"Please do take into account that this is a translation of the original French version validated in the Quality Management System (QMS) of Cliniques universitaires Saint-Luc through the SharePoint PaCo GED. Therefore in case of doubt, differences, inconsistency or discrepancy in this English version, the French version shall prevail"

By default, any clinical study project is covered by the following regulations:

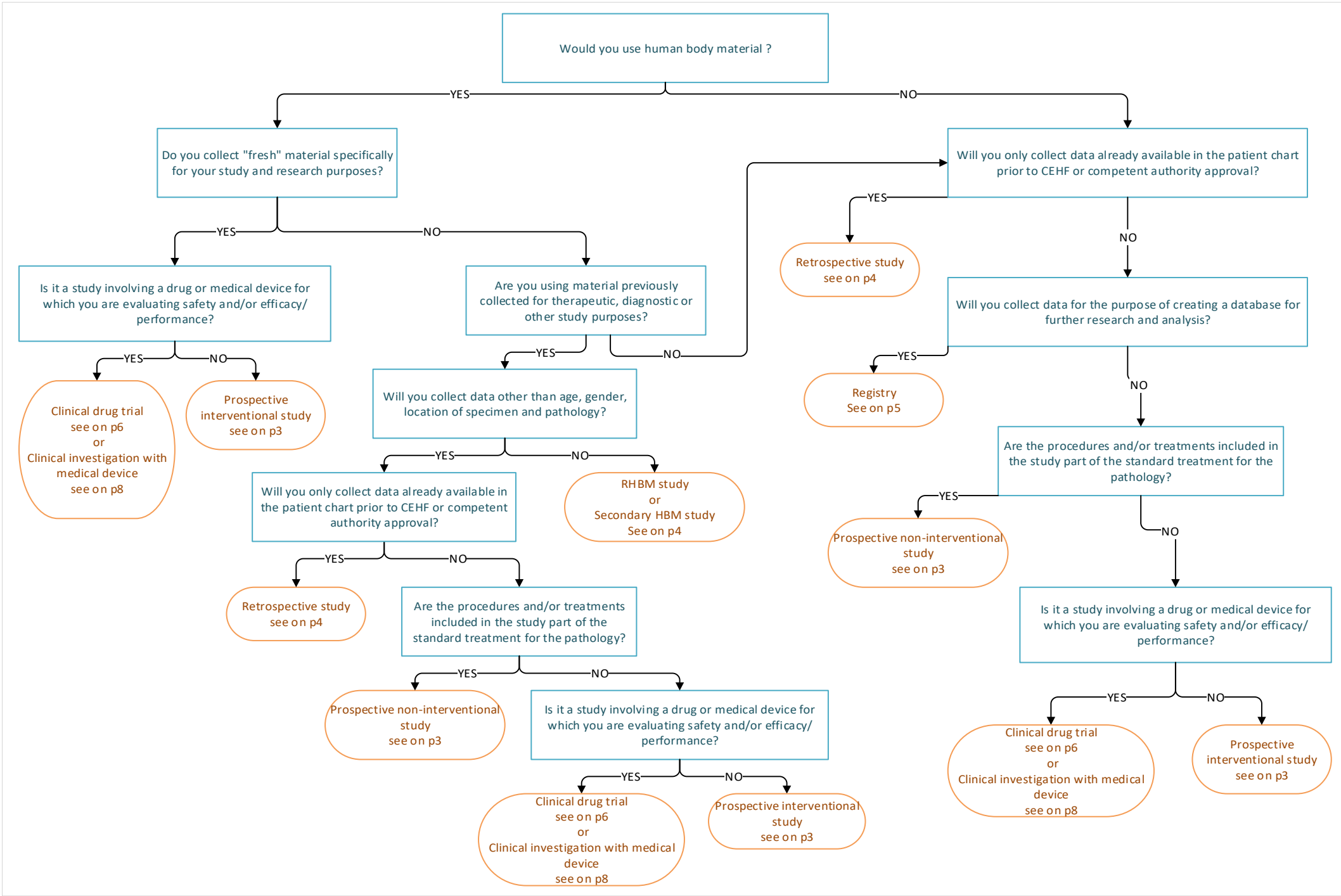
- European Regulation 2016/679 of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data
- Belgian Law of July 30, 2018 on the protection of individuals with regard to the processing of personal data
- Belgian law of 22 August 2002 on the rights of the patient
- Declaration of Helsinki
- ICH Guidelines for Good Clinical Practice E6(R2)

