

## Begeleidende tips voor gebruik van deze template

- Deze template dient als startpunt voor het uitschrijven van een studieprotocol. De secties die hierin worden opgesomd kunnen aangepast of verder aangevuld worden naargelang de vereisten voor de studie.
- [Tekst in het blauw dient als voorbeeldtekst. U kan de tekst aanpassen of verder aanvullen naar gelang de vereisten voor de studie.](#)
- Tekst in een kader geeft toelichting bij de inhoud van enkele secties. Deze kaders moeten verwijderd worden bij het uitschrijven van het protocol.

# Study Protocol

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**Study Title:**

**Study Acronym:**

**Protocol Version and Date:**

**Registry Number (if applicable):**

**Sponsor:**

**Coordinating/Principal Investigator:**

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## PROTOCOL SIGNATURE PAGE

I agree:

- to assume responsibility for the proper conduct of this study
- to conduct the study in compliance with this protocol
- not to implement any deviations from or changes to the protocol without prior review and written approval from the Ethics Committee, or for administrative aspects of the study (where permitted by all applicable regulatory requirements)
- to ensure that all persons assisting me with the study are adequately informed about their study-related duties and functions as described in the protocol
- that I am aware of and will comply with the current good clinical practice (GCP) guidelines and ethical principles outlined in the Declaration of Helsinki
- to conduct the study in accordance with all applicable laws and regulations

Printed name \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

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## 1 Sponsor/Coordinating Investigator Information

Sponsor:  
 Principal Investigator:  
 Subinvestigator(s):  
 Coordinating Investigator *if applicable*:  
 Statistician :  
 Study Coordinator:  
 Study site(s) and co-investigator(s) *if applicable*:

## 2 List of Abbreviations

## 3 Protocol Version History

Version N°	Version Date	Summary of changes

## 4 Trial Registration/Protocol Summary

Information	
Objectives:	
Study population:	
In- and exclusion criteria:	
Factors of interest / Data to be collected:	
Endpoints:	
Target sample size:	

Statistical considerations:	
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## 5 Background and Rationale

Licht bondig de achtergrond en wetenschappelijke relevantie van het geplande onderzoek toe. De lezer dient voldoende inzicht te krijgen in het onderzoeksdomein van dit project. Beschrijf de motivatie om dit onderzoek uit te voeren en licht het doel van het onderzoek toe.

- 5.1 Overview of Relevant Literature
- 5.2 Study Rationale and Purpose

## 6 Study Objectives and Endpoints

Licht kort en bondig de doelstellingen van het onderzoek toe. Beschrijf duidelijk de onderzoeksvragen en/of onderzoekshypothesen.

- 6.1 Primary Objective
- 6.2 Secondary Objectives
- 6.3 Endpoints

## 7 Study Design

Licht bondig het onderzoeksdesign en de rationale hiervoor toe.

- 7.1 Study Design
- 7.2 Date Range for collected study data

## 8 Study Population

- 8.1 Population of interest
- 8.2 Inclusion Criteria
- 8.3 Exclusion Criteria

## 9 Study Assessments and Procedures

Geef een overzicht van de procedures per visite weer in een tabel. Ter aanvulling kan een schematisch diagram toegevoegd worden Geef gedetailleerd weer welke data zal worden verzameld en geef daarbij aan of deze studie-specifiek zijn of deel uitmaken van de standaardzorg.

- 9.1 Schedule of Activities
- 9.2 Detailed Study Assessments/Interventions

## 10 Data Collection and Management

Geef een uitleg over de gebruikte methode (procedure) en/of data-analyse strategie in relatie tot de gestelde onderzoekshypothesen. Leg mogelijke ethische implicaties van de geplande methodologie uit.

### 10.1 Monitoring

The investigator must make all trial documentation and related records available in case a monitoring visit or audit by the Sponsor is requested. Also in case of regulatory inspections all trial documentation should be made available to the inspector(s). All participant data must be handled and treated confidentially.

The Sponsor's monitoring frequency will be determined prior to the start of the trial. A monitoring plan will be generated detailing the frequency and scope of monitoring for the trial. Throughout the course of the trial the monitoring plan can be adjusted as necessary.

### 10.2 Data Collection

An Electronic Data Capture system "*add name of the system in the text*" will be used for data collection. The system is validated and access to all levels will be granted/revoked by the Sponsor representative. Trial data should be entered within reasonable time after the subject attended the visit. Corrections/modifications will be automatically tracked by an audit trail detailing date and time of the correction and the name of person performing the correction.

### 10.3 Database Management and Quality Control

### 10.4 Statistical Considerations and Data Analysis

Geef een uitleg over de gebruikte methode (procedure) en/of data-analyse strategie in relatie tot de gestelde onderzoekshypothesen. Leg mogelijke ethische implicaties van de geplande methodologie uit.

## 11 Ethical Considerations

### 11.1 Ethical Conduct of the Study

#### 11.1.1 Declaration of Helsinki

The trial will be performed in accordance with the Declaration of Helsinki, the conditions and principles of Good Clinical Practice, the protocol and applicable local regulatory requirements and laws.

#### 11.1.2 Ethics Committee

Before the start of the trial or implementation of any amendment, approval of the trial protocol and amendments, informed consent forms and other relevant documents will be obtained from the applicable ethical committee(s).

## 11.2 Informed Consent

Each participant shall provide Informed Consent before performance of any study-related activities. The IC form that is/are used must be approved by reviewing EC and be in a language that the participant can read and understand. The ICF should be in accordance with current ICH and GCP guidelines and with applicable local regulations.

## 11.3 Study Data Protection

The collection and processing of personal data from participants enrolled in the study will be limited to those data that are necessary to fulfill the objectives of this study. These data must be collected and processed with adequate precautions to ensure confidentiality and compliance with applicable data protection laws and regulations.

## 11.4 Subject Identification

The participant identification will be treated as confidential and will be filed by the investigator in an identification log. This log is kept at the participating site and shall not be copied. In all reports and communication between the site and the Sponsor the participant shall be identified with a participant study number.

## **12 Insurance**

UZ Brussel/VUB is, as Sponsor of the trial, responsible for ensuring appropriate general/product liability insurance and as required in accordance with applicable laws and regulations, country-specific liability insurance coverage for claims made by a trial subjects for injury arising from the subject's participation in the trial.

## **13 Reporting and Dissemination**

The data and information collected during this trial will be reported in a publication in a scientific/medical journal. Reporting of trial results will be performed according to local regulations.

Data collected within the UZ Brussel or VUB as an employee or (PhD) student of the VUB are owned by the UZ Brussel VUB. For the correct authorship rules we refer to the International Committee of Medical Journal Editors:

<https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>

## **14 Finance and Conflict of Interest Statement**

Investigators and study team members will provide the Sponsor with sufficient, accurate financial information in accordance with local regulations to allow the Sponsor to submit complete and accurate financial certification or disclosure statements to the appropriate regulatory authorities/ethics committee. Any update of information on financial interests should be disclosed during the course of the study.

## **15 Tables and Figures**

## **16 References**