# Checklist formal requirements

The following checklist is designed to help you fulfill the minimal formal requirements for your application.

Please delete the checklist from your document before submitting your proposal.

**Please note: any deviation from the minimal formal requirements listed below can lead to an instant rejection of your proposal.**

|  |  |
| --- | --- |
| **Minimal formal requirements for the application document:** | **Check: √** |
| **Template used? - DIN A4, font size at least 11 point Arial, 10 point Arial in the synopsis and tables and 9 point Arial for references, margins at least 2 cm and single-spaced lines** | □ |
| **Lay summary in English and German included during electronic submission of the proposal (easyonline)?** | □ |
| **All (sub-)headings included** | □ |
| **Maximum of 7 pages including references (8 pages for resubmissions)** | □ |
| **Reference information throughout the whole document contains full title of publication (similar to Vancouver style; at least 9 point Arial)** | □ |
| **Unterschriftenblatt / Letter of submission with handwritten (scanned) or (qualified) electronic signature of the applicant uploaded with proposal** | □ |
| **Minimal formal requirements for the appendix:** | **Check: √** |
| **List of abbreviations included (max. ½ page, appendix 1)** | □ |
| **Search strategy included (appendix 2)** | □ |
| **No unauthorized/additional attachments included in the application document or the appendix** | □ |

# Application – Conceptual Phase

1. PRoject SYNOPSIS

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

1.1 English LAY SUMMARY

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

2. RELEVANCE

2.1 Medical problem

2.2 Prevalence, incidence, mortality

2.3 Burden of disease

2.4 NEED FOR THE CONCEPTUAL PHASE AND SUBSEQUENT RESEARCH

Novelty:

Clinical impact:

**Patient benefit**:

**Socioeconomic impact**:

3. EVIDENCE

4. Patient and target group INVOLVEMENT

**4.1 Patient and target group involvement plan**

4.2 INTERCONNECTION OF PROJECT PARTner

5. Ethical Considerations

6. Work Plan

**6.1 WORK PACKAGES**

**6.2 time plan**

7. PROJECT PARTNERS

7.1 Major Participants

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

7.2 expertise / RelEVANT EXPERIENCE

|  |  |  |  |
| --- | --- | --- | --- |
| **Year** | **Name or acronym** | **Clinical study or systematic review** | **Reporting status** |
|  |  |  |  |

8. 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:

9. 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

**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 (Optional)**