**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** |  |