Example 10
Trial Manager

Main responsibilities

- Act as the main point of communication for the trial for the research team, recruiting sites and all other relevant bodies.
- Develop, implement and update the Trial Master File and version control relevant study documents
- Develop an in-depth knowledge of the trial protocol, to be able to respond to all queries or appropriately escalate
- Monitor and coordinate intervention supplies and intervention compliance
- Plan and monitor recruitment of participants into the trial, identifying barriers and implementing strategies to improve recruitment.
- Initiate sites, ensuring all have the required documentation, appropriate approvals and an understanding of the protocol.
- In conjunction with the trial statistician and data manager, monitor data quality and assist with data cleaning, to achieve an accurate and complete dataset.
- Schedule and administer Trial Management Group meetings, Trial Steering Committee meetings and Data Monitoring Committee meetings and take minutes as appropriate
- Prepare and submit amendments for ethics and regulatory approval, annual progress reports, contribute to reports to funders and manage communications with the Sponsor organisation. Ensure appropriate contractual arrangements are in place and documents held on file.
- Plan and monitor financial aspects of the trial, including forecasting major expenses and identifying underspend or overspend.
- Produce promotional material and dissemination plans.
- Delegate any tasks as appropriate
- Work, where applicable, with the Chief Investigator, grant co-applicants, data managers, monitors, clinicians, statisticians and external agencies on a daily basis to ensure the project milestones are met
- Coordinate and produce relevant submissions to ethics and R&D committees in a timely manner
- Train and supervise other staff (internal and external) involved in data collection and data entry in the rules and procedures to be used, explaining the reasons/ principles behind them.
- Communicate the underlying medical and scientific rationale of the trial to a wide professional audience, to ensure participant recruitment meets targets
- Plan and organise mailshots, newsletters and publications
- 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 to the Chief Investigator

Example 10
Trial Manager

Main responsibilities

- Ensure that the trial protocol is conducted in accordance with the applicable ethical, regulatory and quality standards and that appropriate records and audit trails are maintained
- Prepare trial progress reports as required
- Identify, recruit and support the participating trial sites, along with other site staff. Monitor progress at each centre and take appropriate action to ensure milestones are met.
- Monitor trial sites to problem solve and review source data where appropriate
- Where appropriate, manage reported SAEs, checking for missing or inconsistent data and querying sites. Ensure reports are reviewed appropriately and sent to any key parties. Ensure all events are followed up to resolution.
- Set up processes for monitoring trial supplies and arranging distribution to sites, designing documents to capture accountability data.
- Work closely with sites to ensure timely data entry, cleaning and query resolution
- Assist with the design and testing of the trial database system for data entry. Perform regular systematic checks of information held on the trial database. Decide what steps need to be taken to correct any missing, contradictory or incorrect data and ensure that these problems are followed through to a satisfactory conclusion within a reasonable timescale.
- Ensure that the collection of trial data is complete, accurate and up to date for analysis according to agreed deadlines. Monitor online data entry, checking for inconsistencies, violations and adverse events.
- Coordinate and support the activities of the trial committees
- Undertake training as required for the post