"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"

1 PROCEDURE'S OBJECT

The procedure describes the regulatory steps for a clinical investigation of a medical device sponsored by Cliniques Universitaires Saint-Luc (CUSL), from the preparation of the project to the notification of its completion.
This procedure also describes the responsibilities and rules to be followed in terms of safety reporting.

A medical device is defined as any instrument, equipment, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, in humans for one or more of the following specific medical purposes:

- diagnosis, prevention, control, prediction, prognosis, treatment or mitigation of a disease,
- diagnosis, control, treatment, mitigation or compensation of an injury or disability,
- investigation, replacement or modification of an anatomical structure or function or a physiological or pathological process or condition
- communication of information by means of in vitro examination of samples from the human body, including organ, blood and tissue donations

and whose principal intended action in or on the human body is not obtained by pharmacological or immunological means or by metabolism, but whose function can be assisted by such means.
The following are also deemed to be medical devices

- devices intended to control or assist conception
- products specifically intended for the cleaning, disinfection or sterilization of medical devices
- accessories for medical devices
- products with no medical purpose :
    - Contact lenses or other items intended to be inserted into or onto the eye.
    - Products intended to be introduced totally or partially into the human body by invasive surgical means for the purpose of altering the anatomy or fixing parts of the body, except for tattoo products and piercings.
    - Substances, combinations of substances or articles intended for use in filling the face or other parts of the dermis or mucous membranes by subcutaneous, submucosal or intradermal injection or other introduction, except those intended for tattooing.
    - Equipment intended to be used to reduce, remove or destroy fatty tissue, such as equipment for liposuction, lipolysis or lipoplasty.
    - Equipment emitting high intensity electromagnetic radiation (e.g., infrared, visible light, and ultraviolet) intended for use on the human body, including coherent and non-coherent, monochromatic, and broad spectrum sources, such

as lasers and intense pulsed light equipment, for skin resurfacing, tattooing, or hair removal, or any other skin treatment
    - Equipment for brain stimulation that applies electric currents or magnetic or electromagnetic fields that penetrate the skull to alter neural activity in the brain.
- a device in the development phase, such as a prototype, tested on subjects to validate parts of the device. Even if the prototype does not yet fulfill the intended medical purpose, the product can be considered a medical device because that is the potential purpose.

Remark:
Products developed solely to demonstrate a working principle for academic purposes, without the objective of turning the product into a medical device do not qualify as a medical device." If the intended device does not meet this definition, it is not subject to this procedure and therefore should not be submitted to the FAMHP. However, any clinical investigation involving it must be submitted to the CEHF according to the Belgian law of 2004.

There are different types of medical devices that determine the type of submission to be made:

- **device with CE marking or CE label**: a marking by which a manufacturer indicates that a device complies with the applicable requirements defined in the regulation and other applicable EU harmonization legislation providing for its affixing.
- **custom-made device**: any device specifically manufactured according to the written prescription of a duly qualified practitioner indicating, under the latter's responsibility, the specific design characteristics and intended to be used only for a specific patient and exclusively in response to the needs and health condition of that patient.
- **'in-house' device**: a medical device manufactured or modified in-house by healthcare institutions to meet, on a non-industrial scale, the specific needs of target patient groups that cannot be met at the appropriate level of performance by an equivalent device available on the market
- **PMCF**: Post-market clinical follow-up investigation: a post-market clinical investigation, initiated by the manufacturer (sponsor), conducted to further evaluate a CE-marked medical device in the context of its intended use, in order to proactively collect clinical data that would confirm safety and/or performance.

2 PROCEDURE'S SCOPE

Cliniques Universitaires Saint-Luc member of the health professions staff acting as the non-commercial sponsor of the clinical investigation on behalf of CUSL, referred to as "the sponsor".

Cliniques Universitaires Saint-Luc physician acting as the principal investigator of the clinical drug trial, referred to as "the Investigator".

Cliniques Universitaires Saint-Luc's academic central office providing administrative support for initial submissions.

3 RESPONSIBILITIES AND AUTHORITIES

3.1 Authorities

Federal Agency for Medicines and Health Products (FAMHP).
Hospital-Faculty Ethics Committee (CEHF) and/or independent (CE).

