**CLINICAL TRIAL OF AN INVESTIGATIONAL MEDICINAL PRODUCT (CTIMP)**

**ANNUAL PROGRESS REPORT TO ERC**

To be completed in typescript and submitted by the Principal Investigator (PI).

1. **Details of PI**

|  |  |
| --- | --- |
| Name: |  |
| Address: |  |
| Telephone: |  |
| E-mail: |  |
| Fax: |  |

1. **Details of study**

|  |  |
| --- | --- |
| Full title of study: |  |
| Protocol number: |  |
| Date of ERC approval: |  |
| Sponsor(if any): |  |

1. **Commencement and termination dates**

|  |  |
| --- | --- |
| Has the study started in Sri Lanka | Yes / No |
| If yes, what was the actual start date in Sri Lanka? |  |
| If no, what are the reasons for the study not commencing?  What is the expected start date? |  |

|  |  |
| --- | --- |
| Has the study finished? | Yes / No |
| If no, what is the expected completion date?  *If you expect the study to overrun the planned completion date this should be notified to the ERC for information.* |  |
| If you do not expect the study to be completed, give reason(s) |  |

1. **Registration**

|  |  |
| --- | --- |
| Is the study registered on a publically accessible database? (Registration of clinical trials is a requirement by the ERC) | Yes / No |
| If yes, please provide the name of the database and the registration number  Database:  Registration number: | |
| If no:   1. What is the reason for non-registration? 2. What are your intentions for registration? | |

1. **Site information**

|  |  |
| --- | --- |
| Number of research sites proposed in original application:  Number of research sites recruited to date: |  |
| Do you plan to increase the total number of sites proposed for the study?  *The addition of any new sites not listed in the original applications to the ERC should be notified in writing* | Yes / No |

1. **Recruitment of participants**

|  |  |
| --- | --- |
| Recruitment status: | pending/ recruiting/ recruitment complete/ recruitment suspended / recruitment |
| Number assessed for eligibility: | |
| Number recruited and randomized: | |
| Number allocated to each intervention/arm: | |
|  | |
|  |  |
|  |  |
| Losses/exclusions after randomization: |  |
|  |  |

*\* In the case of international trials, please provide separate figures for Sri Lankan and non-Sri Lankan participants.*

|  |  |
| --- | --- |
| Have there been any serious difficulties in recruiting participants? | Yes / No |
| If yes, give details: |  |

1. **Safety reports**

|  |  |
| --- | --- |
| Have there been any Suspected Unexpected Serious Adverse Reactions (SUSARs) in this trial in Sri Lanka? | *Yes / No* |
| Have these SUSARs been notified to the ERC within 7 days for fatal/life threatening events and 15days for other events?  *If no, please arrange urgently and give reasons for late notification.* | Yes / No |
| Has the Annual Safety Report (ASR) been submitted? | Yes / No / Not yet due |
| When is the next ASR due? |  |

1. **Amendments**

|  |  |
| --- | --- |
| Have any substantial amendments been made to the trial during the year? | Yes / No |
| If yes, please give details and the date and amendment number for each substantial amendment made. |  |

1. **Trial output**

|  |  |
| --- | --- |
| Summary of Interim/Final data (if available):  Publications:  (Please attach a scanned copy or link to paper) |  |
| Presentations of results at scientific meetings:  (Please attach a scanned copy or link to abstract) |  |

1. **Serious breaches of the protocol or Good Clinical Practice**

|  |  |
| --- | --- |
| Have any serious breaches of the protocol or GCP occurred in relation to this trial during the year? | Yes / No |
| If yes, please give the date of each notification to the ERC. |  |

1. **Other issues**

|  |  |
| --- | --- |
| Are there any other developments in the trial that you wish to report to the Committee?  Are there any ethical issues on which further advice is required?  *If yes to either, please attach separate statement with details.* | *Yes / No*  *Yes / No* |

1. **Declaration**

|  |  |
| --- | --- |
| Signature of Principal Investigator: |  |
| Print name: |  |
| Date of submission: |  |