Centre for Tropical Medicine and Global Health

<table>
<thead>
<tr>
<th>Job title</th>
<th>Head of Clinical Trials Support Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Division</td>
<td>Medical Sciences</td>
</tr>
<tr>
<td>Department</td>
<td>Centre for Tropical Medicine and Global Health</td>
</tr>
<tr>
<td>Location</td>
<td>Mahidol Oxford Tropical Medicine Research Unit (MORU), Bangkok, Thailand</td>
</tr>
<tr>
<td>Grade and salary</td>
<td>Grade 9: £44,620 - £51,702 per annum</td>
</tr>
<tr>
<td>Hours</td>
<td>Full time - 37.5 hours per week</td>
</tr>
<tr>
<td>Contract type</td>
<td>Fixed-Term – Available for 3 years in the first instance</td>
</tr>
<tr>
<td>Reporting to</td>
<td>MORU Unit Director and Chief Operating Officer</td>
</tr>
<tr>
<td>Vacancy reference</td>
<td>140608</td>
</tr>
</tbody>
</table>

The role

WELLCOME TRUST THAILAND MAJOR OVERSEAS PROGRAMME

The Wellcome Thailand Africa and Asia Programme (The MORU Network) is a well-established and highly productive research collaboration between the Faculty of Tropical Medicine, Mahidol University, the University of Oxford, and the Wellcome Trust (UK). The unit conducts world class research into some of the greatest threats to global health in the 21st century. The main research interests are the epidemiology, diagnosis, pathophysiology, pharmacology and treatment of infectious diseases throughout Asia and elsewhere in the developing world.

CLINICAL TRIALS SUPPORT GROUP

The Clinical Trials Support Group (CTSG) was formally established in 2008 to support all aspects of the clinical research process within the unit. This includes providing help, guidance, and support to researchers who are involved in any studies involving human subjects. CTSG is also tasked with ensuring that all clinical research within the unit is closely monitored and carried out to the highest international standards. Core functions of the group involve oversight of all research involving human subjects, clinical trial development (protocol writing, ethical committee applications, statistical support, case report form and database development, trial registration, trials insurance), trial coordination and project management, protocol and Good Clinical Practice (GCP) training, trial monitoring, data management, data analysis, and community and public engagement on the topic of research. In this role at any one time CTSG
Centre for Tropical Medicine and Global Health

coordinates over 70 actively recruiting clinical research projects in 10 to 15 countries in Asia and Africa. CTSG also has its own research remit, conducting studies on aspects of all the above functions, particularly with respect to the tropical/resource-poor setting. The group currently comprises of highly qualified clinical trial coordinators, data managers, statisticians and research nurses to support research studies throughout the programme, irrespective of geography or discipline. The tracking and research coordination function of CTSG has recently expanded to include all research activities of the Unit, whether or not they involve human subjects. CTSG’s 20-member team is one of the leading groups developing pragmatic cost-efficient approaches to managing and conducting high quality clinical trials in resource-limited settings whilst ensuring compliance to local and international requirements.

Responsibilities

Management

• As a member of both the Science & Strategy and Management Committees, provide input into key decisions and strategic direction of the Wellcome Thailand Africa and Asia Programme (The MORU Network). This is an international endeavour with participating sites in Thailand, Laos, Cambodia, Myanmar, Vietnam, Indonesia, India, Bangladesh, Afghanistan, Democratic Republic of Congo, Ethiopia, Kenya and Uganda, and has around 800 full time staff.
• Lead and manage the Clinical Trials Support Group (currently 23 strong) which consists of the, Research Governance Group, Monitoring Team, Data Management Group, and Statistics Team. Maintain and track all clinical research activities across the Network and any related research collaborations; ensure that the CTSG-developed Integrated Research Information System (IRIS) is robust and up to date. The system enables rapid reporting of all research activity of the Unit, and alerts investigators of any pending tasks, such as writing annual reports to ethics committees.

