ASSISTANT TRIALS MANAGER

Job Title:	**ASSISTANT TRIALS MANAGER**
Department:	Department of Population Health
Faculty:	Epidemiology and Population Health
Location:	Keppel Street, London
FTE:	1.00
Grade:	Grade 4 PSP (£28,751 to £32,705)
Reports to:	CTU Directors
Accountable to:	Haleema Shakur-Still & Prof Ian Roberts
Responsible for:	N/A
Job Summary:	The post holder will provide support to the CTU Directors and Trial Managers in all aspects of trial management. They will have a role in the development, coordinating and completing clinical trials, which are being conducted by the CTU. They will be an excellent communicator and have the ability to work as an integral part of the team. They will be able to demonstrate excellent organisational skills and have the intellectual ability to fulfil this job description. They 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.

GENERAL INFORMATION

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 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 Centres, Universities and National Academies, the Association of Schools of Public Health in the European Region, and the Consortium of Universities for Global Health.

FACULTY INFORMATION

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.

CLINICAL TRIALS UNIT INFORMATION

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 portfolio of duties outlined below will vary in accordance with the detailed expectations of the role (attached), which may be varied from time to time, and agreed at your annual Performance and Development Review (PDR).

Principal Duties and Responsibilities *(Examples***)**

- 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

GENERAL

All academic staff are free within the law to question and test received wisdom, and put forward new ideas and controversial or unpopular opinions, to enable the School to engage in research and promote learning to the highest possible standards.

All staff at LSHTM are also expected to:

1. Act at all times in the School's best interests;
2. Treat School staff, students and visitors with courtesy and respect at all times;
3. Comply fully with School policies, procedures and administrative processes relevant to the role, including when acting as Principal Investigator, accepting academic, managerial, financing and ethical responsibility for a project
4. Uphold and support the School's values (as set out in the School Strategy document);
5. Act as ambassadors for the School when hosting visitors or attending external events.

The above list of duties is not exclusive or exhaustive and the role holder will be required to undertake such tasks as may reasonably be expected within the scope and grading of the role.

Role descriptions should be regularly reviewed to ensure they are an accurate representation of the role.

[JAN 2017]

PERSON SPECIFICATION

This form lists the essential and desirable requirements needed by the post holder to be able to perform the job effectively.

Job Title: Assistant Trials Manager
Department of Population Health – Clinical Trial Unit

Essential qualifications and skills

The successful candidate must have:

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

Desirable:

- Undergraduate degree or equivalent nursing qualification

SALARY AND CONDITIONS OF APPOINTMENT

The post is available immediately and is initially funded for 12 months, with potential for extension. The salary will be on the Professional Support scale, Grade 4, in the range £28,751 to £32,705 per annum inclusive.
The post will be subject to the LSHTM terms and conditions of service. Annual leave entitlement is 30 working days per year, pro rata for part time staff. In addition to this there are discretionary "Director's Days". Membership of the Pension Scheme is available.

APPLICATIONS

Applications should be made on-line via our website at http://jobs.lshtm.ac.uk. Applications should also include the names and email contacts of 2 referees who can be contacted immediately if shortlisted. Online applications will be accepted by the automated system until 10pm of the closing date. Any queries regarding the application process may be addressed to jobs@lshtm.ac.uk.

The supporting statement section should set out how your qualifications, experience and training meet each of the selection criteria. Please provide one or more paragraphs addressing each criterion. The supporting statement is an essential part of the selection process and thus a failure to provide this information will mean that the application will not be considered. An answer to any of the criteria such as "Please see attached CV" will not be considered acceptable.
Please note that if you are shortlisted and are unable to attend on the interview date it may not be possible to offer you an alternative date.

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.

Date compiled: March 2017