

LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

FACULTY OF INFECTIOUS AND TROPICAL DISEASES

DEPARTMENT OF CLINICAL RESEARCH

CLINICAL TRIAL PHARMACIST

FURTHER PARTICULARS

LONDON
SCHOOL of
HYGIENE
& TROPICAL
MEDICINE



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

Faculty of Infectious and Tropical Diseases

The Faculty of Infectious and Tropical Diseases encompasses all of the laboratory-based research in the School as well as that on the clinical and epidemiological aspects of infectious and tropical diseases. It is headed by Brendan Wren, who is **Professor of Microbial Pathogenesis**. The range of disciplines represented in the faculty is very broad and inter-disciplinary research is a feature of much of our activity. The spectrum of diseases studied is wide and there are major research groups with a focus on malaria, tuberculosis, HIV/AIDS and other sexually transmitted diseases, vaccine development and evaluation, and vector biology and disease control. The Faculty is organised into four large research departments comprising: Pathogen Molecular Biology, Immunology and Infection, Disease Control, and Clinical Research. There is close interaction between scientists in different research teams. The Faculty has strong overseas links, which provide a basis for field studies and international collaborations in developed and developing countries. The teaching programme includes MSc courses, taught in-house and by distance learning, which are modular in structure, a variety of short-courses and an active doctoral programme (PhD and DrPH). For further information on the Faculty see: <http://www.lshtm.ac.uk/itd/index.html>.

Department of Clinical Research (Head: Professor David Mabey)

The Department of Clinical Research addresses infectious diseases of major public health importance in developing countries. Activities include trials of new therapies, vaccines and educational interventions; the development of new diagnostic tests; studies to elucidate the immunological and molecular correlates of pathogenesis and protective immunity, and to identify genetic polymorphisms conferring protection or susceptibility to infectious diseases; health services research which aims to identify the most efficient and cost-effective way to deliver health care; and health policy analysis. In addition to our many overseas collaborations, we have close links with the Hospital for Tropical Diseases, in purpose-built accommodation on the main UCL Hospital campus, five minutes walk from the School. The Wellcome Trust Bloomsbury Centre for Global Health Research is based in the Department, and supports Clinical Fellows at all levels, most of whom are based overseas.

The Department's main research interests include HIV and related infections; in particular, the interaction between HIV infection and tuberculosis, and other sexually transmitted diseases; malaria; trachoma; leprosy; diagnostic tests for resource limited settings; eye health; disability; and travel medicine.

Department of Disease Control (Head: Professor James Logan)

This multidisciplinary Department includes epidemiologists, entomologists, anthropologists and social scientists, clinical scientists, public health engineers and geographers. This range of expertise provides us with a battery of tools for focusing on the control of diseases that are insect-borne, water-borne or associated with poor hygiene – mostly in developing countries. Much of the research can be categorised as: evaluating disease control interventions; investigating implementation strategies - including working with the private sector; understanding the factors underlying household behaviour in relation to family health; or determining how control resources can be targeted most efficiently. Particular attention is paid to research directed at current health policy issues, including the gap between policy and practice.

The Department's Environmental Health Group plays a leadership role in research and operational support for hygiene behaviour change, household water supply and sanitation. Three key programmes which contribute to the work of the Group are the DFID funded consortium Sanitation and Hygiene Applied Research for Equity (SHARE), the Hygiene Centre (Unilever) and the improved sanitation randomised, controlled field trial jointly funded

by the Bill & Melinda Gates Foundation and International Initiative for Impact Evaluation (3ie).

The Department houses the largest research group in LSHTM working on malaria control. Ongoing projects include: research capacity strengthening in Africa through the work of the Malaria Capacity Development Consortium (MCDC); novel approaches to combating malaria in pregnancy (MiP) in both Africa and India; a number of projects which develop and evaluate delivery mechanisms to improve ACT access, targeting, safety and quality, all funded by the ACT Consortium. In addition, staff are involved in studies of Seasonal Malaria Chemoprevention (SMC) in West Africa and are supporting work on the large Phase 3 clinical trial study of the RTS,S malaria vaccine in children.

