**Date**

**Subject: Application CTIS trial number – initial submission / resubmission**

**Sponsor: Sponsor Name**

**EU Trial number: Trial Number**

**Protocol Number: Protocol Number/Acronym**

**Protocol Title: Protocol Title**

**Instructions for applicant**

* Yellow text contains instructions and information, please remove this from the final version. Grey text should be filled in by the applicant.
* For transition trials, please use the cover letter template for transition trials, available on the [CTCG website](https://www.hma.eu/about-hma/working-groups/clinical-trials-coordination-group.html) (under Key Documents List).
* The cover letter should not describe the clinical trial in detail, and should focus on providing an overview of the submitted documents and on highlighting any relevant details.
* In case of resubmission: describe the reason for resubmission, mention the EU trial number of the previous clinical trial application. Describe any changes compared to the previous submission, upload track-changes version of changed documents, and specify how any unresolved issues from the first submission have now been addressed.
* In case this trial is related to another clinical trial (e.g. part of a platform trial/complex design), then describe the relation and mention the trial number of the related trial(s).
* Adhere to the CTR document coding and naming based on CTR Annex I, as described in the CTCG ‘Best Practice guide naming of documents in CTIS’, which can be found on the [CTCG website](https://www.hma.eu/about-hma/working-groups/clinical-trials-coordination-group.html) under ‘Key documents list’. Make sure that the document titles in CTIS do not contain a version number or date.
* Please consult Annex II of the [CTR Q&A of the European Commission](https://health.ec.europa.eu/document/download/bd165522-8acf-433a-9ab1-d7dceae58112_en?filename=regulation5362014_qa_en%2Epdf) for the language requirements per Member State for Part I documents, and for structured data (‘Fields of the application form’).
* When submitting, make sure to include Part II by ticking the Part II checkbox for each MSC.

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.

BRIEFLY describe the scope of the trial application, including any country-specific details.

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

[ ]  This is a complex clinical trial (CCT). See [CTCG website](https://www.hma.eu/about-hma/working-groups/clinical-trials-coordination-group.html) for more information.

[ ]  This clinical trial is linked to the IMPD-Q-only application with trial number [xxxx].

[ ]  This is a partial application (without Part II, CTR article 11) for the following Member States: [mention Member States]

[ ]  This clinical trial is related to a public health emergency. [provide description]

[ ]  The study population consists of [subjects not able to give informed consent] / [emergency situation subjects (CTR Article 35)] / [minors] / [pregnant women] / [breastfeeding women].

[ ]  The clinical trial involves the first administration of a new active substance to humans (first-in-human trial). If the IMP is a biosimilar or bioequivalent, indicate this here.

[ ]  Scientific advice relating to the clinical trial or the investigational medicinal product has been given by EMA, 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 (AxMP) 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.

[ ]  This trial investigates a new indication for an authorised medicinal product.

[ ]  The following IMPs and AxMPs are used in the clinical trial:

|  |  |  |  |
| --- | --- | --- | --- |
| **Name product** | **IMP/AxMP** | **EU Regulatory status (authorised/unauthorised)** | **Documents submitted (e.g. IB/IMPD/SmPC)** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Only AxMPs that are not authorised or are modified outside the scope of the marketing authorization, need to be entered in CTIS. Unmodified authorised AxMPs should be listed in the table above, but not entered in CTIS.

If clinical batches of an authorised IMP are used, provide a justification why authorised batches are not used instead, and submit a simplified IMPD (sIMPD) or Summary of Changes (SoC) that clearly indicates the differences between the clinical and authorized batches in tabular format.

[ ]  The following **medical devices** are investigated in this trial (not part of the investigational medicinal product or products) (EU MDR 2017/745): Only mention devices that are investigated or in development in this trial, not devices that are used but not investigated.

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of device** | **Not CE-marked** | **CE-marked but used outside intended use** | **In-house device** |
|  |[ ] [ ] [ ]
|  |[ ] [ ] [ ]
|  |[ ] [ ] [ ]

[ ]  The following **in vitro diagnostics** (IVD) are investigated in the clinical trial (not part of the investigational medicinal product or products) (EU IVDR 2017/746): Only mention IVD that are investigated or in development in this trial, not IVD that are used but not investigated.

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of IVD** | **Not CE-marked** | **CE-marked but used outside intended use** | **In-house device** |
|  |[ ] [ ] [ ]
|  |[ ] [ ] [ ]
|  |[ ] [ ] [ ]

[ ]  The study is a low-intervention clinical trial (as defined in CTR article 2). [Please enter here the justification why this is considered to be a low-intervention clinical trial, and explain if the (proposed) RMS is one of the MS where the use of IMP is evidence-based]

[ ]  The following Ethics Committees are proposed to assess the application, if applicable:

|  |  |
| --- | --- |
| **Member State** | **Proposed Ethics Committee** |
|  |  |
|  |  |
|  |  |

[ ]  Reduced safety reporting applies for the clinical trial (ICH E19, CTR article 41. Justification should be provided in the protocol).

The reference safety information of the medicinal products can be found in section [insert section] of the [insert name of the reference document]. This can be either the IB or the SmPC. More information is provided in section 7.8 of the CTR Q&A.

Should you have any questions, please do not hesitate to contact [insert contact name].

Yours sincerely,

Applicant Name and Function:

Organisation / Department: