JOB DESCRIPTION

Job Title: Clinical Trials Assistant
Department: Clinical Trials Unit within the Department of Medical Statistics
Faculty/Professional Service: Epidemiology and Population Health
Location: Keppel Street, London
Reports to: Danielle Beaumont, Senior Trials Manager
Responsible for: N/A
Full Time/Part Time/Casual: Full-Time
Grade: 3
Overall Purpose of the job: To play a key role in our current programme of clinical trials. This is a clerical role and excellent organisational and clerical skills are required, with attention to detail an absolute must. Work will also include assistance with the trial data. The team consists of a group of enthusiastic and committed people with responsibilities for trial management, data management and administration. The post-holder will work closely with the Trial Managers and the CTU Directors and will make a significant contribution to the successful completion of the trial.

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.

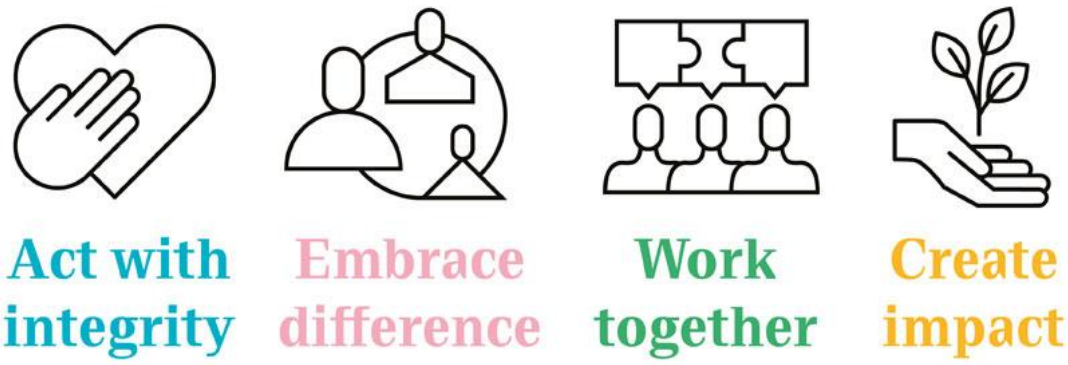
Staff and students are committed to helping create a more healthy, sustainable and equitable world for everyone, because we believe our shared future depends on our shared health.

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 two distance Learning MSc courses: Epidemiology and Clinical Trials. The Faculty also has approximately 220 research students studying for an MPhil, PhD or DrPH degree.

The Dean of Faculty is Professor Elizabeth Allen.

CTU INFORMATION

The CTU comprises 50 academic and professional services staff who are specialists in all aspects of the planning, co-ordination, data management, statistical analysis and reporting of clinical trials.

The CTU also has expertise in IT systems and infrastructure and software development to ensure that the complex needs of trials are well served.
The CTU is accredited by the UK Clinical Research Collaboration and has expertise in a range of topic areas, notably trauma and emergency care, cardiovascular disease, sexual and reproductive health and social and behaviour change studies. The CTU is led by Co-Directors Professor Cari Free and Dr Charles Opondo and Director of Operations Dr Shirine Voller.

OUR TEAM INFOMRATION

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 Trial Manager(s) in checking and identifying problems with trial information received from hospitals worldwide;
- To liaise with site investigators and the trial team(s) to resolve issues under the supervision of the Trial Manager(s) and in line with written procedures;
- To provide guidance to site investigators on how to complete relevant forms and use the Trial Management Systems such as: expressions of interest from potential collaborators, accessing online GCP training and progressing certificates; in line with written procedures and guidance documents;
- To help prepare trial promotion/communications materials such as newsletters, leaflets, posters and short videos; and mail mail-outs using MS Word mail-merges;
- To attend and contribute to trial meetings, take minutes, and any other Trials relevant meetings, as required;
- Communication will be trial sites and colleagues via email, conference calls, instant messaging platforms and trial social media pages, where necessary;

Teamwork and Motivation

- To work under the supervision of Trial Manager(s) to conduct data entry document and, in accordance with written procedures;
- To raise/escalate any concerns noted during data or document review checks with the Trial teams as needed;
- To collate data from the trial database or Trial Master File (TMF) as needed;
- To assist with review of the trial logs and forms, and with completing actions that arise from Trial Quality Control checks;
- To acknowledge data or documents received from investigators, and provide encouragement and motivation to trial teams, 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 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 assist the Clinical Trials Administrator in tracking and sending trial investigational medicinal products in line with written procedures;

- To assist with procurement and payment of invoices under the supervision of the Trial Administrator;

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

- To prepare and send trial documents and materials as required by trial sites and other collaborators in line with written procedures;

- To assist the Trial 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 help Trial Manager(s) in drafting Work Practice Documents (WPDs) and other related procedures, commensurate with the level of the role;

