UKCRC Registered Clinical Trials Units

UKCRC Registered CTU Network – Framework for clinical director role descriptions

UK Clinical Research Collaboration

igniting our potential

Framework for clinical director role descriptions in the UKCRC Registered Clinical Trials Unit Network

Prepared by the UKCRC Registered Trials Units Network Chief Investigator Network Group

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1. Abbreviations

CI – Chief Investigator

CING – Chief Investigator Network Group

CTU – Clinical Trials Unit

FTE – Full Time Equivalent

UKCRC - UK Clinical Research Collaboration

2. Background

There are benefits of collaborative working between CTUs and clinical communities. In this context, "clinical" is used in its broadest sense (Oxford English Dictionary, "Of or relating to the sickbed, spec. to that of indoor hospital patients"), to refer to all health and social care professionals.

The benefits of collaborative working include, but are not limited to:

- Representative and resilient methodological, operational, and clinical leadership of CTUs.
- Alignment of CTU scientific strategy relevant to the mission and strengths of the hosting NHS Trust/Board or Higher Education Institution, and their employees.
- Clinical insight into the development and design of clinical trials in the CTU portfolio.
- Promotion of CTUs to clinical communities, with insight and understanding of CTU operations, business plan, scientific strategy, and methodological expertise.
- Understanding the clinical roles of chief investigators (CIs), their source of questions for clinical trials, and their different roles.
- Representation of the community of clinical trial CIs within the CTU.
- Professional development, education/training, coaching and peer support for CIs of clinical trials.
- Evaluation, feedback, and nurturing the collaboration between CIs of clinical trials and the CTU.

The mission of the UKCRC Registered CTU Network ("Network") is to, "…promote academic trials units and, through its activities, provide its members with information, guidance, and representation in support of the conduct of high-quality, effective, efficient, and sustainable clinical trials research."

In January 2023, the Network appointed a Clinical Director to, "(1) Define the scale and scope of what better relationships between clinical trials units and clinical communities (particularly CIs or potential CIs) look like; (2) Use network resources to plan and carry out some activities to improve this relationship; and (3) Identify metrics that could be used for light touch evaluation of this activity."

2023 UKCRC CTU Network registration criteria include sections relevant to clinical input:

- Adequate and stable senior leadership (1.5)
- Enumeration of clinicians within the staff structure (2.1)
- Senior clinical input at a strategic level (3.5), which is an infrastructure competency that is evaluated for registration

In May 2023, a survey of 53 Network CTU Directors about CTU oversight and collaborative working with CIs yielded 41 responses, which revealed:

- **Variation in the extent and type of clinical leadership for CTUs in the Network**
  - 14 (34%) had a specific clinical director role in their CTU
  - 5 (12%) had a clinical CTU director
  - 6 (15%) had a deputy/associate director who was clinical
  - 16 (39%) did not report any clinical input to CTU leadership

- **Variation in the existence of a clinical advisory group:**
  - 11 (27%) had such a group
  - 7 (17%) had clinical representation within a broader advisory group
  - 23 (56%) did not have a clinical advisory group

- **Neither clinical CTU leadership nor a clinical advisory group** existed at four (10%) of the responding CTUs.

In August 2024, the Network appointed a new **Chief Investigator Network Group (CING)** to, "use their collective expertise to develop and share best practice in building stronger relationships and collaborations between CTUs and the CI community in the conduct of clinical trials." At the first meeting of CING in September 2024, CING identified creating a template framework for CTU clinical director roles as their first objective.

On **16 October 2024**, the Network's clinical director drafted a framework for describing CTU clinical director/equivalent roles, which was reviewed by CING, and was intended to:

(1) document the different models of clinical input to CTUs that exist in the Network,

(2) provide CTUs without clinical input with a framework to inform them if they wished to consider setting up a clinical director/equivalent role, and

(3) enable CTUs with a clinical director/equivalent role to reflect on their model in the light of the others available.

On **30 October 2024**, the Network Executive Committee reviewed and approved the first draft of the framework and asked the Network's clinical director to circulate it to the Directors of CTUs that had reported in the survey in 2023 that they already had or were setting up a clinical director/equivalent role, to inform the next draft of the framework. The Directors of the CTUs that had responded to the survey were approached 1:1 by email by the Network's clinical director, seeking their opinion about the first draft of the framework.

The final version of this framework incorporates feedback from CING, the Network's Executive Committee and the Directors of the CTUs that had responded to the survey. It was reviewed by CING, approved by the Network's Executive Committee (subject to final minor edits) at its meeting on 4 April 2025, and given final approval by CING on 8 May 2025.

Rustam Al-Shahi Salman

UKCRC Registered Clinical Trial Unit Network Clinical Director

3. Framework to consider the standardisation of clinical input in CTU registration criteria

3.1. Aims

The framework below categorises the different UK models for clinical director roles in Network CTUs, which were ascertained by a survey. On the one hand, it is important to reflect the diversity of models for clinical input to CTUs that exist in the Network because of the contextual variation in CTUs' host institutions, CTU sizes, and compositions of CTU portfolios. On the other hand, categorising the main models that exist helps with communication, understanding, and any attempt to standardise the roles.

All models have core responsibilities for CTU scientific strategy, leadership of CIs running clinical trials in the CTU, and representation of these CIs within the CTU. Each model has advantages according to context and capacity, first prioritising CI support in addition to the core responsibilities, extending to resilient CTU Co-Director models sharing operational responsibilities.

