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

Protocol Summary

Synopsis

Study rationale and purpose

Objectives, endpoints, and estimands

Population

Key inclusion/exclusion criteria

Investigational and reference therapy

Study design

Graphical study design

Study flow

Study and treatment periods

Efficacy assessments

Safety and tolerability assessments

Other assessments

Statistical methods

Committees

Visit and assessment schedule

Table of contents

[Sponsor signature page 3](#_Toc124416991)

[Investigator signature page 4](#_Toc124416992)

[Protocol amendment history 5](#_Toc124416993)

[Document history 5](#_Toc124416994)

[Amendment N (DD-Mmm-YYYY) 5](#_Toc124416995)

[Amendment N-1 (DD-Mmm-YYYY) 5](#_Toc124416996)

[Amendment 1 (DD-Mmm-YYYY) 5](#_Toc124416997)

[Protocol Summary 6](#_Toc124416998)

[Synopsis 6](#_Toc124416999)

[Visit and assessment schedule 7](#_Toc124417000)

[List of figures 11](#_Toc124417001)

[List of tables 12](#_Toc124417002)

[List of abbreviations 13](#_Toc124417003)

[1. Background and rationale 14](#_Toc124417004)

[1.1. Background 14](#_Toc124417005)

[1.2. Rationale 14](#_Toc124417006)

[1.2.1. Study rationale and purpose 14](#_Toc124417007)

[1.2.2. Rationale for the study design 14](#_Toc124417008)

[1.2.3. Rationale for the endpoints 14](#_Toc124417009)

[1.2.4. Rationale for the investigational therapy 14](#_Toc124417010)

[1.2.4.1. Rationale for the dose and regimen selection 14](#_Toc124417011)

[1.2.4.2. Rationale for the combination treatments 14](#_Toc124417012)

[1.2.5. Rationale for the reference therapy 14](#_Toc124417013)

[2. Objectives, endpoints, and estimands 15](#_Toc124417014)

[3. Study design 16](#_Toc124417015)

[3.1. Description of the study design 16](#_Toc124417016)

[3.2. Definition of end of study 16](#_Toc124417017)

[3.3. Early study termination 16](#_Toc124417018)

[4. Population 17](#_Toc124417019)

[4.1. Patient population 17](#_Toc124417020)

[4.2. Eligibility criteria 17](#_Toc124417021)

[4.2.1. Inclusion criteria 17](#_Toc124417022)

[4.2.2. Exclusion criteria 17](#_Toc124417023)

[4.3. Screen failure 17](#_Toc124417024)

[4.4. Patient numbering, treatment assignment and blinding 17](#_Toc124417025)

[4.4.1. Patient numbering 17](#_Toc124417026)

[4.4.2. Treatment assignment 17](#_Toc124417027)

[4.4.3. Blinding and unblinding 17](#_Toc124417028)

[5. Treatments 18](#_Toc124417029)

[5.1. Study treatment 18](#_Toc124417030)

[5.2. Dose modifications and delay 18](#_Toc124417031)

[5.2.1. Dose modification 18](#_Toc124417032)

[5.2.2. Dose delay 18](#_Toc124417033)

[5.3. Treatment preparation and dispensation 18](#_Toc124417034)

[5.3.1. Study drug packaging and labelling 18](#_Toc124417035)

[5.3.2. Drug supply and storage 18](#_Toc124417036)

[5.3.3. Study drug compliance and accountability 18](#_Toc124417037)

[5.3.4. Study drug disposal and destruction 18](#_Toc124417038)

[5.4. Concomitant medications, therapies, and procedures 18](#_Toc124417039)

[5.5. Prohibited concomitant medications, therapies, and procedures 18](#_Toc124417040)

[6. Visit and assessment schedule 19](#_Toc124417041)

[6.1. Study flow and visit schedule 19](#_Toc124417042)

[6.1.1. Screening phase 19](#_Toc124417043)

[6.1.2. Pre-treatment phase 19](#_Toc124417044)

[6.1.3. Treatment phase 19](#_Toc124417045)

[6.1.4. Efficacy follow-up phase 19](#_Toc124417046)

[6.1.5. Survival follow-up phase 19](#_Toc124417047)

[6.1.6. Discontinuation of study treatment 19](#_Toc124417048)

[6.1.7. Withdrawal of consent 19](#_Toc124417049)

[6.1.8. Follow-up for safety evaluations 19](#_Toc124417050)

[6.1.9. Loss to follow-up 19](#_Toc124417051)

[6.1.10. Unscheduled assessments 19](#_Toc124417052)

