**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* |