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|  | **FORM – COVER LETTER FOR INITIAL SUBMISSION TO REGULATORY AUTHORITIES – CLINICAL INVESTIGATION WITH MEDICAL DEVICE**  |
| N° : AAHRPP-FORM-001 / REV  001 | N° ENGLISH VERSION : 227 |

**Agence Fédérale des Médicaments et des Produits de Santé (AFMPS)**

**Division Recherche et Développement – Unité de dispositif médical**

**Avenue Galilée 5/03**

**B-1210 Bruxelles**

**Subject: NON-COMMERCIAL CLINICAL INVESTIGATION WITH MEDICAL DEVICE – INITIAL APPLICATION**

**EudraCT / EUDAMED Number :**

**Protocol Number :**

**Title of Protocol :**

**Sponsor :**

Dear Sir/Madam,

Please find enclosed a Clinical Investigation Application for medical device ……. in patients with……..

**The primary objective** of this study is to evaluate …….

**The secondary objectives** of this study are to …….

**The Clinical investigation** is (*brief description of the investigation* - *Attention should be drawn to any particularities of the investigation if applicable, for example specific features of the investigation population, first-in-human investigation, unusual investigation design or particular investigational device features*).

This clinical investigation has connection with (*disclose any connections to ongoing or previous clinical investigation applications and/or clinical trial applications if applicable*).

**The investigation will be conducted** in …. center(s) in Belgium and in …… center(s) in Europe.

A total of ….. patients will be included (…. in Belgium *if other countries involved*).

**The Investigational Medical Device** (IMD) in this clinical investigation is (*brief description of the device*).

The IMD is : (*choose applicable proposition*)

* used within a PMCF investigation involving additional burdensome or invasive procedures
* CE-marked used outside its intended purpose
* without a CE mark and not ‘in-house’ devices
* without a CE mark and custom made for which data will be used for conformity assessment
* without a CE mark and ‘in-house’ or custom made for which data will not be used for conformity assessment

**The Belgian regulatory pathway[[1]](#footnote-1) applicable for this investigation is :** (*choose applicable proposition*)

* Validation FAMHP and opinion EC
* Consolidated opinion FAMHP and EC
* Separate opinion FAMHP and EC

(*In case of separate opinion FAMHP and EC only*)

The protocol is being submitted simultaneously to the **Ethics Committee** « Comité d’Ethique Hospitalo-Facultaire St-Luc-UCL ». You will be provided with their opinion.

All documents of the submission package are enclosed electronically on CESP ; a list of the submitted documents is included to this package.

*In case of a resubmission the applicant should highlight the changes as compared to the previous submission in each document.*

*When an approval is issued the list of approved documents will be attached to the approval letter. It is thus important that the applicant keeps this list of documents up to date, it must be resubmitted it at each change (validation questions, response to RFI, etc.) with a clear indication of which documents have been updated/added.*

I trust this application is satisfactory but please do not hesitate to contact me if you have any queries.

Yours faithfully,

Prof/Dr

Unit/Department

Cliniques universitaires Saint-Luc

Date

Signature

1. Voir AAHRPP-SOP-008 – Procédure de soumission investigation clinique non commerciale avec dispositif médical [↑](#footnote-ref-1)