OXFORD POPULATION HEALTH

Job description

Job title	Clinical Trial Monitor
Division	Medical Sciences Division
Department	Oxford Population Health (Nuffield Department of Population Health, University of Oxford)
Location	Old Road Campus, Headington, Oxford, OX3 7LF Hybrid working available (up to 60% of hours can be worked remotely)
Grade and salary	Grade 7: £38,674 - £51,059 per annum (including Oxford Weighting Allowance and discretionary range)
Hours	Full time
Contract type	Fixed term, 1 year in the first instance
Reporting to	CTSU Lead Monitor and CCO Head of Monitoring
Vacancy reference	179035

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 1000 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 **MSc in Global Health Science and Epidemiology**, the **MSc in Clinical Trials**, and a variety of short courses. Students also come to undertake research for **DPhil degrees**. 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 (CTSU)

CTSU is a world-leading centre for large-scale research into the causes, prevention and treatment of chronic diseases (such as cancer and cardiovascular and kidney disease). It has been responsible for initiating and conducting large-scale randomised trials of different treatments for some of the major diseases affecting public health. Examples of ongoing trials include:

The HPS-4/TIMI 65/ORION-4 study (www.orion4trial.org) has been designed jointly by the Clinical Trial Service Unit (University of Oxford), the TIMI Study Group (Harvard University) and Novartis, and is co-sponsored by the University of Oxford and Novartis. ORION-4 will compare inclisiran sodium 300 mg given by subcutaneous injection at randomization, at 3 months and then every six months versus matching placebo in approximately 15,000 participants with pre-existing atherosclerotic cardiovascular disease. Follow-up for a median of 5 years will allow reliable assessments of any beneficial or adverse effects of inclisiran. The study is run by a Central Coordinating Office at CTSU which is responsible for designing, developing, implementing and monitoring study-wide procedures in close collaboration with Regional Coordinating Offices in the UK and North America. The Regional Coordinating Offices directly oversee around 200 study sites where study participants are recruited and followed-up.

The EMPA-KIDNEY trial (www.empakidney.org) is assessing the safety and efficacy of empagliflozin among 6609 participants with chronic kidney disease. It is the largest trial of SGLT-2 inhibition in chronic kidney disease and is testing the hypothesis among participants both with and without diabetes. Recruitment finished in April 2021 and final follow-up was completed in July 2022.

The LENS trial (www.ctsu.ox.ac.uk/lens) is assessing the efficacy of fenofibrate among at least 1060 participants with diabetic retinopathy. It is the largest trial of fenofibrate for this indication and is being conducted in Scotland using a novel combination of in-person clinics and mail-based design.

The RECOVERY trial (www.recoverytrial.net) is a platform trial assessing several different interventions for the treatment of patients hospitalised with COVID-19. It is the largest trial worldwide for COVID-19 and demonstrated the benefits of dexamethasone and tocilizumab in this population.

ASCEND PLUS (ascend-plus-trial.org) is a randomised, double-blind, parallel-group, placebo-controlled event driven trial designed to test the hypothesis that oral semaglutide reduces cardiovascular events and other complications of diabetes in Clinical Trial Monitor job description, March 2023 4 people with T2DM without a prior myocardial infarction or stroke. The study will use streamlined methodology to randomise approximately 20,000 people with T2DM in the UK and follow them during a scheduled treatment period with a median duration of approximately 5 years.

The EASi-KIDNEY™ trial (**https://www.ctsu.ox.ac.uk/research/easi-kidney**) is a new international, multi-centre randomised double-blind placebo-controlled trial which will aim to recruit about 11,000 people with chronic kidney disease, with or without type 2 diabetes. EASi-KIDNEY™ will assess whether a new drug called vicadrostat (BI 690517), reduces the risk of kidney disease progression, hospitalisation for heart failure or death from cardiovascular disease in people with chronic kidney disease when it is added to standard care including empagliflozin.

The role

We wish to appoint a Clinical Trial Monitor, who is interested in developing their skills by joining CTSU's established training and monitoring team. The successful applicant will work on the ORION-4, EASi-KIDNEY and ASCEND PLUS trials, in addition to any other CTSU trial as required, to provide both on-site and in-house monitoring support. Comprehensive training will be provided to ensure a good understanding of the key aspects of the study and monitoring procedures. There will also be opportunities to work on some of CTSU's other studies, including LENS and RECOVERY, where required.

Responsibilities

- Conduct monitoring visits in the UK for the ORION-4, EASi-KIDNEY and ASCEND-PLUS trials and any other CTSU trial as required, to ensure that the studies are conducted in compliance with the trial protocol, relevant SOPs and the local regulatory and ICH-GCP guidelines, which will include: conducting initiation, interim monitoring and close out visits, as required; reviewing consent form completion, ISF maintenance, facilities and IMP; observing participant visits providing on-site training and mentorship to study nurses; producing feedback and written reports; closing outstanding monitoring actions for allocated sites.

