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.

Universitair Ziekenhuis Brussel

Clinical Trial Center

Study Protocol

Study Title:
Study Acronym:
Protocol Version and Date:
Registry Number (*if applicable*):
Sponsor:
Coordinating/Principal Investigator:

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

Table of Contents

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 crite-ria:	
Factors of interest / Data to be collected:	
Endpoints:	
Target sample size:	

Statistical considerations:	

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

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

8.4 Recruitment strategy

9 Data Collection and Management

Beschrijf hoe de data zullen worden verzameld en verwerkt voor de studieanalyse. Motiveer de keuze van de steekproefgrootte (sample size).

9.1 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. 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.

9.2 Endpoints (primary and secondary)

9.3 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.

10 Ethical Considerations

10.1 Ethical Conduct of the Study

10.1.1 Ethics Committee

Before the start of the trial, approval of the trial protocol, and other relevant documents will be obtained from the applicable ethical committee(s).

10.2 Study Data Protection

The 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 processed with adequate precautions to ensure confidentiality and compliance with applicable data protection laws and regulations.

10.3 Subject Identification

The participant identification will be treated as confidential. In all reports and communication between the site and the Sponsor no identifiers will be used for the transferred data.

11 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

12 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.

13 Tables and Figures

14 References