The London School of Hygiene & Tropical Medicine

The London School of Hygiene & Tropical Medicine is a world-leading centre for research and postgraduate education in public and global health. Our mission is to improve health and health equity in the UK and worldwide; working in partnership to achieve excellence in public and global health research, education and translation of knowledge into policy and practice.

Founded in 1899, the School has expanded in recent years at its two main sites on Keppel Street and Tavistock Place. Our staff, students and alumni work in more than 150 countries in government, academia, international agencies and health services. Research income has grown to more than £110 million per year from national and international funding sources including UK government and research councils, the European Union, the Wellcome Trust, Gates Foundation and other philanthropic sources. The School’s multidisciplinary expertise includes clinicians, epidemiologists, statisticians, social scientists, molecular biologists and immunologists, and we work with partners worldwide to support the development of teaching and research capacity.

Our education provision has expanded to more than 1,000 London-based Master’s and Research students, 3,000 studying postgraduate courses by distance learning, and 1,000 each year on short courses and continuous professional development. Our free online courses (Moocs) are studied by more than 30,000 participants globally.

The School performs well in various global university league tables. In the US News Best Global Universities Ranking 2017, we are ranked sixth in the world (together with Oxford University) in the fields of social sciences and public health. In the 2016 CWTS Leiden Ranking, the School was ranked fifth in the world for research impact across all disciplines, based on the share of institutions’ outputs within the top 1% of papers by citation in all areas of science and independent of size of output.

The School was named University of the Year 2016 by Times Higher Education, in recognition of our response to the Ebola epidemic. The School is a member of the M8 Alliance of Academic Health Centers, Universities and National Academies, the Association of Schools of Public Health in the European Region, and the Consortium of Universities for Global Health.

The Faculty of Epidemiology & Population Health (EPH) houses a large group of epidemiologists, demographers, statisticians and nutritionists working on issues of major public health importance in the UK and globally. EPH has approximately 400 staff members organised into four research departments.

- Department of Infectious Disease Epidemiology
- Department of Medical Statistics
- Department of Non-communicable Disease Epidemiology
- Department of Population Health

The Faculty has a teaching programme consisting of ten MSc courses: Epidemiology, Demography and Health, Medical Statistics, Public Health in Developing Countries (run jointly with the Faculties of Infectious & Tropical Diseases and Public Health & Policy), Nutrition for Global Health, Reproductive & Sexual Health Research, Veterinary Epidemiology (run jointly with the Royal Veterinary College), Global Mental Health (run jointly with Kings College London, Institute of Psychiatry) and the Distance Learning courses in Epidemiology and
Clinical Trials. The Faculty also has approximately 120 research students studying for an MPhil, PhD or DrPH degree. The Dean of Faculty is Professor John Edmunds.

**LSHTM CLINICAL TRIALS UNIT**

The Clinical Trials Unit (CTU) is a world renowned centre of excellence in the design, conduct, analysis and reporting of clinical trials and a fully registered unit with the UK Clinical Research Collaboration (UKCRC). The CTU is based within the Department of Population Health. It has a strong focus on clinical trial methodology, including methods for data monitoring, trial reporting, adaptive designs, non-inferiority trials, surrogate endpoints, multiplicity of data (eg subgroup analyses, composite endpoints, repeated measures) and methods for systematic reviews, and also conducts qualitative research into the views of trial participants. We bring to these processes extensive knowledge and practical experience of trial coordination, gained from holding a respected position within the clinical scientific community. To date, this has led to successful collaborations in many clinical fields, including cardiology, emergency care, adult and neonatal respiratory failure, liver disease and reproductive health.

