**NATIONAL MEDICINES REGULATORY AUTHORITY, SRI LANKA**

**120, Norris Canal Road, Colombo 10, Sri Lanka.**

**Telephone: +94 011 2698896/7 Fax: +94 011 2689704 email: info@nmra.gov.lk**

**Application for amendments to a clinical trial**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Application for amendments to a clinical trial** | | | | | | | | | |
| 1 | **Details of the trial** | | |  |  |  |  | |  |
|  | 1. NMRA reference number of the clinical trial Click here to enter text. 2. Title of the Trial   Click here to enter text. | | | | | | | |  |
|  |  |
| 2 | **Details of holder of letter of authorization** | | | |  |  |  |  |  |
|  | 1. Name Click here to enter text. 2. Designation Click here to enter text. 3. Address Click here to enter text. 4. Contact Number Click here to enter text. 5. Email  Click here to enter text. | | | | | | | | |
|  |
|  |
|  |
| 3 | **Details of contact person** | | |  |  |  |  |  |  |
|  | 1. Name Click here to enter text. 2. Address Click here to enter text. 3. Contact Number Click here to enter text. 4. Email  Click here to enter text. | | | | | | | | |
|  |
|  |
|  |
| 4 | **Purpose of Submission** *(Please tick a box)*  Submission of a notification  Submission of a substantial amendment  Submission of urgent safety measure  Answer to NMRA’s request dated Click here to enter a date. | | | | | | | |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
| 5 | **Information regarding the submission** | | | |  |  |  |  |  |
|  | Regarding |  | |  |  |  |  |  |  |
|  | Click here to enter text. |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  | Rationale/ Information |  | | |  |  |  |  |  |
|  | Click here to enter text. |  |  |  |  |  |  |  |  |
| 6 | **List of documents appended to the form** | | | | |  |  |  |  |
|  | *Please submit only relevant documents and/or when applicable make clear references to the ones already submitted. Make clear references to any changes of separate pages and submit old and new texts. Tick the appropriate box(es)* | | | | | | | | |
|  |
|  |
|  | Cover letter  Extract from amended document  Entire new version of the document (Title, version & Date)  Summary of Changes in tabulated form  Entire document with track changes (Color print out)  Supporting information/Documents | | | | | | | | |
|  |
|  |
|  |
|  |
| 7 | **Mandatory additional information regarding the submission of an investigator’s brochure** | | | | | | | | |
|  | *(Only filled if an investigator’s brochure is submitted)* | | | | | |  |  |  |
|  | 1. Risk/Benefit statement   Click here to enter text.   1. The IB update has impact on study documents   Yes (If yes list documents  No | | | | | | | |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  | The following documents will be updated  Click here to enter text. | | | | | | | |  |
|  |  |
|  |  |
| 8 | **Signature of the applicant** | | |  |  |  |  |  |  |
|  | I hereby confirm on behalf of the sponsor that, | | | | |  |  |  |  |
|  | * The above information given on this request is correct; * The trial will be conducted according to the protocol, national regulation and the principles of good clinical practice; and * It is reasonable for the proposed amendment to be undertaken.      |  | | --- | | ……….…………………. ……………… | | Signature Date | | | | | | | | | |
|  |
|  |
|  |
|  |
|  |
|  |