- Develop and undertake in-house monitoring processes. For example to review delegation of duties logs, generate reports and review metrics, cross-check consent forms and blood test results. Attend and provide/create monthly reports for the CCO process monitoring meetings and circulate the report to all monitors.

- Conduct co-monitoring visits with our external monitors within the UK (and abroad if necessary) which will include: providing on-site training and mentorship to monitors; checking that the monitor fully understands the protocol, the study and monitoring

procedures to be followed; providing feedback to the monitor and producing a written report for the Head of Monitoring of observations made, including an assessment of the monitor's skills.

- Review monitoring reports written by colleagues and various external monitors (including in different countries). This will include: providing advice and solutions to problems found during site visits; ensuring any issues identified are investigated and resolved satisfactorily and within a timely manner; using the study data query system to record data errors and protocol violations; recognising when to escalate any issues identified to the Head of Monitoring and more senior members of the study team.

- Support sites ahead of a potential audit or regulatory inspection, providing the site staff with guidance and support for any preparation necessary, and if requested by senior study staff, being present during the inspection visit.

- Deliver and present trial specific training to study nurses (in the UK, and possibly internationally). This will include attendance at investigator and other training meetings to present and describe the studies, encourage collaboration and participation, as well as ensuring all study staff understand the aims, objectives and procedures of the studies.

- Assist with the development and updating of Standard Operating Procedures and written materials to be provided to local centres. If required, providing a verbal or written contribution to the design and User Requirements Specifications and User Manuals for the studies' validated IT systems.

- Develop the knowledge to respond to questions and emails about a wide range of study procedures, e.g. relating to the use the IT systems for data collection at sites and the reporting of events.

- Represent the monitoring team at regular update meetings within the study teams in CTSU and at meetings with the international RCCs and feed back to the team any issues or points for discussion. Update the monitoring spreadsheet/tracker during the meetings so that the rest of the monitoring team can review the issues in a timely manner.

- Organise and arrange monitor meetings for the UK monitoring team. Write the meeting minutes in a timely manner and circulate them to the rest of the team for review. Responsible for closing any relevant actions in a timely manner.

If the post holder is a UK registered nurse, there will be the opportunity to work occasional sessions in the Oxford ORION-4 study clinic based at the Richard Doll Building, conducting study visits using the bespoke IT systems. Interview procedures may include:

- careful assessment of each participant's cardiovascular and other medical history; explanation of the study and obtaining informed consent from participants;
- measurement of blood pressure, height and weight; collection, processing and analysis of blood samples;
- accurate recording of data, distribution of drug supplies to those participants willing and eligible to enter the study; dealing with routine queries from participants and GPs.

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

- Life sciences degree or a nurse with current UK NMC registration;
- Previous experience of working in a clinical trial environment with a familiarity of clinical trial monitoring procedures, a good knowledge of the key regulations affecting clinical trials and an understanding of the ICH-GCP guidelines;
- Diligent and proven attention to detail;
- Ability to work both independently and within a team to meet deadlines;
- Good organizational skills and the ability to manage own workload, prioritizing where necessary;
- Confident and self-motivated with an understanding of how to encourage others with an influential approach;
- Excellent communication skills with the ability to communicate effectively, both orally and in writing, to a wide range of audiences (e.g. study participants, investigators and other medical staff, colleagues and other study-related personnel);
- A flexible approach to problem solving and the ability to show initiative, make independent considered decisions, and take responsibility for own actions;
- Good computer skills, including familiarity with Word, Excel, PowerPoint and e-mail;
- The capacity and flexibility to travel within the UK (with occasional overnight stays).

Desirable

- Knowledge of cardiovascular and renal disease, including the treatment and management;
- Experience as a clinical trial monitor;
- A training qualification;
- Familiarity of the regulatory frameworks in place for running CTIMP studies in the UK and other countries
- The capacity and flexibility to travel internationally.

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**

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.

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 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 **HR Systems Recruitment support webpage**. If you require any further assistance please **email the Recruitment Support team**.

To return to the online application at any stage, please go to the **University's recruitment website**. 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**. The University's Policy on Data Protection is available on the **University's Compliance webpages**.

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, flexible working options, 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 **https://hr.admin.ox.ac.uk/staff-benefits**

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 **https://staff.admin.ox.ac.uk/health-assured-eap**

University Club and sports facilities

Membership of the University Club is free for University staff. It 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 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 dependants. See **https://staffimmigration.admin.ox.ac.uk/visa-loan-scheme**

Family-friendly benefits

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

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 **https://edu.admin.ox.ac.uk/disability-support.** For information about how we support those going through menopause see **https://hr.admin.ox.ac.uk/menopause-guidance**

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 **https://edu.admin.ox.ac.uk/networks**

The University of Oxford Newcomers' Club

The University of Oxford Newcomers' Club is 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**.

Research staff

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 **https://www.ox.ac.uk/research/support-researchers/connecting-other-researchers/oxford-research-staff-society**