

Summary

Job title	Senior Clinical Trial Programme Manager
Division	Medical Sciences
Department	Department of Biochemistry
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.
Grade and salary	Grade 8: £47,085 – £55,895 per annum, with a discretionary range to £60,921 per annum We would be willing to consider offering the role within the discretionary range for exceptional candidates. This would be discussed with applicants at interview/appointment where appropriate.
Hours	Full time (37.5 hours per week). We would consider a suitably qualified candidate who wishes to work a minimum 3 days per week. Hybrid working options can be considered
Contract type	Fixed Term Contract for up to 2 years in the first instance
Reporting to	Professor Simon Draper and Professor Angela Minassian
Vacancy reference	175310
Additional information	<p>You are required to submit a CV and a supporting statement with your application, outlining how you meet each of the selection criteria for the role (see below for details). Your application will not be processed if you do not include both documents.</p> <p>Whilst the role is a grade 8 position, we would be willing to consider candidates with potential but less experience who are seeking a development opportunity, for which an initial appointment would be at grade 7 (£37,524 - £45,763 p.a.) with the responsibilities adjusted accordingly. This would be discussed with applicants at interview/appointment where appropriate</p>

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 is based at the [Department of](#)



Biochemistry, forming part of a new hub for infectious disease and immunology research in the Dorothy Crowfoot Hodgkin Building and Kavli Institute for Nanoscience Discovery, with the clinical team, led by Associate Professor 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 eleven vaccine candidates, including viral vectors, recombinant proteins-in-adjuvant 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 30 members of staff including clinical research fellows, project managers, administrative staff, research scientists and students.

The post holder is responsible for the management of a portfolio of Clinical Trials of Investigational Medicinal Products (CTIMPs) in the UK and Africa as well as Controlled Human Malaria Infection (CHMI) studies, and will in addition undertake line management responsibilities. In partnership with the Clinical Lead and Operations Manager the post-holder contributes to the overall management of the malaria clinical research programme, through the application of specialist and technical knowledge to ensure that research and strategic objectives are met and regulatory and ethical standards, and wider University policies are adhered to. This is a key role within the Group's senior management team, and requires interactive working with a number of senior investigators and University Professional Services personnel.

The post is based at the Centre for Clinical Vaccinology and Tropical Medicine. Some liaison is also required with the Department of Biochemistry, South Parks Road, Oxford.

Responsibilities

This post has primary responsibility for the day-to-day running and maintaining oversight of our Clinical Trials portfolio in Africa and UK-based trials. Specific duties include:

a) Clinical Trial(s) management

- To lead and oversee on key tasks within clinical trial/study lifecycle. This includes:
 - Coordinating clinical trial/study applications and amendments for various bodies and partners including relevant regulatory authorities and ethics committees.
 - Assisting with preparation and review of all trial related documents.
 - Strategizing and proactively looking for opportunities to accelerate participant recruitment activity and other trial set up and operational activities with team members
 - Monitoring trial conduct from setup to analysis, according to the principles of Good Clinical Practice (GCP) and Standard Operating Procedures (SOPs).
 - Overseeing and facilitating end of trial/study activities
 - Maintaining overall responsibility for TMF management, keeping the records up-to-date, ready for potential audits and compliant to any regulatory requirements.
 - Keeping close contact with study sites (if any), to ensure clear communication and timely implementation of study set up activities, trainings or amendment(s) implementation.
 - Facilitating discussion with Lab team, Study monitor, Quality Assurance team and Data Management team to deliver quality controlled study outcome(s).
- To support Senior Immunologist(s) in HTA adoption and further ethics application where required.

- To contribute and to evaluate the study design, feasibility and logistics of proposed new studies and provide advice on regulatory requirements

b) Project coordination and management

- To facilitate the preparation and review of other project-related documents (e.g. contracts).
- To be responsible for the strategic oversight and co-ordination of clinical studies in the group's clinical portfolio to ensure that the programme's milestones can be met. This includes:
 - Tracking progress, timeline and budget at all times.
 - Ensuring any events impacting the above are effectively communicated to the wider project team after careful analysis and consideration of multiple factors with conclusions on the outcomes and possible actions in a timely and appropriate manner.
 - Following the event(s) up until fully resolved and document as required.
- To maintain regular oversight of clinical study budgets within your portfolio, taking responsibility for the communication of budget changes as required.
- To act as the first point of contact for important project enquiries and decision-making issues relating to your portfolio of studies and when necessary other clinical studies within the group's clinical research portfolio.
- To be responsible for organising and chairing meetings and committees related to the projects:
 - Co-ordinating conference calls and meetings. Presenting the status of the project.
 - Taking and distributing minutes, action points and agendas for any project related meeting.
 - Providing training as required to other team members on minute taking for clinical project meetings
- To support in the production of project plans, milestones, milestone reviews and project budgets for current and future projects.
- To use your expertise and knowledge of both the scientific and financial aspects of CTIMPs contribute to the development of new funding applications.
- To contribute to the preparation of papers for publication.
- To be proactive in promoting the clinical research programme and studies within your portfolio to the academic community, the public, and policy makers. This will require excellent communication skills and the ability to interpret highly technical language to deliver complex information in a concise way to varied audiences.
- To act at all times in the best interest of the University to ensure that the projects are managed in accordance to good research practice.
- To travel to research sites and scientific meetings nationally and internationally to deliver training and share information about trials.
- To attend scientific seminars, meetings and training as appropriate.

c) Team Management

- To be responsible for line management, staff appraisal and supervise one or more multidisciplinary team members.
- To train, support and guide Project managers and Clinical Trial Assistants in project delivery
- To work as an integral member of the clinical senior management team,
- To provide professional leadership and facilitate coordination of a portfolio of clinical trials, setting and adhering to Standard processes, ICH-GCP and other applicable guidelines.
- To establish communicate team performance expectations and clear targets and project milestones.