3.2 Responsibilities of the SPONSOR

The responsibilities of the sponsor include :

- writing the clinical investigation protocol and participant information and consent documents
- assessing and describing the financial impact of the investigation on institutional resources
- preparation of the initial submission file and any substantial amendments
- the initial submission of the clinical investigation and the submission of substantial amendments
- conducting the clinical investigation in accordance with the approved clinical investigation protocol
- informing investigators of the procedures for reporting adverse events. These are also described in the protocol
- recording and reporting of adverse events and device defects to the investigative sites
- continuous evaluation of the benefit/risk ratio of the investigation, taking into account all the characteristics of the clinical investigation
- follow-up of SAEs collected at the center level, as well as their closure
- informing the investigators of any new element that could affect the safety of participants during or after the end of the study
- the procedure for emergency situations that allows the immediate identification and, if necessary, the immediate recall of devices used in the investigation
- control of clinical investigation data submitted by investigators
- transmission of a summary of the results of the clinical investigation that is easily understood by the user for whom the device is intended at the same time as the final report on the clinical investigation.

If the sponsor of a clinical investigation is Cliniques Universitaires Saint-Luc, the physician in charge (principal investigator) is the person responsible for the study. He manages the clinical investigation for the institution of which he is an employee.

In this case, the initial submission of the clinical investigation will be made through the CUSL's Academic Central Office.

The submission of substantial amendments remains the responsibility of the sponsor.

3.3 Responsibilities of the INVESTIGATOR

The Investigator's responsibilities include:

- conducting the clinical investigation in accordance with the approved clinical investigation protocol
- informing participants and obtaining their consent
- collecting, processing, recording, managing, and transmitting to the sponsor data related to the clinical investigation, while respecting the confidentiality of the information and personal data of the participants
- the possibility for the sponsor and/or the competent authorities to control the data related to the clinical investigation
- reporting of adverse events to the sponsor
- reporting of certain minor adverse events and/or abnormal test results to the sponsor
- informing participants of any new safety issues that arise during or after the completion of the clinical investigation

4 PROCEDURE'S REVISION

Version 5.0 : European Regulation (EU) 2017/745 on medical devices (MDR) applicable as of May 26, 2021 and application of the law of December 22, 2020 on medical devices.
Version 6.0: Guidelines FAMHP version 5.0

5 PROCEDURE'S DESCRIPTION

For any new clinical investigation with a medical device with CUSL sponsor, the physician in charge of the study must complete the document AAHRPP-FORM-006 IMP-DEVICE CUSL AVIS DIR MED, which will be submitted to the medical director for validation in order to assess the physician's ability to assume the regulatory and logistical responsibility of his or her project as a sponsor

5.1 Submission

Submissions to the FAMHP are made via the CESP portal pending the implementation of the Eudamed portal.
To obtain CESP access:

- Take the CESP training on PODiCampus
- When you have obtained the training certificate, contact the Academic Office guichetacademique-saintluc@uclouvain.be to obtain the CESP accesses

At the time of the initial submission, a unique EudraCT number (pending the availability of Eudamed) will be assigned to the file by the FAMHP and will be used for all subsequent communication regarding the clinical investigation.

The procedure for submission to the FAMHP is the same whether the clinical investigation is monocentric or multicentric.
In the case of a multicenter clinical trial where submission to the local ethics committee is required, a lead ethics committee must be designated and the submission must be made to all local ethics committees at the same time (application of the law of 7 May 2004).

In the case of a multinational clinical investigation, the sponsor submits an application for authorization via an electronic system to all the Member States in which the clinical investigation is to be conducted. The investigation identification number issued by the submission portal is a unique number valid throughout the European Union.

The initial submission steps described in this procedure are carried out in addition to the submission procedure via the academic office for contract and financial aspects.

The study can start upon receipt of a positive opinion from the competent authorities, the designated ethics committee(s) as well as the agreement of the CTC for the contracts and/or internal agreements.

For non-commercial clinical investigations, no submission fee will be due.

Substantial modifications (amendments) must be notified according to the type of device, following the same type of submission as for the initial submission. The substantial submission steps are described below, for each submission type.

