

Centre for Tropical Medicine and Global Health

Job title	Clinical Trials Manager
Division	Medical Sciences
Department	Centre for Tropical Medicine and Global Health
Location	WHG Building, Old Road Campus, Headington, Oxford OX2 7BN
Grade and salary	Grade 7: £32,236 - £39,609 per annum
Hours	Full time (part time may be considered)
Contract type	Fixed-term (to 31 December 2023)
Reporting to	Director of Science
Vacancy reference	139702



The role

The International Severe Acute Respiratory and emerging Infection Consortium (ISARIC) is a global federation of clinical research networks providing a proficient, coordinated, and agile clinical research response to outbreak-prone infectious diseases. Our mission is to generate and disseminate clinical research evidence for outbreak-prone infectious diseases, whenever and wherever they occur.

The ISARIC Global Support Centre (GSC), currently based in Oxford, provides technical and operational support to ISARIC members and stakeholders wishing to conduct research in preparation for, or in response to, outbreaks. Currently we have 57 member networks spanning 113 countries. Over the past 6 years we have responded to MERS, Ebola, Zika, Monkeypox and Lassa fever. This has included preparing standardised data collection tools, running two clinical trials during the West African Ebola outbreak and writing & disseminating an observational protocol for emerging pathogens (CCP), which recruited recently for MERS and Monkeypox cases. With partners, we run a global SARI observational study called SPRINT-SARI.

We have an ambitious 5 year programme, which includes setting up and running new trials for emerging pathogens. Our portfolio currently includes treatment trials of Lassa fever and plague and pre-positioned protocols for MERS and Nipah. Trials will take place in disease-endemic low and middle income countries. In order to conduct the trials, the GSC is supported by a multi-disciplinary research team, working across a wide range of studies. The role of the Clinical Trials Manager sits within the research team and will lead on ISARIC studies whilst providing cover for other studies being conducted by the research team.

You will have primary responsibility for the day-to-day management of clinical research activities under the supervision of the Director of Science. You will ensure timely data collection, Good Clinical Practice (GCP) compliance and will undertake regular study monitoring, both remotely and on-site. You will also facilitate meetings of trial committees and be responsible for ensuring relevant and timely updates for project stakeholders. Your role will include monitoring and managing the study documentation for both on-going clinical trials and the set-up of new trials as the need arises. You will ensure that all studies comply with Standard Operating Procedures.

The post may involve travel to worldwide study sites, however the requirement for this will fluctuate across the different phases of the programme.

Key responsibilities

- To work effectively as a member of the research team, taking overall responsibility for the day-to-day management of the ISARIC trials, ensuring achievement of project deadlines and regularly attending meetings
- Assist in updating the protocol, study materials, training packages for collaborating sites and trial manuals, and prepare trial specific instructions as required
- Maintain overall ethical approvals, obtain and maintain site-specific approvals for all sites
- Liaise with Research Services to ensure that Clinical Study Agreements are in place before any new sites are opened
- Identify, recruit and support the participating sites; conduct site set-up and regular monitoring visits as appropriate
- Perform site close-out visits, as required
- Track progress at each site and take appropriate action to ensure good recruitment, compliance with the protocol and the quality and timeliness of the data collection. Use initiative to tackle any practical difficulties reported by sites
- Assist with the planning and delivery of trial specific training programmes to staff at participating sites
- Organise regular Study Management Group and Steering Committee meetings, with responsibility for preparing documentation and reports for these meetings
- Be responsible for the Trial Master File and updating study documentation, maintaining effective version control
- In collaboration with data manager, develop monitoring plans and reports to be used across ISARIC
- In collaboration with statistician, contribute to interim analysis
- Work alongside the Chief Investigator and the ISARIC Director of Science to prepare and deliver progress reports to the funder and annual reports to the Sponsor and Ethics Committees, as required, in a timely manner
- Work with the Tropical Medicine finance team to monitor study budgets
- Ensure all aspects of the programme of research are set up and run in accordance with Standard Operating Procedures (SOPs)
- Any other related duties as required as appropriate to the grade of this post

Essential Selection criteria

- Degree in a biomedical or related subject, other relevant qualification, or proven experience in clinical research
- Previous experience of clinical trial project set-up and management
- Working knowledge of the EU Clinical Trials Directive, UK Clinical Trials regulations, Principles of GCP, Data Protection Act, Human Tissue Act and Research Governance Framework legislation and proven ability to apply these to the coordination of a clinical trial
- Evidence of preparing regulatory and ethics submissions and amending protocols, patient information sheets, electronic databases and other relevant trial management documentation
- Experience and understanding of techniques for the management of medical research information e.g. data coding, entry validation and reporting
- Excellent IT literacy e.g. Microsoft Office, Adobe products as well as aptitude for bespoke packages
- Evidence of effective communication, presentation and inter-personal skills
- Proven ability to organise and prioritise workload to meet deadlines
- Proven ability to work independently as well as part of a team
- Ability to work accurately and methodically with a meticulous attention to detail

Desirable selection criteria

- Previous experience or knowledge of an academic research environment
- Experience of working with or in developing countries
- Availability to travel internationally if necessary
- Additional language skills (e.g., French, Spanish)
- Knowledge and/or experience of contracts in a research environment

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



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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.



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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 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.



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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



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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

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 on Data Protection is available at: www.admin.ox.ac.uk/councilsec/compliance/gdpr/universitypolicyondataprotection/.

The University's policy on retirement

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+/.



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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.



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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.



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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

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

