

LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE  
(University of London)

LONDON  
SCHOOL of  
HYGIENE  
& TROPICAL  
MEDICINE



FACULTY OF INFECTIOUS AND TROPICAL DISEASES  
CLINICAL RESEARCH DEPARTMENT

**CLINICAL TRIAL MANAGER:  
SIERRA LEONE  
PHASE III EBOLA VACCINE TRIAL**

We are seeking to appoint a Clinical Lecturer/Senior Lecturer as a Trial Manager to coordinate a Phase III efficacy trial of a prime boost vaccine against Ebola infection as part of the EBOVAC1 project. This is an exciting opportunity to be involved in the EBOVAC1 project that comprises a set of clinical trials to evaluate the safety, immunogenicity and efficacy of the prime boost Ebola vaccine manufactured by Janssen Crucell. The project includes the first in-human Phase 1 studies of the vaccine in 2-3 sites in East Africa and a Phase III efficacy trial in Sierra Leone. The project is a collaboration between LSHTM, Janssen Crucell, University of Oxford, INSERM and collaborating sites in Africa, including in Uganda, Kenya and Tanzania.

The successful applicant will be based full-time in Sierra Leone. Applicants should have a post graduate qualification in epidemiology or a related field and proven technical expertise in the quality management of clinical trials related to infectious diseases and/or vaccines. The post-holder will provide inputs into the study design; assist in location of partner and study sites in-country and coordination between the trial sites; recruit, train and supervise field research teams; coordinate the collection of data and samples in close working relationship with the collaborators and Janssen Crucell; monitor recruitment and follow-up; prepare progress reports; monitor trial procedures, including adverse event reporting; and help to prepare scientific reports and presentations.

The post is available immediately and the contract duration will be for 18 months initially and may be extended for an additional period, subject to progress of the trial. Salary is on the Clinical salary scale at Lecturer level (£33,597 - £56,495 per annum inclusive) or Senior Lecturer level (£52,462 - £73,261 per annum inclusive).

Applications should be made on-line via our website at [jobs.lshtm.ac.uk](http://jobs.lshtm.ac.uk). The closing date for receipt of applications is **10pm Wednesday 8 April 2015**. The reference for this post is **DWJ4A**. Any queries regarding the application process may be addressed to [jobs@lshtm.ac.uk](mailto:jobs@lshtm.ac.uk) or [deborah.watson-jones@lshtm.ac.uk](mailto:deborah.watson-jones@lshtm.ac.uk) or [brian.greenwood@lshtm.ac.uk](mailto:brian.greenwood@lshtm.ac.uk) or [peter.smith@lshtm.ac.uk](mailto:peter.smith@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" will not be considered acceptable.

Interviews will be held in April 2015.

*The London School of Hygiene & Tropical Medicine is committed to being an equal opportunities employer*

## 2. 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 by Sir Patrick Manson, the School has expanded in recent years at its two main sites on Keppel Street and Tavistock Place. 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.

Research income has grown to over £85 million per year from national and international funding sources including the UK government, the European Commission, the Wellcome Trust and philanthropic sources.

Education programmes have grown to more than 1,000 London-based Master's and Research students, 2,900 studying Master's by distance learning and 1,000 on short courses and continuous professional development. We have also launched a series of free online courses, and more than 15,000 people registered on the first of these, Ebola in context. Our staff, students and alumni work in more than 150 countries in government, academia, international agencies and health services.

The School is highly ranked in various university league tables. It was named the world's leading research-focused graduate school in the Times Higher Education World Rankings in 2013. In 2014, it was ranked in the top 10 universities in the world for citation rate by the new EU-supported U-Multirank database, fourth in the world for impact in medical sciences by the Leiden Ranking and third in the world for social science and public health in the US News Best Global Universities Ranking. According to the results of the UK government's Research Excellence Framework, published in December 2014, the School was ranked second overall (after the Institute for Cancer Research) on the key measure of impact.

### 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 interdisciplinary 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 Philippe Mayaud)**

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.

### **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.

### **Teaching requirements**

To contribute to the Faculty teaching programme, up to 15% of your time per annum, subject to the policy of any funding agency (by agreement, some staff may make a greater contribution than this).

