**STUDY PROTOCOL SYNOPSIS**



| **Title** |  |
| --- | --- |
| **Purpose** | *In one sentence* |
| **Sponsor** | *The organization responsible for the trial* |
| **Phase of Development** | *For drugs and biologics, or N/A* |
| **Brief Scientific Rationale**  | *In 2-3 sentences:**Include a short summary of results and conclusions from previous trials, or from a systematic review as appropriate.*  |
| **Scientific Hypothesis** | *In one sentence* |
| **Objectives** | **Primary objective:** * …

**Secondary objective(s):*** …
 |
| **Study Timeline** |  |
| **Study Endpoints** | **Primary endpoint:** * …

**Secondary endpoints:** * …

**Exploratory endpoints (if any):*** …
 |
| **Study Design** | *Please provide the schema of the study. You may insert figures, diagrams, or tables.* |
| **Number of Patients** |  |
| **Principal Eligibility Criteria** | **Inclusion Criteria*** …

**Exclusion Criteria*** …
 |
| **Intervention** | *Please describe the study intervention. If the study intervention is a drug or biologic, include name (generic), dose, and route of administration, as well as the origin (ownership) and type of compound (mechanism of action).* |
| **Duration of Treatment** |  |
| **Response Assessment** |  |
| **Sample size & Statistics** | *Please state the formal and testable null and alternative hypotheses for primary and key secondary endpoints, specify the type of comparison (e.g., superiority, equivalence or non-inferiority), sample size determination, statistical analyses, etc.* |
| **Additional Information** | *Any additional information or N/A* |