# 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* |
| **STATISTICAL ANALYSIS** | Efficacy:  Description of the primary efficacy analysis and population:  Safety:  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): |
| **PATENT, MEDICAL DEVICE AND HEALTH SOFTWARE** | Trial drug under patent protection  no;  yes, until Date:  Trial intervention with a medical device:  no;  yes  If yes: medical device is CE-certified:  no;  yes  Trial intervention with a software application: Application qualifies as a medical device according to MDR Art. 2:  no;  yes |
| **COMPANY INVOLVEMENT** | Is a company involved:  no;  yes  If yes: Company registers as a SME (*dt: KMU*):  no;  yes  Commercial interest:  no;  yes |
| **PREVIOUS BMBF PROJECT NUMBER** |  |
| **OTHER SUBMISSION OF PROPOSAL ELSEWHERE** |  |

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

3. RELEVANCE

3.1 Medical problem

3.2 Prevalence, incidence, mortality

3.3 Burden of disease

3.4 Improvement of therapy / impact of the trial

**Novelty:**

**Clinical impact**:

**Patient benefit**:

**Socioeconomic impact**:

3.5 Patient and target group INVOLVEMENT pLAN

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 |
|  |  |  | Expert for […] at cooperating company XXX (*if applicable*) |
|  |  |  | Representative of Patient / Target Group |
|  |  |  | …. |

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 (without overhead / „Projektpauschale“)** |  |

Commercial interest:

**References**

# APPENDICES

APPENDIX 1: LIST OF ABBREVIATIONS (MANDATORY, max. 1/2 page)

Appendix 2: Search strategy (MANDATORY)

APPENDIX 3: Intervention Scheme / Trial flow (MANDATORY, max. 1 page)

APPENDIX 4: Letter of Submission / Unterschriftenblatt (MANDATORY)

KS2022 – 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** *(entsprechend der eingereichten Projektskizze)*

|  |  |
| --- | --- |
| **(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 Projektleiter/in Datum, Unterschrift Biometriker/in

APPENDIX 5: PATIENT and target group INVOLVEMENT (Optional / DESIRED)

APPENDIX 6: Digital Health Application (Mandatory for REsPectIve trials, MAX. 1 PAGE)

|  |  |
| --- | --- |
| **DIGITAL HEALTH APPLICATION** | Application qualifies as a medical device according to MDR Art. 2:  no;  yes  Application qualifies as a digital health application according to MDR and Section 33a of the German Social Code Book V (Fünftes Buch Sozialgesetzbuch, SGB V):  no;  yes  Application is CE-certified:  no;  yes  Medical device risk class:  I;  IIa  *Please note that Digital Health Applications cannot be rated in a higher risk class than IIa in order to be listed in the BfArM directive of reimbursable digital health applications*  Software complies with all requirements stated in §5 DiGAV and will allow listing of the application in the directory of reimbursable digital health applications (DiGA directory) if a positive care effect can be shown:  no;  yes  BfArM consultation:  planned;  completed |
| 1. Strategy for listing of the application in the DiGA directory  2. Role of company/Corporation Partners involved (if applicable)  3. Next Steps | |