Clinical study protocol template

Author: Jonathan Jaeger

First release: 14-Jan-2021 - Last modification: 24-Jul-2023

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

|  |  |
| --- | --- |
| **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:** |  |

Property of Company Name   
Confidential  
May not be used, divulged, published, or otherwise disclosed without the consent of Company Name

24 hours emergency contact information

Should the emergency contact not be added in the front page, please complete the 24 hours emergency contact information. Ideally, add a global generic phone number and email address. In addition, if required, add toll free numbers for each countries the study is expected to be run.

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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **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

[24 hours emergency contact information 3](#_Toc141087230)

[Sponsor signature page 4](#_Toc141087231)

[Investigator signature page 5](#_Toc141087232)

[Protocol amendment history 6](#_Toc141087233)

[Document history 6](#_Toc141087234)

[Amendment N (DD-Mmm-YYYY) 6](#_Toc141087235)

[Amendment N-1 (DD-Mmm-YYYY) 6](#_Toc141087236)

[Amendment 1 (DD-Mmm-YYYY) 6](#_Toc141087237)

[Protocol Summary 7](#_Toc141087238)

[Synopsis 7](#_Toc141087239)

[Visit and assessment schedule 8](#_Toc141087240)

[List of figures 12](#_Toc141087241)

[List of tables 13](#_Toc141087242)

[List of abbreviations 14](#_Toc141087243)

[1. Background and rationale 15](#_Toc141087244)

[1.1. Background 15](#_Toc141087245)

[1.2. Rationale 15](#_Toc141087246)

[1.2.1. Study rationale and purpose 15](#_Toc141087247)

[1.2.2. Rationale for the study design 15](#_Toc141087248)

[1.2.3. Rationale for the endpoints 15](#_Toc141087249)

[1.2.4. Rationale for the investigational therapy 15](#_Toc141087250)

[1.2.4.1. Rationale for the dose and regimen selection 15](#_Toc141087251)

[1.2.4.2. Rationale for the combination treatments 15](#_Toc141087252)

[1.2.5. Rationale for the reference therapy 15](#_Toc141087253)

[2. Objectives, endpoints, and estimands 16](#_Toc141087254)

[3. Study design 17](#_Toc141087255)

[3.1. Description of the study design 17](#_Toc141087256)

[3.2. Definition of end of study 17](#_Toc141087257)

[3.3. Early study termination 17](#_Toc141087258)

[4. Population 18](#_Toc141087259)

[4.1. Patient population 18](#_Toc141087260)

[4.2. Eligibility criteria 18](#_Toc141087261)

[4.2.1. Inclusion criteria 18](#_Toc141087262)

[4.2.2. Exclusion criteria 18](#_Toc141087263)

[4.3. Screen failure 18](#_Toc141087264)

[4.4. Patient numbering, treatment assignment and blinding 18](#_Toc141087265)

[4.4.1. Patient numbering 18](#_Toc141087266)

[4.4.2. Treatment assignment 18](#_Toc141087267)

[4.4.3. Blinding and unblinding 18](#_Toc141087268)

[5. Treatments 19](#_Toc141087269)

[5.1. Study treatment 19](#_Toc141087270)

[5.2. Dose modifications and delay 19](#_Toc141087271)

[5.2.1. Dose modification 19](#_Toc141087272)

[5.2.2. Dose delay 19](#_Toc141087273)

[5.3. Treatment preparation and dispensation 19](#_Toc141087274)

[5.3.1. Study drug packaging and labelling 19](#_Toc141087275)

[5.3.2. Drug supply and storage 19](#_Toc141087276)

[5.3.3. Study drug compliance and accountability 19](#_Toc141087277)

[5.3.4. Study drug disposal and destruction 19](#_Toc141087278)

[5.4. Concomitant medications, therapies, and procedures 19](#_Toc141087279)

[5.5. Prohibited concomitant medications, therapies, and procedures 19](#_Toc141087280)

[6. Visit and assessment schedule 20](#_Toc141087281)

[6.1. Study flow and visit schedule 20](#_Toc141087282)

[6.1.1. Screening phase 20](#_Toc141087283)

[6.1.2. Pre-treatment phase 20](#_Toc141087284)

[6.1.3. Treatment phase 20](#_Toc141087285)

[6.1.4. Efficacy follow-up phase 20](#_Toc141087286)

[6.1.5. Survival follow-up phase 20](#_Toc141087287)

[6.1.6. Discontinuation of study treatment 20](#_Toc141087288)

[6.1.7. Withdrawal of consent 20](#_Toc141087289)