The regulatory assessment flowchart on page 2 allows you to identify specifically for your research project

- the corresponding type of study
- the applicable regulation
- the submission procedure to follow
- the reference document(s) of the AAHRPP quality system

Follow the flowchart according to the characteristics of your project and refer to the page indicated to consult the various useful information.

The referenced documents are accessible via the Paco - Clinical Research


Would you use human body material ?
YES
NO
Do you collect "fresh" material specifically for your study and research purposes?
YES
NO
Is it a study involving a drug or medical device for which you are evaluating safety and/or efficacy/ performance?
YES
NO
Clinical drug trial see on p6 or Clinical investigation with medical device see on p8
Prospective interventional study see on p3
Are you using material previously collected for therapeutic, diagnostic or other study purposes?
YES
NO
Will you collect data other than age, gender, location of specimen and pathology?
YES
NO
Will you only collect data already available in the patient chart prior to CEHF or competent authority approval?
YES
NO
Retrospective study see on p4
Are the procedures and/or treatments included in the study part of the standard treatment for the pathology?
YES
NO
Prospective non-interventional study see on p3
Is it a study involving a drug or medical device for which you are evaluating safety and/or efficacy/ performance?
YES
NO
Clinical drug trial see on p6 or Clinical investigation with medical device see on p8
Prospective interventional study see on p3
RHBM study or Secondary HBM study See on p4
Will you only collect data already available in the patient chart prior to CEHF or competent authority approval?
YES
NO
Retrospective study see on p4
Will you collect data for the purpose of creating a database for further research and analysis?
YES
NO
Registry See on p5
Are the procedures and/or treatments included in the study part of the standard treatment for the pathology?
YES
NO
Prospective non-interventional study see on p3
Is it a study involving a drug or medical device for which you are evaluating safety and/or efficacy/ performance?
YES
NO
Clinical drug trial see on p6 or Clinical investigation with medical device see on p8
Prospective interventional study see on p3

PROSPECTIVE INTERVENTIONAL STUDY

❖ **Applicable regulations**

Belgian law of May 7, 2004 on human experimentation

Belgian law of December 19, 2008 on the collection and use of human body material intended for human medical applications or for scientific research purposes

❖ **Submission procedure**

Submission to the ethics committee(s) of the site(s) involved in the study

For Saint-Luc / UCLouvain : CEHF - Document 1

❖ **Useful documents**

213 - AAHRPP-SOP-066 Commercial Central Desk - Initial Submission (Procedure)

053 - AAHRPP-DSQ-102 Commercial study – Submission documents (Checklist)

211 - AAHRPP-SOP-064 Academic Central Desk - Initial Submission (Procedure)

058 - AAHRPP-DSQ-111 Academic study – Submission documents (Checklist)

112 - BIOBANQUE-SOP-016 Use of human body material (Procedure)

PROSPECTIVE NON-INTERVENTIONAL STUDY (OBSERVATIONAL)

❖ **Applicable regulations**

Belgian law of May 7, 2004 on human experimentation

Belgian law of December 19, 2008 on the collection and use of human body material intended for human medical applications or for scientific research purposes

❖ **Submission procedure**

Submission to the ethics committee(s) of the site(s) involved in the study

For Saint-Luc / UCLouvain : CEHF - Document 1

❖ **Useful documents**

213 - AAHRPP-SOP-066 Commercial Central Desk - Initial Submission (Procedure)

