**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, information and example texts; please remove these from the final version. Grey text should be filled in by the applicant. The blue section (text between blue header and footer) should be included only for the first SM after transition (see guidance on first SM after trial transition).
* Also mention track-changes (TC) and Summary of Changes (SoC) documents in the lists below.
* 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 under ‘Key documents list’.

This document provides a full overview of changes to documents and data fields for this substantial modification (SM).

**############## 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

In the tables/lists below, clearly indicate for each document which of the 3 categories described applies per document. Letters and number in the table refer to the ‘Best Practice guide naming of documents in CTIS’.

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

**Changes to structured data fields (examples)**

|  |  |  |
| --- | --- | --- |
| **Section** | **Description of changes** | **Justification for changes** |
| MSCs | Subject number updated for MSC | Addition of study arm in MSC |
| Part I | Inclusion criterion #x added | Refer to updated protocol v4 01Jan2024 |
| Part II Member State | Trial site X added | ….. |
| Part II Member State | PI change at site X | ….. |
| … | … | … |

**Changes to documents under Form section in CTIS (examples)**

|  |  |  |
| --- | --- | --- |
| **Section** | **Document name Version and date** | **Details** |
| Substantial modification details | B1\_Cover letter 2024-xxxxxx-xx-00 SM-6  V1.0 22Jan2024 | New |
| Substantial modification details | B1\_Modification Description 2024-xxxxxx-xx-00 SM-6  V1.0 22Jan2024 | New |
| Proof of Payment | Proof of Payment MSC | New |
| … | … | ….. |

**Changes to Part I Documents (examples)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Section** | **Document type** | **Document (including clean and track changes versions, if applicable)**  **Version and Date** | **Details** |
| Protocol information | Protocol | D1\_Protocol 2023-xxxxxx-xx-00  v3.0 31Jan2024 CLEAN | Updated |
| Protocol information | Protocol | D1\_ Protocol-2023-xxxxxx-xx-00  v3 31Jan2024\_TC | New |
| Protocol information | DSMB charter | D3\_DSMB Charter-2023 xxxxxx-xx-00  v1 23May2021 | CTD no update |
| Products | IMPD-Quality | G1\_IMPD Q CLEAN  v2.0 15Dec2023 | Updated |
| Products | IMDP-Quality | G1\_IMPD Q\_TC v2.0 15Dec2023 | New |
| Products | IMPD-Quality | G1\_SoC IMPD Q v2.0 15Dec2023 |  |
| Products | Compliance with GMP | QP declaration  vNA 25Dec2023 | New |
| … | … | … | … |

**Changes to Part II Documents per Member State Concerned (examples)**

**Member state: MSC name (copy for each MSC)**

|  |  |  |
| --- | --- | --- |
| **Section** | **Document name (including clean and track changes version, if applicable)**  **Version and Date** | **Details** |
| Recruitment Arrangements | K1\_Recruitment Procedure  v2.0 31Jan2024 | Updated |
| Recruitment Arrangements | K2\_Patient Brochure  v1.0 31Jan2024 | New |
| Subject Information | L1\_ICF Main Adult CLEAN  v4.0 29Jan2024 | Updated |
| Subject Information | L1\_ICF Main Adult\_TC  v4.0 29Jan2024 | New |
| Suitability of the investigator | M1\_CV Investigator X - site Y  V1.0 21Jan2021 | Removed |
| … | ... | … |