



Job Title: Clinical Trials Coordinator
Grade: 6
Salary: £28,331 – £32,817 per annum
Department: Cardiovascular Sciences
Hours/Contract: Full Time, Fixed term contract for 18 months
Reference: 1113

Role Purpose

To carry out the day-to-day trial management activities within Cardiac Surgery Research in order to maintain the smooth and effective running of the clinical trials and research studies in accordance with protocols, ethics and regulatory approvals, SOPs, the principles of GCP, applicable EU Directives and UK legislation.

Main Duties and Responsibilities	% Time
<ul style="list-style-type: none"> To be a proactive contributing member of the multi-disciplinary team developing and running the clinical trials. This includes having an active involvement with production of the final or amended protocols and all associated documentation, and with obtaining national ethics and regulatory approvals for these, tracking and collating site approvals to grant the ‘green light’ for opening of trial sites, and maintaining the essential documents in the Trial Master File and on any remote data capture system as applicable. 	15%
<ul style="list-style-type: none"> To be the key contact for study conduct in the trials i.e, to provide training/initiation and ongoing troubleshooting guidance to research staff on the practical implementation of GCP and on trial related activities, to enable staff to carry out their duties and tasks in regard to the trials. This requires regular liaison with clinicians, data managers, research nurses, statisticians and other personnel, both in the UK and overseas, to ensure protocol and GCP compliance, and the collection, dissemination and reporting of information on the trials. 	20%
<ul style="list-style-type: none"> To contribute to the development and documentation of trial management tools and procedures, data collection form design and remote data entry systems to ensure quality and consistency of data recorded. To identify and incorporate ongoing improvement in data collection techniques, verification procedures and data quality. To undertake personally and/or to supervise site staff, assistant trial coordinators or data entry clerks carrying out data entry onto the trial database, and to ensure accurate and timely data collection by chasing and resolving queries. In consultation with the trial statistician, data managers and computing officers, develop and run trial specific quality control checks on the data to ensure accuracy and consistency on an ongoing basis and prior to analysis. 	40%
<ul style="list-style-type: none"> To track trial progress and financial expenditure and to provide status reports or datasets for approved requests, in consultation with the Chief Investigator and statistician or senior managers as appropriate. This will include data provision for governance and pharmacovigilance purposes, audits and inspections, DMC review, for presentation/discussion at trial related meetings, for updating of funders, for regular or ad hoc transfer to an international database, or for publication in reports and scientific papers. 	10%





<ul style="list-style-type: none"> To represent Cardiac Surgery Research at national and international trial meetings, to keep abreast of developments and provide updates on trial progress and related issues. 	5%
<ul style="list-style-type: none"> To participate as an active member of the trial team, to review and revise SOPs and working practices and to develop procedural documentation to support these. 	5%
<ul style="list-style-type: none"> To interact with patients in-person, and remotely, in order to undertake study-related procedures such as discussing the trial, collecting data, samples and follow-ups in accordance with the General Data Protection Regulation (GDPR) 	5%

Internal and External Relationships

Internal

- Regular interactions with data management and statistics, with trial administration and IT/database staff for ongoing trial management requirements.
- Liaison with other trial coordinators and with the Departmental Managers and QA Manager to define, develop and ensure consistency in procedures and adherence to SOPs.

External

- Daily phone and email contact with GP’s, investigators, research nurses and data managers in trial sites to ensure timely and accurate recording of trial data and to resolve data queries.
- Regular communications with Chief Investigators, Principal Investigators and clinicians from other specialist disciplines involved in the trial protocol.
- Contact with Remote Data Entry systems staff and facilitators to develop the eCRF and to record data and resolve queries throughout the trial.
- Participation in or giving a formal presentation at trial meetings with clinicians, statisticians and other trials staff to monitor the progress of ongoing trials and to contribute to the development of future trials.
- Presentations to the Patient and Public Involvement group (PPI)
- Potential liaison with NHS patients within the clinical trial
- Organisation and participation in trial Investigator Meetings to launch new trials and attendance at international meetings for collaborative trials as applicable. Organisation and participation in ongoing training days for trials staff

Planning and Organising

Providing Cardiac Surgery Research support to the Chief Investigator with the ethics, regulatory and funding applications, amendments and reporting requirements.

