**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 :** |

|  |  |
| --- | --- |
| ***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:** |