**1. Description of Project**

**1.1 GENERAL INFORMATION**

**1.1.1 Title of project**

**1.1.2 Project coordinator**

**1.2. MEDICAL ASPECTS OF INNOVATION AND RELEVANCE OF THE PROJECT**

**1.2.1 Medical problem**

**1.2.2 Objectives/Research goal**

**1.2.3 Novel aspect and future impact**

**1.2.4 Evidence**

**1.2.5 Safety**

**1.3 Description of PROJECT organization AND WORK PROGRAMME**

**1.3.1 Summary of project structure**

|  |  |
| --- | --- |
| **Partner** | **Function in the project** |
|  |  |
|  |  |
|  |  |

**1.3.2 Scientific discipline and previous work**

**1.3.3 Cooperation**

**1.3.4 Work Programme**

**1.3.5 Milestone Plan**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **WP no.** | **Milestone (▼)** | **year 1** | | | | | | **year 2** | | | | | | **year 3** | | | | | |
|
| 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**1.3.6 Compliance with GLP and GMP**

**1.3.7 Infrastructures**

**1.4 EXPLOITATION**

**1.4.1 Assessment of regulatory aspects**

**1.4.2 Intellectual Property Rights**

**1.4.3 Expertise for exploitation**

**1.4.4 Strategy for exploitation**

**1.5 OTHER FUNDING**

**1.5.1 Co-financing**

**1.5.2 Other funding**

**2. Description of Clinical Trial**

2.1 STUDY SYNOPSIS

|  |  |
| --- | --- |
| **APPLICANT/COORDINATINGINVESTIGATOR** |  |
| **TITLE OF STUDY** |  |
| **CONDITION** |  |
| **OBJECTIVE(S)** |  |
| **INTERVENTION(S)** | Experimental intervention:  Control intervention:  Duration of intervention per patient:  Follow-up per patient:  Accompanying measures:  Marketing authorization for control intervention:  yes  no  Marketing authorization for tested substance (module 1):  yes  no |
| **KEY INCLUSION AND EXCLUSION CRITERIA** | Key inclusion criteria:  Key exclusion criteria: |
| **OUTCOME(S)** | Primary efficacy endpoint(s):  Key secondary endpoint(s):  Assessment of safety: |
| **STUDY TYPE** |  |
| **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): |
| **OTHER SUBMISSION OF PROPOSAL ELSEWHERE** |  |

2.2 Patient INVOLVEMENT

2.3 JUSTIFICATION OF DESIGN ASPECTS

**2.3.1 Schematic diagram of the trial**

**2.3.2 Control(s) / comparator(s)**

**2.3.3 Inclusion / exclusion criteria**

**2.3.4 INTERVENTION(S)**

**2.3.5 Outcome measures**

**2.3.6 Methods against bias**

**2.3.7 Proposed sample size / power calculations**

**2.3.8 Feasibility OF RECRUITMENT**

2.4 Statistical Analysis

2.5 Ethical Considerations

2.6 Strategies for DATA HANDLING

2.7 CONFLICT OF INTEREsT

2.8. 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** |  |

Co-financing of the 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

Commercial interest:

2.9. References