



St George's School of Health and Medical Sciences

City St George's, University of London

**Institute for Infection and Immunity
Centre for Neonatal and Paediatric Infection**

Senior Clinical Trial Manager

Ref: 630-24-R2

JOB DESCRIPTION

Post Title	Senior Clinical Trial Manager
Grade	7
Contract type	Fixed Term 1 Year
Responsible to	Senior Clinical Trial Manager and Group Lead
Accountable to	Operations Manager
Responsible for	Clinical Trial Managers and Clinical Trial Coordinators
Liases with	The Centre for Neonatal and Paediatric Infectious Diseases (CNPI) group and other relevant institutional managers and individual Principal Investigators

Overall purpose of job

This is an exciting opportunity for a Senior Clinical Trial Manager to take part in a range of ongoing clinical research studies within the Centre for Neonatal and Paediatric Infection (CNPI), focusing on Vaccine studies.

The main responsibilities of the post holder will be to coordinate the delivery of multiple medium-to-large scale projects, within the CNPI. You will be responsible for supporting the Senior Clinical Trial Manager and Group Lead, Operations Manager, Chief Investigators, and leading principal investigators in the coordination and project management of the studies, and achievement of its milestone goals.



The Centre for Neonatal and Paediatric Infection (CNPI)

Professor Paul Heath and Professor Mike Sharland have developed the Centre for Neonatal and Paediatric Infection (CNPI) which has undertaken a variety of projects and studies in children focusing on the epidemiology of vaccine-preventable diseases, clinical vaccine trials, cohort studies, perinatal infections and optimisation of the best use of antimicrobials in children. The CNPI attracts funding from major research bodies in the UK and Europe including the European Union (EU), the European Commission (EC), Action Medical Research (AMR), Meningitis Research Foundation (MRF) and many commercial companies focused on research.

The CNPI consists of three research teams:

The Anti-Microbial Resistance (AMR) Team, which focuses on research to optimise the use of Antimicrobials to prevent and treat newborn and child infections. It is led by Professor Mike Sharland and Dr Julia Bielicki, who are the UK and Europe's leading experts in antimicrobial prescribing, resistance and healthcare associated infection in children.

The Vaccinology team is led by Professor Kirsty Le Doare. The portfolio includes a series of clinical and observational studies investigating Group B Streptococcus, which causes disease and death in infancy, and observational studies of COVID-19. These include studies assessing safety and effectiveness of vaccines, sero-epidemiology studies and studies assessing serocorrelates of protection against disease.

The St George's Vaccine Institute Team is led by Professor Paul Heath and Dr Catherine Cosgrove. It focuses on the epidemiology of vaccine-preventable diseases, human clinical trials of paediatric, pregnancy and adult vaccines and studies vaccines against infectious diseases plaguing the most underprivileged members of the world. The team consists of consultants in infectious diseases, obstetricians, clinical research fellows, research nurses, research midwives and a project management team.

This role will be based within the St George's Vaccine Institute Team.

Main Duties and Responsibilities

You will be responsible for the project management, financial planning and reporting activities delegated by the Senior Clinical Trial Manager and Group Lead, Operations Manager and the Principal Investigators (PI)s. You will be expected to work independently with minimum supervision and will be required to anticipate and resolve problems that may prove bottlenecks in the achievement of agreed milestone goals. You will be expected to demonstrate intellectual ability and a significant degree of creativity to devise varied solutions. The post specifically requires an appointment of an individual with proven experience in clinical research preferably in the areas of paediatrics, infectious diseases, immunology, microbiology, epidemiology, public/global health and sufficient breadth and depth of specialist knowledge in established research programmes. This position is key to good communication and professional relationships with clinical investigators and international colleagues.



Project Management and Coordination

- Provide the operational expertise and leadership to ensure the effective and efficient delivery of all aspects of multiple studies through all phases of Clinical Project Management, in accordance with the appropriate quality standards including ICH/GCP and applicable regulations.
- Provide specialist advice on the development and running of complex multi-centre research projects undertaken within the CNPI and work closely with the Senior Clinical Trial Manager and Group Lead, Operations Manager, Principal Investigator and Chief Investigator in the recruitment of participating clinicians and hospitals to create large collaborative groups for trials
- Supervision of progress of projects relative to the time schedule for deliverables and milestones
- Collate, write and disseminate project reports and updates for the project coordinators or funding bodies
- Submission of reports to the sponsor/funder and other project coordinators or funding bodies as and when required and presenting regular progress reports on research to members of the research group or to external audiences
- Support the development of relevant ethical (IRB) and R+D approvals of the CNPI projects
- Support the development of clinical protocols to obtain relevant research material
- Locate and assess the suitability of facilities at a study centre; liaising with doctors/consultants (or investigators) on conducting the trial; setting up the study centres, which includes ensuring each centre has the trial materials and training site staff to trial-specific standards; training site staff involved in conducting trials; assist with trial monitoring throughout its duration, which involves visiting the study centres on a semi-regular basis
- Organise and assist research fellows with pre-study visits, initiation visits, periodic monitoring visits and close-out visits and provide administrative support for recruitment, induction and basic research skills training of new staff and visitor workers
- Monitor and documenting the group's attainment of milestones and objectives
- Monitor progress in each sub project to allow early recognition of any difficulties facing individual participants. Where possible, to facilitate a resolution through which a milestone or objective can still be achieved in good time. Receipt and documentation of deliverables from all participants
- Provide assistance to the project leaders as required, particularly in preparation of submissions annual and final reports
- Facilitate interactions and information dissemination between the SGUL team and wider consortiums



