

## **Template for essential information to be provided for proposals including clinical trials / studies / investigations**

**This template only concerns you if your proposal contains a clinical trial/study/investigation!**

**Please see the important information under 1.9 on a potential future Commission Decision on clinical trial unit costs.** Clinical trials/studies/investigations have a number of methodological and regulatory specificities. Information on these issues is crucial for evaluators to assess the scientific quality of the proposal. The following guidance should help applicants to provide this essential information on clinical trials/studies/investigations in a standardised format.

You will have the possibility to upload the completed template as a separate part of your application in the submission system.

**Single-stage- and stage-2 proposals:** The use of this template is mandatory for any clinical trial/study/investigation included in a single-stage- or stage-2 proposal.

**For each** clinical trial / study / investigation included in the proposal information on the issues listed below should be provided. Each section must be shortly and concisely described. **In case one or more issues do not apply to a particular trial / study / investigation, please briefly explain/justify.**

When information is currently not available (e.g. a clinical trial is planned for a later stage of the project and will be based on data of previous studies) the source of required data should be provided and / or the selection of the applied methodology should be described.

**Stage-1 proposals:** In the limited frame of a stage-1 proposal not all methodological details of clinical trials/studies/investigations can be fully elaborated. The individual characteristics of your trial/study/investigation (and its importance for your overall proposal and) will determine which aspects you will describe in what level of detail. Therefore instage-1 proposals, information on clinical trials/studies/investigations cannot be uploaded as a separate template, but must be included in the core part of the proposal. Nevertheless, the points listed below might serve as an orientation also for the information you provide at stage 1.

Relevant information provided in this template does not need to be repeated elsewhere in the proposal, but can be referred to.

There are no page limitations applicable for this template. Information provided that is not in the scope of this template will not be taken in account for the proposal evaluation.

Ethical considerations have to be addressed in the respective separate section of the proposal.

### **1.1 Identifier**

*Title, short title or unique identifier.*

## **1.2 Study design and endpoints**

*Description of selected study design and primary and secondary objectives (endpoints/outcome measures).*

## **1.3 Scientific advice / protocol assistance / communication with regulatory / competent authorities / ethics committees**

*If scientific advice / protocol assistance from a competent/regulatory authority has been requested, please provide the full text answer of the authority or a comprehensive summary. If the answer is not available provide explanation of current status. Please also include any other relevant correspondence or minutes of meetings with regulatory authorities or ethics committees such as requested or granted approvals of clinical trial applications.*

## **1.4 Subjects/population(s)**

*Definition of study population(s) by inclusion and exclusion criteria. Definition of sub-populations if subgroup analysis is intended*

## **1.5 Sample size**

*Definition and justification (power calculation) of sample size.*

## **1.6 Statistical methods**

*Definition of statistical methods and planning of statistical analysis.*

## **1.7 Conduct**

*Description of planned strategy for study management, monitoring, data management and planned schedule for study conduct (including provisions and timelines for ethics and further administrative approvals). Please specify the trial sponsor (if applicable) and participating clinical centres. If a study medication is required, please provide information on whether manufacturing and/or labelling of the study medication is required and which plans are in place for this.*

## **1.8 Orphan designation**

*If orphan designation has been granted provide the reference of the Commission Decision. If orphan designation has been requested but not granted, provide an update on the current status.*

## **1.9 For information: ‘unit costs per patient’ for clinical trials / studies / investigations**

*The cost related to clinical studies must be declared, and therefore estimated, on the basis of actual costs. However, the Commission may allow other methods concerning the declaration of costs (e.g. unit costs). This may have an impact on the estimation of costs and the data to be included in the proposals. An addendum will be published concerning this. The potential proposers are invited to regularly check the Participant Portal.*