# Application – Conceptual Phase

1. PRoject SYNOPSIS

|  |  |
| --- | --- |
| **APPLICANT/COORDINATINGINVESTIGATOR** |  |
| **MAJOR PARTICIPANTS** |  |
| **TITLE OF CONCEPTUAL PHASE** |  |
| **CONDITION** |  |
| **OBJECTIVE(S)** |  |
| **TYPE OF INVOLVEMENT / COLLABORATION** |  |
| **SUBSEQUENT PROJECT** | Exploratory clinical trial  Confirmatory clinical trial  Systematic review |
| **INTERVENTION(S)** |  |
| **DURATION OF CONCEPTUAL PHASE** |  |
| **PREVIOUS BMBF PROJECT NUMBER** |  |

1.1 English LAY SUMMARY

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

3. RELEVANCE

3.1 Medical problem

3.2 Prevalence, incidence, mortality

3.3 Burden of disease

3.4 NEED FOR THE CONCEPTUAL PHASE AND SUBSEQUENT RESEARCH

Novelty:

Clinical impact:

**Patient benefit**:

**Socioeconomic impact**:

4. EVIDENCE

5. Patient and target group INVOLVEMENT

**5.1 Patient and target group involvement plan**

5.2 INTERCONNECTION OF PROJECT PARTner

6. Ethical Considerations

7. Work Plan

**7.1 WORK PACKAGES**

**7.2 time plan**

8. PROJECT PARTNERS

8.1 Major Participants

|  |  |  |  |
| --- | --- | --- | --- |
| **#** | **Name** | **Affiliation** | **Responsibility/Role** |
|  |  |  | Principal/Coordinating Investigator |
|  |  |  | Scientific partner |
|  |  |  | Patient Organisation |
|  |  |  | Representative of relevant stakeholder group xy (e.g. family caregivers) |

8.2 expertise / RelEVANT EXPERIENCE

9. FINANCIAL SUMMARY

|  |  |  |  |
| --- | --- | --- | --- |
| **Item** | **PM** | **Description / Justification** | **Amount requested (€)** |
| Personnel | - |  |  |
| Scientific |  |  |  |
| Non-Scientific |  |  |  |
| Other |  |  |  |
| Contracts\* | - |  |  |
| Travel Expenses | - |  |  |
| Other Expenses |  |  |  |
| **TOTAL**  **(without overhead / „Projektpauschale“)** |  |  |  |

PM = Person Months

Co-financing of the subsequent 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

If applicable - Commercial interest:

10. References

# APPENDICES

APPENDIX 1: LIST OF ABBREVIATIONS (MANDATORY, max. ½ page)

**APPENDIX 2: Search strategy (MANDATORY)**

**APPENDIX 3: 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 KONZEPTentwicklungsPHASE**

|  |  |
| --- | --- |
| **(KOORDINIERENDE/R) ANTRAGSTELLER/IN** |  |
| **ANTRAGSTELLENDE  INSTITUTION** |  |
| **TITEL DER KONZEPTENTWICKLUNGSPHASE** |  |

Ich bestätige die Kenntnis und – nach meinem aktuellen Wissenstand – die Richtigkeit der Angaben im formlosen Antrag zu oben genannter Konzeptentwicklungsphase für eine klinische Studie / einen systematischen Review.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Datum, Unterschrift Projektleiter/in

**APPENDIX 4: COLLABORATION (MANDATORY)**