The CTU specialises in the conduct of large international multi-centre trials. Examples include the MRC CRASH trial (10,000 patients with traumatic brain injury), the CRASH-2 trial (20,000 patients with traumatic bleeding) and the WOMAN trial (20,000 women with postpartum bleeding). There is experience in conducting phase II (eg international BRAIN trial), III and IV trials, a strong research focus on increasing participation in clinical trials, and an extensive programme of randomised trials of public health interventions (eg MRC txt2stop smoking cessation trial and the injury prevention trials). Additionally, we work in partnership with external Principal Investigators across the UK on many trials including ERICCA, REPAIR, PREVENTT, REVIVED, First Steps and Inclusive. The CTU works closely with clinical collaborators at every stage of a trial’s design and implementation. This includes the development of the clinical question and trial protocol, preparation of applications for funding and research ethics committee approval, all aspects of data collection and statistical analysis, and submission of results for publication.
THE POST

JOB DESCRIPTION

Post: Assistant Trials Manager
Responsible to: Haleema Shakur, CTU Director
Grade: PSP4

Core skills

The post holder will provide support to the CTU Directors and Trial Managers in all aspects of trial management. He/she will have a role in the development, co-ordinating and completing clinical trials, which are being conducted by the CTU. He/she will be an excellent communicator and have the ability to work as an integral part of the team. He/she will be able to demonstrate excellent organisational skills and have the intellectual ability to fulfil this job description. He/she will also be responsible for the day-to-day management of the trials and will work closely with the Chief Investigator and Trial Managers to ensure successful completion.

Responsibilities

- To play an active role in the conduct and management of studies conducted by the Clinical Trials Unit
- To take responsibility for the management of clinical trials where required
- Day to day trial management responsibilities will include:
  - Preparing Standard Operating Procedures (SOPs) and relevant guidance and work procedures
  - Preparing, monitoring and managing ethics committee applications and approvals
  - Preparing, monitoring and managing regulatory authority applications and approvals
  - Assessing the suitability of facilities at a study site
  - Ensuring that trial sites are compliant with GCP and Ethics Approval conditions
  - Setting up study sites ensuring that the trial materials are ready and available
  - Training investigators
  - Developing good working relationships with collaborators and National Co-ordinators worldwide
  - Monitoring the trials throughout their duration involving visiting the study sites
  - Reviewing and writing visit reports
  - Reviewing monitoring reports from trial monitors
  - Closing down study sites on completion of the trial/early withdrawal of sites
  - Communicating trial progress with a worldwide team of trial monitors, National Coordinators and Investigators
  - Overall responsibility to ensure the Trial Master File is maintained in accordance with trial operating procedures, collating, logging and filing trial documentation and reports as appropriate
  - Developing a comprehensive knowledge of the clinical trial protocols and other relevant documentation
  - Maintaining a working knowledge of current trial relevant SOPs and ICH GCP guidelines
  - Organising required documentation of indemnity with Sponsor
  - Covering Data Management as required; safety reporting and reconciliation of adverse events; assisting with data entry in accordance with relevant operating procedure; taking responsibility for the Data Management of clinical trials where required
  - Developing the academic and technical knowledge required to ensure the Clinical Trials Unit effectively detects, assesses, understands and prevents adverse effects or other possible drug related problems within their studies
PERSON SPECIFICATION

Essential qualifications and skills

The successful candidate must have:
  o An understanding of the scientific principles of randomised controlled trials
  o Experience using Microsoft Office suite software (Word, Access, Excel, PowerPoint)
  o Excellent written and oral communication and presentation skills
  o Excellent organisational skills
  o Ability to find innovative solutions to challenging situations
  o Commitment to working as part of a team
  o Ability to travel worldwide
  o Previous experience of working in a clinical trial in healthcare or commercial setting
  o Good understanding of ICH GCP

Desirable:
  o Undergraduate degree or equivalent nursing qualification

ASYLUM AND IMMIGRATION STATEMENT

The School will comply with the Immigration, Asylum and Nationality Act 2006, which requires all employees to provide documentary evidence of their legal right to work in this country prior to commencing employment. Candidates will be required to bring their passport (and visa if applicable) to interview so that it can be copied and verified.

This role does not meet the minimum requirements set by UK Visas and Immigration to enable sponsorship of migrant workers. Therefore we cannot progress applications from candidates who require sponsorship to work in the UK.

Further information about Certificate of Sponsorship and eligibility to work in the UK, can be found at: www.ukba.homeoffice.gov.uk/employers/points