Job description and selection criteria

<table>
<thead>
<tr>
<th>Job title</th>
<th>Trainee Clinical Trial Project Manager, Blood-Stage Malaria Vaccine Programme</th>
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</thead>
<tbody>
<tr>
<td>Division</td>
<td>Medical Sciences</td>
</tr>
<tr>
<td>Department</td>
<td>Nuffield Department of Medicine</td>
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<tr>
<td>Location</td>
<td>Centre for Clinical Vaccinology and Tropical Medicine, Churchill Hospital, Headington, Oxford, OX3 7LE</td>
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<tr>
<td>Grade and salary</td>
<td>Grade 6: £28,098-£33,518 per annum</td>
</tr>
<tr>
<td>Hours</td>
<td>Full time</td>
</tr>
<tr>
<td>Contract type</td>
<td>Fixed-term for 2 years initially</td>
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<tr>
<td>Reporting to</td>
<td>Blood-Stage Malaria Chief Investigator and Project Manager</td>
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<tr>
<td>Vacancy reference</td>
<td>139159</td>
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The role

Due to success in attracting clinical trial funding the Jenner Institute is seeking to appoint a trainee clinical trials project manager to support the Blood-Stage Malaria Vaccine Group research programme at the Institute. You will be based at the clinical trials centre (CCVTM) in Headington, Oxford but may need to spend time liaising with the Old Road Campus Research Building (ORCRB) which is based on the same Old Road Campus site. Your main responsibility will be supporting a variety of clinical projects led by Professor Simon Draper who runs the Blood-Stage Malaria Vaccine Group and Dr Angela Minassian the Chief Investigator on Blood-Stage Malaria Vaccine Group clinical trials. The programme has a diversity of funders, and strong links with industry and a variety of non-industrial / academic collaborators. This will be a key role within the group ensuring successful completion of our clinical research programmes.

Professor Simon Draper’s research group at the Jenner Institute is focused on developing innovative vaccine candidates against the malaria parasite, testing them in pre-clinical studies with an aim to progress the most promising candidates to clinical trials. A number of vaccine candidates are currently being tested in Phase I/IIa clinical trials in Oxford. These include vaccines against both *Plasmodium falciparum* and *Plasmodium vivax*.

The research group has a strong translational focus, seeking to develop innovative and new concepts in vaccine or antibody-based design and delivery. Over the last 10 years we have
translated nine vaccine candidates, including viral vectors and recombinant proteins, into Phase Ia and Ila clinical trials in the UK and Africa. These trials evaluate the safety and immunogenicity in healthy volunteer subjects, including experimental malaria challenge studies to test vaccine efficacy. A number of these trials are conducted at both a national and international level.

The group has a strong record of attracting external grant funding, a strong publication record, and has expanded significantly in recent years. We aim to foster scientific excellence within a friendly, open and free-thinking environment. There is a strong translational emphasis, with full integration of the clinical and laboratory teams.

If you have previous experience and knowledge of clinical trials, perhaps as a clinical trials assistant, particularly Phase I/II CTIMPs and/or human challenge studies, we encourage you to apply.

Informal enquiries about this post can be addressed to: fay.nugent@ndm.ox.ac.uk

Responsibilities

- To support the Clinical Trials Project Manager and the Blood-Stage Malaria Group to ensure clinical trial objectives are met within set timelines and work is conducted within the appropriate standards.
- Work with the Clinical Trial Project Manager on clinical trial applications and amendments for various bodies and partners including the MHRA, and ethics committees.
- Assist in the review of key trial documents for typographical errors prior to submission, ensuring their accuracy and clarity.
- Communicate with a wide range of internal partners, including: clinical trial physicians, clinical research coordinators, laboratory staff, NDM HR and Finance.
- Correspond with study volunteers in a clear and professional manner, coordinating visits and dealing with trial related queries.
- Schedule, prepare information for, and attend regular clinical trial and Group operational meetings and teleconferences. Record accurate minutes and distribute documents in a timely manner.
- Create and manage trial master files and other trial related filing systems. Ensure their accuracy prior to trial monitoring and archiving.
- Use databases to enter and collate trial data for formal trial reports, and assist in database validation.
- Database entry.
- Provide financial administration support (raising requisition orders, and payment request forms), monitoring that invoices and payments are made on time by liaising closely with the project manager and the finance team.
- Set up and keep updated a system for ensuring requisitions are raised on the correct projects for the Group.
- Raise standing orders and purchase orders at the beginning of a trial and set up a monitoring system.
- Assist in all aspects of the team’s activities as appropriate, according to the principles of Good Clinical Practice (GCP) and the Jenner CCVTM Group’s Standard Operating Procedures (SOPs).
- To undertake training in good clinical practice and maintain current awareness of GCP, ethics and regulatory issues.
- To participate in and support the public engagement and widening access activities of the Department and the University e.g. by attending recruitments events such as Fresher’s Fair. This is anticipated to be not more than 2 days per year.
To attend clinical trial seminars, meetings and training as appropriate.
Assist in trial set up and activations; establish links with key members of staff and ensuring essential documentation is in place.
Assist in the collation and submission of trial progress reports as and when required.
Assist with the timely completion of follow-up and study closure, and undertake archiving of paper-based study data.
Proactively look to find better, more efficient ways to carry out clinical trial administrative processes.
To undertake any other reasonable duties as required in the management of the Blood-Stage Group's clinical trials.

