Clinical Trials Unit Manager
Job Description & Person Specification –

A summary of the role responsibilities and person specification

NHS
University Hospitals Bristol and Weston
NHS Foundation Trust

Why Our Trust?

Terms and conditions

Post – Clinical Trials Unit Manager

Division – Specialised Services

Department –Clinical Trials Unit

Band – 8b

Salary - £58,972- ££68,525

Location – Bristol Haematology and Oncology Centre

Annual leave – Up to 33 days dependant on NHS Service

Pension - The NHS Pension Scheme is a defined benefit scheme. Further details and outline of benefits can be found at: www.nhsbsa.nhs.uk/pensions

Job Purpose

Working within the division of specialised services the CTU manager will be accountable for the safe and effective delivery of the highest quality clinical trials portfolio, for the achievement of all relevant national, local trust and divisional objectives/targets and for the successful implementation of agreed strategic priorities. The CTU is integral to the BHOC specialist NHS service provided to patients offering a treatment option as part of a clinical trial. Accountable to specialised services divisional research board for CTU activity, performance and strategic plans. The post holder will develop key relationships with the divisional director, director of R&D, BHOC deputy divisional manager, clinical leads, Oncology and Haematology consultants and BHOC matrons. The post holder will attend quarterly BHOC Research Board, weekly divisional management team meetings and is a member of the BHOC senior management team. The post holder will lead and manage the CTU and develop the strategic direction, ensuring the needs of the patients, researchers, staff and sponsors are met in an ever changing research and funding environment. Ensuring all clinical trial regulatory requirements are implemented and adhered to. The CTU manager is responsible for a substantial cancer clinical trials portfolio, ranging from first in man, phase 1-4 within CTU and local partner trusts.

About us

Our mission is to improve the health of the people we serve by delivering exceptional care, teaching and research every day.

What you'll love about working here

We are outstanding! The CQC rated the organisation as Outstanding for services being caring and well-led. The Trust was the first in the country to go from Requires Improvement to Outstanding in 2017, and is now the first to do this and then retain this rating. The Trust is currently one of only seven in the country to have been rated Outstanding twice, and one of only three general acute Trusts to achieve this.

A digital exemplar- Being appointed as a Global Digital Exemplar means we can realise this vision by implementing digital technologies that will help us to transform the way we work and how we relate to our colleagues, patients and partner organizations.

Sustainable healthcare - We have joined the international movement to declare a climate emergency, recognising the impact climate change is having on the world. Climate change is labelled as the greatest threat to health in the 21st century, with a range of conditions related to heat, cold, extreme weather and air pollution predicted to rise. To lead the way in healthcare the Trust has set ambitious goals to become carbon neutral by 2030.

Access to further opportunities with the Trust - Apprenticeships are a great way to learn and earn on the job. UH Bristol and Weston provides a range of apprenticeships to support a huge number of career opportunities in clinical and non-clinical support services with apprenticeships starting at level 2 through to level 7. As an organisation we encourage further development of all employees to progress upward within their chosen field.

Diversity & Inclusion

A core principle of the Trust is to ensure that patients and staff are treated with dignity and respect. Promoting equality, diversity and human rights and challenging any form of inequality, discrimination, harassment or abuse are central to the Trust's Values.

'Committed to inclusion in everything we do' is the ambition set out in the Trust's Workforce Diversity & Inclusion Strategy.

The Trust will not tolerate discrimination, harassment or bullying under any circumstances and particularly because of a characteristic protected by the Equality Act 2010.

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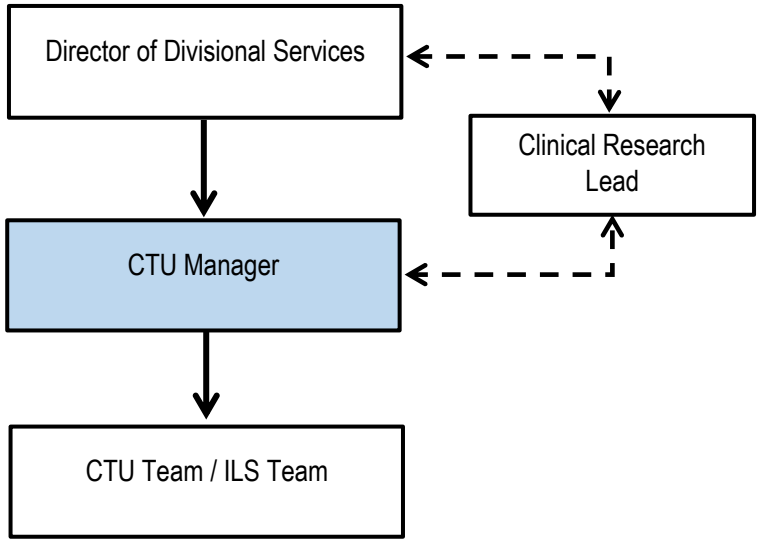
Main duties and responsibilities

Detailed under each of the core accountabilities for the post

Management

1. Responsible for the management of Adult Oncology/ Haematology and Adult Bone marrow Transplant Clinical Trials within University Hospital Bristol and Weston BHS Trust (UHBW) and for trials that span across local trusts, South West collaborating sites and nationally across the UK when BHOC are the lead investigator site for Investigational Medicinal Product Multi-Centre Trials.
2. Accountable for the operational planning and management of a substantial trials portfolio consisting of 150-200 clinical trials; with approximately 90-100 trials open to recruitment, 20-30 in set-up and a large proportion in follow-up at any one time. This involves approximately 1,000 patients being managed within a clinical trial and 900-1000 new referrals for trial entry per year
3. Accountable for overall decision making regarding the complexity, nature, and level of trial activity the unit can support and ultimately manage associated risks; clinical, financial and reputational. Setting the monthly research forum agenda to reflect this.
4. Responsible for managing CTU capacity and balancing trial demand through collaboration with site specific leads/ individual principle Investigators and clinical support departments regarding trial portfolio development.
5. Responsible for determining and overseeing monthly trial activity/performance metrics; monitoring and identifying areas of poor research performance e.g. patient recruitment/ data management/trial set-up and act upon accordingly defining an appropriate course of action.
6. Accountable to quarterly specialised service divisional research board for CTU activity; performance and strategic Plans
7. Develop relationships with UHB support department leads contributing to cancer clinical trials including; pharmacy trials unit, pharmacy production, pharmacy sterile unit, radiology and pathology services. Imperative to the success of the CTU is influencing work priorities within a matrix environment

Organisational Structure



Solid line: Direct reporting. Dashed line: Close working relationship

Key Relationships

Divisional Director, BHOC Research lead, Consultant staff, Director of UHB Research & Innovation Department and Key Team Leads, West of England Clinical Research Network & Cancer Delivery Manager, Nursing and Clinical professional leads, Radiotherapy Service Managers, All UHBW Pharmacy Department Leads Senior Managers within Division and in UHBW

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8. Responsible for effectively managing and prioritising the utilisation of support department resources to most efficiently meet a substantial number of trials (100 plus) milestones, timelines and patient recruitment targets.
9. Lead and manage the CTU team in key result areas: National Institute for Health Research (NIHR) targets for: effective trial set-up timelines, recruiting to contract time and target. Locally, all CTU trial contracts recruitment targets and clinical data returns
10. Responsible for the development, approval and systematic review of all standard operating procedures; ensuring these are in place for CTU BHOC and multi centre trials across collaborating sites. Ensure safeguarding procedures are in place with adequate risk assessments for clinical trials posing a biological safety hazard and early phase high risk trials.

11. Oversee CTU preparation for Medicines and Healthcare Products Regulatory Agency (MHRA) inspections and lead on follow-up actions

12. Responsible for ensuring that all CTU trial related safety reporting is promptly acted upon and communicated according to individual trial protocols' and trust policies and that potential areas of risk to patients participating in cancer clinical trials are identified and addressed in collaboration with relevant clinical leads.
13. Responsible for strategically planning, managing and delivering complex projects with a broad range of activities involving multiple agencies to tight deadlines
14. Using specialist knowledge and experience lead the start -up phase, project manage and facilitate competence development of the team resource to manage:

- **Investigator led Multi-centre Investigational Medicinal Products trials including:**

- Regulatory & ethical approval
- Protocol generation
- Negotiate costs and contract with the funder.
- Procure the services of any external agencies e.g. drug distribution/ randomisation as required by the study
- Case Record Form design
- Data base development
- Site selection of participating sites.
- Lead and project manage the trial set up of all centres across the UK.
- Sign-off multi- site clinical trial monitoring plans

- **Higher Risk clinical trials** where the assessment of the Investigational Medicinal Product (IMP) needs even greater care and expertise than is usual; requiring intensive surveillance during administration and extensive safety reporting
- Early phase trials (Phase 1/1b) assessing safety of a new drug (IMP)
- Experimental treatment of novel therapies
- Gene therapy trials e.g. genetically modified viral vectors
- Responsible for ensuring and authorising safeguarding procedures are in place with adequate risk assessments and risk management strategies for clinical trials posing a biological safety hazard and early phase high risk trials.

- **Process Development** oversees the development of processes and tools to enhance the collection of activity metrics and pursue appropriate benchmarking for funding and skill mix purposes.
- Clinical development of trial treatment delivery and capacity expansion in relation to BHOC developments

People and Resource Management

15. Responsible for the management of an integrated team of research professionals; research nurses/radiographers, trial co-ordinators/officers and administrators. Maintaining an infrastructure to safeguard that research in the department is undertaken to a high standard in accordance with: existing legal requirements, International Conference on harmonisation/Good Clinical Practice (ICH/GCP), the Medicines for Human Use (Clinical Trials) Regulations 2004 & amendments and the Research Governance framework
16. Make judgements based on multiple complex situational variables to flexibly utilise human resource and employment contracts/WTE across the skill mix to achieve maximum trial recruitment/commercial income and deliver budgetary targets.

17. Develop and set –up career pathway structures that are current and fit for service delivery. Within changing budgets, ensure effective utilisation and productivity of team members within a specialised and challenging work environment.
18. In line with current strategy analyse developing areas of the cancer trials portfolio e.g. phase I cellular therapies and leading on multi-site trial developments and develop new posts/ career pathway structures that support these areas.
19. As line manager for the department, responsible for all human resource requirements including; inductions, appraisals, recruitment, career development, performance, sickness and work evaluation

Finance

20. To manage the department's budget; staff salaries, income target and grant funding, total in the region of 2 million
21. Responsible for the financial management of the trusts largest commercial clinical trial portfolio. Authorising and overseeing the management of activity recording and invoicing for 50 plus commercial trials. Ensuring timely and accurate distribution to UHBristol support departments and other UK sites as necessary.
22. Negotiate with stakeholders to secure appropriate levels of funding and allocation of resources for the delivery of clinical trials. This will include negotiating and securing external grant funding with multiple commercial vendors and sponsors; contract research organisations and NHS research networks.
23. Responsible for managing resources to secure the financial viability and further development of the CTU. Restructure and manage the team to effectively execute the assigned trials to meet project milestones, timelines and budget limits.
24. To lead and motivate the research team, keeping up to date with regulatory requirements, local, national and international related to Clinical Research
25. Deliver a departmental annual report and development plan, taking into account key areas e.g. phase 1 development/ translational research; investigator led multi-centre trials and current key result areas.

25. Ensure that local, national and international generic and research related policies and regulations are implemented and interpreted, with training organised when required.
26. Be an active member of the BHOC senior managers Team, updating the team on research related developments and representing CTU at relevant meetings.

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Personal Profile - (E) = Essential (D) = Desirable

Knowledge and Experience

- Substantial experience of both commercial and non-commercial clinical research management (E)
- Substantial experience of multi-disciplinary staff management and research skill mixing within a matrix environment (E)
- Extensive clinical, organisational and managerial skills (E)
- Ability to demonstrate clinical expertise and sound knowledge of clinical issues providing expert advice on clinical trial decision making (E)
- In-depth knowledge and experience of NHS Research and Development requirements (E)
- A thorough understanding of the national Research & Development agenda (E)
- Extensive experience of developing a clinical unit (E)
- In-depth knowledge of the regulations involved early phase trials (E)
- Experience and knowledge of national site set-up (multiple) to ICH GCP standards and experience of pharmacovigilance and the EU requirements for safety reporting (E)
- Experience of working outside the NHS in a commercial research environment (D)

Aptitudes

- Managing a demanding and constantly shifting workload e.g. ability to maintain patient trial activity/recruitment targets by effectively utilising the given research workforce during times of shortage (E)
- Ability to work as part of a multi-disciplinary team (E)
- High levels of personal credibility, presentation and self-awareness (E)
- Attention to detail (E)
- Integrity and impartiality (E)

