

Job description and selection criteria

Job title	Clinical Trials Assistant
Division	Medical Sciences
Department	Paediatrics
Location	Centre for Clinical Vaccinology and Tropical Medicine, Churchill Hospital, Headington Oxford. Some liaison is also required with the Department of Biochemistry, South Parks Road, Oxford. Hybrid working may be possible for this role.
Grade and salary	Grade 5: £31,459 - £36,616 per annum (with a discretionary range to £39,749 per annum)
Hours	Full-time (36.5 hours per week)
Contract type	Fixed-term for 12 months or until 31 March 2026, whichever is sooner
Reporting to	Rachel Roberts, Senior Clinical Trials Manager
Vacancy reference	177094
Additional information	<i>Applications are to be made online, please see the advert for the closing date.</i> <i>This is a readvertisement of vacancy ID 174828. Previous applicants need not reapply.</i>

Principal Investigator / supervisor	Professor Simon Draper
Project team	Draper Group
Project web site	https://draperlab.web.ox.ac.uk/home
Funding partner	The funds supporting this research project are provided by EDCTP MIMVac- AFRICA



The role

Professor Simon Draper leads a vaccine development programme, with a strong focus on malaria, antibody immunology and clinical trials. The Draper Group laboratory team part of the Department of Paediatrics. The Group is based across different locations, including the Dorothy Crowfoot Hodgkin Building and Kavli Institute for Nanoscience Discovery, with the clinical team, led by Dr Angela Minassian, based at the Centre for Clinical Vaccinology and Tropical Medicine at the Churchill Hospital. The group's current website is here: <https://draperlab.web.ox.ac.uk/>.

The research group has a strong translational focus, seeking to develop innovative and new concepts in vaccine or antibody-based design and delivery, and with full integration of the clinical and laboratory teams. Over the last 10 years we have translated nine vaccine candidates, including viral vectors, recombinant proteins-in-adjuvants and virus-like particles, into Phase I and II clinical trials in the UK and Africa. Over half of these trials include an experimental malaria challenge component, either with falciparum or vivax malaria parasites. The group has a strong record of attracting external grant funding, a strong publication record, and has expanded significantly in recent years. We have a diverse funding portfolio and strong links with industry and a variety of non-industrial / academic collaborators. We aim to foster scientific excellence within an open and free-thinking environment. The Draper group has a friendly and collaborative ethos, aiming to provide a supportive environment for all staff working in laboratory-, clinic- and office-based roles. The research group currently consists of approximately 28 members of staff including clinical research fellows, project managers, administrative staff, research scientists and students.

The post holder will provide support in all aspects of trial management for a portfolio of Clinical Trials and/or Controlled Human Malaria Infection (CHMI) studies in the UK and Africa. As the Clinical Trials Assistant, you will have a role in the development, co-ordination and completion of clinical trials conducted. This is a key role within the Clinical Trials Research Team ensuring smooth and effective running of operations and providing day to-day professional support. Previous experience in the clinical trials and good clinical practice (GCP) are also desirable for this position.

Flexible working

This role will be based at the Centre for Clinical Vaccinology and Tropical Medicine, Churchill Hospital, Headington Oxford, however, some liaison is also required with the Department of Biochemistry, South Parks Road, Oxford.

Hybrid working may be possible for this role in agreement with the line manager.

Responsibilities

- Work on clinical trial applications and amendments for various bodies and partners including the regulatory authorities and ethics committees. Ensure that full approvals are in place for all trials and sites, and that deadlines are met.
- Create and improve key trial documents, ensuring their accuracy and clarity.
- Communicate with a wide range of internal and external partners, including: Clinical Trial Doctors, Clinical Research Coordinators, laboratory staff and finance, and external collaborators.
- Schedule, prepare information for, and actively contribute to regular operational meetings and teleconferences. Record accurate minutes and distribute documents in a timely manner.
- Create and manage trial master files and other trial related filing systems, some of which are complex in nature (for example core files, SAE tracking). Ensure their accuracy prior to trial monitoring and archiving.
- Liaise regularly with other UK and international trial sites to ensure they are set up correctly, their Investigator Site Files are maintained, and training needs are addressed.
- Registering and updating trial information on sites such as Clinicaltrials.gov.
- Use databases to enter and collate trial data for formal trial reports, and assist in database validation.
- Provide financial administration support (processing invoices, raising purchase orders and payment request forms), liaising closely with the finance team.
- Undertake general office duties including: stationery orders, mailing, copying, and document management.
- Assist in all aspects of the team's activities as appropriate, according to the principles of Good Clinical Practice (GCP) and the Clinical Trial Unit's Standard Operating Procedures (SOPs).
- Participate in and support the public engagement and widening access activities of the Department and the University. This is anticipated to be not more than two days per year.