The Department is world-leading in applied entomology and insect borne diseases, and has provided a testing service for control products for over 20 years. The Arthropod Control Product Test Centre Arctec provides access to the Department's valuable mosquito colonies and in-house facilities for testing of repellents, insecticides and after-bite treatments. Its entomological field sites in Tanzania, Benin, The Gambia and Kenya are involved in a variety of vector borne disease control trials. The PAMVERC alliance between LSHTM and African partners work in partnership with WHO and the manufacturing industry on product development and evaluation under laboratory and semi-field conditions and in community trials.

Staff from the Department lead on studies investigating how meningococcal meningitis is spread in Africa and the impact of a new serogroup meningococcal A vaccine on reducing transmission (MenAfriCar Consortium). Staff are also assisting in the evaluation of the impact of introduction of a pneumococcal conjugate vaccine into the routine EPI programme of The Gambia and in the initial testing of a new pneumococcal protein vaccine in the same area.

Also based with the Department is the IDEAS (Informed Decisions for Actions) project, which aims to improve the health and survival of mothers and babies through generating evidence to inform policy and practice. The Department also includes a major grouping of researchers using spatial analysis in public health.

Department of Immunology and Infection (Head: Professor Greg Bancroft)

Research in the Department of Immunology and Infection centres on analysis of the host response to infection at the molecular, cellular and population levels. The goals are to develop a greater understanding of basic mechanisms of immunological protection versus pathology, and to apply this knowledge to the development of immunological interventions and the identification of correlates of immune status. Our work involves application of state-of-the-art cellular and molecular approaches to the in vitro analysis of pathogen-host cell interactions, to in vivo studies in models and to the study of immunity at the population level in disease endemic areas. Main areas of research include the regulation of acute and chronic inflammation; macrophage-pathogen interactions; cellular pharmacology; the production of cytokines during innate and acquired immune responses; T-cell function and antigen recognition; the mechanisms of immunopathology; the development of vaccines; and delivery systems for vaccines and drugs.

Current research includes the role of acute phase proteins in resistance to infection, homeostasis and inflammatory disease, mechanisms of macrophage activation, control of cytokine synthesis and mammalian lectin interactions (J. Raynes); intracellular trafficking and secretory pathways of cells of the immune system (T. Ward); the role of innate responses in resistance to the bacterial pathogens, *Mycobacterium tuberculosis* and *Burkholderia pseudomallei*, activity and regulation of natural killer cells and their effect on macrophage activation and recruitment, regulation of chemokine receptors during infection and granulomatous tissue responses in the lung against *Cryptococcus neoformans* and *Mycobacterium tuberculosis* (G. Bancroft); longitudinal studies on immune correlates of

protection against malaria in Uganda and a cluster-randomized trial on the impact of targeted interventions on malaria transmission in Kenya and Mali (T. Bousema); identification and evaluation of novel drugs and formulations for the treatment of leishmaniasis, malaria, human African trypanosomiasis (sleeping sickness) and American trypanosomiasis (Chagas disease). This research includes projects on miltefosine, AmBisome and topical paromomycin as well as on drug – immune response interactions and PK PD relationships (S Croft); correlates of protection against tuberculosis and studies of BCG vaccination, human CD8+ T-cell responses to mycobacterial antigens and synthetic peptides, use of whole blood assays in immuno-epidemiology (H. Dockrell); innate and adaptive immunity to malaria including activation of natural killer cells, cytokine regulation in clinical immunity and immunopathology, regulation of antibody production and immunoglobulin class switching (E. Riley); induction and regulation of innate and adaptive immune responses to malaria pre-erythrocytic stage and blood stage parasites (J. Hafalla); using anti-malarial antibodies as a marker of malaria exposure & assessment of the use of sero-epidemiology to monitor and target malaria control measures www.seromap.com (C. Drakeley) transmission of *Plasmodium falciparum* malaria including antibody responses to gametocyte-infected erythrocyte surface antigens, effect of gamete antigen variability on transmission, gametocyte sequestration and development and gametocytocidal drug therapy (C. Sutherland); drug discovery for helminthic diseases notably schistosomiasis (Q. Bickle); impact of concomitant viral, bacterial, protozoal and helminth infections on induction of immune responses and immunopathology and T cell regulation and induction of mucosal immune responses during intestinal nematode infections (H. Helmby); anti-protozoal chemotherapy with focus on anti-leishmanial drug discovery and development including drug combinations and drug delivery systems, anti-leishmanial vaccine development and immunotherapies, models for drug and vaccine development and the role of macrophages in context of anti-leishmanial drug treatment (K Seifert); the identification and evaluation of novel drugs and drug delivery systems for leishmaniasis, trypanosomiasis and malaria, interaction between antiprotozoal drugs and the immune response (V. Yardley) Host response to vaccination and development of improved vaccine strategies for protection against tuberculosis, growth inhibition assays, T-cell responses and vaccine trial immune monitoring (H. Fletcher) Dissecting red blood cell invasion pathways in the malaria parasite *Plasmodium knowlesi* (R.Moon)

