Clinical study protocol template

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This document is a template for a clinical study protocol. It contains the backbone structures and instructions to fill out the sections. This template is designed to cover, at minimum, the needs for regulatory reporting. Instructions are in italic blue and hidden when document is printed out. Remove this front page before finalizing the document.

Company logo

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| --- | --- |
| **Protocol title:** |  |
| **Protocol number:** |  |
| **Version (date):** |  |
| **Sponsor:** | Company name  Address |
| **Emergency contact:** | Email: [xxx@companyname.com](mailto:xxx@companyname.com)  Telephone: +xx.xx.xxx.xx.xx |
| **Investigational therapy:** |  |
| **Development phase:** |  |
| **EudraCT number:** |  |
| **IND number:** |  |

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Sponsor signature page

This clinical trial protocol was subjected to critical review and has been approved by the sponsor. By my signature, I confirm that the information it contains is consistent with current risk/benefit evaluation of the investigational therapy as well with moral, ethical, and scientific principles governing clinical research set out in the current version of the Declaration of Helsinki, the International Council for Harmonisation (ICH) Good Clinical Practices Guidelines, and local regulations.

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|  |  |  |  |  |
| **Name, Degree(s)**  **Title** |  | **Date** |  | **Signature** |

Investigator signature page

I have read this study protocol, including all appendices. By my signature, I agree to personally supervise the conduct of this clinical study at my study site and to ensure its conduct is in compliance with the protocol, informed consent, Institutional Review Board (IRB)/Ethics Committee (EC) procedures, the current version of the Declaration of Helsinki, International Council for Harmonisation (ICH) Good Clinical Practices Guidelines, and local regulations governing the conduct of clinical studies.

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|  |  |  |  |  |
| **Name, Degree(s)**  **Title**  **Institution name** |  | **Date** |  | **Signature** |

Protocol amendment history

Document history

|  |  |
| --- | --- |
| **Protocol version** | **Date** |
| Amendment N | DD-Mmm-YYYY |
| Amendment N-1 | DD-Mmm-YYYY |
| … | DD-Mmm-YYYY |
| Amendment 1 | DD-Mmm-YYYY |
| Original | DD-Mmm-YYYY |

Amendment N (DD-Mmm-YYYY)

Amendment rationale

Changes to the previous version of the protocol

Amendment N-1 (DD-Mmm-YYYY)

Amendment rationale

Changes to the previous version of the protocol

Amendment 1 (DD-Mmm-YYYY)

Amendment rationale

Changes to the previous version of the protocol

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Study design

Graphical study design

Study flow

Study and treatment periods

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| **Acronym** | **Definition** |
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# Background and rationale

## Background

## Rationale

### Study rationale and purpose

### Rationale for the study design

### Rationale for the endpoints

### Rationale for the investigational therapy

#### Rationale for the dose and regimen selection

#### Rationale for the combination treatments

### Rationale for the reference therapy

# Objectives, endpoints, and estimands

| **Objective** | **Endpoint** | **Condition of evaluation** |
| --- | --- | --- |
| **Primary objective(s)** |  |  |
|  |  |  |
| **Key secondary objective(s)** |  |  |
|  |  |  |
| **Secondary objectives** |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| **Exploratory objectives** |  |  |
|  |  |  |
|  |  |  |
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# Study design

## Description of the study design

## Definition of end of study

## Early study termination

# Population

## Patient population

## Eligibility criteria

### Inclusion criteria

### Exclusion criteria

## Screen failure

## Patient numbering, treatment assignment and blinding

### Patient numbering

### Treatment assignment

### Blinding and unblinding

# Treatments

## Study treatment

## Dose modifications and delay

### Dose modification

### Dose delay

## Treatment preparation and dispensation

### Study drug packaging and labelling

### Drug supply and storage

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### Study drug disposal and destruction

## Concomitant medications, therapies, and procedures

## Prohibited concomitant medications, therapies, and procedures

# Visit and assessment schedule

## Study flow and visit schedule

### Screening phase

### Pre-treatment phase

### Treatment phase

### Efficacy follow-up phase

### Survival follow-up phase

### Discontinuation of study treatment

### Withdrawal of consent

### Follow-up for safety evaluations

### Loss to follow-up

### Unscheduled assessments

## Assessment types

### Efficacy assessments

### Safety and tolerability assessments

### Translational assessments

### Patient reported outcomes

### Healthcare resource utilization

# Safety monitoring and reporting

## Adverse events

### Definition

### Grading and relationship to study drug

### Reporting

### Laboratory and other assessments abnormalities

### Adverse events of special interest

## Serious adverse events

### Definition

### Reporting

## Emergency unblinding

## Pregnancies

## Contraception and barrier guidance

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## Scientific steering committee

## Data monitoring committee

## Safety review committee

## Independent review committee

# Data collection, monitoring and management

## Data confidentiality

## Data collection

## Database management and quality control

## Data monitoring

# Statistical method

## Estimands and statistical hypotheses

## Sample size

### Sample size determination

### Robustness of the sample size

## Analysis sets

## Statistical analyses

### General considerations

### Primary evaluation

#### Definition

#### Main analytical approach

#### Sensitivity analyses

#### Supplementary analyses

### Secondary evaluation

### Exploratory evaluation

### Safety evaluation

## Interim analyses and timing of analyses

# Ethical considerations and administrative procedures

## Regulatory and ethical compliance

## Responsibility of the investigator and IRB/IEC/REB

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## Publication of study protocol and results

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