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|  | **FORM - SUBMISSION LETTER FOR A CLINICAL DRUG TRIAL TO THE FAHMP** |
| N°: AAHRPP-FORM-073 / REV 002 | N° ENGLISH VERSION : 199 |

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

**Division Recherche et Développement**

**Bâtiment EUROSTATION, 8ème étage**

**Place Victor Horta, 40/40**

**B-1060 Bruxelles**

**Subject : CLINICAL TRIAL APPLICATION**

**EudraCT Number :**

**Protocol Number :**

**Title of Protocol :**

**Study phase :**

**Sponsor :**

**NON-COMMERCIAL TRIAL**

Dear Sir/Madam,

Please find enclosed a Clinical Trial Application (CTA) for study drug ……. in patients with……..

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

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

**The Investigational Medicinal Product (IMP)** in this clinical trial is (type + action- specify if narcotic or psychotropic)….

**Mode of action of the IMP :**

The IMP is a radiopharmaceutical product and the approval from the FANC is provided in this submission.

The IMP has a marketing authorisation (MA holder in the EU : …….) and is used in the trial within the conditions of the SmPC.

**OR**

The IMP has a marketing authorisation (MA holder in the EU : …….) and is used in the trial outside the conditions of the SmPC. The use of the IMP in this setting is justified by following pre-clinical and/or clinical data described in this application.

**OR**

The IMP has a marketing authorisation (MA holder : …….) and is used in the trial after modification (e.g.blinding).Qualitative and quantitative data are provided with this application for the IMP and for the placebo.

The SmPC (Summary of Product Characteristics) is included with this submission.

The IMP will be provided (and labelled) by ……. and labelled locally by each hospital pharmacy.

The IMP will be labelled in French/Dutch/German (language derogation requested if administered on site).

**The study will be conducted** in …. centers in Belgium and globally in …… centers in Europe.

A total of ….. patients will be included and among them …. in Belgium.

The IMP is tested on the following vulnerable population : (minors, not able to give informed consent…)

Under the Clinical Trial Directive 2001/20/EC, the sponsor has a responsibility to report Suspected Unexpected Serious Adverse Reactions (SUSARs) to Ethics Committees, as well as to the Regulatory Authorities. Therefore, all SUSARs occurring in the trial with the trial medication will be reported.

The reference safety information for assessing whether an adverse reaction is a SUSAR is specified in study protocol page ….. paragraph …. .

If the IMP is registered : The reference safety information of the IMP are reported in the SmPC (document.pdf)

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 study documents including the XML file of the application form are enclosed electronically on CD-ROM ; a list of the submitted documents is attached to this letter.

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

**List of submitted documents :**

|  |  |  |
| --- | --- | --- |
|  | **File name** | **Type of Version** |
| **PART 1 : GENERAL** |  |  |
| Covering letter | Eudract number-Covering-Letter.pdf | Paper and electronic |
| EU Application form | Eudract number-Application- Form.pdf  Eudract number-Application- Form-Signature.pdf  Eudract number-Application-Form.xml | Pdf : electronic (signed by the applicant : one complete form and the signature page in a separate document)  .xml : electronic |
| List of Competent Authorities within the Community to which the application has been submitted (and details of the decisions) | Eudract number-Competent-Authorities.pdf | Electronic |
| **PART 2 : PROTOCOL RELATED** |  |  |
| Protocol | Eudract number-Protocol.pdf | Electronic (signed and dated by the sponsor and the principal investigator) |
| Protocol summary | Eudract number-Protocol summary.pdf | Electronic (English or French) |
| Ethics committee approval |  | Will be forwarded |
| **PART 3 : IMP RELATED** |  |  |
| SmPC (or investigator brochure updated each year) | Eudract number-SmPC.pdf | Electronic |
| Label content in French/Dutch/German (language derogation if administered on site)   * name, address and telephone number of the sponsor/investigator (if not provided in a separate leaflet) * pharmaceutical dosage form, route of administration, quantity of dosage units, and in the case of open trials, the name/identifier and strength/potency; * the batch and/or code number * a trial reference code * the trial subject identification number/treatment number and where relevant, the visit number; * the name of the investigator * directions for use (reference may be made to a leaflet or other explanatory document intended for the trial subject or person administering the product); * “For clinical trial use only” * the storage conditions; * expiry date * “keep out of reach of children” except when the product is for use in trials where the product is not taken home by subjects. | Eudract number-Label.pdf | Electronic |
| Additional preclinical and/or clinical data to justify the indication if needed | Eudract number-IMP data- IMP name.pdf | Electronic |
| Qualitative and quantitative composition of the IMP/placebo if needed | Eudract number- quality data-IMP name.pdf | Electronic |
| Authorisation of the FANC for radiopharmacy trial | Eudract number-FANC authorization-IMP name.pdf | Electronic |