Investigator Initiated Clinical Trials, Call for Proposals 2020

Letter of Intent

**INSTRUCTIONS**

***Please note that the submission of the letter of intent (LOI) is newly done via mySNF and includes more information on the applicants, project partners than previously. The portal for submission will open on mySNF in the beginning of April 2020.***

*The deadline for the submission of the LOI is on* ***26 May 2020 at 5pm*** *Swiss local time.*

*For the submission of your letter of intent (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.*

*Submit the document in PDF format (not write-protected)**and name the file as follows: IICT2020\_LOI\_[Name of responsible applicant].pdf (e.g. IICT2020\_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. The applications submitted for the IICT Call 2020 are for the first time evaluated by members of the public.*

*In this context please also consider the SPIRIT-PRO Extension: Calvert M, Kyte D, Mercieca-Bebber R, Slade A, Chan A-W, MD, King MT, and the SPIRIT-PRO Group. Guidelines for Inclusion of Patient-Reported Outcomes in Clinical Trial Protocols. The SPIRIT-PRO Extension. JAMA. 2018;319(5):483-494.*

***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 or similar institutions at an early stage to develop the study protocol and ensure the quality of data collection.*

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

|  |  |
| --- | --- |
| Tentative title of trial\* | *Insert a descriptive title identifying the study design, population, interventions, and, if applicable, study acronym. Maximum 180 characters, incl. spaces.* |
| Corresponding 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.* *The number of applicants (including the responsible applicant) is limited to 5 persons.* |
| Project partners\* | *Indicate the names, employers and roles of the project partners (please refer to the IICT call text for definition of project partners).* |
| Clinical trial unit involvement\* | 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 a [ClinO](https://www.admin.ch/opc/en/classified-compilation/20121176/index.html))  Prospective  Randomized  Controlled  Note: 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) max. 60 months: |
| Endpoints (optional) | Primary endpoint:  Secondary endpoint: |
| Sample size (optional) |  |
| Recruitment sites (optional) | No. of centres to be involved:  Names of cities and centres: |
| Funding requested (optional) |  |

1. **Abstract**

*Describe the background, rationale, aim(s) and the methodology of the planned study. The abstract should not exceed 4000 characters, including spaces.*