**Date**

**Subject: Application CTIS trial number SM-number (Part I / Part II / Part I + II)**

**Sponsor: Sponsor Name**

**EU Trial number: Trial Number**

**Application number: SM-x**

**Protocol Number: Protocol Number/Acronym**

**Protocol Title: Protocol Title**

**Instructions for applicant**

* Yellow and blue text contains instructions and information, please remove this from the final version. Grey text should be filled in by the applicant. The section between the blue header and footer should be included only for the first substantial modification (SM) after transition.
* When uploading documents for this SM in CTIS, please enter the SM-number as a Comment in the upload ‘pop-up’ window (e.g. enter “SM-6”).
* For each modified document:
  + The new version should be uploaded using the Update button in CTIS (3rd symbol) behind the title of the existing document.
  + A track-changes (TC) version should always be submitted. If this is not possible (e.g. insurance certificates, QP declarations, MIA, GMP certificates), then the changes should be described in the cover letter.
  + In addition to the track-changes version, a Summary of Changes (SoC) should be provided for the protocol, IB and IMPD (either as a separate document, or as part of the main document itself).
* Please 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’.

Dear Madam, Dear Sir,

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

Please refer to the **Modification Description** document for a detailed overview of all the changes made to the application dossier, including a list of documents. Submit this document in the CTIS upload slot describing the substantial modification (see **Annex II Substantial Modification Description Template first SM after transition vs 1.0 adopted by CTCG March 19 2024**).

BRIEFLY describe the reason and scope of the SM, including any country-specific details. If the SM also contains non-substantial changes, then list these separately from the substantial changes. If the SM application is a resubmission of a previous one, please clarify which changes have been performed.

**## Only if this is the first SM for a transition trial, add the following information to clarify whether the SM application contains new, updated or already authorised documents ##**

* This application contains: (delete those that are not applicable)
  + Documents that were already authorised under the CTD and not included in the transition initial application
  + Updates to CTD documents/placeholders that were included in the transition application
  + New documents in line with CTR requirements
* The addition of new Member States to this trial is planned / expected / currently not expected. (choose one option applying to the trial. If so, then include any relevant details on the trial (as in cover letter for new trials) in the cover letter for the added Member State.)
* The content of the Part II forms on Recruitment Arrangements, Financial Arrangements, Data Protection and Biological Samples (delete those that are not applicable or add other part II forms, if applicable) is fully in line with the earlier authorised CTD documents. If not, specify the new information.
* Indicate whether recruitment and IMP administration has already finished or is still ongoing. For multinational trials, indicate this for each MSC.
* If the sponsor of the trial is not the product owner, indicate if an IMPD-Q only submission or a reference trial is linked to this Part I SM application.
* Indicate if the trial is considered a low-intervention clinical trial.

**############# END OF SECTION FOR FIRST SM AFTER TRANSITION ##############**

**Substantial modifications:**

* Document X was updated to v2.0 dated 01-01-1900. The main changes include ….
* …

**Non-substantial modifications:** (remove this section if there are no non-substantial modifications)

* …
* …

The Sponsor hereby declares that the provided information is complete, the documents are updated in line with the Regulation (EU) No 536/2014 and the clinical trial will be conducted in accordance with the amended documentation.

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

Yours sincerely,

Applicant Name and Function:

Organisation / Department: