**List of changes to the application – Section - RFI Number**

Example: “List of changes – Part I - RFI-CT-2024-512345-99-00-SM06-001”

**Instructions for the applicant**:

* This document should be filled in for every RFI, also when multiple RFI’s are sent in the same section. Upload this document in the RFI under ‘Changes to the application’.
* Yellow text contain instructions and information and examples, please remove this from the final version.
* Documents requested via an RFI should not be uploaded within the RFI, but in the application itself using the Change Application button.
* When uploading documents in response to an RFI, please mention the application number and RFI type as a Comment in the upload window (e.g. enter “SM-6 RFI-001”). This greatly increases recognizability of newly submitted documents for assessors.
* For each modified document:
  + The new version should be uploaded using the Update button (3rd symbol, paper sheet) 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  + Please upload TC and SoC documents as ‘not for publication’, using the + sign (5th symbol) behind the title of the corresponding ‘for publication’ document.
* In the assessment phase, only apply changes that were requested in the RFI. Any other substantial changes can be submitted as a substantial modification after the decision for the current application. Additional non-substantial modifications are allowed, and should be mentioned in the table at the end of this document.
* The RFI Response can only be submitted if a written response has been entered for each consideration, the individual locks of all considerations are opened, and the master lock in the top-left corner of the RFI is closed.

The following changes have been made to the application:

Applicants are free to use their own table/list format, if this provides the same level of overview and detail, so that it is immediately clear for assessors which changes were made.

|  |  |  |  |
| --- | --- | --- | --- |
| **Consideration Number** | **Section** | **Document name (including clean and track changes version, if applicable)**  **Version and Date** | **Details** |
| …-01 | Part II DK - Suitability of the investigator | M1\_CV Investigator [name & site]  V2.0 12Jan2024 | Updated version submitted |
| …-02 | Part I | D1\_Protocol 2024-…. V3.0 18Feb2024 | [Textual response to question] |
| …-03 | Part I | N/A | Updated inclusion criterion 5 (Part I Structured data) |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Additional non-substantial changes**In addition to the changes requested in the RFI, the following non-substantial changes have been made to the application:

|  |  |  |
| --- | --- | --- |
| **Section** | **Document name** | **Details** |
| Part I | D1\_Protocol 2024-…. V3.0 18Feb2024 | Typo corrected in chapter …. |
| Part II (AT) | L1. ICF Adults | Clarification on page … regarding.. |
|  |  |  |