

Job description

Job title	Clinical Trial Administrator
Division	Medical Sciences Division
Department	Oxford Population Health (Nuffield Department of Population Health, University of Oxford)
Location	Old Road Campus, Headington, Oxford, OX3 7LF
Grade and salary	Grade 6: £32,332-£38,205 per annum
Hours	Full time (part time considered)
Contract type	Fixed-term – 2 years
Vacancy reference	174024



About Oxford Population Health

Oxford Population Health (the Nuffield Department of Population Health) provides an excellent environment for multi-disciplinary research and teaching and for professional and support staff. We work together to answer some of the most important questions about the causes, prevention and treatment of disease.

The Department has around 900 staff, students and academic visitors working in a number of world-renowned population health research groups, including the Clinical Trial Service Unit and Epidemiological Studies Unit (CTSU), the Cancer Epidemiology Unit (CEU), the National Perinatal Epidemiology Unit (NPEU) and other groups working on public health, health economics, ethics and health record linkage. It is also a key partner in the Oxford University's Big Data Institute.

In the 2021 Research Excellence Framework (REF), 96% of the research submitted to Unit of Assessment 2: Public Health, Health Services and Primary Care, was ranked either 4* (world-leading in terms of originality, significance and rigour) or 3* (internationally excellent in terms of originality, significance and rigour). This comprised research from Oxford Population Health and research from the Nuffield Department of Primary Care Health Sciences. We scored particularly well for having an environment that is conducive to producing research of world-leading quality and enabling outstanding impact, in terms of its vitality and sustainability.

In addition to its research activities, the Department is home to the <u>MSc in Global Health</u> <u>Science and Epidemiology</u>, the <u>MSc in Clinical Trials</u>, and a variety of short courses. Students also come to undertake research for <u>DPhil degrees</u>. Teaching is provided for undergraduates reading for Medicine and for public health doctors in specialist training.

For more information please visit the Oxford Population Health website.

About the Medical Sciences Division

The Medical Sciences Division is an internationally recognised 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 the Medical Sciences Division website.

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 the **Oxford University website**.

Clinical Trial Service Unit and Epidemiological Studies Unit (CTSU)

CTSU is one of the world's leading centres for research into the causes, prevention, and treatment of chronic diseases (such as cancer, renal and heart disease). The aim of the Unit is to generate and disseminate reliable evidence from observational epidemiology and from randomized trials that leads to practicable methods of avoiding premature death and disability. It has been responsible for initiating and conducting large-scale randomized trials of different treatments for some of the major diseases affecting public health, as well as establishing collaborative systematic overviews ("meta-analyses") of individual patient data from randomized trials, particularly in cancer and vascular disease. It also plays an important role in large prospective epidemiological studies across the world, including in China, Cuba, India, Mexico, Russia and the UK. For more information please visit: <u>www.ctsu.ox.ac.uk</u>

The role

The post-holder's role will be to support the Senior Clinical Trial Managers and the multidisciplinary trials Senior Management Team (SMT) with the administration of the study, with particular emphasis on ensuring agreed study milestones are met and the day-to-day operational aspects of the study run smoothly, playing a key role in troubleshooting any problems that might arise.

Since most of the studies for this Group involve CTIMPs (Clinical Trial of an Investigational Medicinal Product), the study processes are run in compliance with the Good Clinical Practice (GCP), the UK Medicines for Human Use (Clinical Trials) Regulations and its amendments, and local regulations such as the relevant EU directives relating to GCP. The core of GCP is to ensure participant safety and data integrity. Such clinical trials are regulated in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA) who perform on-site inspections.

The post-holder, in addition to other study-related training, must undergo GCP training and subsequent refresher courses.

Examples of ongoing trials include:

- HPS-4/TIMI65/ORION-4: assessing inclisiran (a small interfering RNA which lowers LDL cholesterol) among people at high-risk of cardiovascular disease
- EMPA-KIDNEY: assessing empagliflozin (an SGLT-2 inhibitor) among people with chronic kidney disease
- RECOVERY: a national platform trial assessing multiple interventions among people hospitalised with Covid-19
- LENS: assessing fenofibrate among people with diabetic retinopathy
- AMALFI: assessing screening for atrial fibrillation among people at high risk of stroke
- ASCEND PLUS: a national trial assessing the effect of semaglutide on cardiovascular and other outcomes in people with diabetes
- EASi-KIDNEY: a new international trial of participants with established chronic kidney disease that aims to definitively test the efficacy and safety of a novel aldosterone synthase inhibitor (ASi) BI 690517 given on top of standard of care

These trials and any new trials provide a unique training opportunity in trial methodology and would equip the successful candidate well for a career in clinical trials.

Responsibilities

- Supporting the setting up and management of the clinics, ensuring that they have the required resources at all times.
- Establishing collaborations with clinics/centres.
- Assisting to ensure that all documentation is in order to comply with the relevant trials legislation.
- Liaising with clinics to obtain data (e.g. relating to samples, monitoring etc.).
- Arranging, attending and presenting at study meetings as required.
- Resolving queries and issues in a timely manner and escalating to senior staff as necessary.
- Keeping up to date of study protocols and procedures in the study area.
- Establishing effective working relationships with a variety of stakeholders (e.g. nurses, clinicians, participants, funders, third party suppliers). Ensuring confidentiality and sensitivity and providing support to participants as required.
- Assisting with other administrative duties. E.g. contributing to ensure the smooth running of patient scheduling and visits, and the supply of sample kits and study treatment.

The above list is not exhaustive and the role-holder is required to undertake such duties as may reasonably be requested within the scope of the post. All staff are required to act in a professional, cooperative and flexible manner, in line with the requirements of the post.

Selection criteria Essential

- University degree or equivalent experience.
- Relevant administrative and data management experience.
- Ability to work accurately, paying close attention to detail.
- Logical and analytic approach for developing processes and solving problems.

- Ability to communicate clearly and empathetically, with a good standard of spoken and written English. This will be required to ensure effective communication with study participants and their doctors, colleagues and other external study-related personnel, and to present written work clearly and concisely in the form of study documentation and minutes.
- Effective organisational skills.
- Ability to work cohesively and effectively as part of a busy team.
- Positive and flexible approach to meet the changing demands of the studies.
- Recent experience of using Microsoft software such as Word, Excel, and PowerPoint.

Desirable

- University degree within a scientific discipline.
- Experience of dealing with the public, preferably within a medical environment.
- Understanding of key regulations related to clinical trials.

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 <u>candidate notes</u> on the University's pre-employment screening procedures.

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**.

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 your CV and supporting statement **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 departments.

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 the <u>HR Systems Recruitment support webpage</u>. If you require any further assistance please <u>email the Recruitment Support team</u>.

To return to the online application at any stage, please go to the <u>University's recruitment</u> <u>website</u>. 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 <u>University's Privacy Notice for Job</u> <u>Applicants</u>. The University's Policy on Data Protection is available on the <u>University's Compliance webpages</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 <u>range of other employee benefits</u> <u>and discounts</u> also includes free entry to the Botanic Gardens and University colleges, and discounts at University museums.

University Club and sports facilities

Membership of the <u>University Club</u> is free for all University staff. The University Club offers social, sporting, and hospitality facilities. Staff can also use the <u>University Sports Centre</u> on Iffley Road at discounted rates, including a fitness centre, powerlifting room, and swimming pool.

Information for staff new to Oxford

If you are relocating to Oxfordshire from overseas or elsewhere in the UK, the University's <u>Welcome Service website</u> includes practical information about settling in the area, including advice on relocation, accommodation, and local schools. There is also a <u>visa loan scheme</u> to cover the costs of UK visa applications for staff and their dependents.

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 <u>Work+Family Space</u>, 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.

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 the <u>Childcare Services webpages</u>.

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 the <u>Disability Support webpages</u>.

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 on the <u>Equality and Diversity at Oxford webpages</u>.

The University of Oxford Newcomers' Club

The University of Oxford <u>Newcomers' Club</u> 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.