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| Post Details | | Last Updated: 04/10/2021 | |
| Faculty/Administrative/Service Department | Faculty of Health and Medical Sciences Department of Clinical and Experimental Medicine | | |
| Job Title | Clinical Trial Manager | | |
| Job Family | Professional Services | Job Level | 4 |
| Responsible to | Clinical Project Manager | | |
| Responsible for (Staff) | Clinical Data Coordinator(s)/Assistant(s) | | |
| <u>Job Purpose Statement</u> | | | |
| <p>The post holder will ensure that clinical trials supported by Surrey Clinical Trials Unit (CTU) are effectively managed and that trial data is acquired effectively and efficiently to the appropriate Standard Operating Procedures (SOPs). This role supports the objectives of Surrey Clinical Trials Unit to successfully complete human clinical research studies by ensuring the accurate collection and reporting of study data.</p> | | | |
| <u>Key Responsibilities</u> | | | |
| This document is not designed to be a list of all tasks undertaken but an outline record of the main responsibilities (5 to 8 maximum) | | | |
| <ol style="list-style-type: none"> 1. Ensure that all parties involved in a trial hold a clear understanding of, and are in agreement with, their responsibilities in the conduct of a trial. 2. Maintain an exceptional working knowledge of, and ensure compliance with, UK law, Good Clinical Practice, applicable regulatory and legal requirements, and SOPs; developing and updating those procedures as required. 3. Assist in the production and/or collation of all documentation for ethical committee submission, regulatory submissions and all trial related documentation, including the maintenance of the site master file and subsequent archiving of documentation in accordance with GCP. Ensure the timely submission of data and other documents to the CTU and the necessary reports from the trial team to appropriate regulatory, ethical and funding parties. 4. Responsible for trial management (overview, direction, timelines, outcomes, Serious Adverse Event (SAE) reporting, trial recruitment and data monitoring, and reporting). 5. Preparing for, arranging and facilitating trial oversight meetings such as trial oversight committees, including trial management groups and trial steering committees. 6. Co-ordinate, arrange and prepare for site initiation meetings, trial specific training, monitoring, trial closure visits, audits/regulatory inspections and other trial related activities. 7. To oversee, and be responsible for, the quality and integrity of all trial documents, data and reports generated in the course of a trial through overseeing monitoring and quality control procedures to ensure compliance with UK law and appropriate regulatory requirements, including monitoring external sites that are responsible for trial related tasks. 8. Assist with the development, review and maintenance of the Quality management systems including SOPs and Working Instructions. <p>N.B. The above list is not exhaustive.</p> | | | |

All staff are expected to:

- Positively support equality of opportunity and equity of treatment to colleagues and students in accordance with the University of Surrey Equal Opportunities Policy.
- Work to achieve the aims of our Environmental Policy and promote awareness to colleagues and students.
- Follow University/departmental policies and working practices in ensuring that no breaches of information security result from their actions.
- Ensure they are aware of and abide by all relevant University Regulations and Policies relevant to the role.
- Undertake such other duties within the scope of the post as may be requested by your Manager.
- Work supportively with colleagues, operating in a collegiate manner at all times.

Help maintain a safe working environment by:

- Attending training in Health and Safety requirements as necessary, both on appointment and as changes in duties and techniques demand.
- Following local codes of safe working practices and the University of Surrey Health and Safety Policy.

Elements of the Role

This section outlines some of the key elements of the role, which allow this role to be evaluated within the University's structure. It provides an overview of what is expected from the post holder in the day-to-day operation of the role.

Planning and Organising

- The post holder will work within established processes and standard operating procedures with minimum day-to-day supervision in the organisation and delivery of work objectives. As a key member of the trial team the Clinical Trial Manager has responsibility for the planning, preparation, execution, and reporting of clinical trials. This includes responsibility for ensuring that clinical trials are conducted according to relevant regulatory guidelines and good clinical practice (GCP).
- There is scope for the post holder to apply judgement and initiative when managing their workload, including any medium-term priorities and when responding to any conflicting demands.
- With assistance from the Clinical Project Manager, they must have an understanding of the staffing, facility and equipment requirements of the clinical trial in order to effectively and facilitate the smooth operation of the clinical trial.
- As a Clinical Trial Manager, the post holder will be the first point of contact for any queries from trial sites and will have to have meticulous methods for coordinating and managing the communication between the necessary parties to ensure resolution of these.

