IICT programme

Template interim and final scientific report

Instructions

The reporting is incremental, such that you can use the previous report and adapt it. For the interim reports only sections 1-3 need to be filled.

**Interim scientific report during the preparatory phase**

* Please fill in sections 1-3 in this template (2.4-2.6 can be left empty)
* Update on mySNF the output data (all categories)

Note: once the legal requirements are met and everything is in place to start recruiting the first patient, the preparatory phase is considered as finished. This includes:

* data management and monitoring strategy in place
* (if applicable) data safety monitoring board set up
* necessary contracts/agreements signed
* trial protocol finalized and published onto the registry within 12 months of the start of the trial (see article 8.4 of the call)
* ethics approval for at least one Swiss site
* (if necessary) approval of Swissmedic
* registration in a trial registry (SNCTP Portal as well as on any WHO primary registry or on ClinicalTrials.gov)
* (if applicable) specific conditions in the SNSF decision letter addressed
* Once the preparatory phase is finished, update on mySNF the abstract by adding at the top, the following 4 sentences completed with your information:

This study is registered on the Swiss National Clinical Trials Portal (SNCTP) under the number SNCTPXXXXXXXXX and on ClinicalTrials.gov with the identifier NCTXXXXXXXX.

More information on the study can be found on the trial website: www.xxxxx.ch

Trial protocol: please provide the digital object identifier (DOI) of the publication (example: doi: 10.1016/j.jpsychires.2017.11.014)

**Interim scientific reports once recruitment started**

* Please fill in sections 1-3 in this template
* Update of clinical trial registry (including safety and substantial amendments to the study protocol, end date and enrolment status)
* Update on mySNF the output data (all categories)
* If new information (such as publication of trial protocol or other) is available, update on mySNF the abstract by adding at the top, the following 4 sentences completed with your information:

This study is registered on the Swiss National Clinical Trials Portal (SNCTP) under the number SNCTPXXXXXXXXX and on ClinicalTrials.gov with the identifier NCTXXXXXXXX.

More information on the study can be found on the trial website: www.xxxxx.ch

Trial protocol: please provide the digital object identifier (DOI) of the publication (example: doi: 10.1016/j.jpsychires.2017.11.014)

**Final scientific report**

* Please fill in sections 1-5 in this template
* Update the registry information (SNCTP Portal as well as on any WHO primary registry or on ClinicalTrials.gov) including summary results for non-experts and links to publications and anonymised datasets
* Update on mySNF the output data
* Update on mySNF the abstract by adding

1. At the top, the following 4 sentences completed with your information:

This study is registered on the Swiss National Clinical Trials Portal (SNCTP) under the number SNCTPXXXXXXXXX and on ClinicalTrials.gov with the identifier NCTXXXXXXXX.

More information on the study can be found on the trial website: www.xxxxx.ch

Trial protocol: please provide the digital object identifier (DOI) of the publication (example: doi: 10.1016/j.jpsychires.2017.11.014)

Trial results: please provide the digital object identifier (DOI) of the publication(s) (example: doi: 10.1016/j.jpsychires.2017.11.014)

Note: In case you do not have the final results yet, please provide an estimate on when they will be available.

1. At the bottom, short statements on the following two points by copy/pasting or summarizing section 4 in this template (see screenshot 2):
   * + - Most important research finding
       - Impact on clinical practice / health system

Note: as defined in article 8.4 of the IICT Call text, the SNSF expects the following requirements to be met after the completion of the study:

* Within 12 months of the study’s completion: publication of the summary results for non-experts in the trial registry (everywhere the trial is registered - SNCTP Portal as well as on any WHO primary registry or on ClinicalTrials.gov) regardless of whether the results of the study were positive or negative.
* Within 24 months of the end of the funding period and regardless of whether the results of the study were positive or negative:
  + Publication of the results in a (specialised) journal describing design, methodology and outcome
  + Appropriately anonymised datasets made available on a data repository for further analysis wherever possible.

# General information

|  |  |
| --- | --- |
| Responsible applicant |  |
| Title of trial |  |
| SNSF grant number |  |

# Status report

## Approvals, registration, and publication

|  |  |
| --- | --- |
| Trial registration | *Please provide the registration number (SNCTP Portal as well as on any WHO primary registry or on ClinicalTrials.gov) and the date of the last update*  *Note: registry information should be updated at least once per year (including safety and substantial amendments to the study protocol, end date and enrolment status)* |
| Trial protocol finalization and publication | *Please provide the date when the study protocol was finalised and upload the final version of the protocol.*  *Please provide the DOI to the trial protocol publication and the date*  *Note: the trial protocol must be published within 12 months of the start of the trial* |
| Date ethics approval / amendments | *Please provide a list of authorizations received for each centre including the date of approval. Additionally, please upload any new authorization obtained during the reporting period as pdf.* |
| Date Swissmedic approval (if necessary) | *Please provide the date of the Swissmedic approval and upload the pdf.* |
| Publication of results | *Please provide the DOIs for each publication resulting of this trial. If already available, specifically indicate the main publication.*  *For the final report: if the main publication is not yet published, please provide an estimate on when it will be submitted/accepted.*  *Note: trial results must be published within 24 months of the end of the funding period and regardless of whether the results of the study were positive or negative* |
| Publication of datasets | *Please provide the link to datasets made available for further analysis.*  *Note: within 24 months of the end of the funding period and regardless of whether the results of the study were positive or negative appropriately anonymised datasets must be made available wherever possible* |
| Media / News | *Please provide a link to publications / news / press reports that mention this study* |

## Study setup

|  |  |
| --- | --- |
| Contracts with third parties that provide co-funding and/or donations | *Please provide a list of contracts signed with third parties. For contracts signed with commercial third parties, please provide a confirmation regarding the non-commercial purpose of the research and the independence of the researcher based on the following template and signed both by the corresponding applicant and the concerned institution:*   1. *[concerned institution] confirms that research conducted in the context of the project "Title of proposal" fulfills the following* ***conditions****:* 2. *The freedom and independence of the researchers involved in the project "Title of proposal" is guaranteed.* 3. *The researchers will be able to publish their results according to the Open Access requirements of the SNSF1 and Article 47 of the* [*Funding Regulations*](https://www.snf.ch/media/en/1HxQ3OducIgk1Euw/allg_reglement_16_e.pdf) *and make them available to other researchers without restrictions.* 4. *The funded research cannot and will not generate any direct monetary advantages for the commercial business [concerned institution].* 5. *Upon request, the SNSF may release grantees from these obligations should publication not be advisable for confidentiality reasons (item 2 above, Article 47 of the Funding Regulations), particularly in relation to the acquisition of patents or due to a contractual commitment to observe confidentiality. The exemption can only be granted for valid reasons and upon request.*   *By signing this document, the [concerned institution] confirms that it will respect the conditions according to item I, 1-3 in the context of research work for the project "Title of proposal" and ensure that all persons involved in the research do likewise, and that it has taken note of item II.* |
| Data Management system | *Please state whether the DMS is ready and what GCP-compliant system was used* |
| Monitoring strategy | *Please state whether a monitoring plan is in place for all sites and being followed (including remote and central monitoring).* |
| (if applicable) Data safety monitoring board | *Please state whether the DSMB is set up.* |
| If applicable, conditions in ruling | *In case any specific conditions were listed in the SNSF ruling for your grant, please take position on it here.* |

## Study schedule

*Please provide an updated study schedule (as submitted in the proposal in section 22 – see example below) and indicate the current status as well as time delay, if applicable*

