JOB DESCRIPTION

Job Title: Clinical Trials Data Assistant
Department: Medical Statistics
Faculty/Professional Service: Epidemiology and Population Health
Location: Keppel Street, London
Reports to: Data Manager
Responsible for: n/a
Full Time/Part Time/Casual: Full-time
Hours *(if less than full time):*
Grade: 3
Overall Purpose of the job: The post holder will support the Data Manager(s) and play a key role in the day-to-day Data Management aspects of clinical trials being conducted by the Clinical Trials Unit. The post holder will work closely with the Data Manager and Assistant Data Manager. Liaising with the trial team(s) on day to day to basis is expected. The Clinical Trial Administrator is a crucial member of the clinical trials team and key to supporting the coordination and management of new and on-going trials. The current CTU portfolio includes: CRASH-4 funded by JP Moulton Charitable Foundation/NIHR, WOMAN-2 Programme jointly funded by the Bill & Melinda Gates Foundation and Wellcome and Transform /IM-WOMAN, funded by Unitaid.

General Information

The London School of Hygiene & Tropical Medicine (LSHTM) is one of the world's leading public health universities.

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.

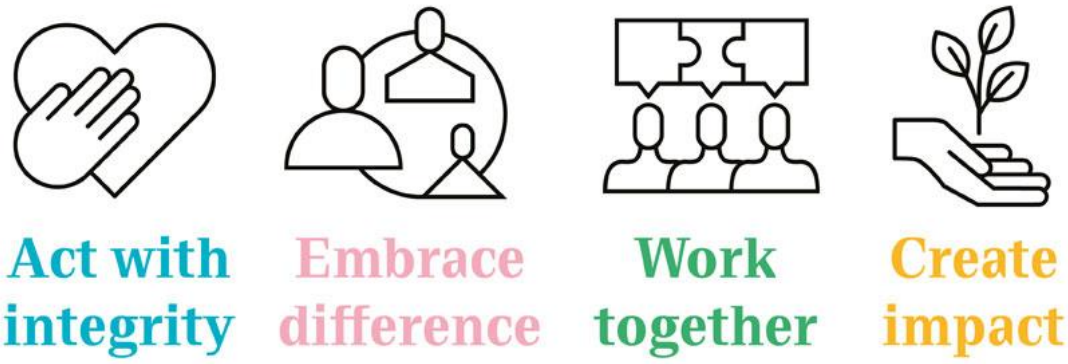
Staff and students are committed to helping create a more healthy, sustainable and equitable world for everyone, because we believe our shared future depends on our shared health.

We embrace and value the diversity of our staff and student population and seek to promote equity, diversity and inclusion as essential elements in contribution to improving health worldwide. We believe that when people feel respected and included, they can be more creative, successful, and happier at work. While we have more work to do, we are committed to building an inclusive workplace, a community that everyone feels a part of, which is safe, respectful, supportive and enables all to reach their full potential.

To find out more please visit our Introducing LSHTM page.

Our Values

Our values establish how we aspire to achieve our mission both now and in the future - demonstrating what it means to work and study at LSHTM. Please visit our LSHTM Values page for further information.



FACULTY/DEPARTMENT 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 employs approximately 560 people in five research departments.

- Department of Infectious Disease Epidemiology & Dynamics
- Department of Infectious Disease Epidemiology & International Health
- Department of Medical Statistics, which includes the Clinical Trials Unit
- Department of Non-communicable Disease Epidemiology
- Department of Population Health

The Faculty has a postgraduate teaching programme including eleven intensive MSc courses: Epidemiology, Demography and Health, Medical Statistics, Health Data Science, Public Health for Development (jointly with Faculties of Infectious & Tropical Diseases and Public Health & Policy), Nutrition for Global Health, Global Mental Health (jointly with Kings College London, Institute of Psychiatry), Reproductive & Sexual Health Research, Sexual & Reproductive Health Policy and Practice (online), Veterinary Epidemiology (run jointly with the Royal Veterinary College) and Climate Change and Planetary Health. There are also three distance Learning MSc courses: Epidemiology, Clinical Trials and Demography in Health. The Faculty also has approximately 240 research students studying for an MPhil, PhD or DrPH degree.

The Dean of Faculty is Professor Elizabeth Allen.

OUR TEAM INFORMATION

We are based within the Department of Medical Statistics and are part of the Clinical Trials at the largest school of public health in Europe. We work with a global network of collaborators from over 50 countries supporting trial coordinating centres in Pakistan, Nigeria and Tanzania.

We have a strong focus on clinical trial methodology, including methods for central 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.

Our special interest is in the conduct of large international multi-centre trials, and have an international reputation for practice changing clinical trials, especially in the area of trauma and emergency care. 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), CRASH-3 trial (12,737 patients with traumatic brain injury), HALT-IT trial (12,000 patients with gastrointestinal bleeding).

Our portfolio of work includes Phase 1, 2 and 3 trials and on improving the efficiency of trials to improve quality, reduce cost and to reduce our carbon footprint, including trial design, recruitment and retention for trials, monitoring efficient ways of conducting clinical trials. We work on finding novel ways of communicating the work we do to clinicians, policy makers and the wider public to make sure patients benefit from the results of our research.

Our mission is to provide valid and reliable answers to important public health questions and to use the answers to improve health and health equity in the UK and worldwide.

Main Duties and Responsibilities

Communications

- To assist Data Manager(s) in checking and identifying problems with trial data received from hospitals worldwide;
- To liaise with site investigators and the trial team(s) to resolve data issues under the supervision of the Data Manager(s) and in line with written procedures;
- To provide guidance to site investigators on how to complete relevant forms and use the Data Management Systems, in line with written procedures and guidance documents;
- To attend and contribute to data and trial meetings, and any other CTU relevant meetings, as required;

Teamwork and Motivation

- To work under the supervision of Data Manager(s) to conduct data entry, data review checks and query management of trial data, in accordance with written procedures;
- To raise/escalate any data concerns with the Data and Trial teams as needed;
- To collate data from the trial database as needed;
- To assist with review of the data quality, and with completing actions that arise from Data Quality Control checks;
- To acknowledge data received from investigators, and provide encouragement and motivation for recruitment and data collection, e.g. when recruitment milestones are met;

Liaison and Networking

- To maintain good relationships with investigators and other trial personnel through regular contact (email, videocalls and telephone) to support data collection for the trial(s). Investigators are based at sites worldwide and so a high level of coordination will be required to schedule calls considering schedules and time zones;

Service Delivery

- To enter data on the Data Management Systems in line with written procedures and guidance from the Data Manager;

- To conduct checks of all data received by site investigators in line with written procedures, to ensure compliance with the trial protocol and data collection guidance;

- To assist the Data Manager(s) with getting data queries resolved, in accordance with written procedures;

- To assist the Data Manager(s) in handling and storing data and relevant documentation in line with written procedures, Good Clinical Practice (GCP) and General Data Protection Regulation (GDPR);

- To assist the Data Manager(s) in the testing and documentation of the trial and Data Management systems, in line with written procedures;

- To assist Data Manager(s) with entry and follow-up of adverse event data, raising and following up on queries as necessary;

- To help Data Manager(s) in drafting Data Management Plans (DMP), Working Practice Documents (WPDs) and other related procedures, commensurate with the level of the role;

- To undertake any other task required by the Data Manager(s) or the CTU Directors, commensurate with the level of the role;

Decision Making

- Using written procedures to identify data issues e.g. misunderstanding by trial sites, falsification, repeated problems and bring them to the immediate attention of the Data Manager;

Planning and Organising

- To assist the Data Manager(s) in ensuring all data and documentation are readily accessible for independent audits and inspections;

- To assist the Data Manager(s) in ensuring data is handled and processed in line with the given time frames as detailed in written procedures;

- To monitor the trial email inboxes relevant to data and directing any enquiries to the correct team member in a timely manner;

- To contribute to the development and implementation of procedures to improve the accuracy and completeness of data collected, commensurate to the level of the role;

Initiative and Problem Solving

- To use initiative to help identify data collection and/or protocol compliance issues during data checks, and bringing any issue to the immediate attention to Data Management and/or Trial Management Group;
- To work with trial sites to resolve queries and problematic data under the supervision of Data Manager(s), in line with written procedures, as required by the role;
- To attend and contribute to trial meetings, and other CTU relevant meetings, as required;

Analysis and Research

- To assist Data Manager(s) in identifying potential problems regarding data collection in adherence with the trial protocol;
- To collate data from the trial database (s) to produce simple summary statistics;
- To handle data in line with relevant regulations, and Good Clinical Practice (GCP) and General Data Protection Regulation (GDPR) training;

Sensory and Physical demands

- To work using computers in different Data Management Systems/Databases, as required;
- To communicate with investigators via email, telephone or videoconference, as necessary;
- To handle and store all data and corresponding communications either electronically or in paper form as per written procedures;
- To file important trial documents in the Trial Master File (TMF) and assist with archiving as per written procedures;

Work Environment

- To work in a number of different electronic systems/databases, as required;
- To attend weekly trial, and data team meetings, as required;

Pastoral Care and Welfare

- To contribute to team meetings and other CTU relevant meetings;

• To collaborate as a member of the Data Team, and support other team members in any tasks that are commensurate to this role;
Team Development • To support the CTU team in accessing and using the data management systems, under the supervision of the Data Manager;
Other • To adhere to Faculty and School policy and procedures at all times; • To show awareness and consideration of other roles in the department • To demonstrate continuous professional development by acquiring relevant skills and competencies e.g. keeping up to date with changes in procedures/regulations, attending relevant training; • To contribute to general activities of the Department and School that help to promote the objectives of the school;

Generic duties and responsibilities of all LSHTM employees

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 consultation with the post-holder.

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 Head of Professional Service.

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

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 Performance and Development Review (PDR).

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.

Competency	Evidence	E / D
Education, Qualifications and Training	• Undergraduate degree in relevant subject or equivalent relevant experience	E
Experience	• Proven relevant data management experience in regulated clinical trials	E
	• Experience of handling personal data and/or ICH Good Clinical Practice (GCP)	E
	• Experience using different software to assess data quality and present data in a usable format	E
	• Experience of using/drafting Data Management plans, Work Procedures and Standard Operating Procedures	E
	• Experience of data quality control procedures	E
	• Experience of processes needed for developing a clinical trial database	D
Knowledge	• Knowledge on the regulatory governance of Data Management in clinical trials including ICH/GCP guidelines	E
	• Good understanding of clinical trials terminology and the scientific principles of randomised controlled trials	E

	• Knowledge of clinical trial processes and ICH/GCP guidelines	E
General	• Excellent written, oral communication and numeric skills	E
	• Excellent organisational skills and ability to prioritise to meet deadlines and be adaptable when faced with changing organisational priorities	E
	• High degree of accuracy and the ability to pay close attention to detail and presentation	E
	• Proficient in the use of the Microsoft Office suite of products, including Word, Excel, PowerPoint, IT skills, Outlook and the Internet	E
	• Excellent interpersonal skills and the ability to work effectively and flexibly in teams and with a wide range of varying stakeholders	E
	• Strong focus on quality of work	E
	• Commitment/ability to work as an effective member of the team	E
	• Strong general administrative skills, and relevant office experience	E
	• Ability to have a flexible approach to work responsibilities, and adaptable when faced with changing organisational priorities	E

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

Date compiled: April 2024

Salary and Conditions of Appointment

The post is fixed term is for 12 months and full-time, 35 hours per week 1.0 FTE. The post is funded by Unitaid and is available immediately. The salary will be on the Professional Services salary scale, Grade 3 in the range £28,614 - £32,307 per annum pro rata (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 “Wellbeing Days.” Membership of the Pension Scheme is available.

LSHTM has a Hybrid Working Framework, which alongside agreed service requirements, enables teams to work more flexibly (if the role allows), promoting a greater wellbeing and work/life balance.

Application Process

Applications should be made on-line via our jobs website. Applications should also include the names and email contacts of 2 referees who can be contacted immediately if appointed. Online applications will be accepted by the automated system until 10pm of the closing date. We regret that late applications cannot be accepted. 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”, “Yes” or “No" will not be considered acceptable and will not be scored.

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

LSHTM will comply with current UKVI legislation, 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 email a copy of their passport (and visa if applicable) to HR prior to their interview and if appointed will be asked to bring the original documents in to be copied and verified before their start date.

This role does not meet the minimum requirements set by UKVI to enable sponsorship under the skilled worker route. Therefore we cannot progress applications from candidates who require sponsorship to work in the UK.