Quality and Compliance

• Promote self-regulation of academic clinical trials by conducting research on research, implementing internal quality management system and conducting audits.
• Responsible for the creation and maintenance of the Unit's clinical research, data management and statistics SOPs; lead and facilitate the compliance to these SOPs. These SOPs and guidelines are in line with University of Oxford SOPs including those of the Centre for Tropical Medicine and the Oxford Tropical Network.
• Ensure and facilitate compliance to Good Clinical Practice guidelines, other applicable local and international trial regulations, and ethical committee requirements.
• Develop cost-effective risk-based strategies to comply with the above requirements for resource-limited settings.
Clinical Trial Operations

- Akin to an in-house "Clinical Research Organisation", provide support in all aspects of clinical trials including traditionally outsourced components - from initial concept to study close out, regardless of geography or discipline by:
  - Developing the research protocol, information sheet, consent form, case report forms, standard operating procedures, data and statistical analysis plans, and other associated documents.
  - Obtaining approvals from ethics committees (including the Oxford Tropical Research Ethics Committee) and local regulatory authorities. This includes submissions, resubmissions, amendments, serious adverse event reports, annual reports, and safety and closure reports.
  - Providing administrative, logistic, data management and statistical support to large clinical trials, as well as web application design and development in areas of need.
  - Together with the Clinical Trials and Research Governance team and the Global Health Network at the University of Oxford, develop best practices in quality management of clinical trials which includes providing risk-based fit-for-purpose GCP monitoring to clinical research sites, and establishing a 21 CFR Part 11 compliant data management system.
  - Oversees the pharmacokinetics clinical study team which conducts pharmacokinetics studies in both patients and healthy volunteers.

Project Management

- Support PI's with grant applications, ensuring CTSG related costs are included in budgets submitted.
- Actively manage the CTSG budget portfolio on all awarded research projects where appropriate.

Training and Capacity Building

- Manage a training programme to provide relevant courses to researchers in collaborative sites, affiliated public hospitals and other local research institutions, including GCP, human subject protection, ethics, monitoring, statistics and data management. CTSG has developed its own courses, as existing courses produced by other organisations, are otherwise inaccessible, too expensive, not suitable for non-product registration trials or simply not available to researchers in some of the countries we work in e.g. Burma, Laos, Nepal.

Selection criteria

- A medical or health/science degree plus a post-graduate degree in a field related to health/medical research
- Extensive experience in the conduct and management of clinical trials including large multi-centre multi-country clinical trials
- Experience in setting up and managing a clinical trials unit, either in an academic or industry setting
Centre for Tropical Medicine and Global Health

- Extensive experience in managing large multinational and multi-disciplinary teams
- Experience of working in resource-poor settings e.g. Asia and Africa including facilitating compliance to international clinical trials requirements in inexperienced research sites
- Experience of working in academia and industry (pharmaceutical industry or contract research organisation)
- Experience in organising and providing training in the conduct of clinical research, including Good Clinical Practice (ICH-GCP), research ethics, data management, clinical trial regulation, coordination and governance
- An expert in ethical requirements and international guidelines for clinical trials e.g. ICH-GCP guidelines as well as UK, EU and US FDA requirements.
- Proven ability to develop a research agenda and build a clinical research programme.
- Proven leadership and management skills

Desirable selection criteria

- Scientific publications in peer-reviewed journals

About the University of Oxford

Welcome to the University of Oxford. We aim to lead the world in research and education for the benefit of society both in the UK and globally. Oxford’s researchers engage with academic, commercial and cultural partners across the world to stimulate high-quality research and enable innovation through a broad range of social, policy and economic impacts.

We believe our strengths lie both in empowering individuals and teams to address fundamental questions of global significance, while providing all our staff with a welcoming and inclusive workplace that enables everyone to develop and do their best work. Recognising that diversity is our strength, vital for innovation and creativity, we aspire to build a truly diverse community which values and respects every individual’s unique contribution.

While we have long traditions of scholarship, we are also forward-looking, creative and cutting-edge. Oxford is one of Europe's most entrepreneurial universities. Income from external research contracts in 2016/17 exceeded £564m and we rank first in the UK for university spin-outs, with more than 130 companies created to date. We are also recognised as leaders in support for social enterprise.

Join us and you will find a unique, democratic and international community, a great range of staff benefits and access to a vibrant array of cultural activities in the beautiful city of Oxford.

For more information please visit www.ox.ac.uk/about/organisation
Medical Sciences

The Medical Sciences Division is an internationally recognized centre of excellence for biomedical and clinical research and teaching. We are the largest academic division in the University of Oxford.

World-leading programmes, housed in state-of-the-art facilities, cover the full range of scientific endeavour from the molecule to the population. With our NHS partners we also foster the highest possible standards in patient care.

For more information please visit: www.medsci.ox.ac.uk

Nuffield Department of Clinical Medicine (NDM)

The Nuffield Department of Clinical Medicine (NDM) is one of the largest departments of the University of Oxford and is part of the Medical Sciences Division, with responsibility for a significant part of the teaching of clinical students within the Medical School. The Department also has a substantial research programme which requires high quality administrative management.

NDM has significant financial turnover and complexity, resulting from its diverse research portfolio, its geographical spread and its close links with NHS funding and strategic teams involved in the development and delivery of increasingly integrated clinical research platforms.

For more information please visit: http://www.ndm.ox.ac.uk/home

........fostering your career in science.

The University of Oxford is a member of the Athena SWAN Charter and holds an institutional Bronze Athena SWAN award. The Nuffield Department of Medicine holds a Silver Athena SWAN award in recognition of its efforts to introduce organisational and cultural practices that promote gender equality in SET and create a better working environment for both men and women.

For more information please visit: www.ndm.ox.ac.uk/working-for-ndm/aboutndmatheneswan/

Tropical Medicine and Global Health

The Centre for Tropical Medicine and Global Health is a world leading Centre within the Nuffield Department of Clinical Medicine, University of Oxford, comprised of research groups who are
Centre for Tropical Medicine and Global Health

permanently based in Africa and Asia as well as across two sites in Oxford. Our research ranges from clinical studies to behavioral sciences, with capacity building integral to all of our activities.

Our research is conducted at three Wellcome Trust Major Overseas Programmes in Kenya, Thailand and Viet Nam as well as a growing Centre in Oxford. The Centre for Tropical Medicine and Global Health also brings together a number of sister groups in Laos, Tanzania, Indonesia, the Democratic Republic of Congo, Myanmar, Cambodia and Nepal, as well as multiple collaborators around the world.

Tackling infectious diseases, which kill many millions of people every year, is one of the greatest challenges of the 21st century. We are researching solutions to the increasingly urgent problems these diseases cause.

The Centre’s annual turnover is in excess of £48m per annum with over 100 externally funded research grants and donations.

For more information please visit:  
http://www.tropicalmedicine.ox.ac.uk/home

How to apply

Before submitting an application, you may find it helpful to read the ‘Tips on applying for a job at the University of Oxford’ document, at https://www.ox.ac.uk/about/jobs/professionalandmanagement/ https://www.ox.ac.uk/about/jobs/research/

If you would like to apply, click on the Apply Now button on the ‘Job Details’ page and follow the on-screen instructions to register as a new user or log-in if you have applied previously. Please provide details of two referees and indicate whether we can contact them now.

You will also be asked to upload a CV and a supporting statement. The supporting statement must explain how you meet each of the selection criteria for the post using examples of your skills and experience. This may include experience gained in employment, education, or during career breaks (such as time out to care for dependants).

Your application will be judged solely on the basis of how you demonstrate that you meet the selection criteria stated in the job description.

Please upload all documents as PDF files with your name and the document type in the filename.

All applications must be received by midday on the closing date stated in the online advertisement.
Information for priority candidates

A priority candidate is a University employee who is seeking redeployment because they have been advised that they are at risk of redundancy, or on grounds of ill-health/disability. Priority candidates are issued with a redeployment letter by their employing departments.

If you are a priority candidate, please ensure that you attach your redeployment letter to your application (or email it to the contact address on the advert if the application form used for the vacancy does not allow attachments).

Should you experience any difficulties using the online application system, please email recruitment.support@admin.ox.ac.uk. Further help and support is available from www.ox.ac.uk/about_the_university/jobs/support/. To return to the online application at any stage, please go to: www.recruit.ox.ac.uk.

Please note that you will be notified of the progress of your application by automatic emails from our e-recruitment system. Please check your spam/junk mail regularly to ensure that you receive all emails.

