# Job description and selection criteria

<table>
<thead>
<tr>
<th>Job title</th>
<th>Clinical Data Manager</th>
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<tbody>
<tr>
<td>Division</td>
<td>Medical Sciences</td>
</tr>
<tr>
<td>Department</td>
<td>The Centre for Tropical Medicine &amp; Global Health, Nuffield Department of Medicine</td>
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<tr>
<td>Location</td>
<td>New Richards Building, Old Road Campus, Roosevelt Drive, Oxford, Headington, OX3 7LG</td>
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<tr>
<td>Grade and salary</td>
<td>Grade 7: £32,817 - £40,322 per annum</td>
</tr>
<tr>
<td>Hours</td>
<td>Full-time</td>
</tr>
<tr>
<td>Contract type</td>
<td>Fixed Term - 24 months</td>
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<tr>
<td>Reporting to</td>
<td>Senior Clinical Trial Manager</td>
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<tr>
<td>Vacancy reference</td>
<td>144853</td>
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Introduction

Overview of the role

The Clinical Data Manager will provide support and advice across projects that require the capture, storage, management, review and reporting of clinical research data. The post holder will be responsible for monitoring the completeness, accuracy, consistency and validity of trial data managed by the ERGO, ensuring that datasets specified for each trial meet the standards of quality expected for reporting to regulatory bodies, with particular consideration of the requirements of ICH GCP, data protection and pharmacovigilance. They will be accountable for the oversight and timely delivery of clinical trial data and documentation according to agreed timelines and quality expectations and will interact with a multi-disciplinary team. They will have an in-depth knowledge of multiple research projects and their respective data requirements.

The post may involve travel to worldwide study sites, however the requirement for this will fluctuate.

The main responsibilities of the Clinical Data Manager will be:

- To provide input into key study documents, focusing primarily on data management issues.
- To produce study-specific Data Management Plans
- To develop electronic Case Record Form (eCRF) specifications, to include eCRF design and edit checks, and subsequent change plans
- To design databases in REDCap, perform queries and generate forms
- To provide technical assistance and training to the staff who may be required to data enter/quality review information that is uploaded to REDCap.
- To facilitate production of study data performance metrics and reports.
- To oversee and project plan data management activities required to achieve timely database lock for individual projects.
- To deliver training to study teams on data entry methods and working practice and create user guides as required.
- To be responsible for data acquisition, review, query management and cleaning.
- To work with the ERGO Study Management Group to implement and improve data management processes, systems and operations
- To work with collaborators to refine existing tools and select appropriate solutions for specific settings
- To work with the study statistician to produce randomization lists and provide input into development of Statistical Analysis Plans
- To work with the study teams to generate unique patient identification numbers and to prepare bar code labels and study kits.
- To ensure timely and accurate coding of adverse events and concomitant medications as required.
- To oversee the arrangements for the transfer of data and reconciliation of datasets as necessary.
- To be responsible for reviewing the study data status and escalating issues of concern in a timely fashion in order to meet timelines for database lock.
- To coordinate the archiving of study databases and related documents.
To ensure that all data management documentation is retained and maintained according to ERGO SOPs and best practice.

In addition the Data Manager will be expected to undertake any other duties as delegated by the Senior Clinical Trial Manager and as appropriate for the grade.

**Selection Criteria**

In addition candidates will be shortlisted for interview based on the extent to which they meet the following essential criteria.

**Essential criteria:**

- A first degree or higher in an appropriate subject area
- Experience in clinical research data management, Good Clinical Practice and related regulatory requirements and terminology.
- Experience working with REDCap
- Experience of using coding dictionaries
- Knowledge of GDPR and national data protection laws
- Confidence and aptitude in presenting and networking
- An interest in developing research capacity in low-income regions and disease outbreaks
- Strong organisational skills and IT competence

**Desirable criteria:**

- Experience in clinical research, ideally in developing countries
- Experience and strong awareness of the issues around data archiving and data sharing
- Project management skills and experience
- Willingness to travel internationally

**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. Income from external research contracts in 2016/17 exceeded £564m and we rank first in the UK for university spin-outs, with more than 130 companies created to date. 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.
The University

The University of Oxford is a complex and stimulating organisation, which enjoys an international reputation as a world-class centre of excellence in research and teaching. It employs over 10,000 staff and has a student population of over 22,000.

Most staff are directly appointed and managed by one of the University’s 130 departments or other units within a highly devolved operational structure - this includes over 6,500 ‘academic-related’ staff (postgraduate research, computing, senior library, and administrative staff) and over 2,700 ‘support’ staff (including clerical, library, technical, and manual staff). There are also over 1,600 academic staff (professors, readers, lecturers), whose appointments are in the main overseen by a combination of broader divisional and local faculty board/departmental structures. Academics are generally all also employed by one of the 38 constituent colleges of the University as well as by the central University itself.

