|  |  |  |
| --- | --- | --- |
|  | | |
| 1.Principle Investigator | | |
| 1.1. Information about the Principal Investigator | | |
| Title (Dr./Prof.): | Academic Degree: | |
| First Name: |  | |
| Last Name:  Name of Institution: |  | |
| Department: |  | |
| Professional address:  City, Country: |  | Email address: |
| Telephone: |  | |
| Date of birth: | ESAIC Membership number: | |
| 1.2. Academic Institution or Hospital | | |
| Name: |  | |
| Address: |  | |
| Head of Department: |  | |
| Telephone: |  | |
| E-mail: |  | |
| ***1.3 Other important information*** *(indicate which one)* | | |
| Have you been awarded an ESAIC Grant or Prize in previous years?  Yes  No | | |
| *If yes, please specify (Type, Year and Title):* | | |

|  |  |
| --- | --- |
| *The format of the Synopsis must not be changed and has to fit on one page only* | |
| 2. Study Synopsis | |
| 2.1. Title and Area of the Study (Please include an acronym) | |
|  | |  |
| ***2.2. Objective(s)*** | |
|  | |
| 2.3. Key Inclusion and Exclusion Criteria | |
| Key Inclusion Criteria: |  |
| Key Exclusion Criteria: |  |
| 2.4. Outcome(s) | |
| Primary endpoint:  Secondary endpoints: | |
| 2.5 Feasibility : Sample Size, Study Duration, and Participating Centres | |
|  | |

*Please prepare your Study Proposal Form not exceeding 5 pages for part 3 to 9 (DIN A4, at least 10 point Poppins)*

3. The Medical Problem

***3.1. Introduction***

***3.2. Research question(s)***

***3.3. The need for a study***

***4. Methods***

***4.1. Preliminary/Pilot data***

***4.2. Inclusion/Exclusion Criteria***

***4.3. Outcome Measures***

***4.4. Methods against Bias***

***4.5. Data collection and set***

***5. Statistical Analysis***

***5.1 Strategy for Statistical Analysis***

***5.2. Proposed Sample Size/Power Calculations***

The recruitment target (and the justification for how it was calculated) will be a very important part of the scoring criteria. We therefore advise you to provide as much detail as possible regarding the target, the timeframe for recruitment and what calculations were done.

***6. Ethical Considerations***

***7. Study Management***

***7.1 Principal Investigator***

***7.2 Clinical studies Expertise*** *(Add list of co-investigator(s) if applicable)*

***7.3. Please describe if your project team includes any early career researchers*** *(no more than five years for MD diploma – if more than one qualifying degree maximum 10 years since first degree)*

***7.4 Clinical studies Statistician***

**7.5 Plans for registration of trial**

**7.6 Projected milestones**

***8. Budget Plan (Up to 30.000 Euros)***

***8.1. Statistician Costs***

***8.2. Travels***

***8.3. Other Costs***

***8.4. Budget Justification***

***8.5. Total funds requested:***

***8.6. Current support for the proposed project (delete inappropriate):***

Is this study currently supported by any other funding agency?  **Yes**  **No**

*(If “yes”, give the name of the organisation(s) and summarise the amount and duration of support, with dates.)*

Is this or a substantially similar proposal currently being considered elsewhere?  **Yes**  **No**

*(If “yes”, by what organisation(s)? By what date is a decision expected?)*

***9. Publication Plan***

***10. Is your project incorporating sustainability ? If yes, please describe***

***11. CV of the Principal Investigator***

***12. Conflict of interest*** *(please tick one of the boxes as appropriate)*

**I declare that I have no conflict of interest with any of the** [**ESAIC Research Committee members**](https://esaic.org/about/governance-and-constituent-bodies/research-committee/) **reviewing the present application**

**I have a conflict of interest with the following ESAIC Research Committee member(s)**

**reviewing this application: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***13. Signature and date***

Date *(DD/MM/YY)*: / /

Signature of the Principal Investigator:

Shape

Description automatically generated with medium confidence