**PROJECT PROPOSAL**

***Please provide all relevant information requested below***

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| ***Applicant***  | Dr: Tel:Email: Hosp: |

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| ***Sponsor*** | Please specify the project sponsor institution name (hospital, university, learned society etc.): |

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| ***Type of project****(Tick the appropriate box)* | [ ] **Epidemiological studies (registries, surveys)**[ ]  **Health-economic / quality of life study**[ ]  **Non-interventional studies (cat. 3)**[ ] **Interventional studies without product (cat. 2)**[ ]  **Animal / experimental study**[ ]  **PASS/PAES**[ ]  **Other** **(please specify):**  |

**Scientific aspects of the project**

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| --- | --- |
| ***Title*** |  |

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| ***Rationale*** |  |

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| ***Objectives*** | * **Primary Objective:** …..
* **Secondary objectives: ……**
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| ***Population****(Describe the main selection criteria)* | * **Inclusion criteria (main):**
* **Exclusion criteria:**
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| ***Evaluation*** ***criteria*** *(Describe the main evaluation criteria according to the listed objectives)* | * **Primary Outcome:**
* **Secondary Outcomes:**
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| ***Statistical aspects****(Please provide all relevant information)* | * **Sample size calculation with hypothesis :**
* **Methodology:**
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| ***Contribution to the field of science***  |  |

**Organisation of the project**

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| ***Timelines***  | * **Total duration of the project:**
* **Study start date (For clinical studies: first patient in expected / For experimental studies: first experiment date):**
	+ **expected start date:**
* **Expected date of global results for publication :**
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| ***Centres*** | * **Single centre study** [ ]
* **Multicentre study** [ ]  **if yes, number of centres:**
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| ***Ethics Committee*** | * **This project has been or will be presented to Ethics Committee for approval** [ ]
* **No need for Ethics Committee approval** [ ]
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| ***Estimated cost***  | * **Total estimated cost of the project:**
* **If estimated costs are more than €15000, please indicate if there is any other funder:**
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