[6.1.8. Follow-up for safety evaluations 20](#_Toc141087290)

[6.1.9. Loss to follow-up 20](#_Toc141087291)

[6.1.10. Unscheduled assessments 20](#_Toc141087292)

[6.2. Assessment types 20](#_Toc141087293)

[6.2.1. Efficacy assessments 20](#_Toc141087294)

[6.2.2. Safety and tolerability assessments 20](#_Toc141087295)

[6.2.3. Translational assessments 20](#_Toc141087296)

[6.2.4. Patient reported outcomes 20](#_Toc141087297)

[6.2.5. Healthcare resource utilization 20](#_Toc141087298)

[7. Safety monitoring and reporting 21](#_Toc141087299)

[7.1. Adverse events 21](#_Toc141087300)

[7.1.1. Definition 21](#_Toc141087301)

[7.1.2. Grading and relationship to study drug 21](#_Toc141087302)

[7.1.3. Reporting 21](#_Toc141087303)

[7.1.4. Laboratory and other assessments abnormalities 21](#_Toc141087304)

[7.1.5. Adverse events of special interest 21](#_Toc141087305)

[7.2. Serious adverse events 21](#_Toc141087306)

[7.2.1. Definition 21](#_Toc141087307)

[7.2.2. Reporting 21](#_Toc141087308)

[7.3. Emergency unblinding 21](#_Toc141087309)

[7.4. Pregnancies 21](#_Toc141087310)

[7.5. Contraception and barrier guidance 21](#_Toc141087311)

[8. Committees 22](#_Toc141087312)

[8.1. Scientific steering committee 22](#_Toc141087313)

[8.2. Data monitoring committee 22](#_Toc141087314)

[8.3. Safety review committee 22](#_Toc141087315)

[8.4. Independent review committee 22](#_Toc141087316)

[9. Data collection, monitoring and management 23](#_Toc141087317)

[9.1. Data confidentiality 23](#_Toc141087318)

[9.2. Data collection 23](#_Toc141087319)

[9.3. Database management and quality control 23](#_Toc141087320)

[9.4. Data monitoring 23](#_Toc141087321)

[10. Statistical method 24](#_Toc141087322)

[10.1. Estimands and statistical hypotheses 24](#_Toc141087323)

[10.2. Sample size 24](#_Toc141087324)

[10.2.1. Sample size determination 24](#_Toc141087325)

[10.2.2. Robustness of the sample size 24](#_Toc141087326)

[10.3. Analysis sets 24](#_Toc141087327)

[10.4. Statistical analyses 24](#_Toc141087328)

[10.4.1. General considerations 24](#_Toc141087329)

[10.4.2. Primary evaluation 24](#_Toc141087330)

[10.4.2.1. Definition 24](#_Toc141087331)

[10.4.2.2. Main analytical approach 24](#_Toc141087332)

[10.4.2.3. Sensitivity analyses 24](#_Toc141087333)

[10.4.2.4. Supplementary analyses 24](#_Toc141087334)

[10.4.3. Secondary evaluation 24](#_Toc141087335)

[10.4.4. Exploratory evaluation 24](#_Toc141087336)

[10.4.5. Safety evaluation 24](#_Toc141087337)

[10.5. Interim analyses and timing of analyses 24](#_Toc141087338)

[11. Ethical considerations and administrative procedures 25](#_Toc141087339)

[11.1. Regulatory and ethical compliance 25](#_Toc141087340)

[11.2. Responsibility of the investigator and IRB/IEC/REB 25](#_Toc141087341)

[11.3. Informed consent procedures 25](#_Toc141087342)

[11.4. Discontinuation of study 25](#_Toc141087343)

[11.5. Publication of study protocol and results 25](#_Toc141087344)

[11.6. Study documentation, record keeping and retention of documents 25](#_Toc141087345)

[11.7. Confidentiality of study documents and patient records 25](#_Toc141087346)

[11.8. Audits and inspections 25](#_Toc141087347)

[11.9. Financial disclosures 25](#_Toc141087348)

[11.10. Protocol adherence 25](#_Toc141087349)

[11.11. Amendment to the protocol 25](#_Toc141087350)

[12. References 26](#_Toc141087351)

[13. Appendices 27](#_Toc141087352)

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** |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

# 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

## Informed consent procedures

## Discontinuation of study

## Publication of study protocol and results

## Study documentation, record keeping and retention of documents

## Confidentiality of study documents and patient records

## Audits and inspections

## Financial disclosures

## Protocol adherence

## Amendment to the protocol

# References

# Appendices