[6.2. Assessment types 19](#_Toc124417053)

[6.2.1. Efficacy assessments 19](#_Toc124417054)

[6.2.2. Safety and tolerability assessments 19](#_Toc124417055)

[6.2.3. Translational assessments 19](#_Toc124417056)

[6.2.4. Patient reported outcomes 19](#_Toc124417057)

[6.2.5. Healthcare resource utilization 19](#_Toc124417058)

[7. Safety monitoring and reporting 20](#_Toc124417059)

[7.1. Adverse events 20](#_Toc124417060)

[7.1.1. Definition 20](#_Toc124417061)

[7.1.2. Grading and relationship to study drug 20](#_Toc124417062)

[7.1.3. Reporting 20](#_Toc124417063)

[7.1.4. Laboratory and other assessments abnormalities 20](#_Toc124417064)

[7.1.5. Adverse events of special interest 20](#_Toc124417065)

[7.2. Serious adverse events 20](#_Toc124417066)

[7.2.1. Definition 20](#_Toc124417067)

[7.2.2. Reporting 20](#_Toc124417068)

[7.3. Emergency unblinding 20](#_Toc124417069)

[7.4. Pregnancies 20](#_Toc124417070)

[7.5. Contraception and barrier guidance 20](#_Toc124417071)

[8. Committees 21](#_Toc124417072)

[8.1. Scientific steering committee 21](#_Toc124417073)

[8.2. Data monitoring committee 21](#_Toc124417074)

[8.3. Safety review committee 21](#_Toc124417075)

[8.4. Independent review committee 21](#_Toc124417076)

[9. Data collection, monitoring and management 22](#_Toc124417077)

[9.1. Data confidentiality 22](#_Toc124417078)

[9.2. Data collection 22](#_Toc124417079)

[9.3. Database management and quality control 22](#_Toc124417080)

[9.4. Data monitoring 22](#_Toc124417081)

[10. Statistical method 23](#_Toc124417082)

[10.1. Estimands and statistical hypotheses 23](#_Toc124417083)

[10.2. Sample size 23](#_Toc124417084)

[10.2.1. Sample size determination 23](#_Toc124417085)

[10.2.2. Robustness of the sample size 23](#_Toc124417086)

[10.3. Analysis sets 23](#_Toc124417087)

[10.4. Statistical analyses 23](#_Toc124417088)

[10.4.1. General considerations 23](#_Toc124417089)

[10.4.2. Primary evaluation 23](#_Toc124417090)

[10.4.2.1. Definition 23](#_Toc124417091)

[10.4.2.2. Main analytical approach 23](#_Toc124417092)

[10.4.2.3. Sensitivity analyses 23](#_Toc124417093)

[10.4.2.4. Supplementary analyses 23](#_Toc124417094)

[10.4.3. Secondary evaluation 23](#_Toc124417095)

[10.4.4. Exploratory evaluation 23](#_Toc124417096)

[10.4.5. Safety evaluation 23](#_Toc124417097)

[10.5. Interim analyses and timing of analyses 23](#_Toc124417098)

[11. Ethical considerations and administrative procedures 24](#_Toc124417099)

[11.1. Regulatory and ethical compliance 24](#_Toc124417100)

[11.2. Responsibility of the investigator and IRB/IEC/REB 24](#_Toc124417101)

[11.3. Informed consent procedures 24](#_Toc124417102)

[11.4. Discontinuation of study 24](#_Toc124417103)

[11.5. Publication of study protocol and results 24](#_Toc124417104)

[11.6. Study documentation, record keeping and retention of documents 24](#_Toc124417105)

[11.7. Confidentiality of study documents and patient records 24](#_Toc124417106)

[11.8. Audits and inspections 24](#_Toc124417107)

[11.9. Financial disclosures 24](#_Toc124417108)

[11.10. Protocol adherence 24](#_Toc124417109)

[11.11. Amendment to the protocol 24](#_Toc124417110)

[12. References 25](#_Toc124417111)

[13. Appendices 26](#_Toc124417112)

List of figures

**No table of figures entries found.**

No numbered figure in the document

List of tables

No numbered table in the document

List of abbreviations

| **Acronym** | **Definition** |
| --- | --- |
|  |  |
|  |  |
|  |  |
|  |  |

# 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

### Study drug compliance and accountability

### 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

# Committees

## 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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## Study documentation, record keeping and retention of documents

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## Audits and inspections

## Financial disclosures

## Protocol adherence

## Amendment to the protocol

# References

# Appendices