JOB DESCRIPTION

Job Title: Assistant Trial Manager
Department: Medical Statistics
Faculty: Epidemiology & Population Health
Location: Keppel Street, London
Reports to: Eni Balogun, Senior Trials Manager
Responsible for: N/A
Full Time/Part Time/Casual: Full-time
Grade: 4
Overall Purpose of the job: The post holder will provide support to the Chief Investigator(s) and Trial Managers in all aspects of trial management, from initiation to completion. They will have a role in the development, coordinating and completing clinical trials. The role holder 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 and academic ability to fulfil this job description, and make a significant contribution to the successful completion of the trial. 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 Trust. Transform/IM-WOMAN funded by Unitaid and WOMAN-3 funded by JP Moulton Charitable Foundation/Open Philanthropy.

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.

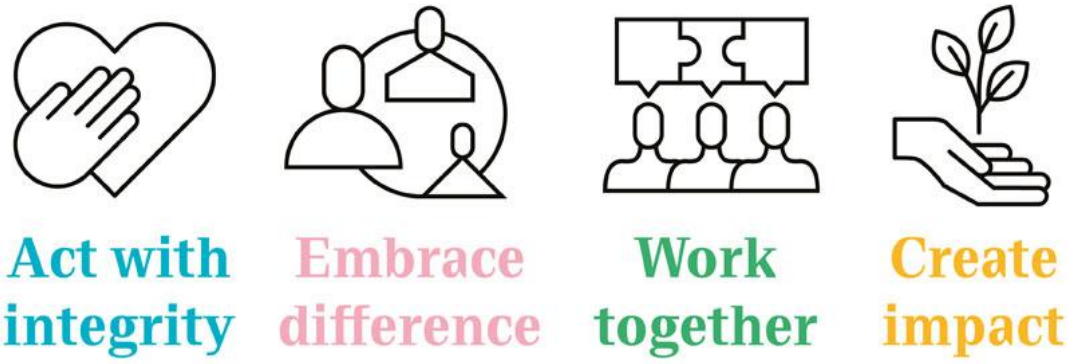
We embrace and value the diversity of our staff and student population and seek to promote equity, diversity and inclusion as essential elements in contribution to improving health worldwide. We believe that when people feel respected and included, they can be more creative, successful, and happier at 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.

The **Department of Medical Statistics (MSD)** specializes in methodological research in medical statistics, especially in relation to clinical trials, observational epidemiology and disease prevention. MSD has established a reputation for being

one of the leading innovative centres in Europe for biostatistical methodology relevant to the planning and reporting of medical research. The department has a leading role in methodological and applied research related to phase III clinical trials, missing data, pharmaco-epidemiology, causal inference and health data science. The Department incorporates a Clinical Trials Research Group (concerned with planning, co-ordination, statistical analysis and reporting of clinical trials), and has a special interest in perinatal health, cardiovascular, respiratory and infectious diseases, including trials conducted in LMIC.

The Head of Department is Tim Collier, and MSD's professors are Liz Allen, James Carpenter, Tim Clayton, Diana Elbourne, Chris Frost, Ruth Keogh, Neil Pearce, Stuart Pocock, Linda Sharples, Jonathan Bartlett, Elizabeth Williamson.

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 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

During Trial Set-up Phase:

- Work as needed with the Trial Manager, Chief/Principal Investigators, National Coordinators, and UK Research Network to identify suitable trial sites;
- Work with Trial Managers at the CTU to ensure all approvals for the conduct of the clinical trial are in place before recruitment commences in accordance with the relevant Regulations;
- Assessing site suitability in line with CTU Standard Operating Procedures (SOPs) and Work Practice Documents (WPDs);
- Setting up study sites and ensuring that they have trial materials prior to starting recruitment;
- Support site initiation (both onsite or remotely via video/teleconference);
- Developing and maintaining excellent working relationships with collaborators worldwide;
- Work with the wider clinical trial team to support the various studies, ensuring training and support to carry out roles;
- Draft Standard Operating Procedures and Work Practice Documents relevant to role.

