Job title	Clinical Trials Monitor
Division	Medical Sciences
Department	Nuffield Department of Medicine
Location	Jenner Institute, Centre for Clinical Vaccinology and Tropical Medicine, Churchill Hospital, Old Road, Headington, Oxford, OX3 7LE
Grade and salary	Standard Grade 7: Salary in range £38,674 - £46,913 per annum (pro rata). This is inclusive of a pensionable Oxford University Weighting of £1,500 per year (pro rata).
Hours	Part-time (22.50 hours/60% FTE)
Contract type	Fixed-term contract until 31 August 2026 Funding is provided by the Bill and Melinda Gates Foundation/UKRI
Reporting to	Senior QA Manager
Vacancy reference	177942

Hybrid working arrangements	**The successful person will need to work on site for a minimum of 1 day per week**
About us	• University of Oxford - www.ox.ac.uk/about/organisation • Nuffield Department of Medicine (NDM) - https://www.ndm.ox.ac.uk • Unit - www.jenner.ac.uk
What we offer	https://hr.admin.ox.ac.uk/staff-benefits • An excellent contributory pension scheme • 38 days annual leave • A pensionable Oxford University Weighting allowance of £1,500 per annum (pro rata) • A comprehensive range of childcare services • Family leave schemes • Cycle loan scheme • Discounted bus travel and Season Ticket travel loans • Membership to a variety of social and sports clubs • A welcoming and diverse community

The role

The Jenner Vaccine Trials team is a vibrant team of project managers, administrators, volunteer recruitment managers, quality assurance managers, clinical research fellows, nurses and Principal and Chief Investigators. We manage and deliver early phase clinical trials for vaccines across a range of infectious diseases, also conducting human challenge studies designed to expedite evaluation of candidate vaccines.

We require an experienced Clinical Trial Monitor to facilitate the set-up, monitoring and closing down of clinical trials in addition to delivering training to site staff as required. The role is based at the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM) on the Churchill Hospital site in Headington, Oxford.

You will assist with development and writing of clinical trial monitoring plans based on the trial risk assessments and use your experience to suggest specific monitoring activities and schedules of monitoring visits. The role requires good time management skills for planning and co-ordination of monitoring and reporting of trials conducted at the CCVTM and participating sites in accordance with the trial protocol, relevant SOPs, the trial specific monitoring plan, Good Clinical Practice (GCP) guidelines on clinical trial monitoring and applicable regulatory requirements.

Responsibilities

You will:

- Monitor the clinical trial progress at Oxford and external sites, using remote data/document review and/or on-site monitoring visits to identify and resolve issues. Effective tracking and timely reporting of all monitoring activities throughout the trial and any deviations from the monitoring plan.
- Review the monitoring plan on an ongoing basis in collabaoration with the senior nursing team, considering monitoring findings, any amendments to the protocol and changes to the trial risk assessment.
- Monitor recruitment and retention of trial participants. Support site teams in efficient screening, recruitment and follow-up.
- Monitor sample collection and accountability of study drug/medical devices/trial supplies at site level, if applicable, and report any issues identified.
- Perform Source Data Verification (SDV) of study data and in collaboration with the data manager raise queries where discrepancies exist.
- Review participant informed consent forms, ensuring the correct versions are in use and completed appropriately.
- Review (Serious) Adverse Events ((S)AE) to confirm timely and complete reporting and assess individual events for accuracy and completeness, as required.
- Ensure all essential documentation and supporting documentation as appropriate is present and correctly filed within Trial Master File (TMF) and Investigator Site Files (ISF).
- Prepare monitoring reports within agreed timelines, send follow-up communications to sites and monitor progress of action points, recording resolution or escalating as needed.
- Develop and maintain strong and effective working relationships and excellent communications with site principal investigators and research teams.
- Maintain strong knowledge of the trial portfolio(s) you are responsible for, ensuring good communication with the senior research management staff, trial project managers, site coordinators, clinical trials assistant and data manager and providing updates on trial monitoring activities as required.

- Contribute to quality assurance team tasks, deputising for QA Managers when required.
- Contribute in the delivering of internal and/or external audits.
- Assist with the preparation for and supporting hosting of Regulatory Inspections.
- You are required to travel to other clinical sites that are taking part in the study being monitored.
- Participate in and support the public engagement and widening access activities of the Department and the University. This is anticipated to be not more than 2 days per year.
- Undertake mandatory training as required by the University, Division and Department. The specific list of training courses may change from time-to-time, in response to both legal and internal University requirements.

Job descriptions can never be comprehensive and you may be required to undertake other similar tasks and responsibilities.

Selection criteria

Essential

- Hold a degree in life sciences, nursing, biotech, medicial sciences or other relevant subject.
- Experience in clinical trials.
- Proven and significant monitoring experience in multicentre clinical trials in investigational medicinal products and/or medical devices.
- Experience of different monitoring activities including, remote, central and on-site monitoring.
- A broad knowledge of clinical trial design and therapeutic areas.
- Comprehensive knowledge of relevant regulations and codes of practice, including Clinical trial, medical device and data protection regulations, UK General Data Protection Regulation (UK GDPR), GCP, Good Clinical Laboratory Practice (GCLP) and Human Tissue Act (HTA).
- Ability to work independently, effectively manage time, and prioritise workload, with the ability to manage monitoring multiple trials concurrently.
- Excellent organisational skills and exceptional attention to detail.
- Excellent interpersonal skills, oral and written communication skills.
- Ability to demonstrate excellent IT literacy, including a strong working knowledge of Microsoft Software systems (e.g. Word, Excel, Powerpoint)

Desirable

- Experience of using eTMFs for monitoring purposes
- Previous experience of using OpenClinica Electronic Data Capture system or a comparable system
- Experience of working in clinical trials in a non-commercial (academic) setting and/or
- Experience of monitoring early phase vaccine and/or challenge 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 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
- Regular manual handling

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.

If you would like to apply, **click on the Apply Now button** on the 'Job Details' page and follow the on-screen instructions to register as a new user or log-in if you have applied previously.

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). Your application will be judged solely on the basis of how you demonstrate that you meet the selection criteria stated in the job description.

Please upload all documents **as PDF files** with your name and the document type in the filename. Please note using a long file name may prevent you from uploading your documents.

- http://www.ox.ac.uk/about_the_university/jobs/professionalandmanagement/

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 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 recruitment@ndm.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.