Problem Solving and Decision Making

- The post holder is expected to provide advice and solutions to routine day-to-day problems within the specialist area in which they are familiar, such as project scheduling, training and competence of research staff and conduct of clinical trials. Resolution for these issues will usually be found through referring to their previous experience of similar problems or through making reference to and applying policies and procedures.
- When faced with new issues, the post holder is required to identify the nature of the problem or issue through analysis and to apply reasonable personal initiative and judgement (where past experience does not apply) to identify a suitable and timely resolution.
- The post holder is expected to refer more complex issues or those outside of the remit of their role to more experienced/senior colleagues including the Clinical Project Manager for guidance and direction, but in these cases they are expected to have a degree of involvement in finding and implementing resolutions to the case.

Continuous Improvement

- The post holder should be willing to undertake CPD to ensure that he/she remains up to date with developments and changes in legislation and regulations in the area of clinical trials.
- The post holder is expected to take a pro-active approach to review and evaluate work practices/materials in order to identify areas for improvement. This will include writing and assisting in the development and updating of Unit SOPs and Work Instructions to ensure compliance with GCP and governing law.

Accountability

- The post holder is required to liaise regularly with the Sponsor, Funder and Chief Investigator/ Principle Investigators (CI/PIs) to ensure they are fully briefed on trial status at all times. In addition, the Clinical Trial Manager is responsible for effectively communicating to Surrey CTU trial team, FHMS and other teams within the University on the trial's status; highlighting areas of resource concern and issues and actions relating to the ongoing status and successful completion of the project.

- The Trial Manager is responsible for the completion of regulatory forms; including Clinical Trial Authorisation (CTA) and research ethics submissions. Alongside the CI and trial team, the Clinical Trial Manager is expected to regularly report to the Research Ethics Committee (REC), Funders and regulatory authorities during the clinical trial including alerts relating to any protocol deviations or SAEs, in accordance with the timelines specified by UK law/ICH-GCP.
- This role is highly responsible and impacts significantly on the validity and integrity of clinical trial data, trial budgets and management.

Dimensions of the role

- The post holder may be responsible for line managing one or more Clinical Data Coordinator(s)/Assistant(s) with oversight from the Clinical Project Manager.
- Any issues relating to budgets and financial aspects of the trials will be referred to the Clinical Project Manager.

Supplementary Information

- As part of the role you may be required to travel within the UK and abroad
- All staff including the post holder will have a role in implementing the practices and collaborative culture which define the success of the essential clinical research functions housed within the Clinical Research Building and across the Department of Clinical and Experimental Medicine.

Person Specification This section describes the sum total of knowledge, experience & competence required by the post holder that is necessary for standard acceptable performance in carrying out this role.

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| Qualifications and Professional Memberships | | |
| Degree in Life Sciences or equivalent vocational qualifications plus a number of years' practical experience in a similar or related role(s) Or: Significant vocational experience, demonstrating development through the acquisition of appropriate professional or specialist knowledge | | Essential |
| Technical Competencies (Experience and Knowledge) This section contains the level of competency required to carry out the role (please refer to the Competency Framework for clarification where needed and the Job Matching Guidance). | Essential/ Desirable | Level 1-3 |
| Experience of working in a clinical trials research environment (ideally a CTU) | E | 2 |
| Comprehensive understanding of UK Clinical Trials Regulations, the European Directives on Clinical Trials and Good Clinical Practice (GCP) and the Department of Health's Research Governance Framework | E | 2 |
| Good working knowledge of MS Office, including Word, Excel, Outlook and PowerPoint and other database software used for managing clinical trials | E | 2 |
| Ability to coordinate the trial team to ensure the trial is managed professionally and effectively | E | 2 |
| Experience of developing trial documentation such as protocols, Case Report Forms (CRFs), trial reports and SOPs | E | n/a |
| Experience in the entry, cleaning and validation of clinical trial data | E | n/a |
| Experience of performing clinical trial on-site monitoring and dealing with pharmacovigilance | D | n/a |
| Special Requirements: | | Essential/ Desirable |
| Willingness to undertake CPD to ensure that he/she remains up to date with developments and changes in legislation and regulations in the area of clinical trials | | E |
| Core Competencies This section contains the level of competency required to carry out this role. (Please refer to the competency framework for clarification where needed). n/a (not applicable) should be placed, where the competency is not a requirement of the grade. | | Level 1-3 |
| Communication | | 3 |

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| Adaptability / Flexibility | 2 |
| Customer/Client service and support | 3 |
| Planning and Organising | 2 |
| Continuous Improvement | 3 |
| Problem Solving and Decision-Making Skills | 2 |
| Managing and Developing Performance | 1 |
| Creative and Analytical Thinking | 2 |
| Influencing, Persuasion and Negotiation Skills | 1 |
| Strategic Thinking & Leadership | n/a |

This Job Purpose reflects the core activities of the post. As the Department/Faculty and the post holder develop, there will inevitably be some changes to the duties for which the post is responsible, and possibly to the emphasis of the post itself. The University expects that the post holder will recognise this and will adopt a flexible approach to work. This could include undertaking relevant training where necessary.