Department of Pathogen Molecular Biology (Head: Professor David Conway)

Research in the Department of Pathogen Molecular Biology focuses on the molecular biology and genetics of pathogens and interaction with their hosts, to improve understanding and control of infectious diseases. This includes: (i) determining mechanisms of infection of globally important viral, bacterial and parasitic pathogens; (ii) deciphering the genetic diversity of disease agents in natural populations to understand epidemiological and functional processes, (iii) studying immune evasion mechanisms of particular disease agents, (iv) exploiting pathogens as model biological systems, and (v) developing practical applications including improved diagnostic tests and characterisation of vaccine candidates or drug targets.

Studies in the Department include analyses of malaria parasites (*Plasmodium* spp), Chagas disease (*Trypanosoma cruzi*), African sleeping sickness (*Trypanosoma brucei*), amoebic dysentery (*Entamoeba*), the Leishmania species, bacterial food borne pathogens (*Campylobacter jejuni* and *Yersinia enterocolitica*), gastric ulcers/cancer (*Helicobacter pylori*), pseudomembranous colitis (*Clostridium difficile*), plague (*Yersinia pestis*), paddy field melioidosis (*Burkholderia pseudomallei*), Tuberculosis (*Mycobacterium tuberculosis*), Pneumonia (*Streptococcus pneumoniae*), Bluetongue viral disease of livestock, Herpesviridae, SARS, hemorrhagic fever viruses, and enteric rotaviruses that cause significant diarrhoeal disease.

The overall aim of our research is to understand the complex and dynamic ways by which pathogens modulate virulence and interact with the human host. Such a holistic approach will vastly increase the scope for the rational of design of long-term intervention strategies

to reduce the burden of infectious disease. In recent years such a mission has been significantly enhanced by the availability of whole genome sequences. Members of the Department are involved in several pathogen genome projects, and post genome studies which facilitate understanding of complex parasites. The interpretation and exploitation of this basic information is the platform for numerous new avenues of research on pathogenesis, epidemiology and the evolution of virulence.

Teaching

The School offers 19 one year full-time taught courses leading to the Master of Science (MSc) degree of the University of London and the Diploma of the London School of Hygiene and Tropical Medicine (DLSHTM). The Faculty of Infectious and Tropical Diseases runs or contributes substantially to ten of these courses and the “Immunology of Infectious Diseases” course is run from within the Department of Immunology and Infection. In addition, the Faculty is responsible for the three-month Diploma in Tropical Medicine and Hygiene (DTM&H), the Diploma in Tropical Nursing and offers a range of specialist short courses lasting usually one or two weeks. Five MSc courses are also offered by Distance-based Learning, including one on Infectious Diseases.

Research Training

The School offers two doctoral training programmes. The MPhil/PhD degrees are designed for those who wish to go on to a full time research career. The DrPH is directed towards those who expect their careers to be more in the practice of public health.

