Example 8

Clinical Trial Manager

Main responsibilities

Trial initiation

- Prepare trial documentation e.g. protocols, trial guidance notes, risk assessments, electronic case report forms (eCRFs), and patient information sheets.
- Prepare regulatory, ethics and HRA submissions, under the guidance of the CTPM, and in collaboration with relevant members of the TMG.
- Ensure the required approvals and agreements are in place before the trial opens to recruitment.
- Set up trial specific procedures in accordance with SOPs to ensure the efficient management of the trial.
- Oversee the design and validation of the clinical study database and registration/randomisation system in liaison with Trial Statistician, IT Programmer, and Data Managers.
- Contribute to the successful launch of the trial including presentation at launch meetings.
- Plan and perform site initiation training via teleconference or face-to-face visits ensuring sites have all applicable documentation in place and that principal investigators and site staff understand the protocol and their responsibilities within the trial.

Trial management

- Oversee the day-to-day conduct of the trial at participating sites, providing support and advice and addressing any logistical issues as they arise.
- Liaise closely with the CI, CTU Lead, Statistician and other key members of the TMG to ensure on-going clinical, scientific and operational oversight.
- Chair and lead internal trial team meetings.
- Act as the principal point of contact for participating sites, sponsor(s), funder(s), pharmaceutical partners, regulatory authorities and the trial oversight committees.
- Organise regular meetings of the TMG, preparing the agenda and meeting papers, presenting updates during the meeting and producing minutes following the meeting in a timely manner.
- Organise and attend meetings of the trial oversight committees, preparing the agenda and meeting papers, and taking minutes as required.
- Develop monitoring plan and perform on-site monitoring visits to participating sites as required, to verify trial activities are compliant with the trial protocol, GCP and all applicable regulations.
- Ensure trial recruitment and retention are monitored and establish procedures for dealing with problems arising from any shortfall in collaboration with relevant members of the TMG.
- Update trial documentation as necessary e.g. protocols, trial guidance notes, case report forms (CRFs) and patient information sheets.
- Prepare and submit amendments to the REC approval/CTA under the guidance of the CTPM, and in collaboration with relevant members of the TMG.
- Draft regular progress and safety reports e.g. to funding bodies, TMG, Trial Steering Committee, REC, MHRA.
- Contribute to the preparation of abstracts, posters and manuscripts.
- Maintain quality control procedures for all aspects of trial conduct to ensure compliance with the principles of Good Clinical Practice, research governance standards and all applicable legislation (e.g. The Medicines for Human Use (Clinical Trials) Regulations, General Data Protection Regulation, Good Clinical Laboratory Practice, Human Tissue Act/Human Tissue Bill (Scotland)).
- Maintain the Trial Master File to ensure a clear audit trail of trial activities is retained.
- Facilitate any audit, inspection or progress visit processes required by regulatory bodies, or sponsor(s).

Example 8
Clinical Trial Manager

Trial promotion

- Liaise with participating sites and potential collaborators to promote trial recruitment.
- Draft and circulate regular newsletters.
- Plan, organise and give presentations at meetings of investigators/research nurses/trial coordinators as appropriate.
- Promote the trial at national scientific meetings developing presentation materials (slides/posters/flyers) as required.

Data management

- Develop the data management plan in liaison with the Trial Statistician, Data Managers and implement and oversee timely and efficient procedures for the collection, entry and verification of all patient data.
- Maintain record management systems for all trial material.
- Liaise with site staff to ensure trial procedures are being followed to promote the reporting of high quality data.
- Prepare data for interim and/or full analysis in collaboration with the trial Data Managers and Statistician.

Biological sample management

- Develop procedures for biological sample management (collection, tracking and shipment) in collaboration with the central laboratory.
- Develop procedures for biological sample reconciliation in liaison with the Data Managers and central laboratory team, under the guidance of the CTPM.

Staff management

- Supervise members of the in-house trial team, e.g. data managers and administrators, providing guidance, training and advice as required.
- Prioritise and allocate workloads within the trial team to ensure the trial is supported effectively and efficiently.
- Line manage members of the in-house trial team, where required, conducting annual appraisals to set objectives, review progress against objectives and identify areas for development.

New research initiatives

- Support the preparation of funding applications for new study proposals.
- Assist senior staff with site feasibility assessment for new studies.