All employees will have to ensure that their work is conducted safely at all times and, in particular, that work is undertaken following the appropriate health and safety policies and procedures for the particular area, without compromise to their own safety or that of others who may be affected.

**Selection criteria**

**Essential**

- Degree in biological science or equivalent;
- Proven relevant clinical trial experience, skills, and knowledge and be familiar with the principles of Good Clinical Practice;
- Highly developed organisation skills, with an ability to meet competing deadlines;
- Ability to communicate effectively to a high standard, including relatively complex matters, with a range of people and organisations both orally and in writing;
- Good interpersonal skills and ability to work effectively with others;

**Desirable**

- Proven relevant clinical trial management experience, skills, and knowledge, in Phase I/II CTIMP studies and/or human challenge studies;
- Experience of grant administration and management within the University of Oxford;
- Understanding of the University research grant management procedures and/or previous relevant experience within the higher education sector;
- Experience of vaccine testing pre-clinically or clinically;
- Experience of therapeutic protein or monoclonal antibody testing pre-clinically or clinically.

**Additional security pre-employment**

- University security screening (eg identity checks)

**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](http://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.

...fostering your career in science

For more information please visit: www.ndm.ox.ac.uk/home

The University of Oxford is a member of the Athena SWAN Charter and holds an institutional Bronze Athena SWAN award. The Nuffield Department of Medicine holds a Silver Athena SWAN award to recognise advancement of gender equality: representation, progression and success for all.

For more information please visit: https://www.ndm.ox.ac.uk/working-for-ndm/aboutndmatheneswan/

The Jenner Institute

The Jenner Institute was founded in November 2005 to develop innovative vaccines against major global diseases. Uniquely it focuses both on diseases of humans and livestock and tests new vaccine approaches in parallel in different species. A major theme is translational research involving the rapid early-stage development and assessment of new vaccines in clinical trials.

For more information please visit: department website http://www.jenner.ac.uk/

The Jenner Institute - Centre for Clinical Vaccinology and Tropical Medicine (CCVTM), Churchill Hospital, Oxford

Scientists at the Jenner Institute, University of Oxford, have developed new candidate vaccines for malaria, tuberculosis, HIV, influenza and a wide range of other pathogens. Clinical trials are in progress for eight infectious disease areas. See www.jenner.ac.uk. The Jenner Institute is one of the largest university based vaccine institutes globally.

Over the last three years a new cancer vaccine immunotherapy programme, including a multi-site trial in prostate cancer, has been in progress in close collaboration with the departments of oncology and surgery.

For more information please visit: http://www.jenner.ac.uk/ & http://www.tropicalmedicine.ox.ac.uk/home

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 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 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).

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 be notified of the progress of your application by automatic emails from our e-recruitment system. Please check your spam/junk mail regularly to ensure that you receive all emails.

### Important information for candidates

#### Pre-employment screening

Please note that the appointment of the successful candidate will be subject to standard pre-employment screening, as applicable to the post. This will include right-to-work, proof of identity and references. We advise all applicants to read the candidate notes on the University's pre-employment screening procedures, found at: www.ox.ac.uk/about/jobs/preemploymentscreening/.

#### The University's policy on retirement

The University operates an Employer Justified Retirement Age (EJRA) for all academic posts and some academic-related posts. From 1 October 2017, 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+](http://www.admin.ox.ac.uk/personnel/end/retirement/acrelretire8+).

From 1 October 2017, 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.

**Information Security**

Information is critical to The University of Oxford operations and failure to protect information increases the risk of financial and reputational losses. NDM is committed to protecting information, in all its forms, from loss of *confidentiality*, *integrity* and *availability*. Users are required to complete information security awareness training and are responsible for making informed decisions to protect the information that they process. Wilful failure to comply with the policy and baseline will be treated extremely seriously by the University and may result in enforcement action on The Nuffield Department of Clinical Medicine and/or an individual. For full details please see [University Information Security Policy and Implementation Guidance](#).
Benefits of working at the University

University Club and sports facilities

The University Club provides social, sporting and hospitality facilities. It incorporates a bar, café and sporting facilities, including a gym. 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 international staff (or those relocating from another part of the UK)

If you are relocating to Oxfordshire from overseas, or elsewhere in the UK, the University's International Staff website includes practical information related to moving to and settling in Oxford such as advice on immigration, relocation, accommodation, or registering with a doctor. See: www.internationalstaffwelcome.admin.ox.ac.uk/

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 to settle into Oxford and to provide them with an opportunity to meet people in the area. See www.newcomers.ox.ac.uk/

Childcare

The University has excellent childcare services with 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.

Family-friendly benefits

The University subscribes to My Family Care (www.admin.ox.ac.uk/personnel/staffinfo/benefits/family/mfc/) and staff are eligible to register for emergency back-up childcare and adultcare services, a 'speak to an expert' phone line and a wide range of guides and webinars through a website called the Work + Family space.

Disabled staff

We are committed to supporting members of staff with disabilities or long-term health conditions. Please visit www.admin.ox.ac.uk/eop/disab/staff for further details including information about how to make contact, in confidence, with the University's Staff Disability Advisor.

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/

Other benefits

Staff can enjoy a range of other benefits such as free visitor access to the University's colleges and the Botanic Gardens as well as a range of discounts. See www.admin.ox.ac.uk/personnel/staffinfo/benefits