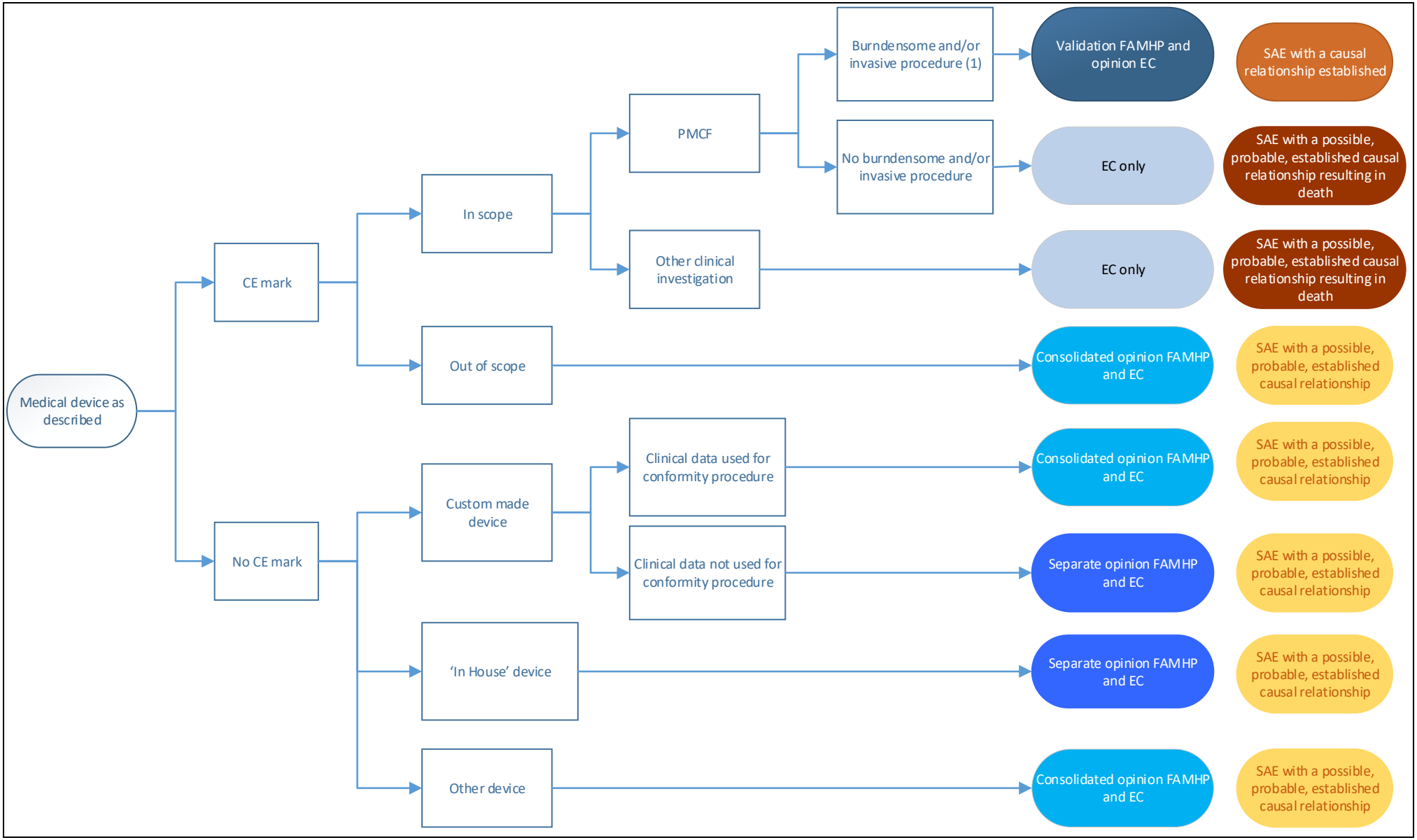
Non-substantial changes must be notified either at the next substantial change submission or as a substantial submission if no substantial change has occurred or is expected within one

year. Non-substantial amendments that have not been notified at the end of the clinical investigation should be notified at the same time as the notification of the end of the investigation (cover letter and amended documents in a clean version and with the identified changes).

The diagram below will allow you to determine the type of submission to be made according to the type of device used in the clinical investigation.
Click on the defined submission type to see the steps.
This diagram also indicates the type of EAS to be reported according to the type of investigation. Refer to the "Safety Monitoring" chapter for details.

