



TARDIS - Working Practice Document – No: 022

Monitoring Plan

The Monitor will be appointed by the Chief Investigator. This may be the Trial Co-ordinator and/or another named person.

To be authorised on the Site Responsibility (Delegation) Log RF2 TA008.

Aims

The purpose of the site monitoring visit is to assess each recruiting site and to determine:

- Evidence of written informed consent/assent on each patient;
- The validity of patient data;
- The conduct of the centre;
- The conduct of the trial is in compliance with the currently approved protocol / amendment(s), with GCP, and with the applicable regulatory requirements.

Central monitoring of the TARDIS database is also carried out by the Chief Investigator with checks of the data for unusual patterns, irregularities and anomalies.

Frequency, scope nature of monitoring

Each recruiting site will get at least one monitoring visit over the 3 year duration of the trial.

At each monitoring visit if the site has recruited 4 or less since the last monitoring visit, all new patients will be monitored. If there are more than 4 patients a list of patient numbers will be created and 4 or 5 chosen at random. Medical records should be available for source data verification on the identified patients.

Responsibilities of Monitor

The named monitor/s will:

1. be familiar with the monitoring plan, the study protocol, the consent processes and the processes for the IMP handling and dates of all authorisations.
2. review any previous monitoring reports and the outcomes of any corrective action
3. contact the site to agree the visit date, confirming
 - a. the purpose of the visit and areas to be covered

- b. the documents to be provided by the site. This must include the Trial Site File.
 - c. The facilities, locations and equipment to be reviewed
4. during the monitoring visit
- a. Check the responsibility (delegation) log, training records and CV s of all investigators for relevant qualification, GCP and trial specific training and that these are kept up-to-date.
 - i. initial central monitoring should have ensured this was correct at time of Site Initiation, however changes will have been made since that time i.e. investigators/PI names, outdated GCP training.
 - b. Verify that the site had all necessary approvals in place prior to being provided access to the live website (as a.i above)
 - c. Verify that the current protocol and associated documents are being used and adhered to and that the ICH essential documents are being maintained
 - d. Verify that consent was obtained before each participant received any trial related procedures and that only eligible participants were enrolled.
 - e. Where applicable, verify that IMP handling procedures are being adhered to and that all relevant IMP documentation is in place. (Pharmacy and/or Investigator Site Trial File)
 - f. Check the source and trial specific documents are accurate, complete, kept up-to-date and maintained and that all data transfers are all accurate
 - g. Determine whether serious adverse events are appropriately reported and verified within the applicable regulatory requirements. Ensure that the Sponsor has been informed of any Suspected Unexpected Serious Adverse Reactions (SUSARS) and that the relevant authorities have been informed.
 - i. Check that all copies of trial reporting, to trial committees (TSC, DMEC), ethics committee and regulatory authority has been done and is up-to-date.
 - j. Review the facilities and ensure security of data adequate.
5. Discuss with Principal Investigator or his/her representative if unavailable, the monitoring 'finds' and agree on any necessary corrective actions.
6. After the visit, the monitor will prepare a letter to the site thanking them for their hospitality and outlining the findings. A signed copy is posted to the Principal

Investigator, Site Research Governance Department and Chief Investigator. All points noted about patient records, site files and other points should be included.

7. A data query form should be completed for each error and forwarded to the trial statistician or data manager for inclusion and amendment to the database.
8. File the monitoring report in the Trial Master File.

The Chief Investigator shall:

9. Consider the monitoring report outcomes, verify and advise on any necessary actions to be taken. Inform any relevant trial committees (TSM, DMEC) and the Sponsor of any significant outcomes and the actions taken.