# I. SITE INFORMATION

Protocol Title:

Protocol Identification number:

Clinical Trial Certificate number:

Name and address of Clinical Site:

Name, address, telephone number and e- mail address of Principal Investigator:

Name, address, telephone number and e- mail address of Sponsor:

Date of last recruitment:

Reason for closure:

Date(s) of Report:

Clinical Site Personnel Involved with the Study:

|  |  |  |
| --- | --- | --- |
| **NAME** | **TITLE** | **CONTACT** |
|  | Local monitor |  |
|  | Site Coordinator |  |
|  | Pharmacist |  |
|  | Other |  |

# II. CLINICAL SITE CLOSE- OUT CHECKLIST

**Instructions:** Please provide comment (s) for each of the items listed below. Additional sheets may be attached if necessary.

|  |  |
| --- | --- |
| **OBJECTIVE** | **COMMENTS** |
| 1. All regulatory and other essential documents (refer to Appendix IV of FDA Guidelines for the Conduct of Clinical Trials, **FDA/ SMC/ CTD/ GL- ACT/ 2013/ 01**) are up-to-date and on file | *Provide list of documents on file at the site* |

1

|  |  |
| --- | --- |
|  |  |
| 2. Notification of all relevant oversight bodies of closure of study |  |

|  |  |
| --- | --- |
| 3. Signed, informed consent is on file for each study participant | *Provide list of participants (use codes/ study IDs)* |
| **OBJECTIVE** | **COMMENTS** |
| 4. Documentation of all protocol violations/ deviations and/ or appropriate note- to- files in the relevant essential document | *Provide list* |

2

|  |  |
| --- | --- |
| 5. Appropriate follow- up and reporting of all SAEs to FDA | *Provide number of SAEs reported. Summary of outcome for SAEs listed is relevant* |
| 6. Completion of all Case Report forms for each participant |  |
| 7. Entry/ submission of all relevant data into database/ to sponsor/ coordination center.    If not complete, indicate the timeline for accomplishing this and document in the comments section |  |
| 8. Status of all outstanding data edits, queries or delinquent forms and timeline for their resolution |  |
| 9. Tentative date for submission of full Clinical Study Report (not FDA timelines, Appendix VII FDA/ SMC/ CTD/ GL- CCT/ 2013/ 01) |  |
| 10. Requirements for retention of study records.    Indicate if each requirement has been fulfilled |  |
| 11. Drug accountability   * Quantity of IPs received      * Quantity of IPs utilized in the study      * Quantity of IPs destroyed (attach copy of destruction certificate (s))      * Quantity of IPs onsite/ returned to sponsor |  |
| 12. Status/ shipment/ analyses of all participant specimen according to protocol requirements (including plans for future shipments or period of time they will be stored on- site) |  |

3

|  |  |
| --- | --- |
| 13. If blinded study drug was used, confirm that the tear- off labels were not opened. For any that were opened, documentation should be obtained noting the reason for unblinding |  |

**Additional comments:**

**III. STATUS OF PAST OBSERVATIONS/ RECOMMENDATIONS MADE DURING**  **MONITORING/ GCP INSPECTIONS: (Have corrective measures been implemented for all observations and recommendations?), Provide summary of measures implemented for each point)**

# IV. OUTSTANDING ISSUES OR ACTIVITIES TO BE IMPLEMENTED: (Include problems identified, if any, and recommendations/ action items for corrections)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Prepared by: Date: .

(Signature)

4