Proactive organisational management of the trial activities and ensuring central retention and site availability of essential documents. Defining and communicating best practice procedures to ensure optimal management and protocol and GCP compliance of the trials.

Checking of clinical trial data received to determine legibility, completeness and accuracy, entry onto the trials database, and generation of data queries for site staff. Taking decisions on the validation of trial data in consultation with data management / statistics.





Keeping abreast of the status and day-to-day developments within each trial, and forward planning and prioritisation of tasks and workload to ensure trial deadlines are met eg ensuring the required data and presentation materials are provided for national or international trial meetings or DMC review etc where decisions are made on the running of the trials.

Qualifications, Knowledge and Experience

Essential

Either

- Academic and vocational qualifications (science related degree or nursing qualification) plus relevant work experience in a similar role*

Or

- Broad vocational experience, acquired through a combination of job related training and considerable on-the-job experience, demonstrating development through involvement in progressively more demanding relevant work or roles*

Plus

- Experience of working with Standard Operating Procedures and a Quality Management System*
- Clear understanding of the standards and regulations required for the conduct and output for the role*

Desirable

- Familiarity with medical terminology*

Skills, Abilities and Competencies

Essential

- Ability of handling of confidential data
- Ability to demonstrate application of a range of IT skills (Word, Excel, PowerPoint, Outlook) as demonstrated in part by your application*
- Ability to demonstrate good organisational skills, flexibility, and evidence of accuracy and attention to detail. i.e. competence to multi-task and work under pressure to ensure deadlines are met, while maintaining focus, clarity and accuracy of information or data.
- Good communication skills (oral and written), ability to deliver formal presentations and informal training, and ability to work well with staff at all levels*.
- Good Clinical Practice certificate or commitment to obtain this
- Evidence of ability to work on own initiative and as a motivator or contributor in a team.*

Desirable

- Willingness to travel to meetings nationally and occasionally internationally

***Criteria to be used in shortlisting candidates for interview**





Criminal Declaration and Disclosure and Barring Service (DBS)

If you become an employee, you must inform your manager immediately, in writing, if you are the subject of any current or future police investigations/legal proceedings, which could result in a criminal offence, conviction, caution, bind-over or charges, or warnings.

This post is exempt from the Rehabilitation of Offenders Act 1974 because the appointee will have substantial access to young people and/or vulnerable adults. Therefore, an appointment to this post will be subject to checking through the Disclosure and Barring Service (DBS). The successful applicant for this post will, therefore, be required to give consent for the University to check and obtain appropriate clearance with the DBS for the existence and content of any criminal record in the form of a standard disclosure check.

Information received from the DBS and the police will be kept in strict confidence and will be destroyed once the University is satisfied in this regard.

Research Passport Requirements

Where it is determined that the duties of this post for the purposes of research involve work with the NHS, it is necessary to ensure that the performance of the duties attached to the post are covered by NHS indemnity arrangements and the appointee must comply with all such arrangements, including occupational health clearance.

VITAL

The University encourages all staff to live our [VITAL values](#) which are:
Valuing People, Innovators, Together, Accountable, Leaders.

Equality and Diversity

We believe that equality, diversity and inclusion is integral to a successful modern workplace. By developing and implementing policies and systems that challenge stereotypes across all aspects of our work, we have a culture that recognises and values the diverse contributions of our staff which benefits everyone. Our strong values of inclusivity and equality support our efforts to attract a diverse range of high quality staff and students, and identify our University as a progressive and innovative workplace that mainstreams equality, diversity and inclusion.

