

Job title	Senior Trial Manager	Job family and level	Research & Teaching, Level 5
School/ Department	School of Medicine, Nottingham Clinical Trials Unit (NCTU)	Location	Nottingham Clinical Trials Unit, University Park

## Purpose of role

To support the development and delivery of the Unit's portfolio of high quality clinical trials of national and international relevance. A significant responsibility of the post is to lead a team of trial managers, coordinators and administrators responsible for the delivery of a portfolio of clinical trial projects. You will oversee the management of their trial portfolio from conception to completion, requiring extensive experience of trial design and trial management, of multidisciplinary working on clinical trials, and of delivering research excellence within trials. You will be expected to work within the multidisciplinary NCTU project development team that supports chief investigators in developing their trial protocol and preparing high quality grant applications, by providing specialist trial management advice. You will be expected to work closely with other members of the Unit's Operations Team to provide effective oversight of NCTU operational management, ensuring effective, high quality and timely project delivery. This will include contributing to publication of the trial protocol and results. Over time, you will be expected to develop a portfolio of trial methodology-related research.

Nottingham Clinical Trials Unit (NCTU) is a UK Clinical Research Collaboration registered Clinical Trials Unit (http://www.ukcrc-ctu.org.uk) based in the School of Medicine at the University of Nottingham. The unit's mission is to conduct high quality, high impact multicentre trials to improve health and well-being.

NCTU has a broad portfolio of trials including studies evaluating medical devices, medicines and complex interventions. The unit currently has around 50 staff, and with the recent investment of strategic development funding from the University this is anticipated to expand to 100 staff over the next 3-5 years.

For further information see: http://www.nottingham.ac.uk/nctu/index.aspx

	Main responsibilities (Primary accountabilities and responsibilities expected to fulfil the role)	% time per year
1	Research  Contributing to developing the NCTU portfolio of high quality research, by working within the NCTU multidisciplinary team supporting chief investigators to prepare high quality grant applications, for example to the NIHR boards, MRC and charities	60 %

Working closely with other members of the Unit's Operations Team to provide effective oversight of NCTU operational management, including developing and implementing standardised 'fit for purpose' processes for high quality trial conduct Maintaining research excellence by providing high quality project management and trial management expertise to a specific programme of trials within the NCTU portfolio. This will include leading a team of trial management staff responsible for the administration of a portfolio clinical trial projects, ensuring high quality compliance with appropriate regulatory and governance requirements For a specific programme of trials: taking a leadership role in ensuring prompt publication of the protocol; and contributing to the writing of the results papers, with timely submission to a peer reviewed journal. Developing specific expertise in clinical topic areas and/or types of trial design relevant to the NCTU portfolio of work Providing project management and trial management expertise to trials which are supported by NCTU, but are primarily co-ordinated from outside the unit Contributing to developing an NCTU programme of methodological research in trial design and conduct Helping ensure NCTU remains up to date with developments in the methodology of clinical trials, by attending relevant conferences and training, and by proving training within NCTU Working with other members of the Operations Team to ensure NCTU is up to date with research regulations and governance. Management Workload planning, monitoring capacity and allocation of projects against measurable metrics Direct line management of trial managers within their team, and providing support to trial managers with line management responsibility for trial coordinators and administrators. Providing induction training, mentoring and personal development and performance reviews for Trial Managers Ensuring that NCTU trials are delivered within target timescale and 2 40% budget Ensuring that the NCTU programme of work complies with the appropriate requirements of research governance and regulation Managing recruitment of new trial project staff including drafting job descriptions, short-listing, and interviewing. Managing the offer and acceptance process, liaising with HR as appropriate Working with the Senior Data Manager to developing effective systems for monitoring NCTU trial-specific activity, and data quality Liaise with appropriate groups/staff both within the University and local organisations on project management issues. Other Any other duties appropriate to the grade and level of the role. We recognise the importance of continuous professional development 3 and therefore the importance of providing opportunities, structured support and encouragement to engage in professional development each year

## Person specification

	Essential	Desirable
Skills	<ul> <li>Excellent project management skills within multi-centre trials and/or other complex research studies</li> <li>Excellent knowledge and expertise in trial design, trial conduct and trial delivery</li> <li>Ability to communicate and work effectively with academics and clinical research collaborators</li> <li>Evidence of peer-reviewed, high impact publications</li> <li>Strong skills in team leadership and motivating staff, and emerging research leadership skills building, leading and managing the performance of collaborative multidisciplinary teams</li> <li>Evidence of being self-motivated within research, and able to take appropriate responsibility</li> <li>Excellent ability to prioritise, and to work flexibly and effectively under pressure. Able to enjoy and work effectively in a demanding and challenging environment.</li> </ul>	<ul> <li>Financial awareness and financial management skills</li> <li>Experience of developing successful grant applications</li> <li>Experience in presenting to national and/or international scientific meetings.</li> </ul>
Knowledge and experience	<ul> <li>Experience in clinical trial coordination/ management and a track record of successful delivery of multi-centre and/or other complex research studies</li> <li>Experience of contributing to aspects of grant applications</li> <li>Experience of writing trial protocols, trial materials, regulatory documentation, and research papers</li> <li>Extensive knowledge of the setup, costing, management and delivery of clinical trials</li> <li>Experience of managing staff.</li> </ul>	
Qualifications, certification and training (relevant to role)	<ul> <li>PhD or equivalent and/or Degree in health related sciences.</li> <li>OR</li> <li>Extensive experience in a clinical trials research.</li> </ul>	<ul> <li>PhD / MSc or equivalent, preferably in clinical trial related subject.</li> </ul>
Statutory, legal or special requirements		<ul> <li>Experience of MHRA and sponsor audits.</li> </ul>

	•	Willingness to adopt the <u>vision and</u> values of the School of Medicine	
Other	•	Travel within the UK sites will be required.	



The University of Nottingham is focused on embedding equality, diversity and inclusion in all that we do. As part of this, we welcome a diverse population to join our work force and therefore encourage applicants from all communities, particularly those with protected characteristics under the Equality Act 2010.

The School of Medicine holds a Silver Athena SWAN award in recognition of our achievements in promoting and advancing these principles. Please see

http://www.nottingham.ac.uk/medicine/about/athena-swan.aspx

## Expectations and behaviours

The University has developed a clear set of core expectations and behaviours that our people should be demonstrating in their work, and as ambassadors of the University's strategy, vision and values. The following are essential to the role:

Valuing people Understands that it is essential to provide a structure that people can

thrive in. Knows how to communicate with people to create a healthy

working environment and get the best out of people.

**Taking ownership** Communicates vision clearly, providing direction and focus. Knows how

to create a productive environment where people are inspired and can

work cross-departmentally in partnership.

Forward thinking Has the ambition to be a pioneer in own area, anticipating the future

change, needs and challenges. Knows how to innovate within their work context and champions others to be inspired to be part of this ambition.

**Professional pride** Keeps up to date on latest thinking, trends and work practices. Supports

team to be thought leaders; willing to challenge if obstacles get in the

way.

Always inclusive Establishes far reaching partnerships, well beyond own area across a

broad range of networks. Understand role to pay due regard to the needs

of the whole community.

## Key relationships with others

