

JOB DESCRIPTION

Job Title	Early Phase Clinical Research Fellow
Reporting to	Dr. Gillian Heap, Director of Research and Innovation Operations
Working with	Clinical Research Fellows, Clinical Director of Research, Director of Research & Innovation Operations, CCC Clinical Lead for BRC, Head of Research Delivery, Head of Research Governance & Sponsorship, Research Practitioners, Research Administrators, Research Quality Manager
Duration of Appointment	12 months (with potential to extend to 24 months)
Time commitment	Full time

Job Overview

This post is a full time appointment for an initial period of 12 months with potential to extend to 24 months. The role to provide medical support to the Early Phase Trials team including consultants, nursing and administration staff by primarily acting as co-investigator on early phase clinical trials. The successful applicant will join a highly motivated and empowered workforce to increase research capacity and deliver innovative early phase research in compliance with Good Clinical Practice (ICH-GCP) and Trust policy.

This is a 10 session non-training post funded through The Clatterbridge Cancer Centre for an initial period of 1 year (potential to extend to 2 years). The Early Phase Clinical Research Fellow role is suitable for individuals towards the end of, or having completed, their specialist oncology training who wish to gain further experience in experimental medicine and Phase I trials, including first-in-human trials, clinical pharmacology trials and translational research.

The position requires an ability to understand and deliver early phase clinical research, liaising across a range of clinical, academic and administrative staff throughout the Trust and with external organisations (pharmaceutical and biotech industry partners, academic institutions and other hospitals).

Background

The Clatterbridge Cancer Centre is one of three specialist cancer centres in England. With 1,700 staff and three sites, we are one of the largest NHS providers of non-surgical cancer treatment. The Trust serves the 2.4 million population across Cheshire & Merseyside and is consistently rated by patients as one of the best performing hospitals.

We opened Clatterbridge Cancer Centre - Liverpool (CCC-L) in June 2020, enabling us to work more closely with clinical colleagues in the neighbouring acute hospital, to support our sickest patients. This state-of-the-art flagship cancer hospital, along with our sites in Wirral and Aintree means we are able to provide care closer to home for cancer patients across Cheshire & Merseyside. The new hospital is based in the heart of Liverpool's Knowledge Quarter enabling us to expand our cancer research programme alongside our academic partner, the University of Liverpool.

We are a tertiary cancer centre, providing non-surgical cancer care. Our reputation and specialist services attract national and international cancer patients. We have a unique multi-site care model consisting of three main sites, four additional systemic anti-cancer therapy (SACT) sites and 15 outpatient centres, making us one of the largest NHS providers of non-surgical cancer treatment

for solid tumours and blood cancers. Our clinical model also includes the provision of chemotherapy in the home and workplace.

Together, this enables us to provide a comprehensive range of inpatient care, acute oncology, radiology, advanced radiotherapy, chemotherapy and other systemic anti-cancer therapies (SACT) including gene therapies and immunotherapies. We are also the only facility in the UK providing low-energy proton beam therapy to treat rare eye cancers and we host the region's Teenage and Young Adult Unit.

One of the most important reasons behind opening a new hospital in Liverpool was the opportunity it has given us to expand our research capacity and capability to improve outcomes for people with cancer. Research is an integral theme and key driver in our activity. We have the infrastructure in place to support investigator-led studies and hosted studies to expand novel cancer research.

CCC is now part of a Biomedical Research Centre (BRC) in partnership with The Royal Marsden. This new collaboration will further enhance Clatterbridge's ability to transform ground-breaking clinical research trials into fully-fledged treatments at our hospitals and so increasingly improve outcomes for our patients. BRC status is the latest sought-after accreditation for CCC after it became a Clinical Research Facility (CRF) earlier this year in conjunction with two other Liverpool hospital trusts to boost delivery of early stage clinical research. Clatterbridge Cancer Center is also the principle clinical partner to the University of Liverpool in the Liverpool Experimental Cancer Medicine Centre (ECMC).

The Early Phase Trials Team is specifically designed to facilitate early phase research. Facilities include inpatient beds, outpatient suites, trials pharmacy, laboratory and administrative space with access to meeting rooms and monitoring rooms for external trials monitors. The remit of the Early Phase Trials team is to undertake cutting edge research in developing new therapeutics and conducting translational research in cancer patients. Early phase trials are an important first step in the drug development process and are not only designed to test the safety and tolerability of novel agents but interrogate new drug formulations, combinations, pharmacokinetics and pharmacodynamics. Our team delivers trials that are designed and led by our staff, collaboratively developed with pharma and biotech partners or studies to which we recruit and which support our academic strategy

Main Duties of Job

The post-holder will participate in a diverse range of clinical research trials as a co-/sub-investigator and manage all aspects of trial patients. The appointee is required to attend 6 trial outpatient clinics per week, Safety Review Committee meetings to discuss trial patients, molecular tumour board meetings and wait list meetings to discuss trial patients and to agree opportunities for patients to enrol in early phase trials.

The post-holder will undertake the administrative duties associated with the care of their patients. The role also involves presenting research work, being involved in the development and delivery of audits, writing papers and reviews and participating in all relevant aspects of clinical governance, under the supervision of the other consultants in the Early Phase Trials team.

The Trust supports the requirements for continuing a level of continuing professional development consistent with the recommendations of the Royal College of Physicians. Appropriate arrangements for study leave will be made in conjunction with colleagues.

Principal Duties and Responsibilities

Role: The successful candidate will be recruited as a Clinical Research Fellow in Early Phase Trials Team.

Research: A diverse range of clinical research trials are in progress and, following training, you will be expected to participate in these studies as a co-/sub-investigator. These include Phase I trials of immunotherapeutics, small molecule inhibitors, next-generation chemotherapy trials, combination / multi-modality Phase I trials, molecular characterisation / translational studies. In addition to the research projects outlined above, the post-holder may be involved with new patient consultation, consent and screening, and reviewing patients at follow-up appointments.

Primarily, patients are seen in the outpatient setting but with some inpatient cover. The appointee is required to attend 6 trial outpatient clinics per week (see indicative timetable).

Protocols: You will be expected to undertake the administrative duties associated with the care of their patients. The appointee will be encouraged to harness opportunities to be involved in the development and planning of new studies.

Professional Development: You will maintain a level of continuing professional development consistent with the recommendations of the Royal College of Physicians.

Appropriate arrangements for study leave will be made in conjunction with colleagues. There is the potential to present research work and you will be expected to be involved in audit, writing papers and reviews. You will also be required to undergo an annual appraisal.

Clinical Governance: You will be expected to participate in all relevant aspects of clinical governance, including maintaining up to date protocols, guidelines and clinical audit, under the supervision of the other consultants in the Early Phase Trials team.

Audit: You will play a full role in clinical audit as a member of Early Phase Trials team. The appointee will develop, supervise and deliver team audit projects.

Continuing Professional Development

The Trust supports the requirements for continuing professional development (CPD) as laid down by the GMC and surgical colleges and is committed to providing time and financial support for these activities.

Role Planning

This is a 10 session non-training specialty registrar (full) level post funded through The Clatterbridge Cancer Centre for an initial period of 1 year with potential to extend to 2 years.

Provisional Sessional Timetable for Early Phase Clinical Research Fellow

Proposed Sessional Activities

Early Phase Review and Consent	5.0
Multi tumour Early Phase Clinic	1.0
Research Administration	1.0
Trial Teleconferences	1.5
Team Meeting	0.5

Audit/CPD	1.0
	10

Indicative Clinical Timetable

Monday	Tuesday	Wednesday	Thursday	Friday
Early Phase review and consent	Early Phase review and consent	Early Phase review and consent	Early Phase review and consent/	Early Phase review and consent
Multi tumour	Research Admin/			Trial Teleconferences/
early phase clinic	Team Meeting	Audit / CPD	Trial Teleconferences	Research Admin

Indicative outputs:

- Minimum of 100 new patients assessed per annum.
- Minimum of 35 patients enrolled onto clinical study/annum (in consultation with consultant staff).
- Minimum of 2 commercial/investigator sponsored studies secured and opened/annum (in consultation with consultant staff).

This job description is not intended to be an exhaustive list of duties, but it aims to highlight the typical main responsibilities of the post. It may be reviewed from time to time to ensure that it relates to the job as then being performed, or to incorporate whatever changes are being proposed. This procedure is conducted in consultation with the post holder.

Equality and Diversity

All employees must demonstrate a positive attitude to The Clatterbridge Cancer Centre NHS Foundation Trust's equality policies and Equality Scheme. Employees must not discriminate on the grounds of sex, colour, race, ethnic or national beliefs, marital status, age, disability, sexual orientation, religion or belief and will treat patients, colleagues and members of the public with dignity and respect.

Health and Safety

The employer will take all reasonably practical steps to ensure your health, safety and welfare while at work. You must familiarise yourself with the employer's Health & Safety policy, and its safety and fire rules. It is your legal duty to take care of your own health and safety as well as that of your colleagues.

Information Security and Confidentiality

During the course of your employment you may have access to, see or hear information of a confidential nature. You are required not to disclose such information, particularly relating to patients or staff. All personal identifiable information must be held in the strictest confidence and should only be disclosed to authorised people in accordance with NHS confidentiality guidelines (Caldicott) and the Data Protection Act 1998, unless explicit written consent is given by the person identified or where information sharing protocols exist. Any failure to comply with this term of your employment will be treated as an act of misconduct under the employer's disciplinary procedure.

Research Governance

Research and Development is at the heart of providing effective treatments and high quality services, supporting a culture of evidence based practice and innovation amongst staff. All staff have a duty to be aware of and comply with their responsibilities for research governance, whether as researchers, as part of the team caring for those participating in research, or as research participants themselves.

Infection Control

All employees are expected to follow consistently high standards of infection control practice, especially with reference to hand decontamination, adherence to dress/uniform code, and for clinical staff, aseptic technique and to be aware of and follow all Trust infection control guidelines and procedures relevant to their work.

Mandatory Training

Mandatory training relates to information and/or training regarding the management of general and specific risk. All staff are required to attend mandatory training, which is relevant to their role as identified in the Trust's risk management mandatory training matrix.

Code of Conduct

As an employee of the Trust, it is a contractual duty that you abide by any relevant code of professional conduct and/or practice applicable to you. A breach of this requirement may result in action being taken against you (in accordance with the Trust's disciplinary policy) up to and including dismissal. In addition, managers are required to carry out their duties in a manner, which complies with the code of conduct for NHS Managers Directions 2002.

Job Description Agreement

I have read and understood the duties that are expected of me.

Manager

Post-Holder

Signature:

Signature:

Date:

Date:

Person Specification – Urology Clinical Research Fellow

	ESSENTIAL	DESIRABLE	METHOD OF ASSESSMENT
QUALIFICATIONS	Completion of core medical training (CMT) or acute care common Stem programme (or equivalent)	CCT in Medical Oncology or equivalent Good Clinical Practice	AF
	MRCP or equivalent	Advanced Life Support	CE
	GMC registration	Higher degree in cancer research	CE
EXPERIENCE AND KNOWLEDGE	Experience in general oncology and internal medicine	Experience in early phase cancer research	AF
	Research/Trials experience		I
	Evidence of clinical leadership skills		R
SKILLS	Experience in teaching undergraduates	Experience in teaching postgraduates Teaching Qualification	AF
	Evidence of clinical skills		I/R
	Excellent written and oral communication skills, flexibility, commitment and team work with colleagues and staff in the department.	Demonstration of excellent communication skills	I/R
	Ability to work under pressure.		AF/I/R
OTHER Work Related circumstances	Evidence of productive ethical research relevant to oncology	Recent publications in peer-reviewed journals	I/R
	Experience of developing, supervising and delivering audit projects		AF
	Capacity for staff motivation	Conference presentations	AF/I/R
	Occupational Health Clearance		I/R
	Enhanced CRB Clearance		CE
			CE

Abbreviations for Methods of Assessment: AF – Application Form, I – Interview, R – References, CE – Certification Evidence