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Investigator Initiated Clinical Trials Programme **Checklist**

last updated February 2024

1 General checklist and resources

Action/Document	Related Link	Comments	Status
Register to mySNF	New user login link: https://www.mysnf.ch/newuser.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.	☐
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)	☐
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. Important resources to be consulted: - Guide for Researchers to Address PPI in Clinical Trials - SCTO Remuneration Policy for PPI: *EN*, *DE*, *FR*, *IT* - Participation Request for PPI Activities Template *EN*, *DE*, *FR*, *IT* - Written Agreement for PPI Activities Template: *EN*, *DE*, *FR*, *IT* SCTO offers a special course for PPI in the IICT programme: Online course: How to successfully address the PPI requirement - scto Other resources: The EUPATI Patient Involvement in Medicines R&D Roadmap Video Patient Engagement Roadmap - EUPATI Toolbox **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 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.	☐
Clinical trial unit involvement	https://www.scto.ch/en/clinical-trial-units.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.	☐

Patient-centered outcome measures PROMs	https://www.ichom.org/patient-centered-outcome-measures/	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	☐
Priority-setting partnerships	https://www.jla.nihr.ac.uk/priority-setting-partnerships/	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.	☐
Interventions	https://www.bmj.com/content/348/bmj.g1687	Please refer to the template for intervention description and replication (TIDieR) checklist for comprehensive reporting of interventions (see also http://www.consort-statement.org/resources/tidier-2)	☐

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	☐
CV and major achievements	CV format	In order to comply with the DORA principles, the SNSF defined a new structure for the CV and requests a standardised set of information from all applicants. **Specifically, applicants will have to compile their CV according to a new template on the SNSF Portal and subsequently upload a PDF in mySNF in the data container "CV and major achievements".** For more details on the new CV format see: CV format The portal can be accessed under: portal.snf.ch This information is intended for evaluators to specifically assess the scientific quality and relevance of the research output. The CV must be written in the language of the research plan.	☐
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	☐
Personal data	https://www.mysnf.ch/	Please provide the personal data of all applicants for a formal eligibility check (i.e. employment, institution, function).	☐
Application data		Please provide some general information on your project: title, starting date, duration, research field, summary, institution	☐
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.	☐

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 the corresponding applicant only.	☐
Application data		Please provide some general information on the pre-application grant: title, starting date, duration, research field, summary, institution Note: maximum duration **01.07.2024-31.10.2024 (4 months)**	☐
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. Please make sure to enter every activity separately and as outlined in the engagement plan.	☐

4 Full proposal

Action/Document	Related Link	Comments	Status
Project description	Template	Use the provided template In English, 25 pages, excluding bibliography	☐
CV and major achievements	CV format	In order to comply with the DORA principles, the SNSF defined a new structure for the CV and requests a standardised set of information from all applicants. **Specifically, applicants will have to compile their CV according to a new template on the SNSF Portal and subsequently upload a PDF in mySNF in the data container "CV and major achievements".** For more details on the new CV format see: CV format The portal can be accessed under: portal.snf.ch This information is intended for evaluators to specifically assess the scientific quality and relevance of the research output. The CV must be written in the language of the research plan. The documents are sent out for peer-reviewing and will be accessible for your research institution.	☐
Letters of commitment	Template LOC PPI	Provide letters of commitment (LOC) for: - Local clinical trial unit - Patient and public representatives - Template LOC PPI - 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.	☐
Quotes	Template for CTU services (Word / Excel)	Please provide a quote for: - Equipment above CHF 50'000 - Clinical trial unit costs above CHF 100'000 using a standardised template for CTU services (Word / Excel)	☐
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 signed by the third party confirming:	☐

		a. the third party confirms that it isthey 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 will guarantee the scientific freedom and independence of the researchers involved; c. in particular, the third party confirms that the researchers will be able to publish their results according to the Open Access requirements of the SNSF and Article 47 of the Funding Regulations (http://www.snsf.ch > Funding > How to > Funding Regulations) and share the results with other researchers without any restrictions; d. the type and amount of the contribution or donation is declared, and the third party confirms the contribution or donation in writing upon submission of the full proposal; e. the SNSF funded research cannot and will not generate any direct monetary advantages for the third party.	
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	☐
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.	☐
Application data		Please provide some general information on your project: title, starting date, duration, research field, summary, institution	☐
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. CTU costs need to be entered as described in the template for CTU services.	☐