Important information for candidates

Training

You are required to undertake mandatory training as required by the University, Division and Department. The specific list of training courses may change from time-to-time, in response to both legal and internal University requirements.

Pre-employment screening

Please note that the appointment of the successful candidate will be subject to standard pre-employment screening, as applicable to the post. This will include right-to-work, proof of identity and references. We advise all applicants to read the candidate notes on the University’s pre-employment screening procedures, found at: www.ox.ac.uk/about/jobs/preemploymentscreening/.

Data Privacy

Please note that any personal data submitted to the University as part of the job application process will be processed in accordance with the GDPR and related UK data protection legislation. For further information, please see the University’s Privacy Notice for Job Applicants at: www.admin.ox.ac.uk/councilsec/compliance/gdpr/privacynotices/job/. The University’s Policy
The University operates an Employer Justified Retirement Age (EJRA) for all academic posts and some academic-related posts. From 1 October 2017, the University has adopted an EJRA of 30 September before the 69th birthday for all academic and academic-related staff in posts at grade 8 and above. The justification for this is explained at: www.admin.ox.ac.uk/personnel/end/retirement/acrelretire8+/

For existing employees, any employment beyond the retirement age is subject to approval through the procedures: www.admin.ox.ac.uk/personnel/end/retirement/acrelretire8+/

From 1 October 2017, there is no normal or fixed age at which staff in posts at grades 1–7 have to retire. Staff at these grades may elect to retire in accordance with the rules of the applicable pension scheme, as may be amended from time to time.

Equality of Opportunity

Entry into employment with the University and progression within employment will be determined only by personal merit and the application of criteria which are related to the duties of each particular post and the relevant salary structure. In all cases, ability to perform the job will be the primary consideration. No applicant or member of staff shall be discriminated against because of age, disability, gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion or belief, sex, or sexual orientation.
Centre for Tropical Medicine and Global Health

Benefits of working at the University

University Club and sports facilities
The University Club provides social, sporting and hospitality facilities. It incorporates a bar, café and sporting facilities, including a gym. Staff can also use the University Sports Centre on Iffley Road at discounted rates, including a fitness centre, powerlifting room, and swimming pool. See: www.club.ox.ac.uk and www.sport.ox.ac.uk/oxford-university-sports-facilities.

Information for international staff (or those relocating from another part of the UK)
If you are relocating to Oxfordshire from overseas, or elsewhere in the UK, the University's International Staff website includes practical information related to moving to and settling in Oxford such as advice on immigration, relocation, accommodation, or registering with a doctor. See: www.internationalstaffwelcome.admin.ox.ac.uk/

The University of Oxford Newcomers’ Club
The University of Oxford Newcomers’ Club is an organisation run by volunteers that aims to assist the partners of new staff to settle into Oxford and to provide them with an opportunity to meet people in the area. See www.newcomers.ox.ac.uk/

Childcare
The University has excellent childcare services with five University nurseries, as well as University-supported places at many other private nurseries. For full details including how to apply and the costs, see www.admin.ox.ac.uk/childcare.

Family-friendly benefits
The University subscribes to My Family Care (www.admin.ox.ac.uk/personnel/staffinfo/benefits/family/mfc/) and staff are eligible to register for emergency back-up childcare and adultcare services, a 'speak to an expert' phone line and a wide range of guides and webinars through a website called the Work + Family space.

Disabled staff
We are committed to supporting members of staff with disabilities or long-term health conditions. Please visit www.admin.ox.ac.uk/eop/disab/staff for further details including information about how to make contact, in confidence, with the University’s Staff Disability Advisor.

Staff networks
The University has a number of staff networks including the Oxford Research Staff Society, BME staff network, LGBT+ staff network and a disabled staff network. You can find more information at www.admin.ox.ac.uk/eop/inpractice/networks/

Other benefits
Centre for Tropical Medicine and Global Health

Staff can enjoy a range of other benefits such as free visitor access to the University’s colleges and the Botanic Gardens as well as a range of discounts. See [www.admin.ox.ac.uk/personnel/staffinfo/benefits](http://www.admin.ox.ac.uk/personnel/staffinfo/benefits)