The Christie NHS
NHS Foundation Trust

JOB DESCRIPTION

Job Details

Job Title:	Advanced Therapy Trials Lead Research Nurse
Department/ Ward:	Research and Development
Division:	Research and Development
Base:	Christie Hospital NHS Trust with cross-site working at Manchester Foundation Trust – both forms the Manchester Clinical Research Facility.

Organisational Arrangements

Accountable to:	1. Operations Directors of Manchester Clinical Research Facility 2. Managing Director of Research and Development
Other accountabilities:	1. Clinical Director for Research and Development 2. Principal and Chief Investigators (Clinically) 3. Chief Nurse and Associate Chief Nurse 4. iMATCH clinical lead

BACKGROUND

A recently formed Manchester health consortium (iMATCH), led by The Christie, but involving the University and MFT and several industrial partners, has been awarded significant funding by Innovate UK, to enable more patients to benefit from a new generation of disease-fighting advanced medicines for cancer and non-cancer illnesses (such as genetic or degenerative diseases). As one of only 3 centres in Britain awarded this funding, Manchester will coordinate a strategy to scale up these Advanced therapies. Advanced therapies use manipulated cells (from the patient or from a donor) or inserted genes (gene therapy) as a 'drug' to treat disease. In some instances cells are taken from a patient, specially treated to create therapeutic properties and re-introduced to the patient's body. In other instances viruses might be used to deliver the relevant gene, after direct administration to the patient.

This partnership consists of The University of Manchester (including input from Cancer Research UK Manchester Institute and Manchester Cancer Research Centre), Manchester University NHS Foundation Trust (including Royal Manchester Children's Hospital and Manchester Royal Infirmary) and nine life science focused businesses.

Currently, clinical trials for advanced therapies are small-scale due to their highly complex, and challenging nature. A lead nurse for Advanced Therapy Medicinal Products (ATMP) trials is being sought in order to ensure appropriate pathways are developed to treat these patients across both the Christie and the Manchester Foundation trust sites.

JOB PURPOSE

1. Provide leadership and management of the cell therapy clinical research team at the Christie. The post holder will have complete oversight of all aspects of clinical research activity within designated teams, this includes:

- Responsibility for delivering the Divisional, Trust and NIHR objectives
- Optimising service provision for clinical research – this will require cross working at Manchester Foundation Trust
- Workforce planning and financial management
- Monitoring of quality standards and escalation of identified risks/ sharing best practice

2. Work across sites to ensure development of appropriate patient pathways for involvement in ATMP trials. This will include:

- Building relationships with all key stakeholders and service departments to ensure appropriate involvement in the iMATCH programme
- Acting as a subject matter expert in relation to ATMP trials
- Contributing to appropriate work packages in relation to patient pathway development

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DUTIES AND RESPONSIBILITIES

ATMP/ iMatch:

- Act as a subject matter expert in all areas of cell therapy / ATMP
- Provide leadership to the cell therapy team at the Christie
- Ensure appropriate pathways are developed for patients undergoing ATMP trials at both Christie and Central Manchester site, including both Clinical Research Facilities and wider hospital areas, such as in- patient and laboratory environments.
- Become a key contributor in appropriate work packages relating to the iMATCH programme.

Management and Leadership

- Provide professional and management leadership to support the development of clinical research activity for defined research nursing teams
- Support Trust-wide Human Resource issues according to Trust policy and procedure.
- Develop a culture of quality utilising performance management tools to ensure divisional Key Performance Indicators are achieved.
- Ensure effective performance review is in place and act to maximise the potential of others.
- Where appropriate, support the Operations Director and wider Division : (i) to represent the Trust within the NHS and community, and with partner organisations, (ii) to work closely with them to institute integrated working in the best interests of research recruitment, (iii) to ensure appropriate public and patient involvement in research activities.
- Coordination of relevant management meetings, multidisciplinary team meetings both internally and externally
- Conduct trial feasibility to assess the impact on workload in defined research groups and the Trust to establish whether there are adequate resources available to meet clinical trial activity.
- To be responsible for the total oversight of Clinical trial submission process
- Ensure systems are in place to develop and maintain clinical competencies within the designated teams.
- Provide divisional representation on trust wide committees relating to governance structures and operational management.
- Work autonomously in all areas of practice relating to clinical research.
- Take a pro active approach in ensuring local and national performance metrics are adhered to and met.
- Work with Trust R&D department and research staff to ensure regulatory and governance frameworks are adhered to
- Delegation of trial related activity to members of the research team

