# Exploratory Clinical Studies - Template

|  |  |
| --- | --- |
| **APPLICANT/COORDINATINGINVESTIGATOR** | Name, address, telephone, fax, e-mail  *In case of multiple applicants the principal investigator / coordinating investigator of the trial who will assume responsibility for conducting the clinical trial, should be listed first.* |
| **TITLE OF STUDY** | *Descriptive title identifying the study design, population, and interventions.* |
| **CONDITION** | *The medical condition being studied (e.g. lymphoma, M. Parkinson)* |
| **OBJECTIVE(S)** | *Which principal research questions are to be addressed? Specify clearly the primary hypotheses that determine sample size calculation.* |
| **INTERVENTION(S)** | *Brief description of the experimental and the control treatments or interventions, if applicable: dose and mode of application.*  Experimental intervention:  Control intervention:  Duration of intervention per patient:  Follow-up per patient: |
| **KEY INCLUSION AND EXCLUSION CRITERIA** | Key inclusion criteria:  Key exclusion criteria: |
| **OUTCOME(S)** | Primary efficacy endpoint:  Key secondary endpoint(s):  Assessment of safety: |
| **STUDY TYPE** | *e.g. randomized / non-randomized, type of masking (single, double, observer blind), type of controls (active / placebo), parallel group / cross-over* |
| **STATISTICAL ANALYSIS** | Efficacy:  Description of the primary efficacy analysis and population:  Safety: *Please describe the strategy for assessment of safety issues in the study. Which are relevant safety variables?*  Secondary endpoints: |
| **SAMPLE SIZE** | To be assessed for eligibility (n = …)  To be allocated to trial (n = …)  To be analysed (n = …) |
| **TRIAL DURATION** | Time for preparation of the trial (months):  Recruitment period (months):  First patient in to last patient out (months):  Time for data clearance and analysis (months):  Duration of the entire trial (months): |
| **PARTICIPATING CENTERS** | To be involved (n): *if applicable; how many centres will be involved? Please also list the cities.* |