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *Months*  *Dates* |  | *1-6* | *7-12* | *13-18* | *19-24* | *25-30* | *31-36* | *37-42* | *43-48* | *49-54* | *55-60* |
| Submitted | Overview | Preparatory phase | First patient in |  |  | Last patient in |  | Last patient out |  | Analysis finished |  |
|  | Numbers (# patients randomised / # patients follow-up finished) |  | 20/0 | 40/20 | 60/40 | 80/60 | 100/80 | 100/100 |  |  |  |
| Update Report 1 (Date) | Overview | Preparatory phase | First patient in |  |  |  | Last patient in |  | Last patient out |  | Analysis finished |
|  | Numbers (# patients randomised / # patients follow-up finished) |  | 10/0 | 25/10 | 45/25 | 70/45 | 95/70 | 100/95 | 100/100 |  |  |

Current status

## Recruitment status

|  |  |
| --- | --- |
| Number of patients (and further study participants) planned / randomised | *Total and within the reporting period, please also provide the percentage (randomised versus planned)* |
| Number of centres planned / initiated | *Please list the names of each centre with their current status (if applicable, please order by country))* |
| First patient in (date) |  |
| Number of patients a) in follow-up & b) with follow-up finished |  |
| Number/Rate of screening failures |  |
| Number/Rate of dropouts | *Please provide the estimated drop-out rate used for the calculation of the sample size and compare it to the current actual number of dropouts* |
| Last patient in (date) | *Please provide the date when the last patient was recruited to this trial. If recruitment is still ongoing, please estimate the date when the last patients will be recruited based on the current recruitment rate* |
| Last patient out (date) | *Please state when the last patient reached or will reach the planned milestone representing the completion of the trial.* |

## Recruitment table

## *Please create a chart that indicates the progress of patient/further study participant recruitment on a cumulative monthly (or quarterly, or biannual) basis for all centres/sites involved (not for each single centre/site). By doing so, also compare your current/actual recruitment rate to your originally planned recruitment rate as anticipated in the full proposal. Begin your timeline with the month/quarter/half year in which the first patient was planned to be recruited and end your timeline with the current status. The chart below represents an example.*

## Recruitment problems and other deviations from the study schedule including proposed solutions

## Patient and public involvement

Based on the table submitted in the proposal under point 21, please provide a status update during each interim report and an evaluation (last column) with the final report

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Phase | Activity/Tasks | What is the role of the PPI contributor(s)? | Objective(s) | Format | Status of PPI activities & timeline | Results / Impact | Costs | Evaluation |
|  |  |  | *Describe the expected benefit and outcome of each PPI activity.* | *Specify the method(s) or setting(s) used to reach the objective(s) (e.g. structured interviews, surveys, focus groups, advisory board meetings, or committee meetings).* | *Select the status of each activity (i.e. planned, on track, delayed, completed, postponed) and provide a time estimate (start/end date and time commitment necessary)* | *Describe how each PPI activity has influenced your research project.* | *Enter costs incurred (all related expenses and compensation).* | *Was each PPI objective met? If not, why not? Are there any immediate actions or long-term measures to be taken?* |
| Management and study process |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Data analysis |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Dissemination and implementation |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Evaluation |  |  |  |  |  |  |  |  |

# Changes/Deviations in Trial Design or Conduct

Please select which aspect of the trial it concerns:

1. Trial design

Controls/Comparators

Dose, mode and scheme of intervention

Additional treatments

Inclusion and exclusion criteria

Determination of primary and secondary measures

Methods against bias

Proposed sample size/Power calculation

Originality and quality of the study

Statistical analysis

Other

1. Trial conduct

Recruitment sites

Staff (including PPI contributors)

CTU involvement

Other

Explain the reason and the nature of the change:

# Outcome and impact - mandatory for final report

## Most important research findings

*Please describe in a few words the most important research findings out of your project so far.*

## Impact on clinical practice / health system

*What have we learnt from your research project so far and what was or will be the expected impact on clinical practice/health system/guidelines?*

# Lessons learnt and feedback – mandatory for final report

*To improve the IICT programme and provide better guidance for future projects, we are interested to find out what the specific lessons learnt from this trial are that could be of relevance for future studies by other groups. Additionally, any feedback regarding the IICT programme and the lifetime management is highly welcome.*