

Summary

Job title	Clinical Trials Manager
Division	Medical Sciences Division
Department	Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences
Location	You will be based in Oxford Trauma, Kadoorie Critical Care Research Centre, John Radcliffe Hospital, Oxford, OX3 9DU but for this particular post you will be able to agree a pattern of regular remote working with your line manager
Grade and salary	Grade 7: £36,024-£44,263 per annum
Hours	Full time (1 FTE), part-time at minimum of 60% FTE will be considered
Contract type	Fixed-term (2 years)
Reporting to	Senior Clinical Trials Manager - Oxford Trauma
Vacancy reference	168887

The role

The purpose of this role is to contribute to the work of the Oxford Trauma and Emergency Care group. You will work as part of a team to manage research trials of complex interventions in the area of Orthopaedic Trauma, both in adults and children.

You will coordinate the implementation and running of large multi-centre clinical trials. You will be responsible for trial set-up including clinical reporting form development, day to day running of the trials, Good Clinical Practice compliance and undertaking monitoring/close down activities with recruiting centres. Data cleaning and query resolving in collaboration with the statistical and health economics team will fall under your remit. You will also facilitate meetings of trial committees and be responsible for ensuring relevant and timely updates for project stakeholders. You will ensure the studies comply with Oxford Clinical Trials Research Unit Standard Operating Procedures.



The post might involve travel to study centers across the UK, however the requirement for this will fluctuate across the different phases of the project. You will be responsible to the Oxford Trauma Senior Trials Manager and may be responsible for a clinical trials administrator and/or data entry clerk.

Responsibilities

- To work autonomously as a Trial Manager, taking overall responsibility for the day-to-day management of multi-centre randomised clinical trials.
- Assist in finalising the protocol, study materials, training packages for collaborating sites and trial manuals, and prepare trial specific instructions.
- Work to design data collection forms and associated documentation as required in collaboration with the trial statistician and Chief Investigator – then work with the trial programmer to assist in the design and testing of the trial database systems for randomisation, data entry, validation and report generation.
- Obtain and maintain overall and site-specific ethical and R&D approvals for all sites and ensure Clinical Trial Agreements are in place before the research commences.
- Identify, recruit and support participating sites; conduct site set-up, delivering trial specific training, track progress at each site and regular monitoring visits as appropriate.
- Oversee data entry on the computer database (assisted by a Data Entry Clerk) and perform regular systematic checks of information held on trial database as required. Resolve contradictory or incorrect data and ensure these are followed through to a satisfactory conclusion within a reasonable timeframe.
- Provide line management and training for administrative trial staff (e.g. trial administrators, data entry clerks).
- Organise regular 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.
- Work alongside the senior trial manager to prepare and deliver progress reports to the funder and annual reports to the Oversight committees, Sponsor, Ethics Committee and local R&D departments, as required, in a timely manner.
- Act as a resource, providing advice and support to colleagues both internal and external to Oxford Trauma Group to promote good research practice.
- Maintain awareness of scientific literature in current field of work.
- Plan expenditure against the programme budget and negotiate with suppliers (i.e. for meetings, travel and trial materials).
- Ensure all aspects of the programme of research are set up and run in accordance with Oxford Clinical Trials Research Unit Standard Operating Procedures (SOPs).

The job description is not intended to be rigid or inflexible, and the main duties and responsibilities of the post listed above may be subject to change in light of experience and developments within the group. You are expected to work flexibly and respond positively to changing needs. Any review will be undertaken in conjunction with you and the senior trials manager

Selection criteria

Essential selection criteria

- Degree in a biomedical or associated subject, or other relevant qualification, or proven experience in clinical research.
- Experience of overseeing the conduct of clinical trials and working to a high standard of Good Clinical Practice and according to the research governance framework.
- Experience of existing UK clinical research structures and regulatory and ethical systems.
- Experience and understanding of techniques for the management of medical research data.
- Experience of preparation of progress reports for internal and external stakeholders.
- Must demonstrate a critical and intelligent attention to detail and high standards of accuracy.
- Proven administrative and project management skills.
- Ability to follow and produce written procedures and set up systems to comply with such procedures.
- Effective written and oral communication skills
- Ability to work well within multi-disciplinary teams and independently.
- Willingness to travel in the UK and further afield on occasion. For some visits it may be necessary to stay overnight, normally within the working week.

