

Summary

Job title	Clinical Trial Manager
Division	Medical Sciences Division
Department	Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences
Location	Botnar Research Centre, Windmill Road, Oxford, OX3 7LD
Grade and salary	Grade 7: £36,024-£40,521 per annum
Hours	Full time (Part time 0.8 FTE over min 4 days considered)
Contract type	Fixed term until (31 August 2027)
Reporting to	Clinical Trials Operational Lead – Experimental Medicine and Rheumatology / Senior Clinical Research Manager, with accountability to Chief Investigator and grant holder
Vacancy reference	169793
Additional information	A lower grade offer may be made (Grade 6: £32,332 - £38,205 p.a.) with commensurate reduction in responsibilities (and amendment in job title to Trainee Clinical Trial Manager if a suitable candidate cannot be found to fill the Grade 7 position.



The role

Following a successful funding application to the NIHR, the Experimental Medicine and Rheumatology (EMR) trials group are seeking a Clinical Trial Manager to take day to day responsibility for the management of one or more clinical trials within their portfolio. The EMR trials groups manages a wide variety of trials, from set up to archiving, in a variety of conditions spanning rheumatology and musculoskeletal conditions, experimental medicine and COVID-19. All trials are run as part of the UKCRC registered Oxford Clinical Trials Research Unit (OCTRU).

Your primary role will be to efficiently develop and coordinate the multi-centre trial on a day-to-day basis in compliance with OCTRU's Standard Operating Procedures and Good Clinical Practice (GCP), ensuring study milestone through to preparation for archive are met including timely data collection. You will work closely with the Chief Investigator and other stakeholder to achieve this and be responsible for keeping stakeholders up to date with progress.

The post holder will have access to OCTRU's extensive training programme delivered by a range of Trial Management professionals as well as other appropriate training opportunities offered by the University and externally, as well as being part of one of the largest and most diverse CTUs in the UK.

The post may involve some travel to UK trial centres, however the requirement for this will fluctuate across the different phases of the project.

Responsibilities

1. Work autonomously as a Trial Manager, taking overall responsibility for the day-to-day management of one or more multi-centre randomised clinical trials. Act as first point of contact for all external and internal stakeholders and enquiries about the trial.
2. Assist in finalising the protocol and other documents required for trial wide approvals. Prepare and update trial documentation such as training material for collaborating sites, trial manuals and trial specific instructions. Coordinate amendments to these documents where needed. Input to other key trials key trial documents, including progress and final reports, and publications.
3. Obtain and maintain overall and site-specific ethical and regulatory (where necessary) and R&D approvals for all sites and ensure appropriate contracts are in place before the research commences.
4. Work to design case report forms and associated documentation in collaboration with the trial statistician and Chief Investigator – then work with the trial programmer to facilitate the set-up and testing of the trial database systems for randomisation, data capture and report generation, including for any changes subsequently needed.
5. Identify, recruit and support participating sites; conduct site set-up, delivering trial specific training, track progress at each site, take appropriate action to ensure good recruitment and undertake monitoring as required. Coordinate close out on study completion.
6. Ensure that the trial protocol is conducted in accordance with the applicable ethical, regulatory and quality standards and that appropriate records and audit trails are maintained.
7. Oversee data collection. Ensure data collection is of adequate quality and timeliness. Perform regular systematic checks of information held on trial databases. Resolve contradictory or incorrect data and ensure these are followed through to a satisfactory conclusion within a reasonable timeframe. Work with the trial statisticians to ensure a complete and clean data set prior to analysis.
8. Coordinate and support the activities of the trial working groups including organisation of regular trial meetings, with responsibility for preparing documentation for these meetings. Provide regular feedback on progress to the Chief Investigator and EMR senior staff.
9. Be responsible for the Trial Master File, maintaining effective version control.
10. Line manage and/or oversee the work of junior trial management staff assigned to the trial.

