### Role profile

<table>
<thead>
<tr>
<th>Job title</th>
<th>Clinical Trials Facilitator</th>
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<tbody>
<tr>
<td>Job family and level</td>
<td>Administrative, Professional and Managerial Level 4</td>
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<tr>
<td>School/Department</td>
<td>School of Medicine - Nottingham Clinical Trials Unit (NCTU)</td>
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<tr>
<td>Location</td>
<td>University Park Campus</td>
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### Purpose of role
To facilitate delivery of the Unit’s portfolio of high quality clinical trials through supporting trial set-up, initiation, conduct (including the planning and conduct of on-site and central monitoring activities) and close down. The Clinical Trials Facilitator will be a member of the Quality Assurance Team but will work closely with the Trial Management, Data Management, and Statistics Teams. They will carry out site management activities related to regulatory compliance both remotely and on-site, ensuring participant safety, monitoring on-going recruitment, protocol adherence, Case Report Form (CRF) compliance and data quality for trials.

### Main responsibilities
(Primary accountabilities and responsibilities expected to fulfil the role)

<table>
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<th>% time per year</th>
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<tr>
<td>Clinical trial management</td>
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- Provide expertise in the start-up and close down phases of clinical trials, applying specialist knowledge in some or all of these key areas
- Lead on all start-up activities prior to first site activation
- Coordinate the development and sign-off of collaboration agreements and contracts, working with University Contracts Office
- Lead on protocol development
- Contribute to CRF development
- Contribute to database development
- Obtain all appropriate regulatory and ethical approvals for individual clinical trials
- Contribute to the preparation of trial monitoring plans and documentation
- Assist sites with queries to ensure any regulatory or compliance issues are resolved at trial set up
- Contribute to the site selection process, identifying potential investigators and assist with assessing the feasibility of potential participating sites.
- Develop and present site initiation material/training for presentation both on site and remotely
- Lead close down activities following database lock, in collaboration with other teams within the Unit.

- 35%
- Lead on ensuring that all NCTU trial related activities are appropriately reconciled, recorded, and reported at the end of a trial in accordance with the protocol, SOPs, GCP and the applicable regulatory requirements.
- Lead on archiving activities related to the Trial Master File and support trial teams with regulatory requirements for end of trial reporting.
- Ensure trial documents are archived to the required timeframe, liaising with sites where necessary.

### Trial Oversight

- Assist in ensuring trials are managed and conducted in compliance with the relevant SOPs and NCTU Quality Management System through conducting monitoring and oversight activities.
- Support central and site-level monitoring processes across the portfolio of trials.
- In conjunction with the Quality Assurance Manager, implement a systematic and risk-proportionate approach to monitoring across the portfolio.
- Contribute to developing robust, relevant and timely central monitoring reports to ensure oversight of on-going data quality.
- Work closely with trial teams to monitor recruitment against targets to identify problems and their potential solutions, and work with sites to implement corrective actions if required.
- Work together with the trial teams to undertake central monitoring activities to ensure compliance to the protocol and applicable regulatory requirements.
- Plan, arrange and conduct appropriate site monitoring visits according to an agreed monitoring plan.
- Maintain effective communications with all relevant site staff.
- Maintain efficient documentation of site visits including reports, letters etc.
- Resolve discrepancies found within data and to address queries raised.
- Feedback to the appropriate team leader, any commonly occurring errors or problems and assist with their resolution.

### Quality Assurance

- Keep up to date with changes in clinical trial regulations and internationally accepted standards for the conduct of clinical trials.
- Contribute to development and review of SOPs and associated Working Practice Documents applicable to the role.
- Contribute to the development of quality management strategies and their implementation within NCTU.
- Plan and deliver presentations to site and NCTU staff to train or engage.
- Identify and report any major or critical findings or suspicion of fraud as per NCTU procedures.
- Assist the NCTU and sites to prepare for external audit or regulatory inspection as and when required. Work with the Trial Manager to develop and present site initiation material/training both on site and remotely.

### Other

- Act as point of contact and contribute to training in all aspects of monitoring within NCTU.
- Undertake regular training to keep up to date with all relevant research methodology and research regulations.
- Any other duties appropriate to the grade and role of the post holder.

### Person specification

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<tr>
<th>Skills</th>
<th>Essential</th>
<th>Desirable</th>
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|        | - Demonstrate initiative to deal with challenges.  
- Ability to communicate and work effectively with colleagues  
- Ability to work both independently and as part of a multidisciplinary team.  
- Ability to plan and manage own schedule and workload  
- Evidence of being self-motivated, organised, and able to take appropriate responsibility.  
- Excellent ability to prioritise, and to work flexibly and effectively under pressure. Able to enjoy and work effectively in a demanding and challenging environment.  
- Excellent MS Office skills (Excel, PowerPoint and Word).  
- Excellent presentation, written and oral communication skills.  
- Excellent attention to detail  
- Ability to lead and manage projects | |

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<tr>
<th>Knowledge and experience</th>
<th>Essential</th>
<th>Desirable</th>
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|                          | - Up to date knowledge and understanding of Clinical Trial Regulations, and research governance guidelines.  
- Comprehensive understanding of trial design, trial conduct and trial delivery  
- Demonstrable experience in project management  
- Demonstrable experience in clinical trial monitoring  
- Knowledge of the close down and archiving process of clinical trials | - Evidence of formal training in monitoring for clinical trials.  
- Extensive knowledge of all regulations and guidelines relating to clinical trials (e.g. medical devices, advanced therapeutics)  
- Experience of reviewing monitoring plans and risk assessments  
- Interest in the application of risk based monitoring methods in clinical trials?  
- Experience of delivering training  
- Experience of MHRA and sponsor audits / inspections |

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<tr>
<th>Qualifications, certification and training (relevant to role)</th>
<th>Essential</th>
<th>Desirable</th>
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|                                                           | - Relevant degree  
OR  
Proven track record of extensive relevant work experience demonstrating practical and | |

|        | Postgraduate/professional qualification in clinical research or similar |


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<th>theoretical knowledge of quality assurance and trial management in a clinical research environment</th>
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<td><strong>Statutory, legal or special requirements</strong></td>
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<td>• Willingness to adopt the <a href="http://www.nottingham.ac.uk/medicine/about/athena-swan.aspx">Ethos and Principles</a> of the School of Medicine to improve the student experience</td>
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<tr>
<td>• Travel within the UK sites will be required</td>
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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 workforce 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](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**  Is always equitable and fair and works with integrity. Proactively looks for ways to develop the team and is comfortable providing clarity by explaining the rationale behind decisions.

**Taking ownership**  Is highly self-aware, looking for ways to improve, both taking on board and offering constructive feedback. Inspires others to take accountability for their own areas.

**Forward thinking**  Driven to question the status quo and explore new ideas, supporting the team to “lead the way” in terms of know-how and learning.

**Professional pride**  Sets the bar high with quality systems and control measures in place. Demands high standards of others identifying and addressing any gaps to enhance the overall performance.

**Always inclusive**  Ensures accessibility to the wider community, actively encouraging inclusion and seeking to involve others. Ensures others always consider the wider context when sharing information making full use of networks and connections.

Key relationships with others

- **Line manager**
- **Role holder**
- **Key stakeholder relationships**
  - Trial Sites
  - Trial Sponsors
  - Colleagues

![Diagram](image-url)