Information sheet

Definition of inclusion and exclusion criteria

The inclusion and exclusion criteria define which patients can be admitted to a clinical research project (clinical trial and observational study) and which patients must be excluded from participation.

Each of the selected inclusion and exclusion criteria needs a comprehensible justification in order to avoid that persons are unnecessarily excluded from participation. Therefore, criteria that neither ensure the safety of study participants nor are relevant to answering the primary research question should be omitted [1-4].

This information sheet covers areas that are frequently identified as inclusion or exclusion criteria but which may be waived or, in justified cases, be specified in order to simplify the inclusion of study participants.

Pregnancy

Inclusion criterion: Negativ pregnancy test
Exclusion criterion: Positiv pregnancy test or confirmed pregnancy

- **Studies in which inclusion of pregnant women is possible:**
  - Comparison of two physical methods (non-drug therapy) for relief of local symptoms if non-drug methods being compared do not increase the risk to the pregnant woman or the unborn.
  - Comparison of two surgical methods/procedures if the surgical intervention would also be performed during pregnancy or is considered the standard intervention in this situation.
  - Observational studies especially "questionnaire studies"
- **Specification of criteria:**
  Indication for pregnancy testing at study entry
  - For studies in which postmenopausal women are also included following specification can be made: Women who have been surgically sterilised or hysterectomised or have been postmenopausal for at least 2 years (if necessary further specify) are not required to have a negative pregnancy test.

Inclusion in emergency situations or in the event of (temporary) incapacity to judge

Inclusion criterion: Presence of personal consent

- This can be waived in emergency situations or in the event of (temporary) incapacity to judge.
- Swissethics provides interpretation aids, templates and further information on the correct procedure and its documentation.
  Please see https://swissethics.ch/en/templates/forschung-in-notfallsituationen

Language skills

Inclusion criterion: Sufficient oral and written German language skills

- The extent to which language skills should be part of the inclusion/exclusion criteria must be carefully considered for each study. The decisive factors are, for example, how complex the completion of questionnaires is and in which languages a validated version of the questionnaires used is available.
- Guidance for the consideration of language skills of participants is provided in the consensus paper "Information of participants in foreign languages" by swissethics and Swiss Clinical Trial Organisation (SCTO).
  Please see https://swissethics.ch/en/themen/weitere-themen

Simultaneous participation in other research projects

Exclusion criterion: Participation in another research project

- **Observational studies:**
  In many cases, parallel participation in different observational studies would not increase the risk for the patients and would also have no influence on the study results. But, for instance studies involving radiological examinations are an exception. In these cases, it must be ensured that participation in several studies does not exceed the legally prescribed radiation exposure.
- **Intervention studies:**
  Whether participation in another trial is justifiable depends essentially on the interventions under investigation and the associated risks. Clinical trials with drugs or method comparisons (other clinical trials) represent different situations and can be assessed differently with regard to simultaneous participation.

Inclusion in the emergency ward

Inclusion/Exclusion criterion: Patients who are admitted from home

- **Extention of the criterion:**
  Patients who are already inpatients or who are admitted from a rehabilitation institution can also be included.

Expansion of diagnostic criteria

Inclusion/Exclusion criterion: Patients hospitalised with moderate COVID-19 symptoms

- **Extention of the criterion:**
  Patients who are already hospitalised for another condition but develop moderate COVID-19 symptoms during hospitalisation (nosocomial COVID-19) may be included.

Note

Often, documents from previous studies are used as templates for the preparation of study protocols. This way certain specifications, also those for inclusion and exclusion criteria, may be transferred by "copy & paste".

Please note, that each of the listed inclusion/exclusion criteria must be justified in the context of a given research project. Excluding conditions do not have to be addressed twice. It is sufficient if a specific condition is formulated either as an inclusion or as an exclusion criterion.

References

[1] https://ctti-clinicaltrials.org/wp-content/uploads/2021/06/CTTI_Recruitment_Recs.pdf; access 28.6.2022

[2] https://ctti-clinicaltrials.org/wp-content/uploads/2021/06/CTTI_Recruitment_Decision_Tree.pdf, access 28.6.2022

[3] Hornberger, Brianna and Rangu, Sneha, "Designing Inclusion and Exclusion Criteria" (2020). . 1. https://repository.upenn.edu/crp/1, Content in this chapter is licensed by the editors under a Creative Commons AttributionNonCommercial-NoDerivatives 4.0 International (CC BY-NC-ND 4.0) license.

[4] https://www.swissethics.ch/assets/pos_papiere_leitfaden/swissethics_fremdsprachige_final_d.docx, access 27.7.2022

Further information on inclusion of women of childbearing age/pregnancy:

Evidence-based pregnancy testing in clinical trials: Recommendations from a multi-stakeholder development process. Morse JE, Calvert SB, Jurkowski C, Tassinari M, Sewell CA, Myers ER. PLoS One. 2018 Sep 12;13(9):e0202474. doi: 10.1371/journal.pone.0202474. PMID: 30208049; PMCID: PMC6135366.

Positionspapier der Swissethics: Schwangerschaft und Magnetresonanz-Untersuchungen in wissenschaftlichen Studien: Ein-/Ausschluss von Schwangeren in wissenschaftlichen Studien, welche Magnetresonanz-Bildgebung (MRI) und- Spektroskopie (MRS) verwenden, verfügbar unter: https://swissethics.ch/assets/pos_papiere_leitfaden/20110906_kek_mri.pdf (zugegriffen am 4.1.2023)

Positionspapier der Swissethics: Empfehlung betreffend Sexualität, Verhütung und Schwangerschaft bei Jugendlichen im gebärfähigen Alter in der biomedizinischen Forschung, verfügbar unter: https://swissethics.ch/assets/pos_papiere_leitfaden/2021_guide_ct_with_adolescents_cbp_e_revised.pdf (zugegriffen am 4.1.2023)

Positionspapier der Swissethics: Empfehlung zur gender-gerechten Forschung, (insbesondere Schritt 4) verfügbar unter: https://swissethics.ch/assets/pos_papiere_leitfaden/201213_gender-gerechte-forschung_de_v1.0.pdf (zugegriffen am 4.1.2023)

Template der Swissethics: Studieninformation für Schwangere und schwangere Partenerinnen von Studienteilnehmern, (Template von swissethics für die Erstellung einer schriftlichen Studieninformation für Projekte unter Einbezug von Personen gemäss HFG/HFV 2.Kapitel (nicht: KlinV oder HFV 3.Kapitel "Weiterverwendung") verfügbar unter: https://swissethics.ch/assets/studieninformationen/schwangerschaftsbeobachtung_final_d.pdf (zugegriffen am 4.1.2023)