





# Job description and selection criteria

Job title	Junior Clinical Trials Manager
Division	Medical Sciences
Department	Paediatrics
Location	Oxford Vaccine Group, CCVTM, Churchill Hospital, Oxford
Grade and salary	Grade 6: £34,982 - £40,855 per annum (with a discretionary range to £44,382 per annum)
Hours	Full-time
Contract type	Fixed-term (12 months)
Reporting to	Emma Plested, Programme and Regulatory Affairs Director OVG
Vacancy reference	176865
Additional information	Applications are to be made online, please see the advert for the closing date.

# The role

Within the Oxford Vaccine Group the Junior Clinical Trials Manager (JCTM) is responsible for the successful delivery of a portfolio of clinical trials across the whole project lifecycle, this includes ensuring they are delivered on time, to budget and to the expected quality standards. This role is a training position focusing on the delivery phase of the clinical trial/study. Working with the support of the Project Manager and Senior Research teams the JCTM will ensure quality in all areas of trial management. The post holder will ideally have previous experience of trial administration and knowledge of the UK regulatory requirements.

# **Flexible working**

The Junior Clinical Trials Manager will be based fully on site at the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM). There may be the opportunity to work remotely one day per week depending on project demands.



# Responsibilities

Study/Trial delivery with support from the Project Management team:

- Manage delivery of commercial or publicly-funded studies/trials
- Oversee the project plan and timelines for deliverables
- Implementation of procedures to ensure adherence to protocols and administrative requirements
- Ensure the timely recruitment of trial participants
- Work with the Project Manager and Quality Assurance Team, to monitor the study/trial progress to ensure compliance with and adherence to quality standards, SOPs, ICH GCP and/or other guidelines and to identify, evaluate and rectify problems
- Work with the Senior Research Team to ensure that the study/trial is meeting its targets, is producing meaningful output and to predict and plan any changes in the protocol, funding or time
- Manage studies/trials pro-actively, anticipating problems and providing resolutions in a timely manner
- Plan, chair and support (as appropriate) the meetings of the stakeholders associated with the project
- Liaise with the Data Management Team to ensure efficient and effective data cleaning
- Work with the team on ethics applications, submissions to the regulatory authority, and NHS Research and Development bodies
- Demonstrate an awareness of your study budgets and monitor spend
- Ensure all administrative closeout procedures are completed and that studies/trials are archived
- Contribute towards the preparation of project reports
- Report to appropriate line managers any anticipated need for additional resources and any needs or concerns regarding level of training or performance
- Provide support and guidance to junior members of the team

# **Selection criteria**

### Essential

- Educated to degree level (or equivalent) in a life science/health-related/project management subject OR equivalent relevant working experience demonstrating the essential skillset
- Excellent organisational skills
- Excellent communication skills, both written and oral
- Ability to delegate tasks effectively
- Ability to be flexible and adapt to change
- Ability to demonstrate initiative and think creatively to resolve problems
- · Ability to work accurately and pay attention to detail
- Understand the need for confidentiality

- Have good interpersonal skills and the ability to work as part of a team
- To be able to work independently and make decisions
- Proven working knowledge of Microsoft Office, including Excel and Access

#### Desirable

- Knowledge of GDPR, GCP, Research Governance and other key regulatory areas and ethical frameworks
- Knowledge of regulatory and governance environment in the UK
- Experience of working across the Higher Education industry/NHS interface
- Experience of working in vaccine research

### **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 cuttingedge. 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.

### **Oxford Vaccine Group**

The Oxford Vaccine Group (OVG) is led by Andrew J Pollard, Professor of Paediatric Infection and Immunity. Staff re based within a purpose-built centre on the Churchill Hospital site and form part of the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM). The aim of OVG is to co-ordinate expertise in the study of microbial diseases and the immune response to microbes, in order to facilitate research on the development and implementation of vaccines. This may include new, improved or combined vaccines for the adult and paediatric population. There is currently a large focus on delivering the COVID-19 vaccine trials.

Core group members include two Consultants in Vaccinology, a Director of Clinical Trials, a Senior Clinical Trials Manager, adult and paediatric clinical research fellows, adult and paediatric research nurses, project managers, QA manager, IT manager, and an administration team. The Infection and Immunity Laboratory includes post doctorate scientists, research assistants and DPhil students. Wider group members include professionals from a range of specialities including immunologists, microbiologists, statisticians, a community paediatrician, the local Health Protection team and a bioethicist.

Recent studies carried out by the group include:

- COVID vaccine trials (Phase 1, 2 and 3), Heterologous regimens and booster studies
- Vaccines against RSV Pneumococcal nasopharyngeal carriage epidemiology
- Meningococcal B vaccine development and evaluation
- Development of a typhoid challenge model More information about OVG may be found at the website: <u>http://www.ovg.ox.ac.uk</u>

### **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 facilitates 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, MDUK, 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: <u>http://www.paediatrics.ox.ac.uk/</u>

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: <u>http://www.medsci.ox.ac.uk/</u>

# How to apply

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

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 dependents).

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: <u>https://staff.web.ox.ac.uk/recruitment-support-faqs</u>

Non-technical questions about this job should be addressed to the recruiting department directly at <u>recruitment@paediatrics.ox.ac.uk</u> 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: <u>https://compliance.admin.ox.ac.uk/job-applicant-privacy-policy</u>. The University's Policy on Data Protection is available at: <u>https://compliance.admin.ox.ac.uk/data-protection-policy</u>.

### 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 70<sup>th</sup> birthday. The justification for this is explained at: <u>https://hr.admin.ox.ac.uk/the-ejra.</u>

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

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

### Employeebenefits

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 <a href="https://hr.admin.ox.ac.uk/staff-benefits">https://hr.admin.ox.ac.uk/staff-benefits</a>.

#### 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 <u>https://staff.admin.ox.ac.uk/health-assured-eap</u>.

### 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 <a href="https://www.club.ox.ac.uk">www.club.ox.ac.uk</a> and <a href="https://www.sport.ox.ac.uk/">https://www.sport.ox.ac.uk/</a>.

### 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 <u>https://welcome.ox.ac.uk/.</u>

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

### Family-friendly benefits

We are a family-friendly employer with one of the most generous family leave schemes in the Higher Education sector (see <u>https://hr.web.ox.ac.uk/family-leave</u>). 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 <u>https://childcare.admin.ox.ac.uk/</u>.

### 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 <a href="https://edu.admin.ox.ac.uk/disability-support">https://edu.admin.ox.ac.uk/disability-support</a>. For information about how we support those going through menopause see <a href="https://hr.admin.ox.ac.uk/menopause-guidance">https://hr.admin.ox.ac.uk/menopause-guidance</a>.

### 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 <a href="https://edu.admin.ox.ac.uk/networks">https://edu.admin.ox.ac.uk/networks</a>.

### 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 <u>www.newcomers.ox.ac.uk.</u>

#### Researchstaff

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 <a href="https://www.ox.ac.uk/research/support-researchers/connecting-other-researchers/oxford-research-staff-society">https://www.ox.ac.uk/research/support-researchers/connecting-other-researchers/oxford-research-staff-society</a>.