*Sponsor’s Name/Logo*

*Sponsor’s Address*

*Sponsor’s Contact details*

*Date Cover letter was issued*

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

**Country:** Ireland

Dear NREC,

Please find enclosed for your review the following application.

(*please select as appropriate*)

Substantial Modification

Substantial Modification & Non-Substantial Modification

Substantial Modification & Completion of Dossier

Substantial Modification of a Combined trial (includes MDR and/or IVDR component)

**Section 1: Study Details:**

|  |  |
| --- | --- |
| Study Title: | *Protocol title* |
| EU CT number: | *Trial number* |
| Application number: | *SM-x* |
| Sponsor: | *Sponsor Name* |

**Section 2: Details of the Substantial Modification**

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 the changes.

\*\*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: (please 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 for the trial)*
* *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 sponsor considers the trial to be a low-intervention clinical trial.*

**Section 3: Table of documents**

This application has been submitted for the review of NREC-CT to review the following documents; (insert/delete rows as required)

**Please ensure the document title on CTIS uses an identical name to the document listed in this cover letter for accuracy.**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Document Name on CTIS (use exact title)** | **Document**  **Type** | **Version Number** | **Version Date** | **Date of Submission** | **Purpose of Submission**  *(examples listed below)* | **Details of Submission**  *(examples listed below)* | **Submission Section** |
| *e.g. ICF* | *Part II* | *1.0* | *01/01/2024* | *03/01/2024* | *E.g. New document for NREC Review* | *Updates to IMP risk benefit ratio* | *Part II - Recruitment Arrangements* |
|  |  |  |  |  | *Updated document for NREC review* | *Addition of site* | *Form- Compliance with Regulation* |
|  |  |  |  |  | *Non-Substantial Modification* | *Dear Investigator Letter* | *Part II – Suitability of the facilities* |
|  |  |  |  |  | *Document submission in response to conditional approval* |  |  |
|  |  |  |  |  | *Completion of Dossier – uploading documentation in line with EU CTR* |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

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

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

Yours sincerely,

[Insert Sponsor Contact name]

[Insert Sponsor Contact details]