|  |  |  |  |
| --- | --- | --- | --- |
|  | | Retrospective clinical study protocol (Template) | Clinical trial Center |
| AAHRPP-DSQ-033\_EN | Version 3.0 | Application date :  15/04/2024 |

*DELETE THIS PAGE IN THE FINAL VERSION OF YOUR DOCUMENT*

**INSTRUCTIONS D’UTILISATION**

* This document is a protocol template based on the Good Clinical Practice guidelines for research (ICH GCP E6 R2[[1]](#footnote-1)).
* It should be used when writing a protocol for a retrospective study.
* The sections proposed in this template can be adapted to suit your needs.
* Some information may also be provided in other documents, which should be referenced in the protocol as appendices.
* The **red text** corresponding to the instructions for use should be removed, as should this first page.
* Text in black should be retained.
* Text in green should be adapted to your study.
* You can modify the title and layout styles. Don't forget to update the table of contents.
* Each protocol version must be numbered and dated in the footer.
* This document is available in English and French.
* Final format: PDF

Protocol Title

|  |  |
| --- | --- |
| Acronym / Protocol code | Fill in |
| Protocol version and date | Fill in |
| Sponsor | Cliniques universitaires Saint-Luc  Belgium |
|  |  |
| Investigator-Sponsor | Name and contact details |

The information contained in this document is the property of the Sponsor/ Investigator-Sponsor and may not be reproduced, published or disclosed to others without written authorization of the Sponsor/ Investigator-Sponsor.

1. Signature page

**INVESTIGATOR-SPONSOR**

Name Signature Date

**SITE PRINCIPAL INVESTIGATOR**

I agree to conduct this study in accordance with the design and specific provisions of this protocol and will only make changes in the protocol after notifying the sponsor.

I understand that I may terminate or suspend enrolment of the study at any time if it becomes necessary to protect the best interests of the study subjects.

I agree to personally conduct or supervise this study and to ensure that all associates, colleagues, and employees assisting in the conduct of this study are informed about their obligations in meeting these commitments.

I will conduct the study in accordance with the protocol, Good Clinical Practice, the Declaration of Helsinki, and the moral, ethical and scientific principles that justify medical research. The study will be conducted in accordance with all relevant laws and regulations relating to clinical experimentation and the protection of patients.

I will ensure that the requirements relating to Ethics Committee review and approval are met.

I agree to maintain adequate and accurate records and to make those records available for audit and inspection in accordance with relevant regulatory requirements including the provision of direct access to data and source documents.

I agree to promptly report to the Ethics Committee any changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without Ethics Committee approval, except where necessary to ensure the safety of study participants.

Name Signature Date

1. Protocol synopsis

1 page max

|  |  |
| --- | --- |
| Study title |  |
| Acronym |  |
| Sponsor | Cliniques universitaires Saint-Luc |
| Investigator-sponsor |  |
| Departments / Study centre(s) and site(s) principal investigator(s) |  |
| Rationale / Literary references |  |
| Objectives | * Primary: * Secondary: |
| Study Design |  |
| Number of patients |  |
| Main criteria for inclusion (inclusion/exclusion criteria) |  |
| Period during which data were collected from patients (source data) :  from ..................................... (DD/MM/YY) to ......................................(DD/MM/YY)  Period during which data will be retrieved from files and analyzed by the investigator:  from ..................................... (DD/MM/YY) to ......................................(DD/MM/YY) | |

Table of contents to be updated

In order for your headings to be included in the table of contents, you must use the heading styles configured in the document. Use the headings provided in the Word document toolbar or create your own heading styles.

Table of contents

[1. Signature page 3](#_Toc164073196)

[2. Protocol synopsis 4](#_Toc164073197)

[3. List of abbreviations and definitions 6](#_Toc164073198)

[4. Ethics 7](#_Toc164073199)

[5. BIBLIOGRAPHIC REFERENCES 8](#_Toc164073200)

[6. Objectives 8](#_Toc164073201)

[7. STUDY DESIGN AND METHODOLOGY APPLIED 8](#_Toc164073202)

[7.1. Design 8](#_Toc164073203)

[7.2. Description of the population 8](#_Toc164073204)

[7.3. Inclusion criteria 8](#_Toc164073205)

[7.4. Exclusion criteria 8](#_Toc164073206)

[8. Data management 8](#_Toc164073207)

[8.1. Data Quality Assurance 9](#_Toc164073208)

[8.2. Statistical Analysis 9](#_Toc164073209)

[8.3. Data handling and record keeping 9](#_Toc164073210)

[8.4. Case Report Form 10](#_Toc164073211)

[8.5. Data storage 11](#_Toc164073212)

[8.6. Access to data 11](#_Toc164073213)

[9. End of study 11](#_Toc164073214)

[10. Archiving 11](#_Toc164073215)

[11. Litterature References 11](#_Toc164073216)

1. List of abbreviations and definitions
2. Ethics

* *This protocol, any amendments to the protocol and any other relevant documents (e.g. recruitment posters) will be submitted to the Ethics Committee (EC) for formal approval to conduct the study. The decision of the EC regarding the conduct of the study will be communicated in writing to the sponsor.*
* *The study will be conducted in accordance with the Good Clinical Practice Guidelines (International Conference on Harmonisation 1996), and the latest version of the Declaration of Helsinki (World Medical Association).*
* *The identity of the participant will be kept confidential in accordance with the General Data Protection Regulation of 27 April 2016 (in application on 25 May 2018), the Belgian law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data and the Belgian law on patient rights (22 August 2002). Personal data will be coded. Subjects will not be identified by name or in any other recognizable way in any records, results or publications related to the study.*

1. BIBLIOGRAPHIC REFERENCES

* Scientific explanation to define the question: discussion of the literature and important data relevant to the study and providing the context for the study.
* Justification of the study in the light of current knowledge: literature references and previously obtained results or data that are relevant to the study and serve as the basis for the study.

1. Objectives

* Statement of research question (+ definition of variables)
* Research objectives

1. STUDY DESIGN AND METHODOLOGY APPLIED
   1. Design

Definition of the characteristics of the research by standard terms:

* Study design
* Monocenter or multicenter (national or international) ; number of centers
* Planned duration (Period during which data will be retrieved from the files and analyzed by the investigator)
* Data collection methods for assessing study objectives
  1. Description of the population
* Patient population to be studied. Characteristics of the subjects to be included: age, sex, weight, height, race, medical history, biological parameters, definition of pathology and listing of its characteristics.
* Number of patients expected.
  1. Inclusion criteria

Indicate that subjects must meet all inclusion criteria in order to participate in the study and list each criterion.

* 1. Exclusion criteria

Indicate that all subjects meeting any of the exclusion criteria at baseline will be excluded from participation in the study and list each criterion.

1. Data management
   1. Data Quality Assurance

All study data will be handled in accordance with the law on General Data Protection Regulation (GDPR) and institutional rules [Belgian law dated on 20 July 2018 and 22 Aug. 2002].

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

Appropriate technical and organizational measures to protect the personal data against unauthorized disclosures or access, accidental or unlawful destruction, or accidental loss or alteration must be put in place. Sponsor and site personnel whose responsibilities require access to personal data agree to keep the identity of subjects confidential.

Patients who come to Cliniques Universitaires Saint-Luc for treatment, or their legal representatives, accept that their medical data may be analyzed retrospectively and confidentially for scientific research purposes. The exercise of rights in connection with the use of medical data for retrospective scientific research purposes must be explicitly expressed to the Cliniques universitaires Saint-Luc Data Protection Officer. The patient may object at any time and withdraw prior agreement without having to justify his or her objection or suffer any inconvenience in the course of treatment. Any objections will be noted in the patient's medical file. Patients can also withdraw their refusal at any time.

