EU trial number: [Insert Trial Number]
Universal trial number: [insert Universal Trial Number]
[Sponsor] Protocol Number: [Insert Protocol Number]

Protocol Title: [Insert Protocol Title]

[Location], [Date]

Subject: Clinical Trial Application – Part I [initial submission / resubmission*]

Dear Madam, Dear Sir,

Please find enclosed the dossier for the application concerning the trial referenced above for your review. All documents needed for your review have been uploaded to the CTIS portal.

[Initial submission: Insert brief description of the clinical trial, including any local specific items] or [Resubmission: Describe resubmission and specify the EU trial number for the previous clinical trial application, highlight the changes as compared to the previous submission and, if applicable, specify how any unresolved issues in the first submission have been addressed]

[Please indicate the proposed Medical Research Ethics Committee to assess the clinical trial. The CCMO can only be the reviewing committee for specific type of research]
The proposed Medical Research Ethics Committee to review this submission is [insert name of MREC , see list MREC].

[Please tick items below which are applicable. Where necessary, complete the specific sections or delete the sections not applicable to your clinical trial]

- ☐ The study population consists of [subjects not able to give informed consent] / [minors] / [pregnant women] / [breastfeeding women].
- ☐ The clinical trial involves the first administration of a new active substance to humans.
- ☐ Scientific advice relating to the clinical trial or the investigational medicinal product has been given by the Agency, a Member State or a third country. This can be found in [insert name of document].
- ☐ The clinical trial [is part] / [is intended to be part] of a Pediatric Investigation Plan (PIP) as referred to in Title II, Chapter 3, of Regulation (EC) No 1901/2006. The Agency [has issued] / [has not yet issued] a decision on the PIP: [enter here the link to the decision of the Agency on its website].
- ☐ The investigational medicinal products (IMP) or auxiliary medicinal products (AMP) are a [narcotic] / [psychotropic] / [radiopharmaceutical].
- ☐ The investigational medicinal product consists of or contains a genetically modified organism or organisms.
- ☐ The investigational medicinal product is considered a prophylactic vaccine.

☐ An orphan designation for the IMP for an orphan condition has been obtained.
☐ The following IMPs and AMPs are used in the clinical trial:

Name of the medicinal product	***IMP/AMP***	***Regulatory status***

☐ The following medical devices are to be investigated in the clinical trial (not part of the investigational medicinal product or products):

Name of the medical device	***CE-marked for the intended use***

☐ The study is a low-intervention clinical trial. [Please enter here the justification why it is considered to be a low-intervention clinical trial and if the proposed RMS is one of the MS where the use of IMP is evidence based, please explain]

The reference safety information of the medicinal products can be found in section [insert section] of document [insert name of the reference document].

Should you have any queries on the enclosed, please do not hesitate to contact [insert applicant contact name].

Yours sincerely,

Signature [if signed, also a cover letter without signature has to be submitted]:

Applicant Name & function:
Institution / department: