DATA ASSISTANT – CLINICAL TRIALS UNIT

Job Title: DATA ASSISTANT – CLINICAL TRIALS UNIT
Department: POPULATION HEALTH
Faculty: EPIDEMIOLOGY AND POPULATION HEALTH
Location: KEPEL STREET, LONDON
FTE: FULL TIME - 35 HOURS
Grade: PROFESSIONAL SUPPORT GRADE 3
Accountable to: PROJECT DIRECTOR, DR HALEEMA SHAKUR-STILL

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 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 for Development (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, Clinical Trials and Demography and Health. 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

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 (15,000 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). 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. Overall, the School currently manages 90+ trials around the world, in a range of interventions such as investigational medicinal products (IMPs), nutritional and macronutrient studies, public health and behavioural interventions, surgery and medical devices. More information about the CTU can be found at ctu.Lshtm.ac.uk.
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JOB DESCRIPTION

Main Activities and Responsibilities

- To assist the DM with testing and documentation of the trial management systems in line with written procedures
- To ensure that all trial documents are handled and stored in accordance with Standard Operating Procedures (SOP) and observing Data Protection regulations
- To track receipt of all data documents using electronic and manual systems
- To enter data on the data management systems
- To assist the DM in checking that data entered by third parties are valid, in accordance with SOPs
- To assist the DM with data query resolution, in accordance with SOPs
- To collate data to produce simple statistics
- To liaise on a daily basis with trial collaborators regarding data matters, by email or verbally under the DM’s supervision
- To prepare and dispatch materials needed for site visits by the trial team
- To prepare and send mailshots using MS Word
- To assist with other administrative tasks as required
- To contribute to team meetings
- To undertake any other task required by the data manager or the CTU directors, commensurate with the level of the role

GENERAL

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's Strategy);
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.
GENERIC DUTIES AND RESPONSIBILITY OF ALL LSHTM EMPLOYEES

1. This job description reflects the present requirements of the post but may be altered at any time in the future as duties and responsibilities change and/or develop providing there is full consultation with the post-holder.

2. The post-holder will carry out any other duties, tasks or responsibilities as reasonably requested by the line manager, Dean of Faculty, Head of Department or Directors of Professional Services.

3. The post holder will be responsible and accountable for ensuring all School policies, procedures, Regulations and employment legislative requirements are adhered to including equality and diversity and health and safety.

4. This job description is not a definitive or exhaustive list of responsibilities but identifies the key responsibilities and tasks of the post holder. The specific objectives of the post holder will be subject to review as part of the individual annual performance review (appraisal) process.
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**Person specification**
This form lists the essential and desirable requirements needed by the post holder to be able to perform the job effectively.

Applicants will be shortlisted solely on the extent to which they meet these requirements.

**Essential:**
- Proven recent relevant office experience
- Good IT skills, including proven proficiency in MS Word and MS Excel
- Experience of using email and internet
- High degree of accuracy and the ability to pay close attention to detail and presentation
- Organised approach with the ability to prioritise work in order to meet deadlines
- Excellent numeric skills
- A flexible approach to work responsibilities
- Excellent communication skills (both written and oral)
- Ability to work as an effective member of the team

**Desirable:**
- Experience of data handling in a clinical trial environment
- Proven knowledge of the Data Protection Act of 1998

Essential: Requirement without which the job could not be done
Desirable: Requirements that would enable the candidate to perform the job well

**SALARY AND CONDITIONS OF APPOINTMENT**
The post is available full-time and available immediately. The post will be available as a fixed-term contract and is funded for 12 months from the start date in the first instance. The salary will be on the LSHTM Professional Support Pathway Grade 3 scale, in the range £24,761 to £28,053 per annum (inclusive of London Weighting). 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.

**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](http://www.ukba.homeoffice.gov.uk/employers/points)

Date compiled: October 2017