

Investigator Initiated Clinical Trials Programme Checklist

1 General checklist

| Action/Document | Related Link | Comments | Status |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Regulations | www.snf.ch/iict | Please carefully read the regulations and make sure that your project fulfils the requirements. In case of questions, please write to iict@snf.ch . Please be available after the full proposal submission deadline to potentially update your proposal if requested (the deadline for the correction is 2 days) | <input type="checkbox"/> |
| Register to mySNF | New user login link: https://www.mysnf.ch/ne_wuser.aspx | Creation of the mySNF account at least one week before the deadline mySNF User Agreement: new users of mySNF are requested to sign a User Agreement and return a copy of the signed document to the following address: mysnfuseragreement@snf.ch ; please follow carefully the instructions provided in the email once registered for a new mySNF account. | <input type="checkbox"/> |
| Patient and public involvement (PPI) | https://www.scto.ch/en/patient-and-public-involvement.html | The engagement of patients, members of their family, carers, the public or respective patient organisations in the entire lifecycle of the project (from the study design, to its management, conduct, data analysis, dissemination and final evaluation) is mandatory. For more information, please refer the SCTO webpage https://www.scto.ch/en/patient-and-public-involvement.html . Preparatory grant for PPI representatives during the development of the application After submission of the letter of intent, 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 must 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. | <input type="checkbox"/> |
| Clinical trial unit involvement | https://www.scto.ch/en/network/ctu-network.html | The involvement of a clinical trial unit (CTU) is highly recommended. You are advised to contact your local CTU as early as possible. A letter of support describing the involvement of the CTU must be submitted together with the letter of intent and the full proposal. | <input type="checkbox"/> |

2 Letter of intent

| Action/Document | Related Link | Comments | Status |
|-------------------------------------------|-----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Letter of intent | Template | Use the provided template; in the patient engagement plan outline the activities planned during the preparation of the full proposal and indicate the budget required that you then enter into mySNF All text must be written in English | <input type="checkbox"/> |
| CV and publication list of all applicants | Instructions | For each applicant (main and co-applicants) please upload two separate documents: <ol style="list-style-type: none"> 1. CV and major scientific achievements (each part must not exceed 2 pages; overall max. 4 pages); name the document "CV_[applicant's name].pdf" 2. Research output list of the last 5 years; name the document "Output_[applicant's name].pdf" | <input type="checkbox"/> |
| Support letter of CTU | N/A | If a clinical trial unit is involved in the grant application, please provide a letter of support confirming their participation | <input type="checkbox"/> |
| Personal data | https://www.mysnf.ch/ | Please provide the personal data of all applicants for a formal eligibility check (i.e. employment, institution, function). | <input type="checkbox"/> |
| Application data | | Please provide some general information on your project: title, starting date, duration, research field, summary, institution | <input type="checkbox"/> |
| Requested funding | | Please enter the approximate lump sum required to conduct the trial outlined in the letter of intent. No further details or cost break-down necessary at this point. | <input type="checkbox"/> |

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

| Action/Document | Related Link | Comments | Status |
|-------------------|-----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Personal data | https://www.mysnf.ch/ | Please provide the personal data of all applicants. | <input type="checkbox"/> |
| Application data | | Please provide some general information on the pre-application grant: title, starting date, duration, research field, summary, institution Note: maximum duration 01.06.2022-31.10.2022 (5 months) | <input type="checkbox"/> |
| Requested funding | | If required and properly justified in the patient engagement plan (part of the letter of intent), you can enter here the budget for involving PPI representatives during the preparation of the full proposal. | <input type="checkbox"/> |

4 Full proposal

| Action/Document | Related Link | Comments | Status |
|-------------------------------------------|---------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Project description | Template | Use the provided template In English, 25 pages, excluding bibliography | <input type="checkbox"/> |
| CV and publication list of all applicants | Instructions | For each applicant please upload two separate documents: 3. CV and major scientific achievements (each part must not exceed 2 pages; overall max. 4 pages); name the document "CV_[applicant's name].pdf" 4. Research output list of the last 5 years; name the document "Output_[applicant's name].pdf" | <input type="checkbox"/> |
| Letters of commitment | N/A | Provide letters of commitment for: - Patient and public representatives - Local clinical trial unit - Recruiting centres consisting of _Confirmation of participation in the trial (giving the title of the trial and PI's name) _Name and position of the person responsible for patient recruitment; _Number of patients that will be included in the trial at the centre; _Evidence for the feasibility of patient numbers, e.g. experiences made in previous studies, patient registers or retrospective case studies. | <input type="checkbox"/> |
| Quotes | N/A | Please provide a quote for: - Equipment above CHF 20'000 - Clinical trial unit costs above CHF 100'000 | <input type="checkbox"/> |
| Co-funding | N/A | In case your study is co-funded by another institution, please upload a confirmation under "Other Annexes". For commercial partners and co-funding please provide a statement confirming: a. applicants confirm that the relevant enterprises or institutions are not the sponsors of the trial; b. applicants provide prove 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 is declared (e.g. supply of drugs or medical equipment for the trial free of charge or at a reduced rate); e. sponsors and owners of enterprises do not derive any direct pecuniary benefit from the SNSF-funded research work; | <input type="checkbox"/> |
| Re-submission | N/A | In case of a resubmission, please join a statement responding point-for-point to the comments raised in the rejection letter In English, max. 10 pages | <input type="checkbox"/> |
| Personal data | Directly enter information on: https://www.mysnf.ch/ | Please provide the personal data of all applicants for a formal eligibility check (i.e. employment, institution, function). Additionally, enter the personal information and function of all project partners. | <input type="checkbox"/> |
| Application data | | Please provide some general information on your project: title, starting date, duration, research field, summary, institution | <input type="checkbox"/> |
| Requested funding | | Salaries, research funds, patient engagement, patient fees and other Please enter each budget item together with a short description in the mask provided on mySNF | <input type="checkbox"/> |
| Data management plan | | For instructions please visit: https://www.snf.ch/en/FAi-WVH4WvpKvohw9/topic/research-policies | <input type="checkbox"/> |