The checklist of documents to be included in the submission files is document AAHRPP-DSQ-008.

5.1.1 Regulatory pathways and safety reporting for a clinical investigation with a medical device



(1) Burndensome and/or invasive procedure: a procedure that may cause pain, discomfort, fear, disruption of personal life and activities, or other unpleasant experiences. See non-exhaustive list in Appendix 1 at the end of this document

5.1.1.1 Regulatory pathway : Validation FAMHP and opinion EC

➔ PMCF investigations involving additional burdensome or invasive procedures

Initial submission

- The complete file must be submitted to the FAMHP via CESP at least 30 days before the start of the clinical investigation.
- The FAMHP validates the file and notifies the sponsor within 5 days of receipt.
- If complete, the file is sent to an independent EC (accredited following the law of 07/05/2017) by the CT-College.
- The EC evaluates the file and the final single opinion is communicated within 30 calendar days following the date of receipt.
- The procedure does not allow for questions concerning the validation. If important documents are missing (e.g. the PMCF plan), the clinical investigation is automatically refused.
- In the case of a multicenter investigation, the EC designated by the CT-College gives an opinion for all participating centers. The submission is unique for all sites involved.

Substantial modifications submission

- The complete file must be submitted to the FAMHP via CESP.
- The FAMHP validates the file and notifies the sponsor within 5 days of receipt.
- The final opinion is communicated within 38 calendar days from the date of receipt.

The procedure does not allow for validation questions. If important documents are missing, the amendment is denied.

5.1.1.2 Regulatory pathway : EC only

➔ PMCF investigations without additional burdensome or invasive procedures.
➔ Other clinical investigations involving CE-marked devices used within their intended purpose

Initial submission

The file must only be submitted directly to the CEHF according to the submission procedure AAHRPP-SOP-104.
The CEHF evaluates the dossier and the final opinion is communicated:

- within 28 calendar days following the date of receipt for PMCF investigations without a binding and/or invasive procedure (law 07 May 2004)
- within 45 calendar days following the date of receipt for medical devices with CE label, SOC use not PMCF (R.D. 18 May 2021)

For multicenter studies, a lead ethics committee must be designated and submission must be made to all local ethics committees at the same time (Act of 07 May 2004).

Substantial modifications submission

The file must be submitted directly to the CEHF.
The CEHF evaluates the file and the final opinion is communicated within 28 calendar days following the date of receipt.

5.1.1.3 Regulatory pathway : consolidated opinion FAMHP and EC

- ➔ Clinical investigations involving CE-marked devices used outside their intended purpose
- ➔ Clinical investigations involving devices without a CE mark which are not 'in-house' devices.
- ➔ Clinical investigations involving custom made devices for which data will be used for conformity assessment.

Initial submission

- The complete file must be submitted to the FAMHP via CESP.
- The FAMHP validates the file and notifies the sponsor within 10 days of receipt of the application.
- If complete, a letter of acknowledgement of receipt (AoR) is sent, notifying the official T0 and including the specific timetable of the procedure.
- If incomplete, validation questions are asked.
- At T28 at the latest, the evaluation reports from the EC and the FAMHP are consolidated and any requests for information (RFI) are sent to the sponsor. In this case, a pause time of maximum 20 days is installed. The calculation of the legal time limit is restarted when the FAMHP receives the response from the promoter by email to ct.rd@fagg-afmps.be or by CESP. Only one set of questions is allowed.
- The FAMHP and the EC issue a joint decision at the latest by T45, an official letter of approval or refusal is sent to the sponsor.
- The FAMHP can extend the legal deadline of 45 days (from T0) by a further 20 days in order to consult experts. If this is the case, the sponsor is informed of this extension by the FAMHP. Consequently, the RFIs will be communicated at the latest at T48 and the single consolidated decision will be notified at the latest at T65.

In the case of a multicentre investigation, the EC designated by the CT-College gives an opinion for all participating centers. The submission is unique for all sites involved.