### **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.

### **3. JOB DESCRIPTION**

#### **Lecturer (Clinical)**

**Post:** Trial Manager Phase III Ebola Vaccine Trial

**Grade:** Lecturer (Clinical), full-time (based in Sierra Leone)

**Responsible to:** Dr Deborah Watson-Jones

**Department:** Clinical Research Department (CRD)

#### **Main Duties and Responsibilities**

1. Assisting in coordination of the Phase III Ebola vaccine trial in Sierra Leone for the EBOVAC 1 project.
2. Assisting in selection of partners and study sites in-country.
3. Acting as the main LSHTM contact person for communication with the trial sites in Sierra Leone and the other partners involved in the project, including Janssen Crucell, INSERM and Ministries of Health, College of Medicine and Health Sciences and with organisations implementing other Phase III Ebola vaccine trials in-country.
4. Ensuring that all necessary research and ethics clearances are obtained and that all necessary reports are submitted to relevant research and ethics authorities as required.
5. Assisting in recruiting, training and supervising field team staff to ensure that the trial is conducted to GCP and international trial standards and conforms to the study protocol, proper use of CRFs, SOPs and other study documentation and that these are up to date and reviewed regularly.
6. Working with research partners to ensure the personal health and safety of all research staff involved in the phase III Ebola Vaccine Trial Study within Sierra Leone. This will include, but not be limited to, helping to develop guidelines for personal health and safety for staff, and checking that these are known and are being followed.
7. Liaising with laboratory staff at trial sites to ensure laboratory testing is performed within the trial schedule deadlines.
8. Undertaking clinical work relevant to the project.
9. Organising and participating in meetings and discussions with in-country partners including the Ministry of Health, LSHTM, Janssen, INSERM and other stakeholders to discuss research progress, findings and any other aspects of the study.
10. Participating in the data management (data processing, data cleaning, etc) and analysis of the results from phase III trial, as required by the Janssen Crucell and LSHTM statisticians.
11. Participating in the writing up of the Ebola vaccine trial results in reports and publications, conference presentations and contributing to other relevant journal publications.

12. Keeping in close contact with the LSHTM senior research team members, and consulting with them on strategic issues and issues that might have any safety or major financial implications for the project. This will include, but not be limited to, collation of weekly written reports of study progress from the trial sites.
13. Preparing reports to the Ebola vaccine trials governance bodies (eg. Clinical Steering Committee, Trial Steering Committee, Data and Safety Monitoring Board) as required.
14. Preparing narrative reports to the funding agency (IMI2) as required.
15. Travel to progress and coordination meetings as required, including meetings in Europe.
16. Contributing to the School's postgraduate teaching programme, as feasible. (normally 10% to 15% of time).
17. Contributing to the academic life of the Clinical Research Department and the Faculty of Infectious and Tropical Diseases and the School.
18. Undertaking other duties as may be required by the LSHTM Principal Investigator that are consistent with the nature and grade of the post.

## **PERSON SPECIFICATION**

### **Lecturer (Clinical)**

#### **Essential**

- Masters-level qualification in epidemiology, public health or a closely-related field.
- Clinically qualified.
- At least two years experience working as a clinical trials coordinator or epidemiologist, or research coordinator, with substantial experience of work in sub-Saharan Africa.
- Practical experience in the management of research teams and coordination of multicentre epidemiological or clinical studies.
- Evidence of practical experience of leading or coordinating GCP compliant studies, including familiarity with study monitoring visits.
- Evidence of having worked effectively both independently and as a member of a multidisciplinary scientific team.
- Evidence of having worked effectively in a multicultural environment.
- Excellent written and oral communication skills in English.
- Ability to start work for LSHTM as soon as possible.
- Willingness to be based in Sierra Leone (potentially outside the capital city), with occasional work travel elsewhere (eg. for conferences or meetings in Europe) for trips usually lasting 3-7 days.

## **JOB DESCRIPTION**

### **Senior Lecturer (Clinical)**

**Post:** Trial Manager Phase III Ebola Vaccine Trial

**Grade:** Senior Lecturer (Clinical), full-time (based in Sierra Leone)

**Responsible to:** Dr Deborah Watson-Jones

**Department:** Clinical Research Department (CRD)

### **Main Duties and Responsibilities**

1. Coordination of the Phase III Ebola vaccine trial in Sierra Leone for the EBOVAC 1 project.
2. Selecting partners and study sites in-country.
3. Acting as the main LSHTM contact person for communication with the trial sites in Sierra Leone and the other partners involved in the project, including Janssen Crucell, INSERM and Ministries of Health and with organisations implementing other Phase III Ebola vaccine trials in-country.
4. Ensuring that all necessary research and ethics clearances are obtained and that all necessary reports are submitted to relevant research and ethics authorities as required.
5. Recruiting, training and supervising field team staff to ensure that the trial is conducted to GCP and international trial standards and conforms to the study protocol, proper use of CRFs, SOPs and other study documentation and that these are up to date and reviewed regularly.
6. Working with research partners to ensure the personal health and safety of all research staff involved in the phase III Ebola Vaccine Trial Study within Sierra Leone. This will include, but not be limited to, helping to develop guidelines for personal health and safety for staff, and checking that these are known and are being followed.
7. Liaising with laboratory staff at trial sites to ensure laboratory testing is performed within the trial schedule deadlines and samples are shipped to external laboratories for ongoing analysis.
8. Undertaking clinical work relevant to the project.
9. Participating in meetings and discussions with in-country partners including the Ministry of Health, LSHTM, Janssen, INSERM and other stakeholders to discuss research progress, findings and any other aspects of the study.
10. Participating in the data management (data processing, data cleaning, etc) and the analysis of the results from phase III trial, as required by the Janssen Crucell and LSHTM statisticians.
11. Taking a leading role in the writing up of the Ebola vaccine trial results in reports and publications, conference presentations and contributing to other relevant journal publications.
12. Maintaining close contact with the LSHTM senior research team members, and consulting with them on strategic issues and issues that might have any safety or major financial implications for the project. This will include, but not be limited to, collation of weekly written reports of study progress from the trial sites.

13. Preparing reports to the Ebola vaccine trials governance bodies (eg. Clinical Steering Committee, Trial Steering Committee, Data and Safety Monitoring Board) as required.
14. Preparing narrative reports to the funding agency (IMI2) as required.
15. Travel to progress and coordination meetings as required, including meetings in Europe.
16. Contributing to the School's postgraduate teaching programme, as feasible. (Normally 10% to 15% of time.)
17. Contributing to the academic life of the Clinical Research Department and the Faculty of Infectious and Tropical Diseases and the School.
18. Undertaking other duties as may be required by the LSHTM Principal Investigator that are consistent with the nature and grade of the post.

## **PERSON SPECIFICATION**

### **Senior Lecturer (Clinical)**

#### **Essential**

- A PhD or DrPH in epidemiology or public health or equivalent experience demonstrated through publications.
- Clinically qualified
- Significant proven experience of working on clinical trials in a senior position with substantial experience of work in sub-Saharan Africa or other low income countries.
- Proven experience of working on vaccine-related research studies.
- Proven experience in the management of research teams and coordination of multicentre epidemiological or clinical studies.
- Evidence of practical experience of leading or coordinating GCP compliant studies, including familiarity of study monitoring visits.
- Evidence of having worked effectively both independently and as a member of a multidisciplinary scientific team.
- Experience in writing or contributing to successful grant applications.
- Evidence of having worked effectively in a multicultural environment.
- Excellent written and oral communication skills in English.
- Teaching experience at university level including seminar/practical facilitation, supervision of students, lecturing/organising sessions and course management.
- Demonstrable significant contribution to publications in high quality peer review journals over the last 3-5 years.
- Experience of making scientific presentations at national and international conferences and workshops, either orally or as posters.
- Ability to start work for LSHTM as soon as possible.

- Willingness to be based in Sierra Leone (potentially outside the capital city), with occasional work travel elsewhere (eg. for conferences or meetings in Europe) for trips usually lasting 3-7 days.

#### **4. SALARY AND CONDITIONS OF APPOINTMENT**

The post will be based in Sierra Leone and will report to the Trial Principal Investigator. The post is available immediately and the contract duration will be for 18 months initially and may be extended for an additional period, subject to progress of the trial. Salary is on the Clinical salary scale at Lecturer level (£33,597 - £56,495 per annum inclusive) or Senior Lecturer level (£52,462 - £73,261 per annum inclusive). Annual leave entitlement is 30 working days per year for all staff (pro-rata for part-time staff). In addition to this there are 6 fixed-date "Director's Days".

#### **5. APPLICATIONS**

Applications should be made online via our website at <http://jobs.lshtm.ac.uk> The reference for this post is **DWJ4A**. Applications should also include the names and email contacts of two referees who can be contacted immediately if shortlisted. Closing date for the receipt of applications is **Wednesday 8 April 2015**. Online applications will be accepted by the automated system until 10pm on the closing date. Any queries regarding the application process may be addressed to [jobs@lshtm.ac.uk](mailto:jobs@lshtm.ac.uk).

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