Terminology can be confusing given the lack of standardisation to date, the complexity of CTUs, the variation in CTU models for clinical input, and the use of the same name for a role to mean different things between CTUs. Therein lies the need to try to clarify and simplify the terminology using this framework.

Finally, recognition of the need for clinical input and the existence of this framework should support conversations between host institutions, CTUs, and clinical communities, and recognition of the time and effort required to provide clinical input.

3.2. Principles

- **Operations versus scientific strategy.** The principal division is between two models of senior clinical input, which are presented to indicate the importance of recognising operational and scientific responsibilities. Some CTU Directors believe that academic and operational responsibilities are necessarily intertwined, whilst others believe that operational and academic responsibilities can be covered by different members of the senior management team. The current framework allows for two approaches to these responsibilities:
    - Responsibility for both CTU operations and scientific strategy to varying extents (i.e. the current '**CTU Director**' role). All of these roles in the framework contain 'CTU' in the title of the role to indicate the existence of some operational responsibility (whereas none of the 'Clinical director/advisor' roles involve operational aspects).
    - Responsibility for scientific strategy alone (currently labelled '**Clinical director/advisor**' by most CTUs that have the role). These roles in the framework do not contain 'CTU' in the title of the role.

- **Joint CTU Director models.** Contemporary approaches to leadership increasingly focus on diversity and resilience, so sharing operational roles and deputisation arrangements are increasingly used. These approaches can involve:
    - '**Co-Director**' models for sharing the CTU Director role.

- ‘**Associate**’ models for supporting and/or deputising for the CTU Director. Just as a Non-Clinical CTU Director may be supported by an Associate Clinical CTU Director, so too may a Clinical CTU Director be supported by an Associate Non-Clinical CTU Director.
- It may be acceptable for more than one person to deputise for the CTU Director, drawing on the experience and expertise of the CTU senior management team, according to local circumstances.

- **Shared Clinical director/advisor models.** Similarly, the diversity of clinical medicine – and, consequently, many CTU portfolios – requires diverse clinical input to CTUs. Sometimes, it may be sufficient for one person to provide this, but often many clinical inputs are required. Therefore, clinical input to scientific strategy may involve one or more of the following:
  - A lone ‘**Clinical director**’
  - Several ‘**Clinical advisors, collaborators, strategic leads, divisional leads**’
  - A ‘**Clinical advisory group**’

- **Responsibilities.** The framework attempts to reflect the many, diverse responsibilities of these various role models. Several CTU Directors identified differences in responsibilities between some of the models in the framework and the model that operates in their CTU, due to the choice of role name, the size and leadership structure of the CTU, or local needs. Therefore the categorisations and allocations of these responsibilities in this framework are for guidance.
  - CTU Directors’ key responsibilities include (1) CTU leadership, (2) CTU operations, (3) CTU business planning, and (4) CTU external representation, although their balance and extent may vary between CTUs. Deputisation may be a responsibility where operational leadership can be shared.
  - Clinical director/advisor roles’ core responsibilities include: (1) advice on CTU scientific strategy, (2) leadership of a community of clinical trial CIs, and (3) representation of the community of CIs of clinical trial within the CTU.
  - CIs of clinical trials should be supported by the CTU, so this responsibility is provided by all roles, apart from clinical advisors / collaborators / strategic leads, who advise a CTU Director who has the responsibility to support CIs.

- **Full Time Equivalent (FTE) estimates.** The framework has broadly estimated FTE allocations for the different roles. The ranges are intended to reflect the information that we have received from CTU Directors about current practice in medium-sized CTUs, although FTE outside the ranges we have quoted may exist and may be acceptable dependent on CTU size and local circumstances.

- **Competing interests.** CTU portfolios are usually prioritised according to the scientific strategies of the host institution(s) and CTU, which involves making decisions about adoption of clinical trial proposals that may involve not only people with clinical roles in the CTU, but also people with non-clinical roles in the CTU. Recognition of these competing interests and having a process for managing them is necessary for any CTU.

4. Framework for clinical director role activities

Responsibilities and full time equivalent (FTE):	Senior clinical input at strategic, operational or other levels			Senior clinical input at a strategic level	
	Clinical CTU Director	Clinical CTU Co-Director (alongside a Non-Clinical CTU Co-Director)	Associate Clinical CTU Director (supports a Non-clinical CTU Director)	Clinical director / divisional lead	Clinical advisor / collaborator / strategic lead / divisional lead
CTU leadership	**X**	**X**			
Deputises for director		**X**	**X**		
CTU operations	**X**	**X**			
CTU business plan	**X**	**X**			
CTU representation	**X**	**X**	**X**		
CTU scientific strategy	**X**	**X**	**X**	**X**	**X**
CI leadership	**X**	**X**	**X**	**X**	**X**
CI representation	**X**	**X**	**X**	**X**	**X**
CI support	**X**	**X**	**X**	**X**	
FTE estimate per person	**50-80%**	**20-50%**	**20-30%**	**10-20%**	**5-10%**

5. Appendix: exemplars of clinical director roles, shared by CTUs

5.1. Clinical CTU Director

Clinical CTU Director example 1

Job Purpose

The University of seeks a dynamic and experienced Director for the Clinical Trials Unit (CTU) to harness the enormous opportunities that exist for inter-disciplinary collaborations and to consolidate and transform the development, design and delivery of its portfolio of clinical trials.

The Director will provide senior leadership in the Institute, as a member of the Institute's Executive Committee and contribute to the ongoing evolution of the research and education strategies of the College. The Director will have a pivotal role in leading a portfolio of internationally leading clinical trials that will transform practice and impact patients, the public and society. The Director will lead on the University's clinical trials strategy, building upon the strengths of the University, its connections with NHS and the broader Scottish health ecosystem in clinical research. The Director will enhance the development and growth of the College's global reputation in clinical trials through a focus on excellence and innovation in trial methodology resulting in the acquisition and delivery of clinical trials grants from competitive funding bodies and the publication of high-quality and impactful work. The Director will pursue excellence in research, teaching and enterprise and inspire others to do the same.

The Director will be responsible for overseeing the strategic, operational and financial management of clinical research activities, clinical trials services, and related educational programming, ensuring compliance with regulatory guidelines, and leading innovations in clinical trial methodologies. This pivotal role will support the objectives of the Institute, , and the University of to advance medical research and education, ensuring the optimisation and safety of new therapies in clinical settings.

The Director will manage demand, align capacity, and monitor resource requirements to ensure that the operations of the CTU are run efficiently and performance is assessed against agreed targets. They will ensure that the CTU portfolio of clinical trials is delivered to the standard required, compliant with the scientific, legal, ethical, research governance and other regulatory requirements applying to clinical trials. There is an opportunity for the incoming postholder to integrate and centralise clinical trials services across the University, becoming a full-service organization, reducing fragmentation of services across the University and providing efficiencies.

CTU is situated within the Institute which is part of at the University. The Director of CTU is a senior appointment, reporting directly to the Director of the Institute. The Director will represent CTU internally within the Institute, and the University of , as well as externally.

Main Responsibilities

	Approximate percentage of time
Operational	
Direct CTU's efficient and effective delivery of an internationally leading research programme in clinical trials, across the trial lifecycle from design to delivery, dissemination, and data sharing. Serve and support academic and professional services colleagues in the design and conduct of clinical trials.	20
Lead on developing and implementing academic, business, and operational strategic plans and a viable business model to deliver CTU's portfolio of clinical trials aligning with the overall objectives of the Institute, and the University's research and education strategies	10
Ensure that appropriate governance and conduct of CTU's activities supports the portfolio of clinical trials and achieves compliance with international scientific, legal, and ethical standards, as well as CTU and ACCORD standard operating procedures, to retain registered CTU status.	5
Lead and mentor a team of clinical research professionals, promoting a culture of high performance, continuous learning, and compliance. Line management of CTU senior leadership team.	5
Represent CTU internally on committees within the University and externally in the UKCRC Registered CTU Network. Serve as the primary liaison with regulatory bodies, institutional leaders, and industry representatives.	5
Academic	
Direct the development, design, and delivery of the portfolio of clinical trials strategically, aligned with objectives of the Institute, and University. Achieve excellence by implementing contemporary best practice in clinical trial design and methodology, and innovating.	20
Lead a personal programme of clinical trial research to develop and strengthen an established reputation of excellence in clinical trials.	15

	Approximate percentage of time
Collaborate and develop excellent working relationships with key stakeholders across the University to develop, design and deliver the clinical trial portfolio. Foster relationships with academic partners, funding bodies, charities, industry, and other stakeholders to secure funding and collaboration opportunities.	5
Support the professional development of clinical trial specialist staff (e.g. trial methodologists, trial managers, and chief investigators) to promote a culture of excellence, continuous learning, and regulatory compliance.	5
Spearhead and foster the further refinement of existing educational programs and actively participate in the development of new educational programs that capitalise on the expertise held in CTU. Lead on inspiring others through teaching about clinical trials within the University, contributing to relevant undergraduate and postgraduate curriculum development and module delivery, supervising students, and their examination.	10

Planning and Organising

- Lead, develop and implement CTU strategic plan and business plan.
- Ensure that CTU operations, infrastructure, staff and capacity meet the needs of its clinical trials portfolio.
- Monitor resource requirements in conjunction with CTU Leadership Team and Senior Management Team, the Institute and to develop and support The University ’s clinical trials.
- Line management of CTU senior management team.
- Contribute academic expertise in clinical trial design and methodology to maximise the quality and success of the University of ’s clinical trial grant applications.
- Monitor the progression of CTU portfolio of clinical trials, and advise about the optimal allocation of resources to support the delivery of the highest quality clinical trials.
- Contribute to module and curriculum development and lead modules at undergraduate and postgraduate levels, inspiring students, and collaborating with colleagues within the Teaching Organisation.

Problem Solving

- Direction of CTU Leadership and Senior Management meetings
- Represent CTU at internal and external meetings (Institute Executive, UK-CRC Directors etc)
- Assessment, approval and issue of letters of CTU support
- Negotiating with Heads of Schools and Institute Directors at in connection with the implementation of policy.

- Negotiating with senior University Managers and Directors to effectively represent the interests of CTU.
- Future discussions with College on CTU direction, funding and other aspects.
- Discussions with CTU Operations and with regard to committing CTU resources
- Problem solving associated with projects/ CTU portfolio

Decision Making

- Accountability for the regulatory aspects of the unit and all official ACCORD and MHRA communication
- Accountability for UKCRC (UK Clinical Research Collaboration) Registration and compliance, and all official communication
- Establish the time frame for contract reviews and renewal
- Approval of contract review and renewal for CTU staff members
- Accountability for CTU strategy and changes in the direction of the portfolio from a resourcing or strategic perspective
- Managing CTU budget

Key Contacts/ Relationships

- Head of the College
- Institute Director (line manager)
- Dean of Medical Research
- Dean of Innovation & Engagement
- Research Office
- ACCORD (Sponsor)
- NHS R&D Director
- Clinical Research Facility Directors
- Institute Board and Executive
- Institute Senior Management
- CTU Leadership Team (Chief Operating Officer and Clinical Director)
- CTU Senior Management Team
- Chief investigators of clinical trials
- Funding agencies
- Regulatory agencies
- Industry partners
- UKCRC registered CTU Network

Knowledge Skills and Experience

Attribute	Essential	Desirable
Education, Qualifications & Training	• Advanced degree (MD, PhD, or equivalent) in a subject closely allied to clinical trial methodology, and/or medicine	
Knowledge & Experience	• Extensive experience (minimum 10 years) of the design and delivery of clinical trials (and clinical research more broadly) • A strong track record in leadership and management, particularly in multi-disciplinary contexts with extensive experience of leadership roles in a clinical trial setting • Demonstration of strategic thinking • Knowledge of clinical trial funding landscape • Thorough knowledge of regulatory requirements and ethical issues surrounding clinical trials. • A strong research reputation evidenced by outputs and an evidenced track record of securing substantial, competitive clinical trial funding (e.g., from MRC, NIHR, Wellcome Trust, EU, and appropriate charities). • Exceptional organisational skills and the ability to manage multiple projects simultaneously while meeting stringent deadlines • Experience of undergraduate and postgraduate teaching and evidence of taking a leading role in the organisation, planning and delivery of modules at undergraduate and postgraduate level. • Excellent communication, negotiation, and other interpersonal skills with a focus on confidentiality and integrity as well as equality, diversity and inclusion. • Ability to work as part of a senior academic team and to engage in senior-level research and strategic planning • Embraces modernisation and appropriate governance with a proven ability to promote and manage change. • Talented in motivating, influencing, and working effectively with colleagues at all levels including skills in effective delegation, time management, and team working. • Demonstrated ability and willingness to develop partnerships, to lead work across	• Knowledge of drug, device, advanced therapy and complex intervention trial designs and regulation. • Knowledge and experience of programmes that improve research culture. • Experience of supporting professional development and teaching. • Awareness of conflict resolution methods.

Attribute	Essential	Desirable
	traditional disciplinary boundaries, and to establish collaborations with academic, service and industry partners across institutions and internationally. • Strong commitment to external engagement activities with communities, practitioners and policy-makers, including the translation of research knowledge and evidence into practice. • Experience with digital data management systems and clinical trial database applications.	

Clinical CTU Director example 2

Director of CTU

Role Summary

The Clinical Trials is a leading national clinical trials unit (CTU) within the College at the University specialising in the design, conduct and analysis of definitive clinical trials and test evaluation studies. It was established in and has evolved into one of the largest CTUs in the UK, undertaking high quality late phase clinical trials, and studies across a wide range of disease areas in care settings. XX now employs over XXX staff, coordinating approximately XXX studies (with a current research grant budget of circa XXX).

As a UK Clinical Research Collaboration (UKCRC) registered CTU, the XXX experience in coordinating multi-centre clinical trials, the presence of expert staff and robust quality assurance systems, and evidence of long-term viability of capacity for trial co-ordination is well recognised. The unit receives National Institute for Health Research (NIHR) CTU funding to support the unit in developing and supporting NIHR trials. Our aim is to help stimulate, develop, conduct, support, analyse and report high quality clinical research to generate more reliable evidence on causes and best treatment of a wide range of diseases. The Unit has a strong track record of coordinating cutting edge clinical trials from initiation through to completion. The principal function is to provide specialist input into all stages of academic clinical trial development from design to publication by collaborating with a large number of clinical investigators at a local, national and international level.

The Director of Clinical Trials Unit primary responsibility is for leading, developing and delivering a robust and effective clinical trials strategy to assure excellence of the research programme of the Clinical Trial Units. XXX sits within the XXX reporting to the Institute Director.

This high profile position offers an excellent opportunity for an experienced clinical trialist to take a leading role in one of the UK’s foremost clinical trial focused Universities.

Main Duties

Strategy and actions

· Lead the existing clinical trials portfolio within XXX to ensure successful and timely completion of the programme of trials.

· Lead the development of new trials, in conjunction with clinicians, from conception to completion, involving refining research questions and determining optimal trial design, outcome measures and sample size, lead successful funding bids which develop and sustain research support, work up the trial proposal into a grant application for a major funder.

· Engage colleagues from other disciplines (e.g., health economists, psychologists) to develop particular aspects of a research project as necessary.

· Maintain and develop further a robust structure to support and deliver these trials.

· Proactively continue the collaboration between XXX and XXX to ensure a comprehensive clinical trials offer across the University and its partners.

· Develop collaboration across the University to expand the clinical trial research portfolio, and open up new collaborative opportunities, particularly within the University's core research themes, to capitalise on the basic and clinical research strengths.

· The continued development of a robust business model, to ensure that the CTU continues to meet the evolving clinical trial needs of the University, will be essential.

· Promote the CTU within the University, local NHS trusts and NIHR Research Networks and represent the CTU on the national CTU directors group.

· Ensure that the research activities of the CTU are undertaken in accord with legal, regulatory, ethical, funders and university requirements.

· Develop and contribute to teaching of research methods on undergraduate and postgraduate degrees, including the MSc in Clinical Trials. Proactively develop CPD activity of the CTU through teaching and CPD course development and supervise MSc projects and PhDs.