Financial Management

- Oversee the finances and financial reporting of the projects and ensure that all contractual funding arrangements are honoured, including grant claims and progress reporting to the relevant bodies
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- Set and manage project budgets working closely with the Joint Research and Enterprise Services, and the Finance Department.
- Provide administrative support for grant applications, obtaining formal costings, developing project initiation documents and facilitating meetings / teleconferences, as well as reviewing scientific documents.

Administration

- Maintenance of the overall projects plans and accounts (including Gantt and Pert charts, calendars, resource allocations, task lists, and recording of decisions) monitoring of the budget
- Ensure all study agreements are in place before any trial activity takes place
- Attendance to meetings, including annual consortium meetings
- Facilitate technology transfer within SGUL and with external third parties and project coordinators or sponsors
- Ensure appropriate adherence to the human tissue act
- Carry out routine administrative tasks associated with the projects to ensure that projects are completed on time and within budget. These might include organisation of project meetings and documentation, financial control and monitoring
- Responsibility for the creation, maintaining and the monitoring of the Sponsor's Trial Master File (TMF) and/or the Investigator Site File (ISF) and progress of some clinical trials by undertaking Source Data Verification (SDV), ensuring that the essential documents and pharmacy records are up to date and in with the requirements of the current legislation
- Oversee forecasting of clinical/non-clinical supplies
- Co-ordination of regular phone conferences; meeting arrangements and dissemination of data within the SGUL team and the project coordinators and other relevant institutional managers and individual Principal Investigators.



Line Management

- Manage junior project management and other staff as required including recruitment, selection, training, appraisal and supervision.

Personal Development

- Keep up-to-date with literature relating to clinical research and regulations.
- Identify training needs to maintain and develop role and ensure mandatory training updates are undertaken in a timely manner
- Be responsible for the Health, Safety and Welfare of self and others and to comply at all times with the requirement of the Health and Safety Regulations
- Ensure confidentiality at all times, only releasing confidential information obtained during the course of employment to those acting in an official capacity in accordance with the provisions of the Data Protection Act and its amendments.

You are also expected to undertake other activities appropriate to your grade as directed by your manager. This job description reflects the present requirements of the post. As duties and responsibilities change, the job description will be reviewed and amended in consultation with the post holder from time to time. City St George's, University of London aims to provide opportunities for all its employees to develop the skills required to be successful in their role and to further develop their careers.

St George's School of Health & Medical Sciences, University of London, is committed to the San Francisco Declaration on Research Assessment (DORA) principles.

Special Factors

The post holder may be required to travel, mainly within the UK.



Person Specification

Criteria	Description	Essential/ Desirable	How it is to be tested
Qualifications	BSc in Immunology, Microbiology, public/global health, infectious diseases or clinical trials (or any other science relevant to the study, or equivalent experience)	E	PQ, AF
	MSc or PhD in relevant field	D	AF
	Professional project management qualification or any additional related qualifications	D	AF
Knowledge/ Experience	Research experience in the fields of paediatrics or microbiology or epidemiology or infectious diseases or global health (or similar)	E	AF, SS1 , INT
	Substantive knowledge and experience of managing clinical trials	E	AF, SS2 , INT
	Track record of successfully managing multiple concurrent, multi-site clinical trials	E	AF, INT
	Experience submitting applications and managing clinical research projects funded by the EU and other national or international funding agencies	D	AF, SS3 , INT
	Previous experience with project budgets/finances	E	AF, SS4 , INT
	Previous experience of project management in a clinical/research setting	E	AF, INT
	Experience in drug research and clinical trials	D	AF, INT
	Experience in neonatal research and/or paediatric research	D	AF, INT



	Experience in developing and implementing effective partnerships with a range of partners and interest groups	D	AF, INT
	Experience managing a team	E	AF, SS5 , INT
Skills	Ability to cope with a heavy and multi-stranded workload and to support others in doing so	E	AF, INT
	Ability to identify, monitor and facilitate resolution of issues - negotiation and facilitation skills	E	AF, INT
	Ability to manage large datasets, ensuring data is handled confidentially and within policy and guidelines.	D	AF, INT
Personal Attributes	Ability to work independently and use initiative as well as part of a team/team building and management skills	E	AF, INT
	Willingness and flexibility to adjust to changing requirements in a challenging environment	E	AF, INT
	Excellent communication skills, both verbal and written, with a wide range of people at all levels, and all cultures. Excellent interpersonal skills.	E	AF, INT
	Ordered, organised and able to determine priorities for self and team	E	AF, INT
	Proactive attitude with the ability to think and plan ahead.	E	INT
	Enthusiastic and positive approach to work	E	INT