During Trial Recruitment Phase:

- Maintenance of the Trial Master File and Local Co-ordinating Centre Master Files where appropriate.
- Ensure that all sites keep Investigator Site Files up to date in response to changes in the protocol or regulations and ensure that the study is run in compliance with the protocol, ICH GCP and all applicable regulations;
- Provide regular feedback to participating sites and the Local Co-ordinating Centres on recruitment to include updates on the completeness and quality of data collected;
- Be proactive in resolving any recruitment and data quality issues that may arise in consultation with the Chief Investigators, Co-ordinating Centres, National Coordinators and the Trial Managers;
- Work with the Data team to resolve any data queries with sites;
- Ensure that the monitoring plan is carried out and provide evidence as requested to the Trial Manager and Chief Investigator to assess its effectiveness. The Monitoring Plan may require travel to trial sites within the UK and Internationally;
- Training investigators on trial procedures;
- Work with Trial Managers at the CTU to ensure maintain all approvals necessary for the conduct of the clinical trial;
- Draft interim reports to the Sponsor, Funder, regulatory authorities and oversight committees as requested by the Trial Manager;

- Prepare monthly trial reports/newsletters for each of your assigned studies and address any matters arising in a timely manner;
- Report recruitment accruals information to the Research Network using the UKCRN portal if needed;
- Ensuring safety reporting is being conducted in an appropriate manner as specified in the protocol and or collaboration agreement and any concerns are being acted on accordingly;

At Trial Closure Phase:

- After successful completion of the study ensure all sites are closed in a timely manner, that all trial materials are returned and dealt with appropriately;
- With support and instruction from the Trial Manager submit all study closure reports to the relevant bodies;
- Ensure appropriate archiving of all Essential Documents;
- Contribute to dissemination activities as needed;

Other responsibilities:

- Maintain webpages, including updating project and output/work package information and other communications materials;
- Support an out of hours call answering service on a Rota basis to trial investigators;
- Communicating with trial sites and colleagues via email, conference calls, instant messaging platforms and trial social media pages, where necessary;
- Handle personal data in line with clinical trial regulations and good clinical practice guidelines;
- The post-holder will be required to undertake such tasks and responsibilities as may reasonably be expected within the scope and grading of the post;
- National & International travel may be required to carry out key trial activities such as set ups, monitoring, auditing and close outs;

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 regulated clinical trials.	E
	• Experience of working to ICH Good Clinical Practice (GCP) guidelines	E
	• Experience of handling personal data/ data quality control procedures	E
	• Experience of using/drafting Trial Management plans, Work Procedures and Standard Operating Procedure	D
	• Experience of project management and research coordination	D
Knowledge	• Knowledge of clinical trial processes and ICH/GCP guidelines	E
	• Knowledge of fundamentals of clinical trials	E
	• Good understanding of data protection principles and how to apply this in clinical trials	E
	• Good understanding of regulations pertaining to clinical trials	E
Personal Qualities	• Excellent written, oral communication and numeric skills	E
	• Excellent organisational skills and ability to prioritise to meet deadlines with a high degree of accuracy and paying close attention to details.	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
	• Experience of using Zoom, Skype, Teams or other packages for hosting online meeting	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: February 2026

Salary and Conditions of Appointment

The post is fixed term for 12 months and full-time 35 hours per week, 1.0 FTE. The post is funded by Open Philanthropy and is available immediately. The salary will be on the LSHTM salary scale, Grade 4 scale in the range £34,741 - £38,986 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 operates a Hybrid Working Framework which, alongside agreed service requirements, enables teams to work more flexibly where the role allows - promoting wellbeing and a better work/life balance. Please note that roles based in London are required to work on-site a minimum of two days per week.

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 job classification, skill level, salary or qualification 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.