Staff development

· XXX has built a strong resource base currently of XXX people, with specialist statistical, methodological, administrative and computing expertise, who currently oversee the design, setup, coordination, analysis and reporting of ongoing trials. Ensure the staff structure provides for full and progressive career development and that staff are fully represented for the contribution made toward the trial design and delivery. Identifying action to encourage continuous improvement, with other colleagues as appropriate. This includes performance of individuals, trial teams, the Unit as a whole.

· Monitoring and reporting the XXX performance against relevant targets and benchmarks, research income leveraged with a diverse partnership portfolio.

· Ensuring that the professional services staff is appropriately aligned with the College's Professional Services structure to; maximise peer support for personal development, consistency of trial management with an efficient and effective professional services team.

Communication, external relationships and committees

· Representing the College on appropriate College and University committees.

· Informing and supporting College decision-making processes on clinical trial priorities.

· Ensuring that the flow of information regarding clinical trial activities and opportunities is appropriate for members of the College and others in the University.

Person Specification

· Excellent national and international reputation in clinical trials, including sitting on external bodies to promote clinical trial activity nationally or internationally, providing expert advice to colleagues, clinical researchers, clinicians and external bodies (e.g., government bodies)

· National reputation in research with an academic profile nationally and internationally, with the potential for (or ongoing) research collaborations. Experience as a senior methodologist on collaborative research projects.

· Experience of leadership of a multidisciplinary research group.

· The successful candidate will be an experienced clinical trial methodologist, with a strong track record in the design, management and analysis of large pragmatic clinical trials

· Significant success in raising research funding.

· Excellent relationship builder, able to establish credibility with key stakeholders including senior University staff and external partners.

· Evidence of successful leadership of a multidisciplinary research group.

· Strong interpersonal, communication, political and influencing skills.

· Positive leadership style that inspires others.

· An understanding of specialist knowledge of clinical trials, to inform risk and opportunity in the context of clinical trial activity.

· Capability to operate at a strategic level, to create and communicate a vision, while also monitoring operational activity and ensuring delivery.

· High levels of personal communication (written and oral) and able to provide examples of successful influencing of and negotiation with others.

Post Details

· The post will be appointed on a 4-year fixed term basis (renewable).

· The role holder will be required to devote an average of 50% of his/her time to the role, to be confirmed on appointment.

5.2. Clinical CTU Co-Director

Clinical CTU Co-Director example

UNIVERSITY OF XXX

Clinical Co-Director of Clinical Trials Unit

JOB PURPOSE

The remit of this position is:

- Joint oversight and implementation of CTU Strategy and Planning
- Joint oversight and implementation of XXX
- Providing clinical advice to CTU Directorate
- Providing clinical advice to Trials Managers, Data Teams and Statisticians as required
- Contributing to pre-award phase of trial development, particularly with clinical advice
- Strategic liaison with NHS XXX and XXX School of Medicine, and other relevant external bodies
- Liaison between CTU and clinical CIs/PIs, at pre-award stage and during trials
- Publicity and marketing to (potential) clinical investigators in XXX, NHS XXXand further field.
- Fostering a culture of continuous improvement and leading initiatives to streamline systems and processes within CTU and improve the training and development of CTU staff through cultural change

5.3. Associate Clinical CTU Director Roles

Associate Clinical CTU Director example 1

DEPUTY INSTITUTE DIRECTOR: Clinical

CTU

Responsible to: Institute Director
Workload remission: 0.1 fte

Tenure: 3 years

Are you an enthusiastic academic leader with a track record of successful and imaginative leadership? Do you have the ability to provide clinical leadership and governance at a strategic level within the Institute?

The Institute is looking to appoint a Deputy Institute Director: Clinical, to provide clinical leadership within the Institute and work closely with the Institute Director in supporting and developing the Institute overall.

The Deputy Institute Director: Clinical will have a leadership responsibility including the development and support of clinical academic staff and Chief Investigators through Institute- and Faculty-wide initiatives. They will be expected to establish a strategic overview of the Institute's approach to clinical leadership and influence and prepare plans for the Institute's development, in collaboration with the Director and, where appropriate, division-specific clinical directors.

The Deputy Institute Director: Clinical will support the Institute Director in taking specific responsibility for allocated actions to ensure continuous improvement within the Institute, embracing new ways of working and taking a proactive stance to staff development.

The role holder will report to the Institute Director providing complementary skills and an appropriate clinical academic balance to the Deputy Institute Directors for Research and Operations. This role will be key in ensuring delivery of the Institute's strategy and maintaining its world-class international research programme.

The role is open to existing members of the Institute or Faculty, at Grade XXX and above (or clinical equivalent), who hold a Chief Investigator role within the Institute.

What does the role entail?

- Establish mechanisms to improve clinical leadership and governance at a strategic level within the Institute.
- Support development of early career clinical academics and establish collaborative opportunities with other Institutes and initiatives across the Faculty and NHS.
- Provide leadership for Clinical Directors and Clinical Advisors across all divisions of the Institute, working with Division Directors to establish and renew these as needed.
- Provide outreach and support to Chief Investigators within divisions, as appropriate
- Provide a clinical perspective, and advise on, local, national and international initiatives impacting delivery of clinical research.
- Be a member of the Institute's Senior Management Team and involved in the development and implementation of Institute Strategy.
- Represent the Institute at local, national and international meetings.
- Be accountable to the Institute Director.
- Support the Institute Director in creating a positive and professional working environment within the Institute through fostering a commitment to the Institute's values and behaviours framework, and the University's Leadership Excellence Behaviours;

- Lead by example to underpin the Institute's and School's culture of zero tolerance towards inappropriate or unacceptable behaviour and ensure any instances are dealt with appropriately.