- To act as a flexible and proactive team member to deliver the clinical research programme's strategy and ensure smooth running of its clinical activities under the direction of the Clinical Lead.
- To work as an integral member of Senior Management team:
 - To manage resource allocation and the staffing budgets for clinical team members in a timely and flexible manner.
 - To identify required resources and support in the preparation of job descriptions and adverts for new clinical posts within the team and sit on interview panels as required.
- To oversee the annual leave or other staff absence and ensure adequate coverage as required for other members of the project team.
- To maintain excellent communication and to develop excellent relationships both internally and externally.

All employees will have to ensure that their work in the laboratory, office or clinic is conducted safely at all times and, in particular, that work is undertaken following the appropriate health and safety policies and procedures for the particular area, without compromise to their own safety or that of others who may be affected.

Selection criteria

Essential selection criteria

1. Educated to a degree level in relevant area of research with extensive experience in trial management.
2. Ability to demonstrate leadership of large and complex clinical projects, for example, with multiple stakeholders, budgets exceeding £1m, long time-frames, and regulatory complexity;
3. Excellent up to date knowledge of clinical trials management of investigational medicinal products and associated regulatory and governance requirements for UK trials;
4. Experience of contributing to quality assurance processes including authoring of standard operating procedures;
5. Experience of line management and staff development, including prioritising and managing own and others workloads, supporting career progression and dealing with performance issues;
6. Highly organised with the ability to manage a vast amount of relatively complex information and to prioritise a demanding workload with competing deadlines;
7. Ability to communicate effectively to a high standard to a broad range of individuals including internationally on complex scientific matters, orally and in writing;
8. Ability and willingness to actively contribute towards developing and improving innovative ways of working and managing projects and research programmes;
9. Ability and willingness to work independently, to support and supervise others as may be necessary, and to work effectively as part of a multi-disciplinary team;
10. Critical thinking ability and good problem-solving skills, an eye for detail and an ability to work to high standards consistently;
11. Advanced computer skills particularly Microsoft Office package.

Desirable selection criteria

1. Experience of the clinical trial management of vaccine trials;
2. Experience of being involved with audits and inspections, e.g. MHRA inspections;
3. Previous experience of conducting clinical trials in Low and Middle Income Countries (LMICs);
4. Understanding of the University research grant management procedures and/or previous relevant experience within the higher education sector;

5. Experience with Project Management software or a certified Project Manager Qualification (e.g. Prince 2);
6. Willingness to travel to Africa and other international destinations as required.

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>

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.

Department of Biochemistry

The Department of Biochemistry in Oxford was established in 1920 and is now one of the largest in Europe. Situated in an attractive area close to the University Parks and River Cherwell, the Department is housed in the University Science Area and is currently undergoing a major expansion programme centred on the recently completed and award-winning New Biochemistry Building. The Science Area includes the Radcliffe Science Library and the Natural History Museum, and is conveniently located for easy access to the town centre and colleges.

The department includes research laboratories working in the areas of Cell Biology, Development and Genetics; Chromosomal and RNA Biology; Infection and Disease Processes; Microbiology and Systems Biology; and Structural Biology and Molecular Biophysics. It is particularly well equipped with an extensive computer network, all the basic hardware essential in today's research, together with an excellent range of state-of-the-art specialist equipment.

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

The University of Oxford is a member of the [Athena SWAN Charter](#) and holds an institutional Bronze Athena SWAN award. The Department of Biochemistry is strongly committed to equality and valuing diversity and we operate a flexible working policy for all staff. The Department holds a departmental Silver Athena SWAN award to recognise advancement of gender equality: representation, progression and success for all.

Centre for Clinical Vaccinology and Tropical Medicine, Churchill Hospital, Oxford

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.

For more information see: <https://www.ovg.ox.ac.uk/about/contact-us>

Medical Sciences Division

The Medical Sciences Division is an internationally recognized centre of excellence for biomedical and clinical research and teaching, and the largest academic division in the University of Oxford. It includes 15 clinical departments and 5 non-clinical departments.

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.ox.ac.uk/divisions/medical_sciences.html

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 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.

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, please email recruitment@bioch.ox.ac.uk

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 online recruitment portal 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.

The University's Policy on Information Security Awareness

The information security awareness training is **compulsory** for all University staff; and as part of our responsibility as a Department, **ALL** employees of the Department will be required to complete the [online information security awareness module](#), which provides a combination of information, case studies and links to additional resources relating to information security. You will be expected to complete this course as part of your induction process, on your first day working in the Department of Biochemistry. This training will also need to be completed in order to successfully complete your probationary period.

In order to ensure that we are compliant and up-to-date with the information security awareness training, we need to ensure that all staff members have completed the latest course, which may be accessed from the Information Security's website by using the following link:

<https://www.infosec.ox.ac.uk/guidance-policy/training-and-awareness>

You will also be required to undertake this course on an annual basis, in order to satisfy the security awareness training requirements of the University's Information Security Policy.

Benefits of working at the University

Employee benefits

University employees enjoy 38 days' paid holiday, generous pension schemes, flexible working options, 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 University staff. It 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 dependants. 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. 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/>. We also subscribe to the Work+Family Space, a service that provides practical advice and support for employees who have caring responsibilities for dependants of all types. See <https://hr.admin.ox.ac.uk/my-family-care>

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 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>