

Example 3

Assistant Trial Manager

Job purpose

The Assistant Trial Manager will assist the Trial Manager in the day to day management of the trial

Main responsibilities

- Act as a point of communication for the trial for the research team, recruiting sites and all other relevant bodies.
- Assist the trial manager in the development, implementation and update of the Trial Master File and version control of relevant study documents
- Develop a good knowledge of the trial protocol, to be able to respond to all queries or appropriately escalate
- Monitor and coordinate intervention supplies and intervention compliance under the direction of the trial manager
- Assist the trial manager with the planning and monitoring of trial recruitment, as appropriate
- Ensure site initiation visits are arranged, timely compilation of Investigator Site Files, Pharmacy Site Files and distribution of trial specific equipment is undertaken in a timely manner to prevent delay with a site recruiting.
- Perform study visits in accordance with the monitoring plan
- Assist in the coordination of Trial Management Group meetings, Trial Steering Committee meetings and Data Monitoring Committee meetings and take minutes as appropriate
- Distribute mailshots, newsletters and publications as directed by the trial manager
- Where needed, the Assistant Trial Manager may be called upon to help coordinate submissions of amendments for ethics and regulatory approval, annual progress reports by obtaining sponsor approval and sign off of such documents.
- Contribute to collaborative decision-making, planning and short and long-term objective setting
- Use initiative and creativity to resolve issues that might arise and identify issues that require onward reporting in liaison with the Trial Manager
- Assist in the creation of trial progress reports as required
- Assist in the recruitment and support of the participating trial sites, along with the monitoring of trial sites to problem solve and review source data where appropriate
- Collate and disseminate reported SAEs for review as requested by the Trial Manager, checking for missing or inconsistent data and querying sites, ensuring all events are followed up to resolution.
- Assist in the cleaning and preparation of data for visit reporting and analysis of study targets.
- Assist with testing of the trial database system for data entry and randomisation system for randomising participants. Onward report to the Trial Manager any missing, contradictory or incorrect data so that these problems are followed through to a satisfactory conclusion within a reasonable timescale.
- Coordinate and support the activities of the trial committees under the direction of the trial manager