The successful applicant will be expected to undertake training and development appropriate for this level of leadership role, including University Equality and Diversity Training.

The appointment will be for a period of three years. The successful role holder will be eligible for reappointment in open competition. The anticipated start-date of the role is May 2024.

University Values

All staff are expected to operate in line with the University's values and standards, which work as an integral part of our strategy and set out the principles of how we work together. More information about the University's strategy and values is available at:

What will you bring to the role?

- Evidence of strong leadership and management skills
- Sound strategic thinking and planning skills allied with the ability to communicate strategy, priorities and imperatives
- Ability to influence others and gain consensus at all levels; acting as a role model to build trust through openness, honesty and integrity
- An enthusiastic, dynamic and solution-focused approach to the opportunities and challenges facing the Institute
- Highly developed communication skills with the ability to build, maintain and develop effective working relationships, being an ambassador for the Institute, inside and outside the University
- A track record of academic excellence and achievement evidenced by a record activity aligned with clinical governance.
- Commitment to the University values and the Leadership Excellence Behaviours Framework

Support and Development Opportunities

Administrative support may be made available through the CTU Business Support team upon further discussion.

Funds will be made available to support relevant and appropriate training and professional development opportunities to be discussed and agreed with the Institute Director.

Associate Clinical CTU Director example 2

Job Description

The XXX Clinical Trials Unit provides a comprehensive clinical trial development and delivery service for a portfolio of interventional and observational research projects (including those of Investigational Medicinal Products and radiotherapy) for patients with a wide range of solid and haematological malignancies. There are currently XXX staff including project managers, clinical trial coordinators, biostatisticians, pharmacovigilance trial coordinators, clinical trial monitors, computer programmers and a range of administrative and support staff. The Unit is hosted by The University XXX where it sits within the School XXX, being physically located XXX

The Unit is managed by a Senior Management Team, currently the Director XXX the Head of Biostatistics, the Operations Director and the Head of IT.

The Lead Clinician is a new role within the Unit which has been created to provide additional clinical leadership within the team, complementing the skills of those already in place, and to enable a talented individual to develop their skills and knowledge in leadership within a CTU environment.

Candidate profile

It is envisaged that this post would be attractive to an appropriately experienced clinician with experience of working in clinical trials and a clinical practice in a relevant cancer specialty or subspecialty. The successful candidate should be eligible for appointment to the XXX Clinical Senior Lecturer level (or above) and should have a relevant higher degree. The role is part time and so it is anticipated that the successful person will hold another role within the University. They should ideally have a track record in clinical trials research. Whilst prior experience of working within a CTU is desirable, it is not essential given the nature of the post.

Outline role

- To be a full member of the Senior Management Team, which is chaired by the Director
- To assist The Director in the day-to-day management of the Unit alongside other members of the Senior Management Team
- To take on specific leadership tasks which may arise, including but not necessarily limited to those of a clinical and scientific nature by agreement with the Director. Examples include the delivery of specific projects, representation of the CTU within external bodies, sitting on appointments panels, etc.
- Supervision of research fellows within the CTU (including, where appropriate, securing grant funding).
- To contribute, alongside the members of the Management Team, to the delivery of the CTU’s scientific strategy.
- To deputise for the Director regarding clinical and scientific matters, where necessary.

- To participate in and contribute towards portfolio decision making.
- To provide scientific and strategic guidance to the Unit's programme of work.

In addition, it is likely that the successful candidate may take additional roles within the CTU (for example by being Chief Investigator on one or more trials) but this is not specifically part of the Lead Clinician role and would be subject to appropriate job-planning with their employer.

Reporting

The Lead Clinician will report to the CTU director with regard to this specific role, but will report to a line manager agreed with the University XXX with regards to other elements of their job, including other roles within the CTU.

Associate Clinical CTU Director example 3

Faculty of XXX Clinical Deputy Director XXX Clinical Trials Unit

XXX Clinical Trials Unit supports the design and development of high-quality clinical trials and clinical studies. These studies investigate the efficacy, effectiveness and efficiency of therapeutic, complex and service-level interventions.

The CTU supports the trials and studies it helps to design through:

- conduct, management and monitoring;
- analysis, interpretation and reporting in conjunction with dedicated statistics and other teams;
- in respect of trial conduct and management, the focus of XXX is on external, sponsor level activities and overall project management.

We are looking to appoint a Clinical Deputy Director, whose roles and responsibilities will include working closely with the Directors to provide clinical and strategic leadership for the XXX. You will be expected to achieve this by demonstrating and leading on key activities including:

- Work closely with the Director and Co-Director to develop and implement a strategic direction for the CTU, ensuring opportunities are optimised and any risks mitigated
- Work with the Directors and Senior Team to develop the XXX clinical study portfolio
- Provide and co-ordinate clinical input, as required, into funding applications and the development of study protocols for studies supported by XXX
- Build an extensive network of clinical collaborators, acting as lead investigator for high profile multicentre randomised controlled trials in own trials and studies, and working with others to develop similar models for other trials
- Contribute to the leadership of clinical trials teaching and education to ensure delivery of high quality, research-led teaching both within and outside the CTU
- Provide strategic input and support to XXX Operations Lead in developing the XXX policies and procedures