053 - AAHRPP-DSQ-102 Commercial study – Submission documents (Checklist)

211 - AAHRPP-SOP-064 Academic Central Desk - Initial Submission (Procedure)

058 - AAHRPP-DSQ-111 Academic study – Submission documents (Checklist)

112 - BIOBANQUE-SOP-016 Use of human body material (Procedure)

RESIDUAL HUMAN BODY MATERIAL STUDY (RHBM)

OR

SECONDARY HUMAN BODY MATERIAL (HBM)

❖ **Applicable regulations**

Belgian law of December 19, 2008 on the collection and use of human body material intended for human medical applications or for scientific research purposes

❖ **Submission procedure**

Submission to the ethics committee(s) of the site(s) involved in the study

For Saint-Luc / UCLouvain : CEHF - Simplified submission form

❖ **Useful documents**

213 - AAHRPP-SOP-066 Commercial Central Desk - Initial Submission (Procedure)

053 - AAHRPP-DSQ-102 Commercial study – Submission documents (Checklist)

211 - AAHRPP-SOP-064 Academic Central Desk - Initial Submission (Procedure)

058 - AAHRPP-DSQ-111 Academic study – Submission documents (Checklist)

112 - BIOBANQUE-SOP-016 Use of human body material (Procedure)

RETROSPECTIVE STUDY

❖ **Applicable regulations**

Default regulation (see p1).
Retrospective studies are excluded from the Belgian law of 07 May 2004.

Belgian law of 19 December 2008 on the collection and use of human body material intended for human medical applications or for scientific research purposes

❖ **Submission procedure**

Submission to the ethics committee(s) of the site(s) involved in the study

For Saint-Luc / UCLouvain : CEHF - Simplified submission form

❖ **Useful documents**

213 - AAHRPP-SOP-066 Commercial Central Desk - Initial Submission (Procedure)

053 - AAHRPP-DSQ-102 Commercial study – Submission documents (Checklist)

211 - AAHRPP-SOP-064 Academic Central Desk - Initial Submission (Procedure)

058 - AAHRPP-DSQ-111 Academic study – Submission documents (Checklist)

112 - BIOBANQUE-SOP-016 Use of human body material (Procedure)

REGISTRY

❖ **Applicable regulations**

Default regulation (see p1).
Registries are excluded from the Belgian law of 07 May 2004.

❖ **Submission procedure**

Submission to the ethics committee(s) of the site(s) involved in the study

For Saint-Luc / UCLouvain : CEHF - Simplified submission form

❖ **Useful documents**

211 - AAHRPP-SOP-064 Academic Central Desk - Initial Submission (Procedure)

058 - AAHRPP-DSQ-111 Academic study – Submission documents (Checklist)

CLINICAL DRUG TRIAL

❖ **Determine that it is a clinical trial**

The table below will help you identify if your project is a clinical trial. If the answer is no, refer to the flowchart on page 2 to determine the type of study.

IS IT A CLINICAL TRIAL OF A MEDICINAL PRODUCT?

This algorithm and its endnotes will help you answer that question. Please start in column A and follow the instructions. Additional information is provided in the notes at the end of the table. If you have doubts about the answer to any of the questions, contact the MHRA clinical trials unit.

