Swansea University
Prifysgol Abertawe

Job Description: CTIMP Trial & Data Manager

Faculty:	**Medicine, Health and Life Science**
Department/Subject:	**Data Science**
Salary:	**Grade 8: £39,355 to £45,413 per annum together with USS pension benefits**
Hours of work:	**Full time, 35 hours per week.**
Number of positions:	**1**
Contract:	**This is a fixed term position until 31st December 2026 due to external funding**
Location:	**This position will be based at the Singleton campus**

Introduction	This position is located within Swansea Trials Unit (STU), a UKCRC registered Clinical Trials Unit. The role requires a trial manager with substantial experience in clinical trial management. The successful candidate will coordinate a Clinical Trial of an Interventional Medicinal Product (CTIMP) and as such should have a thorough understanding of governance requirements and proven experience of clinical trial management in randomised trials.
Background Information	We are seeking a highly talented and enthusiastic researcher, with a broad skill set, to help manage funded STU studies that will include CTIMPs. The researcher will be responsible for day to day management of the study/ies which will involve liaising with the Chief Investigator, study sites, study funder and other personnel working on the studies (statistician, data managers, administrators, qualitative researchers etc). As such they must be organised and have excellent interpersonal and communication skills. They will be responsible for the administrative management of the study, for example maintaining Trial Master File and applying for appropriate governance approvals. They will also be required to develop and manage the trial database.
Main Duties	1. Work with the Chief Investigator, Senior Trial Manager, IT lead and Statistician to coordinate agreed processes for the development of the trial database and project documentation related to site set-up, participant recruitment, data collection and site closure. 2. Pro-actively contribute to and conduct research, including gathering, preparing and analysing data and presenting results, exhibiting a degree of independence in terms of specifying the focus and direction of that research. 3. Prepare reports, draft papers describing the results of the research, both confidential and for publication. The appointee is expected to be actively engaged in the writing and publishing of research papers, particularly those intended for publication in refereed (eg international) journals or comparable as a normal part of their role. 4. Be self-motivated, apply and use their initiative, aiming to determine suitable ways to tackle challenges and seeking guidance when needed. 5. Use creativity to analyse and interpret research data and draw conclusions on the outcomes. 6. Interact positively and professionally with other collaborators and partners within the Faculty, elsewhere in the University and beyond both in industry/commerce and academia.

	7. Contribute pro-actively to the development of external funding applications to support their own work, that of others and the Faculty and the Institution in general. The appointee will be expected as a normal part of their work to be actively engaged in writing, or contributing to writing such applications. 8. Contribute to Faculty organisational matters in order to help it run smoothly and to help raise its external research profile. 9. Keep informed of developments in the field in both technical and specific terms and the wider subject area and the implication for commercial applications and the knowledge economy or academia. 10. When requested act as a representative or member of committees, using the opportunity to extend their own professional experience. 11. Demonstrate and evidence own professional development, identifying development needs with reference to Vitae Researcher Development Framework particularly with regard to probation, performance reviews, and participation in training events. 12. Maintain and enhance links with the professional institutions and other related bodies. 13. Observe best-practice protocols in maintenance and retention of research records as indicated by HEI and Research Councils records management guidance. This includes ensuring project log-book records are deposited with the University/Principal Investigator on completion of the work
General Duties	14. To promote equality and diversity in working practices and maintain positive working relationships. 15. To conduct the job role and all activities in accordance with safety, health and sustainability policies and management systems, in order to reduce risks and impacts arising from the work activity. 16. To ensure that risk management is an integral part of any decision making process, by ensuring compliance with the University's Risk Management Policy. 17. Any other duties as agreed by the Faculty / Directorate / Service Area.
Person Specification	**Essential criteria:** 18. A good degree in a relevant subject or equivalent experience. 19. Evidence of working as a trial manager on randomised trials. 20. Evidence of project management skills and working to tight deadlines. 21. Understanding and experience of conducting research in the NHS. 22. Excellent communication skills. 23. Flexible approach to work and problem solving. 24. Understanding of governance requirements for NHS research and experience of applying for appropriate regulatory approvals. 25. Experience of producing project reports and drafting peer-reviewed publications. 26. Experience of clinical trials within the academic or private health sector. 27. Ability to work independently with minimal supervision. 28. Up to date Good Clinical Practice (GCP) training.

	29. Ability to work to strict Standard Operating Procedures (SOP) for trial management and willingness to review and contribute to the Quality Assurance (QA) processes of the unit such as auditing other projects **Desirable Criteria** 30. A PhD in a relevant area or equivalent relevant work experience. 31. Experience of working on CTIMPs, ideally in a trial manager role. 32. Experience of building and managing databases, preferably using REDCapTM software. 33. Evidence of supporting the writing of applications for external research funding. 34. A commitment to continuous professional development. 35. Relevant publication record.
Welsh Language Level	Level 1 – 'a little' - pronounce Welsh words. Able to answer the phone in Welsh (good morning / afternoon). Able to use very basic every-day words and phrases (thank you, please etc.). Level 1 can be reached by completing a one-hour training course. For more information about the Welsh Language Levels please refer to the Welsh Language Skills Assessment web page, which is available here.
Additional Information	Informal enquiries: Dr Claire O'Neill - c.b.c.oneill@swansea.ac.uk