Selection criteria

Essential

- Educated to an A-Level standard (or equivalent).
- Excellent communication and interpersonal skills, with the ability to communicate confidently and effectively with people at all levels both in writing and verbally.
- Experience of working as part of a team.
- Ability to work independently, using initiative to solve problems and make decisions.
- Proven administrative experience, ideally in the area of clinical trials, with excellent attention to detail, accuracy, and good numerical skills.
- Excellent organisational skills with previous experience of working effectively under pressure, with a demonstrable ability to prioritise and organise own diverse workload to meet competing deadlines.
- Comprehensive working knowledge of computer software packages such as Microsoft Office and willingness to learn new skills and explore new technologies.

- A responsible nature with a professional approach to work.

Desirable

- Previous experience working in a similar clinical/academic environment (training will be provided).
- Understanding and previous experience of Good Clinical Practice and the regulations and guidelines applicable to clinical trials in the UK.
- Further education qualification in a scientific field (ideally a biological science) or equivalent knowledge/experience.
- Previous experience and knowledge of working with different databases, and producing basic management information reports and analyses.

Pre-employment screening

Standard checks

If you are offered the post, the offer will be subject to standard pre-employment checks. You will be asked to provide: proof of your right-to-work in the UK; proof of your identity; and (if we haven't done so already) we will contact the referees you have nominated. If you have previously worked for the University we will also verify key information such as your dates of employment and reason for leaving your previous role with the department/unit where you worked. You will also be asked to complete a health declaration so that you can tell us about any health conditions or disabilities for which you may need us to make appropriate adjustments.

Please read the candidate notes on the University's pre-employment screening procedures at: <https://www.jobs.ox.ac.uk/pre-employment-checks>

Hazard-specific / Safety-critical duties

This job includes hazards or safety-critical activities. If you are offered the post, you will be asked to complete a health questionnaire which will be assessed by our Occupational Health Service, and the offer of employment will be subject a successful outcome of this assessment.

The hazards or safety-critical duties involved are as follows:

- Lone working due to hybrid working

Additional security pre-employment checks

This job includes duties that will require additional security pre-employment checks:

- A satisfactory basic Disclosure and Barring Service check due to the nature of this position working with highly sensitive data
- University security screening (e.g. identity checks)

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 and we rank first in the UK for university spin-outs, and in recent years we have spun out 15-20 new companies every year. 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.

The Draper Lab at the Centre for Clinical Vaccinology and Tropical Medicine

The clinical activities of the Draper Group are undertaken at the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM) which is a purpose-built centre on the Churchill Hospital site. CCVTM is a multi-disciplinary unit which houses physicians, nurses, clinical trial project managers and administrators from a number of other University of Oxford Research Groups, including the Oxford Vaccine Group.

Department of Paediatrics

The Department of Paediatrics is a world leader in child health research and hosts internationally renowned research programmes in drug development, gastroenterology, haematology, HIV, immunology, neuroimaging, neuromuscular diseases and vaccinology. Our work spans from early proof-of concept fundamental science, all the way up to its application in clinical settings.

We continue to shape the landscape of medical science through positively impacting the lives of millions of children from our global research programmes, academic resources, and commitment to success. Our broad research base positions the department in a pivotal role and subsequently a world leader in child health. With research facilities in the UK and abroad, we work on a global scale, building a paediatric network in the medical science community. We are committed to inform and inspire external audiences worldwide through our public engagement and outreach activities.

In 2021, we successfully administered a grant value of £130,895,28 obtained through 168 projects. Our strong relationship with funding bodies have also been a contributor to the successes and milestones in children's health research. With strong support from the Wellcome Trust, NIH, Cancer Research UK, UKRI, MRC, Bill & Melinda Gates Foundation, Academy of

Medical Sciences and the NIHR, we have employed 360+ staff, researchers, and students. These figures continue to grow as we expand our activities to overcome the multitude of challenges within children's research health.

For more information please visit: <http://www.paediatrics.ox.ac.uk/>

The Department of Paediatrics holds a Gold Athena Swan award to recognise advancement of gender equality: representation, progression and success for all.

Medical Sciences Division

We are an internationally recognized centre of excellence for biomedical and clinical research and teaching, and 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: <http://www.medsci.ox.ac.uk/>

How to apply

Applications are made through our online recruitment portal. Information about how to apply is available on our jobs website <https://www.jobs.ox.ac.uk/how-to-apply>.

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

As part of your application you will be asked to provide details of two/three referees and indicate whether we can contact them now.