A	B	C	D	E
A CLINICAL TRIAL OF A MEDICINAL PRODUCT?				**A NON-INTERVENTIONAL CLINICAL TRIAL?**
Is it a medicinal product (IMP)?[i]	**Is it not a medicinal product?**	**What effects of the medicine are you looking for?**	**Why are you looking for those effects?**	**How are you looking for those effects?**
If you answer no to all the questions in column A, the activity is not a clinical trial on a MP. If you answer yes to any of the questions below go to column B.	If you answer yes to the question below in column B the activity is not a clinical trial on a MP. If you answer no to this question below go to column C.	If you answer no to all the questions in column C the activity is not a clinical trial under the scope of SI 1031. If you answer yes to any of the questions below go to column D.	If you answer no to all the questions in column D the activity is not a clinical trial under the scope of SI 1031. If you answer yes to any of the questions below go to column E.	If you answer yes to all these questions the activity is a non-interventional trial which is outside the scope of SI 1031. If your answers in columns A,B,C & D brought you to column E and you answer no to any of these questions the activity is a clinical trial within the scope of the Directive.
A.1 Is it a substance[ii] or combination of substances presented as having properties for treating or preventing disease in human beings? A.2 Does the substance function as a medicine? i.e. can it be administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis or is otherwise administered for a medicinal purpose? A.3 Is it an active substance in a pharmaceutical form?	B.1 Are you only administering any of the following substances? • Human whole blood[iii]; • Human blood cells; • Human plasma; • Tissues except a somatic cell therapy medicinal product[iv]; • A food product (including dietary supplements) not presented as a medicine; • A cosmetic product[vi]; • A medical device	C.1 To discover or verify/compare its clinical effects? C.2 To discover or verify/compare its pharmacological effects, e.g. pharmacodynamics? C.3 To identify or verify/compare its adverse reactions? C.4 To study or verify/compare its absorption, distribution, metabolism or excretion?	D.1 To ascertain or verify/compare the efficacy[vii] of the medicine? D.2 To ascertain or verify/compare the safety of the medicine?	E.1 Is this a study of one or more medicinal products, which have a marketing authorisation in the UK? E.2 Are the products prescribed in the usual manner in accordance with the terms of that authorisation? E.3 Does the assignment of any patient involved in the study to a particular therapeutic strategy fall within current practice and is not decided in advance by a clinical trial protocol[viii]? E.4 Is the decision to prescribe a particular medicinal product clearly separated from the decision to include the patient in the study? E.5 Will no diagnostic or monitoring procedures be applied to the patients included in the study, other than those which are applied in the course of current practice? E.6 Will epidemiological methods be used for the analysis of the data arising from the study?

❖ **Applicable regulations**

Until 31/01/2025: European Directive 2001/20/EC and Belgian Law of 7 May 2004.

Since 31/01/2022: European Regulation 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use, also known as CTR for Clinical Trial Regulation and Belgian Law of 07 May 2017 on clinical trials on medicinal products for human use.

Belgian law of 19 December 2008 on the collection and use of human body material intended for human medical applications or for scientific research purposes

❖ **Submission procedure**

Since 31/01/2022: Submission according to Regulation 536/2014: Submission to the FAMHP and the competent authorities of the other participating countries via the CTIS portal. No joint submission to the ethics committee(s) of the centers involved in the trial.

Until 31/01/2023: The sponsor can still choose a submission according to Directive 2001/20/EC as long as the trial is closed before 31/01/2025. In this case: submission to the ethics committee(s) of the site(s) involved in the study (for Saint-Luc / UCLouvain: CEHF - Document 1) and joint submission to the FAMHP and to the competent authorities of the other participating countries via the CESP portal

❖ **Useful documents**

213 - AAHRPP-SOP-066 Commercial Central Desk - Initial Submission (Procedure)

053 - AAHRPP-DSQ-102 Commercial study – Submission documents (Checklist)

211 - AAHRPP-SOP-064 Academic Central Desk - Initial Submission (Procedure)

058 - AAHRPP-DSQ-111 Academic study – Submission documents (Checklist)

112 - BIOBANQUE-SOP-016 Use of human body material (Procedure)

038 - AAHRPP-SOP-007 Clinical drug Trial - Initial Submission CTR (Procedure)

243 - AAHRPP-DSQ-009 Clinical drug trial – Submission documents (Checklist)

CLINICAL INVESTIGATION WITH A MEDICAL DEVICE

❖ Determine if the study is a clinical investigation with a medical device

The table below will help you identify if your project is a clinical investigation. If the answer is no, refer to the flowchart on page 2 to determine the type of study.