Should significant changes to the Job Purpose become necessary, the post holder will be consulted and the changes reflected in a revised Job Purpose.

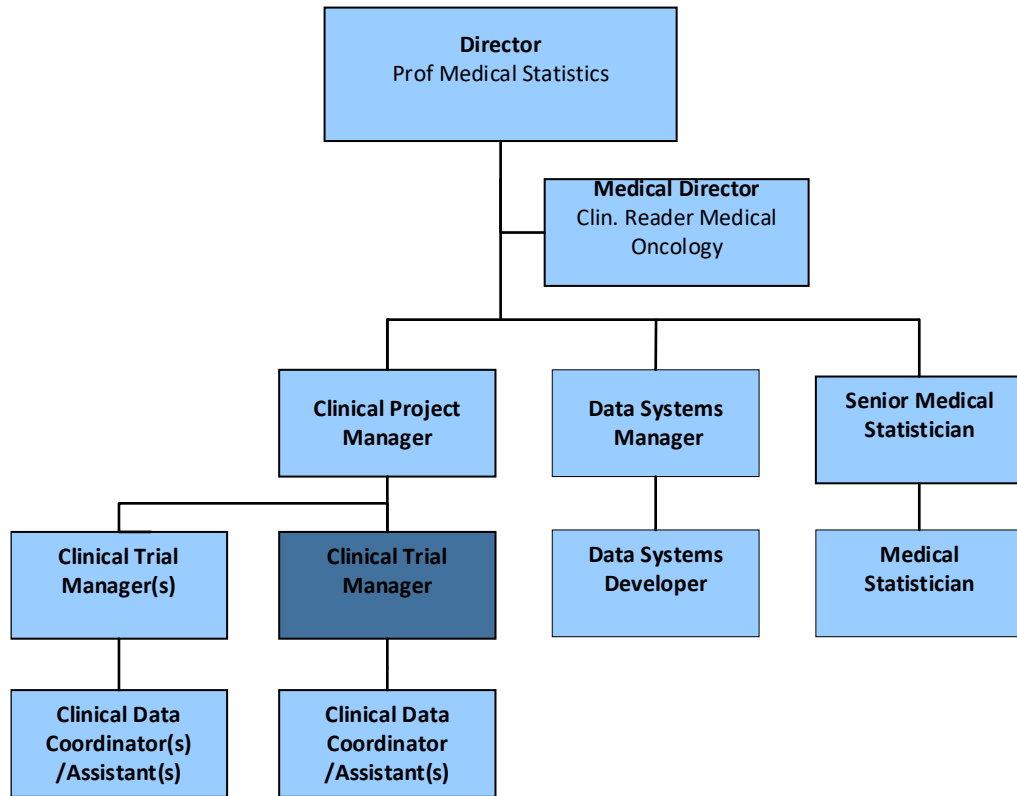
Organisational/Departmental Information & Key Relationships

Background Information

Surrey Clinical Trials Unit is a UK CRC registered CTU, with the expertise and infrastructure to design, develop, manage, analyse and report clinical studies through a core of academic, clinical, research, project and data systems/management staff and statisticians. The CTU is associated with the NIHR Research Design Service SE and works closely with Surrey Health Economics Centre to support the design and delivery of clinical trials and other well designed studies to the highest quality and to Good Clinical Practice (GCP) standards.

The CTU is co-located within the Clinical Research Building with Surrey Clinical Research Facility and Surrey Sleep Research Centre; synergistic units with skilled teams committed to excellence in clinical research and digital health innovation including in sleep/wake research.

Structure Chart



Relationships

Internal

- The Clinical Trial Manager is responsible to the Clinical Project Manager and ultimately to the Director of Surrey Clinical Trials Unit.
- They will liaise, communicate and build relationships with senior colleagues including senior staff in the University of Surrey other academic institutions.

External

- The Clinical Trial Manager is responsible ultimately to the Chief/Principal Investigator (CI/PI).
- They will liaise, communicate and build relationships with senior colleagues including senior staff in external academic institutions, ethics committees, regulatory bodies and NHS Trusts.