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| Last updated: | 9th December 2019 |

**JOB DESCRIPTION**

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| Post title: | Senior Medical Statistician (Scientific Lead) | | |
| Academic Unit/Service: | Cancer Sciences, Southampton Clinical Trials Unit (SCTU) | | |
| Faculty: | Medicine |  |  |
| Career pathway: | Education, Research and Enterprise (ERE) | Level: | 5 |
| \*ERE category: | Research | | |
| Posts responsible to: | Associate Professor Medical Statistics | | |
| Posts responsible for: | Clinical Trials Unit Statisticians (level 4) | | |
| Post base: | Office-based | | |

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| Job purpose |
| To provide statistical leadership and oversight for a portfolio of studies/trials within the Clinical Trials Unit. The post holder will be responsible for all statistical aspects of clinical trials within the portfolio of studies. The post holder will supervise medical statisticians working on all aspects of the CTU clinical trials. The post holder will develop links with investigators throughout the UK to develop new trials and will develop novel statistical methods for translational studies associated with the SCTU trials. The role will provide statistical leadership for a portfolio of research including grant applications and the ability to anticipate and consider potential issues or opportunities, which could affect delivery and growth of the relevant portfolio. |

| Key accountabilities/primary responsibilities | | % Time |
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|  | Management and analysis of trialsLiaise with junior statistics staff and trial managers/clinical data coordinators to ensure completeness and correctness of data during both recruitment and follow-up phases of trials.  * To be responsible for writing, or oversee the writing of, statistical analysis plans which involve carrying out the interim and final analyses of the trial data ensuring compliance with relevant guidelines e.g. ICH Statistical Principles for Clinical Trials.  Provide reports and advice to the Trial Management Group for proactive intervention as necessary for example where trial accrual targets fall short or new clinical advances necessitates a change in recruitment strategy or study design.Undertake central statistical monitoring of data to assist audit and quality control.To be responsible for undertaking, or oversee the production of interim analyses for regular safety reports and submission to Independent Data Monitoring Committees.To be responsible for undertaking, or oversee the production of final analyses and compilation of reports for presentation and publication.Co-author papers reporting trials results.Disseminate clinical trials data and new methodologies through leading peer-reviewed national and international publications, conferences and newsletters to patient groups etc.Liaise and collaborate with trial managers and specialist advisors working on associated studies (e.g. assessing patients’ quality of life, health economics, and translational research).Undertake additional exploratory analyses.Attend trial-specific meetings including those for trial management groups and data monitoring and ethics committees for SCTU–managed trials.Line management of other statisticians, including oversight of their work and reviewing analyses and reports. | 35% |
|  | Initiation and design of trials  * Take a lead in methodological advances in clinical trial design and analysis at the SCTU, advising the Director of the SCTU of the most appropriate state-of-the–art designs and analysis to use in SCTU trials. Develop and oversee the application of innovative and creative methodologies for trial design and analysis.  Develop and define the study question as part of the trial Development Group. This will often include a review of the available literature and analysis of data available to date from other sources.Develop the trial protocol with the Protocol Development Group, particularly the statistical considerations of sample size and analysis strategy.Advise on the design of Case Report Forms and trial databases to ensure data are collected and stored to meet the requirements of statistical monitoring and analysis, and in line with relevant guidelines and legislation (e.g. Data Protection Act, EU Clinical Trials Directive, Research Governance Framework, ICH Statistical Principles for Clinical Trials, Good Clinical Practice).Liaise with potential investigators to ascertain likely levels of accrual.Collaborate as a named co-applicant in funding submissions to external grant awarding bodies and submissions to Research Ethics Committees. | 25% |
|  | To provide guidance to junior medical statisticians working on SCTU portfolio trials. | 20% |
|  | Scientific Leadership and portfolio development  * Through participation in the national clinical trials groups, develop/maintain a national profile in clinical trials methodology and conduct. * Work with the trial management portfolio lead to oversee the portfolio of clinical trials and shape the future trials portfolio bringing in new clinical trials through local and national collaborations. * For the allocated portfolio(s) working closely with the trial management portfolio lead to ensure oversight of performance metrics and that relevant issues are discussed with Heads of Groups, operational and finance staff as required. * To be the statistical lead for new trial development for the relevant portfolio. Working with the trial management portfolio lead to identify gaps in the portfolio and bringing in new relevant trials to the SCTU, taking responsibility for early discussions with potential investigators and working chief Investigators and trial development groups to support the development of trial proposals and grant applications. * To represent the SCTU, and the Director of SCTU, on national groups who have the remit of developing NIHR trials (e.g. NCRI Clinical Studies Groups and their subgroups). * Develop links with other CTU statisticians in the UK | 10% |
|  | Other dutiesSupport review of new requests for SCTU support as part of the SCTU trial review group  * To liaise regularly with the Head of Statistics to escalate issues of concern relating to overall SCTU strategy and/ or resource issues within the statistics group. To regularly meet with the other scientific leads and the Head of Statistics and SCTU directors as required to ensure the statistics group within the CTU work collaboratively across all portfolios. To deputise for the Head of Statistics when required.  Provide occasional consulting advice to clinical and scientific colleagues.Attend statistical and medical meetings both locally and elsewhere, as appropriate.Review and maintain working knowledge of the relevant standard operating procedures for the SCTU. Write SOPs for new statistical procedures as required. | 5% |
|  | Any other duties as allocated by the line manager following consultation with the post holder. | 5% |