- To assist the Trial Manager(s) with getting all trial relevant queries resolved, in accordance with written procedures and trial protocol;

- To print and collate trial documents in required languages and ensure a continuous availability of documents;

- To prepare and send gift incentives and certificates to collaborators and participating trial sites;

- To ensure timely distribution of all of the above, and keep accurate and up to date records of dispatches;

- To order office stationery, to monitor and service the fax machine, printers and other office supplies;

- To log trial documents received from participating sites in the trial database;

- To enter data on the Trial Management Systems in line with written procedures and guidance from the Trial Manager(s);

- To conduct checks of data received by site investigators in line with written procedures:

- To assist with review of the trial logs and forms, and with completing actions that arise from Trial Quality Control checks; in accordance with trial protocol and procedures;

- To undertake any other task required by the Trial Manager(s) or the Chief Investigator (s), commensurate with the level of the role;

Decision Making

- Using written procedures to identify monitoring issues e.g. misunderstanding by trial sites, falsification, repeated problems and bringing them to the immediate attention of the Trial Manager(s);

Planning and Organising

- To assist the Trial Manager(s) in ensuring trial correspondence and documentation are readily accessible for independent audits and inspections;
- To assist the Trial Manager(s) in ensuring trial data and documentation are handled and processed in line with the given time frames as detailed in written procedures;
- To monitor the relevant trial email inboxes and direct any enquiries to the correct team member in a timely manner;
- To contribute to the development and implementation of procedures to improve conduct of the trial, 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 the Data Management and/or Trial Management Group;
- To work with trial sites to resolve queries under the supervision of Trial Manager(s), in line with written procedures, as required by the role;
- To attend and contribute to trial meetings, and other Clinical Trials relevant meetings, as required

Analysis and Research

- To assist Trial 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 and trial documents 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 Trial 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 assist with filing important trial documents in the Trial Master File (TMF) and assist with archiving as per written procedures;

- Assist the Trial team in ensuring data and corresponding communications are correctly stored in the Trial Master File (TMF), as well as e-TMF (Sharepoint) as per procedures;

- To print/prepare documents for trial sites as required;

Work Environment

- To work independently to conduct daily trial queries and review in line with procedures, and timelines set, and escalate as appropriate;

- 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 clinical Trials relevant meetings;

- To provide training /advice to trial collaborators, external researchers, and members of staff, where necessary, as required by the role level;

- To collaborate as a member of the Trial Team, and support other team members in any tasks that are commensurate to this role;

- To ensure all data is handled and stored in compliance with clinical trial regulations and good clinical practice guidelines;

- Be part of a large clinical trials team;

- To undertake any other relevant reasonable duties required by the Trial Manager or Chief Investigator that commensurate with the level of this post;

Team Development

- Initiative should be taken to identify problems and consider the wider impact on the trial and other centres;

- Be part of the development and implementation of strategies to improve trials running including patient recruitment, monitoring process and milestones deliveries; as required by the role;

- To support the Clinical Trials Team in accessing and using the trial website, trial databases and other relevant systems, under the supervision of the Trial Manager;

Other

- To demonstrate the School's values through your behaviour at work, including your duties and responsibilities in respect of equality and diversity, health and safety, data protection, and any other legislative requirements;

- To act as ambassadors for the School when hosting visitors or attending external events; and adhere to Faculty and School policy and procedures at all times;

- To show sensitivity to others' needs and feelings; and 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;

- To maintain trial webpages, including updating trial information and other communications materials;

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 the equivalent relevant experience.	E
Experience	• Proven relevant experience of working in research /regulated clinical trials clinical trials	E
	• Experience of working in a structured environment, and ensuring compliance with Standard Operating Procedures, and administrative processes	E
	• Experience of handling personal data/ data quality control procedures	E
	• Experience using different software to assess data quality and present data in a usable format	E
	• Experience of using/drafting Trial Work Procedures and Standard Operating Procedures	E
	• Experience of maintaining webpages, including updating project information and other communications materials;	D
	• Experience of creating newsletters and short video clips	D
Personal Qualities	• Excellent written, oral communication and numeric skills	E
	• Excellent organisational skills and ability to prioritise to meet deadlines	E
	• High degree of accuracy, the ability to pay close attention to detail and presentation and strong focus on quality of work	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 well and flexibly in teams and with a wide range of varying stakeholders	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
Knowledge	• Knowledge of clinical trial processes and ICH/GCP guidelines • Good understanding of the scientific principles of randomised controlled trials	E 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: December 2024

Salary and Conditions of Appointment

The post is fixed term for 12 months and full-time 35 hours per week, 1 FTE. The post is funded by the NIHR and Unitaid and is available immediately. The salary will be on the Professional Services salary scale, Grade 3 scale in the range £29,514 - £33,207 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.