**CLINICAL TRIAL OUTLINE**

**1. STUDY SYNOPSIS**

|  |  |  |
| --- | --- | --- |
| Applicant/ Coordinating Investigator | Name, address, telephone, fax, e-mail  *(In case of multiple applicants the principal investigator/coordinating investigator of the trial who will assume responsibility for conducting the clinical trial, should be listed first.)* | |
| Title of study | *(The title of the trial should be as precise as possible.)* | |
| Abbreviated title | *(Acronym)* | |
| Condition | *(The medical condition being studied, e.g. asthma, myocardial infarction, depression)* | |
| Objective(s) | **Pilot study:**  *(What is the principal objective of this pilot study? How will it serve to generate data needed to plan a subsequent multi-centre trial?)*  **Subsequent planned multi-centre trial:**  *(Which principal research questions are to be addressed?)* | |
| Intervention(s) | *(Description of the experimental and the control treatments or interventions as well as dose and mode of application. For diagnostic tests or procedures the index test and the reference procedure (gold standard) should be described.)*  Experimental intervention:  xx  Control intervention:  xx  Duration of intervention per patient:  xx  Follow-up per patient:  xx | |
| Key inclusion and Exclusion criteria | Key inclusion criteria:  xx  Key exclusion criteria:  xx | |
| Outcome(s) | *(Precise definition, at what time point)*  **Pilot study:**  Primary endpoint:  xx  Key secondary endpoint(s):  xx  Assessment of safety:  xx  **Subsequent planned multi-centre trial (if already planned):**  Primary endpoint:  xx  Key secondary endpoint(s):  xx  Assessment of safety:  Xx | |
| Study design | *(e.g. randomized/non-randomized, type of masking (single, double, observer blind), type of controls (active/placebo), parallel group/cross-over, prognostic, diagnostic, multicentric, waiting list)*  **Pilot study:**  xx  **Subsequent planned multi-centre trial (if already planned):**  xx | |
| Statistical analysis | **Pilot study:**  Sample size consideration:  *(e.g. short description of rationale of sample size calculation)*  xx  Description of the primary analysis and population:  *(short description of the primary analysis and analysis population. Describe primary analysis of primary outcome.)*  xx  *Safety:*  *(Describe analysis of safety outcome.)*  xx | |
| Sample size | To be assessed for eligibility (n = … *e.g. informed consent*)  To be allocated to trial (n = … *e.g. randomised*)  To be analysed (n = … *e.g. in primary analysis)* | |
| Trial duration | First patient in to last patient out (months): |  |
| Recruitment period (months): |  |
| Subsequent planned multi-centre trial | Funding application for multi-centre trial planned with (eg. BMBF, DFG): xx | |

**2. THE MEDICAL PROBLEM**

*(Which medical problem is to be addressed? What is the novel aspect of the planned trial?*

*Which principal research questions are to be addressed? Bring them into order indicating major and minor motivations/starting hypotheses of the investigation planned.*

xx

**2.1 EVIDENCE**

*(Set your subsequent planned multi-centre trial into perspective. What is the rationale for the intervention? Which trials have been conducted either by you or by others? What is the relevance of their results? Give references to any relevant systematic review(s) and/or (own) pilot studies, feasibility studies, relevant previous/ongoing trials, case reports/series. State what your planned trial adds to the totality of evidence when your study is added to previous work (cf. Clark and Horton: Putting research into context – revisited. Lancet 2010; 376: 10-11). Include a description of how you searched for the evidence (databases, search terms, limits). If you believe that no relevant previous trials have been done, give details of your search strategy for existing information in e.g. databases, clinical trials registries.)*

xx

**2.2 THE NEED FOR A TRIAL**

**Pilot study:**

*(Why is the current pilot study needed to support a subsequent application for a multi-centre trial?)*

xx

**Subsequent planned multi-centre trial:**

*(How significant is the subsequent planned multi-centre trial in terms of its potential impact of relieving the burden of disease and/or improving human health? What impact will the results have on clinical practice? How will the individual patient and benefit from the trial? Describe any potential commercial interest of a company in the results of the trial or explain why no such interest exists. Indicate the funding agency where you intend to apply for funding of the multi-centre trial and whether potential commercial interests will preclude your trial from funding by the intended agency.)*

xx

**3. JUSTIFICATION OF DESIGN ASPECTS**

*(Please provide justifications and do not only list the respective information.)*

xx

**3.1 EXPERIMENTAL INTERVENTION AND CONTROL INTERVENTION**

*(Justify the choice of experimental and control(s)/comparison(s): Is placebo acceptable? Which trials establish efficacy and safety of the chosen control regimen? For diagnostic trials: What is the rationale for the units, cut off and/or categories?* )

xx

**3.2 INCLUSION/ EXCLUSION CRITERIA**

*(Justify the population to be studied, include reflections on generalisability and representativeness.)*

xx

**3.3 OUTCOME MEASURES**

*(Justify the endpoints chosen: Are there other trials that have utilized this endpoint? Are there any guidelines proposing this endpoint/these endpoints? Discuss the clinical relevance of the outcome measures for the target population. Have the measures been validated?)*