Desirable selection criteria

- Previous experience as a trial coordinator/manager of a multi-centre clinical trial
- Previous involvement in development of clinical reporting forms

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: <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:

- Driving on University business

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.

Medical Sciences Division

The Medical Sciences Division is an internationally recognised 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 Orthopaedics, Rheumatology and Musculoskeletal Sciences

The Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS) is part of the Medical Sciences Division and is the largest European academic department in its field, running a globally competitive programme of research and teaching.

Our mission is to discover the causes of musculoskeletal and inflammatory conditions to deliver excellent and innovative care that improves people's quality of life. Our highly skilled teams have expertise in a broad range of areas, including orthopaedic surgery, inflammation, immunology, rheumatology, medical statistics, epidemiology, and clinical trials.

We currently have 480 staff, approximately 120 post-graduate students and have a grant portfolio worth over £180 million.

The **Botnar Research Centre** enables and encourages research and education into the causes of musculoskeletal disease and their treatment.



The Centre provides world-class facilities for scientists in the field of musculoskeletal research. It takes a multidisciplinary approach, encompassing orthopaedic, rehabilitation and rheumatology clinical scientists, bone oncologists, laboratory scientists, epidemiologists, engineers and statisticians. The Botnar also hosts the Oxford Clinical Trials Research Unit (OCTRU) and the Centre of Statistics in Medicine (CSM), providing excellent

statistical support to all aspects of clinical research.

The Botnar opened in 2002, with a large annex completed in 2013. The Botnar is now home to around 300 staff and postgraduate students enjoying the international and friendly atmosphere of this workplace and benefits from the vast knowledge of leading experts in the field of musculoskeletal research.

To accommodate its rapid growth, the Centre has opened another wing in early 2022. The new space provides additional 1000m² of office and 1000m² of laboratory space. The laboratory space includes a GMP clean room facility suitable for the manufacturing of biomaterials for human implantation.

Sharing the site of the Nuffield Orthopaedic Centre, the largest specialist academic musculoskeletal hospital in the UK, puts the Botnar in a unique position to foster the collaboration between basic scientists and clinicians, which is essential to success in medical research.

The Kennedy Institute is a biomedical research centre uniquely bringing together discovery science and early-stage clinical research, to develop transformative new therapies for chronic inflammatory and musculoskeletal conditions.



Broadly focused on the thematic areas of immunity and microbiome, inflammation biology and tissue remodelling and repair, the Institute's research is relevant for a range of common diseases such as arthritis, inflammatory bowel disease, fibrosis and cancer.

The Institute has capacity for up to 260 staff and students who work collaboratively across 25 research groups. This enables a multidisciplinary approach of molecular and cellular biology, combined with analysis of disease

models, patient tissue samples and longitudinal clinical data. Collectively, these studies seek to uncover the biological processes that maintain tissue health and how these pathways break down in disease.

Research at the Institute is supported by a suite of core technology platforms, as well as through strategic partnerships with other basic and clinical research centres in Oxford, across the UK and internationally. These state-of-the-art technologies include the Oxford-Zeiss Centre for Excellence and other advanced microscopy and imaging facilities, mass and flow cytometry, as well as capabilities for microbial genomics and functional microbiome studies made available through the Oxford Centre for Microbiome Studies.

Complementing a strong programme of lab-based research, the Institute has established a core of expertise and technologies in data science including single cell genomics, statistical genetics, computational biology, and research informatics. A recent extension to the Institute building with a new third floor creates additional space purposely designed for computationally intensive research.

A true trendsetter in innovative and transformational research, the Kennedy also boasts a relaxed and friendly atmosphere, revolving around its bright and airy atrium that provides a space for colleagues to meet over coffee and tea to talk about their research and beyond throughout the day.

