Investigator Initiated Clinical Trials, Call for Proposals 2024

Letter of Intent

**INSTRUCTIONS**

*Please note that the submission of the letter of intent (LOI) is done via mySNF. The deadline for the submission of the LOI is on* ***27 May 2024 at 17:00*** *Swiss local time. Full proposals for which no LOI was submitted in due time cannot be considered for evaluation. Information in the pre-proposals are not binding such that changes in the content of the application (i.e. changes in the team of applicants, project partners, budget, etc.) between the LOI and the full proposal are allowed.*

*The LOI enables the SNSF to organise the forthcoming evaluation process and to provide preliminary, non-binding feedback on the formal eligibility of the applicants. The LOIs do not serve as a pre-selection criterion.*

*For the submission of your LOI, the use of this template is mandatory. The structure of the template must not be changed, but subtitles may be added and formatting can be changed.*

*Upload a PDF-file (not write-protected) of your LOI to the data container LOI project description in mySNF. Name the file as follows: IICT2024\_LOI\_[Name of responsible applicant].pdf (e.g. IICT2024\_LOI\_Smith.pdf). Delete the INSTRUCTIONS on the first page and in each textbox before submission.*

*When planning your clinical trial, please consider the following points:*

***Patient and public involvement (PPI)***

*We would like to draw your attention to the importance of PPI in all aspects of a clinical trial, ideally already starting during the study design. For more information on PPI, please consult the SCTO webpage* [*https://www.scto.ch/en/patient-and-public-involvement.html*](https://www.scto.ch/en/patient-and-public-involvement.html)*. The applications submitted for the IICT Call 2024 are for the fifth time evaluated by members of the public.*

*Together with the submission of the LOI, a preparatory grant for patient engagement 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.*

***Patient-centered outcome measures (PROMs)***

*The SNSF highly recommends considering patient-centered outcome measures (PROMs) and thereby specifically highlights the collection of internationally recognised PROMs by the International Consortium for Health and Outcomes Measures ICHOM* [*https://www.ichom.org/patient-centered-outcome-measures/*](https://www.ichom.org/patient-centered-outcome-measures/)

***Priority-setting partnership***

*The James Lind Alliance brings patients, carers and clinician groups together on an equal footing to identify evidence uncertainties which are important to these groups. The resulting ‘Top 10’ lists of jointly agreed uncertainties as research questions can be a great source of input when defining a research question.* [*https://www.jla.nihr.ac.uk/priority-setting-partnerships/*](https://www.jla.nihr.ac.uk/priority-setting-partnerships/)

***Trial management***

*All projects are encouraged to appoint a dedicated trial manager.*

***CTU involvement***

*It is advisable to involve experts of the Clinical Trial Units (CTUs –* [*https://www.scto.ch/en/clinical-trial-units.html*](https://www.scto.ch/en/clinical-trial-units.html)*) or similar institutions at an early stage to develop the study protocol and ensure the quality of data collection. Please upload a letter from the CTU confirming their participation in the planned proposal under “LOI project description”.*

1. **Trial Synopsis** (*grey shaded fields marked by “\*” are mandatory but can be tentative)*

|  |  |
| --- | --- |
| Title of trial\* | *Insert a descriptive title identifying the study design, population, interventions, and, if applicable, study acronym. Maximum 180 characters, incl. spaces.* |
| Responsible applicant\* | *Indicate the name, institution, position, role, phone number, and e-mail address of the applicant responsible for communication with the SNSF.*  |
| Other applicants\* | *Indicate the name, institution, and position of each applicant, as well as her/his specific role and responsibility in the project.* Note: the number of applicants (including the responsible applicant) is limited to 5 persons. |
| Project partners\* | *Indicate the names, institutions and roles of the project partners (please refer to the IICT call text for definition of project partners).*  |
| Clinical trial unit involvement\* | The SNSF highly recommends involving your local clinical trial unit (CTU) in the conception, design and execution of the trial[ ]  Yes - Name of clinical trial unit:[ ]  No |
| Project management (optional) | *Describe role and employment level of project manager.* |
| Sponsor\* | *Indicate the sponsor or sponsor investigator of the planned study including the contact information.* |
| Re-submission\* | [ ]  Yes – Application number:[ ]  No |
| Medical field(s)\* |  |
| Trial type\* | [ ]  Interventional (according to Article 2 letter b [ClinO](https://www.fedlex.admin.ch/eli/cc/2013/643/en))[ ]  Prospective[ ]  Randomized[ ]  ControlledNote: only trials that fulfill all the above-mentioned criteria are eligible for the call |
| Trial duration (optional) | * (if applicable) Preparatory phase (months) max. 12 months:
* First patient in to last patient in/Recruitment period (months):
* Follow-up per patient (months):
* Duration of the entire trial (preparatory phase, recruitment, follow-up, analysis, evaluation) max. 60 months:
 |
| Endpoints (optional) | Primary endpoint:Secondary endpoint: |
| Intervention(optional) |  |
| Sample size (optional) |  |
| Recruitment sites (optional) | No. of centres to be involved:Names of cities and centres:Note: IICT studies should generally involve more than two centres. In case your trial involves only one or two centres, please justify why it cannot be carried out successfully as a multicentric project. |
| Approximate Funding requested  | Total amount: CHF |
| Co-funding, contributions and donations from third parties (optional) | [ ]  Co-funding – Type:[ ]  Donation – Type: Name of third party: Amount: CHFNote: all contributions and donations from third parties need to be confirmed in writing at the time of full proposal submission. Additionally, all points listed in the IICT Call text under 6.2 must be confirmed. |

1. **Abstract**

*Describe the background, rationale, aim(s) and the methodology of the planned study. Maximum 4000 characters, incl. spaces.*

1. **Patient engagement plan**

*Please use the following template to explain the patient engagement planned until the proposal submission. Note: this plan forms the basis for the budget that can be requested as a preparatory grant at the same time as the LOI (but in a separate submission on mySNF).*

|  |  |  |  |
| --- | --- | --- | --- |
| ***Activity*** | ***What is the role of the PPI contributor(s)?*** | ***What is the objective of the activity?*** | ***Budget****\_Compensation (hourly/half-day/day)**\_Reimbursement (travel/accommodation/meals)* |
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|  |  |  |  |
| *Total Sum* |  |  | *Total Cost* |