- Build the profile of XXX by taking a leading role in NIHR research networks and equivalent organisations
- Build positive working relationships with internal and external stakeholders including researchers, lead investigators, funding bodies, the RSS, CRN, local R&D departments, and sponsor representatives
- Generate, and contribute to, high quality clinical research publications alongside XXX colleagues
- Represent XXX at clinical and scientific meetings, and at the UKCRC as needed
- Advise clinical researchers taking on the role of lead investigator for the first time
- Keep up to date with changes to the clinical research regulatory framework within the UK and internationally

To be appointed, you will need to provide evidence of:

- Substantial recognised expertise in leading clinical trials / relevant research
- Understanding of emerging trends in the UK health and care and the funding environment
- Knowledge of the clinical trials landscape as it relates to the NHS
- Significant success in NIHR and other research grants and associated publication record
- Proven leadership, and managerial skills
- Demonstrable ability for strategic thinking and planning
- Knowledge of the regulatory context within which clinical trials are conducted

The Role is open to existing clinical academic colleagues and is appointable for 3 years in the first instance. The role is notionally 40% FTE.

5.4. Clinical director / divisional lead

Clinical director / divisional lead example 1

Appointment of CTU Associate Clinical Director at XXX

The University is seeking to appoint to the role of Clinical Trials Unit Associate Clinical Director XXX in its Faculty.

The successful candidate will be appointed for 1 year in the first instance, but may be up to 3 years. The time commitment will be between 0.1 and 0.2 FTE.

Staff benefit from:

- appropriate support in all aspects of their research or scholarship activity;
- a well-resourced Research and Innovation team to support the process of submitting research grant applications;
- collaborations with clinicians in a wide range of clinical specialities across the region;

strong collaboration within the Faculty of XXX and with other Schools and academic disciplines across the University,
- access to wide-ranging methodological research expertise.

The balance of academic duties is appropriately taken into account in the agreed workload distribution for each member of academic staff.

Members of staff are expected to engage in, and be supported towards, further appropriate personal development and skills acquisition.

MAIN RESPONSIBILITIES

Post: Associate Clinical Director XXX

Reporting to: The Associate Clinical Director XXX will report to the Director XXX and be part of the core senior management team XXX

Main duties will include:

- Provide clinical leadership at a strategic level by participation on the CTU Management Committee and CTU Executive Committee and working with the senior management team of the CTU to develop and deliver the strategic objectives of the XXX research goals and 5 year business plan
- Act as the clinical lead on the review of proposals seeking CTU adoption through contribution to the work of the CTU;
- Contribute to risk mitigation strategies for the design, conduct and analysis of clinical trials where there is a reasonable degree of clinical risk (for example CTIMPs) through interactions with trial teams
- As requested by XXX, contribute to risk mitigation strategies for the design, conduct and analysis of trials sponsored by the XXX
- Provide leadership in their respective discipline and by their clinical trials experience in contributing to the development of high-quality systems for the design, conduct and analysis of clinical trials and other well designed studies.
- Initiate and develop collaborations with industry, clinicians, researchers and trial groups (relevant to own clinical specialty and interest), nationally and internationally.
- In the event of a statutory inspection (MHRA) for GCP, contribute to and participate in the preparation for the inspection.
- Contribute to enhancing the research capacity of the unit by providing teaching, on the job training and mentoring to staff within the CTU or linked to the CTU.
- Contribute to increasing the profile of the unit, through presentations and liaising with staff in XXX, regional and national groups the XXX

PERSON SPECIFICATION
Education, Experience & Achievements
Essential Criteria

- MBBS or equivalent medical qualification
- MRCP (UK) or evidence of relevant equivalent medical experience FY1/FY2
- Experience of clinical trials including grant applications, methodology and conduct of IMP trials.
- Able to contribute in a leadership role to multi-disciplinary teams.
- A desire to support internal and external staff working with the CTU, maintaining a pragmatic and diplomatic approach to problem solving and a commitment to team working.

Desirable Criteria

Skills & Knowledge
Essential Criteria

Desirable Criteria

Personal Attributes
Essential Criteria

Special circumstances
Essential Criteria
The post requires the support of the AD's employer

Clinical director / divisional lead example 2

Role Title:	XXX Clinical Director
Department / School:	XXX
Reporting Structure:	Retains existing line management structure, with feedback from XXX Director to the Clinical Director

Context

XXX is a UKCRC registered clinical trials unit (CTU) within the Institute which provides the infrastructure and expertise to develop, design and deliver clinical trials, and a variety of related clinical research studies. CTU works closely with -based researchers, external collaborators, the Research Office, the University and NHS Co-Sponsors (ACCORD),

University of Research Office, clinical research facility (CRF), NHS and industrial partners on projects that positively impact human health and advance public health policy.

XXX has over XXX staff members across XXX teams/departments (business, research development & trial planning, quality assurance, data management & programming, trial management, statistics and health economics) who work together to deliver a diverse portfolio of around XXX projects that support the XXX Clinical Trials Strategy.

XXX is passionate about research culture and values, with a focus on the fostering of respectful behaviours and building strong relationships to enable the delivery of world-leading research.

Commitment Detail

- Tenure of 5 years, with mutual extension available (upon agreement with Director)
- Existing XXX staff or affiliate, willing to contribute ≥20% FTE of time to XXX
- Joins the XXX Leadership Team (comprising the Director, Chief Operating Officer [COO] and Clinical Director)

Description of Role

- **CTU academic strategy:** Assist in the adherence, review, improvement and implementation of the XXX strategy to support the XXX Clinical Trials Strategy. Provides advice on future trends within clinical trials research across the wide community of trialists with the support of the XXX

- **CTU operations:** Attendance at XXX meetings, as required for success in the role. This includes relevant meetings on XXX Operations, Portfolio, Leadership, and CTU Strategy. Provides input on at-risk projects and their recovery in line with the University's clinical trials strategy and research prioritisation and aspirations. The XXX Clinical Director will take appropriate steps (e.g. leaving a meeting) when conflicted.