Substantial modifications submission

- The complete file must be submitted to the FAMHP via CESP.
- The date of receipt is considered as T0.
- The FAMHP validates the file and notifies the promoter within 3 days of receipt of the application.
- If incomplete, validation questions are asked for which a pause is installed.
- By T24 at the latest, the FAMHP and EC assessment reports are consolidated and any requests for information (RFI) are sent to the sponsor. In this case, a pause of maximum 20 days is installed. Only one set of RFIs is allowed. The calculation of the legal time limit is restarted when the FAMHP receives the response from the promoter by email ct.rd@fagg-afmps.be or by CESP.
- The FAMHP and the EC issue a joint decision by T38, an official letter of approval or refusal is sent to the sponsor.
- The FAMHP can extend the legal deadline of 38 days by 7 additional days in order to consult experts. If this is the case, the sponsor is informed of this extension of time by the FAMHP. Therefore, the RFI will be communicated by T28 at the latest and the authorization will be notified by T45 at the latest.

5.1.1.4 Regulatory pathway : Separate opinion FAMHP and EC

➔ Clinical investigations involving 'in-house' devices or custom made devices for which data will not be used for conformity assessment.

Initial submission

- Two submissions are required:
    - to CEHF via submission procedure AAHRPP-SOP-104
    - to the FAMHP via CESP

The 2 submissions can be made at different times and in the order desired by the sponsor.

- The CEHF notifies its opinion within the usual timeframe (28 calendar days following the date of receipt).

- The FAMHP validates the file and notifies the sponsor within 10 days of receipt of the application.
- After 30 days, if the dossier is complete, a letter of acknowledgement of receipt (AoR) is sent, notifying the official T0 (so T0 = 40 days after submission). This 30 day period of analysis of the dossier allows the promoter to send the final agreement of the EC to the FAMHP.
- If incomplete, validation questions are asked.
- At T30 at the latest, the requests for information (RFI), if any, are sent to the sponsor. In this case, a pause time of maximum 20 days is installed. The calculation of the legal time limit is restarted when the FAMHP receives the response from the sponsor by email at ct.rd@fagg-afmps.be or CESP. Only one round of RFI is allowed.
- The FAMHP makes its decision at the latest at T60.
- Note that the FAMHP must obtain final approval from the EC (separate parallel submission) before giving final approval. We therefore ask the sponsor to provide the EC approval to the Academic office as soon as possible.

Substantial modifications submission

- Two submissions are required:
    - to CEHF via submission procedure CEHF-SOP-109
    - to the FAMHP via CESP

The 2 submissions can be made at different times and in the order desired by the sponsor.

- The CEHF notifies its opinion within the usual deadlines (28 calendar days following the date of receipt).

- The date of receipt of the application by the FAMHP is considered as T0.
- The FAMHP validates the file and notifies the sponsor within 3 days of receipt of the application.
- If incomplete, validation questions are asked for which a pause is installed.
- At the latest on T24, the requests for information (RFI), if any, are sent to the sponsor. In this case, a pause time of maximum 20 days is installed. The calculation of the legal time limit is restarted when the FAMHP receives the response from the sponsor by email at ct.rd@fagg-afmps.be or CESP. Only one RFI cycle is allowed.
- The FAMHP makes a final decision by T38.
- Note that the FAMHP must obtain final approval from the EC (separate parallel submission) before giving final approval. The sponsor must therefore provide the EC approval by email to FAMHP ct.rd@fagg-afmps.be as soon as possible.

5.2 Safety reporting

In the case of a multinational clinical investigation, serious adverse events should be reported at the same time to all competent national authorities where the clinical investigation is taking place.

In the case of a medical device (with CE label and out of scope use or without CE label) used in a clinical drug trial, safety monitoring should be conducted in accordance with the guidelines in this document as well as those in the legislation applicable to clinical drug trials (eudravigilance). The guidelines in this document are not applicable if the purpose of the trial is not to evaluate the safety or performance of the device, as long as the device has a CE mark and is used as intended (In scope). However, the vigilance report must follow the rules of material vigilance. In this case, contact the person in charge of material vigilance at the institution.

In the case of an investigation with a comparison group, SAEs occurring in subjects in the investigation's comparison group must also be reported according to the procedures for reporting SAEs in clinical investigations as described here.

The relationship between the use of the medical device (investigational device and comparator), including the medical and surgical procedure, and the occurrence of each adverse event should be assessed and categorized. For the purposes of harmonized reporting, each event should be categorized into four different levels of causality:
- unrelated
- possibly related
- probable relationship
- causal relationship

All causality assessments should be performed in accordance with Section 9 of the MDCG 2020-10.

