Key Actions for a Clinical Research Associate for

Study Close-Out Visits

The Close-Out Visit (COV) is one of your final monitoring tasks before your site is officially closed!

Use this checklist to make sure your COV is efficient and productive. Please use this checklist as a guide. There may be additional study or company specific parameters you need to follow based on your COV annotated trip report or company's Standard Operating Procedures.

PRIOR TO THE VISIT

- [ ] Confirm a day and time with the Study Coordinator and send a confirmation letter to the site.
- [ ] Confirm your meeting with the Investigator. Request that the Investigator allows time to sign final study documents and speak with you during your COV.
- [ ] Make sure all queries are addressed and all patient casebooks are signed in the Electronic Data Capture (EDC) System.
- [ ] Discuss the status of open action items from the last monitoring visit with the Study Coordinator ahead of the visit to ensure all items have been addressed.
- [ ] Contact the safety teams to confirm all queries are closed and there are no pending questions about specific safety events that have occurred for this site.
- [ ] Review your COV monitoring visit report template and annotations to know what questions need to be asked to ensure you gather all the necessary answers during your visit.
- [ ] Obtain mailing labels and/or instructions for returning supplies or Investigational Product (IP). If the IP will be destroyed on site, ensure you have a copy of the site's IP destruction policy. If not, add this action to your Visit to Do List.
- [ ] Review the latest Trial Management File (TMF) report for documents that need to be collected.
- [ ] Prepare your "Investigator Speech" (i.e. what you would like to discuss when you meet with the Investigator. Ensure you are discussing the points noted in your COV monitoring visit trip report template and annotations).

DURING YOUR VISIT

- [ ] Confirm that all queries within the source have been closed or addressed.
- [ ] Ensure documents are appropriately filed in the regulatory binder.
- [ ] Close out all logs and make copies of documents missing from the Trial Master File.
- [ ] Complete study supply and Investigational Product accountability.
- [ ] Have the site ship the IP back to the drug depot if applicable or provide a copy of the IP destruction documentation upon receipt. Please note, if your site is using a third party destruction company, it can take a few weeks after the COV to receive the certificate of destruction. This may be an outstanding action item after the visit.
- [ ] Collect a copy of the temperature logs for the entire time the Investigational Product was on-site (1-2 days prior to IP arrival through the time of final IP destruction and/or shipment to the depot).
- [ ] Send back extra supplies if requested by the study team.
- [ ] Collect a final count of remaining lab kits and advise the Study Coordinator to disassemble the extra kits.
- [ ] Ensure all study specimen samples have been shipped, especially those stored in -20° freezers for batch shipments.
- [ ] Compare the Interactive Voice Response Systems (IVRS) logs to on-site enrollment logs and resolve any discrepancies.
- [ ] Make sure all study documents are maintained and stored at the research site for at least one year (or the amount of time specified in the study contract). Write the address in your report of where study records will be stored following this period.
- [ ] Advise your site to submit the Close Out status report to their IRB and ensure they provide you a copy of the acknowledgment. This may be an outstanding action item after the visit.

AFTER YOUR VISIT

- [ ] Write your COV Monitoring Visit Trip Report and submit it to your Clinical Trial Manager or another applicable team member for review.
- [ ] Ensure all collected documents are filed in the Trial Master File.
- [ ] Write a Follow-Up Letter and send it to the site.
- [ ] Complete your expense report for the visit.
- [ ] Follow-up with the site team on any open action items at least every 1 - 2 weeks until final resolution.

YOUR NOTES