**Pilot study:**

xx

**Subsequent planned multi-centre trial:**

xx

**3.4 METHODS AGAINST BIAS**

*(Is randomisation feasible? What are the proposed practical arrangements for allocating participants to trial groups? Is blinding possible? If blinding is not possible please explain and consider if blinded assessment of outcome is possible).*

xx

**3.5 SAMPLE SIZE CONSIDERATIONS**

*(What is the justification for the proposed sample size of the pilot study? Note that, in the application for the subsequent multi-centre trial, you will be asked for a justification for the assumptions underlying the power calculations. Will the pilot study generate data for a comprehensible, checkable description of the assumptions on outcome measures for both control and experimental groups? In the application for the subsequent multi-centre trial the sample size considerations also must take into account anticipated rates of non-compliance and losses to follow up. Will the pilot study generate data to underpin these assumptions?)*

**3.6 FEASIBILITY OF RECRUITMENT**

**Pilot study:**

*(What is the evidence that the intended recruitment rate is achievable for the current pilot study?)*

xx

**Subsequent planned multi-centre trial:**

*(Which networks or collaborations will enable you to act successfully as a prinicipal investigator in the subsequent multi-centre trial?)*

xx

**4. STATISTICAL ANALYSIS**

*(What is the proposed strategy of statistical analysis? What is the strategy for analysing the primary outcome?)*

xx

**5. ETHICAL CONSIDERATIONS**

*(Discuss briefly the acceptability of the risk incurred by the individual participant versus the potential benefit for the participant/population concerned.)*

xx

**6 TRIAL MANAGEMENT**

**6.1 MAJOR PARTICIPANTS**

|  |  |  |  |
| --- | --- | --- | --- |
| **#** | **Name** | **Affiliation** | **Responsibility / Role** |
| **1** |  |  | Coordinating investigator |
| **2** |  |  | Trial statistician |
| **3** |  |  | Project coordinator |
|  |  |  |  |

**6.2 TRIALS EXPERTISE**

*(Please indicate trials expertise of all above-mentioned participants by citing relevant publications and/or specifying major role in ongoing trial(s). Has training course (Prüferkurs) been completed, as Coordinating Investigator at least 2 years experience in clinical trials mandatory.)*

xx

**6.3 GOOD CLINICAL PRACTICE**

*(Give a statement, if trial is conducted according to Good Clinical Practice (GCP). Describe by which measures this will be ensured during the trial.)*

xx

**7 FLOW CHART**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *(List the relevant examinations and time points)* | Screening  Examination  xx days to day 1 | Day x  Week x | Day x  Week x | Day x  Week x | Day x  Week x | Week xx | x, x, x, x,  Months | xx  Months | Every xx Months |
| Screening Examination |  |  |  |  |  |  |  |  |  |
| Randomisation/ registration |  |  |  |  |  |  |  |  |  |
| Investigational Medicinal Product |  |  |  |  |  |  |  |  |  |
| Physical Examination |  |  |  |  |  |  |  |  |  |
| Body Temperature (°C)  Weight (kg) |  |  |  |  |  |  |  |  |  |
| Laboratory  (Haematology, clinical chemistry) |  |  |  |  |  |  |  |  |  |
| Imaging (X-Ray, CT, MRI) |  |  |  |  |  |  |  |  |  |
| Adverse Events |  |  |  |  |  |  |  |  |  |
| Concomitant Medication |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

**8 FINANCIAL SUMMARY**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Item** | **Costs (€)** | **External funding (€)** | **Applied funds (€)\*** | **Institution/**  **Recipient** |
| Clinical project management *(e.g. medical expertise for clinical study)* |  |  |  |  |
| Project management *(coordinating the whole trial, incl. regulatory requirements)* |  |  |  |  |
| Case payment |  |  |  |  |
| Data management *(incl. pharmacovigilance)* |  |  |  |  |
| Biostatistics |  |  |  |  |
| Quality assurance *(e.g. clinical monitoring)* |  |  |  |  |
| Travel |  |  |  |  |
| Materials |  |  |  |  |
| Trial drug |  |  |  |  |
| Fees, insurance |  |  |  |  |
| Other *(e.g. central assessment)* |  |  |  |  |
| **TOTAL** |  |  |  |  |

\*This funds must spend complete in 2025.

Co-financing of the trial by a company: xx

For pharmacological interventions: trial drug under patent protection: no; yes, until

For interventions with medical devices: device is CE-marked no; yes

Commercial interest: xx

**9 REFERENCES**

**10 SIGNATURE**

(Please confirm that you have not submitted the proposal elsewhere)

Datum \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Unterschrift \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

In the case of cooperation with the Clinical Trials Unit Co-signature of the Clinical Trials Unit:

Datum \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Unterschrift CTU \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_