# CONCEPT PROTOCOL

# ADMINISTRATIVE INFORMATION

|  |  |  |
| --- | --- | --- |
| Protocol Title: |  | |
| Study Phase: | (if applicable) | |
| Under a classification by a regulatory agency: | |  |
| If so, state the agency and classification: | |  |
| Drug Name | | (only if applicable) |
| Protocol Contact Person(s): | |  |
| Study Timelines: | |  |
| Estimated enrollment date for first subject: | |  |
| Estimated date of last subject visit: | |  |
| Protocol Author(s): | |  |
| Date of Draft/Final Version: | |  |

# Rationale

Rationale for study

# Study Objectives

## Primary Objective

List the primary objective of the study

* To evaluate (obtain, determine, verify, etc.)

## Secondary Objectives

List the secondary objectives

* To evaluate (obtain, determine, verify, etc.)
* To evaluate (obtain, determine, verify, etc.)
* To evaluate (obtain, determine, verify, etc.)

# Study DESIgn

Description of the overall study design

|  |  |
| --- | --- |
| Lead-in Period | Placebo, prior therapy, none, or other Number of days of washout if any |
| Design: | Randomized controlled trial, cohort study, case-control study, open-label, diagnostic test evaluation, economic analysis, case series, etc.  Blinding (open-label, single, double blind)  Control group (placebo, active, both, other) |
| Groups: |  |
| Patient Population: | Inpatient, outpatient or both |
| Number of days on Active Therapy: |  |
| Study Duration per Patients: |  |
| Number of Investigative Sites: |  |

## Study Periods

Describe the phases of the trial including pre-study, treatment and follow-up

# Study Population

## Inclusion Criteria

* List all inclusion criteria

## Exclusion Criteria

* List all exclusion criteria

# Study endpoints

## Primary Endpoints

Specify the primary endpoints of the study including the groups, comparison measure, timing of measurement, (e.g., difference in systolic BP between Group A and B at week 8)

## Secondary Endpoints

Specify key secondary endpoints

* Endpoint
* Endpoint

# Study Drugs and dosages

Description of the dosages and groups (if applicable)

# Measurements and evaluations

## Efficacy and Safety Evaluations

Describe all efficacy, study monitoring and safety evaluations (tests, exams, study instruments)

## Pharmacokinetic evaluations

Describe PK evaluations (if applicable

# Sample size and analysis plan

## Sample Size Justification

Justification for sample size including power analysis or width of confidence interval or other method

## Analysis Plan

Outline analytic approach for analysis of primary and key secondary objectives and endpoints

# DATA Collections

Describe the process and documentation of the data