UNIVERSITY OF LEICESTER

Job Summary

Job Title: Trial Administrator
Grade: 4
Salary: £26,320 to £27,241 per annum
Department: Leicester Clinical Trials Unit (CTU)
Hours/Contract: Full-time, fixed term contract until 1.10.27
Job Family: Management and Administration
Reference: 14052

Role Purpose

To assist with the initiation, organisation and administration of one or more clinical trials supported by the Leicester Clinical Trials Unit (LCTU), working under the direction of CTU senior managers and the trial Chief/Principal Investigator. The post holder will be expected to work proactively as part of a wider team working closely with NHS clinical and academic staff to ensure the highest standards of research governance, and to deliver the trials on time and to budget. You will have trial management knowledge to assist with the smooth and effective running of the clinical trials and research studies in accordance with the study protocols, ethics and regulatory approvals, SOPs, the principles of GCP, applicable EU Directives and UK legislation.

Main Duties and Responsibilities

- Liaise with participating sites ensuring that the trial ISFs are maintained so that clinical trials are conducted in accordance with ethical and regulatory approvals of the protocol, with trial sponsor and CTU quality standards, ensuring all relevant records and audit trails are maintained.
- Provide day to day general secretarial and administrative support to a Senior Trial Manager/Trial Manager responsible for multi-centre RCTs ensuring tasks are completed to given deadlines.
- To be responsible for maintaining the essential documents in the Trial Master File (paper and electronic), ensure secure storage of the documentation and have an integral role in adverse event/SAE reporting.
- To be the key contact in the trial for study conduct, communicating with the study team often across different sites, support the activities of the trial management group, steering and data monitoring committees, including arrangement, agenda preparation and production of minutes.
- To assist the Senior Trial Manager/Trials Manager in documenting and managing of study budgets.

Internal and External Relationships

The post-holder is expected to deal effectively with a wide range of individuals including:

Internal

- Daily – Senior Trial Manager/Trial Manager to assist with management of clinical trials.
- Regular- trial management, IT and data management staff, administration and finance staff, and statisticians in the CTU.

External

- Daily – Chief/Principal Investigators and administrative, nursing, medical, academic and other support staff in the trial team, CRN and hospital Trusts, patients and study participants.
- Regular –administrative and senior members of organisations sponsoring and/or funding the trials including research charities and NHS organisations

Planning and Organising

Athena Swan Silver Award · Race Equality Charter Bronze Award · disability confident LEADER · LGBT+ 2020 - 2021 AWARDEE ORGANISATION · Stonewall DIVERSITY CHAMPIONS

- Assist the Senior Trial Manager/Trial Manager with the trial management in compliance with regulatory guidelines. Maintain up-to-date knowledge of regulatory, ethical and governance requirements and translate this into practical activities.
- Plan and prioritise own work for the week and the week ahead, responding to the work requirements of the line manager.
- Assist with the co-ordination of the trial through effective communication with research staff in trial sites and the networks, collaborators, the trial steering committee and other members of the trial team, representing the LCTU in a professional manner.
- Assist in the day-to-day running of the trial, following established standardised procedures that ensure compliance with the protocol and regulatory standards, monitoring compliance, and escalating issues/decisions as appropriate. A high degree of organisation with good attention to detail is required including high standards of accuracy and an ability to forward plan with prioritisation of tasks and workload to ensure trial deadlines are met.
- Assist in the monitoring of the trial budget, advising the LCTU Senior Trial Manager/Trial Manager of any cause for concern.

Qualifications, Knowledge and Experience

Essential

- Either academic or vocational qualifications (NVQ 2/3, 5 GCSE passes at grade C or above, City and Guilds or equivalents) plus work experience in a relevant role* OR Experience in trials administration in an academic or health-related role*
- Experience in clinical research*
- A working knowledge of the relevant ethical, legislative and research governance requirements relevant to clinical trials*
- An understanding of clinical research and trial methodology
- Experience of working with Standard Operating Procedures and a Quality Management System*

Desirable

- Experience of working in a clinical or research environment*.
- Experience of maintaining patient confidentiality when appropriate*.
- Experience of social media

Skills, Abilities and Competencies

Essential

- Excellent IT skills to include a working knowledge of Microsoft Office applications*
- Ability to prioritise workload, work accurately, and negotiate in order to meet deadlines*
- Excellent interpersonal skills
- Excellent written and oral skills*
- Ability to work effectively individually or as part of a team*
- Effective time management skills*

Desirable

- Willingness to travel to trial sites and to meetings.

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

Reason for Fixed Term Contract

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The reason for the fixed term contract is stated in section 1.9 in the summary of contractual terms in your contract of employment.

Criminal Declaration

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.

Supporting University Activities

As a University of Leicester citizen, you are encouraged to support key university activities such as clearing, graduation ceremonies, student registration and recruitment open days. We encourage all staff as citizens to work flexibly across the University if required. If supporting these activities is likely to affect your workload, please speak to your line manager in the first instance

University Values

Inclusive - We are diverse in our makeup and united in ambition. Our diversity is our strength and makes our community stronger.

Inspiring - We are passionate about inspiring individuals to succeed and realise their ambitions. We challenge our community to think differently, to get involved, and to constantly embrace new ideas.

Impactful - As Citizens of Change we will generate new ideas which deliver impact and empower our community

Freedom of Speech

The University is committed to upholding freedom of speech and academic freedom within the law throughout our recruitment processes. We ensure that all candidates are considered based on merit and suitability for the role, without regard to their lawful viewpoints or the expression of challenging or controversial ideas. Our recruitment policies and practices are designed to protect applicants from discrimination or adverse treatment on the basis of their opinions, and to foster an environment where open debate and diverse perspectives are valued as essential to our academic mission.

Equity and Diversity

We believe that equity, 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.