, personnel situation, co-operation or other aspects which hinder the realization of the project but do not take a major effort to resolve. Accordingly, the project is approved if the applicants are able to prove that they have resolved the problems. If they are unable to do so, the funds shall not be released. No conditions should be set if the application is seriously flawed. In such cases, you should recommend that the application be rejected.

Conditions

Authorisations and reportable experiments

Might other documents be needed for this project besides the authorisations and notifications declared in the application?	☐ Yes
Additionally required authorisations or notifications	

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