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Clinical Trials Manager

Department/Division/Faculty:	Imperial Clinical Trials Unit (ICTU), School of Public Health, Medicine.
Campus/Location:	Stadium House, White City Campus
Job Family/Level:	Professional Services, Level 3b
Responsible to:	ICTU Operations Managers
Line management for:	N/A
Key working Relationships (Internal):	Chief Investigator, Imperial Clinical Trials Unit (ICTU), Research Governance team at sponsor site, Joint Research Office (JRO), investigators and teams within other schools, institutes and departments across Imperial College London.
Key Working Relationships (External):	Investigators and teams within Imperial College Healthcare NHS Trust and other external sites/hospitals, trial co-Investigators, trial funder, contracted service providers, trial oversight committees, and IMP logistics and management partner.
Contract type:	Casual, full time (1.0FTE/ 35 hours a week: £29.71 - £35.91 per hour inclusive of holiday pay)

Background

The Imperial Clinical Trials Unit (ICTU), a member of the UK registered Clinical Trials Unit Network, brings together academic, clinical, and trial management expertise from across Imperial College London and Imperial College Healthcare NHS Trust to deliver world-class clinical trials across all phases and designs.

ICTU collaborates closely with members of the designated Academic Health Science Network for North West London, Imperial College Health Partners, as well as national clinical and scientific key opinion leaders, other UKCRC-registered CTUs, and industry partners.

The Unit primarily leads on the design, conduct, and analysis of national and international multi-centre trials including Clinical Trials of Investigational Medicinal Products (CTIMPs). ICTU staff have specialist disease-area and methodological expertise and contribute at all stages of the trial lifecycle, ensuring that all activities are conducted according to the principles of ICH-GCP and in full compliance with applicable regulatory and ethical requirements.

Current therapeutic areas of expertise include Cancer, Cardiovascular, Respiratory, Emergency and Critical Care, Infectious Diseases, Surgery, and Child Health.

Purpose of the Post

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

This post will be responsible for managing two trials on the ICTU portfolio:

- an active phase 3 clinical trial of an Investigational Medicinal Product (IMP) to treat children 5-11 years with asthma (<https://careukstudy.uk/>).
- a new Phase II multicentre clinical trial of an Investigational Medicinal Product (IMP), investigating faecal microbiota transplantation (FMT) in participants with severe alcohol-related hepatitis (the FAITH Trial).

The role will also include carrying out key set-up tasks for other trials on the ICTU portfolio, as well as supporting the Director of Operations with implementation of new processes to ensure optional delivery of the Unit portfolio.

Start date: ASAP

To apply for this position, please send your CV and covering letter by email to Dr Christina Precht (c.precht@imperial.ac.uk) or Hanna Box (h.box@imperial.ac.uk).

Key Responsibilities

Trial Management and Coordination

- Be responsible for trial coordination, administrative activities, and data management (in collaboration with the Data Manager) to ensure the efficient running of the allocated trial.
- Establish and maintain good communication between all key stakeholders e.g. study team, the Sponsor, the funder, collaborators, and staff at participating sites.
- Implement the principles of the International Conference on Harmonisation Good Clinical Practice (ICH-GCP) guidelines for clinical trials, applicable clinical trial regulations, ICTU Standard Operating Procedures (SOPs) and ensure that all study personnel work according to them.
- Obtain/assist with applications for initial approvals and ensure ongoing adherence to the requirements of the regulatory bodies i.e. NHS Research & Development, Research Ethics Committee (REC) and Health Research Authority (HRA), Medicines and Healthcare products Regulatory Agency (MHRA); and submit amendments as appropriate.
- Contribute to the development of all study documentation, under the guidance of experienced Operations Managers / Chief Investigator (CI) / Trial Management Group (TMG) including Study Protocol, Participant Information Sheet, Consent Form, GP letter and any other study materials as appropriate. Contribute to the development, testing and maintenance of the trial electronic database (OpenClinica).
- Develop and implement comprehensive procedures for timely and clear reporting of trial status including progress and recruitment rates.
- Co-develop standard operating procedures (SOPs) for the initiation and coordination of the study.
- Manage the set-up of new sites.
- Ensure necessary reporting of adverse events, expedited SAE reporting and submission of Progress Reports to the funder.
- Coordinate and support the activities of the Trial Management Group, Steering Committee and Data Monitoring Committee and other collaborative groups, including PPI.
- Provide cross-study cover for other members of the team as required.
- Assist in preparation of presentations and publications.
- Assist in the study risk analysis.
- Maintain central records for the research sites including maintenance of the Trial Master File (TMF) as well as creation and distribution to sites of the Investigator Site Files (ISFs).
- Assist with the preparation and conduct of GCP inspections and internal audits.
- Update the Central Portfolio Management System (CPMS) monthly with recruitment numbers.
- Support the Director of Operations and Operations Managers to oversee delivery of the Unit trial portfolio to the highest standards and in compliance with applicable regulations.

Trial Monitoring

- Oversee the Trial Monitor and all monitoring activities to ensure that the study is conducted in compliance with the protocol, overall clinical objectives, ICH GCP and ICTU SOPs and is run according to agreed timelines.
- Train staff from the research sites in the conduct of the study, documentation, record keeping and regulations.
- Oversee development of a monitoring plan, liaising with the QA manager as appropriate, and ensure its execution as planned.

