TITLE: CLINICAL SITE CLOSE – UP REPORT

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- CCT/ 2013/ 01**) are up-to-date and on file	*Provide list of documents on file at the site*

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*
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)	
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)