JOB DESCRIPTION

Job Title: Clinical Trial Pharmacist	
Department /Division/Unit: CRD	
Faculty/Professional Service: ITD	
Location: Kambia, Sierra Leone	
Reports to: EBOVAC Principal Investigator (PI), Professor Deborah Watson-Jones	
Responsible for: Management and supervision of the pharmacy and project pharmacists, control of Investigational Products (IP), supervision of temperature-controlled stock and cold chain (for IP and other temperature controlled stock), supervision of accountability of pharmacy stock; liaison with sponsor for IP.	
FTE: Full-time (1.0)	Hours <i>(if less than full time):</i>
Grade: Professional Support 7	
<p>Overall Purpose of the job</p> <p>This role is to provide professional pharmacy advice and support to the Clinical Research Department at the London School of Hygiene and Tropical Medicine, specifically the EBOVAC1 clinical trial team in Sierra Leone. The team includes investigators, trial management staff, clinicians, nurses, pharmacists and cold chain technicians. The role would work to ensure that clinical trials conducted by the team in Sierra Leone are compliant with the relevant legislation and guidance on pharmaceutical products' storage and utilisation. The Trials Pharmacist will also assist in the preparation and review of pharmacy specific documentation and contribute to the development/revision of Standard Operating Procedures (SOPs) for Investigational product and other temperature-controlled stock management.</p> <p>The projects: The EBOVAC1 clinical trial team is currently conducting an early phase trial of a vaccine against Ebola virus disease. The first stage is non-randomised and the second stage is a randomised controlled trial to evaluate the safety and immunogenicity of a heterologous prime boost prophylactic Ebola vaccine in adults and children. This trial is ongoing, requiring additional support in cold chain and pharmaceutical stock management. In addition, the site is starting another trial of two Ebola vaccines. Pharmacy input is required in the development of site-specific processes and procedures alongside ongoing support in stock management.</p>	

Main duties and responsibilities:

Communication

1. Provide professional advice to trial management staff, regarding the pharmaceutical products (both investigational and non-investigational) used in

clinical trials conducted by the team, with particular reference to compliance with any relevant regulations and pharmaceutical guidance.

2. Communicating relevant time-/temperature-sensitive stock management information in a timely manner to colleagues e.g. the logistics team. This may include instances of cold chain temperature excursions or other matters relating to the regular maintenance of cold chain equipment.

Teamwork and Motivation

1. To liaise with, and refer to, the Logistics and Operations Managers on any technical issues relating to equipment required for storage and handling of temperature-sensitive items, on all sites, including maintenance and servicing schedules.
2. Provide leadership, direction and professional supervision to trial site pharmacists.
3. To collaborate with the cold chain team, logistics team and clinical team to train those handling IP and other temperature-sensitive products.
4. Chairing regular meetings to motivate team members and ensure uniformity of procedures across different clinical trial clinics.

Liaison and Networking

1. To liaise with the logistics and cold chain team to ensure correct and documented IP transport, validation of refrigeration equipment at all clinic sites including emergency back-up storage and to track responses to/from the Sponsor/ IP supplier regarding IP handling or storage.
2. Liaise with trial management staff regarding substantial protocol amendments to ensure appropriate changes are made to the IP sections of the CTA/ IP supply agreements and the Pharmacy supporting documentation, when appropriate.
3. Liaise with trial monitors and IP suppliers about medicinal product management.
4. Establish and maintain links with key staff at the pharmacy board of Sierra Leone (PBSL) to ensure that there is effective liaison and advice when Regulatory issues arise.
5. To liaise with Clinic staff over the temperature-sensitive supplies available in the Depot to ensure stock is managed and issued appropriately.

Service Delivery

1. Coordinate the development/ review of appropriate Pharmacy Manuals, SOPs, for effective IP/ temperature-sensitive product management.
2. Support the delivery of clinical research in accordance with Good Clinical Practice (GCP), the Declaration of Helsinki, applicable legislation, codes of practice and professional standards.

3. Support the trial management team in the completion of the IP sections of Clinical Trial Agreements (CTAs), IP supply agreements and regulatory authority submissions, including the collection of necessary supporting documentation.

Decision Making

1. Assist in the assessment of suitability of external suppliers of medicinal, non-investigational drugs in country.
2. To report to the trial manager and to conduct other tasks as delegated by the trial manager as reasonably expected for this role and grade.

