Example 1

Clinical Trials Assistant

Job purpose

To provide full and comprehensive administrative and data management support to the trials unit in accordance with the current legislation (EU Clinical Trials Directive and ICH/GCP Guidelines).

Main responsibilities

- Maintain Investigator Site Files
- File trial documentation and maintain the filing systems.
- Assist in the randomising/registering patients for treatment and relaying the treatment allocation to the responsible clinician.
- Assist in the completion of CRFs of patients on long-term follow up in clinical trials. This will involve reviewing/extracting data from hospital case notes, completing appropriate CRF and ensuring all necessary data is collected and up-to-date.
- Assist in the follow up of Serious Adverse Events (SAEs) reports that occur in trial patients to the study sponsor as outlined in the protocol in their area of responsibility.
- Assist in answering queries that may be generated from the data collected within specified timelines. Clarification of the data must be discussed and signed by the clinician responsible for the study.
- Assist in the coordination of start up visits for new studies, ensuring all study personnel are in attendance (i.e. clinician, pharmacists, research nurses) and regulatory documentation is in place (i.e. normal ranges, CVs, GCP certificates, financial disclosures, local R&D approval documentation).
- Assisting with the archiving of study data, which involves sending, retrieving and maintaining the archived study records. The CTU has an archiving day every quarter and it is the responsibility of the CTA to ensure all staff are archiving according to the Unit's SOPs.
- Assisting with the retrieval of case records for the Clinical Trial Co-ordinators as and when required.
- Meeting doodles, distribution of meeting documents and minute taking.
- Support IT in the testing of computer validation checks on study data. This will involve entering of dummy data, generation of computer validation checks, checking the correct validation checks have been output and checking that the validation check message match the database management plan (DMP) for the form.
- Request overdue data and outstanding queries from sites.
- General office duties will include answering the telephone, photocopying, filing, faxing and any other duties necessary to help smooth the running of the trials unit