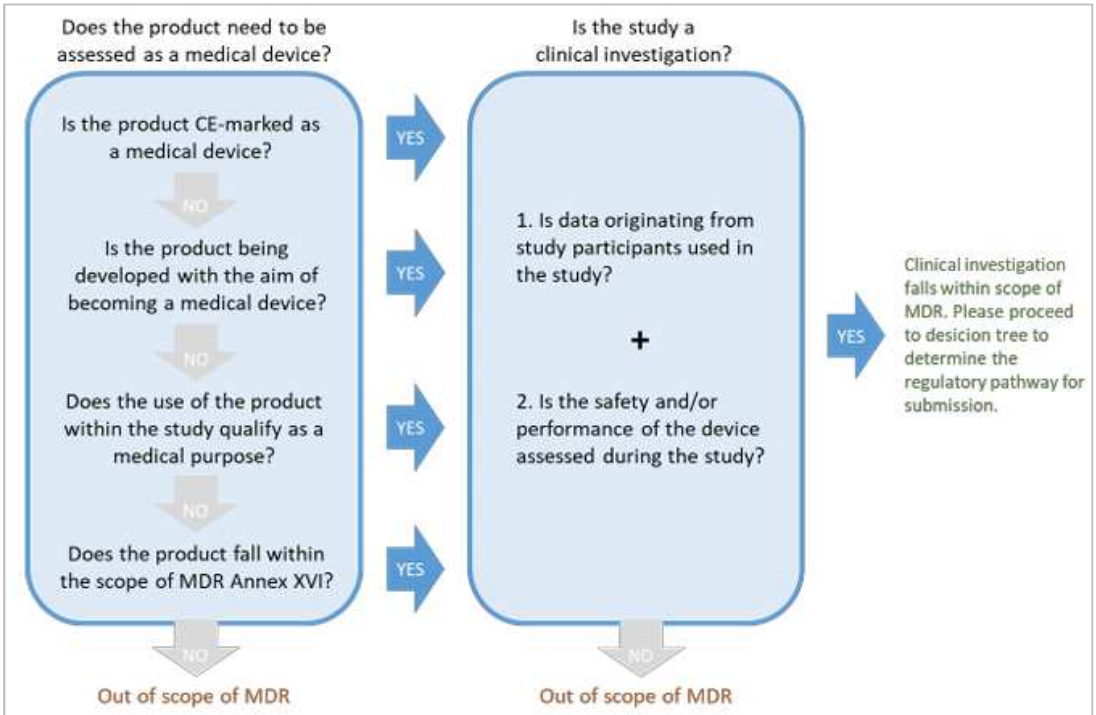


Figure 1. Does the study fall within scope of MDR?

❖ Applicable regulations

European Regulation 2017/745 of 5 April 2017 on medical devices, also known as MDR for Medical Device Regulation

Belgian law of 22 December 2020 on medical devices

Royal Decree of 18 May 2021 on clinical investigations of medical devices

The good clinical practices of the international standard ISO 14155:2020 (07-2020)

Belgian law of 19 December 2008 on the collection and use of human body material intended for human medical applications or for scientific research purposes

❖ Useful documents

213 - AAHRPP-SOP-066 Commercial Central Desk - Initial Submission (Procedure)

053 - AAHRPP-DSQ-102 Commercial study – Submission documents (Checklist)

211 - AAHRPP-SOP-064 Academic Central Desk - Initial Submission (Procedure)

058 - AAHRPP-DSQ-111 Academic study – Submission documents (Checklist)

112 - BIOBANQUE-SOP-016 Use of human body material (Procedure)

039 - AAHRPP-SOP-008 Medical Device - Initial Submission MDR (Procedure)

217 - AAHRPP-DSQ-008 Clinical investigation with a medical device – Submission documents (Checklist)

❖ **Submission procedure**

The diagram below allows you to determine the type of submission to be made according to the type of device used in the clinical investigation