- **CTU leadership:** Member of the XXX Leadership Team, overseeing and advising on CTU operations and academic strategy. Chairs the XXX Clinical Advisory Group (CAG).

- **Professional leadership:** Acts as a role model to other clinical trial chief investigators to improve the culture and behaviours within clinical trial research pursuant to the University strategy on research cultures; and to improve Good

Research Practice, paving the way with exemplary design, conduct, reporting and interpretation of clinical trials.

- **CTU representation:** XXX ambassador to the clinical community to foster relationships between XXX and chief investigators, increasing the awareness of XXX practices and processes to improve project delivery and collaboration, and minimise risks.

- **Professional representation:** Clinical trial chief investigator ambassador to XXX, to foster relationships between the two groups, increasing awareness of clinical trial chief investigators' needs, to improve project delivery and collaboration.

- **Professional support:** Takes a leading role, supported by the XXX, in the coaching of first-time chief investigators of clinical trials to excel at conducting clinical trials in collaboration with CTU.

- **CTU business plan:** Advising and giving input into the CTU business plan, and 5-year plan (future operational strategy), and how these documents are being used to make decisions, mindful of the CTU academic strategy.

- **Bidirectional CTU and professional representation:** The CTU Clinical Director will undertake bidirectional knowledge transfer (CTU to clinical trial chief investigators and vice versa), with appropriate levels of discretion. Communication and exchange of information should be as open as relevant and as closed as necessary.

Knowledge Skills and Experience

Attribute	Essential	Desirable
Education, Qualifications & Training	• Staff/affiliates of the University employed within a clinical professorial or clinical reader role or equivalent senior role with a substantive University contract (or an honorary University contract with a substantive NHS contract).	• Training (e.g. MSc or Diploma) in Epidemiology, Public Health or Clinical Trials, or equivalent.
Knowledge & Experience	• Expert proficiency in leading clinical research, particularly clinical trials • Extensive experience (e.g. at least 10 years)	• Knowledge and experience of PPIE • Knowledge and experience of programmes that improve research culture.

Attribute	Essential	Desirable
	of chief investigator role • Knowledge of trial methodology, and standard and innovative designs, regulations for drug, device, and complex intervention trials, as well as pilot and feasibility studies • Demonstrable experience of strategy development • Knowledge of funding landscape and writing excellent clinical trial grant proposals • Demonstrable expertise in coaching and mentoring • Excellent communicator • Demonstrable influencing and negotiation skills • Passionate about the role of research and the importance of randomised clinical trials • Focus on confidentiality and integrity • Focus on equality, diversity and inclusion	• Experience of professional development and teaching • Awareness of conflict resolution methods

Key Contacts and Relationships

- XXX Leadership Team (Chief Operating Officer and CTU Director)
- XXX Senior Management Team
- Chief investigators of clinical trials
- School Director
- Dean of Medical Research
- Dean of Innovation & Engagement

- Research Office
- Sponsor
- NHS R&D Director
- Clinical Research Facility Directors
- School Board and Executive
- School Senior Management

This role will be part-based on campus in the XXX

5.5. Clinical advisor / collaborator / strategic lead / divisional lead

Clinical advisor / collaborator / strategic lead / divisional lead example

Division Clinical Director

- Lead the clinical development of a sustainable and strategic portfolio of clinical trials and aligned research within your clinical specialty
- Work with relevant Division Director(s), Operations Director(s) and the Clinical Deputy Institute Director, as appropriate, to ensure a robust pipeline of research within your clinical specialty with appropriate funding and scheduling.
- Develop and maintain strategic links with national and international researchers to identify opportunities for collaboration and maximise research value.
- Identify opportunities for future research including clinical trials in areas of clinical unmet need and/or ways to maximise learning from current portfolio.
- Identify routes to impact for research within your clinical specialty and support clinical investigators and Institute staff to utilise these.
- Support early career researchers through identification and supervision of PhDs, fellowships and mentoring for your clinical specialty and/or the Division you work within.
- Identify training needs and areas for development for clinical investigators and Institute staff for your clinical specialty and/or the Division you work within.
- Input into or lead grant applications to provide infrastructure funding for your clinical specialty and/or the Division you work within.
- Troubleshoot issues within your clinical specialty through provision of expert advice to clinical investigators and Institute staff.
- Input into evaluation and adaptation of Institute ways of working to identify improvements related to efficiency, communication and regulatory compliance.
- Attend Division and Portfolio Strategy Meetings relevant to your clinical specialty.
- Work closely with the Clinical Deputy Institute Director and input into the Institute Clinical Advisory Group to identify opportunities and risks which impact beyond your clinical specialty.

- Represent the Institute at local, national and international meetings.

- Foster a commitment to staff development across the Institute and ensure clear objectives are set regularly via XXX for all staff members within the Division
- Work with the SMT to create a positive and professional working environment within the Division through fostering a commitment to the Institute's values and behaviours framework, and the University's Leadership Excellence Behaviours;
- Be accountable and responsible for ensuring that the Division operates in accordance with School, Faculty and University policies and procedures
- Lead by example to underpin the Institute's culture of zero tolerance towards inappropriate or unacceptable behavior and ensure any instances are dealt with appropriately.