Financial & Business Management

- Develop business plans to secure funding for the provision of resources as required
- Work with the Research Business team in forecasting projected income to secure income for the retention and expansion of Clinical trial team nursing and administration posts.
- Procurement/ negotiation of clinical trial related budgets including completion of grant applications
- Budgetary control within defined research teams and oversight of all invoicing and income.

- Responsible for budget setting to ensure all staffing costs meet financial balance and ensure commercial income is sufficient to meet this requirement.

Strategic Development

- Identify workforce requirements to meet the team objectives and have responsibility for the recruitment processes within defined area of responsibility
- Develop SOP's to guide practice in disease specific field and ensure they are reviewed as appropriate
- Set up processes/patient pathways in specialist research areas to promote a cost effective timely service for individual protocols (including specialist clinics)
- Identify strategies for recruiting patients to clinical trials and support team members in implementing these strategies.
- Ensure that targets for patient recruitment are achieved.
- Facilitate integration of clinical trial teams at the cancer centre, associate cancer centres and across the UK.
- Ensure that there is effective communication, across all organisational boundaries in relation to clinical trial activities.
- To represent the Trust at local, National and International meetings and conferences

Clinical

- Able to communicate highly complex and sensitive clinical trial information to a wide range of people including patients, carers and members of the immediate and wider multidisciplinary team
- Oversee the management, implementation and facilitation of patient pathways for Advanced therapy trials across Manchester.
- Adhere to the EU directive and ICH/GCP.
- Promotion of good practice consistent with legislation relating to the informed consent process.
- Demonstration of expert knowledge in specialist area to maintain clinical excellence.
- Responsible for the maintenance and development of professional knowledge and practice by attending mandatory and specialist training (e.g. ICH GCP) in accordance with local policy and research governance.
- Analyse and interpret complex ATMP clinical trial protocols at feasibility meetings to determine capability and capacity requirements of the organisation and whether the trial can be included within the team clinical trial portfolio
- Attend ATMP clinics where appropriate to support patients and undertake clinical duties as required
- In conjunction with investigators analyse and interpret complex clinical trial protocols to respond to adjustments in relation to clinical care of patients Using

judgement respond to clinical trial patient queries and take appropriate and timely action to ensure the safety of patients.

Personal Development

- Maintain professional development whilst evaluating own specialist knowledge and practice through a process of appraisal and personal development planning.
- Ensure own knowledge professionally and clinically is regularly updated and be aware of relevant developments that may impact on service provision
- Undertake Educational courses as required to maintain own specialist knowledge base relating to cancer care, operational management and human resource issues

Education

- To participate in and facilitate National and Regional study days.
- To support pre and post registration education development
- To raise the profile of Clinical research nursing locally and nationally and support nursing research within the Trust.
- Ensure educational opportunities are available to staff and ensure all have personnel development plans as part of the PDR process
- Actively promote the work place as a learning environment, ensuring all staff make effective use of learning opportunities.
- To develop and facilitate educational programs to meet the competencies of the Clinical research nursing and administration teams.

Quality

- Ensure that all research activity is conducted within the relevant governance frameworks.
- Work in close partnership with appropriate key stakeholders to ensure all local, corporate and national initiatives and targets are met.
- Identify and take forward the specific contribution nursing can make to the development of research outcomes.
- Participate in service improvement projects or development programmes that contribute to the modernisation of patient services, providing both professional and clinical advice as necessary.
- Produce clinical trial activity and performance reports using It systems such as R Peake , Tableau etc

Risk Management

It is a standard element of the role and responsibility of all staff of the Trust that they fulfil a proactive role towards the management of risk in all of their actions. This

entails the risk assessment of all situations, the taking of appropriate actions and reporting of all incidents, near misses and hazards.
In addition the Clinical Research Team leader will:

- Work with the Lead Nurse for Clinical Research to monitor risk, investigate Serious Incidents /Breaches and to support the overall risk management of the Division
- Ensuring the risk register is up to date for identified specialities and key actions are completed
- Ensuring that all risk assessments are completed for areas within identified specialities.

