Draft Proposal - Förderinstrument Klinische Studien

1. **Studiensynopse**

|  |  |  |  |
| --- | --- | --- | --- |
| **Applicant/**  **Coordinating**  **investigator** |  | | |
| **Title of trial** |  | | |
| **Medical condition** |  | | |
| **Intervention(s)** | e.g. experimental intervention / control intervention / duration of intervention | | |
| **Trial type/ design** |  | | |
| **Trial objective(s)** | | | **Outcomes(s) / Endpoint(s)** |
| Primary | | | |
|  | | |  |
| Secondary | | | |
| * .. * .. | | | * .... * ... |
| **Inclusion criteria** | | Subjects will only be included in the study if they meet all of the following criteria:  General inclusion criteria:   * Subjects male or female, aged [study-specific lower age limit] to [study-specific upper age limit]. * The patient has given written consent to participate in the study. * Confirmed diagnosis of [study specific indication].   *[Are there any procedures that need to be performed to determine the trial-specific indication? E.g. imaging procedures, histologically confirmed, or laboratory values? Querying whether corresponding positive findings are available.]*  Indication-specific inclusion criteria (examples):   * Life expectancy of xx months * ECOQ Performance status of x | |
| **Ausschlusskriterien** | | Subjects will not be included in the study if any of the following criteria applies:  *[Please, think about and consider if the subject has a history of uncontrolled chronic disease or a concurrent clinically significant illness, medical condition, which in the investigator’s opinion, would contraindicate trial participation or compliance with protocol mandated procedures.]*  General Exclusion Criteria:   * Subject without legal capacity who is unable to understand the nature, scope, significance and consequences of this clinical trial * Subjects with a physical or psychiatric condition which at the investigator’s discretion may put the subject at risk, may confound the trial results, or may interfere with the subject’s participation in this clinical trial * Simultaneous participation in another clinical trial, or participation in a clinical trial taking an investigational product, up to 30 days prior to participation in that clinical trial. * Known or persistent abuse of medication, drugs or alcohol   Exclusion criteria regarding special restrictions for females (if applicable):   * Current (positive pregnancy test, e.g. ß-HCG test in urine/ serum) or planned pregnancy or nursing women * Females of childbearing potential, who are not using and not willing to use medically reliable methods of contraception for the entire study duration (such as oral, injectable, or implantable contraceptives, or intrauterine contraceptive devices) unless they are surgically sterilized / hysterectomized or there are any other criteria considered sufficiently reliable by the investigator in individual cases   Indication specific exclusion criteria (examples):  [Please, think about and consider if the subject has a history of uncontrolled chronic disease or a concurrent clinically significant illness, medical condition, which in the investigator’s opinion, would contraindicate trial participation or compliance with protocol mandated procedures.]   * Known history of hypersensitivity to the investigational drug or to drugs with a similar chemical structure * Known secondary diagnoses that present a risk when using the IMP * Restricted kidney function (creatinine threshold?) * Restricted liver function (bilirubin / ASAT/ALAT limits?) * Use of medication that interacts pharmacologically with the investigational drug | |
| **Regulatory assessment** | | AMG- or MPG-study, §23b MPG, non-AMG/non-MPG… | |
| **Study procedures** | |  | |
| **Statistical analysis** | | Efficacy/test accuracy:  Description of the primary efficacy/test accuracy analysis and population:  Safety:  Secondary Endpoints: | |
| **Sample size** | | To be assessed for eligibility: (n = )  To be assigned to trial: (n = )  To be analyzed: (n = ) | |
| **Trial duration** | | Study duration per patient:  • duration of therapy/intervention: (months/weeks)  • duration of Follow-up: (months/weeks)  • total duration: (months/weeks)  Trial duration:  • Recruitment: xx months  • First patient first visit (FPFV):   * Last patient last visit (LPLV): | |
| **Participating trial sites** | | If applicable | |
| **Previous submissions** | | If applicable | |

1. **The Medical Problem**
   1. **Background**
   2. **Rational and need of the trial**
2. **Regulatory Aspects**

Regulatory assessment of trial

yes  no AMG

yes  no MPG

yes  no §23b MPG

yes  no §7 MPKPV

yes  no non-AMG/non-MPG; further explanations:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Note to the applicant: Regulatory assessement by „Studienzentrale SZB“ is a prerequisite for submission of this proposal. Regulatory assessment is performed on the basis of a (pre)final proposal as well as on the basis of a personal consultation. Applicant should contact Studienzentrale SZB in a timely manner.*

1. **Design aspects**
   1. **Controls / Comparators / Trial arms**
   2. **Proposed sample size/Power calculations**
   3. **Feasibility of recruitment / Trial sites**
2. **Trial Management**
   1. **Key participants/Collaborators**

*Note to the applicant: In case collaborators from UKB or external institutions/parties are involved in the trial, the table below shall be completed.*

*It´s pointed out that in case budget is requested for external collaborators, costs may not be declared as staff costs in the financial summary (see below an in the eAntrag system). Respective collaboration contracts have to be concluded by GB2.5 (Stabsstelle Forschungsverträge). Involvement of GB2.5 has to be take place in a timely manner so that project launch is not delayed.*

|  |  |  |  |
| --- | --- | --- | --- |
| **#** | **Name** | **Clinic/Institute/Institution (Affiliation)** | **Responsibility in trial/Role** |
| 1 |  |  | Principal investigator |
| 2 |  |  | Trial statistician |
|  |  |  |  |

