



Standard Operating Procedure (SOP) 010

Site monitoring

Scope

To describe the procedure for preparing and participating in site monitoring visits.

Purpose

- The purpose of monitoring a study is to actively facilitate and verify the following:
 - the rights and well-being of the participating patients are protected;
 - the reported study data are accurate, complete and verifiable from source documents;
 - the conduct of the study is in compliance with the approved protocol/amendment(s) and with International Conference on Harmonisation Guidelines for Good Clinical Practice (ICH-GCP).

Setting up a monitoring visit

- Monitoring visits will be conducted as appropriate by the PICnIC Trial Management Group, Trial Steering Committee and/or Data Monitoring and Ethics Committee.
- Sites will be contacted by a member of the PICnIC trial team to arrange an appropriate date/time for a visit with the appropriate site research staff and/or the Principal Investigator (PI).
- Once the visit date/time has been agreed, a confirmation email will be sent to the PI and site research staff.
- Site research staff/the PI should inform the ICNARC CTU of any relevant local policies relating the conduct of monitoring visits (e.g. if a letter of access is required).

Requirements for a monitoring visit

- Prior to the monitoring visit, the PICnIC trial team will contact the PI and appropriate site research staff detailing which documents will be reviewed during the visit (note: additional documents may be requested during the visit if required). It is the responsibility of the PI to ensure that the monitor has access to all required information.
- Any action needed to be taken by the site prior to the visit should be discussed between the PICnIC trial team and the site.

- The PI and/or appropriate site research staff should be available during the visit to answer any questions and address any queries.
- Sites should provide a quiet room for the monitor to work from during the visit.

Conduct of the monitoring visit

- The following procedures are to be carried out when monitoring:
 - Checking consent
 - Recruitment (screening/recruited patients)
 - Source Data Verification (SDV)
 - Data storage and obtaining study data in accordance with the protocol
 - Reviewing the Investigator Site File (ISF)
 - Reviewing other documents (as deemed appropriate)
- Specific details regarding which documentation is required by the monitor will be provided to the PI/site research staff prior to the visit, e.g. patient records.
- At the end of the visit, all issues identified and possible resolutions will be discussed with the site research team. Time for these discussions should be specifically allocated at the end of the monitoring visit. Following this, the Monitoring Log (Section 9: Quality Assurance, of the ISF) will be signed off by the site research staff and monitor.

Following the monitoring visit

- A monitoring visit report will be completed by the monitor; this will detail all the findings during the visit.
- A copy of the monitoring visit report will be sent to the PI/site research staff (to be filed in Section 9: Quality Assurance, of the ISF).
- Any outstanding actions addressed in the report should be resolved by the site in a timely manner. Once completed, the report should be signed off by the PI and lead research nurse/team member and returned to the ICNARC CTU for final sign-off.
- If required, and where appropriate, the monitor may arrange a follow-up visit to check that any issues identified at the original visit have been resolved.