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- Conduct regular monitoring visits to participating sites as per the study monitoring plan.
- Review and sign off on site initiation, monitoring and close out reports when these are produced by the Trial Monitor
- Monitor recruitment and assist with site payments, where appropriate.
- Perform Source Data Verification (SDV) of study data at participating sites to check the original source documents against what has been entered into the study database.
- Perform central monitoring via the online study database.
- Identify and resolve queries in between monitoring visits.
- Check participant Informed Consent Forms, ISFs, and Serious Adverse Events (SAEs) for accuracy and completeness on study visits.
- Perform Site Initiation Visits, monitoring visits and study Close Out Visits as required.
- Write reports and follow-up letters to sites following site visits and monitor and record follow-up action points resulting from those visits.
- Raise any areas of concern identified at site visits with the Operations Manager and/or Head of QA as appropriate.
- Distribute and supervise all study documentation required for the study.
- Arrange the creation and maintenance of participant files and study documentation with study staff.
- Always maintain participant confidentiality.
- Maintain a log of participant status in assigned sites.
- Offer administrative and research support to staff in ICTU as required by the Chief Investigator, Operations Manager, and ICTU Directors, including support and guidance to less experienced Managers and Monitors.
- Perform any other monitoring related duties which may be required that are consistent with the nature and grade of the post as required by the Chief Investigator and/or Operations Manager.

Data Management

- Liaise with the Senior Data Manager and Monitor to coordinate data cleaning activities.
- Contribute to preparation of the Data Management Plan
- Ensure accurate MedDRA coding for adverse event reporting.
- Work together with other members of the group to ensure that the electronic CRF is provided in a timely way and works efficiently.
- Manage timely and efficient procedures for collection, computer entry and verification of all participant 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.

Staff management

- Provide direct line management for the Trial Monitor, overseeing recruitment of new staff where required, training and induction, as well as supporting their professional development and annual review conversations.
- Provide cross-study cover for other members of the Unit as required.

Finance

- Monitor trial finances, reviewing expenditure against budget and ensuring compliance with the terms of all relevant contracts, working closely with the Operations Manager, Department Manager, and administrative teams.
- Oversee payments to investigators and support the development and maintenance of payment tracking systems to ensure transparency and accountability.
- Manage contractual arrangements with external organisations, including the development of new contracts with external organisations as required.
- Liaise with clinical sites and other stakeholders to facilitate timely processing of invoices and payments.

General

- Undertake any training required to effectively perform all trial-related 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 ICTU 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 RGIT SOPs.

Other

- Comply with all relevant Imperial College London policies and regulations, including but not limited to: Confidentiality, Conflict of Interest, Data Protection, Equal Opportunities, Financial Regulations, Health and Safety, Imperial Expectations (for leaders, managers, and supervisors), Information Technology, Private Engagements and Register of Interests, and the Smoking Policy.
- Undertake any specific health and safety responsibilities relevant to the role, as outlined in the College's Health and Safety Structure and Responsibilities [webpage](#).

Person Specification

Requirements	Essential (E)/ Desirable (D)
Candidates/post holders will be expected to demonstrate the following:	

Education

• Bachelor’s degree or equivalent in biomedical/scientific field	E
• Postgraduate qualification or equivalent, which includes clinical trials methodology	D

Experience

• Proven track record in successful management of multicentre, multi-stakeholder clinical trials, including Clinical Trials of Investigational Medicinal Products (CTIMPs), from set-up through to close-out	E
• Knowledge of working in clinical paediatric and infection trials.	D
• Evidence of preparing regulatory and ethics submissions, and in drafting or amending key trial documents such as protocols, participant information sheets, case report forms (CRFs/eCRFs), and other essential trial documentation.	E
• Strong IT literacy, including proficiency in MS Office and experience with clinical trial databases (e.g. OpenClinica).	E
• Demonstrated success in managing clinical trial budgets and financial tracking.	E
• Experience of electronic databases, data entry and data management processes using electronic CRFs.	E
• Experience of clinical trial monitoring including source data verification, data integrity, trial compliance and adherence to ICH-GCP.	D
• Experience of working within the NHS or academic clinical research setting.	D
• Demonstrated success in the management of clinical trial budgets.	D
• Line management experience.	D

Knowledge

• Working knowledge of the 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 a clinical trial.	E
• Understanding of the principles of clinical data management and database design in the context of randomised controlled trials.	E
• Familiarity with clinical trial lifecycle processes, including risk-based monitoring and regulatory reporting.	E

Skills & Abilities

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|---|---|
| • Strong motivational skills. | E |
| • Proactive approach to problem solving. | E |
| • Evidence of effective communication, negotiation, presentation and interpersonal skills. | |
| • Proven ability to organise and prioritise workload to meet deadlines. | E |
| • Proven ability to work independently as well as part of a team. | E |
| • Ability to work accurately and methodically with a meticulous attention to detail. | E |
| • Proven excellent organisational and time management skills to effectively handle conflicting priorities and ensure tight deadlines are met. | E |
| • 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 |

Further Information

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.

[Our values](#) are at the root of everything we do and everyone in our community is expected to demonstrate Imperial:

- Respect
- Collaboration
- Excellence
- Integrity
- Innovation

Employees are also required to comply with all Imperial policies and regulations.

We are committed to equality of opportunity, to eliminating discrimination and to creating an inclusive working environment for all. We encourage candidates to apply irrespective of age, disability, marriage or civil partnership status, pregnancy or maternity, race, religion and belief, gender reassignment, sex, or sexual orientation. You can read more about our commitment [on our webpages](#).

Imperial 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/>

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