5.2.1 Declarations to the FAMHP

5.2.1.1 Types of events to be declared by the sponsor

The following events must be reported by the sponsor to the FAMHP (and to all the Member States in which the clinical investigation takes place):

(a) any serious adverse event (SAE) with a causal relationship to the investigational device, comparator or investigative procedure or where such a causal relationship is reasonably possible ;
(b) any device deficiency that could have resulted in a serious adverse event if appropriate action had not been taken, if an intervention had not occurred, or if the circumstances had been less favorable;
(c) any new finding related to an event described in (a) and (b).

5.2.1.2 Event Reports by Clinical Investigation Type

Note: For all types of devices, SAEs classified as not related to the use of the medical device should never be reported to the FAMHP.

a) PMCF investigations involving additional burdensome or invasive procedures
In the case of devices with a CE label and therefore already marketed, the declaration of SAEs must be made in accordance with the material vigilance rules (contact the person responsible for material vigilance at the institution).

However, only SAEs with an established causal link to the device should be reported to the FAMHP according to the guidelines described in this document.

b) PMCF investigations without additional burdensome or invasive procedures
In the case of devices with a CE label and therefore already on the market, the SAE declaration must be made in accordance with the rules of material vigilance (contact the person responsible for material vigilance at the institution).

No declaration to the FAMHP as the submission is only made to the local EC.

Any serious adverse event resulting in the death of the patient should be reported to the Ethics Committee.

c) Other clinical investigations involving CE-marked devices used within their intended purpose
In the case of devices with a CE label and therefore already marketed, the declaration of SAEs must be made in accordance with the rules of material vigilance (contact the person in charge of material vigilance at the institution).

No declaration to the FAMHP as the submission is only made to the local EC.

Any serious adverse event resulting in the death of the patient should be reported to the Ethics Committee.

d) Clinical investigations involving CE-marked devices used outside their intended purpose
SAEs related, probably related, or possibly related to the use of the medical device should be reported.

e) For the following non-CE-labeled devices:
- Clinical investigations involving devices without a CE mark which are not 'in-house' devices.
- Clinical investigations involving custom made devices for which data will be used for conformity assessment
- Clinical investigations involving 'in-house' devices or custom made devices for which data will not be used for conformity assessment

SAEs related, probably related, or possibly related to the use of the medical device should be reported.

5.2.1.3 Deadlines for reporting events

- Immediately and no later than 2 calendar days after the sponsor becomes aware of a new reportable event or new information in relation to a previously reported event, for all reportable events that indicate an imminent risk of death, serious injury, or serious illness and that require prompt corrective action for other patients/subjects, users, or others or a new finding in this regard

- Immediately and no later than 7 calendar days after the sponsor becomes aware of a new reportable event or new information related to a previously reported event, for any other reportable event or new discovery/update

5.2.1.4 How to report events

SAEs are reported via the Clinical Investigation Summary Safety Report Form and sent to the FAMHP R&D division:

- Either by e-mail to ct.rd@fagg-afmps.be with the following in the subject line: "SAE Notification - EudraCT/Eudamed Number" (use the number indicated on the approval letter).
- Or through the CESP, as desired.

Instructions on how to complete the form can be found in Section 10 of the MDCG 2020-10 guide.

Once Eudamed is available and accessible, SAE must be reported via the online form on Eudamed. Follow-up of SAE already reported via the Clinical Investigation Summary Safety Report Form prior to the use of Eudamed will continue to be done via the form until the SAE follow-up is complete.

5.2.2 Reporting to Independent ECs

SAE do not have to be reported to independent ECs unless they request it. The FAMHP will decide if it will forward certain SAE to the EC.

5.3 Termination of clinical investigations, temporary discontinuation or early termination

The following guidelines apply to all types of clinical investigations with medical devices contemplated by this procedure.