* 1. **Trial expertise (your own project-specific publications)**
  2. **Co-financing of the trial by a company (if applicable)**
  3. **Is the trial drug or the therapeutic, diagnostic or prognostic test procedure that is object of this trial under patent protection?**

Yes

No

*(The points 1 – 5 should cover 6 – 10 pages.)*

1. **Bibliography**
2. **Intervention scheme/Trial flow** *(Example)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Visit 1 Screening Day -1** | **Visit 2 Day 0** | **Visit 3 Day 1** | **Visit 4 Day 30** | **Visit 5 End of Trial** | **Follow-Up**  **Day 90 (Telephone Call)** |
| **In-/Exclusion Criteria** | √ |  |  |  |  |  |
| **Informed Consent** | √ |  |  |  |  |  |
| **Medical History** | √ |  |  |  |  |  |
| **Physical Examination** | √ |  |  |  |  |  |
| **Laboratory1** | √ | √ | √ |  |  |  |
| **Randomization** |  | √ |  |  |  |  |
| **Vital Signs** | √ | √ | √ | √ | √ | Lethality |
| **Hemodynamic** |  | √ | √ |  |  |  |
| **Additional Laboratory** |  | √ |  |  |  |  |
| **Trial Drug** |  | √ |  |  |  |  |
| **Diagnoses at time of discharge** |  |  |  |  | √ |  |
| **Concurrent Medication** | √ | √ | √ | √ | √ |  |
| **Blood Products** |  | √ | √ |  |  |  |
| **AEs and SAEs** |  | √ | √ | √ | √ |  |

1 incl. negative pregnancy test for women of childbearing potential

1. **Financial Summary** *(This table does not claim to be complete; please provide all necessary details.)*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Organizational Segment** | **Participant** | **No of items/Kind of equipment/Explanation** | **Qualification of staff** | **months** | **Subtotal Clinic (€)** | **Subtotal (€) partner** | **Total (€)** |
| **1** | **Clinical project management** |  | Study-Coordination, clinical project management, publication, CRF-Review | Physician |  |  |  | **0** |
| Study Nurse |  |  |  | **0** |
| **2** | **Project management** |  | Study-planning, -coordination and administration, project management, Protocol development and review, PI/PIC development, CRF-development, randomization, TMF/ISF set-up and administration, regulatory submission (initial and amendment), vendor assessment, contract management, | Project Manager, Study Coordinator |  |  |  | **0** |
|
|
| **3** | **Data Management** |  | Database-Set-up, validation, DMP, DVP, Data entry, Query management, database clearing and closure, data listings | Data Manager |  |  |  | **0** |
| **4** | **Biometry** |  | Biometry, statistical analysis (incl. SAP), statistical final report | Statistician |  |  |  | **0** |
| **5** | **Monitoring/ Quality Assurance** |  | development Monitoring Manual, Monitor training, On site Monitoring (initiation, routine, close out visits) incl. Travel (5h/visit) | Clinical Monitor and Quality Manager |  |  |  | **0** |
| Quality Assurance (Quality Management System), Sponsor Quality Manual and Quality Reports (every 3 months) incl. Documentation |
| **6** | **SAE Management** |  | Set-up PV-Database, licences, SAE-coordination, SAE-coding, regulatory SUSAR-reporting, compilation of DSUR, database reconciliation, data listings for 2 DSMB-meetings (total: 25 SAEs estimated) | Safety Manager and Safety Assistant |  |  |  | **0** |
| **6** | **Trial committees** | DSMB ( members) | meetings, phone conferences (2 meetings, 500€/ person, external statistician (2.500€/ meeting) |  |  |  |  | **0** |
|  | DSMB-Charter and coordination of meetings | Project Manager |  |  |  | **0** |
| **7** | **Meetings** | Al Part. | 3 investigator meetings |  |  |  |  | **0** |
| **8** | **Case payment/ Radiology** | Trial sites | Total 7.000€/ patient |  |  |  |  | **0** |
| patients | 30€/ day/ patient for 10 days |  |  |  |  | **0** |
| patient travel | 20€/ patient |  |  |  |  | **0** |
| **9** | **Materials & Shipment** | Trial Sites | Consumables, phone calls, QoL-sheets, Holter ECG |  |  |  |  | **0** |
|  | Material ISF, TMF, IC, CRF |  |  |  |  | **0** |
| **10** | **Trial drug** | Pharmacy | Manufacturing, blinding, packaging and labeling, |  |  |  |  | **0** |
| **11** | **Insurance** | Company | 70 € x 90 patients |  |  |  |  | **0** |
| **12** | **Fees / Travel costs** | Authorities | CA, Ethic committees, |  |  |  |  | **0** |
| Travel costs | Monitoring costs |  |  |  |  | **0** |
| **13** | **Laboratory** |  |  |  |  |  |  | **0** |
| **14** | **Archiving** |  | archiving, storage for 10 years and destruction |  |  |  |  | **0** |
|  | **TOTAL** |  |  |  |  | **0 €** | **0 €** | **0 €** |

By signing this proposal all involved parties declare their consent with the proposal including the financial summary and confirm to have had the opportunity to review and confirm the proposal.

|  |  |  |  |
| --- | --- | --- | --- |
| **Role in study / Involved partners:** | **Name surname, Clinic/Institute, Affiliation** | **Date** | **Signature** |
| Applicant |  |  |  |
| Co-Applicant |  |  |  |
| Statistician |  |  |  |
| z.B. Studienzentrale SZB |  |  |  |