| Internal and external relationships |
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| * National Cancer Research Institute (NCRI) Clinical Studies Groups; the post holder will be expected to sit on one or more of the NCRN cancer study group panels and to maintain links with the cancer research community. * NIHR CRN and UKCRC, to access support for research infrastructure and to maintain registered status of SCTU. * Principal Investigators and multi-disciplinary team members * Regulatory agencies – MHRA, R&D departments * Trial funders, including NIHR and Cancer Research UK * SCTU Clinical Trial Team (Clinical Trial Mangers, Co-ordinators, Data Managers and Data Officers) for day to day management and oversight of trial data * TSC / TMG / DMEC for specific trials * Collaboration with other clinical trials units * Liaise with other CTU statisticians nationally, particularly as part of the UKCRC Registered CTUs statistics working group and other Cancer Research UK core funded CTUs where appropriate |

**PERSON SPECIFICATION**

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| Criteria | Essential | Desirable | How to be assessed |
| Qualifications, knowledge & experience | PhD or equivalent professional qualifications and experience in statistics or another relevant discipline  Computer literate.  Familiar with one or more statistical packages (Stata, SAS, SPSS, Splus)  Knowledge of clinical trial methodology and regulatory requirements  Experience in the design, analysis and reporting of clinical trials  Growing and consistent national reputation in statistics or clinical trials or another relevant discipline  Track record of published research | Formal training in ICH-GCP  Experience of publishing papers in academic peer reviewed journals relevant to clinical trials work | Application and Interview |
| Planning & organising | Ability to identify priorities  Methodical, practical, with excellent attention to detail  Able to maintain judgement under pressure and meet deadlines.  Established organisational skills and ability to oversee a number of projects. | Consistently meets deadlines | Application and Interview |
| Problem solving & initiative | Innovative, able to problem solve and be decisive  Able to identify broad trends to assess deep-rooted and complex issues  Able to apply originality in modifying existing approaches to solve problems | Experience of novel statistical methodology development | Interview |
| Management & teamwork | To be able to work both independently and collaboratively with medical, scientific and technical staff  Able to manage, motivate and coordinate research team, delegating effectively. Able to formulate staff development plans, if appropriate  Able to undertake coordinating role in School/Department/university  Able to monitor and manage resources and budgets  Work effectively in a team, understanding the strengths and weaknesses of others to help teamwork development | Be willing to take some responsibility for day-to-day running of projects  Experience of management and supervision of others | Application and Interview |
| Communicating & influencing | Writing skills for drafting protocols, reports, funding applications and regulatory documents  Writing experience of academic papers | Able to communicate complex clinical trial information clearly to a range of staff groups and to potential investigators  Good communication with lay groups and potential study funders | Interview |
| Other skills & behaviours | Willingness to work within a regulatory framework |  | Interview |
| Special requirements | Willingness to travel  Flexibility |  |  |

**JOB HAZARD ANALYSIS**

**Is this an office-based post?**

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| Yes | If this post is an office-based job with routine office hazards (eg: use of VDU), no further information needs to be supplied. Do not complete the section below. |
| No | If this post is not office-based or has some hazards other than routine office (eg: more than use of VDU) please complete the analysis below.  Hiring managers are asked to complete this section as accurately as possible to ensure the safety of the post-holder. |

## - HR will send a full PEHQ to all applicants for this position. Please note, if full health clearance is required for a role, this will apply to all individuals, including existing members of staff.

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| **ENVIRONMENTAL EXPOSURES** | **Occasionally**  (<30% of time) | **Frequently**  (30-60% of time) | **Constantly**  (> 60% of time) |
| Outside work |  |  |  |
| Extremes of temperature (eg: fridge/ furnace) |  |  |  |
| ## Potential for exposure to body fluids |  |  |  |
| ## Noise (greater than 80 dba - 8 hrs twa) |  |  |  |
| ## Exposure to hazardous substances (eg: solvents, liquids, dust, fumes, biohazards). Specify below: |  |  |  |
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| Frequent hand washing |  |  |  |
| Ionising radiation |  |  |  |
| **EQUIPMENT/TOOLS/MACHINES USED** | | | |
| ## Food handling |  |  |  |
| ## Driving university vehicles(eg: car/van/LGV/PCV) |  |  |  |
| ## Use of latex gloves (prohibited unless specific clinical necessity) |  |  |  |
| ## Vibrating tools (eg: strimmers, hammer drill, lawnmowers) |  |  |  |
| **PHYSICAL ABILITIES** | | | |
| Load manual handling |  |  |  |
| Repetitive crouching/kneeling/stooping |  |  |  |
| Repetitive pulling/pushing |  |  |  |
| Repetitive lifting |  |  |  |
| Standing for prolonged periods |  |  |  |
| Repetitive climbing (ie: steps, stools, ladders, stairs) |  |  |  |
| Fine motor grips (eg: pipetting) |  |  |  |
| Gross motor grips |  |  |  |
| Repetitive reaching below shoulder height |  |  |  |
| Repetitive reaching at shoulder height |  |  |  |
| Repetitive reaching above shoulder height |  |  |  |
| **PSYCHOSOCIAL ISSUES** | | | |
| Face to face contact with public |  |  |  |
| Lone working |  |  |  |
| ## Shift work/night work/on call duties |  |  |  |