11. Use initiative to resolve problems identified and encountered, escalating issues to senior staff as appropriate.
12. Act as a resource, providing advice and support to colleagues both internal and external to Experimental Medicine and Rheumatology Group to promote good research practice.
13. Maintain awareness of scientific literature in current field of work.
14. Plan and monitor expenditure against the trial budget and negotiate with suppliers (i.e. for meetings, travel and stocks of trial materials).
15. Ensure all aspects of the trial are set up and run in accordance with OCTRU Standard Operating Procedures (SOPs).
16. To undertake training as required for the post, at the discretion of the EMR senior staff and the Chief Investigator.

Selection criteria

Essential selection criteria

1. Degree in a biomedical or associated subject, or other relevant qualification, or proven experience in management of clinical research.
2. Experience of overseeing the conduct of clinical trials and working to a high standard of Good Clinical Practice.
3. Familiarity with UK clinical research structures, regulatory and ethical systems.
4. Experience and understanding of techniques for data management relating to research participants.
5. Proven administrative and project management skills. Ability to work on own initiative, to problem solve, and to organise and manage the work of a professional team under management guidance.
6. Effective communication and presentation skills in written and spoken English.
7. Must demonstrate a critical and intelligent attention to detail and high standards of accuracy.
8. Ability to follow written procedures and set up systems to comply with such procedures.
9. Evidence of team working skills and good interpersonal skills, including the ability to be comfortable and confident interacting with team members, administrative staff and the broader research community and to negotiate.
10. Ability to prioritize workload and be adaptable to changing priorities.
11. Office management and clerical skills that including IT literacy and competency in Microsoft Office.
12. 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.
13. Demonstrate an understanding of data protection and other statutory requirements and professional guidelines, such as Good Clinical Practice guidelines.
14. Demonstrate an ability to follow departmental guidance in handling sensitive and personal information, including complying with current data protection legislation.

Desirable selection criteria

1. Experience as a clinical trial manager.
2. Previous experience of managing a multi-centre clinical trial in a non-commercial (academic) setting.
3. Experience of research in rheumatology and/or experimental medicine.
4. Understanding of the structure and function of relational databases.

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 career 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 Clinical Trials Research Unit (OCTRU)

OCTRU is one of 52 UKCRC registered Clinical Trials Units, gaining full registration in 2012. OCTRU is a collaboration between three Clinical Departments within the University of Oxford: Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Science, Nuffield Department of Surgical Sciences and the Department of Oncology.

OCTRU is one of the larger CTUs in the country. OCTRU aims to build on existing excellence in design, conduct and reporting in both early and later phase clinical trials in surgery, musculoskeletal sciences, experimental medicine, rheumatology and oncology.

OCTRU is a flexible and responsive organisation that has been shown to be capable of identifying the most important questions for clinical trials, ensuring excellence in design, securing funding, and conducting trials within budget and on time. We expect our research to make a significant impact on patient care and to be world class in standard.

For details of our current and past work please visit our website www.octru.ox.ac.uk

Experimental Medicine and Rheumatology Trials Group (EMR)

Led by Professor Duncan Richards, the EMR trials group is the newest group to work in collaboration with OCTRU. EMR manages a rapidly expanding portfolio of trials of varying sizes, spanning rheumatology and musculoskeletal conditions, experimental medicine, and COVID-19. The team is currently composed of Trial Managers, Trial Coordinators and administrative support staff under EMR's Operational Lead, Dr Anne Francis.

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

HR@ndroms.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**, which with effect from 1 October 2023 will be 30 September before the 70th birthday. The justification for this is explained at: <https://hr.admin.ox.ac.uk/the-ejra>.

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

There is no normal or fixed age at which staff in posts at other grades have to retire. Staff at these grades may elect to retire in accordance with the rules of the applicable pension scheme, as may be amended from time to time.

Equality of opportunity

Entry into employment with the University and progression within employment will be determined only by personal merit and the application of criteria which are related to the duties of each particular post and the relevant salary structure. In all cases, ability to perform the job will be the primary consideration. No applicant or member of staff shall be discriminated against because of age, disability, gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion or belief, sex, or sexual orientation.

Benefits of working at the University

Employee benefits

University employees enjoy 38 days' paid holiday, generous pension schemes, travel discounts, 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 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>

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.