**Synopsis for Investigator Initiated Trials Proposal**

*Please complete all sections of this form. If you use your own synopsis template, please ensure it contains all elements listed in this form.*

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| --- | --- |
| **Sponsor/Institution name:**  | **Product name and active substance:**  |
| **Study title**:  |
| **Clinical Phase** |  |
| **Principal investigator** |  |
| **Number of Sites and Countries** |  |
| **Recruitment period**  | First Patient In:Last Patient Out: |
| **Estimated total study duration** (in months) |  |
| **Background and Rationale** |  |
| **Study design**  |  |
| **Study objectives** | Primary:Secondary: |
| **Study endpoints** |  |
| **Indication to be studied** |  |
| **Inclusion criteria** |  |
| **Exclusion criteria** |  |
| **Test drug**(dose and mode of administration) |  |
| **Comparator**, *if any*(dose and mode of administration) |  |
| **Duration of treatment** |  |
| **Duration of patient participation** (from ICF signature up to any applicable follow-up) |  |
| **Safety evaluation** |  |
| **Sample size determination** |  |
| **Number of subjects / patients** (total and per treatment) |  |
| **Statistical methods** |  |