Our annual income in 2012/13 was £1,086.9m. Oxford is one of Europe's most innovative and entrepreneurial universities: income from external research contracts exceeds £436.8m p.a., and more than 80 spin-off companies have been created.

For more information please visit www.ox.ac.uk/staff/about the university.html

Medical Sciences

The Medical Sciences Division is an internationally recognized 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 Clinical Medicine (NDM)

The Nuffield Department of Clinical Medicine (NDM) is one of the largest departments of the University of Oxford and is part of the Medical Sciences Division, with responsibility for a significant part of the teaching of clinical students within the Medical School. The Department also has a substantial research programme which requires high quality administrative management.

NDM has significant financial turnover and complexity, resulting from its diverse research portfolio, its geographical spread and its close links with NHS funding and strategic teams involved in the development and delivery of increasingly integrated clinical research platforms.

For more information please visit: http://www.ndm.ox.ac.uk/home
The Nuffield Department of Clinical Medicine has been presented with a Departmental Athena SWAN Bronze award in recognition of the commitment made to promote gender equality through our organisational and cultural practices and our efforts to improve the working environment for both men and women. For more information please see our Departmental Athena SWAN pages: [http://www.ndm.ox.ac.uk/athena-swan](http://www.ndm.ox.ac.uk/athena-swan).

**Centre for Tropical Medicine & Global Health**

Tropical Medicine is a collection of research groups within the Nuffield Department of Clinical Medicine, who are permanently based in Africa, Asia and Oxford. Our research ranges from clinical studies to behavioral sciences, with capacity building integral to all of our activities.

The majority of our research is conducted at three Wellcome Trust Major Overseas Programmes in Kenya, Thailand and Viet Nam as well as the Centre in Oxford. Tropical Medicine also brings together a number of sister groups in Laos, Tanzania, Indonesia and Nepal, and collaborators from around the world. There are also major research initiatives led from the UK, including ISARIC, PREPARE and The Global Health Network.

For more information please visit: [www.tropicalmedicine.ox.ac.uk/home](http://www.tropicalmedicine.ox.ac.uk/home)

**The Epidemic diseases Research Group Oxford (ERGO)**

The overarching aim of the Epidemic diseases Research Group Oxford (ERGO) is to reduce the health and socioeconomic impact of emerging and epidemic infections by conducting and enabling clinical research.

To ensure that clinical science is a dependable pillar of the response to epidemic infectious diseases, ERGO is developing methodologies, technologies, and platforms that are designed to overcome the inherent challenges of conducting research on emerging and epidemic infections.

The group is conducting research on a range of epidemic infectious diseases with partners across the world, including Ebola virus, Lassa virus, bubonic plague, monkeypox and non-polio enteroviruses. Our major projects include the International Severe Acute Respiratory and emerging Infection Consortium (ISARIC), the African coaLition for Epidemic Research, Response and Training (ALERRT) and the UK Public Health Rapid Support Team (UK-PHRST). ERGO is based within the Centre for Tropical Medicine and Global Health at the University of Oxford.

**How to apply**

Before submitting an application, you may find it helpful to read the ‘Tips on applying for a job at the University of Oxford’ document, at [www.ox.ac.uk/about/jobs/supportandtechnical/](http://www.ox.ac.uk/about/jobs/supportandtechnical/).

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. Please provide details of two / three referees and indicate whether we can contact them now.

You will also 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.

All applications must be received by **midday** 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).*

Should you experience any difficulties using the online application system, please email recruitment.support@admin.ox.ac.uk. Further help and support is available from www.ox.ac.uk/about_the_university/jobs/support/. 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: www.admin.ox.ac.uk/councilsec/compliance/gdpr/privacynotices/job/. The University’s Policy on Data Protection is available at: www.admin.ox.ac.uk/councilsec/compliance/gdpr/universitypolicyondataprotection/.

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: www.admin.ox.ac.uk/personnel/end/retirement/acrelretire8+/.

For existing employees, any employment beyond the retirement age is subject to approval through the procedures: www.admin.ox.ac.uk/personnel/end/retirement/acrelretire8+/

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 www.admin.ox.ac.uk/personnel/staffinfo/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 www.sport.ox.ac.uk/oxford-university-sports-facilities.

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 www.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 www.admin.ox.ac.uk/personnel/permits/reimburse&loanscheme/.

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 www.admin.ox.ac.uk/personnel/staffinfo/benefits/family/mfc/.

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 www.admin.ox.ac.uk/childcare/.

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 www.admin.ox.ac.uk/eop/disab/staff.

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 www.admin.ox.ac.uk/eop/inpractice/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.