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| Introductory note | The completion of this template is mandatory in order to become eligible for funding and/or Investigational Medical Device Product (ID, Investigational Device) from CGBio (offered as locally commercially available products).Please provide only a brief outline i.e. 3-4 pages.Guidance text is inserted in italics, replace with the applicable wording. |
| Trial title | *Abbreviated*A Clinical Study to Evaluate the Efficacy and Safety of OOO(*Product name*) in the subjects with OOO disease |
| Trial type | Interventional or Observational |
| Trial design and research setting | **Single-center, Investigator-initiated Trials(IIT)**Prospective (or Retrospective),**Single-arm, Open-label, Single-blinded(Assessor-blinded)**(or Randomized, comparator-controlled, parallel-group) |
| Investigator contact information | [Principal investigator]Investigator’s title: Site of Conduct (name of institution): Department name: Full mailing address:Phone number:Fax number:Email address: [Sub-investigator][Clinical research coordinator] |
| CGBio grant request | 🞏 Funding: *Total amount XXX USD*🞏 ID(Investigational Device): *Product Name, Package, Quantity*🞏 Both* Funding: *Total amount XXX USD*
* ID: *Product Name, Package, Quantity*
 |
| Expected trial duration | *State expected:** *EC/IRB submission & Approval: dd – mmm – yyyy~ dd – mmm – yyyy (?-months)*
* *first patient included (i.e. FPFV): dd – mmm – yyyy*
* *trial conclusion (i.e. LPLV): dd – mmm – yyyy (?-months)*
* *final trial report: dd – mmm – yyyy (?-months)*
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| Trial background & rationale | *Provide a brief description of the medical question and the rationale of how the trial addresses the hypothesis and the objectives raised.**Clearly state the specific hypothesis to be tested. The primary efficacy and safety hypotheses should correspond directly with the primary objectives of the trial. All hypotheses should be in the order of priority.**Provide a rationale for the dose schedule outlined for all treatment arms.**IMPORTANT – For any usage outside approved label please cite all necessary references and considerations regarding the safety risks associated with the trial.* |
| Purpose and study objectives | *Provide the main goal of the trial and the study population.**Provide a detailed definition that is directly linked to the primary and secondary objective(s).**In some cases, the detailed description may be more appropriate in the statistical section.*1) Primary objective2) Secondary objective(s) |
| Trial population | *Specify age, gender and other demographic information concerning the selected population* |
| Sample size | *The sample size must reference the primary endpoint.* |
| Investigational medical device | *please indicate: Name, Strength, Dosage Form and Quantity* |
| Dosing regimen | *Specify dose, schedule, duration, any pre-medications, etc.* |
| Main Inclusion criteria | *List the key inclusion criteria necessary to support the trial design and drug safety requirements.*1. Is able to give written informed consent prior to study start and to comply with the study requirements.
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| Main Exclusion criteria | *List the key exclusion criteria necessary to support the trial design and drug safety requirements.* |
| Primary & secondary endpoint(s) | *Brief definition of the primary and secondary endpoint(s). Novel or unconventional endpoints may require explanation in the rationale section. The primary endpoint will be linked to the justification of the sample size.*1) Primary endpoint2) Secondary endpoints |
| Safety endpoint(s) | Assessment of AEs: At every visit  |
| Trial Schedule | *Visit 1 (screening) : Within O days of application**Visit 2 (treatment) : Application**Visit 3 (follow-up 1) : O weeks (±O weeks) after application**Visit 4 (follow-up 2) : O weeks (±O weeks) after application* |
| Statistical plan | *Describe the planned statistical analysis including timing of the primary and secondary measurements and sample size calculation. The range of sophistication will depend on a number of factors, including the size and complexity of the trial. At a minimum, the statistical assumptions surrounding the reporting of the primary endpoint should be included.* |
| Anticipated publication of the trial results | *Outline the planned final reporting of trial results and publications.* |
| References | *List references, studies, and sources that support the trial design.* |
| Funding requested from CGBio | *Estimation of the overall trial cost based on fair market value and estimation of the amount requested from CGBio. Please provide brief justification for each amount stated.* |
| Submission of the Protocol Outline | The Protocol Outline must be sent to the clinical trial manager of CGBio. A current, signed CV of the Sponsor Investigator must always be attached along with the Protocol Outline. |