Skills and Abilities

- Highly developed communication / interpersonal skills (E)
- Autonomous decision making and judgements involving complex situations (E)
- Multi-disciplinary team management and development (E)
- Collaboration and influencing skills within a matrix environment (E)
- Prioritisation of work streams and responding to new circumstances rapidly (E)
- Ability to plan strategically for service development within organisational boundaries (E)
- Negotiation skills across complex organisations with both NHS and commercial partners (E)
- Project management skills (E)
- Process development and management of research performance and metrics (E)
- Budget management, invoicing and resource planning (E)

Qualifications and Training

- Relevant Master's degree or equivalent (E)
- Professional Qualification with current professional clinical Registration (D)

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Transforming Care

Delivering sustainable healthcare services to our patients, which are effective, efficient and driven by excellence, is at the heart of our organisation. Transforming Care is the Trust's overarching programme of transformational change. It enables staff to use a structured approach to continuously improve and innovates their services, strengthen our capability, and deliver our Trust's mission to improve the health of the people we serve by delivering exceptional care, teaching and research, every day.
Our Quality Improvement Academy is open to all staff and leaders across the Trust, and provides training to lead or take part in improvement and transformation activities in their departments and across the Trust. We will support staff to develop the skills and tools to improve services to deliver the best care to our patients and public.

Information Governance

It is the responsibility of all staff to respect the confidentiality of patients and staff, as specified in the Caldicott Principles, Data Protection Act 2018 and the Human Rights Act. It is the duty of every employee to:

- Only access person identifiable information as required in the execution of their duties.
- Disclose information appropriately, in line with the Data Protection Act 2018.
- To ensure good quality data by recording, promptly and accurately, clinical and non-clinical information within agreed timescales to PAS, the health record or the appropriate clinical or non-clinical information system
- Always trace patient notes on the Patient Administration System

Maintain the confidentiality of their passwords / usernames and if in possession of a 'Smartcard' abiding by the terms and conditions of its use.

Workplace Wellbeing

The Trust Workplace Wellbeing Framework encourages all colleagues to look after their own wellbeing as well as supporting the wellbeing of colleagues. Line managers will oversee the wellbeing of their team, making wellbeing a priority when considering ways of working and will undertake regular health and wellbeing conversations that are supportive, coaching-style one-to-one discussions focused on building team resilience. To assist this, the Trust offers comprehensive wellbeing provision for employees, students, volunteers and managers.

Safeguarding Children and Vulnerable Adults

The Trust is committed to safeguarding and promoting the welfare of all children, young people and vulnerable adults, and as such expects all staff and volunteers to share this commitment.

Quality and Clinical Governance

Quality in the NHS has three core dimensions: Patient Safety, Patient Experience and Clinical Effectiveness. Clinical Governance is about the systems, processes and behaviours to ensure that high quality services are provided to patients. Every member of staff has a role to play in striving for excellence: it is important that everyone is aware of and follows policies and procedures that govern their work; and if something goes wrong, everyone has an obligation to report it so lessons can be learned from mistakes, incidents and complaints. If any member of staff has concerns on any clinical governance matters, they should raise them with their line manager, professional adviser, or a more senior member of management. Reference should be made to the Trust's guidance on Raising Concerns about provision of patient care.

Health and Safety

Under the provisions contained in the Health and Safety at Work Act 1974, it is the duty of every employee to:

- Take reasonable care of themselves and for others at work
- To co-operate with the Trust as far as is necessary to enable them to carry out their legal duty
- Not to intentionally or recklessly interfere with anything provided including personal protective equipment for Health and Safety or welfare at work.

Everyone has a responsibility for contributing to the reduction of infections.

Senior Management is responsible for the implementation throughout the Trust of suitable arrangements to ensure the health, safety and welfare of all employees at work and the health and safety of other persons who may be affected by their activities. Where health and safety matters cannot be resolved at Senior Management level the appropriate Executive Director must be notified.

Line Managers are responsible for the health and safety management of all activities, areas and staff under their control. This includes responsibility for ensuring risk assessments are completed and implementation of suitable and sufficient control measures put in place. Health and safety issues are dealt with at the lowest level of management practicable. Where health and safety matters cannot be resolved at a particular management level the appropriate Senior Manager must be notified.