Example 11
Project Manager

Main responsibilities

- Act as a member of project team, working with Medical Statisticians and Clinicians, to design and co-ordinate in-house clinical trials and research projects (regional, national or international). This includes assisting with the development and finalisation of the clinical trial protocol;
- Risk assess in-house studies from which the parameters of study management are set (e.g. agree level of monitoring that is required);
- Prepare and co-ordinate submissions for in-house trials to funding bodies. This primarily involves preparing a costing of the study running costs (staff and overheads) and NHS support costs that will be required to activate and deliver the trial;
- Responsible for costing, preparation, maintenance and budgeting of each project grant managed.
- Ordering of supplies for projects;
- Ensuring staff salaries are allocated from the correct budget;
- Annual reconciliation of budget, liaison with funder to provide proof of appropriate allocation of previous years funding and securing funding for the coming year;
- Preparation of regulatory submissions for the in-house studies (MHRA, Ethics and R&D) in liaison with Clinicians to ensure that the appropriate regulatory paperwork is in place;
- Oversee draft contracts and agreements
- Design of the data collection forms (case record forms (CRFs)) for in-house studies to ensure that all data required for the study endpoints and subsequent analysis is collected in a clear and concise manner;
- Write the database management plan (DMP) for the in-house studies. This includes a general outline of the data handling, data entry conventions, visual data checks, and specifying automated computer verification/validation checks on the data entered on to the database to ensure that the data has been collected in a consistent fashion and no data is missing;
- Putting together Clinical Trial Agreements with participating sites;
- Prepare, in association with the Clinical Trial Co-ordinator (CTC), the data completion guidelines for study CRFs;
- Generating publicity for in-house studies by attending relevant meetings and conferences (this can involve oral or poster presentations) and visiting clinicians to discuss prospective studies;
- Depending on study requirements, organise meetings of Trial Management Group, Data Monitoring Committee and Trials Steering Committee;
- Preparing newsletters and updates for studies as appropriate;
- Work closely with the study CTC to identify and solve any data management issues relevant to the study;
- Work closely with the study Clinical Trial Monitor (CTM) to solve any study issues arising from monitoring visits;