





Job description and selection criteria

Job title	Senior Programme Manager
Division	Medical Sciences
Department	Paediatrics
Location	Department of Paediatrics, Oxford Vaccine Group, CCVTM, Churchill Hospital, Oxford
Grade and salary	Grade 8: £45,585 - £54,395 per annum (with a discretionary range to £59,421 per annum)
Hours	Full time
Contract type	Fixed-term (two years)
Reporting to	Emma Plested, Programme and Regulatory Affairs Director (UK)
Vacancy reference	173982
Additional information	Applications are to be made online, please see the advert for the closing date.



The role

The Senior Programme Manager will be based at the Centre for Clinical Vaccinology and Tropical Medicine and will provide oversight of the management of clinical trials or clinical programs. General areas of responsibility include: Management of Clinical Trial Assistants and Clinical Trial Support Officers; training and support of Project Managers, development and training of project management systems; provide oversight and knowledge to the research group; developing new policies and strategies with the group; sponsor liaison; project assessment and initiation; oversight of ethics and regulatory submissions; resource procurement and planning; project implementation; milestone planning and tracking; ensuring that projects are progressing according to contract and quality standards; SOPs, ICH-GCP, the UL Clinical Trial Regulations; production of key project progress reports; management of communication between the project team, sponsor, contract and financial management.

Responsibilities

Specific duties will include:

- a) Team Management
 - To provide professional leadership and act as an accessible resource on clinical trial management keeping up to date with industry legislation and frameworks
 - To be responsible for line management, staff appraisal and development of support staff, including Clinical Trial Assistants and Clinical Trial Support Officers, liaising with the Departmental HR Team.
 - To train, support and guide Project Managers in project delivery
 - To lead and facilitate a team of staff responsible for the coordination of a portfolio of clinical trials ensuring adherence to Standard Operating Procedures, ICH-GCP and other applicable guidelines
 - To help set up and maintain good working practices and polices within the group, to determine when changes are required and oversee their implementation
 - To establish and communicate team performance expectations and clear targets and project milestones
 - To supervise the study team to ensure good lines of communication and strong working relationships are maintained both internally and externally
 - To oversee the annual leave of staff members and ensure suitable cover during periods of staff absence to ensure studies are adequately covered
- b) Project coordination and management
 - Manage commercial or publicly-funded projects
 - To develop and oversee new systems to track projects including all ethical regulatory review board information, patient recruitment activity and financial management in compliance with the study budget and University Financial Procedures.
 - To have thorough knowledge of both the theoretical and practical aspects of the research studies
 - To identify and participate in initiatives and developments relevant to the management and conduct of clinical trials
 - Serve as primary contact to provide regular feedback, both written and verbal, to study

Sponsors, Investigators (P.I & C.I), and the OVG Operations Manager, including project plans, project status reports and updates, or the study portfolio progress

- To contribute to and evaluate the study design, feasibility and logistics of proposed new studies and provide advice on regulatory requirements
- To assist with the preparation and review of all trial related documents including study protocols, patient information sheets, CRFs and other essential documents required to run the trial
- Be responsible for the oversight of ethics applications, submissions to the regulatory authority, and NHS Research and Development bodies
- To determine what project processes are needed, train and maintain project team knowledge, and apply the project processes
- To participate in the development of SOPs, guidelines, and group procedures and other continuous improvement programs and 'lessons learned' forums.
- To liaise with the Departmental Finance Team and Research Services to provide costings for all proposed studies, manage study budgets, and negotiate funding contracts with clients and third parties
- To ensure the planning, implementation, monitoring of all trials, ensuring progress and overall operational management is maintained
- To liaise with the Departmental Finance Team to ensure all administrative closeout procedures are completed across all studies
- Responsible for oversight of TMF management to ensure studies are inspection ready and regulatory compliant
- To proactively look for opportunities to accelerate recruitment and trial progress across study sites
- To advice on how to resolve issues that arise and to escalate in a timely and appropriate manner
- Contribute to the preparation of papers for publication, and prepare and present written and oral reports as required, including presenting at international meetings
- Work with the Quality Assurance Manager on any necessary audit processes
- Liaise with the IT Manager to ensure efficient and effective data management
- Maintain and regularly review financial records of all project expenses and oversee their payment by liaising with the Departmental Administrator and Departmental Finance Team.
- Support the lead nurse and/or clinical research fellow in the management of the project team to ensure timely and effective completion of project assignment
- Lead team meetings regarding the progress and delivery the study