You will 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).

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

All applications must be received by **midday** UK time on the closing date stated in the online advertisement.

If you currently work for the University please note that:

- as part of the referencing process, we will contact your current department to confirm basic employment details including reason for leaving
- although employees may hold multiple part-time posts, they may not hold more than the equivalent of a full time post. If you are offered this post, and accepting it would take you over the equivalent of full-time hours, you will be expected to resign from, or reduce hours in, your other posts(s) before starting work in the new post.

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 department(s).

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).

If you need help

Application FAQs, including technical troubleshooting advice is available at: <https://staff.web.ox.ac.uk/recruitment-support-faqs>

Non-technical questions about this job should be addressed to the recruiting department directly at recruitment@paediatrics.ox.ac.uk or using the contact details in the online advertisement.

To return to the online application at any stage, please go to: www.recruit.ox.ac.uk.

Please note that you will receive an automated email from our e-recruitment system to confirm receipt of your application. **Please check your spam/junk mail** if you do not receive this email.

Important information for candidates

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: <https://compliance.admin.ox.ac.uk/job-applicant-privacy-policy>. The University's Policy on Data Protection is available at: <https://compliance.admin.ox.ac.uk/data-protection-policy>.

The University's policy on retirement

The University operates an Employer Justified Retirement Age (EJRA) for very senior research posts at **grade RSIV/D35 and clinical equivalents E62 and E82** of 30 September before the 70th birthday. The justification for this is explained at: <https://hr.admin.ox.ac.uk/the-ejra>.

For **existing** employees on these grades, any employment beyond the retirement age is subject to approval through the procedures: <https://hr.admin.ox.ac.uk/the-ejra>.

There is no normal or fixed age at which staff in posts at other grades 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.

Benefits of working at the University

Employee benefits

University employees enjoy 38 days' paid holiday, generous pension schemes, travel discounts including salary sacrifice schemes for bicycles and electric cars and other discounts. Staff can access a huge range of personal and professional development opportunities. See <https://hr.admin.ox.ac.uk/staff-benefits>.

Employee Assistance Programme

As part of our wellbeing offering staff get free access to Health Assured, a confidential employee assistance programme, available 24/7 for 365 days a year. Find out more <https://staff.admin.ox.ac.uk/health-assured-eap>.

University Club and sports facilities

Membership of the University Club is free for all University staff. The University Club offers social, sporting, and hospitality facilities. 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 <https://www.sport.ox.ac.uk/>.

Information for staff new to Oxford

If you are relocating to Oxfordshire from overseas or elsewhere in the UK, the University's Welcome Service includes practical information about settling in the area, including advice on relocation, accommodation, and local schools. See <https://welcome.ox.ac.uk/>.

There is also a visa loan scheme to cover the costs of UK visa applications for staff and their dependents. See <https://staffimmigration.admin.ox.ac.uk/visa-loan-scheme>.

Family-friendly benefits

We are a family-friendly employer with one of the most generous family leave schemes in the Higher Education sector (see <https://hr.web.ox.ac.uk/family-leave>). Our Childcare Services team provides guidance and support on childcare provision, and offers a range of high-quality childcare options at affordable prices for staff. In addition to 5 University nurseries, we partner with a number of local providers to offer in excess of 450 full time nursery places to our staff. Eligible parents are able to pay for childcare through salary sacrifice, further reducing costs. See <https://childcare.admin.ox.ac.uk/>.

Supporting disability and health-related issues (inc menopause)

We are committed to supporting members of staff with disabilities or long-term health conditions, including those experiencing negative effects of menopause. Information about the University's Staff Disability Advisor, is at <https://edu.admin.ox.ac.uk/disability-support>. For

information about how we support those going through menopause see <https://hr.admin.ox.ac.uk/menopause-guidance>.

Staff networks

The University has a number of staff networks including for research staff, BME staff, LGBT+ staff, disabled staff network and those going through menopause. Find out more at <https://edu.admin.ox.ac.uk/networks>.

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 settle into Oxford, and provides them with an opportunity to meet people and make connections in the local area. See www.newcomers.ox.ac.uk.

Research staff

The Researcher Hub supports all researchers on fixed-term contracts. They aim to help you settle in comfortably, make connections, grow as a person, extend your research expertise and approach your next career step with confidence. Find out more <https://www.ox.ac.uk/research/support-researchers/researcher-hub>.

Oxford's Research Staff Society is a collective voice for our researchers. They also organise social and professional networking activities for researchers. Find out more <https://www.ox.ac.uk/research/support-researchers/connecting-other-researchers/oxford-research-staff-society>.