Key:

PQ=Prerequisite Qualification, AF=Application Form, CV=Curriculum Vitae,
SS=Selection/Supporting Statements, ST=Selection Test/Presentation, INT=Interview

Note: Elements marked SS (Supporting Statements) in the Person Specification will be highlighted in Step 6 (Supporting Statements) on the online application form. Applicants' answers to Step 6 are an essential part of the selection process. Applicants should write individual supporting statements to demonstrate how their qualifications, experience, skills and training fit each of the elements highlighted in this section.

Applicants should address other elements of the Person Specification in Step 7 (Additional Information). Shortlisting will be based on applicants' responses to Step 6 **and** Step 7. Therefore applicants should complete both sections as fully as possible on the online application form.

Updated January 2025



About City St George's, University of London

City St George's, University of London is the University of business, practice and the professions.

City St George's attracts around 27,000 students from more than 150 countries.

Our academic range is broadly-based with world-leading strengths in business; law; health and medical sciences; mathematics; computer science; engineering; social sciences; and the arts including journalism, dance and music.

In August 2024, City, University of London merged with St George's, University of London creating a powerful multi-faculty institution. The combined university is now one of the largest suppliers of the health workforce in the capital, as well as one of the largest higher education destinations for London students.

City St George's campuses are spread across London in Clerkenwell, Moorgate and Tooting, where we share a clinical environment with a major London teaching hospital.

Our students are at the heart of everything that we do, and we are committed to supporting them to go out and get good jobs.

Our research is impactful, engaged and at the frontier of practice. In the last [REF \(2021\)](#) 86 per cent of City research was rated as world leading 4* (40%) and internationally excellent 3* (46%). St George's was ranked joint 8th in the country for research impact with 100% of impact cases judged as 'world-leading' or 'internationally excellent. As City St George's we will seize the opportunity to carry out interdisciplinary research which will have positive impact on the world around us.

Over 175,000 former students in over 170 countries are members of the City St George's Alumni Network.

City St George's is led by Professor Sir Anthony Finkelstein.



St George's School of Health and Medical Sciences currently offers a range of employee benefits:

Salary: £50,694 pa, (pro-rated for part-time staff). The salary range for **Grade 7** is £50,694 – £60,321 and appointment is usually made at the minimum point.

Hours: 35 hours per week which can be done flexibly in various ways or part time/job share can also be considered. Staff are expected to work the hours necessary to meet the requirements of the role and this will be dependent on the service area.

Annual leave: 30 days per annum. Plus eight UK public holidays and four days when City St George's, University of London is closed (usually between Christmas and New Year). Part time staff receive a pro rata entitlement.

Pension: Membership of competitive pension schemes with generous employer contribution and a range of extra benefits.

[Superannuation Arrangements of the University of London \(SAUL\)](#)

[London Pension Fund Authority \(LPFA\)](#)

[Universities Superannuation Scheme \(USS\)](#)

[National Health Services Pension Scheme \(NHSPS\) \(existing members only\)](#)

Flexible working Flexible working, including part-time or reduced hours of work, opportunities to work from home for many posts, compressed hours and local flexibility in agreeing start and finish times of work.

Travel City St George's, University of London offers an interest free season ticket loan and participates in the [Cycle to Work Scheme](#).

Gift Aid If you would like to make a tax-free donation to a charity of your choice, this can be arranged through our Payroll.

Sports and Leisure Facilities Rob Lowe Sports Centre, situated on the St George's Healthcare NHS Trust site offers exercise facilities that can be utilised by City St George's, University of London staff.

Within walking distance from St George's is Tooting Leisure Centre. Facilities include a swimming pool, gym and various exercise classes. The Centre offers staff an all-inclusive corporate membership. For more information please contact [Tooting Leisure Centre](#).



Shops and facilities There are a number of shops and facilities situated on site including ATMs, student bar and shop, Pret a Manger, M&S Simply Food store, library and multi-faith room.

Informal enquiries

Informal enquiries may be made via email to: uzkhan@sgul.ac.uk

Making an application

All applicants are encouraged to apply on line at <http://jobs.sgul.ac.uk> as our system is user friendly and the online application form is simple to complete. Please note that CVs only will not be accepted.

For any accessibility issues please contact hrhelp@sgul.ac.uk

Closing date: **04 February 2025**

Interview date TBC. As shortlisted candidates will be notified by email, it is imperative that you provide an email address that is accessed frequently.

Please quote reference **630-24-R2**

We are delighted that you are interested in working at St George's School of Health and Medical Sciences. You will be notified of the outcome of your application by email. We aim to respond to all candidates within 5 weeks of the closing date of the vacancy.

