# Checklist formal requirements

The following checklist is designed to help you fulfill the minimal formal requirements for your outline 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 outline application documents:** | **Check: √** |
| Two separate documents for proposal part A and proposal part B | □ |
| Template used for part A? - DIN A4, font size at least 11 point Arial, 10 point Arial in the tables, margins at least 2 cm and single-spaced lines | □ |
| Template used for part B? - 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 | □ |
| Anonymity of proposal part B intact? No unblinding and ineligible descriptions / references / information given or used? | □ |
| All (sub-)headings included | □ |
| Maximum of 6 pages including references (7 pages for resubmissions) | □ |
| Reference information throughout the whole document contains full title of publication (similar to Vancouver style; at least 9 point Arial) | □ |
| Unterschriftenblatt with handwritten (scanned) or (qualified) electronic signatures of the applicant and the biometrician uploaded with proposal part A | □ |
| **Minimal formal requirements for the appendix:** | **Check: √** |
| List of abbreviations included (part B, appendix 1) | □ |
| All other mandatory appendices included (part B, at least appendices 2 & 3) | □ |
| **Overall minimal formal requirements:** | **Check: √** |
| No unauthorized/additional attachments included in the outline application documents part A, part B, or the appendices | □ |

# Clinical Study Outline Application Part B

# – Confirmatory Study –

1. STUDY SYNOPSIS

|  |  |
| --- | --- |
| **TITLE OF STUDY** |  |
| **ACRONYM** |  |
| **CONDITION** | Rare disease:  no;  yes |
| **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** |  |
| **STATISTICAL ANALYSIS** | Efficacy:  Description of the primary efficacy analysis and population: |
| **SAMPLE SIZE** | To be assessed for eligibility (n = …)  To be allocated to study (n = …)  To be analysed (n = …) |
| **STUDY DURATION** | Time for preparation of the study (months):  Recruitment period (months):  First patient in to last patient out (months):  Time for data clearance and analysis (months):  Duration of the entire study (months): |
| **PARTICIPATING CENTERS** | To be involved (n): |
| **PATENTS AND CERTIFICATION** | Study drug under patent protection  no;  yes, until Date:  Study intervention with a medical device:  no;  yes  If yes: medical device is CE-certified:  no;  yes |

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

3. RELEVANCE

3.1 Medical problem

3.2 Prevalence, incidence, mortality

3.3 Burden of disease

3.4 Improvement of therapy / impact of the study

Novelty:

**Clinical impact**:

**Patient benefit**:

Socioeconomic impact:

3.5 Patient and target group INVOLVEMENT pLAN

|  |  |
| --- | --- |
| **Phase of the Research Process** | **How is / was / were relevant group(s) involved?** |
| Identification of research needs |  |
| Planning of the clinical study |  |
| Conduct of the clinical study |  |
| Exploitation and dissemination of study results |  |

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**

6. Statistical Analysis

7. Ethical Considerations

8. FINANCIAL SUMMARY

|  |  |
| --- | --- |
| **Item** | **Costs (€)**  **Total study duration** |
| Clinical Project Management |  |
| Project Management: (e.g. Protocol, Case Report Form (CRF), Informed Consent, Submission, CRF printing) |  |
| Case Payment |  |
| Patient and Target Group Involvement (e.g. Workshops, Focus Groups, Questionnaires) |  |
| Data Management (e.g. Database Set-up and Validation Data Entry, Coding, Query Management) |  |
| Biostatistics |  |
| Pharmacovigilance |  |
| Quality Assurance (e.g. Pre-Study Visits, On-Site Monitoring, Data Monitoring and Safety Committee) |  |
| Travel (e.g. Study Committees, Meetings) |  |
| Materials |  |
| Study Drug |  |
| Fees, Insurance |  |
| Other |  |
| **TOTAL (without overhead / „Projektpauschale“)** |  |

Commercial interest:

Is a company involved:  no;  yes

If yes: Company registers as a SME (*dt: KMU*):  no;  yes

Commercial interest:  no;  yes

Manufacturer/Supplier information:

If you are not the manufacturer/supplier of the therapeutic intervention:

Is the therapeutic intervention only available at one manufacturer/supplier?

no;  yes;  not applicable

**References**

# APPENDICES

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

Appendix 2: Search strategy (MANDATORY)

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

APPENDIX 4: Digital Health Application (Mandatory for REsPectIve studies, 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  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 | |