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

Athena Swan

The Athena SWAN Awards specifically recognise success in developing employment practices to further and support the careers of women in science, technology, engineering, maths and medicine (STEMM) departments in academia. In May 2015 the charter was expanded to recognise work undertaken in arts, humanities, social sciences, business and law (AHSSBL), and in professional and support roles. Within NDORMS, we feel that we have an established



culture of equality but are using the process to spur on-going improvement that benefits everyone involved in the Department. Our on-going progress was rewarded in May 2014 with an Athena Swan Bronze Award and in October 2015 with a Silver Award.



Our development in this area has resulted in a number of commitments to our staff, central to which are:

- establishing an open, supportive and family-friendly research environment
- supporting career progression through teaching programmes, personal development reviews and mentoring
- proactive communication of support policies such as flexible working, provision of leave, promotion and careers support schemes



NDORMS aims to actively promote the implementation of the University's family-friendly policies to help foster a family friendly working environment, including provision of family leave (such as policies for maternity, paternity, parental, carers and adoption leave), flexible/part-time working and scheduling inclusive meetings.



The University's childcare services support staff with a Childcare Voucher Scheme to help staff save tax and national insurance on childcare costs, offer information on nursery providers and a nursery fee Salary Sacrifice Scheme, work in partnership with playscheme providers to help support families during school holidays and signpost staff to parenting, local authority and other organisations that help support families and parents.

The Department is also committed to ensuring that staff undertaking part-time or flexible working receive the same access to benefits and entitlements as full-time staff, including the same opportunities for training and promotion, a pro-rata entitlement to leave including bank holidays and careful consideration of requests to work part-time (particularly for those by staff returning from maternity leave).

For more information please visit: <http://www.admin.ox.ac.uk/personnel/staffinfo/benefits/family/> and <http://www.admin.ox.ac.uk/personnel/during/flexible/>

We are also actively working to uphold the University's aim of providing an inclusive environment and equal career opportunities by promoting equality, valuing diversity and

maintaining a working, learning and social environment in which the rights and dignity of all staff are respected. Separate University policies are also in place to ensure race, disability and gender equality. For more information, please visit: <http://www.admin.ox.ac.uk/eop/>

Oxford Trauma

The role will be based in The Kadoorie Centre which is a purpose-built research and education facility at the John Radcliffe Hospital. Oxford Trauma and Emergency Care is one of the largest research groups in this field in the world, delivering a full spectrum of clinical effectiveness studies including randomised trials, observational studies and big data projects. The group has close links to basic and translational scientists at the Kennedy Centre and Botnar Research Institute. The Kadoorie Centre provides facilities for approximately 60 research staff, with a clinical skills centre and lecture theatre.

Oxford Trauma and Emergency Care is a sub-theme within NDORMS and the Oxford BRC. It is one of the largest musculoskeletal trauma research groups in the world, delivering a full spectrum of clinical effectiveness studies including randomised trials, observational studies and big data projects. The group has close links to basic and translational scientists at the Kennedy Centre and Botnar Research Institute. The Oxford Trauma and Emergency Care Group is based in the Kadoorie Centre on the John Radcliffe site, providing a unique setting in which researchers interact with practising clinicians and have access to patients with the full range of traumatic injuries. The Kadoorie Centre provides facilities for approximately 60 research staff, with a clinical skills centre and lecture theatre. Clinical academic leadership is provided by Professor Matt Costa (Professor of Orthopaedic Trauma), Professor Dan Perry (Associate Professor of Paediatric Orthopaedic Trauma), Professor Steve Gwilym (Associate Professor of Orthopaedic Trauma) and Professor Simon Graham (Associate Professor of Orthopaedic Trauma Surgery). The team is supported by a full team of academic-related staff under Oxford Trauma and Emergency Care's Research Manager, Dr Juul Achten.

For more information please visit: <https://www.ndorms.ox.ac.uk/Oxford-Trauma-and-Emergency-Care>

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 <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

Help and support is available from: <https://hrsystems.admin.ox.ac.uk/recruitment-support>

If you require any further assistance please email recruitment.support@admin.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 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 all academic posts and some academic-related posts. 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: <https://hr.admin.ox.ac.uk/the-ejra>

For **existing** employees, 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 **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.

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 <https://hr.admin.ox.ac.uk/staff-benefits>

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 <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

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 My Family Care, 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 <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.