5.3.1 Termination of the clinical investigation

- The sponsor notifies the FAMHP within 15 days of the end of the clinical investigation in Belgium.
- Sending an official signed letter by e-mail to ct.rd@fagg-afmps.be with the following mention in the subject line: "Notification of end of clinical investigation - EudraCT/Eudamed number" (use the number provided on the approval letter).
- For multinational studies, the sponsor must notify the FAMHP of the end of the clinical investigation in Belgium and each Member State of the end of the clinical investigation in that country. A second notification must be made to the FAMHP and to all member states when the clinical investigation ends in all member states. Both notifications should be made within 15 days of the end of the clinical investigation.

5.3.2 Temporary or early termination

- The sponsor notifies the FAMHP within 15 days of the temporary or early termination, providing a justification of the event.
- In the case of a temporary stop or early termination for safety reasons, the FAMHP must be notified within 24 hours of the event.
- Notifications should be sent to the FAMHP by e-mail to ct.rd@fagg-afmps.be with the following mention in the subject line: "Temporary stop/early termination - Clinical investigation EudraCT/Eudamed number" (use the number indicated on the approval letter).

5.3.3 Clinical Investigation Report

Within one year after the end of the clinical investigation, the complete final report must be submitted to the FAMHP by e-mail to ct.rd@fagg-afmps.be with the following mention in the subject line: "Clinical investigation report - EudraCT/Eudamed number" (use the number indicated on the approval letter).

In case of temporary discontinuation or early termination, this report must be provided within 3 months.

In accordance with European Regulation 2017/745, the final report must also be made available to the public. In the absence of Eudamed, this public version of the final report may be published on the sponsor's website. The location of this published final report must also be notified to the FAMHP.
Send this report in WORD format to guichetacademique-saintluc@uclouvain.be to be posted on the CUSL website.

For multinational studies, reports should be provided to each member state involved according to the same schedule.
If no patients participated in the investigation, this should be notified to the FAMHP.

6 APPENDIX 1

Classification for additional burdensome or invasive procedures for Belgium

The 2 lists below establish whether an additional procedure should be considered burdensome or invasive. They are both valid until 01/06/2022.

Additional procedures considered burdensome or invasive

- functional testing session with a risk of falling
- (laser) ophtalmoscopy
- magnetic resonance imaging
- any application of radiation (including DEXA examination, x-ray imaging, CT scan, endoradiology examinations such as scintigraphy, …)
- any biopsy (in the case of clinically indicated tissue)
- lumbar puncture, bone marrow aspiration
- invasive cardiac procedure (catheterization, stent, angioplasty)
- ultrasound imaging if contrast agent must be administered
- sedation, anxiolysis
- provocation tests: e.g., lung function examination, stress ECG, stress echo, sleep deprivation

Additional procedures NOT considered burdensome or invasive

- patient surveys, compilation of parameters for the assessment of quality of life, such as pain assessment, dietary assessment, etc.
- semi-automatic or automatic data collection by apps
- (self-)blood pressure monitoring
- cardiac Holter monitoring; EEG and ECG measurements
- ultrasound imaging if no contrast agent must be administered
- thermography
- polysomnography
- blood test
- endoscopy/endoscopic ultrasound (bronchoscopy, gastroscopy, …)
- consultation for clinical-physical examination
- examinations regarding cognitive faculty
- non-invasive collection of other material to be examined (saliva, hair)
- use of surplus examination materials gathered during a diagnostic/therapeutic routine check-up
- hearing and eye tests (ophthalmoscopy, tympanometry)
- venous or capillary blood sampling by finger or heel prick
- collection of urine and/or stool samples (e.g. by means of urine bags)
- oral glucose tolerance test
- bio-impedance analysis
- lung function tests, spirometry

Note: if the additional procedures designed by the sponsor are not listed yet, the sponsor may contact the FAMHP at ct.rd@fagg-afmps.be.

7 DEFINITIONS AND ABBREVIATIONS

8 REFERENCE DOCUMENTS

AAHRPP-SOP-061
AAHRPP-SOP-104
AAHRPP-DSQ-008
AAHRPP-DSQ-048
AAHRPP-FORM-006
CEHF-SOP-109

Belgian law of 07 May 2004
Belgian law of 22 December 2020
European regulation 2017/745
Royal decree of 25 May 2021

Web site FAMHP/AFMPS

9 AAHRPP ACCREDITATION STANDARDS

AAHRPP\DOMAIN 1\Standard I-7\Element I.7.A

AAHRPP\DOMAIN 1\Standard I-8\Element I.8.A