**CLOSE OUT VISIT FOLLOW-UP LETTER**

*<Insert Date>*

**Instructions:**

*Instructional text – requires you to complete the information. Remove the italics / brackets prior to finalising the checklist and ensure all text is black.*

Optional text – delete when not required as applicable to your trial. Ensure any blue text retained is changed to black text upon finalisation of form for your study.

Standard wording – not to be removed or changed without prior consultation with the Sponsor.

If sent as a letter, ensure use of appropriate institute letterhead. Option to send as the body of an email. Ensure either mode of communication is accurately filed in the sites Site Investigator File (SIF).

**DELETE THIS INSTRUCTION BOX UPON FINALISATION OF FORM**

*<Insert Site Name>*

*<Insert Name of Site PI>*

*<Insert Site Address>*

Dear *<Insert PI Name>* and the *<Insert Trial name>* Research Team

**RE: SITE CLOSE OUT VISIT (COV) FOLLOW-UP LETTER**

|  |  |
| --- | --- |
| **Protocol Title:** |  |
| **Site Name:** |  |
| **Site Code:** |  |
| **Site Principal Investigator Name:** |  |
| **Date of Visit:** |  |

Thank you to you and the study team for your time and assistance during the recent Close Out Visit (COV) that took place at your site on *<insert date>.* I would like to thank you for your time in assisting with this visit, as well as, throughout the entire trial.

During the COV, the following was undertaken:

* + - Review of your ISF for completeness, accuracy, and regulatory compliance
    - Review of data entry status, with all queries being corrected and/or resolved
    - The trial dataset has been signed-off by the Site Principal Investigator (PI)
    - Source data and/or source documents have been filed appropriately
    - All trial safety reporting (AEs/SAEs/SUSARs/URSAEs/SSIs/USMs) has been completed in accordance with the study protocol prior to site closure
    - All serious AEs and SAEs (insert other trial-related safety events) reported have been resolved and/or followed up, as specified in the protocol
    - Reconciliation of Investigational Medicinal Products (IMPs) or Investigational Medical Devices (IMDs)
    - Reconciliation of all biospecimens, including confirmation that all biospecimens have been shipped to the receiving/central laboratory
    - All site payments have been fulfilled
* <The close out visit also included a visit to the Pharmacy Department>
* *<insert other items as applicable to your clinical monitoring plan>*
* *<insert other items as applicable to your clinical monitoring plan>*
* *<insert other items as applicable to your clinical monitoring plan>*

Please find below a list of findings and actions resulting from the visit. Please ensure that the action items are resolved by the specified due date so that the ISF can be prepared for archving.

|  |  |  |  |
| --- | --- | --- | --- |
| **Item/Title** | **Open Date** | **Action Required by Site** | **Due Date** |
| *<insert issue identified>* | Click to choose a date. | *<insert action to rectify issue>* | Click to choose a date. |
| *<insert issue identified>* | Click to choose a date. | *<insert action to rectify issue>* | Click to choose a date. |
| *<insert issue identified>* | Click to choose a date. | *<insert action to rectify issue>* | Click to choose a date. |

Please note that any changes made to trial or source documentation as a result of this close out visit should be made leaving a clear audit trail and dated consistently with the time the change is made.

The following issues were also identified during the COV, however, have been addressed by the Trial Monitor/Clinical Trial Manager/Trial Coordinator during the visit and no further action is required:

|  |  |
| --- | --- |
| **Item/Title** | **Action Required by Site** |
| *<insert issue identified>* | NA – Addressed by Monitor during Monitoring Visit |
| *<insert issue identified>* | NA – Addressed by Monitor during Monitoring Visit |
| *<insert issue identified>* | NA – Addressed by Monitor during Monitoring Visit |

For your information, copies of the following documents were obtained from your Investigator Site File, as these were missing from the Sponsor’s files:

1. <insert document name, date and version (if applicable)>
2. <insert document name, date and version (if applicable)>

As discussed with the team during the COV, the Investigator Site File (ISF) can now be prepared for archiving:

* Paper ISF Binders only: Any documents which may fade over time must be copied to preserve them for the duration of the archiving period and any item which may degrade the documentation over time e.g. poly-pockets, paper clips etc. should be removed.
* Identifiable data should be prepared for archiving according to local site policy.
* Please do not archive the ISF until receipt of the Final Close Out letter which is sent by the Trial Monitor/Clinical Trial Manager/Trial Coordinator after all close out actions are resolved.

Lastly, a reminder to file a copy of this letter in Section <insert Section number> of your Investigator Site File (ISF).

It has been a pleasure working with you and your Team on this trial. If you or your Team wish to discuss any of the points in this COV Follow-Up Letter, or have any other issues you wish to discuss, please feel free to contact me on *<insert contact phone number and/or email>*.

Kind Regards,

***<Sign off>***