EU Directive ICH/GCP

All personnel involved in clinical research have a responsibility to ensure that clinical trials are conducted in accordance with the EU Directive and ICH/GCP.

RECORDS MANAGEMENT/DATA PROTECTION ACT

As an employee of the Trust, you have a legal responsibility for all records (including patient health, financial, personal and administrative) that you gather or use as part of your work within the trust. The records may be paper, electronic, microfiche, audio or videotapes, x-ray images. You must consult your manager if you have any doubt as to the correct management of the records with which you work.

HEALTH AND SAFETY REQUIREMENTS

All employees of the Trust have a statutory duty of care for their own personal safety and that of others who may be affected by their acts or omissions. Employees are required to co-operate with management to enable the Trust to meet its own legal duties and to report any circumstances that may compromise the health, safety and welfare of those affected by the Trust undertakings.

CONFIDENTIALITY AND INFORMATION SECURITY

As a Trust employee you are required to uphold the confidentiality of all records held by the trust, whether patient records or trust information. This duty lasts indefinitely and will continue after you leave the trust employment.

All Information which identifies individuals in whatever form (paper/pictures, electronic data/images or voice) is covered by the 1998 Data Protection Act and should be managed in accordance with this legislation.

TRUST POLICIES

The Trust operates a range of policies, e.g. Human Resources, Clinical Practice (available on the Trust intranet). All Trust employees must observe and adhere to the provisions outlined in these policies.

INFECTION CONTROL

Healthcare workers have an overriding duty of care to patients and are expected to comply fully with the best practice standards. You have a responsibility to comply with Trust policies for personal and patient safety and for prevention of healthcare-associated infection (HCAI); this includes a requirement for rigorous and consistent compliance with Trust policies for hand hygiene, use of personal protective equipment and safe disposal of sharps.
Knowledge, skills and behaviour in the workplace should reflect this; at annual appraisal you will be asked about application of practice measures known to be effective in reducing HCAI

Date Prepared: 24th July 2018
Prepared By:
Agreed By:
Employee's Name and Signature: Date:
Manager's Name and Signature: Date:
Date Reviewed:
Reviewed By:

PERSON SPECIFICATION

Job Title: Advanced Trials Lead Research Nurse

	ESSENTIAL	DESIRABLE	METHOD OF ASSESSMENT
QUALIFICATIONS	• First Level Registration • Degree level education • Evidence of management/leadership	• Masters degree or evidence of post graduate study	Certificates
EXPERIENCE	• Substantial Oncology/ Haematology Experience • Significant experience undertaking, co-ordinating and managing clinical research. • Experience of developing and working within multi disciplinary teams and cross organisational working • Ability to organise and prioritise own workload. • Experience of working on ATMP trials	• Teaching/training experience • Experience of staff management	Application Form Interview References
SKILLS	• Excellent communication skills. • Effective team working across professional and organisational boundaries. • Demonstrate broad range of management skills • Capable of leading and initiating change • Working knowledge of office based packages • Able to operate clinical equipment to support patient care and monitoring	• Capable of presenting research related information to a wide audience	Application Form Interview References
KNOWLEDGE	▪ Expert knowledge of clinical trials process and regulatory frameworks ▪ Working knowledge of national research agenda and national research organisations ▪ Working knowledge of professional and NHS issues and policy relating to all sectors of oncology		Application Form Interview References
OTHER (Please Specify)	• Capacity to deal with complexity of issues • Flexible working		Application form Interview

Date Prepared:
Agreed by: Employee
Date Agreed:
Date Reviewed:

Prepared By:
Agreed By: Manager
Date Agreed:
Reviewed by: