#  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.

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| **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

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

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| 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

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| 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

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| 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)   |   |

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| 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)

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 Prepared by: Date: .

(Signature)

4