**Synopsis for Investigator Initiated Trials Proposal**

version XX of DD-MMM-YYYY

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| **Sponsor/Institution name:** | **Product name and active substance:** |
| **Country:** | |
| **Study title**: | |
| **Study type (***observational,interventional, other***)** |  |
| **Clinical Phase (***if applicable***)** |  |
| **Number of Sites and Countries** |  |
| **Recruitment period** | First Patient In:  Last Patient Out: |
| **Total study duration** *(in months*) |  |
| **Number of subjects / patients** *(total and per treatment*) |  |
| **Duration of participation**  (*from IC signature up to any applicable follow-up*) |  |
| **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** |  |
| **Safety evaluation** |  |
| **Sample size determination** |  |
| **Statistical methods** |  |

*Please note that this form must not contain personal data of the Applicant or personal data of third parties*

**Date**

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