UNIVERSITY OF WARWICK

Job Description

Job Title	Clinical Trial Manager
Department	Warwick Medical School, Clinical Trials Unit
Grade	FA 6

Job purpose (a brief summary of the role)	To lead and manage clinical trials activity carried out within the Warwick Clinical Trials Unit (Warwick CTU). You will work collaboratively with clinical and academic staff to meet the highest standards of research excellence, governance, and efficiency, and ensure that our trials are delivered on time and to budget. Working as part of Warwick CTU, based within Warwick Medical School, the Clinical Trial Manager will conduct research as part of a multidisciplinary team, that strengthens Warwick's reputation locally, nationally, and internationally. The Clinical Trial Manager will achieve this by leading all areas of day-to-day clinical trial management and providing expert project management to ensure trial milestones and targets are achieved. Ensuring that our processes are continuously improved and refined to enhance trial performance and integrity, and our activity conforms to the UK Policy Framework for Health and Social Care Research. Excellent interpersonal and team working skills are essential, as you will be required to motivate and support the trial team, foster relationships and drive collaborative success with our partner organisations.
Duties and responsibilities	Key responsibilities include but are not limited to: 1.Adhere to clinical trial process, relevant legislation, and regulations to ensure compliance with Good Clinical Practice (GCP), Standard Operating Procedures (SOPs), General Data Protection Regulation (UK GDPR) and University policies and procedures. 2.To have a leading role in planning, managing, and delivering clinical trials, bringing project management and administrative expertise to the trial team. 3.Take responsibility for the preparation and submission for relevant clinical trial approvals and registration. 4.Supervision and line management responsibility of trial team and support staff. You will be responsible for managing your own workload and that of your team. 5.Fully implementing all aspects of changes and ensuring consistency across all trial documents. 6.Leading on trial set up and activation and establish procedures that ensure compliance with the protocol. Initiate sites ensuring that all have appropriate approvals and a good understanding of the requirements of the protocol. This may involve travelling to sites and providing training. 7.Be responsible for data management processes and in conjunction with the study statistician, monitor data quality to achieve an accurate and complete data set (adhering to UK GDPR). 8.Deliver training and perform monitoring activities remotely or in person which may involve potential travel to sites across the UK.

	9.Exhibit positive, supportive behavior to establish effective working relationships with all internal and external stakeholders, enabling a productive and collaborative environment. 10. Maintain regular contact with the chief investigator and CTU academic leads and act as the main communication source between funding, regulatory agencies, site staff and investigators. 11. Monitor recruitment into the trial, identifying barriers and implementing strategies for improving recruitment. 12. Oversee development and maintenance of trial master files and relevant site files for all participating centres / investigators to ensure all essential trial documentation is up to date and correctly filled. 12. Lead study oversight groups (such as TMG, TSC, DMC) by organising and facilitating meetings, providing accurate reports and documentation to committees, and following up on agreed actions. 13. In depth knowledge of trial protocol with ability to respond to all queries. 14. Coordinate intervention supplies and monitor intervention compliance. 15. Plan and monitor non-staff financial aspects of the trial forecasting expenditure such as site payments, travel and consumables. 16. Ensure appropriate contractual arrangements are in place, and terms are communicated and followed. 17. Use initiative and creativity to resolve issues that might arise and identify issues that require onward reporting to the Chief Investigator, Warwick lead and Senior Project Manager. 18. Display exemplary behaviours which align with, promote, and support the CTU and WMS values. 19. Be responsible for personal professional development by working towards completing the UKTMN competency framework.

Person Specification

The Person Specification focuses on the essential and desirable knowledge, skills, experience and qualifications required to undertake the role effectively. This is measured by (a) Application Form, (b) Test/Exercise, (c) Interview, (d) Presentation.

Essential Criterion No.	Essential Criterion Description	Measured by
E1	Educated to degree level or equivalent qualification.	A
E2	Significant and recent clinical trials management experience across the lifespan of a trial throughout the UK, working with sites to recruit to target.	A, C, & D
E3	Knowledge of International Conference on Harmonisation guidelines on Good Clinical Practice (ICH-GCP), the Medicines for Human Use (Clinical Trials Regulations 2004 (SI 2004/1031), Mental Capacity Act (2005), UK GDPR, Data Protection Act (2018) and UK Policy Framework for Health and Social Care Research.	A,B & C
E4	Excellent interpersonal skills with ability to foster relationships and communicate effectively with a range of people and using a variety of methods.	A & C
E5	Self-motivated, with the ability to motivate and develop others.	A & C

E6	Excellent planning, prioritisation, and organisation skills.	A & C
E7	Excellent project management skills, including the ability to prioritise workload and meet tight deadlines and work collaboratively with a team-oriented approach.	A,B & C
E8	Excellent standard of written and spoken English.	A & C
E9	Ability to maintain confidentiality and deal sensitively and effectively with staff, with previous supervision or line management experience	A & C
E10	Developed IT skills and the ability to use a broad range of computerised systems and data sources to support improved communications, information and data dissemination. Including experience of developing clinical trial data management systems.	A,B,C & D
E11	Ability to work accurately and methodically with excellent attention to detail.	A,B & C
E12	Ability to work effectively independently and cooperatively as part of a team.	A & C
E13	Willingness and flexibility to adjust to changing requirements in a dynamic environment.	A & C
E14	Proven ability to continually improve performance, and demonstrate excellent problem solving and decision-making skills.	A,B,C & D
E15	Demonstrate positive values and motivational behaviours which align with, promote and support the working environment.	A & C
E16	Willingness and ability to travel within the UK providing reasonable notice is given.	C

Desirable Criterion No.	Desirable Criterion Description	*Measured by*
D1	Experience of managing clinical trials of Investigational Medicinal Products (CTIMPS).	A & C
D2	Experience of successfully setting up and managing complex intervention trials testing multi-disciplinary interventions.	A & C
D3	Experience of managing and recruiting to cancer trials.	A & C