# Clinical Trial Outline Application – Exploratory Trial

1. STUDY SYNOPSIS

|  |  |
| --- | --- |
| **APPLICANT/COORDINATINGINVESTIGATOR** |  |
| **TITLE OF STUDY** |  |
| **CONDITION** |  |
| **OBJECTIVE(S)** |  |
| **KEY INCLUSION AND EXCLUSION CRITERIA** | Key inclusion criteria:  Key exclusion criteria: |
| **INTERVENTION(S)** | Experimental intervention:  Control intervention:  Duration of intervention per patient:  Follow-up per patient: |
| **OUTCOME(S)** | Primary efficacy endpoint:  Key secondary endpoint(s):  Assessment of safety: |
| **STUDY TYPE** | *e.g. randomized, type of masking (single, double, observer blind), type of controls (active / placebo), parallel group / cross-over* |
| **STATISTICAL ANALYSIS** | Efficacy:  Description of the primary efficacy analysis and population:  Safety: *Please describe the strategy for assessment of safety issues in the study. Which are relevant safety variables?*  Secondary endpoints: |
| **SAMPLE SIZE** | To be assessed for eligibility (n = …)  To be allocated to trial (n = …)  To be analysed (n = …) |
| **TRIAL DURATION** | Time for preparation of the trial (months):  Recruitment period (months):  First patient in to last patient out (months):  Time for data clearance and analysis (months):  Duration of the entire trial (months): |
| **PARTICIPATING CENTERS** | To be involved (n): *if applicable*  *How many centers will be involved? Please note that at least two centers should be involved and also list the cities.* |
| **PREVIOUS BMBF PROJECT NUMBER** | If *applicable, the BMBF code number of the latest application or of any previous application(s) for project-funding by the BMBF (not other funders) concerning this trial.* |
| **OTHER SUBMISSION OF PROPOSAL ELSEWHERE** | *Please state, if the same or a similar version of this proposal has been submitted in another funding programme, e.g. DFG clinical trials programme.* |

2. Response to reviewers’ comments on a previous version of this trial

3. RELEVANCE

3.1 Prevalence, incidence, mortality

3.2 Burden of disease

3.3 Improvement of therapy / impact of the trial

Novelty:

**Clinical impact**:

**Patient benefit**:

**Socioeconomic impact**:

3.4 Patient AND STAKEHOLDER INVOLVEMENT

4. EVIDENCE

5. JUSTIFICATION OF DESIGN ASPECTS

**5.1 Inclusion / exclusion criteria**

**5.2 Control(s) / comparator(s)**

**5.3 INTERVENTION(S)**

**5.4 Outcome measures**

**5.5 Methods against bias**

**5.6 Proposed sample size / power calculations**

**5.7 Feasibility OF RECRUITMENT**

**5.8 CONDITIONS FOR PROCEEDING WITH A Subsequent confirmatory trial**

6. Statistical Analysis

7. Ethical Considerations

8. Strategies for DATA HANDLING

9. trial Management

9.1 Major Participants

|  |  |  |  |
| --- | --- | --- | --- |
| **#** | **Name** | **Affiliation** | **Responsibility/Role** |
|  |  |  | Principal/Coordinating Investigator |
|  |  |  | Trial Statistician |
|  |  |  | …. |

9.2 Trial expertise

9.3 Trial-supporting facilities

10. FINANCIAL SUMMARY

|  |  |
| --- | --- |
| **Item** | **Costs (€)**  **Total trial duration** |
| Clinical Project Management |  |
| Project Management: (e.g. Statistical Planning, Protocol, Case Report Form (CRF), Informed Consent, CRF printing) |  |
| Case Payment |  |
| Patient Involvement (e.g. Workshops, Focus Groups, Questionnaires) |  |
| Data management (e.g. Database Set-up and Validation Data Entry, Coding, Query Management) |  |
| Biostatistics |  |
| Quality Assurance (e.g. Pre-Study Visits, On-Site Monitoring, Data Monitoring and Safety Committee) |  |
| Travel (e.g. Trial Committees, Meetings) |  |
| Materials |  |
| Trial Drug |  |
| Fees, Insurance |  |
| Other |  |
| **TOTAL** |  |

Co-financing of the trial by a company:

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

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

Commercial interest:

**References**

# APPENDICES

APPENDIX 1: LIST OF ABBREVIATIONS (OPTIONAL)

APPENDIX 2: Intervention Scheme / Trial flow (MANDATORY)

APPENDIX 3: Search strategy (MANDATORY)

APPENDIX 4: LETTER OF SUBMISSION / UNTERSCHRIFTENBLATT (MANDATORY)

KS2021 – Klinische Studien mit hoher Relevanz für die Patientenversorgung

Deutsches Zentrum für Luft- und Raumfahrt e.V. (DLR)

DLR Projektträger

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**Informationen zur STudie**

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| --- | --- |
| **(KOORDINIERENDE/R) ANTRAGSTELLER/IN** |  |
| **ANTRAGSTELLENDE  INSTITUTION** |  |
| **BETEILIGTE/R**  **BIOMETRIKER/IN** |  |
| **TITEL DER STUDIE** |  |

Ich bestätige die Kenntnis und – nach meinem aktuellen Wissenstand – die Richtigkeit der Angaben im formlosen Antrag zur oben genannten klinischen Studie.

Datum, Unterschrift Antragsteller/in Datum, Unterschrift Biometriker/in

APPENDIX 5: PATIENT and STAKEHOLDER INVOLVEMENT (DESIRABLE)