**CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL**

**(CESHARP)**

|  |  |
| --- | --- |
| **Protocol Full Title:** | *[Insert via the StudyBuilder ribbon.]* |
| **Sponsor Confidentiality Statement:** |  |
| **Protocol Number:** | *[Insert via the StudyBuilder ribbon.]* |
| **Version:** |  |
| **Amendment Number:** |  |
| **Amendment Scope:** |  |
| **Compound Number(s):** |  |
| **Compound Name(s):** |  |
| **Trial Phase:** | *[Insert via the StudyBuilder ribbon.]* |
| **Acronym:** | *[Insert via the StudyBuilder ribbon.]* |
| **Short Title:** | *[Insert via the StudyBuilder ribbon.]* |
| **Sponsor Name and Address:** |  |
| **Manufacturer Name and Address:** |  |
| **Regulatory Agency Identifier Number(s):** | Universal Trial Number:*[Insert via the StudyBuilder ribbon.]*  EU CT Number:*[Insert via the StudyBuilder ribbon.]*  IND Number:*[Insert via the StudyBuilder ribbon.]*  CIV-ID/SIN number:*[Insert via the StudyBuilder ribbon.]*  NCT Number:*[Insert via the StudyBuilder ribbon.]*  jRCT Number***:*** *[Insert via the StudyBuilder ribbon.]*  NMPA Number:*[Insert via the StudyBuilder ribbon.]*  EUDAMED Number:*[Insert via the StudyBuilder ribbon.]*  IDE Number:*[Insert via the StudyBuilder ribbon.]* |
| **Sponsor Approval Date:** |  |

**Sponsor Signatory:**

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[Name]

[Title of Sponsor Signatory] [Sponsor Signature Date]

**Medical Monitor Name and Contact Information:**

**Amendment Details**

**History of Amendments**

|  |  |
| --- | --- |
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# PROTOCOL SUMMARY

## Protocol Synopsis

**Primary and Secondary Objectives and Endpoints**

**Overall Design**

|  |  |  |  |
| --- | --- | --- | --- |
| **Intervention Model:** | [intervention model] | **Population Type:** | [population type] |
| **Control:** | [control] | **Population Diagnosis or Condition:** | [diagnosis or condition] |
| **Active Comparator:** | [comparator] | **Population Age:** | Minimum: [minimum age] – Maximum: [maximum age] |
| **Trial Intervention Assignment Method:** | [intervention assignment method] | **Site Distribution:** | [geographic scope] |

**Number of Arms:** [Number of Arms]

**Blinding:** The following roles indicated below will not be made aware of the treatment group assignment during the trial: [blinded roles].

**Number of Participants:**

**Arms and Duration:**

**Committees:**

## Trial Schema

## Schedule of Activities

*[Insert via the StudyBuilder ribbon.]*

# INTRODUCTION

## Purpose of Trial

## Summary of Benefits and Risks

# TRIAL OBJECTIVES, ENDPOINTS AND ESTIMANDS

## {Primary/Secondary/Exploratory} Objective + Associated Endpoint {and Estimand}

*[Insert via the StudyBuilder ribbon.]*

# TRIAL DESIGN

## Description of Trial Design

Figure ‎4‑1 Study design

*[Can be inserted via the StudyBuilder ribbon.]*

### Participant Input into Design

## Rationale for Trial Design

### Rationale for Comparator

### Rationale for Adaptive or Novel Trial Design

### Other Trial Design Considerations

## Access to Trial Intervention After End of Trial

## Start of Trial and End of Trial

# TRIAL POPULATION

## Selection of Trial Population

## Rationale for Trial Population

## Inclusion Criteria

*[Insert via the StudyBuilder ribbon.]*

## Exclusion Criteria

*[Insert via the StudyBuilder ribbon.]*

## Lifestyle Considerations

### Meals and Dietary Restrictions

### Caffeine, Alcohol, Tobacco, and Other Habits

### Physical Activity

### Other Activity

### Screen Failures

# TRIAL INTERVENTION AND CONCOMITANT THERAPY

## Description of Trial Intervention

## Rationale for Trial Intervention

## Dosing and Administration

### Trial Intervention Dose Modification

## Treatment of Overdose

## Preparation, Handling, Storage and Accountability

### Preparation of Trial Intervention

### Handling and Storage of Trial Intervention

### Accountability of Trial Intervention

## Participant Assignment, Randomisation and Blinding

### Participant Assignment

### Randomisation

### Blinding and Unblinding

## Trial Intervention Compliance

## Concomitant Therapy

### Prohibited Concomitant Therapy

### Permitted Concomitant Therapy

### Rescue Therapy

### Other Therapy

# DISCONTINUATION OF TRIAL INTERVENTION AND PARTICIPANT WITHDRAWAL FROM TRIAL

## Discontinuation of Trial Intervention

### Criteria for Permanent Discontinuation of Trial Intervention

### Temporary Discontinuation or Interruption of Trial Intervention

### Rechallenge

## Participant Withdrawal from the Trial

## Lost to Follow-Up

## Trial Stopping Rules

# TRIAL ASSESSMENTS AND PROCEDURES

## Screening/Baseline Assessments and Procedures

## Efficacy Assessments and Procedures

## Safety Assessments and Procedures

### Physical Examination

### Vital Signs

### Electrocardiograms

### Clinical Laboratory Assessments

### Suicidal Ideation and Behaviour Risk Monitoring

## Adverse Events and Serious Adverse Events

### Definitions of AE and SAE

### Time Period and Frequency for Collecting AE and SAE Information

### Identifying AEs and SAEs

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## Medical Device Product Complaints for Drug/Device Combination

### Definition of Medical Device Product Complaints

### Recording of Medical Device Product Complaints

### Time Period and Frequency for Collecting Medical Device Product Complaints

### Follow-Up of Medical Device Product Complaints

### Regulatory Reporting Requirements for Medical Device Product Complaints

## Pharmacokinetics

## Genetics

## Biomarkers

## Immunogenicity Assessments

## Medical Resource Utilisation and Health Economics

# STATISTICAL CONSIDERATIONS

## Analysis Sets

## Analyses Supporting Primary Objective(s)

### Statistical Model, Hypothesis, and Method of Analysis

### Handling of Intercurrent Events of Primary Estimand(s)

### Handling of Missing Data

### Sensitivity Analysis

### Supplementary Analysis

## Analysis Supporting Secondary Objective(s)

## Analysis of Exploratory Objective(s)

## Safety Analyses

## Other Analyses

## Interim Analyses

## Sample Size Determination

## Protocol Deviations

# GENERAL CONSIDERATIONS: REGULATORY, ETHICAL, AND TRIAL OVERSIGHT

## Regulatory and Ethical Considerations

## Committees

## Informed Consent Process

## Data Protection

## Early Site Closure or Trial Termination

# GENERAL CONSIDERATIONS: RISK MANAGEMENT AND QUALITY ASSURANCE

## Quality Tolerance Limits

## Data Quality Assurance

## Source Data

# APPENDIX: ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS – DEFINITIONS, SEVERITY, AND CAUSALITY

## Further Details and Clarifications on the AE Definition

## Further Details and Clarifications on the SAE Definition

## Severity

## Causality

# APPENDIX: DEFINITIONS AND SUPPORTING OPERATIONAL DETAILS

## Contraception and Pregnancy Testing

### Definitions Related to Childbearing Potential

### Contraception

### Pregnancy Testing

## Clinical Laboratory Tests

## Country/Region-Specific Differences

## Prior Protocol Amendments

# APPENDIX: GLOSSARY OF TERMS

# APPENDIX: REFERENCES