Planning and Organisation

1. To maintain a Pharmacy Site File for the clinical trials, oversee and periodically review completion of pharmacy worksheets and checklists across the clinic sites.
2. To create and manage an Incident Log for temperature-sensitive items, assessing trends in order to lead to improvements in the environment or practices surrounding their storage and handling.

Initiative and Problem Solving

1. Ensure issues likely to create difficulties with compliance with the regulations are identified at the earliest possible stage in protocol development or during review of existing standard operating procedures, and appropriate action taken to ensure compliance.
2. To liaise with the Kambia Hospital Emergency Room on medicines and equipment issues, particularly in relation to donation of surplus before expiry.

Analysis and Research

1. To advise on the safe storage and stock control of medicines and other time- and temperature- sensitive products received and distributed from the project depot. The role will include providing overseeing stock take activities and conducting usage projections based on consumption of temperature-sensitive products, not limited to pharmaceutical products, and overseeing maintenance of an expiry date calendar for time-sensitive products.
2. Provide pharmaceutical advice and support to the trial Sponsor, trial investigators, research nurses, pharmacists, as appropriate, to ensure trial site staff have all appropriate and up to date information with respect to IPs and other medicinal products.
3. To ensure GCP-compliant recording and monitoring of time- and temperature-sensitive stock (investigational and non-investigational) at all clinic sites, including in the Vaccine Depot. This may include routine records of temperature-sensitive product handling or ad-hoc instances of temperature-out-of-ranges and coordination of follow-up, quarantine and disposal of product as necessary.

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 full 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 Director of Professional Service.

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.

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 review (appraisal) process.

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.

Job Title: Clinical Trial Pharmacist
Department/Division: ITD/CRD

Competency		E/D
<i>Education, Qualifications and Training</i>	<ul style="list-style-type: none">• Bachelor's degree in pharmacy• Registered with the General Pharmaceutical Council (UK) or the Pharmacy Board of Sierra Leone or equivalent	E E
Experience	<ul style="list-style-type: none">• Previous experience with blinded clinical trials, preferably as a clinical trial pharmacist that has conducted unblinding in medical emergencies• Previous experience with vaccine development trials• Previous experience of temperature-controlled investigational product transport, handling, storage and accountability requirements in	E D E

	<p>accordance with Good Clinical Practice (GCP), Good Manufacturing Practice and Good Distribution Practice</p> <ul style="list-style-type: none"> • Previous experience of IP-related GCP quality procedures including writing SOPs and IP control documentation and audit responses including the preparation of CAPAs • Previous experience in overseeing cold chain management • Previous experience in training colleagues in clinical trials and IP management and ensuring trial procedures and the protocol are followed • Experience/ working knowledge of MSupply software • Experience living and/or working in developing countries 	<p>E</p> <p>E</p> <p>D</p> <p>D</p> <p>D</p>
Knowledge	<ul style="list-style-type: none"> • Excellent computing skills and working knowledge of word processing, working with spreadsheets and database packages • Excellent English language communication skills, both written and verbal • Recent training in GCP 	<p>E</p> <p>E</p> <p>D</p>
Personal Qualities	<ul style="list-style-type: none"> • Highly professional approach to work, methodical with excellent attention to detail • Able to work independently and as part of a multicultural team • Able to work under pressure and to ensure essential deadlines are met • Collaborative and flexible approach and ability to work well and effectively with all colleagues and students with varying levels of expert knowledge/ experience • Commitment to School's policy of equal opportunities and the ability to work harmoniously with colleagues and students of all cultures and background 	<p>E</p> <p>E</p> <p>E</p> <p>E</p> <p>E</p>

E-Essential: Requirement without which the job could not be done

D-Desirable: Requirements that would enable the candidate to perform the job well

SALARY AND CONDITIONS OF APPOINTMENT

The post is based overseas in Sierra Leone and is available immediately. The post is funded by Innovative Medicines Initiative (IMI) until 30 November 2019. The appointment will be made on the School's Professional Support Pathway Grade 7 in the range £44,978 - £51,490 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 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 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