Job Description

Imperial College London

Job Title:	Clinical Trials Manager
Unit/School/Faculty:	Imperial Clinical Trials Unit / School of Public Health / Medicine
Campus location:	White City Campus
Job Family/Level:	Professional Services, Level 3b
Responsible to:	ICTU Operations Manager
Key Working Relationships (internal):	ICTU Operations Manager, Chief Investigator**;** Imperial Clinical Trial Unit (ICTU), ICTU Statisticians, Joint Research Office (JRO) and Regulatory Compliance Team, colleagues across the Faculty of Medicine, clinical staff at Imperial Healthcare NHS Trust.
Key Working Relationships (external):	Site Principal Investigators, Co-investigators, trial funder, contracted service providers, collaborating sites & teams.
Contract type:	Full time, fixed term for 12 months in the first instance

Background:

Imperial Clinical Trials Unit

The UKCRC-registered Imperial Clinical Trials Unit (ICTU) is a research unit working across both Imperial College London and Imperial College Healthcare NHS Trust, with affiliated NHS Trusts delivering world class clinical trials of all phases.

Activities encompass all aspects of all stages of clinical trials from generation to delivery. ICTU provides expertise in trial methodology and all aspects of conduct in several key disease areas including hypertension, HIV and cancer and works closely with the Joint Research Compliance Office of Imperial College London to ensure that the regulatory, legal and quality control aspects of trials are met.

With the expansion of ICTU, there are now exciting opportunities to develop the portfolio of clinical trials, whilst maintaining a reputation for conducting high quality work.

Summary of the post:

This post will be based within the Imperial Clinical Trials Unit (ICTU) in the School of Public Health (SPH) with direct line management provided by an ICTU Operations Manager.

An experienced Trial Manager is required to play a lead role in the management of a UK multi-centre clinical trial aimed at investigating two new investigational medicinal products for the treatment of HIV (the RIO trial). The post holder will be responsible for all aspects of trial management including close liaison with the Chief Investigator and PIs at other centres; and implementing / adapting established ICTU systems to ensure the trial is developed and conducted to the highest scientific and regulatory standards, as well as delivered to time and within budget constraints. The post will include monitoring the quality of data collected from source data and entered on the electronic CRF. The postholder will be expected to travel on occasion between the Imperial College Campuses as well as travel to national sites who are recruiting patients into the trial.

Key Responsibilities

Trial Management and Monitoring

- Be responsible for all coordination, administrative activities, and data management to ensure the efficient running of the allocated trials.

- Establish and maintain good communication between all key stakeholders e.g. study team, JRCO, funder(s), academic collaborators and staff at participating sites.
- Implement the principles of the International Conference on Harmonisation Good Clinical Practice (ICH-GCP) guidelines for clinical trials and ensure that all study personnel work according to them.
- Obtain / assist with applications for initial approvals and ensure on-going adherence to the requirements of the regulatory bodies i.e. NHS Research & Development, Medicines and Healthcare products Regulatory Agency (MHRA) and Research Ethics Committee (REC); and submit amendments as appropriate.
- Maintain the Trial Master File.
- Contribute to the development of all study documentation, under the guidance of other experienced Trial Managers / Operations Managers / Chief Investigator (CI) / Trial Management Group (TMG) including Study Protocol, Patient Information Sheet, Consent Form, GP letter and any other study materials as appropriate.
- Work together with other members of the group to ensure that the electronic CRF is provided in a timely way and works efficiently.
- Develop and implement comprehensive procedures for timely and clear reporting of trial status including progress and recruitment rates.
- Liaise with pharmacies and ensure timely supply of investigational drug to sites.
- Co-develop standard operating procedures (SOPs) for the initiation and coordination of the study.
- Set up new sites and conduct initiation visits as required.
- Plan and conduct site monitoring visits according to the monitoring plan and in line with the study risk assessment.
- Write monitoring visit reports and ensure action points are followed up with sites in a timely manner
- Manage timely and efficient procedures for collection, entry and monitoring of study data
- Ensure necessary reporting of adverse events, expedited SAE/SAR/SUSAR reporting and submission of Annual Safety Reports.
- Coordinate and support the activities of the Trial Management Group, Steering Committee, Data Monitoring Committee and other collaborative groups, including PPI.
- Conduct site close out visits and ensure appropriate plans for archiving are in place.
- Provide cross-study cover for other members of the Unit as required.
- Assist in preparation of presentations and publications.
- Assist with the preparation and conduct of GCP inspections and internal audits.

Translational

- To write, maintain and adhere to SOPs for the collection, transportation and storage of blood and tissue samples to ensure compliance with regulatory requirements.
- To keep up to date a tracking system for all biological samples.
- To facilitate the distribution of samples for analysis and collate results.

Data Management

- Together with the study statistician and Sponsor team, to develop and maintain the study database.
- Manage timely and efficient procedures for collection, computer entry and verification of all patient data, raising queries for missing or incomplete data as appropriate.
- Ensure quality and completeness of data using appropriate quality control measures.
- Assist in the production of written reports as required by the Sponsor and CI.
- Submit accrual figures to relevant groups.