c) Supporting research team

- Make researchers aware of key relevant opportunities for new grant applications.
- Understand the clinical and research training needs of individual key research staff, and support them in meeting these needs
- Support the Principal Investigator in writing new grant applications
- Lead the evaluation of project activities, ensuring that lessons learned are integrated into future proposals
- Assist with recruitment, training and supervision of project team members as appropriate
- Report to the OVG Operations Manager any anticipated need for additional resources and

any needs or concerns regarding level of training or performance

Selection criteria

Essential

- Educated to degree level (or equivalent experience) in life science of health-related subject
- Ability to lead, support, motivate, delegate and line manage staff
- Ability to demonstrate initiative and think creatively to resolve problems, working both independently and part of a team
- Self motivation, and ability to work successfully and confidently to manage conflicting demands and tight deadlines
- Experience of developing new trials and writing and maintaining clinical documents
- Ability to manage mulitiple projects at various stages of development and organisation
- Extensive knowledge of Data Protection Act (1998), ICH GCP, GCLP, Research Governance and other key regulatory areas and ethical frameworks
- Excellent knowledge of regulatory and governance environment in the UK
- Experience of project management in a clinical environment
- Experience of writing reports and presenting complex information clearly
- Experience of creating study costings
- Evidence of effective organisational skills
- Excellent communication skills, both written and oral
- Well-developed interpersonal skills and the ability to work effectively with collaborators at all levels

Desirable

- Evidence of effective negotiation and facilitation skills
- Experience in audits
- Experience of working across the Higher Education / industry / NHS interface
- Information technology skills, especially Microsoft Office software and e-mail

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. 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: <u>https://www.jobs.ox.ac.uk/pre-employment-checks</u>

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.

The University of Oxford has recently published their New Ways of Working framework to ensure professional service staff can continue to support the University's academic mission whilst working on site or remotely. For more information, please visit <u>https://hr.admin.ox.ac.uk/new-ways-of-working</u>

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 are 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.

Core group members include 2 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 of the group include:

• Pneumococcal conjugate vaccine studies in the elderly

- Polysaccharide and conjugate quadrivalent meningococcal vaccine studies in adults
- H1N1 vaccine studies in children
- Pneumococcal nasopharyngeal carriage epidemiology
- Meningococcal B vaccine development
- Development of a typhoid challenge model
- COVID vaccines

More information about OVG may be gained at the website: http://www.ovg.ox.ac.uk

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 silver 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 e-recruitment system and you will find all the information you need about how to apply 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 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.

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**, which with effect from 1 October 2023 will be 30 September before the 70th 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

Employee benefits

University employees enjoy 38 days' paid holiday, generous pension schemes, travel discounts, and a variety of professional development opportunities. Our range of other employee benefits and discounts also includes free entry to the Botanic Gardens and University colleges, and discounts at University museums. See <u>https://hr.admin.ox.ac.uk/staff-benefits</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 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 website 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

With one of the most generous family leave schemes in the Higher Education sector, and a range of flexible working options, Oxford aims to be a family-friendly employer. We also subscribe to the Work+Family Space, a service that provides practical advice and support for employees who have caring responsibilities. The service offers a free telephone advice line, and the ability to book emergency back-up care for children, adult dependents and elderly relatives. See https://hr.admin.ox.ac.uk/my-family-care Childcare

The University has excellent childcare services, including 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 https://childcare.admin.ox.ac.uk/

Disabled staff

We are committed to supporting members of staff with disabilities or long-term health conditions. For further details, including information about how to make contact, in confidence, with the University's Staff Disability Advisor, see https://edu.admin.ox.ac.uk/disability-support

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 <u>https://edu.admin.ox.ac.uk/networks</u>

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>.