Privacy and confidentiality of data generated in the future on stored samples will be protected by the same standards applicable to all other clinical data. The investigator will ensure that the confidentiality of subjects' data will be preserved. On CRFs or any other documents, the subjects will not be identified by their names, but by their study number. Documents that identify the names of participants against their study number will be maintained by the investigator in strict confidence.

In any presentations of the results of this study at meetings or in publications, the subjects’ identity will remain confidential.

* 1. Statistical Analysis
* Reasons for the sample size selected, statistical power of the study, level of significance to be used
* Describe planned analyses, comparisons and statistical tests
* Reasons for excluding subject from an analysis
* Planned monitoring of the results
* Frequency and nature of interim analyses
  1. Data handling and record keeping

Subjects who are included in the study will be assigned a unique study number. On all documents submitted to the sponsor, patients will only be identified by their study number. The subject identification list will be safeguarded by the site. The name and any other directly identifying details will not be included in the study database.

An electronic case report form (eCRF) will be used in REDCap software. This eCRF will include specific pages for inclusion and exclusion criteria, and for reporting each visit. The investigator will review, approve and validate each completed eCRF; the investigator’s signature (validation) serving as attestation of the investigator’s responsibility for ensuring that all data entered on the eCRF are complete, accurate and authentic.

All data will be processed according to the principles that the European General Data Protection Regulation (GDPR) imposes, which is in force since 25 May 2018.

1. Who will responsible for the processing of personal data?

Complete. In general, it is the investigator-sponsor

2. Who is Data Protection Officer for the processing?

The institutional DPO could be reached by this email address : rgpd@saintluc.uclouvain.be

3. The purpose of the processing:

Scientific research

4. The legal basis of the processing:

Legitimate interests pursued by the Institution

5. Who are potential recipients of the personal data?

All researchers involved in this clinical study or in research projects that use materials original from this clinical study. Staff involved in monitoring and ethical evaluation and people from competent authorities.

6. It is possible that the personal data will be viewed by people who are in countries that do not use the same standards as the EU in terms of legal protection of data. In that case, we guarantee that the conditions of European and Belgian legislation on the protection of personal data will be respected.

* 1. Case Report Form

An electronic data capture (EDC) system, i.e. REDCap, will be used for data collection. Data reported on each eCRF should be consistent with the source data. If information is not known, this must be clearly indicated on the eCRF. All missing and ambiguous data will be clarified.

The eCRFs will be developed, based on the protocol. The final eCRF design will be approved by the Investigator-sponsor.

All data entries and corrections will only be performed by study site staff, authorized by the principal investigator. Data will be checked and any errors or inconsistencies will be clarified. The principal investigator must verify that all data entries in the eCRF are accurate and correct.

REDCap is provided and maintained by Vanderbilt University; a license for use was granted to the CUSL. REDCap is a web-based system.

* 1. Data storage

The data is accessed through a web browser directly on the secure REDCap server. The server is hosted within the Cliniques universitaires Saint-Luc campus and meets hospital level security and back-up requirements.

* 1. Access to data

Login in CRF is password controlled. Each user will receive a personal login name and password and will have a specific role which has predefined restrictions on what is allowed in REDCap. Any activity in the software is traced and transparent via the audit trail and log files.

1. End of study

The study end date corresponds to the date on which analysis of the data collected is completed.

This is intended *to indicate the planned completion date*

1. Archiving

Personal data is kept for no longer than is necessary for the purposes for which it is recorded (Law of July 30, 2018, chap V Art 111).

For this study, data will be kept for *specify period in months/years.*

Specify where study documents and collected data are archived, as well as access conditions.

1. Litterature References

List of bibliographic references related to the clinical investigation

1. [ICH GCP E6 (R2) Guide de bonnes pratiques cliniques](https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf) [↑](#footnote-ref-1)