**CLOSE OUT VISIT CONFIRMATION LETTER**

**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, or delete text which is not 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 Date>*

*<Insert Site Name>*

*<Insert Name of Site PI>*

*<Insert Site Address>*

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

**RE: CLOSE OUT VISIT (COV) CONFIRMATION LETTER**

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

This letter is to confirm that your site has a scheduled Close Out Visit (COV) confirmed for the *<insert date>* for the *<insert trial name>* clinical trial.

The COV will be undertaken by the nominated Trial Monitor/Clinical Trial Manager/Trial Coordinator, *<insert name>* and will be completed on-site/remotely by accessing your paper ISF binder/electronic Investigator Site File (eISF) Binder that is maintained via the Sponsors approved eISF platform, Florence eBinders™, in order to ensure that all study procedures, regulatory documents and trial data are 100% completed and all post-study obligations are understood.

As the Site Principal Investigator, you will need to attend a de-brief meeting at the completion of the COV which will take approximately 30 minutes. It is also advisable that the study coordinator/research nurse, *<insert name>,* also attend this meeting. A separate meeting invite with video-conference details will be circulated shortly.

During the COV the following will be completed:

* + - Verify the completeness and accuracy of your ISF to ensure all trial documentation has been appropriately completed and filed prior to archiving
		- Confirm all data has been entered into the trial database, with all queries being corrected and 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 confirming all biospecimens have been shipped to the receiving/central laboratory
* All site payments have been fulfilled
* *<insert other items as applicable to your clinical monitoring plan>*
* *<insert other items as applicable to your clinical monitoring plan>*

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 on this trial. Please feel free to contact me on *<insert contact phone number and/or email>* should you have any questions.

Kind Regards

***<Sign off>***