Finance

- Monitor trial finances, reviewing expenditure against budget and ensure adherence to terms of all relevant contracts in collaboration with the Operations Manager and ICTU Administrative team.
- Oversee payments made to investigators and assist with development of payment / tracking systems to ensure accountability
- Monitor contractual arrangements (including the development of new contracts) with outside organisations as required

Job Description

General

- Undergo any training deemed to be necessary for the full execution of trial duties
- Liaise with other Trial Managers to assist with the smooth running of the ICTU portfolio and to ensure support for other Trial Managers and associated staff as necessary
- Represent the trials unit at meetings as required
- Be familiar with the relevant clinical literature and keep up-to-date with literature relating to clinical research / trial methodology
- Perform any other duties which may be required that are consistent with the nature and grade of the post as required by the Chief Investigator and/or the Operations Manager
- Ensure familiarity with and adherence to all relevant ICTU and JRO SOPs

Person Specification

Requirements Candidates/post holders will be expected to demonstrate the following:	**Essential (E)/ Desirable (D)**
Education	
• Bachelor's degree or equivalent in biomedical / scientific field	E
• Postgraduate qualification or equivalent, which includes clinical trials methodology	D
Experience and Knowledge	
• Proven clinical trial / project management experience gained in multi-centre, phase II and/or phase III, randomised trials including CTIMPs	E
• Proven experience of coordinating HIV trials	D
• Experience of early phase clinical trials	D
• Proven experience of clinical trial monitoring including source data verification	E
• Working knowledge of the current EU Clinical Trials Directive, UK Clinical Trials regulations, Principles of GCP, Data Protection Act and Research Governance Framework legislation and proven ability to apply these to the coordination of clinical trials	E
• Evidence of preparing regulatory and ethics submissions, writing/amending protocols, patient information sheets, case report forms (CRF) /electronic CRF, and other relevant trial management documentation.	E
• Evidence of strong IT literacy (MS Office and InForm)	E
• Experience of data management processes using electronic CRF	E
• Experience of working within the NHS or academic clinical research setting	E
• Evidence of basic understanding of the Human Tissue Act.	D
• Demonstrated success in the management of clinical trials budgets	D
Skills & Abilities	
• Strong motivational skills	E
• Evidence of ability to work independently as well as part of a team	E
• Evidence of effective communication, negotiation, presentation and inter-personal skills	E
• Evidence of ability to work with critical attention to detail and high levels of accuracy	E
• Proven excellent organisational and time management skills to effectively handle conflicting priorities and ensure tight deadlines are met	E
Other	
• Willingness to travel within the UK	E
• Willingness to work flexibly outside of office hours on occasion e.g. for travelling to and from sites	E
• Willingness to undergo any training deemed to be necessary for the full execution of trial duties	E

Please note that job descriptions cannot be exhaustive and the post-holder may be required to undertake other duties, which are broadly in line with the above key responsibilities.

Imperial College is committed to equality of opportunity and to eliminating discrimination. All employees are expected to follow the 7 Imperial Expectations detailed below:

1) Champion a positive approach to change and opportunity
2) Communicate regularly and effectively within and across teams
3) Consider the thoughts and expectations of others
4) Deliver positive outcomes
5) Encourage inclusive participation and eliminate discrimination
6) Support and develop staff to optimise talent
7) Work in a planned and managed way

Employees are also required to comply with all College policies and regulations paying special attention to:

- Confidentiality
- Conflict of Interest
- Data Protection
- Equal Opportunities
- Financial Regulations
- Health and Safety
- Information Technology
- Smoking
- Private Engagements and Register of Interests

They must also undertake specific training and assume responsibility for safety relevant to specific roles, as set out on the College Website Health and Safety Structure and Responsibilities page.

The College is a proud signatory to the San-Francisco Declaration on Research Assessment (DORA), which means that in hiring and promotion decisions, we evaluate applicants on the quality of their work, not the journal impact factor where it is published. For more information, see https://www.imperial.ac.uk/research-and-innovation/about-imperial-research/research-evaluation/

The College believes that the use of animals in research is vital to improve human and animal health and welfare. Animals may only be used in research programmes where their use is shown to be necessary for developing new treatments and making medical advances. Imperial is committed to ensuring that, in cases where this research is deemed essential, all animals in the College's care are treated with full respect, and that all staff involved with this work show due consideration at every level.http://www.imperial.ac.uk/research-and-innovation/about-imperial-research/research-integrity/animal-research/

We are committed to equality of opportunity, to eliminating discrimination and to creating an inclusive working environment for all. We therefore encourage candidates to apply irrespective of age, disability, marriage or civil partnership status, pregnancy or maternity, race, religion and belief, gender identity, sex, or sexual orientation. We are an Athena SWAN Silver Award winner, a Disability Confident Leader and a Stonewall Diversity Champion.

April 2021