JOB DESCRIPTION

Vacancy reference:	JT15105
Post Title:	Senior Clinical Trial Statistician
Grade:	Grade 7
School/Department:	Thames Valley Clinical Trials Unit (TVCTU)
Reports to:	TVCTU Executive Director
Responsible for:	(Junior) Clinical Trial Statistician(s)

Purpose

The Senior Clinical Trial Statistician will provide strategic statistical leadership for the newly established Thames Valley Clinical Trials Unit (TVCTU), working under the guidance of the Executive Director. The Senior Clinical Trial Statistician will be responsible for all statistical aspects of studies within the TVCTU trial portfolio, supporting the validation, analysis, reporting and publication of data collected for trials, and providing expertise in the design and set-up of future studies.

Main duties and responsibilities

- Provide statistical leadership within the newly established Thames Valley Clinical Trials Unit
- Work with the Executive Director, and other senior members of the CTU and partner organisations, to oversee and develop the TVCTU trial portfolio
- Develop links with academics and clinicians across the three partner organisations and externally, to support the development of new trials
- Be responsible for all statistical aspects in relation to the design of clinical trials, providing trial design consultancy, including reviewing available literature and defining the study question
- Support academics and clinicians with the preparation of high quality research proposals by providing expert input into clinical trial protocols, statistical analysis plans and development of data collection forms etc.
- Collaborate as a named co-applicant on funding applications to external funding bodies as appropriate
- Work with database programmers to set-up and maintain trial databases, and assist with development and testing of systems
- Provide sign off on case report forms and database build to ensure data are collected and stored to meet the requirements of statistical monitoring and analysis, and in line with relevant guidelines and legislation
- Lead in the development of appropriate randomisation systems for TVCTU clinical trials
- Be responsible for preparation of statistical analysis plans and the analysis of trial data
- Liaise with TVCTU colleagues during both recruitment and follow-up phases of trials ensuring projects adhere to relevant legislation and CTU SOPs, carrying out data quality checks of on-going studies and reviewing any changes proposed as trials progress.
- Act as Lead Statistician on Trial Management Groups and/or Steering Committees
- Prepare and present data analysis reports for the Data Monitoring Committee overseeing the clinical trials
- Collaborate with the Chief Investigator in producing trial reports for presentations, and in the preparation of high quality research publications arising from trials

- Promote the newly established TVCTU through high quality publications and presentations at conferences/events
- Develop and maintain standard operating procedures for statistical design and analysis, and other processes as required
- Understand and keep abreast of the regulatory and governance requirements relating to clinical trials, and assess the impact of any changes for the statistics team
- Maintain an expert knowledge of clinical trial methodology, ensuring new designs are implemented where appropriate
- Assist with training in research methods and statistics to CTU staff and researchers
- Work closely with members of the TVCTU, collaborating with the clinical and academic community from across the partner organisations and externally
- Support the delivery of clinical research in accordance with Good Clinical Practice (GCP) etc. and applicable University, NHS Trust and funder policies and procedures
- Contribute significantly to the day to day activities of the TVCTU as appropriate, and monitor the resource required to provide statistical support for the portfolio
- Provide line management, prioritisation and personal development for members of the statistics team as they are appointed
- Represent the TVCTU on external research or statistical groups and by attending relevant conferences
- Other duties as required

  Note:
  It may be possible to combine this role with a contribution to teaching on relevant undergraduate or postgraduate courses

Supervision received

The post reports to the Executive Director, who will ensure the job holder has a satisfactory amount and the right level of work. The job holder will also receive guidance from the Executive Director, or other senior members of staff as appropriate, on aspects of training etc.

Supervision given

(Junior) Clinical Trial Statistician (s) once appointed.

Contact

Internally: Colleagues within the TVCTU, including the Executive Director, and academics and clinicians from across the three partner organisations (University of Reading, Royal Berkshire Hospital Foundation Trust, and Berkshire Healthcare Foundation Trust).

Externally: Maintain and enhance close links with a range of relevant external stakeholders including funders, Research Design Service, regulatory bodies, trial management groups and data management committees, investigators from other institutions, the wider CTU community and commercial organisations.

Terms and conditions

This is a full- or part-time, fixed term, post (3 years in first instance with the expectation of extension by two years in the first instance).

This document outlines the duties required for the time being of the post to indicate the level of responsibility. It is not a comprehensive or exhaustive list and the line manager may vary duties from time to time which do not change the general character of the job or the level of responsibility entailed.

Date assessed:

PERSON SPECIFICATION

Job Title	School/Department
Senior Clinical Trial Statistician	**Thames Valley Clinical Trials Unit**

Criteria	Essential	Desirable
Skills Required	• Excellent communication skills, especially in communicating statistics to non-specialists • Confident team worker, able to recognise and take into account multiple perspectives • Excellent skills of consultation, collaboration and influence in order to engage effectively with internal and external stakeholders • Able to use IT systems and software appropriate to the role • Excellent data management skills • Adept at translating clinical problems so that appropriate statistical techniques can be applied • Excellent organisational skills, able to oversee multiple projects and prioritise appropriately • Able to work on own initiative with minimum supervision	• Project management skills
Attainment	• MSc in Medical Statistics or equivalent	
Knowledge	• Broad understanding of the clinical research environment • Excellent knowledge of clinical trial methodology and regulatory requirements. • Working knowledge of mainstream statistical analysis packages • Excellent knowledge of statistical modelling techniques, such as SAS • Knowledge of computer-based database management and data extraction/reporting techniques • Competent computer skills with Microsoft Office programs such as Excel	• Awareness of relevant funding opportunities • Knowledge of validation processes for clinical trial databases

Relevant Experience	• Significant experience of working as a statistician in a Clinical Trials Unit or equivalent • Experience of preparing research grant applications • Successful delivery of clinical trial support, with experience in trial design, analysis and reporting. • Strong track record of published research • Experience of working with researchers from different disciplines and health care professionals	• Line management experience
Disposition	• Highly motivated, purposeful and committed • Innovative, able to problem solve and be decisive • Methodical, practical with excellent attention to detail • Collaborative and consultative, yet decisive • Adaptable and resilient • Self-confident, diplomatic and courteous	
Other	• Willingness to learn new techniques and statistical methodologies, and undertake further training as appropriate • Willingness to travel within the UK	• Willingness to undertake some administrative tasks

Completed by:	Date: